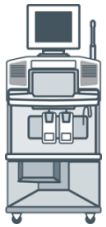
# Automated Breast Ultrasound

## Automated Breast Ultrasound (ABUS)



### Technology In Brief

***What Is It:***

- Automated breast ultrasound (ABUS) is a dedicated ultrasound platform equipped with an ultrasound transducer that automatically acquires standardized breast images from different angles with minimal sonographer intervention required.

***How Does it Work:***

- Once the transducer is placed adjacent to the breast of a seated or prone patient, images are obtained with minimal guidance by the sonographer, contingent upon the system configuration. These images are then transferred immediately to an accompanying screen and reconstructed in a 3-D image.

***Adoption Status:***

- Early adopters

***FDA Status:***

- FDA approved for diagnosis in 2008; approved for screening with U-Systems (GE) ABUS device in September 2012[1]

***Major Vendors:***

- GE Healthcare (SomoV ABUS), Siemens (Acuson S2000 ABVS), Sonociné (Adjunctive Breast Ultrasound System)

***Competing Products:***

- 2D ultrasound, elastography, digital breast tomosynthesis, molecular breast imaging

| Consideration | Service Line Strategy Advisor's Take |
|---|---|
| **Clinical** | • The FDA approved U-Systems' (now GE) somo-v Automated Breast Ultrasound for breast cancer screenings as an adjunct to mammography for asymptomoatic women with dense breast tissue in late 2012 |
| **Reimbursement** | • Dedicated reimbursement is not currently established, although hospitals adopting ABUS may bill using standard breast ultrasound CPT codes |
| **Cost** | • $200K - $300K |
| **Payer Coverage** | • Covered at the same rates as standard breast ultrasound<br>• Currently only covered for diagnostic breast ultrasound, not for screening |
| **Market Potential** | • Large-scale adoption is not expected in the near future due to the lack of robust clinical studies that confirm the effectiveness of the product and lack of reimbursement specific to the exam |
| **Operational Needs** | • The footprint for the portable unit is much the same as for standard portable ultrasound |
| **Impact in Accountable Care** | • ABUS increases the reproducibility of ultrasound exams and studies, with implications for clinical trials and reducing equivocal exams<br>• Cheaper than other second-line modalities |
| **Competitive Take** | • Adds another imaging technology choice for clinicians, potentially increasing competitiveness<br>• However, due to the large number of breast imaging technologies, ABUS is unlikely to differentiate from competitors |
| **Position on the Adoption Curve** | • Early Adopters |

Source: Service Line Strategy Advisor research and analysis.

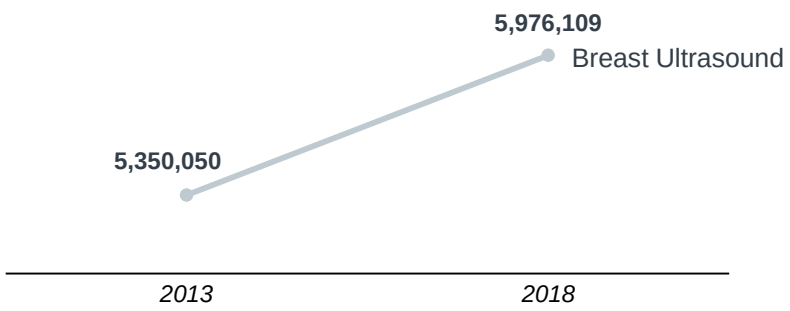


1) http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm320724.htm

# ABUS Minimizes Variation Between Sonographers

## Market & Financial Overview

### Market Estimates




**12%**

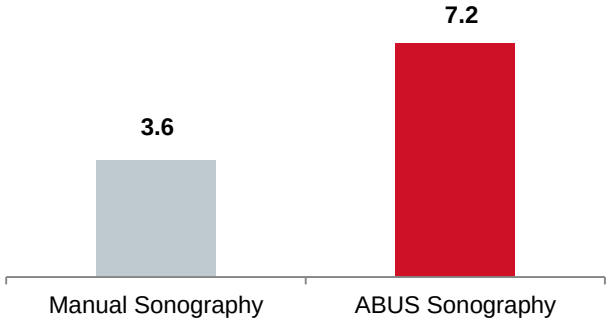
Overall Market Growth

### Reimbursement Rates

| CPT | 2013 Final Rate | 2014 Final Rate | Percent Change |
|---|---|---|---|
| **76645 – Breast Ultrasound** | $64.57 | $90.05 | 39% |

## Clinical Considerations

### Diagnostic Yield Per 1,000 Studies




Early data indicate that ABUS is best indicated for the imaging of dense breasts or for high-risk women whose mammograms are equivocal. While earlier studies have established the clinical utility and acceptance of hand-held ultrasound, research is needed to substantiate the incremental value of ABUS over current technique. Current research suggests ABUS resolution and repeatability is slightly superior to that of conventional ultrasound, but large-scale and cost-effectiveness studies have yet to be concluded.

### Keys for Investment Success

- Assess current women's imaging technology inventory relative to similar institutions
- Determine physician interest, technologist willingness to adopt ABUS
- Consider competing second-line imaging modalities with similar functionality, clinical indications for ABUS
- Project potential market size for ABUS

Source: Service Line Strategy Advisor research and analysis.