

Selenia® Dimensions® and 3Dimensions™ Synthesized 2D Software Physician Labeling

1.1 Manufacturer Contact Information

Hologic, Inc.

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1.2 Prescription Use Statement

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

1.3 Intended Use

1.3.1 Selenia Dimensions

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.



Note

In Canada and Singapore, Tomosynthesis is not approved for screening, and must be used in conjunction with a 2D image (either a FFDM image or 2D image generated from the 3D image set).

1.3.2 3Dimensions

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

The Hologic® 3Dimensions™ system is indicated to generate digital mammographic images that can be used for screening and diagnosis of breast cancer. The 3Dimensions (2D or 3D) system is intended for use in the same clinical applications as a 2D mammography system for screening mammograms. Specifically, the 3Dimensions 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 an FFDM or a 2D image generated from the 3D image set

The 3Dimensions system may also be used for additional diagnostic workup of the breast.



Note

In Canada and Singapore, Tomosynthesis is not approved for screening, and must be used in conjunction with a 2D image (either a FFDM image or 2D image generated from the 3D image set).

1.4 Potential Adverse Effects of Mammography Systems on Health

Below is a list of the potential adverse effects (such as 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, abrasions, or puncture wounds

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

1.5 Major Warnings / Cautions / Contraindications



Note

Refer to the *User Guide* for more information about warnings and precautions.

1.5.1 Warnings



Warning:

Do not make a clinical decision or diagnosis from the synthesized 2D images without reviewing the accompanying tomosynthesis image set.

Use the synthesized 2D images in the same way you would use conventional digital mammography (2D) when performing a screening study employing tomosynthesis.

- While reviewing the synthesized 2D images for items or areas of interest, compare to a prior digital mammogram (2D) if priors exist and then review the related tomosynthesis images carefully.
- Carefully examine the entire tomosynthesis image set before making a clinical decision.



Warning:

The appearance of a synthesized 2D image may differ from that of a conventional digital mammography (2D) image, just as 2D film and digital mammography (2D) images from different vendors may look different.

Users should ensure they are adequately trained and are familiar with the appearance of synthesized 2D images before using them in conjunction with tomosynthesis image sets.

1.5.2 Contraindications

There are no known contraindications.

1.6 Synthesized 2D Software

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

1.7 Clinical Study Summary



Note

The combination of a synthesized 2D image and tomosynthesis images will be referred to as synthesized 2D plus 3D.

1.7.1 Results

Hologic compared the performance of synthesized 2D 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 synthesized 2D 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 synthesized 2D and 3D in these instances. This reader study was designed to evaluate the use of synthesized 2D 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 synthesized 2D 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 synthesized 2D 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 synthesized 2D 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 synthesized 2D plus 3D compared to 2D.

The average ROC curves for the reader study are shown in Figure 1. Synthesized 2D 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 synthesized 2D plus 3D compared to 2D.

Figure 1: Average ROC Curves for the 15 Readers: All Cases

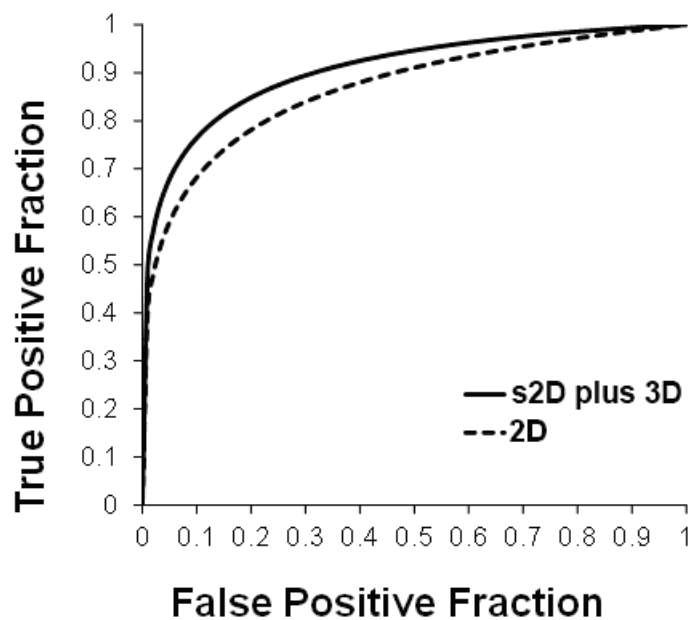
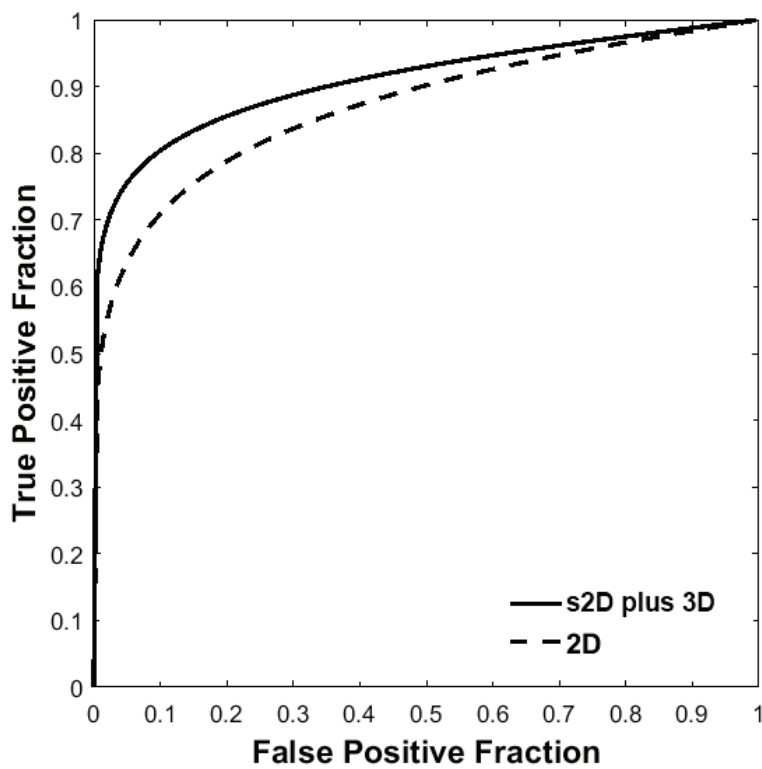


Figure 2: Average ROC Curves for the 15 Readers: Dense Breast Cases



The clinical study results summarized above demonstrate that there is a significant benefit in using synthesized 2D plus 3D imaging for routine screening mammography. Diagnostic accuracy was shown to increase while non-cancer recall rate was shown to decrease with synthesized 2D plus 3D compared to 2D imaging. In particular, synthesized 2D plus 3D demonstrated superior performance, as measured using area under the ROC curve, compared to 2D imaging in women with dense breasts. The non-cancer recall rate was also shown to decrease with synthesized 2D plus 3D compared to 2D imaging in women with dense breasts. In summary, synthesized 2D plus 3D demonstrated superior performance compared to 2D imaging, both in all breast densities, and also in the subgroup of dense breasts.

1.8 Dose Comparison

Mode	Dose (mGy) ¹
2D	1.20
3D	1.45
Synthesized 2D + 3D	1.45
2D and 3D	2.65
Screen-Film ²	1.90

¹ 4.2cm compressed breast with composition of 50% glandularity

² 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.