Facility Certification Extension Requirements, Quality Assurance and Medical Physicists' role for Hologic Selenia Dimensions Digital Breast Tomosynthesis (DBT) System

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Digital Breast Tomosynthesis

- FDA approved the first DBT system in late 2010
- Currently FDA allows use of DBT under MQSA through certificate extension process
- DBT can be installed only in already MQSA certified mammography facilities

Certificate Extension I

What is Certificate Extension?

- FDA's Division of Mammography provide the Certificate Extension for a newly cleared /approved mammography system or a modality where no accreditation body is available

Why does FDA give Certificate Extension ?

- FDA provides certificate extension to facilitate the use of a device which received marketing clearance or approval.

Certificate Extension II

Is Digital Breast Tomosynthesis (DBT) a new modality?

- Digital Breast Tomosynthesis is a new mammographic modality separate from Full Field Digital Mammography.
- In order to use the tomosynthesis portion of the unit, the facility must apply to FDA to have its certificate extended to include that portion of the unit. **The certification extension only applies to the DBT portion of the unit.** The facility must have the 2D portion of the unit accredited by one of the accreditation bodies already approved to accredit the Hologic Selenia Dimensions 2D.

- MQSA statute requires that a facility can only be certified to perform mammography after it is being successfully accredited.

- In absence of an accreditation body for a new device or modality, FDA can thus only allow certificate extension to an already certified facility to add the new device.

Certificate Extension III

The main items that FDA reviews:

- Mammography Equipment Evaluation test results as per the manufacturer's requirements
- A hard copy of a 3D phantom (image from a tomosynthesis slice will do)
- Lead Interpreting Physician Attestation to Staff Personnel Qualifications

What does FDA review for Certificate Extension?

For a complete requirement consult FDA's website:

MQSA Facility Certification Extension Requirements for Hologic Selenia Dimensions Digital Breast Tomosynthesis (DBT) System

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm243765.htm

- Important QC Tests:

AEC Function Performance

Contact Imaging, LFS with Grid								
Phantom Thickness	AEC Mode	kVp	mAs	Filter	Exp Comp Step	Exposure Index	CNR Correction Factor*	Corrected Pixel Value**
2 cm	Auto Filter	26	35	Al	2.1	244.0	0.70	277.14
4 cm	Auto Filter	29	48	Al	3.9	297.0	0.91	271.43
6 cm	Auto Filter	33	64	Al	5.8	439.0	1.46	266.44
8 cm	Auto Filter	38	80	Al	8.0	689.0	2.37	269.62

Corrected Mean Pixel Value	Corrected Pixel Value Range			Allowed Corrected Pixel Value		
271.16	266.44	to	277.14	244.04	to	298.27

Corrected Pixel Value has to be in the range of the allowed values!

Mammography vs. Tomosynthesis: Filter

Part of Combo Exposure	Conventional	Tomosynthesis
Breast thickness (cm)	4.2	4.2
Phantom Serial Number	707104	707104
kVp setting	28	28
Target material	W	W
Filter	Rh	Al
AEC Mode	Auto Filter	Auto Filter
AEC Position	2	2
Exp. Compensation Step	0.0	0.0
Measured HVL (mm Al)	0.541	0.494

Tomosynthesis mode always uses Al filter!

Mammography vs. Tomosynthesis: Resolution

Mammo mode:

Nominal focal spot size (mm)	0.3
kVp setting	28
mAs setting	120
Limiting resolution in cycles per mm	9

Tomo mode:

Nominal focal spot size (mm)	0.5
kVp setting	30
mAs setting	50
Limiting resolution in cycles per mm	5

Resolution is lower for tomosynthesis images!

Mammography vs. Tomosynthesis: Dose

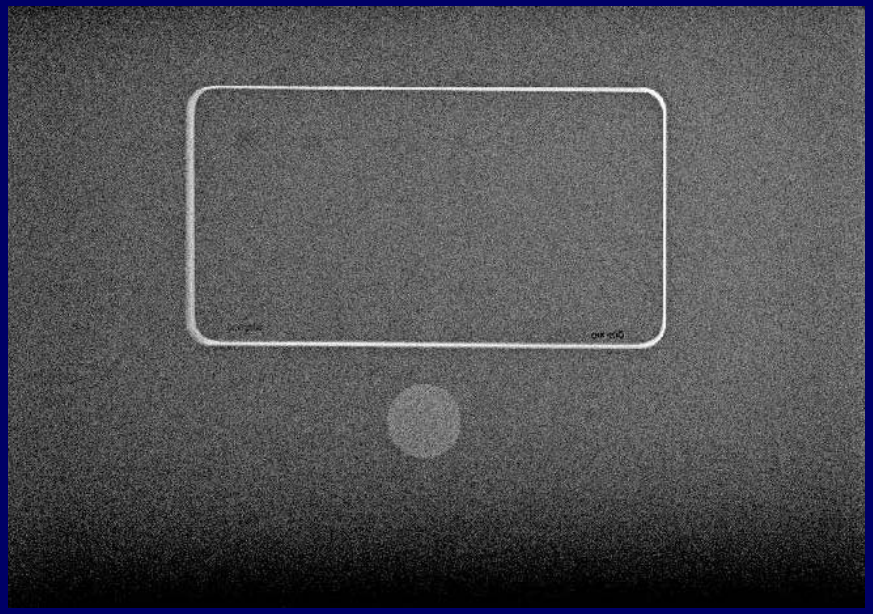
Part of Combo Exposure	Conventional	Tomosynthesis
Inv Square corrected	408.8	528.2
Dose conversion factor from Tables 1-3 (mrad/R)	280.000	267.000
Computed average glandular dose (mrad)	114.5	141.0
Total average glandular dose* (mrad)	255.5	

Average glandular dose must not exceed 300 mrad (3 mGy) for 4.2 cm effective breast thickness!

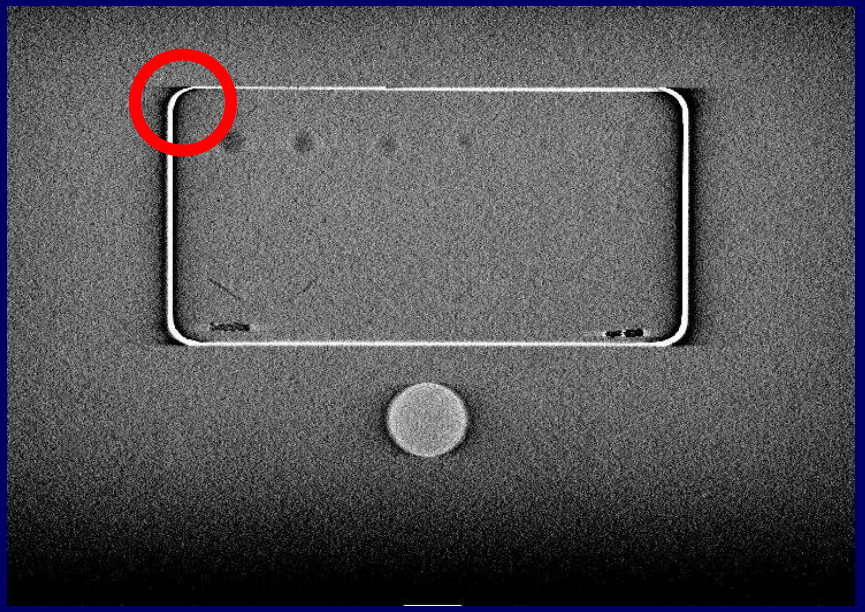
“The doses for 2D and tomosynthesis are measured both in individual tests, and also together as part of the Combo procedure. It is not uncommon nor a defect for the doses to vary in the two modes, i.e. the tomosynthesis dose measured individually and as part of the Combo procedure can differ. The 20 and tomosynthesis dose in the Combo mode are calibrated separately from the 20 and tomosynthesis dose calibrations used in the individual exposure modes and so will not be identical. Additionally, a site might have specifically requested that the doses be set differently in Combo compared to individual exposures such as might be desired for screening and diagnostic applications. The important point is that the doses in each mode (201 tomosynthesis Combo) each meet the specified pass/fail criteria.”

Mammography vs. Tomosynthesis: Images

Projection image:



Reconstructed image:



Objects have a shadow in reconstructed tomosynthesis images!

Questions and Answers

Can a facility perform patient imaging with DBT prior to FDA's certificate extension approval?

a. yes
b. no
c. yes, if application training is performed
d. yes, if a written guarantee of the quality is provided to the patient
e. yes, if a verbal OK is obtained from CDRH

Answer: b

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Questions and Answers

2. Who can perform DBT equipment evaluation after the machine installation ?

a. service engineer

b. rad tech

c. qualified medical physicist only

d. rad tech or a medical physicist

e. rad tech or a radiologist in consultation with a off site physicist

Answer: c

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Questions and Answers

3. What are the important DBT MEE test results that FDA looks at as a part of DBT certificate extension process?

a. collimation and dose results

b. phantom image and monitor QC result

c. resolution, AEC performance, dose and phantom image

d. dynamic range, CNR, SNR and uniformity

e. printer QC, monitor QC, dose and phantom image

Answer: c

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And Hologic Selenia Dimension QC Manual Revision 003