The Next Generation in Upright Breast Biopsy



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



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

 $\begin{tabular}{lll} Accuracy & +/-1 mm \\ Stereotactic Angle & +/-15° \\ Tomosynthesis Angle 1,2 & +/-7.5° \\ \end{tabular}$

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

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