



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.

The C-View™ software uses image data available from a tomosynthesis acquisition to generate one 2D image (also referred to as “synthesized” or C-View 2D image) per tomosynthesis acquisition. The C-View 2D image is created without the need for an additional FFDM exposure. The C-View 2D image is designed to appear similar to and serve the same purpose as a 2D FFDM mammogram when used as part of a screening study employing tomosynthesis. The C-View 2D image is interpreted in combination with a tomosynthesis image set and is not intended to be used without the accompanying tomosynthesis images to make a clinical decision or diagnosis.

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 generate 2D digital mammograms and 3D mammograms. Each screening examination may consist of:

- a 2D FFDM image set, or
- a 2D and 3D image set, where the 2D image can be either a FFDM or a 2D image generated from the 3D image set

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

Contraindications

- There are no known contraindications.

Warnings

- POTENTIAL ADVERSE EFFECTS OF MAMMOGRAPHY SYSTEMS ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device (these risks are the same as for other screen-film or digital mammography systems):

- excessive breast compression
- excessive x-ray exposure
- electric shock
- infection
- skin irritation, abrasion, or puncture wound

- Use the C-View 2D images in the same way you would use conventional 2D FFDM when performing a screening study employing tomosynthesis. Do not make a clinical decision or diagnosis from the C-View 2D images without reviewing the accompanying tomosynthesis image set.
 - While reviewing the C-View 2D images for items or areas of interest, compare to a prior 2D mammogram if priors exist and then review the related tomosynthesis images carefully.
 - Carefully examine the entire tomosynthesis image set before making a clinical decision.
- The appearance of a C-View 2D image may differ from that of a conventional 2D FFDM image, just as 2D film and FFDM images from different vendors may look different. Users should ensure they are adequately trained and are familiar with the appearance of C-View 2D images before using them in conjunction with tomosynthesis image sets.

Theory of Operation

OVERVIEW The C-View software is an image processing application for post-processing the pixel data from tomosynthesis data, captured on a Selenia Dimensions 3D tomosynthesis imaging system, into a 2D image. The C-View 2D image can be used in place of a 2D FFDM mammogram as part of a screening study employing tomosynthesis.

The C-View software processes tomosynthesis data to generate 2D images which are designed to appear similar to and serve the same purpose as a 2D FFDM mammogram when used as part of a screening study employing tomosynthesis.

CONFIGURATION The C-View software has no user-configurable settings that influence the appearance of the resulting C-View 2D images. C-View 2D 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 2D image DICOM header contains the information needed to differentiate it from any accompanying conventional 2D image(s) or tomosynthesis image sets in the same view. An annotation (“C-View”) will also be burned to the C-View 2D 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 2D images, the process of imaging the subject and completing the study is all that is necessary. The C-View software itself operates with no direct human intervention.

Atypical C-View 2D Images

The following table details a situation that may result in atypical C-View 2D images:

Observation	Explanations, Recommendations, and Notes
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Diagnostic paddles: Images containing prominent evidence of diagnostic paddles.

Explanation: Use of C-View software with diagnostic paddles may create visual artifacts at the periphery of the clinical image data.

Recommendation: When using C-View software 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.
