

SELENIA®
Dimensions®
3Dimensions™



1.11 / 2.2 Customer Release Notes

MAN-10572 Revision 001

HOLOGIC®

Selenia[®] Dimensions[®]

3Dimensions[™]

Digital Mammography System

Digital Tomosynthesis System

Customer Release Notes

For Software Versions 1.11 and 2.2

Part Number MAN-10572

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1: Quality Control Requirements (US Sites Only)

1.1 Introduction

This document is provided as an overview of Selenia® Dimensions® software version 1.11 and 3Dimensions™ software version 2.2.



Note

This document is not meant to replace the Selenia Dimensions system or 3Dimensions system *User Guide*. Changes described in these release notes may not be reflected in the current revision of the *User Guide*.

In order to have your system upgraded to Selenia Dimensions software 1.11 or 3Dimensions software 2.2, you may have to have your Acquisition Workstation hardware upgraded to a level that accommodates this new software, as some features have specific hardware requirements. Please check with your Hologic representative about whether a hardware upgrade is necessary.

1.2 Radiologic Technologist



Note

If the system was upgraded from software versions 1.9 or 2.0, this section applies.

This software upgrade requires that the radiologic technologist performs the following QC tests by following the corresponding tests in the technologist section of the Selenia Dimensions/3Dimensions system *Quality Control Manual*, part number MAN-03706:

- Phantom image evaluation
- Signal-to-noise and contrast-to-noise measurements
- DICOM printer quality control

The preceding tests shall be conducted on each individual Selenia Dimensions system and 3Dimensions system that was upgraded to this software release.

1.3 Medical Physicist

The software upgrade does not require any testing by a medical physicist. However, the tests described in the preceding section, which the technologist performs, are considered to be conducted under the oversight of the medical physicist retained by the facility. The medical physicist needs to be made aware of and provided the opportunity to review the results of the tests.

The medical physicist should check that the dose reported on the Mammography QC phantom after the software upgrade is similar to the dose reported during the last phantom image quality evaluation test performed by the technologist prior to the upgrade.

1.4 Applications Support

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

- In the United States: call the Hologic Applications Hotline at 877-371-4372.
- 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: Selenia Dimensions Software 1.11 and 3Dimensions Software 2.2 Release Notes

2.1 Introduction

This chapter provides an overview of the enhancements associated with the Selenia Dimensions 1.11 software upgrade and the 3Dimensions 2.2 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 Selenia Dimensions system and 3Dimensions system *User Guide*. Changes described in these customer release notes may not be reflected in the current revision of the *User Guide*.

2.2 Optional Licensed Features

This release of the Selenia Dimensions software and 3Dimensions software introduces additional optional features, sold separately. The following licensed features are available:

- Genius AI™ Detection
- Affirm® Contrast Biopsy software

In order to have your system upgraded, you may have to have your Acquisition Workstation hardware upgraded to a level that accommodates this new software, as some features have specific hardware requirements. Again, please check with your Hologic representative about whether a hardware upgrade is necessary.



Note

Availability of these optional features may depend on local regulations – please check with your Hologic representative to find out if these features are available in your region.

2.2.1 Genius AI Detection (not available in all markets)

Feature Description

The Genius AI™ Detection software identifies potential lesions in tomosynthesis images using deep learning–based algorithms. The software runs on the Selenia Dimensions or 3Dimensions Acquisition Workstation computer and produces a DICOM Structured Report that can be transmitted to PACS or to the radiologist workstation. In addition to marks that are displayed on tomosynthesis slices, the software creates measures that can be used to prioritize cases for reading.

The Genius AI Detection software processes images as soon as the technologist completes the exam, and the results may be displayed on the Acquisition Workstation as soon as processing completes. An example of a measure that may be used to enhance workflow is the Reading Priority Indicator. This is used to flag cases that have a high level of concern and can be used to prioritize cases for immediate reading.

Prerequisites

Hologic® 3D Mammography™ license

2.2.2 Affirm Contrast Biopsy Software (not available in all markets)

Feature Description

Affirm Contrast Biopsy software allows clinicians to target and acquire tissue samples in lesions identified in contrast-enhanced mammography. Affirm Contrast Biopsy uses the same workflow as stereotactic biopsy, substituting standard scout and stereo pair views with 2D contrast-enhanced views captured at the associated angles.

Prerequisites

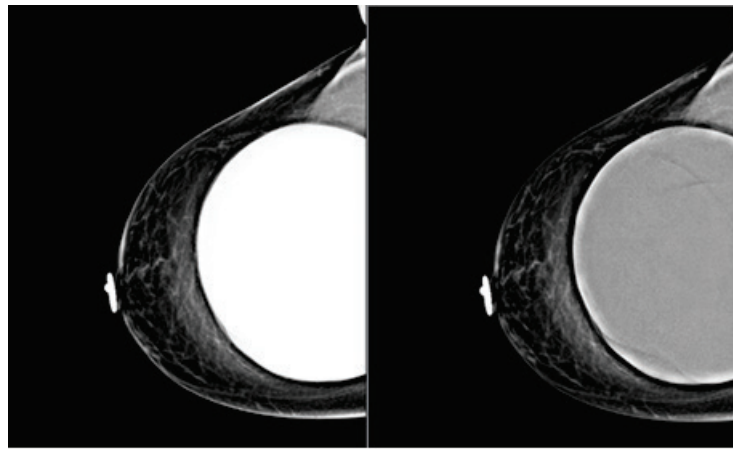
I-View™ contrast enhanced 2D imaging license

3: Software Enhancements

3.1 Image Presentation Enhancements

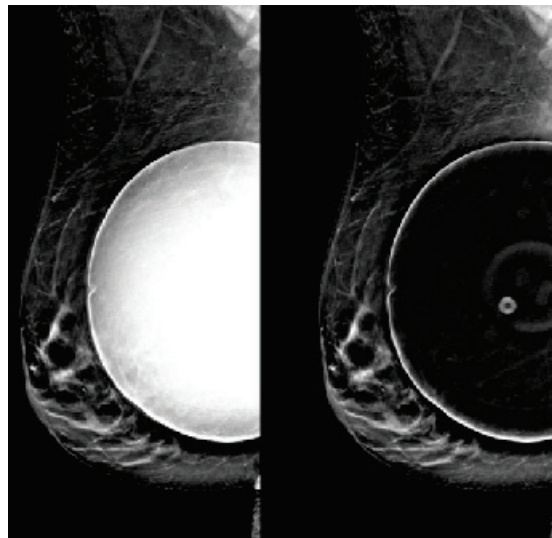
3.1.1 Implant Brightness Option

There is a new optional image processing setting for both 2D and 3D imaging to reduce the implant brightness to improve visibility of the implant/breast boundary region. To enable this option, please contact your Hologic representative.



Standard

Reduced Brightness



Standard

Reduced Brightness

3.2 User Interface Enhancements

3.2.1 Japanese Language Support

User interface translations and DICOM support for the Japanese language have been added to the software.

3.2.2 Print on Accept Capability

The ability to auto-print images on Accept has been added to the software.

3.2.3 ROI Tool for Reconstructed Slices

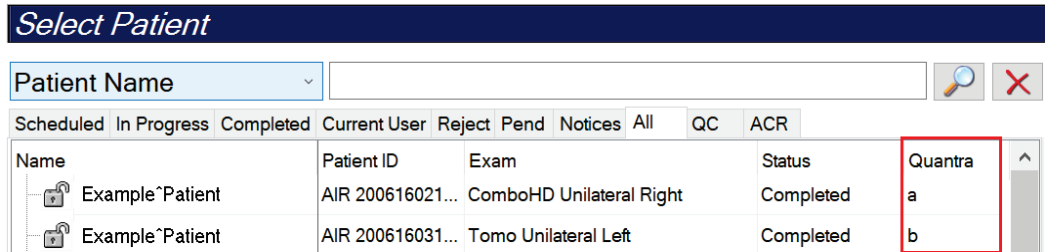
To better support QC, the ability to make ROI measurements on reconstructed images is now available.

3.2.4 QAWeb Software Added

Barco Medical QAWeb software has been added to the system to perform DICOM calibration and automated Quality Assurance where required.

3.2.5 Quantra Breast Density Assessment Results on Select Patient Screen

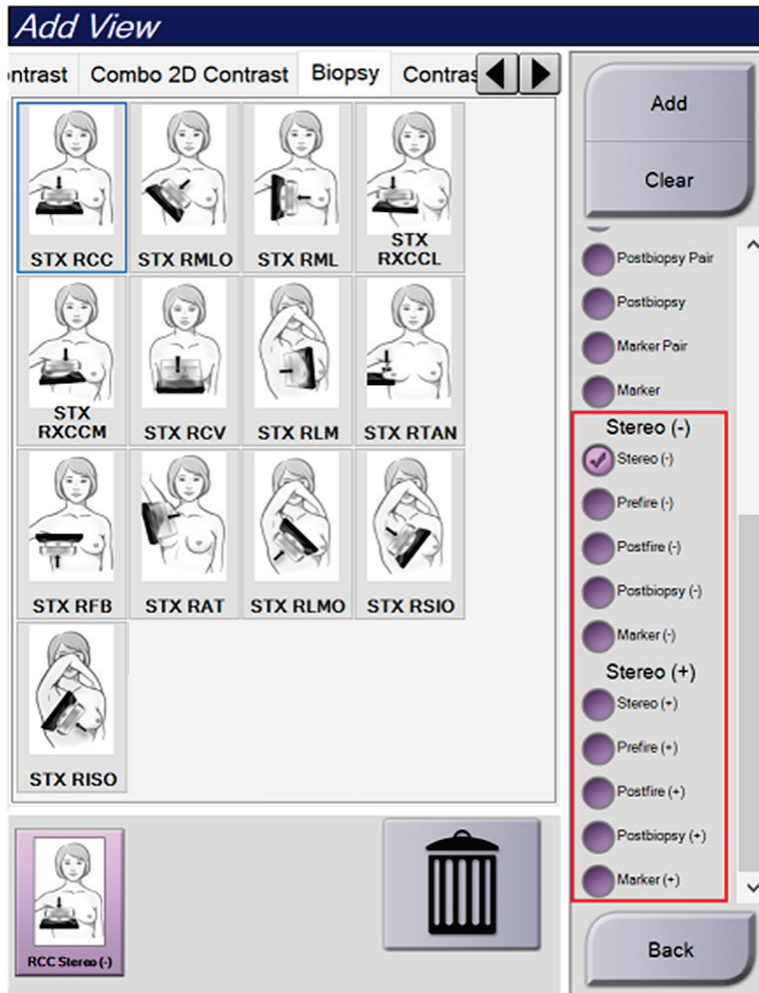
Quantra™ breast density assessment software results now can be displayed on the *Select Patient* screen.



3.3 Biopsy Enhancements

3.3.1 Stereo Biopsy Half-Pair Support Added

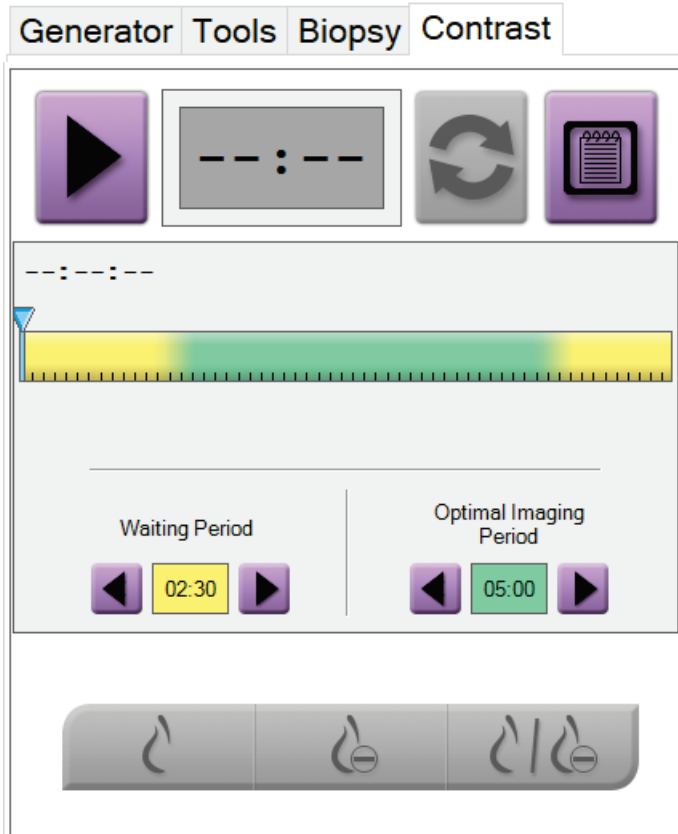
Native support to capture a single -15° or +15° Stereotactic 2D biopsy view has been added to the software. This allows an operator to create a biopsy target utilizing the Stereotactic Scout and the single Stereotactic 2D view.



3.4 CEDM Enhancements

3.4.1 Timer Enhancements

To better facilitate modification of the Waiting Period and Optimal Imaging period on a patient by patient basis, the controls to adjust the Contrast Timer have been moved to the *Procedure* screen.



3.5 Cybersecurity Enhancements

3.5.1 Cybersecurity Hardened Windows 10 Operating System

Hologic's team of Certified Information Systems Security Professionals (CISSP) and Certified Secure Software Lifecycle Professionals (CSSLP), utilizing guidance from the NIST Cybersecurity framework, have designed a custom version of Windows 10 that is hardened against cybersecurity threats. This release incorporates additional Cybersecurity hardening based on the latest NIST guidance.

3.5.2 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.) To better support customization of password policies, there is a new password policy page that can be accessed by any Administrative/Manager us via Admin, System Security, Account Security.

3.5.3 OS Patches

All necessary OS patches released before the final release of this software are installed on the system.