

GE Healthcare

SenoBright Contrast Enhanced Spectral Mammography Technology

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Introduction

Women have up to a 1 in 8 (12.5%) lifetime risk of developing breast cancer.¹ To improve health outcome, imaging techniques are key in screening, diagnosis and therapy for breast cancer.

In a diagnostic setting today, mammography, ultrasound and contrast-enhanced MRI (CE-MRI) are the standard imaging tools to help define suspicious lesions previously seen in screening mammograms. CE-MRI is complementary to mammography and ultrasound since it provides additional functional information of abnormal vascular development in lesions to the morphological information obtained with mammography and ultrasound. Unfortunately, many women have no access to a CE-MRI exam, even if prescribed, because of CE-MRI's cost constraints, availability or contraindications.

To create better healthcare for women at lower cost, increased access and with improved quality and increased efficiency, GE Healthcare is continuously investing in highly innovative technological approaches. One outcome of this investment is SenoBright,* the world's first contrast-enhanced spectral mammography (CESM) product introduced in 2010.

Using an iodinated contrast agent and low radiation dose, SenoBright can provide morphological images similar to standard digital mammograms and also contrast-enhanced images of abnormal vascular development around lesions. SenoBright provides additional information that could help improve diagnosis of lesions previously detected by mammography and could detect mammographically occult cancers.

SenoBright is an upgrade of our current mammography equipment and has thus the potential to become available on any one of the over 4000 breast imaging centers worldwide equipped with a Senographe* Essential or Senographe DS* mammography systems. CESM can be performed by a mammography technologist and reviewed by radiologists specialized in mammography. CESM could be performed on the same day as a mammography exam, reducing the critical time patients often have to wait from detection to diagnosis. CESM images are acquired in familiar mammography views so that they can be quickly and easily correlated, facilitating interpretation and communication to other specialists such as surgeons or oncologists.

This white paper reviews the key principles of CESM imaging and presents GE Healthcare's SenoBright.

Contrast-Enhanced Spectral Mammography (CESM)

Contrast-enhanced mammography depicts areas in the breast associated with hypervascularized breast lesions, after an iodinated contrast agent has been injected.

Conventional mammography energy levels are only slightly sensitive to the presence of iodine in the breast. As demonstrated in Figure 1a, a typical clinical concentration of iodine in the breast results in a low signal intensity, and is hardly distinguishable from the background breast morphology. To obtain images that efficiently highlight iodine, cancellation of the background breast tissue has been proposed.

One option to cancel the background breast tissue and spotlight iodine enhanced areas is Contrast Enhanced Spectral Mammography (CESM), a technique based on dual-energy acquisitions, where two images are acquired using distinct low-energy (LE – standard mammography KV and filtration) and high-energy (HE – higher KV with strong filtration) X-ray spectra (Figure 1a and 1b). The differences between X-ray attenuation of iodine and breast tissues at these two energy levels are exploited to suppress the background breast tissue (Figure 1c).

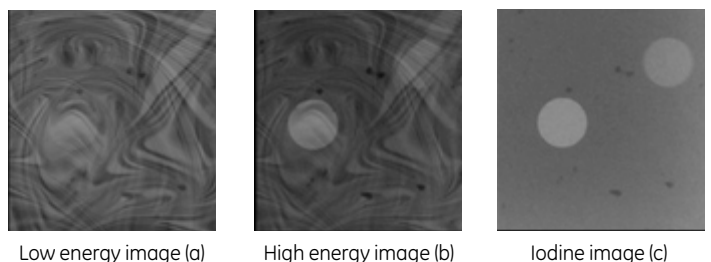


Figure 1. Illustration of CESM principle on a breast tissue equivalent structured phantom containing disks with typical clinical iodine concentrations. (a) The low energy image is acquired using standard mammography energy levels. Note that the iodine is difficult to detect. (b) The high energy image is acquired using a mean energy above the K edge of iodine. Iodine detectability is improved but still limited by the structured tissue equivalent background. Breast tissue contrast is also deteriorated at these high energy levels. (c) In the iodine image, the background tissue is suppressed and the iodine is easily visualized. (The radio-lucent specks are artifacts in the phantom).

SenoBright Solution

SenoBright is a novel addition to GE Healthcare's technology solutions delivering a clinically practical CESM technique. The SenoBright functionality is available in a field upgrade on Senographe Essential and Senographe DS.

Four key aspects were considered to help support the safety, effectiveness, and practicality of the SenoBright solution:

1. X-ray acquisition spectra to provide high-quality contrast-enhanced and morphological images, with highly accurate spatial registration
2. A low patient radiation dose to minimize exposure as much as possible
3. A recombination algorithm to produce images with very high iodine detectability
4. A streamlined patient workflow designed for a comfortable patient experience

1. X-ray spectra

With SenoBright, the LE and HE X-ray spectra are carefully selected for each breast thickness to simultaneously obtain iodine images with optimal iodine image contrast as well as morphological images similar to standard mammograms.

To achieve this, the LE images are acquired using X-ray spectra for standard digital mammography exams, with Mo/Mo, Mo/Rh, and Rh/Rh target/filter combinations and tube voltages (kVp) ranging from 26 to 30 kVp.

The HE X-ray spectra are shaped to maximize iodine contrast and contain energies predominantly above the iodine K-edge, where the iodine attenuation is much higher (Figure 2). To allow acquisitions at these energy levels, GE Healthcare introduced a new multi-layer copper (Cu) filter. HE images are obtained with Mo/Cu or Rh/Cu target/filter combinations and tube voltages higher than those for the LE images (45 to 49 kVp). Figure 2 illustrates typical LE and HE X-ray spectra used with SenoBright.

CESM Auto, the automatic exposure mode (AEC) developed for SenoBright, is dedicated to help achieve repeatable high image quality with acceptable low dose for all breast types. For each breast thickness, a fine-tuning of the LE/HE X-ray spectra and patient radiation dose was performed.

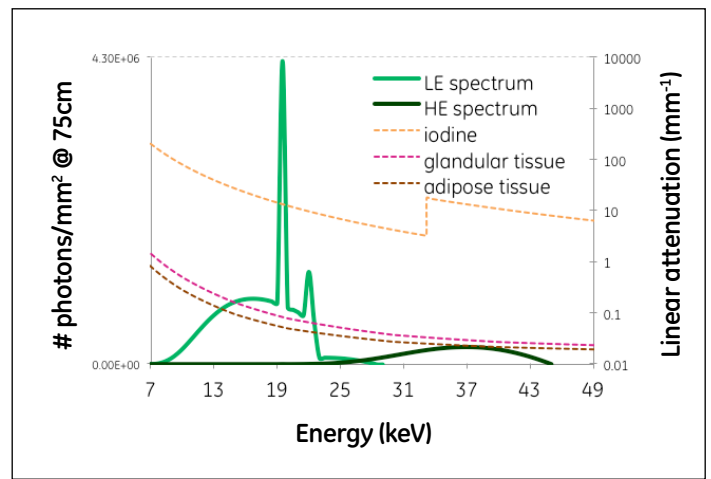


Figure 2. Typical LE and HE spectra used with SenoBright and attenuation of breast tissue and iodine as a function of X-ray energy. The attenuation of iodine is ~5.5 times larger just above the K-edge of iodine than just below the K-edge of iodine. The LE spectrum is generated with a Rh/Rh target/filter combination at 29 kVp and is similar to the spectra used for standard digital mammography. The HE spectrum is obtained using a Rh/Cu target/filter combination at 45 kVp. The largest fraction of the HE spectra occurs above the iodine K-edge.

2. Average glandular dose (AGD)

With a morphological and a functional image for each SenoBright view, the average glandular dose (AGD) to the population of women† is only 20% higher than for a standard screening mammogram acquired with the same equipment. For screening mammography, the reference dose is set at 1.9 mGy; the AGD to the population† of GE Healthcare's Automatic Optimization of Parameters (AOP) Contrast mode.

SenoBright provides a single diagnostic view at about half the maximum AGD limit for a single screening mammogram established by the American College of Radiology (ACR). According to the ACR, the AGD for a 4.2 cm compressed breast with 50% adipose/50% glandular composition should not exceed 3 mGy per view for a screening exam. For this breast, SenoBright offers a diagnostic exam at 1.6 mGy AGD per view.

Also, for the same 4.2 cm compressed breast, SenoBright provides approximately half the AGD of a single magnification view, often used as part of a diagnostic breast evaluation. The AGD for a single magnification view is 3.4 mGy when acquired with 1.8 times magnification and the AOP standard mode. In some cases, several magnification views are required to carefully evaluate the suspicious area.

†AGD to the population is defined as the AGD averaged over the breast thickness and composition distributions in a representative population of women.

3. Recombination algorithm

An optimized recombination algorithm on SenoBright is dedicated to process the LE and HE images into iodine images.³ The algorithm, using as input the LE and HE X-ray spectra and the compressed breast thickness, is designed to efficiently suppress the background breast tissue for all breast thicknesses and density patterns, in order to highlight the iodine-enhanced areas. The recombination algorithm ensures the visibility of 0.5 mg/cm² iodine areal concentration, corresponding to a lower bound of concentration clinically expected.

An iodine image computed with our exclusive recombination algorithm is shown in Figure 1c. The breast tissue is nicely cancelled and the iodine disks are very easy to discern in the iodine images, as opposed to the low-energy (Figure 1a) or high-energy images (Figure 1b).

4. Clinical workflow and patient comfort

SenoBright has been designed to provide a workflow for streamlined clinical use and a comfortable exam experience for the patient.

Including the single iodine contrast agent injection, a SenoBright exam takes less than ten minutes. The system automatically acquires the spectral data necessary to automatically create two images per view. Rapid image acquisition has been made possible by alternating quickly between the LE and HE X-ray spectra, thanks to rapid switching between the X-ray tube voltages and filters and a fast detector read-out.

SenoBright provides several features designed to help enhance workflow efficiency including single button-push LE and HE image acquisitions with the CEM Auto AEC technique, immediate display of LE and iodine images on the acquisition workstation after image acquisition and an easy-to-use stopwatch. The stopwatch allows clinicians to precisely time the delay between iodine contrast agent injection and image acquisition, which is key to perform repeatable exams.

Figure 3 illustrates a typical exam with SenoBright. First, an iodinated contrast agent is injected intravenously while the patient is either comfortably seated or lying down and with the breast uncompressed for patient comfort. Typically two minutes after start of injection, the breast is positioned and compressed for the first view, and a LE/HE image pair is acquired. After image acquisition, the breast is automatically decompressed. The technologist benefits from immediate LE and iodine image previews helping to facilitate a highly reliable exam. Next, three more LE/HE image pairs can be acquired in a similar way, to achieve a complete bilateral two-view exam. A stopwatch allows the technologist to time the whole exam sequence enabling highly repeatable imaging protocols. In this example, the total image acquisition time lasts about 5 minutes and the total procedure lasts about 7 minutes. The ease of use and short exam time add up to an efficient workflow aimed at a comfortable experience for the patient.

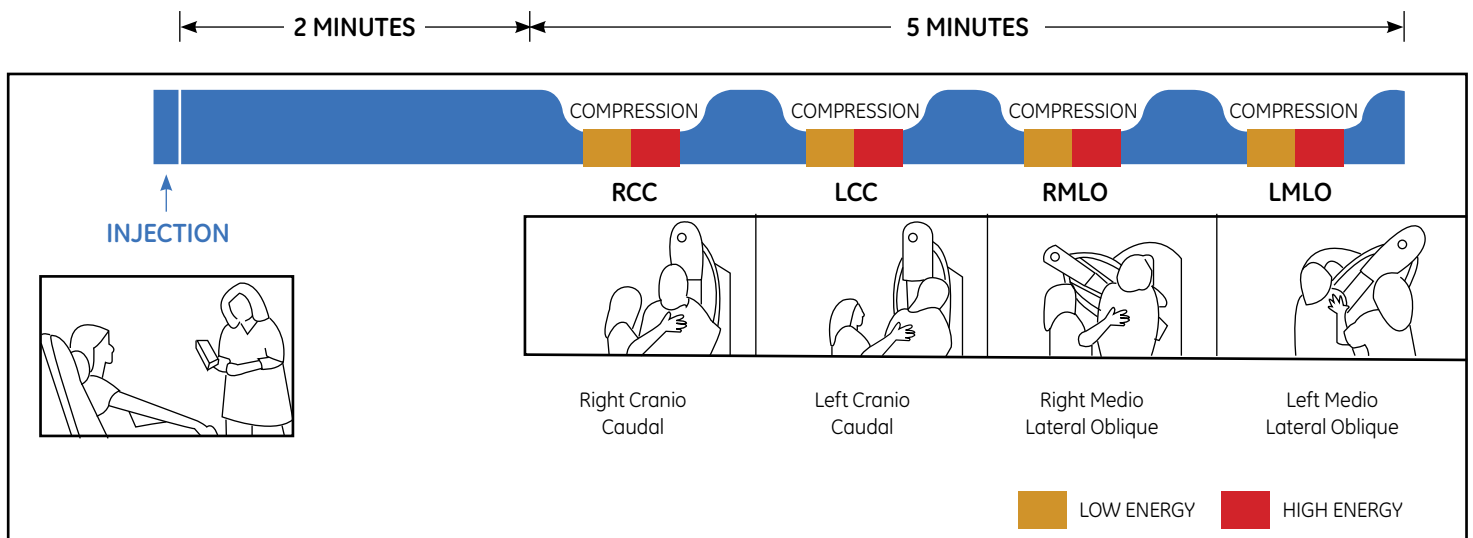


Figure 3. Typical CEM imaging procedure for a bilateral examination with two views per breast.

5. Clinical Summary

In the early 1980s, it was shown for the first time that X-ray imaging with an iodinated contrast agent can demonstrate changes in breast vascularity.^{4,5} Due to the immature technology status, none of the proposed techniques were practical for routine clinical use.

Only twenty years later, the advent of digital mammography stimulated interest in contrast-enhanced mammography. Contrast-enhanced digital mammography, using a temporal subtraction technique, was pioneered in 2002 through research collaborations between GE Healthcare and multiple clinical partners.^{6,7} Images of the breast were acquired before and after intravenous administration of an iodinated contrast agent using a high-energy X-ray spectrum. To obtain iodine enhancement images, logarithmic subtraction of the pre- and post-contrast images was used. Clinical feasibility studies proved the feasibility of temporal subtraction contrast-enhanced mammography and revealed, at the same time, several major limitations. First, the breast is compressed for several minutes, including during contrast agent injection, thus unfavorably impacting patient comfort and causing image artifacts arising from patient motion. Second, temporal subtraction digital mammography provides only iodine-enhanced images and no corresponding morphological breast images. Third, temporally based contrast-enhanced digital mammography with single iodine injection allows imaging of only one breast in one view due to rapid washout of the iodinated contrast agent.

To overcome these limitations, dual-energy (DE) contrast-enhanced digital mammography, also named contrast-enhanced spectral mammography (CESM) has been proposed. Clinical feasibility was demonstrated by Lewin et al in 2003⁸ on a population of 26 women with radiological findings judged to have >50% chance of malignancy.

More recently, Dromain et al published their preliminary findings in European Radiology in 2011⁹ on a study of 120 women with 146 suspect radiological findings on standard mammography or ultrasound. The population of patients was chosen for this study to determine the performance of CESM as a problem solving tool versus the standard techniques of mammography or the paired use of mammography and ultrasound. Further analysis published in Breast Cancer Research in 2012¹⁰ demonstrated improved lesion localization with CESM after mammography and ultrasound pair.

Ongoing studies are comparing the performance of CESM to MRI for women with newly diagnosed breast cancer, with promising early results.

Conclusion

Used as an adjunct following mammography and ultrasound exams, SenoBright offers a new diagnostic tool that helps localize breast lesions by highlighting unusual blood flow, providing information to follow up with the patient faster. With SenoBright, additional tests can be performed right away – using the same mammography equipment, in the same room, with the same staff, on the same day. SenoBright allows a complete bilateral exam using a single iodine injection in less than 10 minutes, with a streamlined clinical use designed for a comfortable exam experience for the patient. SenoBright can provide a high-quality morphologic and iodine image pair, in the same position, at a slightly higher dose compared to standard mammography. GE technology advancements have made SenoBright available as an upgrade to GE's standard mammography systems, the Senographe DS and Senographe Essential.

SenoBright Case Study

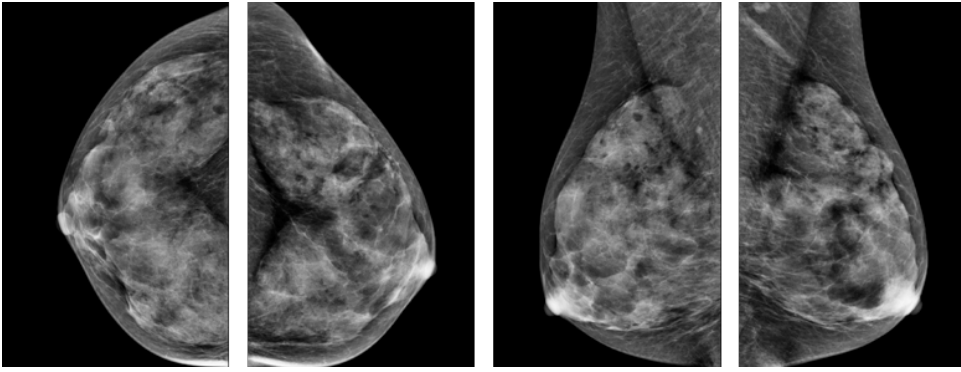


Figure 4a: Original mammography from a 79 y/o patient who presented with palpable mass on left breast. From left: Right cranial-caudal (RCC), Left Cranial-Caudal (LCC), Right Medial-Lateral Oblique (RMLO), and Left Medial-Lateral Oblique (LMLO). No particular findings, but very dense breast tissue.

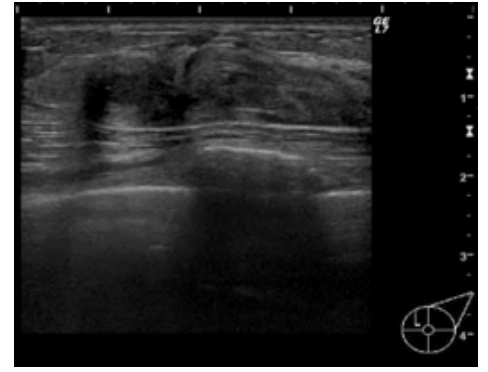


Figure 4b: Ultrasound of the left breast of same patient.

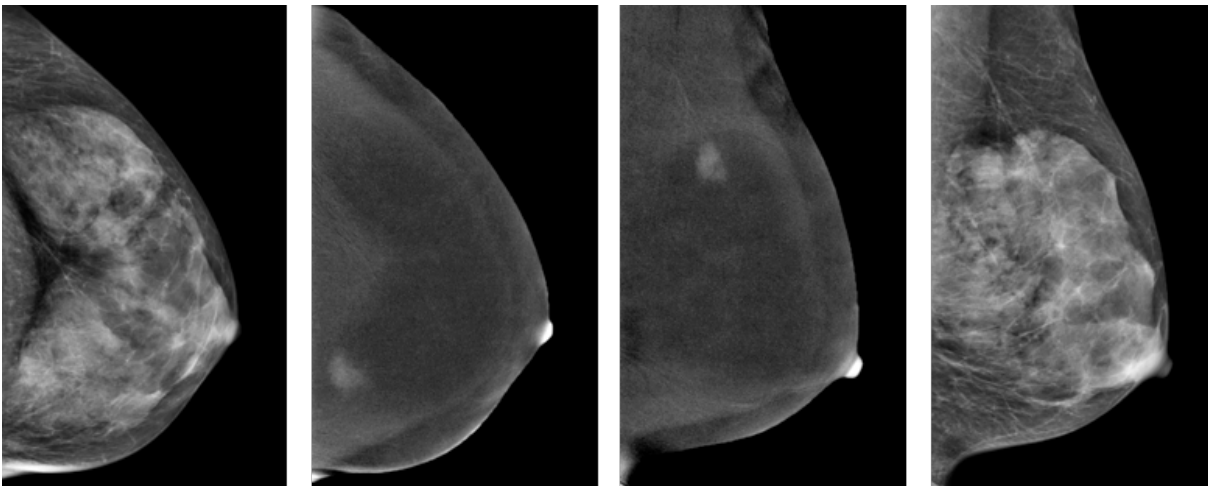


Figure 4c: SenoBright Contrast Enhanced Spectral Mammography exam of the same patient. From left: LCC low-energy, LCC Contrast-enhanced, LMLO contrast-enhanced, LMLO low-energy. The contrast-enhanced images clearly localize and highlight the lesion, which biopsy proved to be invasive ductal carcinoma.

References

1. http://seer.cancer.gov/csr/1975_2009_pops09/results_merged/sect_04_breast.pdf
2. LW Bassett et al., ACR practice guideline for the performance of screening and diagnostic mammography, 2008
3. S Puong et al., Dual-energy Contrast Enhanced Digital Mammography using a new approach for breast tissue canceling, Proc. SPIE Medical Imaging, vol. 6510, pp. 65102H, 2007
4. LV Ackerman et al. Breast lesions examined by digital angiography. Work in progress. Radiology vol 155, pp.65-68, 1985
5. AC Watt et al. Breast lesions: differential diagnosis using digital subtraction angiography. Radiology, vol 159, pp. 39-42, 1986
6. RA Jong et al. Contrast-enhanced digital mammography: initial clinical experience. Radiology vol 228, pp.842-50, 2003
7. C Dromain et al. Evaluation of tumor angiogenesis of breast carcinoma using contrast full-field digital mammography: preliminary results. RSNA, Chicago, 2004
8. JM Lewin et al. Dual-energy contrast-enhanced digital subtraction mammography: feasibility. Radiology vol 229, pp.261-268, 2003
9. C Dromain et al. Dual-energy contrast-enhanced digital mammography: initial clinical results. European Radiology, vol 21, pp.565-574, 2011
10. C Dromain et al. Dual-energy contrast-enhanced digital mammography: initial clinical results of a multireader, multicase study. Breast Cancer Research, vol 14, pp. R94, 2012

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