



# Selenia<sup>®</sup> Full Field Digital Mammography System

## Quality Control Manual

MAN-01476 Revision 002

Selenia<sup>®</sup>  
Digital Mammography System

**HOLOGIC<sup>®</sup>**



# Selenia<sup>®</sup>

## Digital Mammography System

### Selenia Quality Control Manual

Part Number MAN-01476

### Revision 002

September 2014

This manual applies to Selenia mammography systems that use a molybdenum x-ray tube with Mo and Rh filters, or a tungsten x-ray tube with Rh and Ag filters.

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# Table of Contents

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<b>Preface</b>	<b>vii</b>
1.0 Intended Use of the Lorad Selenia FFDM QC Manual .....	vii
2.0 Prerequisites .....	vii
3.0 Terms and Definitions .....	vii
4.0 Warnings, Cautions and Notes .....	x
5.0 Using the Lorad Selenia FFDM QC Manual .....	xi
6.0 Change Summary .....	xii
<b>Chapter 1—Introduction</b>	<b>1</b>
1.0 Personnel Training .....	1
2.0 Responsibilities .....	2
3.0 Alternative QC Standard .....	4
4.0 Quality Control Activities for the Medical Physicist .....	7
5.0 Quality Control Activities for the Radiologic Technologist .....	8
<b>Chapter 2—Quality Control Activities for the Medical Physicist</b>	<b>9</b>
1.0 Mammographic Unit Assembly Evaluation .....	10
2.0 Collimation Assessment .....	11
3.0 Artifact Evaluation .....	15
4.0 kVp Accuracy and Reproducibility .....	20
5.0 Beam Quality Assessment—Half-Value Layer Measurement .....	22
6.0 Evaluation of System Resolution .....	23
7.0 Automatic Exposure Control (AEC) Function Performance .....	25
8.0 Breast Entrance Exposure, AEC Reproducibility, and AGD .....	28
9.0 Radiation Output Rate .....	31
10.0 Phantom Image Quality Evaluation .....	33
11.0 Signal-To-Noise and Contrast-To-Noise Measurements .....	38
12.0 Diagnostic Review Workstation QC .....	44
13.0 Detector Ghosting (Optional) .....	47
<b>Chapter 3—QC Activities for the Radiologic Technologist</b>	<b>51</b>
1.0 DICOM Printer Quality Control .....	52
2.0 Detector Flat-Field Calibration .....	56
3.0 Artifact Evaluation .....	58
4.0 Signal-To-Noise and Contrast-To-Noise Measurements .....	63
5.0 Phantom Image .....	70
6.0 Compression Thickness Indicator .....	75
7.0 Diagnostic Review Workstation QC .....	76
8.0 Viewboxes and Viewing Conditions .....	80
9.0 Visual Checklist .....	81
10.0 Repeat/Reject Analysis .....	82
11.0 Compression .....	84

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<b>Appendix A—QC Forms for the Medical Physicist</b>	<b>85</b>
<b>Appendix B—QC Forms for the Radiologic Technologist</b>	<b>119</b>
<b>Appendix C—Dose Conversion Tables for the Medical Physicist</b>	<b>147</b>
<b>Appendix D—CNR Correction Tables for Systems Equipped with a Tungsten X-Ray Tube</b>	<b>151</b>

# Preface

This document provides the material necessary for a facility using the Lorad® Selenia™ Full-Field Digital Mammography (FFDM) System to maintain an effective Quality Assurance and Quality Control (QA/QC) program to conform to the MQSA Final Regulations and to the guidelines provided by the manufacturer of the Lorad Selenia FFDM System.

## 1.0 Intended Use of the Lorad Selenia FFDM QC Manual

This manual shall be used by Lorad Selenia FFDM facilities in the United States to establish a Quality Assurance and Quality Control program to conform to the rules of the United States Mammography Quality Standards Act (MQSA) or to become accredited by an accreditation body. This manual may also be used as a guide by Lorad Selenia FFDM facilities outside the United States to establish a QA/QC program to conform to the applicable local Standard Acts and Regulations. Users of this manual should be the radiologic technologist and the medical physicist who are qualified to operate the Lorad Selenia FFDM System.

## 2.0 Prerequisites

The procedures in this manual may call for the following documents:

- Hologic®: Selenia operator manual
- American College of Radiology: Mammography Quality Control Manual, 1999 (ISBN 1-55903-142-5)

## 3.0 Terms and Definitions

Accession Number	A DICOM term that refers to a RIS generated number that uniquely identifies a visit to a site by a patient.
AEC	Automatic Exposure Control. A method of limiting the amount of radiation a patient will receive.
Ag	Silver
AGD	Average Glandular Dose.
biweekly	Every two weeks.
Collimator	Device at the x-ray tube used to restrict the area of the receptor that is exposed.
Dialog Box	A pop-up which informs the user, may require a user decision, and requires the action of the user by mouse click before any other activities can occur. It is used for important notices, warnings, and errors.
DICOM	Digital Imaging and Communications in Medicine. An industry standard specification for inter-communication between medical imaging equipment.
Grid	Element within the Digital Image Receptor which reduces scatter radiation during exposure
HTC	High Transmission Cellular Grid

HVL	Beam Quality Half-Value Layer
Image (Object)	A set of modality specific binary data and identifying attributes which represents the result of an imaging procedure performed on a patient. DICOM uniquely identifies image objects with a globally unique identifier (UID).
kVp	An electrical term used in setting x-ray exposure which stands for kilo-volt peak.
LFS	Large Focal Spot
login/logout	The process of logging into and out of the Operating System of the Acquisition Workstation. Upon start-up, this occurs before a user signs into the Acquisition Workstation application, and upon exiting, occurs after a user signs out of the Acquisition Workstation.
mA	An electrical term used in setting x-ray exposure which stands for milliamperes
mAs	An electrical term used in setting x-ray exposure which stands for milliampere-seconds.
Mirror	see Flip.
Mo	Molybdenum
MQSA	Mammography Quality Standards Act
N	Newtons
OD	Optical Density
Operating System (OS)	The basic software control system which runs all functions of a computer.
Outputs	A list of devices the captured, accepted image will be sent to. Outputs consist of a combination of archives, workstations and film printers.
Procedure	A generic pre-defined medical protocol which contains a set of images (views) which are acquired under certain conditions, and are performed together for a singular purpose (e.g. standard screening). Because a procedure is a generic entity in DICOM, there is no procedure instance UID, but DICOM supports identification of requested procedures.
Rh or Rho	Rhodium
ROI	Region of Interest
Series	A set of images which have all been acquired by a single tech for a single patient and procedure on a particular modality with a fixed body part, laterality and view position. DICOM uniquely identifies series with a globally unique instance UID.



SFS	Small Focal Spot
SID	Source to Image Distance
Sign-in	The process of a user identifying him/herself to the Acquisition Workstation application.
Sign-out	The process of a user exiting the Acquisition Workstation application, but not logging out of the OS.
Solaris™	The commercial Sun Microsystems' version of the UNIX Operating System.
TEC	Tissue Exposure Control mode, an enhanced Manual Exposure Control mode.
Technique	Combination of x-ray parameters (kV, mA, etc.) defined for a particular procedural view.
UNIX	Generic term for a class of multitasking, multiprocessing operating systems which are based on the concepts initially developed in the early 1970's by AT&T Bell Labs and later expanded on at the University of California at Berkeley.
View	The combination of a single x-ray image and a specific set of conditions under which the image was acquired. View is not part of DICOM nomenclature, but in the context of DR, is approximately synonymous with a DICOM image object.
Visit	A set of studies identified in a locally unique manner and performed on a particular patient at a particular site for a singular reason. A visit is normally identified by an accession number or a Visit ID and is associated with a diagnosis. DICOM has no concept of a visit instance UID.
W	Tungsten

## 4.0 Warnings, Cautions and Notes

Definitions of Warnings, Cautions and Notes which may be used throughout this manual are as follows:



**WARNING!**

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***This alerts you to procedures that you must follow precisely to avoid causing potentially serious or fatal injury to yourself or others.***

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**Warning:**

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***Warnings point out procedures that you must follow precisely to avoid injury to yourself or others.***

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**Caution:**

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***Cautions point out procedures that you must follow precisely to avoid damage to equipment, loss of data, or corruption of files in software applications***

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**Note...**

***Notes indicate important information that must be followed to ensure the proper operation of the system.***

## 5.0 Using the Lorad Selenia FFDM QC Manual

**Chapter 1—Introduction:** Facilities using x-ray systems other than screen-film mammography must maintain a QA/QC program substantially equivalent to the QA/QC program recommended by the manufacturer. This section lists the requirements that apply to the Lorad Selenia FFDM System as specified by the manufacturer. Facilities that fail to follow the QA/QC program for the system as specified by the manufacturer in this QC Manual may jeopardize their FDA/MQSA certification.

The MQSA Final Regulations mandate that the recommended QA/QC program for the Lorad Selenia FFDM System must be maintained *in addition to* the existing Quality Assurance and Quality Control programs for screen-film mammography.

**Chapter 2—Quality Control Activities for the Medical Physicist:** This section specifies the QC procedures, testing frequency, regulatory action levels and time limits for corrective action for each required Quality Control Activity that falls under the responsibility of the *medical physicist*. These Quality Control Activities performed by the medical physicist are required under MQSA Final Regulations or by the manufacturer of the Lorad Selenia FFDM System. Detailed steps of how to perform the different tests are provided only for QC procedures that are different from the standard QC procedures already in use for screen-film mammography facilities. These detail steps are listed in this manual only to help guide the medical physicist as to how to perform the different tests on a Lorad Selenia FFDM system. The medical physicist may deviate from the steps of the procedures listed in this chapter as long as the final outcome is in full compliance with the Recommended Performance Criteria and Corrective Action defined for each test.

**Chapter 3—QC Activities for the Radiologic Technologist:** This section specifies the QC procedures, testing frequency, regulatory action levels and time limits for corrective action for each required Quality Control Activity that falls under the responsibility of the *radiologic technologist*. These Quality Control Activities performed by the radiologic technologist are required under MQSA Final Regulations or by the manufacturer. Detailed steps are provided only for QC procedures that are different from the standard QC procedures already in use for screen-film mammography facilities.

**Appendix A—QC Forms for the Medical Physicist:** All of the forms necessary for the medical physicist's tests, including the medical physicist's Mammography QC Test Summary, are provided in Appendix A. The medical physicist may also use their own forms (i.e. electronic) that resemble the forms listed in this appendix.

**Appendix B—QC Forms for the Radiologic Technologist:** Forms required for the Radiological Technologist's quality control of the Lorad Selenia FFDM System are provided in Appendix B, or are available in the 1999 *ACR Quality Control Manual*. The radiologic technologist may also use their own forms (i.e. electronic) that resemble the forms listed in this appendix.

**Appendix C—Dose Conversion Tables for the Medical Physicist:** Tungsten/rhodium (W/Rh) and tungsten/silver (W/Ag) dose conversion tables are provided in this appendix for calculating average glandular (AGD) dose on Lorad Selenia FFDM system. These dose conversion tables were derived for the 60 micron filters used on the Lorad Selenia FFDM systems equipped with a tungsten x-ray tube.

**Appendix D—CNR Correction Tables for Systems Equipped with a Tungsten X-Ray Tube:** Tables for the dose conversion for the Tungsten Tube AEC Function Performance

## 6.0 Change Summary

### 6.1 Revision 001

In June 2009 the Quality Control Manual MAN-00093 Revision 008 for Molybdenum and the Quality Control Manual MAN-00523 Revision 003 for Tungsten were merged. The following changes were also made to the combined content.

- Removed the Guidance section.
- Added information to the responsibilities for the medical physicist and radiologic technologist.
- Added a statement that electronic forms which resemble the manual forms may be used.
- *Alternative Standard 6* added. Alternative QC Standard renamed Standard 9.
- Changed Required Equipment to Suggested Equipment.
- Added Appendix D with CNR Correction tables for the dose conversion for the Tungsten Tube AEC Function Performance.

#### Quality Control Activities for the Medical Physicist

- Added a statement that the test procedure steps are for guidance and the medical physicist can deviate from them if the final outcome is in full compliance with the criteria and corrective action for each test.
- *kVp Accuracy and Reproducibility* was edited to include invasive and non-invasive kVp equipment.
- *SNR and CNR Measurements* was revised to include an Automated ROI Creation Method, and a statement for when a new CNR baseline may need to be established.
- *Viewbox Luminance and Room Illuminance* test was removed from this section.

#### Quality Control Activities for the Radiologic Technologist

- Reorganized the test order.
- *Detector Flat Field Calibration* was edited and guidance was added to calibrate the system at normal operating temperature.
- *Image Receptor Artifact Evaluation* removed the statement to use Manual Exposure mode.
- *SNR and CNR Test* was revised to include an Automated ROI Creation Method, and a statement was added regarding when a new CNR baseline may need to be established.
- *Compression Thickness Indicator* added a Note for first time Phantom use.
- *Visual Checklist* added a Corrective Action section.
- *Repeat/Reject Analysis* test was renamed and the report procedure was revised.
- *Compression* added a Corrective Action section.
- *Technologists Data Collection Sheet, SNR Calculation Worksheet, CNR Calculation Worksheet, and Repeat Analysis* report forms were added to Appendix B.

### 6.2 Revision 002

CE mark was removed.

## Chapter 1—Introduction

A facility using the Lorad Selenia FFDM System must establish a Quality Assurance and Quality Control program substantially equivalent to the QA/QC program recommended by the manufacturer—Hologic. The QA/QC program recommended for the Lorad Selenia FFDM System is described in this QC Manual. All facilities in the United States that use the Lorad Selenia FFDM System shall follow this QC Manual in order to conform to MQSA Final Regulations and not jeopardize their FDA/MQSA certification or accreditation. Facilities outside the United States may follow this QC Manual to establish a QA/QC program for the Lorad Selenia FFDM System according to the manufacturer's recommendations. This manual applies to all versions of the Lorad Selenia FFDM System equipped with either a molybdenum or a tungsten x-ray tube and may be used independently of any software version running on the system.

### 1.0 Personnel Training

MQSA Final Regulations require that personnel must receive appropriate training in digital mammography before they qualify to use the Lorad Selenia FFDM System. Required training is as follows:

#### 1.1 Medical Physicist

Before a medical physicist may begin independently performing mammographic surveys of a digital mammography system, the physicist must have met all appropriate MQSA personnel requirements including having received at least eight hours of training in surveying units of digital mammography.

#### 1.2 Radiologic Technologist

Before a radiologic technologist may begin independently performing digital mammographic examinations, the technologist must have met all appropriate MQSA personnel requirements including having at least eight hours of continuing education units in digital mammography.

#### 1.3 Interpreting Physician

Before an interpreting physician may begin independently interpreting digital mammograms, the interpreting physician must have met all appropriate MQSA personnel requirements including having at least eight hours of training in digital mammography.

## 2.0 Responsibilities

### 2.1 Medical Physicist

It is the responsibility of the medical physicist to carry out the Lorad Selenia FFDM System Equipment Evaluations before clinical use commences after the equipment is first installed, moved, or significantly modified-see CFR 900.12(e)(10). The Lorad Selenia Equipment Evaluations must include all QC tests listed under both Quality Control Activities for the Medical Physicist and Quality Control Activities for the Radiologic Technologist in accordance to 900.12(b) and 900.12(e) where applicable. For the installation of a new Selenia system, the applicable tests in Section 900.12(b) are listed in Table 6 in the ACR Q.C. Manual (1999), with the exception of 11, 12, and 13. The applicable tests in Section 900.12(e) are listed in the table below.

In the event of system software upgrades, the list of tests required to be performed by either the medical physicist or the technologist will be given in the release notes describing the corresponding software changes according to the alternative standard described in section 3.0.

The medical physicist must provide operating levels and control limits to the technologist for the QC tests pertained to the radiologic technologist, where appropriate, e.g., SNR and CNR Tests. Such operating levels and control limits must follow the guidelines of the Lorad Selenia FFDM System QC Manual.

The medical physicist is also responsible to perform all QC tests listed under Quality Control Activities for the medical physicist at least annually and monitor the overall Quality Assurance and Quality Control program for the Lorad Selenia FFDM System.

The medical physicist must review the results of the technologist’s QC tests at least annually. The results of the overall Quality Assurance and Quality Control program must be reviewed by the medical physicist with the responsible interpreting physician at least annually.

Table 1-1: Medical Physicist Installation QC Tests

QC Tests To Be Performed by the Medical Physicist Upon Installation (MEE)
Mammographic Unit Assembly Evaluation
Collimation Assessment
Artifact Evaluation
kVp Accuracy & Reproducibility
Beam Quality Assessment – HVL
Evaluation of System Resolution
AEC Function Performance
Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose
Radiation Output Rate
Phantom Image Quality Evaluation
Signal to Noise and Contrast to Noise
Detector Ghosting (Optional)
Diagnostic Review Workstation QC
DICOM Printer QC
Detector Flat Field Calibration
Compression Thickness Indicator
Compression

## **2.2 Radiologic Technologist**

It is the responsibility of the radiologic technologist to carry out the QC tests listed in the Quality Control Activities for the Radiologic Technologist at the specified frequency, review the results and request timely corrective action as necessary. The technologist must review the QC results with the medical physicist and supervising interpreting physician at least annually and consult with the medical physicist any time there are questions about the procedure or the results of these QC tests.

In the event of system software upgrades, the list of tests required to be performed by either the medical physicist or the technologist will be given in the release notes describing the corresponding software changes according to the alternative standard described in section 3.0.

## **2.3 Interpreting Physician**

The supervising interpreting physician must review the results of the quality control program with the medical physicist and radiologic technologist at least annually.

## **2.4 Facility**

As is the case for screen-film QC, the facility must keep records of all Quality Control Activities and all applicable corrective actions for at least 12 months since the last annual inspection which verified compliance (until the next physicist's and inspector's visits), or until the test has been done two additional times at the required frequency, whichever is longer. If the test results exceed the control limits, corrective action must be taken within time frames as specified for each QC test in this QC Manual.

## 3.0 Alternative QC Standard

### 3.1 Alternative Standard 6

Federal regulations, 900.12(e)(10), specify that additional evaluations of mammography units must be conducted after major component changes or repairs. Software changes or upgrades are considered by FDA to be major repairs, thus the facility must have a mammography equipment evaluation performed after installation of such a change or upgrade. The mammography equipment evaluation must be performed and all failures to meet the applicable standards must be corrected before the affected equipment is used for patient examinations. The tests to be included in the mammography equipment evaluation must be specified by the manufacturer and must meet the following conditions:

1. The specified tests must be adequate for determining whether all of the standards of 21 CFR 900.12(b) and (e) that are applicable to the upgrade are met.
2. All the tests included in the mammography equipment evaluation must be either tests that are performed by the quality control technologist as part of the quality assurance program required by the manufacturer, or tests specific to the upgrade which are of no greater complexity than those performed by the quality control technologist as part of the quality assurance program required by the manufacturer.
3. None of the necessary tests after the software upgrade are required to be performed by the medical physicist.

Additional conditions for using this alternative requirement in association with a software upgrade are that:

4. The manufacturer must notify FDA of its intention to install the upgrade. The notification must include a brief description of the upgrade, the model(s) of the units that will be upgraded, a list of the post installation tests that the facility needs to perform, and a copy of the information to be provided to each facility describing the upgrade and the facility's post installation responsibilities.
5. The manufacturer must confirm in the notification to FDA that the tests to be performed for the mammography equipment evaluation are either tests that are performed by the quality control technologist as part of the quality assurance program required by the manufacturer or tests specific to the upgrade which are of no greater complexity than those performed by the quality control technologist as part of that quality assurance program.
6. The manufacturer must confirm that none of the required tests must be performed by a medical physicist.
7. The manufacturer must receive an acknowledgement from FDA of receipt of the upgrade notification before beginning the upgrade installation.
8. By the completion of each individual upgrade, the manufacturer must inform the facility in writing of its post installation responsibilities under the alternative requirement, which are that the facility must:
  - Conduct a mammography equipment evaluation after installation of the upgrade, either during a medical physicist onsite visit or under Medical Physicist Oversight.
  - Include in its mammography equipment evaluation the tests specified by the manufacturer.
  - Perform the mammography equipment evaluation and correct all test failures before the affected equipment is used for patient examinations.
  - Keep records of the test results and follow-up actions in accordance with 21 CFR 900.12(d)(2).



If all the above (1-8) conditions are met, then the mammography equipment evaluation may be conducted either during an onsite visit by a medical physicist or under Medical Physicist Oversight. If any of the necessary tests after the software upgrade are required to be performed by the medical physicist, the mammography equipment evaluation must be performed in its entirety by the medical physicist on site.

FDA's acknowledgement as stated in item 7 above does not constitute approval of the type of testing of the software upgrade in question. FDA will contact the FFDM manufacturer if any issues arise concerning the upgrade in question. As a result, FDA may disallow testing the software upgrade under Medical Physicist Oversight if it determines that one or more of the above conditions were not met.

### 3.2 Alternative Standard 9

Federal regulations, 900.12(e), specify that any time quality control test results fall outside of the action limits for systems with image receptor modalities other than screen-film, the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed.

If any test results fall outside the action limits according to this Alternative Standard, three different action categories apply:

**Category A:** If any of the following quality control tests that evaluate the performance of the *image acquisition components* of the Lorad Selenia FFDM system 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 any further examinations are performed.

Applicable QC tests:

1. Evaluation of System Resolution
2. Breast Entrance Exposure and Average Glandular Dose
3. Phantom Image Quality Evaluation (Medical Physicist)
4. Phantom Image (Radiologic Technologist)
5. Signal-to-Noise and Contrast-to-Noise Measurements
6. Detector Ghosting
7. Detector Flat-Field Calibration
8. Compression
9. Post-Move and Pre-Examination Tests for Mobile Lorad Selenia FFDM systems

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

Applicable QC tests:

1. Phantom Image Quality Evaluation (Medical Physicist)
2. Phantom Image (Radiologic Technologist)
3. Diagnostic Review Workstation QC
4. DICOM Printer Quality Control
5. Viewboxes and Viewing Conditions

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

Applicable QC tests:

1. Mammographic Unit Assembly Evaluation
2. Collimation Assessment
3. Artifact Evaluation
4. kVp Accuracy and Reproducibility
5. Beam Quality Assessment – HVL Measurement
6. Automatic Exposure Control (AEC) Function Performance
7. Automatic Exposure Control (AEC) Reproducibility
8. Radiation Output Rate
9. Viewbox Luminance and Room Illuminance
10. Compression Thickness Indicator
11. Visual Checklist
12. Repeat/Reject Analysis

## 4.0 Quality Control Activities for the Medical Physicist

Table 1-2 lists the QC tests to be performed by a qualified medical physicist at the specified frequency. The medical physicist performing the Quality Control Activities for the Lorad Selenia FFDM System must have met all appropriate MQSA personnel requirements including having 8 hours of training in full field digital mammography.

*Table 1-2: Quality Control Tests to be Performed by the Medical Physicist on All Lorad Selenia FFDM Systems*

QC Test	Frequency	Action Criteria	Chapter 2
Mammographic Unit Assembly Evaluation	Annually	Category C	Section 1.0, page 10
Collimation Assessment	Annually	Category C	Section 2.0, page 11
Artifact Evaluation	Annually	Category C	Section 3.0, page 15
kVp Accuracy and Reproducibility	Annually	Category C	Section 4.0, page 20
Beam Quality Assessment—HVL Measurement	Annually	Category C	Section 5.0, page 22
Evaluation of System Resolution	Annually	Category A	Section 6.0, page 23
Automatic Exposure Control (AEC) Function Performance	Annually	Category C	Section 7.0, page 25
Breast Entrance Exposure, AEC Reproducibility, and Average Glandular Dose	Annually	Category A Category C	Section 8.0, page 28
Radiation Output Rate	Annually	Category C	Section 9.0, page 31
Phantom Image Quality Evaluation	Annually	Category A	Section 10.0, page 33
Signal-To-Noise and Contrast-To-Noise Measurements	Annually	Category A	Section 11.0, page 38
Diagnostic Review Workstation QC	Annually	Category B	Section 12.0, page 44
Detector Ghosting (optional)	Annually	Category A	Section 13.0, page 47

## 5.0 Quality Control Activities for the Radiologic Technologist

Table 1-3 lists the QC tests to be performed by a qualified radiologic technologist at the specified frequency. The radiologic technologist performing the Quality Control Activities for the Lorad Selenia FFDM System must have met all appropriate MQSA personnel requirements including having eight hours of training in full field digital mammography.

*Table 1-3: Quality Control Tests to be Performed by the Radiologic Technologist on Lorad Selenia FFDM Systems*

QC Test	Frequency	Action Criteria	Chapter 3
DICOM Printer Quality Control	Weekly	Category B	Section 1.0, page 52
Detector Flat-Field Calibration	Weekly	Category A	Section 2.0, page 56
Artifact Evaluation	Weekly	Category C	Section 3.0, page 58
Signal-To-Noise and Contrast-To-Noise Measurements	Weekly	Category A	Section 4.0, page 63
Phantom Image	Weekly	Category A	Section 5.0, page 70
Compression Thickness Indicator	Biweekly	Category C	Section 6.0, page 75
Diagnostic Review Workstation QC	Weekly	Category B	Section 7.0, page 76
Viewboxes and Viewing Conditions	Weekly	Category B	Section 8.0, page 80
Visual Checklist	Monthly	Category C	Section 9.0, page 81
Repeat/Reject Analysis	Quarterly	Category C	Section 10.0, page 82
Compression	Semiannually	Category A	Section 11.0, page 84

### 5.1 Selenia Mobile Quality Control Checks

The following check must be performed and results recorded each time the system is relocated and before any patient examinations are performed:

- Compression Thickness
- Artifact Evaluation
- Signal-to-Noise and Contrast-to-Noise Test
- Phantom Image Evaluation

## Chapter 2—Quality Control Activities for the Medical Physicist

This section specifies the QC procedures, regulatory action levels and time limits for corrective action for each required Quality Control Activity that falls under the responsibility of the medical physicist. Detailed steps are provided only for QC procedures that are different from the standard QC procedures already in use for screen-film mammography facilities. These detail steps are listed in this manual only to help guide the medical physicist as to how to perform the different tests on a Lorad Selenia FFDM system. The medical physicist may deviate from the steps of the procedures listed in this chapter as long as the final outcome is in full compliance with the Recommended Performance Criteria and Corrective Action defined for each test. Detailed steps for procedures similar to those applied in screen-film mammography are described in the 1999 ACR Mammography Quality Control Manual.

All tests under the *Quality Control Activities for the Medical Physicist* section of this manual shall be performed at least annually by a qualified medical physicist trained in digital mammography. The logs of the *Quality Control Activities for the Radiologic Technologist* section of this manual shall be reviewed by the medical physicist at least annually.



**Note...**

*Please read the operator manual to become familiar with the basic interface of the Lorad Selenia FFDM System before using the system.*



**Note...**

*An account for the medical physicist is available on the Acquisition Workstation to make certain tools available to the medical physicist that may not be available to the technologist. To take advantage of the medical physicist account, you need to log in to the operating system as “phys” to perform all QC tests. See the Administrator’s Guide for additional information.*



**CAUTION:**

***Direct exposure of the digital detector to high radiation dose may result in damaging the detector. The digital image receptor must be covered with lead during testing for exposures other than those required to qualify image quality. Following the test procedures in this QC Manual will ensure the safety of the digital detector.***

## **1.0 Mammographic Unit Assembly Evaluation**

### **1.1 Objective**

To ensure good and safe working conditions of all interlocks, mechanical detents and safety switches and to ensure mechanical integrity of the x-ray tube and digital image receptor assembly.

### **1.2 Test Procedure**

Perform this test in the same manner as described in the *1999 ACR Mammography Quality Control Manual*, “Mammographic Unit Assembly Evaluation” section.

### **1.3 Record Forms**

Use the *Mammography Equipment Evaluation* form in Appendix A to record the results.

### **1.4 Data Analysis and Interpretation**

Follow the directions under the *1999 ACR Mammography Quality Control Manual*, “Mammographic Unit Assembly Evaluation” section.

### **1.5 Recommended Performance Criteria and Corrective Action**

The system shall perform according to the *1999 ACR Mammography Quality Control Manual*, “Mammographic Unit Assembly Evaluation” section.

If the recommended performance criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

## 2.0 Collimation Assessment

### 2.1 Objective

To assure that the collimator assembly performs in the following way:

- The x-ray field coincides with the light field
- The x-ray field is aligned with the image receptor
- The compression paddle is aligned with the image receptor

### 2.2 Suggested Equipment

- Two 24 × 30 cm mammographic cassettes loaded with mammographic film (if applicable)
- 24 × 30 cm compression paddle
- 18 × 24 cm shifting compression paddle
- Four coins of one size (e.g., pennies), one coin of a larger size (e.g., a nickel)
- Flat Field phantom, 4 cm thick acrylic, or BR-12 attenuating block. The Flat Field phantom is supplied by the manufacturer.



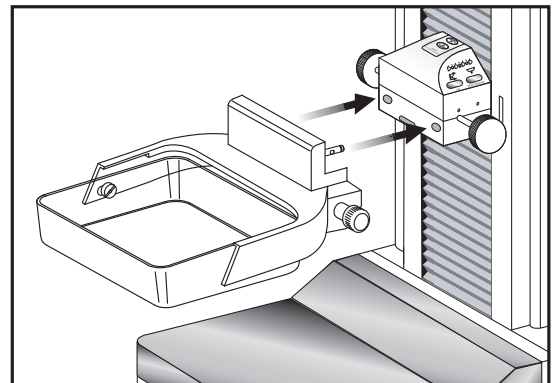
**Note...**

*If a mammographic film-screen cassette cannot be used to perform collimation assessment as described in this test procedure, alternative methods like CR cassettes or self-developing film (e.g., dosimetry film) shall be used to ensure that x-ray field to light field to image receptor alignment performance, as stated in Section 2.6 of this test, is satisfied.*

*Please note that use of self-developing film may require high exposures. It is recommended that you cover the digital detector with 0.5 mm lead, or you may use the 4 cm Flat Field phantom that comes with the system, and make multiple typical exposures.*

### 2.3 Test Procedure

1. Create a test patient on the Acquisition Workstation.
2. Install the 24 × 30 cm compression paddle in the compression device to activate the x-ray tube collimation system as shown in Figure 2-1.
3. Raise the compression paddle to about 15 cm as indicated by the thickness display on the compression device.



*Figure 2-1: Installing the Compression Paddle*

4. Place a 24 × 30 cm mammographic loaded cassette or alternative recording means on top of the image receptor centered laterally. Make sure that the light field is contained within the active part of the cassette and that the cassette extends beyond the digital image receptor enclosure at the chestwall. Two 24 × 30 cm mammographic cassettes may be used if deemed necessary.



**Note...**

The tube side of the cassette(s) should face the x-ray source. In the case where one cassette is used, the chestwall side of the cassette should point towards the chestwall side of the digital image receptor. In the case where two cassettes are used, the chestwall of each cassette should run across the lateral centerline of the digital image receptor.

5. Turn the collimator light on 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 (middle of the penumbra).
6. Tape the larger coin to the bottom of the compression paddle at the chestwall edge. The coin should be placed so that it is tangent to the anterior aspect of the vertical edge of the compression paddle.
7. Move the compression paddle 4.5 cm from the image receptor as indicated by the thickness display on the compression carriage.
8. Place the Flat Field phantom or BR-12 attenuation block on top of the paddle so that all radiation reaching the digital image receptor passes through the block. If the Flat Field phantom is not wide enough to cover the digital image receptor from direct exposure, tape the block directly under the collimator window.
9. Select the first Flat Field view from the examination screen window on the Acquisition Workstation and make a manual exposure:

Table 2-1: Collimation Assessment Exposure Techniques

X-Ray Tube	Mode	kVp	mAs	Filter	Focal Spot
Mo	Manual	28	65	Mo	Large
W	Manual	28	120	Rh	Large

10. Accept the image in the preview window of the Acquisition Workstation display. Process the film from the cassette(s).
11. Replace the 24 × 30 cm compression paddle with the 18 × 24 cm shifting compression paddle and repeat steps 3 through 10 for the three imaging positions—left, center and right—as defined by the shifting paddle (Figure 2-2). Use the second Flat Field view for the left imaging position, the third Flat Field view for the center position and the fourth Flat Field view for the right position.

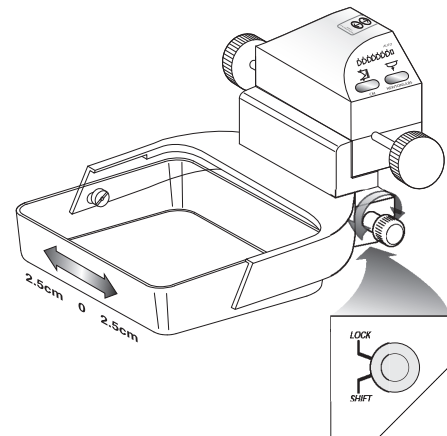


Figure 2-2: The Shifting Paddle

## 2.4 Record Forms

Use the 2.0 Collimation Assessment form in Appendix A to record the results.



## 2.5 Data Analysis and Interpretation

### 2.5.1 X-Ray Field to Light-Field Coincidence

1. On the film exposed in the cassette or alternative means, measure the deviation between the x-ray field (dark portion of the film) and the edge of the light field (defined by the exterior edges of the four small coins). Record the measured deviations between the x-ray field and light field on the record form.
2. Add the magnitude of the deviations at the left and right edges of the image receptor disregarding any signs. Record the total deviation on the record form.
3. Add the magnitude of the deviations at the anterior and posterior edges of the image receptor disregarding any signs. Record this value on the record form.

### 2.5.2 X-Ray Field to Image Receptor Alignment

1. Click the first Flat Field image thumbnail in the examination screen window on the Acquisition Workstation to activate the preview screen. Recall that this corresponds to the 24 × 29 cm imaging mode.

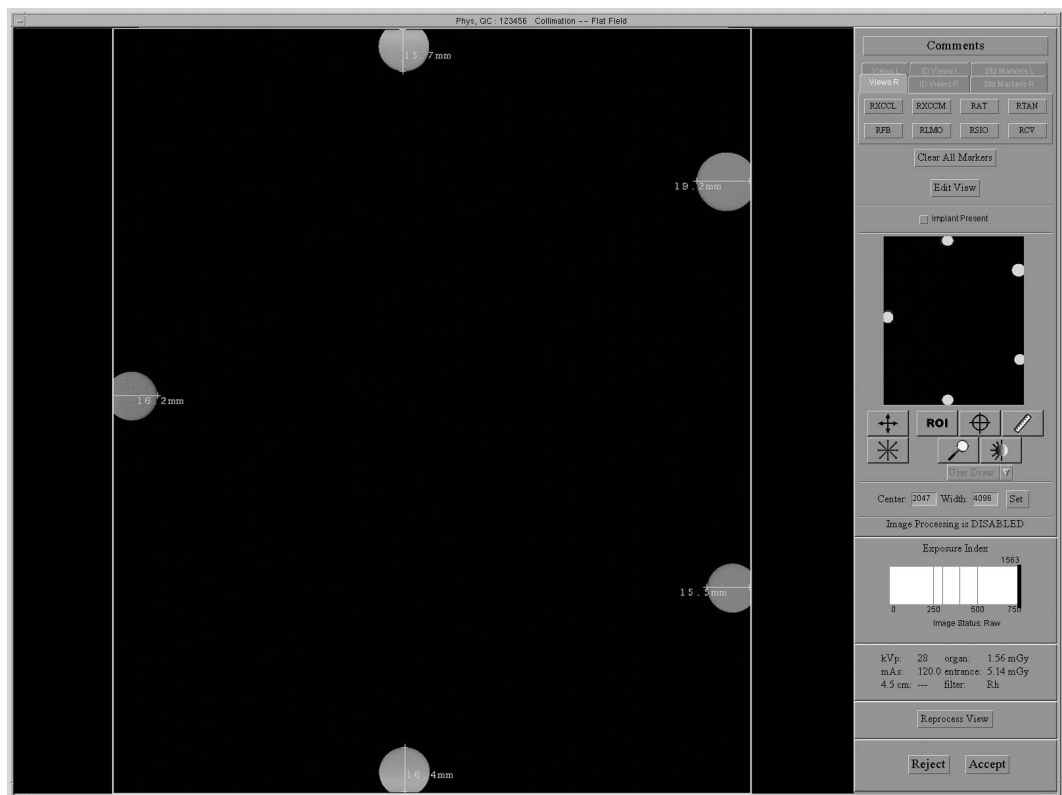


Figure 2-3: Preview Image with Measurements

2. The edges of the preview image represent the boundaries of the image receptor. Use the distance-measuring tool to measure all four distances from the edge of the image to the inner edge of each small coin in the preview window as illustrated in Figure 2-3. Start from the edge of the image moving inwards to assure that the measurement numbers will be displayed on the image window.

3. Measure the same four distances from the edge of the x-ray field to the inner edge of each small coin on the developed film or alternative means corresponding to the first Flat Field view. Multiply these measurements by 1.06 to account for image magnification (this factor includes the thickness of the screen-film cassette).
4. Subtract corresponding measurements between preview and film images and record the values on the record form maintaining any signs.
5. Click the Cancel button to exit the preview window.
6. Repeat steps 1 through 5 to check the alignment of the left, center and right 18 × 24 cm imaging modes using the second, third and fourth Flat Field image thumbnails, respectively.

### 2.5.3 Compression Paddle to Image Receptor Alignment

1. Repeat steps 1 through 5 (24 × 29 cm imaging mode) from the previous procedure for the first and third Flat Field thumbnails corresponding to the 24x29 and 18x24 center position imaging modes.
2. Record the difference on the record form.



**Note...**

*The compression paddle to receptor alignment must be verified for all accompanying paddles at least once during acceptance testing. The alignment for all paddles used for screening shall be repeated every year.*

## 2.6 Recommended Performance Criteria and Corrective Action

### 2.6.1 X-ray Field to Light-Field Coincidence

The total misalignment (sum of the misalignments on opposite sides) must be within 2% of the SID.

If the recommended performance criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

### 2.6.2 X-ray Field to Image Receptor Alignment

The x-ray field must not extend by more than 2% of the SID at any of the four sides of the image receptor.

The radiation field shall extend to the edge of the chestwall side of the digital image receptor.

If the recommended performance criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

### 2.6.3 Compression Paddle to Image Receptor Alignment

The anterior edge of the compression paddle must be aligned just beyond the chest wall edge of the image receptor so that it does not appear in the mammogram. In addition, the anterior edge of the compression paddle must not extend beyond the chest wall edge of the image receptor by more than 1% of the SID.

If the recommended performance criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

## 3.0 Artifact Evaluation

### 3.1 Objective

To assess the degree and source of artifacts visualized in mammograms or phantom images. This procedure allows the source of artifacts to be isolated to x-ray equipment, or DICOM printer.

### 3.2 Suggested Equipment

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

### 3.3 Test Procedure

#### 3.3.1 Image Receptor Artifact Evaluation

1. Create a test patient on the Acquisition Workstation.
2. Make sure that both the Flat Field phantom and the surface of the image receptor are clean. Place the Flat Field phantom on top of the image receptor to cover its entire surface.
3. Remove any compression paddle from the compression device.
4. Select the first Flat Field view from the examination screen window on the Acquisition Workstation and make an exposure:

*Table 2-2: Artifact Evaluation Exposure Techniques*

X-Ray Tube	Mode	kVp	Filter	Focal Spot
Mo	Auto-Time	28	Mo	Large
W	Auto-Time	28	Rh	Large

5. Accept the image in the preview window of the Acquisition Workstation display.
6. Rotate the Flat Field phantom 180 degrees.
7. Select the second Flat Field view and make an exposure:

*Table 2-3: Artifact Evaluation Second View Exposure Techniques*

X-Ray Tube	Mode	kVp	Filter	Focal Spot
Mo	Auto-Time	28	<b>Rh</b>	Large
W	Auto-Time	28	<b>Ag</b>	Large

8. Accept the image in the preview window of the Acquisition Workstation display.

9. Remove the face shield, raise the compression device above the mounting slots in the C-arm and install the magnification platform as shown in Figure 2-4.
10. Make sure that the Flat Field phantom and both surfaces of magnification platform are clean. Place the Flat Field phantom on top of the magnification platform to cover its entire surface.

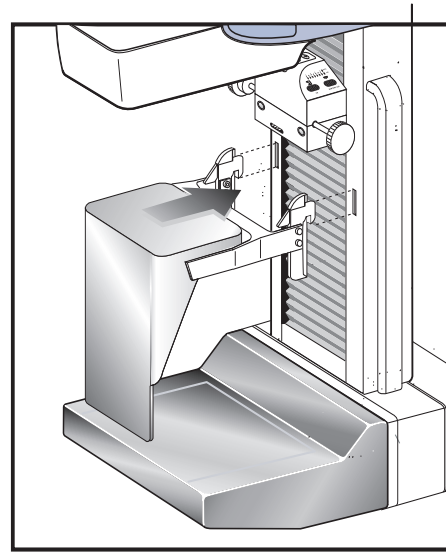


Figure 2-4: Installing the Magnification Platform



**Note...**

Installing the magnification platform automatically retracts the HTC grid and selects the small focal spot (SFS) (see Figure 2-5).

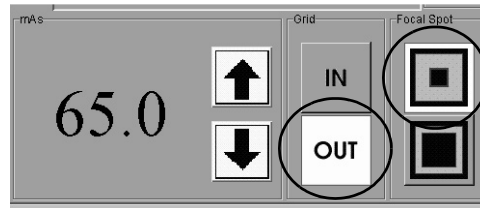


Figure 2-5: Techniques for Grid and Focal Spot

11. Remove any compression paddle from the compression device.
12. Select the third Flat Field view and make an exposure:

Table 2-4: Artifact Evaluation Magnification Exposure Techniques

X-Ray Tube	Mode	kVp	Filter	Focal Spot	Grid
Mo	Auto-Time	28	Mo	Small	Retracted
W	Auto-Time	28	Rh	Small	Retracted

13. Accept the image in the preview window of the Acquisition Workstation display.
14. Rotate the Flat Field phantom 180 degrees.
15. Select the fourth Flat Field view and make an exposure:

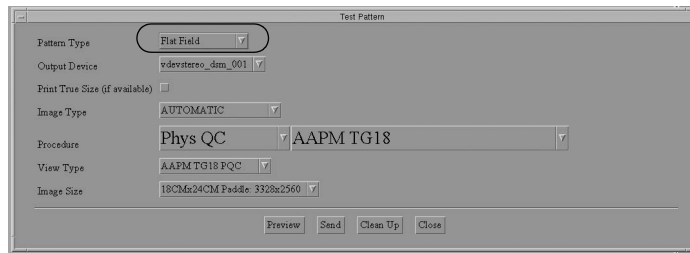
Table 2-5: Artifact Evaluation Magnification Exposure Techniques

X-Ray Tube	Mode	kVp	Filter	Focal Spot	Grid
Mo	Auto-Time	28	<b>Rh</b>	Small	Retracted
W	Auto-Time	28	<b>Ag</b>	Small	Retracted

16. Accept the image in the preview window of the Acquisition Workstation display.
17. Close the examination.

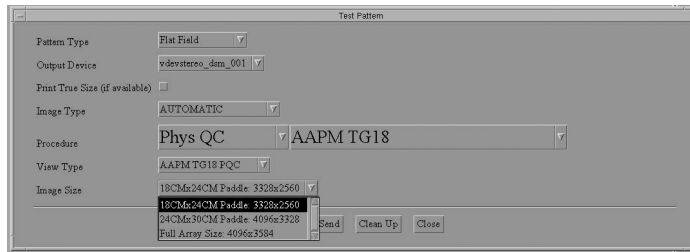
### 3.3.2 DICOM Printer Artifact Evaluation

1. Select **Admin>Test Patterns**. More information on this can be found in the *Administrator's Guide*.
2. Select **Flat Field** from the Pattern drop-down menu.
3. Select the DICOM printer device from the Outputs drop-down menu.



*Figure 2-6: The Test Pattern Dialog Box*

4. Select the **Output film** size: 18 cmx24 cm Paddle 3328x2560, and select **Print true size** if supported for an 18 cm x 24 cm film.



*Figure 2-7: Selecting the Output Film Size from the Drop-down List*

5. Click Send to print the flat field pattern on the selected printer.
6. If the printer supports 24 cm x 30 cm film, select the Output film size: 24cmx30cm Paddle 4096x3328, and select "Print true size" if supported for a 24 cm x 30 cm film.
7. Repeat step Step 5 to print the larger film size.
8. Click OK to close the Image Queued dialog box.
9. Click Close to close the Test Pattern dialog box.



**Note...**

*If you have multiple Selenias printing to a single printer, you only need to perform this test from one Selenia.*



**Note...**

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

### 3.4 Record Forms

Use the 3. *Artifact Evaluation* form in Appendix A to record the results.

### 3.5 Data Analysis and Interpretation

#### 3.5.1 Image Receptor Artifact Evaluation

1. Open the patient examination with the artifact images previously acquired.
2. Click the first flat field image thumbnail in the examination screen on the Acquisition Workstation to activate the preview screen.
3. Adjust the contrast of the image by setting the window and level in the Preview Screen. Use a window width of approximately 500 and a level equivalent to approximately the Exposure Index (EI) of the flat field.
4. Examine the image for artifacts using the zoom/pan function.
5. Click Cancel to close the Preview screen.
6. Repeat Step 2 to Step 5 for the second artifact image.
7. If the appearance of artifacts between the two images changes location corresponding with the rotation of the Flat Field phantom, the artifacts are present in the block and do not indicate problems in system performance. Record the results in the record form.
8. Appearance of artifacts in one of the two images may indicate filtration artifacts. The medical physicist must evaluate these images using the same methods for evaluating screen-film artifact images.
9. Artifacts that appear in identical location on both images indicate a potential problem in the imaging chain. To isolate these types of artifacts between the x-ray source and the digital image receptor:
  - a. Place a loaded mammographic cassette on top of the digital image receptor; place the Flat Field phantom on top of the cassette.
  - b. Open the previously created examination for the purpose of artifact evaluation.
  - c. Add another Flat Field view by clicking on the Add View button in the examination screen window.
  - d. Select the added Flat Field view and make a manual exposure:

*Table 2-6: Collimation Assessment Exposure Techniques*

X-Ray Tube	Mode	kVp	mAs	Filter	Focal Spot
Mo	Manual	28	30	Mo	Large
W	Manual	28	60	Rh	Large

- e. Accept the image in the preview window and process the film.
  - f. Evaluate the screen-film image with regards to the artifacts observed in Step 4. Artifacts that appear on the original digital images but do not appear on the screen-film image may be attributed to the digital image receptor. A qualified service engineer must eliminate any artifacts that may be clinically objectionable.
  - g. Artifacts that appear on both the digital and screen-film images are not caused by the digital image receptor. The medical physicist must evaluate these images using the same methods for evaluating screen-film artifact images.
10. Repeat Step 2 to Step 5 for the third and fourth artifact image.
- Artifacts that appear in identical locations on both images and are different from those identified in Step 4 indicate a problem with the magnification platform.

### 3.5.2 DICOM Printer Artifact Evaluation

1. Review the printed film of the artificial flat field sent to the printer from a single Selenia following the instructions above or from the printer's QC menu.
2. Any artifacts that appear on the printed film are created by the printer alone since the artificial test pattern used contains pixels of a single value across the entire pattern.

## 3.6 Recommended Performance Criteria and Corrective Action

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

The recommendations and corrective actions specified in the *1999 ACR Mammography Quality Control Manual*, "Artifact Evaluation" section shall be followed for DICOM printer artifacts. A qualified service engineer shall correct the source of intolerable artifacts on the DICOM printer within thirty days of the test date.

The acrylic attenuation block provided by the manufacturer and used for detector calibration must be replaced if it has permanent artifacts that may impact detector calibration.



**Note...**

*Artifacts that appear on the digital image receptor and are not dropped pixels or lines may be able to be removed by recalibrating the digital detector according to the Quality Control Activities for the Radiologic Technologist, Calibration section of this manual.*



**Note...**

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

## 4.0 kVp Accuracy and Reproducibility

### 4.1 Objective

To assure that the selected kVp is accurate within limits and reproducible between exposures.

### 4.2 Suggested Equipment

- Calibrated, non-invasive mammographic kVp meter as per the 1999 ACR *Mammography Quality Control Manual*, “kVp Accuracy and Reproducibility” section; or invasive kVp divider or similar equipment (see note).
- 0.5 mm or thicker lead block wide enough to cover the entire surface of the digital image receptor.

### 4.3 Test Procedure



**Caution:**

*The image receptor can be damaged by excessive radiation exposure. Be sure to cover the receptor with a layer of 0.5 mm or thicker lead or lead equivalent (i.e., lead apron) prior to carrying out this procedure.*



**Note...**

*If a non-invasive kVp meter is used to measure kVp, it shall be calibrated to the target-filter combination and kVp range used. Otherwise, an invasive measurement of kVp is recommended. The test may be performed by Hologic Service personnel equipped with the appropriate tools and reviewed by the medical physicist. If you need assistance, please contact Hologic Service. Hologic Service carries calibrated non-invasive kVp meters and has access to invasive devices as a last resort.*

1. Put the system in its Non-Imaging mode by clicking on the **Non-Imaging Mode** button on the main application window as shown in Figure 2-8.



Figure 2-8: The Non-Imaging Mode Button

2. **Important:** Cover the digital image receptor with at least 0.5 mm lead or lead equivalent.
3. Perform this test in the same manner as for screen-film mammography systems described in the 1999 ACR *Mammography Quality Control Manual*, “kVp Accuracy and Reproducibility” section.
4. Exit Non-Imaging Mode by clicking the **End Non-Imaging Mode** button. If you are continuing with the HVL Measurement, do not exit until the end of that test since it also requires the Non-Imaging mode.



#### 4.4 Record Forms

Use the *4. kVp Accuracy and Reproducibility* form in Appendix A to record the results.

#### 4.5 Data Analysis and Interpretation

Follow the directions under the *1999 ACR Mammography Quality Control Manual, “kVp Accuracy and Reproducibility”* section.

#### 4.6 Recommended Performance Criteria and Corrective Action

The system must perform according to the 1999 ACR Mammography Quality Control Manual, “kVp Accuracy and Reproducibility” section. In summary, from the *1999 ACR Mammography Quality Control Manual, “kVp Accuracy and Reproducibility”* section, the kVp shall be accurate within  $\pm 5\%$  of the indicated or selected kVp at:

- the lowest clinical kVp that can be measured by a kVp test device
- the 28 kVp
- the highest available clinical kVp

At 28 kVp, the coefficient of variation of the kVp shall be equal to or less than 0.02.

If the recommended performance criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

## 5.0 Beam Quality Assessment—Half-Value Layer Measurement

### 5.1 Objective

To assure that the half-value layer (HVL) of the x-ray beam is adequate to minimize patient dose without being too excessive to compromise image contrast.

### 5.2 Suggested Equipment

- Calibrated mammographic ionization meter and electrometer as per the *1999 ACR Mammography Quality Control Manual*, “Beam Quality Assessment” section
- Five to six aluminum 1145 or 1100 alloy sheets of 0.1 mm thickness as per the *1999 ACR Mammography Quality Control Manual*, “Beam Quality Assessment” section
- 0.5 mm or thicker lead block wide enough to cover the entire surface of the digital image receptor

### 5.3 Test Procedure



**Caution:**

*The image receptor can be damaged by excessive radiation exposure. Be sure to cover the receptor with a layer of 0.5 mm or thicker lead or lead equivalent (i.e., lead apron) prior to carrying out this procedure.*

1. Put the system in its Non-Imaging mode by clicking on the **Non-Imaging Mode** button on the main application window as shown in Figure 2-8, page 20.
2. **Important:** Cover the digital image receptor with at least 0.5 mm lead or lead equivalent.
3. Perform this test in the same manner as for screen-film mammography systems described in the *1999 ACR Mammography Quality Control Manual*, “Beam Quality Assessment (Half-Value Layer Measurement)” section.
4. Exit Non-Imaging Mode by clicking the **End Non-Imaging Mode** button.

### 5.4 Record Forms

Use the *5. Beam Quality Assessment—HVL Measurement* form in Appendix A to record the results.

### 5.5 Data Analysis and Interpretation

Follow the directions under the *1999 ACR Mammography Quality Control Manual*, “Beam Quality Assessment (Half-Value Layer Measurement)” section.

### 5.6 Recommended Performance Criteria and Corrective Action

The system must perform according to the *1999 ACR Mammography Quality Control Manual*, “Beam Quality Assessment (Half-Value Layer Measurement)” section. In summary:

- For operating kVp range of less than 50, the measured HVL shall be greater than  $(\text{kVp}/100) + 0.03$  (in mm Al).
- For Lorad Selenia FFDM systems equipped with a molybdenum x-ray tube, to meet ACR requirements, the measured HVL shall be less than  $(\text{kVp}/100) + C$  (in mm Al), where  $C = 0.12$  for Mo/Mo,  $C = 0.19$  for Mo/Rh. This requirement does not apply to systems equipped with a tungsten x-ray tube.

If the recommended performance criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

## 6.0 Evaluation of System Resolution

### 6.1 Objective

To evaluate imaging performance, using the system limiting spatial resolution as a performance indicator that may be easily measured in the field.

### 6.2 Suggested Equipment

- 18 x 24 cm compression paddle
- High contrast resolution pattern providing a test up to 15 cycle/mm (c/mm, or lp/mm) with 1 c/mm steps in the range 5 – 15 c/mm
- Flat Field phantom or BR-12 attenuating block

### 6.3 Test Procedure

1. Create a test patient on the Acquisition Workstation.
2. Place the Flat Field phantom on top of the image receptor to cover its entire surface. If the Flat Field phantom is not wide enough to cover the digital image receptor from direct exposure, tape the block directly under the collimator window.
3. Install the 18 x 24 cm compression paddle in the compression device.
4. Raise the compression paddle to a height of 4.5 cm as indicated by the thickness display on the compression device. Use a ruler to verify the height and adjust accordingly, if necessary.
5. Place the resolution test pattern on top of the compression paddle. Position the pattern within 1 cm of the chestwall edge of the image receptor, centered laterally. The test pattern lines shall be at 45° to the anode-cathode axis.
6. Select the Flat Field view from the examination screen window on the Acquisition Workstation and make a manual exposure:

*Table 2-7: Collimation Assessment Exposure Techniques*

X-Ray Tube	Mode	kVp	mAs	Filter	Focal Spot
Mo	Manual	28	65	Mo	Large
W	Manual	28	100	Rh	Large

### 6.4 Record Forms

Use the 6. *System Limiting Spatial Resolution* form in Appendix A to record the results.

### 6.5 Data Analysis and Interpretation

1. Click the Zoom/Pan icon to go into “zoom and pan” to display the resolution pattern in full resolution.
2. Move the pattern to the center of the preview display.
3. Determine the highest frequency lines that are distinctly resolved (and ensure the correct number of lines is visualized) across some part of the resolution pattern. There are likely to be regions where the pattern fades from being resolved, due to imperfect alignment of the bar pattern with the image matrix. Once a blur is seen across the entire length of the lines, a phase shift (bright lines shift to dark, and vice versa), or aliasing (fewer bars are visualized), record this frequency as the limiting spatial resolution.
4. Accept the image in the preview window of the Acquisition Workstation display.

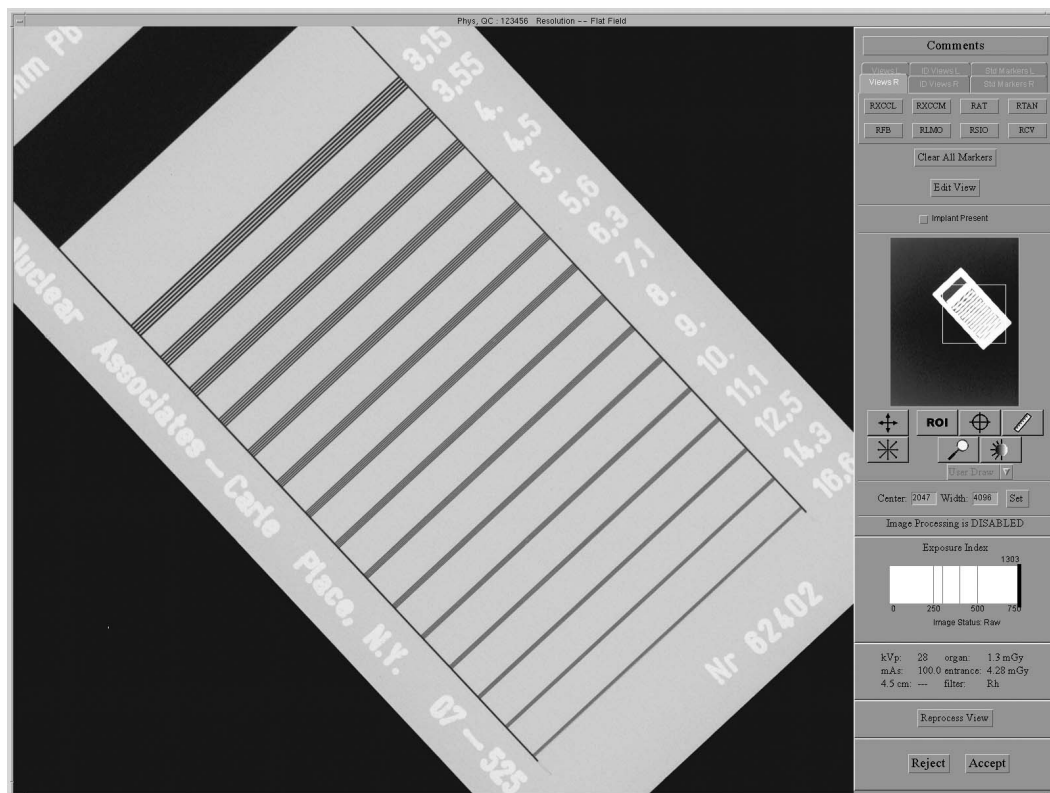


Figure 2-9: The Resolution Test Pattern in the Preview Pane

## 6.6 Recommended Performance Criteria and Corrective Action

The system limiting spatial resolution must be greater than 7 c/mm (lp/mm) when the bars are at 45° to the anode-cathode axis.

If these criteria are not met, a qualified service engineer must correct the problem before using the system for clinical imaging.

## 7.0 Automatic Exposure Control (AEC) Function Performance

### 7.1 Objective

To assess the performance of the automatic exposure control (AEC) function and to maintain consistency in detector signal level for a range of breast thicknesses and all applicable imaging modes. To evaluate the Exposure Compensation function of the AEC.

### 7.2 Suggested Equipment

- 18 x 24 cm compression paddle
- 10 x 10 cm magnification paddle
- Four or more acrylic or BR-12 blocks to provide a phantom of 2, 4, 6 and 8 cm thickness
- Magnification platform

### 7.3 Test Procedure

1. Create a test patient on the Acquisition Workstation.
2. Install the 18 x 24 cm compression paddle in the compression device.
3. Center the first 2.0 cm of acrylic or BR-12 phantom laterally on the image receptor and position it so the chestwall edge of the phantom is aligned with the chestwall edge of the image receptor.
4. Lower the compression device and apply compression force, if necessary, to achieve a compression thickness equal to the thickness of the phantom used.
5. Set the system in the AEC mode that is used clinically (i.e. Auto-Filter).
6. Set the exposure compensation to step 0 or to the step used clinically.
7. Set the AEC sensor to position 2.
8. Select Large Focal Spot.
9. Set filtration and kVp to clinically used values, if applicable in the selected AEC mode.
10. Select the first available view and make a single exposure in the selected AEC mode.
11. Turn on the virtual AEC sensor indication in the preview window.
12. Use an ROI to measure the mean pixel value inside the virtual AEC sensor.
13. Take the ROI mean pixel value, subtract the DC offset of 50 counts from it and record it in the record form under pixel value.
14. Record the kVp, mAs, filter and exposure compensation step in the record form.
15. Accept the image in the preview window of the Acquisition Workstation display.
16. Repeat Step 3 through Step 15 for phantom thicknesses of 4, 6 and 8 cm.
17. Repeat Step 3 through Step 15 for 4 cm phantom thickness at the remaining exposure compensation steps making sure that you make three exposures at step 0.
18. Replace the 18 x 24 cm paddle by the 10 x 10 cm magnification paddle.
19. Install the magnification platform, which automatically retracts the grid and sets the system to SFS.
20. Repeat Step 3 through Step 15 for 4 cm phantom thickness in magnification mode.

## 7.4 Record Forms

Use the *7. Automatic Exposure Control (AEC) Function Performance* form in Appendix A to record the results.

## 7.5 Data Analysis and Interpretation

1. Using the recorded mAs and pixel values calculate a mean mAs value and a mean pixel value for all breast thicknesses and all operating modes.
2. Determine the range of mAs and pixel values recorded for all breast thicknesses and all operating modes.
3. Compute the fractional change in pixel value with respect to the mean pixel value computed for the 0 exposure compensation step (three exposures). This computation can be expressed as the pixel value at a given step divided by the mean pixel value at step 0.

## 7.6 Recommended Performance Criteria and Corrective Action

### Selenia with molybdenum x-ray tube

The AEC function of the Lorad Selenia FFDM system equipped with a molybdenum x-ray tube is trying to maintain constant signal level on the detector as the breast thickness varies in all operating modes. The pixel value of each individual image corresponding to a breast thickness between 2 and 8 cm at any operating mode shall not vary more than 10% of the mean pixel value recorded from all tested breast thicknesses and operating modes.

The exposure compensation steps shall result in the following changes in pixel value when dividing the pixel value at a given step by the mean pixel value at step 0:

- Step -3: 0.50 – 0.61
- Step -2: 0.63 – 0.77
- Step -1: 0.77 – 0.94
- Step +1: 1.04 – 1.27
- Step +2: 1.17 – 1.43
- Step +3: 1.31 – 1.60
- Step +4: 1.44 – 1.76

If the above criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

### Selenia with tungsten x-ray tube

The AEC function of the Lorad Selenia FFDM system equipped with a tungsten x-ray tube is trying to maintain a constant pixel value (detector signal level) independent of AEC mode, operating mode (contact vs. magnification), breast thickness, or selected radiographic technique. As the AEC is trying to maintain constant pixel value for the entire range of breast thickness, the image CNR is decreased slightly at large breast thickness. To compensate for the drop of CNR at large breast thickness, Selenia corrects the AEC computed mAs by a small factor. This correction is a simple multiplication factor applied to the AEC-determined mAs.

As the AEC function targets a constant pixel value independent of breast thickness or operating mode, the pixel value of each acquired image for corresponding breast thickness between 2 and 8 cm at any operating mode shall not vary more than 10% of the mean pixel value recorded from all tested breast thicknesses and operating modes. If a compensation factor was applied to the AEC function by Selenia to boost CNR at large breast thickness, the pixel value shall be corrected to the AEC-computed value to evaluate this test. To correct the pixel value to the one computed by AEC, simply divide the measured pixel value by the CNR correction factor. The CNR correction factors are listed in Appendix D of this manual. The correction factors shall correspond to the compression thickness indicated on the compression device, and not to the physical thickness of the phantom used.

The exposure compensation steps shall result in the following changes in pixel value when dividing the pixel value at a given step by the mean pixel value at step 0:

Step -3: 0.50 – 0.61

Step -2: 0.63 – 0.77

Step -1: 0.77 – 0.94

Step +1: 1.04 – 1.27

Step +2: 1.17 – 1.43

Step +3: 1.31 – 1.60

Step +4: 1.44 – 1.76

If the above criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

## 8.0 Breast Entrance Exposure, AEC Reproducibility, and AGD

### 8.1 Objective

To measure the typical entrance exposure and calculate the corresponding glandular dose for an average patient with approximately 4.5 cm compressed breast thickness of 50% adipose, 50% glandular tissue composition; to assess the reproducibility of the automatic exposure control (AEC).

### 8.2 Suggested Equipment

- 24 x 30 cm compression paddle
- Calibrated mammographic ionization meter and electrometer as per the *1999 ACR Mammography Quality Control Manual*, “Breast Entrance Exposure, AEC Reproducibility, Average Glandular Dose, and Radiation Output Rate” section.
- ACR Mammographic Accreditation Phantom (i.e., RMI 156 by Radiation Measurement, Inc.; 18-220 by Nuclear Associates).

### 8.3 Test Procedure

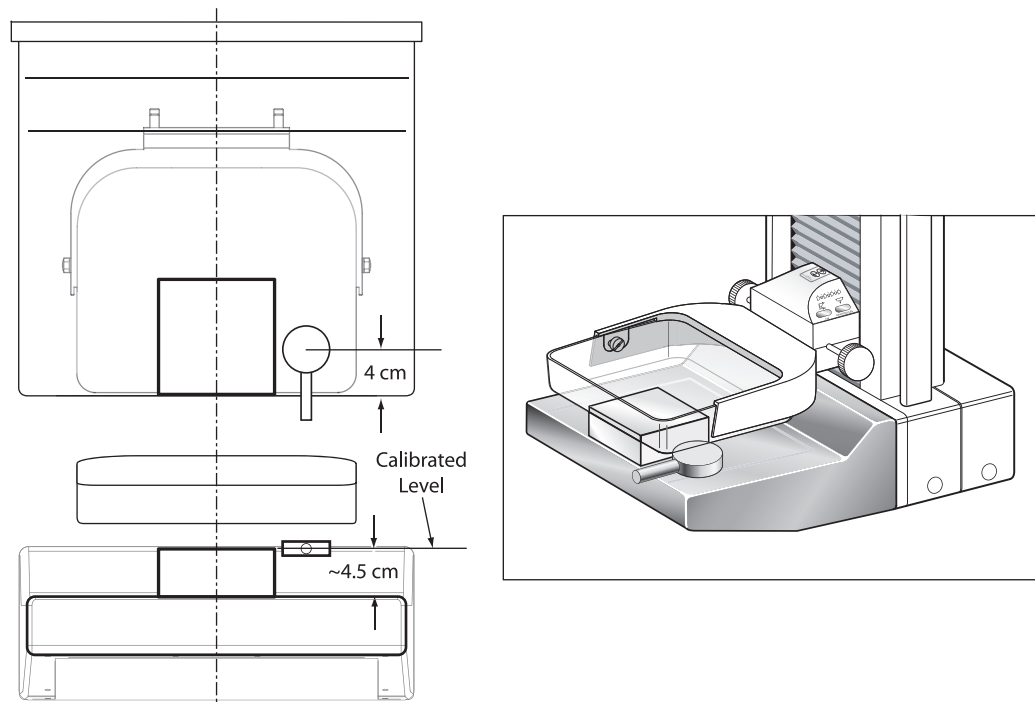


Figure 2-10: ACR Phantom and Ionization Chamber Setup

1. Install the 24 x 30 cm compression paddle in the compression device.
2. Center the ACR phantom laterally on the image receptor and position it so the chestwall edge of the phantom is aligned with the chestwall edge of the image receptor.
3. Position the ionization chamber in the x-ray field beside the ACR phantom, centered 4.0 cm in from the chest-wall edge of the image receptor and with the center of the chamber level with the top surface of the ACR phantom as shown in Figure 2-10, page 28. Assure that the entire chamber is exposed.



4. Secure the chamber in position and do not change the position of the chamber during the following measurements.
5. Lower the compression device so that the compression paddle sits right above the ACR phantom and chamber trying to achieve a compression thickness as close to 4.5 cm as possible. If it is not possible to achieve a compression thickness of 4.5 cm, use the Alternative Equivalent AEC Method described in Section 10.3 of this chapter.
6. Set the system in the AEC mode that is used clinically (i.e. Auto-Filter).
7. Set the exposure compensation to step 0 or to the step used clinically.
8. Set the AEC sensor to position 2.
9. Select LFS.
10. Set filtration and kVp to clinically used values, if applicable in the selected AEC mode.
11. Take four exposures in the selected AEC mode and record the measurements in the record form.

**Note...**

*The phantom thickness as shown on the compression device dictates the kVp used in Auto-kV or Auto-Filter modes.*

## 8.4 Record Forms

Use the *8. Breast Entrance Exposure and Average Glandular Dose* form in Appendix A to record the results.

## 8.5 Data Analysis and Interpretation

1. Record the HVL (previously measured in beam quality assessment test) on the record form assuring that it matches the kVp used to take the exposures.
2. Compute the mean exposure and mAs values and corresponding standard deviations for the four acquired exposures. Record the results in the record form
3. If necessary, correct the average exposure with the chamber's appropriate energy correction factor and with an inverse-square correction factor to obtain the exposure at skin entrance level.
4. Use the appropriate glandular dose table to determine the exposure to glandular dose conversion factor for the kVp and target-filter combination used and measured HVL.
  - **Molybdenum x-ray tube:** from the *1999 ACR Mammography Quality Control Manual*, "Breast Entrance Exposure, AEC Reproducibility, Average Glandular Dose, and Radiation Output Rate" section.
  - **Tungsten x-ray tube:** Appendix C of this manual.
5. Multiply conversion factor obtained in step 4 by the average entrance exposure value computed in steps 2 and 3 paying attention to units. The product represents the mean glandular tissue dose for that specific energy, breast composition, and compressed thickness and is an approximation of the actual patient dose.

**Note...**

The average glandular dose computed using the 1999 ACR Mammography Quality Control Manual, “Breast Entrance Exposure, AEC Reproducibility, Average Glandular Dose, and Radiation Output Rate” section only applies to a 4.2 cm compressed breast of 50-50 tissue composition. Conversion factors for other breast thicknesses and compositions may be found in the literature: Dance DR. “Monte Carlo calculation of conversion factors for the estimation of mean glandular dose.” *Phys Med Biol* 35: 1211-1219 (1990); Wu X, Gingold EL, Barnes GT and Tucker DM. “Normalized average glandular dose in molybdenum target – rhodium filter and rhodium target – rhodium filter mammography.” *Radiology* 193: 83-89 (1994); Sobol WT and Wu X. “Parametrization of mammography normalized average glandular dose tables.” *Med Phys* 24: 547:554 (1997).

Additional literature for tungsten x-ray tubes:

The following references are also relevant to dose computations in mammography: John Boone, “Normalized glandular dose (DgN) coefficients for arbitrary x-ray spectra in mammography: computer-fit values of Monte Carlo data”, *Medical Physics*, 29(5): 869-875 (2002); John Boone at al, “Molybdenum, Rhodium, and Tungsten anode spectral models using interpolating polynomials with application to mammography”, *Medical Physics*, 24(12):1863-1874 (1997); John Boone, “Glandular breast dose for monoenergetic and high-energy x-ray beams: Monte Carlo assessment”, *Radiology*, 213:23-37 (1999).

## 8.6 Recommended Performance Criteria and Corrective Action

The coefficient of variation for both exposure and mAs shall not exceed 0.05.

The mean glandular dose to the ACR Mammographic Accreditation phantom must not exceed 3 mGy (0.3 rad) per view at the recommended techniques for imaging an average breast.

If the reproducibility criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

If the average glandular dose criteria are not met, a qualified service engineer must correct the problem before using the system for clinical imaging.

## 9.0 Radiation Output Rate

### 9.1 Objective

To measure the radiation output rate of the system.

### 9.2 Suggested Equipment

- 24 x 30 cm compression paddle
- Calibrated mammographic ionization meter and electrometer as per the 1999 ACR *Mammography Quality Control Manual*, “Breast Entrance Exposure, AEC Reproducibility, Average Glandular Dose, and Radiation Output Rate” section
- 0.5 mm or thicker lead block wide enough to cover the entire surface of the digital image receptor

### 9.3 Test Procedure



**Caution:**

*The image receptor can be damaged by excessive radiation exposure. Be sure to cover the receptor with a layer of 0.5 mm or thicker lead or lead equivalent (i.e., lead apron) prior to carrying out this procedure.*

1. Install the 24 x 30 cm compression paddle in the compression device.
2. Put the system in its non-imaging mode by clicking on the Non-Imaging Mode button on the main application window as shown in Figure 2-8, page 20.
3. **IMPORTANT:** Cover the digital image receptor with at least 0.5 mm lead or lead equivalent.

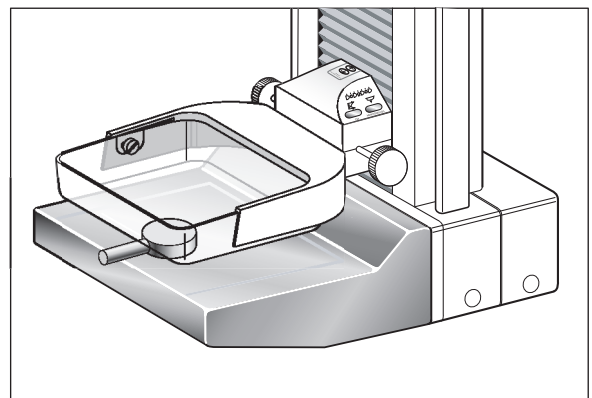
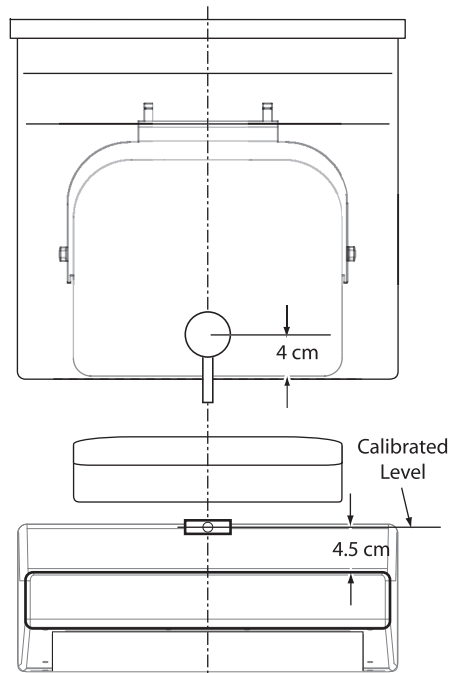


Figure 2-11: Centered Ionization Chamber

4. Position the ionization chamber in the x-ray field centered laterally on the image receptor, 4.0 cm in from the chest-wall edge and with the center of the chamber level at 4.5 cm above the breast support plate as shown in Figure 2-11, page 31. Assure that the entire chamber is exposed.
5. Lower the compression device so that the compression paddle is just in contact with or slightly above the ionization chamber.
6. Select the exposure techniques:

Table 2-8: Radiation Output Rate Exposure Techniques

X-Ray Tube	Mode	kVp	mAs	Filter	Focal spot
Mo	manual	28	320	Mo	large
W	manual	28	320 or 325	Rh	large

7. Make an exposure and record the measured radiation exposure and measured exposure time on the record form. (If the electrometer does not measure exposure time, the x-ray unit's indicated mAs may be used or a separate time-measuring device must be used. The system is using 100 mA at 28 kVp.)
8. Exit Non-Imaging Mode by clicking the **End Non-Imaging Mode** button.

## 9.4 Record Forms

Use the 9. Radiation Output Rate form in Appendix A to record the results.

## 9.5 Data Analysis and Interpretation

1. Calculate the exposure rate by dividing the measured exposure by the measured (or indicated) exposure time.
2. To compute the air kerma rate, multiply the measured exposure rate by 0.00873 mGy/mR.



**Note...** The nominal mA setting for the large focal spot at 28 kVp is 100 mA. For the mA setting at different kVps, please review the system specifications in "Appendix A—Specifications" of the operator or service manual.

## 9.6 Recommended Performance Criteria and Corrective Action

The system shall be capable of producing a minimum output of:

Table 2-9: Output Requirements

X-Ray Tube	kVp	Tube Output in mGy/s	Tube Output in mR/s
Mo	28	7.0	800
W	28	2.0	230

- when measured by a ionization chamber with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the ionization chamber.

If the recommended performance criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

## 10.0 Phantom Image Quality Evaluation

### 10.1 Objective

To assess the quality and consistency of the mammographic image.

### 10.2 Suggested Equipment

- 18 x 24 cm compression paddle.
- ACR Mammographic Accreditation Phantom (i.e., RMI 156 by Radiation Measurement, Inc.; 18-220 by Nuclear Associates).
- Acrylic disc, 4.0 mm thick with 1.0 cm diameter, placed on the top of the ACR Mammographic Accreditation Phantom as per the *1999 ACR Mammography Quality Control Manual*, “Image Quality Evaluation” section.
- Previous annual and original ACR Mammographic Accreditation Phantom images.

### 10.3 Test Procedure

It is important for performing this test that the kVp and filter selection is done at a thickness of 4.5 cm. Using the alternate test procedure guarantees the correct AEC behavior for the test because:

- In Selenia Auto-kV and Auto-Filter modes, kV and filter selections are strictly controlled by compression thickness.
- The mAs value is determined by a short pre-exposure in all AEC modes.

Following the steps in the alternate test procedure is clinically equivalent to acquiring the phantom image at 4.5 cm compression thickness using Auto-Filter or Auto-kV.

#### 10.3.1 Conventional AEC Method

1. Create a test patient on the Acquisition Workstation.
2. Install the 18 × 24 cm compression paddle in the compression device.
3. Follow the next steps or move to the **Alternate Equivalent AEC Method** to complete this procedure.
4. Center the ACR Mammographic Accreditation phantom laterally on the image receptor and position it so the chestwall edge of the phantom is aligned with the chest wall side of the image receptor.
5. Lower the compression device so that the compression paddle sits on the ACR phantom trying to achieve a compression thickness as close to 4.5 cm as possible.
6. Select the Phantom view from the examination screen window on the Acquisition Workstation.
7. Select AEC Sensor position 2 and make an exposure at the clinically used exposure settings (for example, Auto-Filter).
8. Accept the image in the preview window of the Acquisition Workstation display.
9. Record all technique factors in the record form.
10. Close the examination.

### 10.3.2 Alternate Equivalent AEC Method—Clinically equivalent technique to acquire a phantom image under 4.5 cm compression in clinically used AEC mode without using compression

1. Set the system to the clinically used AEC mode (for example, Auto-Filter).
2. Lower the compression paddle, without the ACR phantom in place, until the compression device reads 4.5 cm.
3. Record the kV and filter indicated on the AWS screen.
4. Raise the compression paddle, but always keep it under 7.0 cm, as indicated by the compression device.
5. Center the ACR Mammographic Accreditation phantom laterally on the image receptor and position it so the chestwall edge of the phantom is aligned with the chestwall side of the image receptor.
6. Lower the compression paddle to barely touch the ACR phantom.
7. Change the AEC Mode to AutoTime.
8. Change the kV and filter to the values recorded in Step 3 of this alternate test procedure.
9. Select the Phantom view from the examination screen window on the Acquisition Workstation.
10. Select AEC Sensor position 2 and make an exposure.
11. Accept the image in the preview window of the Acquisition Workstation display.
12. Record all technique factors in the record form.
13. Close the examination.

## 10.4 Record Forms

Use the *10. Phantom Image Quality Evaluation* form in Appendix A to record the results.

## 10.5 Data Analysis and Interpretation



**Note...**

*The 1999 ACR Mammography Quality Control Manual, "Image Quality Evaluation" section must be consulted as to how to score the ACR phantom. Numerous scoring points made in the ACR Mammography Control Manual apply equally in digital mammography.*

Use one of the following two methods to score the phantom image quality, as it best applies to your practice. In the case of a Mobile Selenia with no access to a DICOM printer or a diagnostic review workstation, the third method may be used as an alternative.

### 10.5.1 Method #1: Scoring the Phantom Image on a Diagnostic Review Workstation

1. Select Spool Management from the Admin Menu.
2. Search for the patient name with the ACR Mammographic Accreditation Phantom image previously acquired.
3. Select the thumbnail image of the ACR Mammographic Accreditation Phantom.
4. Select a diagnostic review workstation as the output device under the drop-down list in the Resend Tab.
5. Score the phantom image on the diagnostic review workstation display using the procedure described in the *1999 ACR Mammography Quality Control Manual*, “Image Quality Evaluation” section.
6. Record the results in the record form and in the Phantom Control Chart used by the radiologic technologist (*1999 ACR Mammography Quality Control Manual*, “Phantom Images” section).
7. Close the Spool Management window.



**Note...**

*View Actual Pixels display mode should be used on the review workstation to score the phantom image so that all acquired pixels are displayed on the screen.*

### 10.5.2 Method #2: Scoring the Phantom Image on a Film Printout

1. Select Spool Management from the Admin Menu.
2. Search for the patient name with the ACR Mammographic Accreditation Phantom image previously acquired.
3. Select the thumbnail image of the ACR Mammographic Accreditation Phantom.

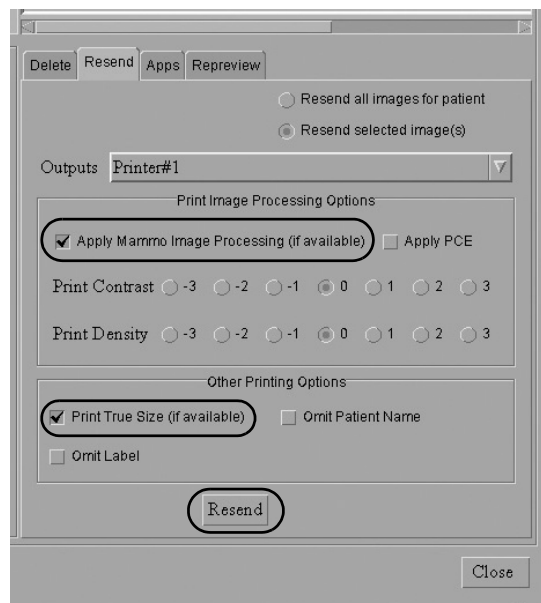


Figure 2-12: Resend Parameters

4. Select the DICOM printer as the output device under the drop-down list in the Resend Tab as shown in Figure 2-12.

5. Ensure that the Apply Mammo Image Processing and Print True Size options are checked and click Resend (Figure 2-12).
6. Score the hardcopy phantom image using the procedure described in the *1999 ACR Mammography Quality Control Manual*, “Image Quality Evaluation” section.
7. Record the results in the record form and in the Phantom Control Chart used by the radiologic technologist (*1999 ACR Mammography Quality Control Manual*, “Phantom Images” section).
8. Close the Spool Management window.

### 10.5.3 Method #3: Scoring the Phantom Image on the Mobile Lorad Selenia Acquisition Workstation

In the event that the Mobile Lorad Selenia does not have access to a printer or a diagnostic review workstation, it is appropriate in this case to score the phantom image on the display of the Acquisition Workstation following the procedure below. Since the display used on the Acquisition Workstation is of lesser quality compared to the display of the diagnostic review workstation, a passing score on the Acquisition Workstation will guarantee a passing score on a diagnostic review workstation (true for Lorad Selenia FFDM systems, only). A failing score on the Acquisition Workstation will be interpreted as a failure unless overruled by a passing score on a printed film or a diagnostic workstation. A failing score on the Acquisition Workstation may be used as a passing score only if that particular failing score has been previously confirmed as a passing score on either a printed film or on a diagnostic workstation.

1. Click the phantom image thumbnail to repreview the image if the preview window is already closed.
2. Click the Zoom/Pan icon to go into the “zoom and pan” to display the phantom image in full resolution.
3. Score the phantom image on the Acquisition Workstation display using the procedure described in the *1999 ACR Mammography Quality Control Manual*, “Image Quality Evaluation” section.
4. Record the results in the record form and in the Phantom Control Chart used by the radiologic technologist (*1999 ACR Mammography Quality Control Manual*, “Phantom Images” section).

**Note...**

*Critical evaluation of ACR Mammographic Accreditation Phantom images may reveal subtle artifacts or variances on phantoms that are not visible with screen-film image receptors. Artifacts associated with the phantom may be identified by repeating the phantom image with the phantom slightly rotated. Artifacts that move with the rotation of the phantom are caused by the phantom and not the imaging system. It is strongly recommended that the same phantom be used to evaluate phantom image quality over time. Should a different phantom (serial number) be used for this QC test, the medical physicist must consider the possibility of manufacturing variability in the phantom itself when evaluating these images, even if the phantoms have the identical manufacturer and model number.*





**Note...**

*The phantom image evaluation shall be done per Selenia FFDM system either using a hardcopy image (digitally printed film) from a single printer or by reviewing the phantom image on a single diagnostic review workstation. Since the purpose of this test is to qualify the image quality of the Selenia FFDM system, a single evaluation per Selenia is adequate. For a Mobile Selenia, the instructions given above shall be followed.*



**Note...**

*It is important to review a sample of phantom images acquired by the radiologic technologist since the previous physicist's visit. Any problems in scoring of image quality by the technologist must be included as a corrective action.*

## 10.6 Recommended Performance Criteria and Corrective Action

The phantom image quality shall meet the passing score shown below.

*Table 2-10: Minimum Passing Scores for ACR Phantom*

ACR Mammography Accreditation Phantom	Fibers	Speck Groups	Masses
Minimum Passing Score	5.0	4.0	4.0

There may be small fluctuations in scoring of the fibers and masses due to phantom variations. If the fiber score is 4.5 and or the mass score is 3.5, then examine the SNR and high contrast resolution of the system. If both those exceed recommended criteria, then a total score of 4.5 fibers, 4.0 specs and 3.5 masses is acceptable.

If the phantom score fails to meet the recommended criteria as specified above, the source of the problem shall be identified. If the source is identified as the digital detector, corrective action shall be taken before any further examinations are performed. If the source is a diagnostic device, imaging on the digital detector can be continued; the diagnostic device shall be corrected before used for mammographic image interpretation.

## 11.0 Signal-To-Noise and Contrast-To-Noise Measurements

### 11.1 Objective

To assure consistency of the digital image receptor by evaluating the signal-to-noise ratio (SNR) and contrast-to-noise ratio (CNR) of the image receptor.

### 11.2 Suggested Equipment

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

### 11.3 Test Procedure

It is important for performing this test that the kVp and Filter selection is done at a thickness of 4.5 cm. Using the alternate test procedure guarantees the correct AEC behavior for the test because:

- In Selenia Auto-kV and Auto-Filter modes, kV and filter selections are strictly controlled by compression thickness.
- The mAs value is determined by a short pre-exposure in all AEC modes.

Following the steps in the alternate test procedure is clinically equivalent to acquiring the phantom image at 4.5 cm compression thickness using Auto-Filter or Auto-kV.

#### 11.3.1 Conventional AEC Method

1. Re-open the Annual ACR Phantom examination created for the Phantom Image Quality Evaluation test or create a test patient on the Acquisition Workstation.
2. In case the previously acquired ACR image is used, click the phantom image thumbnail to repreview the image and skip to step 9.
3. Install the 18 × 24 cm compression paddle in the compression device.
4. Follow the next steps or move to the **Alternate Equivalent AEC Test Method** to complete this procedure.
5. Center the ACR phantom laterally on the image receptor and position it so the chestwall edge of the phantom is aligned with the chest wall side of the image receptor.
6. Lower the compression device so that the compression paddle sits on the ACR phantom trying to achieve a compression thickness as close to 4.5 cm as possible.
7. Add a Phantom view by clicking on the Add view button in the examination screen window.
8. Select the Phantom view from the examination screen window on the Acquisition Workstation.
9. Select AEC Sensor position 2 and make an exposure at the clinically used exposure settings (for example, Auto-Filter).
10. Move to the **ROI Creation** section.

**11.3.2 Alternate Equivalent AEC Method—Clinically equivalent technique to acquire a phantom image under 4.5 cm compression in clinically used AEC mode without using compression**

1. Set the system to the clinically used AEC mode (for example, Auto-Filter).
2. Lower the compression paddle, without the ACR phantom in place, until the compression device reads **4.5 cm**.
3. Record the kV and filter indicated on the Acquisition Workstation display.
4. Raise the compression paddle, but always keep it under 7.0 cm, as indicated by the compression device.
5. Center the ACR phantom laterally on the image receptor and position it so the chestwall edge of the phantom is aligned with the chestwall side of the image receptor.
6. Lower the compression paddle to barely touch the ACR phantom.
7. Change the AEC Mode to **AutoTime**.
8. Change the kV and filter to the values recorded in Step 3 of this alternate test procedure.
9. Select the Phantom view from the Patient View screen on the Acquisition Workstation.
10. Select AEC Sensor position 2 and make an exposure.

### 11.3.3 ROI Creation

#### Automated Method (v 3.4 or higher)

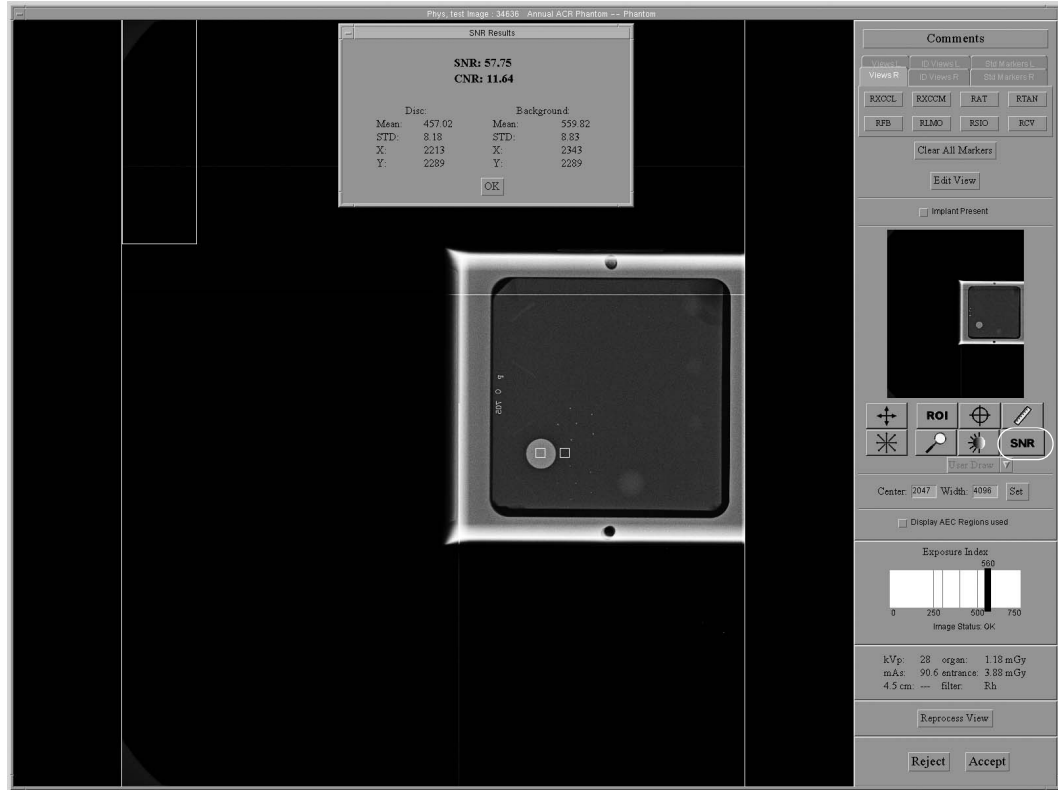


Figure 2-13: SNR Results Dialog Box

When you select the ACR Phantom view, the system assumes that an ACR Phantom is being imaged and adds a SNR button on the preview screen. See Figure 2-13. The system acquires and computes the SNR and CNR values.

Click the **SNR** button. The system places two ROI boxes on the image and displays SNR, CNR and corresponding information used for the calculations.



**Note...**

*If the ROIs placed by the system automatically do not match the relative positions as displayed in figure 2-13, you can manually adjust the location of the ROIs and the SNR and CNR results will be recalculated automatically.*

### Manual Method

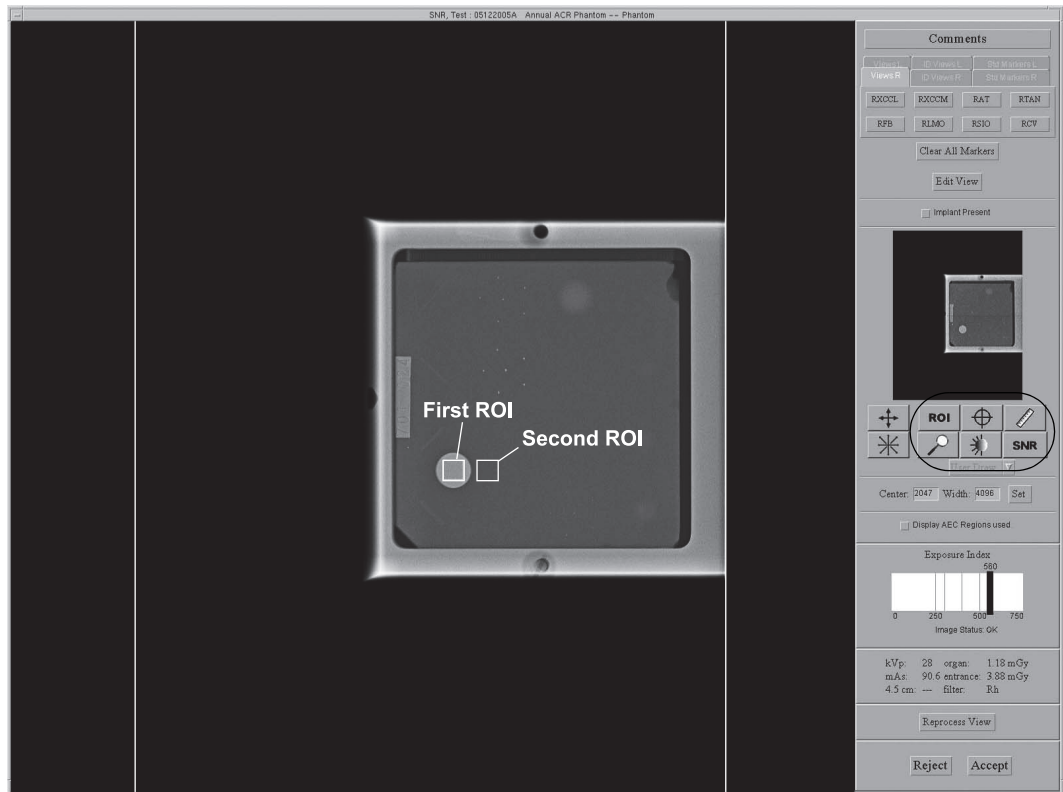


Figure 2-14: ROI Statistics

1. With the phantom image on the screen, select User Draw from the drop-down menu and click the ROI button.
2. Draw an ROI over the image of the acrylic disk—ROI should be slightly smaller than the image of the disk. Alternately, select 64x64 from the drop-down menu and position it on the disk image, with all edges inside the disk. Figure 2-14 illustrates the ROI position.
3. Record the mean value (Mean) given in the ROI Statistics dialog box.
4. Click OK on the ROI Statistics dialog box.
5. Drag the previously drawn ROI with the mouse right next to the acrylic disk, towards the chestwall, as shown in Figure 2-14, page 41. A new ROI Statistics dialog box opens automatically.
6. Record the mean value (Mean), and the standard deviation (std). Do not use the signal-to-noise ratio (SNR) as given by this ROI Statistics dialog box.
7. Accept the image in the preview window of the Acquisition Workstation display.

## 11.4 Record Forms

Use the 11. *Signal-To-Noise Ratio (SNR) and Contrast-To-Noise Ratio (CNR)* form in Appendix A to record the results.

## 11.5 Data Analysis and Interpretation

### 11.5.1 Automated Method (v 3.4 or higher)

With the automated SNR and CNR function, the SNR and CNR are calculated automatically for an appropriately acquired phantom view. The values of SNR and CNR, as well as the ROIs used for the measurement are displayed. The user should check if the ROIs selected by the program are in the appropriate locations. If they are well positioned, record the SNR and CNR values. If the location of one ROI or both ROIs need to be adjusted, move the ROI(s) to the appropriate location and the SNR and CNR values will be automatically updated based on the new ROI location.



**Note...** *The calculation of the SNR value displayed by the automated method already accounts for the DC offset.*

### 11.5.2 Manual Method



**Note...** *The SNR shall be computed using the mean and standard deviation values obtained from the ROI next to the acrylic disk.*

1. Compute the SNR of the detector according to

$$SNR = \frac{mean_{background} - DC_{offset}}{std_{background}}$$

where  $mean_{background}$  and  $std_{background}$  are the mean and standard deviation obtained from the ROI Statistics dialog for the ROI next to the acrylic disk and  $DC_{offset}$  is a DC offset added to the detector signal and is equal to 50.

2. Compute the CNR of the detector according to

$$CNR = \frac{mean_{background} - mean_{disk}}{std_{background}}$$

where  $mean_{disk}$  is the mean value obtained from the ROI Statistics dialog for the ROI on the acrylic disk.

## 11.6 Recommended Performance Criteria and Corrective Action

The measured SNR must be equal to or greater than 40. If it is less than 40, repeat the test.

The computed CNR must be within  $\pm 15\%$  of the value determined by the medical physicist during the equipment evaluation when the image receptor was installed or after a major upgrade.

If these criteria are not met, a qualified service engineer must correct the problem before using the system for clinical imaging.



**Note...**

*When CNR is being computed for the first time on a digital detector, the computed value shall be used to establish the base criteria for the technologist Signal-To-Noise (SNR) and Contrast-To-Noise (CNR) Measurements weekly test. The corresponding form for the technologist shall be completed.*



**Note...**

*The CNR baseline may need to be evaluated and a new value may need to be established under the following conditions:*

- *detector replacement*
- *detector modification (i.e. power supply replacement, readout sequence replacement, etc.)*
- *AEC dose adjustment*
- *ACR phantom replacement or alteration (i.e. permanent repositioning of the acrylic disk)*
- *any other reason the medical physicist feels that may affect the CNR calculation*

## 12.0 Diagnostic Review Workstation QC

### 12.1 Objective

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



**Note...**

*This diagnostic review workstation Quality Control procedure applies specifically to the Hologic's SecurView<sub>DX</sub> diagnostic workstation. This Quality Control procedure may be adopted for use on another vendor's diagnostic review workstation, if that workstation does not have its own Quality Control procedure.*

### 12.2 Suggested Equipment (Applies to CRT and some LCD displays)

- Photometer supplied with each diagnostic review workstation.
- Aperture shield supplied with the photometer. (Applies to CRT displays, only)

### 12.3 Test Procedure



**Note...**

*The room lighting should be similar to that when studies are being read.*

1. If the diagnostic review workstation is equipped with CRT or LCD displays requiring an external photometer, assure that the photometer is connected to the USB port at the back of the computer.
2. Confirm that the aperture shield is available for the CRT display.



**Note...**

*The photometer shall not be disconnected from the computer, otherwise there is a risk of Windows not recognizing it as a plug-in device and further actions may be required by an administrator.*

3. Run the display QC software from the Windows desktop (usually Medical Pro or QAWeb shortcut).

#### 12.3.1 Medical Pro application

1. Click the QA Setup button on the Medical Pro dialog box.
2. Right click **Measure Display White** and select **Run Now**.
3. Follow the instructions on the screen to measure the white level on both displays.
4. Right click **Measure Display White** and select **History**.
5. Click today's date and then click **Details**.
6. Select one of the displays and click Details.
7. Record the value for today's date and repeat for the second display.
8. Repeat Step 3 to Step 7 for the Measure Display Black (applies to CRT displays, only), Measure Quality Level and Measure Uniformity (applies to CRT displays, only) tests.



### 12.3.2 MediCal QAWeb application

1. Click the **Status** button on the MediCal QAWeb.
2. Run all tests listed under scheduled actions other than the Auto-calibration test.
3. Select one of the displays on the new window that comes up and click the **View Detailed Results** to see the test results. Repeat the selection for each display. You can also access the latest results from the status window of the MediCal QAWeb.
4. Close all MediCal QAWeb windows.

## 12.4 Record Forms

Use the *13. Diagnostic Review Workstation QC* form in Appendix A to record the results.

## 12.5 Recommended Performance Criteria and Corrective Action

### 12.5.1 White Level Performance

The operating white level is calibrated at 300 cd/m<sup>2</sup> for the Barco MGD521 display, 400 cd/m<sup>2</sup> for the Barco MGD521M, 600 cd/m<sup>2</sup> for the Barco Coronis MFGD 5621 HD Mammo LCD display, 500 cd/m<sup>2</sup> for the Barco Coronis MFGD 5421 LCD display, and 500 cd/m<sup>2</sup> for the Barco Nio MDNG-5121 display. The warning level is set to  $\pm 3\%$  and the tolerance level at  $\pm 6\%$ .

If the measured white level is outside the tolerance level, the display must be calibrated and the performance criteria shall be met prior to performing mammographic image interpretation on the diagnostic review workstation with the affected display.

### 12.5.2 Black Level Performance (Applies to CRT displays only)

The operating black level of the Barco MGD521 and MGD521M display is calibrated at 0 cd/m<sup>2</sup> using glare and ambient light compensation. The warning level is set to 0.5 cd/m<sup>2</sup> and the tolerance level at 1.0 cd/m<sup>2</sup>.

If the measured black level is outside the tolerance level, the display must be calibrated and the performance criteria shall be met prior to performing mammographic image interpretation on the diagnostic review workstation with the affected display.

### 12.5.3 Quality Level Performance, Compliance Test (DICOM GSDF Compliance Check)

The quality level checks the full display calibration of any Barco display. The display calibration warning level is triggered at 5% deviation from the overall calibration. The tolerance level is set to 10% from the overall calibration.

If the measured quality level is outside the tolerance level, the display must be calibrated and the performance criteria shall be met prior to performing mammographic image interpretation on the diagnostic review workstation with the affected display.

#### 12.5.4 Uniformity Performance (Applies to CRT displays only)

The Barco MGD521 and MGD521M displays provide calibration means to minimize brightness non-uniformities for regions away from the center of the display. The display uniformity warning is triggered at 10% brightness deviation from the brightness at the center of the display. The tolerance level is set to 15% brightness deviation from the brightness at the center of the display.

If the measured non-uniformities are outside the tolerance level, the display uniformity must be calibrated and the performance criteria shall be met prior to performing mammographic image interpretation on the diagnostic review workstation with the affected display.



**Note...**

*A qualified service engineer may have to resolve any issues if tolerance levels cannot be achieved for any of the displays of the diagnostic review workstation.*



**Note...**

*Image acquisition can continue while issues with the diagnostic review workstation are being addressed. Another Selenia approved diagnostic device (i.e. DICOM printer, second diagnostic review workstation) shall be used for mammographic image interpretation.*

## 13.0 Detector Ghosting (Optional)

### 13.1 Objective

To assure that the level of detector ghosting does not interfere with image quality.



**Note...** *The Detector Ghosting test is an optional test that may be performed by the medical physicist in the event of appearance or suspicion of detector ghosting.*

### 13.2 Suggested Equipment

- Flat Field phantom, 4 cm thick uniform attenuation block of acrylic large enough to cover the digital image receptor. The Flat Field phantom is supplied by the manufacturer.
- 0.1mm sheet of aluminum (for example: the filters which are used for the HVL measurement).
- 24 x 30 cm compression paddle.

### 13.3 Test Procedure

1. Click New in the Patient Pane to create a test patient, selecting the Phys QC: Ghosting procedure. Refer to the operator manual for details about adding a new patient.
2. Install the 24 x 30 cm compression paddle in the compression device.
3. Place the Flat Field phantom on top of the image receptor cover positioned such that a little more than half of the digital image receptor is covered and the other half of the digital image receptor is not covered by the Flat Field phantom. See Figure 2-15.



**Note...** *The Flat Field phantom must extend at least 1" beyond the AEC Sensors and cover the sensors.*

4. Lower the compression device until the compression paddle is touching the Flat Field phantom.

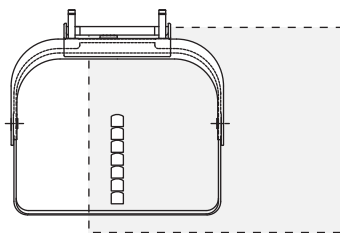


Figure 2-15: First Exposure for Ghosting

5. Set the system in the AEC mode that is used clinically (i.e. Auto-Filter).
6. Set the exposure compensation to Step 0 or the step used clinically.
7. Set the AEC sensor to position "2."
8. Set the filtration and kVp to clinically used values, if applicable in the selected AEC mode.
9. Select the first available view.
10. Make a single exposure in the selected AEC mode.

11. Accept the preview image.
12. Move the Flat Field phantom so that it covers the entire image area of the digital image receptor.
13. Place the 0.1 mm aluminum filter on top of the standard block centered against chestwall edge of the digital image receptor (see Figure 2-16).

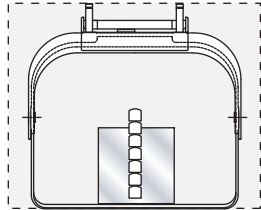


Figure 2-16: Second Exposure for Ghosting

14. Select the second view and make a single exposure in the selected AEC mode as soon as possible, preferably about 1 minute after the completion of the first exposure.

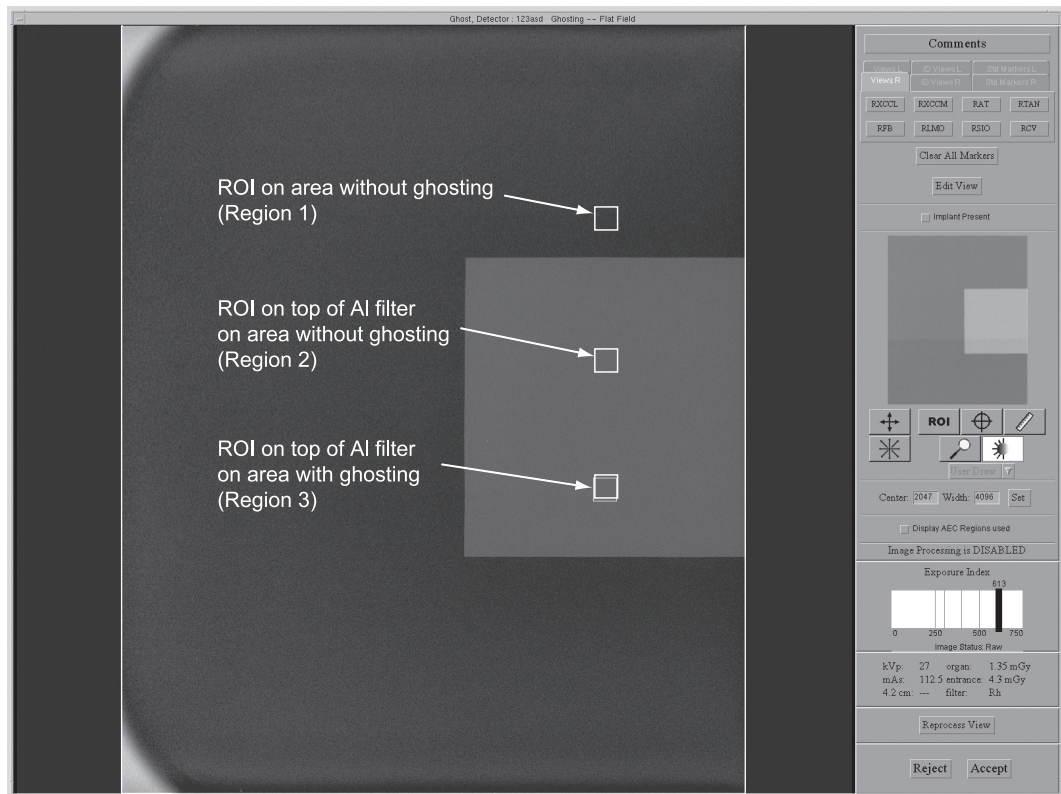


Figure 2-17: Preview Screen Showing Set-up for Detector Ghosting Test

15. Set ROI size to 128 x 128.
16. Measure and record the mean pixel value in the ROI on locations shown in Figure 2-17.

### 13.4 Record Forms

Use the *14. Detector Ghosting* form in Appendix A to record the results.

### 13.5 Data Analysis

Calculate the Ghost Image Factor by using the following formula and record in the form.

$$\text{Ghost Image Factor} = \frac{\text{mean}_{\text{region 3}} - \text{mean}_{\text{region 2}}}{\text{mean}_{\text{region 1}} - \text{mean}_{\text{region 2}}}$$



**Note...**

*Regions 1 and 2 correspond to the section of the detector that was covered by the Flat Field phantom during both exposures. Region 3 corresponds to the section of the detector that was covered by the Flat Field phantom during only one of the two exposures.*

### 13.6 Recommended Performance Criteria and Corrective Actions

The measured Ghost Image Factor must be within  $\pm 0.3$  for consecutive images acquired within approximately 1 minute of each other. If it is greater, repeat the test.

If the recommended performance criteria are not met, a qualified service engineer must correct the problem before using the system for clinical imaging.

**Quality Control Manual**

Chapter 2—Quality Control Activities for the Medical Physicist  
Detector Ghosting (Optional)



## Chapter 3—QC Activities for the Radiologic Technologist

This section specifies the QC procedures, testing frequency, regulatory action levels and time limits for corrective action for each required Quality Control Activity that falls under the responsibility of the *radiologic technologist*. Detailed steps are provided only for QC procedures that are different from the standard QC procedures already in use for screen-film mammography facilities. Detailed steps for procedures similar to those applied in screen-film mammography are described in the *1999 ACR Mammography Quality Control Manual*.

All tests under the *Quality Control Activities for the Radiologic Technologist* section shall be performed at the specified frequency by a qualified radiologic technologist trained in digital mammography.



**Note...**

*Please read the Selenia Full Field Digital Mammography operator manual to become familiar with the user interface and functionality of the Lorad Selenia FFDM System.*



**Note...**

*Unless otherwise specified in the individual test procedure, you need to log into the operating system as “tech” to perform all QC tests.*



**Caution:**

*Direct exposure of the digital detector to high radiation dose may result in damaging the detector. The digital image receptor must be covered with lead during testing for exposures other than those required to qualify image quality. Following the test procedures in this QC Manual will ensure the safety of the digital detector.*

## 1.0 DICOM Printer Quality Control

### 1.1 Objective

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

The intention of printing the SMPTE pattern is not to evaluate the pattern itself and if it conforms to the SMPTE standards, but to give the user the opportunity to measure different density areas and track their stability over time.

### 1.2 Frequency

Weekly or after preventive maintenance, service or software change is performed on the DICOM printer or a Selenia FFDM system.



**Note...** *If you have multiple Selenias, you only need to perform this test from a single Selenia each week, preferably the same Selenia every week.*



**Note...** *This test shall be performed every time preventative maintenance, service or software change takes place on a Selenia FFDM system or the printer itself. If service or software changes affected a Selenia system, then that Selenia system shall be used for performing this one time test, independently of the weekly frequency of this test. The default Selenia system may be used for the following weekly test.*

### 1.3 Suggested Equipment

- Densitometer
- SMPTE test pattern stored on the Acquisition Workstation of the Lorad Selenia FFDM System

### 1.4 Test Procedure

1. Select **Admin>Test Patterns**. The Test Pattern dialog box appears.

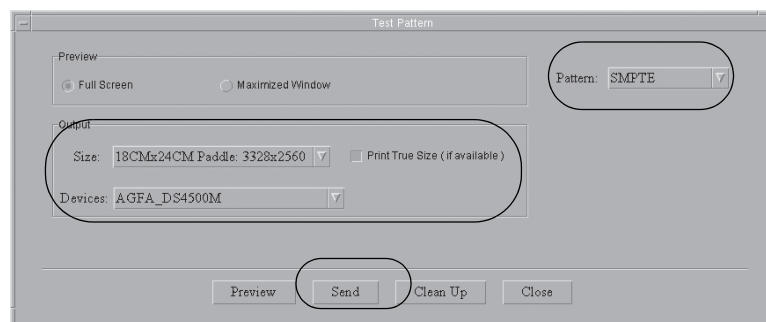


Figure 3-1: Selecting SMPTE Test Pattern

2. Select **SMPTE** from the Pattern drop-down menu.



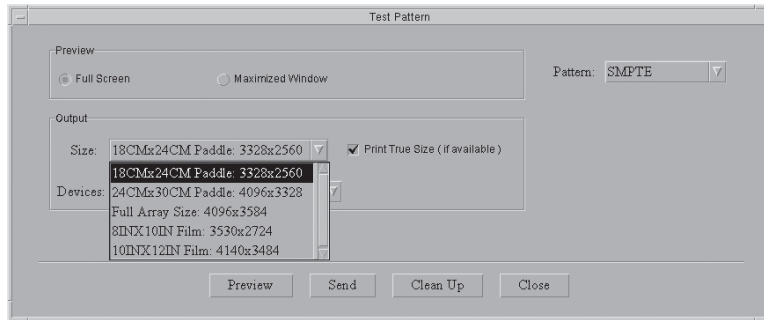


Figure 3-2: Output Size Options for Test Pattern Dialog Box

3. In the Output area of the dialog box:
  - a. Select the image size from the Output Size drop-down menu: either **18 cmx24 cm Paddle: 3328x2560** or **24 cmx30 cm Paddle: 4096x3328**.
  - b. Select your printer from the Devices drop-down menu.
  - c. Uncheck **Print true size**.
4. Click **Send** (see Figure 3-1). An Image Queued dialog box appears informing you that the image is being sent. The SMPTE pattern prints on the selected printer.
5. Click **OK** to close the Image Queued dialog box.

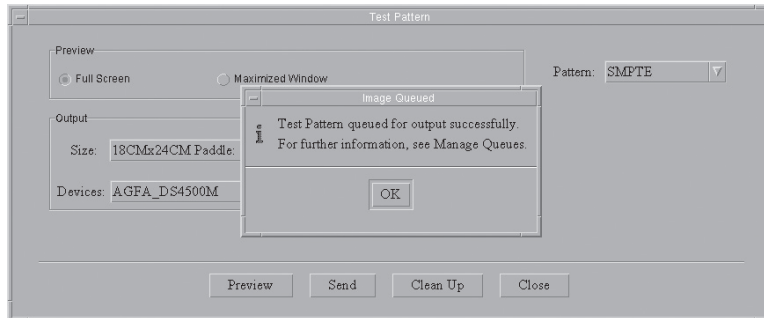


Figure 3-3: Sending Info Dialog Box

6. Click **Close** to exit the Test Pattern dialog box.

## 1.5 Record Forms

Use the *DICOM Printer Quality Control* form in Appendix B to record the results.

## 1.6 Data Analysis and Interpretation

1. Use the densitometer to measure the density of the 10%, 40% and 90% patches, as shown in Figure 3-4, on the SMPTE film. Record the results on the test film and date the film if necessary.
2. Determine and plot the Mid Density (MD), Density Difference (DD) and Lower Density (LD) values on the *DICOM Printer Control Chart*.
  - For MD, use the density measured for the 40% patch.
  - For LD, use the density measured for the 90% patch.
  - For DD, subtract the density of the 40% patch from the density of the 10% patch.

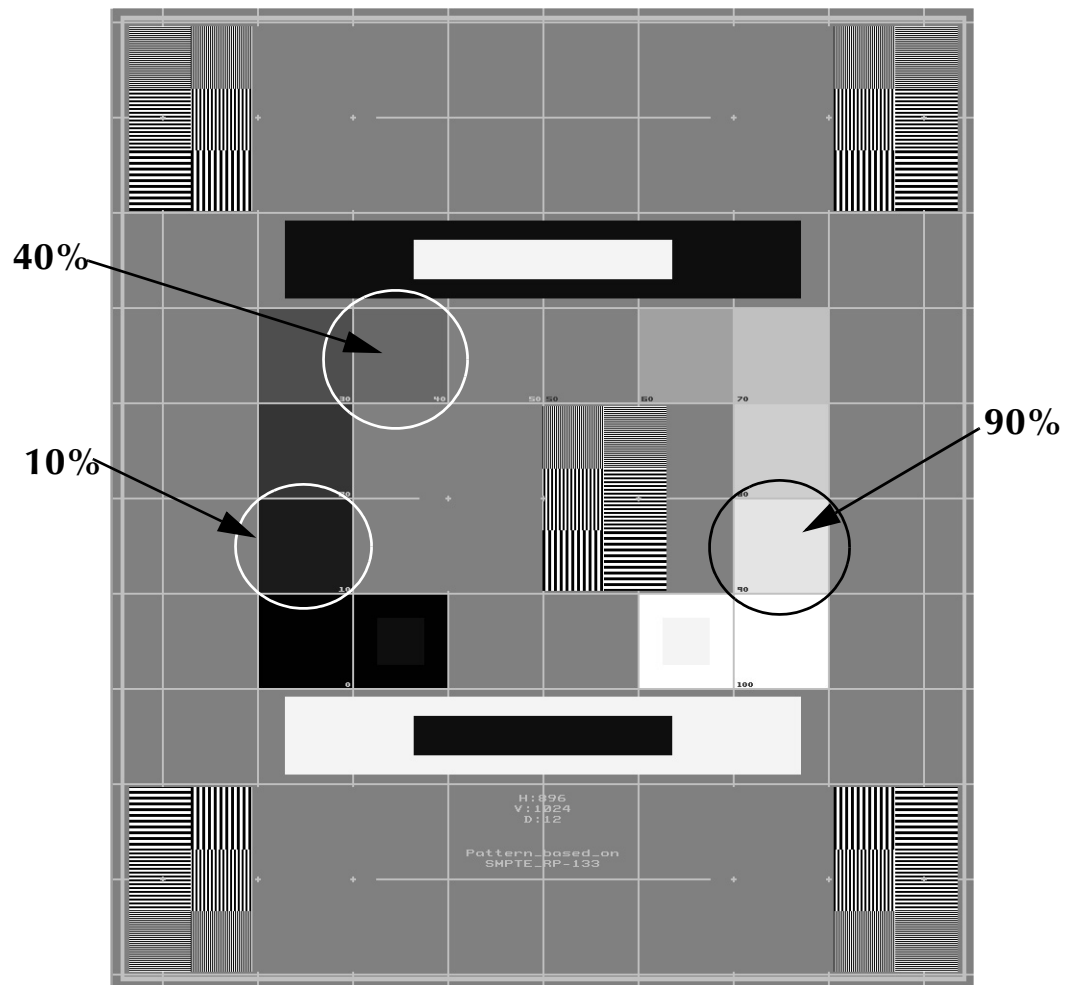


Figure 3-4: SMPTE Pattern

You may use the “Data Collection Worksheet” in “Appendix B” to record your values.

## 1.7 Recommended Performance Criteria and Corrective Action

Operating levels must be established under the supervision of the medical physicist or during application training. Operating levels must be established separately for each printer.

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

*Table 3-1: Density Standards*

Control Value	SMPTE Grayscale Patch	Control Limits
MD	40%	$\pm 0.15$
DD	10% - 40%	$\pm 0.15$
LD	90%	$\pm 0.15$

If any of the values are beyond their respective control limits, repeat the test after recalibrating the printer.

If the test results fall outside the control limits, the source of the problem shall be identified by a qualified DICOM printer service engineer. Corrective actions shall be taken before printing any more clinical or phantom films on this DICOM printer.

Images can still be acquired while any printer issues are being resolved. Alternative diagnostic devices shall be used for mammographic image interpretation until all issues are resolved and the DICOM printer performs within recommended criteria.

## 2.0 Detector Flat-Field Calibration

### 2.1 Objective

To assure that the system is calibrated properly.

### 2.2 Frequency

Weekly

### 2.3 Suggested Equipment

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

### 2.4 Test Procedure

#### 2.4.1 Preparation

1. If the system was recently or just powered up, wait the predefined time required for the digital detector to come up to temperature.
2. Perform the calibration procedure at a room temperature that is average for the duration of the day.
3. Remove any compression paddle from the compression device.
4. Make sure that both the Flat Field phantom and the surface of the image receptor are clean. Place the Flat Field phantom on top of the image receptor covering its entire surface.



**Note...**

*It is important to clean the Flat Field phantom and the surface of the digital image receptor before starting the calibration procedure.*

#### 2.4.2 Calibration Procedure

1. Click **Admin>Calibrate** to open the calibration screen. Directions are displayed on the screen for performing Detector Flat-Field calibration. Keep these instructions in mind when performing the calibration procedure.
2. Take an exposure using manual techniques, following the directions on the screen.
3. Review the preview image for foreign objects and collimation interference.
4. Click **Accept** if the image is clean and the collimation blades do not intrude into the imaging space.
5. Click the **Accumulate Calibration** button if present, and follow the remaining steps as required by the on-screen instructions.



**Note...**

*Detector Flat-Field calibration will not be optimal with fewer exposures than the total number required by the on-screen instructions.*

6. Click **End Calibration Sequence** after accumulating the required exposures.

## 2.5 Record Forms

It is not required to record the execution of this test since the system keeps track of when the test was performed last and prohibits further imaging without a valid calibration. However, a form is included in Appendix B in case the facility would like to keep track of when this test was performed.

## 2.6 Data Analysis and Interpretation



### Note...

*If the calibration fails for any reason, assure that the x-ray field covers the entire surface of the digital image receptor without any interference from the collimation. Assure that the Flat Field phantom also covers the entire surface of the digital image receptor. Calibration failure may also be caused by altering the radiographic techniques between exposures. In the event of calibration failure, restart calibration by clicking the **Restart Calibration Sequence** button. If failure persists, a qualified service engineer must be contacted.*

1. Detector Flat-Field calibration is performed automatically by software on the Acquisition Workstation.
2. Disregard any non-uniformities which appear in the acquired calibration images. Any non-uniformities will be corrected as part of the calibration process.

## 2.7 Recommended Performance Criteria and Corrective Action

If, after calibration, new artifacts appear during imaging, consult with a medical physicist or radiologist for assistance in evaluating these artifacts according to the guidelines provided in this manual under the corresponding Artifact Evaluation sections.

If the calibration procedure fails repeatedly, the source of the problem shall be identified and corrective actions shall be taken before any further examinations are performed.

## 3.0 Artifact Evaluation

### 3.1 Objective

To assure that the image is free of undesirable artifacts.

### 3.2 Frequency

Weekly, preferably before Phantom Image Evaluation.

### 3.3 Suggested Equipment

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

### 3.4 Test Procedure

#### 3.4.1 Image Receptor Artifact Evaluation

##### Preparation

1. Remove any compression paddle from the compression device.
2. Make sure that both the Flat Field phantom and the surface of the image receptor are clean. Place the Flat Field phantom on top of the image receptor to cover its entire imaging surface.
3. Create a “patient” for Weekly QC. Refer to the operator manual for details about adding a new patient. If a Weekly QC patient has already been created, see step 4.
4. Select the **Weekly QC** “patient”.
  - a. Search for the patient named **Weekly QC**.
  - b. When the patient list displays, click **Weekly QC**.
5. Click **New** in the Procedure box.
6. Enter today’s date, numbers only, for the **Accession Number**.
7. Select **Tech QC** for the Procedure Description. Confirm **Weekly QC** is the default.
8. Click **Accept**.
9. Select either **No Outputs** if you do not wish to store the QC images, or a predefined output device if you chose to store them. Put a CD in the CDRW drive if your predefined output includes a CD/DVD writer.

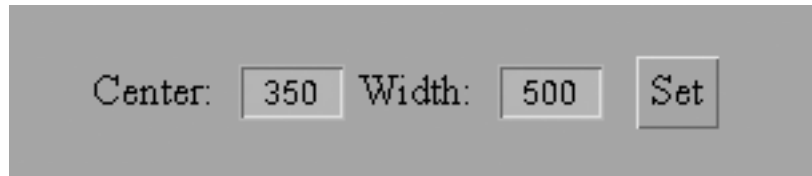
**Acquire First Flat Field Image**

1. Select the first Flat Field view from the examination screen window on the Acquisition Workstation.
2. Acquire an exposure:

*Table 3-2: Artifact Evaluation Exposure Techniques*

X-Ray Tube	Mode	kVp	Filter	Focal Spot
Mo	Auto-Time	28	Mo	Large
W	Auto-Time	28	Rh	Large

3. When the image displays, record the **mAs** value. You may use the “Data Collection Worksheet” in “Appendix B” to record your values.
4. Click **ROI** in the preview tools and then click **User Draw**.
5. Choose **64x64** from the dropdown list.
6. Click in the center of the flat field image, the **ROI Statistics** dialog box appears.
7. Take note of the Mean value number. Click **OK**.
8. Type the Mean Pixel Value from the ROI (use only the first three digits) into the Center box, and type **500** into the Width box.



*Figure 3-5: Example of Setting the Image Display*

**Alternative Method Using the Trackball**

- a. Select the Window/Level icon in the preview window. Hold the left button and adjust, by rolling the trackball, the window and level function, to a window width of **approximately** 500.
- b. Adjust the center to **approximately** the mean pixel value that you can acquire using an ROI at the center of the flat field image.
- c. Click **Set**. The result should be a balanced gray image.

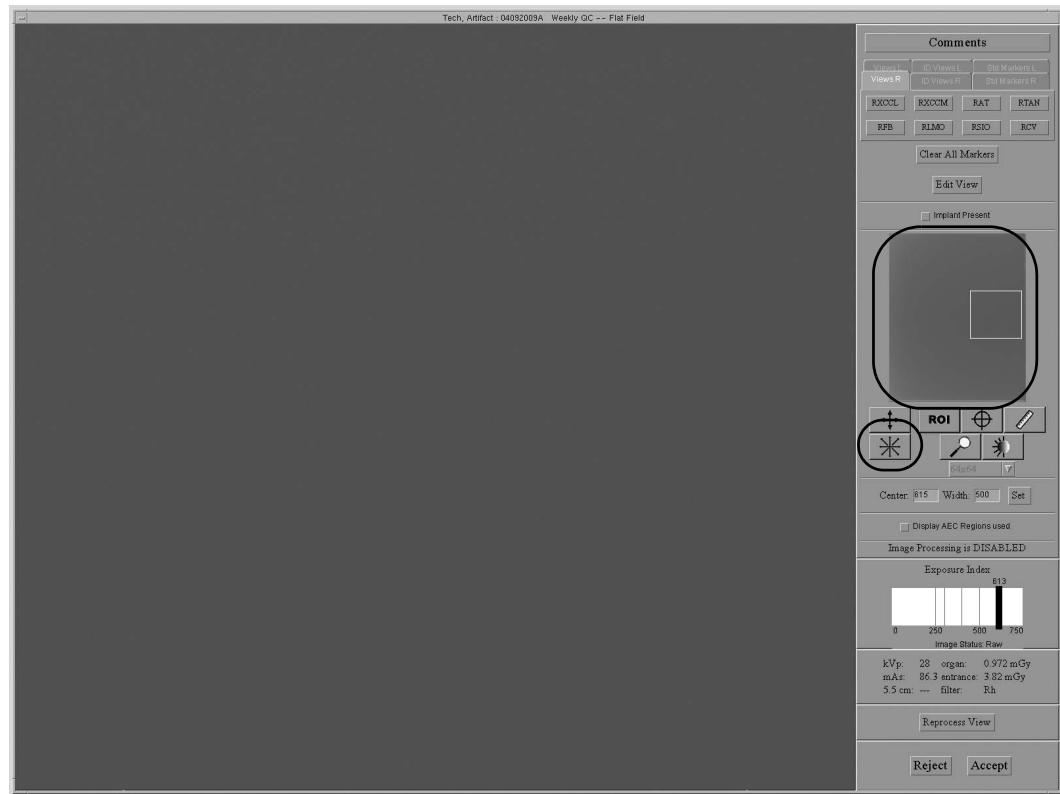



Figure 3-6: Using Zoom/Pan to Check for Artifacts

9. Activate the **Full Zoom/Pan** function  on the preview screen to search for artifacts.
10. Pan across the entire image and record any present artifacts on the record form.
11. Click **Accept**.

**Acquire Second Flat Field Image**

1. Turn the Flat Field phantom 180°.
2. Select the second **Flat Field** view from the examination screen window on the Acquisition Workstation.
3. Make an exposure.

Table 3-3: Artifact Evaluation Second View Exposure Techniques

X-Ray Tube	Mode	kVp	Filter	Focal Spot
Mo	Auto-Time	28	Rh	Large
W	Auto-Time	28	Ag	Large

4. Repeat Step 3 to Step 11 in the previous section.
5. Close the procedure.



### 3.4.2 DICOM Printer Artifact Evaluation



**Note...**

When performing DICOM printer artifact evaluation, an artificial flat field shall be sent to the printer following the procedure steps below. A true flat field acquired on the Selenia using the Flat Field phantom is not appropriate for this test and shall not be used.

1. Select **Admin>Test Patterns**. More information on Test Patterns can be found in “Chapter 2—Administration” of the *Administrator’s Guide* under the “Test Patterns” section.
2. Select **Flat Field** from the Pattern drop-down menu.

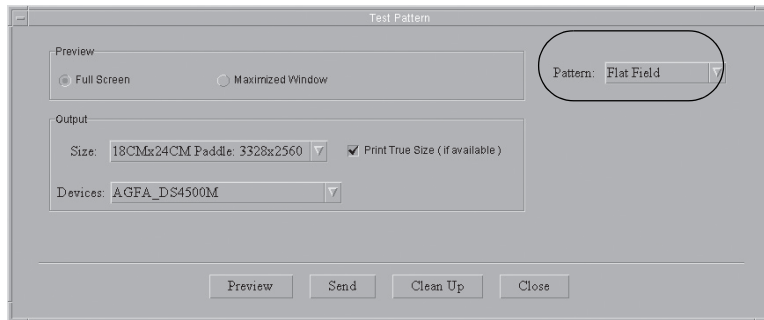


Figure 3-7: The Test Pattern Dialog Box

3. In the Output area of the dialog box:
  - a. Select the Output film size: **18 cmx24 cm Paddle 3328x2560**.
  - b. Select your DICOM Printer from the Output Device drop-down menu.
  - c. Select **Print true size** if supported for an 18 cm x 24 cm film.
4. Click **Send** to print the Flat Field pattern on the selected printer.
5. Click **OK** to close the Image Queued dialog box.
6. If the printer supports 24 cm x 30 cm film, select the Output film size: **24cmx30cm Paddle 4096x3328**, and select **Print true size** if supported for a 24 cm x 30 cm film.
7. Repeat Step 4 and Step 5.
8. Click **Close** to close the Test Pattern dialog box.



**Note...**

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

### 3.5 Record Forms

Use the *Artifact Evaluation* form in Appendix B to record the results.

## 3.6 Data Analysis and Interpretation

### 3.6.1 Image Receptor Artifact Evaluation

1. View the images on the Acquisition Workstation display. If no artifacts are visible, document the result in the Artifact Evaluation form.
2. If any artifacts are visible, rotate the Flat Field phantom about 180° and repeat the above test procedure. If the appearance of any artifacts changes location between the two images, those artifacts are present in the phantom, and do not indicate problems in system performance. The appearance of persistent artifacts in the same location may indicate artifacts that originate in the x-ray system or digital image receptor.
3. View the overall image for uniformity from left to right and top to bottom. Any areas appearing different with sharp lines of demarcation between them indicates a digital image receptor problem. Perform a detector calibration and then repeat the Artifact Evaluation Test.
4. If such artifacts persist, ask your medical physicist to perform a system artifact analysis, described in the “Quality Control Activities for the Medical Physicist” section of this manual.
5. Document the appearance of any artifacts on the “Artifact Evaluation” form.

### 3.6.2 DICOM Printer Artifact Evaluation

Inspect the DICOM printer film for artifacts. See the *1999 ACR Mammography Quality Control Manual*, “Artifact Evaluation” section for further details.

## 3.7 Recommended Performance Criteria and Corrective Action

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

The recommendations and corrective actions specified in the *1999 ACR Mammography Quality Control Manual*, “Artifact Evaluation” section shall be followed for DICOM printer artifacts. A qualified service engineer shall correct the source of intolerable artifacts on the DICOM printer within thirty days of the test date.



**Note...**

*Artifacts that appear on the digital image receptor and are not dropped pixels or lines may be able to be removed by recalibrating the digital detector according to “Detector Flat-Field Calibration,” page 56 of this manual.*



**Note...**

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

## 4.0 Signal-To-Noise and Contrast-To-Noise Measurements

### 4.1 Objective

To assure consistency of the digital image receptor by evaluating the signal-to-noise ratio (SNR) and contrast-to-noise ratio (CNR) of the image receptor.

### 4.2 Frequency

Weekly

### 4.3 Suggested Equipment

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

### 4.4 Test Procedure

It is important for performing this test that the kVp and Filter selection is done at a thickness of 4.5 cm. Using the alternate test procedure guarantees the correct AEC behavior for the test because:

- In Selenia Auto-kV and Auto-Filter modes, kV and filter selections are strictly controlled by compression thickness.
- The mAs value is determined by a short pre-exposure in all AEC modes.

Following the steps in the **Alternate Equivalent AEC Method** test procedure is clinically equivalent to acquiring the phantom image at 4.5 cm compression thickness using Auto-Filter or Auto-kV.

Determine whether the **Alternate Equivalent AEC Method** will be used due to the following:

- Unable to compress phantom to 4.5 cm.
- Mammopad used for majority of patients.

#### 4.4.1 Preparation

1. Re-open the Weekly QC examination created for the Artifact Evaluation test or create a test patient on the Acquisition Workstation.
2. Install the 18 × 24 cm compression paddle in the compression device.
3. Select either **No Outputs** if you do not wish to store the QC images, or a predefined output device if you chose to store them. Put a CD in the CDRW drive if your predefined output includes a CD/DVD writer.
4. Follow the next steps or preferably skip to the **Alternate Equivalent AEC Method** to complete this procedure.

#### 4.4.2 Conventional AEC Method

1. Center the ACR phantom laterally on the image receptor and position it so the chestwall edge of the phantom is aligned with the chest wall side of the image receptor. Place the disk on the top of the phantom as per the *1999 ACR Mammography Quality Control Manual*, “Phantom Images” section. See Figure 3-9, page 66 for an example.
2. Lower the compression device so that the compression paddle sits on the ACR phantom trying to achieve a compression thickness as close to 4.5 cm as possible.
3. Select the **Phantom** view on the Acquisition Workstation.
4. Select **QC Phantom** for the Output.
5. Select **AEC Sensor position 2**.
6. Acquire an exposure at the clinically used exposure settings (for example, **Auto-Filter**).
7. Skip to the **ROI Creation** section.

#### 4.4.3 Alternate Equivalent AEC Method—Clinically equivalent technique to acquire a phantom image under 4.5 cm compression in clinically used AEC mode without using compression

1. Set the system to the clinically used AEC mode (for example, Auto-Filter).
2. Lower the compression paddle, without the ACR phantom in place, until the compression device reads 4.5 cm.
3. Record the kV and filter indicated on the AWS screen. You may use the “Data Collection Worksheet” in “Appendix B” to record your values.
4. Raise the compression paddle, but always keep it under 7.0 cm, as indicated by the compression device.
5. Center the ACR phantom laterally on the image receptor and position it so the chestwall edge of the phantom is aligned with the chestwall side of the image receptor. Place the disk on the top of the phantom as per the *1999 ACR Mammography Quality Control Manual*, “Phantom Images” section. See Figure 3-9, page 66 for an example.
6. Lower the compression paddle to barely touch the ACR phantom.



**Note...**

*Be sure the compression thickness readout is less than 7 cm.*

7. Change the AEC Mode to **Auto-Time**.
8. Change the kV and filter to the values recorded in Step 3 of this alternate test procedure.
9. Select **AEC Sensor position 2**.
10. Select the **Phantom** view on the Acquisition Workstation.
11. Acquire an exposure.
12. Continue with ROI Creation.

#### 4.4.4 ROI Creation

##### Automated Method (v 3.4 or higher)

When you select the ACR Phantom view, the system assumes that an ACR Phantom is being imaged and adds a SNR button on the preview screen. See Figure 3-8. The system acquires and computes the SNR and CNR values.

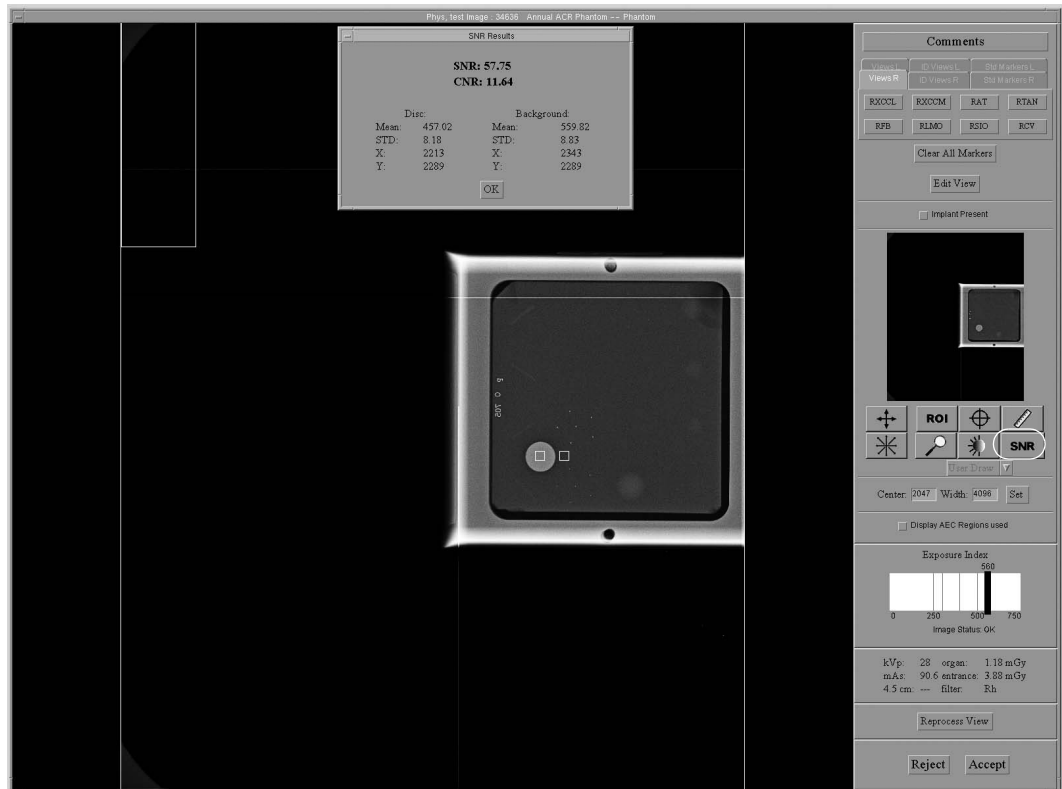


Figure 3-8: The SNR Results Dialog Box

1. Click the SNR button. The system places two ROI boxes on the image and displays SNR, CNR and corresponding information used for the calculations.



**Note...**

*If the ROIs placed by the system automatically do not match the relative positions as displayed in figure 2-13, you can manually adjust the location of the ROIs and the SNR and CNR results will be recalculated automatically.*

2. Click **OK** in the Statistics dialog box.
3. Click **Accept** in the preview window of the Acquisition Workstation display.
4. Click **Close Procedure**.
5. Change **Outputs** back to what you use for patients. If using a CD, wait until the CD drive is finished writing, then click **Admin>Eject** to remove the CD.

Manual Method

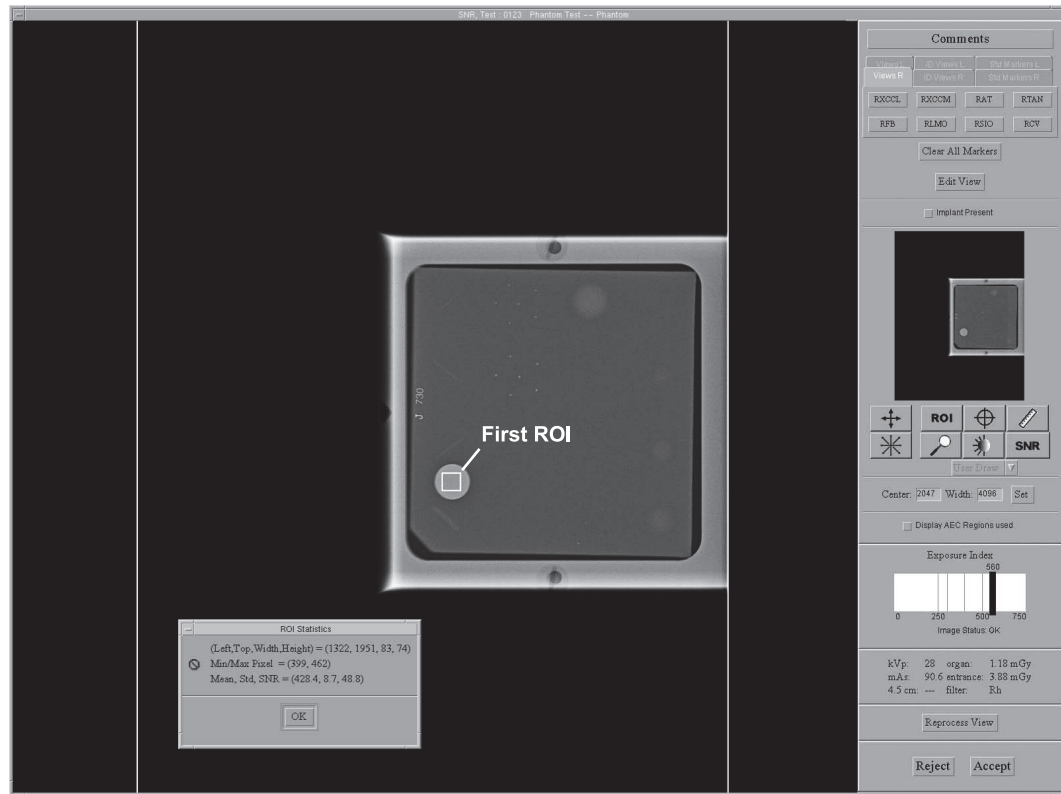


Figure 3-9: ROI Statistics

1. With the phantom image on the screen, select **User Draw** from the drop-down menu and click the **ROI** button.
  - a. Draw an ROI over the image of the acrylic disk—ROI should be slightly smaller than the image of the disk.
  - b. Alternate method: Select 64x64 from drop-down menu and drag the ROI box onto the image of the acrylic disk. All of the box must be inside the disk.
2. Record the mean value (Mean) given in the ROI Statistics dialog box. Figure 3-9 illustrates the ROI position. You may use the “Data Collection Worksheet” in “Appendix B” to record your values.
3. Click **OK** on the ROI Statistics dialog box.

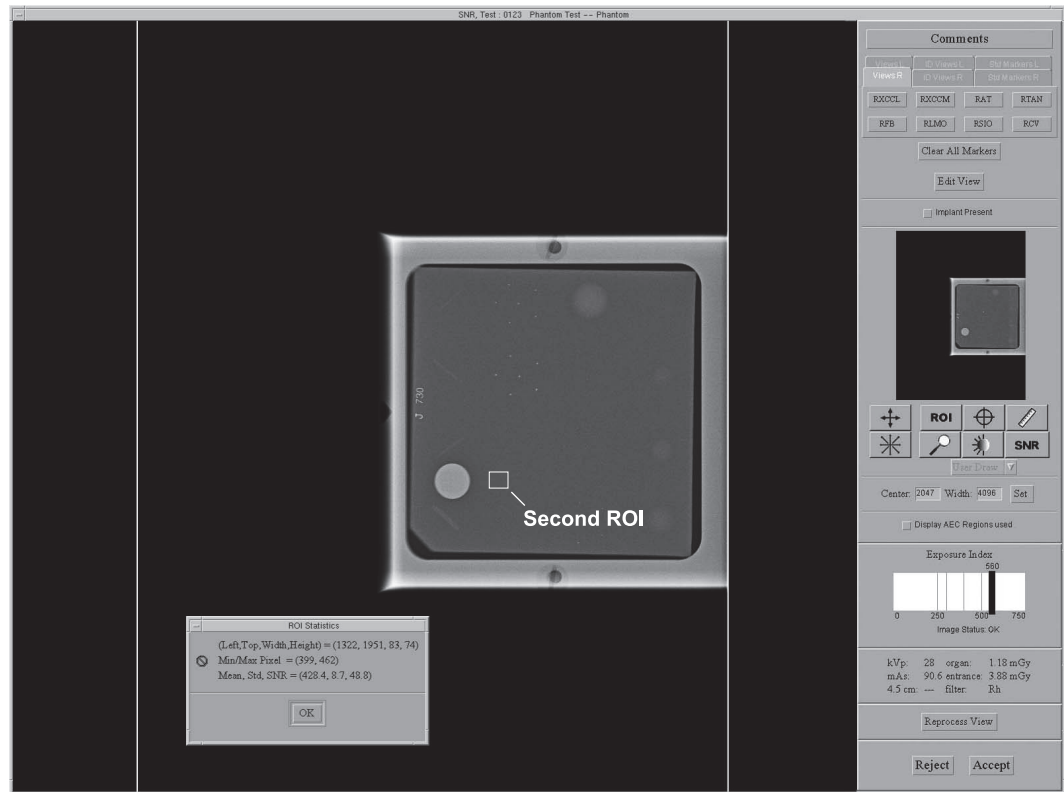


Figure 3-10: Second ROI Box

4. Using the trackball, click and drag the previously drawn ROI right next to the acrylic disk, towards the chestwall, as shown in Figure 3-10. A new ROI Statistics dialog box opens automatically.
5. Record the mean value (Mean), and the standard deviation (std). Do not use the Signal-To-Noise Ratio (SNR) as given by this ROI Statistics dialog box.
6. Click **OK** in the Statistics dialog box.
7. Click **Accept** in the preview window of the Acquisition Workstation display.
8. Click **Close Procedure**.
9. Change **Outputs** back to what you use for patients. If using a CD, wait until the CD drive is finished writing, then click **Admin>Eject** to remove the CD.

## 4.5 Record Forms

Use the *Signal-To-Noise Ratio (SNR) and Contrast-To-Noise Ratio (CNR) Control Chart* form in Appendix B to record the results.

## 4.6 Data Analysis and Interpretation

### 4.6.1 Automated Method (v 3.4 or higher)

With the automated SNR and CNR function, the SNR and CNR are calculated automatically for an appropriately acquired phantom view. The values of SNR and CNR, as well as the ROIs used for the measurement are displayed. The user should check if the ROIs selected by the program are in the appropriate locations. If they are well positioned, record the SNR and CNR values. If the location of one ROI or both ROIs need to be adjusted, move the ROI(s) to the appropriate location and the SNR and CNR values will be automatically updated based on the new ROI location.



**Note...** *The calculation of the SNR value displayed by the automated method already accounts for the DC offset.*

### 4.6.2 Manual Method



**Note...** *The SNR shall be computed using the mean and standard deviation values obtained from the ROI next to the acrylic disk. An SNR Calculation worksheet and a CNR Calculation worksheet are provided in Appendix B for use in performing these calculations.*

1. Compute the SNR of the detector according to

$$SNR = \frac{mean_{background} - DC_{offset}}{std_{background}}$$

where  $mean_{background}$  and  $std_{background}$  are the mean and standard deviation obtained from the ROI Statistics dialog for the ROI next to the acrylic disk and  $DC_{offset}$  is a DC offset added to the detector signal and is equal to 50.

2. Compute the CNR of the detector according to

$$CNR = \frac{mean_{background} - mean_{disk}}{std_{background}}$$

where  $mean_{disk}$  is the mean value obtained from the ROI Statistics dialog for the ROI on the acrylic disk.

3. Compute the deviation from the original CNR measurement according to

$$Diff = \frac{CNR_{measured} - CNR_{base}}{CNR_{base}} \times 100$$

where  $CNR_{base}$  is the CNR base value established by the medical physicist during acceptance testing of the digital detector and is recorded in the *Signal-To-Noise Ratio (SNR) and Contrast-To-Noise Ratio (CNR) Control Chart* included with this manual;  $CNR_{measured}$  is the new CNR computed in step 2.



#### 4.7 Recommended Performance Criteria and Corrective Action

The measured SNR must be equal to or greater than 40. If it is less than 40, repeat the test.

The computed CNR must be within  $\pm 15\%$  of the value determined by the medical physicist during the equipment evaluation when the image receptor was installed or after a major upgrade.

If these criteria are not met, a qualified service engineer must correct the problem before using the system for clinical imaging.



**Note...**

*The CNR baseline may need to be evaluated and a new value may need to be established under the following conditions:*

- *detector replacement*
- *detector modification (i.e. power supply replacement, readout sequence replacement, etc.)*
- *AEC dose adjustment*
- *ACR phantom replacement or alteration (i.e. permanent repositioning of the acrylic disk)*
- *any other reason the medical physicist feels that may affect the CNR calculation*

## 5.0 Phantom Image

### 5.1 Objective

To assure that image quality due to the x-ray imaging system, DICOM printer, and film processor are maintained at optimum levels.

### 5.2 Frequency

Weekly

### 5.3 Suggested Equipment

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

### 5.4 Test Procedure



**Note...** *You may use the same phantom image acquired for the SNR/CNR test. If you do this, you may skip to Section 5.6.*

It is important for performing this test that the kVp and filter selection is done at a thickness of 4.5 cm. Using the alternate test procedure guarantees the correct AEC behavior for the test because:

- In Selenia Auto-kV and Auto-Filter modes, kV and filter selections are strictly controlled by compression thickness.
- The mAs value is determined by a short pre-exposure in all AEC modes.

Following the steps in the alternate test procedure is clinically equivalent to acquiring the ACR phantom image at 4.5 cm compression thickness using Auto-Filter or Auto-kV.

#### 5.4.1 Preparation

1. Re-open the Weekly QC examination created for the Artifact or SNR/CNR test or create a test patient on the Acquisition Workstation.
2. In case the previously acquired ACR image is used, move to **Data Analysis and Interpretation** section of the test.
3. Install the 18 × 24 cm compression paddle in the compression device.
4. Select either **No Outputs** if you do not wish to store the QC images, or a predefined output device if you chose to store them. Put a CD in the CDRW drive if your predefined output includes a CD/DVD writer.
5. Follow the next steps or preferably skip to the **Alternate Equivalent AEC Test Method** to complete this procedure.

#### 5.4.2 Conventional AEC Method

1. Center the ACR phantom laterally on the image receptor and position it so the chestwall edge of the phantom is aligned with the chest wall side of the image receptor. Place the disk on the top of the phantom as per the *1999 ACR Mammography Quality Control Manual*, “Phantom Images” section. See Figure 3-9, page 66 for an example.
2. Lower the compression device so that the compression paddle sits on the ACR phantom trying to achieve a compression thickness as close to 4.5 cm as possible.
3. Select the **Phantom** view from the Patient View screen on the Acquisition Workstation.
4. Select **AEC Sensor position 2**.
5. Acquire an exposure at the clinically used exposure settings (for example, Auto-Filter).
6. Click **Accept** in the preview window of the Acquisition Workstation display.
7. Close the procedure.

#### 5.4.3 Alternate Equivalent AEC Method—Clinically equivalent technique to acquire a phantom image under 4.5 cm compression in clinically used AEC mode without using compression

1. Set the system to the clinically used AEC mode (for example, Auto-Filter).
2. Lower the compression paddle, without the ACR phantom in place, until the compression device reads 4.5 cm.
3. Record the kV and filter indicated on the AWS screen. You may use the “Data Collection Worksheet” in “Appendix B” to record your values.
4. Raise the compression paddle, but always keep it under 7.0 cm, as indicated by the compression device.
5. Center the ACR phantom laterally on the image receptor and position it so the chestwall edge of the phantom is aligned with the chestwall side of the image receptor. Place the disk on the top of the phantom as per the *1999 ACR Mammography Quality Control Manual*, “Phantom Images” section. See Figure 3-9, page 66 for an example.
6. Lower the compression paddle to barely touch the ACR phantom.
7. Change the AEC Mode to **Auto-Time**.
8. Change the kV and filter to the values recorded in Step 3 of this alternate test procedure.
9. Select the **Phantom** view from the Patient View screen on the Acquisition Workstation.
10. Select **AEC Sensor position 2**.
11. Acquire an exposure.
12. Click **Accept** in the preview window of the Acquisition Workstation display.
13. Close the procedure.

### 5.5 Record Forms

Use the *Phantom Control Chart* form in Appendix B to record the results.

## 5.6 Data Analysis and Interpretation

**Note...**

*The 1999 ACR Mammography Quality Control Manual, “Phantom Images” section must be consulted as to how to score the ACR phantom. Numerous scoring points made in the ACR Mammography Control Manual apply equally in digital mammography.*

Use one of the following methods to score the phantom image quality, as it best applies to your practice. In the case of a Mobile Selenia with no access to a DICOM printer or a diagnostic review workstation, the third method may be used as an alternative.

### 5.6.1 Method #1: Scoring the Phantom Image on a Diagnostic Review Workstation

#### Selecting and Sending to the Diagnostic Review Workstation

1. Select **Admin>Image Management**.
2. Search for the patient name with the ACR Mammographic Accreditation Phantom image previously acquired.
3. Click the thumbnail image of the ACR Mammographic Accreditation Phantom.
4. Click the **Resend** Tab. Select the diagnostic review workstation as the output device under the drop-down list as shown in Figure 3-11.
5. Click the **Resend** button.

#### Viewing and Scoring on a Diagnostic Review Workstation

1. Score the phantom on one of the displays of a diagnostic workstation using the procedure described in the *1999 ACR Mammography Quality Control Manual*, “Phantom Images” section.
2. You may use the “Data Collection Worksheet” in “Appendix B” to record your values.
3. Record the results in the *Phantom Control Charts*.

**Note...**

*View Actual Pixels display mode should be used on the review workstation to score the phantom image so that all acquired pixels are displayed on the screen.*

### 5.6.2 Method #2: Scoring the Phantom Image on a Film Printout

1. Select **Admin>Image Management**.
2. Search for the patient name with the ACR Mammographic Accreditation Phantom image previously acquired.
3. Click the thumbnail image of the ACR Mammographic Accreditation Phantom.
4. Click the **Resend** Tab.

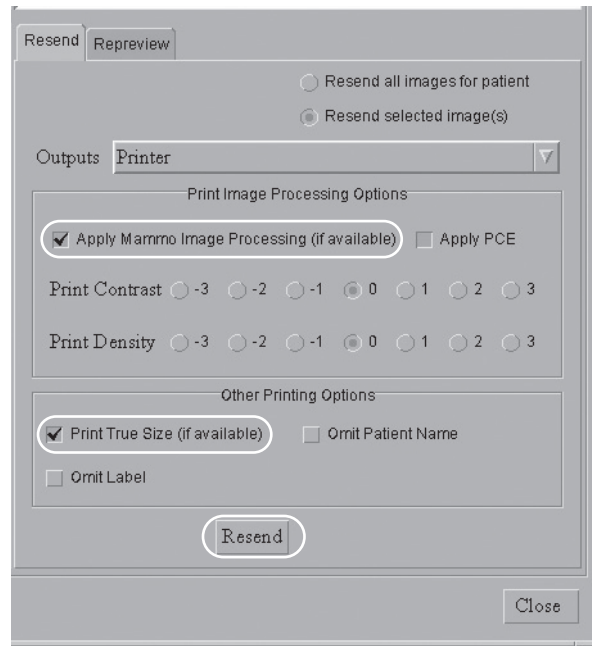


Figure 3-11: Resend Parameters

5. Select the **DICOM printer** as the output device under the drop-down list as shown in Figure 3-11.
6. Ensure that the **Apply Mammo Image Processing** and **Print True Size** options are checked (see Figure 3-11).
7. Click the **Resend** button.
8. Close the **Image Management** window.
9. Score the hardcopy phantom image using the procedure described in the *1999 ACR Mammography Quality Control Manual*, “Image Quality Evaluation” section. You may use the “Data Collection Worksheet” in “Appendix B” to record your values.
10. Record the results in the *Phantom Control Chart*.

### 5.6.3 Method #3 Scoring the Phantom Image on the Mobile Lorad Selenia Acquisition Workstation

In the event that the Mobile Lorad Selenia does not have access to a printer or a diagnostic review workstation, it is appropriate in this case to score the phantom image on the display of the Acquisition Workstation following the procedure below. Since the display used on the Acquisition Workstation is of lesser quality compared to the display of the diagnostic review workstation, a passing score on the Acquisition Workstation will guarantee a passing score on a diagnostic review workstation (true for Lorad Selenia FFDM systems, only). A failing score on the Acquisition Workstation will be interpreted as a failure unless overruled by a passing score on a printed film or a diagnostic workstation. A failing score on the Acquisition Workstation may be used as a passing score only if that particular failing score has been previously confirmed as a passing score on either a printed film or on a diagnostic workstation.

1. Click the phantom image thumbnail to repreview the image if the preview window is already closed.
2. Click the Zoom/Pan icon to go into the “zoom and pan” to display the phantom image in full resolution.
3. Score the phantom image on the Acquisition Workstation display using the procedure described in the *1999 ACR Mammography Quality Control Manual*, “Image Quality Evaluation” section.
4. Record the results in the record form and in the Phantom Control Chart (*1999 ACR Mammography Quality Control Manual*, “Phantom Images” section).



**Note...**

*Critical evaluation of ACR Mammographic Accreditation Phantom images may reveal subtle artifacts or variances on phantoms that are not visible with screen-film image receptors. Artifacts associated with the phantom may be identified by repeating the phantom image with the phantom slightly rotated. Artifacts that move with the rotation of the phantom are caused by the phantom and not the imaging system. It is strongly recommended that the same ACR Mammographic Accreditation Phantom be used to evaluate phantom image quality over time. Should a different ACR Mammographic Accreditation Phantom (serial number) be used for this QC test, the medical physicist must be consulted to determine the possibility of manufacturing variability in the phantom itself when evaluating these images, even if the phantoms have the identical manufacturer and model number.*



**Note...**

*The phantom image evaluation shall be done per Selenia FFDM system either using a hardcopy image (digitally printed film) from a single printer or by reviewing the phantom image on a single diagnostic review workstation. Since the purpose of this test is to qualify the image quality of the Selenia FFDM system, a single evaluation per Selenia is adequate. For a Mobile Selenia, the instructions given above shall be followed.*

## 5.7 Recommended Performance Criteria and Corrective Action

The phantom image quality shall meet the minimum passing score shown below.

*Table 3-4: ACR Mammography Accreditation Phantom Minimum Passing Score*

ACR Mammography Accreditation Phantom	Fibers	Speck Groups	Masses
Minimum Passing Score	5.0	4.0	4.0

There may be small fluctuations in scoring of the fibers and masses due to phantom variations. If the fiber score is 4.5 and or the mass score is 3.5, then examine the SNR and high contrast resolution of the system. If both those exceed recommended criteria, then a total score of 4.5 fibers, 4.0 specs and 3.5 masses is acceptable.

If the phantom score fails to meet the recommended criteria as specified above, the source of the problem shall be identified. If the source is identified as the digital detector, corrective action shall be taken before any further examinations are performed. If the source is a diagnostic device, image on the digital detector can be continued; the diagnostic device shall be corrected before used for mammographic image interpretation.

## 6.0 Compression Thickness Indicator

### 6.1 Objective

To assure that the indicated compression thickness is within tolerance.

### 6.2 Frequency

Biweekly (every two weeks)

### 6.3 Suggested Equipment

- ACR Mammographic Accreditation Phantom (for example, RMI 156 by Radiation Measurement, Inc.; 18-220 by Nuclear Associates)
- 7.5 cm spot contact compression paddle

### 6.4 Test Procedure



**Note...**

*The first time you use the ACR phantom, measure the phantom thickness and record this measurement as the **Base** on the Compression Thickness Indicator chart in Appendix B.*

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

### 6.5 Records Forms

Use *Compression Thickness Indicator* form to track the results.

### 6.6 Recommended Performance Criteria and Corrective Action

The compression thickness indicator shall always be accurate to  $\pm 0.5$  cm from the actual thickness.

If the recommended performance criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

## 7.0 Diagnostic Review Workstation QC

### 7.1 Objective

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



**Note...**

*This diagnostic review workstation Quality Control procedure applies specifically to the Hologic's SecurView<sub>DX</sub> diagnostic workstation. This QC procedure may be adopted for use on another vendor's diagnostic review workstation, if that workstation does not have its own Quality Control procedure.*

### 7.2 Frequency

Weekly for those facilities that use the SecurView<sub>DX</sub> diagnostic review workstation.



**Note...**

*This procedure uses software provided by the display manufacturer. It requires that the weekly tests be carried out on the same day each week. The software automatically performs additional tests on a monthly and quarterly basis. Consequently, the QC tests will take longer to execute once every month. However, no additional steps are required of the technologist.*

### 7.3 Suggested Equipment (Applies to CRT and some LCD displays)

- Photometer supplied with each diagnostic review workstation
- Aperture shield supplied with the photometer (Applies to CRT displays, only)

### 7.4 Test Procedure (Applies to all display types)

#### 7.4.1 Preparation



**Note...**

*The room lighting should be similar to that when studies are being read.*

1. Log out any user from the **SecurView<sub>DX</sub>** application.
2. Press the Windows Key. Select **Programs>Barco**.
3. Select the **MediCal Pro** or **QAWeb** QC application.

#### 7.4.2 Testing the LCD Displays Using the Integrated Sensor

**Using the Medical Pro application:**

1. Click the **QA Setup** button on the Medical Pro dialog box. The Q/A setup box appears.
2. All Q/A tasks, Last Executed (date) and Current Status (results) are listed.
3. Confirm all tests are **OK**.

If a test comes up with a warning, repeat the test. You may still use the SecurView. If the warning continues, contact Selenia Support.

To run tasks not due, or to rerun a task that has a warning or has failed:

- a. Right click the task you want to run.
- b. Click **Run Now**.
- c. Click **OK** in the dialog box that displays after the task has run.



4. Close the **Q/A Tasks** dialog box by clicking on the small **x** in the upper right corner.
5. Close **MediCal Pro** by clicking on the small **x** in the upper right hand corner.
6. The SecurView application is ready for log on.

**Using the Medical QAWeb application:**

1. Click the **Status** button on the Medical QAWeb.
2. Make sure there are no pending actions. If there are pending actions, execute them.
3. Confirm all tests under Scheduled Actions are **OK**.
  - If a test comes up as failed, run **Auto-calibration** and then repeat the test.
  - To run tasks not due, or to rerun a task that has a warning or has failed, click the **Run** link.
  - To view detailed results about a task, click the **Info** link, select the display and then click the **View Detailed Results** link.
4. Close all **Medical QAWeb** windows.
5. The SecurView application is ready for log on.

**7.4.3 Testing the CRT or LCD Display Using an External Photometer**

1. If the diagnostic review workstation is equipped with CRT or LCD displays requiring an external photometer, confirm that the photometer is connected to the USB port at the back of the computer.
2. Confirm that the aperture shield is available for the CRT display.

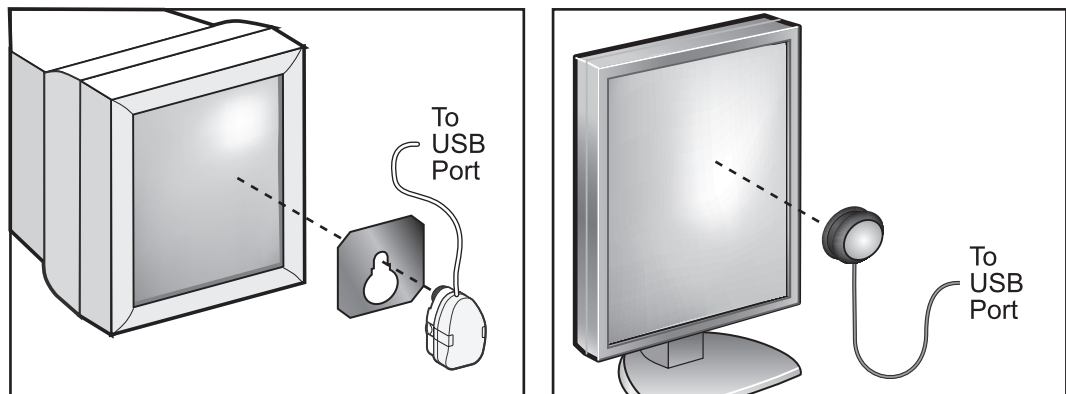


Figure 3-12: Calibrating the Displays with the Photometer



**Note...**

*The photometer shall not be disconnected from the computer, otherwise there is a risk of Windows not recognizing it as a plug-in device and further actions may be required by an administrator.*

### Using the Medical Pro application:

1. Click the **QA Setup** button on the Medical Pro dialog box.
2. Click **Start All Due Tasks** to begin the Display QC.
3. Follow the instructions on the screen till the end. These instructions guide you through all the necessary steps to perform Display QC on both displays at one time.
4. Be sure to check the log to confirm all tests are **OK**.
5. If a test comes up with a warning, repeat the test, but you may still use the SecurView. If the warning continues, contact Selenia Support.
6. To run tasks not due or to rerun a task that has a warning or has failed:
  - a. Right click the task you want to run.
  - b. Click **Run Now**.
  - c. Click **OK** in the dialog box that displays after the task has run.
7. Close the Q/A Tasks box by clicking on the small **x** in the upper right hand corner.
8. Close the MediCal Pro box by clicking on the small **x** in the upper right hand corner.
9. The SecurView application is ready for log on.

### Using the Medical QAWeb application:

1. Click the **Status** button on the MediCal QAWeb.
2. Follow the instructions on the display.
3. Close all MediCal QAWeb windows.
4. The SecurView application is ready for log on.

## 7.5 Record Forms

Internal logs to the software.

Use the *Diagnostic Review Workstation QC* form in Appendix B to record the results.

## 7.6 Data Analysis and Interpretation

1. Operating levels are established during the initial calibration of the equipment by the manufacturer.
2. The computer software analyzes the results and provides an indication if the displays met the pre-programmed control limits. Check the Current Status column to verify that all tests completed successfully. Warning status is acceptable.
3. If any of the tests has failed, repeat the test by right clicking the test and selecting **Run Now (Medical Pro)**, or clicking the **Run** link (Medical QAWeb).
4. The software can display control charts and other information which is required by the medical physicist and MQSA inspector. The display of this information is described in the software manual from the display manufacturer.

## 7.7 Recommended Performance Criteria and Corrective Action

If the test fails after the second attempt, the problem must be corrected before any clinical or phantom images are read on the diagnostic review workstation. The person responsible for display calibration (lead technologist, medical physicist, or service engineer) must perform the display calibration, if necessary, using the appropriate software.

Images can still be acquired while any display issues are being resolved. Alternative diagnostic devices shall be used for mammographic image interpretation until all issues are resolved and the displays perform within recommended criteria.

## **8.0 Viewboxes and Viewing Conditions**

### **8.1 Objective**

To assure that the viewboxes and viewing conditions are optimized and their performance stays constant over time.

### **8.2 Frequency**

Weekly

### **8.3 Suggested Equipment**

- Window cleaner
- Soft towels

### **8.4 Test Procedure**

Perform this test in the same manner as described in the *1999 ACR Mammography Quality Control Manual*, "Viewbox and Viewing Conditions" section.

### **8.5 Record Forms**

Use the *1999 ACR Mammography Quality Control Manual*, "Mammography Quality Control Checklist, Daily and Weekly Tests" form to record the results.

### **8.6 Data Analysis and Interpretation**

Follow the directions under the *1999 ACR Mammography Quality Control Manual*, "Viewbox and Viewing Conditions" section.

### **8.7 Recommended Performance Criteria and Corrective Action**

The procedure must be evaluated according to the *1999 ACR Mammography Quality Control Manual*, "Viewbox and Viewing Conditions" section.

If the recommended performance criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

## 9.0 Visual Checklist

### 9.1 Objective

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

### 9.2 Frequency

Monthly

### 9.3 Suggested Equipment

None

### 9.4 Test Procedure

Perform this test in the same manner as described in the *1999 ACR Mammography Quality Control Manual*, “Visual Checklist” section.

### 9.5 Record Forms

Use the *1999 ACR Mammography Quality Control Manual*, “Mammography Quality Control Visual Checklist” form to record the results.

### 9.6 Data Analysis and Interpretation

Follow the directions under the *1999 ACR Mammography Quality Control Manual*, “Visual Checklist” section.

### 9.7 Recommended Performance Criteria and Corrective Action

The procedure must be evaluated according to the *1999 ACR Mammography Quality Control Manual*, “Visual Checklist” section.

If the recommended performance criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

## 10.0 Repeat/Reject Analysis

### 10.1 Objective

To determine the number and cause of repeated/rejected mammograms.

### 10.2 Frequency

Quarterly



**Note...**

*In order for retake rates to be statistically meaningful, a patient volume of at least 250 patients is needed.*

### 10.3 Suggested Equipment

None

### 10.4 Test Procedure

#### 10.4.1 Preparation

1. Minimize the Selenia application using the dot in the upper right corner of the screen.
2. Double click the Netscape icon on the desktop, or click on the globe icon on the toolbar, or follow the procedure below to run Netscape:
  - a. Right-click the desktop.
  - b. Select **Links>Find Web Page**.
  - c. Click **Accept** to License Agreement. Wait for Netscape Navigator to open.
  - d. If you receive a “Netscape Security Warning”, click the check beside the “Show this Alert Next Time” to deselect it and you will not receive the message next time. Click **Continue Submission**.
3. Type **seLenia:8080** in the web address field and press **Enter**.
4. Log in to Netscape Navigator as **admin**.
5. Press **Enter** or click **Logon to the System**.

#### 10.4.2 Acquire Reject Reports

1. Click **Reject** from the Options list in Administration Tools.



**Note...**

*For more information on using the Repeat/Reject Analysis, including using it remotely, see Appendix A in the [Administrator's Guide](#).*

2. Adjust the **From** and **To** dates, select **all** or an **individual technologist** from the list, and select **Report** for Type.
3. Click **Submit** to compile and display the Reject Analysis report. It may take a while to run the report.
4. If you are working at a computer with a printer, you can click **Print** to print the report using the browser's print button. Otherwise, record the results on the form.
5. To run another report, go to the bottom of the report and click **Return to Reject Page**.

6. Click **Reject Report and Lists**.
7. Repeat from Step 2 until you have the required reports.

#### 10.4.3 Acquire Repeat Reports

1. Run the Repeat Analysis Report following the steps used to get the reject report.



**Note...** *This report is to be run if your software supports it.*

2. Minimize the Netscape application using the dot in the upper right corner of the screen.
3. Double click your site's name icon to redisplay the Selenia application.

### 10.5 Record Forms

Use the *Mammography Repeat/Reject Analysis* forms incorporated into the Acquisition Workstation Repeat/Reject Analysis software or the corresponding *Mammography Repeat/Reject Analysis* forms in Appendix B.

### 10.6 Data Analysis and Interpretation

The data presented in the *Mammography Repeat/Reject Analysis* form provide the repeat/reject statistics.

### 10.7 Recommended Performance Criteria and Corrective Action

If the total rate changes from that previously determined by more than 2.0% of the total films included in the analysis, the reason(s) for the change shall be determined, and corrective action carried out if necessary.

If the recommended performance criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.

## **11.0 Compression**

### **11.1 Objective**

To assure that the mammography system can provide adequate compression in manual and power assisted mode and that compression is controlled.

### **11.2 Frequency**

Semiannually, or whenever reduced compression is suspected

### **11.3 Suggested Equipment**

- Bathroom scale
- Towels

### **11.4 Test Procedure**

1. Click **Edit>Standard Setup** and set the Full Compression to 100% if necessary.
2. Set the Compression Mode to Full if necessary
3. Click **OK** to close Setup.
4. Follow the directions under the *1999 ACR Mammography Quality Control Manual*, "Compression" section.
5. After performing this test, restore any compression settings you changed.

### **11.5 Record Forms**

Use the *1999 ACR Mammography Quality Control Manual*, "Mammography Quality Control Checklist, Monthly, Quarterly and Semiannual Tests" form to record the results.

### **11.6 Data Analysis and Interpretation**

Follow the directions under the *1999 ACR Mammography Quality Control Manual*, "Compression" section.

### **11.7 Recommended Performance Criteria and Corrective Action**

The procedure must be evaluated according to the *1999 ACR Mammography Quality Control Manual*, "Compression" section.

If the recommended performance criteria are not met, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date.



## Appendix A—QC Forms for the Medical Physicist



If electronic forms or forms other than the forms listed in this appendix are used with MAN-01476 Revision 002, it is the responsibility of the user to verify that the alternative forms are equivalent to the forms printed in this manual.

*Table A-1: Quality Control Tests To be Performed by the Medical Physicist on All Lorad Selenia FFDM Systems*

QC Test	Frequency	Action Criteria	Chapter 2
Mammographic Unit Assembly Evaluation	Annually	Category C	Section 1.0, page 10
Collimation Assessment	Annually	Category C	Section 2.0, page 11
Artifact Evaluation	Annually	Category C	Section 3.0, page 15
kVp Accuracy and Reproducibility	Annually	Category C	Section 4.0, page 20
Beam Quality Assessment—HVL Measurement	Annually	Category C	Section 5.0, page 22
Evaluation of System Resolution	Annually	Category A	Section 6.0, page 23
Automatic Exposure Control (AEC) Function Performance	Annually	Category C	Section 7.0, page 25
Breast Entrance Exposure, AEC Reproducibility, and Average Glandular Dose	Annually	Category A Category C	Section 8.0, page 28
Radiation Output Rate	Annually	Category C	Section 9.0, page 31
Phantom Image Quality Evaluation	Annually	Category A	Section 10.0, page 33
Signal-To-Noise and Contrast-To-Noise Measurements	Annually	Category A	Section 11.0, page 38
Diagnostic Review Workstation QC	Annually	Category B	Section 12.0, page 44
Detector Ghosting (optional)	Annually	Category A	Section 13.0, page 47

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**MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY**  
*(continued)*

**Evaluation of Site's Technologist QC Program**

1. DICOM Printer Quality Control
2. Detector Flat-Field Calibration
3. Artifact Evaluation
4. Signal-To-Noise and Contrast-To-Noise Measurements
5. Phantom Image Quality Evaluation
6. Diagnostic Review Workstation QC
7. Viewbox and Viewing Conditions
8. Compression Thickness Indicator
9. Visual Checklist
10. Repeat/Reject Analysis
11. Compression

**Pass-Fail**


**Medical Physicist's Recommendations for Quality Improvement**

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## MAMMOGRAPHY EQUIPMENT EVALUATION

Site:   
 Technologist(s):

### Equipment

Room ID	<input style="width: 100%; height: 20px;" type="text"/>	Date	<input style="width: 100%; height: 20px;" type="text"/>
X-ray unit manufacturer	<input style="width: 100%; height: 20px;" type="text"/>	Model	<input style="width: 100%; height: 20px;" type="text"/>
DICOM printer manufacturer	<input style="width: 100%; height: 20px;" type="text"/>	Model	<input style="width: 100%; height: 20px;" type="text"/>
DICOM printer manufacturer	<input style="width: 100%; height: 20px;" type="text"/>	Model	<input style="width: 100%; height: 20px;" type="text"/>

### Mammography Technique Chart

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

### 1. Mammographic Unit Assembly Evaluation

- Free-standing unit is mechanically stable
- All moving parts move smoothly, without obstructions to motion
- All locks and detents work properly
- Image receptor holder assembly is free from vibrations
- Compressed breast thickness scale accurate to  $\pm 0.5$  cm, reproducible to  $\pm 2$  mm
- Patient or operator is not exposed to sharp or rough edges, or other hazards
- Operator technique control charts are posted
- Operator protected during exposure by adequate radiation shielding
- All indicator lights working properly
- Autodecompression can be overridden to maintain compression (and status displayed)
- Manual emergency compression release can be activated in the event of a power failure

**Pass-Fail-NA**


Comments:

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## 2. Collimation Assessment

Source-to-image receptor distance (SID):  cm

### Deviation between x-ray field and light field:

Target material	Circle target used	Mo   W	Mo   W	Mo   W	Mo   W
Collimator (cm)		24x29	18x24 (L)	18x24 (C)	18x24 (R)
Left edge deviation					
Right edge deviation					
Sum of left and right edge deviations					
<b>Sum as % of SID</b>					
Anterior edge deviation					
Chest edge deviation					
Sum of anterior and chest edge deviations					
<b>Sum as % of SID</b>					

**ACTION LIMIT:** If sum of left plus right edge deviations or anterior plus chest edge deviations exceeds 2% of SID, seek service adjustment.

### Deviation between x-ray field and edges of the image receptor:

Collimator (cm)	24x29	18x24 (L)	18x24 (C)	18x24 (R)
Left edge deviation				
<b>% of SID (retain sign)</b>				
Right edge deviation				
<b>% of SID (retain sign)</b>				
Anterior edge deviation				
<b>% of SID (retain sign)</b>				
Chest edge deviation				
<b>% of SID (retain sign)</b>				

**ACTION LIMIT:** If x-ray field exceeds image receptor at any side by more than 2% of SID or if x-ray field falls within image receptor on the chest wall side, seek service adjustment.

### Alignment of chest-wall edges of compression paddle and image receptor:

Paddle (cm)	24x30	24x30 (Fast)	18x24	18x24 (Fast)	Small Breast
Difference between paddle edge and image receptor					

**ACTION LIMIT:** If 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.

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### 3. Artifact Evaluation

Type of attenuator:	
Attenuator thickness:	
kVp setting:	
DICOM Printer	

#### Acylic Phantom

Image size	24 x 29	24 x 29	18 x 24	18 x 24
Target / Filter *	Mo/Mo   W/Rh	Mo/Rh   W/Ag	Mo/Mo   W/Rh	Mo/Rh   W/Ag
Focal spot	large	large	small	small
Acceptable?				
Describe				

\* Circle Target/Filter used

#### DICOM Printer

Image Size	18 x 24	24 x 29*
Acceptable?		
Describe		

\* If available on the printer

**ACTION LIMIT:** If significant artifacts are visible, contact a qualified service engineer for either the Selenia System or DICOM printer, or both, as appropriate.

#### Remarks

Date	Action

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### 4. kVp Accuracy and Reproducibility

kVp meter used:

Setting:

Nominal kVp setting						
Focal spot						
Exposure time (sec)						
mA						
mAs						
Measured kVp values:						
1						
2						
3						
4						
Mean kVp						
Standard deviation (SD)						
Additional kVp measurements (if needed):						
5						
6						
7						
8						
9						
10						
Recalculated:						
Mean kVp						
Standard deviation (SD)						
Mean kVp - Nominal kVp						
0.05 x Nominal kVp						
% Error						
Coefficient of variation (SD/Mean kVp)						

**ACTION LIMIT:**

If the mean kVp differs from the nominal by more than  $\pm 5\%$  of the nominal kVp, or if the coefficient of variation exceeds 0.02, then seek service correction.

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### 5. Beam Quality Assessment--HVL Measurement

Dosimetry system used:

Nominal kVp setting					
Nominal mAs setting					
Target material	Circle Target used	Mo   W			
Filter	Circle Filter used	Mo   Rh			
Paddle in place		Yes			
<b>Exposure measurements (mR):</b>					
No aluminum filtration, $E_{0a}$					
0.2 mm of added aluminum, $E_{0.2}$					
0.3 mm of added aluminum, $E_{0.3}$					
0.4 mm of added aluminum, $E_{0.4}$					
0.5 mm of added aluminum, $E_{0.5}$					
0.6 mm of added aluminum, $E_{0.6}$					
No aluminum filtration, $E_{0b}$					
<b>Calculations</b>					
$E_0 = (E_{0a} + E_{0b}) / 2$					
$E_{1/2} = E_0 / 2$					
Exposure greater than $E_{1/2}$ : $E_a$					
Al thickness at $E_a$ : $t_a$					
Exposure less than $E_{1/2}$ : $E_b$					
Al thickness at $E_b$ : $t_b$					
<b>Calculated HVL (mm Al)</b>					
<b>Minimum allowed</b>					
<b>Maximum allowed HVL</b>					

$$HVL = \frac{t_b \ln[2E_a/E_0] - t_a \ln[2E_b/E_0]}{\ln[E_a/E_b]}$$

**ACTION LIMIT:**

Molybdenum x-ray tubes:

**Seek service correction if measured HVL < (kVp/100) + 0.03 (in mm Al) or if measured HVL > (kVp/100) + C (in mm Al), where: C = 0.12 for Mo/Mo and C = 0.19 for Mo/Rh**

Tungsten x-ray tubes:

**Seek service correction if measured HVL < (kVp/100) + 0.03 (in mm Al)**

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## 6. System Limiting Spatial Resolution

X-ray Tube Manufacturer:

Model #

Nominal focal spot size (mm)	
Target material	
Nominal kVp setting	
Nominal mA setting	
mAs	
<b>Limiting resolution in cycles per mm</b>	

**ACTION LIMIT:**

If limiting resolution with the bars at 45° relative to the anode-cathode axis is not greater than 7 cycles/mm, contact a qualified service engineer.

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## 7a. Automatic Exposure Control (AEC) Function Performance for Systems Equipped with a Molybdenum X-Ray Tube

AEC Position:

Exposure Compensation Step:

### Performance Capability

Contact Imaging, LFS with Grid						
Phantom Thickness	AEC Mode	Filter	kVp	mAs	Exp Comp	Pixel Value*
2 cm						
4 cm						
6 cm						
8 cm						
Magnification Imaging, SFS without Grid						
4 cm						
Mean Pixel Value	Pixel Value Range		Allowed Pixel Value			
	to		to			

\*Pixel Value = ROI mean - DC offset (50)

**Action Limit:** If the pixel value of each individual image corresponding to a breast thickness between 2 and 8 cm at any operating mode varies more than 10% of the mean pixel value computed for all tested breast thicknesses and operating modes, seek service.

### Exposure Compensation

Mean Pixel Value at Step 0:

Contact Imaging, LFS with Grid							
Phantom Thickness	AEC Mode	Exp Comp	Pixel Value*	Ratio **	Allowed Ratio**		
4 cm		-3			0.50	to	0.61
4 cm		-2			0.63	to	0.77
4 cm		-1			0.77	to	0.94
4 cm		0					
4 cm		0					
4 cm		0					
4 cm		+1			1.04	to	1.27
4 cm		+2			1.17	to	1.43
4 cm		+3			1.31	to	1.60
4 cm		+4			1.44	to	1.76

\*Pixel Value = ROI mean - DC offset (50)

\*\*Pixel value at given step divided by mean pixel value at step 0

**Action Limit:** If the pixel value at each exposure compensation step results in a ratio outside the allowed range, seek service.

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## 7b. Automatic Exposure Control (AEC) Function Performance for Systems Equipped with a Tungsten X-Ray Tube

AEC Position:   
 Exposure Compensation Step:

**Performance Capability**

Contact Imaging, LFS with Grid								
Phantom Thickness	AEC Mode	Filter	kVp	mAs	Exp Comp Step	Pixel Value	CNR Correction Factor	Corrected Pixel Value*
2 cm								
4 cm								
6 cm								
8 cm								
Magnification Imaging, SFS without Grid								
4 cm								
Mean Pixel Value	Pixel Value Range		Allowed Pixel Value					
	to		to					

\*Pixel Value = (ROI mean - DC offset (50)) / CNR Correction Factor

**Action Limit:**            **If the corrected pixel value of each individual image corresponding to a breast thickness between 2 and 8 cm at any operating mode varies more than 10% of the mean pixel value computed for all tested breast thicknesses and operating modes, seek service.**

**Exposure Compensation**

Mean Pixel Value at Step 0:

Contact Imaging, LFS with Grid							
Phantom Thickness	AEC Mode	Exp Comp	Pixel Value*	Ratio **	Allowed Ratio**		
4 cm		-3			0.50	to	0.61
4 cm		-2			0.63	to	0.77
4 cm		-1			0.77	to	0.94
4 cm		0					
4 cm		0					
4 cm		0					
4 cm		+1			1.04	to	1.27
4 cm		+2			1.17	to	1.43
4 cm		+3			1.31	to	1.60
4 cm		+4			1.44	to	1.76

\*Pixel Value = ROI mean - DC offset (50)

\*\*Pixel value at given step divided by mean pixel value at step 0

**Action Limit:**            **If the pixel value at each exposure compensation step results in a ratio outside the allowed range, seek service.**

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### 8. Breast Entrance Exposure, AEC Reproducibility, and Average Glandular Dose

Imaging mode:	Digital	SID (cm):	66
Field Restriction:		Source-detector distance (cm):	
		Source-bucky distance (cm):	
		Dosimeter used:	
		Energy correction factor:	

Breast thickness (cm)	4.5			
Phantom				
Nominal kVp setting				
Target material*	Mo   W			
Filter				
AEC Mode				
AEC Position				
Exp. Compensation Step				
Measured HVL (mm Al)				

\* Circle Target used

#### Breast Entrance Exposure

	R	mAs	R	mAs	R	mAs	R	mAs
Exposure #1								
Exposure #2								
Exposure #3								
Exposure #4								
Mean values								
Standard deviations (SD)								
Coefficient of variation (CV)								

**ACTION LIMIT:** If coefficient of variation for either R or mAs exceeds 0.05, seek service.

#### Average Glandular Dose:

Inv Sq corrected skin exp				
Dose conversion factor from Tables 1-3 (mrad/R)				
Computed average glandular dose (mrad)				

**ACTION LIMIT:** If average glandular dose exceeds 300 mrad (3 mGy) for 4.5 cm effective breast thickness, seek service or technique adjustment.

*Corrective action must be taken before further examinations are performed if the test results fail MQSA regulations.*

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## 9. Radiation Output Rate

Imaging mode:  
Field Restriction:

Digital

SID (cm):  
Source-detector distance (cm):  
Source-bucky distance (cm):  
Dosimeter used:  
Energy correction factor:

66

### Radiation Output Rate: Molybdenum system

	kVp	Anode	Filter	SID (cm)	Exp (mR)	mAs	Time (sec)	Exp Rate (mR/s)	Air Kerma (mGy/s)
4.5 cm above breast support	28	Mo	Mo						
	28	Mo	Mo						

$$\text{Dose Rate (mGy/sec)} = \text{Exp Rate (mR/s)} \times 0.00873 \text{ mGy/mR}$$

**ACTION LIMIT:** Seek service is If output rate is less than 7.0 mGy/s (800 mR/s).

### Radiation Output Rate: Tungsten system

	kVp	Anode	Filter	SID (cm)	Exp (mR)	mAs	Time (sec)	Exp Rate (mR/s)	Air Kerma (mGy/s)
4.5 cm above breast support	28	W	Rh						
	28	W	Rh						

$$\text{Dose Rate (mGy/sec)} = \text{Exp Rate (mR/s)} \times 0.00873 \text{ mGy/mR}$$

**ACTION LIMIT:** Seek service is If output rate is less than 2.0 mGy/s (230 mR/s).

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## 10. Phantom Image Quality Evaluation

Phantom used:

	Previous Image	Current Image	Comments
Date			
kVp setting			
mAs setting			
Number of fibers seen			
<b>Fibers seen after deduction</b>			
<b>Fiber change</b>			
Number of speck groups seen			
<b>Speck groups after deduction</b>			
<b>Speck group change</b>			
Number of masses seen			
<b>Masses seen after deduction</b>			
<b>Mass change</b>			

### ACTION LIMITS:

The largest 5 fibers, 4 spec groups and 4 masses must be visible. There may be small fluctuations in scoring of the fibers and masses due to phantom variations. If the fiber score is 4.5 and or the mass score is 3.5, then examine the SNR and high contrast resolution of the system. If both those exceed recommended criteria, then a total score of 4.5 fibers, 4.0 specs and 3.5 masses is acceptable.

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## 11. Signal-To-Noise And Contrast-To-Noise Measurements

	Current	Last	Comment
Date			
Phantom Serial Number			
Selected kVp			
Selected mAs			
Selected Filter			
Background Mean Value			
Background standard deviation			
<b>Signal-To-Noise Ratio</b>			
Mean value on top of disk			
Standard deviation on top of disk			
<b>Contrast-To-Noise ratio</b>			
<b>CNR difference</b>			

**ACTION LIMIT:** The SNR should be equal to at least 40 and the CNR should not change by more than  $\pm 15\%$ . Corrective action shall be taken before any further examinations are performed if these limits are not met.

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## 12. Diagnostic Review Workstation QC

Date: \_\_\_\_\_  
 Serial Number: \_\_\_\_\_  
 Photometer Serial Number: \_\_\_\_\_

CRT Display	Left Monitor	Right Monitor	Comments
Monitor Serial Number			
White Level Performance	cd/m <sup>2</sup>	cd/m <sup>2</sup>	
Black Level Performance	cd/m <sup>2</sup>	cd/m <sup>2</sup>	
Quality Level Performance	%	%	
Uniformity Performance	%	%	

**ACTION LIMIT:** The white level shall not be different from the monitor calibration level by more than 6%. The black level shall not exceed 1 cd/m<sup>2</sup>. The quality level performance shall not exceed 10%. The uniformity performance shall not exceed 15%.

LCD Display	Left Monitor	Right Monitor	Comments
Monitor Serial Number			
White Level Performance	cd/m <sup>2</sup>	cd/m <sup>2</sup>	
Quality Level Performance	%	%	

**ACTION LIMIT:** The white level shall not be different from the monitor calibration level by more than 6%. The quality level performance shall not exceed 10%.

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### 13. Detector Ghosting Form (Optional)

**Test Exposures**

	Filter	kVp	Exposure Step	mAs
Exposure 1				
Exposure 2				

Region 1	Region 2	Region 3	Ghost Image Factor

**Remarks**

Date	Comments

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## Appendix B—QC Forms for the Radiologic Technologist



If electronic forms or forms other than the forms listed in this appendix are used with MAN-01476 Revision 002, it is the responsibility of the user to verify that the alternative forms are equivalent to the forms printed in this manual.

*Table B-1: Quality Control Tests To be Performed by the Radiologic Technologist on All Selenia FFDM Systems*

QC Test Procedure	Frequency	FORMS		Chapter 3
		1999 ACR QC Manual	Lorad Selenia FFDM	
DICOM Printer Quality Control	Weekly		✓	Section 1.0, page 52
Detector Flat-Field Calibration	Weekly		✓	Section 2.0, page 56
Artifact Evaluation	Weekly		✓	Section 3.0, page 58
Signal-To-Noise and Contrast-To-Noise Measurements	Weekly		✓	Section 4.0, page 63
Phantom Control Chart for Printer and Diagnostic Review Workstation	Weekly		✓	Section 5.0, page 70
Compression Thickness Indicator	Biweekly		✓	Section 6.0, page 75
Diagnostic Review Workstation QC	Weekly		✓	Section 7.0, page 76
Viewbox and Viewing Conditions	Weekly	✓		Section 8.0, page 80
Visual Checklist	Monthly	✓		Section 9.0, page 81
Repeat/Reject Analysis	Quarterly		✓	Section 10.0, page 82
Compression	Semiannually	✓		Section 11.0, page 84

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## Diagnostic Review Workstation QC

Serial Number: \_\_\_\_\_

Year:					
Date:					
Initials:					
Pass/Fail:					

Year:					
Date:					
Initials:					
Pass/Fail:					

Year:					
Date:					
Initials:					
Pass/Fail:					

Year:					
Date:					
Initials:					
Pass/Fail:					

**Remarks**

Date	Action

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### Detector Flat Field Calibration

Serial Number: \_\_\_\_\_

Year:				
Date:				
Initials:				
Completed:				

Year:				
Date:				
Initials:				
Completed:				

Year:				
Date:				
Initials:				
Completed:				

Year:				
Date:				
Initials:				
Completed:				

**Remarks**

Date	Action

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### Artifact Evaluation

Acquisition Workstation

Year:											
Date:											
Initials:											
Attenuator:	Acrylic		Acrylic		Acrylic		Acrylic		Acrylic		
kVp:											
mAs:											
<input type="checkbox"/> Filter Mo:	Mo	Rh	Mo	Rh	Mo	Rh	Mo	Rh	Mo	Rh	
<input type="checkbox"/> Filter W:	Rh	Ag	Rh	Ag	Rh	Ag	Rh	Ag	Rh	Ag	
Focal Spot:	LFS	LFS	LFS	LFS	LFS	LFS	LFS	LFS	LFS	LFS	
Artifacts:											
Acceptable?											

Printed Image Test Pattern

Film Size:										
Year:										
Date:										
Initials:										
Artifacts:										
Acceptable?										

**Remarks**

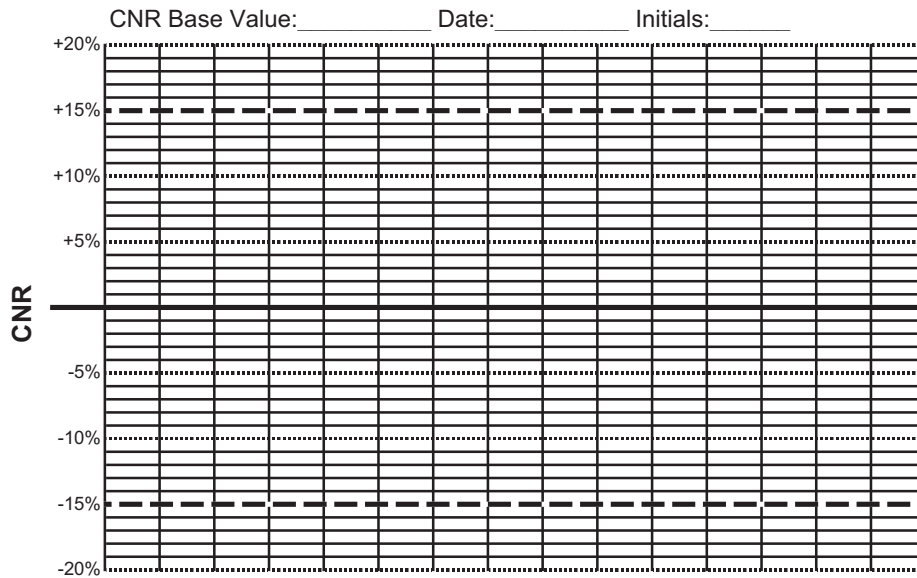
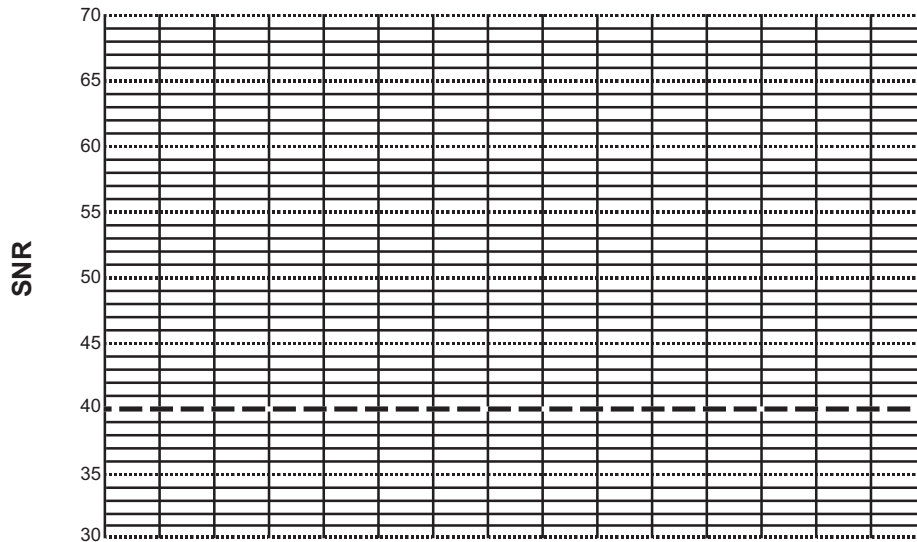
Date	Action

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### Signal-To-Noise Ratio (SNR) and Contrast-To-Noise Ratio (CNR) Control Chart

Year:

Month:																				
Day:																				
Initials:																				
kVp:																				
mAs:																				



CNR Base Value: \_\_\_\_\_ Date: \_\_\_\_\_ Initials: \_\_\_\_\_

Remarks	Date	Action

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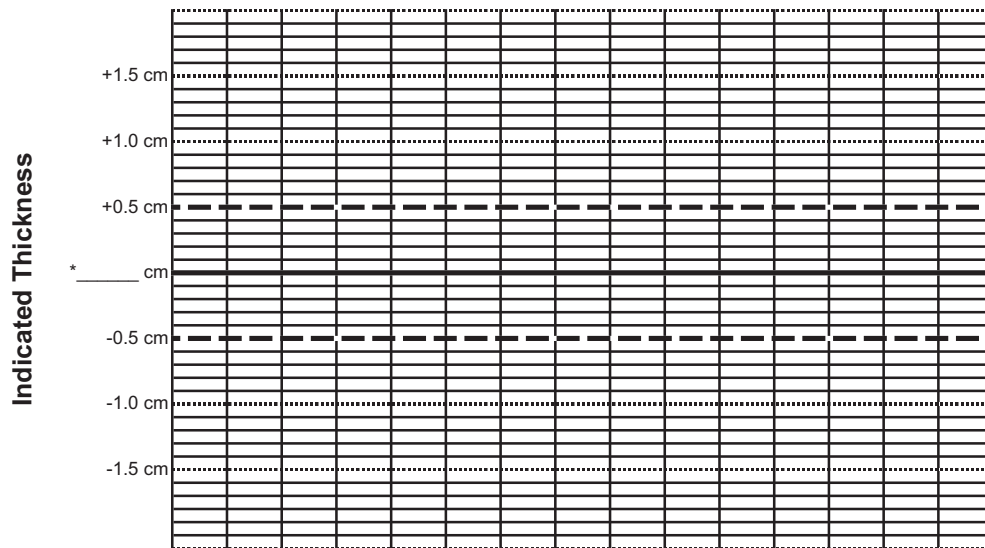


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### Compression Thickness Indicator

Year:																				
Month:																				
Date:																				
Initials:																				

Phantom SN: \_\_\_\_\_



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

**Remarks**

Date	Action

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### Diagnostic Review Workstation QC

Serial Number: \_\_\_\_\_

Year:				
Date:				
Initials:				
Pass/Fail:				

Year:				
Date:				
Initials:				
Pass/Fail:				

Year:				
Date:				
Initials:				
Pass/Fail:				

Year:				
Date:				
Initials:				
Pass/Fail:				

**Remarks**

Date	Action

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### Mammography Reject Analysis

From: \_\_\_\_\_ To: \_\_\_\_\_ Technologist: \_\_\_\_\_

Cause	Number of Exposures						Subtotals	% of Rejects
	Left CC	Right CC	Lef MLO	Right MLO	Left Other	Right Other		
1. Positioning								
2. Patient Motion								
3. Detector Underexposure (excessively noisy images)								
4. Improper Detector Exposure (Saturation)								
5. Artifacts								
6. Incorrect Patient ID								
7. X-Ray Equipment Failure								
8. Software Failure								
9. Blank Image								
10. Wire Localization								
11. Q.C.								
12. Aborted AEC Exposure								
13. Other Reasons								
						Total Reject Reasons		
								% of Total Reject Reasons per Total Exposures
						Total Reject Reasons:		
						Total Exposures:		
Remarks:	Percentage of Rejects may be greater than 100% because a user may select multiple reject reasons.							
Corrective Action:								

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### Mammography Repeat Analysis

From: \_\_\_\_\_ To: \_\_\_\_\_ Technologist: \_\_\_\_\_

Cause	Number of Exposures						Subtotals	% of Repeats
	Left CC	Right CC	Lef MLO	Right MLO	Left Other	Right Other		
1. Positioning								
2. Patient Motion								
3. Detector Underexposure (excessively noisy images)								
4. Improper Detector Exposure (Saturation)								
5. Artifacts								
6. Incorrect Patient ID								
7. X-Ray Equipment Failure								
8. Software Failure								
9. Blank Image								
10. Q.C.								
11. Aborted AEC Exposure								
12. Other Reasons								
						Total Repeat Reasons		
						Total Repeat Reasons:		% of Total Repeat Reasons per Total Exposures
						Total Repeat Reasons:		
						Total Exposures:		
Remarks:								
Corrective Action:								

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## Appendix C—Dose Conversion Tables for the Medical Physicist

The following note applies to the tables in this appendix.



**Note...**

*The average glandular dose computed using the 1999 ACR Mammography Quality Control Manual, “Breast Entrance Exposure, AEC Reproducibility, Average Glandular Dose, and Radiation Output Rate” section only applies to a 4.2 cm compressed breast of 50-50 tissue composition. Conversion factors for other breast thicknesses and compositions may be found in the literature: Dance DR. “Monte Carlo calculation of conversion factors for the estimation of mean glandular dose.” Phys Med Biol 35: 1211-1219 (1990); Wu X, Gingold EL, Barnes GT and Tucker DM. “Normalized average glandular dose in molybdenum target – rhodium filter and rhodium target – rhodium filter mammography.” Radiology 193: 83-89 (1994); Sobol WT and Wu X. “Parametrization of mammography normalized average glandular dose tables.” Med Phys 24: 547:554 (1997). The following references are also relevant to dose computations in mammography: John Boone, “Normalized glandular dose (DgN) coefficients for arbitrary x-ray spectra in mammography: computer-fit values of Monte Carlo data”, Medical Physics, 29(5): 869-875 (2002); John Boone et al, “Molybdenum, Rhodium, and Tungsten anode spectral models using interpolating polynomials with application to mammography”, Medical Physics, 24(12):1863-1874 (1997); John Boone, “Glandular breast dose for monoenergetic and high-energy x-ray beams: Monte Carlo assessment”, Radiology, 213:23-37 (1999).*

**Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure  
W/Rh Target-Filter Combination with 4.2-cm 50/50 Breast**

HVL	X-ray Tube Voltage (kVp)												
	22	23	24	25	26	27	28	29	30	31	32	33	
0.300	152	157	163	166	170	173	175	177	179	182	184	187	
0.325	163	169	174	177	181	183	186	188	190	192	195	197	
0.350	175	180	185	188	191	194	196	198	200	202	205	207	
0.375	186	191	196	199	202	205	207	209	211	213	215	218	
0.400	198	203	207	210	213	215	217	219	221	223	226	228	
0.425	209	214	218	221	224	226	228	230	232	234	236	238	
0.450	221	226	230	232	235	237	238	240	242	244	246	248	
0.475	233	237	241	243	245	247	249	251	253	254	256	258	
0.500	244	248	252	254	256	258	260	261	263	265	267	269	
0.525	256	260	263	265	267	269	270	272	273	275	277	279	
0.550	267	271	274	276	278	279	281	282	284	285	287	289	
0.575	279	282	285	287	288	290	291	292	294	296	297	299	
0.600	290	293	296	297	299	300	301	303	304	306	308	310	
0.625	301	304	306	308	309	310	312	313	315	316	318	320	
0.650	312	314	317	318	320	321	322	323	325	326	328	330	
0.675	322	325	327	328	330	331	332	333	335	336	338	340	
0.700	333	335	337	339	340	341	342	343	345	346	348	350	
0.725	342	345	347	348	349	351	352	353	354	356	358	360	
0.750	352	355	357	358	359	360	361	363	364	366	368	369	
0.775	361	365	367	368	369	370	371	372	374	375	377	379	
0.800	369	374	376	377	378	379	380	382	383	385	387	389	



**Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure  
 W/Ag Target-Filter Combination with 4.2-cm 50/50 Breast**

HVL	X-ray Tube Voltage (kVp)												
	27	28	29	30	31	32	33	34	35	36	37	38	39
0.400	222	226	229	231	234	236	239	241	244	246	248	250	252
0.425	233	236	239	242	244	246	248	251	253	256	258	260	262
0.450	244	247	249	252	254	256	258	260	263	265	267	269	271
0.475	254	257	260	262	264	266	268	270	273	275	277	279	281
0.500	265	267	270	272	274	276	278	280	282	284	286	288	290
0.525	275	278	280	282	284	286	288	290	292	294	296	298	300
0.550	286	288	290	292	294	296	298	299	301	303	305	307	309
0.575	296	298	300	302	304	305	307	309	311	313	315	317	318
0.600	306	308	310	312	313	315	317	319	320	322	324	326	328
0.625	316	318	320	322	323	325	326	328	330	332	333	335	337
0.650	326	328	330	331	333	334	336	338	339	341	343	344	346
0.675	336	338	339	341	342	344	345	347	349	350	352	354	355
0.700	346	348	349	350	352	353	355	356	358	359	361	363	364
0.725	356	357	358	360	361	362	364	365	367	368	370	372	373
0.750	365	367	368	369	370	372	373	375	376	378	379	381	382
0.775	374	376	377	378	379	381	382	383	385	386	388	390	391
0.800	384	385	386	387	388	390	391	392	394	395	397	398	400
0.825	393	394	395	396	397	399	400	401	403	404	406	407	408
0.850	402	403	404	405	406	407	409	410	411	413	414	416	417
0.875	410	411	412	413	415	416	417	418	420	421	423	424	425
0.900	419	420	421	422	423	424	425	427	428	429	431	432	434



## Appendix D—CNR Correction Tables for Systems Equipped with a Tungsten X-Ray Tube

### AEC Table 0 (Default Dose)

#### CNR Correction Factors for Large Focal Spot

Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor
0.0	1.00	5.0	1.00	10.0	1.00
0.5	1.00	5.5	1.00	10.5	1.00
1.0	1.00	6.0	1.00	11.0	1.00
1.5	1.00	6.5	1.00	11.5	1.00
2.0	1.00	7.0	1.10	12.0	1.00
2.5	1.00	7.5	1.15	12.5	1.00
3.0	1.00	8.0	1.15	13.0	1.00
3.5	1.00	8.5	1.15	13.5	1.00
4.0	1.00	9.0	1.10	14.0	1.00
4.5	1.00	9.5	1.00	14.5	1.00

#### CNR Correction Factors for Small Focal Spot

Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor
0.0	1.00	5.0	1.00	10.0	1.00
0.5	1.00	5.5	1.00	10.5	1.00
1.0	1.00	6.0	1.00	11.0	1.00
1.5	1.00	6.5	1.00	11.5	1.00
2.0	1.00	7.0	1.00	12.0	1.00
2.5	1.00	7.5	1.00	12.5	1.00
3.0	1.00	8.0	1.00	13.0	1.00
3.5	1.00	8.5	1.00	13.5	1.00
4.0	1.00	9.0	1.00	14.0	1.00
4.5	1.00	9.5	1.00	14.5	1.00

**AEC Table 1 (Low Screening Dose)**

**CNR Correction Factors for Large Focal Spot**

Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor
0.0	1.00	5.0	1.00	10.0	1.00
0.5	1.00	5.5	1.00	10.5	1.00
1.0	1.00	6.0	1.00	11.0	1.00
1.5	1.00	6.5	1.00	11.5	1.00
2.0	1.00	7.0	1.10	12.0	1.00
2.5	1.00	7.5	1.15	12.5	1.00
3.0	1.00	8.0	1.15	13.0	1.00
3.5	1.00	8.5	1.15	13.5	1.00
4.0	1.00	9.0	1.10	14.0	1.00
4.5	1.00	9.5	1.00	14.5	1.00

**CNR Correction Factors for Small Focal Spot**

Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor
0.0	1.00	5.0	1.00	10.0	1.00
0.5	1.00	5.5	1.00	10.5	1.00
1.0	1.00	6.0	1.15	11.0	1.00
1.5	1.00	6.5	1.15	11.5	1.00
2.0	1.00	7.0	1.15	12.0	1.00
2.5	1.00	7.5	1.15	12.5	1.00
3.0	1.00	8.0	1.15	13.0	1.00
3.5	1.00	8.5	1.15	13.5	1.00
4.0	1.00	9.0	1.15	14.0	1.00
4.5	1.00	9.5	1.15	14.5	1.00

**AEC Table 2 (Limited Dose)**

**CNR Correction Factors for Large Focal Spot**

Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor
0.0	1.00	5.0	1.15	10.0	1.00
0.5	1.00	5.5	1.15	10.5	1.00
1.0	1.00	6.0	1.15	11.0	1.00
1.5	1.00	6.5	1.15	11.5	1.00
2.0	1.00	7.0	1.15	12.0	1.00
2.5	1.00	7.5	1.15	12.5	1.00
3.0	1.00	8.0	1.15	13.0	1.00
3.5	1.00	8.5	1.15	13.5	1.00
4.0	1.00	9.0	1.15	14.0	1.00
4.5	1.00	9.5	1.15	14.5	1.00

**CNR Correction Factors for Small Focal Spot**

Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor
0.0	1.00	5.0	1.00	10.0	1.00
0.5	1.00	5.5	1.00	10.5	1.00
1.0	1.00	6.0	1.00	11.0	1.00
1.5	1.00	6.5	1.00	11.5	1.00
2.0	1.00	7.0	1.00	12.0	1.00
2.5	1.00	7.5	1.00	12.5	1.00
3.0	1.00	8.0	1.00	13.0	1.00
3.5	1.00	8.5	1.00	13.5	1.00
4.0	1.00	9.0	1.00	14.0	1.00
4.5	1.00	9.5	1.00	14.5	1.00

**AEC Table 3 (Auxiliary)**

**CNR Correction Factors for Large Focal Spot**

Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor
0.0	1.00	5.0	1.00	10.0	1.00
0.5	1.00	5.5	1.00	10.5	1.00
1.0	1.00	6.0	1.00	11.0	1.00
1.5	1.00	6.5	1.00	11.5	1.00
2.0	1.00	7.0	1.00	12.0	1.00
2.5	1.00	7.5	1.00	12.5	1.00
3.0	1.00	8.0	1.00	13.0	1.00
3.5	1.00	8.5	1.00	13.5	1.00
4.0	1.00	9.0	1.00	14.0	1.00
4.5	1.00	9.5	1.00	14.5	1.00

**CNR Correction Factors for Small Focal Spot**

Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor	Compression Thickness	CNR Correction Factor
0.0	1.00	5.0	1.00	10.0	1.00
0.5	1.00	5.5	1.00	10.5	1.00
1.0	1.00	6.0	1.00	11.0	1.00
1.5	1.00	6.5	1.00	11.5	1.00
2.0	1.00	7.0	1.00	12.0	1.00
2.5	1.00	7.5	1.00	12.5	1.00
3.0	1.00	8.0	1.00	13.0	1.00
3.5	1.00	8.5	1.00	13.5	1.00
4.0	1.00	9.0	1.00	14.0	1.00
4.5	1.00	9.5	1.00	14.5	1.00



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