

# SENO MEDICAL RECEIVES THE 2023 ENABLING TECHNOLOGY LEADERSHIP AWARD

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*Identified as best in class in the United States  
opto-acoustic ultrasound imaging 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. Seno Medical excels in many of the criteria in the opto-acoustic ultrasound (OA/US) imaging space.

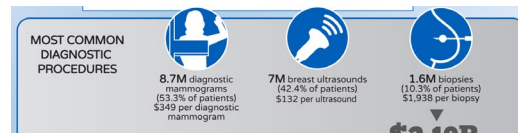
AWARD CRITERIA	
Technology Leverage	Customer Impact
Commitment to Innovation	Price/Performance Value
Commitment to Creativity	Customer Purchase Experience
Stage Gate Efficiency	Customer Ownership Experience
Commercialization Success	Customer Service Experience
Application Diversity	Brand Equity

### Challenges in the Breast Cancer Imaging Industry

Hospitals are experiencing staffing deficiencies, work overload, and retention risks.<sup>1</sup> Radiology, which includes breast imaging, is well documented as a high-stress specialty prone to staff burnout and over-utilization. Staff vacancy rates are the highest seen in decades.

Breast cancer is one of the major cancer types, where early and accurate detection, followed by the right treatment plan, can result in better patient care and an increased survival rate. Clinicians are looking for better or more efficient systems, and tools to increase their confidence in diagnosing both malignant and benign masses.

On average, 70 to 72% of breast biopsies are negative, causing great anxiety for women and driving costs for the USA healthcare system to exceed \$2.1 billion annually in unnecessary biopsies alone.<sup>2</sup> Furthermore, patients undergoing these negative biopsies have typically been through 1 to 4 additional imaging exams before the decision to biopsy was made, adding to the cost and time for both patients and staff, as well as worry and discomfort for patients.



Source: [MKTG-1039-Breast-Procedure-Infographic-FINAL.pdf \(senomedical.com\)](#) using paper Vlahiotis A, Griffin B, Stavros AT, Margolis J. Analysis of utilization patterns and associated costs of the breast imaging and diagnostic procedures after screening mammography. *Clinicoeconomics Outcomes Res* 2018;10:157-167.

<sup>1</sup> Frost & Sullivan; September 2022; “Global Hospital Workforce Scheduling & Support Solutions Growth Opportunities”

<sup>2</sup> Infographic and data are from Seno Medical’s website and validated during company interviews.

**Pioneering a New Imaging Modality for Better Patient Care**

Founded in 2005 in San Antonio, Texas, Seno Medical Instruments, Inc. has commercialized a new modality in cancer screening and diagnosis called opto-acoustic ultrasound (OA/US) imaging, which is opto-acoustics, or what is sometimes known as photoacoustics (PAI), fused with ultrasound to reduce negative breast biopsies. The company leverages this technology to meet both the markets’ and customers’ needs and is well positioned to capitalize on new growth opportunities, thus strengthening its position in the US market.

Seno Medical’s first clinical application is for breast cancer diagnosis. The company acquired early opto-acoustic technology and working pre-prototypes, subsequently developing its own prototypes in this technological field. Moreover, Seno Medical developed its own core patents on opto-acoustic technology and has aggressively pursued new inventions and obtained additional patents in this field. Collectively, these patents constitute an expanding platform technology with many potential follow-on applications, including imaging for the early diagnosis of melanoma, thyroid, prostate, and colon cancers.

**Current Offerings**

**Imagio® Breast Imaging System:** Seno Medical’s first clinical product targets breast cancer diagnosis as an adjunct to screening mammography, incorporates opto-acoustics and ultrasound, and provides clinicians with more confidence in diagnosing malignant or benign masses. In 2021, the Imagio® Breast Imaging System received Pre-Market Approval (PMA) from the US Food and Drug Administration (FDA) for commercial distribution in the United States and supplemental PMA approval in 2022 after incorporating advanced ultrasound technology.

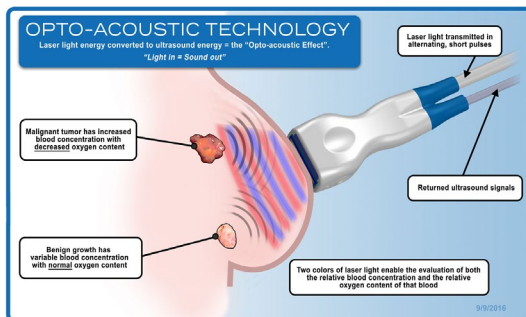


Source: [Seno Medical](#)

**Commitment to Innovation**

Opto-acoustic imaging is a novel technology that uses a combination of anatomic (ultrasound) and functional (opto-acoustic) diagnostic imaging using light (laser optics) and sound (opto-acoustic and conventional ultrasound) in real time to produce high-resolution, high-contrast images for clinicians.

**Opto-acoustic Technology Details<sup>3</sup>**



Source: [Seno Medical](#)

As part of the development process, Seno Medical leverages innovative 3D printing technology to prototype certain production capacities, thus reducing the development time and providing higher-quality parts, compared to traditional machining and/or injection molding.

Another example of an area of ingenuity is the use of advanced high-performance computing capabilities (GPU and CPU) for real-time signal and image processing,

<sup>3</sup> Details from Seno Medical’s website and validated during company interviews.



without the need for specialized hardware, such as field programmable gate arrays (FPGA) or dedicated chips.

Seno Medical is working with a few customers that have expertise in artificial intelligence (AI) and deep learning to create auto-segmenting regions of interest and radiomics. The company's innovative opto-acoustic technology helps radiologists with confident diagnoses reduce the number of biopsies based on the company's real-world registry study to approximately 25% negative biopsies, compared to the 70 to 75% negative biopsies today.

**Important Patient Features:** Seno Medical's opto-acoustic technology for breast imaging is non-invasive, has no ionizing radiation, does not use contrast agents or radionuclides, and does not require the compression that is used in mammography. The technology uses the body's own hemoglobin (organic) as

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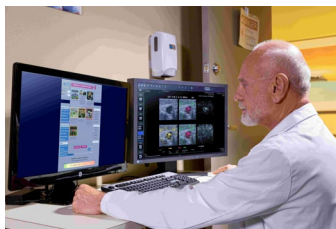
**- Sudhakar Mishra**  
**Senior Director – Growth Advisory HLS**

a natural contrast agent and is thus safe and effective, with only the safety eyewear required that is similar to what is worn at a spa or a dermatology office for laser treatments.

The Imagio® opto-acoustic/ultrasound (OA/US) Breast Imaging System provides clinicians with immediate information offering same-day results, if the center allows. Furthermore, the system saves

patients time by providing clinicians with more information. When a physician uses the company's AI decision support tool, SenoGram®, they save patients time and the worry of needing additional diagnostic exams, and potentially a biopsy. This occurs when the likelihood of malignancy (LOM) is in the BI-RADS 3 or 2 category—(probably benign or benign finding with a LOM of 2% or less chance of malignancy).

**Important Clinician Features:** Clinical studies and interim real-world registry data suggest that this opto-acoustic technology can significantly reduce the diagnostic exams and biopsies of benign masses, without sacrificing sensitivity or cancer diagnosis. With the current significant staff shortages (e.g., technicians, radiologists, and back-office staff), Seno Medical's technology can create capacity in the diagnostic care pathway by reducing diagnostic workups (e.g., additional imaging) and biopsies by 50 to 75%,<sup>4</sup> depending on the center. Seno Medical's AI decision support tool SenoGram® provides clinicians with the ability to score this new modality concisely and consistently to objectively determine the precise likelihood of



Source: Seno Medical

malignancy. This can then be translated into BI-RADS score compared to the current subjective method of reading and assigning BI-RADS. The SenoGram® provides clinicians with more confidence when determining if the mass is malignant or benign.

**Important Hospital and Healthcare Features:** Investment in new technologies, such as OA/US, directly improves staff recruitment, retention, and efficiency, particularly when the technology can eliminate

<sup>4</sup> Data based on discussion with Seno Medical stakeholders and their internal research. Reference: Seiler SJ, Neuschler EI, Butler RS, et al. Optoacoustic Imaging with Decision Support for Differentiation of Benign and Malignant Breast Masses: A 15-Reader Retrospective Study American Journal Radiology 2023;220(5):646-658 and 2022 EUSOBI (European Society of Breast Imagers) Interim Registry Results Presentation (unpublished).



“This is game-changing for breast cancer imaging in that we get functional information—that we would normally get from advanced imaging—but with ultrasound”

- Basak Dogan, MD, Director of Research at UT Southwestern Medical Center's Harold C. Simmons Comprehensive Cancer Center

Source: Information by Seno Medical Leadership

unnecessary steps or exams and offer better precision and confidence in outcomes. Recent studies indicate that patients desire more control over their care journey and want to make decisions with the support of staff who are sensitive to their need for fewer disruptions to their lives.

As Seno evolved, it continued to seek and develop new talent to fill the gaps in its technologies and processes. Following our 2015 clinical study which involved over 2,000 patients, we learned about the interfacing, techniques, and efficiencies we could affect in order to help radiologists and

their staff manage risks. This kept us continuing to innovate. Prior to commercialization, Seno Medical had several noteworthy publications, posters, and presentations which were peer reviewed, well attended, and allowed them to reach a larger audience. Prior to commercialization or FDA approval Seno Medical had ten published peer-reviewed papers from its clinical studies and technology which is extremely rare in most new modality introductions.

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- Sudhakar Mishra  
Senior Director – Growth Advisory HLS

Seno Medical’s attention to detail, experienced leadership, transparency, and cross-functional meetings have encouraged employee participation in idea generation for problem solving. Furthermore, Seno Medical encourages employees to continue their learning and growth by participating in technology and society committees/conferences, such as Photonics West (SPIE), SABCS, and DICOM.

Seno Medical is developing and fostering a culture of innovation from within by inspiring employees with technology challenges and a recognition culture.

### **Commitment to Creativity**

A key functionality and feature of Seno Medical’s Imagio® system is the AI decision support tool called SenoGram® that provides radiologists, or readers, with the methodology to look at the technology’s new information. SenoGram® provides image reference keys to facilitate a more accurate assignment of ultrasound and OA/US feature scores. Reference keys are used for scoring each feature for both ultrasound and opto-acoustics.

The SenoGram® provides an image example and description of what the specific feature characteristic’s score should resemble, from 1 to 5 or 6. Readers can select the image and advance to the next feature or use radial buttons to assign the score once they become more familiar with the scoring methodology and reference key templates. Fundamentally, the higher the score for each feature characteristic, the more malignant that feature is, and, conversely, the lower the score, the more benign looking the feature characteristic is. The AI and machine learning part of this decision support tool incorporates all 10 scores from the ultrasound and opto-acoustics features, along with 5 other demographic variables, to calculate a more objective and precise likelihood of malignancy.

Another key feature of Seno Medical's technology is the laser component, which pulses two wavelengths of laser light to heat the mass briefly, creating a sound wave that comes back to the transducer. Each laser is optimized to show the two clear cancer hallmarks of oxygenation and deoxygenation of the hemoglobin in and around the mass. The oxygenation and deoxygenated hemoglobin give the mass either benign or malignant characteristics, which is the functional aspect of the technology that is derived from the patient, without contrast agents or radionuclides, compared to other functional modalities, such as MRI, CESM, and PEM.

In the engineering space, patents are always a key motivator; therefore, Seno Medical encourages and sponsors patent submissions from employees. Furthermore, Seno Medical's leadership often challenges teams and individuals to solve or enhance specific components or areas of interest and then ensures that the team or individual(s) is supported and recognized.

In the photoacoustic or opto-acoustic community, most organizations focus more on the research aspects of photonics and not on clinical applications, such as the breast or prostate, in the clinical space, unlike Seno Medical. A major reason for this is the time and resources needed to demonstrate this type of commitment. As a result, Seno Medical does not have a direct competitor that is as far along in development and implementation.

### ***Commercialization Success***

Seno Medical is quickly progressing with the commercialization of its OA/US technology in the United States and recently onboarded eight sales professionals mid-2023 to help penetrate across the United States. Many academic institutions across the country have been expressing significant interest, and a few are now scheduled for training. Seno Medical recently installed the Imagio<sup>®</sup> system at a physician-owned breast imaging center in a medium-sized city in North Carolina. As a result, Seno Medical anticipates that its technology will meet the unmet needs of independently owned imaging centers, hospitals, and academic institutions that currently offer diagnostic care for breast cancer patients.

The Imagio<sup>®</sup> Breast Imaging System has been the first novel diagnostic modality since the introduction of 3D mammography in 2011 and automated breast ultrasound (ABUS) for screening in 2012. No modality without injecting contrast agents, provides similar functional information as Seno Medical's OA/US. A new device that provides a non-invasive method to gain invasive information is always disruptive and supersedes existing devices over time.

### ***Application Diversity***

Seno Medical's Imagio<sup>®</sup> Breast Imaging System is approved to diagnose breast cancer only; however, previous proofs of concept and successful feasibility studies have been completed in thyroid cancer and in monitoring neoadjuvant care (NAC) for breast cancer. Seno Medical intends this device to be a platform technology with many relevant future applications.

Another area, similar to breast cancer and thyroid cancer, which tends to generate significant negative biopsies is prostate cancer. Seno Medical has developed a prototype probe for this application and has conducted preliminary investigative work to determine what is needed for a feasibility protocol. In some of the aforementioned disease states, Seno Medical anticipates that its study work will likely be in the

area of determining aggressive cancers, compared to those that are more watchful waiting or in the area of NAC that is determined after the first chemo regimen if the treatment is working or not. From a patient and healthcare cost perspective, Seno Medical believes this early and accurate diagnosis will have the greater impact. Each of these cancer diagnosis applications has significant unmet needs and large market opportunities.

For the breast cancer monitoring of NAC, the company completed a successful feasibility study with the University of Texas Southwest in Dallas, Texas. For thyroid cancer diagnosis, the company conducted a feasibility study at Invision Sally Jobe in Denver, Colorado, and completed a prostate probe prototype, with investigative work yet to be completed as proof of concept.

Future applications may include non-cancerous monitoring of arthritis and joint tissue inflammation, in terms of looking at inflammation photo-acoustically, particularly in monitoring drug development and the impact on the inflammation or injured areas.

### ***Price/Performance Value***

When the Imagio® technology is compared to other functional type modalities, the price point of the device alone is significantly less than MRI, PEM, and CESM modalities.

Most of Seno Medical's customers indicate that diagnostic workups require significant resource time, from back-office schedulers to technologists and breast imagers and are often not cost effective. The company's technology can reduce the time spent on the exams that generate negative findings, providing capacity to perform more exams that generate better returns, minimize the impact for additional equipment and rooms in typical real estate-constrained centers, and allow staff time to slow down or leave on time, thus reducing burnout and improving patient outcomes.

OA/US as a first-order diagnostic exam provides more positive imaging and positive biopsies, thus creating more time and satisfaction for staff (back-office personnel, technologists, and radiologists) and patients.

Seno Medical is in the early stage in this commercialization process with customers and is thus generating real-world white papers or proof statements. The company expects its initial installations will provide it with opportunities to explore, investigate, and communicate the value.

### ***Customer Ownership Experience***

Seno Medical internally captures and logs all customer comments and complaints, with regulatory assessment/quality assessment (RA/QA) further determining if the comments are relevant to product performance, future development potential, or general feedback. A cross-functional group discusses the comments in a quality meeting, and Seno Medical then closes the loop by communicating its actions to customers through sales and marketing representatives.

With each installation, once the customer gains experience reading the OA/US exams, Seno Medical's medical director or peer expert reviews the first few cases with the breast imager to answer any questions and discuss any technique adjustments. Customers find this process rewarding in their adaptation of the technology and in reading this new modality. Seno Medical wants to ensure that all customers feel confident in their outcomes.

Each hospital is offered a tool kit that includes a referring physician and patient information package to be used in social media and on websites to educate the community about this new modality. Healthcare centers understand the benefit of being first to market with a new technology or offering and strive to differentiate themselves in the market.

*“This (OA/US) is equivalent to the step from 2D mammography and tomography. It has a lot of additional information. This can help us save on costs for both the patient and the payers, and we have to think about that.*

**- Ken Kist, MD Breast Imager at University of Texas Health Sciences, San Antonio, TX.**

### **Brand Equity**

As Seno Medical continues to build awareness and adoption of the Imagio® OA/US Breast Imaging System, the Seno Medical brand will become more mainstream across all breast centers. Today, OA/US is already becoming an adopted terminology for the technology.

Seno Medical participates in trade shows and academic forums to increase awareness on the brand and on the technology benefits. The company is slowly gaining good traction within the US market, with no direct competitors close to introducing a similar clinical type of product.

### **Conclusion**

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Seno Medical’s Imagio® Breast Imaging System is the only approved novel OA/US device in the United States. The Imagio® technology for breast imaging is non-invasive; does not require ionizing radiation, contrast agents, or radionuclides; and does not use the compression required in mammography. Seno Medical’s technology can significantly reduce diagnostic exams and biopsies of benign masses without sacrificing sensitivity or cancer diagnoses. In addition, Seno Medical is working toward a technology platform that would support the early detection of melanoma, thyroid, prostate, and colon cancers.

With its strong overall performance, Seno Medical earns Frost & Sullivan’s 2023 United States Enabling Technology Leadership Award in the OA/US imaging industry.



## What You Need to Know about the Enabling Technology Leadership Recognition

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Frost & Sullivan's Enabling Technology Leadership Award recognizes the company that applies its technology in new ways to improve existing products and services and elevate the customer experience.

### Best Practices Award Analysis

For the Enabling Technology Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

#### *Technology Leverage*

**Commitment to Innovation:** Continuous emerging technology adoption and creation enables new product development and enhances product performance

**Commitment to Creativity:** Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

**Stage Gate Efficiency:** Technology adoption enhances the stage gate process for launching new products and solutions

**Commercialization Success:** Company displays a proven track record of taking new technologies to market with a high success rate

**Application Diversity:** Company develops and/or integrates technology that serves multiple applications and multiple environments

#### *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

## About Frost & Sullivan

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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)**

