

Brevera®

Breast Biopsy System



1.1 Customer Release Notes

MAN-06704 Revision 001

HOLOGIC®

Brevera[®]

Breast Biopsy System

Customer Release Notes

For Software Version 1.1

Part Number MAN-06704

Revision 001

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Software Version 1.1 Release Notes

1.1 Introduction

This document provides an overview of the enhancements associated with the 1.1 Brevera® breast 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 *Brevera Breast 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 Brevera breast biopsy system 1.1 software runs exclusively on a customized version of Windows 10.

1.3 Cybersecurity Enhancements

1.3.1 Cybersecurity Hardened Windows 10 Operating System

The Hologic team of Certified Information Systems Security Professionals (CISSPs) and Certified Secure Software Lifecycle Professionals (CSSLPs), utilizing guidance from the NIST Cybersecurity framework, have designed a custom version of Windows 10 that is hardened against cybersecurity threats.

1.3.2 User Management Via Windows 10

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

1.3.3 All ePHI Encrypted at Rest

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

1.3.4 Windows Firewall Enabled

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

1.3.5 Clinical User Accounts Function as Standard Windows Accounts

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

1.3.6 Active Directory

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

1.3.7 Windows Defender

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

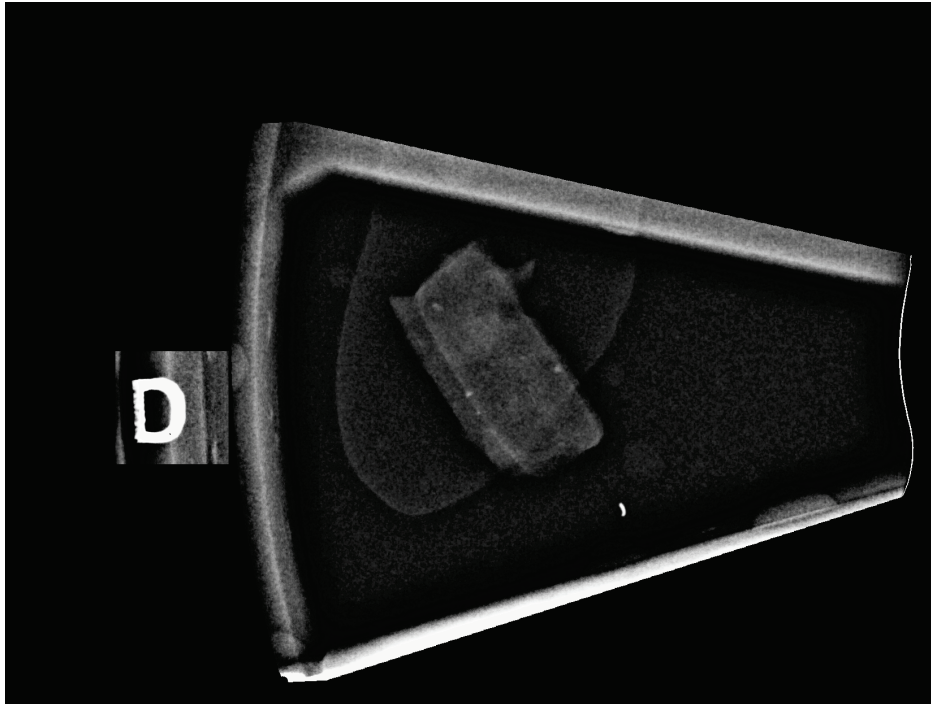
1.3.8 OS Patches

Microsoft releases critical patches on a regular basis, and Hologic is committed to ensuring the integrity of customer systems. Hologic will closely monitor the Microsoft critical patching schedule and actively verify, validate, and release these patches on a regular basis. This will typically be within 30 days of the Microsoft 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 Cyber Security for each product (refer to <https://www.hologic.com/package-inserts/breast-skeletal-health-products/brevera-breast-biopsy-system>).

1.4 Software Enhancements

1.4.1 Image Processing Mask

The CorLumina® system now applies a mask to all images to enhance visualization of the chamber letter and specimen area.



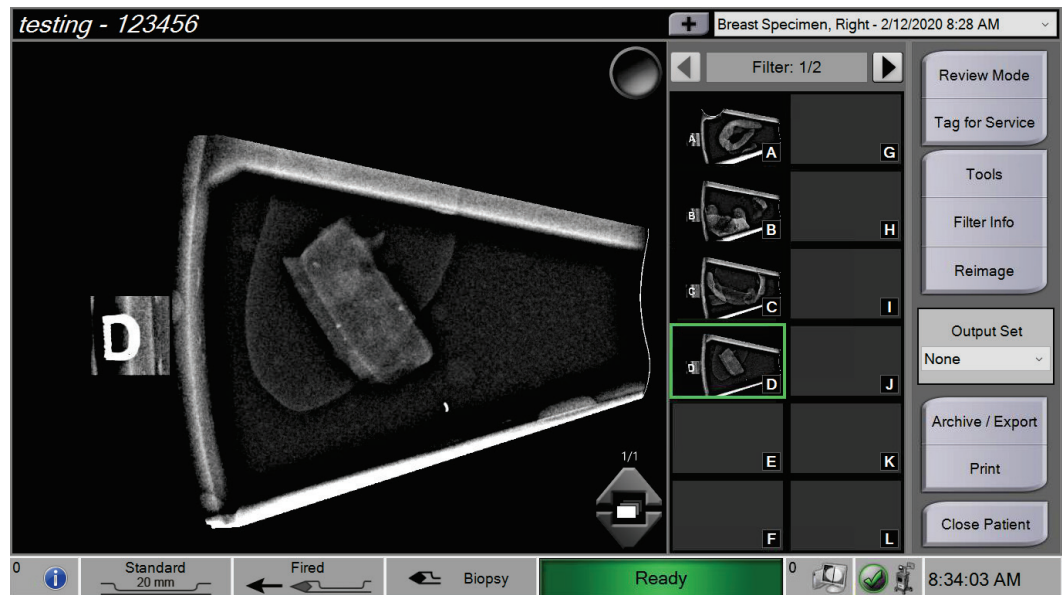
1.4.2 User Interface Localization

The CorLumina® imaging technology user interface can now be displayed in Portuguese, French, Italian, German, Spanish, Dutch, or Swedish language. The user interface display language is determined by the logged-in user locale setting found in **My Settings > Manage Operators**.

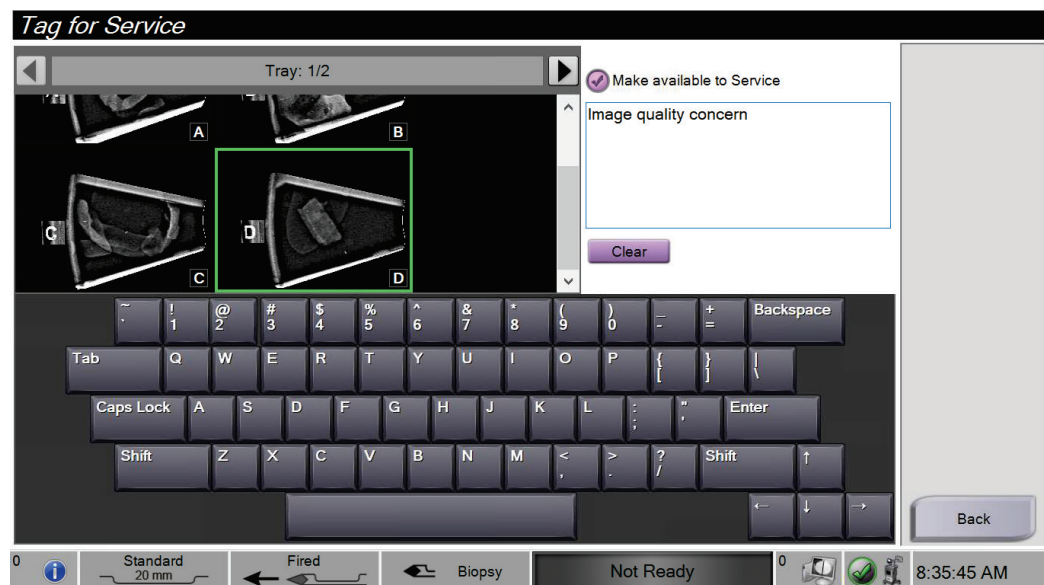
1.4.3 Tag for Service

The CorLumina imaging technology user interface now allows a user to tag an image for easy remote access by Hologic service personnel.

To tag an image of concern for service, select the **Tag for Service** button on the image acquisition screen:



On the *Tag for Service* page, select the image of concern and enter a description of the concern in the text box. Press the **Back** button when complete.



1.4.4 Account Security Settings

The CorLumina imaging technology user interface exposes a subset of the Windows 10 Local Security Policy Password and Account Policy settings to users that are included in the Windows Administrator group (Tech Manager and Hologic Service by default). This allows an administrator-level user to change Windows 10 password settings such as password length, enforce password complexity rules, and others. This page can be found via **Admin -> System Security -> Account Security**.

Account Security

Minimum Password Length*	8
Maximum Password Age (in days, 0 to never expire)*	0
Minimum Password Age (in days)*	1
Enforce Password History (0 to disable)*	0
Attempts Before Lock (0 to disable)*	10

Save

Back

Standard 20 mm Fired Test Not Ready 3:43:40 PM

Account Security

Account Lockout Duration (in minutes, 0 requires admin to unlock)*	5
Password Complexity Requirement Enabled	☒

Save

Back

Standard 20 mm Fired Test Not Ready 3:46:21 PM

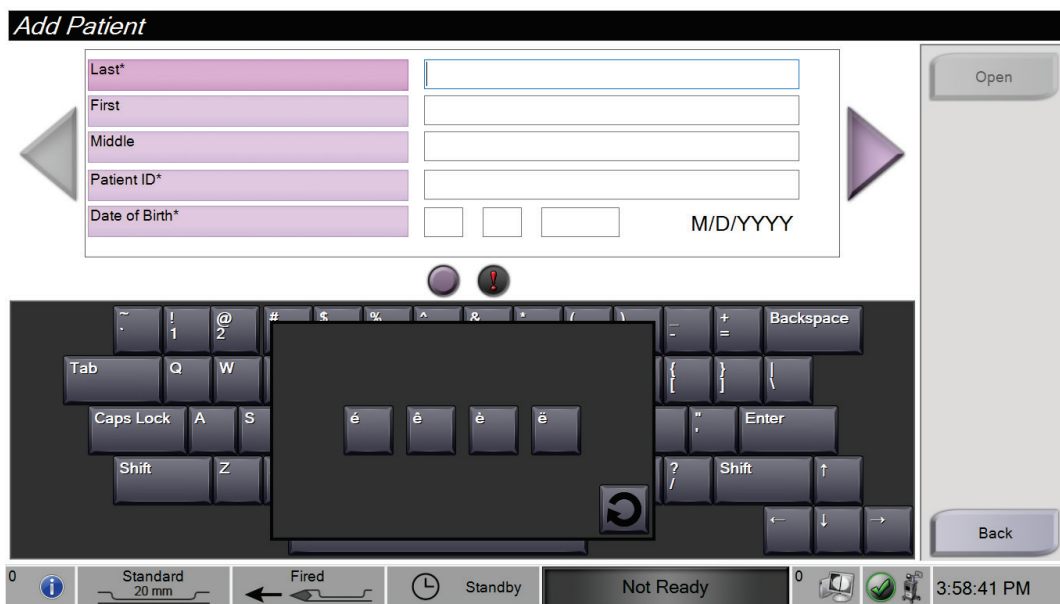
1.4.5 Miscellaneous UI and Workflow Improvements

AZERTY Layout for On-Screen Keyboard

The CorLumina imaging technology user interface now supports both “QWERTY” and “AZERTY” layouts for the onscreen keyboard. The keyboard layout is determined by the logged-in user Keyboard setting found in **My Settings > Manage Operators**.

On-Screen Keyboard Supports Accented Letters

A long press (press-and-hold) on an on-screen keyboard key will display available accented letter variants. For example, when the “e” key is long-pressed:

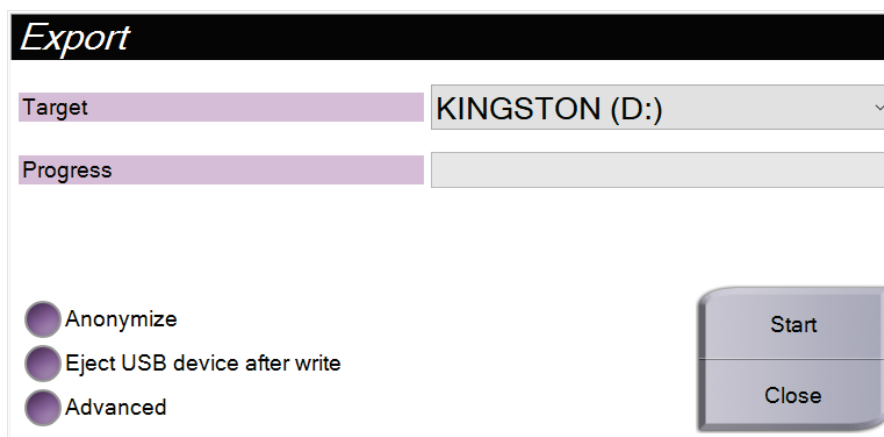


Ejecting USB Thumb Drives

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



A user can also eject a USB device after an Export operation completes.



Printing Images to Standard Printers

Images can now be printed to either a Film printer or a standard paper printer. The standard paper printer must be configured and connected via the Windows 10 operating system for it to be available for printing images.

Electronic User Guide Available Within Application

There is now a button to view the *User Guide* from within the Admin menu.



Additional Device Driver Information in About Page

The serial number and cycle count of the Device Driver is now shown on the *About* page.

Filter Info and Comment Save Confirmation

A confirmation is now displayed when Filter Info and Comments have been saved.

1.5 Product Application Support

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