



GE HealthCare



GoldSeal™ Invenia™ ABUS 2.0

System description

The GoldSeal Invenia ABUS 2.0 (Automated Breast Ultrasound System) is designed for automated breast imaging. The GoldSeal Invenia ABUS 2.0 imaging architecture, built on the cSound™ Imageforming platform, was designed to utilize more software-based processing, relying less on hardware than the predecessor ABUS product.

Scanning features

The GoldSeal Invenia ABUS 2.0 incorporates an integrated ultrasound system and interactive touchscreen user interface with operator configurable workflow protocol icons.



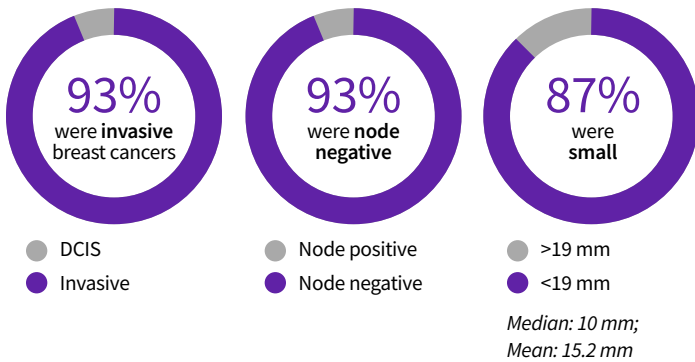
1. Clinical impact

The GoldSeal Invenia ABUS 2.0 system has demonstrated a 35.7% increase* in invasive cancer detection over mammography alone for women with dense breast tissue.

Finding more cancers, at an earlier stage, has the potential to lead to lower mortality rates, increased revenue, and better patient care.¹

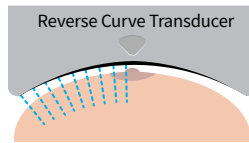
The GoldSeal Invenia ABUS 2.0 has both a screening and a diagnostic indication for use, as well as being the only FDA-approved system for screening women with dense breast tissue based on a multi-center, prospective clinical study with over 15,000 subjects.

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



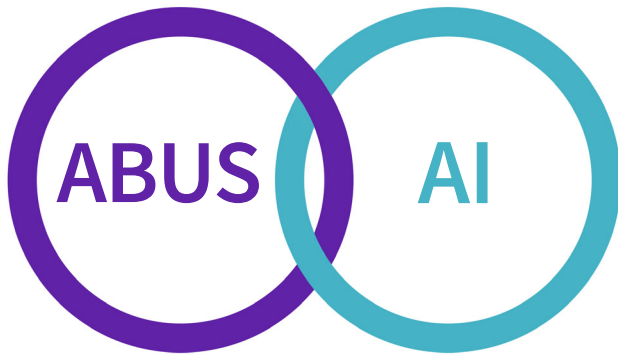
2. Enhanced comfort and image quality

The GoldSeal Invenia ABUS 2.0 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.



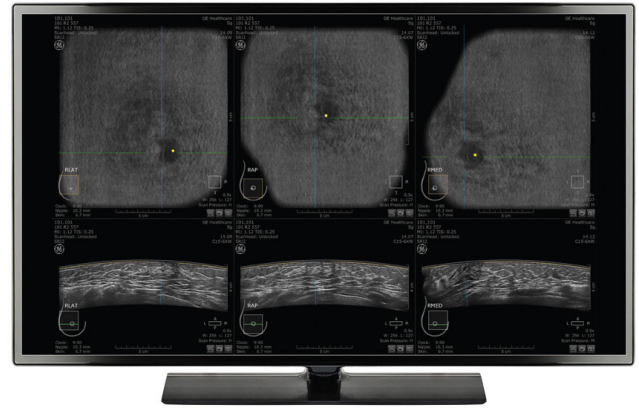
3. Harnessing the power of AI

Open platform that allows the integration of 3rd party AI tools for the detection and characterization.



4. 3D multi-planar review

The GoldSeal Invenia ABUS Viewer software allows the radiologist to review up to three breast volumes simultaneously, in both the coronal and transverse planes. Assessing structures in multiple perspectives may improve reading productivity and clinical confidence.

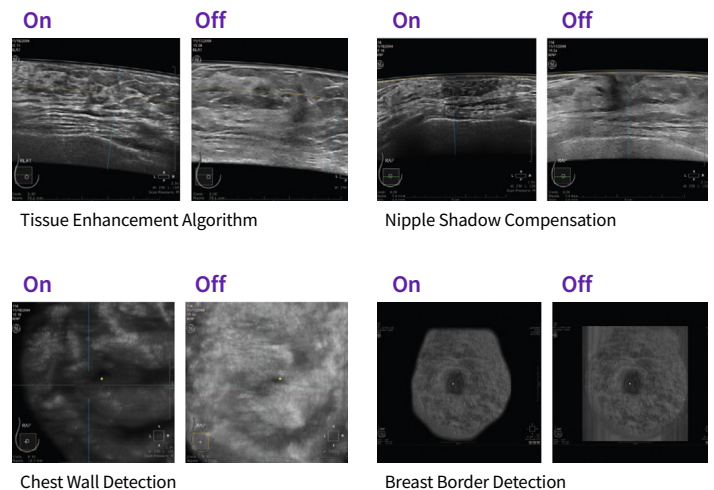


5. cSound Imageformer

This advancement transforms processing from hardware based to software based, and produces exquisite image quality performance far beyond prior GE HealthCare ABUS platforms. The massive processing power of the cSound Imageformer provides many benefits. The acquisition automatically creates focus at every pixel resulting in consistent high resolution image quality, faster acquisitions and reproducibility from user to user.

6. Imaging algorithms

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.





7. Exam amending and communication tools

Comprehensive tool set to allow amending of acquisition views and communication of any acquisition observation.

8. ABUS Mastery Program for physicians

This FDA approved curriculum is a blended learning course of study, designed to teach physicians how to confidently interpret GoldSeal Invenia ABUS 2.0 exams.

Online self-study: 3 hours of self-paced tutorials completed prior to the live virtual class.

Mastery Virtual Class: 5-hour Peer Educator led live virtual class of extensive hands-on clinical case review.

Physicians learn techniques to quickly navigate 3D breast volumes using the coronal plane and understand quality assessment approaches.

9. User repeatability and patient access

GE HealthCare offers accredited training for scan station operators. 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.

10. 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 available with templates, examples and design files to help you develop materials to inform referring physicians, educate patients and reach out to your community.



11. 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.
1. Brem et al, Radiology, March 2015.

Scanner assembly features

Simple, 4-button user interface

- Increase compression
- Decrease compression
- Start scan (one-touch volume acquisition)
- Abort scan

Compression Assist with 3 operator selectable levels of compression between 5 – 20 lbs

Integrated, extra-wide transducer

Transducer description: C15-6XW Reverse Curve

Transducer frequency range: 6 – 15 MHz

Transducer aperture length: 15.3 cm

Transducer travel distance: 16.9 cm

Transducer, number of elements: 768

Element pitch: 0.20 mm

Out-of-plane aperture: 3.5 mm

Transducer bandwidth: 85%

Imaging depths: From 2.5 to 6.0 cm

Single-use stabilization membrane

Single volume acquisition in less than 60 seconds

Multi-row LED task lighting

Removable scanner assembly view window, for easier clean-up

Specifications

| | |
|-----------------------|---|
| Width | 23 in (59 cm) |
| Length | 26 in (66 cm) |
| Height | Scan arm in lowest position: 65 in (165.1 cm) Scan arm in highest position: 85 in (215.9 cm) |
| Footprint | 4.2 sq ft (0.39 sq m) |
| Weight | 227 lbs (103 kg) |
| Scan arm reach (max.) | 42 in (107 cm) |
| Mains voltage | 100 – 240 VAC |
| Maximum current | 10 amps |
| Mains frequency | 50/60 Hz |
| Study transfer | Auto and manual |
| Display | 17 inch high resolution LCD touchscreen on ergonomic arm |
| Cart | Mobile platform with 4-wheel steering and braking |
| Operating system | Windows® 10 Enterprise LTSCe |

* Supported languages include: English, Spanish, French, German, Italian, Portuguese (Brazil and Portugal), Swedish, Danish, Dutch, Finnish, Norwegian, Japanese, Russian.

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Networking/storage/archiving

User login authentication

DICOM® 3.0 compliant

- Worklist (DMWL)
- Store (SCU)

10/100/1000 Base-T ethernet

Exam storage capacity: Approximately 200 studies, with storage status indicator

One-to-many DICOM data transfer

System features

System architecture: cSound Imageforming

Multi-slice B-Mode image acquisition with frame-by-frame 3D position registration

User customizable workflow protocols

Image processing algorithms

- Tissue Equalization Algorithm (TEA)
- Speckle reduction
- Nipple Shadow Compensation (NSC)
- Breast Border Detection (BBD)
- Chest wall detection

Acquisition scout images

- Transverse plane (real-time)
- Transverse plane for image review
- Coronal plane for volume review and nipple placement

Exam amending and communication tools

- Study amend allows new volumes to be added to existing exams
- Study notes allow exam specific notes to be sent with each study
- Virtual skin markers can be added to communicate scar, skin mole, palpable mass and pain locations

User replaceable fan filter

Remote service diagnostics

Multi-language UI support*

Environmental requirements

Operating temperature 41°F to 95°F (5°C to 35°C)

Operating relative humidity 30% to 75% non-condensing

Operating altitude 0 to 3,000 m

Storage temperature 14°F to 140°F (-10°C to 60°C)

Storage humidity 10% to 90% non-condensing

Storage altitude 0 to 3,000 m