

Refer to this sheet for QAS Test and Stereo Biopsy procedures on the Affirm™ Prone Biopsy 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

Run the QAS test before the first case of the day.

1. At the Select Patient screen, select **Admin**.
2. At the Admin screen, select **QAS**.
3. At the QAS screen, select the **Biopsy** tab. Make sure that **QAS** appears in the Device Field.
4. Remove the Compression Paddle.
5. Attach the QAS Phantom at the top of the Z-axis Slide Rail.
6. Press and hold a right or left **Motor Enable** button pair on the Biopsy Control Module. (The QAS Phantom needle moves automatically to pre-programmed X and Y positions of 30/40/50.)
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 **Manual exposure mode, Silver (Ag) filter** in the QAS screen. For QAS Tomo Phantom, use 25 kV, 30 mAs.
9. **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.
10. Select **Create Target** 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.



Note

If the target coordinates are out of range, speak with Applications Support at 1-888-679-0689.

11. Repeat steps 9 and 10 for all unexposed views.
12. Select **End QC** on the Acquisition Workstation screen.
13. Press **Home Position** (Left or Right) to move the QAS Phantom to the side.
14. 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 or Lateral Needle Approach 2D Biopsy

1. Enter the patient information on the Acquisition Workstation.
2. Position and prepare the patient according to the clinical procedure of your facility.
3. Select the device from the drop-down menu in the staging area.
4. If approaching with the lateral arm, move the Biopsy Arm to the appropriate position.
5. Take a scout image.
6. Take a stereo pair and target the lesion.
7. View the staging area to confirm the ability to place the needle.
8. Create the Target and confirm transmission.
9. Place the appropriate needle guide into the needle guide holder.
10. Make sure that the biopsy instrument is in the cocked position (if required) and attach it to the Z-axis.

1.2.2 Prepare the System and Patient for the Standard or Lateral Needle Approach Biopsy

1. Enter the patient information on the Acquisition Workstation.
2. Position and prepare the patient according to the clinical procedure of your facility.
3. Select the device from the drop-down menu in the staging area.
4. If approaching with the lateral arm, move the Biopsy Arm to the appropriate position.
5. Take a Tomo scout image.
6. Target the lesion on the correct slice.
7. View the stage area to confirm the ability to place the needle.
8. Create the Target and confirm transmission.
9. Place the appropriate needle guide onto the needle guide holder.
10. Make sure that the biopsy instrument is in the cocked position (if required) and attach it to the Z-axis.

1.2.3 Perform the Biopsy Procedure

1. Press **Motor Enable** button on Biopsy Control Module 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 differential 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 images.
8. Obtain the sample by operating the biopsy device according to the instructions from the manufacturer.
9. Remove the biopsy device and place a marker, if desired.
10. Slowly release compression while supporting the breast.