

Versatile Solution. Lower Dose.*

Affirm™ Upright Breast Biopsy Guidance System

Transforming Breast Biopsy

The Affirm™ breast biopsy guidance system is a complete biopsy solution for our Selenia® Dimensions® mammography system developed to address the challenges of upright breast biopsy. This novel and efficient solution meets biopsy needs of today and paves the way for future advances in interventional procedures with its ground-breaking 3D™ biopsy option and Lateral Arm accessory. The Affirm™ upright system's 3D™ biopsy procedure enables rapid re-identification and targeting of areas only visible or better seen with 3D Mammography™ exams. Moreover, Affirm™ upright 3D™ biopsy offers superior performance compared to stereotactic biopsy, resulting in more accurate, faster procedures.^{1,2*}

The Affirm™ upright system gives facilities the opportunity to offer minimally invasive stereotactic and 3D™ breast biopsy procedures, as well as wire localization services, right in the breast imaging suite. The Affirm™ upright system is compatible with most biopsy devices available in the market today, giving you maximum flexibility and allowing you to perform breast biopsies on a wide spectrum of patients.



Selenia® Dimensions® system with
Affirm™ upright breast biopsy guidance system
and Eviva® breast biopsy device

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) x 160 mm (height)
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 Workstation³

Workflow Display	1.2 MP Touchscreen Color or Standard Color LCD display
Image Display	2 MP or 3 MP Medical Grade LCD DICOM Display

Biopsy Device Compatibility

Needle Length	Up to 140 mm
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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

¹ Schradling 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. 2014 Nov 12. [Epub ahead of print].

² Smith A, Sumpkin J, Zuley M, et al. "Comparison of Prone Stereotactic vs. Upright Tomosynthesis Guided Vacuum Assisted Core Breast Biopsies." (paper presented at the annual meeting for the Radiological Society of North America. Chicago, IL, November 2014).

³ Refer to the appropriate Selenia® Dimensions® Data Sheet for specifications

* 3D™ biopsy compared with stereotactic biopsy.

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Breast and Skeletal Health

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