

# **Selenia Dimensions C-View Software Module Physician Labeling**

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## 1. Manufacturer Contact Information

Hologic, Inc.  
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Technical Support:  
1-877-371-4372

## 2. Prescription Use Statement

Federal law restricts this device to sale by or on the order of a physician.

## 3. Indications for Use Statement

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.

## 4. Major Warnings / Cautions / 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

No serious adverse events were reported for the patients enrolled in the clinical study.

- 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.

### **Contraindications:**

There are no known contradictions.

## **5. C-View Software Module**

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.

## **6. Clinical Study Summary**

Note: The combination of a C-View 2D image and tomosynthesis images will be referred to as C-View plus 3D.

### Results

Hologic compared the performance of C-View plus 3D breast imaging to conventional full field digital mammography (2D) imaging in a reader study with 15 radiologists. The reader study included 302 cases of which 77 were cancer cases. The study was a fully crossed reader study with a 1 month delay between reading sessions. All radiologists read all cases in both modes (2D and C-View plus 3D). The study cases included images from women with both fatty and dense

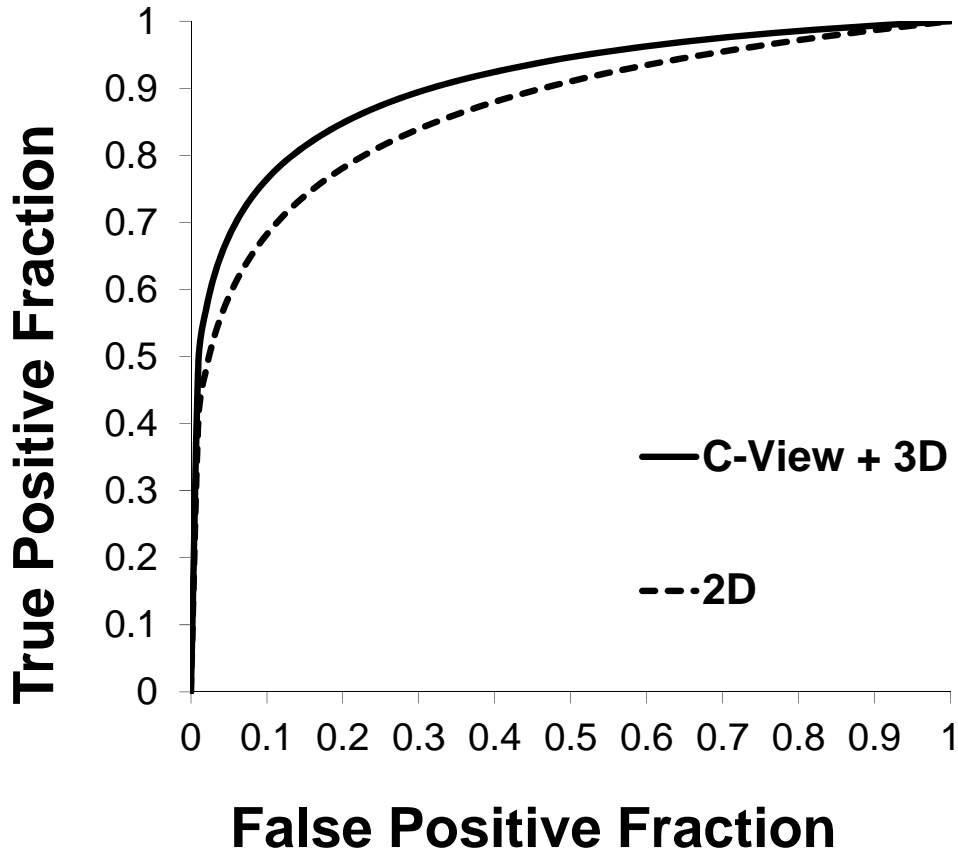
breasts. Women with a prior excisional biopsy, an internal breast marker, breast implants or breasts too large to be imaged in a single compression were excluded from the study. The exclusions were related to the reader study design and additional data on the excluded subjects was collected to support the clinical use of C-View and 3D in these instances. This reader study was designed to evaluate the use of C-View plus 3D imaging in a screening mode compared to conventional 2D screening.

The primary endpoint of this study was to demonstrate that diagnostic accuracy using C-View plus 3D was non-inferior to 2D imaging. Diagnostic accuracy was measured using the area under the Receiver Operating Characteristic (ROC) curve. There were also two secondary endpoints: 1) demonstrate that the diagnostic accuracy of C-View plus 3D was non-inferior to 2D for women with dense breast tissue (BIRADS breast density of 3 or 4) and 2) demonstrate that the non-cancer recall rate for C-View plus 3D was non-inferior to 2D. All endpoints for the reader study were met and in addition to showing non-inferiority, the study demonstrated superior diagnostic accuracy for all cases (primary endpoint) and superior (lower) non-cancer recall rate for C-View plus 3D compared to 2D.

The average ROC curves for the reader study are shown in Figure 1. C-View plus 3D has a superior ROC curve compared to 2D alone. An improved ROC curve is one that is closer to the upper left of the axes. A perfect imaging method would have a true positive fraction of 1 (100%) and a false positive fraction of 0 (0%). These curves also allow estimation of the potential gains in sensitivity and specificity that may be achieved by using C-View plus 3D compared to 2D.

Figure 1  
Average ROC Curves for the 15 Readers:

All Cases



The clinical study results summarized above demonstrate that there is a significant benefit in using C-View plus 3D imaging for routine screening mammography. Diagnostic accuracy was shown to increase while non-cancer recall rate was shown to decrease with C-View plus 3D compared to 2D imaging.

## 7. Dose Comparison

Mode	Dose (mGy)*
2D	1.20
3D	1.45
C-View 2D + 3D	1.45
2D and 3D	2.65
Screen-Film**	1.90

\* 4.2cm compressed breast with composition of 50% glandularity

\*\* Bloomquist AK, Yaffe MJ, Pisano ED et. al. Quality control for digital mammography in the ACRIN DMIST trial: part I. Med Phys 2006; 33: 719-736.