Learning Objectives

- Tomosynthesis
  - Theory, QC
- C-View™ Synthetic 2D Imaging
  - Theory, QC
- I-View™ Dual Energy Mammography
  - Theory, QC
- Tomo-Guided Biopsy
  - Theory, QC

Hologic Breast Tomosynthesis

- Tube moves in a 15° arc
  - 15 low dose images are acquired. Total dose ~ 1 FFDM
  - 3.7 second continuous motion sweep
  - X-rays are pulsed on and off
- Images are reconstructed into 1 mm slices
  - ~ 100 micron in-plane resolution
X-Ray Generation

X-Ray Tube
- Tungsten (W) Anode
  - LFS: 0.3 mm; SFS: 0.1 mm

X-Ray Filtration
- FFDM: 50 μm Rh; 50 μm Ag
- Tumor: 0.7 mm Al
- 4 View: 0.3 mm Cu

X-Ray Generator
- 200 mA max for LFS
- 50 mA max for SFS
- mA varies with kVp
- mA adjusts to target time range

Selenia Dimensions: Technicals

Conventional 2D Imaging
- a-Se detector, 24 x 29 cm area
- 70 μm pixel size
- Rh and Ag filters
- 20-39 kVp
- HTC grid in contact mode
- No grid in magnification mode

Tomosynthesis Imaging
- a-Se detector, 24 x 29 cm area
- 140 μm pixel size
- Al filter
- 20-49 kVp
- No anti-scatter grid
- Moving tube, 15° sweep
- 15 projections
- Moving detector
- 3.7 seconds acquisition
- Reconstruction
  - ~100 μm pixel size
  - 1 mm slice spacing

System Configurations
Clinical Utility of Combo (Tomo+2D) imaging (FDA approved mode for tomo in screening)

Tomo (or DBT)
Visualization of masses and architectural distortions

2D
Rapid review of calcification clusters
Comparison to 2D priors and left/right asymmetry
CAD operates on the 2D images

Clinical Results
2D+3D superior to 2D in cancer detection and false positive rate (Friedewald, …)

C-View™ Image
Provides a 2D-like image
• Helps the radiologist facilitate review
  – Quick overview of breast
  – Compare to 2D Priors
  – Maintain familiar workflow

Does not require additional x-ray exposures
• Original Combo imaging required both 2D and Tomo acquisitions

FDA approved to replace the 2D images in tomo screening exam

Clinical Studies (Skaane, Bernardi, Conant): C-View+3D comparable to 2D+3D

C-View™ (Synthesized 2D)
How does it work?
• Perform a standard tomosynthesis scan
• Reconstruct tomosynthesis slices
• Generate the 2D image
  • Intelligent MIP
• No need for 2D exposure
• Shorter compression time
C-View™ Image and FFDM

- Not intended to have identical appearances
- Small but distinctive differences
  - Important details from the tomosynthesis slices are preserved and enhanced
  - Architectural distortions and calcifications may be more conspicuous
Conspicuity of the calcifications in dense tissue can be higher with C-View™ images.

C-View™ images can maintain details even in dense tissue.
Contrast Enhanced 2D Mammography – I-View™
Dual Energy 2D Imaging

Designed to image an iodine contrast agent
Two exposures are made in rapid sequence:
1. Low kV (normal mammogram, ~28-30 kV, Rh/Ag filters). Below iodine's k-edge of 33 keV

Subtraction gives a 2D iodine contrast image
Repeat as desired
Imaging window ends after ~6 minutes due to contrast redistribution

---

Dual-Energy Subtraction

* You cannot see the iodine contrast drug in high or low kV images
* But you can when you subtract the images

\[ \text{Subtraction} = \text{high kV} - \text{low kV} \]

* Only the low kV and subtraction images are viewed

---

CE2D – Dual Energy 2D

Low kV, High kV images acquired for each view
Views can be any order

---
Dual Energy 2D Combo Imaging

Three exposures are made in rapid sequence:
1. Low kV tomosynthesis scan (~30 kV, Al filter)
2. Low kV (normal mammogram, 28-30 kV, Rh/Ag filters)
3. High kV (~45-49 kV, Cu filter)

Subtraction gives a 2D contrast image

Tomo image is co-registered to the contrast 2D image

Repeat as desired

Imaging window ends after ~6 minutes due to contrast redistribution

Combo CE2D – Dual Energy 2D with Tomosynthesis

Tomo, Low kV, High kV images acquired for each view

Views can be any order

Example Image

Courtesy of Andrea Woodroof, Kentucky Breast Care
CE2D for Discordant Findings

- 52 y.o. female, presented for screening
- 0.8 cm spiculated mass in the left axillary tail noted on both 2D and 3D
- Focal area of possible distortion noted on 3D

Area of distortion couldn’t definitively be correlated on ultrasound for US biopsy
CE2D for Discordant Findings

- Area of distortion couldn’t definitively be correlated on ultrasound for US biopsy
- The enhancing mass on CE2D was correlated with the tomo distortion
- Tomo-guided biopsy ensued

Quality Control Procedures: Digital Breast Tomosynthesis
Image Acquisition Modes

- **Conventional**
  - Acquires 2D images only

- **Tomo**
  - Acquires tomosynthesis images only

- **TomoHD**
  - Acquires tomosynthesis images only
  - Produces C-View images

- **Combo**
  - Acquires 2D images
  - Acquires tomosynthesis images

- **ComboHD**
  - Acquires 2D images
  - Acquires tomosynthesis images
  - Produces C-View images

Image Acquisition Modes (I-View™)

- **2D Contrast Acquisition**
  - 2D low-energy image
  - 2D high-energy image

- **Combo 2D Contrast Acquisition**
  - Tomosynthesis projections
  - 2D low-energy images
  - 2D high-energy images

QC Modes

- **Quality control procedures test**
  - Conventional
  - Tomo
  - Combo
  - I-View™
- **The following modes do not require separate QC testing**
  - C-View™
  - TomoHD
  - ComboHD
Medical Physics
Medical Equipment Evaluation (MEE) Testing

- 12 tests to be performed by the medical physicist
- 5 extra tests that are usually performed by technologists

Medical Physics QC Tests

- 12 tests to be performed by the medical physicist
- 7 of them have DBT components/requirements
Medical Physics QC Tests

3 of them have AView components/requirements.

Technologist QC Tests

12 tests to be performed by the technologist.

2 of them have AView components/requirements.
Alternative Standard 9

- **Category A**
  - Immediate corrective action is required
  - Issue needs to be resolved before resuming imaging

- **Category B**
  - Affects interpretation devices
  - Interpretation device steps out of use until issue is resolved
  - Alternative interpretation device may be used
  - Imaging may continue

- **Category C**
  - Issue needs to be resolved within a predefined time window
  - Imaging may continue up to the end of that time window

Alternative Standard 6

- Additional evaluations must be conducted after major component change or repair
- Software changes are considered as major repairs
- Alternative Standard 6 allows manufacturers to:
  - Evaluate software update for QC requirements
  - Define a series of tests to be performed by the technologist

Mobile Quality Control Checks

Additional checks must be repeated by technologist every time the system moves and before patient imaging

- Compression thickness
- Artifact evaluation
- Phantom image quality
- Signal-to-noise and contrast-to-noise
Hologic QC Manuals

- MAN-01965
  - R003
- MAN-03706
  - R002


Software Version and QC Manuals

MAN-01965
- Applies to software version prior to v1.8.x

MAN-03706
- Applies to software version starting at v1.8.x

Important differences
- Appendix D: CNR Correction Tables

Tomosynthesis Option

Tomosynthesis specific tests are marked with an icon
Icon indicates that a special action is required under tomosynthesis

NOTE: When testing FFDM only, these instructions are ignored
Diagnostic Option

Diagnostic specific tests are marked with an icon
Icon indicates that listed action is only applicable to systems licensed for diagnostic use

NOTE: When testing screening-only FFDM systems, these instructions are ignored

Contrast Option

Iodine contrast specific tests are marked with an icon
Icon indicates that listed action is only applicable to systems licensed for iodine contrast imaging

NOTE: When testing systems that are not licensed for iodine contrast, these instructions are ignored

Tomosynthesis-Specific Quality Control

- Tomo Geometry Calibration
- Usually performed by technologist
CAUTION

Direct x-ray exposure of the image receptor may damage the receptor.

The image receptor should be covered with lead or copper during testing for exposures other than those required to qualify image quality.

Following the test procedures in the Hologic QC Manual will ensure the safety of the image receptor.

CAUTION

System must go from Detector Warming status to All Ready status to perform image quality tests.
Follow the 1999 ACR Mammography Quality Control Manual

1. MAMMOGRAPHIC UNIT ASSEMBLY EVALUATION

Follow the Hologic Selenia Dimensions Quality Control Manual

2. COLLIMATOR ASSESSMENT

2a. X-Ray Field to Light Field

ONLY use the 24x29 cm compression paddle
Cover the image receptor if repeated, high exposures are required (i.e. self-developing film)
2b. X-Ray Field to Image Receptor

Test with the 24x29 cm compression paddle
Test left, center and right x-ray fields with the 18x24 cm compression paddle
Use the Zero-Degree Tomo view to test under tomosynthesis
Follow the directions in the QC manual

2c. Compression Paddle to Image Receptor

Compression paddles
- Manufactured as single pieces
- Do not have adjusting parts
- Designed to comply with the regulations
- Design assumes mild compression (~10lb) to remove play

Follow the Hologic Selenia Dimensions Quality Control Manual

3. ARTIFACT EVALUATION
**Procedure Highlights**

**DICOM printer**  
Send an artificial flat field image to the printer

**FFDM testing**  
Test all focus/filter combinations  
(LFS/Rh; LFS/Ag; SFS/Rh; SFS/Ag; LFS Cu)  
Preview image in full resolution

**DBT testing**  
Test using middle projection  
Preview image in full resolution

---

Follow the 1999 ACR Mammography Quality Control Manual

**4. KVP ACCURACY AND REPRODUCIBILITY**

---

**Procedure Highlights**

Cover the image receptor to protect it from radiation exposure

FFDM extends to 39 kVp; DBT extends to 49 kVp

Use the Zero-Degree Tomo mode to test beyond 39 kVp, if needed

Non-invasive meters must be calibrated to the specific filters and energy range used

Hologic Service can assist with equipment
5. BEAM QUALITY ASSESSMENT—HVL MEASUREMENT

Procedure Highlights

Follow the 1999 ACR Mammography Quality Control Manual

Cover the image receptor to protect it from radiation exposure

Use the Zero-Degree Tomo mode to measure HVL under DBT (Al filter)

NOTE: compression thickness should be <24cm for the system to allow exposure

Non-invasive meters must be calibrated to the specific filters and energy range used

\[ \text{HVL > (kVp/100) + 0.03} \] in mm Al

Follow the Hologic Selenia Dimensions Quality Control Manual

6. EVALUATION OF SYSTEM RESOLUTION
Procedure Highlights

Place the line pair phantom on top of the 4 cm acrylic block

Rotate the line pair phantom 45°

Apply 15-20 lb of compression to avoid vibration during DBT

Use the Flat Field view (no image processing)

Resolution guidelines:

- FFD: > 7 lp/mm @ 45°
- DBT: > 3 lp/mm @ 45°

Follow the Hologic Selenia Dimensions Quality Control Manual

7. AEC FUNCTION PERFORMANCE
### AEC Function Description

**AEC modes**
- Auto-Filter
- Auto-kV
- Auto-Time

**AEC positions**
- Auto AEC: two ~1cm² floating sensors in 5 x 14cm² area
- One of seven manual positions (marked on compression paddle)

**AEC function**
- kVp and filter parameters are determined by compression thickness and AEC technique tables
- kVp can be adjusted upwards if the exposure time will be too long
- Starting mAs is determined from short pre-exposure targeting a specific exposure index (EI)
- Final mAs is adjusted by CNR correction factor

### Procedure Highlights

**Compression thickness must be set using the compression display**

**FFDM testing**
- Range of phantom thickness
- Different operating modes (i.e. mag)
- Exposure compensation steps

**DBT testing**
- Range of phantom thickness

### Exposure Index (EI)

EI is defined as the **digital value of a detector element**

“Raw” EI values need to be corrected by
- Subtracting the DC offset (value of 50)
- Normalizing by the CNR correction factor (given in Appendix D of the Hologic QC Manual)
CNR Correction Factors, FFDM

1.0 CNR Correction - Conventional (Contact)

Note: System default setting in AEC Table 5 is software given in org 1.0 and not shown in Table 5. Selections of 0.7 and 1.5 are shown for reference.

<table>
<thead>
<tr>
<th>Compression Thickness</th>
<th>6.0 mm</th>
<th>6.6 mm</th>
<th>8.0 mm</th>
<th>9.5 mm</th>
<th>10.6 mm</th>
<th>12.7 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Patients</td>
<td>1.80</td>
<td>1.84</td>
<td>1.80</td>
<td>1.80</td>
<td>1.80</td>
<td>1.80</td>
</tr>
<tr>
<td>1.5</td>
<td>1.50</td>
<td>1.50</td>
<td>1.50</td>
<td>1.50</td>
<td>1.50</td>
<td>1.50</td>
</tr>
<tr>
<td>0.7</td>
<td>0.70</td>
<td>0.70</td>
<td>0.70</td>
<td>0.70</td>
<td>0.70</td>
<td>0.70</td>
</tr>
</tbody>
</table>

Note: For standard Tomosynthesis, the CNR correction factors are given in AEC Table 6 and Table 7.

2.0 CNR Correction - Conventional (Magnification)

Note: System default setting in AEC Table 5 is software given in org 1.0 and not shown in Table 5. Selections of 0.7 and 1.5 are shown for reference.

<table>
<thead>
<tr>
<th>Compression Thickness</th>
<th>6.0 mm</th>
<th>6.6 mm</th>
<th>8.0 mm</th>
<th>9.5 mm</th>
<th>10.6 mm</th>
<th>12.7 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Patients</td>
<td>10.5</td>
<td>10.5</td>
<td>10.5</td>
<td>10.5</td>
<td>10.5</td>
<td>10.5</td>
</tr>
<tr>
<td>1.5</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
</tr>
<tr>
<td>0.7</td>
<td>7.5</td>
<td>7.5</td>
<td>7.5</td>
<td>7.5</td>
<td>7.5</td>
<td>7.5</td>
</tr>
</tbody>
</table>

3.0 CNR Correction - Tomosynthesis Option

Note: System default setting in AEC Table 5 is software given in org 1.0 and not shown in Table 5. Selections are given in AEC Table 6 and Table 7.

<table>
<thead>
<tr>
<th>Compression Thickness</th>
<th>All Patients</th>
<th>1.5</th>
<th>0.7</th>
<th>1.5</th>
<th>0.7</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0 mm</td>
<td>1.80</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.6 mm</td>
<td>1.80</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.0 mm</td>
<td>1.80</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.5 mm</td>
<td>1.80</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.6 mm</td>
<td>1.80</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.7 mm</td>
<td>1.80</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Follow the Hologic Selenia Dimensions Quality Control Manual

8. BREAST ENTRANCE EXPOSURE, AEC REPRODUCIBILITY AND AGD

Procedure Highlights

Wait until the image receptor goes from Warming to Ready status.

Use ACR Phantom view to overwrite compression thickness to 4.2 cm.
Procedure Highlights

Test AGD in all three modes
- FFDM
- Tomo
- Combo

Hologic AGD recommended dose for ACR phantom
- FFDM: 1.2 mGy
- Tomo: 1.45 mGy

Performance criteria
- AGD < 3 mGy

Follow the Hologic Selenia Dimensions Quality Control Manual

9. RADIATION OUTPUT RATE

Maximum exposure time under LFS
- 2.5 sec

X-ray tube current at 28 kVp
- 160 mA

Output rate requirement for W/Rh at 4.5 cm above breast platform support
- 230 mR/s (2.0 mGy/s air kerma)
Follow the Hologic Selenia Dimensions Quality Control Manual

10. PHANTOM IMAGE QUALITY EVALUATION

Procedure Highlights

Wait until the image receptor goes from Warming to Ready status

Use ACR Phantom view to overwrite compression thickness to 4.2 cm

Phantom Scoring

Score phantom on AWS display
Review image in full resolution

FFDM scoring
• 5 fibers, 4 specs, 4 masses
• Due to phantom variations: a score of 4.5/4.0/3.5 is acceptable providing SNR and high contrast resolution tests pass

DBT scoring
• Scroll to the slice that puts the different elements in focus
• 4 fibers, 3 specs, 3 masses
11. SNR AND CNR MEASUREMENTS

Follow the Hologic Selenia Dimensions Quality Control Manual

Procedure Highlights

Wait until the image receptor goes from Warming to Ready status
Use ACR Phantom view to overwrite compression thickness to 4.2 cm
ACR Phantom view allows automatic SNR/CNR calculations
Test is performed under FFDM mode only

Automatic Computation
12. DIAGNOSTIC REVIEW
WORKSTATION QUALITY CONTROL

Follow the Hologic Selenia Dimensions Quality Control Manual

Procedure Highlights

The Hologic QC Manual offers an alternative QC procedure for the review workstation
Most review workstation offer their own QC software and QC procedures
Follow their QC procedures and performance requirements

13. DETECTOR GHOSTING
(TROUBLESHOOTING USE ONLY)
**Procedure Highlights**

- Test to be performed if ghosting is noticed on clinical images
- Is not required under acceptance or annual evaluation
- Wait until the image receptor goes from **Warming** to **Ready** status
- Typical reasons for failure
  - Erase LED array failure

**Computation of Ghosting**

\[
\text{Ghost} = \frac{\text{mean } R_3 - \text{mean } R_2}{\text{mean } R_1 - \text{mean } R_2}
\]
How do you biopsy this lesion, occult in 2D and U/S and MRI?

Affirm™
Interventional Add-On Device Utilizing Tomosynthesis Localization
Biopsy: Stereo vs. Tomo-Guided

Stereotactic Biopsy
• Take 2D scout exposure
• Acquire ±30° stereo pairs
• Use triangulation to determine x,y,z lesion location

Tomo-guided Biopsy
• Take Tomo exposure
• Use tomo slices to determine x,y,z lesion location

Tomosynthesis procedure – Target

Tomosynthesis procedure - Target
Prone Biopsy System Technicals

- a-Se detector, 12.5 x 14.3 cm area
- 70 μm pixel size
- Tungsten anode, 200 mA max
- 20-49 kVp
- Al 0.70 mm, Ag 0.050 mm filters
- No anti-scatter grid
- 15° sweep tomo, 30° stereo

Tomo-Guided Biopsy Quality Control

Refers back to 1999 ACR Stereotactic Breast Biopsy QC Manual
Tomo-Guided Biopsy Quality Control

Refers back to 1999 ACR Stereotactic Breast Biopsy QC Manual

<table>
<thead>
<tr>
<th>Test</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>QA/QC Test</td>
<td>Daily - Initially clinical use</td>
</tr>
<tr>
<td>Gain Calibration</td>
<td>Weekly</td>
</tr>
<tr>
<td>Phantom Image Quality Test</td>
<td>Weekly</td>
</tr>
<tr>
<td>Electrolyte Output Quality</td>
<td>Monthly</td>
</tr>
<tr>
<td>Visual Equipment Check</td>
<td>Monthly</td>
</tr>
<tr>
<td>Geometry Calibration</td>
<td>Semi-annually</td>
</tr>
<tr>
<td>Compression</td>
<td>Semi-annually</td>
</tr>
<tr>
<td>Repeat Analysis</td>
<td>Semi-annually</td>
</tr>
</tbody>
</table>

*The signal value should remain within ±10% of the signal obtained for the 4 cm phantom, assuming the signal level for a 4 cm phantom is appropriate.

Digital Mammography QC Program: TRAINING

Required Training
FDA Training Requirements: FFDM

FFDM training is specific to the type of user
Everybody needs FFDM training
• 8 hours for Medical Physicists
• 8 hours for Technologists
• 8 hours for Radiologists

FDA Training Requirements: DBT

DBT is considered a new imaging modality
DBT requires its own training
DBT training is specific to the type of user
Everybody needs additional training
• 8 hours for Medical Physicists
• 8 hours for Technologists
• 8 hours for Radiologists

Medical Physicist DBT Training

8 hours of FFDM training is required
8 hours of DBT training is required
Available training sources
• This AAPM meeting
• MTMI hands-on workshops
• Hologic
  – On-line training
  – Field training during system installation
Facility Certification

2D MQSA certification through ACR or other approved accreditation body
No approved accreditation bodies DBT today
– DBT systems will be accredited under facility’s existing FFDM certification through FDA’s Certification Extension Program
– Facility must be FFDM MQSA certified before applying for DBT extension certification

Certification Extension Program
Division of Mammography Quality and Radiation Programs
FDA/CDRH/OCER
10903 New Hampshire Avenue, WO661
Silver Spring, MD 20903-0002
Phone: 301-796-5710 Fax: 301-847-8502

Quality Control with new ACR Protocol/Phantom

News Releases

FDA Approves New ACR Digital Mammography Quality Control Manual

March 14, 2019

Washington, DC — The Food and Drug Administration (FDA) approved the American College of Radiology’s (ACR) voluntary standard requirements for digital mammography facilities to use the new Digital Mammography Quality Control (QC) device and Digital Mammography QC Phantom in routine QC of digital equipment. The new method and phantom will aid in ensuring uniformity of QC testing.

The FDA requires the mammography field to perform QC of digital imaging equipment twice a week with a QC device, but the frequency of QC testing for digital mammography systems has been inconsistent due to the lack of an appropriate QC phantom. The ACR’s new Digital Mammography QC Phantom is intended to serve as a QC tool that can be used in conjunction with the previously approved ACR mammography QC device. The phantom will aid in ensuring uniformity of QC testing for digital mammography equipment.
Quality Control with new ACR Protocol/Phantom

- Designed to replace the manufacturer’s FFDM QC protocols
- Does not apply to systems with tomosynthesis options
- Does not apply to systems with dual-energy contrast options
- What about clinics with some systems with tomo and other systems FFDM only?

Thank you!

Email: andrew.smith@hologic.com