GE Healthcare

Invenia ABUS Key Considerations

Thank you for considering GE Healthcare for your ABUS screening program. GE Healthcare is a leader in medical imaging in the US and worldwide. One of our key corporate initiatives is to help transform the diagnosis and treatment of breast cancer from reactive to proactive.

It is from this perspective, that we propose our technology for your consideration, and to help you assess the impact of launching an ABUS program for your patient population and institution.

1. **Clinical Impact:** The Invenia™ ABUS system has demonstrated a 55% relative increase* in invasive cancer detection over mammography alone for women with dense breast tissue.[1] Finding more cancers, at an earlier stage, has the potential to lead to lower mortality rates, increased revenue, and better patient care.

   The Invenia ABUS has both a screening and a diagnostic indication for use, as well as being the only FDA-approved system for screening women with dense breast tissue based on a multi-center, prospective clinical study with over 15,000 subjects.

   In the study, the majority of mammographically occult cancers detected were invasive, small, and node negative.

   93% were INVASIVE Breast Cancers

   - ● DCIS
   - ● Invasive

   93% were NODE NEGATIVE

   - ● Node Positive
   - ● Node Negative

   87% were SMALL

   - ● >19 mm
   - ● <19 mm
     (median 10 mm, mean 15.2 mm)

2. **Enhanced Comfort and Image Quality:** The Invenia ABUS system uses Reverse Curve™ transducer technology, which is designed to conform to a woman's anatomy. The Compression Assist feature provides 3 levels of compression. These features offer patient comfort, help maintain edge to edge contact with the breast and deliver outstanding image quality and reproducibility.


   Reverse Curve Transducer
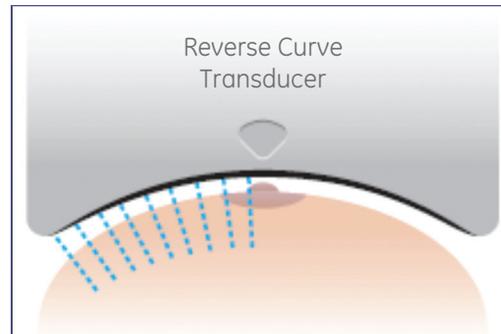
3. **Multi-planar Review of Two Views:** The Invenia ABUS review software allows the radiologist to review two breast volumes simultaneously, in both the coronal and transverse planes. Assessing structures in multiple perspectives may improve reading productivity and clinical confidence.
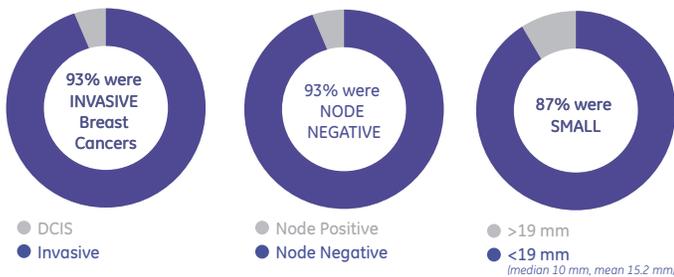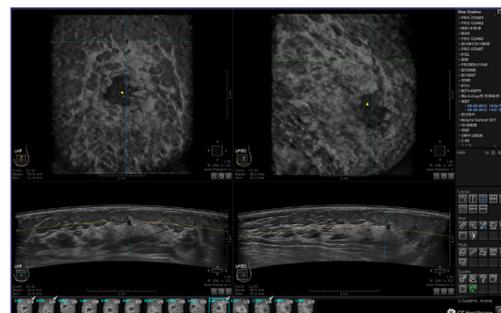

4. User Repeatability and Patient Access: GE Healthcare offers accredited training for 3 operators per site. This prepares them to perform ABUS exams proficiently. Typically, either ultrasound or mammography technologists perform the ABUS exam to provide seamless patient management from the mammogram to screening ultrasound.

5. Imaging Algorithms: Invenia ABUS is the 2nd generation of GE Healthcare's ABUS technology. Tissue Enhancement, Nipple Shadow Compensation, Chest Wall Detection and Breast Border Detection algorithms are all designed to eliminate distractions, and focus the radiologist's attention on the most important data – the anatomy.
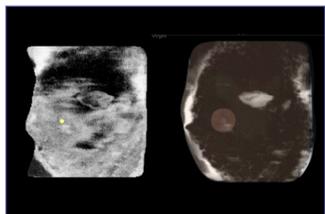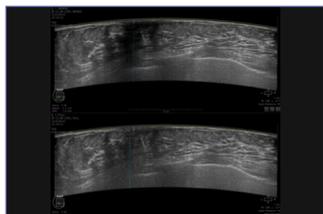
Chest Wall Detection
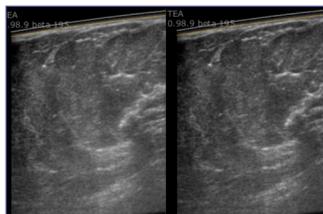
Tissue Enhancement Algorithm
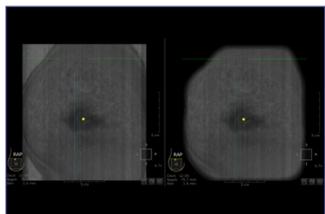
Breast Border Detection

Nipple Shadow Compensation

6. Mastery Program for Physicians: This program provides orientation and instruction on reading Invenia ABUS images as an adjunct to screening mammography. Radiologists learn skills to help promote accurate and rapid interpretation of ABUS for screening using a consistent review methodology on the Invenia ABUS review software. The extensive, progressive, step-wise training consists of 4 modules:

- Module I: 1 hour
  – Peer-to-peer webinar
- Module II: 2 hours
  – Self-paced tutorials
- Module III & IV: 4 hours
  – Remote peer-to-peer ABUS interpretation quality assessment
- Self-assessment: 1 hour
  – Individualized performance feedback

7. Stand-Out in Your Market: With the FDA-approved claim for breast cancer screening, you can market your breast screening proven to help clinicians find more cancers in the dense breast population. A marketing kit is provided with templates, examples and production files to help you develop materials to inform referring physicians, educate patients and reach out to your community.

8. ABUS Club: ABUS users are invited to join our online community that offers resources to help implement, refine and grow your ABUS service line. *www.abusclub.net*

* Increase in sensitivity was associated with a decrease in overall specificity.

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 C or D), 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.

Imagination at work