Realizing the Benefits of

Full-Field Digital Mammography

The Role of the Film Digitizer

Introduction

The use of full-field digital mammography (digital radiography and computed radiography) is increasing rapidly in the United States and around the world. In the two years since the National Cancer Institute's Digital Mammographic Imaging Screening Trial (DMIST) showed significant image quality advantages of digital mammography for several patient categories,[1] more than 22% of mammography facilities in the U.S. have adopted some form of digital imaging capabilities.[2,3] While the analog mammography market has seen a 70% decline in revenues since 2003, sales of digital mammography systems have increased substantially—from 44.5% of the total market in 2003 to 82.1% in 2006.[2] A similar trend is occurring in the European Union, which is experiencing a "digital transition wave" in mammography, driven by government implementation of breast cancer screening programs as well as the need to replace older analog systems.[4] Decreasing prices and technological advances in digital mammography are further fueling this worldwide trend.[2]

Many factors must be evaluated when planning for full-field digital mammography (FFDM) in order for facilities to reap these important benefits. In addition to securing increased capital budget dollars to purchase digital systems, facilities must plan for film storage for hard copy and digital files and address the unique workflow requirements of digital mammography in order to ease the transition to digital imaging.[5] The purchase of an FFDM system usually includes an analysis of how the new digital images will be archived, the FFDM device itself, and acquisition of a Food and Drug Administration (FDA)-approved mammography reading workstation.

A key factor often overlooked during the planning stage is the need to view patients' prior mammography exams for comparison as part of the reading workflow. Medical film digitizers play an important role in the implementation of digital mammography by allowing digitization of prior analog films for side-by-side review of current and prior-year studies—eliminating the need for a cumbersome "dual reading" environment in which mammographers must continually switch from a digital workstation to a light box.

Film digitizers used for mammography must deliver superior image quality. Software also must support unique mammography requirements and, in high-volume applications, software and hardware must work together to integrate sophisticated batch film feeding capabilities. Software is a vital component that reduces steps in the workflow, which for busy centers add up to significant usage cost over time. Armed with the right hardware and software, appropriate digital archive storage space, and sufficient user knowledge, a film digitizing solution for prior images can have a positive impact on the transition to FFDM.

Full-Field Digital Mammography

Full-field digital mammography was introduced in tandem with an overarching trend toward digital imaging in healthcare. While the implementation of digital mammography initially lagged behind that of other digital imaging applications due to costs and other factors, the recent increase in adoption has been spurred in large part by the landmark DMIST trial, conducted by the American College of Radiology (ACR) Imaging Network, which studied nearly 50,000 women at 33 imaging sites. Preliminary results, published in 2005 in *The New England Journal of Medicine,* demonstrated the benefits of digital mammography for women with dense breast tissue, women under age 50, and premenopausal or perimenopausal women.[1] Researchers cited the fact that digital mammography allows the optimization of both image acquisition and display. In particular, it allows manipulation of the degree of contrast in the image, as well as the magnification, orientation, and brightness, in order to obtain a more accurate clinical evaluation.[1]

Digital mammography also allows technologists to quickly verify image quality, contributing to improved workflow and patient satisfaction. Patient satisfaction is increased when images are screened before the patient leaves the facility and follow-up occurs quickly, sometimes in the same day. Reduced patient callbacks of up to 30% have been achieved at some facilities.[5] Improved workflow also provides the potential for facilities to serve more patients, with one facility increasing its patient load from 55–65 patients a day to 150 patients as a result of installing three

digital mammography systems.[5] The ability to store and retrieve images electronically also facilitates the use of off-site screening centers.

Significant workflow issues, however, accompany the need for mammographers to review and compare current digital mammography studies with prior analog films.[5] Mammographers have limited time for reading mammography exams, and the need to move from digital workstation to light box and back is cumbersome and time-consuming, creating a less-than-ideal clinical environment.[6,7] Hybrid viewing also raises issues of quality and consistency, partly due to incompatible optical luminance and illuminance levels. There also are significant costs and resource requirements associated with handling prior analog films, such as the staff time required for retrieval and hanging of film.

Medical Film Digitizers

For mammography centers and radiology departments planning to acquire FFDM systems and film digitizers, procedure volume is a key consideration, along with budget. Appropriate matching of the facility's procedure volume with the choice of a film digitizer and software can support workflow and favorably impact mammographer satisfaction as well as costs—both the initial expenditure and operating costs. But an initial evaluation of image quality must be conducted.

Image Quality

 "An acceptable mammography film digitizer must provide high-quality images at a level of diagnostic accuracy comparable to reading conventional film examinations."[8]

Image quality is a key concern, both for the digital mammography systems and for digitizers used for scanning prior films. The ability to provide a high-quality image is a critical factor in the selection of a digitizer for use with FFDM. This holds true despite the lack of specific FDA or Mammography Quality Standards Act (MQSA) guidelines for digitizers used to scan images for comparison with new digital exams. The MQSA recommends that, "phantom and clinical images produced by such copying or digitization pass all applicable quality control tests and be of such quality that if they were submitted, they would pass

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the facility's accreditation body's phantom and clinical image review process."[9]

The Advantage line of digitizers from VIDAR Systems Corporation excels both in quality control and clinical review. The company's Advantage products provide ADC (Automatic Digitizer Calibration), a closed loop quality assurance (QA) system that calibrates the digitizer automatically before every film digitized. ADC, combined with high-end electronics such as HD-CCD® imaging and LED lighting systems, allows the digitizers to provide excellent spatial and contrast resolution with virtually no variation between digitized films, ensuring superb grayscale reproduction with every scan. The system allows mammographers to be confident that the resulting image is an excellent representation of the original film. This reproducibility, vital for computer-aided detection (CAD) as well as digitized priors, is a hallmark of VIDAR digitizers.

Image quality of VIDAR digitizers in a clinical setting is supported by a comparative study conducted at the Johns Hopkins Medical Institutions and published in the *Journal of Digital Imaging*. Eight radiologists interpreted 120 mammography examinations, half as original films and half as digitized images on a workstation. Results showed no significant differences between the interpretations of conventional film mammography examinations and softcopy exams produced by a mammography film digitizer.[8] The study was conducted using the CAD PRO® Advantage digitizer from VIDAR.

The use of digitized mammography films for comparison is well accepted and current systems, such as those provided by VIDAR, are performing at an exceptionally

high quality level. Digitizers used for mammography must support a small spot size (50 microns or less), in order to see the shape and arrangement of various microcalcifications. There is debate over what bit depth resolution should be used for digitizing mammography films—12- or 16-bit systems both are acceptable. VIDAR offers two film digitizers for this application. *(See Table 1)*

Film Digitizer & Software Requirements for Mammography

A film digitizer must be considered as part of a solution that includes software to drive its operation. When acquiring a digitizer for mammography use, buyers also must educate themselves about the differences between DICOM SC (Secondary Capture) and DICOM MG (Mammography) images, as some applications can display MG images but are not capable of creating an MG-compliant image. *(See DICOM sidebar)* However, a range of software solutions from multiple manufacturers is available. VIDAR's intention is not to promote one software product over another, but rather to open the discussion so that the chosen solution will meet the facility's needs.

Low-Volume, Mixed File Room

Centers with a lower volume of mammography patients (5–20 per day) and mixed mammography and general radiography file rooms often have budgets that will not accommodate the purchase of a separate digitizer for the mammography application. VIDAR's DiagnosticPRO® Advantage film digitizer with software optimized to scan images in DICOM MG and SC is an ideal solution for these facilities. *(See Table 2)*

The DiagnosticPRO Advantage offers a 44-micron spot size selection and 12-bit imaging output, as well as up to 4.0 OD, satisfying the imaging demands of the mammographer. By using software supporting DICOM MG, technicians can manually label each type of film (RCC, LCC, etc.) so that when the images arrive at the mammography reading workstation, they can be used with that radiologist's mammography-specific hanging protocol. This process ensures that each view is placed in the correct order and orientation, according to each mammographer's preference.

For radiology, the DiagnosticPRO Advantage offers variable bit depth and resolution settings (including lower resolution and file size than are needed in mammography) in keeping with regulations for teleradiology and PACS usage from groups such as the ACR. It also offers flexibility for the large variety of film sizes that are seen in the radiology department. The application software supports DICOM SC to correctly view and work with images on the PACS workstation.

Although numerous PACS applications support DICOM SC, few support both DICOM SC and MG, which are necessary when both mammography and general radiography films need to be digitized. To address this challenge, VIDAR offers dual-function capabilities in the ClinicalExpress® 4.0 film acquisition software version. This software supports both the DICOM SC and MG formats, allowing low-volume centers to handle mammography and general radiography with just one digitizer, one software program, and one workstation. Several VIDAR partners also have invested in enhancements to their software specifically for this application.

Table 1: VIDAR Film Digitizers for Mammography

	DiagnosticPRO Advantage	**CAD PRO Advantage**	
	SPOT SIZE 44 µm	**SPOT SIZE** 44 µm	
	BIT DEPTH 32-bit mapped to 8- or 12-bit output	**BIT DEPTH** 32-bit mapped to 12- or 16-bit output	
	OPTICAL DENSITY 0.05–4.0	**OPTICAL DENSITY** 0.05–4.2	

Both products include ADC subroutine, HD-CCD imaging system, and LED lighting system.

Mid-Volume, Mammography Specific

In contrast, mid-volume centers with file rooms dedicated to mammography benefit from mammography-specific film digitizers with an increased optical density range such as VIDAR's CAD PRO Advantage. *(See Table 2)* As with low-volume centers, digitizers that support the DICOM MG standard are critical for these sites so that mammography-specific hanging protocols can automatically place prior studies in the proper order and orientation for the mammographer.

The CAD PRO, a device specific to mammography, offers a higher optical density (up to 4.2 OD) and bit depth capability (up to 16 bits) than the

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DICOM, DICOM MG & DICOM SC

Digital Imaging and Communications in Medicine (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.

DICOM MG

Digital Imaging and Communications in Medicine for Mammography SOP CLASS (DICOM MG) as an SCU (Digital Mammography X-Ray Image Storage—for presentation SOP Class UID 1.2.840.10008.5.1.4.1.1.1.2) deals with the presentation and manipulation of mammography studies. Purchasing systems that abide by this SOP class can dramatically ease the transition from film to FFDM. Specific to digitizing prior films for comparison, the DICOM MG SOP class addresses, among other things, the proper labeling of the specific views of mammographic films so that the digitized images can be oriented and hung automatically on a mammography workstation using a mammographer's specific preferences. The items referenced below are not intended to be a comprehensive review of a DICOM conformance statement but rather to highlight items relevant to the use of hanging protocols. It is important to review a manufacturer's DICOM conformance statement to verify that the solution is made for mammography. Examples of important criteria include:

- **Patient Orientation (0020,0020)**—contains one of these—P\F, P\FL, P\FR, P\L, A\F, A\FL, A\FR, A\L [i.e. A(anterior), P(posterior), R(right), L(left), H(head), and F(foot)].
- **Image Laterality (0020,0062)**—contains either R, L, or B (i.e. Right. Left, Both).
- **View Code Sequence (0054,0222)**—contains one of these: CC, ML, MLO, LM, LMO, FB, SIO, XCC, XCCL, XCCM [i.e. CC(cranio-caudal), MLO (medio-lateral-oblique)].
- **View Code Modifier Sequence (0054,0222)** describes special views such as cleavage, magnification, and spot compression, which typically are not used in a screening application but are critical in diagnostic or symptomatic environments.

Without detailed labeling of these views at the digitizing workstation, it is impossible for the mammography reading workstation to identify the view and place each film properly on the screen. Reading workflow can be complex, with each user likely to have his or her preferences for how studies are viewed. For example, a user might first look at all four newly acquired images, then look at current and prior images together (eight images), and finish by focusing on the current and prior left MLO images to view something suspicious. Mammographers also have specific hanging protocols for various types of studies—screening, symptomatic, pre- and post-treatment, etc. Without proper labeling in the digitizing software, protocols integrating priors are impossible to use.

DICOM SC

The DICOM SC (Secondary Capture) SOP class, the most supported portion of the DICOM format for film digitizing, supports orientation and order of images for use in PACS applications. Many applications provide excellent support of this standard, but DICOM SC is not adequate for mammography.

DiagnosticPRO Advantage, but can only accommodate original mammography images. This increased optical density is ideal for mammography studies, which tend to be darker than other radiography studies. In addition, the CAD PRO Advantage digitizes a four-film study in less than two minutes, enhancing speed and efficiency. VIDAR's ClinicalExpress film acquisition software for mammography is one of a limited number of software solutions that meet the needs of mid-volume centers.

High-Volume, Mammography Specific

High-volume centers also require film digitizers to scan prior mammography films for comparison with current studies. *(See Table 2)* Ideal for this market segment, VIDAR's CAD PRO Advantage digitizer originally was designed and engineered for use with mammography CAD systems. Many centers are successfully using digitized film CAD technology, and the workflow for high-volume centers remains the same whether CAD is added to digitized films or not. As a result, several CAD vendors have created workflow-oriented digitizing systems that go far beyond the DICOM MG standard. And while the CAD PRO Advantage is a key part of a solution for high-volume centers, with its exceptional spatial and contrast resolution and ability to quickly provide a near-exact representation of original film, it is the software that transforms the CAD PRO into a high-performing solution.

These software vendors also take advantage of the excellent speed, high reliability, and maintenance-free operation of VIDAR's SmartFeeder®—a unique, modular 50-sheet film feeder that supports continuous case loading, allowing the technician to add cases without interrupting the digitizing process. This capability is unavailable outside of these specialized mammography applications, even if the digitizer purchased with the solution has a large feeder capacity.

Although solutions differ, much attention has been paid to ways of automating the various QA steps needed to ensure that studies appear flawlessly on the mammographer's workstation. A limited number of high-end solutions are available, most born out of the CAD environment. (Note that VIDAR's ClinicalExpress software is not intended for customers with a patient volume exceeding 50 patients per day.)

Other Considerations

Other considerations for facilities transitioning to FFDM include the large file size of digitized mammography images, education and training for persons operating film digitizers, use of older digitizers for digitizing mammography priors, and the availability of modality worklists.

The large file size of digitized mammography films (40–70 MB) must be considered in planning archive space, networking, and pre-fetching demands. Using

Table 2: Film Digitizer Requirements for Mammography

TYPE OF CENTER	CHARACTERISTICS	VIDAR DIGITIZER SOLUTION	SOFTWARE SOLUTION
Low-Volume	• Single file room (general radiography & mammography) • 5–20 mammography patients per day	DiagnosticPRO Advantage	Supports DICOM MG & SC SOP classes as an SCU
Mid-Volume	• Mammography-specific file room • 20–50 patients per day	CAD PRO Advantage	Supports DICOM MG SOP class as an SCU
High-Volume	• Mammography-specific file room • >50 patients per day	CAD PRO Advantage	Supports DICOM MG SOP class as an SCU & utilizes VIDAR's SmartFeeder for batch digitizing

a lossless compression approved by DICOM, approximately 40% compression can be achieved, for a file size of about 42 MB for a 24 x 30 cm film, and 25 MB for an 18 x 24 cm film. Some applications adjust the spot size of the digital image or allow use of higher levels of compression, resulting in smaller files.

The mammography knowledge of the person performing the digitizing also plays an important role in the success of a program. With PACS, far less skill is required—simply select an appropriate resolution, scan, and send. For mammography, each individual film must be labeled, and the skill of the user is key during the QA process. Do users know the difference between an LCC and LMLO, mag or spot views? The more automated the system, the less opportunity for failure, but experience is required to determine which mammography view to tag with what code. In addition, rules may vary greatly regarding which prior analog images should be digitized (oldest study, most current, all prior, etc.).

Facilities often ask whether an older digitizer can be used for the mammography application. The answer depends on their needs and what type of digitizer they have. New software might be required, and may not be available separately. As a result, it is important to thoroughly discuss this when evaluating digitizer options. For example, an older VIDAR DiagnosticPRO Advantage with software upgrade may provide a solution for low- to mid-volume applications, but not for high-volume digitizing.

In addition, modality worklist options are available, eliminating the need for typing in patient data already contained in a RIS or PACS. While the modality worklist standard was developed for acquiring new studies, not for film digitizers scanning past exams, challenges can be addressed. The exact solution depends on the RIS and PACS environment, the integrating software, and the facility's needs.

Conclusion

Clinical studies have validated FFDM as a key tool for the early detection of breast cancer. As a result,

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an increasing number of breast centers and radiology departments worldwide are converting to the technology in order to improve patient care, enhance workflow and efficiency, eliminate film and film processing costs, and increase mammographer and patient satisfaction.

Chief among the workflow challenges when switching to FFDM is the need to compare current digital studies with prior analog films—a process that is cumbersome and time-consuming for mammographers and staff unless the prior films first are digitized. Selecting the appropriate high-quality film digitizer solution, however, requires that facilities understand their unique needs and the hardware and software features of available solutions. In particular, general digitizing solutions that support DICOM SC SOP but not DICOM MG are not sufficient.

As part of its longstanding commitment to the medical imaging field, VIDAR Systems Corporation offers a variety of digitizers featuring exceptional image quality for dedicated use in specific market segments. VIDAR also works closely with its partners and customers, allowing them to select the best combination of software and hardware for their facilities and ensuring that a digital mammography system delivers both patient care benefits and greater radiologist and staff productivity. ■

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