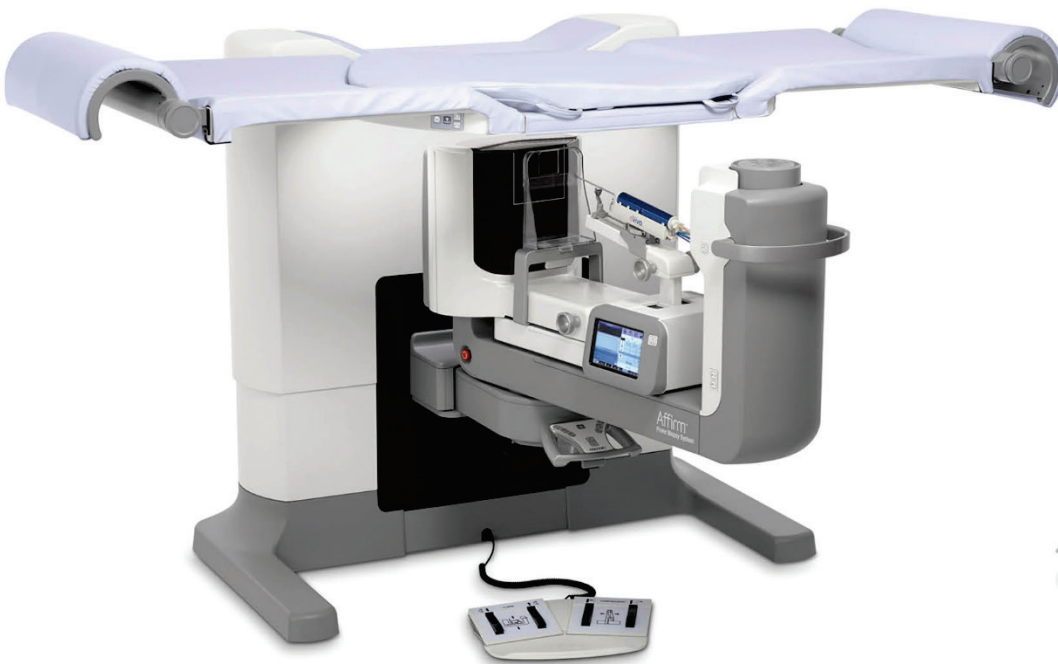


Affirm[®]

Prone Biopsy System



1.0.2 Customer Release Notes

MAN-10923 Revision 001

Affirm®

Prone Biopsy System

Customer Release Notes

For Software Version 1.0.2

Part Number MAN-10923

Revision 001

August 2023

Product Support

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Table of Contents

1: Software Version 1.0.2 Release Notes	1
1.1 Introduction.....	1
1.2 Software Enhancements.....	1
1.3 Security Enhancements.....	4
1.4 Applications Support	4

Software Version 1.0.2 Release Notes

1.1 Introduction

This document provides an overview of the enhancements associated with the 1.0.2 Affirm Prone Biopsy software upgrade. This upgrade can affect daily workflow or other tasks. **Carefully review these customer release notes to understand the new software enhancements and software changes introduced with this upgrade.**




Note

This document is not meant to replace the Affirm® Prone Biopsy system *User Guide*. Changes described in these customer release notes may not be reflected in the current revision of the *User Guide*.

1.2 Software Enhancements

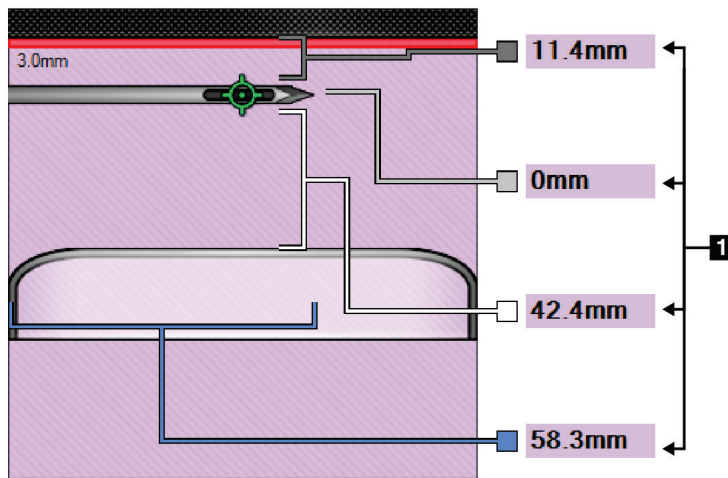
1.2.1 Compression Lock-Out Feature

When the “system lock” switch [] on the control handle is enabled, the system now also locks out motorized compression motion. This new feature is in addition to the current system lock behavior of locking the C-arm and not allowing x-ray images to be taken on the system.

1.2.2 Color Coded Needle Safety Margins

Needle safety margins between the platform and the paddle for lateral needle approach are now color-coded in the biopsy options area of the procedure screen. (The standard approach screen already had color coding of the safety margins.) The distance indicator fields (item 1 in the following figure) change color with the movement of the needle.

- Purple indicates that it is safe to proceed.
- Yellow warns of being near the safety limit.
- Red indicates that the current coordinates exceed the safety margin.

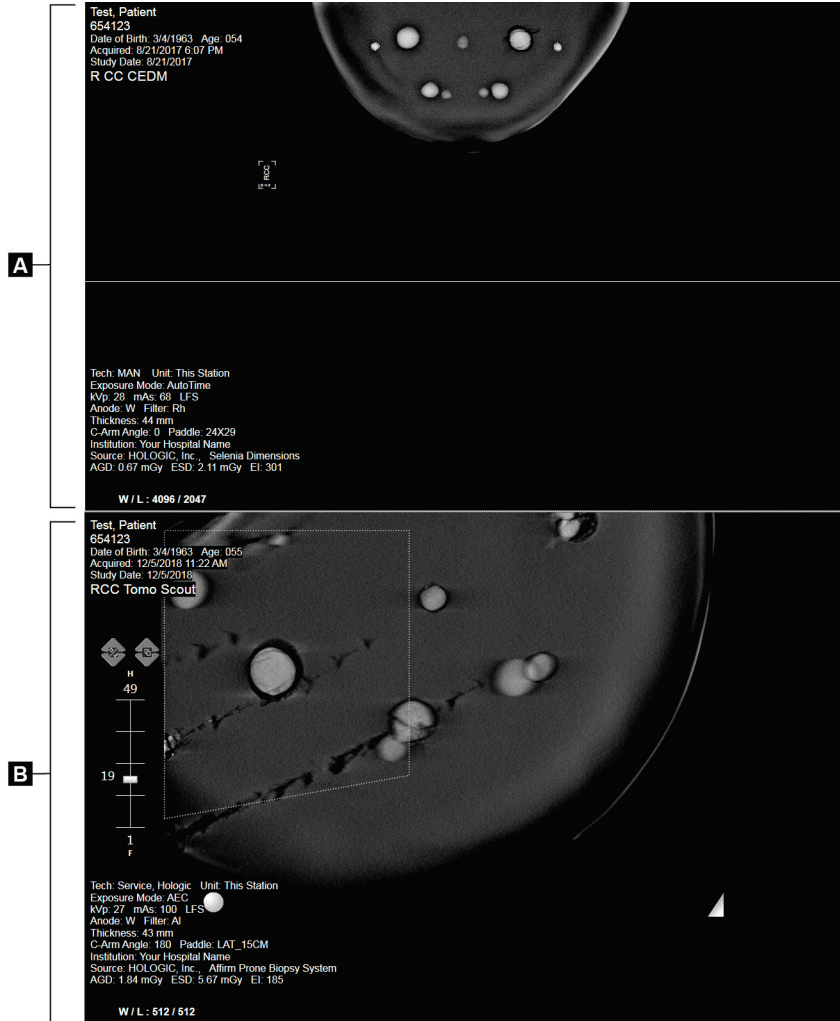


1.2.3 Auto-Select New View after Image Reject

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

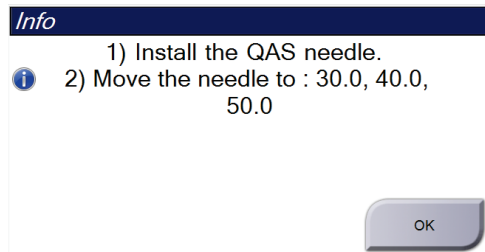
1.2.4 Ability to Hang Non-Biopsy Image Within a Biopsy Workflow

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.



1.2.5 QAS Test Prompt with Coordinates

When the QAS Test is opened, the system now prompts the user to install the QAS phantom and shows the position of the coordinates for the test. (See the following figure.)



1.2.6 View Editor Limited to Apps and Service Users

View Editor under the Admin Tab is now enabled only for Hologic Applications or Service users.

1.2.7 Motorized Compression Usability Improvements

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

1.2.8 Improved Exposure Recovery Time

If an operator aborts a Tomosynthesis exposure, the wait time for the system to become Ready for the next exposure is reduced.

1.2.9 EUREF AEC Table Updates

The system now provides improved AEC dose curves, resulting in better compliance with EUREF QC testing.

1.3 Security Enhancements

1.3.1 OS Patches

This release installs all current OS security patches.

1.4 Applications Support

You can contact Hologic with any questions about this software version.

- In the United States: call Hologic Technical Support at 1-877-371-4372 or email at BreastHealth.Support@hologic.com.
- In Europe and the Middle East: email to BE-Applications@hologic.com.
- In Asia-Pacific: email to AP-AppsSupport@hologic.com.
- In Australia/New Zealand: email to AU-ApplicationsSupport@hologic.com