

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Digital Breast Tomosynthesis Mammography System

Device Trade Name: Selenia Dimensions 3D System
3D Upgrade Kit
Selenia Dimensions Mobile 3D System

Applicant's Name and Address: Hologic, Inc.
35 Crosby Dr.
Bedford, MA 01730

Date of Panel Recommendation: The Radiological Devices Panel met on September 24, 2010, to discuss, make recommendations and vote on the safety, effectiveness, and risk versus benefit of the Selenia Dimensions 3D System.

PMA Number: P080003

Product Code: OTE, Digital Breast Tomosynthesis

Date of Notice of Approval to the Applicant: February 11, 2011

Expedited: Not applicable

II. INDICATIONS FOR 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 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.

III. DEVICE DESCRIPTION

The Selenia Dimensions 3D System is a software upgrade and minor hardware change to the Selenia Dimensions 2D System, approved via P010025/S013 on December 22, 2008. The software upgrade unlocks the 3D controls, allowing their display on the system's acquisition workstation (AWS). The minor hardware change on the Gantry Control

Board enables all 3D functions, including the use of the appropriate aluminum filter for 3D imaging.

The Selenia Dimensions 3D System upgrade enables the acquisition of tomosynthesis three-dimensional (3D) images for screening and diagnostic purposes, allowing the Selenia Dimensions 3D system to acquire 2D and 3D images separately, or combined in a single compression.

The 3D images are acquired by moving the tube head in a 15° arc over the stationary, compressed breast capturing multiple images at multiple angles during a short scan. These individual images are then reconstructed into a series of thin high-resolution slices that can be displayed on a softcopy workstation.

IV. CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

The warnings and precautions can be found in the Selenia Dimensions 3D system's User Manual.

V. ALTERNATIVE PRACTICES AND PROCEDURES

Various methods are available for screening and diagnosing of breast cancer. These include a clinical breast examination, screen-film and digital 2D mammography, ultrasound, and magnetic resonance imaging. A biopsy of an abnormality detected with these exams is often obtained to diagnose the cancer.

VI. MARKETING HISTORY

The Selenia Dimensions 3D System is a software upgrade to the commercially available Selenia Dimensions 2D System, which received FDA approval on December 22, 2008 via PMA Supplement P010025/S013.

The Selenia Dimensions System (2D and 3D) was CE marked in September, 2008, and is commercially available in the countries of the European Union, markets in South America, Asia, Middle East, Asia, and Africa.

VII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

No serious adverse events were reported for the patients enrolled in the clinical study. However, potential adverse effects of any mammography system include:

- excessive breast compression
- excessive x-ray exposure
- electric shock

- infection
- skin irritation, abrasion, or puncture wound

VIII. SUMMARY OF IMAGE QUALITY TESTING

Hologic conducted testing to demonstrate the imaging performance of the Selenia Dimensions 3D System. Testing was performed in tomosynthesis (3D) imaging mode. Performance in 2D imaging mode was demonstrated in PMA P010025/S013.

A. *Overview of 3D Performance Tests*

The Selenia Dimensions 3D system can perform x-ray imaging in 2D, 3D, or both 3D and 2D imaging sequentially in one compression. Since the performance of the Selenia Dimensions 2D system was successfully demonstrated in the approved PMA Supplement P010025/S013, this section is focused on the 3D performance testing of the system.

The following 3D performance tests are reported:

- Linearity of image receptor
- Modulation transfer function (MTF)
- Detective quantum efficiency (DQE)
- ACR accreditation phantom scores
- CD-MAM contrast detail curves

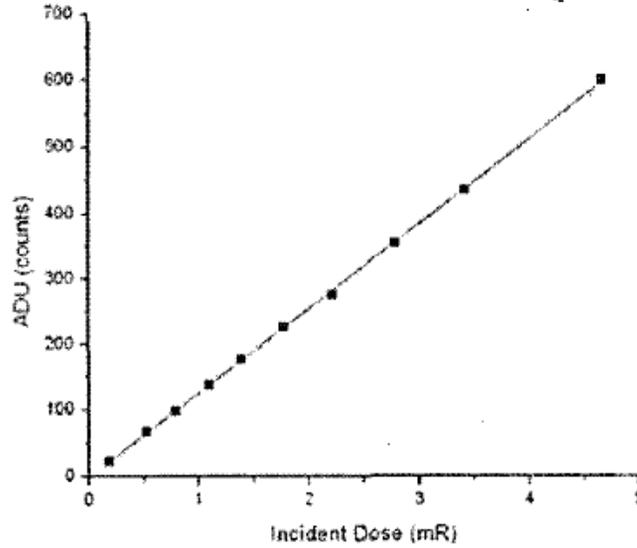
Table 1
Dose Used to Evaluate System Performance in 3D Imaging Mode

Imaging Mode	Nominal Dose to ACR Accreditation Phantom
3D	1.45 mGy

B. Image Receptor Characteristic Curve

Figure 1 shows the characteristic curve of the image receptor on the Selenia Dimensions 3D system in 3D imaging mode.

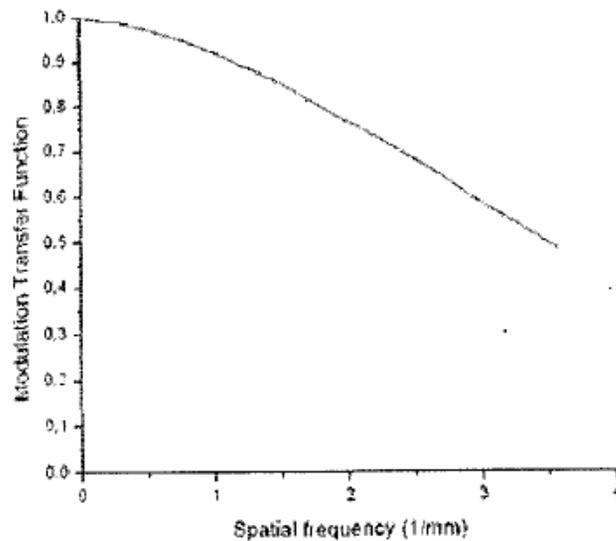
Figure 1
Characteristic Curve of Selenia Dimensions 3D System in 3D Mode



C. Modulation Transfer Function

The MTF of the Selenia Dimensions 3D system in 3D imaging mode is shown in Figure 2.

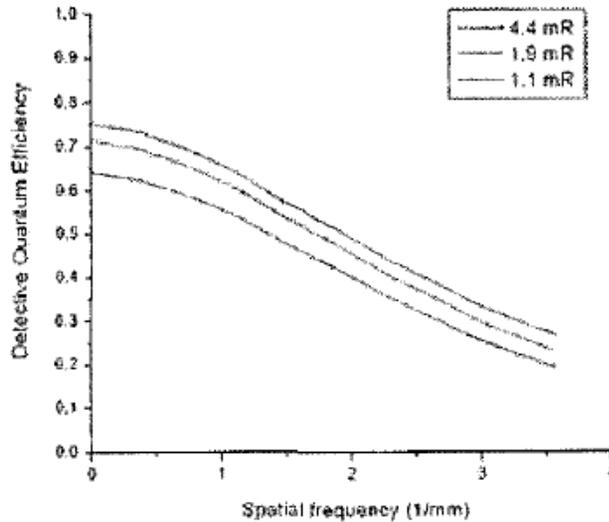
Figure 2
Pre-sampled 3D Imaging MTF for Selenia Dimensions System



D. Detective Quantum Efficiency

The DQE of the Selenia Dimensions 3D system in 3D imaging mode, over a range of incident exposures, are shown in Figure 3.

Figure 3
Detective Quantum Efficiency for Selenia Dimensions System in 3D Mode



E. ACR Accreditation Phantom

The ACR accreditation phantom was designed as a quality control test tool for screen-film mammography systems. It is comprised of six fibers, five groups of aluminum oxide specs, and five simulated masses embedded in a body of tissue equivalent material inside an acrylic box. This phantom can be used to provide an overall measure of the imaging system performance because of its commonly recognizable correlation to image quality in screen-film mammography.

The performance of the system when imaging the ACR accreditation phantom was evaluated in 3D mode.

Table 2 summarizes the scores for Selenia Dimensions 3D system in 3D imaging mode.

Table 2
ACR Scoring for Selenia Dimensions System in 3D Mode

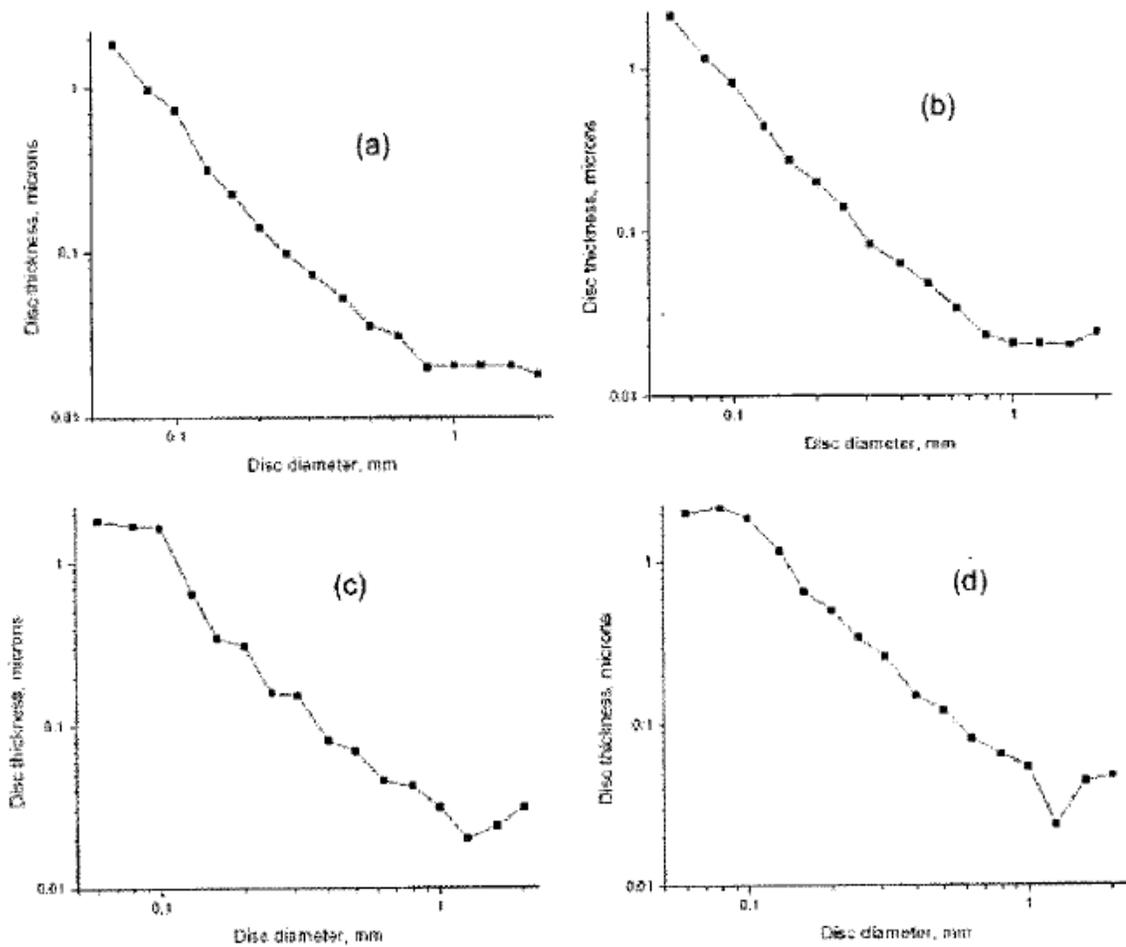
Fibers	Speck Groups	Masses
4.9	3.9	4.2

F. CD-MAM Contrast Detail

The performance of the system was measured using the CD-MAM contrast detail. Performance was measured in 3D imaging mode.

The 3D contrast detail performance is given in Figure 4, for total phantom thickness of 2.5 cm (a), 4.5 cm (b), 6.5 cm (c), and 8.5 cm (d).

Figure 4
CD-MAM Performance in 3D Mode with Varying Phantom Thickness:
cm (a); 4.5 cm (b); 6.5 cm (c); 8.5 cm (d).



G. Summary of Performance Tests

The performance of the Selenia Dimensions 3D System as measured in 3D imaging mode using quantitative tests are as expected.

IX. CLINICAL STUDIES

A. *Image Acquisition Study*

Images and related patient information were obtained from 1192 subjects from 5 clinical US centers under an IRB approved protocol. Images were acquired on a Selenia™ FFDM system and the investigational Selenia 3D system. Subjects were enrolled into the study from one of the following groups:

- Screening Group
 - Subjects who are asymptomatic
 - Subjects scheduled to undergo a routine screening mammogram
- Biopsy Group
 - Subjects scheduled for a biopsy

All subjects underwent standard bilateral 2-view mammograms (MLO and CC) taken both on the Selenia FFDM and the investigational Selenia 3D systems.

Inclusion/Exclusion Criteria for the study included:

Inclusion Criteria

Prior to study enrollment, all subjects must have met the following overall criteria:

- Female
- Any ethnic origin
- No contraindication for routine bilateral mammography

Exclusion Criteria

Subjects who presented with any of the following were not enrolled in the study:

- Subjects who presented with any contraindications to mammographic screening, including, but not limited to:
 - Significant existing breast trauma
 - Pregnancy
 - Lactating
- Previous surgical biopsy
- Previous breast cancer
- Placement of an internal breast marker
- Breast implants
- Subjects who were unable to understand and execute written informed consent

Adverse Events

No expected or unexpected adverse events were reported.

B. Reader Study 1 Summary

Objectives

The purpose of the clinical trial was to compare the performance of 2D plus 3D imaging to that of 2D imaging alone by demonstrating a reduction in recall rate utilizing the initial BIRADS score and an increase in ROC performance as measured by the mean area under the curve in a multi-reader, multi-case ROC analysis.

Study Endpoints

The primary endpoints of the study were:

- Improve area under the ROC curve for 2D plus 3D imaging compared to 2D alone, and/or
- Reduced non-cancer recall rate for 2D plus 3D imaging compared to 2D alone

Methods

A random selection of 312 image sets (48 cancers, 48 benign, 75 negatives, 141 recalls) from the eligible subjects were entered into an enriched reader study, where these images were reviewed by twelve board certified radiologists with varying degrees of mammography experience, who were blinded to the details of the patient histories. Readers were trained in the review of 3D images using an independent set of training images prior to reading the study images.

The 2D images were read first and scored with initial BIRADS, forced BIRADS, and probability of malignancy metrics. The same subject's 3D images were then read and together with the 2D images scored with initial BIRADS, forced BIRADS, and probability of malignancy metrics. No prior films or images were used for a comparative analysis, and readers were not allowed to alter the 2D image score after they had seen the 3D images.

Results

- The ROC endpoint was met. For all readers, the ROC area under the curve (AUC) was superior with 2D plus 3D imaging compared with 2D alone. The average increase in the ROC area under the curve was 0.071 (95% confidence interval: 0.034 to 0.11) for the BIRADS ROC analysis and 0.072 (95% CI: 0.036 to 0.11) for the probability of malignancy ROC analysis. The null hypothesis was rejected as the gains in ROC AUC were highly significant with a p-value of 0.0004 for the BIRADS ROC analysis and 0.0001 for the probability of malignancy ROC analysis.
- The recall endpoint was met with an average reduction in the screening recall rate from 51.5% (95% CI: 41% to 61%) for 2D alone to 12.9% (95% CI: 8.9% to 17%) for 2D plus 3D. This difference was highly significant for all 12 readers with all p-values being 0.0001 or less.

The recall rate went down for each case type (benign, negative, cancer, and recall). With one exception, all readers showed significantly reduced recall rates in all of the non-cancer cases (benign, negative, and recall).

For screening cases, the recall rate went from 51.5% with 2D to 12.9% with 2D plus 3D. If the benign biopsy cases are included in the analysis, the recall rate reduction was slightly less with the rate going from 55.1% (95% CI: 48% to 66%) to 16.7% (95% CI: 13% to 23%). These differences were highly significant for all readers and exceeded the endpoint goal of achieving a 20% reduction in recall rates for screening cases. All readers showed a reduction in recall rate when using 2D plus 3D imaging compared to 2D alone. The differences in recall rates in screening cases were highly significant for all readers.

There was also a significant reduction in the recall rate for cancer patients for 4 of the 12 readers. The average decrease was from 87.2% (95% CI: 81% to 94%) for 2D alone to 80.4% (95% CI: 71% to 89%) when using 2D plus 3D (N=48). For the cancer patients, the recall rate increased for three of the twelve readers, stayed the same for one reader, and non-significantly decreased for the remaining four readers.

- A secondary analysis of sensitivity and specificity was performed based on the forced BIRADS scores. When taking BIRADS 4 or 5 as positive, the sensitivity increased from 65.5% (95% CI: 54% to 78%) for 2D alone to 76.2% (95% CI: 67% to 85%) for 2D plus 3D. The specificity increased from 84.1% (95% CI: 80% to 90%) for 2D alone to 89.2% (95% CI: 84% to 92%) for 2D plus 3D.

Conclusion Summary for Reader Study 1

All study endpoints were met. Tomosynthesis used as an adjunct to conventional 2D FFDM produced large and highly significant gains in radiologists' performance as measured by the ROC curves. The area under the ROC curves was higher for every reader using both methods of scoring (FB and POM). In addition, the recall rates were significantly lower.

C. Reader Study 2 Summary

Objectives

Reader Study 2 was primarily conducted to investigate a finding from Reader Study 1. In Reader Study 1, the scoring was patient-based so that either the case was recalled or it was not; thus, it was not possible to determine if the actual cancer lesion had been identified by the reader for recall. In Reader Study 2, both patient-based scoring and lesion-based scoring was performed. For lesion-based scoring, the readers had to identify the correct breast location and lesion type.

Reader Study 2 also was conducted to investigate if using only one bilateral view of 3D imaging (MLO view) with 2D imaging (2D plus 3D MLO) would provide a significant improvement in recall rate and/or ROC performance as compared to 2D imaging alone (2D). This would allow for a lower dose 2D plus 3D MLO screening exam as compared to using 2D and two bilateral 3D mammography views (MLO and CC).

Reader Study 2 also addressed concerns with the impact of 2D plus 3D on the recall rate of cancer patients. Reader Study 2 used new readers and a new random selection of non-cancer cases. Reader Study 2 reused the cancer cases from Reader Study 1 with the addition of three more cancers.

Study Endpoints

The study was designed to detect a statistically significant difference in the imaging methods by comparing the recall rates and the ROC area under the curve using multi-reader multi-case analysis.

- Improved Area under the ROC curve and/or
- Reduced recall rate

The following comparisons were performed:

- a) 2D versus 2D plus 3D MLO**
- b) 2D versus 2D plus 3D**
- c) 2D plus 3D MLO versus 2D plus 3D**

Methods

A random selection of 310 image sets (51 cancers, 47 benign, 74 negatives, 138 recalls) from the eligible subjects were entered into this reader study, these images were reviewed by fifteen board certified radiologists with varying degrees of mammography experience, who were blinded to the details of the patient histories. None of the fifteen radiologists had participated in Reader Study 1.

The training of the radiologists for Reader Study 2 was revised based on the lessons learned during the previous study. In Reader Study 1, the readers were trained not to dismiss lobulated masses even if they were circumscribed; however, based upon review of the dismissed cancer cases approximately half of the readers did not adhere to that training. In Reader Study 2, the readers were again trained not to dismiss lobulated circumscribed masses and their training was reinforced in written format.

The reader study consisted of first reading a subject's 2D images, then the 2D images with the Tomosynthesis 3D mediolateral oblique (MLO) images and finally reading the 2D images and both the 3D craniocaudal (CC) and 3D (MLO) images. The scoring for each reading consisted of marking the breast location and lesion type (calcification, mass/architectural distortion or asymmetry) for up to 3 lesions. Only lesions that would result in a recall were scored. Following the lesion scoring, the case was scored as either a recall, negative, or benign. Finally, a forced BIRADS score and probability of malignancy score were recorded. No prior films or images were utilized for a comparative analysis.

Statistical analyses were performed to calculate the performance of 2D imaging, 2D plus 3D MLO imaging, and 2D plus 3D imaging, as measured by areas under the ROC curves and recall rates.

Results

All of the study endpoints were met.

- The ROC analysis demonstrated that 2D plus 3D images provide significantly improved clinical performance compared to 2D plus 3D MLO and 2D alone. The 2D plus 3D MLO method was superior to 2D alone and inferior to 2D plus 3D. Similar results were seen for both the BIRADS and probability of malignancy ROC analyses.

The 2D plus 3D mode was superior to 2D alone. For the probability of malignancy analysis, the ROC AUC improved by 0.068 (95% CI 0.041 to 0.095) with a p-value < 0.0001. All 15 radiologists had a higher AUC using 2D plus 3D compared to 2D images alone.

The 2D plus 3D MLO mode was also superior to 2D alone. For the probability of malignancy analysis, the ROC AUC improved by 0.036 (95% CI 0.009 to 0.063) with a p-value of 0.0087. All 15 radiologists had a higher AUC using 2D plus 3D MLO compared to 2D alone. Based on the ROC analysis, 2D plus 3D MLO images provide a lower dose option for using tomosynthesis images with 2D images than using 2D plus 3D, however, the best performance is achieved when using all of the 3D views (2D plus 3D).

The multi-reader and multi-case analysis of variance used to determine the p-values were performed by an independent statistician using the ROC analysis software (DBM MRMC 2.2)¹. The analysis of variance was performed by treating both the

¹ DBM MRMC 2.2, available from <http://perception.radiology.uiowa.edu>

readers and cases as random samples. The curve fitting methodology was proper normal (PROPROC).

- The average screening recall rates were 44.2% for 2D alone, 27.2% for 2D plus 3D MLO, and 24.0% for 2D plus 3D. The average non-cancer recall rates were 48.8% for 2D, 32.7% for 2D plus 3D MLO, and 30.1% for 2D plus 3D. The differences in recall rates between 2D plus 3D MLO and 2D alone were significant for all readers. The differences in recall rates between 2D plus 3D and 2D alone were significant for all readers. Comparing the two tomosynthesis methods, the 2D plus 3D recall rates were significantly lower than 2D plus 3D MLO for 6 readers for the screening and 5 readers for the non-cancer recall rates.

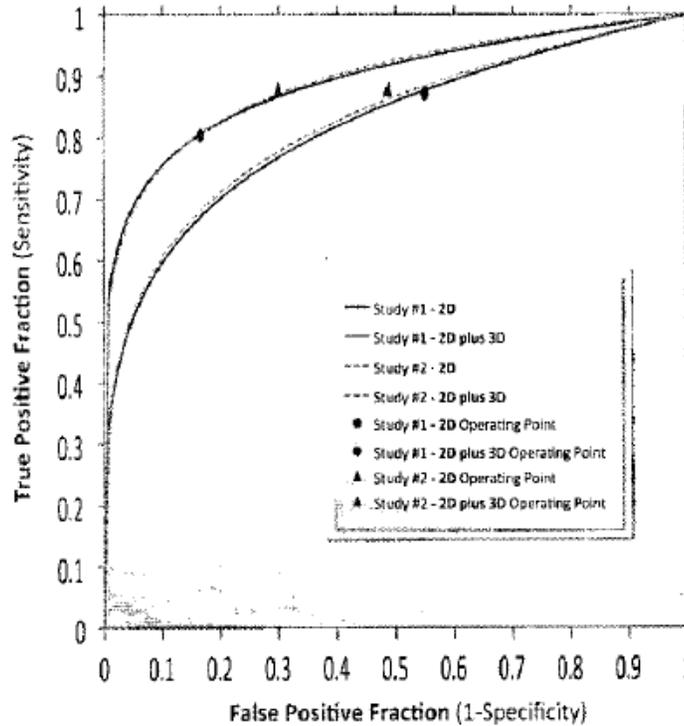
The 2D recall rates in the negative category were relatively high, possibly because of the highly enriched case set and because prior images were not provided for comparison. All readers had a statistically significant reduction in non-cancer recall rates for 2D plus 3D compared to 2D alone.

After Reader Study 1, it was hypothesized that some cancer recalls with 2D images may have resulted from features other than the cancer. For Reader Study 2, the radiologists were asked to mark the lesion location (right or left breast) and the lesion type. The lesion type was considered correct if the reader was able to correctly classify the lesion as calcification versus non-calcification (mass, architectural distortion or asymmetry). Since radiologists looking at the same lesion may call it either a mass, architectural distortion, or asymmetry, these lesion types were grouped together as non-calcification lesions. Therefore, the lesion type was considered correct if a radiologist called any non-calcification lesion either a mass, architectural distortion, or an asymmetry. If a cancer presented with both calcifications and a mass, any lesion type would have been considered a correct lesion type. When correct lesion type and breast location was required, the cancer recall rates were 84.8% for 2D and 85.7% for 2D plus 3D. Although these differences are not significant, the recall rate with localization and lesion type information was highest with 2D plus 3D images.

The pooled ROC curves for all cases in shown in Figure 5.

Figure 5

ROC curves for Reader Study 1 and Reader Study 2 based on probability of malignancy. In both studies, the analysis shows a similar increase in ROC AUC with 2D plus 3D imaging. The recall rates for non-cancer and cancer cases (Operating Points) are shown for Reader Study 1 and Reader Study 2



Conclusion Summary for Reader Study 2

The study endpoints were met and the recall decision operating point provided a reduction in non-cancer recall rate without any change in cancer recall rate for 2D plus 3D (CC and MLO) as compared to 2D alone. 2D plus 3D MLO was shown to improve ROC area under the curve and reduce non-cancer recall rates compared to 2D alone. Therefore, using the 3D MLO images with 2D images provides a lower dose method of improving both ROC performance and non-cancer recall rates compared to using 2D alone. However, the best ROC and lowest recall rate performance was achieved with the use of 2D plus 3D (CC and MLO) images.

D. Conclusion Summary for Reader Study 1 and Reader Study 2

Two key pivotal reader studies were conducted and successfully concluded. The ROC curves for the two studies are almost identical. The operating point measures demonstrate the tradeoff expected from the ROC analysis and suggest the importance of training to help readers find their optimal operating point on the ROC curve. 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.

In these reader studies, there is an inherent inclusion bias against 3D with respect to cancer detection. Nearly all of the cancers included in the reader studies entered the study because they were originally detected on 2D images as part of the standard 2D screening workups. Therefore, it is difficult to show in a reader study enriched with 2D-detected cancers a significant improvement in 2D plus 3D compared to 2D alone. In a clinical screening setting, 2D plus 3D would be expected to detect more cancers given its demonstrated superior ROC performance.

In Reader Study 1, the 2D plus 3D cancer recall rate was less than the 2D only cancer recall rate and the 2D plus 3D non-cancer recall rate was very much less than the 2D non-cancer recall rate. There was only patient based scoring data, but no lesion based scoring data available in Reader Study 1. In Reader Study 2, lesion-based data was available and more realistic training based on the improved lesion margin visibility was used. In this study, the cancer recall rate was equal to or better in 2D plus 3D, but the improvement in non-cancer recall rate, although still highly significant, was not as large as in Reader Study 1.

Additional Analysis

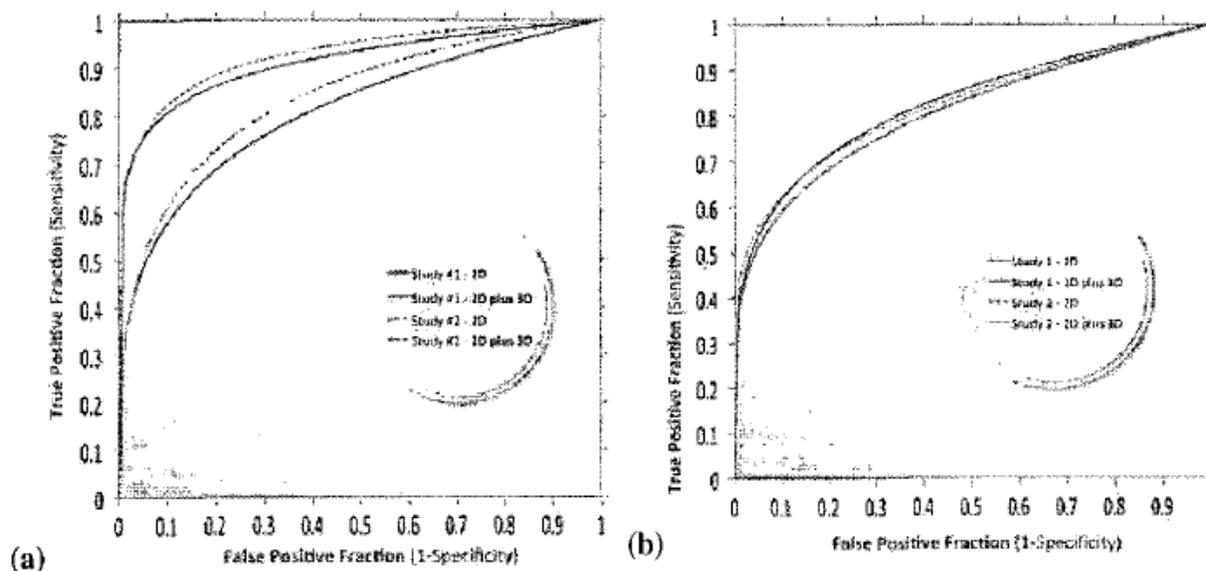
Calcification and Non-Calcification Analysis

An additional ROC curve analysis based on the probability of malignancy scores was performed on all cases following their grouping into calcification or non-calcification sub-groups. There were 83 calcification and 229 non-calcification cases in Reader Study 1. In Reader Study 2 there were 79 calcification cases and 231 non-calcification cases. For calcification cases, the average increase in the area under the ROC curve for 2D plus 3D versus 2D alone was 0.035 with a p-value of 0.073 for Reader Study 1. The AUC difference for Reader Study 2 was 0.014 with a p-value of 0.082. Although the AUC was higher for 2D plus 3D in both reader studies these differences were not statistically significant.

For non-calcification cases the average increase in the AUC for 2D plus 3D versus 2D alone was 0.101 with a p-value of 0.0008 for Reader Study 1. The AUC difference in Reader Study 2 was 0.088 with a p-value of <0.0001. Thus for non-calcification cases the gain in AUC was large and statistically significant in both reader studies. The pooled ROC curves for non-calcification cases and calcification cases are shown in Figure 6.

Figure 6

Pooled ROC curves from Reader Study 1 and Reader Study 2 for (a) non-calcification and (b) calcifications. The gains in ROC AUC for calcifications were not significant while those for non-calcification cases were highly significant in both Reader Study 1 and Reader Study 2.



Dense and Fatty Breast Analysis

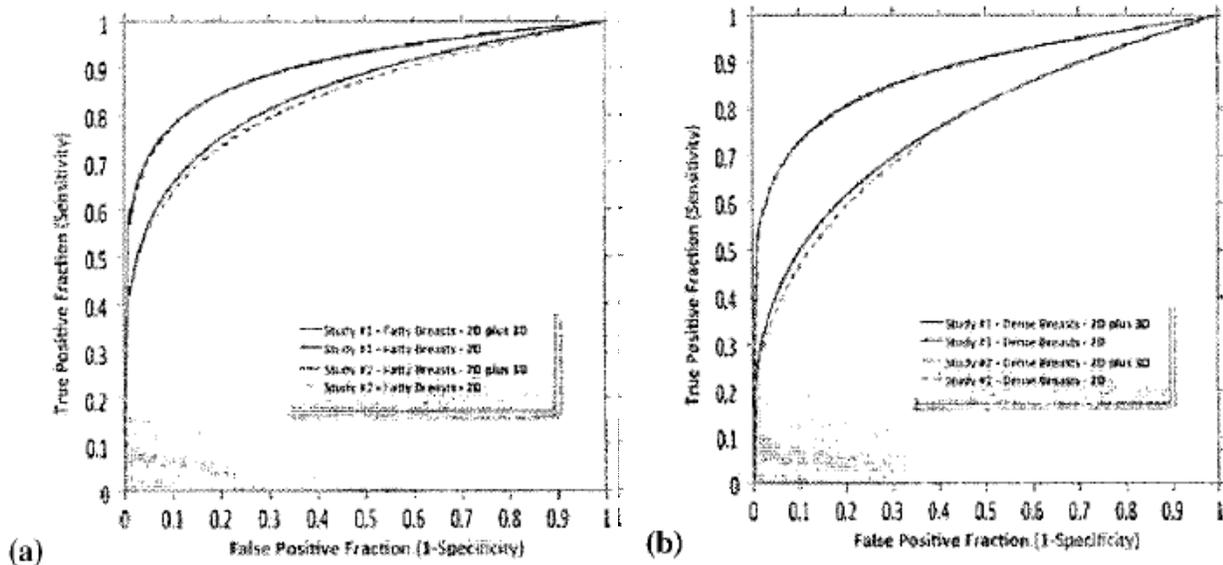
An additional analysis was performed on all cases following their grouping into fatty breast and dense breast sub-groups. Fatty breasts were defined as BIRADS density 1 and 2 and dense breasts were defined as BIRADS density 3 and 4. The classification of breast density was based on the 2D image density scores.

In Reader Study 1, the increase in the AUC for 2D plus 3D compared to 2D alone for dense breasts was 0.103 (p-value 0.001), for fatty breasts the increase was 0.053 (p-value 0.028). In Reader Study 2, the increase in the AUC for 2D plus 3D compared to 2D alone for dense breasts was 0.091 (p-value <0.0001), for fatty breasts the increase was 0.035 (p-value 0.0008). The AUC difference was significant for both the dense breast and fatty breast groups. The pooled ROC curves for fatty and dense breasts are shown in Figure 7.

In Reader Study 1, The recall rate in non-cancer cases for fatty breasts was 55.8% for 2D alone, 15.4% for 2D plus 3D. In dense breasts the recall rate was 54.2% for 2D alone, and 18.3% for 2D plus 3D. In Reader Study 2, the recall rate in non-cancer cases for fatty breasts was 47.7% for 2D alone and 27.0% for 2D plus 3D. In dense breasts the recall rate was 49.9% for 2D alone and 33.1% for 2D plus 3D. The recall rate reductions were large and significant in both dense and fatty breasts.

Figure 7

ROC curves from Reader Study 1 and Reader Study 2 for (a) fatty breasts (BIRADS 1,2) and (b) dense breasts (BIRADS 3,4).



X. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL STUDIES

The results of the image quality and clinical studies described above demonstrate the safety and effectiveness of the Hologic Selenia Dimensions 3D System for screening and diagnostic breast imaging. It is difficult to estimate the clinical risk to benefit ratio from an enriched, retrospective study. The benefit is difficult to quantify but would be related to a decrease in the screening recall rate and a possible increase in earlier cancer detection. The analysis of the increased risk from the radiation is based on a large number of assumptions, which results in a high degree of uncertainty. However, the benefit of the 2D plus 3D is expected to greatly outweigh the potential risks.

The results of the non-clinical and clinical studies support FDA approval of the Hologic Selenia Dimensions 3D System for clinical use in screening and diagnostic mammography.

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTIONS

The Radiological Devices Panel met on September 24, 2010, to discuss, make recommendations and vote on the safety, effectiveness, and risk versus benefit of the Selenia Dimensions 3D System.

The panel discussed clinical data from three multi-reader multi-case (MRMC) studies that compared 2D FFDM alone to 2D FFDM plus 3D DBT. Hologic performed two of

the studies (Reader Study 1 and Reader Study 2) and the third study was independently performed by the University of Pittsburgh².

The panel had initial concerns regarding the MQSA regulations for mammography devices, the sponsor's responsibility for tomosynthesis training, and the potential impact of the new device on the clinical workflow. During the panel deliberations and the FDA question period, the panel arrived at the following general consensus:

1. The design of the reader studies did not raise significant issues for the evaluation of the new 3D tomosynthesis device.
2. The data from Reader Study 2 supported that 2D FFDM plus 3D DBT can reduce the screening recall rate without the loss of cancer patients.
3. Hologic should provide training based on the lessons learned from the reader studies, to all facilities purchasing the 3D DBT unit.
4. The results of Reader Study 1 and Reader Study 2 support the clinical use of 2D FFDM plus 3D DBT for screening and diagnosis. 2D FFDM plus a single DBT view (3D MLO) could be another exam option, but the full 2-view DBT protocol (MLO and CC) would be recommended.

The Panel voted (12-0-0) {yes, no, abstain} that there a reasonable assurance that the Selenia Dimensions 3D System is safe for its intended use in the same clinical applications as traditional screen-film mammographic systems.

The panel voted (12-0-0) there a reasonable assurance that the Selenia Dimensions 3D System is effective for its intended use in the same clinical applications as traditional screen-film mammographic systems.

The panel voted (11-0-1) that the benefits of the Selenia Dimensions 3D System's intended use, in the same clinical applications as traditional screen-film mammographic systems, outweigh the risks of the Selenia Dimensions 3D System's intended use, for the same clinical applications as traditional screen-film mammographic systems.

The Radiological Panel meeting materials are available at:

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/RadiologicalDevicesPanel/ucm226660.htm>

² Gur, et al. Digital Breast Tomosynthesis: Observer Performance Study. AJR. 2009(193):586-591.

<http://www.ajronline.org/cgi/content/abstract/193/2/586>

Note: The Pittsburgh research study is relevant to the discussion, but the study was not designed or intended for the FDA review in this PMA submission. The authors acknowledge support from Hologic for funding on other studies and cases.

XII. CDRH DECISION

CDRH issued an approval order on February 11, 2011. The device manufacturing facilities were inspected and were found to be in compliance with the Quality System Regulation (21 CFR 820).

XIII. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling. Post-approval Requirements and Restrictions: See approval order.

XIV. REFERENCES

1. DBM MRMC 2.2, available from <http://perception.radiology.uiowa.edu>.
2. Gur, et al. Digital Breast Tomosynthesis: Observer Performance Study. AJR. 2009(193):586-591. <http://www.ajronline.org/cgi/content/abstract/193/2/586>.