

The Next Generation in Upright Breast Biopsy

Affirm™
Breast Biopsy Guidance System

Affirm: the Future of Upright Breast Biopsy

The Affirm™ breast biopsy guidance system is a customized solution for our Selenia® Dimensions® digital 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 tomosynthesis biopsy¹ option.

The Affirm system gives facilities the opportunity to offer minimally invasive stereotactic and tomosynthesis breast biopsy¹ procedures, as well as wire localization services, right in the breast imaging suite. The Affirm breast biopsy guidance system is compatible with most stereotactic 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 digital mammography system
with Affirm breast biopsy guidance system
and Eviva® breast biopsy device



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¹ Optional software license and Selenia Dimensions tomosynthesis system is required.

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Specifications

Affirm™ Breast Biopsy Guidance System

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°
Tomosynthesis Angle ^{1,2}	+/-7.5°
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

Affirm 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 Workstation²

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

Accessories

Geometry Calibration Phantom
Quality Assurance Needle
Needle Guide Holder
Affirm Stereotactic Biopsy License (single gantry)
User Manual
Service Manual

Optional Components

Mounting	Standard adapters used on MultiCare® Platinum and Digital StereoLoc® II Systems
Software Options	Affirm Tomosynthesis Biopsy License (single gantry) ¹ Additional Affirm Tomosynthesis Biopsy License (single gantry) ¹ 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

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¹ Optional software license and Selenia Dimensions tomosynthesis system is required.

² Refer to the appropriate Selenia Dimensions data sheet for specifications