

## Surveying and QC of Stereotactic Breast Biopsy Units for ACR Accreditation

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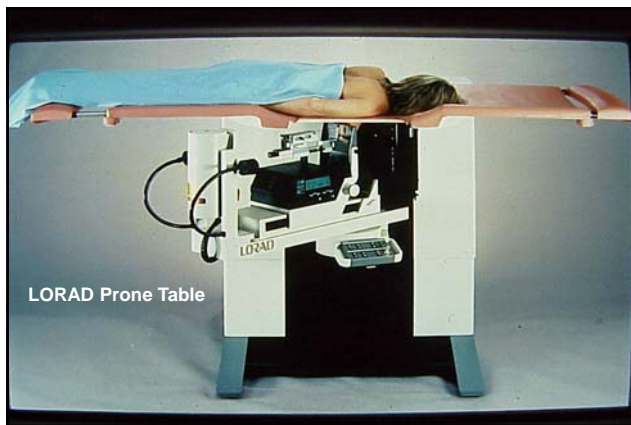
### LORAD Stereotactic Breast Biopsy System



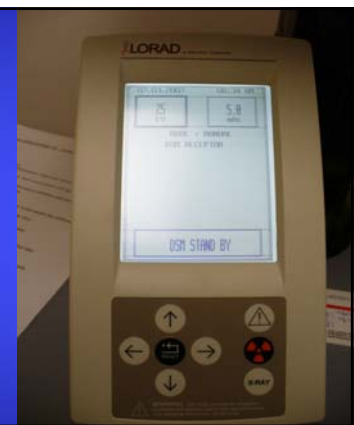
### Learning Objectives

- 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 Stereotactic Breast Biopsy System



### LORAD Stereotactic Breast Biopsy System Control Pendant



### Siemens (Fischer) MammoVision Biopsy System



### Siemens Mammomat Inspiration SBB Add-On

It should be noted that the Siemens MAMMOMAT® Inspiration digital mammography equipment offers a unique advantage. Siemens has developed the MAMMOMAT Inspiration to support the demands of today's medical practice in screening, diagnostics, and biopsy. The optional slip-on biopsy attachment automatically converts the MAMMOMAT Inspiration configuration to stereotactic biopsy, which is operable with the patient in the prone or upright position. For those institutions without a dedicated biopsy unit, this option provides an excellent way to include stereotactic breast biopsy in their scope of service as well as meet the needs of the surgeon.



### Siemens (Fischer) MammoVision Biopsy 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 *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° 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 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



Selenia Dimensions with AWS 8000



Selenia Dimensions with AWS 5000

## 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.

## 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

## 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

## ACR SBB Program Statistics

- The process typically takes 4 to 6 months.
- The review process takes approximately 90 days after the ACR receives the submitted material.
- There are currently no MQSA requirements for personnel performing SBB procedures but there are training and experience requirements for accreditation by the ACR

### 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

### BREAST IMAGING ACCREDITATION PROGRAMS MEDICAL PHYSICIST QUALIFICATIONS

#### STEREOTACTIC BREAST BIOPSY ACCREDITATION

	Medical Physicist
Initial	Licensed or approved by a state or ABR certified or ABMP certified AND Have a master's degree or higher in a physical science with 20 hours of physics and 20 hours of training conducting mammography surveys or if qualified under MQSA before 4/28/1999, have a BS in physical science with 10 hours of physics and 40 hours of training conducting mammography surveys AND 1 facility and 10 mammography units, or if qualified before 4/28/99 with BS in physical science, 1 facility and 20 mammography units AND Performed 1 hands-on stereotactic breast biopsy survey under a qualified medical physicist or at least 3 independent surveys prior to 6/1/97.
Continuing Experience	1 stereotactic breast biopsy unit physics survey per year
Continuing Education	3 Category 1 CEUs in stereotactic breast biopsy every 3 years

### 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

### Quality Control: Medical Physicist'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

### 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

### ACR Quality Control Manual

- Mammography QC Manual (1990, 1992, 1994, 1999)
- **Stereotactic Breast Biopsy QC Manual (1999)**
- 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

### Stereotactic Unit Assembly Evaluation

#### 1. Stereotactic Breast Biopsy Unit Assembly Evaluation (Y = yes, N = no, or N/A = not applicable)

Free-standing dedicated unit is mechanically stable.	Y
All moving parts move smoothly, without obstructions to motion.	Y
All locks and detents 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 only).	Y
Compressed breast thickness scale is accurate to 5 mm, reproducible to $\pm 2$ 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):

Pass

### 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

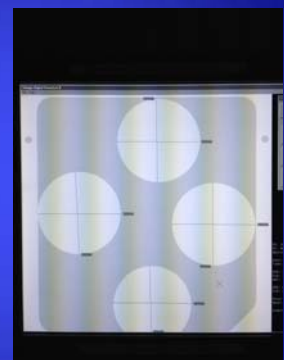
### Collimation Assessment



### 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

### LORAD Upright Biopsy Paddle



### Measurement Tools Available on Screen

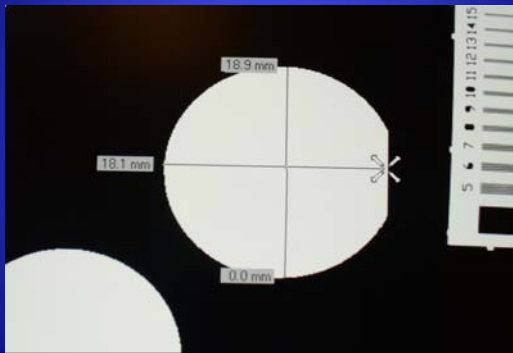


### Collimator Assessment for Add-On Units

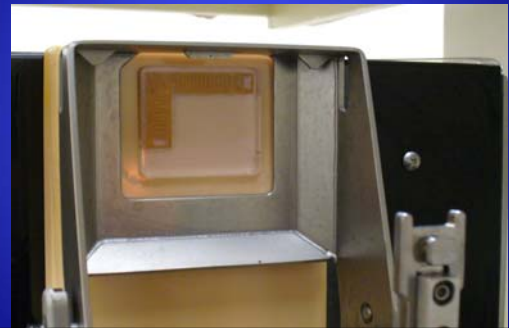
Actual Opening in  
Metal  
Compression  
Plate is 5 x 5 cm  
area



### Collimation Assessment



### Digital Limiting Resolution/Focal Spot



### Collimation Assessment

SID = 84 cm for  
LORAD SBB Tables

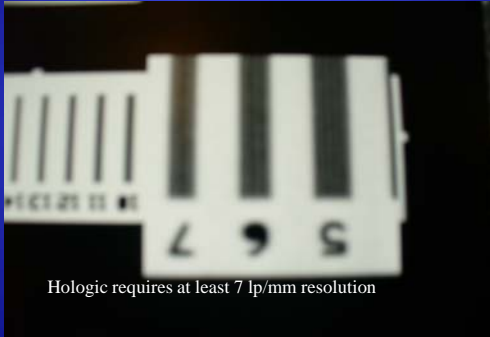
Digital Units					
Digital Image	Collimator (cm x cm):	5 x 5			
	Left Edge Deviation (mm):	0			
	Right Edge Deviation (mm):	0			
	Anterior Edge Deviation (mm):	3.5			
Film Image	Chest Edge Deviation (mm):	1			
	Left Edge Deviation (mm):	0			
	Right Edge Deviation (mm):	0			
	Anterior Edge Deviation (mm):	0			
Evaluation:		Pass			

**Action Limit:** If any edge of radiation field deviates more than 5 mm from the edge of the image receptor, or if any edge of the compression paddle projects into the X-ray field by more than 5 mm, then seek service adjustment.

### Digital Limiting Resolution/Focal Spot



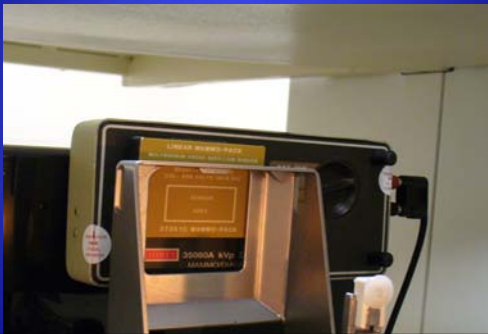
## Digital Limiting Resolution/Focal Spot



## Beam Quality Assessment

Nominal kVp setting	26	27	28	29	30
mA setting	80	80	80	70	70
Time setting (seconds)	1.00	1.00	1.00	1.00	1.00
<b>Exposure measurements:</b>					
No aluminum filtration, $E_a$	0.797	0.892	0.988	0.950	1.041
0.2 mm of added aluminum, $E_b$					
0.3 mm of added aluminum, $E_c$					
0.4 mm of added aluminum, $E_d$					
0.5 mm of added aluminum, $E_e$					
<b>Repeat <math>E_o</math> measurement, <math>E_o'</math></b>					
<b>Record thicknesses (<math>t_a &lt; t_b</math>) and exposures that bracket <math>E_o/2</math>: (<math>E_a &gt; E_b</math>)</b>					
$t_a$	0.00	0.00	0.00	0.00	0.00
$t_b$	0.32	0.32	0.32	0.32	0.32
$E_a$	0.797	0.892	0.988	0.950	1.041
$E_b$	0.381	0.436	0.494	0.482	0.539
Calculated HVL:	0.30	0.31	0.32	0.33	0.34
Evaluation (Pass or Fail)	Pass	Pass	Pass	Pass	Pass

## kVp Accuracy and Reproducibility



## 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 < (kVp/100) (in mm Al)

or

if measured HVL  $\geq$  (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.

## kVp Accuracy and Reproducibility

### 4. kVp Accuracy / Reproducibility

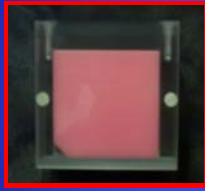
kVp meter used: Kethley Triad Dosimetry System

Nominal kVp setting	26	27	28	29	30	
Nominal focal spot size (mm)						
Exposure time (sec)	2.00	1.50	1.00	0.80	0.50	
mA setting	80	80	80	70	70	
Measured kVp values						
kVp1	26.0	27.1	28.1	28.9	29.9	
kVp2	26.2	27.1	28.1	29.0	29.9	
kVp3			28.1			
kVp4			28.1			
Mean kVp	< kVp >	26.10	27.10	28.10	28.95	29.90
Standard dev.	$\sigma_{kVp}$	0.141	0.000	0.000	0.071	0.000
Additional kVp measurements (if needed)						

## 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

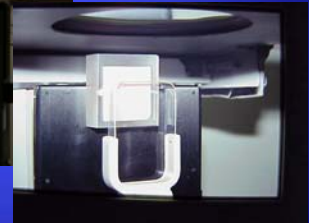


Mammography Accreditation  
Phantom  
RMI 156  
Nuclear Associates 18-220

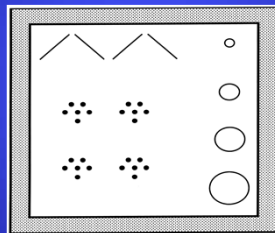
## Image Quality for SBB Units



RMI 156 or NA 18-220  
- MAP Phantom

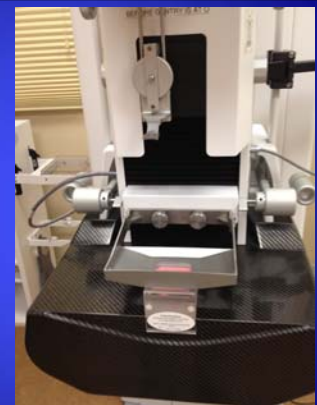


## "Mini" Stereotactic Breast Biopsy Accreditation Phantom



Chest Wall Side

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



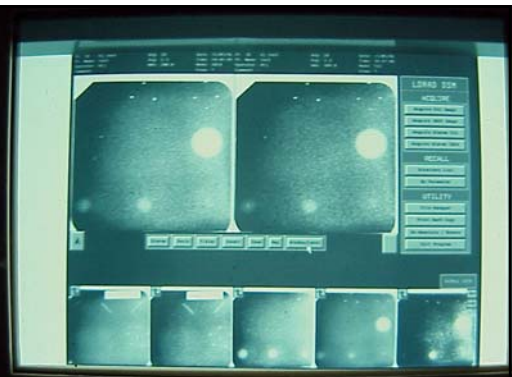
## SBBAP Testing Criteria

Dose and Phantom

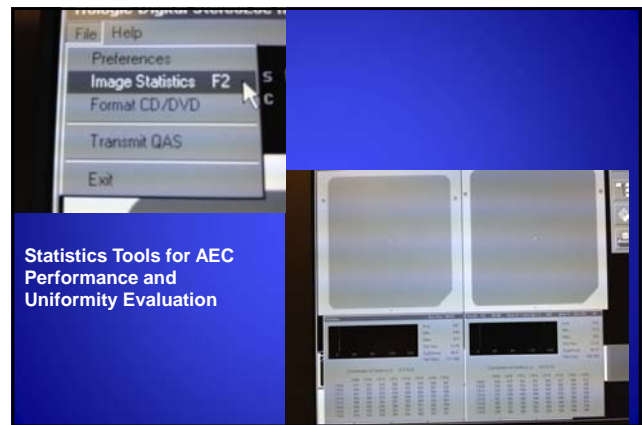
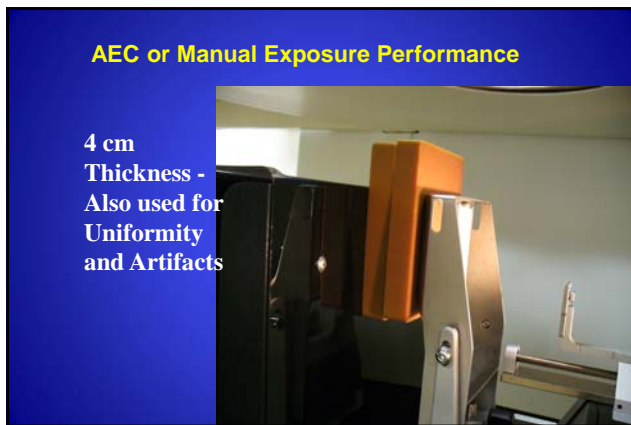
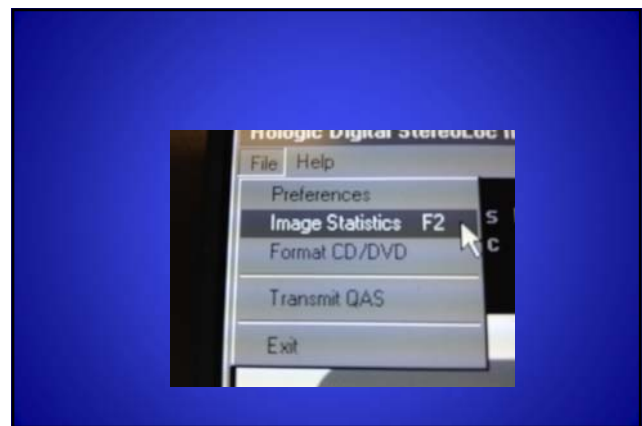
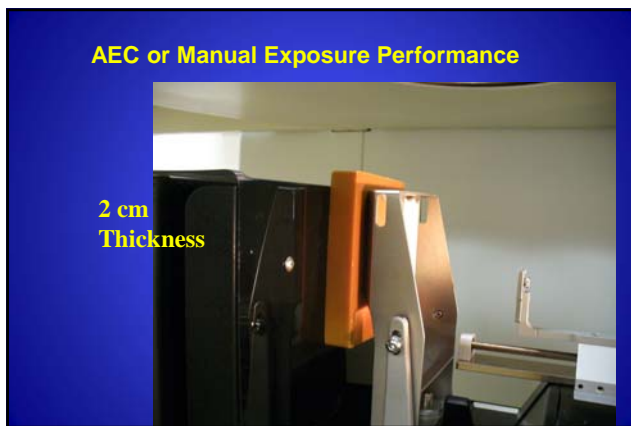
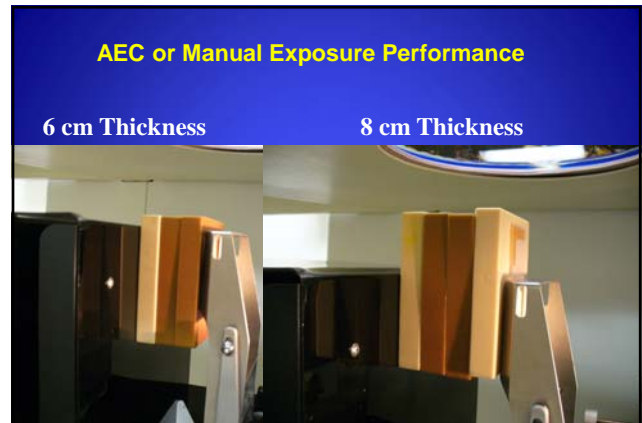
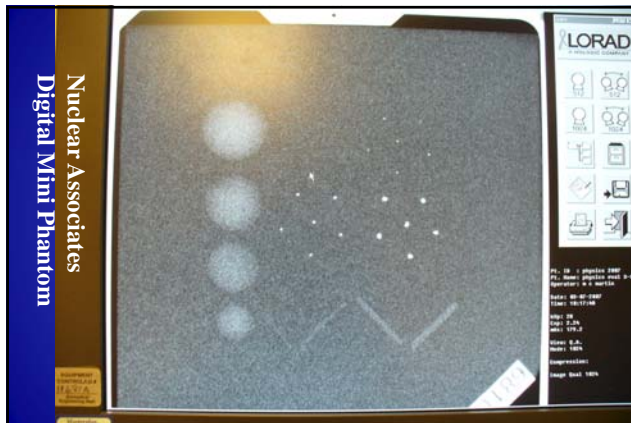
- Dose
  - Must be less than 300 mrad (3 mGy)
- Phantom image quality

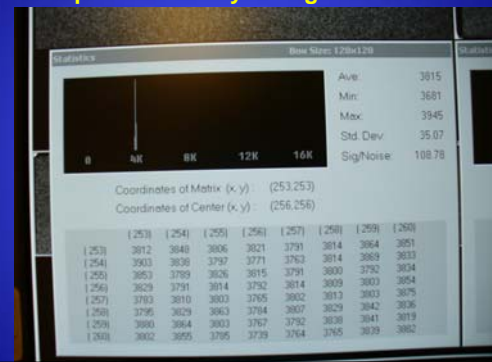
	MAP Phantom		Mini Phantom	
	F/S	Digital	F/S	Digital
Fibers	4.0	5.0	2.0	3.0
Speck Groups	3.0	4.0	2.0	3.0
Masses	3.0	3.5	2.0	2.5

## RMI 156 Accreditation Phantom









## Breast Entrance Exposure, Average Glandular Dose, and Exposure Reproducibility

- Same Procedure as for Mammography
- Recommended Signal Level for Digital
- Digital Matrix Sizes
- Performance Criteria:
  - Coefficient of Variation  $< 0.05$
  - 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



## Entrance Exposure/Mid-Glandular Doses

Detector system used	Cathode Tube		Energy correction factor	1.0
Imaging mode	Digital			
Image receptor	DRM-CCD System		Size	8" by 8" (cm)
Film conversion	Rinnatex			
SID (cm)	34			
Phantom	Digital Mini-Phantom			
Nominal kVp setting	23 kVp	100 kVp		
Target/Filtration	Mo/Mo	Mo/Mo		
AEC density control setting	1.5	1.5		
mAs setting	80	80		
Measured HVL (mm Al)	0.32	0.32		
Measured entrance exposure				
Exposure #1	1.462	120.0	2.626	240.0
Exposure #2	1.465	120.0		
Exposure #3	1.472	120.0		
Exposure #4	1.472	120.0		
Mean values	1.468	120.0	2.626	240.0
Standard deviations (SD)	0.005	0.000		
Coefficients of variation (CV)	0.003	0.000		
Evaluation (Pass or Fail)	Pass	Pass	2.626	
Energy-reduced exposure	1.468			
Dose conversion factor from Table 1-3 (mrad/R)	188		188	
Controlled average glandular dose (mrad)	244		415	
Evaluation (Pass or Fail)	Pass		Special Purposes Only	
Action Limit: If CV for exposure or mAs exceeds 0.05, seek service correction. If average glandular dose exceeds 300 mrad (3 mGy) for 4.2 cm effective breast thickness, seek service or technique adjustment.				

## Entrance Exposure/Mid-Glandular Doses



## Artifact Evaluation

10. Artifact Evaluation	
Type of Alternator	300-12 Rects
Thickness of Alternator	2.01
Target Filter	Mo/Mo
kVp Setting	23
Exposure Setting	120 mAs
Nominal Focal Spot Size	0.25 mm Mo
Image receptor	Film/Screen
Image Viewed on	Digital
Resultant film O.D.	CR7
Artifacts visible? (If yes, continue by checking the appropriate boxes.)	No
Processor artifact*	
Equipment artifact**	
Other artifact	
Describe these artifacts	
Film/Screen:	Artifacts parallel to the two films viewed as in Figure 5A. Artifacts perpendicular to the two films viewed as in Figure 5B.
Evaluation (Pass or Fail):	Pass

## 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

## Gelatin Phantom Biopsy



## 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

## Gelatin Biopsy Images



## 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

#### Object Capture

Was the object captured? Y

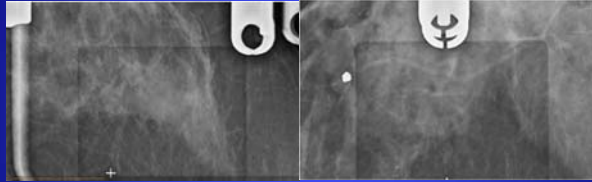
**Action Limit:** IF the biopsy needle captures the intended object, then the unit passes. If the unit fails the test, then service should be called.

If pre-fire images or visual inspection fail to demonstrate needle tip (or sampling notch for suction systems) within (or adjacent to) targeted lesion, the service should be called.

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

## MEDICAL PHYSICIST'S STEREOTACTIC UNIT QC TEST SUMMARY (continued)

### Evaluation of Site's Technologist QC Program

	Frequency	PASS/FAIL
1. Localization Accuracy Test	Daily	Pass
2. Darkroom Cleanliness (not if digital used)	Daily	Pass
3. Processor Quality Control (not if digital used)	Daily	Pass
4. Phantom Images	Weekly	Pass
5. Screen Cleanliness (not if digital used)	Weekly	Pass
6. Viewboxes and Viewing Conditions (not if digital used)	Weekly	Pass
7. Hardcopy Output Quality (if hardcopy produced from digital data)	Monthly	Pass
8. Visual Checklist	Quarterly	Pass
9. Analysis of First Detection in Film (not if digital used)	Quarterly	Pass
10. Compression	Semi-annually	Pass
11. Repeat Analysis	Semi-annually	Pass
12. Screen/Film Contact (not if digital used)	Semi-annually	Pass
13. Darkroom Fog (not if digital used)	Semi-annually	Pass
14. Zero Alignment Test (if required by manufacturer)	Before each patient	Pass
15. Any additional tests required by manufacturer	As required by manufacturer	Pass

### Medical Physicist's Recommendations for Quality Improvement

Comments: All aspects of this Stereotactic Breast Biopsy system are functioning in compliance with all State of California requirements and within all applicable requirements for Accreditation by the American College of Radiology for Stereotactic Breast Biopsy systems at this time.

The QC program is well established, current, and complete.

## Clinical SBB Procedures - Upright System



Stereotactic image with needle in Pre-Fire Position

Stereotactic image post clip placement

## Questions

## MEDICAL PHYSICIST'S STEREOTACTIC UNIT QC TEST SUMMARY

Site Name	Stanford Regional Medical Ctr	Report Date	8/20/2012
Address	1275 R. A. Fulton Avenue, Stanford, CA 94305-5081	Machine Date	8/22/2012
X-Ray Unit Manufacturer	LOECAL (KODAK)	Model	Multi-arc Platform
Date of Installation	NA	Screen ID	88000000
Film (not if digital)	NA	Screen (not if digital)	NA
Film Processor	NA	Model	NA
Digital Image Receptor	LOECAL	Model	2000
Medical Physicist's Name	Tom S. Fisher, M.D., DABM, MPE (MPE)	Signature	

### Medical Physicist's QC Tests

1. Stereotactic Breast Biopsy Unit Assembly Evaluation	PASS/FAIL
2. Calibration Assessment	Pass
3. Final Nerd Performance and System Loading Recalibration	Pass
4. KVP Accuracy and Reproducibility	Pass
5. Beam Quality Assessment (Half-Value Layer Measurement)	Pass
6. AEC System or Manual Exposure Performance Assessment	Pass
7. Receptor Nerd Evaluation	Pass
8. Breast Entrance Exposure, Average Glanular Dose and Exposure Reproducibility	Pass
9. Image Quality Evaluation	Pass
10. Artifact Evaluation	Pass
11. Localization Accuracy Test	Pass

## 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

Ref: ACR QC Manual for Stereotactic Breast Biopsy (1999), p. 68-69.

### 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

### 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?
- C: All SBB units must meet State Regulatory Requirements

Ref: ACR SBB Accreditation FAQ Website

### 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

Ref: QC Manual for Stereotactic Breast Biopsy (1999), page 80.

### 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

Ref: ACR Stereotactic Breast Biopsy Quality Control Manual (1999), page 91.

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#### 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.

#### 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? .

- 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.

Ref: ACR Stereotactic Breast Biopsy Quality Control Manual (1999), page 71.