

# Evaluation of the SomoVu™ by U-Systems in Diagnostic Patients

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**PURPOSE:** To evaluate the performance of an automated breast ultrasound system (SomoVu) versus conventional hand-held ultrasonography by comparing lesion visibility and BIRADS Assessment.

**MATERIALS AND METHODS:** Patients presenting for diagnostic ultrasound were recruited and signed an IRB-approved informed consent. Lesions were imaged using mammography, hand-held ultrasonography (HHUS), and the SomoVu. Visibility of lesions using the SomoVu was compared with visibility of these same lesions using HHUS. BIRADS assessment using mammography plus HHUS was compared to BIRADS assessment using mammography plus SomoVu.

**RESULTS:** A total of 177 breasts in 165 patients were scanned. In these patients 96% of lesions visible on HHUS were also visible on SomoVu. SomoVu performed best in dense breasts (BIRADS Density 3 or 4), where 98.6% of lesions were visualized. The BIRADS assessment derived from mammography plus SomoVu was in agreement with the BIRADS assessment derived from mammography plus HHUS in 94% of breasts analyzed. Lesions successfully visualized with the SomoVu included cancers (DCIS, invasive ductal, invasive lobular) as well as a number of benign findings, including cysts, fibroadenomas, fibrocystic changes, lymph nodes, papillomas, and scars. Observed cancers ranged from 0.4 cm to 3.8 cm in their longest dimension.

**CONCLUSION:** Images made with SomoVu and HHUS have similar visibility and lead to similar BIRADS assessments in greater than 90% of breasts examined. SomoVu is most sensitive in dense breasts, where mammography is less sensitive.

**CLINICAL RELEVANCE/APPLICATION.** The SomoVu is an automated alternative to hand-held ultrasonography of the breast.

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