

Refer to this sheet for QAS Test and Stereo Biopsy procedures on the Affirm® breast biopsy guidance system. It does not replace the instructions in the Affirm system *User Guide*. Be sure to refer to the Affirm system *User Guide* for all warnings and cautions.

1.1 QAS Test

This test is needed only once before the first case of the day.

1. Select the **Admin** button on the Selenia® Dimensions® or 3Dimensions™ digital mammography and digital tomosynthesis systems, and then select the **QAS** button from the Admin screen.
2. Remove the Compression Paddle. When QAS with tomosynthesis is done with 1.7x systems, keep the paddle height to 55-65mm.
3. Attach the QAS Phantom at the top of the Z-axis Slide Rail. If the QAS uses a needle, fully extend the needle.
4. Press and hold a right or left **Motor Enable** button pair on the Biopsy Control Module. (The QAS Phantom moves automatically to pre-programmed X and Y positions of 30/40/50.)
5. Turn the Z-axis Control Knob to show 0.0 on the Diff line in all three columns of the Biopsy Control Module.
6. Select **Manual exposure mode, Rhodium filter** in the QAS screen.
 - For QAS Needle use 25 kV, 10 mAs
 - For QAS Tomo Phantom use 25 kV, 30 mAs
7. **Acquire** and **Accept** the first view in the procedure. The Auto-Accept function is not enabled during the QAS procedure, and targeting on the QAS Phantom occurs automatically.
8. Select the **Create Target** button to send the target to the Biopsy Control Module. Make sure that the target coordinates are within ± 1 mm of X, Y, and Z numbers on the current line of the Biopsy Control Module. If the target coordinates are out of range, speak with Technical Support at 1-877-371-4372.
9. Repeat steps 7 and 8 for all unexposed views.
10. Select the **End QC** button on the Acquisition Workstation screen.
11. Press a **Home Position** button (Left or Right) to move the QAS Phantom to the side.
12. Remove the QAS Phantom from the Z-axis Slide Rail.

1.2 Doing a Procedure



Warning:

It is important to install the device correctly. Be sure to insert the needle through the top and bottom Needle Guides.

1.2.1 Prepare the System and Patient for the Standard 2D Biopsy

1. Record patient information on the Acquisition Workstation.
2. Position and prepare the patient.
3. Select the device from the drop-down menu in the staging area.
4. Take a scout image, using Auto Filter.
5. Take a stereo pair and target the lesion.
6. View the staging area to confirm the ability to biopsy.
7. Create Target and confirm transmission.
8. Place the Needle Guide into the Needle Guide holders.
9. Make sure that the biopsy instrument is in the cocked position, if necessary, and attach it to the Z-axis.

1.2.2 Prepare the System and Patient for the Tomo Biopsy

1. Enter patient information on the Acquisition Workstation.
2. Position and prepare the patient.
3. Select the device from the drop-down menu in the staging area.
4. Take a Tomo scout image, using Auto Filter.
5. Target the lesion on the correct slice.
6. View the staging area to confirm the ability to biopsy.
7. Create Target and confirm the transmission.
8. Place the Needle Guide into the Needle Guide holders.
9. Make sure that the biopsy instrument is in the cocked position, if necessary, and attach it to the Z-axis.

1.2.3 Do the Biopsy

1. Press the **Motor Enable** button to position the Stage at the X and Y coordinates.
2. Move the needle near the skin to indicate the area for the skin nick.
3. Inject anesthesia.
4. Turn the Z-axis to move the needle into the breast until the Diff X, Y, and Z are green.
5. If desired, acquire the pre-fire stereo images as necessary to identify the correct needle position.
6. If applicable, fire the biopsy device.
7. If desired, acquire the post-fire stereo image.
8. Obtain the sample by operating the biopsy device according to the instructions of the manufacturer.