Update on Hologic's High Resolution Breast Tomosynthesis Systems

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The Science of Sure

Disclosure

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System Description

- Tungsten (W) Anode
- 0.7 mm Al filter for DBT
- Large focal spot size: 0.3 mm
- a-Se detector, 24×29 cm area
- 70 µm pixel size

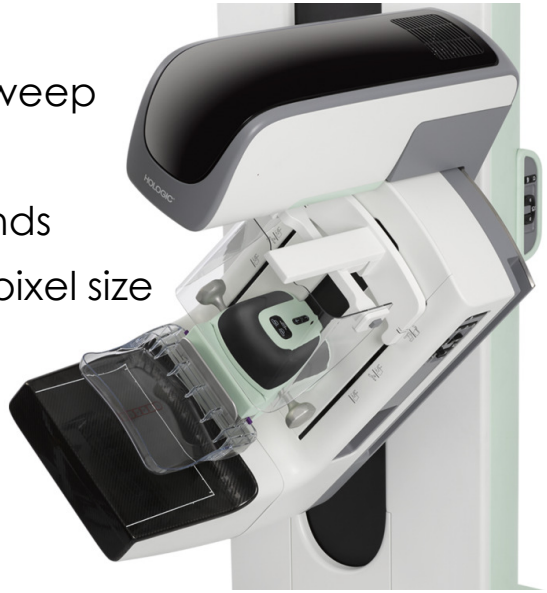
DBT Scan

Standard Resolution

- No grid used in DBT
- Moving tube, 15° sweep
- Moving detector
- Scan time <4 seconds
- Projections: 140 µm pixel size
- Reconstruction
  - ~100 µm pixel size
  - 1 mm slice spacing

Clarity HD™

- No grid used in DBT
- Moving tube, 15° sweep
- Moving detector
- Scan time <4 seconds
- Projections: 70 µm pixel size
- Reconstruction
  - 70 µm pixel size
  - 1 mm slice spacing



Available on both 3Dimensions and Selenia Dimensions (upgrade)

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Synthesized 2D Images

C-View

- Synthetic 2D images derived from standard resolution DBT slices

Intelligent 2D™

- Synthetic 2D images derived from Clarity HD slices

NOTE: The "HD" in TomoHD and ComboHD views means that a synthetic 2D image (C-View or Intelligent 2D) is included with the tomo acquisition. These are not views that are specific to ClarityHD

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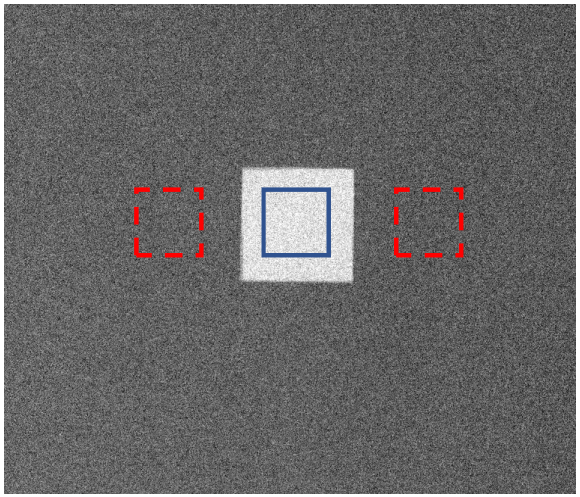
Comparison of Clarity HD and Standard Resolution DBT

Physics Testing

- Signal to noise ratio (SNR)
- Contrast to noise ratio (CNR)
- Projection Modulation Transfer Function (MTF)
- Detective Quantum Efficiency (DQE)
- Contrast-detail mammography (CDMAM)

Signal to Noise Ratio (SNR) and Contrast to Noise Ratio (CNR)

- Contrast to noise ratio (CNR) and signal to noise ratio (SNR) measured in projection images of PMMA phantoms
- A 1 x 1 x 0.2 cm piece of foil used for measuring CNR
- Tested over a range of thicknesses imaged at standard dose levels used on 3Dimensions and Selenia Dimensions
- Same x-ray techniques used for both Clarity HD and standard resolution



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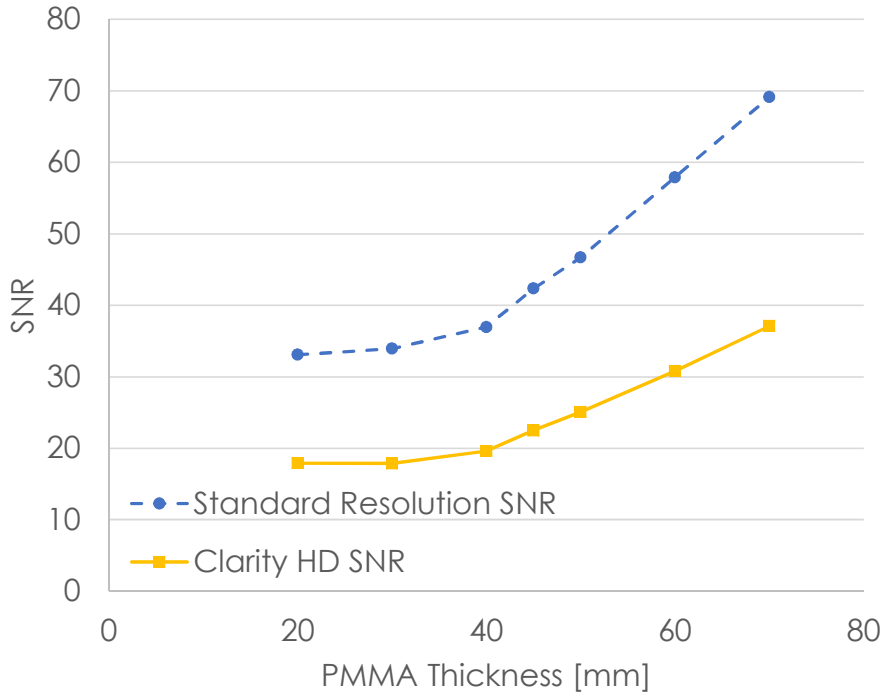
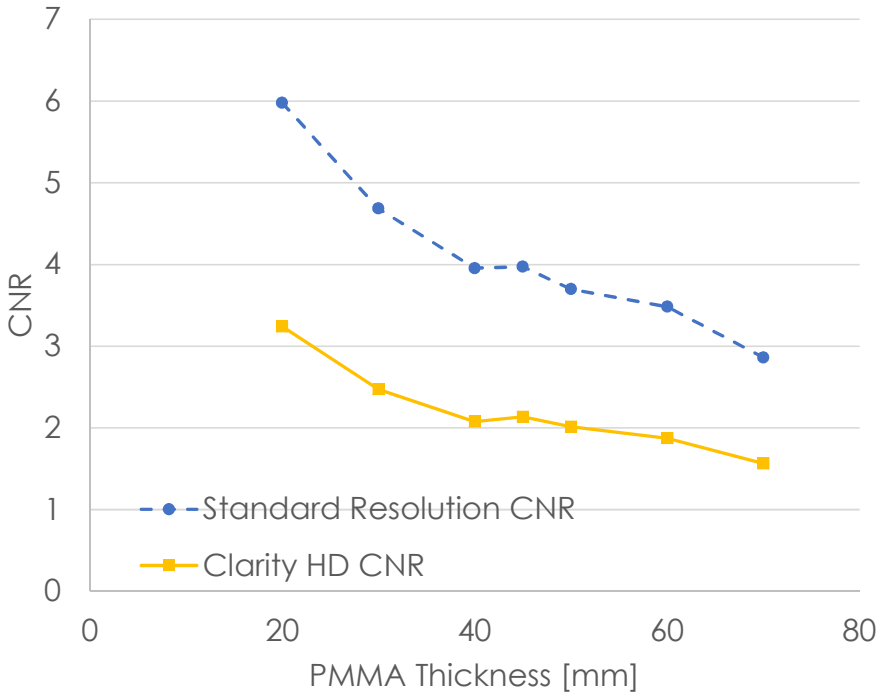
SNR



- SNR calculated from background ROIs in first projection
- For a given phantom, SNR for Clarity HD is lower than that of standard resolution

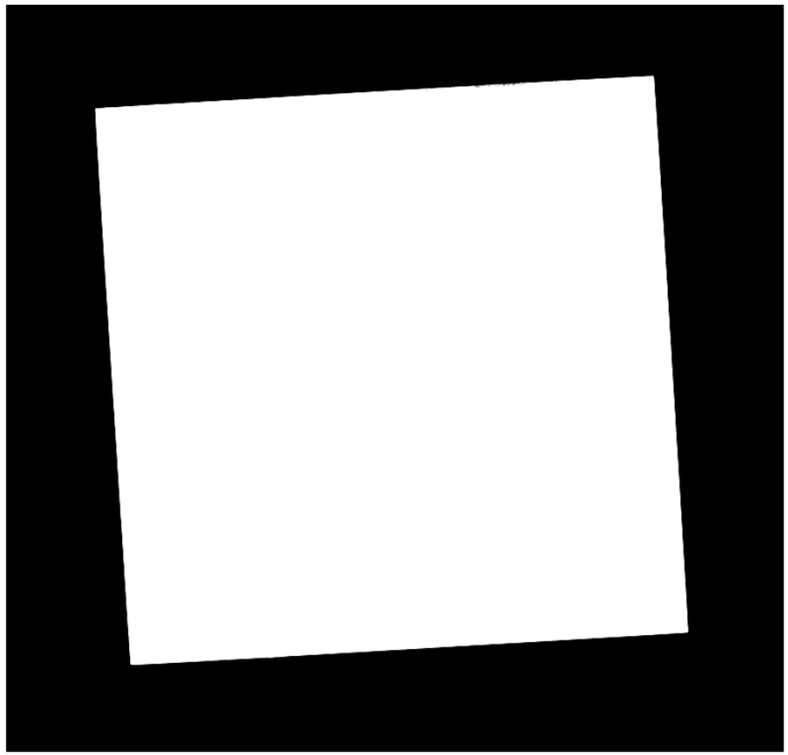
CNR

- CNR for Clarity HD is also lower than for standard resolution
- The decrease in mean pixel value and the increase in standard deviation cause the expected reduction in CNR
- These results alone do not fully characterize the image quality of Clarity HD

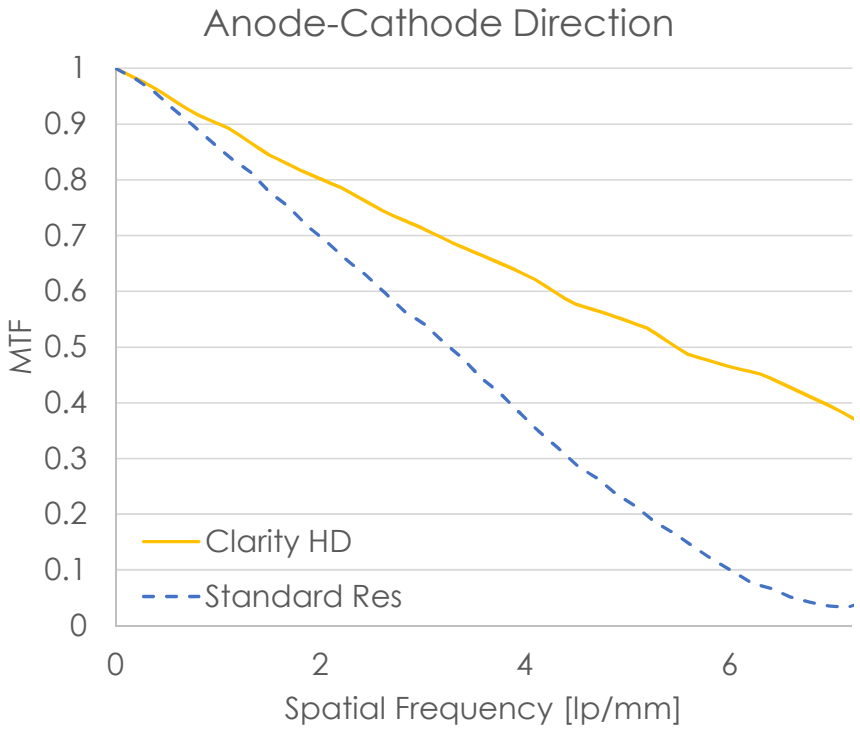


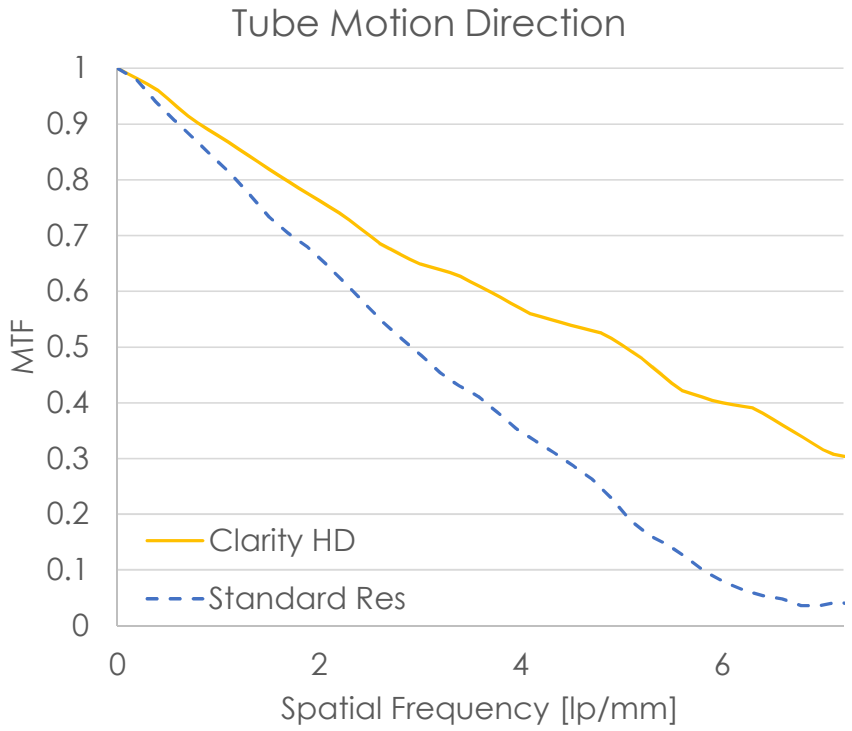
Projection Modulation Transfer Function (MTF)

- MTF calculated from projection closest to 0˚
- Edge tool allowed for MTF to be calculated in both directions from a single image
- Same exposure techniques and system used for acquisition of both data sets
- MTF measured at different heights from breast platform

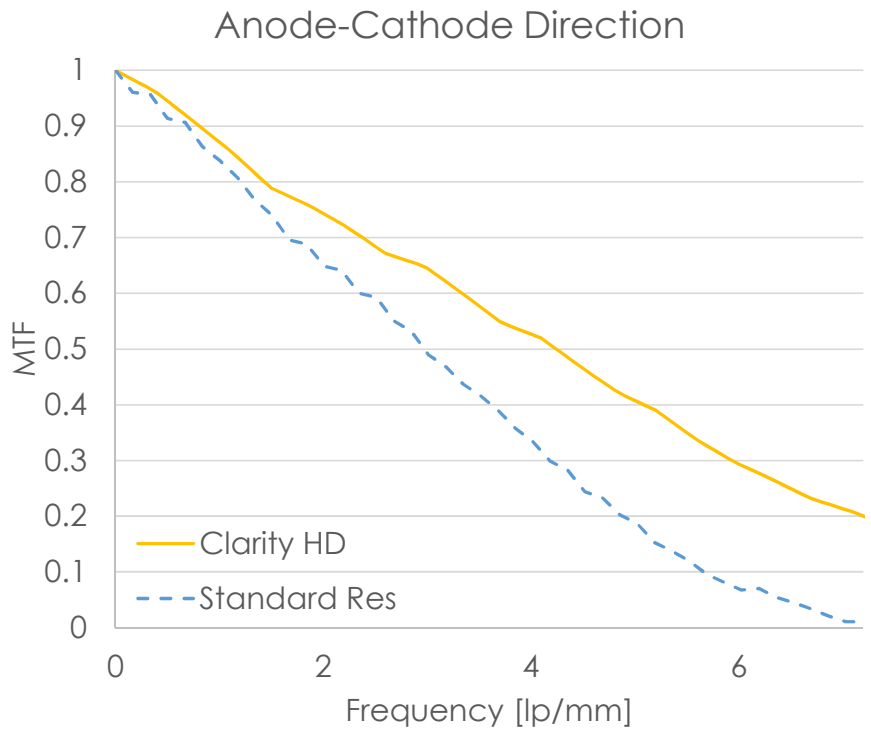


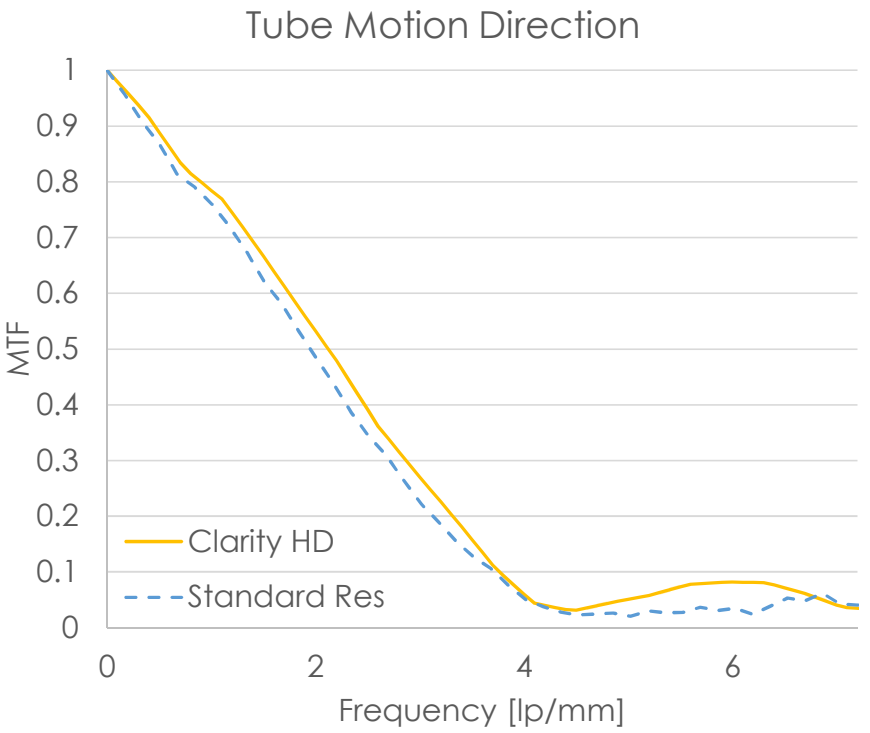
Projection MTF – 0 mm Above Breast Platform





Projection MTF – 70 mm Above Breast Platform





Detective Quantum Efficiency

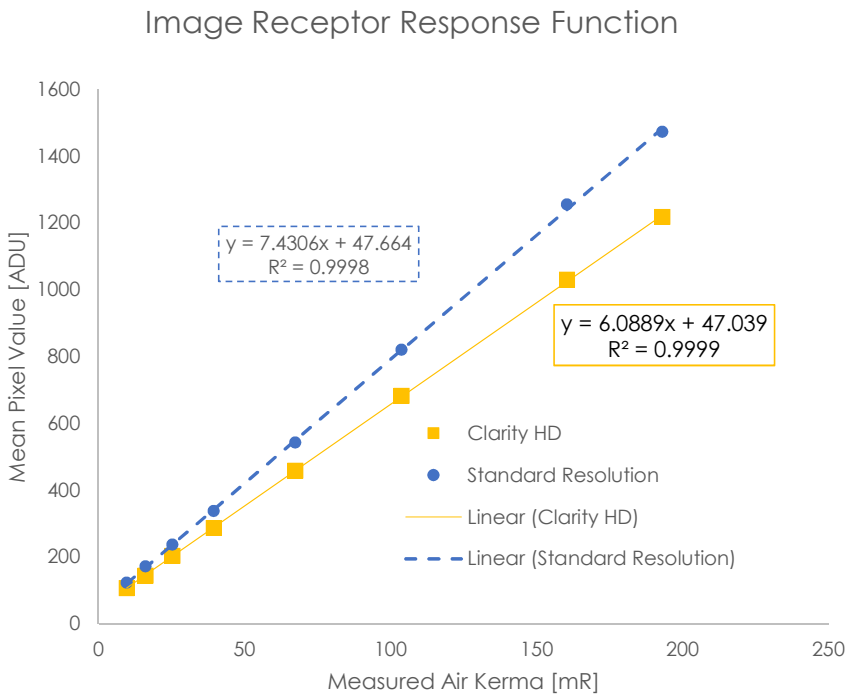
- Detective Quantum Efficiency (DQE) provides more information on detector performance in the two imaging modes
- Standard resolution projection data compared to Clarity HD projection data
- IEC – 62220-1-2 protocol for DQE
- 0˚ stationary scan
- Covering a range of air kerma from 0.4 to 7 mR/projection

$$DQE(u,v) = \frac{SNR_{out}^2(u,v)}{SNR_{in}^2(u,v)} \quad (1)$$

$$DQE(u,v) = MTF^2(u,v)\frac{W_{in}(u,v)}{W_{out}(u,v)} \quad (2)$$

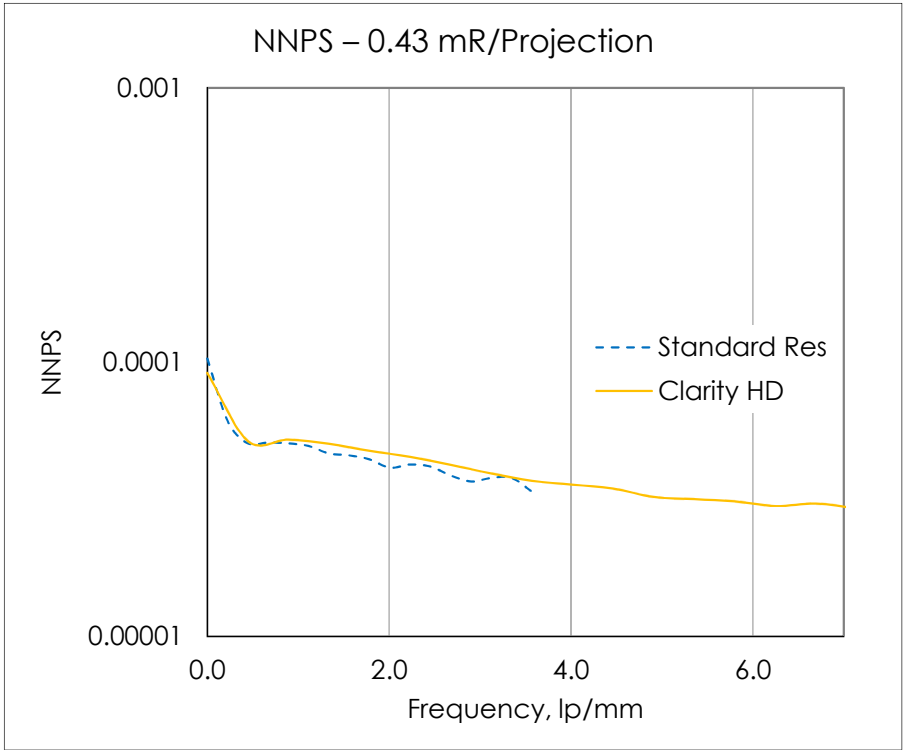
$$W_{in}(u,v) = K_a * SNR_{in}^2 \quad (3)$$

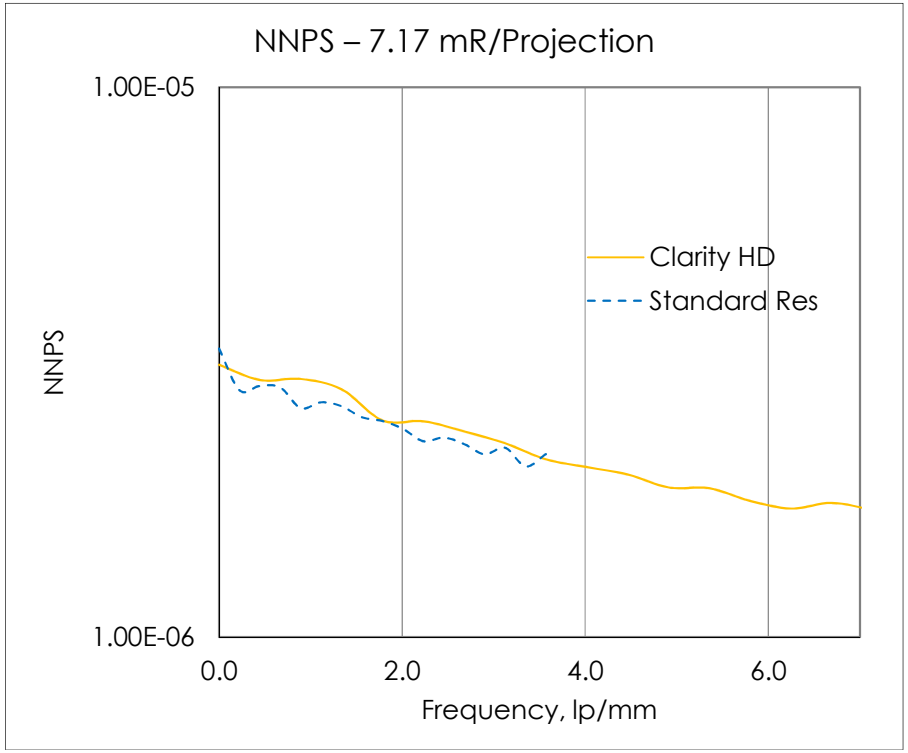
Image Receptor Response



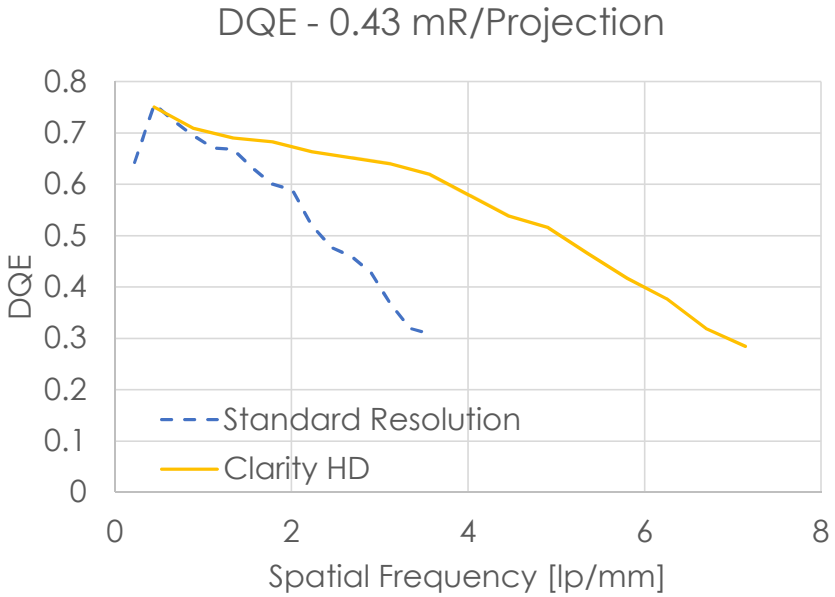
- Response function measured on the same gantry
- Mean pixel value within region of interest (ROI) in first projection
- Detector response increases linearly with air kerma
- Standard resolution tends to have a larger slope due to a higher pixel value when pixels are binned

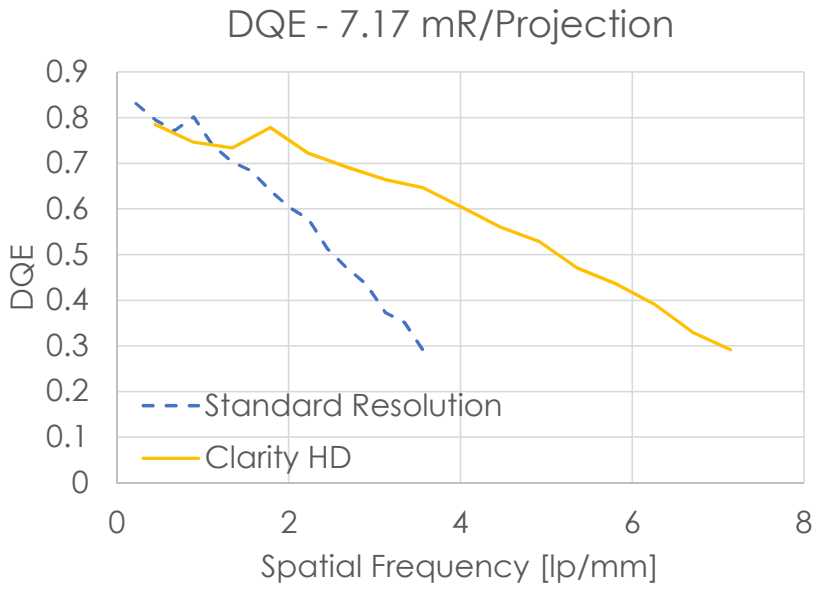
Normalized Noise Power Spectrum (NNPS)





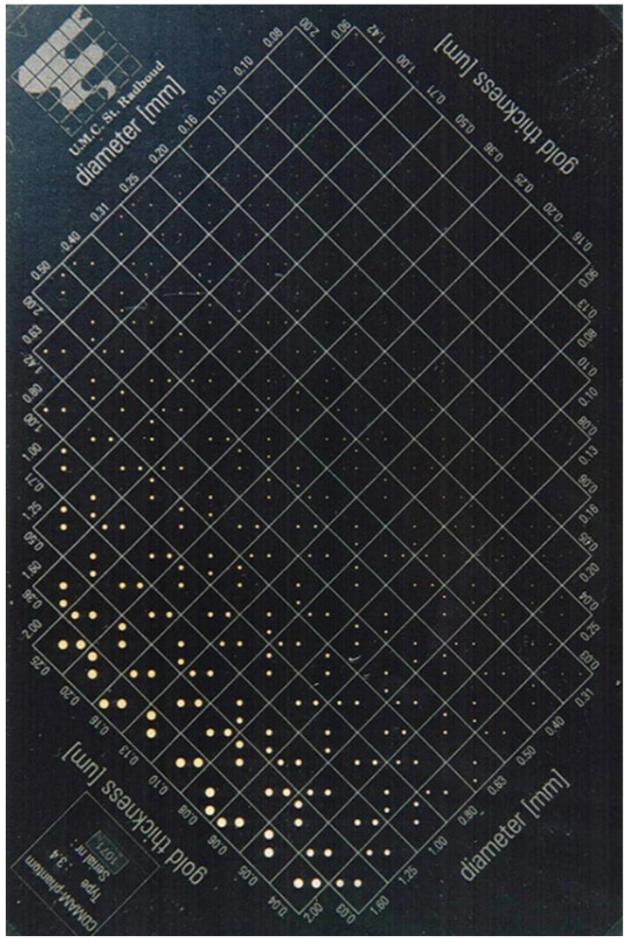
DQE





- Clarity HD has higher DQE
- Increase in MTF compensates for any increase in relative noise

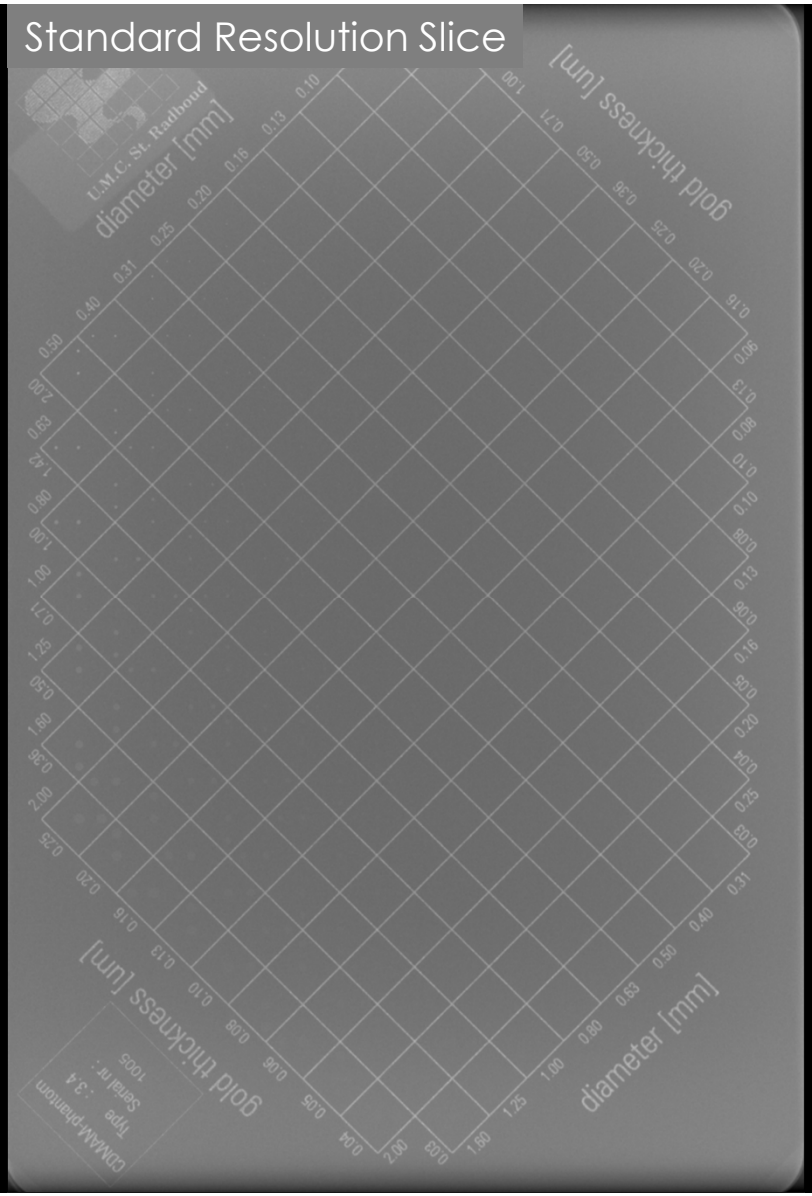
Contrast-Detail Mammography (CDMAM) Phantom



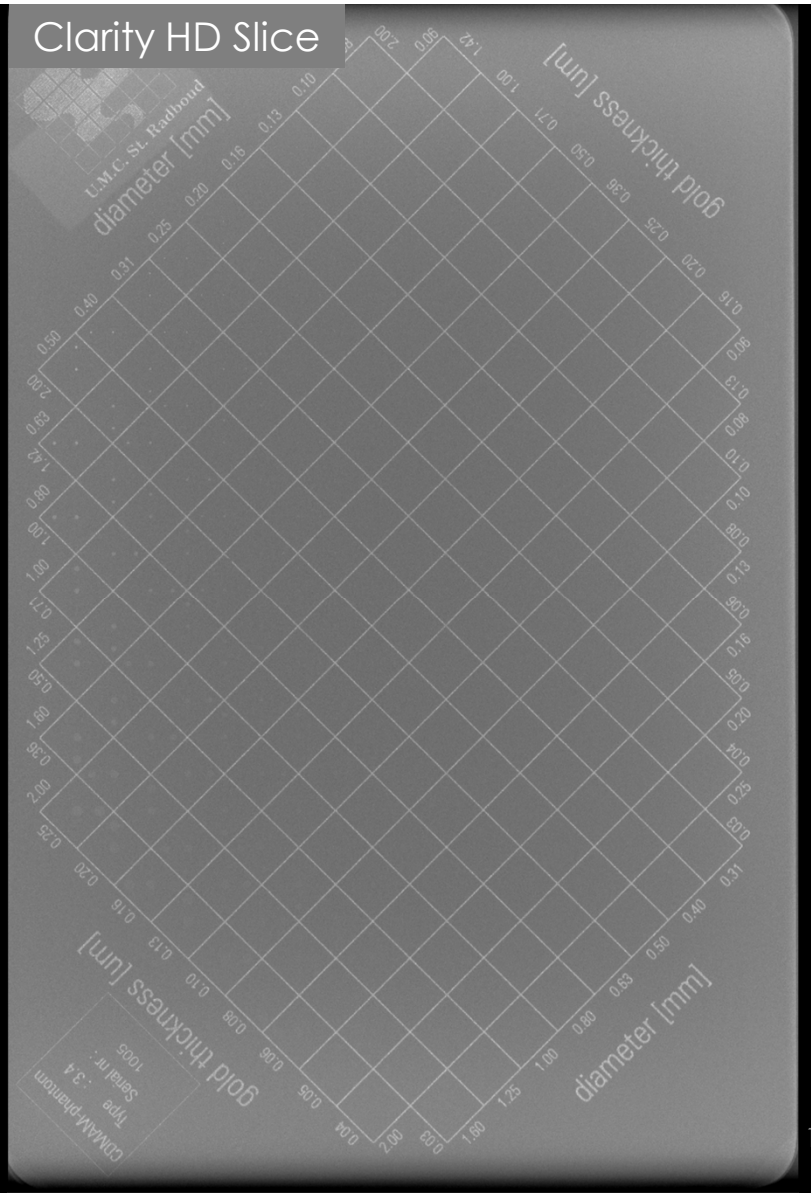
https://capintec.com/product/cd-phantom-for-mammography-cdmam-3-4/

- Contrast-detail phantom centered in stack of 4 cm of PMMA
- 16 scans acquired at full resolution
- Projection images were binned for the standard resolution data set
- X-ray techniques were kept fixed for both data sets
- Images were reconstructed and additional image processing was not applied
- Slice where most of the discs came into focus were selected for contrast-detail analysis
- CDCOM program used to analyze slices

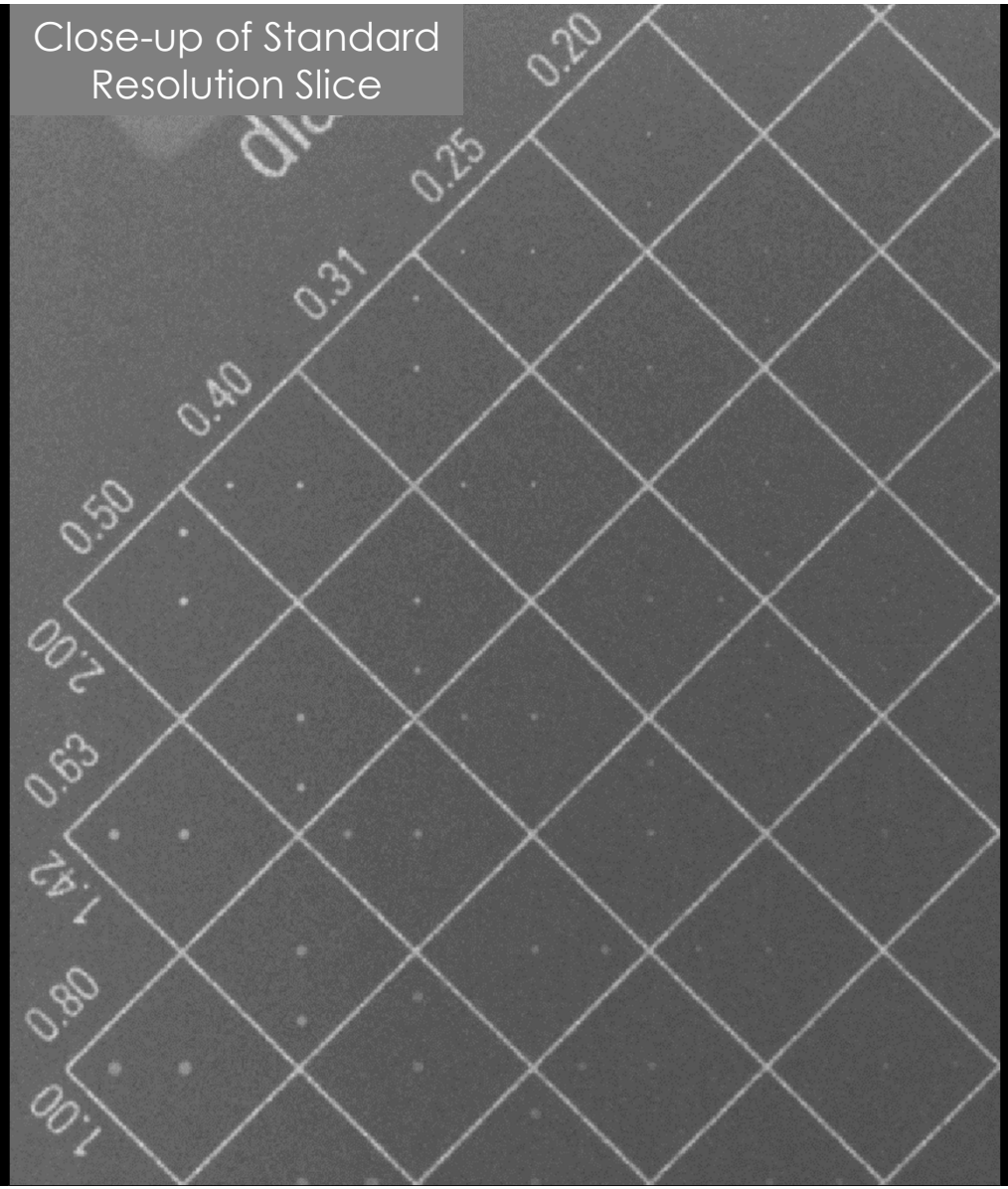
Standard Resolution Slice



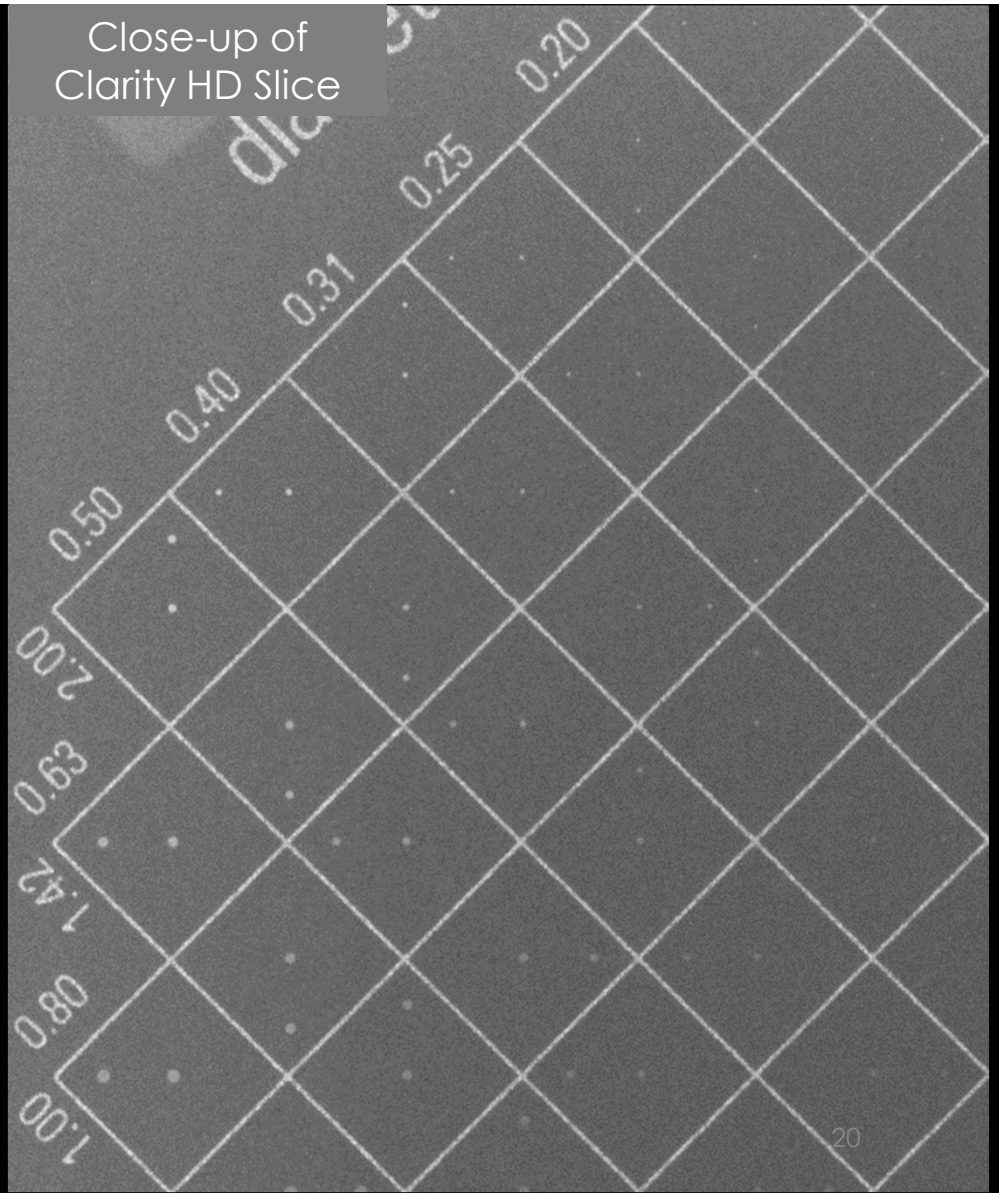
Clarity HD Slice



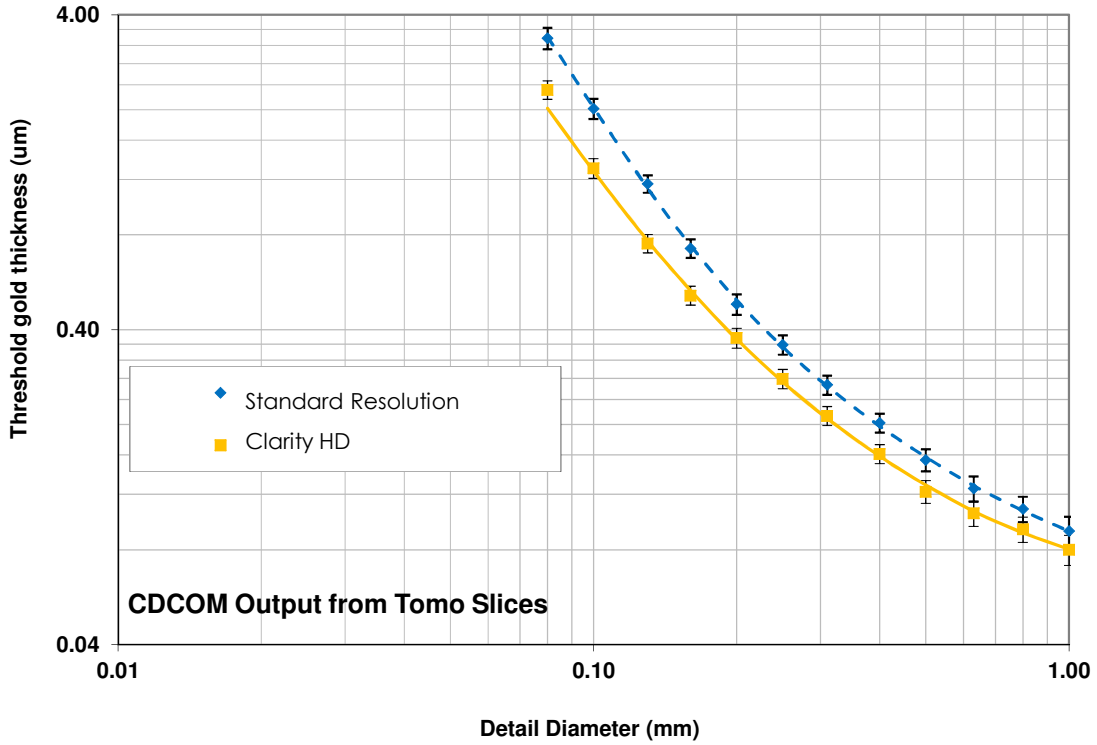
Close-up of Standard Resolution Slice



Close-up of Clarity HD Slice



CDMAM Curve



- For discs of a given diameter, a lower threshold thickness means better low-contrast detection
- Despite lower SNR and CNR, Clarity HD allows for better detection of low-contrast features

Clinical Preference Study

Clinical Preference Study

- Preference study to compare Clarity HD to standard resolution DBT
- Subject images acquired at full resolution
- For the standard resolution data set, projection images were software-binned
- Data sets were reconstructed and synthetic 2D images were derived from each set

Preference Study Readers

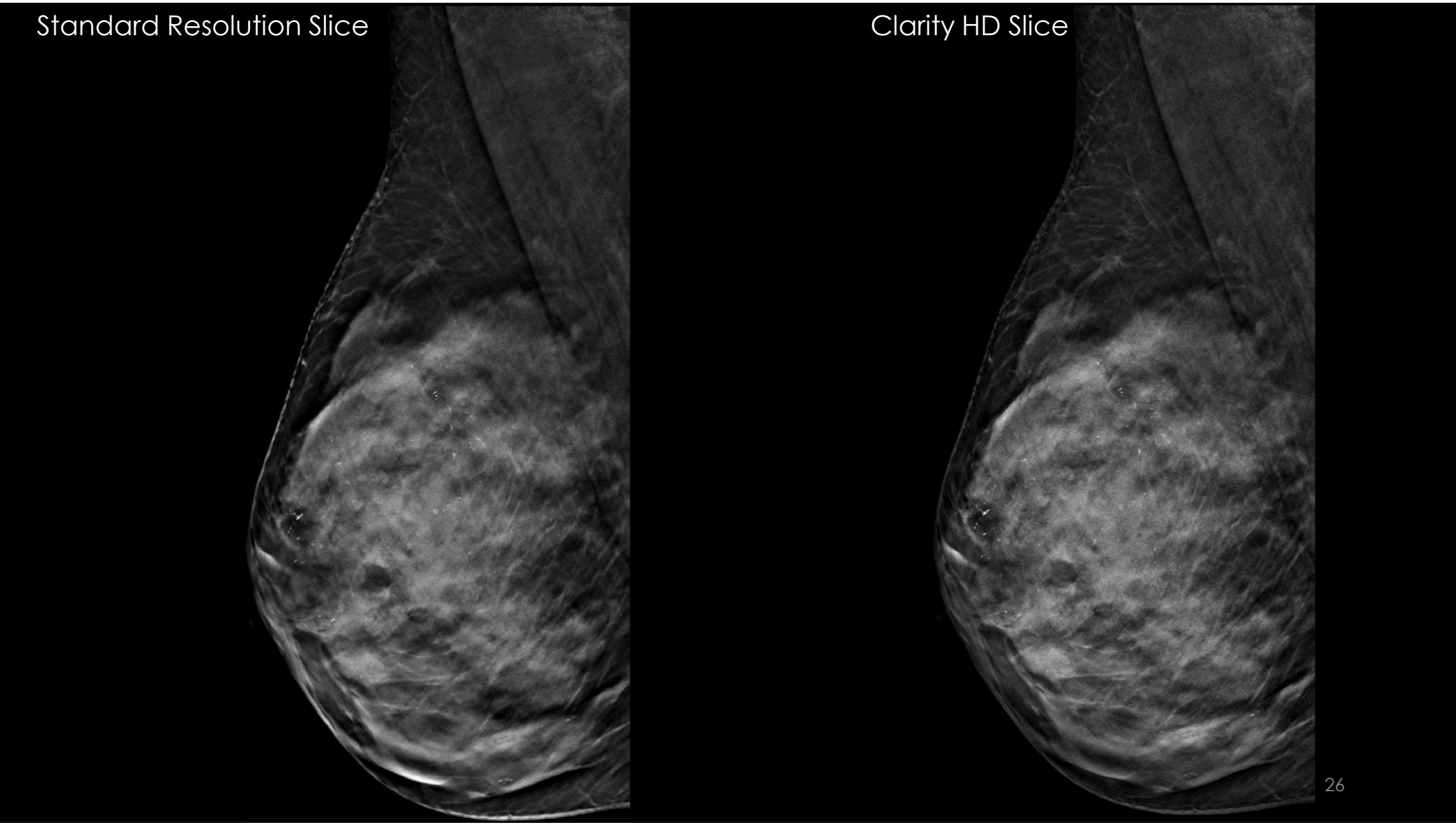
- 7 MQSQ-qualified radiologists
- All reviewers had prior experience with reading DBT and synthetic 2D (C-View) images

Reader	Practice type	Average Annual Mammography Interpretation Volume (Personal)	Years Active	Years of DBT Experience	Prior C-View Experience
1	Academic	3500+	2009- present	4	Yes
2	Community	6000+	1998-present	5	Yes
3	Community	2000	1983-present	8	Yes
4	Academic	5000+	2004-present	7	Yes
5	Community	6000+	1993-present	7	Yes
6	Community	5000+	1994-Present	7	Yes
7	Community	2000	1982-present	7	Yes

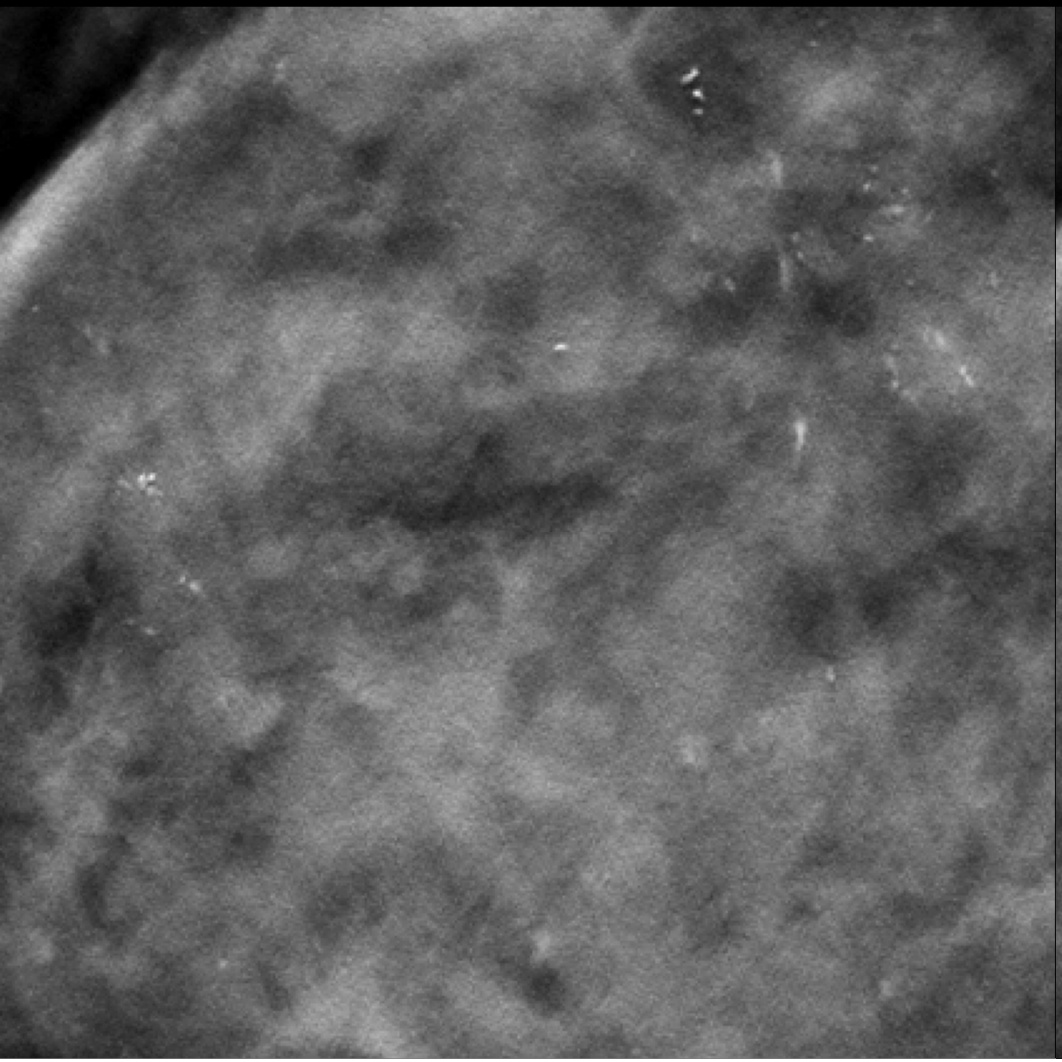
Preference Study Data

- 119 image sets reviewed included a range of breast densities and mammographic findings
- Images were blinded
- Readers were asked to assess:
  - Overall image quality (assessment of noise and artifacts)
  - Conspicuity of masses
  - Conspicuity of calcifications
- For each assessment category, they selected one of the following options:
  - Image set 1 superior
  - Image set 1 moderately better
  - No preference
  - Image set 2 moderately better
  - Image set 2 superior

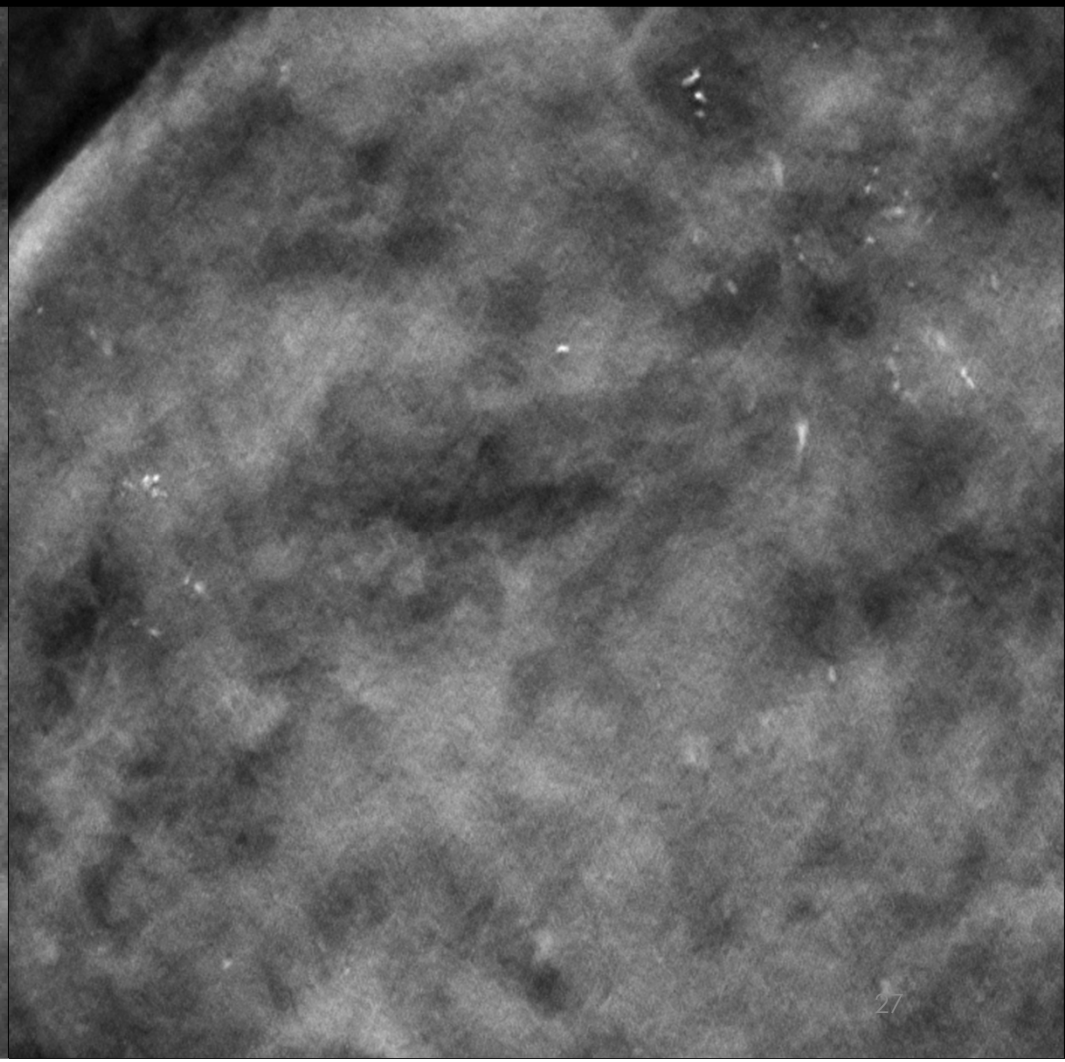
	Malignant	Benign	Total
Mass	35	27	62
Calcifications	18	24	42
Mass and Calcifications	7	3	10
Negative			5
Grand Total			119

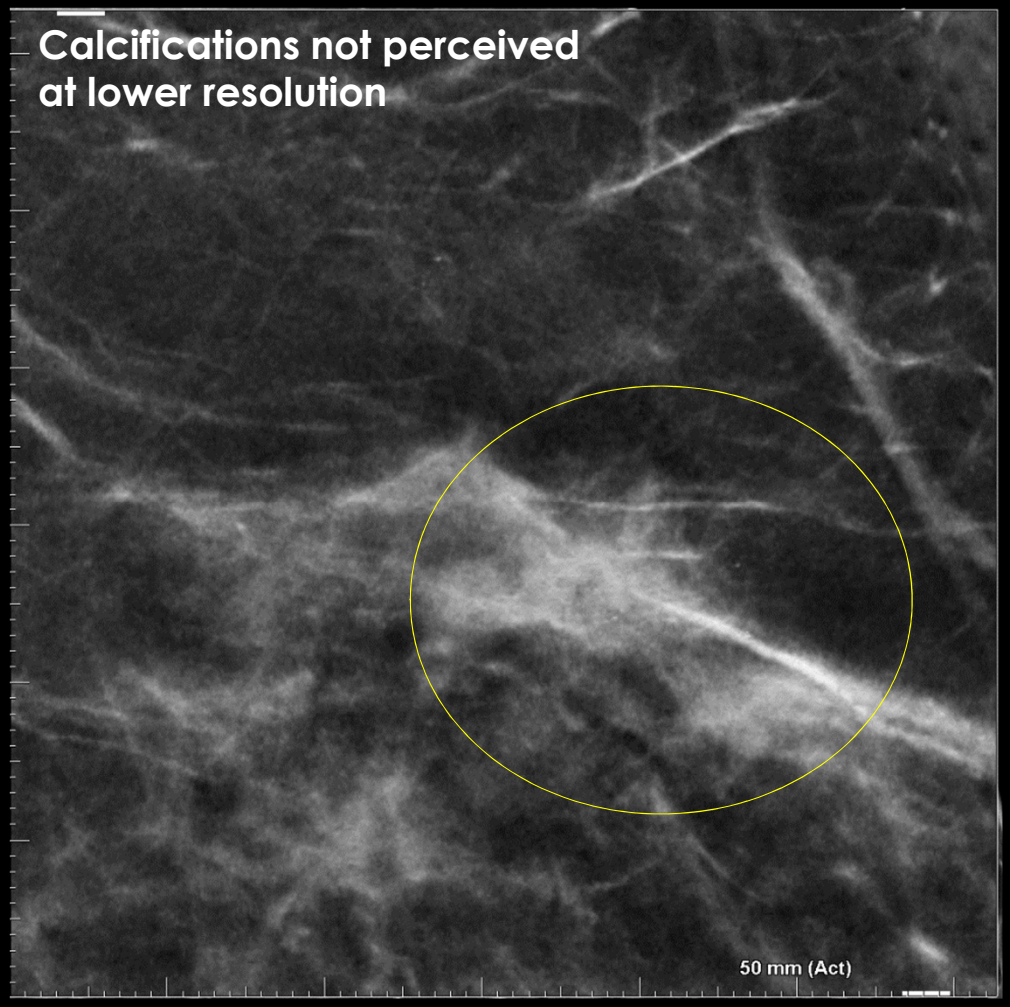

Standard Resolution Slice
Clarity HD Slice

Close-up of Standard Resolution Slice

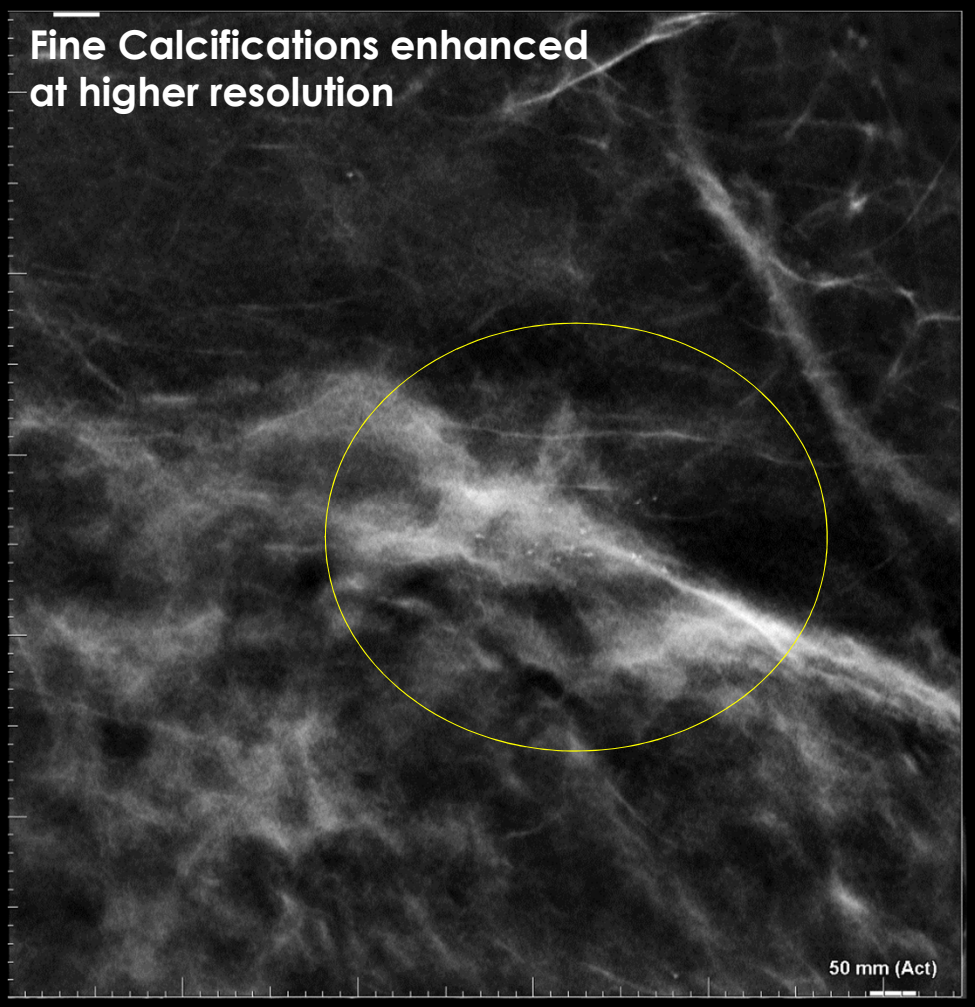


Close-up of Clarity HD Slice





Standard Resolution DBT Slice



Clarity HD Slice

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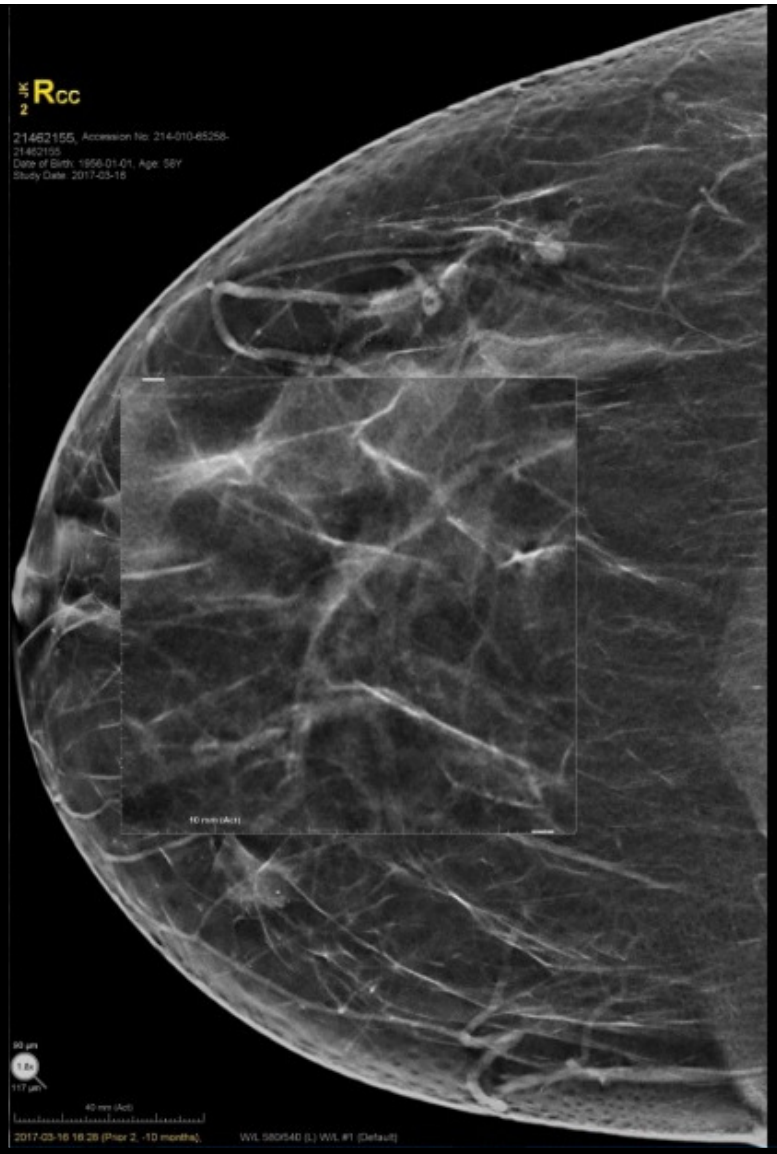
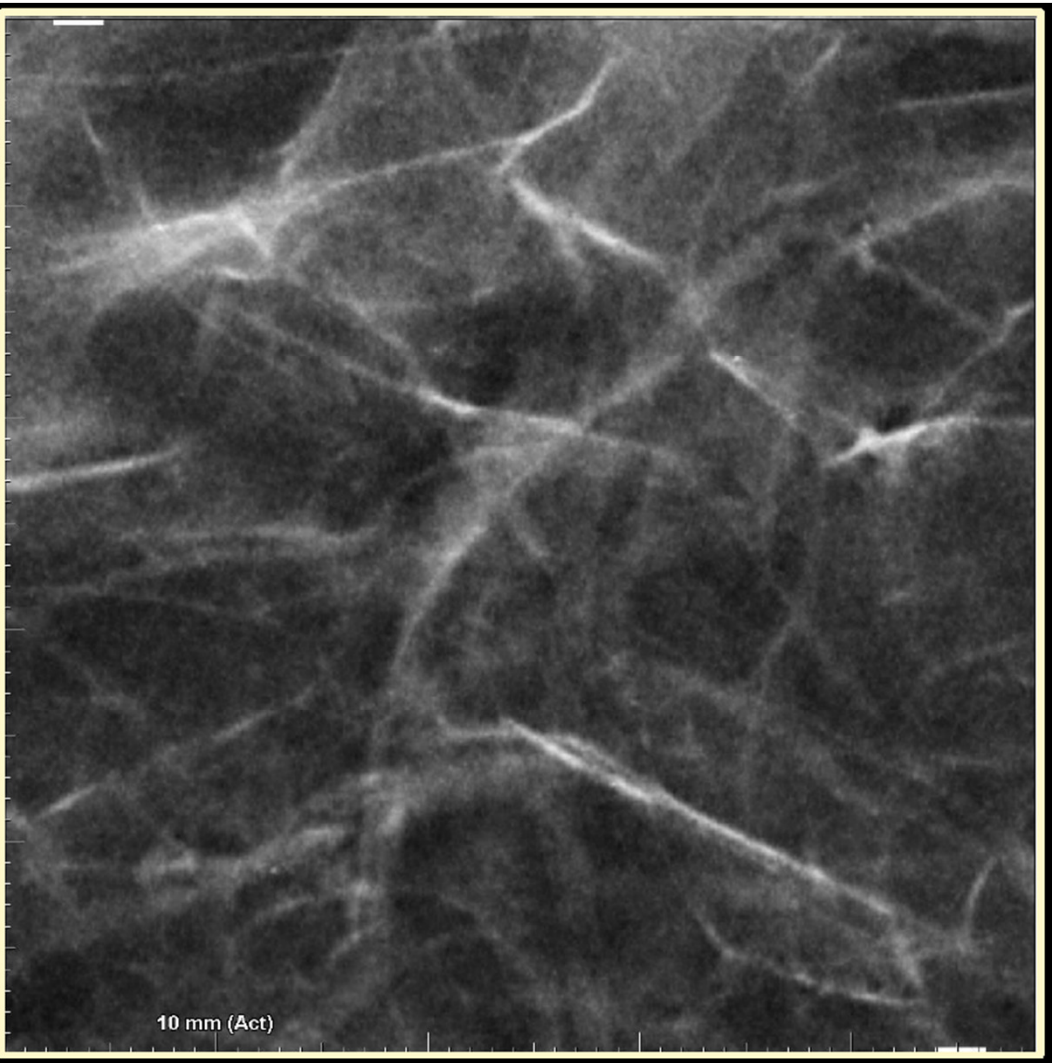
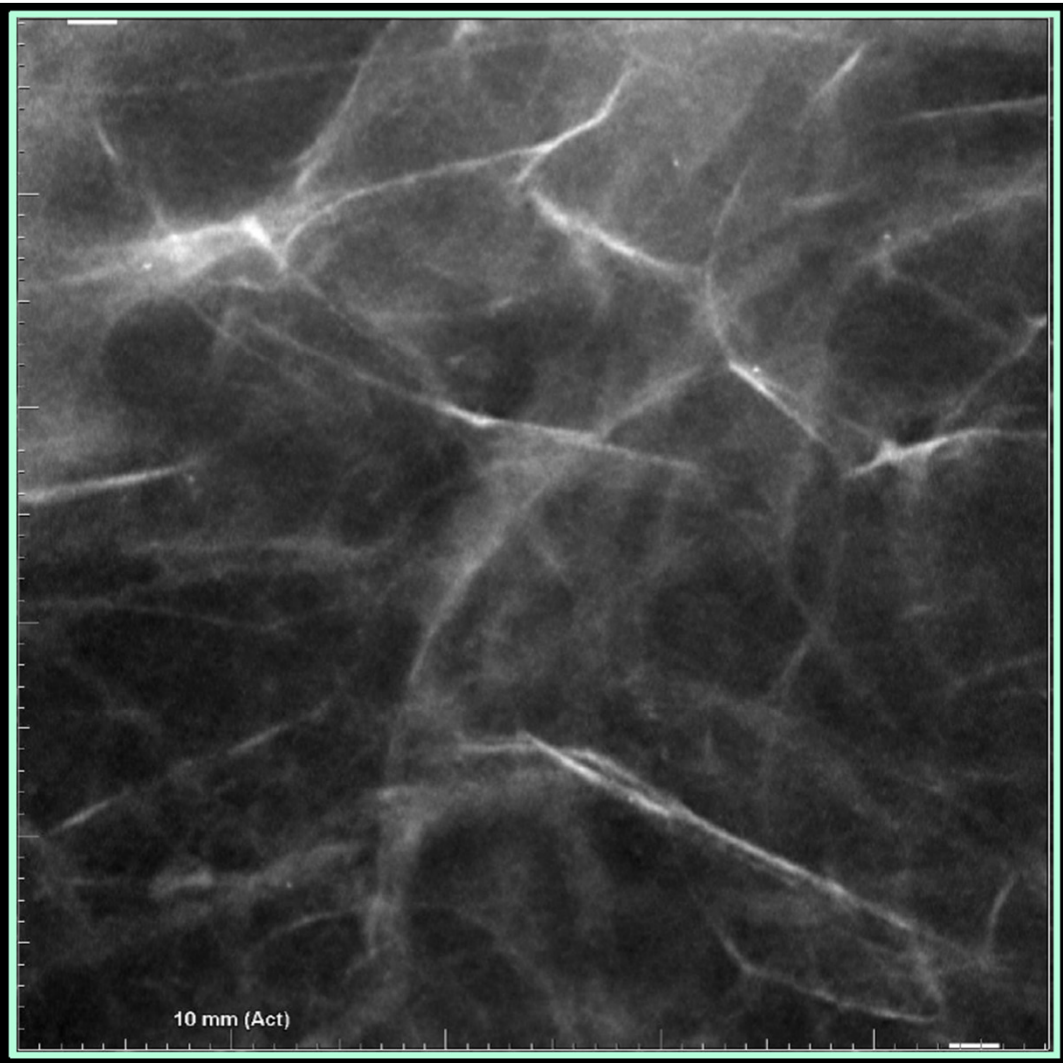


C-View™ 2D image

Intelligent 2D™ image



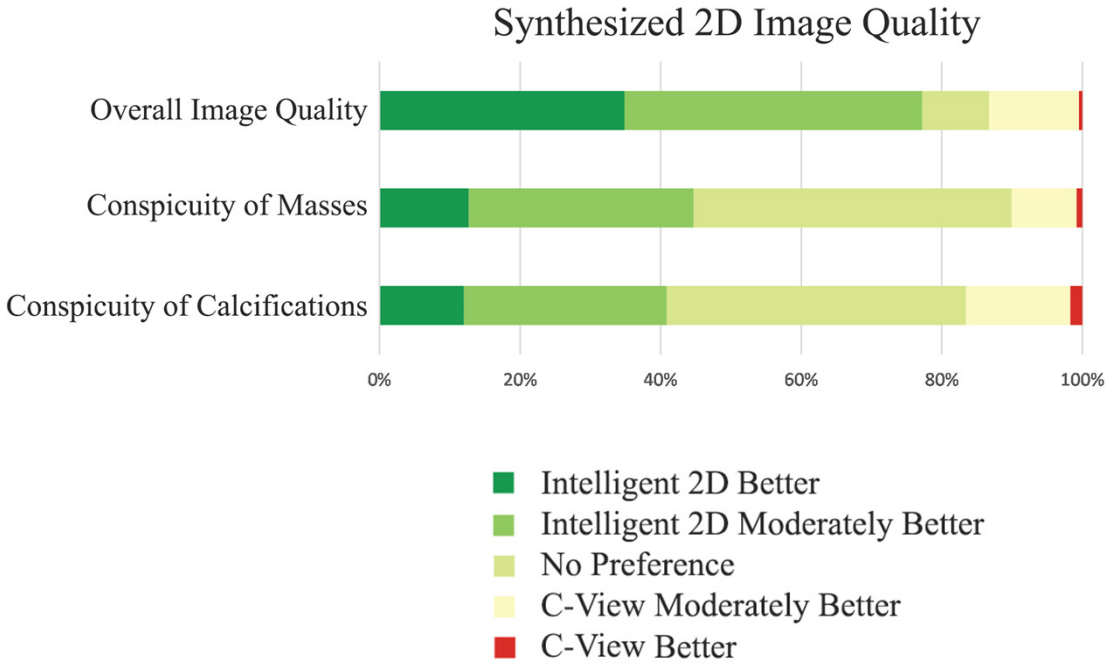
C-View™ 2D image



Intelligent 2D™ image

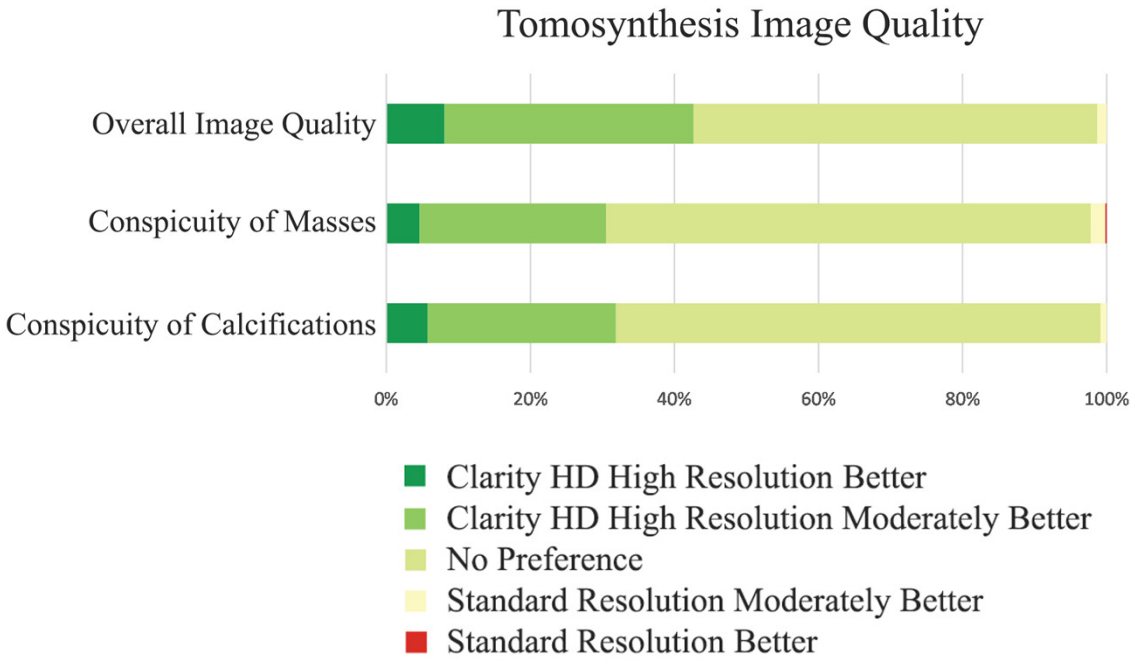
Results of Preference Study – Synthetic 2D Images

- Summary of a total of 833 readings (7 readers, 119 image sets each)
- In comparison to C-View, Intelligent 2D was rated equivalent or better for:
  - 87% of readings for overall image quality
  - 90% of readings involving masses
  - 83% of readings involving calcifications



Results of Preference Study – Reconstructed Slices

- Summary of a total of 833 readings (7 readers, 119 image sets each)
- Clarity HD was rated as equivalent or better than standard resolution for:
  - 99% of readings for overall image quality (noise and artifact assessment)
  - 98% of readings for conspicuity of masses
  - 99% of readings for conspicuity of calcifications

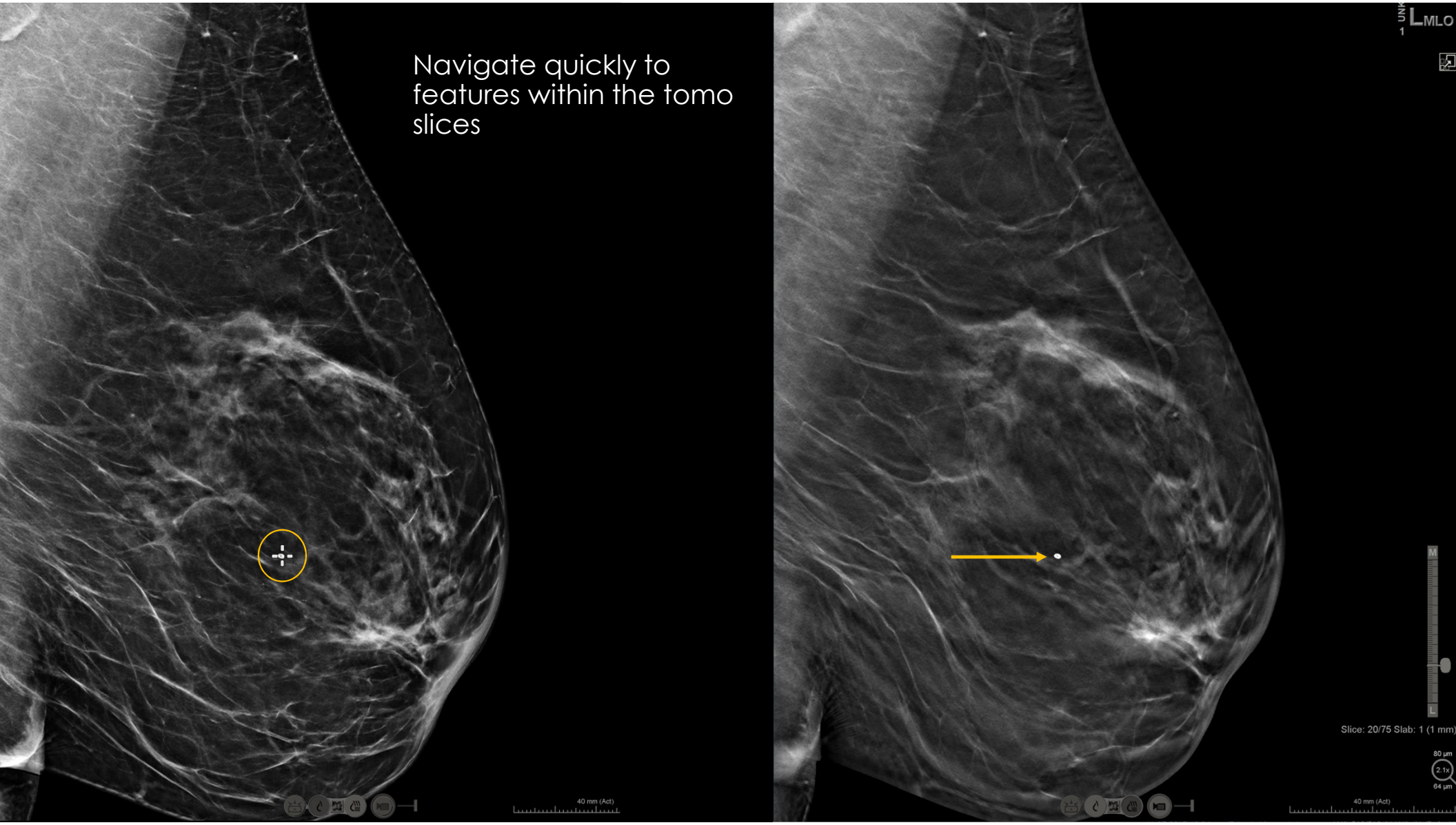


Other New Features

Smart Mapping

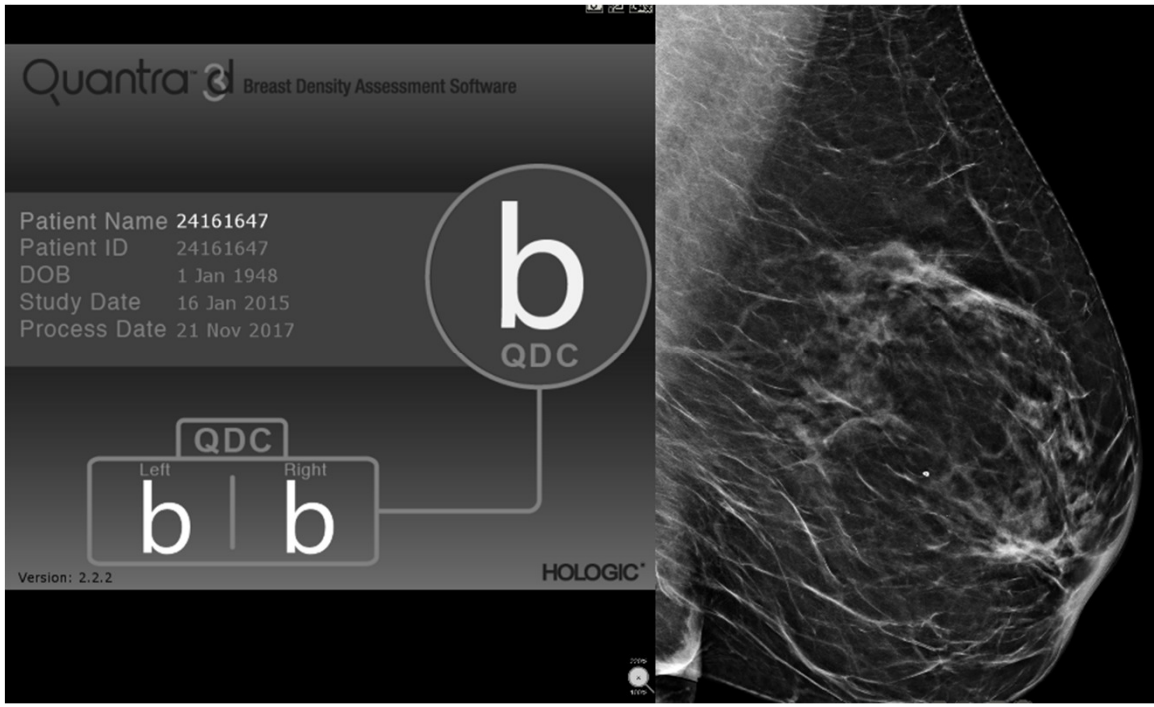
- Smart Map created with the synthesized 2D image
- Maps pixels in the synthesized 2D image to a slice in the tomo data set
- With Smart Mapping, user clicks on a feature of interest in the synthesized 2D image to navigate to the tomo slice where that feature is best visualized

- Feature is available on SecurView and can be activated by clicking on the Smart Mapping icon:


Navigate quickly to features within the tomo slices
LMLO
Slice: 20/75 Slab: 1 (1 mm)
40 mm (Act)
40 mm (Act)

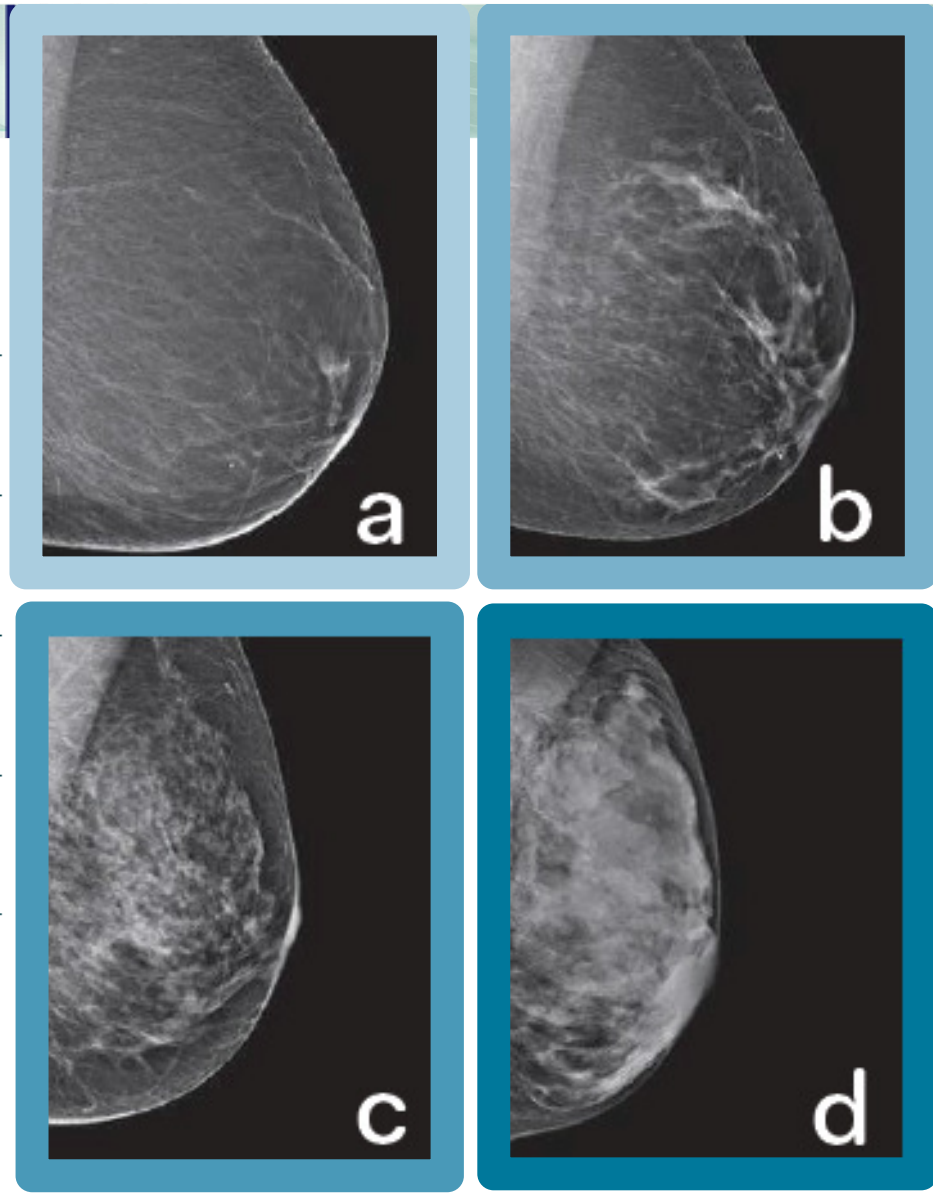
Latest Version of Quantra

- Breast density is a risk factor for breast cancer
- Assessment can be difficult and can be subject to inter-observer variability
- Quantra is an algorithm that can provide a more consistent estimate of breast composition for the radiologist
- Either the Conventional 2D or the DBT slices can be used for the assessment



Breast Density Categories

a	Almost entirely fatty
b	Scattered areas of fibroglandular density
c	Heterogeneously dense
d	Extremely dense



American College of Radiology
BI-RADS, 5th Edition

Quantra Performance in Tomo

- Accuracy of the algorithm was assessed by comparison to radiologists' review
- Set of 230 negative cases read by 5 radiologists
- Readers assigned a BI-RADS density category using ACR BI-RADS 5th Edition
- Median category among all 5 readers' scores was used as the true density
- Quantra is an adjunct software that can provide more consistent estimates of breast density to assist radiologists in their assessment

	a	b	c	d	Per category total	Accuracy
a	20	12	0	0	32	62.5%
b	11	61	9	0	81	75.3%
c	0	7	53	25	85	62.4%
d	0	0	1	31	32	96.9%
				Total	230	

Summary

- Clarity HD has lower SNR and CNR than standard resolution DBT
- However, MTF and DQE data show Clarity HD has superior resolution and detector performance
- Clinical preference data correlate with MTF and CDMAM results, further demonstrating that the overall image quality of Clarity HD and Intelligent 2D are not inferior to standard resolution DBT and C-View
- With Quantra and SmartMapping, these new features aim to cut down on DBT reading times and equip the radiologist with more data for a more confident assessment

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