

# Selenia Dimensions 3D System Physician Labeling

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## 1. Manufacturer Contact Information

Hologic, Inc.  
35 Crosby Drive  
Bedford, MA 01730  
USA  
1-781-999-7300

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 2D mammography systems for screening mammograms. Specifically, the Selenia Dimensions system can be used to acquire 2D digital mammograms and 3D mammograms. The screening examination will consist of a 2D image set or a 2D and 3D image set. The Selenia Dimensions system may also be used for additional diagnostic workup of the breast.

## 4. Major Warnings / Cautions / Contraindications

### Warnings:

This x-ray system can be dangerous to the patient and the user. Always follow the safety precautions for x-ray exposures.

Never leave the patient during the procedure if in contact with the mammography system.

You increase the patient dose to high levels if you increase the AEC exposure adjustment setting. You increase the image noise or decrease image quality if you decrease the AEC exposure adjustment setting.

For exposures except magnification case studies, always use the Face Shield.

The Face Shield does not protect from radiation.

**Cautions:**

Do not make any brightness or contrast adjustments to the display unless the SMPTE test pattern is on the screen.

This system is intended for use by healthcare professionals only.

**Contraindications:**

None known

**5. Clinical Studies Summary**

Hologic compared the performance of 2D plus 3D breast imaging to conventional (2D) imaging in two reader studies with different readers. Reader Study 1 and Reader Study 2 included 312 and 310 cases which were enriched with 48 and 51 cancer cases, respectively. The study cases included images from women with both fatty and dense breasts. These reader studies were designed to evaluate the use of 2D plus 3D imaging in a screening mode in place of conventional 2D screening.

The first reader study (Reader Study 1) was designed to demonstrate that the area under the Receiver Operating Characteristic (ROC) curve for 2D plus 3D was statistically significantly superior to the area under the ROC curve for 2D alone. It was also designed to demonstrate that a significant reduction in recall rate of non-cancer cases could be obtained. In Reader Study 1, using 12 trained radiologists, these endpoints were achieved.

A second reader study (Reader Study 2), using 15 radiologists who did not participate in Reader Study 1, was carried out to investigate the impact of using only the 3D MLO view of the breast instead of both the 3D CC and 3D MLO views. In Reader Study 2, the performance of 3 separate arms was compared: (1) 2D; (2) 2D plus 3D; (3) 2D plus 3D MLO. Arm 1 and Arm 2 were the same in Reader Study 1 and 2, whereas Arm 3 in Reader Study 2 was the new arm with only one 3D view – the MLO. Another difference in Study 2 was that the locations and the types of the lesions recalled by the readers were also recorded to investigate an observation from Reader Study 1. This information was not recorded in the first reader study. ROC and non-cancer recall rate reduction were also the endpoints for Reader Study 2. The outcome for Arm 1 and Arm 2 of Reader Study 2 was almost identical ROC curves for 2D plus 3D and 2D alone as were obtained in Reader Study 1. The study endpoints of Reader Study 2 were achieved. The new Arm 3 of Reader Study 2 had an ROC curve lying midway between the 2D and the 2D plus 3D ROC curves. Statistically significant reduction in non-cancer recall rate was demonstrated in Reader Study 2. Again, all study endpoints were met in Reader Study 2.

In both reader studies, there was an inherent inclusion bias against 3D with respect to cancer detection in a screening population. Nearly all of the cancers included in the reader studies had been detected on 2D images as part of the standard 2D screening workups. This is a bias against 3D

imaging because those cancers that may have been detected using 3D imaging are not included and it is not possible to measure the actual gain in sensitivity (cancer detection) that would occur in clinical practice. In Hologic's reader study case sets where the cancers have been detected using 2D imaging it is not realistic to find improved cancer detection (sensitivity) using 2D plus 3D compared to 2D alone. In a clinical screening setting, given the superior ROC performance demonstrated in Hologic's clinical studies, it would be expected that 2D plus 3D would increase cancer detection.

The pooled ROC curves for Reader Study 1 are shown in Figure 1-1. The pooled ROC curves for both Reader Study 1 and Reader Study 2 are shown in Figure 1-2. 2D plus 3D has a superior ROC curve compared to 2D alone in both studies. A superior 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 2D plus 3D compared to 2D alone and these gains are discussed in the risk benefit section.

Reader Study 2 also measured the ROC performance of 2D plus 3D MLO. The estimated clinical benefit based on the ROC curves of adding just MLO 3D images is shown in Figure 1-2 and is approximately one half of the benefit that may be achieved from adding both the MLO and CC 3D images. Therefore the use of 2D plus 3D (MLO and CC) provides the largest clinical benefit allowing for larger potential gains in both sensitivity (cancer detection) and specificity (recall rate).

The pooled ROC results for primary comparison of 2D versus 2D plus 3D along with the studies' operating points (cancer recall rate and non-cancer recall rate) are shown in Figure 1-3. The ROC curves for the two studies are almost identical, and the operating points are located on the ROC curves. Based on the readers' differential adherence to their training for Reader Study 1 and Reader Study 2, the operating points "move" along the ROC curve. This is the result expected according to ROC methodology when different recall thresholds are used to read mammograms based on different radiologists' approach to interpretation. In both reader studies the statistically superior ROC area for 2D plus 3D imaging compared to 2D imaging is the primary clinical study result which demonstrates the superiority of 2D plus 3D imaging compared to 2D imaging alone.

Figure 1-1  
Pooled ROC curves for all Readers; Reader Study 1

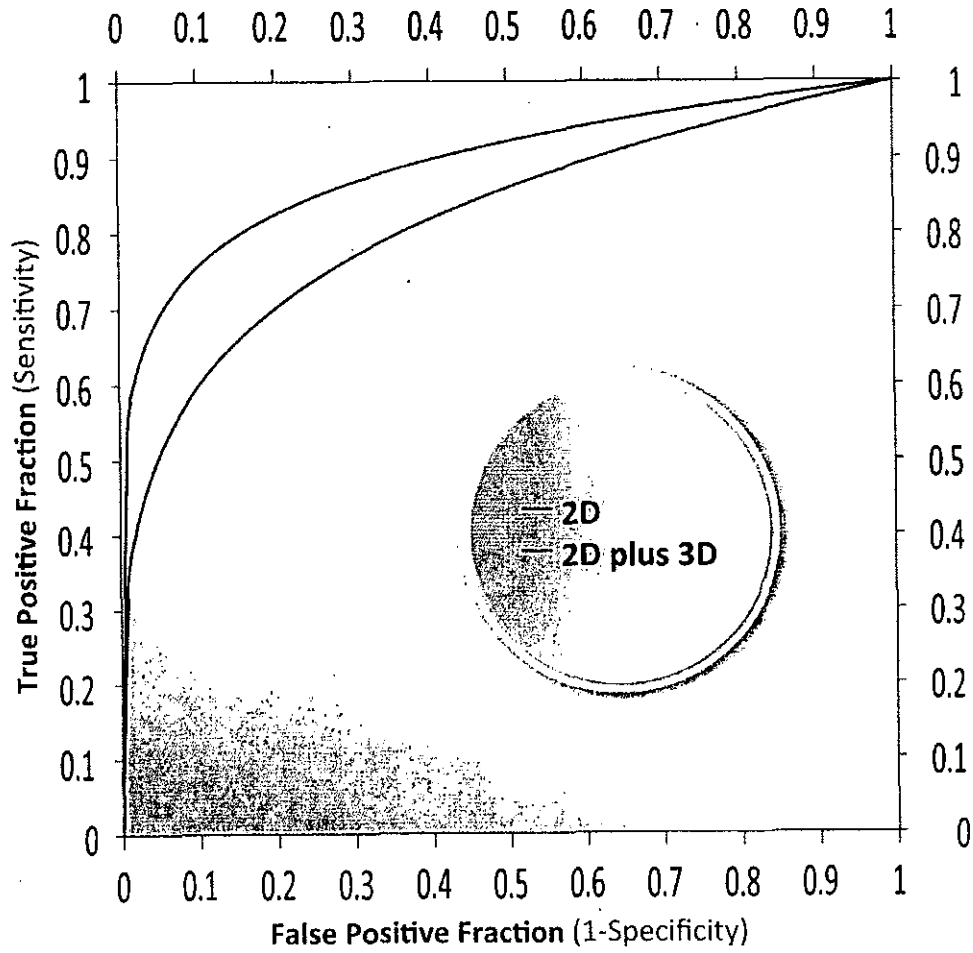


Figure 1-2  
Pooled ROC curves for all Readers; Reader Study 1 and Reader Study 2

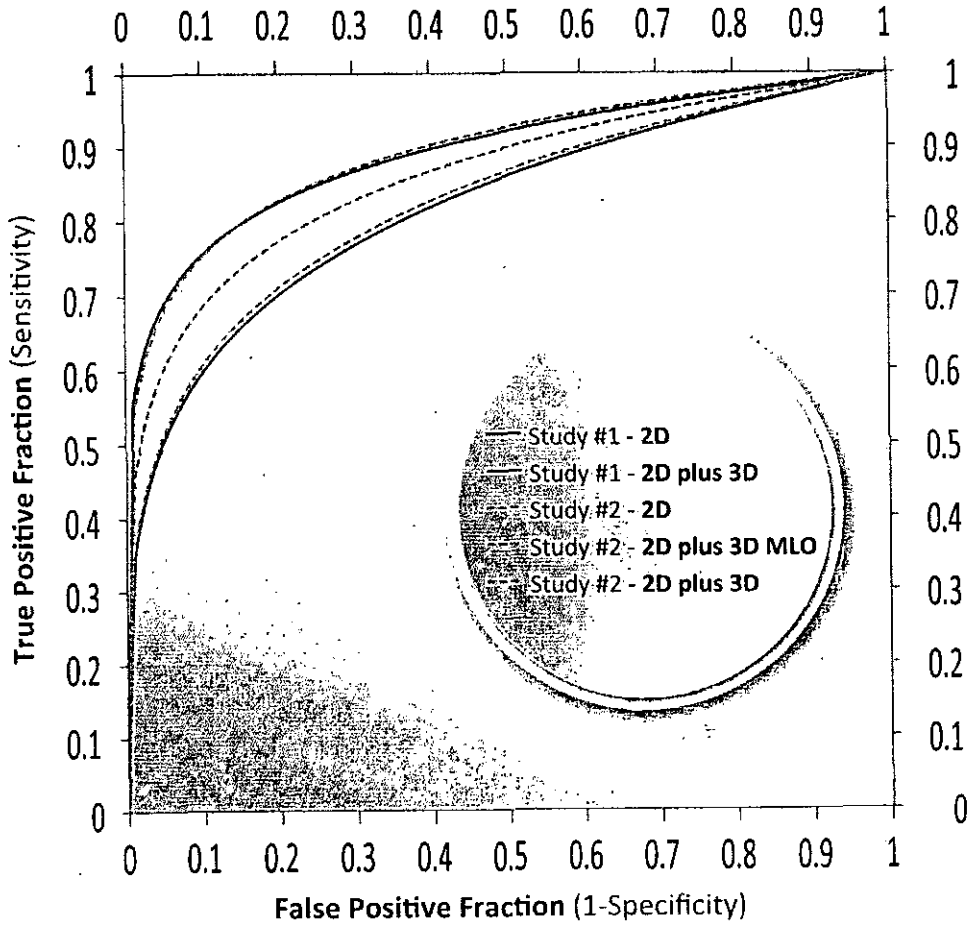
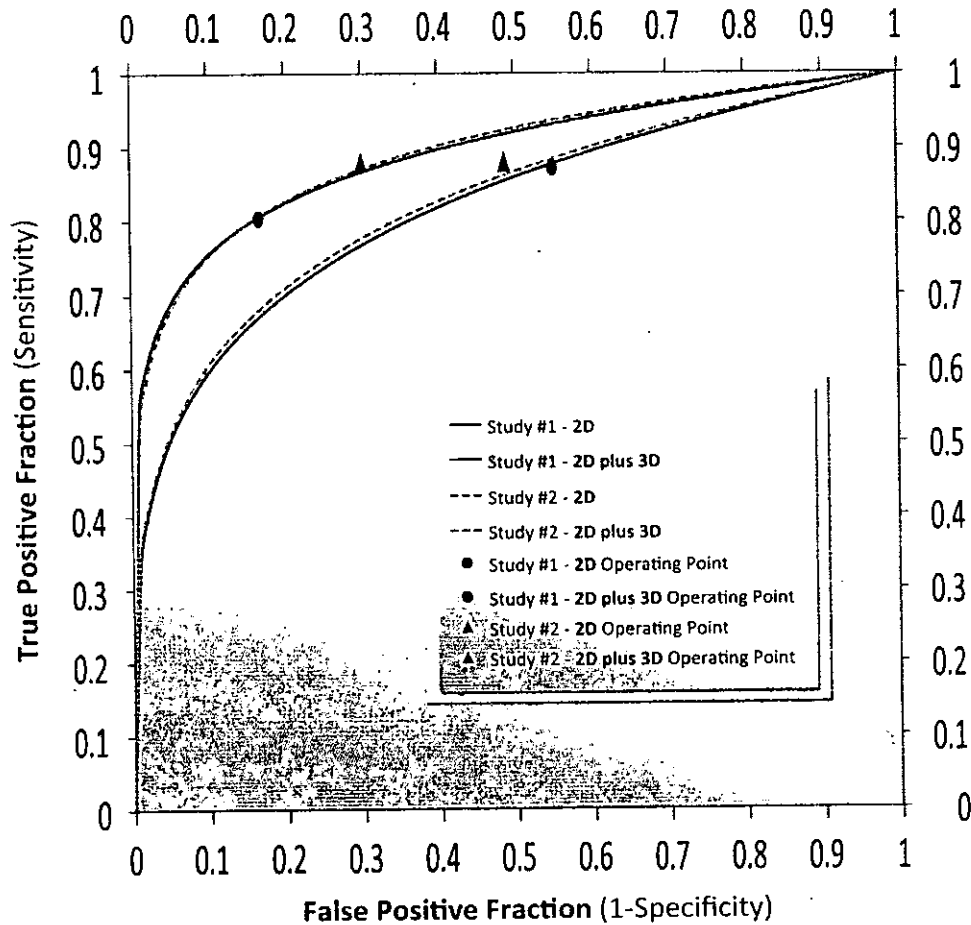


Figure 1-3  
ROC and Operating Points for Reader Study 1 and Reader Study 2



It was observed that tomosynthesis was substantially more effective at improving the detection of masses versus for calcifications and that this, in addition to for the need to compare to priors, was an important reason for continuing to use 2D images in addition to 3D images for screening. Figure 1-4 and Figure 1-5 illustrate this point by showing the ROC improvements for masses and calcifications derived from the same data as Figure 1-1. Generally, superimposition of soft tissue structures does not degrade calcification visibility whereas it does degrade the visibility of masses and other soft tissue lesions. Since tomosynthesis removes tissue superimposition, it explains why the benefit for mass visibility is much greater than that for calcification visibility.

Figure 1-4  
Pooled ROC curves for Calcification Cases; Reader Study 1 and Reader Study 2

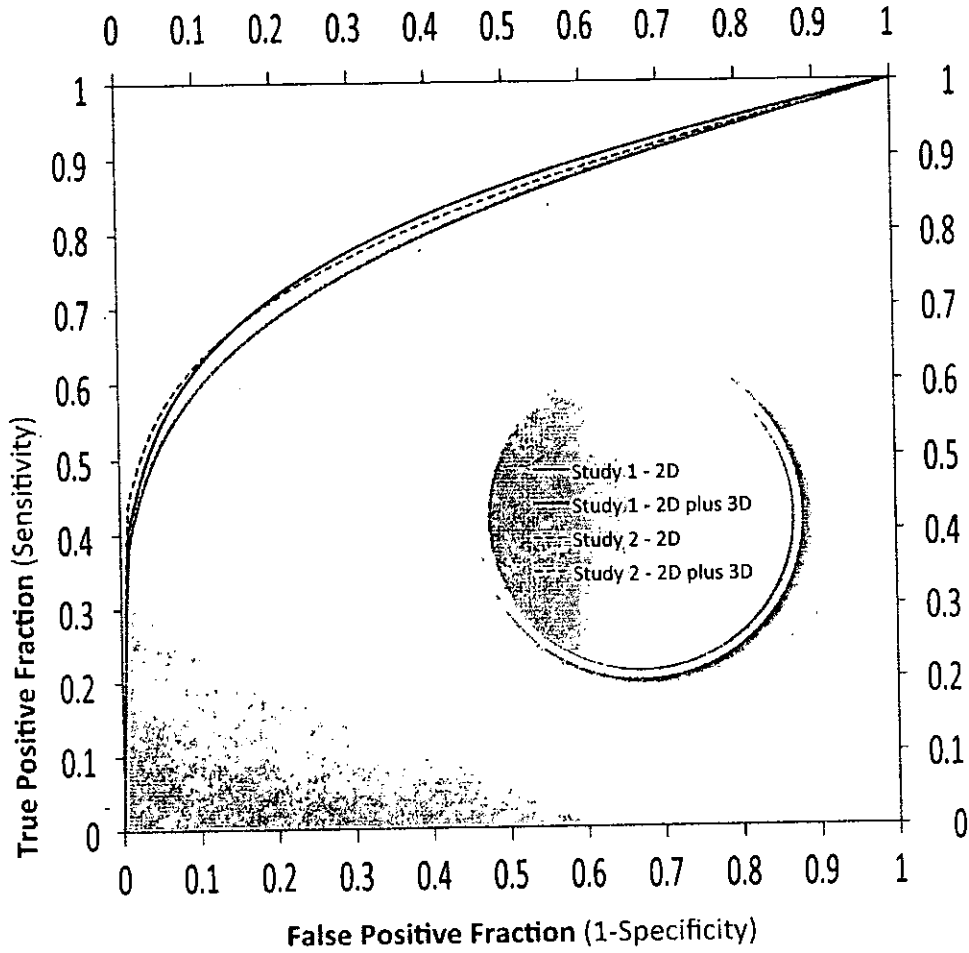
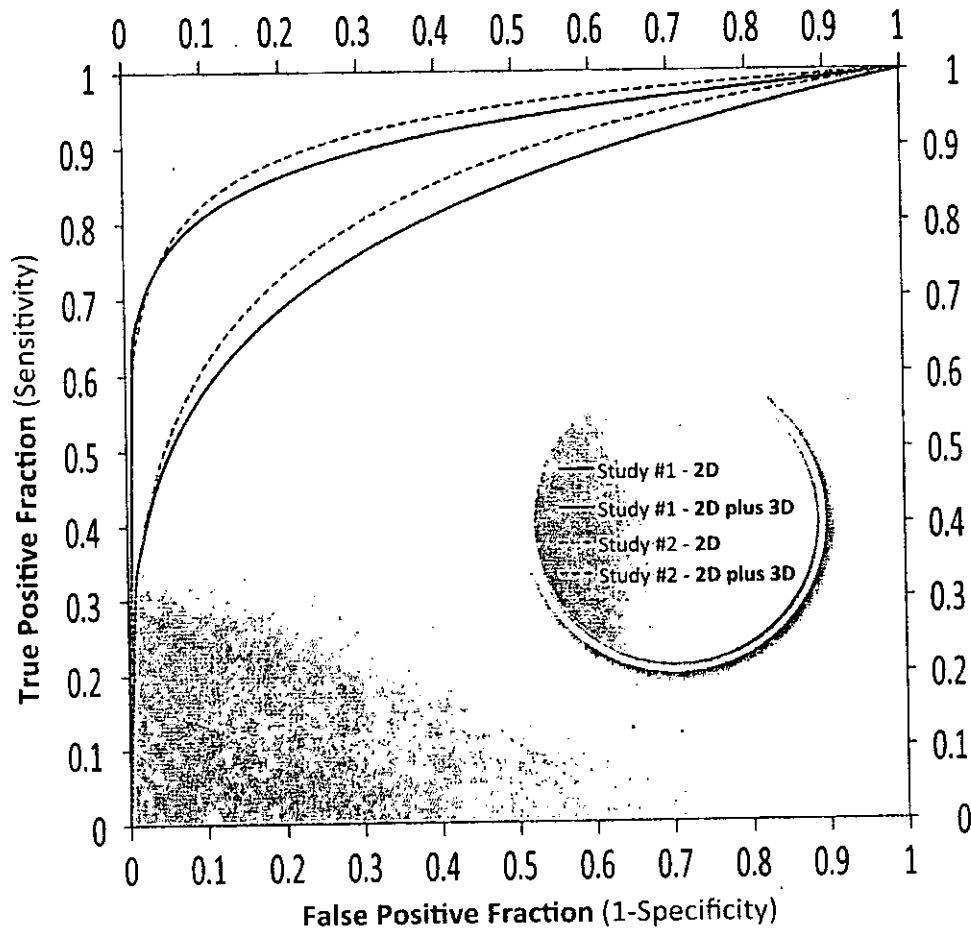




Figure 1-5  
Pooled ROC curves for Non-Calcification Cases; Reader Study 1 and Reader Study 2



The clinical study results summarized above demonstrate that there is a significant benefit in using 2D plus 3D imaging for routine screening mammography. By using both imaging modalities the detection and characterization of calcifications remains at the same level as in the conventional mammogram and the detection and characterization of masses is significantly enhanced. In addition, the comparison with prior 2D images remains unchanged and there is a seamless learning curve available to the radiologist as tomosynthesis becomes integrated into clinical mammography screening.