SENO MEDICAL®

Transforming Breast Cancer Diagnostics

with Light, Sound, and Artificial Intelligence

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Breast cancer diagnosis is at a tipping point

Early and accurate detection of breast cancer is crucial to saving lives, but **the recommended diagnostic pathway is arduous, costly, and often inconclusive.** This creates an enormous burden on patients and clinical practices.

Mammography and ultrasound alone lack the specificity clinicians need to decide the right course for the patient and confidently rule out a malignancy. As a result, three in four patients receive biopsies that turn out to be benign, leading to pain, anxiety, and lost time. Excessive and costly diagnostic procedures create clinical inefficiencies and further strain the limits of an overburdened health workforce.

> The way breast cancer is diagnosed must change.

There is a need to reduce false positives and decrease the number of diagnostic procedures while simultaneously improving specificity and reducing mortality rates.

The burden on patients

A patient whose initial screening indicates a mass can expect to undergo at least 12 weeks of waiting to find out the answer to their all-consuming question: Do I have cancer or not?

Teena, a breast screening patient, explains what this process is like for her.

"Anxiety can consume me when it's time for my mammogram. I have dense breasts, a family history, and an overactive imagination. My hope is for an immediate answer about what's in my imaging. I don't want to wait a week, or even a day. I want to know then and there."[i]

Reduce Stress & Worry

Increased confidence in test results shortens time to diagnosis – reducing patient fear and anxiety.

"I think that if there was some type of medical technology to lessen the amount of breast biopsies being done, it would take a load off a lot of women's minds."

– Lisa
Biopsy Patient
Warwick, RI

[i] Seno Medical

Inconclusive results of diagnostic exams create a negative patient experience.

With the current state of diagnostics, that quick and conclusive answer eludes most patients. Nearly half of all breast diagnostic patients are recalled for a second diagnostic procedure after their initial screening; 20% have three procedures; and 10% have four procedures.[1]

As a result of this drawn-out and uncomfortable process, a recent study shows that patients waiting for breast cancer diagnosis results have stress levels indistinguishable from those of patients with cancer.[2-4]

1. Vlahiotis, A., Griffin, B., Stavros, A. T., & Margolis, J. (2018). Analysis of utilization patterns and associated costs of the breast imaging and diagnostic procedures after screening mammography. *ClinicoEconomics and Outcomes Research: CEOR*, 10, 157–167. https://doi.org/10.2147/CEOR.S150260 **2**. Dinapoli, L., Colloca, G., Di Capua, B., & Valentini, V. (2021). Psychological aspects to consider in breast cancer diagnosis and treatment. *Current Oncology Reports*, 23 (3), 38. https://doi.org/10.1007/s11912-021-01049-3. **3**. Lang, E. V., Berbaum, K. S., & Lutgendorf, S. K. (2009). Large-core breast biopsy: abnormal salivary cortisol profiles associated with uncertainty of diagnosis. *Radiology*, 250 (3), 631–637. https://doi.org/10.1148/radiol.2503081087. **4**. Ozcan, B. B., Xi, Y., & Dogan, B. E. (2024). Supplemental optoacoustic imaging of breast masses: a cost-effectiveness analysis. *Academic Radiology,* 31 (1), 121–130. https://doi.org/10.1016/j.acra.2023.08.042.

"The large volume of wasteful procedures is impacting patients in bad ways," explained Michael Bruno, MD, the vice chair for quality and patient safety at Penn State Milton S. Hershey Medical Center. "We are exposing people to radiation, there is a greater fraction of false positives that then lead to overtreatment and overdiagnosis."[5]

Unnecessary breast biopsies are a significant burden on patients. **One in ten women who receive a diagnostic mammogram will receive a breast biopsy**. However, in nearly three-quarters of cases, these biopsies will be benign. The procedure causes stress and discomfort for patients, and biopsy incisions can be slow to heal.[3]

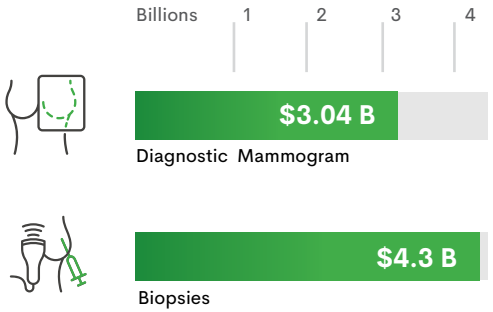
5. Fornell, D. (2023). Mismatch between radiologist shortages, rising exam volumes a growing concern in medical imaging. *Radiology Business*. https://radiologybusiness.com/topics/healthcare-management/healthcare-staffing/mismatch-between-radiologist-shortages-rising-exam-volumes-growing-concern-medical-imaging. **3**. Lang, E. V., Berbaum, K. S., & Lutgendorf, S. K. (2009). Large-core breast biopsy: abnormal salivary cortisol profiles associated with uncertainty of diagnosis. *Radiology*, 250 (3), 631–637. https://doi.org/10.1148/radiol.2503081087.

Costs to the healthcare system

The current process of breast cancer diagnosis creates an enormous strain on the healthcare system and the health workforce.

Diagnostic mammograms cost the U.S. healthcare system approximately **$3.04 billion** annually.

Biopsies cost up to **$4.3 billion** each year.[1]



1. Vlahiotis, A., Griffin, B., Stavros, A. T., & Margolis, J. (2018). Analysis of utilization patterns and associated costs of the breast imaging and diagnostic procedures after screening mammography. *ClinicoEconomics and Outcomes Research: CEOR*, 10, 157–167. https://doi.org/10.2147/CEOR.S150260

Radiologists are especially affected. A 2020 survey of radiologists revealed 29% were experiencing high burnout, and 79% met at least one of the criteria for burnout.[6]

In the years after the pandemic, the radiology workforce continues to struggle with high rates of turnover. They cite increased workloads, low staffing levels, and increased patient volumes as the biggest current challenges in their specialty.

Unsurprisingly, an estimated 85% of outpatient facilities and hospitals face radiology staffing shortages.[7]

29% of radiologists experiencing burnout.[6]

6. Ganeshan, D., Rosenkrantz, A. B., Bassett, R. L., Jr, Williams, L., Lenchik, L., & Yang, W. (2020). Burnout in academic radiologists in the United States. *Academic Radiology*, 27(9), 1274–1281. https://doi.org/10.1016/j.acra.2019.12.029 **7**. Stempniak, M. (2023). Rising patient volumes and staffing challenges: 7 takeaways from a new salary survey of radiologists, techs and administrators. *Radiology Business*. https://radiologybusiness.com/topics/healthcare-management/healthcare-economics/rising-patient-volumes-and-staffing-challenges-7-takeaways-new-salary-survey-radiologists-techs-and

"The cost [of unnecessary diagnostic procedures] is staggering, and we are frankly running up against a limitation of our capacity," Dr. Bruno said. "Especially after the great resignation, we simply don't have enough manpower to keep up with this."[5]

Clinicians do what guidelines and existing care pathways require, but today's technology limits them from having complete diagnostic confidence. As a result, they have little choice but to order additional diagnostics, even if they are fairly confident a mass is benign.

5. Fornell, D. (2023). Mismatch between radiologist shortages, rising exam volumes a growing concern in medical imaging. *Radiology Business*. https://radiologybusiness.com/topics/healthcare-management/healthcare-staffing/mismatch-between-radiologist-shortages-rising-exam-volumes-growing-concern-medical-imaging.

Jeroen Veltman, MD, PhD, a breast radiologist within MRON Radiologie Oost-Nederland, a Seno Medical MAESTRO study site, described this conundrum. "Do I actually want to perform a biopsy on a probable fibroadenoma in a 34-year-old? The chance that I'm wrong [about it being benign] is very low, but the protocol says I have to do a biopsy." (EUSOBI, 2015)

This cycle of inconclusive testing, additional patient management, and inefficient workflows adds more stress on staff and contributes to high rates of turnover and staffing shortages that limit clinical capacity even further. "Attacking the overutilization of medical imaging would go a long way toward offsetting staffing shortages so radiologists and technologists could concentrate on exams that are actually needed," Dr. Bruno posits.[5]

"Do I actually want to perform a biopsy on a probable fibroadenoma in a 34-year-old?"[8]

– Jeroen Veltman, MD, PhD
Breast Radiologist within MRON Radiologie Oost-Nederland

5. Fornell, D. (2023). Mismatch between radiologist shortages, rising exam volumes a growing concern in medical imaging. *Radiology Business*. https://radiologybusiness.com/topics/healthcare-management/healthcare-staffing/mismatch-between-radiologist-shortages-rising-exam-volumes-growing-concern-medical-imaging.

Imagio® Breast Imaging System

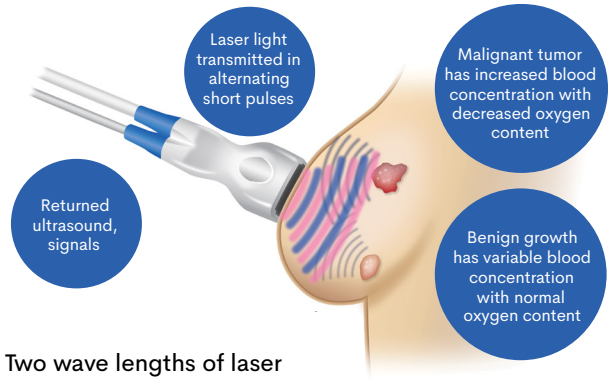
A leap forward in breast cancer diagnosis

There is a need to decrease invasive procedures on benign masses, improve the quality and experience of care for patients seeking breast diagnostics, and reduce costs for the healthcare system.

The solution is the Imagio® Breast Imaging System, an innovative modality that increases diagnostic confidence and reduces false positive biopsies. Imagio® goes beyond current diagnostic methods by combining laser light with ultrasound technology (OA/US) to provide functional imaging in real time. It is the only FDA-approved OA/US device in the U.S, integrating laser optic and OA images with high-quality US breast imaging in one.

Opto-Acoustics

Laser Light In = Sound Out



Two wave lengths of laser light enable the evaluation of both the relative blood concentration and the relative oxygen content of that blood.

Areas of concern can be assessed in real time using opto-acoustics, which pulses a light to detect vascularity and oxygenation within any mass and surrounding breast tissue.

The result is a functional scan of the area of concern. Clinicians are now able to differentiate malignant from benign in masses as small as 3 mm. Imagio® is suitable for the assessment of Breast Imaging Report & Data System (BI-RADS) classifications 3, 4a, and 4b when used alongside screening modalities.

The benefits to patients are considerable.

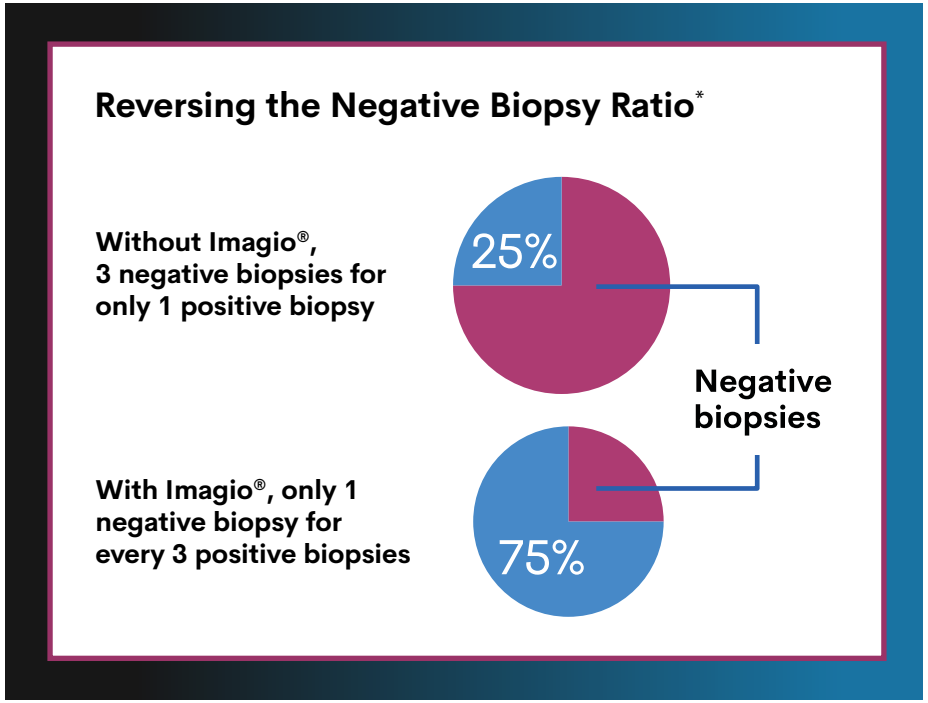
Most importantly, Imagio® can significantly reduce the number of diagnostic exams and biopsies for patients without compromising sensitivity. Based on preliminary findings from a prospective, controlled, multi-center, observational registry (CONFIDENCE Registry, ClinicalTrials.gov ID #NCT05084729) of approximately 150 patients at three sites, Seno estimates that implementation of Imagio® could result in a 75% reduction in unnecessary biopsies.

"The primary benefit of this technology is that it can help the patients avoid the biopsy ordeal. [With OA/US], we're finding that we can more correctly categorize masses we would normally biopsy based on ultrasound features alone… and that's without losing significant sensitivity," said Dr. Dogan, MD, Director of Research at UT Southwestern Medical Center's Harold C. Simmons Comprehensive Cancer Center.[8]

"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."[8]

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

8. Kania, J. (2022) Opto-acoustic imaging: a new modality changing the future of breast imaging. *Radiology Business*. https://radiologybusiness.com/sponsored/57816/seno-medical/topics/medical-imaging/womens-imaging/breast-imaging/opto-acoustic



Based on real-world studies, Seno estimates the use of Imagio® could flip the ratio of negative to positive biopsies from 3:1 to 1:3 in breast cancer diagnosis.

This could translate into **$4.9 billion** savings for the U.S. healthcare system, including $3 billion savings from preventing unnecessary biopsies.[1,8]

*EUSOBI 2022 interim CONFIDENCE registry results.

1. Vlahiotis, A., Griffin, B., Stavros, A. T., & Margolis, J. (2018). Analysis of utilization patterns and associated costs of the breast imaging and diagnostic procedures after screening mammography. *ClinicoEconomics and Outcomes Research: CEOR*, 10, 157–167. https://doi.org/10.2147/CEOR.S150260 **8.**Kania, J. (2022) Opto-acoustic imaging: a new modality changing the future of breast imaging. *Radiology Business*. https://radiologybusiness.com/sponsored/57816/seno-medical/topics/medical-imaging/womens-imaging/breast-imaging/opto-acoustic

Use of Imagio® imaging decreases risk and discomfort for patients – it is non-invasive and does not require ionizing radiation, contrast agents, radionuclides, or compression.

Furthermore, Imagio® provides clinicians with immediate information to enable same-day results, greatly reducing anxiety and waiting times for the patient. Teena reflected on the positive impact on patients like her. "Technology and artificial intelligence are allowing us to take back control of our lives."

Frost & Sullivan Award Winner

In recognition of this pioneering technology, with its clinical application of photoacoustics to improve the lives of patients and the health workforce, Imagio® was awarded the 2023 Enabling Technology Leadership Award by Frost & Sullivan.

The award spotlights Seno Medical's real-world approach at developing and implementing technology that addresses medical challenges by revolutionizing how breast cancer is diagnosed.[9]

9. Frost & Sullivan. (2024) Seno Medical earns Frost & Sullivan's 2023 United States Enabling Technology Leadership Award for delivering a more efficient breast cancer diagnosis with its cutting-edge technology. https://www.frost.com/news/press-releases/seno-medical-earns-frost-sullivans-2023-united-states-enabling-technology-leadership-award-for-delivering-a-more-efficient-breast-cancer-diagnosis-with-its-cutting-edge-technology/

SenoGram®

Enhanced clinical decision-making powered by artificial intelligence.

As advancements continue in breast imaging technology hardware, the evolution of artificial intelligence incorporated into imaging software progresses as well. Recent findings from a multi-reader study showed the use of AI in clinical mammography could play a vital role at increasing sensitivity and specificity, especially for radiologists with less experience assessing breast lesions. An article in *JAMA Network Open* showed the ability of using machine-learning methods, such as the Imagio® AI, to enhance screening interpretations, reducing missed cancers and false positives. This study concluded that AI algorithms, combined with radiologist assessment in a single-reader screening environment, improved overall accuracy. Seno's SenoGram® adds yet another level of diagnostic confidence, improving accuracy for optimum interpretation and appropriate follow-up.[10,11]

10. Bassi, E., Russo, A., Oliboni, E., et al. (2023). The role of an artificial intelligence software in clinical senology: A mammography multi-reader study. *Breast Radiology*. https://link.springer.com/article/10.1007/s11547-023-01751-1 **11.** Schaffter, T., Buist, D. S. M., Lee, C. I., et al. (2020). Evaluation of combined artificial intelligence and radiologist assessment to interpret screening mammograms. *JAMA Network Open.* https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2761795

The diagnostic process is enhanced with SenoGram®, an artificial intelligence (AI) clinical support tool that increases precision, specificity without sacrificing sensitivity, and efficiency in interpreting Imagio® images.

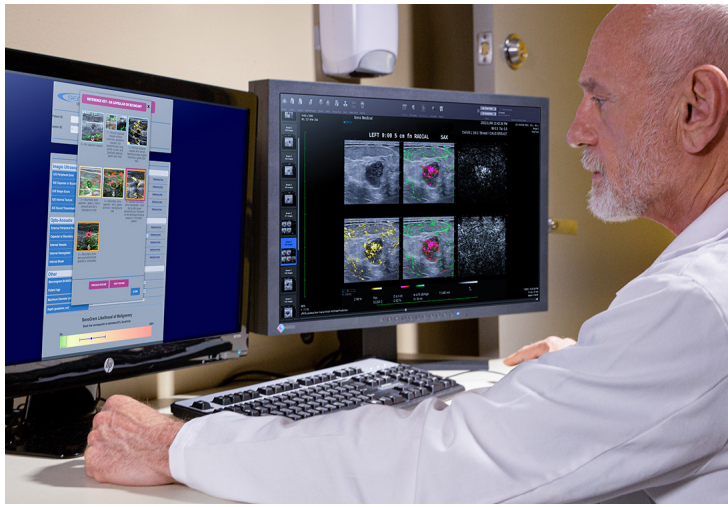
Imagio® with SenoGram® results in better precision and diagnostic confidence. This new modality enables clinicians to gain insights into the nature of a mass, supporting an earlier diagnosis of malignancy and greater specificity when assessing benign masses.

> **"This makes you a better radiologist, having more and deeper information. We can decide more certainly with this anatomic and functional information what is the right path for the patient."[8]**
>
> – Jeroen Veltman, MD, PhD
> MRON Radiologie Oost-Nederland

8. Kania, J. (2022) Opto-acoustic imaging: a new modality changing the future of breast imaging. *Radiology Business*. https://radiologybusiness.com/sponsored/57816/seno-medical/topics/medical-imaging/womens-imaging/breast-imaging/opto-acoustic

The SenoGram® AI decision-support tool, a core component of the Imagio® Breast Imaging System, increases reader accuracy in distinguishing benign from malignant masses.

SenoGram® enables readers to objectively and efficiently interpret the images produced using Imagio®, assess the likelihood of malignancy (LOM), and assign a more precise diagnostic BI-RADS. Using AI and machine learning, SenoGram® integrates findings from the OA/US exam with demographic variables to objectively and precisely calculate LOM.



In essence, **SenoGram® improves what breast imagers can achieve with their subjective assignments of LOM alone.** This technology addresses two key problems faced by readers. First, it reduces information overload that affects the LOM by combining fourteen variables from both the Imagio® scan and demographics in the estimate of LOM. Second, the SenoGram® AI is able to easily overcome discordances that frequently occur in breast masses and provide a "second set of eyes" for radiologists to provide additional precision and confidence in their assignments.[5]

In an independent, multi-reader pivotal study, readers achieved higher specificity at 98% sensitivity using SenoGram® compared to subjective assessments. Readers also reported greater confidence in their assignments of LOM and BI-RADS categories with SenoGram® decision support.[12] The outcome is better diagnosis through data and machine learning.

"By continuously learning from real-time patient data, these machine learning algorithms can adapt and improve their diagnostic accuracy, bringing us closer to a future where cancer is not only detectable at earlier stages, but also more effectively treatable."

– Yunus Abdussalam
Algorithm Engineer, Seno Medical

5. Fornell, D. (2023). Mismatch between radiologist shortages, rising exam volumes a growing concern in medical imaging. *Radiology Business*. https://radiologybusiness.com/topics/healthcare-management/healthcare-staffing/mismatch-between-radiologist-shortages-rising-exam-volumes-growing-concern-medical-imaging. **12.** Seiler, J. S., Neuschler, E. I., Butler, R. S., Lavin, P. T., & Dogan, B. E. Opto-acoustic imaging with decision support for differentiation of benign and malignant breast masses: a 15-reader retrospective study. *Amer J of Roentgenology*. https://www.ajronline.org/doi/abs/10.2214/AJR.22.28470

Michelle's Story

Michelle's journey towards seeking a conclusive diagnosis reflects the experience of many breast cancer diagnostics patients.

Her worry began when she noticed dried blood inside her bra. She made an appointment with her OB who recommended breast imaging right away. This began a frustrating and anxiety-provoking process to learn whether her mass was malignant as she first was referred to a diagnostic mammogram, followed by an ultrasound.

"I thought at least I'll have answers, but those results also came back as inconclusive. My breast specialist had never seen such vague and inconclusive results," Michelle said.

"Had I been able to avoid all the procedures and gone straight to this technology, that would have saved a lot of stress, time, and money."

– Michelle
Imagio® Breast Imaging System Patient

Michelle underwent several more diagnostic procedures, including an MRI that provoked discomfort and claustrophobia. When the MRI was also inconclusive, her breast specialist recommended a biopsy. However, she was warned that since the mass was small, it would be difficult to hit the target. Michelle was faced with the option of whether to do a potentially inconclusive and invasive biopsy or to wait and do imaging every six months—potentially delaying a critical cancer diagnosis. "It was definitely a stressful time—all the questions and uncertainty and not knowing what might be at the end of this road."

However, Michelle's breast specialist was able to offer the option of OA/US imaging using the Imagio® Breast Imaging System. After the scan, she received the good news that the likelihood of cancer was less than 2%. "It was a huge sigh of relief to know what we were dealing with and to be able to decide what to do going forward with that information," said Michelle. After such a long road with inconclusive results, knowing that her mass was most likely benign was the answer she had needed all along. "Had I been able to avoid all the procedures and gone straight to this technology, that would have saved a lot of stress, time, and money."

Imagio® can drastically shorten the pathway to conclusive diagnosis for patients like Michelle. It also eases the burden on clinicians by streamlining the diagnostic process and enabling them to more confidently and precisely classify a mass.

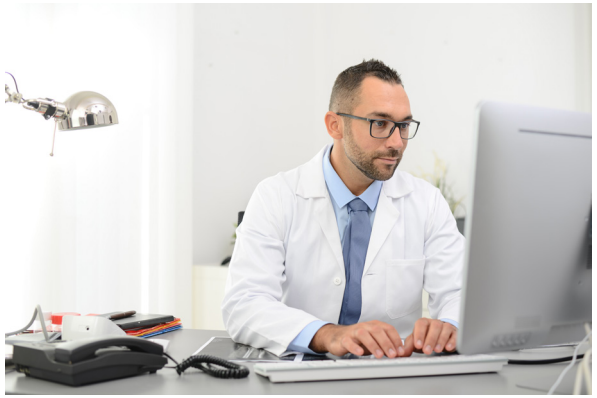
"The problem we have is that appearances alone aren't good enough. We need to look into the character [of the mass]. That's what OA/US does, it gives us insight we never had before," said Dr. Steven Harms, a breast imager with over 40 years of experience. In Michelle's case, the inconclusive features her clinician faced when examining her mass using mammography, US, and MRI were clarified using the Imagio® anatomical and functional images in combination with the SenoGram® AI decision-support tool. Dr. Harms continued, "We can reduce the false positives and pick up the false negatives that otherwise would have slipped through. That's why I'm so hopeful that this test is going to change breast imaging."

Michelle also hopes, through the use of Imagio®, more patients will avoid the anxiety and discomfort she experienced and receive a faster diagnosis. "I think if it were available for everybody, it would be so widely used and appreciated."

Impact on practice operations

Improve practice efficiencies and gain a competitive advantage.

In today's healthcare landscape where staffing shortages and high costs can make or break the bottom line, imaging centers are seeking ways to improve the patient and staff experience while also increasing efficiencies. Implementing Imagio® has a considerably positive impact on practice operations, capacity, and profitability.



Imagio® is more cost-effective than ultrasound in differentiating benign or malignant breast masses.[4] Utilizing Imagio® in the breast diagnostic pathway can create a favorable return on investment for breast centers by minimizing additional diagnostic testing.

It is estimated to result in a 46% reduction in first diagnostic imaging exams and a 60% reduction in unneeded second or third imaging exams.[1] The use of Imagio® eliminates time spent on exams that result in negative findings and costs related to unnecessary diagnostic workups.

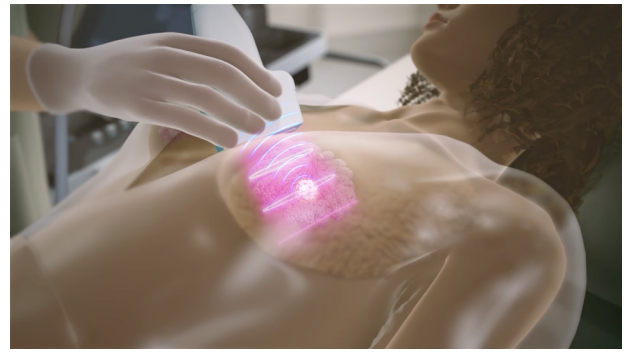
Case Study: Freestanding Breast Imaging Center*

Breast Imaging Volumes	Results Utilizing Imagio®
25,000 annual screens	—
4,625 annual workups	**43%** increase in positive biopsies
555 core biopsies	**31%** reduction in negative biopsies
	$116k net annual profit increase

*Seno Medical Economic Model, 2023

4. Ozcan, B. B., Xi, Y., & Dogan, B. E. (2024). Supplemental optoacoustic imaging of breast masses: a cost-effectiveness analysis. *Academic Radiology*, 31 (1), 121–130. https://doi.org/10.1016/j.acra.2023.08.042. **1**. Vlahiotis, A., Griffin, B., Stavros, A. T., & Margolis, J. (2018). Analysis of utilization patterns and associated costs of the breast imaging and diagnostic procedures after screening mammography. *ClinicoEconomics and Outcomes Research: CEOR*, 10, 157–167. https://doi.org/10.2147/CEOR.S150260

Imagio® enables staff to redirect their efforts to focus on exams that are more likely to find malignancies. It also improves the bottom line by decreasing workloads for staff and increasing satisfaction with their jobs, which is crucial in reducing burnout and turnover.[13]



Imagio® is at the cutting-edge of cancer diagnostics. This innovative technology is the first breakthrough in breast imaging since 3D mammography. It also costs less than MRI, positron emission mammography, and contrast-enhanced spectral mammography systems.[13] Furthermore, the potential future applications of OA/US imaging are promising, with studies showing that this technology may be a game-changer for diagnosing thyroid and prostate cancers.[14]

13. Thomas, A.J. (2021) How health systems are leveraging technology to improve talent recruitment, retention, and their bottom lines. https://hire.vivian.com/blog/how-health-systems-are-leveraging-technology-to-improve-talent-recruitment-retention-and-their-bottom-lines **14.** Jeesu, K., Min-Hee, K., Kwanhoon, J., Jeonghoon, H., Yongmin, K., Dong-Jun, L., Chulhong, K., Photoacoustic analysis of thyroid cancer in vivo: a pilot study, Proc. SPIE 10064, *Photons Plus Ultrasound: Imaging and Sensing*. 2017, 1006408 (3 March 2017); https://doi.org/10.1117/12.2251646

Investing in the Imagio® Breast Imaging System positions practices at the forefront of breast cancer imaging and diagnostic solutions and underscores their commitment to a positive patient experience.

"Especially in large markets and large cities, where hospital systems compete against each other, it's nice to be able to say that our radiology practice offers the newest technology, including cutting-edge opto-acoustic imaging," said Kenneth Kist, MD, a recently retired radiologist from UTHealth San Antonio, a participating center in a prospective, controlled multicenter study of OA/US imaging [ClinicalTrials.gov ID: NCT01943916].[8]

"When it comes to healthcare, women seek out technologies that can help them."[8]

– Kenneth Kist, MD
Retired Radiologist
UTHealth San Antonio

8. Kania, J. (2022) Opto-acoustic imaging: a new modality changing the future of breast imaging. *Radiology Business*. https://radiologybusiness.com/sponsored/57816/seno-medical/topics/medical-imaging/womens-imaging/breast-imaging/opto-acoustic

Imagio® is a powerful option that is also easy to adopt with minimal requirements at your location.

The process of incorporating Imagio® into your workflow is similar to how you implemented tomosynthesis into your practice. Seno Medical offers a robust platform that provides training in usage and in reading imaging exams, developed by a world-leading breast ultrasound expert, Dr. A Thomas Stavros. Clinicians noted the ease of use following training. Thanh Van, MD, a breast radiologist at UT San Antonio stated, "Once you scan a few patients, say five or six, you get the feel of the system and gain confidence in what you are seeing in the images." Dr. Veltman added, "[OA/US] interpretation we need to learn, but using the SenoGram® makes it remarkably easy. It makes you better, correlating acoustics and ultrasound. Scanning is easy and quite robust. I was surprised at how quickly you get good."[8]

"...using the SenoGram® makes it remarkably easy. It makes you better, correlating acoustics and ultrasound."[8]

– Jeroen Veltman, MD, PhD
Breast Radiologist within MRON
Radiologie Oost-Nederland

8. Kania, J. (2022) Opto-acoustic imaging: a new modality changing the future of breast imaging. *Radiology Business*. https://radiologybusiness.com/sponsored/57816/seno-medical/topics/medical-imaging/womens-imaging/breast-imaging/opto-acoustic

The system includes ongoing product support, software updates, and equipment servicing packages.

Seno Medical has also created a complete toolkit for adoption to raise awareness in the marketplace and sensitize staff, with an activation plan and timeline, communications targeting patients and clinicians, and marketing materials.

Summary

The current diagnostic pathway for breast cancer poses challenges for patients and practices alike. Clinicians, constrained by existing technologies, face difficulties in confidently diagnosing malignancies with precision. Patients with a positive screening frequently undergo extensive and unnecessary diagnostic procedures, with as many as 75% of biopsies proving benign. This inefficient process strains the health workforce and costs the U.S. healthcare system billions of dollars a year.

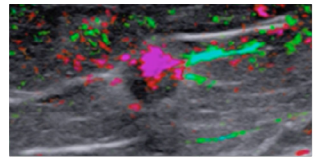
The Imagio® Breast Imaging System offers an innovative solution. **Using light, sound, and artificial intelligence (AI), Imagio® enhances diagnostic sensitivity and specificity and reduces additional diagnostics.** The integration of opto-acoustic and ultrasound technologies provides anatomical, morphologic, and functional insights into breast masses, enabling clinicians to confidently differentiate between benign and malignant lesions.

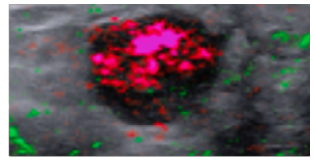
Supported by the SenoGram® decision-support tool, Imagio® empowers radiologists with greater diagnostic accuracy.

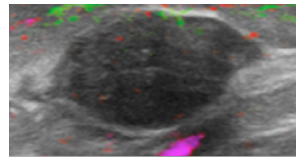
Incorporating Imagio® results in increased efficiency and effectiveness in diagnosing breast cancer, improved patient experiences, and reduced costs to imaging centers and the healthcare system.

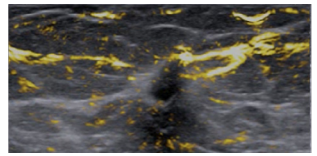
Take the next step in the evolution of breast cancer diagnostics with the Imagio® Breast Imaging System.

This is a critical moment in breast cancer screening and diagnosis. The Imagio® Breast Imaging System offers solutions that patients and practices have been looking for—increased confidence in diagnosis, a less arduous diagnostic pathway, and better outcomes for patients and staff.


Luminal B Cancer


Triple Negative Cancer


Fibroadenoma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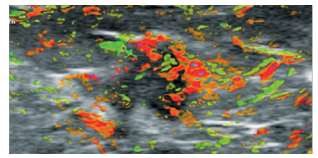
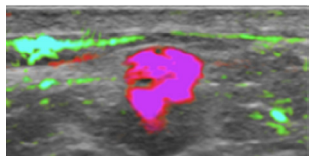

HER 2+ Cancer


Fibrocystic Inflamed Cyst

To learn more or request a demo, contact:

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