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GRANT NUMBER DAMD17-96-1-6187

TITLE: High Resolution and Sensitivity Digital X-Ray Imager for Mammography

PRINCIPAL INVESTIGATOR: Darold Wobschall, Ph.D.

CONTRACTING ORGANIZATION: Sensor Plus, Incorporated
Amherst, New York 14226

REPORT DATE: August 1999

TYPE OF REPORT Annual

PREPARED FOR: Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE

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1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE August 1999		3. REPORT TYPE AND DATES COVERED Annual (1 Jul 98 - 30 Jun 99)	
4. TITLE AND SUBTITLE High Resolution and Sensitivity Digital X-Ray Imager for Mammography				5. FUNDING NUMBERS DAMD17-96-1-6187	
6. AUTHOR(S) Darold Wobschall, Ph.D.					
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Sensor Plus, Incorporated Amherst, New York 14226				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSORING/MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES					
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited				12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200) A digital x-ray imager with a full-size (8"x10") screen and high resolution (40m) is being developed. By applying current engineering devices and practices, a low cost and noise imager is expected. A long-term goal is to incorporate the lower noise x-ray light valve (XLV) into the imager. We expect to achieve the same size, resolution and image quality as film/screen. During the third year the first generation imager design (6x6 array, without XLV) was finished and a prototype of the CCD electronics and digital signal processor was tested. The mosaic image reconstruction software was further refined and the reconstruction accuracy tested for various algorithms and applications. The circuit design, circuit board layout, and mechanical design for the full scale imager were completed. A 3x3 section with temporary lens was tested.					
14. SUBJECT TERMS Breast Cancer				15. NUMBER OF PAGES 33	
				16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited		

FOREWORD

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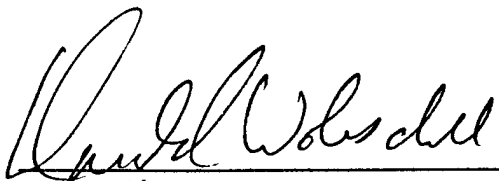
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High Resolution and Sensitivity Digital X-Ray Imager for Mammography
Annual Report (July 1999)
Darold Wobschall, PI
Sensor Plus, Inc., prime subcontractor
with Univ. of Toronto (Sunnybrook)
and SUNY/Buffalo (ECMC)

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Introduction

The introduction in italics is unchanged from last year's report.

The aim of this project is to develop a low-cost, full-size digital x-ray imager for mammography, which is comparable to film/screen in quality (spacial resolution, contrast, and sensitivity). Advantages of digital imaging (ease of storage, transmission to distant locations, image enhancement, and computer-aided diagnosis) are widely recognized. A summary of the goals and relevance is given in the previous yearly reports.

Our mosaic approach is to break the image into segments or tiles which are individually imaged by lenses onto relatively small CCDs and then to combine the small images, by software, into the larger full size image (8"x10"). Except for the XLV screen, this project is basically an engineering development which optimizes both performance and low production cost.

Many experts expect that eventually flat panel imagers (e.g. thin film transistors) will be the technology of choice. However it seems likely that the production costs of flat panel imagers will be very high for some years, as indicated by the projected prices of full-scale imagers which are being introduced by several major medical imaging companies. Rather than aim our imager development solely at better performance (e.g. higher resolution or sensitivity) than competitive commercial imagers, we have concluded that a good use of the grant resources is to first develop a moderate performance, but much lower cost, digital imager to serve groups or markets which would not otherwise be able to afford a digital imager. The introduction of new, lower cost CCDs and other electronic devices have made this plan practical. Accordingly we have redesigned, and are fabricating the data acquisition electronics with the new cost/performance criteria. Little change in software is needed since the basic mosaic imaging approach remains the same. Our aim is to have a functional, pre-production, full-size digital imager ready by the end of the grant period.

The development of the XLV version will continue but testing will be deferred until the conventional screen is done.

The design approach during the third year was unchanged. Furthermore the decision to focus on the low cost market and to base the first generation design in the CMOS sensor was strengthened by several events. One event was the further efforts of the first tier medical imaging companies to enter the digital mammography market with high performance, but high cost, imagers. Another is the continuous technical improvements of commercially available CMOS sensors, which may soon equal or exceed the performance of the more expensive CCD sensors. Finally the XLV, which the first generation low-cost imager does not use, is not ready yet and if we had required this, it would have slowed development. We conclude that the decision to focus on the low-cost mammographic application using CMOS sensors was a correct decision.

It should be noted that the planned second-generation imager will use the XLV. Assuming that the XLV can be successfully developed and manufactured at a low-cost, it is expected

to improve mammographic sensitivity (DQE), which could be a critical factor in the acceptance of the low cost imager.

Time Extension

A no-cost extension of this project from three to four years was obtained. Therefore this is a third year report rather than a final report (now due July 2000).

Work Accomplished During Third Year

The main effort during this year was to finish the design, fabrication, and testing of the electronics, including the CMOS sensor circuits and digital signal processor (DSP) circuits.

IMAGER HARDWARE (Sensor Plus)

CMOS Sensor Image Quality Optimization

An evaluation of the VV5850 CMOS image was performed to demonstrate its feasibility for x-ray imaging. The evaluation included determination of both fixed pattern and random noise levels of the sensor, determination of noise levels for various exposure lengths, characteristics of dark current vs. exposure time, sensor linearity, and overall sensor signal-to-noise ratio, SNR. Figures 1.1-1.8 show the results of these noise measurements:

Figures 1.1 and 1.2 show the noise performance for both fixed patterned and random sources with respect to the pixel readout frequency. From our measurements, the prototype imager exhibited better performance with readout rates in the range of 2-3MHz. This occurs since the overall leakage current at each pixel increases as the pixel rate decreases, hence increasing the fixed patterned noise. At 5MHz the on-chip high frequency clocking noise increased the overall noise.

Figures 1.3 and 1.4 show the fixed patterned noise and random noise with respect to exposure time. As expected, the noise levels rise with increasing exposure time, however at exposures of 2-3 seconds the overall noise only decreases approximately 4-5dB from the sensor's maximum SNR, as shown in figure 1.8. After subtracting the fixed patterned noise from the image, the overall noise present is significantly reduced and allows SNR's in the range of 60dB for longer exposures (2-3 seconds) and high pixel readout rates (2-3MHz).

Figure 1.5 shows the overall average dark current level with respect to exposure time. With a maximum signal range of 2400 ADU's, this CMOS sensor exhibited a range reduction by a factor of 2 (1200 ADU's) at an exposure time of approximately 26 seconds. At exposure times of 2 seconds as used to acquire test images, the reduction of the available signal range was only 5 percent. Thus, the dark current level did not inhibit the image SNR much.

All noise measurements during this period were conducted at approximately 25 degrees C temperature. However, the CMOS sensor was also tested at 4.4 degrees C to evaluate the overall SNR increase with temperature decrease. The following results were obtained:

Temperature [degrees C]	RMS Noise Floor [ADU's]	SNR [dB]
25	1.7	63
4.4	1.2	66

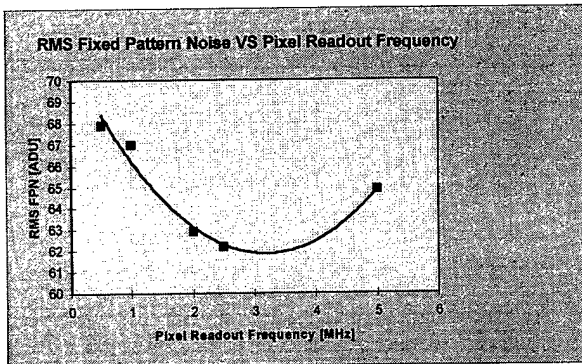


Figure 1.1 - S_{FPN} vs. f , $N_{avg}=16$, $t_e=2$ s.

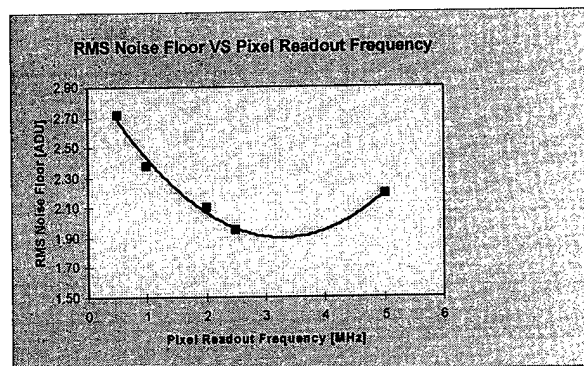


Figure 1.2 - S_{FLOOR} vs. f , $N_{avg}=16$, $t_e=2$ s.

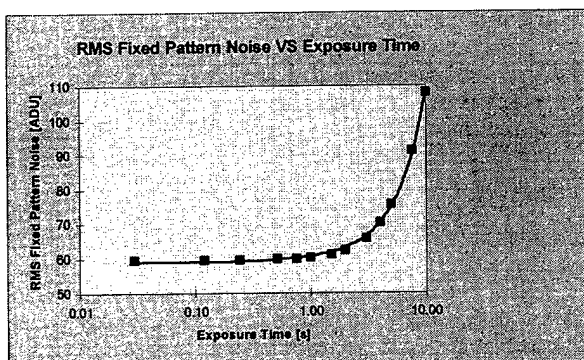


Figure 1.3 - S_{FPN} vs. t_e , $N_{avg}=16$, $f=2.5$ MHz

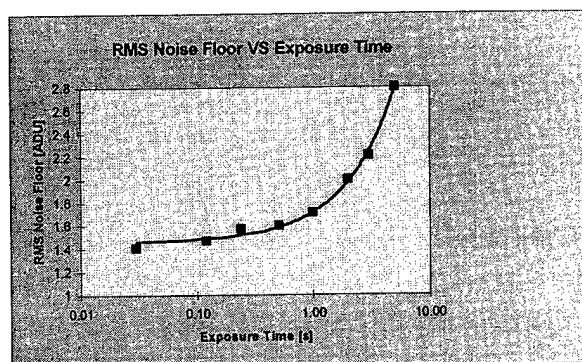


Figure 1.4 - S_{FLOOR} vs. t_e , $N_{avg}=16$, $f=2.5$ MHz

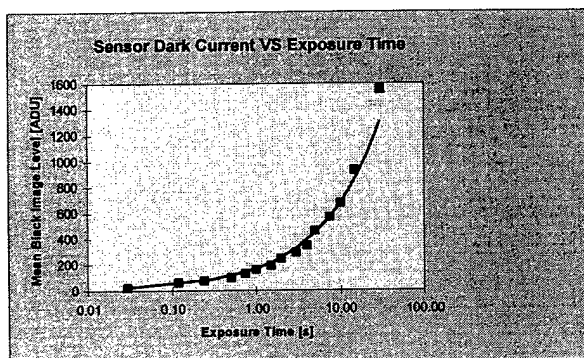


Figure 1.5 - S_{DARK} vs. t_e , $N_{avg}=16$, $f=2.5$ MHz

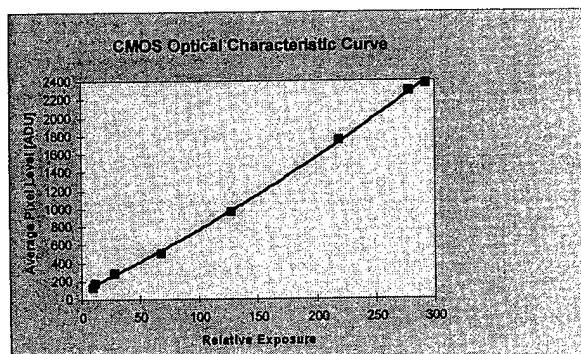


Figure 1.6 - R_{exp} , $N_{avg}=16$, $f=2.5$ MHz

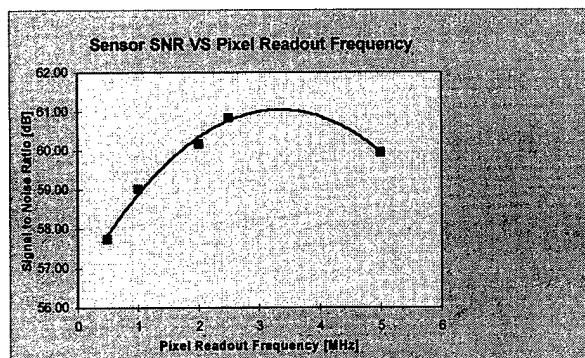


Figure 1.7 - SNR vs. f , $N_{avg}=16$, $t_e=2$ s, the noise value used was calculated after subtraction of SFPN from the acquired image.

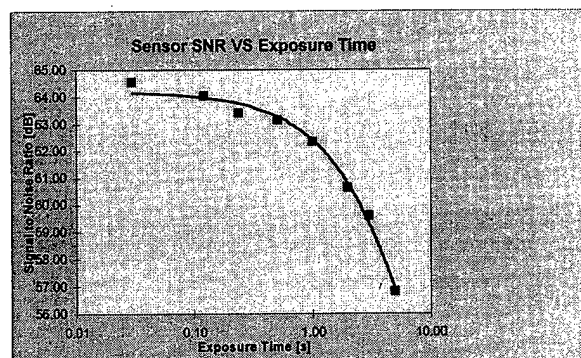


Figure 1.8 - SNR vs. t_e , $N_{avg}=16$, $f=2.5$ MHz, the noise value used was calculated after subtraction of SFPN from the acquired image.

The minimum temperature for operation of the VV5850 sensor is 0 degrees C as specified by the manufacturer. Operation of the sensor would need to be close to 0 degrees C for optimal SNR performance.

DSP Design and Tests

The electronics block diagram of the 3x3 imager is shown in (Fig. 2). The photographs in Fig. 3B show the 3x3 sensor module and lens mounting plate.

The 3x3 block is a quarter of the full imager. Each block is identical and they are placed next to each other, and fit, to form the full size imager.

Each of the 9 image sensor channels contains a CMOS sensor, analog support circuitry, 12-bit A/D converter, and a 16-bit buffer for digital data output. The output buffers are connected to two parallel digital channels, which enter the DSP. The M4 programmable logic devices controls the timing generation and multiplexing of the image data from each sensor. The chosen pixel rate was 1.25MHz for each sensor, requiring the DSP to acquire 25MB/s (2 bytes per pixel, 5 image sensor channels). All the image data was demultiplexed in the DSP and read out through the IEEE1394 interface to the PC for viewing and storage. The reconstruction of the images was done using PC software.

The high-speed DSP circuits with the 128 Mbyte RAM, analog circuits, CMOS timing circuits, were redesigned (custom designed) for this imager. Because of the large amount of data handling capacity and the low noise requirement, this was a difficult and time-consuming task. The result, however, was high quality (production quality) printed circuit boards.

Along with the board development was the migration of software previously done on the PC to processing on the DSP. Now the image processing, as well as the image acquisition, is done on the DSP.

A single CMOS sensor imager was also constructed and used for all the tests shown in Fig. 1 and to obtain x-ray images to test feasibility. The photograph on Fig. 3A shows this imager: Note a reflective mirror was used along with the imager electronics mounted with the lens horizontal to the object plane. This was done to create a thinner imager case and to test the concept for possible use in a production version. The x-ray scintillating screen was placed on the top of the imager case with the lens focused at the object plane.

Firewire™ Serial Bus

The PC and DSP connection through IEEE 1394 (FireWire™)

This mammography system processes a huge amount image data for a single shot (about 40 MB/image when using 6x6 imager). Therefore, a fast data transfer scheme is necessary. If the PC's parallel port were used, it would take over 40 seconds. We chose the faster serial data transfer method called IEEE 1394d4 or FireWire™. A current transfer

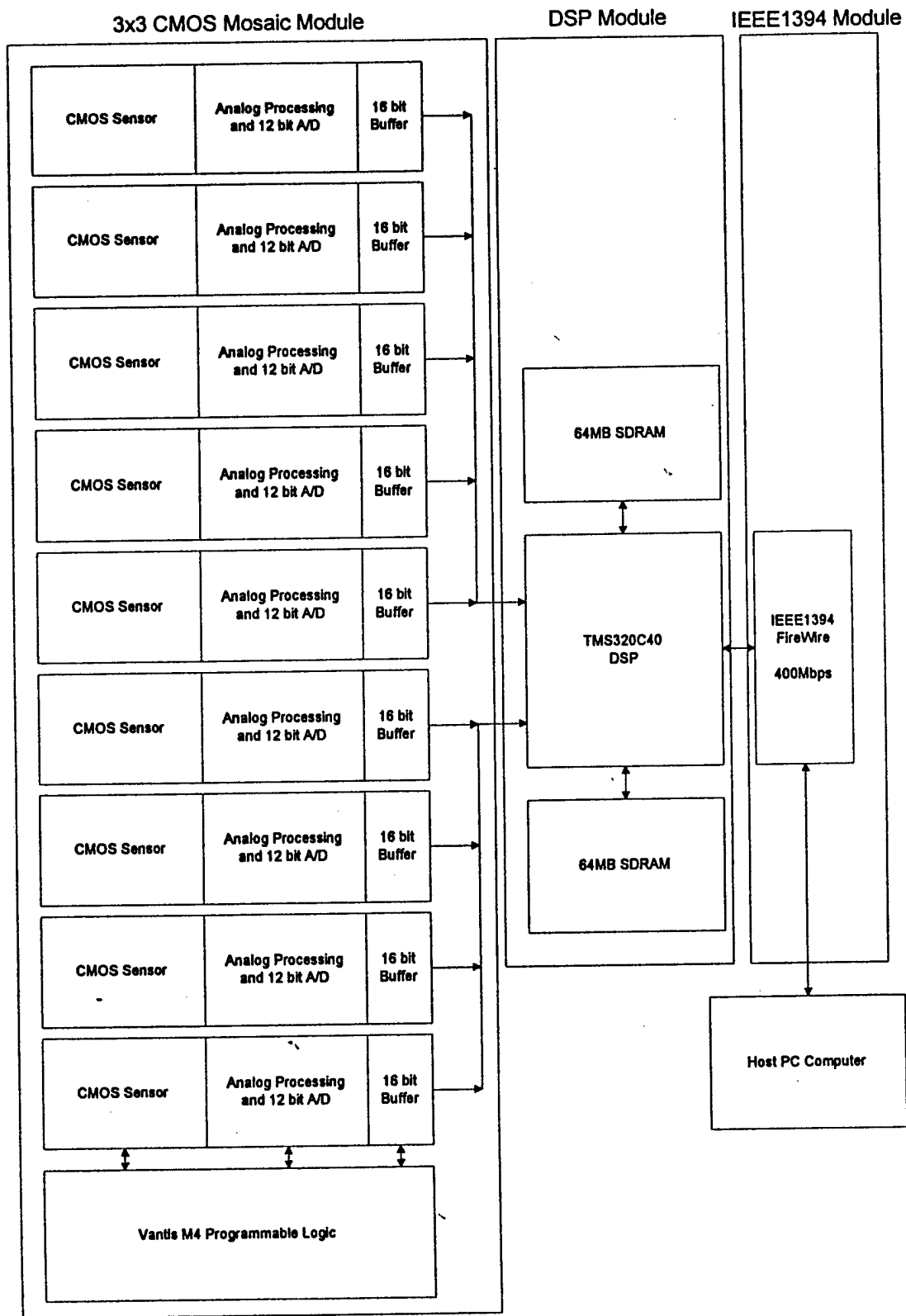


Figure 2: Block diagram of 3x3 mosaic imager including DSP and IEEE1394 electronics.

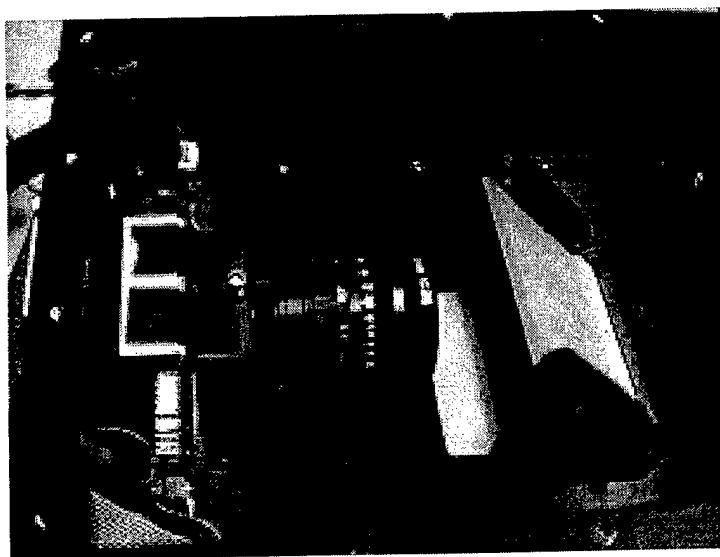


Figure 3A: Photograph of mirror reflective prototype imager used to acquire x-ray images.

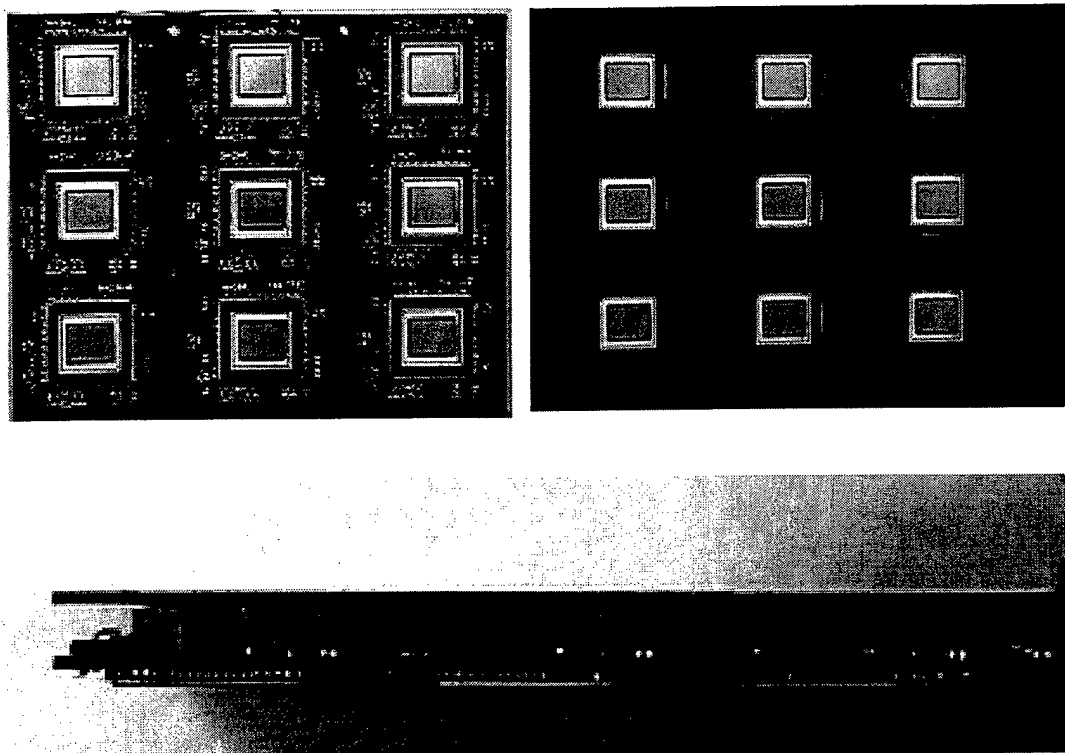


Figure 3B: Photographs of the 3x3 CMOS imager hardware module (top left), 3x3 CMOS mosaic with lens mounting plate attached (top right), and side view of 3x3 imager hardware module (bottom).

speed for FireWire™ is 400 Mb/sec. It takes one second to transfer a whole image under ideal situation. Figure 4 shows a block diagram of the FireWire connection between the PC and DSP using two FireWire™ boards. One FireWire™ plug-in board for PC is the off-the-shelf product that can be purchased by a vendor such as Texas Instruments. The other FireWire™ board was designed and fabricated by Sensor Plus. The board is a production quality printed circuit board (5"x7"). The board supports IEEE 1394 standards capable of transmitting/receiving data at 100, 200 and 400 Mb/sec. It was fully tested and shown to operate at the required rate.

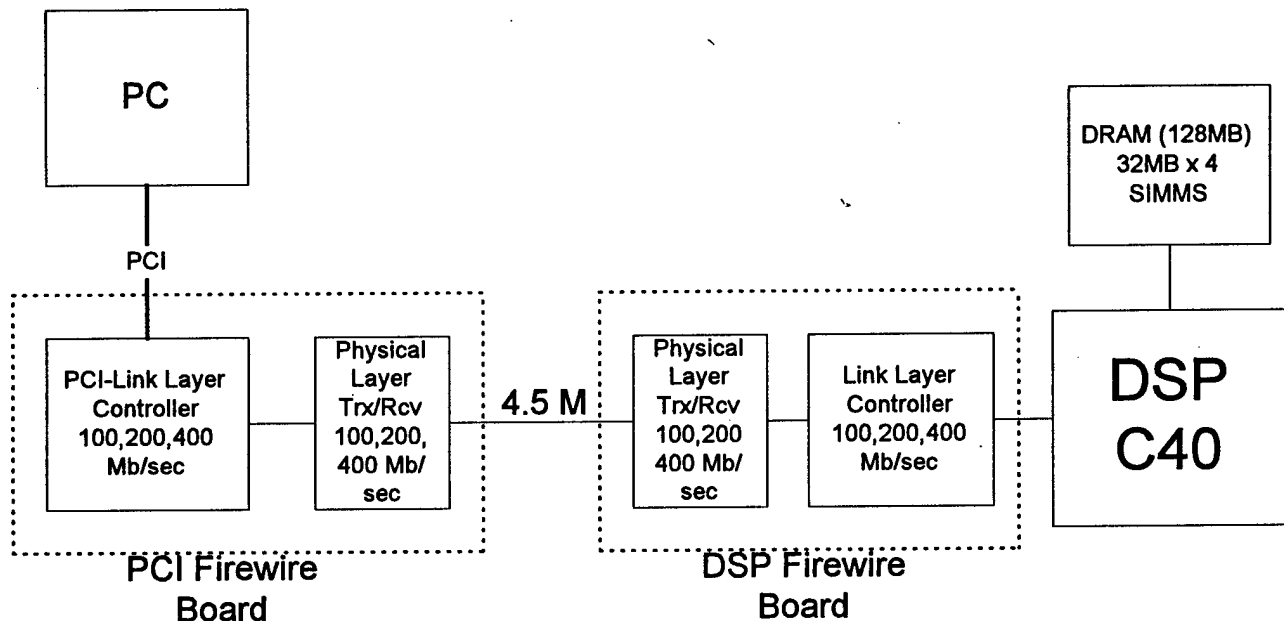


Figure 4 The PC and DSP connection through FireWire™

Lens Design and Fabrication

The light collection efficiency of the lens is an important fact in determining the image quality, specifically the image background noise. A drawback of lens coupling in several is that the light transfer from the x-ray conversion screen has a relatively poor efficiency. The two main factors which increase efficiency are (1) use of a small demagnification (we have chosen 4.4) and (2) use of a fast, low $f\#$ lens (e.g. 1.1), see [ref]. A small demagnification is important. As discussed in previous reports, the mosaic approach allows a relatively small demagnification per lens. Once the array size is chosen (6x6), the input screen size is established (8"x10"), and the imaging sensor size (8.4x10mm) is selected, then the demagnification (4.4) is fixed.

The other factor is the lens $f\#$. A large aperture with short focal length, that is a low f -number lens combined with a wide angular field of view is desired. However it is difficult to make a lens with a low $f\#$ which still provides high resolution over the full field. The

image at the sensor must have a resolution of better than $8\mu\text{m}$ even at the edges. Also it must be physically small so that the lens can be placed close together. No satisfactory commercial lens was found, even after an extensive search. The closest available lens was a f1.3, 1-inch format CCTV type, but it could not focus over the full field unless stopped down excessively (and it was too large).

A custom lens design and manufacture was subcontracted to J.A. Optics (Utica, NY). They designed a 7-element lens, which, by simulation, had the required properties (f#1.1, $7\mu\text{m}$ spot size over full field at demagnification of 4.4 with an object area of $35 \times 25 \text{ mm}$). Unfortunately, it has taken much longer to manufacture than expected, but a prototype lens was delivered after the end of the report period (as this report was being written). Preliminary tests indicate the lens does meet specifications but full tests have not yet been done.

One concern is the production cost of the lens since initial estimates cover a wide range (pleasantly low to very high cost). Now that a lens has been delivered more accurate cost estimates will be established.

If the lens meets specifications, it is unlikely that significant improvement in performance (e.g. f# reduction) can be obtained with further development, at least in a lens of this size. We have reached this conclusion by discussion with lens designers and manufacturers.

The optical throughput of this lens is about 1.5%. A higher throughput (lower f#) might be obtained with a much smaller lens, and with a much smaller image size, but then the number of lenses and sensors would have to be increased significantly (e.g. to 100 or 400) which we consider undesirable. Therefore we consider this lens to be close to the best available for this approach (generation I low cost imager, without the XLV).

Commercial Mammographic Machine Acquisition

A Phillips Diagnosis UM mammography x-ray unit was acquired at Sensor Plus, without charge, through the generosity and advocacy of the SUNY Medical Physics Group. It is a high-resolution modem with a 10 to 40 Kvp energy range. Although an older model, it is in excellent condition. A unit at our facilities has greatly speeded up testing.

IMAGER CHARACTERIZATION

Acquired X-ray Images

The first x-ray images were acquired using the single CMOS detector, lens, and standard Agfa MR detail phosphor screen (green). The system setup included a Bennett Contour mammography unit, the prototype CMOS imager, and a Pentium 166MHz computer with an internal TMS320C40 digital signal processor board for acquisition and image processing. A digital mammography phantom from Nuclear Associates was used as well as a standard resolution pattern to observe the characteristics of the imager. Each image was taken with a fixed exposure of 30kVp and exposure time of 2 seconds. The lens was

an off-the-shelf f1.3, 12.5mm focal length CCTV lens. The x-ray images are shown in Figure 5 and 6 (following pages).

A red Eu doped Y2O2S phosphor screen was fabricated to improve the light collection efficiency of the x-ray system. The screen consists of a phosphor coating with a particle size of 30-40mg/cm² and a TiO₂ reflector layer all mounted to 1mm thick bakelite. This screen was tested during this year and produced approximately 25% greater intensity as compared with a Kodak standard high resolution gadolinium oxysulfide (Agfa MR Detail). The measured resolution using an off-the-shelf f/0.95 imaging lens was approximately 8 lp/mm and approaches the projected 10 lp/mm specified in the screen design. Figures 7 and 8 show the x-ray images obtained with this new screen:

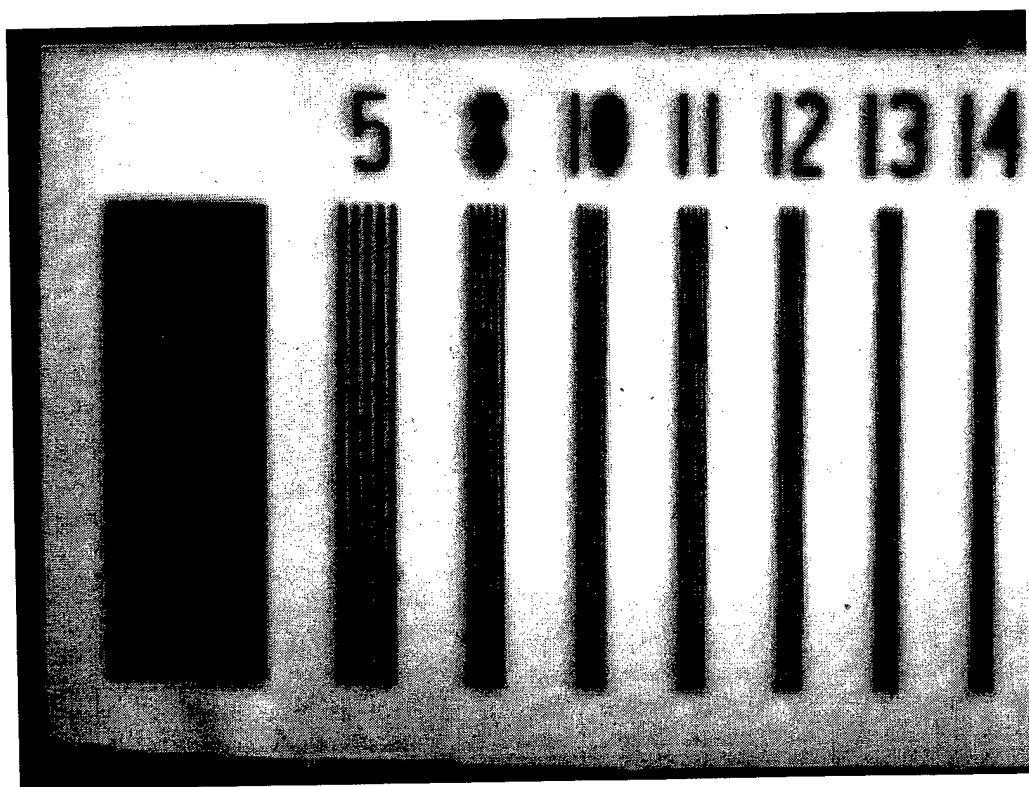


Figure 5 - This image shows the resolution obtained with a standard X-ray resolution bar pattern. The numbers at the top represent resolution in line-pairs per mm. The resolution approaches the limit of the detector at 12 lp/mm (0.0415 mm line width) since the pixel size at the image plane is 0.043 mm.

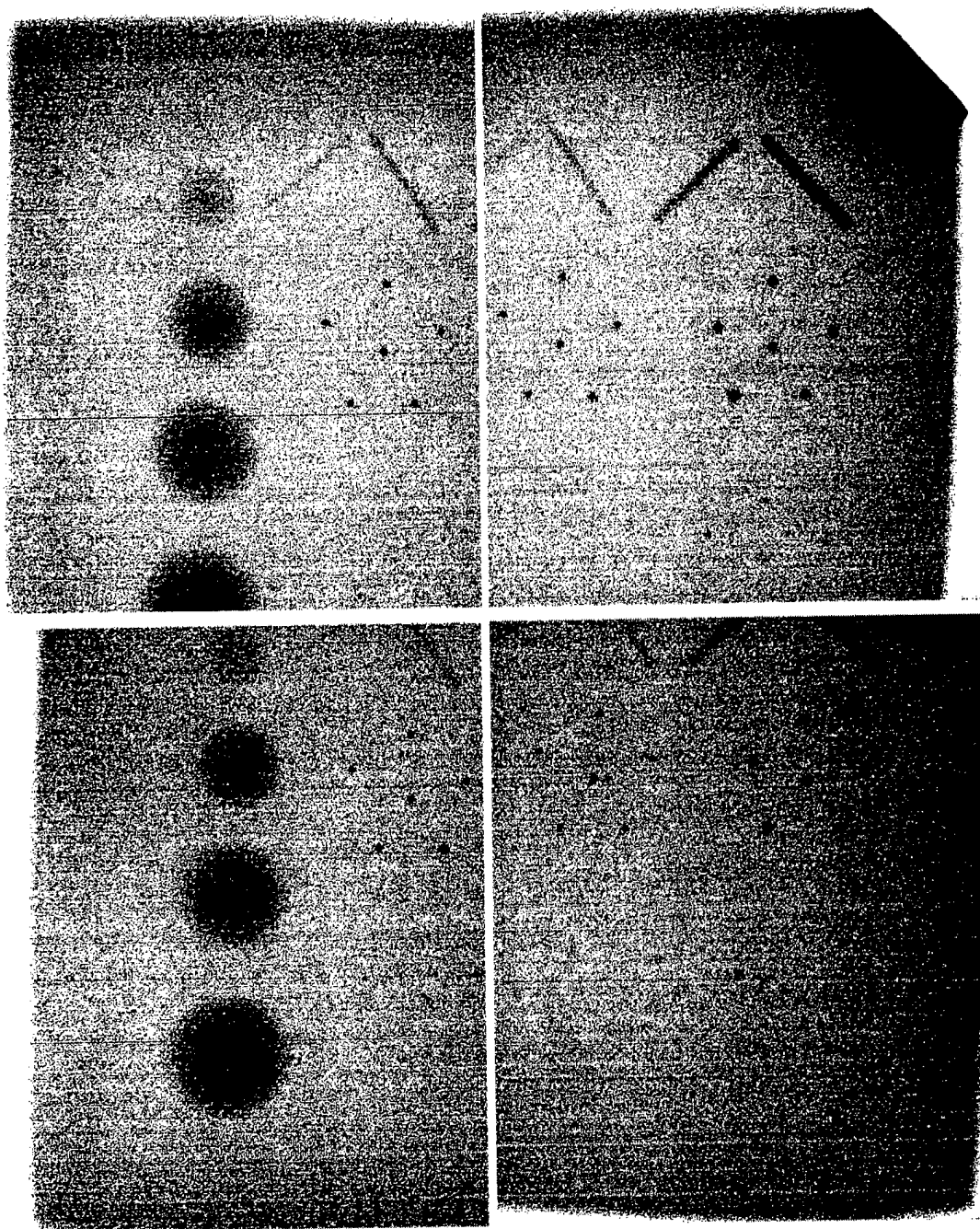


Figure 6 - 4 separate images acquired of a digital mammography phantom. The position of the phantom was translated to cover its full area. There are 4 large circular masses with varying sizes (left side of phantom), 4 clusters of structures representing microcalcifications, each cluster contains 6 structures in a star pattern, and 4 bar structures (top of phantom) at alternating 45 degree angles. The microcalcification structures range in size as: 540, 320, 240, and 200 microns. Note that it is difficult to extract visual information for the 200 micron structures.

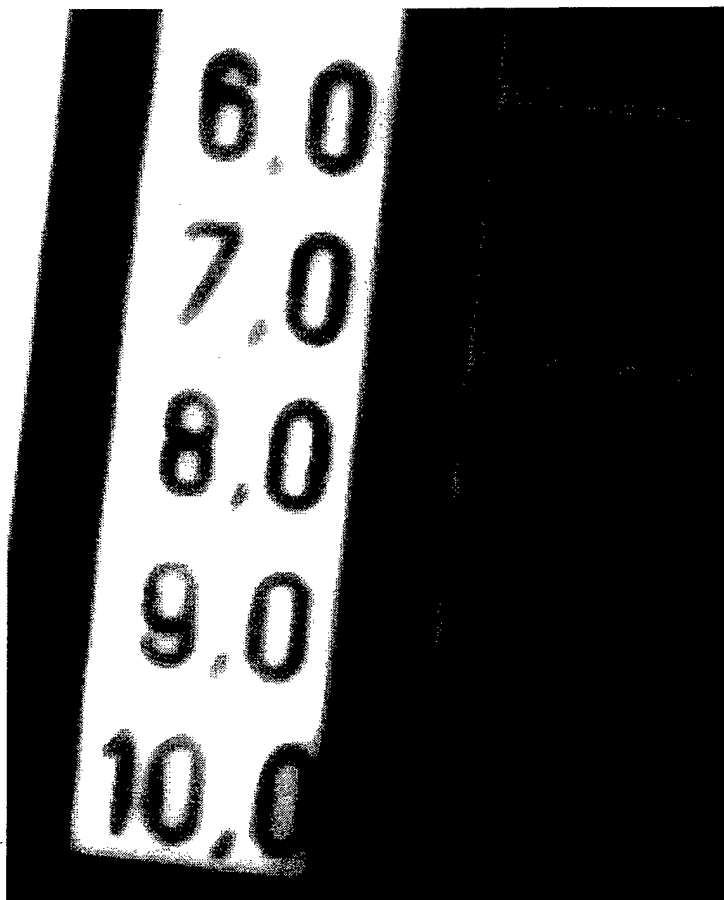


Figure 7: X-ray of resolution pattern using Eu doped Y₂O₂S phosphor screen (red). Numbers represent resolution in line pairs/mm. Note that 8 lp/mm is visible.

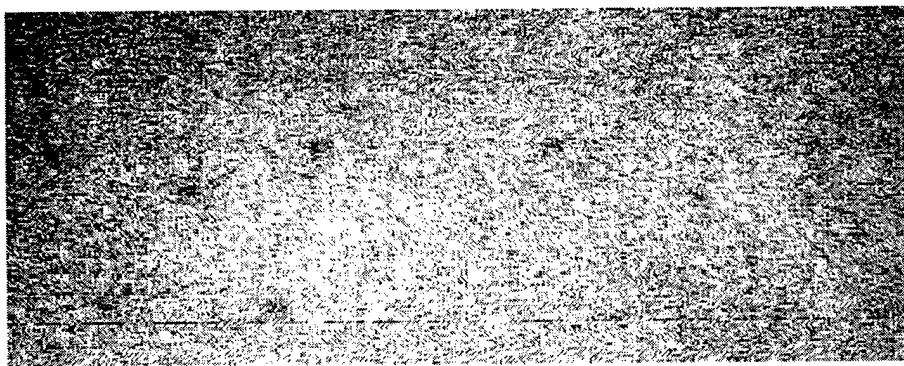


Figure 8: X-ray image of mammography phantom with 2 inch thick lucite. There should be two five point star patterns each containing 6 microcalcification structures.

2x2 Mosaic Image Reconstruction Tests

As a test of the image reconstruction, four optical images were acquired using a 2x2 section of the 3x3 imager. A single lens was used and four separate exposures were taken with the lens moved to adjacent sensors to cover a 2x2 area. A single lens was used since the custom lens was not available.

First, the calibration patterns were acquired and then images of a standard bar resolution pattern. Each calibration image was corrected for lens and geometric distortions and then the stitching boundaries were located. All the reconstruction coefficients were then saved and applied to the real images of the resolution pattern. Figures 9 and 10 show the original four images acquired before corrections and the resulting 2x2 corrected image respectively:



Figure 9: Four optical images of a bar resolution pattern acquired using a 2x2 section of the 3x3 imager.

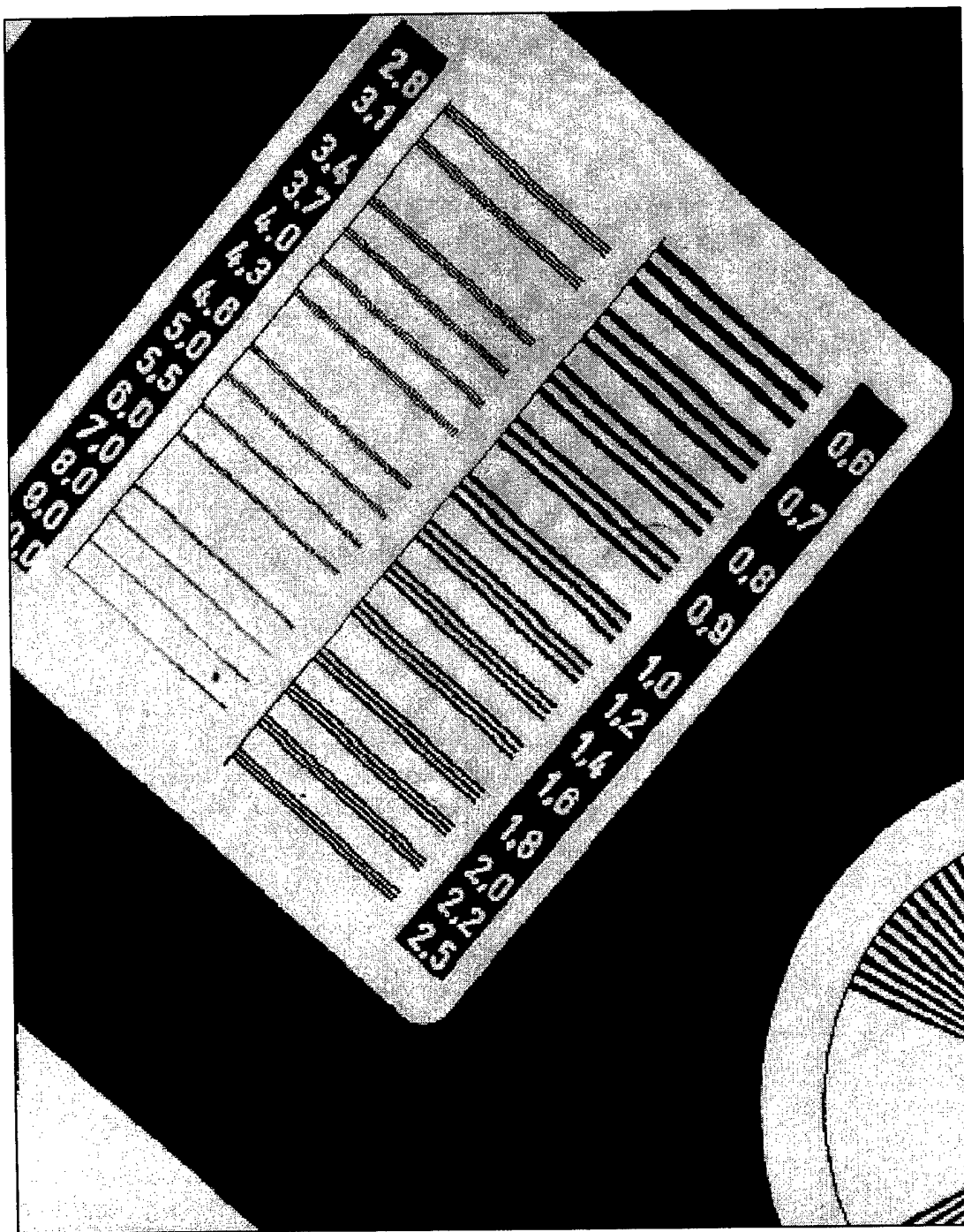


Figure 10: Reconstructed image of the four segments shown in figure 9. The total image size is approximately 1800 x 1300 pixels.

- Distortion correction artifacts
- Intensity level mismatch

The distortion correction artifacts occur due to a precision problem in the calculation of the correction points from the calibration pattern. The intensity level mismatch occurs since each image contains varying brightness and contrast levels. These problems will be addressed in the next year.

Sensitivity and Resolution Requirements

To meet our goals that the digital imager have an image quality at least as good as film, it is necessary that both the resolution and sensitivity be sufficiently high. Studies of resolution requirements indicate that a resolution of $50\mu\text{m}$ (10 lp/mm) is desirable but that diagnostic accuracy is not effected if the resolution is reduced to $100\mu\text{m}$ or $150\mu\text{m}$ (the GE mammographic digital imager is $100\mu\text{m}$). The x-ray resolution tests described above indicate that the resolution of our images approximately 10lp/mm, which is consistent with the $43\mu\text{m}$ screen pixel size. This easily meets our goal but we plan further, more quantitative, tests (modulation transfer function) with the new lens to verify the results.

Sensitivity for our generation I imager is more of a concern. Lens coupling of the light is inefficient (only 1.5% with the high performance lens). Since we estimate the red conversion screen to produce about 1000 light photons per x-ray photon, there will be about 15 light photons hitting the CMOS sensor. With the current sensor, the noise level is somewhat higher than the signal (from one x-ray phantom), a sub-optimal condition. With the improved sensors, available this fall, we expect that the signal will be slightly higher than the noise, which is just adequate.

Imager noise is expressed quantitatively by the detective quantum efficiency (DQE). The DQE of film is about 0.5 (low spacial frequencies) and the best digital imagers are about 0.7 (1 is maximum). We expect the DQE of our imager to be 0.1 to 0.5 but we have not as yet made measurements because the new lens (and CMOS sensors) were not available.

There is no DQE specification on commercial mammographic equipment, but rather the requirement that specific set of features on a mammographic phantom can be discerned (see Fig. 6) with the radiation dose under a given limit. Preliminary tests indicate that this requirement is met, or close to being met, but much more testing is needed.

Higher quality, lower noise images can always be obtained by increasing the radiation dose. For many medical applications, such as emergency medicine, the higher dose is acceptable. However it is not acceptable, or at least undesirable, for mammographic screening. This is why the emphasis is placed on high sensitivity.

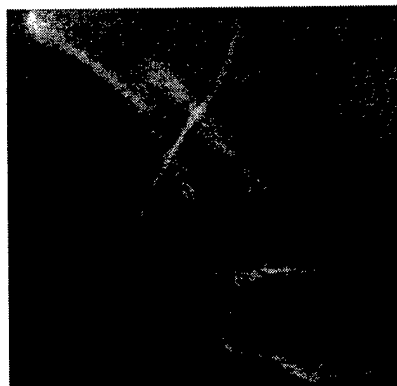
We expect that the generation II imager, with the XLV, when it is finished will have a very high DQE and thus no sensitivity problems.

XLV Screen Development (Sunnybrook)

The practical implementations of the liquid crystal light valve (XLV) has previously been shown to have visible contrast (see Fig. 11), good resolution (~ 11 lp/mm), but still had problems associated with limited dynamic range, imperfections in the image and poor sensitivity to radiation. It was found that it could only operate at very small applied

Figure 11: Image of Finger Phantom

XLV image of a finger phantom at ~ 100 V bias.



potentials (~ 50 - 100 V) compared to the design potential of 1500 V, due to the high potential causing the liquid crystal to modulate the readout light prior to exposure.

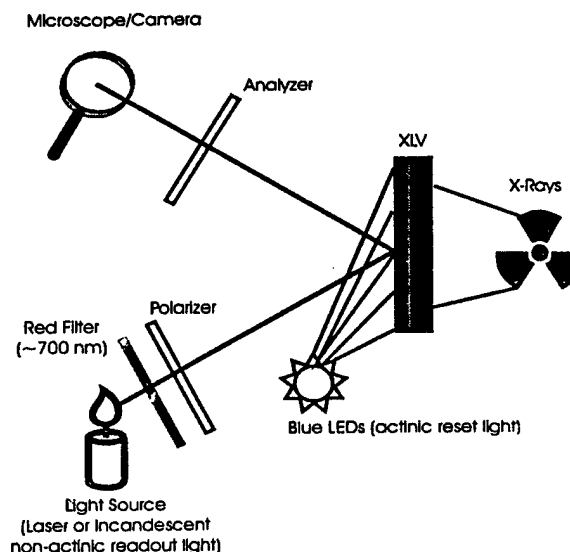
Our program this year has been to identify the causes of these problems and propose methods to overcome them. We have previously modeled the operation of the XLV and had checked the proper operating conditions and design parameters of the components. Thus when the device was constructed and did not operate as expected there was obviously some problem, but the cause was unclear. Either the component values had shifted during manufacture or the model was not correct. Once the device is completed then the test procedures we used on components are no longer useful. Instead, system level testing is needed to identify problems.

The major problems related to both image imperfections and inadequate sensitivity were both deemed to be the low operating potential. Thus the problem is to identify the reasons for limiting the bias potential were a primary focus. It was considered that there could be two possible reasons for the need to operate at very low biases, the first was that the dark current had been inadvertently increased in the process of making the XLV and the second was that the resistance of the LC layer was higher than expected. Given that the observed effect seemed to indicate that a potential in excess of prediction was present across the LC layer, the second of the two possibilities seemed the most likely.

Testing this theory involved the development of a tool that would indicate potential division across the layers of the XLV, using the liquid crystal itself as a probe. The operation of the tool utilizes the fact that a cell operated in reflective mode shows a peak in light intensity at some voltage characteristic of the given liquid crystal material, and the intensity rapidly diminishes to low levels after the bias potential is increased past this key value. The test procedure is illustrated in Fig. 12.

Figure 12: XLV Evaluation Arrangement

Light source (laser or white incandescent light with coloured filter) passes through polarizer and reflects off mirror surface of XLV. Reflected light passes through analyzer (optical axis at 90° to polarizer) to the microscope and CCD camera. The blue LEDs are used to clear the image charge and are not illuminated during x-ray exposure and read-out.

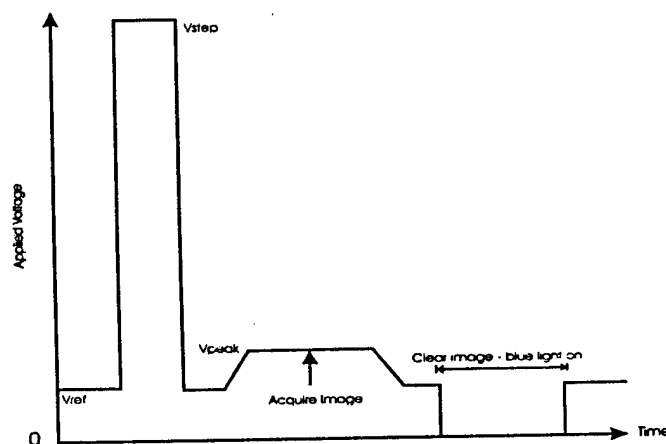


Therefore, by observing the transmission of the XLV over a range of applied voltage values, the transmission intensity peak can be used as an indicator of when the XLV corresponds to this characteristic voltage across the liquid crystal. The image on the front surface of the XLV is viewed by a CCD camera attached to a frame grabber computer system. The XLV itself is connected to a function generator which can produce linear voltage ramps at user defined values of peak voltage value and frequency. The frame grabber acquires data during the application of the ramp, and transmission characteristics can be plotted for individual pixels or small sub-groups of pixels.

Based on these results we propose a solution to our low operating potential problem that should permit high quality images to be produced. It is an approach that eliminates the effect of the biasing field simply by removing the biasing field before readout is attempted. This entails applying a short pulse of high voltage to the XLV, exposing to x-rays while the selenium is properly biased, and then reducing the voltage below the characteristic voltage of the liquid crystal and then capturing the image by reading out the CCD camera. A timing diagram for this approach is shown in Fig. 13.

Figure 13: Schematic of pulsed mode operation

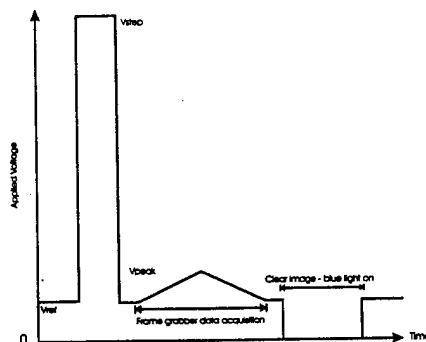
X-rays will be applied during the high voltage (V_{step}) pulse, and the image will be at V peak. Blue light clears the image after read-out to prepare XLV for next exposure.



The second major problem was limited dynamic range when operating in the hybrid field mode to permit front side illumination and readout. This was addressed by investigating a novel readout scheme that uses the time at which a given pixel has a maximum intensity. Namely, since the x-ray signal produces an extra bias across the liquid crystal, an exposed area will peak sooner than a shielded area since it will require less applied bias to reach its characteristic voltage. A timing diagram for this approach is illustrated in Fig. 14.

Figure 14: Time-dependent Image Acquisition

Image data is acquired during the ramp to V_{peak} . For each pixel in the region of interest over the ramp time the frame number at which intensity is maximal is found and used to construct the image.



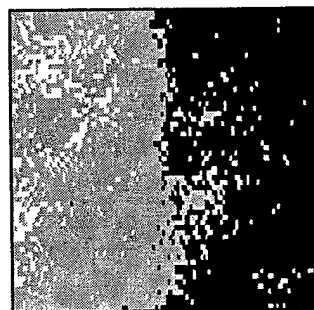
This discovery indicated that an alternate way of obtaining images might be useful. For a given region of interest, obtaining the location in frame numbers of the intensity peak for each pixel to create the image. Since the frame number is a direct correspondence to the time at which that frame was taken and therefore to the applied voltage at that time, the frame number will vary depending on how much signal charge was deposited on the area of the XLV corresponding to that pixel.

This idea was tested using a lead block covering half the region of interest, thereby providing a shielded area and exposed area for comparison. A computer program was written which located the peak value for each pixel and constructed the image. An example of an image obtained using this procedure is shown in Figure 15.

Remaining tasks involve determining the final material parameters (type of liquid crystal material, thickness of liquid crystal layer) of the prototype XLV.

Figure 15: Sample Constructed Image of Edge

The following equalized image (approximate area 0.4 mm^2) was taken using a 650 nm laser as a light source. Blotches in the image are due to the interference pattern made by the laser on the surface.



IMAGER TESTING BY SUNY/BUFFALO - MEDICAL PHYSICS GROUP

The physics group has:

- Performed testing at mammographic x-ray energies of limiting resolution and light output efficiency of several new phosphors for use on the imager including two red emitting phosphors which may be better matched to the spectral response of CCD and CMOS sensors.
- Also performed testing of a range of phosphors for response time. This was presented at the 40th Annual meeting of the AAPM with the following published abstract:
S Rudin, JJ Patel, DR Bednarek: Decay time measurement of imaging phosphor materials. (PO-D-18) Medical Physics 25(7): A214, July 1998, Part 1.
- Prepared for testing the prototype imager by developing IDL software for calculating modulation transfer function (MTF), noise power spectra (NPS) and detective quantum efficiency (DQE).
- Developed and tested an automatic bootstrap sensitometry program for determining the characteristic curves of the new imagers. This is essential for linearizing the system response so the MTF, NPS and DQE can be determined. This work is to be presented at the 41st Annual Meeting of the AAPM with the following published abstract:
DR Bednarek, S Rudin, CJ Yang: Automatic bootstrap characteristic curve segment matching. Scientific exhibit. 41th Annual Meeting of the American Association of Physicists in Medicine, Nashville, TN, July 24-29, 1999. Medical Physics 26(6): June 1999, (PO-D-16) 1174.
- Worked with SP to test the new CMOS system on the Bennett X-Ray unit. Measured and determined characteristic curve for CMOS detector array. Co-authored paper presented at SPIE Medical Imaging 1999:
ST Smith, DR Bednarek, DC Wobschall, H Kim, M Jeong, S Rudin: Evaluation of a CMOS image detector for low cost and power medical x-ray imaging applications. Medical Imaging 1999, (San Diego, CA) SPIE Vol. 3659: 952-961, 1999.
- Began initial studies of the possibility of developing a microstrip gas detector as a digital mammography image receptor with tissue differentiation. This work is to be presented at the 41st Annual Meeting of the AAPM with the following published abstract:
Chattopadhyay A, Barasch EF, Bednarek DR, Rudin S: Design strategies for pressurized xenon microstrip detectors in radiography. (abstract). 41th Annual Meeting of the American Association of Physicists in Medicine, Nashville, TN, July 24-29, 1999. Medical Physics 26(8): August 1999, (WIP-D-11).
- Acquired without charge a Philips Diagnost UM mammography x-ray unit for installation at Sensor Plus (SP) to provide more efficient time utilization in on-site testing of x-ray imaging components. Radiation safety testing was performed of the installation and paperwork was prepared for New York State registration of the unit.
- Obtained university staff status for an employee of Sensor Plus (S.S.) for greater accessibility to University Equipment including a Bennett Contour mammography unit and a Fischer Mammotest / MammoVision digital stereotactic breast biopsy unit.

This grant has supported in part the research on a microradiographic imaging device with CCD camera and fiber optic minifier for high resolution equal to that required for mammography. This work has led to the following publication:

- S Rudin, DR Bednarek, AK Wakhloo, BB Lieber, CYJ Chang, D Nazareth: Region of interest microangiography: radiographic imaging optimized for vascular interventions. Medical Imaging 1999, (San Diego, CA) SPIE Vol. 3659: 708-717, 1999.

And presentations at the 84th Scientific Assembly and Annual Meeting of the RSNA

- S Rudin, AK Wakhloo, DR Bednarek, CJ Yang, WE Granger: Comparison of a new high resolution region of interest (ROI) microangiographic digital detector with standard image intensifier and screen-film receptors for visualizing vascular stents. Scientific program of the 84th Scientific Assembly and Annual Meeting of the RSNA, Nov 29-Dec 4, 1998, Chicago, exhibit #0520PH. Suppl. Radiol. 1998, 209(P):583. Received **Merit Award for Scientific Excellence**. (Invited Category I CME Credit course.)
- S Rudin, AK Wakhloo, DR Bednarek, CJ Yang, WE Granger: Stent visualization with a new high resolution region of interest (ROI) microangiographic digital detector. Scientific program of the 84th Scientific Assembly and Annual Meeting of the RSNA, Nov 29- Dec 4, 1998, Chicago, #963. Suppl. Radiol. 1998, 209(P):358.

And at the SPIE Meeting "Medical Imaging 1999":

- S Rudin, DR Bednarek, AK Wakhloo, BB Lieber, CJ Yang, D Nazareth: Region of interest (ROI) micro-angiography: radiographic imaging optimized for vascular imaging. Program Update, SPIE Medical Imaging 1999, Paper 3659-73, page 148.

And at the 41st Annual Meeting of the AAPM with the following published abstract:

- Nazareth D, Chattopadhyay A, Rudin S, Yang CJ, Bednarek DR: Initial study of the micro-angiographic determination of elastic properties of vessels (abstract). 41th Annual Meeting of the American Association of Physicists in Medicine, Nashville, TN, July 24-29, 1999. Medical Physics 26(6): June 1999, (PO-D-11) 1173.

IMAGE DISPLAY SOFTWARE

Infi-med had been assigned to work on this. They have not worked on this yet mostly because we do not have a full-size image for them to display. Furthermore Sensor Plus has developed a package of image display software (worldviewer) so this is not necessary, at least at this time.

Production/Technology Transfer Plans

We expect that the low-cost imager now being tested (Generation I) will be developed to the pre-production prototype stage during the next year. We want this product to be manufactured and marketed as soon as possible since this is the reason this project has been undertaken. As a small business, Sensor Plus does not have the funds to bring this product into production nor does it have the marketing experience. To solve these problems, two approaches are being tried.

The first is to obtain funding from local (Western New York) investors. A business plan has been prepared and being shown to investment/venture capital groups. The plan includes development to the production stage and adding an experienced medical equipment marketing expert to the management team. Selling stock over the internet is also being considered but we think it best to start by getting some backing of local high technology business development groups. Two applications of the digital x-ray imager are combined in the business plan, mammography and emergency medicine.

The second approach is to partner with, if necessary transfer the technology to, an existing medical imaging company. A six-page document describing digital imager technology and the medical (marketing) areas for which it is appropriate has been sent to a number of companies. The second-tier medical imaging companies have been targeted since we expect that they would be most interested in technology developed outside their own company.

Problems Encountered

The main problems encountered during the third year were:

- **Lens Procurement**
There were various delays in formulating specifications, selecting a subcontractor, design, and fabricating the high performance lens. This delayed our detailed tests on the system DQE and MTF, which are critical. One lens was delivered during July while this report was being written.
- **Electronic Circuit Board Tests**
The layout, fabrication, troubleshooting and tests of the circuit boards took longer than expected perhaps because of our stress on high (production level) quality boards.
- **Image Stitching**
We found that the image correction and stitching software, which previously appeared very effective using several test methods, was found not as good as expected. This must be corrected.
- **XLV Prototype Delay**
A prototype of the x-ray light valve was not made available for testing at Sensor Plus, as originally planned because of problems in the development of a reliably functioning unit. While the XLV has the highest development risk, it also has the most potential for a performance improvement (generation II imager).

Conclusions

As a development project, the conclusions are expressed as the degree to which the planned specifications for the instrument are being met and a judgement as to the continuing relevance of the specifications to producing a useful medical product.

The resolution goals are being achieved on smaller size imagers and the extension to the full-size imager is on track, although delayed. Also the electronics has been developed to near the production stage. However, the sensitivity for the generation I imager appears marginal even with the planned improvements (better sensors). Completing the XLV for the generation II imager would solve this problem but the outcome is uncertain.

We still consider that a low-cost digital x-ray imager for mammography is needed and that there will be a market for it in smaller, rural hospitals and in developing countries. Plans to bring the mammography imager into production were discussed above.

TASK SCHEDULE

Status of task schedule, as of 30 June 1999, follows:

Task 1. Build Prototype (low resolution)
Done

Task 2. System Design
Done

Task 3A. Fabricate and Evaluate Small Area, XLV Prototype
This task is the same as that previously planned but is yet finished.

A. Fabricate Hi-Resolution X-ray Light Valve (XLV)

An improved XLV will be made by Kent State with the help of new facilities at Sunnybrook. It will have a resolution over 15 lp/mm in an area of 80x80 mm or larger.

B. Test of XLV

The high resolution XLV will be characterized by Sunnybrook and methods of improvement suggested, as required.

Task 3B. Fabricate Small Screen Prototype

A. Fabricate Optical System
Done

B. Fabricate and Test Electronics Section
Done

C. Fabrication and Test of Workstation Interface
Done

Task 4. Fabricate and Test Full Size Imager

A. Fabricate Full Size, CCD Array and Circuit Boards
Done

B. Fabricate and Test Electronics Section
Mechanical done but lens finished just after end of this period and not tested.

C. Refinement of Image Processing Software
Mostly done but refinements continue.

Task 5. System Performance Test

A. Test of Imager

The imager will be tested at SUNY (ECMC) using phantoms, and also specimens from Roswell Park Cancer Institute (RPCI) if appropriate. In addition to resolution and noise, image distortion and discontinuities between segments will be examined. Work in progress.

B. Comparison with Film/screen

Standard x-ray film/screens images will be compared (at ECMC) with those obtained by the imager under development. The objective is to demonstrate that no artifacts exist. Not done.

C. Clinical Trial Planning

Planning for future clinical trials will be made primarily by SUNY (ECMC) and the consultants. Not done.

Task 6. Preparation, Radiographic Workstation Software

A. Implementation of Standard Viewing Software

Partly done.

B. Verification of Image Quality Robustness

Tests will be made at SUNY (ECMC) to verify that the image quality is not effected by improper software sequences. Not done.

C. Image Compression

A method of image compression and storage will be selected and implemented at InfiMed. Not done.

D. Display Tests

The quality of the display will be evaluated at InfiMed, SUNY (ECMC and RPCI). Not done.

Task Assignments by Investigator

A. Sensor Plus Inc. (Prime Contractor)

Dr. Darold Wobschall, (Principal Investigator)

Project Manager

Overall System Design

Design of Analog Electronics

Myeoung Jeong

Development of camera connection software, including distortion and alignment. Working part-time since task is mostly done.

Scott Smith

Design and testing of DSP hardware and CCD data acquisition

H. Kim

Design and testing of DSP parallel processor and image transmission system

Tom Cordier

Circuit assembly supervision

Circuit board layout and EMI reduction

Kevin Swindell

DSP circuit testing and optical design

B. Sunnybrook (U. Toronto)

Dr. John Rowlands

Supervisor of XLV screen fabrication

XLV design and testing

C. State University of New York at Buffalo

Dr. Stephen Rudin

Imager configuration and assuring compatibility with existing x-ray equipment

Helping with optical design

Dr. Daniel Bednarek

Associate of Dr. Rudin at Erie County Medical Center. Planning of x-ray testing

William Granger

Graduate student assisting Drs. Rudin and Bednarek

D. InfiMed, Inc.

Design of workstation software.

Dr. Thomas Vogelsong (VP) (left Infimed in June, 1999)
Planning of workstation software
Marketing

E. Consultants

Dr. Raj Acharya
Software signal processing and image reconstruction

J. Antonelli
Designed and fabricated the lens.

Statement of Work

This is same as last year's report.

I. Perform the following tasks described under the revised TASKS in the proposal. See task list given previously.

II. Design and fabricate a mammographic imager and work station with the following characteristics:

- * 8x10 inch active area*
- * Pixel size approximately 42 microns over full image size.*
- * 12 bit effective a/d dynamic range (gray scale)*
- * The border on one side of the imager must be under 3mm and preferably 1mm.*
- * The workstation must have the capability to acquire complete radiographs at high resolution (4000 x 5000 pixel minimum). It will display the full image at reduced resolution (relative to the internal resolution), and it will be able to zoom in to view portions of the image at full resolution.*
- * The basic imager will work with standard mammographic x-ray sources.*

List of Publications

1. Scott T. Smith, Daniel R. Bednarek, Darold C. Wobschall, Myoungki Jeong, Hyunkeun Kim, Stephen Rudin, Evaluation of a CMOS Image Detector For Low Cost and Power Medical X-ray Imaging Applications, SPIE Medical Imaging, vol. 3659, 1999.
2. Vivek Swarnakar, Scott T. Smith, Myoungki Jeong, Hyunkeun Kim, and Darold C. Wobschall, Evaluation of A Digital Mosaic Mammographic Imager, 4th International Workshop on Digital Mammography, June 1998.
3. Scott T. Smith, Hyunkeun Kim, Vivek Swarnakar, Myoungki Jeong, and Darold C. Wobschall, Parallel hardware architecture for CCD-mosaic digital mammography , SPIE Medical Imaging, vol. 3335, 1998.
4. Vivek Swarnakar, Myoungki Jeong, Scott T. Smith, Hyunkeun Kim, and Darold C. Wobschall, Effect of the reconstruction technique on the quality of digital mosaic mammograms, SPIE Medical Imaging, vol. 3340, 1998.
5. V. Swarnakar, M. Jeong, R. Wasserman, E. Andres, and D. Wobschall, An Integrated Distortion Correction and Reconstruction Technique For Digital Mosaic Mammography, SPIE Medical Imaging, vol. 3031, pp. 673, 1997.

Planned Publication

A minimum of three reports on this work is planned in the next year:

- A presentation at the Era of Hope Conference (Washington, DC, June 8-10, 2000).
- A presentation at the 5th conference on Digital Mammography (Toronto, June 11-14, 2000)
- A paper in a scientific journal emphasizing the overall design and image quality test results.

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10. Henry, J.M., Yaffe, M.J., Pi, B., Venzon, J., Augustine, F., and Tumar, T.O., "Solid state x-ray detectors for digital mammography," Medical Imaging 1995: Physics of Medical Imaging, Ed. R.I. Van Metter and J. Beutel, Proc. SPIE 2432, 392-401 (1995).
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12. Zhao, W., and Rowlands, J.A., "Digital radiology using self-scanned readout of amorphous selenium," Medical Imaging 1993: Physics of Medical Imaging Ed. by: R. Shaw, Proc. SPIE 1896, 114-120 (1993).
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