



DIGITAL Mammography

A How-To Manual for
Seamless Implementation

Valerie Andolina, RT (R) (M)
Theresa Wade, MPHA, ACMPE

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Theresa Wade, MPHA, ACMPE, has been the Administrator/Business Manager at the Elizabeth Wende Breast Clinic in Rochester, NY, since 1983. Her professional memberships include the Medical Group Management Association, the Radiology Business Management Association, the Monroe County Medical Society, Managers Committee, and the Monroe County Information Technology Committee.

About the reviewer

Kathleen M. Willison, RT (R) (M), is a graduate of the Genesee Hospital School of Radiological Technology and has specialized in breast imaging and advocacy for improved methods of breast cancer detection for over twenty years. She has served as the Director of Clinic Development at the prestigious Elizabeth Wende Breast Clinic (EWBC), where she developed numerous creative programs to advance breast disease diagnosis while ensuring EWBC's continued clinical leadership. Collaborating with manufacturers and clinical experts, Ms. Willison implemented and completed several clinical studies and IRB-approved trials that resulted in improved outcomes for many breast cancer patients. Her most recent activities have included the clinical evaluation of "cutting edge" technologies and the advancement of Full Field Digital Mammography. To that end, she has been instrumental in initiating and coordinating the first Digital Mammography Working Group through the RSNA's Integrating the Healthcare Enterprise (IHE). As an expert and educator in breast imaging, Ms. Willison is a featured speaker at national symposia, has conducted educational courses for Radiologic technologists, and has published several textbooks and articles in peer-reviewed journals. She is currently serving as Director of Clinical Affairs at Koning Corporation, a transfer technology start-up company developing CT for the breast and other small body parts.

Introduction

Dear Reader,

We've received numerous phone calls lately from people at facilities across the country asking for our advice on issues related to making the conversion to digital mammography.

Our facility, the Elizabeth Wende Breast Clinic, in Rochester, NY, was one of the first to jump into the digital mammography arena. As part of the conversion process, we've participated in clinical trials and research related to digital equipment, and tried out several different digital systems.

We believe our experiences in making the switch—a process we have still not completed and which we outline in this book—will be valuable to those who are just embarking on the same journey.

The Elizabeth Wende Breast Clinic was founded by Wende Logan-Young, M.D., in 1976, and was the nation's first freestanding mammography and breast imaging center devoted to breast disease detection. It is ranked as one of the nation's leading breast care facilities, serving 75,000 patients each year, and is considered a "Center of Excellence."

At present we have nine film and five digital units, one of which is used only for a clinical trial. We plan on fully converting to digital in the next few years, as costs permit.

We're pleased to be able to offer digital imaging to the patients for whom it will be most beneficial, and we strongly believe other facilities that make the digital conversion will feel the same way. In September 2005, the results of the international, multi-year Digital Mammographic Imaging Screening Trial (DMIST) were released. The trial, which was sponsored by the American College of Radiology Imaging Network (ACRIN), was designed to compare the performance of digital mammography to film mammography. Researchers found that digital equipment not only produced images that were equivalent to the quality of analog, but actually provided superior cancer detection for certain groups of women, among them younger, pre- and perimenopausal women, as well as those with dense breasts.

But while the transition comes with a substantial payoff in increased cancer detection potential, it's still not an easy one to make. Expect the process to be fun and exciting because you're learning new things—and very frustrating at the same time.

There will be new terminology to learn, systems problems to work out, and a sharp learning curve that cannot be avoided.

To minimize these problems, be certain to plan well before you jump in and make the transition. And keep in mind that digital mammography is an evolving technology—still in its toddler years, so to speak—so you need to be prepared for numerous changes in the years ahead.

In this book, we offer you tips based on our experiences and try to help you steer clear of some of the potholes that we fell victim to along the way.

INTRODUCTION

Our most important advice is to be patient and hang in there as you go through the process. The transition will take time and patience, but the payoff is worth it in the end.

Film screen mammography has taken us as far as it could, and digital mammography is the future. We hope that the advice we offer in this book will help you to embrace it.

Sincerely,

Valerie Andolina and Theresa Wade

Full Field Digital Mammography (FFDM) Overview

The following are descriptions and photos of the various systems and equipment you may come across when making the transition to digital mammography.

Direct Radiography (DR)

- Acquisition Unit

- o Modality stand: This is the traditional C-arm that is used for film/screen mammography, but instead of a cassette holder, the image receptor is replaced with a digital detector. This is where the breast is placed during imaging. There are two types of DR systems, one that converts x-ray to light and then to digital signal and one that converts x-ray to digital signal without the light conversion step. Depending on the technology, a typical moving bucky may or may not be included in a digital detector.



GE DS Acquisition unit

- o Acquisition workstation: This is where the technologist sets the techniques and parameters for the image, as well as inputs the patient's demographics (usually from a worklist). As the images are acquired, they are seen by the technologist on the attached monitor, where he or she can review the positioning and technical factors. Once acquired, the images are sent to

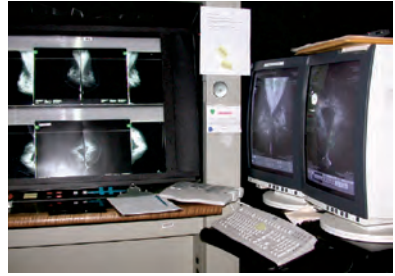


GE DS Acquisition workstation

CAD and to the Soft-Copy Review Workstation, as well as to PACS. How this works within the network is determined by each facility and its workflow patterns.

- o Diagnostic Soft-Copy Review Workstation (SCR) (DX):

This is the workstation where the radiologist will view and interpret the images on high-resolution monitors. The workstation will include a keypad with tools for navigating the radiologist through the electronic reading. These include zoom, pan, window/level, and others, depending on the manufacturer. Third-party SCRs are also available through some PACS vendors, but they must be FDA approved to display mammography and also qualified for use with the manufacturer's equipment.



GE workstation set up with adjacent film alternator to view prior studies performed on film.



GE DS SCR workstation and keypad



LoRad Selenia keypad



Sectra PACS SCR workstation and keypad

Computed Radiography Mammography (CR)

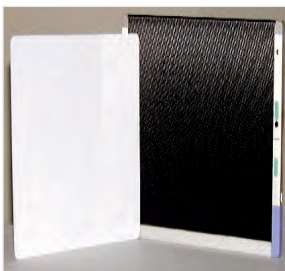
The workflow for acquisition of CR images is mostly the same as for film/screen mammography.

Cassettes are inserted into the bucky on an existing dedicated film/screen mammography unit and are exposed. The cassettes are then processed through a CR processor, which transforms the image data within the cassette into

an electronic file. At this point, the workflow would divert from traditional film to a PACS workflow; the electronic images can then be sent from the processor to PACS and

read on a SCR workstation.

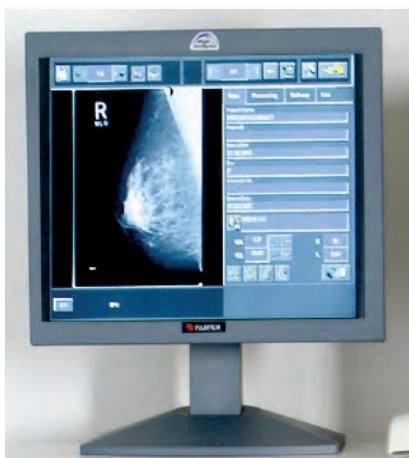
This is not yet available in the United States.



Fuji FCRm Cassette and Imaging Plate



Fuji FCRm CR Reader



Fuji FCRm IIP Technologist Workstation



Kodak Direct/View CR Reader

Images of CR equipment used with permission of FujiFilm Medical Systems and Eastman Kodak Co.

Network Infrastructure

The Infrastructure or Network is the part of the imaging chain that is usually least understood by the medical personnel that use the imaging equipment. It is usually only visible as the outlet where the cables from the unit are plugged into the wall, but it is the pipeline that moves data, both imaging and text, from the RIS to the imaging units and to the PACS and workstations. This involves cabling throughout the facility, but also can be wireless as well as the servers that they communicate with, while sending the electronic signal (digital image) to the right places. This is the area in which an IT person is invaluable.

Each link within the network chain and the manner in which they are all connected will have an impact on the speed with which information is transported and where it can be transported to. The network can be very simple or very complex, depending on the functions it performs and the number of devices on the network. Each network will be unique to the facility or facilities that use it.

Chapter
1

Going
digital

Going digital

Digital Mammographic Imaging Screening Trial

For years, mammography facilities have struggled with “the digital question”: Should they switch from film to digital; does the image quality of digital equipment equal that of film; is the switch worth the financial and time investments?

The mammography world changed in September 2005, when the results of the international, multi-year Digital Mammographic Imaging Screening Trial (DMIST) were released. The trial, which was sponsored by the American College of Radiology Imaging Network (ACRIN), was designed to compare the performance of digital mammography to film mammography.

The results have ended the debate of digital versus film. The study proves that digital equipment is no passing trend. Researchers found that digital equipment not only produced images that were equivalent to the quality of analog, but actually proved better for imaging younger women and those with dense breasts. For information about the DMIST trial, see the box on the next page.

Facts about the DMIST trial

Name: Digital Mammographic Imaging Screening Trial

Conducted by: American College of Radiology Imaging Network

Purpose: To study the “small but potentially clinically important differences in diagnostic accuracy between digital and film mammography,” wrote study authors.

Enrollment: 49,528 women

Average age of women: 54.6

Eligibility: Women who came in for a screening mammogram at the study sites were eligible to participate unless they

- had symptoms of breast cancer
- had breast implants
- thought they might be pregnant
- had had a mammogram for any reason in the past 11 months
- had a history of breast cancer treated with a lumpectomy and radiation

Ethnic backgrounds of the women in the trial:

- White, 81.9%
- Hispanic or Latina, 4.1%
- Black or African American, 11%
- Native Hawaiian or other Pacific Islander, 0.1%
- Asian, 1.9%
- American Indian or Alaskan Native, 0.1%
- Other, 0.1%

Facts about the DMIST trial (cont.)**Menopausal status of women in the trial:**

- Premenopausal, 10.5%
- Perimenopausal, 8.7%
- Postmenopausal, 59.9%
- Unknown or data missing, 2.3%

Breast density of women in the trial:

- Almost entirely fat, 10.5%
- Scattered fibroglandular densities, 42.9%
- Heterogeneously dense, 38.7%
- Extremely dense, 7.5%
- Data missing, 0.4%

Study sites: 33 sites in the United States and Canada

Digital equipment used: Five different types of digital equipment were used in this trial. They are as follows:

- SenoScan, Fischer Medical
- The Computed Radiography System for Mammography, Fuji Medical
- The Senographe 2000D, General Electric Medical Systems
- The Digital Mammography System, Hologic
- Selenia Full Field Digital Mammography System, Hologic

The process: Women underwent both a digital and a film mammogram in random order. Two radiologists independently interpreted the examinations for each woman. Readers rated the mammograms using the seven-point BI-RADS malig

Facts about the DMIST trial (cont.)

nancy scale. Breast density was also recorded using the BI-RADS scale. If a woman had a BI-RADS 4 or 5 finding, she underwent a biopsy or aspiration of the suspicious-appearing lesion. All participants were asked to return for a follow-up mammogram after one year.

A participant was considered to be positive for cancer if the cancer was verified within 455 days of the initial study mammogram. A participant was considered to have a negative finding if tests on a pathology report were normal or if the follow-up mammogram at one year did not show any cancer.

Note: Because of the length of time allowed for cancer detection, the sensitivities of both digital and film equipment appeared lower than sensitivities in other similar studies.

Cancers diagnosed: During the course of the trial, 335 cancers were diagnosed. Of these cancers,

- 75.8% were diagnosed between 366 and 455 days after the study mammogram
- 81% were diagnosed between 366 and 455 days after the study mammography

Source: Diagnostic Performance of Digital versus Film Mammography for Breast Cancer Screening. For more information on the study, go to the American College of Radiology Imaging Network Web site at <http://www.acrin.org/>.

The researchers noted that, in addition to providing superior cancer detection in certain groups of patients, the technology had other advantages, including the following:

- Easier access to images
- Easier use of computer-assisted diagnosis
- Improved transmission of images
- Improved storage and retrieval of images
- Lower average dose of radiation exposure for the patient, while providing images of the same quality

As digital mammography moves into the forefront of the mammography field, radiologists, referring physicians, and even patients are going to be looking for access to digital equipment. The question for mammography facilities has thus changed from “Should we should make the digital conversion?” to “When?” and, more important, “How?”

Advantages of digital mammography

The advantages of digital mammography are far-reaching, benefiting patients and staff alike. Arguably, one of the most important advantages of digital technology is its improved contrast resolution compared to its screen film counterpart, which allows for improved cancer detection. This technology will benefit many patients, but the ACRIN trial found that digital mammography is most accurate in women under the age of 50 years, women with radiographically dense breasts, and premenopausal or perimenopausal women. Screening these women with digital equipment increases the chances that a cancer will be found that might otherwise have been missed.

Technologists tend to favor digital imaging because the imaging system is more forgiving. For instance, over-exposure or under-exposure is less of a problem in digital imaging, because the image can be manipulated electronically to visualize the breast tissue. With film, the only option is to retake an image. There is no such thing as too dark or too light in digital imaging, but there is under- and over-exposure, typically revealed by low signal-to-noise ratio and a reduced dynamic range, respectively.

Technologists also favor the technology because there is less running around. With digital imaging, the technologist can check the quality of the images while the patient remains in the room, instead of leaving the room to take care of films. This will reduce the number of footsteps for the technologist and will likely ease patient anxiety and improve patient satisfaction. This is particularly evident during pre-operative wire localizations, since the doctor can instantly view the images in the x-ray room.

Typical film processing problems are eliminated with digital technology, as are the headaches that go with them. There will be no more mixing and dumping chemistry, and no more problems with films that are too dark or too light. Eliminating processing makes digital mammography more portable than film. Images can be shipped electronically in a matter of minutes, and because the reading radiologist can be anywhere, digital imaging may finally make mobile mammography a viable alternative, opening up access to underserved areas. Digital images can then be stored or transmitted to the radiologist for interpretation.

Improved contrast resolution is just one aspect of imaging that is improved with digital technology. Another promising aspect of digital imaging is the capacity to re-build the image electronically in order to provide a three-dimensional view of

the breast. The two-dimensional mammogram is limited, and the superimposition of structures accounts for missed cancers as well as additional work-up to prove patients do not have cancer. Tomosynthesis is one such technology that may build upon existing systems and improve the overall accuracy of mammography.

Disadvantages of digital mammography

Although the prospect of improved ability to detect cancer should make the decision to transition to digital equipment easy, the change isn't always straightforward for facilities. Digital equipment brings with it a number of disadvantages, the most glaring of which is its cost.

Cost

One digital unit can cost approximately \$500,000, and many facilities will need multiple units. And the investment won't end there. A facility making the digital leap will also need to spend money in other, less obvious areas, from image storage systems to air conditioning units. Each electronic mammographic study requires about 100 megabytes (MBs) of secure, accessible storage space. Solutions include use of an existing picture archiving and communication system (PACS), purchasing a new system, or leasing or purchasing off-site storage.

The electronic components of digital systems produce more heat than analog systems and have cooling requirements to keep them at peak operating parameters. Temperature fluctuations can affect the unit's detector and accompanying computer. Maintaining the temperature of a room can become a challenge, especially if a facility shuts down heating/cooling over holidays and weekends. As a result, special cooling needs will have to be addressed.

Aside from the digital system and the archiving system, a network will have to be installed and maintained to connect the two systems. Existing networks may need upgrading to allow the increased need of bandwidth for digital mammography images. New equipment will likely bring networking and maintenance woes. A facility will need to ensure that new systems can work in unison with existing systems.

Connectivity is the term used to describe how systems talk with one another to allow the accurate labeling, transfer, and storage of digital images within or outside a facility. Many facilities use equipment from various vendors, which may or may not be compatible with each other. As a result, new connectivity issues may frequently crop up, and you will need staff trained to solve these problems. One way to avoid, or at least minimize, connectivity problems is to determine the requirements of existing equipment and the connectivity and storage needs, and then write the requirements and needs into a “Request for Proposal” (RFP) prior to purchase. Securing a manufacturer’s assurance of compatibility with existing systems helps shift the responsibility to the vendor. Purchasing a digital system without an RFP may leave you with a \$500,000 headache. The Radiologic Society of North America’s (RSNA) Integrating the Healthcare Enterprise (IHE) is publishing guidelines for writing an RFP. See Chapter 3 for further discussion of IHE.

Service contracts are also more costly with digital systems and are not really optional; the systems are just too complex to go without one. Although digital technology has been around for a number of years, it is still a relatively new technology, which means it’s still evolving. You may encounter more problems with this generation of digital equipment than with typical analogs. Vendors have been working hard to create solutions, but you should be prepared to deal with some hassles.

Loss of efficiency

Your facility may experience a temporary slowdown in workflow when it converts to digital equipment.

- **Staff must be trained on the new technology, which will take time and cost money.** And although staff members may recognize the value of this new technology, it can be difficult for them to switch to machines on which they will initially be slower and less efficient.
- **New workflow paradigms will have to be designed.** Trying to fit digital technology into an existing analog workflow will result in unrealized efficiencies. Technologists and radiologists, as well as administrative personnel, must have the flexibility to alter workflow based on the digital equipment and electronic imaging. Each analog task, no matter how meaningless it may seem, must be transferred to an electronic world in order to assure that efficiencies are realized and that accuracy in viewing, storage, and retrieval are maintained.
- **Quality control (QC) will initially take longer.** Most technologists are proficient with the testing necessary for film/screen, but digital imaging involves a totally different technology. It will take time for technologists to discover the nuances of the units and how they work. Also, each vendor has its own QC procedures, based on what was submitted for FDA approval and so required by the Mammography Quality Standards Act (MQSA), and a facility may end up following several different protocols if it has different types of equipment. The American College of Radiology (ACR) is currently in the process of establishing standard QC procedures for equipment, which should ease the process, but these standards won't be immediately available. (See box on the following page.)

The American College of Radiology standards

What it is: The American College of Radiology Commission on Quality Safety, Committee on Mammography Accreditation, Subcommittee on Digital Mammography

Its purpose: The subcommittee's work involves reviewing all aspects of the digital mammography accreditation process and providing oversight to the development of the Digital QC Manual. Once it has drafted a complete QC manual, there will be discussions with vendors about their concerns with the draft and about the best way to implement some of the testing that has been suggested. It is hoped that the committee will work quickly to establish standards.

Who is on the committee:

Martin Yaffe, PhD (chair), Lawrence Bassett, MD, Maryann Chorlton,

RTRM, Edward Hendrick, PhD, Andrew Karellas, PhD, Murray Rebner, MD, Mark Williams, PhD, Judy Destouet, MD, Julianne Greenberg, MD, Ellen Mendelson, MD, Valerie Andolina, RTRM

ACR Staff—Priscilla Butler, MS, Marion Boston, RTRM, Joyce Hahn, RN, PhD

- **Radiologists will likely experience some efficiency problems during the switch.** Not only will they have to compare the new digital images against past film images, which will slow them down, but they will have to become accustomed to the nuances of digital images. Studies have shown that there is a sharp learning curve for radiologists who are new to interpreting digital mammography images, and the process is slower than with interpretation of film images by a ratio of about 2:1.
- **At some facilities, there are problems with technologists appreciating motion on the low resolution monitors of full field digital mammography (FFDM) acquisition stations.** Because these monitors are generally only 1 megapixel (MP), as opposed to the 5MP monitors that are used on the radiologist's workstation, it is difficult to discern whether motion is present, not because motion is not apparent, but because the low resolution of the monitors makes even good images look somewhat blurry. A technologist needs to view an image at 1:1 resolution to determine whether it is necessary to retake the image. Vendors are aware of this issue and are upgrading monitors at the modality workstation. Meanwhile, the radiologists' monitors will have the best view.

The big picture

Although the list of disadvantages seems long, the technology can certainly enhance your operations. Over time, digital equipment will pay off in increased efficiency of technology staff, reduced staffing, cost savings on film and chemistry, and physical storage space needed for charts. But most important, digital technology will take breast imaging into the future and improve the way we image patients today.

As digital mammography becomes widespread in the radiology community, many facilities will have to embrace the advantages while finding ways to work around the disadvantages.

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