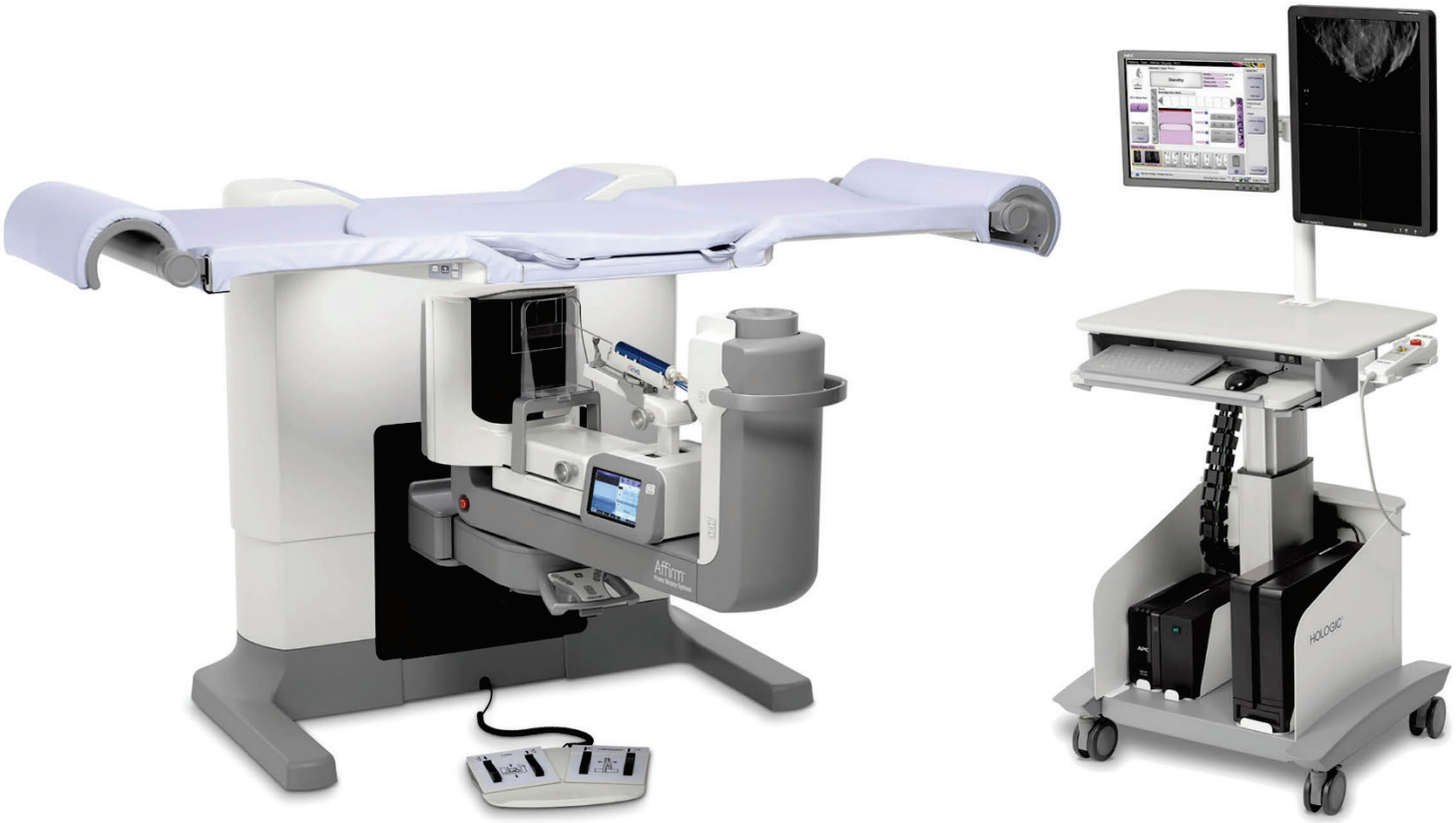
Affirm®
Prone Biopsy System



Customer Release Notes

MAN-06082 Revision 003

HOLOGIC®

Affirm®

Prone Biopsy System

Customer Release Notes

For Software Version 1.1

Part Number MAN-06082
Revision 003
June 2022

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1: Software Version 1.1 Release Notes

1.1 Introduction

This document provides an overview of the enhancements associated with the version 1.1 Affirm® prone biopsy system 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 Windows 10 Operating System

The Affirm prone biopsy system version 1.1 software runs exclusively on a customized version of Windows 10, which has mainstream support from Microsoft® until October 2025.

1.3 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*

2: Cybersecurity Enhancements

2.1 Cybersecurity Hardened Windows 10 Operating System

Hologic's team of Certified Information Systems Security Professionals (CISSP) and Certified Secure Software Lifecycle Professionals (CSSLP), using guidance from the NIST Cybersecurity framework, have designed a custom version of Windows 10 that is hardened against cybersecurity threats.

2.2 User Management Via Windows 10

All user management and authentication, including password policies, are now handled by the Windows 10 operating system (for local authentication) or domain level (if Active Directory is used).

2.3 All ePHI Encrypted at Rest

All ePHI on disk, both within the DICOM image files and within the database, are encrypted using AES-256 strong encryption.

2.4 Windows Firewall Enabled

Windows Firewall is now enabled by default with the appropriate port exclusions configured.

2.5 Clinical User Accounts Function as Standard Windows Accounts

All clinical user accounts operate on non-administrator Windows user accounts for better system security.

2.6 Active Directory

The Affirm prone biopsy system 1.1 software now supports Active Directory for better and easier enterprise user management.

2.7 Windows Defender

Windows Defender, the built-in anti-malware software included in Windows 10, is enabled by default to provide baseline protection against malware. Customers can still install and configure their own enterprise antivirus solution. See the Product Antivirus Installation document for more guidance.

2.8 Cryptographic Security Enhancements

To further enhance security, the deprecated protocols TLS 1.0, TLS 1.1, SSL v3 protocols, and RC4 Ciphers have all been disabled. In addition, Remote Desktop has also been disabled.

2.9 FIPS 140-2 Encryption Now Supported

The system now utilizes FIPS 140-2 compliant encryption within the Windows 10 operating system.

2.10 SHA256 Used For all Hashing

All hashing operations within the system now use a SHA256 algorithm to generate hashed data.

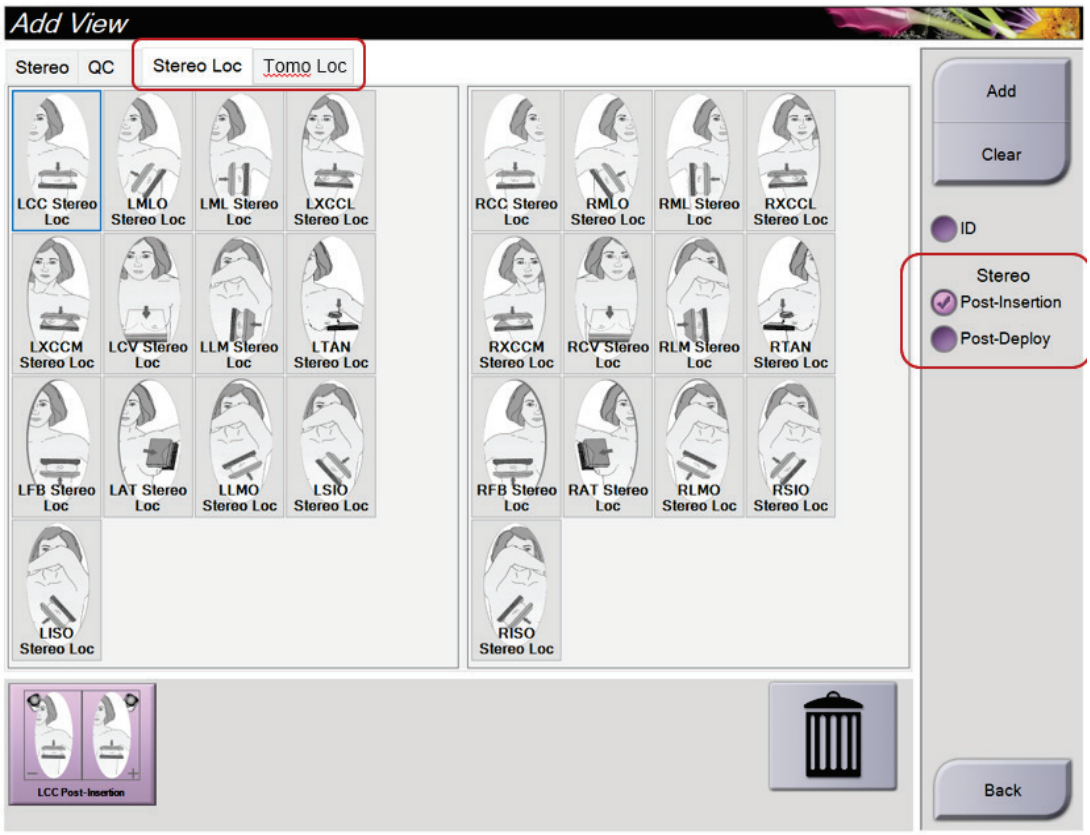
2.11 OS Patches

Microsoft releases critical patches on a regular basis, and Hologic is committed to ensuring the integrity of our customers' systems. Hologic will closely monitor Microsoft's critical patching schedule and actively verify, validate, and release these patches regularly. This will typically be within 30 days of Microsoft's patch release but may vary based on the complexity of the patch or the threat assessment of the vulnerability. After validating the patches, Hologic will provide a list of patches for our customers via the Hologic.com support website under Cybersecurity for each product (see *https://www.hologic.com/support/usa/breast-skeletal-products-cybersecurity*).

3: Software Enhancements

3.1 Localization Procedures

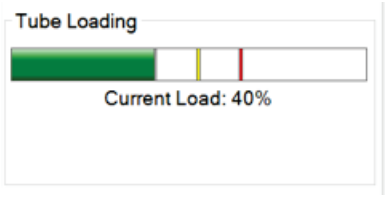
Two new localization procedures – “Stereo Loc” and “Tomo Loc” - were added to the list of default procedures. These may be used during demanding localization procedures calling for multiple images and multiple placements (for example, lesion bracketing). The special features of these new localization procedures revolve around the newly introduced “Post-Insertion” and “Post-Deploy” views. The “Post Insertion” view may be used to determine correct positioning of localization device(s), and the “Post Deploy” view may be used to confirm deployment of localization device(s). The “Post-Insertion” and “Post-Deploy” views have been designed to deliver a lower dose to the patient so that the total dose to the patient during such complex localization procedures will be minimized to as low as reasonably achievable. In addition, the new views place a lighter load on the X-ray tube, allowing for longer procedures with less chance of requiring extra tube cooling time.



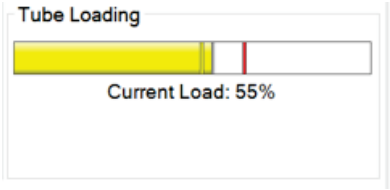
3.2 Tube Loading Warning

The Affirm prone biopsy system version 1.1 software has added an X-ray tube heat load indicator gauge to the **Generator** tab on the *Procedure* screen. Similar to the Dimensions system, the system icon will indicate an X-ray tube over-use condition by making the tubehead area of the system icon glow red when the tube heat load is above a certain threshold. The X-ray tube heat load indicator gauge will display one of the following three scenarios:

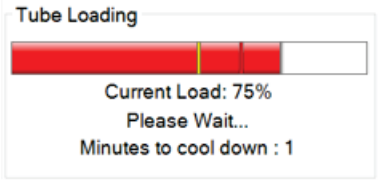
- X-ray Tube heat load below all thresholds



- X-ray Tube heat load above warning threshold (default = 53%) but below over-use threshold (default = 65%)



- X-ray tube heat load above over-use threshold (default = 65%)



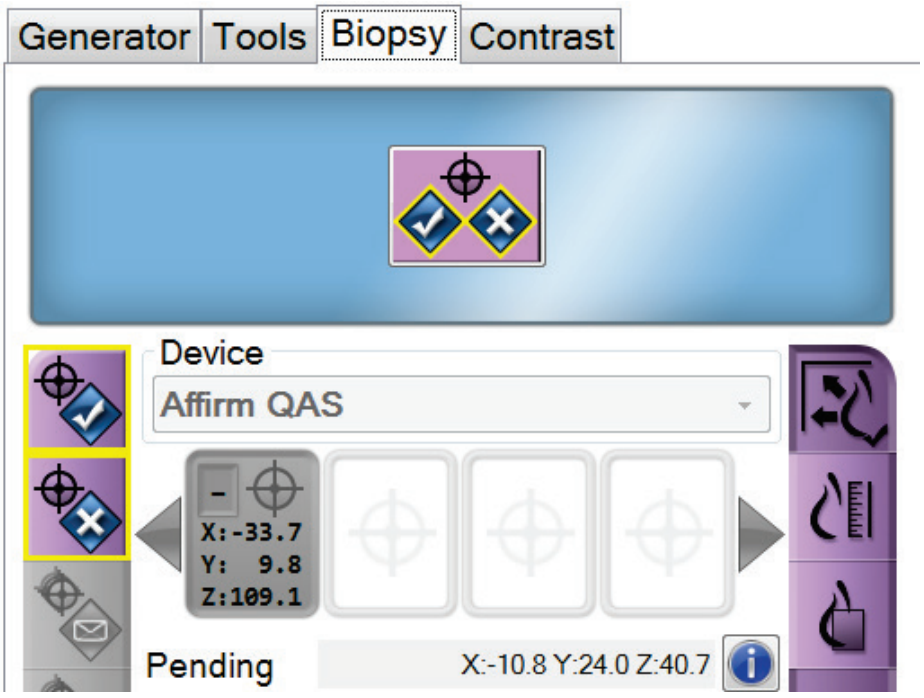
3.3 Miscellaneous UI and Workflow Improvements

3.3.1 Clarified C-Arm Locked/Unlocked Dashboard Icon

The system provides a new “C-Arm Lockout Switch Unlocked” icon and corresponding alert message. This replaces the less-obvious “C-Arm Locked” icon and message previously displayed when the C-arm lockout switch was in the unlocked state.

3.3.2 Additional Indicator to Accept/Reject Targets

After a biopsy target has been created on the Image Display monitor, the System Messages panel now displays the indicator with a blue background (see the following figure) to alert the operator to Accept or Reject the target.



3.3.3 Brevera Breast Biopsy System Needles Added to the Default Needle List

The system now includes the Hologic Brevera® breast biopsy system with options for both the 20 mm Standard and 12 mm Petite arming distances ("Brevera 9gx13cm, 20mm" and "Brevera 9gx13cm, 12mm", respectively).

3.3.4 Verification of Needle Parameters

The system software has modifications to the *Biopsy Devices* page so that all AWS needle parameters are now validated.

3.3.5 Ejecting USB Thumb Drives

There is now a button to safely eject a USB device from within the *Admin* menu.

3.3.6 Warning Displayed When a Target Is Created with a Non-Clinical Needle

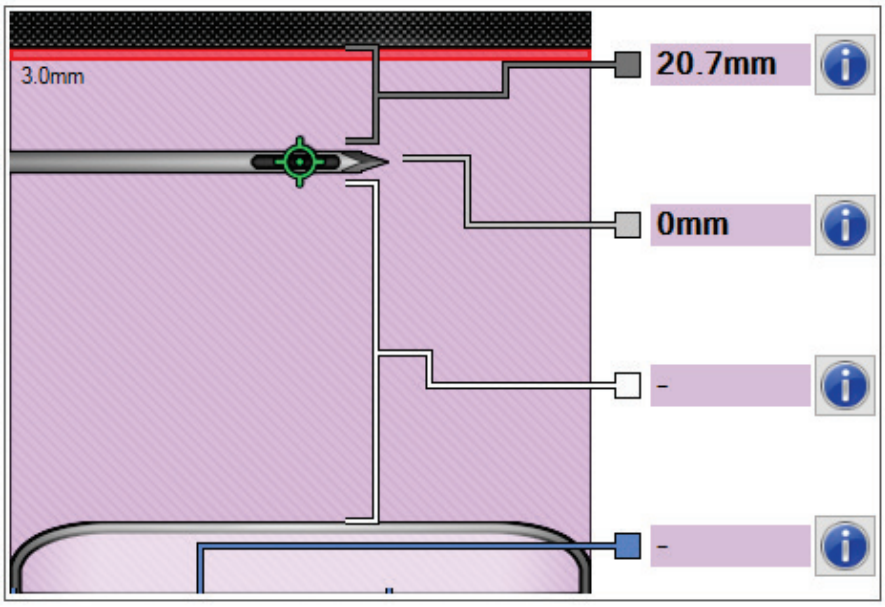
A warning dialog box will now be displayed to the user when a biopsy target is created on a patient image with a non-clinical needle selected (such as the QAS needle).

3.3.7 Audible Alert When Target Position Reached

The system will now produce the "3 beeps" sound indicating end-of-motion, not only when motored motion completes but also after manual Z-axis activation when the needle position arrives within 0.05 mm of the target. The system will not beep again unless the user moves at least 0.2 mm away from the target and then returns to the target.

3.3.8 Value No Longer Shown for Invalid Safety Limit

To reduce confusion, the system will no longer show values for paddle measurements and will instead display a “-“when no paddle is installed.



3.3.9 Image Processing Improvements

Improvements have been made to reduce saturation for tomosynthesis images acquired on thick breasts.

3.3.10 Improved Handling of Invalid DICOM Information

Multiple improvements have been made to handle invalid or non-typical DICOM information on imported patient images and Modality Worklist responses.