US

GE Healthcare

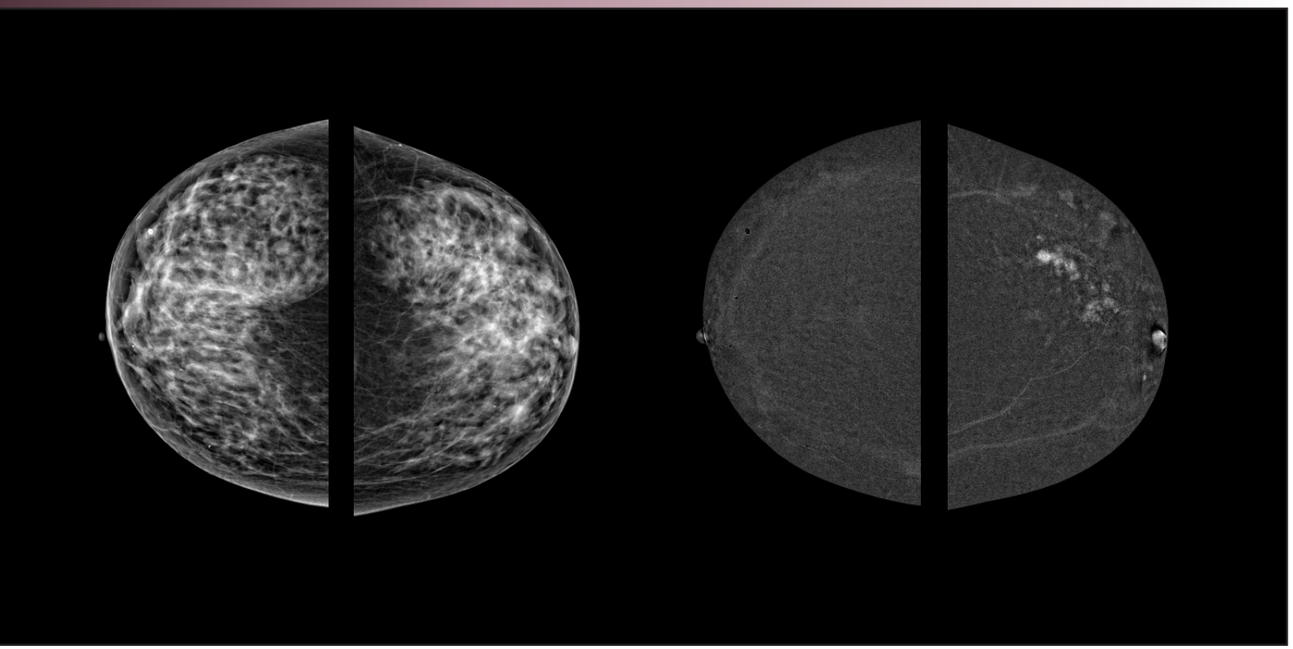
SEE DIFFERENTLY
SEE IN **CONTRAST**

Seno**Bright**™ HD

Contrast Enhanced Spectral Mammography

gehealthcare.com/SenoBright

SenoBright™ HD Contrast Enhanced Spectral Mammography



A gold standard at your fingertips

Mammography is the most reliable imaging technique for breasts, but limitations can exist due to breast density. This is especially the case in dense breasts where tissues may overlap.

For a final diagnosis, radiologists often need complementary imaging, such as breast MRI. However, these modalities can present other challenges (access, contra-indication, waiting list, cost, etc). At GE, we introduced Seno**Bright**™ HD to enable fast, clear decisions when an exam is inconclusive. Using Seno**Bright** HD helps you remove uncertainty.

Provide answers to your patients right away and help them avoid the agonizing wait they face when they get an inconclusive exam.

Seno**Bright** HD Contrast-Enhanced Spectral Mammography from GE Healthcare

BREAST CARE PATH ENHANCEMENT

Increase your diagnostic confidence

With Seno**Bright** HD the image you need is never out of reach.

Women with dense breasts are at increased risk of breast cancer, so you cannot settle for uncertainty. You need complementary imaging solutions that deliver better visualization of breast lesions.

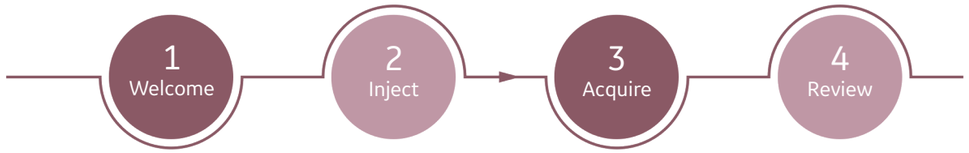
Seno**Bright** HD offers the confidence of MRI with fewer costs overall and it enables you to free up your center's prize modality for those who really need it.

Furthermore, its high specificity helps you reduce unnecessary biopsies and surgeries and it's brilliant when contraindications arise, access is a challenge, or you simply need a faster turnaround.

A SIMPLE USE

How can you easily implement Seno**Bright** HD in your clinical routine

Four simple steps



An intravenous iodine injection is performed on the patient in the same room as the mammogram exam. Four customary mammography views are acquired 2 minutes after the iodine has been injected. There is no need to change the setting or imaging equipment.

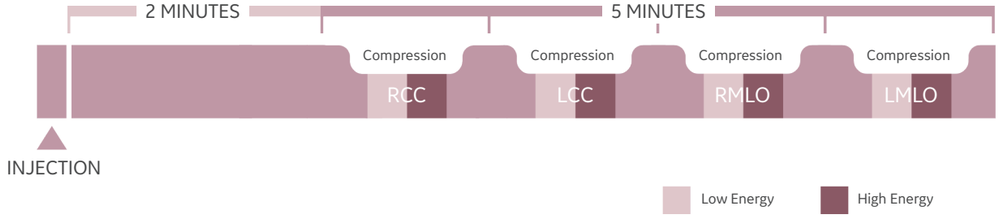
The four standard mammographic views are acquired on the same mammographic system. The entire exam takes less than seven minutes and the images are available for immediate review by the radiologist.

With Seno**Bright** HD the image you need is never out of reach.

The images stack up

With Seno**Bright** HD, nothing needs to be lost in translation. Strikingly simple images allow other clinicians to see just as you see, giving your report a mental replay whenever the ultra-clear Seno**Bright** HD image stack is accessed.

It's the no-nonsense picture that's accessible to everyone, enabling sure, shared and supportive steps forward. After an inconclusive mammogram and ultrasound, the exam lasts less than 7 minutes.

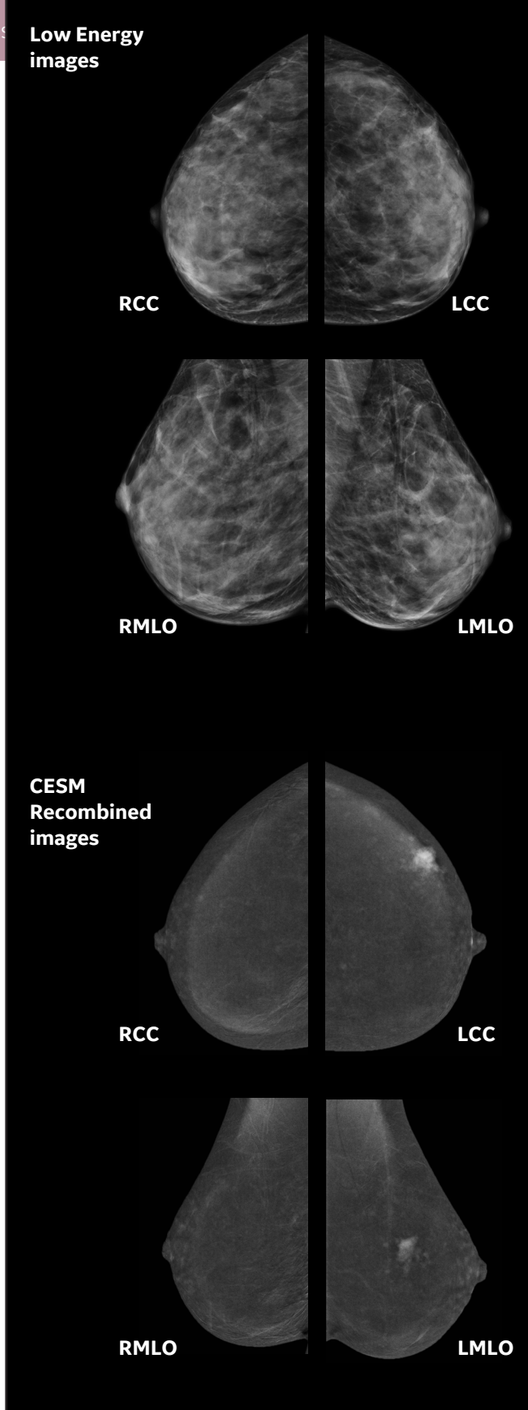


Exceptionally clear visualization

The Seno**Bright** HD contrast agent highlights areas of unusual blood flow.

Seno**Bright** HD uses multiple x-ray exposures to reduce background signal, effectively highlighting contrast enhanced areas.

Two images per view are provided.
A standard mammographic image and the recombined image in the exact position'
(not all images are enhanced, if there is no lesion, there is no contrast enhancement).



Increase your diagnostic confidence

Localize known or suspicious lesions with iodine contrast

High specificity:
Seno**Bright** HD provides high specificity to reduce false-positives and help prevent unnecessary exams.

High sensitivity:
Seno**Bright** HD delivers high sensitivity for more accurate breast cancer diagnosis and help prevent unnecessary exams

Clear image quality:
Seno**Bright** HDdelivers clear images to enhance diagnostic confidence with an exam performed within 10 minutes.

This compares us to ourselves, and the recent study has shown that our acquisition time is much longer than HOX. This claim is only for Essential IB asking us about acquisition time on Pristina.

Transform your patients' experience

Reduce patient anxiety by providing a diagnosis in one appointment, one setting

When a woman receives an inconclusive mammogram result, every minute waiting for definitive answers seems like an eternity.

By performing a Seno**Bright** HD exam at the same time as a mammogram, in the same room, with the same equipment, you can help eliminate waiting times, lengthy exams and contraindications to breast MRI – sparing your patients additional emotional, physical and financial burdens. Provides peace of mind.

Two out of three patients prefer the Seno**Bright** HD experience to a breast MRI, with faster procedure time, greater comfort, lower noise level and lower rates of anxiety[1].

Free-up time and reduce diagnosis costs

Benefit from an affordable complementary exam that reduces unnecessary exams and frees up time on your other imaging systems.

SenoBright HD is a less expensive alternative diagnostic method. Its high specificity helps you reduce unnecessary biopsies and surgeries, while freeing up MRI time for other exams.

SenoBright™ HD Contrast Enhanced Spectral Mammography

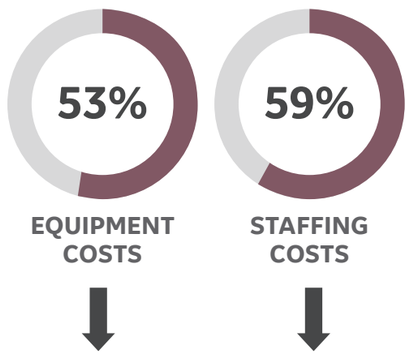
Enhance productivity and grow your bottom line

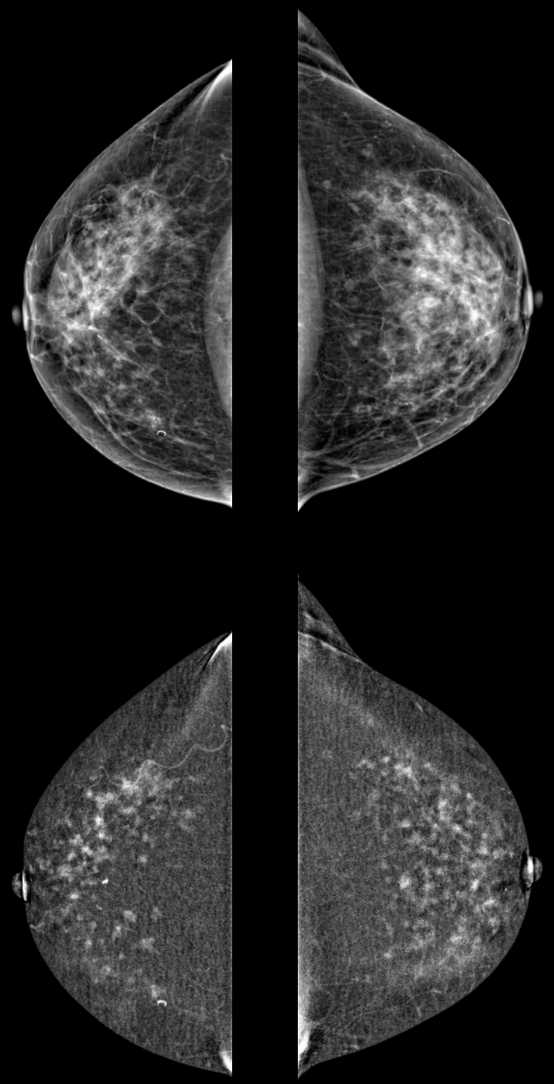
Augment clinical capabilities

Facilities without an MRI don't need to invest in expensive technology or refer patients outside your health system. SenoBright HD is a cost-effective alternative to help you reach a confident diagnosis.

Alleviate strains on budget

Providers with MRI systems can reduce staffing costs and free up valuable MRI time for other procedures. Research indicates a 53% reduction in equipment costs in addition to 59% reduced staffing costs compared to breast MRI[2].





Higher clarity at optimized dose

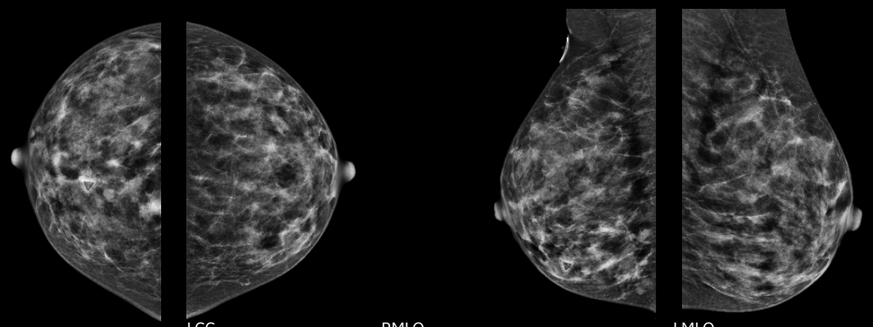
On Senographe Pristina, the Automatic Optimization of Parameters (AOP) selects the appropriate mAs based on radiological density and breast thickness. Seno**Bright** HD delivers a personalized and optimized radiation dose based on the breast glandularity. Because we are as committed to your patients' wellbeing as you are.

SenoBrightHD Contrast Enhanced Spectral Mammography

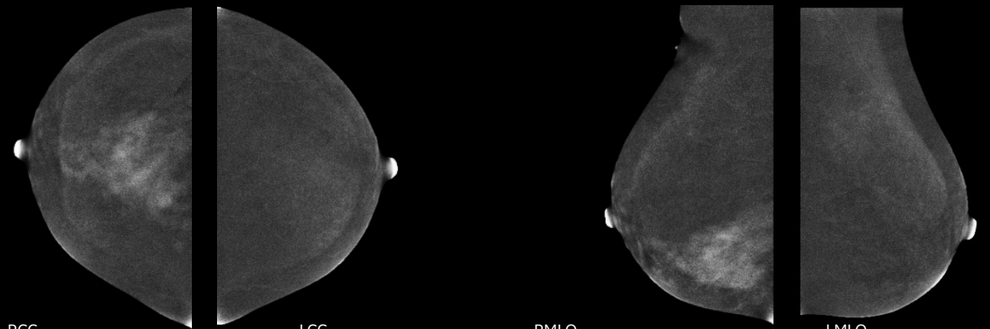
CLINICAL CASES

Invasive Ductal Carcinoma

CESM Low energy images



CESM images



History

Patient presented for a baseline with palpable right breast lump. Heterogeneously dense nodular tissue with regional amorphous calcifications and 4-5 discrete masses. Multiples findings on ultrasound. A CESM was recommended.

Technique

Injection : Iodine Contrast volume : 95 ml injected at a flow rate of 3ml/sec with pressure injector.
Acquisition: 4 standard mammographic views.

CESM Results

CESM showed a large area of enhancement in the lower inner quadrant (CESM images).

Conclusion

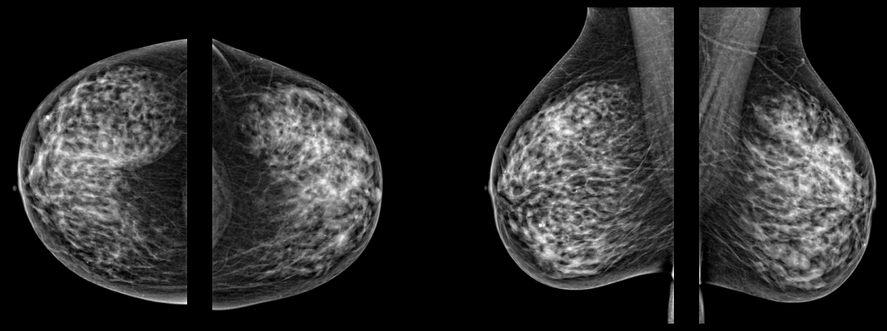
Ultrasound biopsy was performed and yielded multiple invasive ductal carcinoma pathologies.

SenoBrightHD Contrast Enhanced Spectral Mammography

CLINICAL CASES

Case Solving: Positive

CESM Low energy images



RCC LCC RMLO LMLO

Low-energy images

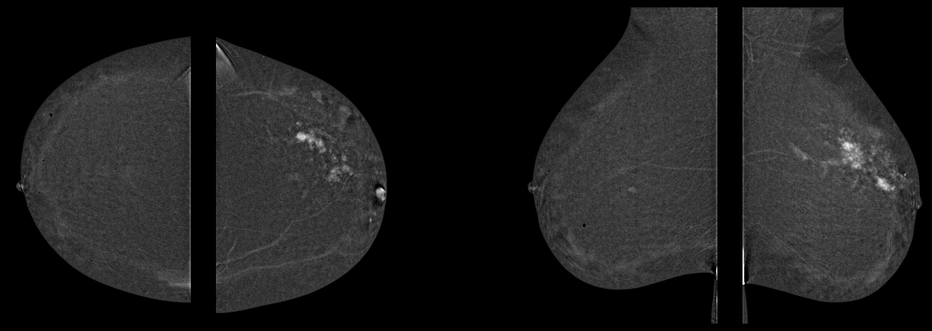
Left: focal asymmetry (with clip at biopsy site) and diffuse calcifications.

Right: diffuse calcifications.

Clinical comments

The area of suspicious enhancement has diminished greatly since the prior exam. It involved over 11cm of tissue on the prior per-treatment study. There is patchy enhancement over ~7.5cm now but the enhancement is much less confluent, indicating significant response to therapy.

CESM images



RCC LCC RMLO LMLO

CESM Results

Left: contrast uptake well depicting the extent of the lesion.

Right: no significant enhancement.

Pathology

Lesion classification: Malignant other

Pathology: Unknown

GE Healthcare

Serena **Bright**™

Contrast Enhanced Guided Biopsy

See and biopsy what matters

Don’t Seek. Biopsy with certainty with Serena **Bright**™

You know Seno**Bright** HD contrast enhanced spectral mammography is a next level mammography technology that offers an astonishingly clear way of seeing what matters in the breast. It subtracts the fibroglandular tissue that can cloud your view and increases the signal of iodine contrast, resulting in an unobscured, ultra-informative image that provides additional reporting confidence to unite patient and clinical team around a shared reality.

Lesions identified with contrast may be difficult to biopsy under conventional techniques like ultrasound or mammography. Contrast enhanced spectral mammography allows you to be more certain whether biopsy is necessary and now with Serena **Bright**, contrast-enhanced guided biopsy provides **exceptional clinical confidence and accuracy** without shifting to MRI.

Accessible breast biopsy without barriers

Once you've identified areas of suspicion with contrast, typically the next step in diagnosis would be scheduling the patient for an MRI-guided breast biopsy which may result in familiar challenges that come with it. Barriers such as scheduling availability, patients with implanted electronic devices like pacemakers, patient discomfort, reactions to gadolinium-based contrast media and menstrual cycle timing are likely some of the reasons you performed a contrast enhanced mammography exam in the first place.

Accessibility is critical for accurate biopsy procedures, especially when facing challenging cases. The biopsy platform - Pristina Serena - gives you the option of accessing the breast with the newly designed side approach to create a large working space to ease patient positioning, reduce needle visibility to help ease patient anxiety, and accurately access patients regardless of the location of lesion.

Now with Serena **Bright**, you can remove barriers and proceed to the next step toward diagnosis under the same image guidance with contrast enhanced biopsy.

> Patients who had breast MRI in the past, described their experience with contrast biopsy was much easier and tolerable.
> Anat Kornecki, MD, St. Joseph Hospital, Ontario, Canada

Serena **Bright**™ **Contrast Enhanced Guided Biopsy**

Compare like to like for increased biopsy correlation

You need complementary imaging solutions that deliver better visualization of breast lesions. Serena **Bright** combines the clarity of contrast enhanced imaging with the versatility of our Serena biopsy platform for a clear path forward for patient care.

CESM allows you to clearly target lesions identified with contrast so you ensure you are targeting the area of suspicion by correlating lesion location with the diagnostic contrast enhanced mammogram with the advantage of the high sensitivity and specificity of CESM[1] to drive accuracy in biopsy.

No more seeking the correlating lesion in MRI, clearly see the lesion in CESM and sample with certainty.

1. 510(k) K172404

Shorten the time to biopsy and diagnosis

Your patients deserve a definitive answer as quickly as possible, with Serena **Bright** you may be able to shorten the time frame to biopsy and diagnosis for a definitive answer.

No more delays waiting for MRI availability or enduring a lengthy 60-90 minute[2] MRI-guided breast biopsy procedure. CESM guided biopsy can be performed within 15 minutes from first image to clip placement image.[3] Your patients will benefit from a fast procedure done in a familiar setting with familiar staff helping to relieve some of the stress of a biopsy procedure.

A shorter biopsy lead time and quicker biopsy procedure may speed up a definitive diagnosis and faster path to treatment.

> As in most hospitals, our MRI system is not solely dedicated to breast examinations so in practice there is a waiting list of several weeks for our cases. The waiting list for MRI-guided biopsy is even longer.
> Dr. Rodrigo Alcantara, Hospital Del Mar, Barcelona, Spain

2. https://www.cedars-sinai.edu/Patients/Programs-and-Services/Imaging-Center/For-Patients/Exams-by-Procedure/MRI/MR-Guided-Breast-Biopsy/MR-Guided-Breast-Needle-Core-Biopsy-Procedure-Information.aspx
3. Data on file 2020, GE HEalthcare

Serena **Bright**™ **Contrast Enhanced Guided Biopsy**

One Room, Multiple Uses.

With the Serena biopsy platform, you can switch from diagnostic to interventional on the same system within your current room configuration and adapt your practice as needed to accommodate your patients needs.

Fast set-up in 2 minutes[4] with the add-on biopsy kit without long and mechanical needle installation.

4. Data on file 2019, GE Healthcare

Serena **Bright**™ **Contrast Enhanced Guided Biopsy**

CLINICAL CASES

Certain with Serena **Bright**™

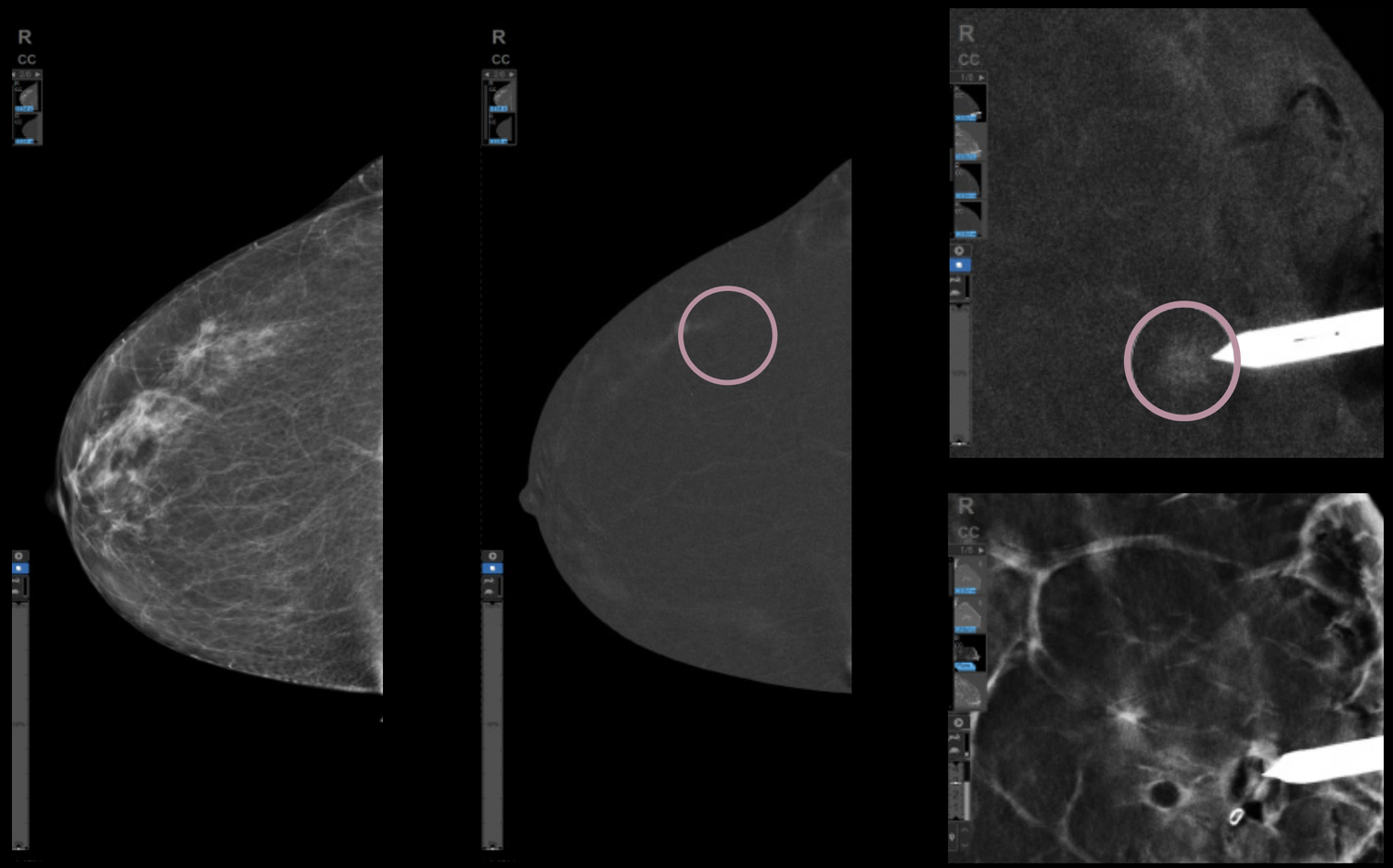
Case 1

Routine CESM shows a 5mm uptake, nodule, in the R breast UOQ. Not visible on the US. Depicted in the LE as well. Exam performed on CESM to reassure themselves on the technic Contrast uptake shown at 3min_ MLO, 5min_CC, 6min_ML.

Horizontal approach, Sitting patient, external access, Spacer in place.
Encor 113,10g, full
Patient prepositioned on the gantry, no compression.

Completed in 10 minutes from start of injection till clip deployment

Result : Invasive Ductal Carcinoma



Serena **Bright**™ **Contrast Enhanced Guided Biopsy**

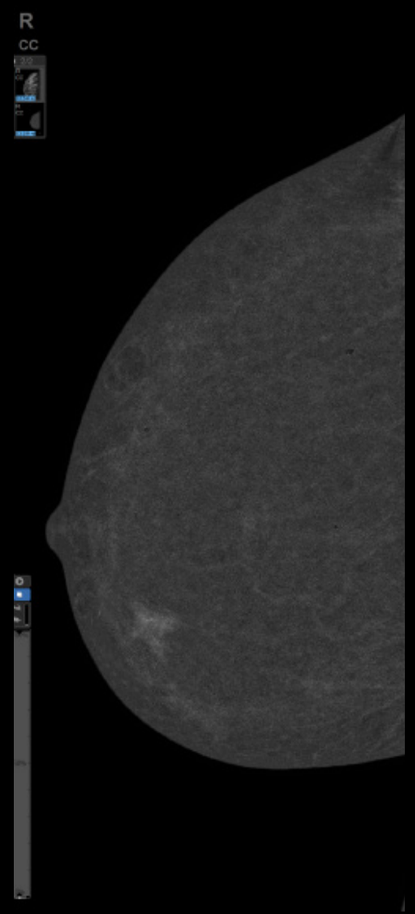
CLINICAL CASES

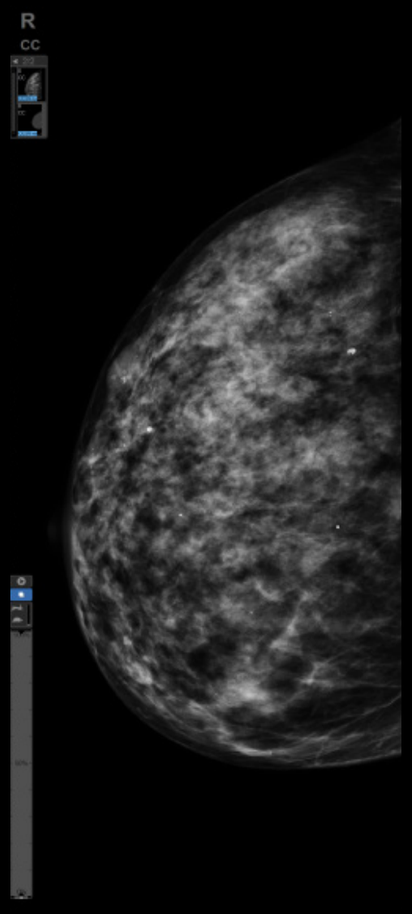
Case 2

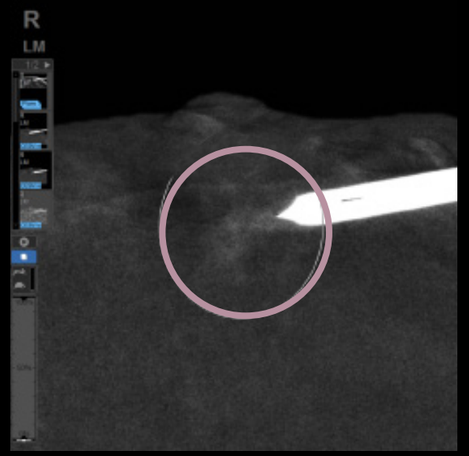
44 years old women
Suspicious enhancement right breast located medial line inner Q, close to the nipple.

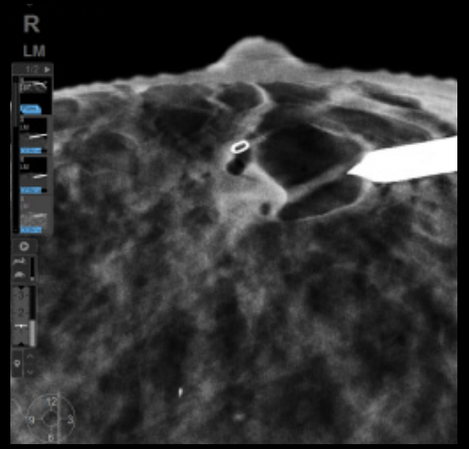
Right breast
Recumbent position
Horizontal approach
Inferior Internal lesion, close to areola. Horizontal approach, inferior access.

Completed in 8 minutes from start of injection till clip deployment





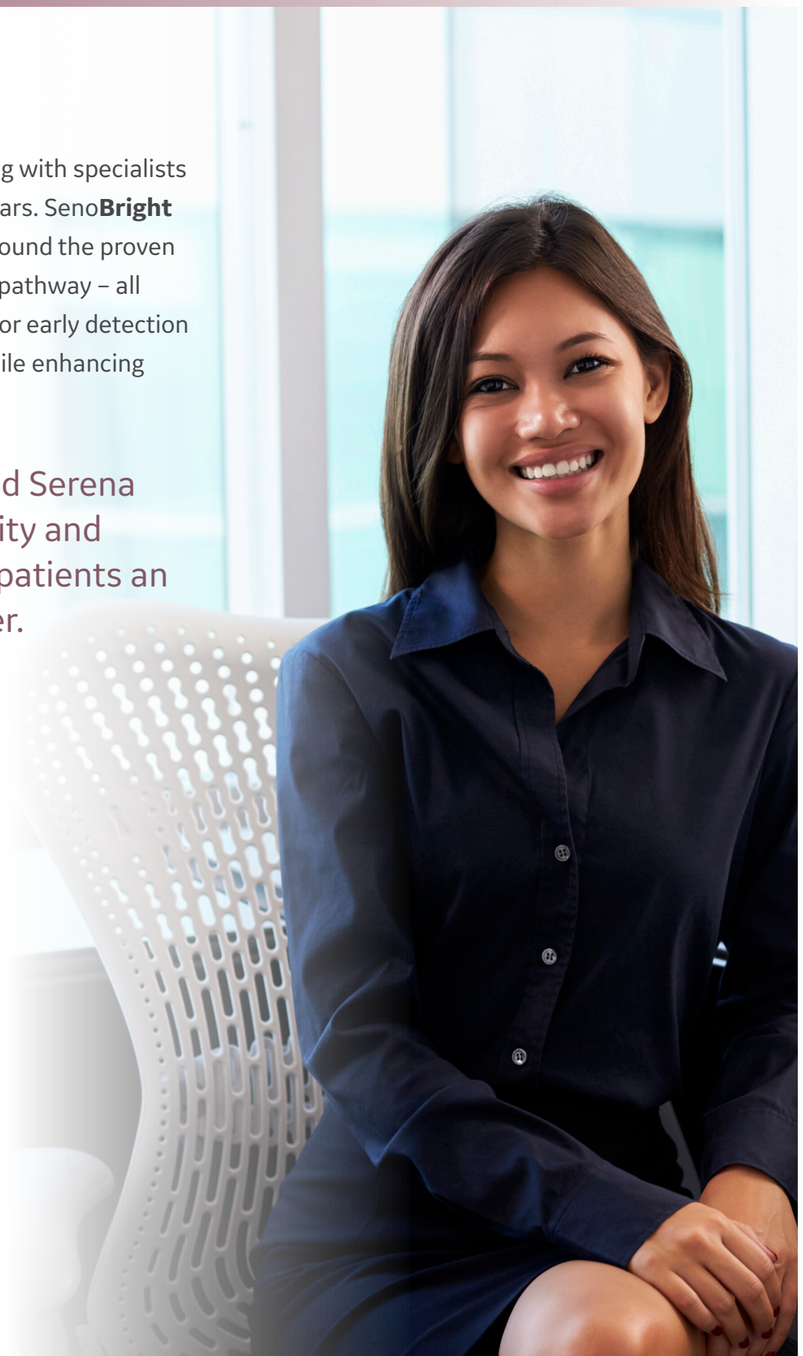




SenoBright™ HD Contrast Enhanced Spectral Mammography

GE Healthcare has been partnering with specialists in breast imaging for almost 50 years. Seno**Bright** HD and Serena **Bright** are built around the proven innovations in the GE breast care pathway – all designed to give you better tools for early detection and diagnosis of breast cancer while enhancing patient wellbeing.

With Seno**Bright** HD and Serena **Bright** you gain the clarity and confidence to give your patients an accurate diagnosis faster.



Product may not be available in all countries and regions.
Full product technical specification is available upon request.
Contact a GE Healthcare Representative for more information.

GE Healthcare is a leading global medical technology and digital solutions innovator. GE Healthcare enables clinicians to make faster, more informed decisions through intelligent devices, data analytics, applications and services, supported by its Edison intelligence platform. With over 100 years of healthcare industry experience and around 50,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping drive productivity and improve outcomes for patients, providers, health systems and researchers around the world.

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and **Insights** or visit our website **www.gehealthcare.com** for more information.

[1] Hobbs et al., J Med Imaging Radiat Oncol. 2015
[2]Patel et al., AJR Am J Roentgenol. 2017

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