Automated Ultrasound System for Breast Imaging

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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 4-6x

The clinical need for supplemental screening

Ultrasound can find additional, mammographically occult breast cancers

2. Kolb et al Radiology October 2002

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USA breast ultrasound screening 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

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

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

Study results compiled from USI 20082002, clinicaltrial.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\(^c\) and an increase in detection of 35.7%\(^c\)
ABUS Technology
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 faster\(^1\) acquisition times

- **Patented Reverse Curve Transducer Technology**
  - The design matches a woman’s anatomy

- **Intelligent Imaging Algorithms**
  - Single button optimization helps provide reproducibility

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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 minutes

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

- Synthetic Transmit Focus at every pixel
- Ex. Beam #1, Beam #2, Beam #n
- 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 footprint\(^1\) 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

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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