American College of Radiology

DRAFT

Stereotactic Breast Biopsy QC Manual

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Physician's Section

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I. INTRODUCTION

The widespread use of mammographic screening to decrease breast cancer mortality can lead to the discovery of suspicious, nonpalpable lesions that may be malignant. This was improved with the introduction of Full Field Digital Mammography (FFDM) and Digital Breast Tomosynthesis (DBT) technology for screening mammography. Tissue sampling is necessary to determine whether these findings represent cancer, which is usually present in only 20-30% of detected lesions. In the past, tissue sampling was done with surgical biopsy, often with preoperative localization under imaging control. Surgical biopsy is expensive, more invasive and time consuming, however, and can result in breast scarring, breast deformity, and confusing findings on follow-up mammograms. The ability to perform needle biopsies on these lesions percutaneously with stereotactic or tomosynthesis imaging guidance decreases or eliminates these factors and thereby diminishes the cost of breast biopsy.

Image-guided core-needle biopsy (CNB) has become the procedure of choice for most image-detected breast lesions requiring tissue diagnosis. Its advantages over surgical biopsy are well recognized, including less scarring, fewer complications, faster recovery, lower cost, and similar accuracy [1-9].

Percutaneous biopsy techniques have decreased the number of surgical biopsies of benign tissue resulting from breast imaging programs and have decreased the number of surgical procedures needed to treat breast cancer [3,5-7]. Therefore, minimally invasive biopsy is preferable to open surgical biopsy for diagnosing breast lesions and is associated with low complication rates [10]. High-quality breast imaging evaluation is necessary to detect early or subtle breast lesions as well as to accurately target these lesions for image-guided biopsy. Several imaging modalities are commonly available and in clinical use for image-guided breast interventions, x-ray image guidance, ultrasound (US), and magnetic resonance imaging (MRI). The choice of guidance technique will depend on lesion visualization and accessibility, availability of the imaging modality, efficiency, safety, patient comfort, and the practitioner’s experience [1].

Mammography guidance enables percutaneous placement of a needle within the breast to sample mammographically detected suspicious breast lesions. Successful use of mammography guided breast interventional procedures relies on high-quality imaging, expertise in breast imaging feature analysis, experience in stereotactic-guided or tomosynthesis-guided techniques for accurate lesion targeting and sampling, and effective methods of obtaining tissue for analysis [11-14]. DBT may be used with or without stereotactic guidance as another biopsy technique, either for findings visible only on DBT, or if preferred in certain cases over stereotactic guidance for mammographically visible findings, including calcifications, asymmetries, and especially architectural distortion. The imaging features and the histopathologic interpretations should be assessed for concordance by the physician performing the biopsy, and records should be kept to document results and patient management recommendations [1].

The ACR Stereotactic Breast Biopsy Accreditation Program was introduced in 1996. The highly successful ACR Mammography Accreditation Program, established in 1987, was used as its model. The program strived to assure that stereotactic breast biopsy procedures were being performed by appropriately trained personnel, that the equipment functions properly, that the radiation dose during each exposure is within accepted limits, that a facility's complication rate is not excessive, and that women are appropriately followed up after the biopsy results are known.

Communication with all stakeholders (e.g., technologists, performing physicians, medical physicists, administration) is essential to a successful program. It is important that the physicians who perform mammography guided breast biopsy procedures provide feedback to the technologist(s) to improve the program. Some feedback may best be shared during the procedure for optimal impact, while some may need to be discussed away from the patient. Technologist(s) should be encouraged to ask for feedback as well as to provide their own feedback for process improvement. Positive feedback for a job well done as well as constructive criticism should be provided at the stakeholder's request. This process can be informal through verbal discourse or part of a structured process that can be documented for future reference. Additional guidance on structuring local Quality Management, Quality Assurance, and Quality Control may be found in the ACR-AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF STEREOTACTIC/TOMOSYNTHESIS-GUIDED BREAST BIOPSY SYSTEMS, available online.

Important: The continuity of the QC program is very important to comply with the ACR accreditation program and to maintain a high level of quality service. The continuity of the QC program is the responsibility of the Supervising Physician. When the designated QC Technologist leaves a facility, goes on vacation, goes on leave, or is absent for any reason, it is vital that the QC program be continued by another technologist. A contingency plan is needed to prevent any lapse of the QC program. This includes the naming of an alternate QC Technologist who can continue the QC program at any time. The alternate QC Technologist must be trained in the performance of all QC tests. The alternate QC Technologist should have continuing experience in the performance of the QC tests. The alternate QC Technologist should be familiar with the current state of the QC program to be aware of any possible concerns or indications of possible test failures. This is important especially if the facility is aware of an upcoming absence of the QC Technologist. The facility's medical physicist should be used as a resource in the training and advisement of the alternate QC Technologist.

II. DEFINITIONS

A. Quality Assurance

Quality Assurance (QA) is a component of quality management practices instituted by the lead mammography radiologist to ensure that process outputs are at expected levels of quality. These patient care outputs should include:

- Every biopsy procedure is necessary and appropriate to the clinical problem at hand.
- The images generated contain information critical to the solution of that problem.
- The recorded information is correctly interpreted, and results made available in a timely fashion to the patient and their physician.
- The procedure results in the lowest possible radiation exposure, cost, and inconvenience to the patient consistent with imaging objectives.

The QA program comprises many facets, including efficacy studies, continuing education, quality control, preventive maintenance, and calibration of equipment. An essential part of a QA program is the quality assurance committee (QAC). This group is responsible for oversight of the program, setting the goals and direction, determining policies, and assessing the effectiveness of QA activities. The QAC should consist of one or more radiologists or physicians, a medical physicist, a supervisory breast biopsy radiologic technologist, and other breast biopsy department personnel involved in caring for biopsy patients. This may include a nurse, desk attendant, medical secretary and others. It may also include medical and paramedical staff from outside the radiology department, such as a surgeon, referring physician, nurse educators, a nurse from a comprehensive breast clinic, etc. The QAC may also conduct the additional responsibilities of a Quality Management Team (QMT), or report QA and relevant QC results to a QMT that has broader operational oversight (e.g., multimodality), or practices can choose another reasonable model that fosters local safety and success.

B. Quality Control

Quality Control (QC) is an integral part of QA that includes assessing distinct technical performance characteristics to ensure the proper equipment operation, e.g. a biopsy procedure that visualizes, targets, and samples the appropriate lesion. Four discrete steps are involved:

- Acceptance testing to detect defects in equipment that is newly installed or has undergone major repair
- Establishment of the baseline performance of the equipment
- Detection and diagnosis of changes in equipment performance before they become clinically apparent, through routine and ongoing QC tests
- Verification of equipment performance after service has been performed

Specifics of the QC program for stereotactic- and tomosynthesis-guided breast biopsy systems are provided by the American College of Radiology in this manual.

> **Important:** The QC program provides a frame of reference from which even gradual or subtle problems can be identified, isolated and resolved ***before*** they significantly impact the quality of patient procedures.

III. USING THIS MANUAL

The supervising physician, medical physicist, and QC technologist, working together as a team, are the keys to providing optimum quality biopsy procedures, which will ultimately provide the best medical care possible to the patient. Biopsy team members are strongly encouraged to review the other sections of this manual that are not directed towards them. For example, the physician should be familiar with Technologist's QC tests. The radiologic technologist should review the Medical Physicist's Test Evaluation of Site's Technologist QC Program, and the medical physicist should be familiar with all of the radiologic technologist's tests.

- The ***supervising physician*** has the responsibility for ensuring that all quality assurance requirements are met.
- The ***medical physicist*** is responsible for overseeing all equipment-related quality assurance practices.
- A primary ***quality control technologist*** must be identified by the facility to conduct all quality assurance activities not assigned to supervising physician or the medical physicist.

The quality control and quality assurance responsibilities for the radiologic technologist and the medical physicist are outlined in the two sections that follow. The physician should understand that the physician's responsibilities are all-inclusive and that the physician is ultimately responsible for the frequency, quality and documentation of the quality control and quality assurance tasks that are performed by other personnel. However, each member of the breast biopsy team should review the complete manual to understand the overall QC program goal and each member's responsibilities in achieving those goals.

The continuity of the QC program is very important to comply with the ACR accreditation program and to maintain a high level of quality service. The continuity of the QC program is the responsibility of the Supervising Physician. When the designated QC Technologist leaves a facility, goes on vacation, goes on leave, or is absent for any reason, it is vital that the QC program be continued by another technologist. A contingency plan is needed to prevent any lapse of the QC program. This includes the naming of an alternate QC Technologist who can continue the QC program at any time. The alternate QC Technologist must be trained in the performance of all QC tests. The alternate QC Technologist should have continuing experience in the performance of the QC tests. The alternate QC Technologist should be familiar with the current state of the QC program to be aware of any possible concerns or indications of possible test failures. This is important especially if the facility is aware of an upcoming absence of the QC Technologist. The facility's medical physicist should be used as a resource in the training and advisement of the alternate QC Technologist.

The stated frequency for each quality control test is a minimum frequency. A test should be done more frequently when it is being introduced and whenever inconsistent results are found. In addition, it is important to adopt the attitude that quality assurance is a continuous, not an episodic, process. An effective quality control program will not eliminate problems, but it will allow identification of problems before they seriously affect clinical results.

Each image obtained during each procedure should be viewed by the physician and technologist with quality control in mind. Deviations from high-quality performance may occur quickly or gradually. The quality control program provides a frame of reference within which even gradual or subtle problems can be identified, isolated, and resolved. The QC program can help identify the causes of changes in image quality or in the accuracy of needle positioning.

The QC testing described in this ACR Quality Control Manual should be a central part of the site's QA/QC documentation. The facility's QA/QC program should contain:

- Clearly assigned responsibilities for QA items and QC testing
- Clearly developed procedures for QA items and QC testing
- Records of the QC tests performed by the QC technologist and the medical physicist
- Records of any corrective action
- Records of routine and non-routine equipment service and maintenance
- Records of Quality Assurance Committee meetings
- A description of the orientation program for operators of the imaging and biopsy equipment, including its duration and content
- Procedures for proper use and maintenance of equipment
- Mammographic techniques to be used, including pertinent information on positioning, compression, imaging modes, and kVp-target-filter combinations if applicable
- Precautions to protect the participants in the procedure, the patient, and individuals in surrounding areas from radiation exposure
- Policies and employee responsibilities concerning personnel radiation monitoring
- Procedures for cleaning and disinfection of imaging and biopsy equipment

IV. RESPONSIBILITIES

A. Supervising Physician

The facility should select a Supervising Physician to assume the primary responsibility for the quality of biopsy procedures and for the implementation of an effective QA program at their site. The staff's commitment to high quality will often mirror that of the Supervising Physician. The individuals performing QC tests need to know that the Supervising Physician understands the program and is interested in the results. The Supervising Physician needs to review the test results and trends periodically and provide direction when problems are detected.

The Supervising Physician's specific responsibilities in mammography guided breast biopsy QC are to:

- Ensure that physicians, technologists, and medical physicists involved in these procedures have adequate training and continuing education in mammography and stereotactic- and tomosynthesis-guided breast biopsy.
- Provide an orientation program for technologists based on a carefully established procedure manual.
- Ensure that an effective QC program exists for all biopsies performed at the site. (The physician should provide motivation, oversight, and direction to all aspects of the QC program.)
- Select a primary QC technologist to perform the prescribed QC tests for consistency and to oversee tests that have been delegated to other individuals. It is not desirable to rotate this assignment among a group of technologists, as this introduces variability into the test results that is extraneous to the tests themselves. Additionally, properly trained alternate QC technologists are essential to provide continuity when the primary QC technologist is unavailable. The alternate QC technologist must perform the QC tasks when the primary QC Technologist is unavailable.
- Ensure that appropriate test equipment and materials, and time, are available to the QC technologist to perform the QC tests.
- Arrange staffing and scheduling so that adequate time is available to carry out the QC tests and to record and interpret the results. (Most tests take little time; however, the necessary time must be incorporated into the daily schedule.)
- Provide frequent and consistent positive and negative feedback to the technologists about clinical image quality and QC procedures.
- Select a medical physicist who will oversee the equipment-related QC program and perform the medical physicist's tests.
- Review the technologist's test results at least quarterly or more frequently if consistency has not yet been achieved. (See Facility QC Review in the Radiologic Technologist Section)

- Review the medical physicist's test results annually, or more frequently when needed.
- Oversee or designate a qualified individual to oversee the radiation protection program for employees, patients, and other individuals in the surrounding area.
- Ensure that records concerning employee qualifications, imaging technique and proficiency, infection control procedures, QC, safety, and protection are accurately maintained.

B. All Physicians

All physicians who perform mammography guided breast biopsies in the practice are required to:

- Ensure that the outcomes of procedures are documented, and that appropriate patient follow-up care has been provided.
- Document the number and causes of complications, including specific needles used during each procedure in which complications occur.
- Record the number of, and reasons for, repeated procedures.
- Provide documentation of his or her current qualifications to each facility where they practice according to local rules and any relevant accreditation program requirements.

C. Medical Physicist

The medical physicist's responsibilities primarily relate to equipment performance and include:

- Overall equipment function and performance
- Image quality assessment
- Radiation dosimetry
- Operator safety concerns

D. Radiologic Technologist

The radiologic technologist's general responsibilities center on patient care and image quality, including:

- Equipment setup
- Patient positioning
- Image production
- Assessing if the area of interest is in the target window
- Image processing
- Infection control

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Technologist's Section

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I. Introduction

A Quality Control (QC) program includes the performance of routine equipment function tests, interpretation of the results, and taking corrective actions for adverse results, with appropriate documentation of each step. The objective of QC is to detect, identify, and correct equipment-related problems before they negatively affect clinical exams.

Due to their day-to-day contact and familiarity with stereotactic- and tomosynthesis-guided breast biopsy equipment, radiologic technologists are the front line of defense against potential imaging and biopsy equipment problems. This section's purpose is to provide effective and consistent methods of detecting and identifying such problems. Along with the Quality Management Team (QMT) or Quality Assurance Committee (QAC), which must include the supervising physician, the medical physicist and the QC Technologist, the radiologic technologists (sometimes aided by equipment service personnel), can help identify and eliminate these problems before patient care is affected. A byproduct of conducting the QC described in this manual is greater familiarity with the operation and performance of the breast biopsy system, the image quality expected from these systems (and how it compares to image quality in screening mammography), and the required accuracy of needle placement during breast biopsy procedures.

The Technologist's QC tests with their minimum frequencies are listed in Table 1 in this section. All Technologist's QC tests in Table 1 must be performed before first clinical use of a new installation. New installations include those new from the factory and those that have been moved and installed at a new location.

For each of the required technologist QC tests included in this manual, the purpose and frequency of each test is stated. The equipment and materials required to carry out each test are listed, and a step-by-step procedure is provided. After each procedure is a discussion of precautions and caveats. Performance criteria are provided along with suggestions for the types of corrective actions needed or recommended to resolve problems.

Any tests, additional to those in Table 1, that your equipment manufacturer recommends, should be performed. You should be familiar with the user's manual for your imaging and biopsy system and any unit-specific QC tests recommended by the equipment manufacturer. The performance of the QC tests at their frequencies that are described in this manual are required for acquiring and maintaining ACR Accreditation.

QC is a team effort with contributions from the supervising physician, medical physicist and QC Technologist.

- The ***supervising physician*** has the responsibility for ensuring that all quality assurance requirements are met.
- The ***medical physicist*** is responsible for overseeing all equipment-related quality assurance.
- A primary ***quality control technologist*** must be identified by the facility to conduct all quality assurance activities not assigned to the supervising physician or the medical physicist.

Important: The continuity of the QC program is very important to comply with the ACR accreditation program and to maintain a high level of quality service. The continuity of the QC program is the responsibility of the Supervising Physician. When the designated QC Technologist leaves a facility, goes on vacation, goes on leave, or is absent for any reason, it is vital that the QC program be continued by another technologist. A contingency plan is needed to prevent any lapse of the QC program. This includes the naming of an alternate QC Technologist who can continue the QC program at any time. The alternate QC Technologist must be trained in the performance of all QC tests. The alternate QC Technologist should have continuing experience in the performance of the QC tests. The alternate QC Technologist should be familiar with the current state of the QC program to be aware of any possible concerns or indications of possible test failures. This is important especially if the facility is aware of an upcoming absence of the QC Technologist. The facility's medical physicist should be used as a resource in the training and advisement of the alternate QC Technologist.

Optional procedures and forms are provided to aid in enhanced program assessment and improvement with consistent documentation. Repeat Analysis is one such optional test and details of its procedure are contained herein. The Physician Feedback procedure and form enables the Supervising Physician to provide constructive feedback to technical staff when asked to perform biopsy using sub-optimal images and to commend the technical staff for exceptional performance.

The manual includes several management forms to help organize and reference important information. The ACR Techniques and Summaries form provides a location to record techniques used for routine QC testing. The manual's downloadable forms provide a central location to record all corrective action in the Corrective Action Log.

All ACR-accredited facilities must have manual Technique Charts posted in each room where stereotactic- or tomosynthesis-guided biopsies are performed.

Even with the wider latitude of exposure permitted with digital image receptors, it is still very important to have clearly established exposure technique factors. Exposure factors that underexpose the digital receptor will create noisier images which makes it hard or impossible to distinguish low contrast objects. An overexposed detector could saturate pixels which fills in spaces between small objects, leading to the loss of resolution.

The Medical Physicist will provide the Technique Charts during acceptance testing, or at any time that the Medical Physicist finds that the current Technique Charts are not appropriate. The Technique Charts may be generated by the Medical Physicist or provided by the manufacturer, in which case the Medical Physicist should review the manufacturer-provided Technique Charts. The technique used on individual patients may be modified based on experience with the equipment and patients.

The technique charts should be supplemented with suggested techniques for patients with breast augmentation, pacemakers, stimulators, or any other implant or device which may influence or interfere with the procedure. The Technique Chart provided in the QC Forms can be modified for these special cases.

For units to be ACR-accredited, the medical physicist must conduct Acceptance Testing of the unit and acquisition workstation displays before the unit is used clinically. The medical physicist must perform the Acceptance Testing according to the Medical Physicist's

Section of this manual. This is important to provide testing techniques and procedures for the QC technologist to use during routine QC. After this is done, the QC Technologist must start performing the QC tasks according to the Technologist's Section of this Manual. For current information, more details and clarifications on using this ACR Stereotactic Breast Biopsy Quality Control Manual, visit the ACR website.

The minimum frequencies for both the technologist's and medical physicist's tests are listed in Table 1.

The technologist and medical physicist can use the forms provided in the Appendix and downloadable on the ACR Accreditation website to record the data and results of the QC tests.

For recurring problems or equipment showing instability, it may be necessary to perform appropriate tests more frequently to identify problems before they affect clinical image quality or patient safety. For newly established QC programs, it may be valuable to carry out QC tests more frequently for the first few months. The QC technologist will quickly gain experience and better baseline data will be gathered regarding the reliability of imaging equipment.

The necessity of performing tests designated as "Optional" or "If applicable" is left to discretion of the Quality Management Team, especially the supervising physician, QC technologist, and medical physicist, who are most familiar with the facility's equipment and the quality needs of the practice.

In addition to performing the QC tests at their minimum frequencies, tests should be performed on new equipment, when problems are suspected and after any service or preventive maintenance. For example, the compression test should be carried out when a new x-ray system is installed and after any service adjustment of compression force.

For any test failures, the set up and techniques employed in the test must be rechecked, and the test repeated before initiating corrective action. Corrective action must be taken ***before*** any further procedures are performed using that component of the imaging and biopsy system that failed. Failures of non-critical tests must be corrected within 30 days of the test date (Table 1)

Table 1: Quality Control Tests and Frequencies

Test	Minimum Frequency	Corrective Action Timeframe[+]
Technologist Tests		
1. Localization Accuracy	Daily* (Craniocaudal Approach); Monthly (Lateral Approaches) - if applicable	Before clinical use
2. Phantom Image Quality	Weekly*	Before clinical use
3. Visual Checklist	Monthly	Critical items: before clinical use; non-critical items: within 30 days
4. Compression Thickness Indicator	Monthly	Within 30 days
5. Acquisition Workstation Monitor QC	Monthly	Within 30 days
6. Compression Force	Semi-Annually	Before clinical use
7. Manufacturer Calibrations *(if applicable)*	Mfr. Recommendation	Mfr. Recommendation
8. Facility QC Review	Annually	Not Applicable
Optional - Repeat Analysis	As Needed	Within 30 days
Optional - Radiologist or Physicist Feedback	As Needed	Not Applicable
Medical Physicists Tests		
1. Phantom Image Quality	Acceptance and Annual	Before clinical use
2. Artifacts	Acceptance and Annual	Before clinical use
3. Spatial Resolution	Acceptance and Annual	Within 30 days
4. DBT Volume Coverage	Acceptance and Annual	Within 30 days
5. Automatic Exposure Control System Performance	Acceptance and Annual	Within 30 days
6. Average Glandular Dose	Acceptance and Annual	Before clinical use
7. Unit Checklist	Acceptance and Annual	Critical items: before clinical use; non-critical items: within 30 days
8. Localization Accuracy	Acceptance and Annual	Before clinical use
9. Acquisition Workstation Monitor QC	Acceptance and Annual	Within 30 days
10. Evaluation of Site’s Technologist QC Program	Acceptance and Annual	Within 30 days
Manufacturer’s Calibrations *(if applicable)*	Mfr. Recommendation	Mfr. Recommendation
Collimation	Acceptance, Post-Repair, or Troubleshooting	Within 30 days**
Compression Thickness Indicator Accuracy	Acceptance, Post-Repair, or Troubleshooting	Within 30 days**
Evaluation of Compression Force	Acceptance, Post-Repair, or Troubleshooting	Before clinical use
kVp Accuracy and Reproducibility	Acceptance, Post-Repair, or Troubleshooting	Within 30 days**
Beam Quality (Half-Value Layer) Assessment	Acceptance, Post-Repair, or Troubleshooting	Within 30 days**
Ghost Image Evaluation (optional)	Troubleshooting	Before clinical use

[+]For tests performed as part of the FFDM survey (For attachments), corrective action timeframe specificized by the QC manual used For FFDM supersedes the requirements of this QC manual.

*On days or weeks when biopsy system is used clinically

**When the test is performed for an acceptance evaluation or post-repair evaluation, all failures *should* be corrected before clinical use, but *must* be corrected within 30 days. When the test is performed for troubleshooting, all failures must be corrected within 30 days.

II. Technologist Quality Control

A. Test Procedures

1. Localization Accuracy

Objectives

The targeting system of your unit is tested in this procedure. This test ensures that the biopsy system can accurately calculate the location of an object whose actual location is known. This test also ensures that the needle guidance system accurately places the needle at the targeted location.

The test procedure emphasizes testing the approach that you mainly use. The geometry of many modern systems can be flexibly configured; the direct approach has the needle moving towards the image receptor, and the indirect approach has the needle moving across the plane of the image receptor. The direct approach is referred to as the Craniocaudal (CC) approach and the indirect approach is referred to as the lateral approach in this manual.

Frequency

Variable depending on approaches available and/or clinically used, according to the table below:

Approach (Used Clinically)	Imaging Mode (Used Clinically)	QC Testing Performed on Day of Biopsy	QC Testing Performed Monthly
Craniocaudal (CC)	Stereotactic	Yes[1]	N/A
	Tomosynthesis	Yes[1]	N/A
Lateral Left[2]	Stereotactic	Optional[3]	Yes
	Tomosynthesis	Optional[3]	Yes
Lateral Right[2]	Stereotactic	Optional[3]	Yes
	Tomosynthesis	Optional[3]	Yes

Notes:

1. This test must be done in clinically used imaging modes (Stereotactic and Tomosynthesis) as applicable.
2. The lateral approaches need only be performed if they are available with the equipment used, are used clinically and are performed using a separate accessory for the approach. If the lateral approach is performed using the same arm as the craniocaudal approach, but is simply angled as in prone tables, a separate localization QC test is not necessary.
3. The lateral approaches can be tested more frequently to maintain user competency or if accuracy is suspect.

Definitions

Approach: Different manufacturers use different terms for the approach. This refers to the direction from which the biopsy is performed. The most commonly used approach is craniocaudal, sometimes referred to as “direct” or “vertical” by manufacturers. There are also lateral approaches for thin breasts, sometimes referred to as “indirect” or “horizontal” or “complimentary” by manufacturers.

Imaging Mode: The imaging mode refers to the type of imaging used for localization. This is either stereotactic or tomosynthesis mode.

Test Equipment

A vendor-provided or a self-manufactured phantom (localization test device) with a high atomic number (Z) attenuating fixed target that comes to a point that can be targeted for verification of localization accuracy. (Medical Physicist may need to approve and assist in acquiring this test phantom.)

Most manufacturers have an appropriate and dedicated test tool for performing this test; if so, it is required to use such tools. If your system does not have a dedicated test tool for this test, use the breast biopsy needle that is used clinically.

If using a clinically used needle for the test:

- Needle information to be entered into the targeting computer.
- A biopsy needle holder with a needle guide or an automated biopsy device with a needle guide.
- A needle should be dedicated for QC purposes.

Test Procedure

If the manufacturer of your equipment has a procedure for this test, it must be followed. This test must be tested in all imaging modes (stereotactic and/or tomosynthesis) and for the approaches specified by the table above.

In the absence of a manufacturer’s procedure, the facility must use the procedure described below.

This test is to be performed in the approach or approaches used by the facility. (For example, if the lateral (horizontal) approach is used, then this test should also be performed with the needle in the lateral (horizontal) approach.)

Place the dedicated QC biopsy needle in the biopsy device.

1. Mount the biopsy device onto the imaging equipment and cock the biopsy device.
2. Move the needle to the calibration location/ home position. If your manufacturer requires, zero the needle z position per your manufacturer’s requirements.

If using a localization test device

3. Mount the localization test device and using the compression paddle, apply sufficient compression to secure the device’s position within the biopsy window.
4. Acquire the preliminary (scout) images of the test device.

5. Select an object on the test device to be the Target. The Target should be near or at the center of the image.
6. Acquire the targeting images (stereotactic or tomographic) of the Target. Using the computer, designate that object as the Target, and compute the Target's coordinates.
7. Record the Target's coordinates in the data form.
8. Using the computer, move the needle tip to the Target's coordinates that were calculated by the computer.
9. For each of the coordinates (x, y, and z), calculate the difference in location between the Needle tip's location and the Target's location. For example, for the x coordinate, subtract the value of the real location's x-coordinate, from the calculated value of the x-coordinate.
10. Variations to this procedure are permitted. Refer to manufacturer guidance. For example, the total difference between the needle's tip and the target may be measured physically.

If your manufacturer does not provide a localization test device

3. Move the needle tip to a location with known coordinates (e.g., x = +30 mm, y = +40 mm, z = +50 mm.)
4. Acquire the preliminary (scout) image to ensure that the needle tip is in the image and within the biopsy window.
5. Acquire targeting images (stereotactic or tomographic) of the needle tip. Designate the needle tip as the Target in the targeting computer and compute the Target's coordinates.
6. Record the Target's coordinates in the data form.
7. For each of the coordinates (x, y, and z), calculate the difference in location between the Target's location and the needle tip's real location. For example, for the x coordinate, subtract the value of the real location's x-coordinate, from the calculated value of the x-coordinate.

Data Analysis and Interpretation

Calculate or record the difference between the calculated coordinates and the coordinates of the real target location.

Precautions and Caveats

This test is performed in air to avoid the needle being deflected in a solid or semi-liquid phantom. Possible causes for test failure include but are not limited to:

- The wrong needle was used.
- A needle was bent or warped.
- Incorrect needle information was entered into the targeting computer.
- The biopsy device was not cocked.

- There is excessive play in the needle guide.
- The biopsy device was mounted incorrectly in the holder.

Performance Criteria and Corrective Action

Each calculated coordinate (x, y, and z) must be within 1 mm of the coordinates of the real location, regardless of which procedure was used.

> You must use the manufacturer's procedure if one is provided. However, the results must meet the performance criteria of ±1 mm specified for this test, even if the manufacturer's criteria are less stringent.

Corrective action is to find and correct the cause of the test failure. The test may be repeated with attention taken to identify the cause of failure.

A repeat of the test with passing results demonstrates that the corrective action was successful.

Units that cannot pass this test must be repaired by a qualified service person.

Timeframe for Corrective Action

The cause of the test failure must be corrected before clinical use.

> The Medical Physicist has a similarly named test procedure in the Medical Physicist's Section of this manual. The Medical Physicist's test is to verify that the clinical staff can image and accurately place a needle for sampling of a targeting phantom. It is strongly recommended that a Technologist demonstrate this test to the physicist in person. Please refer to the procedure in the Medical Physicist's Section.

2. Phantom Image Quality and Artifacts

Objectives

To ensure that the image acquisition chain is consistently producing adequate image quality in each clinically used imaging mode.

To ensure that artifacts are not clinically significant.

Frequency

Weekly, for weeks when the biopsy system is used clinically, and upon installation of new equipment (before first clinical use).

After each relocation, before biopsy procedures (mobile units).

> **Note for upright units with biopsy attachments:** Phantom image quality and artifact evaluation must be performed under clinical biopsy conditions, including compression paddle(s). For upright units with biopsy attachments, evaluations made during other mammography unit QC may not be appropriate for this test because the AEC settings and detector calibrations may be different. In this case, phantom image quality and artifact evaluation need to be repeated using clinical biopsy procedure settings, which have been provided by the medical physicist.

Test Equipment

An Original ACR Mammography Phantom, a "Mini" Phantom, or an ACR Digital Mammography (DM) Phantom

Once a phantom is selected, it is recommended that it remain the same for consistency.

Test Procedure

Due to the available detector size and paddle combinations for these units, the entire phantom can be captured either in a single exposure or it may require multiple exposures to capture the appropriate phantom test objects. It is the responsibility of the QC Technologist to capture the appropriate images needed to assess the image quality of the unit.

For Stereotactic Biopsy units, the stereo images are expected to have the same quality as the scout, and the image quality is tested using a scout image.

Systems capable of performing biopsies in stereotactic mode and tomosynthesis mode should be tested in all clinically used modes.

Acquiring the image(s)

1. Initiate an exam at the acquisition workstation as you would for a patient or from the QC menu.

2. Use a name and image designation system that allows for tracking of the QC images. This image ID is important if these images are sent to PACS, or if there is more than one acquisition unit.
3. Select a phantom or scout image type necessary to perform an exposure. Note: phantom images must be “for presentation” (i.e., “processed,” not “for processing” or “raw”) for viewing and scoring (if applicable).
4. Make the exposure with the technique and setup that was specified by the medical physicist. Record paddle type, density setting, AEC cell used, AEC mode, view, compression force, tube-potential (kVp), target/filter combination, and tube-current-time product (mAs) after the exposure.
5. If necessary, reposition the phantom and make additional exposures until all phantom test objects are imaged.

If the system is capable of performing biopsies using both stereotactic guidance and tomosynthesis guidance, then the phantom image quality should be tested in all clinically used modes. Repeat the steps above for the tomosynthesis mode, if available.

Using the Mini Phantom

Center the phantom in the biopsy window and make one exposure. The entire phantom should be visible in the image. For prone units, the phantom is kept from falling by a lip on the phantom that, with the compression paddle, provides support for the phantom. Otherwise, the lip allows for consistent positioning of the phantom.

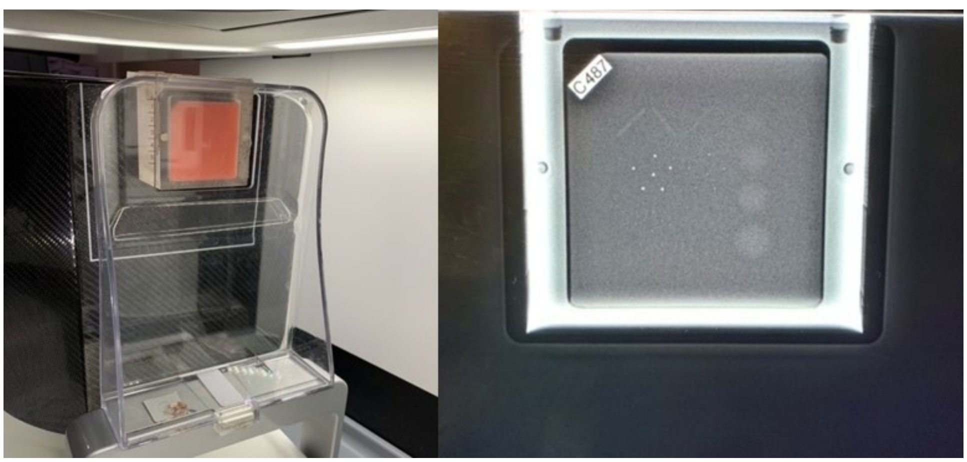


Figure 2-1: Showing that the Mini phantom is fully inside the biopsy window of the compression paddle and that all test objects in the phantom are inside the field of view.

Using the Original ACR Phantom

If your system can image all test objects within the biopsy window in a single exposure, then only one exposure is required. However, most systems will need additional exposures to meet this criteria. A sufficient number of overlapping sections of the phantom are required to image all test objects. The technologist will work with the physicist to establish an appropriate protocol to meet these requirements. One possible example is shown in the figure below.

Figure 2-2: Showing that the Original ACR Phantom was imaged twice to make sure all test objects could be visualized inside the view window.

Using the ACR Digital Mammography (DM) Phantom

If your system can image all test objects within the biopsy window in a single exposure, then only one exposure is required. However, most systems will need additional exposures to meet this criteria. A sufficient number of overlapping sections of the phantom are required to image all test objects. The technologist will work with the physicist to establish an appropriate protocol to meet these requirements. One possible example is shown in the figure below.

Figure 2-3: Showing that the ACR DM Phantom was imaged twice to make sure all test objects could be visualized inside the view window.

Data Analysis and Interpretation

1. Use the acquisition workstation display monitor to evaluate the image. Optimize the viewing conditions in the room before scoring the phantom and evaluating the image for artifacts. Reduce the lighting in the room to eliminate glare from the acquisition workstation display.
2. Adjust the window level (WL) and window width (WW) to optimize the visualization of the test objects. Do not use unreasonably narrow WWs. While a narrow window width may enhance the contrast of the test objects, it will also tend to enhance the appearance of artifacts. For guidance on approximate WL and WW values, consult with your medical physicist or use the levels that may be recorded in the medical physicist's annual report.
3. The WL and WW may need to be adjusted for each test object to be scored. The Zoom or magnifier tool may be used to detect the test objects.
4. Examine the image for both broad-area and detailed artifacts. Record the observed artifacts and whether the artifacts are clinically significant.

Scoring Test Objects

Fibers:

i. The fibers are manufactured to be approximately the same length. Starting with the largest fiber, evaluate whether the fiber is in the correct location and has the correct orientation.

ii. Count each fiber as a whole fiber (earning a full point) if the fiber appears to be the same length as the largest fiber. If a small gap in the fiber is visible, and the gap is less than the width of the fiber, then count the fiber as a whole fiber.

iii. Count a fiber as a ½ point if the fiber is shorter than a whole fiber, but not less than half the length and with no breaks in that half fiber.

iv. Stop counting fibers after scoring a fiber as a half or as not seen. The fiber score is the number of whole fibers plus any half point.

Speck groups:

i. There are 6 specks in a speck group. Starting with the speck group with the largest specks. Count each speck group as a whole group if 4 to 6 specks are visible, the group is located in the proper location, and the specks are in the correct location within the group. A whole group is given 1 point.

ii. If only 2 or 3 specks within a group are visible, then the speck group is given ½ point.

iii. Stop counting speck groups after scoring a speck group as a half or as not seen.

Masses:

i. Starting with the largest mass. Count the mass as 1 point if the object is in the correct location, and if the object is generally circular against the background. If at least ¾ of the border is continuous and the object is generally round, then the object is awarded 1 point.

ii. Count the mass as ½ point if a mass-like object is visible in the correct location but does not have a generally circular appearance (greater than ½ but less than ¾ of a circle).

Enter the final scoring in each category (fibers, speck groups, and masses) on the form. Be sure that the final score includes total test objects visible of each type across the acquired images.

Do not deduct for artifacts (that is, reducing the score of visible test objects for seeing artifacts that mimic test objects). Deducting for artifacts is not part of the procedure for scoring test objects.

Artifact Evaluation

The evaluation of artifacts is separate from the scoring of the Phantom Image for detection of test objects. Artifacts that mimic test objects are not to be deducted in the scoring of the phantom. The evaluation for Artifacts is a pass or fail test. Artifacts on the phantom must not be clinically significant. This aspect of the test fails if any artifacts are in a location that could impact clinical interpretation and

i. Artifacts are as prominent as (or more prominent than) the visible test objects in the phantom image, or

ii. Artifacts obscure test objects in the phantom, or

iii. Artifact could affect clinical performance.

Artifacts that do not meet the definition above will be considered not clinically significant. While the lesser severity of these artifacts allow more flexibility in taking corrective actions, these artifacts are not to be ignored.

Broad-area artifact: Display the phantom image at acquisition size (1:1 pixel ratio). Distance yourself to best visualize artifacts such as large non-uniformities, blotches and streaks. Record any artifacts that are seen and evaluate the artifacts as being clinically significant or not significant.

Detailed artifacts: Display the phantom image at acquisition size (1:1 pixel ratio). Examine the image for small artifacts such as black or white pixels, black or white clusters of pixels. Record any artifacts that are seen and evaluate the artifacts as being clinically significant or not significant.

Phantom Image Scoring Key, including Artifact Evaluation

Test Object	Full Point	Half Point
Fibers	• Correct location • Correct orientation • Full length visible * • 1 break allowed (must be ≤ width of fiber)	• Correct location • Correct orientation • At least half of length visible • 1 break allowed (must be ≤ width of fiber)
Speck Groups	• Correct locations • 4 - 6 specks visible	• Correct locations • 2 - 3 specks visible
Masses	• Correct location • Signal difference visible • Border is continuous and generally circular (≥ ¾ border visible)	• Correct location • Signal difference visible • Border is not continuous or generally circular (≥ ½ and < ¾ border visible)
Artifacts	Only fail for artifacts if they are in a location that could impact clinical interpretation ***and*** they are clinically significant. Fail if: • Artifacts are as prominent as (or more prominent than) the visible test objects in the phantom image, or • Artifacts obscure test objects in the phantom, or • Artifacts could affect clinical interpretation	

*The fiber construction on the ACR DM phantom is standardized enough to define the length of full and half fiber. The full fiber is considered greater than 8mm. A half fiber is between 5 and 8 mm.

Precautions and Caveats

In prone units, it is imperative that any auto decompression function be disabled, or the phantom could drop and get damaged.

If using the large ACR DM Phantom, it is highly recommended that you build up a spacer below the phantom to help support the weight. This may prevent the phantom from being dropped. An example of this is seen in the figure below.

If there is sufficient space, the ACR DM phantom may be positioned with the chest wall edge of the phantom against the chest wall edge of the biopsy window.

Due to the many different paddle sizes, it is up to the discretion of the medical physicist to choose an appropriate size compression paddle to be able to image the wax insert. Once the paddle is chosen the size should be documented on the QC form. Going forward, this paddle should be used for this test and for the Technologist's QC.

The images created for this QC program may not meet the requirements of the images for submission for accreditation. The instructions contained in the submission package must be followed.

Performance Criteria and Corrective Actions

Phantom Scoring

There are differences in numbers of test objects and their respective sizes between the 3 approved phantoms. The sizes of the test objects can be seen in Table * in Appendix A. The passing criteria for each of these phantoms are summarized in the table below.

The passing criteria for each of these phantoms are as follows:

	Original ACR Phantom	Mini Phantom	ACR DM Phantom
Fibers	4	2	2
Speck Groups	3	2	3
Masses	3	2	2

Artifact Evaluation

The cause of the artifact should be identified and isolated to determine if it originates from the x-ray system, the detector, or the monitor. If the artifact is confirmed to originate from the detector, a detector recalibration may be needed. Artifacts isolated to other components of the imaging chain should be investigated. Your Medical Physicist may be helpful in this investigation. After the artifact is resolved, repeat the phantom artifact test. If a clinically significant artifact persists, the facility should contact its authorized service representative. If the clinically significant artifact originated from the x-ray/detector system, patient procedures should not be performed until it is corrected. If the clinically significant artifact originated from the workstation, perform the procedure for Acquisition workstation monitor performance assessment.

Timeframe for Corrective Action

The cause of the phantom image quality and/or artifact failure must be found and corrected before clinical use. Your medical physicist may be helpful in identifying and correcting the cause of failure. For artifacts that do not meet the criteria for clinical significance in Table XY above, corrective action must be performed within 30 days. Service may be required in either case.

3. Visual Checklist

Objectives

This task ensures that all features and functions of the breast biopsy system are working properly. This task ensures that the equipment is mechanically rigid and stable.

Frequency

Monthly, after relevant service (before next clinical use), and upon installation of new equipment (before first clinical use).

Test Equipment

Visual Checklist form

Test Procedure

This is a visual test; buttons or switches need not be activated.

1. Visually inspect each item on the system that is listed on the Checklist for proper operation.
2. Record on the Checklist the item's pass or fail status.
3. Add any item that is vital or important to your system's operation or as required by the medical physicist.
4. Date and initial the Checklist.

Data Analysis and Interpretation

None.

Precautions and Caveats

Items that are degrading toward failure but not yet failing should be documented. These items should be addressed before failure.

The Critical Items on the checklist pertain to patient safety, operator safety, high-quality images, and accurate needle placement leading to accurate tissue sampling.

Items that are specific to your unit, facility or procedure should be added to the checklist. Items that do not pertain may be crossed off, and marked N/A.

At least one operational footswitch for the application of compression should be available.

Performance Criteria and Corrective Action

All Critical Items must pass before the system is used clinically.

Service should be called to repair any serviceable items.

Timeframe for Corrective Action

Failures of Critical Items must be corrected before clinical use.

Failures of non-Critical Items must be corrected within 30 days of the test.

4. Compression Thickness Indicator

Objective

This test ensures that the indicated compression thickness is within tolerance.

Frequency

Monthly, after relevant service (before next clinical use), any time the compression thickness indicator is suspected to be inaccurate, and upon installation of new equipment (before first clinical use).

After each relocation, before biopsy procedures (mobile units).

Equipment

- An object to be used as a compression thickness indicator phantom.
  - This object must not be compressible.
  - This object must be of known thickness, between 4 cm and 8 cm in thickness.
  - This object must not have sharp edges or features that will damage the compression paddle or the breast support.
  - The mammography phantom may be used.
  - This test object must be labeled and set aside for use only for this test (if other than the mammography phantom).
- A paddle that is used clinically for biopsy procedures.
- A metric ruler.

Test Procedure

1. Record on the QC form, what item is used as the test object. With a ruler, measure and record the thickness of the test object. Use the same units of measurement that are used by the machine (mm or cm).
2. Position the test object along the chest wall edge of the breast support. Initially, apply sufficient pressure to hold the test object in place.
3. Apply a compression force that is used clinically. The same amount of compression force should be consistently applied from test to test.
4. Read the indicated thickness and record it in the QC form. Record the amount of compression force that was used.

Data Analysis and Interpretation

Subtract the thickness of the test object from the indicated thickness. Record this difference in the QC form.

Precautions and Caveats

To prevent damage to the test object or phantom, care must be taken to ensure that the test object is held securely while applying compression and while under compression.

The test object must not have any features that may damage the breast support or the compression device.

The contrast disk may damage the compression paddle.

If items are added to protect the equipment or the unit, then their thicknesses must be included in the thickness of the test object.

An inaccurate thickness indicator can cause problems with the unit's selection of exposure factors, causing problems with image quality and patient dose.

When releasing compression, be sure to secure the test object to avoid damage.

Performance Criteria and Corrective Action

1. The compression thickness indicator must be accurate to within 5 mm (0.5 cm).
2. If the test fails, initially, repeat the measurements, including the measurement of the test object.
3. If the test fails again, the unit should be serviced.

Timeframe for Corrective Action

The cause of the test failure must be corrected within 30 days.

5. Acquisition Workstation (AW) Monitor QC

OBJECTIVE

- To ensure that all AW monitors are clean and free from dust, fingerprints, and other marks that may interfere with clinical information.
- To ensure that AW monitors used for procedure guidance are calibrated, with brightness and contrast settings correctly set.
- To ensure that monitors used for procedure guidance meet manufacturer specifications via the conduction of Monitor Manufacturer Automated Tests (if available).

> **Important:** Monitor Manufacturer Automated Tests are required if such tests are available in the manufacturer's documentation.

FREQUENCY

Monthly, after relevant service (before next clinical use), and upon installation of new equipment (before first clinical use).

TEST EQUIPMENT

Dry, soft, lint-free cloth or cleaning tissue recommended by your AW manufacturer.

> **Note:** Any other cleaning methods may lead to damage of the anti-reflective screen coating. Please follow your AW manufacturer's recommendations for proper cleaning and cleaning material. If you don't have them, ask the AW manufacturer.

The American Association of Physicists in Medicine (AAPM) TG-270 test patterns and performance recommendations are preferable if available. The updated AAPM TG18-OIQ test pattern and performance recommendations identified in TG-270 should be used if they are available. However, if TG18-OIQ is not available, either TG18-QC or a standard SMPTE test pattern is also an acceptable option. If a pattern is not already installed, an authorized service representative should install either test pattern or one that permits the measurements in Figure 8. If it is not possible to install a relevant test pattern on the monitor, this part of the test is not applicable.

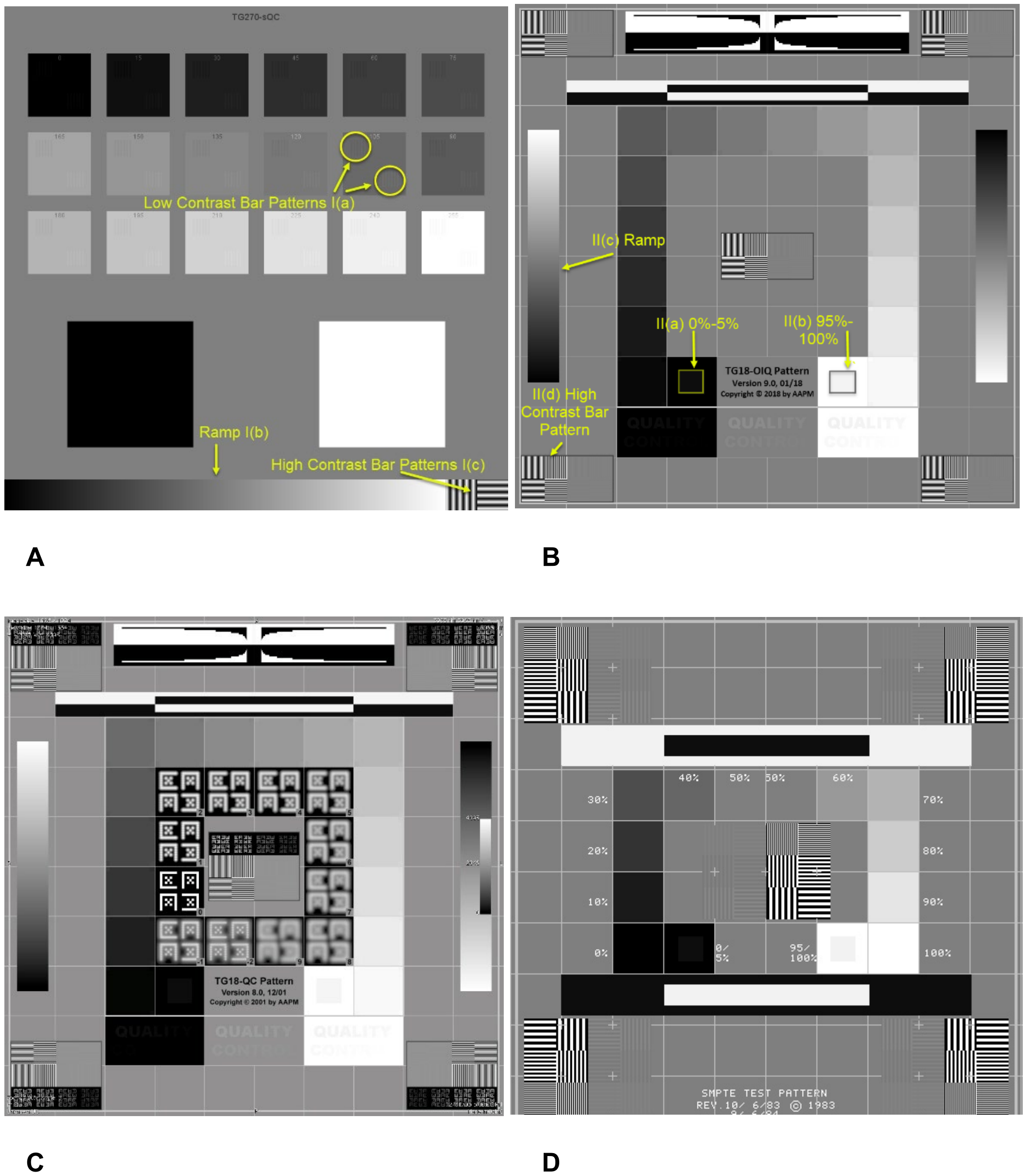


Figure 2-4: Test patterns: A) TG270-sQC, B) AAPM TG18-OIQ. C). TG18-QC, D) SMPTE.

Test Procedure

Monitor Condition

1. Visually inspect the surface of the monitor for the presence of dust, scratches, defects, fingerprints, shiny patches (from grease or gel), and other foreign material (e.g., pen marks, etc.).

2. Wipe the monitor screen gently using a soft lint-free cloth dampened with water to remove any dirt, fingerprints, or other foreign material, then wipe with a dry, soft, lint-free cloth. A special-purpose screen cleaning tissue or cloth recommended by the monitor manufacturer may be used.

3. After drying, recheck the monitor surface to be sure the items noted in step 1 have been eliminated. If they were not, clean the monitor again.

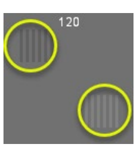
4. Record significant findings on the form (see Performance Criteria and Corrective Actions).

Test Pattern Image Quality

1. Set the lighting conditions in the procedure room as you would have during a biopsy.
2. Display the test pattern on the monitor used for procedure guidance. (If an appropriate test pattern is not available on the AW, skip this test.)
3. Evaluate the test pattern for the following visible targets and record pass or fail on the form.
4. Follow the procedure (below) for the correct Test Pattern on your system

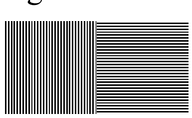
For Test Pattern A:

a. Are the low contrast bar patterns in the top and bottoms of the 18 gray patches discernable? Note that the bar patterns may not be fully visualized in patches 0 and 255 which is acceptable.



b. Is the grayscale gradient bar continuous, without steps or breaks?

c. Are the high contrast line-pair images at the bottom right visible and clearly distinguishable?



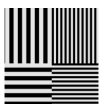
For Test Patterns B-D (see example arrows on Pattern B for similar features on C-D)

a. Are the 0%-5% contrast boxes visible? 

b. Are the 95%-100% contrast boxes visible?

c. Is the grayscale gradient bar continuous, without steps or breaks (this patch is not available on pattern D)?

d. Are the line-pair images at the center and four corners visible and clearly distinguishable?



Monitor Manufacturer Automated Test (if available)

1. Open the monitor manufacturer automated test program.
2. Review the results and verify that all tests have passed.
3. Record an overall pass or fail on the form at the designated frequency.

Data Analysis and Interpretation

None.

Precautions and Caveats

Ideally, all monitors should be free of dust, fingerprints, and other marks. Similarly, there should be no "shiny" patches or obvious non-uniformities on the surface. As described below, significant blemishes that interfere with the interpretation or QC of images ***must*** be corrected.

Most problems can be corrected by cleaning according to the manufacturer's instructions. However, if cleaning does not correct the problem, the manufacturer should be contacted to evaluate and correct the problem.

Do not use cleaning products, abrasive materials, or alcohols that will damage the anti-reflective coating on the screen.

Although this thorough check must be done and documented by the technologist monthly, technologists should clean significant dirt from their AW as it occurs if it is noted during daily use.

In most cases, Monitor Manufacturer Automated Tests and action limits are available in manufacturer manuals or documents published by the manufacturer. These tests are extremely valuable in maintaining quality and are specific to each manufacturer. The medical physicist should assist the facility in verifying that any installed automated test system is set up and functioning properly.

Performance Criteria and Corrective Actions for Monitors Used for Procedure Guidance

Monitor Condition

Any large, significant blemish that interferes with the visualization or QC of images is a failure. (If there are questions regarding the significance of a monitor blemish, the Supervising Physician should be consulted.)

Test Pattern Image Quality (Test Patterns A if available)

The bar patterns in the top and bottom of each of the middle 16 swatches are all visible. Note that the bar patterns may not be fully visualized in patches 0 and 255 which is acceptable.

The high-contrast line-pair patterns ***must*** be distinguishable in bottom right corner.

Test Pattern Image Quality (Patterns B-D as necessary)

The 0%-5% and 95%-100% contrast boxes ***must*** be visible.

The high-contrast line-pair patterns ***must*** be distinguishable at the center and corners.

Monitor Manufacturer Automated Test (if available)

Monitors ***must*** pass all manufacturer tests.

Timeframe for Corrective Action

Monitor Condition

All failures ***must*** be corrected before clinical use.

Test Pattern Image Quality (if available) and Monitor Manufacturer Automated Test (if available)

All failures ***must*** be corrected within 30 days.

6. Compression Force

Objectives

This test ensures that the unit can compress the breast sufficiently to immobilize the breast for the entire procedure. This test ensures that the maximum compression force is not excessive. This test evaluates 1) the maximum compression force attained by the use of the initial power-drive mode (typically applied by the use of a footswitch or other power switch), 2) the maximum final compression force (typically manually applied) and 3) that adequate compression can be sustained.

Frequency

Semiannually, after relevant service (before next clinical use), any time the compression system seems to behave abnormally, and upon installation of new equipment (before first clinical use).

Test Equipment

Force scale (e.g., bathroom scale). A scale (analog or digital) designed specifically to measure compression force may be used. A bathroom scale that is flat and is an analog-type may be used.

Towels or pads should be used to protect the surfaces of the compression paddle and the breast support (detector) from the surfaces of the scale.

Test Procedure

1. Attach or position the protective material to the breast support and to the compression paddle. Use tape or other devices to keep the protective material in place.
2. Place and center the scale between the compression paddle and the breast support. The scale display should be visible. For prone units, items may be placed under the scale to help support the scale. Ensure that these items do not interfere with the application of the compression.
3. Using power drive (if available), activate the compression device and operate until compression stops automatically.
4. Read and record the initial automatic compression force on the Compression Force form.
5. Continue to apply compression using the power drive and record the maximum compression achieved. Release the unit from the maximum compression force.
6. Manually apply compression using the fine-adjustment knob until the maximum compression force is achieved.
7. Read and record the maximum compression force on the Compression Force form. Release the unit from the maximum compression force.
8. Apply a compression force that is used clinically (at least 10 pounds): Test that the compression force is maintained for a reasonable length of time (about 2 minutes).

9. Release the scale from compression.

Data Analysis and Interpretation

None.

Precautions and Caveats

Digital bathroom scales may not respond properly if pressure is applied slowly and may be inappropriate to use for this test.

The compression device or the breast support may be damaged if the pressure scale is improperly positioned.

The compression device or the breast support may be damaged if excessive force is applied. The safety mechanism must stop the initial power-drive mode from applying compression force in excess of 45 lb.

If the application of the automatic initial compression causes the pressure to exceed 45 lbs, then the test should be halted immediately, and the unit be serviced.

To prevent damage to the compression device or to the breast support, caution should be exercised when applying the pressure manually.

Releasing the compression without controlling the scale may cause the scale to fall.

Performance Criteria and Corrective Action

The compression force using the power drive mode must be at least 10 pounds, sufficient to stabilize the breast before final positioning, and must not exceed 45 pounds.

The unit must be able to hold a compression of at least 10 pounds for at least 2 minutes and should not vary by more than one pound.

The manually applied compression force must be at least 10 pounds but may exceed 45 pounds.

Timeframe for Corrective Action

The cause of the test failure must be corrected before the next clinical use.

7. Facility QC Review

Objective

To ensure the Quality Management Team (or QA Committee) consisting of the Supervising Physician, QC Technologist (and a Manager/Supervisor if appropriate) are aware that all QC tests are performed at the required frequencies, that data are collected, results are adequately documented, that corrective action is taken, and that no patient exams are conducted when tests fail that require correction before clinical use.

Frequency

Annually.

Test Equipment

- Technologist QC forms from the last medical physicist's survey.
- Evaluation of Site's Technologist QC Program form

Test Procedure

1. QC data/notebooks must be reviewed by the Quality Management Team. This review may be done as a group in person, remotely or through individual review. Prior to the meeting or review:
2. Enter the QC results from the most recent Medical Physicist's QC Test Summary form into the Facility QC Review form or attach a copy of the summary and findings.
3. Enter QC results from the Technologist QC performed since the previous review into the form.
4. The QA Committee or Quality Management Team should review the last year of QC data. Review each QC test and its results.
5. For any test failures, note in your review any corrective action taken and documented.
6. Discuss reasons for the failures, as well as the appropriateness and timeliness of the corrective actions.
7. Review the most recent Medical Physicist's Review of the QC Program.
8. Document completion of the review in writing, listing all participants, date(s) of review, with signature(s) of the Supervising Physician and other relevant personnel. This can be accomplished by using the form provided in the manual or equivalent.

Data Analysis and Interpretation

None.

Precautions and Caveats

The Supervising Physician has the general responsibility of ensuring that the quality assurance program meets the ACR accreditation program requirements. This responsibility cannot be delegated to any individuals such as the medical physicist or QC Technologist(s).

Routine and appropriate performance of the Facility's QC Review demonstrates that this responsibility is being properly exercised. The Quality Management Team must review the QC test results at a frequency to ensure adherence to the ACR accreditation program. This must be performed at least annually and more frequently if needed. The Quality Management Team should ensure that all tests, results, and corrective actions are properly documented. They should document their review by signing and dating the review document.

Performance Criteria and Corrective Actions

The Medical Physicist's Review of the QC Program that is performed during the Annual Survey will reflect the facility's QC program's adherence to the ACR standards. The pass/fail criteria used by the medical physicist is outlined in the Medical Physicist's Section of this manual, and should be used by this committee.

If tests are not performed at the correct frequency, the Quality Management Team should take steps to ensure that the tests are performed as often as needed. Additional time and/or training should be allocated if needed.

If corrective action was not already performed, the Quality Management team should take steps to enact the corrective action. The medical physicist should be consulted for any assistance or training regarding the performance of tests.

Timeframe for Corrective Action

Any issue(s) revealed during the Facility QC Review must be documented and have a corrective action plan in place following the timeline specified in the relevant QC test(s) procedure(s).

8. Manufacturer calibrations (if applicable)

Objectives

To detect and automatically correct equipment problems. This may include digital detector performance, compensating for dead or over-responding pixels, structured or other noise, nonlinear response, or other technical performance parameters.

Manufacturers may require technologists to perform unit-specific calibrations (or tasks) as part of routine QC. These calibrations should be performed according to the manufacturer's recommendations. If you have questions regarding manufacturer calibrations, you should contact your equipment manufacturer (or service engineer) and your medical physicist for guidance.

Frequency

According to the manufacturer's recommendations, after relevant service (before next clinical use), and upon installation of new equipment (before first clinical use).

Test Equipment

According to the manufacturer's recommendations.

Test Procedure

According to the manufacturer's recommendations.

Data Analysis and Interpretation

According to the manufacturer's recommendations.

Precautions and Caveats

According to the manufacturer's recommendations.

Performance Criteria and Corrective Action

According to the manufacturer's recommendations.

Timeframe for Corrective Action

The corrective action must be performed according to the manufacturer's recommendations.

9. Optional – Physician Feedback

Objective

To encourage the physician(s) performing biopsies to provide feedback to the technologists on the quality of the biopsy procedures, and to promote uniformity of patient care.

Communication with all stakeholders (e.g., technologists, performing physicians, medical physicists, administration) is essential to a successful program. It is important that the physicians who perform mammography guided breast biopsy procedures provide feedback to the technologist(s) to improve the program. Some feedback may best be shared during the procedure for optimal impact, while some may need to be discussed away from the patient. Technologist(s) should be encouraged to ask for feedback as well as to provide their own feedback for process improvement. Positive feedback for a job well done as well as constructive criticism should be provided at the stakeholder's request. This process can be informal through verbal discourse or part of a structured process that can be documented for future reference.

Frequency

As needed, at the request of the performing physician(s), the technologist, or medical physicist.

An annual process review is encouraged.

Test Equipment

Radiologist/Physician Feedback QC Form.

Test Procedure

1. The physician should review the total quality of the biopsy procedure. The physician should assess the components of the procedure (image quality, targeting, needle placement, sampling).
    a. See Tech QC Form 9. For Radiologist/Physician Feedback Forms as example.
        i. Individual case form
        ii. Annual summary form.
5. The physician should also give positive feedback if the procedure went well.
6. Following the facility's established internal protocol, the physician should ensure that the technologist receives all pertinent feedback.
7. The technologist should be encouraged to ask for physician feedback.
8. The technologist should be encouraged to present the technologist's viewpoint.

Data Analysis and Interpretation

The facility management and staff should routinely evaluate this information to examine possible areas for quality improvement.

Precautions and Caveats

Feedback should be presented as means to improve the procedure and the outcomes of the procedures. Critiques should be objective, about the program, and never become personal.

Performance Criteria and Corrective Actions

It is useful for the physician to provide feedback for image quality or procedural issues that could affect the patient welfare or procedure efficacy or efficiency.

It is important to provide positive feedback to the technologist for a job well done (for example, in cases where difficult cases went well).

Results should be reviewed and discussed at Facility QC Review meeting.

Timeframe for Corrective Action

Not Applicable.

10. Optional – Repeat Analysis

Objective

This test determines the number and cause of patient exposures that are repeated on each specific unit. Analysis of these data will help identify ways to improve efficiency and reduce patient breast dose.

Frequency

Semiannually, and after six months of clinical use following installation of new equipment.

Test Equipment

- Patient biopsy exams with repeated images
- Repeat Analysis Data forms

Test Procedure

Definition: A repeat biopsy exposure is when the first image is inadequate, and an additional exposure is made to replace or supplement the first exposure.

1. Keep track of each repeated exposure using a copy of the Repeat Analysis Data form for each individual biopsy unit
2. Enter the starting and ending date for each worksheet.
3. Collect the set of worksheets from six months of data. Calculate the total of the repeated exposures for each category of causes for repeating. Categories are summarized in the table below.
4. Calculate or estimate the total number of exposures for the period of data. An estimate of the total number of exposures may be calculated by multiplying the number of patients in the period by the average number of exposures per patient. Please note that the average number of exposures per patient may vary depending on mode used (stereo vs DBT) and physician protocol preference.
5. Calculate the Overall Biopsy Exposure Repeat Rate by dividing the number of repeated exposures by the total number of exposures for the period and then multiplying that number by 100%.
6. Determine the Percent of Biopsy Exposure Repeats in each category by dividing the number of biopsy exposure repeats in each category by the total number of repeated biopsy exposures and multiplying each of those numbers by 100%.

> **Note:** Repeat biopsy exposures are those acquired in addition to those included in normal protocols. As an example: Facility A uses one scout, a stereo pair pre-fire, a stereo pair post-fire, and a stereo pair for clip placement, for a total of seven exposures. Each exposure in addition to the standard seven exposures is considered a repeat.

Sample Reasons for Repeated Biopsy Images

Patient-Related Repeats	Technical Repeats	Miscellaneous Repeats	Do Not Count as Repeats
Positioning	Exposure too low (excessive noise)	Blank images	All localizations (eg, wire, I-125 seed, etc.
Patient motion	Exposure too high (image saturation)	Good image (no apparent reason)	Quality control
Patient-caused artifacts	Equipment-caused artifacts	Procedural-induced target shift	
Incorrect patient ID	X-ray equipment failure	Incorrect targeting	
	Software failure	Other miscellaneous	
	Aborted exposure due to AEC		
	Inadequate Tissue Sampling		
	Failed Marker Deployment		

Data Analysis and Interpretation

> **Note:** Some equipment manufacturers provide an automated system to collect, record, and analyze repeated clinical mammography images. These automated reports may be used instead of the procedure in this section as long as they include the following two key elements:
>
> - The total number of exposures made for biopsy procedures during the evaluation period
> - The percent repeats for biopsy procedures during the same period (# repeat biopsy exposures / Total # Biopsy Exposures x 100%)
>
> Automated manufacturer reports may include 2D mammo/DBT repeats. Facilities that use these reports must proceed with caution and only use repeat and total exposures for biopsy procedures. If the automated report cannot meet these criteria, then the procedure in this manual should be followed instead. If the overall percent biopsy repeat rate exceeds 20%, the Repeat Rate in each category must be calculated going forward. This may require using the manual methodology to determine these rates.

1. Determine the overall percentage of repeated biopsy exposures by dividing the total number of repeated biopsy exposures by the total number of patient biopsy exposures made during the analysis period and multiply by 100%.

$$\%\ \boldsymbol{Biopsy\ Exposure\ Repeats} = \left(\frac{\boldsymbol{Total\ \#\ Repeat\ Biopsy\ Exposures}}{\boldsymbol{Total\ \#\ Biopsy\ Exposures}}\right) * \mathbf{100}$$

2. Determine the percentage of biopsy exposure repeats in each “Reason for Repeat” category by dividing the repeats in the category by the total number of repeated biopsy exposures.

$$\%\ \boldsymbol{Biopsy\ Exposure\ Repeats} = \left(\frac{\boldsymbol{\#\ Biopsy\ Repeat\ Exposures\ in\ Category}}{\boldsymbol{Total\ \#\ Biopsy\ Repeat\ Exposures}}\right) * \mathbf{100}$$

Including mammography guided breast biopsy procedures on at least 150 patients allows for a sufficient number of repeated exposures so that reasonable statistics can be obtained for the analysis. Facilities that do not examine 150 patients in each six-month period should still perform Repeat Analysis at least every six months to determine the primary causes of repeats.

> **Note:** This procedure is unit based Repeat Analysis designed to identify outliers for individual units. If a facility has multiple Mammography Guided Biopsy Units, they may wish to perform a facility based Repeat Analysis. This can be done by summing the data from each individual unit and following the same process for all units as was done for individual units.

Precautions and Caveats

All exposures that are repeated should be included in the repeat analysis, not just those that the Radiologist asked to have repeated. Some facilities may keep repeated images in the patient's medical record along with good images. These repeated images must be included in the repeat analysis.

If your biopsy system utilizes a small field of view, then it may be more difficult to find the desired target in the preliminary images, and a slightly higher repeat rate of scouts may be possible.

An adequate number of the total of breast biopsy exposures is needed for optimal statistical results. It is important to note that even if the number of total images is small, the repeat analysis results are still useful in identifying areas in need of improvement.

Care should be taken that the # Repeats and the # Total exposures for this analysis contains only biopsy exposures.

Capturing accurate data for this may be difficult when it is done after the biopsy procedure is performed. It may not be remembered that an exposure was repeated. The cause for the image to be repeated may not be remembered. A simple data sheet used during the procedure may be an easy way of capturing that data.

It is important to note that it may be difficult to estimate the total number of exposures performed over a six month period due to the use of different modes (stereo vs DBT) and different physician protocol preferences. Careful consideration must be used to accurately determine this total as it can greatly affect your overall repeat rate.

Repeat Analysis is intended to reveal opportunities for improvement in patient care. Repeated imaging must not be removed from patient records, as they provide information that enables this performance improvement.

Performance Criteria and Corrective Action

With a fully operational biopsy QC program, the overall repeat rate should be lower than 20%. If the overall repeat rate exceeds 20% then the repeat rate in each category can be used to identify areas for improvement.

With enough repeated exposures, patterns may emerge. The pattern may show the underlying causes for repeats. Those underlying causes for repeats can then be addressed.

Timeframe for Corrective Action

A corrective action plan should be implemented within 30 days and assessed at the next six month interval.

B. Mobile Units

Mobile stereotactic- and tomosynthesis-guided biopsy systems are subject to all the QC requirements and frequencies that apply to stationary systems. Additionally, the tests listed below must be performed after each move of the mobile system to an examination location.

The evaluations should be made at the mobile unit's site of operation to verify that the mobile unit is performing adequately before any patient examinations are conducted. If the image quality is inadequate, then immediate corrective action is required and the results of the corrective action need to be verified via repeat testing before proceeding.

QC Tests required after each move, prior to performing patient procedures
• Localization Accuracy
• Phantom Image Quality and Artifacts
• Compression Thickness Indicator

C. Quality Control Forms

Routine and complete documentation of QC and corrective actions is critical part of quality stereotactic- and tomosynthesis-guided breast biopsy. QC forms have been developed to help you meet this goal. The QC form number corresponds to the test procedure number provided in the previous section. Each form has been set up with a brief summary of the test procedure, an area to record the test conditions and techniques (to ensure that you do not change test conditions that could cause variability in the results), and with reminders of action limits and timeframes for corrective action. Be sure to consult the quality control test procedure for the complete instructions if you have questions about performing tests or analyzing data. For your convenience, the electronic QC forms are provided online (URL TBD).

D. Management Forms

1. Corrective Action Log

The Corrective Action Log provides a method for documenting QC events needing corrective action that occur within a stereotactic- or tomosynthesis-guided biopsy facility. This includes problems detected during Technologist QC Tests, Medical Physicist Surveys, and any other miscellaneous events that may arise. The Corrective Action Log is in the Technologist's QC Forms.

2. QC Summary Checklist

To assist with the oversight of the QC program, a two-page checklist is provided to record the Weekly, Monthly, Quarterly, and Semi-Annual Tests. This checklist provides a schedule of when QC tasks are due and a record indicating that the tasks have been completed in a timely manner. In addition, the ACR will request a copy of the checklist during the accreditation process to document that all required QC tests were performed at the required frequencies. The QC Summary Checklist is in the Technologist's QC Forms.

QC test completion should be documented on the checklist by the performing technologist. If a test is not performed because a system is not in use, the QC technologist should put an "X" in the box and include a note of why the test is not being performed.

E. Infection Control

Personnel must follow the facility's established Infection Control procedures. For additional guidance on infection control, refer to OSHA's Bloodborne Pathogens and Needlestick Prevention page and OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030), any additional state and local regulations on this subject that may be applicable to the facility, and the manufacturer's procedures specific to its equipment.

III. Appendix

Phantom test object sizes

	Original ACR Phantom		Mini Phantom		ACR DM Phantom	
	Object Number	**Size (mm)**	**Object Number**	**Size (mm)**	**Object Number**	**Size (mm)**
Fibers	1	1.56				
	2	1.12				
	3	0.89	1	0.93	1	0.89
	4	0.75	2	0.74	2	0.75
					3	0.61
	5	0.54	3	0.54	4	0.54
	6	0.40			5	0.40
			4	0.32	6	0.30
Specks	1	0.54	1	0.54		
	2	0.40				
	3	0.32	2	0.32	1	0.33
					2	0.28
	4	0.24	3	0.24	3	0.23
			4	0.20	4	0.20
	5	0.16			5	0.17
					6	0.14
Masses	1	2.00				
	2	1.00	1	1.00	1	1.00
	3	0.75	2	0.75	2	0.75
	4	0.50	3	0.50	3	0.50
					4	0.38
	5	0.25	4	0.25	5	0.25
					6	0.20

Medical Physicist's Section

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I. INTRODUCTION

Since the publication of the previous edition of this manual, the technology of medical imaging has evolved quickly and dramatically. X-ray image guided breast biopsy has benefited greatly from those improvements. Large area digital image receptors have propelled Full Field Digital Mammography (FFDM) imaging systems into general use. The development of Digital Breast Tomosynthesis (DBT) has improved detectability of certain features and has provided an alternative to stereotactic imaging for needle guidance. Biopsy attachments that are mounted to diagnostic mammography units permit those units to perform biopsy procedures using either stereotactic or tomosynthesis-guidance. Stand-alone prone stereotactic breast systems continue to be used, but the accessory units provide biopsy capabilities without the need of a dedicated space or equipment.

Previous limitations of the equipment used in breast biopsy have been either eliminated or alleviated. With that, novel ways of using that equipment have been developed. Having the task of understanding how the equipment works and is used, the Medical Physicist (MP) has had to keep up with all the changes.

However, the fundamental responsibility of optimizing the quality of medical imaging and maintaining that optimization has remained for the MP. The physics of x-ray generation, beam modification, radiation interaction with tissue, and scatter reduction has not changed. The largest changes center on the image receptor's detection of the incident radiation, its transformation into an image, and the display of those images.

The role of the MP involves understanding the systems' use by the physician. This is necessary should the physician need technical help that can be provided only by a person with the knowledge and experience of the MP.

The MP has the traditional responsibility of overseeing the Technologist's QC program. The MP is required to thoroughly understand how these QC tests are performed at each facility. That understanding should give the MP insight should there be any issues with the QC tests or their results. That understanding also eases discussions with the QC Technologist regarding any issues brought up by the MP or by the QC Technologist.

This section of the QC manual provides the procedures for tests that are to be performed for the Medical Physicist's Annual Survey. These tests should be performed for Acceptance Testing, supplemented by tests deemed appropriate by the MP. Appropriately selected tests should be used at the MP's discretion for the purpose of troubleshooting problems at the facility. Also, because "detector" can be appropriately used for both a digital image detector and the physicist's radiation measurement device(s), this manual refers to a digital image detector for breast imaging as an "image receptor", whereas devices used by the physicist for testing the x-ray beam (either solid state or ion chamber) are collectively referred to as a "dosimeter".

Breast imaging equipment has specific requirements imposed by their manufacturers. Therefore, the manufacturer's specified procedures for the QC tests on their equipment should be followed. The procedures included in this manual should be followed in the absence of manufacturer-defined procedures. Should a medical physicist's test required by the Breast Biopsy be a duplicate of a test required of the FFDM or DBT system, the test need not be repeated, but the results need to be reported.

The inclusion of the QC tests listed in this manual (or the manufacturer's equivalent tests) for the annual survey is required for attaining and maintaining ACR Accreditation. The MP's findings and recommended corrective actions are required for Accreditation.

As a reminder, stereotactic and DBT breast biopsy systems are not governed by the requirements of the Mammography Quality Standards Act (MQSA). However, adherence to this QC program is required for ACR Accreditation and may be required to satisfy any pertinent regulation.

All the effort of performing the tests that are part of the survey (acceptance testing, annual survey, or troubleshooting) is wasted if the results are not adequately communicated to the clinical staff. That communication should be clear and concise. That communication is especially important if there are findings that are affecting image quality, lesion targeting, or radiation exposure. Any findings and recommendations should be brought forward in the report so the clinical staff are immediately made aware of those findings and recommendations. Verbal communication of any vital findings must precede the submission of the written report. The written report should be written with sufficient detail such that the clinical staff or service engineer can understand and institute any required corrective action. A written report with a structure that facilitates the documentation of corrective actions will enhance the value of that report.

A workbook file is available to be downloaded for your use. The workbook includes Summary Forms to assist in communicating the test results. The workbook will help standardize the report format within your company and nationally. Still, the format of your report is totally yours to design.

If a test that is required for the Breast Biopsy Unit Survey is identical to a test already performed for the screening/diagnostic unit, it is not required that the test be repeated. The test results may be entered into the Breast Biopsy Survey report if the results are within 30 days of the Breast Biopsy Survey. The procedure from the ACR DM QC manual or the procedure from the Manufacturer's QC manual, as appropriate, may be used to perform these tests.

It is strongly recommended that the report that is submitted to the facility (which in turn will be submitted to the ACR for accreditation) be cohesive without pages from the diagnostic unit survey inserted into the Breast Biopsy Survey report. Therefore, it is recommended that the test results from the redundant tests (mentioned in the paragraph above) be entered in the Breast Biopsy Report format.

Select references and resources are listed in the Appendices.

A. Responsibilities

A facility's Supervising Physician (typically a radiologist) often has the general responsibility of ensuring that the quality assurance program meets all requirements.

In a facility where more than one technologist performs biopsies, one technologist should be assigned the responsibilities of QC (the QC technologist). Other qualified individuals may perform specific QC tests, but they should be reviewed and evaluated by the primary QC technologist. The primary QC technologist is responsible for ensuring that QC tasks are performed properly by standardizing test methodology, reviewing all data, overseeing repeat testing before calling the medical physicist or service personnel, and conferring with the radiologist and medical physicist.

Each facility must have the services of a medical physicist to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. The medical physicist is required to conduct acceptance tests of new equipment and follow up testing after major repairs. This survey must be done and all relevant tests including those associated with the biopsy portion must be passed prior to first use of digital mammography equipment on patients. The medical physicist is also required to perform an annual survey on each unit (up to 14 months between surveys is acceptable). During this annual survey, the medical physicist must also review the technologist's QC test results and provide written recommendations if there are problems or suggestions for improvement. If the medical physicist's annual survey results indicate a need for corrective action, the medical physicist should instruct the facility to provide a copy of their full report to the equipment service engineer.

Thorough reviews of the technologist's QC program by the radiologist and medical physicist ensure that the QC program is carried out consistently and provide oversight to make sure that changes in image quality are not inadvertently overlooked.

Important: The continuity of the QC program is very important to comply with the ACR accreditation program and to maintain a high level of quality service. The continuity of the QC program is the responsibility of the Supervising Physician. When the designated QC Technologist leaves a facility, goes on vacation, goes on leave, or is absent for any reason, it is vital that the QC program be continued by another technologist. A contingency plan is needed to prevent any lapse of the QC program. This includes the naming of an alternate QC Technologist who can continue the QC program at any time. The alternate QC Technologist must be trained in the performance of all QC tests. The alternate QC Technologist should have continuing experience in the performance of the QC tests. The alternate QC Technologist should be familiar with the current state of the QC program to be aware of any possible concerns or indications of possible test failures. This is important especially if the facility is aware of an upcoming absence of the QC Technologist. The facility's medical physicist should be used as a resource in the training and advisement of the alternate QC Technologist.

B. QC Tests, Frequencies, and Timeframes for Corrective Action

Table 1: Quality Control Tests and Frequencies

Test	Minimum Frequency	Corrective Action Timeframe[+]
Technologist Tests		
1. Localization Accuracy	Daily* (Craniocaudal Approach); Monthly (Lateral Approaches) - if applicable	Before clinical use
2. Phantom Image Quality	Weekly*	Before clinical use
3. Visual Checklist	Monthly	Critical items: before clinical use; non-critical items: within 30 days
4. Compression Thickness Indicator	Monthly	Within 30 days
5. Acquisition Workstation Monitor QC	Monthly	Within 30 days
6. Compression Force	Semi-Annually	Before clinical use
7. Manufacturer Calibrations *(if applicable)*	Mfr. Recommendation	Mfr. Recommendation
8. Facility QC Review	Annually	Not Applicable
Optional - Repeat Analysis	As Needed	Within 30 days
Optional - Radiologist or Physicist Feedback	As Needed	Not Applicable
Medical Physicists Tests		
1. Phantom Image Quality	Acceptance and Annual	Before clinical use
2. Artifacts	Acceptance and Annual	Before clinical use
3. Spatial Resolution	Acceptance and Annual	Within 30 days
4. DBT Volume Coverage	Acceptance and Annual	Within 30 days
5. Automatic Exposure Control System Performance	Acceptance and Annual	Within 30 days
6. Average Glandular Dose	Acceptance and Annual	Before clinical use
7. Unit Checklist	Acceptance and Annual	Critical items: before clinical use; non-critical items: within 30 days
8. Localization Accuracy	Acceptance and Annual	Before clinical use
9. Acquisition Workstation Monitor QC	Acceptance and Annual	Within 30 days
10. Evaluation of Site's Technologist QC Program	Acceptance and Annual	Within 30 days
Manufacturer's Calibrations *(if applicable)*	Mfr. Recommendation	Mfr. Recommendation
Collimation	Acceptance, Post-Repair, or Troubleshooting	Within 30 days**
Compression Thickness Indicator Accuracy	Acceptance, Post-Repair, or Troubleshooting	Within 30 days**
Evaluation of Compression Force	Acceptance, Post-Repair, or Troubleshooting	Before clinical use
kVp Accuracy and Reproducibility	Acceptance, Post-Repair, or Troubleshooting	Within 30 days**
Beam Quality (Half-Value Layer) Assessment	Acceptance, Post-Repair, or Troubleshooting	Within 30 days**
Ghost Image Evaluation (optional)	Troubleshooting	Before clinical use

[+]For tests performed as part of the FFDM survey (For attachments), corrective action timeframe specificized by the QC manual used For FFDM supersedes the requirements of this QC manual.

*On days or weeks when biopsy system is used clinically

**When the test is performed for an acceptance evaluation or post-repair evaluation, all failures *should* be corrected before clinical use, but *must* be corrected within 30 days. When the test is performed for troubleshooting, all failures must be corrected within 30 days.

C. Equipment Adjustments, Changes, or Repairs

If a major component is replaced or repaired, a Medical Physicist should be contacted to evaluate the need for performance testing of the breast biopsy system. The scope and timeline of the evaluation should be determined by the Medical Physicist based on the type of component that was replaced or repaired and shall adhere to applicable local and federal regulatory requirements.

All adjustments, changes, or repairs must include some form of verification testing to demonstrate that the effected equipment meets the applicable standards.

Table 5: Equipment Adjustments, Changes, or Repairs

Component		Major Repair
Automatic Exposure Control (AEC)	***AEC Replacement***	***Y***
	AEC recalibration that affects dose	N
	AEC sensor replacement	***Y***
	AEC circuit board replacement	***Y***
	Density control - internal adjustment*	N
	Thickness compensation - internal adjustment*	N
DM Detector	***Replacement***	***Y***
Grid	Replacement	N
	Adjustment	N
Collimator	***Replacement***	***Y***
	Reassembly with blade replacement	***Y***
	Adjustment	N
Compression Device	Pressure adjustment	N
	Thickness scale accuracy adjustment but only if it affects AEC performance	N
Compression Paddle	Paddle (new to facility)	N
	Deflection adjustment	N
	Adjustment due to extension beyond allowable limit, or visible on images	N
X-ray Unit	***Installation***	***Y***
	Reassembly	***Y***
	X-ray tube replacement	***Y***
	High voltage generator replacement	***Y***
	Filter replacement	***Y***
	Manufacturer's software upgrade or modifications	***Y***
	kVp, mA, or time - internal adjustment*	N
Acquisition Workstation Monitor	New installation or replacement	N
	New video card or software upgrade	N
	Relocation	N
Biopsy Device	***New targeting assembly or biopsy attachment***	***Y***
	New targeting assembly motor	N
	New QA phantom/ needle	N
	New vacuum biopsy unit	N
	New type/ size biopsy needle	N

** Internal adjustment refer to equipment adjustments that typically cannot be made by the operator*

II. MAMMOGRAPHY GUIDED BREAST BIOPSY EQUIPMENT QUALITY CONTROL TESTS

A. Test Procedures

1. Phantom Image Quality

OBJECTIVES

To ensure that the image acquisition chain consistently produces adequate image quality in each clinically used imaging mode.

FREQUENCY

As part of the acceptance testing of new units, annually, and after relevant service.

> **Note for upright units with biopsy attachments:** For upright units with biopsy attachments, evaluations made during other mammography unit QC may not be appropriate for this test because the AEC settings and detector calibrations may be different. In this case, phantom image quality needs to be repeated using clinical biopsy procedure settings.

TEST EQUIPMENT

- Phantom: Original ACR Mammography Phantom, ACR Mini Phantom, or the ACR Digital Mammography (DM) Phantom
- Compression paddle*
- Phantom Image Quality Form

*Once a phantom and a compression paddle is selected, it is recommended that they remain the same for consistency.

TEST PROCEDURE

Due to the available image receptor size and paddle combinations for these units, the entire phantom can be captured in a single exposure, or it may require multiple exposures to capture the appropriate phantom test objects. It is the responsibility of the medical physicist to capture the appropriate images needed to assess the image quality of the unit. If multiple images are required to cover the phantom test objects, the entirety of the wax insert should be imaged.

1. Initiate an exam at the acquisition workstation as you would for a patient or from the QC menu.
2. Use a name and image designation system that allows tracking of the QC images. This image ID is important if these images are sent to PACS, or if there is more than one acquisition unit.
3. Select a phantom or scout image type necessary to perform an exposure. Note: phantom images must be “for presentation” (i.e., “processed,” not “for processing” or “raw”) for viewing and scoring (if applicable).
4. Select an appropriate compression paddle for the chosen phantom.

5. Position the phantom so that the appropriate portion of the wax insert is seen in the window.
6. Make the exposure with the clinically used AEC mode. Record paddle type, density setting, AEC cell used, AEC mode, view, compression force, tube-potential (kVp), target/filter combination, and tube-current-time product (mAs) after the exposure. The pre-exposure Technique Factors should be recorded for use by the QC Technologist.
7. If necessary, reposition the phantom and make additional exposures until all phantom test objects are imaged.

If the system is capable of performing biopsies using both stereotactic guidance and tomosynthesis guidance, then the phantom image quality should be tested in all clinically used modes. Repeat the steps above for the tomosynthesis mode, if available.

Appropriate setup will vary depending on which phantom is being used:

ACR Mini Phantom (2.6 inch square)

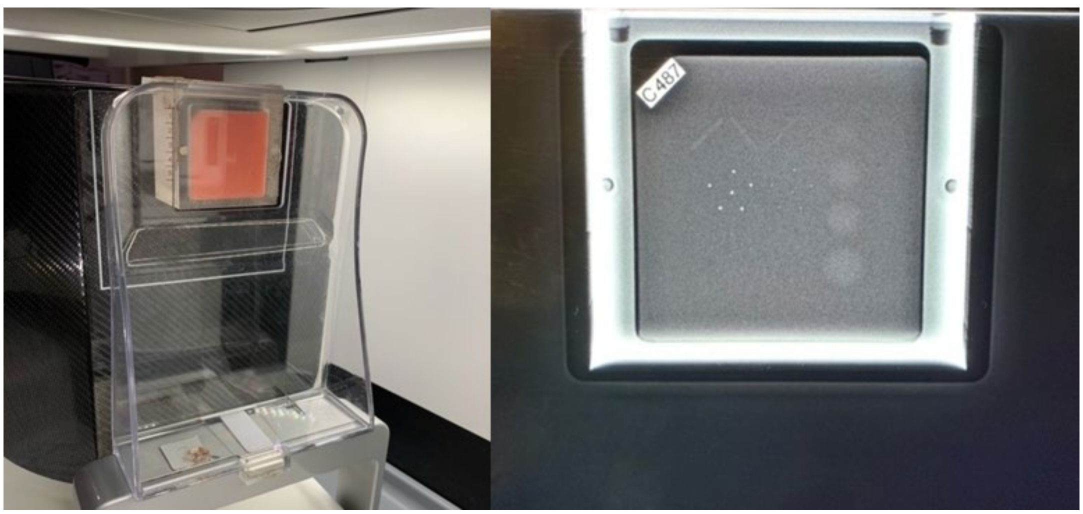


Figure 3-1: Mini phantom is fully inside the view window of the compression paddle and all the test objects in the phantom are inside the field of view.

ACR Original Phantom (4 inch square)

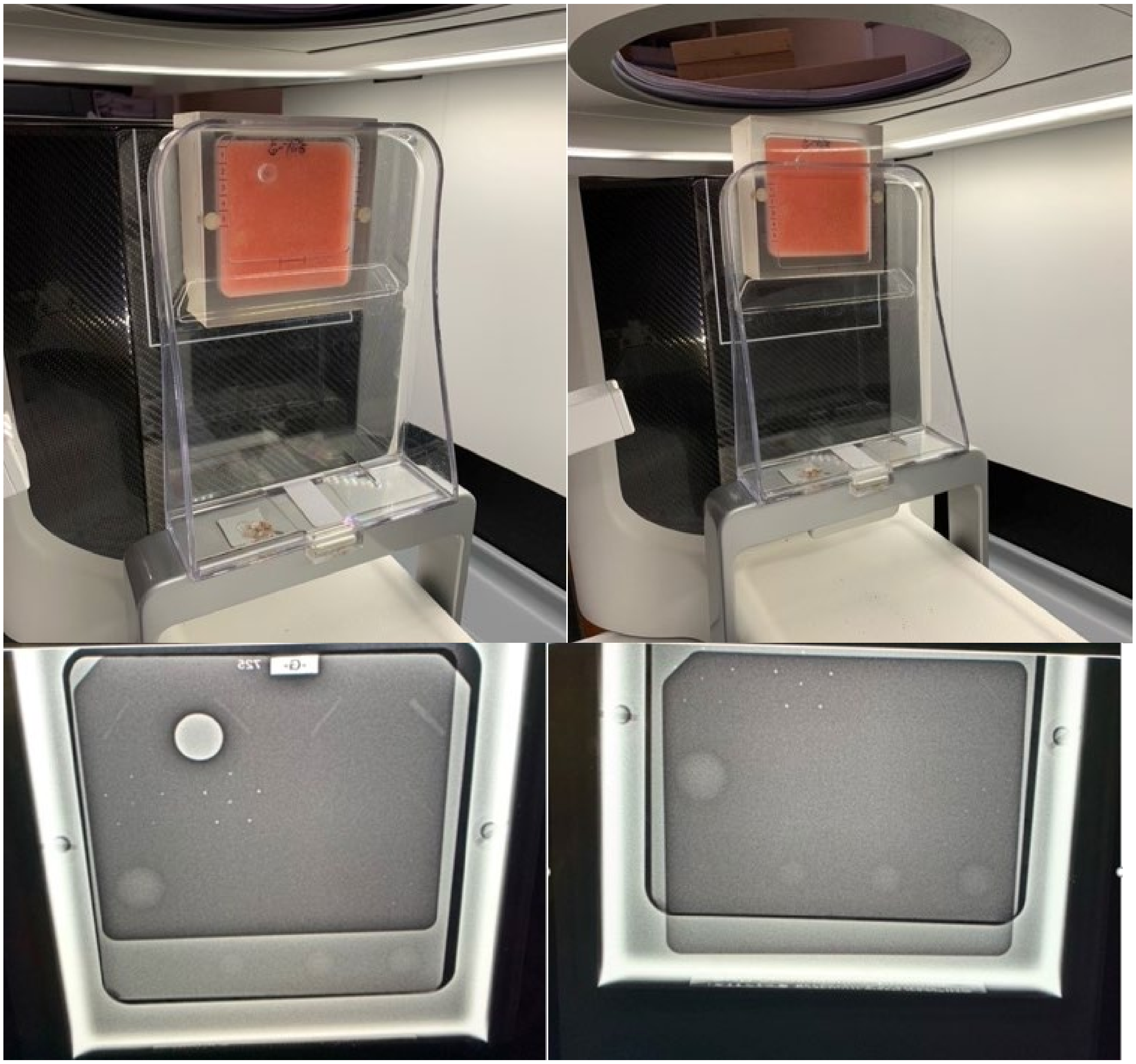


Figure 3-2: Original ACR phantom imaged twice to make sure all test objects could be visualized inside the view window.

ACR Digital Mammography (DM) Phantom

Figure 3-3: ACR DM phantom imaged twice to make sure all test objects could be visualized inside the view window.

ANALYSIS AND/OR INTERPRETATION

Adjust the WW, the WL and the image magnification to optimize the visualization of the test objects. For each group of test objects, the WW, the WL and the magnification may be adjusted to best display those test objects. Alternately, the system's manufacturer may have specific settings of the WW and the WL to be used.

Record the WL and WW. These values may be used for reference in future surveys and by the QC Technologist.

Fibers:

i. The fibers are manufactured to be approximately the same length. Starting with the largest fiber, evaluate whether the fiber is in the correct location and has the correct orientation.

ii. Count each fiber as a whole fiber (earning a full point) if the fiber appears to be the same length as the largest fiber. If a small gap in the fiber is visible, and the gap is less than the width of the fiber, then count the fiber as a whole fiber.

iii. Count a fiber as a ½ point if the fiber is shorter than a whole fiber, but not less than half the length and with no breaks in that half fiber.

iv. Stop counting fibers after scoring a fiber as a half or as not seen. The fiber score is the number of whole fibers plus any half point.

Speck groups:

i. There are 6 specks in a speck group. Starting with the speck group with the largest specks. Count each speck group as a whole group if 4 to 6 specks are visible and the group is located in the proper location and the specks are in the correct location within the group. A whole group is given 1 point.

ii. If only 2 or 3 specks within a group are visible, then the speck group is given ½ point.

iii. Stop counting speck groups after scoring a speck group as a half or as not seen.

Masses:

i. Starting with the largest mass, count the mass as 1 point if the object is in the correct location, and if the object is generally circular against the background. If at least ¾ of the border is continuous and the object is generally round, then the object is awarded 1 point.

ii. Count the mass as ½ point if a mass-like object is visible in the correct location, but does not have a generally circular appearance (greater than ½ but less than ¾ of a circle).

Note: Do not deduct for artifacts when scoring the test objects. Deducting for artifacts has been removed from the phantom scoring procedure.

Figures 4-6 can be used to confirm the location of the test objects in your chosen phantom.

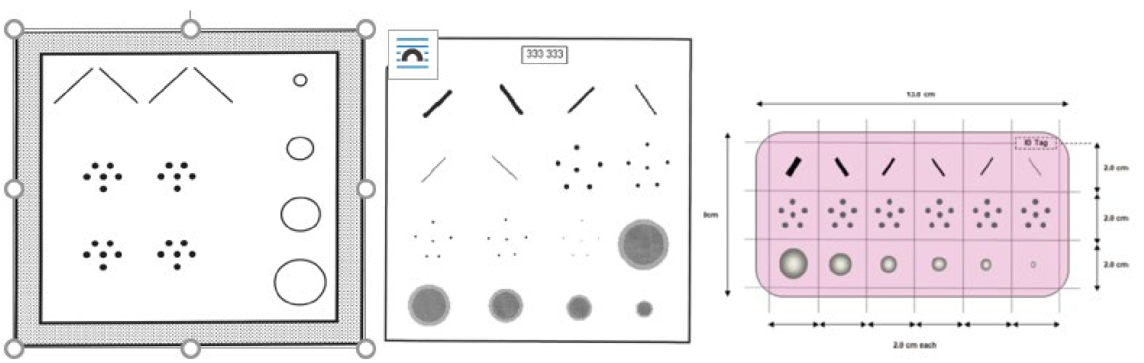


Figure 3-4: Mini, Original, and DM Phantoms

After scoring the phantom, enter the final score in each category (fibers, speck groups, and masses) on the appropriate QC form for each clinically tested mode. The 3D image should be scored using the slice that best displays the test objects. If slices are not available, then the slab that best displays the test objects should be selected.

Phantom Image Scoring Key, including Artifact Evaluation

Test Object	Full Point	Half Point
Fibers	• Correct location • Correct orientation • Full length visible * • 1 break allowed (must be ≤ width of fiber)	• Correct location • Correct orientation • At least half of length visible • 1 break allowed (must be ≤ width of fiber)
Speck Groups	• Correct locations • 4 - 6 specks visible	• Correct locations • 2 - 3 specks visible
Masses	• Correct location • Density difference visible • Border is continuous and generally circular (≥ ¾ border visible)	• Correct location • Density difference visible • Border is not continuous or generally circular (≥ ½ and < ¾ border visible)

*The fiber construction on the DM phantom is standardized enough to define the length of full and half fiber. The full fiber is considered greater than 8mm. A half fiber is between 5 and 8 mm.

PRECAUTIONS AND CAVEATS

In prone units, it is imperative that any auto decompression function be disabled, or the phantom could fall and sustain damage. If using the large ACR DM Phantom, it is highly recommended that you build up a spacer below the phantom to help support the weight. An example of this is seen in the figure below.

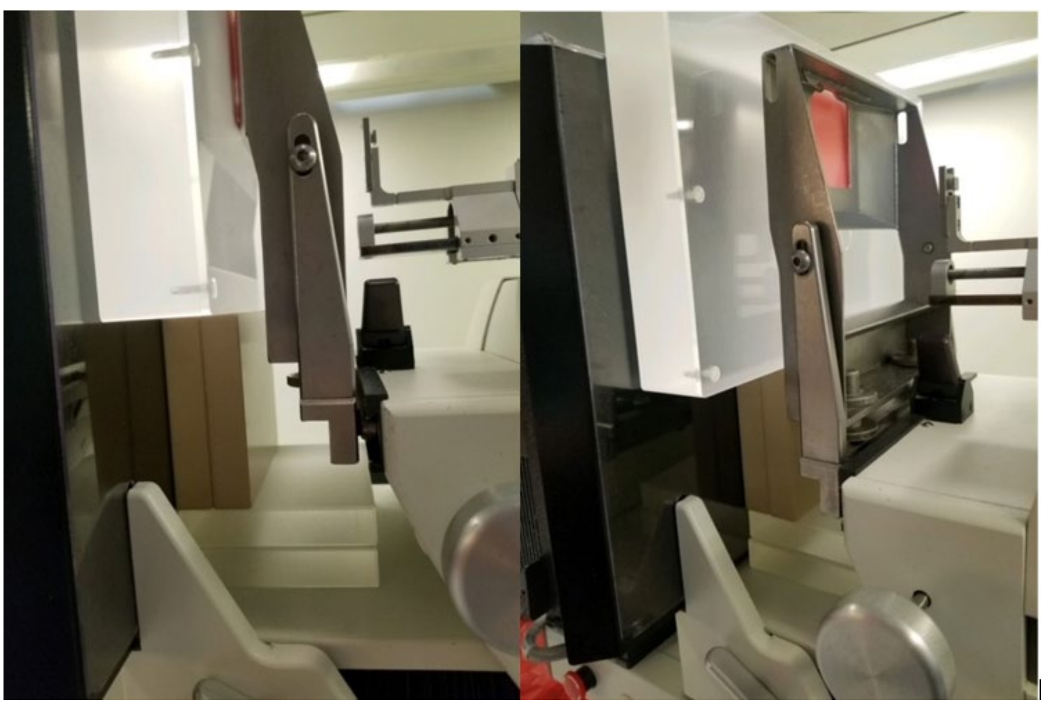


Figure 3-5: Two views of the ACR DM Phantom being imaged on a prone stereotactic unit with spacer to prevent falling.

Due to the many different paddle sizes, it is up to the discretion of the medical physicist to choose an appropriate size compression paddle to be able to image the wax insert. Once the paddle is chosen the size should be documented on the QC form. Going forward, this paddle should be used for this test and for the Technologist's QC.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

There are differences in numbers of test objects and their respective sizes between the 3 approved phantoms. The sizes of the test objects can be seen in Table * in Appendix A.

The passing criteria for each of these phantoms are as follows:

	Original ACR Phantom	**Mini Phantom**	**ACR DM Phantom**
Fibers	4	2	2
Speck Groups	3	2	3
Masses	3	2	2

TIMEFRAME FOR CORRECTIVE ACTION

The cause of the phantom failure must be found and corrected before clinical use. Please contact your service provider.

2. Artifacts

OBJECTIVES

To ensure that artifacts are not clinically significant.

FREQUENCY

As part of the acceptance testing of new units, annually, and after relevant service.

> **Note for upright units with biopsy attachments:** For upright units with biopsy attachments, evaluations made during other mammography unit QC may not be appropriate for this test because the detector calibrations may be different. In this case, artifact evaluation needs to be repeated using clinical biopsy procedure settings.

TEST EQUIPMENT

- Uniform tissue-simulating attenuator(s) (e.g., PMMA, BR-12, BR-50) providing approximate thickness of 4 cm of sufficient area to cover the entire field of view. The ACR DM Phantom may be used for this test. If the ACR DM Phantom is used, the Artifact Evaluation be performed on the image(s) from the phantom image quality test.
- Artifact Form

TEST PROCEDURE

The object of this test is to determine if there are any artifacts visible in all target/filter combinations, in all clinically used modes (i.e. stereotactic-guided or tomosynthesis-guided). In many modern units there is a separate image receptor calibration file for each mode and target/filter combination. The artifact evaluation should be completed for each target/filter/mode combination.

1. Initiate an exam at the acquisition workstation as you would for a patient or from the QC menu.
2. Use a name and image designation system that allows tracking of the QC images. If these images have the possibility of being confused as being from a different unit, it is important to be able to identify the acquisition unit and date of acquisition. This image ID is important if these images are sent to PACS, or if the facility has more than one acquisition unit.
3. Select a flat field or scout image type necessary to perform an exposure. (The “exam tag” or “exam view” used to take these images should create an image “FOR PROCESSING”, RAW or an unprocessed image).
4. Place a uniform sheet of tissue-equivalent attenuator large enough to cover the full area of the exposed image receptor on the breast support assembly.
5. Make an exposure using AEC for all target/filter combinations used clinically in 2D mode at the phantom kVp.

6. If the tomosynthesis mode is used clinically, this test should be repeated for all target/filter combinations used in this imaging mode.

ANALYSIS AND/OR INTERPRETATION

Adjust the window width (WW) and window level (WL) settings to an appropriate setting; if using the ACR DM phantom this should correspond with the setting that best visualized the test objects in the phantom evaluation. Alternately, the system's manufacturer may have specific settings for WW and WL.

Examine the entire flat field image for both broad area artifacts and detailed artifacts.

Broad area artifacts (e.g., non-uniformities, blotches, and streaks) usually are best seen while not magnified (at full resolution).

Detailed artifacts (e.g., Black or white pixels, cluster of pixels, lines, or dust particles) are usually best seen while observing the flat filed at full spatial resolution (one to one pixel ratio) or with magnification using a zoom factor greater than 1.0.

Record the absence or presence of artifacts and assign it as a pass or fail on the appropriate form.

This should be completed for each clinically used target/filter combination in stereotactic (Scout) mode. If tomosynthesis mode is available, this should be repeated for any clinically used target/filter combinations. In tomosynthesis mode the reconstructed slices and/or slabs should be used to evaluate for artifacts.

PRECAUTIONS AND CAVEATS

It is important not to use an unreasonably narrow WW~~s~~ that may exaggerate the appearance of artifacts. This could unnecessarily cause a clinically insignificant artifact to fail this test.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Artifacts on the flat field must not be clinically significant. This aspect of the test fails if any artifacts are in a location that could impact clinical interpretation and

- Artifacts are as prominent as (or more prominent than) the visible test objects in the phantom image, or
- Artifacts obscure test objects in the phantom, or
- Artifact could affect clinical performance.

The cause of the artifact should be isolated and identified to determine if it originates from the x-ray system, the image receptor, or the monitor. If the artifact is confirmed to originate from the image receptor, a recalibration or flat-fielding of the image receptor may be needed. Artifacts isolated to other components of the imaging chain should be investigated.

After the artifact is resolved, repeat the phantom artifact test. If a clinically significant artifact persists, the facility should contact its authorized service representative. If the clinically significant artifact originated from the x-ray or image receptor system, patient procedures must not be performed until it is corrected. If the clinically significant artifact originated from the monitor, the monitor must not be used until it is corrected.

TIMEFRAME FOR CORRECTIVE ACTION

If the artifact is deemed clinically significant, the facility must have service perform repairs prior to clinical use. If there are artifacts deemed clinically insignificant, they should be corrected within 30 days or monitored for further degradation to determine appropriate timing for corrective action.

3. Spatial Resolution

OBJECTIVES

To measure the limiting spatial resolution as an indicator of image receptor performance.

FREQUENCY

As part of the acceptance testing of new units, annually, and after relevant service.

TEST EQUIPMENT

- ACR Digital Mammography (DM) Phantom, or
- Uniform tissue-simulating attenuator(s) (e.g. PMMA, BR-12, BR-50) providing approximate thickness of 4 cm.
- Line pair (lp) pattern with frequencies up to 10 lp/mm
- Spatial Resolution Form

> **Note for upright units with biopsy attachments:** This test may have been performed/satisfied during the survey of the mammography unit. Results from the performance evaluation of the mammography unit satisfy the requirement for this test.

TEST PROCEDURE

1. Set up the unit to acquire a "for processing" or "raw" image.
2. Install appropriate compression paddle.
3. Place a uniform tissue-simulating attenuator with a thickness of 4 cm on the detector assembly. If using the ACR DM phantom, place the clear plastic portion in the beam. Place the line pair pattern on the phantom at a 45° angle (See Figure XX) 2 cm from the chest wall edge of the receptor, centered laterally.
4. Make one exposure using a manual technique as close to the phantom technique from **Test 1 – Phantom Image Quality** as possible.
5. Repeat steps 3-6 for any other clinically used targets.

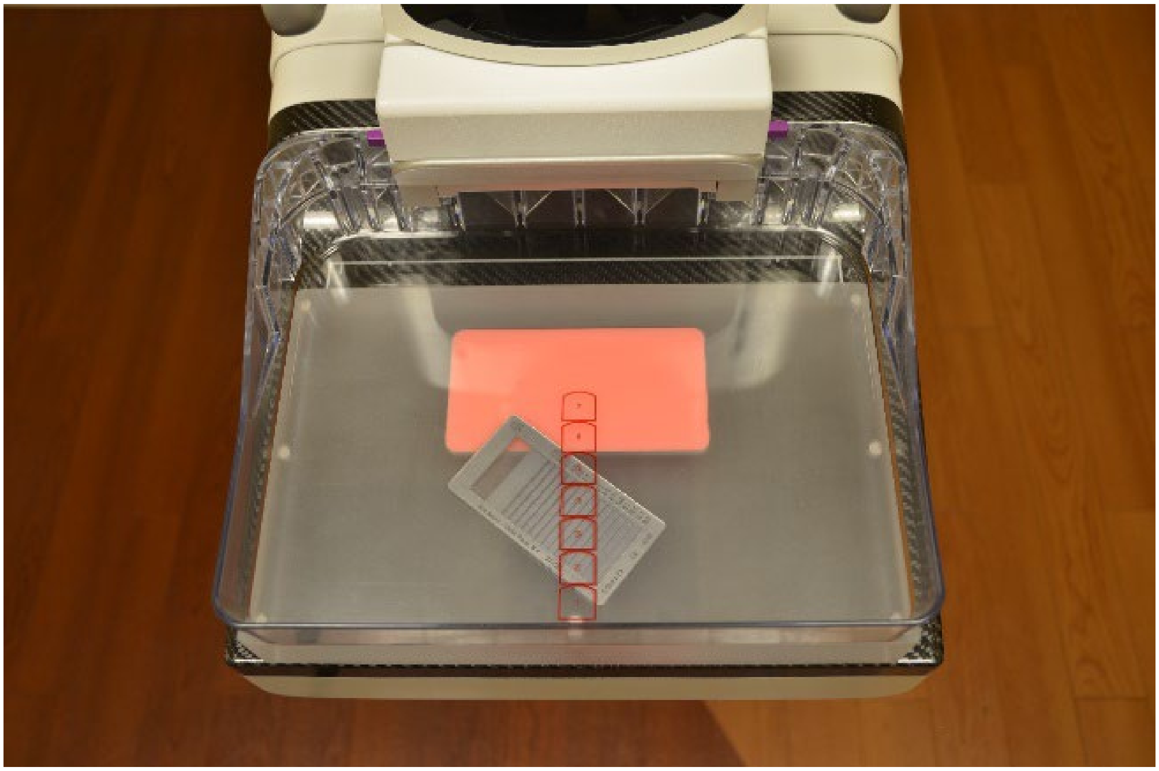


Figure 3-6: Bar pattern placement for the Spatial Resolution test on a 2D system. The bar pattern is at a 45° angle to the chest-wall edge.

ANALYSIS AND/OR INTERPRETATION

At the acquisition workstation, view each image using full resolution at a sufficient zoom level to adequately visualize the test pattern. Adjust WW/WL and most importantly, magnification for optimal visualization of line pairs. Record the highest frequency for which at least half the length of the lines can be continuously resolved in each image. Ensure that the polarity of the lines does not reverse (i.e., aliasing). If reversal occurs, the limiting resolution has been surpassed.

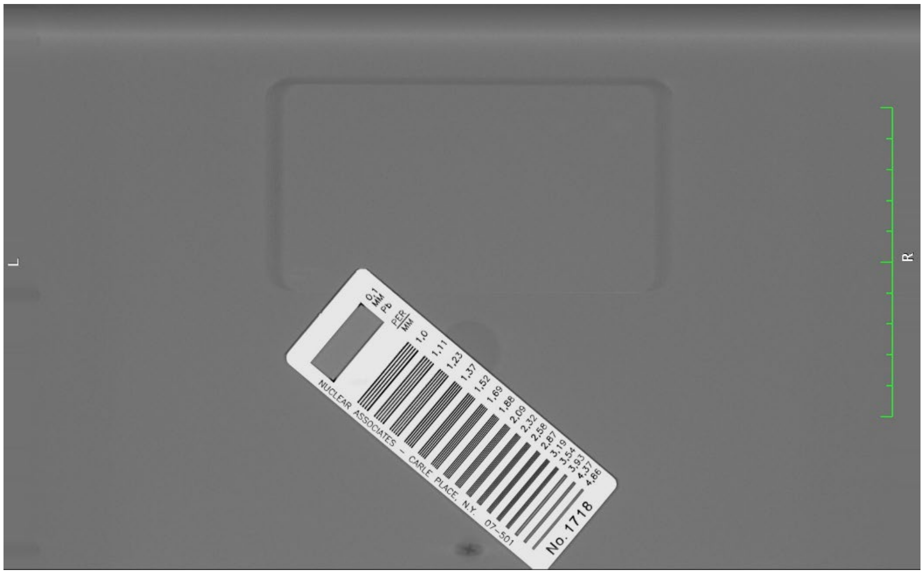


Figure 3-7: Image of bar pattern properly positioned for the Spatial Resolution Test.

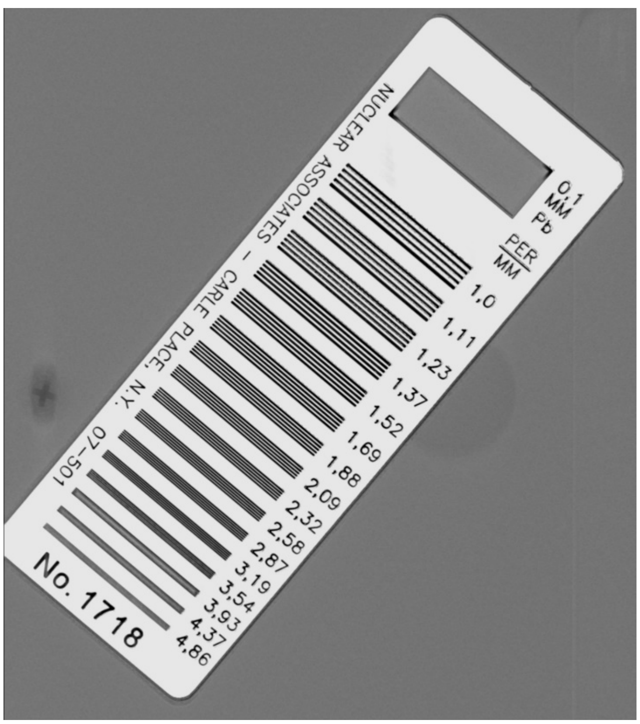


Figure 3-8. Bar pattern magnified for analysis.

PRECAUTIONS AND CAVEATS

It is recognized that limiting spatial resolution is an imperfect substitute for a detailed determination of modulation transfer function (MTF). However, limiting spatial resolution is more easily measured in the field and serves as an acceptable alternative method for purposes of image receptor performance consistency.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Spatial resolution of 2D image(s) must be ≥ 4.0 lp/mm. If limiting spatial resolution does not meet this criterion, service must be scheduled.

TIMEFRAME FOR CORRECTIVE ACTION

Failures must be corrected within 30 days.

For acceptance testing, failures must be corrected before clinical use.

4. DBT Volume Coverage

OBJECTIVES

A visual test to assure that the entire breast volume is imaged during the DBT acquisition.

FREQUENCY

As part of the acceptance testing of new units, annually, and after relevant service.

TEST EQUIPMENT

- Uniform tissue-equivalent attenuator(s) (e.g., PMMA, BR-12, BR-50) providing approximate thickness of 4 cm; or phantom used in **Test 1 – Phantom Image Quality** (i.e., Original ACR Phantom, Mini ACR Phantom, or ACR DM Phantom)
- Two 0.1-mm thick sheets of aluminum
- DBT Volume Coverage Form

> **Note for upright units with biopsy attachments:** This test may have already been performed during the survey of the mammography unit. Results from the performance evaluation of the mammography unit satisfy the requirement for this test.

TEST PROCEDURE

1. Initiate a tomosynthesis guided biopsy at the acquisition workstation as you would for a patient.
2. Use a name and image designation system that allows tracking of QC images. If these images have the possibility of being confused as being from a different unit, it is important to be able to identify the acquisition unit and date of acquisition. This image ID is important if these images are sent to PACS, or if there is more than one acquisition unit.
3. Select an appropriate compression paddle for the chosen phantom and record the paddle used in the DBT Volume Coverage form.
4. Place the phantom on the breast support as shown in Figure XX. Ensure that the phantom is centered left-to-right and that the edge of the phantom is aligned with the chest wall edge of the digital image receptor.
5. Place 0.1 mm aluminum sheets on top and below the phantom as shown in Figure XX.
6. Manually compress the paddle to 5 decanewtons or 12 pounds of compression force. It is important to use the same compression force each time for this test. Note that at this compression force, the compressed breast thickness may not read the exact physical thickness of the phantom being used.
7. Acquire a tomosynthesis scout using a manual technique similar to that of the DBT phantom technique from Test 1.

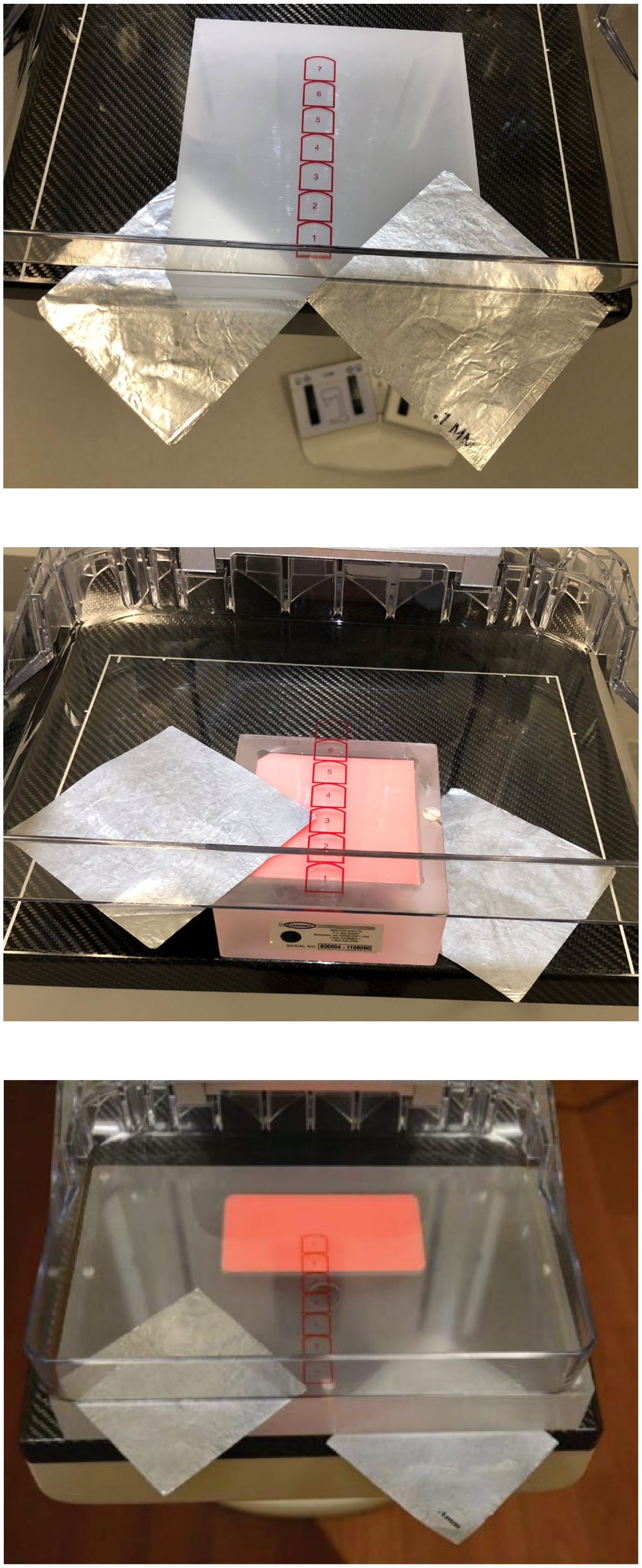
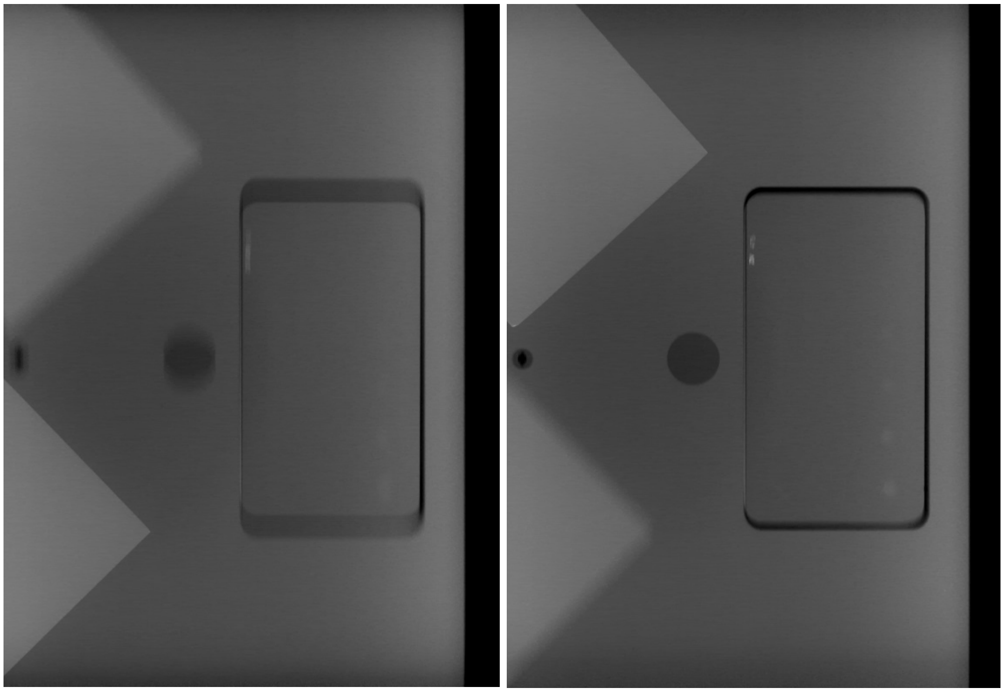


Figure 3-9. Placement of aluminum sheets with the attenuator options.

ANALYSIS AND/OR INTERPRETATION

At the acquisition workstation, scroll through the image set using the thinnest slices available. Determine if both the top and bottom aluminum sheets are well defined and in focus in their respective planes, as shown below in Figure 3-10.



A **B**

Figure 3-10: A) Image of ACR DM Phantom with aluminum sheets in focus at bottom of phantom. B) Image of ACR DM Phantom with aluminum sheets in focus at top of phantom.

PRECAUTIONS AND CAVEATS

If the system fails the test, verify that the aluminum sheets are properly positioned and repeat the test.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Each aluminum sheet must be well defined within one slice, or the system is not imaging the entire breast volume.

TIMEFRAME FOR CORRECTIVE ACTION

Failures must be corrected within 30 days.

When the test is performed for acceptance testing or relevant post-repair testing, all failures should be corrected before clinical use but must be corrected within 30 days.

5. Automatic Exposure Control System Performance

OBJECTIVES

To assess the performance of the automatic exposure control (AEC) function and to verify consistency in image receptor signal-to-noise level for a range of breast thicknesses.

To acquire exposure technique information and utilize that information to establish Technique Charts for the Technologist.

FREQUENCY

As part of the acceptance testing of new units, annually, and after relevant service.

> **Note for upright units with biopsy attachments:** For upright units with biopsy attachments, evaluations made during other mammography unit QC may not be appropriate for this test because the AEC settings and detector calibrations may be different. In this case, AEC System Performance Testing needs to be repeated using clinical biopsy procedure settings.

TEST EQUIPMENT

- Tissue-equivalent attenuators (e.g., PMMA, BR-12, BR-50) providing approximate thicknesses of 2, 4, 6, and 8 cm of sufficient area to resemble an average-sized compressed breast and cover the AEC area. The chosen attenuator should be kept the same for each evaluation for consistency.
- Automatic Exposure Control System Performance Form
- Technique Chart Forms

TEST PROCEDURE

1. Create a test patient on the acquisition workstation.
2. Install the small size paddle, if available. Otherwise, install the large size paddle. Record paddle used.
3. Set the system to acquire an image using the AEC mode used clinically.
4. If applicable, set the density control function (or exposure compensation step) to 0.
5. If applicable, set the AEC sensor to the center of the phantom.
6. Center 2.0 cm of tissue-equivalent attenuator on the image receptor and position it so the chest-wall edge of the attenuator is aligned with the chest-wall edge of the image receptor. (See Figure XX) Note the attenuator material.
7. Select the large focal spot.
8. Make an exposure.
9. Record the relevant technique information (AEC Mode, Density Setting or Exposure Compensation, target, filter, kVp, mAs, etc.) on the form.
10. Repeat steps 3 – 9 for the 4, 6, and 8 cm phantoms.
11. Repeat steps 3 – 9 in DBT mode (if applicable).

TECHNIQUE CHART CREATION

The Medical Physicist will generate and provide the Technique Charts during acceptance testing, or at any time that the Medical Physicist finds that the current Charts are not appropriate. The Technique Charts will be based on the AEC mode used during the AEC performance evaluation and the results from the testing.

1. At acceptance testing, review the exposure techniques that resulted from your testing above.
2. Record the techniques in the provided technique chart forms for the corresponding breast thicknesses.
3. Provide the forms to technologist.

The technique chart can be written by hand or will automatically be populated from the AEC tab in the provided Medical Physicist QC Forms. In the event the manufacturer provides a technique chart, the site may choose to adopt this alternative. However, the physicist should compare this chart to the AEC testing results to ensure clinical applicability prior to implementation.

ANALYSIS AND/OR INTERPRETATION

Use only the 0-degree, raw projection image for analysis.

1. If the manufacturer provides a DC offset, record this value on the form.
2. Record the SNR results from the previous year (if available) on the form. (This does not apply to acceptance tests.)
3. Calculate the lower limit for each mode/attenuator SNR as 85% of the previous year's SNR and record.
4. On the acquisition workstation, use a circular or rectangular ROI (approximately 3 cm from chest wall and centered left to right) to measure the mean signal value (or mean ADU) in the middle of the phantom. (See Figure XX.) When performing this test in DBT mode, SNR measurements should be made on the "for-processing" 0-degree projection image (not to be confused with the pre-pulse image) as opposed to the reconstructed slices)
5. Record the mean signal value as Mean Bkgd Signal on the form; record the standard deviation as Std Dev of Bkgd. On the tomosynthesis images, use a raw projection for analysis.
6. Calculate the signal-to-noise ratio (SNR) as:

$$SNR = \left(\frac{\text{Mean Bkgd Signal} - \text{DC offset}}{\text{Std Dev of Bkgd}} \right)$$

(Omit the DC offset if this does not apply for the DM unit being tested.)

PRECAUTIONS AND CAVEATS

Manufacturer operating manuals and/or guidance documents should be checked to see if there are DC offset values that should be used for the calculation of the SNR.

PMMA is the preferred attenuator. However, the chosen attenuator material should remain constant for each evaluation since differing materials can affect SNR and may require a re-establishment of the baseline value.

The baseline values may need to be re-established following repair, service or replacement of major components. The baseline also may be re-established at the discretion of the medical physicist.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Acceptance Testing and Post-Repair Testing

The data from these measurements are used to establish baseline SNR values.

The data from these measurements are used to establish the Technique Charts.

Annual Surveys

The SNR must be ≥ -15% of the baseline SNR, i.e., not lower than 85% of the baseline SNR, for each thickness and mode tested.

If test results are not within action limits, the test should be repeated. If results remain below the performance criteria, the facility should contact its authorized service representative.

Record and date any comments and required corrective action in the Technologist's Corrective Action Log form.

TIMEFRAME FOR CORRECTIVE ACTION

Failures must be corrected within 30 days.

6. Average Glandular Dose

OBJECTIVES

To determine the reference air kerma for a phantom simulating a "standard breast" as defined by the FDA (approximately 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue by mass) and calculate the associated average glandular dose (AGD).

FREQUENCY

As part of the acceptance testing of new units, annually, and after relevant service.

TEST EQUIPMENT

- Ionization chamber and electrometer or other appropriate dosimetry device calibrated at mammographic x-ray beam energies.
- An integrated, solid-state instrument (one that automatically measures kVp, half-value layer [HVL], and dose) is also acceptable. (The instrument must be calibrated for the target/filter combination in use or be adjusted with an appropriate correction factor. See Precautions and Caveats. Mammographic phantom simulating a standard breast
- Biopsy paddle used for routine clinical use
- Average Glandular Dose Form.

> **Note for upright units with biopsy attachments:** For upright units with biopsy attachments, evaluations made during other mammography unit QC may not be appropriate for this test because the AEC settings, detector calibrations, and compression paddles may be different. In this case AGD needs to be repeated using clinical biopsy procedure settings.

TEST PROCEDURE

1. Place a lead sheet or other protective device on the image receptor. This is intended to protect the image receptor from repeated exposures.
2. Position the dosimeter on top of the breast support, above the protective device, 5cm in from the chest-wall edge of the breast support and centered laterally at the midline of the detector as shown in Figure 3-11. Record the distance from the x-ray source to the plane of measurement (l_m) on the form.
    - Note: The air kerma measurement being performed should not include backscatter. Solid-state dosimeters are generally lead-backed and backscatter insensitive, as are many ion chambers designed for mammography, permitting this measurement to be performed at the surface of the breast support. However, if there is concern that dosimeter being used is sensitive to backscatter then the dosimeter should be raised above the breast support by ~10cm.
3. Raise the compression paddle to the highest position permitted by the system (i.e as close to the x-ray tube as possible). Ensure that the dosimeter is within the biopsy window (if applicable).
4. Set the target material, filtration, and kVp at the values at which the phantom image from the Phantom Image Quality Test was acquired.

5. Manually set mAs as close as possible to that obtained under the AEC exposure of the phantom in Test 1 and record the value on the form.
6. Make a manual exposure and record the measured air kerma on the form.
7. Repeat step 6 until three measurements have been recorded.
8. Repeat steps 4-7 for each applicable mode. If the system permits, it is recommended that tube motion be disabled for DBT (i.e. tube remains stationary) for this measurement.

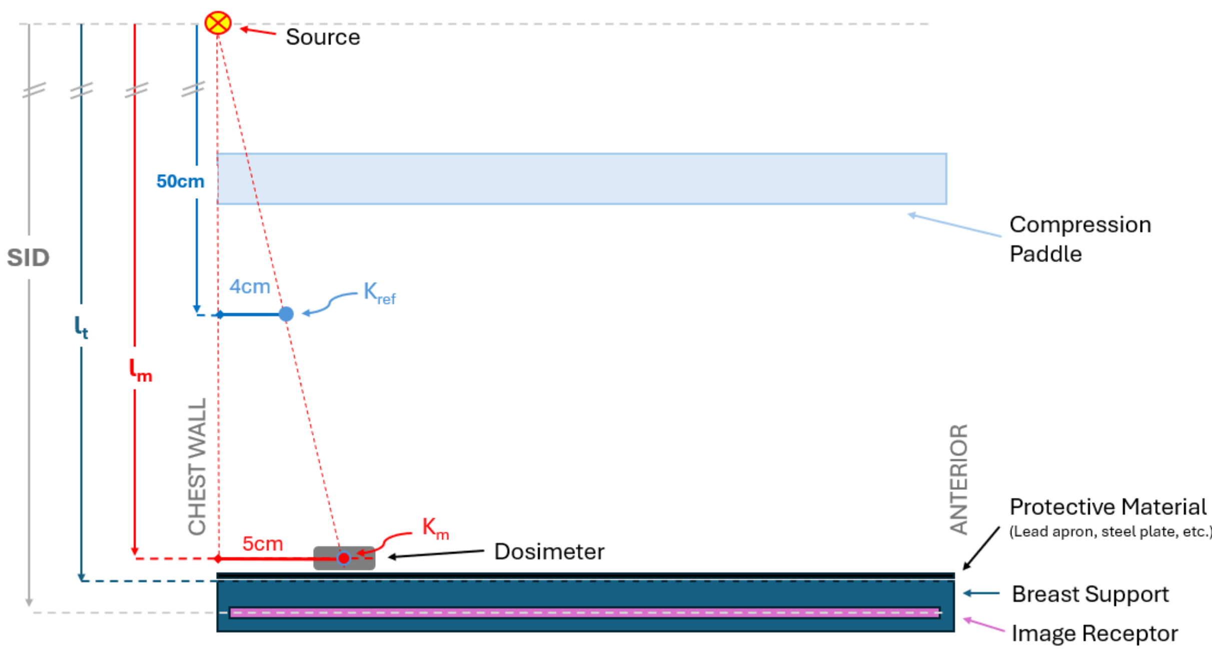


Figure 3-11: Setup diagram for air kerma measurements.

ANALYSIS AND/OR INTERPRETATION

<u>Definitions</u>

Reference point: Defined as the point on a plane 50cm from the x-ray source towards the imaging detector, centered laterally in the field of view, and 4cm in from the chest-wall edge of the x-ray field

K_{ref}: The air kerma free-in-air at the reference point; expressed in units of milliGray (mGy)

K_m: The air kerma free-in-air at the measurement point; expressed in units of milliGray (mGy)

L_m: The shortest distance between the source and the plane where K_m is measured; expressed in units of millimeter (mm)

L_t: The shortest distance between the source and the breast support table; expressed in units of millimeter (mm)

Γ: The dose conversion coefficient, used to convert the air kerma at the reference point to an estimated average glandular dose, for the system being assessed.

Γ_{sim}: The dose conversion coefficient, used to convert the air kerma at the reference point to an estimated average glandular dose, under the system geometry assumed for Monte Carlo simulations.

1. **1.** If necessary, correct the average measured air kerma with the dosimeter's appropriate energy correction factor.
2. **2.** Obtain the air kerma at the measurement point ($K_{m,phantom}$) for the AEC exposure of the phantom by correcting the average air kerma measured using the manual technique ($K_{m,manual}$) for any difference in mAs between the manual and photo-timed exposures.

$$K_{m,phantom} = K_{m,manual}\left(\frac{mAs_{phantom}}{mAs_{manual}}\right)$$

3. **3.** Calculate the air kerma at the reference point

$$K_{ref} = K_{m,phantom}\left(\frac{l_m}{500}\right)^2 (1.032)$$

4. **4.** Compute the average glandular dose for a "standard breast" as defined by the FDA ($D_{g,FDA}$):
   a. Determine the conversion coefficient under simulation conditions (Γ_{sim}) and correct for system geometry:

$$\Gamma = \Gamma_{sim}\left(\frac{648mm - 42}{l_t - 42}\right)^2$$

      i. Γ is the dose conversion factor for a cranio-caudal view of a 4.2 cm breast of 50% glandularity at the defined beam quality (Table X) and is derived from TG-282 [1].

   b. Calculate $D_{g,FDA}$ using the following equation:

$$D_g = K_{ref}\Gamma$$

5. **5.** Compute the average glandular dose for a 4.2cm breast with average (typical) glandularity ($D_{g,average}$):
   a. Note: this metric is calculated for informational purposes only. TG-282 recommends that vendors utilize the 50th percentile volumetric breast density (%VBD) for calculating the AGD that is displayed for clinical exams.
   b. Determine the conversion coefficient under simulation conditions (Γ_{sim}) and correct for system geometry:

$$\Gamma = \Gamma_{sim}\left(\frac{648mm - 42}{l_t - 42}\right)^2$$

  i. Γ is the dose conversion factor for a cranio-caudal view of a 4.2 cm breast with the glandularity set to the 50th percentile %VBD at the defined beam quality (Table X) and is derived from TG-282 [1].

c. Calculate $D_{g,average}$ using the following equation:

$$D_g = K_{ref}\Gamma$$

PRECAUTIONS AND CAVEATS

This manual utilizes spectral conversion factors derived from the methodology published in the Joint AAPM Task Group 282/EFOMP Working Group Report: Breast dosimetry for standard and contrast-enhanced mammography and breast tomosynthesis, to calculate average glandular dose. This differs from the 1999 ACR Stereo Quality Control Manual (which used a method adapted from Wu et al) and the 2018 ACR Digital Mammography QC manual (which used the method published by Dance et al). While there is a minor difference in the calculated AGD between the latter two methodologies (~1%), utilizing the TG-282 methodology will result in a calculated AGD (for the same beam quality and breast composition) that is approximately 30% lower on average. This difference is primarily due to the incorporation of more anatomically accurate Monte Carlo models of the breast.

> **Note:** This manual utilizes the spectral conversion coefficients derived from AAPM TG-282. Individual manufacturers many utilize other methodologies to derive displayed AGD; if this is the case, differences between the AGD displayed by the system and the calculated AGD are to be expected.

The FDA defines a "standard breast" as having 50% glandularity by mass, which corresponds with a volumetric breast density (%VBD) of 35%. TG-282 recommends that vendors utilize the 50th percentile %VBD for calculating the AGD that is displayed for clinical exams. The 50th percentile (10% VBD) derived from large population data sets are significantly lower than the value corresponding to the "standard breast" defined by the FDA (35% VBD). The conversion coefficients for a 4.2cm breast with typical glandularity will generally be 10-20% higher than those for the FDA's "standard breast".

Additionally, many manufacturers use the air kerma measured with the compression paddle without the biopsy window. This must also be considered when comparing measured versus displayed AGD values for measurements obtained using the compression paddle with the window.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

The average glandular dose for a single cranio-caudal view of the phantom for a stereo scout or DBT scout must not exceed 3.0 mGy. If the calculated value exceeds these levels, action must be taken to evaluate and eliminate the cause of excessive dose.

TIMEFRAME FOR CORRECTIVE ACTION

Average glandular doses exceeding 3 mGy must be corrected before clinical use.

7. Unit Checklist

OBJECTIVE

To ensure that all locks, detents, angulation indicators, and mechanical support devices for the x-ray tube and breast support assembly are operating properly.

FREQUENCY

As part of the acceptance testing of new units, annually, and after relevant service.

TEST EQUIPMENT

- Unit Checklist Form

TEST PROCEDURE

1. Verify that the biopsy unit is mechanically stable under normal operating conditions (*critical test).
2. Verify that all moving parts move smoothly, without undue friction; that cushions or bumpers limit the range of available motions; and that no obstructions hinder the full range of motions within these limits (*critical test).
3. Set and test each lock and detent independently to ensure that mechanical motion is prevented when the lock or detent is set (*critical test).
4. Verify that the image receptor assembly and compression paddle are free from vibrations during normal operation (*critical test).
5. Verify that in normal operation the patient and operator are not exposed to sharp or rough edges or other hazards including electrical hazards (*critical test).
6. Verify that compression paddles are intact with no cracks or sharp edges (*critical test).
7. Verify that all indicators work properly.
8. Verify that the compressed breast thickness indicated at the gantry is accurate to within ± 5 mm over thicknesses 2 to 8 cm, and reproducible to within ±2 mm. If this is an FFDM unit with a stereo attachment, this test should be performed with the stereo attachment in place.
9. Verify that the needle holder and needle guides are firmly attached and support the needle without allowing the needle to deflect, bend, curve, or droop excessively (i.e., by more than 1 mm in any direction (*critical test).
10. Verify that the compression paddle can be manually released in the event of a power failure by turning power off to the equipment (*critical test)
11. Verify that the biopsy area is clean from significant dust and debris that may cause artifacts.
12. Verify that the operator and other personnel are protected by adequate radiation shielding during the exposure (*critical test).
13. Verify that the Technique Chart is posted and acceptable.

14. Verify that the audible exposure indicator is at an appropriate volume level.
15. Verify that the DBT assembly moves as designed through its range of motion (*critical test). (if applicable)
16. Verify that the biopsy unit is clean and free of dried blood or other fluids (*critical test).
17. Add other unit-specific checks as necessary.
18. Record the pass or fail of each inspection item on the form.

ANALYSIS AND/OR INTERPRETATION

Not applicable

PRECAUTIONS AND CAVEATS

When testing the unit under a power-off condition, the unit should be powered-down using the normal procedure or the gantry/console emergency stop switch, never using the circuit breaker. Interruption of the power at the circuit breaker may damage the unit.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Critical items that are hazardous, inoperative, or operate improperly must be repaired by appropriate service personnel or replaced.

Failures of critical tests (*) must be corrected before clinical use, less critical tests must be corrected within 30 days; for Acceptance Tests, before use on the first patient.

8. Localization Accuracy

OBJECTIVE

To ensure that the biopsy needle is accurately placed for sampling under stereotactic or tomosynthesis guidance. The test procedure emphasizes testing the most commonly used mode and approach combination. The geometry of many modern systems can be flexibly configured; the direct approach has the needle moving towards the image receptor, and the indirect approach has the needle moving across the plane of the image receptor. The direct approach is referred to as the craniocaudal (CC) approach and the indirect approach is referred to as the lateral approach in this manual.

FREQUENCY

As part of the acceptance testing of new units, annually, and after relevant service.

- The evaluation must include localization of a target in the most common clinically used mode and approach. (i.e., stereotactic or tomosynthesis mode, CC or lateral approach)
- The medical physicist must evaluate the localization accuracy in air for all other clinically used modes and approaches. The evaluation can be performed in-person or as a review of the technologist's QC records.

REQUIRED TEST EQUIPMENT

- Targeting phantom with appropriately small (<5mm diameter) targets (i.e., gelatin or improvised phantom)
- A core biopsy system and core biopsy needle (a clinically used type and gauge) or alternative tissue sampling device will be needed. The biopsy needle does not need to be sterile and can be reused for QC if fully functioning.
- Manufacturer-provided localization device, if applicable
- Localization Accuracy Form

TEST PROCEDURE

A technologist who assists in performing stereotactic- or tomosynthesis-guided biopsies should perform the localization in a phantom test while the medical physicist observes and analyzes the results.

The lateral approach need only be performed if it is available with the equipment used, is used clinically and is performed using a separate accessory for the approach. If the lateral approach is performed using the same arm as the CC approach, but is simply angled as in prone tables, a separate localization QC test is not necessary.

It is strongly recommended that the medical physicist observe this test in person with a technologist. If a technologist is unavailable (i.e., acceptance testing before application training or evaluation after hours), an alternative method such as remote video conferencing or image review can be used to verify accurate sampling.

> **Important:** Image review requires the facility to provide phantom or anonymized clinical images of a successfully targeted lesion. This image set must be from within 30 days of this test. The selected image sequence should include the scout, pre-fire and/or post-fire images (showing needle tip), and biopsy sample radiograph (if available). Clinical images may be reviewed onsite (e.g., during the medical physicist's annual survey) or remotely via screensharing (e.g., teleconferencing) on a secure platform, but in the interest of maintaining privacy of protected health information (PHI), transfer of patient data is prohibited. All federal, state, and local privacy requirements must be met.

Localization in a phantom

Use the manufacturer's recommended procedures for targeting a lesion.

<u>The following steps are provided as a generic guide</u>

1. Initiate a biopsy procedure at the acquisition workstation as you would for a patient.
2. Place the phantom on or against the image receptor with the biopsy compression paddle centered over a target. Apply sufficient compression to secure the phantom.
3. A scout image of the phantom should be acquired to confirm proper positioning of the target within the biopsy window.
4. Acquire the targeting image(s) (stereotactic or tomographic) of the target. Mark the center of the target in each image.
5. Once the target's center location is determined by the system, the primed needle should be installed in the biopsy device and the biopsy device assembly securely attached to the device holder.
6. If your manufacturer requires, zero the needle z-position per your manufacturer's requirements.
7. Advance the needle tip to the target's coordinates that were calculated by the computer.
8. Acquire pre-fire image(s) (stereotactic or tomographic); if the unit is well calibrated, the needle tip should be within the target. On some units a small amount of needle pull-back is required before firing.
9. Once the needle is fired, post-fire image(s) (stereotactic or tomographic) should show the tip of the needle beyond the center of the target and the trough area (if visible) within the target. Sample collection of target material is not required for a medical physicist's in-person evaluation.

Localization in air

Localization in air may be performed to verify accuracy in lieu of targeting in a phantom/patient for mode and approach combinations other than the most clinically used mode and approach. Documentation must be included to verify all combinations were evaluated and passed.

Manufacturers may have an appropriate and dedicated test tool for performing this test; it is required to use such tools. If your system does not have a dedicated test tool for this test, use the breast biopsy needle that is used clinically.

In the absence of a manufacturer's procedure, the facility must use the procedure described below.

This test is to be performed in all mode and approach combinations used by the facility other than those already tested with the localization in a phantom procedure.

1. Place the dedicated QC biopsy needle in the biopsy device.
2. Mount the biopsy device onto the imaging equipment and cock the biopsy device.
3. Move the needle to the calibration location/ home position. If your manufacturer requires, zero the needle z-position per your manufacturer's requirements.

If using a localization test device

1. Mount the test device and using the compression paddle, apply sufficient compression to secure the device's position within the biopsy window.
2. Acquire a scout image of the test device.
3. Select an object on the test device to be the target. The target should be near or at the center of the image.
4. Acquire the targeting image(s) (stereotactic or tomographic) of the target. Using the computer, designate that object as the target, and compute the target's coordinates.
5. Record the target's coordinates in the data form.
6. Using the computer, move the needle tip to the target's coordinates that were calculated by the computer.
7. For each of the coordinates (x, y, and z), calculate the difference in location between the needle tip's location and the target's location. For example, for the x coordinate, subtract the value of the real location's x-coordinate, from the calculated value of the x-coordinate.
8. Variations to this procedure are permitted. Refer to manufacturer guidance. For example, the total difference between the needle's tip and the target may be measured physically.

If your manufacturer does not provide a localization test device

1. Move the needle tip to a location with known coordinates (e.g., x = +30 mm, y = +40 mm, z = +50 mm.)
2. Acquire a scout image to ensure that the needle tip is in the image and within the biopsy window.
3. Acquire targeting image(s) (stereotactic or tomographic) of the needle tip. Designate the needle tip as the target in the targeting computer and compute the target's coordinates.
4. Record the target's coordinates in the data form.
5. For each of the coordinates (x, y, and z), calculate the difference in location between the target's location and the needle tip's real location. For example, for the x coordinate, subtract the value of the real location's x-coordinate, from the calculated value of the x-coordinate.

ANALYSIS AND/OR INTERPRETATION

The test results can be considered passing for localization in a target if any of the following is achieved:

- The needle tip is within the target in the pre-fire images (if applicable) and beyond the target in the post-fire images with the trough area (if visible) within the target.
- The target material is visible in the specimen radiograph.
- If the vacuum system is unable to pull the target material into the specimen collection device, visual inspection of the needle trough confirms the target was captured.

The test results can be considered passing for localization in air if any of the following is achieved:

- The calculated coordinates (x, y, and z) are within 1 mm of the coordinates of the real location for all alternative mode/approach combinations
- A review of technologist localization QC records for alternative mode/approach combinations are satisfactory if the most recent test is within 1 mm of the real location. To be able to use this methodology the most recent test must have been tested within 30 days of the physicist's evaluation. If the most recent test does not pass or was not performed within 30 days, the localization in air must be repeated manually to confirm the approach is targeting appropriately.

PRECAUTIONS AND CAVEATS

The localization in a phantom procedure assumes use of a large gauge cutting needle or vacuum assisted biopsy needle for tissue sampling. Other sampling methods, including fine needle aspirations, may also be used, or may be used exclusively by the site. Testing procedures may require modification to accommodate those different methods of tissue-sampling to test the accuracy of needle placement based on stereotactic and/or tomosynthesis imaging.

Localization in air avoids the needle being deflected in a solid or semi-liquid phantom. Possible causes for test failure include but are not limited to:

- The wrong needle was used.
- A needle was bent or warped.
- Incorrect needle information was entered into the targeting computer.
- The biopsy device was not cocked.
- There is excessive play in the needle guide.
- The biopsy device was mounted incorrectly in the holder.

Documentation of acceptance testing may indicate "Pending" for this test to allow accreditation applications to proceed. However, the medical physicist must perform or review this test before clinical imaging (post applications training) can commence for acceptance of a new biopsy unit.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

If passing criteria for localization in a phantom and/or localization in air are not met, the reasons for these errors should be determined and the procedure repeated. If localizations continue to be inaccurate, a service engineer should be contacted by facility personnel and the problem corrected.

TIMEFRAME FOR CORRECTIVE ACTION

Failures must be corrected before clinical use.

9. Acquisition Workstation (AW) Monitor QC

OBJECTIVE

- To ensure that all AW monitors are clean and free from dust, fingerprints, and other marks that may interfere with clinical information.
- To ensure that AW monitors used for procedure guidance are calibrated, with brightness and contrast settings correctly set.
- To ensure that monitors used for procedure guidance meet manufacturer specifications via the conduction of Monitor Manufacturer Automated Tests (if available).

> **Important:** Monitor Manufacturer Automated Tests are required if such tests are provided in the manufacturer's documentation.

FREQUENCY

As part of the acceptance testing of new units and annually.

> **Note for upright units with biopsy attachments:** For upright units with biopsy attachments, evaluations made during other mammography unit QC may not include all the tests and criteria outlined in this section. In these instances, acquisition workstation monitor QC needs to be repeated using the procedure in this section.

TEST EQUIPMENT

The American Association of Physicists in Medicine (AAPM) TG-270 test patterns and performance recommendations are preferable if available [cite TG-270]. The updated AAPM TG18-OIQ test pattern and performance recommendations identified in TG-270 should be used if they are available. However, if TG18-OIQ is not available, either TG18-QC or a standard SMPTE [6] test pattern is also an acceptable option. If a pattern is not already installed, an authorized service representative should install either test pattern or one that permits the measurements in Figure XX. If it is not possible to install a relevant test pattern on the monitor, this part of the test is not applicable.

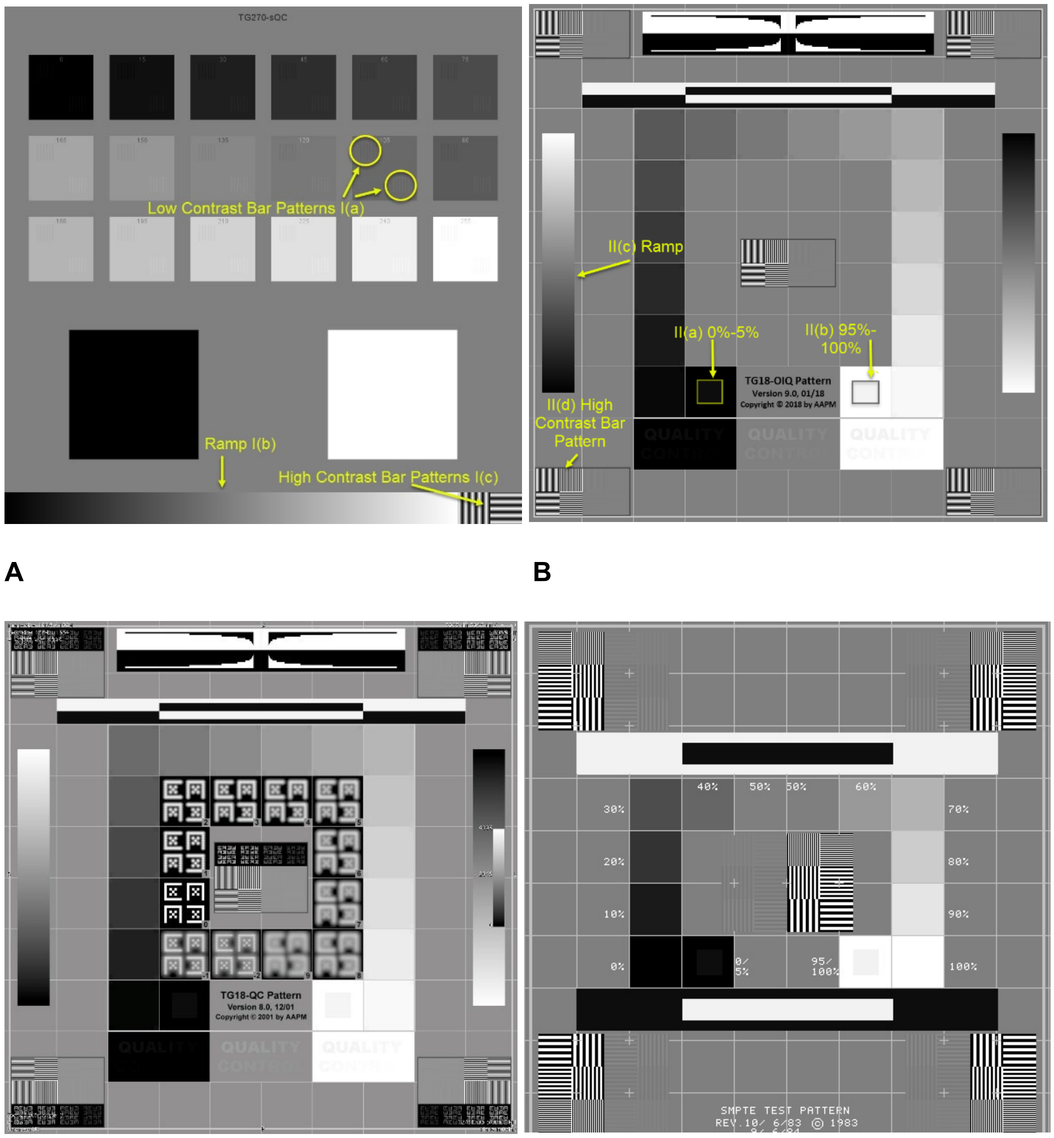


Figure 3-12. Test patterns: A) TG270-sQC, B)AAPM TG18-OIQ. C). TG18-QC, D). SMPTE.

- AAPM TG270-sQC test pattern is preferred and may be used for the luminance check. However, TG18 LN8-01 and LN8-18 test patterns may also be used for the luminance check, or other patterns that allow for measurement of L_{min} and L_{max} (if available). See Figure XX.
- AAPM TG270-ULN8-100, or variant similar to TG18 UNL80 test pattern for luminance uniformity, or other patterns that allow for measurement of luminance uniformity (if available). See Figure XX.
- Calibrated Luminance meter
- Acquisition Workstation Monitor Form

TEST PROCEDURE

Monitor Condition

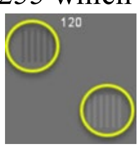
1. Visually inspect the surface of the monitor for the presence of dust, scratches, defects, fingerprints, shiny patches (from grease or gel), and other foreign material (e.g., pen marks, etc.).
2. Record significant findings on the form (see Performance Criteria and Corrective Actions).

Test Pattern Image Quality Check (if available)

1. Set the lighting conditions in the procedure room as you would have during a biopsy.
2. Display the test pattern on the monitor used for procedure guidance. (If an appropriate test pattern is not available on the AW, skip this test.)
3. Evaluate the test pattern for the following visible targets and record pass or fail on the form:

   TG270-sQC

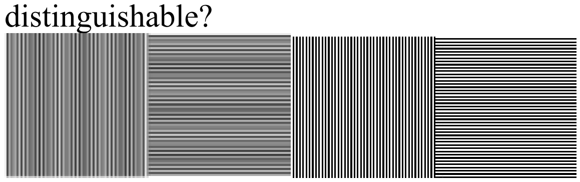
   a. Are the low contrast bar patterns in the top and bottoms of the 18 gray patches discernable? Note that the bar patterns may not be fully visualized in patches 0 and 255 which is acceptable.

   b. Is the grayscale gradient bar continuous, without steps or breaks?

   c. Are the high contrast line-pair images at the bottom right visible and clearly distinguishable?

   AAPM TG18-OIQ or equivalent

   a. Is the test pattern centered appropriately?
   b. Are the 0%-5% contrast boxes visible?
   c. Are the 95%-100% contrast boxes visible?
   d. Are the alphanumerics sharp and legible?
   e. Are the line-pair images at the center and four corners visible and clearly distinguishable?
   f. Are the grayscale gradient bars smooth and continuous?

Maximum and Minimum Luminance

1. The TG270-sQC test pattern can be used for checking L_{min} and L_{max}. You may also use the TG18 LN8-01 and LN8-18 test patterns, or an alternate method.
2. Measure L_{min} and L_{max} with a luminance meter in the center of each box.

3. Record these values on the form.
4. If possible, obtain the manufacturer specifications for L_{min} and L_{max} and enter them on the form.
5. Determine a max luminance baseline during acceptance testing of the AW.

Luminance Uniformity

1. Using the TG270-ULN8-100, or TG18 UNL80 test pattern, or an alternate method (e.g., an acquired flat-field image with WL set to maximum and WW set to the minimum), measure the luminance at each of the four corners of the monitor and at the center of the monitor.
2. Record these values on the form.

DICOM Grayscale Display Function (if available)

1. If possible, use the monitor manufacturer's built-in software to verify that the result of the DICOM GSDF grayscale test meets the monitor manufacturer's performance criteria.
2. The medical physicist may perform this test manually if they believe an independent verification is needed or if the manufacturer does not provide built-in software.

Manufacturer Automated Test(s) (if available)

1. Open the monitor manufacturer automated test program.
2. For initial setup, review the monitor manufacturer's frequencies, action limits, and other test parameters to verify appropriateness.
3. Review the results and verify that all tests have passed.
4. Record an overall pass or fail on the form.

ANALYSIS AND/OR INTERPRETATION

Luminance Ratio

Determine the L_{max} and L_{min} and use them to calculate the luminance ratio (LR') using the following equation.:

$$LR' = \frac{L'_{max}}{L'_{min}}$$

Where L'_{max} and L'_{min} are the maximum and minimum measured luminance values with ambient luminance included, respectively. In the absence of known reflection coefficients, suggested default values from TG-270 or 0 may be used.

Luminance Uniformity (if available)

Calculate the percent difference of the luminance values measured in the image display area using the following equation:

$$\%\,difference = \frac{200 * (L_{max} - L_{min})}{(L_{max} + L_{min})}$$

Where L_{max} and L_{min} are the maximum and minimum measured luminance values, respectively.

PRECAUTIONS AND CAVEATS

All monitor screens should be free of dust, fingerprints, and other marks. Similarly, there should be no "shiny" patches or clinically significant nonuniformities on the surface. As described below, significant blemishes that interfere with the interpretation or QC of images must be corrected.

Most problems can be corrected by cleaning according to the manufacturer's instructions. However, if cleaning does not correct the problem, the manufacturer should be contacted to evaluate and correct the problem.

In most cases, Monitor Manufacturer Automated Tests and action limits are available in manufacturer manuals or documents published by the manufacturer. These tests are extremely valuable in maintaining quality and are specific to each manufacturer.

If automated testing is available, the medical physicist should assist the facility in verifying that the automated system is set up and functioning properly.

It is important to distinguish between monitors used for procedure guidance, and those used for other imaging tasks. Quantitative evaluation only applies to those monitors used for procedure guidance.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Monitor Condition

Any clinically significant blemish that interferes with the visualization or QC of images is a failure. (If there are questions regarding the clinical significance of a monitor blemish, the Supervising Physician should be consulted.)

Test Pattern Image Quality (TG270-sQC) (if available)

The bar patterns in the top and bottom of each of the middle 16 swatches are all visible. Note that the bar patterns may not be fully visualized in patches 0 and 255 which is acceptable.

The high-contrast line-pair patterns ***must*** be distinguishable in bottom right corner.

Test Pattern Image Quality (TG18-OIQ or equivalent) (if available)

The test pattern must be centered appropriately.

The 0%-5% and 95%-100% contrast boxes must be visible.

Alphanumerics must be sharp and legible.

High-contrast line-pair patterns must be distinguishable at the center and corners.

Gradient bars must be smooth and continuous.

Luminance Check (if available)

L'_{min} is only used to determine the luminance ratio.

L'_{max} should be greater than or equal to 420 cd/m^2. The L'_{max} must be within 10% of the value specified by the manufacturer, if available, or within 10% of the baseline initially determined by the physicist.

Luminance ratio must be LR' ≥ 350.

Luminance Uniformity (if available)

Calculated % difference for an individual monitor must be ≤ 30%.

DICOM Grayscale Display Function (if available)

The measured contrast response values must not deviate from the targeted contrast response by more than ± 10%.

Manufacturer Automated Test(s) (if available)

Monitors must pass all manufacturer tests.

TIMEFRAME FOR CORRECTIVE ACTION

Monitor Condition

All failures must be corrected before clinical use.

Test Pattern Image Quality, Luminance Check, Luminance Uniformity, DICOM Grayscale Display Function, Monitor Manufacture Automated Test(s) (if available)

All failures must be corrected within 30 days.

10. Evaluation of Site's Technologist QC Program

OBJECTIVE

To ensure that technologist QC is being performed correctly, to compare the QC technologist's and the medical physicist's Phantom scores, and to identify areas where image quality and QC testing can be improved.

To present an opportunity for the medical physicist to provide or recommend further education to the QC Technologist, if deficiencies are noted.

> **Important:** The continuity of the QC program is very important to comply with the ACR accreditation program and to maintain a high level of quality service. The continuity of the QC program is the responsibility of the Supervising Physician. When the designated QC Technologist leaves a facility, goes on vacation, goes on leave, or is absent for any reason, it is vital that the QC program be continued by another technologist. A contingency plan is needed to prevent any lapse of the QC program. This includes the naming of an alternate QC Technologist who can continue the QC program at any time. The alternate QC Technologist must be trained in the performance of all QC tests. The alternate QC Technologist should have continuing experience in the performance of the QC tests. The alternate QC Technologist should be familiar with the current state of the QC program to be aware of any possible concerns or indications of possible test failures. This is important especially if the facility is aware of an upcoming absence of the QC Technologist. The facility's medical physicist should be used as a resource in the training and advisement of the alternate QC Technologist.

FREQUENCY

As part of the acceptance testing of new units (within 45 days) and annually.

TEST EQUIPMENT

- Technologist QC forms since the last medical physicist's survey
- Evaluation of Site's Technologist QC Program Form

TEST PROCEDURE

General Procedures

1. Evaluate for each technologist's QC test:
   a. Test is being performed correctly, at the appropriate frequency and that QC data appear to be correct
   b. Test is analyzed correctly, that calculations are performed according to the Technologist Section procedures, and that results are compared to the procedures' action limits
   c. Results and needed corrective actions are being performed and documented
2. On the form, record any deficiencies such as missing data, incorrect scoring or calculations, missing corrective action documentation, and any other observed problems.
3. Provide comments and findings as necessary. If the QC technologist is doing a good job on the routine QC, it is helpful to provide this positive feedback, as well as feedback on items that need improvement.

ANALYSIS AND INTERPRETATION

1. Although all noted deficiencies should be recorded on the form, only significant deficiencies should lead to a “Fail” assessment for the Overall Technologist QC Program. For the program to receive an overall PASS,
    a. There must be no significant missing data,
    b. The tests must be analyzed without gross errors, and
    c. Appropriate corrective action for failures must be taken and documented.
2. The following items can be used as guidance to determine whether the Overall Technologist QC Program fails:
    a. Not conducting a phantom image test for 2-3 weeks in a consecutive 12-week working period,
    b. Failure to conduct a phantom image test at clinical settings, and
    c. Not taking timely corrective action for failed items.
3. The medical physicist should use their judgement to determine what constitutes a significant deficiency. The following are examples:
    a. Two weeks of the weekly Phantom Image Quality testing were missing in the entire year (one in April, another in November). Although the medical physicist should note this on the form, the overall evaluation for the site’s technologist QC program should be PASS.
    b. The 2 most recent consecutive weeks of the weekly Phantom Image Quality testing were missing in the evaluated year (with no explanation or corrective action in the QC records). The overall evaluation for the site’s technologist QC program should be FAIL, and the medical physicist should point out that this may be a trend in need of correction.
    c. All weekly QC tests were missing 4 weeks in a row, but in the QC records the facility manager and Supervising Physician noted that they are aware of this occurrence, why it occurred, and that corrective action was taken so it would not occur again. The site’s technologist QC program would PASS since corrective action was taken to prevent future occurrences. The medical physicist should make a note of the circumstances and corrective action on the form. For example, “the QC technologist was on temporary disability; since that time a backup QC technologist was trained to assume QC responsibilities in case of future unexpected absences.”
    d. The QC technologist was routinely subtracting for artifacts when scoring the Phantom. Although the medical physicist should note this on the form, the overall evaluation for the site’s technologist QC program should PASS. (However, if the medical physicist notes during the following year’s annual survey that the same QC technologist continues to subtract for artifacts, the overall evaluation for the site’s technologist QC program should FAIL.)
4. Be sure to note on the Evaluation of Site’s Technologist QC Program Form if the QC technologist is performing their QC responsibilities well.

PRECAUTIONS AND CAVEATS

The medical physicist should conduct this review so that the facility is confident that all required tests have been correctly completed at the required intervals and appropriate corrective action was taken if necessary. For example, when reviewing the tests of a QC technologist or facility that is new to the medical physicist, they should review all the tests and corrective actions for the previous year. Similarly, if the equipment is new to the facility, a thorough review of QC should be done. If the medical physicist establishes confidence that QC is being conducted as required, they may only need to review samples of the QC during future surveys. If the samples reveal missing data, irregular results, or missing corrective action, a complete review should be conducted.

If tests are found missing, however, it is imperative that the QC technologist does not perform and back-date any tests to compensate for the omissions. The medical physicist should advise the facility to make a note that they are aware of the missing tests and document efforts to prevent occurrence in the future.

Medical physicists should provide the QC Technologist with one-on-one training or recommend sources of appropriate training if deficiencies in the conduct of the tests are noted. Although it is the medical physicist's responsibility to perform this review annually and to bring any deficiencies to the attention of the facility and Supervising Physician, it is the responsibility of the facility and Supervising Physician to see that measures are taken to ensure that all required tests are performed as specified by the medical physicist and at the required frequencies.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

The Site's Technologist QC Program must receive an overall PASS evaluation.

If significant deficiencies are found, they must be documented in the form, and action should be taken to correct the problems. Depending on the nature of the deficiency, correction may entail actions such as obtaining appropriate test equipment or providing additional training or coursework for the QC technologist, or facility management could decide to provide sufficient time for the QC technologist to perform the required duties. QC technologists should be assisted by both the medical physicist and facility management to resolve any identified issues.

TIMEFRAME FOR CORRECTIVE ACTION

Failures must be corrected within 30 days.

11. Acceptance/Post-Repair/Troubleshooting – Manufacturer Calibrations

OBJECTIVE

Manufacturer's Calibrations (if applicable): To detect and automatically correct equipment problems, especially related to digital image receptor performance. This may include compensating for dead or over-responding pixels, structured or other noise, nonlinear response, and other technical performance parameters.

FREQUENCY

As part of the acceptance testing of new units, and after relevant service, as recommended by the manufacturer.

> **Note:** Equipment calibrations are procedures that are used to detect **and automatically correct** equipment problems. For example, digital image receptor manufacturers create calibration procedures that optimize image receptor performance by compensating for dead or over-responding pixels, structured or other noise, nonlinear response, and other technical performance parameters. **QC tests** are procedures that detect problems but **the procedure itself does not correct the problem**. Manufacturers should clearly identify the calibration procedures necessary to keep their systems in optimal operating condition. Questions whether a manufacturer's procedure is a "calibration" or a "QC test" should be addressed to the equipment manufacturer.

REQUIRED TEST EQUIPMENT

- Equipment specified by manufacturer's recommendations
- Manufacturer Calibrations Form

TEST PROCEDURE

1. See manufacturer's documentation for exact procedure steps. The medical physicist should help the facility in locating and implementing these procedures.
2. Enter the results or verification of completion on the form.

ANALYSIS AND/OR INTERPRETATION

Follow manufacturer's recommendations.

PRECAUTIONS AND CAVEATS

Most manufacturers provide specific instructions for system calibrations (e.g., image receptor calibrations). See the manufacturer's documentation for precautions and caveats.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Manufacturer recommendations should be followed.

TIMEFRAME FOR CORRECTIVE ACTION

Manufacturer recommendations should be followed.

12. Acceptance/Post-Repair/Troubleshooting – Collimation

OBJECTIVE

To ensure that the collimator allows for full coverage of the image receptor by the x-ray field but does not allow significant radiation beyond its edges.

To ensure that the biopsy window aligns with the x-ray field.

> **Note for upright units with biopsy attachments:** This test may have already been performed during the survey of the mammography unit. Results from the performance evaluation of the mammography unit satisfy the requirement for this test.

FREQUENCY

As part of the acceptance testing of new units and after relevant service.

REQUIRED TEST EQUIPMENT

- The collimation test tool is left to the discretion of the medical physicist. Several options exist, for example:
  - film-screen cassettes
  - diagnostic x-ray CR cassettes
  - mammography CR cassettes
  - self-developing film
  - electronic radiation "rulers"
- As each of test tool requires different setup and exposure conditions than the others, only general directions are provided below. Specific implementation must be adapted to the particular test tool(s) used.
- Collimation Assessment form

TEST PROCEDURE

1. Initiate an exam at the acquisition workstation as you would for a patient or from the QC menu.
2. Use a name and image designation system that allows for tracking of the QC images. If these images have the possibility of being confused as being from a different unit, it is important to be able to identify the acquisition unit and date of acquisition. This image ID is important if these images are sent to PACS, or if the facility has more than one acquisition unit.
3. Select a flat field or scout image type necessary to perform an exposure.
4. Attach the most common standard biopsy paddle (with biopsy window) used clinically. Record paddle used.
5. Place the selected collimation test tool on top of the breast support. If the tool does not cross each edge of the radiation field, use either multiple detectors or multiple exposures to capture all four borders of the x-ray field.

6. Make an exposure appropriate to achieve a useable image of the test tool on the unit's detector, as well as visualize the radiation field on the test tool itself (for some test tools, this may require separate exposures).

ANALYSIS AND/OR INTERPRETATION

Using the collimation test tool and image at the image acquisition workstation, determine the difference between the edge of the radiation field and the edge of the active area of the image receptor: if the radiation field extends beyond the active area of the image receptor, record the value as positive; if the radiation field does not extend fully to the edge of the image receptor, record the value as negative.

PRECAUTIONS AND CAVEATS

Care should be taken to avoid overexposing the image receptor when performing this test.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

The x-ray field should cover the entire active area of the image receptor but shall not extend beyond any of the four sides of the image receptor by more than 2% of the source-to-image distance (SID).

TIMEFRAME FOR CORRECTIVE ACTION

When the test is performed for an acceptance testing or post-repair evaluation, all failures should be corrected before clinical use but must be corrected within 30 days.

When the test is performed for troubleshooting, all failures must be corrected within 30 days.

13. Acceptance / Post-Repair / Troubleshooting – Compression Force

OBJECTIVE

This test ensures that the unit can compress the breast sufficiently to immobilize the breast for the entire procedure. This test ensures that the maximum compression force is not excessive. This test evaluates 1) the maximum compression force attained by the use of the initial power-drive mode (typically applied by the use of a foot-switch or other power switch), 2) the maximum final compression force (typically manually applied) and 3) that adequate compression can be sustained.

FREQUENCY

As part of the acceptance testing of new units, after relevant service and as indicated for troubleshooting an issue.

TEST EQUIPMENT

- Bathroom scale (The scale should be a flat, conventional, analog type. Digital scales sample the data and may not respond properly as additional pressure is applied slowly to the scale. Digital scales designed specifically to measure compression force may be used.)
- Protective cushioning (e.g., Several towels) to protect the compression paddle and breast support.
- Other calibrated tools specifically designed to measure compression force (such as digital gauges or compression force tools) may also be used.
- Compression Force Form.

TEST PROCEDURE

1. Place (or for prone systems, tape) a towel or pad on the breast support surface, then place the scale on top of (or in front of) the towel with the read-out positioned outward for easy reading. Center the scale directly under (or behind) the compression paddle (for prone systems, it may help to place small objects under the scale for support and stability). Place (or tape) a towel or pad between the compression paddle and the scale.
2. Using power drive (if available), activate the compression device and operate until compression stops automatically.
3. Read and record the initial automatic compression force on the Compression Force form.
4. Continue to apply compression using the power drive and record the maximum compression achieved. Release the unit from the maximum compression force.
5. Manually apply compression using the fine-adjustment knob until the maximum compression force is achieved.
6. Read and record the maximum compression force on the Compression Force form. Release the unit from the maximum compression force.

7. Apply a compression force that is used clinically (at least 10 pounds): Test that the compression force is maintained for a reasonable length of time (about 2 minutes).
8. Release the scale from compression.

ANALYSIS AND/OR INTERPRETATION

None.

PRECAUTIONS AND CAVEATS

Digital bathroom scales may not respond properly if pressure is applied slowly and may be inappropriate to use for this test.

The compression device or the breast support may be damaged if the compression device is improperly positioned.

The compression device or the breast support may be damaged if the safety mechanism does not stop the initial power-drive mode from applying compression force from exceeding 45 pounds.

If the application of the automatic initial compression causes the pressure to exceed 45 pounds, then the test should be halted immediately, and the unit be serviced.

To prevent damage to the compression device or to the breast support, caution should be exercised when applying the pressure manually.

Releasing the compression without controlling the scale may cause the scale to fall.

If tools specifically designed to measure compression force are used, the above procedures may need to be modified.

PERFORMANCE CRITERIA AND CORRECTIVE ACTION

The compression force using the power drive mode must be at least 10 pounds, sufficient to stabilize the breast before final positioning, and must not exceed 45 pounds.

The unit must be able to hold a compression of at least 10 pounds for at least 2 minutes and should not vary by more than one pound.

The manually applied compression force must be at least 10 pounds but may exceed 45 pounds.

TIMEFRAME FOR CORRECTIVE ACTION

Failures must be corrected before clinical use.

14. Acceptance/Post-Repair/Troubleshooting – Tube Potential (kVp) Accuracy and Reproducibility

OBJECTIVE

To ensure that the kVp is accurate (within ±5% of the indicated kVp) and that the kVp is reproducible, having a coefficient of variation equal to or less than 0.02.

FREQUENCY

As part of the acceptance testing of new units, after relevant service or component replacement.

> **Note:** Because modern generators used in digital mammography and biopsy units are very stable, the kVp accuracy and reproducibility tests need only be done as part of acceptance testing of new units, after relevant services or component replacement and if additional troubleshooting is needed to diagnose a potential problem. It is not required to be performed annually.

> **Note for upright units with biopsy attachments:** This test may have already been performed during the survey of the mammography unit. Results from the performance evaluation of the mammography unit satisfy the requirement for this test.

REQUIRED TEST EQUIPMENT

- kVp meter capable of determining kVp to an accuracy of ±1.5 kVp and a precision of 0.5 kVp within the mammographic range
- Lead Sheet or attenuator to protect the image receptor.
- An integrated, solid-state instrument (which automatically measures kVp, half-value layer [HVL], and dose quantities) is also acceptable (see Precautions and Caveats).
- kVp Accuracy and Reproducibility Form.

TEST PROCEDURE

1. In the manual exposure mode, select the most commonly used clinical kVp setting (within the specified accuracy range of the meter) and record on the data form. This tends to be the kVp used for the phantom technique. Also record the nominal focal spot size, exposure time, and mA (or mAs) setting.
2. Place a lead sheet or other protective device on the image receptor. This is intended to protect the image receptor from repeated exposures.
3. Position the dosimeter on top of the breast support, above the protective device, 5cm in from the chest-wall edge of the breast support and centered laterally at the midline of the detector.
    a. Note: The air kerma measurement being performed should not include backscatter. Solid-state dosimeters are generally lead-backed and backscatter insensitive, as are many ion chambers designed for mammography, permitting this measurement to be performed at the surface of the breast support. However, if there is concern that

dosimeter being used is sensitive to backscatter then the dosimeter should be raised above the breast support by ~10cm.

4. Raise the compression paddle to the highest position permitted by the system (i.e as close to the x-ray tube as possible). Ensure that the dosimeter is within the biopsy window (if applicable).
5. Be sure that the needle support system is out of the field during this test. If the needle support system shadows the active area of the meter, it will affect the kVp measurement.
6. For reproducibility, make three exposures in the same manual mode settings at the most commonly used clinical kVp used in either the stereotactic or the DBT mode. Record the kVp measurements in the kVp data form. (Reproducibility only needs to be checked at the most commonly used clinical kVp unless variability is suspected at other settings.)
7. If both stereotactic and DBT modes are used clinically, repeat a single measurement in the mode not selected in step 4 (above) at the most commonly used clinical kVp.
8. For either mode, make a single measurement at the lowest clinically used kVp that can be measured by the kVp test device, and the highest available clinically used kVp.

DATA ANALYSIS AND INTERPRETATION

To determine the accuracy of the measurement, take the average of each kVp tested and compare it to the nominal kVp setting. To determine the kVp reproducibility, compute the standard deviation of each kVp tested then calculate the coefficient of variation (standard deviation divided by the mean value) for each value.

PRECAUTIONS AND CAVEATS

If an integrated, solid-state instrument (one that automatically measures kVp, HVL, and dose) is used, the above procedures may not apply. Be sure that the meter is calibrated for the target/filter combination as well as the kVp range in use.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

If the average measured kVp differs by more than ±5% (for example, ±1.5 kVp at 30 kVp) from the nominal kVp setting, the unit should be checked by appropriate service personnel. If the coefficient of variation exceeds 0.02 for any kVp setting, the unit should be checked by appropriate service personnel.

TIMEFRAME FOR CORRECTIVE ACTION

When the test is performed as part of acceptance testing or post-repair testing, all failures should be corrected before clinical use but must be corrected within 30 days.

When the test is performed for troubleshooting, all failures must be corrected within 30 days.

15. *Acceptance/Post-Repair/Troubleshooting* - Beam Quality (Half-Value Layer) Assessment

OBJECTIVE

To ensure that the half-value layer (HVL) of the X-ray beam is adequate to optimize the patient breast dose.

FREQUENCY

As part of the acceptance testing of new units and after relevant service.

> **Note:** If the facility changes technique factors (that impact beam quality and dose) for a 4.2cm-thick compressed breast consisting of 50% glandular and 50% adipose tissue, and the HVL was not previously determined for those factors, the medical physicist should measure the HVL for the appropriate factors during the annual survey. Also, if there is any concern regarding a significant dose change, the HVL should be reevaluated.

> **Note for upright units with biopsy attachments:** For upright units with biopsy attachments, evaluations made during other mammography unit QC may not be appropriate for this test because the paddle material is in the biopsy field during the measurement. In this case, HVL measurements need to be repeated using the compression paddle used for clinical biopsy procedures, which is typically an open-window paddle.

REQUIRED TEST EQUIPMENT

- Ion chamber and electrometer or an integrated, solid-state instrument that automatically measures kVp, HVL, and dose quantities, calibrated at mammographic x-ray beam energies. Hereafter both types being referred to as “dosimeter.”
- 0.1-mm thick sheets of high-purity aluminum (99.9% pure) or 99% pure (i.e., type 1100 aluminum alloy) of length and width sufficient to cover the dosimeter fully. (The stated thickness should be accurate to within ±0.005 mm.)
- High Z attenuator to protect the image receptor.
- Beam Quality (HVL) Assessment form.

TEST PROCEDURE

Integrated, solid-state dosimeters typically provide automated HVL readings with a single exposure per kVp setting. If using an ion chamber type dosimeter, follow the procedure below.

1. Place a lead sheet or other protective device on the image receptor. This is intended to protect the image receptor from repeated exposures.
2. Position the dosimeter on top of the breast support, above the protective device, 5cm in from the chest-wall edge of the breast support and centered laterally at the midline of the detector. Record the distance from the x-ray source to the plane of measurement (l_m) on the form.
    a. Note: The air kerma measurement being performed should not include backscatter. Solid-state dosimeters are generally lead-backed and backscatter insensitive, as are

many ion chambers designed for mammography, permitting this measurement to be performed at the surface of the breast support. However, if there is concern that dosimeter being used is sensitive to backscatter then the dosimeter should be raised above the breast support by ~10cm.

3. Raise the compression paddle to the highest position permitted by the system (i.e as close to the x-ray tube as possible). Ensure that the dosimeter is within the biopsy window (if applicable).
4. Select the target/filter and kVp at which the system is used clinically (phantom technique) and record the settings on the data form. Set a manual mAs close to the phantom technique.
5. Make an exposure without the aluminum sheets between the x-ray tube and dosimeter.
6. Only 2 additional exposures are necessary to complete the test. Select two thicknesses of aluminum that result in an exposure just above and just below one-half the original exposure reading (taken without any added aluminum sheets between the x-ray tube and dosimeter).
7. Add sufficient aluminum (e.g., 0.3 mm) between the x-ray tube and the dosimeter. Use the light field (if available) to verify that the x-ray path to the dosimeter is fully blocked by the aluminum sheets. Make an exposure and record the dosimeter reading. This reading should be greater than one-half the original exposure reading.
8. Repeat with an additional 0.1mm sheet of aluminum between the x-ray tube and dosimeter, and record the dosimeter reading. This last reading should be less than one-half the original exposure reading.
9. Repeat steps 4-8 for the highest and lowest kVp settings used clinically, and for any other clinically used target/filter combination(s).

ANALYSIS AND/OR INTERPRETATION

To calculate the HVL by logarithmic interpolation, use the following notation and procedure. The HVL may be computed using the formula

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

where the HVL will be given in the same units as t_a and t_b (i.e., millimeters of aluminum) and:

E_0	Exposure reading without any attenuators in beam path
E_a	Exposure reading with the attenuator in beam path that results in an exposure above $E_0/2$
E_b	Exposure reading with the attenuator in beam path that results in an exposure below $E_0/2$
t_a	Thickness of Al attenuator that results in measurement of E_a
t_b	Thickness of Al attenuator that results in measurement of E_b

PRECAUTIONS AND CAVEATS

During acceptance testing the medical physicist must determine the HVLs for select clinically used kVp settings (phantom, highest, and lowest), and for each target/filter combination used clinically. If, after the acceptance testing, the facility uses a new clinical kVp, it may not be necessary for the medical physicist to perform another HVL measurement. If the new kVp is bracketed by kVps used for previous HVL measurements, the medical physicist may interpolate a new HVL to use in average glandular dose assessments for the new kVp.

If an integrated, solid-state instrument (one that automatically measures, kVp, HVL, and Dose) is used, the above procedures would not apply. The HVL may be entered into the results area of the form.

The use of type 1100 aluminum alloy for HVL measurement can give (depending on specific sample) HVL values up to 7.5% lower than those measured using high-purity aluminum. As such, it is strongly recommended to use high-purity aluminum. If type 1100 aluminum is used, results should be corrected to agree with those obtained using high-purity aluminum.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

At a given kVp setting in the mammographic kilovoltage range (below 50 kVp), the HVL determined must be equal to or greater than the values in the table from the FDA regulations below.

The HVL shall meet the specification of the FDA performance standards for Ionizing Radiation Emitting Products (Part 1020.30) for the minimum HVL. These values extrapolated to the mammographic range are shown below. Values not shown may be determined by linear interpolation or extrapolation.

X-ray Tube Voltage (kilovolt peak) and Minimum HVL		
Designed Operating Range (kV)	*Measured Operating Voltage (kV)*	*Minimum HVL (millimeters of aluminum)*
Below 50	*20* *25* *30*	*0.20* *0.25* *0.30*

TIMEFRAME FOR CORRECTIVE ACTION

When the test is performed for an acceptance testing or post-repair testing, all failures should be corrected before clinical use but must be corrected within 30 days.

When the test is performed for troubleshooting, all failures must be corrected within 30 days.

16. Troubleshooting – Ghost Image Evaluation (optional)

OBJECTIVE

To evaluate the extent to which previous exposures impact later exposures on the image receptor. “Ghosting” is a term used to describe residual signals or shadows of prior images on the image receptor. Ghost images may be due to earlier exposures changing the sensitivity of the image receptor - leading to an inaccurate response to later images, or simply residual images being retained on the image which are added to subsequent images.

FREQUENCY

As needed.

REQUIRED TEST EQUIPMENT

- Uniform attenuator large enough to cover the entire image receptor (the ACR Digital Mammography (DM) Phantom works), hereafter referred to as “attenuator.”
- 0.1-mm thick aluminum, approximately 10 cm × 10 cm (aluminum used for half-value layer attenuation works well).
- Timer (watch, stopwatch, etc.).
- Ghost Image Evaluation form.

TEST PROCEDURE

1. Create a test patient.
2. Turn off all image processing, if possible.
3. Install the largest compression paddle.
4. Place the attenuator on the right half of the breast support plate with the edge placed at the middle of the image receptor, running from chest wall to the anterior edge such that it extends approximately 2.5 cm beyond the left-to-right center line of the breast image. If the system has automatic exposure control (AEC) sensors, they must be fully covered by the phantom. (See Figure 3-13)
5. If possible, select an AEC detector location approximately 5 cm from the chest wall.
6. Lower the paddle and compress to 5 decanewtons.
7. Acquire an image using the technique used for imaging the ACR phantom.
8. Immediately start timing.
9. Move the attenuator so that it covers the entire breast imaging area. Place the aluminum in the center of the imaging field, on top of the attenuator, and aligned with the chest-wall edge of the paddle, ensuring that it extends at least 2 cm beyond the previous edge of the attenuator. (See Figure 3-13)
10. One minute after the first image was acquired, or within as short a time as the system will allow if longer than 1 minute, acquire a second image using the same techniques as the first image.

11. Use a circular or rectangular region of interest tool (area ~1 cm2) to measure the mean signal value in the following 3 regions in the raw version of the second image acquired (See Figure 3-14):

    i. Mean signal (S1) value over the attenuator on the side where the attenuator was present in the first image

    ii. Mean signal (S2) value over the attenuator plus the aluminum square on the side where the attenuator was present in the first image

    iii. Mean signal (S3) value over the attenuator plus the aluminum square on the side where no attenuator was present in the first image

Figure 3-13. Note offset and coverage of AEC

Figure 3-14. Note coverage of image receptor and placement of aluminum

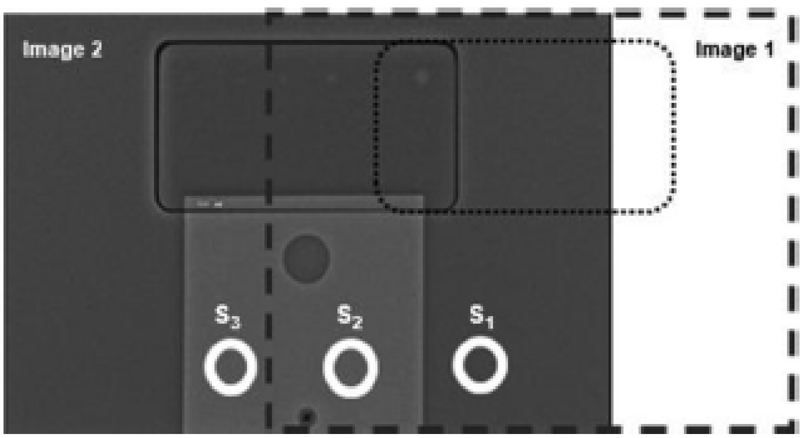


Figure 3-14. Region of interest guidance on 2 images.

ANALYSIS AND/OR INTERPRETATION

Calculate the Ghosting Index using the following formula:

$$\text{Ghosting Index} = \frac{S_3 - S_2}{S_1 - S_2}$$

PRECAUTIONS AND CAVEATS

None.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

If the ghosting index is more than ±0.3, repeat the test. If the ghosting index still exceeds ±0.3, service personnel should be contacted.

TIMEFRAME FOR CORRECTIVE ACTION

Failures must be corrected before clinical use.

III. RESOURCES

- Sechopoulos I, Dance DR, Boone JM, Bosmans HT, Caballo M, Diaz O, van Engen R, Fedon C, Glick SJ, Hernandez AM, Hill ML, Hulme KW, Longo R, Rabin C, Sanderink WBG, Seibert JA. Joint AAPM Task Group 282/EFOMP Working Group Report: Breast dosimetry for standard and contrast-enhanced mammography and breast tomosynthesis. Med Phys. 2024 Feb;51(2):712-739. doi: 10.1002/mp.16842.
- Wu X, Barnes GT, Tucker DM. Spectral dependence of glandular tissue dose in screen-film mammography. Radiology. 1991;179:143–148.
- Dance DR, Skinner CL, Young KC, Beckett JR, Kotre CJ. Additional factors for the estimation of mean glandular breast dose using the UK mammography dosimetry protocol. *Phys Med Biol*. 2000;45:3225-3240.

IV. APPENDIX A: Phantom Scoring

Table * Test object sizes for each approved phantom

	Original ACR Phantom		Mini Phantom		ACR DM Phantom	
	Object Number	**Size (mm)**	**Object Number**	**Size (mm)**	**Object Number**	**Size (mm)**
Fibers	1	1.56				
	2	1.12				
	3	0.89	1	0.93	1	0.89
	4	0.75	2	0.74	2	0.75
					3	0.61
	5	0.54	3	0.54	4	0.54
	6	0.40			5	0.40
			4	0.32	6	0.30
Specks	1	0.54	1	0.54		
	2	0.40				
	3	0.32	2	0.32	1	0.33
					2	0.28
	4	0.24	3	0.24	3	0.23
			4	0.20	4	0.20
	5	0.16			5	0.17
					6	0.14
Masses	1	2.00				
	2	1.00	1	1.00	1	1.00
	3	0.75	2	0.75	2	0.75
	4	0.50	3	0.50	3	0.50
	5	0.25	4	0.25	4	0.38
					5	0.25
					6	0.20

Artifact Evaluation Guide – TBD

V. APPENDIX B: Dance et al Method for Breast Dosimetry

The physicist may wish to estimate the average glandular dose using the Dance method, for comparison purposes or otherwise. This calculation can be performed from the measurements acquired during Test 6 using following the steps below.

Definitions

L_s: The shortest distance between the x-ray source and the plane where the surface of the breast is located; expressed in units of millimeter (mm)

K_s: The air kerma free-in-air at the surface of a 4.2cm breast; expressed in units of millGray (mGy)

g: The dose conversion factor for a breast with 50% glandularity

c: The factor c corrects for any difference in breast composition from 50% glandularity.

s: The factor s corrects for differences due to the choice of x-ray spectrum

Calculate the incident air kerma at the surface of the breast

$$K_s = K_{m,phantom}\left(\frac{l_m}{l_s}\right)^2$$

Compute the average glandular dose (AGD) using the following equation

$$AGD = K_s gcs$$

Where g, c, and s are the dose conversion and correction factors for a cranio-caudal view of a 4.2 cm breast of 50% glandularity at the defined beam quality and are derived from Dance et. al.

See:

Dance DR, Skinner CL, Young KC, Beckett JR, Kotre CJ. Additional factors for the estimation of mean glandular breast dose using the UK mammography dosimetry protocol. *Phys Med Biol*. 2000;45:3225-3240.

Dance DR, Young KC, van Engen RE. Further factors for the estimation of mean glandular dose using the United Kingdom, European and IAEA breast dosimetry protocols. *Phys Med Biol*. 2009;54(14):4361-4372.

Dance DR, Young KC, van Engen RE. Estimation of mean glandular dose for breast tomosynthesis: factors for use with the UK, European and IAEA breast dosimetry protocols. *Phys Med Biol*. 2011;56:453-471.