FUJIFILM

Aspire FCRm/CRm

Fujifilm CR for Mammography

Quality Control Manual

8th Edition: May 2013

Fujifilm Medical Systems U.S.A., Inc.

897N0602G

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(*) Portions of this test were reprinted from the ACR Mammography Quality Control Manual. American College of Radiology; 1999

FOREWORD

Quality assurance (QA) in mammography means the planned and organized actions designed to provide confidence that mammographic equipment and related components operated in a facility will reliably and consistently produce diagnostic quality mammograms for the screening and diagnosis of breast cancer with minimum dose to patients and staff.
This document, FCRm/CRm Quality Control for Mammography Operation Manual, describes how to confirm and verify that the Fuji Computed Radiography System when used with an MQSA compliant X-ray system for screen-film is working in a consistent manner according to the specifications for use as part of a Full Field Digital Mammography (FFDM) system.
This document applies to the CR-IR 348CL (hereinafter referred to as "CR Console") and the CR-IR 363AWS (hereinafter referred to as "AWS-c").

> Always follow all applicable laws and regulations for your jurisdiction. If anything in this document is in conflict with applicable laws or regulations, the applicable law or regulation shall take precedence.

Acknowledgement

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Introduction to Measurements

To produce consistently high quality images, each part of the imaging chain must function within the limits of performance given. Users must therefore be able to evaluate the status of the acquisition system, including detector, the processing system and the display systems.

Assumption

Many tests in this manual are specific to the Fuji Computed Radiology (FCR) mammography system and its related components. Some tests are designed to verify use of the FCR mammography system in conjunction with an X-ray generator and imaging chain components. It is therefore required that the X-ray generator and the collimator are performing and calibrated in accordance with MQSA requirements for screen-film systems. The display systems used for final interpretation (soft copy and/or hard copy) must be calibrated and performing in accordance with the manufacturer's quality control program for mammography use.

Processing System Software

The processing system is evaluated by the inspection and scoring of a test set of phantom images that have been processed in the CR Console/AWS-c with the standard mammography processing algorithms EDR (Exposure Data Recognizer), and MFP (Multi-Objective Frequency Processing). Processing parameters should be fixed as a baseline for QC tests, specifically the American College of Radiology (ACR) mammography accreditation program phantom (MAPP) or other appropriate phantom (RMI 156 etc.) test.

Dedicated Imaging Plates (IPs) and Cassettes

Some of the tests described in this manual utilize both sizes of the IPs and cassettes that are designed for the imaging of high resolution mammograms. The customer should reserve one of each size IP and one of each size cassette for Quality Control testing only, and should clearly identify these items as intended for QC only. These IPs should not be used for patient imaging; and only these reserved IPs, and cassettes should be used for QC procedures unless otherwise directed in this manual.

Use only the cassette and IP type designated for use with your Reader Unit (RU for mammographic imaging and QC testing.

- Clearview RU: Cassette Type DM with HR-BD IP.
- Aspire CRm RU: Cassette Type CH with HR-VI IP.

Cautions:

- Perform the S value Conformation test prior to the remaining Acceptance and QC tests, using only molybdenum (Mo) target and Mo filter at 25kVp.
- If the mammography X-ray unit will not allow 20 mR exposure, you may use the lowest mR exposure available greater than 20. Always use 25 kVp for this test. Do not use any additional filtration. The use of another filter may cause an error.

S value

FCRm/CRm associates an S value with each FCRm/CRm image. Usually the S value is displayed with other data in the hard copy or soft copy display.
Technically, the S value is defined by the equation $S = 4 \times 10^{(4-Sk)}$, which is derived from the Sk value determined by the Exposure Data Recognizer (EDR).

The meaning of the S value differs from that of relative sensitivity or relative speed used with screen-film systems. Nonetheless, the S value can be used as a guide that roughly represents relative sensitivity.

Note however, that:

- With all other factors constant, the S value changes with time as the photomultiplier tube in the FCRm/CRm equipment ages requiring periodic calibration.
- The S value varies if the positioning setup changes even if the X-ray exposure and tube voltage remain unchanged.
- If the exposure voltage (kVp) changes, the histogram changes, varying the S value.
- If the X-ray apparatus changes, the S value changes even if the same exposure conditions are used.
- If the FCRm/CRm exposure menu is changed, the EDR conditions change so S value comparisons would be invalid.
- Even when exactly the same conditions are employed, the S value changes if the time interval between IP exposure and IP insertion changes. When the X-ray generator, tube voltage, patient, menu, positioning setup, and elapsed time from exposure remain unchanged, the S value is a relative measure of the X-ray dose and is inversely proportional to it. For example, the S value is approximately doubled when the dose is reduced by half.

Overview of Testing

FREQUENCY	TEST DESCRIPTION	RESPONSIBILITY
SECTION A : Getting Started	Set-up & Baseline Images	Technologist and Medical Physicist
SECTION B : Weekly (and when problems are suspected)	CNR Weekly Check	Technologist
	Phantom Image	
	Printer QC*	Technologist
	Monitor QC*	
SECTION C : Monthly (and when problems are suspected)	Visual Checklist	Technologist
SECTION D : Quarterly (and when problems are suspected)	Repeat Analysis	Technologist
SECTION E : Semi-Annual (and when problems are suspected)	Compression	Technologist
	Imaging Plate (IP) Fog	
SECTION F : Annual (and when problems are suspected)	Viewing and Viewing Conditions*	Medical Physicist
	Annual Printer QC*	
	Annual Monitor QC*	
	S Value Confirmation	
	System Resolution	
	CR Reader Scanner Performance	
	Mammographic Unit Assembly Evaluation	
	Collimation Assessment	
	Automatic Exposure Control (AEC) System Performance Assessment	
	System Artifact Evaluation	
	Image Quality Evaluation	
	Dynamic Range	
	Primary Erasure	
	Inter-Plate Consistency	
	kVp Accuracy and Reproducibility	
	Dose	
	Beam Quality Assessment and Half-Value Layer Measurement	
	Radiation Output	

(*) Follow the manufacturer's approved QC program if available.

A

Section A Getting Started

Set-up & Baseline Images

This section will guide you through the initial set-up and use of this manual. The tests are performed by conducting a quantitative and visual inspection of test images and the ACR Mammography Accreditation Program Phantom (MAPP).

Use this QC manual in conjunction with the operation manual for the FCRm/CRm reader unit, the CR Console/AWS-c, and the FCRm/CRm User Guide. In the FCRm/CRm User Guide, refer to Chapter 3 Getting Started - Calibrating the AEC for FCRm/CRm.

BASELINE TESTS OF FCRm/CRm SYSTEM

Complete the installation of the X-ray room and Fujifilm Computed Radiography system before beginning the QC testing. Perform the tests in the table below as the baseline (first measurement) for each QC test. If you are unsure about the status of your equipment, then ask the Fujifilm imaging specialist, service engineer, or your physicist. Verify who is responsible for which device: the X-ray manufacturer for the X-ray unit, Fujifilm service personnel for the FCRm/CRm and related equipment.

FCRm BASELINE TESTS

Printer QC (Annual)	System Resolution*	Dynamic Range*
Monitor QC (Annual)	CR Reader Scanner Performance*	Primary Erasure*
CNR Weekly Check*	AEC System Performance Assessment	Inter-Plate Consistency
Image Quality*	Imaging Plate Fog	Dose
S Value Confirmation*	System Artifact Evaluation*	

* Indicates tests to be preformed when adding or replacing an FCRm/CRm Reader Unit.

Upon successful completion of the FCRm/CRm Reader Unit baseline tests, satisfy any MQSA obligations prior to clinical use.

STEP 1: SETTING BASELINE TEST CONDITIONS

When testing equipment, it is very important that the test conditions are reproducible and consistent. This involves setting up a baseline log for the X-ray room, FCRm/CRm system parameters, and viewing conditions. These must be recorded in the EXPOSURE & IMAGE PROCESSING SET UP. Always start by using your most consistent X-ray room and equipment. Decide on the X-ray room and record it in the EXPOSURE & IMAGE PROCESSING SET UP. Select an IP and cassette of each size that are in good condition to be put aside for the QC tests. Label them as such and write this information in the EXPOSURE & IMAGE PROCESSING SET UP. Now record the AEC sensor position, settings, X-ray generator, target, filter, grid and Image processing parameters that are being used clinically and that you will use for the ACR MAPP.

Ensure that the menus shown in the following table are available. If you cannot find the menus, create the menus according to the table on the following page.

FCRm QC Test Menus and Parameters

	GP				MFP						PEM *			
	GA	GT	GC	GS	MRB	MRT	MRE	MDB	MDT	MDE	PRN	PTE	PTC	PRE
CREATED FROM HR SENSITIVITY														
Physics, Sensitivity	1.0	A	1.2	0.00	B	F	0	A	A	0	A	A	A	0
Physics, Artifacts	1.0	A	1.2	0.00	B	F	0	A	A	0	A	A	A	0
CREATED FROM CONTRAST														
Physics, Collimation	1.3	C	1.2	0.00	B	R	0	A	A	0	A	A	A	0
Physics, IP Fog	1.3	C	1.2	0.00	B	R	0	A	A	0	A	A	A	0
CREATED FROM AVE5C16														
Physics, Dynamic Range	1.0	A	1.6	0	C	R	0.0	A	A	0.0	A	A	A	0.0
Before evaluating the Physics, Dynamic Range test image, set the L value to 4.0.														
CREATED FROM AVE5CB08														
Physics, ACR MAPP	1.4	T	0.6	-	C	P	1.3	E	F	0.4	B	J	G	2.0

Notes for the Physics ACR MAPP menu:
1) Change these image processing parameters to those parameters used for typical clinical images at your facility, if necessary.
2) Set the GS value in the BASE LINE TEST so that the background image brightness or film density is acceptable

* PEM is only used with the Clearview RU-based FCRm systems.

NOTE

In order to set up a different image processing parameter, please change MPM code of the menu created.

Select a viewbox or diagnostic workstation designed for final interpretation of mammographic images that is located in a low ambient light environment. Also, mask unexposed areas of the image to reduce glare. Luminance and ambient light measurements are recommended in order to check that viewing conditions are adequate. These are included as part of a yearly physics QC tests. The use of a magnifying lens with 2x magnification or greater is recommended for evaluating tests from film.

STEP 2: THE QC TESTS

Before starting, read through the tests that make-up the QC program. Ensure that you have access to everything listed under “Required Test Equipment” before beginning each test. The relevant test result forms are found at the end of each test section.

It is important that you prepare for the quarterly REPEAT ANALYSIS as soon as you begin using this QC program. Although you will only be doing the test quarterly, you will need to start collecting the reject images now.

The annual tests are intended for the medical physicist and are more involved than the other tests. A dose meter and densitometer will be required. These must be calibrated and have a calibration certificate. These tests may also be needed if a problem arises during the daily, weekly, monthly and quarterly testing. For example, if artifacts appear on images, it is recommended that you do the artifact evaluation test.

Test images should be stored for future reference as directed in the test procedure.

STEP 3: TAKING THE FIRST ACR MAPP IMAGES

Prior to producing the first phantom image, confirm that the display (image printer and/or diagnostic workstation) is in control. Confirm that the FCRm reader unit has successfully passed the S Value Confirmation Test.

Using the baseline setup from Step 1, expose the ACR MAPP or other FDA approved phantom following the procedure in Phantom Image test (Test 2, Section B) and produce a baseline image. Repeat this twice so that you now have 3 images with the same level of quality. If significant variation is seen between the 3 images, it is important that the system is checked before continuing with the QC program. Consult with the Fujifilm applications specialist. Choose one of the 3 comparable ACR MAPP images to be used as a reference for future tests.

Also, in accordance with the procedures of the Image Quality Evaluation Test, score the phantom image to determine how many fibers, speck groups and masses are visible. These scores will form the baseline for the ACR MAPP image tests.

STEP 4: TESTING AND CORRECTIVE ACTION LOG

Once the baseline values have been recorded and ACR MAPP baseline images have been acquired and logged, it is possible to begin the QC program. During routine QC testing, a result may exceed the acceptable limits. When this occurs, repeat the test to confirm the results. If the re-test still exceeds the acceptable limits record the occurrence on the “MAINTENANCE & CORRECTIVE ACTION LOG”. Investigate and correct the problem as directed in the test procedure.

DATE:	

Baseline Phantom Exposure Settings

Room _____ X-ray Generator _____

Target _____

Cassette ID No. _____ Filter _____

IP ID No. _____ KVp _____

AEC Sensor Position _____ mAs _____

AEC Density Setting _____ Grid _____

Baseline Image Processing Parameters

Basic

GA _____
GT _____
GC _____
GS _____

Multi-Frequency MFP

MRB _____ MDB _____
MRT _____ MDT _____
MRE _____ MDE _____

Pattern Enhancement PEM*

PRN _____
PTE _____
PTC _____
PRE _____

* PEM is only used with the Clearview RU-based FCRm systems.

NOTE

Refer to User Guide - Mammography for detailed information about Image Processing Parameters.

B

Section B Weekly (QC Technologist)
(and when problems are suspected)

1 CNR Weekly Check – QC Technologist

OBJECTIVE

To establish an operating level of Contrast to Noise Ratio (CNR) at a specific exposure and weekly confirm that the CNR remains consistent, within limits over time at the same exposure setting.

NOTE

This procedure is designed to measure the performance of the exposure system FCR mammography system is a digital imaging system. Image density is programmed to a specific level when using the auto or semi auto modes such as those used in routine mammographic projections. Unlike screen-film systems, optical density is not directly related to exposure. Density and contrast are controlled by image processing.

FREQUENCY

This test must be performed at installation after relocating the image reader as in a mobile setting before imaging patients. In routine use, perform at a frequency of no less than weekly.

REQUIRED TEST EQUIPMENT

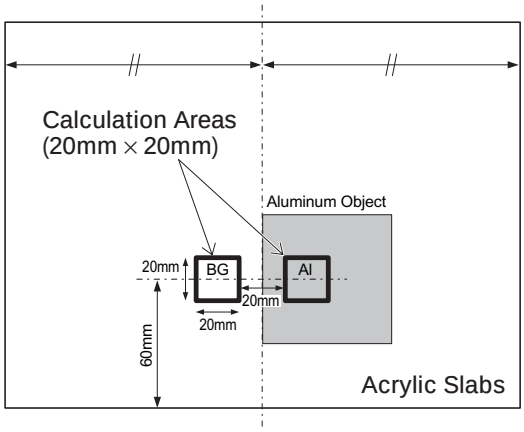
- A 4cm phantom made of acrylic (PMMA) of fully covering an 18x24cm field size.
- A 0.2 mm Al CNR test object.
- The 18×24cm dedicated QC Mammography cassette and Imaging Plate.
- CNR BASELINE WORKSHEET
- Watch/Timer

PROCEDURE

1. Using the 18x24cm dedicated mammography QC cassette, erase an IP using the secondary erasure mode on the reader. Place the loaded cassette in the cassette holder assembly. Set a manual technique using the following factors: large focal spot, Mo/Mo 26 kVp and 125 mAs. If 125 mAs is not available on the X-ray generator, use the next highest mAs setting.

   Note: Establish the baseline CNR value by performing this test five times and averaging the five CNR values. As the positioning of the aluminum plate may have some effect on the calculated CNR, remove and reposition the aluminum plate after each exposure to reflect this normal variation in the baseline. Record the CNR value from each exposure on the CNR BASELINE WORKSHEET. Calculate the average CNR and ±20% values and record them as indicated on the CNR BASELINE WORKSHEET. Repeat this process whenever a new baseline is required (see Precautions and Caveats).

2. Place the 4cm thick acrylic phantom with a 0.2mm thick aluminum object on top. Make sure that the aluminum object completely covers the area shown in the diagram below.



3. Bring the compression device into contact with the phantom.
4. Make an exposure using the technique factors described in Step 1.
5. Wait the predetermined interval time and process the IP using the "Physics ACR MAPP" menu.

NOTE

To reduce the influence of IP image fading characteristics on this test, it is important to control the time interval between X-ray exposure and reading of the IP. It is important that the interval be consistent whenever this test is performed. We recommend choosing an interval between 5 and 10 minutes, then using the same interval consistently.

6. Calculate CNR using the QC calculation tool and record the value in the data form.
7. Perform the Weekly CNR Test on all mammographic exposure units at your facility that use this CR Reader.

PRECAUTIONS AND CAVEATS

Always be sure to use the same IP and cassette for this test. Always use the same exposure technique as established in Step 1. Always wait the same amount of time between exposure and processing of the IP when performing this test. Always erase the IP before performing this test.
Each exposure unit will produce a unique CNR baseline value. Be sure to only compare weekly test results against the baseline of the same exposure system.
CNR baselines must be re-established after major service or replacement events. These include but are not limited to:

- X-ray tube replacement
- Filter replacement
- Replacement of the compression paddle
- Change in the phantom used
- Change of IP and/or cassette used (always use the same IP and cassette)
- Change of grid or table surface
- Change of X-ray generator calibration
- Change of CR Reader calibration

Following any of these events, a new baseline must be set. Calculate the new CNR baseline from 5 times of measured tests as described above and establish a new baseline.

PERFORMANCE AND CORRECTIVE ACTION

The CNR of the new (weekly) image must be within +/- 20% of the baseline image (CNR) established for the same exposure room.

If the CNR of the new image exceeds these limits, repeat the test confirming that all technique factors are correct. If the new test results in a passing score record the results of the new test on the Phantom Control/CNR Chart. Failure of this test can be a problem with the X-ray exposure unit or CR reader unit. If the CR reader unit is used with more than one mammography X-ray exposure unit, continue to perform the Weekly CNR Test on all mammographic exposure units used with the CR reader unit.

If one exposure system fails and other exposure system(s) pass, it is likely that the cause of failure is related to a change in the X-ray exposure system. Retest the failed system.

If the system fails the second test, the problem must be identified and corrective action taken before any further examinations are performed using that exposure system. Record the corrective actions on the Maintenance & Corrective Action Log of the Phantom Control/CNR Test Report.

Review the PRECAUTIONS AND CAVEATS section to help determine if the change in CNR is related to a service event or replacement product change that requires a resetting of baseline CNR values.

If all exposure rooms fail and there has been no service calls or change in equipment in the exposure room, the problem may be related to the CR reader unit. If this test produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken on the component(s) that caused the failure before any further examinations are performed using the failed component(s). If the component(s) that caused the failure (e.g. exposure unit, CR reader unit, display device) is replaced by an alternative device and the mammography system passes the re-test, image acquisition and interpretation may continue using that combination of devices.

CNR BASELINE TEST

DATE:	

Phantom : 4cm
0.2mm Al
26kVp 125mAs

X-ray generator Number :	
Cassette - IP Number :	
FCRm/CRm reader ID :	

CNR 1 :	
CNR 2:	
CNR 3 :	
CNR 4 :	
CNR 5 :	
AVE. CNR (BASELINE):	
+/-20% :	to

SIGNATURE: _____

2 Phantom Image (Weekly) — QC Technologist

OBJECTIVE

To assure that contrast, uniformity and image quality (due to the X-ray exposure system, CR reader unit, printer, and workstation) are maintained at optimum levels.

FREQUENCY

This test must be carried out initially at installation, after appropriate calibration of the equipment to establish a baseline level. Subsequently, it must be carried out at least weekly, after service to any equipment, (i.e. the X-ray generator, FCRm/CRm reader unit, image laser printer, and workstation) and whenever changes in image quality are suspected.

With mobile mammographic equipment, the performance of the system must also be confirmed after arriving at a new location and prior to imaging patients, in addition to the weekly test.

REQUIRED TEST EQUIPMENT

- ACR MAPP
- Acrylic 4mm × 1cm diameter disc (for hardcopy QC only)
- Designated cassette and imaging plate used for mammography
- Densitometer (for hardcopy QC only)
- Phantom Control/CNR Charts
  HARD COPY PHANTOM CONTROL/CNR CHART
  SOFT COPY PHANTOM CONTROL/CNR CHART
- Watch/Timer

PROCEDURE

1. Using the designated mammography cassette, erase the IP using the secondary erasure mode on the reader.
2. Place the cassette in the bucky tray.
3. Place the phantom on the cassette holder and position it so the edge of the phantom is fully covering and aligned with the chest wall side of the image receptor. Center the phantom, left to right.
4. The 4mm thick acrylic disc required to be placed on the phantom for hard copy QC may be present during softcopy QC, but is not required for softcopy QC. For QC of softcopy used for final interpretation, proceed to step 6.
5. For hardcopy QC, secure the acrylic disk to the top of the phantom within the image area but position it so it will not obscure details in the phantom. A suitable location is between and slightly below the first and second largest fibers. Once located, the disc may be permanently attached to the phantom with super glue.
6. Bring the compression device into contact with the phantom.
7. Verify the location of the AEC detector. It should be in the same location used for previous phantom images and completely covered by the phantom.

8. Make an exposure using the AEC technique factors (target, filter, kVp, grid, density control setting, etc.) currently used clinically for a 4.2-cm compressed breast of 50/50 composition.
9. Optionally, you may plot the mAs on the control chart after making the exposure. Recall that mAs will change significantly in the AEC mode if a different kVp, target, or filter is selected. This step, plotting mAs, is optional and not required.
10. After exposure, ensure that a predetermined interval time between 5 and 10 minutes elapses prior to the reading process. Process the IP using the "Physics, ACR MAPP" menu.

    NOTE

    It is important to control the time interval between exposure and reading of the IP. To minimize variability, it is recommended that an interval be chosen somewhere between 5 and 10 minutes and that this same interval be used consistently.

11. Record the AEC density control setting on the control chart.
12. For printed images as a final interpretation: Measure the following densities. The background density should be measured at the geometric center of the phantom image. The measured OD must not be less than 1.20.

    The DD measurement is obtained by subtracting the density inside the acrylic disc from the density directly adjacent to the disc, in the direction perpendicular to the anode-cathode axis. For consistent results, these measurements must be made at the same location each time. Plot the background optical density and the DD on the Hard Copy Phantom Control Chart.

    For softcopy images as a final interpretation: Plot the S value from the phantom image exposure on the S value range line on the SOFT COPY PHANTOM CONTROL/CNR CHART .

VIEWING CONDITIONS

Phantom images should be read under optimal viewing conditions. General lighting should be at a low level and diffused. Viewboxes or workstations should be positioned to avoid light from windows, other viewboxes, and other sources of bright light, either direct or reflected. Images should be masked to eliminate extraneous light. Use a magnification of 2X or higher for scoring speck groups as well as other test objects.

DATA ANALYSIS AND INTERPRETATION

1. When scoring the phantom image, each object is scored separately. Always count the number of visible objects from the largest object of a given type (i.e., fiber, speck group or mass) downward until a score of 0 or 0.5 is reached, then stop counting for that object type.
2. Count each fiber as one point if the full length of the fiber is visible and the location and orientation of the fiber are correct.
   Count a fiber as 0.5 if not all, but more than half, of the fiber is visible and its location and orientation are correct. Add each full or partial fiber to the total score, from the largest down to the smallest visible, until a score of 0 or 0.5 is reached.
3. After determining the last fiber to be counted, look at the overall background for artifacts.
   If a fiber-like artifact appears anywhere in the wax insert area of the image, but not in an appropriate location or orientation, deduct the “artifactual” fiber from the last “real” half or whole fiber score if the artifactual fiber is equally or more apparent.
   Deduct only from the last real fiber.
   Record the final score after artifact deduction in the appropriate space on the chart.

4. Use large field–of-view magnification to assist in the visualization of specks. For hardcopy images, use a 2X or higher magnifying glass. For softcopy images, use the workstation's electronic magnification function. Starting with the largest speck group, count each speck group as one point if four or more of the six specks in the group are visible in the proper locations. Count a speck group as 0.5 if two or three of the six specks in the group are visible in the proper locations. Count a speck group as 0 if none or only one of the six specks in the group is visible in the proper location.
   Add each full or partial speck group to the total speck group score, from the largest down to smallest visible group, until a score of 0 or 0.5 is reached.
5. After determining the last speck group to be counted, look at the overall background for artifacts. If noise or speck-like artifacts are visible in the wrong locations within the area of the wax insert, and are as apparent as the "real" specks, deduct them one for one from the individual specks counted in the last whole or half speck group scored, and adjust the score of the last group appropriately. Record the final score after artifact deduction in the appropriate space on the chart.
6. Count each mass as one point if the minus density object is visible in the correct location, and the mass appears to be generally circular against the background (i.e., greater than ¾ of the perimeter or circumference is visible). A mass is counted as 0.5 point if the minus density object is visible in the correct location, but the mass does not have a generally circular appearance.
   Add each full or partial mass to the total mass score, from the largest mass down and until a score of 0 to 0.5 is reached.
   Record the "raw" mass score before artifact deduction.
7. After determining the last mass to be counted, look at the overall background for artifacts.
   If a mass-like artifact is seen in the wrong location within the area of the wax insert, deduct the "artifactual" mass from only the last "real" whole or half mass scored if the artifactual mass is equally or more apparent. Record the final score after artifact deduction in the appropriate space on the chart.
8. Using magnification, carefully examine the image for non-uniform areas, the presence of dirt or dust artifacts, grid lines, processing artifacts, or any other artifacts and compare the image to the original and previous images.
9. Notice any artifacts or grid lines on the image. Investigate the source of any artifacts or grid lines and record the events on the Maintenance/Corrective Action Log of the Phantom Control Chart. The medical physicist can provide assistance in identifying the source of the artifacts.

NOTE

Mammography phantom images should always be viewed

- By the same person, if possible
- On a quality-controlled QA Workstation, Primary Interpretation Workstation, or Viewbox
- Under the same viewing conditions as the Radiologist review stations
- Using the same type of magnification used for reading mammograms
- Soft copy images should be window and leveled to best demonstrate the objects of interest

PRECAUTIONS AND CAVEATS

This test measures the output from all components in the imaging chain. Changes in image quality may be due to film, cassettes, IP's, X-ray generator, added filtration, printer, or workstation. Consequently, other tests will be necessary to determine the component, or components, causing the change. It is also necessary to check if settings for the image reading mode or image processing parameters are changed. These factors will have a large influence on the results of this test.

When any image parameters are changed, it is recommended to perform the Phantom Exposure test to re-determine the new baselines. Record the imaging parameters used for this test on the "Exposure and Image Processing Set Up" located in this manual.

A weekly phantom image-evaluation is required for only the most commonly used cassette size (18 × 24 cm), however, it may be useful to also image the phantom periodically with a large (24 × 30 cm) cassette.

A phantom image should be produced and evaluated if clinical images suggest problems with either size formats. Typical examples of problems that are specific to the bucky size are grid lines, or compression paddle artifacts.

Non-uniformity in the images can degrade the quality of clinical mammograms. To evaluate uniformity, expose an Fuji IP Cassette on top of the cassette holder to compare image uniformity with and without the grid.

PERFORMANCE AND CORRECTIVE ACTION

The total number of simulated masses, speck groups, and fibers visible in the phantom image should not decrease by more than one-half, assuming the same individual is viewing the images under identical conditions.
If a change in the number of test objects is noted, then the present image should be compared to the original image and the previous image to determine if the change is real or if the individual viewing the image has changed his or her criteria.

NOTE

At a minimum, the four largest fibers, the three largest speck groups and the three largest masses must be visible. If your baseline image exceeds the above minimum scores, the new image score should not decrease by more than one half object point from the original baseline level, however the score must not fall below the four largest fibers, the three largest speck groups and the three largest masses.

If printed images are used for final interpretation: The optical density (OD) of the film shall be within control limits of ± 0.20, from the established operating level.

The acrylic discs used for the measurement of the density difference (DD) may vary in thickness. Consequently, the density difference is a relative, not absolute measurement and is to be used only for quality control purposes. It is essential to use the same acrylic disc if comparisons are to be made between different facilities.

The density difference (disc vs. adjacent density) shall not vary by more than ± 0.05 OD from the established operating level. If a new operating level for background optical density is chosen, then a new operating level for density difference must be established. It is essential that all printers used to

print mammography images at one facility produce similar film optical densities. It is not acceptable to have one unit producing a film with an OD of 1.40 and another producing an OD of 1.80.

If softcopy images are used for final interpretation: The S value of the phantom image confirms the exposure unit output and the FCRm/CRm reader sensitivity setting. The S value result must be plotted on the SOFT COPY PHANTOM CONTROL/CNR CHART and must not vary by greater than ±20%. If the results exceed this control limit, make sure that the kVp and mAs are set properly and that the correct menu is selected.

For both softcopy and hardcopy:

If the performance criteria for this test are not met, a second phantom image test should be performed and evaluated. If the criteria are still not met, the reasons for this failure must be investigated, corrective action taken, and the results documented before patients are examined with this system. Any visual difference between the current phantom image and the saved original phantom image should be investigated. Printer or FCRm/CRm reader unit artifacts, grid lines, or grid artifacts should not be present since any of these may degrade clinical images.

The appearance of artifacts, grid lines, or grid artifacts; the number of masses, specks and fibers visualized; or any other change in the visual appearance of the image should be reported immediately to the medical physicist for further evaluation.

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken on the component(s) that caused the failure before any further examinations are performed using the failed component(s). If the component(s) that caused the failure (e.g. exposure unit or CR reader unit) is replaced by an alternative device and the mammography system passes the re-test, image acquisition and interpretation may continue using that combination of devices.

If the failure has been determined to be of a diagnostic device used for mammographic image interpretation (e.g. laser printer, physician's review station) the source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation. Clinical imaging may be continued. If available, an alternative approved diagnostic device may be used for mammographic image interpretation

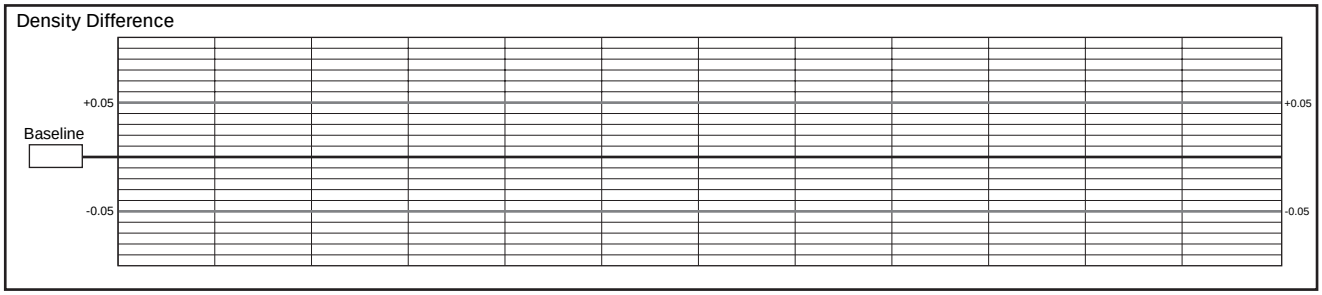
NOTE

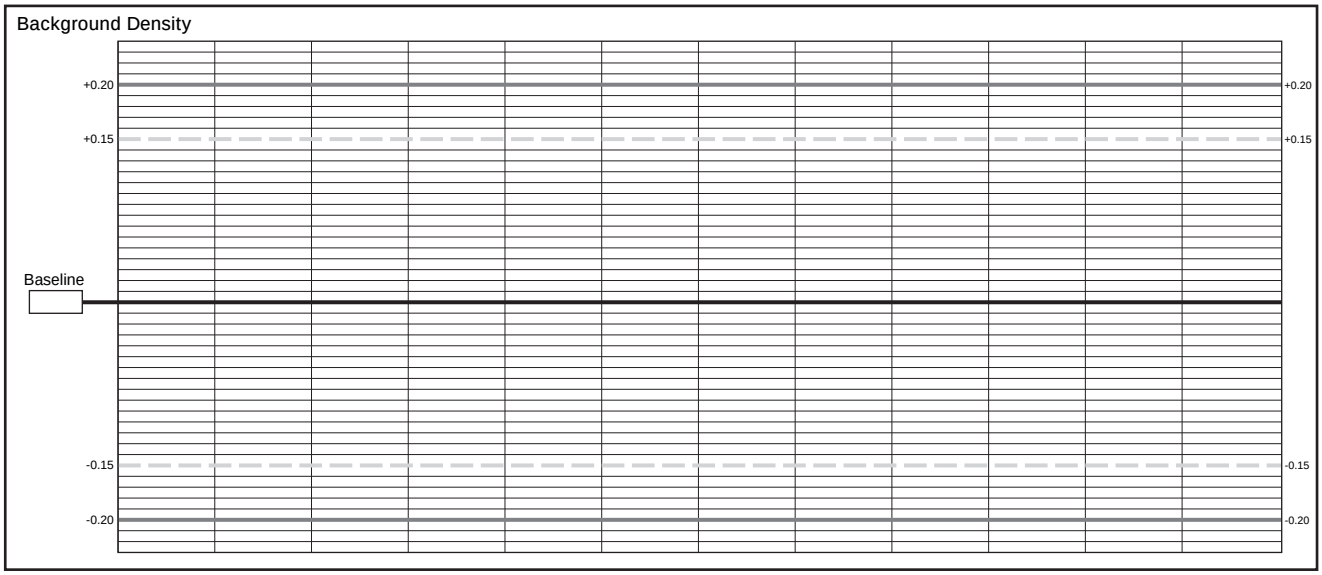
Phantom images must be retained in the QC records for the last full year. (Softcopy images can be "locked" on the QA and PACS workstation). The original baseline image must be retained until it is necessary to establish a new baseline image.

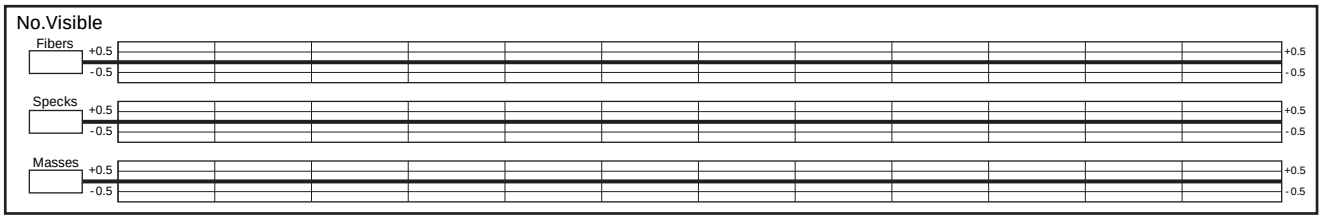
HARD COPY PHANTOM CONTROL/CNR CHART

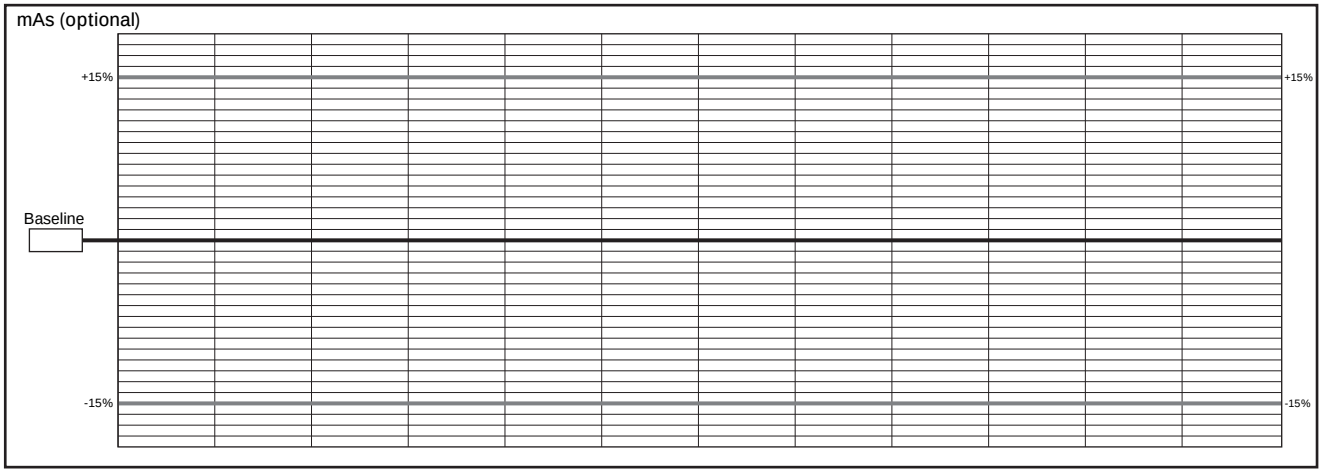
Room:_____ Cassette ID No.:_____ IP ID No.: _____ Year:_____

Month:												
Date:												
Initials:												
AEC SETTING:												
CNR Value:												
CNR OK:												





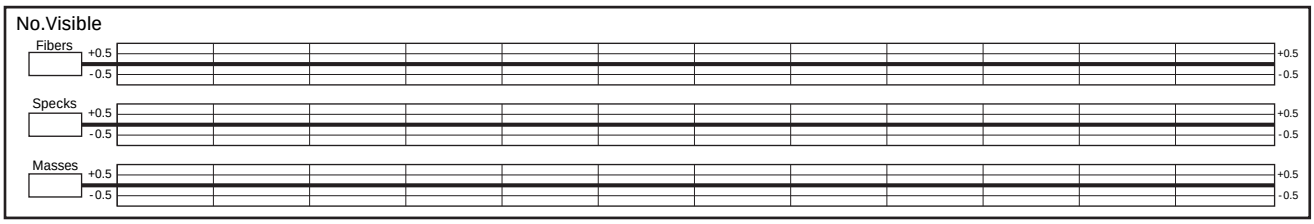


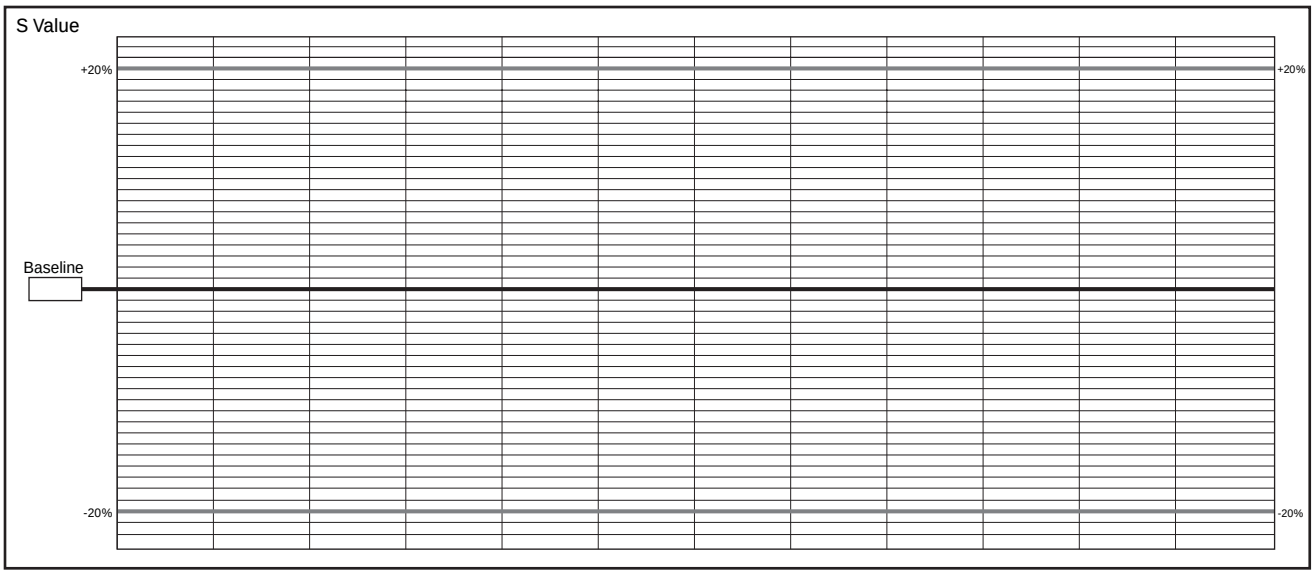


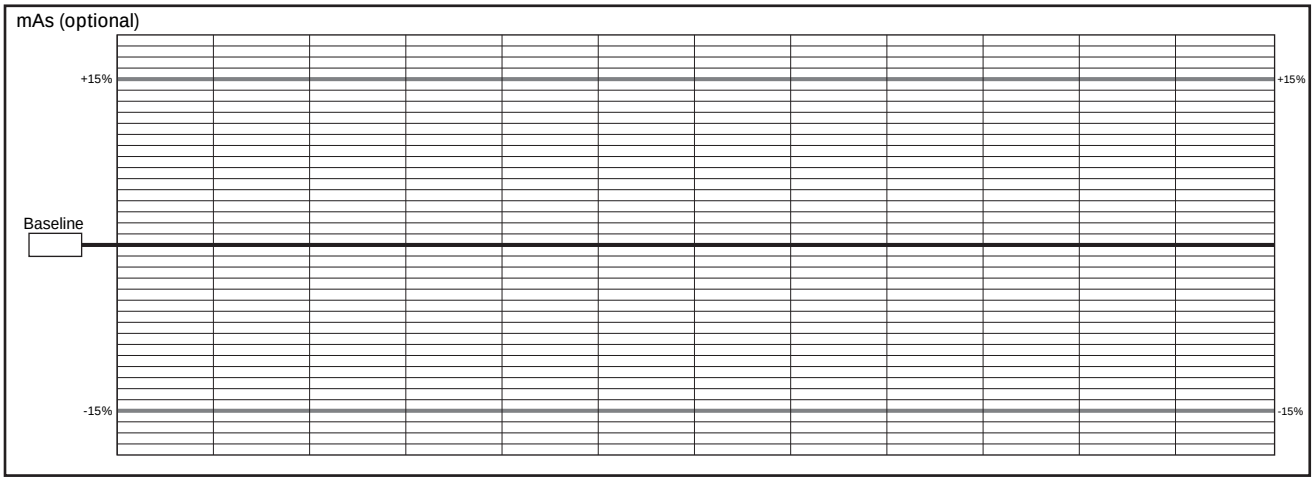
SOFT COPY PHANTOM CONTROL/CNR CHART

Room:_____ Cassette ID No.:_____ IP ID No.: _____ Year:_____

Month:												
Date:												
Initials:												
AEC SETTING:												
CNR Value:												
CNR OK:												







MAINTENANCE & CORRECTIVE ACTION LOG

DATE	PROBLEM	CORRECTIVE ACTION TAKEN	SIGNATURE

Prepared by_____

3 Printer QC (Weekly*) – QC Technologist

OBJECTIVE

The printer used to produce films for final interpretation of mammography images must be cleared by FDA for that purpose. The objective of this test is to assure that the printer used for final interpretation is performing according to the manufacturer's specifications.

PRINTERS WITH MANUFACTURER-PROVIDED QC PROGRAM

*Follow the printer manufacturer's QC program for test frequency, procedure, performance and corrective action.

PRINTERS WITHOUT MANUFACTURER-PROVIDED QC PROGRAM

If the manufacturer does not provide a mammography printer QC program use the following.

FREQUENCY

This test must be performed initially before interpreting mammograms. *Perform weekly for dry print imagers, daily before printing mammographic images for wet print imagers. Perform after any service or maintenance on the mammographic printer system and whenever problems are suspected.

REQUIRED TEST EQUIPMENT

- QC pattern with a fixed digital value grayscale (e.g. TG18-QC or TG18-PQC). Contact your printer manufacturer for details.
- Calibrated densitometer.
- Report form, available from your printer manufacturer.

PROCEDURE

SET UP

1. Print the QC pattern.
2. Measure the image to identify the step which has an optical density closest to but not less than 1.20. Designate this step as the mid-density (MD) step.
3. Measure the image to identify the step with an optical density closest to but not less than 2.20 and the step that has an optical density closest to but not less than 0.45. Designate these steps as the high-density (HD) and low-density (LD) steps. The difference between these two steps is designated as the density difference (DD).
4. Measure the lightest (B+ F or unexposed) portion of the image. This is designated as B+F.

RECORDING THE QUALITY CONTROL STEPS

1. Print the QC pattern. Write the date and time on the film. Label the film with the printer ID if there is more than one printer.

2. Measure the densities of the designated steps.
3. Plot the mid-density (MD), the density difference (DD) and the base-plus-fog (B+F) on the control chart.
4. Determine if any of the data points exceed the control limits. If not, go to step 6. If so, expose and process a second QC strip, double checking that the correct procedure is followed. If the same results are obtained, proceed to step 5.
5. Circle any out-of-control data points and repeat the test. If any data point is still out of control, correct the cause of the problem and repeat the test to confirm that the problem has been corrected. Note the cause of the problem and the corrective action and plot the in-control point.
6. Determine if there are any trends, i.e., three or more data points moving in one direction (either upwards or downwards), in the MD, DD, or B+F. If trends are present but the data points have not, as yet, exceeded the control limits, clinical mammogram images can be printed. It is necessary to determine the cause of the trend and to monitor the processor closely to assure that the control limits are not exceeded.
7. Retain the test film for at least the MQSA prescribed period, e.g., the last full month for daily QC and the last 12 weeks for weekly QC.

PRECAUTIONS AND CAVEATS

* Perform this test using only the test patterns described above. Test patterns are specific to the image matrix size and bit-depth. Using other patterns could yield erroneous results.

Film is produced in batches. Consequently, there may be slight variations in the characteristics of the film between batches. In addition, film aging and storage conditions can also affect the sensitometric characteristics of the film. Whenever a new emulsion of film is opened, it is necessary to perform a laser density calibration with the new film. The operating level on the control chart should be adjusted to the new levels for MD and DD.

PERFORMANCE AND CORRECTIVE ACTION

If the MD and DD are within ± 0.15 of their respective operating levels, and the B+F is within + 0.03 of its operating level, the printer is in control, and no further action is required. If the MD and DD fall outside the above control limits, corrective action must be performed and then confirmed by performing the QC test again. The source of the problem must be corrected before any mammographic images are printed. If this test produces results that fall outside the action limits as specified above or by the manufacturer (whichever is applicable), the source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation.

Clinical imaging may be continued. If available, an alternative FDA-approved for mammography diagnostic display device may be used for mammographic image interpretation, provided it has passed the applicable QC tests.

4 Monitor QC (Weekly*) – QC Technologist

OBJECTIVE

The objective of this test is to assure that monitors are performing according to the monitor manufacturer's specifications. Both the monitors used for final interpretation of mammography images (primary monitors), and monitors used for acquisition QC (secondary monitors) must be tested. An additional requirement is that monitors used for final interpretation must have been cleared by FDA for that purpose.

Commercial calibration software programs supporting the American Association of Physicists in Medicine (AAPM) Assessment of Display Performance for Medical Imaging Systems (AAPM On-Line Report No. 03, www.aapm.org) are available for use with this test.

MONITORS WITH MANUFACTURER-PROVIDED QC PROGRAM

*Follow the monitor manufacturer's QC program for test frequency, procedure, performance and corrective action.

MONITORS WITHOUT MANUFACTURER-PROVIDED QC PROGRAM

If the manufacturer does not provide a mammography monitor QC program, use the following.

FREQUENCY

This test must be performed initially before interpreting mammograms, weekly, after any service to the monitor, and whenever problems are suspected.

REQUIRED TEST EQUIPMENT

- AAPM TG18-QC, SMPTE RP133 or other patterns appropriate for the monitor to be tested (contact your monitor or QC software manufacturer for details*).
- A photometer to measure luminance of primary monitors.
- Your own or the QC software manufacturer-provided report form. Note: The results of this and other tests can be stored electronically as permitted by MQSA regulation or guidance

PROCEDURE

1. Display the QC pattern.
2. <u>For primary monitors only:</u> record the maximum and minimum luminance levels as directed by your monitor or QC software manufacturer. The maximum luminance (Lmax) is typically specified by the monitor manufacturer as the highest value that can be used without compromising other performance characteristics, such as lifetime or resolution. The minimum brightness (Lmin) is influenced by Lmax.
3. <u>For both primary and secondary monitors:</u> examine the image carefully to determine the visibility of the following features:
   a. Verify that the 5% signal level inset is visible in the larger 0% signal field.
   b. Verify that the 95% signal inset is visible in the 100% signal field.

c. Verify that each gray level step from 0% to 100% can be distinguished individually.

d. Verify that the alphanumeric characters in the image appear sharp and in focus.

e. Verify that the high-contrast bar images in the center and at the corners of the QC pattern are distinguishable. The low-contrast patterns are not evaluated in this test.

f. Record the results of the evaluations on your own form or one provided by the QC software manufacturer.

PRECAUTIONS AND CAVEATS

*Perform this test using only the test patterns described above. Test patterns are specific to the image matrix size and bit-depth. Using other patterns could yield erroneous results.

PERFORMANCE

If the following conditions are met, the Monitor QC Weekly check is acceptable:

- For primary monitors only: the maximum luminance value (Lmax) is within the range specified by the monitor manufacturer. For reference, the AAPM report recommends that once set, the target level (Lmax) is maintained within ± 10% of the desired value.
- For both primary and secondary monitors: the 5% inset in the 0% field and the 95%- inset in the 100% field shall be visible and the 0% to 100% gray level steps shall be distinguishable from the adjacent steps.
- The alphanumeric characters appear sharp and focused.
- The high contrast line-pair patterns are distinguishable at the center and the corners of the display in both the horizontal and vertical orientations.

NOTE

The ability to distinguish the low-contrast line-pair patterns is not a requirement for this test.
Unless required by the monitor manufacturer, there is no action limit specification for Lmin in this procedure

CORRECTIVE ACTION

For primary monitors (used for final interpretation). If this test produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation. Clinical imaging may be continued. If available, an alternative approved diagnostic display device may be used for mammographic image interpretation, provided it has passed the applicable QC tests.

For secondary monitors (used for image acquisition QC). If this test produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken on the monitor that failed before any further examinations are performed using that monitor. If the monitor that failed is replaced by an alternative monitor that passes the test, image acquisition may resume using the alternative monitor.

MONITOR QC (WEEKLY) REPORT

Room:	
Left or Single Monitor Serial Number:	
Right Monitor Serial Number:	

Date:				
Monitor	LEFT		RIGHT	
Luminance (primary only) Record values:	MIN / MAX		MIN / MAX	
Lmax Pass/Fail:	PASS	FAIL	PASS	FAIL
0%-5% contrast:	YES	NO	YES	NO
95%-100% contrast:	YES	NO	YES	NO
Gray Steps:	YES	NO	YES	NO
Alphanumeric:	YES	NO	YES	NO
Line-pair images:	YES	NO	YES	NO

SIGNATURE ____________________

Date:				
Monitor	LEFT		RIGHT	
Luminance (primary only) Record values:	MIN / MAX		MIN / MAX	
Lmax Pass/Fail:	PASS	FAIL	PASS	FAIL
0%-5% contrast:	YES	NO	YES	NO
95%-100% contrast:	YES	NO	YES	NO
Gray Steps:	YES	NO	YES	NO
Alphanumeric:	YES	NO	YES	NO
Line-pair images:	YES	NO	YES	NO

SIGNATURE ____________________

Date:				
Monitor	LEFT		RIGHT	
Luminance (primary only) Record values:	MIN / MAX		MIN / MAX	
Lmax Pass/Fail:	PASS	FAIL	PASS	FAIL
0%-5% contrast:	YES	NO	YES	NO
95%-100% contrast:	YES	NO	YES	NO
Gray Steps:	YES	NO	YES	NO
Alphanumeric:	YES	NO	YES	NO
Line-pair images:	YES	NO	YES	NO

SIGNATURE ____________________

Date:				
Monitor	LEFT		RIGHT	
Luminance (primary only) Record values:	MIN / MAX		MIN / MAX	
Lmax Pass/Fail:	PASS	FAIL	PASS	FAIL
0%-5% contrast:	YES	NO	YES	NO
95%-100% contrast:	YES	NO	YES	NO
Gray Steps:	YES	NO	YES	NO
Alphanumeric:	YES	NO	YES	NO
Line-pair images:	YES	NO	YES	NO

SIGNATURE ____________________

C

Section C Monthly (QC Technologist) (and when problems are suspected)

5 Visual Checklist (Monthly) – QC Technologist

OBJECTIVE

To assure that mammographic X-ray system indicator lights, display, and mechanical locks and detents are working properly and that the mechanical rigidity and stability of the equipment is optimum.

FREQUENCY

This test should be carried out monthly or after any service or maintenance on the mammographic X-ray system.

REQUIRED TEST EQUIPMENT

- VISUAL CHECKLIST

PROCEDURE

1. Review all of the items listed on the visual checklist and indicate the status. Be sure to rotate the C-arm the way you would for patient imaging.
2. Date and initial the checklist where indicated.

PRECAUTIONS AND CAVEATS

Some of the items on the visual checklist are operator convenience features. However, many of the items are essential for patient safety and high quality diagnostic images. It may be necessary to add additional items to the list that are specific to particular equipment or procedure.
These should be included on the checklist and in each evaluation.

PERFORMANCE AND CORRECTIVE ACTION

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period.

VISUAL CHECKLIST

Facility: _____ Room#: _____

Unit: _____ Year: _____

Pass = ✓
Fail = F
Does not apply = NA

	Month											
	Day											
	Initials											
C-Arm												
SID indicator or marks												
Angulation Indicator												
Locks (all)												
Field Light												
High tension cable/other cables												
Smoothness of Motion												
Cassette Holder												
Cassette Lock (small and large)												
Compression Device												
Compression Scale												
Amount of Compression:	Automatic											
	Manual											
Grid												
Control Booth												
Hand Switch Placement												
Window												
Panel switches/lights/meters												
Technique charts												
FCRm/CRm												
Condition of cassettes												
Condition of IPs												
Other												
Shields/Aprons/Gloves												
Cones or collimators												
Cleaning Solution												

D

Section D Quarterly (QC Technologist)
(and when problems are suspected)

6 Repeat Analysis (Quarterly) – QC Technologist

OBJECTIVE

To determine the number and cause of repeated radiographs. Analysis of this data will help identify ways to improve efficiency and reduce costs, as well as reduce patient exposure.

FREQUENCY

Repeated images shall be evaluated quarterly.
In order for the repeat rates to be meaningful, a patient volume of at least 250 patients or 1,000 exposures is needed.

REQUIRED TEST EQUIPMENT

- All rejected images (including data for repeated images that may have been placed in a patient's film jacket)
- The total number of images produced during the test period
- Means for sorting images (hardcopy or softcopy) during analysis
- REPEAT RATE ANALYSIS data form

PROCEDURE

1. Start by removing all existing reject images (hardcopy) in the department taken prior to the start of the analysis.
2. Take inventory of the image supply as a starting point to determine the total number of images consumed during this test.
3. Start collecting all rejected images. Continue to collect for the length of time needed to radiograph at least 250 consecutive patients.
4. Sort the rejected images into categories such as poor positioning, motion, compression, under exposure, (these might be due to exposure or processing), artifacts (streaks, spots, etc.).
   Good images (they appear to be acceptable mammograms when retrospectively evaluated during the repeat analysis) may have also been repeated.
   Some images may not have resulted in an additional exposure of the patient but may have also been rejected. These include clear and QC images. Although it is appropriate to include wire localization images as part of the reject analysis, they should not be included in the repeat analysis because they are taken as part of the wire localization process.

NOTE

Rejected images are all images that are in the reject bin, including repeated images. Repeated images are images that are retaken for inadequate quality. The reject bin does not include additional views required to image selected tissue seen on the first image. It also does not include images taken for the purposes of including tissue that could not be positioned on the image receptor due to the size of the breast. For facilities using softcopy for final interpretation maintain a list of repeated images using the REPEAT RATE ANALYSIS form included in this procedure.

5. Some facilities place all images (repeated and good images) in the patient's film jacket so there are no repeated images in the department. In this case, the reject/repeat analysis chart should be completed as patient examinations are carried out.
6. Tabulate the counts from Steps 4 and 5, determining the total number of repeated images, rejected images, and the total number of images exposed during the analysis period.
7. Determine the overall percentage of repeated images by dividing the total number of repeated images by the total number of images exposed during the analysis period, then multiply by 100. Next, determine the overall percentage of rejected images by dividing the total number of rejected images by the total number of images exposed during the analysis period, and multiply by 100.
8. Determine the percentage of repeats in each "reason for repeat" category by dividing the repeats in the category by the total number of repeated images and multiply by 100.

PRECAUTIONS AND CAVEATS

All images that are repeated should be included in the repeat analysis, not just those rejected by the radiologist. Repeated images that have been placed in the patient's jacket must be included in the repeat analysis.

Including examinations on at least 250 patients (approximately 1000 images) allows for a minimum number of rejected images so that reasonable statistics can be obtained for the analysis.
Collecting rejected images from a larger number of patients is encouraged because it will yield more reliable data when evaluating causes for repeats. Facilities that do not examine 250 patients in a quarter must still assess repeat images at least quarterly to determine the primary causes of repeated images.
There is a danger that technologists may alter their routine procedures or criteria for accepting images if they know their repeated images will be analyzed. This should be avoided.

NOTE

If the Auto or Semi EDR mode is selected, underexposed images will exhibit normal density, however they may possess a grainy appearance and a higher than normal S value. Because of this density adjustment, overexposed images will also appear normal in density but typically produce a lower than normal S value. Consult with your medical physicist to optimize AEC or manual exposures to ensure that optimal image quality is maintained at minimal dose.

PERFORMANCE AND CORRECTIVE ACTION

The overall repeat rate ideally should be approximately 2% or less, but a rate of 5% is probably adequate if the radiologist and medical physicist agree that this is a reasonable level.
These rates should be based on a image volume of at least 250 patients to be meaningful.
A "reason for repeat" that is significantly higher than the others indicates an area for potential improvement.

If the repeat rate exceeds the selected acceptance level of either 2% or 5%, or if the repeat or reject rate changes from the previously measured rate by more than ±2%, the change must be investigated and corrective action taken if necessary.

Any corrective action should be recorded on the bottom of the repeat analysis form.
The effectiveness of the corrective actions must be assessed by performing another repeat analysis after the corrective actions have been implemented.

It is important to study films that are too dark or too light to determine if the underlying cause is the exposure equipment, image printer, patient positioning, technique or sub-optimal setting of digital image processing.

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period.

REPEAT RATE ANALYSIS

DATE:	

FACILITY:		FROM:		TO:	

TOTAL NUMBER OF EXAMS:	

TOTAL NUMBER OF FILMS:	18×24	24×30	OTHER	TOTAL

REASON FOR REJECT	PROJECTION						
	CC	MLO	ML or LM	AXILLARY	OTHER	TOTAL REPEATS	% of REPEATS
POSITIONING							
PATIENT MOTION							
COMPRESSION							
ARTIFACTS							
X-RAY EQUIP MALFUNCTION							
SOFTWARE MALFUNCTION							
AEC MISPLACEMENT							
UNDER EXPOSURE							
OVER EXPOSURE							
INCORRECT PATIENT ID							
WASTE							
SUB-TOTAL							
				GRAND TOTAL			

REPEAT RATE = $\frac{\text{REPEATS}}{\text{TOTAL FILMS INCLUDING REPEATS}}$ REPEAT RATE = _____%

REJECT RATE = $\frac{\text{ALL REJECT FILMS}}{\text{TOTAL FILMS INCLUDING REPEATS}}$ REJECT RATE = _____%

COMMENTS FOR CORRECTIVE ACTION AND GOALS:

_____

_____

_____

_____

SIGNATURE: _____

E

Section E Semi-Annual (QC Technologist) (and when problems are suspected)

7 Compression (Semi-Annual) – QC Technologist

OBJECTIVE

To assure that the mammographic system can provide adequate compression in the manual and powered modes and that the equipment does not allow too much compression to be applied.

Adequate compression is essential for high quality mammography. Compression reduces the thickness of tissue that must be penetrated by the radiation, thereby reducing scattered radiation and increasing contrast, while reducing the breast thickness. Compression improves image sharpness by reducing the breast thickness, thereby minimizing focal spot blurring of structures in the image, and minimizing patient motion. In addition, compression makes the thickness of the breast more uniform; resulting in more uniform film densities and a film which is easier to interpret.

FREQUENCY

This test should be carried out initially, then semi-annually, as part of a Mammography Equipment Evaluation (MEE), and whenever reduced compression is suspected.

REQUIRED TEST EQUIPMENT

- Analog Bathroom scale (the scale must be flat)
- Several towels
- COMPRESSION data form

PROCEDURE

1. Place a towel on the cassette holder (to protect the cassette holder), then place the analog bathroom scale on the towel, with the dial or read-out positioned for easy reading. Locate the center of the scale directly under the compression device.
2. Place several towels on top of the scale to prevent damage to the compression device.
3. Using the power drive, activate the compression device and allow operation until it stops automatically.
4. Read and record the compression.
5. Release the compression device.
6. Using the manual drive, move the compression device downward until it stops.
7. Read and record the compression.
8. Release the compression device.

PRECAUTIONS AND CAVEATS

If the compression force exceeds 200 newtons (20.4 kilograms or 20 deca-newtons or 45 pounds) in the initial power drive mode, immediately release the compression device and ask a qualified service engineer to make appropriate adjustments.

PERFORMANCE AND CORRECTIVE ACTION

A compression force of at least 111 newtons (11.3kilograms or 25 pounds) shall be provided. The maximum compression force for the initial power drive mode must be between 111 newtons (11.3kilograms or 25 pounds) and 200 newtons (20.4kilograms or 45 pounds).

If these requirements are not met, a qualified service engineer must make the appropriate internal adjustments and the system must be retested and pass the test before further exams are performed.

COMPRESSION

DATE:	

SCALE I.D.:		
MAMMOGRAPHIC UNIT	AUTOMATIC COMPRESSION	MANUAL COMPRESSION
	lbs.	lbs.
	lbs.	lbs.
	lbs.	lbs.
	lbs.	lbs.

ACCEPTANCE LIMITS

AUTOMATIC (25 - 45 lbs)	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
CORRECTIVE ACTION DESCRIPTION:		
CORRECTIVE ACTION TAKEN?	YES	NO
CORRECTIVE DATE:		
RESULTS OF NEW TEST:	PASS	FAIL

Comments:

SIGNATURE: _____

8 Imaging Plate (IP) Fog – QC Technologist

OBJECTIVE

To verify that IPs stored in the exposure room exhibit no evidence of unintentional exposure (fog).

Unintentional exposure of an IP may result in images with reduced contrast, increased graininess, or exposure-related artifacts.

FREQUENCY

This test should be performed initially before any patients are imaged and then semi-annually or whenever the location of the storage space for the IP's relative to the X-ray exposure unit or the radiation shielding is changed. In mobile mammography, it is not necessary to perform this test after each relocation if the storage space for the IP's relative to the X-ray exposure unit or the radiation shielding is not changed.

REQUIRED TEST EQUIPMENT

- One coin
- Adhesive tape
- One cassette with loaded IP
- IP FOG data form

PROCEDURE

1. Select an FCRm/CRm cassette from the exposure room stock. Erase the IP using the secondary erasure mode on the FCRm/CRm image reader.
2. Tape the coin to the front (exposure side) of the cassette and place the cassette in the cassette storage area of the room with the coin facing the X-ray tube (i.e. the coin is between the X-ray tube and the IP so that any X-ray exposure from the tube would cast a shadow on the IP.)
3. Leave the cassette in place for a minimum of 3 clinical studies, or produce 10 exposures of the accreditation phantom to simulate clinical use.
4. Remove the coin and process the IP in the FCRm/CRm reader unit using the "Physics, IP Fog" menu.
5. Examine the image to see if the coin is visible and record the results on the IP Fog report form.

PRECAUTIONS AND CAVEATS

Reading the image using the wrong menu may give an erroneous result.

PERFORMANCE AND CORRECTIVE ACTION

A shadow of the coin should not be visible. If a shadow is visible, move the IP's to a more protected location and perform the test again.

If this test produces results that fall outside these action limits, corrective action shall be taken before further studies are performed. Image interpretation may be continued during this period.

IP FOG

DATE:	

Reader Unit ID:	
S value:	
Storage Location:	
# of Exposures:	

ACCEPTANCE LIMITS

COIN VISUALIZED?	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
CORRECTIVE ACTION DESCRIPTION:		
CORRECTIVE ACTION TAKEN?	YES	NO
CORRECTIVE DATE:		
RESULTS OF NEW TEST:	PASS	FAIL

SIGNATURE: _____

F

Section F Annual (Medical Physicist) (and when problems are suspected)

Some or all of the annual tests may be required as part of a Mammography Equipment Evaluation (MEE).

9 Viewing and Viewing Conditions (Annual) — Medical Physicist

NOTE

This evaluation is specific to the viewbox and reading room conditions, for images for final interpretation.

When interpreting hardcopy FCRm/CRm images, it is suggested that you view the printed FCRm/CRm images under the same conditions as you would screen-film mammography images. Film masking devices and "hot" lights must be available for use by the interpreting physician. The 1999 ACR Mammography Quality Control Manual includes a section on viewbox luminance, room illuminance, and masking, which may be used as a reference.

When interpreting softcopy images, follow the monitor manufacturer's quality control procedures. For monitors without a manufacturer-provided QC program, follow the monitor QC procedures provided in this manual.

PERFORMANCE AND CORRECTIVE ACTION

Softcopy final interpretation

If the Monitor QC (Annual) test performance criteria, other than interpretation environment illumination, are not met, identify and correct the source of the problem before further final interpretation of images displayed on those monitors.

Set the final interpretation environment illumination to the lower of a) that recommended in the monitor manufacturer's quality control program, if applicable, or b) 20 lux or lower. If the illumination is greater than the value set as described above, the source of the problem must be identified and corrective action taken before interpreting mammograms under these conditions.

10 Printer QC (Annual*) – Medical Physicist

OBJECTIVE

The printer used to produce films for final interpretation of mammography images must be cleared by FDA for that purpose. The objective of this test is to assure that the printer used for final interpretation is performing according to the manufacturer's specifications.

PRINTERS WITH MANUFACTURER-PROVIDED QC PROGRAM

*Follow the printer manufacturer's QC program for test frequency, procedure, performance and corrective action.

PRINTERS WITHOUT MANUFACTURER-PROVIDED QC PROGRAM

If the manufacturer does not provide a mammography printer QC program use the following.

FREQUENCY

This test must be performed initially upon installation before interpreting hard copy mammograms, and after major repairs, such as those requiring a mammography equipment evaluation (MEE), and then annually.

REQUIRED TEST EQUIPMENT

- QC pattern with a fixed geometric pattern (e.g. TG18-QC or SMPTE RP133). Contact your printer manufacturer for details.
- Metric Ruler
- Report form, available from your printer manufacturer.

PROCEDURE

SET UP

1. Print the QC pattern.
2. Identify lines in each dimension that have a specified relationship (e.g. fixed length or distance between lines). Use these same lines for subsequent testing.
3. Measure the length of lines in the step above to establish a baseline. If the printer manufacturer provides a test image with specified distances, compare your measurement to the provided specification.

RECORDING THE OBSERVATIONS

1. Print the QC pattern.
2. Using the ruler, confirm that the lines are straight and undistorted.

3. Measure the length of the lines.
4. Inspect the image for artifacts.
5. Inspect the image for banding and jagged edges of the straight lines.
6. Note any unusual mechanical noises or other observations.

PRECAUTIONS AND CAVEATS

*Perform this test using the QC pattern supplied (or recommended) by the printer manufacturer for that printer model. If none is available, use a QC test pattern recommended by the AAPM or by one of the approved MQSA accreditation bodies for this purpose. Using other patterns could yield erroneous results. Unless otherwise specified by the printer manufacturer, the visual observations should be made without magnification.

PERFORMANCE AND CORRECTIVE ACTION

The tolerance for film printer artifacts should be similar to the tolerance for artifacts in screen-film mammography. According to the 1999 American College of Radiology Mammography Quality Control Manual, not all artifacts can be totally eliminated. It may be useful to use the concept of ALARA (as low as reasonably achievable) when assessing artifacts. If they can be easily eliminated, they should. If the artifact is difficult or expensive to eliminate and is subtle (not mimicking or obscuring clinical information), it may be tolerable. The medical physicist should consult with the interpreting physician as to whether the artifact is tolerable. Tolerances for artifacts should be lower with new imaging equipment.

If any of the following problems exist:

- The lines are bowed, bent or distorted
- The lines exhibit jagged borders
- The printer exhibits print or processing artifact that is judged intolerable
- Measured distances vary by more than 1% from the reference standards
- Artifacts are objectionable and can mimic or obscure clinical information

The source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation.

Clinical imaging may be continued. If available, an alternative approved diagnostic display device may be used for mammographic image interpretation.

11 Monitor QC (Annual*) – Medical Physicist

OBJECTIVE

The objective of this test is to assure that monitors are performing according to the monitor manufacturers specifications and that they are calibrated (or configured) to perform the DICOM Grayscale Standard Display Function (GSDF). Both the monitors used for final interpretation of mammography images (primary monitors), and monitors used for acquisition QC (secondary monitors) must be tested. An additional requirement is that monitors used for final interpretation must have been cleared by FDA for that purpose.

Commercial calibration software programs supporting the American Association of Physicists in Medicine (AAPM) Assessment of Display Performance for Medical Imaging Systems (AAPM On-Line Report No. 03, www.aapm.org) are available for use with this test.

MONITORS WITH MANUFACTURER-PROVIDED QC PROGRAM

*Follow the monitor manufacturer's QC program for test frequency, procedure, performance and corrective action.

MONITORS WITHOUT MANUFACTURER-PROVIDED QC PROGRAM

If the manufacturer does not provide a mammography monitor QC program use the following.

FREQUENCY

This test must be performed initially before interpreting soft copy mammograms, annually, and after major repairs, such as those requiring a mammography equipment evaluation (MEE), and whenever problems are suspected.

REQUIRED TEST EQUIPMENT

- For the monitor image quality pattern: AAPM TG18-QC, SMPTE RP133 or other patterns appropriate for the monitor to be tested (contact your monitor or QC software manufacturer for details*).
- For the monitor luminance response: gray scale images (supplied by the monitor or QC software manufacturer or AAPM TG18-LN).
- Calibrated photometer
- The Monitor QC (Annual) report form, your own, or the QC software manufacturer provided report form. Note: The results of this and other tests can be stored electronically as permitted by MQSA regulation or guidance.

PROCEDURE

MONITOR IMAGE QUALITY

1. For both primary and secondary monitors: display the QC pattern.
2. Record the maximum and minimum luminance levels as directed by your monitor or QC software manufacturer. The maximum luminance (Lmax) is typically specified by the monitor manufacturer as the highest value that can be used without compromising other performance characteristics, such as lifetime or resolution. The minimum brightness (Lmin) is influenced by Lmax.
3. Examine the image carefully to determine the visibility of the following features:
   - Verify that the 5% signal level inset is visible in the larger 0% signal field.
   - Verify that the 95% signal inset is visible in the 100% signal field.
   - Verify that each gray level step from 0% to 100% can be distinguished individually.
   - Verify that the alphanumeric characters in the image appear sharp and in focus.
   - Verify that the high-contrast bar images in the center and at the corners of the QC pattern are distinguishable. The low-contrast patterns are not evaluated in this test.
   - Record the results of the evaluations on your own form or one provided by the QC software manufacturer.

MONITOR LUMINANCE RESPONSE

For monitors featuring DICOM GSDF display functionality, confirm that the monitors are set for DICOM DISPLAY (GSDF) and that the monitors successfully meet the criteria of Monitor Image Quality Test Procedure step 3. If so, you have successfully completed the Monitor QC (Annual) test.

For monitors that do not provide DICOM DISPLAY (GSDF), or fail the Monitor Image Quality Test Procedure step 3, perform the GSDF calibration and follow the steps below.

1. Perform the luminance response test as described in the AAPM report.
2. Record the results of the evaluation on the Annual Monitor Evaluation report.

PRECAUTIONS AND CAVEATS

*Perform this test using only the test patterns described above. Some test patterns are specific to the image matrix size and bit-depth. Using other patterns could yield erroneous results.

PERFORMANCE

If the following conditions are met, the Monitor QC (Annual) check is acceptable:

MONITOR IMAGE QUALITY:

- The maximum luminance value (Lmax) is within the range specified by the monitor manufacturer. For reference, the AAPM report recommends that once set, the target level (Lmax) is maintained within ± 10% of the desired value.
- The 5% inset in the 0% field and the 95%- inset in the 100% field shall be visible and the 0% to 100% gray level steps shall be distinguishable from the adjacent steps.
- The alphanumeric characters appear sharp and focused.

- The high contrast line-pair patterns are distinguishable at the center and the corners of the display in both the horizontal and vertical orientations.

NOTE

The ability to distinguish the low-contrast line-pair patterns is not a requirement for this test. Unless required by the monitor manufacturer, there is no action limit specification for Lmin in this procedure.

MONITOR LUMINANCE RESPONSE

Both primary and secondary monitors must be calibrated to DICOM Grayscale Standard Display Function (GSDF). The luminance differences between each measured value must agree with the expected difference associated with the GSDF and the measured contrast response at any given point must not exceed 10% of the standard for primary monitors and must not exceed 20% for secondary monitors.

CORRECTIVE ACTION

For primary monitors (used for final interpretation). If this test produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation. Clinical imaging may be continued. If available, an alternative approved diagnostic display device may be used for mammographic image interpretation, provided it has passed the applicable QC tests.

For secondary monitors (used for image acquisition QC). If this test produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken on the monitor that failed before any further examinations are performed using that monitor. If the monitor that failed is replaced by an alternative monitor that passes the test, image acquisition may resume using the alternative monitor.

MONITOR QC (ANNUAL) REPORT FORM

DATE:	

Room:	
Workstation:	
Left Monitor Serial Number:	
Right Monitor Serial Number:	
mAs:	

Final Interpretation?	YES	NO	
Cleared by FDA?	YES	NO	NA

MONITOR IMAGE QUALITY REPORT

	Left or Single Monitor		Right Monitor	
Monitors have DICOM Display Functionality feature applied	YES	NO	YES	NO
Lmax target:				
Lmax measured:				
(Lmax measured – Lmax target)/Lmax target x 100%:	%		%	
Within ± 10%:	YES	NO	YES	NO
5% patch is visible in 0% patch?	YES	NO	YES	NO
95%-patch is visible in 100% patch?	YES	NO	YES	NO
Gray steps distinguishable?	YES	NO	YES	NO
Alphanumeric characters sharp?	YES	NO	YES	NO
Line-pair images (center), distinguishable?	YES	NO	YES	NO
Line-pair images (corners) distinguishable?	YES	NO	YES	NO
Overall, all tests pass?	YES	NO	YES	NO

LUMINANCE RESPONSE*

	Left or Single Monitor	Right Monitor
	Measured Result ok?	Measured Result ok?
Measured contrast response at any given point does not deviate more than a) 10% of the standard for final interpretation or b) 20% of the standard for other use.		

* It is not necessary to measure Monitor Luminance Response on monitors that feature DICOM GSDF display functionality and pass the Monitor Image Quality test.

SIGNATURE: _____

12 S Value Confirmation (Annual) — Medical Physicist

OBJECTIVE

To assure that the amount of exposure reaching the IP is assigned a proper “S value”.

FREQUENCY

This test must be performed initially before any patients are imaged and then annually as part of routine service PM (preventive maintenance), and whenever the FCRm/CRm reader unit PMT (photomultiplier tube) calibration is suspect.

NOTE

This is a test of the FCRm/CRm reader unit and only needs to be conducted using one X-ray generator per reader.

REQUIRED TEST EQUIPMENT

- Calibrated mammography dose meter
- Watch/timer
- The 18 x 24 cm cassette and IP dedicated for QC
- S VALUE CONFIRMATION data form

PROCEDURE

1. Using the designated QC cassette, erase the IP using the secondary erasure mode on the reader.
2. Remove the compression paddle from the field and place the dose meter on the bucky surface as described in illustration.
3. Select 25kVp and a Mo target and filter combination. Adjust the mAs to give the dose meter reading closest to but not less than 20 mR. Record the technique.

   NOTE

   If the mammography X-ray unit will not allow 20 mR exposure, you may use the lowest mR exposure available that is greater than 20. Always use 25 kVp for this test.
   Do not use any additional filter except the designated Mo filter. The use of another filter may cause an error.

4. Once you have established the proper technique for your X-ray generator, make a series of at least three exposures prior to removing the meter or placing the cassette in the field. Record the exposure technique and record the measured mR for each exposure.
5. Verify that the mR readings are within 5% of each other. If they are not, repeat the test on a more reproducible X-ray unit.
6. Average the mR readings from the three test exposures.
7. Remove the dose meter from the beam and place the erased Fuji IP / Cassette on the top of the breast support surface centered in the X-ray field.

8. Expose the cassette at the predetermined settings. Wait 10 minutes and process the IP using the "Physics, Sensitivity" menu. Repeat this step two additional times creating a total of three images. Record the S value for each exposure.
9. Calculate the exposure average(mR) and S value average. Divide the averaged exposure results by 20(mR) where 20(mR) is a fixed standard value. Multiply by the averaged S value to obtain the corrected S value.

   Example: 25 kVp
   Averaged exposure = 30.0mR
   Averaged S value = 83
   Corrected S value = 30.0mR/20mR × 83 = 124.5

10. Record the "corrected S value" on the chart

PRECAUTIONS AND CAVEATS

The measurement of 20 mR requires a highly sensitive and accurate dose meter. Contact your medical physicist or Fuji service engineer and confirm that he is equipped with a calibrated device for use in this test. If other measuring devices are used, some error in measurement may occur.

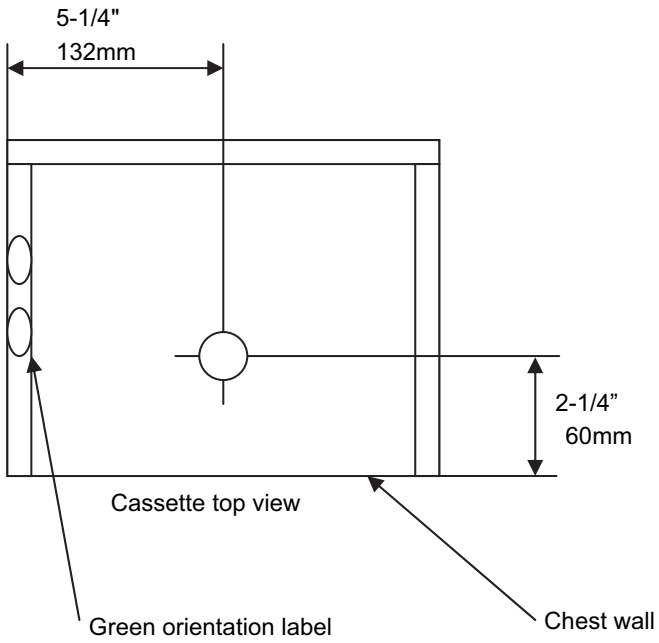
PERFORMANCE AND CORRECTIVE ACTION

The "corrected S value" shall not exceed the range of 120 ± 20% ($96 \leq$ Corrected S value ≤ 144).

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period.

Measure the dose using a mammographic dose meter at the location shown below.

- 18×24 cassette tube side view



S VALUE CONFIRMATION

DATE:	

Exposure Unit ID:	
Reader Unit ID:	
Dose Meter ID:	
kVp:	
mAs:	

Exposure 1:	
Exposure 2:	
Exposure 3:	
Average:	

mR readings are within 5%?	Yes	No

IP Exposure Time 1:	
IP Exposure Time 2:	
IP Exposure Time 3:	

IP Read Time 1:	
IP Read Time 2:	
IP Read Time 3:	

S value 1:	
S value 2:	
S value 3:	
Average:	

Corrected S value:	

ACCEPTANCE LIMITS:

Corrected S value (must be between 96 and 144):	PASS	FAIL
Corrective Action Needed:	YES	NO
Corrective Action Description:		
Corrective Action Taken:	YES	NO
Corrective Date:		
Results of New Test:	PASS	FAIL

Comments:

SIGNATURE: _____

13 System Resolution (Annual) – Medical Physicist

OBJECTIVE

To measure the spatial resolution of the imaging chain.

FREQUENCY

Must be performed initially before any patients are imaged and then annually at routine PM and whenever the system resolution is suspect.

REQUIRED TEST EQUIPMENT

- Line pair test tool measuring up to 10 lp/mm or greater
- A 4.0 cm thick uniform sheet of defect free acrylic large enough to cover a 18 x 24 cm mammographic cassette.
- Magnifying lens of at least 7X magnification
- The dedicated 18 x 24 cm Fuji IP Cassette and IP designated for QC
- SYSTEM RESOLUTION data form

PROCEDURE

1. Using the designated cassette, erase the IP using the secondary erasure mode on the reader unit.
2. Insert the cassette in the cassette holder.
3. Place the acrylic attenuating material on the surface of the bucky.
4. Center the resolution pattern laterally, on top of the absorber and along the chest wall edge at a slight (3 to 5 degree) angle.
   In this position, the pattern's bars lie parallel to the anode-cathode axis for the first image.
5. Select the focal spot used for imaging an average breast and set a manual exposure based on the kVp and mAs established for the phantom image test.
6. Process the IP using the "Physics, ACR MAPP" menu.
7. Repeat steps 1-6 with the bars oriented perpendicular to the anode-cathode axis and with the highest line frequency of the bar phantom positioned against the chest wall at a slight (3 to 5 degree) angle.

PRECAUTIONS AND CAVEATS

The image background density will affect the visibility of the test tool. The density is controlled by image processing. Magnify the image on the workstation monitor so the density of the finer line pairs can be evaluated. Window/level adjustment (GA/GS) can be used on the CR Console/AWS-c to fine- tune density prior to printing or viewing on a mammographic diagnostic workstation.

DATA INTERPRETATION AND ANALYSIS

1. View the resolution pattern with magnification as needed.
2. Note the highest frequency pattern where lines are distinctly visible throughout at least half of the bar length and record.

PERFORMANCE AND CORRECTIVE ACTION

Images displayed for final interpretation shall be capable of demonstrating 8 lp/mm ± 2 lp/mm of system resolution in both the IP-scan and IP-subscan directions.

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken on the component(s) that caused the failure before any further examinations are performed using the failed component(s). If the component(s) that caused the failure (e.g. exposure unit, CR reader unit, display device) is replaced by an alternative device and the mammography system passes the re-test, image acquisition and interpretation may continue using that combination of devices.

SYSTEM RESOLUTION

DATE:	

Exposure Unit ID:	
Reader Unit ID:	

Parallel to Anode-Cathode Axis

S VALUE:	
OPITICAL DENSITY of IMAGE BACKGROUND: (Hardcopy only)	

ACCEPTANCE LIMITS

8 lp/mm ± 2 lpmm	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
CORRECTIVE ACTION DESCRIPTION:		
CORRECTIVE ACTION TAKEN?	YES	NO
CORRECTIVE DATE:		
RESULTS OF NEW TEST:	PASS	FAIL

Perpendicular to Anode-Cathode Axis

S VALUE:	
OPITICAL DENSITY of IMAGE BACKGROUND: (Hardcopy only)	

ACCEPTANCE LIMITS

8 lp/mm ± 2 lpmm	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
CORRECTIVE ACTION DESCRIPTION:		
CORRECTIVE ACTION TAKEN?	YES	NO
CORRECTIVE DATE:		
RESULTS OF NEW TEST:	PASS	FAIL

SIGNATURE: _____

14 CR Reader Unit Scanner Performance (Annual) – Medical Physicist

OBJECTIVE

To establish that the IP reader unit and printer optics and transport system do not exhibit scan or print jitter.

FREQUENCY

Must be performed initially before any patients are imaged and then annually at routine PM and whenever the laser optics- related components are serviced.

REQUIRED TEST EQUIPMENT

- One pair of 6 inch steel rulers
- The dedicated 24 x 30cm Fuji IP Cassette and IP designated for QC
- LASER PERFORMANCE TEST data form

NOTE

This is a test of the CR Reader and only needs to be conducted using one X-ray generator per Reader.

PROCEDURE

1. Using the designated cassette, erase the IP using the secondary erasure mode on the reader.
2. Position the cassette for a non-grid exposure, centered so the X-ray beam covers as much of the cassette front as possible.
3. Place the steel rulers on the cassette surface so the rulers form the letter “T”.
   Place the “T” into the X-ray field centered along the chest wall side of the cassette.
4. Expose and process the cassette using the same exposure and image processing menu as used in the S Value Confirmation test.

PRECAUTIONS AND CAVEATS

Adjust exposure or the window/level settings so that the contrast of the rulers vs. background density creates a bright white “T” against the background density. The rulers forming the “T” must have smooth borders free from jagged edges or defects.

PERFORMANCE AND CORRECTIVE ACTION

Upon inspection, the edges of the "T" should appear smooth and sharp. After reviewing the "T", look at the white frame surrounding the image area of the film. Linear jagged edges visible to the naked eye indicate scan or print error of the IP reader unit or printer. The workstation or positioning monitor can be of help in evaluating the error caused by the IP reader unit. If images are well displayed on those devices, the film printer may be suspect.

If the printer generates excess jitter, mammography images can be saved within the workstation or network until the printer laser optics and transport is serviced.

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken on the component(s) that caused the failure before any further examinations are performed using the failed component(s). If the component(s) that caused the failure (e.g. exposure unit or CR reader unit) is replaced by an alternative device and the mammography system passes the re-test, image acquisition and interpretation may continue using that combination of devices.

If the failure has been determined to be of a diagnostic device used for mammographic image interpretation (e.g. laser printer, physician's review station) the source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation. Clinical imaging may be continued. If available, an alternative approved diagnostic device may be used for mammographic image interpretation.

CR Reader Unit Scanner PERFORMANCE TEST

DATE:	

Reader Unit ID:	
Image Reader ID:	

Parallel to Chest Wall side

ACCEPTANCE LIMITS

WORKSTATION MONITOR	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
LASER FILM PRINTER*	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
CORRECTIVE ACTION DESCRIPTION:		
CORRECTIVE ACTION TAKEN?	YES	NO
CORRECTIVE DATE:		
RESULTS OF NEW TEST:	PASS	FAIL

Perpendicular to Chest Wall side

ACCEPTANCE LIMITS

WORKSTATION MONITOR	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
LASER FILM PRINTER*	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
CORRECTIVE ACTION DESCRIPTION:		
CORRECTIVE ACTION TAKEN?	YES	NO
CORRECTIVE DATE:		
RESULTS OF NEW TEST:	PASS	FAIL

* If hard copy is used for final interpretation

SIGNATURE: _____

15 Mammographic Unit Assembly Evaluation (Annual) — Medical Physicist

OBJECTIVE

To ensure that all locks, detents, angulation indicators, and mechanical support devices for the X-ray tube and image receptor holder assembly are operating properly.

FREQUENCY

This test must be performed at installation of the mammography exposure unit and on an annual basis and as part of a Mammography Equipment Evaluation (MEE).

REQUIRED TEST EQUIPMENT

- MAMMOGRAPHIC UNIT ASSEMBLY EVALUATION data form

PROCEDURE

1. Verify that the freestanding dedicated mammography unit is mechanically stable under normal operating conditions.
2. Verify that all moving parts move smoothly, without undue friction, that cushions or bumpers limit the range of available motions, and that no obstructions hinder the full range of motions within these limits.
3. Set and test each lock detent independently to ensure that mechanical motion is prevented when the lock or detent is set.
4. Verify that the image receptor holder assembly is free from wobble or vibration during normal operation.
5. Verify that the image receptor slides smoothly into the proper position in the image receptor holder assembly and that the image receptor is held in place securely by the image receptor compartment for any orientation of the image receptor holder assembly.
6. If provided, verify that the compressed breast thickness scale (analog or digital) is accurate to within ±0.5 cm under conditions of moderate compression (15 - 20 lbs.) and reproducible to within ±2mm between 1 and 8 cm. The phantom used for this test should be large enough to simulate a typical breast and be positioned towards the chest-wall side of the bucky. The compressed breast thickness should be measured at the center of the chest-wall position of the automatic exposure control (AEC) sensor. This should be done for at least the small and large image receptors and compression paddles.
7. Verify that in normal operation, the patient and operator are not exposed to sharp or rough edges or other hazards including electrical hazards.
8. Perform the decompression test as described in MQSA final regulations and record the result on the Mammographic Unit Assembly Evaluation Chart.
9. Verify that the operator is protected by adequate radiation shielding during exposure.
10. Verify that all indicator lights are working properly.

PERFORMANACE AND CORRECTIVE ACTION

Items that are hazardous, or operate improperly must be repaired by appropriate service personnel before further exams are performed with this unit.

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period.

MAMMOGRAPHIC UNIT ASSEMBLY EVALUATION

DATE:	

Facility:_____ Room#:_____

X-ray Generator:_____

Pass = ✓
Fail = F
Does not apply = NA

1. Free-standing unit is mechanically stable ☐
2. All moving parts move smoothly, without obstructions to motion ☐
3. All locks and detent work properly ☐
4. Image receptor holder assembly is free from vibrations ☐
5. Image receptor slides smoothly into holder assembly ☐
6. Image receptor is held securely by assembly in any orientation ☐
7. Compressed breast thickness scale accurate to 0.5 cm, reproducible to 2 mm ☐
8. Patient or operator is not exposed to sharp or rough edges, or other hazards ☐
9. Operator technique control charts are posted ☐
10. Operator protected during exposure by adequeate radiation shielding ☐
11. All indicator lights working properly ☐
12. Auto decompression can be overridden to maintain compression with continuous display of the override status. ☐
13. Manual emergency compression release can be activated in the event of a power failure ☐

Comments: _____
_____
_____
_____

SIGNATURE: _____

16 Collimation Assessment (Annual) — Medical Physicist

NOTE

This test is intended to evaluate the mammographic X-ray unit, not the CR reader.

OBJECTIVE

To assure that the collimator or cone allows full coverage of the image receptor by the X-ray field but does not allow significant radiation beyond the edges of the image receptor. To assure that the chest wall edge of the compression paddle aligns with the chest wall edge of the image receptor without showing on the image.

FREQUENCY

This test must be performed upon installation or major service of the X-ray tube or collimator, when a problem related to collimation is suspected, and annualy thereafter.

REQUIRED TEST EQUIPMENT

- Five coins, four of one size and one of a larger size.
- Four mammographic cassettes and IP from the clinical inventory: one small and three large.
- A uniform 2-cm thickness of defect free acrylic large enough to cover a 24 x 30 cm mammographic cassette.
- Accurate ruler.
- COLLIMATION ASSESSMENT data form

PROCEDURE

1. Place an appropriately sized cassette loaded with an erased IP in the normal orientation in the image receptor holder.
2. Load an erased IP in the second cassette.
3. Place the large cassette on top of the image receptor holder with the front of the cassette toward the X- ray source and assure that the large cassette extends beyond the image receptor holder on the chest-wall side by about 1 cm.
4. Place the collimator to be evaluated in position.
5. Remove the compression paddle. (The compression paddle should be removed before placement of the coins to assure a sharp demarcation at the edges of the light field.)
6. Turn on the collimator light and place the four identical smaller coins inside the light field with one edge of each coin just touching the edge of the light field. The coin on the chest-wall side should be shifted to the right of center about 2 inches so it does not superimpose the AEC detector.
7. Replace the compression paddle and position it 4.2 cm from the breast support.

8. Tape the larger coin underneath the compression paddle shifted about 2 inches to the left so it does not superimpose the AEC detector. Be sure the coin's outer edge is tangent to the inner lip of the chest-wall side of the compression paddle. This coin marks the chest-wall edge of the paddle.
9. Place a sheet of acrylic attenuating material on top of the paddle, so that all radiation reaching the cassettes must pass through the attenuator.
10. Make an exposure using AEC at the lowest setting on the X-ray generator and process the IP's using the "Physics, Collimation" menu.
11. Repeat steps 1 through 9 for all routinely used collimator/bucky/compression paddle combinations and target materials. When testing the large image receptor, the top cassette may be positioned diagonally to capture all four edges of the X-ray field, or two large cassettes may be used on top of the image receptor holder.

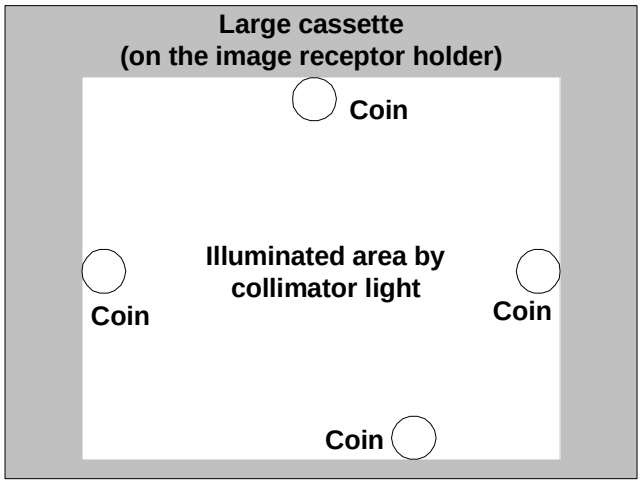


Figure 1 Arrangement of Procedure Step 6

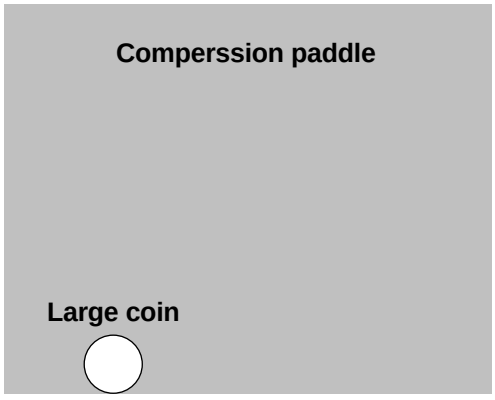


Figure 2 Arrangement of Procedure Step 8

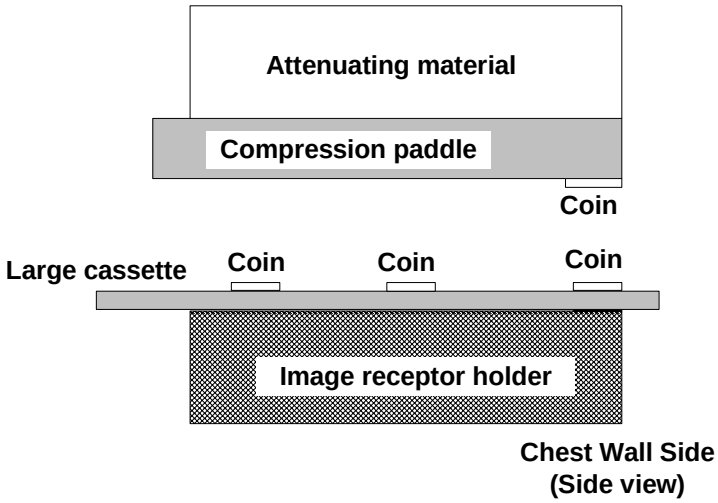


Figure 3 Arrangement of Procedure

DATA INTERPRETATION AND ANALYSIS

From the image created in the top cassette, measure the deviation between the X- ray field (dark portion of the image) and the edge of the light field (defined by the exterior edges of the four smaller coins) for all four sides of the field. The magnitudes of the deviations at the left edge and right edge (ignoring + or - signs) should be entered on the data form and added together. Similarly, the deviations at the anterior and posterior (chest-wall) edges should be entered (without regard to sign) and the magnitudes added together. Record the unit source-to-image distance (SID) on the data form and calculate the % SID by dividing each sum by the SID and multiplying by 100.

Measure the deviations between the edges of the X- ray field and all four sides of the image receptor. Use the Image that was placed in the image receptor holder for this measurement. This can be done by individually aligning the outer edges of the smaller coin on both images and measuring the distance that the X- ray field edge of the top image extends beyond the image in the image receptor holder.

Note that slight magnification differences between the two images should be taken into account. Enter the measured deviations between the X-ray field and image receptor holder image on the data form. If the X- ray field extends beyond the image, it should be given a "+" sign; if it falls within the image, it should be given a "-" sign. Calculate the % SID for each side, retaining the + or - signs.

Next, measure the deviation between the edge of the compression paddle (delineated by the outer edge of the large coin) and the edge of the image receptor. When measuring the distance, note the difference in sizes of the larger coin on the two images. (The coin image will be bigger on the bottom image.) Distances should be measured on or referred to the image in the image receptor holder cassette.

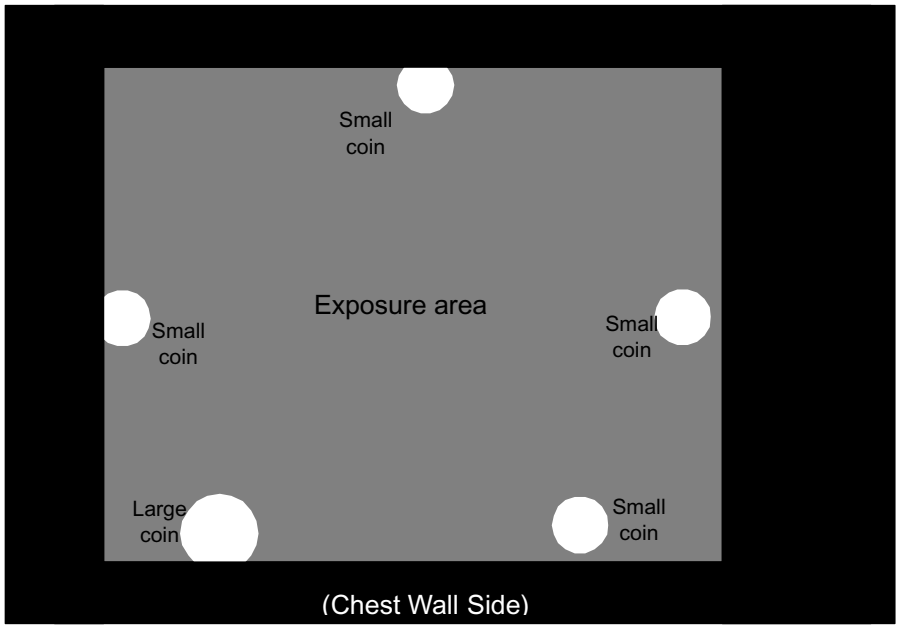


Figure 4 Image obtained from the cassette in the receptor holder

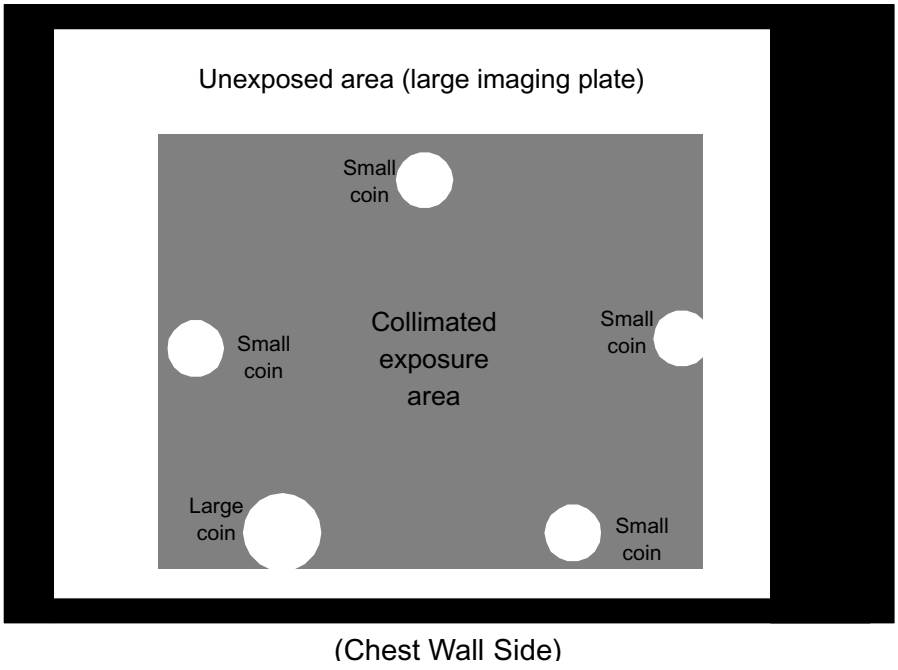


Figure 5 Image obtained from the cassette on the top of the receptor holder

PERFORMANACE AND CORRECTIVE ACTION

All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the X-ray field does not extend beyond any edge of the receptor by more than 2% of the SID.

If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2% of the SID.

The chest wall edge of the compression panel shall not extend beyond the chest wall edge of the image receptor by more than 1 % of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period.

COLLIMATION ASSESSMENT

DATE:	

Exposure Unit ID:	

Source to Image Receptor Distance (SID) in mm:	

Deviation between X-ray field and light field:

Collimator	18 × 24 cm	24 × 30 cm			
Target Material					
Left Edge deviation (mm):					
Right Edge deviation (mm):					
Sum of left and right edge deviations:					
Sum as % of SID					
Anterior Edge deviation (mm)					
Chest Edge deviation (mm)					
Sum of anterior and chest wall deviations (mm)					
Sum as % of SID					

Action Limit: If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2% of the SID.

Difference between X-ray field and image receptor:

Collimator	18 × 24 cm	24 × 30 cm			
Target Material					
Left Edge deviation (mm)					
Difference as % of SID					
Right Edge deviation (mm)					
Difference as % of SID					
Antererior Edge deviation (mm)					
Difference as % of SID					
Chest Wall deviation (mm)					
Difference as % of SID					
X-ray Field Extends to Chest Wall	Yes / No	Yes / No			

Action Limit: All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the X-ray field does not extend beyond any edge of the receptor by more than 2% of the SID.

Alignment of chest wall edges of compression paddles and image receptors:

Collimator	18 × 24 cm	24 × 30 cm			
Target Material					
Difference between compression paddle edge and image edge					
Difference as % of SID					
Paddle Edge Visible on Image Receptor?	Yes / No	Yes / No			

Action Limit: If the chest wall edge of compression paddle is within the image receptor or projects beyond the chest wall edge of the image receptor by more than 1% of SID, seek service correction.

JUDGEMENT:	PASS	FAIL

Comments: _____

_____

SIGNATURE: _____

17 Automatic Exposure Control (AEC) System Performance Assessment (Annual) — Medical Physicist

OBJECTIVE

To assess the performance of the mammography X-ray exposure unit's AEC system with regard to image quality, thickness tracking, and reproducibility and to check the "density control" (see note) selector function.

NOTE

This procedure assesses the performance of the X-ray exposure unit. FCRm/CRm is a digital imaging system. FCRm/CRm controls film density or image brightness to a specific level when using the auto or semi auto modes such as those used in routine mammographic projections. Unlike screen-film systems, FCRm/CRm image brightness or film density is not directly controlled by exposure.

FREQUENCY

This test must be performed prior to the first clinical use with FCRm/CRm on each mammographic exposure unit, annually thereafter, and as part of a mammography equipment evaluation (MEE).

REQUIRED TEST EQUIPMENT

- Required - Large acrylic (PMMA) slabs capable of covering a 24x30cm field and combined to produce thicknesses of 2, 4, and 6cm are required to perform the CNR Per Object Thickness test.
  Optional- for the other non-imaging tests (AEC Density Control Function and AEC Reproducibility), standard size 10x12.5cm acrylic or BR-12 absorbers can be used.
- A 0.2mm thick Al sheet approximately 10x10cm.
- One 18×24cm and one 24x30cm image receptor (cassette with IP) from the clinical inventory and the 18x24cm dedicated QC receptor.
- Ionization chamber and electrometer calibrated at mammographic X-ray beam energies.
- AEC System Performance Assessment forms.

PROCEDURE

AEC DENSITY CONTROL FUNCTION

1. Select a loaded 18x24cm mammography cassette from the clinical inventory. Erase the IP using the secondary erasure mode on the image reader. Place the cassette in the bucky.
2. Position a 4cm thick absorber on the patient support. Lower the compression device to contact with the absorber. Make sure that the absorber completely covers the AEC detector area clinically used for a 4cm thick compressed breast.
3. Select the kVp used to image the ACR MAP phantom and record the value on the chart labeled DENSITY CONTROL FUNCTION.
4. Expose the 4 cm absorber at the AEC system's 0 density control setting. Do not process the IP in the image reader.
5. Record the mAs delivered and the AEC density control setting on the chart.

6. Repeat steps 4-5 for the other density control settings used clinically.
7. Erase the IP (which has been exposed multiple times without processing and erasure) using the primary erase mode on the FCRm/CRm reader unit.

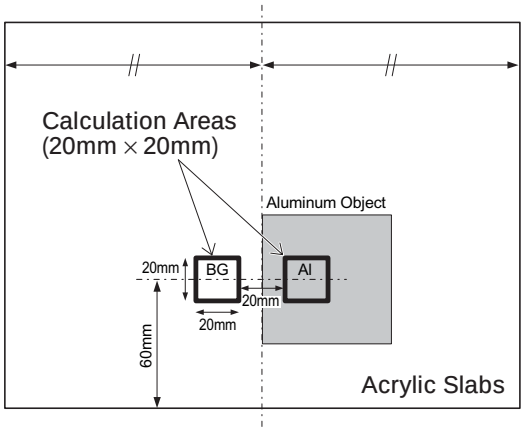
AEC REPRODUCIBILITY and IMAGE MODE TRACKING

1. Select a loaded 18x24cm mammography cassette from the clinical inventory; erase the IP using the secondary erasure mode of the FCRm/CRm reader unit.
2. Insert the loaded cassette in the Bucky.
3. Place the 4cm thick absorber in the X- ray field, lower the compression device into contact with the absorber.
4. For systems equipped with multiple positions for the AEC sensor, select the position used most often clinically. Make sure that the absorber completely covers the AEC sensor position most often used clinically.
5. Prepare the mammography X-ray unit for operation in the AEC mode, selecting the density control setting that is most often used clinically (typically 0).
6. Position the ion chamber in the X-ray beam without covering the AEC sensitive area.
7. Expose the cassette and IP using a fixed kVp and target/filter combination typically used for a 4cm breast.
8. Record the resultant mAs and the measured air kerma of each exposure on the data form titled REPRODUCIBILITY CHART.
9. Repeat steps 6 and 7 three more times, completing the AEC REPRODUCIBILITY test.
10. Erase the exposed IP using the Primary Erasure mode of the FCRm/CRm reader unit.
11. Using AEC, expose the 4cm thick absorber for each imaging mode that is used clinically on that X-ray unit (e.g. small image receptor and grid, large image receptor and grid, magnification mode with small focal spot, and no grid). It is not necessary to measure or record air kerma during the IMAGE MODE TEST.
12. Enter the results of each exposure on the IMAGE MODE TRACKING form.
13. Erase all exposed IP's using the Primary Erasure mode of the FCRm/CRm reader unit.

CNR PER OBJECT THICKNESS

1. Using the designated 18x24cm QC mammography cassette and IP, erase the IP using the FCRm/CRm reader unit's secondary erasure mode. Place the loaded cassette in the 18x24cm bucky.
2. Place the 2cm thick 24x30cm acrylic absorber on the patient support. The absorber may extend beyond the chest wall side of the 18x24cm patient support.
3. Lower the compression device into contact with the absorber.
4. Move the AEC sensor to its most forward position (closest to the chest wall).

5. Place the 0.2mm Al sheet on the top of the compression device (not directly on top of the absorber) and position it as shown in the diagram. Use the field indicator light as a guide for the center of the bucky and to identify the AEC sensor positions. Position the Al sheet as shown in the diagram so that the Al covers the indicated "Calculation Area" while positioned as far as possible from the most forward AEC sensor position.



6. Make an AEC exposure using the AEC MODE and kVp normally used clinically for a 2cm thick compressed breast.
7. After the predetermined interval, process the IP using the "Physics Sensitivity" menu.

NOTE

To control the effect of image fading with time on this test, it is important to control the time interval between X-ray exposure and reading of the IP so that the interval be consistent whenever this test is performed. The interval may be as short as possible consistent with the testing workflow. We recommend trying an interval between 5 and 10 minutes, adjusting as necessary, and then using the same interval consistently.

8. Calculate CNR of the image using the QC calculation tool function on the CR Console/AWS-c, and record the kVp, target, filter, mAs, and CNR value on the CNR PER OBJECT THICKNESS data form.
9. Repeat steps 6 through 8 using 4cm and 6cm thick 24x30 acrylic absorbers using the kVp and AEC exposure settings normally used clinically for 4 and 6cm compressed breasts respectively.
10. Assigning the CNR value from the 4cm exposure a value of 100%, calculate the relative CNR percentage values for 2cm and 6cm and record them on the data form.

PRECAUTIONS AND CAVEATS

Use the 18x24cm QC IP and cassette for the CNR PER OBJECT THICKNESS test.
Always wait the same time between exposure and processing of the IP when performing this test.
CNR will change after major service or replacement events. These include but are not limited to:

- X-ray tube replacement
- Filter replacement
- Replacement of the compression paddle
- Change in phantom used
- Change of grid or table surface
- Change of X-ray generator calibration
- Change of CR Reader calibration

PERFORMANCE AND CORRECTIVE ACTION

DENSITY CONTROL FUNCTION

Each increase or decrease of the AEC DENSITY setting should result in a 5 to 15% change of mAs.

REPRODUCIBILITY

The coefficients of variation for either air kerma and mAs must not exceed 0.05

IMAGE MODE TRACKING

There should not be a significant difference in exposure between the small bucky and the larger bucky when employing similar grid types.

CNR PER OBJECT THICKNESS

This is an annual test. Establish a new CNR 4cm reference value each time this test is performed. (The technologist monitors CNR over time by performing the CNR Weekly test.)

When evaluating the performance of the AEC system, the following two trends should be demonstrated:

1). First, at a given beam quality (kVp, target, and filter), mAs should increase with increasing phantom thickness.
2). Second, at a given phantom thickness, the mAs should decrease with increasing kVp.

Evaluate CNR by establishing a baseline CNR value from the 4 cm phantom image and assign the 4 cm CNR image a value of 100%.

The relative CNR of the 2cm image must be equal to or greater than 100%.
The relative CNR of the 6cm image must be equal to or greater than 75%.

If this test produces results that fall outside these action limits, corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period.

Automatic Exposure Control (AEC) System Performance Assessment

DATE:	

Small Cassette ID:_____ Large Cassette ID:_____

Reader Unit ID:_____ Exposure Unit ID:_____

DENSITY CONTROL FUNCTION CHART

Imaging mode:	Small Image Receptor with Grid			
Focal Spot:	Large Focal Spot			
Phantom thickness:	4cm			
kVp:				
AEC Density Control Setting	mAs	% mAs change		Acceptable level
+5			PASS / FAIL	5-15% difference per step
+4			PASS / FAIL	
+3			PASS / FAIL	
+2			PASS / FAIL	
+1			PASS / FAIL	
0 (Normal)		0%	PASS / FAIL	
-1			PASS / FAIL	
-2			PASS / FAIL	
-3			PASS / FAIL	
-4			PASS / FAIL	
-5			PASS / FAIL	

REPRODUCIBILITY CHART

Imaging mode:	Small Image Receptor with Grid			
Focal Spot:	Large Focal Spot			
Phantom thickness:	4cm			
kVp:				
Exposure Number	Air kerma	mAs	Acceptance	Action Limit
1				
2				
3				
4				
Mean values				
Standard Deviations (SD)				
Coefficients of variation (CV)			PASS / FAIL	The coefficients of variation for both air kerma and mAs must not exceed 0.05

Continued on the following page.

DATE:	

Small Cassette ID:_____ Large Cassette ID:_____

Image Reader ID:_____ Exposure Unit ID:_____

IMAGE MODE TRACKING

Absorber: 4 CM
Focal Spot: L
Density Control:

Technique	AEC MODE	kVp	Target	Filter	mAs	Comments
18 x 24 Bucky						
24 x 30 Bucky						
Mag / No Grid						

CNR PER OBJECT THICKNESS

Imaging Mode:	
Focal Spot:	
Density Control:	
AEC Mode(s):	

Phantom Thickness	kVp	Target	Filter	mAs	CNR Measured	CNR (relative to 4cm PMMA)	Acceptable level
2 cm							>100%
4 cm						100%	100%
6 cm							>75%
						PASS / FAIL	

SIGNATURE:_____

18 System Artifact Evaluation (Annual) — Medical Physicist

OBJECTIVE

To assess the degree and source of artifacts visualized on hardcopy mammograms or phantom images. This procedure allows the source of artifacts to be traced to X- ray equipment, cassette, IP, FCRm/CRm reader, or printer/processor so that appropriate measures for elimination of artifacts can be taken.

FREQUENCY

This test must be performed at installation and annually and whenever artifact evaluation is needed.

REQUIRED TEST EQUIPMENT

- A uniform 4-cm thick (approximately) sheet of defect free acrylic large enough to cover a 24×30 cm mammographic cassette
- The previously selected QC cassettes and IPs of each size
- For hardcopy only, mask the illuminated portion of the viewbox outside the area of the film
- For hardcopy only, an optical densitometer
- SYSTEM ARTIFACT EVALUATION data form

PROCEDURE

1. Use technique factors normally used clinically, choosing the lowest kVp setting used clinically (to be most sensitive to artifacts). If AEC is normally used, use it in this test. Start with the most commonly used image receptor size (usually 18 × 24 cm). Record the technique factors on the data form.
2. Place a uniform sheet of acrylic that is large enough to cover the mammographic cassette and thick enough to have an exposure time of 0.5 second or greater on the image receptor holder assembly.
3. Erase the IP using Primary Erase and insert the cassette into the cassette holder.
4. Position a lead marker such as the number “1” or an arrow on the acrylic sheet in a corner of the radiation field, preferably outside the normal location of the breast, and pointing along the long axis of the IP and cassette.
5. Make an exposure.
6. Process the IP using the “Physics, Artifacts” menu. Record all pertinent information on the data form for this test.
7. Measure the optical density in the center of the printed film, verifying that it is greater than 1.20, and record on the data form for this test.
8. Repeat this process for the other image receptor size. Also, repeat for all available focal spot sizes, targets and filters used clinically.

PRECAUTIONS AND CAVEATS

If artifacts are visible on hardcopy but not during workstation review, the cause of the artifact could be due to the image printer or film processor.

Compare printed images against the same images viewed on the FCRm/CRm workstation using magnification and rotation if helpful. There is no need to change window/level or image processing.

If the artifacts appear on both hardcopy and softcopy, the cause of the artifact could be the X-ray generator, FCRm/CRm reader unit, cassette or IP.

- X-ray generator:
  Potential sources of artifact include irregular density or projection artifacts from the X-ray tube, filter, collimator, compression paddle, image receptor holder or grid. To help isolate artifacts caused by the X-ray generator, produce a second image with the cassette rotated 180 degrees compared to the first image. If the artifact remains the same relative to the position of the marker it is likely coming from the exposure system. If the artifact reverses relative to the marker it is likely coming from the FCRm/CRm reader unit, cassette/IP or image printer.
  To help isolate grid artifact, the IP cassette can be exposed on top of the bucky. A non grid image will help identify artifacts caused by uneven absorption of the bucky surface and the quality of the grid. If the compression paddle is suspect, images can be produced with and without the compression paddle in the beam. Contact the X-ray generator manufacturer for additional information.

- FCRm/CRm Reader Unit:
  Potential causes of artifact in the FCRm/CRm reader unit are misalignment or dirt on the light collector, improper imaging parameter setup or an error in spatial uniformity of the digitization process.
  Misalignment of the light collector can produce non-uniform density across the long axis of the image. If required, a qualified service engineer should check the position of the light collector and/or perform a shading correction. Image processing parameters are set up and confirmed by a qualified Imaging Specialist during the turnover of the system. Image processing changes should only be made by qualified personnel. Errors in spatial uniformity are highly visible on any image and require immediate attention from the service engineer.

- Image Printer:
  Potential Printer artifacts include non-uniform density across the image, white spots or streaks and film scratches. Non-uniform density can occur in the printing and/or development cycles of the printer. White spots can be caused by dirt or other particles that prevent laser light or thermal interaction with the film. Dirt or defect in the thermal head of dry printers can produce black or white lines traveling in the direction of film transport. In order to differentiate printer artifact from IP damage or dirt, reprint the image using “Twin Format”. If the artifact appears in the same position on both images it is an X-ray generator, IP or reader artifact. Artifacts that exist outside the image field borders of the film typically indicate a printer problem exists.
  Contact the printer manufacturer for additional information.

PERFORMANCE AND CORRECTIVE ACTION

If significant artifacts are noted, contact the person maintaining that system component. Not all artifacts can be totally eliminated. It may be useful to use the concept of ALARA (as low as reasonably achievable) when attacking artifacts. If they can be easily eliminated, they should be.
If the artifact is difficult or expensive to eliminate and is subtle (not mimicking or obscuring clinical information), it may be tolerable. The medical physicist should consult with the interpreting physician as to whether the artifact is tolerable. Tolerances for artifacts should be lower with new imaging equipment. If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period.

SYSTEM ARTIFACT EVALUATION

DATE:	

Reader Unit ID:	
Exposure Unit ID:	
Type of Attenuator	
Thickness of Attenuator	
kVp Setting	

All Target and Filter combinations used clinically must be evaluated. All available focal spot sizes and magnification modes used clinically must be evaluated.

Exposure Conditions

Cassette - IP Number				
IP Size				
mAs or AEC setting(s)				
Optical Density				
Target/Filter Type				
Focal Spot Size Large or Small				
Magnification Factor Used				

Exposure Equipment Artifact

Acceptable?	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
CORRECTIVE ACTION DESCRIPTION:		
CORRECTIVE ACTION TAKEN?	YES	NO
CORRECTIVE DATE:		
RESULTS OF NEW TEST:	PASS	FAIL

FCRm/CRm Reader Artifact

Acceptable?	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
CORRECTIVE ACTION DESCRIPTION:		
CORRECTIVE ACTION TAKEN?	YES	NO
CORRECTIVE DATE:		
RESULTS OF NEW TEST:	PASS	FAIL

Printer Artifact

Acceptable?	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
CORRECTIVE ACTION DESCRIPTION:		
CORRECTIVE ACTION TAKEN?	YES	NO
CORRECTIVE DATE:		
RESULTS OF NEW TEST:	PASS	FAIL

If significant artifacts are visible, contact the appropriate person maintaining or servicing the digital mammography equipment, printer or X-ray generator.

19 Image Quality Evaluation (Annual) — Medical Physicist

OBJECTIVE

To assess mammographic image quality and to detect temporal changes in image quality.

FREQUENCY

This test must be carried out initially, at installation, after appropriate calibration of the equipment to establish a baseline level. Subsequently, it must be carried out at least annually to compare with the previous test image.

REQUIRED TEST EQUIPMENT

- ACR MAPP
- Acrylic 4mm x 1cm diameter disc (for hardcopy QC only)
- Designated cassette and Imaging Plate used for mammography
- Image Quality Evaluation Control chart
- Watch/Timer
- Previous Image

PROCEDURE

1. Using the designated cassette, erase the IP using the secondary erasure mode on the reader.
2. Place the cassette in the cassette holder.
3. Place the phantom on the cassette holder and position it so the edge of the phantom fully covers and is aligned with the chest wall side of the image receptor. Center the phantom, left to right.
4. The 4mm acrylic disc is not needed for softcopy QC. If softcopy is used for final interpretation, proceed to step 6.
5. For hardcopy QC, secure the acrylic disc to the top of the phantom within the image area but positioned so it will not obscure details in the phantom. A suitable location is between and slightly below the first and second largest fibers. Once located, the disc may be permanently attached to the phantom with super glue.
6. Bring the compression device into contact with the phantom.
7. Verify the location of the AEC detector. It should be in the same location used for previous phantom images and should be completely covered by the phantom.
8. Make an exposure using the AEC technique factors (target, filter, kVp, grid, density control setting, etc.) currently used clinically for a 4.2-cm compressed breast of average density.

.

9. Record the mAs on the control chart after making the exposure.
10. After exposure, ensure that a predetermined interval time between 5 and 10 minutes elapses prior to the reading process. Process the IP using the "Physics, ACR MAPP" menu.

> NOTE
> It is important to control the time interval between exposure and reading of the IP. To minimize variability, it is recommended that and interval be chosen somewhere between 5 and 10 minutes and that this same interval be used consistently.

11. Record the AEC density control setting on the control chart.
12. If printed images are used for final interpretation: Measure the following densities. The background density should be measured in the geometric center of the phantom image. The DD measurement is the density inside the acrylic disc subtracted from the density directly adjacent to the disc, perpendicular to the anode-cathode axis. For consistent results, these measurements must be made at the same location each time the background optical density and the DD on the control chart.

    If softcopy images are used for final interpretation: Record the S value from the phantom exposure image on the background density line of the control chart.

VIEWING CONDITIONS

Phantom images should be read under controlled viewing conditions. General lighting should be at a low level and diffused. Viewboxes or workstations should be positioned to avoid light from windows, other viewboxes, and other sources of bright light, either direct or reflected. Images should be masked to eliminate extraneous light. Use large field–of-view magnification to assist in the visualization of specks as well as other test objects. For hardcopy images, use a 2X or higher magnifying glass. For softcopy images, use the workstation's electronic magnification function.

DATA ANALYSIS AND INTERPRETATION

1. When scoring the phantom image of the approved phantom, each object is scored separately. Always count the number of visible objects from the largest object of a given type (i.e., fiber, speck group or mass) downward until a score of 0 or 0.5 is reached, then stop counting for that object type.
2. Count each fiber as one point if the full length of the fiber is visible and the location and orientation for the fiber are correct. Count a fiber as 0.5 if not all, but more than half, of the fiber is visible and its location and orientation are correct. Add each full or partial fiber to the total score, from the largest down to the smallest visible, until a score of 0 or 0.5 is reached.
3. After determining the last fiber to be counted, look at the overall background for artifacts. If a fiber-like artifact appears anywhere in the wax insert area of the image, but not in an appropriate location or orientation, deduct the "artifactual" fiber from the last "real" half or whole fiber score if the artifactual fiber is equally or more apparent. Deduct only from the last real fiber, not from additional deduction. Record the final score after artifact deduction in the appropriate space on the chart.

4. Use large field–of-view magnification to assist in the visualization of specks. For hardcopy images, use a 2X or higher magnifying glass. For softcopy images, use the workstation's electronic magnification function. Starting with the largest speck group, count each speck group as one point if four or more of the six specks in the group are visible in the proper locations. Count a speck group as 0.5 if two or three of the six specks in the group are visible in the proper locations. Count a speck group as 0 if none or only one of the six specks in the group is visible in the proper location.
   Add each full or partial speck group to the total speck group score, from the largest down to smallest visible group, until a score of 0 or 0.5 is reached.
5. After determining the last speck group to be counted, look at the overall background for artifacts. If noise or speck-like artifacts are visible in the wrong locations within the area of the wax insert, and are as apparent as the "real" specks, deduct them one for one from the individual specks counted in the last whole or half speck group scored, and adjust the score of the last group appropriately. Record the final score after artifact deduction in the appropriate space on the chart.
6. Count each mass as one point if the minus density object is visible in the correct location, and the mass appears to be generally circular against the background (i.e., greater than ¾ of the perimeter is visible). A mass is counted as 0.5 point if the minus density object is visible in the correct location, but the mass does not have a generally circular appearance. Add each full or partial mass to the total mass score, from the largest mass down and until a score of 0 to 0.5 is reached. Record the "raw" mass score before artifact deduction.
7. After determining the last mass to be counted, look at the overall background for artifacts. If a mass-like artifact is seen in the wrong location within the area of the wax insert, deduct the "artifactual" mass from only the last "real" whole or half mass scored if the artifactual mass is equally or more apparent. Record the final score after artifact deduction on the appropriate space on the chart.
8. Using magnification, carefully examine the image for non-uniform areas, the presence of dirt or dust artifacts, grid lines, processing artifacts, or any other artifacts and compare the film image to the original and previous images.
9. Circle any artifacts or grid lines on the film image. Investigate the source of any artifacts or grid lines.

NOTE

Mammography phantom films images should always be viewed
- On the same viewbox or viewing device
- By the same individual
- Under the same viewing conditions
- Using the same type of magnification used for reading mammograms
- Softcopy images should be window and leveled to best demonstrate the objects of interest

PRECAUTIONS AND CAVEATS

This test measures the output from all components in the imaging chain. Changes in image quality may be due to the film, cassettes, IP's, X-ray generator, FCRm/CRm reader unit, added filtration, printer, viewbox, or workstation. Consequently, other tests will be necessary to determine the component, or components, causing the change.

It is also necessary to check if settings for the image reading mode or image processing parameters are changed. These factors will have a large influence on the results of this test.

When any image parameters are changed, it is necessary to perform the Phantom Exposure test to re-determine the new baselines. Confirm the imaging parameters used for this test on the "Exposure and Image Processing Chart".

PERFORMANCE AND CORRECTIVE ACTION

The total number of simulated masses, speck groups, and fibers visible in the phantom image should not decrease by more than one-half, assuming the same individual is viewing the images under identical conditions.
If a different number of objects are noted, the current image should be compared with previous images and the original image to determine if a change has really occurred. Because the medical physicist may not have the opportunity to measure phantom image quality as frequently as the QC technologist, it is important to review a sample of the phantom images acquired by the technologist since the previous visit, comparing results with your own assessment of image quality. Any apparent problems in scoring the phantom should be included as a corrective action and lead to a discussion with the QC technologist about phantom scoring. The acrylic discs used to produce an image for the measurement of the density difference may vary in thickness. Consequently, the density difference is a relative, not absolute measurement and is to be used only for quality control purposes. It is essential to use the same acrylic disc if comparisons are to be made between different facilities.

NOTE

At a minimum, the four largest fibers, the three largest speck groups and the three largest masses must be visible. If your baseline image exceeds the above minimum scores, the new image score should not decrease by more than ½ from the baseline levels.

The mAs noted on the generator read-out typically does not change by more than ±15%. If your measurements exceed this amount, it may be due to a change in kVp, mAs, target material, filter material, generator calibration, or AEC calibration since the previous image.

If printed images are used for final interpretation:
The optical density (OD) of the film shall be within control limits of ± 0.20, from the established operating level.

The acrylic discs used to produce an image for the measurement of the density difference may vary in thickness. Consequently, the density difference is a relative, not absolute measurement and is to be used only for quality control purposes. It is essential to use the same acrylic disc if comparisons are to be made between different facilities.

The density difference (disc vs. adjacent density) shall not vary by more than ± 0.05 from the established operating level. If a new operating level for background optical density is chosen, then a new operating level for density difference must be established. It is essential that all printers used to print mammography images at one facility produce similar film optical densities. It is not acceptable to have one unit producing a film with an OD of 1.40 and another producing an OD of 1.80.

If softcopy is used for final interpretation:
The S value of the phantom image confirms the exposure unit output and the CR reader sensitivity setting. The S value result must be recorded on the QC chart and must not vary by greater than +/- 20%. If your results exceed this control limit, make sure that the kVp and /or mAs and the menu selected are correct and repeat the exposure.

For both softcopy and hardcopy:
If the performance criteria and corrective action for this test are not met, a second phantom image should be taken and evaluated. If the criteria are still not met the reasons for this failure must be investigated, corrective action taken, and the results documented before patients are examined with this system. It is essential that all mammography units, CR mammography readers, and printers at one facility produce similar film optical densities. It is not acceptable to have one unit, reader or dry laser printer producing a film with an OD of 1.40 and another producing an OD of 1.80.

Any visual differences between the current phantom film image and the saved original phantom film image should be investigated. Printers or CR reader artifacts, grid lines, or grid artifacts should not be present since any of these may degrade clinical images.

Document corrective action for future reference on the Phantom Image "Maintenance and Corrective Action Log". All sources of significant artifacts should be eliminated.

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken on the component(s) that caused the failure before any further examinations are performed using the failed component(s). If the component(s) that caused the failure (e.g. exposure unit or CR reader) is replaced by an alternative device and the mammography system passes the re-test, image acquisition and interpretation may continue using that combination of devices.

If the failure has been determined to be of a diagnostic device used for mammographic image interpretation (e.g. laser printer, physician's review station) the source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation. Clinical imaging may be continued. If available, an alternative approved diagnostic device may be used for mammographic image interpretation.

NOTE

Phantom Images should be retained in the QC records for the last full year (softcopy images can be "locked" on the QA and PACS workstation). The original baseline image should be retained until it is necessary to establish a new baseline.

IMAGE QUALITY EVALUATION

DATE:	

Exposure Unit ID:	
Reader Unit ID:	
Phantom ID#:	
AEC Detector position:	
Cassette size:	
IP & Cassette#:	

	Previous Image	Current Image	Comments
kVp setting			
Density control			
Phototimed mAs			
mAs change			
% mAs change = mAs change / mAs × 100			
S value			
S value Change			
*Background density			
*Background density change			
*Density outside disc			
*Density inside disc			
*Density diff = outside-inside			
*Density difference change			
Number of fibers seen			
Fibers seen after deduction			
Fiber change			
Number of speck groups seen			
Speck groups after deduction			
Speck groups change			
Number of masses seen			
Masses seen after deduction			
Mass change			

* Hardcopy for final interpretation only.

JUDGEMENT	PASS / FAIL

Comments: _____

_____

_____

_____

SIGNATURE: _____

20 Dynamic Range (Annual) — Medical Physicist

OBJECTIVE

To confirm the dynamic range of the FCRm/CRm reader unit and imaging plate.

FREQUENCY

At installation and then annually, and when decrease in the dynamic range is suspected.

REQUIRED TEST EQUIPMENT

- Uniform 2 cm and 4 cm thicknesses of defect free acrylic
- Previously-selected 18 x 24 cm CR QC cassette for mammography and IP used for mammography
- Dynamic Range data form

PROCEDURE

NOTE

This is an evaluation of the CR reader unit. Select one exposure unit for this evaluation.

1. Using the dedicated mammography cassette, erase the IP using the secondary erasure mode on the reader.
2. Place the cassette in the bucky tray.
3. Place the 2 cm and an additional 4 cm thickness of acrylic attenuating material on the surface of the Bucky tray as shown in Figure 1.
4. Bring the compression device into contact with the phantom attenuators.
5. Verify the location of the AEC detector. It should be completely covered by the 2 cm and 4 cm thicknesses of acrylic.
6. Make an exposure using the AEC technique factors (target, filter, kVp, grid, density control setting, etc.) currently used clinically for a 6cm compressed breast of 50/50 composition.
7. Read the IP using the "Physics Dynamic Range" menu.
8. Using the QA function on the CR Console/AWS-c, set the L Value to 4.0.
9. View the image on the display (monitor or hardcopy) used for final interpretation, and record your findings on the Dynamic Range report form.

PRECAUTIONS AND CAVEATS

Be sure to process the image using the correct menu.

PERFORMANCE AND CORRECTIVE ACTION

It is required that the three exposure areas (no acrylic, 2 cm acrylic, and 6 cm acrylic) be discernable.

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken on the component(s) that caused the failure before any further examinations are performed using the failed component(s). If the component(s) that caused the failure (e.g. exposure unit or CR reader unit) is replaced by an alternative device and the mammography system passes the re-test, image acquisition and interpretation may continue using that combination of devices.

If the failure has been determined to be of a diagnostic device used for mammographic image interpretation (e.g. laser printer, physician's review station) the source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation. Clinical imaging may be continued. If available, an alternative approved diagnostic device may be used for mammographic image interpretation.

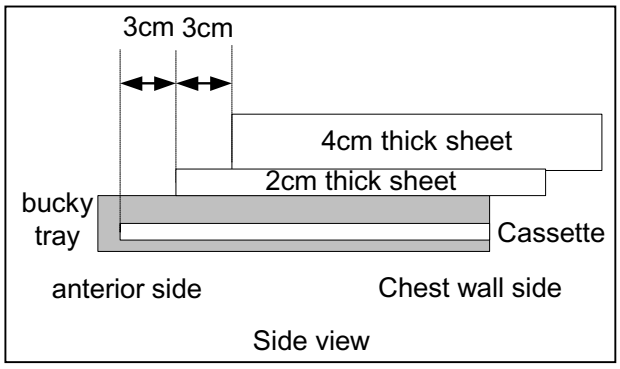


Figure 1. Test Object Arrangement

Dynamic Range

DATE:	

X- ray generator Number	
Cassette / IP Number	
CR Reader Unit ID / Number	

	Target	Filter	kVp	mAs
Exposure conditions				

Dynamic Range evaluation

Acceptable?	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
CORRECTIVE ACTION DESCRIPTION:		
CORRECTIVE ACTION TAKEN?	YES	NO
CORRECTIVE DATE:		
RESULTS OF NEW TEST:	PASS	FAIL

SIGNATURE: _____

21 Primary Erasure (Additive and Multiplicative Lag Effects) (Annual) — Medical Physicist

OBJECTIVE

To assess the erasure performance of the FCRm/CRm image reader unit and imaging plate

FREQUENCY

At installation and then annually and when incomplete erasure is suspected.

REQUIRED TEST EQUIPMENT

- ACR MAPP
- A uniform 4 cm thick plate of defect-free acrylic large enough to cover an 18 × 24 cm cassette
- Previously selected and loaded 18 x 24 cm CR mammography QC cassette and imaging plate
- Watch/timer
- Primary Erasure data form

PROCEDURE

NOTE

This is an evaluation of the CR image reader. Select one exposure unit for this evaluation.

Additive Lag test

1. Erase the IP using the secondary erasure mode on the reader.
2. Place the cassette in the Bucky tray.
3. Place the ACR MAPP on the patient support and position it so the edge of the phantom is aligned with the chest wall side of the image receptor. Center the phantom, left to right.
4. Bring the compression device into contact with the phantom.
5. Verify the location of the AEC detector. It should be in the same location used for the “Phantom Image” test and should be completely covered by the phantom.
6. Make an exposure using the AEC technique factors (target, filter, kVp, grid, density control setting, etc.) currently used clinically for a 4.2 cm compressed breast of 50/50 composition.

7. Process the IP using the "Physics, ACR MAPP" menu.
8. Record the S value on the data form.
9. Wait one minute and re-process the same IP using the "Physics, ACR MAPP" menu without making additional exposure.
10. On the new image, change the S value to 10 times that of the original S value recorded during Step 8 using the QA function of the CR Console/AWS-c.
11. Inspect the image for the visibility of the outline of the ACR MAPP.

Multiplicative Lag test

12. Repeat steps 2 through 7 using the same cassette as in the first test.
13. Disregard the image produced. Remove the returned cassette and IP from the reader and insert it into the bucky tray.
14. Place a uniform 4 cm thick acrylic plate that is large enough to cover the mammographic entire cassette on top of the bucky tray.
15. Make an exposure using the AEC technique factors (target, filter, kVp, grid, density control setting, etc.) currently used clinically for a 4 cm compressed breast of 50/50 composition.
16. Process the IP using the "Physics, ACR MAPP" menu.
17. Inspect the image for the visibility of the outline of an ACR phantom.

PRECAUTIONS AND CAVEATS

Be sure to read the image using the "Physics, ACR MAPP" menu.

PERFORMANCE AND CORRECTIVE ACTION

If significant artifacts are noted, contact the person who maintains that system component, the CR reader. Not all artifacts can be totally eliminated. It may be useful to use the concept of ALARA (as low as reasonably achievable) when attacking artifacts. If they can be easily eliminated, they should be. If the artifact is difficult or expensive to eliminate and is subtle (not mimicking or obscuring clinical information), it may be tolerable. The medical physicist should consult with the interpreting physician as to whether the artifact is tolerable. Tolerances for artifacts should be lower with new imaging equipment.

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken on the component(s) that caused the failure before any further examinations are performed using the failed component(s). If the component(s) that caused the failure (e.g. exposure unit, CR reader, display device) is replaced by an alternative device and the mammography system passes the re-test, image acquisition and interpretation may continue using that combination of devices.

Primary Erasure (Additive and Multiplicative Lag Effects)

DATE:	

Exposur Unit ID:	
Cassette - IP Number:	
CR Reader Unit ID:	

Additive Lag test

Exposure conditions	Target	Filter	kVp	mAs
ACR MAPP				

S value of the ACR MAPP	①	
	①×10	
S value applied to non-exposure image	About ①×10	

Artifact evaluation

Acceptable?	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
CORRECTIVE ACTION DESCRIPTION:		
CORRECTIVE ACTION TAKEN?	YES	NO
CORRECTIVE DATE:		
RESULTS OF NEW TEST:	PASS	FAIL

Multiplicative Lag test

Exposure conditions	Target	Filter	kVp	mAs
ACR MAPP				
A uniform 4 cm sheet image				

Artifact evaluation

Acceptable?	PASS	FAIL
CORRECTIVE ACTION NEEDED?	YES	NO
CORRECTIVE ACTION DESCRIPTION:		
CORRECTIVE ACTION TAKEN?	YES	NO
CORRECTIVE DATE:		
RESULTS OF NEW TEST:	PASS	FAIL

The mAs noted on the generator read-out must not change by more than ±15% from the previous test.

SIGNATURE: _____

22 Inter-Plate Consistency (Annual) – Medical Physicist

OBJECTIVE

To confirm the X-ray absorption and SNR consistency of imaging plate/cassette pairs of one type and size.

FREQUENCY

At installation, annually, and before introducing new imaging plates or cassettes.

NOTE

The inter-plate consistency test must be performed on new imaging plates and imaging plate cassettes prior to clinical use. When adding or replacing imaging plates and cassettes of the same type already in use between annual physicist's surveys, the QC technologist may perform this test on the new imaging plates and cassettes under the oversight of the medical physicist prior to their first clinical use, recording the results on the inter-plate consistency data form for review by the medical physicist during the next annual survey. These new imaging plates and cassettes must meet the criteria established for the group to which they will be added. If the new imaging plates and cassettes do not fit the criteria for an existing group and require more exposure, then the testing must be performed by the medical physicist.

REQUIRED TEST EQUIPMENT

- A uniform 4 cm thick sheet of defect free acrylic large enough to cover a 24×30cm cassette
- Imaging plates and cassettes to be evaluated
- Watch/timer
- Inter-Plate Consistency data form

PROCEDURE

1. Select a cassette used for mammography, and erase the IP using the secondary erasure mode of the reader.
2. Place the cassette in the bucky tray.
3. Place the 4-cm thick acrylic attenuating material (phantom) on the patient support surface.
4. Lower the compression device into contact with the phantom.
5. Make an AEC exposure in the auto mAs mode. Fix the other technique factors (target, kVp, filter, grid, density control setting, etc.) used clinically.
6. Wait a predetermined time interval and process the IP using the "Physics Sensitivity" menu. This menu should be set in the “Semi mode” and all image should be set to zero (MRE, MDE, PRE).

NOTE

To reduce the influence of IP image fading characteristics on this test, it is important to control the time interval between X-ray exposure and reading of the IP. It is important that the interval be consistent whenever this test is performed. Choose an interval between 5 and 10 minutes, and then use the same interval consistently.

7. Record the mAs of the test exposure on the Inter-Plate Consistency data form.
8. Repeat the procedure from Step1 to Step 7 for all IP's of the same type and size to be evaluated. All IP's of the same type and size are considered a "group".
9. Repeat steps 1 through 8 for other groups to be evaluated.
10. Calculate the SNR of all images using the QC calculation tool.
11. Record the SNR result on the Inter-Plate Consistency data form.
12. Before using new imaging plates clinically, compare the consistency of the new imaging plates against the inventory of all imaging plates of the same group by performing steps 1 through 11.

PRECAUTIONS AND CAVEATS

This test is sensitive to changes in beam quality (kVp, target and filter material). Use an AEC mode that varies mAs only and does not permit changes in kVp, target and filter material.
This test is also sensitive to changes in the patient support and anti-scatter grid. Because the patient support and grid change as the size of the IP is changed, comparisons of IP's of different sizes will also reflect the differences in mAs and SNR introduced by differences in the support and grid.

PERFORMANCE AND CORRECTIVE ACTION

The variation of mAs value must be within ±10%
The variation of SNR must be within ±15%

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period.

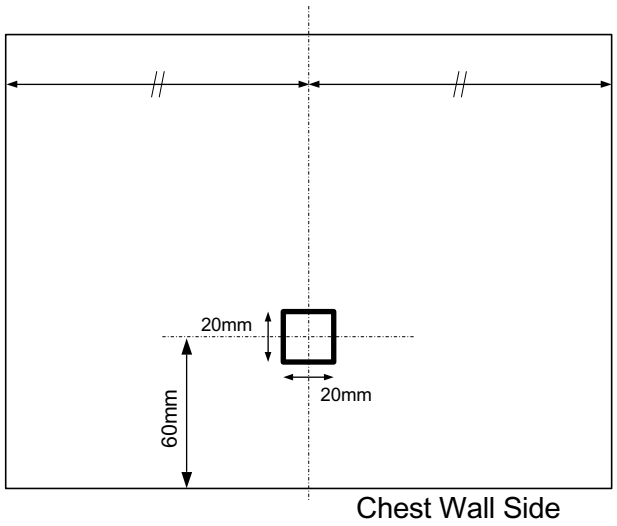


Figure 1: ROI of the inter-plate sensitivity test

INTER-PLATE CONSISTENCY

DATE:	

Exposure Unit ID:	
CR Reader Unit ID:	

	AEC-mode	Target	Filter	kVp
Exposure conditions				

Group: _____

Cassette ID	mAs	Average Value	Limiting Value	SNR	Average Value	Limiting Value	Acceptable?
							PASS / FAIL
							PASS / FAIL
							PASS / FAIL
			to			to	PASS / FAIL
							PASS / FAIL
							PASS / FAIL
							PASS / FAIL
							PASS / FAIL
			(±10%)			(±15%)	PASS / FAIL
							PASS / FAIL

Group: _____

Cassette ID	mAs	Average Value	Limiting Value	SNR	Average Value	Limiting Value	Acceptable?
							PASS / FAIL
							PASS / FAIL
							PASS / FAIL
			to			to	PASS / FAIL
							PASS / FAIL
							PASS / FAIL
							PASS / FAIL
							PASS / FAIL
			(±10%)			(±15%)	PASS / FAIL
							PASS / FAIL

SIGNATURE: _____

23 kVp Accuracy and Reproducibility (Annual) – Medical Physicist

NOTE

This test is specific to the X-ray generator and not the FCRm/CRm system. Follow the procedures in the ACR Mammography Quality Control Manual for screen-film systems. If a cassette and imaging plate are used, erase the plate after each exposure using the "Primary Erase" cycle.

FREQUENCY

This test must be performed annually.

PERFORMANCE AND CORRECTIVE ACTION

A. The kVp shall be accurate within ±5% of the indicated or selected kVp at:
   1. The lowest clinical kVp that can be measured by a kVp test device
   2. The most commonly used kVp;
   3. The highest clinical kVp, and
B. At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period.

24 Dose (Annual) — Medical Physicist

NOTE

This test is specific to the X-ray generator and not the FCRm/CRm system. Follow the procedures in the ACR Mammography Quality Control Manual in accordance with MQSA requirements for screen-film systems. If a cassette and imaging plate are used, erase the plate after each exposure using the "Primary Erase" cycle.

FREQUENCY

This test must be performed at installation and annually.

PERFORMANCE AND CORRECTIVE ACTION

The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken on the component(s) that caused the failure before any further examinations are performed using the failed component(s). If the component(s) that caused the failure (e.g. exposure unit, CR reader unit, display device) is replaced by an alternative device and the mammography system passes the re-test, image acquisition and interpretation may continue using that combination of devices.

25 Beam Quality Assessment and Half-Value Layer Measurement (Annual) — Medical Physicist

NOTE

This test is specific to the X-ray machine and not the FCRm/CRm system. Follow the procedures in the ACR Mammography Quality Control Manual in accordance with MQSA requirements for screen-film systems. The X-ray machine will require a cassette to be present in the cassette holder before an exposure can be made. Either an FCRm/CRm or screen-film cassette may be used for this purpose. As no images are recorded in this test, it is not necessary to load an IP in the cassette or a film in the screen-film cassette. However, if an IP in a cassette is used in this test, erase the IP using the image reader primary erase cycle after completing this test and before performing other imaging tests or clinical use.

FREQUENCY

This test must be performed annually, after service to the X-ray machine which may effect beam quality, and as part of an mammography equipment evaluation (MEE).

PERFORMANCE AND CORRECTIVE ACTION

The HVL shall meet the specifications of 21 CFR 1020.30(m) for the minimum HVL.
These values, extrapolated to the mammographic range, are shown below.
Values not shown below may be determined by linear interpolation or extrapolation.

Designed Operating Range (kV)	Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
Below 50	20	0.20
	25	0.25
	30	0.30

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period.

TYPICAL HVL MEASUREMENTS FOR DIFFERENT TUBE VOLTAGE AND TARGET FILTER COMBINATIONS

The specified minimum HVL values in the performance and corrective action section above must be achieved for the Mo/Mo target/filter combination. Typical HVL values for Mo/Mo and other target/filter combinations as published by EUREF are provided below for reference and are optional.

	HVL (mm Al) for target filter combinations(1)			
KV	Mo/Mo	Mo/Rh	Rh/Rh	W/Rh
25	0.33±0.2	0.40±0.2	0.38±0.2	0.52±0.3
28	0.36±0.2	0.42±0.2	0.43±0.2	0.54±0.3
31	0.39±0.2	0.44±0.2	0.48±0.2	0.56±0.3

(1) All values include the effects of attenuation by a compression paddle.
From the EUREF, The European Protocol for the Quality Control of the physical and technical aspects of mammography screening, Addendum on Digital Mammography To chapter 3 of the European Guidelines for Quality Assurance in Mammography Screening Version 1.0, November 2003 See Section 14, References, for additional information about EUREF.

26 Radiation Output (Annual) — Medical Physicist

NOTE

This test is specific to the X-ray generator and not the FCRm/CRm system. Follow the procedures in the ACR Mammography Quality Control Manual in accordance with MQSA requirements for screen-film systems. If a cassette and imaging plate are used, erase the plate after each exposure using the "Primary Erase" cycle.

FREQUENCY

This test must be performed annually and upon Mammography Equipment Evaluation (MEE) of the X-ray system.

PERFORMANCE AND CORRECTIVE ACTION

A. The system shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) when operating at 28 kVp in the standard mammography mode (Mo/Mo) at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector.
B. The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

If this test produces results that fall outside the action limits as specified, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period.

Revision History

Revision	Issue Date	Reason
First Edition 897N0602	07.2006	New Release
2nd Edition 897N0602A	10.2006	Change of corporate logo and references to Fuji Photo were changed to FUJIFILM on pages 1 and 2 only. No other changes to content. The 2nd Edition was never released.
3rd Edition 897N0602B	02.2007	1) Revised to reflect 21 CFR 900.12 (e) (8) Use of test results. The FDA approved alternative requirement dated August 2, 2006. 2) Revised weekly and annual Monitor QC and Printer QC tests when the device manufacturer does not provide a QC program. 3) Added Printer and Monitor QC to Baseline Tests and indicated which tests must be performed when adding or replacing an FCRm image reader. Changed required Baseline Test from Phantom Image to Image Quality. 4) The Imaging Plate (IP) Fog test was changed from annual physicist test to semi-annual technologist test. 5) The Automatic Exposure Control (AEC) System Performance Assessment test was revised. • It is no longer required to measure air kerma during the image mode tracking portion of this test. • All exposures made during the CNR per object thickness portion of this test can be made using AEC exposure. • The corrective action limits have been changed. 6) A revision table is added to the manual to identify changes to the previous manual.
4th Edition 897N0602C 5th Edition 897N0602D	—	Never released.
6th Edition 897N0602E	12.2009	1) The CNR figures on pages 35 and 96 have been changed to the same as those in 897N100001A. 2) Revised wording for annual Monitor QC test. 3) Changes have been made along with the release of the AWS-c.
7th Edition 897N0602F	01.2012	Changes were made to incorporate the CRm system consisting of the Carbon XL-2 Reader Unit with HR-VI imaging plates and CH-type IP Cassettes.
8th Edition 897N0602G	05.2013	Added Soft Copy Phantom Control / CNR Chart to page 26. This chart was missing from page 26 in the 01.2012 release.

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