Instructions for Use

Affirm™

Breast Biopsy Guidance System

HOLOGIC®

MAN-02866

Affirm™
Breast Biopsy Guidance System

Instructions for Use

For Software Version 1.6

Part Number MAN-02866

Revision 002

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Preface

1.0   Intended Use

R Only   United States federal law restricts this device to use by, or on the order of, a physician.

The Affirm™ breast biopsy guidance system is an optional accessory for the Selenia® Dimensions® digital mammography system. Its function is to localize lesions accurately in the breast in three dimensions, using information extracted from stereotactic pairs of two-dimensional images. It is intended to provide targeting guidance for interventional procedures such as biopsy, presurgical localization, or treatment devices.

2.0   Quality Control

Facilities that are ACR accredited must follow the 1999 Stereotactic Breast Biopsy Quality Control Manual. Facilities that are not ACR accredited can follow the above manual or perform the QAS Needle Test described in this manual at the required interval.

3.0   User Profiles

3.1   Mammography Technologist

- Meets all requirements that apply to the location in which the Mammography Technologist operates.
- Completed training on the mammography system.
- Has training in mammography positions.
- Knows about Stereotactic breast biopsy procedures.
- Knows how to operate a computer and its peripherals.
- Can lift 20 pounds to shoulder height with two hands (necessary for upright stereotactic systems).
- Understands sterile procedures.

3.2   Radiologists, Surgeons

- Meets all requirements that apply to the location in which the Physician operates.
- Knows about Stereotactic breast biopsy procedures.
- Knows how to operate a computer and its peripherals.
- Understands sterile procedures.
- Gives local anesthesia.
- Knows about basic surgical procedures for core biopsy.

3.3   Medical Physicist

- Meets all requirements that apply to the location in which the Medical Physicist operates.
- Knows about mammography.
- Has experience with digital imaging.
- Knows how to operate a computer and its peripherals.

4.0   Training Requirements

In the United States, users must be Registered Radiologic Technologists meeting criteria to perform mammography. The mammography users must meet all applicable MQSA personnel requirements under FDA guidelines for conventional and digital mammography.

The user has options available for training, which include but are not limited to onsite applications, training by a Hologic Clinical Services Specialist, and facility on the job training also known as peer training. Additionally, the user's instruction manual is a reference for directions on how to use the system.

Your Hologic representative can arrange for training by a clinical services specialist.

All users must ensure that they receive training on proper use of the system prior to use on patients.

Hologic does not accept the responsibility for injury or damage from wrong system operation.

5.0 Product Complaints

Report any complaint or problem in the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to Hologic. (See the title page for contact information.)

6.0 Technical Support

Refer to the title page of this manual for contact information for product support.

7.0 Terms and Definitions

Affirm	The breast biopsy guidance system for the Selenia Dimensions
Biopsy Control Module	The user control device for the Affirm breast biopsy guidance system
Biopsy Guidance Module	Holds and operates the biopsy device. Responds to commands from the Biopsy Control Module to move the device into position and do the biopsy.
Comm	Communication
Diff	Differential
C-Arm Mode	Lets the C-arm and Tube Arm to move together to the Needle Approach angle for the Localization procedure.
Exposure Technique	Combination of x ray parameters (kVp, mAs, filter) for an acquired image
Needle Approach Angle	The angle of incidence of the needle to the breast
QAS	Quality Assurance Standard
Safety Margins	The minimum space allowed between the biopsy device needle that is installed and components of the Selenia Dimensions system.
Stereo Mode	Lets the Tube Arm rotate for acquisition of stereotactic images while the C-Arm stays in position.
Stereotactic Procedure	A type of examination that allows stereotactic views at the Acquisition Workstation.
Stereotactic View	A specialized image view that causes the application to capture a stereotactic images.

| Stroke Margin | The safety margin (in mm) that remains between the fired needle position and the breast platform. |
| View | The combination of one x-ray image and a specified set of conditions for image acquisition. |

X-axis	• The (lateral) axis from left to right across the biopsy window
Y-axis	• The (longitudinal) axis from front to back above the biopsy window
Z-axis	• The (vertical) axis through the biopsy window
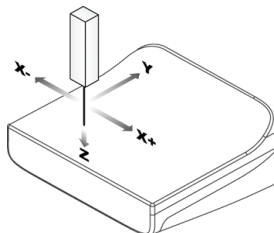
8.0 International Symbols

This section describes the International Symbols on this system.

	Potential Equalization terminal
	Protective Earth terminal
	"On" and "Off" (power) for the computer and display.
	Discard electrical and electronic equipment separately from standard waste. Send decommissioned material to Hologic or contact your service representative.
	Manufacturer
	Date of Manufacture

9.0 Warnings, Cautions, and Notes

Descriptions of Warnings, Cautions, and Notes used in this manual:

	WARNING!	**The procedures that you must follow accurately to prevent possible dangerous or fatal injury.**
	Warning:	**The procedures that you must follow accurately to prevent injury.**
	Caution:	**The procedures that you must follow accurately to prevent the damage to equipment, loss of data, or damage to files in software applications.**
	Note	Notes indicate additional information.

Chapter 1
General Information

1.0   System Description

The Affirm attaches to the Selenia Dimensions. A biopsy device attaches to the Affirm. X- and Y-axes motors in the Affirm move the biopsy device left or right and forward or back. Z-axis movement is manual. The Affirm Biopsy system has two main components:

- Biopsy Guidance Module
- Biopsy Control Module

The Tube Arm on the Selenia Dimensions moves separately from the Compression Arm to allow the acquisition of stereotactic images for the procedure. Refer to the *Instructions for Use* for the Selenia Dimensions for complete information about that system.

Affirm licensing displays on the AWS screen as "Stereo Licensed". Refer to Licensing Setup in System Tools of the Operating System.
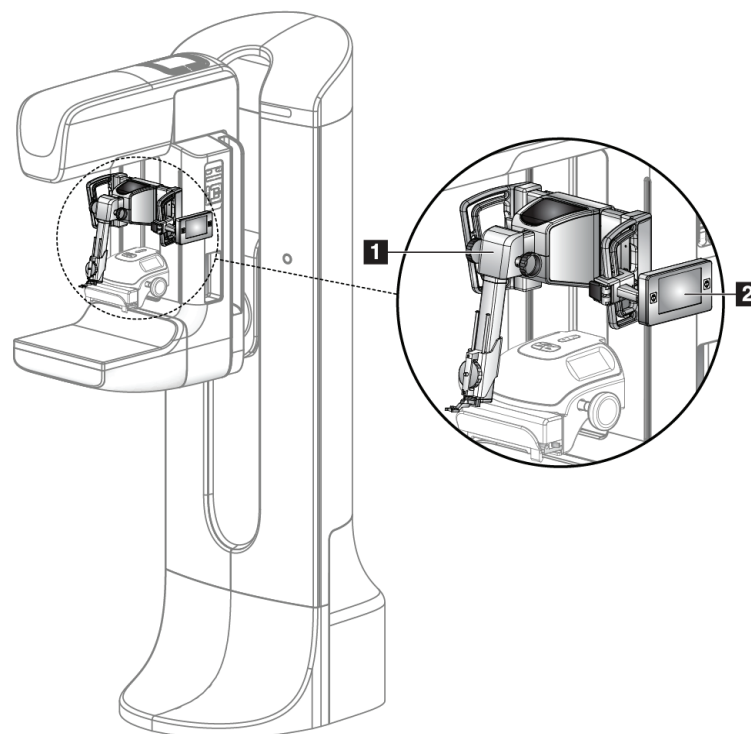
Figure 1: Affirm on the Selenia Dimensions

Figure Legend

1.   Biopsy Guidance Module
2.   Biopsy Control Module

2.0   How to Handle the Biopsy Guidance Module

⚠ **Caution:**   To prevent damage or alignment problems with the
                                  Needle Guidance Stage, be careful when you move the
                                  Biopsy Guidance Module.

⚠ **Caution:**   The Affirm Biopsy Guidance Module weighs 15 pounds.
                                  When you move it, be sure to have a secure grip on the
                                  handles.

• Only lift the Biopsy Guidance Module with the handles.
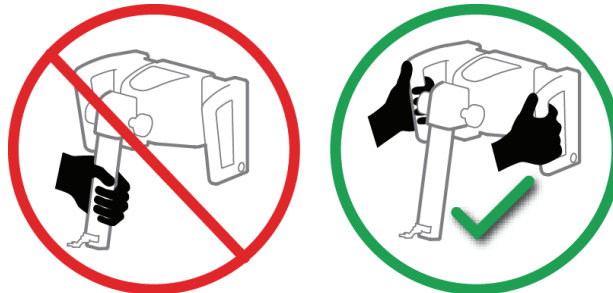
Figure 2: How to Lift the Biopsy Guidance Module

• When the Biopsy Guidance Module is not in use, put the device on its back.

Figure 3: How to Store the Biopsy Guidance Module

3.0   Biopsy Guidance Module Components

The Biopsy Guidance Module installs on the front of the Selenia Dimensions. A lock lever (item 8) secures this module in position. A cable (item 7) connects to the Selenia Dimensions for operation of the biopsy guidance system.
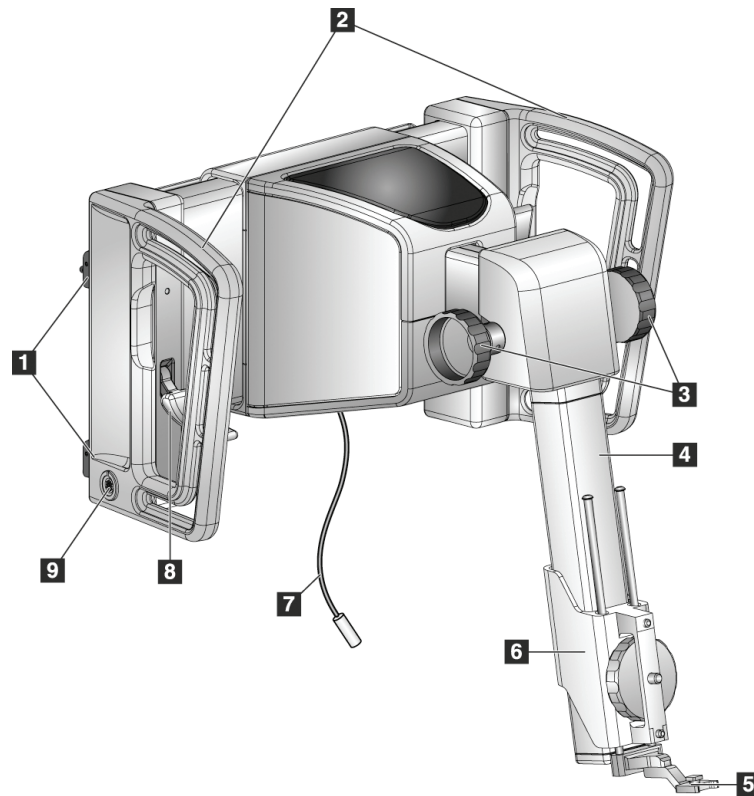
Figure 4: Biopsy Guidance Module

Table 1: Components of the Biopsy Guidance Module

#	Name	Description
1	Attachment Hooks	Two on each side hold the Biopsy Guidance Module on the Selenia Dimensions gantry.
2	Handles	One on each side. Hold both to lift the Biopsy Guidance Module.
3	Z-axis Control Knobs	Rotate either knob to move the biopsy device along the Z-axis.
4	Z-axis Slide Rail	Holds the biopsy device holder and provides the track for Z-axis movements.
5	Front Needle Guide	Attaches to the Needle Guide Mount on the Biopsy Device Holder.
6	Biopsy Device Holder	Holds the biopsy device. Moves along the Z-axis Slide Rail when a Z-axis Control Knob is rotated.
7	Cable	Connects to Selenia Dimension to bring power to the Affirm.
8	Lock Lever	One on each side. Engage both to lock the Biopsy Guidance Module in position and on the Selenia Dimensions gantry.
9	Receptacle	Accepts the cable from the Biopsy Control Module.

4.0 Biopsy Control Module Components

The Biopsy Control Module attaches to either the left or right handle on the Biopsy Guidance Module by means of a bracket (item 5). The display screen (item 2) is a touch screen for the user to perform the desired tasks. Motor Enable buttons (item 3) on either side of this module (and at the rear) activate motorized movement of the biopsy device.
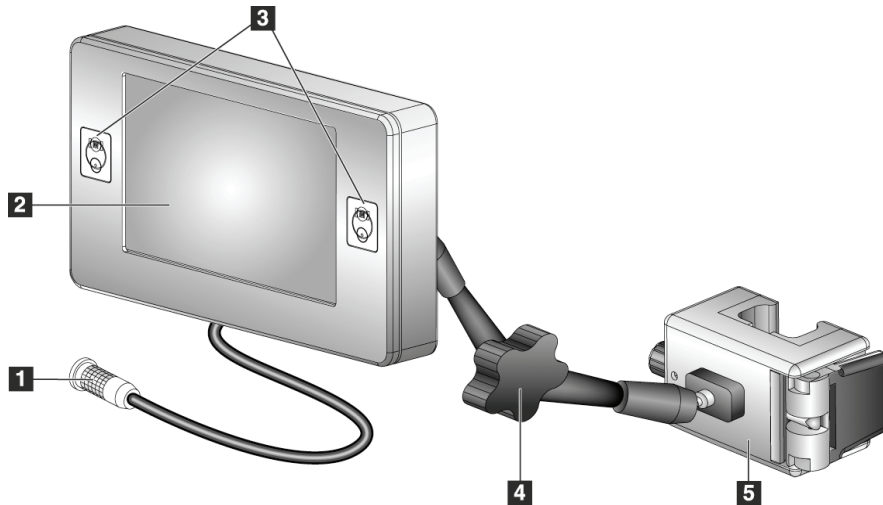
Figure 5: Biopsy Control Module

Table 2: Components of the Biopsy Control Module

#	Name	Description
1	Cable	Connects to Biopsy Guidance Module.
2	Display Screen	Shows targets, system status, name of the biopsy device, and safety margins. Touch buttons allow option selection.
3	Motor Enable Buttons	Front and back button pairs on either side of the display. Press the front and back buttons of either side at the same time to activate a motor movement.
4	Articulating Arm Lock and Release	Rotate to release the lock and adjust the module. Rotate in the opposite direction to lock the arm and hold the module in the new position.
5	Attachment Bracket	Attaches to either handle of the Biopsy Guidance Module.

5.0   Safety

Read and understand this manual before you use the system. Keep this manual available during the patient exams.

Always follow all the instructions in this manual. Hologic does not accept the responsibility for injury or damage from wrong system operation. Hologic can arrange for training at your facility.

The system has protective devices, but the Technologist must understand how to safely use the system. The Technologist must remember the health hazards of x rays.

Do not connect this equipment to any system or component not described in this manual. A combination of components must have the data to validate the safety of the patient, personnel, and the environment. Any additional certification becomes the responsibility of the user.

⚠	**WARNING!**	**After power failure, remove the patient from the system before you apply power.**
⚠	**Warning:**	**You make x rays when you use the procedures in this manual.**
⚠	**Warning:**	**Only qualified users can use this system.**
⚠	**Warning:**	**Do not use this equipment if any faults or problems are detected**
⚠	**Warning:**	**The user must arrange for preventive maintenance by an authorized Service Engineer.**
⚠	**Warning:**	**The user or a service engineer must correct problems before the system is used.**
⚠	**Warning:**	**Do not leave the patient unattended during the exam.**
⚠	**Warning:**	**Keep the hands of the patient away from all buttons and switches at all times.**
⚠	**Warning:**	**The C-Arm movement is motorized.**

	Warning:	The Tube Arm movement is motorized.
	Caution:	To prevent damage or misalignment, be careful when you move the Affirm.
	Caution:	The Affirm Biopsy Guidance Module weighs 15 pounds. When you move it, be sure to have a secure grip on the handles.
	Note	The system does not have any parts that are serviced by the user.

6.0   Compliance Information

6.1   Requirements

The manufacturer is responsible for the effects of safety, reliability, and performance of this equipment, with the following provisions:

• The equipment is used in accordance with *Instructions for Use*.

• Assembly operations, extensions, re-adjustments, modifications, or repairs are performed by authorized persons only.

6.2   Label Locations
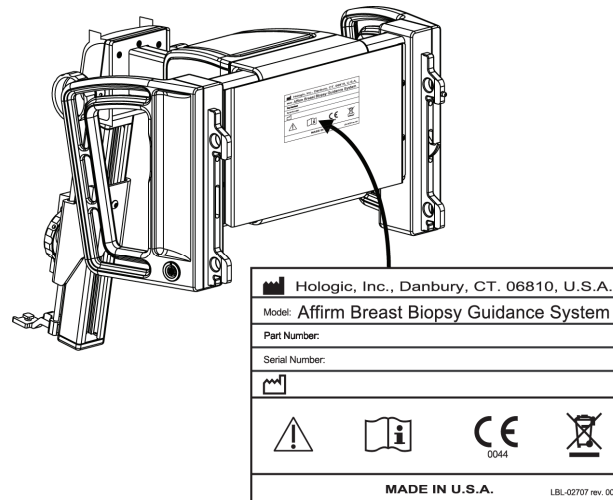
Figure 6: Label Location

Chapter 2
How to Install or Remove the System

1.0   Installation of Components

1.1   How to Attach the Biopsy Guidance Module

You can install the Biopsy Guidance Module with the Selenia Dimensions power on or off.

⚠ **Caution:** **To prevent damage or alignment problems with the Needle Guidance Stage, be careful when you move the Biopsy Guidance Module.**

⚠ **Caution:** **The Affirm Biopsy Guidance Module weighs 15 pounds. When you move it, be sure to have a secure grip on the handles.**
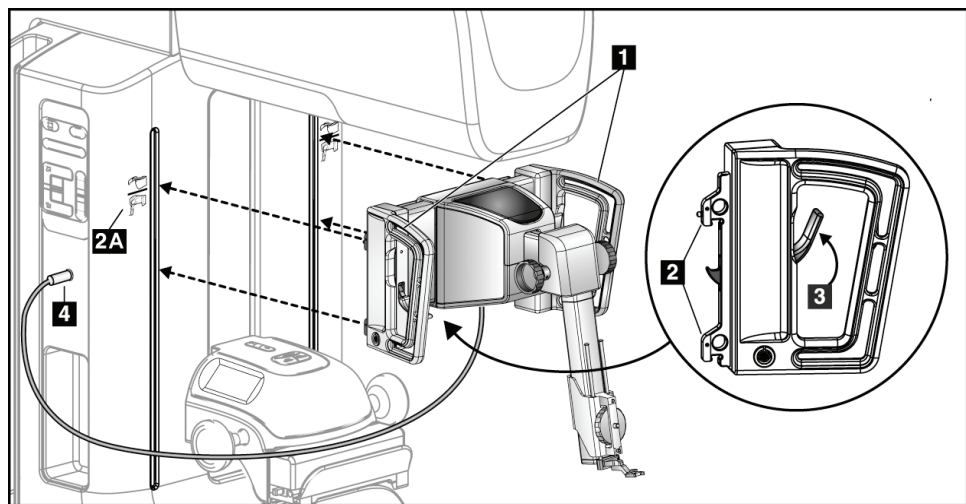
Figure 7: Installation of the Biopsy Guidance Module

1. Move the Compression Device down.
2. Hold the Biopsy Guidance Module by both handles.
3. Slide the top hooks (item 2) of the Biopsy Guidance Module into the slots marked with the Affirm icon (item 2A) on the front of the Selenia Dimensions gantry. Make sure the top and bottom hooks attach to the Selenia Dimensions gantry.
4. Push the Lock Levers (item 3) on the Biopsy Guidance Module into the Up position to lock the Module against the Selenia Dimensions.
5. Align the red dot on the cable (item 4) from the Biopsy Guidance Module with the red dot on the receptacle on the Selenia Dimensions gantry. Connect the cable to the receptacle.

1.2   How to Attach the Biopsy Control Module

The Biopsy Control Module attaches to either the left or right handle on the Biopsy Guidance Module.
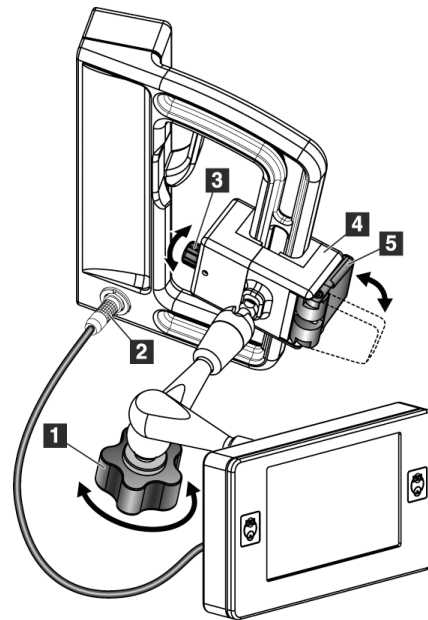
Figure Legend

1.   Lock Knob for Articulating Arm
2.   Biopsy Control Module Cable
3.   Clamp Adjust Knob
4.   Attachment Bracket
5.   Attachment Bracket Lock

Figure 8: Attachment of the Biopsy Control Module

1.   Release the Articulating Arm Lock Knob (item 1).
2.   Position the Attachment Bracket (item 4) until the side with the Lock (item 5) is on the front side of the handle.
3.   Attach the Lock side of the Attachment Bracket around the handle.
4.   Slide the opposite side of the Attachment Bracket around the handle. The Bracket attaches on to the patient handle.
5.   If necessary, adjust the Clamp Adjust Knob (item 3).
6.   Push the Attachment Bracket Lock to the locked position (item 5).
7.   Verify that this adjustment holds the bracket in position. If the bracket moves, or you cannot get the bracket lock completely into the locked position, make adjustments with the Clamp Adjust Knob (item 3).
8.   Connect the Biopsy Control Module Cable (item 2) to the Biopsy Guidance Module.

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1.2.1   How to adjust the bracket height

1. Release the Attachment Bracket Lock (item 5).

2. Slide the bracket to the required height.

3. Put the Attachment Bracket Lock (item 5) into the locked position.

1.2.2   How to adjust the Biopsy Control Module position

1. Release the Lock Knob (item 1) for the Articulating Arm.

2. Tilt or change the current angle of the Biopsy Control Module.

3. Turn the Lock Knob (item 1) to lock the Biopsy Control Module in the new position.

2.0   Installation and Removal of Accessories

2.1   Biopsy Compression Paddles
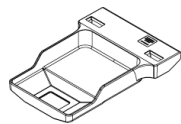
5 cm x 5cm Standard Biopsy Paddle	6 cm x 7 cm Standard Biopsy Paddle	5 cm x 5 cm Axillary Biopsy Paddle
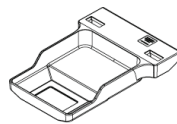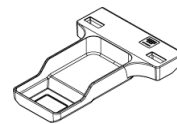
The biopsy compression paddles attach to the compression device on the Selenia Dimensions. Refer to the *Selenia Dimensions Instructions for Use* for instructions on installation and removal of the paddles.

Affirm Instructions for Use
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Installation and Removal of Accessories

2.2   Biopsy Device Holder

To install a biopsy device holder:

1. Align the holes (top and bottom) in the holder with the guide pins on the mount.

2. Align the center hole with the mount screw.

3. Turn the thumbwheel on the mount to attach the device holder.
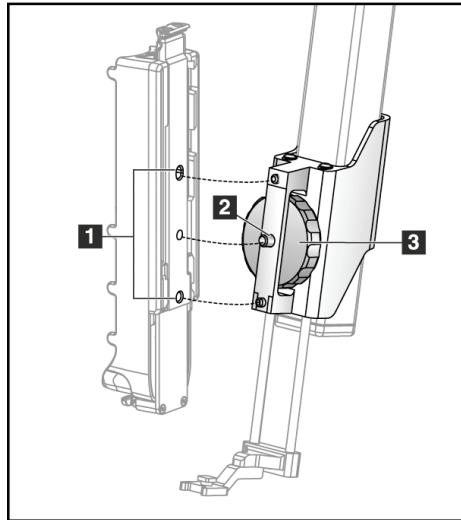
Figure Legend

1. Biopsy Device Holes
2. Mount Screw
3. Thumbwheel

To remove a biopsy device holder:

1. Turn the thumbwheel on the mount to release the device holder.

2. Remove the device holder from the mount.

Affirm Instructions for Use
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2.3 Needle Guides

Warning: **Always use sterile techniques when you use needle guides during the patient procedures.**

To install a disposable Needle Guide:

1. Align the Needle Guide so that the raised-square side of the Needle Guide fits between the two lobes of the Needle Guide Mount.
2. Slide the open area of the U-shape in the Needle Guide around the pin in the Needle Guide mount.
3. Push the Needle Guide in until the guide locks into position.

Figure Legend

1. Needle Guide
2. Needle Guide Mount
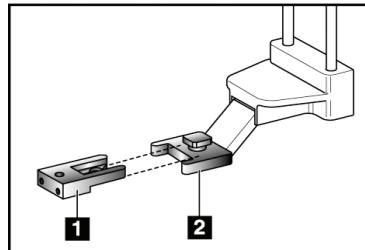
Figure 9: How to Install the Needle Guides

Note The Needle Guides can look different from the Needle Guide shown.

To remove a disposable Needle Guide:

1. Remove the biopsy device from the Z-axis Slide Rail.
2. Pull the Needle Guide away from the pin and remove from the Needle Guide Mount.
3. Discard the Needle Guide Mount in accordance with local regulations.

3.0 Removal of Main Components

3.1 Biopsy Control Module

To remove the Biopsy Control Module from the Biopsy Guidance Module:

1. Disconnect the cable of the Biopsy Control Module from the Biopsy Guidance Module.
2. Release the bracket lock.
3. Remove the Biopsy Control Module from the Biopsy Guidance Module.
4. Store the Biopsy Control Module in a protected location.

3.2 Biopsy Guidance Module

To remove the Biopsy Guidance Module from the Selenia Dimensions:

1. Disconnect the Biopsy Guidance Module Cable from the Selenia Dimensions.
2. Hold a handle of the Biopsy Guidance Module with one hand while you release the Locking Levers with the other hand.
3. Put a hand on each handle and lift the Biopsy Guidance Module from the slots in the Selenia Dimensions.
4. Store the Biopsy Guidance Module in a safe location. Make sure that you put the unit on its back (hooks down).
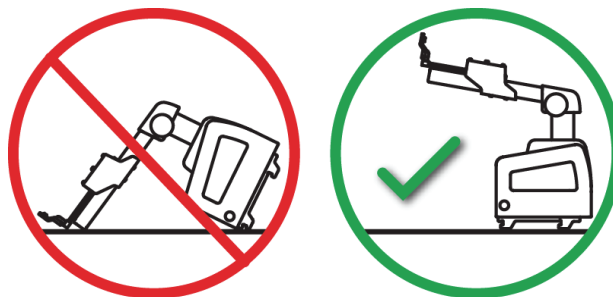
Caution: To prevent damage or alignment problems with the Needle Guidance Stage, be careful when you move the Biopsy Guidance Module.

Caution: The Affirm Biopsy Guidance Module weighs 15 pounds. When you move it, be sure to have a secure grip on the handles.

Chapter 3
How to Use the System

1.0   System Verifications

1.1   Confirm the Host Connection

When the Selenia Dimensions is On and the Affirm cable connections are correct, the Home screen displays on the Biopsy Control Module.
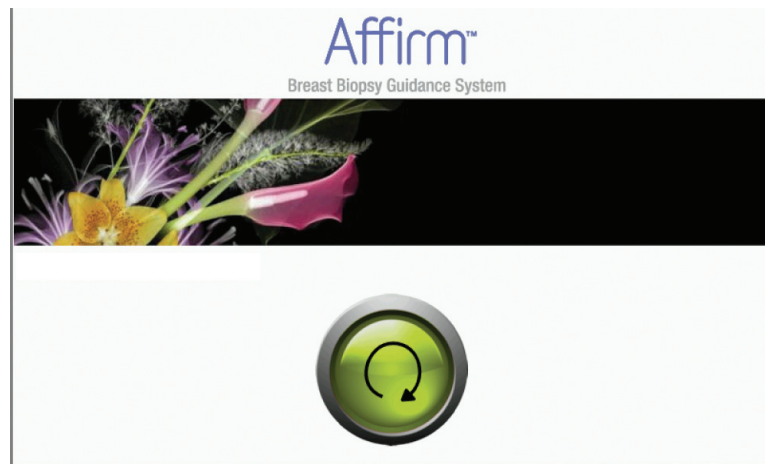
Figure 10: Home Screen on the Biopsy Control Module

1.2   Perform the QAS Needle Test

Perform this test one time each day you plan to use the system to confirm the system accuracy. Record your results in the *QAS Needle Test Checklist* on page 45.

⚠	**Caution:**	**Do not extend the QAS Needle unless the needle is attached to the Biopsy Guidance Module, and the module is installed on the C-arm.**

You can use Auto Biopsy Mode or Manual Biopsy Mode for the QAS Needle Test. The two sections that follow describe each method. For more information about biopsy modes, see *Stereo Biopsy Modes* on page 28.

1.2.1   Auto Biopsy Mode

1. Select the Admin button on the Selenia Dimensions, then select the QAS button from the Admin screen.
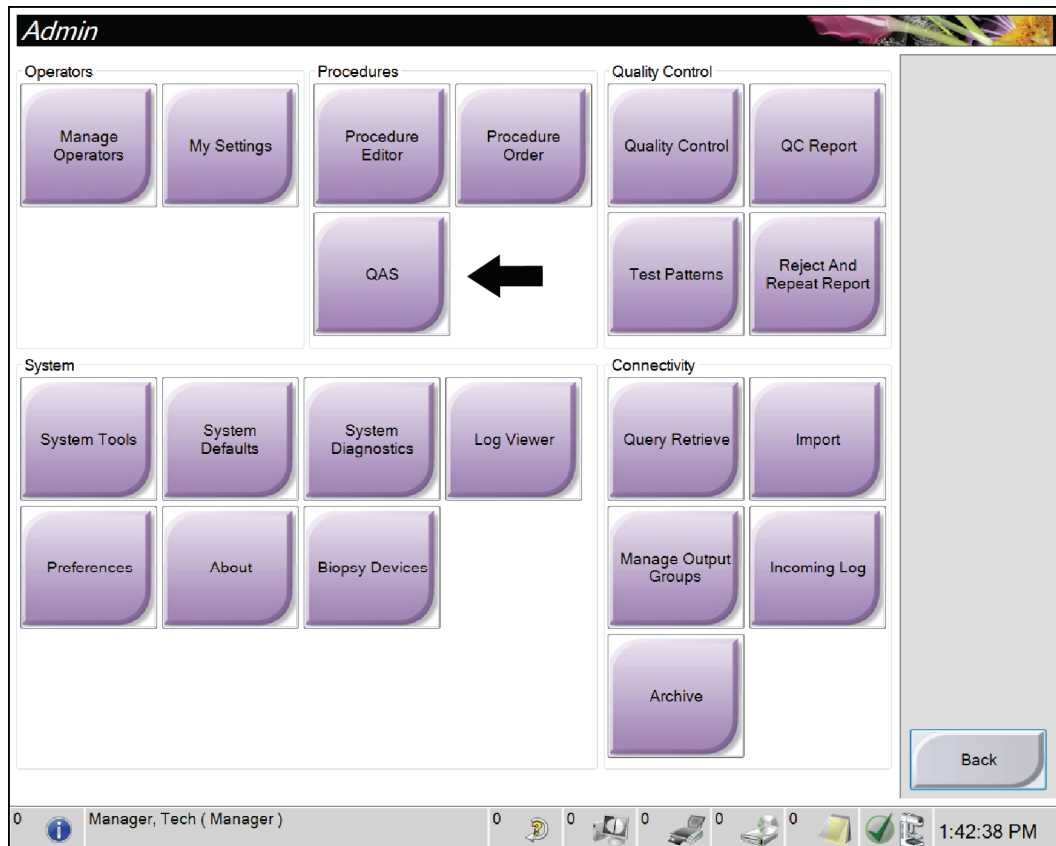
Figure 11: Admin Screen

2. When the QAS screen displays on the Selenia Dimensions Acquisition Workstation, select the Biopsy tab.

3. Confirm that QAS appears in the Device field.
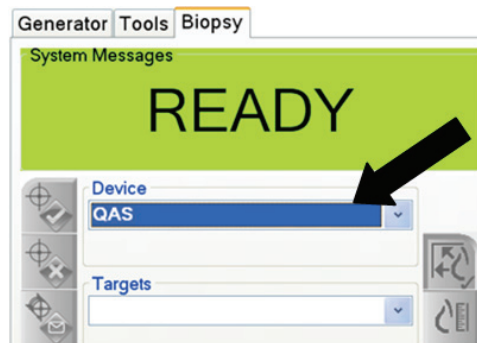
Figure 12: Device Field in the Biopsy Tab

4. Remove the Compression Paddle.

5. Attach the QAS Needle at the top end of the Z-axis Slide Rail, then fully extend the QAS Needle.

6. Press and hold a right or left Motor Enable button pair on the Biopsy Control Module (see *Biopsy Control Module Components* on page 4). The QAS Needle moves automatically to pre-programmed X and Y positions.

7. Turn the Z-axis Control Knob to show 0.0 on the Diff line in all three columns of the Biopsy Control Module.

8. Select the Manual exposure mode, 25kV, 10 mAs, Rhodium filter in the QAS screen.

9. Acquire the stereo images, then Accept the images. The Auto-Accept feature is not enabled during the QAS procedure.
    The targeting of the ball at the needle tip occurs automatically.

10. Select the Create Target button to send the target to the Biopsy Control Module.

    •   Verify that the targeting coordinates are within ± 1mm of X, Y, and Z numbers on the Current line of the Biopsy Control Module.

⚠	**Warning:**	**If the targeting coordinates are not within ± 1mm, contact Technical Support. Do not try to adjust the system. Do not perform any biopsy procedure with the Affirm until Technical Support indicates the system is ready for use.**

⚠	**Warning:**	**The user or a service engineer must correct problems before the system is used.**

    •   Document X, Y, and Z Diff values on the QAS Needle Test Checklist in *QAS Needle Test Checklist* on page 45.

11. Select the **End QC** button on the Acquisition Workstation screen.

12. Press a **Home Position** button (Left or Right) to move the QAS Needle away from the target.

13. Retract the QAS Needle.

14. Remove the QAS Needle from the Z-axis Slide Rail.

1.2.2 Manual Biopsy Mode

1. Perform steps 1 to 8 as stated for the *Auto Biopsy Mode* on page 16.

2. Press the **C-Arm Stereo Mode button** in the Target Guidance screen.

   Refer to the table in *C-Arm Rotation in the Biopsy Modes* on page 28.

3. Rotate the Tube Arm to the first 15° position.

4. Press the x-ray button and acquire the first 15° image.

5. Rotate the Tube Arm to the opposite 15° position.

6. Press the x-ray button and acquire the opposite 15° image.

7. **Accept** the images. The Auto-Accept feature is not enabled during the QAS procedure.

   The targeting of the ball at the needle tip occurs automatically.

8. Select the **Create Target** button to send the target to the Biopsy Control Module.

   - Verify that the targeting coordinates are within ± 1mm of X, Y, and Z numbers on the Current line of the Biopsy Control Module.

   - If the targeting coordinates are not within ± 1mm, contact Technical Support. Do not try to adjust the system. Do not perform any biopsy procedure with the Affirm until Technical Support indicates the system is ready for use.

⚠	Warning:	**If the targeting coordinates are not within ± 1mm, contact Technical Support. Do not try to adjust the system. Do not perform any biopsy procedure with the Affirm until Technical Support indicates the system is ready for use.**
⚠	Warning:	**The user or a service engineer must correct problems before the system is used.**

   - Document X, Y, and Z Diff values on the QAS Needle Test Checklist in *QAS Needle Test Checklist* on page 45.

9. Select the **End QC** button on the Acquisition Workstation screen.

10. Press a **Home Position** button (Left or Right) to move the QAS Needle away from the target.

11. Retract the QAS Needle.

12. Remove the QAS Needle from the Z-axis Slide Rail.

2.0   Biopsy Control Module Screens

2.1   Home Screen

The Home screen displays the name or initials of the user who logs in and any error messages. The **Go** button takes the user to the Target Guidance screen.
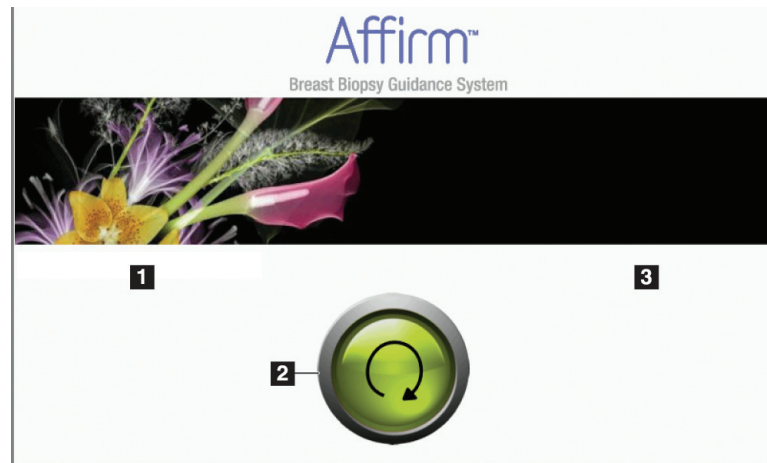
Figure 13: The Home Screen

Figure Legend

1.   User ID Area
2.   Go Button
3.   Error Message Area

2.2 Target Guidance Screen

The figure below shows the main screen of the Biopsy Control Module. This screen indicates the current position of the biopsy device, the selected target coordinates and the Cartesian difference between the two positions.

The buttons in the Target Guidance screen allow the user to go to the Previous screen (item 3), go to the screen for target selection (item 2), go to the screen for motorized movement of the biopsy device in the X and Y axes (item 1), select the C-Arm Mode or Stereo Mode for the C-arm rotation (item 5), and cancel an audible signal (item 7).

The display area (item 4) of the Target Guidance screen shows the difference between the current position of the biopsy device and the target coordinates, the status of the system (item 10), the biopsy device installed on the system (item 8), and the safety margins (item 9).

(The figure and the figure legend appear on the next page.)
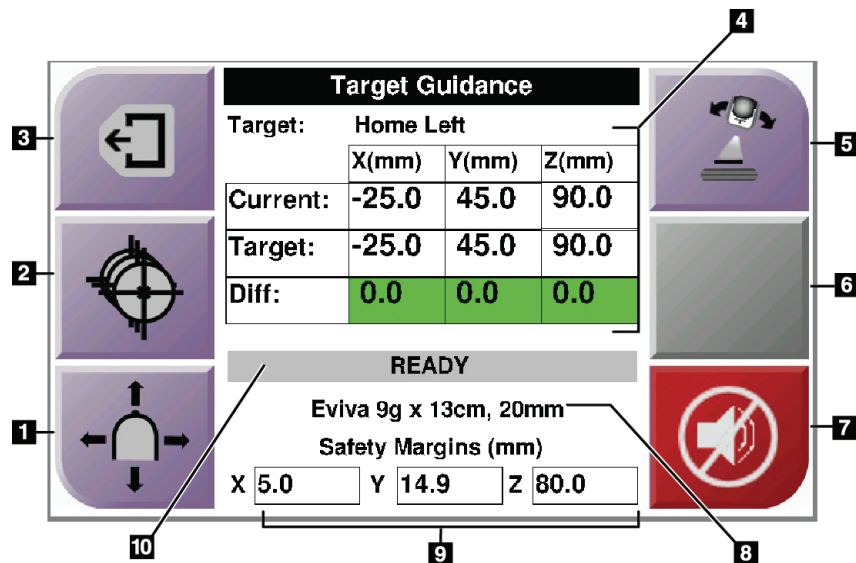
Figure 14: Target Guidance Screen

Figure Legend

1. Go to the Jog Mode screen
2. Go to the Select Target screen
3. Go to the Previous screen
4. Target Information
5. Switch between C-Arm Mode or Stereo Mode (when system is set for Manual Biopsy Mode).
6. This button is gray and disabled.
7. Mute or Enable Sound (An icon displays on this button and an alarm sounds when there is a system fault. See *The Sound Button* on page 23.)
8. Selected Biopsy Device
9. Safety Margins
10. System Status

Note   The X, Y, and Z cells in the screen can change color as target coordinates change. See *Colored Cells in the Screens* on page **22**.

2.2.1 Colored Cells in the Screens

Green Cells

When all Diff cells are green, the biopsy device is in the correct position for the selected target. When the biopsy device is fired, the lesion is at the center of the aperture of the device.
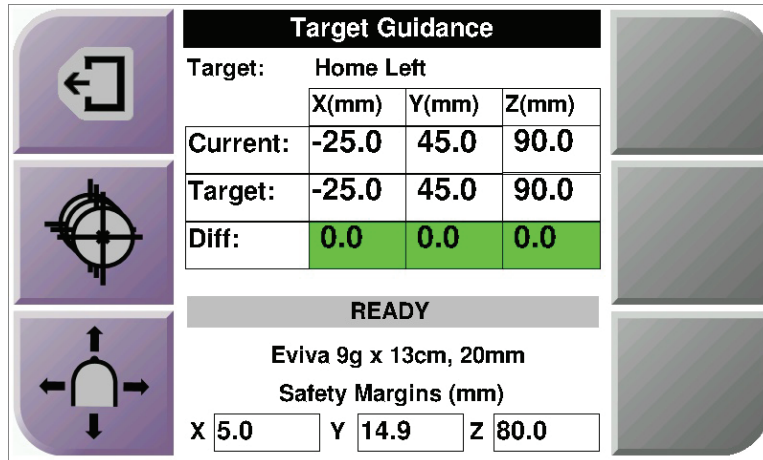
Figure 15: Green Differential Cells

Yellow and Red Cells
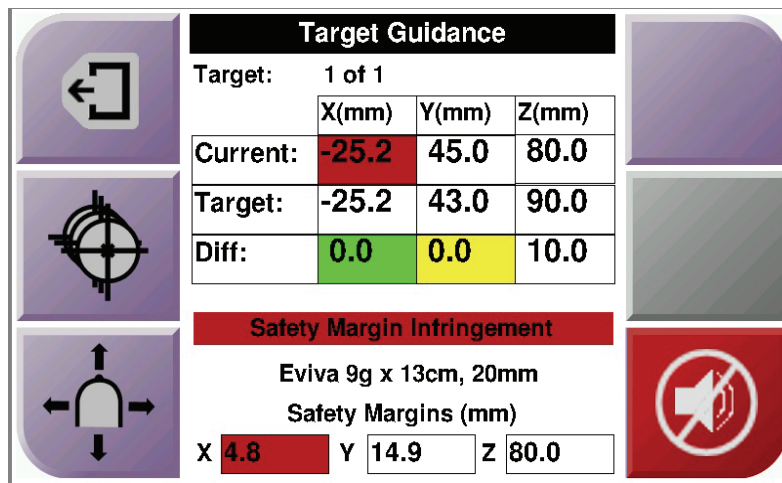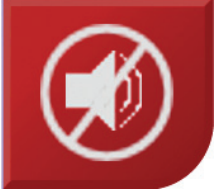
Figure 16: Yellow and Red Cells

- **Yellow** indicates the biopsy device is in the correct position for that axis, but you must move the device to the final Z-position. When the biopsy device is in the final Z-position, the yellow cell changes to green.

- **Red** indicates a problem with a safety margin. The **Sound** button appears and the system makes repeated beeps. Make adjustment in the axis indicated by red. When the cell is not red, the device is within the safety limits.

2.2.2   The Sound Button

The **Sound** button is enabled when there is a system fault. When the **Sound** button displays, you can control system sounds related to alarms and motor movements of the biopsy device.

*Table 3: How to Use the **Sound** Button*

Sound	
Figure 17: Alert Sounds are Audible	• When a safety margin is violated, this icon displays and the system repeats a beep sound. • To stop the sound, press the **Sound** button. All system beep sounds are muted, and the icon on the button changes. • When you correct the safety margin violation, the icon on the button disappears. • If you press the button and do not correct the system fault within two minutes, the system beep sounds are enabled automatically.
Figure 18: Alert Sounds are Muted	• When this icon appears on the **Sound** button, you have the option to enable the system beep sounds. • To enable the system beep sounds, press this button. • If you do not press this button, system beep sounds are enabled automatically within two minutes after this icon displays.

2.3   Jog Mode Screen

This screen allows the user to manually overwrite the targeting coordinates of the Biopsy Guidance Module. The arrow buttons in the Jog Mode screen change the Jog value of the X and Y coordinates. Other buttons in this screen allow the user to go to the Target Guidance Screen (item 5), and cancel (item 7) an audible signal that sounds when there is a problem with a safety margin.

The display area (item 4) of the Jog Mode screen shows the difference between the current position of the biopsy device and the target coordinates, the status of the system (item 10), the biopsy device installed on the system (item 8), and the safety margins (item 9).

⚠	**Warning:**	**Red cells indicate a problem with a safety margin. Patient injury or equipment damage may occur if you continue. Make adjustments to be within safety limits.**

(The figure and the figure legend appear on the next page.)
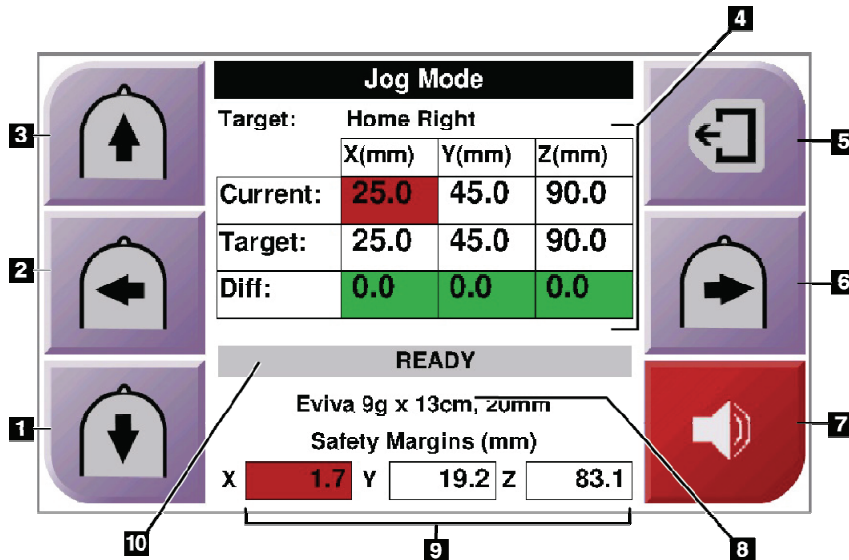
Figure 19: Jog Mode Screen

Figure Legend

1. Change Y-axis Jog value in negative direction
2. Change X-axis Jog value in negative direction
3. Change Y-axis Jog value in positive direction
4. Target Information
5. Go to the Previous screen
6. Change X-axis Jog value in positive direction
7. Mute or Enable Sound
   (An icon displays on this button and an alarm sounds when there
   is a problem. See *The Sound Button* on page 23 for more
   information about the Sound button.)
8. Selected Biopsy Device
9. Safety Margins
10. System Status

2.4   Select Target Screen

This screen allows the user to select a different target for biopsy guidance or to move to one of the Home positions. The buttons in the Select Target screen allow the user to go to the Previous screen (item 1), go to the Target screen (item 2), or go to the Left or Right Home Position (item 3 or item 6).

The display area (item 4) of the Select Target screen shows one of more sets of target coordinates. The name of the biopsy device that was selected also displays (item 5).

To move the biopsy device to one of the targets shown in this screen:

1.   Press one of the target coordinates icons or the home buttons.

    The system changes to the Target Guidance screen.

2.   Press and hold a right or left **Motor Enable** button pair on the Biopsy Control Module. The needle moves to the X and Y positions.
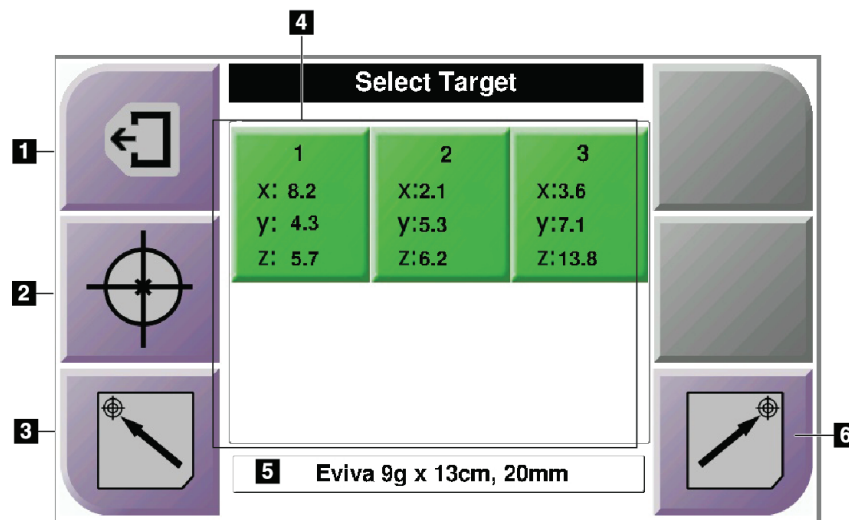
Figure 20: Select Target Screen

Figure Legend

1.   Go to the previous screen
2.   Go to the Target Guidance screen
3.   Go to the Home Left Position
4.   Target Coordinates
5.   Biopsy Device
6.   Go to the Home Right Position

Note   You must simultaneously press both switches of a right or left **Motor Enable** pair to start the motor movement.

3.0 Selenia Dimensions

3.1 Stereo Views

3.1.1 How to Add a Stereo View

1. From the Procedure screen, select the **Add View** button.
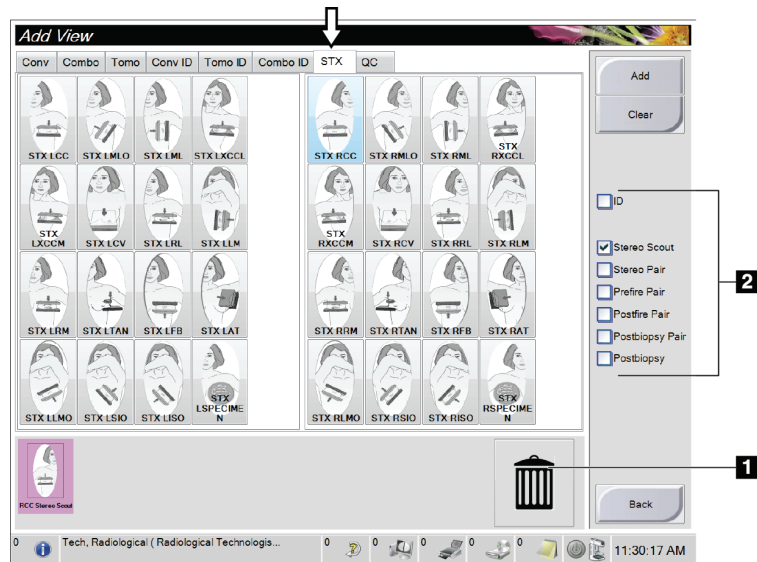
Figure 21: Add a Stereo View

Figure Legend

1. Trash icon
2. View Modifier

2. Select the STX tab, then select the view to add and the appropriate View Modifier.

3. Select the **Add** button.

To remove the selected view, select the view then press the Trash icon.

3.2   Stereo Biopsy Modes

Acquire the stereo images in either the Auto Biopsy Mode or the Manual Biopsy Mode. Make the Biopsy Mode selection at the Acquisition Workstation (refer to *How to Select the Biopsy Mode for Image Acquisition* on page 30).

3.2.1   C-Arm Rotation in the Biopsy Modes

The action of C-arm rotation for stereotactic image acquisition is different in Auto and Manual Biopsy Modes.

	Note	All C-Arm movement is disabled when a compression force of 22 Newtons (5 pounds) or greater is applied.

In Auto Biopsy Mode

In the Auto Biopsy Mode, the Target Guidance screen does not display the **C-Arm Stereo Mode** button. In the Auto Biopsy mode, the system automatically allows the C-arm to move separately from the Tube Arm to acquire the stereo images. When the x-ray button is pressed to start stereo image acquisition, the Tube Arm automatically moves to the first 15° position, acquires the image, rotates to the opposite 15° position and acquires that image.

	Note	The System Status menu (refer to *How to Select the Biopsy Mode for Image Acquisition* on page **30**) provides the option to position the Tube Arm for the first stereo image. When you select either of the 15 degree positions, the Tube Arm automatically rotates to the selected position. This option operates in both biopsy modes.

In Manual Biopsy Mode

In Manual Biopsy Mode, the **C-Arm Stereo Mode** button displays on the Target Guidance screen. The default setting is Stereo Mode. See the table that follows.

Note	The C-Arm Stereo Mode button displays if the system is set for Manual Biopsy Mode. In Auto Biopsy Mode, this button is not displayed.

Table 4: The C-Arm Stereo Mode Button

Icon	Description of Function
Figure 22: Stereo Mode	• The Tube Arm rotates while the C-Arm remains in position. • Select Stereo Mode to acquire stereo images (when the system is set for Manual Biopsy Mode).
Figure 23: C-Arm Mode	• The C-arm and Tube Arm rotate together. • Select C-Arm Mode to rotate the C-arm and Tube Arm together to a new patient positioning angle.

1. After you set the patient positioning angle (with the C-Arm Mode engaged), press the **C-Arm Stereo Mode** button on the Target Guidance screen to put the C-arm into Stereo Mode.

2. Rotate the Tube Arm to the first 15° position.

3. Press the **X-ray** button and acquire the first 15° image.

4. Rotate the Tube Arm to the opposite 15° position.

5. Press the **X-ray** button and acquire the opposite 15° image.
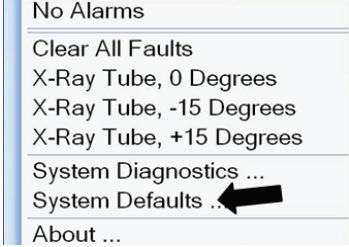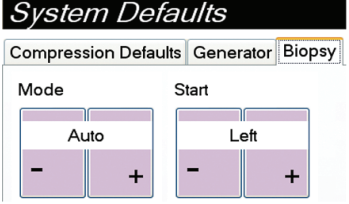
Note	Keep the X-ray button pressed until the exposure stops. An audible beep indicates the image acquisition has finished.

>>

3.2.2 How to Select the Biopsy Mode for Image Acquisition

Table 5: How to Select the Biopsy Mode

1. Select the **System Status** icon.	*Figure 24: System Status Icon*
2. Select **System Defaults** from the System Status menu.	*Figure 25: System Status Menu*
3. Select the **Biopsy tab** in the System Defaults screen. 4. Select **Auto (or Manual)** from the Mode section.	*Figure 26: System Defaults Screen*

3.3 Biopsy Tab
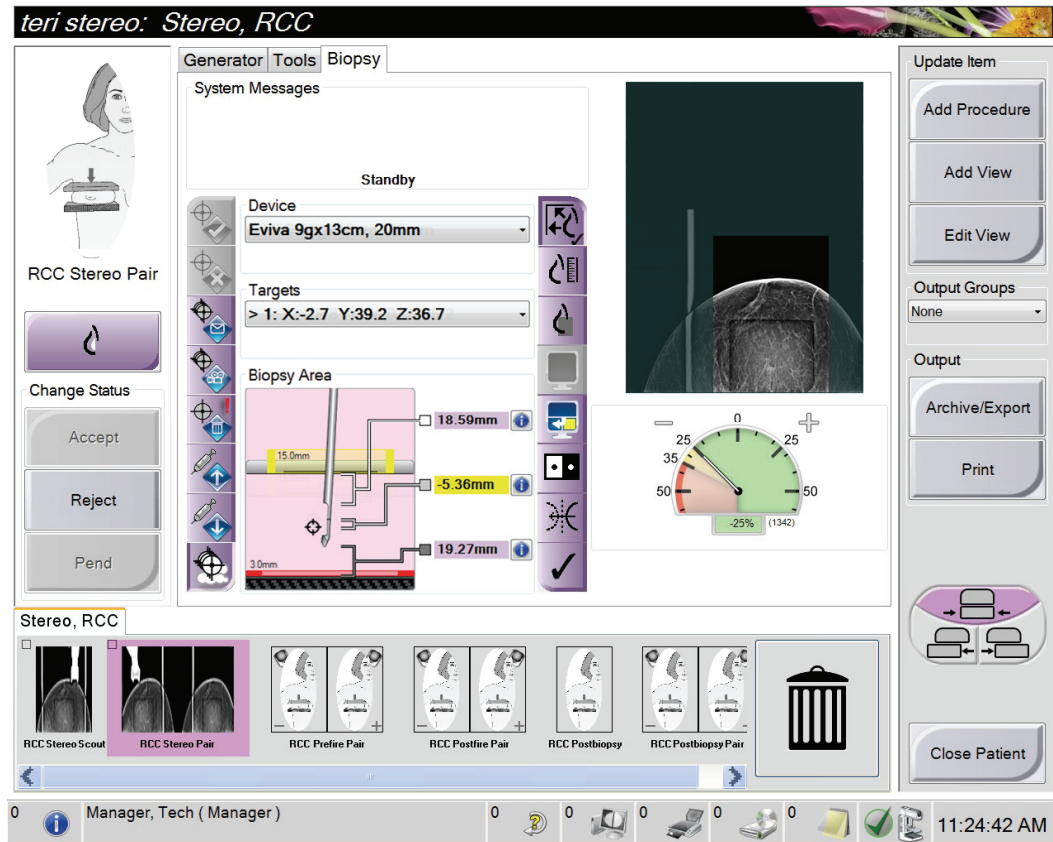
Figure 27: The Biopsy Tab

When you select the Biopsy tab, the Biopsy screen appears. This screen displays information about the targets and the biopsy device that is installed on the system. The buttons on the left side of this information allow you to communicate selected targets to the Biopsy Control Module. See *Biopsy Staging* on page 32 for information about the buttons and data fields on the Biopsy tab screen.

3.4 Biopsy Staging

The buttons on the Biopsy Staging area communicate target information to the Biopsy Control Module. The fields on the right side of the buttons show the selected target and biopsy device.
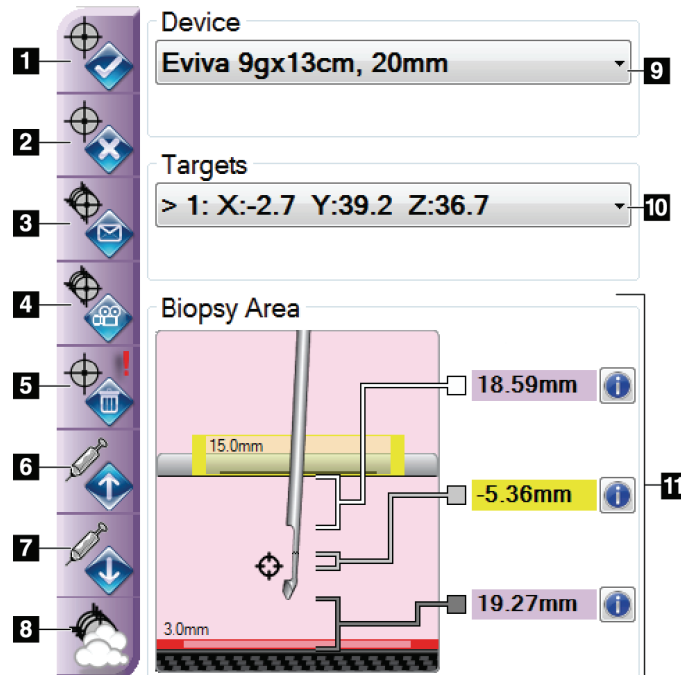
Figure 28: Function Buttons and Data on the Biopsy Tab

Figure Legend

1. **Create Target** sends the current target list that shows in the Biopsy Staging area to the Biopsy Control Module.

⚠ **Caution:** | If the Biopsy Control Module is unplugged after the targets are transmitted, the Biopsy Control Module deletes the targets. Resend the targets.

2. **Reject Target** removes the selected target from the list that displays in the Biopsy Staging area, if that target was not created.

3. **Resend Target** resends the selected target set to the Biopsy Control Module.

4. **Project Target** shows the selected target on an additional stereo pair on the Preview screen.

5. **Delete Target** deletes the selected target if that target was created.

6. **Move Z-Target Up** moves the final position of the needle away from the Breast Platform and the graphic of the lesion downward. The values for the safety margins change accordingly.

7. **Move Z-Target Down** moves the final position of the needle toward the Breast Platform and the graphic of the lesion upward. The values for the safety margins change accordingly.

8. **Show/Hide Targets** shows/hides all targets in the list of targets in the Biopsy Staging area.

9. **Device** shows the name of the attached biopsy device that was selected from the related drop-down list. The name, dimensions, and aperture size in the needle for the selected biopsy device display.

Warning: **Patient injury can occur if the device you select in the Biopsy tab is not the device that is installed on the system.**

Note If your biopsy device does not show in the drop-down menu, contact Technical Support. A Service Engineer must enter the device specifications.

10. **Targets** shows the current target selected from the list of created targets in the drop-down menu. The active target is the last one created. This target is at the top of the list and displays with an arrow before the coordinates.
When multiple targets are created on an image, a target set is created. All targets in the current target set show with an arrow before the coordinates. When you send the target set to the Biopsy Control Module, only the active targets (those with the arrows) transfer and can be selected at the Biopsy Control Module.

11. **Status** shows the distance between the biopsy paddle and the top of the aperture, the distance of the target from the center of the aperture, and the distance from the needle tip (post fire) to the breast platform. The distance indicator fields change colors with movement of the needle.

- Purple indicates that is safe to proceed.
- Red indicates that the current coordinates exceed the safety margin.
- Yellow warns of being near the safety limit.

Note When you select another image and create a target on this image, the new target moves to the top of the target list, becomes the active target and displays with an arrow. The targets created on the previous image move to the bottom of the list and display without an arrow.

Note To make a target set the active target set, select one of the targets in the set and select the **Resend** button.

3.5 Lesion Targeting

| Note | You can use the Zoom tool (in the Tools tab or View Actual Pixels button) to magnify the area of interest in an image. |

| Note | If the exam data in the image blocks detection of the lesion, click the Information icon in the Tools tab to hide the data. |

1. Select the Accept button to save the stereo images.

| Note | Your service representative can configure the system to Auto-Accept new images. |

2. Click in the center of the lesion in one of the stereo images.
3. Click on the other stereo image, then click in the center of the lesion.
4. Select the Create Target button to save the target. The active target set automatically transfers to the Biopsy Control Module every time a new target is created.
5. Repeat this procedure to create multiple targets (a maximum of six).

| Note | The target that displays on the Target Guidance screen of the Biopsy Control Module is the last target created. The target or target set that shows on the Select Target screen is the last target or target set sent to the Biopsy Control Module. |

| Note | To target a lesion, you can also use the Scout and one of the stereo images. |

3.6 Verify the Position of the Biopsy Device

1. Acquire the pre-fire images as necessary to identify the correct needle position.
   - Verify the needle position.
   - If necessary, make adjustments.
2. If applicable, fire the biopsy device.
3. Acquire the post-fire stereo images.
   - Verify the needle position.
   - If necessary, make adjustments
4. Acquire specimens with use of the attached biopsy device, if desired.

3.7 Post Biopsy

1. Put in a marker, if desired.

2. Rotate the Z-axis Control Knob to move the biopsy device away from the breast.

3. Acquire images as necessary.

4. Release compression.

3.8 Printing Stereo Images

When you select a stereo pair from the thumbnail area of the Print screen, the image mode buttons change. See the *Selenia Dimensions Instructions for Use* for   instructions on use of the Print screen.

• Select the -15 button to show that stereo image in the display area.

• Select the +15 button to show that stereo image in the display area.

• Select the middle button to make a 2-up horizontal film with the +15 degree image on top and the -15 degree image on the bottom.
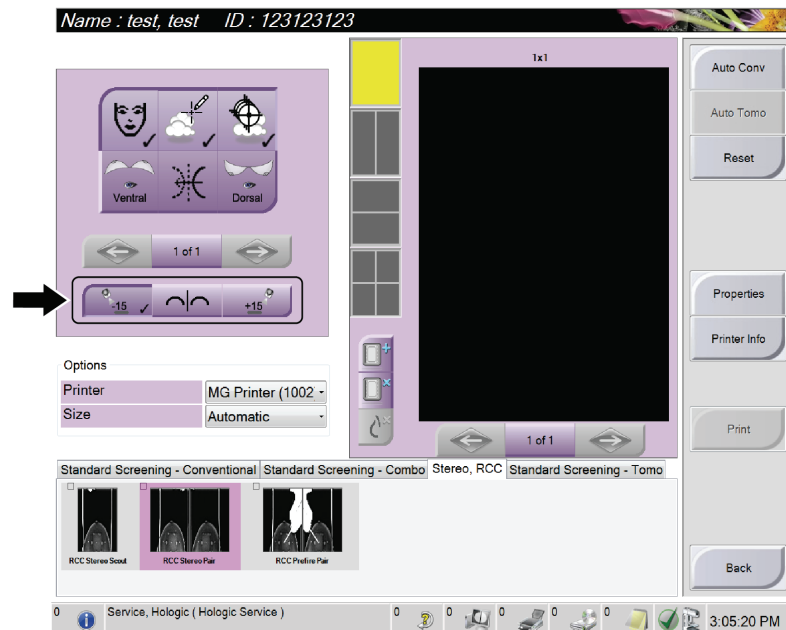
Figure 29: Stereo Pair Print Screen

Chapter 4
Care and Cleaning

1.0   General Information

Before each examination, clean and use a disinfectant on any part of the system and any accessory which touches a patient.

2.0   Preventive Maintenance Schedule

Table 6: Radiologic Technologist Preventive Maintenance Schedule

Maintenance Task Description	Each use	Daily	Semiannually
Clean the Biopsy Paddle with a disinfectant after use.*	x		
Clean the Breast Platform with a disinfectant after use.*	x		
Inspect the Biopsy Paddle for damage before use.	x		
Inspect the calibration Phantom for damage.	x		
Inspect all cables for wear and damage before use.	x		
Verify the Affirm locks in position.	x		
Make sure the Needle Guides are installed correctly before use.	x		
Make sure all displays are illuminated.	x		
Perform QAS Procedures once each day before use of the system.		x	
Geometry Calibration (see *Geometry Calibration* on page 39)			x
*Call Technical Support for the current list of recommended cleaning solutions.			

Note   The Preventive Maintenance Schedule for the Service Engineer is in the Service Manual.

3.0 For General Cleaning

Use a lint-free cloth or pad and apply a diluted dishwashing liquid.

	Caution:	**Use the least possible amount of cleaning fluids. The fluids must not flow or run.**

If more than soap and water is required, Hologic recommends any one of the following:

- 10% chlorine bleach and water with one part commercially available chlorine bleach (normally 5.25% chlorine and 94.75% water) and nine parts water
- Commercially available isopropyl alcohol solution (70% isopropyl alcohol by volume, not diluted)
- 3% maximum concentration of hydrogen peroxide solution

After you apply any of the above solutions, use a pad and apply a diluted dishwashing liquid to clean any parts which touch the patient.

	Warning:	**If a paddle touches possible infectious materials, contact your Infection Control Representative for decontamination instructions.**

	Caution:	**To prevent damage to the electronic components, do not spray disinfectant on the system.**

3.1 How to Clean the Biopsy Control Module Screen

There are many commercially available products to clean LCD screens. Make sure the product you select is free of strong chemicals, abrasives, bleach, and detergents that contain fluorides, ammonia, and alcohol. Follow the directions of the manufacturer of the product.

3.2   To Prevent Possible Injury or Equipment Damage

Do not use a corrosive solvent, abrasive detergent, or polish. Select a cleaning/disinfecting agent that does not damage the plastics, aluminum, or carbon fiber.

Do not use strong detergents, abrasive cleaners, high alcohol concentration, or methanol at any concentration.

Do not expose equipment parts to steam or high temperature sterilization.

Do not let liquids enter the internal parts of the equipment. Do not apply cleaning sprays or liquids to the equipment. Always use a clean cloth and apply the spray or liquid to the cloth. If liquid enters the system, disconnect the electrical supply and examine the system before returning it to use.

⚠️	**Caution:**	**Wrong cleaning methods can damage the equipment, decrease imaging performance, or increase the risk of electric shock.**

Always follow instructions from the manufacturer of the product you use for cleaning. The instructions include the directions and precautions for the application and contact time, storage, wash requirements, protective clothing, shelf life, and disposal. Follow the instructions and use the product in the most safe and effective method.

4.0   Geometry Calibration

Geometry calibration is required semiannually. Perform this calibration using the Geometry phantom supplied with the system.

4.1   Geometry Calibration Procedure

1. Inspect the calibration phantom for damage.
2. Select the **Admin > Quality Control > Technologist tab > Geometry Calibration** procedure on the Acquisition Workstation.
3. Select **Start**.
4. Follow the instructions on the screen and take the predefined exposure. Do not change the preselected techniques.
5. **Accept** the image. When you see the message that the geometry calibration was completed successfully, click **OK**.
6. Select **End Calibration**.

Chapter 5
Troubleshooting

1.0   Audible Alerts

Table 7: Affirm Audible Alerts

Activity	Frequency	Duration	Repeats?
At Power Up:	3	250 ms	No
Any Needle position within the safety margin limit:	1	50 ms	Yes
BGM calibrate or configuration operation, Move or Jog:			
• If the operation is prevented	3	50 ms	No
• If the operation succeeds	1	100 ms	No
Start of each Move, including Jog:	1	250 ms	No

2.0   Error Messages

Table 8: Affirm Error Messages

Error Message	How to Correct
No Device Select	Select a biopsy device.
No Paddle	Install a biopsy paddle.
User is not logged in	Log in at the Acquisition Workstation.
Unit is unlatched	Put both lock levers into the locked position (see the *figure Installation of the Biopsy Guidance Module* on page 9).
Unknown Error	1. Select the system status icon in the taskbar of the Selenia Dimensions. 2. Select the Clear All Faults options. 3. If the message continues to display, contact Technical Support.
Unrecoverable Error	Contact Technical Support. Software must be reloaded.
Safety Margin Infringement	Move the biopsy device to outside of the safety margin. Press the **Sound** button to mute the warning sound.
Calibration Required	Contact Technical Support.
Motion Fault	1. Select the system status icon in the taskbar of the Selenia Dimensions. 2. Select the Clear All Faults options. Another message that is related to the cause of this error can appear. 3. If the Motion Fault message continues to display, contact Technical Support.

Table 8: Affirm Error Messages

Error Message	How to Correct
Comm Error	1. Select the system status icon in the taskbar of the Selenia Dimensions. 2. Select the Clear All Faults options. This error can occur when the manual Z-control is turned quickly.
Hardware Error	1. Select the system status icon in the taskbar of the Selenia Dimensions. 2. Select the Clear All Faults options. 3. If the message continues to display, contact Technical Support.
Selftest Error	1. Disconnect the Affirm cable from the Selenia Dimensions. 2. Re-connect the Affirm to the Selenia Dimensions. 3. If the message continues to display, contact Technical Support.
Stuck Switch Fault	1. Disconnect the Biopsy Control Module from the Biopsy Guidance Module. 2. Re-connect the Biopsy Control Module to the Biopsy Guidance Module.

Appendix A
System Specifications

1.0   Affirm Measurements
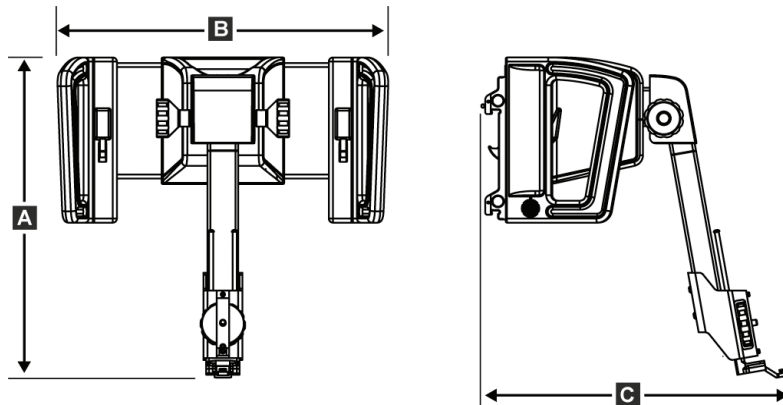
A. Height	37.1 cm (14.6 inches)
B. Width	37.8 cm (14.9 inches)
C. Depth	35.6 cm (14 inches)

2.0   Biopsy Guidance Module

Weight	*15 pounds*
Accuracy	*± 1 mm*
Range of Movement	*X-axis: ±35 mm*
	Y-axis: +72.8 mm
	Z-axis: + 161 mm
Speed of Motorized Movements	*Continuous: No faster than 5 mm per second)*
	Incremental: 0.5 mm steps
Power System	*Input from Selenia Dimensions: +15Vdc±10% and +5Vdc±10%*
	Output: +12Vdc

3.0   Biopsy Control Module

Display Window	*Touch screen controls*
Weight	*3 pounds*
Power System	*Input from Biopsy Guidance Module: +5Vdc±10%*

Affirm™
Breast Biopsy Guidance System

Appendix B
Forms

1.0   QAS Needle Test Checklist

Date	Tech	X Error	Y Error	Z Error	Pass/Fail

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