Surveying and QC of Stereotactic Breast Biopsy Units for ACR Accreditation

AAPM Annual Clinical Meeting
Indianapolis, IN August 5, 2013

Melissa C. Martin, M.S., FACR, FAAPM, FACMP

Learning Objectives

- Become familiar with the recommendations and requirements of the ACR Stereotactic Breast Biopsy Accreditation Program (SBBAP) - 1999 Quality Control Manual Information for image quality, patient dose, and needle placement accuracy
- Become familiar with the operation and performance of SBB systems - both prone table and upright add-on systems

LORAD Prone Table

LORAD Stereotactic Breast Biopsy System

LORAD Stereotactic Breast Biopsy System

LORAD Stereotactic Breast Biopsy System Control Pendant
Siemens (Fischer) MammoVision Biopsy System

Siemens (Fischer) MammoVision Biopsy System

Siemens Mammomat Inspiration SBB Add-On

It should be noted that the Siemens MAMMOGRAPHY Inspiration (SBB) mammography equipment offers a unique advantage. Siemens has developed the MAMMOGRAPHY Inspiration to support the demands of today’s medical practice in screening, diagnostics, and biopsy. The optional biopsy biopsy attachment automatically converts the MAMMOGRAPHY Inspiration to mammographic biopsy, which is operable with the patient in the prone or upright position. For those institutions wanting a dedicated biopsy unit, this option provides an excellent way to include mammographic breast biopsy in their scope of service as well as meet the needs of the surgeons.

Affirm™ Biopsy Guidance System

Affirm™ Biopsy Guidance System

the next generation of breast biopsy

- State-of-the-art solution for upright biopsy procedures
- Advanced ergonomic design
- Novel features to minimize procedure steps and simplify workflow
- Versatile and flexible solution for any setting
- Platform for future advances in biopsy

Advanced, Ergonomic Design

Advanced, Ergonomic Design

easy to use and install

- Lightweight, compact device
  - ~7 kg (~15 lb)
- Balanced design
- Easy grasp handles
- Installs easily, in just seconds
Enhanced Visualization
intuitive targeting

- Uses a novel 10° angle to enter the breast
  - Biopsy device is removed from path of x-ray for unobstructed view of lesions
- Uses intuitive, Cartesian targeting
  - Allows user to think in Cartesian space for targeting
  - Software automatically factors in angle, making adjustments seamless to users

Fully Integrated System
increased efficiency

- Add-on to any Dimensions*
- Utilizes existing detector and compression mechanism
  - Superb image quality
  - Large field of view simplifies positioning
- 70 cm SID – longest in the industry!
  - Provides comfortable working space and better patient access
  - Allows easier, faster installation of biopsy devices
- Allows you to biopsy under the same imaging modality

*Affirm comes standard with a single gantry 2D biopsy license. Additional licenses are available for purchase.

Simplified Workflow
streamlined procedures

- Fully integrated user interface
  - All activities performed on the easy-to-use Dimensions AWS
- Automated image acquisition
  - C-arm moves automatically to the appropriate location for stereo views
  - Requires minimal steps
  - Shortens procedure time
- Accurate and efficient
  - Targeting software removes guesswork
  - Provides visual feedback of needle placement

Versatility and Flexibility
wide range of use

- All Selenia Dimensions are biopsy-ready and tomosynthesis capable
  - Dimensions with AWS 5000 may require display upgrade (minimum 2 MP medical grade grayscale monitor)
- Affirm is compatible with wide array of biopsy devices
  - Pre-programmed for Hologic’s ATEC and Eviva

ACR SBB Program Statistics

- As of January 1, 2012, ACR has accredited 1052 units at 1020 facilities providing Stereotactic Breast Biopsy Procedures
- In 2011, the first attempt pass rate for new or renewing units was 82%. Almost all facilities pass on their second attempt at accreditation after taking appropriate corrective action to improve image quality
ACR Accreditation of SBB Units

- Currently, mammography units used exclusively for SBB procedures are not required to be certified under MQSA.
- Facilities must have an accredited SBB program to be named as a Center of Excellence for Breast Care by the ACR.

Goals of QC for Stereotactic Breast Biopsy

- To ensure that image quality in Stereotactic Breast Biopsy equals or exceeds that of screening and diagnostic mammography.
- To ensure that equipment designed specifically for Stereotactic Breast Biopsy performs properly.
- To ensure that needle localizations are accurate.

General Requirements for SBBAP

- Qualified TEAM: Physicians, Technologist, and Medical Physicist.
- Equipment: Table or “add-on”; film or digital.
- Technologist’s QC Testing - daily, weekly, monthly, semi-annual - 6 tests.
- Medical Physicist’s QC Testing - acceptance and annual - 11 tests.

Quality Control: Medical Physicist’s Evaluation

- Acceptance Test Before Patient Use.
- Report Required as Part of ACR Application.
- Annually Thereafter.
- Detailed instructions on 11 Required Physicist’s tests.

ACR Quality Control Manual

- Sent free to all facilities in program.
- To purchase, call ACR Pubs: (800) 227-7762.
- QC forms available to anyone on Web site.
Rad Tech QC Tests
Mammo QC Tests Also Apply if Screen-Film Used
- Localization Accuracy - daily
- Phantom Image - weekly
- Hardcopy Output Quality - monthly, if app
- Visual Checklist - monthly
- Compression Force - semi-annually
- Repeat Analysis - semi-annually
- Zero Alignment Test – before ea patient, if app

Medical Physicist’s Quality Control Tests
1. Stereotactic Unit Assembly Evaluation
2. Collimation Assessment
3. Focal Spot Performance & Digital System Limiting Resolution
4. kVp Accuracy and Reproducibility
5. Beam Quality Assessment (HVL)
6. AEC or Manual Exposure Performance

Medical Physicist’s Quality Control Tests
7A. Uniformity of Screen Speed
7B. Digital Receptor Uniformity
8. Breast Entrance Exposure, Average Glandular Dose, and Exposure Reproducibility
9. Image Quality Evaluation
10. Artifact Evaluation
11. Localization Accuracy Test

Stereotactic Unit Assembly Evaluation

Collimation Assessment

LORAD Upright Biopsy Paddle
**Measurement Tools Available on Screen**

**Collimation Assessment**

- SID = 84 cm for LORAD SBB Tables

**Collimator Assessment for Add-On Units**

- Actual Opening in Metal Compression Plate is 5 x 5 cm area

**Digital Limiting Resolution/Focal Spot**
**Digital Limiting Resolution/Focal Spot**

Hologic requires at least 7 lp/mm resolution

---

**kVp Accuracy and Reproducibility**

### Beam Quality Assessment

<table>
<thead>
<tr>
<th>Exposure measurements (mm Al)</th>
<th>E0 (mm Al)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No aluminum filtration, E0</td>
<td>0.797</td>
</tr>
<tr>
<td>0.2 mm of added aluminum, E2</td>
<td>0.892</td>
</tr>
<tr>
<td>0.3 mm of added aluminum, E3</td>
<td>0.998</td>
</tr>
<tr>
<td>0.4 mm of added aluminum, E4</td>
<td>0.960</td>
</tr>
<tr>
<td>0.5 mm of added aluminum, E5</td>
<td>1.041</td>
</tr>
</tbody>
</table>

---

**Beam Quality Specifications for SBB Units**

- The minimum acceptable Half-Value Layer measurement on a digital or film/screen SBB unit is
  - Action: If measured HVL < (kVp/100) (in mm Al) or
  - if measured HVL ≥ (kVp/100) + C (in mm Al)
  
  where C = 0.12 for Mo/Mo, C = 0.19 for Mo/Rh, and C = 0.22 for Rh/Rh,
  
  then seek service correction.

---

**Image Quality Evaluation (Phantom)**

- Objective: Ensure Image Quality for SBB meets at least the minimum that is required for screening mammography, and to detect temporal changes in image quality
  - Procedure: Same as for Mammography, except ACR phantom must be imaged in 4 separate quadrants for digital because of small field of view if facility is using RMI 156 or equivalent phantom or meets minimum requirements for mini-phantom for digital stereotactic units as noted later in slides
Two Types of Approved Phantoms

“Mini” Stereotactic Breast Biopsy Accreditation Phantom
Nuclear Associates 18-250

Mammography Accreditation Phantom
Nuclear Associates 18-220

“Mini” Stereotactic Breast Biopsy Accreditation Phantom

Chest Wall Side

SBBAP Testing Criteria
Dose and Phantom

- Dose
  - Must be less than 300 mrad (3 mGy)
- Phantom image quality

<table>
<thead>
<tr>
<th></th>
<th>MAP Phantom</th>
<th>Mini Phantom</th>
</tr>
</thead>
<tbody>
<tr>
<td>F/S Digital</td>
<td>F/S Digital</td>
<td></td>
</tr>
<tr>
<td>Fibers</td>
<td>4.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Speck Groups</td>
<td>3.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Masses</td>
<td>3.0</td>
<td>3.5</td>
</tr>
</tbody>
</table>

Image Quality for SBB Units

RMI 156 or NA 18-220
- MAP Phantom

LORAD Upright Add-on with Mini-Phantom for Image Quality Test

RMI 156 Accreditation Phantom
AEC or Manual Exposure Performance

4 cm Thickness - Also used for Uniformity and Artifacts

6 cm Thickness 8 cm Thickness

Statistics Tools for AEC Performance and Uniformity Evaluation
AEC or Manual Exposure Control Performance Requirement

- Action Limit (Digital): If the signal range exceeds ±20% of signal for 4 cm phantom, revise technique chart.
- Action Limit (Screen-Film): If the density range exceeds ±0.15 of mean, revise technique chart.

Digital Receptor Uniformity

Digital Receptor Uniformity - Image Statistics

Digital Receptor Uniformity Requirements

- For Units with ROI statistics measurement capability:
  Action Limit: If SNR(I) / SNR(Center) is > 1.15 or < 0.85, seek service correction.

Digital Receptor Uniformity Requirements

- For Units without ROI statistics measurement capability:
  Action Limits: If geometric pincushioning > 1 cm from edge of image or
  If non-uniform areas (w/o black dots) > 10% of image or
  If line w/o black dots > 1/4 length of image, seek service correction

Breast Entrance Exposure, Average Glandular Dose, and Exposure Reproducibility

- Same Procedure as for Mammography
- Recommended Signal Level for Digital
- Digital Matrix Sizes
- Performance Criteria:
  a) Coefficient of Variation < 0.05
  b) Av. Glandular Dose < 3 mGy for Screen/Film and for Digital Image Receptors
Entrance Exposure/Mid-Glandular Doses

Artifact Evaluation

11. Localization Accuracy: Gelatin Phantom

- **Objective**: To assure that the biopsy needle is accurately placed for sampling as directed from the stereotactic scout images
- Technologist to perform test
- Physicist to observe and analyze results
- End-to-End test which supplements the daily in-air positioning accuracy test
Localization Accuracy: Gelatin Phantom Method

1. Position Needle:
   - Target Lesion Using Stereo Views
   - Position Core Needle to Proper X, Y, and Z Coordinates

2. Verify Needle Position:
   - Acquire Stereo Pre-fire Images
   - Needle Tip should be within Lesion

3. Fire Gun

Localization Accuracy: Gelatin Phantom Method

4. Verify Post-Fire Position
   - Acquire Post-Fire Stereo Images
   - Needle Tip should be beyond Center of Lesion

5. Verify Sampling of Lesion
   - Examine Contents of Core Sample

Gelatin Phantom Biopsy

Gelatin Biopsy Images

Localization Accuracy

Clinical SBB Procedures - Upright System

- Images are acquired on the same Full Field Digital Detector with the same image processing as original screening/diagnostic images
- First step is to acquire a scout image to confirm lesion positioning
Clinical SBB Procedures - Upright System

Stereotactic image with needle in Pre-Fire Position  Stereotactic image post clip placement

Questions

Question # 1

Which of the following would be an acceptable value for half-value layer at 28 kVp with a Mo/Mo target on a Stereotactic Breast Biopsy Unit?

- A: 0.25 mm Al
- B: 0.27 mm Al
- C: 0.35 mm Al
- D: 0.43 mm Al

Question # 2:

- What is the maximum value for the Mean Glandular Dose calculated for a Mo/Mo target/filter combination on a Stereotactic Breast Biopsy Unit for a 4.2 cm compressed breast?
  - A: 150 mrad
  - B: 200 mrad
  - C: 250 mrad
  - D: 300 mrad

Question # 2

- The Mean Glandular Dose calculated for a Mo/Mo target/filter combination on a Stereotactic Breast Biopsy Unit for a 512 x 512 matrix may not exceed
  - D: 300 mrad


Question # 3

- Which of the following is the regulatory compliance requirement of SBB units?
  - A: All SBB units must meet MQSA requirements
  - B: All SBB units must be Accredited by the ACR
  - C: All SBB units must meet State Regulatory Requirements
  - D: All SBB units are exempt from all MQSA and State Regulatory Requirements

Question # 3

- Which of the following statements is correct regarding regulatory compliance requirements of SBB units?
  - C: All SBB units must meet State Regulatory Requirements

Ref: ACR SBB Accreditation FAQ Website

Question # 4

- When using the “Mini” phantom for SBB unit image quality evaluation, which of the following options is the minimum acceptable image quality scores when viewed on a digital imaging system?
  - A: 3 fibers, 3 speck groups, 2.5 masses
  - B: 3 fibers, 3 speck groups, 3 masses
  - C: 3 fibers, 3 speck groups, 4 masses
  - D: 3.5 fibers, 3 speck groups, 3.5 masses

Question # 4

- When using the “Mini” phantom for SBB unit image quality evaluation, which of the following options is the minimum acceptable image quality scores when viewed on a digital imaging system?
  - A: 3 fibers, 3 speck groups, 2.5 masses

Question # 5

- When evaluating the AEC or Manual Exposure Control Performance with a uniform density phantom varying from 4 to 8 cm in thickness, what is the variation allowed in mean signal value relative to the mean signal of the 4 cm phantom?
  - A: +/- 10% of the mean signal value for the 4 cm phantom.
  - B: +/- 15% of the mean signal value for the 4 cm phantom.
  - C: +/- 20% of the mean signal value for the 4 cm phantom.
  - D: +/- 25% of the mean signal value for the 4 cm phantom.


Melissa C. Martin, M.S., FACR, FAAPM, FACMP
Therapy Physics, Inc.
879 West 190th St., Ste 400, Gardena, CA 90248
e-mail: Melissa@TherapyPhysics.com