



BREAST CARE MAGAZINE

Women's Health at heart



CESM:

EXPERTS SHARE
THEIR VISIONS

INNOVATIONS IN MACRO-BIOPSY:

FROM 2D TO
CONTRAST ENHANCED
GUIDED BIOPSY

ARTIFICIAL INTELLIGENCE IN MAMMOGRAPHY:

HOW TO DEAL WITH THE
CHALLENGES OF DBT?

IMPROVING PATIENT EXPERIENCE

UNTIL RECOVERING
THE SENSE OF FEMINITY



Laura Hernandez
Product & Marketing
Director Europe
Women Health & X-ray



Colin Auclair
Product Marketing
Manager Europe
Mammography

Dear Reader,

Delivering the best possible care in this constantly evolving environment is critical to improving outcomes. When it comes to treating breast care, there are many questions that can come up and as a result the scientific community is taking a hard look at the various options available to effectively help reduce mortality related to breast cancer.

When it comes to screening, progress can be linked both to technology progress and patient-centered innovation. On the one hand, we see positive results coming from tomosynthesis trials as well as the rapid rise of artificial intelligence in breast imaging that introduces new and alternative perspectives. We also see innovations such as contrast mammography or automated breast ultrasound as emerging investigation tools with promising results. At the same time, there are new trends in breast care that put the patient at the center of the thinking process and that are designed to educate and make the breast care experience as positive as possible. This patient-centric thinking can help maximize compliance to screening programs. Finally, we continue to see a significant impact from results of the first trials focused on personalizing the imaging pathway after characterizing individual patient risk in developing breast cancer.

In diagnostic breast imaging, the search for efficiency and reducing potentially avoidable steps to diagnosis, can help reduce anxiety in the waiting time for results. Today more than ever, we see a strong focus on this current search for improved efficiency. For example, the increasing interest of the scientific societies in contrast imaging is due to the technology's very high sensitivity as well as the progress related to biopsy techniques. These are two of very interesting innovations that seem to be taking the breast care industry by storm.

What you will see in this first release of our GE Healthcare Breast Care Magazine, is our perspective with respect to these respective challenges, which will be presented via a variety of articles and testimonials of users that have embraced changes in their own way. Our hope is that this GE Healthcare Breast Care Magazine will provoke your interest, answer questions or stimulate ideas.

We wish you good reading and remain your partner in elevating personalized breast care.

Local Contact Information:

GE Healthcare Buc
283, rue de la Minière
78533, Buc Cedex, France

Chief Editor: Camille La Fay

Editorial Team: Camille La Fay, Mathilde Dauchez, Colin Auclair, Dorotea Vallet, Diane Uriell, Grégory Pessato, Jean-Baptiste Brunet, KDM, Jean-Marc Peyronnet, Stacie Stands, Tracy Deems, Anne Clément, Ana Ward, Florian Akpakpa, Tara Mourty, Caroline Nouveau

Design: Nathalie Ollivier & Mathilde Dauchez

Many thanks to our contributors:

Dr. Marc Lobbes, Zuyderland Medical Center, Netherlands

Dr. Valentina Lotti, University of Modena and Reggio Emilia, Italy

Dr. Rodrigo Alcántara Souza, Hospital del Mar, Barcelona, Spain

Dr. François Tachet, Center for Radiology and Tumor Treatments (CRTT), Versailles, France

Mme Christel Lefevre, Center for Radiology and Tumor Treatments (CRTT), Versailles, France

M. Jean-Marc Naillou, Center for Radiology and Tumor Treatments (CRTT), Versailles, France

Dr. Axel Gräwingholt, Radiologie am Theater, Paderborn (Germany)

Dr. Patrick Toubiana, Center Of Radiology and Medical Imagery Beaufort, Paris, France

Dr. Marchand, Centre Mosaïque, Blois (France)

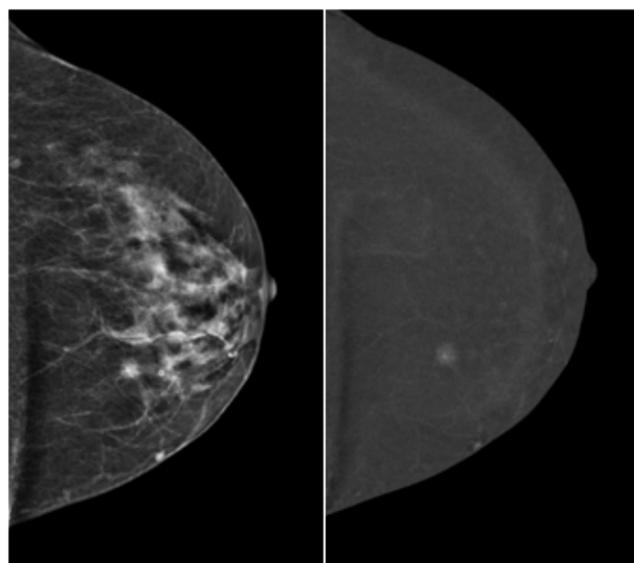
Mme Christel Schaal, Centre Mosaïque, Blois (France)

Dr. Carluccio Gatti, Studio Medico, Pavia (Italy)

Mme Nicoletta Balzaretto, Studio Medico, Pavia (Italy)

Alexia Cassar, tattoo artist in complex art of 3-D nipple tattooing (France)

BREAST CARE MAGAZINE



Innovations in biopsy

22_ Don't guess, see it clearly and biopsy it with contrast enhanced guided biopsy

27_ Contra-lateral lesion biopsy in a dense breast using CESM guided biopsy | Clinical case. **First Contrast enhanced biopsy case**

30_ Breast care in a new mammography center at Versailles in France

36_ Macro-biopsy of superficial microcalcifications | Clinical case

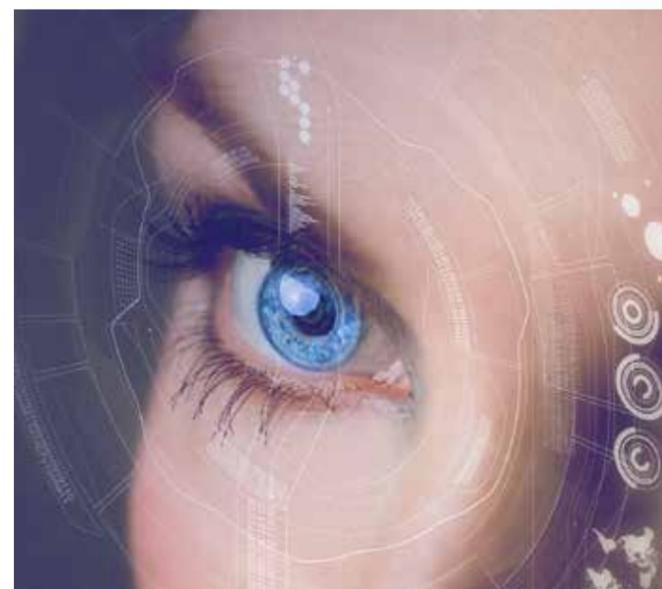
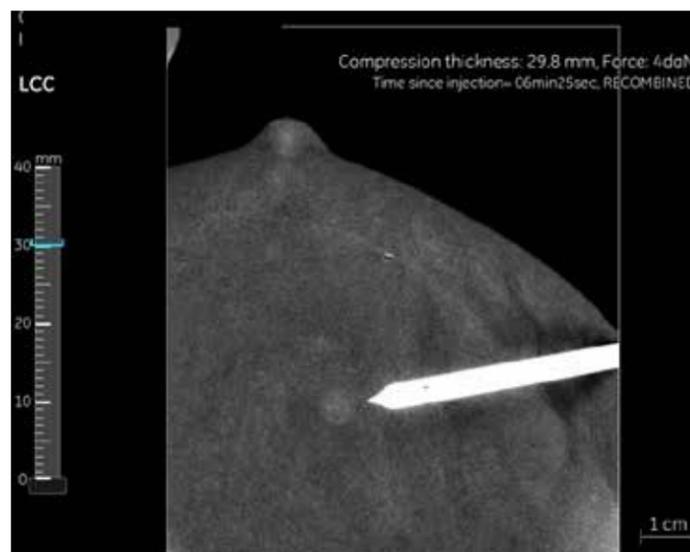
Contrast-Enhanced Spectral Mammography

06_ Infographic: the past, present, and future of CESM

10_ Focus on CESM in screening recall, with Dr. Lobbes' interview

14_ Screening recall | Clinical case

16_ Overcoming the challenges of different patient demographics with contrast-enhanced mammography



Artificial Intelligence

40_ How can ProFound AI™ help with the challenges of tomosynthesis

44_ Invasive Lobular Carcinoma | Clinical case

Patient Experience

48_ Involving patients by using Pristina Dueta™

54_ Alexia Cassar brings wholeness back to breast cancer survivors one nipple at a time

From analog to digital

58_ The experience in Pavia with Dr. Gatti

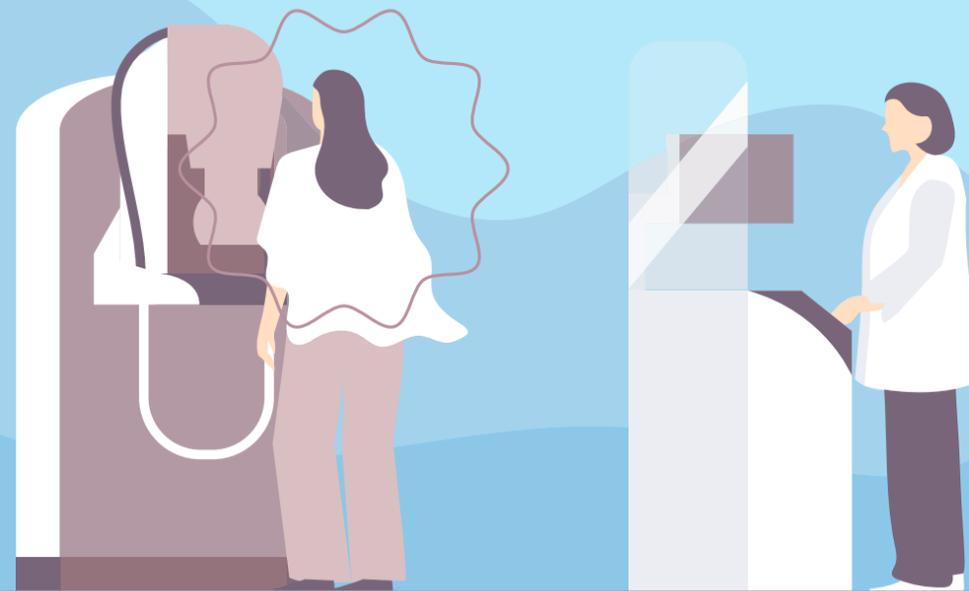
62_ Global center of excellence for mammography manufactures





What is contrast-enhanced mammography?

CEM pairs standard mammography with iodine contrast to reveal hyper-vascularized regions in the breast indicative of cancer growth.



How it works

CEM pairs standard mammography with iodine contrast to reveal hyper-vascularized regions in the breast indicative of cancer growth.

1.



Patients get an intravenous iodine injection in the exam room.

2.



About two minutes later, they have a traditional four-view mammogram with two different energies of X-rays, for a total exam time of less than seven minutes.²

3.



The radiologist can instantly review the images composed of standard mammography images and contrast-uptake images computer from the images acquired at two energies.

History of CEM

CEM was created to detect suspicious lesions that may be obscured in standard mammograms by normal breast tissue but may be differentiated from the normal tissue through their hyper-vascularization as it is the case in most cancers. This added clinical value of CEM is even stronger in dense breasts where conventional mammography is known to have a limited sensitivity.²



Past

Regulators approve CEM in dual-energy settings and research pours in as early adopters use the technology after inconclusive screenings, to evaluate disease progression, and to assess treatment response.



SenoBright is cleared by the U.S. Food and Drug Administration.⁴



2010

The first-ever contrast-enhanced spectral mammography (CESM) technology, SenoBright™ CESM by GE Healthcare, launches in Europe and Asia.³

2011

2012

An American Association of Physicists in Medicine paper introduces CEM's potential for finding new cancers not seen with traditional mammograms, as well as showcasing cancer progression.⁵

Present

Interest in CEM as second-line screening gains traction as studies show potential among existing cancer patients—as well as those with high and intermediate risks.

2014

A study among 80 newly-diagnosed breast cancer patients found that CEM identified the cancer in 100% of patients, compared to standard mammogram (82.5%) and MRI (97.5%).⁶

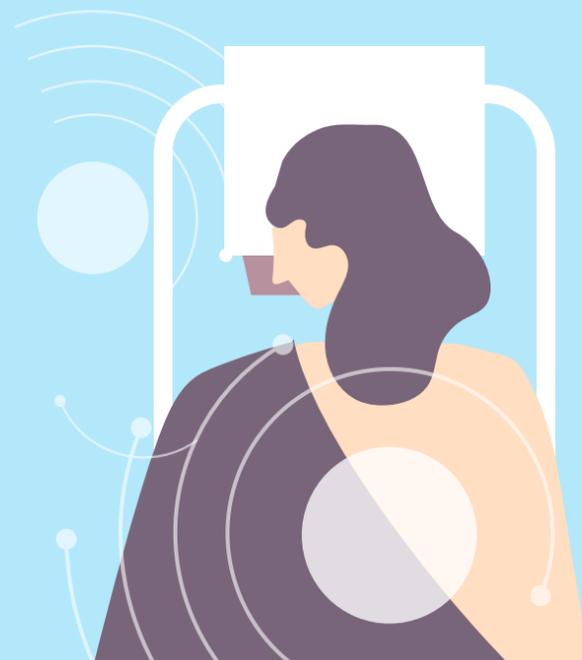


2015

Among 102 patients who had follow-up exams to investigate suspicious lesions, CEM yielded a sensitivity of 100% (compared to 93% for MRI) and an accuracy of 79% (compared to 73% for MRI).⁷

2018

A study among 611 middle-risk patients with family history or dense breasts shows CEM's improved sensitivity as a supplemental screening tool (90.5% for CEM vs. 52.4% for standard mammography).⁸



2019

A study published in Clinical Radiology among 76 postoperative patients showed CEM in tandem with traditional mammography increased sensitivity, specificity, accuracy, and positive and negative predictive values.⁹

Future

Researchers believe CEM has the potential to detect cancers even faster, even among low-risk populations, while improving the patient experience:



Researchers could explore questions related to lower-dose radiation and contrast.

Improvements to equipment, training, and protocols could support even more powerful technology.

CEM may continue to be combined with other modalities, such as tomosynthesis to deliver contrast-enhanced 3D images of the breast.

CEM could replace breast MRI in situations where it is contraindicated, too expensive, or inaccessible.¹⁰

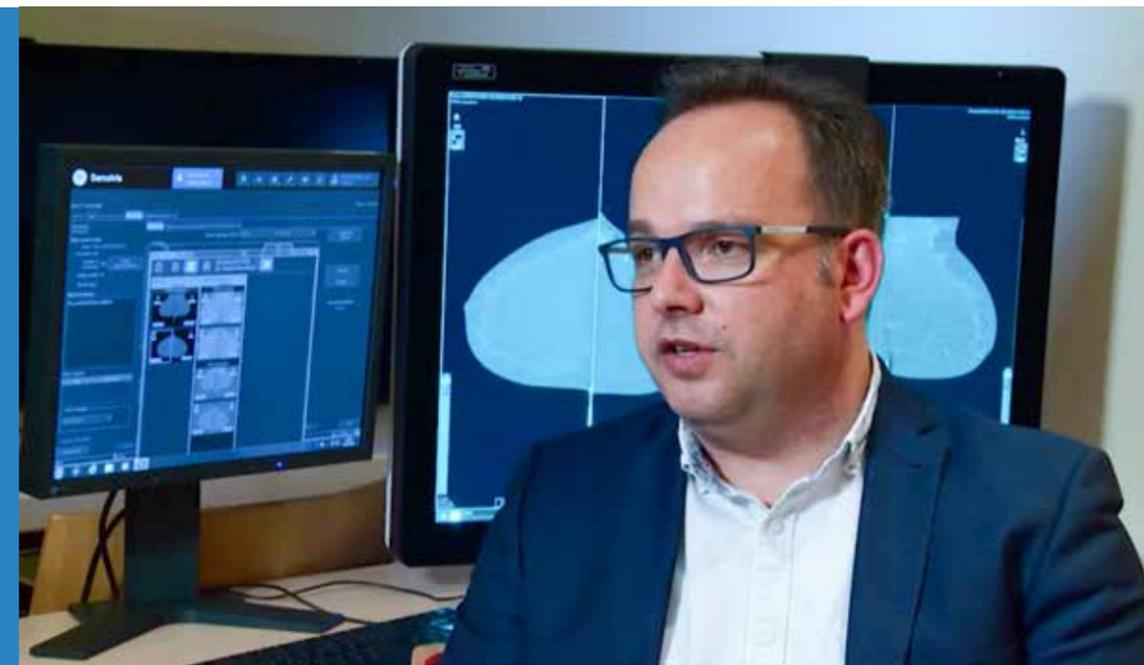
1. www.who.int/cancer/detection/breastcancer/en/index1.html
2. www.gehealthcare.com/~media/downloads/us/product/product-categories/mammography/seno-bright/SenoBright-HD-Brochure-USA-only-JB52217US.pdf
3. www.radiologytoday.net/archive/rt0212p34.shtml
4. www.fdanews.com/articles/140926-fda-approves-ge-rsquo-s-senobright-spectral-mammography-device
5. www.aapm.onlinelibrary.wiley.com/doi/abs/10.1118/1.4735804
6. www.ncbi.nlm.nih.gov/pubmed/24048724
7. www.ncbi.nlm.nih.gov/pubmed/25963880
8. www.radiologybusiness.com/topics/care-delivery/cesm-eective-breast-cancer-screening-dense-breasts
9. healthimaging.com/topics/advanced-visualization/contrast-enhanced-spectral-mammography-cancer
10. www.auntminnie.com/index.aspx?sec=rca&sub=ecr_2018&pag=dis&itemID=120092

Focus on CESM in screening recall

Contrast-Enhanced Spectral Mammography (CESM), as a fast and affordable technology allowing for the visualization of vascularized lesions in the breast, is changing the game in clinical practice. The combination of morphologic and physiologic information provided by CESM has been shown to have a better diagnostic accuracy compared to digital mammography¹. CESM is routinely used in different clinical contexts such as a problem solving tool in case of non-concordant mammography and ultrasound images. There is ongoing research of potential interest of using CESM as a first-line tool in screening recalls², for challenging breasts such as very dense¹ or post-op patients operated ones³, and/or as a tool in treatment planning or for monitoring neoadjuvant chemotherapy⁴. In addition, research currently explores the interest of this tool in a screening setting for high risk and dense breast patients. From a patient perspective, CESM is preferred (over MRI) as it is faster, of greater comfort and generates less anxiety⁵.

Dr. Marc Lobbes is a member of the Board of the European Society of Breast Imaging (EUSOBI), Member of the Dutch College of Breast Imaging (DCBI), Breast radiologist of both Zuyderland Medical Center and Maastricht University Medical Center.

As dedicated breast radiologist, he annually views over 500 breast MR exams, over 3,000 clinical mammograms, and performs over 60 MR guided biopsies. He participates in the Dutch breast cancer screening program, viewing over 8,000 screening mammograms annually. Due to his training and vast experience in evaluating breast MRI exams, he frequently acts as a consultant for other hospitals. Dr. Marc Lobbes is the author of more than 90 scientific papers (of which 17 papers on CESM) and author of multiple book chapters on CESM.



Could you please briefly introduce yourself?

Dr. Lobbes: I have been the Director of the Breast Imaging Department for 16 years in Maastricht University Hospital. I recently moved to the Zuyderland Medical Hospital which is a large general hospital located in Sittard-Geleen in the southern part of the Netherlands.

Can you share with us your experience with contrast mammography?

Dr. Lobbes: We've been early adopters of contrast enhanced mammography. The first clinical cases we handled were in November 2012, and we really started using it regularly since January 2013. We focused our initial experiences with Contrast enhanced mammography on screening recalls as

we thought it would be a very interesting study population. And since that period, we tried to extend the indications for CESM, gaining more confidence, and more experience.

What are the main advantages of using CESM in your practice?

Dr. Lobbes: I think the main benefit of using contrast enhanced mammography in screening recalls is that, as a doctor i am much more confident that what I am looking at is really the truth. So I am much more confident in the lesions that I am detecting, seeing whether it's benign or malignant, and even if I don't see anything abnormal on either the low energy image or your recombined contrast image, I feel much more confident that it's safe to call these patients back in two years for regular screening, instead of keeping having

them come back for follow-up every six or twelve months. So I avoid keeping healthy people within a hospital system while they should really go out and not worry about it, then return within two years for a regular screening.

What would be your message to a multidisciplinary team starting with contrast?

Dr. Lobbes: I think the most important thing that I would give as a take home message for the other members of a multidisciplinary team is that they really can rely on the images that they see. The image quality is good and we know from literature - and not only one publication but several publications now - that the diagnostic accuracy of contrast enhanced mammography matches the quality of breast MRI¹.

"Using CESM in recall from screening, I am much more confident in the lesions that I am detecting, seeing whether it's benign or malignant, and even if I don't see anything abnormal on either the low energy image or the recombined contrast image I feel much more confident that it's safe to send these people back within two years for regular screening, instead of keep having them call back for a follow-up in six or twelve months"

So, members of an MDT [MultiDisciplinary Team] should really consider it as a powerful tool, not only detecting breast cancer but also looking at the disease or even response monitoring. They really can have confidence in this technique.

Tomosynthesis was made available to radiologists about the same

time as contrast mammography, however tomosynthesis was more rapidly adopted. Do you see any particular reason for this?

Dr. Lobbes: I think the reason why tomosynthesis was much more widely adopted than contrast enhanced mammography is that if you use these synthetic mammograms, the

additional dose is much lower than what you would have in a contrast enhanced mammogram. And a further disadvantage of contrast enhanced mammography is that you use intravenous injection of iodinated contrast agent, which can cause some kind of kidney injury or perhaps hypersensitivity reactions. Even-though the occurrence of such adverse event is extremely low, that's I think, the main reasons why people were more likely to accept DBT at first over contrast enhanced mammography. □

The statements by Dr. Lobbes reported here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

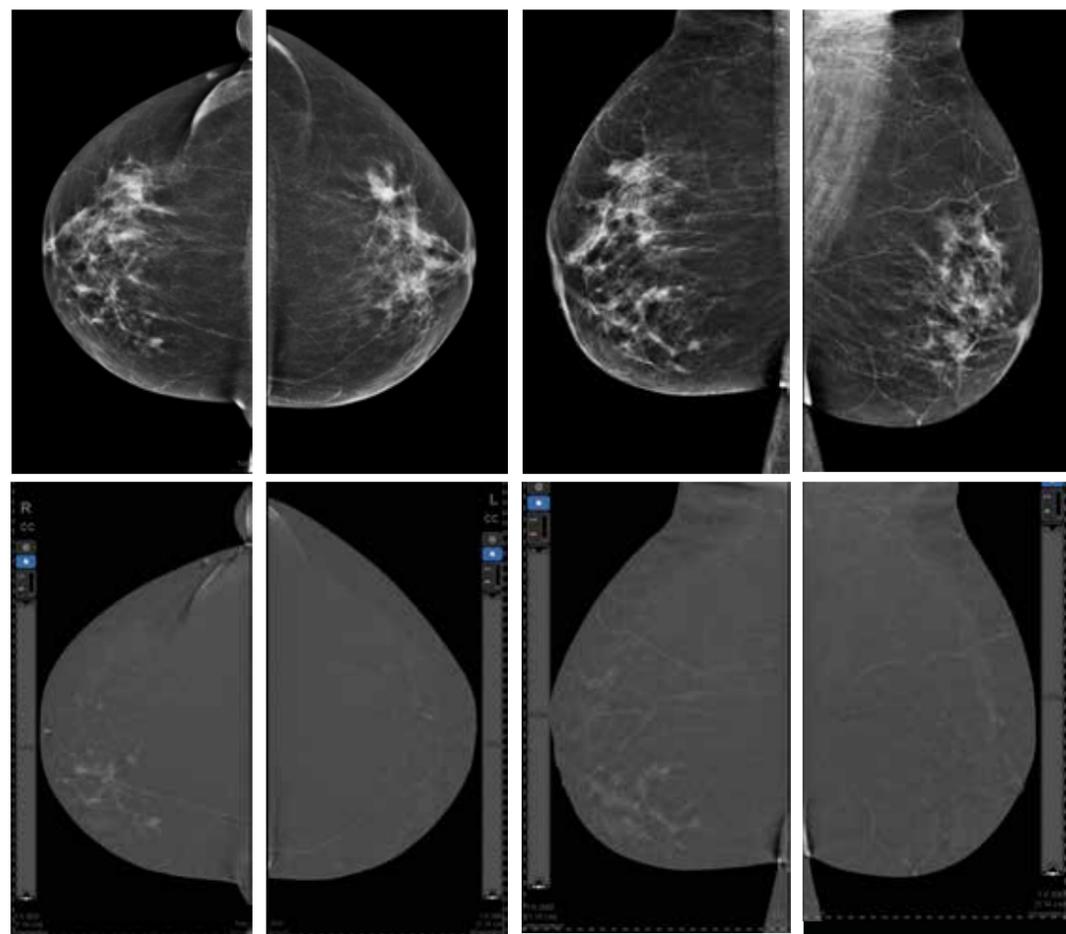
1. Data on file. Ge Healthcare 2017. All countries except USA.
 2. Lobbes MB and al, Contrast-enhanced spectral mammography in patients referred from the breast cancer screening programme, European Radiology 2014.
 3. Helal MH et al The role of contrast-enhanced spectral mammography in the evaluation of the postoperative breast cancer, 2019 Clinical Radiology.
 4. Iotti V and al, Contrast-enhanced spectral mammography in neoadjuvant chemotherapy monitoring: a comparison with breast magnetic resonance imaging , 2017e Breast Cancer Research
 5. Hobbs et al, Contrast-enhanced spectral mammography (CESM) and contrast enhanced MRI (CEMRI): Patient preferences and tolerance, J Med Imaging Radiat Oncol. 2015

Clinical case: CESM in screening recall

Courtesy of Dr. Lobbes, Zuyderland Medical Center, Netherlands.

Clinical context

60 year old female. Recall from screening for a mass in the lower inner quadrant of the left breast . No complaints. Mother died of breast cancer at the age of 52.



Clinical findings

Low-energy images

- Right breast: Linear orientated pleiomorphic calcifications in combination with ill-defined irregular masses
- Left breast: no abnormalities

Recombined images:

- Right breast: Area of nodular non mass enhancement corresponding with the findings seen on the low-energy image
- Left breast: Small enhancing mass at 12 o'clock position

Pathology

- Right breast: pT1(m)N0M0 in large area of DCIS (up to 7 cm)
- Left breast: Targeted US negative; MRI guided biopsy: adenosis

Benefits of CESM :

After one single exam:

- Identification of disease extent on right Breast
- Identification of contra-lateral lesion enhancing



GE Healthcare
Breast ACADEMY

To watch GE Breast Academy replays join us on GE Cares



Overcoming the challenges of different patient demographics with contrast-enhanced mammography

Dr. Liao, Enterprise Director for Thomas Jefferson University Breast Imaging Enterprises in Philadelphia, USA



Dr. Liao, Enterprise Director for Thomas Jefferson University Breast Imaging Enterprises in Philadelphia, USA.

diagnose dense breast and high risk individuals with a family history of the disease, CESH is a complementary method that can help to minimise the likelihood of a missed diagnosis or a false positive result¹. Dr Lydia Liao, Enterprise Director for Thomas Jefferson University Breast Imaging Enterprises in Philadelphia, has long been an advocate of this technique, and has worked with colleagues in the United States and her native China to champion the establishment of CESH facilities.

Putting CESH into practice

Dr. Liao first encountered CESH almost a decade ago when she was Director of the Breast Imaging service at a hospital in South Jersey. When FDA clearance was granted for GE's CESH system in 2011, she was quick to introduce the technique to the practice. Since then, Dr Liao has gone on to establish a clinical service for contrast-enhanced mammography at Thomas Jefferson, as well as working with teams in China to drive implementation of the technology there.

"By 2016, I had personally reviewed more than 2,000 contrast-enhanced mammography studies. I am now very confident about its diagnostic power and what it can help with in terms of problem-solving or high-risk screening. In addition to a very good sensitivity (comparable to MRI), CESH can also help to down grade a lesion to avoid an unnecessary biopsy. For example, when a probably benign lesion is identified during a regular mammogram, adding CESH often allows us to downgrade our preliminary findings and rule out further investigations. Without CESH,



Contrast-enhanced spectral mammography (CESM) is a comparatively recent addition to the portfolio of technologies used for breast diagnostic. Traditional mammography has long been the first line approach to breast screening to detect secondary signs of breast cancer, such as masses, microcalcifications or architecture distortions, and has played a significant role in the early detection of cancer. However, for women with dense breast tissue, where lesions can hide within breast tissue, the cancer can be difficult to distinguish. CESH not only detects secondary signs of breast cancer as mammograph does, but it also detects breast cancer when cancer just started as a nest of vessels (angiogenesis) before a lesion is formed. CESH is not affected by breast density therefore it is very helpful to

CESH matches MRI¹

The practical benefits of CESH are clear, but the diagnostic performance and quality of the imaging must also be as good as breast MRI because they both can detect breast cancer at a very early stage. A publication database built up over a period of almost nine years has confirmed this, showing that CESH is comparable to breast MRI for the identification of lesions that have been missed by other studies, for monitoring the treatment response, for high risk screening, and for patient safety. Another important factor is that CESH may offer even greater specificity for some lesions than breast MRI. Almost everything enhances on an MRI scan, including benign lesions, however, these are not visible with CESH, which helps to rule out malignancy and avoid putting the patient through an unnecessary biopsy².

every lesion seen during primary screening could be biopsied, because information about the vascularity is not usually available. If the lesion is not enhanced with CESH, we can be more confident it is not a cancer and will probably not do a biopsy," says Dr Liao.

Setting up a CESH facility is quite straightforward; existing mammography equipment can often be upgraded to include CESH and a powered injector can be installed. All that is needed then is a contrast agent and medical staff trained in IV access. A protocol must be drawn up to prevent, record and follow any adverse reaction, although these are rare. There is a fast learning curve, as the images are not difficult to interpret; it is just treated as a two-part mammography exam. The first part is just a regular mammogram that is carefully checked for secondary finding. The second part is the contrast-enhanced image, where normal breast tissue has been subtracted to highlight abnormal findings. This enhancement makes the image very easy to read.

Breast imaging radiologists soon see the benefits, as Dr Liao explains: *"I once had a new breast imaging radiologist join my team, who was trained in tomosynthesis. As soon as he saw the first couple of contrast-enhanced mammography images, she was converted. She felt it gave him potentially more information than tomosynthesis or ultrasound for detecting early breast cancer, especially where there is no abnormal anatomical structure but just angiogenesis."*

SENSITIVITY
TO INCREASE DIAGNOSTIC ACCURACY

up to **20%**

High sensitivity

SenoBright HD achieves a better diagnosis performance for breast cancer than mammography diagnosis. For dense breasts, it improves breast cancer detection up to 20%.

Practical benefits for radiologists and patients

Along with the technical advantages, CESH also offers a number of logistical benefits compared to MRI. It is a combination of mature, well-established exam modalities. In fact, a lot of patients can be self-referred by radiologists. As previously stated, existing equipment can be upgraded to include CESH technology, so the radiologist's workflows and protocols are similar to those already in use for mammography. The exam is relatively easy to perform, and the process does not add significantly to the examination time³. It is cost effective too, comprising a diagnostic mammogram and IV administration of a contrast dye – far less than the cost of breast MRI⁴. However, perhaps the biggest benefit of CESH is that it can be widely provided to patients needing functional studies to identify or eliminate a problem when standard mammogram and ultrasound exams have not been conclusive; most

women will have access to mammography services even if MRI is not available.

From the patient's perspective, a CESH exam is very similar to a conventional mammogram, and they usually receive their results immediately afterwards. It also takes less time than an MRI scan⁴, which requires the patient to lie in a scanner without moving for as long as half an hour, followed by a longer waiting time for the images to be reviewed and the results confirmed.

Dr Liao agrees: *"CESH is an alternative for patients unable to undergo an MRI scan. It is potentially more comfortable for the patient, quicker, and they don't have the stress of going home and waiting for somebody to phone with the results. Importantly for the hospital, it doesn't cost much more than a standard mammogram to perform."*

CESM for high risk patient

Another key benefit of CESM is for diagnostic individuals at high risk of developing breast cancer. In the US, the family history needs to place women in the top 20 per cent of people at risk in order to qualify for breast MRI. Women with a high risk who are not able to access MRI or whose medical insurance does not cover the procedure will, understandably, be anxious and looking for answers. For this population, CESM is often the solution.

“Many of these women will be young, with dense breast tissue, and our current procedure for them is to use contrast mammograms for diagnostic in conjunction with ultrasound. It’s a very good approach because of its accessibility. You can perform the exam just before or after the ultrasound and give the patient the result straightaway. It’s very quick, with instant reporting,” says Dr Liao.

Ultrasound vs mammography

China has one of the largest populations in the world and, therefore, huge numbers of women to screen. The implementation of a screening programme – included in some insurance policies for certain populations – along with growing awareness of the disease, has contributed to an increased detection rate. Currently, China’s screening policy⁶ is to use ultrasound rather than mammography because of the demographic of dense breast tissue.

This makes sense, since mammography would not be sufficiently sensitive to identify suspicious findings in these women, other than calcification. Ultrasound is also comparatively less expensive than a mammogram for screening.

However, although commonly used, ultrasound is not an ideal tool for a breast evaluation program. The technique is operator dependent, which can affect the efficiency of identification of lesions, and not all malignancies can be detected, for example, invasive lobular cancers. This combination non-uniform evaluations and under detection results in a large percentage of women experiencing a delay in diagnosis – missed calculi, multicentric, multi-focal or contralateral breast cancers – and treatment, only presenting once they have symptoms. This is scenario where contrast-enhanced mammography, can prove highly beneficial.

With as many as 70 per cent of Chinese women having dense breast tissue, its incorporation into routine protocols would enhance dense breast and high-risk women helping to improve cancer detection rates. If a suspect finding is detected during the frontline screen, CESM can be used for follow-up diagnostics to identify the likely problem, providing an indication of the level of suspicion. It also gives an idea of what else is hidden in the breast tissue that cannot be seen on a mammogram. This helps to avoid missed or wrongly diagnosed findings and unnecessary treatment. Clearly,

contrast-enhanced mammography has much to offer the female population of China.

“The big challenge for China is that mammography cannot be used for screening. However, some major cities, including Shanghai and Beijing, have adopted CESM, although predominantly for problem-solving and not routine screening. There is undoubtedly a huge opportunity to explore the use of contrast-enhanced mammograms to help physicians to detect early breast cancer in China. The good thing is that the Chinese have now approved the use of contrast-enhanced mammography, and this new service is coming into clinical use,” Dr Liao concludes.

Benefits for women worldwide

Contrast-enhanced mammography is a great step forward in breast care pathway. Its ability to distinguish lesions in dense breast tissue is highly beneficial in many circumstances, providing rapid results that can rule out benign lesions and help stratify suspicious findings. While this is important for the global female population, it is even more significant for Chinese women, simply because their biology is different.

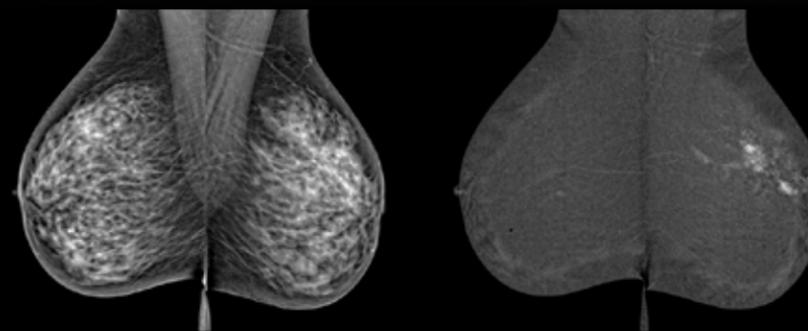


GE Healthcare

SEE DIFFERENTLY SEE IN CONTRAST

SenoBright™ HD

Contrast Enhanced Spectral Mammography



SenoBright HD Contrast-Enhanced Spectral Mammography technology offers an **astoundingly 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**¹.

gehealthcare.com/SenoBright

1. Jin J. Breast Cancer Screening Guidelines in the United States. JAMA. 2015;314(15):1658. | 2. He J, Chen WQ. Chinese Cancer Registry Annual Report 2012. Beijing: Tsinghua University Press; 2016 (in Chinese). | 3. Li J, Zhang BN, Fan JH, et al. A nation-wide multicenter 10-year (1999–2008) retrospective clinical epidemiological study of female breast cancer in China. BMC Cancer. 2011;11:364. | 4. Wang F, Tse LA, Chan WC, et al. Disparities of time trends and birth cohort effects on invasive breast cancer incidence in Shanghai and Hong Kong pre- and post-menopausal women. BMC Cancer. 2017;17(1):362. | 5. Yuan X, Yi F, Hou C et al. Induced Abortion, Birth Control Methods, and Breast Cancer Risk: A Case-Control Study in China. J Epidemiol. 2019;29(5):173-179

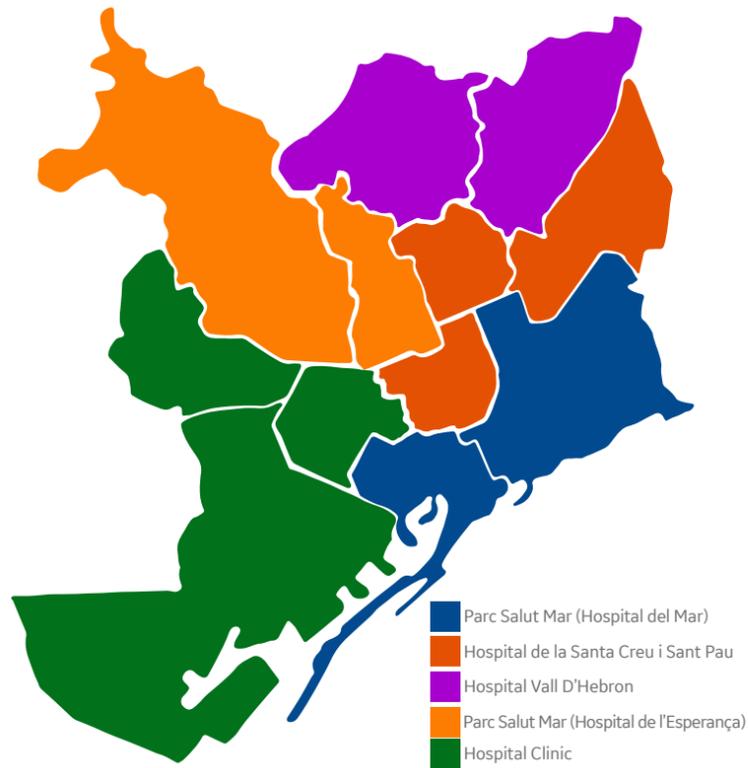
The statements by GE’s customers reported here are based on results that were achieved in the customer’s unique setting. Since there is no “typical” hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

Don't guess, see it clearly and biopsy it with contrast enhanced guided biopsy

Hospital del Mar is the second hospital in the world performing contrast enhanced guided biopsy for the diagnosis of breast cancer.

The interest of Contrast-Enhanced Spectral Mammography (CESM) has significantly increased over the past few years. Main reasons for this, are firstly, the superior diagnostic accuracy compared to diagnostic mammography alone with 20% increased sensitivity in dense breasts, and secondly, the similar clinical performance to breast MRI that makes it an excellent alternative. However, despite the many benefits of CESM, up until now the technique had the inconvenience that taking a biopsy of any suspicious lesion detected by CESM meant that the biopsy guidance had to be carried out using another imaging modality. This situation has now been addressed with the introduction of the Pristina Serena Bright CESM biopsy solution from GE Healthcare.

PARC DE SALUT MAR



BREAST IMAGING 2018



- FFDM: 6,417
- CEMM: 341
- US: 4,995
- MRI: 344
- FNA: 278
- US Core-Biopsies: 629
- Stereo/DBT VAB: 164
- MRI VAB: 7

SCREENING PROGRAM

- Women invited: 34,895
- FFDM: 18,501 (53%)
- Recall: 894 (4,8%)
- Invasive procedures: 262 (1,4%)
- Diagnosed cancer: 98 (34%)

BREAST CANCER UNIT 2018

- Breast cancer: 294
- Breast surgeries: 360

Barcelona, January 30, 2020.

Since October 2019, Hospital del Mar, has been equipped with a new breast biopsy tool called Prisitina Serena Bright™ – the healthcare industry’s first contrast-enhanced mammography solution for biopsy.

For any mammograms labeled with “suspicious findings,” interventional and biopsy procedures are typically the next step in breast cancer diagnosis. Until recently, contrast-enhanced biopsy was typically performed with breast MRI for lesions not seen on mammography or ultrasound, which can be more time-consuming, uncomfortable and costly for patients. On top of this, patients can wait several weeks just to schedule the MRI exam.

15 cases performed

The professionals at Hospital del Mar have performed 15 biopsies guided by contrast mammography. Dr. Rodrigo Alcántara, the doctor in charge of the Breast Radiology section, highlighted the reliability of this technique. *“The most important thing for the patient is to undergo a reliable procedure, and this technique helps us to locate lesions accurately that are hidden for other imaging methods.”*

The introduction of breast biopsy guided by contrast mammography can be relatively rapid since it uses the same equipment. As explained by Dr. Josep Maria Maiques, head of the Radiology Service, *“magnetic resonance biopsy, being a complicated technique, is always limited to cases in which there are no alternative. But the*

contrast mammography biopsy is a technique with an easy and fast workflow, so it will become, without any doubt, a more common technique. □



Dr. Rodrigo Alcántara, MD

Head of Breast Imaging Section in the Radiology Department of Hospital del Mar in Barcelona, Spain. Head Radiologist of the Breast Cancer Screening Program.

Dr. Rodrigo Alcántara Souza is a consultant radiologist and interventional breast imaging specialist at Hospital del Mar in Barcelona -

Spain, with a special dedication to imaging in oncology clinical trials, interventional procedures in breast imaging and breast cancer screening program. He also practices as an Assistant Professor in the Medical School at the Pompeu Fabra University and for the University of Barcelona. Dr. Alcántara Souza has been extensively working with CEMM as a problem solving tool and is now a pioneer in Contrast Enhanced guided biopsy.

Contrast enhanced guided biopsy is designed to allow a proper access to enhancing lesions that cannot be reliably sampled under ultrasound or mammographic guidance. What has your experience been with this technology?

Dr. Alcántara: “We had this technology available since October 2019 in our department, under board approval for the use of the healthcare industry’s first contrast-enhanced mammography solution for biopsy.

Our initial findings have been incredibly successful in reliably targeting enhancing lesions to ultimately find cancer earlier.

We, radiologists, have lots of experience in dealing with mammographic guidance for breast biopsy, it’s in our daily practice, so the

implementation and the workflow of a novel mammographic procedure is easy, and the software interface is very intuitive.

The procedure itself is similar to a standard stereotactic biopsy, with an additional step of contrast agent injection 2 minutes before starting imaging. Like in CEMM, each acquisition is composed of a low-energy (LE) and high-energy (HE) exposure and the radiologist can use both the LE images (equivalent to mammograms) and the recombined images (where the contrast uptake is visible) to reliably target the lesion”.

How does this compare to breast MRI?

Dr. Alcántara: “MRI and CEMM are both functional breast imaging modalities where we can depict contrast uptake in

areas of suspected neoplasia.

We have a large experience in the implementation and use of the MRI and CEMM technique in our department.

Sometimes, there are some suspected findings that you can only see and biopsy with a functional contrast enhanced technique and so far, the only one available was the MRI guidance.

For most of doctors and technicians, preparing and performing a MRI procedure is somehow stressful, it’s not routinely done and sometimes the lesion is difficult to approach, making it last more than expected.

This novel approach has the potential to be a more affordable and faster alternative to MR-guided biopsy for suspect enhancing lesions”.

How many exams have you done so far?

Dr. Alcántara: "So far we biopsied 15 cases. Considering the clinical context and our area of influence, this is an interesting number. Remember that suitable indications are for lesions that you cannot access by ultrasound or standard mammo guidance".

What has the patient feedback been?

Dr. Alcántara: "The overall patient feedback is good and they usually state that the procedure was much less intimidating than what they expected. Of course, having a scheduled breast biopsy intervention causes stress and disturb the patient's normal life, so having this in a fast,

efficient and easy way may be of help.

In the other hand, MRI guidance itself is very useful, but costly, time demanding, difficult to implement and very stressful for both patients and radiologists. The positioning is a major issue to the patients as the procedure is not fast and may be uncomfortable.

So far, our procedures last for around 12 to 16 minutes, from the first compression to the clip placement, that's a very good deal".

Anything else you'd like to share?

Dr. Alcántara: "The role of the breast radiologist has evolved from simply cancer screening and detection to a more complete diagnosis and management with the widespread

adoption of image-guided interventions. In the same way, the percutaneous biopsy has proven to be a reliable alternative to surgical biopsy and recently there has been considerable progress in terms of diagnostic, interventional techniques and devices. This is the beginning of a new profile of breast radiologists, more participative, clinical and interventional". □



The statements by GE's customers reported here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

Contra-lateral lesion biopsy in a dense breast using CESM guided biopsy

Courtesy of Dr. Rodrigo Alcántara Souza, Hospital del Mar, Barcelona, Spain.

Patient history

The Patient is 61 years old. She has a palpable lump in the lower Inner quadrant of the right breast which is easily visible on the Low Energy images.

Step 1
CESM findings

The recombined images show a strong enhancement in a mass with ill defined margins. They also reveal an external posterior foci. Both lesions were found and biopsied with US.

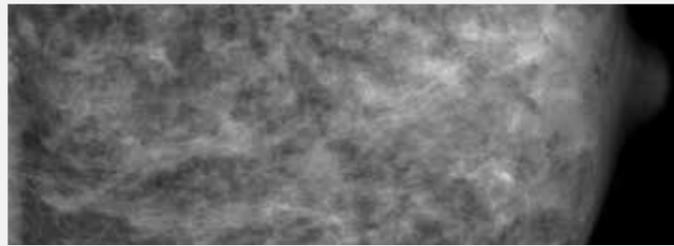
*Histopathology result :
Grade I Invasive Ductal Carcinoma.*

*On top of the findings in the right breast, CESM reveals an additionnal mass of 6 mm à 12 o'clock
An ultra sound biopsied was decided.*

In the left breast there Is an additional finding on diagnostic CESM, a 6mm enhancement at 12 o'clock.

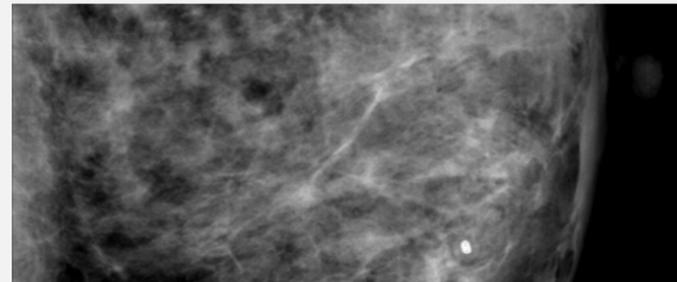
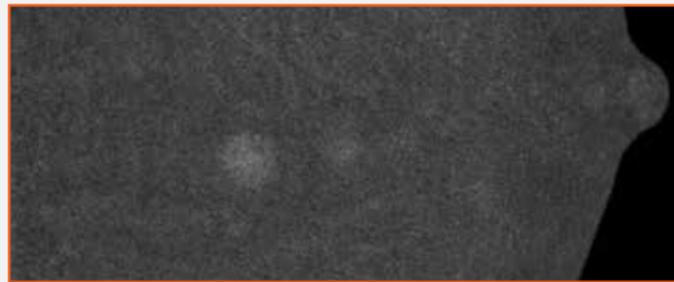
Step 2

Ultrasound guided biopsy



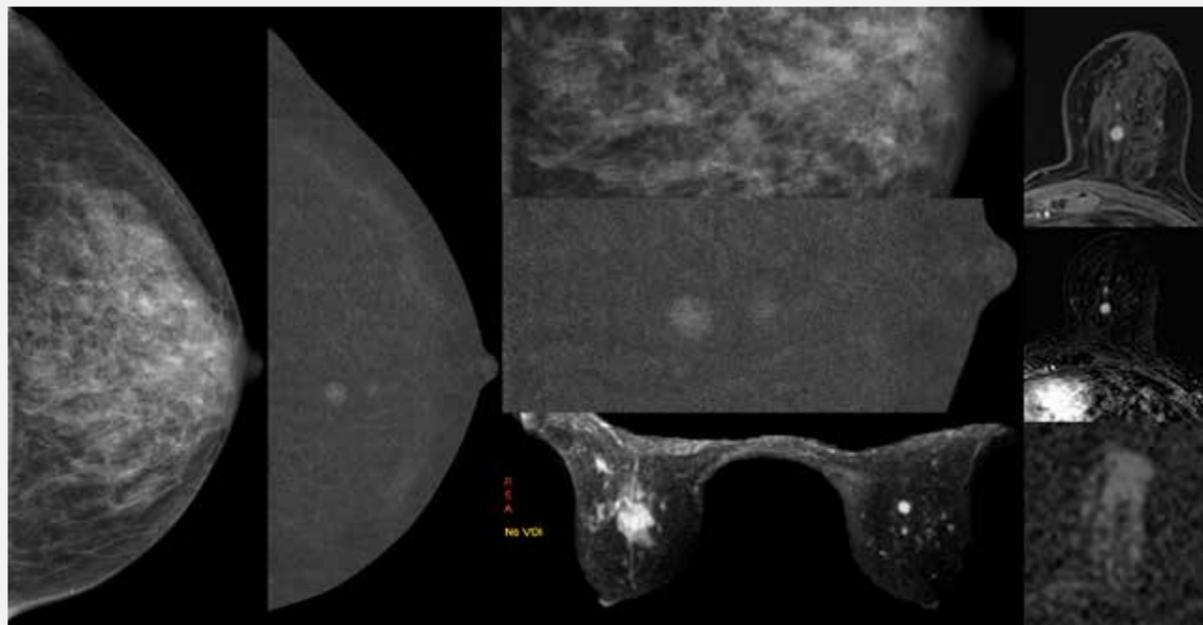
A first ultrasound biopsy was performed in what seemed to be the lesion. But as imaged, the marker does not correspond to the enhancing lesion.

Histopathology results report no valuable alteration. It is therefore decided to wait for an MRI assessment.



Step 3

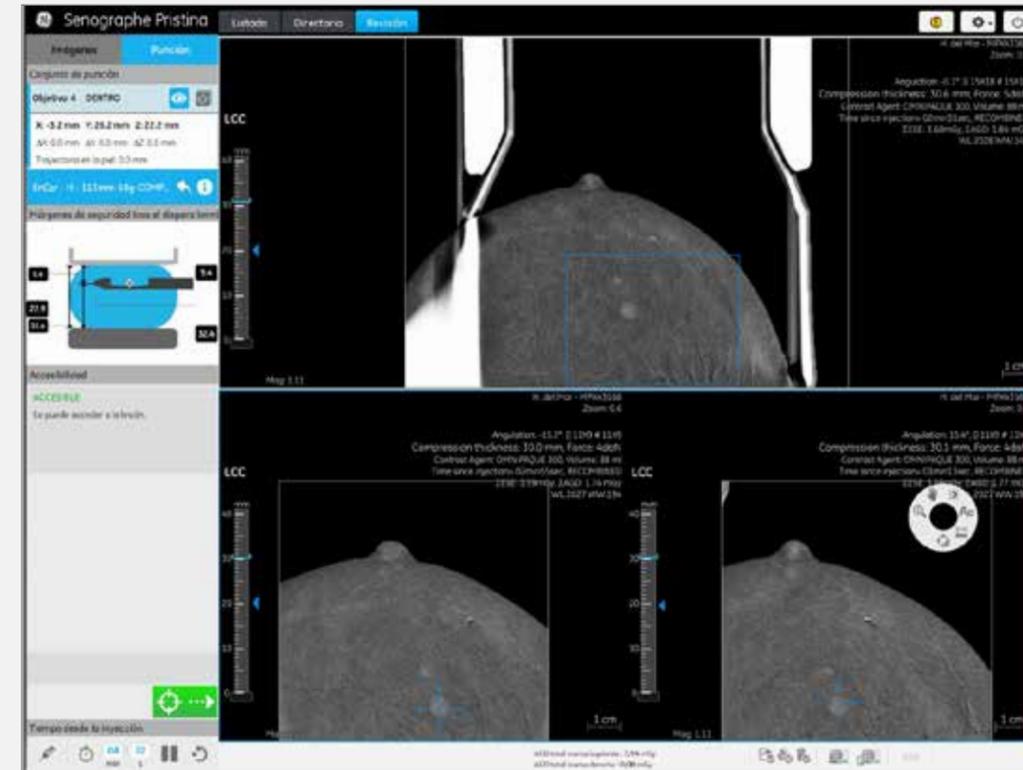
MRI examination



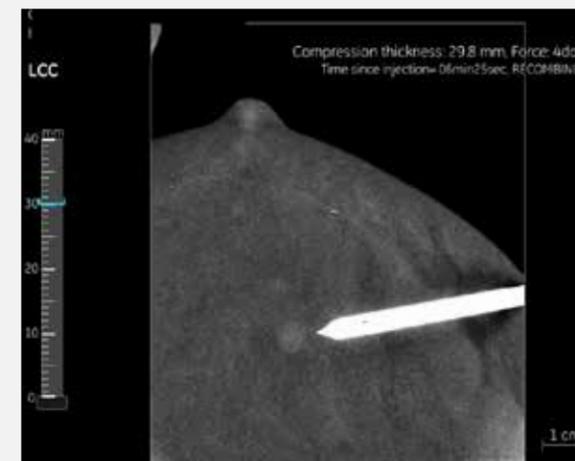
MRI exam confirmed the extension of the right affection. The ultrasound biopsied lesion did not match with the enhancing left mass and presents with suspicious morphology, enhancing pattern and with restriction on ADC map. This MRI took place the same week the evaluation of CESM guided biopsy started at Hospital del Mar. It was therefore decided to propose it to the patient.

Step 4

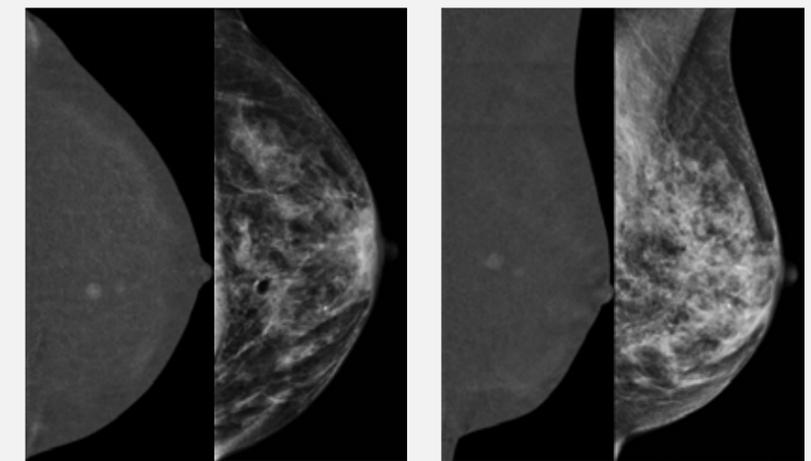
Contrast Enhanced guided biopsy



For this case, the patient was sitting and a horizontal approach was chosen. The lesion and the little satellite enhance both in the scout and angulated images.

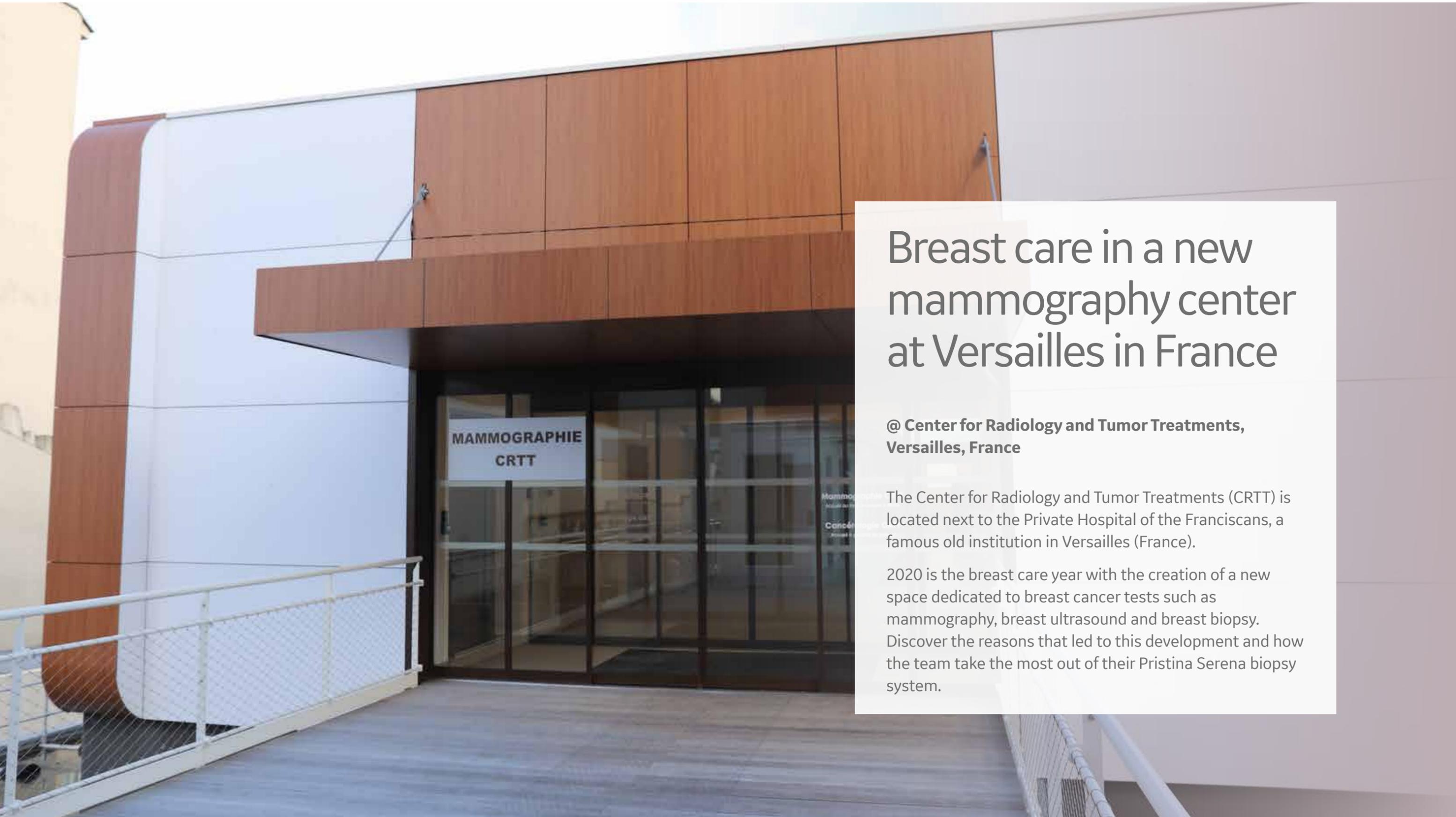


First pre-fire image, after the anesthetic. The needle tip points exactly to the enhancing lesion.



Finally, on the 2D post-procedure image, one can see the correlation between the enhancement and the clip position. Histopathology result: Grade II Invasive Lobular Carcinoma.

The statements by GE's customers reported here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.



Breast care in a new mammography center at Versailles in France

@ Center for Radiology and Tumor Treatments, Versailles, France

The Center for Radiology and Tumor Treatments (CRTT) is located next to the Private Hospital of the Franciscans, a famous old institution in Versailles (France).

2020 is the breast care year with the creation of a new space dedicated to breast cancer tests such as mammography, breast ultrasound and breast biopsy. Discover the reasons that led to this development and how the team take the most out of their Pristina Serena biopsy system.



You and your colleagues have been at the forefront of this mammography unit initiative, what reasons motivated you to pursue this transformation?

Dr. Tachet: We have been trying for several years to create a unit entirely dedicated to mammography within the hospital's radiology department. But the floor space constraints and other radiology activities posed difficulties. The construction of a new floor in the oncology building provided an opportunity for us to create this unit. The architects added a floor to the building, so today we have a much larger space in a quieter location, which we consider essential to make our patients feel as comfortable as possible.

How does your radiology department for women work?

Dr. Tachet: The center now has a single dedicated reception, a dedicated waiting room, a mammography room adjoining a breast ultrasound room, both with changing cabins (see map next page). In our center we perform both diagnostic and screening mammograms as part of a screening program. We also perform biopsies and installations of clips and hook wires. The team is made up of four radiologists and six assistants.

Do you see some difference in the way you operate and in the satisfaction level following this transformation?

Dr. Tachet: We had three goals: improve the quality of the patient experience, facilitate medical procedures and give patients the ability to see an oncologist on site. This is necessary within the context of continuous medical services that both our patients and the authorities are looking for. Patient experience is a very important element. Having a mammogram is not an everyday experience. Our new environment makes a positive change to the patient journey. The extra space and workplace ergonomics have also contributed to improving medical procedures, especially when handling patients. Finally, sharing premises with our oncology colleagues promises improvements in overall care.

What does having this new unit mean for the future?

Dr. Tachet: Now we can combine advantages of a local clinic dedicated to women. In addition we are thinking about setting up a « breast care program » that would bring together the clinic's multidisciplinary team focused on breast care: surgeons, radiotherapists, anatomical pathologists and radiologists in order to improve and reduce the amount of time patients spend here by making all examinations possible in one day.

Speaking again of the innovations brought into the clinic, you received the biopsy unit more than a year and a half ago. What is your

experience after these months using this system?

Dr. Tachet: It is a great tool which makes mammography biopsies clear, clean and simple! I appreciate the fact that the process is computer assisted and improves patient safety. Thanks to precise data on needle size and lesion position plus an awareness of the surroundings (breast support and chest wall), the system can alert if there is a risk of collisions, a risk regarding the chest wall or skin tears. I like how the machine makes my patients feel safe and allows for adjustments when performing a biopsy. □



Christel Lefevre
Technologist at CRTT

You have been a mammography assistant for 30 years. What are the impacts of the latest mammography technologies on a daily basis from your perspective?

I have noticed that innovations related to the design and comfort have had a significant and direct impact on patients. For example, the compression paddles that we use for the mammograph can adapt to a patient's breasts during compression. Consequently, women experience less pain, and once a patient feels relaxed, my work certainly becomes simpler.

I also found that the Dueta remote control (Patient-assisted compression device) has a reassuring effect on some women. When they feel too much pain on their breasts, they start resisting on the compression and they can stop it when they want, with my supervision.

And finally, the colorful design and decorative lighting make the mammograph look less like a medical

device and so patients feel less stressed and more comfortable with their examination.

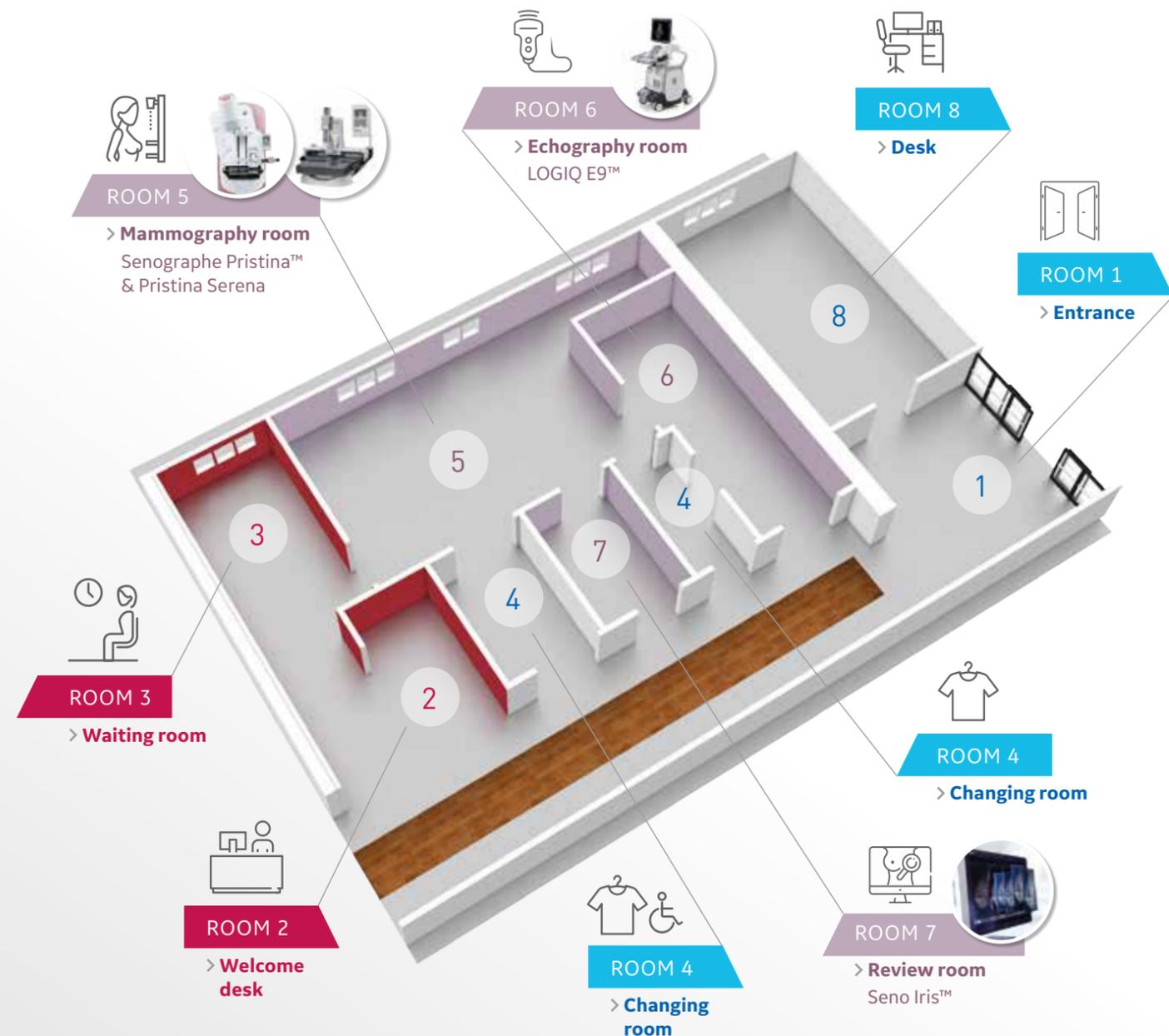
You have been performing biopsies for 8 years. What is the main challenge in this procedure and how does Pristina Serena help?

During a biopsy procedure, one of the most difficult scenarios for me is to find myself in a "borderline" situation, when the biopsy area is very superficial or very close to the detector or when breasts are very thin.

Pristina Serena makes our work easier in these difficult cases by signaling at the acquisition station if there is a risk of collision or skin tear, and by preventing an approach attempt if necessary. □

Center for Radiology and Tumor Treatments

Les Franciscaines, Versailles



1. A new approach to breast compression in Mammography, Imaging for Women, LLC, Kansas city, MI, 2019

The statements by GE's customers reported here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

Macro-biopsy of superficial microcalcifications with Pristina Serena™

Courtesy of Dr. Tachet, CRTT Versailles, France.

Clinical case

Screening exam

A 63 year-old patient without any risk factor, presented for her screening exam.

A cluster of granular but polymorphic calcifications are visible in the upper-inner quadrant of the right breast with an almost linear topography in the CC view (Fig. 1).

They have been ACR4b classified and therefore, a macro-biopsy was indicated.

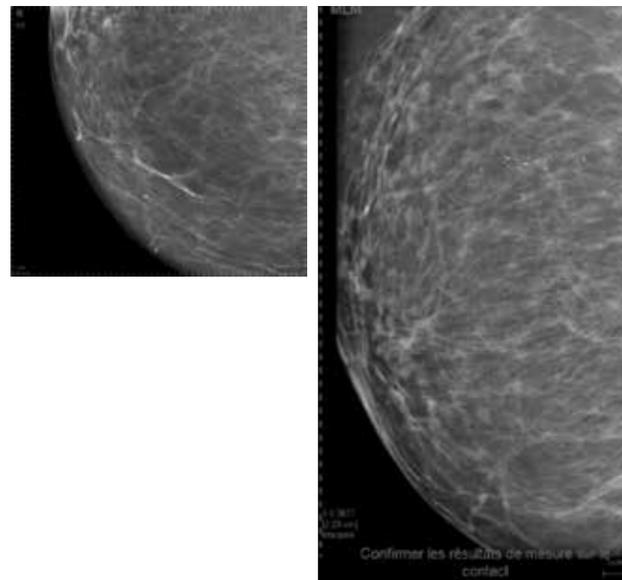


Fig. 1 Screening exam : Right Breast in CC and MLO view.

Step 1 Positioning and targeting

For such a challenging lesion location, which approach do you chose ?

For this procedure, we chose to position the patient in lateral decubitus and went for a vertical approach in the internal quadrant.

Scout view, +15° and -15° views are acquired to target the microcalcifications (Fig. 2)

The microcalcifications are located 7 mm above the compression paddle plane.

We tried to push them down with the local anesthetics but their position did not significantly change.

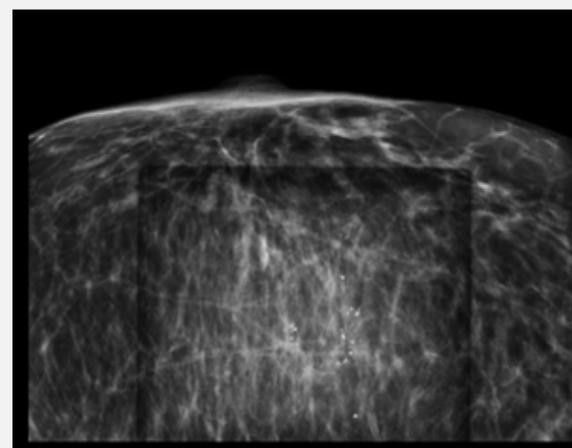


Fig. 2 Scout view for targeting.

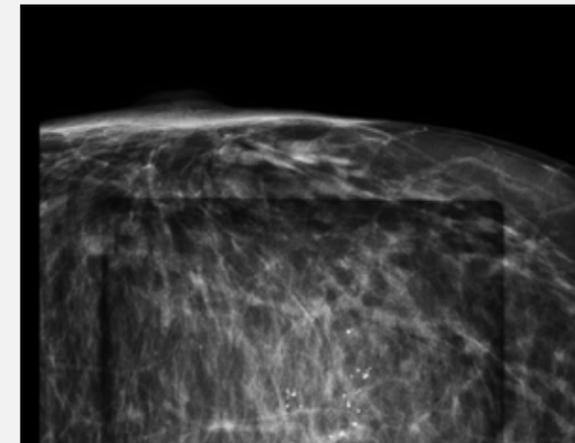


Fig. 2 +15° view

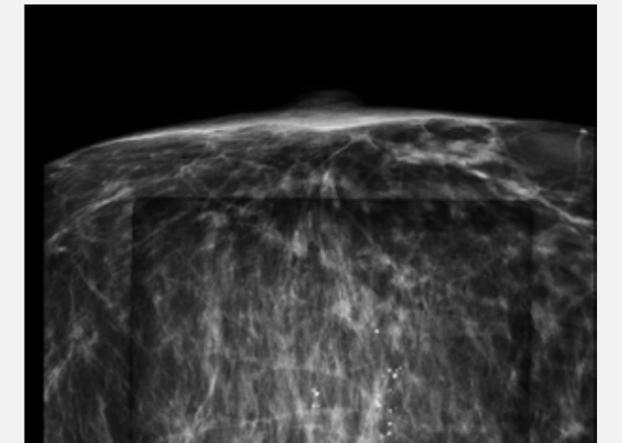


Fig. 2 -15° view

At this step, are you confident you can continue the procedure without any risk for the patient ?

Yes, let me explain why. First, I am confident that the system will allow to send the target only if there is no risk of collision and no risk for the patient. In this case the system warns me about a "Risk of skin tear" (Fig. 3).

The position of the lesion versus the needle is easy to understand with the dynamic schema and explanation. (Fig. 4). Target markers can be placed up to 10 mm above the upper surface of the compression paddle.

I have performed enough biopsies with Pristina Serena to trust what the system advises and to know that I will be able to adjust manually the needle position if necessary.

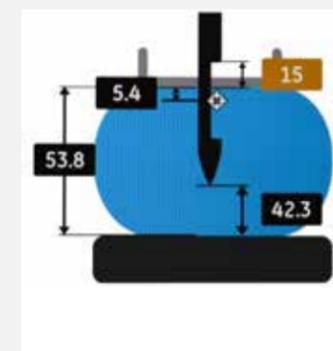


Fig. 3 Warning on the acquisition console before sending the target.



Risk of skin tear

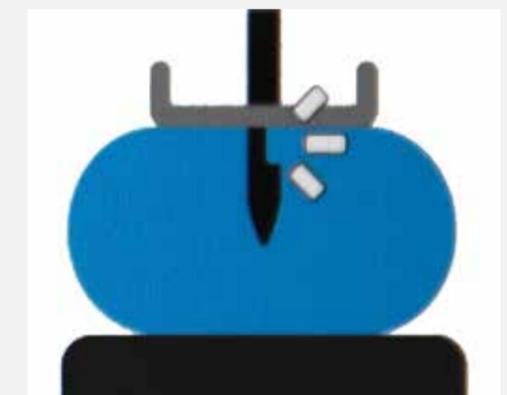


Fig. 4 dynamic schema on the acquisition console.

Step 2
Fine tuning
the needle position

The schema on the biopsy touch screen makes it very clear that, considering the lesion coordinates, and the needle dimensions, there was a risk of skin tear (5a).

To avoid this, I manually adjusted the position of the needle on the touch screen to move it 10 mm down (Fig. 5b).

On the display, I can check that

- The target is still in the biopsy notch, towards the upper part
- The needle is further away from the skin, avoiding any risk of skin tear.

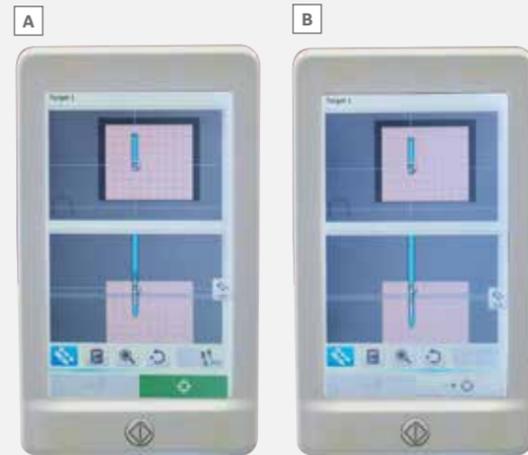


Fig. 5 Visualization of the needle (blue), the biopsy volume (pink) and the paddle (grey line) on the touch screen on the Pristina Serena
A: Initial position of the needle : risk of skin tear
B: Adjusted: no risk of skin tear

“I really believe Pristina Serena allows the duo radiologist – technologist to perform secure and precise biopsy procedure, in comfortable conditions for the patient. Thanks to the possibility to do adjustments on the touch screen next to the patient.”

Dr. Tachet



Step 3
Pre-fire - Post fire
Sampling - Clip

The biopsy can be performed, monitoring the skin and the position of the needle notch.
Pre and Post fire + 15° views are acquired.

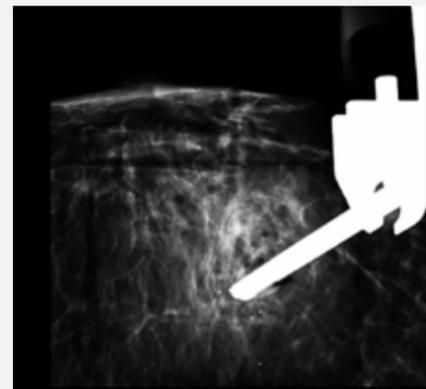


Fig. 6 Post fire view

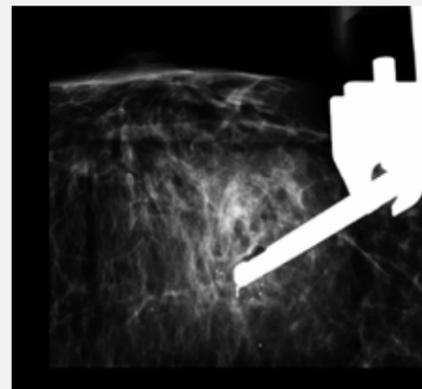


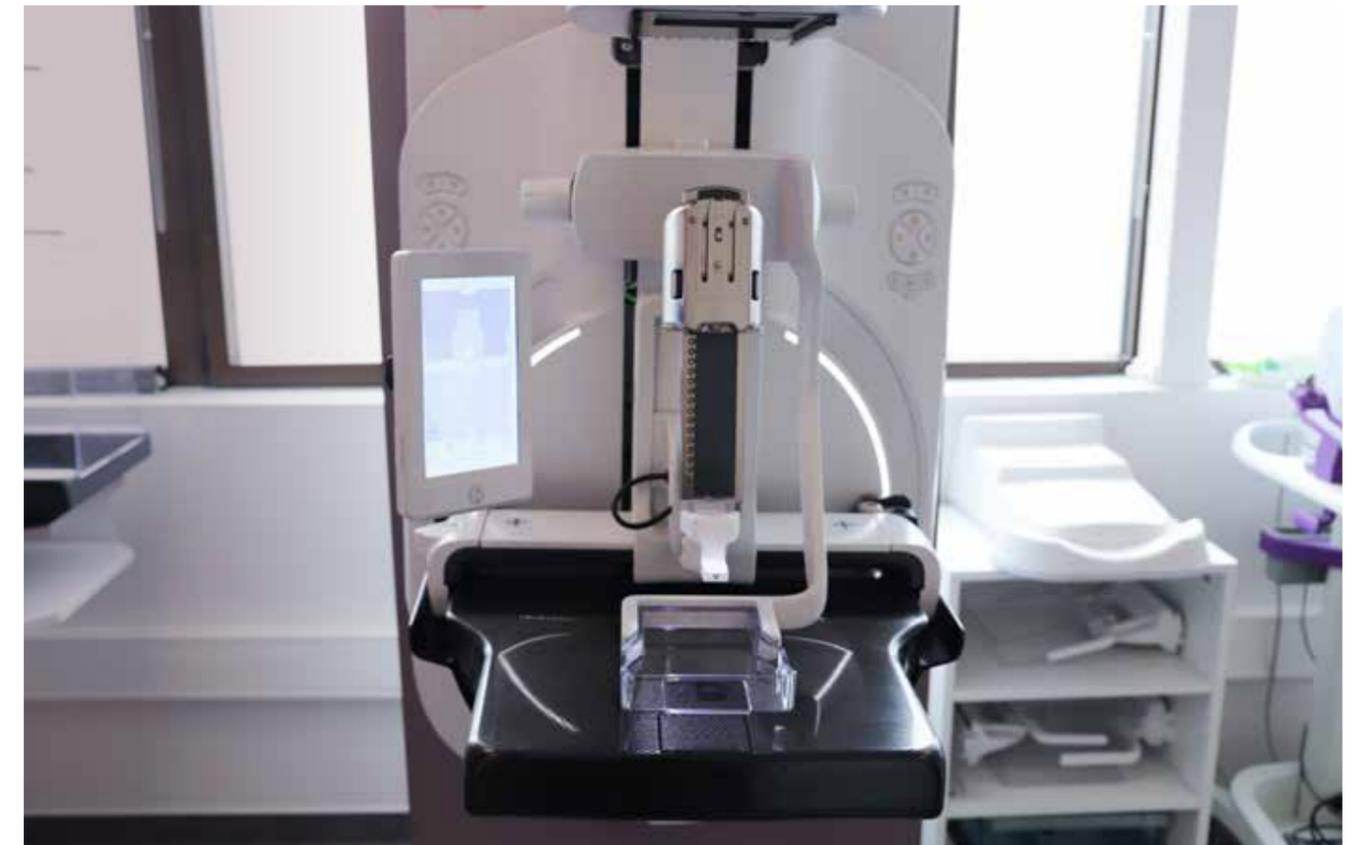
Fig. 7 Clip release.



Fig. 8 Images of the sample.

Histo-pathology result:

Hematoma associated with signs of resorption and lipophagic granuloma, on breast parenchyma in adipose involution. Absence of atypical character.



The statements by GE's customers reported here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

How can ProFound AI™ help with the challenges of tomosynthesis

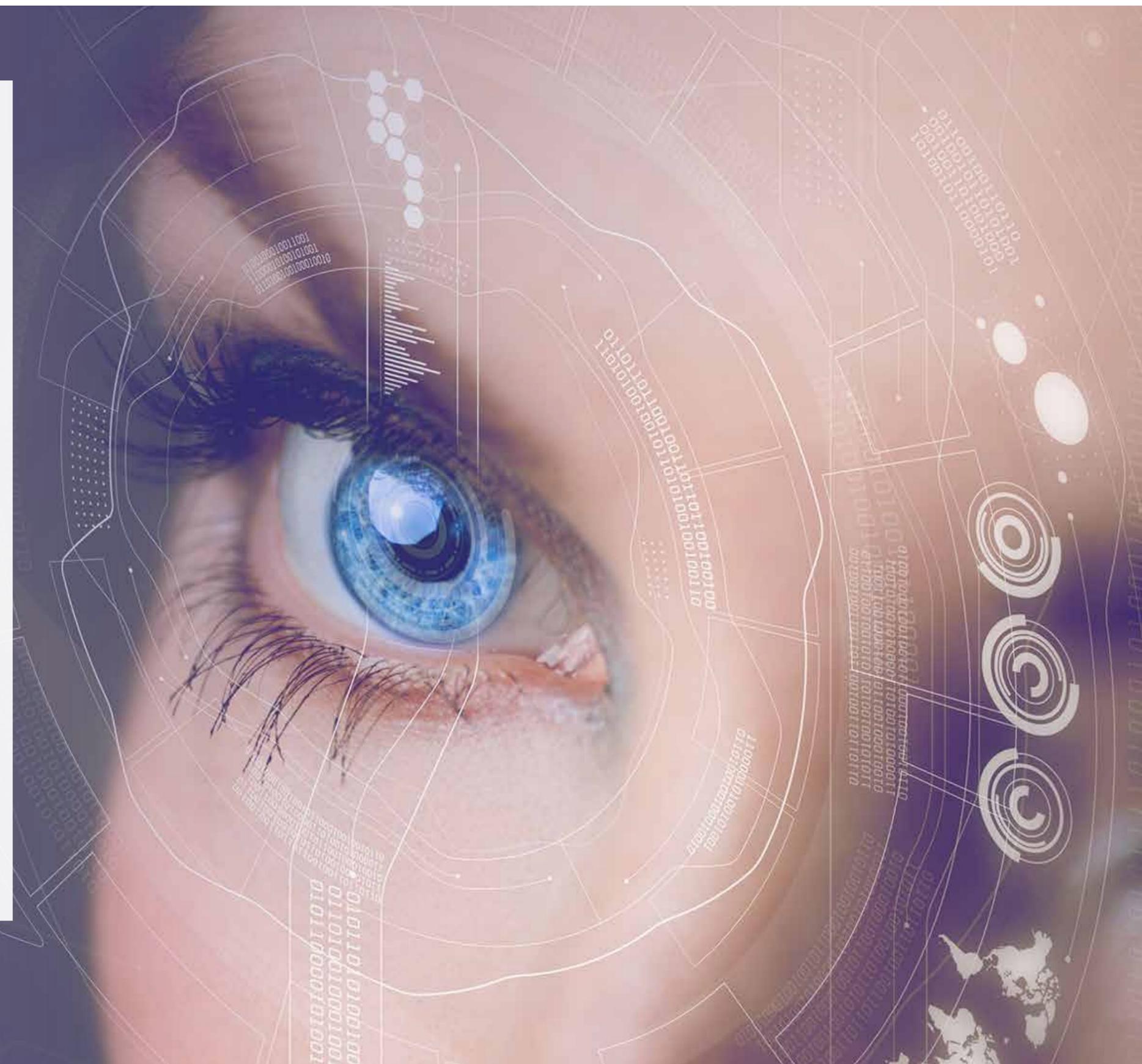
Interview of Dr. Axel Gräwingholt, MD, Radiologie am Theater, Paderborn (Germany)

AI is a very hot topic in Radiology in general and especially in the field of mammography.

Why? Simply because breast radiologists have high volumes of exams to read which are actually normal: those are the one which radiologists want to be read by a computer. And going from 2D to 3D imaging the volume of images radiologists need to read is 50 times higher!

The interesting point is that mammography is a radiology field that favours most AI capabilities as it is a very standardized environment. Standard exams (2 views per breast), standard reporting system (BIRADS lexicon). So it's ideal to explore the potential of AI.

Let's see how ProFound AI, a deep learning based algorithm can help with the challenges of tomosynthesis.





Dr. Gräwingholt is a radiologist specialized mainly in breast imaging. He is the co-owner of a private radiology practice in Germany with a screening unit for the official German breast cancer screening program. He is also Clinical co-chair of European guidelines for breast cancer. Dr. Gräwingholt is involved in several screening programs in Europe as a reader or consultant (Germany, Switzerland, Norway). He participates in a large trial in Germany (TOSYMA) to assess the value of tomosynthesis in organized screening programs. He annually views between 10-15000 mammo/tomo exams.

Where do you see the benefit of Artificial Intelligence in that context?

Dr. Gräwingholt: One point why tomosynthesis is so difficult to use in for example screening settings, is that the resources required timewise are so high that it is, if you have a large population, barely possible to read all these tomosynthesis images without help from an AI algorithm. Especially considering the future lack of radiologists and breast radiologists.

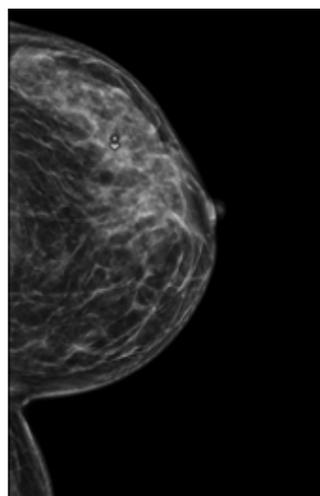
What did the use of Artificial Intelligence change in your daily clinical practice?

Dr. Gräwingholt: I think I'm a little more relaxed about the workload, because if I use Artificial Intelligence, I can be pretty sure it helps me during my daily routine. I can sort the difficult cases from the easier ones and it also improves the quality of my image screening. At present, we cannot use it in our screening program, but we hope we will in the future.

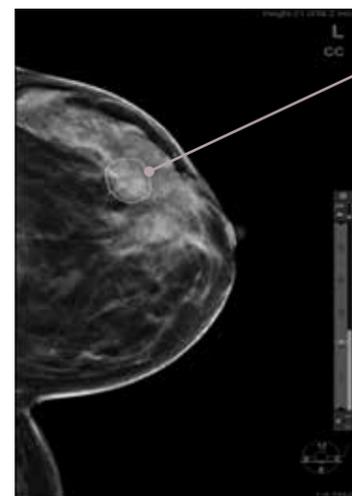
How do you see Artificial Intelligence evolving over the next couple of years?

Dr. Gräwingholt: As a radiologist I'm very much in favor of the early detection of cancer in the breast. Because studies have shown that detection is better in tomosynthesis than in 2D mammography, I believe that eventually tomosynthesis will become the main method of screening. But because of the

workload this is difficult. So the biggest benefit will be obtained when tomosynthesis is implemented together with AI algorithms to read in screening programs: to help detecting the lesion and request the exams for those who are most likely to be cancers. Most radiologists do not see possible "overdiagnosis" and a "false positive recall" as harmful as others might do – radiologists are there to detect what



Synthetic 2D with ProFound AI marker on the finding.



Tomosynthesis Planes of Interest / when clicking on the marker, it jumps to the planes of interest.

can possibly be detected with the most appropriate device and with the best possible outcome for the patient. But because of the workload and the difficulties in reading this is sometimes hard to achieve. So from what I see at his point, I really believe that workload can be decreased while maintaining quality, meaning higher detection, can be improved.

What is the impact on the patient?

Dr. Gräwingholt: I think the impact on patients is first of all that they can be more secure about lesions being found by the radiologist because the radiologist already has a second opinion. This applies especially to health care settings where a double reading of mammograms is not foreseen or impossible due to a lack of radiologists.

Another one is that if everybody would use AI algorithms, patients or women could get a similar quality everywhere – a very "European approach" - seeing the still varying quality between European countries in detection of breast cancer. But, AI algorithms must be tested thoroughly, quality assurance and certification processes for the use in standard care must be developed before all this can become true.

Do you expect to see tomosynthesis in European screening guidelines in the near future?

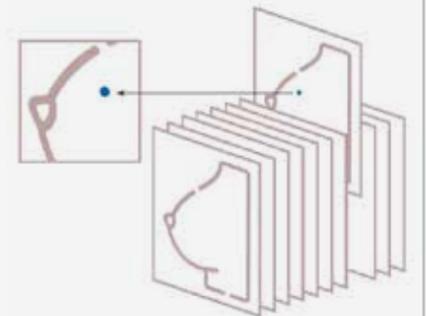
Dr. Gräwingholt: At present there is a lot of ongoing research about tomosynthesis and the benefits of tomosynthesis for diagnostic imaging and breast cancer and also a lot of talks about tomosynthesis in screening programs. But some challenges (DBT protocol, data storage, interval cancer detection...) remain to be solved, and studies still need to be conducted. Personally, as a radiologist, I would be in favour of doing tomosynthesis rather than FFDM in all cases in the future, but this is

a personal opinion based on my experience on breast imaging and dealing with women and patients every day for so many years now. □

The statements by GE's customers reported here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

How does ProFound AI work ?

The ProFound AI deep learning algorithm reads all DBT planes and subsequently reports microcalcifications, masses and architectural distortions. ProFound AI also displays markers or areas of interest in different DICOM formats that can be shown on a Seno Iris and PACS workstations.



The iCAD reader study shows not only increased sensitivity, but most importantly specificity, which means that ProFound AI performs better than conventional 2D CAD with regard to false positives¹.

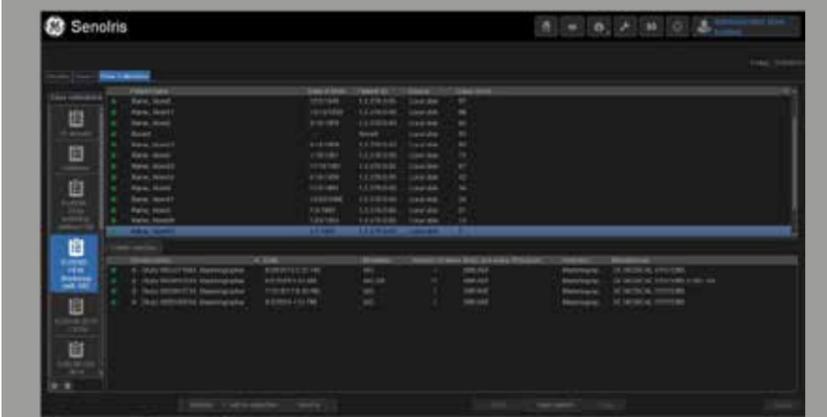
information provided by ProFound AI. Findings are marked on the 2D synthesized view, on the slabs and on the planes of interest. The display of markers is integrated directly in the reading protocol. Case and Lesion scores are integrated respectively in the worklist and displayed as overlaying annotations. Seno Iris navigation and CAD inspector tools allow a fully efficient workflow.

Seamless integration on Seno Iris™ SP3

Seno Iris integrates seamlessly the

Integrated with Seno Iris. ProFound AI displays case scores in the worklist.

A Case Score is assigned to each case by the ProFound AI algorithm. The Case Score represents how confident the algorithm is that a case is malignant, taking into account all detections in the case.



¹ Compared to reading without ProFound AI. iCAD labelling and user manual, DTM160 rev C. Reading times may vary based on the specific functionality of the viewing application used for interpretation

Invasive Lobular Carcinoma with ProFound™ AI by iCAD

Courtesy of Dr. Patrick Toubiana, Center Of Radiology and Medical Imagery Beaurepaire, Paris, France.

Patient history

- A 74-year-old woman presenting for her screening exam
- Clinical Exam: Normal
- No family risk factor

Acquisition

Personalized screening:

- 2D CC & MLO
- CC & MLO Tomosynthesis views

Step 1

2D & DBT Results

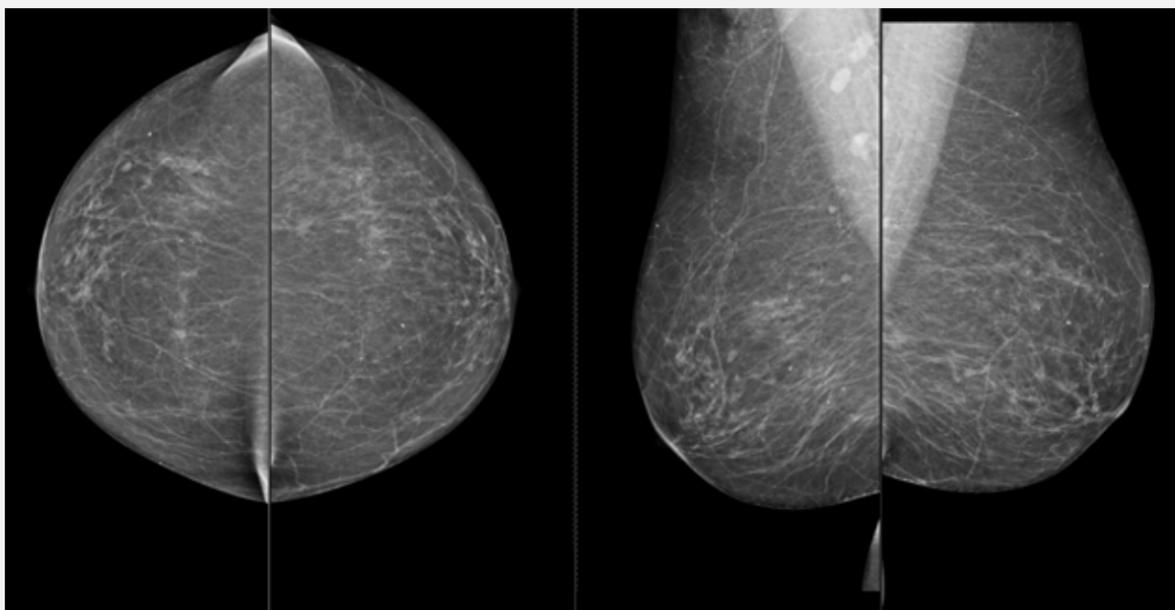


Fig. 1: 2D CC & MLO views

The 2D views reveal a low breast density (Fig.1), which is fairly easy for a radiologist to read. Small round opacities can be seen immediately in the right breast. These are probably either micro-ganglions or micro-cysts, in any case nothing to attract attention and consequently nothing of concern.

Step 2

Results with ProFound AI

The next step is to read the tomosynthesis volumes using iCAD's ProFound AI, a deep-learning artificial intelligence software trained to detect malignant soft tissue densities and calcifications. It's algorithm rapidly analyzes each individual image, or slice, circles the abnormal lesions detected in the tomosynthesis volumes and provides us with a malignancy suspicion score. A first marker is displayed on the left breast MLO view, showing a low score of 18% (Fig. 2a).

The CC view shows a score of 36% for the same lesion (Fig. 2b). 36% does not seem high but is nevertheless suspicious.

At first glance, one can indeed see a slightly denser area that can easily be missed, assuming that it's normal glandular tissue. Specifically, on the MLO view, there is nothing to see if not a discrete density that can be identified, once we know the algorithm's results.

The advantage is precisely to alert us and to help us identify a very subtle spot which is in fact the very start of a cancer.



Fig 2a: MLO with ProFound AI

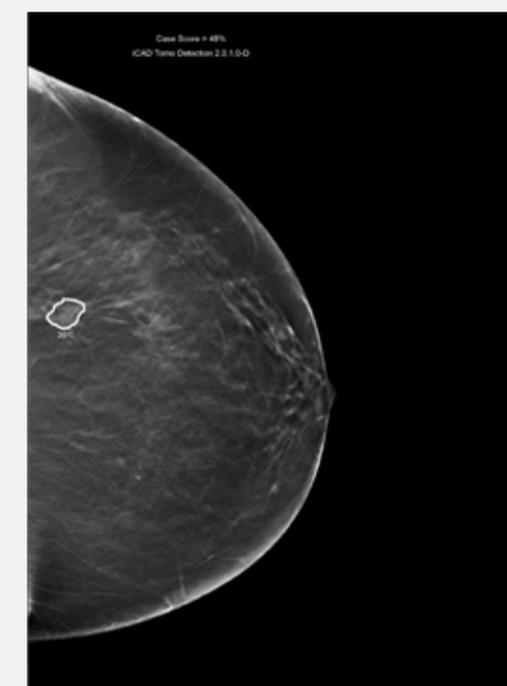


Fig 2b: CC View with ProFound AI

The basic assumption would be to believe that 18% is a low score, and therefore assume that there is no malignancy. But the CC DBT volume indicates a score of 36%, which is higher, and shows that the contours of the image are finely spiculated, which is very symptomatic of an incipient cancer.

The overall score of the case is actually 48%, meaning that the probability of the case being malignant is almost one out of two. The overall score considers the score of the lesion that was detected as well as the density of the breast, but also the existence of other lesions such as diffused micro-calcifications or other small lesions that are less alarming.

All of this will be combined to give an overall score of 48%. At our facility, we will require additional tests for every case above 40%.

Step 3

Ultrasound results

On the ultrasound, a small black triangular area that attenuates the ultrasound beam was observed, looking highly suspicious. Lesion was 7 mm. This finding led to the realization of a targeted biopsy.



Step 4

Biopsy results

The biopsy showed an 8mm invasive lobular carcinoma. When this type of lesion is diagnosed early enough, the recovery prognostic is excellent.

Clinical Benefits

Compared to 2D mammography, we feel that tomosynthesis offers improved clinical accuracy. With the new 3D Artificial Intelligence's tool, we feel we increased our confidence even more.

The statements by GE's customers reported here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.



CAPITALIZE ON ONLINE RESOURCES

to facilitate trainings and increase
your professional skills

GE Cares is a **community** where you **connect** with healthcare professionals, **share** your experience, publish contents and **learn** new techniques by having a direct access at the clinical webinars, protocols, clinical cases helping you improve your skills. You can also contact GE application specialists whenever you need to ask a question or get supported.



CONNECT

Connect with other healthcare professionals and grow your network. Interact with key opinion leaders and view their publications.



SHARE

Share your experience, publish content and stay up to date with the latest clinical trends shared by your peers.



LEARN

Learn new techniques and increase your skills in your daily practice. Access online trainings, educational contents, clinical webinars built by experts for experts.

Join the community now on **GECARES.COM**

Involving patients by using Pristina Dueta™

The experience at the Centre Mosaïque, Blois (France)

Globally, breast cancer is the most common cancer among women. With this in mind, in 2003 the European Commission recommended population-based screening for women in the age range 50 to 69. However, even with a screening program in place in almost all European Union countries, there is still variation in target population coverage and initiatives to maximize participation in screening examinations¹.

Mammography, the primary option for breast examination, is something many women find painful or uncomfortable due to the breast compression required. The thought of pain or discomfort can be a concern to women and put them off taking their screening exam². Accordingly, patient-assisted compression or self-compression was developed as a new feature. Evaluations have shown that the patient's perception of discomfort using patient-assisted compression was significantly lower than for compression performed by the technician³.



About the Centre Mosaïque

-Mosaïque santé is a medical center in France with a dedicated senology department. It performs both screening and diagnostic breast exams, and sees up to 25 patients per day. Christel - who is the radiographer - and Dr. Marchand have been working together in this center for many years. GE Senographe Pristina was introduced in 2017.

Experience of using Senographe Pristina™

The manipulations involved in mammography are repetitive, and physically demanding for the radiographer. Working in a

"Overall, this machine makes the work faster and easier"

mammography room may require the radiographer to adopt postures which can impact their health, namely via work-related musculoskeletal disorders. According to Costa et al⁴ the most awkward posture in mammography is when positioning for MLO views short-stature patients.

Christel explains: *"With the Senographe Pristina, the change in design was very noticeable. The positions are more natural, the workflow is easier. Overall, this machine makes the work faster and easier."*

Patient benefits

A major challenge during mammography, and one which has been extensively understood, is patient anxiety. Patient anxiety is mainly associated with fear of pain and fear of the results. Christel first observed the impact of patient involvement in the examination at another facility, which was already using patient self-compression. Christel says *"Working with a tool like Dueta that helps us better manage the fear of pain aroused our curiosity, and we were keen to try it out in our context."*

Her experience with patients shows that even if they are sometimes reluctant initially, patients generally feel enthusiastic about using Dueta



after the first image is taken. Changing their role, from undergoing an exam to participating in the exam, changes their focus and how they feel about it. Dueta helps in managing very anxious, extremely tense patients. Christel adds, *"The vast majority of them are very fond of this new technique. I often see them in the waiting room, discussing their experience of using Dueta"*.

"Christel proposes the use of Pristina Dueta™ and most of them accept it"

Another indication of the success and positive impact of the technique came when several patients were asking for Dueta again for their 6-monthly follow up examination. Christel has also found that reduced patient anxiety and greater relaxation makes positioning the patient easier. She says: *"Several times, I noticed it was easier to get deep tissue on the image, simply because the patient was less tense."*

Effect on Workflow

About half of the examinations performed in the center involve mammography screening. For screening exams, the usual protocol followed at this site is 4 views in 2D, supplemented by 2 DBT views. Appointments are scheduled for 20 minutes, with each appointment including image acquisition, image reading, potential extra views, a clinical examination and potential additional ultrasound images.

Patients due to undergo exams are given a leaflet informing them about the availability of Dueta before entering in the waiting room. Unless the patient advises they have an implant, Christel routinely suggests that they get involved in the compression process by using Dueta, and most of them agree to it. In these cases, Christel runs through the instructions from the leaflet again, and

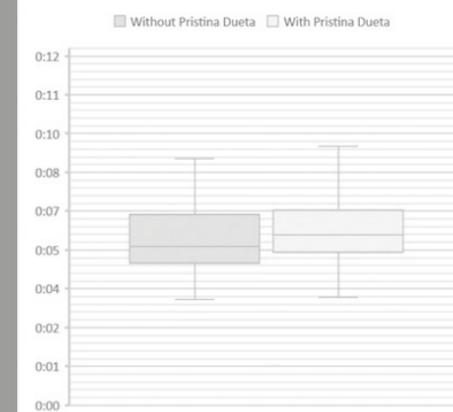
informs them that they will be using Dueta under her supervision. She tells the patients she will position them and compress them as usual, and overseeing that the compression performed by the patient is to an acceptable level.

While Dueta was being established, there was an initial transition phase during which Christel worked on how to explain and instruct patients in a minimum of time. Once this explanation was perfected, Christel found there was no change in the workflow. With or without Dueta, it takes her about 6 minutes to perform a full examination with 4x2D views and 2xDBT views. Christel says, *"I have more time to take care of my patients, talking to them and interacting with them, rather than manipulating them."*



A measurement of the examination time, for comparable examinations (4x2D and 2xDBT images) on 387 randomly selected exams over 2 consecutive months show no significant difference. Time is measured between the opening and the closing of the examination procedure and include the positioning of the patient, the compression process and the acquisition time⁵.

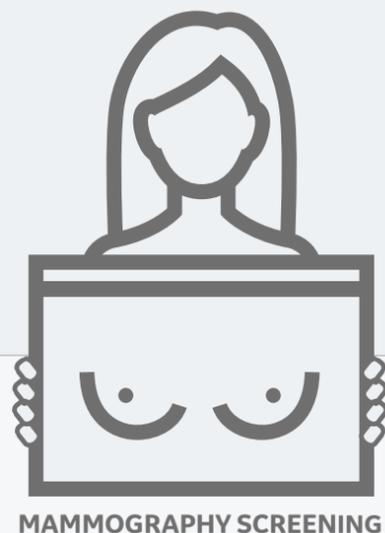
EXAM DURATION DISTRIBUTIONS IN MINUTES



1. Altobelli E, Lattanzi A. Breast cancer in European Union: an update of screening programmes as of March 2014 (review). Int J Oncol. 2014 Nov;45(5):1785-92. doi: 10.3892/ijo.2014.2632. Epub 2014 Sep 2.
 2. Whelehan P, Evans A, Wells M, Macgillivray S. The effect of mammography pain on repeat participation in breast cancer screening: a systematic review. Breast. 2013 Aug; 22(4):389-94.
 3. Kornguth PJ, Rimer BK, Conaway MR, Sullivan DC, Catoe KE, Stout AL, Brackett JS. Impact of patient-controlled compression on the mammography experience. Radiology. 1993 Jan;186(1):99-102.
 4. Costa S, Oliveira E, Reis C, Viegas S, Serranheira F. Mammography equipment design: impact on radiographers' practice. Insights into Imaging. 2014;5(6):723-730. doi:10.1007/s13244-014-0360-2.
 5. Analyses from two months of use on Centre Mosaïque, France.

The statements by GE's customers reported here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

REDUCING THE PAIN AND ANXIETY ASSOCIATED WITH MAMMOGRAPHY EXAMS



To help reduce barriers limiting a woman's willingness to go for a breast cancer screening exam, GE recognized **the importance of reducing the pain and anxiety** associated with mammography exams*



35%

Regular mammography screening exams can reduce breast cancer mortality for women between the ages of 50-69 years by up to 35%². And yet, many women who are invited to participate in breast cancer screening programmes throughout Europe do not attend the exams.

80%¹

Pain associated with mammography exams has been identified as an obstacle limiting women's participation in breast cancer screening programmes³.

94%

Stated that they were **less anxious or not anxious at all** during the exam

83%

Had a **more positive experience** compared to previous exams

77%

Would prefer to have their **next exam** with the **same system**

80%

Found that the **patient-assisted compression** device made the exam **more comfortable**

*To test this theory, GE partnered with a private radiology centre in France and a public oncology centre in Italy to perform a study that evaluated the impact of the GE Senographe Pristina™ mammography device on 315 patients' perception of the exam experience¹. De Groot et al, What determines pain in mammographic breast compression?, ECR 2012, 10.1594/ecr2012/C-2384.
2. International Agency for Research on Cancer (2016) IARC Handbooks of Cancer Prevention, Volume 15, Breast Cancer Screening. IARC, Lyon, France.
3. Whelehan P, Evans A, Wells M, Macgillivray S. The effect of mammography pain on repeat participation in breast cancer screening: a systematic review. Breast. 2013; 22(4):389-94.

Alexia Cassar brings wholeness back to breast cancer survivors one nipple at a time

As if the experience of breast cancer itself weren't devastating enough for a woman, the disease attacks her very sense of self and femininity, especially if she needs a mastectomy. Although many women choose to undergo breast reconstruction after mastectomy, the procedure isn't complete because surgeons can't create a realistic looking nipple.



Enter Alexia Cassar, 43, who lives in Marly-la-Ville, a village in north Paris. Three years ago, Cassar quit her job as an oncology researcher to apprentice herself to a tattoo artist and learn the complex art of 3-D nipple tattooing. In the process, she also learned how to restore a woman's sense of self.

"The effects of breast cancer and its treatment on a woman's professional, personal, and intimate lives is huge and often misunderstood," she said. *"Women lose their hair, lashes, brows,*

breast, body shape, and above all, self-confidence. They can feel disconnected from their bodies."

After cancer treatment ends, she said, family, friends, the medical community, and society push women to move forward and take control of their lives. *"But as long as they do not feel completely confident in themselves, there is a kind of barrier they cannot overcome and they can stay stuck in this 'after cancer' world,"* she said. *"The cancer may be gone, she*

said, but women often feel as if their body has been through war zone."

Experiencing Cancer Firsthand

Cassar's transition from cancer biologist to tattoo artist began in 2013 when her 10-month-old daughter was diagnosed with acute myeloblastic leukemia, requiring months of intensive chemotherapy and almost two years of follow up. *"I had been*

projected into the reality of the concerns of cancer patients' relatives and now had to rethink my contribution in health care," she said.

She found her calling when she saw the work of Vinnie Myers, an American tattoo artist who developed a 3-D nipple tattooing process 15 years before. *"It was like a secret call to me,"* she said.

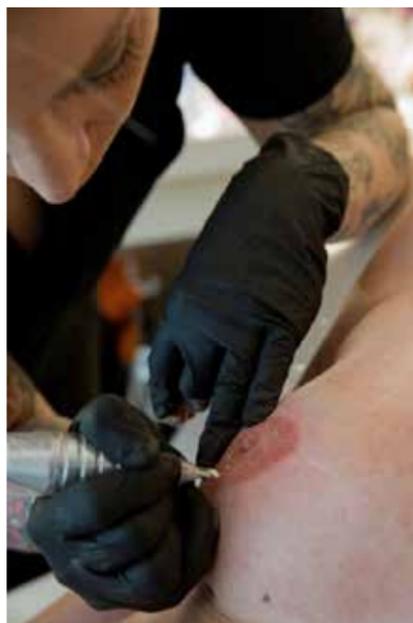
Although popular in the US, the

technique, also called micropigmentation, had yet to arrive in Europe. Cassar set out to change that. She spent a year learning about breast reconstruction from surgeons, then quit her job to spend a year apprenticed to a tattoo master. A year later, unable to find the training she needed for the 3-D nipple tattoos in France, she flew to San Antonio, Texas for more training. Overall, she spent more than 2,500 hours training to master the craft of tattooing over

radiated, surgically grafted skin and scar tissue.

Rebuilding Survivors' Self Esteem

Cassar opened the Tétons Tattoo Shop in September 2017 in Paris, the first tattoo parlor in the country dedicated to providing nipple tattoos to breast cancer survivors or, as she puts it, *"to rebuilding breast cancer survivors'*



Understanding a Woman's Journey

Cassar typically connects with clients online, who send photos so she can see if she can help (survivors require at least a year of healing after their last round of surgery and radiotherapy; two years if they also want a tattoo to hide their scars). She also contacts their physician to ensure there are no contraindications to the procedure.

When she meets them, they talk first about the woman's cancer journey. "I need to understand all its steps to evaluate her skin status later," she said. Then she explains the procedure, takes photos, and draws a template of the nipple.

self-esteem after a mastectomy." Unlike medical tattoos, which need to be redone every year, this type of tattoo is permanent, she said. "It's a breakthrough advance for cancer patients."

"Creating the image of a personalized, realistic, and above all, permanent, nipple is a way for women to accept their reconstructed breast as a part of them," she said. In a way, she acts like a midwife guiding the return of their self-esteem and femininity.

Since opening her parlor, she has tattooed almost 600 breast cancer survivors, including seven men. She is working with the National Tattoo Artist Syndicate to have breast tattooing recognized as an artistic alternative to surgery, and to have the national and private health care system cover the costs. Ten private payers currently cover the procedure, she said.

One of the greatest challenges is determining the correct color, which won't be clear until the tattoo is healed in three or four weeks. She carefully examines the woman's skin tone, moles, freckles, and hairline while also considering the effects of radiation, the fragility of the skin, the type of reconstruction used, and the woman's healing before deciding on a color. She also warns patients that they may need a touch up later if the color isn't perfect.

It takes 30 to 45 minutes to complete a nipple. There is usually very little pain as the area typically has little sensation after surgery.

"Once they discover the result in the mirror, we all feel a lot of joy and relief," she said.

She treats about 300 clients a year. But she knows the need is much greater given that about 6,000 women in France undergo reconstruction after

mastectomy each year. So she plans to start training apprentices and create a national network of specialized artists to provide the tattoos.

"They just want to feel whole again."

She is also hoping to partner with surgeons to conduct a clinical study on the procedure and is now working on a documentary about her work and what it means to the women she treats. □

Contact

Alexia Cassar

www.thetetonstattooshop.com

 https://www.instagram.com/_alx_c_/channel/ or https://www.instagram.com/the_tetons_tattoo_shop/

 <https://www.linkedin.com/in/alexia-cassar-20aab1b/?originalSubdomain=fr>



GE Healthcare

Pristina Dueta™

An industry first, patient-assisted compression device



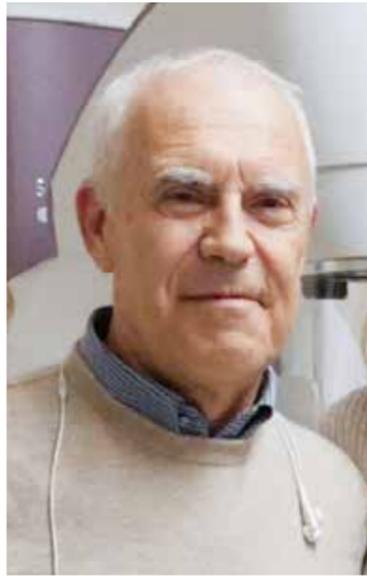
LEADERSHIP THROUGH INNOVATION

From analog to digital

The experience in Pavia, Italy

Do you know where to find the most beautiful Marble of Italy? The Duomo of Firenze or Milan might come first to your mind as magnificent masterpiece in Candoglia marble. But 35 km away from Milan, in the little and lovely town called Pavia, a town where people still have time to stand and stare, the private practice of Dr. Gatti hides a beautiful marble environment.

Dr. Gatti puts his patients at the center of his work, he designed a pleasant practice, and takes the time for them. He has moved from analogic to digital two years ago and tells us about his journey.



Dr. Gatti is a biologist by education. He then started with ultrasound and felt in love with Mammography. In 1980 he founded his private practice in Pavia, in the south of Milan
Since then he lives his two passions: taking care of women through Mammography and playing music.



Nicoletta is a radiographer by vocation, she has been working together with Dr. Gatti since the beginning, 30 years ago. Thanks to her empathy, calm and softness, she is excellent at making women feel at ease even though they are having a difficult exam. Together, they are a fantastic duo.

What is your educational background?

I graduated in Biological Sciences and, after having worked in the radiology department, I then decided to go back to University, graduated in Medicine and got my specialization in Radiology.

How is a day in your job? What type of exams do you perform?

I started doing mammography at the beginning of the 90s. I mainly deal with breast imaging, both mammography and ultrasound. Most of the time I perform routine exams and annual screenings on women who are generally asymptomatic, and who come to the center to do these screenings for preventive purposes. However, here in the clinic we also perform specific and diagnostic exams requested by patients when they notice something unusual in their breasts. So we also carry out very focused exams highly diagnostic and driven by the symptoms noticed by the patient.

What is the approach adopted in your clinic?

In comparison to the approach adopted in national hospitals, in this radiology center we can dedicate more time to the patient, to welcome, to talk with patients, to collect the medical history and to understand the particular reason why the patient requested the exam. The visit starts with the medical examination, then we perform the mammography and finally the ultrasound breast scan.

When did you switch to Digital? How do you find it?

We have been using Crystal Nova, our new mammography platform, for about 2 years: it's fully digital! Crystal Nova offers high quality images, and this is obvious when we compare current images with those generated years ago (on analog or CR systems). I really think images generated by digital mammographs are much more convenient to read.

How is it to work with Crystal Nova?

I really love working with Crystal Nova. It's a system that gives great satisfaction to work with; it's easy to use. One feature is the highly sensitive detector that requires a lower dose¹ than the one needed with previous systems.

Crystal Nova provides very accurate diagnostic images the image quality makes the diagnosis easier. Compared to the past, I am today more confident in the diagnostic I do. If the radiologist is more confident with the images, the patient can feel it. The patient senses if the image can be correctly interpreted from a diagnostic standpoint or if it's unclear or uncertain. So the image quality enhances the radiologist's diagnostic confidence and, as a consequence, improves the patient's ease of mind.

How was your first experience with Crystal Nova?

At the very beginning I was a bit afraid of using Crystal Nova, because switching to a new system is always scary, but with Crystal Nova everything went well. The system is very easy to use and our patients are enthusiastic about it.

It's also a very intuitive system. From a technical standpoint, it's very comfortable and it makes the radiographer's job much easier by making the tasks more automated and simpler to perform.

What is the feedback you get from patients?

First, they immediately notice that it's far less painful in comparison to other systems. Second, patients are very aware of radioprotection, so they are pleased to learn that the dose emitted by this system is very low.

How does Crystal Nova help you with positioning?

Correct positioning of the patient is crucial for a radiographer, as it enables the radiologist to get the highest quality image and this system makes positioning far easier. The patient can easily find a comfortable position. The system is light, easy to move and quick to use. Being able to perform a quick exam is key and also contributes to making the patient feel less exposed and therefore more protected.

Can you summarize your experience with Crystal Nova in a few words?

Crystal Nova is a very intuitive system, and the learning curve is very fast. Easy to use from day one, it makes you feel incredibly comfortable and confident in using it. □



The statements by GE's customers reported here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

Product may not be commercially available in all markets. Please contact your sales representative for more information.

1. Gennaro G1, Dose comparison between screen/film and full-field digital mammography, European Radiology 2006

GE Healthcare's global center of excellence for mammography Pristina's development and manufacturing.

Buc, France, March 2020

GE Healthcare announces the production of the 2,000th Pristina, its mammography Senographe Unit at its site of excellence for mammography in Buc, France.

Entirely designed and manufactured in France, the Senographe Pristina is exported worldwide. The release of the 2000th system was officially & with great pride, celebrated by the teams on March, 13th.

The first X-ray machine dedicated to mammography, called "Senographe", was developed in Buc, France by Jean Bens and Emile Gabbay, two engineers from former Compagnie Générale de Radiologie, which was bought by GE Healthcare in 1987. This marked GE Healthcare's foray into mammography technology.

Since then, the device has continuously evolved, and the teams of engineers and designers collected and processed feedback from patients, radiologists and healthcare personnel to improve medical diagnosis and

patient experience during this medical examination.

"We are delighted with the production of the 2000th mammography unit at our site of excellence in Buc. Our ambition is to improve the quality of care we provide to our patients, considering their fears and expectations, while giving them access to the latest generation of technologies," said Catherine Lézy, General Manager Mammography.

Today, engineers are developing and manufacturing the 4th generation digital mammography units. GE Healthcare was the first manufacturer to develop a self-compression technique, a new method of breast compression. Thanks to a pocket remote control, the patient can control the compression applied to her breast. This innovation from GE Healthcare France, installed for the first time at the Gustave Roussy Institute in July 2014, allows better pain and stress management for women facing the examination.

Of the Senographs manufactured by

GE Healthcare in Buc, 25% of the production is intended for Europe, 44% is exported to the United States and around 20% to Asia. The rest of the production go to South America, the Middle East and Africa.

On the production side, the Buc factory started a lean manufacturing process a few years ago. Thus an in line conveyor chain has been installed -a "moving line"- so that all the mammograms in the course of manufacture can move from one workstation to another, where the parts are added and then assembled.

This new production process, which is based on the quantities sold, has halved the cycle time and the number of faults/systems, thanks to ANDON's approach, a visual and auditory alert system to report dysfunctions in the production chain.

GE Healthcare teams have cut assembly time in half compared to previous systems. □





GE Healthcare

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. Follow us on Facebook, LinkedIn, Twitter and Insights , or visit our website www.gehealthcare.com for more information.

gehealthcare.com

© 2020 General Electric Company - All rights reserved

The statements by GE's customers reported here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.