

TRUE 3D IMAGING | NO COMPRESSION | LOW DOSE



A BETTER WAY OF BREAST IMAGING



Table of Contents

STANTON KONING

01

A note from Koning Corporation

02 - 05

Advancing breast imaging technology

06 - 10

The Koning advantage

11 - 17

Your future with Koning

18 - 21

Case studies: Koning benefits in action

22 - 25

Other info you should know

26

Contact us



5555 Oakbrook Parkway, Suite 640 | Norcross, GA | US 30093

In this binder you'll find a clear illustration of the limitations of the current state of breast imaging, including cancer miss rate, compression and 2D mammography resulting in overlapping structures that hide cancers, inconclusive results leading to additional imaging processes, and the low level of efficiency in the process this imaging continuum delivers. Conversely, Koning has brought to the market a new and innovative approach to breast imaging that will mitigate all of the previously mentioned issues that have, unfortunately, come to be the industry standard.

Koning is introducing the first FDA-cleared breast imaging technology that eliminates the need for breast compression and introduces *true* isotropic 3D imaging technology to the breast imaging space. Patients are typically adverse to having mammograms due to the pain associated with compression - that discomfort is eliminated with the Koning Vera Breast CT (KBCT). Radiologists will appreciate a device that illustrates abnormalities more directly and in less time than it takes to interpret the screening mammogram, the diagnostic mammogram, and the ultrasound. In addition, patients will be less likely to miss exams due to the ease and comfort of prone positioning on the Koning table. Administrators will prefer KBCT because of attractive financials rivaling diagnostic mammograms.

We are happy to introduce this technology to you and look forward to future conversations, at which point we can bring KBCT into your clinic. Please feel free to contact us with any questions while reviewing the data.

Sincerely,

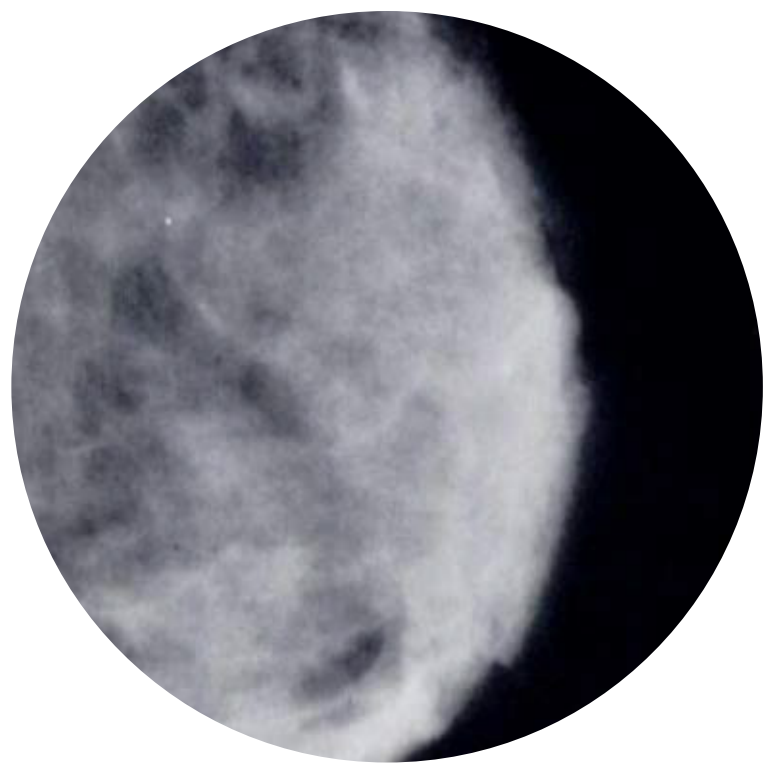
Koning Corporation

ADVANCING BREAST IMAGING TECHNOLOGY

HISTORY OF BREAST IMAGING TECHNOLOGY

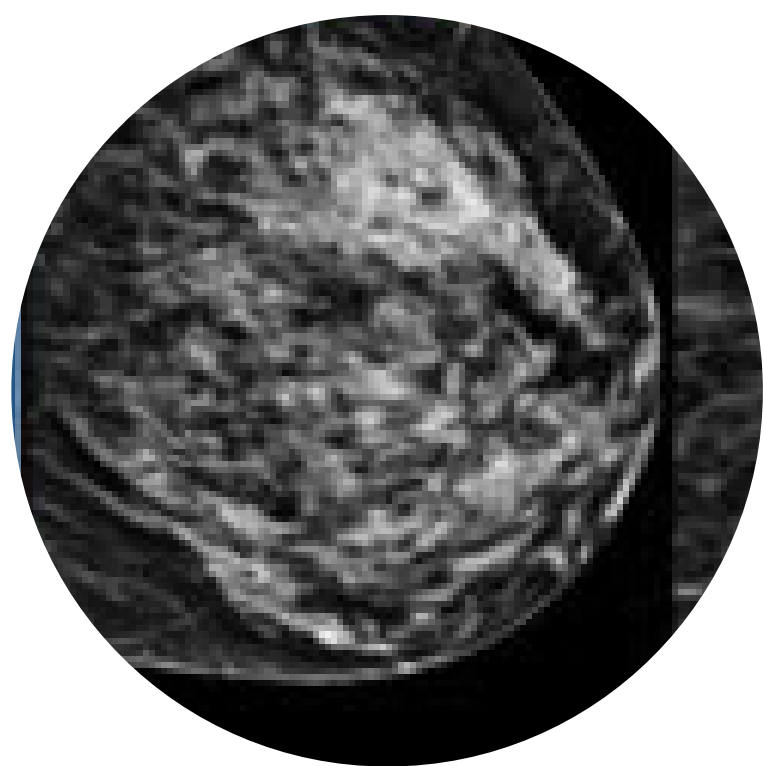
Since the beginning of widespread use of mammogram machines in the 1950s, little progress has been made on breast imaging technology. Rather, different forms of technology started to be used in order to offset the lack in accuracy of mammography.

1960s - 1980s



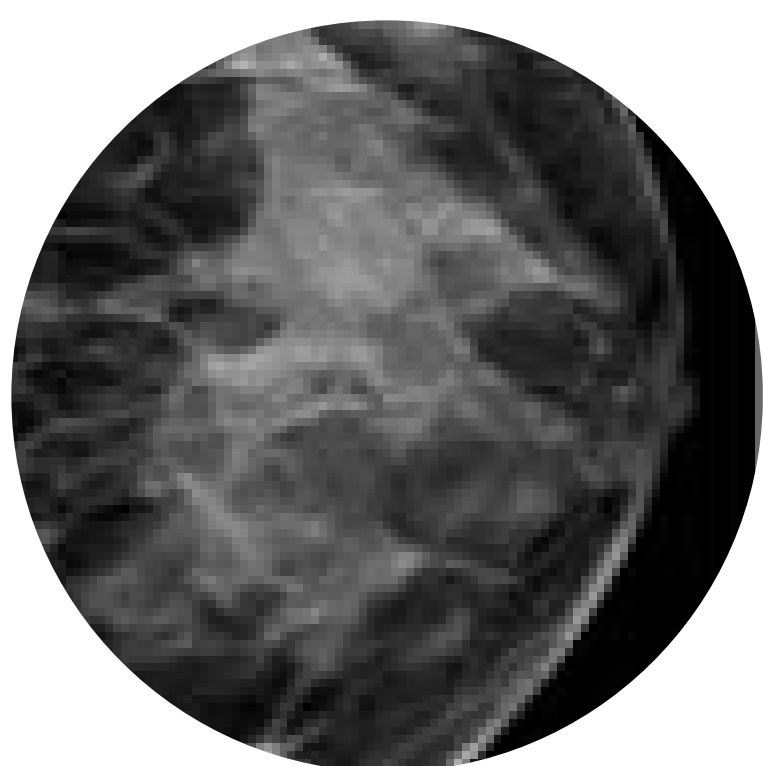
During this time period, film/screen analog imaging was commonly used. An oblique mammographic view was introduced in the 70s. This was a single-view screening process, however, and soon a two-view technique was used. Two views found more cancers and resulted in less callbacks. In the 80s, screening mammography became more common.

1990s - 2000s

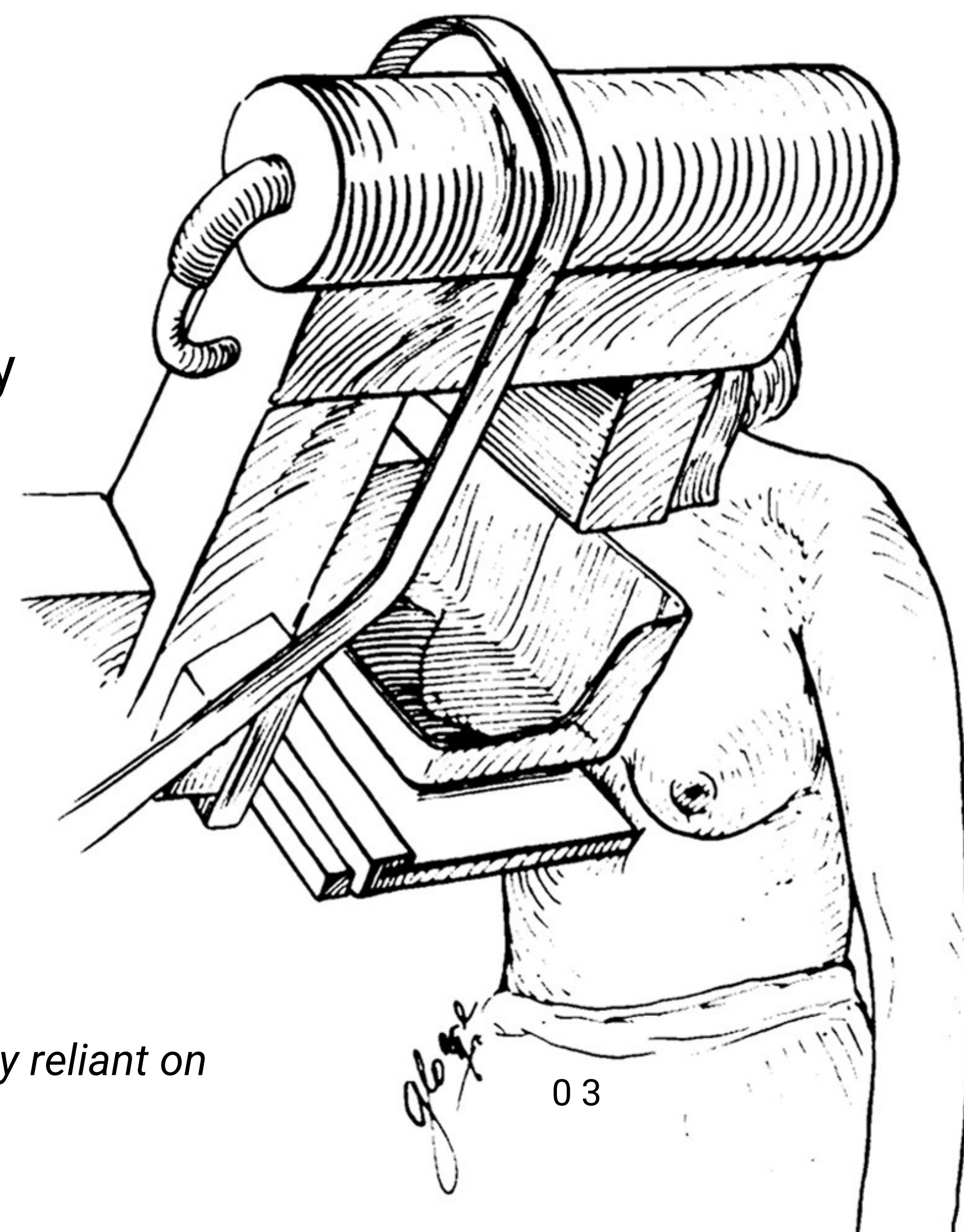


In the early 90s, federal regulations were placed on mammography processes with the implementation of MQSA. Equipment and facilities were inspected closely in order to standardize exams. The conversion to digital mammography happened slowly during this time period.

2010s



By the 2010s, digital mammography became the most prominent form of mammogram examinations (typically called full-field digital mammography, or FFDM). Limited sweep angle linear breast tomography was also introduced during this time period.*



**None of these changes eliminated compression, and they are still completely reliant on 2-dimensional imaging capture.*

BREAST CANCER DETECTION

CURRENT STATE OF THE INDUSTRY

BREAST IMAGING TECHNOLOGY TODAY

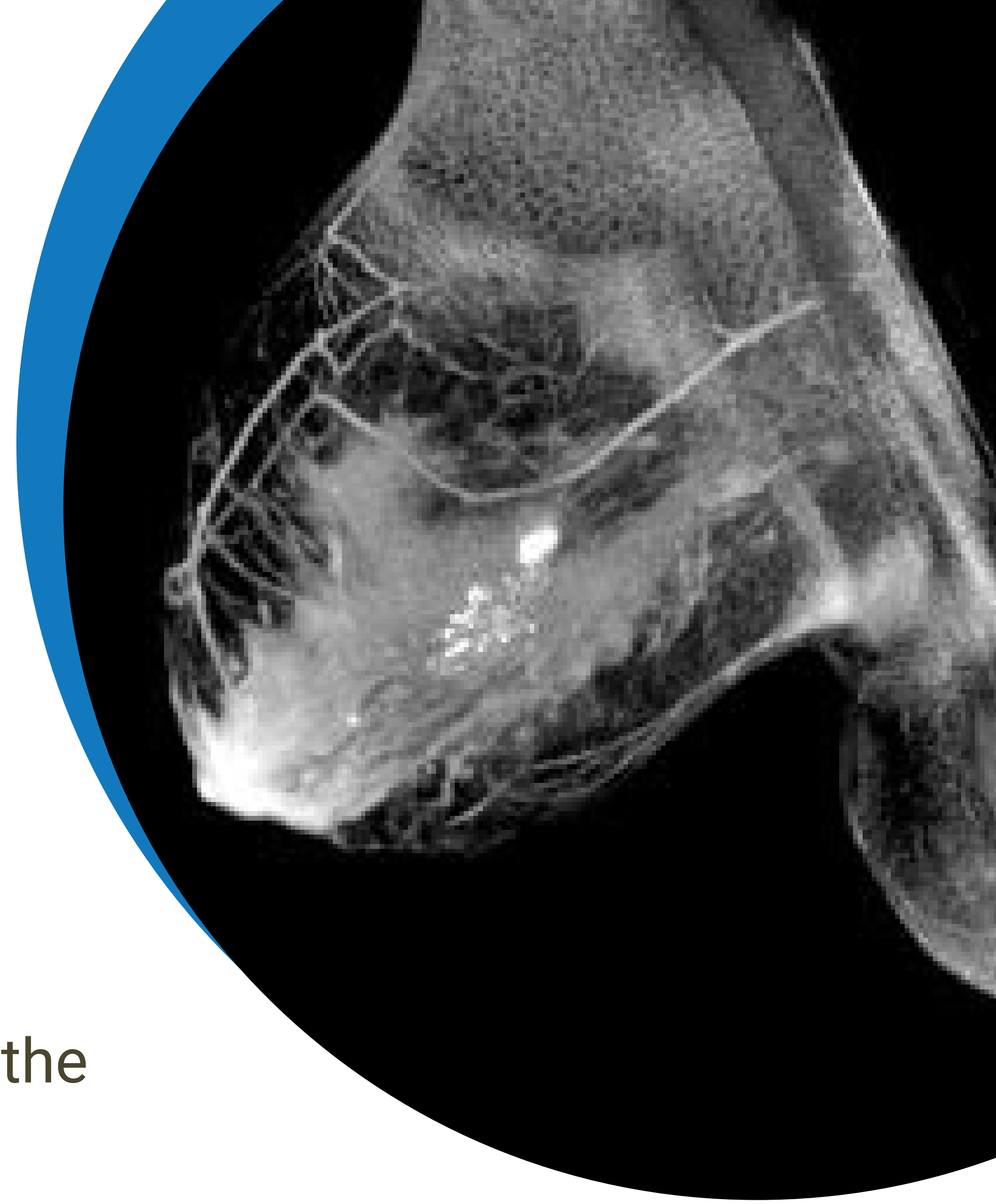
As previously mentioned, FFDM and DBT are the main forms of breast screening options available. When radiologists aren't able to give a clean bill of health in good conscience, however, patients can be sent for ultrasounds and MRI. And yet, breast imaging continues with 2D projection imaging and compression, resulting in well-documented limitations.

PATIENT PROBLEMS

Despite its shortcomings, mammography is still recommended annually for women over 40. However, due to the pain of compression and inconclusive results, patients often end up skipping their yearly exams. This is especially prevalent with women who have dense breasts, as they usually need to return for follow-up imaging.

WHAT WE PROPOSE: CT TO CATCH HIDDEN CANCERS

Why breast CT? CT allows for isotropic imaging. Isotropic imaging is not available with FFDM or DBT mammography and allows for measuring, viewing and co-registration of areas of interest in multiple planes. These planes are Axial, Sagittal, and Coronal. FFDM and DBT, on the other hand, require physicians to extrapolate data from 2D projection images.



IMAGING MODALITIES USED TODAY HAVE NOT SOLVED THE EARLY STAGE BREAST CANCER DETECTION PROBLEM

TECH TODAY	DESCRIPTION	LIMITATIONS
MAMMOGRAPHY	Current standard of care for screening.	2D projection imaging causing tissue overlap. Painful procedure for patients (breast compression).
DIGITAL BREAST TOMOSYNTHESIS (DBT)	Slightly better form of mammography. Limited angle linear tomography. Pseudo-3D imaging.	Pseudo 3D – (non isotropic) requires extrapolation vs. co-registration. Painful procedure for patients (breast compression).
ULTRASOUND	Used in conjunction with mammogram or DBT.	Limited resolution. Unable to detect calcifications. Highly dependent on sonographer's skills.
MRI	Primarily used in last step of imaging to determine extent of disease.	Expensive, lengthy exam. High false positive rate. Cannot easily find calcifications. Gadolinium controversy.

OVERARCHING PROBLEM

According to the American Cancer Society, there is a one in eight chance that a woman will develop breast cancer during her lifetime - almost 290,000 women are diagnosed **yearly** with invasive breast cancer.

Breast cancer is the second leading cause of death in women, having reached 43K deaths in 2022.

This is unacceptable.

THE KONING ADVANTAGE

KONING'S PUSH FOR BREAST CT:
OUR PROPOSAL

WHY DOES KONING USE CT FOR BREAST IMAGING?

CT imaging is the only imaging modality that can capture complete images of the body, producing an isotropic data set which allows for images unencumbered by overlapping structures. CT imaging also provides radiologists with the ability to co-register findings in multiple planes. Neither FFDM nor DBT provide these advanced imaging management tools. Instead they require the radiologist to extrapolate information from the limited data acquired by FFDM or DBT.



WHY CT?

1.

Breast CT provides the radiologist with tools similar to whole body CT, but with radiation dose 4-8 times lower than whole body CT and dose equivalent to conventional mammograms

2.

CT is the most common form of imaging for cancer detection

3.

Non-compressed isotropic images eliminate overlapping structures

4.

Improved region of interest identification in 3D and MPR

5.

Common to CT imaging, contrast is utilized when necessary

6.

3D guided biopsy-ready. Replaces stereotactic biopsy and requires 50% less dose

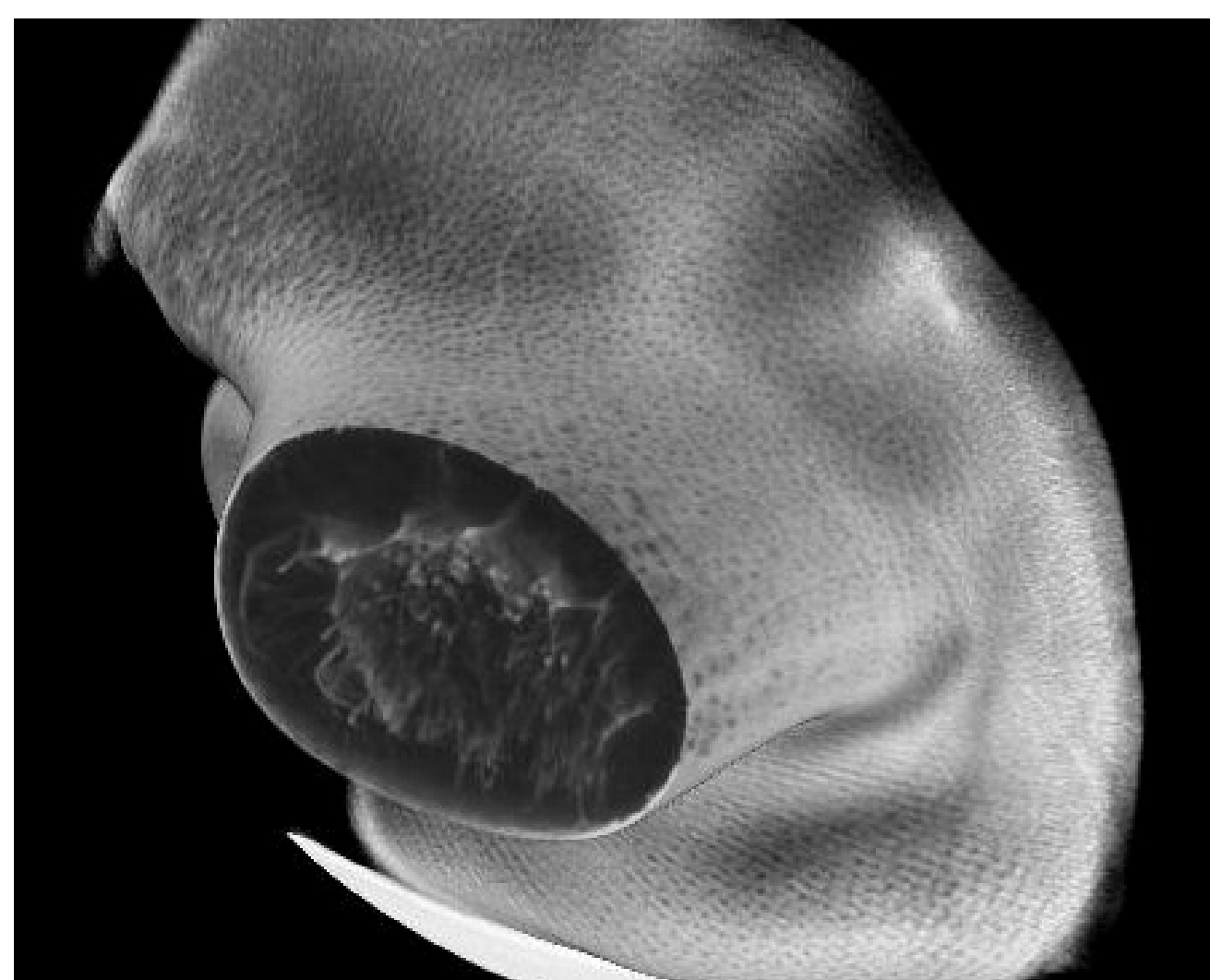
CLINICAL ADVANTAGES

KONING BENEFITS

Current mammogram techniques are falling short of expectations. With documented limitations, it is absurd that more steps haven't been taken to mitigate these issues. The benefits of Koning Breast CT are evident; KBCT rotates 360° around the breast, acquiring a true isotropic 3D dataset in 7 seconds. For the first time in breast imaging history, KBCT has introduced co-registration in multiple planes using TRUE 3D volumetric imaging.

OTHER BENEFITS INCLUDE

- Compelling economics
- Higher throughput
- High quality, true isotropic 3D imaging giving you reliable exam results
- Ability to perform biopsies
- Capital equipment efficiency - replaces need for multiple devices
- Small footprint, limited facility modifications
- Superior detection capabilities



CURRENT LIMITATIONS OF FFDM AND DBT

- Breast Compression (inherently excludes chest wall)
- Compression artifacts
- Ambiguity of distribution
- Measurement inaccuracies
- Difficulty in defining extent of disease
- Poor spatial representation of ROI

PATIENT ADVANTAGE

NO COMPRESSION, NO PAIN, NO DEFORMATION

Breast presented in unhindered, natural form making for a more comfortable and accurate exam experience

QUICK SCAN

Fast scan time of only 7 seconds

SAFE, LOW DOSE

Radiation is in range of diagnostic mammograms

FULL 3D IMAGE

No extra views needed. Receive all information with one scan; high quality imaging allows patient to be confident in the results she receives

NO TISSUE OVERLAP

Better chance to find lesions as small as 2mm. This is especially beneficial in patients with dense tissue

EASY TO IMAGE ALL BREAST TYPES

Small, large, dense, implants (without displacement views)

ALLOWS FOR ACCURATE DIAGNOSIS

With one exposure, an entire breast image is acquired in isotropic 3D, allowing potential abnormalities to be visualized without additional views.



WHAT PEOPLE ARE SAYING

"Mammograms aren't the most comfortable experience. Koning's Breast CT was much more comfortable with no compression. Quick and completely painless."

-Breast CT Patient

"Since I have very dense breasts, I generally do not like mammograms because of the pain and compression. I went to a facility in Sarasota, Florida where I did a CT scan on the 3D KBCT (Koning) machine. The process was so quick and seamless."

-Breast CT Patient

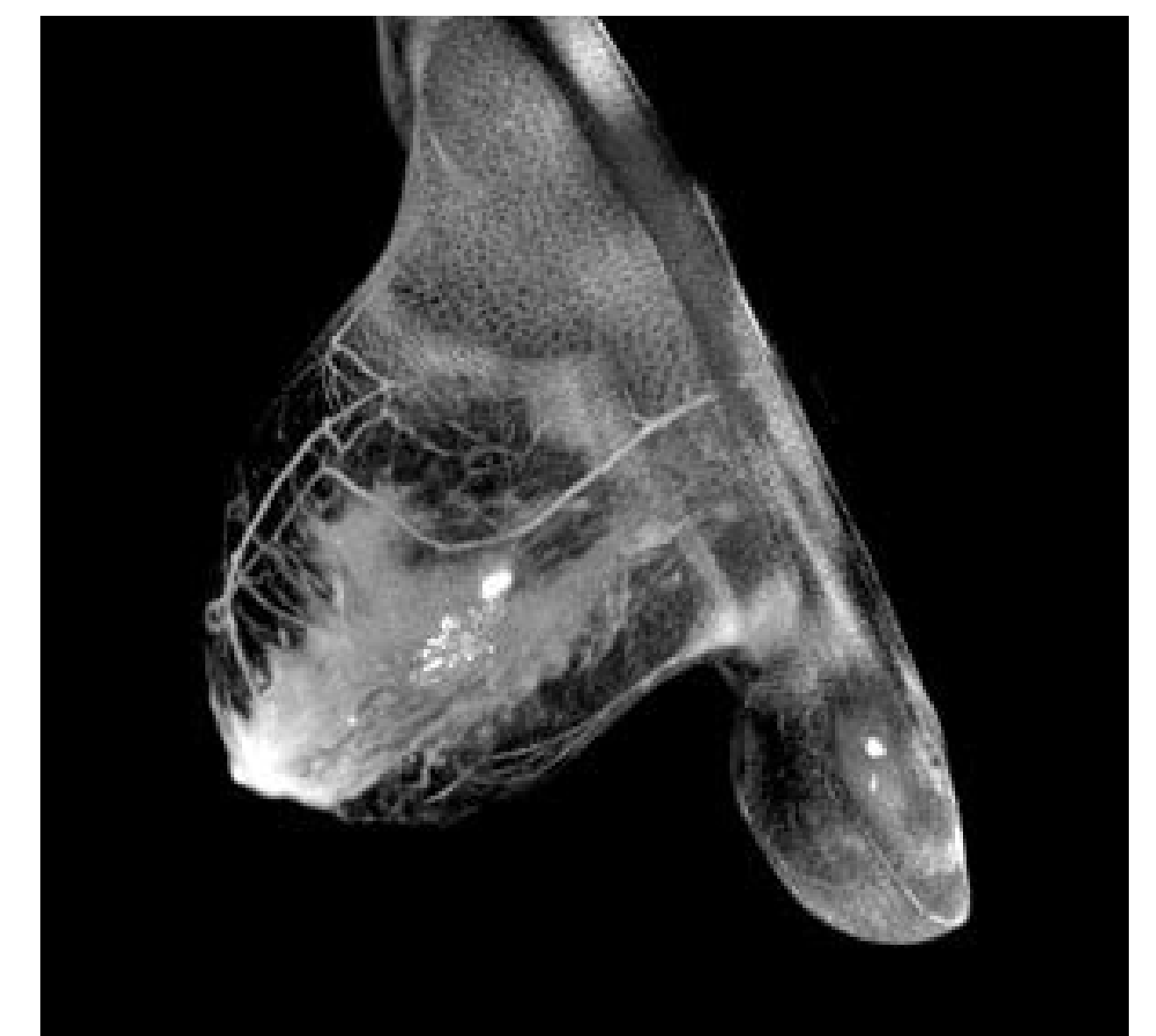
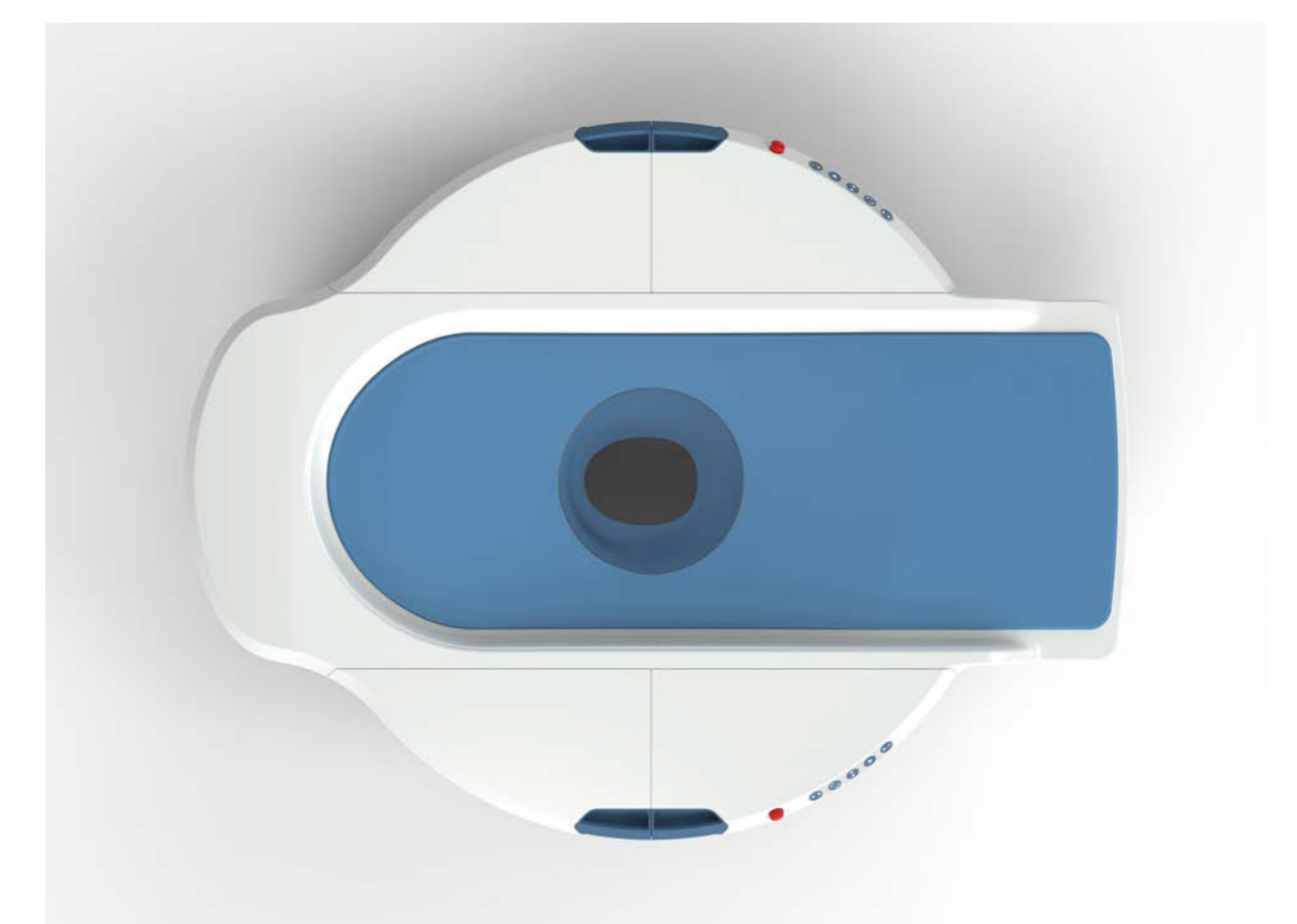
"I wish every woman could enjoy the incredible experience I enjoyed at my recent KBCT exam!"

-Breast CT Patient

"If we can find breast cancer when it's really small, before it spreads from the breast, we can save a woman's life. The Koning Breast CT is a true 3-dimensional image of the breast. Cancers have nowhere to hide. There's no way for overlapping tissue to be in the way from every angle. The images are very high quality and show cancers well."

-Dr. Etta Pisano

Chief Research Officer, American College of Radiology



ACCURACY

CLINICAL COMPARISON DATA FROM FDA AND CFDA TRIALS

Modality	AUC
CE-CBBCT	0.9337
Mammography	0.8136
Difference	0.1201

AUC of CBBCT is higher than digital mammography. The difference is larger than 0.05 with statistical significance.

Note: AUC difference larger than 0.05 is considered clinically significant improvement.

KBCT vs. FFDM	CBBCT	Mammography	Difference
Average Sensitivity (%)	85.63	77.66	7.97
Average Specificity (%)	79.47	73.10	6.37
Average Accuracy (%)	82.03	75.00	7.03

CE KBCT vs. FFDM	CE-CBBCT	Mammography	Difference
Average Sensitivity (%)	92.73	76.10	16.63
Average Specificity (%)	75.24	71.43	3.81
Average Accuracy (%)	84.86	74.00	10.86

KONING'S WORK TO DRIVE THE BREAST IMAGING INDUSTRY INTO THE FUTURE

The breast imaging market has long awaited a technology that removes painful compression and produces a true 3D image at low dose. The Koning Vera Breast CT provides this critical change. Clinical outcomes and financial value will improve by integrating breast CT while providing a better experience overall to the patient. Breast imaging facilities that are enthusiastic about providing the best service can make this technology available now.

FDA APPROVAL

Koning is the first Breast CT imaging device to receive FDA approval for commercial, diagnostic use.

REIMBURSEMENT

The AMA has added 6 new breast CPT codes to allow for clinic reimbursement. Reimbursement has already been accepted by both private payors and Medicare.

PERFECTING THE TECHNOLOGY

The market is poised for expansion. Koning is ready to bring the Koning Vera Breast CT (KBCT) to any clinic that purchases it, allowing those clinics to proudly say they provide cutting-edge breast imaging examinations to their patients.

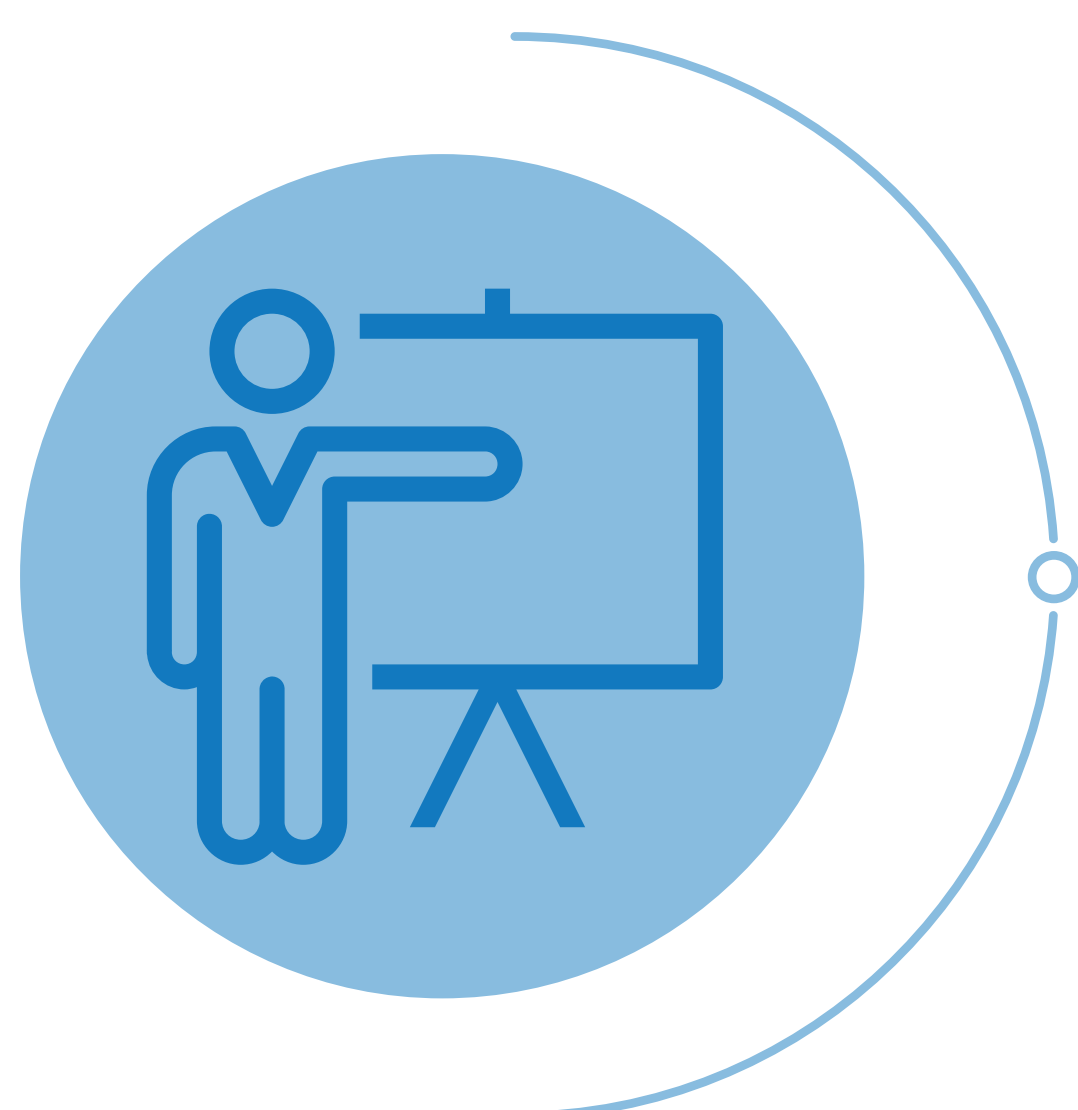
YOUR FUTURE WITH KONING

KONING IS HERE TO HELP ON-BOARD YOUR PRACTICE



Reimbursement & Billing

- Training for billers
- Playbook and denial response templates and scripts to work with payors
- Dedicated reimbursement consultant to guide you through any issues
- Whitepapers, clinical data, and case studies from other clinics



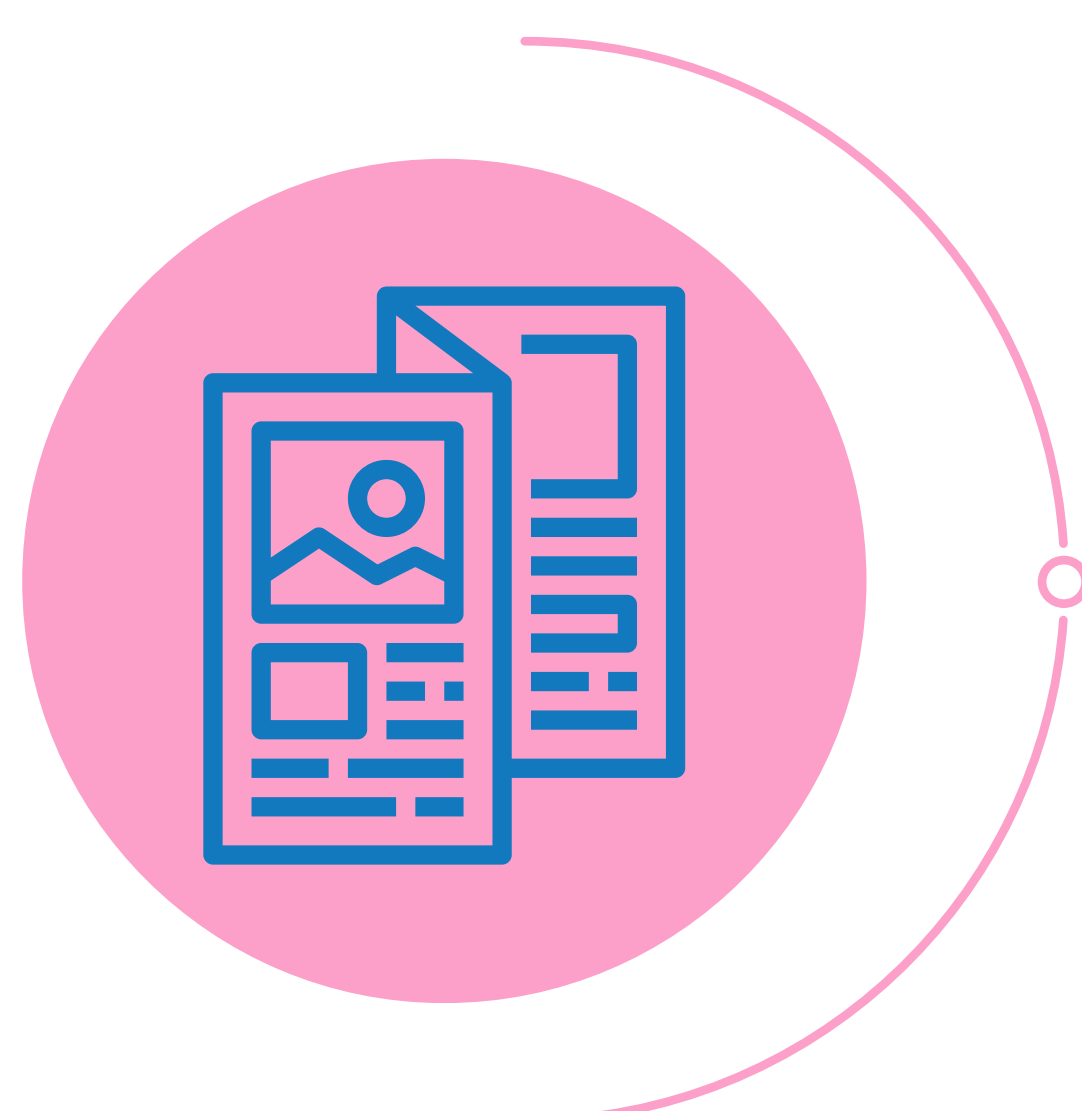
Training

- Technical training for rad techs
- Script writing and indications of use for referring physicians
- Large image library for clinical review



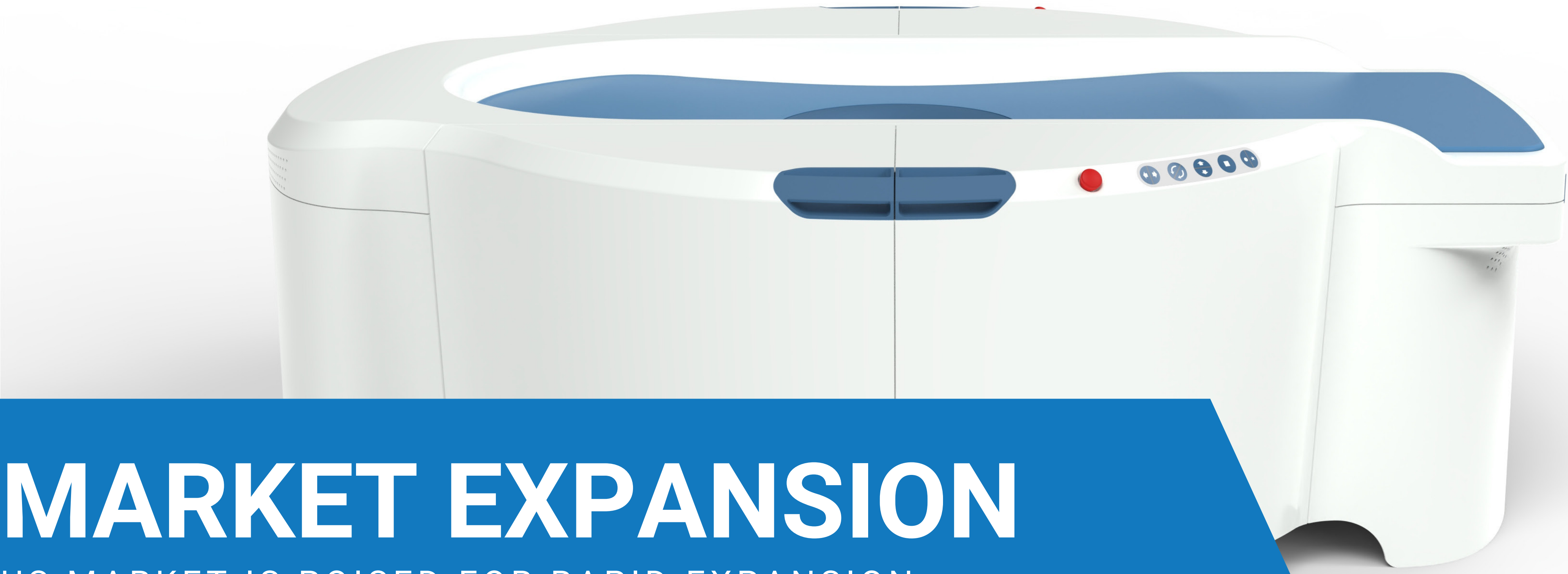
Presentations

- Presentations to payors on clinical benefit and value based healthcare
- Classes for network referring physicians



Marketing Assets

- Graphics, videos, and other marketing assets
- Personalized brochures and pamphlets to place in your office
- Localized marketing campaigns



MARKET EXPANSION

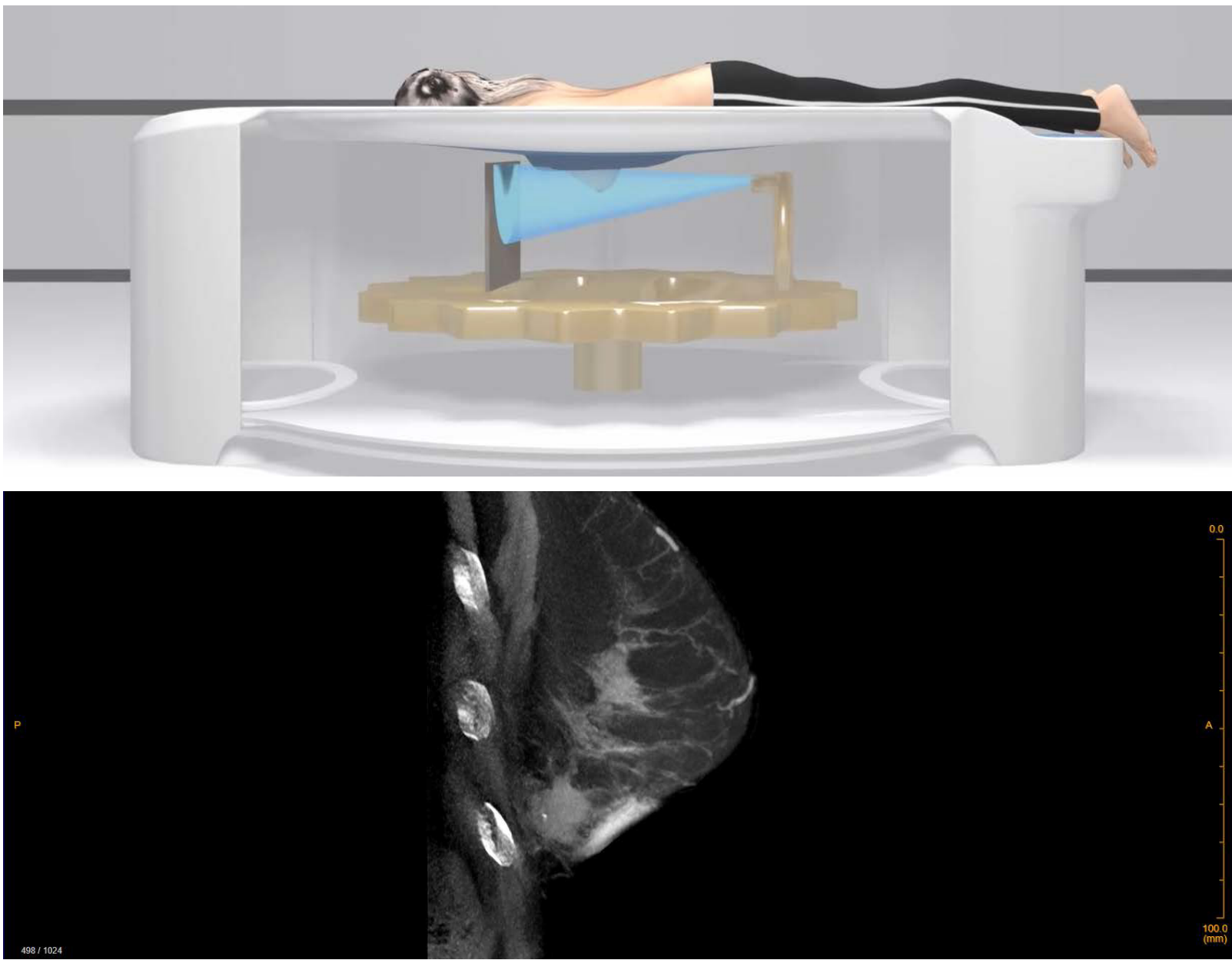
US MARKET IS POISED FOR RAPID EXPANSION
AFTER RECEIVING BREAST CT CPT CODES

Key Milestones

- AMA application directly supported and submitted by the American College of Radiology
- 6 CPT codes approved in May 2020 for both bi-lateral and uni-lateral scans, with and without contrast
- Codes published in Oct 2020, went live January 2021
- CMS has published national Medicare reimbursement rates – dissemination to local MACs remains underway

KONING VERA BREAST CT

3 PROCEDURES, 3 OPTIONS TO FIND BREAST CANCER EARLY



NORMAL SCAN¹

3 min from time patient enters exam room

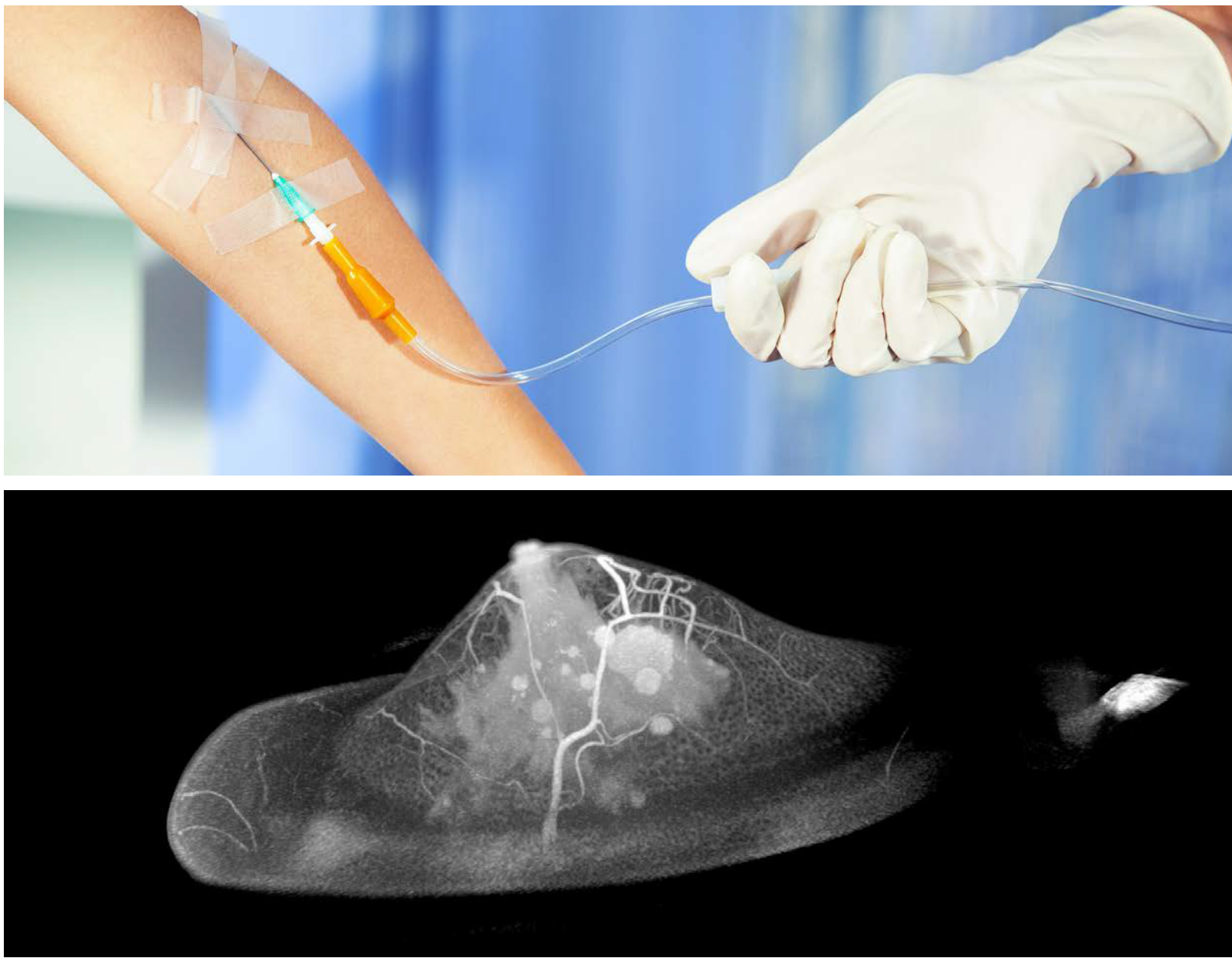
CPT CODES

Unilateral without contrast: 0633T
Bilateral without contrast: 0636T

Avg private payor Reimbursement*
\$350

**National Medicare Avg
Reimbursement**
\$218.53

Onsite staffing requirement:
Radiology Tech
Nurse



CONTRAST-ENHANCED SCAN²

5-7 min from time patient enters exam room

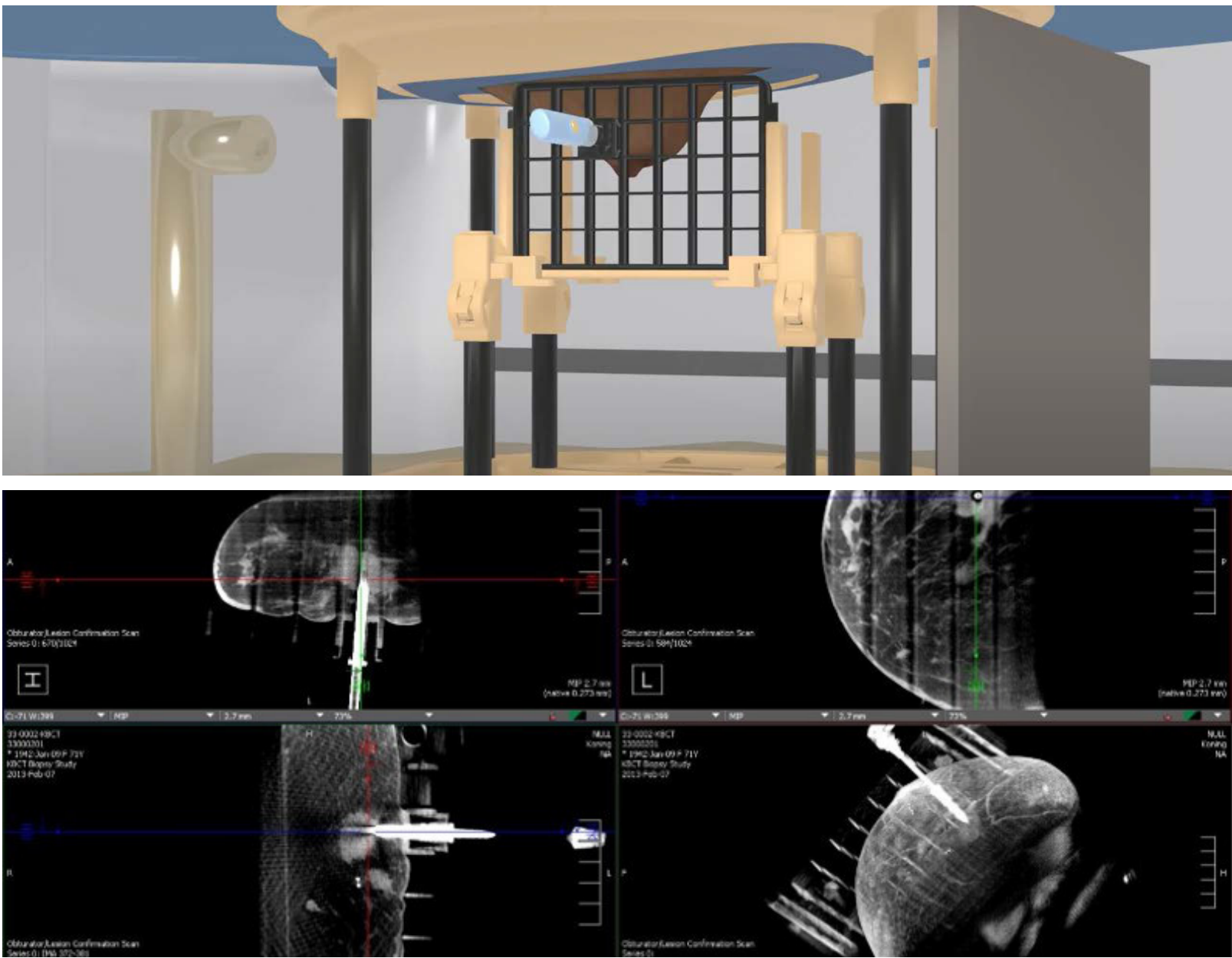
CPT CODES

Unilateral with contrast: 0634T
Bilateral with contrast: 0637T

Avg private payor Reimbursement*
\$600

**National Medicare Average
Reimbursement**
\$423.88

Onsite staffing requirement:
Doctor or PA



BIOPSY SCAN³

Up to 20 min from time patient enters exam room

CPT CODES

First lesion: 19081
Each additional lesion: +19082

Avg private payor Reimbursement*
\$850

**National Medicare Average
Reimbursement**
First lesion: \$625.79
Each additional lesion: \$504. 53

Onsite staffing requirement:
Specialist doctor (E.g. Breast radiologist,
breast surgeon)

¹ Primarily Bilateral
² Either Unilateral or Bilateral
³ Predominantly Unilateral
*Reimbursement rates will vary based on location and payor

FINANCIAL ADVANTAGE

REIMBURSEMENT

The AMA has granted 6 dedicated CPT codes for Breast CT. The reimbursement rates vary based on location and payor group. For more in depth analysis, Koning can provide a revenue forecast calculator to determine what your clinic's revenue will be with the use of Koning Vera Breast CT.

Exams, Medicare*	Low Reimbursement	Average Reimbursement	High Reimbursement
Unilateral Dx, Non-CE	\$150	\$218.53	\$267
Bilateral Dx, Non-CE	\$150	\$218.53	\$267
Unilateral Dx, With Contrast	\$225	\$423.88	\$564
Bilateral Dx, With Contrast	\$225	\$423.88	\$564
Biopsy	\$400	\$625.79	\$785

INDICATIONS FOR USE

AMA CPT CODES 0633T- 0638T

Below are indications for use and suggested guidelines based on the Breast CT CPT codes provided by the AMA.

Reasoning: Incomplete or Negative **(when being recalled; use of ultrasound, or need additional views)**

Medical Necessity:

Breast Density **R92.2**
(Mirco) Calcifications **R92.0/ R92.1**
Abnormal or Incomplete findings **R92.8**
Sign or Symptoms **N64.59**
Other Specified Disorder **N64.89**
History of Breast Cancer **Z85.3**
Strong Family History **Z80.3**
Family Hx of Ovarian Cancer **Z80.41**
Genetic Suspicious of BC **Z15.01**
Implants **Z98.82**

Reasoning: Benign or Probably Benign **(when nodules, densities, displaced views, findings are present or any diagnostic follow up)**

Medical Necessity:

Breast Cyst **N60.01/N60.02**
Fibroadenosis **N60.21/N60.22**
Nodules **N63.1X/ N63.2X/ N63.3X/ N63.4X**
Benign nodule **D24.1/D24.2**
Breast Density **R92.2**
(Mirco) Calcifications **R92.0/ R92.1**
Asymmetries, Scars, Abnormal Findings **R92.8**
Sign or Symptoms **N64.59**
Other Specified Disorder **N64.89**
History of Breast Cancer **Z85.3**
Strong Family History **Z80.3**
Genetic Suspicious **BC Z15.01**
Implants **Z98.82**

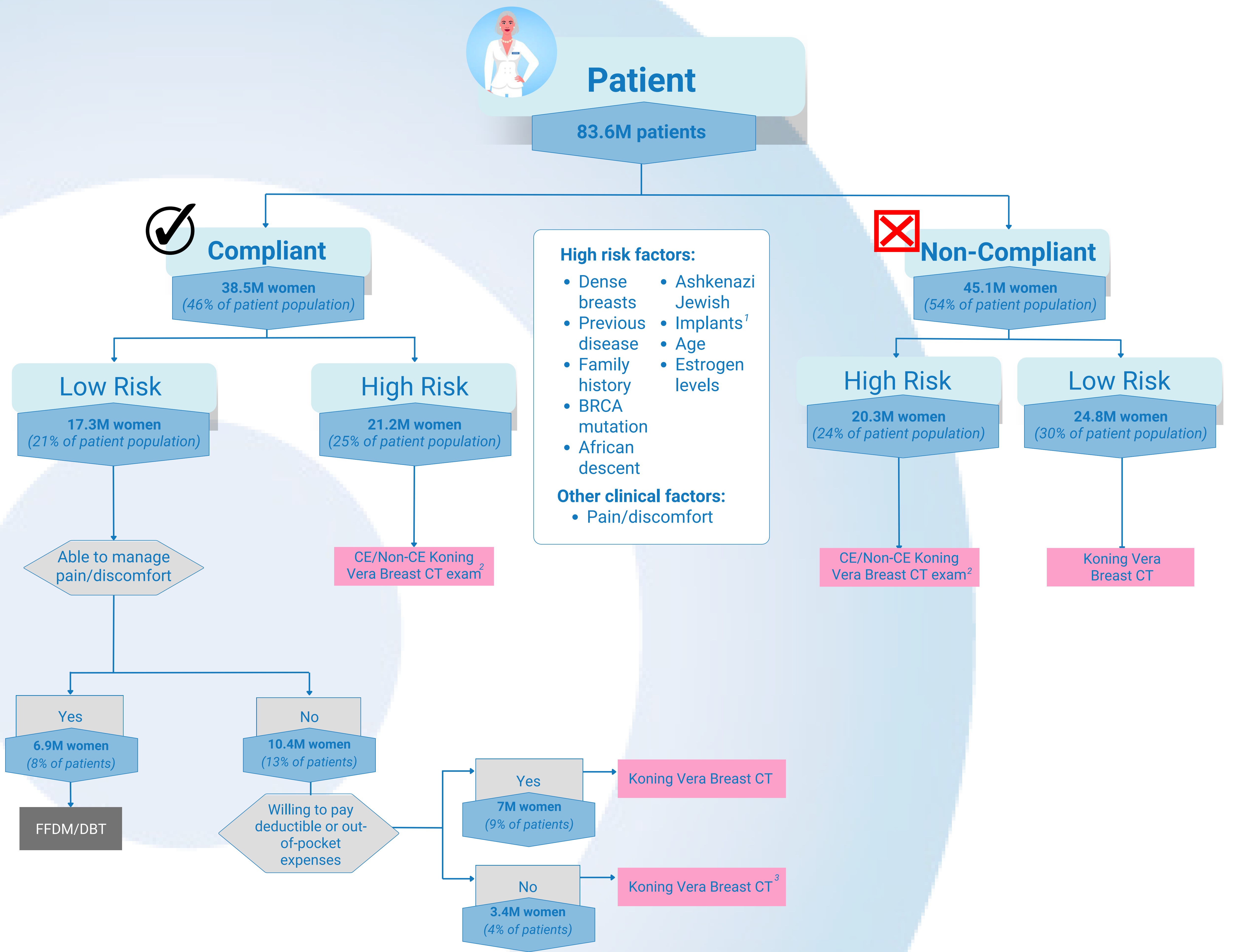
Reasoning: Suspicious or Highly Suspicious **(when suspicious nodules, abnormality, biopsy required, any diagnostic follow up)**

Medical Necessity:

Breast Cyst **N60.01/ N60.02/ N60.11/ N60.12**
Fibroadenosis **N60.21/N60.22**
Nodules **N63.1X/ N63.2X/ N63.3X/ N63.4X/ N60.4X**
Malignancies **D05.0X/D05.1X/C50.XXX**
Benign nodule **D24.1/D24.2**
Breast Density **R92.2**
(Mirco) Calcifications **R92.0/ R92.1**
Asymmetries, Scars, Abnormal Findings **R92.8**
Axilla/Lymph **N63.3X/R59.9/C77.3**
Sign or Symptoms **N64.59**
Other Specified Disorder **N64.89**
History of Breast Cancer **Z85.3**
Strong Family History **Z80.3**
Genetic Suspicious **BC Z15.01**
Implants **Z98.82**

FUTURE OF BREAST IMAGING

Based on Patient Risk Profile



Koning Vera Breast CT
can serve **76.7M** US women

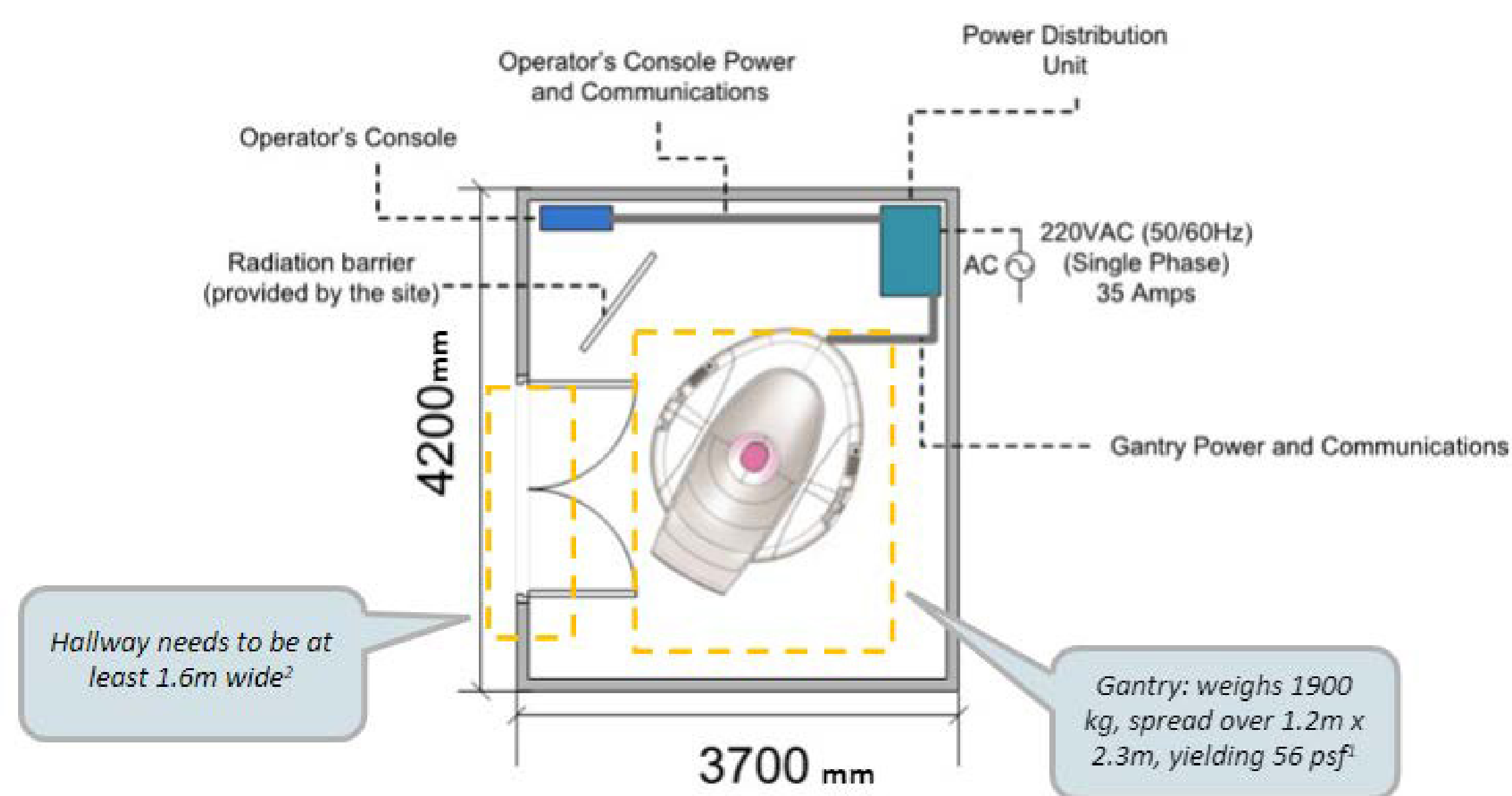
Compliant, High Risk	Compliant, Low Risk, unable to manage pain/discomfort	Non-Compliant, High Risk	Non-Compliant, High Risk
21.2M women	10.4M women	20.3M women	24.8M women

92% of the population

Source: MQSA/FDA, NCI, Census data, Siemens and Koning market survey results 2022
¹ Implants present higher risks of rupture and multi-dose radiation
² Contrast/Non-Contrast depending on other risk factors
³ Up to clinic discretion

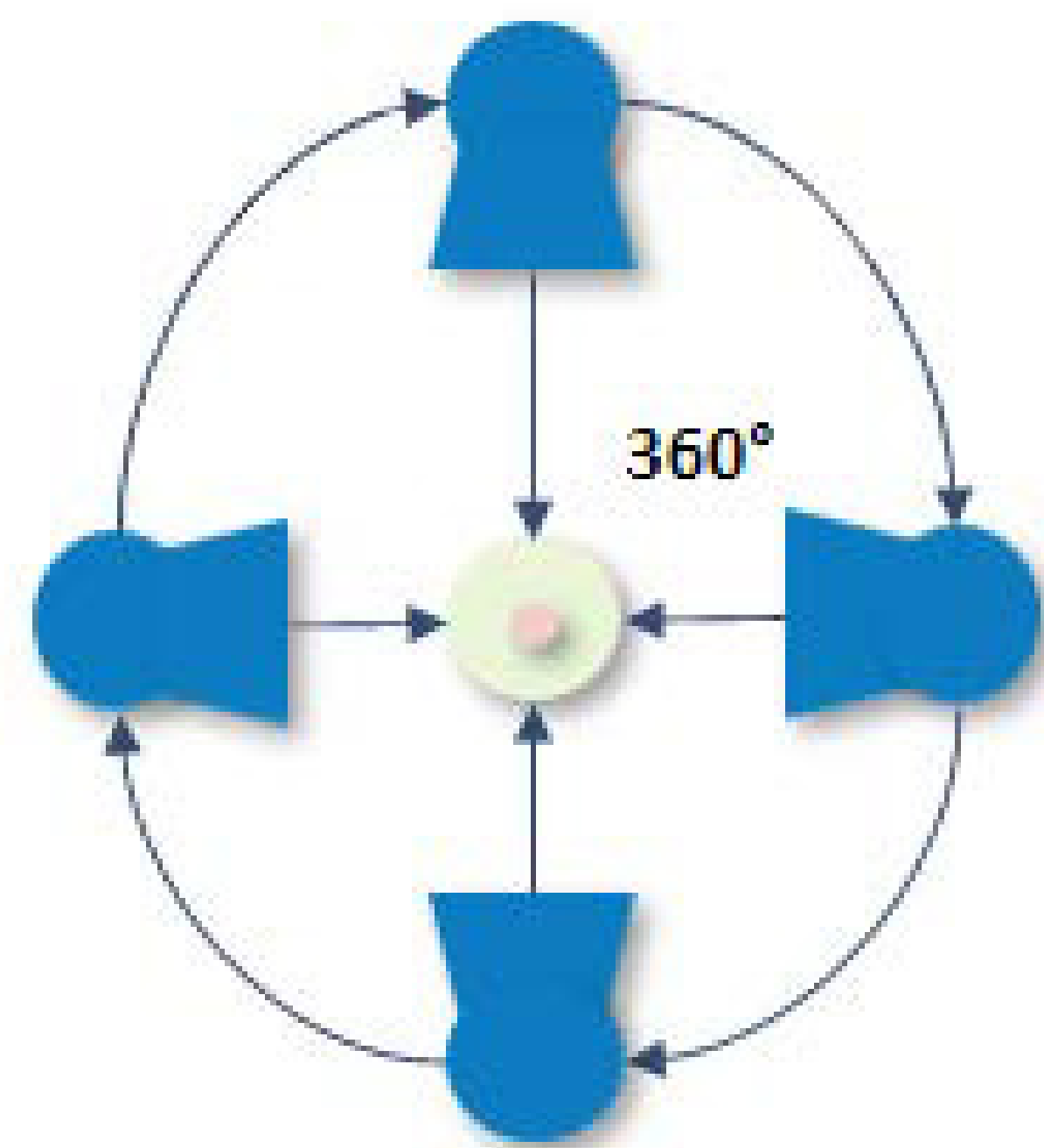
FACILITIES PLANNING

KBCT CAN BE INSTALLED IN MOST STEREOTACTIC BIOPSY ROOMS



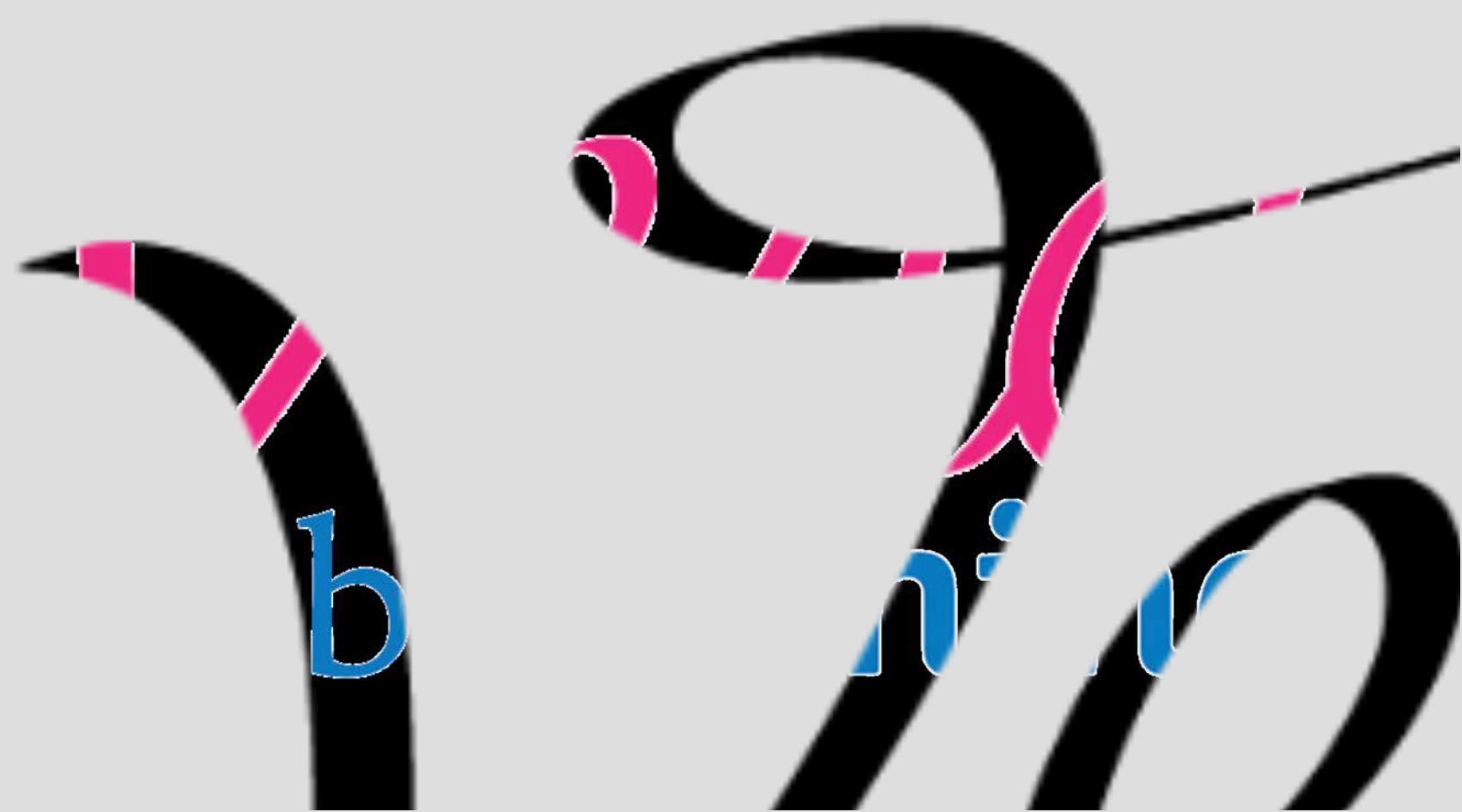
KBCT SPECS

- **Electrical:** 220V – 35 Amp Sgl.¹
- **Table Capacity:** 441 lbs.
- **Patient Table Height:** 28" to 50" for biopsy
- **Room Size:** 10 ft. x 14 ft.²
- **Resolution:**
 - Voxel size in Standard mode = $(0.19\text{mm})^3$
 - Voxel size in High Resolution mode = $(0.1\text{mm})^3$



1. Other electrical configurations available
2. 4200 cm x 3700 cm = 14 ft x 12 ft

PRODUCT COMPARISON SHEET



In 2022, Koning completed v2.0 of our Koning Breast CT and rebranded to Koning Vera Breast CT. Within the product hierarchy, we offer two different iterations of Koning Vera: Vera Complete, and Vera Prime3D.

Below is a comparison of the two versions, the features included, and the purpose of each of the features.

Note: feature options are subject to change.

FEATURE	PURPOSE	 	
7 second scanning per breast	Rapid throughput	✓	✓
No compression	Patient Comfort	✓	✓
300 images per breast	Complete data set for MPR	✓	✓
PACS integration	DICOM connectivity	✓	✓
Table Separation	Allows Large breast imaging	✓	✓
Calcium image improvement	Optional accessory	✓	✓
Table Elevation	Required for biopsy	✓	
3D biopsy targeting SW	Accurate localization	✓	
Doors open on both sides	Patient access for biopsy	✓	
Contrast Image SW	Allows CE BCT	✓	✓
Neoadjuvant Therapy Monitoring	Use of contrast imaging	✓	✓
Post Surgical Follow up Imaging	Pain free and Isotropic 3D	✓	✓

KONING CASE STUDIES

In the following pages you'll notice a clear difference between the images collected from conventional mammograms and KBCT. KBCT rotates 360° about the breast, acquiring a true isotropic 3D dataset in 7 seconds.

For the first time in breast imaging history, KBCT introduces co-registration in multiple planes using TRUE 3D volumetric imaging.

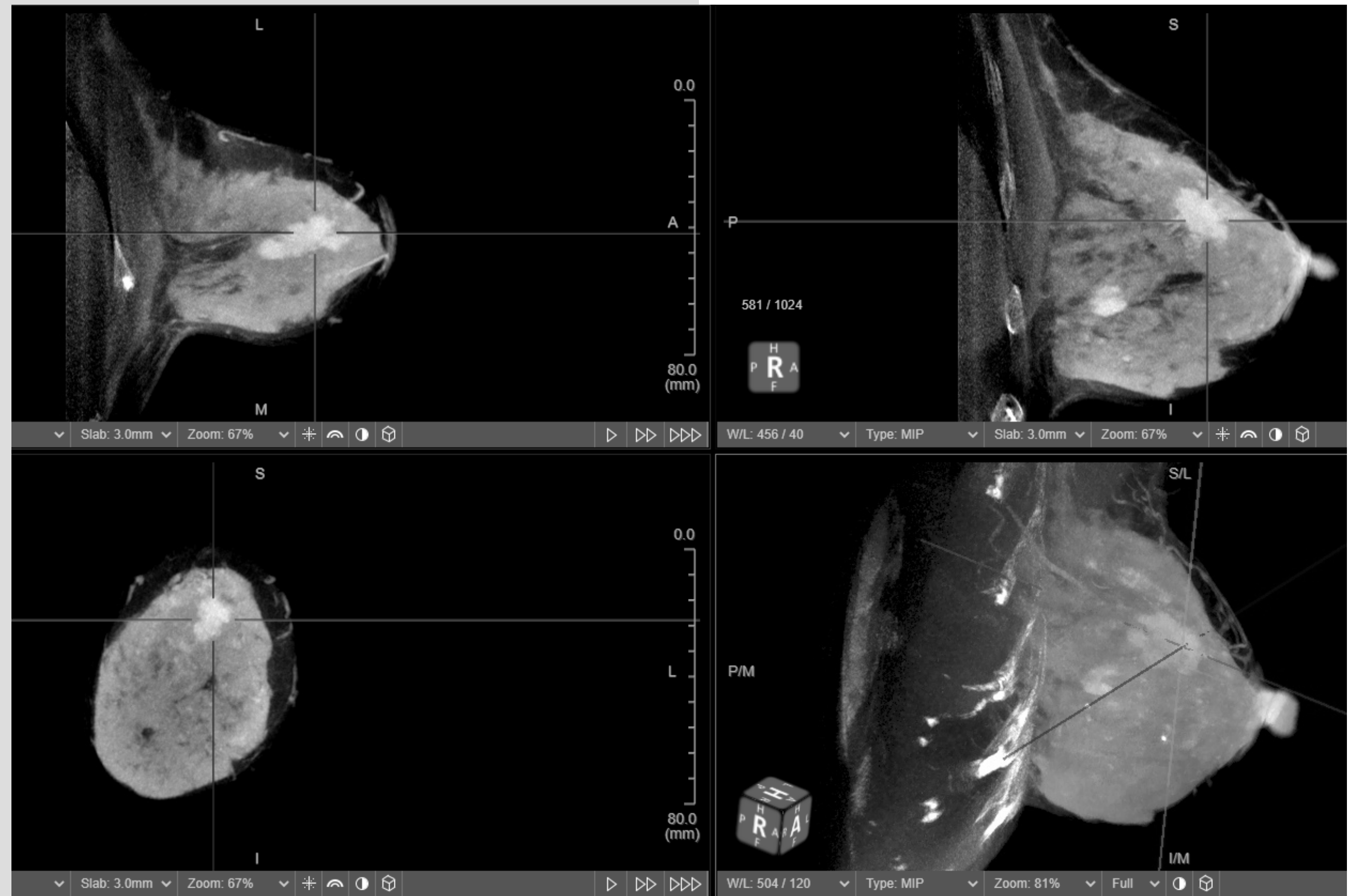
CASE STUDY #1

Patient:

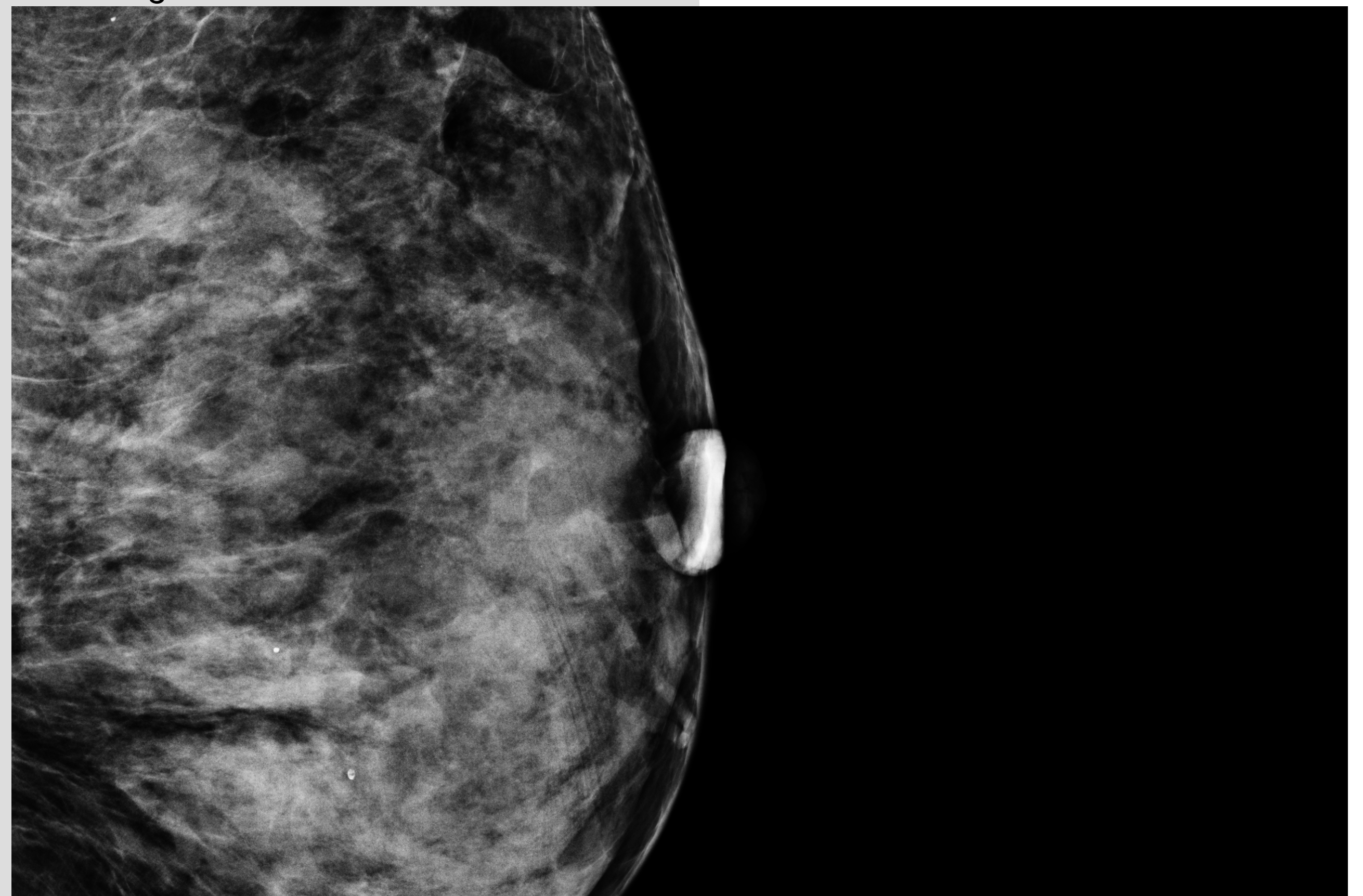
57 years old
Dense Breast

Contrast-enhanced KBCT identifies multi-focal malignant masses in two different quadrants while mammography was negative.

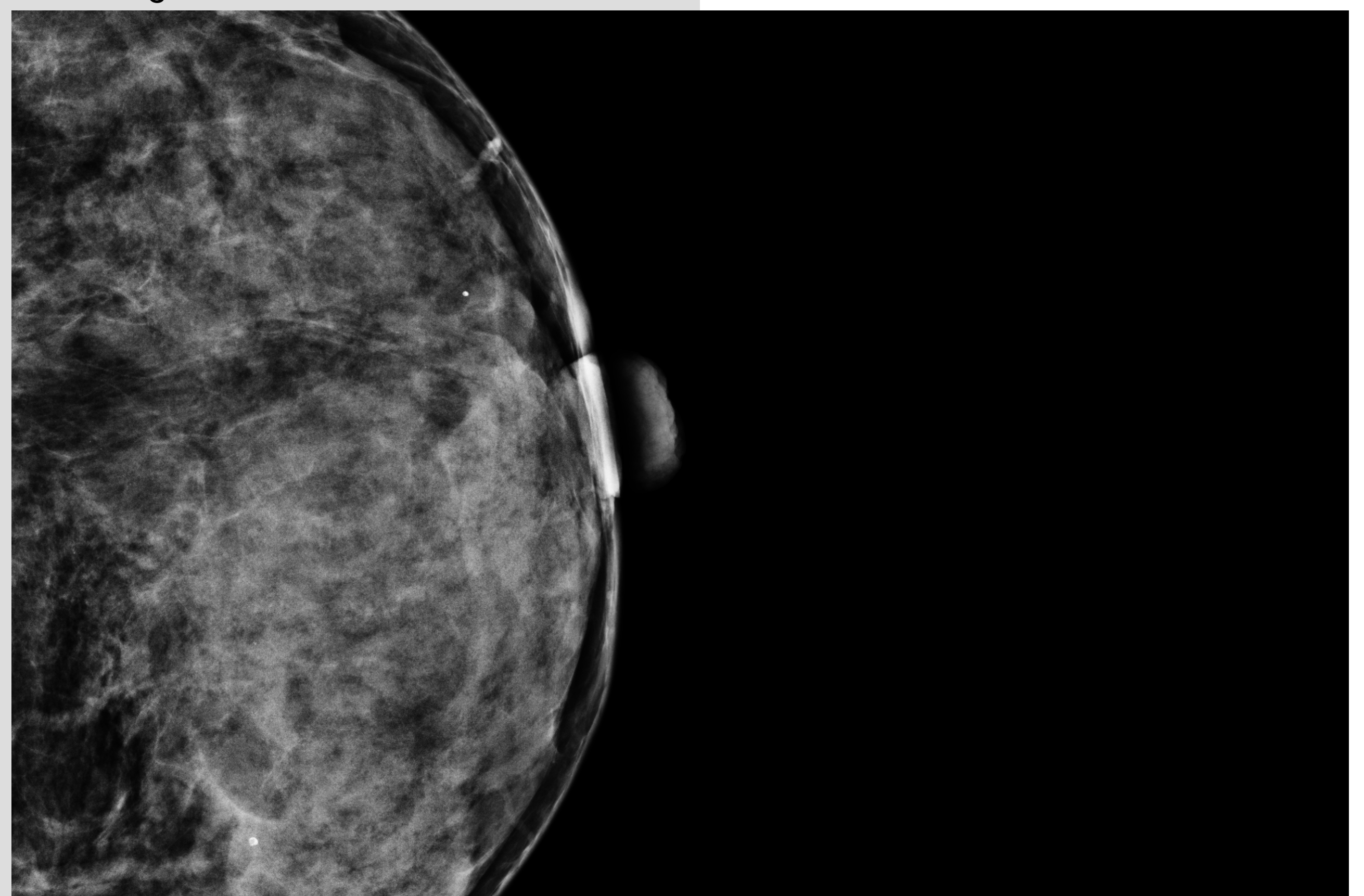
KBCT with contrast



Mammogram - LMLO



Mammogram - LCC



CASE STUDY #2

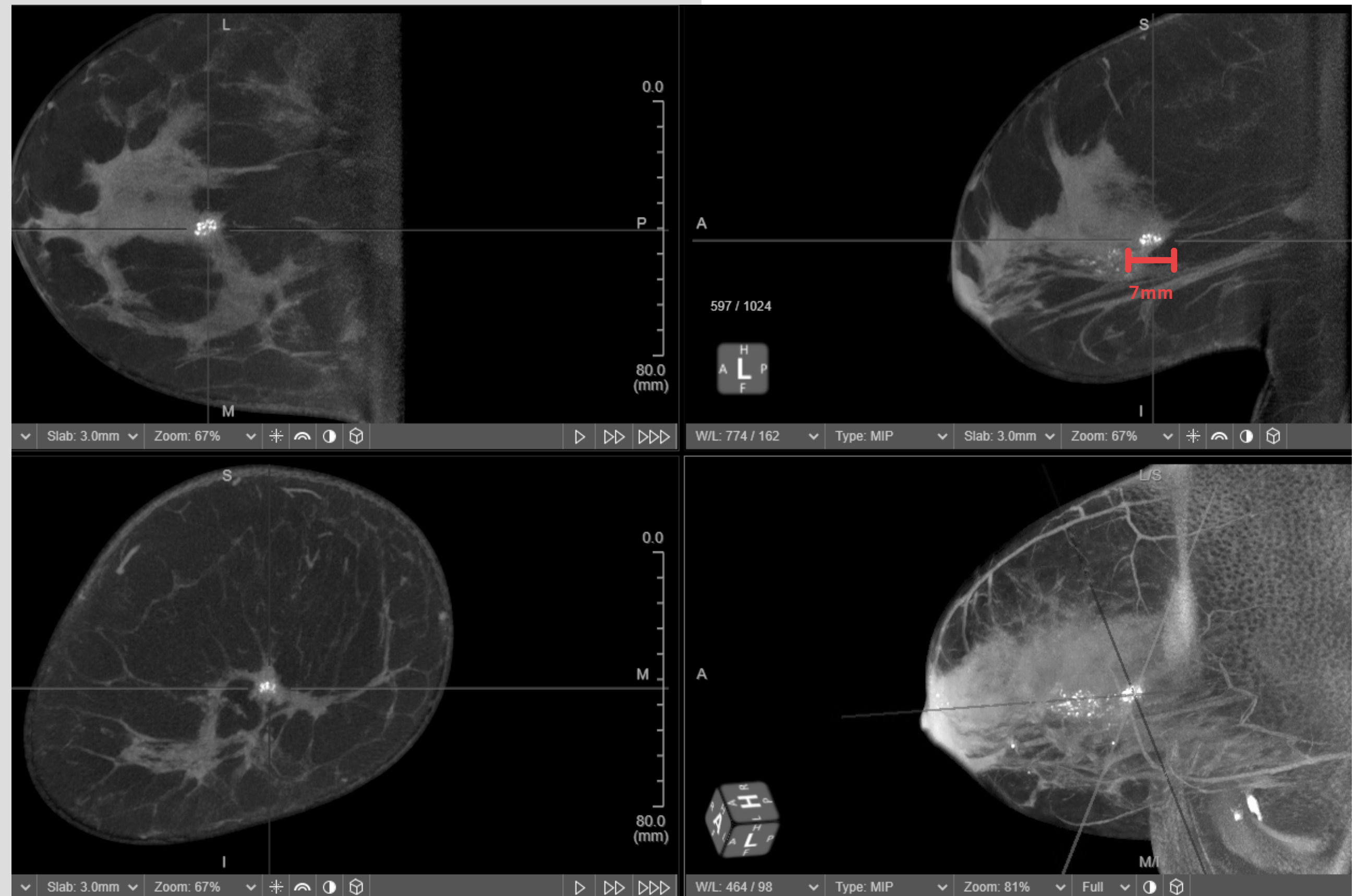
Patient:

60 years old

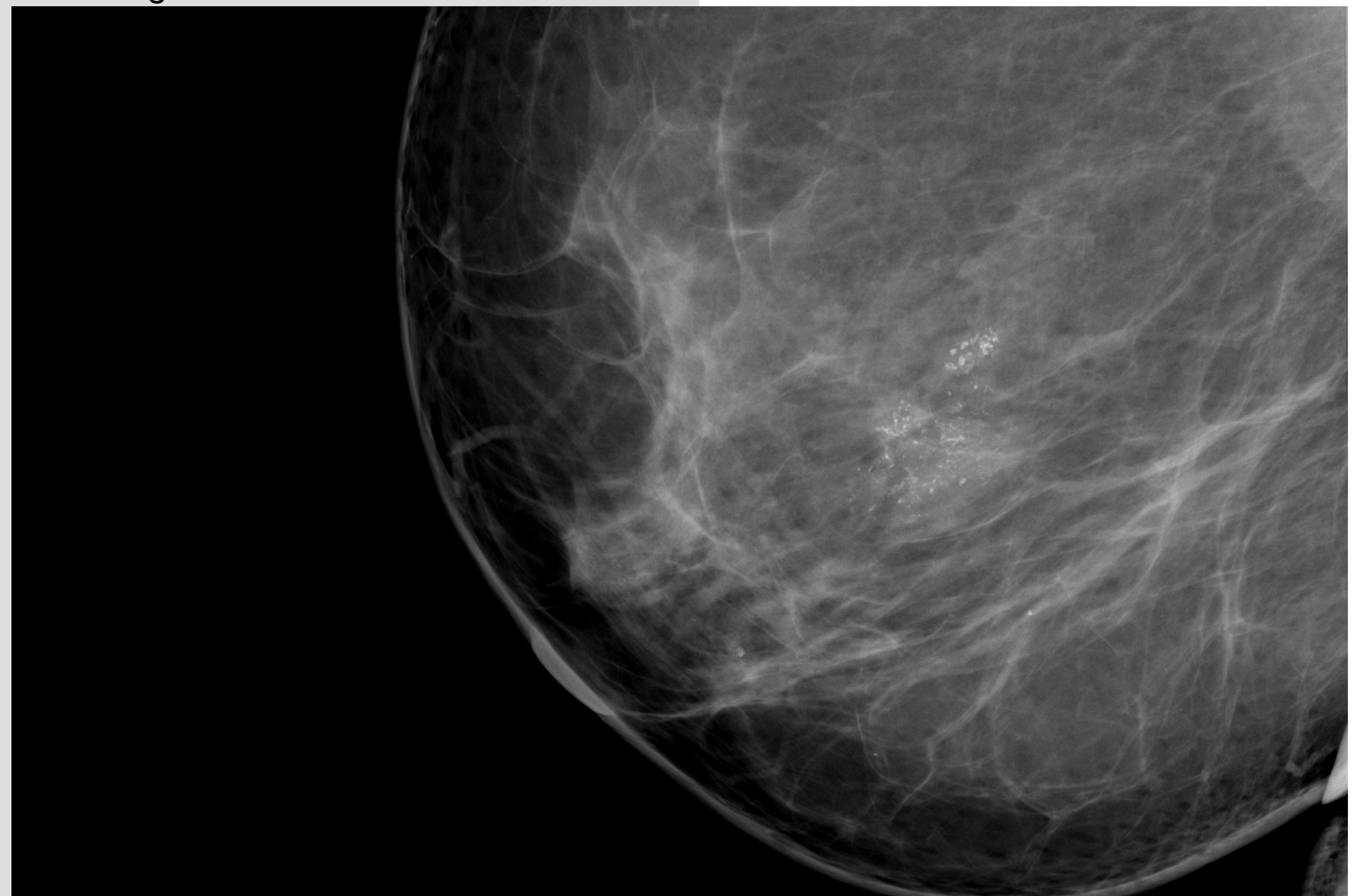
Pathology: Ductal
Carcinoma in Situ

KBCT displays 3D distribution
of the calcification clusters.

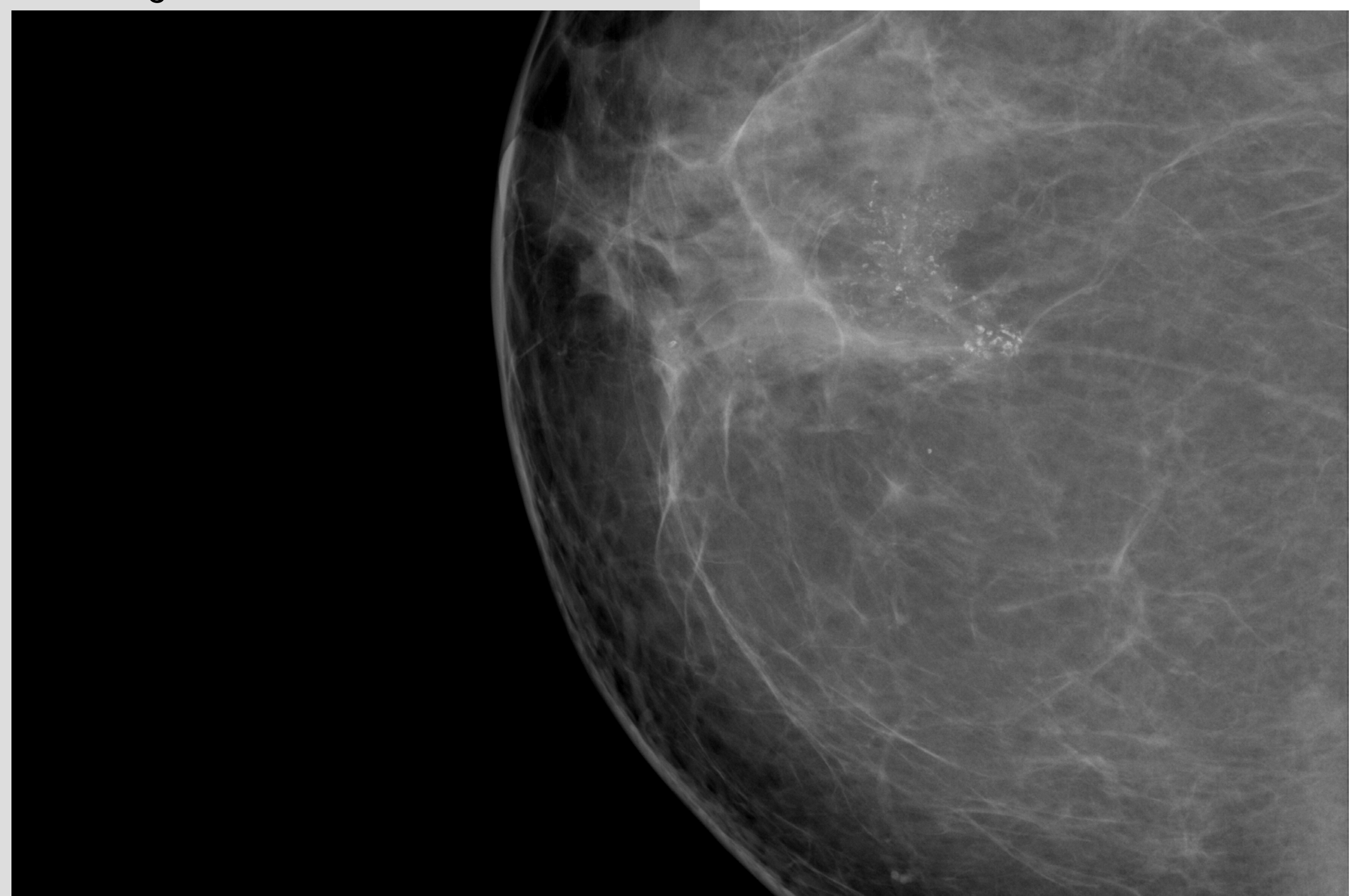
KBCT



Mammogram - RMLO



Mammogram - RCC



CASE STUDY #3

Patient:

61 years old.

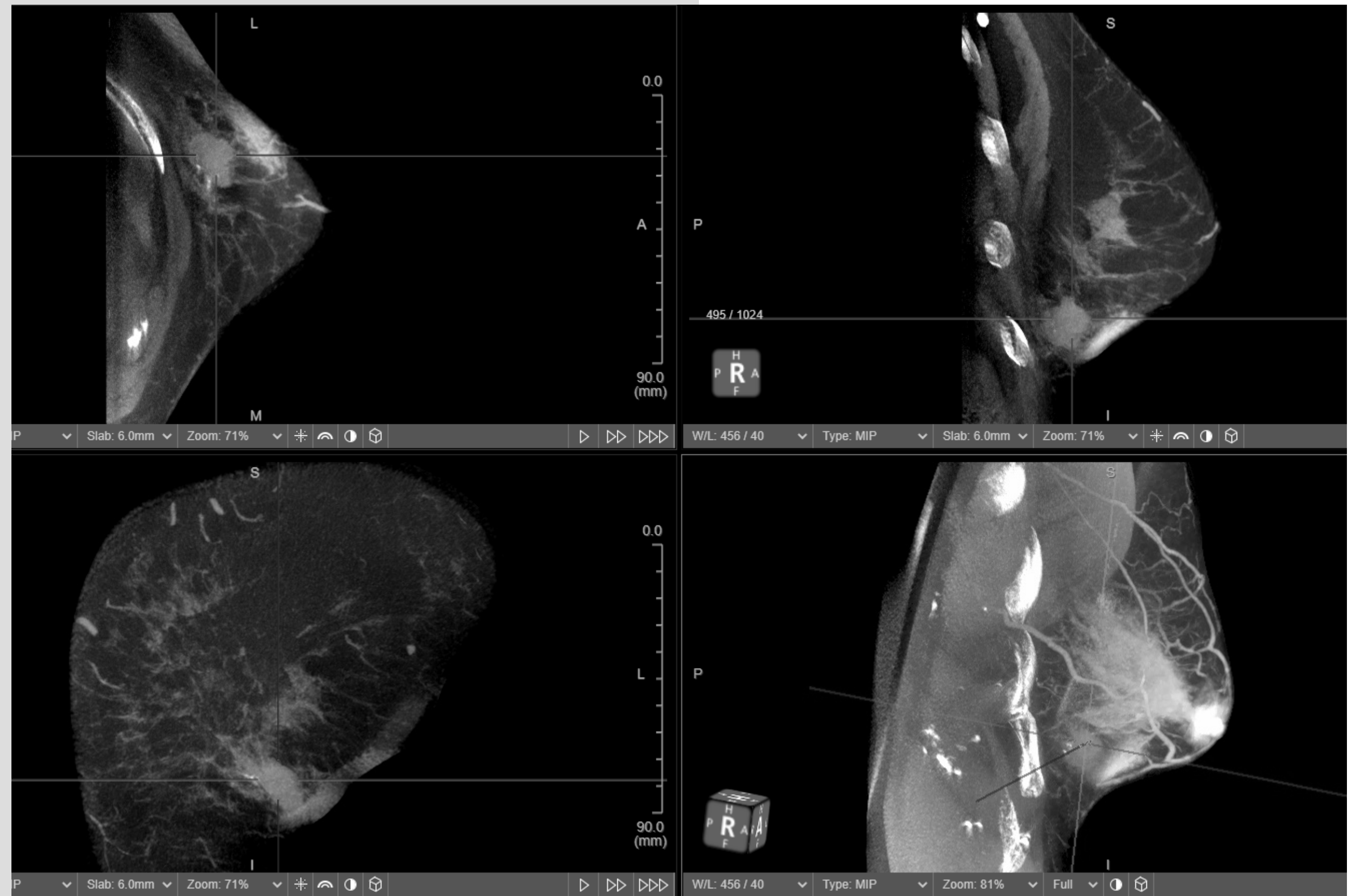
Small breast

Pathology: Invasive Ductal
Carcinoma Grade 3 (Poorly
differentiated)

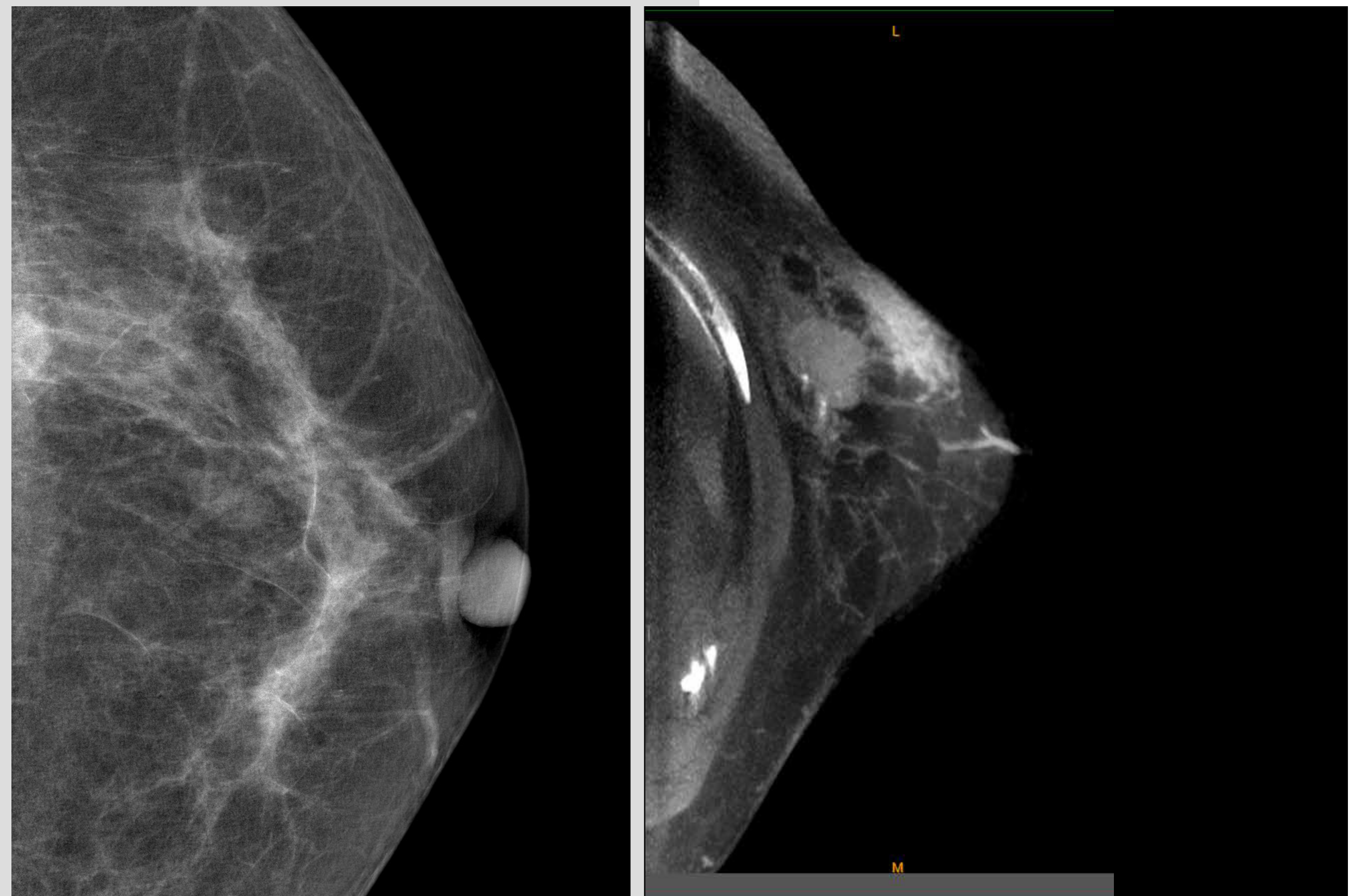
Mammography has poor
coverage. KBCT covers the
whole breast including the
chest wall and ribs. (b)(c)

KBCT fully visualizes the
lesion and posterior tissue. (a)

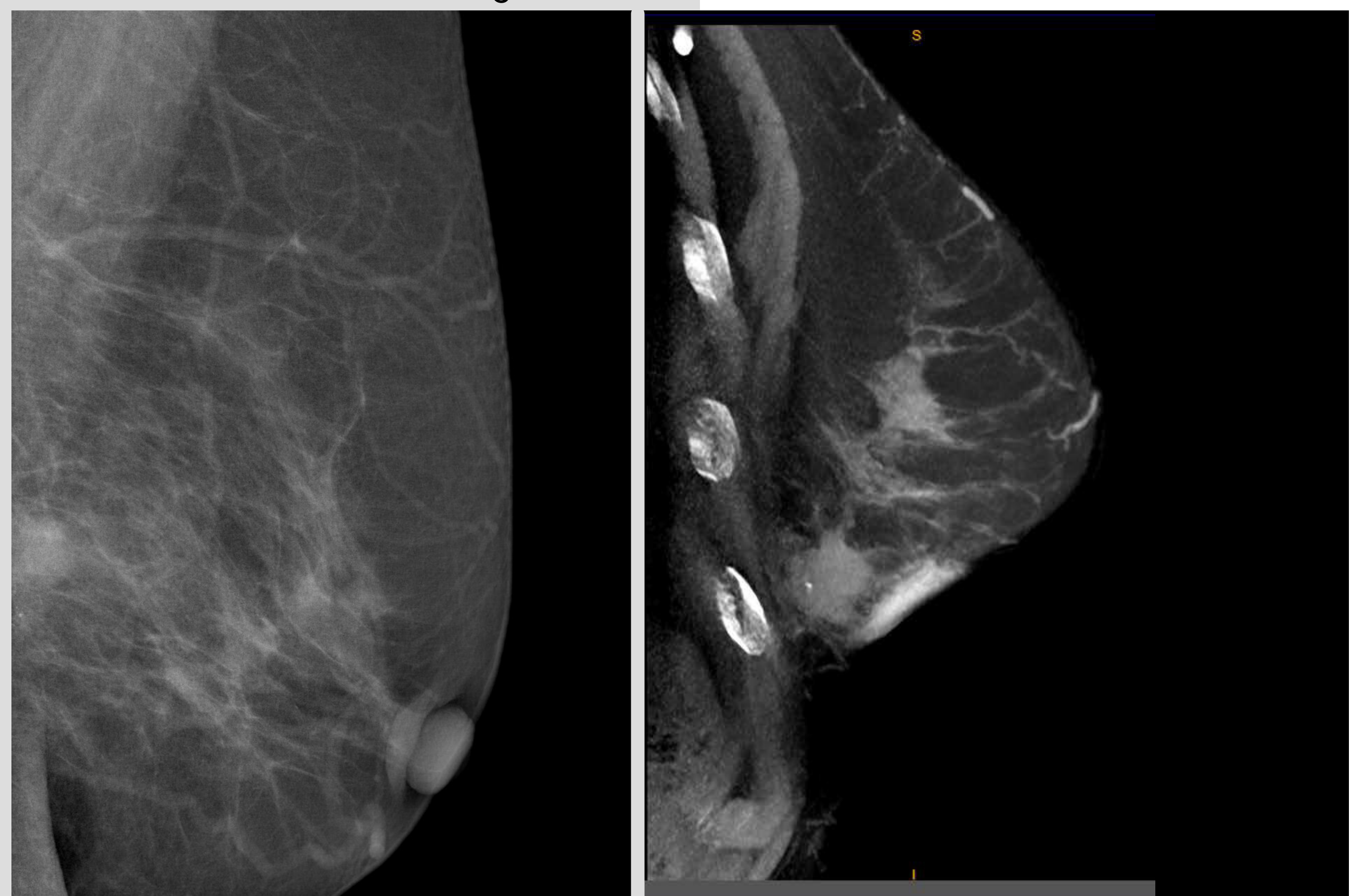
KBCT



Mammo - LCC vs. KBCT - transverse



Mammo - LML vs. KBCT - sagittal



OTHER INFO YOU SHOULD KNOW

Koning Vera Breast CT FAQ

Koning is revolutionizing medical imaging through our advanced Computed Tomography technology. We believe our Koning Vera Breast CT (KBCT) will dramatically improve the way clinicians visualize and evaluate breast tissue, aiding in the optimization of early disease detection, diagnosis, intervention and treatment.

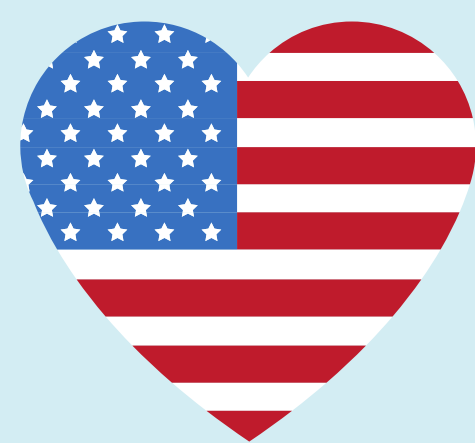
Our hope is to improve survival rates and outcomes for millions of patients around the world with the power and versatility of KBCT.

What is Koning Vera Breast CT?

Koning Vera Breast CT provides isotropically accurate images of the breast, allowing the detection of early stage cancers with NO BREAST COMPRESSION. The Koning device provides diagnostic and biopsy-guided exams with and without the use of contrast.

Where are they built?

KBCT machines are made in the USA.



Is KBCT safe? How much radiation does it emit?

Radiation dose of Koning Vera Breast CT was measured to be in the same range as diagnostic mammograms. KBCT biopsy imaging dose was measured as a 50% reduction when compared to stereotactic biopsies.

Is Koning Vera Breast CT approved for use in the US?

After rigorous study, Koning Vera Breast CT obtained FDA PMA approval for both breast CT and 3D-guided biopsy. This is the highest bar of approval for the FDA.



Is there reimbursement for the procedure?

Effective 1/2021, the American Medical Association provided Breast CT with 6 dedicated CPT codes. The codes are being accepted by both public and private payers.

How is KBCT different from conventional mammograms?

Mammograms are painful due to breast compression. KBCT is a 3D breast imaging exam with no compression that takes only 7 seconds to complete. Mammograms are a 2-dimensional technology. For this reason, cancers are frequently missed, especially in dense breasts where tissue overlap obscures cancers.

I thought 3D mammography already existed – how is this different?

Compressional DBT has been marketed as 3D when, in fact, it is not true 3D. For an image to be true 3D it must be "isotropic" (the same from any angle). Breast CT is true 3D - the image can be viewed from any angle equally, which eliminates any overlapping structures. It acquires true 3D images without compression.



Where can I get this in the US?

At this time, KBCT is in clinical use in Knoxville, TN, Naples, FL, Norcross, GA, and Birmingham, AL

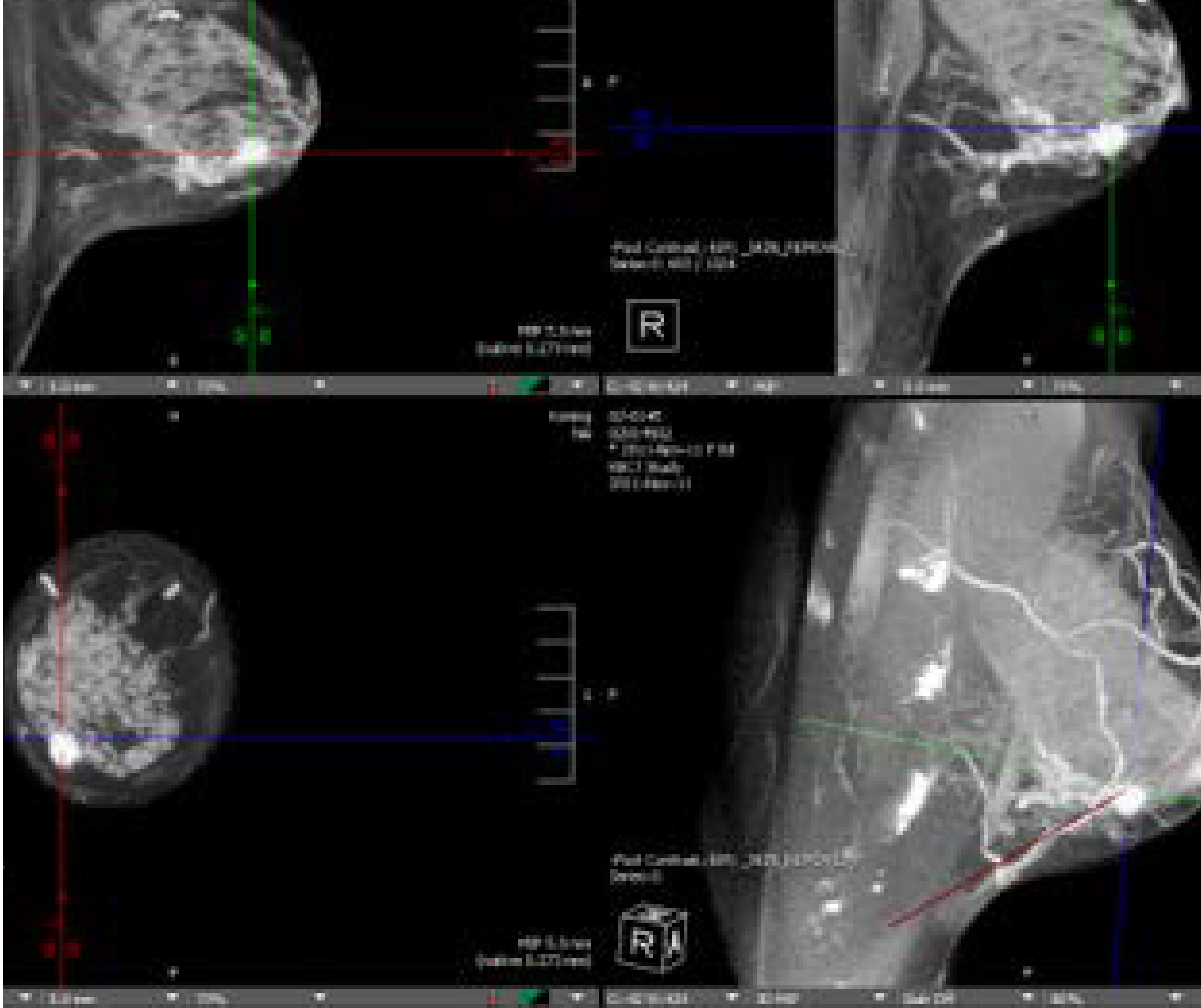


LET'S COMPARE

BREAST IMAGING OPTIONS



	KBCT	FFDM	DBT	ULTRASOUND	MRI	CT
REAL 3D IMAGING	✓	✗	✗	✗	✓	✓
NO COMPRESSION	✓	✗	✗	✓	✓	✓
LOW RADIATION	✓	✓	✓	✓	✓	✗
DETECTS SMALL TUMORS	✓	✓	✓	✓	✓	✗
SAFE CONTRAST ENHANCEMENT	✓	✓	✓	✗	✗	✓
LOW IMPLANT RUPTURE RISK	✓	✗	✗	✓	✓	✓
DETECTS CALCIFICATION CLUSTERS (DCIS)	✓	✓	✓	✗	✗	✗
DENSITY DISTRIBUTION MEASUREMENT	✓	✗	✗	✗	✓	✓
SPATIAL REPRESENTATION OF STRUCTURES	✓	✗	✗	✗	✓	✗
LOW COST	✓	✓	✓	✓	✗	✗
HIGH THROUGHPUT	✓	✓	✓	✓	✗	✗



KONING'S

CLINICAL PARTNERS & ADVISORS

CLINICAL PARTNERS

Dr. Avice O'Connell - *University of Rochester*

Dr. Etta Pisano - *Deaconess Hospital*

Harvard School of Medicine

Dr. Andrew Karellas - *University of Arizona*

Dr. Wu Peihong - *Sun Yat-Sen Univ. Cancer Ctr., Guangzhou, China*

Dr. Ye Zhaoxiang - *Tianjin Medical University Cancer Hospital, Tianjin, China*

Dr. Kamilia Kozlowski - *Knoxville Comprehensive Breast Center*

SCIENTIFIC ADVISORY BOARD MEMBERS

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Dr. Kristina Siddall - *Bayview Imaging*

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FOR ANY ENQUIRIES CONTACT US

020 8146 6839 | +44 75 2990 2750

info@euronoxmedical.com

www.euronoxmedical.com

35 Berkeley Square, Mayfair, London, W1J 5BF