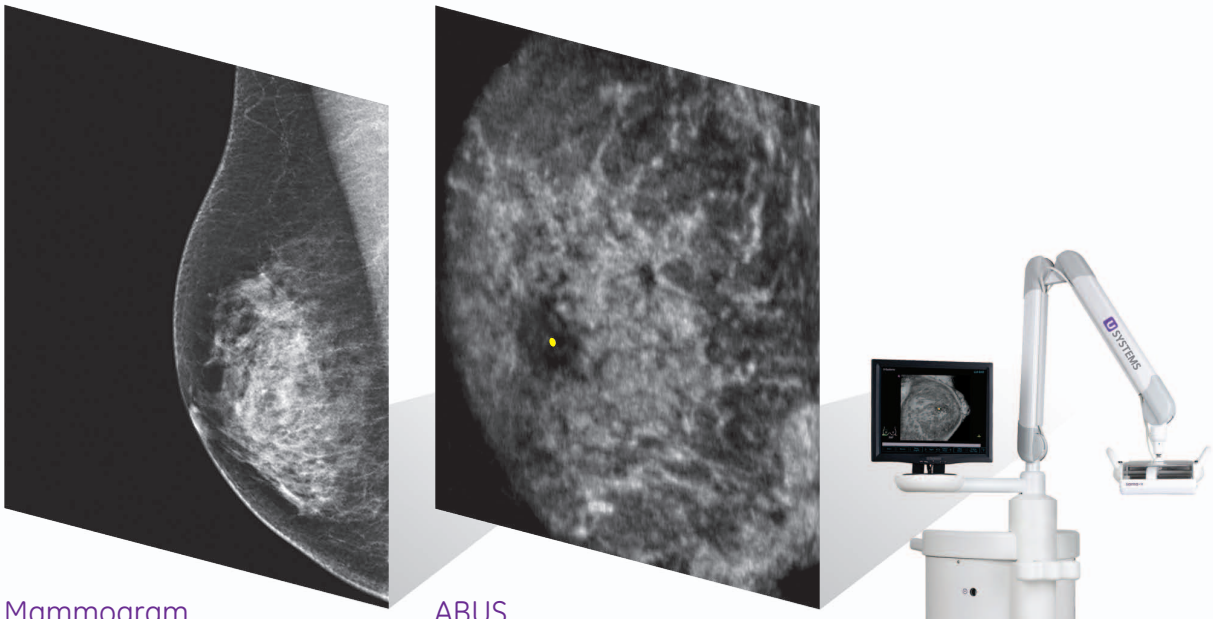
somo·v ABUS

Automated Breast Ultrasound

When it comes to dense breast tissue... It's how you look at it.



Mammogram

- BI-RADS Density 3, BI-RADS Assessment 2
- No suspicious interval masses or calcifications seen
- Annual mammographic follow-up recommended

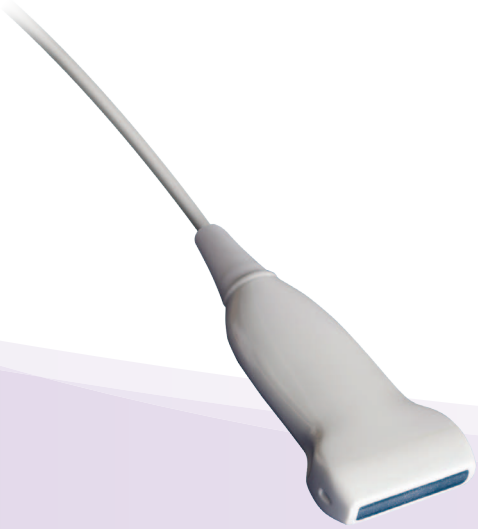
ABUS

- Hypoechoic, 8 mm mass with irregular margins
- BI-RADS Assessment 0, suspicious for neoplasm
- Pathology confirmed Invasive Ductal Carcinoma

U SYSTEMS
A GE Healthcare Company

The difference is automatic

All breasts are not the same – and no single imaging technology is right for all patients. The value of mammography in the early detection of breast cancer is undeniable. However, cancers in dense breast tissue can be hard to identify with mammography – in fact, breast density obscures cancers that screening with somo•v* ABUS* can detect.



This is not for screening

Handheld

Handheld ultrasound systems are utilized primarily for diagnostic imaging - not for breast cancer screening. A manual scan of an entire breast with a handheld transducer can be very difficult because it is:

- Not Reproducible
- Operator Dependent
- ~30 minute exam

This is designed for screening

Automated

somo•v ABUS Automated Breast Ultrasound is designed specifically for breast cancer screening. It uses a wide field-of-view transducer to precisely scan a patient's entire breast. A simple, automated procedure ABUS screening is:

- Reproducible
- Operator Independent
- ~15 minute exam

* Trademark of General Electric Company

somo·v ABUS
Automated Breast Ultrasound

This should be automatic – for patients with dense breast tissue

somo•v ABUS automates image acquisition and separates the acquisition from image interpretation. The result is a highly streamlined and efficient breast ultrasound screening procedure.

Acquire Images 1

- Automated Image Acquisition
- 15cm Field-of-View Transducer
- Image Complete Breast in ~5 Minutes

2 Interpret Images

- Accurate Image Interpretation
- Review 3D Image Sets on Workstation
- Read Entire Case in ~3 Minutes[1]

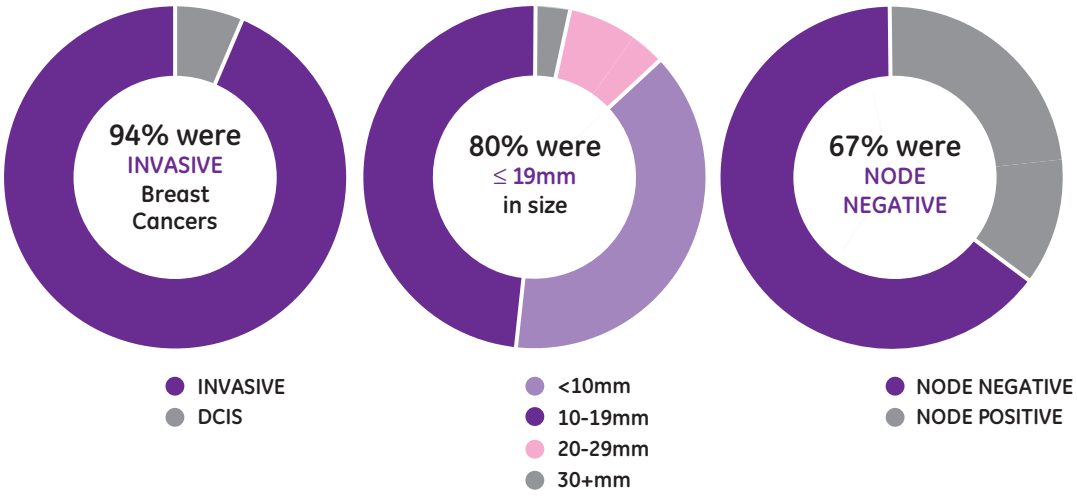
[1] ARRS 2012 Breast Imaging: Screening/Emerging Technologies Oral Abstract; Radiologist Interpretation Time for 3D Automated Breast Ultrasound Screening, R. Brem

somo•v ABUS Automated Breast Ultrasound uses the only technology specifically developed and FDA approved** for screening women with dense breast tissue.

** FDA PMA P110006

Scientific Data for Evidence-Based ABUS Automated Breast Ultrasound for Breast Cancer Screening

Multiple clinical research studies demonstrate that radiologists can detect more cancers at an earlier, more treatable stage when using ABUS as an adjunctive screening tool combined with mammography. 94% of the ABUS-detected cancers with normal or negative mammography were pathologically confirmed as invasive, in this asymptomatic screening population of women with dense breast tissue and no prior breast interventions. The majority of these invasive malignant lesions were also small and node negative.



Study USI2011001 in support of FDA approved PMA P110006[2]

Multi-reader, multi-case ROC study, 5,032 total radiologist reads, demonstrated scientific evidence[3] of a statistically significant improvement in AUC (ΔAUC = 21.5% (95% CI: 0.101, 0.330; p<0.001) when screening mammography (XRM) and ABUS are combined to screen asymptomatic women for breast cancer who had >50% parenchymal breast density, normal or negative mammography and no prior breast interventions.

In this same population, a 35.7% (95% CI: 17.8%, 54.0%; p<0.001) increase in cancer detection sensitivity was observed when ABUS was used in conjunction with XRM, compared to XRM alone. Additionally, this significant increase in sensitivity was not associated with a statistically significant reduction in specificity, which is typically expected with a new modality. The ΔSpecificity = -2.0% (95% CI: -7.9%, 3.9%; p=0.520).

Study USI2008002 SOMO•INSIGHT Registry Study[4]

Prospective Registry study with a total of >15,500 asymptomatic participants demonstrated preliminary scientific evidence (awaiting publication) that there is a 27% increase in cancer detection sensitivity over XRM alone when XRM and ABUS are combined in the detection of mammography-negative breast cancers in women with >50% parenchymal breast density.

Clinical Indications for Use

FDA PMA P110006:This device [somo-v Automated Breast Ultrasound System (ABUS)] is indicated as an adjunct to mammography for breast cancer screening in asymptomatic women for whom screening mammography findings are normal or benign (BI-RADS Assessment Category 1 or 2), with dense breast parenchyma (BI-RADS Composition/Density 3 or 4), and have not had previous clinical breast intervention.

[2] ClinicalTrials.gov Identifier: NCT01424956, includes patient's with prior breast interventions.
[3] RSNA 2012 Oral Abstract; Clinical Reader Study Examining the Performance of Mammography and Automated Breast Ultrasound, M E Giger, PhD, D P Miller
[4] ClinicalTrials.gov Identifier: NCT00816530, includes patient's with prior breast interventions.

FDA PMA Approval P110006, September 18, 2012
FDA 510(k) Clearance K052355, September 14, 2005

U SYSTEMS
A GE Healthcare Company

U-Systems Inc.
447 Indio Way, Sunnyvale, CA 94085
Tel: +1 (866) 364-6777
inquiries@u-systems.com
www.u-systems.com

somo·v ABUS
Automated Breast Ultrasound