

# Introducing Whole Breast Ultrasound

By Deborah Abrams Kaplan | March 24, 2011

Mammography is the only screening technology approved by the FDA, but it's far from perfect. The X-ray technology may miss cancers in those with dense breasts. And women with a dense breast tissue are at greater risk for developing breast cancer.

MRI, the traditional adjunctive screening tool for women with dense breasts, also has its limitations from its cost, volume of images to read, high false positive rate, contraindications for some women, and more limited availability. Newer imaging modalities are providing other options and gaining traction in the radiology community. Molecular breast imaging (MBI) and breast-specific gamma imaging (BSGI) are one approach. These new imaging studies are cost effective and easy to read with a high sensitivity and specificity. However the higher radiation dose is a concern for more widespread screening

Another technology recently introduced is the U-Systems sono-v INSIGHT whole breast ultrasound. The U-Systems (the only company developing this technology) currently has 510(k)-clearance for adjunctive diagnostic use with mammography, and will be seeking approval to use it for a dense breast tissue indication.

[A JAMA study](#) published in 2008 shows that when adding ultrasound to mammographic screening, researchers found an additional 1.1 to 7.2 cancers per 1,000 in women with dense breasts. U-Systems recently completed its own study for automated breast ultrasound cancer screening and reported that so far, the study has identified a significant number of cancers from the sono-v INSIGHT ultrasound, which were mammographically negative.

Of course ultrasound technology is not new, and it is already used on the breast as an adjunctive screening tool and to assist during biopsy. Advantages are it's a no-dose, non-invasive test. One complaint about ultrasound in general, however, is that it's operator-dependent and requires a lot of training to do properly. It's also known to be slow, and gives high false positive readings, resulting in unnecessary biopsies.

The U-Systems technology was well received by providers queried for the KLAS Breast Imaging 2010: A More Complete Picture report released in December 2010. KLAS, an independent research firm, reports on the performance of healthcare technology vendors. The report found that providers feel sono-v INSIGHT ultrasound technology helps them diagnose smaller cancers earlier, and that they can get a clear image. Unlike traditional ultrasound machines, providers liked that the U-Systems machine is automated, easy to use and less prone to human error.

Some physicians they spoke to mentioned that whole breast ultrasound would be a great screening tool, but that most providers currently cannot get reimbursed for screening with it, according to Emily Crane, co-author of the report. She added that reimbursements for breast ultrasound vary by state. Connecticut is the only state in the country mandating that insurance companies cover comprehensive ultrasound breast screening if the mammogram shows dense breast tissue.

The other issue is that breast ultrasound may take a little longer than a mammogram or nuclear medicine study, so it wasn't fast enough to be cost-effective as a screening tool.

That said, the KLAS report showed that 71 percent of the U-Systems users would buy the machine again, and 7.1 out of 9 say they're getting their money's worth. The equipment has 86.5 percent satisfaction rating by users.

