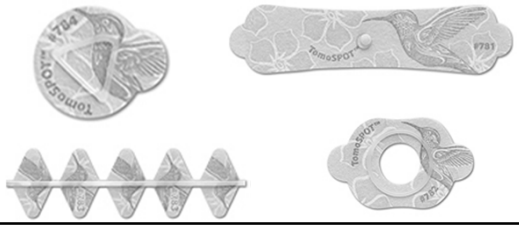
Hologic Digital Breast Tomosynthesis
GE Digital Breast Tomosynthesis
Siemens Digital Breast Tomosynthesis
Fujifilm Digital Breast Tomosynthesis

Hologic Dimensions 2/2011
GE Senoclaire 8/2014
Siemens 4/2015
Fujifilm 1/2017
GE Pristina 3/2017
Hologic Genius 6/2017

Tested and proven for 3D breast tomosynthesis, TomoSPOT® skin markers provide clear visualization with the least potential for "slinky" artifact compared to other mammography skin markers. Combining tomosynthesis with a TomoSPOT® skin marking protocol supports your efforts to achieve a lowest possible recall rate, higher specificity, and has been proven to reduce radiologist reading time on average by 1.34 minutes per case.*



BEST IN KLAS® 2011

Mammography

- Screening
  - Pt. asymptomatic
  - Standard 4 views
  - Annual exam age 40 and over
  - Earlier in high risk women
    - Begin 10 years earlier than youngest relative's age at diagnosis
- Diagnostic
  - Pt. with clinical signs or symptoms or abnormality detected on screening
  - Standard views + special (e.g. spot or magnification) views +/- ultrasound
- Analog (screen/film) vs. Digital

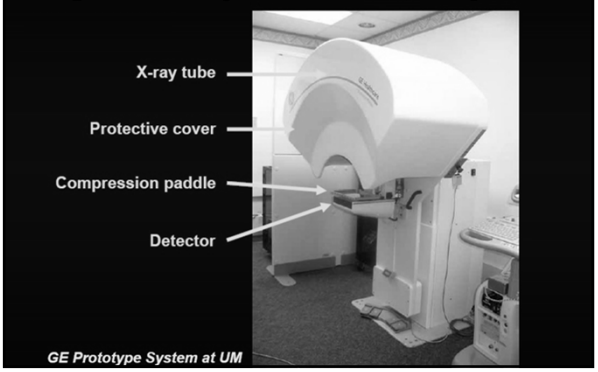
How Will Tomosynthesis Be Used?

- Radiologists may customize the use of breast tomosynthesis to their practice- or patient-specific needs.
- Potential uses include:
  - Screening
    - General population
    - Targeted populations such as high risk or women with dense breasts
  - Diagnostic
    - As supplement to the standard 2D diagnostic imaging procedures
  - Other uses established by radiologists for specific needs.

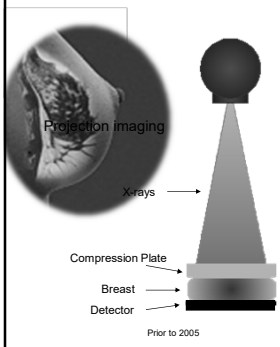
Digital Mammography

- Screen/Film replaced by detectors which produce an electronic signal that is digitized
- Wide exposure latitude and better soft tissue contrast
- Digital enhancement/analysis
- Filmless environment
- Telemammography

Digital Tomosynthesis Mammo System



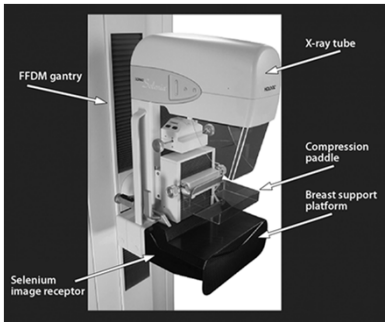
Digital tomosynthesis first reported in 2005



Until 02/11/2011 , all mammography images were captured in 2D mode, relying upon a select number of views to assess tissue structure in the breast. While serving as the gold standard for breast cancer screening and diagnosis, 2D mammography (either film or digital) is challenged by the superimposition of tissue, which can mask suspicious areas, and thus, requires follow-up by other imaging modalities or biopsy. With 3D breast tomosynthesis, a series of thin-resolution images are acquired and aggregated to generate a 3D image of the breast, further allowing the radiologist to scroll through sub-millimeter cross-sections, effectively eliminating the tissue superimposition problem. Tomosynthesis has been available in Europe and other countries recognizing the CE mark since 2008.

- Lets look behind the scenes of how it came to be.
- Looking at a stand point other than a technologist view.
- We only see the end result of many trials and tears.
- So here we go……

—Photograph of prototype tomosynthesis unit (Genesis, Hologic).



Poplack S P et al. AJR 2007;189:616-623

The angle arch was 28° with 11 projections

AJR

FDA Executive Summary

Meeting of the **Radiological Devices Advisory Panel**
On September 24, 2010 they made recommendations and voted on a pre-market approval (PMA) application for the Selenia Dimensions 3D* digital breast tomosynthesis
(DBT) system (P080003), sponsored by Hologic, Inc. The Selenia Dimensions 3D system is intended for use in the same clinical applications as 2D full field digital mammography (FFDM). The screening examination is intended to consist of a 2D FFDM image set plus a 3D DBT image set.

Federal Notice
http://edocket.access.qpo.gov/2010/2010-18416.htm
Panel Date and Location
September 24, 2010 from 8 AM to 6 PM
Hilton Washington DC North/Gaithersburg
620 Perry Pkwy., Gaithersburg, MD 20877

What is difference in I, II, III Medical Devices

- Class I: General Controls examples bandages, hand held surgical instruments
- Class II: General controls with special controls examples powered wheelchairs, infusion pumps
- Class III: General controls and premarket approval; examples pacemakers, breast implants, endosseous implants

Hologic conducted two reader studies using images from the initial clinical trial data set. The reader
study results were analyzed using Receiver Operating
Characteristics (ROC) methodology, with the area under
the curve measuring the ability of individual radiologists
(readers) to correctly characterize the presence or absence of
disease in subjects in a study population.

Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is normally longer. Before approving or denying a PMA, the appropriate FDA advisory committee may review the PMA at a public meeting and provide FDA with the committee's recommendation on whether FDA should approve the submission. After FDA notifies the applicant that the PMA has been approved or denied, a notice is published on the Internet (1) announcing the data on which the decision is based, and (2) providing interested persons an opportunity to petition FDA within 30 days for reconsideration of the decision

Reader Study

Reader Study 1 was the pivotal study of the PMA(Pre market approval). Hologic submitted Reader Study 2 and the Pittsburg study in response to deficiencies from the FDA.

Table 1: Summary of the 2D/3D notation used in the executive study. "2D alone" refers to a set of conventional 2-view FFDM images; a cranio-caudal (CC) and mediolateral oblique (MLO) view for each breast. "2D plus 3D MLO" refers to the conventional 2D FFDM plus 1 MLO tomosynthesis view. "2D plus 3D" refers to conventional 2D FFDM plus 2 DBT views (MLO and CC).

Mode	Images	Reader Study 1	Reader Study 2	Pittsburgh Study
2D alone	2-view FFDM (MLO and CC)	Yes	Yes	Yes
2D plus 3D MLO	2-view FFDM (MLO and CC), and 1-view DBT (MLO)	-	Yes	-
2D plus 3D	2-view FFDM (MLO and CC), and 2-view DBT (MLO and CC)	Yes	Yes	Yes

Hologic conducted a large multi-center clinical trial comparing the performance of 2D digital mammography
plus tomo imaging (combo-mode) to that of 2D mammography alone in support of its FDA tomosynthesis
submission. Images were acquired from 5 clinical centers in the U.S. under an IRB(institutional review board)-approved protocol and informed patient consent.

Reader Study 1 was the pivotal study of the PMA. Hologic submitted Reader Study 2 and the
Pittsburgh study in response to deficiencies from FDA. In particular, the results of Reader Study
2 were provided to support a lower dose tomosynthesis protocol (i.e., 2D plus 3D MLO) as well
as address concerns with the reader scoring methodology (i.e., identification of the correct
location of a malignant lesion was not required for crediting readers with a true positive result)
and 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.

Reader Study

A. Study design
Because a prospective study is prohibitive due to low prevalence of cancer, retrospective studies were conducted that were enriched with cancer cases.

The studies conducted have the following limitations, which might affect the generalizability of the results to the intended population:

- Radiologists are reading images knowing that their readings do not affect patient management;
- Radiologists are scoring the image without the use of prior images or clinical history;
- Enrichment with recalls and cancer cases that were identified based on standard imaging, including FFDM, may bias the study against 3D relative to 2D FFDM;

Reader Study

The primary objective for recall rate was to show a significant reduction in the recall rate among the screening cases.

In Reader Study 1, the average recall rate for screening cases went from 51.5% with 2D to 12.9% with 2D plus 3D, and in Reader Study 2, the average recall rate for screening cases went from 44.2% with 2D to 24.0% with 2D plus 3D.

In Reader Study 1, the average recall rate of *cancer* patients also decreased (from 87.2% to 80.4%); the decrease in the recall rate of cancer patients was significant for 4 of 12 readers.

In Reader Study 2, the recall rate of cancer patients remained the same, at 88%, on average across readers.

Reader Study

- Radiologists know or will learn that the case set is highly enriched with cancer cases;
- Making multiple readings successively in different modes (sequential reading) potentially confounds modality effects with the effects of having additional reading time;
- Ground truth (information collected) is not established definitely for normal cases (BIRADS=0) because they were not followed up to confirm that they did not have cancer.

In addition, prior to the second Hologic study (Reader Study 2), the training was enhanced based on the types of errors made during Reader Study 1; this also raises concern as the same cancer cases were used in both studies.

Reader Studies

In both studies, the performance of 2D mammography plus tomo was shown to be significantly superior to the performance of 2D alone, as demonstrated by an improved area under the ROC curve. In addition, both studies showed a reduced non-cancer recall rate.

Reader Study

B. Screening claim
In both Reader Study 1 and Reader Study 2, use of 2D FFDM plus 3D DBT significantly increased the area under *the* ROC curve (AUC) and significantly decreased the recall rate of non-cancer patients.

In Reader Study 1, the model-based AUC estimate increased from 0.821 for 2D to 0.894 for 2D plus 3D for a difference of 0.072 (p-value 0.0001).
In Reader Study 2, the model-based AUC estimate increased from 0.828 for 2D to 0.895 for 2D plus 3D for a difference of 0.068 (p-value < 0.0001).

AUC-Accuracy is measured in the area under the ROC curve
ROC-Receiver Operating Characteristic-plot test graft of sensitivity
P-value-measures consistency between results actually obtained in a study

These results were consistent with those of an independent third reader study from University of Pittsburgh researchers who found a 7% improvement in the area under the ROC curve for 2D plus tomo compared to 2D alone.3 The FDA advisory panel considered all three reader studies in their unanimous vote that Hologic's application demonstrated both the effectiveness and safety
of tomosynthesis.

Reader Study

C. Diagnostic claim
In addition to the primary endpoints, the sponsor provided a "Forced BIRADS" task based comparison of using 2D alone with using 2D plus 3D tomosynthesis in order to support the intended use of the device for "screening and diagnosis".

FDA would like the panel to consider whether there is sufficient data to support 3D tomosynthesis for use as another exam option in the diagnostic setting (i.e., the "...and diagnosis" part of the intended use).

Forced BIRADS-a BIRADS score of 1-5 which the reader must give if they had given the case an initial BIRADS score of 0. The score is based solely on the mammogram images presented to the reader and not the actual results of any additional work-up that may have been preformed pertaining to that specific case.

Reader Study 1

The study was designed to have a minimum of 10 readers reading all cases, a minimum of 75 recall screening cases, and a minimum of 50 cancer cases. The study included fourteen readers, but only the results of the 12 radiologists who successfully completed all of the reader training requirements were included in the analysis.

The reader scores were used to perform three main analyses:
1) ROC area under the curve (AUC), based on the probability of malignancy (POM);

2) Recall, based on the reader scores of BIRADS (0,1,2); and

3) Sensitivity and specificity based on the "Forced BIRADS" scores.

AUC-Accuracy is measured in the area under the ROC curve
ROC-Receiver Operating Characteristic-plot of test sensitivity

A. Reader Study 1 (Pivotal Study) **Truth=information collected**

i. Study Design

OBJECTIVE	To compare the clinical performance of conventional 2D FFDM plus 3D tomosynthesis images to those of 2D FFDM images alone.
PATIENT POPULATION	1192 Subjects from 5 clinical US centers; subjects were from either a screening group or a biopsy group.
IMAGING	2-view 2D FFDM (MLO and CC) 2-view 3D DBT (MLO and CC)
GROUND TRUTH	Two different radiologists classified each image to one of the following four categories: 1. Negatives: Scored BIRADS 1 or 2 by both the 2D site reader and the 3D site reader; truth was based on a negative independent double reading. 2. Recalls: Screening cases recalled (BIRADS=0) by either the 2D or 3D site reader. Each patient was followed to determine the outcome of the additional imaging or biopsy. Truth was determined from the imaging results unless a biopsy was performed. If a biopsy was done, the pathology results were used to determine the truth. 3. Benign: Biopsy cases where pathology/histology demonstrated a benign lesion. 4. Cancers: Biopsy cases where pathology/histology demonstrated a cancer.
STUDY DATA	75 Negatives 141 Recalls (does not include cancer patients) 48 Benign 48 Cancers Of the original 1192 subjects, 1083 subjects were eligible to be randomized into the reader study. 316 were randomized into the study, but 4 cases were excluded for the presence of radio opaque markers on the images found during the image review. The final dataset consisted of 312/1083 (28.8%) subjects, 222/856 (25.9%) subjects from the Screening Group and 90/227 (39.7%) subjects from the Biopsy Group. All pathology proven cancers that had complete data and passed the quality control review were included. Negative, benign and recall (non-cancer) cases were randomly selected.

Reader Study 1

The primary study objectives were to show a 20% decrease in recall rate among the screening cases and a 0.05 increase in area under the ROC curve (AUC-area under curve) using all cases either based on a probability of malignancy scale (1-100) or a forced BIRADs scale (initial BIRADS 0 score in recall analysis forced to BIRADs 1-5).

After the study was completed and the PMA submitted, the study objectives were clarified in a subsequent meeting with FDA on August 25th, 2008, and in the sponsor's responses to FDA deficiencies.

The success criteria were actually to show any statistically significant improvement in AUC and any statistically significant improvement in recall rate among the screening cases.

PMA – pre market approval

AUC-Accuracy is measured in the area under the ROC curve
ROC-Receiver Operating Characteristic-plot of test sensitivity

READERS	14 Radiologists participated in the reader study. Only the results of the 12 radiologists who successfully completed the reader training were included in the analysis. The 12 readers, included: 5 highly experienced, 2 experienced, and 5 less experienced radiologists.
IMAGE SCORING	Readers were asked to provide the following information after reading the 2D images and then after reading both the 2D plus 3D images. 1. Probability of Malignancy (POM) score of 0 to 100 *(for ROC analysis)*; 2. Initial BIRADS score of 0,1, or 2 *(for recall analysis)*; and 3. Forced BIRADS score of 1, 2, 3, 4, or 5 when initial BIRADS score is 0 *(for sensitivity/specificity analysis)*

Reader Study 1

Study Population
Table 2 presents the distribution of calcification and non-calcification in the dataset. The distribution of breast density (fatty or dense) of the cases in the study was not available at the time of writing.

Table 2: Distribution of calcification and non-calcification for 308 of the 312 cases in the reader study.

Study	Case Type	Calcification	Non-Calcification	Total
Reader Study 1	Cancer	24	24	48
	Recall	31	108	139
	Benign	28	19	47
	Negative	0	74	74
	Total	83	225	308

Reader Study 1

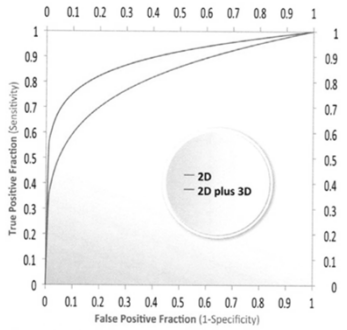


Figure 2: (Reader Study 1) ROC curves comparing reader performance with 2D alone to 2D plus 3D. 95% confidence intervals for the change in ROC AUC are presented in the text.

Reader Study 1

Table 4: Recall rates for Reader Study 1 (averaged over all readers); 95% confidence intervals calculated by FDA.

Study	Mode	Cancer Recall Rate (N=48)	Non-Cancer Recall Rate (N=264)	Screening Cases, Recall Rate†
Reader Study 1	2D	87.2% (81%, 94%)	55.1% (48%, 66%)	51.5% (41%, 61%)
	2D plus 3D	80.4% (71%, 89%)	16.7% (13%, 23%)	12.9% (8.9%, 17%)

†Primary analysis objective

Sensitivity(Is it there)(True positive)
The sensitivity of a test refers to how many cases of a disease a particular test can find. A very sensitive test is likely to give a fair number of false-positive results, but almost no true positives will be missed. In mammography sensitivity is the probability of finding a cancer when the cancer exist. Diagnosing a patient correctly.

Specificity (what is it)(True Negative)
The specificity of a test refers to how accurately it diagnoses a particular disease without giving false-positive results. In mammography the probability of a normal mammogram when no cancer exist.

Reader Study 2

Hologic submitted Reader Study 2 in response to deficiencies from FDA.

In particular, the results of Reader Study 2 were provided to support a lower dose tomosynthesis protocol (i.e.,2D plus 3D MLO) as well as address concerns with the reader scoring methodology (i.e., identification of the correct location of a malignant lesion was not required for crediting readers with a true positive result) and 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.

DM vs DM plus DBT ("forced" BI-RADS 1-3=negative)

Assessing Radiologist Performance Using Combined Digital Mammography and Breast Tomosynthesis Compared with Digital Mammography Alone: Results of a Multicente Multireader Trial

Table 3
Diagnostic Sensitivity, Specificity, and Positive and Negative Predictive Values

Parameter	Reader Study 1			Reader Study 2		
	Digital Mammography	Mammography plus Tomosynthesis	Difference	Digital Mammography	Mammography plus Tomosynthesis	Difference
Sensitivity (%)	65.5	76.2	10.7	62.7	78.7	16.0
Specificity (%)	84.1	89.2	5.1	86.2	84.5	−1.7
Positive predictive value (%)	42.9	56.2	13.3	47.3	50.1	2.8
Negative predictive value (%)	93.0	95.4	2.4	92.1	95.3	3.2
Sensitivity for invasive cancers (%)	63.8	78.6	14.8	60.6	82.3	21.7
Sensitivity for in situ cancers (%)	68.8	71.4	2.6	67.5	70.8	3.3

Note.—Cases with BI-RADS scores of 4 and 5 were considered positive and cases with BI-RADS scores of 1, 2, and 3 were considered negative.

Sensitivity(%): 64 vs 77
Specificity(%): 85 vs 87

Rafferty et al Radiology Published online before print November 20, 2012, doi: 10.1148/radiol.12120674

Reader Study 2

i. Study Design

OBJECTIVE	*To investigate the potential of an alternative, lower dose option (2D plus 3D MLO); to include scoring for a lesion-based analysis.*
PATIENT POPULATION *(same as Reader Study 1)*	1192 Subjects from 5 clinical US centers; subjects were from either a screening group or a biopsy group.
IMAGING *(same as Reader Study 1)*	2-view 2D FFDM (MLO and CC) 2-view 3D DBT (MLO and CC)
GROUND TRUTH *(same as Reader Study 1)*	Two different radiologists classified each image to one of the following four categories: 1. Negatives: Scored BIRADS 1 or 2 by both the 2D site reader and the 3D site reader; truth was based on a negative independent double reading. 2. Recalls: Screening cases recalled (BIRADS=0) by either the 2D or 3D site reader. Each patient was followed to determine the outcome of the additional imaging or biopsy. Truth was determined from the imaging results unless a biopsy was performed. If a biopsy was done, the pathology results were used to determine the truth. 3. Benign: Biopsy cases where pathology/histology demonstrated a benign lesion. 4. Cancers: Biopsy cases where pathology/histology demonstrated a cancer.
STUDY DATA *(3 new cancers; new random selection of non-cancers cases)*	74 Negatives 138 Recalls (does not include cancer patients) 47 Benign 51 Cancers The 48 cancer cases used in Reader Study 1 were supplemented with 3 cancer cases for which the pathology reports had not previously been available. A new randomized selection of non-cancer cases was performed; 123/259 (47%) of the non-cancer cases were the same in Reader Study 1 and Reader Study 2.

Reader Study 2

READERS *(new radiologists, additional training)*	15 new radiologists (5 highly experienced, 6 experienced, and 4 less experienced). Readers received additional 3D training based on the types of errors made during Reader Study 1.
IMAGE SCORING *(addition of lesion based scoring, #4)*	Readers were asked to provide the following information after reviewing a full set of 2D images (CC and MLO), followed by the 2D plus 3D MLO images, followed by the full set of 2D plus 3D images. 1. Probability of Malignancy (POM) score of 0 to 100 *(for ROC analysis);* 2. Initial BIRADS score of 0,1, or 2 *(for recall analysis)*; and 3. Forced BIRADS score of 1, 2, 3, 4, or 5 *(for sensitivity/specificity analysis)* *4. Breast location and lesion type (calcification, mass/architectural distortion or asymmetry) for any lesion that would result in a recall (initial BIRADS 0)*

Reader Study 2

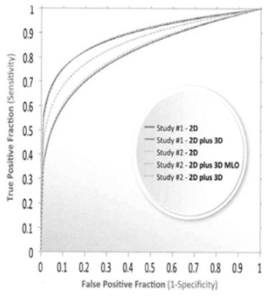


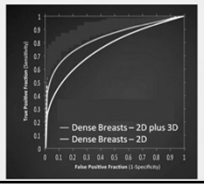
Figure 5: ROC curves for Reader Study 1 and Reader Study 2. In both studies, the ROC curves for the 2D alone and the 2D plus 3D modes are essentially the same. In Reader Study 2, the ROC curve for 2D plus 3D MLO is between the 2D alone and 2D plus 3D modes. 95% confidence intervals for the change in ROC AUC are presented in the text.

Reader Study 2

PRIMARY ENDPOINTS *(new 2D plus 3D MLO comparisons)*	(a) Improved ROC area under the curve (AUC) and/or (b) Reduced recall rate Comparisons: (a) 2D versus 2D plus 3D (b) 2D versus 2D plus 3D MLO (c) 2D plus 3D verses 2D plus 3D MLO

Performance in Dense Breasts

- Cases were divided into:
  - Fatty – BIRADS density 1 or 2
  - Dense – BIRADS density 3 or 4
- Tomo improved ROC performance in fatty breasts
- In dense breasts, ROC performance increase 3X that of fatty
- Tomo useful in fatty breasts, more useful in dense breasts



Reader Study 2

ROC Area under the curve (AUC)
The best reader performance was achieved when using 2D plus 3D (all views).

The lower dose 2D plus 3D MLO option was also superior to 2D alone.

The following are the results using the probability of malignancy scores; the BIRADS based change in ROC AUC is similar.

• The 2D plus 3D mode was superior to 2D alone; ROC AUC improved by 0.068 (95% CI0.041 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.

Reader Study 1 and 2 Recall Rate

Recall Rate

The screening recall rates were 44.2% for 2D alone, 27.2% for 2D plus 3D MLO and 24.0% 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.

There was a significant reduction in the recall rate (score BIRADS=0) for non-cancer patients when using 2D plus 3D (or 2D plus 3D MLO) compared to 2D alone. In Reader Study 2, the recall rate for cancer patients was 88.0% for both 2D plus 3D and 2D alone; for the 2D plus 3D MLO, the recall rate for cancer patients was lower at 84.2%. The results were similar with lesion-based scoring (i.e., when correct lesion type and location were required).

Table 11: Recall rate for Reader Study 1 and Reader Study 2; additional information to evaluate lesion-based scoring was collected in Reader Study 2.

Study	Scoring Method	Mode	Cancer Recall Rate	Non-Cancer Recall Rate	Screening Cases, Recall Rate
Reader Study 1	Patient-based	2D	87.2%	55.1%	51.5%
		2D plus 3D	80.4%	16.7%	12.9%
Reader Study 2	Patient-based	2D	88.0%	48.8%	44.2%
		2D plus 3D MLO	84.2%	32.7%	27.2%
		2D plus 3D	88.0%	30.1%	24.0%
	Lesion-based	2D	84.8%	48.8%	*
		2D plus 3D MLO	81.5%	32.7%	*
		2D plus 3D	85.7%	30.1%	*

*Not available at time of writing.

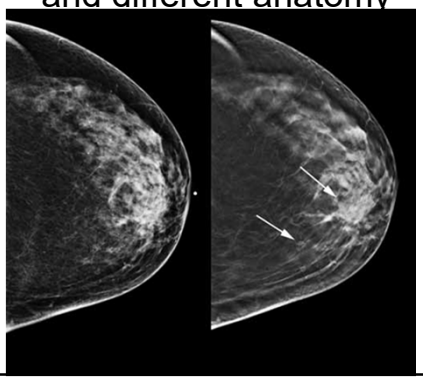
Technical Data Provided

Hologic provided experimentally measured data, including: sensitometry, spatial resolution as described by the modulation transfer function (MTF), and SNR transfer, as described by detective quantum efficiency (DQE).

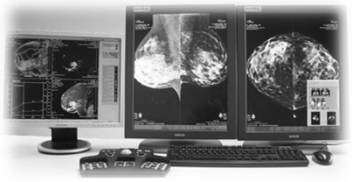
Hologic provided the results of imaging experiments using multiple phantoms, including the FDA approved ACR accreditation phantom and the CD-MAM Phantom (Contrast Detail Mammography).The sponsor used phantoms of thickness 2-6 cm to estimate the average glandular dose for exposures made with the Automatic Exposure Control (AEC) system with varying breast phantom compositions (i.e., 70/30, 50/50, and 30/70) of glandular and adipose tissue, respectively.

Hologic used the methodology described in "Contrast Detail Phantom Scoring Methodology", Thomas, Chakrabarti, Kaczmarek and Romanyukha, Med. Phys. Vol. 32,No. 3, p.807-814, 2005. The sponsor provided test information on both the prototype used for the clinical study and the Selenia Dimensions 3D system.

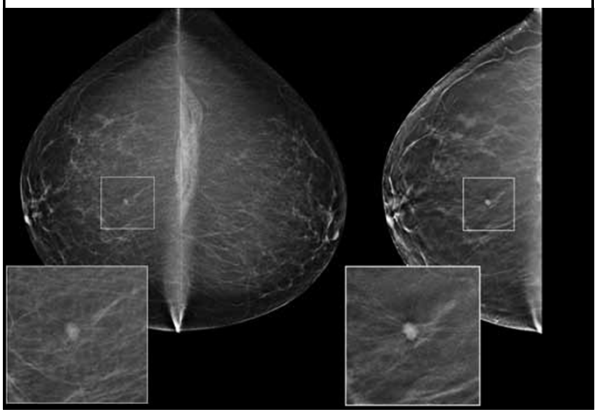
Examples of each breast type and different anatomy



Viewing Technical Data

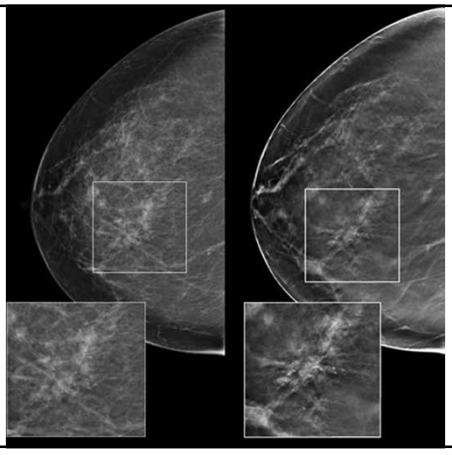


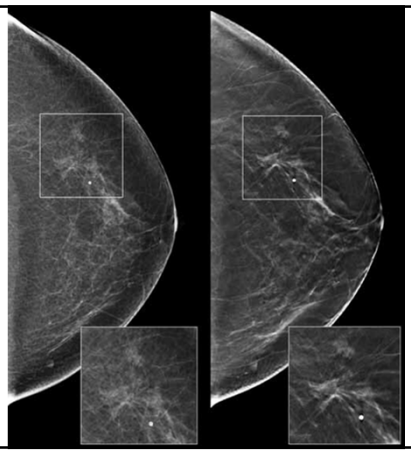
The Selenia Dimensions 3D PMA application does not include the display system or review workstation. There are no special hardware requirements for the workstation to support the review of tomosynthesis images beyond the current mammography requirements. Images can be reviewed on the Hologic's SecureView DX Diagnostic Workstation (K062107) and with hardcopy printers that are approved for mammography.



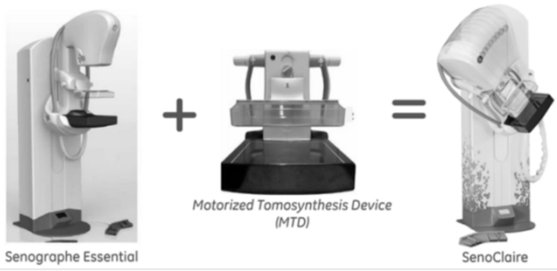
Potential Benefits for FFDM vs Tomo

- Reduce recall rate of patients by reducing confusion which arises from tissue overlap
- Biopsy rate decreased as there is improvement in separation and visualization of parenchyma structures
- Time will possibly show improvement in cancer detection particularly in patients with dense breast tissue
- Fewer images required for diagnosis=reduction in dose



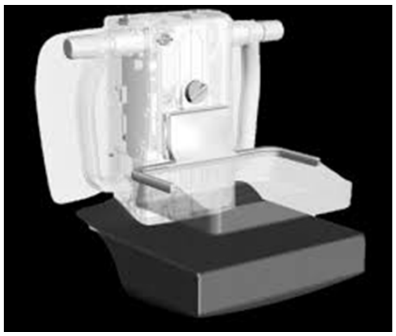


SenoClaire is an upgrade for Senographe Essential

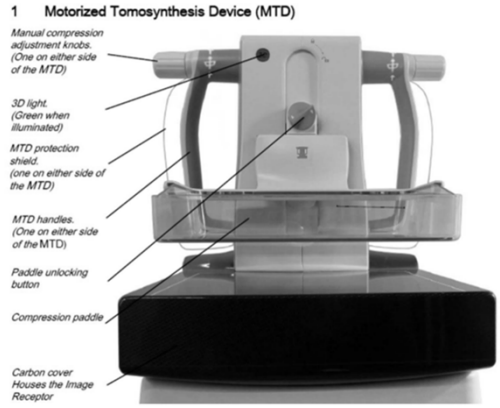


The Units…. Buckle your seatbelts





Lets look at GE Senographe Senoclaire first



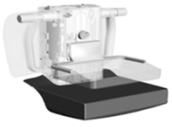
Installing the MTD

Scatter mgt: 2D/3D antiscatter grid (3/3)

Challenge: rotating the grid leaves very little space for the grid to move

Solution:

- match the grid line frequency to the detector pitch
- compact, high precision actuators driving small movements: piezoelectric transducers



Motorized Tomosynthesis Device

Baseplate without covers

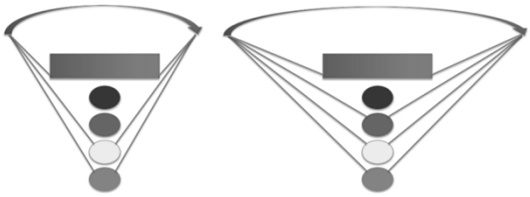
Close Up of Piezo Actuator

SenoClaire (GE Breast Tomosynthesis)

SenoClaire Key Features

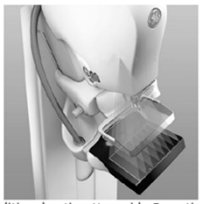
- 9 Projections
- Stop-and-shoot
- Sweep angle 25° (+/- 12.5)
- Sweep time <10 sec*
- Detector pixel size 100 um in 2D & 3D
- 2D/3D-grid for scatter reduction
- ASiR^{DBT} Iterative Reconstruction
- No dose increase (3D vs. 2D)
- BTO DICOM format
  (Breast Tomosynthesis Object)

Sweep angle

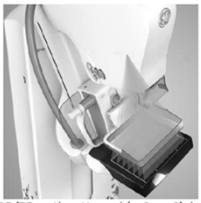


With a wider sweep angle you can separate closer objects

Imaging with the MTD

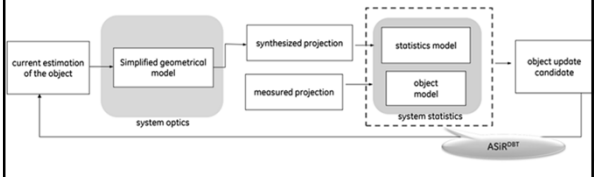


Traditional antiscatter grid - Essential
View of system positioned for a left MLO view

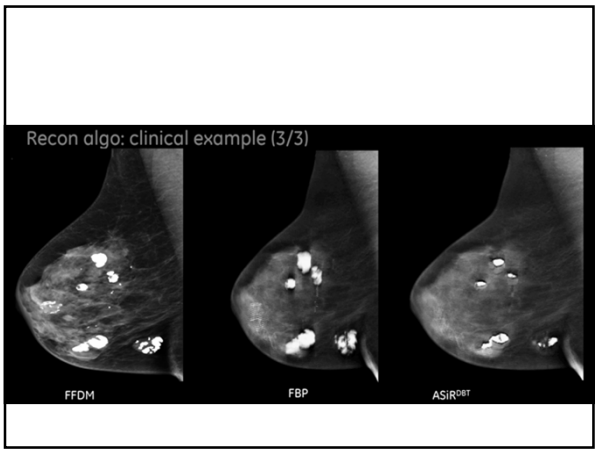


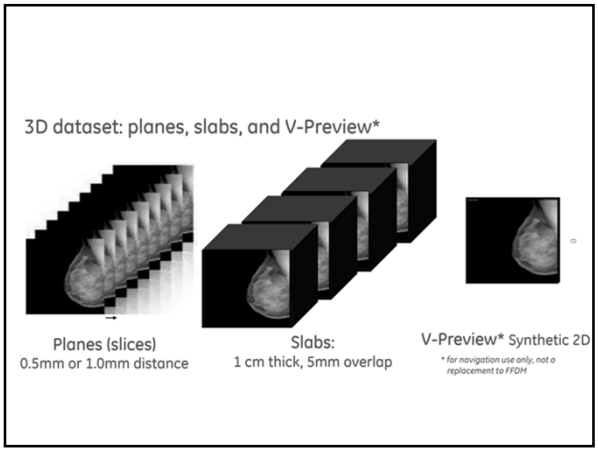
2D/3D antiscatter grid – SenoClaire's MTD
View of system positioned for a left MLO view

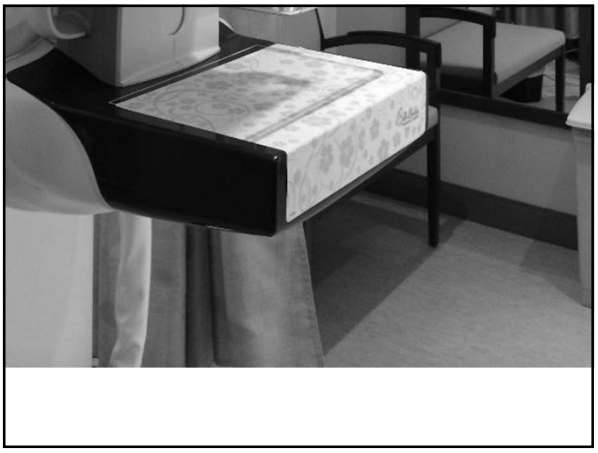
Reconstruction algorithm

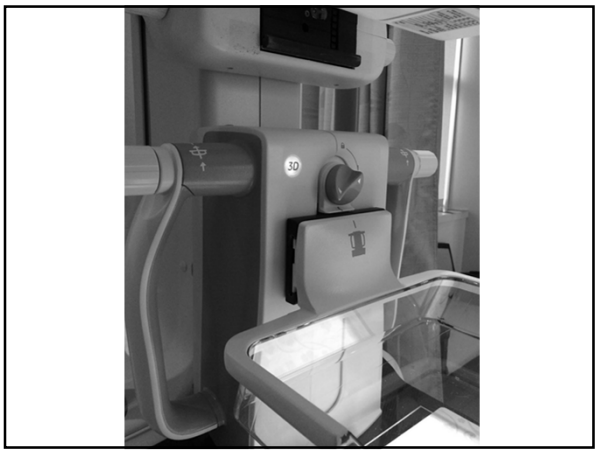


ASiR^{DBT} (Adaptive Statistical Iterative Reconstruction) enables dose reduction and mitigation of artefacts

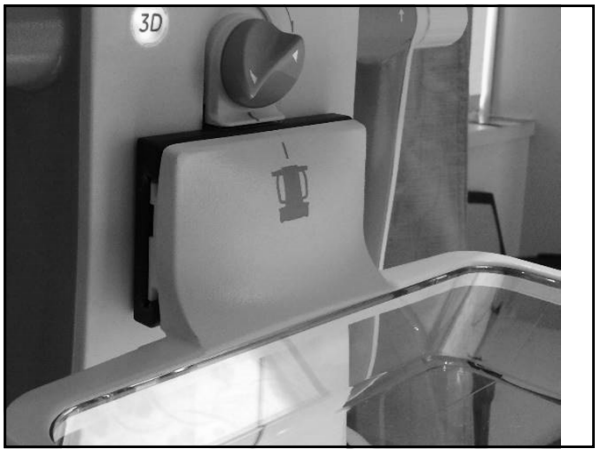

Recon algo: clinical example (3/3)
FFDM
FBP
ASiR^DBT

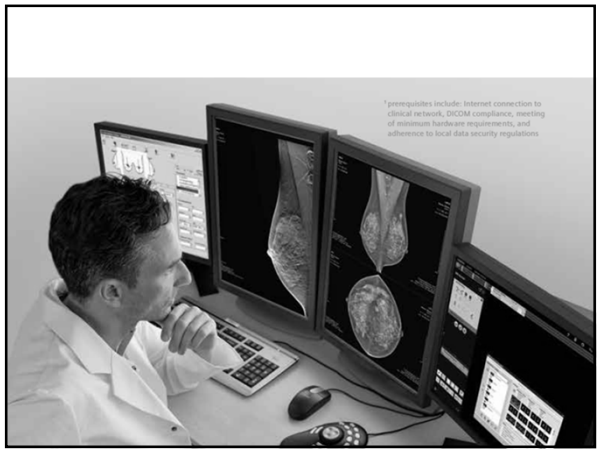

3D dataset: planes, slabs, and V-Preview*
Planes (slices)
0.5mm or 1.0mm distance
Slabs:
1 cm thick, 5mm overlap
V-Preview* Synthetic 2D
* for navigation use only, not a replacement to FFDM

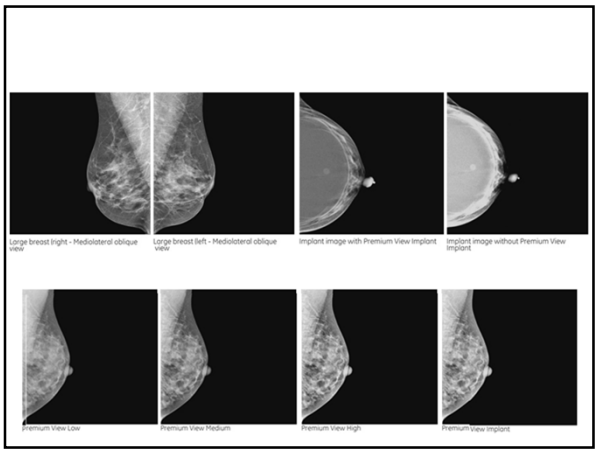




- 25 degree angle
- Pivot point 12 ½
- 9 projection images



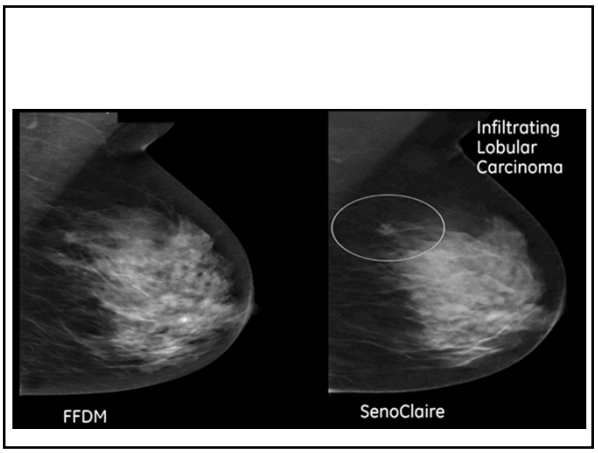




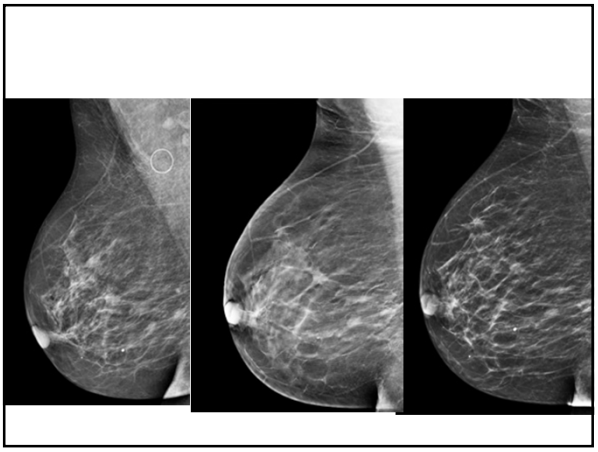
SensorySuite

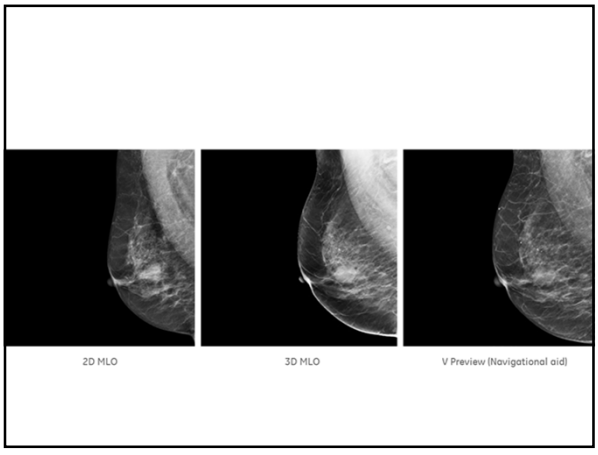
SensorySuite is designed to stimulate a woman's senses to distract her from the perceived discomfort, pain, and anxiety of a mammogram. SensorySuite lets your patient choose the environmental ambiance she prefers for her mammogram: Seaside, Garden, and Waterfall. You control the experience you want to offer your patients.
SensorySuite is available for use with existing or new GE Senographe* Essential, Senographe Care or Senographe DS* systems.

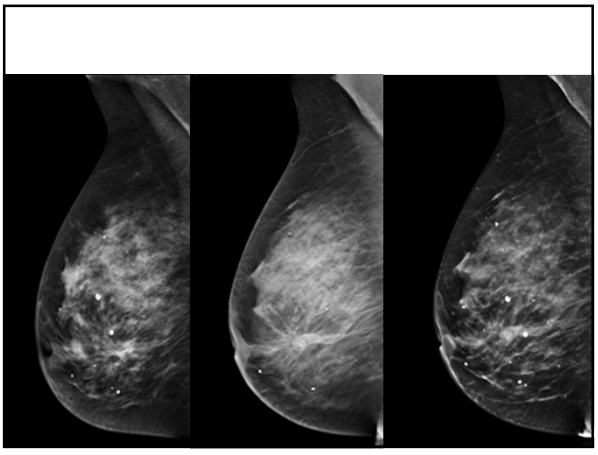
GE's IDI Mammography Workflow Solution is a comprehensive review system designed to enhance your performance through seamless connectivity, easy collaboration, and intuitive viewing and reporting.
Because the tools you're given can affect how you work, we've designed the IDI Workflow Solution to help you work efficiently—and the way you want to. All workflow offerings provide DICOM connectivity for easy interface with virtually any PACS.
The IDI Mammography Workflow Solution can help enhance your performance through seamless RIS/MIS/PACS connectivity, easy collaboration, and review innovations, like automatic pre-fetching of prior exams, automatic scaling and aligning, and custom hanging protocols. The IDI Mammography Workflow solution also offers built-in flexibility due to its upgrade capabilities.

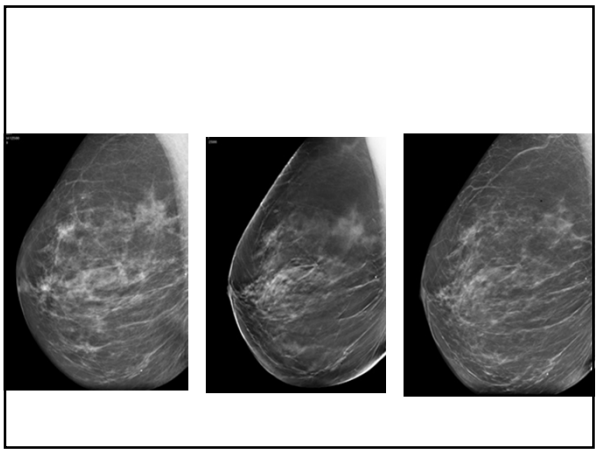


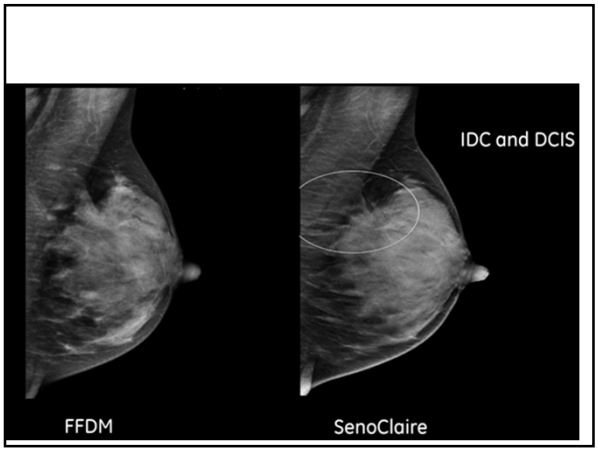
1.The dose of a SenoClaire 3D view is equivalent to that of a 2D standard acquisition of the same view.
2. GE190-004 BIE (Blinded Imaging Evaluation) study - US. A Multicenter Study to Test the Non-Inferiority of Digital Breast Tomosynthesis Compared to FFDM as measured by the area under the Receiver Operating Characteristic (ROC) curve in Detecting Breast Cancer. A summary of this study can be found on the U.S. Food and Drug Administration website under the following reference: SenoClaire P130020.
3. V-Preview is a navigation tool, and is not intended for diagnostic use. V-Preview has not been shown to be equivalent to FFDM. It is not intended to replace the FFDM view.
Date of publication: 1/23/2015 - Document ID: JB22539USd, JB22539USd(1)a, JB27591US





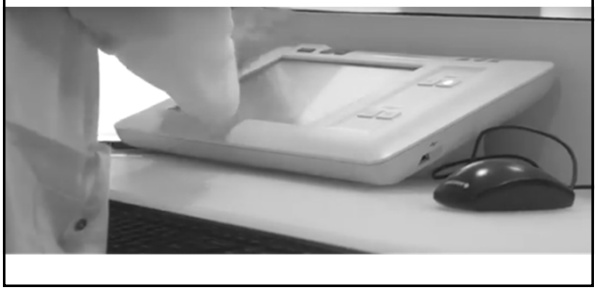






Rethinking patient comfort
Senographe Pristina helps ensure that patients are comfortable during their mammogram.
•The soft armrests have replaced the typical hand grips. So rather than tensing muscles to hold a hand grip, patients can rest their arm comfortably on the arm rest and relax their muscles, which can simplify compression and image acquisition. The gentle, rounded corners of the bucky may reduce anxiety, discomfort and even mammogram pain.

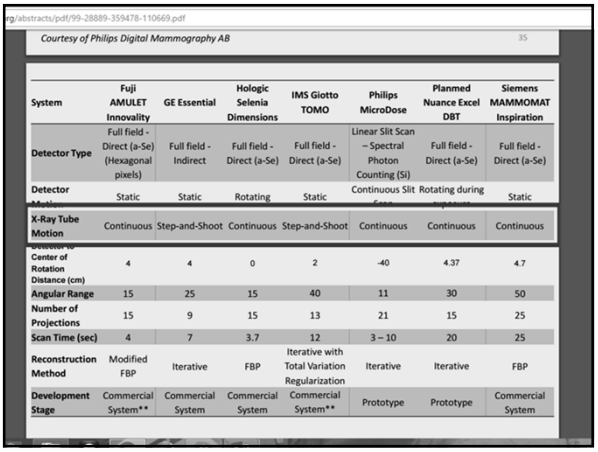
New GE Pristina 3/2017



GE Senographe Pristina

- Approval for GE Senographe Pristina 3D Digital Breast Tomosynthesis system indicated for acquisition of multiple projection views to produce 3D digital mammography images suitable to be used in screening and diagnosis of breast cancer. Senographe Pristina 3D uses similar DBT technology as SenoClaire and consists of a software and hardware upgrade option that enables the acquisition of projection images of the breast in order to reconstruct tomosynthesis images

Patient remote control for compression



Courtesy of Philips Digital Mammography AB

System	Fuji AMULET Innovality	GE Essential	Hologic Selenia Dimensions	IMS Giotto TOMO	Philips MicroDose	Planmed Nuance Excel DBT	Siemens MAMMOMAT Inspiration
Detector Type	Full field - Direct (a-Se) (Hexagonal pixels)	Full field - Indirect	Full field - Direct (a-Se)	Full field - Direct (a-Se)	Linear Slit Scan – Spectral Photon Counting (Si)	Full field - Direct (a-Se)	Full field - Direct (a-Se)
Detector	Static	Static	Rotating	Static	Continuous Slit	Rotating during	Static
X-Ray Tube Motion	Continuous	Step-and-Shoot	Continuous	Step-and-Shoot	Continuous	Continuous	Continuous
Center of Rotation Distance (cm)	4	4	0	2	-40	4.37	4.7
Angular Range	15	25	15	40	11	30	50
Number of Projections	15	9	15	13	21	15	25
Scan Time (sec)	4	7	3.7	12	3 – 10	20	25
Reconstruction Method	Modified FBP	Iterative	FBP	Iterative with Total Variation Regularization	Iterative	Iterative	FBP
Development Stage	Commercial System**	Commercial System	Commercial System	Commercial System**	Prototype	Prototype	Commercial System

Siemens Mammomat Inspiration

Siemens gets U.S. approval for breast tomo

By AuntMinnie.com staff writers

April 23, 2015 -- Siemens Healthcare has received U.S. Food and Drug Administration (FDA) approval for a digital breast tomosynthesis (DBT) add-on option to its Mammomat Inspiration digital mammography platform.

Siemens is now the third vendor able to market DBT technology in the U.S., joining Hologic's Selenia Dimensions system and GE Healthcare's SenoClaire DBT system. Available for Mammomat Inspiration and Mammomat Inspiration Prime Edition, the breast tomosynthesis option has been used since 2009 in Europe, Asia, and South America, according to the vendor.

In tomosynthesis mode, Mammomat Inspiration's x-ray tube rotates in a circular motion around the breast, acquiring an image every 2° while moving through an angular range of 50°. Three-dimensional DBT images are reconstructed from the resulting 25 projections, according to the firm.

Siemens said that in a recent study involving 22 readers with a broad range of experience, all readers achieved better accuracy in detecting and diagnosing cancers when using DBT as an adjunct to full-field digital mammography.

Compression

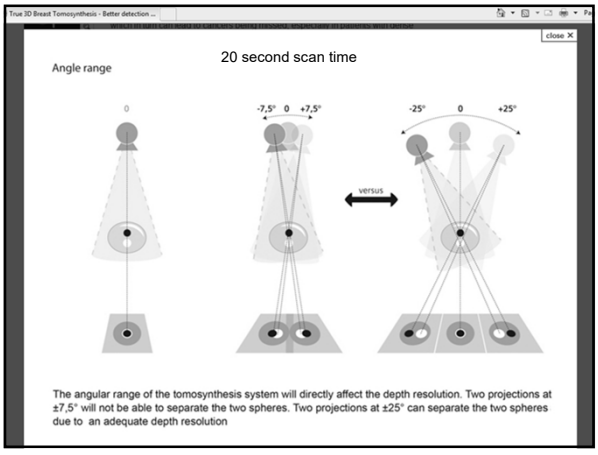
Mammography can be unpleasant, because the compression of the breast is painful. Some women may even refrain from further mammographic procedures. DBT requires a scan time of 20 seconds (see above) which may cause further discomfort and thus create motion artefacts.
In a phantom study, Saunders et al. [18] found that for a constant glandular dose, mass and microcalcification conspicuity remained almost constant with decreasing compression, up to 12%.
Förnvik et al. [19] found that compression could be performed using only half of the force automatically proposed by the equipment before exposure without losing any important diagnostic information. There was a tendency to more noise in the thickest part of the breast (oblique projection, pectoral area) but this presented no difficulties for the readers. Reduced compression is also of value in contrast-enhanced tomosynthesis (CE-DBT) for ensuring appropriate blood
flow in the breast [20,21].

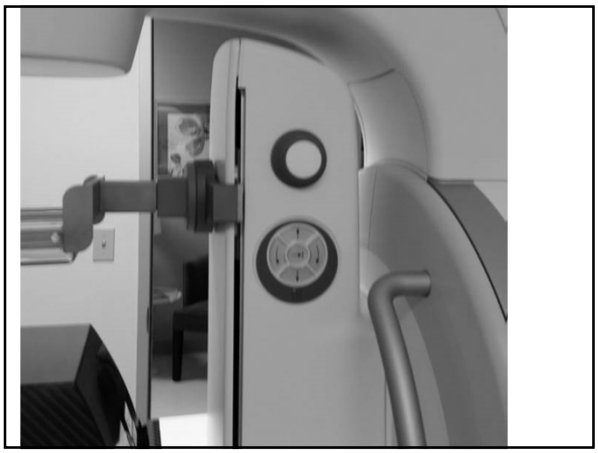
Siemens Mammomat Inspiration Prime

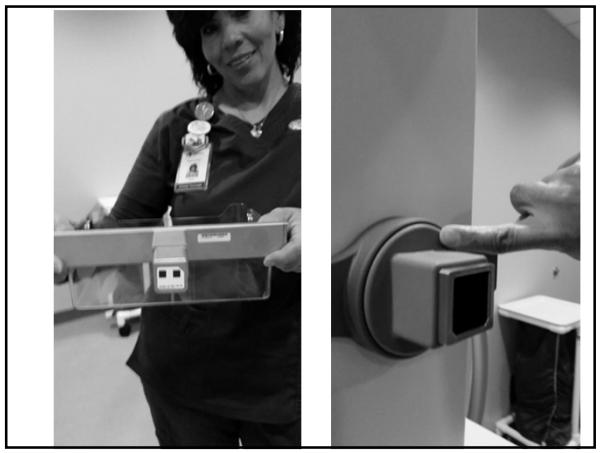
- In digital X-ray breast imaging, radiation passes through the examined breast to a detector. Primary radiation supplies the information needed to provide the X-ray image, while scattered radiation is absorbed by special grids positioned between the breast and the detector. Unfortunately, since these scatter grids also absorb a portion of the all-important primary radiation, physicians must utilize a higher dose to obtain images of desired quality. The ability to minimize patient dose is important, as women are encouraged to undergo regular mammography screening.

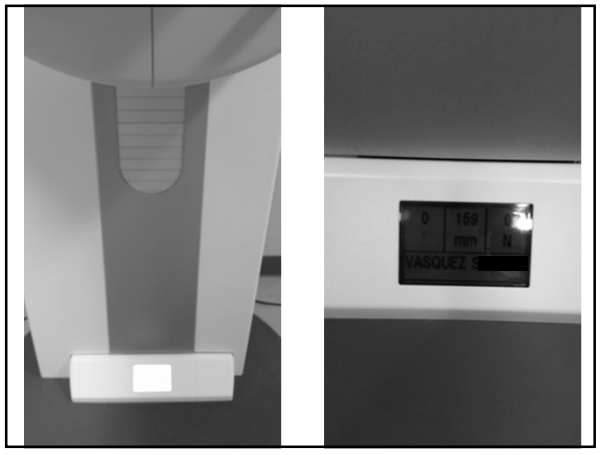
Siemens Mammomat Inspiration Prime

- Siemens' new reconstruction algorithm for the MAMMOMAT Inspiration system – known as Prime (Progressive Reconstruction, Intelligently Minimizing Exposure) –eliminates the need for the scatter radiation grid of conventional mammography systems. The Prime algorithm corrects the scattered radiation by identifying scatter-causing structures and recalculating the image, leaving intact the primary radiation upon which radiologists rely. For this reason, the design of the MAMMOMAT Inspiration Prime Edition obviates the need for a grid, and lower patient doses are sufficient to generate high-quality breast images. The grid-free imaging technology of the MAMMOMAT Inspiration Prime Edition reduces dose up to 30 percent compared to its predecessor model, depending on the thickness of the patient's breast tissue.





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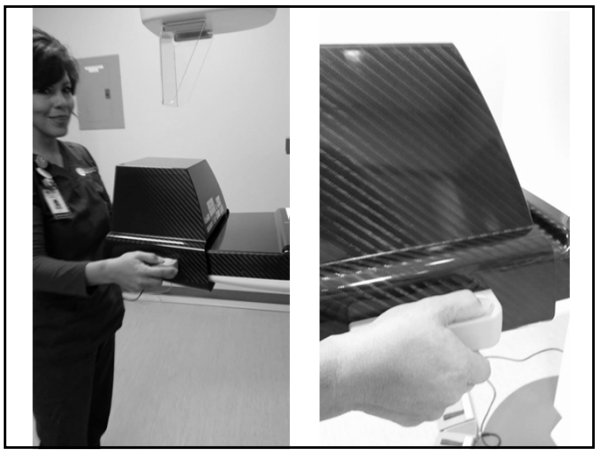
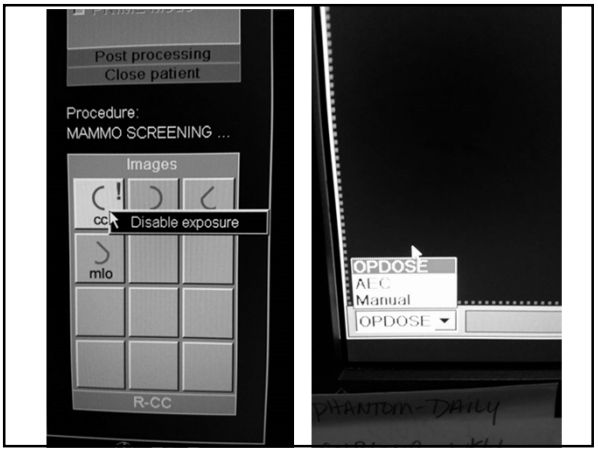
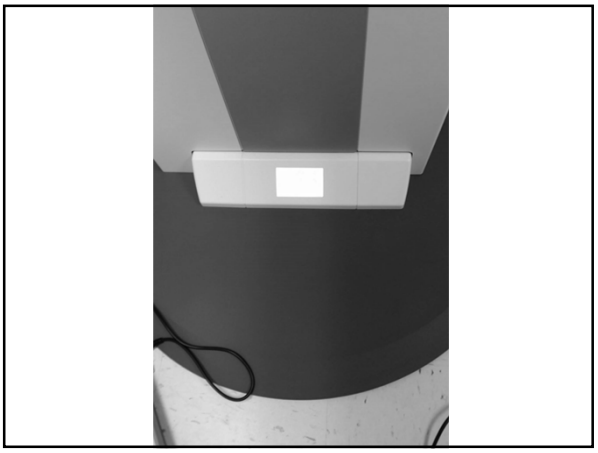



SIEMENS
SIEMENS


Post processing
Close patient
Procedure:
MAMMO SCREENING ...
Images
Disable exposure
mlo
R-CC
OPDOSE
AEC
Manual
OPDOSE



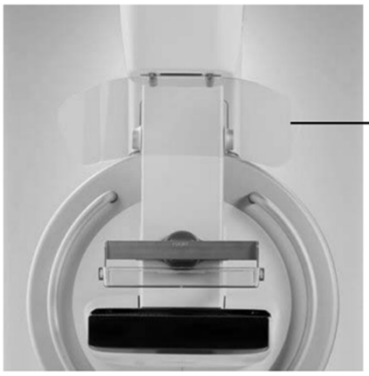
First view First exposure during tomo scan which the swivel arm is at an angle of 0°. When using **2D+Tomo-Scan** the first image is the 2D image.

Slices Stack of images parallel to the detector surface reconstructed from projections with the purpose of display at the workstation monitor.

Bounding box Region of interest, describing the area that will be reconstructed. Using the handles you can adjust the bounding box to the breast tissue area to be reconstructed for slices.

Reconstruction The calculation of the stack of slices (3D volume) from the projections using a reconstruction algorithm.

Reprocessing Processing of the projections and 2D image with new parameter set (OpView).

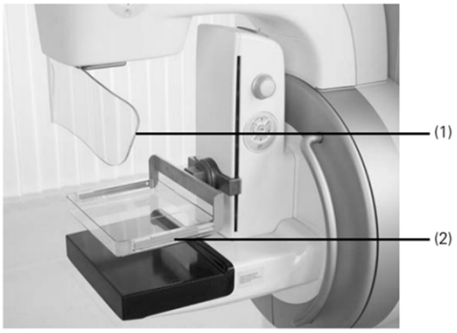


(1) Face shield

Exposure parameters for 3D implant exposures

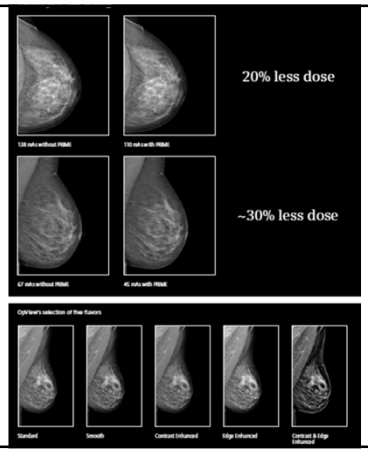
Note that these figures are just suggested guideline values for the exposure. It may be necessary to adjust the exposures depending on the nature of the breast or implant concerned.

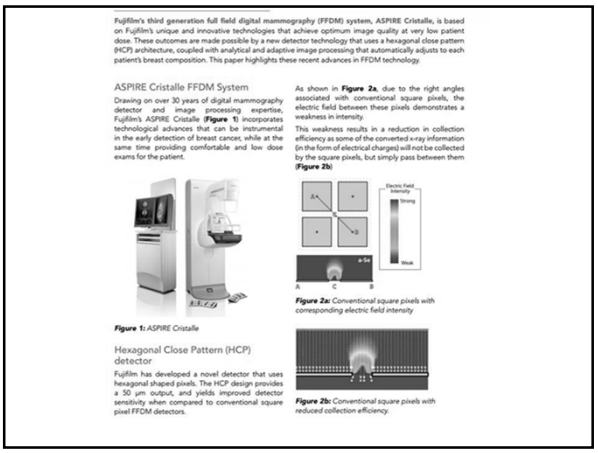
Thickness (mm)	Anode/filter combination	kV	mAs only with function 2D + Tomo-Scan	mAs Tomo
20	WRh	25	50	~100
30	WRh	26	70	~140
40	WRh	26	90	~180
50	WRh	27	110	~220
60	WRh	28	120	~240
70	WRh	29	130	~260
80	WRh	30	140	~280
90	WRh	30	160	~320
100	WRh	31	180	~360



(1) Face shield

(2) Compression plate





Fujifilm's third generation full field digital mammography (FFDM) system, ASPIRE Cristalle, is based on Fujifilm's unique and innovative technologies that achieve optimum image quality at very low patient dose. These outcomes are made possible by a new detector technology that uses a hexagonal close pattern (HCP) architecture, coupled with analytical and adaptive image processing that automatically adjusts to each patient's breast composition. This paper highlights these recent advances in FFDM technology.

ASPIRE Cristalle FFDM System

Drawing on over 30 years of digital mammography detector and image processing expertise, Fujifilm's ASPIRE Cristalle (**Figure 1**) incorporates technological advances that can be instrumental in the early detection of breast cancer, while at the same time providing comfortable and low dose exams for the patient.

As shown in **Figure 2a**, due to the right angles associated with conventional square pixels, the electric field between these pixels demonstrates a weakness in intensity.

This weakness results in a reduction in collection efficiency as some of the converted x-ray information (in the form of electrical charges) will not be collected by the square pixels, but simply pass between them (**Figure 2b**)

Figure 1: *ASPIRE Cristalle*

Figure 2a: *Conventional square pixels with corresponding electric field intensity*

Figure 2b: *Conventional square pixels with reduced collection efficiency.*

Hexagonal Close Pattern (HCP) detector

Fujifilm has developed a novel detector that uses hexagonal shaped pixels. The HCP design provides a 50 µm output, and yields improved detector sensitivity when compared to conventional square pixel FFDM detectors.

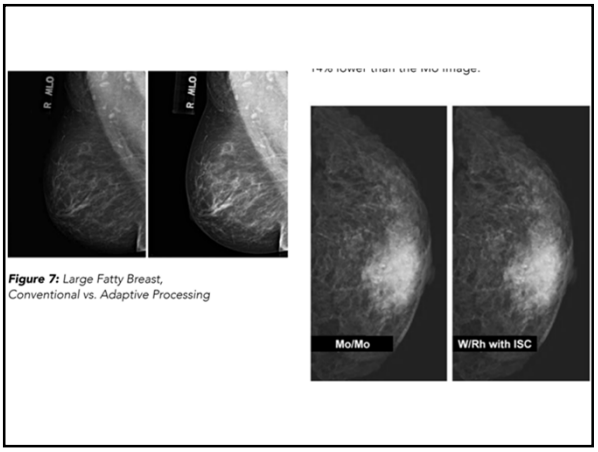


Figure 7: *Large Fatty Breast, Conventional vs. Adaptive Processing*

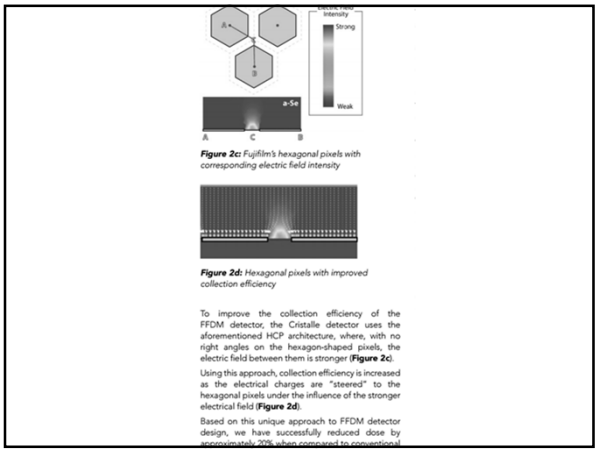


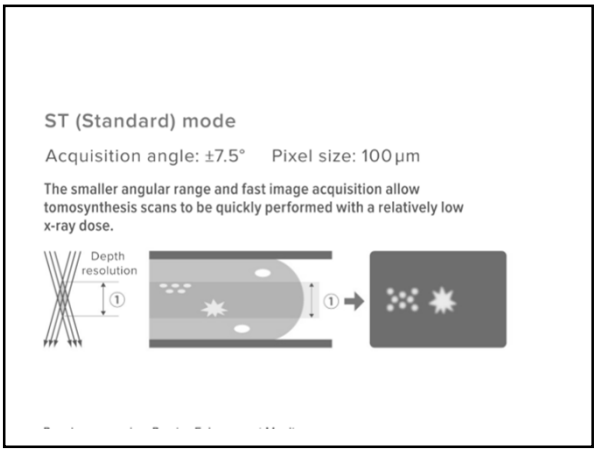
Figure 2c: *Fujifilm's hexagonal pixels with corresponding electric field intensity*

Figure 2d: *Hexagonal pixels with improved collection efficiency*

To improve the collection efficiency of the FFDM detector, the Cristalle detector uses the aforementioned HCP architecture, where, with no right angles on the hexagon-shaped pixels, the electric field between them is stronger (**Figure 2c**).

Using this approach, collection efficiency is increased as the electrical charges are "steered" to the hexagonal pixels under the influence of the stronger electrical field (**Figure 2d**).

Based on this unique approach to FFDM detector design, we have successfully reduced dose by approximately 20% when compared to conventional



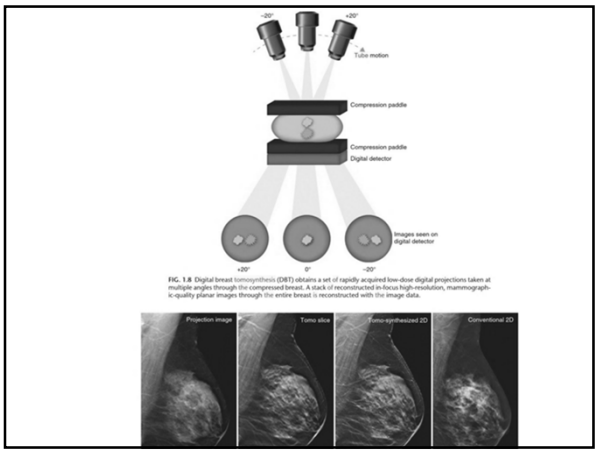
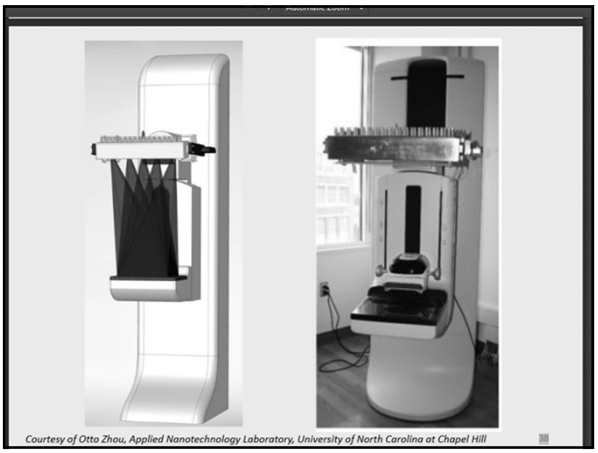


FIG. 1.8 Digital breast tomosynthesis (DBT) obtains a set of rapidly acquired low-dose digital projections taken at multiple angles through the compressed breast. A stack of reconstructed in-focus high-resolution, mammograph-ic-quality planar images through the entire breast is reconstructed with the image data.



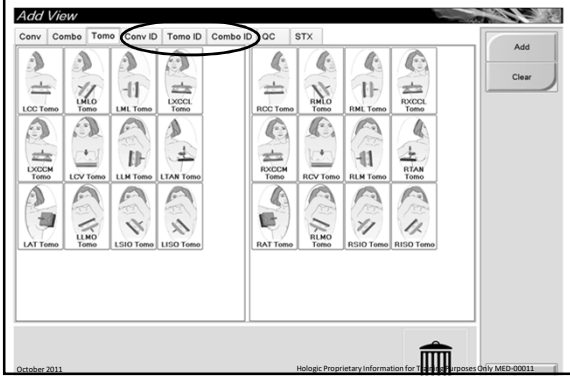
Hologic Selenia Dimensions

- The first approved machine in the US and what started it all ……..

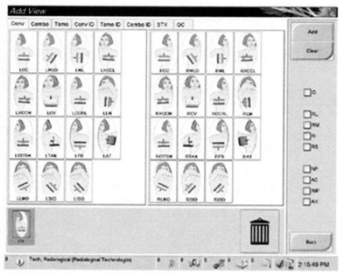
Tomosynthesis on Implant Patients

- **Selenia Dimensions 3000 -** The evergreen 2D system that offers the benchmark Hologic customers expect, with essential ergonomics and functional workflow features at an attractive price. Plus, the Selenia Dimensions system 3000 package offers the agility to evolve with you.
- **Selenia Dimensions 3D™ Performance System -** The 3D™ system that offers the benchmark Hologic customers expect, with essential ergonomics and functional workflow features, as well as the Genius™ 3D Mammography™ exam, at an attractive price.
- **Selenia Dimensions 6000 -** The 2D/3D™ system that redefines ergonomics, matched with the perfect balance of enhanced workflow features, taking your performance to the next level.
- **Selenia Dimensions 9000 -** The premium 2D/3D™ system that delivers on high performance through its outstanding, optimal ergonomics and elevated, intelligent workflow features that amplify your performance.

Old Software



New software

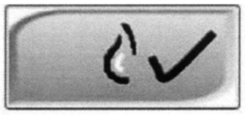


View Modifiers
ID = Implant Displaced
RL = Rolled Lateral
RM = Rolled Medial
RI = Rolled Inferior
RS = Rolled Superior
NP = Nipple in Profile
AC = Anterior Compression
IMF = Infra-Mammary Fold
AX = Axillary Tissue

Figure 24: The Add View Screen

If you accepted the image

- Re-preview the image
- Select the Implant Present button on the Procedure screen to correct the image. A checkmark appears on the button and the image reprocesses
- Select the accept button to accept the changes

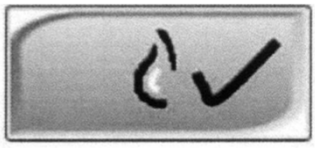


Implant Present

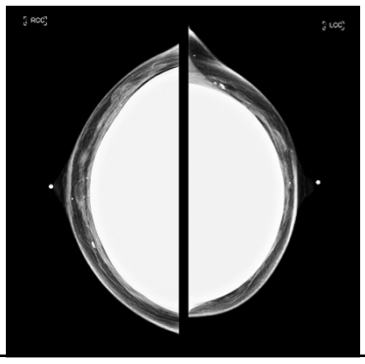
- For proper image processing of implant cases to be used on both implant and implant displaced views
- When selected a checkmark appears on the button

If you did not accept the image yet

- Select the Implant Present button on the Procedure screen to indicate an implant exists
- A checkmark appears on the button and the image reprocesses



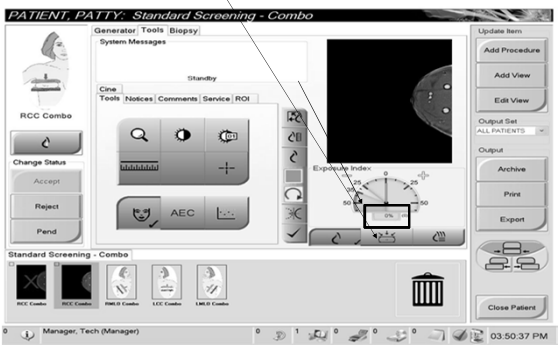
Breast Implants



Projection vs. Reconstructed

- Projection images should be reviewed before accepting to detect motion
- Reconstructed slices may be reviewed if the technologist feels it is necessary

Review Projections for Motion



Go mobile with the leader in women's health

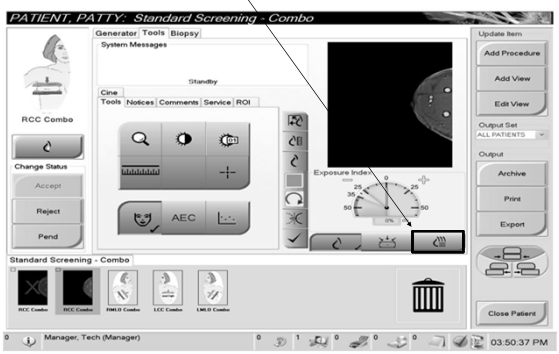
Around the world, there is an overwhelmingly large percentage of women who do not have access to breast cancer screening services. Instead of accepting this obstacle to care, many women's imaging sites are looking to mobile technologies as a means to expand the reach of their care. Mobile coaches make it possible to bring care to the most remote areas, as well as to offices and medical centers that do not offer women's health screening services.

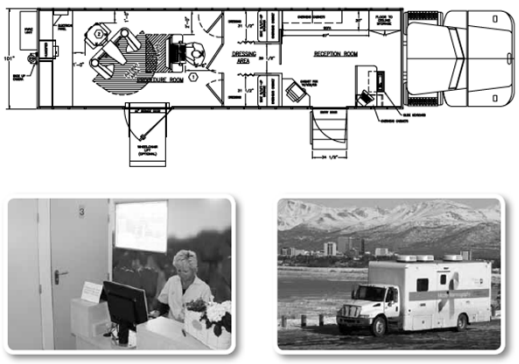
Bringing screening services to women in a mobile environment not only establishes convenient access to care, it's also an opportunity to improve compliance and control the quality of care patients receive. The same state-of-the-art technology, like a Selenia Dimensions system, that is adopted in a hospital today can now be offered in a mobile environment.

Hologic is working with imaging sites all over the world to bring mobile screening programs to women. We have the technology, the experience and the resources to help find the right mobile solution for any imaging center.

This is just another way Hologic works with our customers to bring the highest level of care to more than 3.3 billion women around the world.

Reviewing of Reconstructions





Selenia Dimensions 5000

Buttons to move console

- Buttons on the right side of unit help to move the console up and down to the height of the technologist. Helps with mechanical ergonomics for technologist.

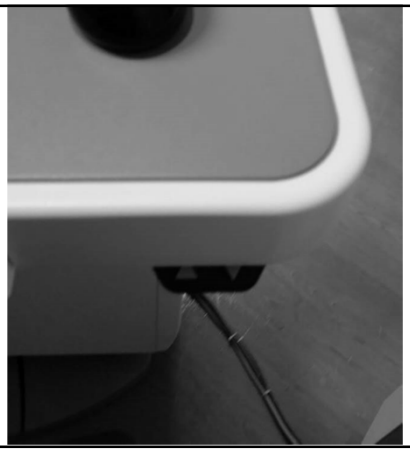
Selenia Dimensions 6000

The Selenia Dimensions system 6000 package offers a flexible platform equipped with enhanced ergonomics to boost your performance. Package highlights include:

- Advanced application options such as 3D MAMMOGRAPHY™, 2D/3D® interventional procedures or contrast enhanced 2D imaging, which can be fused with tomosynthesis images.
- Powered height adjustment allows each user to rapidly adjust the workstation to their preferred height.
- Ergonomic X-ray exposure footswitch helps to reduce repetitive motion injuries and is particularly beneficial when conducting a combined tomosynthesis scan.
- Includes four screening and diagnostic SMART flexing paddles, designed for comfort enhanced tissue grip
- Flexibility for use in screening/diagnostic mobile environments.
- A host of paddles, accessories and licenses offer the ability customize the system package for your facility to meet your workflow and practice goals.

The Selenia Dimensions Avia 3000 package offers entry into the renowned Hologic image quality while providing an evergreen system that has ability to grow with your practice.

- Start with 2D screening or screening/diagnostic system and have confidence that you can add capabilities such as interventional procedures, breast tomosynthesis, advanced diagnostic procedures and more workflow features in the future with a simple upgrade.*
- Large tabletop X-ray exposure button on a fully functional tabletop set at an ergonomic height.
- Includes two screening SMART flexing paddles, designed for comfort enhanced tissue grip
- Choice of additional paddles, accessories and license options to meet your unique

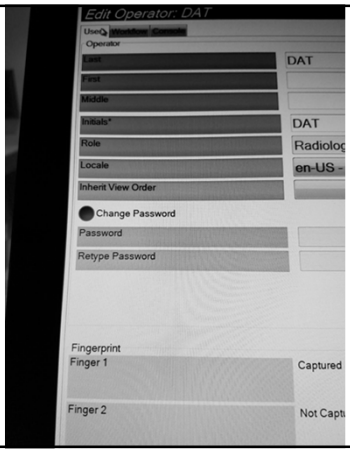


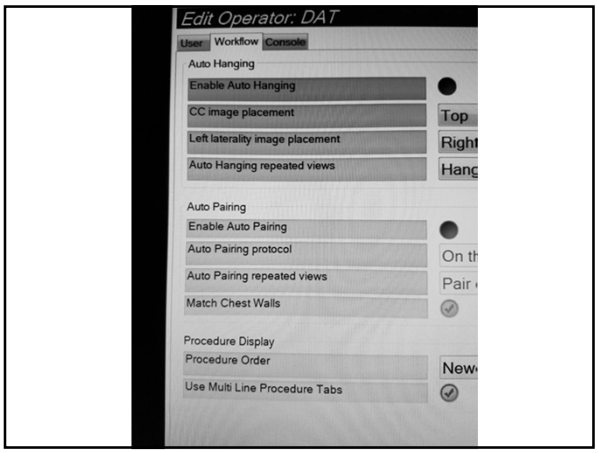
Selenia Dimensions 9000

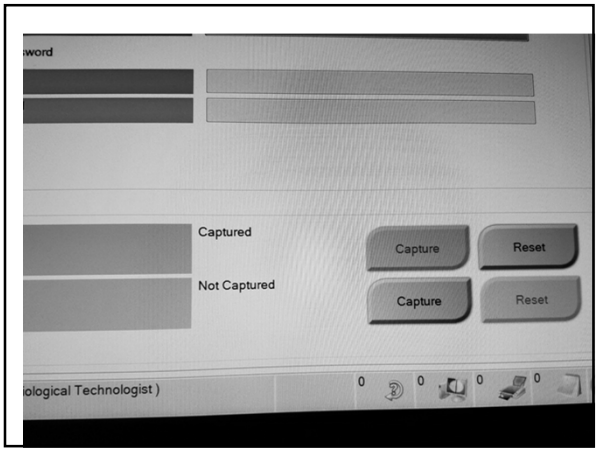
Hologic is redefining ergonomics and workflow with the introduction of its new system packages. With three robust packages and the ability to customize with options to your facilities unique needs; you now have the ability to build your ideal mammography suite.

The Selenia Dimensions system 9000 package is our flagship offering that delivers on high performance with its elevated design, optimal ergonomics and intelligent workflow features. Package highlights include:

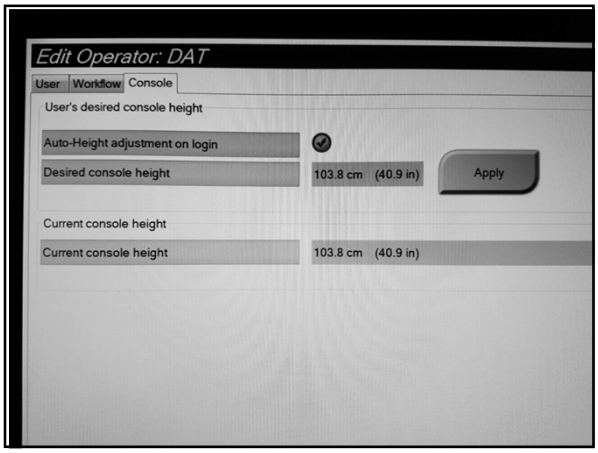
- Advanced application options such as 3D MAMMOGRAPHY™, 2D/3D* interventional procedures or contrast enhanced 2D imaging, which can be fused with tomosynthesis images.
- World's first in mammography! Biometric login with memory height adjustment, enabling the operator to begin an exam with pre-configured workflow preferences including their personalized workstation height. Simply set the height that is most comfortable and the system will automatically move to the perfect level with each log in.
- New! Ergonomic X-ray exposure footswitch helps to reduce repetitive motion injuries and is particularly beneficial when conducting a combined tomosynthesis scan.
- Advanced connectivity pack, bar code scanner, touch screen controls and intuitive icons allow for easy workflow for efficient navigation through exams.
- Includes eight screening and diagnostic SMART flexing paddles, designed for comfort enhanced tissue grip
- Flexibility for use in screening/diagnostic mobile environments.
- Additional options are available to customize your package today!

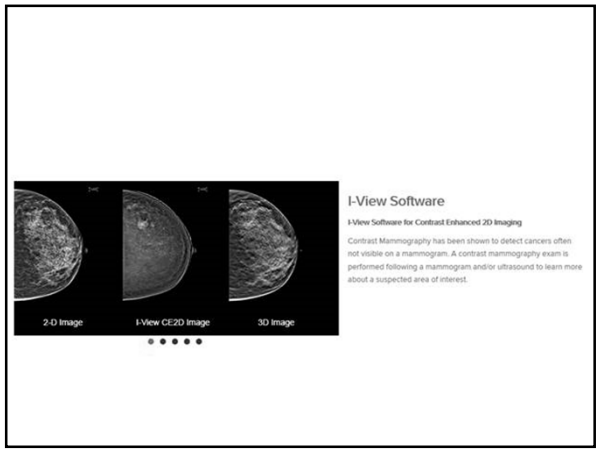



Edit Operator: DAT
User
Workflow
Console
Auto Hanging
Enable Auto Hanging
CC image placement
Top
Left laterality image placement
Auto Hanging repeated views
Auto Pairing
Enable Auto Pairing
Auto Pairing protocol
Auto Pairing repeated views
Match Chest Walls
Procedure Display
Procedure Order
Use Multi Line Procedure Tabs


Captured
Capture
Reset
Not Captured
Capture
Reset


POWER
CPU
UPS


Edit Operator: DAT
User
Workflow
Console
User's desired console height
Auto-Height adjustment on login
Desired console height
103.8 cm (40.9 in)
Apply
Current console height
Current console height
103.8 cm (40.9 in)


2-D Image
I-View CE2D Image
3D Image
I-View Software
I-View Software for Contrast Enhanced 2D Imaging
Contrast Mammography has been shown to detect cancers often not visible on a mammogram. A contrast mammography exam is performed following a mammogram and/or ultrasound to learn more about a suspected area of interest.

genius3D
MAMMOGRAPHY EXAM ™

Premium Selenia 8000

93%
say it's more comfortable.[1]

SmartCurve™ Breast Stabilization System

1-trackball
2-scrool wheel
3-compression release
4-emergency off
5-fingerprint scanner
6 exposure-x-ray button
7-touchscreen display
8-keyboard
9-DC-DVD Drive
10-bar code scanner
11-LED for preview display power
12-preview display

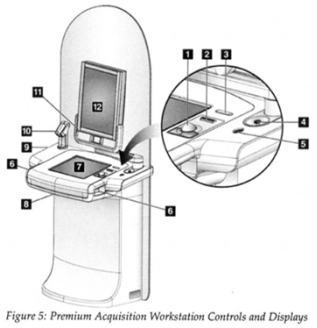


Figure 5: Premium Acquisition Workstation Controls and Displays

1. Rotation Angle Displays (each side)
2. C-Arm Controls (each side)
3. Compression Device
4. Patient Handles (each side)
5. Emergency Off Switches (each side)
6. Compression Handwheels
7. Patient Face Shield
8. Tubehead Display
9. Footswitches

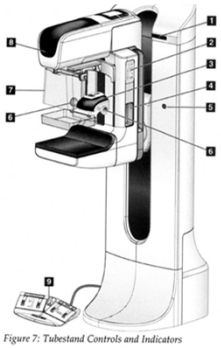


Figure 7: Tubestand Controls and Indicators

Compression Device Controls and Display

1-manual compression
2-paddle shift buttons
3-AEC sensor buttons
4-compression device display
5-FAST compression paddle mode slide
6-paddle clamp

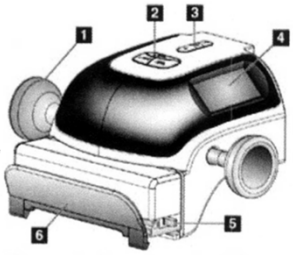


Figure 9: Compression Device

C-Arm Controls

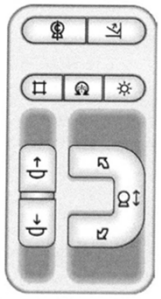


Figure 8: C-Arm Controls

Display on Compression Device

•AEC sensor position
•compression force (displays 0.0 when force is less than 4 pounds)
•Compression thickness
•Angle of C-Arm after rotation (for 5 seconds)

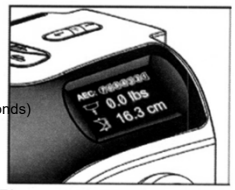


Figure 10: Compression Display

SID(Source Image Distance)

- Is it better to have a larger or smaller SID for mammography? Why?

Tube head Display

- SID
- Filter type
- Collimator setting
- Paddle position

Figure 11: Tubehead Display

SID

- Lager SID is better. You get less geometric blur for the same focal spot size with a larger SID. The tradeoff is that it takes more mAs to get the same exposure so longer exposure time and more tube loading you can get more motion.

Also the larger the SID the better is is for scatter radiation. Acts like air gap and the lower energy photons escape so it doesn't reach the receptor.

The Unit

- 70 cm constant SID
- Tube display
  - SID
  - Filter
  - Collimator
  - L, R, C position of paddle

Dual Function Foot Paddles

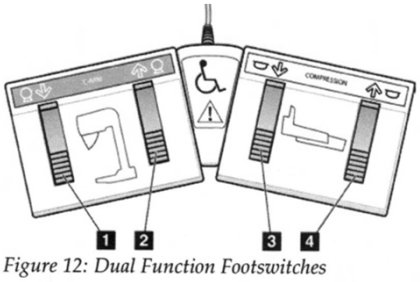
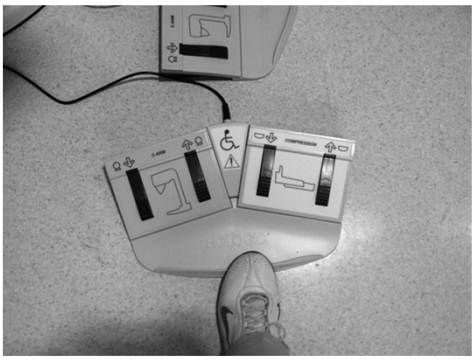
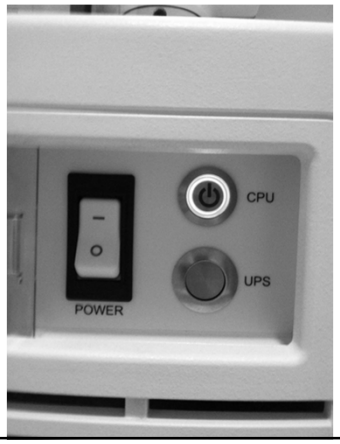


Figure 12: Dual Function Footswitches

The Unit

- CPU button on back of console to turn unit on-do not touch power button
- Can be programmed to turn on and off at set times in order to be warmed up when staff arrives-2 hours before start time-programmed during applications
- Technologist monitor 3 megapixel-Selenia is a 2 megapixel
- Export QC to thumb drive to transfer to computer
- Fingerprint log in or manual log in



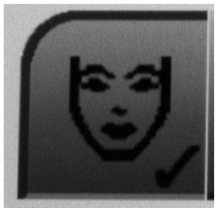


The Unit

- Compression is the same
- Tungsten tube-AL filter for tomo hardens the beam increase kVp for faster exposure time
- 7cm below uses Rhodium/higher uses Ag
- 3D-higher mA=shorter exposure
- Patients DO NOT need to hold their breath but most centers have pt's hold their breath because of a small chance of motion,
- Collimator override for acrylic handle on spot paddle if it is distracting to Radiologist-will not hurt detector to collimate down

The Unit

- Anonymous- It strips patient information



Does 3D Breast Tomosynthesis Require Less Compression?

NO

- Has fast paddle (Fully Automated Self-Adjusting Tilt) not spring loaded
- More like a flex paddle
- No fast paddle for mags or loc's
- Paddles are icon driven
- Compression does not register until 4 lbs
- Paddle auto moves for MLO views you can override if you only want to move a little bit
- If you use fast paddle on patients must use for QC

The Unit

- Mag stand
  - The way it attaches has been changed because on original unit technologists have a hard time getting it on- on original unit you must tilt it down not toward yourself, upgrade needed for new one
  - Old one has clamps on handles you have to push on
  - New one does not, it has two black buttons instead and it has audible and visual prompts for proper installation
  - 1.8 top or 1.5 lower - mag factor choice

- Paddles clamp on
- Paddles are color coded
  - Purple-screen
  - Green-diagnostic
  - Gold-magnification
  - Red-localization

- Has modifier so you can add
  - Anterior compression
  - Nipple profile
  - etc

Detector not dependent on room temperature but is affected by it-will get a warning if too hot or too cold

How to use the retractable face shield

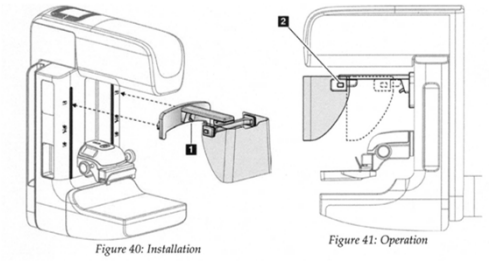
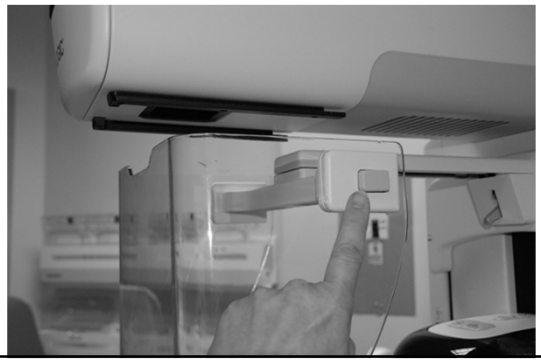
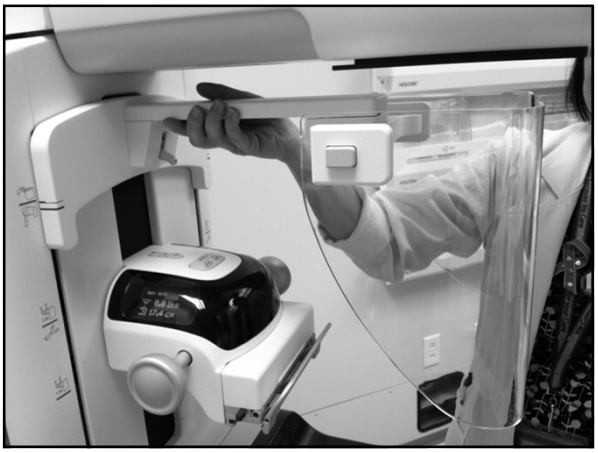


Figure 40: Installation

Figure 41: Operation



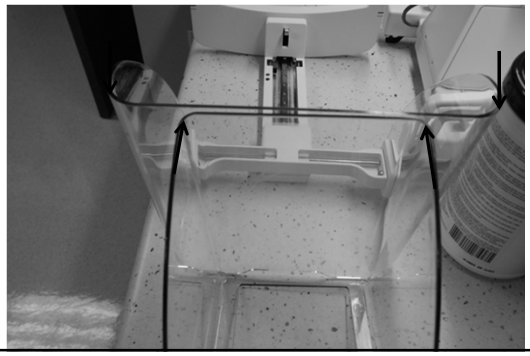
The retractable face shield



The retractable face shield for ease of positioning for both technologist and patient

The Retractable Tomo Face Shield

Use standard face shield for 2D



The Conventional Face Shield

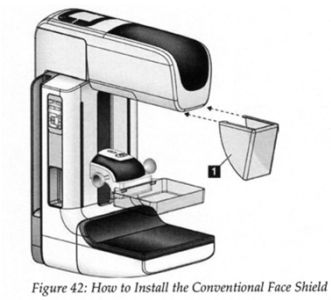
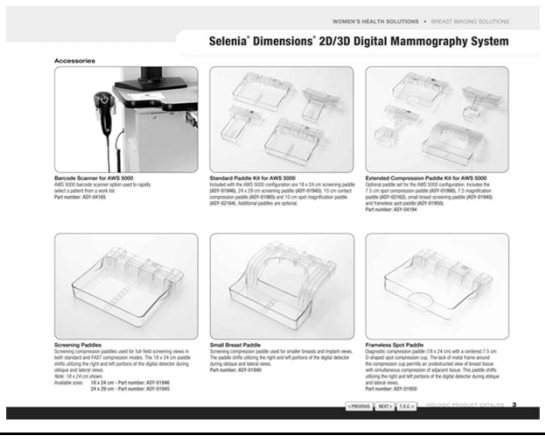
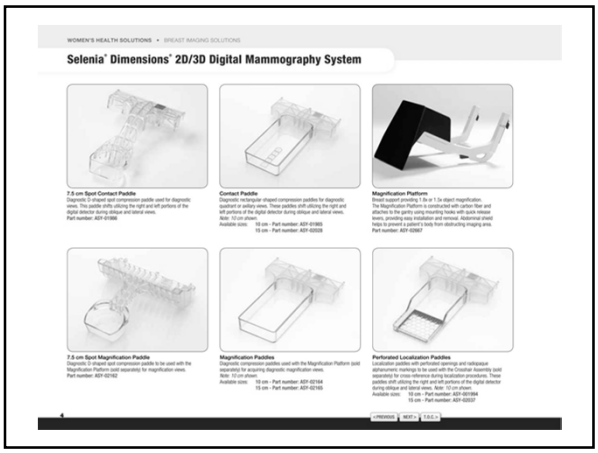
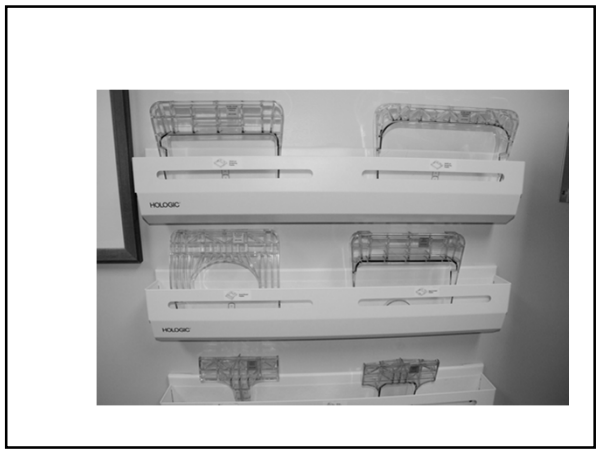


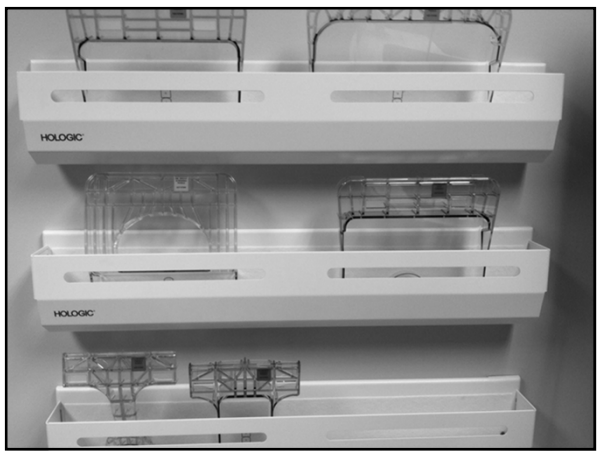
Figure 42: How to Install the Conventional Face Shield




WOMEN'S HEALTH SOLUTIONS • BREAST IMAGING SOLUTIONS
Selenia® Dimensions® 2D/3D Digital Mammography System
7.5 cm Spot Contact Paddle
Contact Paddle
Magnification Platform
7.5 cm Spot Magnification Paddle
Magnification Paddles
Perforated Localization Paddles


HOLOGIC
HOLOGIC


HOLOGIC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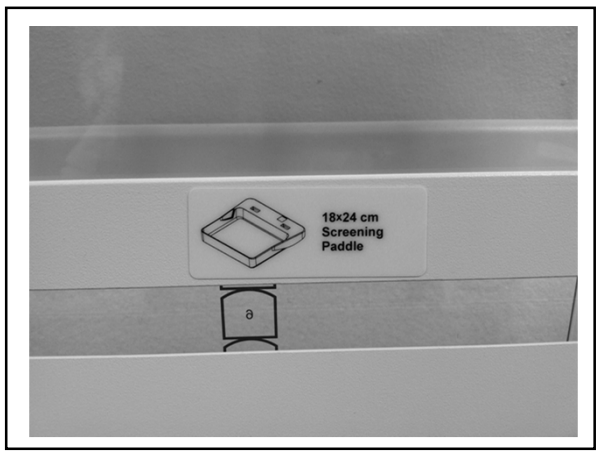
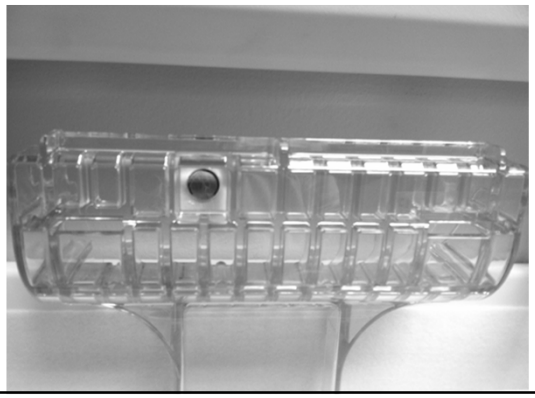

18x24 cm
Screening
Paddle



Removing the compression paddles

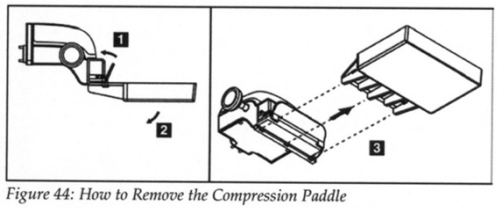
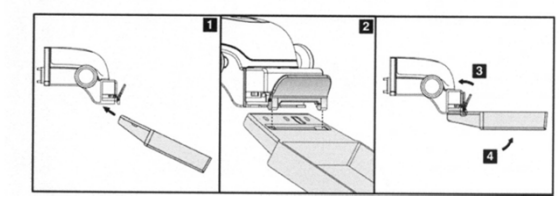


Figure 44: How to Remove the Compression Paddle

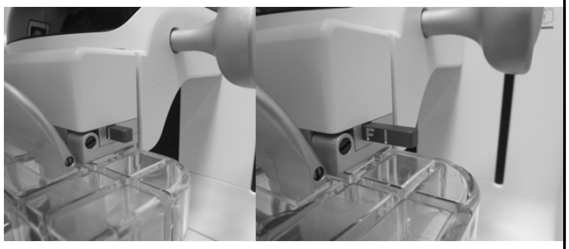
Attaching the paddles

Installing Compression Paddles

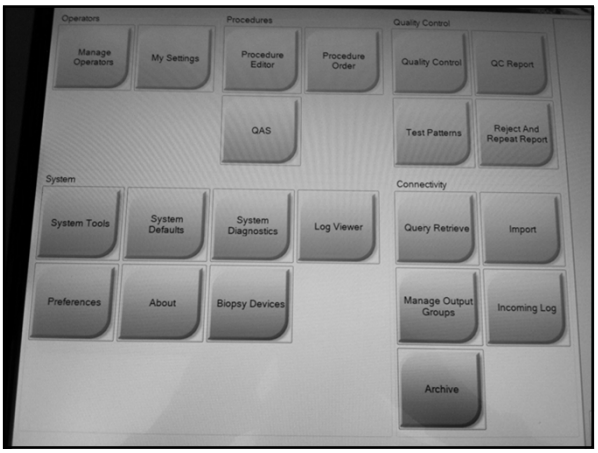


Attaching the paddles

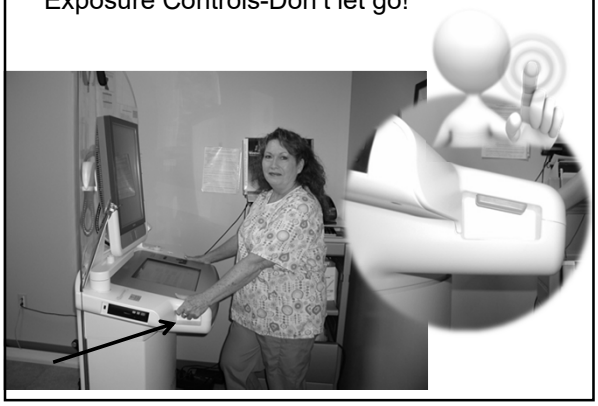
The FAST Paddle

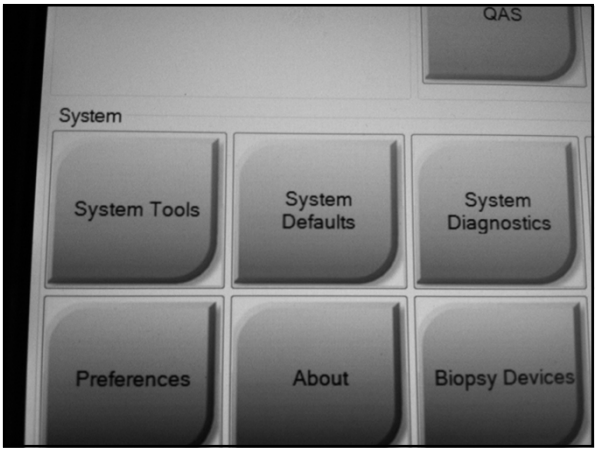


FAST Paddle Off (F) FAST Paddle On

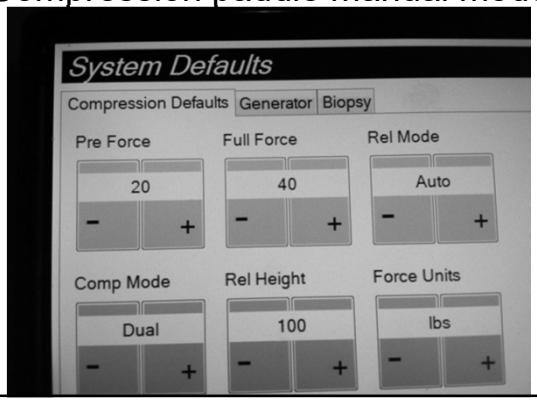


Exposure Controls-Don't let go!





Compression paddle manual mode



The Procedure Screen

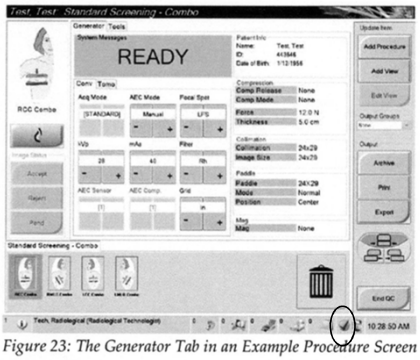
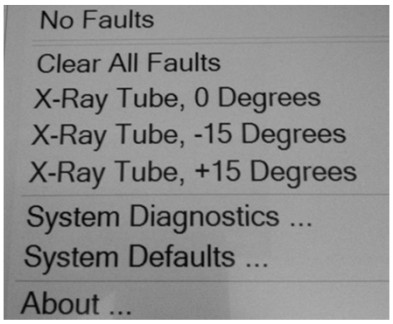
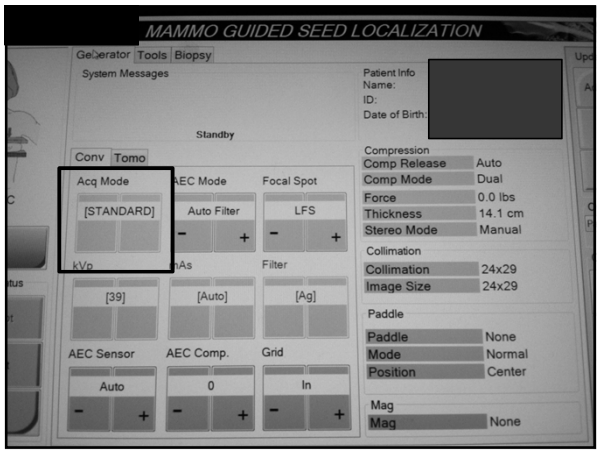


Figure 23: The Generator Tab in an Example Procedure Screen



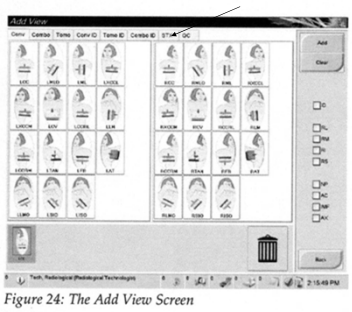


Setting the Exposure Parameters

- Image acquisition mode (tomosynthesis option)
  - Standard-for routine tomosynthesis screening procedures
  - Enhanced-for diagnostic tomosynthesis views. This mode increases patient dose.

Add a View Screen

Stereotactic modifiers



View Modifiers
ID = Implant Displaced
RL = Rolled Lateral
RM = Rolled Medial
RI = Rolled Inferior
RS = Rolled Superior
NP = Nipple in Profile
AC = Anterior Compression
IMF = Infra-Mammary Fold
AX = Axillary Tissue

Figure 24: The Add View Screen

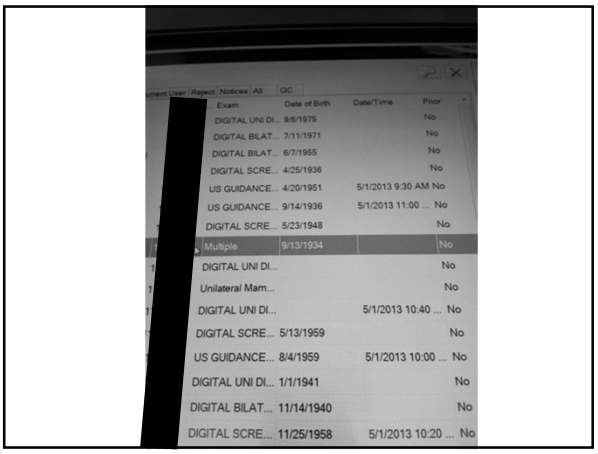
Enhanced Exposure Parameters

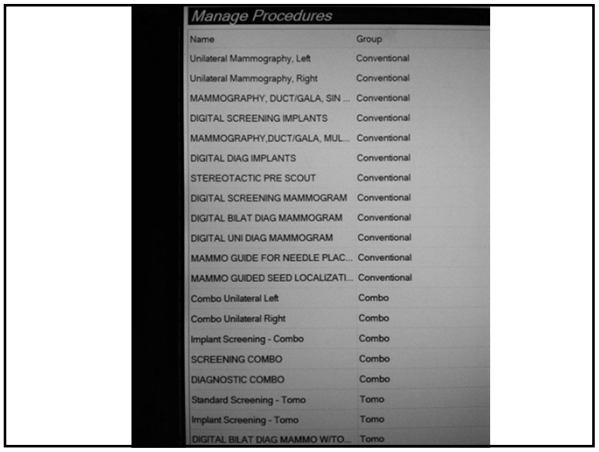
- Allows the technologist to acquire a diagnostic tomo view with significantly improved image quality to allow for better visualization and characterization of abnormalities

The enhanced mode might be used for instance:

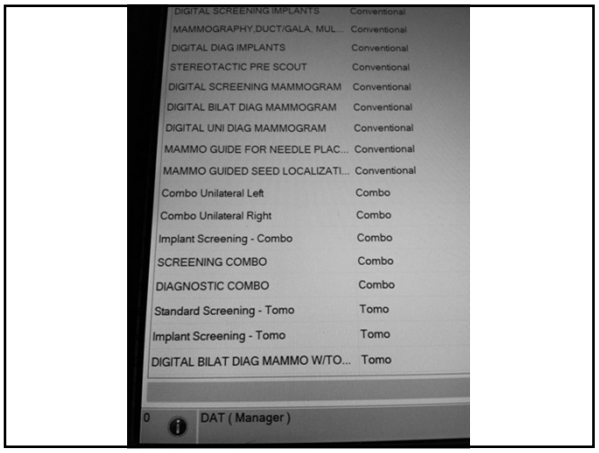
- if there is a faint calcification or small spiculated mass that is very difficult to see
- if the image looks generally noisy, possibly due to very dense breast tissue

This is a view the radiologist would be taught to order as a diagnostic view since the dose is increased

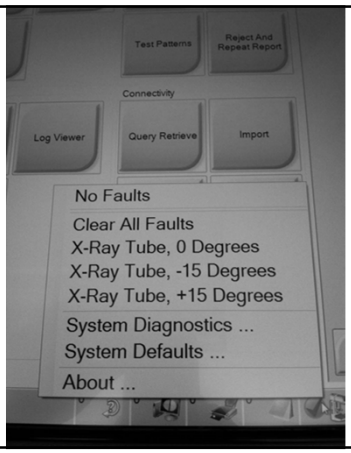

Exam Date of Birth Date/Time Prior
DIGITAL UNI DI... 9/6/1975 No
DIGITAL BILAT... 7/11/1971 No
DIGITAL BILAT... 6/7/1955 No
DIGITAL SCRE... 4/25/1936 No
US GUIDANCE... 4/20/1951 5/1/2013 9:30 AM No
US GUIDANCE... 9/14/1936 5/1/2013 11:00 ... No
DIGITAL SCRE... 5/23/1948 No
Multiple 9/13/1934 No
DIGITAL UNI DI... No
Unilateral Mam... No
DIGITAL UNI DI... 5/1/2013 10:40 ... No
DIGITAL SCRE... 5/13/1959 No
US GUIDANCE... 8/4/1959 5/1/2013 10:00 ... No
DIGITAL UNI DI... 1/1/1941 No
DIGITAL BILAT... 11/14/1940 No
DIGITAL SCRE... 11/25/1958 5/1/2013 10:20 ... No


Manage Procedures
Name Group
Unilateral Mammography, Left Conventional
Unilateral Mammography, Right Conventional
MAMMOGRAPHY, DUCT/GALA, SIN ... Conventional
DIGITAL SCREENING IMPLANTS Conventional
MAMMOGRAPHY,DUCT/GALA, MUL... Conventional
DIGITAL DIAG IMPLANTS Conventional
STEREOTACTIC PRE SCOUT Conventional
DIGITAL SCREENING MAMMOGRAM Conventional
DIGITAL BILAT DIAG MAMMOGRAM Conventional
DIGITAL UNI DIAG MAMMOGRAM Conventional
MAMMO GUIDE FOR NEEDLE PLAC... Conventional
MAMMO GUIDED SEED LOCALIZATI... Conventional
Combo Unilateral Left Combo
Combo Unilateral Right Combo
Implant Screening - Combo Combo
SCREENING COMBO Combo
DIAGNOSTIC COMBO Combo
Standard Screening - Tomo Tomo
Implant Screening - Tomo Tomo
DIGITAL BILAT DIAG MAMMO W/TO... Tomo

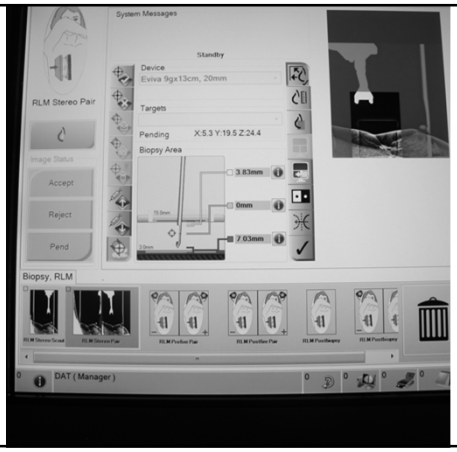

Affirm breast biopsy guidance system with the Eviva® breast biopsy device

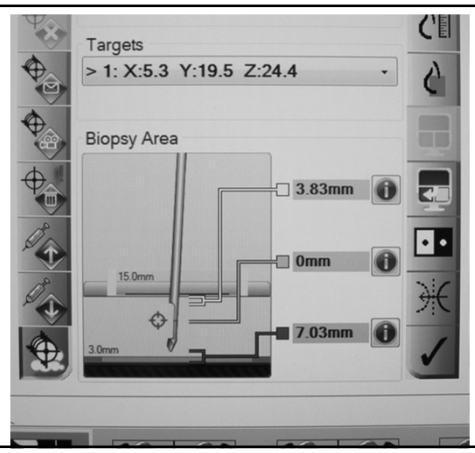

DIGITAL SCREENING IMPLANTS Conventional
MAMMOGRAPHY,DUCT/GALA, MUL... Conventional
DIGITAL DIAG IMPLANTS Conventional
STEREOTACTIC PRE SCOUT Conventional
DIGITAL SCREENING MAMMOGRAM Conventional
DIGITAL BILAT DIAG MAMMOGRAM Conventional
DIGITAL UNI DIAG MAMMOGRAM Conventional
MAMMO GUIDE FOR NEEDLE PLAC... Conventional
MAMMO GUIDED SEED LOCALIZATI... Conventional
Combo Unilateral Left Combo
Combo Unilateral Right Combo
Implant Screening - Combo Combo
SCREENING COMBO Combo
DIAGNOSTIC COMBO Combo
Standard Screening - Tomo Tomo
Implant Screening - Tomo Tomo
DIGITAL BILAT DIAG MAMMO W/TO... Tomo
DAT (Manager)

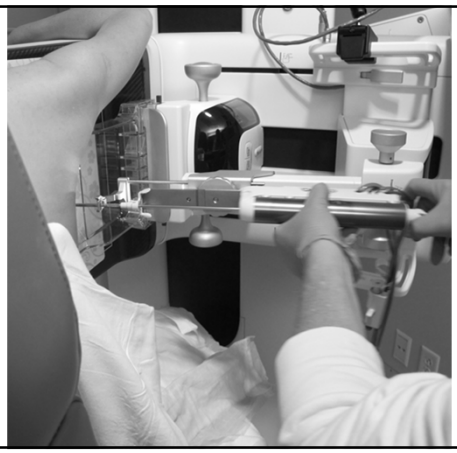

HOLOGIC

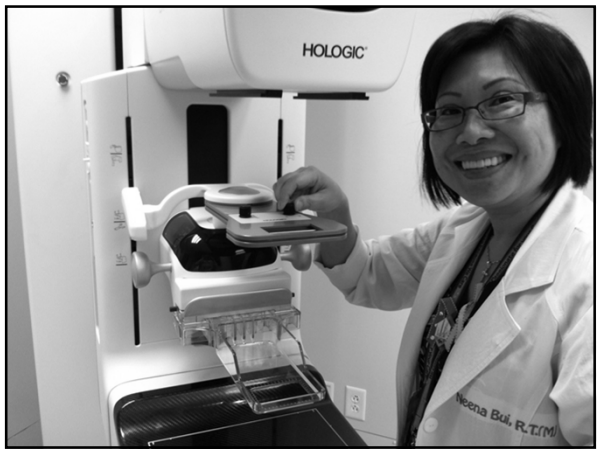

Test Patterns
Reject And Repeat Report
Connectivity
Log Viewer
Query Retrieve
Import
No Faults
Clear All Faults
X-Ray Tube, 0 Degrees
X-Ray Tube, -15 Degrees
X-Ray Tube, +15 Degrees
System Diagnostics ...
System Defaults ...
About ...

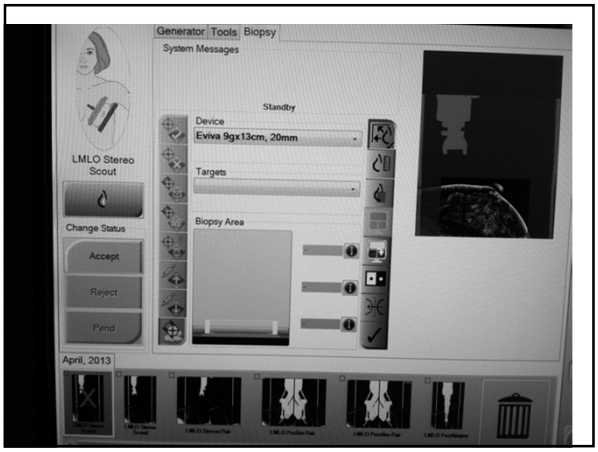

System Messages
Standby
Device
Eviva 9gx13cm, 20mm
Targets
Biopsy Area
RLM Stereo Pair
Change Status
Accept
Reject
Pend
Biopsy, RLM
DAT (Manager)


System Messages
Standby
Device
Eviva 9gx13cm, 20mm
Targets
Pending
X:5.3 Y:19.5 Z:24.4
Biopsy Area
3.83mm
0mm
7.03mm
RLM Stereo Pair
Image Status
Accept
Reject
Pend
Biopsy, RLM
DAT (Manager)

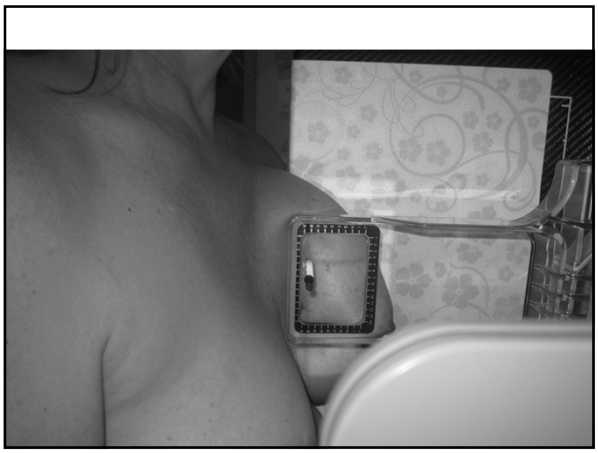

Targets
> 1: X:5.3 Y:19.5 Z:24.4
Biopsy Area
3.83mm
0mm
7.03mm
15.0mm
3.0mm

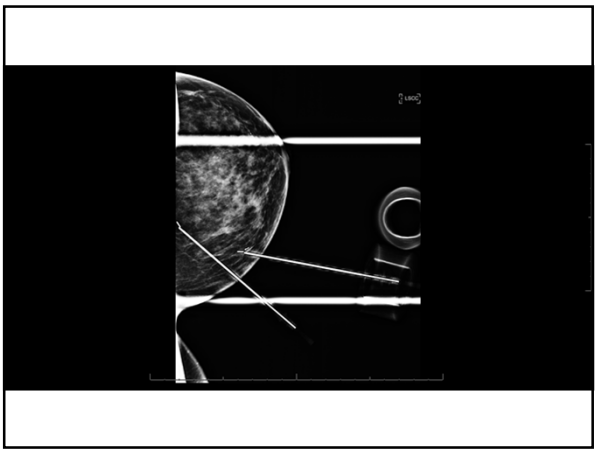


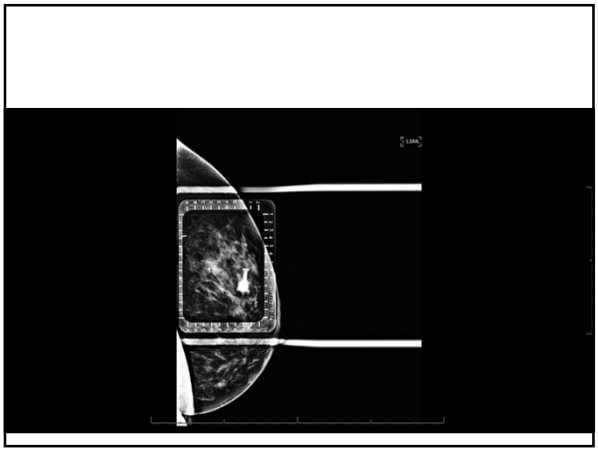


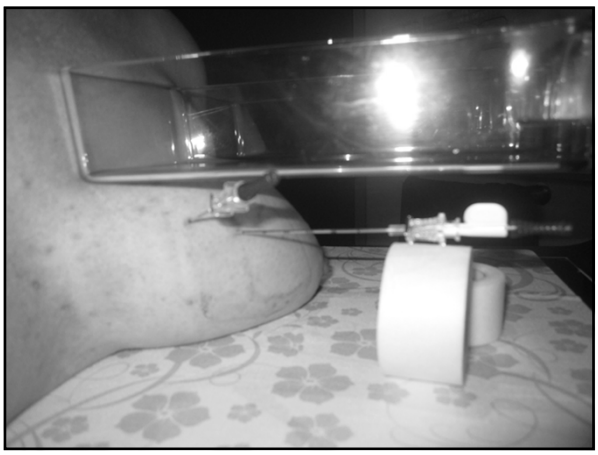


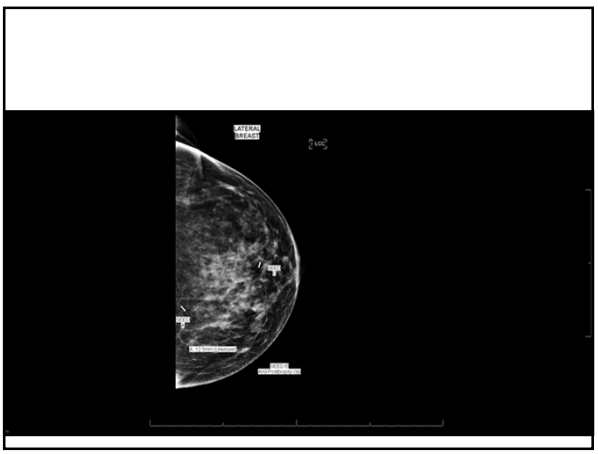
Needle and Seed Localizations

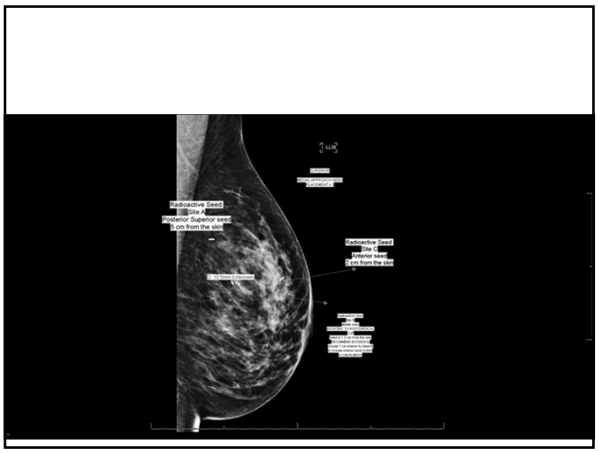


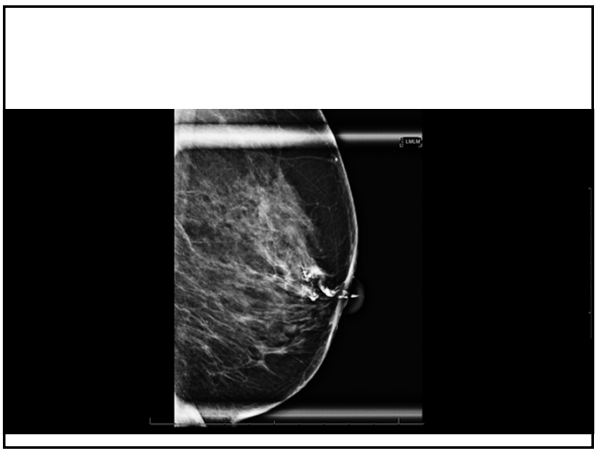


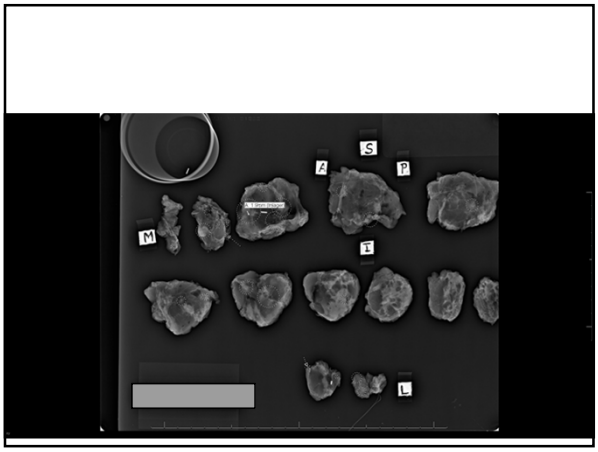


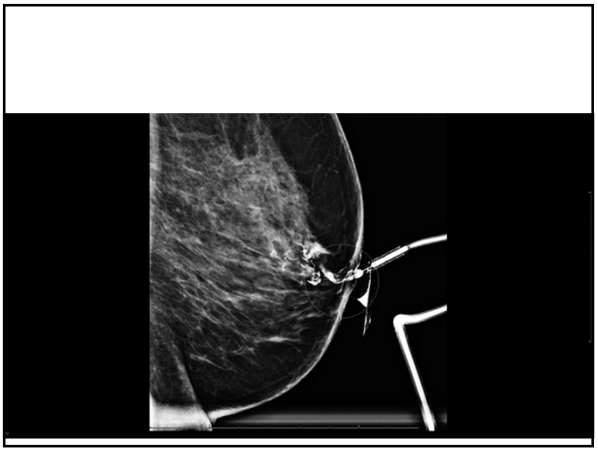




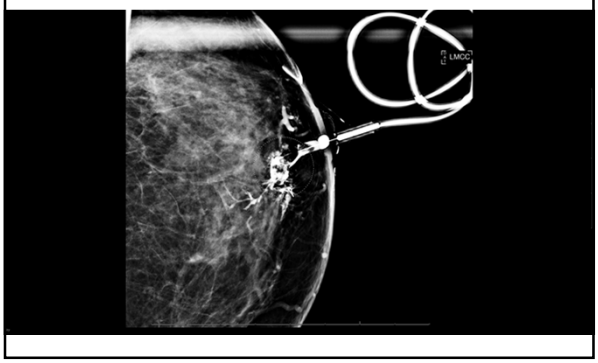








Ductograms



Breast Needle Localization Tomosynthesis Mode

Procedure for Needle Localization with Tomosynthesis

1. Install a Localization Paddle, and install the Crosshair Device at the Tubehead. Be sure that the crosshair guides are out of the x-ray field.
2. Open a new procedure with a Tomo or TomoHD view for your approach.
3. Position the patient and apply compression.
4. Acquire a Tomo Scout. Make sure that the ROI is visible inside the Localization Paddle opening. If not, reposition the patient and repeat.
5. Note the Compression Thickness, and note the thickness of the excess tissue through the opening of the Localization Paddle.
6. Scroll through the reconstruction slices to identify where the lesion is best seen. Note the slice number (each slice is 1 mm in thickness).
7. Place the Acquisition Workstation crosshair on the lesion.
8. To find the coordinates for the Gantry Crosshair Device, scroll through the reconstructions until you can identify the alpha numeric coordinates.
9. Calculate the needle depth:

Example

Value	Example
Breast Compression Thickness	50 mm
(+) Thickness of the tissue through the opening of the paddle	+ 7 mm
(-) Slice number where the lesion is found	- 30 mm
(+) Optional distance past the ROI for the wire	+ 5-15 mm
(=) Needle depth of the localization wire	32– 42 mm

line rather then from paddle
50 thickness plus 7 bulge = 57 – 30 = 27

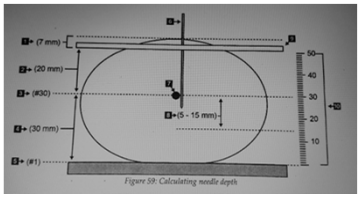
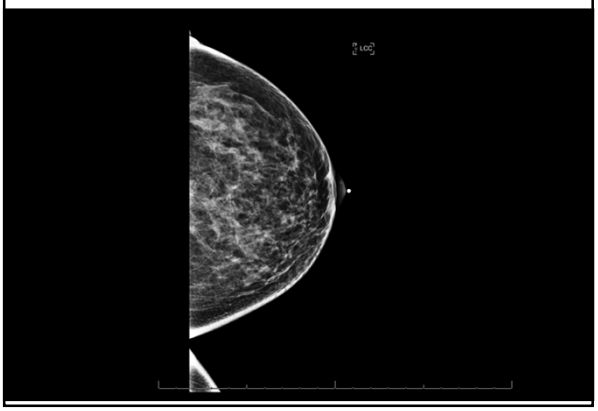
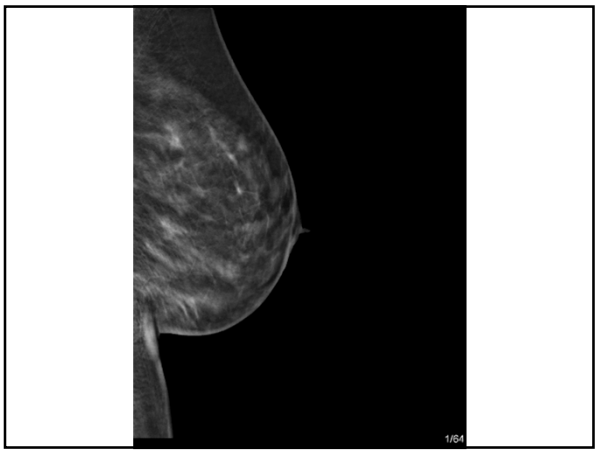


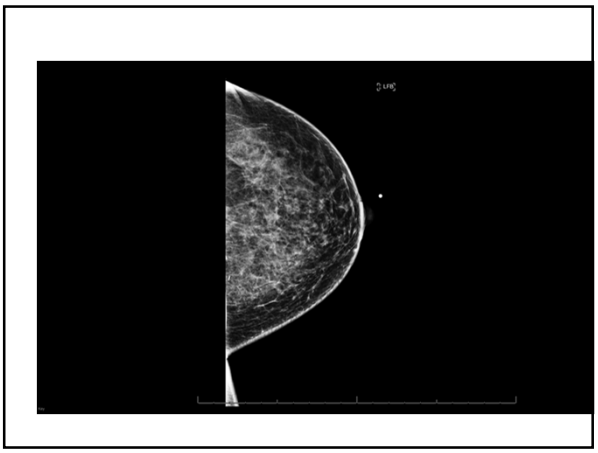
Figure 59: Calculating needle depth

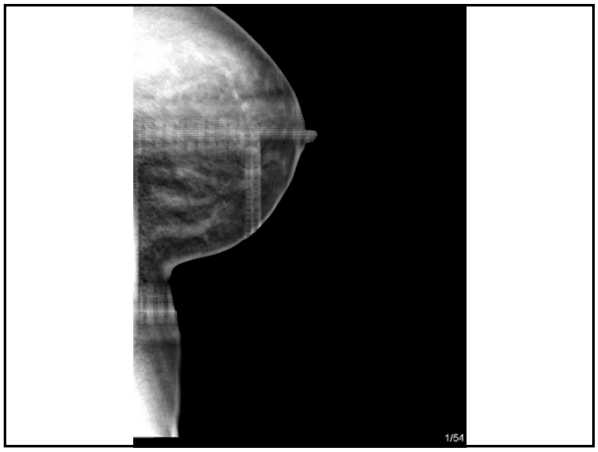
10. Turn on the collimator light and align the Crosshair Device at the Tubehead to match the Acquisition Workstation crosshair.
11. Position and insert the needle.
12. Move the Crosshair Device guides out of the x-ray field.
13. Acquire another Tomo image to be sure that the needle is in the correct location. To calculate if a correction is necessary, compare the slice number of the point of the needle and the slice number of the lesion.
14. Insert the guide wire through the needle, and then remove the needle, if desired, leaving the wire in position.
15. If desired, complete the following steps:
    a. Acquire a Conventional or Tomo view to be sure of correct wire placement.
    b. Take the orthogonal view to document wire or needle placement (either in Tomo or conventional).
16. Only add one view icon at a time for orthogonal views to remove the possibility of paddle shift due to possible minimal compression.

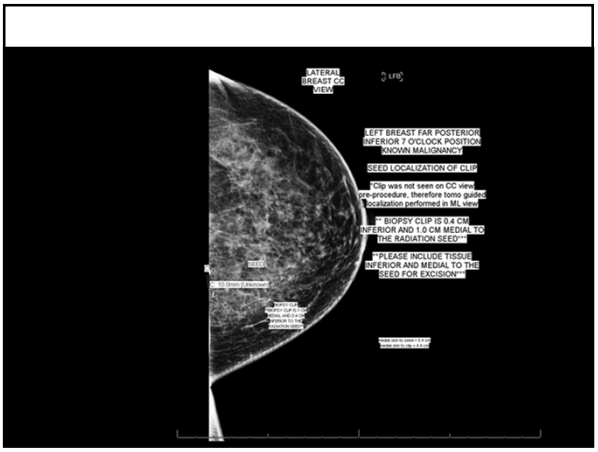
Item	Description	Example
1	Thickness of the tissue through the opening of the localization paddle	7 mm
2	Thickness measured from the localization paddle to the lesion	
3	Lesion slice number (the slice number where lesion is best seen (clearest))	30 mm
4	Thickness measured from the detector to the lesion	
5	Slice number 1	
6	Needle	
7	Lesion	
8	Advancing the needle 5 - 15 mm more than the lesion (optional)	5 - 15 mm
9	Localization paddle	
10	Thickness of the breast compression from the detector (0 mm) to the localization paddle (50 mm in this example)	50 mm

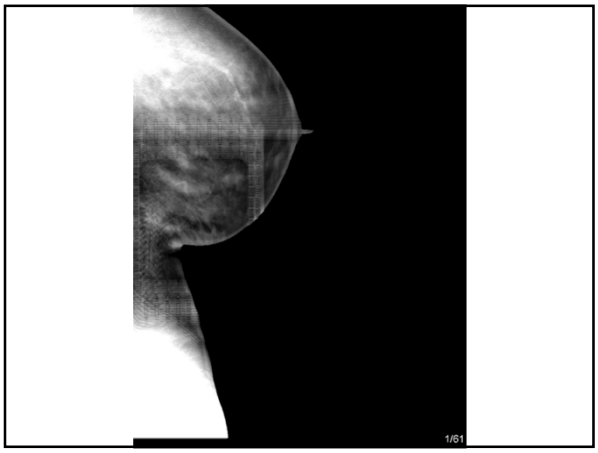


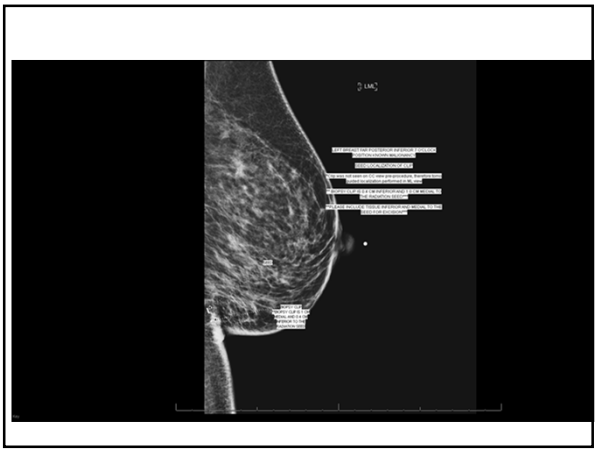

1/64


LATERAL
BREAST CC
VIEW
LEFT BREAST FAR POSTERIOR
INFERIOR 7 O'CLOCK POSITION
KNOWN MALIGNANCY
SEED LOCALIZATION OF CLIP
**Clip was not seen on CC view
pre-procedure, therefore tomo guided
localization performed in ML view**
**BIOPSY CLIP IS 0.4 CM
INFERIOR AND 1.0 CM MEDIAL TO
THE RADIATION SEED***
**PLEASE INCLUDE TISSUE
INFERIOR AND MEDIAL TO THE
SEED FOR EXCISION**


1/54




1/61



Edit a View…you know!!

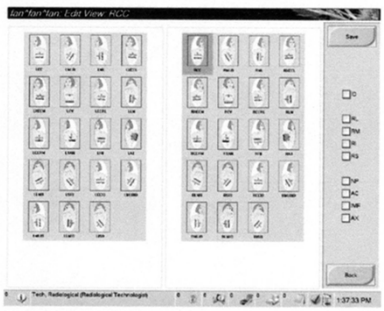
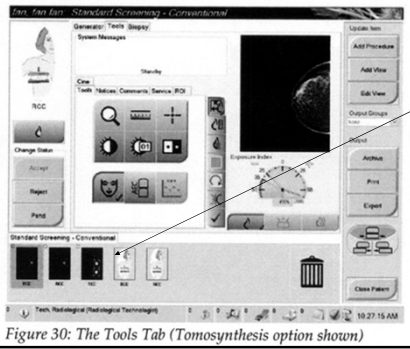


Figure 26: The Edit View Screen

Tomosynthesis Imaging Sequence of Events

- Wait for the image reconstruction to complete
- Review projection slices for motion
- Accept, reject or pend the images

Reviewing the Images



Select any thumbnail image to display that image in the preview screen

Figure 30: The Tools Tab (Tomosynthesis option shown)

- Reject
- pend

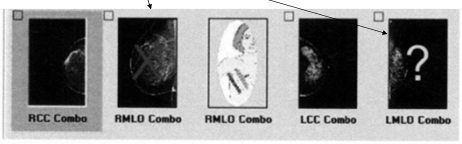
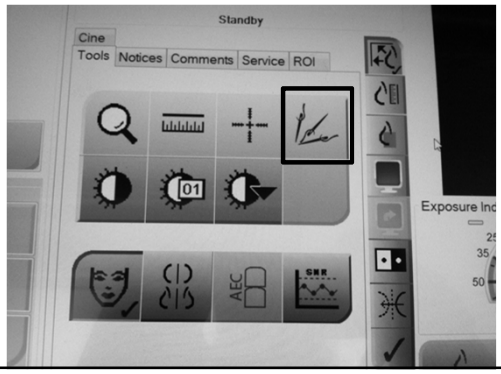


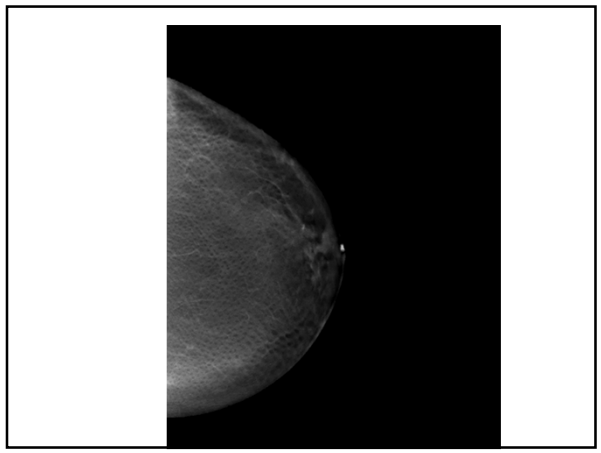
Figure 31: Marked Images in a Procedure (Tomosynthesis option shown)

Conventional Imaging Sequence of Events

- Review the image after exposure
- Review the conventional image for motion
- Accept, reject or pend the images

Upgrade 4/2013





The Notices Tab

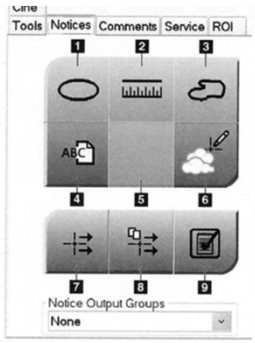


Figure Legend

1. Draw an Oval marking on the image.
2. Measure a distance on the image.
3. Draw a Freehand marking on the image.
4. Add a text note to the image without a marking.
5. Future use.
6. Show or hide the Notice Markings and Annotations.
7. Send the Notice for the current image to the selected destination.
8. Send the Notices for all images in the opened study to the selected destination.
9. Change the Patient's Notices status to viewed.

Figure 33: The Notices Tools Tab

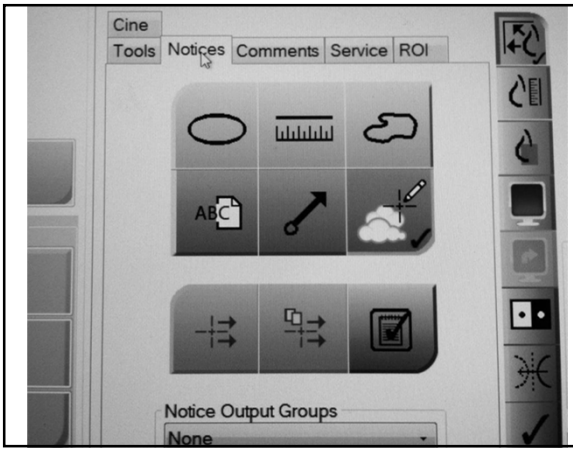


Image Review Tools Tab

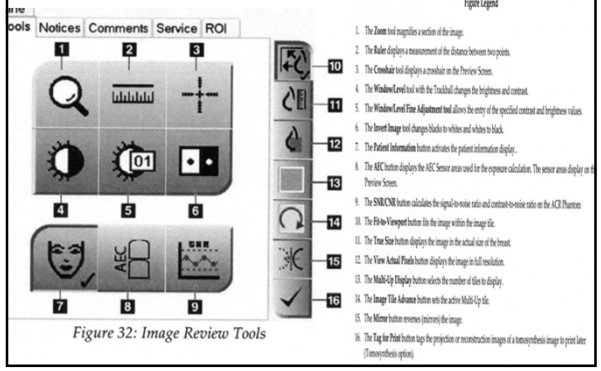


Figure Legend

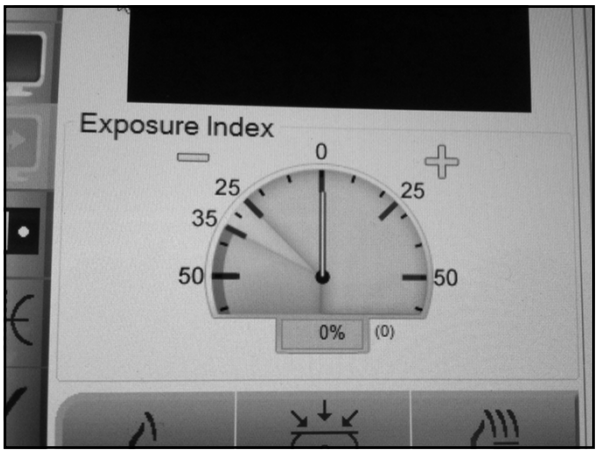
1. The **Zoom** tool magnifies a section of the image.
2. The **Ruler** displays a measurement of the distance between two points.
3. The **Crosshair** tool displays a crosshair on the Preview Screen.
4. The **Window/Level** tool with the Trackball changes the brightness and contrast.
5. The **Window/Level Fine Adjustment tool** allows the entry of the specified contrast and brightness values.
6. The **Invert Image** tool changes blacks to whites and whites to black.
7. The **Patient Information** button activates the patient information display.
8. The AEC button displays the AEC Sensor areas used for the exposure calculation. The sensor areas display on the Preview Screen.
9. The **SNR/CNR** button calculates the signal-to-noise ratio and contrast-to-noise ratio on the ACR Phantom
10. The **Fit-to-Viewport** button fits the image within the image tile.
11. The **True Size** button displays the image in the actual size of the breast.
12. The **View Actual Pixels** button displays the image in full resolution.
13. The **Multi-Up Display** button selects the number of tiles to display.
14. The **Image Tile Advance** button sets the active Multi-Up tile.
15. The **Mirror** button reverses (mirrors) the image.
16. The **Tag for Print** button tags the projection or reconstruction images of a tomosynthesis image to print later (Tomosynthesis option).

Figure 32: Image Review Tools

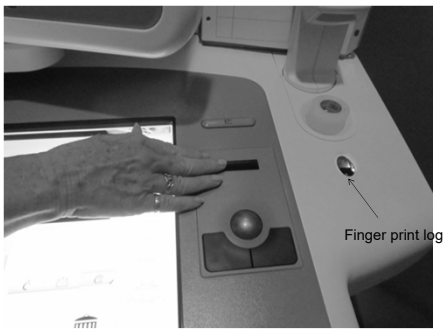
Exposure Index

- An image quality guide
- When the exposure index indicated the red or yellow area you must review the image for noise and make a decision about a retake

Figure 36: Exposure Index



Scroll for Tomo images



Display Modes (tomosynthesis option)

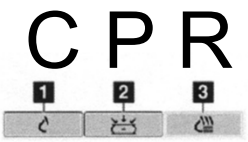
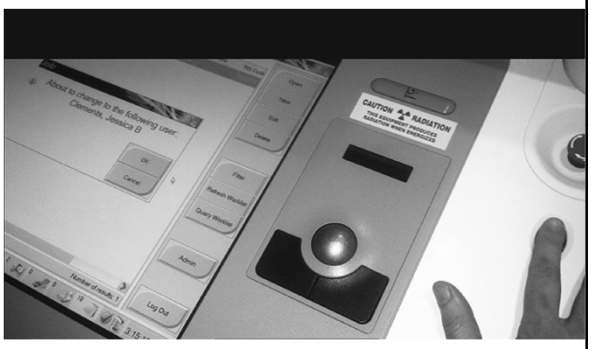


Figure 37: Exposure Index

Figure Legend

1. Conventional button
2. Projections button
3. Reconstruction button



Administrative Screen

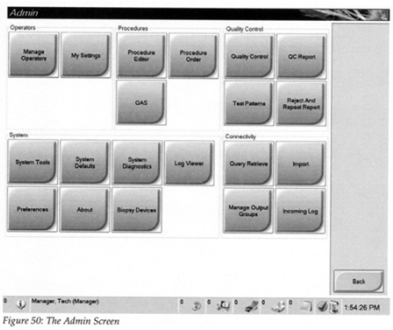
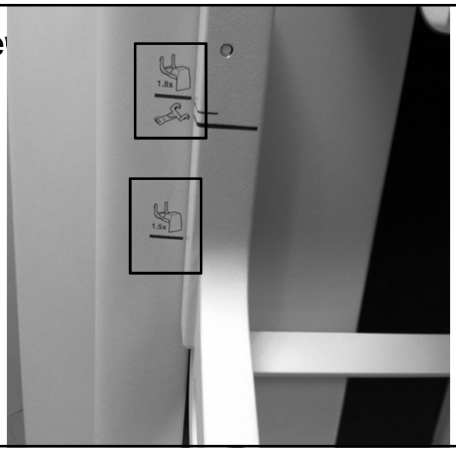


Figure 50: The Admin Screen

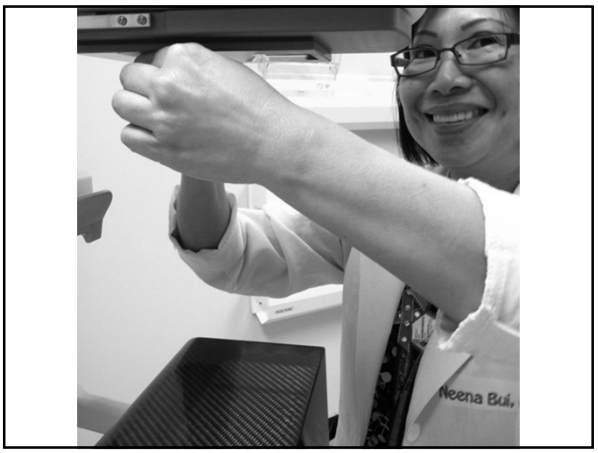
- You must have permissions to access all features. The permission level controls the functions you can change.

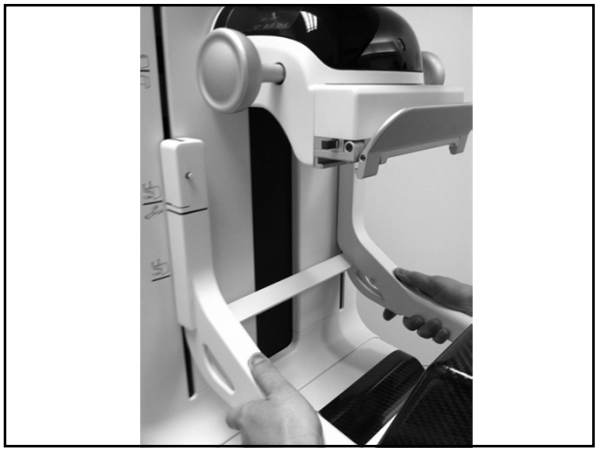
Optional mouse on screen

Ne

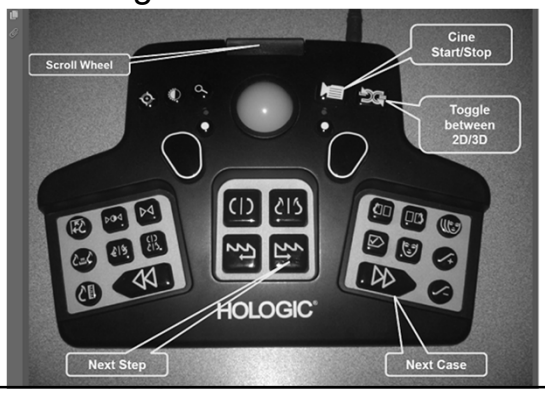


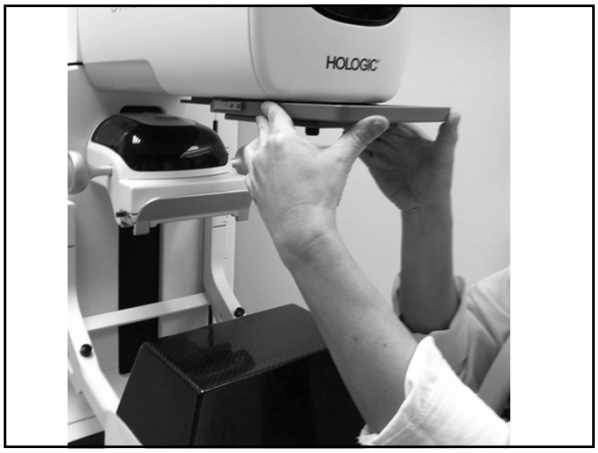
Keyboard

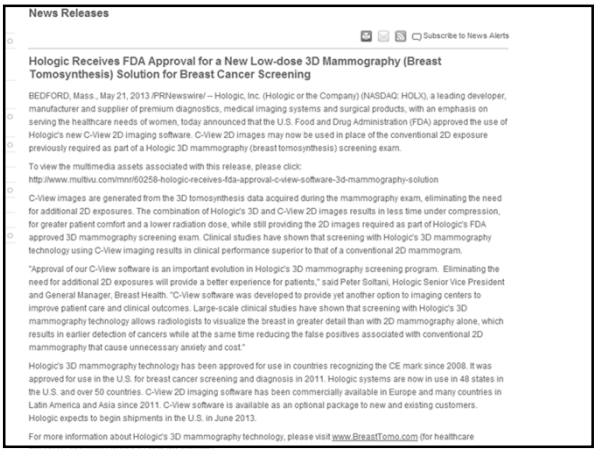




Radiologist Review Workstation







News Releases

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Hologic Receives FDA Approval for a New Low-dose 3D Mammography (Breast Tomosynthesis) Solution for Breast Cancer Screening

BEDFORD, Mass., May 21, 2013 /PRNewswire/ -- Hologic, Inc. (Hologic or the Company) (NASDAQ: HOLX), a leading developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products, with an emphasis on serving the healthcare needs of women, today announced that the U.S. Food and Drug Administration (FDA) approved the use of Hologic's new C-View 2D imaging software. C-View 2D images may now be used in place of the conventional 2D exposure previously required as part of a Hologic 3D mammography (breast tomosynthesis) screening exam.

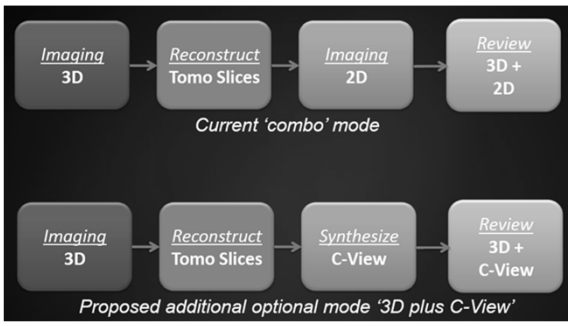
To view the multimedia assets associated with this release, please click: http://www.multivu.com/mnr/60258-hologic-receives-fda-approval-c-view-software-3d-mammography-solution

C-View images are generated from the 3D tomosynthesis data acquired during the mammography exam, eliminating the need for additional 2D exposures. The combination of Hologic's 3D and C-View 2D images results in less time under compression, for greater patient comfort and a lower radiation dose, while still providing the 2D images required as part of Hologic's FDA approved 3D mammography screening exam. Clinical studies have shown that screening with Hologic's 3D mammography technology using C-View imaging results in clinical performance superior to that of a conventional 2D mammogram.

"Approval of our C-View software is an important evolution in Hologic's 3D mammography screening program. Eliminating the need for additional 2D exposures will provide a better experience for patients," said Peter Soltani, Hologic Senior Vice President and General Manager, Breast Health. "C-View software was developed to provide yet another option to imaging centers to improve patient care and clinical outcomes. Large-scale clinical studies have shown that screening with Hologic's 3D mammography technology allows radiologists to visualize the breast in greater detail than with 2D mammography alone, which results in earlier detection of cancers while at the same time reducing the false positives associated with conventional 2D mammography that cause unnecessary anxiety and cost."

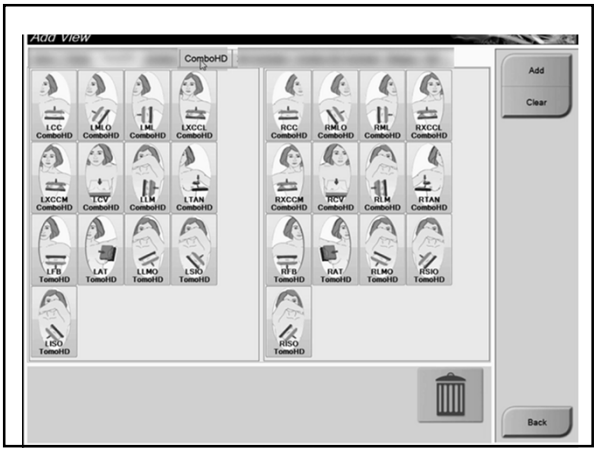
Hologic's 3D mammography technology has been approved for use in countries recognizing the CE mark since 2008. It was approved for use in the U.S. for breast cancer screening and diagnosis in 2011. Hologic systems are now in use in 48 states in the U.S. and over 50 countries. C-View 2D imaging software has been commercially available in Europe and many countries in Latin America and Asia since 2011. C-View software is available as an optional package to new and existing customers. Hologic expects to begin shipments in the U.S. in June 2013.

For more information about Hologic's 3D mammography technology, please visit www.BreastTomo.com (for healthcare



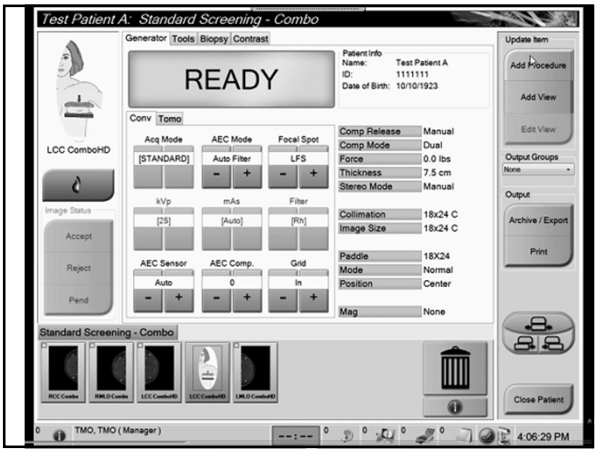
System Changes

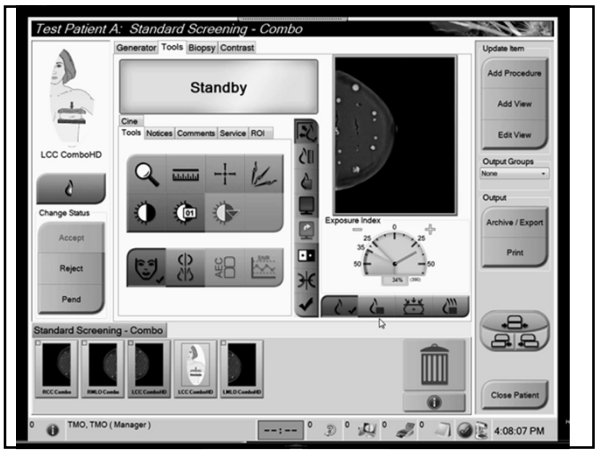
- The synthesized 2D algorithm is a software module
- New 3D plus C-View mode is an **option**
- Optional mode available along with existing 2D plus 3D modes

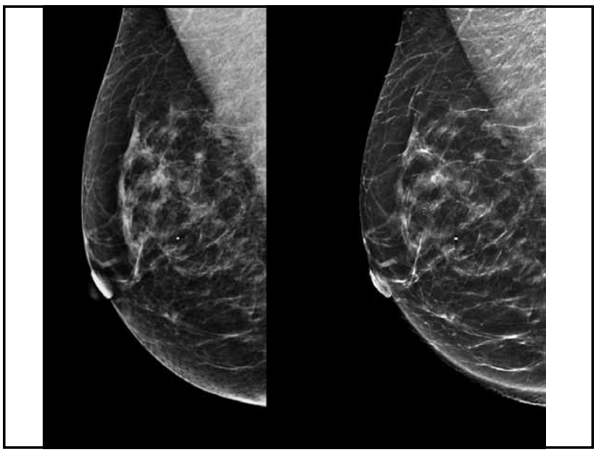


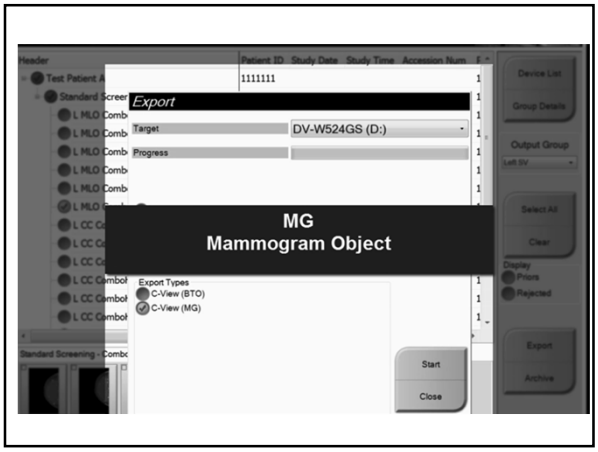
Similar to MIP in MRI

- Maximum intensity projection
- Mapping that gives more contrast to certain objects in the breast
- Like masses and calcifications
- Enhances the objects.
- Projects the voxels with the most information and enhances the images with the highest detail.

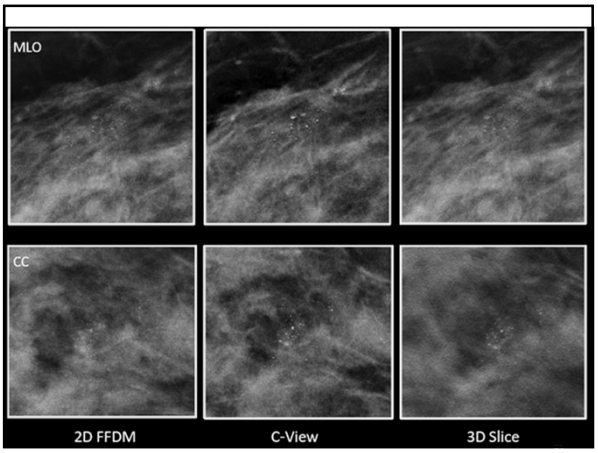


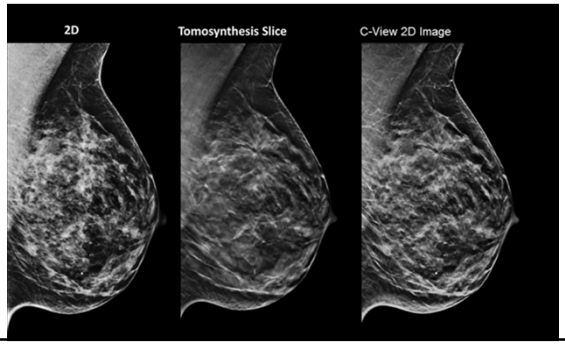

Test Patient A: Standard Screening - Combo
Standby
Add Procedure
Add View
Edit View
Archive / Export
Print
Close Patient
Accept
Reject
Pend
Standard Screening - Combo




Export
Target
DV-W524GS (D:)
Progress
MG
Mammogram Object
Export Types
C-View (BTO)
C-View (MG)
Start
Close


There Are
No
Changes To QC


MLO
CC
2D FFDM
C-View
3D Slice



There are technical challenges to creating a synthesized 2D image that is close in quality to that of a true 2D image, however much progress has been made in this area.

Gur has studied the performance of an early version of synthesized 2D in a pilot study.30 He concluded that a minor improvement in the quality of a synthesized 2D image could lead to an acceptable diagnostic quality and eliminate the need for acquiring both a 2D and tomo dataset during tomosynthesis based screening.

The C-View software was introduced for sale throughout the European Economic Area and in other countries recognizing the CE Mark.

This approach would provide the advantage of reducing the number of exposures, leading to slightly shorter exam times and reduced patient dose.

The dose would be approximately half the dose of a 2D plus tomo exam, and approximately the same as a 2D exam alone This could be an important evolution of this technology, especially in dose-sensitive regions.

This is certainly promising and offers the possibility of providing the improved performance gain of two-view breast tomosynthesis with doses comparable to current 2D mammography levels.

The algorithms to create such a synthesized image that approximate the necessary components of the true 2D involve smart summing of the individual slices that make up the tomosynthesis image set.

In clinical use, the synthesized 2D image will be reviewed together with the tomosynthesis image set.

Tomosynthesis Computer-Aided Detection (CAD)

Just as in conventional 2D digital mammography, CAD may help find suspicious objects in a tomosynthesis dataset.

However, there are differences in the use for CAD in tomosynthesis.

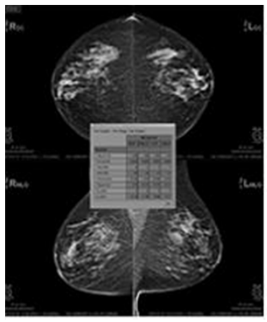
Conventional 2D CAD helps find both masses and microcalcifications.

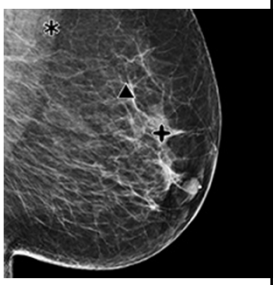
In tomosynthesis, there may be less of a need for a mass-detection algorithm, because often the masses and distortions are found very quickly and easily by the human observer.

The situation is different in the case of microcalcifications. It can be time consuming to have to carefully search a large number of slices, and there is the potential for the reviewer to overlook some subtle microcalcifications.

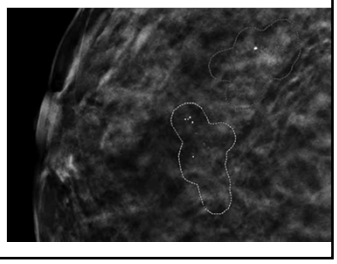
An efficient and sensitive calcification CAD algorithm could help speed up the search.

For example, CAD could identify suspicious calcification clusters on a scout image and rapidly navigate to the appropriate slices of interest.



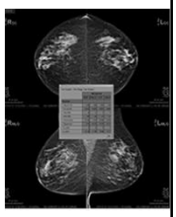


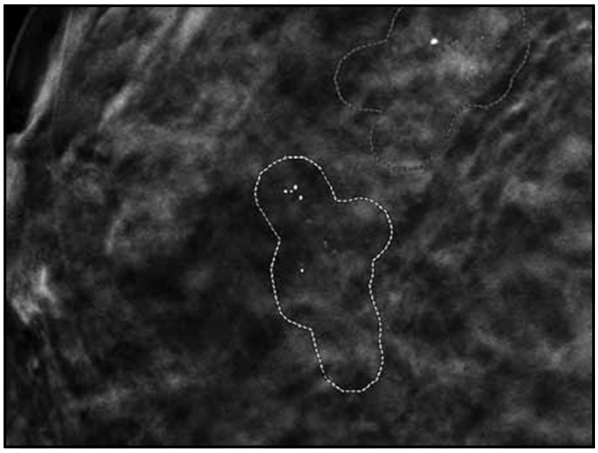
An example of a CAD algorithm marking potentially suspicious microcalcifications on a single slice from a tomo study.



R2 Image metrics

- Number of calcifications
- Size (Long Axis)
- Distance to nipple
- Distance to chest wall
- Measure of density
- Degree of spiculations
- Contrast
- CAD Operating Point





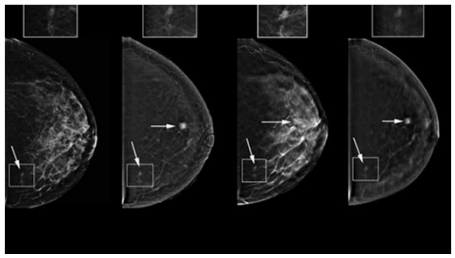
Hologic has developed an extension to its Image Checker® CAD product line for identification of potential calcifications in tomosynthesis slices.

ImageChecker 3D Calc CAD is available in Canada and throughout the European Economic Area and in other countries recognizing the CE Mark.

Contrast Enhanced Breast Imaging

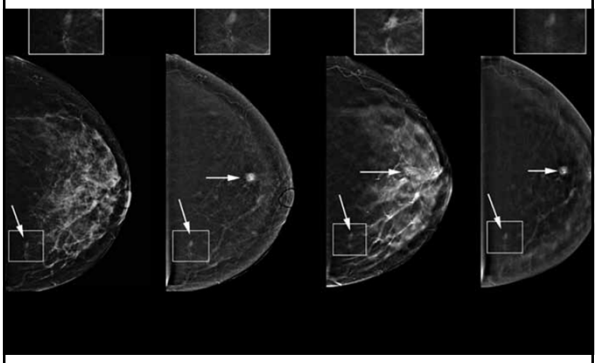
Contrast enhanced breast imaging is a procedure that images the distribution of an iodinated contrast agent using either 2D or tomosynthesis x-ray imaging technologies.

This technology is in its early evaluation stage but may offer some advantages relative to contrast breast MRI in terms of reduced cost, comparable care to patients for whom MRI is contraindicated, and access to patients in areas where MRI systems are not available.



CONTRAST IMAGING: This study of 2D and tomosynthesis iodine contrast mammography was acquired under a single compression. The proven cancer in the subareolar breast (horizontal arrow) is not visible on the enhanced 2D mammogram except for the clips placed at biopsy but is easily seen on the 2D and tomosynthesis dual energy contrast images. Contrast imaging led to the detection of an additional cancer in the far medial breast (downward arrow.) The tomosynthesis image shows the irregular shape of the lesion, making it highly likely that the lesion is malignant.

Contrast enhanced breast imaging combines functional information from the distribution of the contrast agent and morphological information from the x-ray images.



Hologic is investigating this technology using a dual modality system, capable of imaging the functional 2D contrast uptake and the morphological tomosynthesis image in rapid sequence, and combining these two image sets into a single fused study.

In the fused study, the 2D or tomo contrast image can identify potential lesions based on their physiological state which causes increased contrast agent uptake.

The standard tomo image can then be overlaid and provide morphological information on the lesion, such as improved visibility of associated spiculations.

Conclusions

Tomosynthesis is an exciting new technology that will likely revolutionize mammography.

It offers the potential for improvements in both screening and diagnostic evaluations.

The improvements in clinical performance, compared to 2D mammography, are significant.

Hologic's clinical study results demonstrate that 2D mammography plus tomo can offer either improved cancer detection rate, or reduced recall rate, or both, compared to 2D alone.

Conclusions

These are certainly very positive results, and are much stronger than the ACRIN DMIST study results which compared the performance of digital to screen-film mammography, and found no average difference in performance between the two technologies.

Reader studies considered by the FDA advisory panel using the Hologic breast tomosynthesis system demonstrated superior performance in the detection of masses and architectural distortions and equivalent or slightly better performance in the detection of microcalcifications in using 2D plus tomo imaging compared to 2D alone.

- Let's go to the case studies.....

Conclusions

There is a growing body of evidence that tomosynthesis has the potential to reduce the number of exposures needed for diagnostic imaging and provide other diagnostic benefits including enhanced performance in assessing tumor size and stage and more clearly demonstrating margins and extent of lesions.

Conclusions

Future advances in tomosynthesis include CAD algorithms to facilitate the rapid identification of suspicious clusters of calcifications, development of a synthesized 2D image to reduce the number of exposures in an exam while still providing a 2D-equivalent image for ease of review, and contrast enhanced imaging for patients where access to breast MRI is limited or contraindicated.