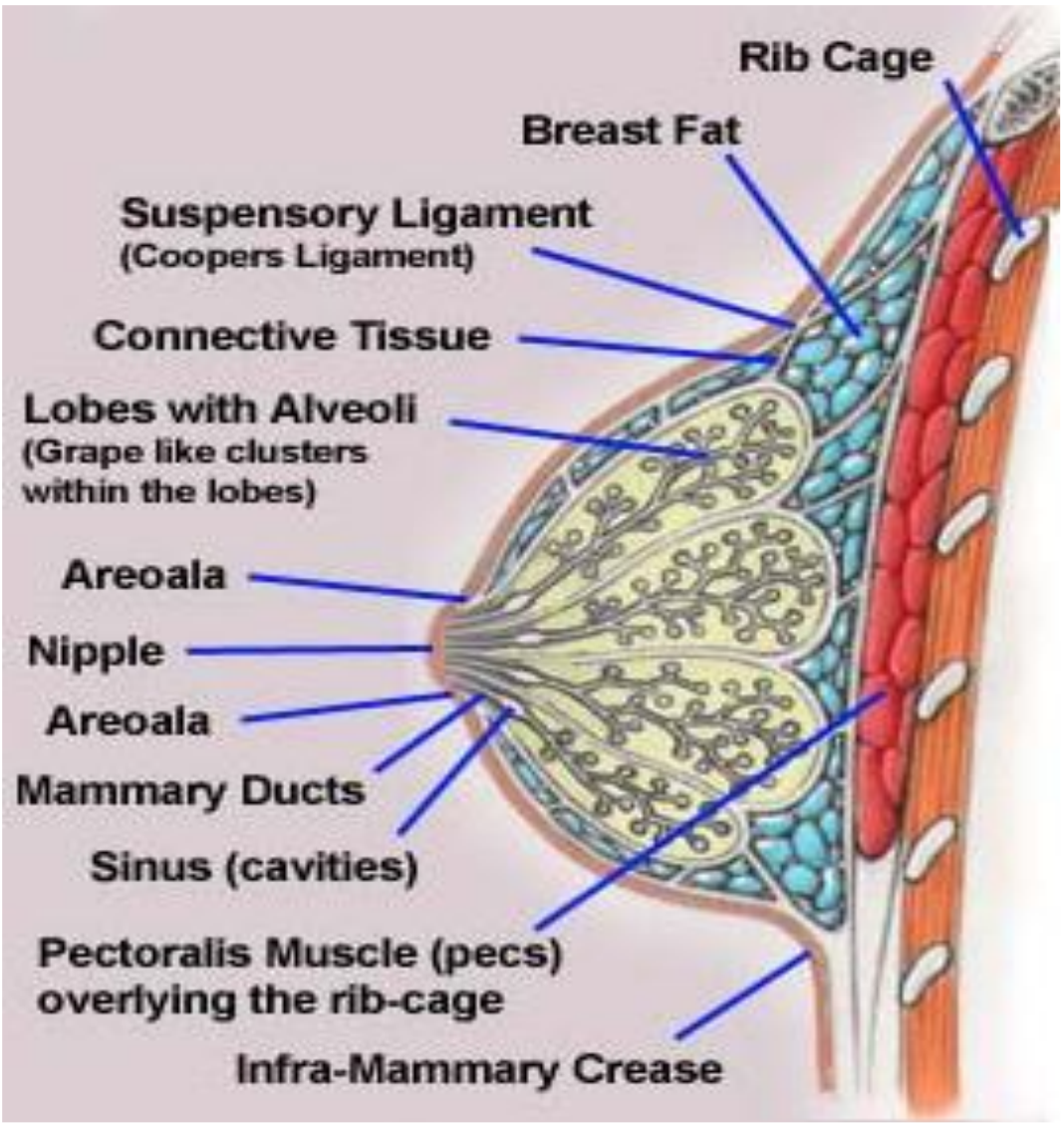
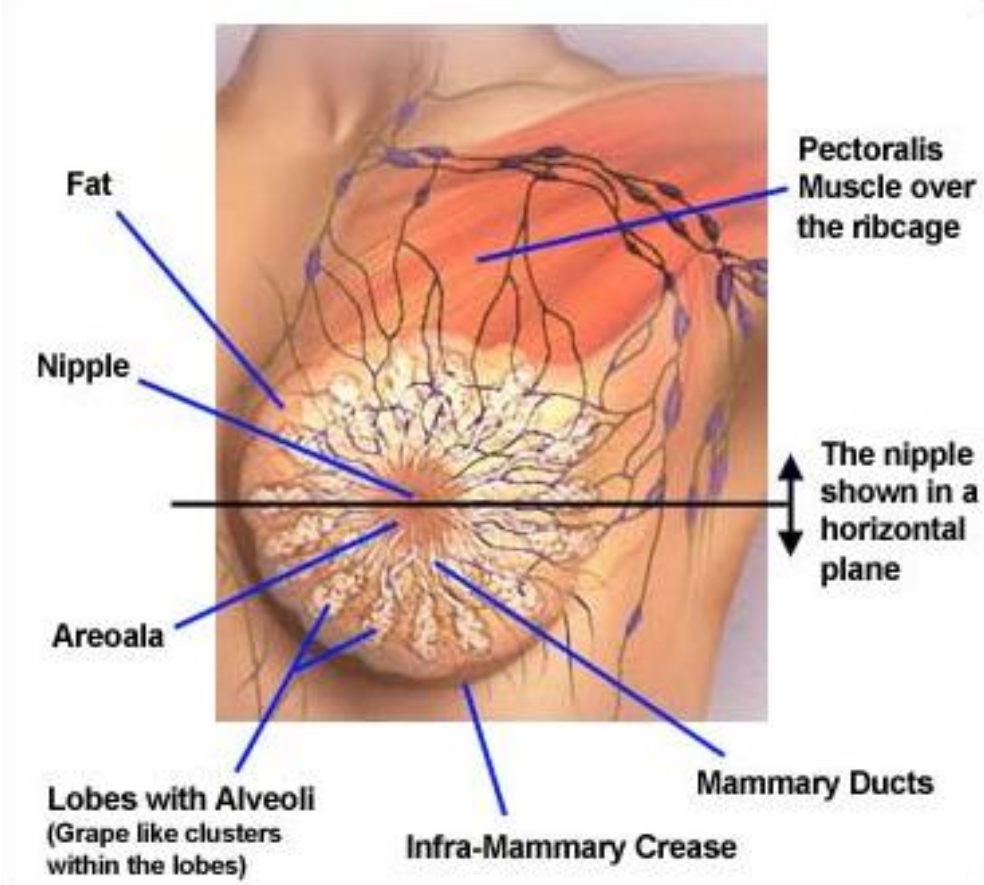
Digital Mammography and Clinical Applications

Breast Cancer Statistics:

- About 13% (about 1 in 8) of U.S. women are going to develop invasive breast cancer in the course of their life.
- In 2026, an estimated 316,950 new cases of invasive breast cancer are expected to be diagnosed in women in the U.S., along with 59,080 new cases of non-invasive (in situ) breast cancer.
- About 2,800 new cases of invasive breast cancer are expected to be diagnosed in men in 2026. Lifetime risk is 1 in 1,000.
- As of January 2026, there are more than 4 million women with a history of breast cancer in the U.S. This includes women currently being treated and women who have finished treatment.
- Breast cancer is the most commonly diagnosed cancer among American women.
- In 2026, it's estimated that about 30% of newly diagnosed cancers in women are going to be breast cancers
- A woman's risk of breast cancer nearly doubles if she has a first-degree relative (mother, sister, daughter) who has been diagnosed with breast cancer.
- Approximately 15% of women who get breast cancer have a family member diagnosed with it.
- About 5% to 10% of breast cancers can be linked to known gene mutations inherited from one's mother or father.
- Mutations in the BRCA1 and BRCA2 genes are the most common.
- The most significant risk factors for breast cancer are being a woman and getting older.
- Approximately 42,170 women in the U.S. are expected to die in 2026 from breast cancer.

BREASTCANCER.ORG

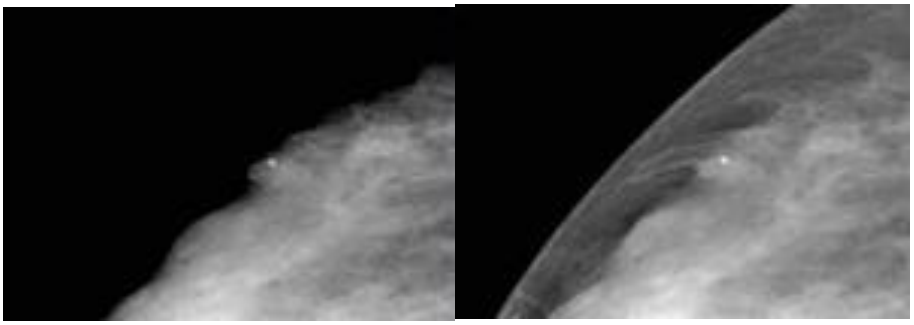

Rib Cage
Breast Fat
Suspensory Ligament
(Coopers Ligament)
Connective Tissue
Lobes with Alveoli
(Grape like clusters
within the lobes)
Areoala
Nipple
Areoala
Mammary Ducts
Sinus (cavities)
Pectoralis Muscle (pecs)
overlying the rib-cage
Infra-Mammary Crease



- A study of 42,760 women at 33 sites across the United States and Canada, including Johns Hopkins, found that digital mammography is better than standard X-ray mammography at locating cancer in young women and those with dense breast.

- The study was conducted by the American College of Radiology, funded by the National Cancer Institute, and reported September 16, 2005, in a special online publication of the *New England Journal of Medicine.*
- Digital mammography detected up to 28% more cancers than X-ray mammography in women 50 and younger, premenopausal and perimenopausal women, and women with dense breasts, according to the American College of Radiology Imaging Network (ACRIN) and the Digital Mammographic Imaging Screening Trial (DMIST).
- However, the ACRIN results showed no difference between digital and film (X-ray) mammography in detecting breast cancer for the general population of women.
- National Cancer Institute sponsored trial.

Stage	5 Year Relative Survival Rate According to the American Cancer Society
0	100%
I	98%
IIA	88%
IIB	76%
aIIIA	56%
IIIB	49%
IV	16%



Screen-film mammography: Headed the way of xeromammography?

In July 2015, fifteen years after full-field digital mammography (FFDM) first came into clinical use, the number of FFDM units in use as a percentage of all mammography units in use exceeded 97%. Although for the first several years after their introduction, the uptake of FFDM units was relatively slow — not until 2008 did the number of FFDM units reach 50% of the total number of units in use — it has accelerated in recent years. At the present time, there are less than 400 screen-film units currently in use in MQSA-certified facilities.

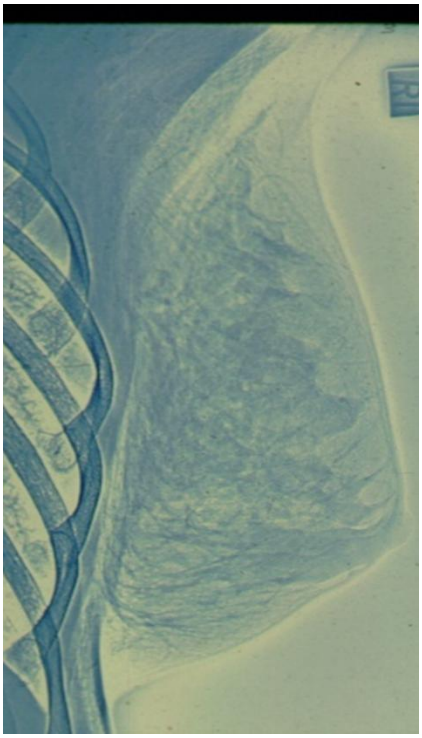
Yet despite the recent rapid drop in the number of screen-film units since 2008, screen-film facilities have been over-represented in facilities with image quality issues, evidenced by requests from FDA or accreditation bodies for Additional Mammography Reviews (AMR) and the ordering of Patient and Provider Notifications (PPN) by the FDA. When an accreditation body receives or discovers information that suggests inadequate image quality, or if the FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the accreditation body will review a facility's clinical images or other aspects of a facility's practice to assist FDA in determining whether the facility's practice poses a serious risk to human health. The AMR can help the agency determine whether a facility is in compliance with the quality standards. Based on an evaluation of the results of the AMR, the FDA may determine that mammograms performed by a facility were so inconsistent with established quality standards as to pose a significant risk to individual or public health and direct a facility to conduct a PPN, notifying all at-risk patients and their referring health care providers.

Between 2005 and 2014, facilities using screen-film mammography accounted for 61.5% of all AMR's and 62.6% of all PPN's.

Between 2009—the first year in which screen-film accounted for less than 50% of certified facilities—and 2014—when the use of screen-film had decreased to less than 5% of facilities, screen-film facilities still accounted for 38% of all AMRs and 42% of all PPNs.

In 2014, even with their greatly reduced numbers, facilities using screen-film units nevertheless accounted for one-quarter of all AMRs and two-thirds of all PPN's. With the very small number of screen film units left, and if the current trend continues, it seems that screen film mammography might go the way of xeromammography in the not too distant future. The overrepresentation of this technology in compliance issues serves as food for thought about the appropriateness of the declining use of screen- film mammography in the U.S.

XeroMammography Image



Compression: Another Critical Factor in Image Quality

- The mammography equipment industry has contributed technical innovations to improve the overall comfort of mammography while maintaining image quality.
- The FDA has cleared for U.S. marketing many devices, accessories, or features which may lessen the discomfort of breast compression.
- These include:
    - A cushion for the breast on the surface of the mammography unit.
    - Compression paddles with fixed or dynamic tilt that distribute compression across the front and back of the breast.
    - A curved compression paddle to fit some breast contours.
    - A compression paddle control device used by the patient, under the guidance of the technologist, to assist the technologist in adjusting the amount of compression.
- Another factor which plays an important role in quality imaging is breast compression.
- Inadequate compression played a role in up to 38% of image quality deficiencies?

Benefits of Compression

- Best reason breast thickness is even throughout the whole image.
- Reduce breast thickness, which reduces geometric blurring.
- Reduce motion, unsharpness.
- Reduce scatter radiation.
- Increases contrast.
- Separates superimposed breast tissue.
- Reduces radiation dosage.

Benefits of Digital Mammography

- Lower Dose.
- Improved Image Quality.
- Computer-aided diagnosis software.
- Softcopy review and digital archiving.
- Elimination of physical storage.
- **Large dynamic range** or depth of recorded signals.
- **Window width**- a parameter which adjusts the gray scale or contrast.
    - Window level- a parameter which adjusts the density of the image or black scales. This is the brightness of an image.
    - Increased exposure latitude- related to the dynamic range of exposure techniques that will produce an acceptable range of densities.
    - Directly related to the contrast- This is a wider range of acceptable exposures without repeating.

DIGITAL MAMMOGRAPHY TERMINOLOGY

- **Indirect capture** – first converts the x-rays into visible light with a scintillator. The visible light is then converted into an electrical signal.
- **Direct capture** – the x-rays are not converted into light but directly into an electrical signal.
- **Amorphous silicon** (a-si) uses a Scintillator made of Cesium iodide to convert x-rays into light which is then captured by the photodiodes.
- What was the scintillator used in film/screen?
- **Contrast resolution** – the number of shades of gray that a detector can capture
- **High contrast resolution** – capable of capturing thousands of shades of gray (far more than the human eye can appreciate) This permits the imaging of areas that would otherwise be under or overexposed on conventional film.
- **CCD** – charged coupled device – small computer chips which create a digital image used in Fischer SenoScan.
- **Micron** – a unit of length equal to one millionth (1/1,000,000) of a meter
- **Pixel** – the basic unit of the composition of an image on a television screen, computer monitor, or a similar display (picture element).

- **Pixel Pitch –** center of one pixel to the center of another pixel. One way a pixel matrix is measured. How else is a pixel matrix measured?
- **Scintillator** - a substance that glows when hit by high-energy particles or photons.
- **Amorphous selenium** (a-se) the Scintillator is replaced with the amorphous selenium plate that converts the x-ray photons directly onto electron-hole pairs.
- **DEL-** detector element.
- **Latitude**-1000:1- wide in digital allowing a broader range of exposures that will produce an acceptable image.
- **Dynamic Range-** depth of the recorded signal intensity, as gray-scale shades.
- **No more bucky**, it is now called an image receptor or image detector.
- **CPU - Central Processing Unit**-heart of every computer, extracts info from a permanent memory that loads an operating system program into the working memory.
- **Fiber Optics** – science of light transmission through very fine, flexible glass or plastic fibers.
- **SMPTE**– a test pattern used for evaluating monitor calibration (Society of motion picture and television engineering).
- **Raid** – redundant array of independent disks, provides image storage capabilities.
- **UPS** – uninterruptible power supply that provides conditional line power to the review station computer, the raid and the magneto-optical drive. During a power failure the UPS automatically engages without losing data.
- **Magneto-optical drive (MO**) – used to archive patient records for permanent long-term storage.
- **ADU** - analog to digital unit.
- **RMS** - root mean square.
- **Line Pair** – consists of two elements – a bar and a "space". The bar is the high attenuating element, and the space is the low attenuating element.
- **AWS** – acquisition workstation- the monitor the images are initially acquired on during the procedure in the mammography room.
- **RWS** – review workstation – the monitors the images are displayed on for the radiologist interpretation.
- **ROI** – region of interest.
- **CR** - computed radiology.

Fundamentals of Digital Acquisition

Algorithms:

Digital Mammography uses many different algorithms in the quality control program.

Algorithms are defined as a step-by-step problem-solving procedure, especially an established, recursive computational procedure for solving a problem in a finite number of steps

Thickness Equalization:

- The tissue equalization process happens automatically.
- Without equalization, window and level would be required to bring out detail.
- Tissue equalization allows visualization from the chest wall through the dense areas and to the skin line, without adjusting techniques and speed and without taking additional images.
- A process where the detector looks at variations in pixel density across the image and the estimates the thickness of the breast at each pixel.

- **Histogram** - a chart representing a frequency distribution.
- **DQE** – (detective quantum efficiency) an expression of the efficiency of an imaging system's transfer from its input to its output of both signal and noise.
    - It is expressed as a percentage.
    - It is the measure most represented of image quality in terms of an observer's ability to detect objects of interest in an image (Dose Efficiency).
    - The most important parameter in the digital mammography process.

Detector Performance is Commonly Quantified by Two Metrics:

- Modulation Transfer Function (MTF) a measure of resolution/spatial frequency response.
- Detective Quantum Efficiency (DQE) is a measure of dose efficiency.

MTF

The modulation transfer function is, as the name suggests, a measure of the transfer of modulation (or contrast) from the subject to the image.

Detective Quantum Efficiency (DQE)

- Even with a high MTF, at high spatial frequencies, small objects can get lost in the noise of the system.
- MTF & DQE provide quantitative measurement of imaging performance.
- MTF measures spatial resolution, while DQE is a measure of signal-to-noise ratio, contrast resolution and dose efficiency.

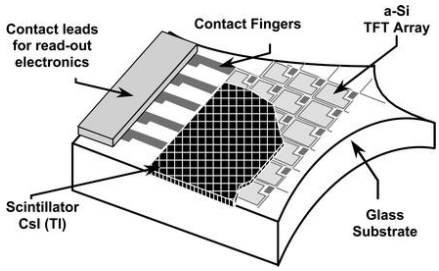
Even though the machine is digital, you still need a technique chart in view of the mammogram machine. It is a requirement for MQSA inspection.

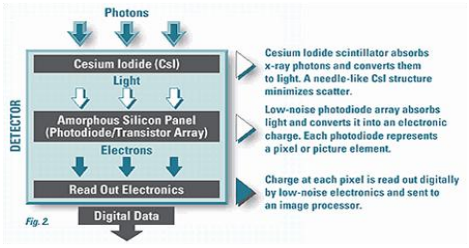
Increasing signal and decreasing noise (some electronic noise) in the system increases visibility of small structures.

Fundamentals of Digital Equipment

Phosphor Silicon Flat Panel

A scintillator layer, such as cesium iodide, is doped with thallium to capture the x-ray energy and converts the x-ray into light. Thin-film diodes convert the light photons into electronic signals that are captured using TFT's.





Selenium Flat Panel

- X-rays are absorbed by a photoconductor and generates a signal.
- The photoconductor is amorphous selenium.
- It is under the influence of an external electric field.
- Holes drift towards a pixel electrode and they are collected on a pixel capacitor.

- Very little lateral charge spreading occurs.
- The photoconductor (Sel) is made sufficiently thick in order to stop the majority of incident X-rays.
- 95% of the X-rays are useful, compared to F/S that counts for 50/70 % of efficiency.

Semiconductor arrays for direct conversion detectors are much easier to fabricate than arrays for indirect detectors because selenium-based detectors do not require a photodiode structure on top of the TFT.

In the direct acquisition detector, x-rays are absorbed by a thick photoconductor such as amorphous selenium (a-Se), which directly releases a corresponding number of electrons (and holes) that rapidly migrate under a large voltage placed across the selenium to the local storage capacitor.

Direct Ray detectors are manufactured under stringent "clean room" conditions in a specially designed manufacturing site.

Tubes and Filters

- **Ge**- Mo/Rh anode Mo/Rh/Al filter
- **Fischer**-Tungsten (W)/Rh target with Al filter (used due to the possible problem of excessive heat loading during the required duration of x-ray).
- **Lorad** - Mo anode with a Mo/Rh filter. Newer Machines have W anode with Rh/Ag filters.
- **Siemens**- Anode/ filter combo Mo/Mo, Mo/Rh, W/Rh with a Tungsten Tube
    - The images on high-resolution screens or printouts look sharper only because the available pixels are grouped into a much smaller area—not because there are more pixels.
    - The smaller an image is displayed from a given file; the sharper it will appear.
    - When enlarged too much, sharpness begins to fade and eventually the square pixels will begin to show—the image becomes pixilated.

Matrix

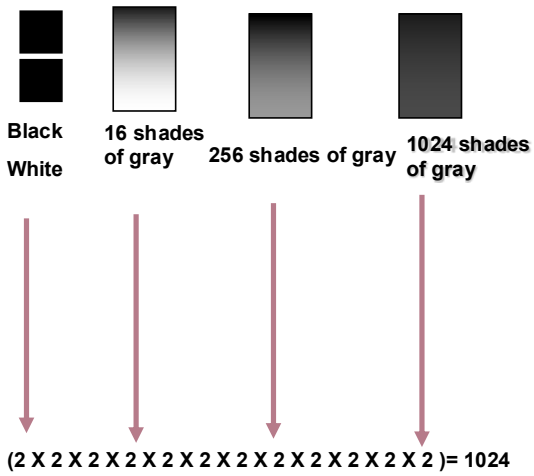
The matrix is an area comprised of the number of pixels in the x and y coordinates (height and width).

* The depth is measured in bits and is known as the different shades of gray.
* 6-bit image = 64 shades of gray.
* 7-bit image = 128 shades of gray.
* 8-bit image = 256 shades of gray and so on.

Matrix- A digital image is a matrix of pixels in the proper order.

How many bits are there?
(2 x the bit depth number)

Fuji CR system is 10(1024)-bit depth
Fischer Senoscan is 12(4096)-bit depth.
GE Senograph is 14(16384)-bit depth.
Lorad Selenia is 14(16384)-bit depth
Siemens Novation is 14(16384)-bit depth



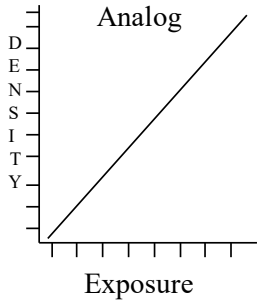
Shades of gray or data available - Bit depth

DIGITAL MAMMOGRAPHY THEORY & PHYSICS

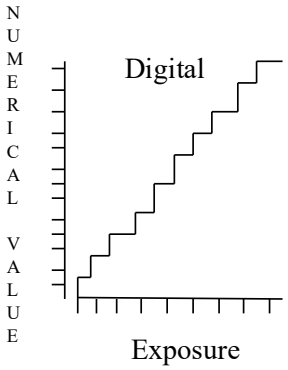
ANALOG: Continuous in intensity values at a point variation of intensity from point-to-point.

DIGITAL: Discrete in intensity values at a point location at which values are known.

Analog vs. Digital



continuous level



discrete, discontinuous steps

Analog Verses Digital

Advantages	Disadvantages
• Time Saved Due To No Film Changing& No Processing Film • Instant Image To Review • Display With Multiple Optimizing Capabilities • Image Storage Minimal • No Lost Images • Constant Updating Of Advanced Applications	• Initial Cost Very Expensive • Patient Can See Image Asks Many Questions • High Maintenance Cost Due To Computer Knowledge Needed From Service Personnel

One of the biggest advantages of digital mammography is…

DIAGNOSTIC PROCEDURES!

Per se, Pre-surgery needle localizations and Ductograms (galactograms), pneumocystograms, Sentinel lymph node needle guide.

- Less compression time.
- Less motion due to quick image recovery.
- Annotations on films for breast surgeons.

Digital Detector

- Electronic
  -Indirect Conversion
  -Direct Conversion

Indirect Conversion:

- Uses a scintillator (like cesium iodide) to convert x-rays into light photons, which are then detected by a photodiode array.
- Thin-film transistors (TFTs) or charge-coupled devices (CCDs) are used to read out the signals.

Direct Conversion:

- Uses a photoconductive material like amorphous selenium (a-Se) to directly convert x-rays into electrical signals.
- Thin-film transistors (TFTs) are used to read out the signals.

Monitors

Dual monitors (side by side)

- 5 megapixels. Minimum required to read
- About $15 thousand per pair.

One monitor

- 12 megapixels. Minimum required to read
- About $18-20 thousand for one monitor.

Computer Aided Detection in Digital Mammography

*What year was the first CAD approved by the FDA? 1998
*What manufacturer had its CAD product approved first? Hologic R2
*How much can CAD cost? $12,000 to $15,000

- While the development of FFDM and CAD have been, for the most part, independent, it is likely that for either system to gain wide clinical acceptance they will have to be sold together as a package. A packaged system of FFDM and CAD would be significantly cheaper than buying the two components separately.
- It is nearly as easy as adding CAD software to the existing FFDM system.
- Computer-aided detection (CAD) technology can significantly increase the number of cancers detected with mammography.
- CAD technology can help detect cancers in very early stages when breast cancer treatment is most likely to be successful.

Computerized Inspection of Mammograms - The Software

- Currently, mammograms are visually examined by humans in search of subtle and complicated indicators of breast cancer.
- This can be a difficult, tedious, and time-consuming task since mammograms are complicated images and since only one in a thousand may show an abnormality of concern.

Since the computer serves as a second opinion rather than acting alone, it doesn't have to be perfect to make a substantial difference.

Radiologists will continue to make the final diagnostic decisions.

FDA approved systems:

- ✓ R2 ImageChecker® System
- ✓ CADX Medical Systems-Second Look™
- ✓ iCAD MammoReader™
- ✓ iCAD MammoReader II™
- ✓ iCAD MammoWriter™
- ✓ Kodak CAD system

- CAD can mark up to about 20 areas but only picks about 4 or 5.
- If too many marks were on the image, it would cover up most of the breast imaged and distract the Radiologist when reading.
- Make sure to send images with and without CAD.

Image Storage

- Each digital unit has its own way and different type of image storage.
- RAID (redundant array of independent disks) provides image storage capability for the Senoscan.
- The standard 22 gigabyte raid has a storage capacity of approximately 3000 Senoscan images.
- Multiple RAID arrays or arrays of higher capacity may be used with some system configuration.
- MO (magneto-optical drive). The optional magneto-optical drive may be used to archive patient records for permanent long-term storage.
- Data stored on optical disk will not degrade overtime and is unaffected by electromagnetic influence.

To restore exam images that have been previously recorded, the restore function allows the operator to archive to DICOM compatible PACS over a tcp/ip network or to the locally configured MO drive.

Another service for outside images

- We know life image is a way to send images through the same software systems.
- E-Global is a new service for retrieving outside images that allows images being sent through image retrieving techniques from a broader area.

DICOM

Digital Imaging and Communications in Medicine

- Communications protocol used to transfer medical images and information between computers.
- DICOM is a standard for handling, storing, printing, and transmitting information in medical imaging.
- It includes a file format definition and network communications protocol.
- The communication protocol uses TCP/IP to communicates between systems.
- DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format.

DICOM enables the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into a PACS system. Devices come with DICOM conformance statements that identify which DICOM classes they support. DICOM has been widely adopted by hospitals and is making inroads in smaller applications such as dentist and doctor offices.

Storage

- **Long Term – More than 1 month.**
- Where images are kept for the life-time of the patient.
- **Short Term – Local storage/Review Station.**
- Time depends on size of hard drive and size of studies - 2 weeks to 1 month.
- Need to pre-fetch prior studies from long term storage to short term storage for comparison.
- PACS (picture archiving and communication system is generally required to make a digital mammography system economically viable.
- CAD (computer-aided detection) computer-aided detection is defined as a diagnosis made by a radiologist who considers the output of a computer analysis of the image when making his or her interpretation.
- DICOM (digital imaging and communications in medicine) has a standard that allows the connection of image acquisition units, displays, archives and

reporting systems from different vendors, the practical integration of these devices usually hinges on a balance of technical and business factors.

- Tcp/Ip (Transmission control protocol/internet protocol) the suite of communications protocols used to connect hosts on the internet. It is built into the unit operating system and is used by the internet.

DICOM functions such as send, query/retrieve and worklist support enable a smooth and streamlined workflow. Access to reports, examination requests and other patient-data provides complete information for qualified reporting. Siemens know-how and experience in IT systems means fully integrated solutions. Thus, radiology information systems such as Novius or MagicSAS can run on the same hardware platform as the workstations.

Laser printers

- The laser imager (printer) allows high-quality hard-copy images to be printed from the review station computer.
- The quality of the hard-copy images is similar to that of the on-screen image provided by the high-resolution monitor.

FDA Policy as of 2012

Question 5: We have an FFDM unit and do not keep hardcopy of our exams (we retain the images electronically). When patients request the release of their exam, we create a hardcopy for them. May we charge the patient for the cost of creating the hardcopy?

The facility may not charge for creating the first hardcopy version of the mammogram. However, if the patient requests a second one or more additional hard copies copy of the mammogram, the facility may pass the costs of that reproduction the additional hardcopies on to the patient.

QC for Laser Printers

FFDM Mfr	Model	Laser Printer QC
General Electric	Senographe 2000D, DS and Essential	Follow the laser printer manufacturer's QC manual
Fischer	SenoScan	Follow the laser printer manufacturer's QC manual
Fuji	FRCm	Follow the laser printer manufacturer's QC manual
Lorad	Selenia	Follow the Lorad Selenia QC Manual
Siemens	Mammomat Novation DR	Follow the laser printer manufacturer's QC manual (but conduct QC every day that images are printed

Over the past 20 years, there has been significant evolution in mammography, with the shift from screen-film to digital imaging being the most prominent change. As the technology has evolved, so has the role various peripheral devices played. The utilization of film printers by facilities was prevalent, especially when digital mammography first entered the market. Some of the needs the printers served at that time were the provision of hard copy comparison images from digital facilities to requesting facilities that were not capable of viewing digital images, the submission of images for accreditation, and providing copies of mammograms to be viewed in the operating room.

Digital mammography was introduced into clinical use fifteen years ago, and today fewer than 350 screen-film units remain in use in the U.S. The nearly universal availability of computers for viewing of digital images diminishes the need for a facility to maintain a printer. Another change in current practice was the introduction of digital breast tomosynthesis (DBT) in 2011 and its rapid clinical adoption. DBT images are intended solely for soft-copy interpretation.
Today, with many mammograms shared on computer media such as compact discs or via online access, the provision of printed hard copies is becoming obsolete. Many medical facilities have the ability to review images on monitors throughout their facilities. Please note that any exchange of images between requesting and image-providing facilities is to be accomplished in a mutually agreed-upon format since there is no regulation dictating format. Additionally, all FDA-approved accreditation bodies can accept images electronically needed for accreditation, additional mammography reviews, etc.

Therefore, in today's world, the option to maintain a printer and/or the ability to print hard-copy images is a decision left to each individual facility.

If a facility chooses to maintain a printer, it must follow all the quality control requirements that are prescribed by the manufacturer of the printer and mammographic unit. The manufacturer's quality control program benefits the facility that wants to provide the best possible quality in any hard copy mammography images it prints. Although the FDA's MQSA inspection program has removed printer QC questions from its inspection procedures, if a facility decides to maintain a printer, medical physicists must continue to include that printer QC in the Mammography Equipment Evaluation upon installation, after a major repair, and annually, if required by the printer's or image receptor's manufacture quality control program.

Operating Procedures for Transferring Digital Images

When a facility is requesting digital mammography films for comparison, can the facility accept images on a CD, or can they obtain hardcopy films?

For purposes of transferring films, the facility must be able to provide the medical institution, physician, healthcare provider, patient, or patient's representative, with hardcopy films of final interpretation quality or, when it is acceptable to the recipient (e.g., a transfer between two FFDM facilities), with original or lossless compressed full field digital images electronically.

Telemammography

- Uses satellite communications.
- Usually located in large medical facilities.
- Good for rural low populated areas.
- Some barriers for telemammography.
- Size of the digitized image (20-40Mbytes).
- Combination of cost of transmission media verses time to transmit like high bandwidth compared to low bandwidth.
- Maintaining diagnostic quality for telemammography equal to current film base screening method.
- Not all states allow this

Other factors affecting telemammography and digital image transfer are:

- File size for data archiving.
- Networking system software.
- Signal propagation times for satellite.
- PACS
- Medical community acceptance.

Digitizers

FDA Policy

Question 5: Can a facility copy or digitize a film screen mammogram and use that copied or digitized image for retention purposes or final interpretation?
No. While not allowed for final interpretation, copied, or digitized images of previously obtained mammograms may be used for comparison purposes if the interpreting physician deems that acceptable. However, such images cannot be used toward initial or continuing experience requirements by physicians.

We recommend that if copied or digitized images are used for comparison purposes that:

- Only copiers or digitizers approved or cleared by FDA's Office of Device Evaluation for such purposes be used.
- In addition, we recommend that phantom and clinical images produced by such copying or digitization pass all applicable quality control tests.
- Be of such quality that if they were submitted, they would pass the facility's accreditation body's phantom and clinical image review process.

Division of Diagnostic Imaging Library Letter put in Patient's file

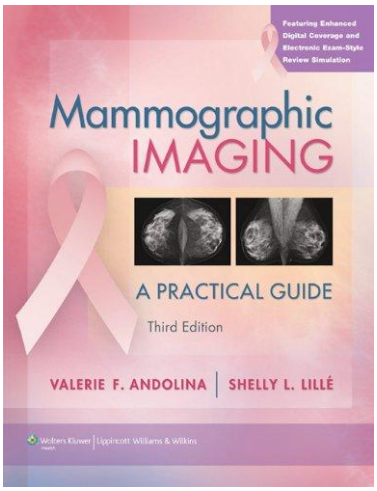
Enclosed please find a CD or films that contain Diagnostic imaging studies. The images have been digitized or uploaded into our electronic storage system, and the originals are enclosed.

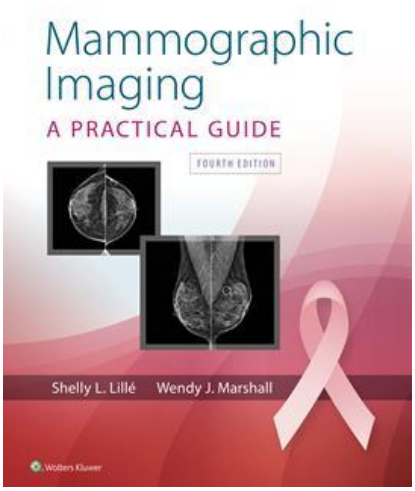
Please feel free to return them back to your health care provider or keep them for your personal records. Should you have any questions, please contact the Diagnostic Imaging Image Library at phone number …….Thank You

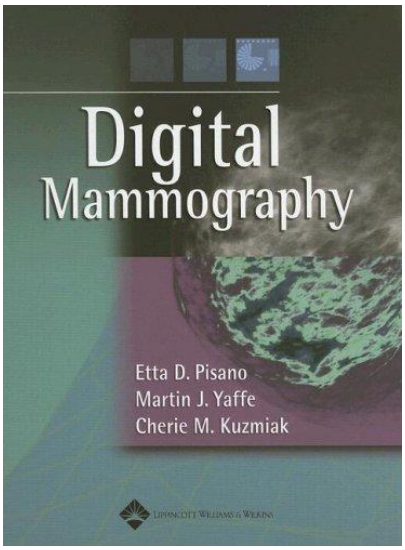
GE Premium View

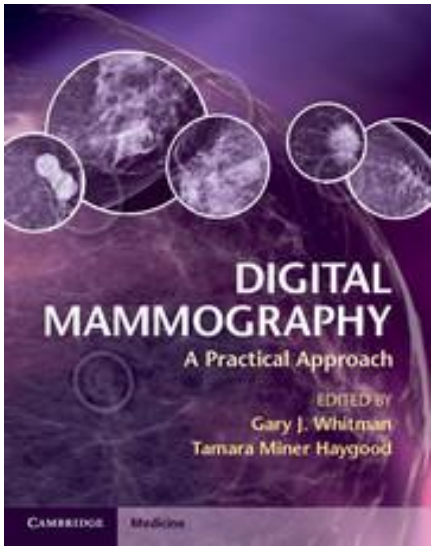
- A tool that optimizes image contrast ad automatically displays more detailed information to assess breast cancer.
- Premium View optimizes the contrast in breast images in one image window, reducing the need for windowing and additional steps to view the images, increasing radiologists' productivity. It improves visualization of the breast in dense regions while maintaining peripheral contrast at the skin line and chest wall.

STANDARDS FOR OPTIMAL POSITIONING









Product Information from the Manufacturers

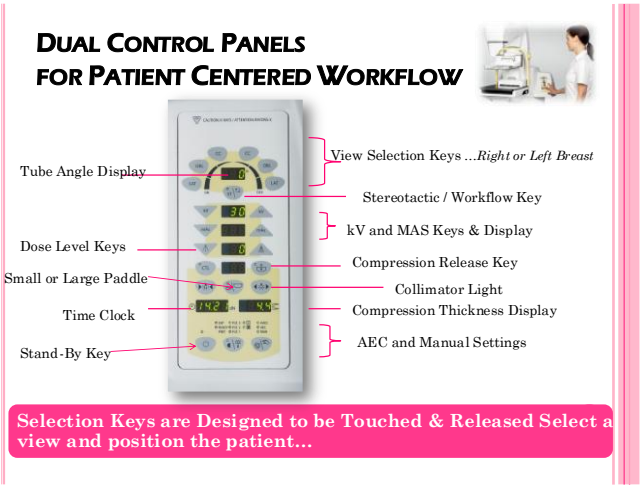
NUANCE EXCEL

- Ideal for high throughput screening mammography practices, where the equipment has to be fast, reliable and simple to use.
- Images are previewed on a high-resolution 3-megapixel grey scale monitor

PLANMED NUANCE EXCEL

AMORPHOUS SELENIUM DIRECT DIGITAL CAPTURE

Detector Size	24 x 31cm
Pixel Size	85 microns
Image Matrix	2816 x 3584 pixels
Selenium Thickness	200 microns
Operating Temperature	+15° to +35 °C 59° to 95° F



Side Access Positioning

- Can be Used in Any Projection
- Better Patient Accessibility While Positioning
- Tube Rotates 30°…Breast Support Remains Stationary
- Good Ergonomics for Technologist

Acquisition Workstation

- 3 MP Monitor
- Manage Patient Information
- Acquire Exams and Review
- Archiving

- Quality Control
- Raw data 8 sec, processed in 15 sec

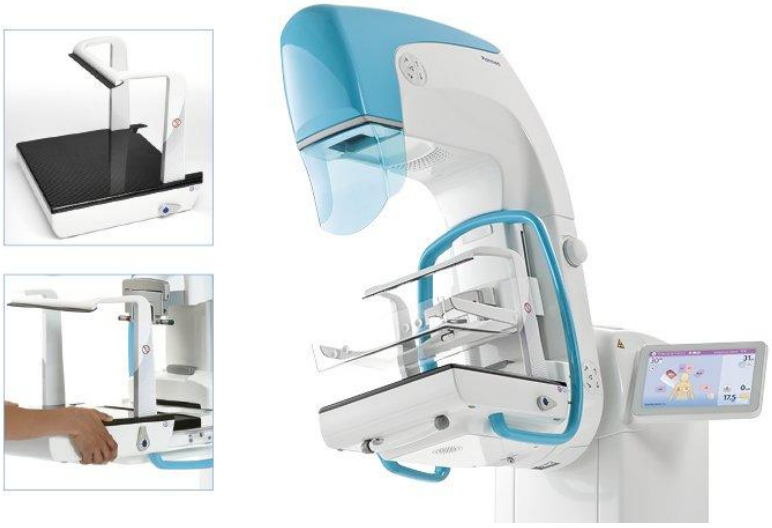
Geometric Magnification

- 1.6x or 1.8x magnification stand
- Magnification paddles of different shape and sizes

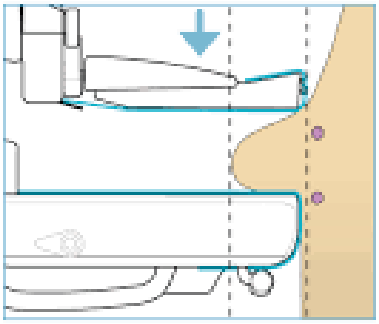
DigiGuide Stereotatic Biopsy

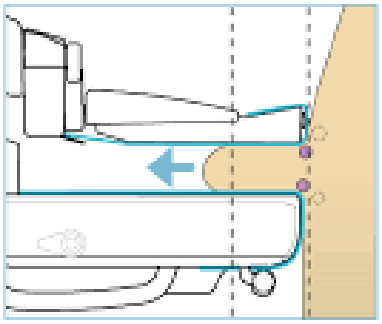
- Light Weight Needle Guidance System
- Intuitive Graphical User Interface
- Compatible with Vacuum Assisted Devices

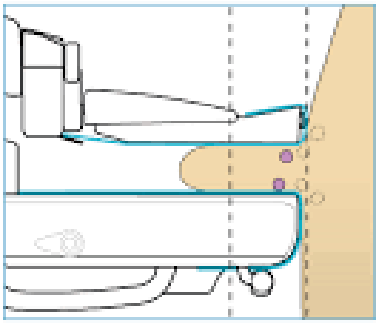
Planmed Clarity Digital Mammography



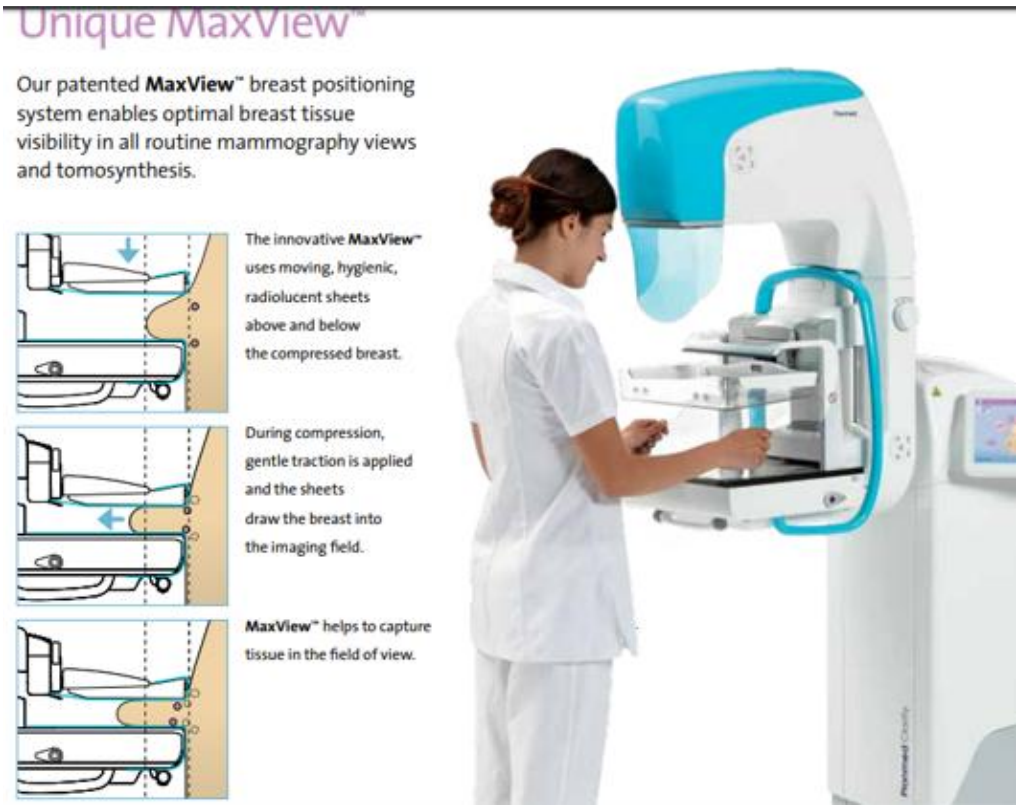
Planmed Clarity also has breast traction





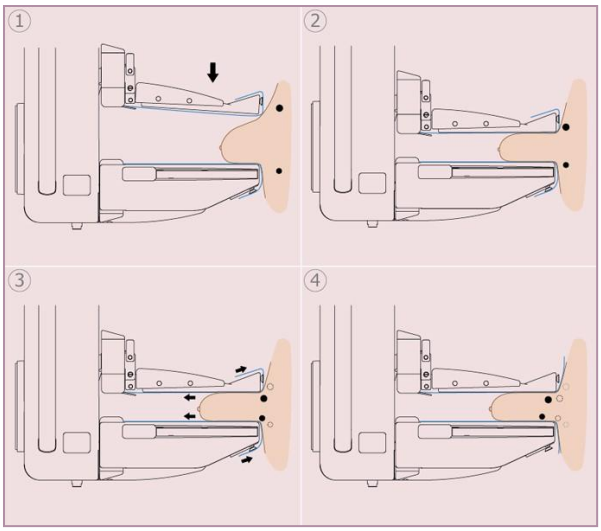


Skillful breast positioning is a prerequisite for each mammography examination. MaxView is designed to enhance technologists' positioning skills by capturing more tissue at the chest wall where even a few millimeters can make a difference.



MAXVIEW AT A GLANCE

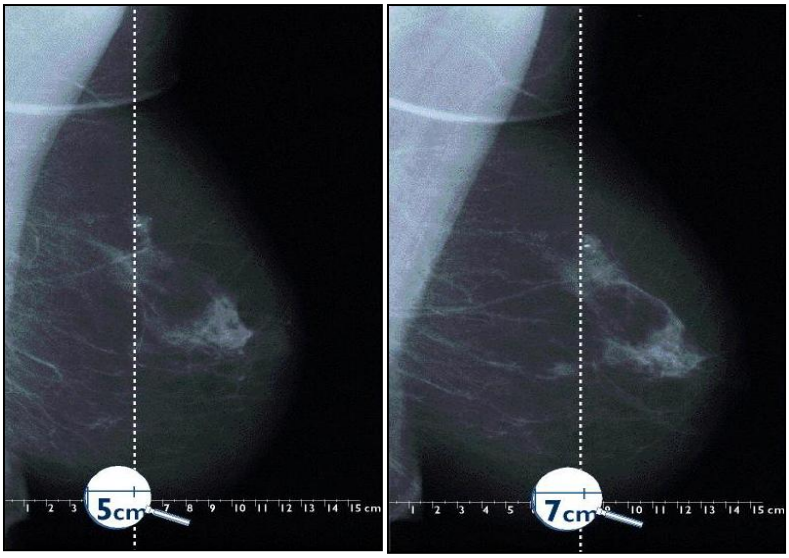
- Insert Radiolucent Disposable Sheets
- Position Patient
- Begin Breast Compression
- Apply Traction with Footswitch
- Make Exposure
- Sheets Return to Ready Position



- Massachusetts General Hospital
- 57 Women: Ages 40-79
- 2 Additional Views Taken of One Breast
- Positioned By Skilled Technologist
- Images Compared and Measured

STUDY GOAL: Determine how much more tissue is seen on image when using traction.

MaxView Clinical Research

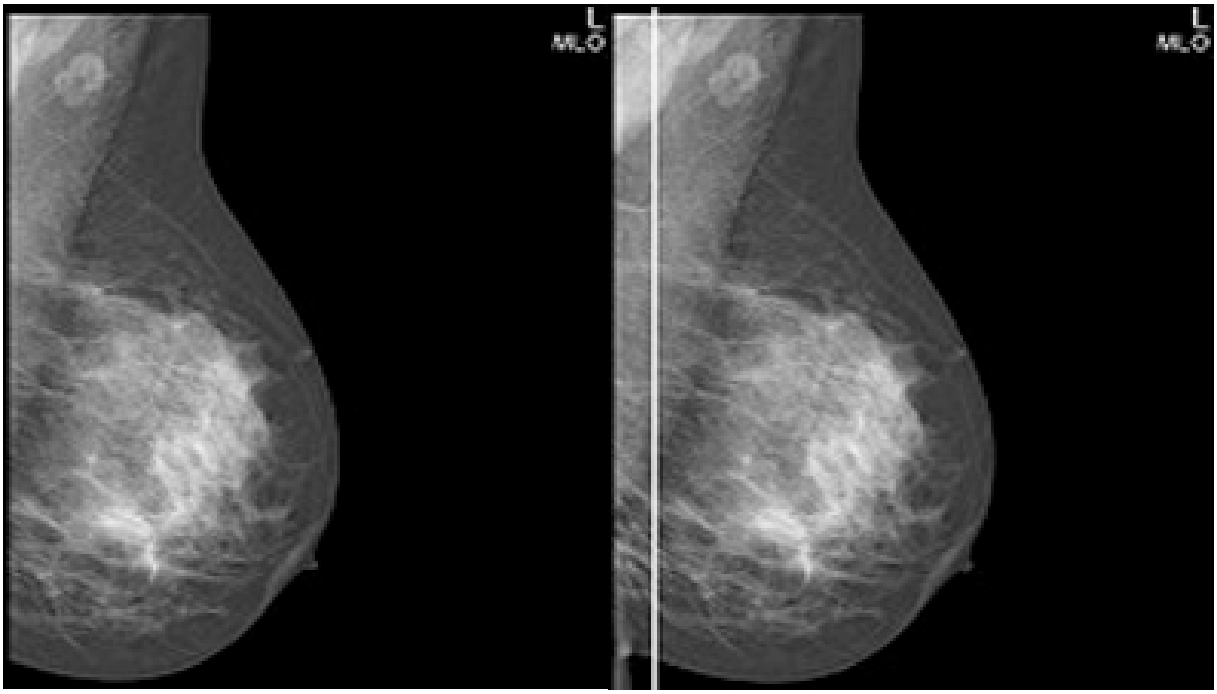


An Average Gain of 6.4mm Noted
Patients Tolerated Traction

Tech Positioning Patient

In addition to extra tissue visibility, MaxView also enhances separation of tissue structures, increasing the chance for early lesion detection.

The inclined gantry of GIOTTO IMAGE 3D means more comfort for the patient as they lean into the bucky. This position allows the pectoral muscle to be relaxed and up to 2 cm more breast tissue can be compressed and visualized, allowing more breast tissue to be visualized for diagnosis.



Giotto Image 3D/3DL

Giotto Image 3D is not provided with handles.

- Gripping on handles causes muscle contraction which in turn causes breast retraction: gravity lessens this effect.

Giotto Image 3D comes with SCS (Sensitive Compression System) to decrease patient discomfort during breast compression.

- The computer selects the compression speed sensing the density of the breast
- Direct conversion technology a-Se detector
- Tungsten anode & special filter for low dose levels

Giotto Image + Stereotatic Biopsy=Versatility

- Biopsy with lateral, straight, and inclined holders
- 360° access to the breast
- Prone biopsy & Mammography with the same detector
- Giotto Image 3D is the only digital mammography system able to able to perform stereotactic biopsy with the patient in a prone or upright or lateral position, using the same detector!
- The conversion to prone unit is quick and easy. The stereotactic device “Biopsy Digit” simply slides in replacing the bucky. With a gentle movement the gantry tilts up to the horizontal position.

- **Fuji Aspire HD**

- The new format detector has a proprietary panel structure with a double layer of amorphous selenium that was developed by combining Fujifilm's Device Development Technology and Vacuum Deposition Technology.
- With high X-ray absorption properties, the first layer efficiently converts X-rays into electrical signals, while the second layer employs the innovative "Direct Optical Switching Technology," that captures high resolution and low noise image electrical signals rather than using electrical switches such as conventional TFTs
- Optimal 24x30cm detection area
- By delivering both "50µm fine pixel size (higher resolution) and low noise," the Aspire HD system provides superb image quality that enhances visualization of breast tissue and greater detail of breast abnormalities.
- World's smallest pixel pitch of 50µm^2, a first in a dual-layer amorphous-selenium, direct-to-digital DR FFDM system
- Exclusive new Fujifilm innovation: Direct Optical Switching Technology replaces the need to use Thin Film Transistors (TFT) as in conventional DR FFDM
- Tungsten x-ray tube with a rhodium filter reduces radiation dose without sacrificing image quality
- Ergonomic bucky design to maximize visualization of tissue at the chest wall



Fuju Cristalle

First Direct Capture FFDM

Upright Stereotatic Attachment

Philips (Sectra) MicroDose L30

Scanning Sysem, Photon Counting

Photon counting detector technology has been a paradigm shift in mammography, allowing for high dose efficiency.

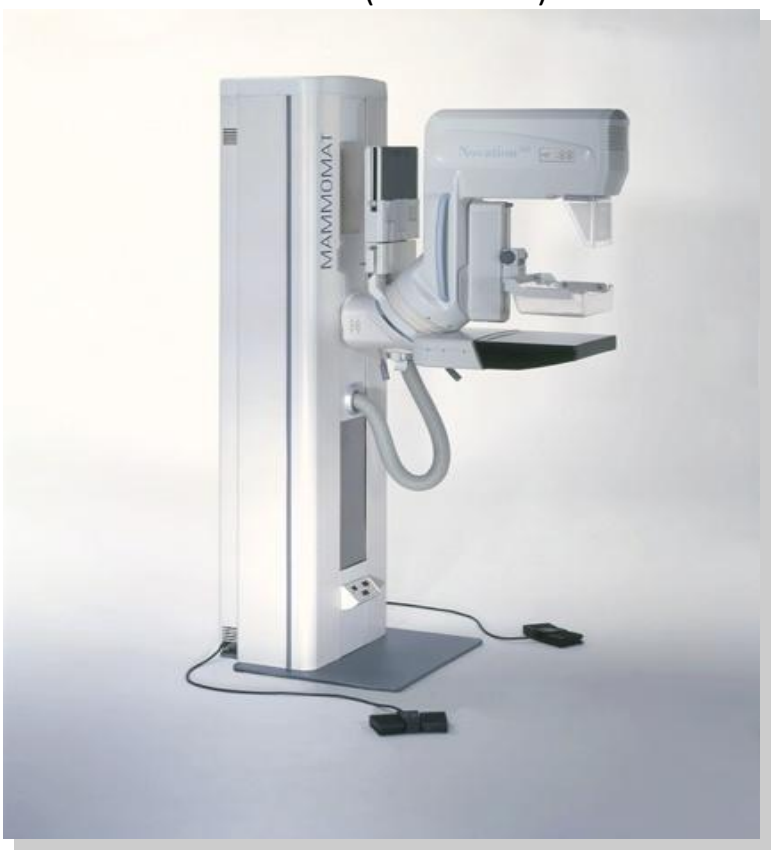
- Excellent Image Quality
- Photon-counting technology combines exceptional dose-efficiency with industry-leading 50µm resolution
- Multi-slit collimator design rejects 97% of the scatter that would degrade image quality (without using a grid)
- 100%-pixel warranty
- Dramatic Dose Reduction
- 18 to 50 % lower radiation dose than used on other digital mammography systems, with an average dose reduction of 40%.
  * The actual result of the average dose reduction will vary based on variations of digital mammography systems.
- SmartAEC adjusts dose and image quality in real-time.

MicroDose delivers future-proof technology that will allow you to be competitive and deliver excellent patient care. Its exclusive photon counting detector technology opens up opportunities for advanced breast applications.

MAMMOMAT Novation DR
Excellent Image Quality with aSe Detector

- Excellent resolution
  - 7 lp/mm spatial resolution
  - 70 microns
- Dynamic Range > 9cm
- Based on 2nd generation flat detector technology (aSe)*

detector (24 x 29 cm)



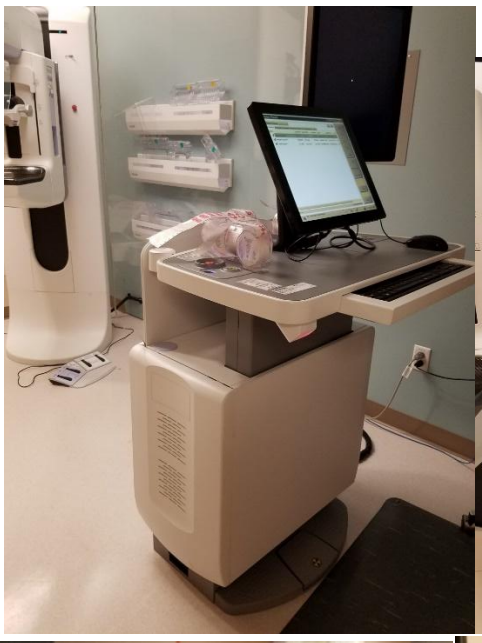
- Tungsten tube
- Three anode/filter combinations (Mo/Mo, Mo/Rh, W/Rh)
- a-Se detector
- Direct conversion technology
- Large format detector (24 cm x 29 cm)

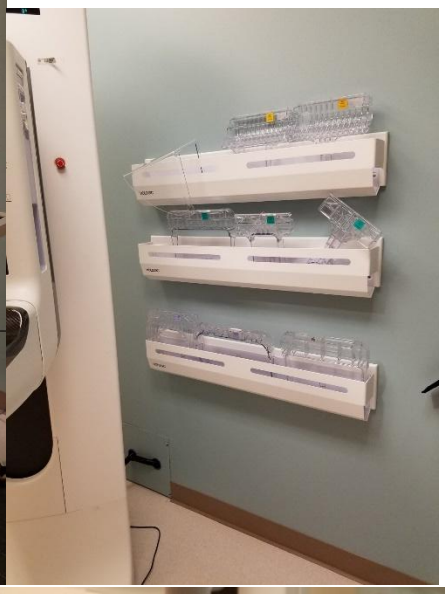
SIEMENS MAMMOMAT INSPIRATION

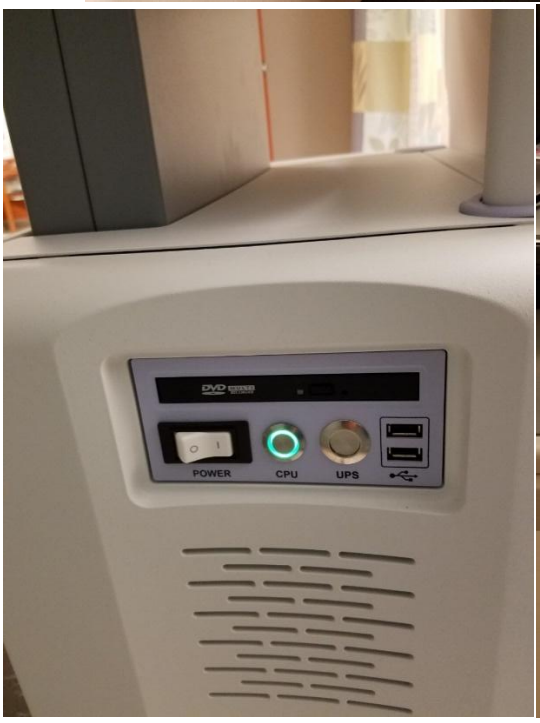

SIEMENS
Healthineers

Selenia Dimensions 3000

The evergreen 2D system that offers the benchmark Hologic customers expect, with essential ergonomics and functional workflow features at an attractive price. Plus, the Selenia Dimensions system 3000 package offers the agility to evolve with you.






POWER
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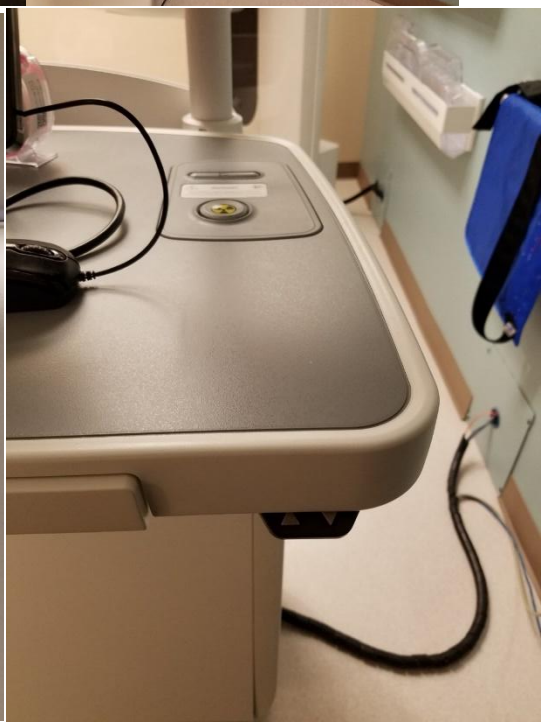
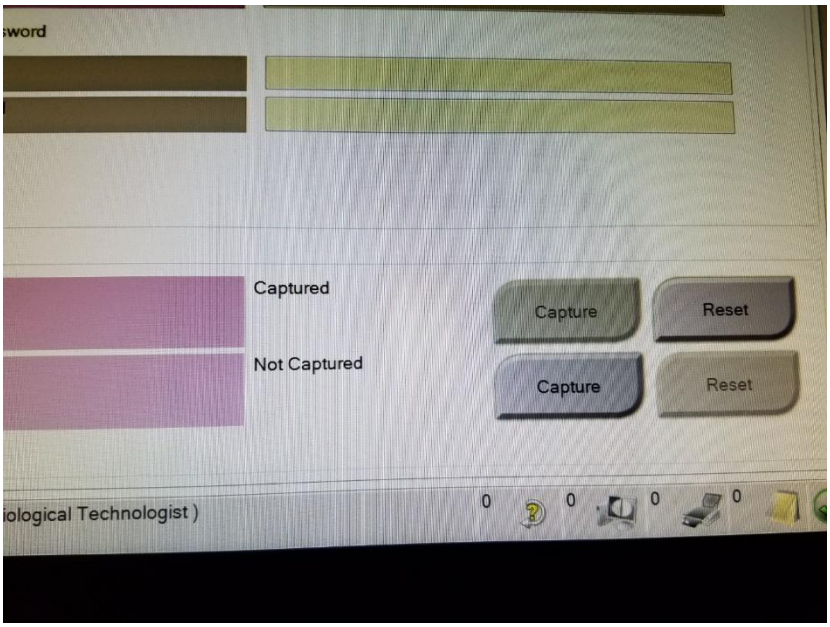
UPS

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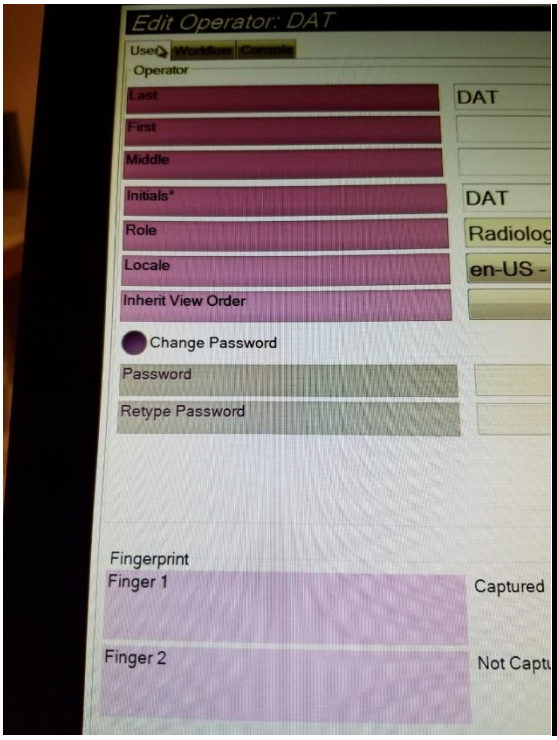
Edit Operator: DAT
Operator
Last
DAT
First
Middle
Initials*
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Role
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Locale
en-US -
Inherit View Order
Change Password
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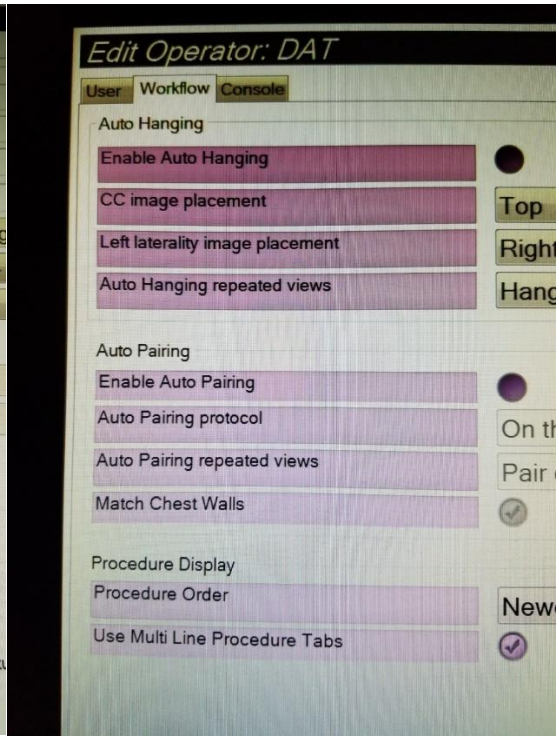
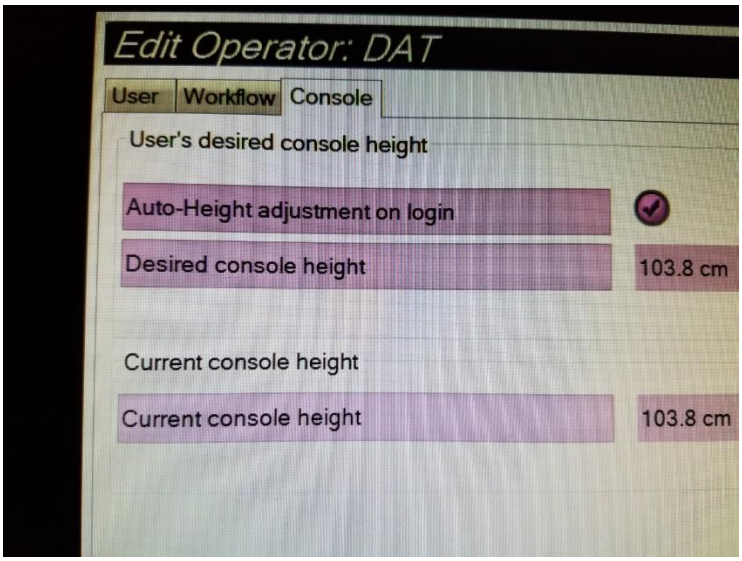

Edit Operator: DAT
User
Workflow
Console
Auto Hanging
Enable Auto Hanging
CC image placement
Top
Left laterality image placement
Right
Auto Hanging repeated views
Hang
Auto Pairing
Enable Auto Pairing
Auto Pairing protocol
On th
Auto Pairing repeated views
Pair
Match Chest Walls
Procedure Display
Procedure Order
New
Use Multi Line Procedure Tabs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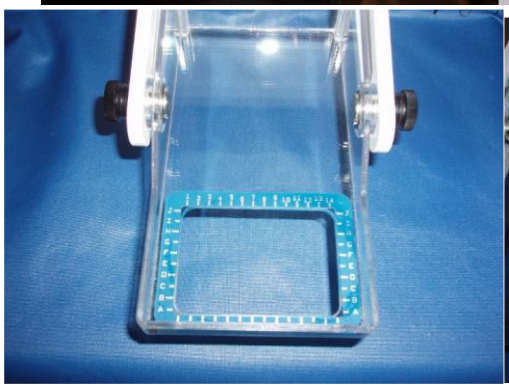
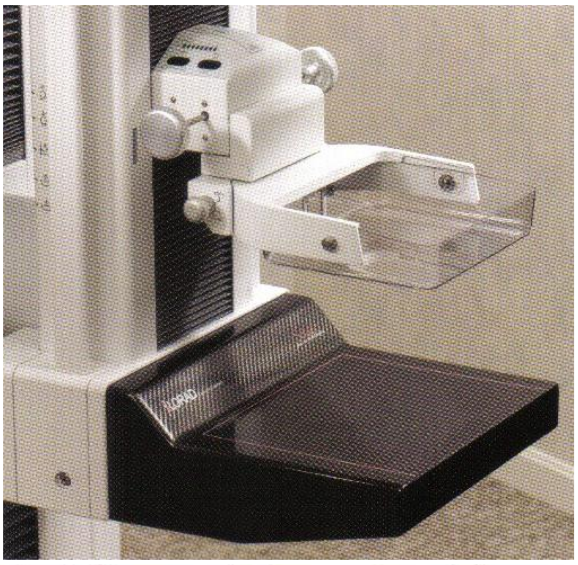
Workflow
Console
User's desired console height
Auto-Height adjustment on login
Desired console height
103.8 cm
Current console height
Current console height
103.8 cm





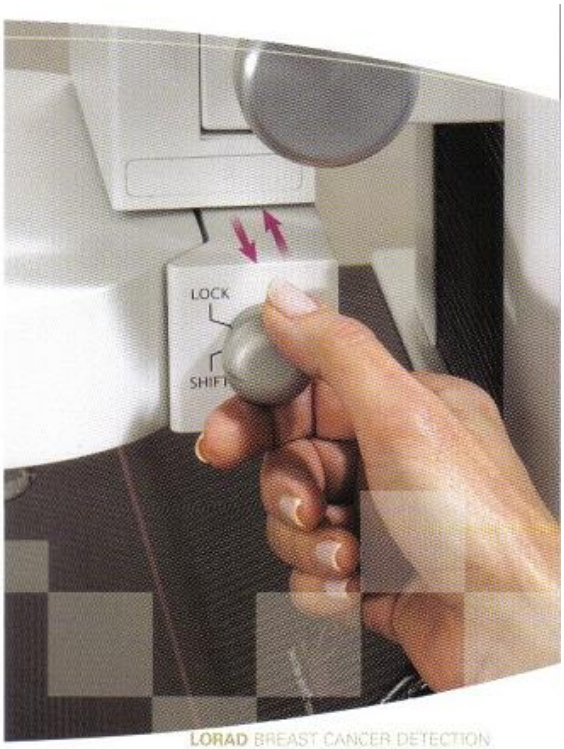
The Selenia features the largest digital detector in the industry. With a 24 X 29 cm field of view, almost all mammography patients can be imaged with a single exposure, for improved patient care and higher patient throughput.

Smart Paddle System

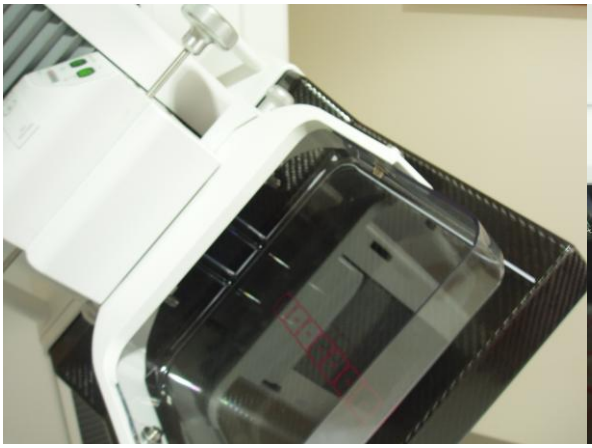
The system's patented Smart Paddle System is engineered to provide a unique level of precision and control. Each compression paddle contains a microprocessor that controls movement of the system's Automatic Exposure Control* (AEC) and automatic collimation function. When the paddle is placed in one of three positions (craniocaudal, left mediolateral oblique, or right mediolateral oblique), AEC and collimation controls automatically shift to the proper position. This effortless operation streamlines workflow, enables accurate positioning and assures consistent acquisition of high quality mammographic images.

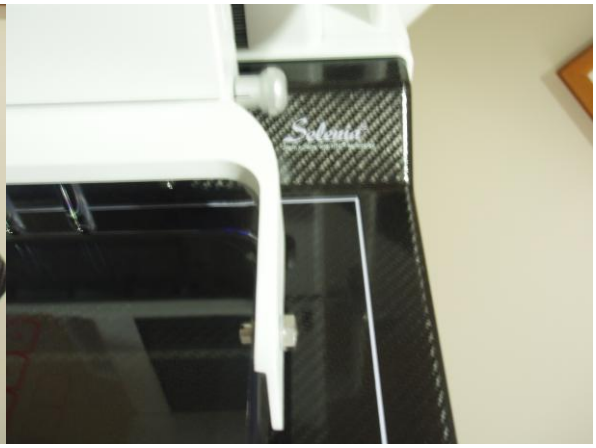
The system's seven-position AEC virtual sensor extends up to 12.5cm from the chest wall to allow greater tissue sampling and accurate calculation of proper exposure technique. In fully automatic mode, the AEC determines the densest area of breast tissue, assuring the utmost precision in exposure settings.

* *AEC is a Works-in-Progress—FDA Clearance required.*



LORAD BREAST CANCER DETECTION





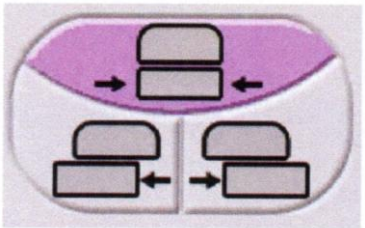


Figure 28: Paddle Shift Buttons

In procedure screen when you select an unexposed view the paddle moves to
the default position for that view
Paddle shift section you can bypass the default paddle position for the selected view and the paddle will move to the new position

SmartCurve™ Breast Stabilization System

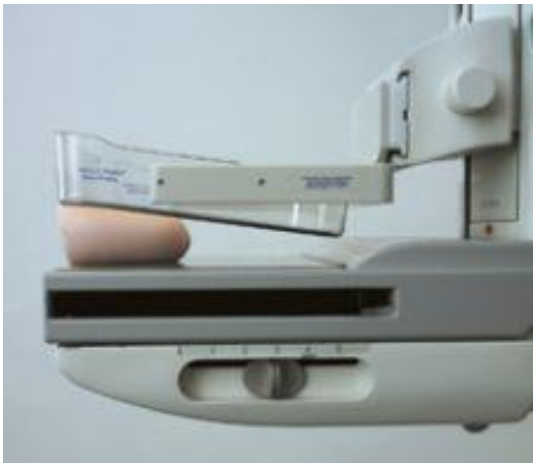
SmartCurve

SmartCurve™ Breast Stabilization System

SmartCurve

FAST PADDLE

- FAST (Fully, Automatic, Self-Adjusting, Tilt)
- It Is spring loaded and tilts



S.O.F.T PADDLE

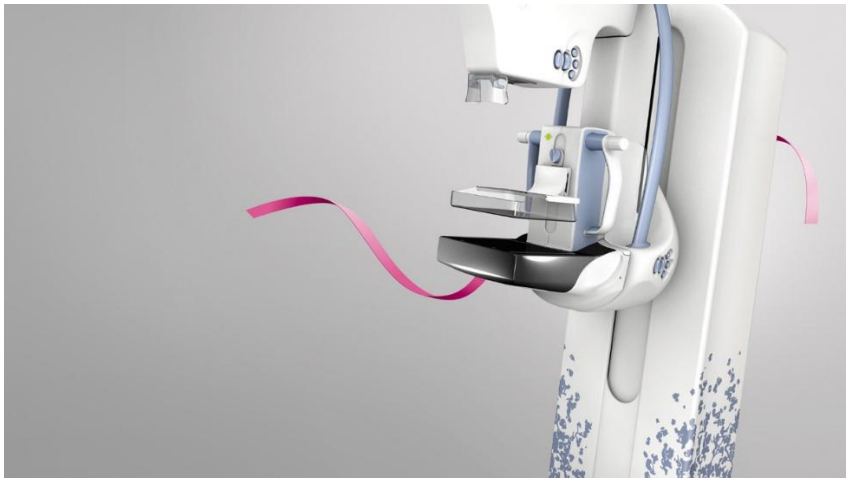
- SOFT (Special, Optimized, Full, Tilt)
- Fixed tilt, always angled down same degree

DIMENSION 9000 PACKAGE

genius3D MAMMOGRAPHY EXAM ™

HOLOGIC DIMENSIONS GENIUS

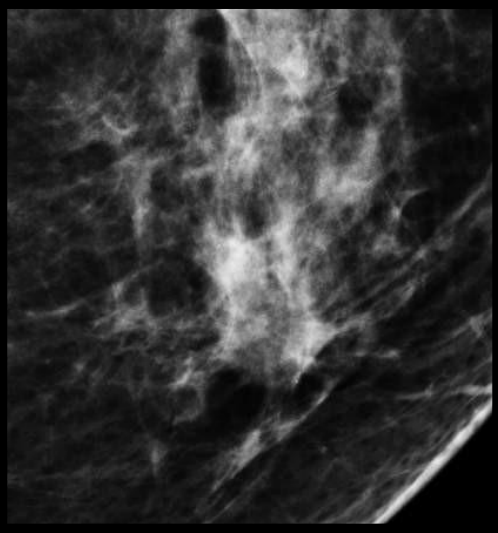
GE SENOCLAIRE TOMOSYNTHESIS



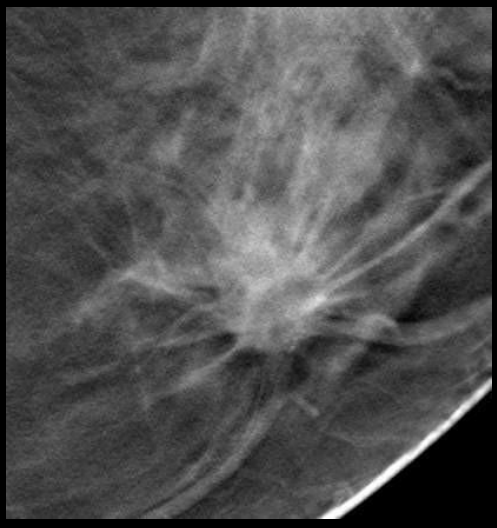
GE SENOGRAPHE PRISTINA

Reshape the mammography experience with comfort, confidence and clarity Senographe Pristina TM 3D

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



2D



3D

MammoPad® Breast Cushion

MammoPad Breast Cushion

The MammoPad breast cushion is a soft, warm cushion that provides a more comfortable mammogram. The cushions are latex-free, hypo-allergenic and FDA listed. The MammoPad breast cushion is compatible with most full-field digital mammography and tomosynthesis systems.

Large (29 x 30 cm)
MammoPad breast cushion; compatible with most full-field digital mammography systems.
Case of 50.
Part number: MP301

Small (20 x 24 cm)
MammoPad breast cushion; compatible with any analog system with an 18 x 24 bucky.
Case of 100.
Part number: MP101

Medium (25 x 29 cm)
MammoPad breast cushion compatible with any analog system with a 24 x 30 cm bucky.
Case of 50.
Part number: MP201

Use of Cushion Pads While Testing Full-Field Digital Mammography (FFDM) Units

Since FDA has recently received some questions regarding the use of cushion pads during QC testing, we want to take this opportunity to remind everyone that the following Question and Answer (Q&A) regarding this issue is in the Policy Guidance Help System under phantom image testing:

> ***Question 18:*** *We are using an FDA cleared single-use cushion pad when performing mammograms on some of our patients. Do we have to include the pad when performing the phantom and dose QC tests?*
>
> **Answer:** If you are not using a cushion pad for the majority of your patients, you do not have to include the cushion pads when performing the phantom and dose QC tests. However, if you are using a cushion pad for the majority of your patients, you must include the cushion pads when performing the weekly phantom and annual phantom and dose QC tests in order to simulate as closely as possible your typical clinical conditions (21 CFR 900.12(e)(2)). If you routinely use the cushion pad on both the bucky and the compression paddle, you must use 2 layers of the cushion pad when performing the phantom and dose QC tests. When used clinically, the cushion pad is a single-use device. Because of this, QC testing with the cushion pad in place is most appropriate when performing the phantom and dose tests. Therefore, the facility does not have to include the cushion pad when performing other QC tests.

The above Q&A was written before FFDM systems came into widespread use. DMQRP has received questions recently about whether the cushion pad (e.g., MammoPad) must be used when performing QC tests on FFDM units if the facility uses the pad on the majority of its patients. While FDA recommends that tests performed on FFDM units, such as the phantom test, be done under clinical conditions, we can only REQUIRE that the pad be included during the test(s) when the manufacturer's QC manual specifies a pad to be present during QC testing. As 21 CFR 900.12(e)(6) states that, "…the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer," the unit manufacturer's QC manual defines the test conditions for the phantom image and other QC tests.

HOLOGIC®
CLARITY OF VISION

LORAD®
IMPORTANT NEWS COMMUNIQUE

USE OF BIOLUCENT MAMMOPAD WITH SELENIA

As you are aware, the BioLucent MammoPad has been used successfully in the past with our screen-film products with no known negative impact on image quality. Until recently; however, no data existed to document the impact of use of the MammoPad with our Selenia system. Hologic has now completed such an evaluation and we are pleased to report that our tests found there is no compromise in overall image quality when the MammoPad is used on the Selenia.

Attached is a letter on Hologic letterhead outlining the results of this evaluation. Please feel free to provide a copy of this to any existing or potential customer questioning the appropriateness of use of the MammoPad with our Selenia system.

Please note, however, that this is not an endorsement of the product. The determination of whether or not to use the MammoPad rests solely with the facility, based on their standards of care and the needs of the patient.

Please feel free to contact Nikos Gkanatsios (ngkanatsios@hologic.com or 203.731.8432) or Georgia Hitzke (ghitzke@hologic.com) if there are any questions.