Imagio®
Breast Imaging System

Transforming Breast Cancer Diagnostics with Light, Sound, and Artificial Intelligence

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 new 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.

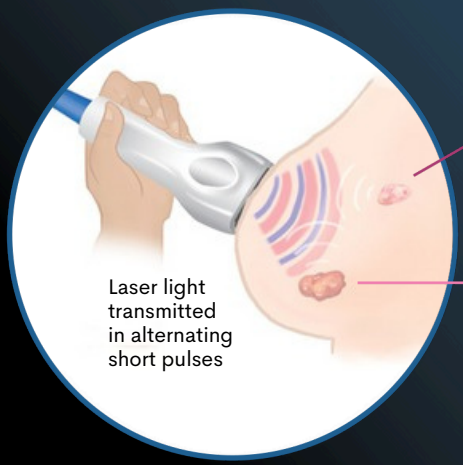
It is the **only FDA-approved OA imaging device** in the U.S., integrating laser optic images with high-quality ultrasound breast imaging in one.

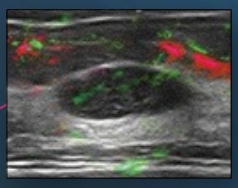
How Does Imagio® Work?

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

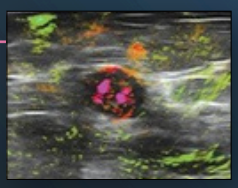
The result is a real-time functional scan of the area of concern without injections. Clinicians are now able to differentiate malignant from benign in masses as small as 3.5 mm.1 Imagio® is suitable for the assessment of Breast Imaging Report & Data System (BI-RADS) classifications 3, 4a, and 4b when used with adjunctive screening modalities or palpable masses.

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





Benign growth has variable blood concentration with normal oxygen content.



Malignant tumor has increased blood concentration with decreased oxygen content.

Why Is OA Imaging Effective?

Functional information generated through OA imaging has direct correlation to tumor histopathology and supports a clinician's decision-making as to a lesion's risk of malignancy and the need for biopsy. Recent multicenter clinical studies of the **Imagio® Breast Imaging System** demonstrated the following2:

- Greater confidence in determining whether a mass is benign or malignant.
- Increased specificity to more than 50 percent,3 with no significant loss of sensitivity.
- Better visualization of presence, absence, and morphology of tumor neoangiogenesis than mammography or CDU.
- Downgrade of BI-RADS 3, 4a, and 4b masses in many cases.
- Superiority over ultrasound alone to reduce the need for biopsy or short interval follow-up imaging in masses classified as BI-RADS 3 or higher by ultrasound.

All this culminates in a more patient-centric technology with a shorter, less invasive pathway to definitive diagnosis and without ionizing radiation or contrast injections.

Considerable Benefits to Patients

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, multicenter, 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 Imagio®], 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," according to Dr. Basak Dogan, MD, Director of Research at UT Southwestern Medical Center's Harold C. Simmons Comprehensive Cancer Center.4

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.4,5

Reversing the Biopsy Ratio

Without Imagio®
3 negative biopsies for only 1 positive biopsy

VS.

With Imagio®
Only 1 negative biopsy for every 3 positive biopsies

Scan to learn more!

1. PIONEER Clinical Study Report. 2. Results from MAESTRO Study of BI-RADS 4a and 4b. 3. Results from Reader-02 Study. 4. 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 5. 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:10, 157–167. https://doi.org/10.2147/CEOR.S150260

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