

Turn the invisible into the visible.

I-View[®] 2.0 Contrast Enhanced Mammography Software

Create comprehensive diagnostic studies that reveal exceptional clinical detail and sensitivity with Contrast Enhanced 2D imaging (CEM). Contrast Enhanced 2D imaging and past 3D[™] mammography studies can be viewed to help identify cancers.



Diagnostic Performance

Increase diagnostic confidence to help guide the clinical pathway. Contrast enhanced mammography provides equivalent diagnostic performance to contrast breast MRI.^{1,2}

Expanded Capabilities

Offering contrast enhanced mammography exams expands your capabilities using existing mammography equipment.

Patient Experience

Patients greatly prefer contrast mammography over bMRI, for reasons such as faster procedure time, greater comfort, lower anxiety, and lower noise level.³

III I-View[®] 2.0 Contrast Enhanced Mammography

More diagnostic information, one seamless workflow.

The Selenia® Dimensions® and 3Dimensions® systems acquire high and low energy images and show regions of abnormal blood flow by subtracting the background breast parenchyma.

I-View 2.0 contrast enhanced mammography (CEM) software is a simple upgrade to any Selenia Dimensions or 3Dimensions system, giving breast imaging practices an efficient pathway to expanded diagnostic capabilities.

	CEM vs. MRI		
	Faster Screening Time	Patient Impact	Better Patient Experience
MRI	30-60 minutes imaging time 60-90 minutes room time ⁴	Only 58% compliance ⁵ ; time- consuming for pre-authorization insurance process	Extended time in one position in loud gantry
CEM	8-20 minutes imaging time 30 minutes room blocking time	25% of the cost of MRI ⁶ ; radiologists can order immediately without pre-authorization	79% of patients prefer CEM over MRI ⁷ ; same positioning as standard mammogram

See I-View 2.0 CEM requirements on page 4.

The Future of Biopsy Is Now Brighter Affirm[®] Contrast Biopsy software

Affirm Contrast Biopsy is an optional software license for Hologic's Selenia Dimensions and 3Dimensions systems for use with the Affirm breast biopsy guidance system and I-View 2.0 CEM software. Affirm Contrast Biopsy allows clinicians to target and acquire tissue samples in lesions identified with contrast enhanced mammography (CEM) where a correlate may not be found on a FFDM, DBT or ultrasound image. Contrast enhanced 2D images are utilized for stereotactic targeting following an IV injection of an iodinated contrast agent.







Biopsy with Contrast

- Affirm Contrast Biopsy allows you to target and acquire tissue samples in lesions identified in contrast enhanced mammography.
- Biopsy and compare post-marker images in the same modality as the initial diagnostic contrast exam
- Select multiple targets in the breast if more than one lesion requires biopsy.

Efficient Workflow

- Familiar workflow similar to stereotactic biopsy
- Biopsy with a lateral approach with the optional Affirm lateral arm biopsy accessory.
- Procedures can be performed using Hologic's ATEC®, Eviva®, or Brevera® breast biopsy devices.
- Experience ease of scheduling for the mammography suite

Patient Experience

- May be better tolerated than an MRI contrast biopsy⁸
- Patients experience familiarity of the same room and equipment from the diagnostic mammogram
- Patient's may experience familiarity and continuity of care following prior examinations





Affirm Contrast Biopsy Workflow

The optimal imaging window is approximately 2 to 8 minutes post injection.



I-View 2.0 CEM Software

Includes

- I-View CEM software license (single gantry)
- Copper filter
- One day of hands-on training including patient examinations. Additional online training is available on HologicEd.com.

Requirements

- Selenia Dimensions or 3Dimensions system with minimum 1.10/2.1 software on Windows 10 OS*
- Diagnostic license for the Dimensions system
- HDT (high definition) detector (standard or high-resolution)

Affirm Contrast Biopsy Software

Includes

- Affirm Contrast Biopsy software license
- One day of hands-on training including patient examinations. Training is provided after an imaging center is experienced with both CEM and the Affirm biopsy system.

Requirements

- Selenia Dimensions or 3Dimensions system with minimum 1.11/2.2 software
- Affirm breast biopsy guidance system and license
- I-View 2.0 CEM software and hardware (copper filter)

*Although sites may start by offering only CEM, consider adding the license to the same gantry used with the Affirm upright biopsy system. This will simplify implementation of ACB at a later date as both CEM and the Affirm system must be on the same gantry. References:

1. Chou C, Lewin J, Chiang 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(2):2501-8. [Epub 2015 Oct 1]. 2. Jochelson M, Dershaw D, Sung J, et al., Bilaterial contrast-enhanced dual-energy digital mammography; feasibility and comparison with conventional digital mammography and MR imaging in women with known breast carcinoma, Radiology 266 (3) (2013) 743–751 3. Hobbes M, Taylor D, Buzynski S et al. "Contrast-enhanced and contrast enhanced MRI (CEMRI): Patient preference and tolerance" J Med Imaging Radiat Oncol. 2015 Jun;59(3):300-5. [Epub 2015 Apr 21]. 4. https://www.radiologyinfo.org/en/info.cfm?pg=breastmre 5. Berg, WA, et al. Reasons Women at Elevated Risk of Breast Cancer Refuse Breast MR Imaging Screening: ACRIN 6666, Radiology Jan 2010. 6. Patel BK., et al, Potential Cost Savings of Contrast-Enhanced Digital Mammography. AJR Apr 2017. 7. Phillips J, et al., Contrast-enhanced Spectral mammography (CESM) versus MRI in the high-risk screening setting: patient preferences and attitudes. Clin Imaging. Mar - Apr 2017. 8. Kaur, Piccolo, Arasaratham. Implementation of Contrast-Enhanced Mammography in Clinical Practice, chapter 7, Nori, Kaur (eds.), *Contrast-Enhanced Digital Mammography (CEDM)*. Springer, 2018. FDA clearance: KI23873 and K202294

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