



Affirm[®] Upright Breast Biopsy Guidance System

A better solution¹ – for you and your patients

The world's first 3D[™] breast biopsy guidance system gives you the power to quickly transition from screening to 2D or 3D[™] interventional procedures using any Hologic 3D Mammography[™] capable system. With the Affirm[®] 3D[™] upright biopsy option, you can clearly localize lesions often visible only with tomosynthesis imaging – to help you confidently biopsy even challenging cases.

Affirm[®]

Breast Biopsy Guidance System



Superior Imaging²

Pinpoint subtle lesions and faint calcifications – including those that may only be visible with tomosynthesis with the 3D[™] biopsy option.



Streamlined workflow

Efficient, fast, easy to learn and use. The system provides a simplified user interface to help deliver a fast biopsy with fewer steps and a lower patient dose.²



Versatile Solution

Transition from screening to interventional procedures to biopsy a wide spectrum of patients either seated or decubitus. Quickly and easily switch between standard and lateral needle approaches.

Technical Specifications

Biopsy Volume	
Standard or Axillary Paddle	5 cm x 5 cm x 10 cm
Wide Access Paddle	6 cm x 7 cm x 10 cm
Compression Method	Motorized and Manual Compression
Compression Range	Up to 15 cm
Image Area	18 cm x 24 cm
Breast Positioning Area	24 cm x 29 cm
SID	70 cm
Weight	<7kg (<15lb)

Breast Biopsy Guidance	
Needle Guidance	Cartesian Coordinate System Z-Axis has 10° tilt
Accuracy	+/-1 mm
Stereotactic Angle	+/-15°
C-Arm Positioning	+180° to -140° (stereo start locations)
Guidance Movements	X- and Y-Axes: Motorized Z-Axis: Manual
Range of Movement	75 mm (width) x 70 mm (depth)
Home Positions	Far Left, Far Right
Biopsy Field Illumination	Integrated LED

Biopsy Control Module	
Display Window	Touchscreen Color LCD 800 pixels x 600 pixels
Lesion Coordinate Display	Numeric, Cartesian
Display Mode	Target Guidance, Jog Screen, Select Targets

Acquisition Workstation ⁴	
Workflow Display	Touchscreen Color LCD Standard Color LCD display
Image Display	2 MP or 3 MP Medical Grade LCD DICOM Display
Display Mode	Target Guidance, Jog Screen, Select Targets

Biopsy Compression Paddles	
Standard Biopsy Paddle	
Compression Area	14 cm x 18 cm
Biopsy Opening	5.4 cm x 5.2 cm
Standard Biopsy Paddle	
Compression Area	14 cm x 18 cm
Biopsy Opening	7.4 cm x 6.2 cm
Axillary Biopsy Paddle	
Compression Area	9.4 cm x 18 cm
Biopsy Opening	5.4 cm x 5.2 cm

Requirements
Selenia® Dimensions® system diagnostic license and dynamic tube head motion license for biopsy

Accessories
Geometry Calibration Phantom
Targeting Phantom
Quality Assurance Needle
Needle Guide Holder
Affirm Biopsy License (single gantry)
Tabletop Stand
User Manual
Service Manual

Optional Components	
Lateral Arm	Enables needle access parallel to the detector from either the lateral left or right position
Biopsy Device Mounting	Standard adapters used on MultiCare® Platinum and Digital StereoLoc® II
Software Options	Affirm 3D™ Biopsy License (single gantry) Additional Affirm 3D™ Biopsy License (single gantry) Additional Affirm Stereotactic Biopsy License (single gantry)

Environmental Conditions	
Operating Temperature	20° to 30° C
Operating Relative Humidity	20% to 80%, non-condensing
Storing Temperature	-10° to 40° C
Storing Relative Humidity	0% to 95%, non-condensing

www.hologic.com | info@hologic.com | +1.781.999.7300

References: 1. Compared to previous generation Hologic upright biopsy systems 2. Schradning S, Martine D, Dirrachs T, et al. "Digital Breast Tomosynthesis-guided Vacuum-assisted Breast Biopsy: Initial Experiences and Comparison with Prone Stereotactic Vacuum-assisted Biopsy." *Radiology*. 2015 274:3, 654-662 E-pub 2014 Nov 12.

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