

U-SYSTEMS RECEIVES HEALTH CANADA APPROVAL FOR ULTRASOUND BREAST CANCER SCREENING

First-Ever Approval for Ultrasound Breast Cancer Screening in Canada Granted to U-Systems' somo•v Automated Breast Ultrasound (ABUS) System

SUNNYVALE, Calif., August 16, 2011 - U-Systems, the leader in automated breast ultrasound, today announced that it has been granted a medical device license by the Medical Devices Bureau of Health Canada to sell and market the somo•v® Automated Breast Ultrasound (ABUS) system as an adjunct to mammography for screening asymptomatic women for breast cancer in Canada. Approval was based on extensive clinical evidence and includes the following indication: "The somo•v ABUS ultrasound device is intended for use as an adjunct to mammography to provide physicians with an increase in the sensitivity of breast cancer detection in diagnostic symptomatic and screening asymptomatic women."

The somo•v ABUS system is the only ultrasound device approved for breast cancer screening by Health Canada, the agency responsible for assessing medical device safety, effectiveness and quality in Canada. The somo•v ABUS system is also the only ultrasound device approved for breast cancer screening in the 27 European Union countries. In the United States, the somo•v ABUS system is cleared by the Food & Drug Administration (FDA) for adjunctive diagnostic use with mammography.

"With this approval from Health Canada, we are proud to make this critical screening tool available to improve the early detection of breast cancer in Canada," said Ron Ho, president and CEO of U-Systems. "The somo•v Automated Breast Ultrasound System is not intended as a replacement for mammography. However, there is a growing body of scientific evidence that supplementing mammography with ultrasound detects more cancers than mammography alone."

Using proprietary technology to automate the breast ultrasound imaging process, the U-Systems' somo•v ABUS is ideally suited for the high-volume, screening environment. The somo•viewer™ Advanced 3D Workstation enables fast review and archive of patient exams, optimizing breast ultrasound screening workflow.

U-Systems is also the sponsor of the national SOMO•INSIGHT Clinical Study, which is designed to evaluate whether digital mammography in combination with somo•v ABUS is more sensitive than a routine screening mammogram alone in detecting breast cancer in women with dense breast tissue. More than 15,000 women have participated in the study which is actively recruiting up to 20,000 women at multiple breast imaging centers nationwide. To date, the study has identified a significant number of mammographically negative breast cancers that were subsequently detected by ABUS.

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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