Automated Breast Ultrasound (ABUS)

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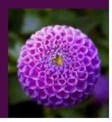

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Learning Objectives

1. Motivation for breast cancer screening with Ultrasound
2. Role of ABUS in breast cancer screening
3. Acquisition of ABUS volumes
4. Imaging Strategies for ABUS
5. Image reconstruction and processing
6. FDA Regulatory requirements for ABUS systems
7. Rationale and implementation of quality control procedures
8. Benefits/Challenges of ABUS in breast cancer screening

Motivation for Breast Cancer Screening with Ultrasound

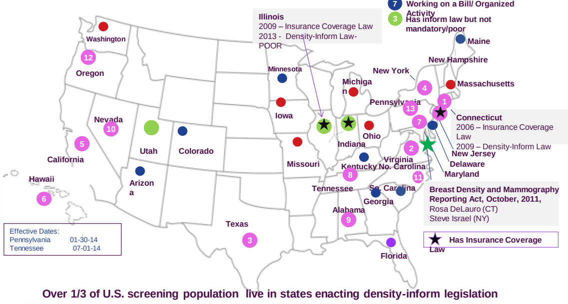
Unique women, innovative tests

- Mammography has limited effectiveness in women with dense breasts[see slide 6]
- Approximately 40% of American women have dense breasts[1]
- Having dense breasts increases cancer risk by a factor of 4-6x[2]
- Need for supplemental screening (ex. Ultrasound screening)

1. Tabár L, et al. Swedish two county trial: impact of mammographic. 2011;260:658-663.
2. Boyd, et al, NEJM Jan 2007

USA breast density movement

Breast density awareness
Legislative & grass-roots activities – January 2014



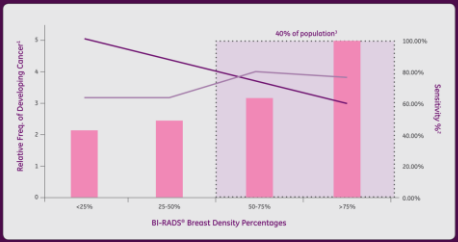
Over 1/3 of U.S. screening population live in states enacting density-inform legislation

Source data from Are You Dense, Advocacy, dated January, 2014

DOC1458880

The clinical need for ultrasound supplemental screening

Ultrasound can find additional, mammographically occult breast cancers



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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Role of ABUS in Breast Cancer Screening

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Screening with hand-held Ultrasound

- Whole breast ultrasound
- Not routine in most clinics with special training required
- Sonographer acquires image snap shots
- Labor-intensive with long acquisition times
- Impractical for broad-scale breast cancer screening
- Not FDA approved
- Sonographer adjusts
  - Focal zones, Transducer frequency, Gain and dynamic range, TGC/DGC, sound speed, On/off harmonics, speckle, compounding
  - Annotates each image capture with clock position, location

Caregiver and Patient perspective 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

- Quick and comfortable procedure
- No radiation and contrast
- Low cost procedure for patient

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Caregiver's perspective → Guidelines for Imaging Architecture

Caregiver's perspective: Automated image acquisition to minimize the operator dependency, high image quality and good tissue coverage for clinical confidence

Imaging Guidelines:

- Image a large portion of the breast in one sweep
- High frame rate to minimize motion artifacts
- Optimized high quality images requiring no adjustments

No focal zones Automatic imaging presets: • transducer frequency • Gain, DNR, TGC/DGC, • sound speed, harmonics Minimizing image artifacts and reduce noise

- Automatic image capture/transfer with location information

Invenia ABUS for Screening

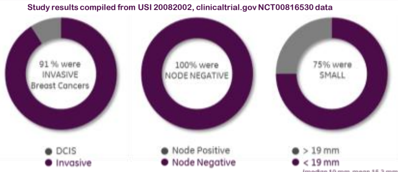
FDA PMA approved system for screening women with dense breast tissue

- New generation ABUS
- Similar scan head as somo•v ABUS*
- Innovative **imaging engine**
- Point and click scan station software for quick clinical throughput
- 15 cm long transducer– large imaging field of view

**somo-v ABUS demonstrated a 35.7% increase in cancer detection sensitivity when used in conjunction with mammography, over mammography alone (in patients with no prior breast interventions) [FDA PMA Approval P110006, Sept. 18, 2012].*

ABUS Clinical Trial Results[1]

(Mammography Vs Mammography + ABUS)



- The majority of mammographically **occult** cancers detected were invasive, small, and node negative
- 35.7% increase in cancer detection sensitivity over mammography alone when ABUS is used in conjunction with mammography

1. FDA PMA P110006 summary of safety and effectiveness

Acquisition of ABUS volumes

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ABUS Workflow: Separates acquisition and interpretation

Technologist:

- Position patient
- Acquire 3D image data sets in a automated manner from both breasts (multiple views if needed)
- Complete exam and push to reading workstation for radiologist

Radiologist:

- Reviews 3D image sets on workstation
- Read entire case in ~3-5 minutes[1]

1. FDA PMA P110006

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Imaging Strategies for ABUS

Goals:

- High frame rate
- High image quality (no adjustments)
    - Contrast
    - Resolution
    - Uniformity

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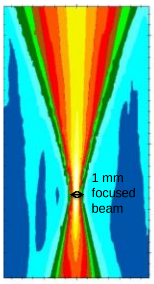
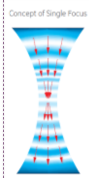
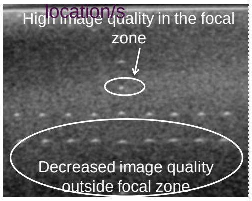
Focused Beams

User picks focal zone/s and location/s







Axial Resolution=2λ=2(c/f)

Typical range of 'c' and 'f':

- C=1470-1540 m/s or 1.47-1.54 mm/μs
- f=8-15 MHz

Spatial pulse length governs axial resolution in B-mode imaging. It is defined as SPL=2λ. For a 10MHz probe, calculate the SPL, assuming speed of sound in tissue as 1540m/s. Possible answers are -

17%	A. 0.3 mm
25%	B. 1 mm
17%	C. 0.15 mm
17%	D. 1 cm
25%	E. 0.3 cm

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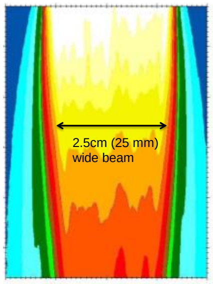
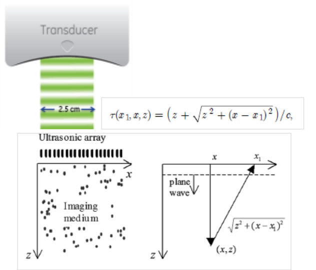
(b) 1 mm
(c) 0.15 mm
(d) 1 cm
(e) 0.3 cm

Answer: a → 0.3mm

Ref: "AAPM/RSNA Physics Tutorial for Residents: Topics in US B-mode US: Basic Concepts and New Technology", Radiographics, 23(4):1019-1033, 2003.

Wide Beams

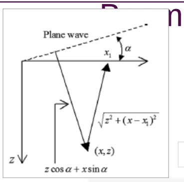




$$\tau(x_1, x, z) = \left(z + \sqrt{z^2 + (x - x_1)^2}\right)/c,$$

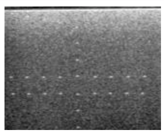
Coherent plane-wave compounding. IEEE UFFC. 2009, 56(3):489-506

Steered Wide Beams

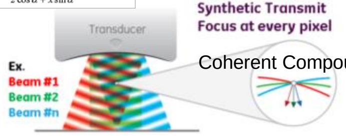


$$\tau_{ec}(\alpha, x, z) = (z\cos\alpha + x\sin\alpha)/c,$$
$$\tau_{rec}(x_1, x, z) = \sqrt{z^2 + (x - x_1)^2}/c.$$
$$\tau(\alpha, x_1, x, z) = \tau_{ec} + \tau_{rec}.$$

Coherent plane-wave compounding. IEEE UFFC. 2009,56(3):489-506



Synthetic Transmit Focus at every pixel



Coherent Compounding

High resolution throughout the image

No focal zones!

Operator independence

Assuming the speed of sound as 1600 m/s (or 1.6mm/µs), the round-trip travel time (in µs) for a pulsed wave emitted from the center of a transducer to 3cm depth and back to a transducer receiving element 4cm lateral to its center is:

15%	A. 50 ms
20%	B. 80 mm
15%	C. 35 µs
0%	D. 50 µs
30%	E. 65 µs

Assuming the speed of sound as 1600 m/s (or 1.6mm/µs), the round-trip travel time (in µs) for a pulsed wave emitted from the center of a transducer to 3cm depth and back to a transducer receiving element 4cm lateral to its center is:

(a) 50 ms
(b) 80 mm
(c) 35 µs
(d) 50 µs
(e) 65 µs

Answer: d → 50 µs

Ref: "Coherent Plane-Wave Compounding for Very High Frame Rate Ultrasonography and Transient Elastography", IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, 56(3), 489-506, 2009.

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Phantom Image Comparison

Steered Wide Beams

Focused Beam

Image Reconstruction and Processing

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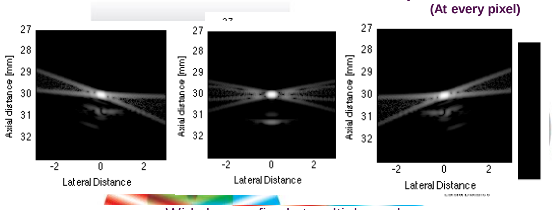
Image Reconstruction with Steered Wide Beams: Point Target Example

Why steered wide beams?

Synthetic Transmit Focus (At every pixel)



Wide beams fired at multiple angles
Transmission of wide beams
Data coherently compounded
Resulting in a synthetic transmit focus

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How to image a large volume of breast tissue?

Imaging architecture

Approach:

- Flexible hardware → transmit wide beams, focused beams
- Large transducer → that is covered by sub-apertures and a transverse image created using aperture synthesis
- Imaging strategy → designed for high frame rate to minimize motion artifacts
- Moving transducer → that can capture several such transverse images as it is moving across the breast
- Computational power → for reconstruction, beamforming and display

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12.5 cm of breast tissue is scanned with an Automated Breast Ultrasound System. Calculate the highest possible frame-rate achievable with this system when imaging to 3.8 cm depth. The system configuration comprises of –

(i) 12.5 cm transducer with 640 elements that are divided into 5 apertures of 128 elements each,
(ii) all apertures used in a sequential manner to cover the field of view,
(iii) 40 steered plane waves applied per aperture,
(iv) travel time for the ultrasound waves to 3.8 cm and back is 50µs.

The possible answers are:

5%	A. 10 Hz
5%	B. 100 Hz
5%	C. 1 KHz
5%	D. 1 Hz
14%	E. 10 KHz

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(a) 10 Hz
(b) 100 Hz
(c) 1 KHz
(d) 1 Hz
(e) 10 KHz
Answer: b – 100 Hz

Ref: "Coherent Plane-Wave Compounding for Very High Frame Rate Ultrasonography and Transient Elastography", IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, 56(3), 489-506, 2009.

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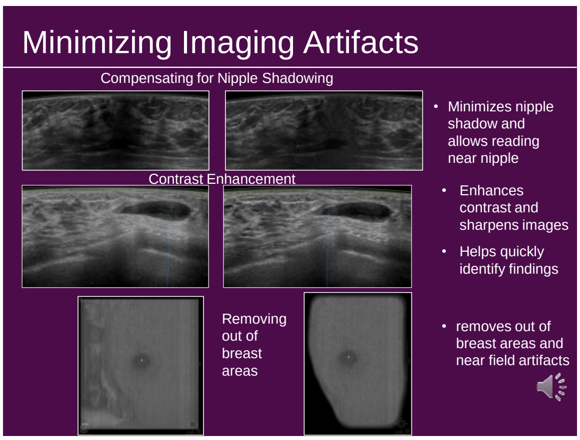

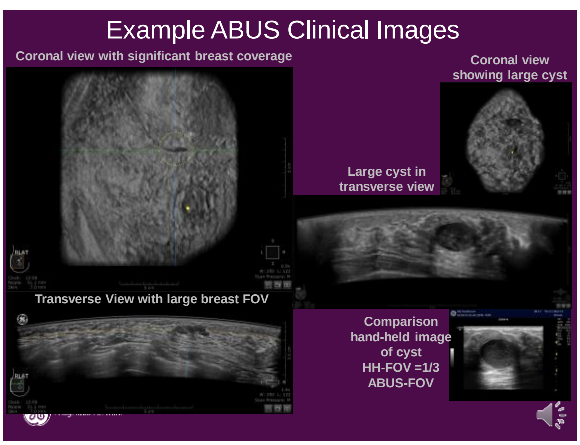

FDA Regulatory requirements for ABUS systems

FDA requirements for ABUS

- On Sept 18th 2012, the FDA approved the PMA submission for somo-v ABUS for use in combination with standard mammography in women with dense breast tissue who have a negative mammogram and no symptoms of breast cancer.
- In June 2013, the FDA approved a PMA supplement for Invenia – ABUS as an enhancement to somo-v.
- As part of the approval, FDA requires
  - **training for physicians and technologists using the ABUS device**,
  - **Clear user manual clearly defining system tests and quality control measures**.

From: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm319867.htm

Rationale and implementation of quality control procedures

Quality Control for ABUS

User perspective
- Training for physicians
  - peer-peer education on how to read ABUS scans
  - Provide orientation and instruction on ABUS images as an adjunct to screening mammography
  - Provide physicians with training to help promote accurate and rapid interpretation using a consistent review methodology.

- Training for technologists
  - Applications training on how to scan using ABUS machines

Manufacturing perspective
- Phantom imaging to check for contrast, resolution, uniformity of coronal, sagittal and axial planes

Benefits/Challenges of ABUS in breast cancer screening

Benefits of ABUS

- ABUS enhances image reproducibility and reduces variability in scanning/imaging
- Uncouples image acquisition from interpretation→ physician reviews image data set, technologist only positions for automated scan
- No image adjustments are needed enabling quick workflow
- Large FOV compared to hand-held ultrasound
- Designed for patient comfort
- Increase sensitivity in dense breast tissue

Challenges of ABUS

- New clinical workflow requires an intensive training, education and ramp-up time to gain the clinical confidence
- Wide adoption needs extensive clinical evidence, dedicated CPT code for screening and patient awareness
- Current technical limitation -
  - Higher standard for the image quality due to limited the scanning manipulation
  - A larger set of image data requires additional reading time
  - May need other imaging modes, such as Color Flow or Elastography as a quick follow-up
  - Need new algorithms to minimize some scanning artifacts and reduce the reading time

Thank You