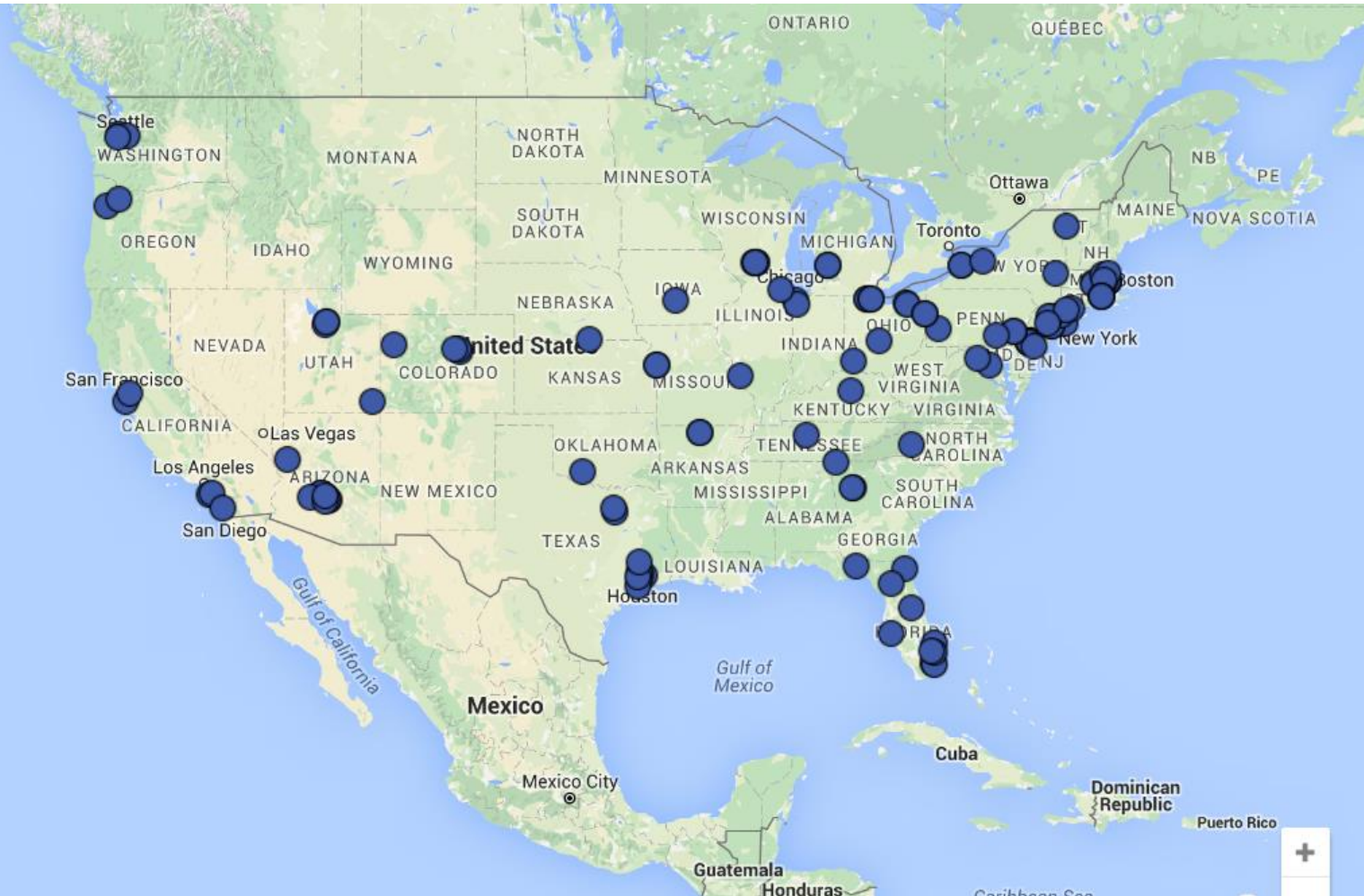


# Tomosynthesis Clinical Implementation and Read Out

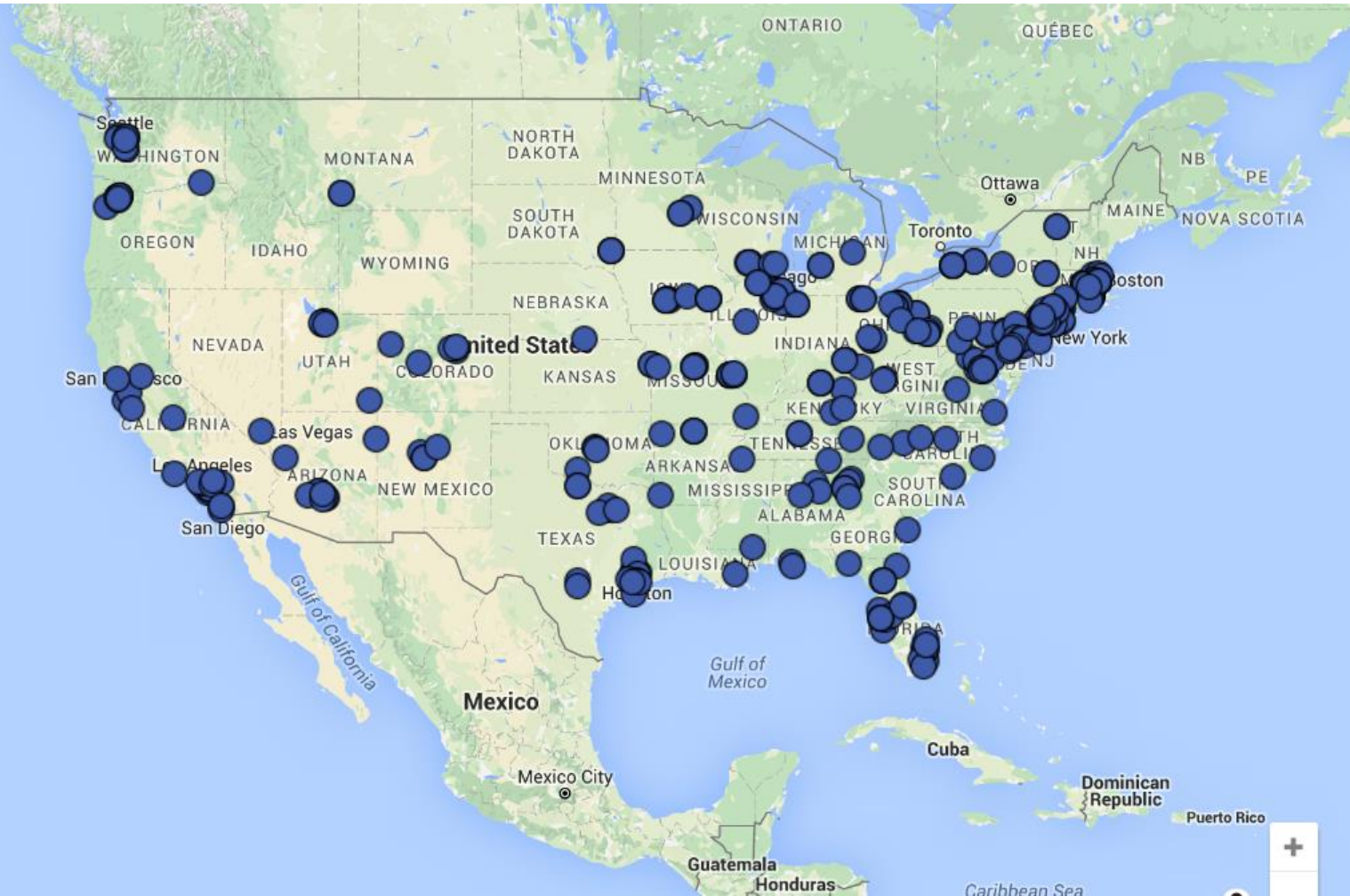
Sarah M. Friedewald, MD, FACR, FSBI  
Academic Division Chief, Breast Imaging  
Mass General Brigham



# 2011 FDA Approval



2012



## 2013 Oslo Trial Published

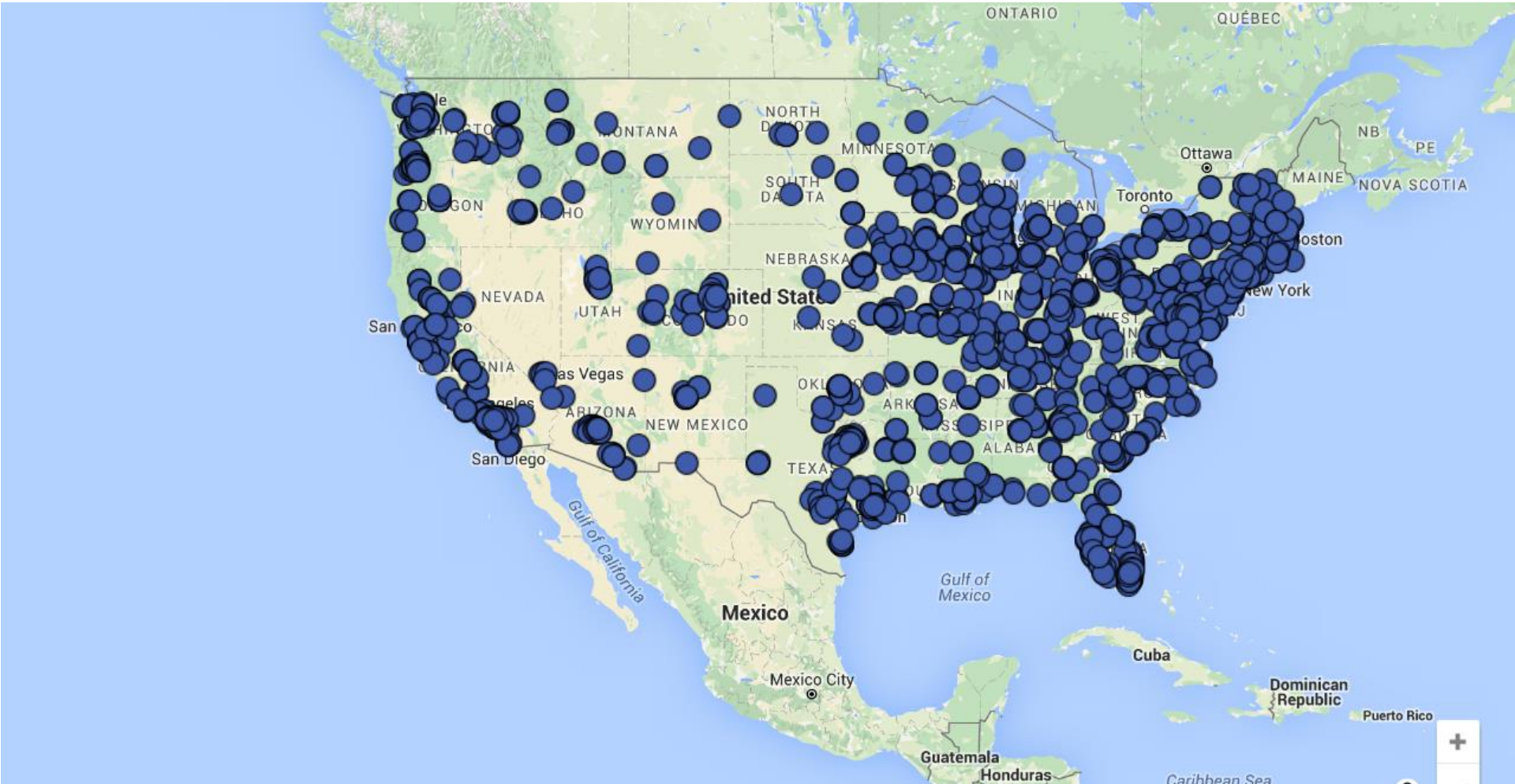


# 2014

## US Studies Published JAMA; JNCI



# 2015 CMS covers tomosynthesis



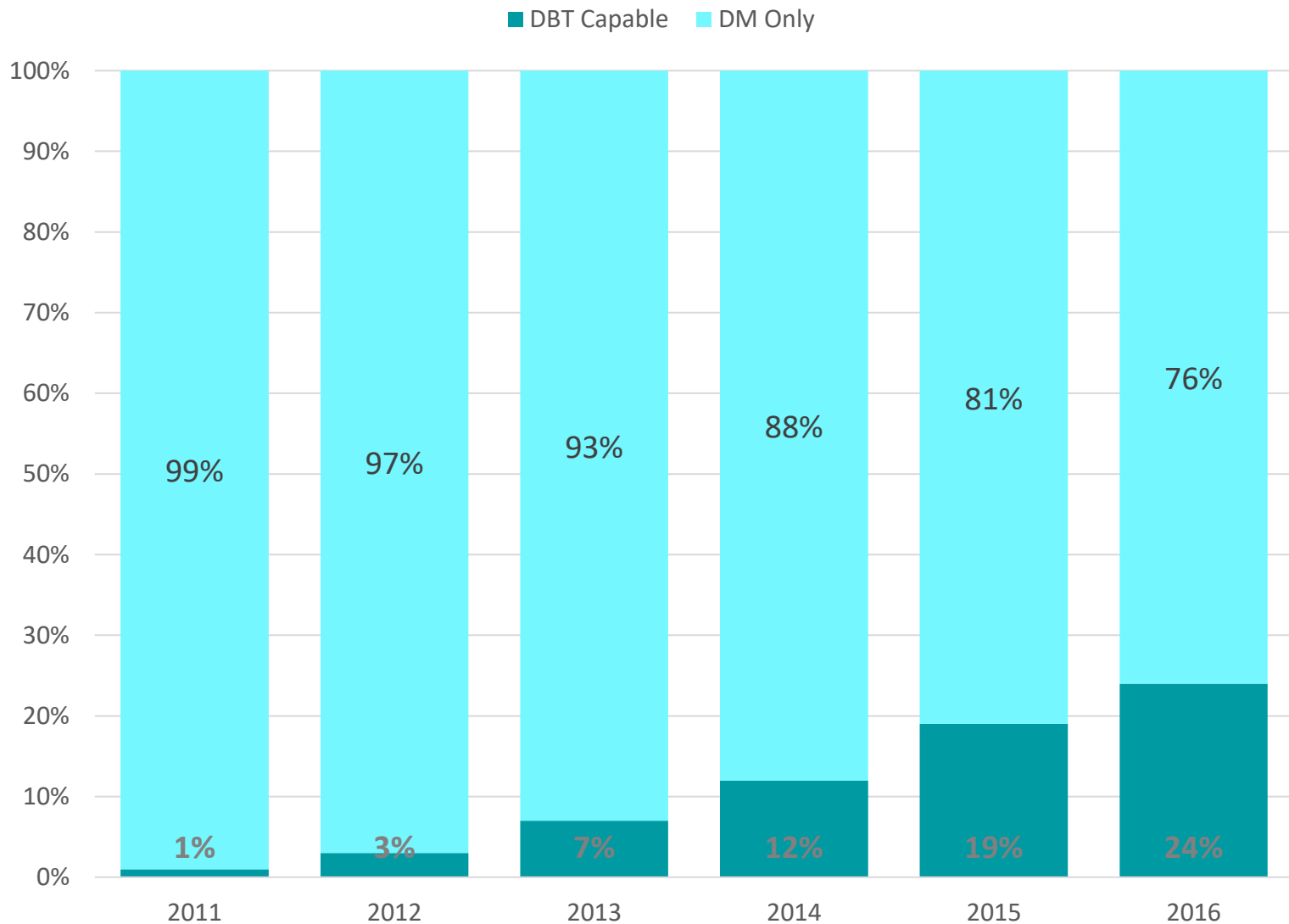
## FDA Accredited Units as of June 1, 2005

## FDA Accredited Units as of June 1, 2016

|        | Facilities | Units  | %     |  | Facilities | Units  | %     |
|--------|------------|--------|-------|--|------------|--------|-------|
| Total  | 8,911      | 13,621 | 100%  |  | 8,740      | 16,155 | 100%  |
| Analog |            | 12,747 | 93.6% |  |            | 285    | 1.8%  |
| FFDM   |            | 874    | 6.4%  |  |            | 12,508 | 77.4% |
| DBT    |            | 0      | 0%    |  |            | 3,362  | 20.8% |

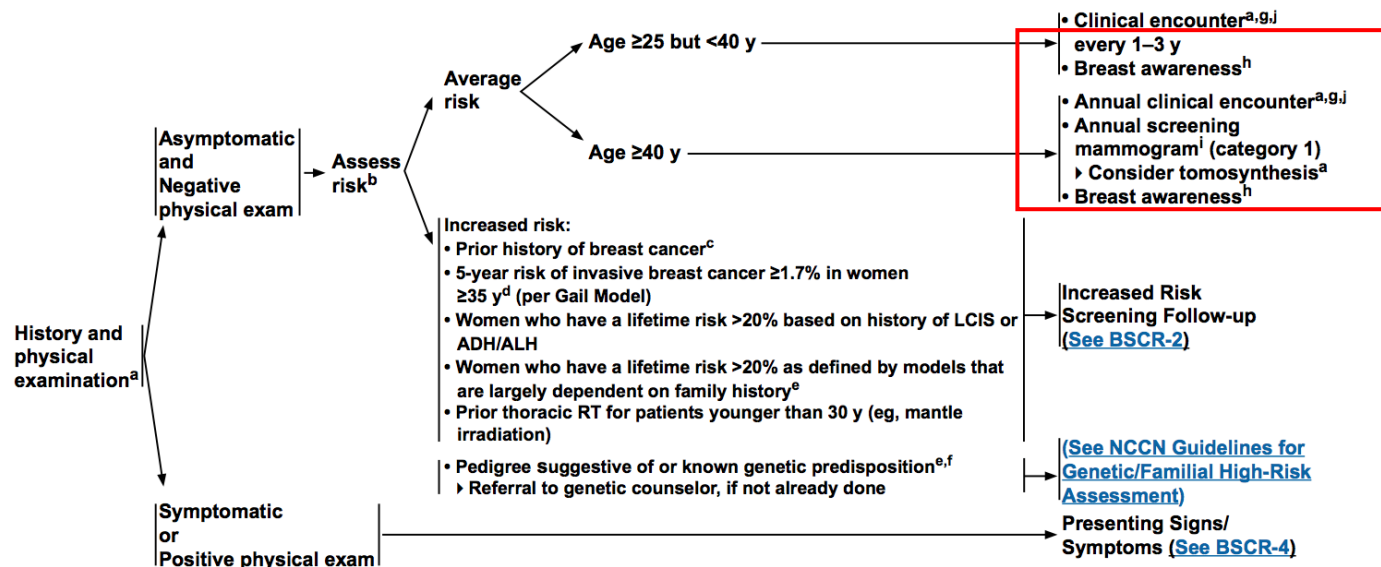


## Breast Tomosynthesis Installs in the U.S.



|                                                                                        |                |
|----------------------------------------------------------------------------------------|----------------|
| Certified facilities, as of October 1, 2024                                            | 8,931          |
| Certification statistics, as of March 1, 2025                                          |                |
| <u>Total certified facilities</u> / <u>Total accredited units</u>                      | 8,963 / 26,539 |
| Certified facilities with 2D digital units <sup>2</sup> / Accredited 2D digital units  | 8,962 / 13,759 |
| <u>Certified facilities with DBT units<sup>3,4</sup></u> / <u>Accredited DBT units</u> | 8,266 / 12,780 |
| FY 2025 inspection statistics, as of January 1, 2025                                   | 92.2% 48.2%    |
| Facilities inspected                                                                   | 3,435          |
| Total units at inspected facilities                                                    | 10,051         |
| Percent of inspections where the highest noncompliance was a:                          |                |
| Level 1 noncompliance                                                                  | 1.2%           |
| Level 2 noncompliance                                                                  | 22.1%          |
| Percent of inspections with no noncompliance                                           | 76.7%          |
| Total annual mammography procedures reported, as of March 1, 2025 <sup>1</sup>         | 43,052,991     |



**NCCN Guidelines Version 1.2016  
Breast Cancer Screening and Diagnosis**[NCCN Guidelines Index](#)[Table of Contents](#)[Discussion](#)**SCREENING OR SYMPTOM CATEGORY****SCREENING/FOLLOW-UP<sup>a</sup>**<sup>a</sup>See [Breast Screening Considerations \(BSCR-A\)](#).<sup>b</sup>Refer to the [NCCN Guidelines for Breast Cancer Risk Reduction](#) for a detailed qualitative and quantitative assessment.<sup>c</sup>See [NCCN Guidelines for Breast Cancer - Surveillance Section](#).<sup>d</sup>See [Risk Factors Used in the Modified Gail Model, Age ≥35 Years \(BSCR-B\)](#).<sup>e</sup>Risk models that are largely dependent on family history (eg, Claus, BRCAPRO, BOADICEA, Tyrer-Cuzick). See [NCCN Guidelines for Breast Cancer Risk Reduction](#).<sup>f</sup>There is variation in recommendations for initiation of screening for different genetic syndromes. See [NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast and Ovarian](#).<sup>g</sup>Clinical encounter should encompass ongoing risk assessment, risk reduction counseling, as well as a clinical breast exam.<sup>h</sup>Women should be familiar with their breasts and promptly report changes to their health care provider.<sup>i</sup>See [Mammographic Evaluation \(BSCR-19\)](#).<sup>j</sup>Randomized trials comparing clinical breast exam versus no screening have not been performed. Rationale for recommending clinical encounter is to maximize earliest detection of interval breast cancers..**Note:** All recommendations are category 2A unless otherwise indicated.**Clinical Trials:** NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.**BSCR-1**

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# Provider Challenges

# Advocate Lutheran General Hospital

Large community hospital in suburban Chicago

Part of a larger healthcare system with 12 hospitals

Comprehensive breast center with 2.5 rads reading breast a day

40,000 examinations a year

20,000 screening examinations

3 screening units

3 diagnostic units



Caldwell Breast Center

Caldwell Breast Center, Advocate Lutheran General Hospital



# Advocate Lutheran General Hospital

What patients to you image?

Do you charge patients?

Do you ask the patients if they want tomosynthesis?

Who makes the decision?

Acquired one tomosynthesis unit in 2011



# Advocate Lutheran General Hospital

Started with diagnostic patients

Allows the technologists to get used to the new technology, breathing technique

Allows the radiologists to get comfortable with interpretation

- US confirmation
- Higher likelihood of malignancy

Were not maximizing the technology

Not as many patients benefited from technology

Could not advertise, had to select patients

Had no one to ask for help (5<sup>th</sup> in country to install, 1<sup>st</sup> in Midwest)



# Advocate Lutheran General Hospital

Switched to screening after hours (only two machines screening)  
Started to advertise the technology  
Encouraged patients to come after hours  
All patients will get tomosynthesis  
No decisions for the technologists  
Maximized the benefit of tomosynthesis



# Northwestern Memorial Hospital

Tertiary academic medical center in Chicago

40,000 patients screened each year

85,000 total procedures each year

16 mammogram units

- 6 used for screening

7 ultrasound units



# Northwestern Memorial Hospital

Used for diagnostic patients

Some patients requested screening

Underutilized

Only one workstation for interpretation

15 radiologists needed to train

- Not enough experience for each



# Northwestern Memorial Hospital

January 1, 2015: CPT code available for Tomosynthesis  
Two machines available at main center out of 4  
screening rooms

- Patients randomized to tomosynthesis rooms

Patients complained because they were getting charged  
for what they thought was a covered examination



# Northwestern Memorial Hospital

*Switched to informing patients at the front desk that there may be a charge associated with the examination*

Front desk not capable of answering questions about tomosynthesis

- Benefits, risks, dose, cost

Technologists have 15 min slots and can't wait for patients to call insurance company and/or explain the benefits

Backlog of patients choosing to have tomosynthesis

Patients leaving because of the wait



# Northwestern Memorial Hospital

## Developed a sticker system

- Message left on reminder call to investigate
- Information was in waiting area about the benefits of the technology
- Front desk asked if they wanted tomosynthesis
  - Yes- green dot sticker
  - Uncertain- yellow dot sticker
  - No- red dot sticker



# Northwestern Memorial Hospital

Purchased 4 more machines in 2016

6/6 screening units were tomosynthesis capable

July 2016- Illinois legislation requiring insurance companies to pay for DBT

Maximize the screening capability of tomosynthesis

Opportunity to advertise the technology

All patients will get tomosynthesis

No decision for the technologists

No time restrictions with imaging



# Interpretation

# How to Handle all of the Images!

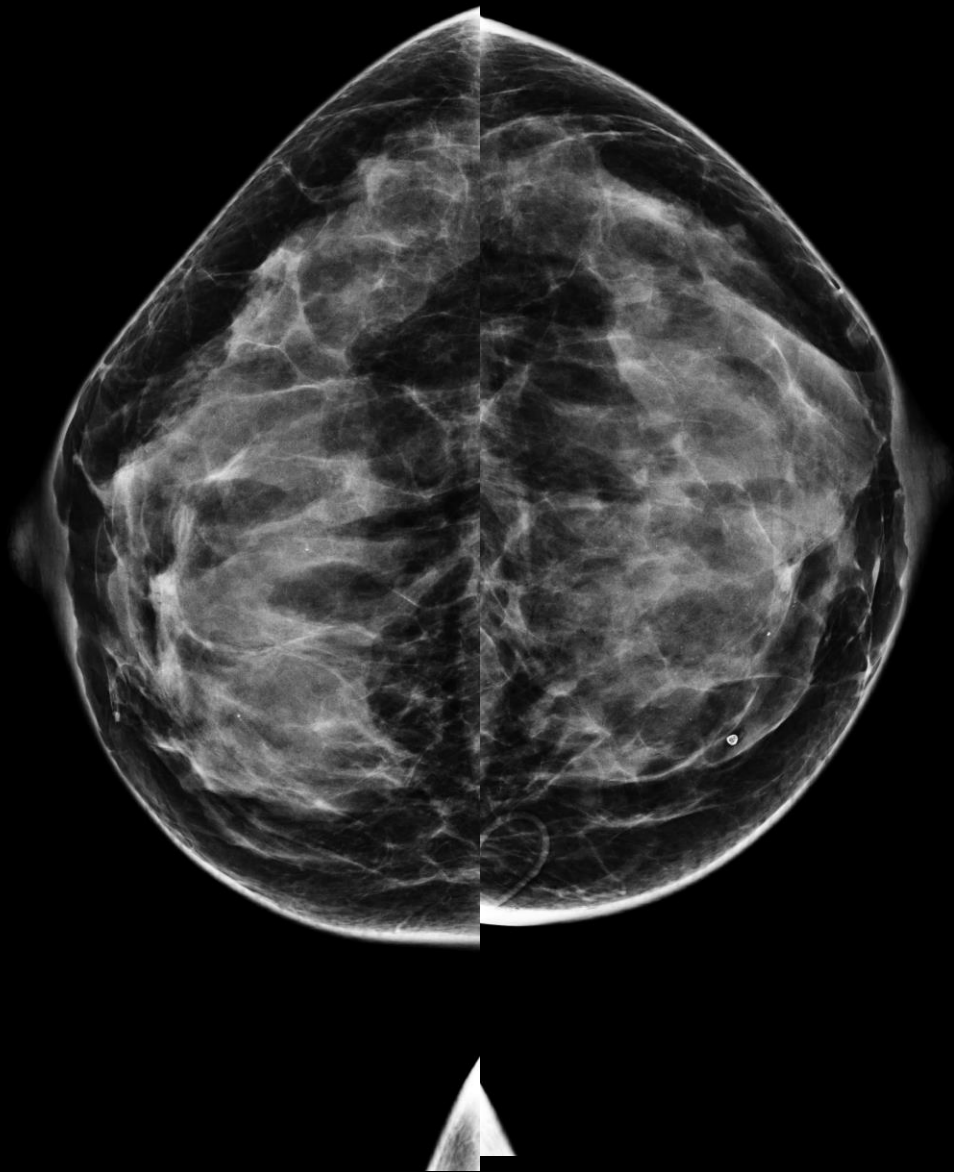
Different work flows for each radiologist

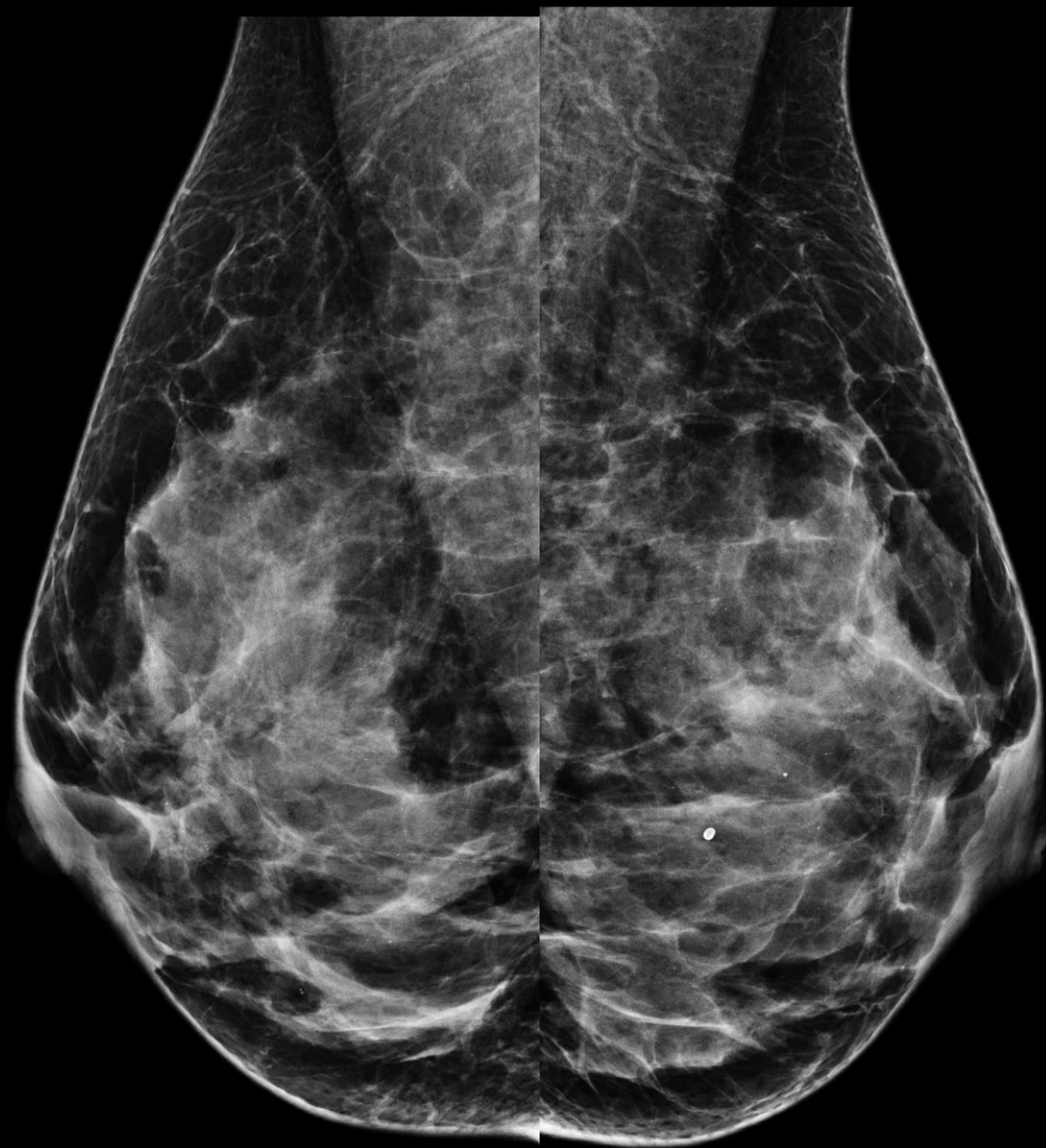
Doesn't matter how you approach it as long as it is the same way each time

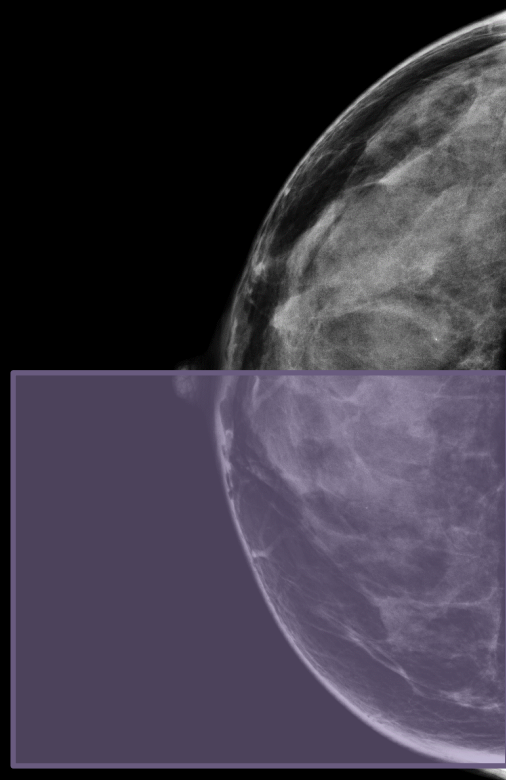
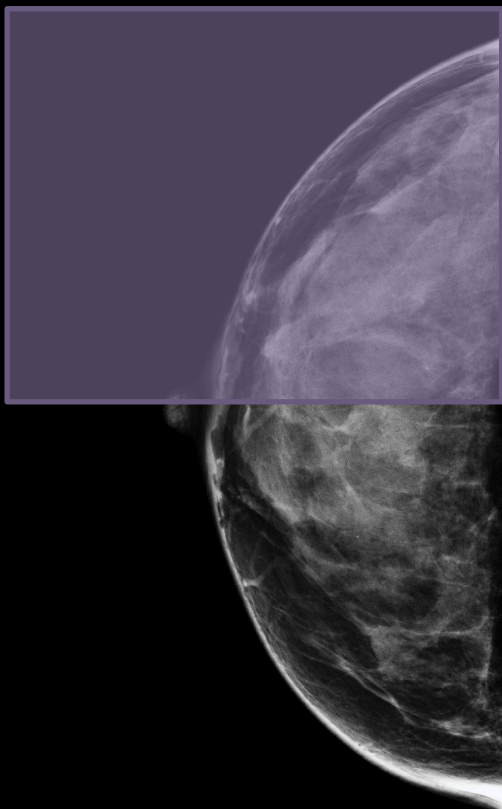
Depends on the PACS display

At NMH, we only had 2 machines capable to interpret tomosynthesis









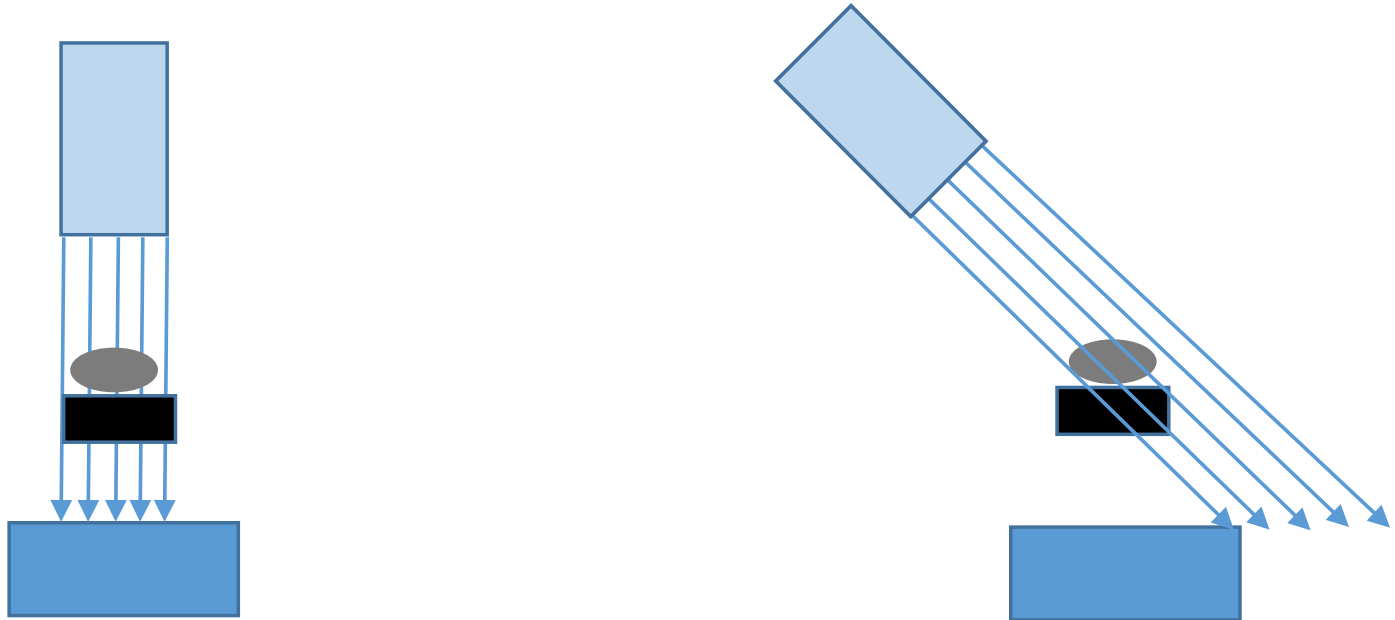
# Diagnostic Imaging with Tomosynthesis

# Diagnostic Imaging

- Improves ultrasound scan time
- Increases or decreases pre-test probability of lesions being benign or malignant
- Spot compression views can help with areas typically susceptible to motion



# No Magnification Views in Tomosynthesis



# Triangulation

## Four Reasons Why Scroll Bar May Not Appear Accurate

Reader did not take into consideration principles of triangulation on non-orthogonal views

True center of the breast may not be at the middle slice

Compression paddles flex, leading to greater compression in the anterior portion of the breast

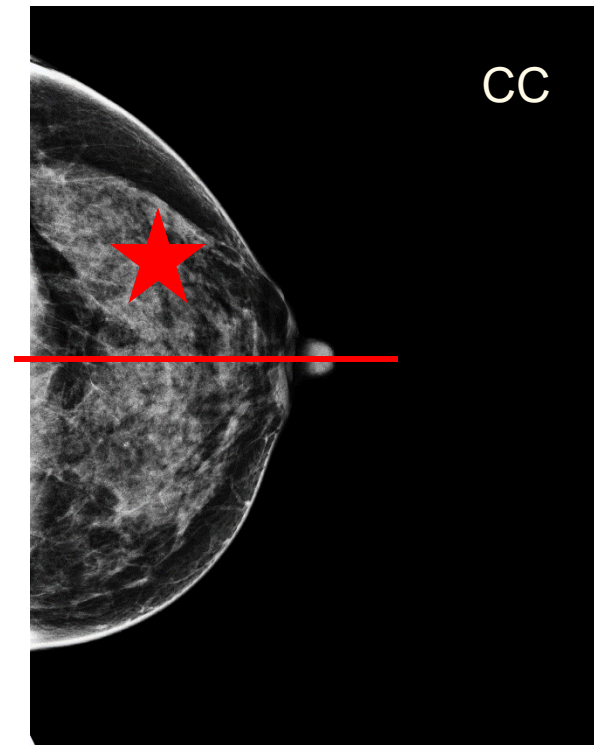
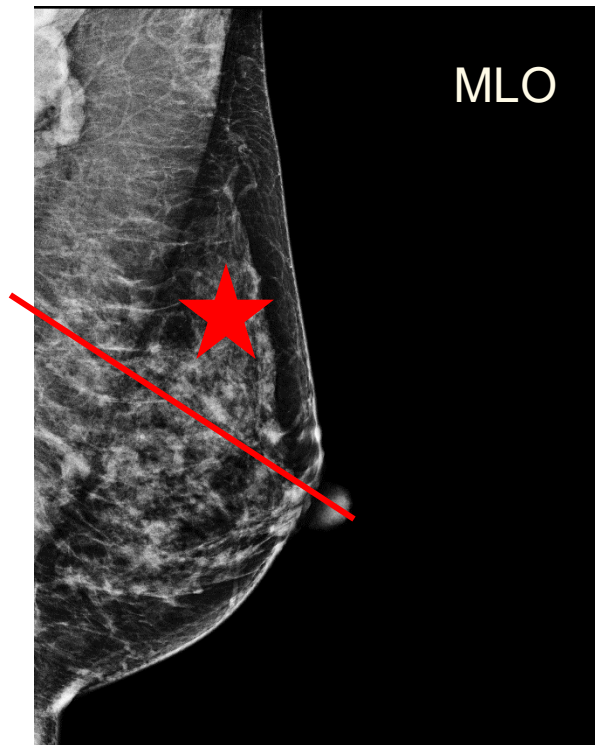
Superficial lesions are rolled between CC and MLO views



# Localizing Lesions in Digital Mammography

Standard views of the breast can determine general lesion location

★ Upper outer quadrant



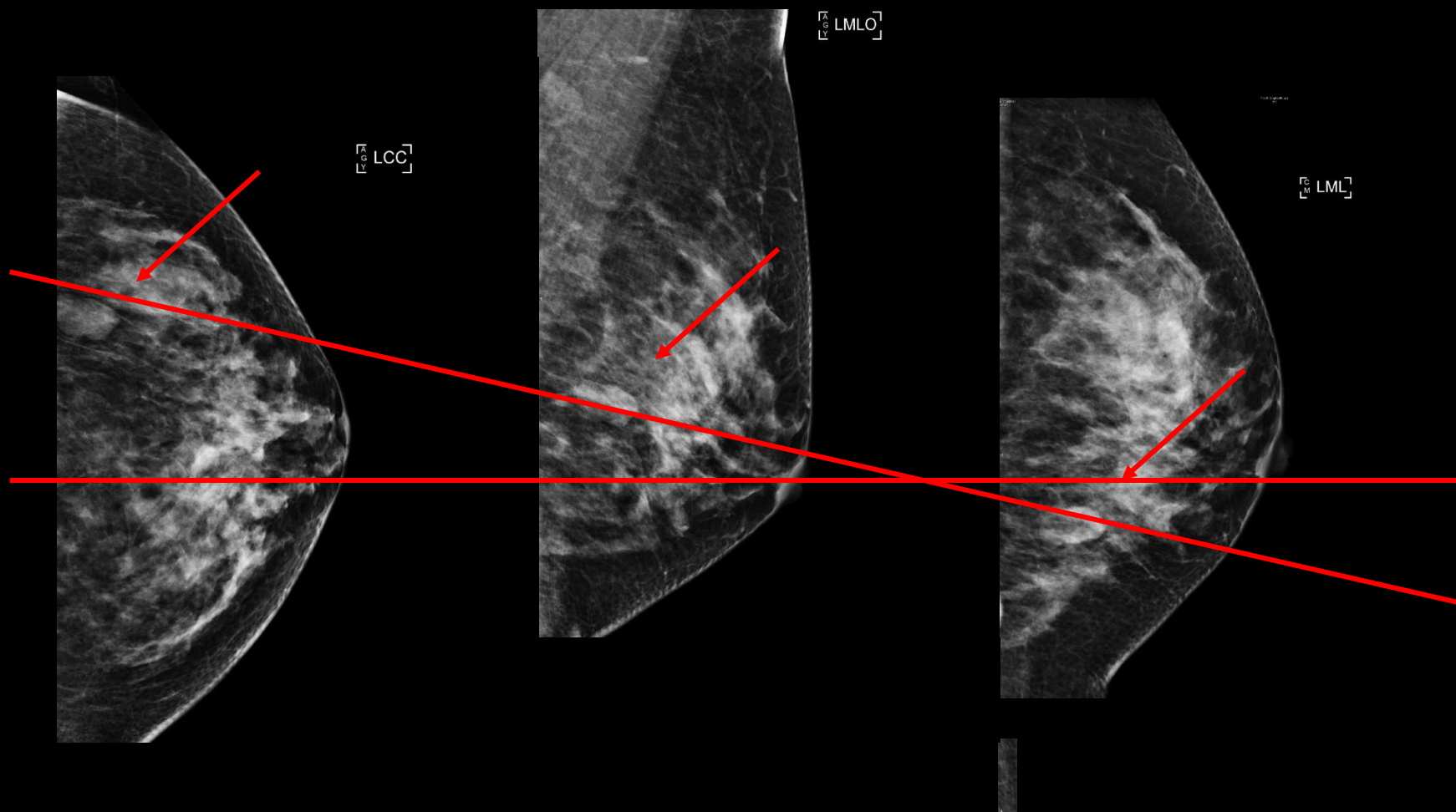
# Localizing Lesions in Digital Mammography

MLO view and CC view are not orthogonal views

- Can predict the true location on a lateral view based on triangulation principles
  - Lateral lesions move **lower** on the true lateral view compared to the MLO view
  - Medial lesions move **higher** on the true lateral view compared to the MLO view



# Localizing Lesions in Digital Mammography



# Principles of Lesion Localization with DBT

Lesion location can be determined with tomosynthesis on each view

- Approximation, these are not true 3D images
- On CC view, scroll bar indicates the slice being viewed is
  - Toward the **cranial** aspect
  - Toward the **caudal** aspect

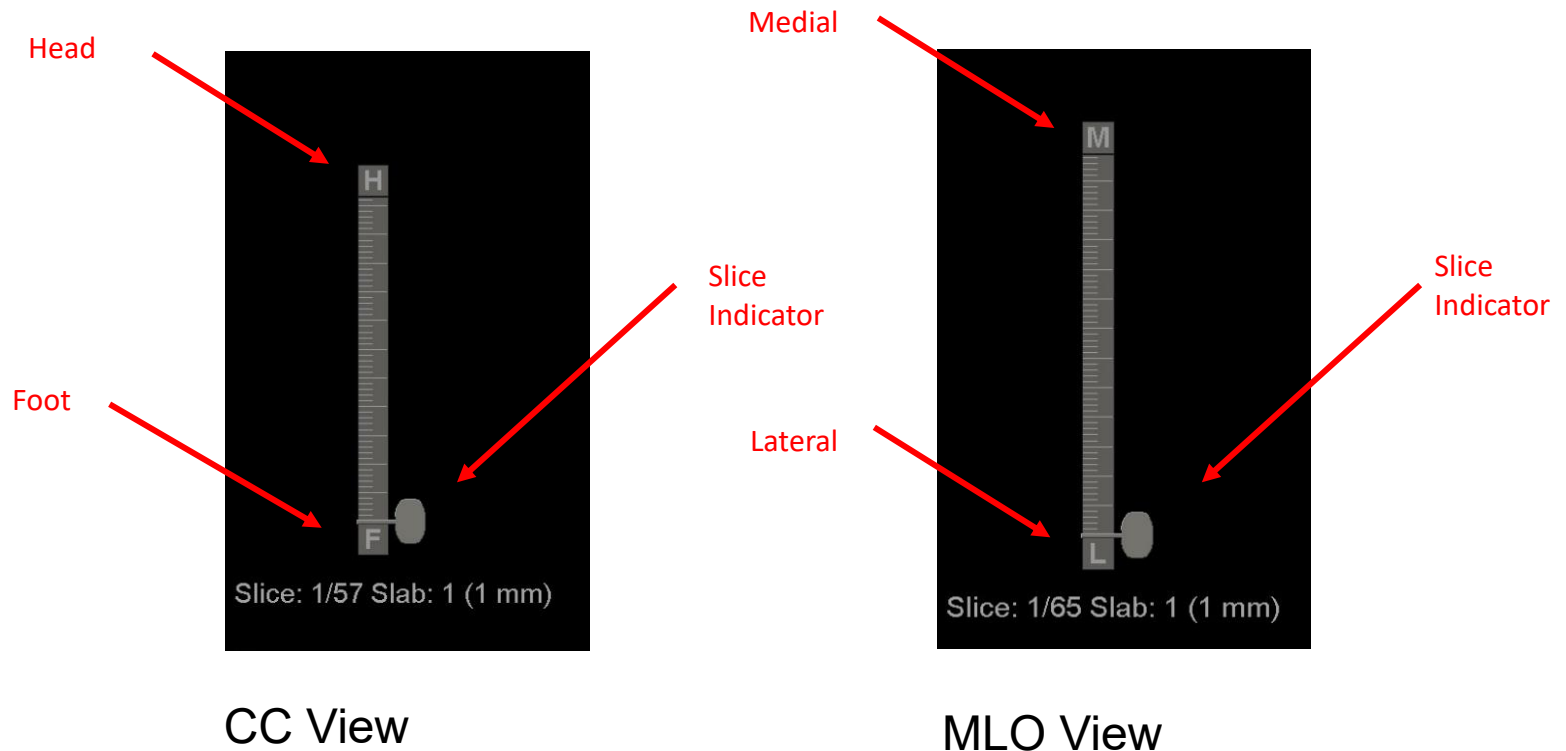
**Key point: The CC scroll bar reflects position on a true lateral view not MLO view!**

- On MLO view, scroll bar indicates the slice being viewed is
  - Toward the **medial** aspect
  - Toward the **lateral** aspect

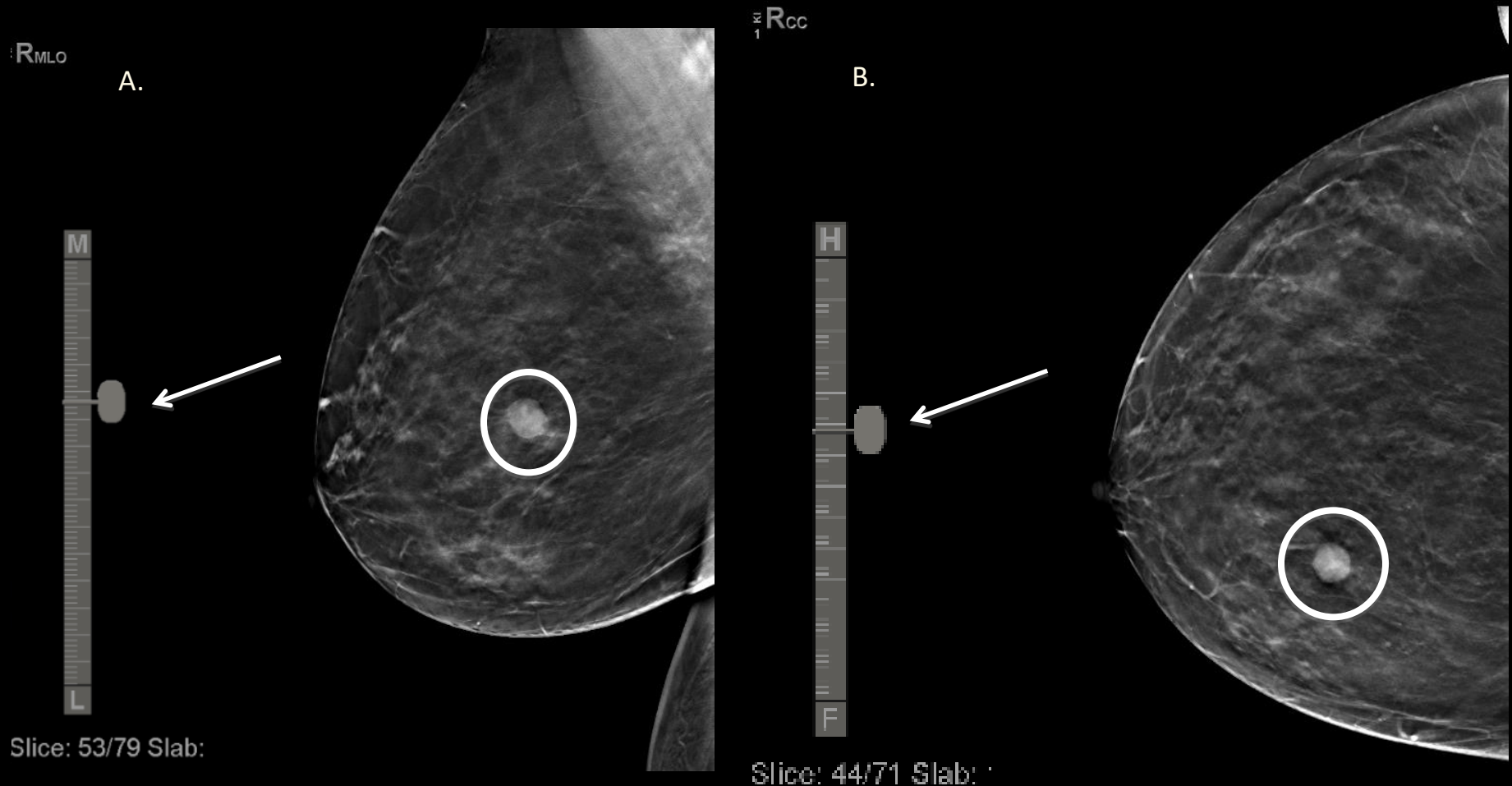


# Review of the Scroll Bar

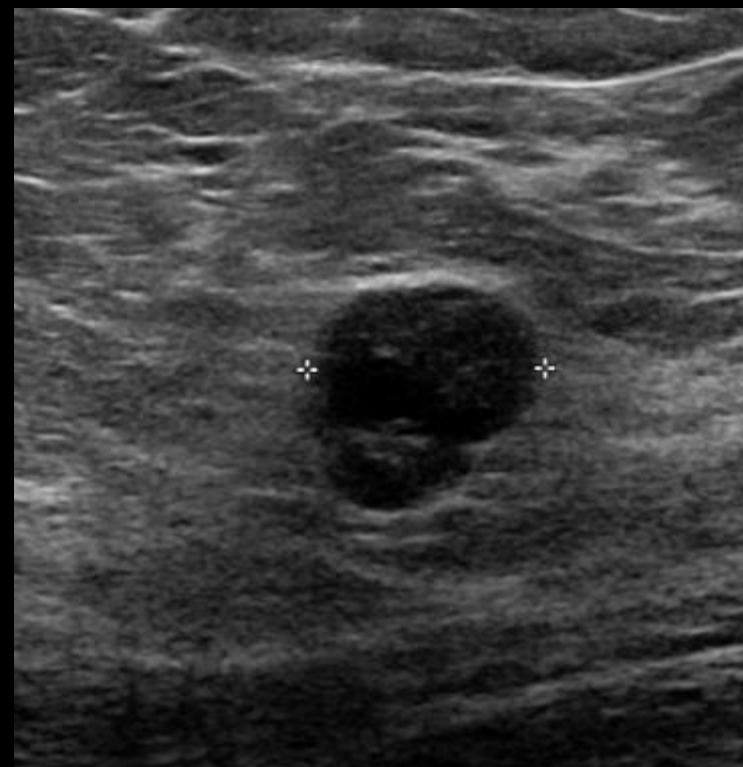
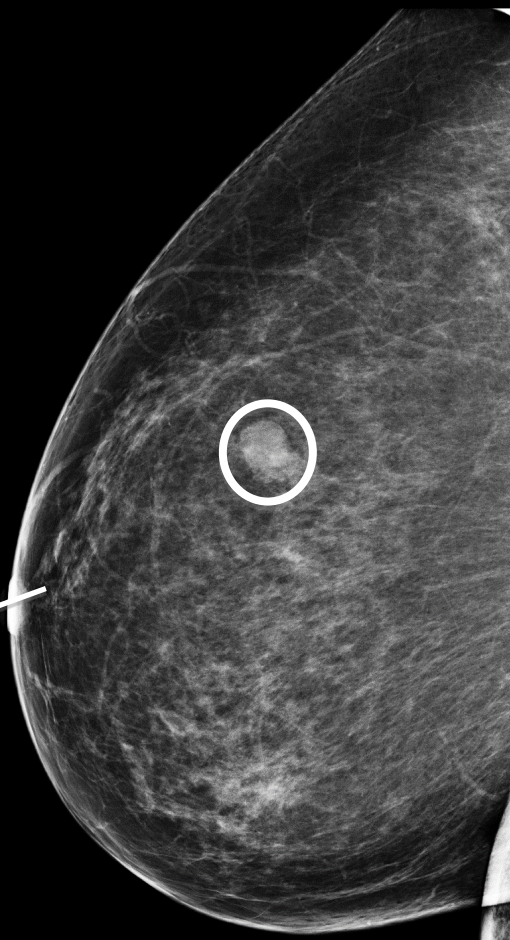
## DBT scroll bar displaying the slice location



# Basic Principles of Triangulation in Non-Orthogonal Views With DBT



S  
D RLM



Rt Brst 2:00 5cm Rad

Slice: 44/71 Slab: 1

# Four Reasons Why Scroll Bar May Not Appear Accurate

Reader did not take into consideration principles of triangulation on non-orthogonal views

**True center of the breast may not be at the middle slice**

Compression paddles flex, leading to greater compression in the anterior portion of the breast

Superficial lesions are rolled between CC and MLO views

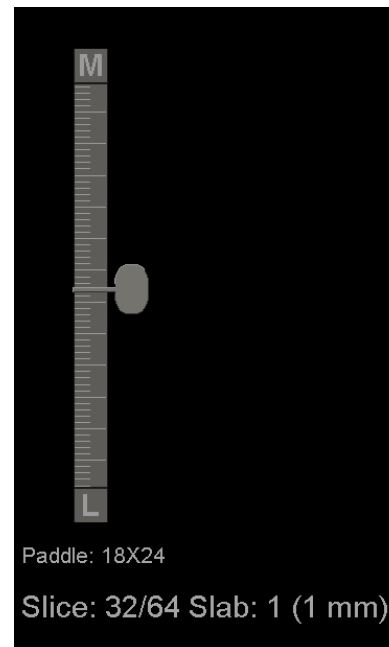


# True Center of the Breast

Nipple location ideally is located in the exact center of the breast

True center of the breast may be medial/lateral or superior/inferior to middle slice of the scroll bar

Nipple location is not always exactly in center of the scroll bar

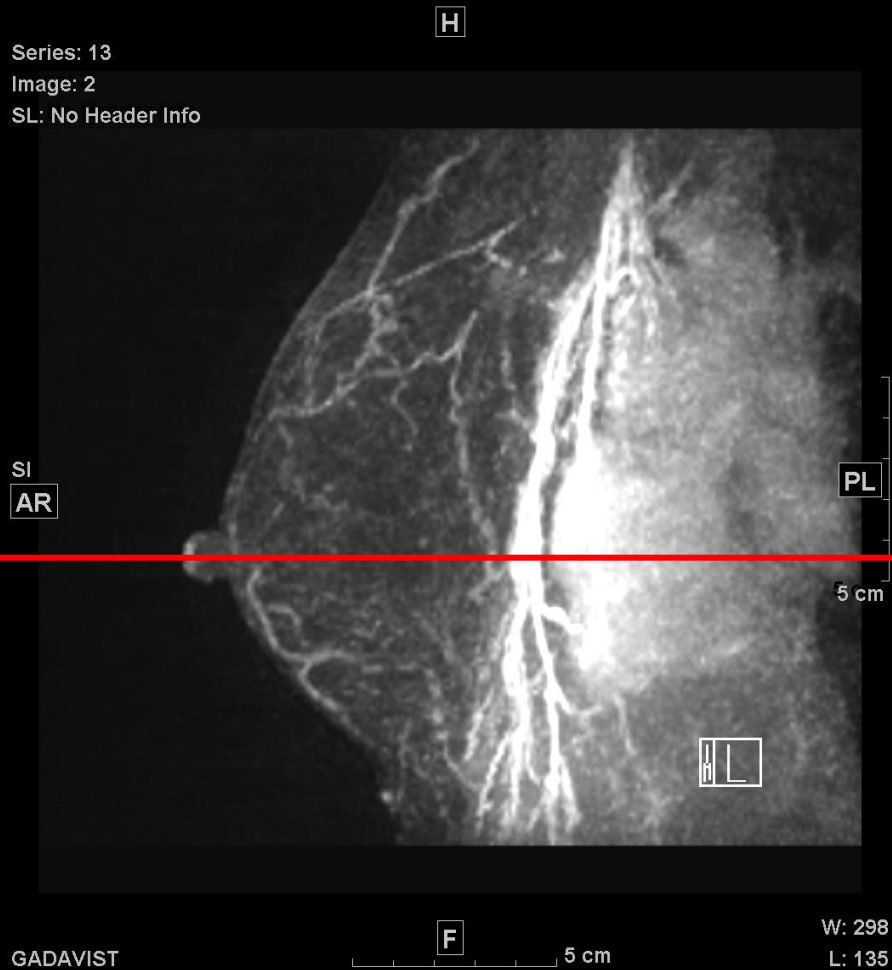


## True Center of the Breast

As in other modalities such as CT and MR, the center of the breast is not always in the center of the image  
Therefore, assuming the center of the breast is in the center of the scroll bar is misleading

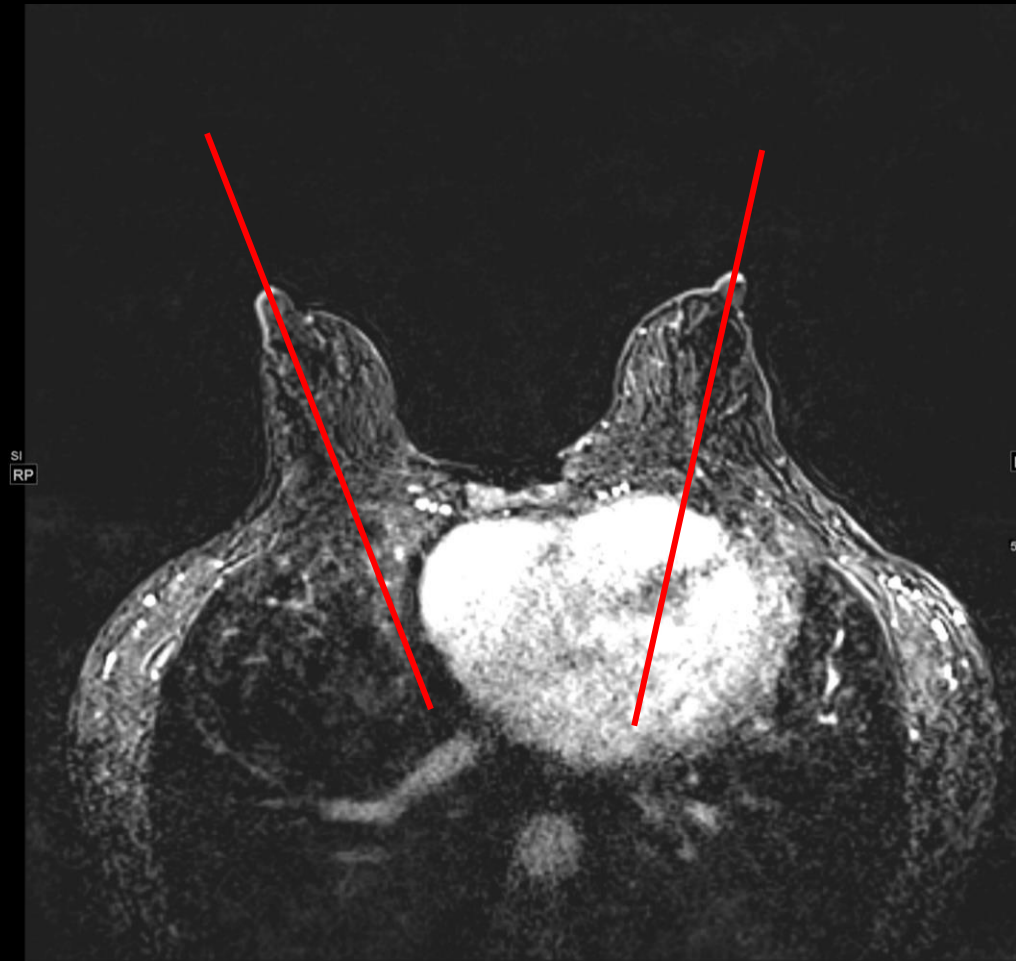


# True Center of the Breast



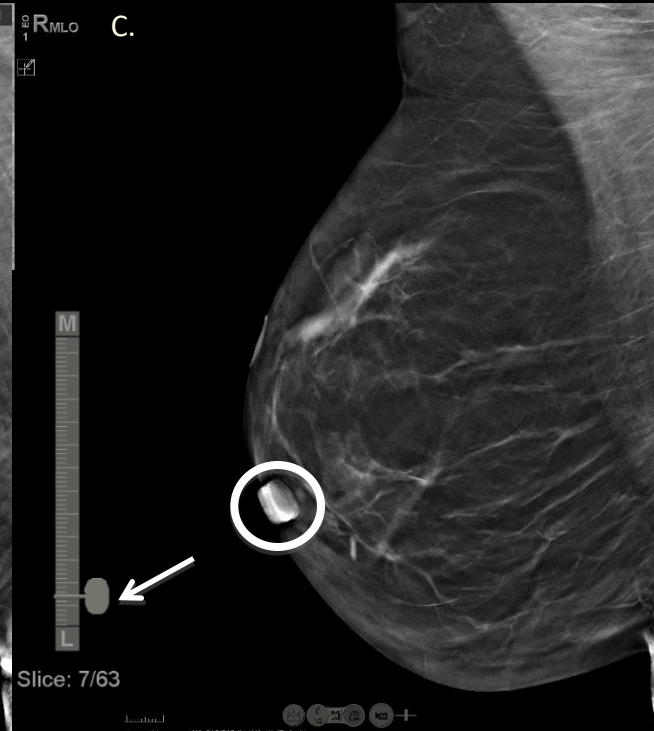
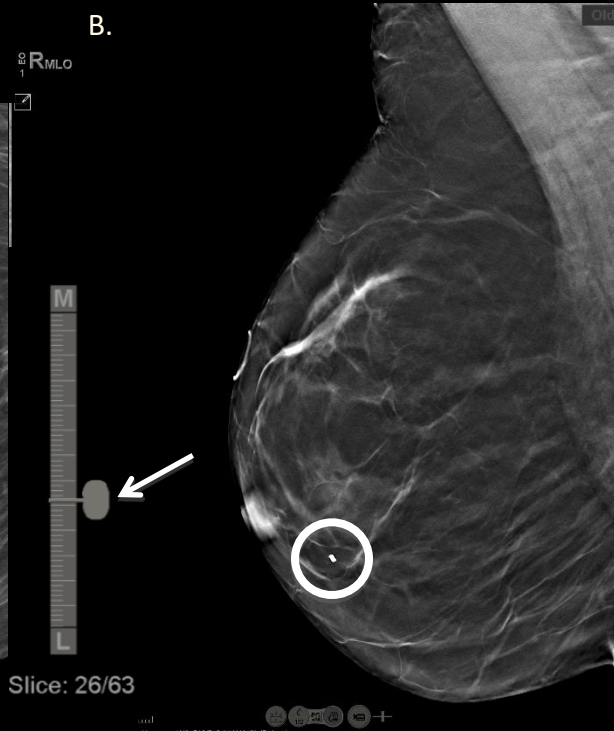
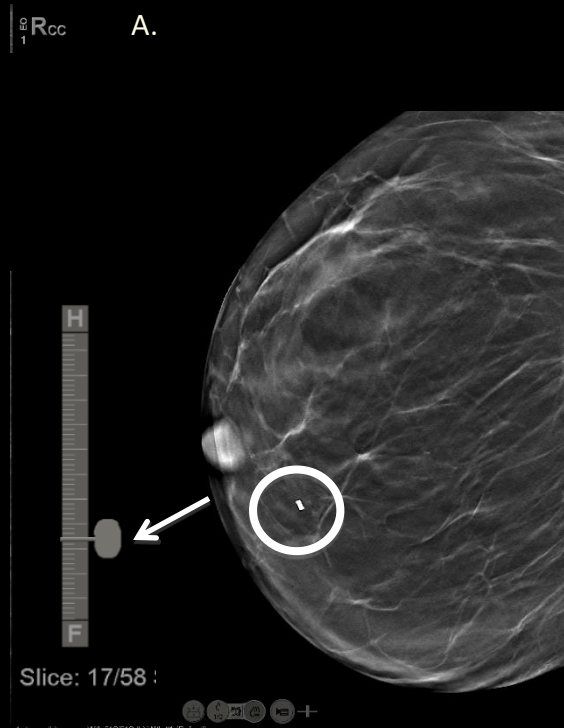
Sagittal MR view of the left breast demonstrating that greater than 50% of the breast is superior to the nipple.

# True Center of the Breast



Axial MR view of both breasts demonstrating that a significant amount of tissue is medial to the nipple.

# Nipple Position



# Four Reasons Why Scroll Bar May Not Appear Accurate

Reader did not take into consideration principles of triangulation on non-orthogonal views

True center of the breast may not be at the middle slice

Compression paddles flex, leading to greater compression in the anterior portion of the breast

Superficial lesions are rolled between CC and MLO views



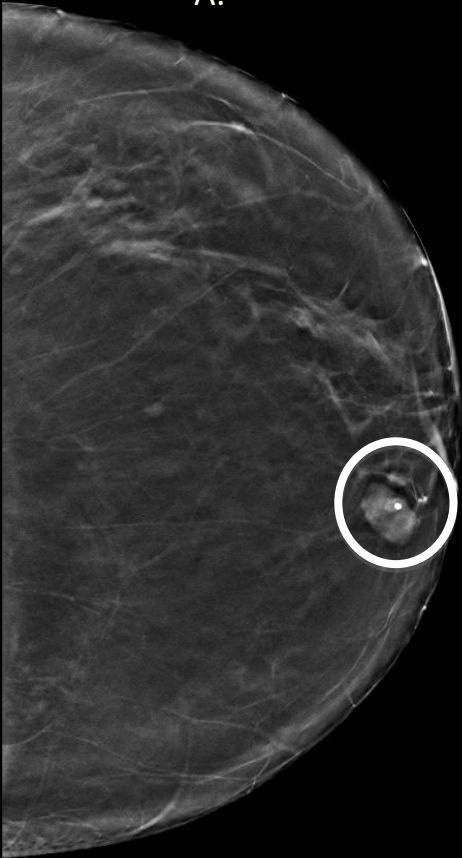
# Paddle Flex

Anterior breast is compressed more than the posterior breast  
Anterior lesions will localize closer to the detector side because the breast is thinner  
Scroll bar is fixed

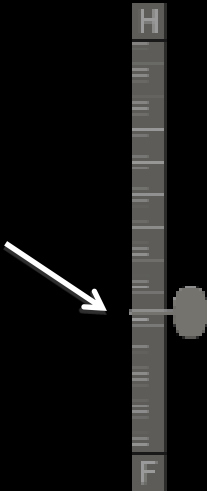


# Paddle Flex

A.

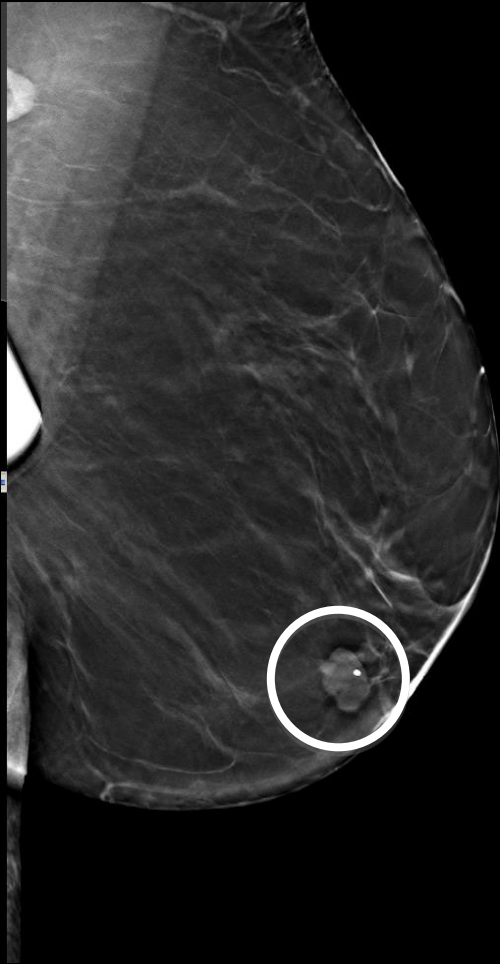


$1^{CA}$  L<sub>CC</sub>

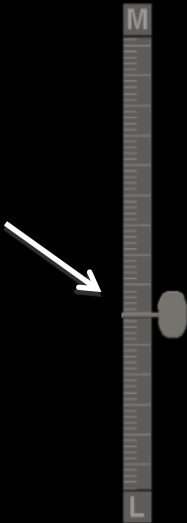


Slice: 22/63 Slab: 1 (1 mm)

B.



$1^{CA}$  L<sub>MLO</sub>



Slice: 30/76 Slab: 1 (1 mm)

# Four Reasons Why Scroll Bar May Not Appear Accurate

Reader did not take into consideration principles of triangulation on non-orthogonal views

True center of the breast may not be at the middle slice

Compression paddles flex, leading to greater compression in the anterior portion of the breast

**Superficial lesions are rolled between CC and MLO views**



# Superficial Location

DBT is not a true 3-Dimensional image

- Breast is repositioned between the CC and MLO views
- Unlike CT and MRI, the images cannot be reconstructed into different planes

Superficial lesions are most affected by breast repositioning/rolling of breast

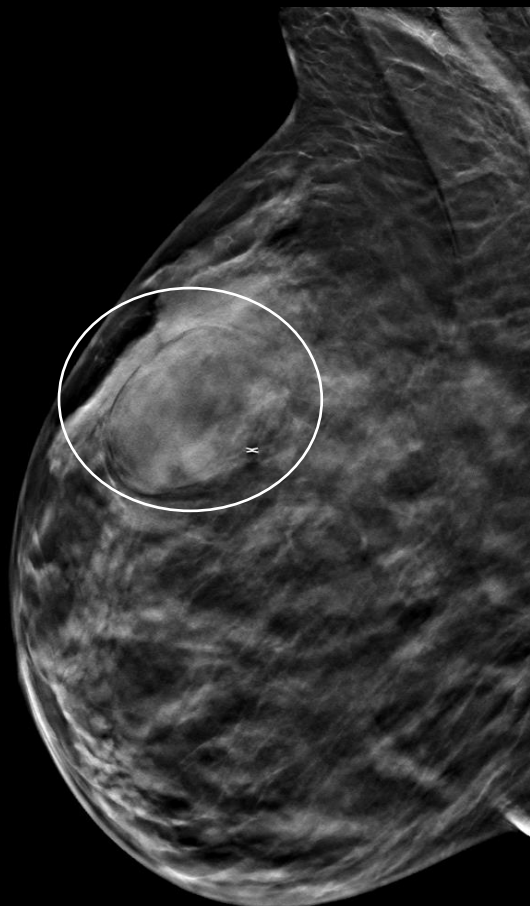
- More likely these lesions will localize differently on the orthogonal view





Paddle: 18X24

Slice: 12/47 Slab: 1 (1 mm)

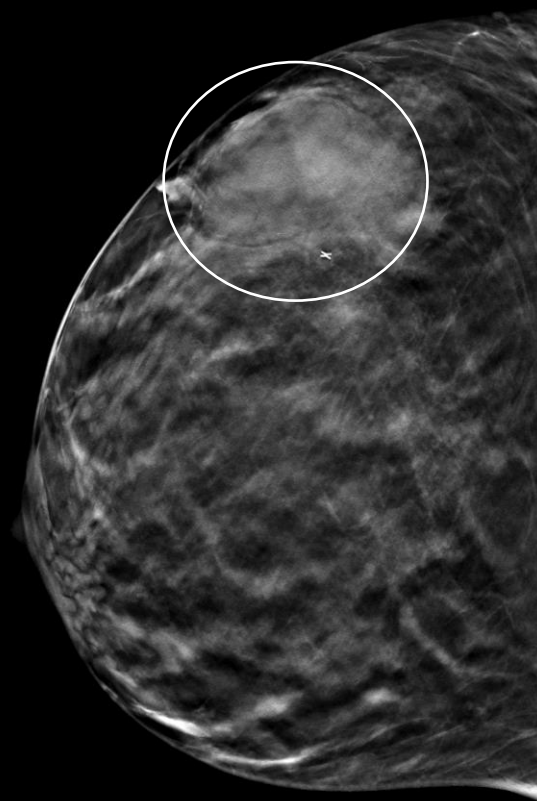


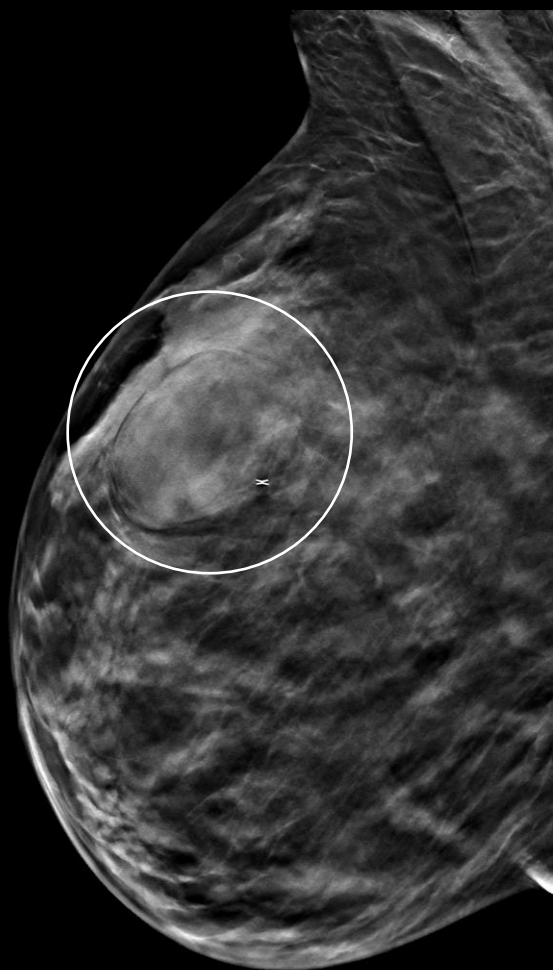
CC



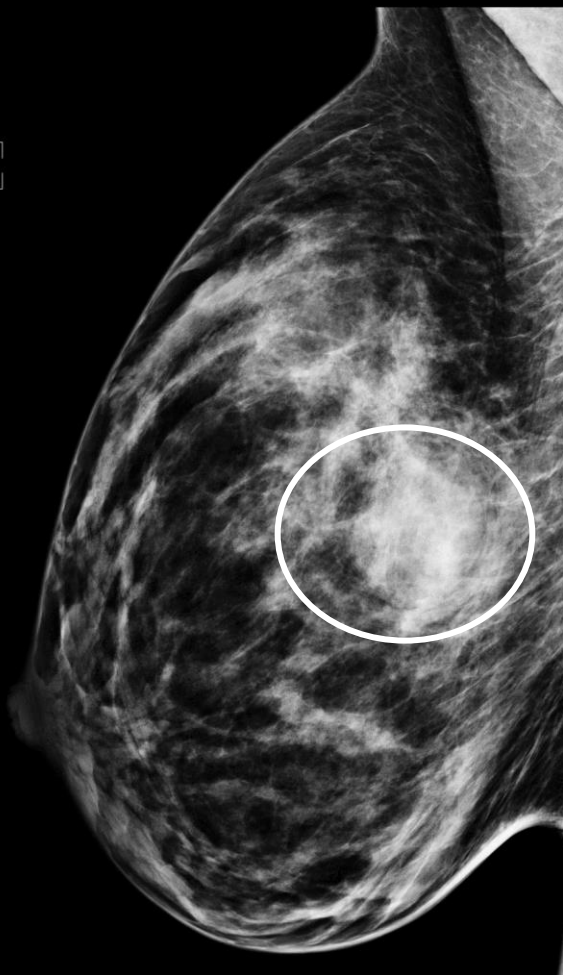
Paddle: 18X24

Slice: 22/46 Slab: 1 (1 mm)

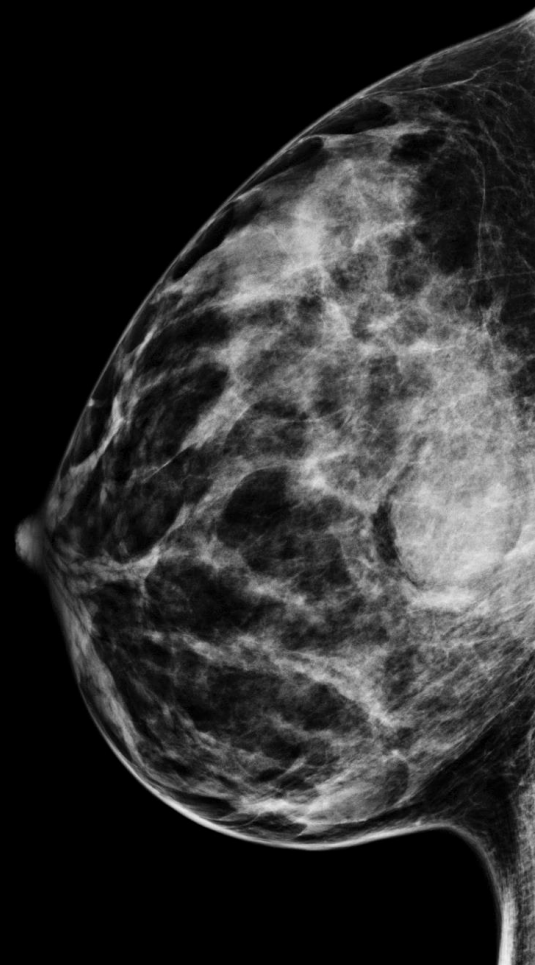




A  
F RMLO



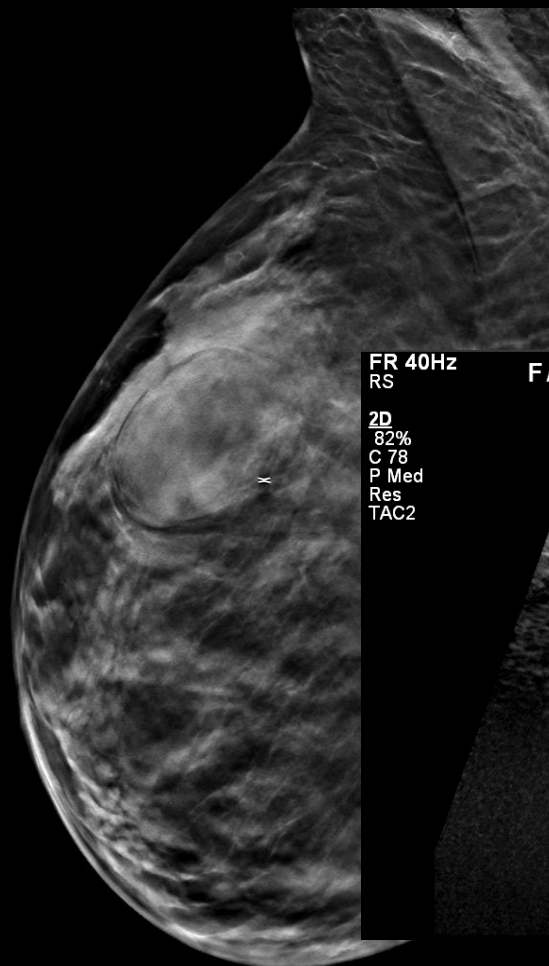
D  
S RML





Paddle: 18X24

Slice: 22/46 Slab: 1 (1 mm)



FR 40Hz  
RS

F / 40

M4

2D  
82%  
C 78  
P Med  
Res  
TAC2



Rt Brst 9:30 6cm Arad

3.5

# Triangulation with DBT

It is important to remember triangulation principles to accurately localize a lesion on non-orthogonal views

The compression paddle flexes anteriorly which changes the thickness of the breast. Therefore, lesions tend to localize closer to the detector side more often than expected

The nipple is not always in the center of the scroll bar

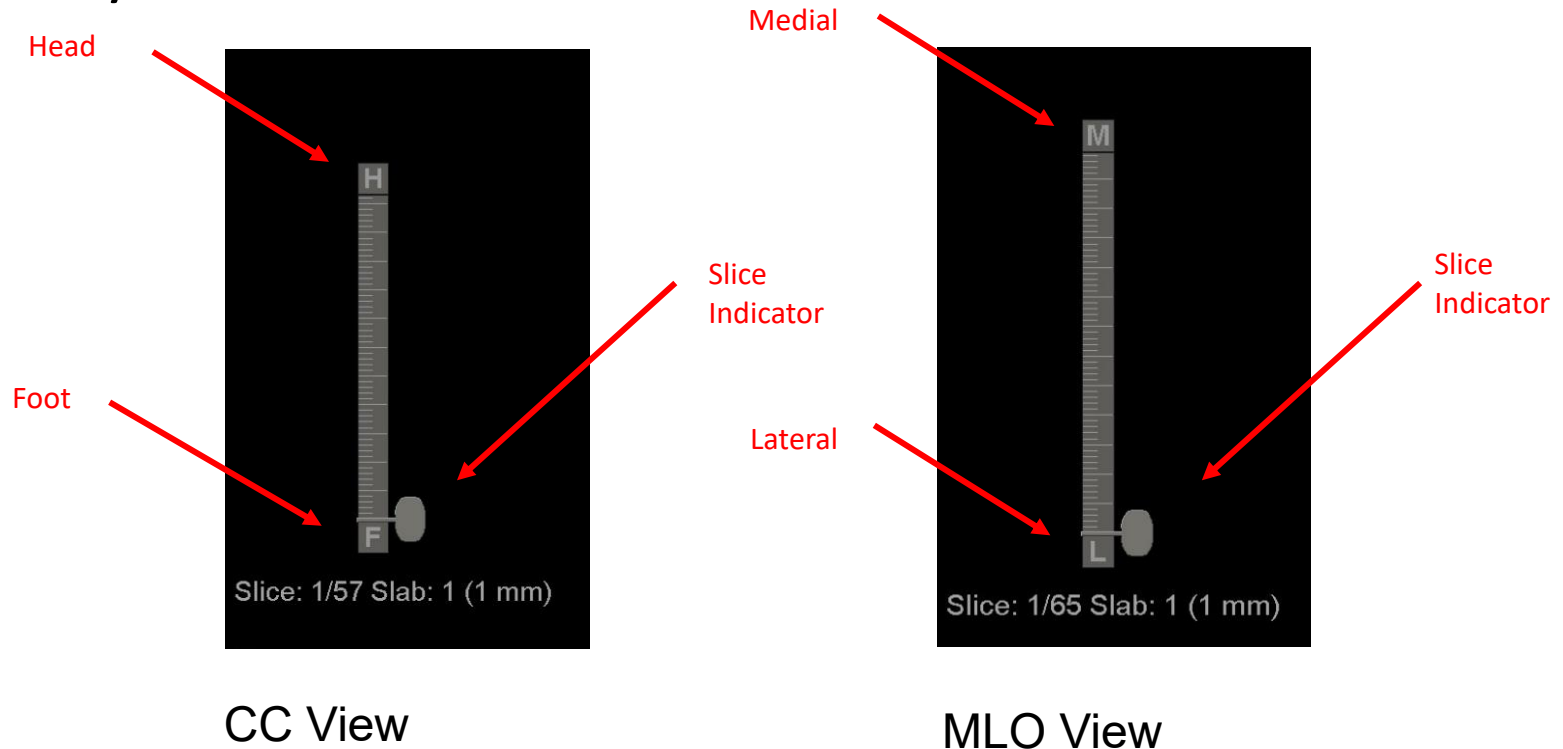
Superficial lesions will move upon repositioning between CC and MLO views and therefore, may not consistently localize to the same location on both views



# Review of the Scroll Bar

DBT scroll bar displaying the slice location

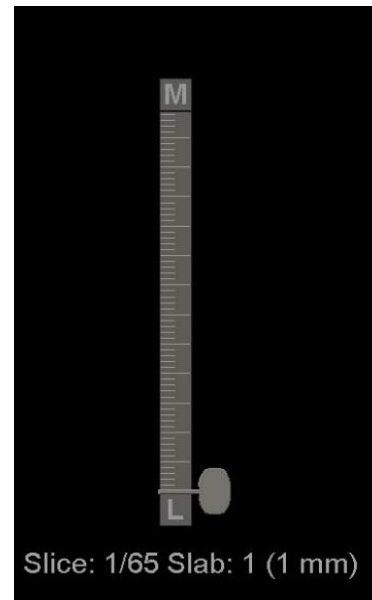
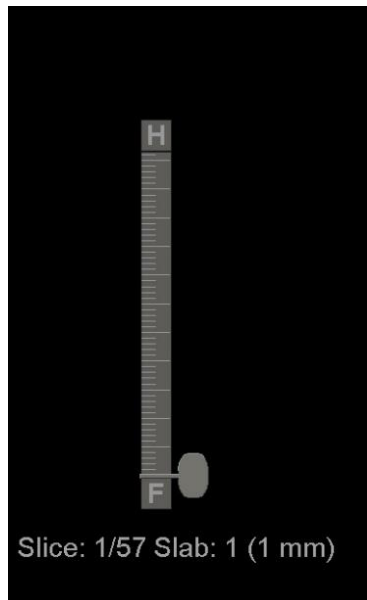
Make sure you know: slice # location and detector location



# Additional Slices Added

Some vendors have additional reconstructed slices generated at the compression side of the stack

- Inability to measure compression accurately down to 1mm
- Additional slices allows for up to 5mm error





← Compression  
Paddle Side  
} 5 extra slices

- Image information:  
6cm thickness  
65 slices
- 5 extra slices added
- In reality the breast may be compressed to 6.2 cm
- If didn't add extra slices miss the last 2 mm of the breast

← Detector Side

Slice: 1/65 Slab: 1 (1 mm)

# Skin Calcifications

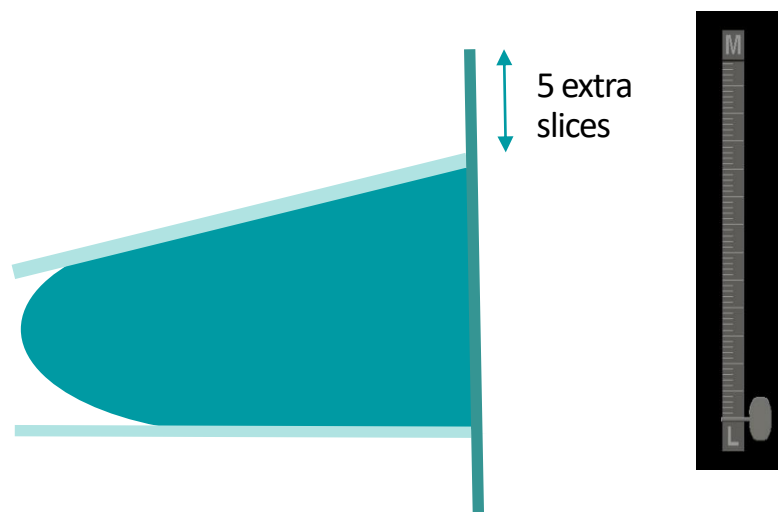
The 5 extra slices are important in verifying skin calcifications  
If calcifications are identified within the first or last 3 slices of the tomosynthesis stack

- Calcifications are within the skin

However, not all skin calcifications are located within the first or last 3 slices

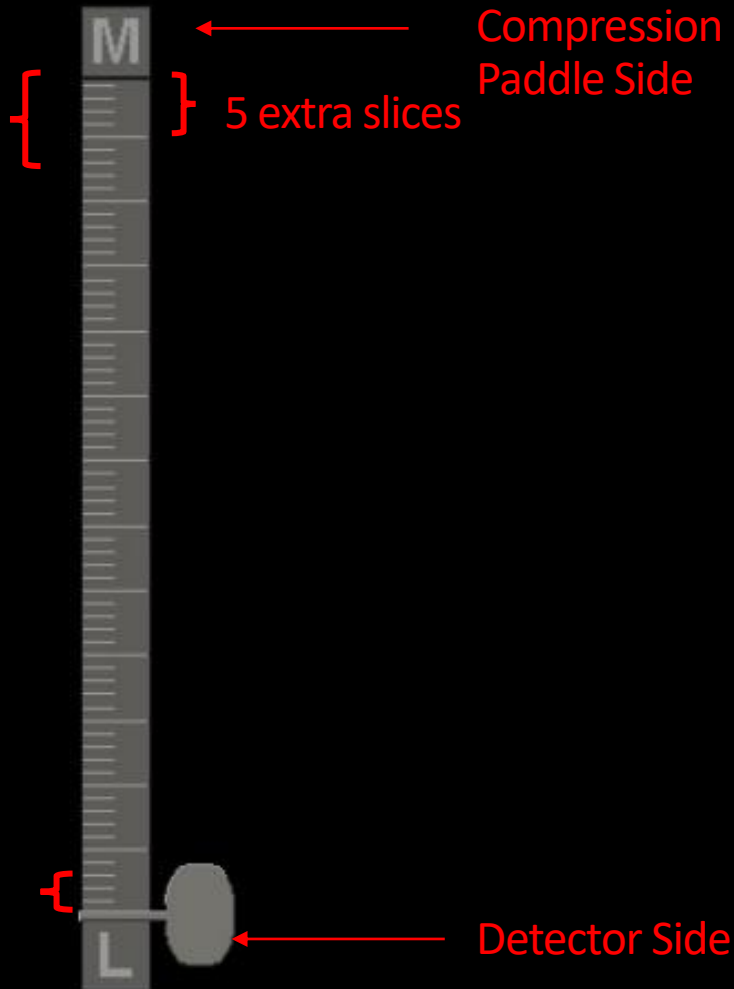
- Calcifications are on the compression paddle side and the measurement of the compression is perfect

 **Make sure you know which side on your display is the compression side and which is the detector side**



Skin calcifications can be here

Calcifications will be here



Slice: 1/65 Slab: 1 (1 mm)

# Skin Calcifications

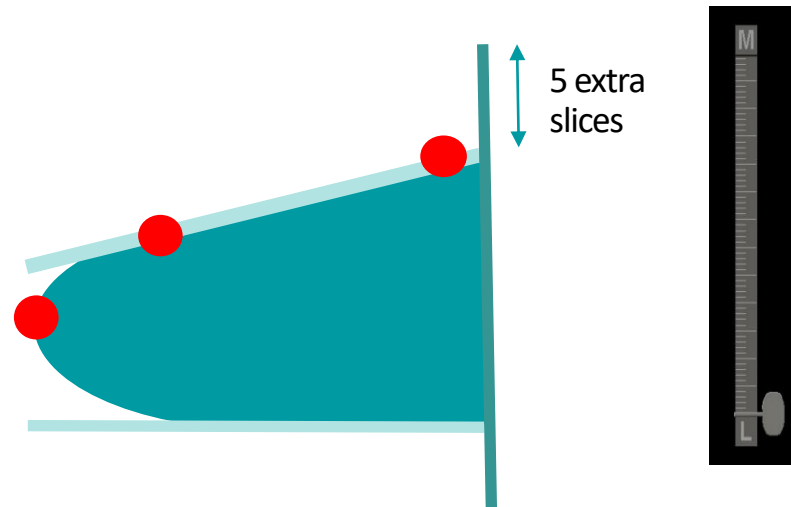
The 5 extra slices are important in verifying skin calcifications

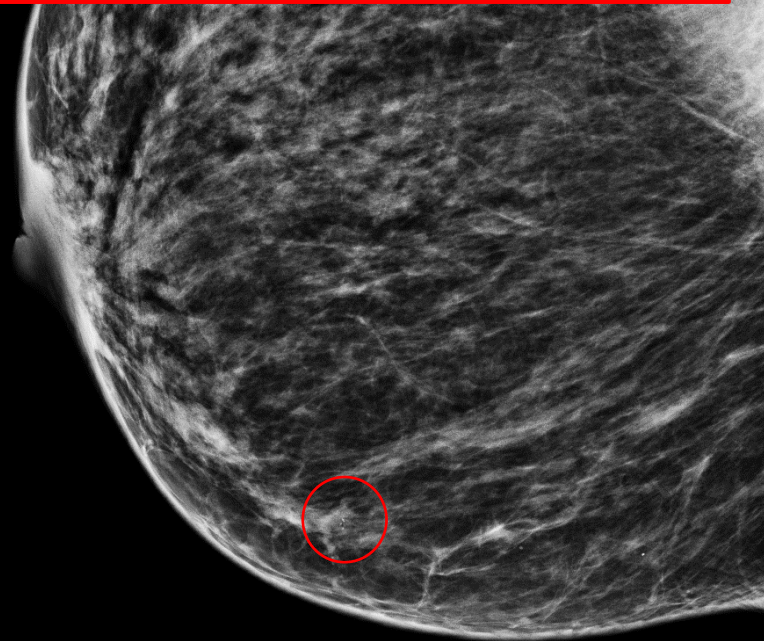
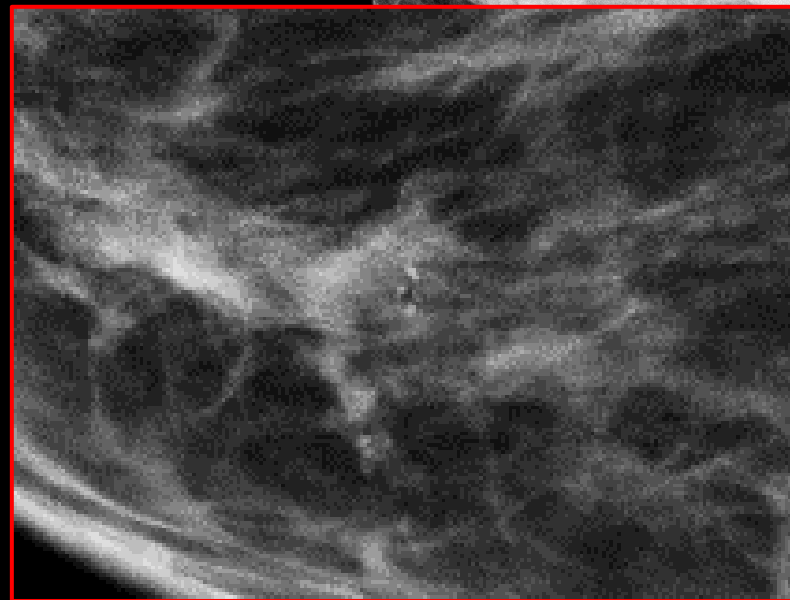
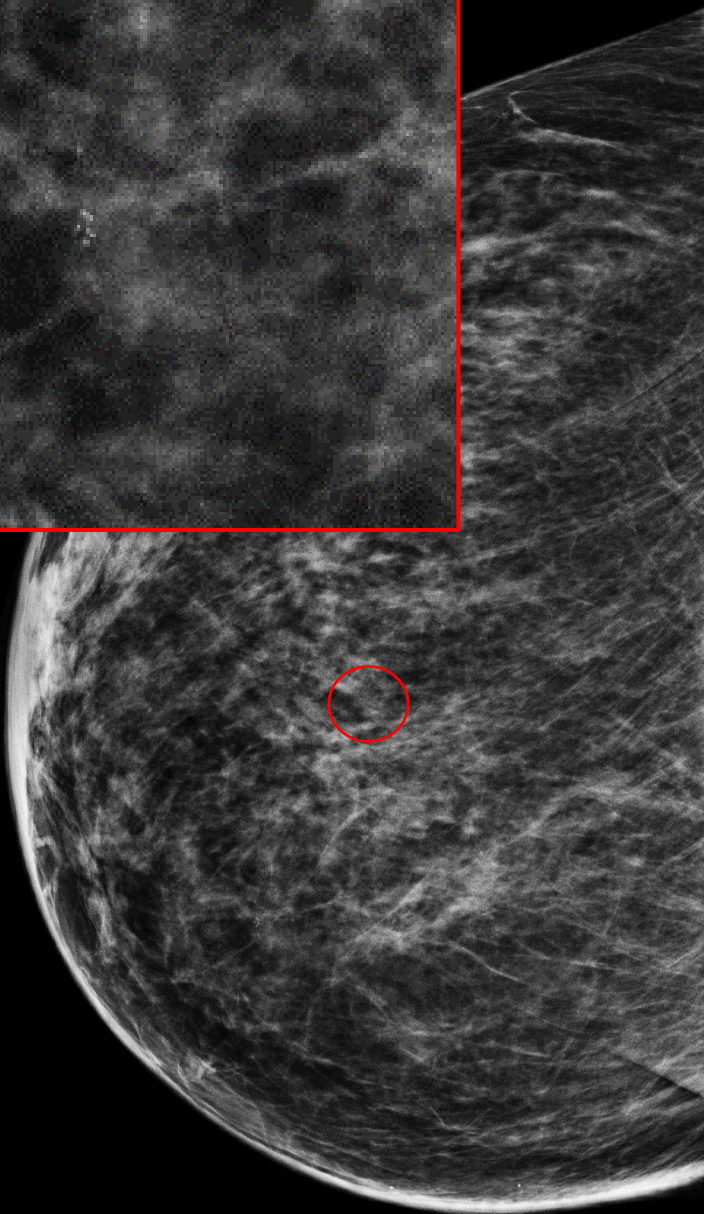
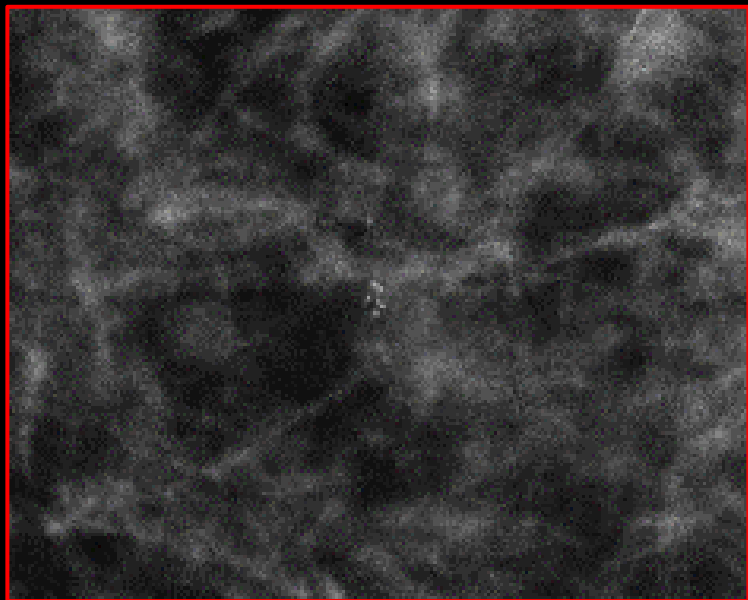
If calcifications are identified within the first or last 3 slices of the tomosynthesis stack

- Calcifications are within the skin

However, not all skin calcifications are located within the first or last 3 slices

- Calcifications are on the compression paddle side and the measurement of the compression is perfect
- Skin is not touching the detector or compression paddle
- Paddle flex

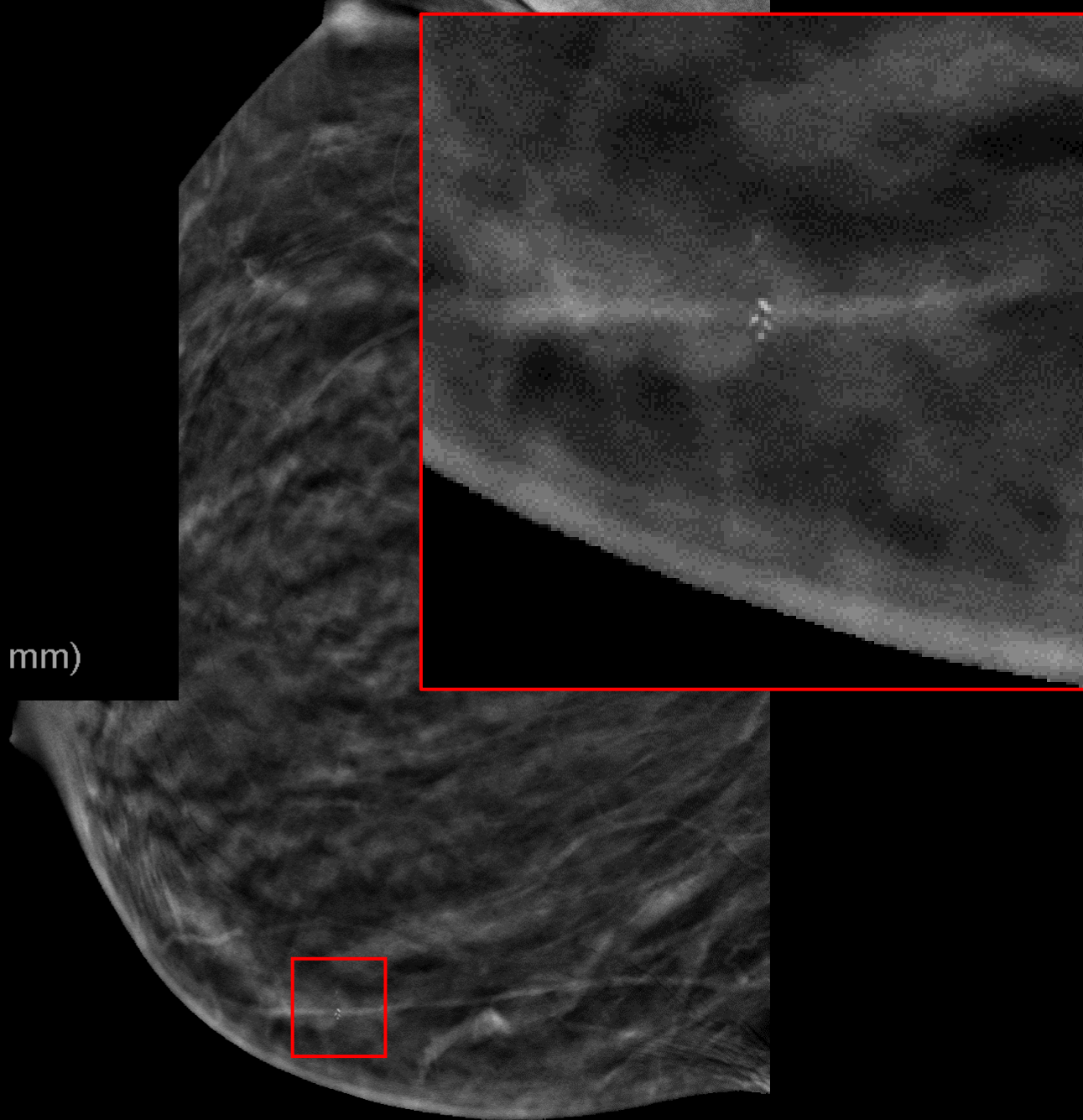






Paddle: 18X24

Slice: 1/50 Slab: 1 (1 mm)



## Decrease in Recall: Skin Calcifications

Don't need to be recalled if on the detector side

Screening:

If the calcifications are located on the compression paddle side and are deeper into the stack than the last 3 slices, you have to recall the patient

Diagnostic:

Place that portion of the breast on the detector

- e. g. calcs are on the medial side
- Take a LM view to prove they are on the first three slices



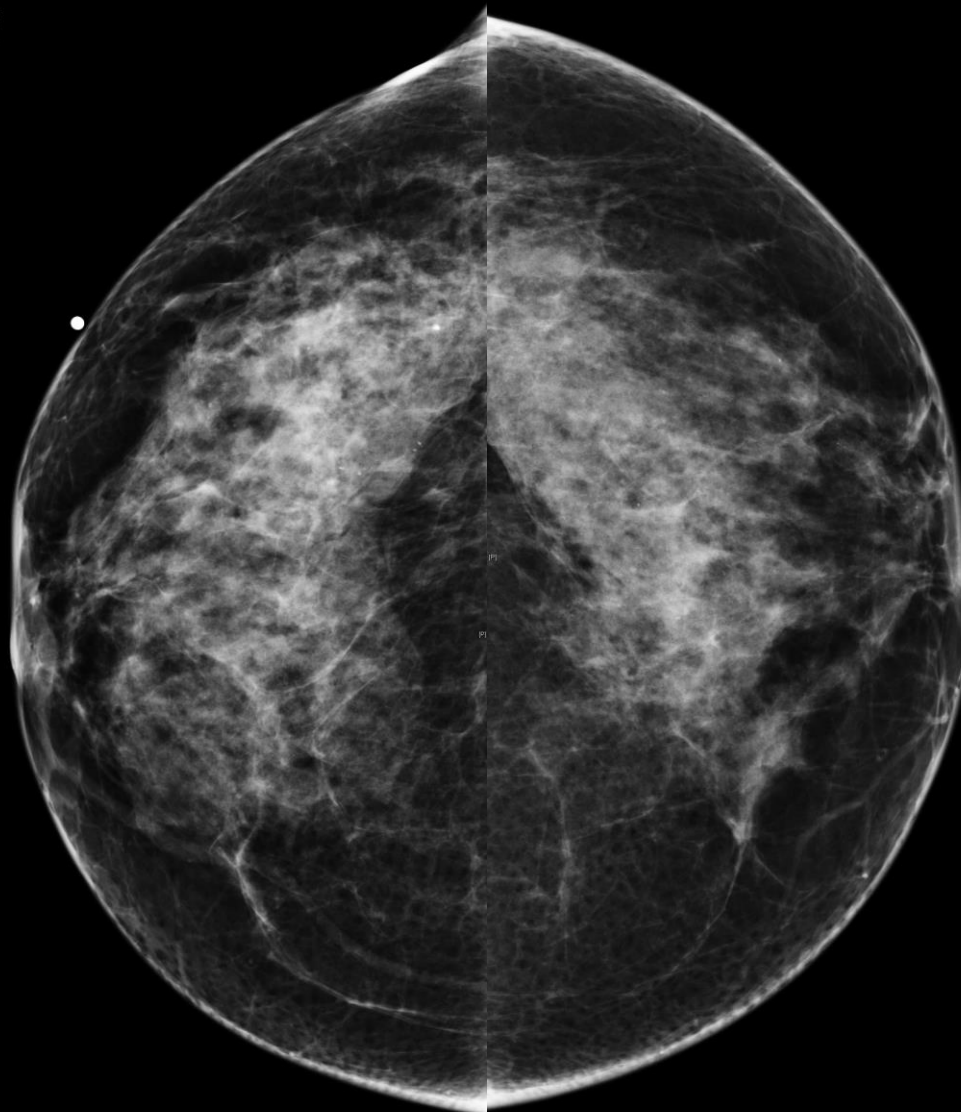
# Case 1

RMLO

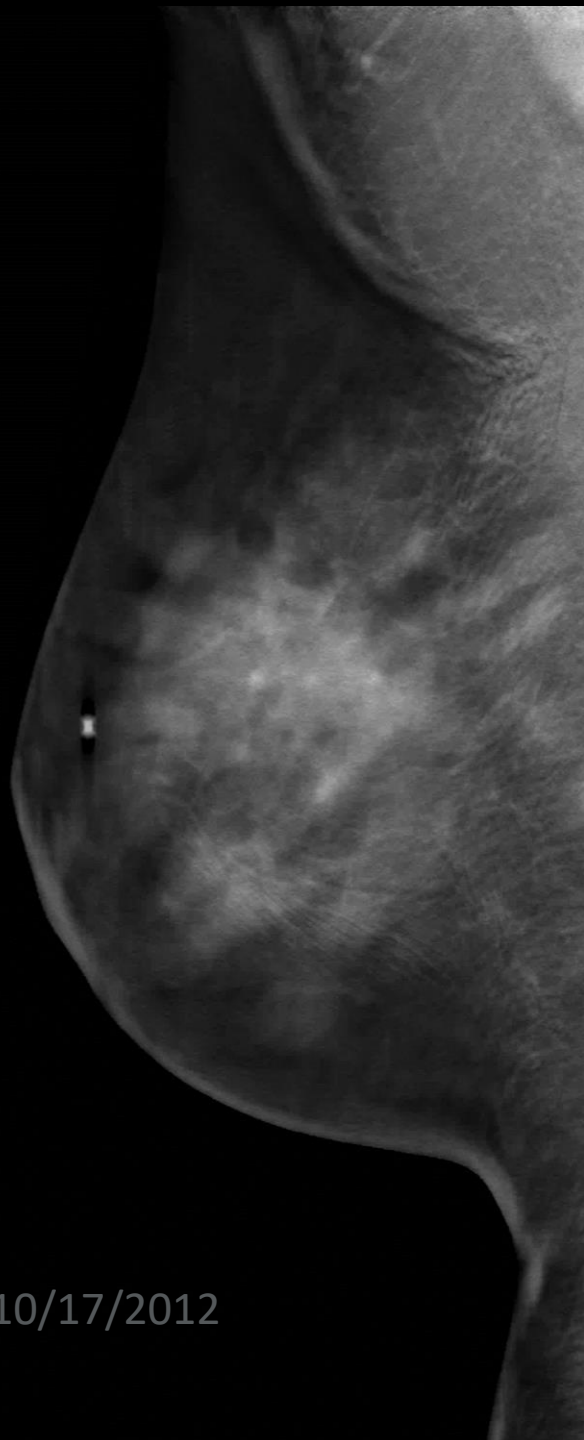
LMLO

Outside Study

RS RCC  
LA



Outside Study 10/17/2012



Outside Study 10/17/2012



Study Date: 10/17/2012

Study Time: 2:25:41 PM

15L8w-S

MRN:

14.0MHz

45mm

Breast

General SC

68dB SC1/+2/2/2

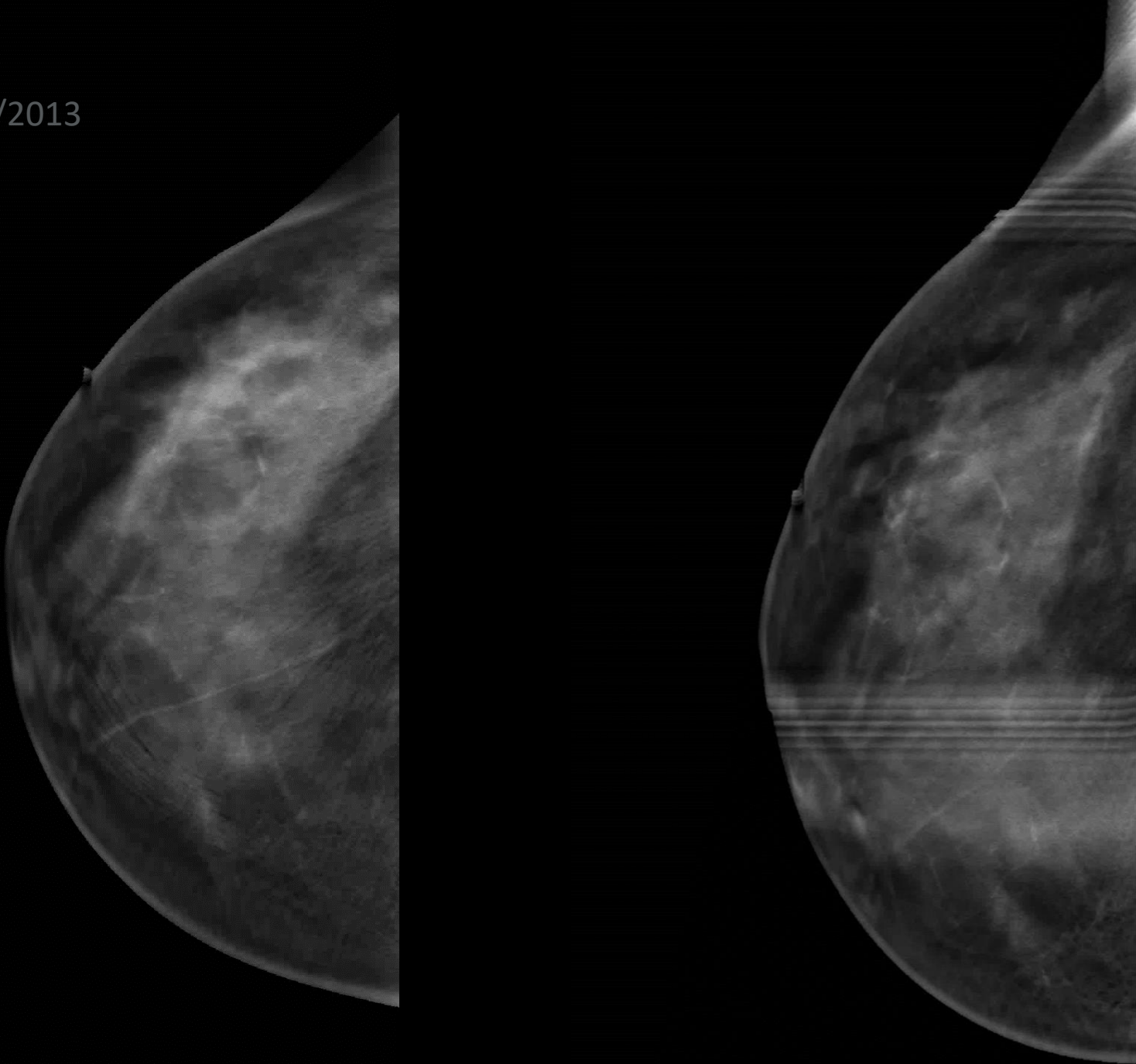
Gain= 4dB  $\Delta=2$

Store in progress

RADIAL  
BREAST  
RIGHT  
09

PALP LUMP

ALGH 1/28/2013



GE  
L9

0- B CHI  
Frq 10.0 MHz  
Gn 60  
S/A 1/1  
Map H/0/0  
D 5.0 cm  
DR 66  
FR 14 Hz  
- AO 100 %



4-

-

-

|   |           |
|---|-----------|
| ● | ■         |
| 1 | L 4.23 cm |
| 2 | L 2.36 cm |

RIGHT BREAST LONG  
9-11 O'CLOCK 6CM FN  
PALPABLE

CP

C128  
W256





# Thank You

[sfriedewald@mgh.harvard.edu](mailto:sfriedewald@mgh.harvard.edu)