

User Manual

Affirm™

Breast Biopsy Guidance System

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-axis motors in the Affirm move the biopsy device left or right and front 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. See the User Manual for the Selenia Dimensions for complete information about the system.

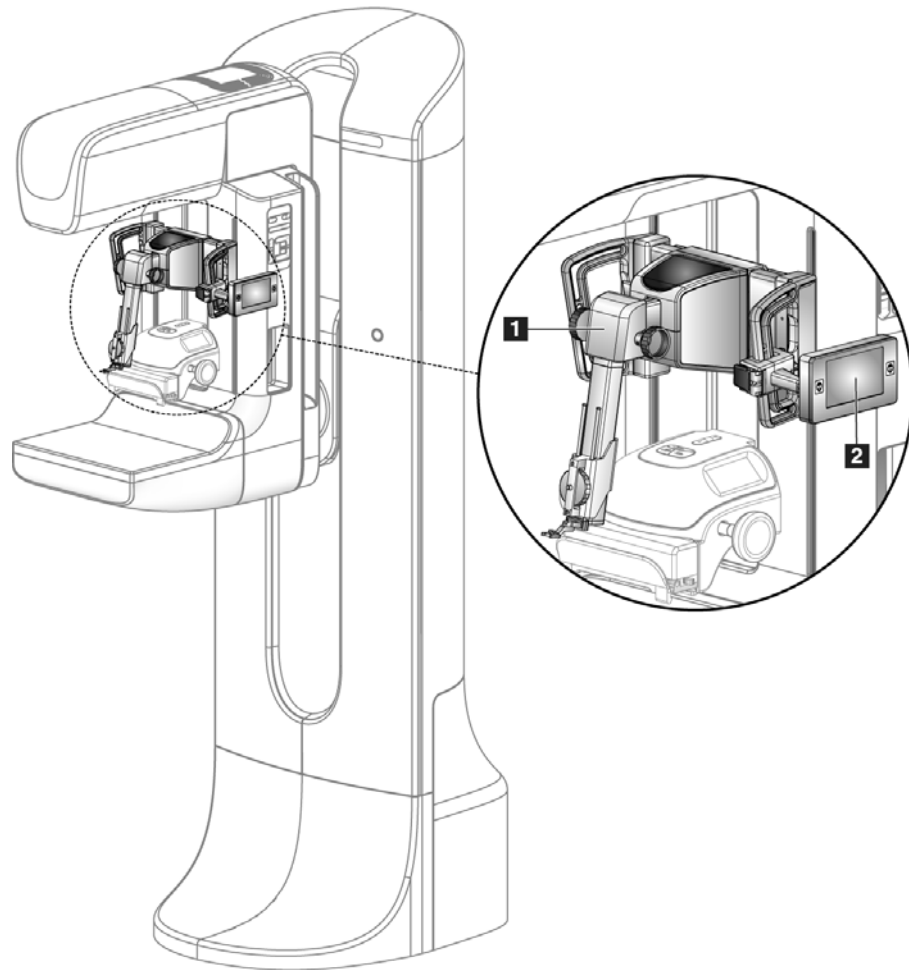


Figure 1-1: Affirm on the Selenia Dimensions

Legend for Figure 1-1

1. Biopsy Guidance Module
2. Biopsy Control Module

2.0 Biopsy Guidance Module Components

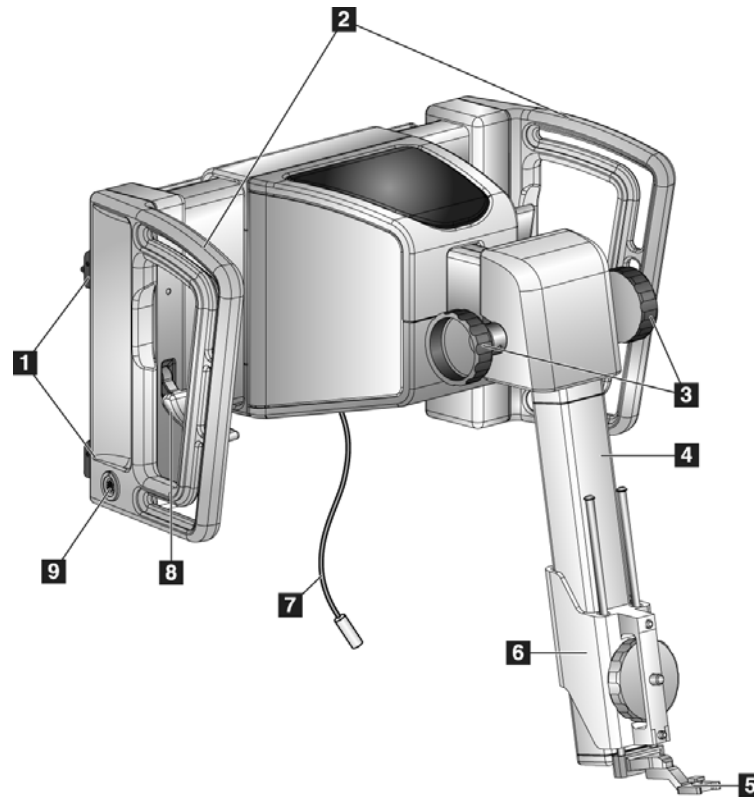


Figure 1-2: Biopsy Guidance Module

Table 1-1: 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	Biopsy Device Slide	Holds the biopsy device 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 Biopsy Device Slide 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.

3.0 Biopsy Control Module Components

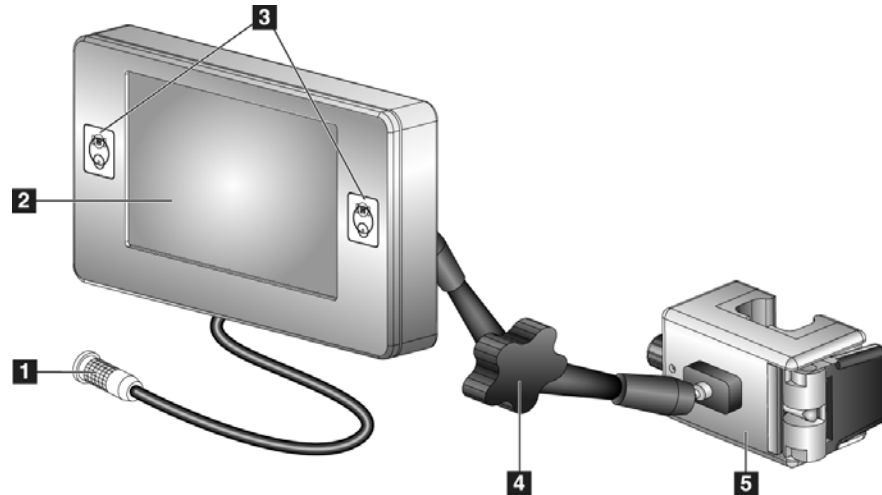


Figure 1-3: Biopsy Control Module

Table 1-2: Components of the Biopsy Control Module

#	Item	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.

4.0 Safety

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

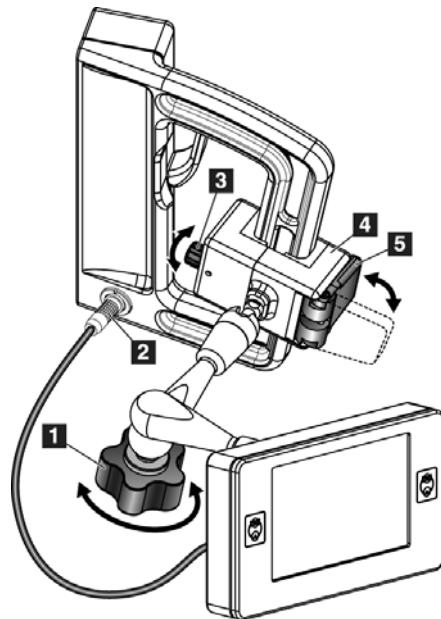
Always follow all the instructions in this manual. Hologic does not accept the responsibility for injury or damage from wrong system operation. Hologic can arrange for training at your facility.

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.

1.2 How to Attach the Biopsy Control Module

1. Release the Articulating Arm Lock Knob (1).
2. Position the Attachment Bracket (4) so that the side with the Lock (5) will be on the front side of the handle. See Figure 2-2.
3. Attach the Lock side of the Attachment Bracket over 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, tighten the Clamp Adjust Knob (3).
6. Push the Attachment Bracket Lock to the locked position (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 (3).
8. Connect the Biopsy Control Module Cable (2) to the Biopsy Guidance Module.



Legend for Figure 2-2

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

Figure 2-2: Attachment of the Biopsy Control Module

1.2.1 How to adjust the bracket height

1. Release the Attachment Bracket Lock (5).
2. Slide the bracket to the required height.
3. Put the Attachment Bracket Lock (5) into the locked position.

1.2.2 How to adjust the Biopsy Control Module position

1. Release the Lock Knob (1) for the Articulating Arm.
2. Tilt or change the current angle of the Biopsy Control Module.
3. Turn the Lock Knob (1) to lock the Biopsy Control Module in the new position.

2.0 System Verifications

2.1 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.

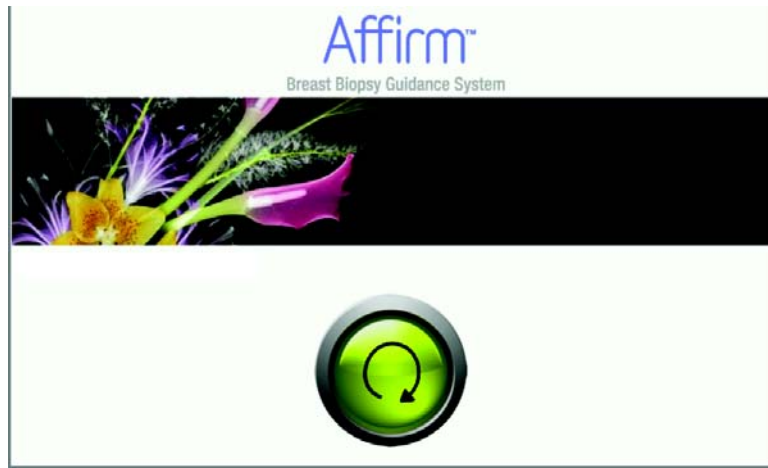


Figure 2-3: Home Screen on the Biopsy Control Module

2.2 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 Checklist in Chapter 7, page 33.

2.2.1 Auto Biopsy Mode

1. Select the **Admin** button on the Selenia Dimensions, then select the **QAS** button.

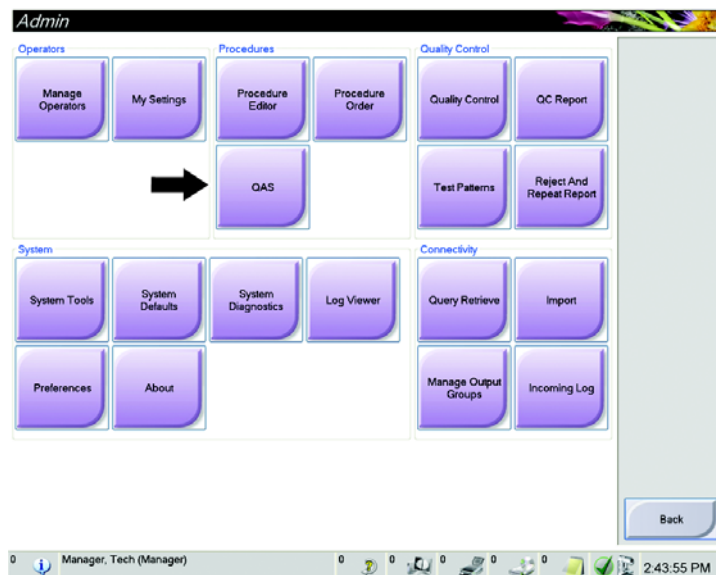


Figure 2-4: Admin Screen

1.2 Target Guidance Screen

This is the main screen of the Biopsy Control Module. This screen indicates to the user the current position of the biopsy device, the intended target coordinates and the difference between the two positions.

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

The display area (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 (10), the biopsy device installed on the system (8), and the safety margins (9).

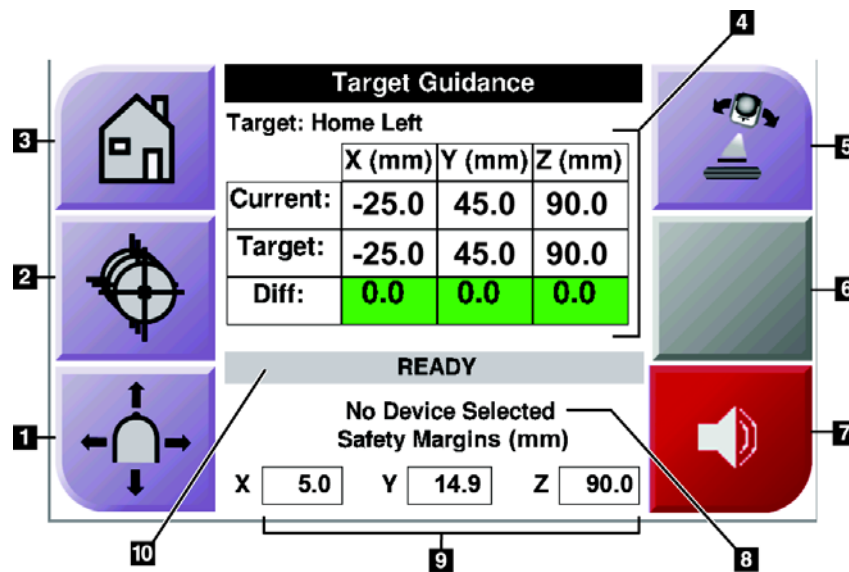


Figure 3-2: Target Guidance Screen

Legend for Figure 3-2

1. Go to the Jog Mode Screen
2. Go to the Select Target Screen
3. Go to the Home Screen
4. Target Information
5. Switch between C-Arm Mode or Stereo Mode
(An icon displays on this button when the system is in Manual Biopsy Mode. See Table 3-2, page 22. In Auto Biopsy Mode this button is grey and disabled.)
6. Future Use
7. Mute or Enable Sound (An icon displays on this button and an alarm sounds when there is a system fault. See Section 1.2.2, page 18.)
8. Selected Biopsy Device
9. Safety Margins
10. System Status



Note...

The Fields can change color as target coordinates change. See Section 1.2.1, page 17 for information.

1.2.1 Colored Fields in the Screens

Green Fields

When all Diff fields are green, the biopsy device is in the correct position for the selected target, and when the biopsy device is fired, the lesion is at the center of the aperture of the device.

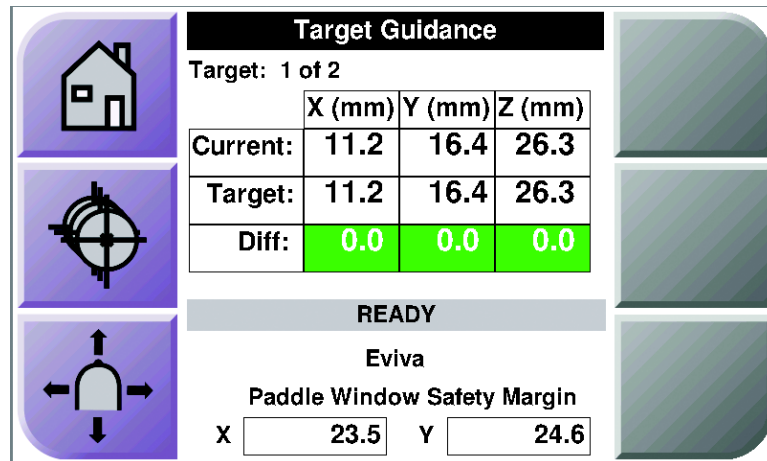
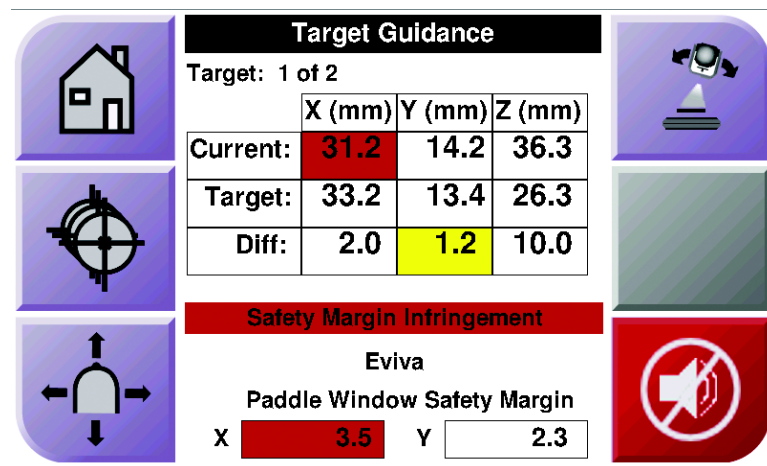


Figure 3-3: Green Fields Indicate Correct Position

Yellow and Red Fields



- **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 field 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 field is not red, the device is within the safety limits.



Warning:

Red fields indicate a problem with a safety margin. Patient injury or equipment damage may occur if you continue. Make adjustments to be within safety limits. See Section 1.2.1, page 17 for more information.



Note...

You must press both the front and back sides of a **Motor Enable** button at the same time to start the selected Jog movement. Keep both sides of the **Motor Enable** button pressed until the movement stops.

2.0 Selenia Dimensions

2.1 Stereo Views

2.1.1 How to Add a Stereo View

1. From the Procedure screen, select the **Add View** button.

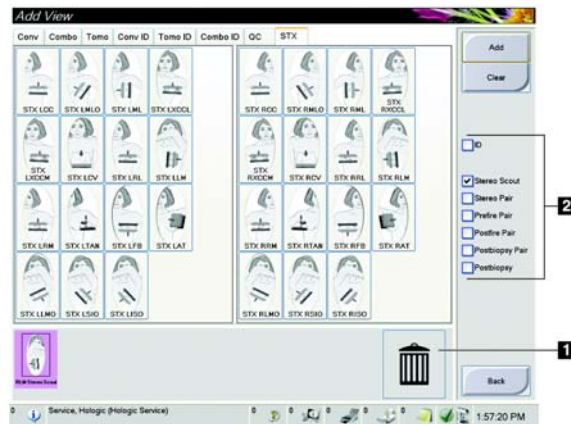


Figure 3-8: Add a Stereo View

Legend for Figure 3-8

1. Trash icon
2. View Modifiers

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

2.2 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 (see Section 2.2.2, page 23).

2.2.1 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.

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 Affirm to acquire the stereo images. When the x-ray button is pressed to start stereo image acquisition, the C-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 (see Figure 3-12) 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 Table 3-2, page 22.



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 3-2: The C-Arm Stereo Mode Button

Icon	Description of Function
 <p>Figure 3-9: Stereo Mode</p>	<ul style="list-style-type: none"> The C-arm rotates while the Affirm remains in position. Select Stereo Mode to acquire stereo images (when the system is set for Manual Biopsy Mode).
 <p>Figure 3-10: C-Arm Mode</p>	<ul style="list-style-type: none"> The C-arm and Affirm rotate together. Select C-Arm Mode to rotate the C-arm and Affirm 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 C-arm to the first 15° position.
3. Press the x-ray button and acquire the first 15° image.
4. Rotate the C-arm to the opposite 15° position.
5. Press the x-ray button and acquire the opposite 15° image.


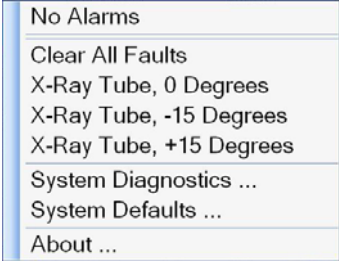
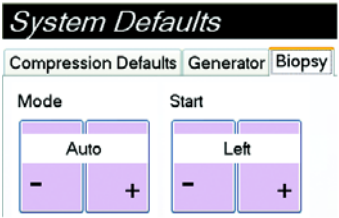


Note...

Keep the x-ray button pressed until the exposure stops. An audible beep indicates the image acquisition has finished.

2.2.2 How to Select the Biopsy Mode for Image Acquisition

Table 3-3: Select the Biopsy Mode

1. Select the System Status icon.	 <i>Figure 3-11: System Status Icon</i>
2. Select System Defaults from the System Status menu.	 <i>Figure 3-12: System Status Menu</i>
3. Select the Biopsy tab in the System Defaults screen. 4. Select Auto (or Manual) from the Mode section.	 <i>Figure 3-13: System Defaults Screen</i>

2.3 Biopsy Tab

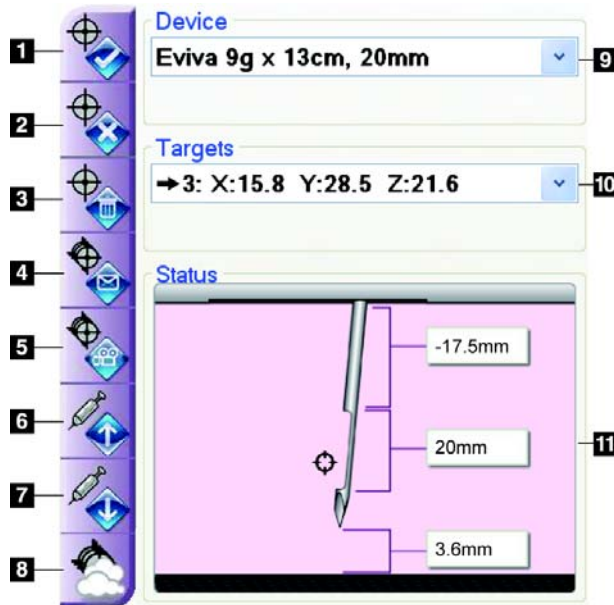


Figure 3-14: Function Buttons and Data on the Biopsy Tab

Legend for Figure 3-14

1. **Create Target** sends the current target list that displays on the Biopsy tab screen 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, if that target was not accepted.
3. **Delete Target** removes the selected target.
4. **Resend Target** sends the selected target set to the Biopsy Control Module.
5. **Project Targets** shows the selected targets on the active image.
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 on the Biopsy tab screen.
9. **Biopsy Device** shows the name of the attached biopsy device that was selected from the drop-down list. The name, dimensions, and aperture size in the needle for the selected biopsy device display.