Breast Tomosynthesis Imaging on Selenia® Dimensions® and 3Dimensions™ Systems Physician Labeling

Including 3DQuorum® Software

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

1.1 Manufacturer Contact Information

Hologic, Inc.

600 Technology Drive

Newark, DE 19702 USA

1-800-447-1856

Technical Support:

1-877-371-4372

1.2 Prescription Use Statement

℞ONLY 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 System

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 an FFDM or a 2D image generated from the 3D image set and the 3D image set can be viewed as either 1-mm 3D slices or 6-mm 3D SmartSlices.

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 an FFDM image or 2D image generated from the 3D image set).

1.3.2 3Dimensions System

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 and the 3D image set can be viewed as either 1-mm 3D slices or 6-mm 3D SmartSlices.

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 an FFDM image or 2D image generated from the 3D image set).

1.4 Definition of Hologic Tomosynthesis Product

Standard Resolution Tomosynthesis: A licensed Hologic feature enabling a standard resolution breast tomosynthesis (BT) scan. The standard resolution tomosynthesis image has a pixel resolution of approximately 100 microns.

Hologic Clarity HD® High-resolution Tomosynthesis: A licensed Hologic feature enabling a high-resolution breast tomosynthesis (BT) scan. The high resolution tomosynthesis image has a pixel resolution of 70 microns.

High-resolution Tomosynthesis with 3DQuorum® Technology: A licensed Hologic feature enabling a high-resolution breast tomosynthesis image with a pixel resolution of 70 microns and a slice thickness of 6 millimeters.

1.5 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.

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

1.6 Major Warnings / Cautions / Contraindications

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

1.6.1 Warnings

WARNING!
Risk of electric shock. Only connect this equipment to supply mains with Protective Earth.

WARNING!
For North American electrical safety requirements, use a Hospital Grade receptacle to supply a correct Ground.

WARNING!
Electrical equipment used near flammable anesthetics can cause an explosion.

WARNING!
To correctly isolate the system, attach only approved accessories or options to the system. Only approved personnel can change the connections.

WARNING!
Keep a 1.5-meter safe distance between the patient and any non-patient devices. Do not install non-patient system components (like the Workflow Manager, a diagnostic review workstation, or a hard copy printer) in the Patient Area.

Warning:
C-Arm movement is motorized.

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

Warning:
You increase the patient dose to high levels when you increase the AEC exposure adjustment. You increase the image noise or decrease image quality when you decrease the AEC exposure adjustment.

Warning:
Control the access to the equipment according to local regulations for radiation protection.

Warning:
To prevent a higher radiation dose to the patient, only put approved materials in the X-Ray beam path.

Warning:
This system can be dangerous to the patient and the user. Always follow the safety precautions for X-Ray exposures.

Warning:
Risk of entrapment. Make sure that the C-Arm has 50 cm (20 inches) of clearance to any object during C-Arm rotation. Do not use Auto Rotation when C-Arm clearance is less than 50 cm (20 inches).

1.6.2 Cautions

Caution:
The system is a medical device and not a normal computer. Only make approved changes to the hardware or software. Install this device behind a firewall for network security. The computer virus protection or network security for this medical device is not supplied (for example, a computer firewall). The network security and anti-virus provisions are the responsibility of the user.

1.6.3 Contraindications

There are no known contraindications.

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

1.7 Clinical Studies Summary – Standard-Resolution Tomosynthesis

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 lesions recalled by the readers were also recorded to investigate an observation from Read 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. A 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.

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

The pooled ROC curves for Reader Study 1 are shown in Figure 1. The pooled ROC curves for both Reader Study 1 and Reader Study 2 are shown in Figure 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 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 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.

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

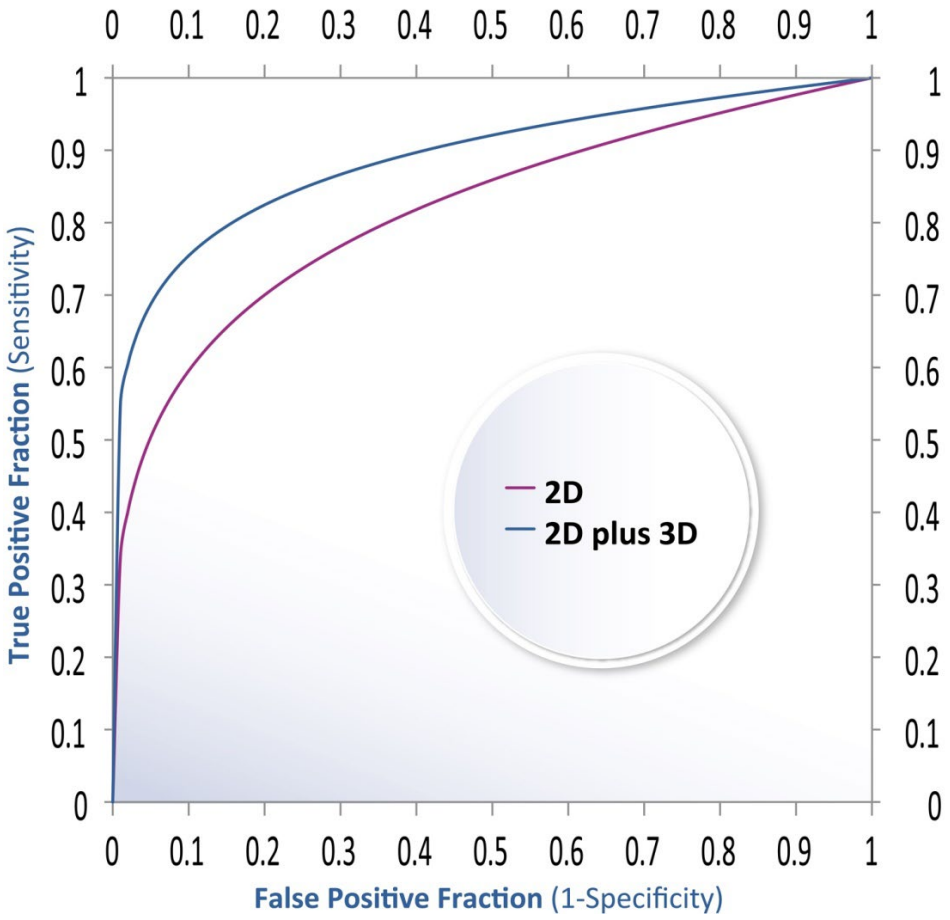

Figure 1: Pooled ROC curves for all Readers; Reader Study 1

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

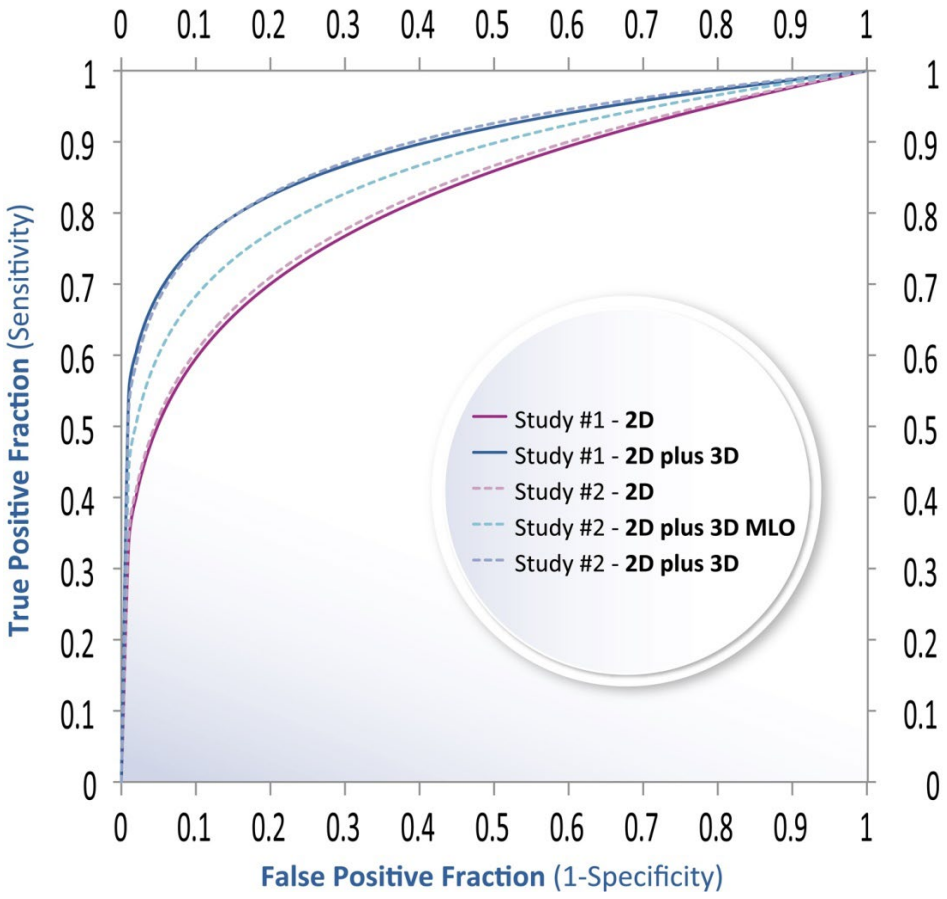

Figure 2: Pooled ROC curves for all Readers; Reader Study 1 and Reader Study 2

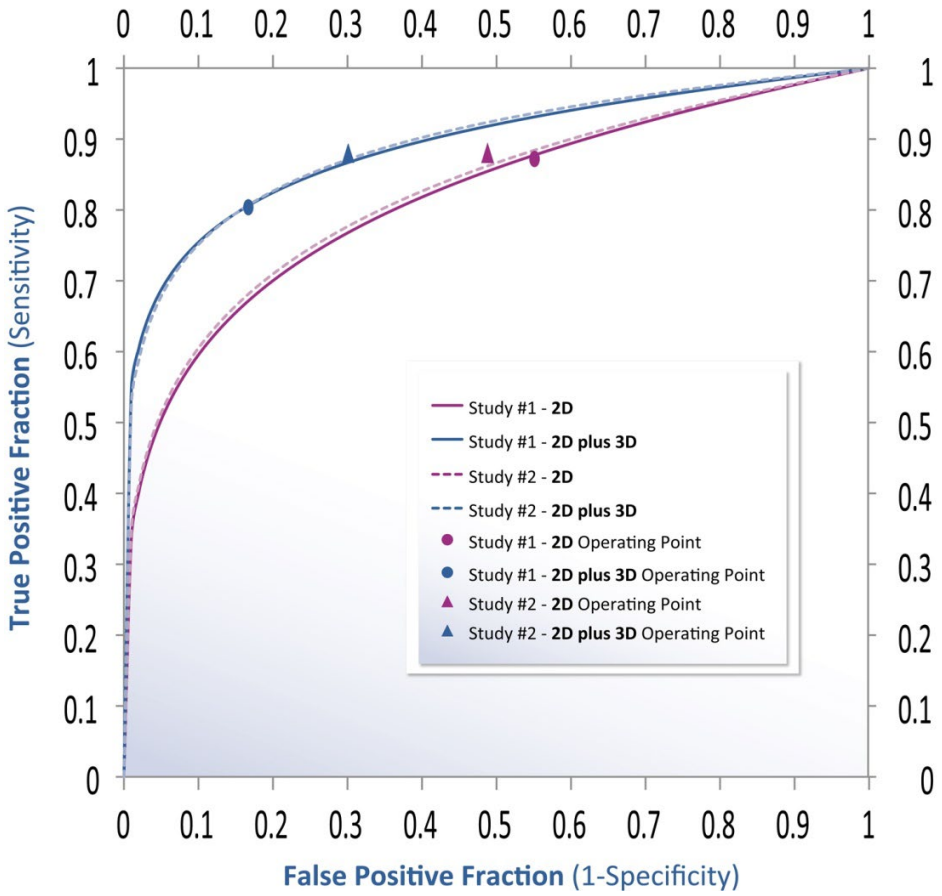

Figure 3: ROC and Operating Points for Reader Study 1 and Reader Study 2

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 4 and Figure 5 illustrate this point by showing the ROC improvements for masses and calcifications derived from the same data as Figure 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.

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

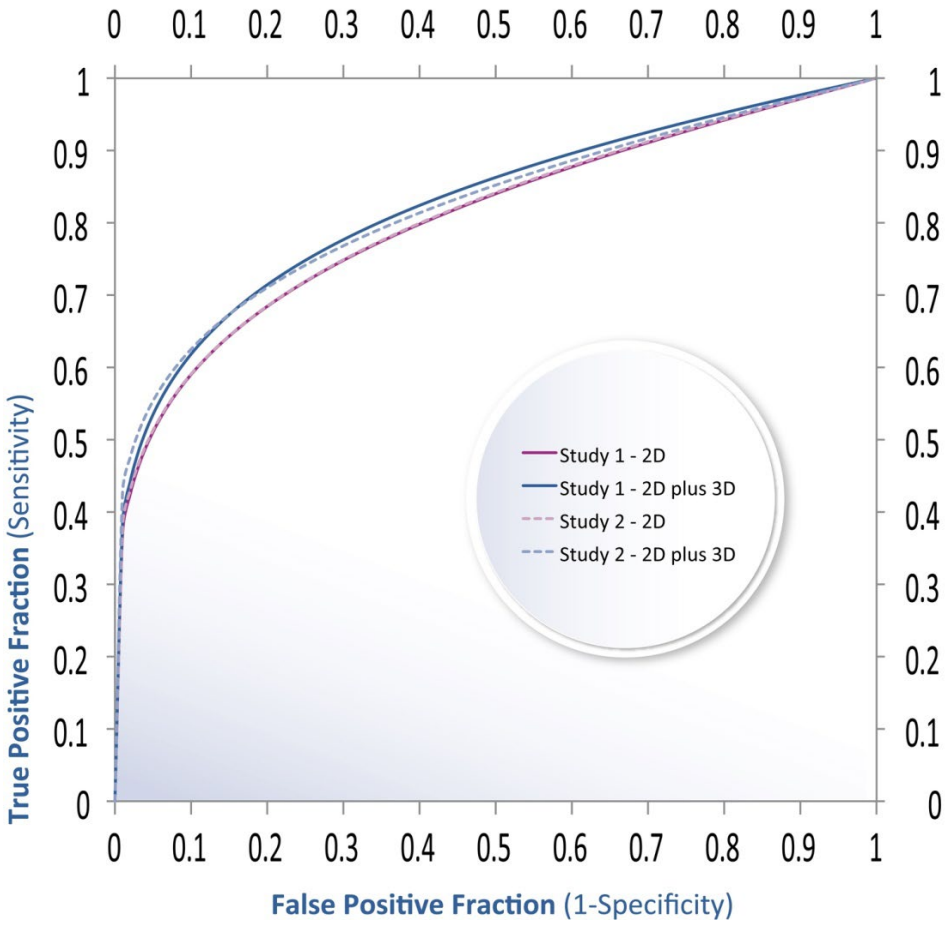

Figure 4: Pooled ROC curves for Calcification Cases; Reader Study 1 and Reader Study 2

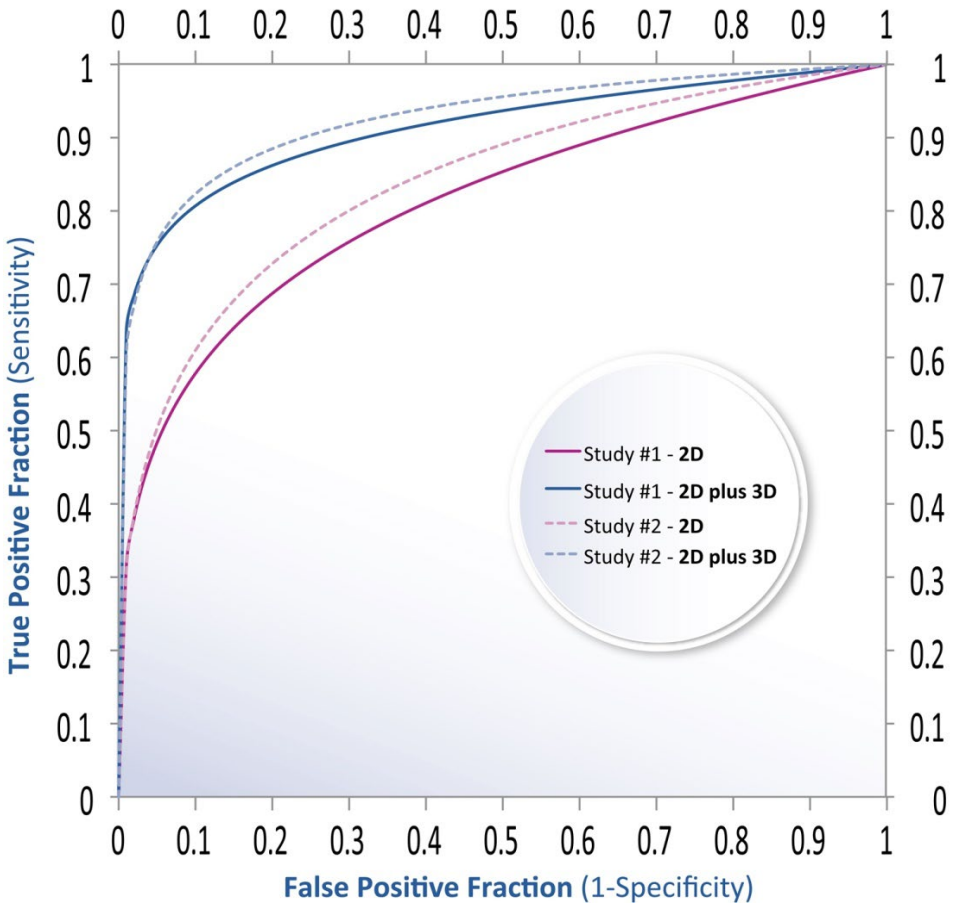

Figure 5: Pooled ROC curves for Non-Calcification Cases; Reader Study 1 and Reader Study 2

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.

Note
For the Clinical Study Summary specific to synthesized 2D, see Selenia® Dimensions® and 3Dimensions™ Synthesized 2D Software Physician Labeling, MAN-10814.

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

1.8 Clinical Studies Summary – Dense Breast Data

Hologic compared the performance of 2D plus 3D breast imaging to conventional (2D) imaging in women with dense breasts. In this analysis, there were 25 cancer cases with dense breasts. There was a significant (P <0.001) benefit to AUC (8.42%) in all dense breasts.

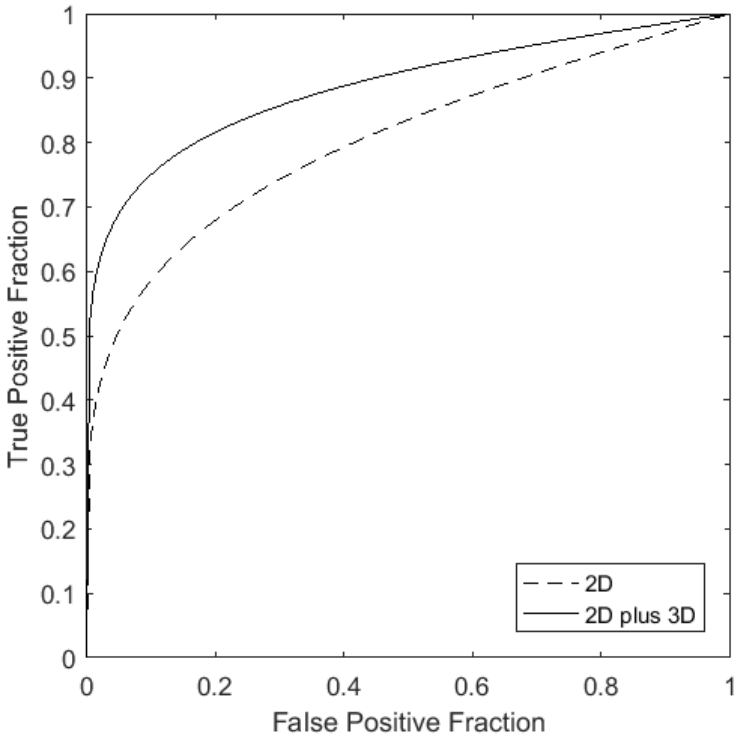

Figure 6: Pooled ROC Curves for Dense Breast Analysis; Reader Study 2

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

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

1.9 Clinical Studies Summary – High-Resolution Tomosynthesis

A preference study was conducted to compare the image quality for the Hologic Clarity HD® High-resolution tomosynthesis image sets to Standard-Resolution tomosynthesis image sets. Seven MQSA-qualified radiologists reviewed 119 images that were acquired with both Hologic Clarity HD® High-resolution and Standard Resolution. The radiologists had experience reading tomosynthesis images. Readers included in the evaluation study had a range of backgrounds and prior experience, as described in the following table:

Reader number	Practice type	Average Annual Mammography Interpretation Volume (Personal)	Breast Imaging Fellowship	Years Active	Years of Tomosynthesis Experience	Prior C-View Experience
1	Academic	3500+	Yes	2009- present	4	Yes
2	Community	6000+	No	1998-present	5	Yes
3	Community	2000	No	1983-present	8	Yes
4	Academic	5000+	Yes	2004-present	7	Yes
5	Community	6000+	No	1993-present	7	Yes
6	Community	5000+	Yes	1994-Present	7	Yes
7	Community	2000	No	1982-present	7	Yes

The cases represented a range of breast densities and mammographic findings. The distribution of case findings is shown in the following table:

	Malignant	Benign	Total
Mass Lesion	35	27	62
Calc Lesion	18	24	42
Mass and Calcification Lesion	7	3	10
Negative			5
Grand Total			119

In the reading session, the radiologists were asked to compare Overall Image Quality (including assessment of noise and artifacts), Conspicuity of Masses, and Conspicuity of Calcifications of two images, one of which was the Hologic Clarity HD® High-resolution tomosynthesis image set and the other the Standard Resolution Tomosynthesis Image set. The images were blinded and occurred in random order on the left and right workstation monitors. The radiologist scored their preference as to which image set was superior, moderately better, or if there was no preference.

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

The results obtained from 833 readings (seven readers, 119 images) are shown in Figure 7. Overall, Image Quality of the Hologic Clarity HD® High-resolution images, Conspicuity of Masses, and Conspicuity of Calcifications were found to be equivalent to Standard Resolution Tomosynthesis images. In summary, 99% of readings for Overall Image Quality, 98% of readings involving masses, and 99% of readings involving calcifications were rated equivalent or better for Hologic Clarity HD® High-resolution images as compared to Standard Resolution tomosynthesis images.

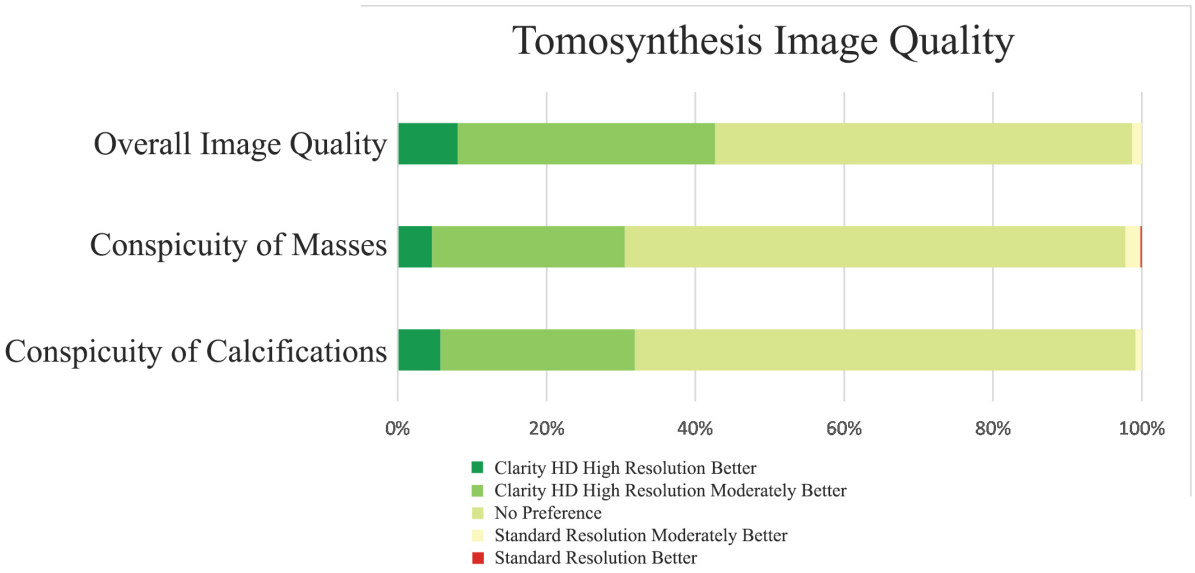

Figure 7: Tomosynthesis Image Quality Preferences 7 readers, 119 images. Overall, Image Quality had no missing values. Conspicuity of Masses had 3 missing values of 504 responses (7 readers, 72 cases with masses). Conspicuity of Calcifications had 17 missing values of 364 responses (7 readers, 52 cases with calcifications)

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

1.10 3DQuorum® Software Technology

The Hologic® Selenia® Dimensions® and 3Dimensions™ 3D systems generate reconstructed slices at 1 mm intervals resulting in a large number of images for radiologists to review. The 3DQuorom® software is an option for generating thicker 6 mm slices (also referred to as SmartSlices) so as to reduce the total number of images that need to be reviewed by a radiologist without loss of diagnostic information. The method of combining the slices preserves the clinically important details in the images while reducing the total number of images presented for review and reduces the file storage required. Each SmartSlice may be perceived as a thick version of a tomosynthesis slice synthesized to represent the smartly combined information of six 1-mm tomosynthesis slices. In order to preserve the continuity of information, an overlap of 3 slices is maintained to generate a series of SmartSlices, thus reducing the total number of slices to be reviewed to approximately one third of the number of 1 mm tomosynthesis slices.

1.11 Clinical Study Summary – 3DQuorum® Technology

Hologic performed a multi-reader, multi-case (MRMC) clinical study using a fully-crossed design (i.e., all readers read all cases) conducted over 2 reading sessions divided by a minimum of a 4-week washout period between sessions. A total of 1705 cases of various dispositions were acquired from 5 clinical sites between January 2016 and April 2017. From this set of 1705 cases, a stratified random sample of 391 cases was drawn from each disposition category for use in the clinical study. The objective of this study was to establish the safety and efficacy of the proposed 3DQuroum product image set (6mm-slice-thickness 3D image set + synthesized Intelligent 2D™ image, abbreviated here as 3DQ/I2D) by comparing its clinical performance to the 1mm-slice-thickness 3D image set + synthesized Intelligent 2D™ image (abbreviated here as 1mmSet), approved in PMA P080003/S001, comparator arm in an enriched MRMC study. All primary and secondary pre-specified endpoints were met.

Fifteen readers with a range of clinical and tomosynthesis experience participated in the study. All readers were board-certified and MQSA-qualified and representative of the intended users. Readers were given a series of 10 training exams (independent from the cases included in the main study) to review the two image reconstructions included in the MRMC (standard-of-care 1mm and the 3DQuroum 6mm reconstructions, including their synthesized 2D image sets) prior to the start of the reader study. No cases used for training or reader assessment were used in the pivotal reader study. A summary description of the 15 readers' experience is provided in Table 1.

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

Table 1: Participating Reader Experience Levels

Reader number	Practice type	>500 Tomo-synthesis exams in the last two years	Average Annual Mammogram Interpretation Volume (Personal)	Breast Imaging Fellowship	Years Active	Years of Tomo-synthesis Experience	Prior CView (Synthesized 2D Mammo-graphy) Experience
1	Private	Yes	1000	No	2013-present	2	Yes
2	Academic	Yes	20000	Yes	2007-present	7	Yes
3	Academic	Yes	2500	No	1992-present	8	No
4	Community Hospital	Yes	~3000	No	2007-present	5.5	Yes
5	Community Hospital	No	2000	No	2015 to present	6	Yes
6	Community Hospital	Yes	2500	No	2009-present	3	No
7	Community Hospital	No	3500	Yes	2004-present	4.5	Yes
8	Community Hospital	Yes	4680	Mini fellowship	1996-present	5	No
9	Community Hospital	Yes	About 4000	No	2012-present	4	Yes
10	Hospital-based	Yes	3761	Yes	2012-present	6	Yes
11	Community/ Academic/ Private	Yes	18500	Yes	2012-present	6	Yes
12	Academic	Yes	7000	Yes	2011-present	5	Yes
13	Academic & Private practice	Yes	5,000 - 6,000	Mini fellowship	2007-present	5	Yes
14	Hospital-based	Yes	9000	Yes	2010-present	6	Yes
15	Outpatient	Yes	6700	Yes	2004-present	7	Yes

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

Primary Endpoints

The first primary endpoint evaluated whether the ROC area under the curve (AUC) performance for the 3DQ/I2D (6mm-slice-thickness 3D image set + synthesized Intelligent 2D™ image) was non-inferior to the 1mmSet (1mm-slice-thickness 3D image set + synthesized Intelligent 2D™ image). The non-inferiority margin was pre-specified: the 3DQ/I2D image set was to be considered non-inferior if the lower limit of the one-sided 95% CI for the difference in AUCs (3DQ/I2D – 1mmSet) was greater than -0.05. The difference in the AUC 3DQ/I2D – 1mmSet was +0.027 (95% CI lower limit = 0.002; p-value = 0.027), in favor of 3DQ/I2D. The first primary endpoint of non-inferior AUC was thus met. Table 2 provides the AUC breakdown by reader and image set type. Figure 8 provides the per-reader and pooled ROC curve plots for 3DQ/I2D versus 1mmSet performance.

Table 2: AUC break down by reader and image set type for the primary endpoint evaluating the diagnostic accuracy of 3DQ/I2D images vs 1-mm image set

Reader	ROC AUC		Difference
	1mmSet	3DQ/I2D	
1	0.726	0.779	0.053
2	0.846	0.858	0.012
3	0.739	0.810	0.072
4	0.828	0.815	-0.014
5	0.746	0.815	0.069
6	0.781	0.798	0.017
7	0.809	0.842	0.033
8	0.715	0.722	0.007
9	0.811	0.825	0.014
10	0.851	0.838	-0.013
11	0.770	0.750	-0.020
12	0.824	0.843	0.019
13	0.859	0.846	-0.013
14	0.711	0.755	0.044
15	0.823	0.835	0.012
Mean	0.789	0.809	0.020
p-value			0.027
Lower Limit - 95% CI			0.002

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

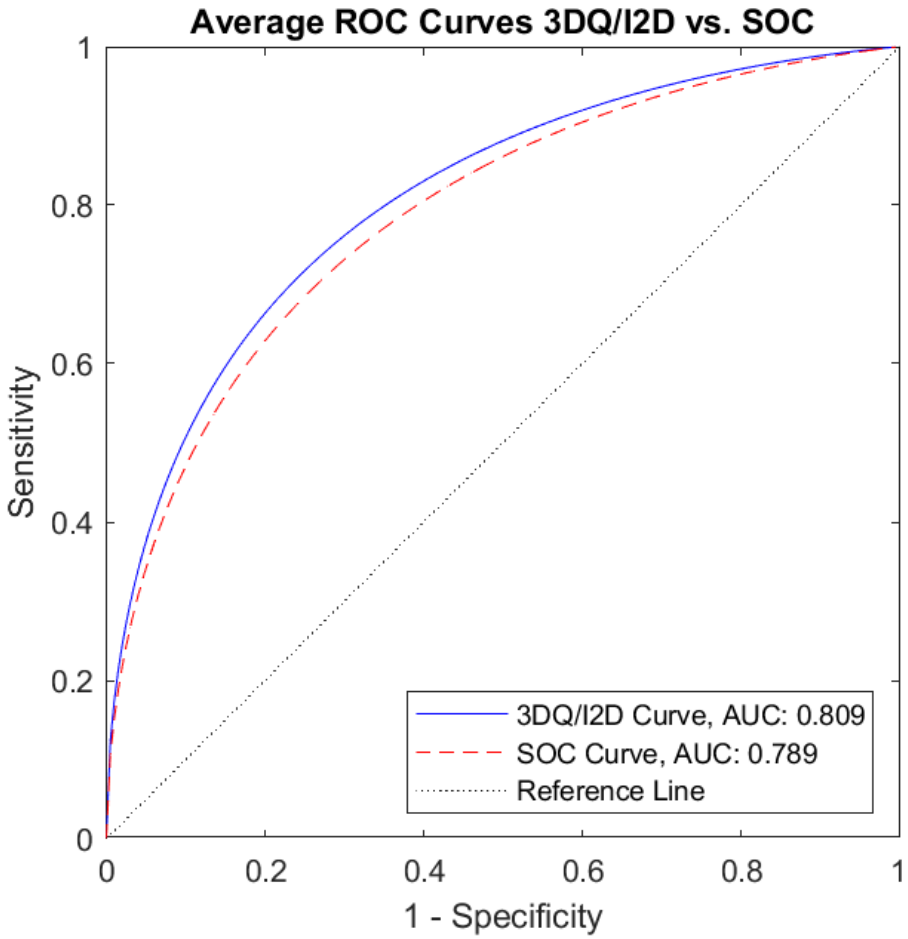

Figure 8: 3DQ/I2D and 1mm Set pooled ROC curves averaged across the 15 participant readers, with reference/chance line (AUC: 0.5) provided for reference

The second primary endpoint was demonstration of a non-inferior recall rate of calcification-only cancer cases by readers (i.e., sensitivity) when reviewing the 3DQ/I2D image set relative to the 1mmSet, with a pre-specified non-inferiority margin of -0.05 of the 95% confidence interval. Mixed regression demonstrated a +0.047 recall rate difference (95% CI lower limit = -0.005; p-value = 0.08) in calcification-only cancers (N=43) in favor of 3DQ/I2D, thus the second primary endpoint of non-inferior recall rate for cancers presenting as calcifications only was met. Table 3 provides the breakdown by reader and image set type for the primary endpoint evaluating the recall rate of calcification-only cancer cases.

Table 3: Recall rate breakdown by reader and image set type for the primary endpoint evaluating the recall rate of calcification-only cancer cases (N=43)

Reader	Recall Rate (%)		Difference
	1mmSet	3DQ/I2D	
1	37.2%	44.2%	7.0%
2	30.2%	39.5%	9.3%
3	53.5%	72.1%	18.6%
4	55.8%	60.5%	4.7%
5	60.5%	69.8%	9.3%
6	41.9%	46.5%	4.7%
7	81.4%	90.7%	9.3%
8	41.9%	41.9%	0.0%
9	46.5%	51.2%	4.7%
10	62.8%	62.8%	0.0%
11	88.4%	86.0%	-2.3%
12	67.4%	62.8%	-4.7%
13	48.8%	41.9%	-7.0%
14	72.1%	74.4%	2.3%
15	48.8%	62.8%	14.0%
Mean	55.8%	60.5%	4.7%

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

Secondary Endpoints

- The recall rate of cancer cases by readers (i.e., sensitivity) using 3DQ/I2D is non-inferior to 1mmSet, on average across all readers, with a non-inferiority margin of -0.05.
- The recall rate of non-cancer cases by readers (i.e. specificity) using 3DQ/I2D is non-inferior to the 1mmSet, on average across all readers, with a non-inferiority margin of +0.05.
- The false positive rate due to detection of calcifications in known negative cases in 3DQ is non-inferior to that of 1mmSet with non-inferiority margin of +0.05.
- The diagnostic accuracy for cases presenting with a solid-tissue component (i.e., mass) averaged among all readers reading with the 3DQ/I2D is non-inferior to that of 1mmSet, with non-inferiority margin of -0.05 as measured by area under the ROC curve.
- The average reading time using 3DQ/I2D is lower (anticipated effect size 20%) than reading time necessary using 1mmSet, on average across all readers with non-inferior diagnostic accuracy to that of 1mmSet.

All secondary endpoints were met. The effect size for the endpoint that evaluated average reading time was 13%.

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856

1.12 Dose Comparison

Mode	Standard Resolution Dose (mGy)[1]	High Resolution Dose (mGy)[1]
2D	1.20	1.20
3D[2]	1.45	1.45
3D[2] + Synthesized 2D	1.45	1.45
2D and 3D[2]	2.65	2.65
Screen-Film[3]	1.90	1.90

[1] 4.2cm compressed breast with composition of 50% glandularity

[2] This includes either 1-mm slices or 6-mm SmartSlices.

[3] 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.

1.13 File Size Comparison

Mode	Average File Size, Single View (MB)	Average Study Size (MB)
3D (Standard resolution)	147	587
3D (Standard resolution) with synthesized 2D	154	615
Hologic Clarity HD® (High resolution)	367	1467
Hologic Clarity HD® (High resolution) with synthesized 2D	384	1535
3DQuorum SmartSlices (High resolution)	138	553
3DQuorum SmartSlices (High resolution) with synthesized 2D	155	622

The file size comparison was performed on all the images from the MRMC study described in *Clinical Study Summary – 3DQuorum® Technologlarity* in section 1.11.

600 Technology Drive, Newark, DE 19702 USA ● 1.800.447.1856