Surveying and QC of Stereotactic Breast Biopsy Units for ACR Accreditation

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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 Control Pendant
Siemens (Fischer) MammoVision Biopsy System

Siemens Mammomat Inspiration SBB Add-On

Affirm™ Biopsy Guidance System

Advanced, Ergonomic Design

- 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

Siemens (Fischer) MammoVision Biopsy System

Advanced, Ergonomic Design

easy to use and install

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

*intuitive targeting*

- Uses a novel 10\(^\circ\) 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

**Versatility and Flexibility**

*wide range of use*

- All Selenia Dimensions are biopsy-ready and tomosynthesis capable
  - Dimensions with AWS 8000 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

**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

**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 view
  - Requires minimal steps
  - Shortens procedure time
- Accurate and efficient
  - Targeting software removes guesswork
  - Provides visual feedback of needle placement

**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

*Affirm comes standard with a single gantry 2D biopsy license. Additional licenses are available for purchase.*
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 Stereo 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
- QA Program, Manual, and Committee
- Technologist's QC Testing - daily, weekly, monthly, semi-annual - 6 tests
- Medical Physicist’s QC Testing - acceptance and annual - 11 tests

Quality Control: Medical Physician’s Evaluation

- Acceptance Test Before Patient Use
- Report Required as Part of ACR Application
- Annually Thereafter
- The 1999 ACR SBB Quality Control Manual has a section for the Medical Physicist with suggested Test Procedures, Forms, and Summary Report Format
- 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

Stereotactic Unit Assembly Evaluation

Free-standing dedicated unit is mechanically stable. Y
All moving parts move smoothly, without obstruction to motion. Y
All leads and detectors work properly. Y
Image receptor holder assembly is free from vibrations. Y
Image receptor is held securely by assembly in any orientation. Y
Image receptor slides smoothly into holder assembly (screen-film units). Y
Compressed breast thickness scale is accurate to ±5 mm, reproducible to ±2 mm. Y
Patient or operator is not exposed to sharp or rough edges, or other hazards. Y
Operator technique control charts are posted. Y
Operator protected during exposure by adequate radiation shielding. Y
Needle holder and needle guides adequately support needle. Y
Evaluation (Pass or Fail)

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

Collimation Assessment

LORAD Upright Biopsy Paddle
Measurement Tools Available on Screen

Collimation Assessment

Collimator Assessment for Add-On Units

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

Collimation Assessment

Digital Limiting Resolution/Focal Spot

SID = 84 cm for LORAD SBB Tables

Collimation Assessment

Digital Limiting Resolution/Focal Spot

Digital Limiting Resolution/Focal Spot

Action Limit: If any edge of radiation field deviates more than 1 cm from the edge of the image receptor, or if any edge of the compression plate/foil projects into the X-ray field by more than 1 cm, then send service adjustment.
Digital Limiting Resolution/Focal Spot

Hologic requires at least 7 lp/mm resolution

Beam Quality Assessment

<table>
<thead>
<tr>
<th>Nominal kVp setting</th>
<th>25</th>
<th>27</th>
<th>29</th>
<th>30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft setting</td>
<td>80</td>
<td>80</td>
<td>70</td>
<td>70</td>
</tr>
<tr>
<td>Tube setting (seconds)</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
</tr>
</tbody>
</table>
| Exposure measurements:  
  No aluminum filtration: $E_0$ | 0.787 | 0.892 | 0.898 | 0.920 | 1.041 |
  0.3 mm of added aluminum: $E_3$ | 0.797 | 0.892 | 0.898 | 0.920 | 1.041 |
  0.6 mm of added aluminum: $E_6$ | 0.797 | 0.892 | 0.989 | 0.920 | 1.041 |

Repeat Cu measurement: $E_C$

| Record thicknesses ($t_a$ in mm) | $t_0$ | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| and exposures ($t_x$ in mm)     | $t_x$ | 0.32 | 0.32 | 0.32 | 0.32 | 0.32 |
| that bracket $E_x/t_x = (E_x - E_0) / t_x$ | $E_x$ | 0.797 | 0.892 | 0.898 | 0.920 | 1.041 |

Calculated HVL: $E_x$ 0.381 0.439 0.449 0.462 0.519

Evaluation (Pass or Fail): Pass Pass Pass Pass Pass

Beam Quality Specifications for SBB Units

- The minimum acceptable Half-Value Layer measurement on a digital or film/screen SBB unit is
- Action
- Limit: If measured HVL < \( \frac{kVp}{100} \) (in mm Al)
  or
  If measured HVL > \( \frac{kVp}{100} \) + 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 or exceeds that of 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
Two Types of Approved Phantoms

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

Mammography Accreditation Phantom
RMI 156
Nuclear Associates 18-220

Image Quality for SBB Units

RMI 156 or NA 18-220
- MAP Phantom

“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>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>

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

RMI 156 Accreditation Phantom
Nuclear Associates
Digital Mini Phantom

AEC or Manual Exposure Performance
6 cm Thickness 8 cm Thickness

AEC or Manual Exposure Performance
2 cm Thickness

AEC or Manual Exposure Performance
4 cm Thickness
Also used for Uniformity and Artifacts

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

- **Performance Capability**
  - Sensitivity Compensation
  - Imaging Mode: Digital
  - Position: Target, Filter, Source, Signal to Noise Ratio
  - 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 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

Digital Receptor Uniformity - Image Statistics

- **For Units with ROI statistics measurement capability:**
  - **Action Limit:** If SNR(I) / SNR(Center) is > 1.15 or < 0.85, 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 Measurements on LORAD Add-on Units

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

Localization Accuracy

11. Localization Accuracy (Gelatin Phantom) Test

<table>
<thead>
<tr>
<th>Object Capture</th>
<th>Was the object captured?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Y</td>
</tr>
</tbody>
</table>

Active Limit:

- If the biopsy needle captures the intended object, then the unit passes. Firm and hold the test, then service should be called.
- If the biopsy needle does not capture the intended object, then reposition the needle tip or reposition the target. If the biopsy needle captures the intended object, then the unit passes.
- If the biopsy needle does not capture the intended object, then reposition the needle tip or reposition the target. If the biopsy needle captures the intended object, then the unit passes.

Evaluation (Pass or Fail): **Pass**
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

The half-value layer acceptable for 28 kVp with a Mo/Mo target/filter on a Stereotactic Breast Biopsy Unit is

- A: 0.25 mm Al
- B: 0.27 mm Al
- C: 0.35 mm Al
- D: 0.43 mm Al
Question # 1

The half-value layer acceptable for 28 kVp with a Mo/Mo target/filter on a Stereotactic Breast Biopsy Unit is

- C: 0.35 mm Al


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
  - A: 150 mrad
  - B: 200 mrad
  - C: 250 mrad
  - D: 300 mrad


Question # 3

- Which of the following statements is correct regarding regulatory compliance requirements 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

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 2 to 8 cm in thickness, the mean signal value range should not exceed which of the following?
  
  - A: For phantoms of 2 to 6 cm thickness, the mean signal should be within +/-15% of the mean signal value for the 4 cm phantom.
  - B: For phantoms of 2 to 6 cm thickness, the mean signal should be within +/-20% of the mean signal value for the 4 cm phantom.
  - C: For phantoms of 4 to 8 cm thickness, the mean signal should be within +/-15% of the mean signal value for the 4 cm phantom.
  - D: For phantoms of 4 to 8 cm thickness, the mean signal should be within +/-20% of the mean signal value for the 4 cm phantom.