SELENIA® Dimensions®

3Dimensions™

Customer Release Notes

Software Versions 1.12 and 2.3

MAN-11063 Revision 003

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 003
October 2024

Product Support

USA:	+1.877.371.4372
Europe:	+32 2 711 4690
All Other:	+1 781 999 7750
Asia:	+852 37487700
Australia:	+1 800 264 073
Email:	BreastHealth.Support@hologic.com

© 2024 Hologic, Inc. Printed in the USA. This manual was originally written in English.

Hologic, Selenia, Dimensions, 3Dimensions, 3D Mammography, Affirm, C-View, Cenova, Clarity HD, Genius, Genius AI, I-View, ImageChecker, Quantra, and associated logos are trademarks and/or registered trademarks of Hologic, Inc., and/or its subsidiaries in the United States and/or other countries. All other trademarks, registered trademarks, and product names are the property of their respective owners.

This product may be protected by one or more U.S., or foreign patents as identified at www.Hologic.com/patent-information.

HOLOGIC®

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

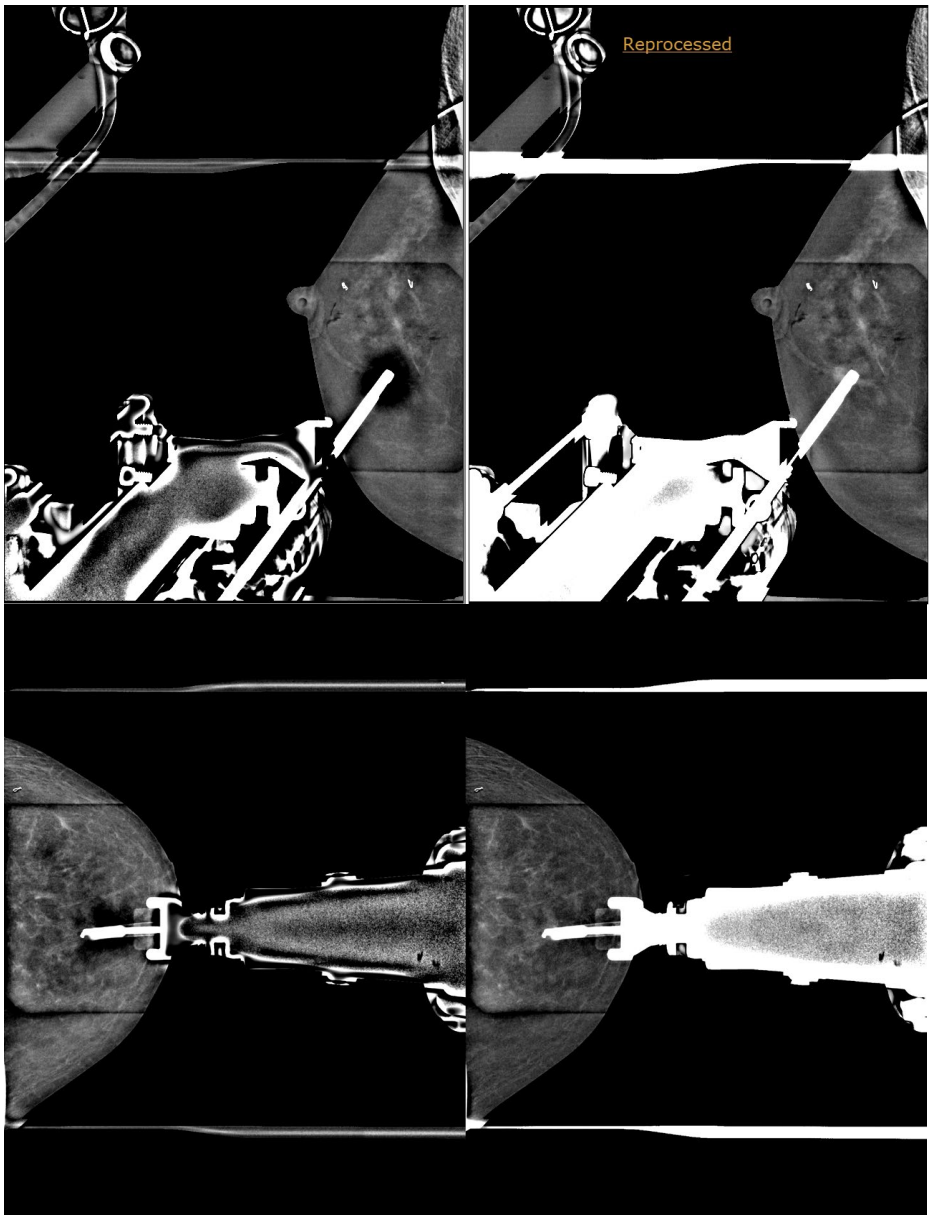
This chapter provides an overview of the enhancements associated with the Selenia Dimensions 1.12 software upgrade and the 3Dimensions 2.3 software upgrade. This upgrade can affect daily workflow or other tasks. **Carefully review these customer release notes to understand the new software enhancements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

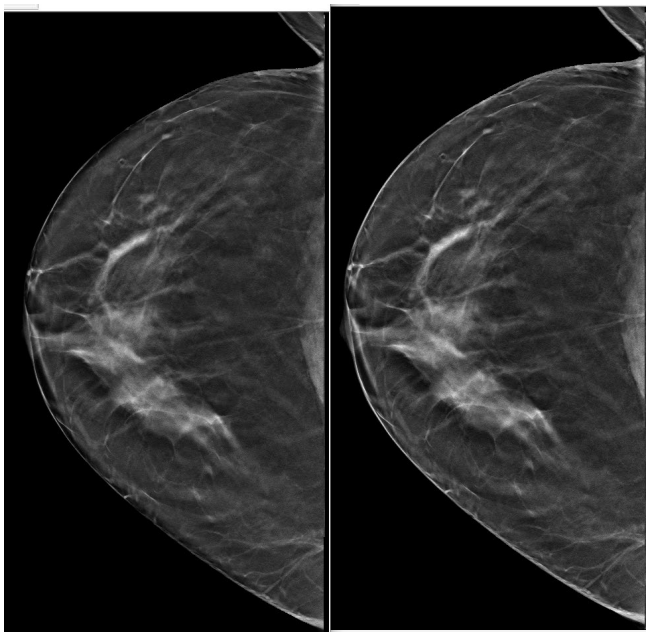
2.2.3 Image Processing Improvements for Tomosynthesis Images

The following image processing enhancements are present in 1.12.0:

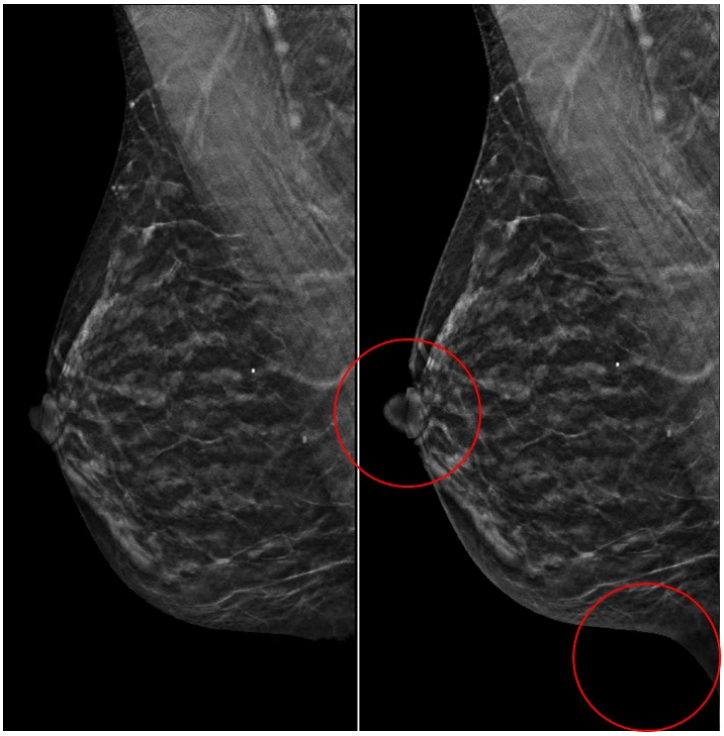
- Improvements to skin line, IMF, and nipple visibility
- Improvements to the visibility of very fatty or uncompressed areas, such as IMF or pectoral muscle, where tissue was missing (burnt out)

This new image processing algorithm will affect tomosynthesis images, including processed projection images, reconstructed slice images, synthesized 2D image (C-View and Intelligent2D), and 3DQuorum. There is no impact to conventional 2D images.

Below is a comparison of some example images (between the same selected reconstruction slice) to demonstrate both the improvement of the skin line/IMF and the visibility of the nipple and skin line overall.



Case 1: A reconstruction slice processed with AWS 1.11 (left) and AWS 1.12 (right) with improved visibility of the skin line.



Case 2: A reconstruction slice processed with AWS 1.11 (left) and AWS 1.12 (right). The new algorithm brings the burnt-out fatty IMF corner back and improves the visibility of nipple and skin line.

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.

HOLOGIC®

Hologic Inc
600 Technology Drive
Newark, DE 19702 USA
1.800.447.1856

Australian Sponsor **Hologic (Australia & New Zealand) Pty Ltd.**
Level 3, Suite 302
2 Lyon Park Road
Macquarie Park NSW 2113
Australia
1.800.264.073

EC REP **Hologic BV**
Da Vincilaan 5
1930 Zaventem
Belgium
Tel: +32 2 711 46 80
Fax: +32 2 725 20 87

CE 2797

Refer to the corporate website for more facilities worldwide.
www.hologic.com