

U-SYSTEMS ANNOUNCES INITIATION OF EUROPEAN BREAST ULTRASOUND SCREENING STUDY

First Participants Enrolled in European Asymptomatic Breast Cancer Screening Study at
Capio Saint Göran Hospital, Stockholm, Sweden

Sunnyvale, Calif. Wednesday, 17 November 2010

U-Systems, the leader in Automated Breast Ultrasound (ABUS) technology announced participant enrollment has begun in the European Asymptomatic Screening Study (EASY) at Capio Saint Göran Hospital, in Stockholm, Sweden. The clinical study is designed to determine whether Full Field Digital Mammography combined with the somo•v® Automated Breast Ultrasound (ABUS) can improve breast cancer detection when compared to Mammography alone in women with dense breast tissue. This study is particularly relevant to the many population based screening programs in Europe which practice a double-reading methodology for screening, where two different radiologists independently review breast imaging exams. The study protocol has accommodated the standard screening practices in Sweden and outlined a process for integrating ABUS review into an existing double-read system.

Screening mammography, the mainstay for breast cancer detection, has known limitations in women with dense breast tissue and these women have a higher risk of breast cancer. A new approach is needed to improve breast cancer detection for women with increased breast density. The EASY breast cancer screening study will help determine if using this 3D ultrasound imaging technology in combination with a digital mammogram could improve the accuracy of routine screenings for women with dense breast tissue, for which mammography can be less effective. The study intends to recruit 8,000 asymptomatic women with dense breast tissue.

“The initiation of this study is extremely important for European women. It represents an exciting milestone in evaluating automated breast ultrasound in combination with mammography to improve cancer detection” said Karin Leifland, M.D., Ph.D., Head of Radiological Breast Diagnostics, Medical Head of Radiology, Unilabs AB, Sweden.

Ron Ho, President and CEO of U-Systems said, “European breast cancer screening methods differ from the United States and typically result in higher cancer detection rates. It is essential we understand how somo•v ABUS in combination with mammography will aid European physicians, and ultimately women, in earlier detection of breast cancer.”

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 System (ABUS) and somo•VIEWer Advanced 3D Workstation are cleared under 510(k), and indicated for 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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