

ISONO HEALTH RECEIVES THE 2023 NEW PRODUCT INNOVATION AWARD

*Identified as best in class in the United States breast
ultrasound industry*



Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. iSono Health excels in many of the criteria in the breast ultrasound space.

AWARD CRITERIA	
<i>New Product Attributes</i>	<i>Customer Impact</i>
Match to Needs	Price/Performance Value
Reliability	Customer Purchase Experience
Quality	Customer Ownership Experience
Positioning	Customer Service Experience
Design	Brand Equity

Disruptive Innovation: A Massive Leap Forward to Democratizing ABUS

Headquartered in San Francisco, California, iSono Health is carving a new automated breast ultrasound (ABUS) market category. Cleared by the US Food and Drug Administration (FDA) in May 2022, iSono Health ABUS ATUSA is the world’s first automated and wearable 3D breast ultrasound for breast imaging with a

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Consultant**

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it is operator-independent and does not require trained technicians to operate.

While the image it produces is technically 2D, advanced 3D reconstruction algorithms create a 3D volume

of the whole breast and allow for 3D visualization of the tissues. HCPs can access and view the images on a computer or tablet, where they may interact with the 3D images and access radial, coronal, sagittal, and transversal views of the tissue to identify lesions.

The ATUSA system features intuitive software for automated image acquisition and analysis. The wearable accessory and intuitive user interface of ATUSA ensure easy, quick, and comfortable image acquisition. As a hand-carried system, it can be used in any setting in the hospital. Its use in population-based screening programs will gain significant importance thanks to its portability, patient comfort, and precise diagnosis. Radiologists can use any web-enabled device to view the images regardless of location.

Simplifies Patient Workflows

ATUSA shortens imaging logistics and patient workflows, accelerating the diagnostic process drastically. Conventional ABUS systems spend an average of 15 minutes per patient; this results in study backlogs and long patient wait times, while ATUSA scans in less than 2 minutes. It negates the need for technologist on-site availability and is independent of operator experience.

The iSono Health ATUSA portable system ensures patient comfort and safety and at the same time provides quality imaging and diagnosis. It has the potential for regular screening and monitoring of high-risk individuals and identifies lesions precisely and at a faster time frame in patients with dense breast tissues. The company trains HCPs upon purchase, which takes about 15 minutes to set up and drive the system and about 15 minutes for software use. The company also provides comprehensive instructional videos for system operation and an initial live demo/training session during equipment purchase.

“The 3D visualization allows end users to see tissues from different planes and detect lesions in any part of the breast volume. This path-breaking ABUS system is ideally suitable and affordable for private clinics and community-based health centers whose budgets may be limited. The ATUSA’s striking operational features are key to optimizing workflows and saving critical time in identifying life-threatening abnormalities, impacting patient outcomes significantly.

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Accessibility Sparks Utility

Designed to deliver both value and performance, iSono Health ATUSA maximizes operational efficiencies to enable cost-effective quality care of breast imaging for actionable outcomes. Its unique design features and accessibility-enhanced operational efficiencies make it a preferred modality for the diagnosis and screening of breast cancer. The 3D visualization allows end users to see tissues from different planes and detect lesions in any part of the breast volume. This path-breaking ABUS system is ideally suitable and affordable for private clinics and community-based health centers whose budgets may be limited. The ATUSA’s striking operational features are crucial to optimizing workflows and saving critical time in identifying life-

threatening abnormalities, impacting patient outcomes significantly. At the same time, hospitals benefit from scaling up their procedural volumes. This has also resulted in a distribution partnership with Abdul Latif Jameel Health in 2023 to penetrate 31 countries in the Middle East and North Africa, Africa, South Asia, and Southeast Asia, as hospitals perceive the product’s worth and its clinical outcomes.

Frost & Sullivan recognizes ATUSA’s enormous customer experience value at point of care and in mobile settings, especially in the developing and developed economies where population-based breast cancer

screening programs are low. Detecting breast cancer lesions and regions of interest quickly saves critical time, impacting patient outcomes significantly. At the same time, hospitals benefit from scaling up their procedural volumes.

Stretching the Limits: High-growth Opportunities and Potential

iSono Health envisions a two-pronged growth strategy approach. It anticipates complementing imaging offerings from customers with traditional ultrasound machines, adding ABUS with AI capabilities to those that cannot afford capital expenditures—community and rural hospitals—and extending services to underserved populations. The company fits all its target customers' budgetary needs with these two flexible pricing models. Beyond offering users a portable and user-friendly scanning tool, the device is also quite affordable at a price ranging a third or fourth of existing automated ultrasounds.

Thanks to its portability, accessibility, and precise screening, iSono Health AI-powered portable ABUS ATUSA complements the conventional ABUS path forward—especially in emerging and developing economies where cancer screening programs may be lacking. In that context, Frost & Sullivan analysts believe that iSono Health is well-poised for enormous and rapid market expansion.

Conclusion

With breast cancer incidence increasing year on year, the need for early and precise diagnosis is vital. Population-based screening programs using mammography have decreased mortality in the last decade. However, mammographies can be inconvenient or uncomfortable for the patient. iSono Health's ATUSA system addresses the challenges of mammography with its lightweight, compact, and user-friendly ABUS. Its wearable accessories allow imaging patients at the point of care and generate preliminary results within minutes. As a result, clinicians can make evidence-based decisions at their bedside. The product streamlines patient and clinical workflows, eliminating delays and negating the need for trained technicians. The system extends access to cost-effective imaging and, subsequently, its clinical utility and healthcare value in breast cancer detection will be well received across geographies.

With its strong overall performance, iSono Health earns Frost & Sullivan's 2023 United States New Product Innovation Award in the breast ultrasound industry.

What You Need to Know about the New Product Innovation Recognition

Frost & Sullivan's New Product Innovation Award recognizes the company that offers a new product or solution that uniquely addresses key customer challenges.

Best Practices Award Analysis

For the New Product Innovation Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

New Product Attributes

Match to Needs: Customer needs directly influence and inspire product design and positioning

Reliability: Product consistently meets or exceeds customer performance expectations

Quality: Product offers best-in-class quality with a full complement of features and functionality

Positioning: Product serves a unique, unmet need that competitors cannot easily replicate

Design: Product features an innovative design that enhances both visual appeal and ease of use

Customer Impact

Price/Performance Value: Products or services provide the best value for the price compared to similar market offerings

Customer Purchase Experience: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

Customer Ownership Experience: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

Customer Service Experience: Customer service is accessible, fast, stress-free, and high quality

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty

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The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.

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Key Impacts:

- **Growth Pipeline:** Continuous Flow of Growth Opportunities
- **Growth Strategies:** Proven Best Practices
- **Innovation Culture:** Optimized Customer Experience
- **ROI & Margin:** Implementation Excellence
- **Transformational Growth:** Industry Leadership



The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.

Analytical Perspectives:

- **Mega Trend (MT)**
- **Business Model (BM)**
- **Technology (TE)**
- **Industries (IN)**
- **Customer (CU)**
- **Geographies (GE)**

