SELENIA® Dimensions®

3Dimensions™

Customer Release Notes

Software Versions 1.12 and 2.3

MAN-11063 Revision 001

HOLOGIC®

Selenia® Dimensions®
3Dimensions™

Digital Mammography System

Digital Tomosynthesis System

Customer Release Notes

For Software Versions 1.12 and 2.3

Part Number MAN-11063
Revision 001
September 2023

Product Support

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Table of Contents

1: Quality Control Requirements (US Sites Only)

1.1 Introduction

This document provides an overview of Selenia® Dimensions® digital mammography system software version 1.12 and 3Dimensions™ system software version 2.3.

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*.

To upgrade your system to Selenia Dimensions software version 1.12 or 3Dimensions software version 2.3, you may need to have your Acquisition Workstation (AWS) hardware upgraded to a level that accommodates this new software, as some features have specific hardware requirements. Consult your Hologic representative to determine if a hardware upgrade is necessary.

1.2 Radiographic Technologist

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

This software upgrade requires the radiologic technologist to perform the following Quality Control (QC) 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 with 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

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 1.12 and 3Dimensions Software 2.3 Release Notes

2.1 Introduction

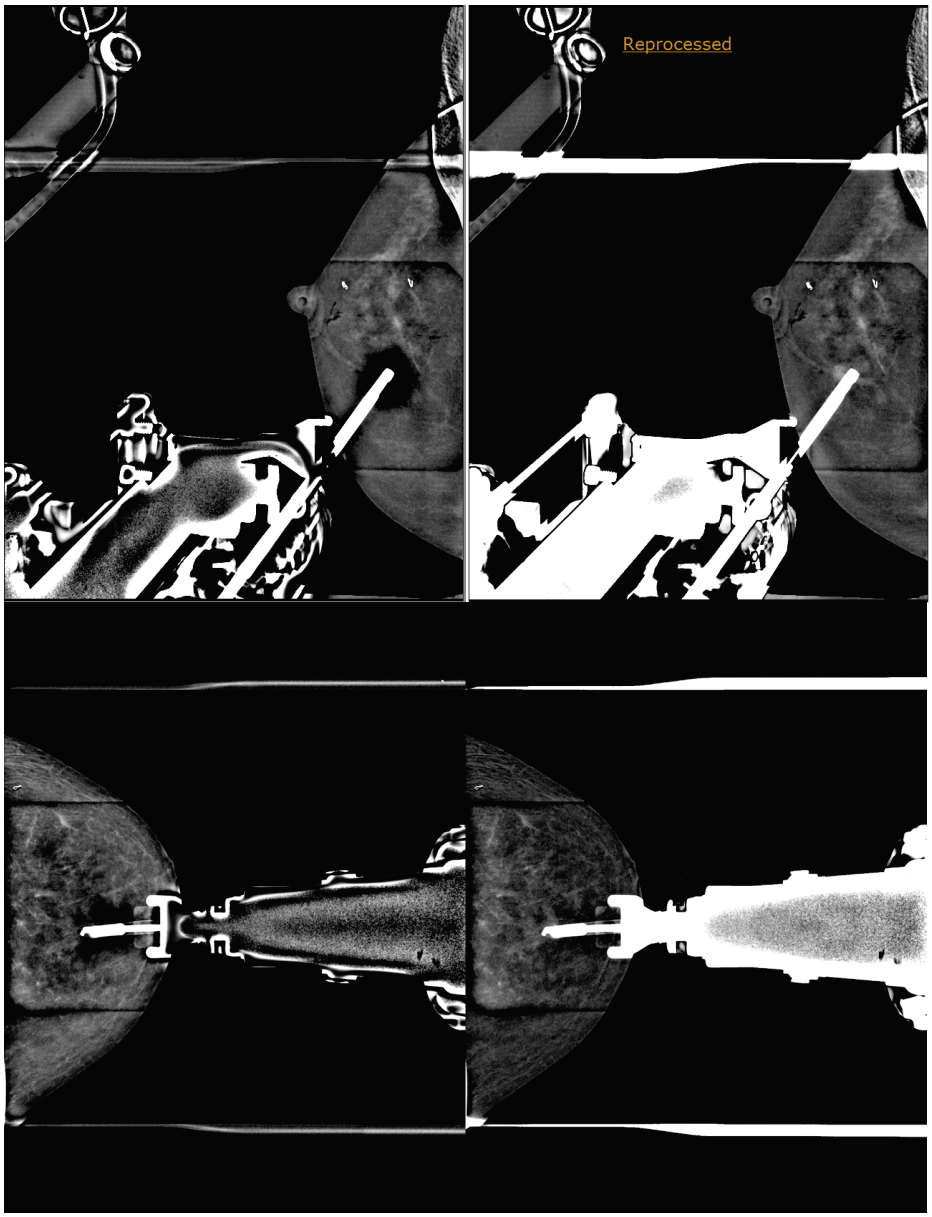
This chapter provides an overview of the enhancements associated with the Selenia Dimensions 1.12 software upgrade and the 3Dimensions 2.3 software upgrade. This upgrade can affect daily workflow or other tasks. **Carefully review these customer release notes to understand the new software enhancements and software changes introduced with this upgrade.**

Note
This document is not meant to replace the Selenia Dimensions system and 3Dimensions system *User Guides*. Changes described in these Customer Release Notes may not be reflected in the current revision of the *User Guides*.

2.2 Image Presentation Enhancements

2.2.1 Contrast Biopsy Processing Enhancements

Image processing for contrast biopsy images has been enhanced to reduce the shadow artifact along the biopsy device. The following images illustrate the differences between 1.11.1/2.2.1 (on the left) and 1.12/2.3 software (on the right).



2.2.2 Hologic Clarity HD Imaging Technology Implant Processing Performance Enhancement

Implant processing under Hologic Clarity HD® Imaging Technology has been accelerated. Time to process implant views is now equivalent between standard resolution and Hologic Clarity HD tomosynthesis.

2.3 Feature Enhancements

2.3.1 Modified Tube Heat Tolerance for Contrast Enhanced Image Acquisition

The maximum tube heat allowed to begin or continue a Contrast Enhanced exam has been increased. Customers will on average be able to acquire more of this image type before being warned about tube heat.

2.3.2 Genius AI Detection Software Version 2.0

The Genius AI® Detection software licensable feature has been upgraded to version 2.0. This is a replacement for version 1.0; if a customer is already licensed for version 1.0, no new licensing is required. The following improvements are included in the 2.0 version:

- Algorithm enhancements to improve performance
- Ability to detect and report “correlated” findings between CC and MLO view position images
- Ability to process view positions considered “equivalent” to CC and MLO, including FB, XCCL, XCCM for CC, and ML, LM, LMO, SIO, ISO for MLO
- Ability to process view positions with modifiers other than implant displaced (AT, TAN, RI, RS, RL, RM, NP, AC, AX, IMF)
- Ability to process implant displaced views

3: Cybersecurity Features

Note
The latest information on patches, vulnerabilities, and best practices for Hologic products can be found at:
https://www.hologic.com/support/usa/breast-skeletal-products-cybersecurity

3.1 Cybersecurity Hardened Windows 10 Operating System (OS)

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.

3.2 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 user via Admin > System Security > Account Security.

3.3 Operating System Patches

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