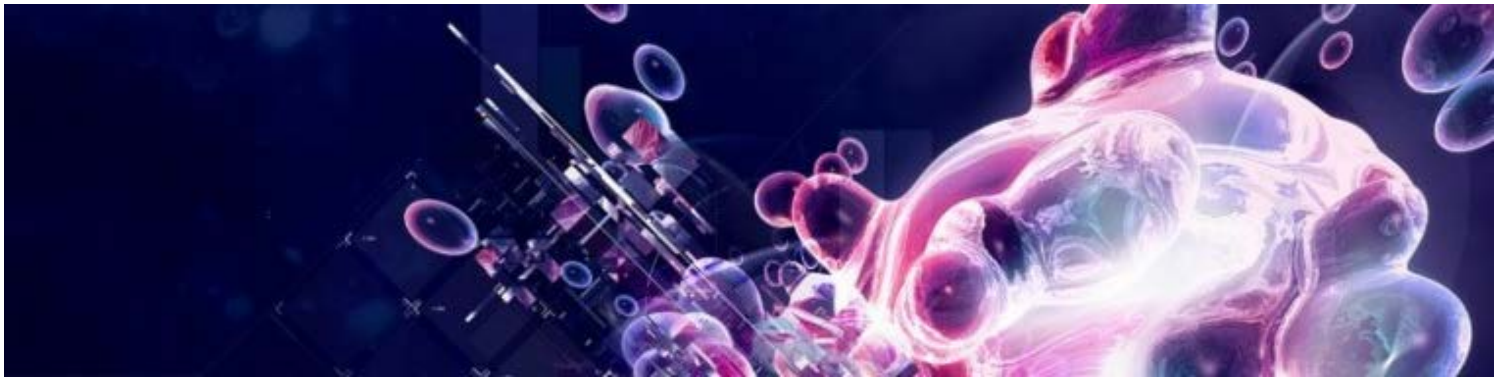

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Automated Breast Ultrasound System (‘ABUS’) for full breast scanning: The beginning of structuring a solution for an acute need!

November 13, 2012 by Dror Nir

3 Votes

Author: Dror Nir, PhD

GE Healthcare announced this week the acquisition of U-Systems, Inc. U-systems has developed the first and only Automated Breast Ultrasound System (ABUS) on the market – somo•v®, to receive FDA approval as an adjunct to mammography screening for breast cancer of; “asymptomatic women, with greater than 50 percent dense breast tissue and no prior breast interventions.”

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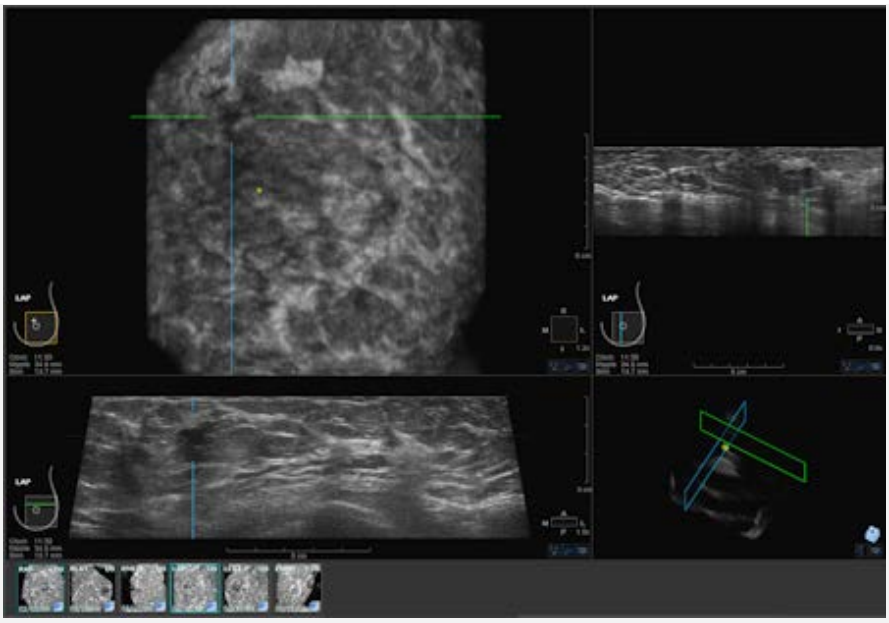

somo•v® screen shot, showing mass in upper-outer quadrant of the left breast. Image courtesy of U-Systems.

I became aware of somo•v® already in 2004, when Prof. *André Grivegnée*, head of the breast screening unit at Jules Bordet – European oncology center in Brussels, Belgium, invited me to participate in a technology assessment of U-Systems' somo•v® product. On that occasion, I also shared with U-System's developers the idea of incorporating tissue characterisation into their product, an idea which they did not take on board.

There is nothing more vivid to fully understand the meaning of this acquisition for breast cancer screening then the following quote from AuntMinnie's report "GE taps interest in ABUS with U-Systems acquisition": "You know you're onto something when the big boys come calling. GE Healthcare today announced its acquisition of automated breast ultrasound (ABUS) developer U-Systems, a move that highlights the rapid evolution of ABUS from a **niche technology** into a promising adjunct to screening mammography. "

First savvy: The reality of medical device startups is that it doesn't matter how real and large is the need for your technology. Until one of the big boys will adopt it, it is prone to be considered as **niche technology**.

I discussed the potential role of ABUS in future breast screening in my recent posts: Closing the Mammography gap**;** Introducing smart-imaging into radiologists' daily practice. As noted, in recent years, several ABUS systems were developed. An intriguing question is; why did GE choose to buy the somo•v® and not one of the other systems? Why now and not 2 or 3 years ago?

The answer must have to do with the fact that in September 2012, somo•v® became **the first** ABUS system to receive premarket approval (PMA) for its application to use the system in a breast cancer screening environment.

Until then, somo·v was indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with an automatic scanning linear array transducer or a handheld transducer. The PMA has extended somo·v's Indication For Use (IFU) allowing a claim that **it increases breast cancer detection in a certain patients population.**

Second savvy: Having a PMA approval for a compelling indication for use, in a significant enough patient group, will dramatically increase "big boys" interest in your product.

From the information available on the FDA site, one can get an insight into U-

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System's regulatory strategy. They were smart enough to be satisfied with achieving a small step; increasing the detection rate of mammography-based screening. Therefore, the same radiologist who read the mammograms also read the ultrasound image. This increases the probability that your device's sensitivity will not be worse than that of mammography. U-Systems did not try to go all the way to become an alternative to mammography. A claim that would significantly increase the complexity of the required clinical study; e.g. will require comparison of cancer detection-rates between modalities by independent, blinded-readers.

Therefore, "**the device is not intended to be used as a replacement for screening mammography"**.

Third savvy: The most expensive component, in time and money, in a regulatory pathway are the clinical studies. A cost-effective regulatory strategy is linked to good understanding of the market segmentation. Identifying what kind of IFU differentiates your products from its competition in a large enough niche-market is key. It will also lead to the simplest clinical-study design possible.

As an entrepreneur, I cannot help congratulating U-Systems' team for pulling through continuous hurdles to reach the point all medical device startups are hoping for. They certainly picked up the right item to focus their efforts on: i.e. PMA approval for breast cancer screening.

Finally, I will reiterate my vision that embedding real-time tissue characterization in an ultrasound system, capable of performing fast and standardized full breast scanning is: a. Technologically achievable; and b. in the long-term, will be an excellent alternative to mammography for breast cancer screening.

Additional readings:

Two studies related to somo•v® will be discussed at the 2012 RSNA meeting:

" A study led by Dr. Rachel Brem of George Washington University Medical Center: **ABUS plus mammography finds cancer early in women with dense tissue** Brem's study found that ABUS enabled detection of early-stage cancers in women with dense breasts, giving healthcare providers time to start early treatment. In all, 88% of cancers found by ABUS alone in a group of 15,000 women were grade 1 or 2."

"A study presented by Maryellen Giger, PhD, of the University of Chicago: **ABUS boosts mammography's performance** this study results showthat adding ABUS to mammography for women with dense breast tissue improved sensitivity by 23.3 percentage points, from 38.8% for mammography alone to 63.1% for mammography plus ABUS."

As I mentioned already, there are other ultrasound modalities out there, some are ABUS and some are not. All are adjunct to mammography screening. Related studies will also be presented during that same meeting.

Written by: Dror Nir, PhD

Posted in Imaging-based Cancer Patient Management | Tagged ABUS, cancer, cost efficient

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One Response

Aviva Lev-Ari on November 17, 2012 at 5:04 AM | Reply

Dr. Nit,
Thank you for this insightful and very well written post.
Sorry in the delay of revewing and commenting. The “big guys” have market dominance of technologies in the marketplace. My comment to your previous post was about the existing install base of mamography and ultra sound equipment in use and future use in clinics.

Ultrasound, you concluded will not replace mammography equipment, thus, the discussion is on the proportion of imaging centers, that currently carry mammography equipment, how many of them will also be penetrated by the new technology of total breat ultrasound screening.

Since GE Health a Phillips have at present time market dominance in terms og the footprint of medical devices for breast screening, thus, any new technology developed by a start up will have to penetrate the market via a contract with the big guys or the novel technology to be acquire by one of the big guys.

You reported on a success story of a new economic contract with GE Health.
This situation prevails in most industries with high barriers to entry.

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