1.5.x Customer Release Notes

SELENIA®

Dimensions®

Selenia Dimensions

1.5.x Customer Release Notes

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Table of Contents

Chapter 1
Selenia Dimensions 1.5.2 Release Notes

1.0   Introduction

This document provides an overview of the fixes associated with the 1.5.2 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 User Manual. Changes described in these customer release notes may not be reflected in the current revision of the User Manual.

2.0   Quality Control Requirements for This Software Upgrade (US Sites, Only)

This software upgrade corrects a number of known software issues.   It does not alter and does not affect the performance of the Selenia Dimensions system. The following two sections describe the tests that need to be performed after this upgrade and prior to clinical use.

2.1   Radiologic Technologist

This software upgrade requires the performance of the following tests by a radiologic technologist 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.

2.2   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 upgrade is similar to the dose reported during the last phantom image quality evaluation test performed by the technologist prior to the upgrade.

3.0   Software Enhancements

3.1   Resolved Known Software Issues

The following known software issues have been resolved in this release:

- A memory fault caused by the grid line correction algorithm applied to images of small breasts has been corrected *(SCR-28061, SCR-28095)*;

- The sorting order of the image thumbnails on an added procedure has been corrected to follow user preferences *(SCR-28079)*;

- The timing of communication messages has been improved to remove nuisance errors during detector powering up *(SCR-28082)*;

- The Exposure Index tool will now be visible when images are acquired using a Flat Field image thumbnail *(SCR-28098)*;

- Management of Flash Memory has been improved to avoid accidental loss of configuration data *(SCR-28099)*;

- Known issues with communicating with a Modality Worklist Provider have been fixed to mitigate possible software crashes *(SCR-28123)*;

- False reporting of un-commanded C-arm motion errors leading to potential gantry shut-downs have been corrected *(SRS-28132)*.

Chapter 2
Selenia Dimensions 1.5.1 Release Notes

1.0   Introduction

This document provides an overview of the enhancements associated with the 1.5.1 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 User Manual. Changes described in these customer release notes may not be reflected in the current revision of the User Manual.

2.0   Quality Control Requirements for This Software Upgrade (US Sites, Only)

This software upgrade adds workflow functionality enhancements for the radiologic technologist and corrects a number of known software issues.   It does not alter and does not affect the performance of the Selenia Dimensions system. The following two sections describe the tests that need to be performed after this upgrade and prior to clinical use.

2.1   Radiologic Technologist

This software upgrade requires the performance of the following tests by a radiologic technologist by following the corresponding tests in the technologist section of the Selenia Dimensions Quality Control Manual:

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3.0 Software Enhancements

3.1 Image Presentation Enhancements

3.1.1 Contrast Presentation of Magnification Views

The default contrast parameters that control the final window and level of magnification views have been fine-tuned to match the contrast presentation of the screening images.

3.1.2 Processing of Implant Images

The contrast and brightness of images that contain implants can now be adjusted separately so that the tissue next to the implant can be presented with better contrast and brightness to better match the screening images.

In addition, the detection of the implant borders has been fine-tuned for better segmentation of the implant from the rest of the breast tissue.

3.1.3 Display of Hologic Breast Tomosynthesis Images on Selenia Dimensions 2D Licensed Systems

Selenia Dimensions FFDM systems that are not licensed to acquire breast tomosynthesis images are now able to display Hologic breast tomosynthesis images without requiring special licensing.

3.1.4 Window/Level Reset

After adjusting window and level settings on an image via the available W/L tools, the user can reset the image to its original window and level settings by double-clicking on the image on the preview screen.

3.1.5 Enhancements to Multi-Vendor Display of Mammography Images

A number of changes were made to fine tune the display of multi-vendor mammography images on the acquisition workstation as specified by the *IHE Mammography Image Display* profile.

- VOI LUT sequences are preferred over simple window/level settings when displaying images that contain both sets;
- Minor issues displaying Fuji, Fischer and legacy GE images have been addressed;
- Secondary capture images will now display consistently on the acquisition workstation;
- Image thumbnails will be displayed correctly and will represent the corresponding image accurately;
- The acquisition workstation can now export multi-vendor images to media.

3.2　User Interface Enhancements

3.2.1　Contrast Inversion Function

A new tool was added to the *Tools* tab in the *Exam Procedure* page. The new tool allows the user to invert the image pixel data resulting in inverse contrast. This function follows IHE guidelines, where the air is suppressed and not inverted when inverting the image pixel data.

The tools in this tab were also regrouped to be more functional.
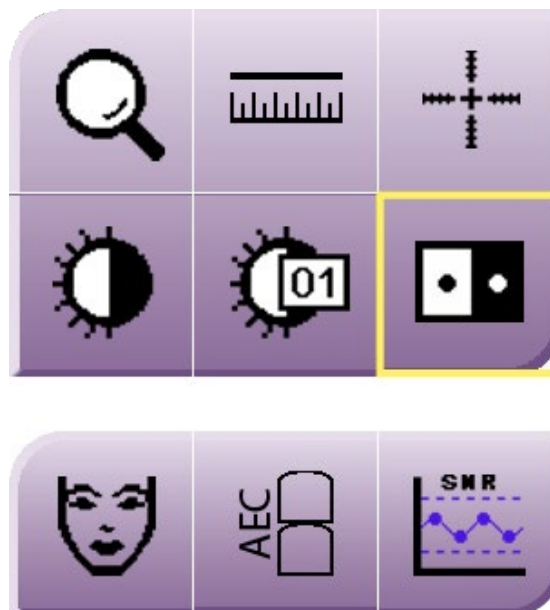
3.2.2　Magnification Tool

The magnification tool functionality (Tools tab) was updated to resolve a number of usability issues. The contents of the mag box now update after an image changes orientation. The behavior of the mag box was corrected in Multi-Up display mode to restrict the movement of the mag box within the current image tile. Lastly, the magnification tool function stays selected after resetting the image.

3.2.3 Markings and Annotations

The *Notices* tab was revised to represent the updated and enhanced markings and annotations functionality.   The followings are descriptions of the available functions in this tab:

    a.   Draw an ellipse marking with annotation on the image;

    b.   Draw a measurement on the image;

    c.   Create a freehand marking and annotation on an image;

    d.   Add a text note to the image;

    e.   Show or hide markings and annotations;

    f.   Send the markings and annotations of the selected (displayed) image to the selected destination;

    g.   Send the markings and annotations of all images in the opened study to the selected destination;

    h.   Mark the procedure that contains new notices as viewed;

   i.   Select the destination to send the markings and annotations.
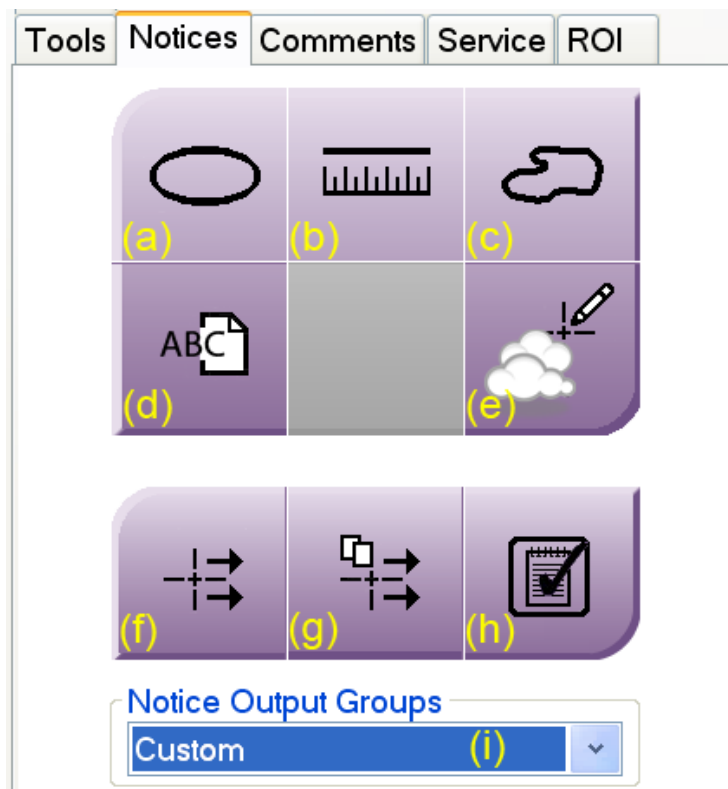
3.3   Quality Control Enhancements

3.3.1   ACR (US) and EUREF Dose Reporting

The acquisition workstation can be configured by the field service engineer to report the dose using the simplified *ACR* dose calculation method (default) or the more advanced and recently revised calculation method as defined by a series of Dance et al publications and recommended by *EUREF*.

3.3.2   System Dose Calibration and Verification

The system now supports dose calibration by a field service engineer using PMMA phantom material.   Specialized views have been added in the QC tab of the *Add View* form to allow for dose verification using variable thickness of PMMA phantom material.
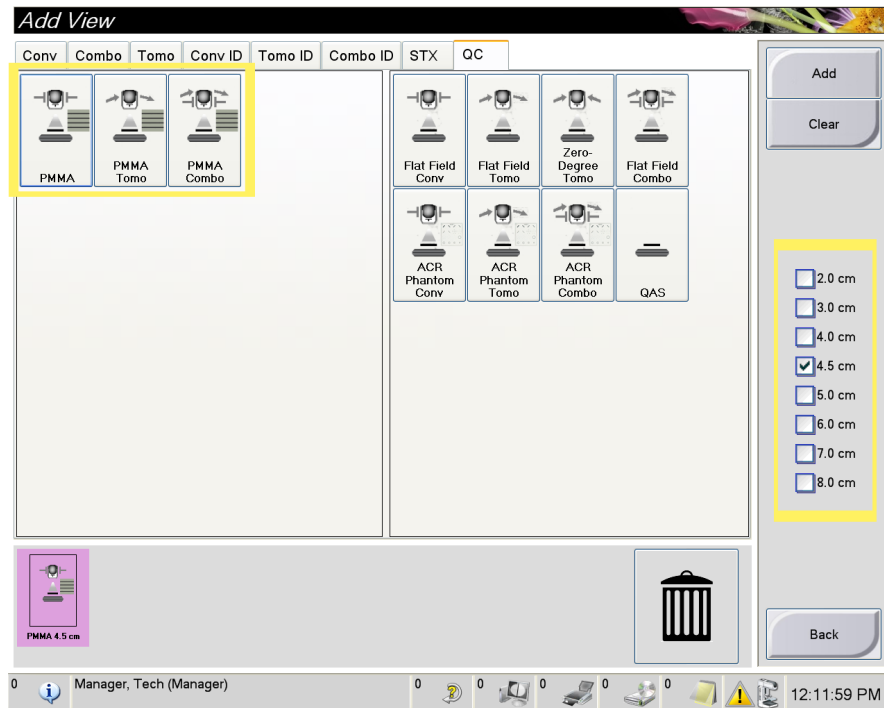

3.3.3   Gain Calibration Enhancements

A number of enhancements were made to the gain calibration of the FFDM modality of the system.   These enhancements allow for reduction of the number of exposures required in each calibration mode to half.   Thus, the time required to perform the gain calibration will be reduced to about half.

3.3.4 AEC Compensation Steps

The AEC compensation function should not be used during the acquisition of tomosynthesis images. Thus, the AEC compensation steps were disabled in the *Tomo* acquisition tab of the user interface.

The AEC compensation function is applicable to the acquisition of conventional FFDM images, only. Changing the AEC compensation steps in the *Conv* acquisition tab of the user interface will only affect the AEC function during the acquisition of conventional FFDM images, even when a combination procedure is acquired.
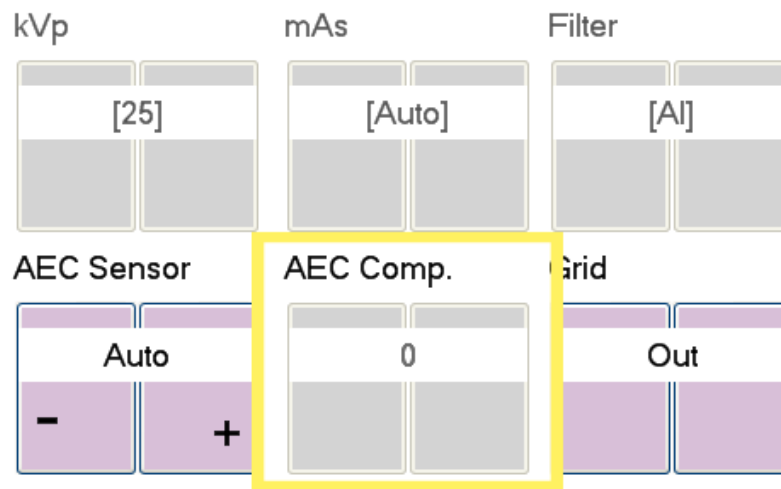
3.3.5 Dose Reporting for Magnification Procedures

In the past, the dose reporting algorithm used the x-ray tube output measured for the large focal spot to compute mean glandular dose for magnification views. As magnification views use the small focal spot, a small error (about 10%) was introduced to the dose calculation for such views.

During HVL and tube output calibration, the field service engineer will measure the difference in x-ray tube output between the small and large focal spots. The dose reporting algorithm will now use x-ray tube output values that resemble more closely the output of the small focal spot when used. Accuracy of the reported dose will be improved with this release.

3.3.6 Reject/Repeat Analysis Reports

Each reject and repeat analysis report will now include the total number of rejected or repeated views, the total number of views performed on the system or by an individual user and the corresponding repeat/reject ratio.

3.4 Workflow Enhancements

3.4.1 MPPS Enhancement

For those systems that are configured to use MPPS messaging, the acquisition workstation may be configured to bypass certain MPPS restrictions and allow the user to add or edit a view, or change the disposition of a study, i.e. from "*Discontinued*" to "*Completed*" or "*In progress*".

3.4.2 Scanning an Accession Number on the Barcode Scanner

The behavior of scanning an accession number on the barcode scanner has been enhanced. There are two options available to the user. The system can be configured so that when the user scans an accession number on the acquisition station,

1. The system will open the full patient, but it will select automatically and display the study that corresponds to the scanned accession number (default option). In this case, all other studies that belong to this patient, i.e. priors, will be accessible to the user in the *Exam Procedure* screen.

2. The system will open the patient partially to include only the study that corresponds to the scanned accession number. All other studies that belong to the same patient will not be available to the user. This option can be configured by the field service engineer.

3.4.3   Print-To-Fit Ability

A new option was added to the *Print* screen.   This option allows the user to print an image in print-to-fit the film mode.   The function may be used to print QC patterns on a film so that the pattern will cover the entire film or to print small breasts on larger films, if desired.   True size needs to be disabled when printing to fit.
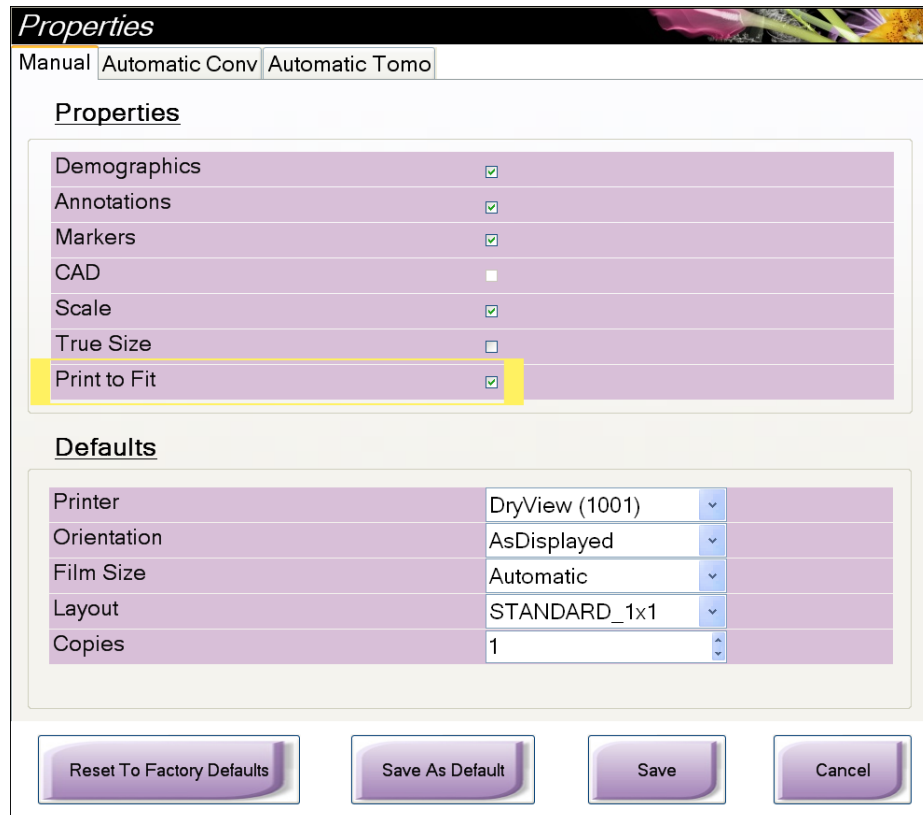
3.4.4   View Order for New Users

When a new user is created on the acquisition workstation, it inherits the view order as is defined in each procedure for the *Manager* user.

3.4.5   Support for Multiple Studies under the Same Accession Number

The patient list now supports the ability to accept multiple studies that share the same accession number from a modality worklist.   When the user opens the patient from the patient list, all studies are available in the *Exam Procedure* screen, despite the fact that they may share the same accession number.   Previously, only the first study was available to the user.

3.4.6 Communications with the Advanced Workflow Manager

The Selenia Dimensions will now be able to integrate with the Advanced Workflow Manager (AWM) option, which will create an enterprise mammography acquisition workflow that will bring all Selenia Dimensions systems under one umbrella.

3.5 Breast Biopsy Enhancements (Option)

3.5.1 Internationalization of Biopsy Control Module (BCM)

The Biopsy Control Module (BCM) is now sensitive to the different locales available on the acquisition workstation.   All text and numbers displayed on the BCM screen will be displayed according to the rules of the selected locale corresponding to the logged in user.

The operator may change the locale in the *Edit Operator* page.   At this point, the languages supported by this software release are *English*, *French*, *Italian*, *German, Spanish*, *Dutch*, *Swedish* and *Portuguese* (Brazil).   Any other selected locale will default to the English language.   Setting of the locale is unique to each operator and it is activated when the operator logs on the system.

Nom de famille	Tech
Prénom	Radiological
Second prénom	
Initiales*	TEC
Rôle	Manipulateur radio
Langue locale	fr-FR - français (France)

☐ Modifier le mot de passe

| Mot de passe | |
| Saisir à nouveau le mot de passe | |

3.5.2 Edit View Enhancements

The *Edit View* functionality has been extended to the biopsy specific views.   Biopsy views can be edited by the user with the restriction that a single view, i.e. scout, will only be edited to another single view and double views, i.e. stereopair, will only be edited to another double view.

After editing a biopsy specific view, any targets previously created in that view are retained and remain valid targets in the corresponding target set.

3.5.3   Targeting Enhancements

The following targeting enhancements were added to this software release:

*   When the user jogs the needle up or down to the extent that the selected target falls outside the aperture of the biopsy device, the *Z-value* of the "*Targets Pending*" is displayed in yellow as a warning that the removed tissue may not include the targeted area.
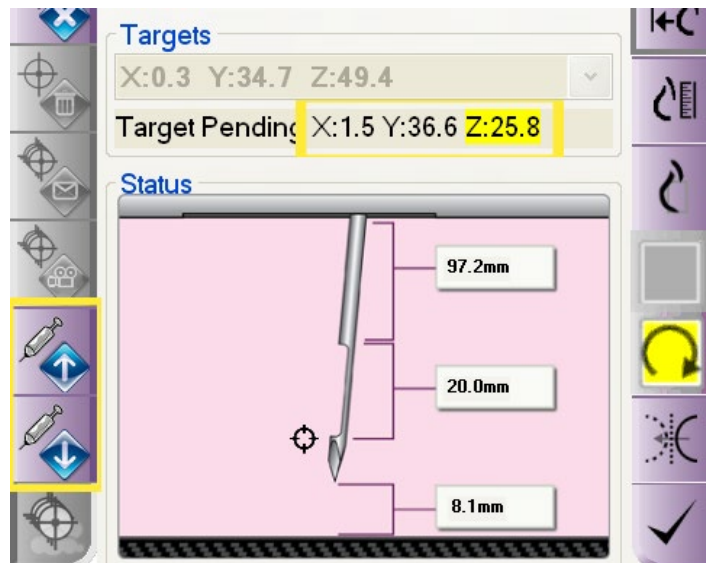
*   The *X* and *Y* jogged information of a target on the BCM is only temporary.   The target jogged information stays valid for the duration that target is displayed on the BCM.   Selecting a different target, reselecting the same target from the BCM *Select Target* screen or resending the targets to the BCM from the acquisition workstation will overwrite any jogged target information with the original target information

*   The active target set will be recomputed automatically when the user selects a different biopsy device from the drop-down list.   The revised target set will be resent to the BCM automatically following the device change.

3.5.4   Automatic Targeting in QAS Needle Accuracy Check

Targeting automation has been added to the QAS needle accuracy check to simplify this task for the operator.   After the user acquires the stereopair images in the *QAS* template (*Admin* page), the system analyzes the two stereotactic images to find the microsphere attached to the end of the QAS needle.   The system proceeds with creating the target automatically and displaying the "*Target Pending*" information.   At this point the user needs to press the *Create Target* button to accept the target so that the targeting information is sent to the BCM.   Evaluation of the *Diff* information on the BCM will provide the accuracy information.

3.5.5   Delete Target Function

The *Delete Target* button was moved lower on the biopsy toolbar in the *Biopsy* tab to limit the chances of the user activating it by mistake.   In addition, a warning will now appear every time the user presses the *Delete Target* button asking the user to confirm the delete action.

3.5.6   Home Function

The *Home* function has been replaced by the *Back* function.   Anytime the *Back* function is used, the BCM display will go back to the previous screen and not the *Home* screen.
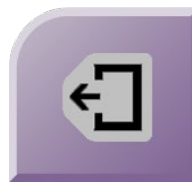
<div align="center">is replaced by   or</div>

3.6   DICOM Enhancements

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

- The definition of the series number (0020,0011) was changed where the last two digits are always set to "00" while maintaining 8-character strings;

- All biopsy images acquired on Selenia Dimensions are assigned the spot "S" view modifier to tag them as spot images;

- A number of tags were corrected, added or removed from the biopsy images acquired on Selenia Dimensions to make these images to be more accurate to the DICOM standard definition.

- A new SOP instance UID will be assigned to any tomosynthesis objects after editing or reprocessing the corresponding view.

3.7   Resolved Known Software Issues

The following known software issues have been resolved in this release:

- Under certain circumstances, one or both stereopair images of the QAS needle appeared with inverted contrast;

- The geometry calibration test in the QC due test list could not be marked as completed on systems that were licensed for stereotactic biopsy, but were not licensed for breast tomosynthesis;

- The detector temperature was not reported correctly in the *About* page;

- Projected targets in stereotactic biopsy images would not re-appear after turning off/on target display;

- The ROI tool could be engaged mistakenly when displaying breast tomosynthesis reconstructed slices;

- The SNR/CNR dialog box was displayed after moving to a different ACR Phantom view displaying data from the first view;

- Image resolution mode did not reset correctly when switching between different objects of a tomo or combo view;

- The repeat reason dialog was engaging after image reprocessing under certain circumstances;

- Erroneous alarms were generated and needed to be attended to by the user when images or other DICOM objects of unsupported content were received by the acquisition workstation;

- Breast tomosynthesis projections did not display in true size when the user activated the true size display mode;

- The acquisition workstation was trying to process FOR PROCESSING images from other vendors;

- Numerous multi-up display issues have been resolved or optimized;

- Image reprocessing did not function consistently within multi-up display;

- Warning icons appearing on the *System Messages* area were double registering unintentionally in the   warnings pop-up dialog of the status bar;

- Newly added views did not appear in the right order within the thumbnail list of views in the *Procedure Screen*;

- After completing a magnification view, the focal spot was set to small;

- Auto AEC might be disabled after collimating down to a smaller x-ray field;

- C-Arm/Stereo mode button on the BCM did not operate as expected in manual biopsy rotation mode.

- After early termination of a tomo exposure where the tube arm has not moved away from the center position, the system gets in an intermediate state that disallows further exposures requiring to move the tube arm back to center position;

- Manual overriding of the collimation does not reset after installing the Affirm Breast Biopsy Guidance system.

3.8   Existing Software Issues

3.8.1   Print button

A *Print* button is now available on the user interface to allow the operator to print QC and Repeat/Reject reports.   In order for the *Print* button to work, a printer has to be connected directly to the USB port of the acquisition workstation.   The system does not have the ability to print the reports on printers attached to the facility's network.

4.0   Hardware Enhancements

4.1   Hardware Components

4.1.1   Fast Compression Mode

The compression device is modified to soften the compression springs used under FAST mode.   This change will make the Selenia Dimensions FAST mode tilt similarly to the Selenia FAST paddle.   The correction will limit the paddle tilt during FAST mode and will limit thickness non-uniformities from the chestwall to the nipple area of the breast.

In addition, the algorithms that compute the compression thickness under FAST compression mode were enhanced to improve the accuracy and reproducibility of the measurements.

4.2   Software Enhancements to Hardware

4.2.1   kVp Jumping During Magnification Views

The kVp jumping function was extended to cover views acquired under magnification. This algorithm allows the AEC system to raise or drop the preselected kVp in *Auto-kV* and *Auto-Filter* AEC modes, as the system tries to maintain an optimum exposure time, i.e. between 0.4 sec and 2.0 sec.   If the AEC system determines that the time will be outside this exposure window, the system alters the predetermined kVp to bring the exposure time within operating limits avoiding long exposures or aborting the exposure.

4.2.2   Gridline Correction Algorithm

Changes were made to the triggering mechanism of the grid line correction algorithm to assure removal of potential grid lines on images that contain breast implants.   Other changes were made to this algorithm to optimize its memory utilization and assure efficient removal of potential grid lines in all images.

4.2.3   Compression Device Enhancements

The behavior of the dual compression mode was corrected in this release.   The first activation of compression will compress the breast to the pre-compression force setting and the second activation will bring the compression to the full force setting.

The stability of reading the compression force was improved so that small fluctuations to the compression force do not put the system in *Standby* mode. Also, the time the system stays in Standby mode after changing compression thickness was reduced to improve usability.

4.2.4   E-Stop Enhancements

Two enhancements were made to the E-Stop behavior.   The first one prompt the user to turn the gantry on after resetting the E-Stop switch despite the fact that power to the system may have been reset in the meantime.   The second enhancement removes erroneous faults that may appear after resetting any of the E-Stop switches.

4.2.5   Detector Power Control

The detector readiness timer will now indicate 3 min as the maximum time that the user needs to wait after a system reboot and before acquiring clinical or QC images.   Prior indication was 5 min.

The system will now require a total of 15 minutes for the detector to come up to temperature and condition its electronics, when the detector is powered up from a cold start.   Prior required conditioning time was 45 min.

4.3   Known Hardware Issues

NONE