1.1 Introduction

This addendum updates your Affirm® Prone Biopsy system *User Guide* (MAN-04480) for software version 1.0.2 changes.

Place this addendum with your *User Guide* for future reference.

1.2 Changes in Version 1.0.2

The following changes to the User Guide are based on the release of the v1.0.2 software:

Compression Lock-Out Feature

The following text modifies section *3.2.2 Control Handle Controls:*

When the "system lock" switch [] on the control handle is enabled, the system:

- locks the C-arm
- locks out the motorized compression motion
- prevents x-ray images to be taken on the system

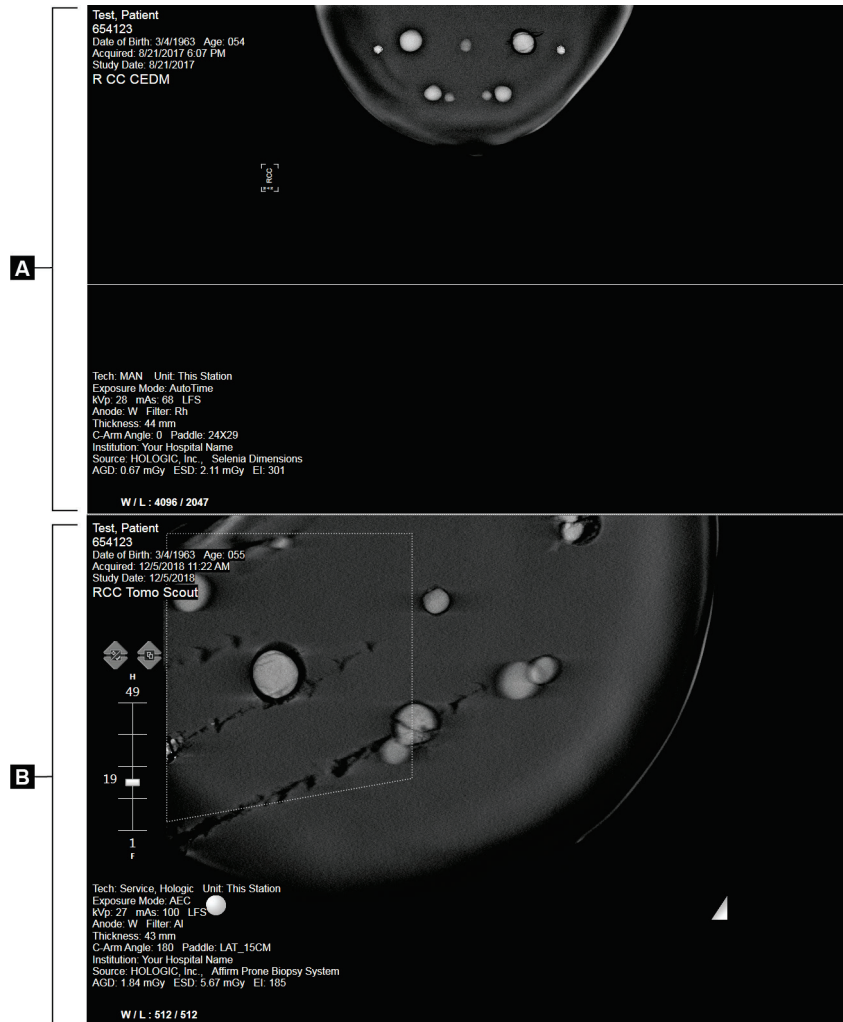### Motorized Compression Usability Improvements

The following text modifies section *3.2.2 Control Handle Controls,* section *3.2.3 Footswitch Controls,* and section *4.2.1 Compression Functional Tests:*

The system allows motorized motion to move the compression device back into the travel range without first requiring an extra manual adjustment. This situation can happen when the compression device has reached the end of its travel range and motion is automatically stopped.

Ability to Hang Non-Biopsy Image Within a Biopsy Workflow

The following text modifies section *5.5.3 How to Add or Remove a View:*

When selecting a prior view in the Procedure screen, the prior view (item A in the following figure) shows on the image display monitor along with the current biopsy view (item B) in a 2-up manner.

Auto-Select New View After Image Reject

The following text modifies section *7.1.1 Conventional Imaging Sequence of Events*, and section *7.1.2 Tomosynthesis Imaging Sequence of Events*, and section *7.2 How to Acquire an Image:*

When rejecting an image in a Biopsy procedure, the system selects the newly created view automatically.

Improved Exposure Recovery Time

The following text modifies section *7.1.2 Tomosynthesis Imaging Sequence of Events,* section *7.2 How to Acquire an Image,* and section *8.5 Lesion Targeting with Tomosynthesis:*

When aborting a Tomosynthesis exposure, the wait time for the system to become Ready for the next exposure is reduced.

Color Coded Needle Safety Margins

The following text modifies section *8.3.1 Biopsy Options* (item 11 in Figure Legend):

Color-coded needle safety margins between the platform and the paddle apply to both standard and lateral needle approaches.

View Editor Limited to Hologic Applications and Service Users

The following text modifies section *9.2 The Admin Screen:*

View Editor is no longer available for Hologic customers and has been removed from the Admin screen.

QAS Test Prompt with Coordinates

The following text modifies section *12.3 QAS Test* and should be inserted after step 2:

The *QAS* screen opens. A dialog box prompts you to install the QAS phantom and shows the position coordinates for the test.
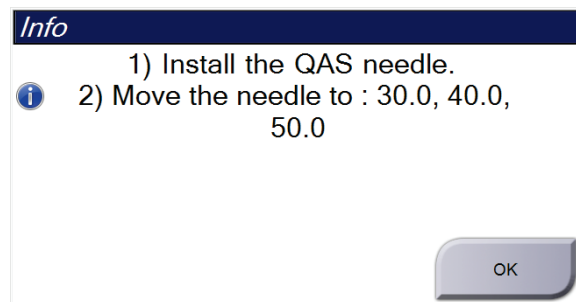
Note
The dialog box says to install the QAS "needle" but is referring to the QAS phantom.

Figure 1: QAS Test Info Dialog Box