

SELENIA®
Dimensions®
3Dimensions™



1.10 and 2.1 Customer Release Notes
MAN-10267 Revision 001

Selenia[®] Dimensions[®]

3Dimensions[™]

Digital Mammography System

Digital Tomosynthesis System

Customer Release Notes

For Software Versions 1.10 and 2.1

Part Number MAN-10267

Revision 001

July 2023

Technical Support

USA: +1.877.371.4372

Asia: +852 37487700

Europe: +32 2 711 4690

Australia: +1 800 264 073

All Other: +1 781 999 7750

Email: BreastHealth.Support@hologic.com

© 2023 Hologic, Inc. Printed in the USA. This manual was originally written in English.

Hologic, Selenia, Dimensions, 3Dimensions, Affirm, C-View, Cenova, 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/patents.



Hologic Inc.
600 Technology Drive
Newark, DE 19702 USA
1.800.447.1856

Australia Hologic (Australia) Pty Ltd.
Suite 402, Level 3
2 Lyon Park Road
Macquarie Park NSW 2113
Australia
1.800.264.073

HOLOGIC[®]

Table of Contents

1: Quality Control Requirements (US Sites Only)	1
1.1 Introduction.....	1
1.2 Radiologic Technologist.....	1
1.3 Medical Physicist	1
1.4 Applications Support	2
2: Selenia Dimensions Software 1.10 and 3Dimensions Software 2.1 Release Notes	3
2.1 Introduction.....	3
2.2 Optional Licensed Features	3
2.3 ImageChecker Computer Aided Detection (CAD) Software.....	4
2.4 Quantra Breast Density Assessment Software.....	4
3: Windows 10 Operating System	5
4: Software Enhancements	6
4.1 Image Presentation Enhancements.....	6
4.2 User Interface Enhancements.....	7
4.3 Biopsy Enhancements	8
4.4 Cybersecurity Enhancements.....	8
4.5 Quality Control Enhancements.....	9

1: Quality Control Requirements (US Sites Only)

1.1 Introduction

This document is provided as an overview of Selenia® Dimensions® software version 1.10 and 3Dimensions™ software version 2.1.



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 1.10 or 3Dimensions software 2.1, 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 sales 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 1.10 and 3Dimensions Software 2.1 Release Notes

2.1 Introduction

This chapter provides an overview of the enhancements associated with the 1.10 Selenia Dimensions software upgrade and the 2.1 3Dimensions 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 two optional features, sold separately. The following licensed features are available:

- ImageChecker® Computer Aided Detection (CAD) Software
- Quantra™ 2.2 Breast Density Assessment 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 sales representative about whether a hardware upgrade is necessary.



Note

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

2.3 ImageChecker Computer Aided Detection (CAD) Software

2.3.1 Feature Description

ImageChecker 10.0 computer aided detection (CAD) that is currently offered in the Hologic Cenova™ image analytics server is now also available in the Selenia Dimensions 1.10 and 3Dimensions 2.1 software.

2.3.2 Prerequisites

None

2.4 Quantra Breast Density Assessment Software

2.4.1 Feature Description

Quantra 2.2 breast density assessment software that is currently offered in the Hologic Cenova image analytics server is now also available in the Selenia Dimensions 1.10 and 3Dimensions 2.1 software.

3: Windows 10 Operating System

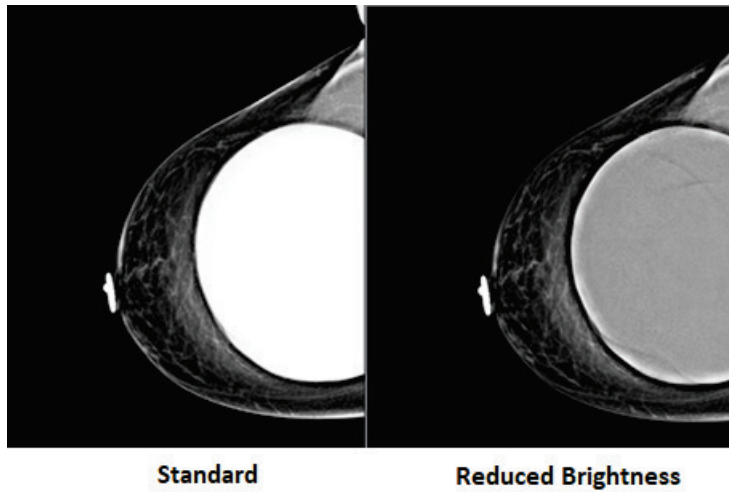
The Selenia Dimensions 1.10 and 3Dimensions 2.1 software runs exclusively on a customized version of Windows 10, which has mainstream support from Microsoft until October 2025.

4: Software Enhancements

4.1 Image Presentation Enhancements

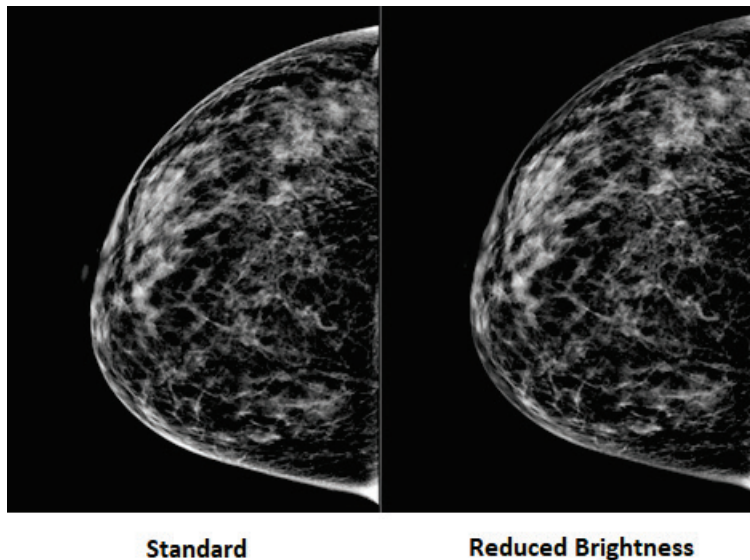
4.1.1 Implant Brightness Option

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



4.1.2 Skin Line Brightness Reduction Option

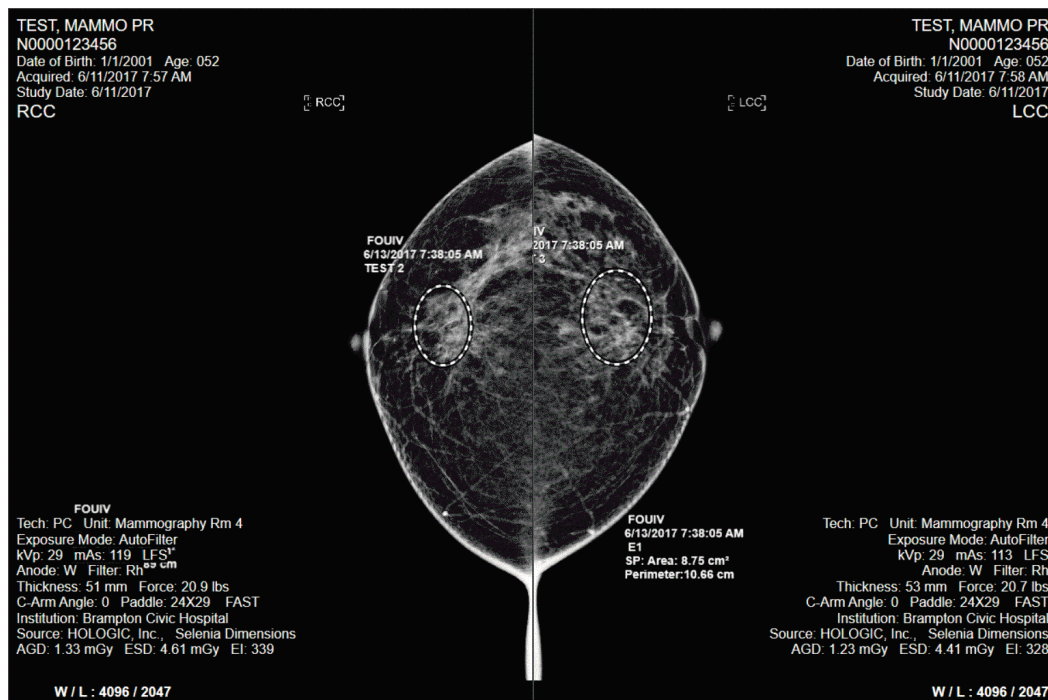
There is a new optional image processing setting for 2D imaging to reduce the brightness and overshadow of the skin on screening views. To enable this option, please contact your Hologic Field Service Engineer.



4.2 User Interface Enhancements

4.2.1 Support for Siemens Grayscale Presentation State (GSPS) Objects

Grayscale Presentation State (GSPS) overlays created on Siemens Workstations can now be viewed on the Acquisition Workstation.

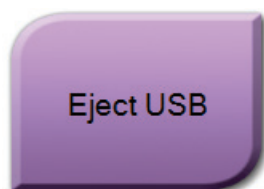


4.2.2 Cine Tab Automatically Selected when Projection Image Is Selected

To better facilitate reviewing projection images for motion, when the Projection Image view button is selected, the Tools menu will automatically select the Cine tool tab.

4.2.3 Eject USB

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



4.2.4 Auto Pair Override Now Automatically Moves to 1-Up Display

When the Auto-Pair override button is selected, the image display will now automatically revert to 1-Up mode.

4.3 Biopsy Enhancements

4.3.1 Resend Targets Button Now Disabled when No Active Targets on View

To better differentiate the Resend Targets button from the Project Targets button, when the current biopsy view has no active targets, the Resend Targets button will be disabled.

4.3.2 Warning Displayed when a Target Is Created with a Non-clinical Needle

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

4.4 Cybersecurity Enhancements

4.4.1 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.

4.4.2 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.)

4.4.3 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.

4.4.4 Windows Firewall Enabled

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

4.4.5 Clinical User Accounts Function on Standard Windows Accounts

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

4.4.6 OS Patches

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

4.5 Quality Control Enhancements

4.5.1 QC Phantom CEDM and CEDM Combo Views Added

QC Phantom CEDM and CEDM Combo Views have been added to the software.

4.5.2 Additional Test Patterns Included

The following patterns have been natively added to the software and are available on the Test Patterns screen: TG18-LPH10, TG18-LPH50, TG18-LPH89, TG18-LPV10, TG18-LPV50, TG18-LPV89.