Introduction to DBT

The goal of mammographic imaging is:

- Detection.
- Characterization.
- Evaluation of findings suggestive of breast cancer and other breast diseases.

Digital Breast Tomosynthesis:
Alphabet Soup of Terminology

* Digital Breast Tomosynthesis (DBT).
* 3D Mammography .
* 3D Breast Tomosynthesis.
* 3D Tomosynthesis.
* Tomosynthesis.
* Breast Tomo.

Terminology for imaging techniques to demonstrate focal “slices” of tissue without superimposition.

1. Linear Tomography.
2. Poly Tomography.
3. Computed Tomography
4. Tomosynthesis.

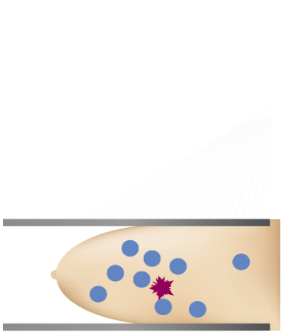
Difference between tomography and tomosynthesis is:

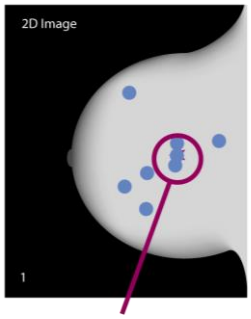
- **Tomography is imaging by sections or sectioning.**
- **Tomosynthesis is the creation of an image of part of the body <u>by digitally processing multiple x-rays.</u>**

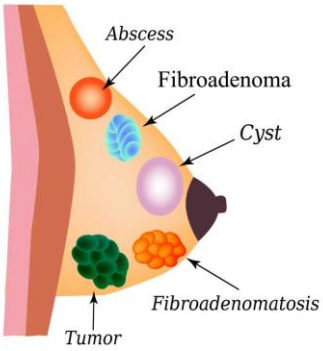
3DBT produces quasi–three-dimensional (3D) images of the breast.
The images are reconstructed in thin sections that allow reduction of anatomic noise or overlap of fibro glandular tissue.

In 2D FFDM:

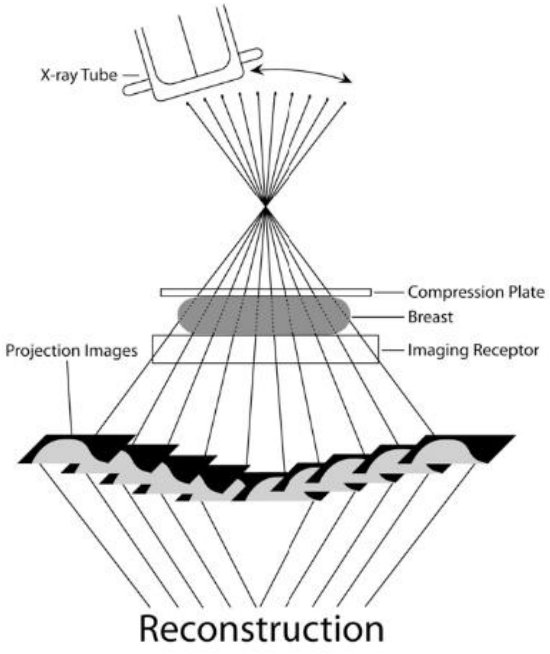
* Tissue superimposition hides pathologies in 2D.
* Tissue superimposition mimics pathologies in 2D.







- As experienced mammographers or interpreting physicians the biggest challenges in breast imaging are the absolute uniqueness of each person's breasts and their individual breast tissue.
- Traditional 2D mammography superimposes all the tissue of the breast (normal and abnormal) in one image.
- The **sole purpose of tomosynthesis** (image slices of the breast) is to **counter superimposition of tissues** by eliminating "structural noise" and creating multiple focused image layers at different depths, blurring the tissue layers above and below the focal plane of interest to better demonstrate tissue and architectural structure of the breast.



Mammography Screening Requirements for the United States

Systems must be capable of:

- Imaging the whole breast.
- Image all types of breasts.
- Image all lesion types, masses, calcifications, distortion.
- Fast and reasonable cost.
- Low radiation dose.

Knowledge of the evolution of mammographic imaging can enhance your understanding of technology and why it evolved.
You must understand your past to know your future.

Evolution of X-ray Mammography

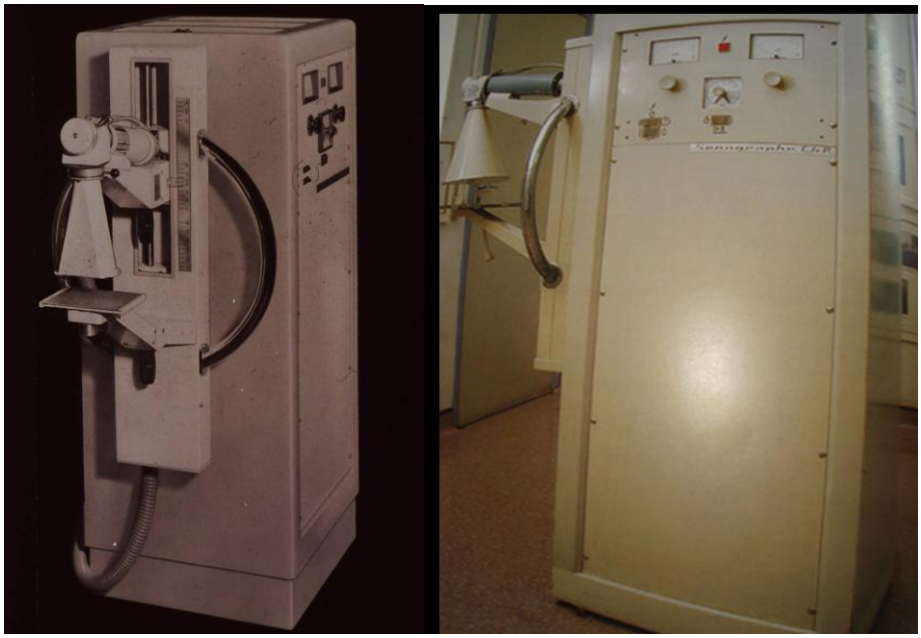
- 1950: Direct exposed film with conventional units.
- 1969: 1st dedicated unit with Mo target.
- 1971: Xeroradiography.
- 1972: DuPont Lo-Dose Film/Screen system.
- 1976: Kodak Min-R film, DuPont LoDose.
- 1977: Magnification: Pfizer Microfocus tube.
- 1978: Dedicated Mammo grid.
- 1991: Rhodium Targets and Filters.
- 2000: Full Field Digital Mammography.
- 2011: Tomosynthesis.

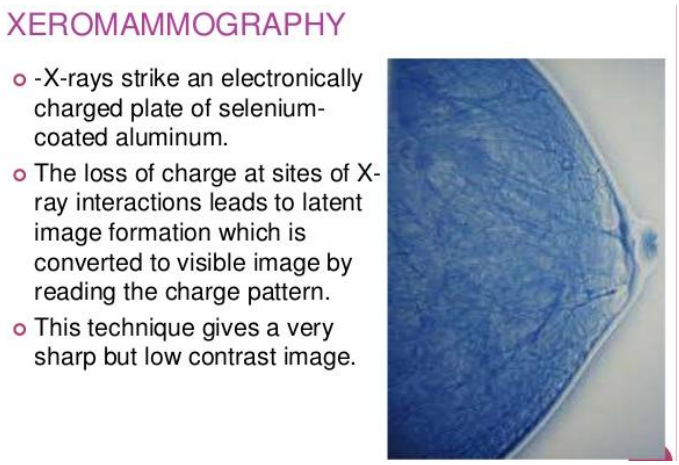
Radiographic projections and technical factors for performing mammography were developed by Egan and taught to radiologists throughout the United States during the1960s. Teaching aids were often used to reduce patient dose however grids were not used until 1978.

In the picture you see a patient positioned using a traditional x-ray machine:

- Tungsten target x-ray tube.
- Short SID.
- No grid.
- Industrial film (no screen cardboard).
- Developed in a darkroom using "hand tanks" and a time and temperature film development process.

Until the mid-1960s, mammography was performed with general-purpose radiographic equipment. The inability of this equipment to produce finely detailed, high-contrast images led to development of the first prototype of **dedicated mammography unit by Charles Gros**. This in turn became the CGR mammography system. **1st CGR Dedicated Mammographic Unit**





Xerography replaced by film mammography processed in darkroom automatic film processor.

Digital Tomosynthesis First Reported in 2005

Until 02/11/2011, all mammography images were captured in 2D mode.
3D breast Tomosynthesis is a series of thin-resolution images acquired and aggregated to generate a 3D image of the breast. Allows the radiologist to scroll through sub-millimeter cross-sections, effectively eliminating the tissue superimposition problem.

Mammography Imaging Screening Trials: (DMIST)

Most significant clinical trial and the largest study of digital mammography to date:

- Organized by American College of Radiology Imaging Network (ACRIN) October 2001.
- Funding provided by National Cancer Institute.
- Goal of DMIST study:
  - To evaluate the diagnostic accuracy of digital mammography vs film/screen in asymptomatic women presenting for screening mammograms.
- Results published in New England Journal of Medicine in October 2005.

DMIST Results:

- Full-Field Digital Mammography (FFDM) is a better imaging tool when compared to film/screen mammography (FSM) in certain subsets of women:
    - Women under the age of 50.
    - Women with very dense glandular breast tissue.
    - Women who are pre-menopausal.

Tomosynthesis Mammographic Imaging Screening Trial (TMIST)

TMIST: Should Tomosynthesis replace digital mammography for breast cancer screening?

- Collecting results of mammograms from:
    - 100 sites.
    - 165,000 planned participants from US and Canada.
    - Asymptomatic participants between the age 45-74.
    - No personal history of breast.
    - No breast implants or pregnant/lactating.

TMIST:

- 1st randomized breast cancer screening trial comparing 2D to 3D mammography and their ability to discover advanced breast cancers in the screening population.
- Question: Is the newer technology reducing a woman's risk of developing a life threatening (advanced) cancer compared with 2D mammography?
- Advanced or aggressive cancers are defined as:
    - All invasive cancers over 2.0cm in size.
    - All invasive tumors that are over 1cm in size which have prognostic markers suggest aggressive behavior (triple negative or her2 positive breast cancers).
    - All tumors that have positive nodes or metastases at the time of diagnosis TMIST.
- Statistically the majority of women in the study **will not** develop breast cancer.

* If a woman receives a cancer diagnoses of any type while participating in the study, she will receive all traditional treatment as she would if she were not part of the TMIST and but will continue to be followed as part of the trial.
* More information about this important trial or if you are interested in participating visit the National Cancer Institute website and search for the TMIST Clinical Trials.
* This study will collect data on any medical follow-ups and breast cancer status until at least 2027, with results in 2028.
* As of January 15, 2025, the trial has achieved the enrollment goal of more than 108,000 women across the world. It has become one of the most racially diverse populations of any NCI trial.

Limitations of Conventional 2D Digital Mammography

* The complexity of interpreting mammography is the overlaying layers of structures and breast tissue.
* Complicated by cancer and glandular tissue both appearing radiographically dense on images.
* In an effort to increase consistency in reporting a classification system for breast tissue density was developed by the American College of Radiology (ACR).

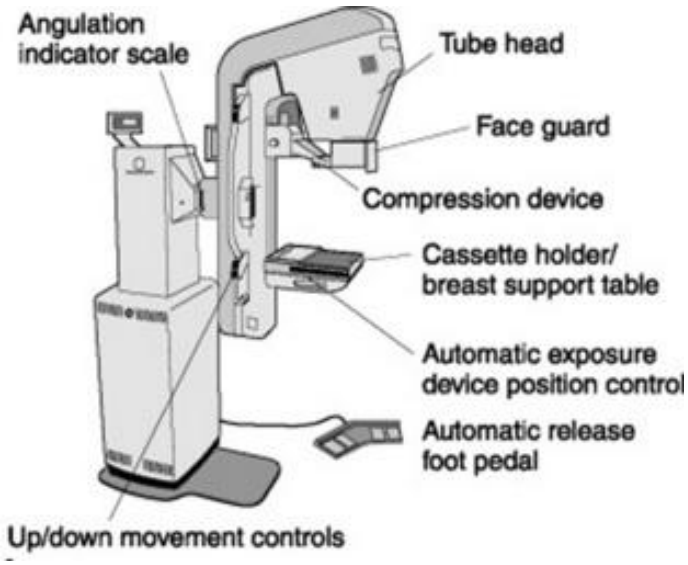
Compression in traditional mammography

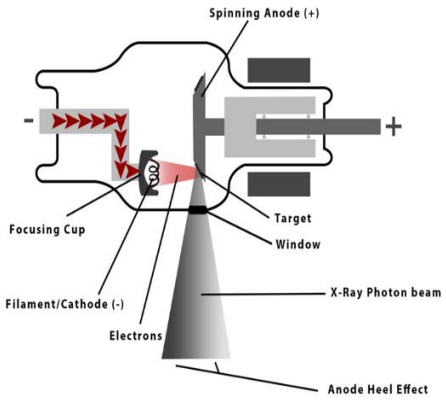
* Primary purpose is to minimize tissue superimposition.
    * Reduces:
        * Scatter.
        * breast dose.
        * motion artifact.
        * Increases amount of tissue in field of view.

Fundamentals of Digital Imaging Acquisition

Analog film system replaced by digital x-ray

It would take days to demonstrate the equipment variances both physically and in the software.





Let us look at a basic FFDM unit and discuss the major components and their role in image production.

* X-ray Tube and target Material
* FFDM
* AEC
* Foot Pedals
* Up and Down Controls
* Magnification
* Mammographer Workstation
* Face Guard
* Compression
* Old Software
* New software
* Ancillary Equipment

Analog film system replaced by digital x-ray

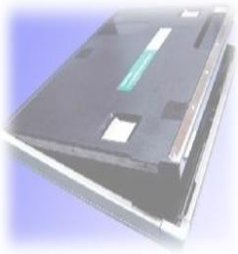
ANALOG MAMMOGRAPHY

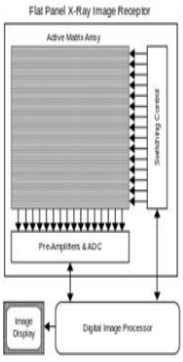
DIGITAL MAMMOGRAPHY

Film Receptor

VS.

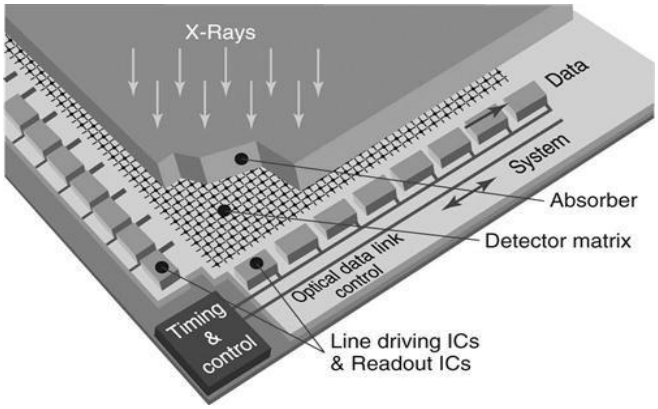
Flat Panel Digital Receptor



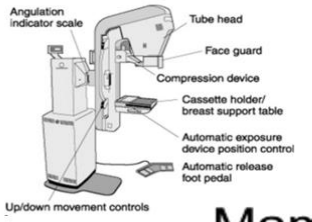


FFDM

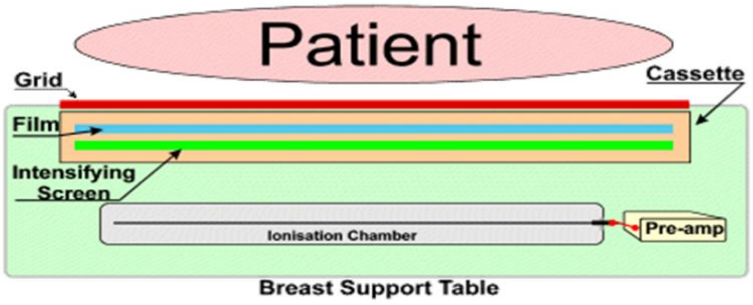
Digital Mammography



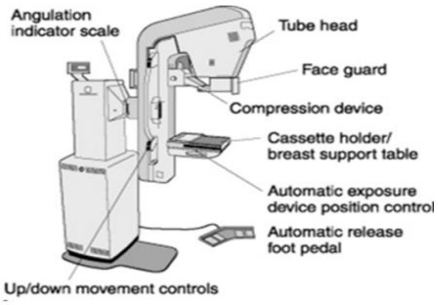
AEC



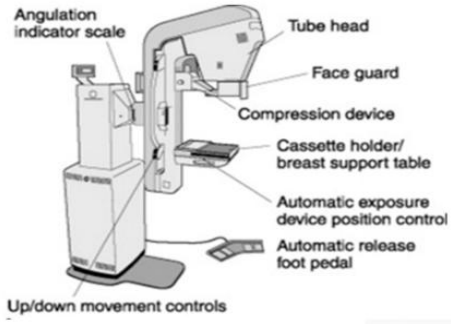
Mammography AEC Chamber



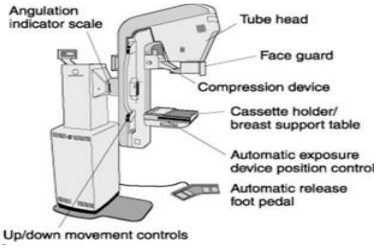
Foot Pedals

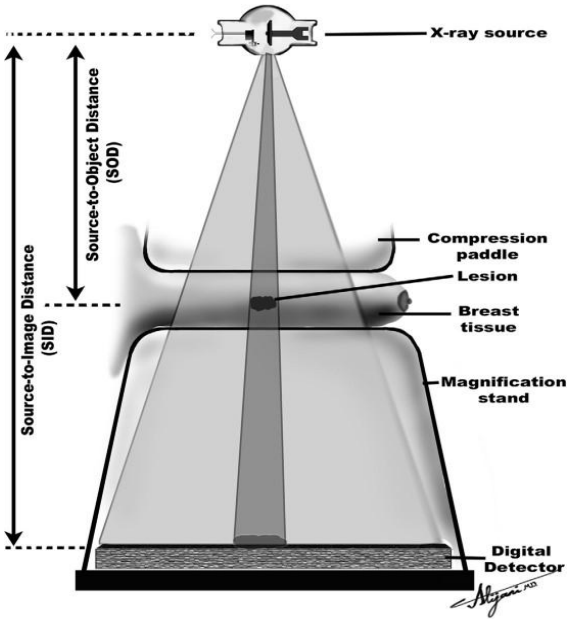


Up and Down Controls

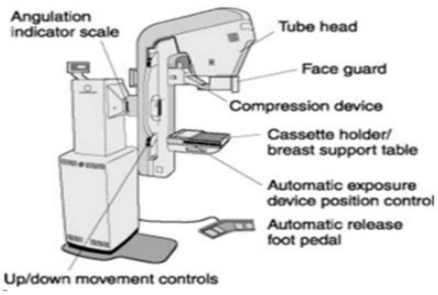


Magnification



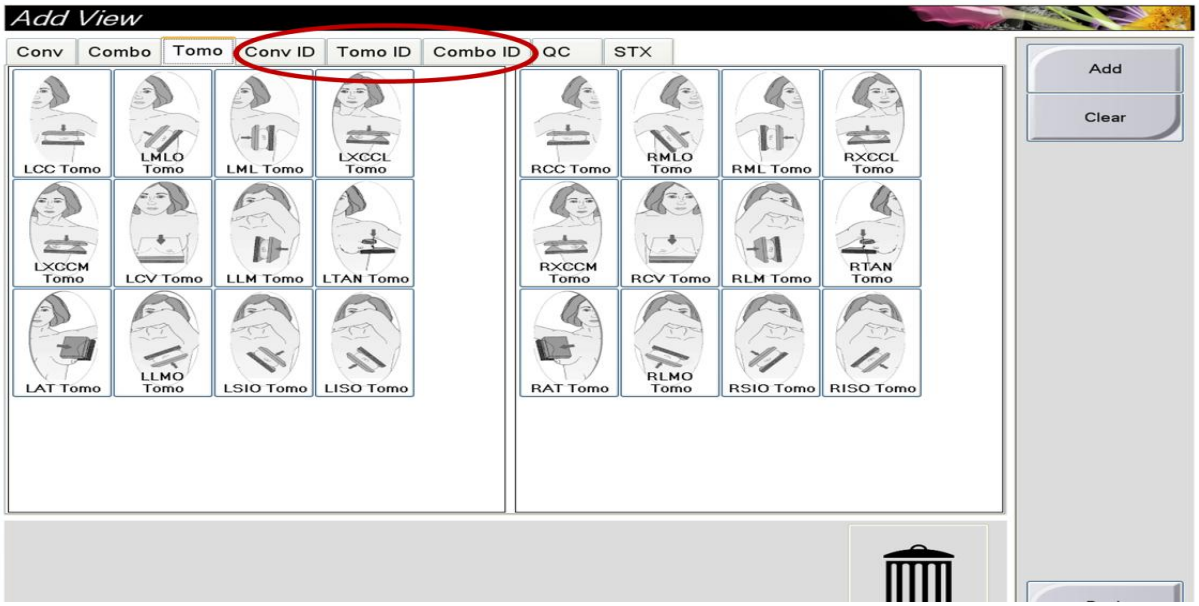


Face Guard

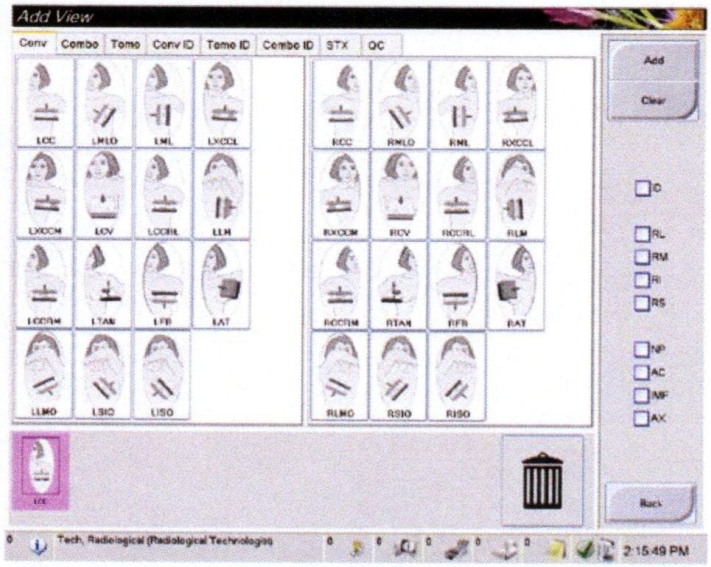


Compression

Old Software



New software



View Modifiers

ID = Implant Displaced
RL = Rolled Lateral
RM = Rolled Medial
RI = Rolled Inferior
RS = Rolled Superior
NP = Nipple in Profile
AC = Anterior Compression
IMF = Infra-Mammary Fold
AX = Axillary Tissue

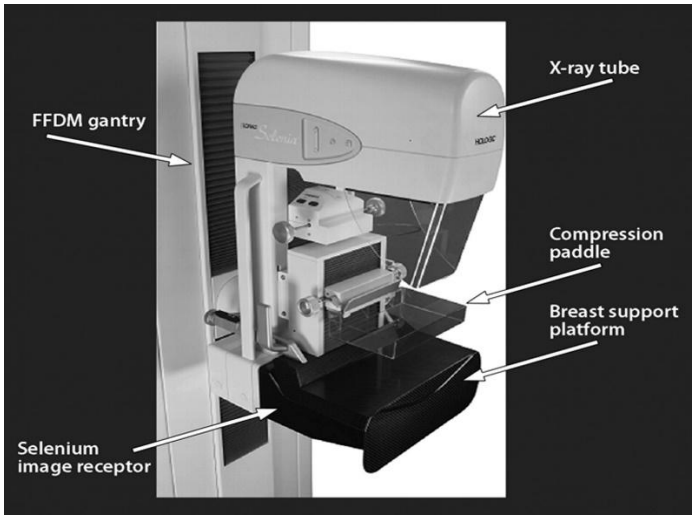
Figure 24: The Add View Screen

2D Digital Mammography: The Gold Standard

- 2D FFDM it appears to be slightly more sensitive than digital breast tomosynthesis for the detection of calcifications.
- Diagnostic performance as measured by area under the curve using BI-RADS was not significantly different.
- Improvements in processing algorithms and display, digital breast tomosynthesis could potentially be improved for this purpose.

2D FFDM:

- Tissue superimposition hides pathologies in 2D.
- Tissue superimposition mimics pathologies in 2D.



2D Mammography Challenges/Limitations

Imaging Challenge

- Overlapping tissue hides or mimics breast disease leading to false positive results

Impact

- As many as 20% of breast cancers will be missed by mammography[1]

In the U.S. ~10% of women are recalled for additional diagnostic work-up

- A significant portion prove to have no abnormality, resulting in unnecessary anxiety and cost[1]

How are digital images created?

- In a digital image the most important number is the total output of X-ray photons.
- The number of photons is divided among the pixels.
- Each pixel must have enough photons to separate out a range of gray scale.

The advantage of digital information is that each location and nature of each digital level are known and can be adjusted. Each Pixel in an image matrix contains only ONE unique type of information.

Processing

Using Algorithms to change image

Signal processing improves quality of an image in general:

- Window/level adjustment provides the ability to look at a specific region of interest by selecting the data that corresponds to the region of interest and excluding data that does not.
- Unsharp masking enables us to see fine structures using a low pass filter.
- Noise suppression distinguishes low contrast lesion from the background breast tissue.
- Intensity equalization visualizes skin and subcutaneous structures clearly.

Digital Radiography Quality Characteristics

Like all medical images, digital radiographs have the five specific quality characteristics:

- Spatial Resolution.
- Contrast Resolution.
- Noise (signal).
- Detail.
- Artifacts.
-

Digital Images

- Digital images in x-ray are a numeric representation of x-ray intensities that are transmitted through the patient.
- They are viewed on a computer monitor and are known as 'soft-copies'.
- Each digital image is two-dimensional (just like screen-film) and is formed by a matrix of picture elements called pixels.
- Pixel: represents one extremely small portion of the original information
- Matrix: made up of many pixels.
- Digital processing involves algorithms which are systematic application of highly complex mathematical formulas. Algorithms are applied by the computer to every dataset before the tech sees the image.

Digital medical imaging process

- The collection of data concerning the interaction of some form of radiation with tissue.
- The transformation of these data into an image (or a set of images) using specific computational tools.

#1: Brightness

- The intensity of light that represents the individual pixels in the image on the monitor.
- The controlling factor of brightness is the processing software through the application of predetermined digital processing algorithms.
- Density cannot be altered post-processing in film imaging, but the brightness can be adjusted in the digital image after exposure.

#2: Contrast

- The difference between light and dark areas of an image.
- Similar to film imaging in that contrast is the difference in density of adjacent areas on the film.
- **Contrast resolution**: imaging system's ability to distinguish between similar tissues.
- Controlling factors: pixels and bit depth, pixel sizes and scatter radiation control.

#3: Resolution

- The recorded sharpness or detail of structures on the image (same as film imaging).
- Resolution in digital relies on the same factors in film imaging (focal spot size, geometric factors and motion) but also acquisition pixel size. Resolution size is measured in microns v. line pairs. Current acceptable range for digital is 100-200 microns.
- Other than pixel size, another controlling factor for resolution is the display matrix. Perception of the image is dependent on the display capabilities.

#4: Distortion

- Again, this definition is the same as in film imaging: The misrepresentation of object size or shape as projected onto radiographic recording media.
- Factors that affect distortion also remain the same: SID, OID and CR alignment.

#5: Exposure Index

- Numeric value that is representative of the exposure the image receptor received. Also known as the S value, S number or sensitivity number.
- Exposure index is reliant on the intensity of the radiation striking the detector.
- It is a calculated value from the effect of mAs, kV, total detector area irradiated, and objects exposed.

#6: Noise

- Random disturbance that obscures or reduces clarity. This translates into a grainy or mottled appearance of the radiographic image.
- SNR: signal-to-noise ratio: the describing of noise in the digital image. High SNR is desirable, low is not. The number of x-ray photons that strike the detector can be considered the "signal" and other factors like scatter can be classified as "noise".

Image DATA reflects characteristics:

- Frequency.
- Contrast.
- Noise.

Matrix Characteristics

Each pixel is assigned a numeric value that represents a shade of gray based on the attenuation characteristics of the volume of tissue imaged.

X-ray Attenuation Spatial Frequencies

- low frequency = contrast.
- high frequency = detail.
- The most abrupt change occurs at an edge. Images of edges contain the highest spatial frequencies.

Algorithms – use of pixel data

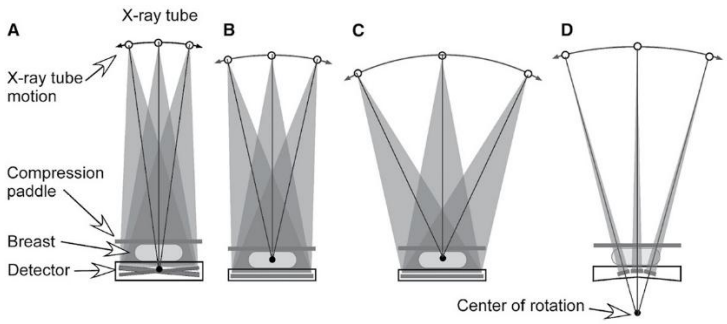
Image Digitization

- To convert captured analog images into numeric data for processing by the computer.
- 3 steps
    - Sampling.

- Quantization.
- Image construction.

Creating a CBT (Voxel) image from stacked matrix slices

- Voxel processing is a means of visualizing 3-dimensional shapes and structures implied by a series of cross-sectional images.
- Each image or *slice* in each dataset is made up of several picture elements or pixels.

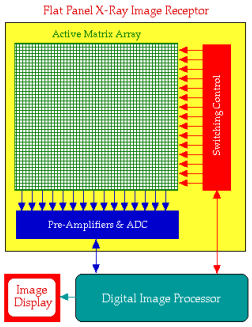


Raw data is reconstructed at 1mm intervals through the breast tissue.
Viewed as a series of high-resolution slices.

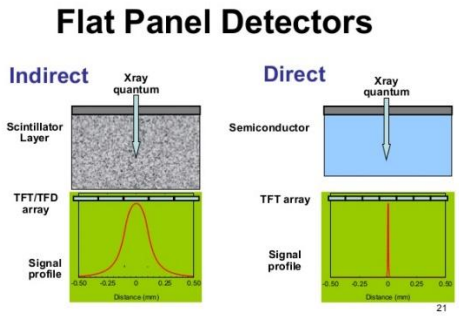
The underlying secret of flat plate technology is a large area integrated circuit called an active-matrix liquid crystal display array.

An intensifying screen or a photoconductor coupled to such an active-matrix array forms the basis of flat panel X-ray image receptors.

Each detector of the matrix is connected to a row line for driving voltages and to a column line for readout via an active switching element, which may be either a thin-film diode or a thin-film transistor.



Signal profile reflects scintillation vs. direct capture; less resolution with broader signal profile.



Two Types of Flat Panel Detectors – Direct & Indirect

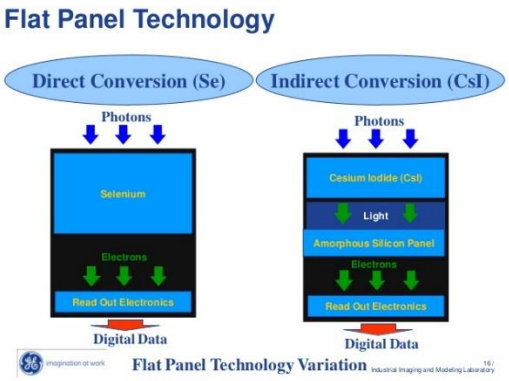
Scintillation - Indirect
Cesium iodide receptor is used in FFDM as well as amorphous selenium.

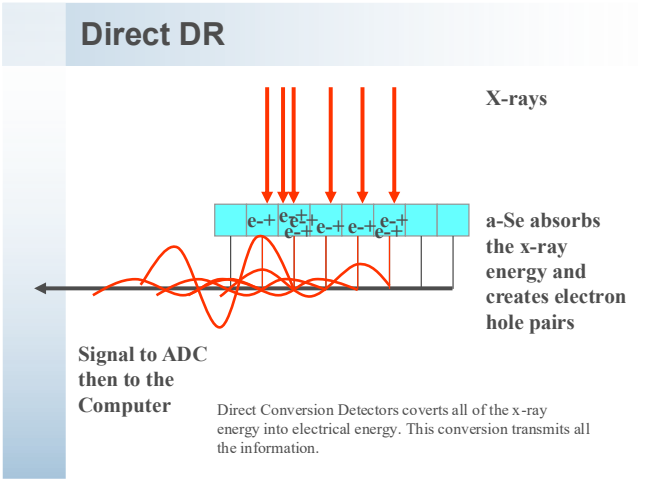
Signal to ADC and then to the Computer.
***Not used in tomosynthesis**

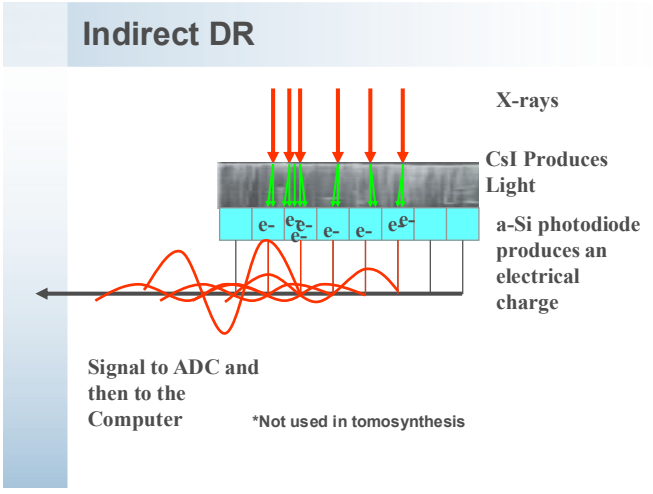
No Scintillation- Direct
*Amorphous selenium receptor is the only receptor used for tomosynthesis.

Direct Conversion Detectors coverts all of the x-ray energy into electrical energy. This conversion transmits all the information.

- Direct Digital flat-panel detectors (FPD) used in x-ray breast imaging [full field digital mammography (FFDM) or digital breast tomosynthesis (DBT)] utilize semiconductor-based sensors, which directly convert incident x-ray photons into charge pulses.
- Indirect scintillator-based sensors which, first, absorb x-rays and then re-radiate the energy in a form of optical light, which is subsequently collected by photodiodes'.







Digital Breast Tomosynthesis vs. 2D Planar Image

Planar: Best demonstrates calcifications.
Tomosynthesis: Best demonstrates tumors, lesions, and overlapping tissues.

Standard acquisition parameters common to both full-field digital mammography (FFDM) and 3DBT are:

- Combinations of x-ray tube voltage.
- Current exposure time.
- Anode target and filter combinations.

Image acquisition parameters specific to 3DBT are:

- Tube motion.
- Sweep angle.
- Number of projections acquired.

Tomosynthesis Theory

- **The Evolution of Tomography**
  - Prior to digital era we had conventional linear tomography which was used for various body parts.
  - X-ray rooms were fitted with a tomographic attachment for the production of radiographs called tomograms.
  - Computed Tomography originated from development in two fields, X-ray imaging and computer technology.
  - CT first performed in 1973 at Mayo Clinic.
  - Magnetic Resonance Imaging (MRI) was introduced in 1980.
  - PET/CT was introduced in 2000 and combines information from a PET scan and a CT scan in a single device.

Rationale for using 2D + 3D

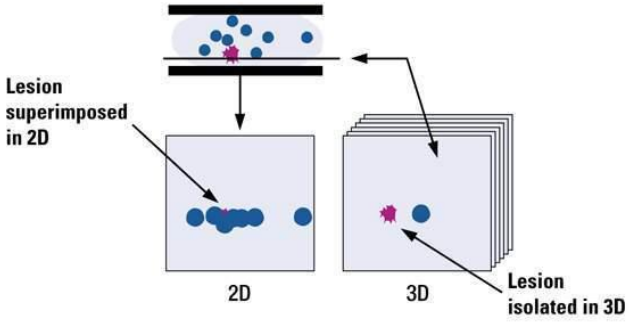
- Comparison of current images with prior images is standard mammography practice and critical to perceive subtle changes which may be associated with a cancer.
- Obtaining a 2D exam along with the 3D exam will allow direct comparison of current 2D images with prior 2D images.

Potential Benefits and Why We Need 3D Imaging

- Reduce recall rate of patients by reducing confusion which arises from tissue overlap.
- Biopsy rate decreased as there is improvement in separation and visualization of parenchymal structures.
- Updated software has a possible increase in cancer detection particularly in patients with dense breast tissue.
- Fewer images required for diagnosis equals a reduction in dose.
- Compression is a must at this time. NO changes yet but in future may be possible.

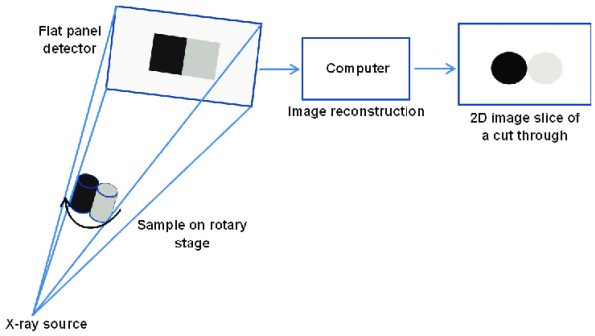
The Solution is 3D Breast Tomosynthesis

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



3D Image Quality and Depth Resolution Directly Depend On:

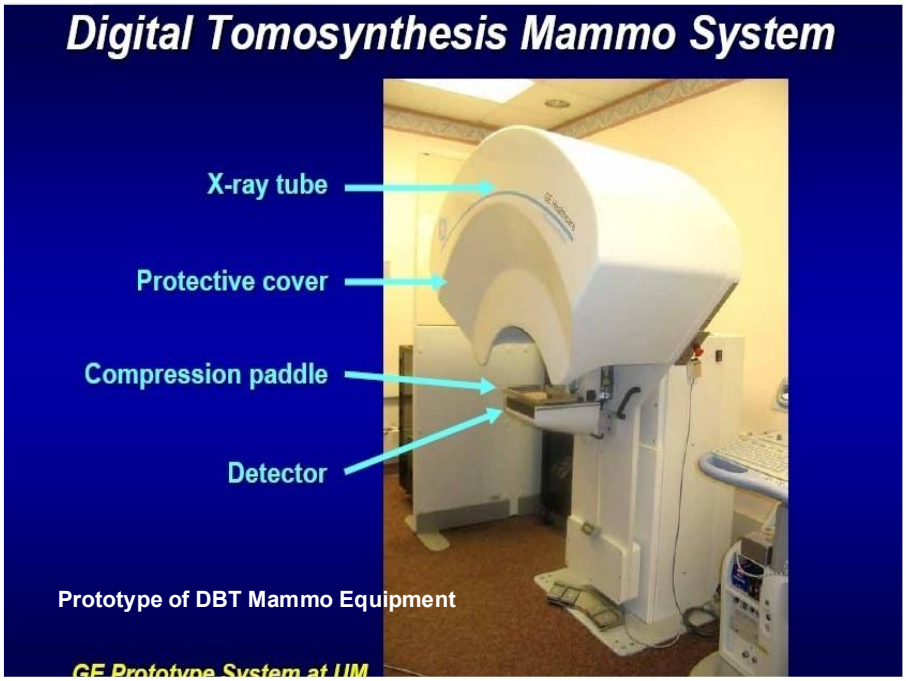
- Number of projection images.
- Angle of degree.
- Reconstruction algorithm software.

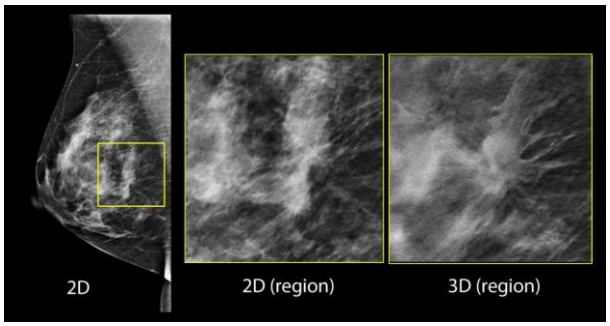


Tomosynthesis

- **Benefits for Radiologist**
  - Able to view the entire breast at once or view a series of thin, high-resolution slices typically 1-mm thick.
  - Can be displayed individually or in a dynamic cine mode.
  - Eliminates challenges of overlapping structures within the breast.
  - Better visualization of suspicious lesions allows Radiologist to characterize the lesion on the screening study often eliminating the need for additional imaging such as spot compression views.
  - Increases Radiologist confidence.

Digital Tomosynthesis Theory and Technology

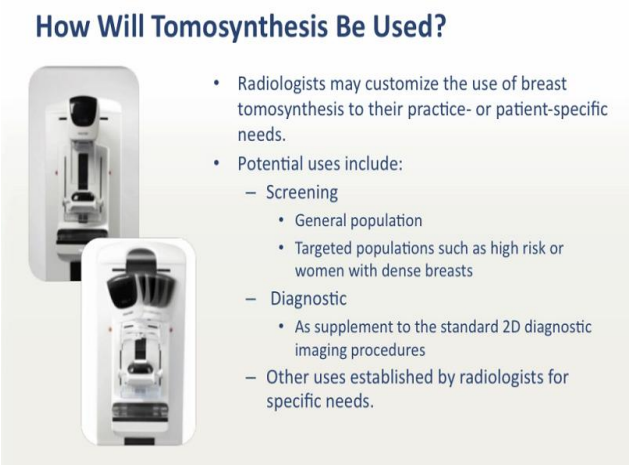




The sole purpose of mammographic tomosynthesis is to counter the difficulty in reading a 2D mammogram with tissues superimposed.

Slice views (tomosynthesis) eliminates a great deal of superimposition and thus the reader can better appreciate masses, tumors, and architectural distortions of the breast in specific unique planes.

DBT in Clinical Practice



DBT Imaging Modes

- **Four Imaging Modes**
  - Conventional Full-field digital mammography (2D) only.
  - Breast Tomosynthesis (3D only).
  - Combo mode.

        - Allows acquisition of a traditional 2D and 3D tomosynthesis scan in the same compression.
        - System first performs a 3D scan and then the x-ray tube returns to the perpendicular position and acquires a 2D image and results in a co-registered 2D and 3D images.
    - 3D plus C-View includes acquisition of 3D tomosynthesis images and synthesized 2D image.

Tomosynthesis

- **What is Tomosynthesis:**
    - A 3-dimensional method of imaging that can reduce or eliminate the tissue overlap effect present in conventional 2D mammography.
- **Who:** Hologic Breast Tomosynthesis System (DBT)
- **When:** Approved by FDA as a new breast imaging modality in February of 2011.
- **Where:** Massachusetts General Hospital was the 1st site in US to perform mammographic screening using a Hologic DBT system.
- **How:** 3D mammography captures multiple, low dose images from different angles around the breast for each projection vs 2D screening mammography which use a single X-ray image of the breast for each projection.
- **Result**: The images captured from side to side (sagittal) and top to bottom (cranial caudal) are used to produce 3D reconstruction of the breast.

3D 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 Compared to Ultrasound

- Tomosynthesis like ultrasound has a superior performance in dense breasts relative to mammography.
- Tomosynthesis improves sensitivity without increasing recall rate.
- More research needed to identify respective roles of tomosynthesis and ultrasound particularly in screening dense breasts.

Tomosynthesis Theory

Differences Between CT and DBT

- CT scanning permits structures be imaged in multiple slices form the front to back (coronal), side to side (sagittal) and from top to bottom (cranial caudal) views. **DBT can only image from side to side and top to bottom.**
- CT scan images are acquired in a full 360-degree rotation a detector/X-ray source around the patient. **DBT the rotation of the detector source is limited (15 degrees for Hologic) and (50 degrees for Siemens).**
- CT captures more images, and the radiation dose is higher**. DBT uses an arc like linear motion because most of the breast structures are oriented from chest wall to the nipple.**

DBT System Requirements

- Same basic components of digital mammography.
  - Direct or indirect capture full field digital detector.
  - Breast support device and compression paddle.
  - X-ray tube mounted on an arm.
- Hardware that transforms a system to a DBT is the ability of the X-ray tube to rotate around the detector and having a detector with relatively fast readout.

DBT Design Requirements:

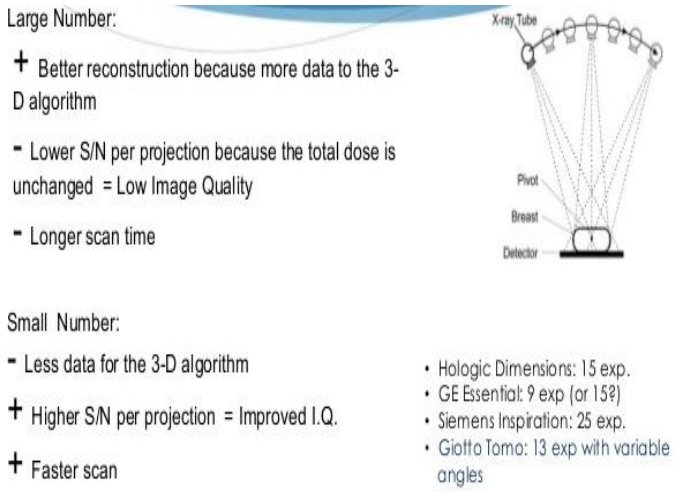
- Works well for screening and diagnostic imaging.
- System supports conventional 2D imaging and tomosynthesis.
- Improves clinical performance over digital mammography alone.
- Provide fast scan times to reduce patient motion.
- Can acquire tomosynthesis images in all orientations (CC, MLO, LM, etc.).
- Provides rapid reconstruction to support quick screening through put
- Facilitates comparison of prior images.
- Supports tomosynthesis-guided interventions and biopsies.

- Keeps Radiologist interpretation times short enough to accommodate screening studies.

DBT System Requirements

- **Digital detectors for DBT**
  - Faster reading time to minimize total acquisition time of all projections.
  - Minimal ghosting and lag which produces artifacts.
  - Minimal reduction in detective quantum efficiency (DQE) at low exposures.

Pros & Cons Considering the Number of Projections:



Three imaging modes available:

- Conventional full field digital mammography (2D only)
- Tomosynthesis imaging (3D only)
- "Combo imaging"(2D plus 3D)
  - Conventional 2D image plus tomosynthesis scan acquired during same compression, resulting in co-registered 2D and 3D images and both datasets are available for review

Modes of Acquisition

- **DBT equipment characteristics vary by manufacturers**
  - Arc of angle.

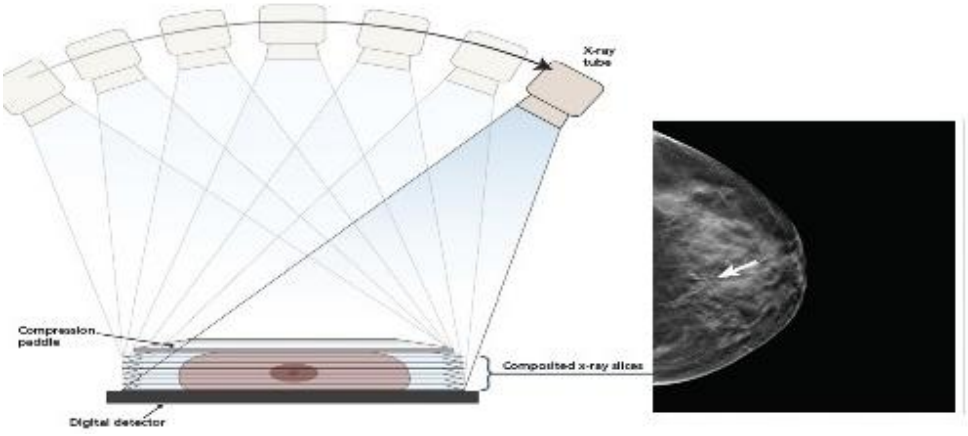
- Step and shut vs continuous motion of the tube.
- Target filter combinations.
- How their AEC function.
- With and without scatter grids.
- Number of projection images.
- Reconstruction algorithm.
- Scan times.
- Detector pixel size.

Arc Angle

Modes of Acquisition

- **What is Scan Angle? The total angular range covered by the x-ray tube.**
  - 0 angulation = a 2D mammography image.
  - 360-degree angle = would be similar to CT/MRI.
  - Function of the scan angle.
    - Directly related to depth resolution but must maintain an acceptable exam time.
    - Wider sweep angle better separate objects.
    - Narrow sweep angle makes lesion margins appear sharper.

ARC of travel, the greater the degree of tube travel the "thinner" each slice is.

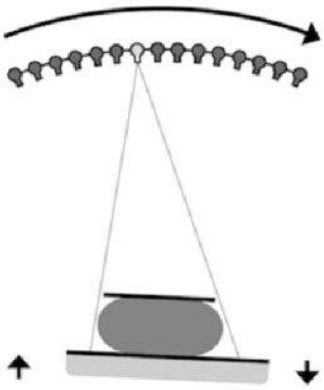


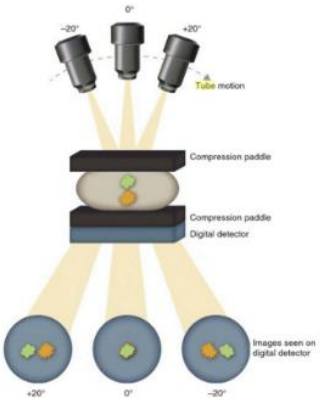
Angular Range

Larger angular range gives increased reconstructed slice separation.

Smaller angular ranges keep more structures in focus in a given slice.

- It might be desired for resolving closely lying structures but could impair the appreciation of a cluster of microcalcifications because the individual calcifications would appear in different slices or the appearance of spiculations lying in more than one narrow plane.





Modes of Acquisition

- Individual Images are projections and vary by manufacturer based on arc angles.
- Projections are then reconstructed into tomosynthesis slices.
  - Hologic: 15 degrees = (7.5/-7.5).
    - 15 projections/4 sec scan time = app. 60 reconstructed tomo slices.
  - Siemens Inspiration with DBT 50 degree = (+25/-25).
    - 25 projections/2 sec scan time = 25 projections.
    - Lots of reconstructed images!

Take Away for Angle Acquisition

- **Benefit:**

- Wider angle/more exposures will allow reconstruction with less artifacts and increased reconstructed slice separation.
- Narrow angle allows rapid exposure with a lower dose.

- **Disadvantage:**
  - Wide angle.
    - more prone to motion because of longer scan times/ time it takes to complete procedure in a screening setting.
    - increased Dose.
    - May cause interference with edge of the compression paddle.
  - Narrow angle.
    - Less depth resolution.
- Slab/Slabbing.
- Can increase the thickness of a projection slice thickness for better inspection of microcaclification groups.
- Sometime requested by the Radiologist to view segmental and clustered calcifications which are present in multiple slices.
- Increase from 1mm slice to a 10mm slab.

Performing the Acquisition

* The breast is compressed in a standard way.
* While holding the breast stationary, the x-ray tube is rotated over a limited angular range.
* A series of low dose exposures are made every degree, creating a series of digital images.

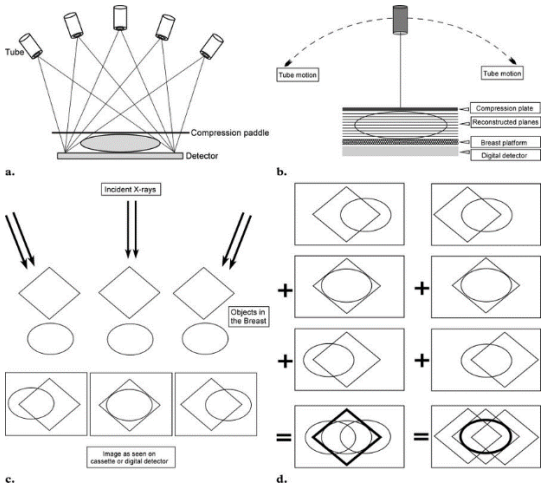
Acquisition Mode for Tube Motion

- **Continuous Motion**
  - X-ray tube fires in very short (50 milliseconds or less) pulses to avoid focal spot motion to avoid focal spot motion) tube is in motion when making the exposure.

- Hologic scan time is less than 4 seconds.
- Siemens is 25 seconds.

- **Step and Shoot Method**
  - X-ray tube pauses, makes an exposure, and then moves to the next area before making another exposure so the tube is stationary for the exposure.
    - GE scan time is 7 seconds.

Step and Shoot Mode



Use of Grids in DBT

- GE SenoClaire is the 1st DBT system to use an antiscatter grid that works for both 2D and 3D.
- Hologic and Siemens use a retractable grid for the tomo images.
- To obtain a 2D and 3D exam in the same breast compression you must have an automatic retraction grid.
- Permits the system to rapidly and automatically switch between 2D and 3D imaging modes.

Projection Image

- Must have projection image to create slices.

- Reconstruction images are born of projection image.
- Projection image is checked for motion by technologist.
- Slices are from detector to paddle in all views.
- Example
  - CC-foot to head.
  - MLO-lateral to medial.

1mm slices: Number of slices dependent upon compressed breast thickness that are reconstructed from projection images.

5cm compressed breast

- 50 1mm slices + 5.
- Always adds 5 to clear the paddle.

Projections are the Basis of the "Displayed Slices".

- While stabilizing the breast, images are acquired at a number of different x-ray source angles.

➢ Objects at different heights in the breast display differently in all projections.

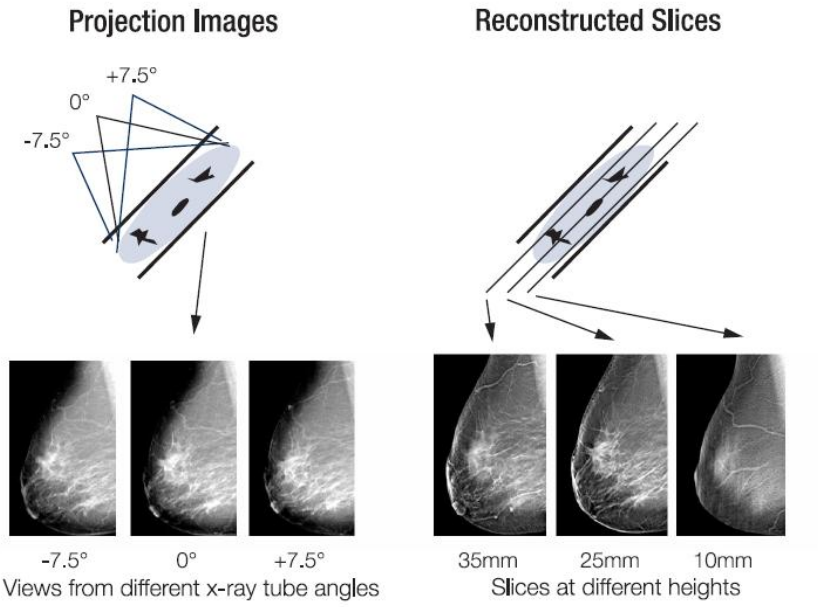
Image Reconstruction

- Another difference between manufacturers!
- Most common image reconstruction methods used in 3D mammography are computer algorithms:
  - **Filtered Back Projection (FBP)**
    - Hologic and Siemens.
    - Computer algorithms reconstruct a volume rapidly with excellent image quality.
  - **Iterative Reconstruction (IR)**
    - GE Senographe Pristina (adaptive statistical iterative reconstruction ASIR).
    - Siemens (enhanced multiple parameter IR).

Sole Purpose: Remove Structured Noise (Superimposed Tissue)

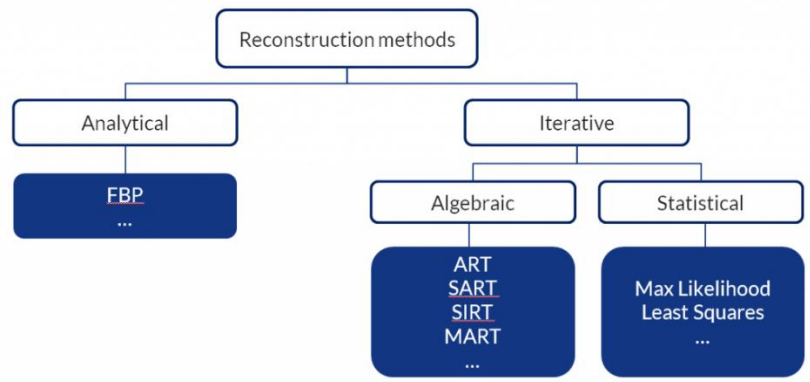
1. Tomosynthesis does not provide direct projection images, but reconstructed images of individual layers through several available algorithms, aimed to remove from the reconstructed slice the upper and lower layers "structured noise".
2. Reconstruction computer algorithms are used to provide this function.

Image Reconstruction



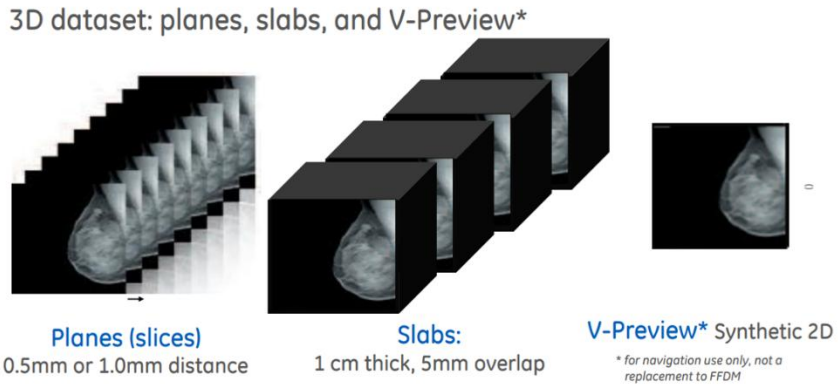
t image shows three of the 15 projection images acquired through the breast at different angles. Right image shows three of the 1-mm cross-sectional reconstructed slices

Reconstruction of Tomographic Image Slices

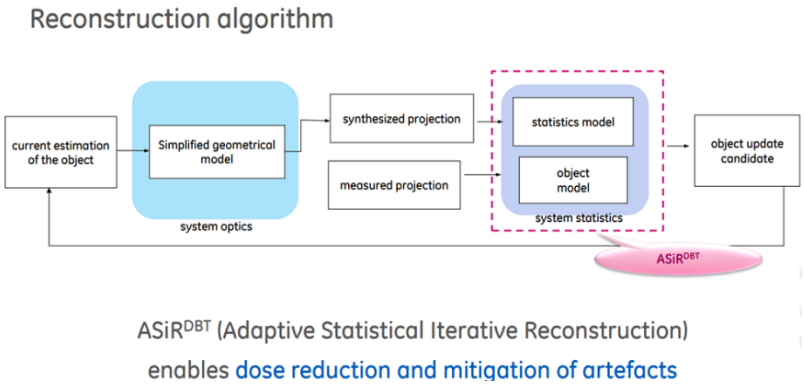


Originally too slow but with improved computer speed/power used in lieu of FBP as time for reconstruction is now comparable.

Iterative Reconstruction Used for 2D and 3D Reconstruction.



Iterative reconstruction instead of filtered back projection used in tomographic scanning image reconstruction.



The final step in the tomosynthesis process is reconstructing the data to generate images that enhance objects from a given height by appropriate shifting of the projections relative to one another.

Typical Study Time

	Time
Tomosynthesis only	
Time from start of exposure until decompression	29s
Time from start of exposure until next exposure is possible	80s
Time from decompression until reconstructed image displayed	80s
Combination mode (Tomosynthesis plus 2D)	
Time from start of exposure until decompression	41s
Time from start of exposure until next exposure is possible	88s

In Figure 1, two objects (a spiculated lesion and ellipse) superimpose when the x-rays are at 0º, but the off-axis acquisitions shift the objects' shadows relative to one another in the images.

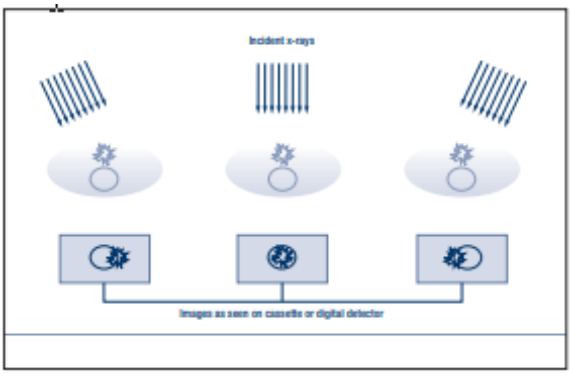
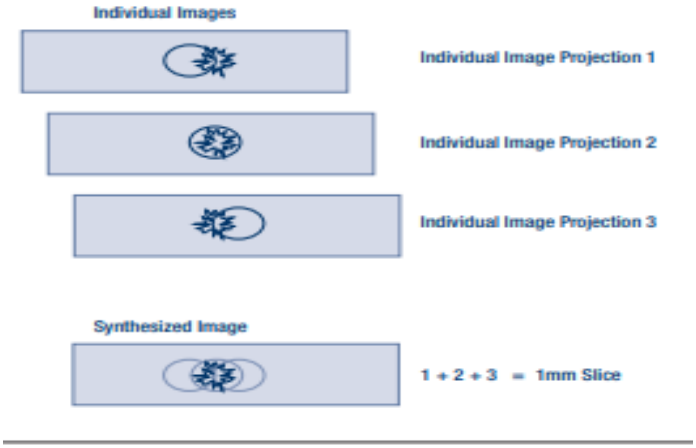
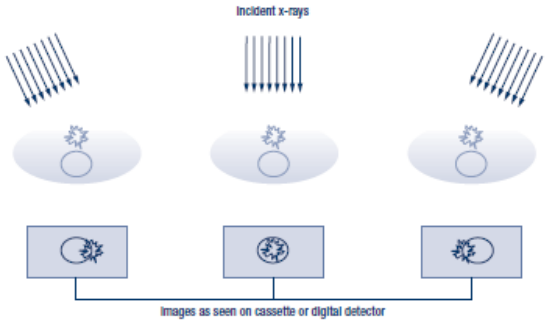


Figure 2 where we reconstruct a cross sectional slice at one specific height. In this example, the images are summed, shifting one relative to another in a specific way that reinforces the spiculated lesion object and reduces the contrast of the ellipsoidal object by blurring it out.



3D Tomosynthesis

Two objects (a spiculated lesion and ellipse) superimpose when the x-rays are at 0º, but the off-axis acquisitions shift the objects' shadows relative to one another in the images.

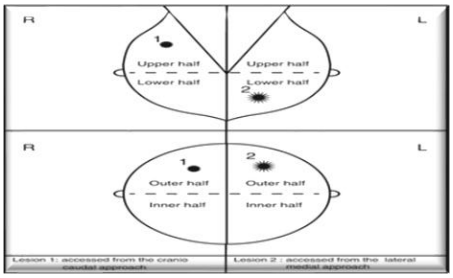


Two objects (a spiculated lesion and ellipse) superimpose when the x-rays are at 0º, but the off-axis acquisitions shift the objects' shadows relative to one another in the images.

Objects at different heights in the breast display differently in the different projections.

Co-Registration

The positioning and compression are exactly the same on the 2D and 3D which allows the radiologist to view the 2D image and the tomosynthesis slices with perfect co-registration on top of each other or side by side.



Benefits of Co-registration for 2D & 3D Breast Images for Radiologist

- Facilitates comparison to priors and images from other facilities.
- Single compression allows co-registration of 2D and 3D images..

For Administration:

- Reimbursement is available for 2D image and 2D CAD, allowing the facility to continue to generate revenue while offering latest technology and now there is a 3D Tomosynthesis code.
- Patient throughput is not impacted.

For Technologists:

- 2D and 3D scan acquired with a single positioning/view.
- Workflow is same as FFDM; no learning curve.

For Patients:

- The clinical trials proved a reduction in recall rates.
- Reduced recalls can lead to reduced anxiety & reduced inconvenience.
- No noticeable difference in breast screening experience.

Display for Radiologist Viewing

- Like CT reconstructed slices, images can be viewed one at a time or display as cine loop.
- 2D images can also be viewed 2D and 3D acquired in the same compression are completely co-registered.

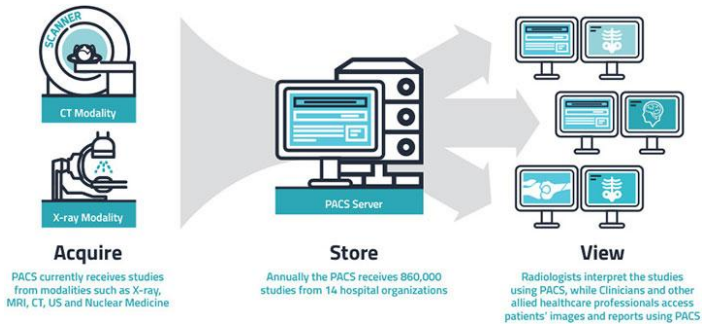
Radiologist Read Time

Equated to going from film screen to digital.

Now digital 2D to 3D-same learning curve, about 1- 2 years to get use to what abnormalities can look like in 3D imaging.

CAD is applied to 2D images and then compares to slices what was marked on the 2D CAD.

PACS



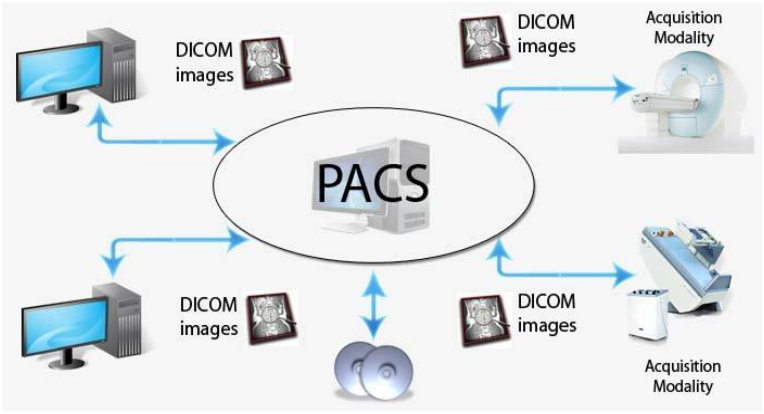
A PACS consists of four major components:

1. The imaging modalities.
2. A secured network for the transmission of patient information.
3. Workstations for interpreting and reviewing images.
4. Archives for the storage and retrieval of images and reports.

DICOM – PACS

The universal format for PACS image storage and transfer is DICOM (Digital Imaging and Communications in Medicine).

PACS



- Combined with available and emerging web technology, PACS can deliver timely and efficient access to images, interpretations, and related data.
- PACS breaks down the physical and time barriers associated with traditional film-based image retrieval, distribution, and display.

Introduction to Motion Unsharpness

- Most common patient-related artifact.
- Motion: local/regional or involves the entire breast.
- Gross or Subtle.
- Repeats for motion increase radiation dose.
- Potential to miss breast cancer.

Factors contributing to Motion Unsharpness

- Inadequate Compression.
- Poor Positioning.
- Exposure Time.
- Patient Movement.

Heart Motion Tomosynthesis (3D) Motion Unsharpness

- Occurs at about the same frequency as conventional mammography 2D.
- Presents the same issues as 2D motion, EXCEPT that motion may go undetected.

2D Mammography

- Acquisition time is brief.
- Captures a moment in time.
- One image.
- Technologists/Radiologists adept at detecting motion.
- Repeats are left up to the Technologist.

3D Tomosynthesis

- Longer acquisition time.
- Multiple image data set..
- Images acquired over a period of time.

3D motion occurs at about the same rate as 2D.

3D Motion may be unrealized and unchecked.

Appreciating 3D Motion

Tomosynthesis and Motion

- Radiologists do not routinely review the projection dataset where motion can be confirmed or ruled-out.
- Projection dataset may not be available to the radiologist.
- It is up to the technologist to detect motion and repeat when advised.

Important notes:

- We do not yet fully understand the full impact of 3D motion on image quality and when repeat is necessary.
- Motion can occur at one-point, multiple points or through-out the duration of the entire projection series.
- Motion can occur at different areas of the breast, which may or may not impact breast tissue.
- May affect conspicuity, sharpness of detail.

Projection Series

- The x-ray tube moves in a path parallel to the chest wall.
- The resulting breast image(s) and objects should move smoothly along this same pathway.
    - Medial to Lateral /Lateral to Medial.
- Anterior/posterior movement of the breast images or objects indicates motion.

Reviewing Projection Images for Motion

- **Review the Projections**
    - Cine Mode.
    - Moderate to fast speed.

- **Chest wall**
    - Movement of the Pectoral Muscle.
    - Structures that shift in and out of view.

- **Inframammary fold**
    - Abdomen motion.
    - Determine if it impacts the inferior and posterior breast.
- **Calcification**
    - Should move in a straight line parallel to the chest wall.
    - More evident with large chunky calcifications.
- **Axilla**
    - Lymph Nodes shift back and forth or out of view.

Engage Patient in Technique

- Inform the patient of the new 3D/2D technology.
- Describe the c-arm movement.
- As typical for standard mammography, explain that motion can affect the image.
- Instruct the patient in the breathing technique.
    - Explain that STOP BREATHING means just that.
    - Patient SHOULD NOT take in a breath & hold it.

Breathing Technique: The Steps

- Compress exposure controls.
- While the x-ray tube is moving into position to start the tomosynthesis:
- Instruct patient to STOP breathing for the 3D acquisition at the conclusion of the tomosynthesis sweep.
- Instruct patient to breathe.
- As the tube moves to center, listen for the completion of the grid movement.
- Then instruct the patient to stop breathing for the 2D acquisition.

Motion Repeats

- Motion can be difficult to see sometimes, looks for landmarks in the breast to check for blurred lines or incorrect movement of landmark.
- Can be a big issue especially when evaluating calcifications.

C-View 2D Synthetic Image

- **What is C-View 2D Synthetic Image**
  - A software module approved by the FDA in 2013 (Hologics C-View 2D) which when added to the DBT system allows reconstruction of a 2D mammographic image from the acquired tomosynthesis data.
  - Eliminates the need for standard mammographic views in addition to the tomosynthesis data.
  - Allows for C-View images to be used in place of conventional 2D exposure which was part of the initial screening exam protocol for Hologic.

- **Benefits of Using C-View 2D Synthetic Images**
  - C-View makes lower dose mammography possible, the patient can receive both the CC and MLO screening views in 3D mode with no added dose.
  - Less time under compression for the patient.
  - Greater patient comfort.

2025 DBT Equipment Key Players

- Hologic
- GE Healthcare
- Siemens
- Fuji
- Internazionale Medico Scientifica

Potential Benefits:

FFDM vs Tomosynthesis

- Reduce recall rate of patients by reducing confusion which arises from tissue overlap.
- Biopsy rate decreased as there is improvement in separation and visualization of parenchyma structures.
- Time will possibly show improvement in cancer detection particularly in patients with dense breast tissue.
- Fewer images required for diagnosis=reduction in dose.
- Tomosynthesis is a three-dimensional mammographic examination that can minimize the effects of structure overlap within the breast.

2D Imaging vs. 3D Imaging on Most of the Tomosynthesis Machines

2D

- Either molybdenum or tungsten x-ray tube.
- 20 to 39 kVp.
- Moly or rhodium or silver filters.
- 100 mA.
- Grids.

3D

- Tungsten x-ray tube.
- 20 to 49 kVp.
- Aluminum filter.
- 200 mA.
- No grid.

No GRID-when the tube is off axis you would see grid lines.

Indications for Use

Hologic Selenia Dimension DBT System

- Acquires and generates mammographic images that can be used for screening and diagnosis of breast cancer.
- The Selenia Dimensions (2D or 3D) is used in the same clinical applications as a 2D mammography system for screening mammograms. The system can generate 2D digital mammograms and 3D mammograms and may be used for additional diagnostic workups of the breast.

- Screening Exam may consist of:
  - 2D FFDM image set or
  - 2D and 3D image set.
  - 2D image can be either FFDM or a 2D image generated from the 3D image set.

System Components

- Automatically positioned AEC based on pre-exposure sample shot; technologist can override the automatic positioning of the AEC cells.
- Technologist acquisition workstation with a touch screen for display of workflow and administrative tasks.
  - System logs using fingerprint recognition or password using the keyboard.
  - Trackball and rotating wheel for scrolling.
  - Barcode scanner to select patient from the list.
- 3 MP greyscale monitor for display.
- Powered by 220/240 single phase supply, generator is integrated into the gantry.
- Tungsten target with a small (.1) and large (.3) focal spot.
- Filters
  - Rhodium and silver for two-dimensional imaging.
  - Aluminum for tomosynthesis.
- Source to image distance (SID) is 70 cm.
- Selenia uses amorphous selenium direct conversion technology.

Source Image Distance (SID)

Is it better to have a larger or smaller SID for mammography? Why?

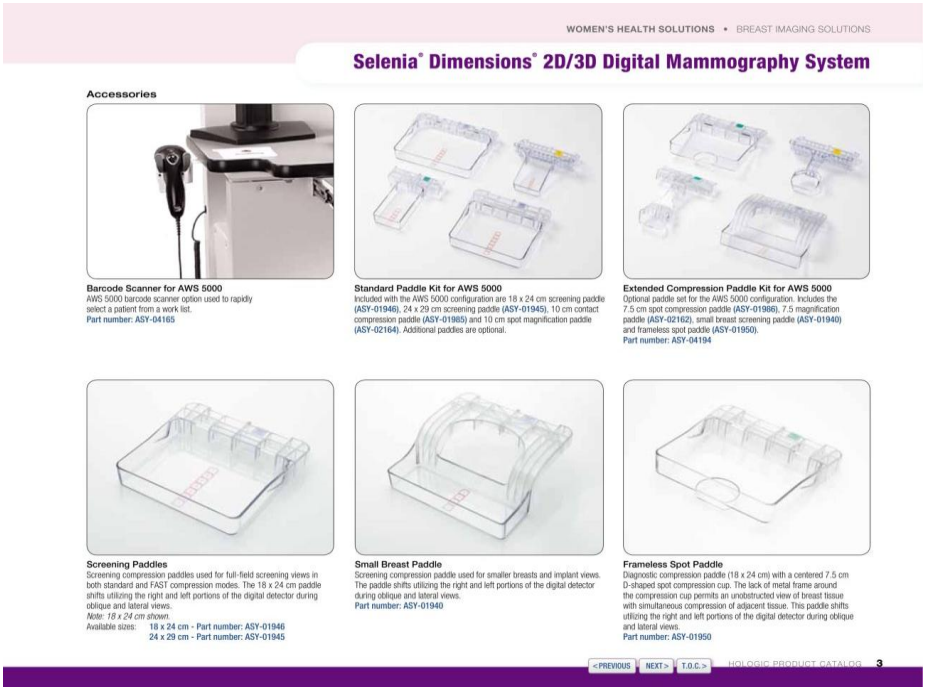
- Larger SID is better. You get less geometric blur for the same focal spot size with a larger SID.
- The tradeoff is that it takes more mAs to get the same exposure, so longer exposure time and more tube loading can result in motion.

- The larger SID reduces scatter radiation because it acts like an air gap and the lower energy photons escape so it doesn't reach the receptor.

The Unit

- Compression is the same for DBT.
- Tungsten tube-AL filter for tomo hardens the beam increases kVp for faster exposure time.
- 7cm below uses Rhodium/higher uses Ag.
- 3D-higher mA=shorter exposure.
- Patients need to hold their breath. Have them stop breathing. DO NOT have them take in a breath, this can pull tissue out of view.
- CPU button on back of console to turn unit on-do not touch power button.
- Can be programmed to turn on and off at set times in order to be warmed up when staff arrives-2 hours before start time-programmed during applications.
- Technologist monitor; 3 megapixel (Hologic Selenia is a 2 megapixel).
- Export QC to thumb drive to transfer to computer.
- Fingerprint log in or a manual log in Mag stand.
    - The way it attaches has been changed because on original unit technologists had a hard time getting it on- on original unit you must tilt it down not toward yourself, upgrade needed for new one.
    - Old one has clamps on handles you have to push on.
    - New one does not, it has two black buttons instead and it has audible and visual prompts for proper installation.
    - 1.8 top or 1.5 lower - mag factor choice.
- Has fast paddle (Fully Automated Self-Adjusting Tilt) not spring loaded.
- More like a flex paddle.
- No fast paddle for mags or locs.
- Paddles are icon driven.
- Compression does not register until 4 lbs.
- Paddle auto moves for MLO views you can override if you only want to move a little bit.

- If you use fast paddle on patients must use for QC.
- Paddles clamp on.
- Paddles are color coded.
    - Purple-screen.
    - Green-diagnostic.
    - Gold-magnification.
    - Red-localization.
- Has modifier so you can add:
    - Anterior compression.
    - Nipple profile.
    - etc…



WOMEN'S HEALTH SOLUTIONS • BREAST IMAGING SOLUTIONS

Selenia® Dimensions® 2D/3D Digital Mammography System

Accessories

Barcode Scanner for AWS 5000
AWS 5000 barcode scanner option used to rapidly select a patient from a work list.
Part number: ASY-04165

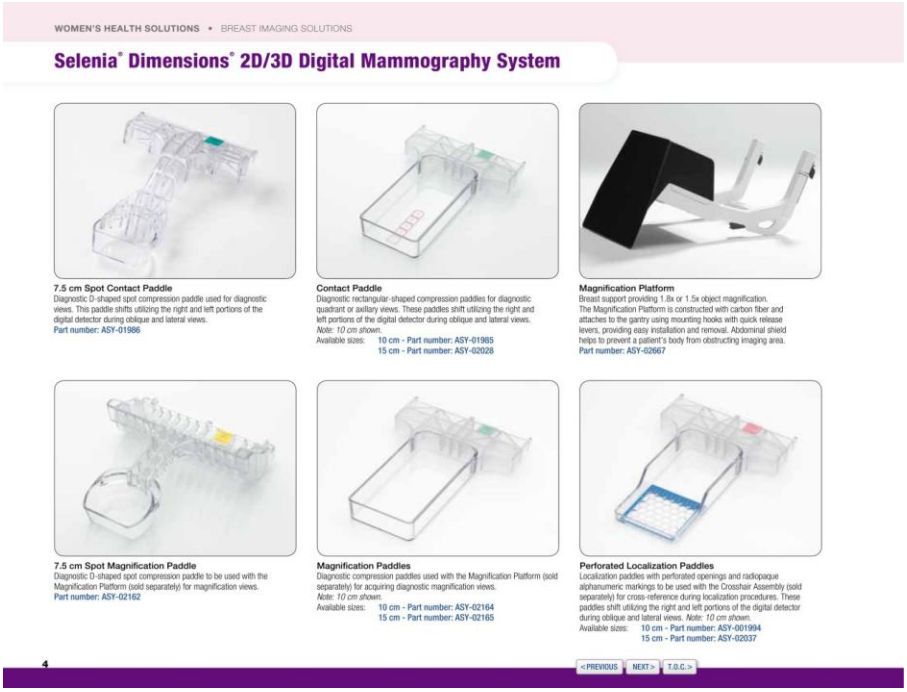
Standard Paddle Kit for AWS 5000
Included with the AWS 5000 configuration are 18 x 24 cm screening paddle (ASY-01946), 24 x 29 cm screening paddle (ASY-01945), 10 cm contact compression paddle (ASY-01985) and 10 cm spot magnification paddle (ASY-02164). Additional paddles are optional.

Extended Compression Paddle Kit for AWS 5000
Optional paddle set for the AWS 5000 configuration. Includes the 7.5 cm spot compression paddle (ASY-01986), 7.5 magnification paddle (ASY-02162), small breast screening paddle (ASY-01940) and frameless spot paddle (ASY-01950).
Part number: ASY-04194

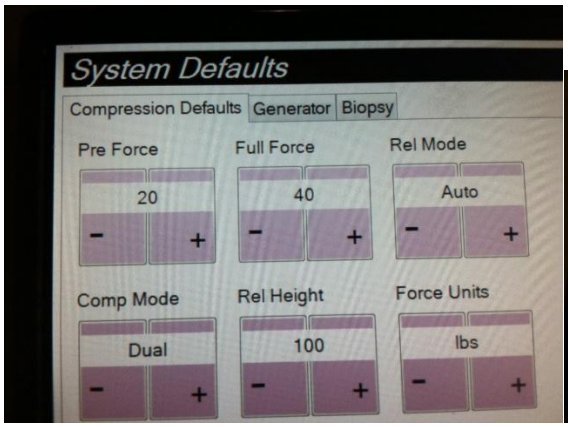
Screening Paddles
Screening compression paddles used for full-field screening views in both standard and FAST compression modes. The 18 x 24 cm paddle shifts utilizing the right and left portions of the digital detector during oblique and lateral views.
Note: 18 x 24 cm shown.
Available sizes: 18 x 24 cm - Part number: ASY-01946
24 x 29 cm - Part number: ASY-01945

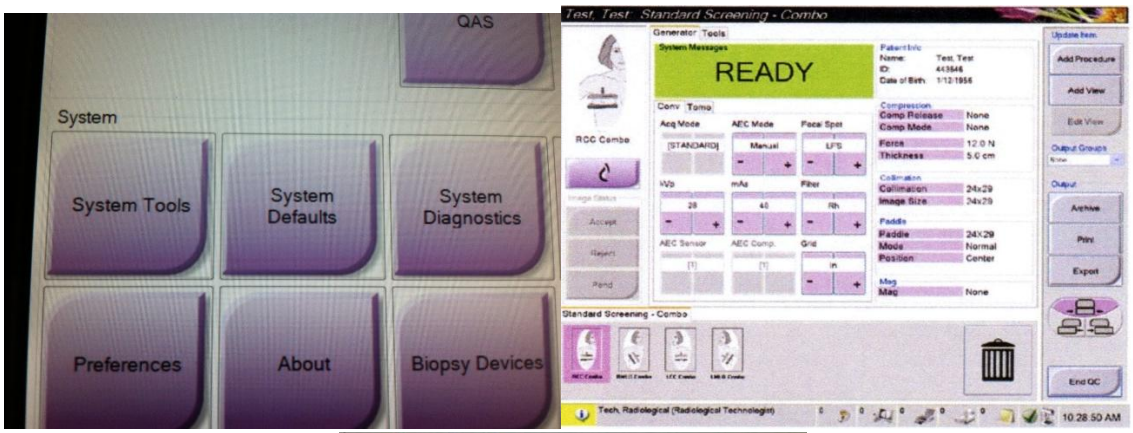
Small Breast Paddle
Screening compression paddle used for smaller breasts and implant views. The paddle shifts utilizing the right and left portions of the digital detector during oblique and lateral views.
Part number: ASY-01940

Frameless Spot Paddle
Diagnostic compression paddle (18 x 24 cm) with a centered 7.5 cm D-shaped spot compression cup. The lack of metal frame around the compression cup permits an unobstructed view of breast tissue with simultaneous compression of adjacent tissue. This paddle shifts utilizing the right and left portions of the digital detector during oblique and lateral views.
Part number: ASY-01950



Compression paddle manual mode





Setting the Exposure Parameters

Image acquisition mode (tomosynthesis option)

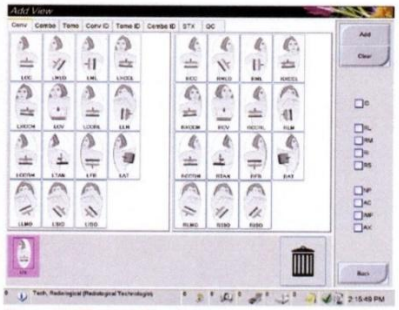
- Standard-for routine tomosynthesis screening procedures.
- Enhanced-for diagnostic tomosynthesis views. This mode increases patient dose.

Enhanced Exposure Parameters

- Allows the technologist to acquire a diagnostic tomo view with significantly improved image quality to allow for better visualization and characterization of abnormalities.

The Enhanced Mode Might Be Used for Instance:

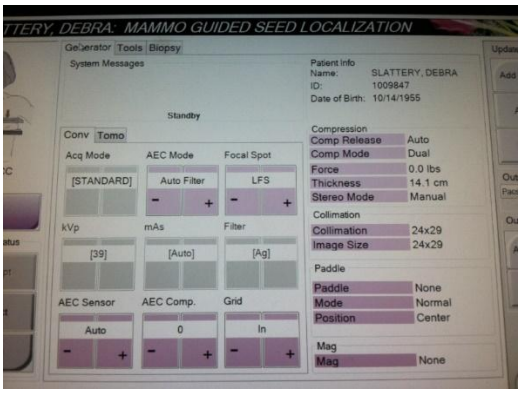
- If there is a faint calcification or small spiculated mass that is very difficult to see.
- If the image looks generally “noisy”, possibly due to very dense breast tissue.



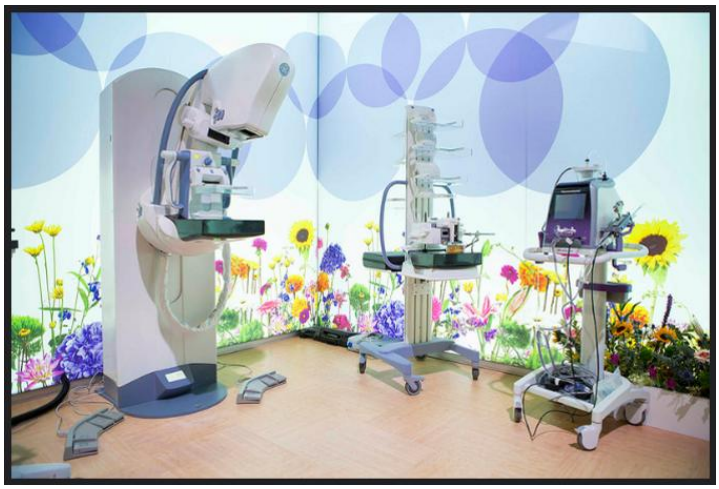
View Modifiers

ID = Implant Displaced
RL = Rolled Lateral
RM = Rolled Medial
RI = Rolled Inferior
RS = Rolled Superior
NP = Nipple in Profile
AC = Anterior Compression
IMF = Infra-Mammary Fold
AX = Axillary Tissue

Figure 24: The Add View Screen



GE Senographe Senoclaire 8/2014



Indications for Use

- GE SenoClaire DBT (2014) is an upgrade for Senographe Essential.
- System acquires 2D images and also acquires multiple projections views to produce 3D DBT images suitable for screening and diagnosis of breast

cancer. The SenoClaire option can be used for the same applications as traditional mammography for screening mammography.

- Screening Exam
  - 2D image set CC & MLO view
  - Or
  - 2D CC and 3D MLO image set.

In 2014, GE Healthcare's SenoClaire™ DBT device ("SenoClaire") was approved by the FDA with a screening protocol that consisted of 2D craniocaudal (CC) and 3D mediolateral oblique (MLO) views. Because both 2D and 3D images were still required, GE Healthcare sought extension of SenoClaire's approval to include 3D CC in the screening protocol.

SenoClaire (GE Breast Tomosynthesis)

SenoClaire Key Features

- 9 Projections
- Stop-and-shoot
- Sweep angle 25° (+/- 12.5)
- Sweep time <10 sec*
- Detector pixel size 100 um in 2D & 3D
- 2D/3D-grid for scatter reduction
- ASIR^{DBT} Iterative Reconstruction
- No dose increase (3D vs. 2D)
- BTO DICOM format (Breast Tomosynthesis Object)

Indications for Use

- **GE Senographe Pristina with DBT (2017)**

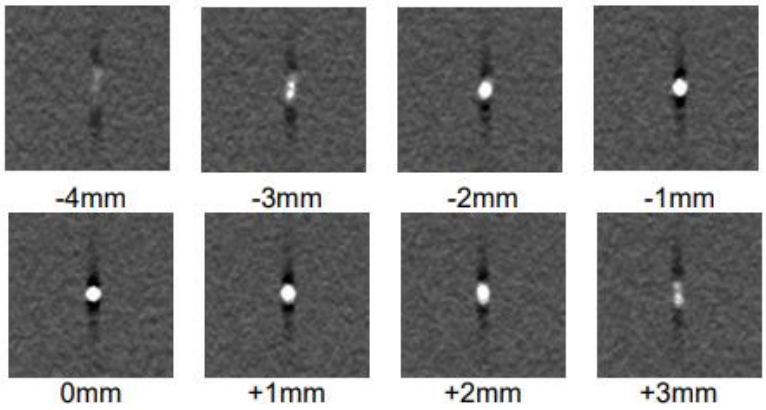
- Acquires multiple projections views to produce 3D digital mammo images suitable to be used in screening and diagnosis of breast cancer. Senographe Pristina 3D uses similar DBT technology as Senographe and has software and hardware upgrade potions that enables the acquistion of projection images of the breast in order to reconstruct tomosynthesis images.
    - Screening Exam
        - 2D image set CC & MLO view
        - Or
        - 2D CC and 3D MLO image set.
        - 3D system may be used for additional work-up.
- Senographe Pristina 3D uses similar DBT technology as SenoClaire and consists of a software and hardware upgrade option that enables the acquisition of projection images of the breast in order to reconstruct tomosynthesis images.

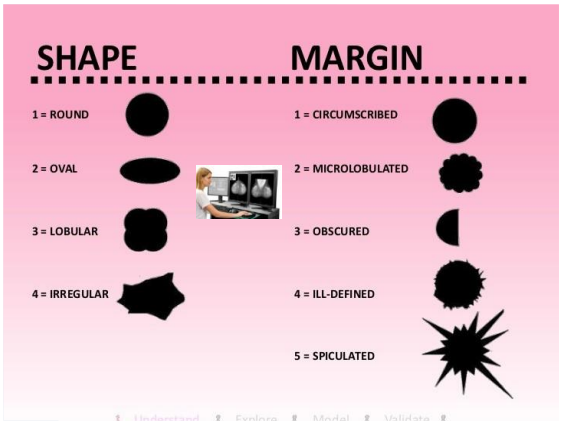
Approval for GE Senographe Pristina 3D Digital Breast Tomosynthesis system indicated for acquisition of multiple projection views to produce 3D digital mammography images suitable to be used in screening and diagnosis of breast cancer.

How Does GE Senoclaire/Pristina Tomosynthesis work?

- Tube moves in a 25 º arc.
- 9 low dose images are acquired.
    - 1 image at 2.8 degree.
- Images are reconstructed into .5 mm-1mm slices. Depends on set up.
- In combo-mode imaging, the 2D and 3D are taken in the same compression, with no additional positioning for the patient.

I mm slices – resolution at different levels.
Appearance of 1mm aluminum ball in reconstructed focal planes at 1mm intervals, from 4mm below to 3mm above the plane of best focus.

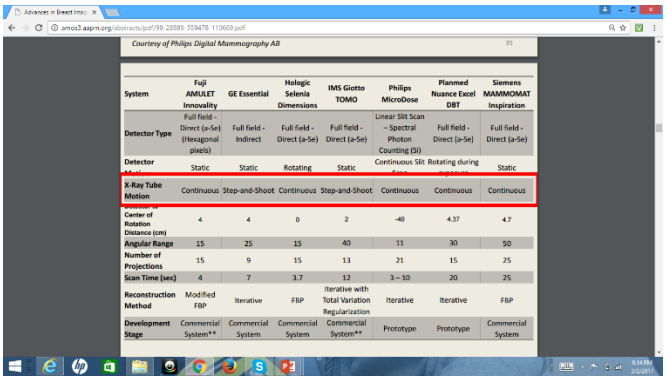




Rethinking Patient Comfort

Senographe Pristina helps ensure patients comfort during their mammogram

- The soft armrests have replaced the typical hand grips. So rather than tensing muscles to hold a hand grip, patients can rest their arm comfortably on the arm rest and relax their muscles, which can simplify compression and image acquisition.
- The gentle, rounded corners of the bucky may reduce anxiety, discomfort and even mammogram pain.

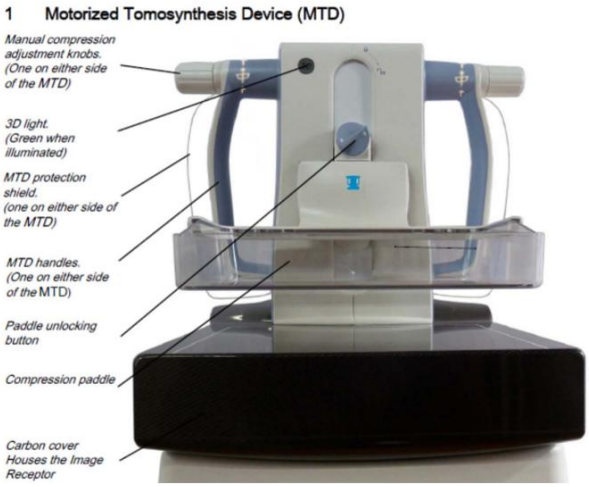


Courtesy of Philips Digital Mammography AB

System	Fuji AMULET Innovality	GE Essential	Hologic Selenia Dimensions	IMS Giotto TOMO	Philips MicroDose	Planmed Nuance Excel DBT	Siemens MAMMOMAT Inspiration
Detector Type	Full field - Direct (a-Se) (Hexagonal pixels)	Full field - Indirect	Full field - Direct (a-Se)	Full field - Direct (a-Se)	Linear Slit Scan – Spectral Photon Counting (Si)	Full field - Direct (a-Se)	Full field - Direct (a-Se)
Detector Motion	Static	Static	Rotating	Static	Continuous Slit	Rotating during	Static
X-Ray Tube Motion	Continuous	Step-and-Shoot	Continuous	Step-and-Shoot	Continuous	Continuous	Continuous
Distance of Center of Rotation Distance (cm)	4	4	0	2	-40	4.37	4.7
Angular Range	15	25	15	40	11	30	50
Number of Projections	15	9	15	13	21	15	25
Scan Time (sec)	4	7	3.7	12	3 – 10	20	25
Reconstruction Method	Modified FBP	Iterative	FBP	Iterative with Total Variation Regularization	Iterative	Iterative	FBP
Development Stage	Commercial System**	Commercial System	Commercial System	Commercial System**	Prototype	Prototype	Commercial System

Motorized Tomosynthesis Device

- **GE Essential and SenoClaire**
  - Traditional anti-scatter grid vs motorized tomosynthesis device (MTD).
  - GE MTD
    - Attaches to SenoClaire.
    - Weighs 26 pounds.
    - Stored on a cart that should be removed before installing on the unit.
    - Care must be taken not to damage components with attaching/detaching.



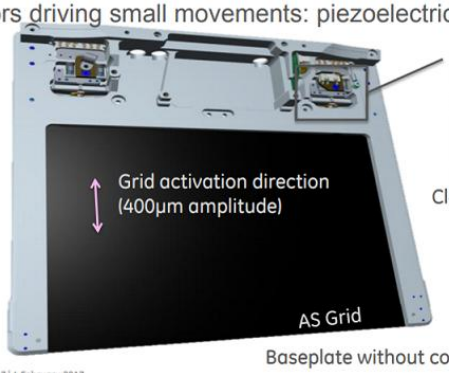
Scatter mgt: 2D/3D antiscatter grid (3/3)

Challenge: rotating the grid leaves very little space for the grid to move

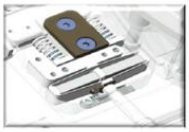
Solution:

- match the grid line frequency to the detector pitch
- compact, high precision actuators driving small movements: piezoelectric transducers

Motorized Tomosynthesis Device



Baseplate without covers



Close Up of Piezo Actuator

Imaging with the MTD

Traditional antiscatter grid - Essential
View of system positioned for a left MLO view

2D/3D antiscatter grid – SenoClaire's MTD
View of system positioned for a left MLO view

Installing the MTD

Siemens TRUE Tomosynthesis

With **True** 3D Breast Tomosynthesis, Siemens has opened a new chapter in mammography diagnostics. High spatial resolution and the largest acquisition angle allow for excellent resolution depth and superior reconstruction results. This leads to fewer artifacts and greater image detail, thereby improving diagnostic capabilities immensely.

Indications for Use

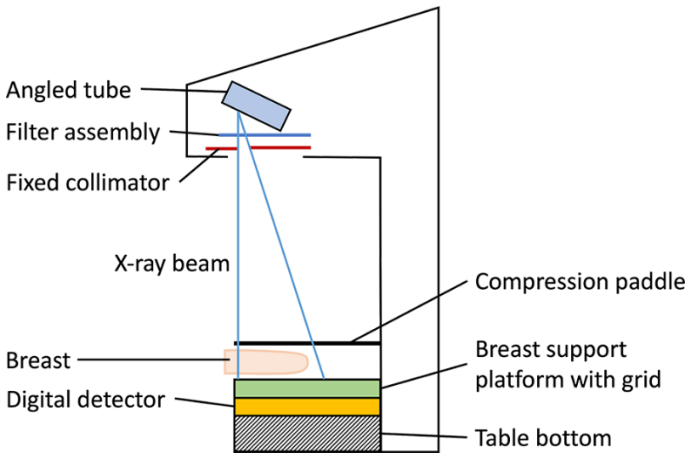
- **Siemens MAMMOMAT Inspiration DBT Option (2015)**
- Indicated for acquisition of 2D & 3D digital mammography images to be used in screening and diagnosis of breast cancer.
    - Screening Exam may consist of:
        - 2D image set

          Or

        - 2D and 3D image set.
        - The screening exam may consist of 2D FFDM images set with or without the 3Dimage set.

How Does Siemens Inspiration Tomosynthesis Work?

- Tube moves in a **50 º** arc.
- **25** low dose images are acquired.
    - 1 image at 2.0 degree.
- 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.



Scatter grids absorb a portion of the all-important primary radiation, a higher dose is needed to obtain images of desired quality.

The ability to minimize patient dose is important, as women are encouraged to undergo regular mammography screening.

Siemens Mammomat Inspiration PRIME

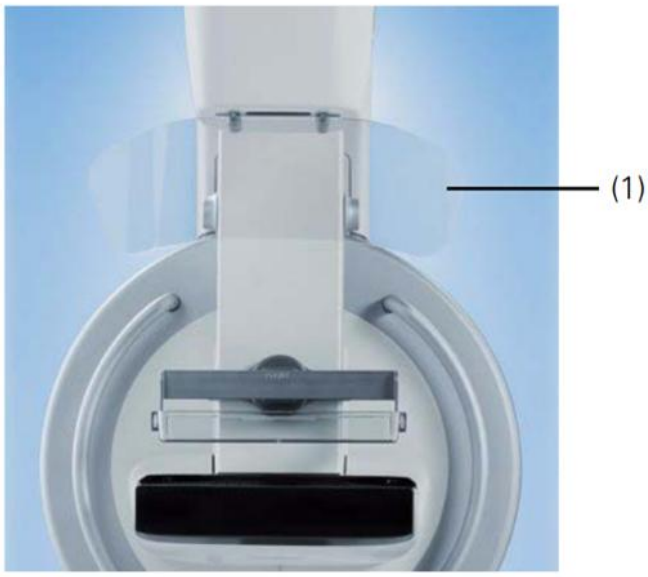
- In digital X-ray breast imaging, radiation passes through the examined breast to a detector. Primary radiation supplies the information needed to provide the X-ray image, while scattered radiation is absorbed by special grids positioned between the breast and the detector.
- Siemens' new reconstruction algorithm for the MAMMOMAT Inspiration system – known as Prime (Progressive Reconstruction, Intelligently Minimizing Exposure) –eliminates the need for the scatter radiation grid of conventional mammography systems.
- The Prime algorithm corrects the scattered radiation by identifying scatter-causing structures and recalculating the image, leaving intact the primary radiation upon which radiologists rely.

Siemens Mammomat Revelation PRIME Technology

***No Grid = Less Radiation Required per Exposure Inspiration**.

- Prime Edition obviates the need for a grid, and lower patient doses are sufficient to generate high-quality breast images.
- The grid-free imaging technology of the MAMMOMAT Inspiration Prime Edition reduces dose up to 30 percent compared to its predecessor model, depending on the thickness of the patient's breast tissue.

- Reduce dose by up to 30% without compromising image quality using the world's first software based anti-scatter solution for mammography.
- Sliding back the mechanical grid means there is no longer a fixed object absorbing radiation between breast and detector, so you can utilize 100% of the primary radiation –and achieve lower overall dose levels.



(1) Face shield

(1) Face shield

(2) Compression plate

Face Shield & Compression impact positioning and motion

Fujifilm Aspire Cristalle with DBT Option 2017

Indications for Use

- Acquires and generates FFDM and DBT images and is intended for use in the screening and diagnosis of breast cancer.
- Screening exam may consist of sets of CC and MLO images.
    - FFDM mode only.
    - FFDM image set and DBT image set acquired in the ST (standard mode).
    - FFDM image set and the DBT image set must be acquired with N-mode dose setting, and may be acquired in one compression (Tomo set mode) or separate compressions (FFDM and DBTmode).

How Does Fujifilm Cristalle Tomosynthesis work?

- Tube moves in a **40 º** and 15 º arc.
- **15** low dose images are acquired.
    - 1 image at every degree.
- 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.

Figure 1: *ASPIRE Cristalle*

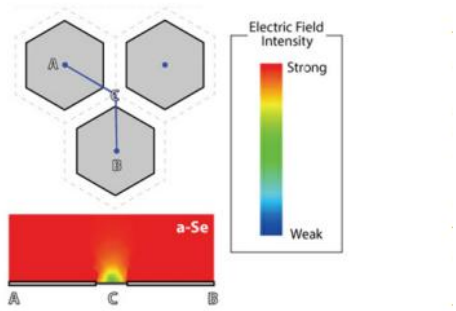


Figure 2c: *Fujifilm's hexagonal pixels with corresponding electric field intensity*

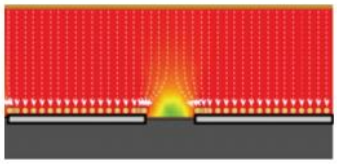


Figure 2d: *Hexagonal pixels with improved collection efficiency*

The Need for Quality Control

A growing body of research shows mammographic image quality errors are associated with suboptimal care for women, including unfavorable outcomes like late cancer detection (false negatives) and overtreatment (false positives).

The Mammography Accreditation Program provides facilities with peer review and constructive feedback on staff qualifications, equipment, quality control, quality assurance, image quality and radiation dose. The Mammography Quality Standards Act (MQSA) requires all U.S. mammography facilities to be accredited.

ACR Position Statement on DBT

- DBT is no longer investigational.
- Tomosynthesis has been shown to improve key screening parameters compared to digital mammography.
- The ACR has assembled information to assist members in working with private payers to secure coverage of this important technology.

Importance of Quality Control Testing for DBT Mammography

- Reduce ionizing radiation exposure to patient and personnel.

- Ensure adequate and consistent diagnostic image quality.
- Detect and correct for potential image quality problems prior to demonstrating them in the diagnostic mammographic image.

Quality Control

- There is **no** Quality Control Standard for DBT Systems.
- FDA/MQSA requires technologists and medical physicist use the most current edition of the operator's manual when conducting QC testing on Tomosynthesis equipment.
- FDA requires facilities with FFDM/3DBT systems comply with a QC program that is substantially the same as that recommended by the image receptor manufacturer.

Facilities Options for QC:

- Following the manufacturer recommendations
- Following the QC outlined in the ACR's 2018 Digital Mammography QC Manual
    - The 2018 ACR Digital Mammography Quality Control Manual includes QC procedures that cover both 2D mammography and 3DBT, allowing a single, unified QC program for all facilities regardless of unit type or manufacturer.

Importance of QC in Mammography Imaging

ACR Quality Assurance Definition

- A comprehensive concept that comprises all management practices instituted by the lead mammography radiologist to ensure:
    - Every imaging procedure is necessary and appropriate to the clinical problem at hand.
    - Images created contain information critical to the solution of that problem.
    - Recorded information is correctly interpreted and results made available in a timely fashion to the patient and her physician.

- Examination results in the lowest possible radiation exposure, cost, and inconvenience to the patient consistent with imaging objectives.

Process by Which Image Quality for Mammography 3DBT is Maximized Entails Cooperation Between:

- Interpreting radiologists (LIP)
  - Mandated by MQSA and has responsibility for ensuring all QA requirements are met.
- Mammography radiologist (IP)
  - Must follow facility procedures for corrective action when images they are ask to interpret are of poor quality.
- Medical physicists (MP)
  - Responsible for overseeing all equipment related quality assurance practices.
- Radiologic technologists
  - Must be identified by the facility to conduct all quality assurance activities not assigned to the (LIP) or (MP).
- **ACR Quality Assurance**
  - QA program comprises many facets including:
    - Efficacy studies.
    - Continuing education.
    - Quality control.
    - Preventive maintenance.
    - Calibration of equipment.
    - Medical outcomes audit.
- **QA/QC Procedure Manual**
  - Developed by the team.
  - Proper documentation of procedures and test results.
  - Can be maintained electronically or hardcopy.
  - Must be available at the facility for review by the MQSA inspector and accreditation body.
  - Establishes a method to the madness!

According to MQSA

If one or more images presented for interpretation do not meet at least minimum quality standards set by the facility's accreditation body, the Interpreting Physician should give feedback to the RT, as noted in section

900.12(d)(1)(ii)(A) of the regulations. Unless there are extenuating circumstances, those images should generally be repeated.

In theory each mammographic system has the same output – They do not! Even a single system has a different exposure output each time an exposure is made. We regulate the image quality based upon the MINIMAL variance in output from a known standard and this is the basis of Quality Control and Quality Assurance.

Quality Control for DBT

They are currently four different equipment manufacturers of DBT equipment

- Hologic
- GE
- Siemens
- Fujifilm

All have specific DBT tests that are performed for QC purposes.

- Many tests performed in 2D FFDM are also performed in 3D tomosynthesis mode.
- Some are similar between manufacturers, but the names of the test may be different.
- Many of the same test are performed by the technologist and MP but the frequency may be different.

Challenging Due to Difference Between Manufacturers

- Some DBT perform both FFDM and DBT Imaging.
- Other systems are capable of synthesizing a 2D image from the DBT data set.
- Important to always access the most current version of the manufacturers QC manual.
- 2018 ACR Digital Mammography Quality Control Manual includes QC procedures that cover both 2D mammography and 3DBT, allowing a single, unified QC program for all facilities regardless of unit type or manufacturer.
- QC records and all applicable corrective actions must be maintained for at least 12 months since the last annual inspection that verified compliance or

until the test has been done two additional times at the requested frequency, whichever is longer.

- 2D QC test must still be completed by the Technologist and Medical Physicist.
- Many of the QC test performed for 2D mammography are also performed in 3D mode.

Mammography Technologist

- Mammography Technologists who plan to on taking ARRT Mammography Advanced Level Exam in the future:
    - Content specifications for the ARRT exam include Digital and DBT QC tests required to be completed by the technologist and the Medical Physicist.
    - Technologist are expected to have a working understanding of all Technologist QC tests and basic understanding of the MP QC tests.

Demonstration of Manufacturing Differences

Parameter	Hologic Selenia Dimensions	GE SenoClaire	Siemens Mammomat	Fujifilm Aspire	GE Senographe
X-ray tube					
Anode target	W	Mo/Rh	W	W	Mo/Rh
Filter*	Al (700 μm)	Mo (30 μm)/Rh (25 μm)	Rh (50 μm)	Al (700 μm)/Rh	Mo (30 μm)/ Rh (30 μm)
Tube motion	Continuous	Step and shoot	Continuous	Continuous	Step and shoot
Flat-panel detector					

Al = aluminum
ASiR = adaptive statistical iterative reconstruction
CsI = cesium iodide,
FBP = filtered back projection,
HR = high resolution,
Rh = rhodium,
Mo = molybdenum
Se = selenium
Si = silicone
ST = standard mode
W = tungsten

*** Some systems use combinations of targets and filters that are specific to 3DBT and not used for FFDM.**

Summary of Quality Control Tools

Tools Used in QC Testing

- **Detector Flat Field Calibration**
  - Ensures flatness and homogeneity when reconstructing tomo planes through a flat field phantom.
  - Flat field test object is an acrylic block.
  - Performed weekly by technologist.
  - Technologist and Medical Physicist.
- **Geometry Calibration (Tomosynthesis option only)**
  - Checks that equipment is calibrated properly.
- **ACR Mammography DM Accreditation Phantom**
  - Assures image quality is maintained.
- **Line Pair Phantom**
    - Used to test line pair resolution.

  - **Polymethyl methacrylate plates (PMMA), Acrylic Sheets, Acrylic Plates**
    - Varying thicknesses.
    - Used for testing:
      - Phototimer consistency.
      - Automatic Exposure Control (AEC).
      - Collimator Assessment.
  - **Aluminum Plates/Sheets**
    - Used in conjunction with acrylic plates when testing volume coverage.
  - **Dosimeter**
    - Measures the typical entrance exposure in 3D mode using a standard breast (ACR Accreditation Phantom).
  - **Fujifilm 1 Shot Phantom M Plus**
    - Performs a daily quantitative test on 10 items with a single exposure.

Because FFDM and 3DBT share the same components, such as the detector and x-ray tube, many 3DBT QC tests are similar to those for FFDM and often can be performed at the same time.

ACR 2018 Digital Mammography Quality Control Manual

Revised 2nd Edition May 2020

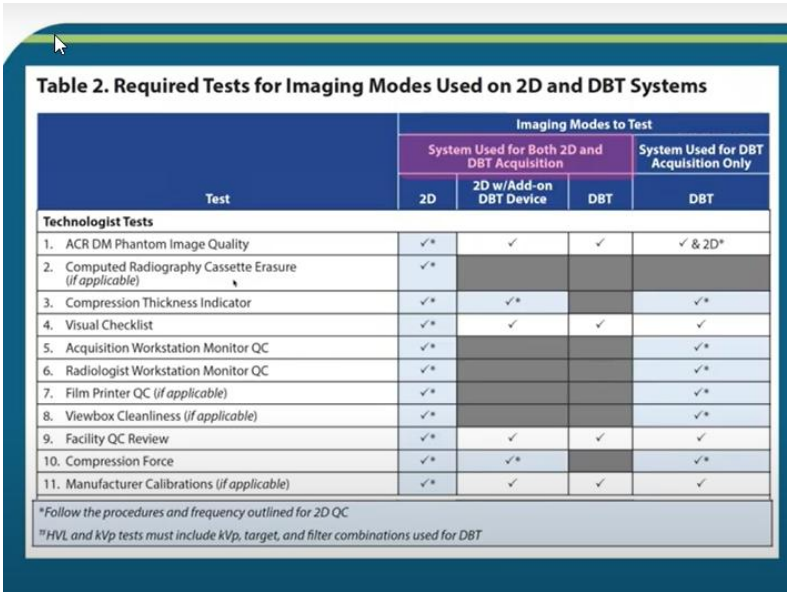


Table 2. Required Tests for Imaging Modes Used on 2D and DBT Systems

Test	Imaging Modes to Test			
	System Used for Both 2D and DBT Acquisition			System Used for DBT Acquisition Only
	2D	2D w/Add-on DBT Device	DBT	DBT
Technologist Tests				
1. ACR DM Phantom Image Quality	✓*	✓	✓	✓ & 2D*
2. Computed Radiography Cassette Erasure (*if applicable*)	✓*			
3. Compression Thickness Indicator	✓*	✓*		✓*
4. Visual Checklist	✓*	✓	✓	✓
5. Acquisition Workstation Monitor QC	✓*			✓*
6. Radiologist Workstation Monitor QC	✓*			✓*
7. Film Printer QC (*if applicable*)	✓*			✓*
8. Viewbox Cleanliness (*if applicable*)	✓*			✓*
9. Facility QC Review	✓*	✓	✓	✓
10. Compression Force	✓*	✓*		✓*
11. Manufacturer Calibrations (*if applicable*)	✓*	✓	✓	✓

*Follow the procedures and frequency outlined for 2D QC

[†]HVL and kVp tests must include kVp, target, and filter combinations used for DBT

Digital Mammography Quality Control Tests Radiologic Technologists (2D & DBT) Testing Schedule

Test	Minimum Frequency	Corrective Action
ACR Digital Mammography Phantom Image Quality	Weekly	Before Clinical Use
CR Cassette (erasure if applicable)	Weekly	Before Clinical Use

Digital Mammography Quality Control Tests Radiologic Technologists (2D & DBT) Testing Schedule

TEST	MINIMUM FREQUENCY	CORRECTIVE ACTION
Compression Thickness Indicator	Monthly	Within 30 days
Visual Checklist	Monthly	Critical before clinical use
Acquisition Workstation Monitor QC	Monthly	Before clinical use/ within 30 days
Radiologic Workstation QC	Monthly	Before clinical use/ within 30 days
Film Printer QC (if applicable)	Monthly	Before Clinical Use
View box Cleanliness (if applicable)	Monthly	Before Clinical Use

Digital Mammography Quality Control Tests Radiologic Technologists (2D & DBT)

Test	Minimum Frequency	Corrective Action
Facility QC Review	Quarterly	Not Applicable
Compression Force	Semiannual	Before Clinical Use
Manufacturer Calibration (which is not QC but machine calibration)	Manufacturer Recommendation	Before Clinical Use

Digital Mammography (2D&DBT)
Quality Control Weekly Tests

ACR Digital Mammography (DM) Phantom Image Quality

Objective: To ensure image acquisition chain is consistently producing adequate image quality and that artifacts are not clinically significant.

Frequency: Weekly, after relevant service and upon installation of new equipment.

Test Equipment: ACR DM Phantom **Required

Perform Test and Score Phantom

Phantom IQ 3D
How to Perform: Use the ACR DM Phantom and expose in 3D acquisition. Scroll through the volume to find best in-focus plane for each structure.

Document:	**3D Scoring**	***2D Scoring remains**
Fibers	at least 4	Fibers 5
Speck groups	at least 3	Specks groups 4
Masses	at least 3	Masses 4

Same technique and action limit as for 2D.

The CIRS Model 086, **ACR Digital Mammography** (**DM**) **Phantom** was designed under the sponsorship of the American College of Radiology (**ACR**) to **test** the

performance of FFDM systems. **Objects** within the phantom simulate calcifications, ducts and tumor masses.

Compression Thickness Indicator

Objective: To ensure that the indicated compression thickness is within tolerance.

Frequency: Monthly, or whenever inaccurate indicator performance is suspected and upon installation of new equipment.

Test Equipment: An object to use as a compression thickness indicator phantom.

Test Procedure: Record a description of the compression thickness indicator phantom.

Performance Criteria: The compression thickness indicator must be accurate to within ±0.5cm of the actual thickness.

Timeframe for Corrective Action: The source of the problem must be identified and action taken with 30 days.

Visual Checklist

Objective: To ensure that digital mammo system indicator lights, displays, mechanical locks and detents are working properly and that the mechanical rigidity and stability of the equipment is optimum.

Frequency: Monthly, or after relevant service accurate and upon installation of new equipment before clinical use.

Test Equipment: Visual checklist form.

Test Procedure: Review all items on the list and indicate their status. Date and initial checklist.

Performance Criteria: The following test listed in the Visual Checklist are critical before clinical use as applicable.

Timeframe for Corrective Action: The source of the problem must be identified, and action taken with 30 days.

Visual Checklist

Performance Criteria: The following test listed in the Visual Checklist are critical before clinical use as applicable.

- Cleaning solution must be available.
- All locks must work correctly.
- Paddles/face shields must not be cracked.
- Breast support must not be cracked.
- The cassette holder for CR must hold and lock the cassette properly (small and large).

Timeframe for Corrective Action: Failures of critical tests must be corrected before clinical use; failures of less critical tests must be corrected within 30 days.

Acquisition Workstation (AW) Monitor QC

Objective: To ensure that AW monitors are clean and free from dust, fingerprints, and other marks that may interfere with clinical information.

Frequency: Monthly, or after relevant service and upon installation of new equipment before clinical use.

Test Equipment: Dry, soft and lint free cloth or cleaning tissue recommended by your AW manufacturer.

Test Procedure: Visual inspection and action and record significant findings.

Performance Criteria: Any large, significant blemish that interferes with the visualization or QC of images is a failure. * There may be additional manufacturers tests for quality.

Timeframe for Corrective Action: Failures must be corrected before clinical use.

Radiologist Workstation (RW) Monitor QC

Objective: To ensure that AW monitors are:

- clean and free from dust, fingerprints, and other marks that may interfere with clinical information.
- monitors are calibrated correctly, and the brightness and contrast settings are set correctly.
- Image acquisition chain is producing adequate image quality and working consistently.

- Monitors meet manufacturer specifications via the conduct of Monitor Manufacturer Automated Tests if applicable.

Frequency: Monthly, or after relevant service and upon installation of new equipment before clinical use.

Test Procedure: Visual inspection and action and record significant findings

Performance Criteria: Any large, significant blemish that interferes with the visualization or QC of images is a failure. * There may be additional manufacturers tests for quality.

Timeframe for Corrective Action: Failures must be corrected before clinical use

Test Equipment: Dry, soft, lint-free cloth or cleaning tissue recommended by the manufacturer.

Test Procedure: Inspect monitor condition, clean and document as needed, review an ACR DM phantom image that was acquired on of the digital mammo unit and evaluate for artifacts and score the phantom. *See phantom performance criteria.

Performance Criteria: Any large, significant blemish that interferes with the interpretation or QC of images is a failure. * If there are questions regarding the significance of a monitor blemish, the (LIP) should be consulted. There may be additional manufacturers tests for quality.

Timeframe for Corrective Action: Failures must be corrected before clinical use.

Radiologist Workstation (RW) Monitor QC

Test Equipment: Dry, soft, lint-free cloth or cleaning tissue recommended by the manufacturer.

Test Procedure: Inspect monitor condition, clean and document as needed, review an ACR DM phantom image that was acquired on of the digital mammo unit and evaluate for artifacts and score the phantom. *See phantom performance criteria.

Performance Criteria: Any large, significant blemish that interferes with the interpretation or QC of images is a failure. * If there are questions regarding the significance of a monitor blemish, the (LIP) should be consulted. There may be additional manufacturers tests for quality.

Timeframe for Corrective Action: Failures must be corrected before clinical use.

Film Printer QC (if applicable)

Objective: To ensure adequate and consistent image quality on printed images provided to referring physicians, patients, and other radiologist.

Frequency: Monthly, or if printer is used less than monthly, before clinical films are printed.

Test Equipment: ACR Digital (DM) Phantom, densitometer, and film printer QC form.

Test Procedure: Print the phantom image without adjusting parameters using most common film size. Print image w/o magnification or minification and view the image.

Performance Criteria: Artifacts must not be clinically significant or in a location that could impact clinical interpretation.

Timeframe for Corrective Action: Failures must be corrected before clinical use.

Facility QC Review

Objective: To ensure the lead interpreting radiologist and facility manager are aware that all QC tests are performed at the required frequencies, that data are collected appropriately, that results are adequately documented, that corrective action is taken, and that no patient exams are conducted when tests requiring correction before clinical use failed.

Frequency: Quarterly.

Test Equipment: Facility QC forms and facility QC review forms.

Test Procedure: QC data/notebooks must be reviewed by both the (LIP) and facility manager. These reviews may be done in person or remotely.

Facility QC Review

Test Procedure: QC data/notebooks must be reviewed by both the (LIP) and facility manager. These reviews may be done in person or remotely. Items to be included are:

- Enter QC results form the most recent Physicist QC test summary form into the Facility QC Review form prior to the meeting.
- Enter QC results from most recent week of Tech QC into the form prior to the meeting.
- Review the most recent quarter of QC data.
- Review each QC test and its results.
- If any test fail, not that corrective action was documented.
- Discuss reasons for failure documented corrective action.
- Review the Medical Physicist's ACR DR QC Test Summary and report for each mammography unit.
- Record performance of this quarterly review and annual review with initials and date on the form.

Facility QC Review

Performance Criteria and Corrective Actions:

- If test are not being done at an appropriate level or frequency, or if corrective action for failures are not implemented and /or documented, the facility needs to determine the reasons and allocate appropriate training and/or time so the work is done properly.
- If there are questions regarding the conduct of the test or data interpretation, the medical physicist should be consulted for assistance and additional training.

Compression Force

Objective: To ensure the mammography system can provide adequate compression in both manual fine adjustment and hands free, initial power-drive modes, that the equipment does not allow too much compression to be applied

when used in initial power-drive mode, and that adequate compression can be maintained throughout the image acquisition.

Frequency: Every 6 months (semiannual), whenever reduced, excessive, or unstable compression is suspected, and upon installation of new equipment.

Test Equipment: A calibrated bathroom scale and documentation form.

Test Procedure: Print the phantom image without adjusting parameters using most common film size. Print image w/o magnification or minification and view the image.

Performance Criteria: Artifacts must not be clinically significant or in a location that could impact clinical interpretation.

Timeframe for Corrective Action: Failures must be corrected before clinical use.

Compression Force

Test Procedure: Follow test in QC manual.

Performance Criteria:

- A compression force of at least 25 pounds (111 newton's or 11.1 decanewtons) must be provided in both the initial power-drive and manual fine adjustment modes.
- For the initial power-drive mode, the max compression force must be at least 25 pounds but no more than 45 pounds.
- The initial power-drive mode must maintain a compression force of at least 25 pounds for the length of time it usually takes to engage the fine-adjustment control. The fine-adjustment control must then maintain a compression force of at least 25 pounds for the length of time it usually takes to complete an average exposure.

Timeframe for Corrective Action: Source of the problem must be identified, and corrective action taken before any examinations are performed.

Manufacturer Calibrations

Objective: To detect and automatically correct equipment problems, especially related to digital detector performance. This may include compensating for dead or over-responding pixels, structured or other noise, nonlinear response, and other technical performance parameters.

Frequency: Must be performed at the frequency specified by the manufacturer and upon installation of new equipment.

Test Equipment: Manufacturer calibrations form.

Test Procedure: Follow manufacturer performance and documentation steps.

Performance Criteria: The unit must meet the prescribed periodic calibrations.

Timeframe for Corrective Action: Failures must be corrected before clinical use.

Optional-Repeat Analysis

Objective: To determine the number and cause of repeated mammograms. (Analysis of these data will help identify ways to improve efficiency, as well as reduce patient exposure.

Frequency: As needed **A volume of at least 250 patients is needed, if possible. Some facilities choose to conduct routine repeat analysis.

Test Equipment: All repeated mammograms including data for repeated mammograms that may have been placed in the patients' medical record, means to count total # of patient exposures made during the test period, means for sorting and optional repeat analysis forms.

Test Procedure: See recommendations in QC manual.

Performance Criteria: Overall repeat rate ideally should be 2% or less, but a rate of 5% is probably adequate if the radiologist and medical physicist agree that this is a reasonable level.

Timeframe for Corrective Action: The source of the problem should be identified, and corrective action taken within 30 days of the repeat analysis.

DBT Quality Control

ACR Digital Mammography (DM) Phantom Image Quality

Objective: To ensure image acquisition chain is consistently producing adequate image quality and that artifacts are not clinically significant.

Frequency: Weekly, after relevant service and upon installation of new equipment.

Test Equipment: ACR DM Phantom **Required

Perform Test and Score Phantom

Phantom IQ 3D
How to Perform: Use the ACR DM Phantom and expose in 3D acquisition. Scroll through the volume to find best in-focus plane for each structure.

Document:	**3D Scoring**	***2D Scoring remains**
Fibers	at least 4	Fibers 5
Speck groups	at least 3	Specks groups 4
Masses	at least 3	Masses 4

Same technique and action limit as for 2D

- A few seconds after the exposure has ended, the image appears on the image preview display. Switch to the reconstruction icon and scroll to the bring the ACR elements in focus. (usually when you can see the serial number really clear, slice 36 or 37).
- The phantom can be scored on the preview screen (3mega pixel monitor). It does not have to be sent to the radiologist's display.
- The minimum passing score for Tomosynthesis mode is:
  - 4 fibers
  - 3 speck groups
  - 3 masses

Criteria and Corrective action:
Artifacts associated with the phantom may be identified by repeating the phantom with the phantom slightly rotated.
If the score fails, the source of the problem just be identified. If the source is the detector, corrective action must be taken before any further patients can be done. If the source is a diagnostic device, that device must be corrected before its used for image interpretation. (i.e. printer or monitors).

Phantom Image Tomo

This does not mean the Tomosynthesis score is lower than the 2D score.
The goal of 3D Tomosynthesis is to remove superimposed tissue. If the phantom had tissue analogs, the Tomosynthesis score would be a lot higher than the 2D score.
Even with the ACR phantom, the Tomosynthesis score may exceed 5 fibers, 4, speck groups and 4 masses.

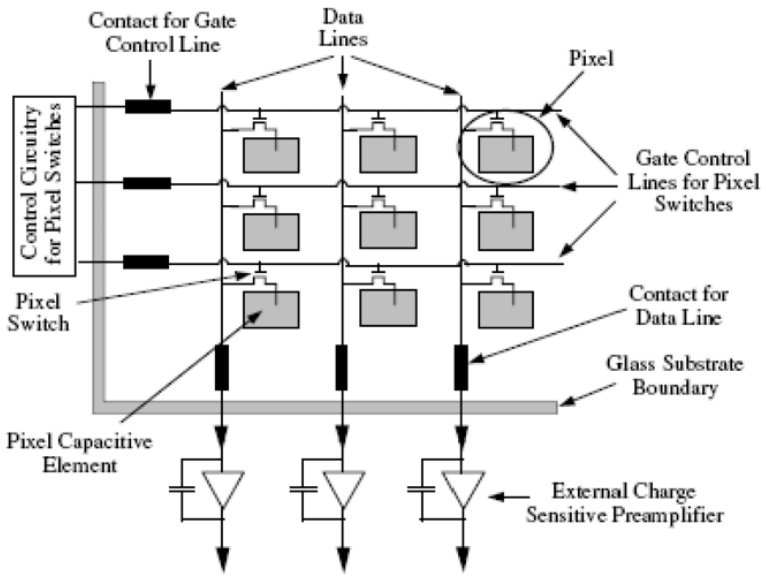
Flat Field 3D Calibration

Technologist

Weekly

Action Criteria

- **Purpose:** Test is to ensure flatness and homogeneity when reconstructing planes through a flat field phantom.
- **How to Perform:** Use a thick acrylic test object provided by manufacturer to cover detector, an automatic 3D acquisition is made with no compression device and a pre-programed set of exposures.
- **Document:** Preview images are reviewed for foreign objects, gross artifacts or other non-uniformities. Document the status of the test as pass or fail.
- **Flat-field correction** is a technique used to improve quality in digital imaging. It cancels the effects of image artifacts caused by variations in the pixel-to-pixel sensitivity of the detector.



Automatic Optimization of Parameters (AOP)

3D Mode AOP

Technologist
Monthly

- **Purpose:** Test checks the correct exposure parameters are selected in AOP 3 mode.
- **How to Perform:** Three acrylic plates of different thicknesses (25,50,60) are exposed with various exposure parameters such as track/filter, mAs, kvp.
- **Document:** The resulting exposure parameters should match what is specified by the manufacturer.

Geometry Calibration

Technologist

Semi Annually * Category (A) Action Criteria

Purpose: Test is performed to assure the system is properly calibrated.

How to Perform: Assure the x-ray field covers the entire surface of the digital image receptor without interference from collimation, the calibration phantom is correctly installed and pressing on the digital image receptor.

Document: The software at the acquisition workstation automatically conducts the test and records the results as pass or fail. If a calibration failure occurs:

- Start the geometry procedure from the beginning.
- If failures persist contact a service engineer and the source of the problem must be identified and corrective action taken before any further Tomosynthesis exams are performed.

Testing for Volume Coverage and Geometric Accuracy This test is performed to ensure that the entire imaged object is included in the reconstructed image, with minimal distortion.

Artifact Evaluation
Technologist **Medical Physicist**
Weekly **Annually**
*** Category Action Criteria**

- **Purpose:** Test is used to evaluate the degree and source of image artifacts
- **How to Perform:** Use acrylic block provided by manufacturer without the compression paddle to test 2D and 3D. A series of exposures are taken rotating the block 180 degrees following each exposure.
- **Document:** If visualization of unacceptable artifacts are noted and cannot be resolved contact the medical physicist for evaluation and service engineer if required. Any artifacts that compromise the interpretation by the Radiologist are considered unacceptable and fall into Category A.

**** Most common artifacts are dead pixels visualized as a cluster or a complete or partial row or column.**

Detector-related artifacts arise directly from problems with the detector.
The artifacts can be:

- single dead pixels
- groups of dead pixels
- dead or unread lines
- ghosting.
- These artifacts can obscure or mimic breast disease.

DBT Artifacts

Artifacts Occurring During Acquisition

- These are primarily truncation artifacts where a portion of the breast is not recorded due to the limited size of the detector and the x-ray beam.
- Show as a bright area and where the detector does recognize the presence of breast tissue.
- Staircase Artifacts are demonstrated by the presence of multiple lines at the ends of the image providing a staircase like appearance.

Artifacts Due to Reconstruction

- These occur when a high-density structure, though blurred remains visible in sections apart from the one in which it is actually located. This phenomenon marked with high intensity structures like calcification.
    - **Blur and Ripple Affect:** These artifacts occur due to incomplete cancellation of objects outside the plan of interest.
    - **Halo Artifact:** Reconstruction of very low signal around a high-density object such as calcifications leads to the production of a halo artifact.
    - **Halos** are particularly pronounced along the sweep directions.

Understanding the QC process is crucial to be able to identify artifacts as they occur so they can be corrected promptly.

Skin Thickening Artifact

The skin of the breast inferior to the nipple has not been adequately blurred in adjacent sections directions.

Slinky Artifact
Example from Beekley

- Mole markers (intended for 2D) is visualized in a slice but continues to image on other slices.
- Mole markers for 3D are thinner and lower density and subsequently reduces the slinky artifact.

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GE DB Quality Control Tests
Follow Manufacturers Recommendations

Selenia Dimensions QC Manual

2D QC

- DICOM Printer Quality Control Weekly.
- Detector Flat Field Calibration Weekly.
- Artifact Evaluation Weekly.
- Phantom Image Weekly.
- Signal-To-Noise and Contrast-To-Noise Measurements weekly.
- Compression Thickness Indicator Biweekly.
- Diagnostic Review Workstation Quality Control Weekly.
- Viewboxes and Viewing Conditions Weekly.
- Visual Checklist Monthly.
- Repeat/Reject Analysis Quarterly.
- Compression Semiannually.

Tomosynthesis QC

1. Detector Flat Field Calibration.
2. Geometry Calibration (Tomosynthesis option only).
3. Artifact Evaluation- Detector Phantom.
4. Phantom Image Quality Evaluation.

Quality Control Test Requirements with DBT Components.

Test requirements vary by equipment manufacturers.

GE-Technologist and Medical Physicist Requirements

1. Phantom IQ 2D with MTD.
2. CNR and MTF measurement with MTD Weekly.
3. Flat field 3 D test.
4. Phantom IQ 3D test.
5. MTD grid texture test.
6. AOP 2D and SNR check with MTD Monthly.

    1. AOP 3D check.
    2. Visual checklist.
    3. Compression force test Semi-annually.

- **Only four of the 12 tests as described in the manual have changed:**
- **Detector Flat-Field Calibration** (Gain Calibration)
    - 5 additional exposures for the Tomosynthesis Gain Calibration with Al (aluminum) filter.
- **Geometry Calibration**
    - 1 exposure
- **Artifact Evaluation**
    - 1 additional Tomosynthesis Artifact Evaluation image.
- **Phantom Image Quality Evaluation**
    - 1 additional Tomosynthesis Phantom image.
    - (Combo exposure vs. a 2D exposure).

Quality Control Test Requirements with DBT Components

GE-Medical Physicist Requirements in addition to those listed on previous slide for the technologist:

1. Compression paddle to chest wall alignment with MTD.
2. Breast entrance exposure and AGD in 2D with MTD.
3. Breast entrance exposure and AGD in 3D Annually.
4. Artifact evaluation and flat field uniformity with MTD.
5. Volume coverage of DBT.

Hologic DBT Quality Control Tests

Follow Manufacturers Recommendations

Quality Control Test Requirements with DBT Components

Hologic
Technologist QC Tests Requirements

- Geometry calibration (tomo option) Semi Annually Category A.
- Artifact evaluation Weekly Category C.
- Phantom image-Weekly.

Hologic
Medical Physicist QC Tests Requirements

- Collimation assessment Annually Category C.
- Artifact evaluation Annually Category C.
- Phantom image quality evaluation Annually Category A.
- Beam quality assessment/HVL Annually Category C.
- Evaluation of system resolution Annually Category A.
- AEC function performance Annually Category C.
- Breast entrance exposure, AEC reproducibility, and average glandular dose Annually Category A/C.

Siemens DBT Quality Control Tests
Follow Manufacturers Recommendations

Quality Control Test Requirements with DBT Components

Siemens
Technologist and Medical Physicist QC Tests Requirements

- Glandular Dose MP Annually.
- Geometric accuracy in X&Y direction Z-resolution MP Annually.
- Radiation Field MP Annually.
- Phantom image quality MP Annually.
- Phantom image quality RT Daily.
- *Only on days when doing tomo.
- With tube head at 0.
- Artifact detection MP Annually.

Fujifilm DBT Quality Control Tests
Follow Manufacturers
Recommendations

Phantom Image Artifacts

- Criteria and Corrective action:
- Artifacts associated with the phantom may be identified by repeating the phantom with the phantom slightly rotated.
- If the score fails, the source of the problem just be identified. If the source is the detector, corrective action must be taken before any further patients

can be done. If the source is a diagnostic device, that device must be corrected before its used for image interpretation. (i.e. printer or monitors).

Medical Physicist QC Test For your Reference

Quality Control Tests

- **Volume Coverage**
- **Medical Physicist**
- **Annually**

- **Purpose:** Test ensures the entire imaged object is reconstructed on the Z-axis (perpendicular to the detector).
- **How to Perform:** Two sheets of aluminum are placed between acrylic plates; a manual exposure is made in 3D mode using a typical compression force. The test is repeated using thicker acrylic plates.
- **Document:** The Medical Physicist visually verifies that the top and bottom aluminum sheets are visible in the of reconstructed volume.

Beam Quality Assessment/HVL Measurement

Medical Physicist

Annually

*** Category (C) Action Criteria.**

- **Purpose: To test the beam quality.**
- **How to Perform: A high resolution pattern is placed on flat field phantom approximately 1 cm from chest wall edge, with pattern angled 45 degrees to anode-cathode axis. Testing for 2D is according to routine practice. The HVL is also measured in 2D mode using zero-degree tomo mode.**
- **Document: Action limit are (HVL greater than (kvp/100) +0.03 in mm AL.**

Evaluation of System Resolution

Medical Physicist

Annually **Category (A) Action Criteria.**

- **Purpose: To test system resolution**
- **How to Perform:**
- **Document: The results are recorded. Resolution guidelines for DBT are greater 3 lp/mm at 45 degrees.**

*** 2D limiting resolution must be greater than 7 lp/mm.**

Automatic Exposure Control (AEC) Function Performance
Medical Physicist
Annually **Category (C) Action Criteria.**

- **Purpose:** To test (AEC) performance function
- **How to Perform:** AEC performance is checked at various thicknesses and in various imaging modes for 2D and 3D.
- **Document:** The "Pass" as indicated on the control panel.

***Action limits:** Pixel value should not vary more that 10% of the mean pixel value computed for all tested breast thicknesses and imaging modes.

Breast Entrance Exposure, AEC Reproducibility & Average Glandular Dose (AGD)
Medical Physicist
Annually
Category (A) or (C) Action Criteria
Purpose: To calculate the mean, standard deviation, and coefficient of variation (COV) for mAs.
How to Perform: Four exposures are made using the ACR phantom which simulates a 4.5 cm compressed breast of 50% adipose and 50% glandular tissue composition.
Document: The results must meet the following action limits:

- **Action limits:** Average Glandular Dose (AGD) must not exceed 300mrad (2mGy) for 4.2 effective breast thickness for 2D, Tomo or 2D

+ Tomo. ** Failure of this aspect of the test it is a Category (A) due to the seriousness of the problem.

- **Action limits:** When the coefficient of variation (COV) exceeds 0.05, service must be called Category (C).

Alternate Test for Average Glandular Dose (AGD)

Medical Physicist

Annually **Category (A) Action Criteria**

- **Purpose:** This method for calculating (AGD) for the Tomosynthesis exam is similar to that used in 2D.
- **How to Perform:** Under compression with various breast thicknesses, 20mm,40mm and 60mm using the polymethyl methacrylate (PMMA) plate the specified kvp is selected. The MP records the mAs and the displayed (AGD) for each mm plate.
- **Document:** The value for average glandular dose (AGD) for a standard breast **must not exceed** 3 mGy (300mrad) per 3D acquisition.
  - **** Requires immediate correction if this value is exceeded.**

Geometric Accuracy in X and Y Direction and Z Resolution

Medical Physicist

Siemens

- **Purpose: To measure geometric accuracy**
- **How to Perform Geometric Accuracy:** The Medical Physicist uses the polymethyl methacrylate (PMMA) plate, the ACR phantom and the tomo compression paddle to perform three scans with the plate and phantom in various positions.
  - The outer dimensions (X &Y) on the phantom are measured and recorded.

- Slices are chosen for the best visible fibers, specks, and masses on the tomo scan.

Document: The action limit for this test requires X and Y must be measurable with an accuracy of +/- 2%

- **How to Perform Z-Resolution:** The Medical Physicist determines pixel values of the largest specks (a) and the background between the specks (b) Artifact spread function (ASF) is calculated for (a) and (b)
-
    - **Shot Phantom M Plus.**
    - **Fujifilm Manufacturer.**
    - **Ten Daily Items Tested.**

        - Missed tissue at chest wall.
        - CNR.
        - System sensitivity.
        - Geometric distortion.
        - System artifact (the whole image).
        - Uniformity.
        - Dynamic range.
        - Spatial resolution.
        - LCD.
        - Linearity/Beam quality.

Radiation Dose Considerations for DBT

Full-field digital mammography (FFDM) units display the mean glandular dose (MGD) and the entrance or incident air kerma (*K*) to the breast following each exposure.

Prescribed Dose Measurement Procedure

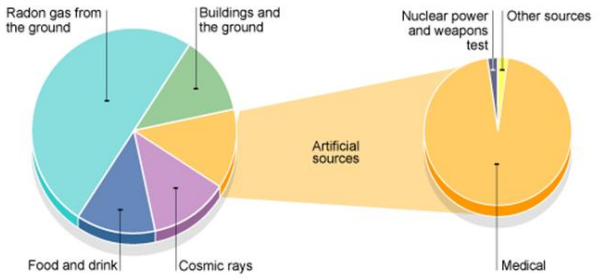
- Phantom:
  - Mammography phantom (equivalent to approximately 4.2 cm compressed breast tissue – 50-50 composition) or
  - A phantom made of either acrylic or BR-12 and consisting of at least four 2 cm thick slabs to provide thicknesses of 2, 4, 6 and 8 cm of linear dimensions representative of typical breast sizes may be used to determine doses for other breast thicknesses (optional)

Average Glandular Dose

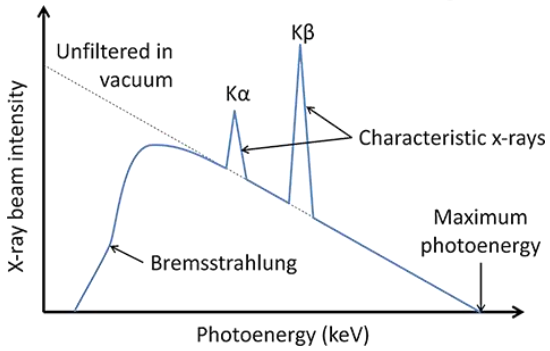
- Required measurement performed by medical physicist as part of Mammography quality Control Tests
- Objective: To measure the typical entrance exposure for an average patient (approximately 4.3 cm compressed breast thickness – 50% adipose, 50% glandular composition, to calculate the associated average glandular dose,.....

Background Radiation

- Radioactivity is present throughout the whole universe with radiation dose varying depending on where you live.
- In the United States the dose of natural radiation can vary anywhere between 100 mrem to 1000 mrem per year depending on geographical regions.

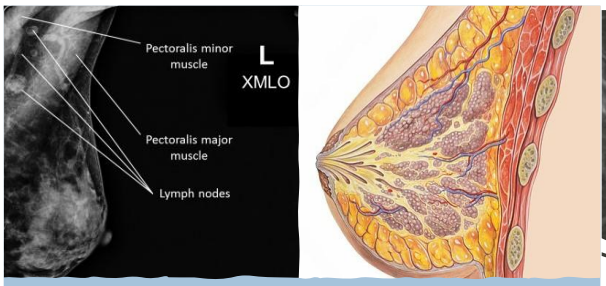


The potential biological effects and damages caused by radiation depend on the conditions of the radiation exposure.

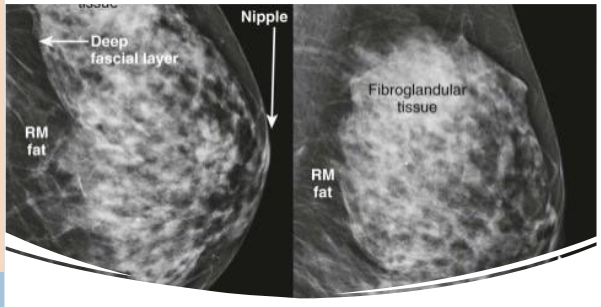


The dose to the breast of an individual patient is determined by a combination of three factors:

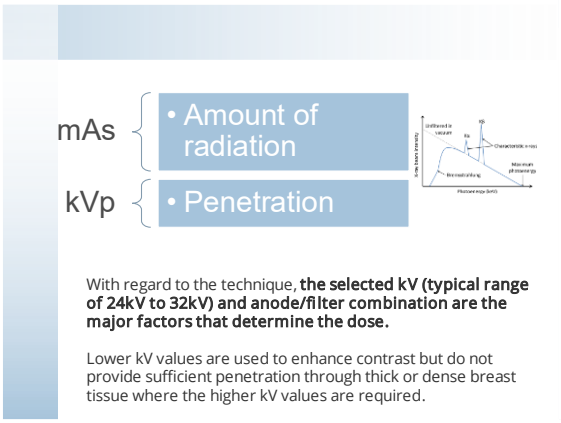
The characteristics of the equipment being used	The technique factors selected for the examination	The size and density of the patient's breasts

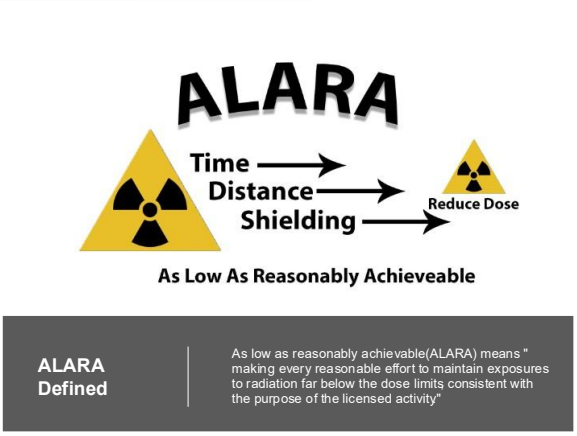


A radiographic image is composed of a 'map' of X-rays that have either passed freely through the body or have been variably attenuated (absorbed or scattered) by anatomical structures. The denser the tissue, the more X-rays are attenuated.



Contrast within the overall image depends on differences in both the density of structures in the body and the thickness of those structures. The greater the difference in either density or thickness of two adjacent structures leads to greater contrast between those structures within the image.



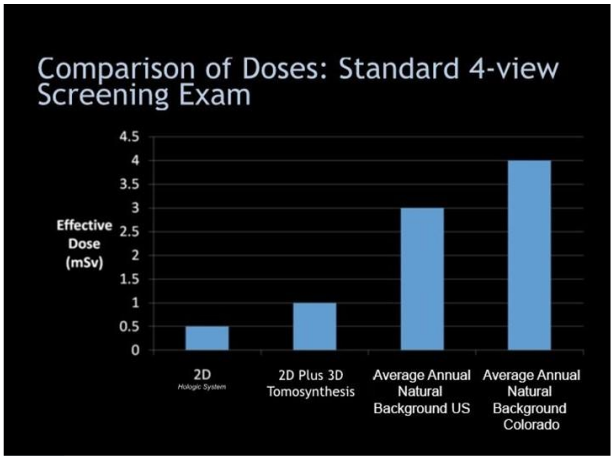


MQSA

- The 2D and 3D combination screening mammogram is well under the MQSA dose limit **of 3mGy.** Although it is reassuring that the average radiation dose exposure for annual screening mammography is well under the national limit, how does that amount of radiation exposure compare to other forms of radiation exposure?

Radiation Dose: *2D plus 3D* Tomosynthesis

- The additional effective dose of 3D Tomosynthesis is equivalent to about 2 months of annual natural background radiation in the United States.
- This is less than natural variations in background radiation.
- Risk from these levels of radiation is low.
- For example, breast cancer incidence is lower in Colorado versus the average US, even though natural background radiation is higher.



Dose: 2D + 3D Tomosynthesis (Combo Mode)

FDA panel of experts voting, unanimously agreed the **benefits** of combo mode imaging outweigh the **risks**.

It is often suggested by manufacturers that both DM and 3DBT should be used together (DM&3DBT) in breast cancer screening. Some limitations include the increased reading time and image storage capacity.

The main concern of introducing single or double-view 3DBT in screening together with DM is the additional dose to the patient or to the healthy woman who attends screening for early breast cancer diagnosis. There is the radiation protection requirement to keep the dose as low as reasonably practical or in other words, to make sure that the diagnostic advantage of 3DBT outweighs the additional dose to the patient.

Beyond the Procedure

MQSA, Accreditation and More

Digital Breast Tomosynthesis (DBT)
MQSA (from FDA.gov)

MQSA defines a mammographic modality as "a technology for radiography of the breast." Under MQSA, DBT is considered a mammographic modality.

Course module objectives

- Relate the accreditation process to improved image quality.
- Name the components of the DBT accreditation process.
- Discuss the training requirements for DBT Modality Specific Training.
- List 5 proven benefits of DBT.
- Identify the CPT specific to DBT procedures.

Diagnostic Errors

- **More Common, Costly and Harmful Than Treatment Mistakes**
  - In reviewing 25 years of U.S. malpractice claim payouts, Johns Hopkins researchers found that:

- Diagnostic errors — **not surgical mistakes or medication overdoses** — accounted for the largest fraction of claims, the most severe patient harm, and the highest total of penalty payouts.
- Diagnosis-related payments amounted to $38.8 billion between 1986 and 2010.

David E. Newman-TokerM.D., Ph.D., an associate professor of neurology at the Johns Hopkins University School of Medicine and leader of the study published online in BMJ Quality and Safety:

"This is more **evidence that diagnostic errors could easily be the biggest patient safety and medical malpractice problem in the United States,"** there's a lot more harm associated with diagnostic errors than we imagined."

FACT

- Suits involving breast cancer are the most common cause of malpractice litigation in the United States.
- True despite:
  - Breast cancer is relatively common.
  - Diagnostic pathways are well established.
  - Patients often request breast cancer–specific evaluation.
  - Benefit to early diagnosis is well documented.
- The vast majority of cases allege:
  - Delay in diagnosis.
    - Diagnostic error.
    - Poor communication.
    - Therapeutic acts of omission or commission.

Are You or Your Facility at Risk?

Poor positioning has been found to be the cause of most clinical image deficiencies and most failures of accreditation.

- ACR found that of all clinical images which were deficient on the first attempt at accreditation **92% were because of positioning deficiencies.**

Reports on Failures Due to Positioning:

- ACR -79%

MQSA: Intended to Improve the Quality of Mammograms

The Eight Clinical Image Parameters Percentages are in order of resultant causes of clinical image failure:

1. Positioning 20%
2. Exposure 15%
3. Compression 14%
4. Sharpness 13%
5. Contrast 13%
6. Artifacts 11%
7. Labeling ID 8%
8. Noise 5%

Most Common Positioning Errors

- Poor visualization of posterior tissue.
- Sagging breast.
- Inadequate amount of pectoralis major muscle on image.
- Excessive exaggeration.

Mammography Accreditation:
Is Your Facility at Risk?

Positioning failures of clinical images often lead to an Additional Mammography Review (AMR).

- **If the AMR reveals failing results:**
  - FDA will determine whether the facility's practice of mammography represents a serious risk to health.
  - May order a facility to cease performing mammography.
  - May notify all affected patients and their referring health care providers about the facility's image quality problems.
  - Consequences of poor positioning can be very significant not just for individual patients, but for mammography facilities as well.

Additional Mammography Review (AMR)

Trends in corrective action by AB

- Mandated hands-on training for technologists.
    - Sometime tech whose name was on the procedures, sometimes all technologists.
        - 8 hours of hands-on training provided by a trainer who is not part of the facility accreditation.
        - Trainer must document their expertise/experience and provide a summary report of the training accomplishments.

Mammography Accreditation

Technologist performs the mammogram, but the responsibility for correct positioning is shared by the technologist and the interpreting physician.

- This shared responsibility is reflected in MQSA. The Preamble to the MQSA Final Rule emphasizes that all interpreting physicians are **"the final arbiters of the quality of mammography images".**
- It is important that they communicate their satisfaction or dissatisfaction with the quality of the images they are provided to interpret to the technologists who produced them.
- Such communication is the crucial first step in the identification of problems and the initiation of corrective actions.

Statistical Terms in Mammography

Screening Digital Mammography

Sensitivity is approximately 84%

- Meaning 84% of the patients screened who have breast cancer are correctly identified.

Specificity is approximately 90%

- Meaning that 90% of healthy women are correctly identified as NOT having breast cancer.

Sensitivity and specificity are statistical terms used describe a test in relationship to an established value. An accurate mammogram examination is described as "normal" when there is absence of disease.

- **Sensitivity**: Correctly identifies those patients who have breast cancer.
- **Specificity**: Correctly identifies those patients who **DO NOT** have cancer on a screening mammogram.
    - **Example:** MRI has a high statistical sensitivity (it show you everything) but has a lower specificity (it does not tell you what it is) leading to false positives.

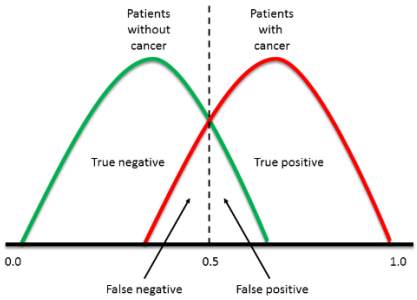
Sensitivity (Is it there) (True positive)

The sensitivity of a test refers to how many cases of a disease a particular test can find. A very sensitive test is likely to give a fair number of false-positive results, but almost no true positives will be missed. In mammography sensitivity is the probability of finding a cancer when the cancer exists. **Diagnosing a patient correctly.**

Specificity (What is it) (True Negative)

The specificity of a test refers to how accurately it diagnoses a particular disease without giving false-positive results. In mammography the probability of a normal mammogram when no cancer exists.

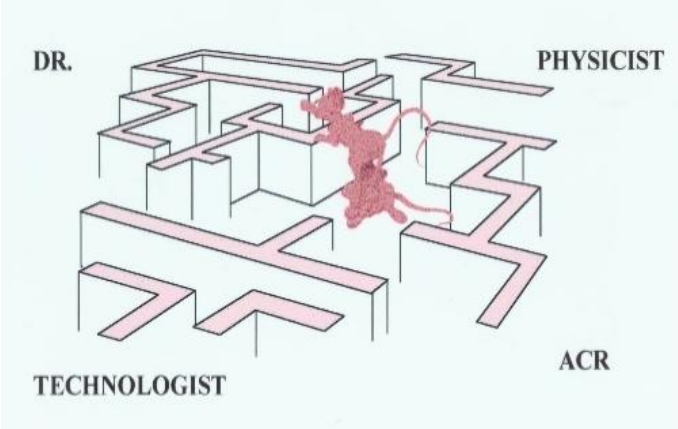
Statistical Terms in Mammography



- **Digital Breast Tomosynthesis (DBT)**

- The continued goal for screening mammography is to improve the **sensitivity and specificity** rates in an effort to diagnose cancers at an earlier stage to improve outcomes with a minimal dose to the patient.
- DBT **has proven its efficacy** in breast imaging by:
  - Reducing patient recall rates.
  - Providing an alternate for patients with dense breast.
  - Reducing biopsy rates.
  - Improving sensitivity and specificity.

The Mammography Team



The Mammography Accreditation Program provides facilities with:

- Peer review.
- Constructive feedback.
- Staff qualifications.
- Equipment.
- Quality control/quality assurance.
- Image quality.
- Radiation dose.

The Mammography Facility Database is updated periodically based on information received from the four FDA-approved accreditation bodies: the American College of Radiology (ACR), and the state of Arkansas.

- To be accredited by the States of Arkansas, a facility must be located in that accreditation body's state.

- Under MQSA regulations, a facility located in a state with an FDA-approved accreditation body may be accredited either by the state or by the ACR.
- However, if state law requires every facility to have state accreditation or state certification, facilities must satisfy those regulations. These state requirements are independent of MQSA.

Obtaining a New Mammography Certification

- To obtain a new mammography certification, choose either the State of Texas Mammography Accreditation Program or the American College of Radiology (ACR) as the facility's mammography accreditation body.

Contact the Mammography Accreditation Program at (512) 231-5700 at least 30 days prior to facility opening date, for information regarding the required documents, the correct forms and fees.

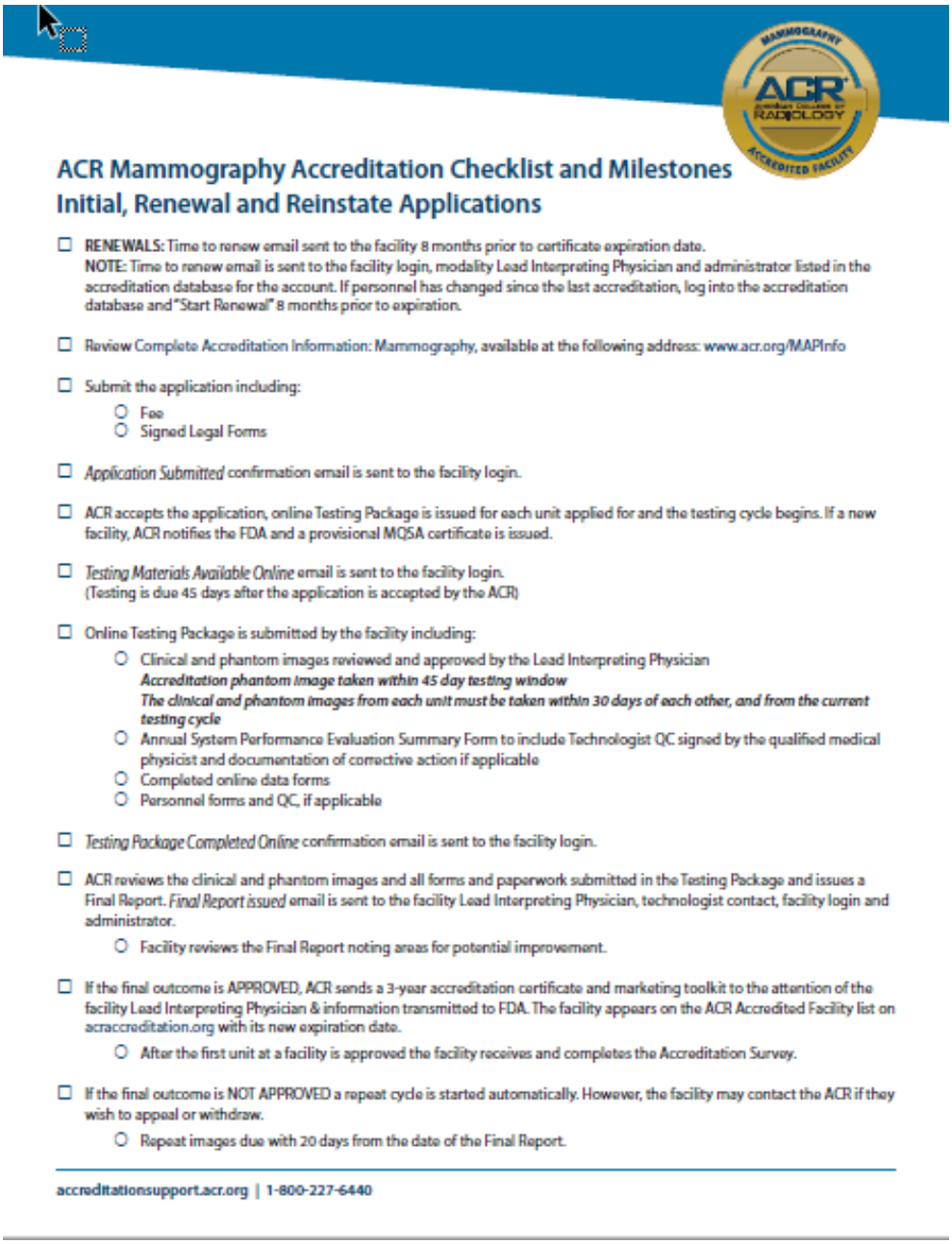
FDA Required Breast Tomosynthesis Training

- ❑ The Mammography Quality Standards Act (MQSA) requires that before a mammography facility can legally perform mammography, it must be certified.
- ❑ Before a facility can be certified, it must meet applicable MQSA requirements, including those established by its accreditation body to obtain accreditation.
- ❑ To begin the process, the facility must first contact its accreditation body and apply for accreditation.

Accreditation and Certification Overview

The FDA-approved accreditation bodies (AB) are:
American College of Radiology
1891 Preston White Dr.
Reston, VA 20191
1-800-227-6440

State of Arkansas
Arkansas Department of Health
4815 W. Markham, Slot 30
Little Rock, Arkansas 72205-3867
1-501-661-2301



ACR Mammography Accreditation Checklist and Milestones
Initial, Renewal and Reinstate Applications

- ☐ **RENEWALS:** Time to renew email sent to the facility 8 months prior to certificate expiration date.
  NOTE: Time to renew email is sent to the facility login, modality Lead Interpreting Physician and administrator listed in the accreditation database for the account. If personnel has changed since the last accreditation, log into the accreditation database and "Start Renewal" 8 months prior to expiration.
- ☐ Review Complete Accreditation Information: Mammography, available at the following address: www.acr.org/MAPInfo
- ☐ Submit the application including:
  - ○ Fee
  - ○ Signed Legal Forms
- ☐ *Application Submitted* confirmation email is sent to the facility login.
- ☐ ACR accepts the application, online Testing Package is issued for each unit applied for and the testing cycle begins. If a new facility, ACR notifies the FDA and a provisional MQSA certificate is issued.
- ☐ *Testing Materials Available Online* email is sent to the facility login.
  (Testing is due 45 days after the application is accepted by the ACR)
- ☐ Online Testing Package is submitted by the facility including:
  - ○ Clinical and phantom images reviewed and approved by the Lead Interpreting Physician
    Accreditation phantom image taken within 45 day testing window
    The clinical and phantom images from each unit must be taken within 30 days of each other, and from the current testing cycle
  - ○ Annual System Performance Evaluation Summary Form to include Technologist QC signed by the qualified medical physicist and documentation of corrective action if applicable
  - ○ Completed online data forms
  - ○ Personnel forms and QC, if applicable
- ☐ *Testing Package Completed Online* confirmation email is sent to the facility login.
- ☐ ACR reviews the clinical and phantom images and all forms and paperwork submitted in the Testing Package and issues a Final Report. *Final Report issued* email is sent to the facility Lead Interpreting Physician, technologist contact, facility login and administrator.
  - ○ Facility reviews the Final Report noting areas for potential improvement.
- ☐ If the final outcome is APPROVED, ACR sends a 3-year accreditation certificate and marketing toolkit to the attention of the facility Lead Interpreting Physician & information transmitted to FDA. The facility appears on the ACR Accredited Facility list on acraccreditation.org with its new expiration date.
  - ○ After the first unit at a facility is approved the facility receives and completes the Accreditation Survey.
- ☐ If the final outcome is NOT APPROVED a repeat cycle is started automatically. However, the facility may contact the ACR if they wish to appeal or withdraw.
  - ○ Repeat images due with 20 days from the date of the Final Report.

accreditationsupport.acr.org | 1-800-227-6440

Mammography Accreditation
Clinical Image Review Sheet

ACR American College of Radiology — Quality in Our Image

Use this form to review your clinical images before you submit them for accreditation, or as part of your facility QA.

ATTRIBUTE	PROBLEM(S) NOTED	POSSIBLE CAUSE(S)
A. Positioning	☐ MLO: Poor visualization of posterior tissues ☐ MLO: Sagging breast ☐ MLO: Inadequate amount of pectoral muscle shown on image ☐ MLO: Inadequate inframammary fold (IMF) ☐ CC: Poor visualization of posterior tissues ☐ CC: Excessive exaggeration ☐ Portion of breast cut off ☐ Skin folds ☐ Other body parts projected over breast ☐ Breast positioned too high on image receptor ☐ Posterior nipple line (PNL) on CC *not* within 1 cm of MLO PNL	☐ Technologist technique ☐ Inappropriate mammographic projections ☐ Wrong size recording system ☐ Uncertain
B. Compression	☐ Poor separation of parenchymal densities ☐ Non-uniform exposure levels ☐ Patient motion	☐ Under compression by technologist ☐ Unsuitable compression device ☐ Technologist positioning of compression device ☐ Uncertain
C. Exposure Level	☐ Generalized underexposure ☐ Generalized overexposure ☐ Inadequate penetration of dense areas ☐ Excessive penetration of lucent areas	☐ Film development ☐ Under compression with phototiming ☐ Radiologist preference ☐ Phototimer variability ☐ Uncertain
D. Contrast	☐ Inadequate contrast ☐ Excessive contrast	☐ Film development ☐ Improper kVp ☐ Excessive scatter ☐ Underexposure ☐ Digital: window width too wide ☐ Digital: window width too narrow ☐ Uncertain
E. Sharpness	☐ Poor delineation of linear structures ☐ Poor delineation of feature margins ☐ Poor delineation of microcalcifications	☐ Patient motion ☐ Poor screen contact ☐ Film-screen selection ☐ Uncertain
F. Noise	☐ Visually striking mottle pattern ☐ Noise limited visualization of detail	☐ Film development ☐ Recording system speed ☐ Improper kVp ☐ Digital: inadequate SNR ☐ Digital: window width too narrow ☐ Uncertain
G. Artifacts	☐ Punctate or lint ☐ Scratches or pickoff ☐ Roller marks ☐ Grid related artifacts ☐ Hair, deodorant, etc ☐ Film handling ☐ Film fogging ☐ Poor screen-film alignment ☐ Digital: image receptor artifact ☐ Digital: laser printer artifact ☐ Digital: laser printer "scanning" lines	☐ Poor screen maintenance ☐ Development related ☐ Unsuitable grid or Bucky ☐ Film exposed to light ☐ Lack of patient preparation ☐ Poor cassette closure ☐ Damaged cassette ☐ Digital: detector calibration (e.g. uniformity calibration) ☐ Digital: foreign objects calibrated into calibration file ☐ Digital: laser printer needs service ☐ Uncertain
H. Exam ID	☐ Patient name and additional patient identifier ☐ Facility name and location (city, state and zip) ☐ Date of examination ☐ View and laterality ☐ Unit identification (if more than one) ☐ Technologist identification ☐ Cassette-screen identification	☐ Technologist error ☐ Missing or non-standard labeling method ☐ Improper positioning of label ☐ Uncertain

DBT Accreditation

Chronology of DBT Accreditation

- 2011 when DBT approved FDA (AB) did not have a process in place to accredit new technology.
- Temporary Certificate Extension Program to allow for the new technology to be legally performed under MQSA.
- April 6, 2018, FDA ended the Certificate Extension Program for DBT.
- April 9, 2018, all MQSA accrediting were approved to accredit DBT systems.

Mammography Accreditation Program (MAP)

- **MAP**
  - Provides facilities with peer review and constructive feedback.
  - Personnel qualifications.
  - Equipment.
  - Quality control/Quality Assurance,
  - Image quality.
  - Radiation dose.
- **MAP**
  - DBT accreditation is unique because the FFDM and DBT unit are housed in a single unit.
  - Differences in technology require the components of the system to be accredited as two separate units.
  - Both components must be accredited even if you only utilize the DBT system.
  - DBT mode relies on a properly functioning FFDM system.
  - MQSA onsite inspection requires individual inspection of both components.

Scenario 1. DBT - 2D Synthesized Images Available (whether or not 2D-Syn is used for interpretation)

Testing to be Submitted by Facility		
Type	**2D FFDM Accreditation**	**DBT Accreditation**
Clinical Testing (a clinical set = cc and mlo of 1 fatty and 1 dense case)	Whatever is primarily used clinically: 2D clinical set (cc and mlo), **or** 2D-Syn clinical set (cc and mlo), **or** 2D cc and 2D-Syn mlo clinical set, **or** 2D-Syn cc and 2D mlo clinical set	2D-Syn clinical set (cc and mlo), **or** 2D cc and 2D-Syn mlo clinical set, **or** 2D-Syn cc and 2D mlo clinical set
Phantom Testing	2D phantom image	3D best-slice phantom image*

Scenario 2. DBT - 2D Synthesized Images Not Available on System

Testing to be Submitted by Facility		
Type	**2D FFDM Accreditation**	**DBT Accreditation**
Clinical Testing (a clinical set = cc and mlo of 1 fatty and 1 dense case)	2D clinical set	2D clinical set
Phantom Testing	2D phantom image	3D best-slice phantom image*

Once you have 8 hours Tomography Training

Peer to peer

- Peer to peer review, but must be specific topics

TO: _____

FROM: _____

DATE: _____

MR # _____

ISSUE

Case Overview: _____

Please complete a Focused Peer Review for the case listed above.
Return to Dr. ..... before __/__/_____. Thank you!

Reviewdate: ___/___/__ _____ _____
Reviewer Name **Reviewer Signature**

Division Director's or Reviewer's Comments:

Interpreting Radiologists Comments: _____

Quality Review:

Diagnosis	Class	Description of Disagreement	Case Disposal (Circle one)
			A. No further action B. Issue addendum C. Request for skill enhancement D. Reportable event

Class 1 = Concur with the interpret
Class 2 = Difficult diagnosis, not ordinarily expected to be made
Class 3 = Significant discrepancy, no clinical impact
Class 4 = Significant discrepancy, clinical impact
Class 5 = Not applicable

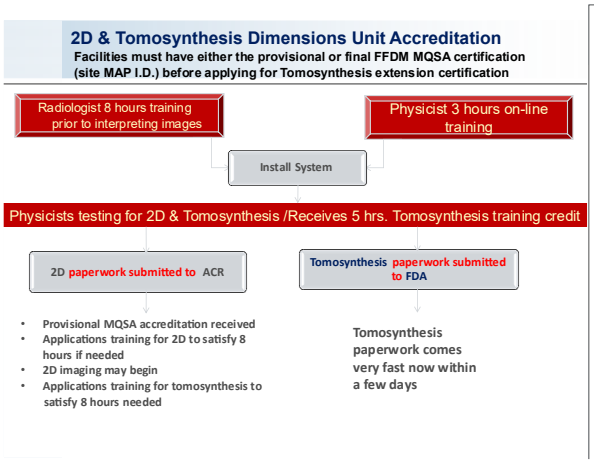
Cause of Error:

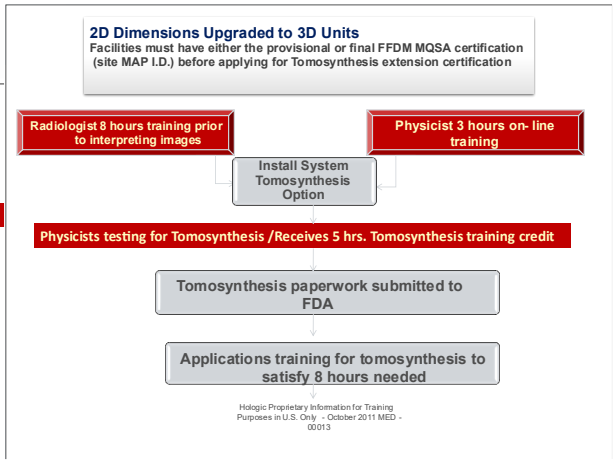
( ) Perceptive ( ) Problem Solving ( ) Did not follow protocol
( ) System Related: Old films not provided, labs not checked ( )Technologist Related: Incomplete or poor quality study

Appeal:

Chairman's Decision:
( ) No action
( ) Change in Privilege or Credentials
( ) Policy, Protocol or Guideline Review
( ) Provider Letter / Counseling
( ) Written Warning (1st), (2nd)

Division Director.....Vice Chair.....Chairman.....Date .../...../....





Do personnel who have received 8 hours of DBT training specific to one manufacturer's system meet the requirements for the initial 8 hours of DBT training for another manufacturer's system?

Yes. Personnel need to have acceptable documentation of a total of 8 hours of training in the new mammographic modality. While the FDA's Division of Mammography Quality Standards (DMQS) recognizes there are some features that are unique to each specific DBT system, **personnel need only to obtain training on one DBT** system, or **general DBT training**, to meet the new modality training requirement.

Tomosynthesis Training

- Radiologists 8 hours of new modality training for Tomosynthesis
- Physicists 8 hours of new modality training for Tomosynthesis
- Technologists 8 hours of new modality training for Tomosynthesis

Tomosynthesis Training for Radiologists:

- Radiologists must meet all MQSA requirements.
- Radiologist will need 8 hours of training in the interpretation of breast tomosynthesis will be offered through non-CME courses.

PERSONNEL QUALIFICATIONS: INTERPRETING PHYSICIANS WHO ARE QUALIFIED TO INTERPRET DBT MAMMOGRAMS

List the current interpreting physicians who:

(1) meet all the requirements of 21 CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999; and (2) have 8 hours of initial new-modality training in DBT, either including or supplemented by training in the unique features of the specific manufacturer's DBT system.

Lead Interpreting Physician Attestation to Staff Personnel Qualification

Example of Attestation:

- To the best of my knowledge and my belief, the information provided in this document is true and correct. I understand that FDA may request additional information to substantiate the statements made in the document. I understand that knowingly providing false information in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to $10,000 fine and imprisonment of up to five years, or civil liability under MQSA, or both.
- Signature (Lead Interpreting Physician) _____
- Print Name _____
- Date_____

Qualified Radiologic Technologist

Certified by:

- American Registry of Radiologic Technologists (ARRT), ***or***
- American Registry of Clinical Radiologic Technologists, ***or***
- Licensed to perform general radiographic procedures in a state

AND

- 40 hours of training in mammography including:

- Training in breast anatomy and physiology, positioning and compression, QA/QC techniques, and imaging of patients with breast implants, ***and***
- 25 mammography examinations under direct supervision of an appropriate MQSA-qualified individual.

Certified Mammographer

- 8 hours of training in using a mammographic modality (e.g., digital, tomosynthesis), before beginning to use that modality independently.
- **Continuing Experience : Perform 200 mammographic examinations over a 24-month period**

Continuing Education :

- **15 category 1 CE's/ in mammography during 36 months.**
- Once certified in mammography, Registered Technologists (R.T.s) must complete 24 Category A or A+ continuing education (CE) credits each biennium.
- A two-year period that begins at the start of his or her birth month.

How must I document initial new modality training on a DBT system?

8 hours of general training in DBT **or**

8 hours of training on a particular manufacturer's DBT system.

Both count towards the new mammographic modality training requirement.

- Documentation may include:
- Letters.
- Certificates of completion or other documents from manufacturer's formal training courses.
- Confirming letter from a Continuing Education Unit granting organization.
- An attestation about experience with investigational units using DMQS's recommended form.

Tomosynthesis Computer-Aided Detection (CAD)

- Just as in conventional 2D digital mammography, CAD may help find suspicious objects in a tomosynthesis dataset.
- However, there are differences in the use for CAD in tomosynthesis.
- Conventional 2D CAD helps find both masses and microcalcifications.

- In tomosynthesis, there may be less of a need for a mass-detection algorithm, because often the masses and distortions are found very quickly and easily by the Radiologist.

Computer-Aided Detection (CAD)

- **The Use of CAD in DBT: Developed to detect suspicious soft-tissue densities in DBT planes and has the ability to extract abnormalities from the planes were detected and blend into the synthesized image.**
    - Sensitive algorithm used for DBT are valuable for micro calcifications.
    - Assist the radiologist in speeding up the search for groupings of micro calcifications.
    - Reduced need for mass and distortion algorithm when in the DBT mode because DBT is superior in this area.
    - 2018 study revealed the use of CAD in conjunction with DBT resulted in 29% faster interpretation time.

CAD Use in DBT

The situation is different in the case of microcalcifications.

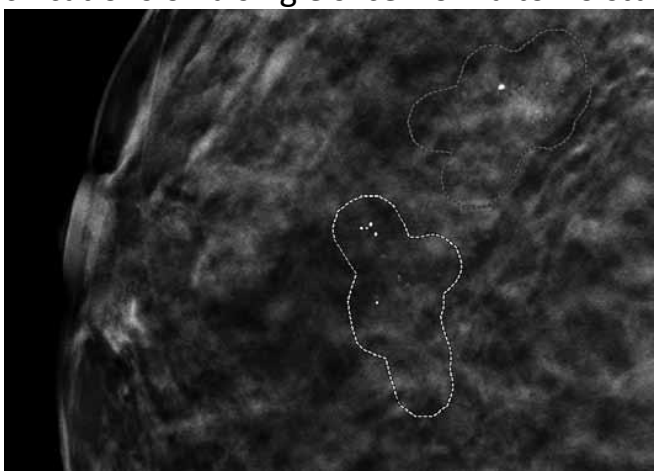
It can be time consuming to have to carefully search a large number of slices, and there is the potential for the reviewer to overlook some subtle microcalcifications.

An efficient and sensitive calcification CAD algorithm could help speed up the search.

For example, CAD could identify suspicious calcification clusters on a scout image and rapidly navigate to the appropriate slices of interest.

CAD Marking Microcalcifications

- An example of a CAD algorithm marking potentially suspicious microcalcifications on a single slice from a tomo study.



Hologic has developed an extension to its Image Checker® CAD product line for identification of potential calcifications in Tomosynthesis slices.

ImageChecker 3D Calc CAD is available in Canada and throughout the European Economic Area and in other countries.

Breast Tomo: CPT Codes

- 2015 CMS created billing codes for Medicare patients for DBT screening and diagnostic studies after receiving evidence of the technology's effectiveness.
- DBT Codes are used in conjunction with the 2D mammography procedure codes.
- Some insurance companies deny the DBT charges because they view DBT as investigational.
- Number of insurance providers allowing charges continue to increase.

CPT Code

- 77061 Digital Breast Tomosynthesis Unilateral
- 77062 Digital Breast Tomosynthesis Bilateral
- 77063 Screening DBT Bilateral

** Coded in addition to the primary code 77067

- **Note:** Patients will not be responsible for any co-pays associated with the new screening DBT codes.
- The screening tomosynthesis add-on code, 77063, would be subject to the same co-insurance/deducible policies as other screening mammography services.
- Code G0279 relates to a diagnostic procedure; therefore, it would not follow the same policies as those established for the screening studies.

Site of Service

Physician Office Setting

In the office setting, a physician who owns the radiology equipment and performs the service may report the global code without a -26 modifier.

Hospital Outpatient Setting

When the mammography service is performed in the hospital outpatient setting, physicians may not submit a global charge to Medicare because the global charge includes both the professional and technical components of the service.

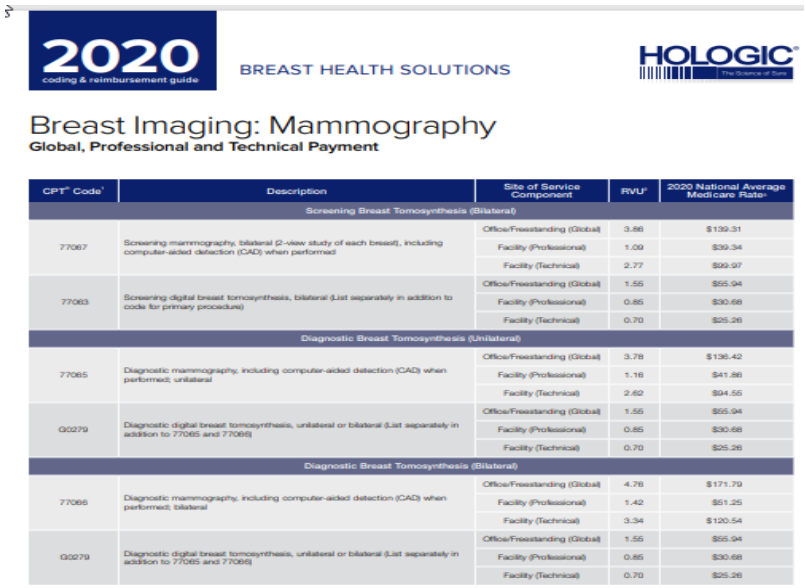
If the procedure is performed in the hospital outpatient setting, the hospital may bill for the technical component of the mammography service as an outpatient service.

Hospital Inpatient Setting

Charges for the mammography services occurring in the hospital inpatient setting would be considered part of the charges submitted for the inpatient stay and payment would be made under the Medicare MS-DRG payment system. However, the physician may still submit a bill for his/her professional services regardless. Note: Medicare reimburses for services when the services are within the scope of the provider's license and are deemed medically necessary.

Table 1: 2018 Medicare Reimbursement for Mammography, With or Without CAD and Digital Breast Tomosysthesis Procedures[8]
(Reflects national rates, unadjusted for locality)

CPT/HCPCS Code[9]	Reimbursement Component	Medicare Physician Fee Schedule Payment[10]	APC	Hospital Outpatient Payment[11]
Mammography, 2D – Screening/Diagnostic				
77065*** Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral	Professional (-26)	$40.32	N/A	$96.12****
	Technical (-TC)	$96.12****		
	Global	$136.44 ****		
77066*** Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral	Professional (-26)	$50.04	N/A	$122.76****
	Technical (-TC)	$122.76****		
	Global	$172.80****		
77067*** Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed	Professional (-26)*	$38.16	N/A	$101.52****
	Technical (-TC)**	$101.52****		
	Global	$139.68****		
Tomosynthesis – Screening/Diagnostic				
77063 Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)	Professional (-26)	$30.60	N/A	$25.56
	Technical (-TC)	$25.56		
	Global	$56.16		
G0279 Diagnostic digital breast tomosynthesis, unilateral or bilateral	Professional (-26)	$30.60	N/A	$25.56
	Technical (-TC)	$25.56		
	Global	$56.16		



2020 coding & reimbursement guide

BREAST HEALTH SOLUTIONS

HOLOGIC

Breast Imaging: Mammography

Global, Professional and Technical Payment

CPT® Code*	Description	Site of Service Component	RVU*	2020 National Average Medicare Rate*
Screening Breast Tomosynthesis (Bilateral)				
77067	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed	Office/Freestanding (Global)	3.86	$139.31
		Facility (Professional)	1.09	$39.34
		Facility (Technical)	2.77	$99.97
77063	Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)	Office/Freestanding (Global)	1.55	$55.94
		Facility (Professional)	0.85	$30.68
		Facility (Technical)	0.70	$25.26
Diagnostic Breast Tomosynthesis (Unilateral)				
77065	Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral	Office/Freestanding (Global)	3.78	$136.42
		Facility (Professional)	1.16	$41.86
		Facility (Technical)	2.62	$94.55
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (List separately in addition to 77065 and 77066)	Office/Freestanding (Global)	1.55	$55.94
		Facility (Professional)	0.85	$30.68
		Facility (Technical)	0.70	$25.26
Diagnostic Breast Tomosynthesis (Bilateral)				
77066	Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral	Office/Freestanding (Global)	4.78	$171.79
		Facility (Professional)	1.42	$51.25
		Facility (Technical)	3.34	$120.54
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (List separately in addition to 77065 and 77066)	Office/Freestanding (Global)	1.55	$55.94
		Facility (Professional)	0.85	$30.68
		Facility (Technical)	0.70	$25.26

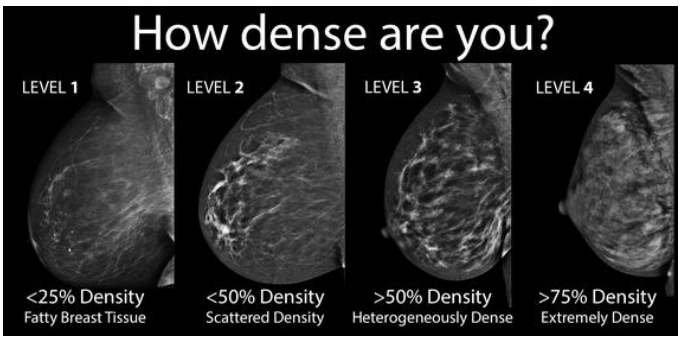
Current Supplemental Screening Options

- **ACR recommends breast cancer screening based on risk factors:**
  - **Intermediate Risk**
    - Screening Mammogram with US or MRI as an adjunct depending on patient specific risk factors.
  - **High Risk**
    - Women with prior mantle radiation between 10-30 years mammography is recommended 8 years after therapy but not before age 25 Screening Mammogram and/or DBT.
      - Women with a genetic predisposition, annual screening is recommended beginning 10 years earlier than the affected relative at the time of diagnosis but not before age 20.
      - Annual screening MRI is recommended in high-risk women as an adjunct to mammography.
      - Screening Breast Ultrasound.
      - Breast MRI.
      - 3D Digital Breast Tomosynthesis.

ACR recommends breast cancer screening based on risk factors

- Average Risk Beginning at 40.
  - Screening Mammogram and/or DBT.
- Ultrasound (US) useful as an adjunct to mammography in women with dense breast.

Breast Density Why Does It Matter?

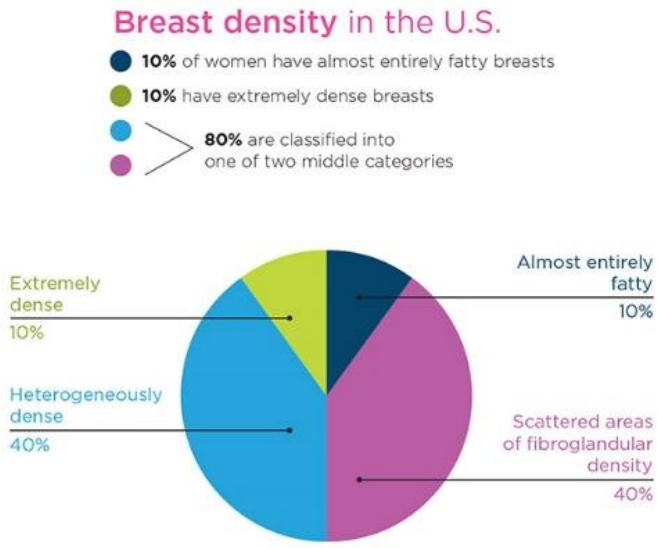


Breast Imaging Reporting and Data System (BI-RADS)

- **Breast Tissue Composition**
  1. The breasts are almost entirely fatty.
  2. There are scattered areas of fibro glandular density.
  3. The breasts are heterogeneously dense which can obscure small masses.
  4. The breasts are extremely dense, which lowers sensitivity of mammography.

Breast Composition

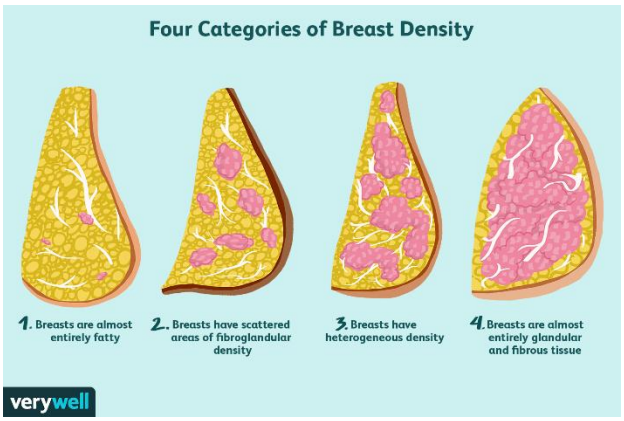
- In the BI-RADS edition 2013 the assignment of the breast composition is changed into **a, b, c and d-categories** followed by a description:
- **a**- *The breast are almost entirely fatty.*
  Mammography is highly sensitive in this setting.
- **b**- *There are scattered areas of fibroglandular density.*
  The term density describes the degree of x-ray attenuation of breast tissue but not discrete mammographic findings.
- **c**- *The breasts are heterogeneously dense, which may obscure small masses.*
  Some areas in the breasts are sufficiently dense to obscure small masses.
- **d** - *The breasts are extremely dense, which lowers the sensitivity of mammography.*



About half of all women have breasts that fall into the dense category (levels 3 and 4).

Breast Imaging Reporting and Data System (BI-RADS)

- **Breast Tissue Composition**
  - According to the ACR's BI-RAD's Atlas 5th edition described breast density:
    - Category "C" density could obscure detection of small masses.
    - Category "D" density can lower the sensitivity of mammography.



Breast Density Measurements

- Screening of women with dense breast is complicated by three issues:
  - Dense tissue mask cancers and reduces sensitivity by tissue overlap.
  - Increased risk of developing breast in women with dense breast tissue.
  - Increased risk of developing more aggressive breast cancers in women with dense breast tissue.

Breast Density

- A patient is considered to have dense breast tissue if the radiologist categorizes it in categories “C” or “D”.
- 40% of women aged 40-years and older fall into the dense breast categories.
- Dense breast tissue is now recognized as a risk factor for developing breast cancer.
- Four to six times more likely to develop a breast cancer than women with fatty breast.
- Radiologist categorization of breast density is subjective visual assignment.
- Objective and more reproducible methods of assessment have been developed that measure breast density directly from the mammogram.
  - Example is a software product called VolparaDensity:
    - Based on the true 3D properties of a woman’s breast.
    - Volumetric breast density is calculated by determining the volume of fibro glandular tissue in the breast divided by the total volume of tissue within the breast.

- Method provides reproducible measurement.

Breast Imaging &Reporting & Data System

- BI-RADS (Breast Imaging-Reporting and Data System).
- A risk assessment and quality assurance tool developed by American College of Radiology that provides a widely accepted lexicon and reporting for imaging of the breast. It applies to mammography, ultrasound, and MRI. This article reflects the 5th edition, published in 2013[1].

BI-RADS Classifications

Breast imaging studies are assigned one of seven assessment categories:

- BI-RADS 0: Incomplete
  - Need additional imaging evaluation (additional mammographic views or ultrasound) and/or
  - For mammography, obtaining previous images not available at the time of reading.

- BI-RADS 1: Negative
  - Symmetrical and no masses, architectural distortion, or suspicious calcifications.

- BI-RADS 2: Benign
  - 0% probability of malignancy.

- BI-RADS 3: Probably benign
  - <2% probability of malignancy.

- BI-RADS 4: Suspicious for malignancy
  - 2-94% probability of malignancy.

For mammography and ultrasound, these can be further divided:

- **BI-RADS 4A**: Low suspicion for malignancy (2-9%).

- **BI-RADS 4B:** moderate suspicion for malignancy (10-49%).
- **BI-RADS 4C:** high suspicion for malignancy (50-94%).
- Biopsy should be considered.

- **<u>BI-RADS 5</u>: Highly suggestive of malignancy**
  - >95% probability of malignancy.
  - Appropriate action should be taken.

- **<u>BI-RADS 6</u>: Known biopsy-proven malignancy**

When there are multiple findings, the BI-RADS category for the exam is assigned the highest category in the following hierarchy, from lowest to highest: 1, 2, 3, 6, 0, 4, 5.

The **vast majority of screening mammograms fall into BI-RADS 1 or 2 [4].** Screening mammograms with **suspicious findings should generally be assigned BI-RADS 0 to indicate a callback for diagnostic evaluation**, meaning additional views to confirm and further evaluate the finding.

Image Management

DBT places a large demand on image management because of the size of the image files:

- DBT image studies are 10 times the size of 2D images.
  - Need full integrated PACS.
  - Adequate image storage space.
  - Adequate bandwidth for the transfer of images to offsite storage.
  - Image compression.
    - MQSA advised if a mammogram was originally produced in a digital form (FFDM/DBT) it should be retained and in a fully retrievable form, either as an uncompressed digital image or using only Lossless data compression.

Image Compression Terms

- "Lossless" Compression
  - Refers to the methods of data compression in which all the original data is preserved and can be completely restored.

- "Lossy" Compression
  - Refers to methods in which the original data cannot be completely reconstituted.

MQSA Baseline Standard Requirements for Image Retention

- Length of time for retention depends on both the exam date and the date (if any) when the patient last returned to the facility.
- Minimum of at least 5-year retention.
- If patient returned within that 5-year window only the most recent 5-year exams must be retained.
- If patient doesn't return within that 5-year time the exams must be retained an additional 5-years for a total of 10 years.
- State or facility specific requirements may differ.

MQSA Transfer of Mammograms

- The original digital mammography (FFDM and DBT) images are rarely transferred.
- Digital copies of mammograms are usually released while the facility retains the original data sets of the images.

DBT in Clinical Practice

- The use of 3D in clinical practice varies between facilities
- Facilities make decisions about utilization based on:
  - Number of digital systems available.
  - Volume of procedures.
  - 3D for diagnostic only.
  - 3D for screening women with dense breast or a family history.
  - 3D for all patients or allow patient to choose.
  - No existing standard for the use of tomosynthesis.

Implementing DBT into Clinical Practice

Protocols vary from facility to facility and clinical trials continue to identify the optimal ways to use 2D and 3D mammography.

- Example Protocols
  - Both 2D+3D in CC & MLO positions for screening.
  - 2D CC's + 3D MLO's for screening patients.
  - 3D MLO's only for screening.
  - 3D imaging for diagnostic patients only.
  - 3D imaging only for patients with dense breast.
- The future of breast screening may be moving to a more "patient centric" approach.
- The FDA's approval of the use of C-view 2D images in place of conventional 2D exposure has led to suggested changes to screening protocols.
- Clinical trials will determine changes in clinical practice for the future.
- Some of the considerations:
  - Which patients will benefit from 3D?
  - Screening vs Diagnostic?
  - How does 3D impact workflow?
  - How does 3D impact Radiologist interpretation time?
  - Cost effectiveness of 2D+3D versus 2D + Ultrasound?
- Image storage requirements.

The Mammographer and DBT

Mammographer's Role in Performing 3D

- Slight differences in manufacturers variations.
- Very similar to performing traditional 2D.
- Positioning is similar.
- Patient explanation regarding the tube arc.
- Scans vary between 4-25 seconds.
- Breathing instructions are important.
- Additional views used in 2D aren't necessary in 3D.
- Reduces recalls for additional views on screening patients and can expedite breast ultrasound.
- Skin markers are still a valuable tool in 3DManufacturers suggest both DM and 3DBT should be used together in breast cancer screening. Some limitations include the increased reading time and image storage capacity.

- Main concern of introducing single or double-view 3DBT in screening together with DM is the additional dose to the patient or to the healthy woman who attends screening for early breast cancer diagnosis.
- There is the radiation protection requirement to keep the dose as low as reasonably practicable or in other words, to make sure that the diagnostic advantage of 3DBT outweighs the additional dose to the patient.