

# Affirm<sup>®</sup>

## Contrast Biopsy



## User Guide

MAN-10383-002 Revision 001

**HOLOGIC<sup>®</sup>**

# Affirm<sup>®</sup> Contrast Biopsy

Software

## User Guide Supplement For Affirm Breast Biopsy Guidance Systems

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## Chapter 1 Introduction

Read all this information carefully before operating the system. Follow all warnings and precautions as stated in this manual. Keep this manual available during procedures. Physicians should tell patients about all potential risks and adverse events described in this manual with respect to the operation of the system.

**Note**

Hologic configures some systems to meet specific requirements. Your system configuration may not have all the options and accessories included in this manual.

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**Note**

For complete instructions on using the Affirm system, refer to the Affirm breast biopsy guidance system *User Guide*.

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### 1.1 Indications for Use

R<sub>x</sub>Only

Caution: United States federal law restricts this device to sale by or on the order of a physician.

#### 1.1.1 Affirm Breast Biopsy Guidance System

The Affirm® breast biopsy guidance system is an optional accessory for the Selenia® Dimensions® 2D full field digital mammography system and the 3Dimensions™ mammography system. It is designed to allow the accurate location of lesions in the breast in three dimensions. It is intended to provide guidance for interventional purposes such as biopsy, pre-surgical localization or treatment devices.

#### 1.1.2 Affirm Contrast Biopsy

Affirm® Contrast Biopsy is indicated as an optional accessory for the Selenia® Dimensions® 2D full field digital mammography system and the 3Dimensions™ system. It is designed to allow the accurate location of lesions in the breast in three dimensions, using information extracted from stereotactic pairs of two-dimensional images. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices). Contrast Enhanced Digital Mammography (CEDM) is an extension of the existing indication for diagnostic mammography with the Selenia Dimensions system and 3Dimensions system. The CEDM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and/or ultrasound exams to localize a known or suspected lesion. Affirm Contrast Biopsy is intended for patients recommended for biopsy who have had a suspicious finding on previous contrast enhanced imaging or have lesions that may be occult under other modalities.

### **1.2 Patient Target Group**

Affirm Contrast Biopsy is intended for patients recommended for biopsy who have had a suspicious finding on previous contrast enhanced imaging or have lesions that may be occult under other modalities.

### **1.3 Clinical Benefits**

Affirm Contrast Biopsy is anticipated to have a beneficial effect on the patient's health by providing an additional targeting modality that can enhance the likelihood of accurate localization and biopsy of lesions in the breast, further contributing to the beneficial effects of the Affirm breast biopsy guidance system listed above.

## Chapter 2 Biopsy

**Warning:**

**Patients may move during the breast compression required for a biopsy procedure. This movement can result in making the target invalid.**

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**Note**

For complete information on image acquisition, refer to the Selenia Dimensions system and 3Dimensions system *User Guides*.

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**Note**

For complete information on targeting and biopsy options, refer to the Affirm breast biopsy guidance system *User Guide*.

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### 2.1 Affirm Contrast Biopsy

**Warning:**

**Patients can have adverse reactions to contrast agents. Refer to the Instructions for Use for the contrast agent for complete information.**

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**Warning:**

**Contrast biopsy uses contrast agents that are injected intravenously. Allergic reactions can occur.**

---

**Warning:**

**If the lesion is not visible using full field digital mammography or digital breast tomosynthesis, use a different imaging modality.**

---

**Warning:**

**For a successful biopsy workflow, targeting must be completed before washout occurs.**

---

**Warning:**

**Do not perform biopsy procedures unless the patient is positioned in a chair.**

---

**Note**

Hologic configures some systems to meet specific requirements. Your system configuration may not have all the options and accessories included in this manual.

---



### 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.



### Note

Make sure that the biopsy device is out of the imaging area.



### Note

The overall targeting accuracy is equal to the combined targeting accuracy of the Biopsy Guidance Module and the biopsy device. When using the biopsy device, the maximum deviation from the target coordinate will not be more than 2 mm from either side.

1. Select the **Contrast** tab to access the Contrast Biopsy function.

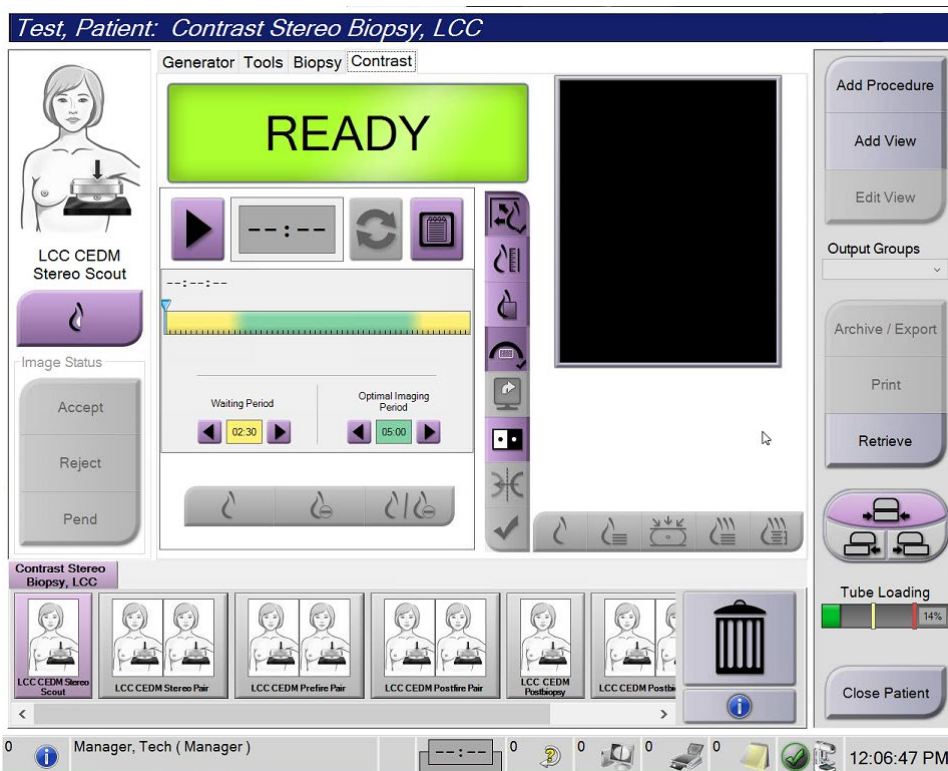


Figure 1: Contrast Stereo Biopsy Screen

2. Set the contrast settings. For more information, refer to [How to Configure the Contrast Settings](#) on page 10.



### Note

When you set contrast information, it appears in the DICOM header of the images.

- To begin the contrast dose and start the timer, select the **Start** (arrow) button.

The timer begins in the **Waiting Period**, which appears with a yellow background.



### Note

When performing Affirm Contrast Biopsies, position and compress the patient after the injection of the contrast agent is complete.



### Note

You can adjust the length of time for the **Waiting Period** and **Optimal Imaging Period** phases of the timer for each procedure. Use the left and right arrows.



### Note

You can adjust the default length of time for the **Waiting Period** and **Optimal Imaging Period** phases of the timer. Refer to *Set the Contrast Defaults* in the Selenia Dimensions system and 3Dimensions system User Guides.



Figure 2: Contrast Biopsy Screen, Waiting Period



### Note

The timer function does not allow you to stop the timer, only to start and reset it. The timer stops only when you exit the patient procedures.

After the **Waiting Period**, the timer begins the **Optimal Imaging Period**, which appears with a green background.

4. Acquire the images during the **Optimal Imaging Period**.  
After you acquire an image, a marker will appear below the timer.

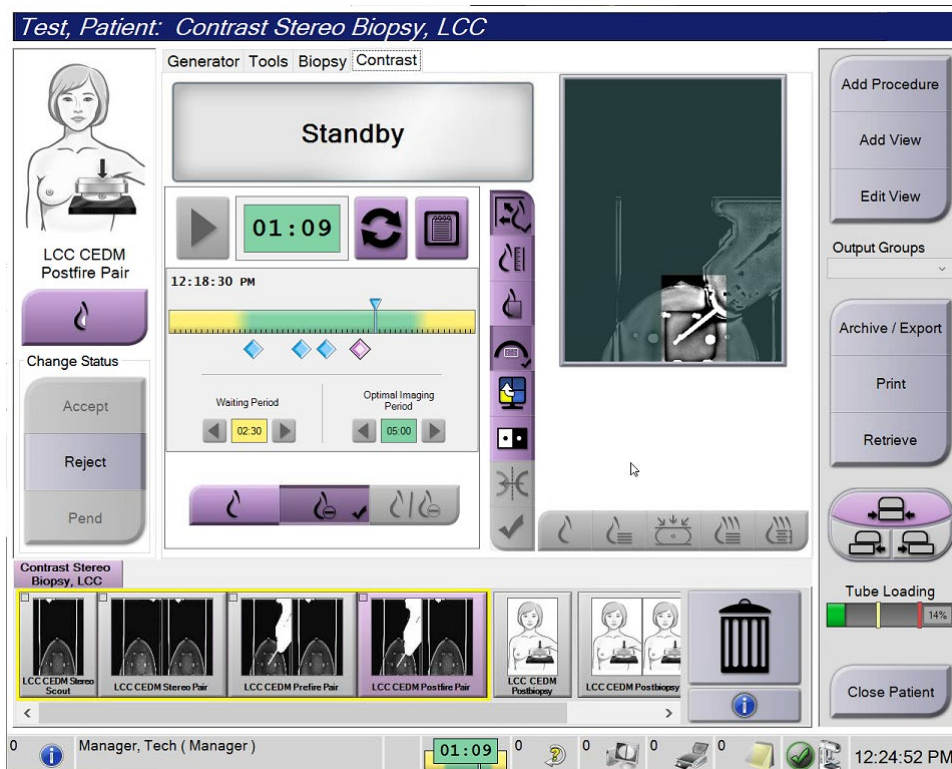


Figure 3: I-View 2D Contrast Screen, Optimal Imaging Period

5. Select the low and high exposure buttons to display both low and high energy images.
  - **Low:** Conventional low-energy image
  - **Sub:** Contrasted, subtracted image
  - **Low Sub:** Shows both the low and sub screen images side-by-side in a split screen.

**Caution:**

Performing a Contrast procedure increases the recovery time the machine needs before more images are acquired. When the System Status icon appears red



, a recommended wait time is shown. This wait time lets the x-ray tube temperature decrease to avoid damage that can void the x-ray tube warranty. Always

make sure that the System Status icon is green  before starting a Contrast procedure. If the System Status icon turns red during a procedure, wait for the recommended amount of time before acquiring any more images, and then complete the procedure quickly using the minimum number of exposures.

The x-ray tube heat load is tracked by the tube loading indicator. Be aware of the tube loading status when acquiring Affirm Contrast Biopsy images. Refer to [Tube Loading Indicator](#) on page 9.

6. Select the **Accept** button to save the stereo images.

**Note**

Your Service representative can configure the system to Auto-Accept new images.

7. Click in the area of interest of the lesion in one of the stereo images.
8. Click the other stereo image, then click in the area of interest of the lesion.
9. Select the **Create Target** button to save the target. The active target set automatically transmits to the Biopsy Control Module with the creation of each new target.
10. Repeat this procedure to create multiple targets (a maximum of six).

**Note**

The target that shows 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.

## 2.2 Verify the Position of the Biopsy Device

If desired, use the following steps to verify the position of the biopsy device.

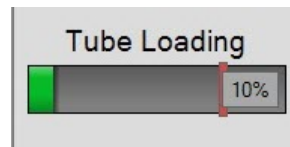
1. Acquire the pre-fire images as necessary to identify the correct needle position.
  - Verify the needle position.
  - Make adjustments as necessary.
2. If applicable, fire the biopsy device.
3. If desired, acquire the post-fire images.
  - Verify the needle position.
  - If necessary, make adjustments.
4. If desired, acquire specimens with the attached biopsy device.
5. If desired, acquire post procedure images.

## 2.3 Tube Loading Indicator

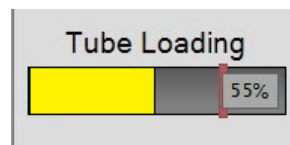
When you have the license for Affirm Contrast Biopsy, the *Procedure* screen includes a Tube Loading indicator. This indicator shows the current heat load of the X-ray tube.

The Tube Loading indicator displays one of the following three statuses:

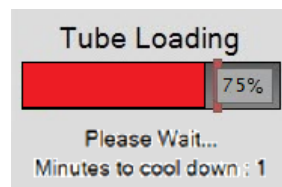
- The X-ray tube heat load is at an acceptable level. The system status icon in the taskbar is green. Continue to acquire images and finish the procedure.



- The X-ray tube heat load is above the warning limit (default = 40%) but below the maximum limit (default = 72%). Finish acquiring the current image, then allow the X-ray tube to cool before finishing the procedure.



- The X-ray tube heat load is above the maximum limit (default = 72%). The system status icon in the taskbar is red and shows the number of minutes required for the X-ray tube to cool. Do not acquire any images. Delay the procedure until the X-ray tube cools.



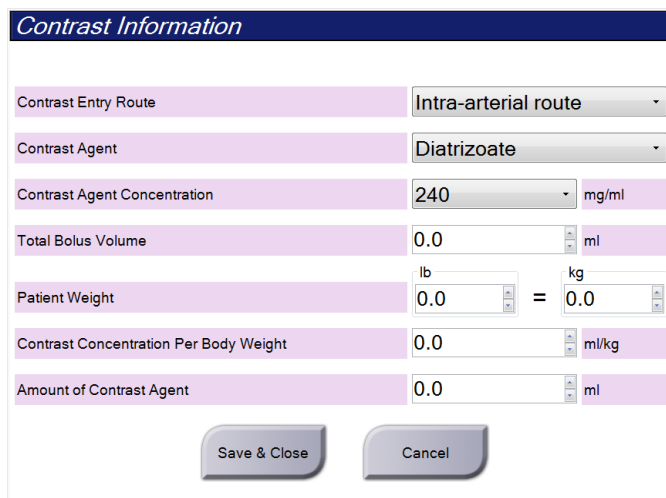
### Caution

Excessive heat buildup can damage the X-ray tube.

---

## 2.4 How to Configure the Contrast Settings

1. From the **Contrast** tab, select the **Configure Contrast** button to edit the contrast settings. The Contrast Information dialog box opens.



The image shows a dialog box titled "Contrast Information" with a dark blue header. The dialog contains several input fields and buttons. The fields are: "Contrast Entry Route" (dropdown menu showing "Intra-arterial route"), "Contrast Agent" (dropdown menu showing "Diatrizoate"), "Contrast Agent Concentration" (dropdown menu showing "240" with "mg/ml" unit), "Total Bolus Volume" (text input showing "0.0" with "ml" unit), "Patient Weight" (text input showing "0.0" with "lb" unit, followed by an equals sign and a text input showing "0.0" with "kg" unit), "Contrast Concentration Per Body Weight" (text input showing "0.0" with "ml/kg" unit), and "Amount of Contrast Agent" (text input showing "0.0" with "ml" unit). At the bottom, there are two buttons: "Save & Close" and "Cancel".

Figure 4: I-View 2D Contrast Information

2. Use the drop-down lists to select the appropriate settings.
3. Enter data for the **Contrast Concentration Per Body Weight** field or the **Amount of Contrast Agent** field. The other field automatically populates with the correct information.
4. Select the **Save & Close** button.

## Chapter 3 Quality Control

MQSA has no requirements for interventional procedures (such as breast biopsy). If your facility is ACR accredited for breast biopsy, refer to the 1999 ACR Stereotactic Breast Biopsy Quality Control Manual on how to do quality control. If your facility is seeking ACR accreditation, refer to the 1999 ACR Stereotactic Breast Biopsy Quality Control Manual to start a quality control program.

Outside of the United States, follow local requirements (such as EUREF guidelines) to create a quality control program for breast biopsy systems).

**Note**

Refer to [CNR Correction for Affirm Contrast Biopsy](#) on page 13 for CNR correction factors.

---

### 3.1 Required Quality Control Procedures

The following procedures are necessary for correct system operation.

*Table 1: Required Procedures for Affirm Breast Biopsy Guidance System*

| Test                                  | Frequency                   |
|---------------------------------------|-----------------------------|
| QAS Test for Standard Needle Approach | Daily - before clinical use |
| QAS Test for Lateral Needle Approach  | Daily - before clinical use |
| Geometry Calibration                  | Semi-annually               |

**Note**

For the Quality Control procedures required for the Affirm breast biopsy guidance system, refer to the Affirm breast biopsy guidance system *User Guide*.

---

*Table 2: Required Procedures for Affirm Contrast Biopsy*

| Test                         | Frequency |
|------------------------------|-----------|
| CEDM Biopsy Gain Calibration | Weekly    |

### 3.2 CEDM Biopsy Gain Calibration

CEDM Biopsy Gain calibration is required weekly. Perform this calibration using the Flat Field phantom supplied with the system.



#### Note

This QC procedure is in addition to the Quality Control procedures documented in the Affirm breast biopsy guidance system *User Guide*.

---



#### Note

Before performing an image quality test, allow the system to warm up and the system status to change to “Ready”.

---



#### Note

This procedure requires the Flat Field phantom.

---

#### 3.2.1 Gain Calibration Procedure

1. Make sure that both the Flat Field phantom and the surface of the image receptor are clean. Place the Flat Field phantom on top of the image receptor covering its entire surface.
  2. Select **Admin > Quality Control > Technologist tab > CEDM Gain Calibration** procedure on the Acquisition Workstation.
  3. Select **Start**.
  4. Follow the instructions on the screen and take the first predefined exposure. Do not change the preselected techniques unless otherwise instructed.
  5. Review the image for foreign objects, gross artifacts other than non-uniformities, or collimation interference.
  6. Select **Accept** if the image is clean and the collimation blades do not intrude into the imaging space.
  7. Repeat steps 4 to 6 for all unexposed views.
- 



#### Note

All predefined exposures need to be completed for the CEDM Biopsy Gain Calibration to be completed successfully. Ending the calibration sequence in the middle of the procedure will invalidate the current calibration and revert back to the previous calibration.

---

8. After acquiring and accepting the last predefined exposure, select **End Calibration**.

## Appendix A CNR Correction for Affirm Contrast Biopsy

### A.1 CNR Correction for Affirm Contrast Biopsy



**Note**

System default setting is AEC Table 0 for imaging under contrast stereo biopsy mode. Listed values apply to software revisions Selenia Dimensions 1.11 and above and 3Dimensions 2.2 and above.

#### A.1.1 AEC Table 0 (Affirm Contrast Biopsy Dose)

| Compression Thickness | Low Energy                     |                                |
|-----------------------|--------------------------------|--------------------------------|
|                       | Detector Serial #:<br>XX6xxxxx | Detector Serial #:<br>XX8xxxxx |
| 2.0 cm                | 0.86                           | 0.86                           |
| 4.0 cm                | 1.00                           | 1.00                           |
| 6.0 cm                | 1.58                           | 1.66                           |
| 8.0 cm                | 1.75                           | 1.87                           |

| Compression Thickness | High Energy                    |                                |
|-----------------------|--------------------------------|--------------------------------|
|                       | Detector Serial #:<br>XX6xxxxx | Detector Serial #:<br>XX8xxxxx |
| 2.0 cm                | 0.72                           | 0.72                           |
| 4.0 cm                | 0.90                           | 0.90                           |
| 6.0 cm                | 1.71                           | 1.71                           |
| 8.0 cm                | 2.22                           | 2.22                           |

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