



## U-SYSTEMS RECEIVES APPROVAL FOR ULTRASOUND BREAST CANCER SCREENING

### First-Ever Approval for Ultrasound Breast Cancer Screening Indication Granted to U-Systems' **somo•v™** Automated Breast Ultrasound (ABUS) System

**SUNNYVALE, Calif., September 13, 2010** - U-Systems, the leader in automated breast ultrasound, today announced that it has received approval to market the **somo•v™** Automated Breast Ultrasound (ABUS) system as an adjunct to mammography for screening asymptomatic women for breast cancer in the European Union.

Approval was based on extensive clinical evidence and includes the following indication: "The intended use of the **somo•v** ABUS system is to provide a significant increase in breast cancer detection and sensitivity of Interpreting Physicians in diagnosing symptomatic and screening asymptomatic women as an adjunct to mammography."

"We are excited that the **somo•v** ABUS now has CE mark approval for breast cancer screening. The **somo•v** ABUS is the first and only approved automated ultrasound system for screening asymptomatic women," said Ron Ho, president and CEO of U-Systems. "This represents a major advancement in breast health for women as study after study, have demonstrated a need for additional tools to improve the early detection of breast cancer, particularly in women with dense breast tissue which impacts detection and carries an increased risk of breast cancer."

"The **somo•v** ABUS is not intended as a replacement for mammography, which remains the most effective screening tool for many women. However, we have strong scientific evidence that for women with dense breast tissue, supplementing mammograms with **somo•v** ABUS can substantially increase breast cancer detection," added Ho.

"The sensitivity of screening mammography is limited in women with dense breasts, as low as 30-50%," said László Tabár, M.D., F.A.C.R. (Hon) Professor of Radiology, Uppsala University School of Medicine, and Medical Director at the Department of Mammography Falun Central Hospital, Falun, Sweden. "It is essential to have a multimodality screening approach for detecting breast cancer at an early stage, to prevent women from dying from this disease. The **somo•v** Automated Breast Ultrasound system fulfills this important need in the multimodality approach."

U-Systems is currently sponsoring the **SOMO•INSIGHT** Clinical Study, the largest clinical research study ever undertaken by an ultrasound company. The study is designed to evaluate whether digital mammography in combination with the **somo•v** Automated Breast Ultrasound system is more sensitive than a routine screening mammogram alone in detecting breast cancer in women with greater than fifty percent dense breast tissue. To date, more than 9,000 women have participated in the study which is actively recruiting up to 20,000 women at multiple breast imaging centers in the United States. The **SOMO•INSIGHT** Clinical Study has identified a significant number of mammographically negative breast cancers that would not have been detected had the participants not had an ABUS exam. Learn more about the **SOMO•INSIGHT** Study at: <http://www.somoinstightstudy.org>.

#### About U-Systems

As the leader in automated breast ultrasound technology U-Systems is establishing the standard for breast ultrasound screening. The U-Systems **somo•v** Automated Breast Ultrasound (ABUS) system and **somo•viewer** Advanced 3D Workstation are cleared under 510(k) for diagnostic use as an adjunct to mammography. For more information about U-Systems, please visit our website at <http://www.u-systems.com>.

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