When the glove doesn't quite fit: surveying breast biopsy attachments and tomo-guided biopsy units

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Outline

- Stereotactic versus tomo-guided biopsies
 - Clinical workflow
 - Commercially available units
 - Technical and clinical considerations
- Accreditation and testing
 - What's required?
 - Evaluating add-ons for breast biopsy
 - Adapting the 1999 stereo QC manual for DBT
- Future Directions
 - 2020 ACR-AAPM Technical Standard
 - ACR SBB QC Manual Update



Stereo vs. Tomo-guided Breast Biopsies Clinical Workflows



Nomenclature

- Stereotactic-guided breast biopsy
- Tomosynthesis-guided breast biopsy

What method is used to localize the target?





What method is used to localize the target?



Scout (DBT)



- 54 yo female
- Area of architectural distortion in right breast
 - upper outer aspect, middle depth
- RIS Comments "with TOMO guidance"



Stereo-Guided Biopsy

Scout Image

Stereo Pair

Advance Needle

Pre-fire Stereo Pair

Fire Needle

Post-fire Stereo Pair

Tomo-Guided Biopsy

DBT Scout (localize off DBT slice)

Advance Needle

Pre-fire Stereo Pair or DBT

Fire Needle

Post-fire Stereo Pair or DBT



Scout (DBT)

Post-Fire (DBT)



Stereo-Guided Biopsy

Scout Image

Stereo Pair

Advance Needle

Pre-fire Stereo Pair

Fire Needle

Post-fire Stereo Pair

Image Specimen

Tomo-Guided Biopsy

DBT Scout (localize off DBT slice)

Advance Needle

Pre-fire Stereo Pair or DBT

Fire Needle

Post-fire Stereo Pair or DBT

Image Specimen



Scout (DBT)

Post-Fire (DBT)

Specimen





Stereo-Guided Biopsy

Scout Image

Stereo Pair

Advance Needle

Pre-fire Stereo Pair

Fire Needle

Post-fire Stereo Pair

Image Specimen

Biopsy Clip Confirmation (Stereo)

Tomo-Guided Biopsy

DBT Scout (localize off DBT slice)

Advance Needle

Pre-fire Stereo Pair or DBT

Fire Needle

Post-fire Stereo Pair or DBT

Image Specimen

Biopsy Clip Confirmation (DBT)



Scout (DBT)



Stereo-Guided Biopsy

Scout Image

Stereo Pair

Advance Needle

Pre-fire Stereo Pair

Fire Needle

Post-fire Stereo Pair

Biopsy Clip Confirmation (Stereo)

Image Specimen

Post-procedure Mammogram

Tomo-Guided Biopsy

DBT Scout (localize off DBT slice)

Advance Needle

Pre-fire Stereo Pair or DBT

Fire Needle

Post-fire Stereo Pair or DBT

Biopsy Clip Confirmation (DBT)

Image Specimen

Post-procedure Mammogram &/or DBT



Pathology Result

- Benign
- Focal chronic inflammation and fibrosis suggestive of a ruptured cyst

Scout (DBT)



- 49 yo female
- Biopsy of calcifications
 - Upper outer left breast at far posterior depth
- RIS Comments none



Scout (DBT)



Post-Fire (DBT)

Specimen

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Post-procedure mammograms



Pathology Result

 Benign sclerosing adenosis (SA) with calcifications present

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Stereo vs. Tomo-guided Breast Biopsies Commercially Available Units



Prone Systems



Hologic Multicare Platinum END OF LIFE AS OF 2017 Hologic Affirm



Add-ons



Not pictured:

- Fuji ASPIRE Cristalle
- GE Serena Bright
- Siemens Inspiration
- Giotto Biopsy Digit (can be used prone or upright)

Hologic Affirm

GE Pristina Serena

Siemens Revelation



Photograph of GE Pristina courtesy of Jonathon Meuller



Geometries





Center of Rotation at Breast Surface

Center of Rotation at Detector



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Design Considerations

- Clear paddles
 - Better visualization of abnormalities outside the biopsy window







Design Considerations

Lateral needle approach

- Thin breasts
- Deep lesions
- Fewer artifacts from needle (for DBT)



Prone Units	DBT-Guided Biopsies?	Lateral Needle Approach?	CESM Guided Biopsies?
Hologic Multicare Platinum (EOL)	×	×	×
Hologic Affirm (Prone)	\checkmark	\checkmark	×

Add-on Biopsy Units	DBT-Guided Biopsies?	Lateral Needle Approach?	CESM Guided Biopsies?
Fuji ASPIRE Cristalle	\checkmark	\checkmark	×
Hologic Affirm	\checkmark	\checkmark	
GE Pristina Serena	\checkmark	\checkmark	×
GE Serena Bright	\checkmark	\checkmark	\checkmark
Giotto Biopsy Digit	\checkmark	?	×
Siemens Inspiration			×
Siemens Revelation	\checkmark	×	×



Stereo vs. Tomo-guided Breast Biopsies

Technical and Clinical Considerations







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Stereo-Guided Biopsy

Scout Image					
Stereo Pair					
	2D Biopsy Procedure (mGy)	3D [™] Biopsy Procedure (mGy)	Full 3D [™] Biop- sy Procedure (mGy)		
Scout	1.6	1.8	1.8		
Targeting	3.2	_	_		
Pre-fire*	3.2	3.2	1.8		
Post-fire*	3.2	3.2	1.8		
Post-procedure	3.2	1.8	1.8		
TOTAL	14.4	10	7.2		
% Reduction (compared to 2D)	_	31%	50%		

Table 2. Radiation dose (mGy) for 2D, hybrid, and tomosynthesis only guided stereotactic biopsies. Radiation dose estimates are based on a 4.2 cm, 50% fatty 50% glandular tissue, assuming 1.6 mGy per 2D image and 1.8 mGy per tomosynthesis image set.

(Grimm, 2020)

Tomo-Guided Biopsy

DBT Scout (localize off DBT slice)

(Hologic Affirm Prone)

8.5.9 Dose Calibration

For locations following ACR standards, verify that the dose is set for:

- Stereotactic Biopsy Dose 1.60 mGy
- Tomosynthesis Dose, 30 projections 1.80 mGy

For dose calibration, refer to the procedures in the Detector section of CalTool.

(MAN-04482 Rev 004)











JJ Carret al, Stereotactic localization of breast lesions: How it works and methods to improve accuracy. RadioGraphics2001; 21:463–473





Field of View (FOV) Limitations -Stereo

Center of Rotation at Breast Surface:

• Limited FOV for deep lesions

Center of Rotation at Detector:

• Limited FOV for proximal lesions that are off-centered on scout





(Slide courtesy of I. Reiser, "Physics of stereo vs. tomosynthesis-guided breast biopsy", 2020 AAPM Annual Meeting)

Clinical Indications

Stereotactic Guided Biopsy

• Calcifications

Tomo Guided Biopsy

- Architectural distortion
- Isodense or low density lesions
- Single View Findings

Clinical Indications

- Compared with digital mammography stereotactic biopsy, digital breast tomosynthesis—guided biopsy was associated with a higher rate of biopsy for
 - architectural distortion
 - radial sclerosing lesions

(Rochat, 2020)



Procedure Time

- Initial reporting suggests procedure time might be reduced to almost half that of stereo-guided biopsy procedure when tomo-guidance is used (Rochat, 2020)
 - Fewer "steps" Initial tomo is used to localize (no need for scout)
 - Localizing is "easier" (single click)
 - Targeting errors happen less frequently
 - Less likely to need to reposition the patient in order to view the lesion

	Stereo	DBT	
Advantages	 Visualization of calcifications No artifacts from the needle for pre- and post-fire images 	 Reduced patient dose for the procedure Reduced procedure time Better visualization of architectural distortion, lesions only seen on DBT, or single-view findings 	
Disadvantages	 Depth uncertainty Potential errors from confusing lesions between stereo pairs Field-of-view limitations (particularly for rotating detector) 	Artifacts from needle (in pre- and post-fire images) Clusters of calcifications may not be visualized as well	


Accreditation and Testing

What's required?





State Regulations (MQSA does not apply!)

ODH 3701:1-66-08 ← OHIO

(G) Quality control testing by a medical physicist shall be conducted on mammography radiation-generating equipment used for invasive localization or having stereotactically-guided breast biopsy capability. Quality control testing for stereotactically-guided breast biopsy equipment shall follow the "American College of Radiology (ACR) Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedures" (as revised in 2016). This document is available from the "American College of Radiology, 1891 Preston White Drive, Reston, Virginia 20191, telephone (703) 648-8900."

VII. EQUIPMENT QUALITY CONTROL

Refer to ACR stereotactic breast biopsy quality control manual [54].



ACR Accreditation



(A Supplement to the Mammography Quality Control Manual)



"... a voluntary accreditation program for facilities offering percutaneous needle biopsy of the breast <u>under stereotactic imaging</u> <u>control</u>." (Page 3)



Hendrick RE, Dershaw D., et al." Stereotactic Breast Biopsy Quality Control Manual". Reston, Va: American College of Radiology; 1999

What's required

- DBT guided biopsies not addressed
- Add-ons
 - Addressed in Accreditation Support
 - "Special Cases in Stereotactic Breast Biopsy Quality Control"
 - <u>https://accreditationsupport.acr.org/support/solutions/articles/11000072242-special-cases-in-stereotactic-breast-biopsy-quality-control</u>



Accreditation and Testing

Evaluating Add-Ons





Add-on Testing

- SBB uses same image receptor and x-ray tube as DM unit
- All the required tests must be performed
 - Several of these may already be covered by the manufacturer's QC manual for the digital mammography unit
 - If items have been verified as part of DM annual test, they do not need to be repeated



Documentation

- Separate reports?
 - Cleaner, avoids confusion with the ACR
 - Tests in the expected order for SBB
 - Copy over the relevant tests from the DM survey
- One combined report?
 - Make sure to include the ACR "QC Test Summary" pages for SBB as well as those for DM

Guidance for Add-ons

A	ccreditation Support	
Home	Solutions	
How ca	an we help you today?	
Enter y	our search term here	SEARCH
Solution ho Biopsy	ome / Stereotactic Breast Biopsy Accreditation / Equipment, QC and Q	A: Stereotactic Breast
🖹 Specia	l Cases in Stereotactic Breast Biopsy Quality	Control
(Revise Modified or	ed 12-12-19) n: Fri, 13 Dec, 2019 at 1:01 PM	Print

https://accreditationsupport.acr.org/support/solutions/artic les/11000072242-special-cases-in-stereotactic-breastbiopsy-quality-control

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If follow ACR DMQC Manual...



<u>using either the Small ACR</u> <u>Mammography Phantom or the Mini</u> <u>Digital Stereotactic Phantom</u>

Image Quality Evaluation

Localization Accuracy Test

Additional SBB Tests required by ACR



https://accreditationsupport.acr.org/support/solutions/articles/11000072242-special-cases-in-stereotactic-breast-biopsy-quality-control

Things to keep in mind

- AEC settings might be different for stereo versus normal 2D
 - Stereo uses separate CNR tables from screening on Hologic
- Detector calibration may have separate file for stereo mode (impacts artifact detection)



Collimation

For upright systems, may use MQSA criteria (±2% of SID) instead of 5mm criteria

Solution home / Stereotactic Breast Biopsy Accreditation / Equipment, QC and QA: Stereotactic Breast Biopsy

Quality Control: Stereotactic Breast Biopsy (Revised 12-12-19)

Modified on: Fri, 13 Dec, 2019 at 12:58 PM

Collimation Assessment

Ensures that the x-ray collimation does not allow significant radiation to extend beyond the edges of the image receptor and that the biopsy window aligns with the x-ray field (Collimation Test criteria requires "5 mm on any side" but per MQSA criteria, it is acceptable in upright systems if the collimation results fall within ±2% of the SID.)

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HVL

- Has been verified as part of DM annual test
 - BUT for dosimetry should repeat measurement without paddle material in place for SBB dose calc





AEC Testing

• Per the ACR

 "The equivalent test of automatic exposure control that is annually performed for the digital mammography unit may be used to satisfy the requirements for the stereotactic breast biopsy unit. It should be representative of stereotactic breast biopsy performance."



AEC Testing

• HOWEVER

- AEC settings might be different for stereo versus normal 2D
 - Hologic has CNR correction tables specifically for stereo
- Different field size = different scatter conditions



AEC Testing: Tips!

• Hologic Affirm (upright):

- For the correct CNR correction table to be applied across all thicknesses must use clinical view
 - i.e. "RCC Stereo Scout" (NOT "ACR Phantom Stereo Scout" or "PPM Stereo Scout")
 - Stereo CNR Correction tables listed in the Affirm User Guide
- mAs values are not automatically displayed on the scout images
 - Need to enable the "patient information" overlay
 - (under "Tools"!)



Image Receptor Uniformity

 Needs to be performed if the vendor does not have a quantitative image receptor uniformity test



Uniformity: Tip!

- Hologic Affirm (upright):
 - Recommendations from the vendor*:
 - Use standard biopsy paddle
 - Override default collimation (18x24cm) to 10x10cm
 - Reduces scatter
 - Measure uniformity within the biopsy window
 - 64x64 ROI size
 - Do not place the ROIs too close to the chest wall edge



*Resolution provided via email by Hologic technical support in response to failure in uniformity measurements

AGD

- AGD should be measured in stereo mode
 - Separate AEC settings, smaller field size, hole in biopsy paddle
- 2D Scout image
- Use HVL and output measured without paddle material in place



Image Quality

- Mini ACR phantom or small ACR mammography phantom
- 2D scout image
- Clinical technique for a standard breast
- Standard biopsy paddle
 - Be consistent!!



Stereo only (ignoring tomo for the moment...)

ACR Annual SBB Tests	QC Manual for FFDM	Add-on: Repeat for stereo?
Unit Assembly Evaluation	\checkmark	No
Collimation Assessment	\checkmark	No
Limiting Resolution	\checkmark	No
kVp Accuracy and Reproducibility	\checkmark	No
Beam Quality Assessment (HVL)	\checkmark	Yes* (for dosimetry)
AEC Manual Exposure or Performance Assessment	\checkmark	Yes*
Digital Image Receptor Uniformity	Some	Yes (if not part of DM survey)
Breast Entrance Exposure, Average Glandular Dose and Exposure Reproducibility	\checkmark	Yes
Image Quality Evaluation	\checkmark	Yes
Artifact Evaluation	\checkmark	Yes*
Localization Accuracy Test	n/a	Yes

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* Not required from an accreditation perspective, but physicist should consider performing

Accreditation and Testing

Adapting the 1999 ACR QC Manual for DBT





What's required

- For accreditation, technically "nothing"
 - Tomo-guided breast biopsies are not addressed by ACR
- Tomo-guided breast biopsy procedures are more prevalent
 - So... what should we test?



Considerations for Tomo:

- May have different target/filter combinations and kVp ranges for tomo-guided biopsies
- Detector may have separate calibration file for tomo mode
- AEC will have different settings for tomo (vs stereo)





Prone units – (ignoring add-ons for the moment...)

ACR Annual SBB Tests	Prone: SBB	Prone: Repeat for tomo?
Unit Assembly Evaluation	\checkmark	No
Collimation Assessment	\checkmark	No
Limiting Resolution	\checkmark	Yes*
kVp Accuracy and Reproducibility	\checkmark	Maybe*
Beam Quality Assessment (HVL)	\checkmark	Maybe*
AEC Manual Exposure Performance Assessment	\checkmark	Yes*
Digital Image Receptor Uniformity	\checkmark	Yes*
Breast Entrance Exposure, Average Glandular Dose and Exposure Reproducibility	\checkmark	Yes*
Image Quality Evaluation	\checkmark	Yes*
Artifact Evaluation	✓	Yes*
Localization Accuracy Test	✓	Yes*

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* Not required from an accreditation perspective, but physicist should consider performing

Collimation Assessment



Setup for assessing congruence of x-ray field to active area of detector

Hologic Affirm:

- Radiation field larger than biopsy window
- White line does NOT correspond with radiation field, neither does light field



Limiting Resolution

High-contrast resolution differs between DM and DBT

Digital System Limiting Resolution (Digital Systems Only)

Flat-Panel Monitor System	Previous	Current	Previous	Current
Viewing Mode:	LCD		l	.CD
Mode:	Conv	Conv (2D)		omo
Parallel to A-C axis (lp/mm):	6	6	5	5
Perpendicular to A-C axis (lp/mm):	6	6	5	5
Oriented at 45 degrees (lp/mm):	9	9	7	7

Action Limit: Note any significant degradation from previous measurement and seek service.





Physicist, Hologic (Medical Physicist)

Not required



kVp Accuracy and Reproducibility

- Reproducibility:
 - Four exposures at the "most commonly used clinical kVp"
- Accuracy:
 - Single exposure at "clinically important" kVps
 - kVp ranges may differ for DBT versus DM



Hologic Affirm (Prone)

Automatic Exposure Control (AEC) Technique Chart

Site:

Clinical Techniques (2D)

Breast Thickness (cm)	Target / Filter	k∨p	mAs
< 2.4	W/Ag	25	AEC
2.5 - 3.4	W/Ag	26	AEC
3.5 - 3.9	W/Ag	27	AEC
4.0 - 5.4	W/Ag	28	AEC
5.5 - 5.9	W/Ag	29	AEC
6.0 - 6.4	W/Ag	30	AEC
6.5 - 6.9	W/Ag	31	AEC
7.0 - 7.4	W/Ag	32	AEC
7.5 - 7.9	W/Ag	33	AEC
8.0 - 8.4	W/Ag	34	AEC
8.5 - 9.0	W/Ag	35	AEC
9.0 - 9.4	W/Ag	36	AEC
9.5 - 10	W/Ag	37	AEC
10 - 10.5	W/Ag	38	AEC
> 10.5	W/Ag	39	AEC

Focal	spot size:
Source-to-Image	Distance:

0.3 mm 80.0 cm

All 2D imaging uses W/Ag target/filter combination All Tomo imaging uses W/Al target/filter combination All clinical exams use AEC except where noted Room:

Clinical Techniques (Tomo)

Breast Thickness (cm)	Target / Filter	k∨p	mAs
< 4.0	W/AI	26	AEC
4.0 - 4.4	W/AI	27	AEC
4.5 - 4.9	W/AI	28	AEC
5.0 - 5.4	W/AI	29	AEC
5.5 - 5.9	W/AI	30	AEC
6.0 - 6.4	W/AI	31	AEC
6.5 - 6.9	W/AI	32	AEC
7.0 - 7.4	W/AI	33	AEC
7.5 - 8.0	W/AI	34	AEC
8.0 - 8.4	W/AI	35	AEC
8.5 - 8.9	W/AI	37	AEC
9.0 - 9.9	W/AI	38	AEC
10.0 - 10.4	W/AI	39	AEC
10.5 - 10.9	W/AI	40	AEC
11.0 - 11.5	W/AI	41	AEC
11.5 - 11.9	W/AI	42	AEC
12.0 - 12.4	W/AI	43	AEC
12.5 - 12.9	W/AI	44	AEC
13.0 - 13.4	W/AI	45	AEC
13.5 - 13.9	W/AI	46	AEC
14.0 - 14.4	W/AI	47	AEC
> 14.5	W/AI	48	AEC



- "Clinical kVp" (4.2 cm, 50/50 breast)
 2D: 28 kVp
 Tomo: 27 kVp
- kVp range:
 2D: 25-39 kVp
 Tomo: 26-48 kVp



Beam Quality Assessment (HVL)

- Measure for:
 - Target-filter/kVp at which the system is normally used clinically
 - Repeat for "clinical" technique for tomo (will need later for dosimetry)
 - Repeat for other target-filter/kVp settings ranging from lowest to highest used clinically



Beam Quality Assessment (HVL)

- Considerations:
 - Paddle
 - With or without hole? Or both?
 - If lateral approach is used for the biopsy, paddles without a hole may be used

Setup we use:

kVp, HVL, and output/linearity (used later in AGD calculation)

Paddle pictured = LAT 15 cm



Performance Capability (Conv - 2D):							
			"Clinical"				
Nominal k∨p setting:		25	28	30	35	39	
Target:		W	W	W	W	W	
Filter:		Ag	Ag	Ag	Ag	Ag	
Focal spot (mm):		0.3	0.3	0.3	0.3	0.3	
mAs:		100	100	100	100	100	
Exposure time (ms):		769.9	770.4	625.7	589.5	556.3	
mGy:		2.51	3.641	4.37	6.143	7.64	
			Measured k	Vp values:			
1:		25.5	28.5	31.0	36.2	40.0	
2:			28.5				
3:			28.5				
4:			28.5				
Mean kVp:		25.5	28.5	31.0	36.2	40.0	
Standard deviation (SD):			0.0000				
		Additiona	al kVp measu	rements (if n	eeded):		
5:							
Calculated HVL (mm Al):		0.502	0.566	0.595	0.654	0.684	
		Analysis:					
Mean k∨p:		25.5	28.5	31.0	36.2	40.0	
Standard deviation (SD):			0.0000				
Mean k∨p - Nominal k∨p:		0.5	0.5	1	1.2	1	
0.05 x Nominal k∨p:		1.25	1.40	1.50	1.75	1.95	
% Error:		2.0%	1.8%	3.3%	3.4%	2.6%	
Acceptably Accurate?:		Yes	Yes	Yes	Yes	Yes	
Coefficient of variation:			0.0000				
Acceptably Reproducible?:			Yes				
Mod	e:		Сог	וע (2D)			
mou			"Clinical"				
Nominal k∀p settin	g:	25	28	30	35	39	
Nominal mAs settin	g:	100	100	100	100	100	
Target materia	al:	W	W	W	W	W	
Filte	er:	Ag	Ag	Ag	Ag	Ag	
Paddle in plac	e:	Yes	Yes	Yes	Yes	Yes	
					· · · · · · · · · · · · · · · · · · ·		
Calculated HVL (mm A):	0.502	0.566	0.595	0.654	0.684	
Minimum allowed HV	:	0.28	0.31	0.33	0.38	0.42	
Maximum allowed HVL	*:						
Acceptable	?:	Yes	Yes	Yes	Yes	Yes	

Exposure Linearity (2D):



Clinical kVp	Clinical kVp:					
mAs	mGy	mGy/mAs	Linear			
16	0.59	0.037				
25	0.92	0.037	Yes			
50	1.83	0.037	Yes			
100	3.64	0.036	Yes			
200	7.25	0.036	Yes			
400	14.50	0.036	Yes			

Action Limit: The system shall be linear, such that the average ratios of exposure to the indicated milliampere-second product ((C/kg)/mAs or mR/mAs) obtained at any two consecutive tube current or mAs selector settings shall not differ by more than 0.10 times their sum.



Performance Capability (Tomo):							
		i	"Clinical"				
Nominal kVp setting:		26	27	35	40	48	
Target:		W	W	W	W	W	
Filter:		AI	AI	AI	AI	AI	
Focal spot (mm):		0.3	0.3	0.3	23	0.2	
mAs:		100	100	100	100	100	
Exposure time (ms):		3645	3643	3637	3636	3644	
mGy:		4.358	4.921	10.28	13.98	18.57	
	•		Measured k	/p values:			
1:		26.8	27.7	35.6	40.7	48.0	
2:			27.7				
3:			27.5				
4:			27.7				
Mean k∨p:		26.8	27.7	35.6	40.7	48.0	
Standard deviation (SD):			0.1000				
		Additiona	l kVp measu	rements (if n	eeded):		
5:							
Calculated HVL (mm Al):		0.470	0.500	0.668	0.764	1.050	
			Analy	sis:			
Mean k∀p:		26.8	27.7	35.6	40.7	48.0	
Standard deviation (SD):			0.1000				
Mean k∀p - Nominal k∀p:		0.8	0.65	0.6	0.7	0	
0.05 x Nominal k∀p:		1.30	1.35	1.75	2.00	2.40	
% Error:		3.1%	2.4%	1.7%	1.8%	0.0%	
Acceptably Accurate?:		Yes	Yes	Yes	Yes	Yes	
Coefficient of variation:			0.0036				
Acceptably Reproducible?:			Yes				
			-				
Mod	le:		Tom	o-Only			
			"Clinical"				
Nominal k∀p settir	ng:	26	27	35	40	48	
Nominal mAs settir	ng:	100	100	100	100	100	
Target materi	al:	W	W	W	W	W	
Filter:		Al	Al	Al	AI	AI	
Paddle in plac	Paddle in place:		Yes	Yes	Yes	Yes	
Calculated HVL (mm A	J):	0.470	0.500	0.668	0.764	1.050	
Minimum allowed HV	'L:	0.29	0.30	0.38	0.43	0.51	
Maximum allowed HVI	*:						
Acceptable	?:	Yes	Yes	Yes	Yes	Yes	

Exposure Linearity (Tomo):



Clinical kVp	27				
mAs	mGy	mGy mGy/mAs			
16	0.86	0.054			
25	1.24	0.050	Yes		
50	2.51	0.050	Yes		
100	4.92	0.049	Yes		
140	7.08	0.051	Yes		

Action Limit: The system shall be linear, such that the average ratios of exposure to the indicated milliampere-second product ((C/kg)/mAs or mR/mAs) obtained at any two consecutive tube current or mAs selector settings shall not differ by more than 0.10 times their sum.

Raysafe X2:

- MAM sensor will not read above 40kVp
- Will need to switch to RF sensor for 48 kVp, and possibly for 40 kVp



AEC Performance Assessment

• Measure for:

- 2, 4, 6, and 8cm
- Considerations:
 - Paddle to use?
 - Material to use
 - (BR-12, Acrylic)?





AEC Performance Assessment

Thickness Compensation (2D):								
C	CONTACT IMAGING, Lg FS w/ Grid AEC Position:					3		
Phantom Thickness (cm)	Mode	Filter	KVp	mAs	Density	Exposure Index	CNR corr	Corrected Pixel Value
2	AEC	Ag	25	71	0	724	0.71	949.3
4	AEC	Ag	28	122	0	934	0.94	940.4
6	AEC	Ag	30	301	0	1298	1.30	960.0
8	AEC	Ag	34	441	0	1663	1.71	943.3
Corrected N	lean Pixel		Allowed Range					
Val	ue	Corrected Pixel Value Range		(±20% of 4cm value)		ue)	Pass / Fail	
948	.2	940.4	to	960.0	752.3	to	1128.5	Pass

Action Limit: If the signal range exceeds +/- 20% of signal for 4 cm phantom, Revise technique chart

Thickness Compensation (Tomo):									
CONTACT IMAGING, Lg FS w/o Grid AEC Position:						3			
Phantom									
Thickness						Exposure	CNR	Corrected	
(cm)	Mode	Filter	KVp	mAs	Density	Index	corr	Pixel Value	
2	AEC	AI	26	53	0	170	0.88	136.4	
4	AEC	AI	27	109	0	177	0.94	135.1	
6	AEC	AI	31	136	0	257	1.53	135.3	
8	AEC	AI	35	162	0	357	2.32	132.3	
Corrected Mean Pixel		Allowed Range							
Value		Corrected Pixel Value Range			(±20% of 4cm value)			Pass / Fail	
134.8		132.3	to	136.4	108.1	to	162.1	Pass	

Action Limit: If the signal range exceeds +/- 20% of signal for 4 cm phantom, Revise technique chart

<u>EXAMPLE</u> (Hologic Affirm Prone)

Vendor Setup:

- Paddle = LAT 15cm
- AEC Position 3
- Set exact thickness (if possible)



AEC Performance Assessment

Thickness Compensation (Stereo):								
Phantom Thickness	Target	Filter	k∨p	mAs	Mean Signal ∀alue	SNR		
2 cm	W	Rh	26	46.1	719.8	108.0		
4 cm	W	Rh	28	96.3	716.9	104.2		
6 cm	W	Rh	30	192.0	716.0	100.9		
8 cm	W	Rh	32	330.6	714.6	93.6		
Mean Pixel Value	Signal Range			Allowed Range (4 cm value ± 20%)				
716.8	715	to	720	574	to	860		

Action Limit: If the signal range exceeds +/- 20% of signal for 4 cm phantom, revise technique chart.

Thickness Compensation (Tomo):

Phantom Thickness	Target	Filter	kVp	mAs	Mean Signal	SNR	
2 cm	W	Rh	26	70.3	185.6	25.1	
4 cm	W	Rh	28	142.8	186.9	24.9	
6 cm	W	Rh	30	276.0	187.0	24.0	
8 cm	W	Rh	32	485.6	194.5	23.3	
Mean Pixel Value	Signal Range			Allowed Range (4 cm value ± 20%)			
188.5	186	to	195	150	to	224	

<u>EXAMPLE</u> (Siemens Revelation)

- Use clinical procedure / exam tag
- Measure values off of RAW images
 - 0 degree projection for tomo



Digital Receptor Uniformity

- Considerations:
 - Use reconstructed tomo slice or RAW projection image?
 - We use 0 degree projection image

Note for Hologic: acquisition workstation does not permit ROI measurements on reconstructed tomo slices (but it does on projections!)


<u>EXAMPLE</u> (Hologic Affirm Prone)

Attenuator: Acrylic Thickness: 4 cm Target / Filter: W/Ag kVp: 28 Focal Spot: 0.3 mm AEC Position: 3 Imaging Mode: 2D	Attenuator: Acrylic Thickness: 4 cm Target / Filter: W/AI KVp: 27 Focal Spot: 0.3 mm AEC Position: 3 Imaging Mode: Tomo
mAs: 122	mAs: 109
Performance Capability (2D) For units with ROI measurement capability	Performance Capability (Tomo) For units with ROI measurement capability
Mean* 881.9 Minimum 891 Upper Left Maximum SD 10.62 SNR* 83.0 SNRUL / SNR _{Center} 0.99	Mean* 128.8 Minimum 150 Upper Left Maximum 212 SD 7.94 SNR* 16.2 SNRUL / SNRCenter 0.99
Mean* 885.6 Minimum 893 Maximum 975 SD 10.54 SNR* 84.0	ROI Center Mean* 128.9 Minimum 145 Maximum 208 SD 7.9 SNR* 16.3
ROI Mean* 884.9 Lower Left Minimum 889 SD 11.59 SNR* 76.3 SNRL_/ SNR_center 0.91	Mean* 128.3 Mean* 128.3 Lower Left Maximum 144 ROI Maximum 146 SD 8.31 SNR* 15.4 SNR_L / SNR_{Center} 0.95 SNR_L / SNR_L / SNR_Center 0.94

Use image acquired with 4cm of acrylic/BR-12 during AEC Performance Assessment

(we use this image for artifact detection too!)



Entrance Exposure, AGD, Reproducibility

- Considerations:
 - If comparing displayed AGD to calculated AGD:
 - Which paddle does the vendor assume to estimate HVL and entrance skin exposure?



Entrance Exposure, AGD, Reproducibility

Imaging Mode:	Digital		SID (cm):		80	
Field Restriction:	Auto	matic]			
Propot thicknood (cm):	4	2	4	2		
Diedst tillckriess (cill).	4	.2	4.Z			
Phantom Manufacturer.	Gan	Gammex		Gammex		
Phantom Senai.	48	483F		483F		
Digital Acquisition Mode:	Conv	Conv (2D)		Tomo-Only		
l arget:	V	V	V	V		
Filter:	A	Ag		AI		
AEC Mode:	Al	AEC		AEC		
AEC Position:		3		3		
Exp Compensation Step:	(0		0		
Nominal kVp setting:	2	28		27		
Measured HVL (mm AI):	0.566		0.500			
Breast Entrance Exposure (Air Kerr	Intrance Exposure (Air Kerma):					
	mGy	mAs	mGy	mAs		
Exposure #1:	5.0	136.0	6.2	123.0		
Exposure #2:	5.0	137.0	5.9	118.0		
Exposure #3:	4.9	134.0	6.2	123.0		
Exposure #4.	4.9	135.0	0.2	123.0		
Standard doviation (SD):	4.9	1 2010	0.1	2 5000		
Coefficient of variation (CV):	0.0470	0.0005	0.0205	0.0205		
Accentably Reproducible?	Yes	Yes	Yes	Yes		
Action Limit: If coefficient of variation for either B or m	As oxcoods 0	05 sook son		100		
Action Emilier recention of variation for entier R of his	na exceeda U.	00, 300K 30K				
Average Glandular Dose:						
Corrected incident skin air kerma (mGy):	4.	4.93		6.11		
Dose conversion factor (mrad/R):	2	294		265		
Dose conversion factor (mGy-g/mGy-air)	0.3	0.336		0.302		
Computed average glandular dose (mGy):	1.	1.66		1.85		

Action Limit: If average glandular dose exceeds 300 mrad (3 mGy) for 4.2 cm effective breast thickness at the clinical acquisition technique (512x512 unless otherwise specified), seek service or technique adjustment. <u>Corrective action must be taken before</u> further examinations are performed if the test results fail ACR regulations.

<u>EXAMPLE</u> (Hologic Affirm Prone)

Consistency:

Use same paddle used for HVL and output measurements

Image Quality Evaluation

Imaging Mode: 2D	Previous Image	Current Image
kVp:	28	28
Phototimed mAs:	142.0	136
mAs change:		-6.0
mAs difference (%):		-4%
Exposure Index:	981.0	913
Background signal change (%):		7%
Number of fibers seen:	3.5	3.5
Fibers seen after deduction:	3.5	3.5
Fiber change:		0.0
Number of speck groups seen:	3.0	3.0
Speck groups after deduction:	3.0	3.0
Speck group change:		0.0
Number of masses seen:	3.5	3.5
Masses seen after deduction:	3.5	3.5
Mass change:		0.0

Imagin Mode: Tomo	Previous Image	Current Image
kVp:	27	27
Phototimed mAs:	118.0	123
mAs change:	-	5.0
mAs difference (%):		4%
Exposure Index:	177.0	174
Background signal change (%):		2%
Number of fibers seen:	3.0	3.0
Fibers seen after deduction:	3.0	3.0
Fiber change:		0.0
Number of speck groups seen:	3.0	3.0
Speck groups after deduction:	3.0	3.0
Speck group change:		0.0
Number of masses seen:	3.0	3.0
Masses seen after deduction:	3.0	3.0
Mass change:		0.0

<u>EXAMPLE</u> (Hologic Affirm Prone)



Artifact Evaluation

- Considerations:
 - Review projection images only, or reconstructed tomo slices?

-0-	0	
-	-	
Flat Field	Flat Field Tomo	



EXAMPLE (Hologic Affirm Prone)





Slice 31 ©

Note: this is "normal" (present on ALL of our Affirm prone units)

Was advised by Hologic that the tomo reconstruction and image processing doesn't handle uniform objects well, and that <u>only the projection</u> <u>images should be reviewed</u> for artifact detection <u>purposes</u>

Localization Accuracy Test

- Purpose is 3-fold:
 - Accuracy of localization
 - Should be verified under stereo-guidance and tomoguidance
 - Standard approach
 - Lateral approach (if applicable)
 - Repeat for Left and Right Lateral?
 - Technical competency
 - Ability of biopsy system to successfully obtain a sample



In Summary

- Hologic makes it easy for you they assume that you will perform all applicable tests in tomo mode as well as stereo
 - Applications trained our technologists to perform QC for both as well
- Note which paddle you have used for each test and keep it consistent



Add-on Units w/ Tomo-Guidance

- On upright units, AEC settings and detector calibration files for DBT are typically the same, whether a biopsy is being performed or not
 - AEC performance and artifact evaluation do not need to be repeated with the stereo attachment in place
- BUT paddle with hole is often used for biopsy procedures:
 - HVL, AGD, and Phantom Image Quality should be repeated with standard biopsy paddle in place



ACR Annual SBB Tests	QC Manual for FFDM	Add-on: Repeat for stereo?	Add-on: Repeat for tomo biopsy?
Unit Assembly Evaluation	\checkmark	No	No
Collimation Assessment	\checkmark	No	No
Limiting Resolution	\checkmark	No	No
kVp Accuracy and Reproducibility	\checkmark	No	No
Beam Quality Assessment (HVL)	\checkmark	Yes* (for dosimetry)	Yes* (for dosimetry)
AEC Manual Exposure or Performance Assessment	\checkmark	Yes*	No
Digital Image Receptor Uniformity	Some	Yes (if not part of DM survey)	Yes* (if not part of DM survey)
Breast Entrance Exposure, Average Glandular Dose and Exposure Reproducibility	\checkmark	Yes	Yes*
Image Quality Evaluation	\checkmark	Yes	Yes*
Artifact Evaluation	\checkmark	Yes*	No
Localization Accuracy Test	n/a	Yes	Yes*

* Not required from an accreditation perspective, but physicist should consider performing

Technologist QC

Localization Accuracy Test (Daily)

Phantom Images (Weekly)

Hardcopy Output Quality *if applicable* (Monthly)

Visual Checklist (Monthly)

Compression (Semiannually)

Repeat Analysis (Semiannually)

Zero Alignment Test *if applicable* (Before each patient)

Prone:

- Consider having the technologist perform in 2D and tomo mode
 Upright Add-On:
- Phantom image quality for DBT already being performed during routine QC of mamm unit



Future Directions ACR-AAPM Technical Standard ACR SBB QC Manual Update



ACR-AAPM Technical Standard

2020 (CSC/BOC)

ACR-AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF STEREOTACTIC / TOMOSYNTHESIS-GUIDED BREAST BIOPSY SYSTEMS

https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Breast-Stereo-Tomo-Guided-Standard.pdf

- Effective October 1, 2020
- Consensus-based guidance document



ACR-AAPM Technical Standard

• The Qualified Medical Physicist's monitoring of performance characteristics must comply with appropriate federal, state, and local regulations. The 2018 ACR Digital Mammography Quality Control Manual may be used as a guide in performing many of the tests outlined below [2]. If an add-on biopsy device is used on a 2-D or digital breast tomosynthesis (DBT) full-field digital mammography system, the 2-D or DBT results obtained following the 2018 ACR Digital Mammography QC Manual or the manufacturer's QC manual may be used to fulfill applicable tests in the sections below.



Additional Acceptance Tests

Acceptance tests must include tests performed during the annual performance evaluation and, additionally, should include the following items in both conventional and tomosynthesis modes if applicable:

- 1. Compliance with applicable local and federal regulatory requirements
- 2. Compliance with all terms and line items of the purchase agreement or contract (*if the documentation is available to the Qualified Medical Physicist*)
- 3. Compliance with manufacturer's relevant imaging and safety performance specifications
- 4. Evaluation of radiation shielding
- 5. Verify that manufacturer calibrations have been completed
- 6. Compression thickness indicator accuracy evaluation
- 7. Evaluation of compression force
- 8. Tube potential (kVp) accuracy and reproducibility measurements
- 9. Beam quality assessment (eg, half-value layer measurement)
- 10. Collimation assessment
- 11. Ghost image evaluation (optional)

No longer recommended as annual tests



https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Breast-Stereo-Tomo-Guided-Standard.pdf

Recommended Annual Tests

- 1. The performance of each stereotactic/tomosynthesis-guided system must be evaluated at least annually. At a minimum, this evaluation should include the following items in both conventional and tomosynthesis modes if applicable:
 - a. Stereotactic/tomosynthesis-guided system unit assembly assessment (ie, unit checklist)
 - b. Image quality and artifact evaluation
 - c. Assessment of receptor uniformity
 - d. Spatial resolution assessment
 - e. Automatic exposure control (AEC) system
 - f. Average glandular dose measurement
 - g. Verification of localization accuracy
 - h. Acquisition workstation monitor performance assessment
 - i. Evaluation of site's technologist quality control (QC) program
 - j. Verify that there are policies in place for the quality, safety, infection control, and patient education programs

Outlined in 2018 ACR

DMQC Manual

k. Additionally, for breast biopsy equipment with tomosynthesis capabilities, the performance evaluation should include tomosynthesis volume coverage.



https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Breast-Stereo-Tomo-Guided-Standard.pdf

ACR Update

- ACR's Breast X-Ray Imaging Physics Subcommittee has launched a revision of the SBBAP QC Manual
- The subcommittee consists of *the audience's colleagues* who understand and share the challenges the audience faces and the concerns they have
- AAPM Annual Meeting will include another brief update from Bill Geiser during the ACR Activities session



References

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- ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Stereotactic / Tomosynthesis-Guided Breast Biopsy Systems, 2020 (CSC/BOC) (<u>https://www.acr.org/-</u> /media/ACR/Files/Practice-Parameters/Breast-Stereo-Tomo-Guided-Standard.pdf)
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