

Imagio® Breast Imaging System

A New Hybrid Modality to Improve the Breast Cancer Diagnostic Process

The Imagio® Breast Imaging System combines laser light and sound with conventional ultrasound technology to provide fused functional and anatomic images (referred to as opto-acoustic/ultrasound or OA/US) in real time, increasing confidence in diagnostic accuracy.

HOW DOES IT WORK?

The Imagio® System incorporates traditional b-mode gray-scale ultrasound images with patterns of laser light absorption, creating color maps of oxygenated and deoxygenated blood, as well as hemoglobin concentration. This combination of hemoglobin and its relative oxygenation has been shown to have good diagnostic accuracy.¹

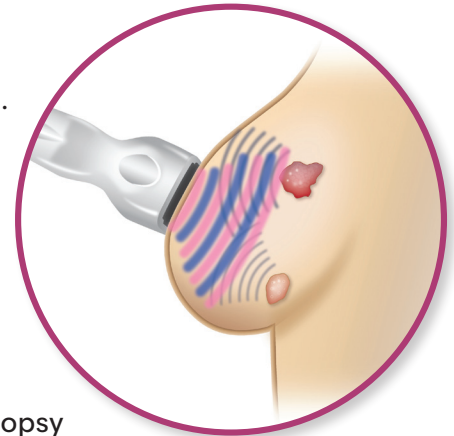
With the OA/US breast imaging system, clinicians have been able to identify and classify tumors as small as 3 millimeters, as well as visualize submillimeter vascular structures.

WHY IS IT EFFECTIVE?

Functional information generated through OA/US technology 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 multi-center 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 percent³, 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, respectively.
- Superiority over ultrasound alone to reduce the need for biopsy or short interval follow-up imaging in masses classified as BI-RADS 3 by ultrasound.



Two wavelengths of laser light enable the evaluation of the relative difference between the oxygenation and deoxygenation of blood.

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.

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BRINGING NEW LIGHT TO DIAGNOSTIC CONFIDENCE™

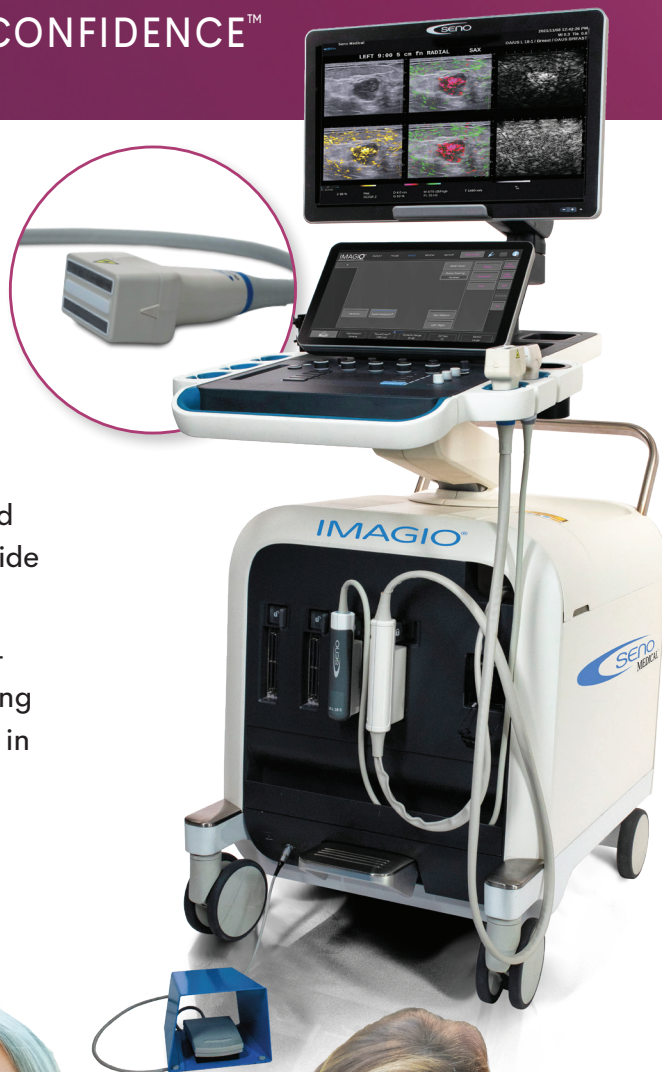
ABOUT THE IMAGIO® BREAST IMAGING SYSTEM

The Imagio® Breast Imaging System is a functional fusion imaging modality that improves the breast cancer diagnostic process, featuring:

- A single, dual-purpose diagnostic imaging device that can perform standard b-mode gray-scale ultrasound independently or in combination with opto-acoustics.
- Detailed, high-resolution OA/US six-on-one color maps and images that can be acquired and viewed in real time to provide more confidence in classifying benign or malignant lesions.
- Artificial Intelligence machine learning decision support - SenoGram® - assists the radiologist in objectively assigning the probability of malignancy, providing greater accuracy in distinguishing benign from malignant masses.³

REFERENCES

1. *Academic Radiology* 2005; 12:925-933
2. Results from MAESTRO Study of BI-RADS 4a and 4b
3. Results from Reader-02 Study



8023 Vantage Drive,
10th Floor, Suite 1000
San Antonio, TX 78230
Phone (210) 615-6501
www.senomedical.com

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For more information, please contact Sales and Marketing at (210) 615-6501
Imagio® Breast Imaging System (9100) PMA approved 2022. Pending CE Mark.

MKTG 1246 C 11022023