



Invenia™ ABUS Premium: Advancing ABUS performance through technology

Breast cancer is the most diagnosed cancer worldwide, with an estimated 2.3 million new cases and 764,000 deaths in 2023. According to the Global Burden of Disease Study Breast Cancer Collaborators, the number of new breast cancer cases worldwide is predicted to rise to over 3.5 million in 2050 and the annual global breast cancer death toll is forecast to increase by 44% to nearly 1.4 million.¹

Present in about 40% of Caucasian women² and in 70% of Asian women,³ dense breast tissue remains a significant health challenge. One of the strongest and most common risk factors for developing the disease,⁴ dense breast tissue can mask the presence of small cancers on mammograms, with studies indicating that up to 50% of breast cancers may be missed in extremely dense breasts.⁵

ABUS: Designed for extraordinary patient care

The Invenia ABUS Premium system represents a new generation of three-dimensional breast ultrasound technology, especially for women with dense breast tissue to be used as an adjunct to mammography. The patient-friendly, highly efficient platform leverages AI solutions to improve early cancer detection in dense breasts. By offering extraordinary image quality, reproducibility, and efficient workflow, the system can help streamline clinical operations and reduce costs.⁶

Clinical studies, including the BRAID trial, show that supplemental imaging with ABUS when used alongside mammography improves cancer detection rates with maintaining low recall rates and is well accepted by patients.^{7,8}

Technical innovations deliver clinical and operational improvements

This whitepaper provides a comprehensive overview of recent technological innovations designed to enhance image analysis, workflow efficiency, and operational performance of the Invenia ABUS Premium. Technical upgrades like the Reverse Curve™ C16-6XW probe, state-of-the-art Verisound™ AI algorithms for image analysis and workflow optimization, streamline clinical workflow, enhance user confidence, and help reduce operational costs by minimizing the need for repeat imaging.*

The Invenia ABUS Premium features standardized, user-independent workflow for consistent acquisition and interpretation. For fast, streamlined reading, physicians can use the Invenia ABUS Viewer with AI Assistant⁹ enabling independent reading, batch review and addressing staff shortages⁹ by enabling faster, confident interpretations of patient exams. In certain regions, Invenia ABUS Prime is available alongside Invenia ABUS Premium. Depending on the configuration, systems may include some, but not all, of the AI features described in this paper.

The result is an advanced ABUS solution that not only addresses the clinical challenges of imaging dense breast tissue but also improves operational efficiency and supports the development of robust dense breast screening programs.*

“ABUS is an excellent complement to mammography, particularly in women with dense breasts, where mammography alone has limitations. It provides a standardized, reproducible overview of the entire breast, supporting reliable lesion assessment and confident follow-up, independent of the operator. Compared to traditional breast ultrasound, ABUS offers full-breast coverage and consistent measurements over time. Patients value the exam because it is comfortable, well tolerated, and gives them confidence that the whole breast is thoroughly assessed using advanced technology.”

Auto Nipple Detection enabled by Verisound AI

Clinical application of Auto Nipple Detection

In breast ultrasound imaging, the nipple is an important landmark to locate lesions and compare ABUS images to other modalities, such as mammography, DBT and MRI. The description of a clinical finding during a breast ultrasound examination requires a location for the finding(s) using a clock-face system and distance from the nipple. Current ABUS clinical workflows require the user to place the nipple mark manually after scanning each volume. To simplify users' operation and streamline workflow, a new AI-based feature called Auto Nipple Detection has been integrated into the new Invenia ABUS Premium.

To detect the nipple in the ABUS volume, an AI-based segmentation model is deployed to segment the nipple from multiple coronal projections. **The full process pipeline includes three steps:**

1. **Pre-processing:** Extract coronal projections from depth close to skin.
2. **Segmentation:** Segment the nipple from pre-processed projections using a U-net based model.
3. **Post-processing:** Combine mask's output from multiple projections to eliminate false positive detections and calculate centroid of the final mask as nipple coordinate.

A U-net based model is used to segment the nipple. U-net is a convolutional network architecture for fast and precise segmentation of images, and it is widely used in medical imaging. Model training is performed in Tensorflow 2.0 framework. Dice Loss is used as loss function of the segmentation task.

A total of 1,016 ABUS volumes from 156 patients were used for training and validation in the development phase.**

Auto Nipple Detection workflow

After a volume is scanned, a Preview page will display the coronal view at the default coronal depth, and a yellow circle mark is placed automatically by Auto Nipple Detection on the detected nipple position. From the Preview page, users can confirm or adjust the nipple position. If the position is incorrect, users can drag the nipple marker to the desired location. Once the Complete icon is selected, the nipple coordinate will be saved to the DICOM® file.

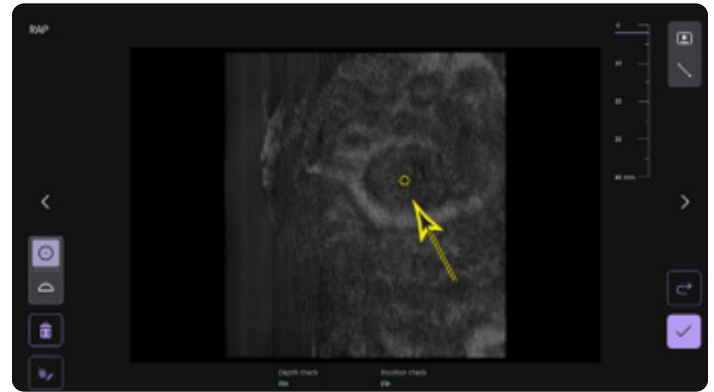


Figure 1: Preview page with nipple marker (yellow circle).

Auto Nipple Detection can be switched on/off in the Configuration settings. When Auto Nipple Detection is turned off, the nipple marker will not be automatically positioned.

Validation

An inter- and intra-observer variability study involving 20 patients was performed to set the accuracy threshold for the AI Auto Nipple Detection feature. These data were not used for training/validation/testing of the model. For nipple marker placement, the human intra-observer variability was 2.723 ± 1.865 mm, and the human inter-observer variability was 3.350 ± 2.757 mm. The clinically adequate minimal success rate is to reach similar levels as human inter-observer variability.

A dataset of 439 volumes was used for algorithm testing. To avoid data overlapping between the testing set and the training/development sets, data was collected from medical institutions different from the training/development sets.** The accuracy of Auto Nipple Detection was evaluated by the Euclidean distance between predicted nipple position. Wilcoxon rank sum test was performed. Results show that Auto Nipple Detection provides a high level of accuracy in nipple positioning, beyond typical human inter-observer variability.

Conclusion

Auto Nipple Detection automatically detects the positioning of the nipple to reduce users' operation time and streamline ABUS exams. It also shows better accuracy of nipple positioning compared with manual operation and adds another layer of reproducibility to the exam.***

Scan Quality Assessment enabled by Verisound AI

Clinical application of Scan Quality Assessment

ABUS provides high-quality, reproducible 3D imaging of the breast tissue. ABUS also reduces operator dependence associated with traditional breast ultrasound. Compared with traditional ultrasound devices, ABUS features separation between image acquisition and image interpretation with images acquired by technicians and interpreted later by radiologists.

While ABUS provides standardized and repeatable imaging of the breast, effective acquisition depends on positioning by the technician, depth selection, and proper compression to minimize artifacts. A poor-quality exam may prevent the proper coverage of the breast, adversely affect image acquisition and obstruct the ability of radiologists to complete a diagnostic evaluation. This may result in the patient being called back for rescan, which would increase screening costs and staff workload.

Current clinical workflows require scan quality to be checked manually to verify whether breast tissue has been adequately covered after scanning all volumes in the scan protocol. The intended use of Scan Quality Assessment, enabled by Verisound AI, is to automatically check scan quality to help users detect image quality issues at the time of acquisition, offering the ability to rescan before the patient leaves the room.

Scan Quality Assessment includes two functions:

- **Single view scan quality assessment**, which evaluates probe positioning and scan depth
- **Breast tissue coverage assessment**, which checks for adequate coverage of the breast tissue by the scan

Scan Quality Assessment methodology

Probe position assessment takes detected nipple positioning from Auto Nipple Detection as input. For different views, there are different requirements on the nipple position. The pass/fail criteria for each view are calculated by statistical analysis of the development dataset. When the nipple position is within the range of pass criteria, a grade “fit” is given. Otherwise, a grade “not fit” is given.

Depth assessment and breast tissue coverage assessment share the same pre-processing and AI model methodology. For pre-processing, transverse slices are down sampled from ABUS volumes, resized and normalized. A U-net based model is used to segment breast tissue and chest wall. Different post-processing pipelines are designed for these two tasks.

The post-processing steps of depth assessment are:

1. Define different ROIs for different view types, e.g., central of AP view, lateral of LAT view and medial of MED view.
2. Calculate feature vector based on mask of breast tissue and chest wall in ROI. Feature vector contains three elements: **Y1**: bottom most y coordinate of dense tissue mask within ROI, **Y2**: y coordinate of centroid of chest wall mask within ROI and **Y3**: top most y coordinate of chest wall mask within ROI.
3. Calculate scan depth grade based on feature vector. The scan depth grading calculation is a non-AI algorithm. The fit/too deep/too shallow criteria are calculated by statistical analysis of the development dataset.

The post-processing steps of breast tissue coverage are:

1. Calculate coronal view projection of breast tissue mask.
2. Calculate breast border with Otsu’s thresholding.
3. Merge different views belonging to the same side of breast.
4. Detect uncovered breast tissue for each side of breast. If the distance between breast border and breast tissue border is below a threshold, a warning of potential breast tissue not fully covered will be shown.

A total of 4,127 ABUS volumes from 662 patients were used for algorithm development.** A subset of the data was annotated for the U-net model training and validation in the development phase.

Scan Quality Assessment workflow

After a volume is scanned, the Preview page will show assessment results of position (fit or not fit) and depth (fit or too shallow or too deep) (Figure 1). From the Preview page, users can confirm the results. If users think the scan quality is acceptable, they select the Complete icon to verify the view. If users think the scan quality is not acceptable and a rescan is needed, they select the Rescan icon to re-acquire the view in question.

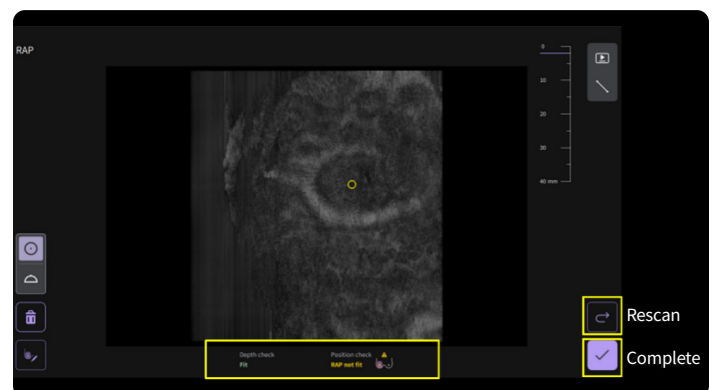


Figure 1: Depth and position assessment result in Preview page.

After all views in the scan protocol have been scanned, the system will switch to the Verify page, and the result of breast tissue coverage assessment is shown on the Verify page (Figure 2). For each side of breast, the breast is divided into nine sections. If there is potential breast tissue missing in any sections, they will be marked as grey. Otherwise, sections will be marked as green, indicating the breast tissue has been appropriately imaged (Figure 3). Users can check the results and decide if there is breast tissue not covered by the scans. If there is breast tissue missing, users can switch back to the imaging page and scan supplementary views. Breast tissue coverage result will be updated each time a new volume is scanned.

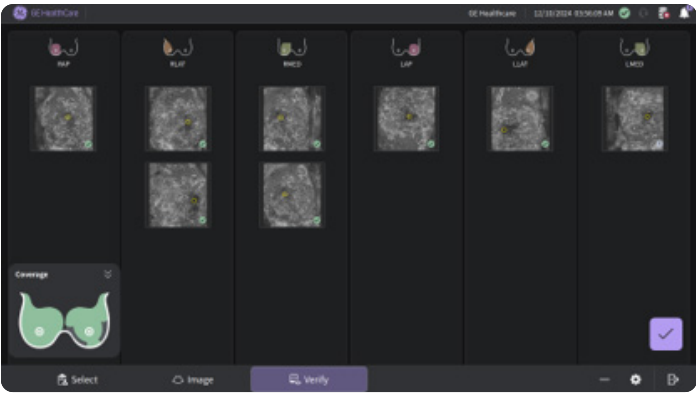


Figure 2: Breast tissue coverage results in Verify page.



Figure 3: Nine sections of breast tissue coverage assessment and example of coverage result.

Each assessment item in Scan Quality Assessment can independently be turned on/off in the Configuration settings. When the assessment item is turned off, the assessment result will not be displayed to the user. For each assessment item, three levels (Low, Medium and High) of grading criteria can be selected in Configuration. Level High represents stricter grading criteria and Level Low represents looser grading criteria. Users can select the level based on their preference.

Views applicable

Depth and position in scan quality assessment are limited to support views of RAP, LAP, RLAT, LLAT, RMED and LMED. For other views, a warning message of unsupported view will be given.

Validation

An inter- and intra-observer variability study involving 40 patients was performed to set the accuracy threshold for the AI Scan Quality Assessment feature. The data was not used in training/validation/ testing for the model. For inter-observer variability study, two annotators performed annotation on the dataset independently, named as Annotator1 and Annotator2. For intra-observer variability study, the same annotator performed annotation on the dataset in two

different periods which were more than two weeks apart, named as Annotator1 and Annotator1_2. Inter- and intra-observer variability measured by Cohen’s Kappa (κ) of different grading items are listed in Table 1. Mean sensitivity and specificity for each grading item are also listed in Table 1. A reviewer reviewed and arbitrated the grade. If the grades by Annotator1, Annotator2 and Annotator1_2 were not the same, the grade by the reviewer was used as the ground truth for calculating sensitivity and specificity. The clinically adequate minimal success rate is to reach similar levels as human average sensitivity and specificity.

Grade item	Kappa index		Average sensitivity ($\pm$ SE)	Average specificity ($\pm$ SE)
	Intra-observer variability	Inter-observer variability		
Probe positioning	0.8134	0.7935	0.9452 ($\pm$ 0.0154)	0.9535 ($\pm$ 0.0093)
Scan depth	0.7758	0.7928	0.8925 ($\pm$ 0.0323)	0.9938 ($\pm$ 0.0031)
Breast tissue coverage	0.9573	0.9318	0.9167 ($\pm$ 0.0360)	0.9778 ($\pm$ 0.0110)

Table 1: Intra- and inter-observer variability.

A dataset of 427 volumes collected was used for algorithm testing. To avoid data overlapping between the testing set and the training/ development sets, data was collected from medical institutions different from the training/development sets.** Sensitivity and specificity results of Scan Quality Assessment are listed in Table 2.

Comparison of the performance results show that specificity of scan depth is slightly lower (0.9752 vs. 0.9938) than human performance. However, sensitivity of scan depth by AI Scan Quality Assessment is significantly higher than human performance (0.9810 vs. 0.8925). These results demonstrate that the AI Scan Quality Assessment has achieved the clinically adequate minimal success rate.***

Grade item		All data	P value
Positioning	Sensitivity ($\pm$ SE)	0.9873 ($\pm$ 0.0127)	0.4375
	Specificity ($\pm$ SE)	0.9741 ($\pm$ 0.0085)	0.3341
Depth	Sensitivity ($\pm$ SE)	0.9810 ($\pm$ 0.0134)	0.5376
	Specificity ($\pm$ SE)	0.9752 ($\pm$ 0.0087)	1.0
Breast tissue coverage	Sensitivity ($\pm$ SE)	0.9600 ($\pm$ 0.0400)	1.0
	Specificity ($\pm$ SE)	1.0000 ($\pm$ 0.0000)	1.0

Table 2: Sensitivity and specificity on testing dataset.

Conclusion

Scan Quality Assessment provides an immediate qualitative evaluation during ABUS exam acquisition for proper breast tissue coverage, positioning and depth. Sensitivity and specificity of this automatic assessment are equivalent or better compared with manual assessment.*** This feature is designed to improve acquisition performance and confidence for ABUS users and reduce patient callback rates due to inadequate scan quality.

New Reverse Curve C16-6XW probe and image quality improvements

Clinical image quality enhancements with novel technologies

A number of optimizations have been introduced to Invenia ABUS Premium and Invenia ABUS Prime to improve image quality. One key enhancement comes from the introduction of the new Reverse Curve C16-6XW probe, which provides better image quality compared with legacy C15-6XW probe on Invenia ABUS 2.0.*** A new version of the Nipple Shadow Compensation algorithm has also been integrated into the system, which significantly improves image quality in the area beneath the nipple.***

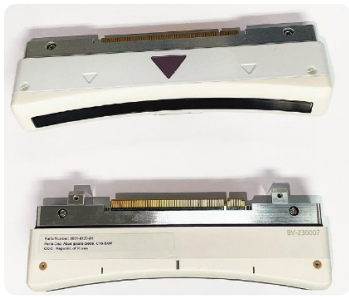


Figure 1: Comparison of C15-6XW (upper) and new C16-6XW (below).

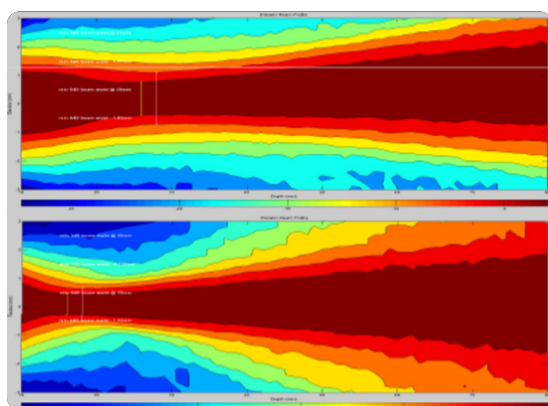
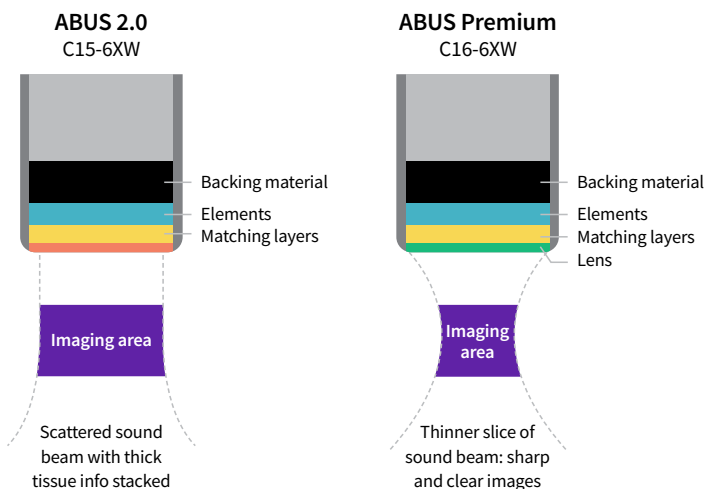


Figure 2: C16-6XW with RTV lens (top). Elevation beam profile of C15-6XW (upper) and C16-6XW (below) for Impulse TX (bottom).

New C16-6XW probe

The new C16-6XW probe has been integrated into Invenia ABUS Premium to replace the C15-6XW probe. The two probes share many specifications, such as 15.3 cm wide field-of-view and 6–15 MHz wide bandwidth. A main upgrade for C16-6XW is that it applies a Room Temperature Vulcanizing Silicone (RTV) lens for elevation focusing to replace crystals grinding used by C15-6XW. This new design provides a thinner elevation beam width than C15-6XW for improved spatial and contrast resolution. Moreover, the C16-6XW probe, with larger acceptance angle, shows better nipple shadow performance than C15-6XW.*** The new probe resolves artifacts common to the C15-6XW, such as cat-scratch and white stripe artifacts and provides easier cleaning of ultrasound lotion and gel. **Patients familiar with the Invenia ABUS 2.0 system have reported improved comfort during scanning as a result of the new acoustic lens layer integrated with the Invenia ABUS Premium.*****

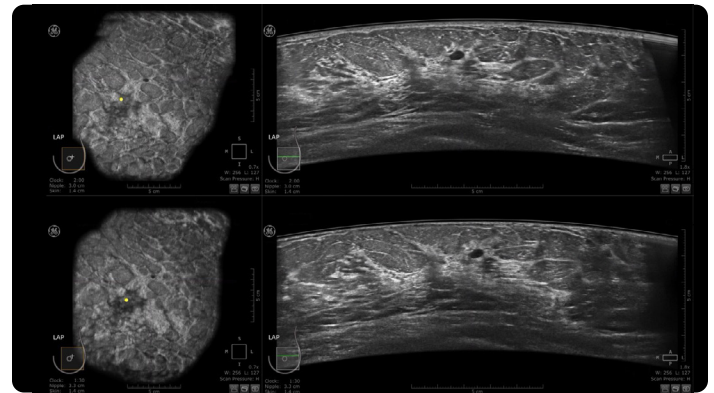


Figure 3: Improved contrast and spatial resolution with the new C16-6XW (top).

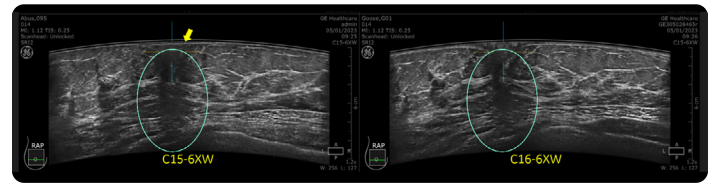


Figure 4: The new C16-6XW showed reduced artifactual shadowing beneath nipple (cyan circle). White stripe artifact (yellow arrow) is not observed with C16-6XW.

New Nipple Shadow Compensation algorithm

Due to the impedance mismatch between breast tissue and the nipple, ultrasound reflection at the interface can impede the formation of a clear image under the nipple. The Nipple Shadow Compensation algorithm is designed to apply brightness enhancement in a predefined cylindrical portion right below the nipple.

Integrated into Invenia ABUS Premium, the new Nipple Shadow Compensation algorithm is a combination of Wavelet Transform and a modified legacy nipple shadow compensation processing block. Wavelet Transform is a powerful signal processing technique that enhances, denoises, and analyzes images by decomposing signals into localized time-frequency components. The input image data goes

through a biorthogonal forward Wavelet Transform three times. At each level, the shadow compensation is applied to the approximation of the Wavelet Transform output. A flow chart of the algorithm is summarized as Figure 5.

Nipple Shadow Compensation is applied to a cylindrical region centered around the selected nipple location. For a given pixel within the ROI, the mean, standard deviation and variance around the target pixel over a kernel size is calculated. This kernel size changes as the wavelet band changes. These statistic values together with histogram parameters (peak, standard deviation) of the entire volume are used to calculate an enhancement value for each pixel. The enhancement value is then multiplied by two weight values: dw1 and dw2. dw1 is an exponentially decaying function pointing radially outwards. This means that the nipple shadow compensation enhancement amplitude will decay exponentially as one moves away from the center line of cylinder. dw2 is a kernel based smoothing weight parameter.

The new Nipple Shadow Compensation algorithm showed improved signal intensity compensation performance with proper control of noise amplification.*** The anatomic structure under the nipple is much easier to observe with the new Nipple Shadow Compensation algorithm.

Conclusion

The new Invenia ABUS Premium features a number of optimizations designed to improve image quality. First, the new C16-6XW probe provides better image quality compared with legacy C15-6XW probe on Invenia ABUS 2.0.*** Second, a new version of the Nipple Shadow Compensation algorithm has also been integrated into the system, which significantly improves image quality in the area beneath the nipple.***

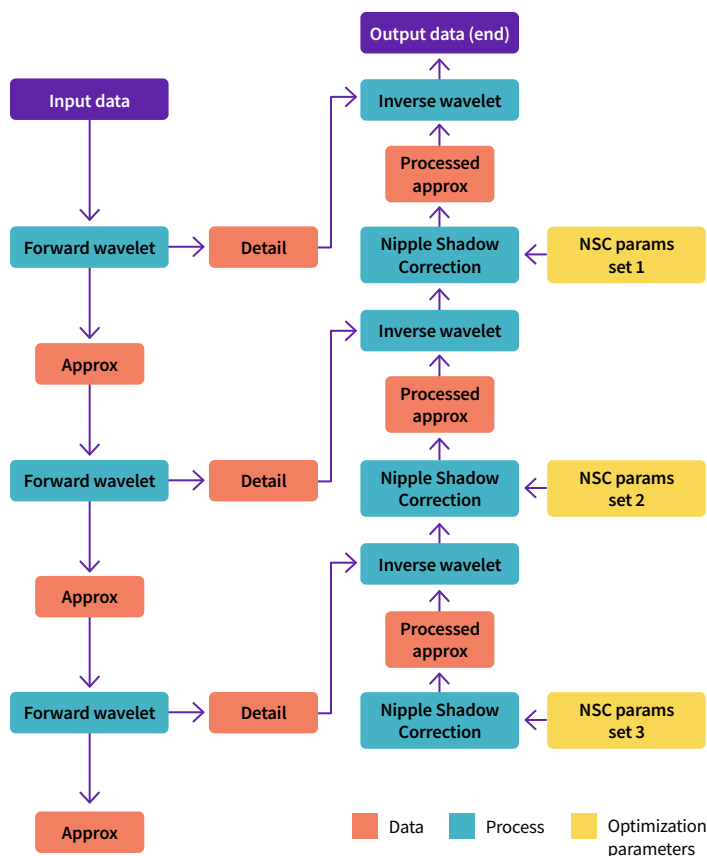


Figure 5: Flow chart of new NSC algorithm.

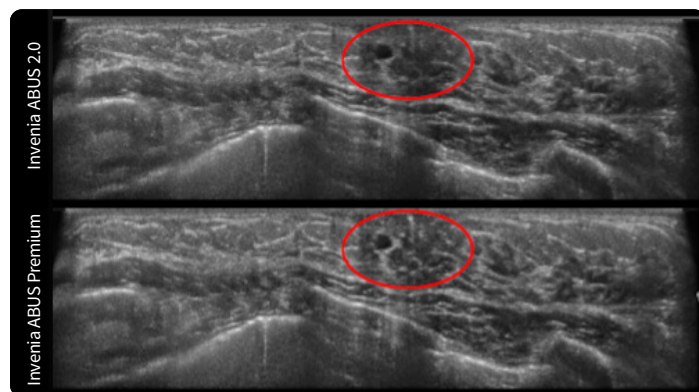


Figure 6: Comparison of NSC in Invenia ABUS 2.0 and Invenia ABUS Premium.

Fast Scan

Clinical application of Fast Scan

ABUS systems utilize a mechanized scan head attached to a robotic arm, which automatically moves the transducer across the breast, acquiring over 300 2D images in transversal sweeps from the skin to the chest wall. This technology is designed to overcome the operator dependency of traditional ultrasound.

Fast Scan is a new feature available with the Invenia ABUS Premium technology,[†] designed to accelerate scanning speed and shorten scan time with minimal impact on image quality.

Accelerated scan time

Utilizing a mechanized, moving scan head, ABUS systems perform standardized, automated, 3D breast imaging. After pressing the green start button, the probe starts moving following a pre-defined scan path.

The scan consists of three phases:

1. Probe moves from the initial position to start position of scanning.
2. Probe moves from inferior to superior within the scan head assembly to complete a full volume scan.
3. Probe moves from the end position to the initial position of next scan.

Only images captured during phase 2 are used to reconstruct the 3D volume. In previous ABUS products, the motor speed is 5 mm/s in phase 1, 5 mm/s in phase 2 and 8 mm/s in phase 3. In Invenia ABUS Premium, the speeds have increased to 7 mm/s, 7 mm/s and 11 mm/s, respectively.

Fast Scan increases scan speed by 40%*

The reduction in scan time for ABUS 2.0 and ABUS Premium are listed in Figure 1.

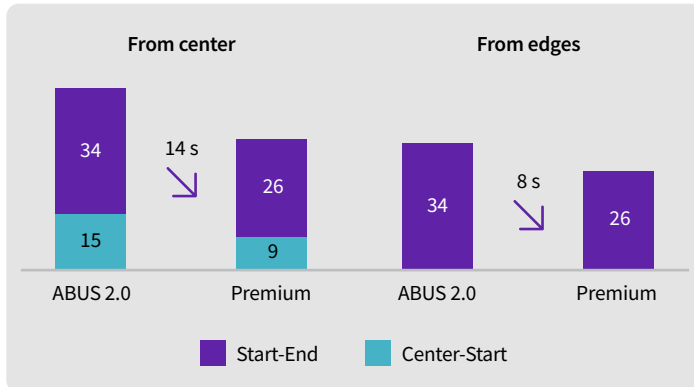


Figure 1: Scan time difference for Invenia ABUS 2.0 and Invenia ABUS Premium and Prime.

Image quality optimization

Image quality has been optimized for Fast Scan to accelerate scanning speed and shorten scan time with minimal impact on image quality.*** A comparison of image quality is in Figure 2.

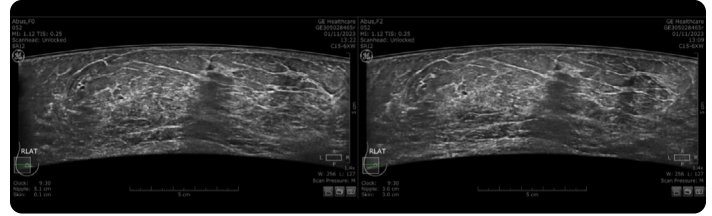


Figure 2: Image by normal scan (left). Image by Fast Scan (right).

Conclusion

Invenia ABUS Premium offers users an option to accelerate scan speed. With Fast Scan, users can accelerate the speed of ABUS scans by 40% with minimal difference in image quality.***

Seamless Integration of AI tools

Operational efficiencies of AI integration

AI is increasingly becoming an integral component of the breast imaging environment. These AI algorithms allow the possibility of second reading, identifying, segmenting, and classifying potential lesions with high accuracy. The Invenia ABUS platform uses AI to enhance cancer detection in dense breast tissue, reduce reading time and increase diagnostic sensitivity. Key benefits include higher detection rates, reduced workload,⁷ and lower false positives.¹⁰

New AI applications integrated into the Invenia ABUS Premium scanner highlighted in this paper include:

- **Scan Quality Assessment** provides an immediate qualitative evaluation during ABUS exam acquisition to assist with proper breast tissue coverage, positioning and depth
- **Auto Nipple Detection** automatically detects the positioning of the nipple to reduce users' operation time, improve reproducibility and streamline ABUS exams

Optimized ABUS reading and reporting

For simple and streamlined reading experience, physicians can quickly review and interpret patient exams using the AI Assistant toolset. These advanced AI tools enhance the review of ABUS 3D datasets, supporting the detection and characterization of breast lesions. Leveraging the open platform integration, additional third-party AI solutions can be seamlessly integrated to help improve clinical confidence and reading efficiency, and address staff shortages.

QVCAD™⁰⁰ by Qview Medical Inc. was the first CAD system for 3D Automated Breast Ultrasound in the detection and assessment of breast cancer:

- The integration of QVCAD experiences up to 93% sensitivity for lesion detection and can reduce reading time by 33%^{11,12}
- Uses AI algorithm trained on over 10,000 exams
- Findings can be reviewed directly on the Invenia ABUS Viewer

MONCAD ABS DX[®] from Monitor Corporation is a deep learning-based CADE/x solution that automatically detects and marks suspicious regions in 3D ABUS volumes:

- MONCAD ABS DX bridges proficiency gaps, enabling less experienced readers to achieve a diagnostic AUC of 0.947, matching senior specialists working without AI¹³
- An AI-guided triage strategy has been proven to eliminate the need for full radiologist review in 84% of screening cases by accurately identifying negative findings¹⁴
- The system has been proven to significantly accelerate the diagnostic process, saving an average of 25 seconds per case (approx. 40%) across all experience levels¹³

BU-CAD[®] from TaiHao Medical Inc. supports advanced multi-lesion detection. It provides independent feature extraction and result assessment for specific lesions, translating findings into standard BI-RADS[®] classification:

- A recent clinical study demonstrated high diagnostic accuracy, resulting in sensitivity of 91.1%, specificity of 92.4%, and an area under the curve (AUC) of 0.948, performing comparably to experienced radiologists¹⁵

Koios DS[™] Breast[®] automatically provides an AI-based quantitative risk assessment that aligns to a BI-RADS category.

- Uses a proprietary AI algorithm that includes >900,000 clinical breast lesion images
- One button click to analyze, a color-coded confidence scale generates a likelihood of malignancy (LoM) aligned to the appropriate BI-RADS category
- A recent clinical study demonstrated a decrease in benign biopsies of up to 55%¹⁶

Seamless integration of AI tools



By leveraging the integration of AI tools, ABUS users can benefit from significant reduction in reading time,¹² high sensitivity detection,¹¹ reduction in call back rates, AI-guided triage strategy¹⁴ and clinical decision support.¹⁶

Conclusion

Invenia Automated Breast Ultrasound (ABUS) Premium, the latest in 3D breast ultrasound technology, offers advanced AI capabilities to drive faster, reproducible supplemental screening and streamlines exam readings on patients with dense breasts and along the entire Breast Care Pathway. The new Verisound AI tools for scanning and 3rd party AI tools for reading exams can help clinicians work smarter and more efficiently and can help administrators get the most out of their ABUS program.

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* Compared to Invenia ABUS 2.0.

** Appropriate clinical data collection and/or research agreements have been duly established.

*** Results are based on internal validation study and customer feedback from clinical evaluations.

† Invenia ABUS Premium and Prime are not available in all territories. Some features described in this document may not be included in the standard configuration of Invenia ABUS Prime, including Auto Nipple Detection, Scan Quality Assessment, and Fast Scan. Please contact your local sales representative for availability and configuration details.

◇ AI Assistant covers 3rd party solutions such as QVCAD, MONCAD ABS DX, BU-CAD, and Koios DS Breast. Not all solutions are available in all regions. Contact your GE HealthCare representative.

◇◇ AI solutions mentioned in the material are third-party solutions and may be subject to government regulations and may not be available in all countries. Shipment and effective sale can only occur after approval from the regulator. Please check with your local GE HealthCare representative for details. **QVCAD**: approved by FDA and available in USA, not CE marked. **MONCAD ABS DX**: Not approved by FDA and not available in USA, not CE marked. **BU-CAD**: Not approved by FDA and not available in USA, not CE marked. **Koios DS Breast**: approved by FDA, available in USA and CE marked.

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