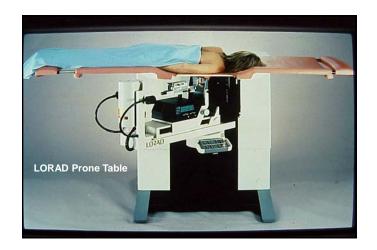
Surveying and QC of Stereotactic Breast Biopsy Units for ACR Accreditation

AAPM Annual Clinical Meeting Indianapolis, IN August 5, 2013

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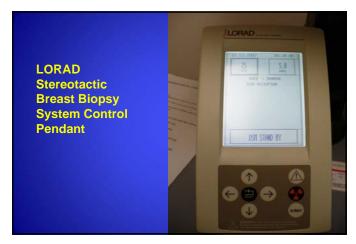
Learning Objectives

- 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





















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

firm 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



elenia Dimensions with AWS 8000



Selenia Dimensions with AWS 5000

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 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

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

BREAST IMAGING ACCREDITATION PROGRAMS MEDICAL PHYSICIST QUALIFICATIONS STEREOTACTIC BREAST BIOPSY ACCREDITATION Medical Physicist Licensed or approved by a state or ABR certified or ABMP certified AND Have a master's degree or higher in aphysical science with 20 hours of physics and 20 hours of staining conducting mammography surveys or if qualified under MGSA before training conducting mammography surveys or physics and 40 hours of training conducting mammography surveys or if qualified the hours of training conducting mammography units 0 hours of physics and 40 hours of training conducting mammography units 0 hours of physics and 40 hours of training conducting mammography units 0 hours of physics and 40 hours of training a conducting mammography units 0 hours of training 1 stereotactic breast biopsy unit physics survey under a qualified medical physicist or at least 3 independent surveys prior to 61/197. Continuing 1 stereotactic breast biopsy unit physics survey per year Experience Continuing 3 Category 1 CEUs in stereotactic breast biopsy every 3 years

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

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

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

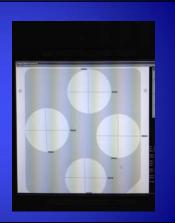
- 7A. Uniformity of Screen Speed
- 7B. Digital Receptor Uniformity
- 8. Breast Entrance Exposure, Average Glandular Dose, and Exposure Reproducibility
- 9. Image Quality Evaluation
- 10. Artifact Evaluation
- 11. Localization Accuracy Test

Stereotactic Unit Assembly Evaluation

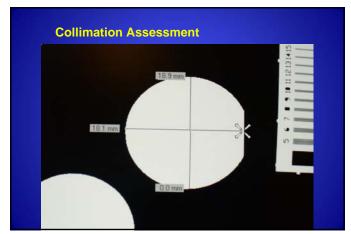
 Stereotactic Breast Biopsy Unit Assembly Evaluation (Y = yes, N = no, or N/A = no 	ot applicable)
Free-standing dedicated unit is mechanically stable.	Y
All moving parts move smoothly, without obstructions to motion.	Υ
All locks and detents work properly.	Υ
Image receptor holder assembly is free from vibrations.	Υ
Image receptor is held securely by assembly in any orientation.	Υ
Image receptor slides smoothly into holder assembly (screen-film only).	Υ
Compressed breast thickness scale is accurate to 5 mm, reproducible to ±2 mm.	Υ
Patient or operator is not exposed to sharp or rough edges, or other hazards.	Υ
Operator technique control charts are posted.	Υ
Operator protected during exposure by adequate radiation shielding.	Υ
Needle holder and needle guides adequately support needle.	Υ
Evaluation (Pass or Fail):	Pass

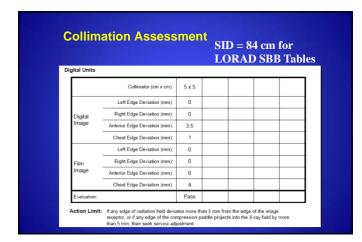


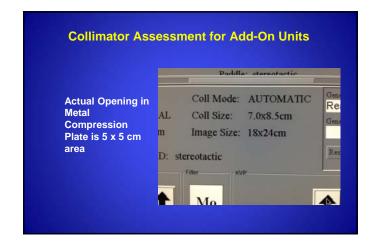


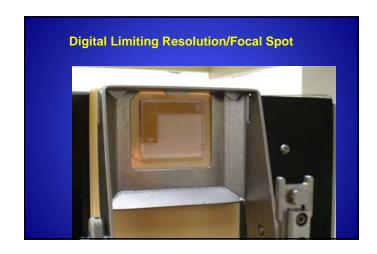








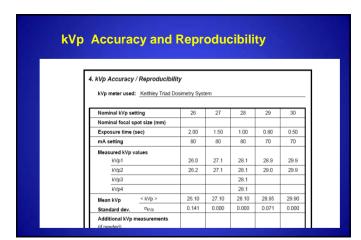










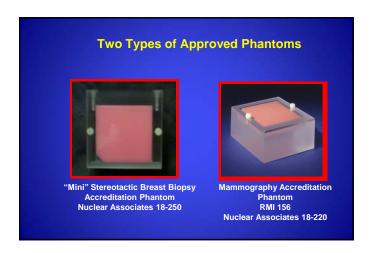


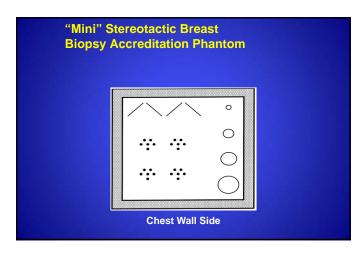
Beam Quality As	ses	smer	nt			
Nominal kVp setting		26	27	28	29	30
mA setting		80	80	80	70	70
Time setting (seconds)		1.00	1.00	1.00	1.00	1.00
Exposure measurements: No aluminum filtration, E _o		0.797	0.892	0.988	0.950	1.041
0.2 mm of added aluminum, E	2					
0.3 mm of added aluminum, E	3					
0.4 mm of added aluminum, E	4					
0.5 mm of added aluminum, E	5					
Repeat Eo measurement, E ₀ '						
Record thicknesses (t _a < t _b)	ta	0.00	0.00	0.00	0.00	0.00
and exposures	t _D	0.32	0.32	0.32	0.32	0.32
that bracket $E_0/2$: $(E_a > E_b)$	Ea	0.797	0.892	0.988	0.950	1.041
	Eb	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

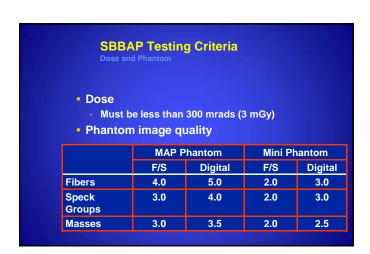
Beam Quality Specifications for SBB Units ■ The minimum acceptable Half-Value Layer measurement on a digital or film/screen SBB unit is Action Limit: If measured HVL < (kVp/100) (in mm Al) or if measured HVL ≥ (kVp/100) + C (in mm Al) where C = 0.12 for Mo/Mo, C = 0.19 for Mo/Rh, and C = 0.22 for Rh/Rh,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

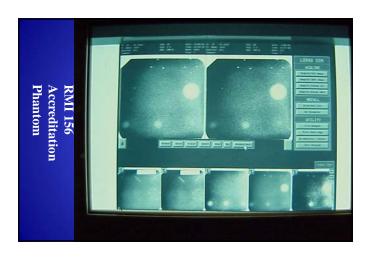


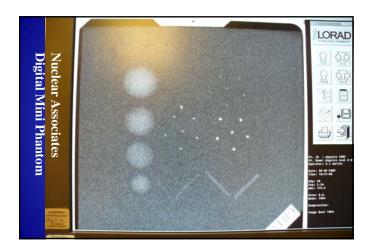


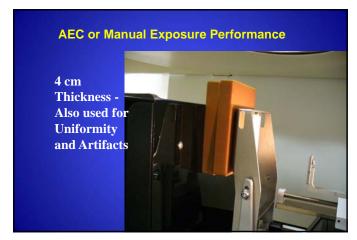




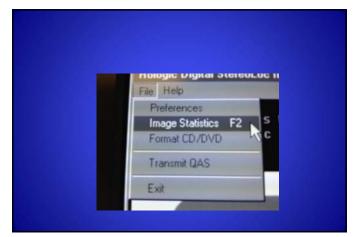


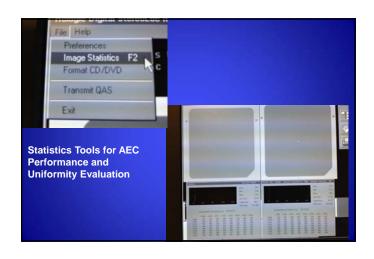


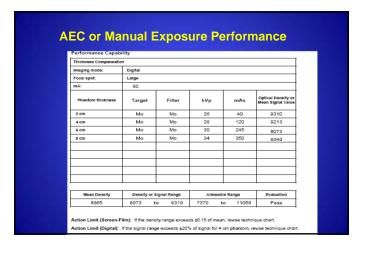






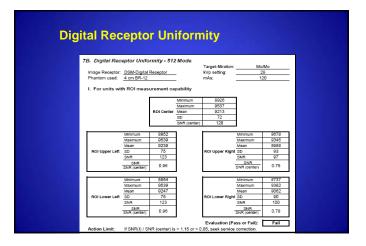


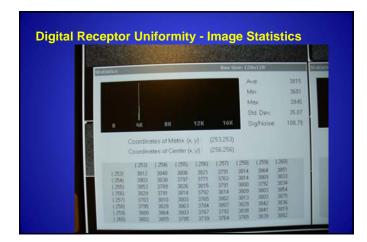




AEC or Manual Exposure Control Performance Requirement

- 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 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

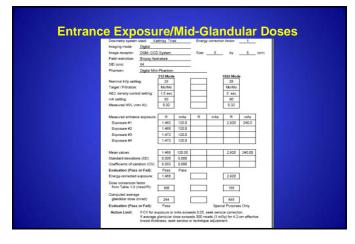
Breast Entrance Exposure, Average Glandular Dose, and Exposure Reproducibility

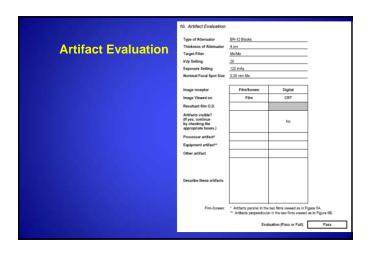
- Same Procedure as for Mammography
- Recommended Signal Level for Digital
- Digital Matrix Sizes
- Performance Criteria:
 - a) Coefficient of Variation < 0.05
- b) Av. Glandular Dose < 3 mGy for Screen/Film and for Digital Image Receptors











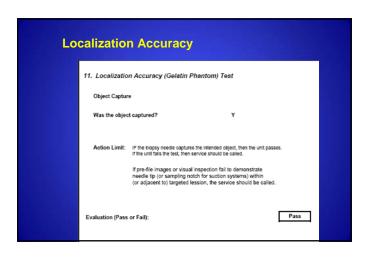
11. Localization Accuracy: Gelatin Phantom Objective: To assure that the biopsy needle is accurately placed for sampling as directed from the stereotactic scout images Technologist to perform test Physicist to observe and analyze results End-to-End test which supplements the daily in-air positioning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

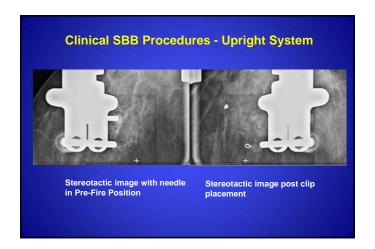
Localization Accuracy: Gelatin Phantom Method 4. Verify Post-Fire Position - Acquire Post-Fire Stereo Images - Needle Tip should be beyond Center of Lesion 5. Verify Sampling of Lesion - Examine Contents of Core Sample











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Evaluation of Site's Technology	ologist QC Program	
	Frequency	PASSFAIL
Localization Accuracy Test	Dany	Pesa
2. Darkroom Cleaniness (NA Englaruset)	Dally	164
3. Processor Quality Control (NA / right) week	Daily	166
4. Phantom Images	Weekly	Pass
5. Screen Cleaniness over regard used:	Weekly	366
6. Viewboxes and Viewing Conditions INA # applications	Weekly	166
7. Hardcopy Output Quality of Auritrapy produced from digital data)	Monthly	Fase
8. Visual Checklist	Monthly	Free
9. Analysis of Fixer Retention in Film (NA riligital swell	Quarterly	164
10. Compression	Semi-annually	Pese
11. Repeat Analysis	Semi-annually	Free
12. Screen-Film Contact (NA F Hybri used)	Semi-annually	314
13. Darkroom Fog (NA # reptur used)	Semi-annually	160
14. Zero Alignment Test in required by manufactured	Before each patient	Face
15. Any additional tests required by manufacturer	As required by manufacturer	Pass
Medical Physicist's Recommendation Comments: All aspects of this of this Stereotactic Breast Bops of California requirements and wiftin all applicagle requirements Radiology for Stereotactic Breast Biophy systems at this time.	y system are functioning in compl	lance with all State
The QC program is well-established, current, and complete.		



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

Question #1

B: 0.27 mm Al

C: 0.35 mm Al

D: 0.43 mm Al

Question # 1

C: 0.35 mm Al

If measured HVL
$$<\frac{kVp}{100}$$
 + 0.00 (in mm Al) or
 If measured HVL $>\frac{kVp}{100}$ + C (in mm Al),

where C = 0.12 for Mo/Mo

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

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

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

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

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

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.

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?
- C: 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.

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

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