Invenia™ ABUS
Automated Breast Ultrasound

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Unmet Clinical Need

The Clinical Need for Supplemental Screening

Ultrasound can find additional, mammographically-occult breast cancers

Different Tests for Different Breasts

Patient Risk

- Dense breasts increase cancer risk 4-6x affecting >40% of US women
- Each woman’s risk factors are different
  - Personalized screening approach needed

Clinical Dilemma

- For every cancer found, a cancer is missed in extremely dense breast tissue
- Supplemental screening finds more cancers, but needs reasonable callback and biopsy rate
- Dense tissue also is challenging for diagnostic and surveillance exams

Societal Impact

- Early detection enables
  - Less invasive treatment
  - Lower morbidity
  - Reduced treatment cost
- Awareness and density notification legislation is growing
Major Publications 2015-2016

SomolInsight Study (Brem, Radiology, March 2015)
- In asymptomatic screening, ABUS + Mammo detects significantly more cancers in patients with dense breasts than Mammo alone (55% relative sensitivity increase, or additional 1.9 per 1000)

EASY Study (Wilczek, EJR, June 2016)
- Adding ABUS to Mammo in women with BI-RADS densities III and IV found additional 2.4 cancers per 1000 without raising the recall rate significantly (57% relative sensitivity increase)

ABUS FDA PMA Reader Study (Giger, AJR, April 2016)
- Adding ABUS to Mammo increased sensitivity by 110% for cancers originally missed with Mammo alone in patients with no prior interventions
- Increase in sensitivity did not show a statistically significant decrease in specificity

Ongoing ABUS Research

Invenia™ ABUS System

Invenia™ ABUS Scan Station

Invenia™ ABUS Imaging Architecture
- Extraordinary image quality
- Operator independence for reproducibility
- Screening environment analogous to mammography
- Year-over-year longitudinal fidelity

Reverse Curve™ Transducer
- Conforms to female anatomy
- Improved compression, user comfort and tissue contact
- 15 cm field of view with 6-15 MHz bandwidth

Intelligent Imaging Algorithms
- Single button optimization for reproducible image quality

Image Acquisition with Invenia™ ABUS

Invenia™ ABUS Review Software

Tools for Streamlined Review
- Whole breast coronal view for quick orientation using the nipple and chest wall
- Patented 2.0 mm coronal slice viewing for detecting abnormal terminal ductal lobular units (TDLUs) and architectural distortions in smaller invasive cancers
- Radial slice viewing for accurate lesion characteristics, including size, margins, spiculation, and shadows
- 3D-volume visualization
- Customizable hanging protocols
- Separation of acquisition and interpretation

Regional Studies
- 2 active studies in China
- 2 active studies in USA
- Active studies in Korea, Thailand, Sweden
- Studies coming up for Japan, Austria, Netherlands, Brazil and France

Areas of focus
- Value of adding ABUS to current screening practice
- Comparison of ABUS to DBT and HHUS
- Cancer detection, recall rate
- 2 views vs 3 view in small breast
- ABUS in BIRADS 0 / diagnostic
- ABUS adoption tools
- Influencing local guidelines

New Products
- Discovery
- Development
- Acceptance
- Expansion

Existing Products
- Discovery
- Development
- Acceptance
- Expansion
Invenia™ ABUS Technology

**Features** | **Advantages**
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Powerful imaging architecture | Transmits wide ultrasound beams rapidly across the whole breast volume.
Image reconstruction powered by NVIDIA™ GPUs | Software beamforming uses wide ultrasound beams and dynamic focusing to create volumes with superb spatial resolution at every depth.
Quick data acquisition | Creates full volumes in less than 60 seconds and allows for 15-minute exams with medium-sized breasts.
Intelligent Imaging Algorithms | Nipple shadow compensation, speckle reduction imaging (SRI), and breast border detection streamline reading workflow.

### Focused Beams vs. Wide Beams

- **Focused Beams**
  - 2.5 cm high spatial resolution
  - No focal zones!
  - Sonographers pick the focus depth

- **Wide Beams**
  - High spatial resolution throughout the image
  - No focal zones!

### Invenia™ ABUS Image Reconstruction

*Why do we use beam steering?*

#### Calculating transmit delays for each voxel:

- Focused beam
- Wide beam

### Incoherent Compounding

**Coherent vs. Incoherent**

- **Coherent compounding** gives great spatial resolution but produces a distinctive speckle pattern.
- **Incoherent compounding** (Crossbeam™ technology in GE Logiq™ systems) combines the steered beams in three separate angle groups.
- This improves contrast resolution of breast structures by smoothing out the speckle patterns.
**Invenia™ ABUS Imaging Architecture**

- Reverse Curve Transducer
- Breast
- Focused image created using compounded steered beams
- Active elements / aperture
- Wide beam acquisitions with multiple angle groups

**Nipple Shadow Compensation**

- NSC off
- Minimizes nipple shadow and allows reading near the nipple
- NSC on

**Speckle Reduction Imaging (SRI)**

- Decreases speckle noise
- Minimizes distractions caused by noise
- Speckle off
- Speckle level 1
- Speckle level 2

**Breast Border Detection**

- BBD off
- BBD on
- Estimates boundary between breast tissue and the background
- Removes out of breast areas and nearfield artifacts
- Reduces reading time spent on these areas

**Invenia™ ABUS Image Quality Control**

- Largely follows the precedence set by GE Logiq™ systems
- Image uniformity and penetration is pre-optimized

**New System, Familiar Tests**

**B-mode Image Quality**

- Despite advances in software image reconstruction and algorithms, the core technology in ABUS is the familiar pulse-echo ultrasound
- Similar image quality requirements as handheld ultrasound
- Image artifacts, uniformity, penetration, spatial resolution, contrast resolution, speckle noise

**Invenia™ ABUS Image Quality Control (IQC)**

- Largely follows the precedence set by GE Logiq™ systems
- Image uniformity and penetration is pre-optimized

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**Imagination at Work**

3/17/2017
Invenia™ ABUS IQC

IQC Parameters
- Display monitor fidelity
- Image artifacts
  - Electromagnetic noise
  - Dead transducer elements (coronal lines)
  - Spatial resolution
  - Contrast resolution
- Distance accuracy
- Dynamic range
- Speckle

Recommended Phantom
- ATS Laboratories Model QC SEEM Small Parts Phantom
  - Urethane rubber phantom shaped to match the Invenia™ ABUS curvature
  - 0.5 dB/cm/MHz
  - 1450 m/s ± 1% @ 23°C

IQC Principles

Display Monitor Fidelity
- Scan Station uses Planar PT1785P-BK
- Workstation uses NEC P242W-BK
- Verify that there are no visible damage or dead pixel(s)
- Verify that the monitor's correct ICC profile is installed
- Backup any configuration prior to any changes
- Use the monitor's on-screen display (OSD) to correct any color, brightness, or contrast configurations
- If needed, use Windows Color Calibration or a SMPTE image for adjustment
- Verify any changes with clinical images

IQC Principles

Image Artifacts
- Check for any electromagnetic noise using a uniform section of the test phantom
- Electromagnetic noise shows up as bright arcs in the image
- Note: ultrasound reflection off of the bottom of the test phantom is expected
- Check for any dead transducer elements by performing a full scan
- Any faulty element should be dark and distinct in the coronal view

IQC Principles

Spatial Resolution
- Distance can be measured on the Workstation using the caliper tool
- Scan a test phantom and send the case to the Workstation
- Verify the distances between the linear line target (5 mm)
- Repeat for different depths and horizontal positions
- Verify the distances between the targets in the axial-lateral resolution arrays
- Consider the transverse view pixel spacing (axial 82 µm, lateral 200 µm)
- Verify voxel sizes in the DCOM headers: (0018,0088) Spacing Between Slices (0028,0030) Pixel Spacing

Invenia™ ABUS Imaging Demo
Mammo negative; Biopsy-proven IDC with multifocal disease

Mammo negative; Biopsy-proven IDC with MRI

Biopsy-proven fibroadenoma

Invenia™ ABUS Imaging Architecture
Detection of Cancer in Dense Breast Tissue

A total of 15,318 women were included and classified as having breast density in BI-RADS category III (n=11,488, 75.0%) or IV (n=3,830, 25.0%). Breast cancer was diagnosed at screening in 112 women: 82 by full-field digital mammography (FFDM) and an additional 30 by ABUS.

Adding ABUS to Mammo

The addition of ABUS to FFDM yielded an additional 1.9 detected cancers per 1000 (95% CI 1.2, 2.7; p<0.001) screens.

*Sensitivity increase was associated with a decrease in overall specificity.

SomolInsight Study (Brem et al.1)

**EASY** Study (Wilczek et al.2)

Adding ABUS to Mammo

- The study included 1,668 women with no prior history of breast cancer.
- 6.6 cancers per 1000 women screened by FFDSM + 3D-ABUS.
- 4.2 cancers per 1000 women screened by FFDSM alone.
- ABUS produced a relative increase of 57%.
- Sensitivity +36.4% and specificity -0.7%.

**Callback Rate**

- 2.3% callback rate for FFDSM + 3D-ABUS.
- 2.1% callback rate for FFDSM alone.

**Conclusion**

- FFDM + ABUS significantly increases the breast cancer detection rate without raising the recall rate significantly.


FDA PMA Reader Study (Giger et al.)

**Enriched Reader Study**
- ROC analysis
- 185 cases of which 52 were cancer and 133 were non-cancer
- 17 radiologists were presented with FFDM and then FFDM plus ABUS image sets

**Adding ABUS to Mammography**
- 110% sensitivity increase for cancers originally missed with FFDM and no prior interventions
- Overall, specificity decreased only slightly with the addition of ABUS from 78.1% to 76.2% which was not statistically significant

**Conclusion**
- “The addition of ABUS to screening mammography showed a significant increase in cancer detection with a nominal, insignificant decrease in specificity.”

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

GE Healthcare Breast Portfolio