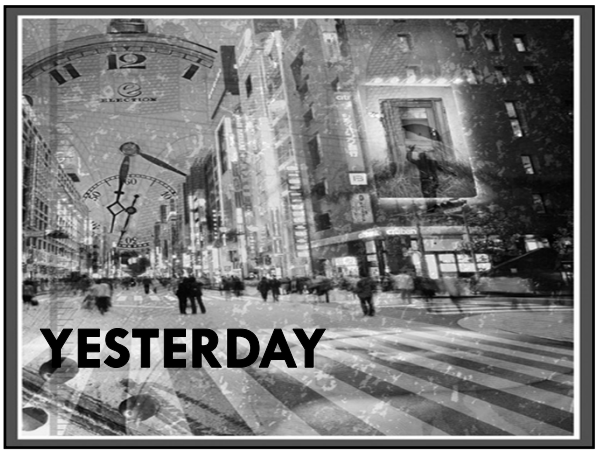



## IN THE BEGINNING

Mammography technology has come a long way since the first machine specifically designed for producing mammograms was introduced in 1966.

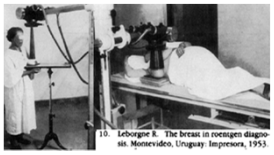
*The first mammography system was essentially a tripod supporting a special X-ray camera*

## EARLY MILESTONES IN MAMMOGRAPHY

- 1913 - Albert Solomon, a surgeon in Berlin, uses a conventional X-ray machine to visualize breast cancers in 3,000 mastectomy specimens.
- 1949 - Uruguayan Raul Leborgne emphasizes the need for breast compression to identify calcifications.
- 1956 - Robert Egan, a radiologist in Houston, introduces dedicated film for mammography to produce simple and reproducible images with improved detail.
- 1966 – The first dedicated mammography system is introduced.
- 1971 – Commercial introduction of xeromammography
- 1980 – Introduction of single emulsion film; 2x faster at significantly lower dose

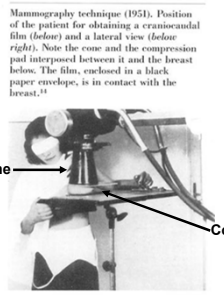
## REMEMBER THIS?

1953 Uruguay




If you do, you've been working way too hard…and too long!

## EARLY POSITIONING AND COMPRESSION




CC in standing position

MLO view done in reclining position

**How long do you think this exam took?**

## MANY VENDORS SAW THE POTENTIAL…

- PHILIPS(LORAD)
- BENNETT
- CONTINENTAL
- LORAD TRANSPO
- CGR-500T
- GE800T
- INSTRMENTARIUM
- GENRAD
- PLANMED
- SIEMENS

## WHAT ABOUT THIS?

- Usually done when a patient had a very large palpable mass
- Limited productivity; 4-5 patients imaged per day
- Limited to CC and MLO views; no ability to do extra diagnostic views

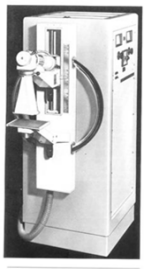
*If you remember this, I know your age!*

## FDA Approval

- Approvable Letter
- 510K—manufacturer "claims" product is substantially equivalent----used for proven technology-Today
- PMA---manufacturer "proves" product is substantially equivalent----used for new technology

## DEDICATED MAMMOGRAPHY SYSTEMS

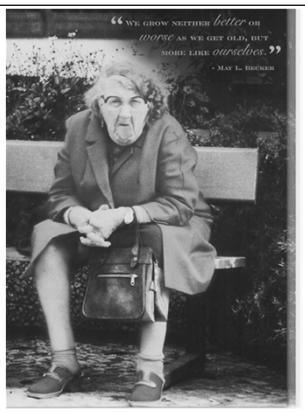
- The first systems developed specifically for mammograms were released in 1966.
- Rotating C-arm allowed both CC and MLO views to be taken with patient in standing or sitting position, for better efficiency
- Additional diagnostic views enabled
- Image quality was limited due to limitations in film capabilities



First production model of the CGR Senographe (1966).[36]

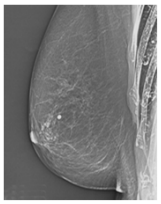
## OTHER BENEFITS

- More comfortable procedure for the patient
- Dedicated work areas for Radiologists and Technologists, for improved productivity
- Birth of the "**team approach**" in mammography




## THE NEXT ADVANCE XEROMAMMOGRAPHY

- First introduced in 1971
- Provided better image quality than systems using industrial film packs
- Allowed excellent visualization of chest wall
- The Grandpappy of Selenium digital technology
- Key Inventor – Lothar Jeromin ("Mr. Xerox")
  - Holds 23 patents

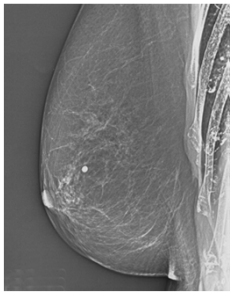


*Xeroradiographs (blue and white prints), as shown above, gave adequate image quality; however, the radiation dose to the breast was much higher than current imaging methods.*

## Is This Your Past

## XEROMAMMOGRAPHY DIFFERENT PERSPECTIVES

- **LOVE**
  - **Radiologists and Surgeons** loved the image quality and ability to see chest wall and ribs
- **DREAD**
  - **Technologists** were uncomfortable with length of exam and lack of training in positioning (all on the job, at that time)
- **FEAR**
  - **Patients** were very uneasy, as the exam was not expected to bring good results (done primarily for symptomatic patients at that time)



## Is This Your Past

## AND IT APPEALED TO THE PUBLIC…

- Advertisement in Life and Glamour magazine promoting the new technology, xeromammography
- Your Mother's Mammogram

***Model demonstrates the latest in mammography technology and fashion. Check out the hosiery***

## BUT WHAT A MESS!

- Technologists were the original Smurfs!
- Lots of blue, on your shoes, uniforms, hands,hair etc.

## A GLIMPSE OF THE FUTURE LOTHAR'S STORY

- As a testimonial of faith in their xeromammography system, Xerox offered free mammograms to female employees in the breast cancer at-risk age group.
- ONE non-symptomatic woman was indeed diagnosed with breast cancer

**And so the seeds of a screening program were sown ……**

## IMPROVEMENTS IN XEROMAMMOGRAPHY

- In 1985, xeromammography changed from blue powder toner to black liquid toner
- This resulted in substantial dose reductions (and cure of Smurf-syndrome in technologists)

*1983 prototype of low-dose xeromammography system*

*Lothar Jeromin with low-dose xeromammography system at RSNA 1985*

## 80s AND 90s PROFICIENCY DEVELOPMENT

- Worldwide acceptance of mammography as the first line of defense
- Radiologists became MAMMOGRAPHERS and in many facilities multitasked
- Technologists began to seek out specialized training courses
- Administrators & Technologists worked together on creating "The Breast Center"
- MQSA enacted to ensure consistently high quality in all mammography facilities

## AT THE SAME TIME….

- Single emulsion film for use in mammography was being introduced, with the promise of providing faster processing, improved image quality, and significantly decreased dose
- By 1986, screen-film mammography was being used by more than half of all radiologists
- Production of xeromammography was halted in 1989, due to declining sales
- Screen-film mammography became the gold standard in the late 1980's – early 1990's

## MILESTONES IN MODERN MAMMOGRAPHY

- 1985 – Declaration of Breast Cancer Awareness Week, which led to Nation Breast Cancer Awareness Month
- 1988 – Congress passes legislation to provide annual screening mammography benefit for Medicare recipients
- 1990 – Breast and Cervical Cancer Mortality Prevention Act implemented to provide free or low cost mammograms and pap smears to low-income women
- 1998 – First Computer Aided Detection (CAD) system for mammography approved by FDA
- 1999 – National Mammography Quality Standards Act implemented
- 2000 – First Full Field Digital Mammography system approved by FDA

## THE 80'S and 90's DECADES OF AWARENESS

- Significant increase in incidence of breast cancer diagnoses between 1980 - 1987 attributed to implementation of screening programs, enabling earlier detection of smaller breast cancers
- Earlier detection has led to decreases in mortality
  - **Breast cancer mortality rates have decreased approximately 2% annually since 1990!**
- The "WAR" on Breast Cancer has been the biggest American accelerator for development of better detection technologies and improved treatment options in the last two decade

American Cancer Society Making Strides Against Breast Cancer · susan g. komen for the cure · Y-ME National Breast Cancer Organization · YOUNG SURVIVAL COALITION

## The Image Interpreter's Challenge: Find Waldo

**Find Waldo:**

**Breast Cancer Awareness has led to an intensified movement to promote life-saving early detection by**

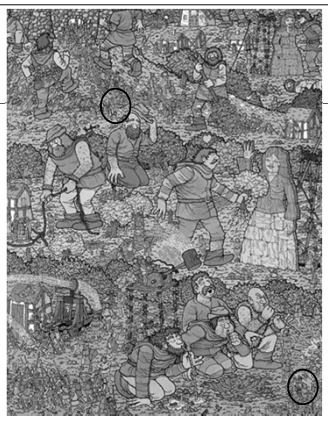
**RADIOLOGISTS**
**TECHNOLOGISTS**
**PHYSICISTS**

Are there ANY?

Are there MANY?

Where?

Are you sure?



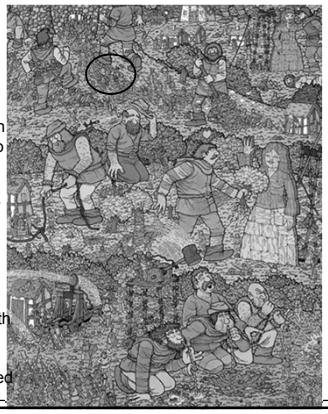
**Your time's up!**

## The Image Interpreter's Challenge:

FIND "WALDO"

(In USA), screening Mammography exam is two views per breast, = 4 images/study

Typically, the previous 4 images are compared with the latest 4 images, = 8 images viewed



If radiologist interprets 40 patient studies/hour, = 1 study every 90 seconds

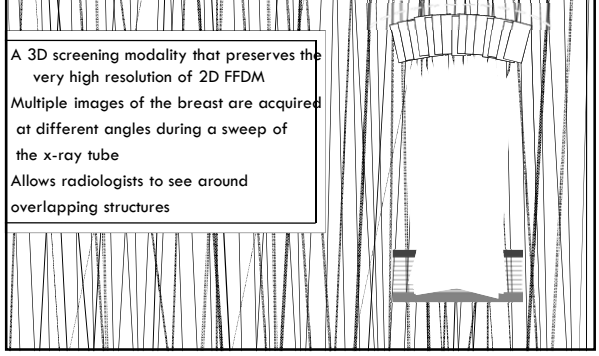
Reviewing 8 images every 90 seconds = 11 seconds per image!


## Breast Tomosynthesis

A 3D screening modality that preserves the very high resolution of 2D FFDM

Multiple images of the breast are acquired at different angles during a sweep of the x-ray tube

Allows radiologists to see around overlapping structures



# Tomosynthesis

## Why is There a Need for Tomosynthesis?

In 2D FFDM:

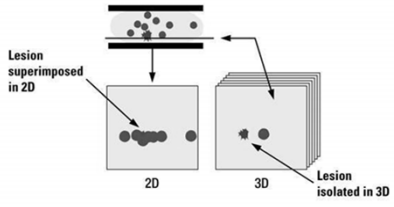
Tissue superimposition hides pathologies in 2D

Tissue superimposition mimics pathologies in 2D



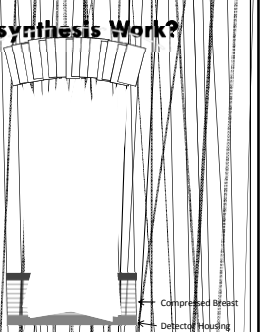
## The Solution is Tomosynthesis

Tomosynthesis is a three-dimensional mammographic examination that **can minimize the effects of structure overlap** within the breast

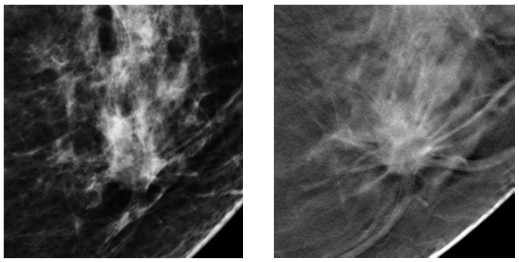


## How Does Hologic's Tomosynthesis Work?

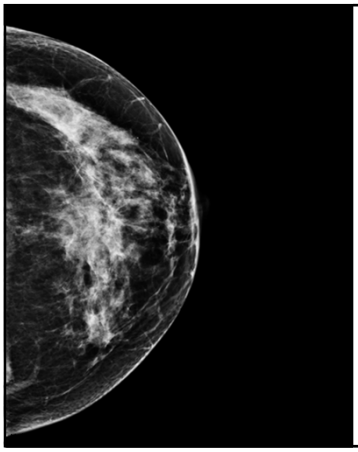
Tube moves in a 15° arc
15 low dose images are acquired
1 image at each degree
Four second sweep
Images are reconstructed into 1 mm slices
In **combo-mode** imaging, the 2D and 3D are taken in the same compression, with no additional positioning for the patient.




The 2D Mammography Image next to one slice of a 3D Image Set

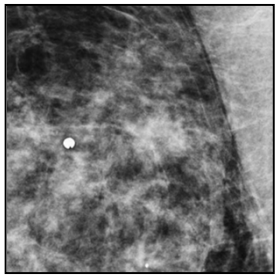


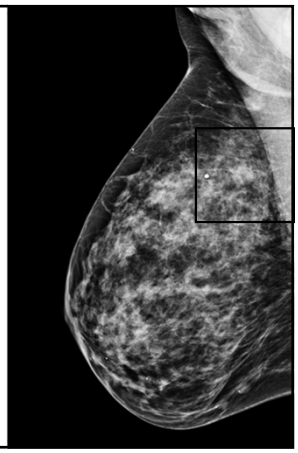
2D 3D

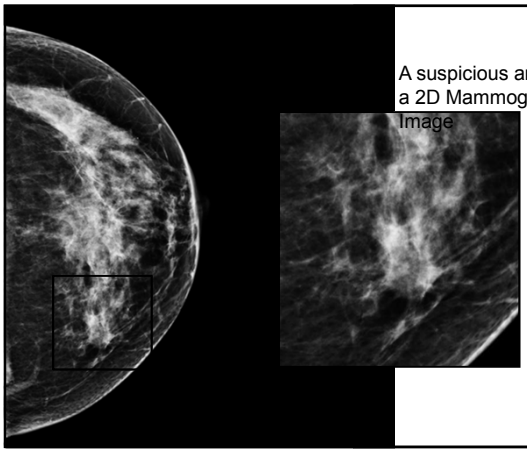


A 2D Mammography Image

A 2D Mammography Image with a suspicious area identified and blown up

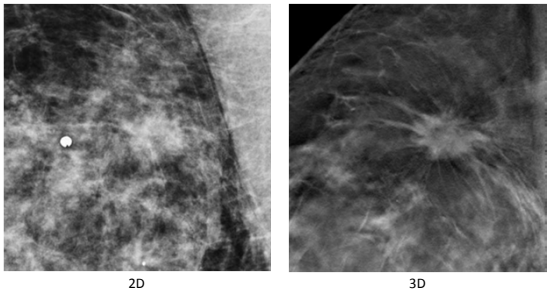






A suspicious area in a 2D Mammography Image

The 2D Mammography Image next to one slice of a 3D Image Set

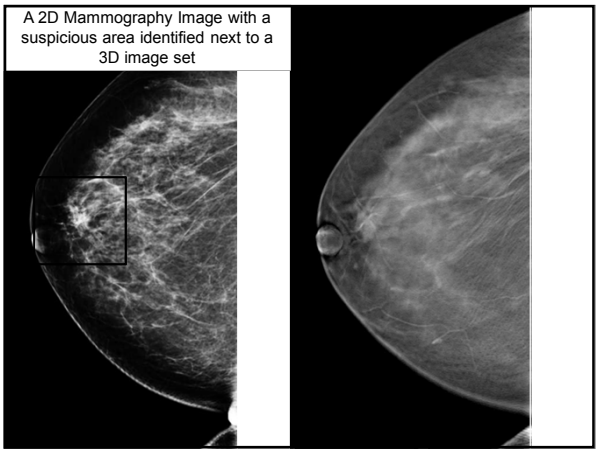


2D 3D

Recall Reduction
Superimposed Tissue Examples

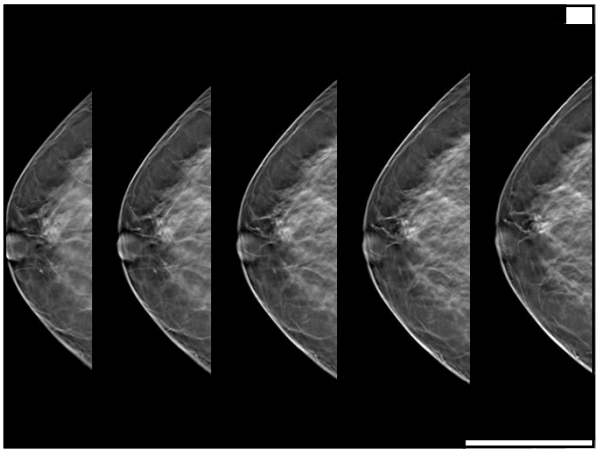
## Hologic C View

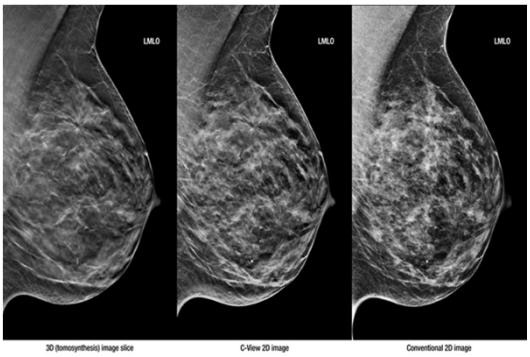
A 2D Mammography Image with a suspicious area identified next to a 3D image set



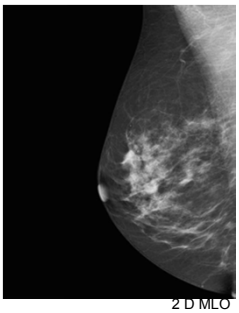
## C-View

- 2D reconstruction algorithm
- Eliminates the need for a 2D mammogram
- Creates synthesized images from single tomosynthesis scan
- Reduces dose
- Additional cost

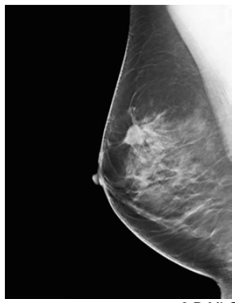




## GE SenoClaire



2 D MLO

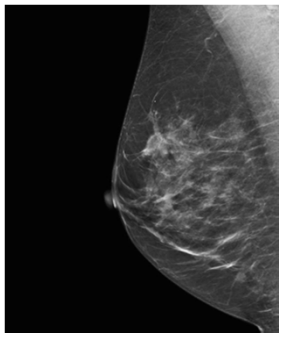


3 D MLO

- Routine for GE tomosynthesis-FDA Approval-Screening
  - 2 D CC
  - 3 D MLO
- Diagnostic Exam
  - 3 D CC
  - 3D MLO

**V-Preview**

A 2 D image generated from the raw DBT projection data that helps the user get a overview of the entire stack of images before reading individual tomosynthesis images



V-View

## GE SenoClaire

- Step and shoot mode preserves microcalcification sharpness and avoids image blur, since the tube makes a complete stop for each of nine exposures
- Anti scatter solution designed for tomosynthesis, the SenoClaire grid in 3 D reduces scattered radiation while preserving dose and performance
- SenoClaire uses ASIR ®-A calcification correction reconstruction algorithim

## Ultrasound

ABUS-Automated Breast Ultrasound
Breast Density
Elastography

## Ultrasound

- Began in the 1950's
- Incorporated the use of A mode technology
- Immersion, compression, and contact transducers for sonographic breast imaging continued through the early 1960's
- In the late 1960's and early 1970's, B-mode transducers with frequencies ranging between 1.5 MHz to 10.0 MHz produced images that could differentiate types of breast tissues

## ACRIN 6666-ABUS Study

- 21 sites
- 2809 women (at least heterogeneously dense in one quadrant)
- Mammography and physician performed handheld full breast ultrasound
- Diagnostic yield of mammo vs. mammo plus ultrasound

## Ultrasound

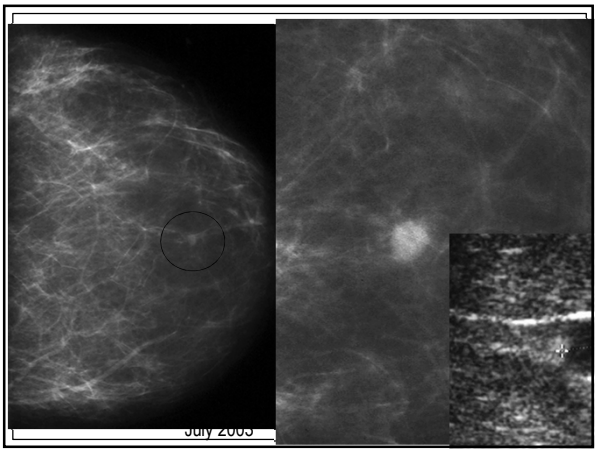
- Up until the early 2000's, breast sonography was used to differentiate between solid and cystic masses.
- Today, breast sonography uses high-frequency, high resolution, real time systems.
- Transducers should be 10 MHz or higher
- ABUS-Automated Breast Ultrasound System

## ACRIN 6666

- Physicians underwent consistent training
- 20 minutes avg. scan time plus interpretation
- Mammography alone 7.6/1000 cancers detected
- Mammography plus US 11.8/1000
- 12 cancers detected by US alone

## Ultrasound

- An important adjunct to mammography
- Screening tool for dense breasts?



somo•v™ by U-Systems®
Automated 3D Breast Ultrasound

## ABUS

- Automatically scans a woman's breast capturing multiple images
- Displays them in 3-D for a radiologist review
- Ideal for women with dense breasts where effectiveness of mammography may be limited


somo•v™ by U-Systems®
Automated 3D Breast Ultrasound

**SonoCine AWBUS**
**Automated Whole Breast Ultrasound**

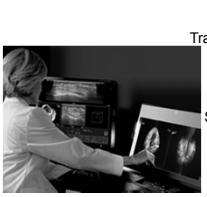
## Reverse Curve Transducer

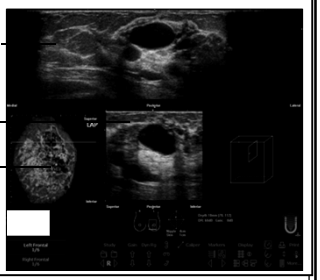
- Creates a uniform compression across the entire breast
- Enables a greater penetration due to the convergent scan line geometry
- Improves detail resolution at depth
- Anatomically correct

**SonoCiné – System**

**Use existing Ultrasound System**

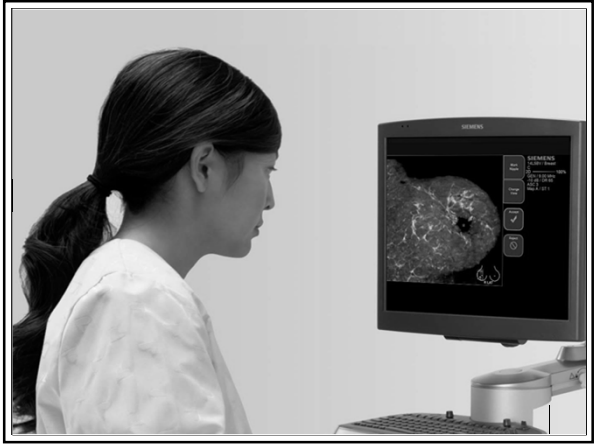
The resulting 3D data is sent to the somo·v display console for review and rendering.






somo·v™ by U-Systems®
Automated 3D Breast Ultrasound

- The AWBUS™ articulating arm, which uses the transducer of your ultrasound system, provides whole breast coverage while still allowing the operator to adjust the angle and pressure of the transducer

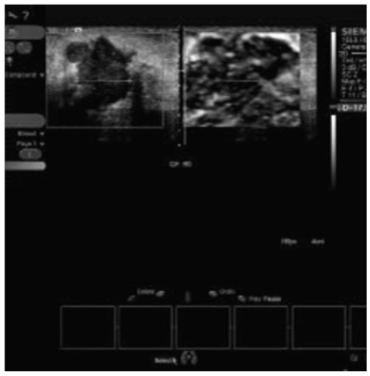


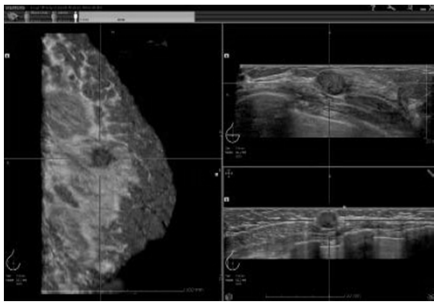
## Siemens

**ACUSON S2000 ABVS- Automated Breast Volume**

**Can be used for both ABVS and hand held exams**

Can be used for elasticity studies





## Breast Density Challenges

- Challenge of determining breast density is that it is based on a 2D image as opposed to the breast actually being a 3 dimensional organ that varies in size, shape, and composition
- An area that appears almost white on a mammogram could be a single highly dense area or several densities overlying each other
- Density can be evenly distributed or the area near the skin could be dense while the center of the breast could be largely replaced by fatty tissue

## BREAST DENSITY

What does it mean?

## Breast Density Software

- Determines the density of the tissue
- It is the volume of the dense breast tissue divided by the volume of the breast and then multiplied by 100
- The breast density will be consistent and used to detect early breast cancers by picking the first sign of change

## Breast Density

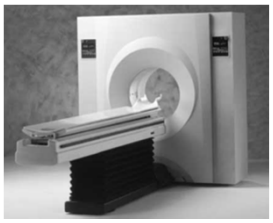
- Has received a lot of attention lately
- Linked to an increase in cancer risk
- Need for accurate, reproducible density measurement
- Density has historically been measured by radiologists comparing the light and dark parts of the mammogram
- This method is operator dependent and is very subjective

## Elastography

## Elastography

Non-invasive technique that adds value to the sonographic examination by evaluating the stiffness of tissue. It detects the stiffness or elasticity compared to normal tissue

## Positron Emission Tomography (PET)

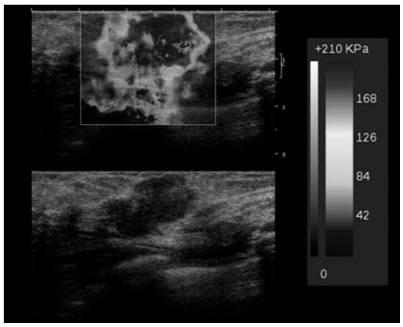


## Elastography

- A small amount of pressure is applied to the breast, just enough to move it slightly.
- With the pressure applied, the ultrasound system takes another image
- A computer than takes the two images and compares how elastic the different regions are
- A hard, inflexible lump is almost always a carcinoma. A flexible lump is usually benign.

## PET

- Physiologic image to detect cancer or cancer therapy results
- Indicates if cells are active and growing or inactive and shrinking
- A molecule is tagged with a positron emitting isotope (Radioactive substances combined with a natural body compound)
- 18-F fluorodeoxyglucose (a probe)
- Radioactive 18-F tagged with a glucose




## PET Scan

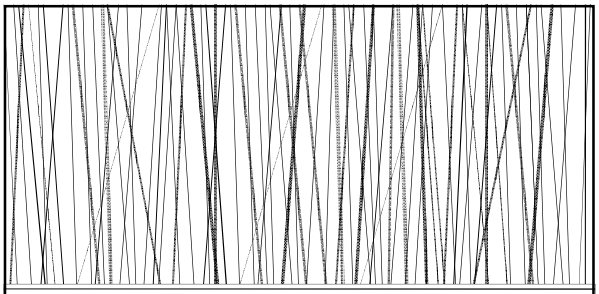
- Positrons annihilate nearby electrons, emitting photons
- Photons are detected by the scanner
- Cancer accumulates glucose more than normal tissue (glucose metabolism)
- Patient prep is required (fasting, limited exercise)
- 45-90 minutes rest post injection
- 30-45 minutes scan time

## PET Scan

- High FP (esp. lobular and well differentiated Ca)
- High Cost: Cyclotron is needed near PET, isotopes are short lived (hours)
- Combine functional imaging of PET with anatomical imaging of CT

## PEM

- Following a 4 hour fast, serum blood is drawn to determine blood glucose level
- 10mCi FDG is injected intravenously and imaging is acquired one hour later
- Imaging is obtained in a similar manner as mammography
- Breast is imaged with slight compression



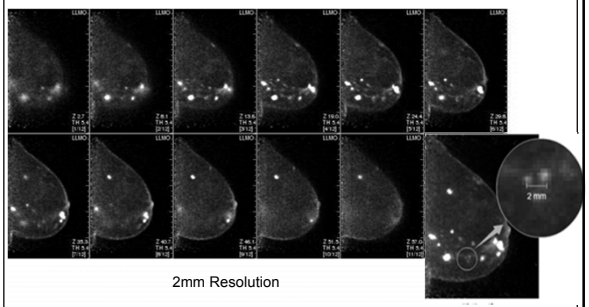
**PEM Positron Emission Mammography**

## Naviscan PEM

## PEM

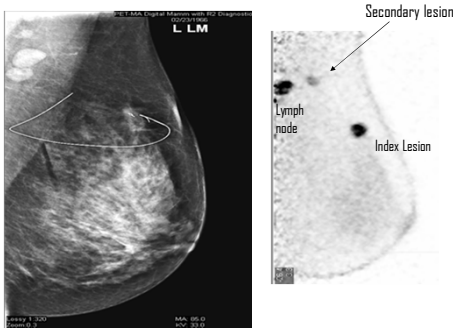
- Nuclear medicine exam that uses intravenous injectable FDG (fluoro-deoxyglucose)
- A glucose analog that accumulates in glucose avid cells
- Accumulates in both inflammatory and cancerous states

## Tomographic Display




2mm Resolution

## PEM Compared to Mammography



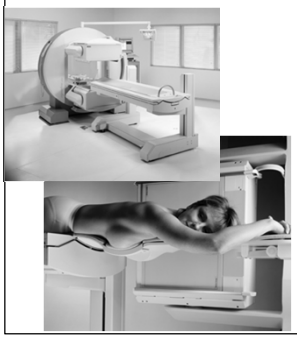

## PEM

- Great value in preoperative identification of non-invasive breast cancer (DCIS)
- DCIS accounts for 30% of newly diagnosed patients
- DCIS is often difficult to quantitate with mammography and MRI
- Used for preoperative surgical staging

## PEM

- Dose 1.4-7mSv
- Approx $800K purchase price
- Reimbursement is controversial
- $1000 - $2000
- Need to improve the markers (FDG) to improve sensitivity

## Molecular Breast Imaging



- Scintimammography FDA approved 1997
- Traditional multi-purpose gamma camera
- Indicated for planar imaging to assist mammography
- No significant difference in detection fatty vs. dense breasts
- Limitation with lesions less than 1cm
- Positioning an issue to image the entire breast

## PEM

Reimbursed for:

- Pre-surgical planning and staging
- Monitoring for recurrence
- Neo-adjuvant therapy
- Equivocal exams following diagnostic workup

## Scintimammography/Breast Specific Gamma Immaging

- Uses a radioactive tracer that "lights" up any areas of cancer inside the breast-
- Tracer is injected into the body through a vein in the arm
- Breast cancer cells take up the radioactive substance much more than normal cells do
- A nuclear medicine scanner that scans the breast looking for areas where the radioactive substance is concentrated

## MBI-BSGI/Scintimammography

- Imaging performed 5 minutes post injection
- Breast is lightly compressed between 2 detectors
- Images are obtained in cranial caudel and mediolateral oblique projections
- Easily compared to mammography

The Dilon 6800 Gamma Camera *can replicate any mammographic view*

## MBI-Sensitivity

- MBI has an overall sensitivity of about 90% with a sensitivity of 82% for lesions less than 10 mm in size
- Sensitivity is lowest for lesions less than 5 mm in size
- Tumor detection does not appear to be dependent on tumor type, but rather on tumor size

## Breast Specific Gamma Imaging BSGI

Brem study of 167 lesions in 146 patients:

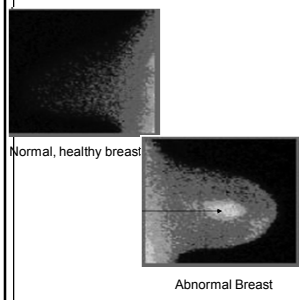
Sensitivity = 96.4%

Specificity = 59.5%

Purchase cost $240K

Reimbursement $700-1200

## Nuclear Medicine




- Holds special promise in determining cancerous lesions in dense breast
- Use of scintimammography after abnormal mammogram offers higher level of diagnostic specificity

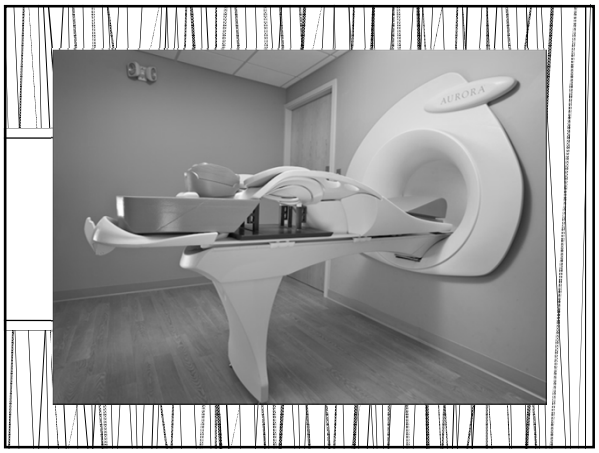
## BREAST MRI

## Breast MRI

- Breast MRI the most rapidly growing segment of MR Imaging
- Improvements in MRI resolution, contrast, biopsy devices, CAD software
- American Cancer Society (ACS) recommendations published
- Clinical trials proved its worth (ACRIN 6667)

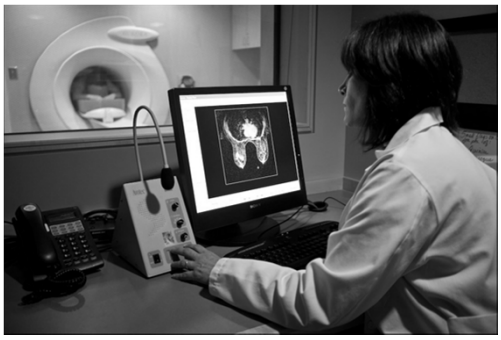

## MRI Screening

- 7 studies identified missed cancers
- Improved the cancer detection rate 10-40 per 1000 of the high risk women screened
- Average 22/1000
- Specific populations benifit




## ACS Guidelines

- BRCA mutation
- First degree relative with breast cancer
- Lifetime risk 20-30% as defined by BRCAPRO or other models that are family history based
- ? Radiation to the chest age 10 – 30 yrs
- NOT dense breasts



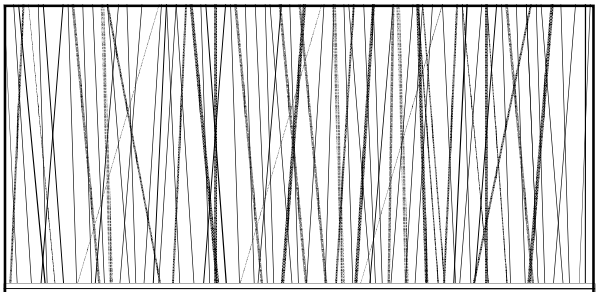
## Breast Thermography

- Based on the principle that chemical and blood vessel activity in both pre-cancerous tissue and the area surrounding a developing breast cancer is almost always higher than in the normal breast

## MRI Biopsy

## Breast Thermography

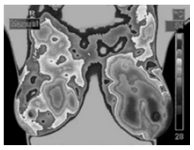
- Since pre-cancerous and cancerous masses are highly metabolic tissues, they need an abundant supply of nutrients to maintain their growth
- This increases circulation to their cells by sending out chemicals to keep existing blood vessels open, recruit dormant vessels and create new ones
- This process results in an increase in regional surface temperatures of the breast

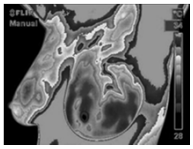


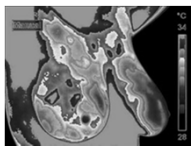
## Thermography

## Breast Thermography

- Uses ultra sensitive infrared cameras and sophisticated computers to detect, analyze and produce high-resolution diagnostic images of these temperature and vascular changes







## HOWEVER

- American Society of Breast Surgeons (ASBrS) conducted a study with results presented at their annual meeting in Phoenix in May
- The conclusion is—Thermography is not a reliable breast cancer screening tool

## REASON

- Too many benign biopsies are performed based on suspicious imaging abnormalities
- Women are seeking an alternative to radiation based imaging techniques