

## **U-Systems Launches [www.somoinstightstudy.org](http://www.somoinstightstudy.org), supporting a Breast Cancer Screening Clinical Study for Women with Dense Breast Tissue**

Educational Web Site Supporting National Clinical Research Study Evaluating Automated Breast Ultrasound as an Adjunct to Mammography for Breast Cancer Screening

**SUNNYVALE, July 20, 2010** – To help women learn more about breast density and the national multi-center clinical research study evaluating the use of automated breast ultrasound (ABUS) for screening women with dense breast tissue, U-Systems, Inc. has launched [www.somoinstightstudy.org](http://www.somoinstightstudy.org). The educational web site for the SOMO•INSIGHT Clinical Study offers detailed information on the prospective study, participation requirements and critical information about breast density and its impact on breast health.

U-Systems, a leader in the development of Automated Breast Ultrasound Systems, is the sponsor of the SOMO•INSIGHT study, a nationwide multi-center clinical research study designed to evaluate whether Automated Breast Ultrasound (ABUS) technology combined with mammography is more accurate than a routine screening mammogram alone in detecting breast cancer in women with dense breast tissue. To date, more than 7,000 women have been enrolled in the study which is recruiting at up to 11 breast imaging centers nationwide.

Stephanie Annable, 50, of Kansas City, Kansas, a two-time breast cancer survivor, was first diagnosed in 2000. After successfully completing treatment, Annable now has a mammogram every six months and decided to participate in the SOMO•INSIGHT clinical research study at the University of Kansas Cancer Center. “I had a feeling this could come back and I wanted to do everything in my power to be fully armed and ready. When my mammogram showed nothing abnormal, I was shocked to learn that the ABUS technology revealed a lesion that was later confirmed as stage one cancer,” said Annable. “I’m so fortunate that because of the clinical study, my cancer was found early. Until a cure is found, it is research and tools like this that provide women hope.”

The launch of the SOMO•INSIGHT Study web site comes on the heels of a national survey of U.S. women ages 40 and older that revealed 95 percent of women do not know their breast density. And while two-thirds indicate they get mammograms on a regular basis, only 13 percent knew that breast density increases the risk of developing breast cancer.

According to Marc Inciardi, MD, SOMO•INSIGHT principal investigator and breast imaging radiologist at the University of Kansas Cancer Center in Kansas City, mammography is effective for most women as a breast cancer screening tool and women aged 40 and above should have annual mammograms. “However in women with dense breasts, the breast density can obscure a cancer. As breast density goes up, the mammogram’s accuracy goes down. That is why we need additional approaches to improving breast cancer detection in women with dense breasts.

“While ultrasound is a proven tool throughout the diagnosis and treatment of breast cancer, it has not typically been used during the screening process. Several studies have shown that for women with dense breast tissue, supplementing mammograms with ultrasound can increase detection from 48 to 97 percent. We’re conducting the SOMO•INSIGHT study in hopes of establishing a solid scientific basis for the use of automated breast ultrasound as a cancer screening tool for women with dense breasts,” added Dr. Inciardi.

The patient tools on [www.somoinstightstudy.org](http://www.somoinstightstudy.org) include:

- **What is Breast Density and What Does it Mean:** Facts women should know about breast density and the growing body of research demonstrating a strong link between breast density and an increased cancer risk of 4-6 times. One study, published in the New England Journal of Medicine, showed 35 percent of breast cancer goes undetected by mammography in women with dense breasts.
- **How Does Breast Density Impact Early Detection:** Since both dense breast tissue and cancer appear white on a mammogram, it is difficult to detect cancer when there is a lot of dense breast tissue. Analogous to looking for a specific cloud in a cloudy sky, as breast density goes up, the accuracy of the mammogram goes down.
- **SOMO•INSIGHT Study Summary:** Detailed information about the prospective study that is designed to evaluate whether digital mammography in combination with the Automated Breast Ultrasound System is more accurate than a routine screening mammogram alone in detecting breast cancer in women with dense breast tissue; includes details about Study procedures and requirements.
- **Participation Requirements and Online Informational Eligibility Quiz:** Helps women learn about the eligibility requirements to participate in the SOMO•INSIGHT Study. The quiz is for informational purposes only and does not guarantee eligibility; only an authorized Study Coordinator or Investigator may perform an official assessment of qualifications and confirm eligibility for enrollment in the research study.
- **Find participating SOMO•INSIGHT Clinical Sites:** There are multiple clinical sites around the country recruiting and enrolling participants. A map shows sites accepting volunteers for determination of eligibility.

The SOMO•INSIGHT Study web site, as well as the clinical study protocol, has been reviewed and approved by an Institutional Review Board (IRB), an ethics committee that is independent of the study physicians and the sponsor (U-Systems). The purpose of the IRB is to protect the rights and safety of people who volunteer to take part in research studies.

### **About U-Systems**

U-Systems is the leader in developing dedicated breast ultrasound systems. The FDA-cleared **somo•v** Automated Breast Ultrasound System (ABUS) 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. U-Systems is the sponsor of the SOMO•INSIGHT multi-center study that will enroll up to 20,000 women at clinical study sites in the United States to determine the sensitivity of mammography and FDA-cleared **somo•v** Automated Breast Ultrasound Systems (ABUS) together, compared to mammography alone for women with greater than fifty percent dense breast tissue. For more information, please visit our website at [www.u-systems.com](http://www.u-systems.com).

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