

A Brighter Future for Breast Biopsy

Affirm® Contrast Biopsy combines contrast-enhanced diagnostic capabilities with accurate lesion targeting in one seamless workflow for an efficient breast biopsy procedure.



Affirm Contrast Biopsy software*, in combination with I-View™ Contrast-Enhanced Mammography technology and the Affirm Upright Breast Biopsy Guidance System, offers **the Complete Contrast Biopsy Solution designed to maximise workflow efficiency whilst delivering compassionate patient care.**

III I-View™ 2.0 Contrast Enhanced Imaging

Turn the invisible into the visible with I-View 3-in-1 Contrast-Enhanced Imaging software. Allowing you to leverage the ability to provide 2D, contrast-enhanced, and tomosynthesis images under one compression,¹ increasing diagnostic confidence to help guide the clinical pathway from diagnosis to surgical management.

Affirm® Breast Biopsy Guidance System

Transition from screening to 2D or 3D™ interventional procedures for optimal system versatility with this simple add-on to any Hologic 3D Mammography system. Enabling you to confidently biopsy even the faintest calcifications.²

Affirm® Contrast Biopsy

Target and acquire breast tissue identified with CEM and simplify the breast biopsy process, even for the most challenging lesions.² Deliver a more efficient breast biopsy procedure with the combination of I-View Contrast-Enhanced Imaging, and the Affirm Upright Breast Biopsy Guidance System.^{2,3}

The Complete Contrast Biopsy Solution

Experience greater diagnostic information during breast biopsy procedures with one seamless workflow.^{3,4}

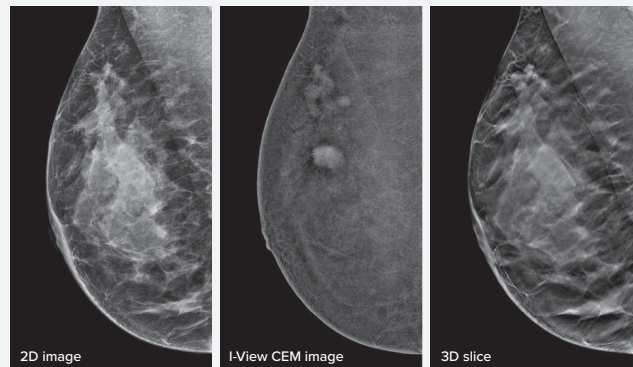
I-View™ Contrast Enhanced Imaging

Enhance the imaging of suspicious lesions and expedite the diagnostic process with contrast-enhanced mammography.^{3,4,5}

Following an injection of iodinated contrast agent,¹ the 3Dimensions™ or Selenia® Dimensions® Mammography System with I-View imaging technology acquires high and low energy images. The CEM images show regions of abnormal blood flow while the background breast parenchyma is subtracted. Consistent distinction between lesions and background using CEM may reduce unnecessary biopsies, especially in dense breasts.^{6,7}

With the I-View software you can combine the power of CEM with 2D and tomosynthesis images all in one compression to provide anatomical and functional imaging, all in one exam.⁵

CEM compares favourably to breast MRI with similar sensitivity, higher specificity, and higher positive predictive value.^{6,7}

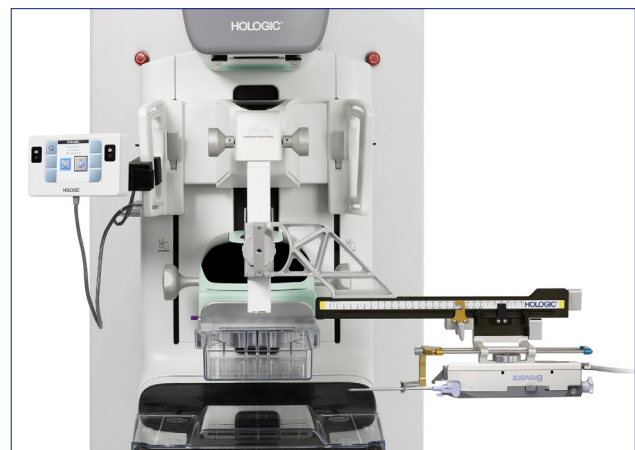


I-View: 3-in-1 Contrast-Enhanced Mammography Imaging

Affirm® Upright Breast Biopsy Guidance System

Increase your breast biopsy capabilities and pinpoint subtle lesions with the Affirm Upright Breast Biopsy Guidance System.²

The Affirm Upright Breast Biopsy Guidance System is designed to integrate with any 3Dimensions or Selenia Dimensions mammography system, providing you with a fast and efficient biopsy procedure.² Plus, the Affirm Lateral Arm accessory enhances your access to a wide range of challenging lesions, enabling you to address them quickly, easily and confidently.^{2,8}



Affirm Upright Breast Biopsy Guidance System with Affirm Lateral Arm



Affirm® Contrast Biopsy

Exceptional clinical detail and sensitivity,
for breast biopsy with more visibility.

Affirm Contrast Biopsy combines the benefits of enhanced lesion visualisation using CEM with the immediate biopsy targeting and acquisition of breast tissue - all in one streamlined process in the mammography suite, supported by familiar technology.³ The Complete Contrast Biopsy Solution is designed to maximise workflow efficiency, whilst simplifying the breast biopsy process,** even for challenging lesions.

Affirm Contrast Biopsy provides a time-saving and cost-effective alternative to magnetic resonance imaging (MRI)-guided biopsy, for an improved patient experience.^{4,6,7}

	Faster screening time	Reduced cost and easier to authorise	Better patient experience
CEM	8-20 min. imaging. 30 min. room time.	25% of the cost of MRI ⁴ Can be ordered immediately without pre-authorization.	79% of patients prefer CEM over MRI ⁹ same positioning as standard mammogram.
MRI	30-60 min. imaging. 60-90 min. room time. ¹⁰	Only 58% compliance ¹¹ - Time-consuming for pre-authorization insurance process.	Extended time in one position in loud gantry.



BIOPSY WITH CONTRAST

Target and biopsy lesions identified with 2D contrast-enhanced mammography through a stereotactic-based procedure, with a comparable diagnostic performance to breast MRI procedure.^{12,13} Compare post-marker images in the same modality as the initial diagnostic contrast exam.



EFFICIENT CLINICAL WORKFLOW

Improve the diagnostic experience by conducting the biopsy in the same room as the diagnostic imaging. Combining Affirm Contrast Biopsy software with the Affirm Upright Guidance System provides a familiar workflow, due to similarities with stereotactic biopsy.



IMPROVED PATIENT EXPERIENCE

Improve the patient experience with a shorter procedure time, higher tolerability and accessibility compared to breast MRI.^{13,14} Patients experience the familiarity of the same room and equipment used during their diagnostic mammogram.

With over 30 years of Breast & Skeletal Health expertise, Hologic's interventional products are designed to work together as a complete set of breast biopsy solutions to help you improve efficiency, optimise the patient experience, and deliver the best outcome possible.

Commercial Part Numbers	
DIM-LIC-ACB-UP	Affirm® Contrast Biopsy license - upgrade
DIM-LIC-IVIEW-ACB	I-View 2.0 and Affirm Contrast Biopsy license bundle
DIM-LIC-IVIEW-ACB-UP	I-View 2.0 and Affirm Contrast Biopsy license bundle – upgrade
DIM-LIC-TRIAL-ACB	Affirm Contrast Biopsy license – trial
STLC-00004	Affirm Upright Biopsy guidance system
ASY-09880	Affirm Upright Lateral Arm

System requirements

- Selenia® Dimensions® or 3Dimensions® Mammography System with 1.11/2.2 (or later) software version
- I-View™ 2.0 (or later) software license & hardware (copper filter)
- Affirm Upright Breast Biopsy Guidance System
- Affirm Contrast Biopsy software license

Optional: Affirm Lateral Arm biopsy guidance accessory

Additional requirements

- Contrast power injector: single or dual head
- Contrast reaction kit

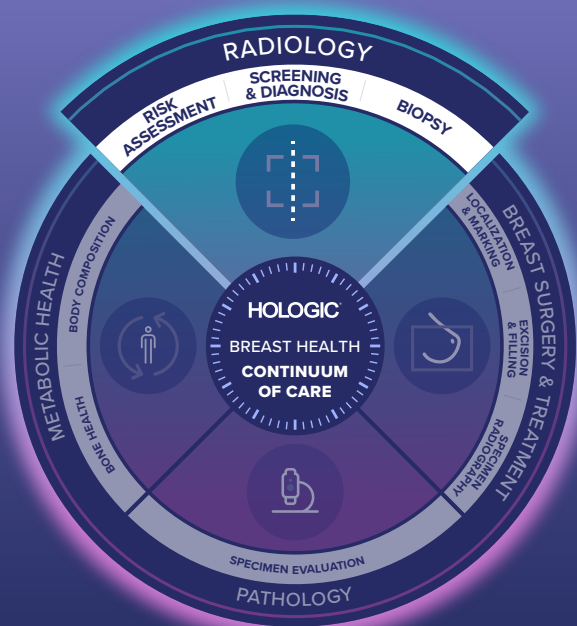
For additional details please contact your local Hologic representative.

Hologic's Breast Health Continuum of Care

At Hologic, we know time is critical when it comes to the detection, diagnosis and treatment of breast cancer. We strive to save you time at every step along the Breast Health Continuum of Care.

Our pioneering, integrated technologies help you deliver maximum clinical confidence, workflow efficiencies, and an enhanced patient experience to advance the earlier diagnosis of breast cancer.

Hologic, your trusted Breast and Skeletal Health partner.



References: 1. Chou C, Lewin J, Chlang C et al. "Clinical Evaluation of Contrast-Enhanced Digital Mammography and Contrast Enhanced Tomosynthesis-Comparison to Contrast-Enhanced Breast MRI" Eur J Radiol. 2015 Dec; 84(12):2501-8. [Epub 2015 Oct]. 2. Schrading S, Martine D, Dirrichs T, et al. "Digital Breast Tomosynthesis-guided Vacuum-assisted Breast Biopsy: initial Experiences and Comparison with Prone Stereotactic Vacuum-assisted Biopsy." Radiology. 2015 274:3, 654-662 E-pub 2014 Nov 12. 3. PLN-10394_001_01 – Affirm Contrast Biopsy Study.pdf. 4. Patel BK, Gray R, Pockaj BA, et al. Potential Cost Savings of Contrast-Enhanced Digital Mammography. AJR Am J Roentgenol. 2017;208(6):W231-37. 5. Burhenne LJW, Wood SA, D'Orsi CJ, et al. Potential Contribution of Computer-aided Detection to the Sensitivity of Screening Mammography. Radiology 2000; 215:554-562. 6. Li L, Roth R, Germaine P, et al. Contrast-enhanced spectral mammography (CESM) versus breast magnetic resonance imaging (MRI): A retrospective comparison in 66 breast lesions. Diagnostic and interventional imaging 2017;98(2):113-123. 7. Xing D, Lv Y, Sun B, et al. Diagnostic Value of Contrast-Enhanced Spectral Mammography in Comparison to Magnetic Resonance Imaging in Breast Lesions. J Comput Assist Tomogr 2019;43(2):245-251. 8. Affirm Breast Biopsy Guidance System v1.11-2.2 User Guide. MAN-06411-002, Rev 003 2021. 9. Phillips J, Miller MM, Mehta TS, et al. Contrast-enhanced spectral mammography (CESM) versus MRI in the high-risk screening setting: patient preferences and attitudes. Clin Imaging. 2017;42:193-197. 10. [https://radiologyinfo.org/en/info/breastmr=](https://radiologyinfo.org/en/info/breastmr/) (accessed 30 January 2022). 11. Berg WA, Blume JD, Adams AM, et al. Reasons women at elevated risk of breast cancer refuse breast MR imaging screening: ACRIN 6666. Radiology. 2010;254(1):79-87. 12. Alcantara R, Posso M, Pitarch M et al, Contrast-enhanced mammography-guided biopsy: technical feasibility and first outcomes. Eur Radiol. 2023 Jan;33(1):417-428. 13. Kamal R, Mansour S, Farouk A et al, Contrast-enhanced mammography in comparison with dynamic contrast-enhanced MRI: which modality is appropriate for whom?, Egypt J Radiol Nucl Med 52, 216 (2021). 14. Hobbs MM, Taylor DB, Buzynski S, et al. Contrast-enhanced spectral mammography (CSEM) and contrast-enhanced MRI (CEMRI): Patient preferences and tolerance. J Med Imaging Radiat Oncol. 2015;59(3):300-305.

*Affirm Contrast Biopsy software not CE marked. Not available for sale in Europe.
**Compared to MRI procedures.

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