Stereotactic Breast Biopsy Accreditation and Advances in Technology

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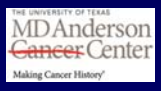

Introduction

- Objectives
- Program Requirements
- Physicists Role
- Testing Requirements
- Tomosynthesis Guided Biopsy

Educational Objectives

- Understand the annual test requirements for stereotactic breast biopsy systems accredited by the American College of Radiology for both upright add on systems and stand alone prone biopsy.
- Understand the operation of tomosynthesis guided breast biopsy systems.

Physicists Role

- Stereotactic Breast Biopsy Accreditation
  - Annual Testing (required)
  - QC Program Review (required)
  - Dose Measurement (required)

Stereotactic Breast Biopsy Physicist

- Initial Qualifications
  - Qualified to perform Mammography surveys under MQSA
  - Perform one (1) hands on survey of a stereotactic breast biopsy unit under a QMP or at least 3 independent surveys prior to 6/1/97
- Continuing Experience
  - Upon renewal, 2 SBB surveys in the prior 24 months
- Continuing Education
  - Upon renewal, 3 CEU's in SBB in prior 36 months

Ref:
http://www.acraccreditation.org/~/media/ACRAccreditation/Documents/Stereotactic/Requirements.pdf?la=en

Stereotactic Breast Biopsy Program Requirements

- Quality Assurance Questionnaire
- Test Image Data Sheet
- Clinical Images (still on film or high quality photographic paper)
- Phantom Images (on film)
- Medical Physicists Annual Survey Report
- Daily, Weekly Tech QC (one month)
- Monthly, Quarterly, Semi-annual Tech QC records (one year)

Technologist Quality Control

- Daily – Localization Accuracy Test
- Phantom Imaging (weekly)
- Printer QC (monthly)
- Visual Checklist (monthly)
- Compression (semi-annually)
- Repeat Analysis (quarterly)
- Zero Alignment Test (per manufacturer)
- Dark Room Testing (if using film screen)

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Daily Localization Accuracy Test

Upright Stereo Biopsy

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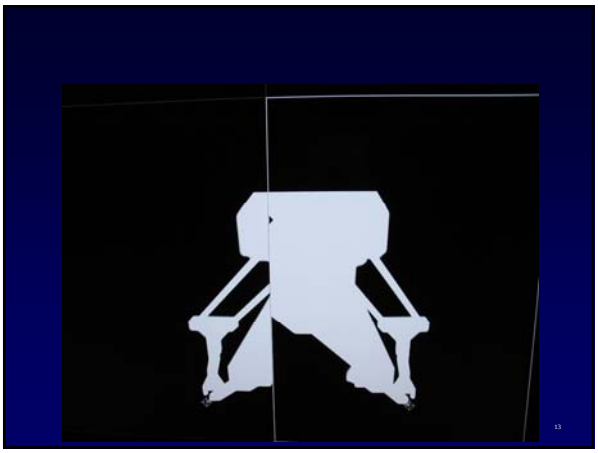

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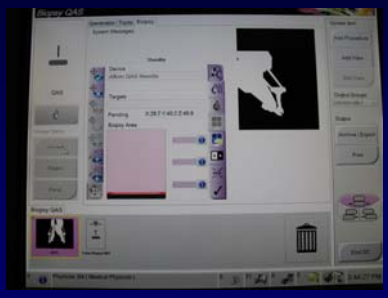

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Stereotactic Breast Biopsy

- Annual testing required by physicist
- ACR QC Manual available

Ref: Stereotactic Breast Biopsy Quality Control Manual
1999 American College of Radiology

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Stereotactic Breast Biopsy Annual Test – Prone Table

- Unit Assembly Evaluation
- Collimation Assessment
- Focal Spot Performance and System Limiting Spatial Resolution
- kVp Accuracy
- Beam Quality Assessment (Half Value Layer)

Stereotactic Breast Biopsy Annual Test – Prone Table

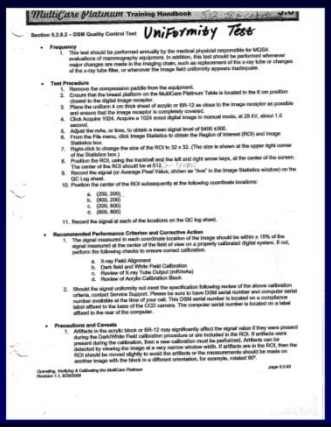
- Automatic Exposure Control (AEC) or Manual Exposure Assessment
- Uniformity of Screen Speed (Screen Film Systems)
- Digital Receptor Uniformity (For Digital Image Receptors)
- Breast Entrance Exposure, Average Glandular Dose, and Exposure Reproducibility

Stereotactic Breast Biopsy Annual Test – Prone Table

- Image Quality Evaluation
- Artifact Evaluation
- Localization Accuracy Test

Digital Field Uniformity

- May require manufacturers service manual for procedure.



MultiCare Platinum Training Handbook

Section 5.2.8.2 – DSM Quality Control Test: Uniformity Test

- Frequency
  1. This test should be performed annually by the medical physicist responsible for MQSA evaluations of mammographic equipment. In addition, this test should be performed whenever major changes are made in the imaging chain, such as replacement of the x-ray tube or changes of the x-ray tube filter, or whenever the image field uniformity appears inadequate.
- Test Procedure
  1. Remove the compression paddle from the equipment.
  2. Ensure that the breast support on the MultiCare Platinum Table is located in the 6 cm position closest to the digital image receptor.
  3. Place the uniform 4 cm thick sheet of acrylic or BR-12 as close to the image receptor as possible and ensure that the image receptor is completely covered.
  4. Click Acquire 1024. Acquire a 1024 scout digital image in manual mode, at 28 kV, about 1.0 second.
  5. Adjust the mAs, or time, to obtain a mean signal level of 8400 ±300.
  6. From the File menu, click Image Statistics to obtain the Region of Interest (ROI) and Image Statistics box.
  7. Right-click to change the size of the ROI to 32 x 32. (The size is shown at the upper right corner of the Statistics box.)
  8. Position the ROI, using the trackball and the left and right sense keys, at the center of the screen. The center of the ROI should be at 512, 512.
  9. Record the signal (or Average Pixel Value, shown as "Ave" in the Image Statistics window) on the QC Log sheet.
  10. Position the center of the ROI subsequently at the following coordinate locations:
      a. (200, 200)
      b. (800, 200)
      c. (200, 800)
      d. (800, 800)
  11. Record the signal at each of the locations on the QC log sheet.
- Recommended Performance Criterion and Corrective Action
  1. The signal measured in each coordinate location of the image should be within ± 15% of the signal measured at the center of the field of view on a properly calibrated digital system. If not, perform the following checks to ensure correct calibration.
     a. X-ray Field Alignment
     b. Dark field and White Field Calibration
     c. Review of X-ray Tube Output (mR/mAs)
     d. Review of Acrylic Calibration Block
  2. Should the signal uniformity not meet the specification following review of the above calibration criteria, contact Service Support. Please be sure to have DSM serial number and computer serial number available at the time of your call. This DSM serial number is located on a compliance label affixed to the base of the CCD camera. The computer serial number is located on a label affixed to the rear of the computer.
- Precautions and Caveats
  1. Artifacts in the acrylic block or BR-12 may significantly affect the signal value if they were present during the Dark/White Field calibration procedure or are included in the ROI. If artifacts were present during the calibration, then a new calibration must be performed. Artifacts can be detected by viewing the image at a very narrow window width. If artifacts are in the ROI, then the ROI should be moved slightly to avoid the artifacts or the measurements should be made on another image with the block in a different orientation, for example, rotated 90°.

Operating, Verifying & Calibrating the MultiCare Platinum
Revision 1.1, 8/26/2008
page 5.2.8.2

Breast Entrance Exposure Average Glandular Dose, and Exposure Reproducibility

- Use AEC to expose Phantom
- Find closest manual technique
- Replace phantom with ion chamber
- Make 4 exposures

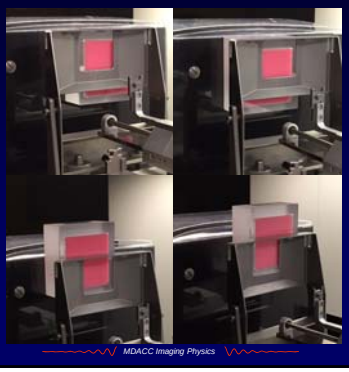
Dose

Dose

- Check both 512 and 1024 modes
- Made change to technique chart to get 1024 mode to be less than 300 mrad (3 mGy)
- "The average glandular dose to an average (4.2 cm compressed) breast should not exceed 3 mGy (300 mrad) per view for film-screen or digital image receptors"

Image Quality Evaluation – Mini Phantom

Image Quality Evaluation – ACR Mammography Phantom



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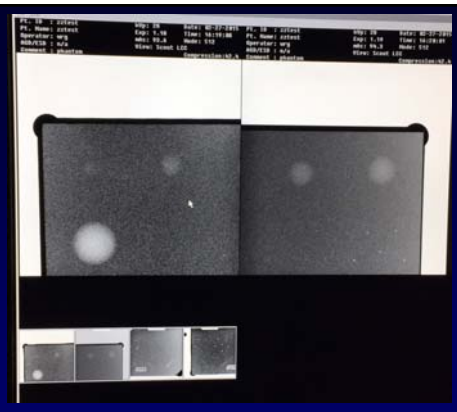

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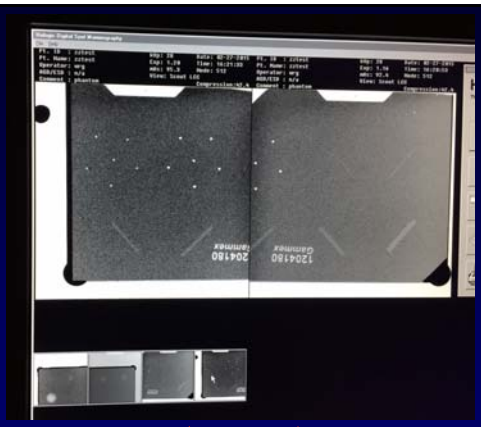

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Required Minimum Scores - Digital Receptor

- Mammography Accreditation Phantom
  - 5.0 Fibers
  - 4.0 Specs
  - 3.5 Masses
  - Total: 12.5
- Mini-phantom
  - 3.0 Fibers
  - 3.0 Specs
  - 2.5 Masses
  - Total: 8.5

Add On Biopsy Systems

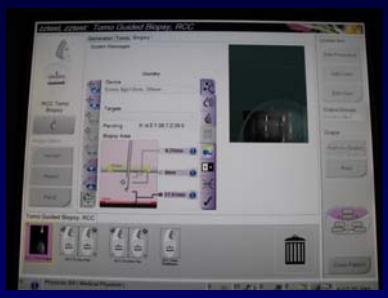
Stereotactic Breast Biopsy Annual Test – Upright Add On

- Unit Assembly Evaluation
- Beam Quality Assessment (Half Value Layer)
  - With paddle and at kVp for stereo phantom
- Breast Entrance Exposure, Average Glandular Dose
- Image Quality Evaluation (with mini phantom)
- Localization Accuracy Test

Beyond Mammography Annual Testing

- HVL at Phantom kVp with Stereo Paddle
- HVL Measurement for Tomo Biopsy
- Dose Measurement for Phantom for Both
- Image Quality with Stereo Phantom
- Localization

New Technology – Tomosynthesis Guided Biopsy



FDA Approved Systems

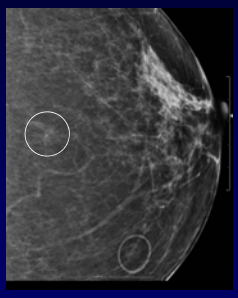
- Hologic Dimensions with Affirm Biopsy Attachment
- Hologic Affirm Prone Biopsy System
- GE and Siemens coming soon!
- Fuji?
- No Manufacturers QC Program
  - Do what you think is best

Prone Table w/ Tomosynthesis

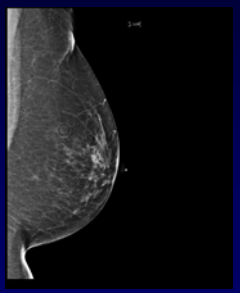
- Hologic Prone System
  - Tungsten x-ray tube with Silver filtration
  - aSe detector with 70 micron detector element
  - 33 cm x 21 cm field size with a FOV of 14.3 cm x 11.7 cm
  - 15 degree tomo acquisition angle

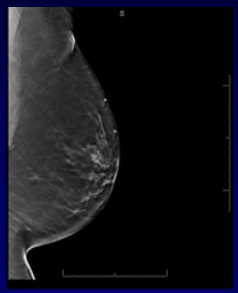
Clinical Case

- 61 Y.O. female screening 2D only
- Called back for asymmetry
- Diagnostic Tomo showed small lesion.
- No ultrasound correlate
- Recommend tomosynthesis guided biopsy

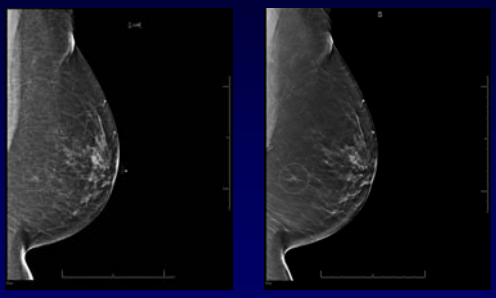


Clinical Case

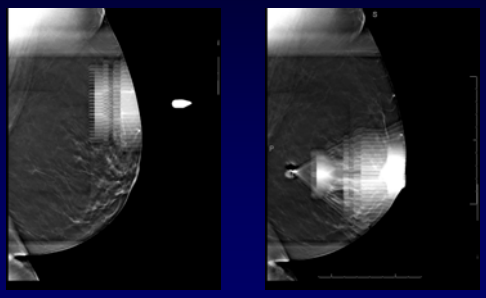




Clinical Case



Clinical Case



Clinical Case

- Pathology showed invasive mammary carcinoma Grade I, T1, N0, M0
- Histologic markers showed ER positive 100%, PR positive 90%, HER2/neu2+ negative
- Patient opted for segmental mastectomy

Conclusion

- ACR accreditation for biopsy systems needed for BICOE
- Tomosynthesis guided biopsy gaining converts
- No required testing for tomosynthesis guided biopsy – do what you think best

Questions?