

**HOLOGIC®**  
The Science of Sure

**Advanced X-ray Breast Imaging**  
*Andy Smith, Ph.D.*  
*Vice President, Image Research*

Hologic 2016. HOLOGIC 1

---

---

---

---

---

---

---

---

**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 2016. HOLOGIC 2

---

---

---

---

---

---

---

---

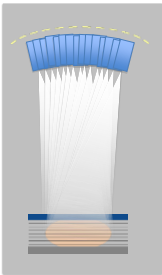
**Hologic Breast Tomosynthesis**

**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



Hologic 2016. HOLOGIC 3

---

---

---

---

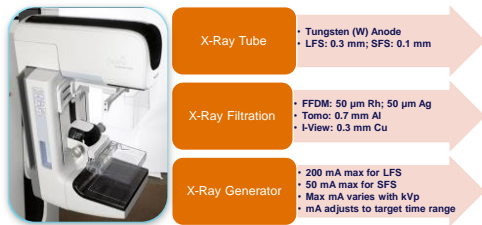
---

---

---

---

### X-Ray Generation




---

---

---

---

---

---

---

---

### Selenia Dimensions: Technicals

#### Conventional 2D Imaging

- a-Se detector, 24x29 cm area
- 70  $\mu$ m pixel size
- Rh and Ag filters
- 20-39 kVp
- HTC grid in contact mode
- No grid in magnification mode

#### Tomosynthesis Imaging

- a-Se detector, 24x29 cm area
- 140  $\mu$ m 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  $\mu$ m pixel size
  - 1 mm slice spacing

---

---

---

---

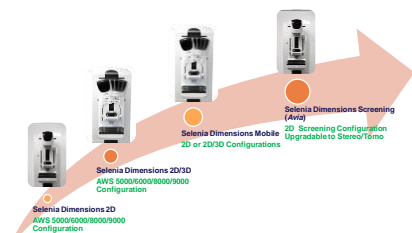
---

---

---

---

### 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, ...)

Hologic 2016 | **HOLOGIC** | 8

---

---

---

---

---

---

---

---

**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**

Hologic 2016 | **HOLOGIC** | 8

---

---

---

---

---

---

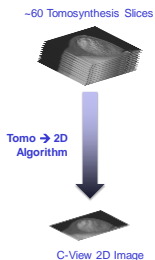
---

---

**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



Hologic 2016 | **HOLOGIC** | 8

---

---

---

---

---

---

---

---

### 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

---

---

---

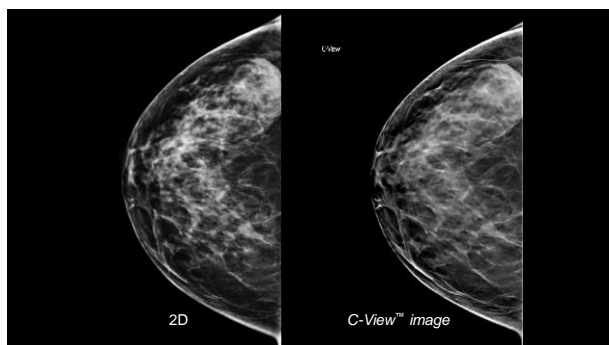
---

---

---

---

---



---

---

---

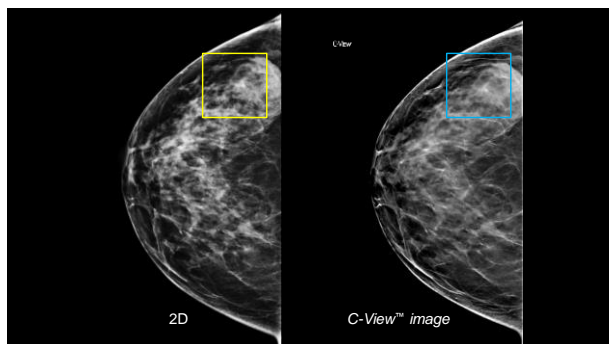
---

---

---

---

---



---

---

---

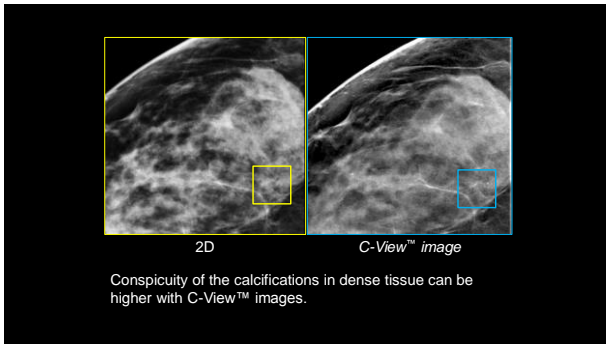
---

---

---

---

---



---

---

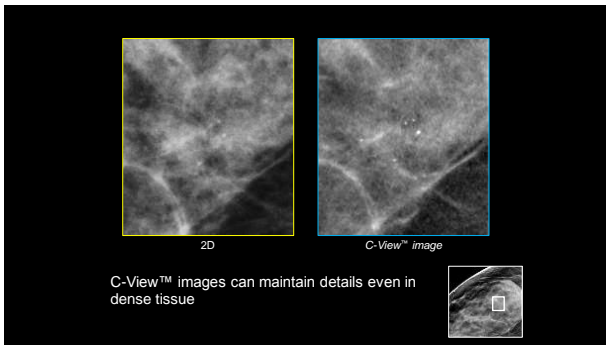
---

---

---

---

---



---

---

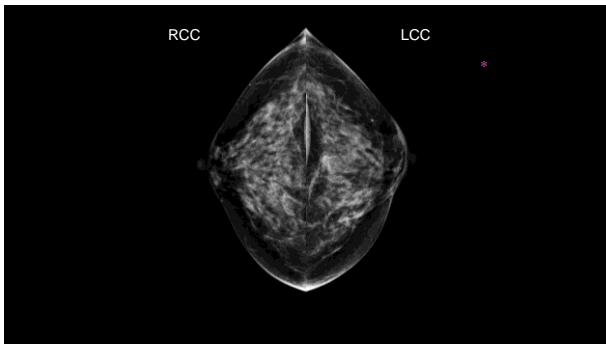
---

---

---

---

---



---

---

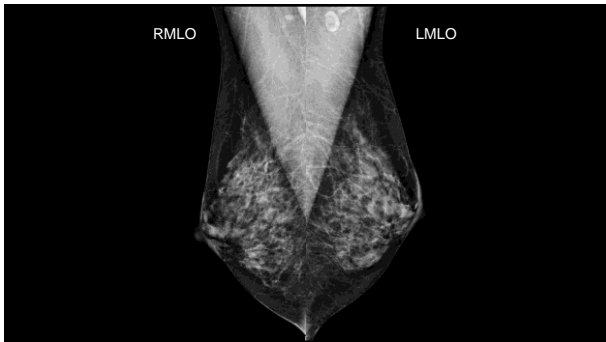
---

---

---

---

---



---

---

---

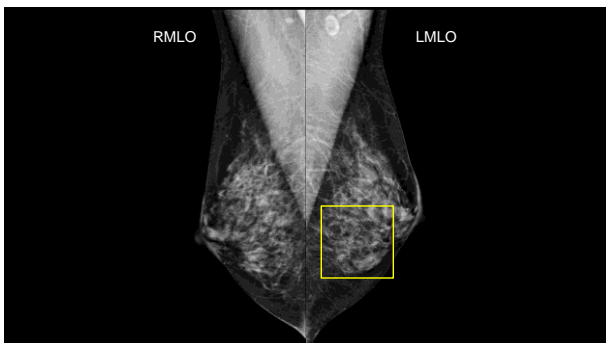
---

---

---

---

---



---

---

---

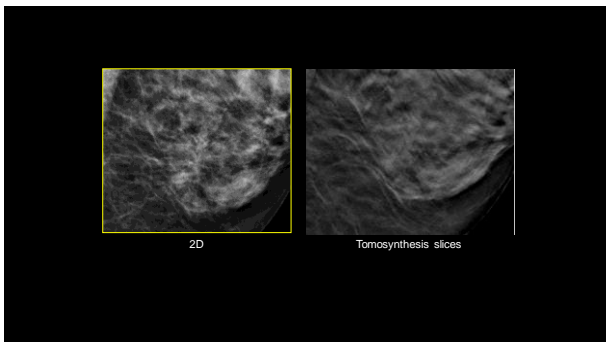
---

---

---

---

---



---

---

---

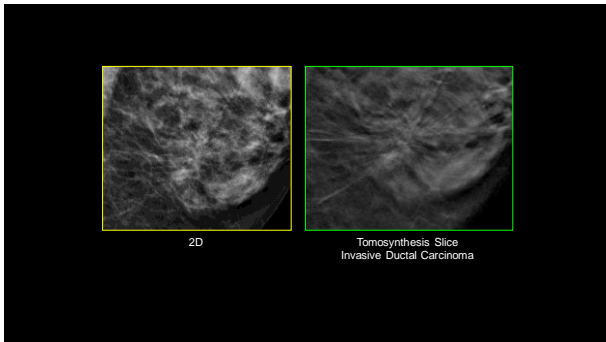
---

---

---

---

---



---

---

---

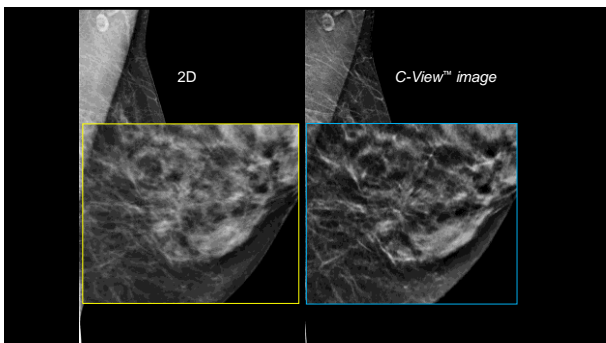
---

---

---

---

---



---

---

---

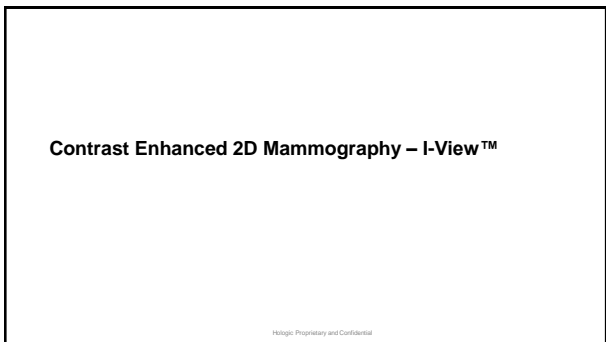
---

---

---

---

---



---

---

---

---

---

---

---

---

### 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
2. High kV (~45-49 kV, Cu filter). Above Iodine's k-edge.

Subtraction gives a 2D iodine contrast image

Repeat as desired

Imaging window ends after ~6 minutes due to contrast redistribution

Hologic Proprietary and Confidential ©image 2016

---

---

---

---

---

---

---

---

### Dual-Energy Subtraction

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

Subtraction = high kV - low kV



- Only the low kV and subtraction images are viewed

©image 2016 HOLOGIC

---

---

---

---

---

---

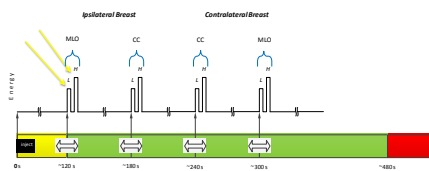
---

---

### CE2D – Dual Energy 2D

Low kV, High kV images acquired for each view

Views can be any order



©image 2016

---

---

---

---

---

---

---

---



### 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

Hologic Proprietary and Confidential Image 2014

---

---

---

---

---

---

---

---

### Combo CE2D – Dual Energy 2D with Tomosynthesis

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

Views can be any order

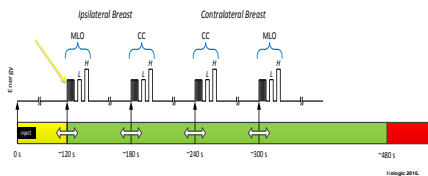


Image 2014

---

---

---

---

---

---

---

---

### Example Image

Courtesy of Andrea Woodroof, Kentucky Breast Care

Hologic Proprietary and Confidential

---

---

---

---

---

---

---

---

### 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

Image: Proprietary and Confidential

---

---

---

---

---

---

---

---

### CE2D for Discordant Findings

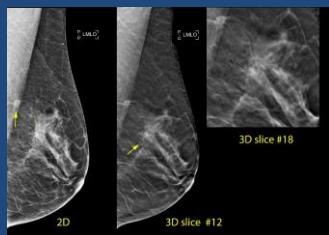


Image: Proprietary and Confidential

---

---

---

---

---

---

---

---

### CE2D for Discordant Findings

- Area of distortion couldn't definitively be correlated on ultrasound for US biopsy

Image: Proprietary and Confidential

---

---

---

---

---

---

---

---

### CE2D for Discordant Findings



---

---

---

---

---

---

---

---

### 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



©Hologic 2016.

---

---

---

---

---

---

---

---

**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



©Hologic 2016.

---

---

---

---

---

---

---

---

**QC Modes**

- **Quality control procedures test**
  - Conventional
  - Tomo
  - Combo
  - I-View™
- **The following modes do not require separate QC testing**
  - C-View™
  - TomoHD
  - ComboHD



©Hologic 2016.

---

---

---

---

---

---

---

---

**DBT QUALITY CONTROL**

**DBT Quality Control**

---

---

---

---

---

---

---

---

---

---

**Medical Physics  
Medical Equipment Evaluation (MEE) Testing**

12 tests to be performed by the medical physicist

5 extra tests that are usually performed by technologist

**Table 1-1: Medical Physicist Installation Quality Control Tests**

Quality Control Test	Frequency	Action Criteria	Chapter 2
Mammographic Unit Assembly Evaluation	Annually	Chapter 2, Section 1.8, page 10	Mammography Diagnostic Radiology Technologist Section
Collimator Assessment	Annually	Chapter 2, Section 1.8, page 10	
Artifacts Evaluation	Annually	Chapter 2, Section 1.8, page 10	
VFP Accuracy & Reproducibility	Annually	Chapter 2, Section 1.8, page 10	
Beam Quality Assessment - HV	Annually	Chapter 2, Section 1.8, page 10	
Declaration of System Readiness	Annually	Chapter 2, Section 1.8, page 10	
RF Spurious Interference	Annually	Chapter 2, Section 1.8, page 10	
Beam Entrance Exposure, AEC, Reproducibility and Average Glanular Dose	Annually	Chapter 2, Section 1.8, page 10	
Radiation Output Rate	Annually	Chapter 2, Section 1.8, page 10	
Fluoroscopic Image Quality Evaluation	Annually	Chapter 2, Section 1.8, page 10	
Signal to Noise and Contrast to Noise	Annually	Chapter 2, Section 1.8, page 10	
Diagnostic Beam Characteristics Quality Control	Annually	Chapter 2, Section 1.8, page 10	
DR-ORM System Quality Control (Radiologic Technologist section)	Annually	Chapter 2, Section 1.8, page 10	Diagnostic Radiology Technologist Section
Detector Flat Field Calibration (Radiologic Technologist section)	Annually	Chapter 2, Section 1.8, page 10	
Geometry Calibration for Amorphous Silicon (Radiologic Technologist section)	Annually	Chapter 2, Section 1.8, page 10	
Compton Scatter Index rate (Radiologic Technologist section)	Annually	Chapter 2, Section 1.8, page 10	
Compton Scatter (Radiologic Technologist section)	Annually	Chapter 2, Section 1.8, page 10	

8/10/16, 2016

---

---

---

---

---

---

---

---

---

---

**Medical Physics  
QC Tests**

12 tests to be performed by the medical physicist

7 of them have DBT components/requirements

**Table 1-2: Quality Control Tests to be Performed by the Medical Physicist on Systems**

Quality Control Test	Frequency	Action Criteria	Chapter 2
Mammographic Unit Assembly Evaluation	Annually	Chapter 2, Section 1.8, page 10	Mammography Diagnostic Radiology Technologist Section
Collimator Assessment	Annually	Chapter 2, Section 1.8, page 10	
Artifacts Evaluation	Annually	Chapter 2, Section 1.8, page 10	
VFP Accuracy & Reproducibility	Annually	Chapter 2, Section 1.8, page 10	
Beam Quality Assessment - HV	Annually	Chapter 2, Section 1.8, page 10	
Declaration of System Readiness	Annually	Chapter 2, Section 1.8, page 10	
RF Spurious Interference	Annually	Chapter 2, Section 1.8, page 10	
Beam Entrance Exposure, AEC, Reproducibility and Average Glanular Dose	Annually	Chapter 2, Section 1.8, page 10	
Radiation Output Rate	Annually	Chapter 2, Section 1.8, page 10	
Fluoroscopic Image Quality Evaluation	Annually	Chapter 2, Section 1.8, page 10	
Signal to Noise and Contrast to Noise	Annually	Chapter 2, Section 1.8, page 10	
Diagnostic Beam Characteristics Quality Control	Annually	Chapter 2, Section 1.8, page 10	
Detector Flat Field Calibration (Annually)	Annually	Chapter 2, Section 1.8, page 10	Diagnostic Radiology Technologist Section
Geometry Calibration for Amorphous Silicon (Annually)	Annually	Chapter 2, Section 1.8, page 10	
Compton Scatter Index rate (Annually)	Annually	Chapter 2, Section 1.8, page 10	
Compton Scatter (Annually)	Annually	Chapter 2, Section 1.8, page 10	
Beam Entrance Exposure, AEC, Reproducibility and Average Glanular Dose (Annually)	Annually	Chapter 2, Section 1.8, page 10	
Radiation Output Rate (Annually)	Annually	Chapter 2, Section 1.8, page 10	
Fluoroscopic Image Quality Evaluation (Annually)	Annually	Chapter 2, Section 1.8, page 10	

8/10/16, 2016

---

---

---

---

---

---

---

---

---

---





### Hologic QC Manuals

**MAN-01965**  
R008

**MAN-03706**  
R002

**MAN-01476**  
R001

- <http://www.hologic.com/support/dimensions-3d-breast-tomosynthesis-dimensions-2d-full-field-digital-mammography>
- <http://www.hologic.com/support/selenia-digital-mammography>

Hologic 2016

---

---

---

---

---

---

---

---

---

---

### 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

Hologic 2016

---

---

---

---

---

---

---

---

---

---

### 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*

Hologic 2016

---

---

---

---

---

---

---

---

---

---



### 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*



©Hologic 2016

---

---

---

---

---

---

---

---

### 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*



©Hologic 2016

---

---

---

---

---

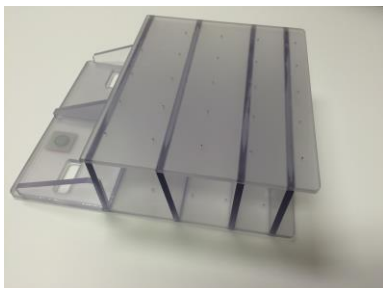
---

---

---

### Tomosynthesis-Specific Quality Control

- Tomo Geometry Calibration
- Usually performed by technologist



©Hologic 2016

---

---

---

---

---

---

---

---





Follow the 1999 ACR Mammography Quality Control Manual

### 1. MAMMOGRAPHIC UNIT ASSEMBLY EVALUATION

Hologic 2016

---

---

---

---

---

---

---

---



Follow the Hologic Selenia Dimensions Quality Control Manual

### 2. COLLIMATOR ASSESSMENT

Hologic 2016

---

---

---

---

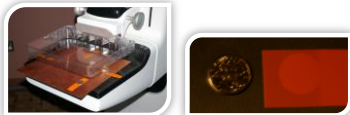
---

---

---

---

#### 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)

Hologic 2016

---

---

---

---

---

---

---

---



### 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

Hologic 2016.

---

---

---

---

---

---

---

---

### 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

Hologic 2016.

---

---

---

---

---

---

---

---



Follow the *Hologic Selenia Dimensions Quality Control Manual*

### 3. ARTIFACT EVALUATION

Hologic 2016.

---

---

---


---

---

---

---



---

 **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

Hologic 2016

---

---

---


---


---

---

---

---





Follow the 1999 ACR Mammography Quality Control Manual

**4. KVP ACCURACY AND REPRODUCIBILITY**

Hologic 2016

---

---

---


---


---

---

---

---

 **Procedure Highlights**



Conventional Tomo Stationary Tomo

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

Hologic 2016

---

---

---


---


---

---

---

---





Follow the *1999 ACR Mammography Quality Control Manual*

### 5. BEAM QUALITY ASSESSMENT— HVL MEASUREMENT

Hologic 2016

---

---

---


---

---


---


---


---



#### Procedure Highlights

  
Conventional

  
Tomo

  
Stationary Tomo

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  
 [HVL > (kVp/100) + 0.03] in mm Al

Hologic 2016

---

---

---


---


---

---

---

---





Follow the *Hologic Selenia Dimensions Quality Control Manual*

### 6. EVALUATION OF SYSTEM RESOLUTION

Hologic 2016

---

---

---

---

---

---

---

---



### 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:

FFDM: > 7 lp/mm @ 45°

DBT: > 3 lp/mm @ 45°



Hologic 2016

---

---

---

---

---

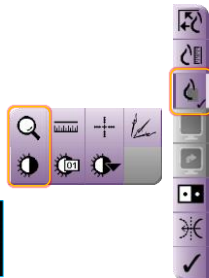
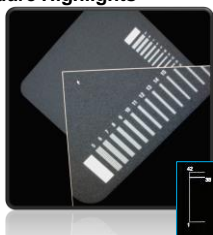
---

---

---



### Procedure Highlights



Hologic 2016

---

---

---

---

---

---

---

---



Follow the Hologic Selenia Dimensions Quality Control Manual

## 7. AEC FUNCTION PERFORMANCE

Hologic 2016

---

---

---

---

---

---

---

---

### AEC Function Description

#### AEC modes

- Auto-Filter
- Auto-kV
- Auto-Time

#### AEC positions

- Auto AEC: two ~1cm<sup>2</sup> floating sensors in 5 x 14cm<sup>2</sup> 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

Hologic 2016.

---

---

---

---

---

---

---

---



### 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



Hologic 2016.

---

---

---

---

---

---

---

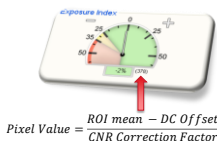
---

### 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)



$$\text{Pixel Value} = \frac{\text{ROI mean} - \text{DC Offset}}{\text{CNR Correction Factor}}$$

Hologic 2016.

---

---

---

---

---

---

---

---



### CNR Correction Factors, FFDM

**LFS**

**1.0 CNR Correction – Conventional (Contact)**

Note: System default setting is AEC Table 4 for imaging under contact mammography.

**AEC Table 4 (Uniform CNR Screening Dose)**

Compression	Prior to Software Rev 1.7.x		After Software Rev 1.7.x	
	All Detectors	Detectors Serial #: X18xxxx	Detectors Serial #: X18xxxx	Detectors Serial #: X18xxxx
2.0 cm	1.00	1.00	1.00	1.00
4.0 cm	1.00	1.00	1.00	1.00
6.0 cm	1.30	1.30	1.35	1.35
8.0 cm	1.70	1.70	1.70	1.82

---

---

---

---

---

---

---

---

### CNR Correction Factors, FFDM

**SFS**

**2.0 CNR Correction - Conventional (Magnification)**

Note: System default setting is AEC Table 0 for software prior to rev 1.7.x and AEC Table 6 for software after rev 1.7.x when imaging under magnification mammography.

**AEC Table 6 (Enhanced Magnification Dose)**

Compression	Prior to Software Rev 1.7.x		After Software Rev 1.7.x	
	All Detectors	Detectors Serial #: X18xxxx	Detectors Serial #: X18xxxx	Detectors Serial #: X18xxxx
2.0 cm	N/A	1.50	1.50	1.50
4.0 cm	N/A	1.50	1.50	1.50
6.0 cm	N/A	1.50	1.55	1.55
8.0 cm	N/A	1.50	1.67	1.67

---

---

---

---

---

---

---

---

### CNR Correction Factors, FFDM

**LFS**

**3.0 CNR Correction - Tomosynthesis Option**

Note: System default setting is AEC Table 0 for imaging under digital breast tomosynthesis.

**AEC Table 0 (Standard Tomosynthesis Dose)**

Compression	Prior to Software Rev 1.7.x		After Software Rev 1.7.x	
	All Detectors	Detectors Serial #: X18xxxx	Detectors Serial #: X18xxxx	Detectors Serial #: X18xxxx
2.0 cm	0.70	0.70	0.70	0.70
4.0 cm	0.92	0.92	0.92	0.92
6.0 cm	1.46	1.46	1.55	1.55
8.0 cm	2.37	2.37	2.37	2.78

---

---

---

---


---

---

---

---

**Calculation Example**



Contact Imaging, Tomo										
Phantom thickness	AEC Mode	Fiber	KVP	mAs	Exp Corr	RCR Mean Value	CNR Factor	Pixel Value		
2 cm	Auto-Mtr	AI	26	32	0	207	0.7	224		
4 cm	Auto-Mtr	AI	29	45	0	252	0.91	222		
6 cm	Auto-Mtr	AI	33	61	0	305	1.46	216		
8 cm	Auto-Mtr	AI	38	74	0	365	2.37	218		
<b>Mean Pixel Value</b>										
220										
<b>Pixel Value Range</b>										
216										
<b>Pass/Fail</b>										
Pass										
<b>Allowed Pixel Value</b>										
198										
<b>Pixel Value = (ROI mean - DC offset (50)) / (CNR Correction Factor)</b>										
<b>Action Limit:</b>	If the pixel value of each individual image corresponding to a breast thickness between 2 and 8 cm at any operating mode varies more than 10% of the mean pixel value computed for all tested breast thicknesses and operating modes, seek service.									

Hologic 2016.

---

---

---

---

---



---

---

---

---

---

Follow the Hologic *Selenia Dimensions Quality Control Manual*

## 8. BREAST ENTRANCE EXPOSURE, AEC REPRODUCIBILITY AND AGD

Hologic 2016.

---

---

---

---

---


---

---

---


---

---

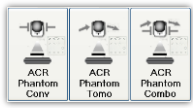


### Procedure Highlights

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



Use **ACR Phantom** view to overwrite compression thickness to 4.2 cm



Hologic 2016.

---

---

---

---

---

---

---

---

---

---

**TOMO TV**

**Procedure Highlights**

**Test AGD in all three modes**

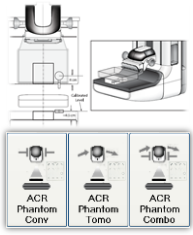
- FFDM
- Tomo
- Combo

**Hologic AGD recommended dose for ACR phantom**

- FFDM: 1.2 mGy
- Tomo: 1.45 mGy

**Performance criteria**

- AGD < 3 mGy



Hologic 2016

---

---

---


---

---

---

---

---



Follow the Hologic *Selenia Dimensions Quality Control Manual*

**9. RADIATION OUTPUT RATE**

Hologic 2016

---

---

---

---

---

---

---

---

**Procedure Highlights**

**Maximum exposure time under LFS**

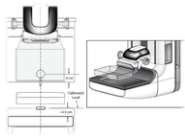
- 2.5 sec

**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)



Hologic 2016

---

---

---



---

---

---

---

---

Follow the Hologic *Selenia Dimensions Quality Control Manual*

## 10. PHANTOM IMAGE QUALITY EVALUATION

Hologic 2014

---

---

---


---

---

---


---

---




### 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



Hologic 2014

---

---

---


---

---

---

---

---



### Phantom Scoring

Score phantom on AWS display

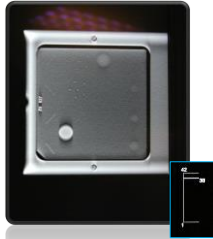
Review image in full resolution

#### 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



Hologic 2014

---

---

---

---

---

---

---

---



Follow the Hologic *Selenia Dimensions Quality Control Manual*

## 11. SNR AND CNR MEASUREMENTS

Hologic 2016

---

---

---

---

---

---

---

---

### 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



Hologic 2016

---

---

---

---

---

---

---

---

### Automatic Computation



Hologic 2016

---

---

---

---

---

---

---

---



Follow the Hologic *Selenia Dimensions Quality Control Manual*

### 12. DIAGNOSTIC REVIEW WORKSTATION QUALITY CONTROL

Hologic 2016

---

---

---

---

---

---

---

---

#### 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



Hologic 2016

---

---

---

---

---

---

---

---



Follow the Hologic *Selenia Dimensions Quality Control Manual*

### 13. DETECTOR GHOSTING (TROUBLESHOOTING USE ONLY)

Hologic 2016

---

---

---

---

---

---

---

---

**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

©Kipco 2016

---

---

---

---

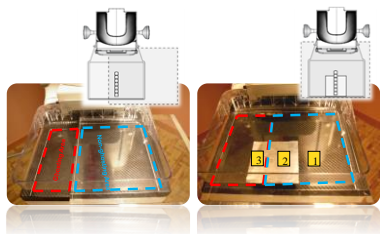
---

---

---

---

**Procedure Highlights**



©Kipco 2016

---

---

---

---

---

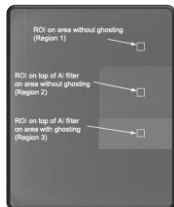
---

---

---

**Computation of Ghosting**

$$Ghost = \frac{mean_{R3} - mean_{R2}}{mean_{R1} - mean_{R2}}$$



©Kipco 2016

---

---

---

---

---

---

---

---

### Tomo-guided Biopsy



---

---

---

---

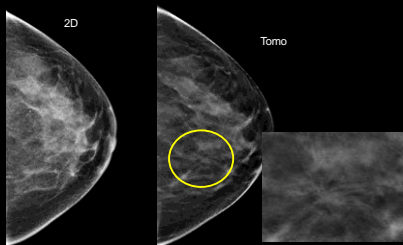
---

---

---

---

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  $\pm 30^\circ$  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



Hologic 2016. HOLOGIC 37

---

---

---

---

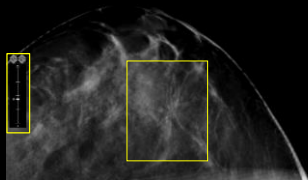
---

---

---

---

**Tomosynthesis procedure – Target**



HOLOGIC 38

---

---

---

---

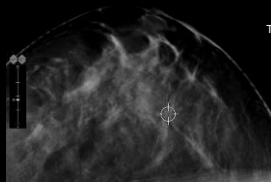
---

---

---

---

**Tomosynthesis procedure - Target**



Targeting      Lesion coordinates



HOLOGIC 39

---

---

---

---

---

---

---

---

### Prone Tomosynthesis-Guided Breast Biopsy



8/2/2016 Hologic 100

---

---

---

---

---

---

---

---

### Prone Biopsy System Technicals

- a-Se detector, 12.5 x 14.3 cm area
- 70  $\mu$ m 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

8/2/2016 Hologic 101

---

---

---

---

---

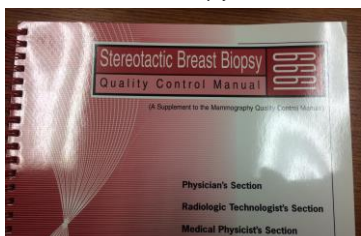
---

---

---

### Tomo-Guided Biopsy Quality Control

Refers back to 1999 ACR Stereotactic Breast Biopsy QC Manual



8/2/2016 Hologic 102

---

---

---

---

---

---

---

---

### Tomo-Guided Biopsy Quality Control

Refers back to 1999 ACR Stereotactic Breast Biopsy QC Manual

Test	Frequency
QA5 Test	Daily - before clinical use
Gain Calibration	Weekly
Phantom Image Quality Test*	Weekly
Hardcopy Output Quality Test	Monthly
Visual Equipment Check	Monthly
Geometry Calibration	Semi-annually
Compression	Semi-annually
Repeat Analysis	Semi-annually

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

HOLOGIC 103

---

---

---

---

---

---

---

---

---

---



### Digital Mammography QC Program: TRAINING

HOLOGIC  
The Complete Mammography Solution

---

---

---

---

---

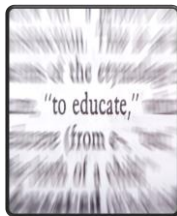
---

---

---

---

---



### Required Training

HOLOGIC

---

---

---

---

---

---

---

---

---

---

**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

Hologic 2016

---



---



---



---



---



---



---

**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

Hologic 2016

---



---



---



---



---



---



---

**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

Hologic 2016

---



---



---



---



---



---



---

### 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/DCSR  
 10903 New Hampshire Avenue, W066-4621  
 Silver Spring, MD 20903-0002  
 Phone: 301-796-5710 Fax: 301-847-8502*

8/16/16

---

---

---

---

---

---

---

---

### Quality Control with new ACR Protocol/Phantom

8/16/16 Hologic 110

---

---

---

---

---

---

---

---

### Quality Control with new ACR Protocol/Phantom

#### News Releases

#### FDA Approves New ACR Digital Mammography Quality Control Manual

March 09, 2016

Washington, DC — The Food and Drug Administration (FDA) approved the American College of Radiology's (ACR's) alternative standard request to allow mammography facilities to use the new Digital Mammography Quality Control (QC) Manual and Digital Mammography QC Phantom in routine QC of digital equipment. The new manual and phantom will aid in ensuring uniformity of QC testing.

The FDA requires digital mammography facilities to perform QC for approved imaging

8/16/16 Hologic 111

---

---

---

---

---

---

---

---

### 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?

Hologic 2016. HOLOGIC 112

---

---

---

---

---

---

---

---

**Thank you!**

**Email:**  
[andrew.smith@hologic.com](mailto:andrew.smith@hologic.com)

Hologic 2016. HOLOGIC 113

---

---

---

---

---

---

---

---



HOLOGIC 114

---

---

---

---

---

---

---

---