



## **U-SYSTEMS INTRODUCES SIGNIFICANT UPGRADE TO SUPPORT GROUND-BREAKING ULTRASOUND BREAST CANCER SCREENING STUDY**

### **INSIGHT Class Release Delivers Image Quality and Analysis Enhancements Designed To Better Differentiate Complex Breast Tissue for Fast, Accurate Data Review**

**CHICAGO – November 30, 2009** – U-Systems, Inc., the leader in developing automated breast ultrasound systems, announced a significant upgrade for its **somo•v™** Automated Breast Ultrasound System (ABUS) here at the 95<sup>th</sup> Annual Meeting of the Radiology Society of North America. The INSIGHT Class release incorporates a series of image quality and analysis enhancements designed to better visualize and differentiate complex breast tissue and enable fast and accurate image review. These enhancements were designed and developed to provide the foundation functionality for U-Systems' ground-breaking, prospective SOMO•INSIGHT study, a nationwide multi-center clinical study designed to evaluate whether digital mammography in combination with the **somo•v** ABUS is more sensitive to detecting breast lesions when compared to digital mammography alone in women with dense breasts. The SOMO•INSIGHT study is notable in its scope and potential impact on women's health.

"Ultrasound is an effective adjunct to mammography especially for women with dense breasts who as a group, have a 4-6 times greater risk of breast cancer," said Rachel Brem, MD, principal investigator for the SOMO•INSIGHT clinical study at The George Washington University Medical Center. "The **somo•v™** Automated Breast Ultrasound System (ABUS) is a robust ultrasound technology that allows for additional evaluation of women in whom mammography may be more challenging.

"SOMO•INSIGHT is a pivotal study, designed to evaluate the sensitivity of mammography and **somo•v** ABUS together, as compared to mammography alone in women with dense breasts. We are excited to participate in this important study evaluating potential new approaches to the early detection of breast cancer. This scientifically rigorous study will evaluate over 20,000 women to determine the incremental increase in cancer detection with automated whole breast ultrasound in women with dense breasts," Dr Brem added.

Studies show that approximately 35 percent of breast cancer goes undetected by mammography in women with dense breasts. This multi-center study, which intends to recruit over 20,000 women, is an important milestone in evaluating new approaches to improved cancer detection in this population. ABUS uses ultrasound (sound waves) at a safe frequency to create images of the breast tissue, unlike mammography, which uses radiation. Ultrasound has been shown to find cancer not visible with mammography in women who have dense breasts.

“We are working with 12 dedicated breast imaging centers across the country in this landmark study with more to be added as we progress,” said Ronald Ho, president and CEO of U-Systems. “More than 2,000 asymptomatic women meeting the eligibility requirements have been enrolled, thus far, with the remainder expected to be enrolled through 2010. To date, the SOMO-INSIGHT study has resulted in the detection of cancers previously undetected by mammography. The data analysis from the SOMO-INSIGHT study may provide the scientific foundation for the establishment of the standard for ultrasound breast cancer screening.”

### ***somo•v ABUS Advances***

The INSIGHT Class release provides significant upgrades for the *somo•v* Automated Breast Ultrasound System. Improvements include the new LHD (linear high definition), ultra broadband transducer with 25 percent greater bandwidth and 1.5MHz higher center frequency. The higher center frequency significantly sharpens detail resolution while the greater bandwidth enables distinct contrast differentiation of complex breast tissues. The resulting image quality improvement leads to greater diagnostic confidence.

New Auto Acquisition Sequencings, enabled by U-Systems proprietary pattern recognition software, automatically detects the woman’s unique anatomical tissue signature and optimizes system scan parameters accordingly, customizing each scan to the woman’s anatomy and tissue type. The result is consistent and reproducible images, allowing the radiologist to compare images and views from prior exams resulting in greater diagnostic confidence for the radiologist and increased peace of mind for the woman. The same pattern recognition software enables a feature called Auto Labeling, designed to automatically detect the type of image being acquired and labels the views accordingly. Exam times can be reduced which increases patient throughput.

### ***somo•viewer Workstation Advances***

Advances to the *somo•viewer* workstation include new thick-slice coronal or C plane views now incorporated into U-Systems unique hanging protocols. Visualization of the C plane is instrumental for correlation of normal and abnormal anatomical breast structures. This type of anatomical correlation viewed in the thick slice C plane is not possible with transverse or sagittal views obtained with conventional hand-held ultrasound. The hanging protocols allow for real time slice thickness adjustment from 0.1 to 10.0mm in 0.5mm increments. Variable slice thickness settings allows for precise visualization of anatomical structures. New navigational short-cut tools allow radiologists to mark and rapidly zoom-in on areas of interest, providing smooth workflow for quick and accurate image and data review.

A suite of real-time image processing features have been added to the workstation and are collectively known as TEA (Tissue Equalization Algorithms). The TEA are third generation, border detection tools which enable real-time image segmentation and classification. The result should provide faster and more efficient review of patient exams.

#### **About U-Systems**

U-Systems is the leader in developing dedicated breast ultrasound systems. For more information about the company, please visit our website at <http://www.u-systems.com>. For further information about the SOMO-INSIGHT clinical study, visit [www.somoinstightstudy.org](http://www.somoinstightstudy.org). The U-Systems somo•v Automated Breast Ultrasound System (ABUS) is currently cleared under 510(k). *The device is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with an automatic scanning linear array transducer. The device is not intended to be used as a replacement for screening mammography.*

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