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



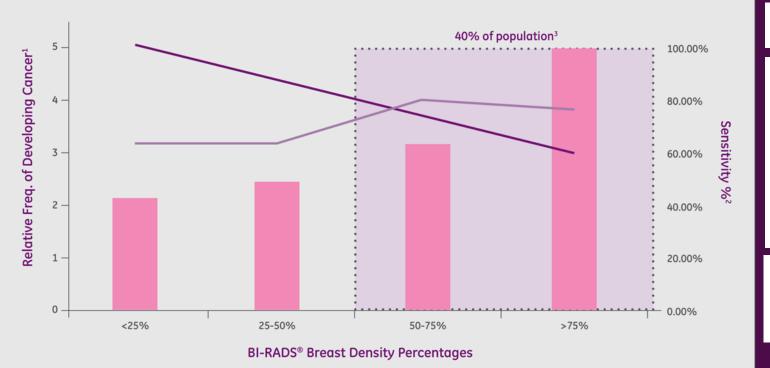
1. Boyd, et al, NEJM Jan 2007



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The clinical need for supplemental screening

Ultrasound can find additional, mammographically occult breast cancers



US sensitivityMammo 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

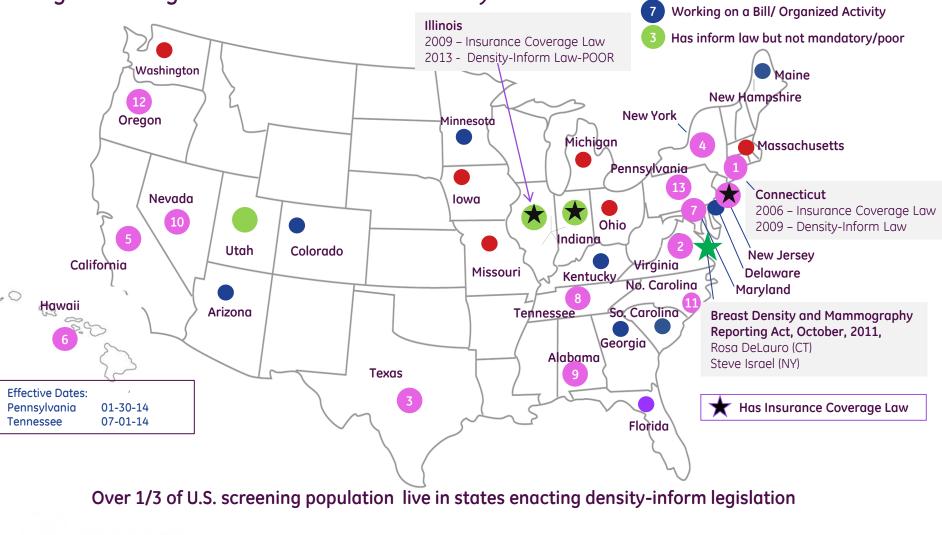
Mandatory Density-Inform

6

Introduced inform or notify bill

Breast density awareness

Legislative & grass-roots activities – January 2014



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

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.

| 1 50 | DEPARTMENT OF HEALTH & HUMAN SERVICES | Food and Drug Administration |
|------|--|---|
| Ste | | 10903 New Hampshire Avenu Silver Spring, MD 20993 |
| | Mr. Ron Ho SEP 18 | 2012 |
| | President and CEO U-Systems, Inc. | |
| | 447 Indio Way | |
| | SUNNYVALE CA 94085 | |
| | Rc: P110006 | |
| | somo-v® Automated Breast Ultrasound System (ABUS) | |
| | Filed: September 15, 2011 | |
| | Amended: September 15, 2011; November 23, 2011; December | |
| | 2012; February 21, 2012; April 19, 2012; May 9 Procode: PAA | P. 2012; June 8, 2012 |
| | | |
| | Dear Mr. Ho: | |
| | The Centre for Devices and Radiological Health (CDRH) of the Foo has completed its review of your premarkst approximate application (P) Breast Ultrasound System (ABUS). This device is indicated as an a cancer recenting in asymptomatic women for whom screening many brings (IB+RADS Assessment Category 1 or 2), with dense breast p Composition/Density 3 or 4), and have not had previous clinical brea- intended to increase breast ancore detection in the doscribed patients inform you that the PMA is approved. You may begin commercial accordance with the conditions of approval described below. | #A) for the some-v [®] Automated djutet to mamme graphy for breast mography findings are normal or arenchyma (BI-RADS ast intervention. The device is population. We are pleased to |
| | The sale and distribution of this device are restricted to prescription 80.109 and under section $315(dy(1)(B)(x))$ of the Federal Food, Dru device is further verticited under section $35(dy(1)(B)(x))$ of the art the specific training or experience practitioners nosed in order to use these restrictions on sale and distributions are necessary to provide or effectiveness of the device. Your device is therefore a restricted devi- sections $502(q)$ and (r) of the ext, in addition to the many other FDA raunificure, distribution, and markeding of devices. | g, and Cosmetic Act (the act). The msofar as the labeling must specify the device. FDA has determined that assomable assurance of the safety and ice subject to the requirements in |
| | Continued approval of this PMA is contingent upon the submission. CFR 814.84, at Intervals of one year (unless otherwise specified) for PMA. Two copies of this report, identified as " <u>Annual Report</u> " (ple interval is more frequent than one year) and bearing the applicable be submitted to the address below. The Annual Report should indicate period covered by the report and should incident be information result. | m the date of approval of the original ase use this title oven if the specified MA reference number, should be the beginning and ending date of the |

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Anaual Report must include, separately for each model number (if



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.

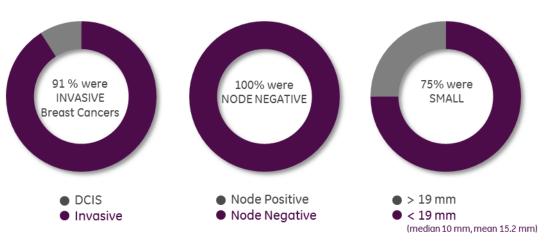




imagination at work

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

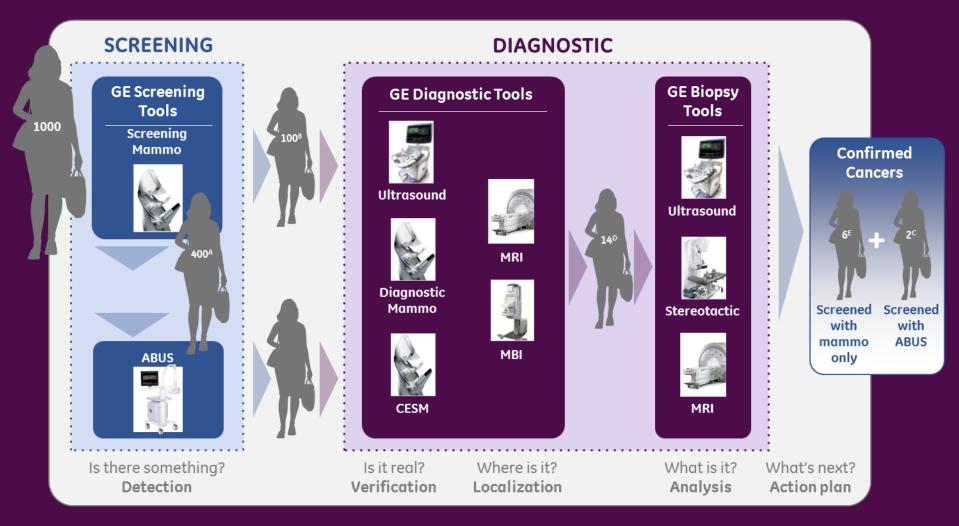


1. FDA PMA P110006 summary of safety and effectiveness



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^E 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 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

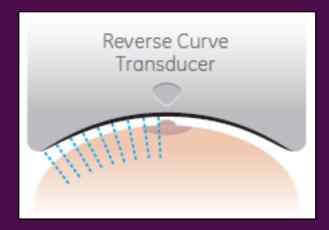


Reverse CurveTM

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

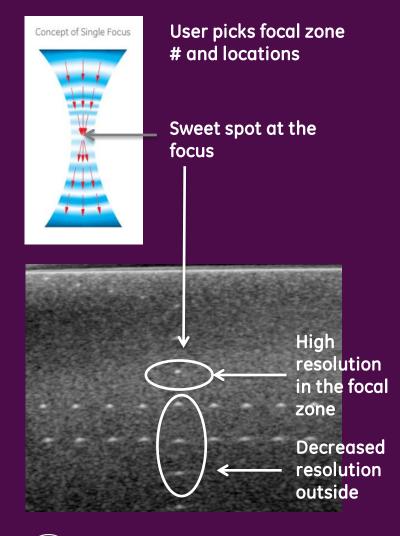


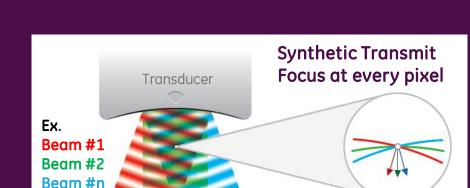


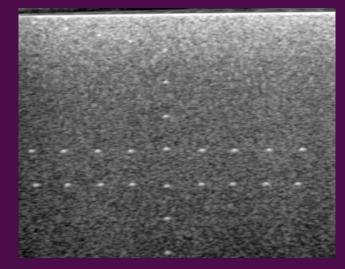


Focused Beam

Multi-angle Wide Beams







Operator independent All areas are sweet spots!

High resolution throughout the image

No focal zones!

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

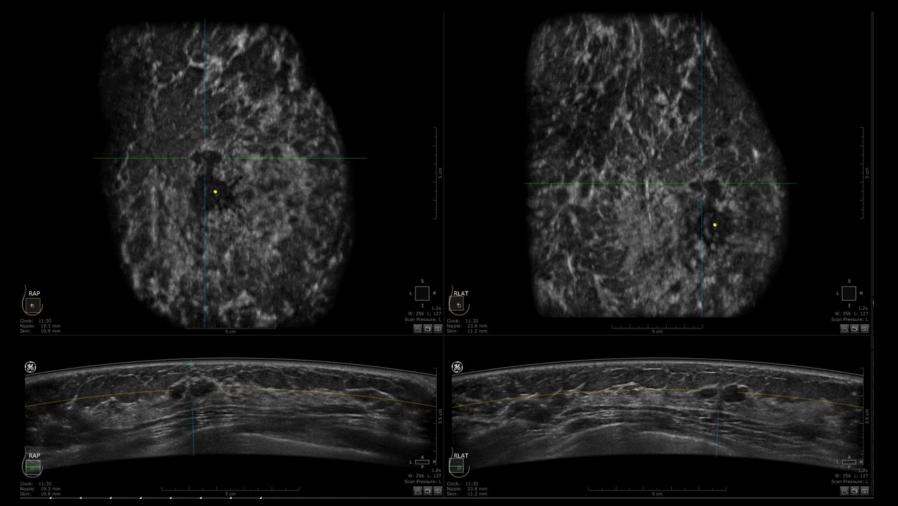
Benefit:

- 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



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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

MODULE II 3 hours

MODULE III & IV 4 hours

Self Assessment 1 hour



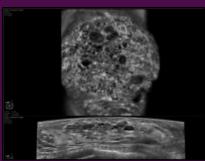
Peer-to-Peer Webinar



Self-Paced Tutorials



Remote Peer-to-Peer Invenia ABUS Interpretation Quality Assessment



Individualized Performance Feedback



Thank You



