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.12

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.
## Specifications

### Biopsy Volume

<table>
<thead>
<tr>
<th>Type</th>
<th>Dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard or Axillary Paddle</td>
<td>5 cm x 5 cm x 10 cm</td>
</tr>
<tr>
<td>Wide Access Paddle</td>
<td>6 cm x 7 cm x 10 cm</td>
</tr>
</tbody>
</table>

### 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 Workstation

#### 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

### Biopsy Compression Paddles

#### Standard Biopsy Paddle

<table>
<thead>
<tr>
<th>Type</th>
<th>Dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compression Area</td>
<td>14 cm x 18 cm</td>
</tr>
<tr>
<td>Biopsy Opening</td>
<td>5.4 cm x 5.2 cm</td>
</tr>
</tbody>
</table>

#### Axillary Biopsy Paddle

<table>
<thead>
<tr>
<th>Type</th>
<th>Dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compression Area</td>
<td>9.4 cm x 18 cm</td>
</tr>
<tr>
<td>Biopsy Opening</td>
<td>5.4 cm x 5.2 cm</td>
</tr>
</tbody>
</table>

### Requirements

- Selementa® 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

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3. Refer to the appropriate Selementa® Dimensions® Data Sheet for specifications

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## Breast and Skeletal Health

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