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# Evaluation of the SomoVu™ by U-Systems— Interim Report 11/18/05

**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 62 patients with 65 lesions have been enrolled to date. In these patients 94% of lesions visible on HHUS were also visible on SomoVu. Similarly, 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. Each of the 15 biopsy-proven cancers in this series was visible on the SomoVu.

**CONCLUSION:** These preliminary results suggest that images made with SomoVu and HHUS have similar visibility and lead to similar BIRADS assessments in greater than 90% of breasts examined.

The U-Systems SomoVu has been developed to allow efficient automated acquisition of multi-plane ultrasound images of the breast. The device allows a mammography or ultrasound technologist to acquire serial images in a volume of up to 14.5x17x5 cm. The images are interpreted at the BreastView Station, which has a number of features that allow the radiologist to efficiently review the breast images.

The first clinical evaluation of the SomoVu is being conducted on diagnostic patients with breast lesions that have been evaluated with mammography and handheld ultrasonography.

## **MATERIALS AND METHODS**

Patients presenting for diagnostic ultrasound secondary to abnormal or equivocal mammography or physical examination were recruited into the study. All subjects signed an IRB-approved informed consent. The SomoVu has been cleared for commercialization by the US Food and Drug Administration (FDA) and was used in accordance with its cleared labeling.

Following mammography, patients were examined with conventional hand-held ultrasonography (HHUS) and the location of the finding was identified. After HHUS the following SomoVu scans were performed on the affected breast:

- The Region of Interest (ROI) was scanned by centering the lesion on the scanning receptor.
- A medial-frontal scan was performed by positioning the receptor between the sternum and the nipple.
- A lateral-frontal scan was performed by positioning the receptor between the mid-axillary line and the nipple.
- The investigator could also order any custom view in addition to the above.

For this clinical evaluation, imaging data (mammography, HHUS, and SomoVu) were interpreted for each case by the radiologist, who recorded the following specific observations:

- BIRADS density category by mammo-graphy (1, 2, 3, or 4)
- BIRADS assessment, based on the mammogram and HHUS only
- Visibility of the lesion on the ROI view for each of the available presentations provided by the BreastView station.
- Visibility in any presentation of the medial frontal and lateral frontal views (MF+LF analysis).
- BIRADS Assessment based only on the mammogram and SomoVu image (disregarding the HHUS findings).

## **RESULTS**

### **Recruitment**

A total of 65 breast lesions in 62 protocol-valid patients have been scanned to date. An additional 5 breasts were scanned outside the protocol guidelines. The reasons for exclusion of these 5 breasts were:

- no identified ROI (3),
- no hand-held ultrasound (1) and biopsy done prior to SomoVu (1).

### **Summary of Lesions Scanned**

Each lesion was classified into one of 5 categories, listed below. The observed frequencies for each type are summarized in Table 1.

**Table 1. Summary of Lesions Scanned**

<b>Lesion type by HHUS</b>	<b>Number seen with HHUS</b>	<b>Comments</b>
<b>Highly suggestive of cancer</b>	10	9 biopsy-proven cancers, 1 fibroadenoma
<b>Suspicious</b>	23	6 biopsy-proven cancers, 12 benign (mostly fibroadenomas) 5 pathology reports pending
<b>Fibroadenoma</b>	12	7 biopsied – benign, 5 not biopsied
<b>Cysts</b>	11	
<b>“Other”</b>	9	Fibrocystic changes, lymph node, sebaceous cyst, ductal ectasia, fibroadenoma, fibrosis

### **Success by Investigational Site**

The overall success rate (percent of findings visible on SomoVu) was 94% (61/65) for the ROI scan and 94% (61/65) for the combination of medial frontal and lateral frontal views. The percentage of lesions seen with the SomoVu reported by the different investigational sites ranged from 75% to 100% for the region of interest view and from 75% to 100% for visibility in the medial frontal or lateral frontal views. Although there did not appear to be a measurable difference in the percent success by investigational site, the number of patients is too small to justify a statistical analysis.

### **Success by Density**

Eighty-two percent of patients recruited into the study had BIRADS Density of 3 or 4. Although the sample size is still small, there does not appear to be any difference in success rate related to breast density.

## DISCUSSION

### Ability to see lesions

The observed overall visibility of lesions with the SomoVu exceeded 90%. This sample contained cancers as well as benign lesions including fibroadenomas and cysts. The lesions that were not seen with the SomoVu included benign fibroadenomas and fibrocystic changes. The observed performance of the SomoVu did not appear to be related to investigational site or breast density.

### BIRADS Assessments

With regard to patient outcomes, a critical result of the diagnostic examination is the BIRADS assessment score. Typically, patients assessed at 1 or 2 are sent home with the recommendation to continue with annual screening mammography. Patients assessed at 4 or 5 are generally sent to biopsy. Category 3 patients are often recommended to have follow-up examination, which may include mammography, physical exam, and ultrasound, at 6 months.

Since the SomoVu is intended to be used as an adjunct to mammography, an appropriate evaluation is the BIRADS assessment category using mammography plus SomoVu, since this is the way the device will be used in practice.

In this evaluation concordance in BIRADS assessment category followed the same general trends as lesion visibility. The overall agreement of BIRADS Assessment category between HHUS and SomoVu was over 90%. The observed concordance did not appear to be related to investigational site or breast density.

## CONCLUSION

The overall success rate for visualization and BIRADS assessment of known lesions was greater than 90% for these preliminary results.

The results are summarized in Table 2, below.

**Table 2. Success Rate by BIRADS Density**

<b>BIRADS Density</b>	<b>Lesions seen/Total ROI</b>	<b>Lesions seen/Total MF+LF</b>
<b>2</b>	9/11 (82%)	9/11 (82%)
<b>3</b>	30/31 (97%)	31/31(100%)
<b>4</b>	21/22 (91%)	20/22 (91%)
<b>Not Recorded</b>	1/1 (100%)	1/1 (100%)
<b>Totals</b>	61/65 (94%)	61/65 (94%)

### Summary of Missed Lesions

- A total of 4 of 65 lesions (6%) were seen with HHUS but not seen on the ROI view using the SomoVu. These 4 lesions were characterized as fibroadenoma (2), normal breast tissue (1) and suspicious (1).
- A total of 4 of 65 lesions (6%) were seen with HHUS but not seen on either the medial frontal or medial lateral views using the SomoVu. All 4 were benign and were characterized on biopsy as fibroadenoma (2) or fibrocystic changes (2).

### Differences in BIRADS Assessment by Site

- Overall the concordance between BIRADS Assessments made by mammography plus HHUS versus Mammography plus SomoVu was 94% (61/65). The concordance reported by the different investigational sites ranged from 60% to 100%. Inter-site differences did not appear significant, but the small sample size does not justify statistical analysis.

### Difference in BIRADS Assessment by Density

- Although the sample size is still small, there does not appear to be any relationship between concordance of BIRADS assessments and breast density. The results are summarized in Table 3, below

**Table 3. Differences in BIRADS Assessment by Density**

<b>BIRADS Density</b>	<b>Concordant BIRADS/ Total</b>
<b>2</b>	11/11 (100%)
<b>3</b>	30/31 (97%)
<b>4</b>	19/22 (87%)
<b>Not Recorded</b>	1/1 (100%)
<b>Totals</b>	61/65 (94%)