SELENIA®
Dimensions®

Customer Release Notes

MAN-11032 Revision 001

HOLOGIC®

Selenia® Dimensions®

Digital Mammography System

Customer Release Notes

For Software Version 1.7.4

Part Number MAN-11032
Revision 001

February 2024

HOLOGIC®

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Chapter 1
Quality Control Requirements (US Sites, Only)

1.1   Introduction

This section lists the quality control tests to be performed by a medical physicist or a radiologic technologist under medical physicist supervision after the software upgrade is performed by the manufacturer.   The listed quality control tests are proposed by the manufacturer following the guidelines in the Alternative Standard 6 described in the Selenia Dimensions Quality Control Manual.

1.1.1   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*:

1. Phantom image evaluation;
2. Signal-to-noise and contrast-to-noise measurements;
3. DICOM printer quality control.

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

1.1.2   Medical Physicist

The software upgrade does not require any testing to be performed by a medical physicist.   However, the tests described above, which the technologist will perform, 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 ACR 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.

1.2   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
*   In Asia-Pacific: email to AP-AppsSupport@hologic.com
*   In Australia/New Zealand: email to AU-ApplicationsSupport@hologic.com

Chapter 2
Selenia Dimensions 1.7.4 Release Notes

2.1   Introduction

This document provides an overview of the enhancements associated with the 1.7.4 Selenia Dimensions software upgrade.   This upgrade may affect daily workflow or other tasks. **These customer release notes should be reviewed carefully 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

- Added enhancements to C-View to support future driver versions for improved performance.
- Added support to display Unique Device Identification (UDI) information on the About Page. For more information on UDI, see: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/

2.2.1   Resolved Known Software Issues

- Improved error handling for Notice sending failures (*SCR-34294*)
- Reliability improvements for grid retraction during Combo imaging (*SCR-34338*)
- Adding an image comment to a C-View image does not cause the image to appear blank on the radiologist workstation *(SCR-33933)*

Chapter 3
Selenia Dimensions 1.7.3 Release Notes

3.1 Introduction

This document provides an overview of the enhancements associated with the 1.7.3 Selenia Dimensions software upgrade. This upgrade may affect daily workflow or other tasks. **These customer release notes should be reviewed carefully 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 Software Enhancements

3.2.1 DICOM Enhancements

3.2.1.1 C-View Image Orientation Enhancements

The native orientation of Selenia Dimensions AWS C-View images stored in MG DICOM objects now matches the corresponding conventional image to better support review on third-party review workstations.

3.2.2 Resolved Known Software Issues

- Reprocessing Tomosynthesis views when auto-pairing is enabled now works as expected (*SCR-33909*)
- Storage Commitment now fully supports C-View images (*SCR-33986*)
- A safeguard was added to prevent exporting a C-View image before processing has been completed (*SCR-33935*)
- Auto-Time exposures are now consistent across the full range of thicknesses and do not apply an mAs multiplier unless configured to do so (*SCR-33962*)
- An improper marker is no longer added to biopsy views after an Edit View (*SCR-33987*)
- The Automatic Compression Release no longer occasionally moves the paddle up more than needed (*SCR-33971*)
- C-View images captured before a Patient Edit now contain all needed DICOM tags without requiring another reprocess (*SCR-33933*)

Chapter 4
Selenia Dimensions 1.7.2 Release Notes

4.1   Introduction

This document provides an overview of the enhancements associated with the 1.7.2 Selenia Dimensions software upgrade.   This upgrade may affect daily workflow or other tasks.   **These customer release notes should be reviewed carefully 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*.

4.2   Software Enhancements

4.2.1   User Interface Enhancements

4.2.1.1   Landscape Printing

Printing is now supported in Landscape mode. By setting the Film Orientation to Landscape on the print page, the system will orient the film horizontally rather than vertically for flexibility in creating 2-Up prints.
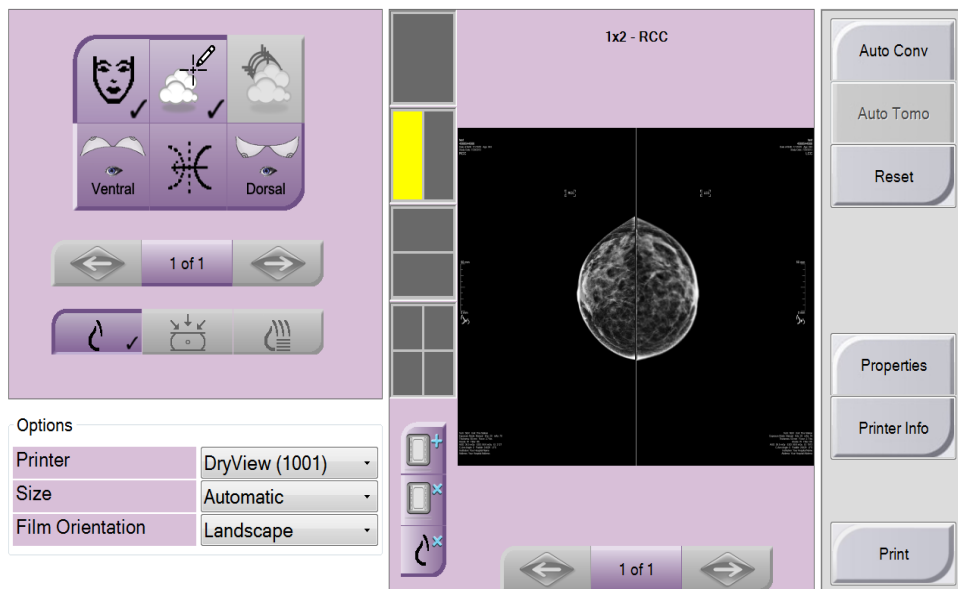
4.2.2 Quality Control Enhancements

4.2.2.1 CNR Correction Factors

This release adjusts the CNR correction factors to accommodate differences between digital detector types. Refer to the *Selenia Dimensions Quality Control Manual* MAN-01965 for more information.

4.2.3 DICOM Enhancements

4.2.3.1 Tomo and C-View Image Orientation Enhancements

The Selenia Dimensions AWS can be configured to reorient digital breast tomosynthesis images stored in CT DICOM Objects and C-View images stored in MG DICOM objects to meet the image hanging preference of sites using third-party review workstations.

4.2.4 Resolved Known Software Issues

- Tomosynthesis projections captured using an 18x24 compression paddle could occasionally create a flashing effect during display (*SCR-32609*)
- Demographic information on Test Pattern prints could be clipped (*SCR-32522*)
- Markers can now be burned into C-View images (*SCR-32922*)
- AEC Density Setting recorded in DICOM header was incorrect for images acquired in Combo mode (*SCR-32517*)
- Support added for XCC view (*SCR-33013*)
- Image processing was incorrectly applied to test patterns (*SCR-33013*)
- An additional safeguard was added that will stop the compression device from contacting the face shield (*SCR-33072*)

Chapter 5
Selenia Dimensions 1.7.1 Release Notes

5.1 Introduction

This document provides an overview of the enhancements associated with the 1.7.1 Selenia Dimensions software upgrade. This upgrade may affect daily workflow or other tasks. **These customer release notes should be reviewed carefully 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*.

5.2 Optional Licensed Features

The current release of the Dimensions software introduces four optional features, sold separately. The following four licensed features are now available:

1. Tomosynthesis Biopsy;
2. C-View Synthesized 2D Imaging;
3. Diagnostic Imaging;
4. DICOM CT Output.

In order to have your system upgraded to Dimensions 1.7.1, 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. 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.

5.2.1 Biopsy under Tomosynthesis (Not Available in All Markets)

5.2.1.1 Feature Description

This option lets users define the biopsy targets using a single tomosynthesis view in place of a scout and a stereo pair of 2D images. This option may accelerate the biopsy procedure by reducing the number of steps while reducing overall patient dose.

5.2.1.2   Prerequisites

Affirm Breast Biopsy Guidance System; Affirm Stereotactic Biopsy License; Tomosynthesis Imaging License.

5.2.2   C-View™ Synthesized 2D Imaging (Not Available in All Markets)

5.2.2.1   Feature Description

This option introduces C-View™ synthesized 2D images to the Dimensions platform.   It allows the technologist to create imaging studies in two new modalities: *TomoHD*, which combines tomosynthesis imaging and C-View synthesized 2D images, and *ComboHD*, which combines combo-mode 2D plus tomosynthesis imaging with C-View synthesized 2D images.

5.2.2.2   Prerequisites

Tomosynthesis Imaging License.

5.2.3   Diagnostic Imaging (Only Applies to Dimensions 2D Screening Configuration)

5.2.3.1   Feature Description

Systems purchased as screening-only systems can now be field upgraded to include diagnostic imaging capabilities.

5.2.3.2   Prerequisites

Any necessary hardware upgrades to support Diagnostic Imaging.

5.2.4   DICOM CT Output for Tomosynthesis

5.2.4.1   Feature Description

This option allows users to output tomosynthesis studies as DICOM CT objects.   While not the preferred output form for breast tomosynthesis, this option may be used to accommodate review of tomosynthesis images on workstations that do not support the DICOM Breast Tomosynthesis Image object.

5.2.4.2   Prerequisites

Tomosynthesis Imaging License.

5.3   Software Enhancements

5.3.1   Image Presentation Enhancements

5.3.1.1   Image Presentation Options

5.3.1.2   Small Breast Paddle Images

When the Small Breast paddle is used, the Dimensions image processing masks the area beyond the far edge of the paddle to hide the paddle support structure from showing in the image.   This type of masking is specific to the Small Breast paddle and is applied on 2D and tomosynthesis images.

5.3.1.3   Metal Artifact Reduction on Tomosynthesis Views

An enhancement was added to the tomosynthesis processing, which reduces the artifacts created by metal clips or inserted needles. The metal artifact reduction is triggered automatically when a needle localization paddle is used, or a Specimen icon has been selected. Under image acquisition using any other paddle, the metal artifact reduction may be triggered via the "de-metal" button in the *Tools* tab (see the figure below).   A second trigger of the "de-metal" button will reprocess the tomosynthesis view and disable the effect of the metal artifact reduction, if desired.

This function only applies to tomosynthesis images and has no effect on similar metal artifacts under conventional imaging.   Metal artifact reduction is fully automatic on all conventional images.
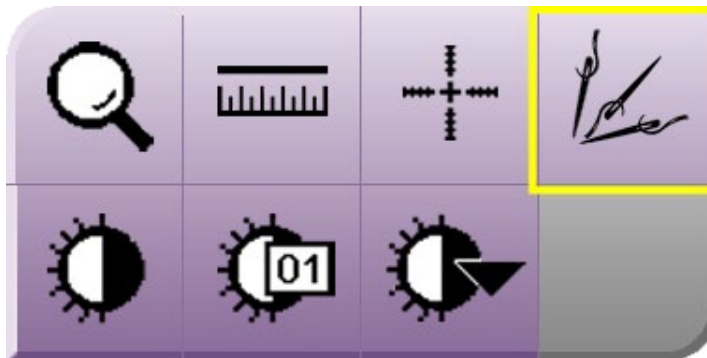
Figure 1: Metal artifact reduction for tomosynthesis images.

5.3.1.4   Tomo Processing Adjustments

Small adjustments have been made to the tomosynthesis processing library to achieve the following visualization improvements:

1.   Improve image contrast when imaging large breasts;
2.   Improve image contrast on breasts with implants;
3.   Improve the appearance of skin line when imaging thin breasts;
4.   Improve brightness and contrast of tomo images under biopsy.

5.3.2   User Interface Enhancements

5.3.2.1   Print-to-Fit Indication on Printed Films

To become more flexible and independent of printer configuration, an icon was added to the bottom of the ruler (see the figure below) to indicate that an image was printed in print-to-fit mode instead of true-size mode.   When this icon appears on the film, measurements performed on the printed image need to be correlated with the printed ruler to get a real indication of true size.
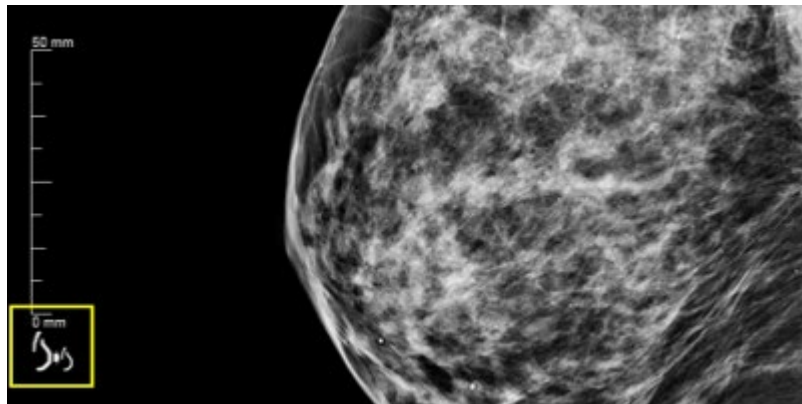

Figure 2: Print-to-fit indicator

5.3.2.2   Missing Image Indicator on Modality Toolbar

If the conventional portion of a Combo image capture fails, the 2D icon will be grayed out and an "X" indicator will be presented in the icon (see the figure below).   A similar effect will be noticed when during the import of a combo view, one of the objects is missing or failed to import. The thumbnail will still be labeled as "Combo".

Figure 3: Indication of a missing object of a Combo view on the modality toolbar.

5.3.2.3   Automatic Hanging Enhancement

The auto hanging of priors takes place when a patient is opened, if enabled for that user. A button was added in the *Tools* tab (see the figure below) to trigger automatic hanging of any selected exam.

Figure 4: Manual triggering of automatic hanging

5.3.2.4 Arrow Annotations

A button was added in the *Notices* tab to allow the user to create arrow annotations on images.   The Arrow annotation tool (see the figure below) allows the user to paint a variable length arrow on any displayed image and add associated text to it.
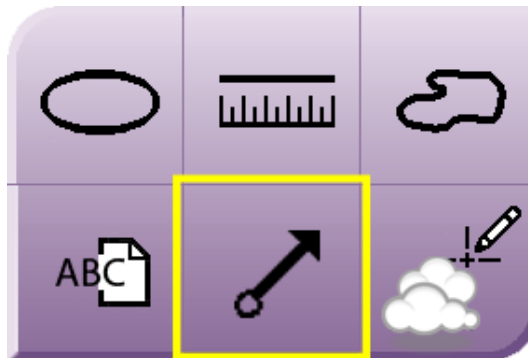
Figure 5: Annotate an image using an arrow.

5.3.2.5 Print Tools Behavior

All Print tools (see the figure below) in the *Print* page now act on the entire film instead of per image.   For example, when the patient information button is pressed, all image tiles on the print layout will be affected, rather than only the selected tile.   The exception to this rule is the image mirror button, which acts on the selected tile only.
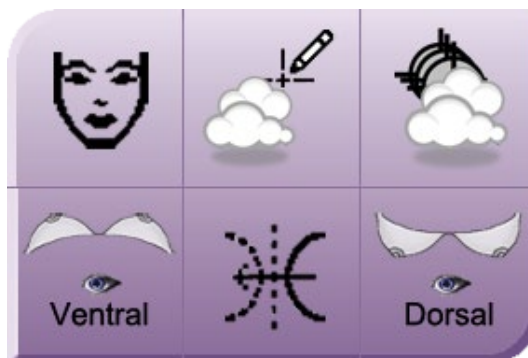

Figure 6: Print tools.

5.3.2.6 Tomosynthesis Slice Indicator Enhancements

The following elements were added to the tomosynthesis slice indicator (see the figure below):

1. Up and Down arrows let you change between tomosynthesis slices that are tagged for printing or contain a biopsy target.
2. Up and Down arrows let you change between tomosynthesis slices that contain markings and annotations.
3. Slices that are tagged for printing or contain biopsy targets.
4. Tomosynthesis slices that contain markings and annotations.
5. Scroll bar moves through the tomosynthesis slices of the breast reconstructed volume.
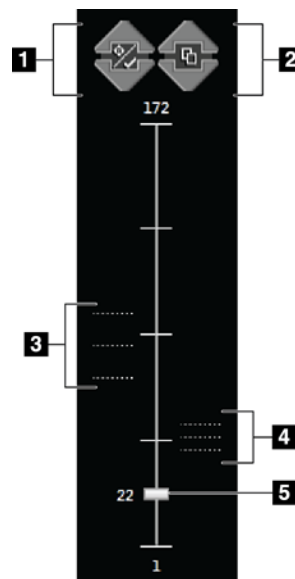
Figure 7: Enhancements on the tomosynthesis slice indicator.

5.3.2.7 Displayed Information on Markings and Annotations; Maximum Annotation Length

When creating a marking or an annotation on an image, the user information and the creation date and time are originally suppressed.   When the markings and annotations are sent as notices to a DICOM destination, then the creator, date and time that the notice was sent become visible on the image.   Markings and annotations that originate from external notices will display similar information.

The maximum length of each annotation has been increased to 256 characters.

5.3.3   Workflow Enhancements

5.3.3.1   Minimum Compression Thickness during Tomosynthesis

The system requires that the minimum compression thickness is at least 0.5 cm prior to allowing the acquisition of a tomosynthesis view.   In the event that the compression thickness registered on the compression device is below 5 mm, the system message shown in the figure below will appear requiring immediate action prior to allowing the tomosynthesis exposure.

Figure 8: System message on minimum compression requirements.

5.3.3.2   Automatic Pairing of Current Views to Prior Images

Auto Pairing has been improved. This function searches for the most recent current or prior screening image that matches the view currently being acquired.   That image is then displayed next to the currently acquired view to facilitate immediate comparison of the newly acquired image with its prior.   The default views that will participate in the Auto Pairing function are CC, MLO, ML, and LM views.   However, it is possible to add more views to the default configuration.   For further configuration, please ask your Hologic Applications specialist or Service Engineer.

The Auto Pairing function is user specific and follows the individual user configuration as shown in the figure below.   Each user can enable this feature individually and configure the behavior of this function to match their personal preferences.   The user may find the Auto Pairing configuration under the *Workflow* tab in the *Edit Operator* page (*My Settings*).
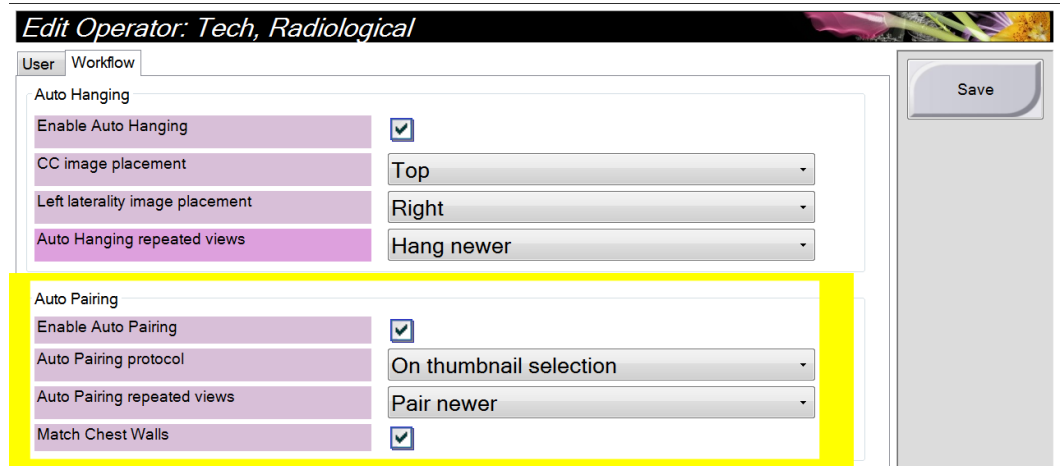
Figure 9: Configuration of the Auto Pairing function.

5.3.3.3   Support for FB Views

An FB view has been added to the *Add View* page.   The Dimensions gantry is now able to acquire 2D, Combo, and tomo images at 180 degrees under the FB view.

5.3.3.4   Adding Views under Prior Procedures

If a prior procedure is selected when the user is trying to add a view, a warning message (see the figure below) will appear alerting the user that the view is being added to a prior procedure.   This message is introduced to avoid situations where added views are inadvertently added to a prior, rather than current exam.
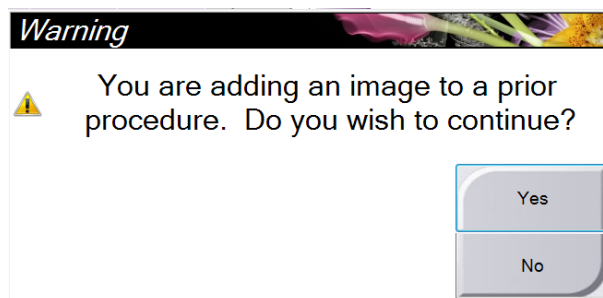

Figure 10: Add View warning message.

5.3.3.5   Markings and Measurements on 3rd Party Images

The system now allows the creation of annotations (markings and measurements) on mammography images imported from other vendors.

5.3.4 Quality Control Enhancements

5.3.4.1 Automated SNR/CNR Computation

The automated computation of SNR and CNR has been optimized to work on conventional images of the ACR phantom only. As a result, the SNR/CNR button is enabled only when a conventional image of the ACR phantom is displayed on the preview display.

The SNR/CNR function has been improved to allow the user the flexibility to recalculate SNR and CNR by adjusting the location of the automatically positioned ROIs.

5.3.4.2 QAS Test

The QAS test used under the optional biopsy feature is now treated as another QC test. The QAS test will be included in the QC reports and will be accessible in the *QC* tab similar to all other QC tests.

5.3.4.3 DIN Standard (Germany)

A new AEC technique table was introduced to improve AEC compliance with the updated DIN 6868-162, January 2012.   The system may be configured to use AEC Table 6 for conventional imaging (DIN specific table) to assure that AEC performance tested under the DIN standard is optimal.

All Dimensions systems are configured to use AEC Table 4 as the default table for conventional imaging.

5.3.4.4 Default Magnification Table

The 1.7.1 release changes the default Magnification (small focal spot) dose table from Table 0 to Table 4. Use the scale factors below for AEC Table 4 when evaluating AEC performance. Refer to the *Selenia Dimensions Quality Control Manual* MAN-01965 for the corresponding CNR correction factors.

5.3.5 Breast Biopsy Enhancements (Option)

5.3.5.1 Collimation Persistence during Biopsy

When the user adjusts the collimation from the default 18cm x 24cm field to a smaller field during the course of a biopsy procedure, the collimation will maintain its field size until compression is released.   After compression is released, the collimation will reset to its default 18cm x 24 cm field size.

5.3.5.2 Needle Localization Procedures

Selection of a needle localization device will trigger the correct graphics to be displayed on the user interface to assist the user with targeting and carrying out a needle localization procedure.

5.3.5.3   Visual Enhancement of Displayed Targets

The size of the target marks will remain constant in size on the display even if the magnification window is used or the display is switched to actual-pixels.   This enhancement allows the user to better visualize the targets even under significant zoom.

5.3.6   DICOM Enhancements

5.3.6.1   Support of the CT DICOM Format in Tomosynthesis (Licensable Option)

The Selenia Dimensions AWS added support of the CT DICOM standard for exporting Digital Breast Tomosynthesis images.   The tomosynthesis reconstructed slices can now be stored using CT DICOM objects in addition to the original Hologic proprietary Secondary Capture object and the new Digital Breast Tomosynthesis DICOM object.

The Selenia Dimensions AWS supports the following functions in conjunction with the CT DICOM object:

- Store CT DICOM objects to PACS;
- Export CT DICOM objects to media.

The selection of the DICOM format for the tomosynthesis reconstructed slices is managed via the AWS output devices.   Separate output devices may be created to store the tomosynthesis reconstructed slices in one of the three formats.   Thus, when sending tomosynthesis reconstructed slices to an outside device or media, the selection of the output device will control the format in which the tomosynthesis study will be stored.

Note...   Tomosynthesis projections will continue to be stored using the Hologic proprietary Secondary Capture format.

5.3.6.2   Additional Changes in the DICOM Header

The following changes have been made to the DICOM header of the Selenia Dimensions images:

- Added paddle ID description back in the DICOM header under private tag (0019,1026) in addition to (0018,11A4) to accommodate incompatibilities with the current SecurView workstation.
- Appended a biopsy identifier in the Series Description tag (0008,103E) when appropriate.
- Biopsy targets have been appended to the DICOM header using private tags to assist with troubleshooting targeting issues in the field.
- All private attributes have been grouped under the (0019,10xx) group of DICOM tags.   Private attributes previously residing in (0019,11xx) and (0019,12xx) groups have been migrated to the (0019,10xx) group.
- The ID view modifier has been added to the Series Description of views acquired with that modifier to accommodate legacy PACS and allow them to hang the implant images more efficiently.

5.3.7   Security Enhancements

5.3.7.1   Failed Login Attempts

The system may be configured to lock an account when its owner is trying to log in unsuccessfully for a preconfigured number of times.   A user account may also be locked by a manager account at any time to prevent a user form logging into the system without having to remove the account.

5.3.7.2   Remote Assistance

The native Windows OS remote assistance function has been disabled on this software version and going forward. This should not be confused with the Hologic Connect function on Selenia Dimensions.

5.3.7.3   OS Patches

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

5.3.7.4   Password Complexity Feature

The system now may be configured to require complex user passwords.   Password complexity may involve letters, numbers, case sensitivity, password renewal policy, and password memory.

5.3.8   Resolved Known Software Issues

The following software issues have been resolved in this release:

- Fixed issue with failed implant processing under tomosynthesis (SCR-29768)
- GE images appearing washed out was addressed to render correctly on the display (*SCR-29993*).
- Raw tomosynthesis projections failed to import (*SCR-29619*).
- Test patterns were printed aligned to one side of the film instead of centered (*SCR-30686*).
- Notices on Selenia images imported on Dimensions were lost due to converting them to tomosynthesis DICOM objects (*SCR-30341*).
- AEC settings were lost when exiting the Exam screen during a biopsy procedure (*SCR-30051*).
- Right size interpolation was creating a vertical line artifact at the edge of an image (*SCR-29817*).
- Length or arrow marking changed after sending a notice (*SCR-29495*).
- User could not always scroll through slices using the mouse wheel in the Print page (*SCR-29374*).

- Image comments entered prior to accepting an edited view were lost (*SCR-29358*).
- Changing printers after rendering images will not resize films to supported film sizes (*SCR-29210*).
- Default technique parameters under System Defaults screen were not set correctly under some conditions (*SCR-29838*).
- The displayed coordinates of the ROI box was not correct (*SCR-29412*).
- The thumbnails of imported specimen images get the wrong modality identifier (*SCR-29347*).
- The user could not enter an annotation on free-form markings created on projections images (*SCR-28455*).
- Images rejected by the system automatically due to system faults did not count against the logged in user (*SCR-29705*).
- Nuisance warning during biopsy procedures have been addressed (*SCR-29612*).
- The *Edit View* button is not enabled if the system is set to auto-accept the images (*SCR-29624*).
- Mag and spot images were interfering with the Auto hanging function (*SCR-29540*).
- Patients protected against deletion on the AWS were deleted during a software upgrade (*SCR-28895*).

5.3.9   Known Software Issues

The following issues have not been resolved in this release:

- GE images with W/L function is not rendered using the sigmoid presentation appearing burned out.
- GE images with W/L and VOI LUTs are rendered using the VOI LUTs, only.

5.4   Hardware Enhancements

5.4.1   Software Enhancements to Hardware

5.4.1.1   Exposure Audible Alarm

The behavior of the audible alarm during a combo exposure has been modified to help avoid premature releases of the x-ray buttons by the user.   The audible alarm is now a continuous alarm that covers the full extent of the combo acquisition from the initiation of the exposure to the end of the conventional view.   There is no interruption of the audible signal between tomosynthesis and conventional exposures to avoid false indication of the completion of the combo exposure that may trigger a release of the exposure switch.

5.4.1.2   Error Reporting Mechanism

The error reporting mechanism was revised to provide to the user simplified and focused information.   In previous software releases a single error propagated to multiple

components causing a cascading effect to the errors reported to the user.   The error reporting mechanism was revised in this release to identify the primary cause of the error and communicate that to the user, so that the user can take the appropriate action.   The mechanism was also revised to classify errors according to user interest and only display errors pertaining to the logged in user while logging errors of interest to other users—i.e. service.

5.4.1.3   Compression Release

The compression device considers that the breast is under compression at any force registering 5 lb (22 N) or more.   Sensing compression that results in more than 5 lb (22 N) will lock all C-arm movements.   The previous threshold was at 10 lb (44 N).

5.4.1.4   C-Arm Travel on Selenia Dimensions Mobile Configuration

The C-arm vertical travel is now monitored by software so that the system will not allow the C-arm to hit the ground during downwards motion or during a rotation.   This issue affected the mobile configuration of the Selenia Dimensions.

5.4.1.5   C-Arm Auto-Rotation

The C-arm auto-rotation feature is now enabled by default on all Selenia Dimensions systems.   This feature is accessible via the side C-arm controls.   For more details on how to use this feature please refer to the Selenia Dimensions *User Guide*.

5.4.1.6   Potential Differences to the Exposure Index

Customers with detectors with serial numbers starting with YM800xxx or CM800xxx will notice a change in their "Exposure Index" values after this upgrade. This change is by design. This change does not affect the signal-to-noise (SNR), contrast-to-noise ratio (CNR), image quality, or breast dose of the system.

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Refer to the corporate website for more facilities worldwide.
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