Invenia ABUS Fact Sheet

The basics of ultrasound technology and Invenia ABUS technology

What is ultrasound?

Ultrasound is a non-invasive and expedient way to look inside the body at organs and soft tissue. There is no exposure to ionizing radiation as there is with X-ray or Computed Tomography (CT) exams. Instead, ultrasound uses high frequency sound waves to create a detailed image of the organ or tissue being examined. Sound waves are sent into the body through a hand-held device called a transducer, which is pressed against and moved over the skin. The 'echoes' that bounce back are then displayed as an image in real time on the ultrasound monitor.

How is ultrasound used?

Most people associate ultrasound with prenatal exams to view developing fetuses, but ultrasound has many applications. It can be used to help make a diagnosis, determine therapy options and guide medical procedures. Advances in ultrasound technology continue to expand its capabilities.

Why Breast Ultrasound?

- Ultrasound is a key technology to watch in the wake of spreading breast density reporting legislation due to its affordable costs, widespread availability, ongoing technological advancements and significant improvements in detection accuracy when used to supplement mammography. Ultrasound has shown that it can increase breast cancer detection when added to mammography. However, traditional hand-held ultrasound has inherent issues that do not make it well suited for screening. The GE Healthcare, PMA-approved Invenia™ ABUS creates reproducible, wide field-of-view volumes in a time efficient manner, thus well-suited for a screening workflow.
- In terms of detection accuracy in women with dense breasts, an "ultrasound + mammography" screening protocol has been demonstrated to increase detection of cancer in the breast by 35.7 percent; this is double the detection rate relative to using mammography alone. The ease of use, comfort, and non-ionizing characteristics of ultrasound also make it an attractive option for breast screening. Moreover, automated technologies like those offered by Invenia ABUS continue to improve the workflow and sensitivity of ultrasound.
- Invenia ABUS reduces the time and operator dependency as compared to conventional hand-held breast ultrasound through its use of a wide field-of-view transducer that automatically scans the breast, acquiring volumetric image datasets.
- Some disadvantages of patient screening with hand-held ultrasound include the fact that hand-held ultrasound is not designed for a screening environment. While ideal for diagnostic use, hand-held ultrasound is known for low reproducibility, requires a highly trained operator and is not automated for screening.

What is Automated Breast Ultrasound?

(Also referred to as whole breast ultrasound or automated whole breast ultrasound) With 3D ultrasound volumes and ABUS software, radiologists can look through hundreds of breast tissue image "slices," looking at layers of dense tissue to find breast cancers which may have been missed on a mammogram. This is different than routine ultrasound of the breasts since the images from ABUS allow you to see in projections that routine ultrasound cannot, which results in the ability of physicians to detect more breast cancers and less false negatives (findings due to images which are not cancer).

What makes the Invenia™ ABUS a valuable screening tool?

The Invenia ABUS system is the only FDA ultrasound device approved for breast cancer screening in the United States as an adjunct to mammography for asymptomatic women with dense breast tissue. Invenia ABUS helps physicians differentiate tissue and view tumors more clearly. The Invenia ABUS system from GE Healthcare is designed to help improve the consistency, reproducibility, and sensitivity of whole breast ultrasound, demonstrating a 35.7 percent improvement in cancer detection (sensitivity) in women with dense breasts without prior breast intervention.[1] (1. FDA PMA Approval P110006, Sept. 18, 2012.) Using Invenia ABUS can help physicians provide answers sooner regarding the presence or absence of breast cancer.

What is special about Invenia ABUS technology?

- **Technology advancements:** Using proprietary technology to automate the ultrasound imaging process, the Invenia ABUS system was created specifically for breast screening. Advanced algorithms automate the imaging process to help provide remarkable image quality and reproducibility from user to user.
- **Reading station:** Developed specifically for the high-volume, breast cancer screening environment. The advanced 3D Invenia ABUS Workstation enables fast, accurate review and archiving of patient exams, optimizing the breast ultrasound screening workflow.
- **Reverse Curve Transducer:** The Reverse Curve™ transducer enhances both patient comfort and breast coverage during the exam. The 15 cm, wide field-of-view transducer automatically creates uniform compression across the entire breast for consistent, reproducible image quality independent of the operator.

How does Invenia ABUS benefit the patient?

- Ultrasound is a proven diagnostic tool in breast imaging. With its non-invasive, non-ionizing radiation, real-time and economical nature, ultrasound is an important screening modality as an adjunct to mammography. In some cases, this innovative system may also help reduce the need for invasive tests or provide an alternative to exams with X-ray or CT that expose patients to radiation.
- Invenia ABUS has been proven to increase cancer detection by 35.7 percent in women with dense breasts and no prior breast interventions.
- Invenia ABUS exams are short and comfortable.

How does Invenia ABUS benefit physicians?

- With improved contrast resolution, the Invenia ABUS has the potential to reduce false positives and improve diagnostic confidence when characterizing lesions.
- With the coronal view capabilities provided by Invenia ABUS, clinicians have the ability to interrogate suspicious areas in a 3D plane. The ability to see the entire breast, not just the sample images, gives clinicians greater control over the review process, supporting more confident decisions.

How does the Invenia ABUS benefit practices?

Quick, automated acquisition helps overcome operator dependence and long exam times associated with hand-held ultrasound or conventional ultrasound.

- Where hand-held ultrasound exams are typically scheduled in 45 minute increments, a bilateral, full-field Invenia ABUS exam can be completed and sent for review in approximately 15 minutes.
- The faster Invenia ABUS workflow enables sites to free rooms more quickly and free technologists for diagnostic breast ultrasounsds and other exams. The result can be better resource utilization and potential for revenue opportunities.

Brief Statement

The Invenia ABUS is indicated as an adjunct to mammography or breast cancer screening in asymptomatic women for whom screening mammography findings are normal or benign (BI-RADS® Assessment Category 1 or 2), with dense breast parenchyma (BI-RADS Composition/Density 3 or 4), 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. See the device manual for detailed information, contraindications, warnings, precautions, potential adverse events.

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