

## Change of the Authorized Representative

This document updates your product manuals to change the address of the European Commission Authorized Representative (EC Rep). This change is effective on the first day of November 2015. The new address is:

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Place this document with your product manuals for future reference.



**Selenia® Dimensions® digital mammography system**  
**Selenia® Dimensions® digital tomosynthesis system**  
1.8.3 Customer Release Notes

MAN-04326 Revision 001



**HOLOGIC®**



## Selenia Dimensions

### 1.8.3 Customer Release Notes

## Part Number MAN-04326

## Revision 001

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## Chapter 1: Quality Control Requirements (US Sites Only)

### 1.1 Introduction

This document is provided as an overview of Selenia® Dimensions® version 1.8.3.



#### Note

This document is not meant to replace the *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 Dimensions 1.8.3, you may have to have your Dimensions AWS 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

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 Quality Control Manual*:

- 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 that was upgrade 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 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.

If the I-View™ Contrast Enhanced 2D imaging software option is installed following the Selenia Dimensions 1.8.3 upgrade, the medical physicist must perform the necessary testing associated with that option.

## **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 888-679-0689.
- In Europe and the Middle East: email to [AppsSupport.ROW@hologic.com](mailto:AppsSupport.ROW@hologic.com).
- In Asia-Pacific: email to [AP-AppsSupport@hologic.com](mailto:AP-AppsSupport@hologic.com).
- In Australia/New Zealand: email to [AU-ApplicationsSupport@hologic.com](mailto:AU-ApplicationsSupport@hologic.com).

## Chapter 2: Selenia Dimensions 1.8.3 Release Notes

### 2.1 Introduction

This chapter provides an overview of the enhancements associated with the 1.8.3 Selenia Dimensions 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 *User Guide*. Changes described in these customer release notes may not be reflected in the current revision of the *User Guide*.

### 2.2 Software Enhancements

#### 2.2.1 Breast Tomosynthesis Object (BTO) Support Enhancements

##### Breast Tomosynthesis Object Image Orientation Enhancements

The Selenia Dimensions Acquisition Workstation can be configured to reorient digital breast tomosynthesis images stored in BTO DICOM Objects to meet the image hanging preference of sites using third-party review workstations.

##### Display of Breast Tomosynthesis DICOM Objects from Non-Hologic vendors

The Selenia Dimensions AWS can import and display BTO DICOM Objects created by Non-Hologic vendors.

### 2.3 C-View™ Diagnostic Paddle Support

C-View™ synthesized 2D images are now able to be created when using a diagnostic paddle in contact mode.

### 2.4 Security Enhancements

#### 2.4.1 OS Patches

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

### 2.5 Resolved Known Software Issues

The following software issues have been resolved in this release

- The Radiation Dose SR Measured Value Sequence has been added to the Radiation Dose SR Object (*SCR-35910*)
- The Value Representation (VR) of uncompressed BTO objects is now represented at OW. (*SCR-28946*)
- I-View™ Contrast Agent configuration now allows the use of fractional values (*SCR-35311*)
- Content Date and Time is now updated during an image reprocessing (*SCR-35667*)
- JPEG Lossless support has been added for I-View™ images (*SCR-34360*)
- The Modality Performed Procedure Step (MPPS) DICOM object now populates Organ Dose to four decimal places of precision (*SCR-35502*)



## Chapter 3: Selenia Dimensions 1.8.2 Release Notes

### 3.1 Introduction

This chapter provides an overview of the enhancements associated with the 1.8.2 Selenia Dimensions software upgrade. This upgrade may 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 *User Guide*. Changes described in these customer release notes may not be reflected in the current revision of the *User Guide*.

### 3.2 Optional Licensed Features

The 1.8.2 release of the Selenia Dimensions software introduces an optional I-View™ Contrast Enhanced Digital Mammography Imaging feature, sold separately. I-View Software provides Contrast Enhanced Digital Mammography capabilities in a procedure referred to as CE2D (Contrast Enhanced 2D). It can be used with Hologic 3D Mammography in a procedure referred to as CE2D Combo.

The new Advanced Connectivity License Bundle includes both the MPPS and the new Radiation Dose SR software licenses. If your system has been licensed for MPPS in the past, it has been replaced with an Advanced Connectivity License on your system which enables both MPPS and Radiation Dose SR capabilities.



#### Note

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

#### 3.2.1 I-View™ 2D Contrast (CE2D) Functionality

##### Feature Description

The I-View™ software option for Contrast Enhanced 2D Imaging adds functional imaging information to the highly detailed 2D images from Selenia Dimensions. This feature also has the ability to combine Contrast Enhanced 2D Imaging with 3D Mammography imaging, creating CE2D Combo studies. The results provide both the functional imaging benefits of contrast and benefits of 3D Mammography.

### 3.3 Software Enhancements

#### 3.3.1 Image Presentation Enhancements

##### Tomosynthesis Processing Improvements

Improvements have been made to the Tomosynthesis processing library to achieve the following visualization improvements:

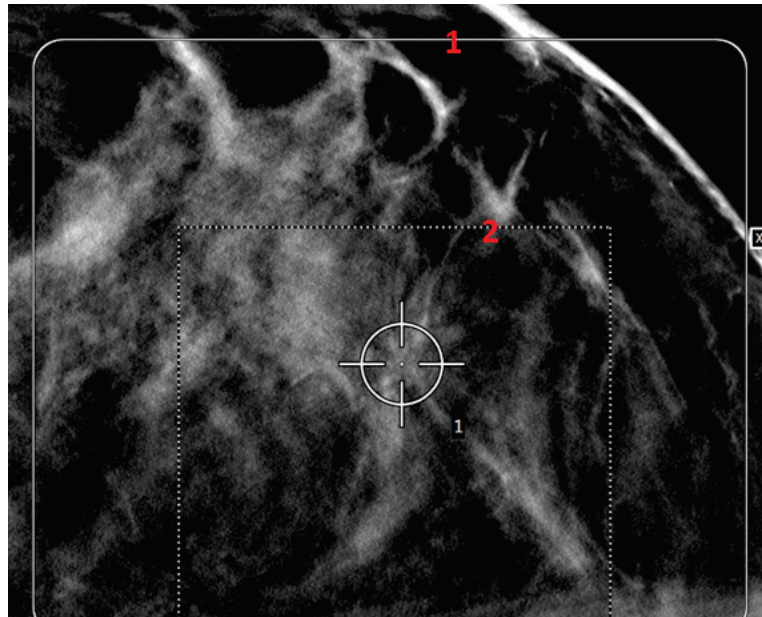
- Improve image contrast when imaging large breasts
- Improve the appearance of the skin line when imaging large breasts
- Improved image clarity through noise reduction in all breasts

#### 3.3.2 Biopsy Enhancements

##### Affirm Tomosynthesis Biopsy Enhancements

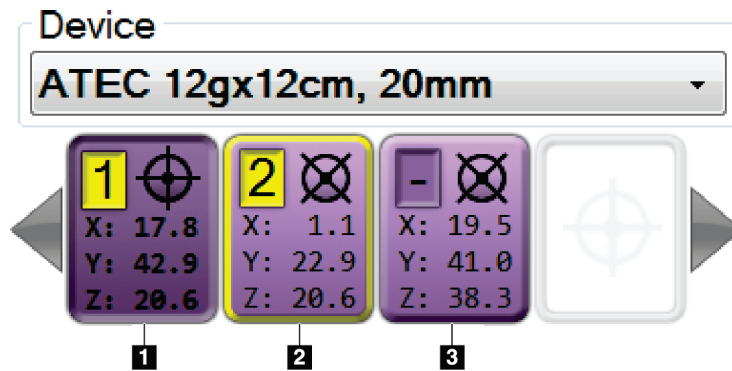
Several improvements were made to the workflow of the Affirm Tomosynthesis Biopsy option.

- Paddle Window Outline: A thin solid line overlay has been added to Affirm Tomosynthesis Biopsy images to indicate the approximate location of the paddle at all positions within the volume.
- Targetable Area Indicator: A thin dashed line overlay has been added to denote which areas are accessible with the current needle.



### Enhanced Target Display

The dropdown Listbox containing visible targets has been replaced with visual indicator and selection tool (see following image).



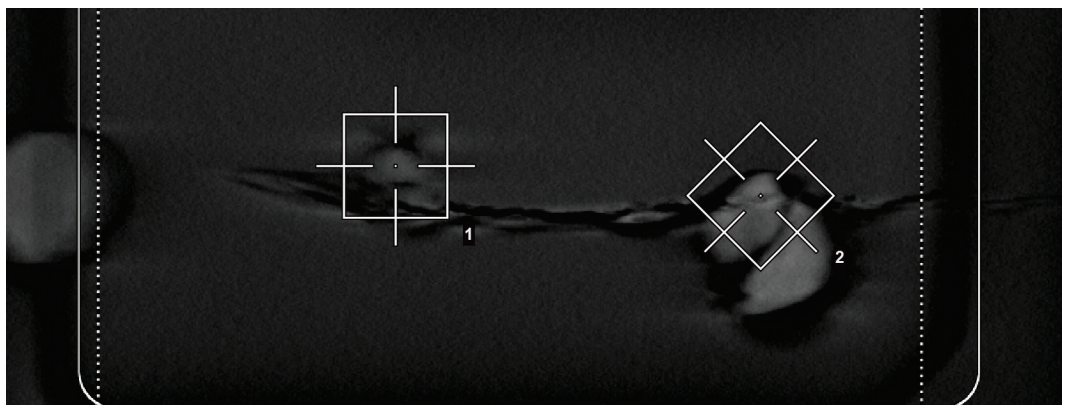
- The targets are now numbered and the target that is currently selected on the Acquisition Workstation [item 1 in preceding image] is shown depressed and the corresponding numbered target mark on the display monitor shown in the vertical (not tilted) position [see also item 1 in following image].



**Note**

Target Selection on the Acquisition Workstation does not change the selected target on the Affirm Biopsy Control Module (BCM).

- [items 1 and 2 in preceding image] - All targets that are available on the Affirm Biopsy Control Module (BCM) are shown numbered with a yellow background.
- [Item 2 in preceding image] - The target that is currently selected on the Affirm Biopsy Control Module (BCM) is shown with a yellow border.
- [item 3 in preceding image] - Any targets that are visible on the display monitor but not available on the Affirm Biopsy Control Module (BCM) are shown without a number and colored background.
- In Stereo Biopsy images, the calculated active target is now shown as a square [item 1 in following image], while the inactive target is a diamond [item 2 in following image].



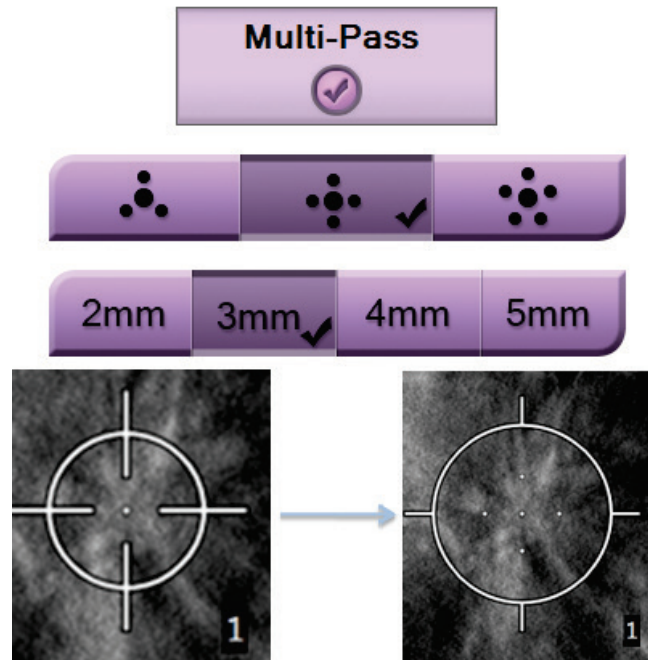
### Multi-Pass Support

Multi-Pass functionality allows the creation of multiple, independent targets from a single placed biopsy target. The Multi-Pass control allows seamless creation of 3, 4, or 5 additional targets from the original target, at distances of 2, 3, 4 or 5 millimeters.



**Note**

Each target appears as its own individual target on the Affirm Biopsy Control Module.



### Target Accept/Reject Notification

To aid the biopsy workflow, after a target has been placed, the background on the *Target Accept* and *Target Reject* buttons becomes highlighted.



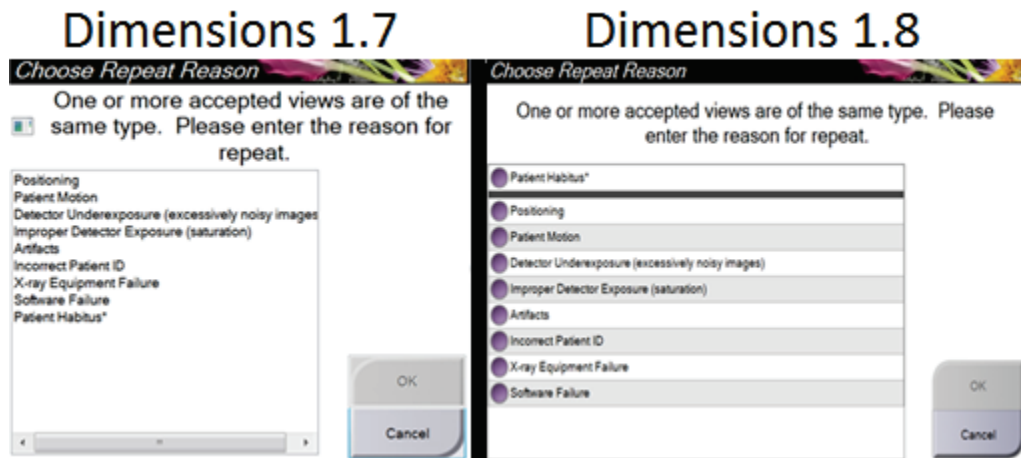
### Additional Biopsy Features Added

- The Affirm system now issues an audible alert after the Biopsy needle has moved to the correct X and Y position.
- Biopsy Targets are now numbered on the Display Monitor. The number shown correlates with both the number in the new Enhanced Target Display on the Acquisition Workstation as well as the number shown on the Affirm Biopsy Control Module (BCM).
- Biopsy Scout views now do not automatically clear the display monitor, allowing comparison of two Scout Views.
- Support for Post-Clip/Post-Marker Biopsy views has been added.

### 3.3.3 User Interface Enhancements

#### Enhanced Graphics and Improved Layout

The graphical interface has been enhanced and certain dialogs have been reorganized for better usability.



## Repeat and Reject Report Improvements

### Institution Information

The Institution Name, Institution Address, and Station Name have been added to the top of all Reject and Repeat reports.

**Reject Report**

General Hospital (Room 2)  
1234 Main St.

**Mammography Reject Analysis**  
From: 3/1/2014 To: 3/31/2014 Technologist: ALL Source: Default

Reason	Projection					Subtotals	% of Total
	Right	Left	Right	Left	Right		

### Specimen Images on Reject and Repeat Reports

By default, Specimen images are now excluded by Reject and Repeat tracking.

### Reject and Repeat Reports for Affirm Biopsy and I-View™ CE2D Imaging

Repeat and Reject reports are now available for Affirm Biopsy and I-View™ CE2D imaging.

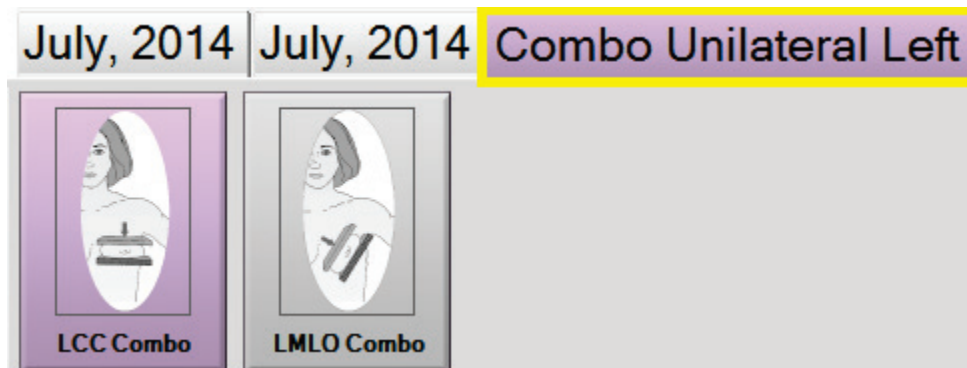


#### Note

By default, the user is not prompted for a specific reason and all reasons are recorded as "Other." To enable prompting for specific reasons for Biopsy and I-View™ CE2D imaging, contact your Hologic Field Engineer.

### Procedure Tab Highlighting

The currently selected Procedure tab is now better highlighted to differentiate it from other Procedures

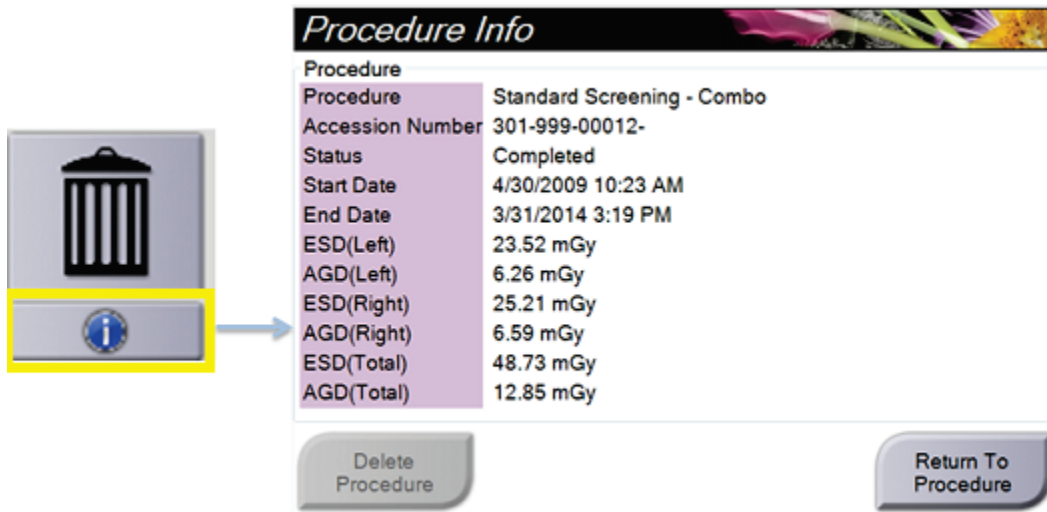


### Procedure Information Dialog

A *Procedure Information* button has been added beneath the *Delete View* button, which displays a popup showing the following information.

- Procedure Name
- Accession Number
- Procedure Status
- Procedure Start and End Date and Time
- Dose Information (Cumulative and per Breast)

For Procedures that contain no exposed views, a *Delete Procedure* button is available from within the Procedure Information Dialog which removes the selected procedure from the patient.

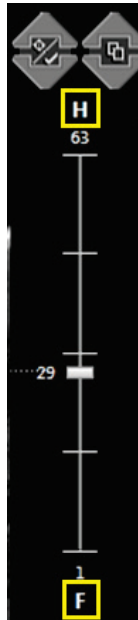


Procedure	
Procedure	Standard Screening - Combo
Accession Number	301-999-00012-
Status	Completed
Start Date	4/30/2009 10:23 AM
End Date	3/31/2014 3:19 PM
ESD(Left)	23.52 mGy
AGD(Left)	6.26 mGy
ESD(Right)	25.21 mGy
AGD(Right)	6.59 mGy
ESD(Total)	48.73 mGy
AGD(Total)	12.85 mGy



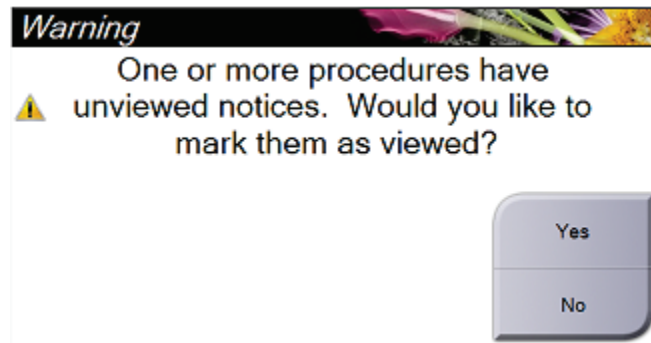
### Tomosynthesis Slice Indicator Improvements

The Anatomical Region (“H” for head and “F” for foot) has now been added to the Tomosynthesis Slice Indicator.



### Unviewed Notices Warning

The system now alerts the operator when closing a procedure that contains received Notices that have not been marked as viewed.

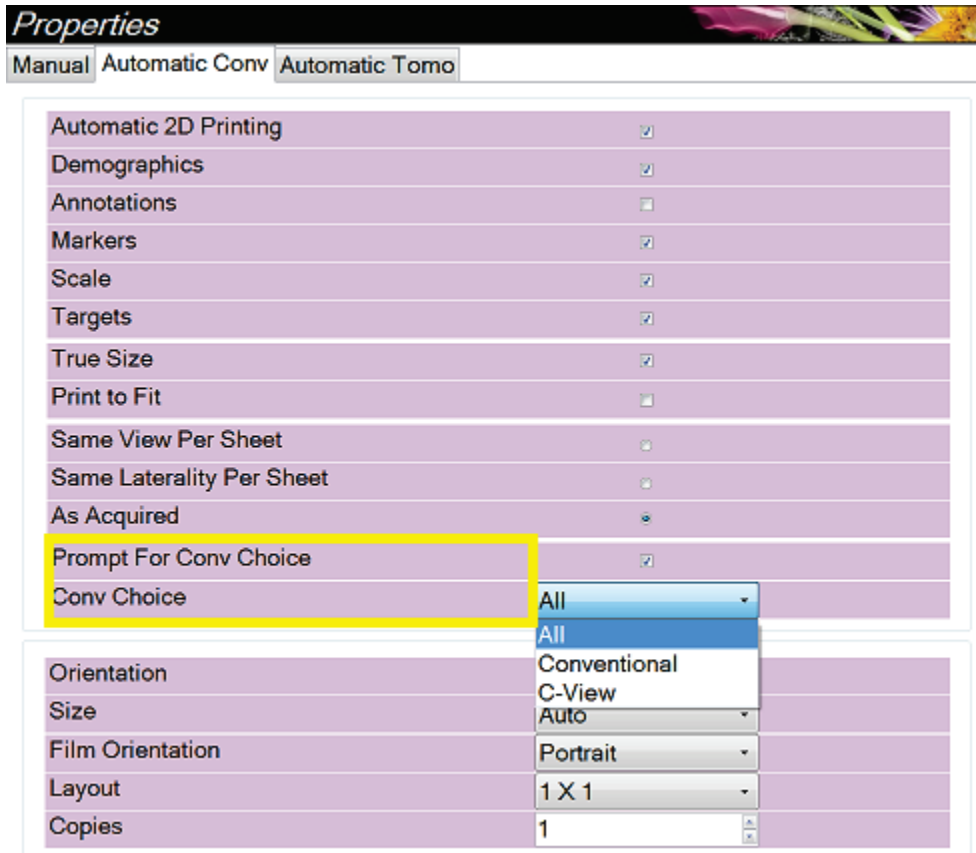




### Printing Options

The Print Properties page now allows the selection of C-View 2D, Conventional 2D, or All (Both) when using Auto-Conventional printing or when a printer is installed in an output group.

Auto-Conventional printing can also be configured to prompt for this selection.



### Additional UI Improvements

- You now have the ability to Import and Export Procedure List.
- Demetal can now be selected before image acquisition.
- If Auto-Hanging is enabled and prior procedures are being transferred from the Advanced Workflow Manager, the procedure now Auto-Hangs once the transfer has completed.
- A progress bar is now displayed for Advanced Workflow Manager transfers.
- A progress bar is now displayed on system startup.
- The date order that Procedure Tabs appear can now be customized for each operator.
- The TAN modifier can now be selected for all views.

## **3.4 DICOM Enhancements**

### **3.4.1 JPEG 2000 Support**

Support for the JPEG 2000 DICOM Lossless Compression (1.2.840.10008.1.2.4.90) has been added.

### **3.4.2 MPPS Routing**

For systems using MPPS and multiple Modality Worklist (MWL) providers, the MPPS messages now route intelligently based on which MWL provider the procedure was localized. MPPS is an optional feature that is a part of the Advanced Connectivity License Bundle.

### **3.4.3 Radiation Dose SR**

Support for the Radiation Dose SR (Structured Report) module, a feature designed to record patient dose, has been added. This module allows more accurate recording of accumulated patient dosages than using MPPS. Radiation Dose SR is an optional feature that is a part of the Advanced Connectivity License Bundle.

### **3.4.4 CAD on C-View Support**

Support for CAD on C-View 2D images has been added, an option which works with the Cenova 2.4 or above server. See the Image Checker CAD User Manual (MAN-03682) for configuration information.

### **3.4.5 Interoperable Biopsy Targets**

Support for Interoperable Biopsy Targets specified in DICOM CP-1269 as part of the IHE Radiology Stereotactic Mammography Image profile has been added.

## **3.5 Security Enhancements**

### **3.5.1 Native Encryption of all Protected Health Information (PHI)**

The system now natively encrypts all Protected Health Information stored in the DICOM files and log files on disk. Log files are now natively encrypted and protected in transit and require a Hologic proprietary viewer for access.

### **3.5.2 OS Patches**

All necessary OS patches releases prior to the final release of this software have been installed on the system.

### 3.6 Resolved Known Software Issues

The following software issues have been resolved in this release

- Attempting to navigate to the Archive or Print Pages while images are transferring from the Advanced Workflow Manager would cause an error (*SCR-33050*)
- Locus Line occasionally cannot appear when making multiple clicks to target under Stereotactic Biopsy (*SCR-30976*)
- Thumbnails for Tomosynthesis Gain Calibration images processed slowly (*SCR-31552*)
- Use of non-screening paddles with C-View software has been disabled. (*SCR-34428*)
- Archive page would fail to load if a device was removed from the system but was still contained in an output group (*SCR-31569*)
- Support for a Schedule Procedure Step start time less than six characters has been added (*SCR-31328*)
- Images added to an imported non-Hologic procedure now always have a modality of MG (*SCR-34360*)
- SMPTE Pattern artifact under certain sizing modes has been corrected (*SCR-34587*)  
Enhanced support for importing non-Hologic images (*SCR-34360*)