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TITLE: CLINICAL EVALUATION OF A DIGITAL MAMMOGRAPHY BASED
ON MICRO-LITHOGRAPHY (BREAST CANCER)

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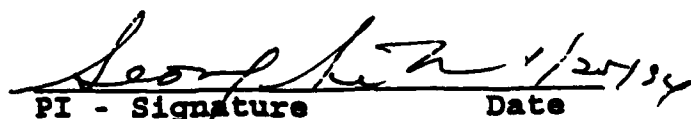
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**CLINICAL EVALUATION OF A DIGITAL MAMMOGRAPHY
BASED ON MICRO-LITHOGRAPHY**

REPORT ON FIRST YEAR OF PROJECTS

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ENHANCEMENT OF CURRENT TECHNOLOGIES FOR DIGITAL MAMMOGRAPHY

1.0 INTRODUCTION:

The first year of the project was spent gathering preliminary data essential to understanding the image acquisition requirements for digital mammography based on amorphous selenium and insulating layers. There are almost no publications in this field relevant to the specific work done in this project.

Although digital mammography is in limited clinical use in Europe (1,2,3,4), it is still considered an experimental technique in the United States where it has been described as being promising, but not having sufficient resolution (4,5,6) or of insufficient resolution with the possibility of improved resolution far in the future (7). Based on our experiments in system optimization, we believe we understand the disagreement in opinions is likely due either to differences in exposure factors used or differences in the image processing parameters used by different centers. Unfortunately, the actual image processing parameters used by various authors and the actual exposures used are usually not mentioned in these articles, but as our work suggests, the appropriate setting of these factors is essential to high quality digital mammography.

The narrative summary that follows is based on the development project that 3M has been conducting in collaboration with Georgetown research team.

2.0 THE ASSIGNED TASKS FOR THIS PROJECT ARE:

1. Evaluate the physical image quality of a prototype digital mammography based on a micro-lithography technology by 3M.
2. Determine a MDIS compatible user interface.

3. Conduct a clinical evaluation of the imaging device, if the physical measurements are acceptable.

3.0 THE THREE COMPONENTS FOR SUCCESSFUL DIGITAL MAMMOGRAPHY:

There are three components required for the successful development of a digital mammography system. These are the methods of image acquisition, the methods of image processing, and the methods for image display. This research deals primarily about the first two factors and image display is handled in a more comprehensive manner in a separate but related project. The research from the first year has demonstrated the requirements for image acquisition and has demonstrated appropriate parameters for portions of the necessary image processing.

This report will deal with the first two items in the tasks listed above.

4.0 IMAGE ACQUISITION FOR DIGITAL MAMMOGRAPHY

4.1 Initial state of knowledge:

Relevant Prior Publications:

Publications on digital mammography implied that the development of a digital mammography system would require the development of new detectors because existing systems did not have adequate resolution. (4,5,6,7)

We could find no articles specifying the required resolution for digital mammography. There are a few articles describing that 100 micron pixel size appears not to be sufficient. One source (7) suggested specific resolutions were based on the assumption that it should equal the high contrast resolution of screen-film mammography: 20 line pairs per mm.

Oestmann (10) reporting work with a 5 lp/mm storage phosphor system reported that while a 5 lp/mm system was sufficient to detect all clusters of microcalcifications, that individual microcalcifications were less well seen at this resolution. He reports that he selected image processing settings that resulted in

images "similar to those of conventional mammography." He used the same exposure as used for the conventional screen film images he obtained for comparison (30KVP at 250 mAs). This is a higher KVP than would normally be used for conventional mammography and would be expected to decrease the contrast of calcifications on the conventional images (our most common setting is 26 KVP).

Chan (11) reporting on the use of high quality film digitization at 100 micron pixel size found that digitized mammograms provided lower detectability of subtle microcalcifications than conventional screen film mammography. She found that unsharp masking improved the detectability of the calcifications, but that even with unsharp masking, the conventional screen film mammograms still had a higher detectability rate. She indicates that this is due to their being a higher false positive rate.

4.3 Exposure:

We assumed that any system developed would have to use the same or less exposure than conventional screen-film mammography.

4.4 Methods of obtaining a digital mammogram:

There are two methods of creating a digital mammogram: direct digital acquisition and digital transformation of an analog image. Direct digital mammography systems either existing or under development use storage phosphor plates, charged coupled devices (CCD), selenium plates or electron capture devices. Film digitization devices can be based on laser, monochromatic or diffuse light.

4.4.1 Direct Digital Mammography Devices:

A survey of existing direct digital mammography machines revealed that only Fuji Corporation had a working FDA approved system for digital mammography. We acquired such a system for testing in September, 1993. No other existing commercial machine was identified. Research devices are under development by Dr. Martin Yaffee in Toronto, by Lorad Corporation, 3M, and by Fischer Corporation in the U.S. and Fuji Corporation in Japan. In addition, several smaller companies are exploring various devices. We are working with 3M and with Princeton Instruments on their

machines and have had discussions with Photometrics, Lorad and others. These devices are not yet finished and were unavailable for testing. Images from some of these machines have been reviewed. Currently the Lorad images are the most promising, but we were unable to due a true assessment of the machine.

4.4.2 Film Digitization for Digital Mammography:

There are existing devices for film digitization based on laser or CCD technology using 100 to 200 micron pixel sizes available from multiple vendors including Lumisys, Vidor, Vision 10, and others. There are a few companies claiming 50 micron digitization capabilities, usually over a limited range of optical densities. We have been investigating the technology under development by DBA, Inc. This 42 micron pixel system has had construction delays and should be delivered to us in January, 1994, for intensive testing. Should film digitization prove to be an appropriate technology for further investigation, then the required pixel size for this technology could be determined. Tests to determine the preferred contrast characteristics for mammograms to be digitized will be determined once the machine is on site.

4.5 An Evaluation of the Resolution Requirements for Digital Mammography:

At the start of this project, we could find no information related to the pixel size that a digital mammography machine would have to have to equal the detectability of objects seen on screen-film mammography. The two articles mentioned above (Oestmann and Chan) suggested that 100 micron pixel size was insufficient. Screen-film mammography systems can have up to 20 line pairs per millimeter (lp/mm) of high contrast resolution. This would imply that one would need a system with 25 micron pixel size to equal the high contrast resolution of screen-film. The only contemplated systems that we are aware of that come close to this resolution are film scanners. If indeed this resolution was required, then all of the direct digital systems under development would end up being insufficient for digital mammography. Because of this we undertook both an experimental and theoretical approach to determine the effect of different pixel sizes on the detection of very small radiodense objects. The theory will be presented first followed by the experimental evidence that supports it. This will then be followed by a discussion of the implications of these

findings for further research. (This material was presented at the Computer Assisted Radiology (CAR) Meeting in Berlin, June, 1994.)

5.0 High Resolution Detector based on selenium detector

One approach to a digital x-ray detector is to use a photo-conductor which generates hole-electron pairs in response to the x-ray flux, which are separated by an electric field and stored as a latent image for later readout. A prototype digital x-ray imaging device under development by 3M consists of an x-ray detector and an image reader. The x-ray detector is a thick-layer amorphous Selenium and insulation layer device that stores the x-ray latent image as a charge distribution at the Selenium/insulator interface. It can be modelled as two capacitors in series, with charge injected through the photoconductor to the pc-insulator interface by radiation. The reader is a scanning device that uses a pulsed HeCd laser (441 nm) to read the latent x-ray image stored in the detector. The image reading laser pulse releases the latent image charge from the interface. The released charge is detected, digitized, and stored by the image reader.

The prototype device operates with a large dynamic range and produces linear x-ray signal response for clinically reasonable x-ray exposure. Clinical quality images can be obtained at x-ray exposures that are comparable to those used for state of the art film screen systems. The resolution of the image (pixel size and pixel spacing) is determined by the size and placement of the image reading laser. The prototype is routinely operated at resolutions from 50 micron to 170 micron.

The performance of the device will be compared with theoretical results. Initial results show linear x-ray signal response to x-ray dose for low exposures, and a large dynamic range. For example, with typical parameters (430 micron Se, 188 micron insulator, 10 volt/micron field) the model x-ray-signal from the readout is 0.35 nCoul/sq.cm per mR, with dynamic range to 30 nC/sq. cm at 200 mR X-ray exposure.

Currently final engineering work is underway so that the prototype system can be shipped to Georgetown for clinical installation. It should be noted that the development of the system is entirely funded by 3M and it is outside the scope of this project. Technical collaboration and clinical evaluation is are part of this funded project.

6.0 Workstation

MDIS compatible workstation features are developed in collaboration with Major Donald Smith, MDIS project officer at Department of Radiology, Madigan Army Medical Center.

General.

The workstation shall provide multiple image manipulation and enhancement functions through use of a graphical user interface (GUI). The selection of these functions will be done by pull down menus, soft buttons, and quick key options. The pull down menus and soft buttons must be duplicated on each monitor. The following are required performance parameters.

Worklist/Patient list.

The workstation shall automatically generate a worklist of unread (those images not already dictated) exams to enable each radiologist to review the amount of work ready for review. The worklist can be created for a specific radiologist. The worklist must include the patient name, ID number with family member prefix (FMP), date of exam, time of exam, number of images, requesting physician, and requesting location. Additional data necessary to be displayed with the image in a data window is family history, hormone replacement therapy history, and any history of biopsy. Graphical information about location of moles, biopsy scars, breast masses as well as an comment box must be available at the QC workstation for input by the technologists in a mouse driven free hand form. This worklist/ patientlist will be printed out to a printer on an ad hoc basis. When the diagnosis is made, the exam will automatically be deleted from the worklist and be placed on a recently read reviewing list. A special conference list with images will be possible with dearchiving the night before which will typically have 5-10 exams with one historical exam for each. The different worklists will be chosen by using a pull down menu option.

Soft Buttons.

Various functions described below will be utilized by using an icon represented soft button on the monitors. (see appendix a) The soft button is activated by clicking the mouse driven cursor on the function desired. The soft buttons will be duplicated and displayed on all workstation monitors. They should be logically grouped according to function. Context sensitive display of soft buttons may be used to conserve monitor real estate.

Image Selection.

A mouse driven cursor selection/ deselection tool will allow individual images to be selected/ deselected for image manipulation. One option is to sequentially select images. A second option will deselect the previous choice before the next image selection so that only one image is selected at a time for image manipulation. These choices will be activated by A pull down menu or quick key option will select all images in an exam for image manipulation.

Image Rearrangement and Display.

The workstation shall allow display of multiple images on a single monitor with a rearrangement capability. Rearrangement of images between monitors also shall be possible. Individual images will be moved by a mouse dragging option with overlap of images possible. A pull down menu and quick key options will arrange the images in the closest fit for the multiformat option chosen.

Multiformat Image Tool.

The workstation will have the interactive option to display multiple images across multiple monitors in a 1:1, 2:1, 4:1 and 6:1 option as a minimum. (e.g., a current and three previous mammography exams are to be compared. Each exam has two CC and two MLO views. The 4:1 image option will allow all the exams too be viewed across four monitors in a minified view , four images of one exam seen on each monitor.) The images will be sized to fit the monitor viewing boundary automatically. The multiformat selections will be chosen by pull down menu, quick keys, and monitor soft buttons. These images would be enlarged to full monitor size by the tool described below. A page up and down soft button and quick key will be available when more images are available

than displayed on one or more monitors depending on the multiformat and default display protocol chosen. (e.g., six images are available and a 1:1 format was chosen. A page down button would display the remaining two images on monitors A and B of a four monitor workstation.)

Double Click Image to Full Size.

An Image displayed in a multiformat manner will be enlarged to full monitor viewable size by a double click of the mouse button. The double click of the image again will minify the image back to the previously selected multiformat size. Each monitor will act independently of each other as this tool is utilized.

Default Display Protocol.

This required function displays the images of a patient study in a user-selectable protocol, activated each time the individual user logs on the workstation. If no individual default exists for the user, the department default and protocol is utilized. (See Appendix A for details of these protocols.) Ideally the software will recognize Right, Left, Cranio-Caudad, Medial-Lateral-Oblique, Direct Medial-Lateral, and other special image view images as identified initially by the technologist. In most cases the position of the breast for the standard views will be the same allowing for easy identification of the type and orientation of the images. As a minimum, the correct orientation of the image will be presented to the Radiologist as part of the default display protocols below. The different presets for these protocols will be activated by pull down menu, quick keys, or soft buttons.

Next Exam.

A pull down menu, quick key, and soft button will be available for choosing the next exam on the worklist awaiting diagnosis. This will also close the exam that was just read and diagnosed. The option to skip the current exam (needing additional views for a current or call-back patient) and go on the next exam will be available. The next exam displayed will follow the default display protocols as above.

Image Enhancements Defaults.

The workstation shall include multiple user-selectable image enhancement defaults for gray scale windowing and leveling, variable degrees of edge enhancement, and inverse video, activated each time the individual user logs on the workstation. The images of an exam displayed will automatically be window and leveled at a user's and/or departmental default. These defaults will be easily modified by the user and be activated by pull down menu and quick key options.

Edge Enhancement.

The workstation shall process and display the image with a user selectable degree of edge enhancement (e.g., unsharp masking). Different kernel sizes, Enhancement boost factor, and energy dependent differential filtering will be possible. The entire image will be processed with the selected variables in less than 2 seconds. The edge enhancement presets will be activated by use of a pull down menu or quick keys.

Window and Level.

The workstation shall provide dynamic window and level through the entire image gray scale data set. This function shall be provided for images on all monitors, a single monitor, or a specified region of interest on a single monitor. This function will operate in a rapidly smooth and continuous manner when applied to the entire image in a 1:1 displayed option on the 2k monitor. The window/ level will be applied only to the images selected (See section II. no. 4, "Image Selection") which may be all images or only a selected subset of an exam. This function will be chosen by pull down menu, quick key, or soft button.

Inverse Video.

Display of the inverse video of the whole image or any selected region of interest shall be supported. This function will be selected by pull down menu or quick key options. In inverse video, the system shall detect the skin edge of the breast and automatically blacken the region outside of the patient

Cursor.

The workstation control cursor shall move easily within and between monitors in a smooth continuous manner. The cursor shall always be visible during its movement. Cursor movement shall be controlled with a pointing device (mouse or trackball). The use of keyboard keys for the image cursor movement is not acceptable. A orientation arrow at the top of the monitor will identify the direction to find the cursor location when lost among the four monitors. A user configurable accelerometer function will be provided for the mouse. This functions allows for differential speed of the cursor movement for fine movements versus moving the cursor quickly (e.g., moving the cursor from the left hand monitor to the right hand monitor. Various image manipulation tools when selected will have an identifying cursor to indicate that choice. (e.g., When the measurement tool is used, a cross hair cursor will be over the image to indicate the function selected.)

Screen Blanking.

The workstation shall include automatic screen blanking with a user-selectable time default.

Automatic Shutdown.

A user selectable time elapse of workstation non-use will cause the workstation and monitors to shut down.

Zoom.

The workstation shall be capable of enlarging the workstation two and four times and display it by simple replication of pixel values. The workstation shall also be capable of variably enlarging the image display it by interpolation. The image will zoom about the user selectable point (e.g., the location of the cursor when the function is activated.) This function will operate in a continuously smooth manner when rapidly done. This tool will be selected by pull down menu, quick keys or soft button. When zoom is activated, a quick key while depressed will allow for the mouse driven image roam function (see below).

Image Roam.

The workstation shall provide **rapidly smooth continuous movement** of a 4K by 5K by 16 bit image data set or zoomed portion of the image in the workstation memory through a 2K by 2.5K window monitor utilized in the mammography workstation. This tool will be selected by pull down menu, quick key, or soft button.

Digital Magnifying Glass.

The workstation shall be able to display the full data set of a computed radiography image within a quickly resizeable moving region of interest (ROI). This function will be **rapidly smooth and continuous when operated**. The digital magnifying option will be chosen by pull down menu or soft button. The function within a ROI will occur by use of depressing the mouse button and moving the mouse. The resizing of the ROI will occur during the use of a quick key while depressed. The window/ level within the actively used digital magnifying glass ROI will be interactively changed while depressing the window/ level quick key. Likewise, a quick key will allow differential degrees of magnification within the activated digital magnifying glass ROI to be interactively selected. Inverse video gray scale will be supported in the moving digital magnifying glass ROI selectable by pull down menu option or quick key.

Rotation and Flip.

The workstation shall allow sequential 90 degree clockwise and counter-clockwise rotation of the image as well as 180 degree flip in the horizontal and vertical axes.(e.g., right to left or top to bottom). The new orientation shall be saved for future retrieval. These functions will be activated by pull down menu or soft buttons.

Mensuration.

The workstation shall compute point-to-point measurement with automatically calibrated, user-selectable scales (e.g., cm or inches). It shall also perform angular measurement, area and perimeter measurement based

on ellipses and pointing device control tracing. The workstation shall compute and display these functions for multiple measurements simultaneously (10 or less) on the same image and save them as an overlay which can be toggled on and off. When multiple measurements are made on the same image, a legend will identify each of the measurements to the location measured. These options will be activated by use of the pull down menu, quick keys, or soft buttons.

Text and Graphics Annotations.

The workstation shall utilize and display user-selectable locations and orientations for graphic symbols (e.g., arrowheads and circles) and text annotation with simultaneous displays on the same image. Free hand tracing shall be possible. The annotation(s) shall be saved as an overlay which can be toggled on and off. This tool will be activated by pull down menu or soft button.

Image Identification.

When the images are displayed, the images shall be identified with the following patient data as a minimum; patient name, social security account number (SSAN) with the family member prefix (FMP), and the exam date and time.

Delete.

The workstation shall be capable of user-selected auto-delete from local storage, and allow marking of selected images for non-deletion. Typically this will be a first in first out, however, some exams awaiting additional views will need to be kept on local storage until the view is acquired and the diagnosis made. This should be a pull down menu option only.

Hard Copy Generation.

The workstation shall include a one keystroke equivalent (OKSE) method for image hard copy generation of an image or exam selected from the workstation console. The goal here will be to interface to the MDIS networked laser image printer. An additional strategy will be to provide an ultra high resolution paper printer or quick photo device (e.g., Sony) for printing of selected images or

exams. In most cases this will probably be sufficient for the referring clinician. This function will be chosen by pull down menu.

Command Reversal (Undo).

The workstation shall be capable of reversing the last one key command and in the event that the command is not reversible the operating system shall indicate such a condition by a warning signal issued prior to executing the requested command. If a command is given which will take an extended length of time, then an abort function will be provided. This function will be operated by pull down menu or quick key options.

Save.

The exams involving research and teaching images shall identified in the database for future easy retrieval. This function will be operated by pull down menu or quick key options.

System is Working (SIW).

User operations that require time delays, for example some image processing operations, shall be indicated on the screen (e.g., a ticking icon) to let the user know that the operation is underway and the system is operating. At user option, this process can be shifted to background so that other work can continue.

Reporting.

The workstation will allow the use of the ACR software reporting software, Breast Imaging Reporting Database (BIRD), program. This program provides the standard lexicon of terms used in mammography reports. This approach may require an additional standard VGA monitor and CPU integrated as far as data sharing with the diagnostic workstation but usable with a separate or same mouse as two options. The separate mouse would be used when a staff radiologist is working with a resident and one could be using the diagnostic workstation and the other is inputting the report. A single mouse would be used when only one person was working. (Point of Contact for the software is Nick Croce, American College of Radiology, 800-227-5463 or 800-553-8996).

A laser printer will be connectable to the workstation for hardcopy report generation. The analysis of the database information will be possible using Microsoft Excel or like spread sheet. This tool will be chosen by pull down menu or quick key options.

Follow-up Exams.

The exams that require an additional view when the patient must be called back must be tracked in an effective and transparent way to the technologist and radiologists. A utility to confirm the follow up exam that is requested has been accomplished is mandatory. A method to place the exam back on a specific radiologist's worklist is necessary. An option to log in scheduled absences of the radiologist is needed so that any call back patients will have their exam interpreted without delay by the reader for that day. This way the routinely assigned mammographer for the day will read the call back exam. The list of call-back patients will have access to the patient demographic data, especially the patient's phone number.

Additional Image Marking.

A moveable region of interest for focal cone compression, focal cone magnification compression or simple magnification at 1.5 magnification (or other designated magnification factor) will be identified within a fixed field of view for a given image. This image shall be stored as an overlay to the original image. This information will be sent back to the QC workstation to be matched up with the patient's image for technologist reference in order to accomplish the additional view(s). The images obtained as focal cone compression, focal cone magnified or simple Magnification views will marked as such on the image along with the degree of magnification. The ROI will be moved to the area of concern by using the mouse and deposited with a mouse click. These choices will be indicated by pull down menu, quick key, or soft buttons.

Surgical and Core Biopsy Results Input.

A method to quickly input the pathology results from surgery and core biopsies into the patient database will be provided. Ideally, this input can be input to the QC workstation and then downloaded to the mammo diagnostic

workstation. by using standard site configurable language. The selections will be mouse driven with input of non-standard language by keyboard use. Scheduling of patient biopsies will be part of the results reporting utility.

Automatic Adaptive Histogram Equalization.

Automatic adaptive histogram equalization will be provided as a toggled option for optimal softcopy display of mammographic images. This will be a pull down menu option only.

Automatic Capture of Mammographic Technique Exposure Parameters.

The exposure factors will be part of the patient database information on the QC workstation. This information will automatically be sent with the image to the QC workstation and will include as a minimum the Kvp, Mas, thickness of the breast as compressed, and source to skin distance. This information should be captured at the time of mammographic exposure by linking the automatic exposure record (whenever the mammographic machine provides it) to the barcode of the imaging plate or direct image capture host processor. The link of the exposure information to the imaging plate barcode may precede or follow the link between the patient ID barcode and imaging plate barcode in the case of using a separate phosphor plate as the image receptor.

Computer Assisted Diagnosis (CADx).

The workstation must be Cadx hardware capable. The image processing must occur automatically in background and not interfere with interactive image manipulation for the displayed exam. The CADx for a four image exam must take less than 30 seconds. At least three different levels of sensitivity must be user selectable. The displayed areas of interest identifying masses and microcalcifications will be marked with variable size graphics (e.g., circles or arrowheads) that can be toggled on and off. The variable size of the markers as an overlay will indicate the position and degree of confidence of the finding being a true positive. When the user is ready for display of this overlay a pull down menu, quick key, or soft button will be used. The CADx software should also allow for a pointing function to allow the user to select a ROI and query the CADx program for its analysis of that location.

option b: the left CC view is on monitor A
the right CC view is on monitor B
the left MLO view is on monitor C
the right MLO view is on monitor D

option c: the right MLO view is on monitor A
the left MLO view is on monitor B
the right CC view is on monitor C
the left CC view is on monitor D

option d: the left MLO view is on monitor A
the right MLO view is on monitor B
the left CC view is on monitor C
the right CC view is on monitor D

Option e:
Prior right and left cc views on monitor A
Current right and left cc views on monitor B
Current right and left MLO views on monitor C
Prior right and left MLO views on monitor D

If no prior exam, monitors A and D are black.

NEW EXAM WITH ONE OLD EXAM:

using option a from above: The initial presentation of the exam is to view the new images first across all four monitors.

the right CC view is on monitor A
the left CC view is on monitor B
the right MLO view is on monitor C
the left MLO view is on monitor D

The next step is to have two soft buttons to view the new and old exams in a 1:1 image format across four monitors.

the previous right MLO view is on monitor A
the previous left MLO view is on monitor B
the new right MLO view is on monitor C
the new left MLO view is on monitor D

the previous right CC view is on monitor A
the previous left CC view is on monitor B
the new right CC view is on monitor C
the new left CC view is on monitor D

A third soft button is available to view the old exam in the following manner.

the previous right CC view is on monitor A
 the previous left CC view is on monitor B
 the previous right MLO view is on monitor C
 the previous left MLO view is on monitor D

A fourth soft button will allow you to indicate if the previous exam for the above examples is the first previous v. the second, third, etc. exam to be used for the first three soft buttons.

The above soft button paradigms will have quick key equivalents for the power user.

A fifth / sixth soft button (and quick keys) will toggle a next or prior function for going through the initial new exam and first to third soft button examples quickly.

A seventh soft button (with quick key) will allow the new exam to displayed across the four monitors at any time.

A eighth soft key will then restore the previous image arrangement.

Initial image presentation options (b, c, and d) will follow the image arrangement paradigm as described above for option a.

SOFT BUTTON FUNCTIONS

FUNCTION	SOFT BUTTONS	COMMENTS
Image Multiformat	4	1:1, 2:1, 4:1, and 6:1
Default Display Protocol	8	see appendix a
Next Exam	1	
Window/ Level	1	
Image Zoom	1	
Image Roam	1	
Digital Magnifying Glass	1	
Rotation and Flip	4	rotate L&R, up/down, L/R Flip
Mensuration	3	distance, angle, area
Text and graphics.	2	text & free hand tracing
Additional Image Marking	3	FCM, FC, andMAG only
CADx	1	display of imagaee processing

7.0 SUMMARY:

During the first year of this research grant we have done a large number of small projects to define the essential parameters for digital mammography to be successful. We believe that our work to date has given us a much better

understanding of the parameters necessary for proper image acquisition, image processing and display, and that this preliminary data will allow us to proceed rapidly with the remainder of the project.

This project was focused in defining the characteristics of existing digital mammographic systems and to test their applicability for digital mammography as a replacement for conventional mammography.

8.0 THE ASSIGNED TASKS FOR THIS PROJECT ARE:

1. Evaluate the physical image quality of a prototype digital mammography based on a micro-lithography technology by 3M.

Prototype will be delivered to Georgetown during the first quarter of 1994.

2. Determine a MDIS compatible user interface.

First cut specification is completed as described.

3. Conduct a clinical evaluation of the imaging device, if the physical measurements are acceptable.

Clinical evaluation will start during the first quarter of 1994.

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