



Breast Tomosynthesis

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Hologic Inc.

Presented by **Hologic Medical Education**

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Breast Cancer Fact

1 in 8

This is the lifetime risk of a woman in the United States
of developing breast cancer

There is no way to prevent breast cancer

Breast Cancer Fact

However –

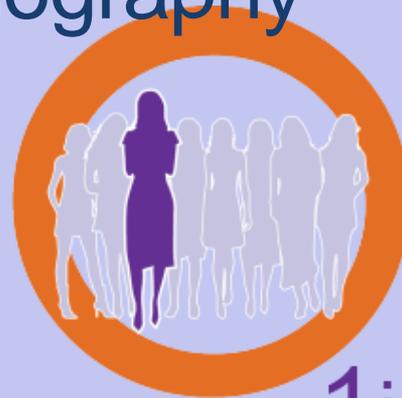
if found early, 98% will survive

- When breast cancer is detected before it has spread to the lymph nodes, **the five year survival rate is**
 - 98%
- This makes Screening the best tool in the fight against breast cancer.

The Challenge of Mammography



The American Cancer Society recommends women age 40 and older should have a screening mammogram every year



1 in 8

12% of women in the US will develop breast cancer during their lifetime

Traditional digital mammography is one of the most advanced technologies available today, but it has some limitations. For every...

1000

WOMEN
SCREENED

100

CALLED
BACK

20

BIOPSIED

4

CANCERS
FOUND

1

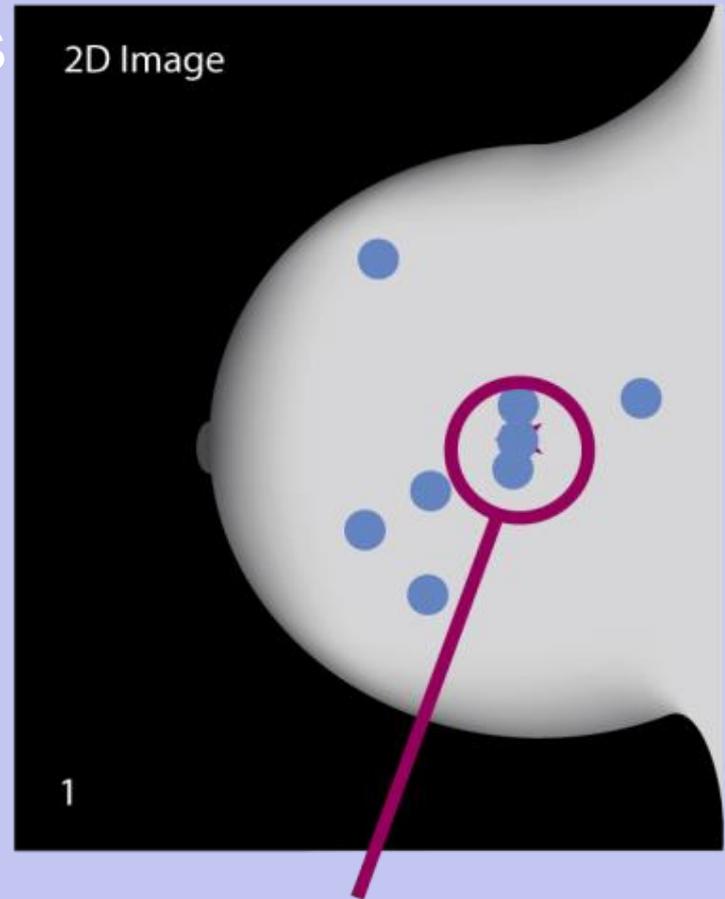
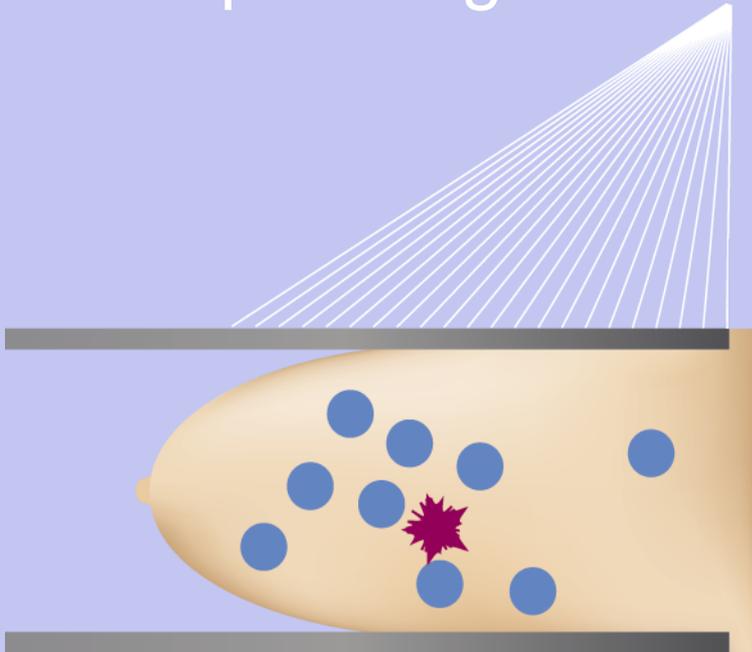
CANCER
MISSED

HOLOGIC

Why is There a Need for Tomosynthesis?

In 2D FFDM:

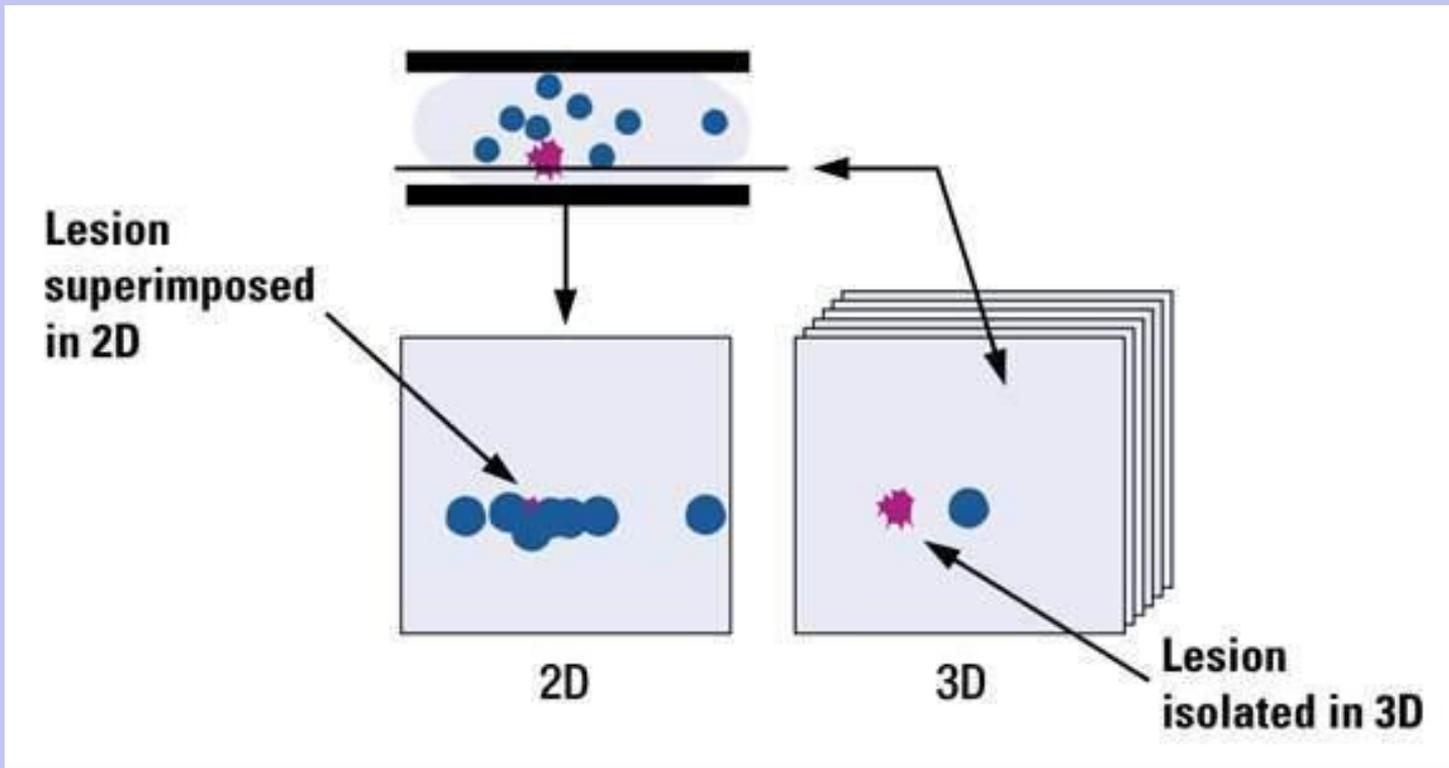
- Tissue superimposition hides pathologies in 2D
- Tissue superimposition mimics pathologies in 2D



Lesion Superimposed in 2D

Digital Breast Tomosynthesis

a three-dimensional mammographic examination that can minimize the effects of structure overlap within the breast



Digital Breast Tomosynthesis Status



Hologic
FDA approved
February 2011



GE Medical Systems
FDA approved –
August 2014



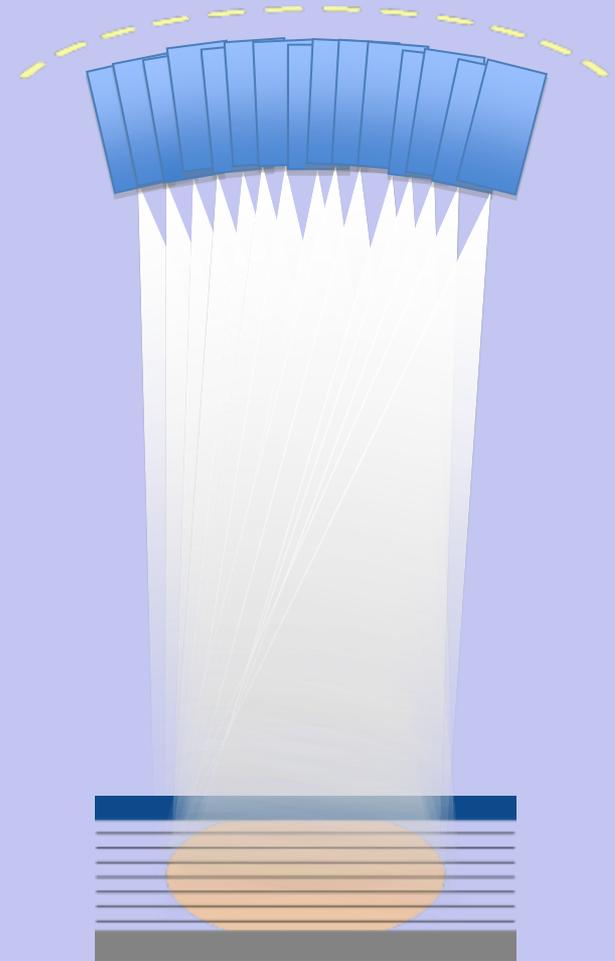
Siemens Medical
Systems Approved
April 2015

Tomosynthesis Protocols

- Hologic
 - Approved for 2D CC and MLO
 - Approved for 3D CC and MLO
- GE
 - Approved for 2D MLO
 - Approved for 3D CC
- Siemens
 - Unknown at this time

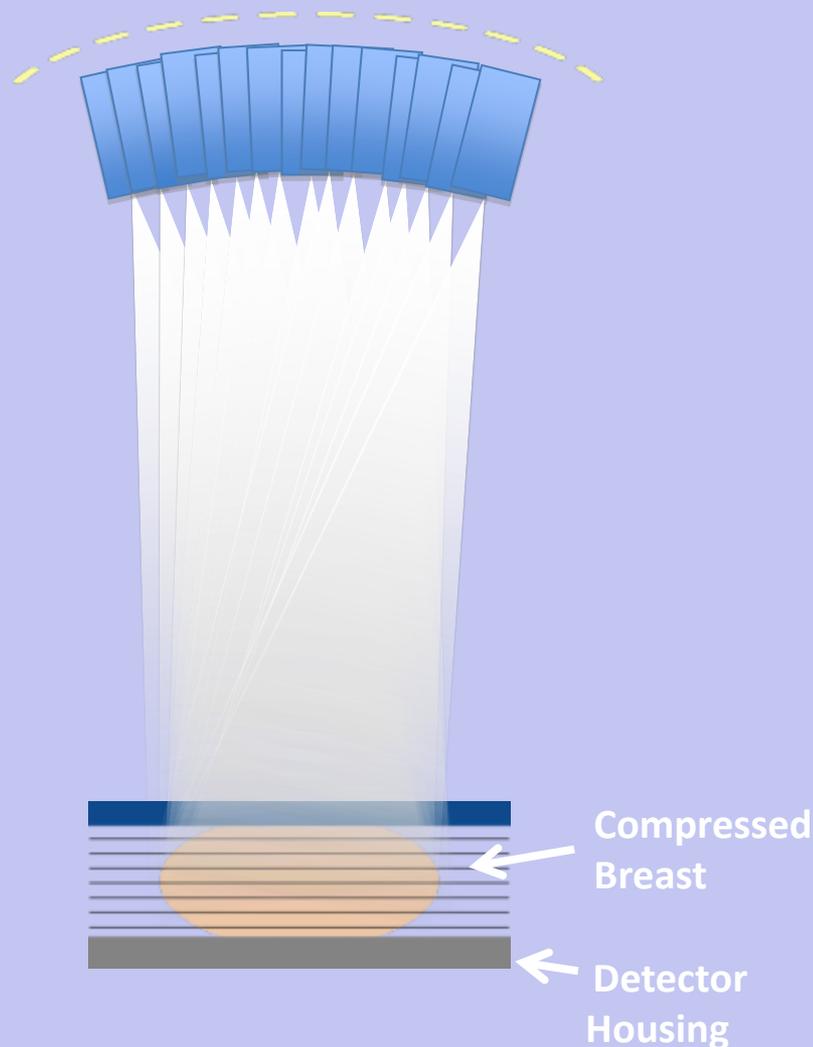
3D Mammography

- Preserves the very high resolution of a 2D FFDM
- Multiple images of the breast are acquired at different angles during a sweep of the x-ray tube
- Allows radiologists to see around overlapping structures



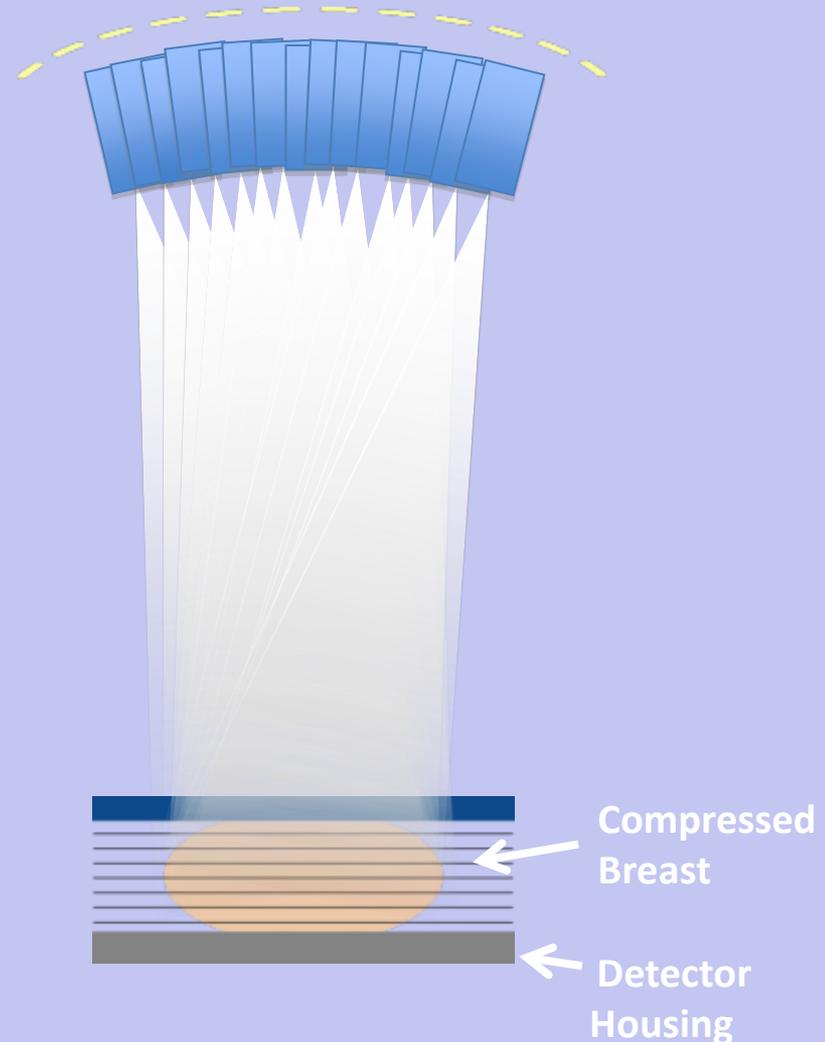
Hologic 3D Mammography

- Tube moves in a 15° arc
- 15 low dose images are acquired
 - 1 image at each degree
 - Four second sweep
- Images are reconstructed into 1 mm slices



3D Mammography

- Tube moves in an arc
 - GE 25° sweep
 - Siemens 50° sweep
- low dose images are acquired
 - GE 9 images
 - Siemens 25 images
- Images are reconstructed into .5 or 1 mm slices



Benefits of Tomosynthesis

Increased breast cancer detection

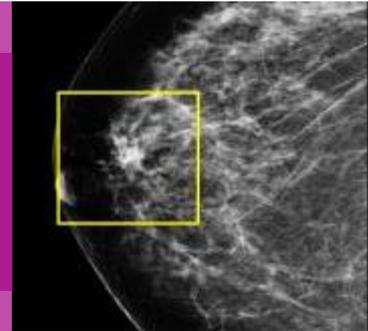
Decreased workup rate for non-cancer cases

Tomosynthesis

Improved lesion margin visibility

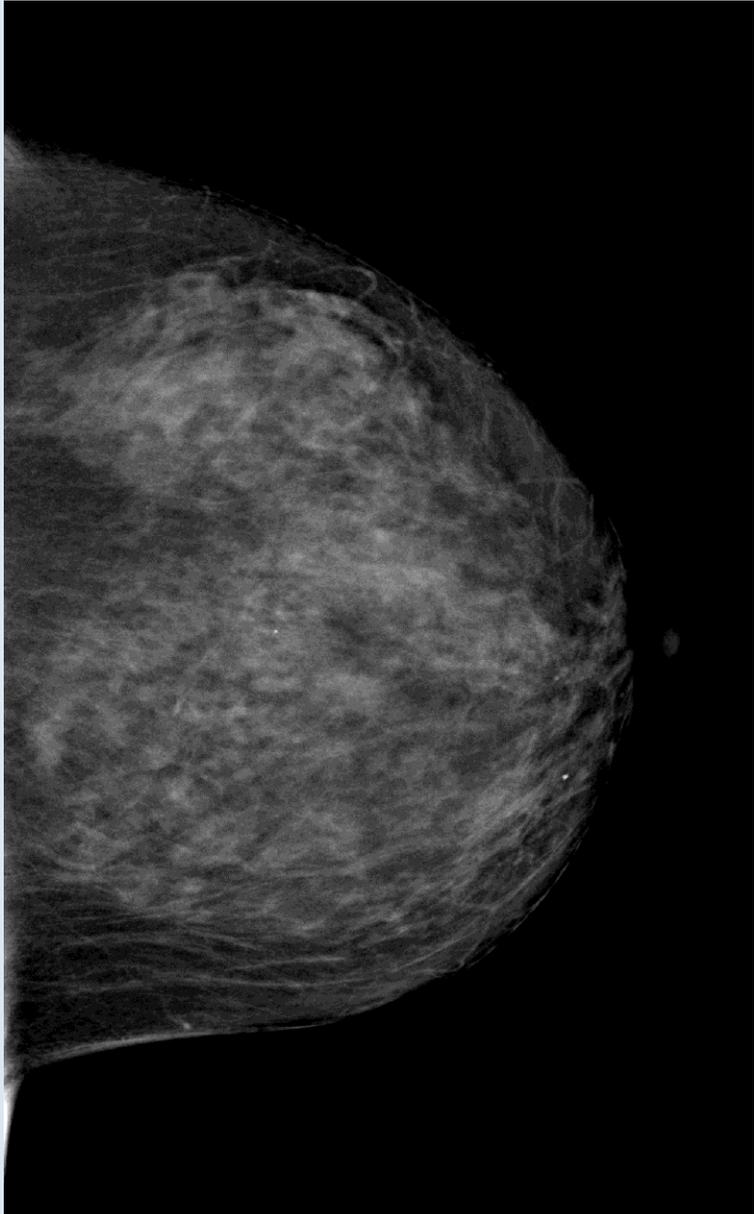
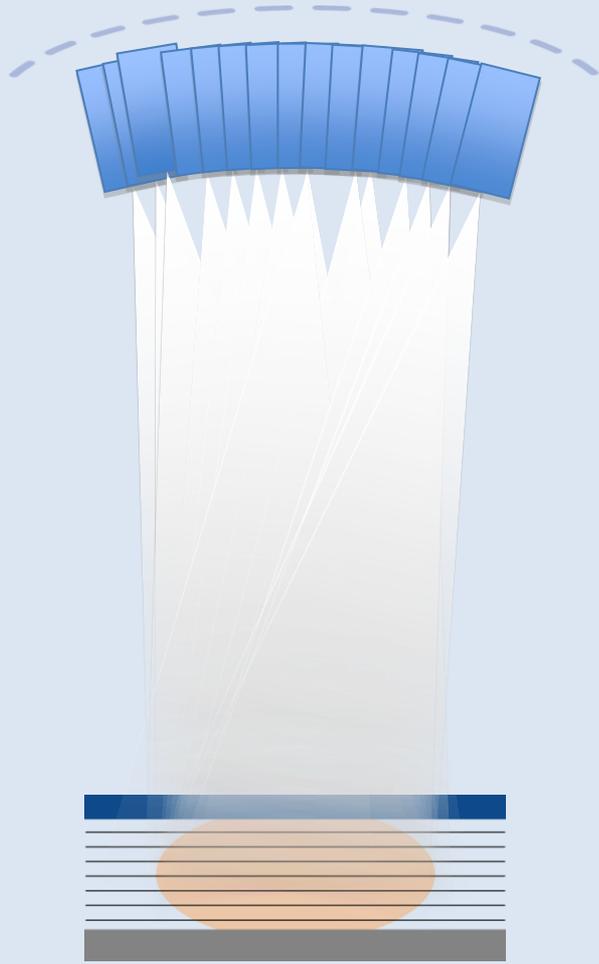
Precise lesion localization

Combo Mode Acquisition 2D and 3D



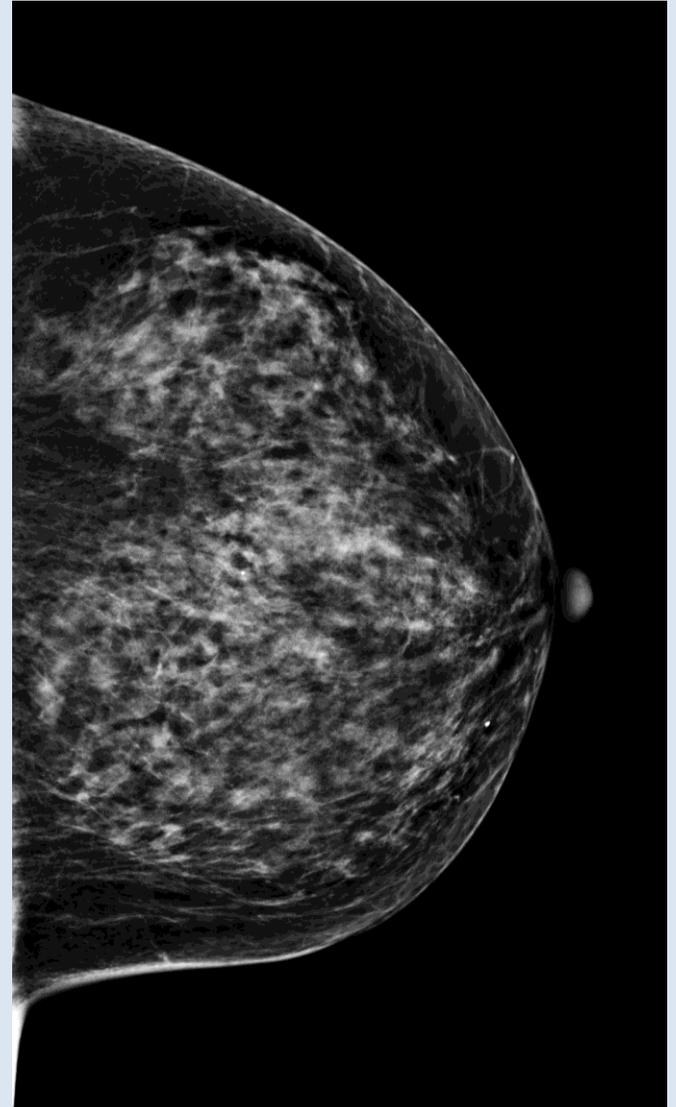
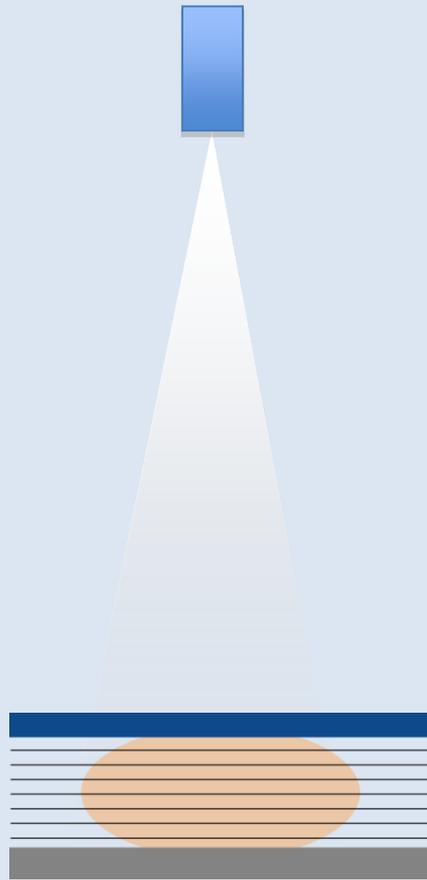
Combo Acquisition - Tomosynthesis

Arc of motion of x-ray tube, showing individual exposures

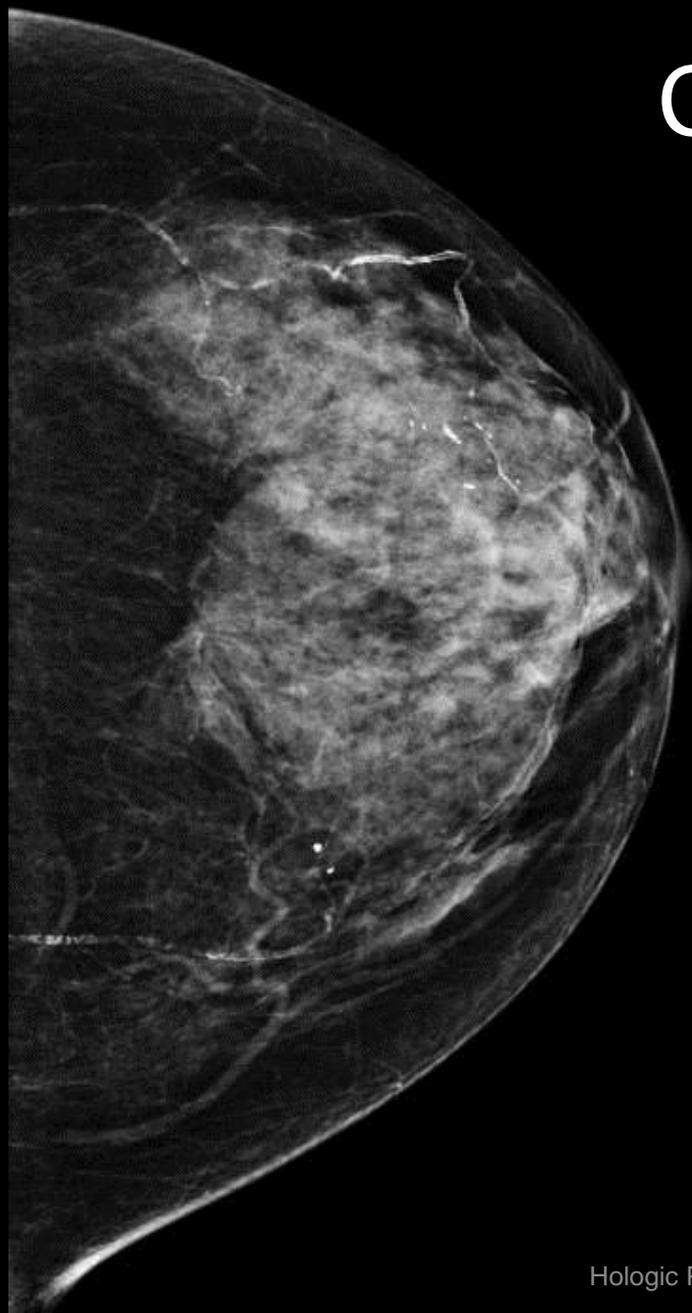


Combo Acquisition – 2D

Finishing with the 2D exposure

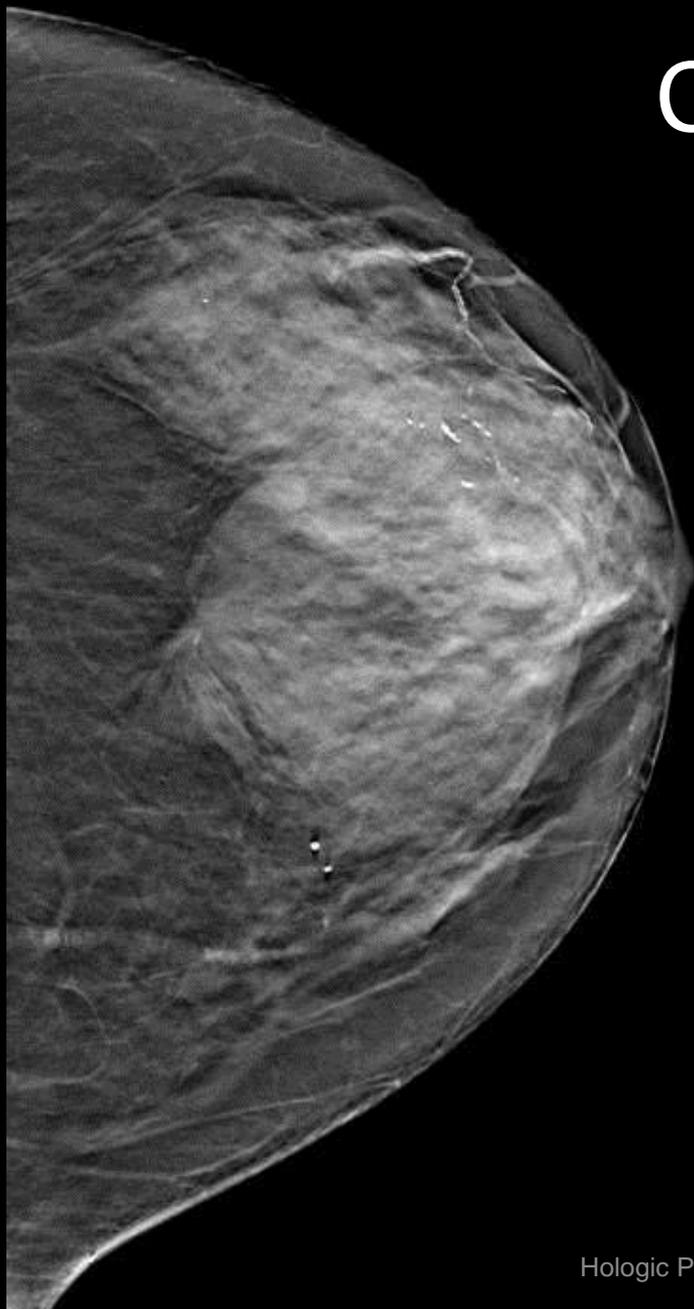


Co-registered



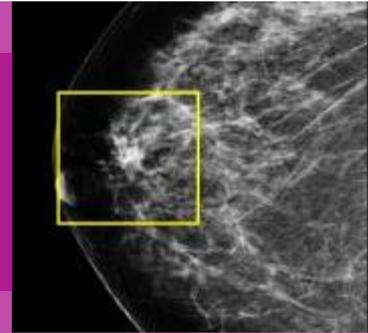
2D

Co-registered

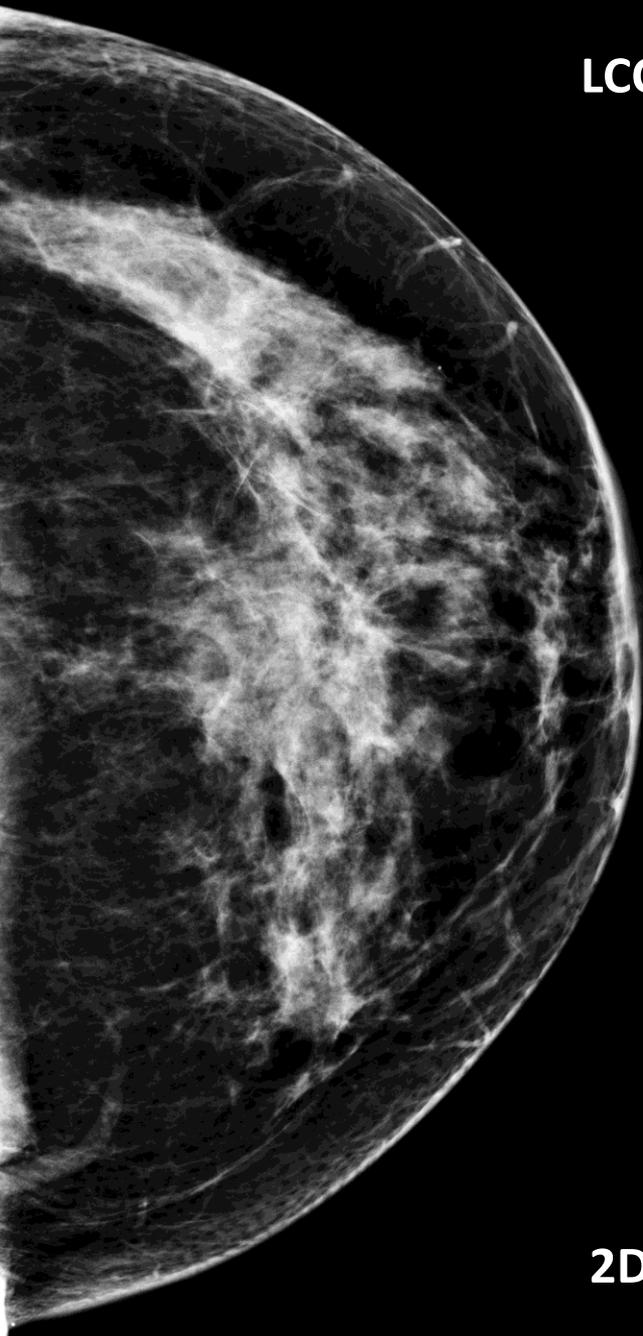


Tomosynthesis

Example Cases

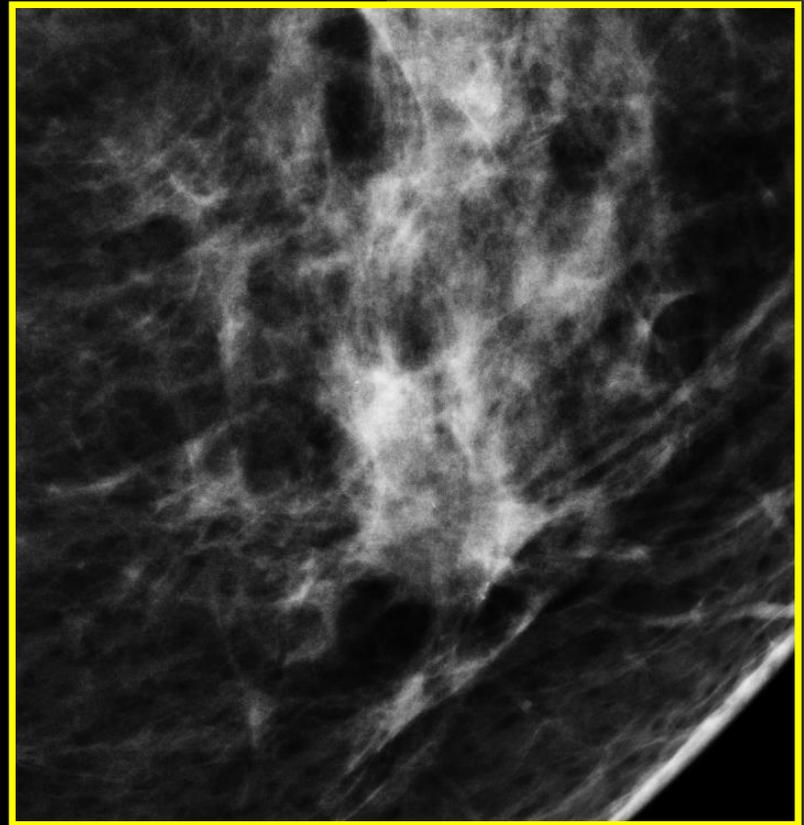
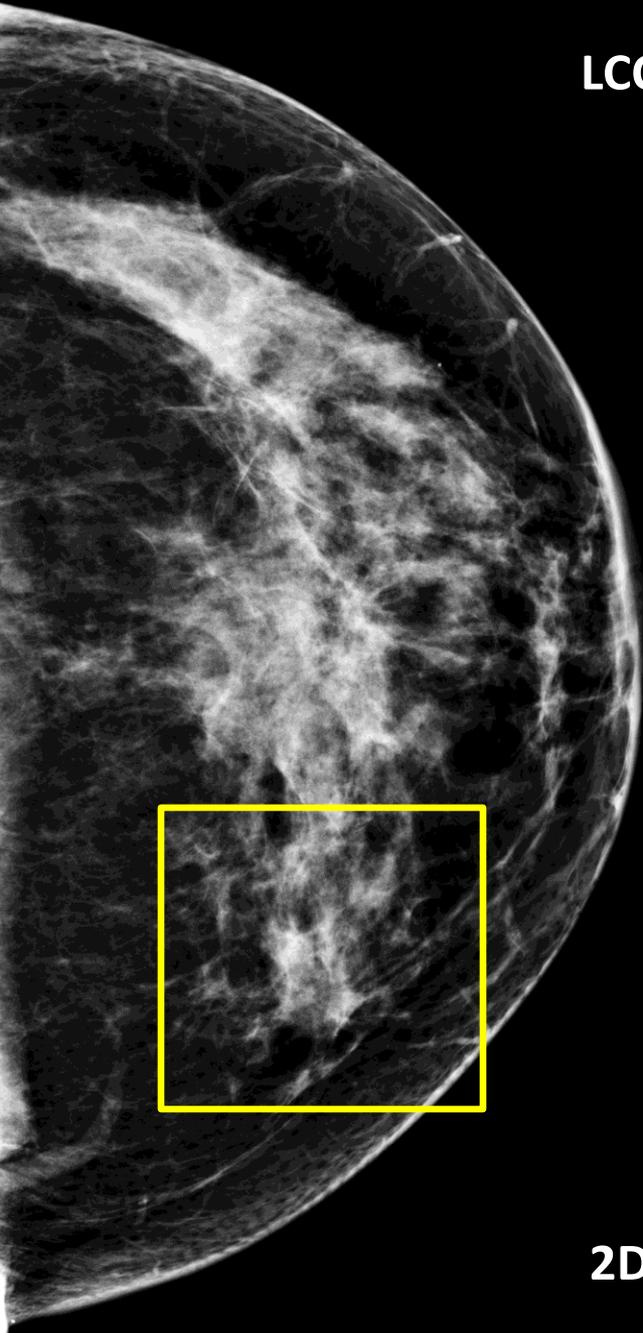


LCC

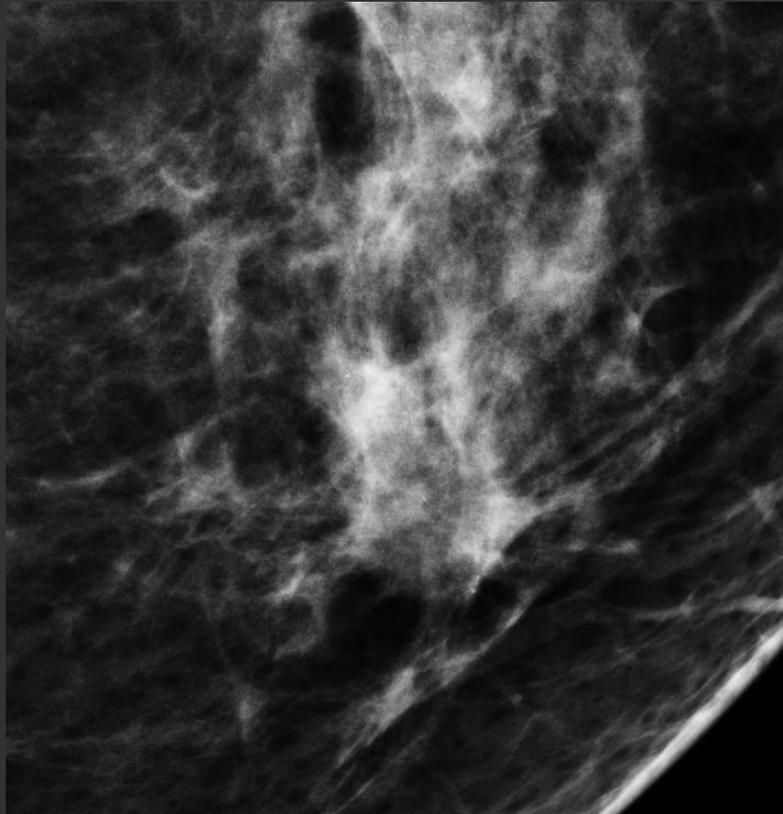


2D

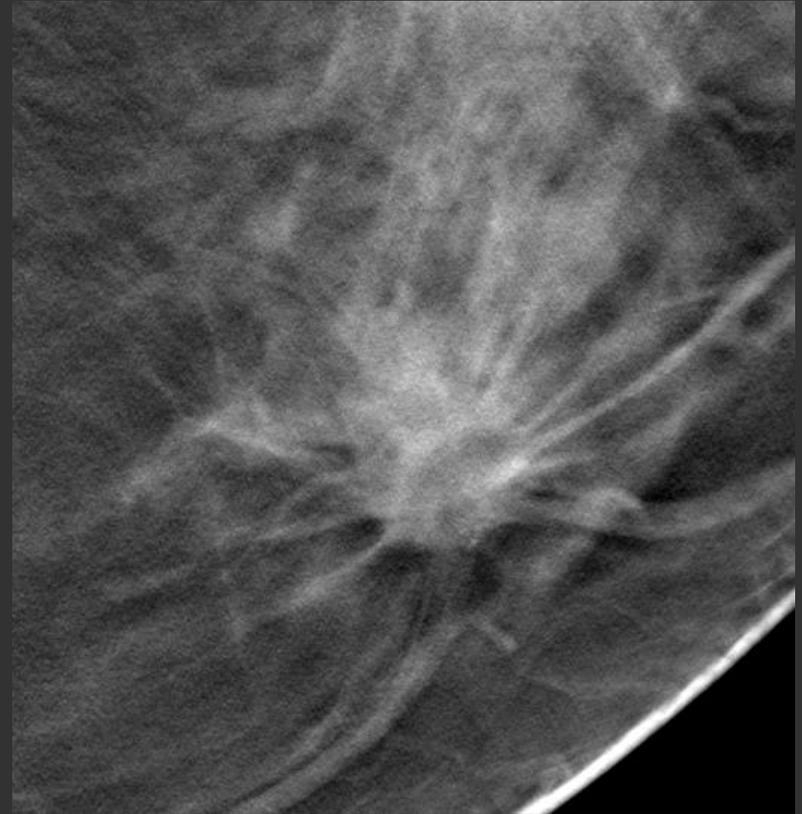
LCC



2D



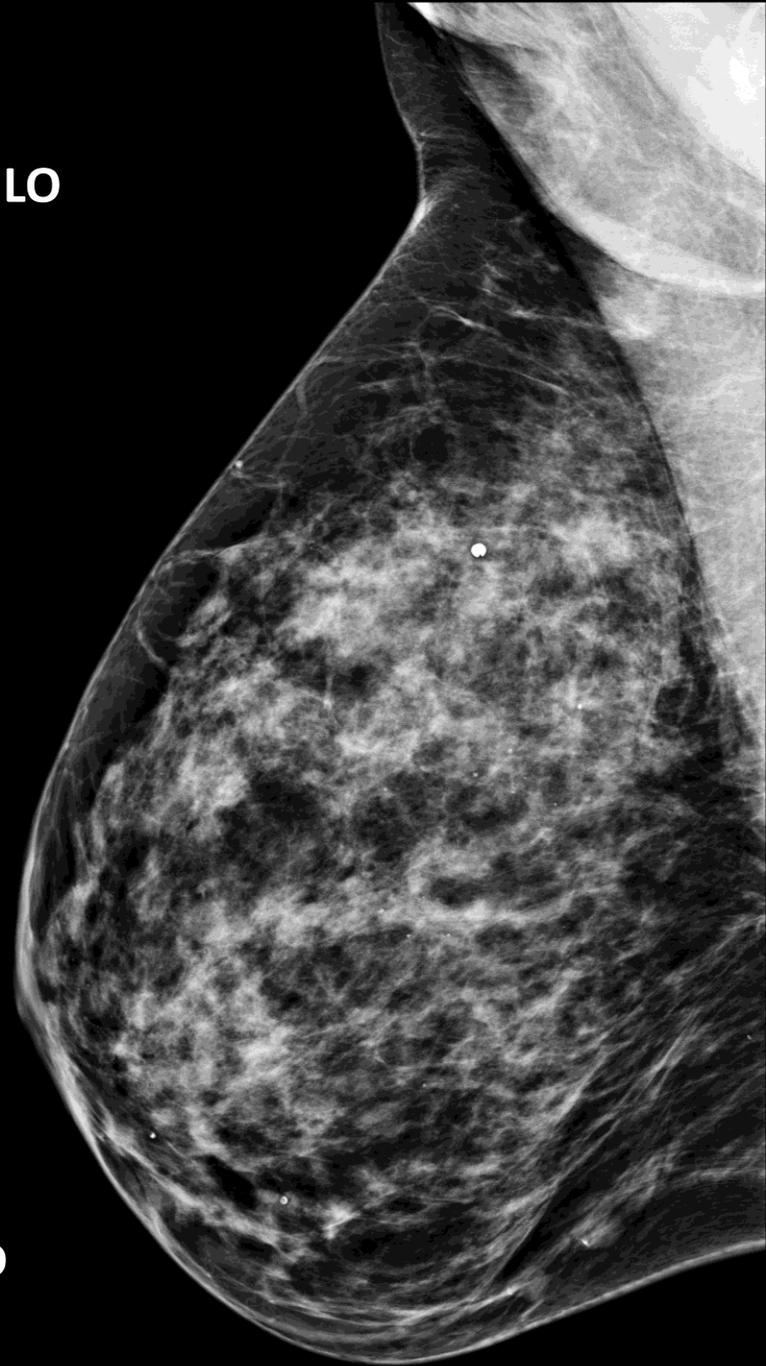
2D

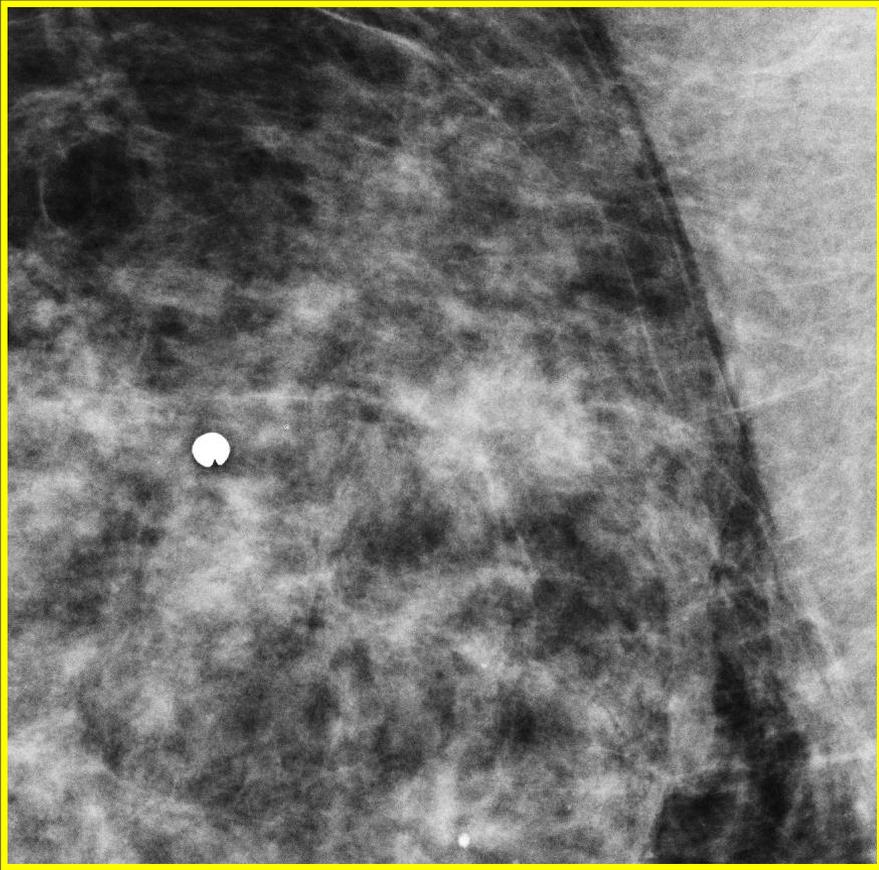


3D

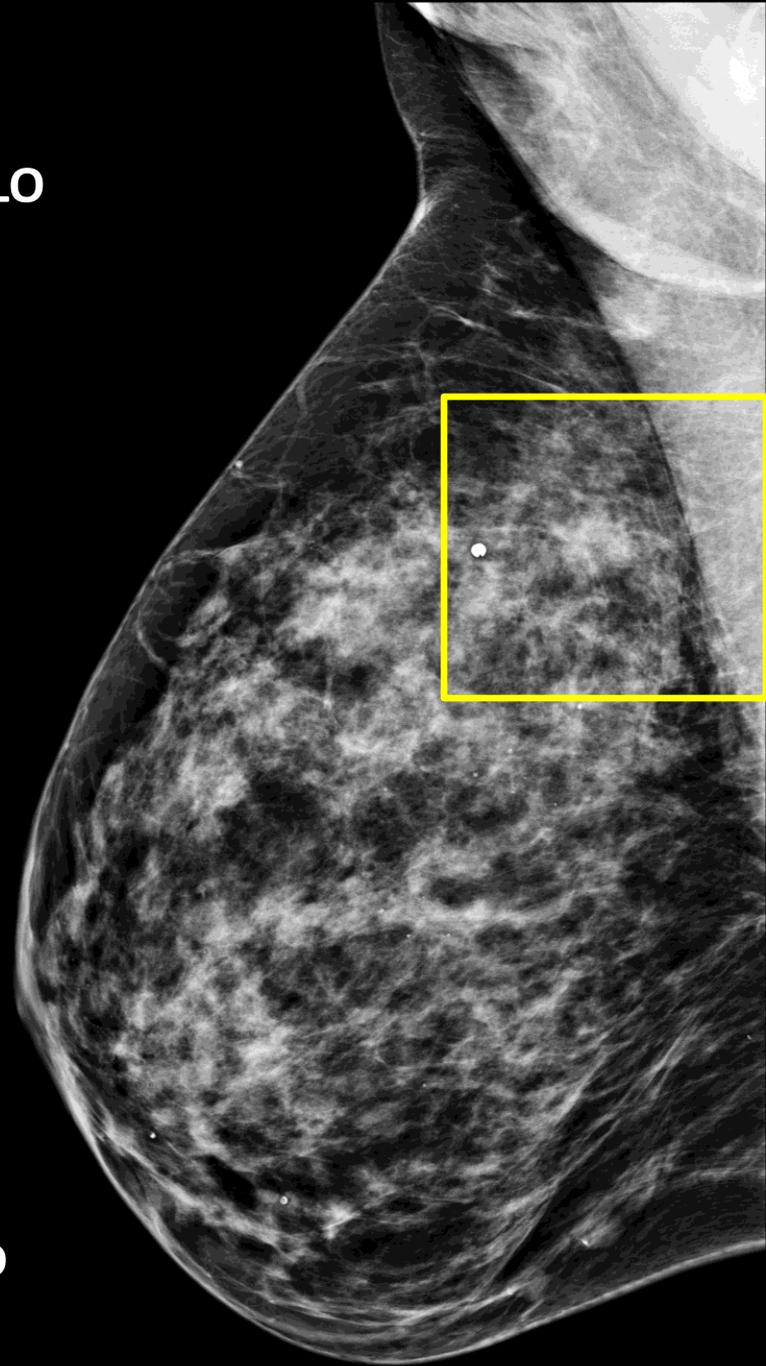
RMLO

2D

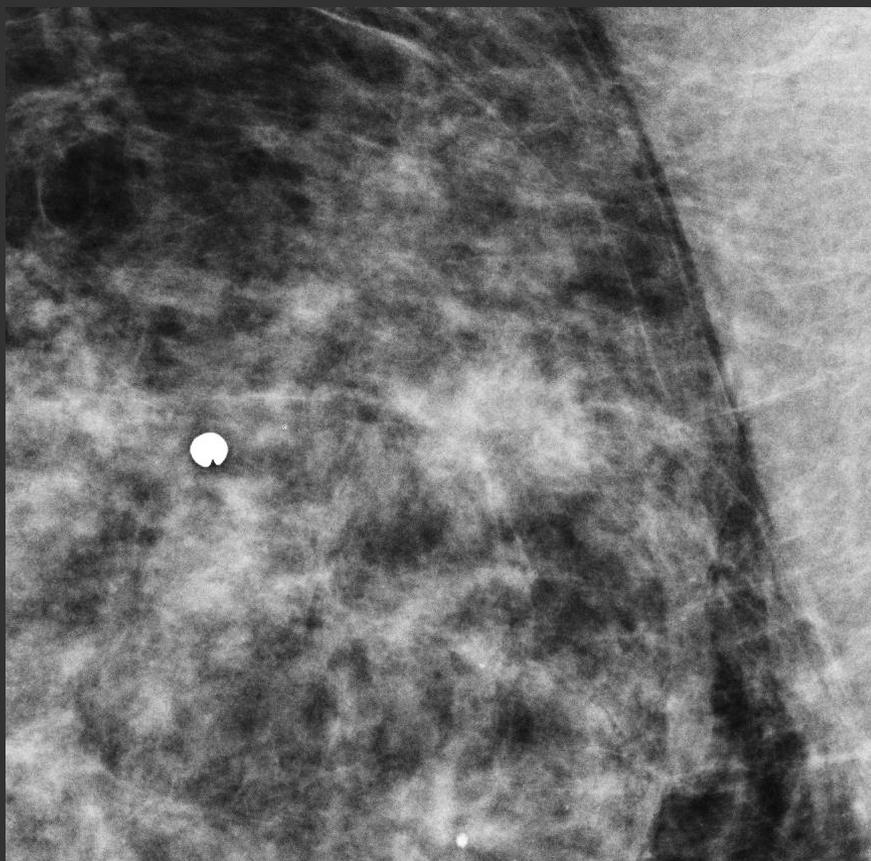




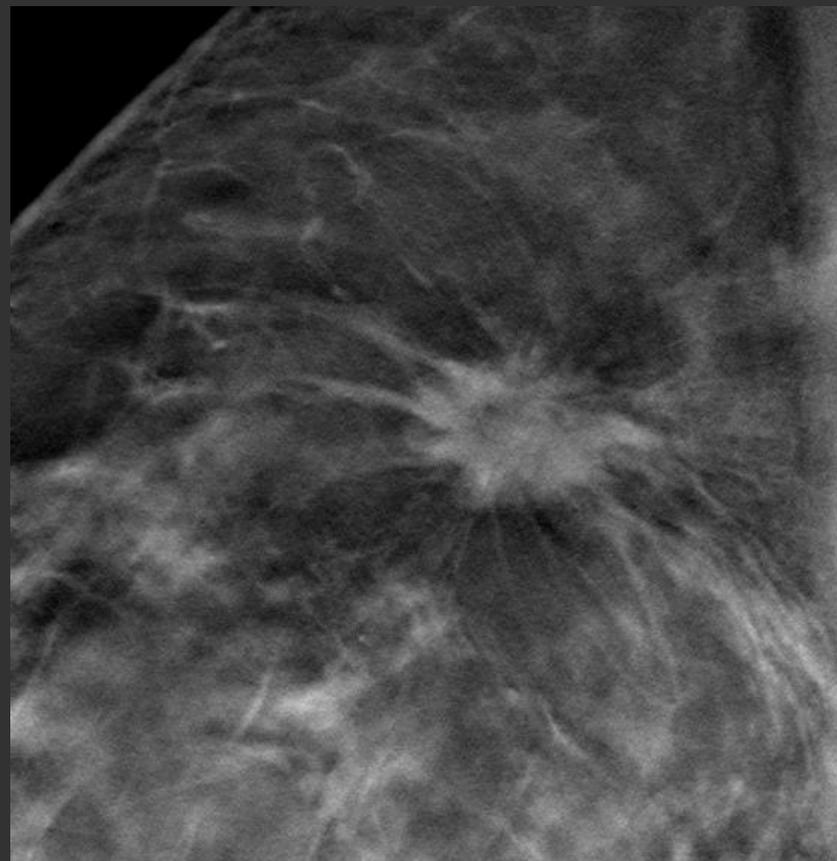
RMLO



2D



2D



3D

Tomosynthesis: Improved Clinical Outcomes

Earlier Detection

Breast cancer screening with **Tomosynthesis** finds **40% more invasive cancers** than 2D¹⁻³

Reduced Recalls

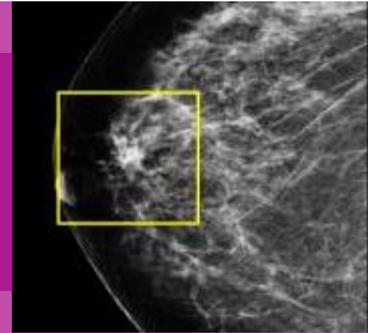
Tomosynthesis enables **20-40% reduction in recall rates** depending on practices^{2,4}

Better Visualization

Masses, distortions and asymmetric densities are **better visualized with Tomosynthesis**⁵

1. Ciatto S, Houssami N, Bernardi D, et al. "Integration of 3D Digital Mammography with Tomosynthesis for Population Breast-Cancer Screening (STORM): A Prospective Comparison Study" *The Lancet Oncology*. Epub 2013 Apr 25.
2. Rose S, Tidwell A, Bujnock L, et al. "Implementation of Breast Tomosynthesis in a Routine Screening Practice: An Observational Study." *American Journal of Roentgenology*. Epub 2013 May 22.
3. Skaane P, Bandos A, Gullien R, et al. Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program. *Radiology*. 2013 Apr; 267(1):47-56. Epub 2013 Jan 7.
4. Conant E, Gavenonis S, Weinstein S et al. Early Implementation of Digital Breast Tomosynthesis: Comparison of Call-back and Cancer Detection Rates in a Clinical Screening Practice. Radiological Society of North America annual meeting. Chicago, IL, 2012.
5. Zuley M, Bandos A, Ganott M, et al. Digital Breast Tomosynthesis versus Supplemental Diagnostic Mammographic Views for Evaluation of Noncalcified Breast Lesions. *Radiology*. 2013 Jan; 266(1):89-95. Epub 2012 Nov 9.

Hologic C-View™ Software Generated 2D Images



Tomosynthesis Reconstructed Slices and Generated 2D Images

Less patient dose through fewer x-ray exposures

Greater patient comfort via fast, 4 second scan time

Heightened detail retained from tomosynthesis images

Superior performance compared to traditional 2D alone¹

¹(FDA PMA submission P080003/S001)

Generating 2D Images

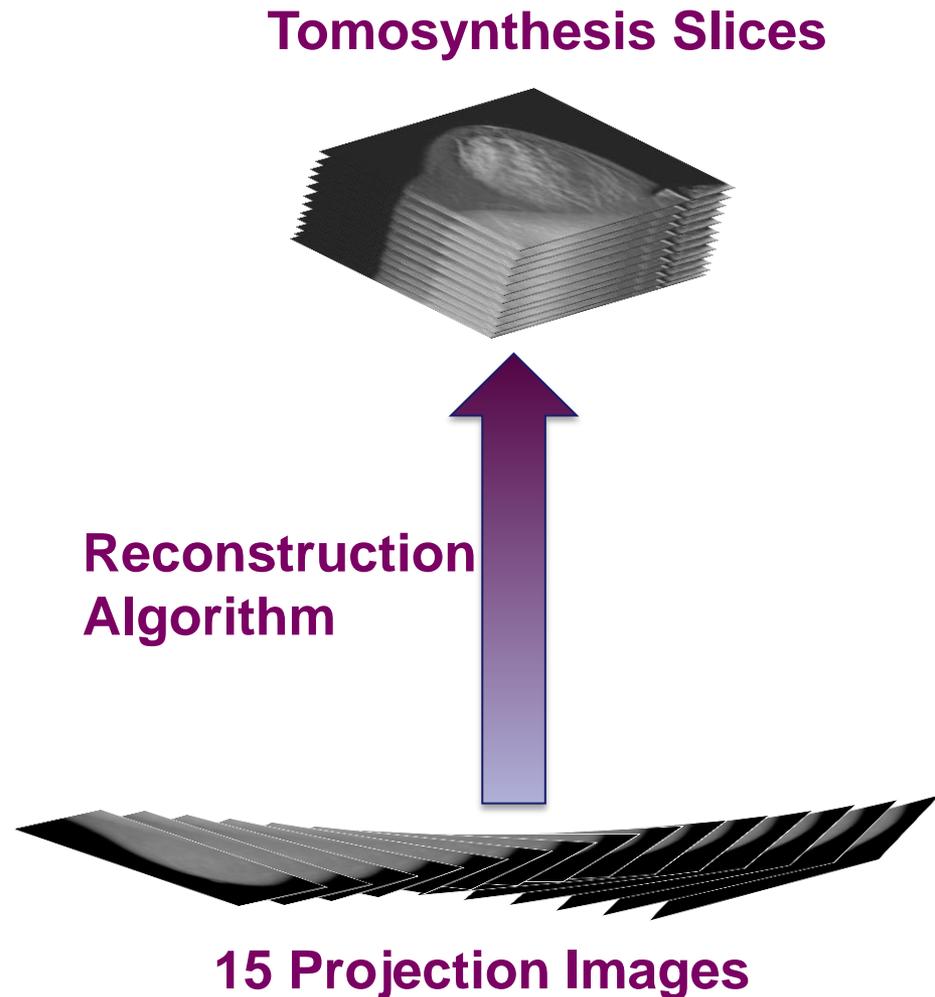
- Perform a standard tomosynthesis scan



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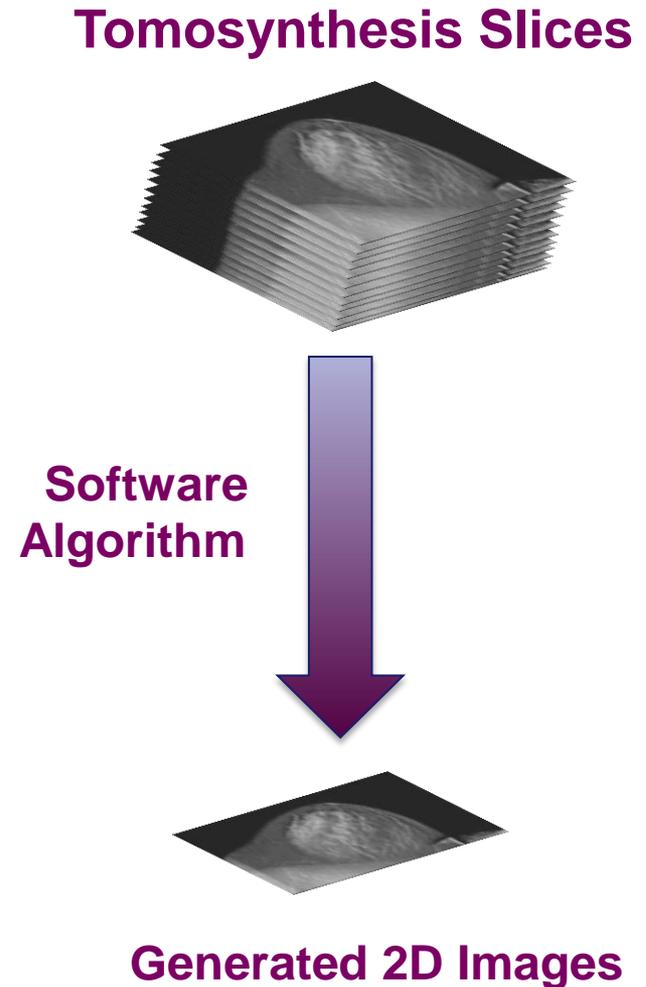
Generating 2D Images

- Perform a standard tomosynthesis scan
- Reconstruct tomosynthesis slices



Generating 2D Images

- Perform a standard tomosynthesis scan
- Reconstruct tomosynthesis slices
- Synthesize 2D image



Generating 2D Images

- Facilitates current to prior exam review
- Maintains important details from tomosynthesis slices
 - Interpreted in combination with tomosynthesis images

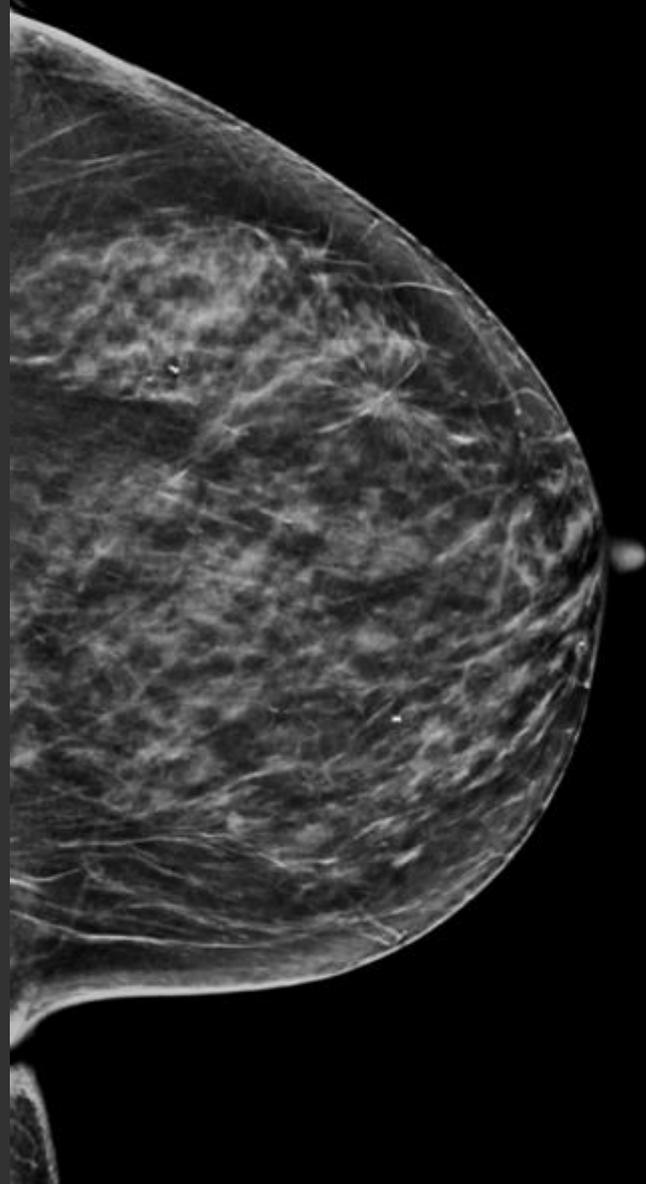


Image Comparison: Case 1

2D

Tomosynthesis Slice

Generated 2D

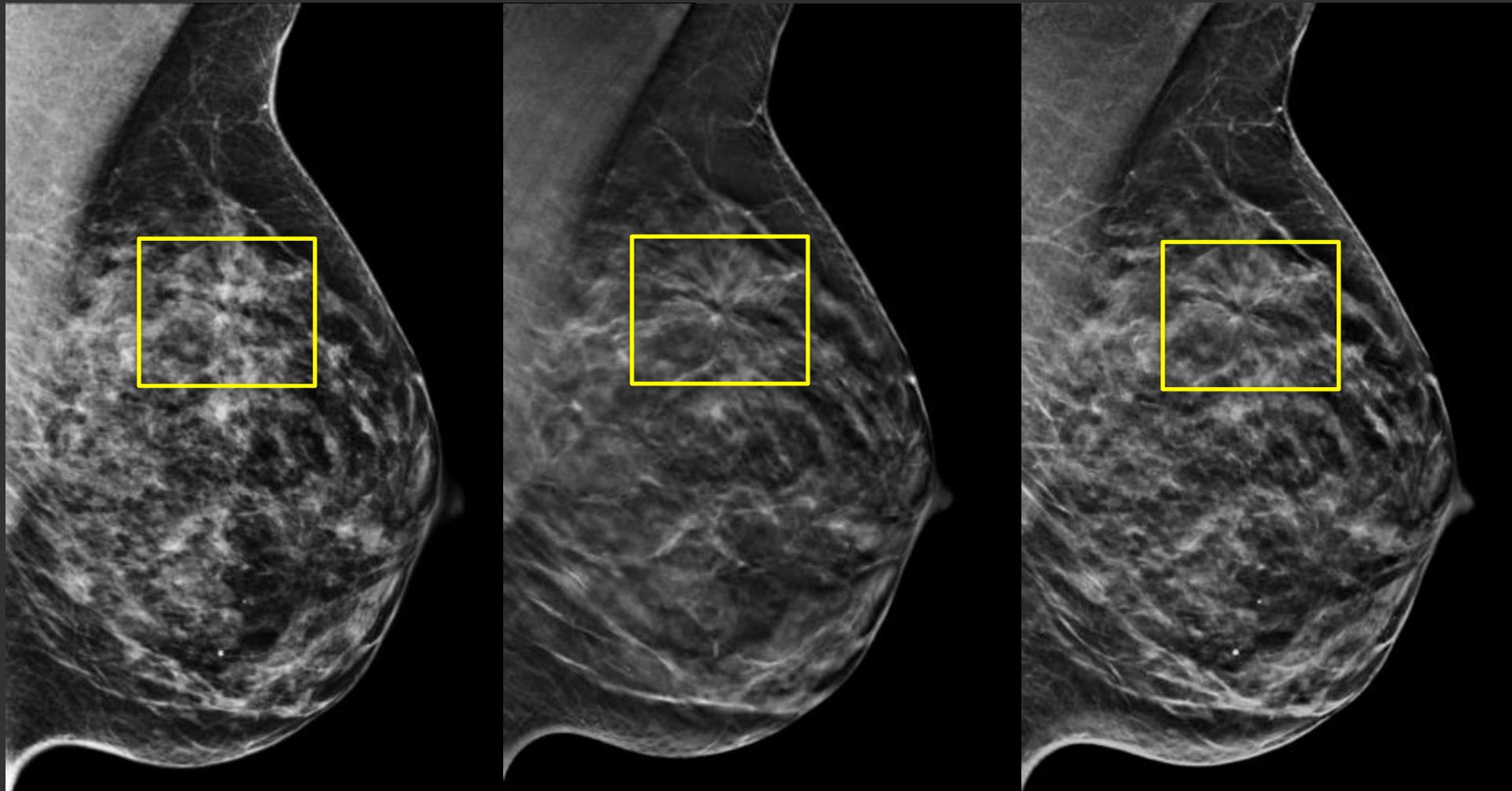


Image Comparison: Case 1

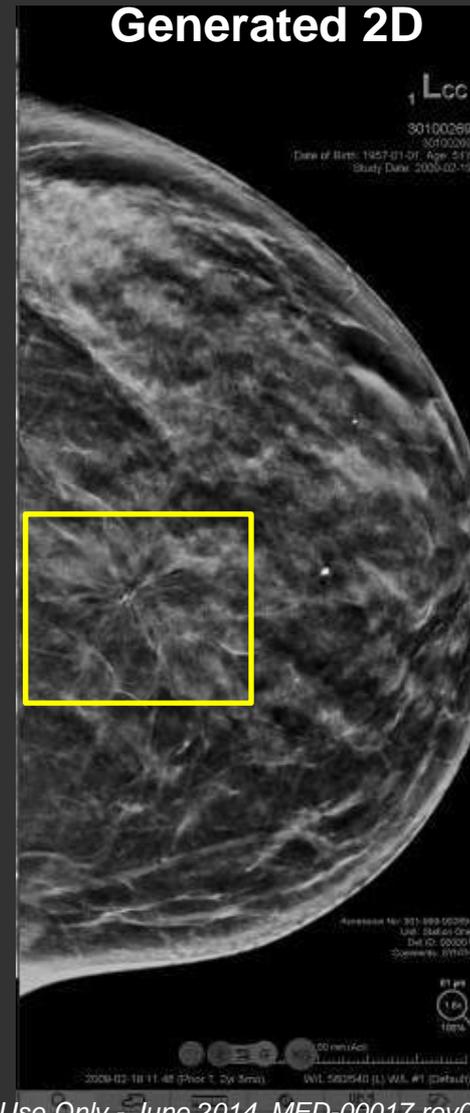
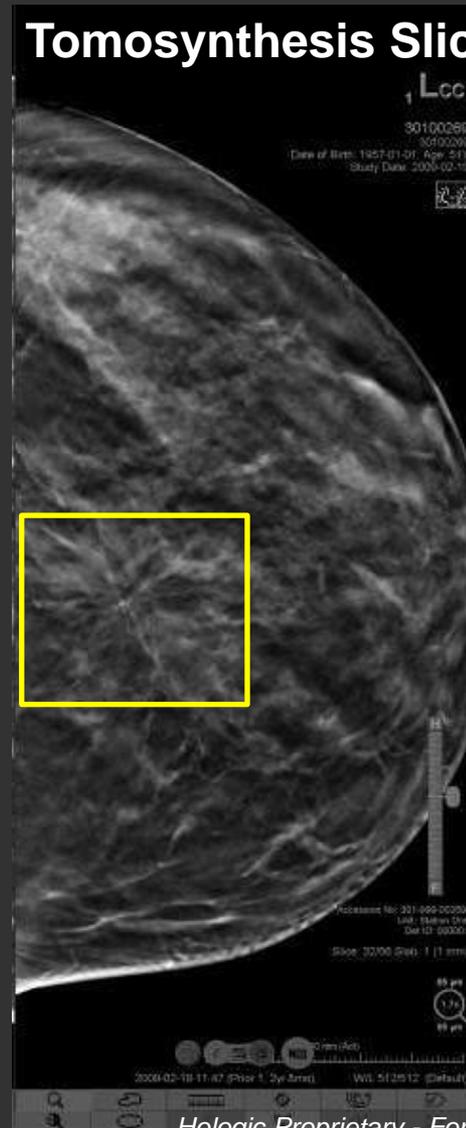
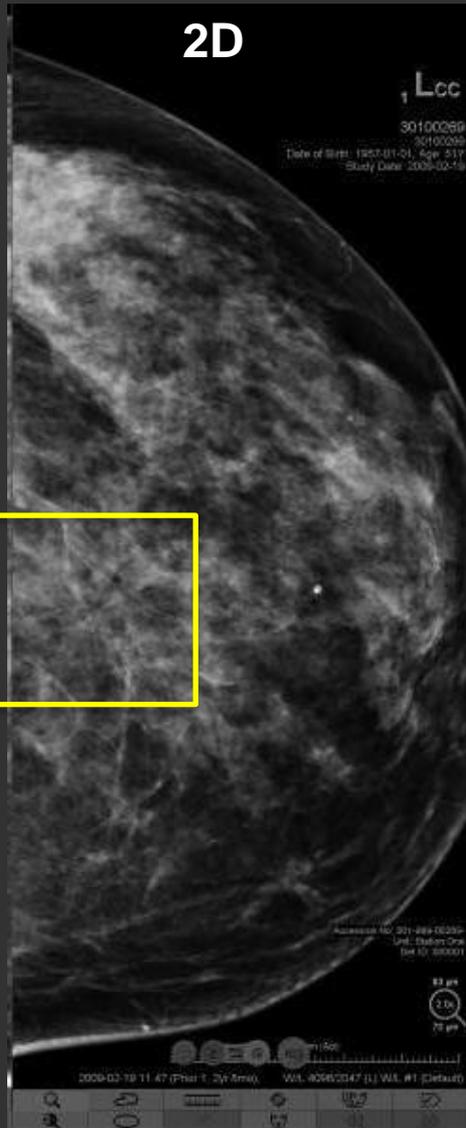
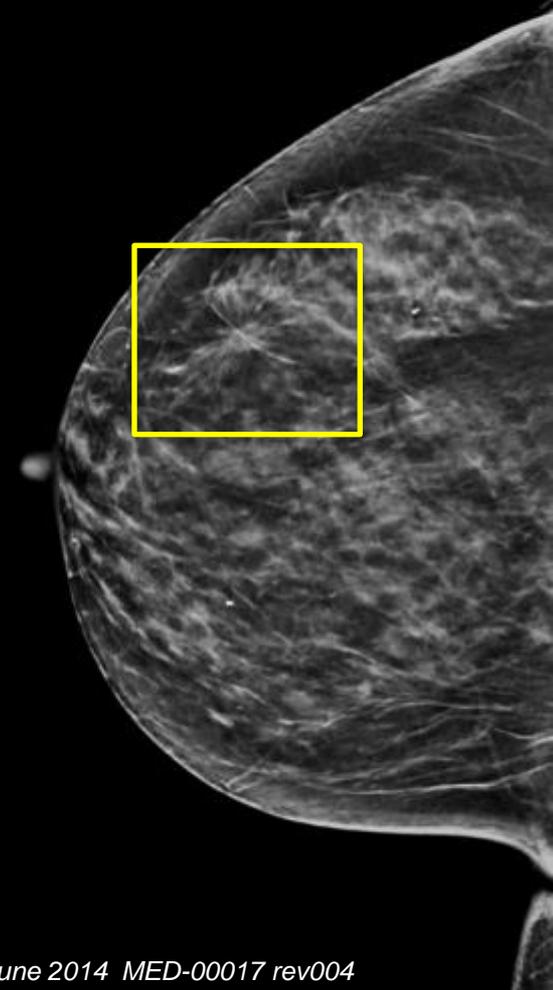
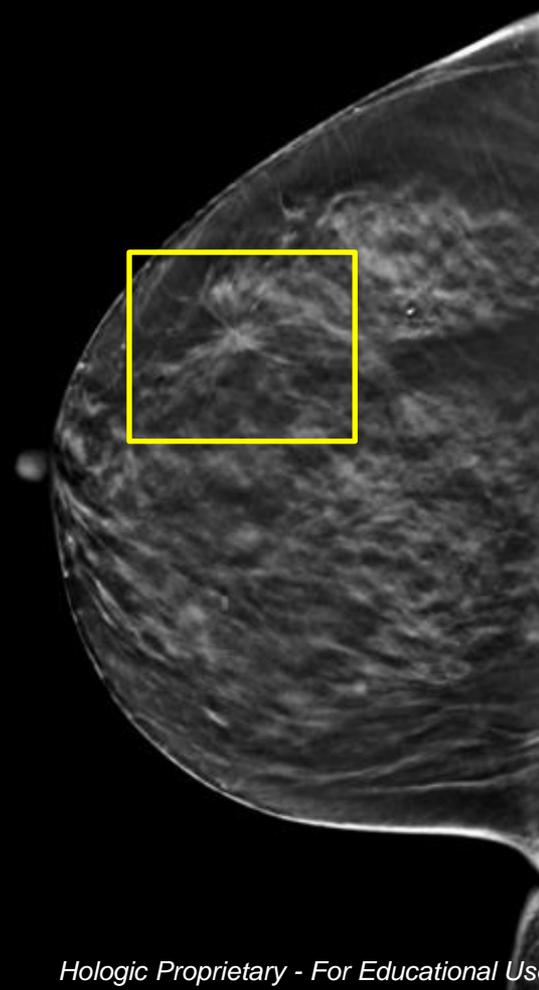
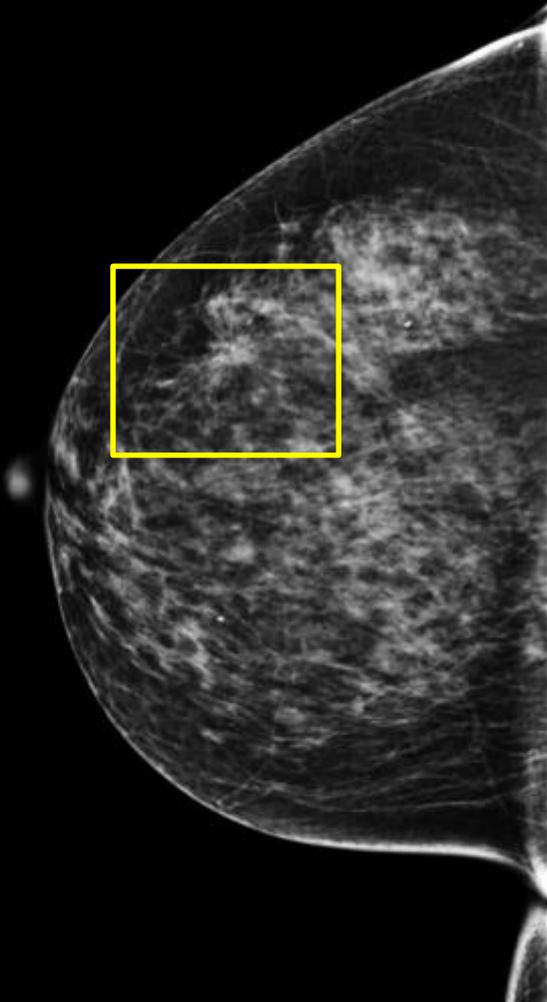


Image Comparison: Case 2

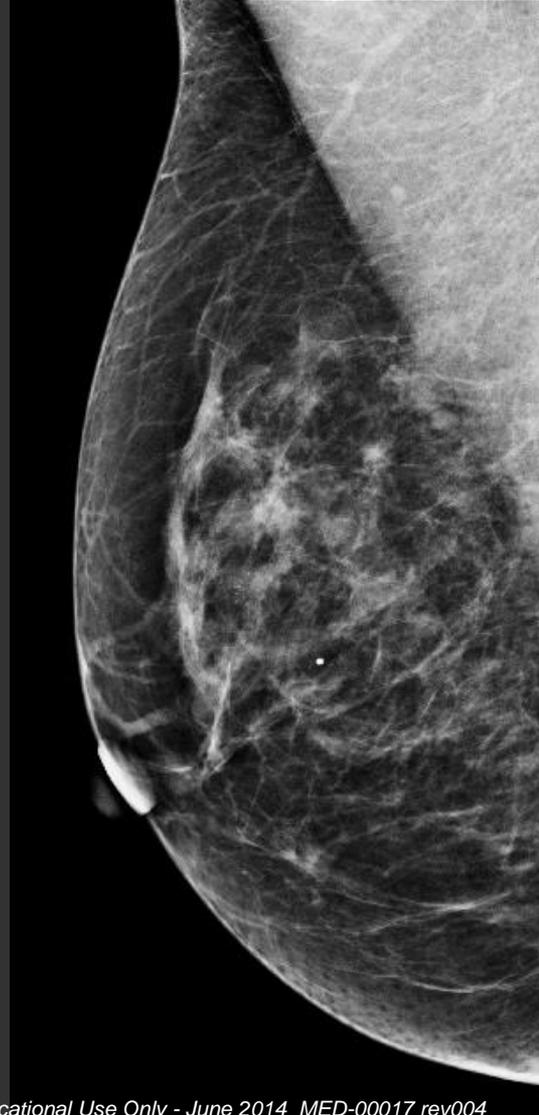
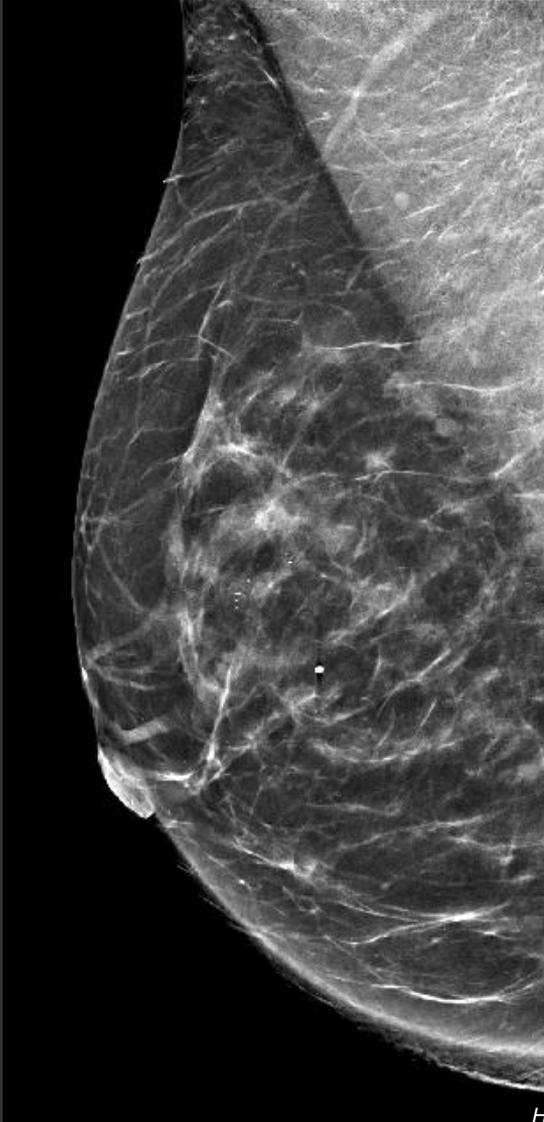
2D

Tomosynthesis Slice

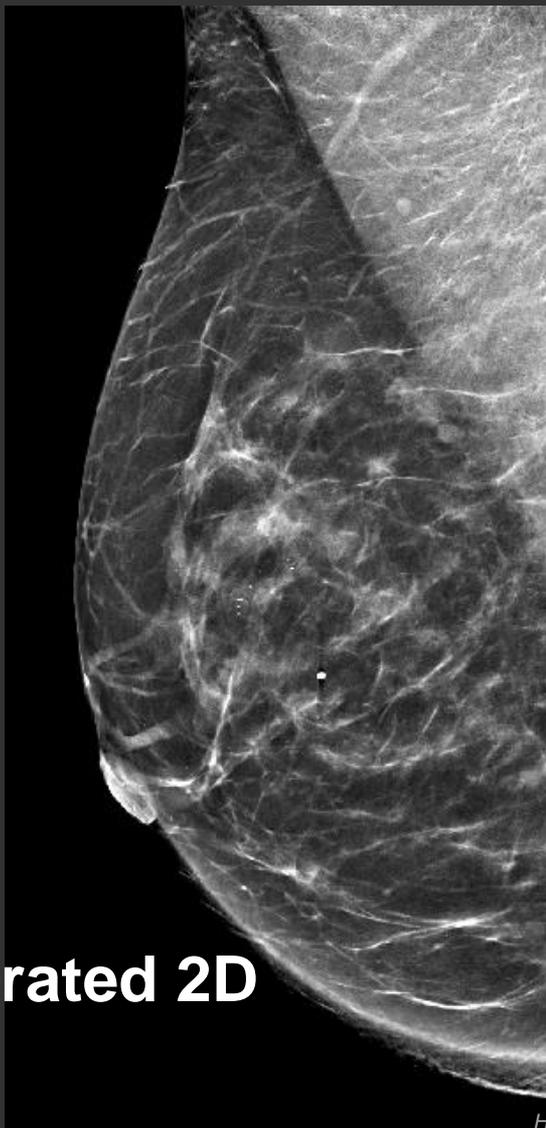
Generated 2D



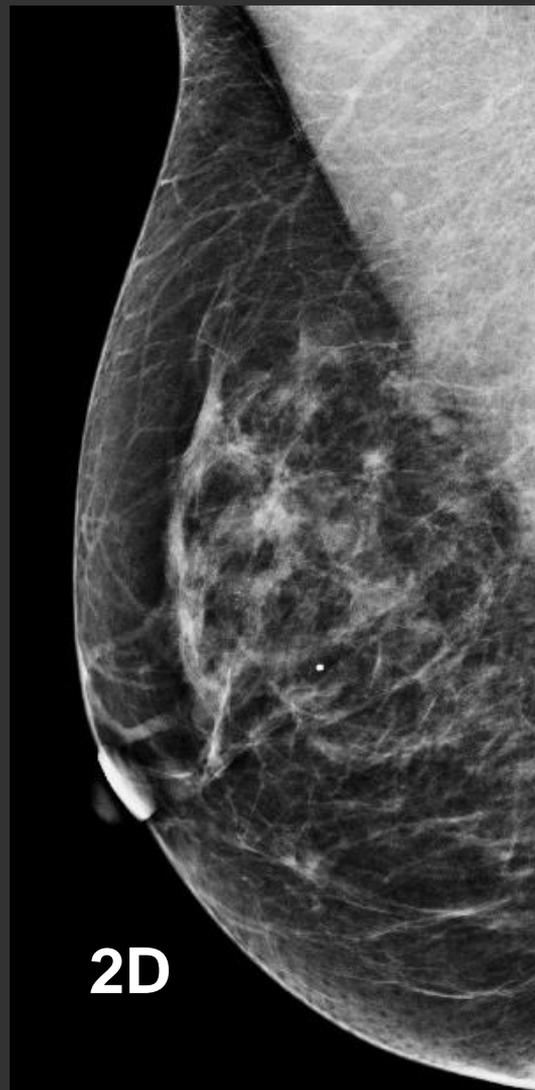
Which is Which?



Which is Which?



Generated 2D



2D

U.S. Dose Comparison

Combo Mode

- Tomo + FFDM
- 10 second scan time
- ACR Dose = 2.65 mGy

TomoHD Mode

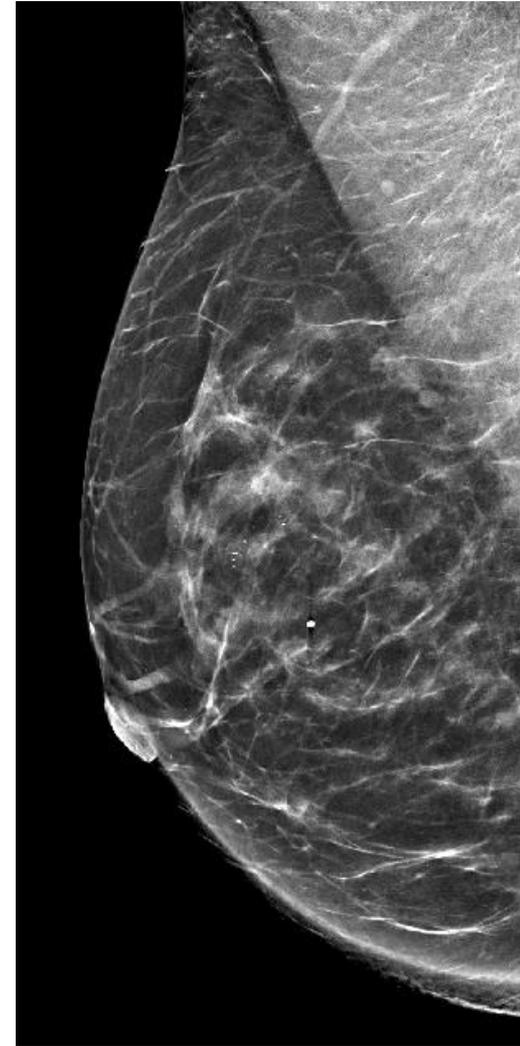
- Tomo + Generated 2D
- 4 second scan time
- ACR Dose = 1.45 mGy

- ***Scan Time Reduction***
- ***Lowers Risk of Patient Motion***
- ***Patient Dose Reduction***

Summary:

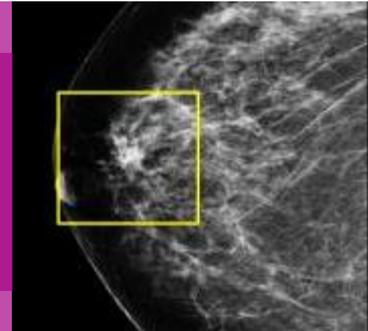
Tomosynthesis + Generated 2D

- Lower patient dose
- Shorter compression time
 - Increased patient comfort
 - Lowered risk of patient motion
- Superior performance compared to traditional 2D alone¹

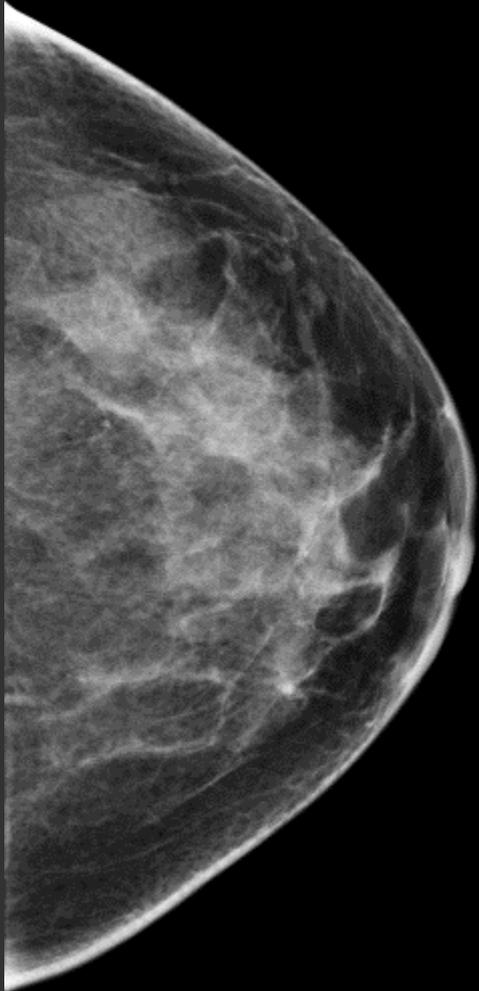


¹Compared to 2D alone. FDA PMA submission P080003/S001

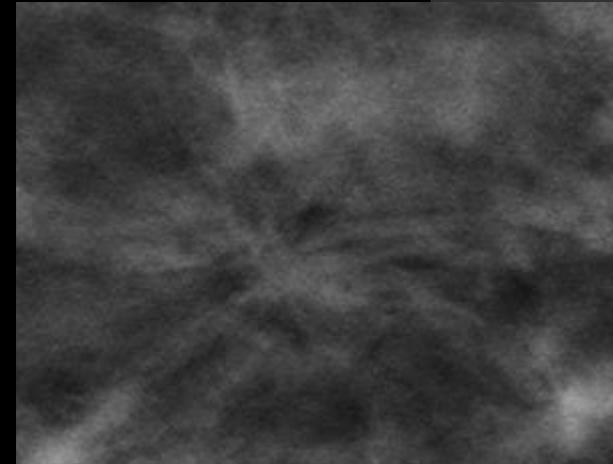
Tomosynthesis Guided Breast Biopsy



2D



Tomosynthesis slice



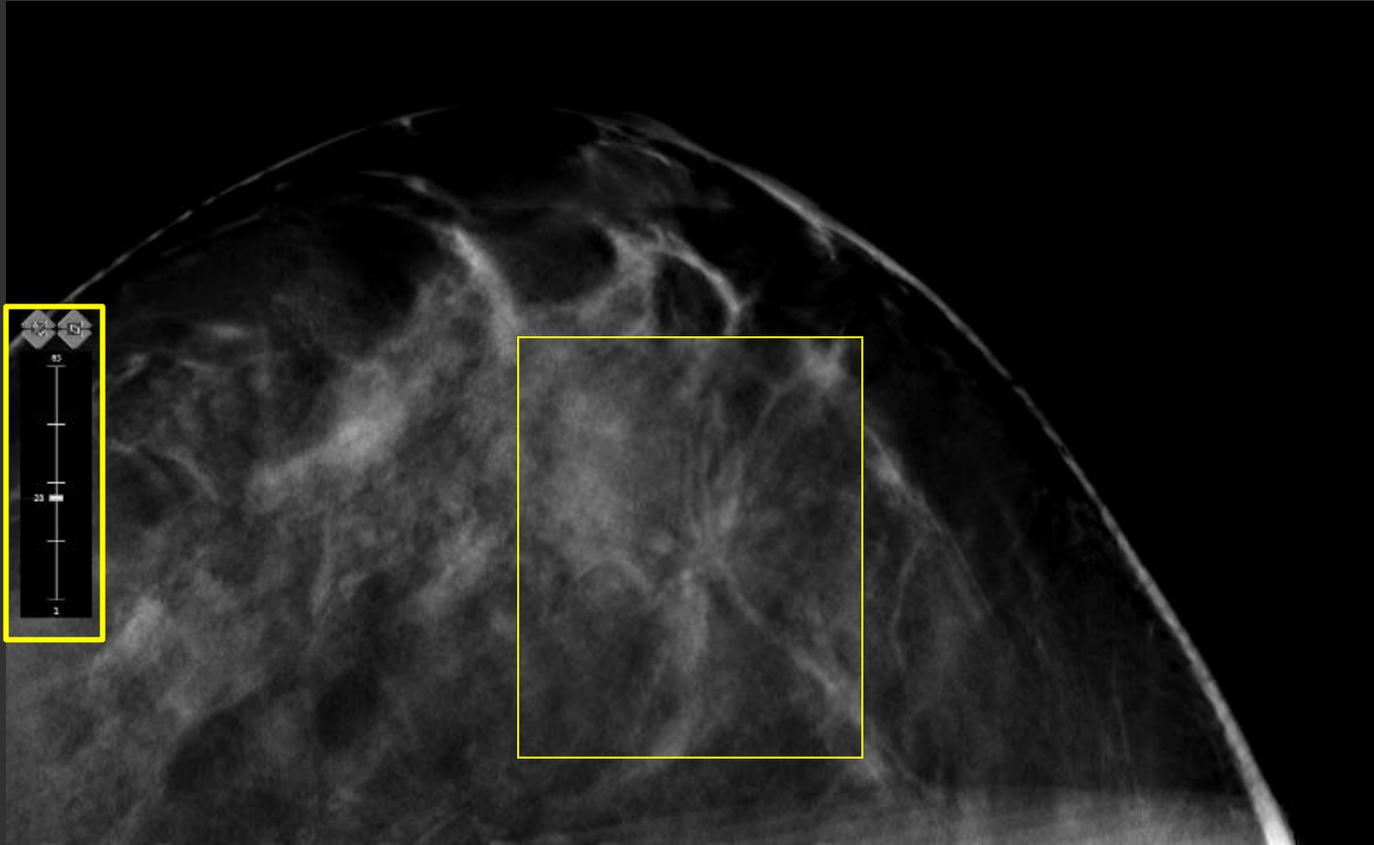
Hologic Dimensions[®] system with Affirm[™] Breast Biopsy Guidance System



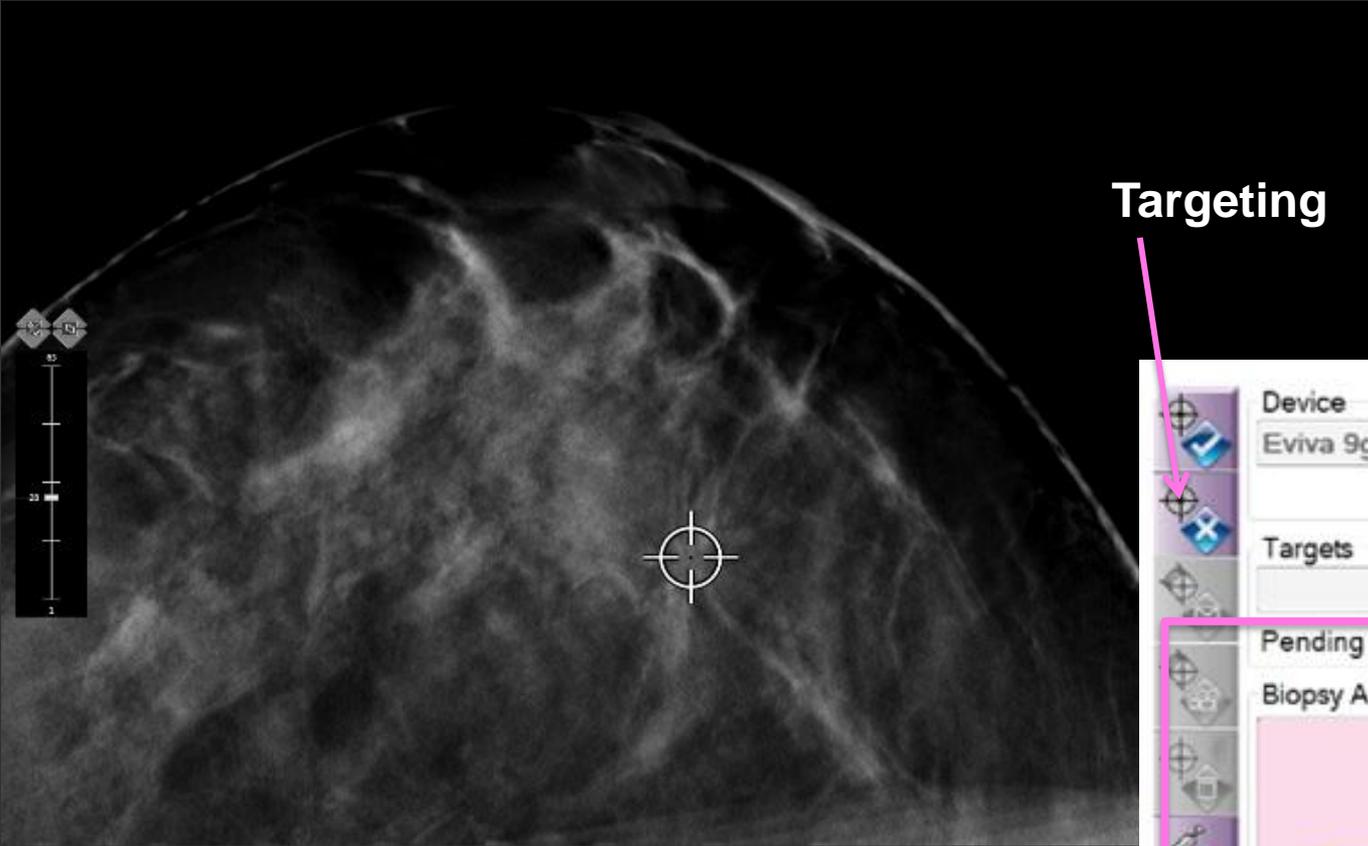
Tomosynthesis Procedure Scout



Tomosynthesis Procedure Target



Tomosynthesis Procedure Target



Targeting

Lesion coordinate

The software interface displays the following information:

- Device:** Eviva 9gx13cm, 20mm
- Targets:** Pending X:-1.4 Y:28.8 Z:21.9
- Biopsy Area:** A diagram showing a biopsy needle with a yellow highlighted area of 15.0mm. Dimensions are shown as 21.4mm, 0mm, and 4.46mm. A 3.0mm scale is also visible at the bottom of the diagram.

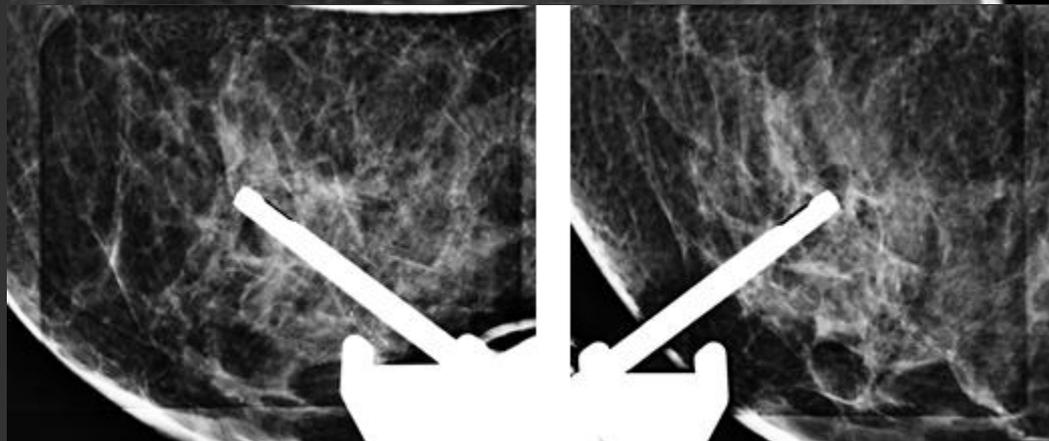
Tomosynthesis procedure

2D Pre-Fire (optional)

Tomo Scout



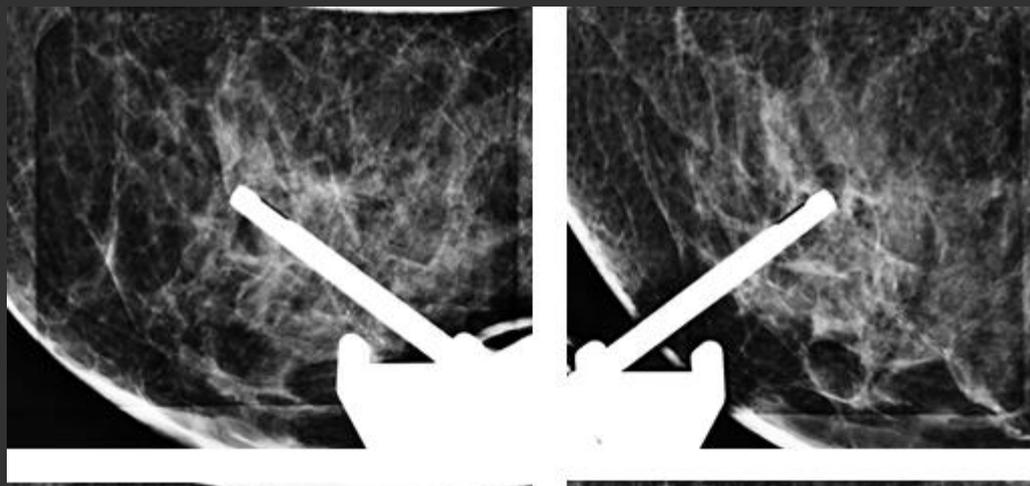
Pre-fire images



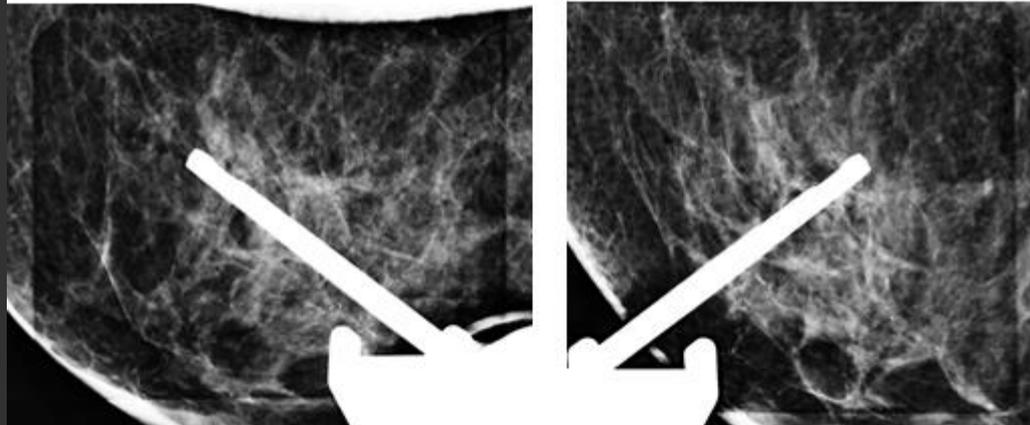
Tomosynthesis procedure

2D Pre-Fire & Post-Fire (optional)

Pre-fire



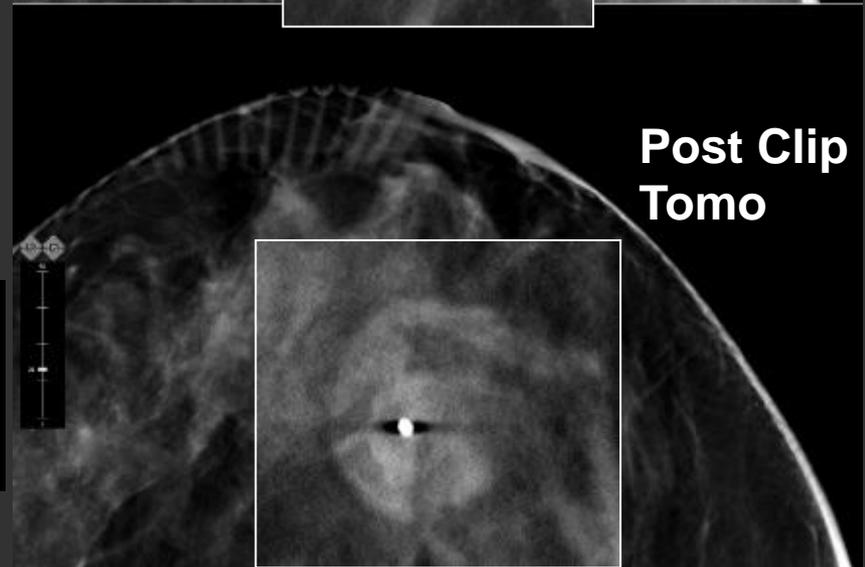
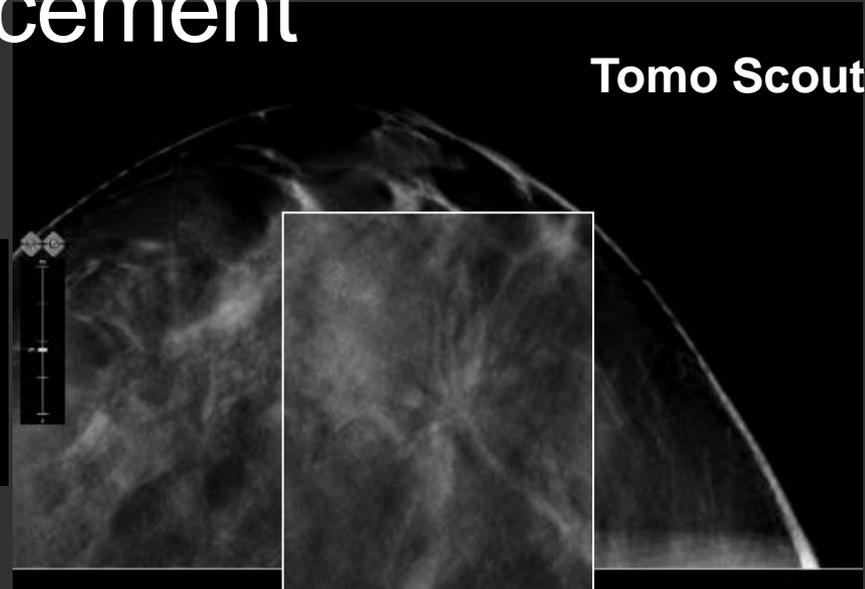
Post-fire



Tomosynthesis procedure

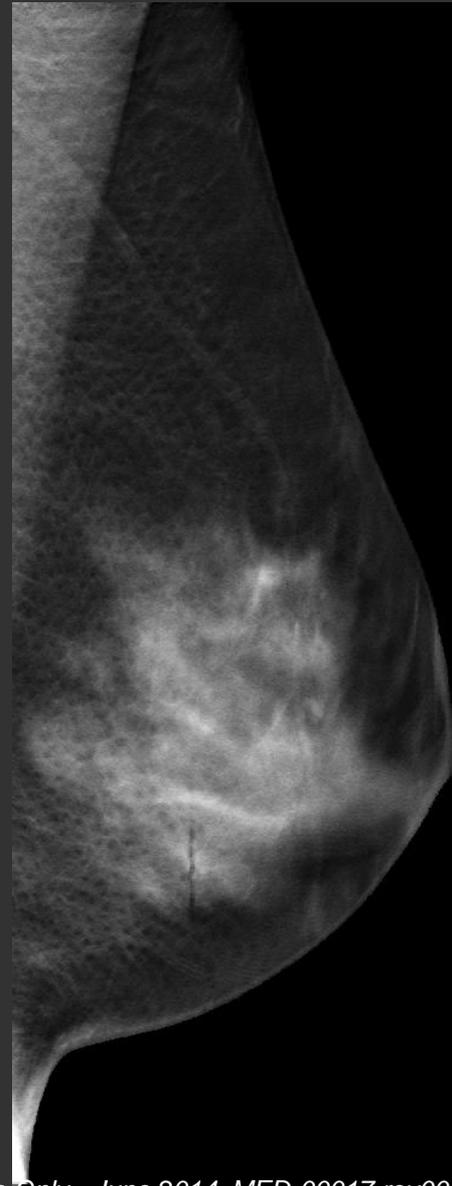
Post Biopsy & Clip Placement

- Display original tomo scout to view target
- Scroll up and down on post biopsy tomo
 - Check if lesion is gone
 - Compare depth hematoma/cavity ↔ lesion on target
- View Clip



Tomosynthesis procedure

- Total time biopsy: 10 minutes
- Post-biopsy tomo lateral
- Pathology result:
 - Invasive ductal carcinoma



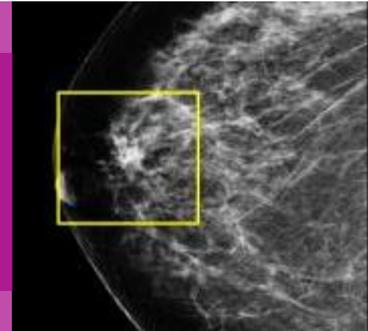
Tomosynthesis Guided Breast Biopsy Summary

- Workflow is improved:
 - Biopsy lesions in fewer steps
 - Reduced procedure time compared to 2D stereotactic biopsy¹
- Patient care is improved:
 - Biopsy lesions not found under 2D or other modalities²
 - Dose reduction from fewer exposures
 - 2D scout and stereo pair not required

¹Affirm 1.7.x User's Guide MAN-03209 rev3 March2013

²Skaane P, Bandos A, Gullien R, et. al. Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program. Radiology. 2013 Jan 7

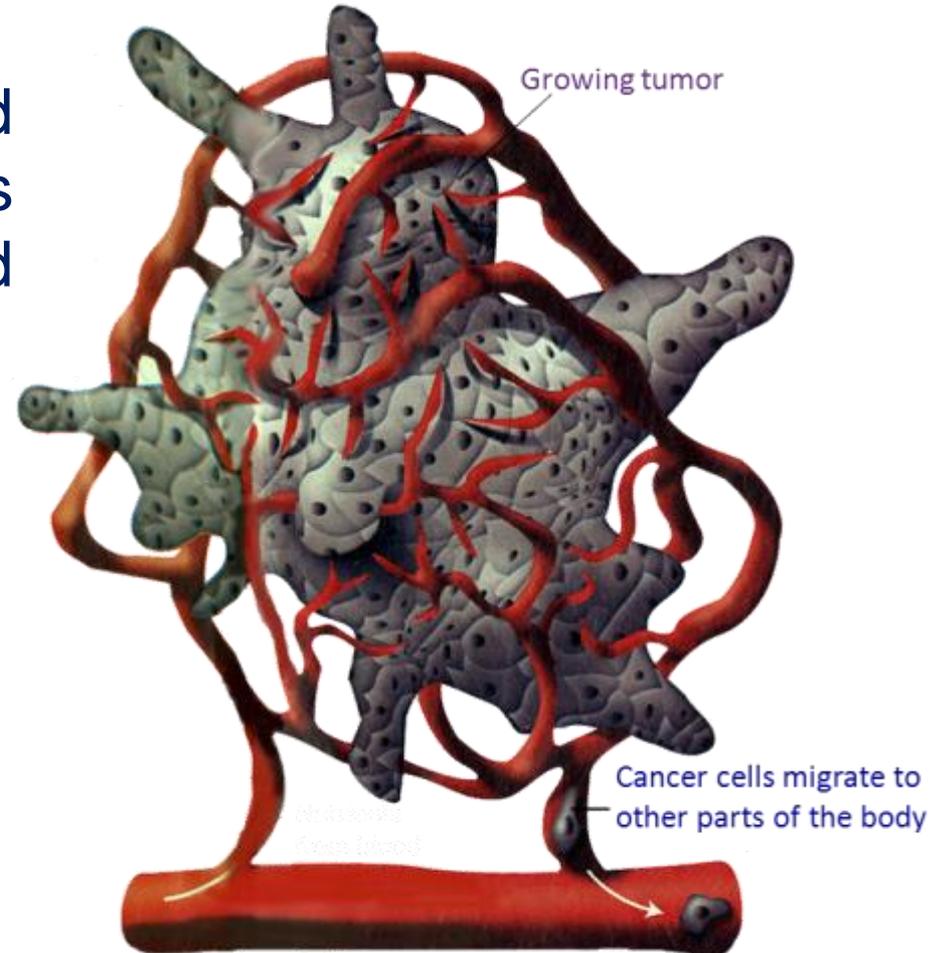
Contrast Enhanced Digital Mammography - CEDM



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Contrast Enhanced Digital Mammography (CEDM)

Detection of increased formation of blood vessels (angiogenesis) associated with tumor development



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Potential Clinical Applications

- Alternative to Breast MRI
 - Evaluate difficult to interpret mammograms¹
 - Screening women with elevated risk for breast cancer¹
 - Patients contraindicated for MRI²
 - Monitor effectiveness of drug therapy³
- Identify potential undetected malignancies¹

¹ Lewin et al. Contrast Mammography Reveals Hard-to-Find Cancers. RSNA Press Release. 30th September 2003.

² Weinstein SP, Localio AR, Conant EF, Rosen M, Thomas KM, Schnall MD. Multimodality screening of high-risk women: a prospective cohort study. J Clin Oncol. 2009 Dec 20;27(36):6124-8. doi: 10.1200/JCO.2009.24.4277. Epub 2009 Nov 2.

³ <http://www.acr.org/~/media/2a0eb28eb59041e2825179afb72ef624.pdf>

Potential Clinical Applications for CEDM

PROS

Useful as an alternative to MRI in underserved areas

Less expensive than MRI

Valuable for women who have contraindications to MRI*

CONS

Efficacy is not fully known yet

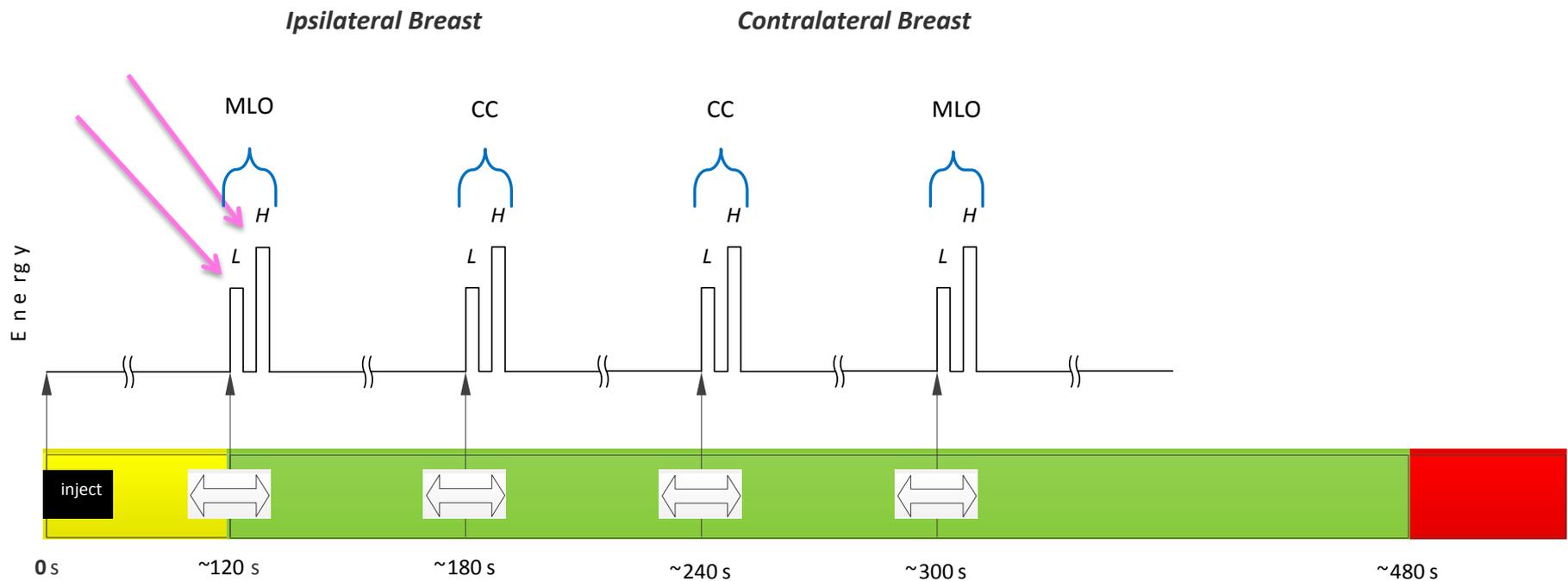
Iodine contrast

Difficult to image both breasts at the specific time-points

*Lewin, et.al, RSNA News Release Contrast Mammography Reveals Hard-to-Find Cancers

CE2D – Dual Energy 2D

- Low kV, High kV images acquired for each view
- Views can be any order

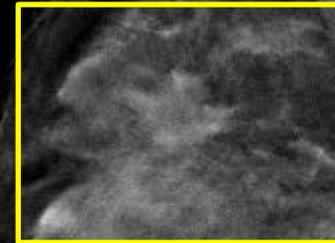
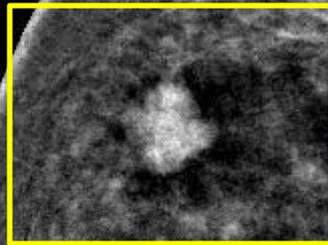
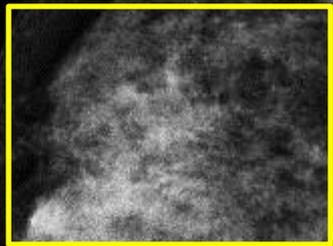


2D

Right MLO Projections

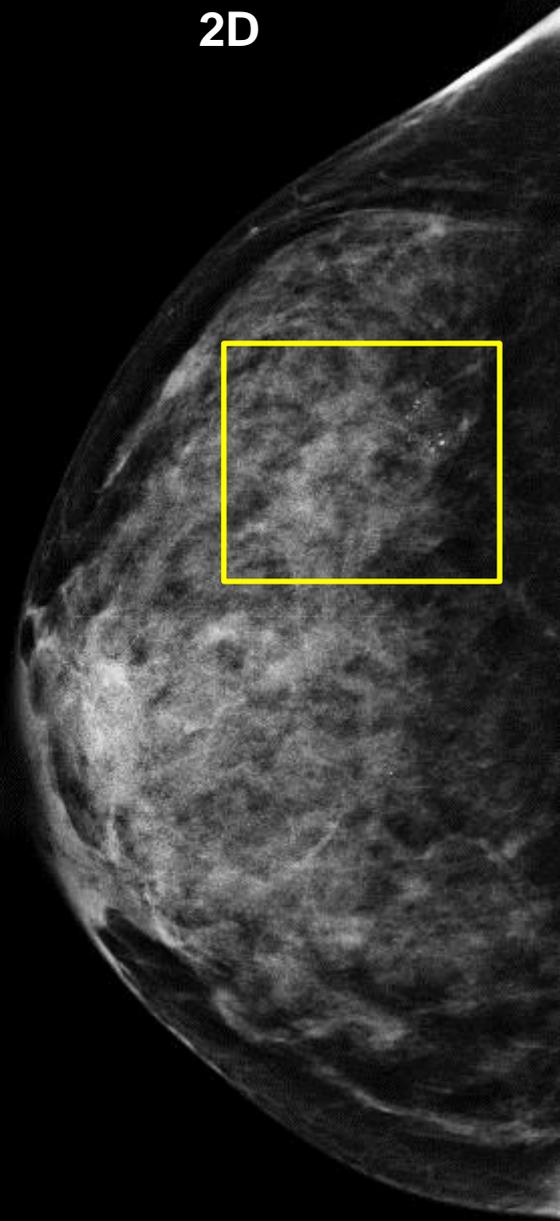
CE2D

Tomo slice 32/54

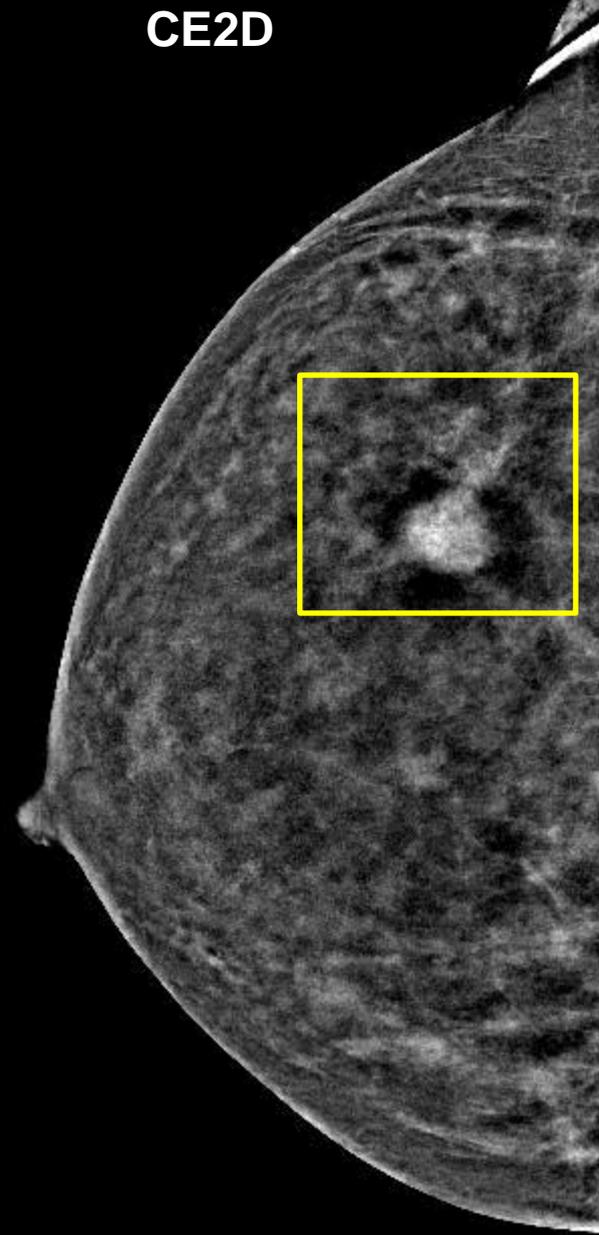


Right CC Projections

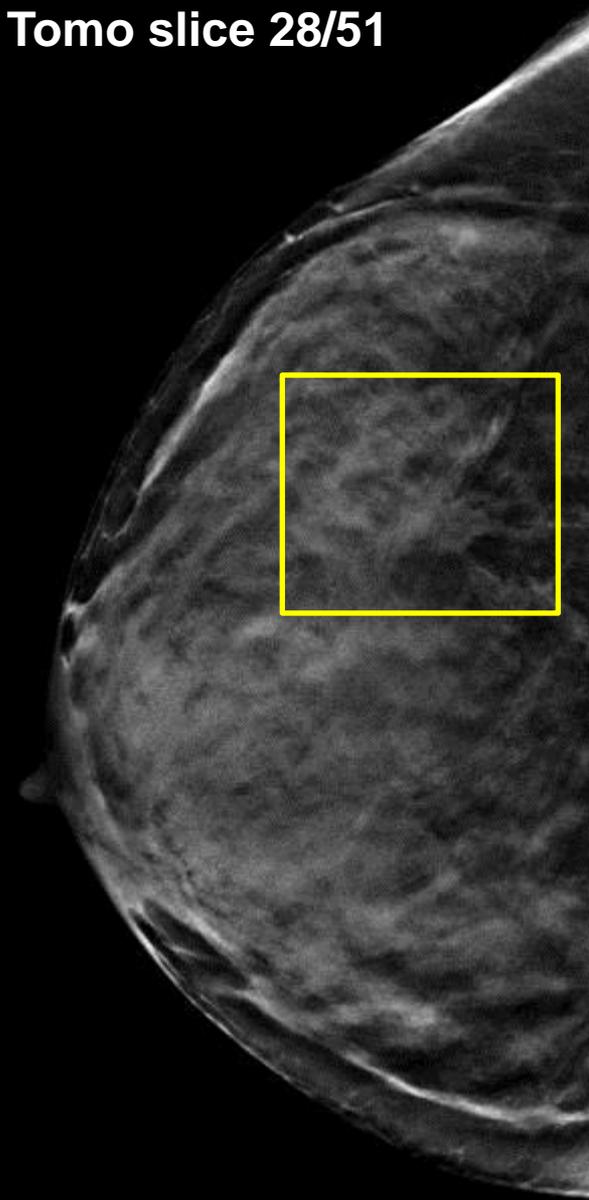
2D



CE2D



Tomo slice 28/51



Thank you!

