## Quality Control Activities for the RadiologicTechnologist

SELENIA® Dimensions®

GE Healthcare

## #24: Approval of an Alternative Standard for Using the Quality Assurance Program Recommended by the ACR Digital Mammography Quality Control Manual for Full-Field Digital Mammography Systems and Supplement for Digital Breast Tomosynthesis Mammography Systems

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This alternative standard was approved and became effective on July 13, 2018. It has no time limit. Alternative Standard #24 was amended to allow for the use by mammography facilities of the Supplement for Digital Breast Tomosynthesis portion of the *ACR Digital Mammography Quality Control Manual* as an alternative to the quality assurance program recommended by the image receptor manufacturer. The FDA has determined that the ACR's quality control manual is, as required in § 900.18(a)(1): *Alternative Requirements*, "at least as effective in assuring quality mammography" as following the manufacturers' QC manuals.

The original standard is 21 CFR 900.12(e)(6), which states:

900.12(e)(6): *Quality control tests--other modalities.* 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.

The approved alternative which amends and replaces the previous Alternative Standard #24 is:

900.12(e)(6): Quality control tests--other modalities. For full-field digital mammography and digital breast tomosynthesis systems, the quality assurance program shall be substantially the same as the quality assurance program recommended by the ACR Digital Mammography Quality Control Manual and Supplement for Digital Breast Tomosynthesis (or such a manual that incorporates the Supplement and may be known by a different name but is unchanged in content) when used with the ACR Digital Mammography Phantom, 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.

## Objectives

**2D Quality Control**
Review current 2D required tests

**QC Differences**
Identify the changes between 2D and tomosynthesis QC

**Tomosynthesis Quality Control**
Discuss what's required, objective, implementation, frequency and criteria





## One-Shot Phantom Quality Control Program

To facilitate a comprehensive mammography quality control program, all Fujifilm FFDM systems include a quality control package consisting of the One Shot Phantom M Plus (**Figure 9**) and corresponding QC software.

Through a single exposure of the One Shot Phantom M Plus, the QC software will automatically analyze the acquired phantom image and provide pass / fail results for the following system-related tests:

- Missed Tissue at Chest Wall
- Contrast-to-Noise Ratio (CNR)
- Sensitivity
- Geometric Distortion
- Uniformity
- Dynamic Range
- Spatial Resolution
- Low Contrast Detectability
- Linearity / Beam Quality

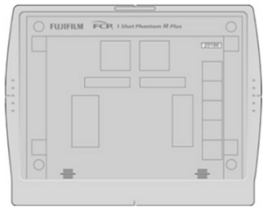
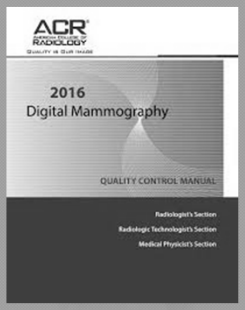



***Figure 9:*** *One Shot Phantom M Plus*

## New changes for Tomosynthesis July 2018




## Fujifilm's exclusive Mammography QC Phantom for MQSA and ACR QC Tests

- Performs 10 QC Tests with one exposure
- Tracks and compares changes in system stability
- Compares QC Tests to baselines set during installation
- Recorded data can be downloaded and stored
- Perfect for routine weekly, semi-annual and annual QC Tests

Fujifilm offers two QC sizes: 18x24cm and 24x30cm.
The 24x30cm is required for DBT.

| 12 Quality Control Test | | FORMS | |
|---|---|---|---|
| Quality Control Test Procedure | Frequency | 1999 ACR Quality Control Manual | Selenia Dimensions |
| DICOM Printer Quality Control | Weekly | | ✓ |
| Detector Flat Field Calibration | Weekly | | ✓ |
| Geometry Calibration (Tomosynthesis Option) | Semiannually | | ✓ |
| Artifact Evaluation | Weekly | | ✓ |
| Phantom Control Chart for Printer and Diagnostic Review Workstation | Weekly | | ✓ |
| Signal-To-Noise and Contrast-To-Noise Measurements | Weekly | | ✓ |
| Compression Thickness Indicator | Biweekly | | ✓ |
| Diagnostic Review Workstation Quality Control | Weekly | | ✓ |
| Viewbox and Viewing Conditions | Weekly | ✓ | |
| Visual Checklist | Monthly | ✓ | |
| Repeat/Reject Analysis | Quarterly | | ✓ |
| Compression | Semiannually | ✓ | |

## 3D Tomosynthesis QC for GE MTD is Motorized Tomosynthesis Device

| Minimum Frequency | Procedure |
|---|---|
| Weekly | Phantom IQ Test with MTD |
| | CNR and MTF Measurement with MTD |
| | Flat field 3D Test |
| | Phantom IQ 3D Test |
| Monthly | Grid texture Test |
| | AOP 2D and SNR Check with MTD |
| | AOP 3D Check |
| | Visual Checklist |
| Semi-annually | Compression Force Test |

October 2011

## Quality Control Tests

**2D QC**

- DICOM Printer Quality Control Weekly
- Detector Flat Field Calibration Weekl
- Artifact Evaluation Weekly
- Phantom Image Weekly
- Signal-To-Noise and Contrast-To-Noise Measurements weekly
- Compression Thickness Indicator Biweekly
- Diagnostic Review Workstation Quality Control Weekly
- Viewboxes and Viewing Conditions Weekly
- Visual Checklist Monthly
- Repeat/Reject Analysis Quarterly
- Compression Semiannually

**Tomosynthesis QC**

1. **Detector Flat Field Calibration**
2. **Geometry Calibration (Tomosynthesis option only)**
3. **Artifact Evaluation- Detector**
4. **Phantom**

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## SenoClaire QC Tests for the Technologist

- 2D Tests:
  - Section 3: Phantom IQ Test with MTD - Checks for consistency of image quality.
  - Section 4: CNR and MTF Measurement with MTD - Checks for consistent production of good contrast images.
  - Section 8: AOP 2D and SNR Check with MTD - Checks for correct operation of AOP mode with MTD.
- MTD Test: Section 7: Grid Texture Test - Checks for consistency of image quality regarding grid texture.
- 3D Tests:
  - Section 5: Flat-field 3D Test - Checks for consistency of image quality.
  - Section 6: Phantom IQ 3D Test - Checks for consistency of image quality.
  - Section 9: AOP 3D Test - Checks for correct operation of AOP mode in 3D.
- Section 10: Visual Checklist (page 27).
- Section 11: Compression Force Test - Checks for the correct level of compression force.
- Section 12: Test Results Forms - Provides charts for use in recording test results. It is recommended that you copy these chart pages to record test results.

For record keeping and further analysis, data generated on the Acquisition Workstation (AWS) for Flat-field, CNR, MTF, AOP and SNR tests can be exported as text files to a CD-R.

## 3D Tomosynthesis QC differences

- **Detector Flat-Field Calibration** (Gain Calibration)
  - 5 additional exposures for the Tomosynthesis Gain Calibration with Al (aluminum) filter
- **Geometry Calibration**
  - 1 exposure
- **Artifact Evaluation**
  - 1 additional Tomosynthesis Artifact Evaluation image
- **Phantom Image Quality Evaluation**
  - 1 additional Tomosynthesis Phantom image
  - (Combo exposure vs. a 2D exposure)

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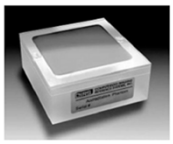
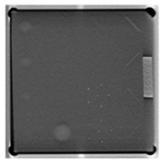
| Minimum frequency | Test | Essential | | SenoClaire (w/ MTD) | | |
|---|---|---|---|---|---|---|
| | | No X | 2D | No X | 2D | 3D |
| Daily | Monitor cleaning | X | | | | |
| Weekly | Flat field | | X | | | X |
| Weekly | Phantom IQ | | X | | X | X |
| Weekly | CNR & MTF | | X | | X | |
| Weekly | Viewbox & Viewing | X | | | | |
| Monthly | AOP Mode & SNR | | X | | X | X |
| Monthly | Visual Checklist | X | | X | | |
| Quaterly | Repeat Analysis | X | | | | |
| Semi-anually | Compression Force | x | | x | | |
| Monthly | Grid Texture | | | | X | |

## Phantom IQ 3D Test (Weekly)



**Objective**
Ensure adequate and consistent IQ of 3D images

**Equipment required**
ACR mammography accreditation phantom



**Procedure**
- 3D acquisitiion with Rh/Rh track/filter, 29 kV, 56 mAs
- Review the volumes; "score" the phantom

*Scroll through the volume to find the best in-focus plane for each structure!*

**Action Limit**
The score must be: Fibers ≥ 4, Speck groups ≥ 3, Masses ≥ 3

Same technique & action limit as for the 2D test

## Grid Texture Test (monthly)

**Objective**
Measures the amount of grid texture in 2D images

**Equipment required**
Flat field test object

**Procedure**
- Automatic acquisition of 10 2D images with increasing mAs
- Record the dispayed test results

**Action Limit**
The texture level must not exceed 0.002

## Flat field 3D Test (Weekly)

**Objective**
Ensure flatness and homogeneity of when reconstructing planes through a flat field phantom

**Equipment required**
Flat field test object

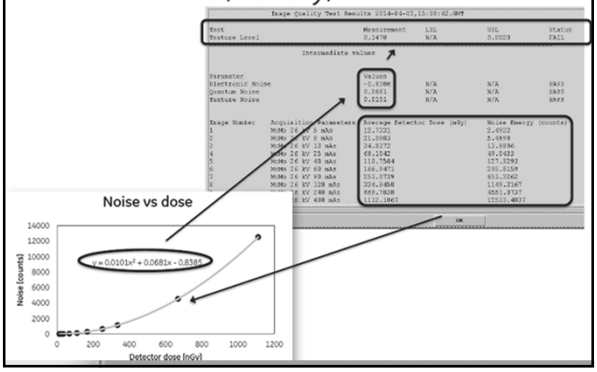
**Procedure**
- Automatic 3D acquisitiion
- Record the displayed test results

Image Quality Test Results 2014-04-02,15:29:21,GMT

| Test | Measurement | LSL | USL | Status |
|---|---|---|---|---|
| Brightness Non Uniformity | 14.17 | N/A | 15.00 | PASS |
| SNR Non Uniformity | 50.01 | N/A | 50.00 | FAIL |
| Configuration | 3D | | | |

**Action Limit**
Both Brightness non-uniformity* and SNR non-uniformity* tests must pass

## Grid Texture Test (monthly)




## Visual Checklist (monthly)

**Objective**
To assure that GE Breast Tomosynthesis indicator lights, displays, and mechanical locks and detents are working properly and that the system is mechanically stable.

**Equipment required**
Visual checklist Chart 5. Grid texture test, Visual Checklist and Compression Record of Checks (page 36).

**Procedure**
- Review each item on the visual checklist and indicate its status

**Action Limit**
Each of the items listed in the Visual Checklist must pass (ie, receive a check mark)

## AOP 3D Check (Monthly)

**Objective**
Check that the correct parameters are selected in AOP 3D mode

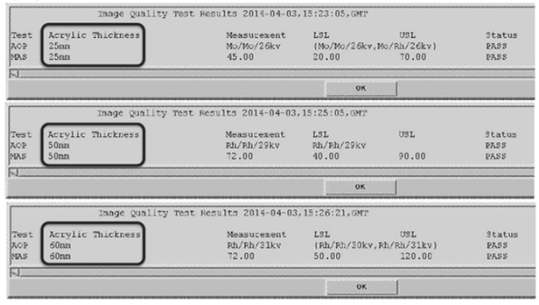
**Equipment required**
Set of acrylic plates (same as for the AOP 2D Check)

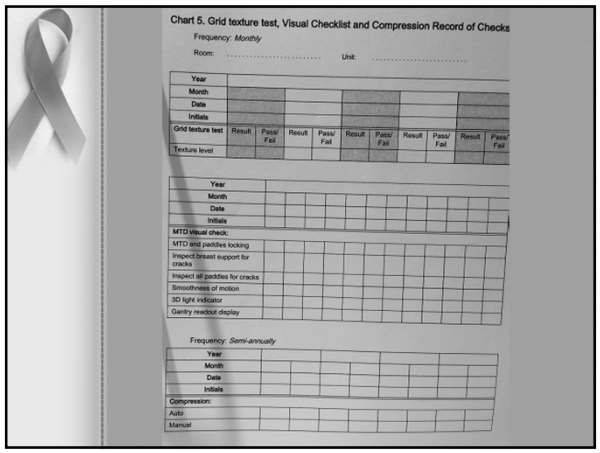
**Procedure**
- 3D AOP acquisition on 25mm, 50mm, and 60 mm of acyrlic
- Record the exposure parameters

**Action Limit**

| Acrylic Thickness (mm) | Exposure parameters | | |
|---|---|---|---|
| | Track/Filter | mAs | kV |
| 25 | Mo/Mo or Mo/Rh | 20-70 | 26 |
| 50 | Rh/Rh | 40-90 | 29 |
| 60 | Rh/Rh | 50-120 | 30 or 31 |

Displayed results




# Conclusion

Additional QC Tests for SenoClaire (with MTD installed)

Technologist Tests

1. Phantom IQ 2D Test with MTD
2. CNR and MTF Measurement with MTD
3. Flat-field 3D Test
4. Phantom IQ 3D Test

Weekly

5. MTD Grid Texture Test
6. AOP 2D and SNR Check with MTD
7. AOP 3D Check
8. Visual Checklist

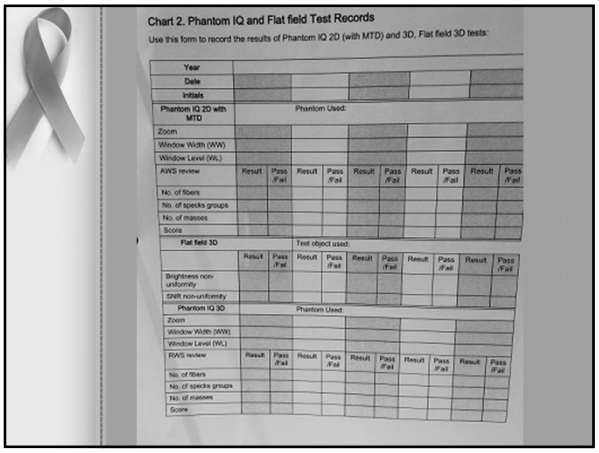
Monthly

9. Compression Force Test

Semi-annually

## Quality Control

- Quality control is the part of the quality assurance program that deals with techniques used in monitoring and maintenance of the technical elements of the systems that affect the quality of the image.
- Level I – Noninvasive and Simple
- Level II – Noninvasive and Complex
- Level III – Invasive and Complex




## Action Categories

**Category A:** If any of the following quality control tests that evaluate the performance of the *image acquisition components* of the Selenia Dimensions system produces results that fall outside the action limits as specified by the manufacturer, the source of the problem must be identified and corrective action must be taken before any further examinations are performed.

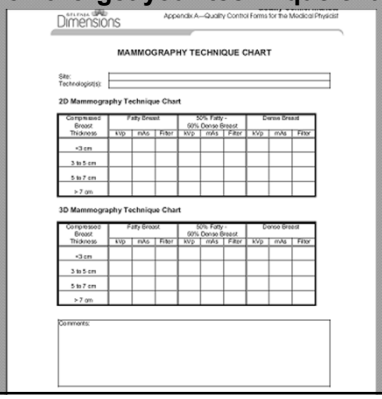
**Category B:** If any of the following quality control tests that evaluate the performance of a *diagnostic device used for mammographic image interpretation* (i.e. DICOM printer, physician's review station) produces results that fall outside the action limits as specified by the manufacturer, the source of the problem must be identified and corrective action must be taken before that device can be used for mammographic image interpretation. Clinical imaging can be continued and alternative approved diagnostic devices must be used for mammographic image interpretation.

**Category C:** If any of the following quality control tests that evaluate the performance of *components other than the digital image receptor or the diagnostic devices used for mammographic image interpretation* produces results that fall outside the action limits as specified by the manufacturer, the source of the problem must be identified and corrective action must be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation can be continued during this period.

| Quality Control Test | Frequency | Action Criteria |
|---|---|---|
| DICOM Printer Quality Control | Weekly | Category B |
| Detector Flat Field Calibration | Weekly | Category A |
| Geometry Calibration (Tomosynthesis Option) | Semiannually | Category A |
| Artifact Evaluation | Weekly | Category C |
| Phantom Image | Weekly | Category A |
| Signal-To-Noise and Contrast-To-Noise Measurements | Weekly | Category A |
| Compression Thickness Indicator | Biweekly | Category C |
| Diagnostic Review Workstation Quality Control | Weekly | Category B |
| Viewboxes and Viewing Conditions | Weekly | Category B |
| Visual Checklist | Monthly | Category C |
| Repeat/Reject Analysis | Quarterly | Category C |
| Compression | Semiannually | Category A |

- Flat Field uniformity – is an analysis of the homogeneity of the detector field
- MTF Modulation Transfer Function – is a measure of image sharpness.
- 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.

## Don't forget your technique chart


Dimensions

Appendix A—Quality Control Forms for the Medical Physicist

MAMMOGRAPHY TECHNIQUE CHART

Site:
Technologist(s):

2D Mammography Technique Chart

| Compressed Breast Thickness | Fatty Breast | | | 50% Fatty - 50% Dense Breast | | | Dense Breast | | |
|---|---|---|---|---|---|---|---|---|---|
| | kVp | mAs | Filter | kVp | mAs | Filter | kVp | mAs | Filter |
| <3 cm | | | | | | | | | |
| 3 to 5 cm | | | | | | | | | |
| 5 to 7 cm | | | | | | | | | |
| > 7 cm | | | | | | | | | |

3D Mammography Technique Chart

| Compressed Breast Thickness | Fatty Breast | | | 50% Fatty - 50% Dense Breast | | | Dense Breast | | |
|---|---|---|---|---|---|---|---|---|---|
| | kVp | mAs | Filter | kVp | mAs | Filter | kVp | mAs | Filter |
| <3 cm | | | | | | | | | |
| 3 to 5 cm | | | | | | | | | |
| 5 to 7 cm | | | | | | | | | |
| > 7 cm | | | | | | | | | |

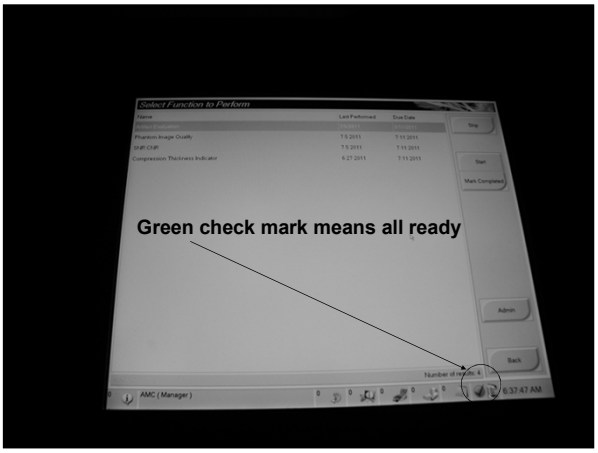
Comments:

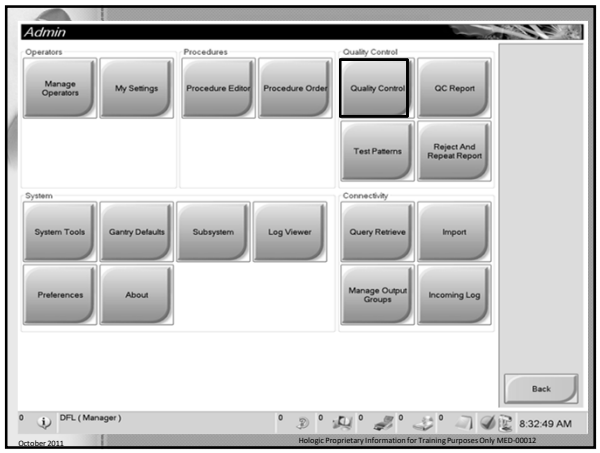
## Status

- Detector must go from a Detector warming status to an All Ready status before any image quality test is performed
- Make sure paddle clamp is out of the way and remove all paddles to start quality control

## That was then…..this is now

| | |
|---|---|
| • Old Terms | New Terms |
| • Film screen contact | Flat Field Uniformity |
| • Screen cleaning | MTF |
| • Darkroom Fog | CNR |
| • Fixer Rentention | SNR |






- *Any steps in the QC test procedures that are specific to digital breast*
- *Tomosynthesis are indicated by the wording "Tomosynthesis Option" and the icon on the side of the step.*

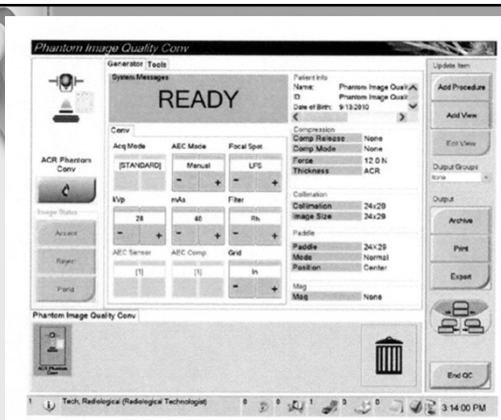


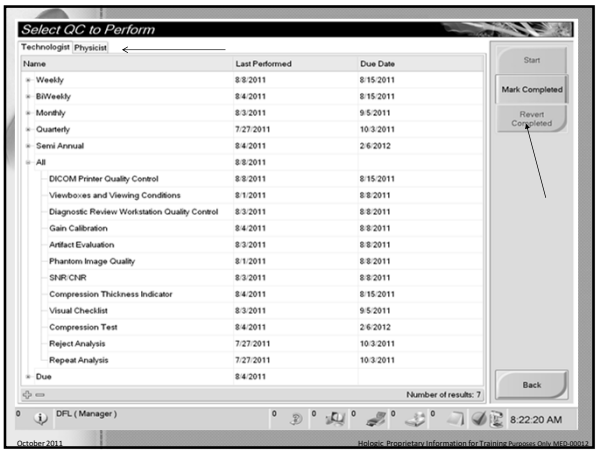
*Figure 18: An Example Quality Control Screen*

## Quality Control Icon

- Quality Control icon which is accessed via the Admin page which is visible at the top.
- Once the Quality Control icon is selected, it opens up to display all required Quality Control tests.

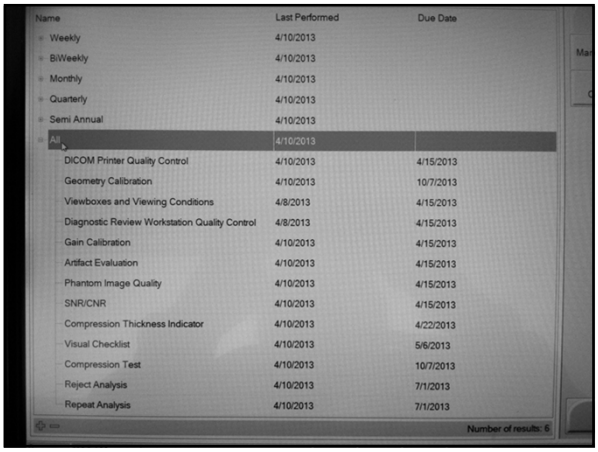
## Technologists QC

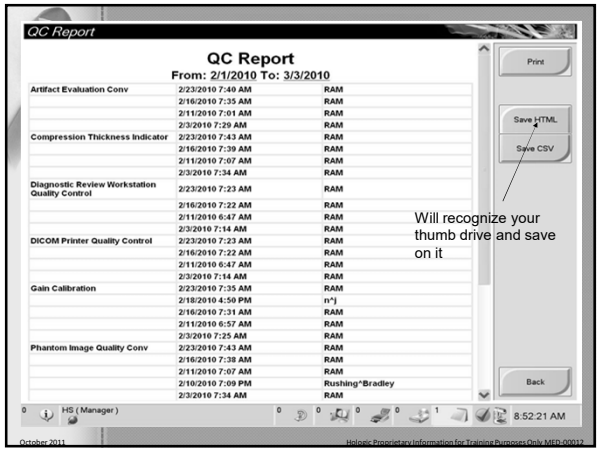
- When beginning Quality Control, there are two tabs. One tab is for the Radiologic Technologist, and the other tab is for the Medical Physicist.
- For test that do not require any image acquisition, the operator has the ability to complete the test and select the "Mark Completed" button to close the test and update the information.
- Please note the "revert completed" tab. This tab is beneficial if a technologist marks a test competed by mistake and wishes to change the status of the completion.

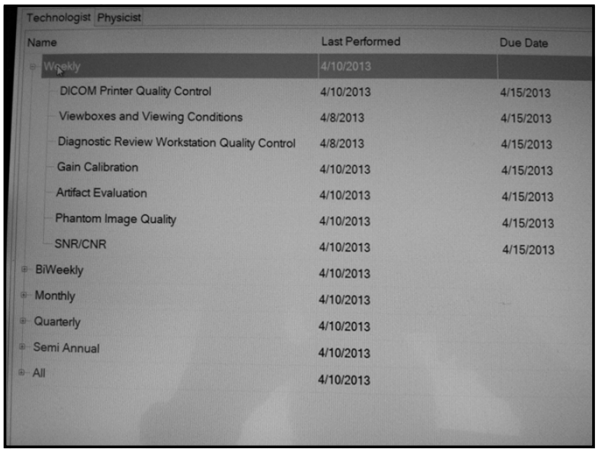



## QC Report

- The QC Report is an optional feature.
- The report list each test with a completion date and time.
- It also records the technologist that performed the exam.
- This report can be exported in two different formats; HTML or a CSV . HTML (hyper text mark-up level) is what they are currently useing. The other one, CSV (comma separated value) is more in the form of an excel spreadsheet. Keep in mind, this is currently not a requirement and is only an optional feature.

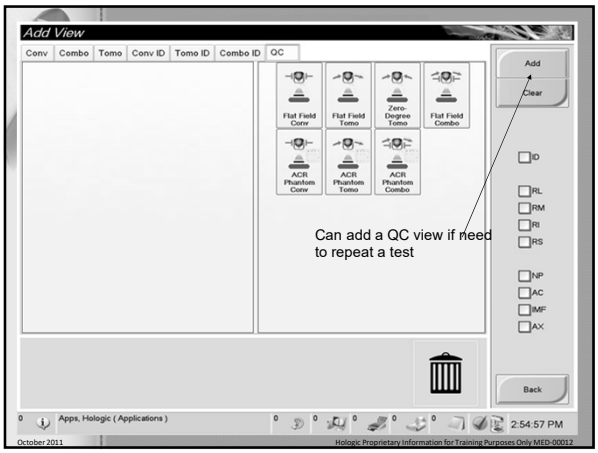



## Add QC Views

- Along with the conventional and Tomosynthesis views, there is a tab that allows Technologists to add additional QC views such as Flat fields and the Phantoms, both conventional and Tomosynthesis. In case a test was done incorrectly or did not pass.




**Suggested Equipment**
- Densitometer
- SMPTE test pattern stored on the Acquisition Workstation

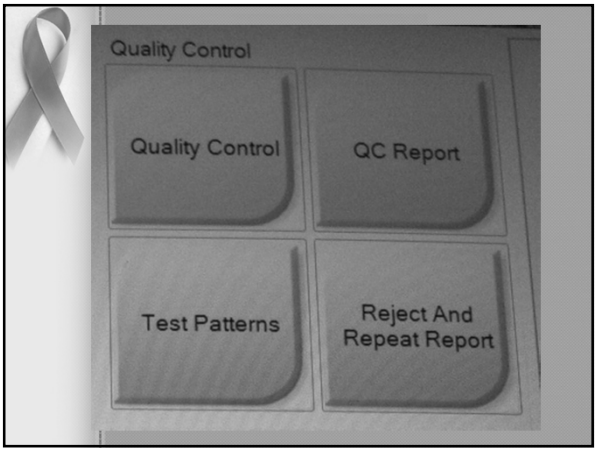
Select the **SMPTE pattern as the test pattern.**
Select the image size: **2560 x 3328.**
Select the **DICOM Device printer from the Output list and select 8 x 10 inch or 18 x24cm film**
Under Option uncheck **True Size Printing and also check clinic information tab**
Select **Send to print the SMPTE pattern on the selected printer.**
Repeat the test for all other printers used for printing clinical images.
Select **Back. Select Yes or No to confirm completion of the selected procedure.**

## DICOM Printer Quality Control

To assure consistency of DICOM printer performance. This procedure is analogous to film processor Quality Control, performed on traditional film processors used to process mammograms.

**Frequency**
Weekly or after preventive maintenance, service or software change is performed on the DICOM printer or a Dimensions system.

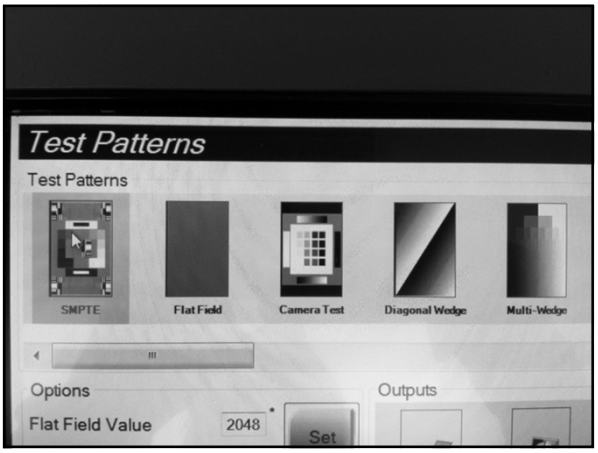
*If you have multiple Selenia, Selenia Dimensions or combined systems, you only need to perform this test from a single system each week, preferably the same system every week.*

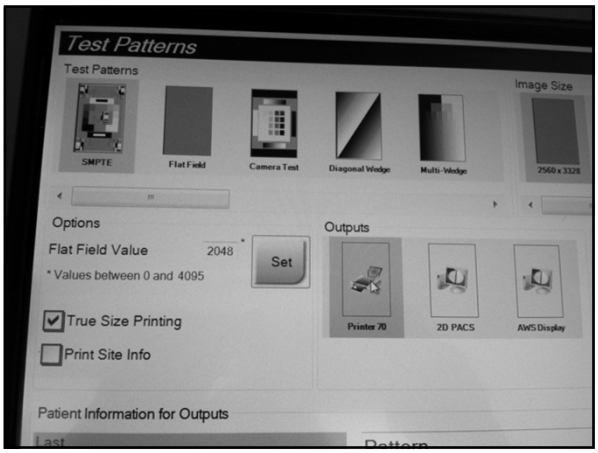


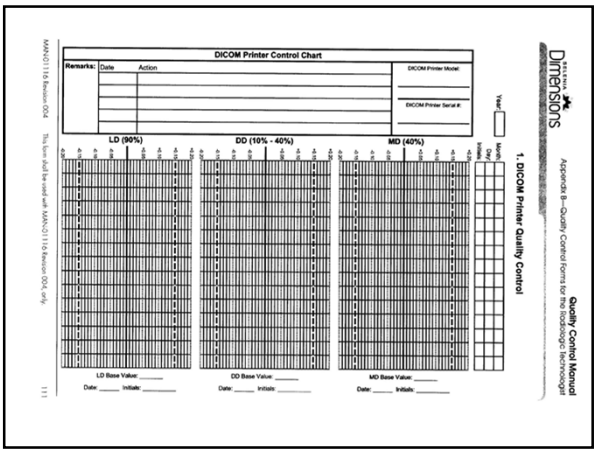

### Objective

To assure consistency of DICOM printer performance. This procedure is analogous to film processor Quality Control, performed on traditional film processors used to process mammograms.

***Note…*** *The intention of printing the SMPTE pattern is not to evaluate the pattern itself and if it conforms to the SMPTE standards, but to give the user the opportunity to measure different density areas to track the printer stability over time as well as verify that software changes to either the printer or the system did not alter the interface configuration. Thus, it is important that the SMPTE pattern is printed from the system and not from the printer itself.*



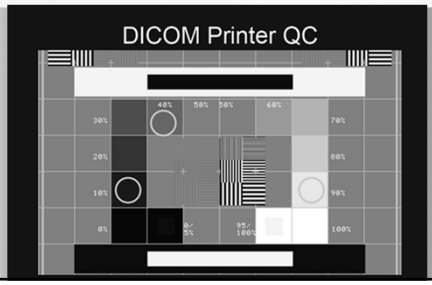



Use the densitometer to measure the density of the 10%, 40% and 90% patches on the SMPTE test pattern. Record the results on the test film and date the film.

Determine and plot the Mid Density (MD), Density Difference (DD) and Lower Density (LD) values on the *Laser Printer Control Chart.*

- For MD, use the density measured for the 40% patch, as shown in Figure 1-3.
- For LD, use the density measured for the 90% patch.
- For DD, subtract the density of the 10% patch from the density of the 40% patch.

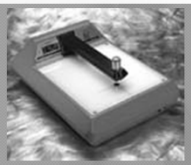



## Calibration

- **calibration** - the act of checking or adjusting
- The words "calibrate" and "calibration" entered the English language during the American Civil War
- Started with description with Artillery

The Mid Density, Density Difference and Lower Density values must track over time within ±0.15 of the established standards as shown in the table below.

| Control Value | SMPTE Grayscale Patch | Control Limits |
|---|---|---|
| MD | 40% | ±0.15 |
| DD | 40% - 10% | ±0.15 |
| LD | 90% | ±0.15 |



**MD- Speed, DD- Contrast, LD- B&F**

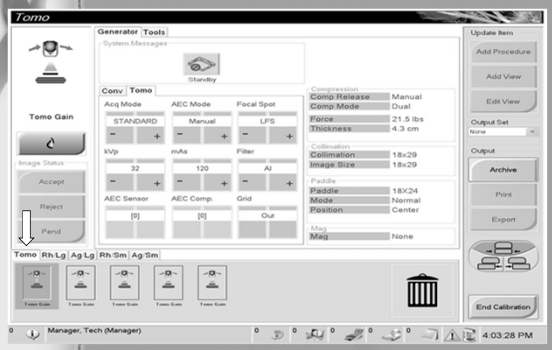
## Detector Flat Field Calibration (Gain)

- **Frequency:**
  - Weekly
- **Objective:**
  - To assure the system is calibrated properly.
- **Changes:**
  - 5 additional exposures for Tomosynthesis with the Al (Aluminum) filter.
  - If the calibration procedure fails repeatedly, the source of the problem must be identified and corrective action must be taken before any further patients are done.

## Detector Flat Field Calibration-Weekly

Remove any compression paddle from the compression device.
Move the compression device at a distance between 5 and 7 cm above the detector platform as indicated by the thickness display.
Make sure that both the Flat Field phantom and the surface of the image receptor are clean.
Place the Flat Field phantom on top of the image receptor covering its entire surface.
After first image is taken, window and level image to see all contrast available. But only the frist image

## Gain Calibration





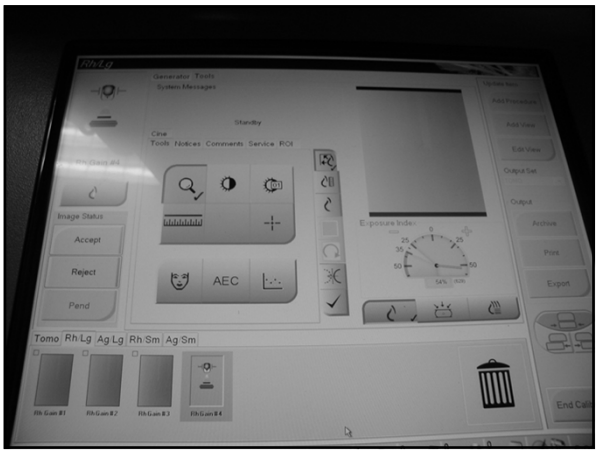


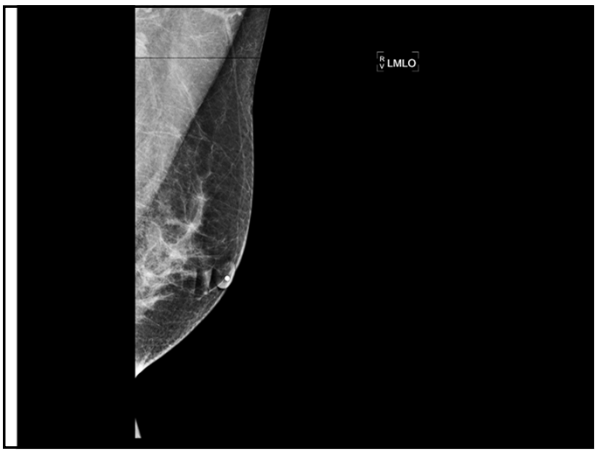
## Flat field calibration (Gain)




## Detector Flat Field Calibration-Weekly

- Select Gain Calibration procedure
- You will make 21 exposures with different filters and focal spot size *** Older verson
  - Tomo Gain 1-5
  - RH Gain LG-1-4
  - AG Gain LG-1-4
  - RH Gain SM-1-4
  - AG Gain SM-1-4
- ***New version 13 exposures are needed with different filters and focal spot size
  - Tomo Gain 1-5
  - RH Gain LG 1-2
  - AG Gain LG 1-2
  - RH Gain SM 1-2
  - AG Gain SM 1-2

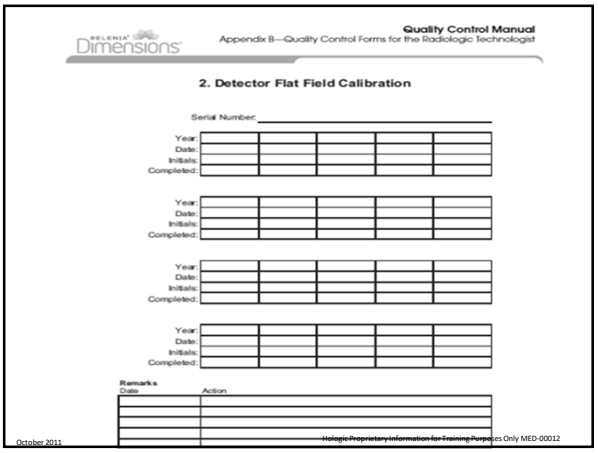



When instructed to install the magnification platform, use the 1.8x insertion points. Do not hit Ok on the monitor until mag stand is installed. You can create artifacts.
Review the preview image for foreign objects, gross artifacts other than non-uniformities or collimation interference.
Select **Accept** if the image is clean and the collimation blades do not intrude into the imaging space.
Also when done with calibration test hit complete before you take off the mag stand.

**Record Forms**
It is not required to record the execution of this test since the system keeps track of when the test was performed last and prohibits manual removal of the test from the Due test list.

However, a "Detector Flat Field Calibration" form is included in Appendix B in case the facility would like to keep track of when this test was performed.

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**2. Detector Flat Field Calibration**

Serial Number: _____

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| Year: | | | | | |
| Date: | | | | | |
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| Remarks Date | Action |
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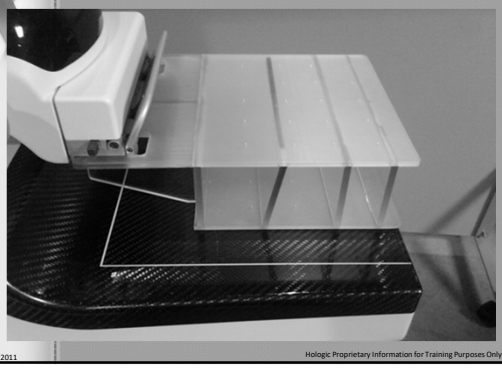
Hologic Proprietary Information for Training Purposes Only MED-00012

## Geometry Calibration (Tomosynthesis Option)







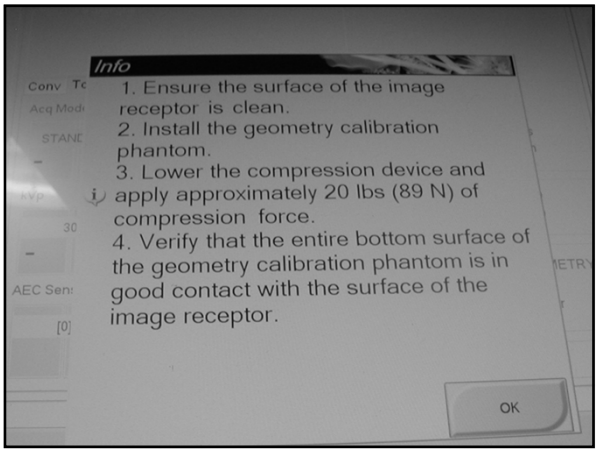


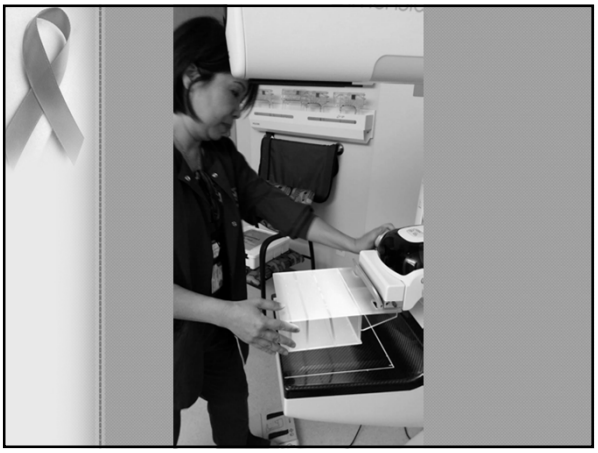

## Geometry Calibration (Tomosynthesis Option)

- **Frequency:**
  - Semi-annually
- **Objective:**
  - To assure the system is calibrated properly.
- **Procedure Info:**
  - Embedded lead beads in each level of the paddle should project to an exact X/Y position in the detector
  - System performs automatic validation
  - Test will fail if lead does not project as expected
  - System inherits and they do not need to be exported

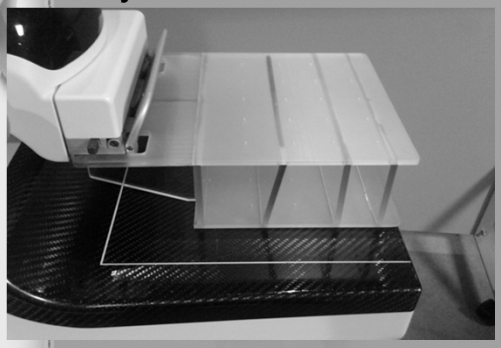






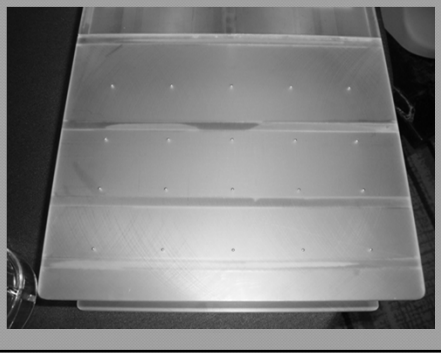



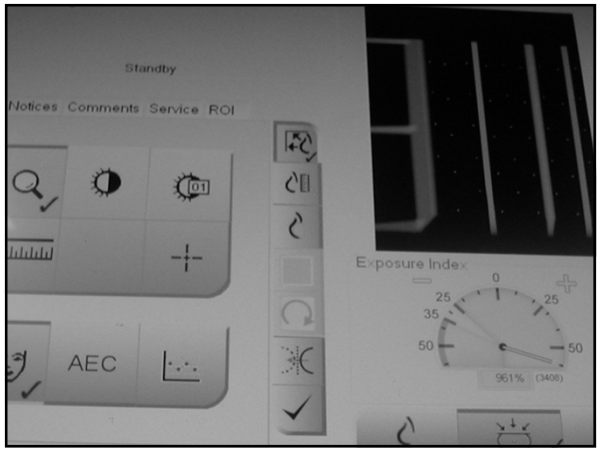

## Geometry Calibration



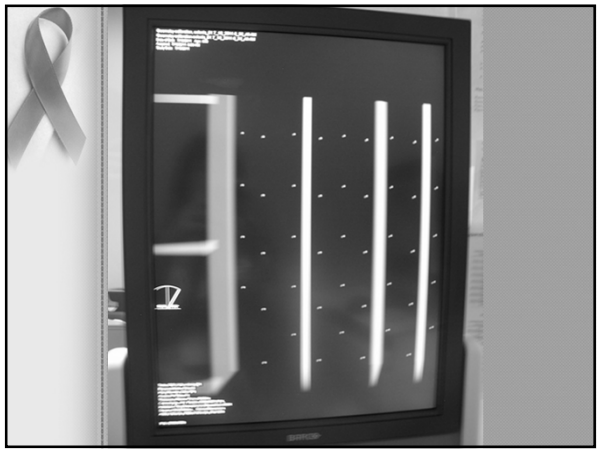



## Top of paddle-skin on top of breast






## Bottom of paddle-skin on bottom of breast



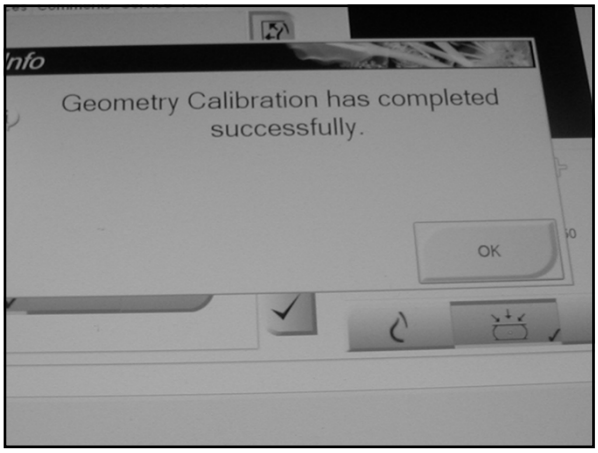
## If you have upright stereo attachment

- After you take the tomo geometry test it will promt you to do the stereo scout and stereo pair for the geometry automatically . So you will do that also

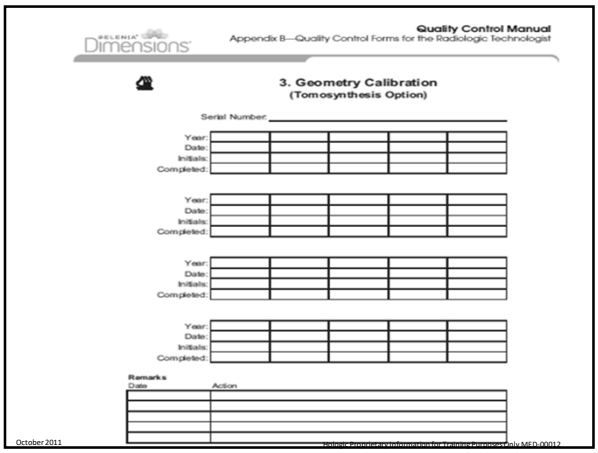
- If fails reconstruction images would be incorrect the items would not be at correct mm level in breast tissue
- If it fails you can still do 2D but you cannot do tomo
- The system performs analysis of the calibration phantom images
- If you have stereotactic it will cycle to this test and you do a stereo pair

It is not required to record the execution of this test since the system keeps track of when the test was performed last and prohibits manual removal of the test from the Due test list.

However, a “Geometry Calibration” form is included in Appendix B in case the facility would like to keep track of when this test was performed




- Just to let you know that the image is not stored in your QC files on the machine. You can retrieve all of the images of QC. Because the geometry calibration test uses a raw image.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3. Geometry Calibration
(Tomosynthesis Option)

Serial Number: _____

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| Year: | | | | | |
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Remarks

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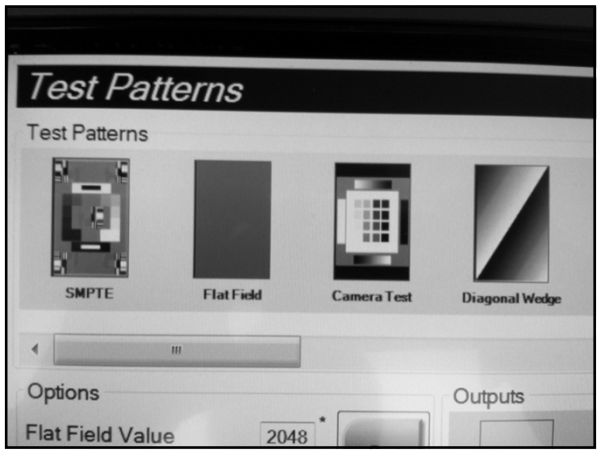



**DICOM Printer Artifact Evaluation**

*If you have multiple Selenia or Selenia Dimensions systems printing to a single printer, you only need to perform this test from a single system, since this test is used to access the printer artifact performance and is equivalent regardless of which system is used to perform this test.*

***It is recommended that System Artifact Evaluation is executed after Detector Flat Field Calibration when possible***

*When performing DICOM printer artifact evaluation, an artificial flat field must be sent to the printer following the procedure steps. As an alternative, you can print a flat field image from the Quality Control menu of the printer, if available. A true flat field acquired on a Selenia or Selenia Dimensions using the Flat Field phantom is not appropriate for this test and must not be used.*

**System Artifact Evaluation**

Select **Admin>Test Patterns.**
Select the **Flat Field pattern from the Pattern list as the test pattern.**
**For 8 x 10 inch (18 x 24 cm) printer film**
a. Select the **Image size: 2560 x 3328.**
b. Select the **DICOM printer device from the Outputs list and select 8 x 10 inch or 18 x 24 cm film.**
c. Under Options check **True Size Printing if available.**
d. Select the **Send button to print the flat field pattern on the selected printer.**
**For 10 x 12 inch (24 x 30 cm) printer film, if supported**
a. Select the **Image size: 3328x4096.**
b. Select the **DICOM printer device from the Outputs list and select 10 x 12 inch or 24 x 30 cm film.**
c. Under Options check **True Size Printing if available.**
d. Select the **Send button to print the flat field pattern on the selected printer.**
Repeat the above steps for all other printers used for printing clinical images.
Select the **Back button to return to the Admin screen.**

**Objective**
To assure that the image is free of undesirable artifacts.

**Frequency**
Weekly, preferably before Phantom Image Evaluation.

**Suggested Equipment**

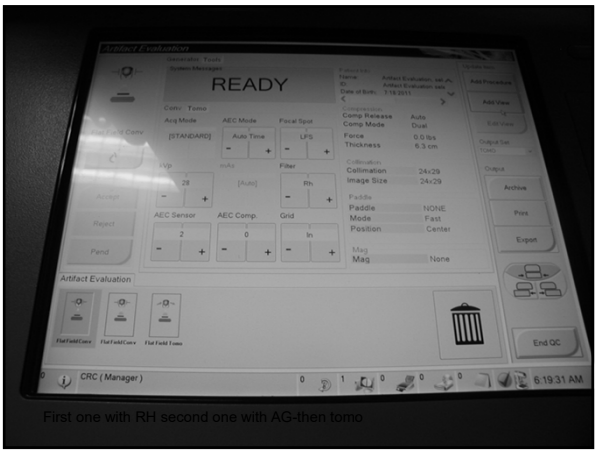
Flat Field phantom: 4 cm thick uniform attenuation block of acrylic large enough to cover
the digital image receptor. The Flat Field phantom is supplied by the manufacturer.

**Procedure:**

Flat Field phantom used (4 cm thick attenuation block of acrylic is used to cover the receptor)

It is recommended that the Artifact Evaluation is executed after the Detector Flat Field Calibration when possible.

Most common artifacts include streaking, Ghosting, and dead pixels.




First one with RH second one with AG-then tomo

## Artifact Evaluation-Weekly-Rhodium Option

- Send both size flat field test pattern the printer
- Acrylic on detector
- Compression paddle off and compression device between 5-7 cm , most use 6 to be consistent.
- No output or PACS if desired
- Select Flat field Conv view
- Set technique for RH exposure (Auto time-28 kVp-RH-LG/FS-AEC sensor position 2)

**QC differences- One additional exposure for Tomosynthesis with the Aluminum (Al) filter**






## Artifact Evaluation-Weekly-Silver Option

- All target/filter combinations need to be examined, which include
- Rh in 2D mode using large focal spot (LFS)
- Ag in 2D mode using the large focal spot (LFS)
- Al in Tomo mode using large focal spot (LFS)
- All images will be taken using Auto Time at 28 kVp, with the AEC sensor set to location 2 except Flat Field Tomo mode is in Auto-Time 30 with AEC sensor set at 2 .
- If you have the standard machine instead of the premium machine you must use 31 kVp.

## Artifact Evaluation

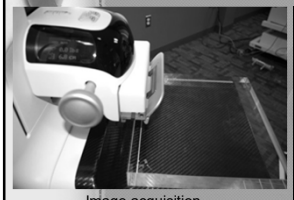


Image acquisition

**"Actual Pixel" button to display 1:1 display mode (1 detector pixel to 1 monitor pixel)**

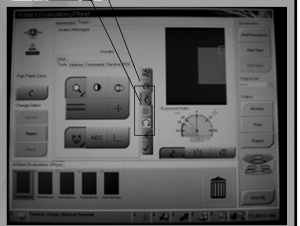


Image review

## Artifact Evaluation-Weekly

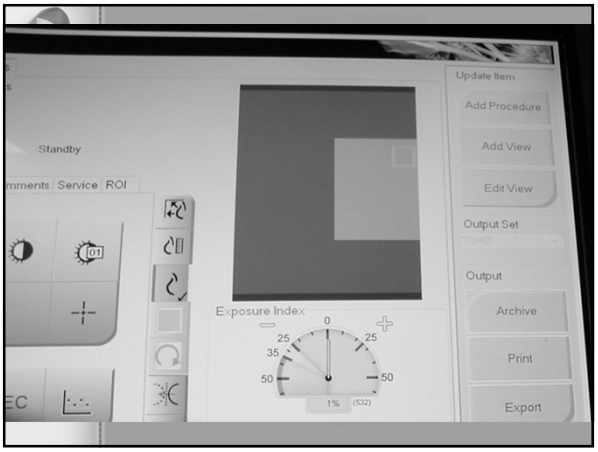
- For Tomosynthesis mode, 15 projections will be acquired, but only the middle projection at zero degrees need to be evaluated.
- The recommendations and corrective actions specified in the 1999 ACR Mammography Quality Control Manual, “Artifact Evaluation” section must be followed for DICOM printer artifacts. A qualified service engineer must correct the source of intolerable artifacts on the DICOM printer within 30 days of the test date.

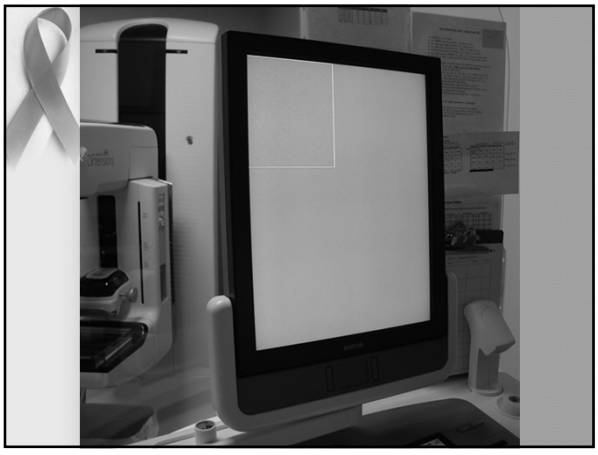
## Artifact Evaluation

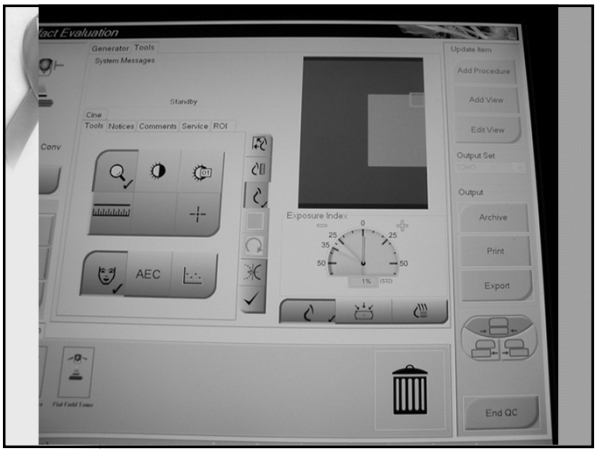
- Adjust the contrast of the image by setting the window and level in the screen.
- Use a window width of 500
- Level index exposure-0

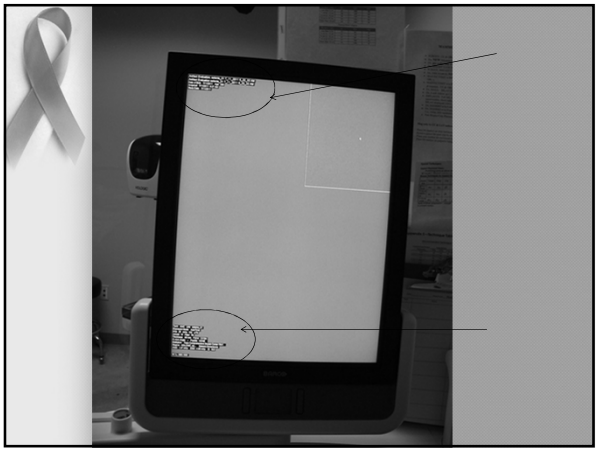
## Artifact Evaluation-Weekly

- Artifacts that are traced to the digital image receptor or the x-ray unit must be eliminated by a qualified service engineer with 30 days of the test date. If artifacts cannot be eliminated, the medical physicist must consult with the radiologist for assistance in evaluating whether any remaining artifacts may interfere with image interpretation or may be tolerable.



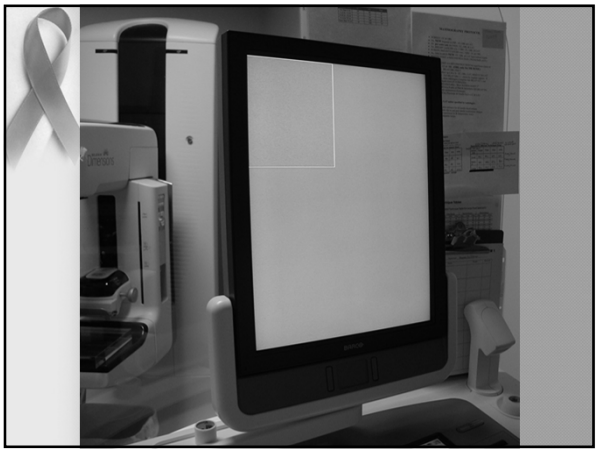





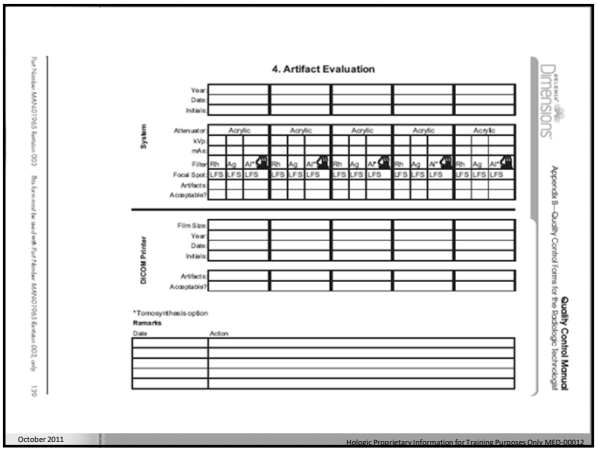



**Artifact Evaluation-Weekly-Tomosynthesis Option**

- Acquire exposure at 30 Auto time 2 AEC sensor
- Scroll to the center projection located at 0° and select Actual Pixels button to bring image into full resolution
- Pan through entire image with patient information turned off
- Look for bad pixels or sharp line of demarcation
- Select accept




*Artifacts that appear on the Flat Field phantom provided by the manufacturer must not be overlooked. Such artifacts will have an impact on detector calibration since the same block is being used during detector calibration. Replacement of the Flat Field phantom must be considered.*

4. Artifact Evaluation

| | | | | | |
|---|---|---|---|---|---|
| System | Year | | | | |
| | Date | | | | |
| | Initials | | | | |
| | Attenuator | Acrylic | Acrylic | Acrylic | Acrylic | Acrylic |
| | kVp | | | | | |
| | mAs | | | | | |
| | Filter | Rh Ag Al | Rh Ag Al | Rh Ag Al | Rh Ag Al | Rh Ag Al |
| | Focal Spot | LFS SFS LFS | LFS SFS LFS | LFS SFS LFS | LFS SFS LFS | LFS SFS LFS |
| | Artifacts | | | | | |
| | Acceptable? | | | | | |
| DICOM Printer | Film Size | | | | | |
| | Year | | | | | |
| | Date | | | | | |
| | Initials | | | | | |
| | Artifacts | | | | | |
| | Acceptable? | | | | | |

*Tomosynthesis option

Remarks

| Date | Action |
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Appendix B—Quality Control Forms for the Radiologic Technologist

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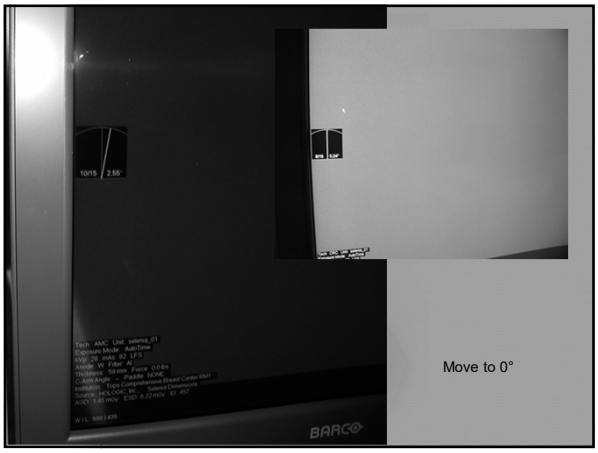


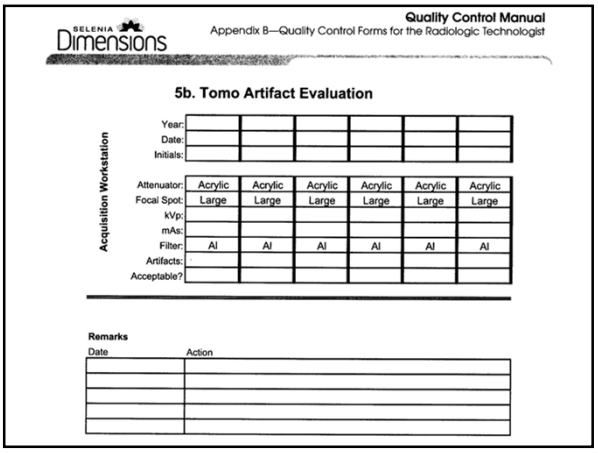

Quality Control Manual

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5b. Tomo Artifact Evaluation

| Acquisition Workstation | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Year: | | | | | | |
| | Date: | | | | | | |
| | Initials: | | | | | | |
| | Attenuator: | Acrylic | Acrylic | Acrylic | Acrylic | Acrylic | Acrylic |
| | Focal Spot: | Large | Large | Large | Large | Large | Large |
| | kVp: | | | | | | |
| | mAs: | | | | | | |
| | Filter: | Al | Al | Al | Al | Al | Al |
| | Artifacts: | | | | | | |
| | Acceptable? | | | | | | |

Remarks

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SELENIA Dimensions

**Quality Control Manual**

Appendix B—Quality Control Forms for the Radiologic Technologist

**5a. 2D Artifact Evaluation**

**Acquisition Workstation**

| | | | | | | |
|---|---|---|---|---|---|---|
| Year: | | | | | | |
| Date: | | | | | | |
| Initials: | | | | | | |
| Attenuator: | Acrylic | | Acrylic | | Acrylic | |
| Focal Spot: | Large | Large | Large | Large | Large | Large |
| kVp: | | | | | | |
| mAs: | | | | | | |
| Filter: | Rh | Ag | Rh | Ag | Rh | Ag |
| Artifacts: | | | | | | |
| Acceptable? | | | | | | |

**Printed Image Test Pattern**

| | 2560x3328 | 3328x4096 | 2560x3328 | 3328x4096 | 2560x3328 | 3328x4096 |
|---|---|---|---|---|---|---|
| Year: | | | | | | |
| Date: | | | | | | |
| Initials: | | | | | | |
| Artifacts: | | | | | | |
| Acceptable? | | | | | | |

**Remarks**

| Date | Action |
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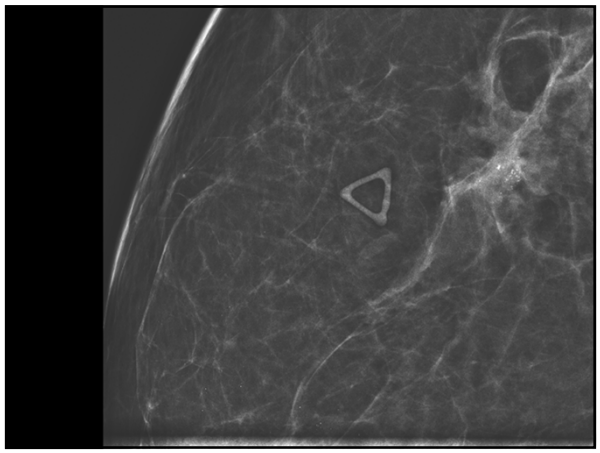
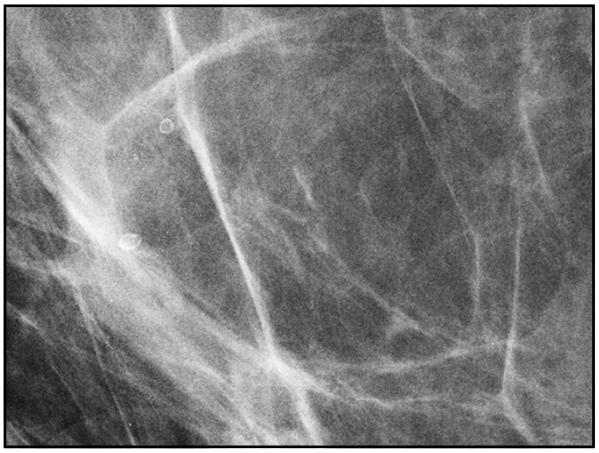
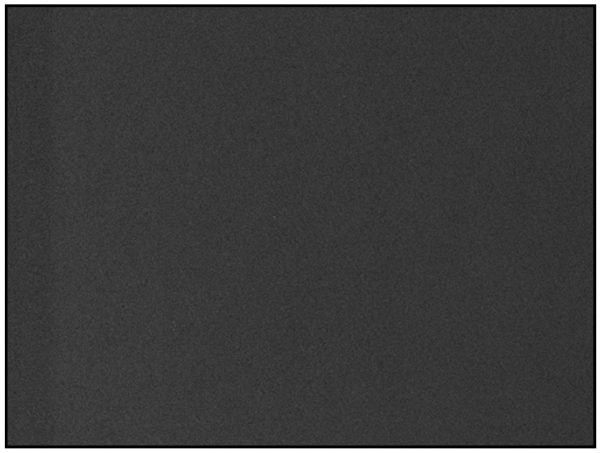
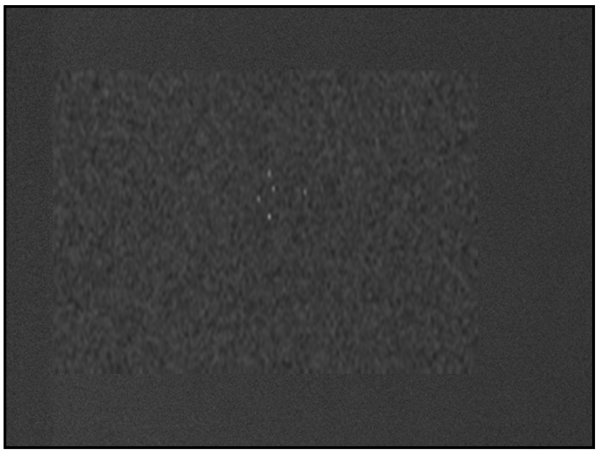


## Case Study for Artifact Evaluation

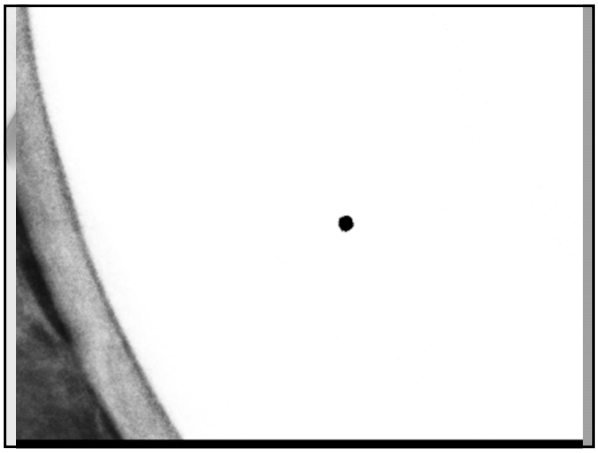
**Performed a flat field test**

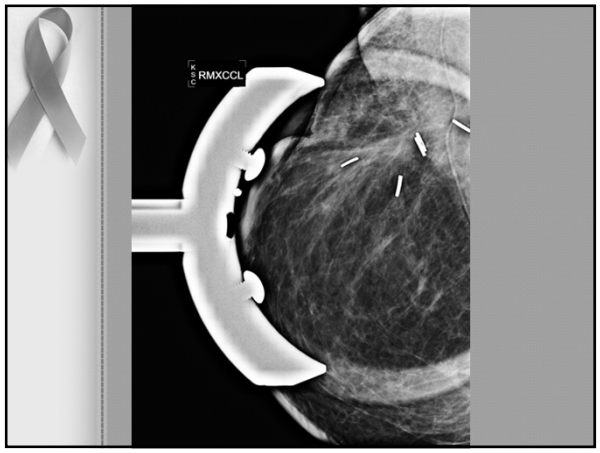






Results, Detector going bad. Had to replace it.
It wasn't reading all the pixel information
Cannot be 2 or more neighbors of bad pixels





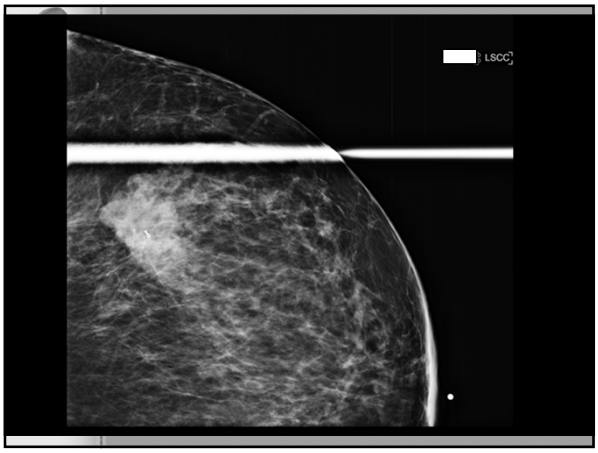
## Phantom Image

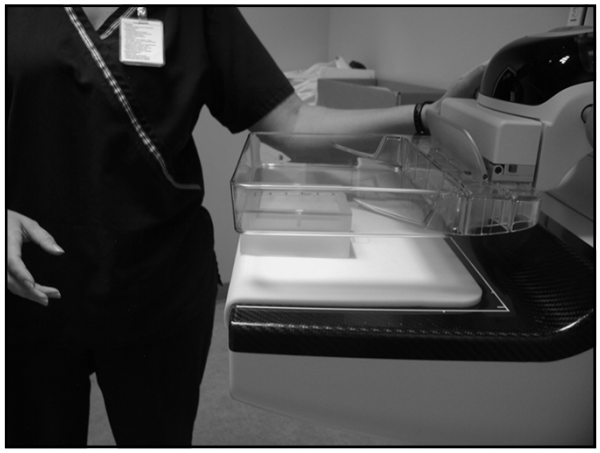
- **Frequency**:
  - Weekly
- **Objective:**
  - To assure the image quality due to the x-ray imaging system, DICOM printer, and film processor are maintained at optimum levels. Also for consistency of the mammography image.

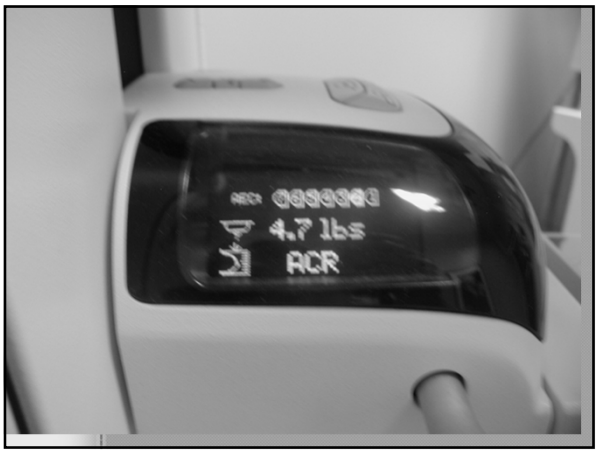



## Phantom Image-Weekly

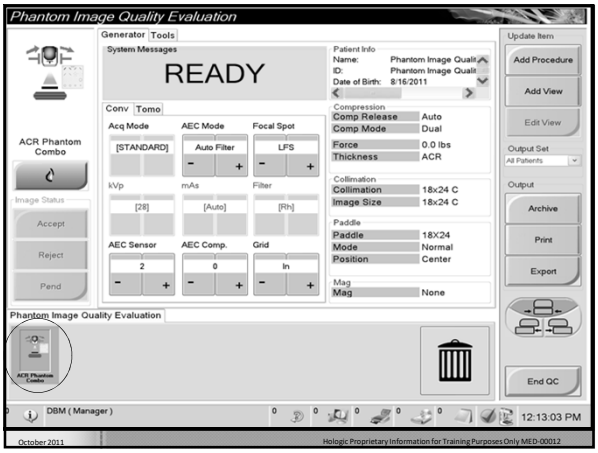
- Phantom and disk
- 18 x 24 compression paddle
- Select ACR Phantom Conv or ACR Phantom Combo from procedure screen most use ACR Phantom Combo mode
- Compression thickness no longer determines the acquisition technique but recommended to use same as possible-go by lbs does not give thickness
- Compress enough to stabilize phantom-does not have to be the same every time but the compression thickness can be higher than 4.2.
- Output normal for storage of image



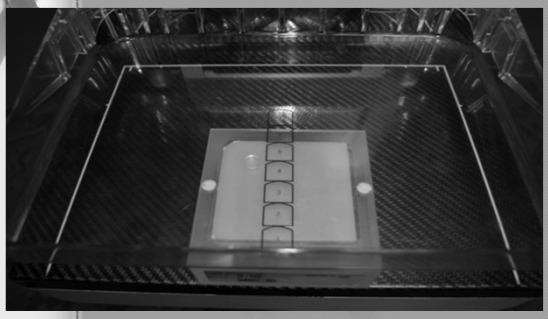





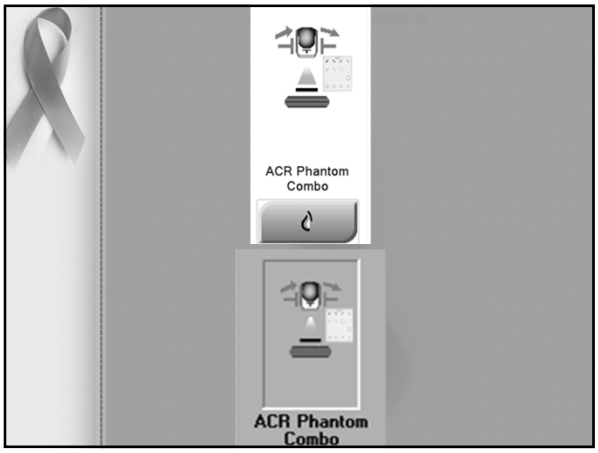

- Acquire phantom image for both modes
  - Auto filter
  - Large FS
  - AEC sensor position 2
  - AEC Compensation Step set at 0
    - Acquire phantom image for both modes and score
    - Document technical factors and EI (exposure index)
    - On tomo scroll to score to fine tune




## Phantom Image







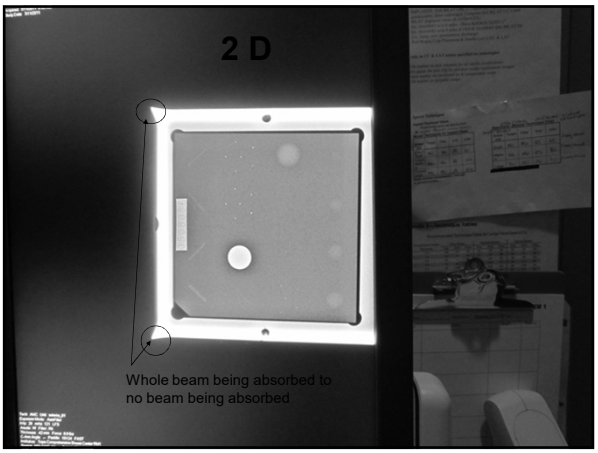

## Phantom Image Tomo

- A few seconds after the exposure has ended, the image appears on the image preview display. Switch to the reconstruction icon and scroll to the bring the ACR elements in focus. (usually when you can see the serial number really clear, slice 36 or 37)
- The phantom can be scored on the preview screen (3mega pixel monitor) It does not have to be sent to the radiologist's display.

- The minimum passing score for Tomosynthesis mode is:
- 4 fibers
- 3 speck groups
- 3 masses

## Phantom Image Tomo

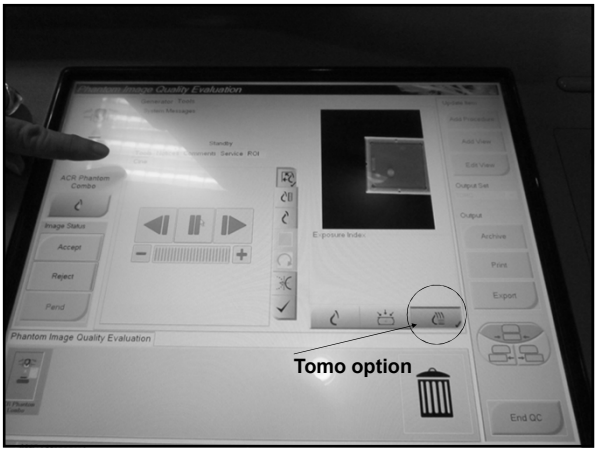
- This does not mean the Tomosynthesis score is lower than the 2D score.
- The goal of 3D Tomosynthesis is to remove superimposed tissue. If the phantom had tissue analogs, the Tomosynthesis score would be a lot higher than the 2D score.
- Even with the ACR phantom, the Tomosynthesis score may exceed 5 fibers, 4, speck groups and 4 masses.

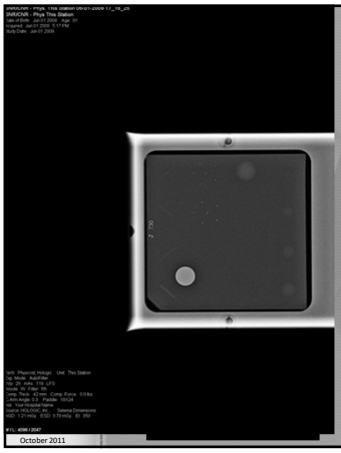



## Phantom Image Tomo

.

- Criteria and Corrective action:
- Artifacts associated with the phantom may be identified by repeating the phantom with the phantom slightly rotated.
- If the score fails, the source of the problem just be identified. If the source is the detector, corrective action must be taken before any further patients can be done. If the source is a diagnostic device, that device must be corrected before its used for image interpretation. (i.e. printer or monitors)

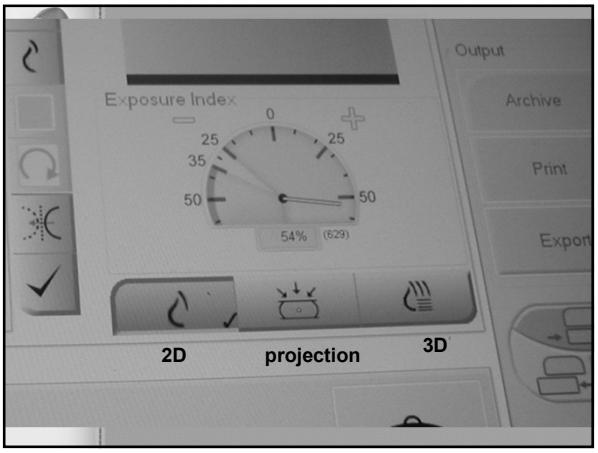


2D Criteria:
Fibers (5.0), Specks (4.0), Masses (4.0)

Tomosynthesis Criteria:
Fibers (4.0) Specks (3.0)
Masses (3.0)



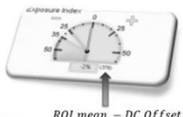



## Exposure Index (EI)

**EI is defined as the *digital value of a detector element***

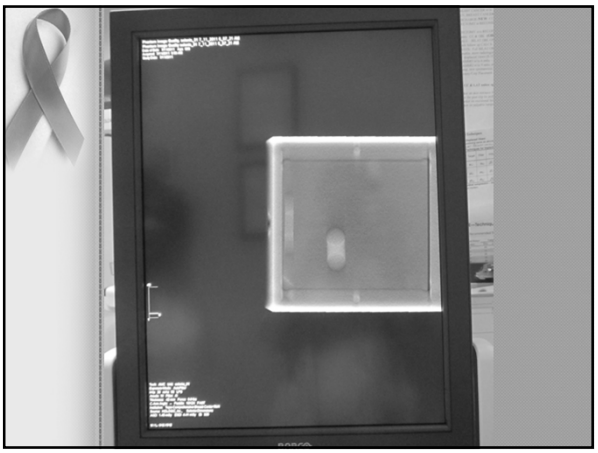
**"Raw" EI values need to be corrected by**

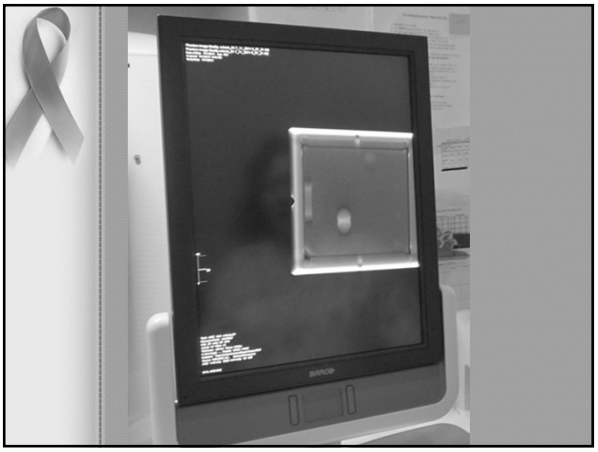
- Subtracting the DC offset (value of 50)
- Normalizing by the CNR correction factor (given in *Appendix D* of the *Hologic QC Manual*)

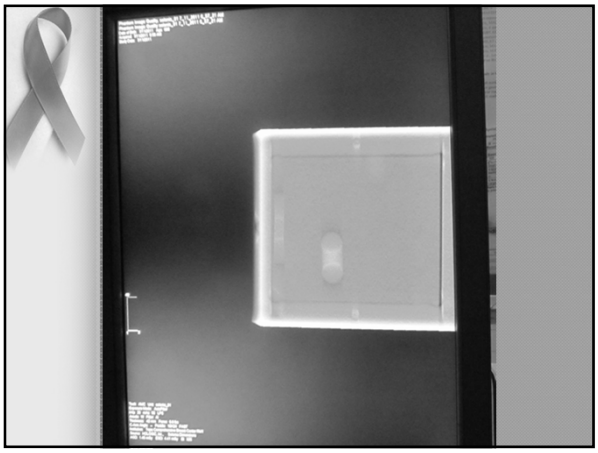


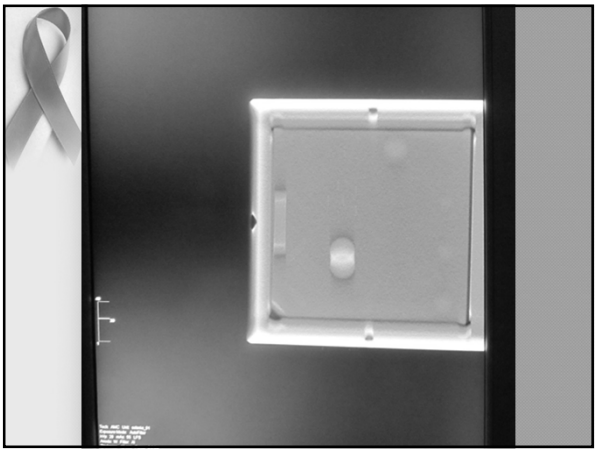

$$Pixel\ Value = \frac{ROI\ mean\ -\ DC\ Offset}{CNR\ Correction\ Factor}$$

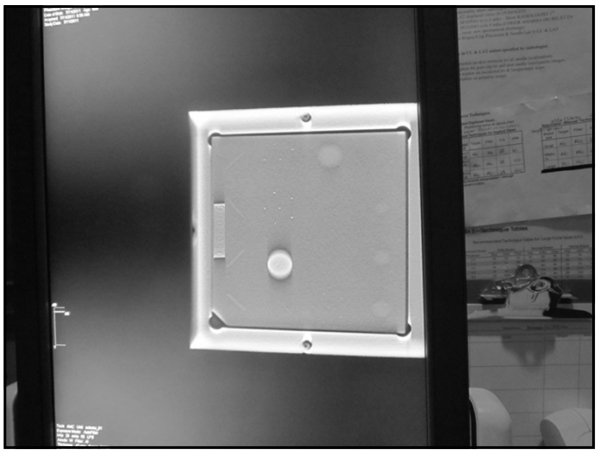
Hologic 2016.

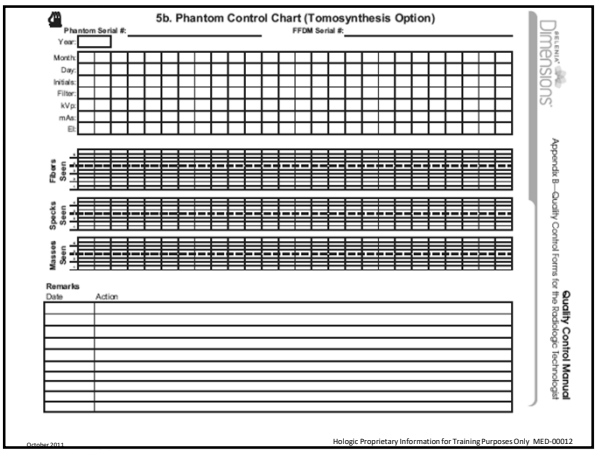


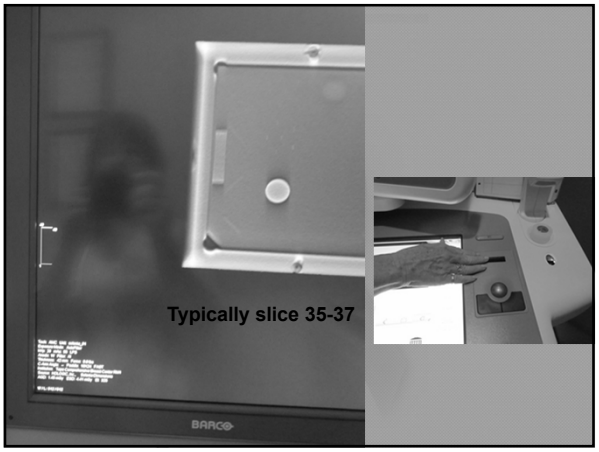







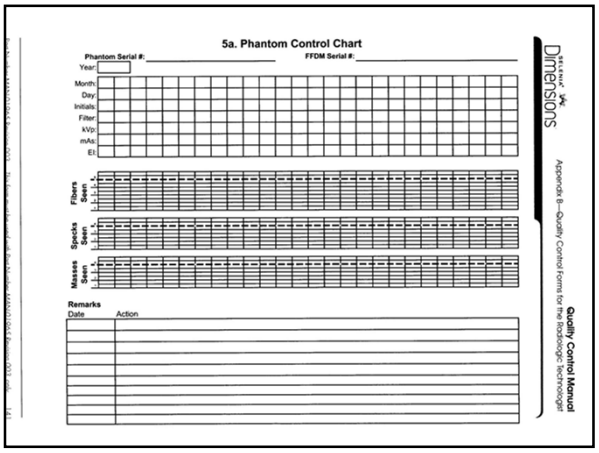





## SNR and CNR

- To ensure that the image quality of the system is maintained at optimal levels
- 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




## *Signal-to-noise ratio (SNR)*

- *Uniformity, which is the variation of the SNR over the whole image*

- The Signal-To-Noise test is another measurement related to our ability to detect objects in the image.
- Signal refers to the average of the numerical values in an area of the image. The signals in the image are the anatomical structures such as glandular tissue, adipose tissue, calcifications, fibers, and masses, which are evaluated in interpreting a mammogram.

- The SNR is also important because it sets the limit on the amount of contrast enhancement you can use to try to make the objects easier to see. Such enhancement generally increases both the signal and the noise and reduces the SNR. If the initial SNR is not sufficiently high, the enhancement lowers the SNR to the point where the contrast-enhanced noise eventually obscures the objects of interest.

- Noise refers to the random variation of the signal.
- This random variation can obscure the clinical information the observer is trying to detect.
- The signal-to-noise ratio is a measure of the relative strengths of the signal and noise. That is, the signal, or useful image information, divided by the noise, or random information.

In digital imaging the relative level of a signal or contrast to the image noise is the more relevant measure of image quality.

Therefore, the measure of consistency of CNR is used as a replacement for the measure of consistency of DD.

- When the signal-to-noise ratio is large, then noise does not obscure the objects of interest in the image.
- When the SNR is small, objects and noise can be confused and the objects of interest; for example, masses and calcifications, may be difficult to detect.

**Contrast to Noise**

- Define contrast to be the signal difference between two tissues A and B

  $C_{AB}=S_A-S_B$
- We are assuming that $S_A > S_B$ so that contrast is always positive.
- CNR – Contrast to noise ratio is a measure of the detectors ability to distinguish between objects in an image and the image noise.

**Signal-To-Noise and Contrast-To-Noise Measurements**
**Objective**
To assure consistency of the digital image receptor by evaluating the signal-to-noise ratio (SNR) and contrast-to-noise ratio (CNR) of the image receptor.

**Frequency**
Weekly

**Suggested Equipment**
- 18 x 24 cm compression paddle
- ACR Mammographic Accreditation Phantom (i.e., RMI 156 by Radiation Measurement, Inc.; 18-220 by Nuclear Associates)
- Acrylic disc, 4.0 mm thick with 1.0 cm diameter, placed on the top of the ACR Mammographic Accreditation Phantom as per the *1999 ACR Mammography Quality Control Manual, "Phantom Images" section*

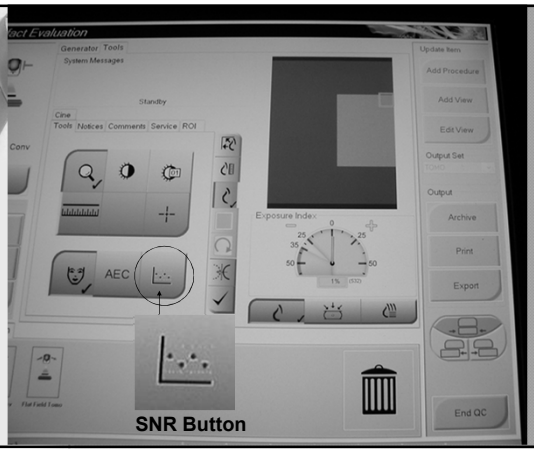
**Perform the Procedure Using a Previously Acquired ACR Phantom Image**

Select the **QC tab on the Select Patient screen. Select the previously acquired Phantom Image Qualiity Evaluation exam with the correct completed date and time.**
Select the **Open button.**
Select the first **ACR Phantom Conv (Tomosynthesis Option: ACR Phantom Combo) thumbnail image to display in the Preview screen.**

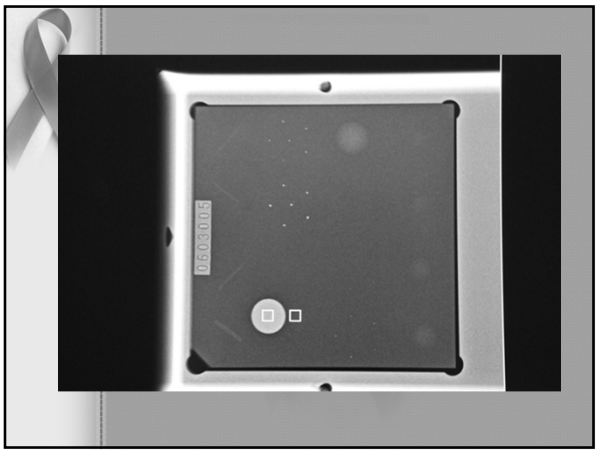
## SNR & CNR-Weekly

- A SNR button will be added to the tools tab on the touch screen
- When chosen the system places two ROI boxes on the image
- SNR and CNR values automatically computed
- Record results

**Automatic ROI Creation**
When you use the ACR Phantom view to acquire an image, the system assumes that an ACR Phantom is being imaged and adds a SNR button to the Tools tab window on the Procedure screen. The system automatically acquires and computes the SNR and CNR values.

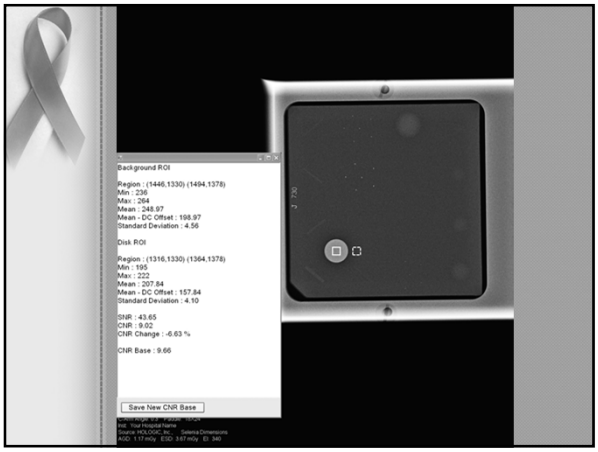


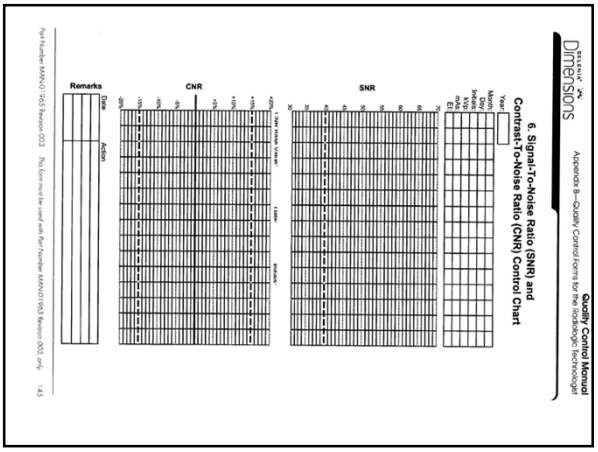
SNR Button

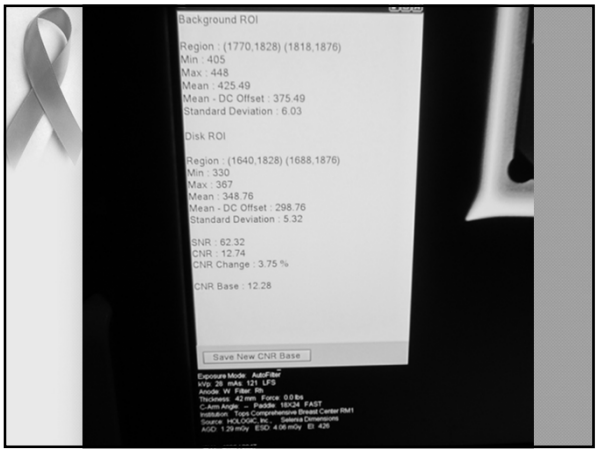


## Performance Criteria

- The measured SNR must be equal to or greater than 40. If it is less than 40, repeat the test.
- The computed CNR must be within ±15% of the value determined by the medical physicist during the equipment evaluation when the image receptor was installed or after a major upgrade.
- If these criteria are not met, a qualified service engineer must correct the problem before using the system for clinical imaging.




**Compression Thickness Indicator**

**Objective**
To assure that the indicated compression thickness is within tolerance.

**Frequency**
Biweekly (every two weeks)

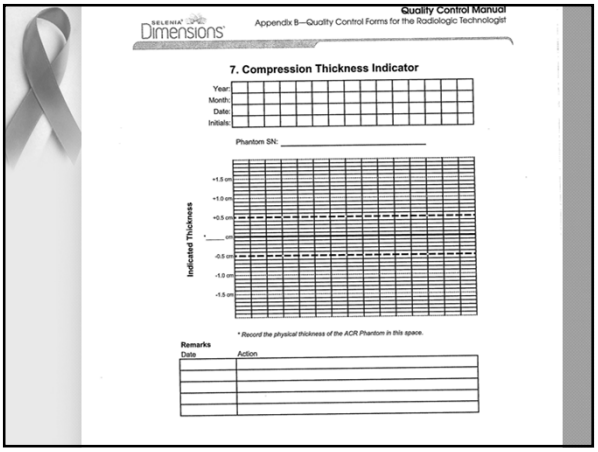
**Suggested Equipment**
- ACR Mammographic Accreditation Phantom
- 7.5 cm spot contact compression paddle

Center the ACR phantom laterally on the image receptor and position it so the chest wall
edge of the phantom is aligned with the chest wall side of the image receptor.
Install the 7.5 cm spot contact compression paddle in the compression device.
Apply Full Automatic Compression of approximately 30 pounds to the ACR phantom.

Record the thickness indicated on the compression device on the record form. The compression thickness indicator must always be accurate to ±0.5 cm from the actual thickness.

**Records Forms**
Use “Compression Thickness Indicator” form to track the results.




Quality Control Manual
Appendix B—Quality Control Forms for the Radiologic Technologist

**7. Compression Thickness Indicator**

Year:
Month:
Date:
Initials:

Phantom SN: _____

Indicated Thickness

+1.5 cm
+1.0 cm
+0.5 cm
0
-0.5 cm
-1.0 cm
-1.5 cm

* Record the physical thickness of the ACR Phantom in this space.

Remarks

| Date | Action |
|---|---|
| | |
| | |
| | |
| | |

**IF YOU HAVE STANDARD MACHINE USE PADDLE COMES WITH EQUIPMENT**

**Diagnostic Review Workstation Quality Control**

To assure consistency of the brightness, contrast and image presentation of the radiologist’s diagnostic review workstation.

***Note…*** *This diagnostic review workstation Quality Control procedure must be followed only if the workstation manufacturer does not provide an approved Quality Control procedure with their diagnostic review workstation.*

**Frequency**
Weekly when applicable.

**Suggested Equipment**
**(Applies to CRT and some LCD displays)**
Photometer supplied with each diagnostic review workstation

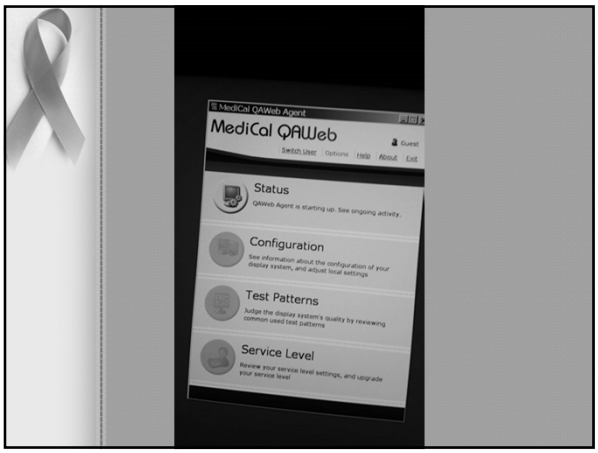
Run the display Quality Control software that comes with each diagnostic review workstation.. Measure the display white level for each CRT or LCD display.
Measure the display black level for each CRT only display.
Measure the DICOM GSDF compliance for each CRT or LCD display.
Measure the white level uniformity performance for each CRT display.

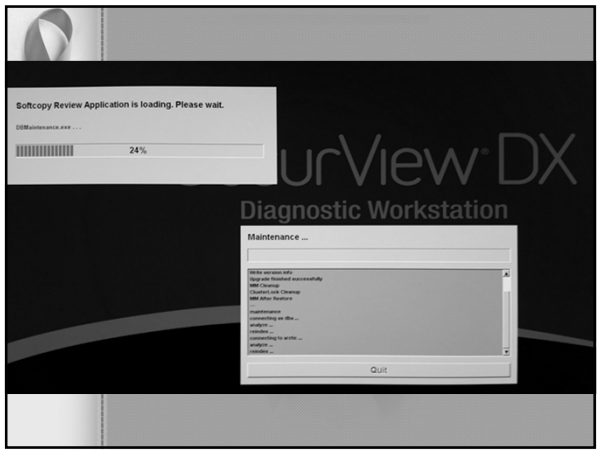
**White Level Performance**
The operating white level for
5421 LCD display, and 500 cd/m2 for the Barco Nio MDNG-5121 display.
The tolerance level for white level performance is ±6%.


Done on both monitors at one time.
Instructions on screen.
Operating levels established during initial calibration by manufacturer.
Uses a photometer
Computer software analyzes results and indicates if monitors met the pre-programmed control limits.

Technologist verifies all tests are completed successfully

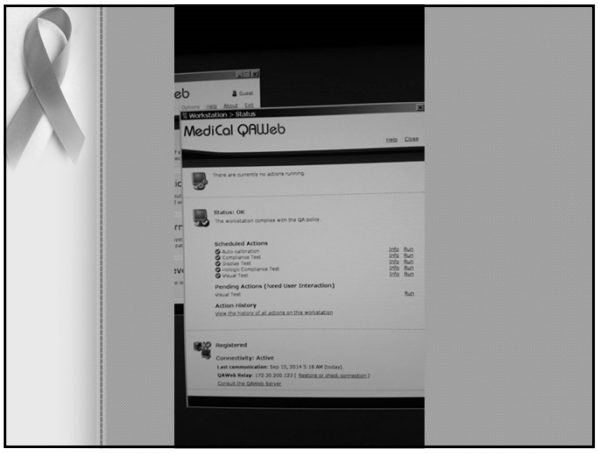
Internal records for physicist and MQSA inspection

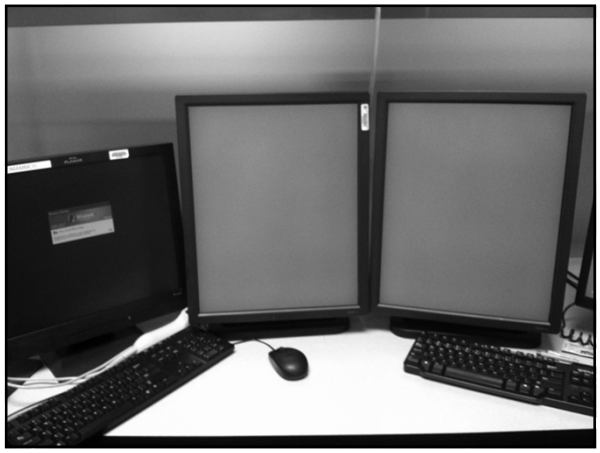


MediCal QAWeb Agent
MediCal QAWeb
Guest
Switch User | Options | Help | About | Exit
Status
QAWeb Agent is starting up. See ongoing activity.
Configuration
See information about the configuration of your display system, and adjust local settings
Test Patterns
Judge the display system's quality by reviewing common used test patterns
Service Level
Review your service level settings, and upgrade your service level

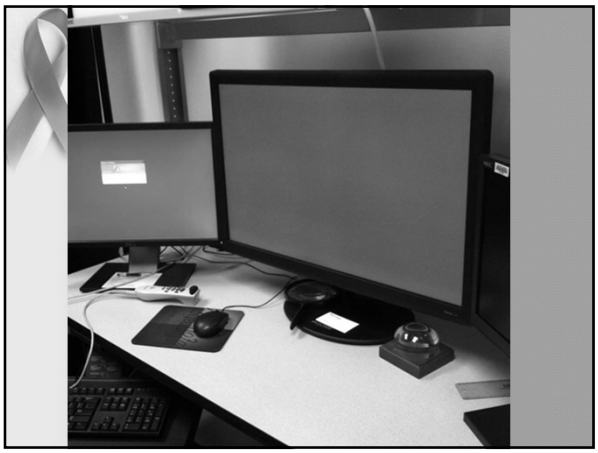

Softcopy Review Application is loading. Please wait.
DBMaintenance.exe . . .
24%
urView DX
Diagnostic Workstation
Maintenance ...
Quit


MediCal QAWeb Agent
MediCal QAWeb
Guest
Switch User | Options | Help | About | Exit
Status
Review the status of your workstation and the QAWeb Server connection
Configuration
See information about the configuration of your display system, and adjust local settings
Test Patterns
Judge the display system's quality by reviewing common used test patterns
Service Level
Review your service level settings, and upgrade your service level


Barco MediCal Q/A check
Please Wait...
Barco MediCal Q/A check
Please Wait...

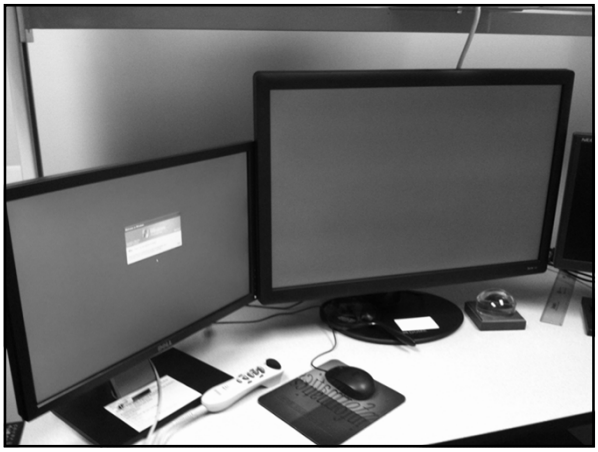

MediCal QAWeb
Workstation > Status
Help | Close
There are currently no actions running.
Status: OK
This workstation complies with the QA policy.
Scheduled Actions
Pending Actions (%need User Interaction)
Action History
Registered
Connectivity: Active

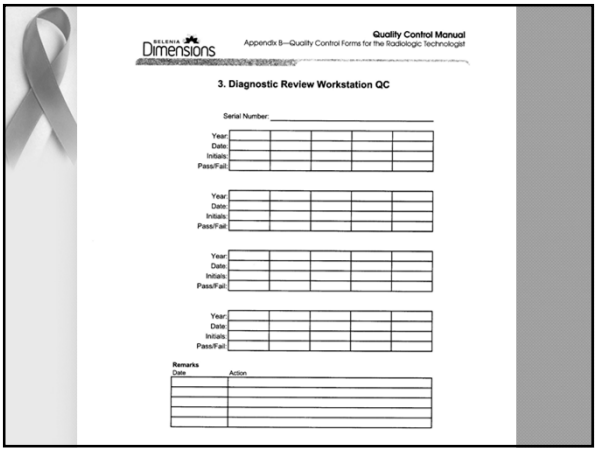




**Record Forms**

Internal logs to the software.
Use the "Diagnostic Review Workstation Quality Control" form in Appendix B to record the results.





Quality Control Manual
Appendix B—Quality Control Forms for the Radiologic Technologist

**3. Diagnostic Review Workstation QC**

Serial Number: _____

| | | | | | |
|---|---|---|---|---|---|
| Year | | | | | |
| Date | | | | | |
| Initials | | | | | |
| Pass/Fail | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Year | | | | | |
| Date | | | | | |
| Initials | | | | | |
| Pass/Fail | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Year | | | | | |
| Date | | | | | |
| Initials | | | | | |
| Pass/Fail | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Year | | | | | |
| Date | | | | | |
| Initials | | | | | |
| Pass/Fail | | | | | |

**Remarks**

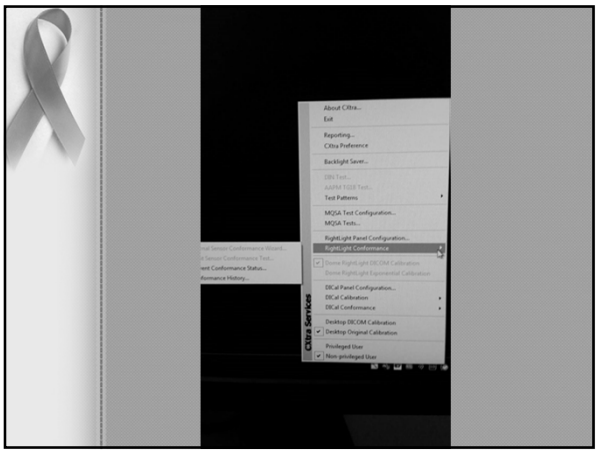
| Date | Action |
|---|---|
| | |
| | |
| | |
| | |

## Difference in Monitors

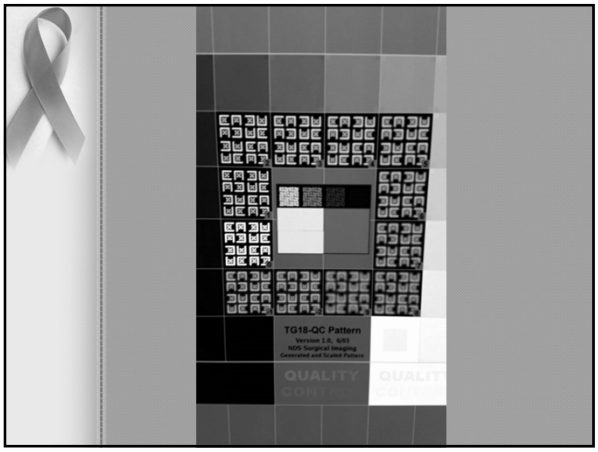
- Dual  monitors side by side
- 5 mega pixel
- About15 thousand per pair

- One monitor
- Many options on set up
- 10 mega pixel
- About 18-20 thousand for one monitor

Checking Monitors for correct Luminance and white levels



- Clean viewbox surfaces using window cleaner and soft paper towels.
- Assure that all marks have been removed.
- Visually inspect the viewboxes for uniformity of luminance.
- Assure that all viewbox masking equipment is functioning properly and easily.
- Visually check the room illumination levels and assure that sources of bright light are not present in the room and are not being reflected from the viewbox surface.




Visual Checklist

**Frequency:**

Monthly and after any service or maintenance on the mammography system.

**Objective:**

To assure that the mammographic x-ray system indicator lights, displays, and mechanical locks and detents are working properly and that the system is mechanically safe.

Perform funtiontional test as part of your visual checklist.

Viewbox and Viewing Conditions Test

**Frequency:**

Weekly

**Objective:**

To ensure good image review conditions by keeping the view boxes free of dust, finger prints, and other marks and the viewing conditions optimized.

**Procedure:**

This test is not unique to digital mammography systems.

Follow accepted mammographic QC procedures and action limits to complete this test.

## Functional Tests

This is part of your monthly Visual checklist. Do this Functional test monthly also At the same time.

**Perform the Functional Tests**

**Figure Legend**

1. Compression Release
2. (Provisional use)
3. Light Field Lamp
4. (Provisional use)
5. Collimator Override
6. Clockwise C-Arm Rotation
7. C-Arm Up and Down
8. Counterclockwise C-Arm Rotation
9. Compression Up
10. Compression Down

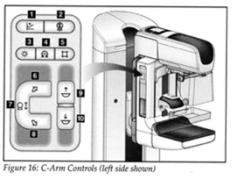


*Figure 16: C-Arm Controls (left side shown)*

There is a C-arm control panel on both the left and right sides of the Gantry.

Perform the Functional Tests as part of your monthly visual checklists to make sure that the control operates correctly.

*Table 1: C-Arm Functional Tests*

| Function | Functional Test |
|---|---|
| Compression Down | Press a Compression Down button:<br>• The compression brake engages.<br>• The light field lamp illuminates.<br>• The compression device lowers.<br>*Note… When you press the Compression Down button, the compression brake remains engaged until the Compression Release button is pressed.*<br>Compression down movement stops:<br>• When you release the button.<br>• When you reach the Down Force limit.<br>• When you reach the lower travel limit. |

## Functional Test

*Table 1: C-Arm Functional Tests*

| Function | Functional Test |
|---|---|
| Compression Up  | Press a Compression Up button:<br>• The Compression Device moves toward the top.<br>• The Compression Up button *does not* release the Compression Brake.<br>Compression Up movement automatically stops:<br>• When you release the button.<br>• When you reach the upper travel limit. |
| Compression Release  | Press the Compression Release button:<br>• The Compression Motor Brake releases.<br>• The Compression Device lifts. |
| C-Arm Up  | Press the C-Arm Up button:<br>• The C-Arm movement automatically stops when the button is released.<br>• The C-Arm movement automatically stops when the C-arm reaches the upper travel limit.<br>• The C-Arm movement is disabled when a compression force of 45 N (10 pounds) or greater is applied. |

*Table 1: C-Arm Functional Tests*

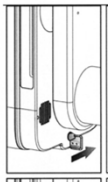
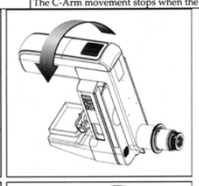
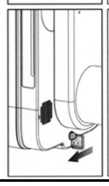
| Function | Functional Test |
|---|---|
| C-Arm Rotation Switch | Push the C-Arm Rotation switch away from you to move the C-Arm toward you.<br>Pull the C-Arm Rotation switch toward you to move the C-Arm away.<br>The C-Arm movement stops when the switch is released. |
|  |  |
|  |  |

*Table 1: C-Arm Functional Tests*

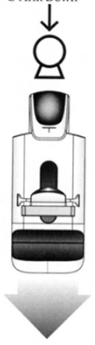
| Function | Functional Test |
|---|---|
| C-Arm Down  | Press the C-Arm Down button:<br>• The C-Arm movement automatically stops when the button is released.<br>• The C-Arm movement automatically stops when the C-arm reaches the lower travel limit.<br>• The C-Arm movement is disabled when a compression force of 45 N (10 pounds) or greater is applied. |

*Table 1: C-Arm Functional Tests*

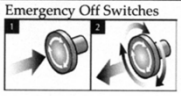
| Function | Functional Test |
|---|---|
| Collimator Override | The Collimator Override button changes the collimation through the different x-ray fields.<br>Press the light field lamp button to show the x-ray field, then press the Collimator Override button to select an x-ray field. |
| Light Field Lamp | Press the light field lamp button to see the x-ray field for approximately 30 seconds.<br>The light field lamp automatically illuminates with the start of the Compression Down movement. |
| Motor Enable | Reserved for provisional use. |
| C-Arm Zero | Reserved for provisional use. |
| Shifting Paddle System | The 18 x 24 cm Screening Paddle moves approximately 2.5 cm into the left, center, or right position. While compression is applied, you can not move the paddle. The collimator is programmed to follow the position of the paddle.<br>To test this function:<br>1. Install the 18 x 24 cm paddle in the Compression Device.<br>2. Select a view. Use the Paddle Shift buttons on the procedure screen to override the position.<br>Verify that the paddle automatically moves to the new position.<br>3. Turn on the light field lamp. Confirm that the collimator position matches the paddle position.<br>4. Repeat this procedure for the other paddle positions. |
|  | A FAST Compression Mode Slide on the Compression Device lets you set the system for FAST Compression Mode or for Normal Compression Mode.<br>To select the mode, move the Slide to the "F" position from either side of the Compression Device. |

*Table 1: C-Arm Functional Tests*

| Function | Functional Test |
|---|---|
| Counterclockwise C-Arm Rotation<br>**Left Panel** **Right Panel**  | Press the Counterclockwise C-Arm Rotation to start counterclockwise C-arm rotation. |
| Clockwise C-Arm Rotation<br>**Left Panel** **Right Panel**  | Press the Clockwise C-Arm Rotation button to start clockwise C-Arm rotation. |

NOTE: C-Arm movement is disabled when a compression force of 45 N (10 pounds) or greater is applied.

*Table 1: C-Arm Functional Tests*

| Function | Functional Test |
|---|---|
| Emergency Off Switches  | There are three emergency Off switches, one on each side of the Gantry and one on the Acquisition Workstation.<br>Press any of the Emergency Off switches to turn Off the Gantry and disable the Standard Acquisition Workstation Lift Mechanism.<br>Turn the Emergency Off switch by one-quarter turn to reset the switch. |

## Repeat Analysis

- Select the Reject Analysis procedure
- Select the starting date and the ending date then type (reject, repeat or both) and the operator
- Select the Go button to get the report

## How is your visual checklist?


Don’t drink and make signs!

**Action Limit:**

The overall repeat rate is ideally should be approximately 2 % or less, but a rate of 5% is probably adequate if the radiologist and medical physicist agree.

If the total repeat rate changes from the rate determined for the previous analysis period by more than 2.0% of the total exposures included in the analysis, the reasons for the change must be determined. Any corrective actions taken must be recorded and an assessment must be made of their effectiveness.

Repeat Analysis Check

**Frequency:**

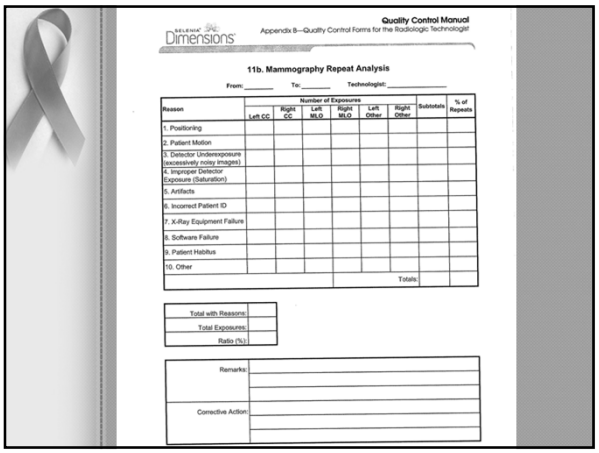
Quarterly. For the repeat rate to be meaningful, an analysis period that yields a patient volume of at least 250 patients or 1,000 exposures is needed.

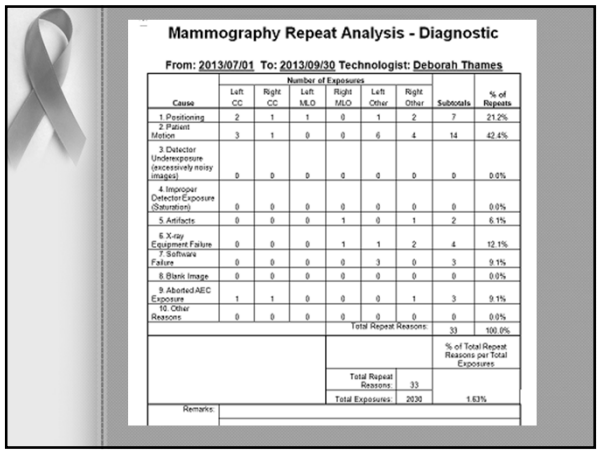
**Objective:**

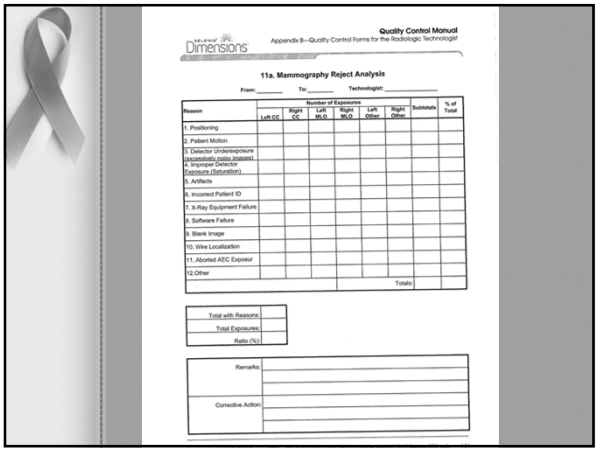
To determine the number and cause of repeated digital mammograms. Analysis of this data can help identify ways to improve system efficiency and reduce digital retakes and patient exposure.

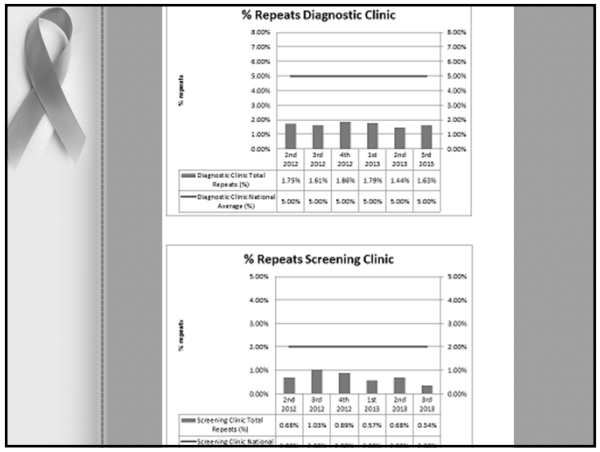
## Tomo repeat analysis

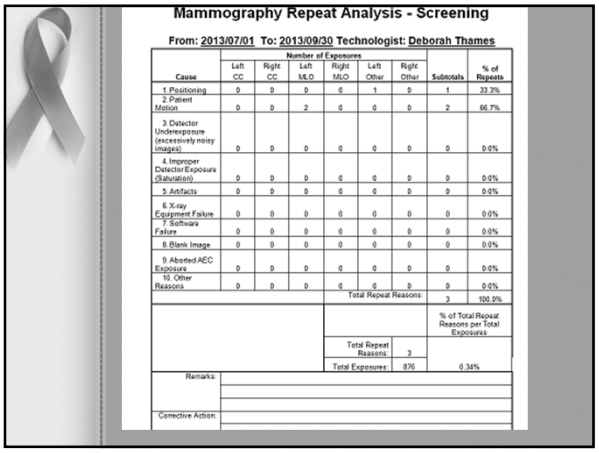
- Combo repeat only counts as one
- Rejects do not count in repeat rate

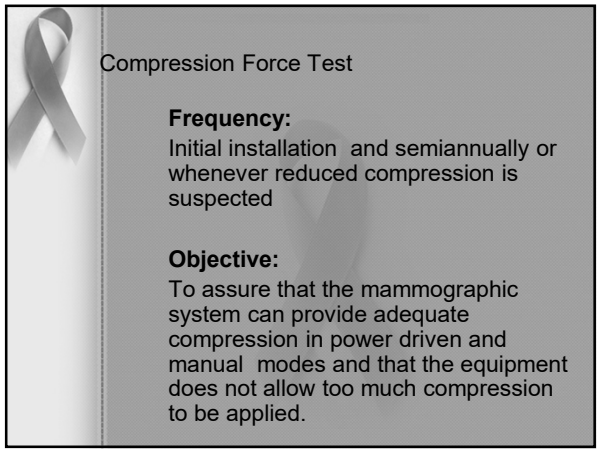

Quality Control Manual
Appendix B—Quality Control Forms for the Radiologic Technologist
Dimensions
11b. Mammography Repeat Analysis
From: _____ To: _____ Technologist: _____
Reason
Number of Exposures
Left CC
Right CC
Left MLO
Right MLO
Left Other
Right Other
Subtotals
% of Repeats
1. Positioning
2. Patient Motion
3. Detector Underexposure (excessively noisy images)
4. Improper Detector Exposure (Saturation)
5. Artifacts
6. Incorrect Patient ID
7. X-Ray Equipment Failure
8. Software Failure
9. Patient Habitus
10. Other
Totals:
Total with Reasons:
Total Exposures:
Ratio (%):
Remarks:
Corrective Action:


Mammography Repeat Analysis - Diagnostic
From: 2013/07/01 To: 2013/09/30 Technologist: Deborah Thames
Number of Exposures
Cause
Left CC
Right CC
Left MLO
Right MLO
Left Other
Right Other
Subtotals
% of Repeats
1. Positioning 2 1 1 0 1 2 7 21.2%
2. Patient Motion 3 1 0 0 6 4 14 42.4%
3. Detector Underexposure (excessively noisy images) 0 0 0 0 0 0 0 0.0%
4. Improper Detector Exposure (Saturation) 0 0 0 0 0 0 0 0.0%
5. Artifacts 0 0 0 1 0 1 2 6.1%
6. X-ray Equipment Failure 0 0 0 1 1 2 4 12.1%
7. Software Failure 0 0 0 0 3 0 3 9.1%
8. Blank Image 0 0 0 0 0 0 0 0.0%
9. Aborted AEC Exposure 1 1 0 0 0 1 3 9.1%
10. Other Reasons 0 0 0 0 0 0 0 0.0%
Total Repeat Reasons: 33 100.0%
% of Total Repeat Reasons per Total Exposures
Total Repeat Reasons: 33
Total Exposures: 2030
1.63%
Remarks:

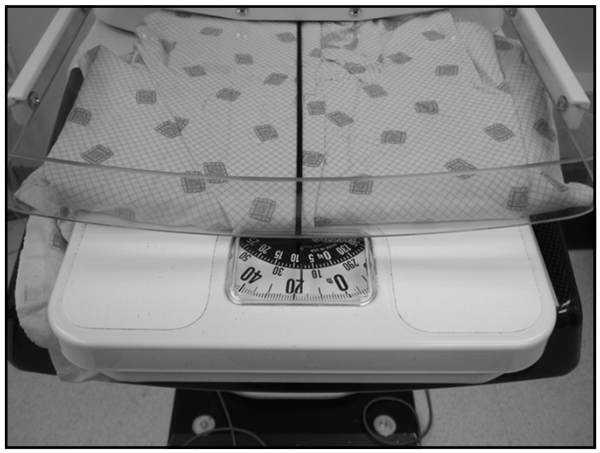

Quality Control Manual
Appendix B—Quality Control Forms for the Radiologic Technologist
Dimensions
11a. Mammography Reject Analysis
From: _____ To: _____ Technologist: _____
Reason
Number of Exposures
Left CC
Right CC
Left MLO
Right MLO
Left Other
Right Other
Subtotals
% of Total
1. Positioning
2. Patient Motion
3. Detector Underexposure (excessively noisy images)
4. Improper Detector Exposure (Saturation)
5. Artifacts
6. Incorrect Patient ID
7. X-Ray Equipment Failure
8. Software Failure
9. Blank Image
10. Wire Localization
11. Aborted AEC Exposur
12.Other
Totals:
Total with Reasons:
Total Exposures:
Ratio (%):
Remarks:
Corrective Action:


% Repeats Diagnostic Clinic
% repeats
8.00%
7.00%
6.00%
5.00%
4.00%
3.00%
2.00%
1.00%
0.00%
2nd 2012
3rd 2012
4th 2012
1st 2013
2nd 2013
3rd 2013
Diagnostic Clinic Total Repeats (%)
1.75% 1.61% 1.86% 1.79% 1.44% 1.63%
Diagnostic Clinic National Average (%)
5.00% 5.00% 5.00% 5.00% 5.00% 5.00%
% Repeats Screening Clinic
% repeats
5.00%
4.00%
3.00%
2.00%
1.00%
0.00%
2nd 2012
3rd 2012
4th 2012
1st 2013
2nd 2013
3rd 2013
Screening Clinic Total Repeats (%)
0.68% 1.03% 0.89% 0.57% 0.68% 0.34%
Screening Clinic National


Mammography Repeat Analysis - Screening
From: 2013/07/01 To: 2013/09/30 Technologist: Deborah Thames
Number of Exposures
Cause
Left CC
Right CC
Left MLO
Right MLO
Left Other
Right Other
Subtotals
% of Repeats
1. Positioning 0 0 0 0 1 0 1 33.3%
2. Patient Motion 0 0 2 0 0 0 2 66.7%
3. Detector Underexposure (excessively noisy images) 0 0 0 0 0 0 0 0.0%
4. Improper Detector Exposure (Saturation) 0 0 0 0 0 0 0 0.0%
5. Artifacts 0 0 0 0 0 0 0 0.0%
6. X-ray Equipment Failure 0 0 0 0 0 0 0 0.0%
7. Software Failure 0 0 0 0 0 0 0 0.0%
8. Blank Image 0 0 0 0 0 0 0 0.0%
9. Aborted AEC Exposure 0 0 0 0 0 0 0 0.0%
10. Other Reasons 0 0 0 0 0 0 0 0.0%
Total Repeat Reasons: 3 100.0%
% of Total Repeat Reasons per Total Exposures
Total Repeat Reasons: 3
Total Exposures: 876
0.34%
Remarks:
Corrective Action:


Compression Force Test
Frequency:
Initial installation and semiannually or whenever reduced compression is suspected
Objective:
To assure that the mammographic system can provide adequate compression in power driven and manual modes and that the equipment does not allow too much compression to be applied.

- Breast compression is equally important for digital mammography as it is for film screen. It contributes to digital image quality by immobilizing the breast (reduces motion unsharpness), producing a more uniform, thinner tissue (lowers scatter radiation, more even penetration of x-rays, less magnification or geometric blurring, less anatomical superimposition), and lowering dose



**Procedure:**

This test is not unique to digital mammography systems.

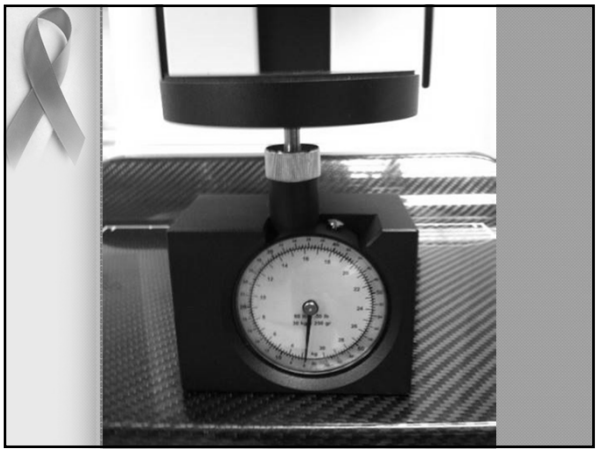
Follow accepted mammographic QC procedures to perform this test.

Record the results.

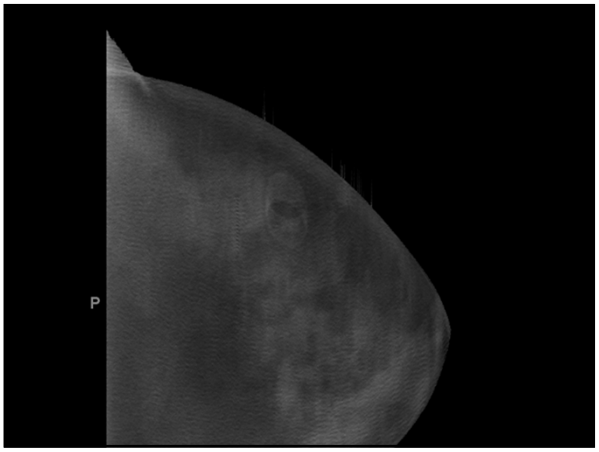
**Action Limit-Lorad**

The maximum compression force for the initial power drive must be between 11 and 20 daN (25-45lbs)

## Breast Tomosynthesis Artifacts



The new ACR manual will promote uniformity of testing since it will allow facilities with applicable systems to follow one manual instead of the dozens of different manuals that are mandated for the varying manufacturers and models of digital mammography equipment," said Eric Berns, PhD, lead author and chair of the ACR Subcommittee on Mammography Quality Assurance. "The new manual focuses on tests that are clinically relevant for high-quality imaging and the structure for a thorough and complete quality control program," he added.




## About the new ACR Digital manual

- Q. When will the new ACR Digital Mammography QC Manual be available? A. The manual will be available in late spring of 2016. Q. How will the new ACR Digital Mammography QC Manual be distributed?
- A. The manual will be provided, at no charge, to all ACR-accredited mammography facilities (and to those applying for accreditation) in a PDF format.
  Medical physicists associated with ACR-accredited facilities will also be allowed to download the manual at no charge. All others may purchase the manual PDF from the ACR catalog. Hard copies will not be available.

## Upcoming Changes in QC for FFDM

- New BI-RAD's and lexicon changes
- New ACR FFDM QC Control Manual
- New Digital Phantom for FFDM
- Possibly a new Phantom for DBT

## Update as of 8/2016

ACR Digital Mammography Quality Control Manual Now Available

**August 02, 2016**

The 2016 American College of Radiology (ACR) Digital Mammography Quality Control Manual is now available in electronic format.

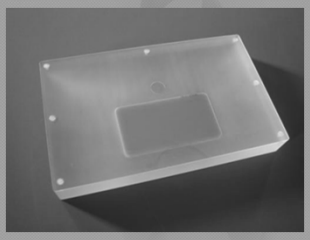
Manual author Eric Berns, PhD, notes, "This is an important development for modern breast imaging practices, where the overwhelming majority of facilities work with digital equipment. The new ACR manual will enable facilities to consolidate their quality control responsibilities by working from a single resource."

A link was automatically sent to all mammography facilities accredited by the ACR to download the new manual at no charge. (Lead technologists and online facility users should share this link with their colleagues at the facility.) Medical physicists associated with these facilities may also obtain the link from their facilities to download the new manual at no charge. Individuals not associated with ACR-accredited facilities may purchase the manual from the ACR catalog.

**More questions….**

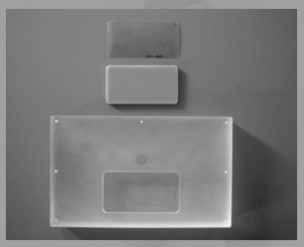
- Our facility has a mammography unit that performs 2D imaging using computed radiography (CR). Will we be allowed to use the new ACR Digital Mammography QC Manual instead of our CR manufacturer's QC manual for QC on this unit?
- A. Yes.

**The ACR FFDM Phantom 24 X 30**

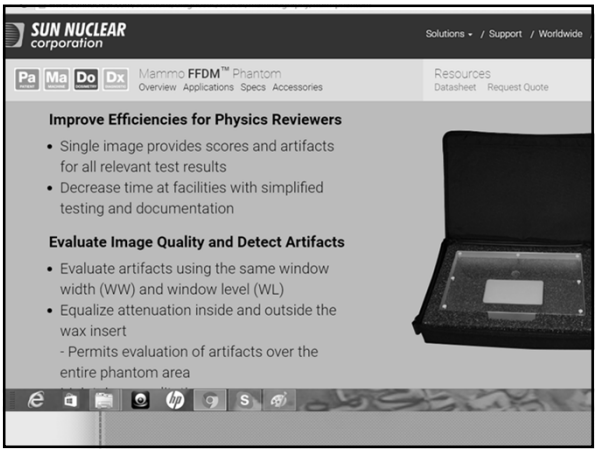


- Q. Our facility would like to begin using the new ACR Digital Mammography QC Manual. Can we do so as soon as we receive our new manual?
- A. Before the facility QC technologist may start using the new DMQC Manual on a particular unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the new manual and phantom. This is important to provide testing techniques and procedures for the QC technologist to use during routine QC. After this is done, the QC technologist may start performing routine QC using the new manual.

**The ACR FFDM Phantom**



- Q. May I use our old ACR phantom to perform the tests in the new ACR Digital Mammography QC Manual instead of obtaining the new ACR Digital Mammography Phantom?
- A. No. The new ACR Digital Mammography QC Manual procedures were designed around the new ACR Digital Mammography Phantom. The old ACR phantom cannot be used to conduct the tests in the new manual.

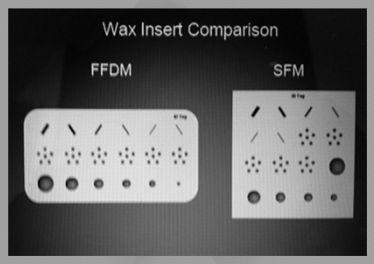


Overview Applications Specs Accessories Datasheet Request Quote

## Specifications

**Wax and acrylic equivalent to 4.2 cm thick compressed breast tissue. 50% adipose and 50%**

| | |
|---|---|
| **Mammography Phantom:** | FFDM |
| **Nylon Fibers (Fibrils):** | 6 Groups |
| **Micro-calcifications (Specks)** | 6 Groups, $Al_2O_2$ |
| **Masses:** | 6 |
| **Dimensions (L/W/H):** | 31.0 ± 0.1 x 19 ± 0.1 x 4.1 ± 0.03 cm |
| **Dimensions: Wax Insert (L/W/H):** | 12.98 (+ 0, - 0.04) x 6.98 (+0, -0.04) x 0.7 ± 0.02 cm |
| **CNR Cavity Depth:** | 0.1 ± 0.005 cm |
| **CNR Diameter:** | ± 0.05 cm |
| **Compensator:** | 9 mil Polyvinylidene |




Pa Ma Do Dx Mammo **FFDM**™ Phantom
Overview Applications Specs Accessories Resources Datasheet

**Simplify Testing and Save Time**

The Mammo FFDM Phantom is designed to evaluate artifacts over the entire detector with a single image, supporting quick detection of objects from 0.14 to 1.0 mm.*

The Mammo FFDM Phantom was evaluated and accredited by the ACR, and is also referred to as the ACR Digital Mammography Phantom. The Mammo FFDM Phantom simulates radiographic characteristics of compressed breast tissue, including micro-calcifications, ductal fibrous structures and tumor-like masses. Identification of these small structures is essential to the early detection of breast cancer.

**ACR FFDM QC Manual Project**

- ACR Subcommittee on Quality Assurance
- –Clinical Representatives
- – MITA Representatives
- –ACR Representatives
- Information written by

…….Et al. Eric Berns, PhD

**The ACR FFDM Phantom**

**ACR FFDM QC Manual Project**

- Subcommittee Charge:
- – Design ACR Accreditation Phantom for FFDM
- – Write QC Manual for ACR FFDM Mammography
- Accreditation Program

## ACR Digital QC Manual

- Structure of Manual:
- – Radiologist's Section
- – Clinical Image Quality Section
- – Radiologic Technologist's Section
- – Medical Physicist's Section
- – Educational, Guidance, and Troubleshooting Section
- – Glossary
- – References
- – Index

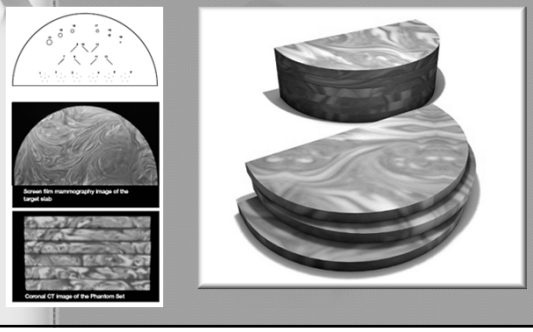
## ACR Digital QC Manual

- • Benefits of Phantom Design
- – Provides view of entire detector – artifact evaluation
- – W/L optimized for test objects optimizes for artifact eval
- – Finer gradations of test objects
- – Test objects go to smaller sizes
- – AGD measurement & limit same as SFM – Meets MQSA
- – Provides single image/exposure for evaluation(s)
- – Minimal training (~ 25,000 Techs currently trained)
- – Provides basis for monitor and laser printer QC
- – ACR Physics Reviewers
- • Can see scores and artifacts on single submitted film (or image)
- • Do not need different WW/WL settings

## What will be New?

- Tech Section
- – Enhanced positioning and image quality section
- – New Test: Monitor QC for the Radiologist
- – New Test: Facility QC Review
- – New Format: Corrective Action Log
- – New Documentation: Facility Equipment Inventory
- – Instructions for Mobile Units
- – Eliminating calculations (Yet to be determined)

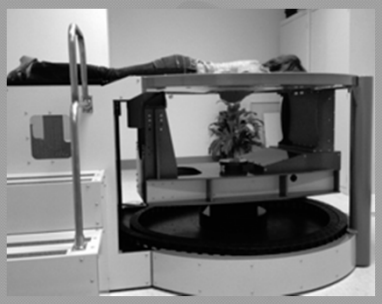
**CIRS Model 020 BR3D Mammography Phantom**
**Used on FFDM, Breast Tomo, and Breast CT Internationally**
**Will this be used in U.S.?**




## Design Summary

- Differences from screen-film phantom
- • Eliminate subtraction for artifacts
- • Add "Fail" for artifacts
- • Improve specific rules for scoring
- • Change pass/fail criteria from
- – 4,3,3 to 2,3,2
- – **But, objects are the same (effective) size as SFM phantom

## Dedicated Breast CT Scanner



Another promising technology—the dedicated breast CT system—creates a full 3D representation of the breast. The scan is taken while the patient lies face down on a bed with her breast suspended through a cup and the X-ray machine rotates around it. For patients, the procedure is more comfortable than regular mammography because the breast isn't compressed. Also, there's less radiation exposure than during a CT exam of the entire chest because only the breast is exposed to X-rays.

Health care practitioners using this technology have to learn how to read and interpret hundreds of high-resolution images produced by the scanner. But what makes the task easier is that the images have less distortion than mammography, and the system is optimized to differentiate between the breast's soft tissue and cancer tissue.

"These images will be very different from 2D mammograms. They're truly 3D images of the breast from any orientation. You can scroll through the slices—up and down, left and right—and get a unique view of the breast like never before," Myers says. "It gives doctors tremendous freedom in how they look at the interior of the breast and evaluate its structures. It's almost like seeing the anatomy itself."

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

**Product Name:** Koning Breast CT (CBCT 1000)
**PMA Applicant:** Koning Corporation
**Address:** 150 Lucius Gordon Drive Suite 112, West Henrietta, NY 14586
**Approval Date:** January 14, 2015
**Approval Letter:**
http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130025a.pdf

**What is it?** The Koning Breast CT (KBCT) system is a dedicated breast imaging system that acquires computed tomography (CT) images without compressing the breast. The KBCT produces 3D images to aid in the diagnosis of breast cancer.

**How does it work?** The patient lies face down on a table that is mounted above the KBCT hardware. The table has an opening to allow one breast to hang through it. In less than 10 seconds, the KBCT hardware rotates around the breast without compressing it. The KBCT acquires data that is used by the software to reconstruct cross-sectional 3D images of the entire breast.

**When is it used?** The KBCT is intended for breast cancer diagnosis in women who have suspicious signs or symptoms of breast cancer, or who have abnormal imaging findings, and who need more imaging tests to determine whether a biopsy should be performed. KBCT images should be read by a physician along with standard screening mammograms. The KBCT is not intended for breast cancer screening.

**What will it accomplish?** The 3D images of the entire breast provide additional information to help physicians determine if any of the patient's clinical or imaging abnormalities may be breast cancer.

**When should it not be used?** There are no known contraindications.

**Additional information**: The Summary of Safety and Effectiveness Data and labeling are available online.

Other Resources

## Breast CT Scanners

- John Boone, PhD. has developed a dedicated breast CT scanner at the University of California in 2001.
- It produces 3-D images of the breast to help radiologists detect those hard-to-find tumors.
- A breast CT scanner has better contrast resolution than mammography.
- The scanner has an x-ray tube and detector - positioned on opposite sides of a patient.
- It rotates 360 degrees while sending x-rays through the body at many different angles.

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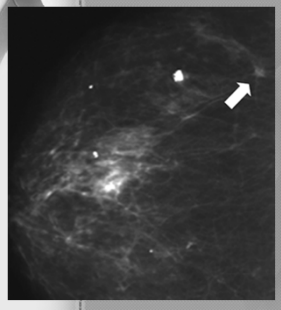
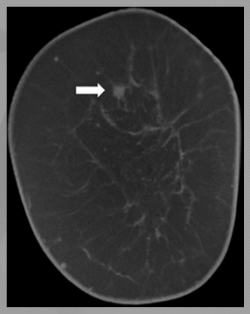
- The CIRS Model 020 BR3D Mammography Phantom was designed to assess detectability of various size lesions within a tissue equivalent, complex, heterogeneous background. This phantom provides more realistic challenges for standard screen and FFDM mammography systems as well as Tomosynthesis and breast Computed Tomography.

## Dedicated Breast CT Scanner



CC view shows 4 mm IDC



Coronal view CT shows 12:00 4mm IDC

## CIRS Model 020 BR3D Mammography Phantom

- The phantom consists of a set of six (6) slabs made of heterogeneous breast equivalent material that exhibits characteristics of real breast tissue and demonstrates how underlying targets can be obscured by varying glandularity. Each slab contains two tissue equivalent materials mimicking 100% adipose and gland tissues "swirled" together in a approximate 50/50 ratio by weight. One of the slabs contains an assortment of micro-calcifications, fibrils and masses.

# That's enough QC!!

**Mammo Cats**