

Lily MedTech Inc.

Developing a 3D whole breast ultrasound diagnostic imaging system, detecting cancer regardless of dense tissue

www.lilymedtech.com

Lily MedTech Inc.
Entrepreneur Plaza 701
c/o the University of Tokyo
7-3-1 Hongo
Bunkyo-ku, Tokyo
Japan 113-0033

Founded in: May 2016
Founder & CEO: AZUMA, Shiho
No. of employees: 40
Type of Ownership: private
Primary stock exchange: N/A

May 2020: Founded by a woman engineer caring for women's health, the 3D whole breast ultrasound diagnostic imaging system demonstrates not only leading-edge technology but also considerate features for examinees.



Venture Valuation (VV) interviewed, Mrs. Shiho AZUMA, Founder and CEO.

VV: **Your system, *Ring Echo*, looks like a comfortable single bed. How does it work?**

AZUMA: Our system is, as the image shows, a medical device in the shape of a bed, which is thoroughly designed for examinee comfort.

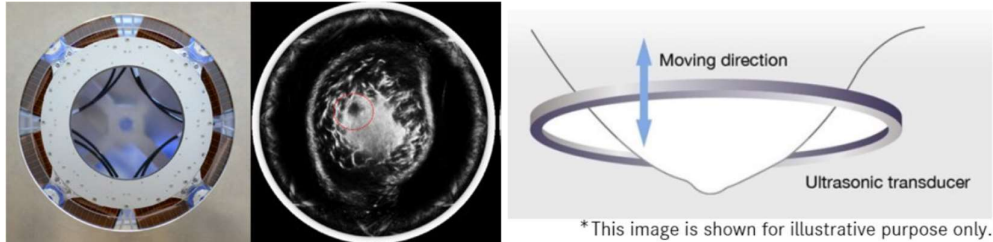
The device is easily fitted in any room in a clinic/hospital because the ultrasound device needs no specific installation requirements as do mammography and MRI (Magnetic Resonance Imaging) devices.

It has a hole in the chest area of the bed where the ring-shaped ultrasound transducer is installed. The hole is filled with warm water. The examinee lies on her stomach on device and places a breast in the hole. Scanning takes for 10 to 15 minutes but it will be shorter in near future. We noticed that some examinees are so relaxed that they almost fall asleep.



The transducer moves vertically emitting ultrasound waves to take a 3D image of the breast. It takes tomographic images while changing

positions for reception and transmission in a ring array to obtain data.
(see images on next page)



A U.S. competitor is applying the same circular transducer concept. The U.S. company's aim is to improve diagnostic imaging functions. It seems that its device has received FDA clearance excluding the use for replacing mammography screening.

Ring Echo system, developed by our CTO, Dr. Takashi AZUMA, was conceived to provide a more general and practical screening system by adopting, to some extent, the current ultrasound diagnostic standards.

VV: **Currently mammography is considered the gold standard. For women having dense breasts, there are additional screening tests available such as breast tomosynthesis, breast MRI, breast ultrasound, molecular breast imaging (MBI), and so on. In addition to its high accuracy for dense breasts, how do you differentiate it from the existing tests?**

AZUMA: Cancer and dense breast tissue both appear white on a mammogram. Therefore, dense breasts may rise the risk that cancer will be undetected on a mammogram.

Our system will complement existing screening systems and provide patients with screening test options. It is characterized mainly by 1) no radiation risk, 2) no injection of contrast material or radioactive tracer, 3) no expertise required to operate, 4) no pain by direct contact / squeezing breast, 5) total comfort for examinees, and 6) AI-driven image diagnostic functions.

Breast tomosynthesis (3D mammogram) exposes the examinee to radiation albeit very low, similar to MBI. Breast MRI requires injection of contrast material, and MBI injection of a radioactive trace. Unlike breast ultrasound which relies on skilled medical professionals, Ring Echo system's operations are all automated so that no expertise is required. We would be delighted to introduce a relaxing screening option to those who are aware of the pain caused by being squeezed at mammography.



AI-driven functions will conduct first screening so that doctors can focus on fewer number of cases, help to diagnose whether a tumor is benign or malignant and to detect even small-early stage tumors. Subsequently, the use of needle biopsy will be avoided, which also means saving medical costs.

VV: You are intending to launch your system in Japan in a few years. What is your business development plan in Japan and outside Japan?

AZUMA: We are in the process of submitting our medical device application to get homologation in Japan. Hopefully, our system will be available in two years for all women, especially the relatively young generations who are most likely to have dense breast tissue.

In terms of pricing, our system may be ranged between 3D mammogram and MRI. We are going to promote the device to major university hospitals in the beginning, then to regional hospitals, breast centers, and clinics providing breast cancer screening.

Our business model is not only supplying diagnostic imaging system to medical institutions but also offering services such as subscription-model remote diagnoses by leveraging AI-driven image diagnosis functions in collaboration with experienced radiologists. We expect this model will also work internationally.

To develop our business worldwide, we are interested in partnering with pharmaceutical companies developing breast cancer drugs, for which our system would be useful for reducing clinical study costs. As our system demonstrates high reproducibility of diagnostic images, it is suitable to scan the breasts regularly to monitor the size / status of tumors to check the result of medicines.

By using our system from the beginning of developing protocol of clinical trial, pharmaceutical companies can save time and cost. Lily MedTech has already conducted clinical research to monitor NAC (neoadjuvant chemotherapy) result every month with the University of Tokyo Hospital. Currently, during clinical studies, pharmaceutical companies normally use costly MRI system because there is no other imaging system which can provide 3D images of whole breast at this moment. We are confident that our system will cut down the research & development budget.



VV Comments after the interview:

Just as it is for other cancers, early detection is crucial for breast cancer, the most common cancer among women. According to the WHO (World Health Organization)¹, breast cancer impacts 2.1 million women every year worldwide and causes the highest number of cancer related deaths with women. In 2018, around 627,000 women are estimated to be its victims, almost 15% of all cancer deaths among women.

Scientific development and an innovative approach to various imaging tests will improve women's lives. Lily MedTech, a rare femtech (technology related to women's health) company in Japan, is a challenger in the creation of a promising market segment in the breast cancer imaging industry.

The global breast cancer imaging market is projected to grow from an expected 3.7 billion USD in 2020 to 5.4 billion USD in 2025.² While large companies have already established their positions in the market, start-ups like Lily MedTech bring in inventive technology and services changing the market landscape. It is fascinating to observe how Ring Echo system will become de facto standard by being adopted by the industry and the customers.

Contact **Mariko Hirano**, m.hirano (at) venturevaluation.com

Venture Valuation specializes in independent assessment and valuation of technology-driven companies in growth industries, such as the Life Sciences (Biotech, Pharma, and Medtech), ICT, Femtech, Nanotech, Cleantech and Renewable Energy. In addition to valuation products, Venture Valuation offers high-quality, focused information services like the Global Life Sciences Database, Biotechgate.com and this "*Let's Interview Series*" with companies with interesting technologies and services. We select and interview thriving companies and organizations all over the world.

¹ www.who.int/cancer/prevention/diagnosis-screening/breast-cancer/en/

² <https://www.marketsandmarkets.com/Market-Reports/breast-imaging-technologies-market-897.html>