SIEMENS

Quality Control Manual
MAMMOMAT Inspiration
VA10

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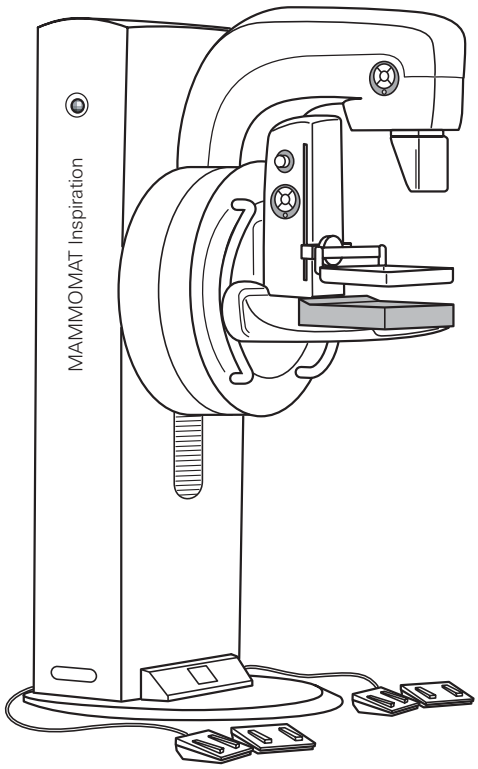

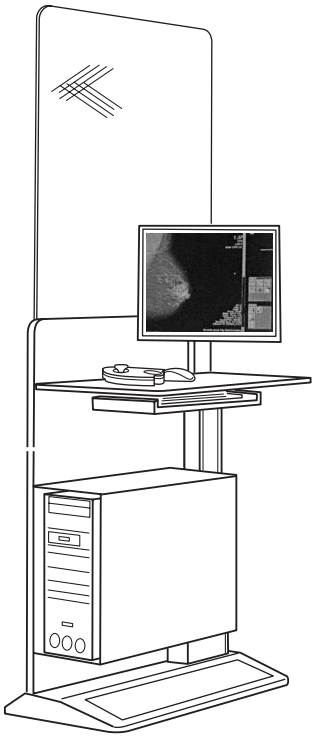

CE 0123

The original version of this manual was written in English language.

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List of Common Abbreviations

AEC	Automatic Exposure Control
AWS	Acquisition Work station
FD	Flat Detector
kV	Kilovolt
mAs	milliAmperesecond
MEE	Mammography Equipment Evaluation
Mo/Mo	Molybdenum/Molybdenum
Mo/Rh	Molybdenum/Rhodium
MP	Medical Physicist
PMMA	Poly Methyl Methacrylate
ROI	Region of Interest
SMPTE	Society of Motion Picture and Television Engineers
SNR	Signal-to-Noise-Ratio
T	Technologist
W/Rh	Tungsten/Rhodium

Abbreviations

For notes

Introduction

Mammography Equipment Evaluation (MEE) - Medical Physicist (MP)

The MEE tests of the MAMMOMAT Inspiration should be performed whenever a new MAMMOMAT Inspiration system has been installed and whenever changes that might affect performance have been made to an existing system. For example, the MEE tests shall be performed if the system has been disassembled and reassembled or if major components have been changed or repaired.

The MEE tests of the MAMMOMAT Inspiration involve performance of all QC procedures in this Quality Control Manual, ensuring that a basic minimum image quality criteria is met before the system is used on patients. For each part of the MEE tests, action levels that must be met are specified. Furthermore, the values obtained during the MEE tests are to be used as baseline values, and then referred to during future tests to determine if equipment performance is stable or changing.

Annually - Medical Physicist (MP)

These tests may be performed by the MP. The tests include comparisons to values measured during the MEE tests to ensure that performance has not degraded.

Monthly - Technologist (T)

These tests shall be done on a monthly basis. They shall be done on the first working-day of the month before patients are examined with the MAMMOMAT Inspiration system.

When Needed - Technologist (T)

These tests shall be done whenever there is suspicion of artifacts or incorrect settings to determine if patients can be examined.

Recommended Frequency of QC Tests

The following table describes when the different tests must be performed and by whom.

Test	MEE	Annually	Monthly	When needed
1. AEC Test	MP		MP	
2. Artifact Detection	MP		T	
3. Detector Uniformity	MP		T	
4. Detector Linearity	MP	MP		
5. Phantom Imaging Quality	MP		T	
6. Spatial Resolution (optional)				T
7. Mechanical Tests	MP	MP		
8. Acquisition Workstation Monitor Check	MP	MP		
9. Printer Check (optional)	MP	MP		

Table 1 Frequency of Tests

For the qualification of the printer please follow the printer manufacturer's recommendations.

Important Notes

Before performing any quality control test, be sure to be familiar with the operating instructions described in the MAMMOMAT Inspiration Operator Manual.

The enclosed test form tables can be used to document test parameters used and results obtained during each test.

Recommended Corrective Action

Whenever there is a result from a test described in this manual that fails to reach the action level stated, the problem must be detected and corrected before further examinations are performed with the system. The result shall be reported to a service engineer and proper corrective action shall be taken to address the problem.

If a result meets the action level, but a clear degradation is seen compared to the result obtained during the latest test, the system may continue to be used, but the degradation shall be reported to a service engineer, and it is recommended that corrective action be taken within 30 days.

More details are given in association with each test.

Required Documents

- MAMMOMAT Inspiration Operator Manual
- Quality Control Manual of used viewing station (optional - for systems that use softcopy review station)

Required Equipment

The measurement devices listed below must always display a valid calibration stamp to ensure compliance with the described measurement and calibration intervals.

- Lint-free, non-woven cotton or gauze (100% cotton)
- Water or lukewarm diluted aqueous solution of household dishwashing liquid
- Compression plate 24 x 30 cm^2
- Radiation shielding plate in object table size (e.g. 2 mm steel or lead plate)
- PMMA plates of 10 x 10 cm^2 and 20 mm, 30 mm, 40 mm, 50 mm, 60 mm, 70 mm thicknesses
- Collimator mountable PMMA phantom (40 mm thick)
- Dose meter for air kerma measurement usable for target/filter combinations Mo/Mo, Mo/Rh, W/Rh
- ACR (RMI 156) phantom
- Bar pattern phantom applicable for mammography
- Compressible phantom
- Stop watch
- Calibrated densitometer (option)

Prerequisites

Objective

To determine whether the detector is damaged or has dust on it and is calibrated.

Required Equipment

a) Lint-free, non-woven cotton or gauze (100% cotton)

b) Water or lukewarm diluted aqueous solution of household dishwashing liquid

Procedure

1. Wipe the detector surface with a wet lint-free, non-woven cotton cloth or cotton (100%) pad. For moistening, use water or lukewarm diluted aqeous solution of household dishwashing liquid.

NOTE!

Do not spray the unit! The cleaning fluid must under no circumstances penetrate into the unit.

2. Calibrate the detector according to the chapter *Calibrating the detector* in the MAMMOMAT Inspiration Operator Manual.

CAUTION!

Improper operation can lead to reduced image quality.

Let the MAMMOMAT Inspiration warm up for at least 30 minutes to ensure optimum results when performing an image quality test or a calibration.

CAUTION!

For startup and login, see MAMMOMAT Inspiration Operator Manual.

CAUTION!

Before starting the quality control tests the detector calibration shall be performed to ensure that the tests are based on correct detector settings, see MAMMOMAT Inspiration Operator Manual.

Performance Criteria and Corrective Action

No visual damage to the detector should be observable.

No artifacts should be visible.

Calculations

1 Statistical calculations

For all numerical calculations necessary in this quality control manual the testing person should use the formulae indicated in the following text together with a pocket calculator or appropriate software for numerical evaluations.

Preliminaries:

From the knowledge of any finite set of measurement values x_1, x_2, ..., x_N the following fundamental statistical quantities can be established.

1.1 Global average of values

$$x_{av} = \frac{x_1 + x_2 + x_3 + ... + x_N}{N}$$

x_N = each value (e.g. x_1 = value of pixel 1, x_2 = value of pixel 2)

N = number of measurement values (e.g. 6, for 6 PMMA thicknesses)

x_{av} = global average of values

1.2 Standard deviation

$$\sigma_x = \sqrt{\frac{1}{N} \cdot ((x_1 - x_{av})^2 + (x_2 - x_{av})^2 + ... + (x_N - x_{av})^2)}$$

σ_x = standard deviation

With the average value x_{av} calculated according to Global average of values.

1.3 Coefficient of variation

$$c_{var,x} = \frac{\sigma_x}{x_{av}}$$

$c_{var, x}$= coefficient of variation

With the average value x_{av} and the standard deviation σ_x calculated according to Global average of values and Standard deviation respectively.

1.4 Relative deviation from corresponding average

Each sample x_n from the set of measurements x_1, x_2, ..., x_N possesses its own relative deviation $\Delta x_{rel,\,n}$ from the average x_{av} according to the following definition:

$$\Delta x_{rel,n} = \left| \frac{x_n - x_{av}}{x_{av}} \right|$$

n = 1, 2, ..., N

$\Delta x_{rel,\,N}$= relative deviation for each value

Average value x_{av} calculated according to Global average of values.

For maximum relative deviation select highest value of all calculated relative deviations.

2 Linear correlation coefficient and offset

Calculate for quantity x = pixel value and quantity K= input air kerma value.

Assume that in total N (generally different) sample values K_1, K_2, ..., K_N for the input air kerma have been selected and the mean pixel values x_1, x_2, ..., x_N in the corresponding X-ray images have been recorded.

a) Calculate global average of all pixel values (x_{av}) and global average of all input air kerma values (K_{av})

b) Calculate average of pixel and input air kerma values $(x \cdot K)_{av}$ and K^2

$$(x \cdot K)_{av} = \frac{x_1 \cdot K_1 + x_2 \cdot K_2 + x_3 \cdot K_3 + ... + x_N \cdot K_N}{N}$$

$$(K^2)_{av} = \frac{K_1^2 + K_2^2 + K_3^2 + ... + K_N^2}{N}$$

c) Calculate standard deviation of all pixel values (σ_x) and standard deviation of all input air kerma values σ_K.

d) Calculate linear correlation coefficient R

$$R = \frac{(x \cdot K)_{av} - x_{av} \cdot K_{av}}{\sigma_x \cdot \sigma_K}$$

e) The offset (zero input signal) d_{off} of the X-ray detector is derived from

$$d_{off} = \frac{(K)^2_{av} \cdot x_{av} - (K_{av} \cdot (K \cdot x)_{av})}{\sigma_K^2}$$

3 SNR - Signal-to-noise ratio

Provided that the detector offset d_{off} is known, for each individual X-ray image (or a region-of-interest located therein) the pixel signal-to-noise ratio SNR can be calculated from the pixel value x_N of each image and the corresponding standard deviation σ_x:

$$SNR = \frac{x_N - d_{off}}{\sigma_x}$$

Test 1: AEC Test

Objective

To test the AEC security cut-off

To measure AEC stability for different object thicknesses

Required Equipment

a) Shielding plate in object table size, e.g. 2 mm steel or lead plate

b) PMMA plates of 10 x 10 cm^2 and 20 mm, 30 mm, 40 mm, 50 mm, 60 mm, 70 mm thicknesses

c) Compression plate 24 x 30 cm^2

Procedure

1. Create a new patient record in the local database.
   Fill in: Last Name: Test_One
   First Name: AEC
   Patient ID: day+time when the test is performed (example: 200707071030)
   DOB: 05 05 1955
   Gender: Other
2. Choose procedure **QC-raw**.

AEC security (step 3 - 10)

3. Select exposure technique AEC
   28 kV
   target/filter combination mostly used
   grid in
   auto decompression off
   OPCOMP off
   AEC segmentation on
   low dose mode off
4. Place shielding plate on object table.
5. Mount compression plate and perform compression.
6. Perform an exposure.
7. Check that the radiation signal lights up very shortly and exposure is interrupted, tube load is below 5 mAs.
8. Check that a warning is shown.
9. Note result in Test form Test 1.
10. Deactivate examination, remove shielding plate.

AEC stability (step 11 - 23)

11. Select exposure technique Opdose
    grid in
    auto decompression on
    OPCOMP on
    AEC segmentation on
    low dose mode off
12. Position 20 mm PMMA plate on object table according to Figure 1.

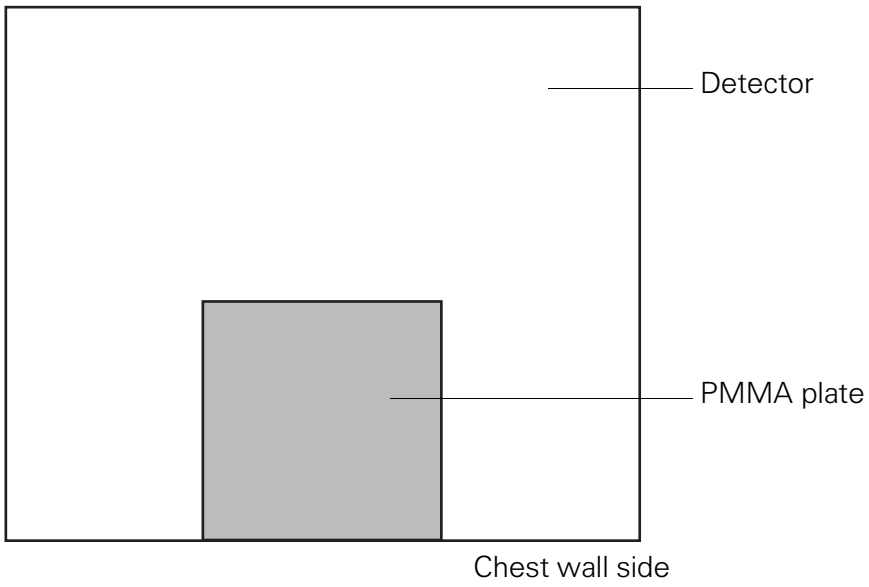

Figure 1 Placing the PMMA plate

13. Perform compression until OPCOMP is reached.
14. Perform an exposure with the Opdose program according to PMMA thickness, note exposure data.
15. Select **Tools > AEC region** to show the AEC region of the acquired image.
16. Check that the AEC region of the acquired image remains inside the edges of the PMMA plate.

17. Define a ROI within the AEC region according to Figure 2.

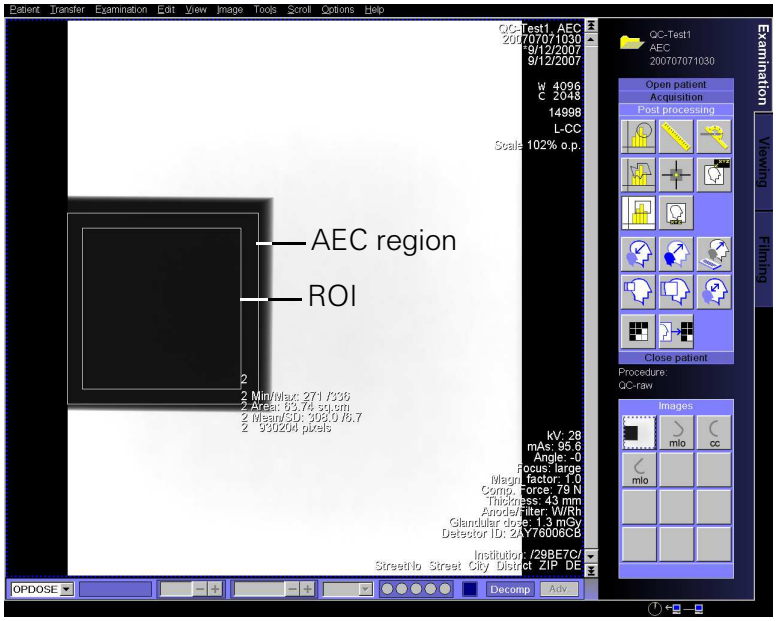

Figure 2 ROI within the AEC region

18. Note the displayed mean pixel value in Test form Test 1.
19. Repeat steps 11 to 18 for PMMA thicknesses 30 mm, 40 mm, 50 mm, 60 mm, and 70 mm
20. Close examination.
21. Calculate global average of all mean pixel values over all PMMA thicknesses
    - derive standard deviation of mean pixel values from global average over all PMMA thicknesses
    - derive resulting coefficient of variation (see Calculations, page 12)
    - Note results in Test form Test 1
22. For each PMMA thickness calculate the relative deviation between the detected mean pixel value and the global average of all mean pixel values and note result in Test form Test 1.
23. Identify and note the maximum relative deviation out of the results from step 22.

Performance Criteria and Corrective Action

The AEC security cut-off mechanism shall work properly in such a way that in cases where no radiation reaches the detector no tube load beyond 5 mAs can be delivered.

The AEC segmentation should be able to select an AEC region that:

- completely remains inside the shadow of the PMMA plates, and
- whose borders are close to the ones of the PMMA.

The coefficient of variation for the mean pixel values should not exceed 5 % when going through all PMMA thicknesses.

The maximum relative deviation for the mean pixel values should not exceed 10 % when going through all PMMA thicknesses.

Test form Test 1

	Passed	Failed
AEC security cut-off	❑	❑
Warning shown	❑	❑

Thick-ness of PMMA (mm)	Voltage (kV)	Tube load (mAs)	AEC region inside PMMA plates		Mean pixel value	Relative deviation of mean pixel value from global average
			Passed	Failed		
20			❑	❑		
30			❑	❑		
40			❑	❑		
50			❑	❑		
60			❑	❑		
70			❑	❑		

		Performance Criteria	Passed	Failed
Global average of mean pixel values over all PMMA thicknesses				
Standard deviation of mean pixel values from global aver-age over all PMMA thick-nesses				
Resulting coefficient of variation		< ± 5 %	❑	❑
Maximum relative deviation		< ± 10 %	❑	❑

Test 2: Artifact Detection

Objective

To determine if the detector is dusty, damaged or shows artifacts of any kind.

Required Equipment

a) Collimator mountable PMMA phantom

b) Compression plate 24 x 30 cm^2

Procedure

1. Create a new patient record in the local database.
   Fill in: Last Name: Test_Two
   First Name: Artifact Detection
   Patient ID: day+time when the test is performed (example: 200707071030)
   DOB: 05 05 1955
   Gender: Other
2. Select procedure **QC-raw**.
3. Select exposure technique MANUAL
   28 kV
   90 mAs
   target/filter Mo/Mo
   grid in
   auto decompression off
   OPCOMP off
   Change all projection views to L-CC
4. Mount PMMA phantom close to collimator.
5. Mount compression plate and perform compression.
6. Perform exposure.
7. Look at the image for clinically relevant artifacts, e.g. defective pixels, clusters of defective pixels or defective lines/columns. Use magnification tool, select acquisition size, adapt windowing values. If problems regarding viewing conditions appear send image to viewing station for further evaluation.
8. Repeat step 3 to 7 for target/filter combinations Mo/Rh and W/Rh.
9. If artifacts are visible make sure that the detector is free of dust, perform a new calibration, and repeat test.

10. If artifacts are still visible on any image after step 9 call Siemens customer service.
11. Note result in Test form Test 2.
12. Close examination.

Performance Criteria and Corrective Action

No clinically relevant artifacts shall be visible on image.

Test form Test 2

	Target/filter combination Mo/Mo		Target/filter combination Mo/Rh		Target/filter combination W/Rh	
	Passed	**Failed**	**Passed**	**Failed**	**Passed**	**Failed**
No clinically relevant artifacts detected	❑	❑	❑	❑	❑	❑

Test 3: Detector Uniformity

Objective

To measure the uniformity of the detector response over its entire surface

Required Equipment

a) Collimator mountable PMMA phantom

b) Compression plate 24 x 30 cm^2

Procedure

1. Create a new patient record in the local database.
   Fill in: Last Name: Test_Three
   First Name: Detector Uniformity
   Patient ID: day+time when the test is performed (example: 200707071030)
   DOB: 05 05 1955
   Gender: Other
2. Select procedure **QC-raw**.
3. Mount PMMA phantom close to collimator.
4. Mount compression plate and perform compression.
5. Select exposure technique AEC
   28 kV
   target/filter combination Mo/Mo
   grid in
   auto decompression off
   OPCOMP off
   AEC segmentation off
   low dose mode off
   Change all projection views to L-CC
6. Perform exposure.

7. Define an ROI with a size of approximately 20 x 20 mm^2 in arbitrary position inside the image.
8. Move this ROI subsequently to each of the five positions indicated in Figure 3. If helpful switch off image text, menu **View > No Text**.

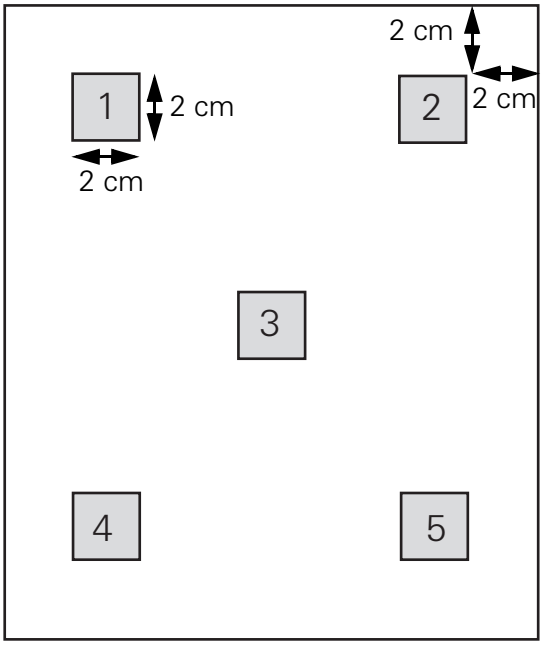

Figure 3 ROIs on the detector

9. For each of these five ROI positions note the corresponding mean pixel value in Test form Test 3.
10. Calculate global average of mean pixel values over all five ROIs.
11. For each ROI calculate relative deviation from global average (see Relative deviation from corresponding average, page 13).
12. Identify and note the maximum relative deviation out of the results from step 11.
13. Repeat steps 6 to 12 for target/filter combinations Mo/Rh and W/Rh.
14. Close examination.

Performance Criteria and Corrective Action

The maximum relative deviation from global average should not exceed 7 %.

Test form Test 3

Target/filter combination **Mo/Mo**

	Mean pixel value	Relative deviation from global average
ROI 1		
ROI 2		
ROI 3		
ROI 4		
ROI 5		
Global average of mean pixel values		

		Performance Criterion	Passed	Failed
Maximum relative deviation		≤ 7 %	❑	❑

Target/filter combination **Mo/Rh**

	Mean pixel value	Relative deviation from global average
ROI 1		
ROI 2		
ROI 3		
ROI 4		
ROI 5		
Global average of mean pixel values		

		Performance Criterion	Passed	Failed
Maximum relative deviation		≤ 7 %	❑	❑

Test 3: Detector Uniformity

Target/filter combination **W/Rh**

	Mean pixel value	**Relative deviation from global average**
ROI 1		
ROI 2		
ROI 3		
ROI 4		
ROI 5		
Global average of mean pixel values		

		Performance Criterion	**Passed**	**Failed**
Maximum relative deviation		≤ 7 %	❑	❑

Test 4: Detector Linearity

Objective

To measure the linearity of the detector response against input air kerma for all target/filter combinations.

To measure the noise of the system

Required Equipment

a) Collimator mountable PMMA phantom

b) Dose meter for air kerma measurement usable for target/filter combinations Mo/Mo, Mo/Rh, W/Rh

c) Compression plate 24 x 30 cm^2

Procedure

1. Create a new patient record in the local database.
   Fill in: Last Name: Test_Four
   First Name: Detector Linearity
   Patient ID: day+time when the test is performed (example: 200707071030)
   DOB: 05 05 1955
   Gender: Other
2. Select procedure **QC-raw**.
3. Select exposure technique Manual,
   28 kV
   5 mAs
   target/filter combination Mo/Mo
   grid in
   auto decompression off
   OPCOMP off
   AEC segmentation off
   low dose mode off
4. Mount PMMA phantom close to collimator.

5. Position dose meter on object table according to Figure 4.

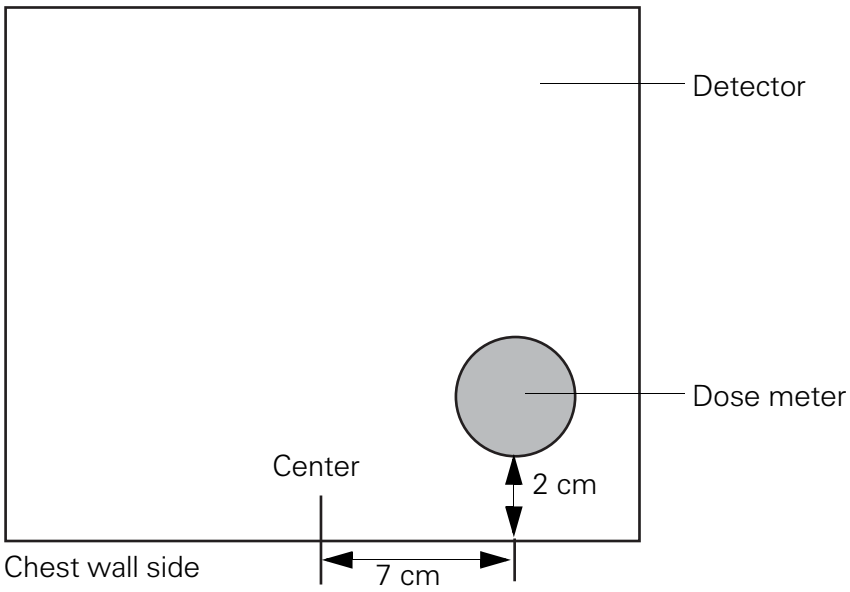

Figure 4 Positioning the dose meter

6. Mount compression plate and perform compression.
7. Perform exposure.
8. Note measured input air kerma in Test form Test 4.
9. Define a ROI according to Figure 5, making sure that there is a distance of at least 2 cm between ROI and dose meter.

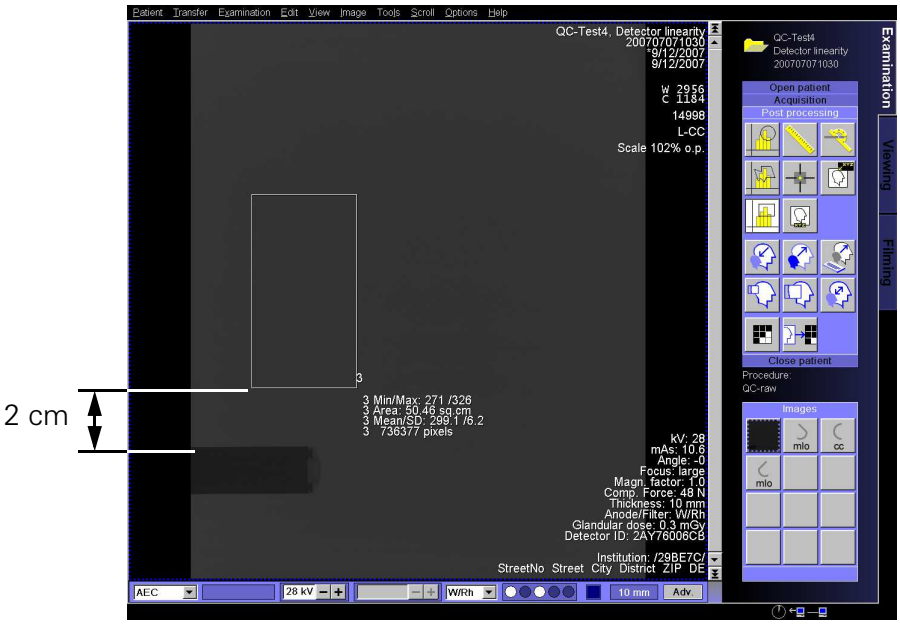

Figure 5 ROI Positioning

10. Note mean pixel value and standard deviation (SD) inside ROI.
11. Repeat steps 7 to 10 for all tube load values in Test form Test 4.
12. Calculate the linear correlation coefficient between input air kerma and resulting mean pixel value (see Linear correlation coefficient and offset, page 13).
13. Calculate detector offset for mean pixel value versus input air kerma (see Linear correlation coefficient and offset, page 13).
14. For each of the images generated in steps 7 to 11 calculate the SNR in the corresponding evaluation ROIs by taking into account the result for the detector offset from previous step (step 13); note SNR into corresponding column in Test form Test 4.
15. Repeat steps 7 to 14 for target/filter combinations Mo/Rh and W/Rh. Note corresponding results in Test form Test 4.
16. Close examination.

Performance Criteria and Corrective Action

The linear correlation coefficient should be greater than 0.99.

The Offset should be between 45 and 55.

The SNR should exceed indicated lower thresholds.

Test form Test 4

Target/filter combination: **Mo/Mo**, tube voltage 28 kV

Exposure No.	Tube load (mAs)	Air kerma (mGy)	Mean pixel value	SNR
1	5			
2	10			
3	20			
4	40			
5	63			
6	80			
7	110			
8	180			
9	280			
10	360			

	Performance Criteria	Passed	Failed
Detector offset _____	40 - 60	❑	❑
Linear correlation coefficient _____	0.99	❑	❑

Target/filter combination: **Mo/Rh**, tube voltage 28 kV

Exposure No.	Tube load (mAs)	Air kerma (mGy)	Mean pixel value	SNR
1	5			
2	10			
3	20			
4	40			
5	63			
6	80			
7	110			
8	180			
9	280			
10	360			

	Performance Criteria	Passed	Failed
Detector offset _____	40 - 60	❑	❑
Linear correlation coefficient _____	0.99	❑	❑

Test 4: Detector Linearity

Target/filter combination: **W/Rh**, tube voltage 28 kV

Exposure No.	Tube load (mAs)	Air kerma (mGy)	Mean pixel value	SNR
1	5			
2	10			
3	20			
4	40			
5	63			
6	80			
7	110			
8	180			
9	280			
10	360			

	Performance Criteria	Passed	Failed
Detector offset _____	40 - 60	❑	❑
Linear correlation coefficient _____	0.99	❑	❑

Test 5: Phantom Imaging Quality

Objective

To ensure that adequate phantom imaging quality is achieved

Required Equipment

a) ACR (RMI 156) phantom

b) Compression plate 24 x 30 cm^2

Procedure

1. Create a new patient record in the local database.
   Fill in: Last Name: Test_Five
   First Name: Phantom Imaging Quality
   Patient ID: day+time when the test is performed (example: 200707071030)
   DOB: 05 05 1955
   Gender: Other
2. Select procedure **QC-raw**.
3. Select exposure technique AEC
   28 kV
   target/filter combination Mo/Mo
   grid in
   auto decompression off
   OPCOMP off
   AEC segmentation on
   low dose mode off
   Change all projection views to L-CC

4. Position phantom on object table according to Figure 6.

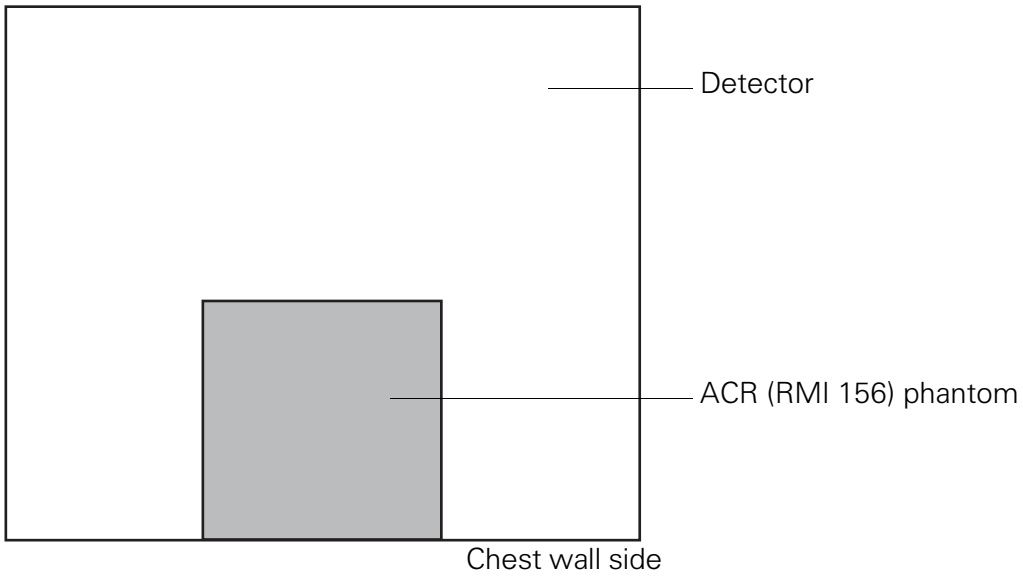

Figure 6 Position of Phantom

5. Mount compression plate and perform compression.
6. Perform an exposure.
7. Examine the image. For evaluation use magnification, zooming or gray scale inversion, adapt windowing values, if helpful. If the viewing conditions are considered to be inferior while looking at the image on AWS, send image to viewing station for additional examination of the achieved image.

8. Determine how many fibers, specks and masses can be identified.
   a) Select object class (mass, speck group, fiber), see Figure 7.
   b) For the selected object class start evaluation at the easiest visible sample.
   c) Count number of visible samples of one class.
      - A fiber is regarded as visible if it is found at correct orientation and location and at least half of its length is recognized
      - A speck group is regarded as visible if it is found at correct orientation and location and at least four of its specks are recognized.
      - A mass is regarded as visible if it is found at correct location and its circular appearance is recognized.
   d) Note result in Test form Test 5.
5. Repeat steps 6 to 8 for target/filter combinations Mo/Rh and W/Rh.
6. Close examination.

Performance Criteria and Corrective Action

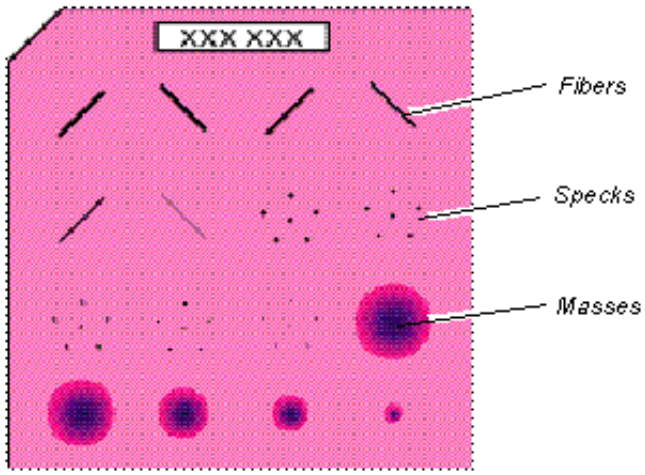

Figure 7 ACR (RMI 156) phantom

Number of objects that shall be detected:

Fibers ≥ 5
Specks ≥ 4
Masses ≥ 4

Test form Test 5

Target/filter combination **Mo/Mo**

Tube load: _____ mAs	**Performance Criteria**	**Passed**	**Failed**
Fibers	≥ 5	❑	❑
Specks	≥ 4	❑	❑
Masses	≥ 4	❑	❑

Target/filter combination **Mo/Rh**

Tube load: _____ mAs	**Performance Criteria**	**Passed**	**Failed**
Fibers	≥ 5	❑	❑
Specks	≥ 4	❑	❑
Masses	≥ 4	❑	❑

Target/filter combination **W/Rh**

Tube load: _____ mAs	**Performance Criteria**	**Passed**	**Failed**
Fibers	≥ 5	❑	❑
Specks	≥ 4	❑	❑
Masses	≥ 4	❑	❑

Test 6: Spatial Resolution (optional)

Objective

To detect assumed spatial resolution problems in different parts of the detector

Required Equipment

a) Bar pattern phantom (containing line groups with spatial frequencies of 5 lp/mm, 6 lp/mm, 7 lp/mm, 8 lp/mm) applicable for mammography

b) Collimator mountable PMMA phantom

c) Compression plate 24 x 30 cm^2

Procedure

1. Create a new patient record in the local database.
   Fill in: Last Name: Test_Six
   First Name: Spatial Resolution
   Patient ID: day+time when the test is performed (example: 200707071030)
   DOB: 05 05 1955
   Gender: Other
2. Select procedure **QC-raw**.
3. Select:
   exposure technique MANUAL
   28 kV
   90 mAs
   target/filter combination clinically used
   grid in
   auto decompression off
   OPCOMP off
4. Mount PMMA phantom close to collimator.
5. Move bar pattern phantom on object table to a position where a problem with the spatial resolution of the detector is assumed.
6. Mount compression plate and perform compression.
7. Perform exposure.

8. Examine the image. For evaluation use magnification, zooming or full resolution, adapt windowing values, if helpful. If viewing conditions are considered to be inferior while looking at the image on AWS, send image to viewing station for additional examination of the achieved image.
9. Determine the highest visible spatial frequency where bars and adjacent spaces can be clearly distinguished.
10. If problems with spatial resolution are assumed in further detector parts, move phantom to the suspicious regions and repeat evaluation.
11. Note results in Figure 8.
12. Close examination.

Performance Criteria and Corrective Action

The maximum detectable spatial frequency shall be 7 lp/mm.

Test form Test 6

Mark where the required spatial frequency is not reached.

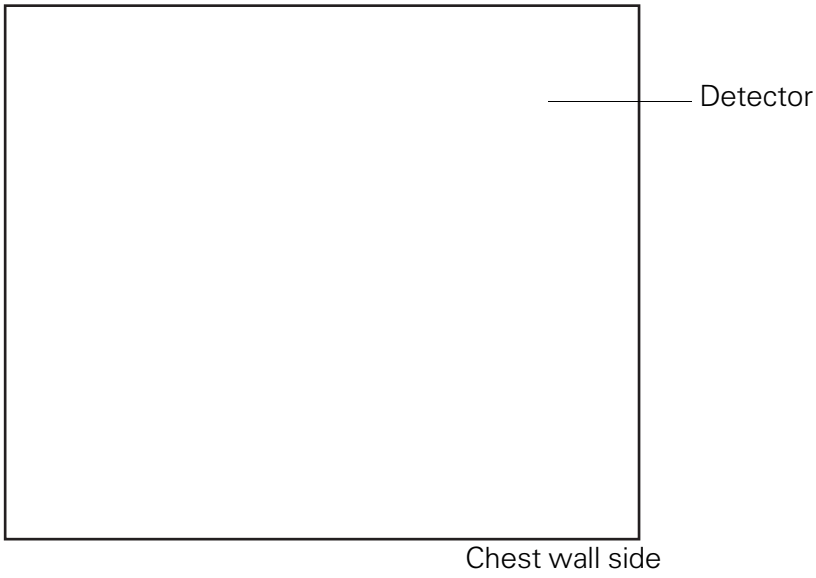

Figure 8 Indication of inferior spatial resolution

Test 7: Mechanical Tests

Objective

To ensure the mechanical integrity of the system

Required Equipment

a) Compressible phantom

b) ACR (RMI 156) phantom

c) Stop watch

d) Compression plate 24 x 30 cm^2

Procedure

1. Check that the control panel lights up to show that the power is switched on.
2. Turn the swivel-arm system to 180° (tube head is straight upside down). Lower the system as close to the floor as possible. Check that system stops above the floor. Raise and turn the swivel-arm system back.
3. Check the motorized movements for smooth running and normal function.
4. Check that all foot switches operate correctly.
5. Check that the height adjustment and rotation of the swivel-arm system are blocked, when the displayed compression force is ≥ 30 N.
6. Check the emergency stop button for correct function. Note that with the button depressed, all motorized movements shall be blocked, and x-ray release is not possible. Release emergency stop button, Mammo unit will be reset and examination can be continued. Confirm message on AWS.
7. Check that object table surface and all compression plates show no sharp edges or cracks which could injure the patient.
8. Check that the edges of the radiation shield are clearly defined so that the user is aware of the outline.
9. Check that the manual compression/decompression functions properly.
10. If automatic decompression is set up the compression plate should release compression after an exposure automatically. The deactivation of automatic release should also work correctly.
11. Check that the decompression button on the control box works correctly.
12. Check that the emergency decompression button works correctly.

13. Compression force:
    - Position compressible phantom on object table
    - Mount compression plate
    - Compress phantom until applied compression force reaches 100 N
    - Wait approximately one minute
    - After one minute the compression force must not differ more than 10 N from the applied value.
    - Remove compressible phantom
    - Position ACR (RMI 156) phantom on object table
    - Compress with 70 N
    - Select Opdose mode and perform exposure
    - Read out the indicated thickness from image. Check that displayed thickness is between 39 mm and 45 mm.

Performance Criteria and Corrective Action

To ensure the mechanical integrity all steps should be passed.

Test form Test 7

Test no.:	Performance Criteria	Passed	Failed
1. Control panel lights	**---**	❑	❑
2. System stops above floor	---	❑	❑
3. Check motorized movements	---	❑	❑
4. Foot switches	---	❑	❑
5. Movements blocked	---	❑	❑
6. Emergency stop button	---	❑	❑
7. No sharp edges or cracks on object table surface and compression plates	---	❑	❑
8. Radiation shield	---	❑	❑
9. Manual compression	---	❑	❑
10. Auto decompression	---	❑	❑
11. Decompression button on control box	---	❑	❑
12. Emergency decompression	---	❑	❑
13. Measured Thickness: _____ mm	**39 mm - 45 mm**	❑	❑

Test 8: Acquisition Workstation Monitor Check

Objective

To assess the quality of the acquisition workstation monitor.

Required Equipment

a) SMPTE test pattern (provided in *syngo*)

Procedure

1. Clean the monitor

   a) The monitor surface should be cleaned with a soft tissue material, such as cotton or lens cleaning paper.

   b) If necessary, stubborn stains can be removed by moistening part of a cloth with water to enhance its cleaning power.

3. Select the **Viewing** task card.
4. Open the **Patient Browser**, select **Service images**, technical images.
5. Open the SMPTE in the **Viewing** task card. Make sure that the SMPTE covers the entire viewing area, e.g. the window should not be divided in four viewing areas.
   Check that the window center is set to 2048. Check that the image is displayed in acquisition size under **Image > Acquisition Size**.
6. The gray scale is shown as a series of squares in the center of the SMPTE image, ranging from black (0%) to white (100%) in a rectangle. The 0% and 100% squares each contain smaller squares within them that represent a signal level of 5% and 95% respectively (see Figure 9). You should be able to differentiate the inner square from the corresponding outer square. The 5% square is normally quite difficult to differentiate. If the viewing conditions are considered to be inferior, perform this test again with dimmed room light.

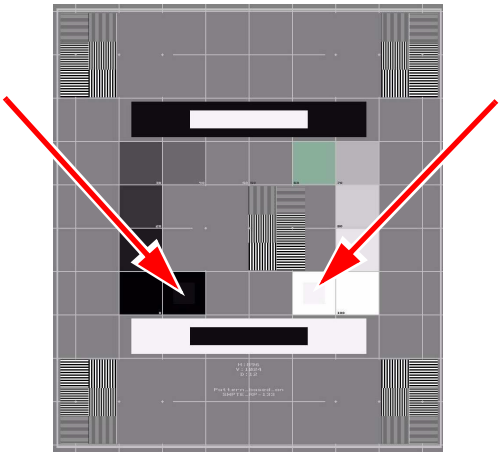

Figure 9 Location of 5 % and 95 % squares

7. Visually check the monitor's performance by looking for streaking, fluttering and shadows.
8. The spatial resolution and aliasing of the monitor are considered to be within acceptable limits if the high contrast bar patterns in the test image can be seen as patterns of white and black pairs. To use the pattern, inspect the 6 squares filled with varying widths of alternating black/white horizontal and vertical lines in each corner (see Figure 10) of the image as well as in the very center. You should be able to differentiate all the lines, from wide to narrow (6 pixels, 4 pixels, and 2 pixels) both horizontally and vertically.

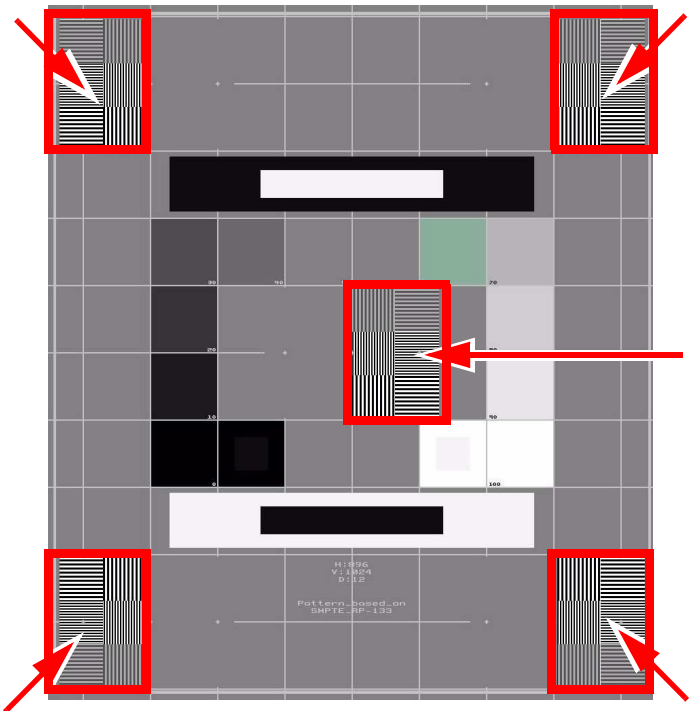

Figure 10 Location of bar patterns

9. Option 3MP Monitor.
    - If a 3MP Monitor is available open test images from service, (**Option > Service > Local Service**) logon without service key. Select **Acquisition System > Quality Test**, -> Display -> Start -> Testimages, Select AWS Testimages.
    - Perform steps 6 - 8.
    - Move image over the entire monitor.
    - Close service menu.
10. Close examination.

Performance Criteria and Corrective Action

- The 5% and 95% squares shall be visible. (The preset values for brightness and contrast on the monitor may not be adequate to fulfill this requirement. Adjust brightness and contrast according to *For the qualification of the printer please follow the printer manufacturer's recommendations.* and repeat *Test 8: Acquisition Workstation Monitor Check*.
- All different bar patterns in the four corners and in the center in the image (see of the Figure 10) shall be visible.

If any level is found to be beyond any action level stated, the source of the problem must be identified and the problem corrected by a Siemens customer service engineer and successfully retested by the MP before further examinations are performed using the system.

Test form Test 8

Gray Scale Contrast:	Yes	No
5% square is visible inside 0% square	❑	❑
	Performance criteria: Yes	
95% square is visible inside 100% square	❑	❑
	Performance criteria: Yes	

Spatial resolution:	Yes	No
All lines in all bar patterns can be differentiated	❑	❑
	Performance criteria: Yes	

Visual Inspection:

	Yes	No
Streaking	❑	❑
	Performance criteria: No	
Fluttering	❑	❑
	Performance criteria: No	
Shadows	❑	❑
	Performance criteria: No	

Test 9: Printer Check (optional)

This test is only required if a laser camera is used.

Objective

To assess the quality of the laser camera.

Required Equipment

a) Calibrated densitometer

Procedure

1. Mark the service patient in the **Patient Browser**.
2. Choose SMPTE image from service image patient and open it in the **Viewing** task card.
3. Send the image to a printer.
4. The printer shall be configured for **Min Density** to 20 and **Max Density** to 350.
5. Evaluate the printed SMPTE image by measuring the eleven density values from 0 to 100% with the densitometer and note the measured values in Test form Test 9.

Performance Criteria and Corrective Action

The values for the different optical densities must be within the action limits as stated in table on Test form Test 9.

If any level is found to be beyond any action level stated, the source of the problem must be identified and the problem corrected by a Siemens customer service engineer and successfully retested by the MP before further examinations are performed using the system.

For the qualification of the printer please follow the printer manufacturer's recommendations.

Test form Test 9

Customer values for Min and Max Density	
Min Density	
Max Density	

Step	Corr16b-bspline (LUT)			Linear LUT*		
	Ref. LUT	Maximum density	Minimum density	Ref. Density	Maximum density	Minimum density
1	0.20	0.23	0.17	0.20	0.23	0.17
2	0.34	0.38	0.30	0.52	0.56	0.49
3	0.47	0.51	0.43	0.86	0.90	0.82
4	0.64	0.69	0.59	1.18	1.23	1.13
5	0.81	0.87	0.75	1.52	1.58	1.46
6	1.05	1.12	0.99	1.84	1.91	1.78
7	1.31	1.38	1.24	2.18	2.25	2.11
8	1.66	1.74	1.58	2.52	2.60	2.44
9	2.10	2.19	2.01	2.85	2.94	2.77
10	2.68	2.77	2.59	3.18	3.27	3.08
11	3.50	3.60	3.40	3.50	3.60	3.40

* LUT = Look-Up-Table

Step	MG1_5bCorr-bspline (LUT)		
	Ref. LUT	Maximum density	Minimum density
1	0.20	0.23	0.17
2	0.44	0.48	0.40
3	0.68	0.72	0.64
4	0.94	0.99	0.89
5	1.18	1.24	1.12
6	1.45	1.52	1.39
7	1.73	1.80	1.66
8	2.01	2.09	1.93
9	2.32	2.41	2.23
10	2.73	2.82	2.64
11	3.50	3.60	3.40

Step	Corr16b-bspline (LUT)				
	Ref. LUT*	Recommendation Maximum density	Recommendation Minimum density	Required Maximum density	Required Minimum density
1	0.20	0.23	0.17	0.30	0.10
2	0.34	0.38	0.30	0.44	0.24
3	0.47	0.51	0.43	0.57	037
4	0.64	0.69	0.59	0.74	0.54
5	0.81	0.87	0.75	0.91	0.71
6	1.05	1.12	0.99	1.15	0.95
7	1.31	1.38	1.24	1.41	1.21
8	1.66	1.74	1.58	1.76	1.56
9	2.10	2.19	2.01	2.20	2.00
10	2.68	2.77	2.59	2.78	2.58
11	3.50	3.60	3.40	3.60	3.40

* LUT = Look-Up-Table

Step	MG1_5bCorr-bspline (LUT)				
	Ref. LUT	Recommenda-tion Maximum density	Recommendation Minimum density	Required Maximum density	Required Minimum density
1	0.20	0.23	0.17	0.30	0.10
2	0.44	0.48	0.40	0.54	0.34
3	0.68	0.72	0.64	0.68	0.58
4	0.94	0.99	0.89	1.04	0.84
5	1.18	1.24	1.12	1.28	1.08
6	1.45	1.52	1.39	1.55	1.35
7	1.73	1.80	1.66	1.83	1.53
8	2.01	2.09	1.93	2.11	1.91
9	2.32	2.41	2.23	2.42	2.22
10	2.73	2.82	2.64	2.83	2.63
11	3.50	3.60	3.40	3.60	3.40

Test 9: Printer Check (optional)

If your values do not meet the values specified above, then please refer to the printer manufacturer's quality control procedure. You can create your own baseline with the measured values that result from the initial installation of the printer that was installed per the manufacturer's QC procedure.

SMPTE [%]	Step	Measured OD*	Passed	Failed
100	1		❑	❑
90	2		❑	❑
80	3		❑	❑
70	4		❑	❑
60	5		❑	❑
50	6		❑	❑
40	7		❑	❑
30	8		❑	❑
20	9		❑	❑
10	10		❑	❑
0	11		❑	❑

* OD = Optical Density

QC manual required by printer manufacturer was followed:

Compliance	Yes	No
Date _____	❑	❑
Date _____	❑	❑
Date _____	❑	❑

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