C-View User Instructions

SELENTIA®

Dimensions®

HOLOGIC®

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C-View User Instructions
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Introduction and General Information

Rx Only United States federal law restricts this device to use by, or on the order of, a physician.

Hologic developed the C-View image to be an aid in the review of tomosynthesis screening images. The C-View Software generates one C-View image (synthesized 2D image) for each tomosynthesis volume processed. The software also preserves the appearance of microcalcifications and other tissue properties, such as spiculations and densities.

C-View images are useful for comparing mammographic contralateral, for quickly surveying the distribution of microcalcifications throughout the breast and for comparing to prior conventional 2D images in the absence of current conventional 2D images.

Intended Use

The Hologic Selenia Dimensions system generates digital mammographic images that can be used for screening and diagnosis of breast cancer. The Selenia Dimensions (2D or 3D) system is intended for use in the same clinical applications as a 2D mammography system for screening mammograms. Specifically, the Selenia Dimensions system can be used to acquire 2D digital mammograms and 3D mammograms. Each view in a screening examination will consist of:

- a 2D image set, or
- a 2D and 3D image set, or
- a 3D image set in combination with a synthesized 2D image set

The Selenia Dimensions system may also be used for additional diagnostic workup of the breast.

Contraindications

- There are no known contraindications.

Warnings

- Use the C-View images as an aid while examining the tomosynthesis images. Do not make a clinical decision or diagnosis from the C-View images alone.
  - While reviewing the C-View images for items or areas of interest, review the related areas in the tomosynthesis images carefully.
  - Carefully examine the full tomosynthesis data set before making a clinical decision.
- Should C-View fail to produce an output image for any reason:
If the study was performed for screening purposes, the view cannot be completely interpreted without the C-View image unless the view also included a conventional 2D image.

If the study was performed for diagnostic purposes, the view may be suitable for interpretation without C-View.

Precautions

- The C-View Software may not create a C-View image in some circumstances. Please review the Atypical Images section below for more details.
- The C-View Software may create a C-View image that is suboptimal in some circumstances. Please review the Atypical Images section below for more details.

Theory of Operation

OVERVIEW The C-View Software is an image processing application for post-processing the pixel data from tomosynthesis images, captured on a Selenia Dimensions 3D tomosynthesis imaging system, into a synthesized 2D image, known as a C-View image. The C-View image is used as an aid to the radiologist during review of tomosynthesis images.

C-View images are created through a process similar to slabbing on a workstation. In the process of generating the synthesized 2D images, the C-View Software works to preserve the local contrast of linear and point structures on tomosynthesis slices. The result is a single 2D image that contains much of the textural information from the original tomosynthesis slices.

CONFIGURATION The C-View software has no user-configurable settings that influence the appearance of the resulting C-View images. Trained service personnel can adjust two C-View software parameters; one is a general contrast adjustment, and the other is an adjustment of the contrast of the skin line. C-View images are produced in either DICOM Breast Tomosynthesis Image object format, as a single thick slice, or DICOM Digital Mammography Image object format. The site PACS administrator, in consultation with Hologic connectivity engineers, can select the output format most appropriate for the site’s IT infrastructure and workstations. Each C-View image DICOM header contains the information needed to differentiate it from any accompanying conventional 2D image(s) or tomosynthesis data sets in the same view. An annotation (“C-View”) may also be burned to the C-View image pixel data.

WORKFLOW As with any imaging study, the technologist selects the patient and identifies the type of imaging procedure that will be done. For an exam with C-View images, the process of imaging the subject and completing the study is all that is necessary to create C-View images.

The C-View Software itself operates with no direct human intervention, though the method of operation can vary:
When the C-View Software is integrated into the acquisition workstation, C-View processing is triggered through selection of the desired exam with C-View. C-View images become available for viewing on the integrated image display as soon as processing is complete. The C-View images are sent to configured DICOM destinations upon close of study.

When the C-View Software is integrated into an external server, the C-View processing is not triggered until the DICOM tomosynthesis data set arrives at the external processor, following acceptance of the tomosynthesis images at the acquisition workstation. The C-View image output is sent from that server to configured DICOM destinations as soon as the processing is complete.

Atypical Images

Some atypical images can affect the appearance of C-View images. The following table provides explanations and recommendations for these situations:

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<tr>
<th>Observation</th>
<th>Explanations, Recommendations, and Notes</th>
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| **Large man-made object in view**: Image was acquired with a man-made object within the field of view | Explanation: Images acquired with man-made objects, such as breast implants, within the field of view may cause atypical C-View images. If the man-made objects are of high x-ray absorption, regions of the C-View image may contain less tissue information.  
**Recommendation**: Since the tomosynthesis slices are the true diagnostic images, interpret that view without the aid of C-View.  
**Note**: Most notable man-made objects in this category include: breast implants (not imaged in the Eklund position), pacemakers, and Port-a-Cath type catheters. |
| **Diagnostic paddles**: Images containing prominent evidence of diagnostic paddles. | Explanation: C-View is designed as an aid to radiologists, especially during the detection phase of screening. As the tomosynthesis slices are the primary diagnostic images, it is presumed that they contain the most important information during interpretation. Use of C-View with diagnostic paddles may create visual artifacts at the periphery of the clinical image data.  
**Recommendation**: During interpretation, radiologists should primarily rely only on tomosynthesis slices, 2D plus 3D imaging, or conventional 2D imaging. When using C-View with diagnostic paddles, ignore any visual artifacts at the periphery of the clinical image data or collimate down to mask that part of the image.  
**Note**: Diagnostic paddles are a specific sub-type of man-made object (see prior Observation) that should only be present in diagnostic work-up procedures. As C-View expects an unfettered view of the breast geometry, without visual interference from objects such as diagnostic paddles, C-View may not be able to complete processing of an image. |
| **Patient motion**: Images were acquired while patient was moving. | Explanation: As is true in all mammographic-type imaging, patient motion can reduce the clarity of the resulting images.  
**Recommendation**: When C-View images are available at the acquisition console, the technologist should review them for quality prior to releasing the subject from screening and to closing of study. The technologist should evaluate whether a view should be repeated due to motion blur.  
**Note**: Patient motion can cause poor quality C-View images, perhaps... |
making it necessary to recall the patient for additional imaging.

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<th><strong>Mastectomy view:</strong> Images are of a subject post-mastectomy.</th>
<th><strong>Explanation:</strong> The breast region of a subject post-mastectomy generally is not only directly parallel to the pectoralis muscle, but also has an uneven appearance, which can interfere with C-View processing. <strong>Recommendation:</strong> The clinician should rely on conventional 2D imaging, or 2D plus 3D imaging or tomosynthesis imaging alone (without C-View). C-View images may not be able to be generated on mastectomy view images. <strong>Note:</strong> C-View utilizes knowledge of breast geometry, such as location of the chest wall, pectoralis muscle and skin line, in the course of performing its image processing. A C-View image of a mastectomy view may overemphasize the skin line as the skin line may appear in a very narrow band above the detector.</th>
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<td><strong>Surgical specimen:</strong> Images are of tissue after surgical removal.</td>
<td><strong>Explanation:</strong> During the course of its processing, C-View relies on an image “looking like a mammogram”. <strong>Recommendation:</strong> Conventional 2D imaging, or 2D plus 3D imaging or tomosynthesis imaging alone (without C-View) should be considered the primary imaging courses for surgical specimens (including biopsy core samples). <strong>Note:</strong> C-View utilizes knowledge of breast geometry, such as location of the chest wall, pectoralis muscle and skin line, in the course of performing its image processing. When those geometric boundaries cannot be found in the image set, C-View may not be able to complete processing of an image.</td>
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