

# X-ray Gantry Specifications

## Gantry Mechanics

C-Arm	
Design <sup>■</sup>	Split C-arm, biopsy and tomosynthesis capable
Vertical Range	70.5 cm +5.1/-0 cm (27.75 in +2.0/-0 in) to 141 cm +0/-17.8 cm (55.5 in +0/-7.0 in)
Vertical Travel	Motorised
Rotation	2D: +195° to -155° Biopsy and 3D: +180° to -140°
Source-Image Distance (SID)	70 cm <b>3.2.7</b>
Patient Face Shield	2D: Removable 3D: Retractable and removable
Breast Compression	
Modes of Operation	Selected by Operator
Pre-compression Range	70 to 134 N (15.6 lbs to 30 lbs)
Full-compression Range	89 to 178 N (20 lbs to 40 lbs)
Dual-compression Function	1st activation: pre-compression Subsequent activations: incremental increase up to full-compression
Manual-compression Force Limit	300 N (67.4 lbs) maximum
Compression Tilt	Standard or FAST Paddle™ system, User-selectable
Magnification <sup>+</sup>	
Platform	Lightweight carbon fiber with frame
Magnification Factors	1.5x, 1.8x <b>3.3.6</b>
X-ray Collimation	
Collimation Modes	Fully-automatic or User-selectable
Pre-defined Collimation Sizes	24x29 cm, 18x24 cm 15x15 cm, 10x10 cm, 7x8.5 cm, <sup>+</sup> 18x29 cm <sup>+</sup>

## Digital Image Receptor **3.3**

Technology	
Type	TFT-based direct capture <b>2, 3.3.1</b>
X-ray Absorption Material	Amorphous selenium <b>3.3.1</b>
Image Receptor Size	Single plate 24 cm x 29 cm <b>3.3.2</b>
Pixel Size <b>3.3.3</b>	70 microns (2D), 100 microns (Tomo)
Limiting Spatial Resolution	2D: 7.1 lp/mm <b>3.3.4</b> 3D: 3.5 lp/mm
Dynamic Range	Linear response over 400:1 in X-ray exposure
Captured Image Bit Depth	14-bits
Saturation X-ray Exposure Level	> 500 mR
Image Capture Geometry	
Non-magnified	24 cm x 29 cm (3328 x 4096) center position 18 cm x 24 cm (2560 x 3328) left, center and right positions
Magnified	18 cm x 24 cm (2560 x 3328) center position
Anti-scatter Grid	
Grid Structure	HTC™ High Transmission Cellular Grid
Grid Behavior <b>3.3.5</b>	Auto-retracts for magnified 2D and all 3D views
Storage Environment	
Storage Temperature Range	10° C to 30° C (50° F to 86° F)
Maximum Rate of Temperature Change	< 10° C per hour
Relative Humidity Range	10% to 80%, non-condensing

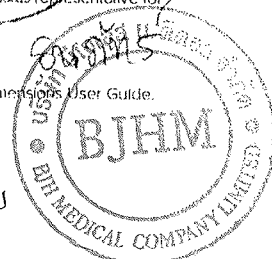
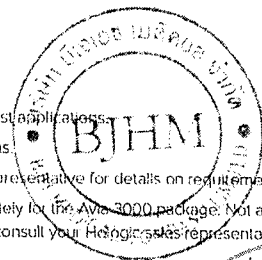
## X-ray Subsystem

Integrated Generator	
Design	Zero footprint, fully integrated
Type <b>3.1.1</b>	Constant Potential High Frequency Inverter
Rating	7.0 kW max. (ISOWatt); 200 mA @ 35 kV
Electrical Power Capacity	9.0 kW max. <b>3.1.1</b>
kV Range <b>3.1.2</b>	2D: 20 to 39 kV, 2D, 1 kV steps (0.5 kV steps option) 3D: 20 to 49 kV, 2D, 1 kV steps <sup>+</sup>
mAs Range <b>3.1.3</b>	3.0 to 500 mAs
mA Range <b>3.1.4</b>	200 mA, large focal spot 50 mA, small focal spot <sup>+</sup>
X-ray Tube	
Anode Type <b>3.2.2</b>	Tungsten, rotating
Anode Design <b>3.2.2</b>	Bi-angular
Anode Speed <b>3.2.1</b>	9500 RPM (high speed)
Heat Capacity <b>3.2.3</b>	222 kJ (300,000 HU)
Target Tube Angle	16°, large focal spot; 10°, small focal spot <sup>+</sup>
Focal Spot Size <b>3.2.4</b>	0.3 mm, large focal spot; 0.1 mm, small focal spot <sup>+</sup>
Filtration <b>3.2.5</b>	0.05 mm Rhodium (Rh) 0.05 mm Silver (Ag) 0.70 mm Aluminum (Al) (3D) <sup>+</sup> 0.30 mm Copper (Cu) (CE2D) <sup>+</sup>
Port <b>3.2.6</b>	0.63 mm Beryllium
Electrical Requirements	
Input Line Voltage	200/208/220/230/240 VAC
Input Current	3.5 A standby 65 A for 5 s at 208 VAC 40 A max. breaker rating
Frequency	50/60 Hz ± 5%
Number of Phases	Single, permanently wired

## X-ray Control

Exposure Modes	
Manual	User selects all parameters
Auto-Time <b>2</b>	System selects mAs; User selects filter, kV
Auto-kV	System selects kV, mAs; User selects filter
Auto-Filter	System selects filter, kV, mAs
X-ray Activation	Single exposure, either table-top button or integrated footswitch <sup>+</sup>

- - Included capability.
- - Optional capability, sold separately.
- ▲ - Recommended for biopsy and contrast applications.
- ◆ - Not available for mobile configurations.
- ✦ - Please consult your Hologic sales representative for details on requirements.
- - Optional future capability, sold separately for the Avio 3000 package. Not available at the time of initial purchase. Please consult your Hologic sales representative for details on additional requirements.
- \* - At time of initial order only.



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## Overall System Specifications

### General Operating Conditions

Temperature Range	20°C to 30°C
Max. Rate of Temperature Change	<10°C / hr
Relative Humidity Range	20% to 80% non-condensing

### Electrical Specifications

System Protection	
Integrated UPS †	1000 VA
Electrical Requirements	
Input Line Voltage 3.4.10	100/120/220/230/240 VAC
Input Current	2.0 A max. @ 200/220/230/240 VAC 3.5 A max. @ 100/120 VAC
Frequency 3.4.10	50/60 Hz

### General Specifications 3.4

Computer and Reconstruction Subsystem	
Design	Fully integrated, zero footprint
CPU Type 3.4.1	Multi-core Intel
Memory 3.4.2	8 GB RAM (min.) 16 GB RAM (max.)
Hard Drive 3.4.3	1.0 TB (min.)
Operating System	Win 7/64 Embedded
Ethernet	10/100/1000 base-T
Removable Storage 3.4.4	CD/DVD +/- R/W
USB Ports	Dual USB 2.0
Local Image Buffer Capacity	
Image buffer 3.4.8	2D: ~9,000 4-view studies; 3D: ~3,000
Graphics Processors ††	
Advanced capabilities	Generated 2D Imaging

### Additional Options\*

Biopsy ††	
Affirm™ breast biopsy guidance system	
Affirm stereotactic biopsy additional system license	
Affirm 3D biopsy license	
Affirm 3D biopsy additional system license	
Advanced Diagnostics ††	
I-View software license for Contrast Enhanced 2D Imaging	
Advanced Imaging †	
C-View software license for Low-dose 3D MAMMOGRAPHY Imaging	
Image Analytics	
Cenova® server	
ImageChecker® 2D and C-View 2D CAD License	
ImageChecker 3D CAD License*	
Quantra™ 2D and 3D breast density analysis software licenses	

### Documentation

Manuals and Reference Documents	
User Manual 4.1.11	
Service Manual 4.1.11	
Quality Control Manual	
DICOM Conformance Statement	

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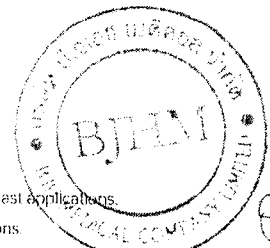
## System Options and Accessories

### 4.4.1

### Paddles and Accessories

Selenia Dimensions Packages					
	Avia 2D 3000	2D 6000	2D 9000	3D 6000	3D 9000
Screening Compression Paddles					
24x29 cm Screening Paddle 4.1.2	●	●	●	●	●
18x24 cm Screening Paddle 4.1.1	○	○	○	○	○
Small Breast Screening Paddle 4.1.6	○	○	○	○	○
Diagnostic Compression Paddles					
10 cm Contact Paddle	○	●	●	●	●
15 cm Contact Paddle	○	○	○	○	○
7.5 cm Spot Contact Paddle 4.1.3	○	○	●	○	●
Frameless Spot Contact Paddle	○	○	●	○	●
Magnification Compression Paddles					
10 cm Magnification Paddle 4.1.5	○	●	●	●	●
15 cm Magnification Paddle	○	○	○	○	○
7.5 cm Spot Magnification Paddle	○	○	●	○	●
Localisation Compression Paddles					
10 cm Open Localisation Paddle	○	○	○	○	○
15 cm Open Localisation Paddle	○	○	○	○	○
10 cm Open Magnification Localisation Paddle	○	○	○	○	○
10 cm Perforated Localisation Paddle	○	○	○	○	○
15 cm Perforated Localisation Paddle	○	○	○	○	○
10 cm Perforated Magnification Localisation Paddle	○	○	○	○	○
Ultrasound Compression Paddles					
Ultrasound Paddle	○	○	○	○	○
Imaging Accessories					
Magnification Platform 4.1.4	○	●	●	●	●
Localisation Cross-hairs	○	○	○	○	○
Magnification Localisation Cross-hairs	○	○	○	○	○
Other Accessories					
Dual-function footswitches (2) 4.1.7	○	●	●	●	●

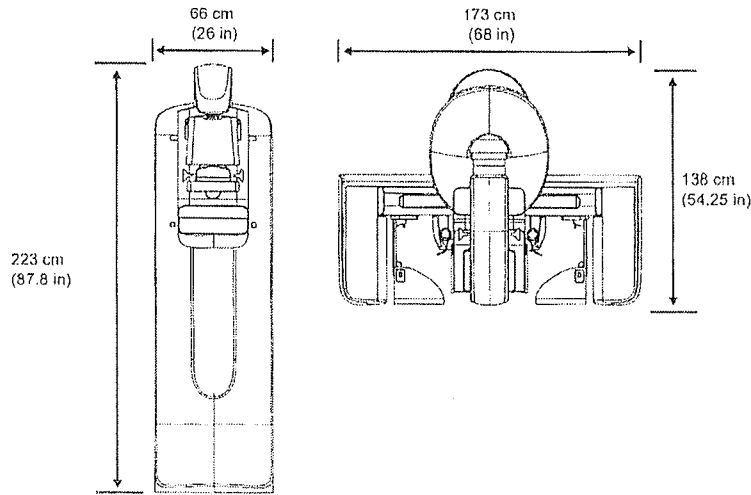
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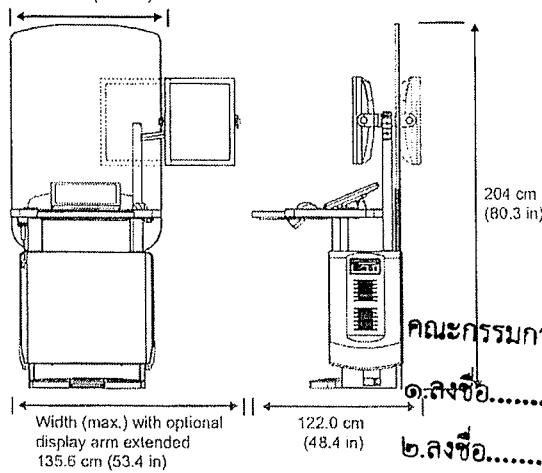
Not FDA approved or available for sale in the U.S.

**Selenia Dimensions System**

Optional equipment shown.



Width (max.) with standard display arm 93.8 cm (36.9 in)



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Complimentary site planning is available with your purchase, including connectivity planning and custom room drawings.

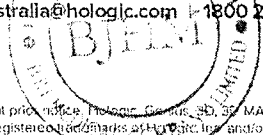
1. Friedewald S, Rafferty E, Rose S, et al. "Breast Cancer Screening using Tomosynthesis in Combination with Digital Mammography." Journal of the American Medical Association. 2014 July;311(24):2499-2507. Epub 2014 June 24. 2. Skarac P, Bandos A, Guillen P, et al. "Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program." Radiology. 2013 Apr; 267(1):47-56. Epub 2013 Jan 7. 3. Clotte S, Houssami N, Bernard D, et al. "Integration of 3D Digital Mammography with Tomosynthesis for Population Breast-Cancer Screening (STORM): A Prospective Comparison Study." The Lancet Oncology. 2013 Jun;14(7):583-589. Epub 2013 Apr 25. 4. Rose S, Tidwell A, Bujnock L, et al. "Implementation of Breast Tomosynthesis in a Routine Screening Practice: An Observational Study." American Journal of Roentgenology. 2013 Jun; 200(6): 1401-1408. Epub 2013 May 22. 5. McCarthy A, Kantos D, Synnestvedt M, et al. "Screening outcomes following implementation of digital breast tomosynthesis in a general-population screening program." J Natl Cancer Inst. 2014 Oct 13;106(11). 6. Greenberg J, Javitt M, Katzen J, et al. "Clinical Performance Metrics of 3D Digital Breast Tomosynthesis Compared With 2D Digital Mammography for Breast Cancer Screening in Community Practice." AJR Am J Roentgenol. 2014 Sept; 203:687-693. Epub 2014 Jun 11. 7. Zuley M, Bandos A, Ganott M, et al. "Digital Breast Tomosynthesis versus Supplemental Diagnostic Mammographic Views for Evaluation of Noncalcified Breast Lesions." Radiology. 2013 Jan; 266(1):89-95. Epub 2012 Nov 9. 8. Brodersen J, Siersma V. "Long-Term Psychosocial Consequences of False-Positive Screening Mammography." The Annals of Family Medicine 2013 Mar; 11(2):105-15. 9. Aicovsky M, Philipotts L, Bonafede M, et al. "The patient burden of screening mammography recall." J Womens Health 2014 Sep; 23 Suppl 1511-9. 10. Bonafede M, Miller J, Lenhart G, et al. "Health Insurer Burden of Patient Recall Following Breast Cancer Screening Mammography: Potential Impact of 3D Mammography." Value Health 2014 May; 17(3): AB2. 11. Kalia V, Haas B, Farnan H, et al. "Cost-Effectiveness of Digital Breast Tomosynthesis." Paper presented at the annual meeting of the Radiological Society of North America, Chicago, IL, November 2012. 12. Rafferty E, Park J, Philipotts L, et al. "Assessing Radiologist Performance Using Combined Digital Mammography and Breast Tomosynthesis Compared with Digital Mammography Alone: Results of a Multicenter, Multireader Trial." Radiology. 2013 Jan; 266(1):104-13. Epub 2012 Nov 20. 13. FDA PMA submission P080003

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**Breast and Skeletal Health**

Genius 3D MAMMOGRAPHY exams are only available on the Hologic Selenia Dimensions 3D system.

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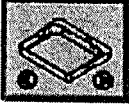
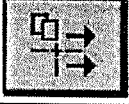


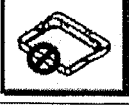

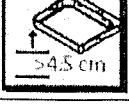



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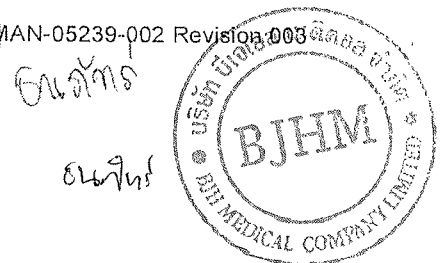
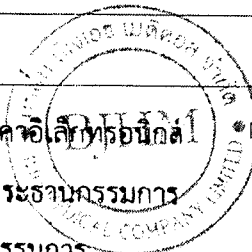
B.2.2 System Messages **3.2.8**

When the following system messages show, do the step shown in the User Action column to clear the message and allow the next exposure.

Table 22: System Messages



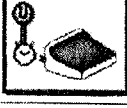





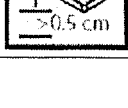
Icon	Message	User Action
	Paddle is moving	No action needed.
	Sending notice	No action needed.
	Invalid use of Magnification Stand	You selected a tomographic view with the Magnification Stand installed. Select a non-tomographic view. (Tomosynthesis option)
	Face shield is not secured	Fully extend or fully retract the Face Shield. (Tomosynthesis option)
	Invalid use of compression paddle	Remove the Magnification Stand or install the Magnification Paddle.
	Paddle position does not match selected view	Shift the Paddle to the correct location for the selected view.
	Compression is less than 4.5 cm during calibration	Move the Compression Paddle higher than 4.5 cm to complete the calibration procedure.
	FAST compression is engaged	Disengage FAST compression and install a paddle designated for this mode.
	License is missing	A license is necessary to use this feature or function. (This message is for your information only. There are no user actions.)
	Invalid detector calibration	Install the Magnification Stand for Small Focal Spot calibration. Remove the Magnification Stand to do Large Focal Spot calibration.

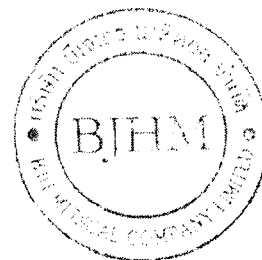
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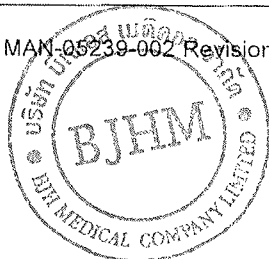
Table 22: System Messages

Icon	Message	User Action
	Invalid geometry calibration	Repeat the geometry calibration before you try to take an exposure. (Tomosynthesis option)
	Configuration file is missing	Applies to Service Personnel.
	Waiting for Detector	No action needed.
	System in Test Mode	Applies to Service Personnel.
	Tube needs to be manually positioned (move to 0 degrees)	Rotate the C-arm to 0 degrees.
	Tube needs to be manually positioned (move to -15 degrees)	Rotate the C-arm to -15 degrees.
	Tube needs to be manually positioned (move to 15 degrees)	Rotate the C-arm to +15 degrees.
	The Emergency Stop switch has been engaged.	Turn the Emergency Off switch one-quarter turn to reset the switch.
	Compression too low for tomo reconstructions.	Move the Compression Paddle higher than 0.5 cm to take tomography exposures.



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# ImageChecker™ 3.6 Computer-aided Detection

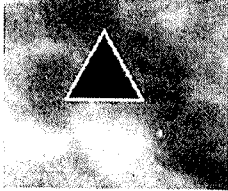
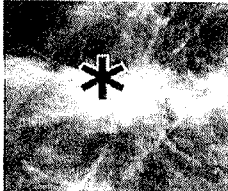
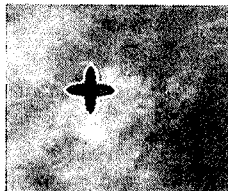


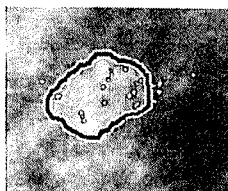
## Quick Reference Guide

Hologic's ImageChecker CAD is software designed to assist radiologists as they read two-dimensional digital mammography images by identifying areas on the 2D mammogram that may warrant a second review. ImageChecker CAD identifies and marks regions of interest, which can include areas suggestive of calcification clusters or masses. It does not look for skin thickening or nipple retraction. Not all CAD display features are available on all diagnostic workstations.

### 3.6.1

	<b>Calc</b>
Calc	Indicates a cluster of calcifications and Microcalcifications
	<b>Mass</b>
Mass	Indicates a mass or architectural distortion
	<b>Malc</b>
Malc	Indicates a region where a mass and one or more clusters of calcifications are present.

### 3.6.1

	Calc	Mass	Malc
RightOn Marks			
PeerView Marks			

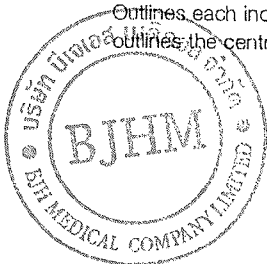
### 3.6.1

#### RightOn™ Marks

Placed directly over the center of the region of interest.

#### PeerView™ Marks

Outlines each individual calcification, and also outlines the central portion of the mass.



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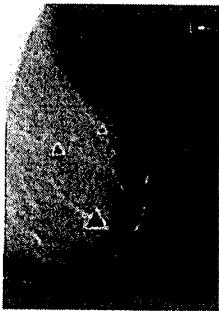
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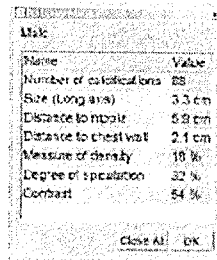
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**EmphaSize™**

- Variable size marks that indicate the prominence of features in the detected region of interest.
- Larger marks indicate more prominent features.
- Marker size is not related to the probability of malignancy.
- Marker size does not relate to the actual size of the lesion.



**LesionMetrics™**

- Additional CAD information that may be seen on SecurView® workstations.
- Information relates to each individually marked region of interest.
- On SecurView, double left click on any displayed CAD mark to view LesionMetrics for that region of interest.

	Operating Point Conventional 2D*			Operating Point C-View 2D**
	1	2	3	4
Calcification	96%	98%	99%	96%
Mass	86%	89%	91%	86%
Overall	89%	91%	93%	88%
Specificity	53.46%	39.85%	29.31%	22%
Calc FP/Image	0.09	0.13	0.16	0.23
Mass FP/Image	0.20	0.29	0.38	0.46
Total FP/Case	1.14	1.67	2.16	2.74

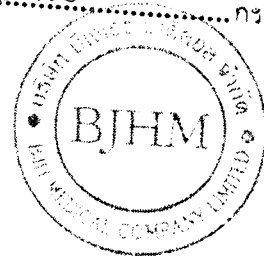
\* The provided values for the available three operating points for conventional mammography images were measured on Hologic's digital image test database of biopsy-proven malignancies and confirmed normal cases in addition to recall cases for the four screening views.

\*\* The provided values for C-View 2D images are as measured on Hologic's C-View 2D image test database of biopsy-proven malignancies and confirmed normal cases in addition to recall cases for the four screening views.

More detailed information is available in the "Understanding ImageChecker CAD 10.0 User Guide".

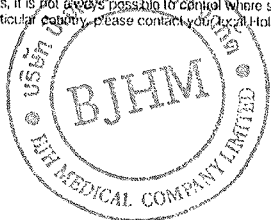
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 ๑.ลงชื่อ..... ประธานกรรมการ  
 ๒.ลงชื่อ..... กรรมการ  
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# SecurView® DX Workstation 3.5 Comprehensive Breast Imaging Review

SecurView DX  
Diagnostic Workstation

## Workflow Solutions for the Breast Imaging Suite

Hologic's dedication to women's health and mammography extends to its image viewing and analysis products. The SecurView DX diagnostic workstation and options offer flexible, interactive and comprehensive diagnostic tools designed to help radiologists see more clearly and work more efficiently.

### 3D Breast Tomosynthesis Workflow Tools

- User preferences for scrolling mode, cine speed, default slab thickness and default initial slice
- Display initial hanging snapshot for a four-view tomosynthesis study in less than two seconds
- Registration of, and instant toggle between, 2D and 3D images
- Automatic scrolling through a limited range of slices
- Generate tomosynthesis "movies" as AVI files for presentation
- Annotate or tag reconstructed slices and store to PACS as a GSPS annotation or DICOM Secondary Capture image
- Tag reconstructed slices to save as TIFF images for presentation and printing

### Efficient Review

- Personalize ReportFlows for any clinical situation
- Single-click navigation through each programmed step
- Automatic selection of desired ReportFlow based on exam type
- Intelligent roaming through quadrants at full resolution

### Ergonomic, Intuitive Keypad (optional on some systems)

- Single-touch support for navigation through tomosynthesis images, including scrolling, cine and toggle between 2D and 3D views
- Single-click access to commonly used functions
- Minimal keystrokes for all breast imaging modalities

### Image Distribution

- Automatic retrieval of prior studies from PACS upon receipt of new images (auto-fetching)
- Manually or automatically merge patient cases if patient presents with a different ID and date of birth combination (does not affect permanent archival on PACS)
- Receive and analyze images from remote sites and mobile units through an existing PACS or Hologic SecurXchange® products

### Full Compliance With IHE Mammography Image Profile

- Display of standardized mammography images for all FFDM vendors
- Correct comparisons of current and prior images
- Clarifies display of CAD marks and information (2D only)
- Consistent patient, study and image information labeling

### Application Synchronization (optional)

- Synchronization of user and patient context with over 45 commonly used third-party dictation, reporting and RIS systems

### Cluster Configuration (optional)

- Provides shared database and instant access to images from any workstation
- Creates, reviews and archives annotations from any workstation

### Instant Bi-directional Communication With Technologists (when paired with the SecurView RT technologist or the Selenia™ Dimensions™ acquisition workflow manager (AWM))

- Digital communication channel between the radiologist and technologist independent of PACS
- Exchange markings, annotations, comments, queries and instruction. Option to save to PACS
- Alerts for incoming markings to identify patients needing additional views

### Advanced Image Analytics (optional, for 2D images)

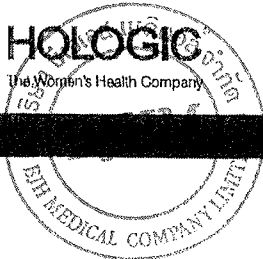
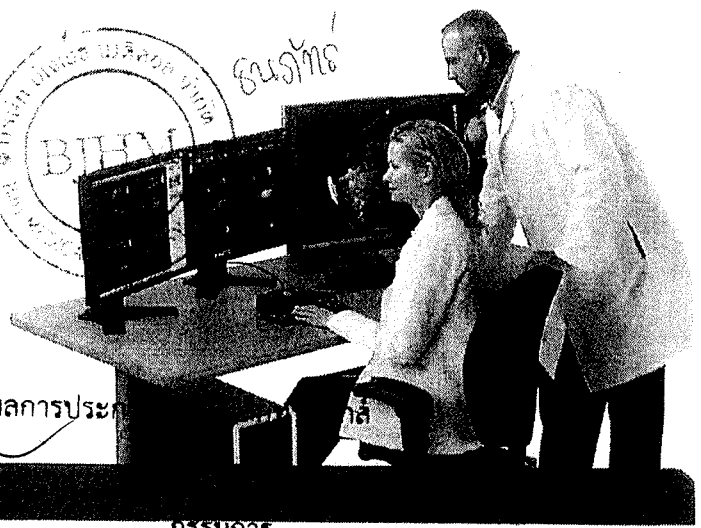
- ImageChecker™ CAD display of Malc™ marks, and RightOn™ and PeerView™ presentation formats
- Additional CAD-specific data with EmphaSize™ and LesionMetrics™ tools
- Quantra™ breast density assessment display
- DigitalNow™ HD LookUp Tables to assist with digitized screen-film comparison

### Multimodality Image Display (optional)

- Addition of one or two color displays for review of other breast imaging modalities
- Software support for multimodality ReportFlows
- View reports stored as Secondary Capture images

### Mammography Prior Enhancement™ Software (optional)

- MPE software facilitates comparison of prior unprocessed GE FFDM images with current Hologic 2D images



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# SecurView® DX Workstation Comprehensive Breast Imaging Review

## SecurView DX Diagnostic Workstation

### SecurView DX Diagnostic Workstation Specifications

Computer	Workstation Class Hardware, Windows -based System
CPU	3.5.1 High-end Quad Core Processor, 2.5 GHz Minimum
Memory	16GB High Speed RAM Minimum 3.5.2
Storage Space	3.5.3 2.0 TB Minimum
Network Interface	10/100/1000 Base T Ethernet 3.5.4

#### Display Hardware

Barcode Displays	High contrast dual 5 Megapixel LCD display with built-in auto-calibration & 10 bit graphics card 3.5.5
	Single 10 Megapixel LCD display with built-in auto-calibration & 10 bit graphics card
	Standard dual 5.8 Megapixel LCD display with 8 bit graphics card. External sensor for calibration.

Scaled Clone application projects video output from dual 5MP or 10MP displays to a high resolution projector for presentations.

Barco MediCal QAWeb automated, online QA and calibration system

Display Cards	High-end Medical Grade 3.5.6
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#### Attached Devices

User Interface	Multi-function Mouse, Back-lit Keyboard
Power	UPS

#### Software

Operating System	Windows 7, 64 bit
Reviewing Software	Dedicated Mammography Based Image Review Software Customized for Radiologist Use
CAD Display	Integrated (Licensing may be required)

#### DICOM Services

Query/Retrieve, Print, Storage, Media Export/Import

#### IHE Compliance

Mammography Image Profile as Image Display

#### Manuals

User Guide, QC Manual

### System Options

#### Advanced Multimodality Solution

Software Module, and 1 or 2 DICOM calibrated 24" color displays with high-end graphics card

#### Aegis® Software MRI Reading Solution

Software, and optional color display

#### Application Synchronization

Software, and optional color display

#### Mammography Prior Enhancement (MPE) software

Enhances unprocessed GE priors to facilitate comparison with current Hologic 2D images.

#### Dedicated Mammography Workflow Keypad (included with some systems)

#### Barcode Scanner

#### SecurView DX Manager

One SecurView DX Manager can support multiple SecurView DX clients, depending on volume and workflow.

### SecurView DX Software-Only Option

The workstation, manager, and multimodality software is available for sites providing their own hardware and IT support. Please consult your Hologic representative for system hardware, software and installation specifications. This software-only option is for a customer configured dedicated SecurView workstation. Installation of the SecurView software on a PACS workstation is not supported.

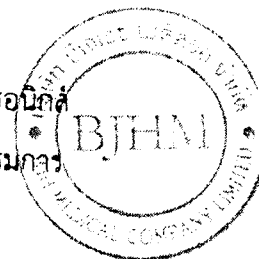
\*MAN-03030 System Requirements Document

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