

Automated Ultrasound System for Breast Imaging

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Unique women, innovative tests

- Mammography has limited effectiveness in women with dense breasts
 - Approximately 40% of American women have dense breasts

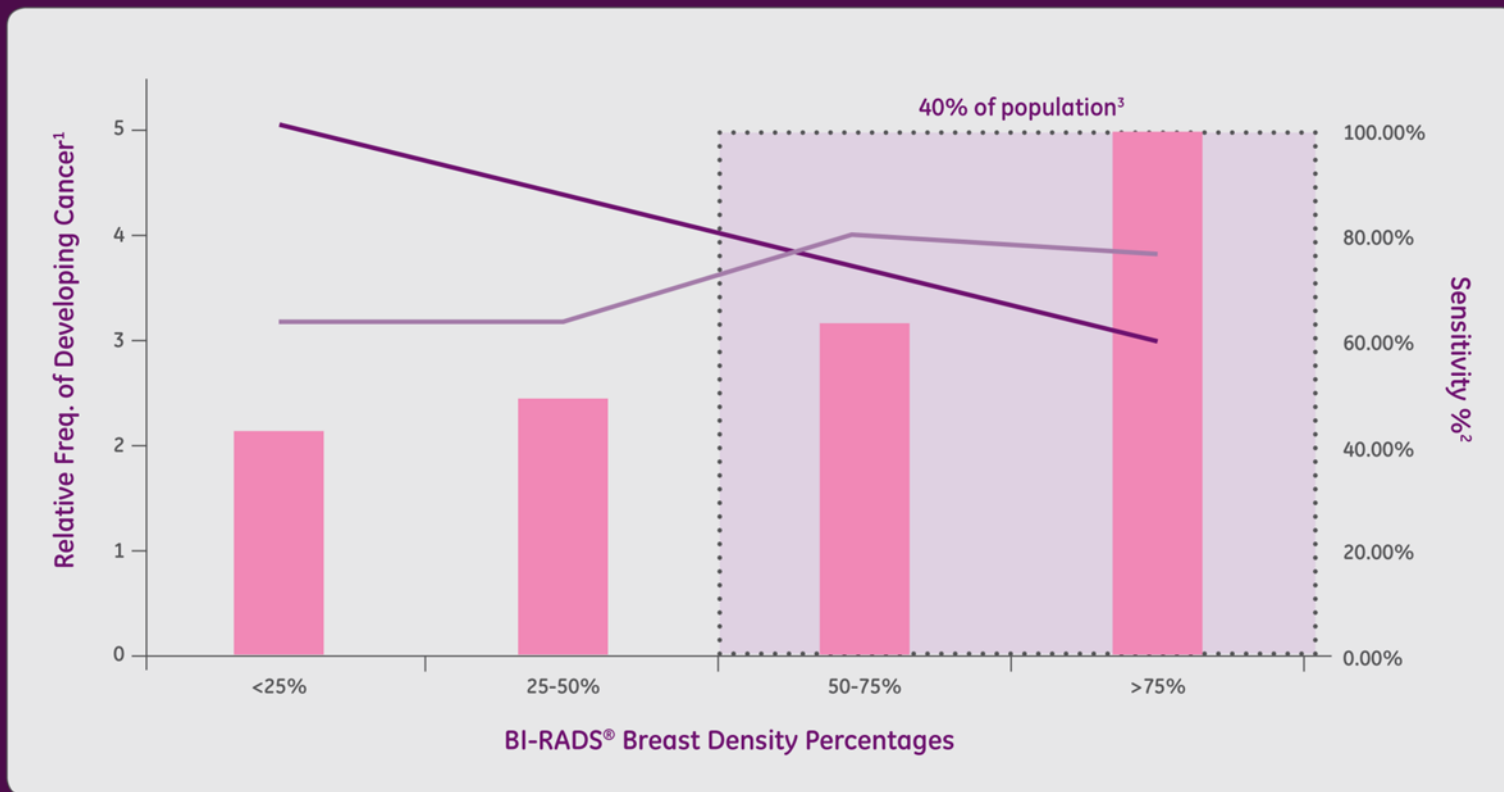
Having dense breasts increases cancer risk by a factor of 4-6x¹



1. Boyd, et al, NEJM Jan 2007

The clinical need for supplemental screening

Ultrasound can find additional, mammographically occult breast cancers



— US sensitivity
— Mammo sensitivity

1. Richard J. Santen, M.D., and Robert Mansel, M.D., Ph.D.: Benign Breast Disorders. N Engl J Med 2005; 353:275-285
2. Kolb et al Radiology October 2002
3. Pisano et al. Diagnostic Performance of Digital versus Film Mammography for Breast -Cancer Screening. NEJM 2005;353:1773

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USA breast ultrasound screening movement

Breast density awareness

Legislative & grass-roots activities – January 2014

- 14 Mandatory Density-Inform
- 6 Introduced inform or notify bill
- 7 Working on a Bill/ Organized Activity
- 3 Has inform law but not mandatory/poor

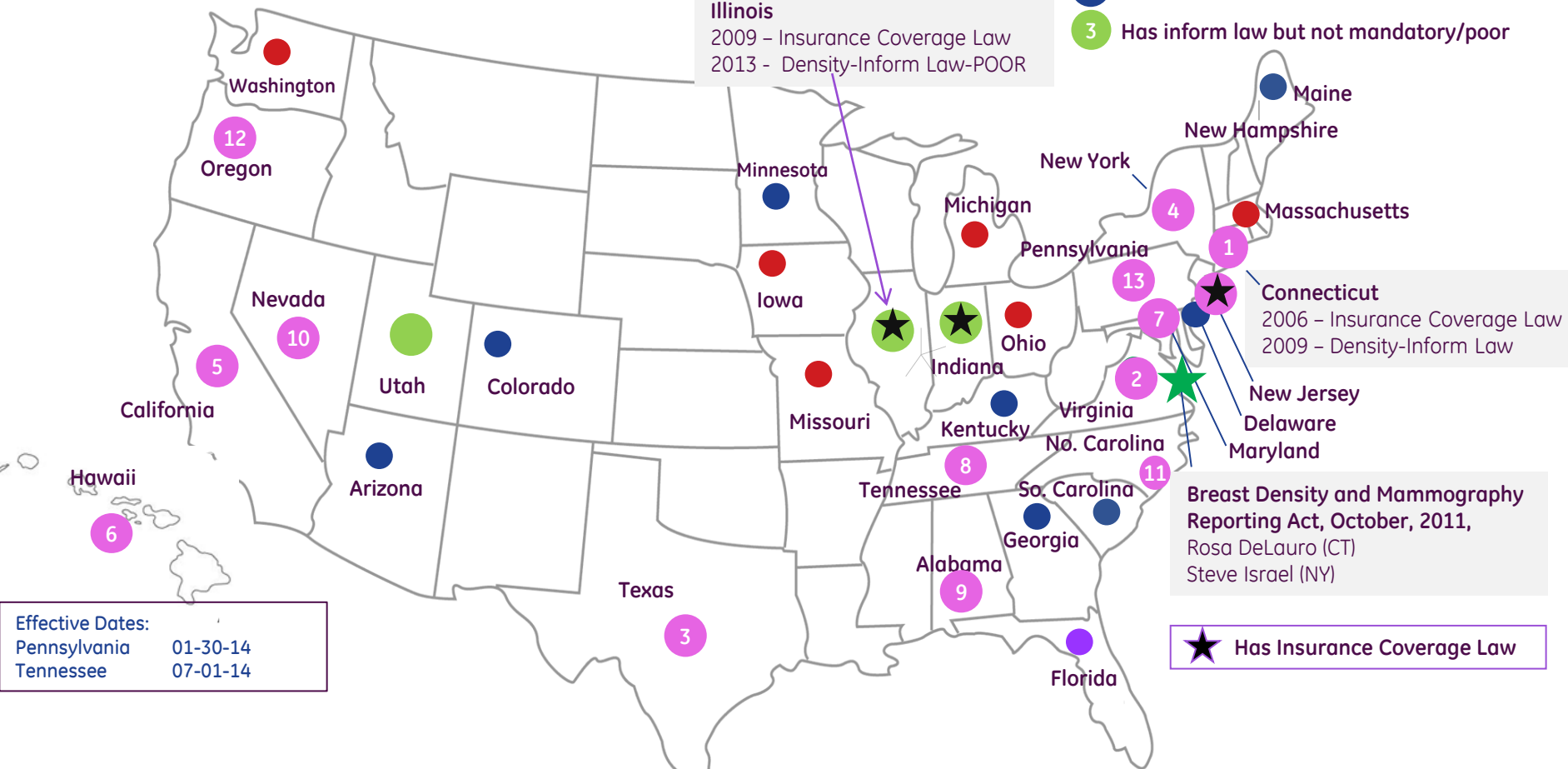
Illinois
 2009 – Insurance Coverage Law
 2013 – Density-Inform Law-POOR

Connecticut
 2006 – Insurance Coverage Law
 2009 – Density-Inform Law

Breast Density and Mammography Reporting Act, October, 2011,
 Rosa DeLauro (CT)
 Steve Israel (NY)

Effective Dates:
 Pennsylvania 01-30-14
 Tennessee 07-01-14

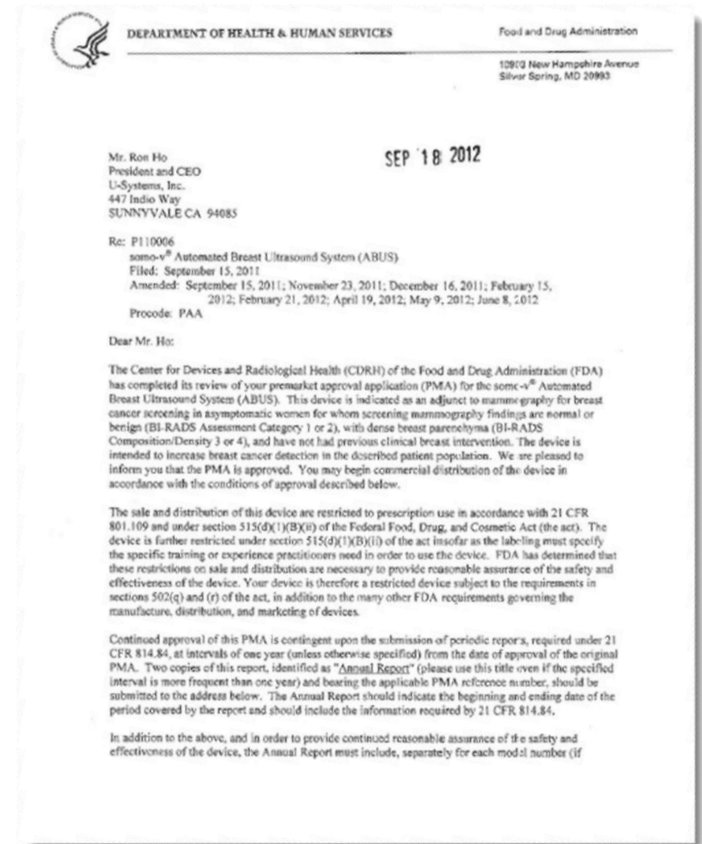
★ Has Insurance Coverage Law



Over 1/3 of U.S. screening population live in states enacting density-inform legislation

PMA approval

On September 18, 2012: U-Systems received PMA approval allowing the market introduction of ABUS as an adjunct to mammography for screening in asymptomatic women with >50% dense breast tissue and no prior breast interventions.



Invenia ABUS

Automated Breast Ultrasound



Invenia ABUS

Sole manufacturer of systems FDA-approved for screening women with dense breast tissue*

The Invenia ABUS is indicated as an **adjunct** to mammography for breast cancer screening in asymptomatic women for whom screening mammography findings are normal or benign, with **dense breast parenchyma**, and have not had previous clinical breast intervention.

The device is intended to **increase breast cancer detection** in the described patient population.

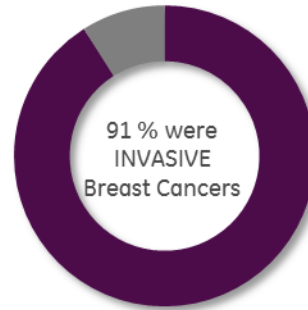
The Invenia ABUS may also be used for diagnostic ultrasound imaging of the breast in symptomatic women.



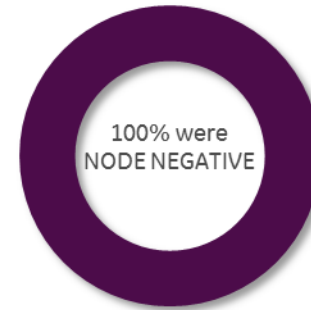
*as of Nov. 11, 2013

Supported by strong clinical results

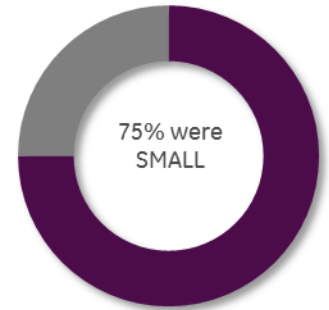
- The majority of mammographically occult cancers detected were invasive, small, and node negative
- 35.7%¹ increase in cancer detection sensitivity over mammography alone when Invenia ABUS is used in conjunction with mammography (in patients with no prior breast interventions)



● DCIS
● Invasive



● Node Positive
● Node Negative



● > 19 mm
● < 19 mm
(median 10 mm, mean 15.2 mm)

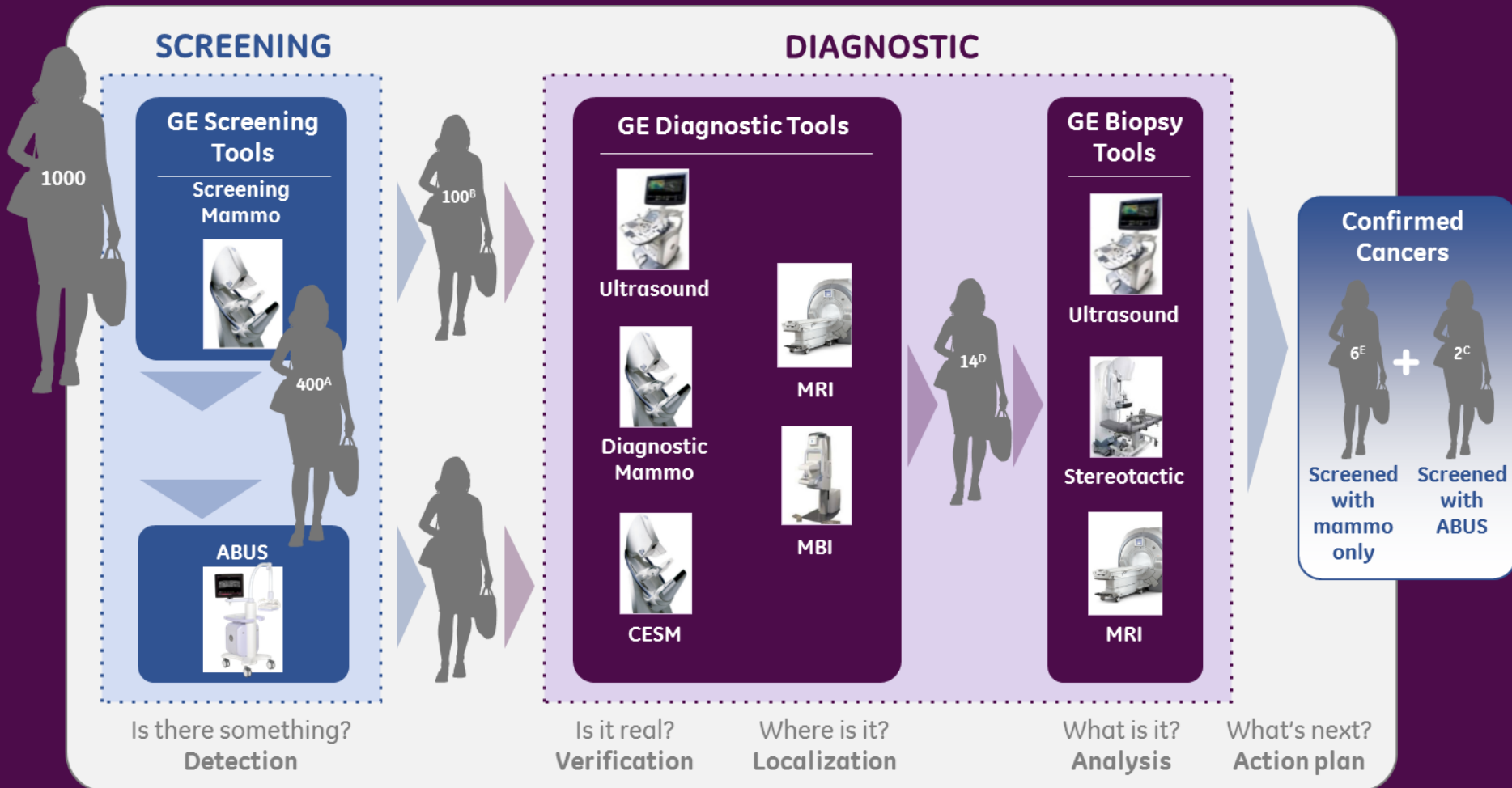
Study results compiled from USI 20082002, clinicaltrials.gov NCT00816530 data



1. FDA PMA P110006 summary of safety and effectiveness

ABUS in the Breast Care Pathway

Enhanced sensitivity for the over 40% of women with dense breast tissue



Hypothetical results for demonstration purposes only based on breast cancer detection rate of 6/1000^E and an increase in detection of 35.7%^C

ABUS Technology



imagination at work

Basic Technical Requirements for Screening U/S

Caregiver's perspective

- Automated image acquisition to minimize the operator dependency
- Standardized procedure for reproducibility and workflow efficiency
- High image quality and good tissue coverage for clinical confidence
- Ergonomic machine human interface

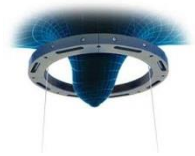
Patient's perspective

- A quick and comfort procedure (~15 min room time)
- No radiation and contrast
- Low cost procedure for patient

Automated Breast Ultrasound Technologies

Approaches

- Patient's position: Supine, Prom, Standing
- Ultrasound imaging: Echo, Through transmit, ...
- Transducer: Flat linear, Curved linear, Ring, ...
- Coupling: Gel, Lotion, Water, ...



Advancements in automation technology

- **Invenia ABUS Imaging Architecture**
 - Integrated, Operator-independent extraordinary image quality provides faster¹ acquisition times
- **Patented Reverse Curve Transducer Technology**
 - The design matches a woman's anatomy
- **Intelligent Imaging Algorithms**
 - Single button optimization helps provide reproducibility



1. As compared to somo-v ABUS

Separates acquisition & interpretation

Acquire images

- Automated image acquisition
- 15 cm field-of-view transducer
- Image acquisition time less than 3 minutes each breast
- Total exam time ~15 minutes



Interpret images

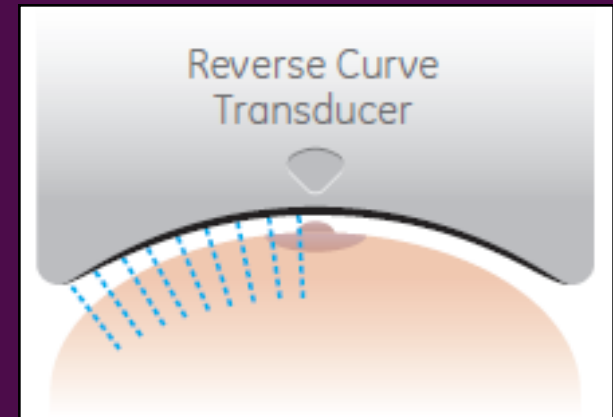
- Supports image interpretation
- Review 3D image sets on workstation
- Read entire case in ~3 minutes¹

1. ARRS 2012 Breast Imaging: Screening/Emerging Technologies Oral Abstract; Radiologist Interpretation Time for 3D Automated Breast Ultrasound Screening, R. Brem

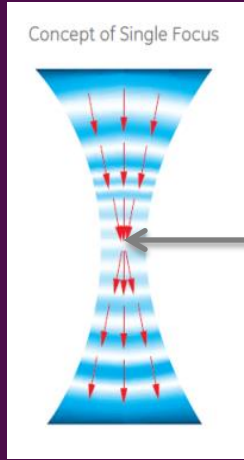
Reverse Curve™

Designed to match a woman's anatomy

- Uniform compression across the entire breast
- 15 cm wide field of view
- 6-15 MHz wide bandwidth
- Designed for patient comfort

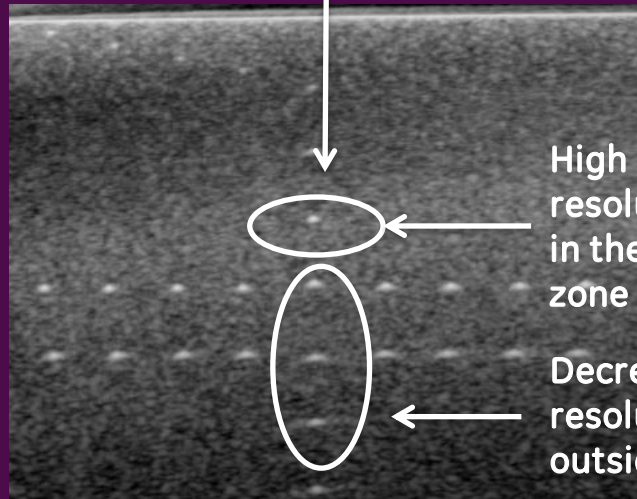


Focused Beam



User picks focal zone # and locations

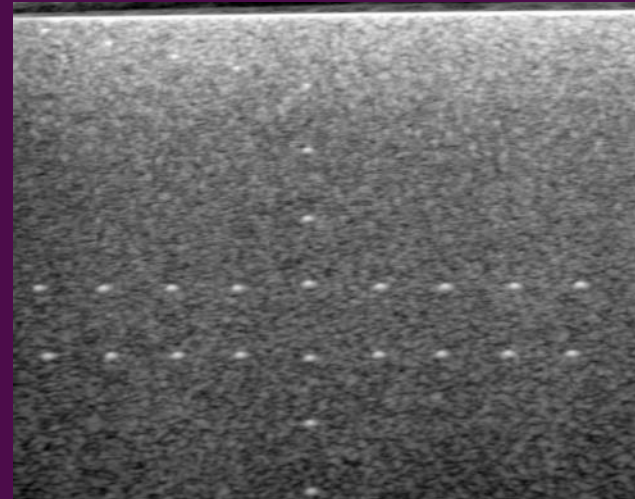
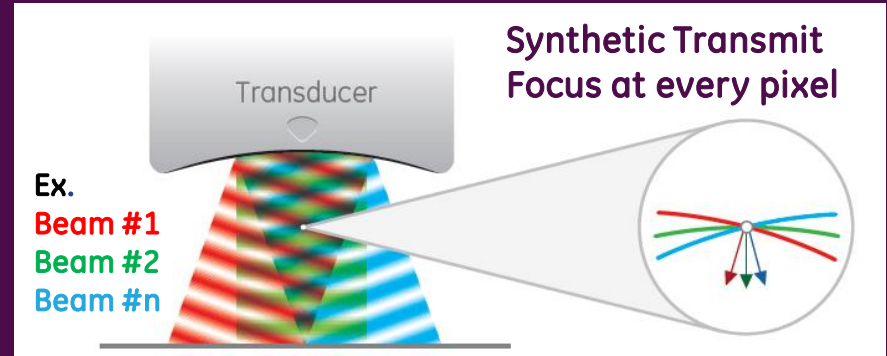
Sweet spot at the focus



High resolution in the focal zone

Decreased resolution outside

Multi-angle Wide Beams



High resolution throughout the image

No focal zones!

Operator independent
All areas are sweet spots!

Invenia Image Architecture for Volume breast imaging

Imaging Requirements:

- Image large breast volume* in <45 s
- No adjustments to images

*Volume dimension:
15 cm wide x 17 cm along x 5 cm deep

Approach:

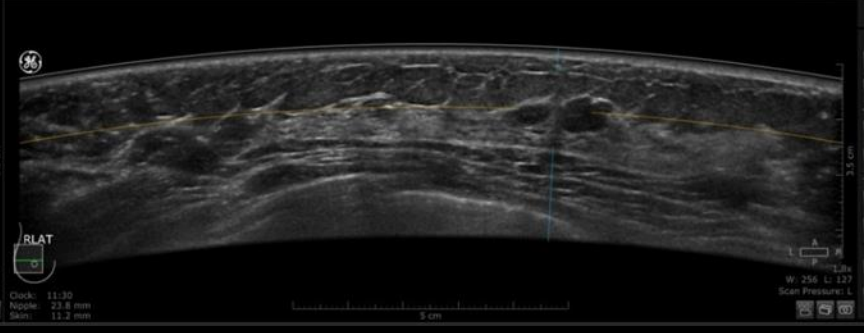
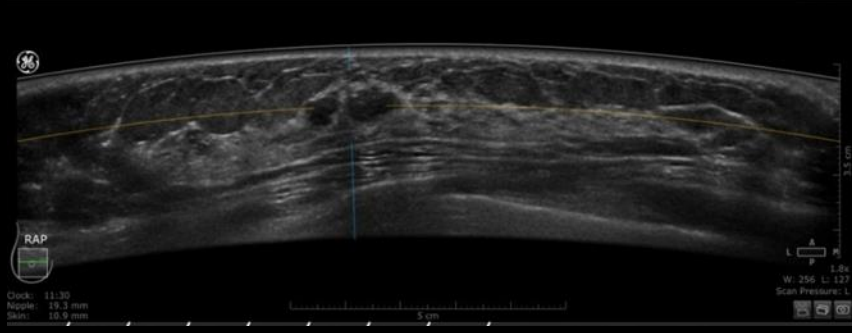
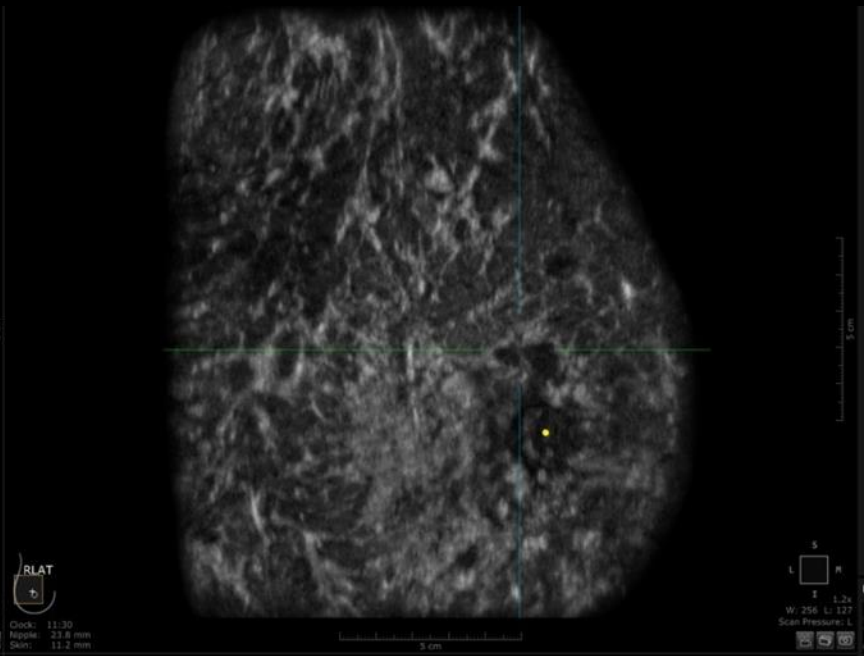
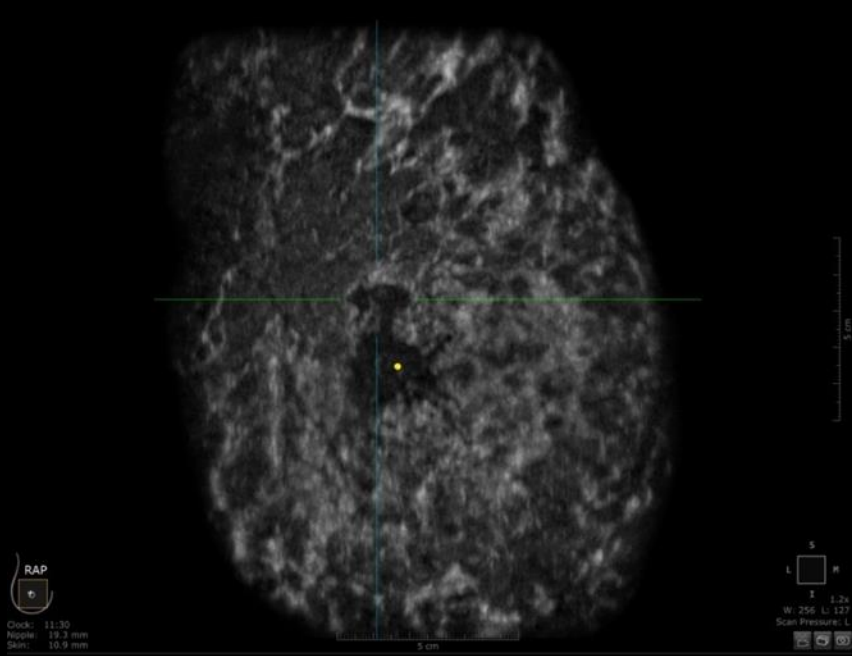
- Flexible hardware → allows transmit of steered wide beams for FR>10 Hz
- GPUs → works at several million pixels per second used for computation

Benefit:

- Overall quick workflow
- Optimized image

Comparison: Focused beams with 4 focal zones; Frame rate: 4 Hz; Volume acquisition: 80 s

High Quality Images



Designed for the operator

- **Compact Design**
 - Smaller physical footprint¹ fits various room configurations
- **Intuitive Icon Driven Touchscreen**
 - Adaptive and intuitive workflow helps enhance productivity
- **Advanced Compression Assist System**
 - Acquisition with patient comfort and operator ergonomics in mind

1. As compared to somo-v ABUS



Beyond the technology

Mastery Program for Physicians

Provides orientation and instruction on using Invenia ABUS images as an adjunct to screening mammography and to provide physicians with training to help promote accurate and rapid interpretation of Invenia ABUS for screening using a consistent review methodology on the Invenia ABUS Workstation.

Extensive, progressive, step-wise training consisting of four modules

MODULE I
1 hour



Peer-to-Peer
Webinar

MODULE II
3 hours



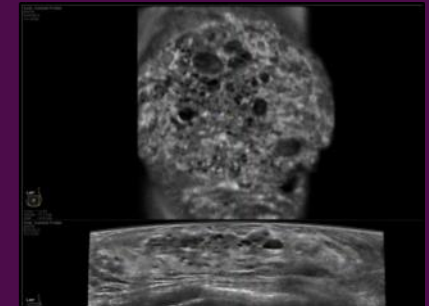
Self-Paced Tutorials

MODULE III & IV
4 hours



Remote Peer-to-Peer
Invenia ABUS
Interpretation
Quality Assessment

Self Assessment
1 hour



Individualized
Performance
Feedback

Thank You

