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Two previously developed x-ray imager technologies, the x-ray light valve (XLV) and mosaic (segmented) digital imager are being combined into a larger area (8"x10") screen with high resolution image (50μm) suitable for mammography. By applying current engineering devices and practices, a low cost and noise imager is expected. We expect to achieve the same size, resolution and image quality as film/screen.

During the second year the overall imager design was finished and a prototype of the CCD electronics and digital signal processor was tested. The mosaic image reconstruction software was refined and the reconstruction accuracy tested for various algorithms and applications. An additional, intermediate goal of designing an imager with the array (6x6), but without the XLV, was added with the expectation that it can be produced earlier and at a lower cost than competitive imagers.

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Randall Wohschall 7/28/98

PI - Signature Date

High Resolution and Sensitivity Digital X-Ray Imager for Mammography
Annual Report (July 1998)

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Sensor Plus, Inc., prime subcontractor
with InfiMed, Inc., Univ. of Toronto (Sunnybrook)
and SUNY/Buffalo (ECMC)

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Introduction

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 report and in Appendix A.

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 most testing will be deferred until the conventional screen is done.

Additional Goal - Low Cost Digital Mammographic Imager

Evaluation of Commercial Digital Mammographic Imagers

This project has the aim of developing a full-size, low-cost digital imager for mammography which is better than film/screen. The advantages of digital imaging over film/screen (teleradiography, easy storage/availability, simple image enhancement, and computer-aided diagnosis) were assumed to be accepted. At the time the project was proposed was unclear whether commercial x-ray imaging companies were prepared to develop a full-size digital imager in the near future. Several companies had tried but apparently abandoned efforts, perhaps waiting for further progress in University or government-sponsored work. Now, however several commercial full-scale imagers have been developed to the point where clinical trials required for FDA approval (510K) are well underway. As reported at the Fourth International Digital Mammography Conference at Niymegan (June 1998), these trials have gone well and it is probable that one or all of the following machines will be approved and become available for general use in the USA.

•Trex Medical Imaging (Lorad and Bennet Divisions)

This unit is based on fiber optic taper coupling to a 3x4 CCD (19x25 cm) array or mosaic with 40 μm resolution (4800x6400 pixels). The DQE is 0.5 (DC) over a wide exposure range and is better than film/screen over the entire range. The output is a computer screen.

Extensive testing has been completed and data is being summarized. It is likely this will be the first unit approved (510K) by the FDA. Price for the imager has not been fixed but is likely to be in the $250K to $500K range (plus $100K for x-ray source and more for computers, data storage, display, etc.).

•GE Medical Systems

The imager, based on amorphous silicon, is undergoing clinical testing. Images are also of high quality, better than film/screen. The image has 2000x2500 pixels 100 μm) and the output is film. A computer-aided diagnosis developed by R2 (Image checkers) will be included.

•Fischer Medical Imaging

This uses a scanned slot detector (24 x 3.2 mm). Fiber optic tapers to several CCD arrays are used. Data is stitched to form the final full size image. Image is 4000x5000 pixels (50 μm) and film output is also used. In this design the detector is smaller but the mechanical scanning system more complex. The x-ray tube current loading and curved receptors (compression plates) are problems.

Note that there is some dispute as to whether the output should be on a computer display screen or as film (e.g. Kodak laser printer).

Three other companies are in the advanced state of development for full scale digital mammography imagers.

•Fein Focus

A German company with a magnification feature 282x406mm, 127 μm pixels, 2:1 uses a thin film/screen transistor (amorphous se) technology. It will be introduced in Germany first.

•Siemens

A small area (spot) imagers based on fiber optic coupling is being sold. No details on the full scale imager were released but they are working on a full scale versions (Trixell).

•Fuji Medical Systems

No information released but they are working on it.

We conclude that these companies have developed a full scale x-ray imager which, although costly, have a performance better than film/screen. This has caused us to re-evaluate our priorities. Our original design would offer better performance, if the design goals are fully achieved, but may not be commercially acceptable based on technical performance alone. However our basic design has a significant potential cost advantage, and with some moderate redesign, we can increase the cost differential to about 5:1, the point where our design would become commercially viable. We have decided to take this approach so that the imager we produce will be useful and valuable contribution to the medical community.

The relatively high cost of these imagers ($250K to $500K) is likely to be acceptable to larger medical centers in US urban areas but may be unacceptable to smaller hospitals in rural areas or poorer countries. Yet it is the smaller hospitals that could benefit most by digital imaging, especially the teleradiology and computer aided diagnosis features.

Low Cost Digital Imager Design

Recognizing that the primary value in our design approach (lens coupled mosaic) is low cost and component availability (off-the-shelf hardware), the design was altered to minimize production costs while still maintaining adequate performance. Another major reason was that a full size, defect-free XLV screen was not yet available (see below) but that even if it were available, we were concerned that the production cost might be too high. In the new design, a standard fluorescent screen (Lanex) is used to convert the x-rays to visible light and this light coupled by lenses to a CCD array (6x6). This is a method we and others have used previously but had the disadvantage of low light collection efficiency (e.g. 0.2%), a consequence of the large demagnification required (5 to 10). However, fortunately a CMOS CCD (specifically the VV5820, 992x800 10.8 μm pixel CCD made by VLSI Vision Ltd.) was recently introduced which has both significantly better geometry for our application (larger active area, smaller package) and much lower cost. The light collection efficiency is 5x higher (1.5%) the cost 5x lower. The device is more difficult to use because of complex timing and patterning corrections in software but our hardware design (analog data acquisition with one DSP) is flexible enough to handle this.

The geometry of the image is shown in Fig. 1.

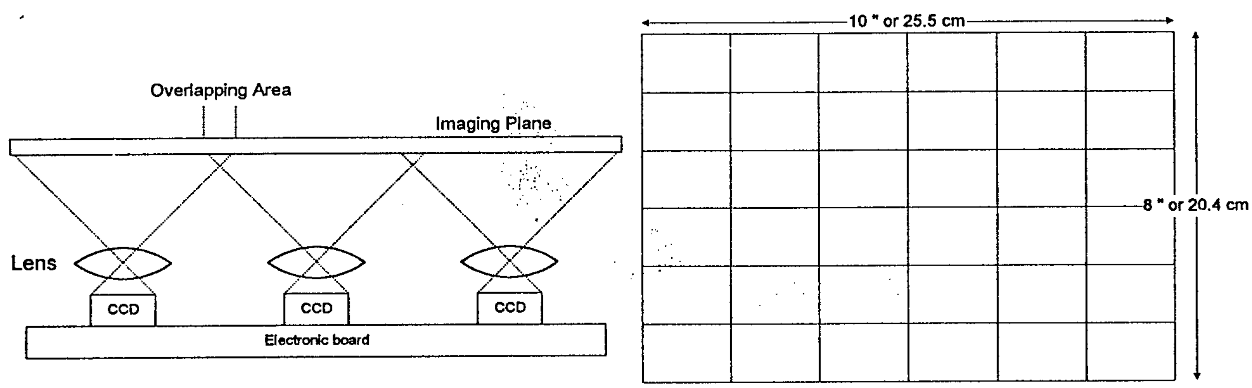


Fig. 1 Geometry of Low-Cost X-ray Imager for Mammography

A detailed discussion of the CCD and sensitivity is given in Appendix B.

The input pixel size in the new design is 42 μm, a slight improvement. By comparison, the GE mammographic digital imager is 100 μm. Studies of the effect of pixel size on the interpretation of mammograms indicate that 100 μm is adequate for screening and detection of microcalcifications but 50 μm (or smaller) may be needed for diagnosis (shape determination). However, we plan to average pixels to reduce noise to compensate for CCD defects and software stitching irregularities and also to reduce image storage requirements so that our normal display (output) pixel size would then be 82 or perhaps 126 μm. We consider this resolution adequate for mammography and perhaps better than expected for a low cost imager. However the higher resolution would be available as an option.

It should be noted that cost minimization, while maintaining adequate performance, requires the consideration of multiple, partly conflicting factors such as array size lens/CCD costs, and signal acquisition complexity/costs. A number of designs were considered before deciding upon the one described here.

To reduce production costs, a single DSP rather than the previously planned multi-processors will be used. Data will be transmitted via the printer port to the main computer (Pentium PC) for most of the image correction and reconstruction. The main disadvantage is that the process will be slower (perhaps 1 min from exposure to display). A higher speed, multi-processor we have already designed (and partly tested) could be provided but we expect most users would not want to pay the higher cost, but since the cost of computer components such as these typically decrease with time the higher speed may become attractive later.

Like the Trex imager, a drawback to the imager we are developing is size. It is thicker (4-6") than some other digital imagers which are closer to a film/screen cassette in size. There is room underneath (opposite the x-ray source) in standard mammographic x-ray machine for the imager, with modest modifications, and thus we do not consider this a major drawback.

One potential disadvantage of our low-cost imager version with conventional screen is that the sensitivity will be somewhat less than the high cost/performance digital images (described above), and considerately less than our XLV version. Still we expect it to produce a good image within the recommended maximum x-ray patent dose (100 to 300 mRad, (mean glandular).

We expect the selling price of the low cost imager (conventional screen) to be about $60K or about 20% of the price of commercial imagers.

Work Accomplished During Second Year

Imager Hardware (Sensor Plus)

2x4 CCD Mosaic Prototype

A complete 2x4 CCD mosaic imager has been designed and a 2x2 sections has been completely built. A total of four printed circuit boards were designed for the CCD sensors, analog electronics, DSP interface electronics, and timing and power distribution electronics respectively. A complete lens assembly was designed and fabricated to fit the prototype so that each lens may be separately focused and replaced. The case was also custom made for this prototype and is entirely made from aluminum. An adjustable image plane was designed to allow the testing of various lenses that possess different focal distances. Once the correct image plane distance is found for a particular lens it may be fixed into position for X-ray testing.

Electronics

The main focus of this revision of the electronics was to reduce the overall noise in the CCD and analog circuits, create a modular design to ease changes associated with individual sections, and add clock driving circuitry required to drive the signals of large arrays of circuits (multiple CCD's, CDS's, and A/D's). The overall functionality of each board was tested and small modifications were made to ensure functionality. Once a single CCD channel was constructed and operational, 3 more channels were added to produce the 2x2 imaging electronics.

Once operational, the effective RMS noise floor with 3 different configurations of the analog signal processing chain were measured. A total of 768x512 samples were digitized in each case and the RMS noise floor was computed from these "noise images":

Measurement Configurations	ADU rms	mV rms	electrons rms
A/D with floating input	0.8	0.39	39
CDS and A/D	1.5	0.73	73
CCD, CDS, and A/D	2.9	1.42	142

With these measured noise values the maximum S/N ratio that may be achieved with this imager is approximately 600 which computes to about 9.2 bits. This does not take into consideration the noise contributions from the X-ray and optical systems.

Lens Design and Cost Issues

A single lens was custom designed as discussed, in the previous report. An additional element was added to this lens to further reduce defocusing at the edges of the images. Although this lens proves to achieve the desired imaging constraints, the cost is very high ($890/lens for 8 lenses). If these lenses were to be used in the final imager, the cost would exceed the CCD and analog electronics costs combined. This problem was addressed by considering larger diameter off-the-shelf lenses which would approach our imaging needs. Currently we are evaluating the performance of these lenses to see if they will be feasible for our application. This approach coincides with our effort to shift to a low cost X-ray imager which would need a low cost solution for the lenses.

Mammography Machine Interface Circuitry

To synchronize the X-ray exposure with the image capturing time, an interface circuit is being be developed. Signals originating at the bucky plate of an existing ECMC mammography machine is used for this synchronization. The bucky begins movement before the X-rays begin and will therefore signal the imager electronics to get ready to capture an image (see Figs. 15, 16). An X-ray detector will also be used to signal the imager to capture an image when the X-rays are on.

This circuit must be included for testing the 2x4 prototype since we are using a phosphor screen which does not allow the image to be held after the X-rays turned off.

Large Area LED Light Source

A mosaic of large area, red, rectangular, LED sources was designed and constructed to approximate a uniform light source over the imaging area. Since the final imager will have an imaging area of 10" x 8", the light source must be larger than this area to test image quality before the X-ray tests. This light was constructed so that the LED's can be pulsed on during the exposure time of the CCD. Also, this source is monochrome and approximates the monochrome nature of the phosphor screen.

Commport to Host (PC) Interface

A host interface between a DSP(TMS32C40) comport and a PC's bi-directional printer port using ISA Bus was designed and tested. It has many advantages, including freeing up the DSP bus and treating the host PC as a virtual DSP node within a system of Multiple DSP devices.

This interface uses a bi-directional PC printer port interface. Logic circuits, buffers and resistors convert logic control levels driven from the printer port into DSP's commport control signals. Signals driven from the DSP are converted into status signals, which can be polled in software by the PC. In addition, the PC's printer port provides the byte-wide data path into and out of the PC.

With this printer port application, one can use this I/O interface for host-data communication, boot loading (code), and debug operations. With proper buffering and software control, it is also possible to build long and reliable links. The overall speed is primarily dependent on the speed of the host. When using a PC as the host, the speed is limited by the PC's I/O channel speed. If higher rates are needed, one can use a memory-mapped version of the printer port in the PC.

Most popular printer ports have used ISA Bus for more than 12 years. However, now it has lacks the performance and capability to take advantage of new high-speed microprocessors. On the other hand, the PCI bus is designed to work with the newest processors and to transfer data at rates much faster than what was previously possible with ISA and EISA (Table 1).

Because digital x-ray mosaic mammography handles huge amount of image data (about 28.8 Mbytes), it is necessary to perform data transfer as fast as possible. Therefore the PCI Bus based printer port interface was chosen for our system.

	PCI	ISA	EISA
Bus Speed	33 MHz	8 MHz	8 MHz
Theoretical peak throughput (Mbyte/sec)	132 MB/s	8 MB/s	32 MB/s
Sustained throughput of 8-bit data to system memory	80 MB/s w/DMA	1.8 MB/s w/DMA	10 MB/s w/DMA

DSP and Memory

Digital x-ray mammography imager acquires image data with a 18 MHz clock. In order not to miss any pixel data, the DSP should read and save it faster than acquiring speed. Static RAM is fast enough but the cost is too high for a large memory system. Conventional Dynamic RAM is cheap but access time is not appropriate to our system. Our DSP will use synchronized dynamic random access memory (SDRAM) for system's main memory. Functionally, an SDRAM resembles a conventional DRAM. Since it is dynamic and must be refreshed. However, the SDRAM architecture has improvements over standard DRAMs, such as internal pipe-lining, to improve throughput and on-chip interleaving to eliminate gaps in output data. The addition of a clock signal allows fully synchronous operation with the system clock (30 MHz in our x-ray imager). This SDRAM enables image data acquiring successful without losing any pixels. Figure 2 shows block diagram for DSP and SDRAM.

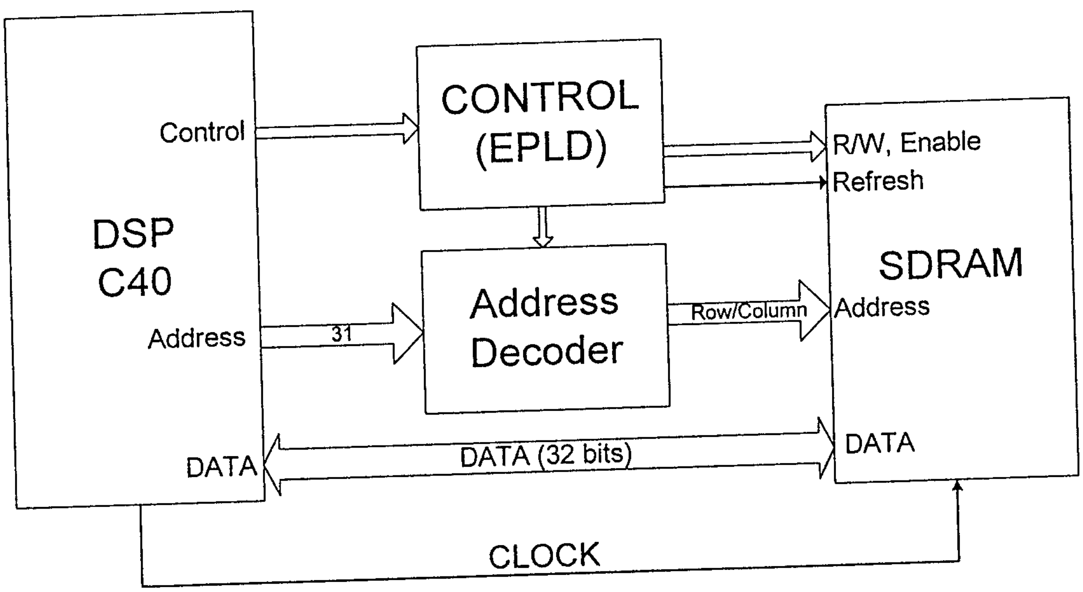


Figure 2. Block diagram for DSP and SDRAM

Image Reconstruction (Sensor Plus)

This section provides a summary of the software tasks carried on during the period of August 1997 - July 1998. The following tasks are next described in detail:

- Development of several distortion correction schemes
- Evaluation of the reconstructed image quality by different correction schemes.

Part of results obtained from the software related tasks was presented at the 1998 SPIE's - Medical Imaging conference [spie '98 mi].

Reconstruction Algorithms for imager

The final image quality of a digital mosaic imager depends on schemes for distortion correction and stitching. The distortion correction is critical for obtaining a high image quality. During the period covered by this report, the primary objective was to develop several improved schemes for distortion correction, and also to improve the stitching technique developed previously.

Correction schemes for image distortion

Several approaches have been developed to correct the distortions introduced by the optical components of an imaging system. All the approaches are based on the use of a calibration pattern containing fiducial markers. The schemes we have developed include piece-wise linear interpolation, bilinear interpolation, bicubic spline interpolation, Bezier composite surface interpolation, bicubic B-spline surface interpolation, and polynomial modeling. All schemes are based on the relation of corresponding control points between the reference image and the acquired image of a calibration pattern. It should be noted that the bilinear interpolation, bicubic spline interpolation, and polynomial modeling approach are global correction schemes, while the piece-wise linear interpolation, Bezier composite surface interpolation, bicubic B-spline surface interpolation are local correction ones. To reconstruct a full image without losses of detailed information such as micro-calcifications, it is desirable to employ a localized scheme. A comparison between a localized scheme and global schemes will be presented in the evaluation section. To calculate the correction coefficients, we have developed a new calibration pattern (Figure 3) which was acquired using a prototype 2x2 imager. The intersections of grid are used as control points. We have developed this calibration pattern by assuming that the distortion in an acquired image will be largest in the edge area. Figure 4 shows a stitched image with distortion correction using cubic spline surface interpolation.

Stitching Technique

Stitching is based on the extracted information from a calibration pattern, as presented previously in [spie '97 mi]. We are currently developing a more accurate scheme to improve the image quality in the overlapping area. The basic idea is that it uses the extracted information from a calibration pattern as an initial estimation for stitching information since it is fairly accurate in the range of one pixel. However, this accuracy is variable depending on the detection accuracy of control points. Using the initially estimated information, we add one additional step such as cross-correlation, to find the most accurate location for stitching. We are comparing both the current scheme and improved schemes in terms of computation time and accuracy.

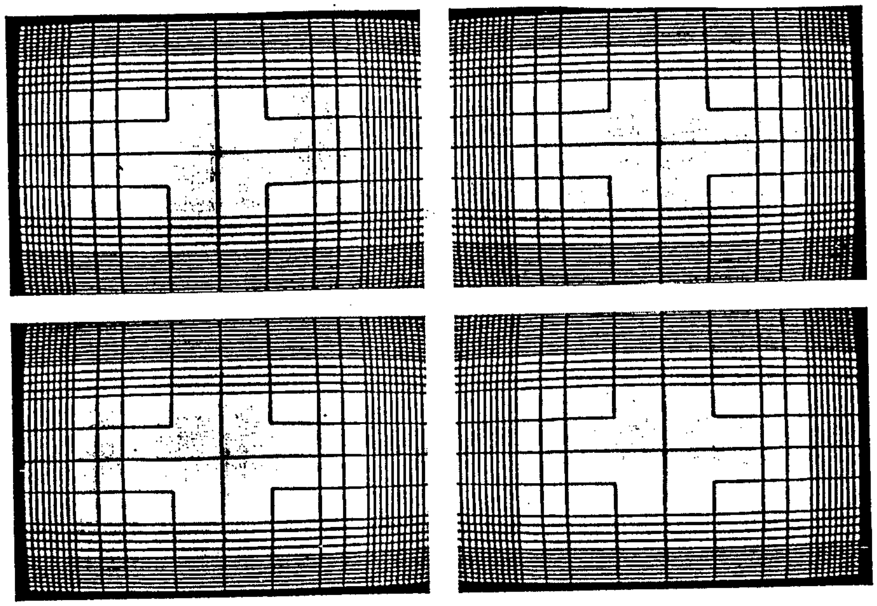


Figure 3. Images of the calibration pattern as acquired by each CCD sensor.

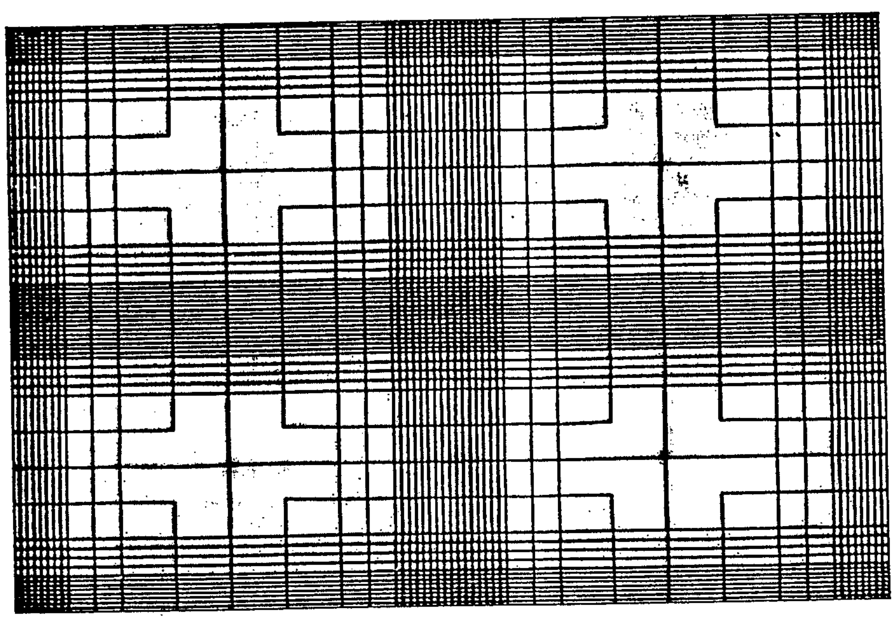


Figure 4. Mosaic image reconstructed using the spline interpolation algorithm.

Evaluation of correction schemes

To evaluate the quality of each correction scheme, we have carried out the quantitative analysis and visual analysis using three types of features:

- Circumscribed mass
- Spiculated mass
- Micro-calcification.

Some of results are presented for visual analysis. Refer to [spie '98 mi] for details. We have evaluated one of localized schemes - piece-wise linear interpolation and two of global schemes - cubic spline interpolation and bilinear interpolation. The evaluation of other schemes is underway. Results presented here simulate a system where four CCD sensors are used to create the digital mosaic. The method is identical for larger arrays (e.g. 6x6). By simulation it is meant that a mathematical model of the individual imaging components was employed instead of testing the hardware system. The overlap area of four tiles is where the most severe distortions are expected to occur. In order to evaluate the quality of the reconstructed features, each mammogram was translated and placed in a larger image such that the feature of interest falls on the overlap region of all four tiles. The mammograms are centered in a larger image using the center coordinates of the feature of interest as the center point of the larger image. The size of the large image is 1497x969 pixels which is the same as that of the calibration pattern. Next four overlapping subsections of size 768x512 are extracted from the large image. The resolution of the CCD's used in the imager is also 768x512 pixels. This will enable the application of the imager's distortion function to the mammogram images. It should be noted that each sub-image undergoes a slightly different transformation. The distortion function used was based upon a Barrel Distortion model. As it can be observed from the images in Figures 3 and 4 this function is suitable to approximate the imager optics. Once each sub-image is distorted using the distortion function the three correction schemes, Piece-wise linear approximation, Bilinear interpolation and Spline interpolation were applied to correct each sub-image. Sections from the corrected sub-images that do not belong to the overlap area are extracted and then placed together to form the reconstructed mosaic. The sections that do not fall in the overlap area were of size 729x485 pixels. Consequently the reconstructed image is the same size as the initial large mammogram image.

In Figure 5, a series of images of the areas with features of interest are shown. These images were enhanced using the un-sharp filtering operation. As it can be observed the differences between each reconstruction scheme are better seen under such a transformation. Also, this operation is usually applied to images prior to using a computerized analysis algorithm. Therefore the effects of these differences will reflect in the performance of the computer algorithm. A simple edge enhancement and detection routine is applied to the filtered images. Results from this operation are shown in Figures 6-A,B, and C.

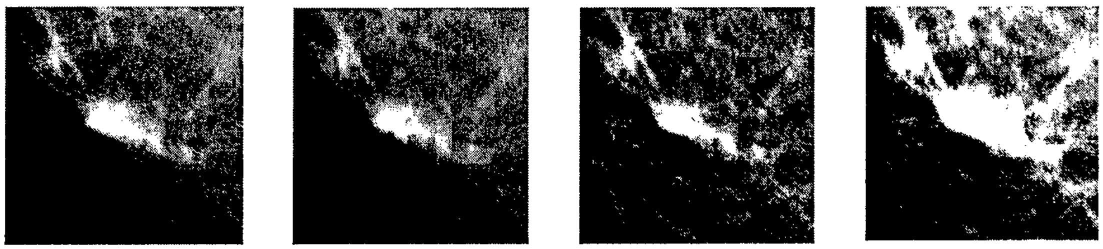
It is clear the computer algorithm's performance differs significantly for each of the images analyzed. When observing the smaller feature visually images, it can be argued that the piece-wise linear interpolation approach provides better results relatively even though some artifacts can be noticed as shown in Figures 5 and 6. However, when observing just the calibration pattern, the cubic spline interpolation provided the best results as shown in Figure 4. The edge enhancement algorithm was least influenced when the images were reconstructed using the piece-wise linear scheme. It also can be assumed that the artifacts introduced are related to the calibration pattern employed. A different calibration pattern will introduce different types of artifacts. In Figures 5 and 6, one can see the difference between the localized scheme and the global schemes. It is observed that the global schemes result in a difference from the original as compared with the localized scheme.

Software Development Plans

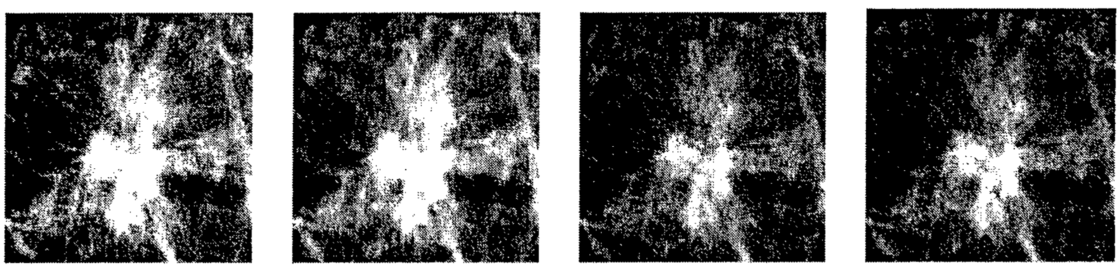
The evaluation results indicate that both the bilinear interpolation scheme and the bicubic spline interpolation in numerical evaluation provide better consistent results, regardless of the type of features present in the mammogram. Visual evaluation, on the other hand, indicated that the piece-wise linear interpolation gives the smallest difference with features of interest. Thus, it can be concluded that to reconstruct an image without losses, such as micro-calcifications, one must employ a localized scheme. However, it also should be noted that when using a localized scheme, there are some artifacts and lack of smoothness, which should be considered and compensated. Also stitching scheme will affect the quality of image around stitching area.

The following issues will be addressed in the period from August 1998 to July 1999:

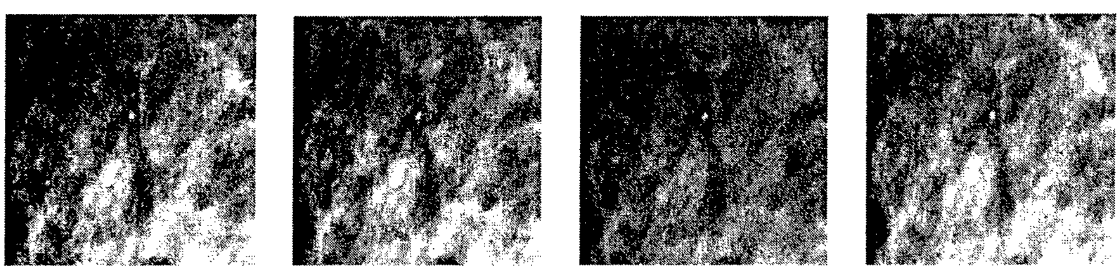
- Testing of an improved stitching scheme
- Evaluation of remaining correction schemes
- Improvement of a correction scheme selected from evaluation
- Modification of the calibration pattern
- Optimization of program code to speed up the processing time.



5-A Circumscribed Mass



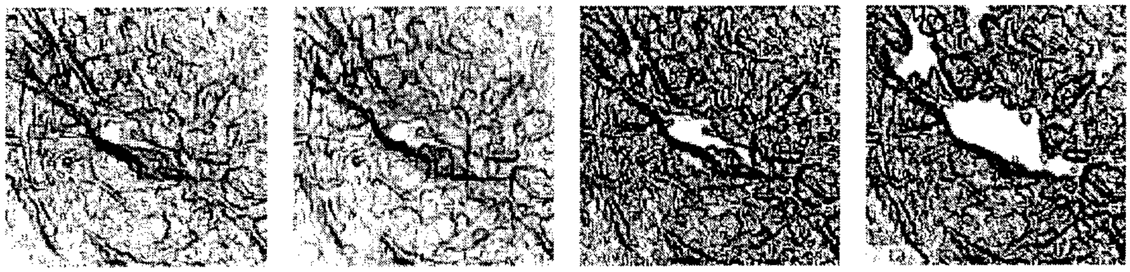
5-B Spiculated mass



5-C Micro-calcification

Fig. 5 Original Image

Original *Piece-wise Linear* *Bilinear* *Spline*

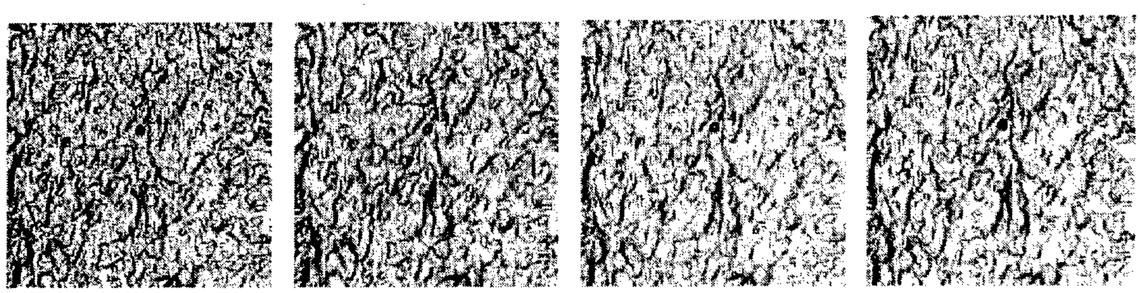


6-A Circumscribed Mass

Original *Piece-wise Linear* *Bilinear* *Spline*

6-B Spiculated mass

Original *Piece-wise Linear* *Bilinear* *Spline*



6-C Micro-calcification

Fig. 6 Filtered Image

XLV Screen Development (Sunnybrook)

Several x-ray light valve (XLV) designs have been investigated. The key design parameters are liquid crystal type, which controls the characteristic curve of the XLV, and the illumination method.

Figure 7 shows the cross-section of the first prototype XLV. It was a sandwich structure composed of the following layers from the top down: a glass substrate with a transparent, conductive, Indium Tin Oxide (ITO) coating; a ~ 100-500 μm thick a-Se layer; a 1000-5000 Å thick polyamide (PI) alignment layer; a ~5-15 μm thick LC cell formed by spacers for uniform separation between the substrates and doped nematic LC; and a bottom glass

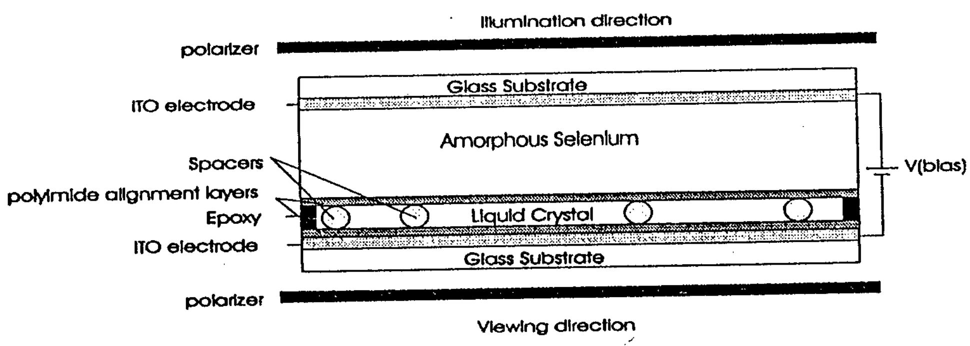


Figure 7 Cross section of transmission type twisted nematic x-ray light valve built on a transparent substrate

substrate with a conductive ITO coating and PI alignment layer. The two main steps in the manufacturing of the prototype XLV are the a-Se evaporation and the construction of an LC cell.

This approach has demonstrated high resolution images (see for example the line pair phantom showing 9 lp/mm, Figure 8) but does have several problems including fixed pattern noise associated with inadequate production methods. However, this the most fundamental problem is the difficulty in illumination and readout as this approach requires access to both sides, the first side to introduce illumination and the second side to view the complete image.

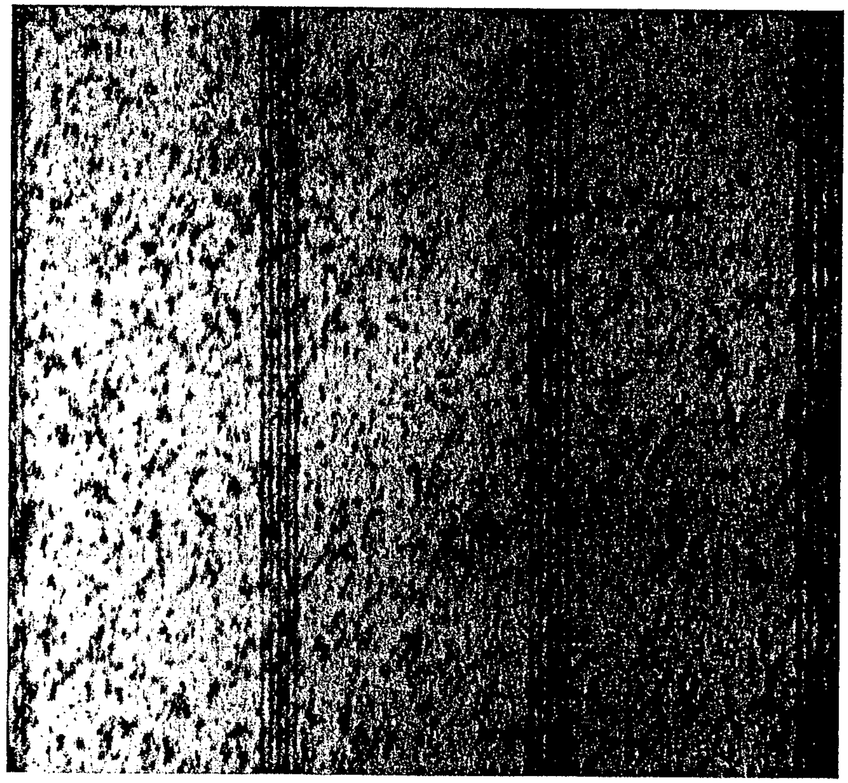


Figure 8 Image of lead bar pattern (9 lp/mm on left, 6.3 Ip/mm on right) using a twisted nematic liquid crystal light valve built on a transparent substrate

In order to address this problem we investigate two other methods both of which permit readout and illumination from the same direction. A design for an XLV built on an opaque substrate is shown in Figure 9.

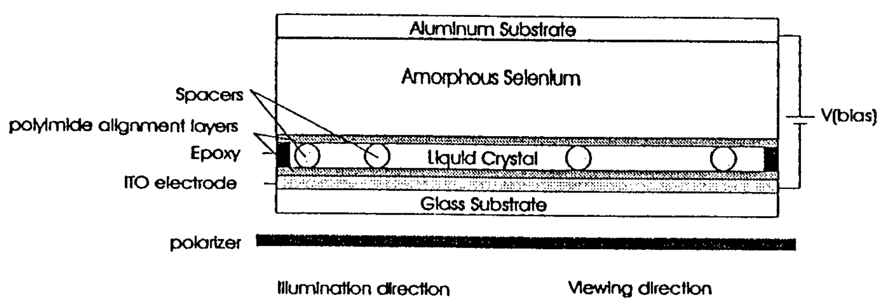
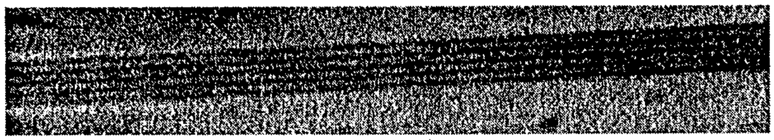


Figure 9 Cross section of aluminum substrate reflection type twisted nematic x-ray light valve

Light from the illumination source passes through the polarizer and liquid crystal layer and is reflected by the selenium surface. It is then passed back through the liquid crystal layer and the same polarizer.

Images were created using this procedure and an example is shown in Figure 10.



10 lp/mm

Figure 10 Image obtained using a reflection type twisted noematic x-ray light valve with an opaque (aluminum) substrate

Finally, a theoretical investigation of the feasibility of a polymer dispersed x-ray light valve was performed. The potential advantage for this approach is the simplicity of the illumination methods which does not require the use of polarizers and since a mirror surface is not used there is no need to have a high quality diffuse source. There have been several important papers on polymer dispersed optical light valves[1], although they have not been used as x-ray light valves previously.

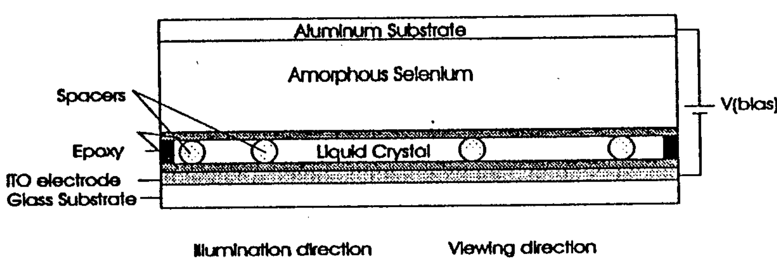


Figure 11 Cross section of polymer dispersed liquid crystal x-ray light valve (Reflection type, no polarizer needed)

[1]J.K. Takizawa, H. Kikuchi, H. Fujikake, Y. Namikawa and K. Tada, "Reflection mode Polymer-dispersed liquid crystal light valve," Jpn. J. Appl. Phys. 33, 1346-1351 (1994)

Imager Testing (SUNY/Buffalo)

Review of Activities 1997-8 for UB Medical Physics Group

Our group has proceeded to prepare for the testing of the proposed prototype; however, because of the lack of delivery of an amorphous selenium based detector we have substituted other more conventional high resolution x-ray imaging detectors to verify our evaluational methods. As originally proposed for Task 1 section E of the original proposal, we have acquired a number of standard mammography test phantoms and radiation measurement equipment in order to be prepared to test the new imagers. Additionally, we have proceeded to develop evaluational software and have acquired PC-based versions of IDL, Matlab, and SigmaPlot as well as unix-based Analyse which we have used to develop image testing methods. We have carefully evaluated the electrical requirements for interfacing the prototype to the standard mammography equipment available to us at the Women's Health Initiative (WHI) on the Main St. Campus as part of the system design phase (Task 2 section G of the original proposal) and have suggested a variety of signals available from the Bennett Contour Unit which could be used to synchronize image acquisition with the x-ray emission. We have proceeded to test other standard and special high resolution imagers as indicated in Task 3 section F of the original proposal. We are confident that we now have methods able to test the new imaging detector to be developed in the project.

A specific listing of the tasks accomplished during the past year are given below with addendums containing some samples of data acquired.

1. Compatibility to Bennett Contour mammographic unit.

We intend to use the mammographic unit at the WHI for testing of the new imager. For this testing some interfacing of the x-ray machine and the detector will be needed and we thus evaluated several signals available. The most easily accessible were those leads controlling the Bucky grid assembly. As described in detailed documentation provided previously, we tested and recorded using a storage oscilloscope the electrical outputs available from the Contour unit and found the temporal relationship between those from pins #3 and #9 of the Bucky connector and the measured times of radiation emission from the unit. We tested the temporal relationship for all modes of radiography, i.e. various mA settings for both the large and small grid operation. We found consistent and reproducible relationships based upon which can be designed trigger pulses for clearing and beginning the CCD readout after termination of x-ray exposure. For pin #3 the x-rays are initiated 40 ms for the small grid and 25 ms for the large grid after the beginning of the rise of the signals at this pin. For pin #9 the delay is longer: 375 ms to 420 ms depending on the specific parameters set. Synchronization will be crucial to reduce dark current, fading, drift, and noise. This result implies that the new imager should be able to be interfaced with conventional mammography equipment with minimal problem.

2. Testing of CCD optical module

Prior to obtaining standard evaluational values we were able to linearize a CCD detector module by carefully measuring the characteristic curve of the detector (see enclosed drawing). Using a 10 micron slit and visible light exposure, we were able to measure the line spread function (LSF) of one of the CCD optical modules and derive the MTF (see enclosed example drawings). This methodology has been developed so as to be applicable to any imaging detector which result from this project.

3. Demonstration of digital image transfer capability

Software and protocols for digital image transfer between Sensor Plus, U/B School of Engineering and the Department of Radiology at ECMC were set up and verified. The digital image matrices used for evaluation of the Sensor Plus CCD modules were sent to ECMC using this network link. This capability will be important when continued testing of various prototype imagers are required.

4. Participation in back-light panel for prototype readout.

Our group has been involved in the design and prototype testing of the back light panel to be used for reading out the liquid crystal once the prototype detector is exposed to x-rays. We have discussed the problem and design in detail over many months with the proposed supplier, BriteView Technologies. Important design considerations discussed include; light output uniformity, x-ray absorption, the possibility of adding a reflective coating to the light pipe to increase output, point input light sources vs. linear input light sources and the effect on output uniformity, stacked light pipe technology to accommodate the need for two different wavelength light sources and the possibility of using cold cathode fluorescent lamps (CCFLs) to meet our design needs. We tested a sample of the light diffuser provided by Mr. Chen-Yu Tai, the principal of this company, and further verified that the illumination could be somewhat uniform and that the x-ray transmission was acceptable for the thickness provided. We are prepared to evaluate the larger panel when it is ordered to meet the most current specifications for the prototype design.

5. Test pattern evaluation.

Our group provided testing for the bar pattern alignment test tool designed by Sensor Plus for both optical and radiographic alignment of the lenses and CCDs. This testing was performed on a mammographic x-ray unit using mammographic screen-film cassettes. We made suggestions regarding how the pattern could be made more radiographically opaque so as to provide more radiographic contrast.

6. Device for generating digital high resolution radiographic images

In order to progress in the evaluation software development without an amorphous selenium prototype available, we built a small imager capable of 12-14 lp/mm using phosphor technology and a fiber taper coupled to a CCD. With this camera we were able to image fine specks of about 100 μm size as well as features of various phantoms, both high and low contrast. We are proceeding to use these images to further develop evaluational software.

7. To provide a basis for comparative studies we have developed methods to extract digital images from a Fischer Mammotest Stereoscopic unit available to us on the U/B Main St. Campus in the Women's Health Initiative. The 1024x1024x12bit images are transferred to a PC for evaluation at this point with a removable hard drive and as compressed files on floppy media. The proprietary file structure has been determined and we have begun to evaluate this 5x5 cm limited field of view imager using objective as well as anthropomoric phantoms in order be able to get quantitative comparisons with any imagers developed during this project.

8. Phantom development

We have found the commercial phantoms not to be completely satisfactory in evaluating digital mammographic equipment and have begun to develop our own proprietary phantoms using specks and very small diameter micro tubes. We expect some of these phantoms to be useful in any high resolution digital imaging application.

9. Resource development

The following is a list of phantom, equipment, and other resources acquired to be used in the evaluation of prototype imagers resulting from this project:

software:	IDL, Matlab, SigmaPlot, Analyse phantoms: BR12 and Lucite sections, mammographic aluminum step wedge, constant thickness glandular material step wedge, 0.5 degree star pattern, high resolution (20 lp/mm) line pair pattern test tool, digital mammography evaluation phantom.
test equipment:	Keithley 96035 mammographic ionization chamber and 35050A dosimeter

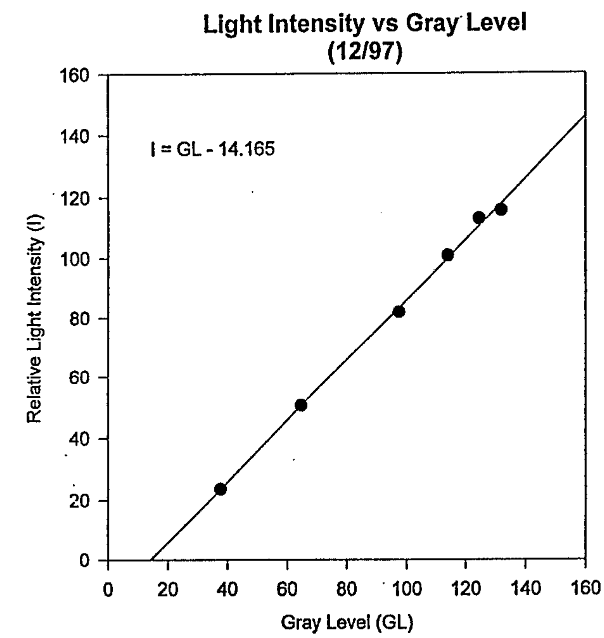


Fig. 12 Measured relation between gray level provided by the CCD detector and the light intensity which produced that level. This curve is used to linearize the CCD signal for various quantitative functional analyses.

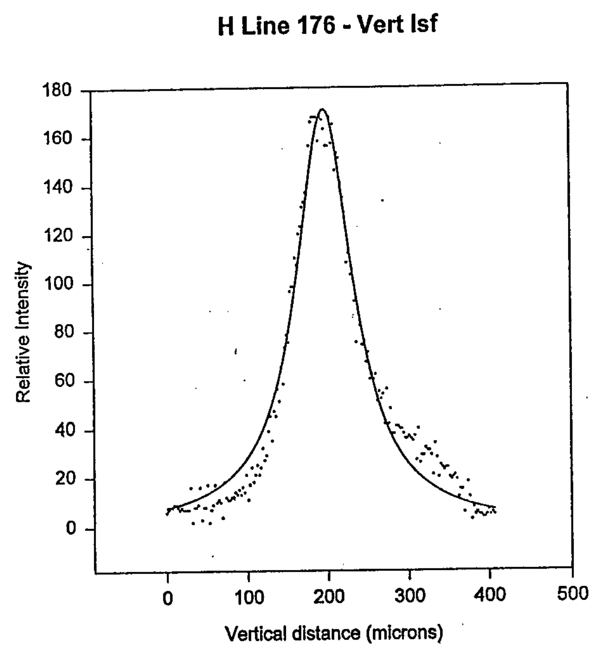


Fig. 13 Sample line spread function data obtained with a slit angled at approximately 1.5 degrees with respect to the CCD array. A curve fit to the data is also shown.

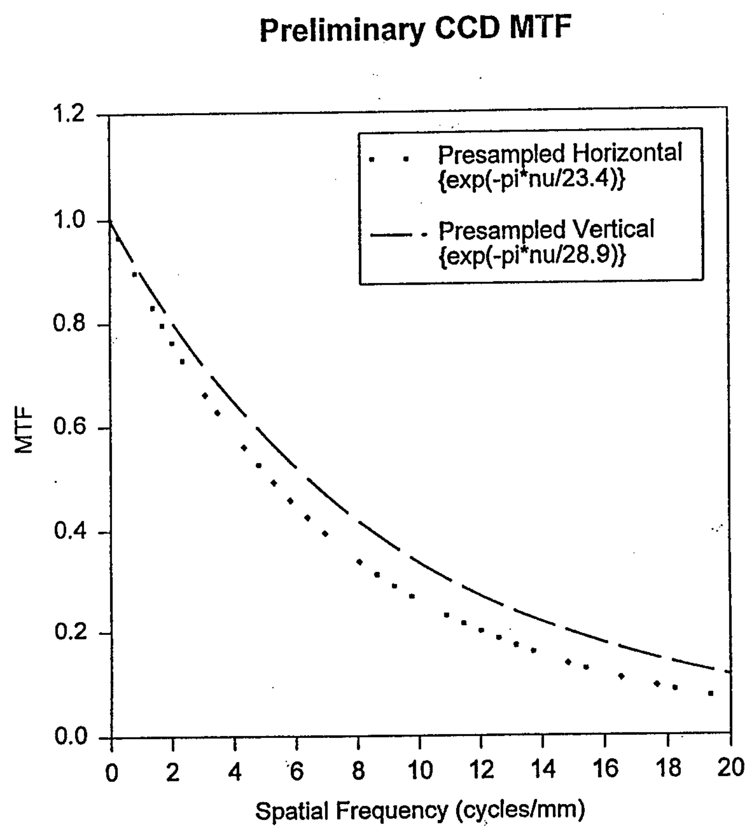


Fig. 14 Presampled MTF's obtained in the vertical and horizontal directions of the CCD array.

Channel #1 - X-ray Exposure

Channel #2 - Pin #3 from Bucky Connection

Exposure Factors: 40 mA 100 nsec

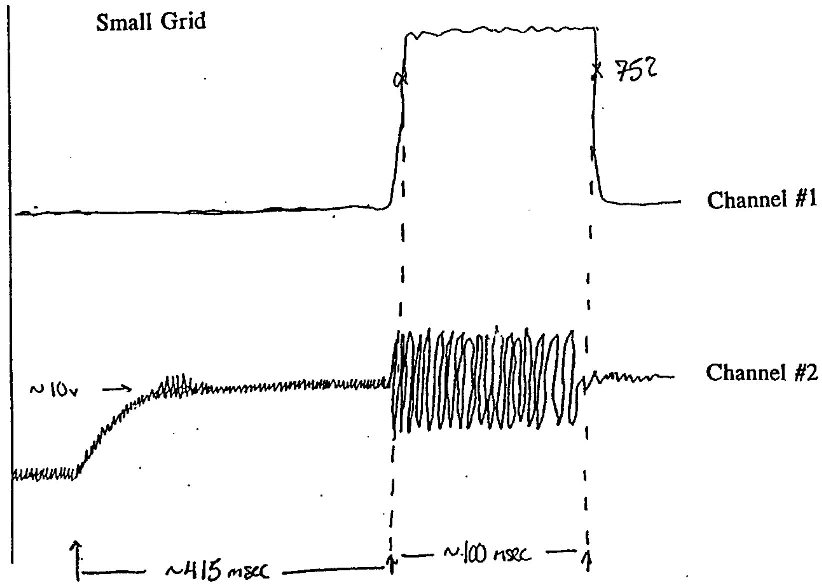


Fig. 15 Schematic of oscilloscope output showing x-ray exposure waveform in channel #1 and corresponding signal measured at pin #3 of the Bucky connector in channel #2.

Channel #1 X-ray Exposure

Channel #2 Pin #9 from Bucky Connector

Exposure Factors: 40 mA 100 ms

Small Grid

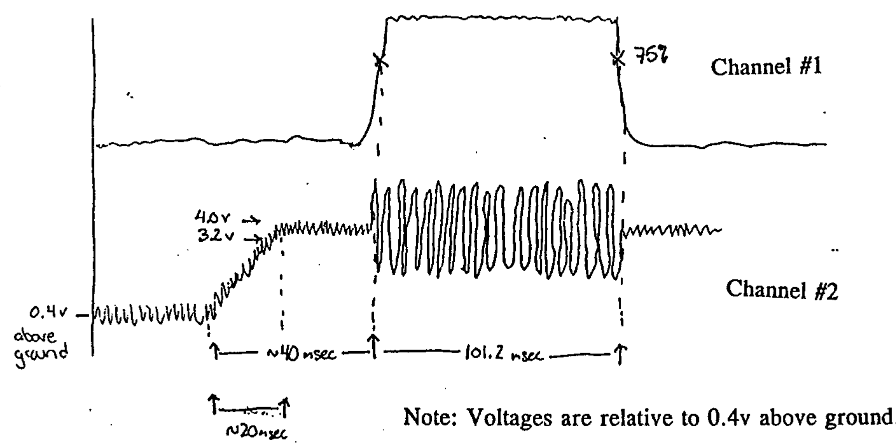


Fig. 16 Schematic of oscilloscope output showing x-ray exposure waveform in channel #1 and corresponding signal measured at pin #9 of the Bucky connector in channel #2.

Problems Encountered

A continuing problem is that the fabrication of a full size, defect-free XLV screen was not yet done, as discussed in the report by Sunnybrook (Rowlands). However, with the improved twisted nematic liquid crystal material a spacial resolution of 11 line pairs/m was obtained in a small screening, which is close to the target resolution (although the image has defects due to an uneven amorphous Se coating). It is important that this was achieved by a reflection type liquid crystal which allowed the light source to be on the same side as the CCD, a favorable geometry. In the new, low-cost imager design this screen is an optional, rather than a critical, component. Efforts to fabricate a full-size high-performance screen will continue with the hope that it will be available during the next year.

Another problem was the recognition that competition from digital imager manufacturers would soon render our original imager component selection to be of limited practical value even before completion. This is why the original goal or altered approach was adopted. As described in detail above, the low-cost imager involves using a standard screen (Lanex) instead of the XLV screen (at least in the standard option), a change to CMOS CCDs, redesign of the optics and a simplification of the electronics so that the production cost is reduced to a low, and presumably competitive, level.

A more minor problem is that a detailed analysis of the mosaic reconstruction/stitching software indicated discrepancies which could be a problem with computer aided diagnosis routines (a major use of digital imagers) even though no differences were visible on screen or printouts until processed through digital filters (Fig. 5,6). This problem was corrected by proper choice of distortion correction algorithms. Overall the software is working well and only it requires refinement and rescaling for the new design.

The selection or design of a lens which is both high performance and moderate cost has been more difficult than expected. A custom-designed lens worked well for our first prototype (high f#, good resolution, proper image sizes) but the estimated production cost is too high. Simple, off-the-shelf lenses (single element achromats) did not work well for our initial design. The new design does not require as high a quality lens (and fewer of them) and therefore we again searching for (better grade) commercially available lenses.

The project is behind schedule but we see no major obstacles in completing the low cost, high resolution digital imager with conventional screen and are now seeing good progress in the XLV screen version as well.

TASKS

The task schedule has been revised into the following tasks.

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 was not yet finished.

A. Fabricate Hi-Resolution X-ray Light Valve (XLV)
An improved XLV will be made by a subcontractor to be determined. 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 (as above) and methods of improvement suggested, as required.

Task 3B. Fabricate Small Screen Prototype

A. Fabricate Optical System
Based on the results of Tasks 1 & 2, case construct a small (2 x 2 array) is being constructed at Sensor Plus. It will soon be completed.

B. Fabricate and Test Electronics Section
The video data-acquisition system consisting of the CMOS CCD, (with CDS) 12-bit A/D and digital signal processor is being fabricated, and tested. It is being done on final, size (6x6) printed circuit board.

C. Fabrication and Test of Workstation Interface
The control (DSP) which acquires the outputs of the individual segments and transfers the data to the computer will be added to the new geometry.

Task 4. Fabricate and Test Full Size Imager

A. Fabricate Full Size, CCD Array and Circuit Boards
Task 3B, C will be finished.

B. Fabricate Optical System
The optical system will be fabricated at Sensor Plus.

C. Refinement of Image Processing Software
The software for camera correction and image stitching will be retested and any needed improvements made.

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.

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.

C. Clinical Trial Planning

Planning for future clinical trials will be made primarily by SUNY (ECMC) and the consultants.

Task 6. Preparation, Radiographic Workstation Software

A. Implementation of Standard Viewing Software

Software features required by users will be implemented by InfiMed.

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.

C. Image Compression

A method of image compression and storage will be selected and implemented at InfiMed.

D. Display Tests

The quality of the display will be evaluated at InfiMed, SUNY (ECMC and RPCI).

Statement of Work (revised)

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) - Note 1
* The border on one side of the imager must be under 3mm and preferably 1mm.
* The work station 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.

Note 1: System dynamic range is expected to be 8 to 11 bits, depending on dose.

This is only slightly altered from the original proposal. (See Appendix C)

Task Assignments by Investigator

A. Sensor Plus Inc. (Prime Contractor)

Dr. Darold Wobschall, (Principal Investigator)
- Project Manager
- Overall System Design
- Design of Analog Electronics

Vivek Swarnakar (left Sensor Plus Jan., 1998)
- Software Development Manager
- Reconstruction of Segmented Images

Myeoung Jeong
- Development of camera connection software, including distortion and alignment. Now managing software development at Sensor Plus (since Jan. 1998).

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 (started June, 1998)
- 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.

Prelim, design of workstation software.

Dr. Thomas Vogelsong (VP)

Planning of workstation software

Marketing

E. Consultants

Dr. Raj Acharya

Software signal processing and image reconstruction

J. Antonelli

Designed and fabricated the lens. Provided optical design consultation.

Conclusions

As a mostly engineering project, our conclusions are based on tests and analysis of the imager components and approaches.

1. X-ray Light Value (XLV) Development

A significant achievement is that a high resolution (11 lp/mm), reflection type prototype has been fabricated and tested. This is the best geometry for our CCD array and optics. However, a full-size, defect-free screen has not been made as yet. The XLV is the most research-oriented and uncertain component of the imager development and we consider this the reason why progress has been less smooth than the engineering aspects.

This high performance (high resolution and sensitivity) screen, while very desirable, is no longer critical to the imager project since we plan to first make a low-cost imager with conventional screen.

2. Mosaic Imager Electronics and Software

The segmented or mosaic image optics and electronics (lens, CCD, CDS, A/D, DSP and PC) are working and being tested with the Kodak CCD. The resolution, noise level (dynamic range), and image quality were good (within specifications). However, because of the decision to change to the CMOS CCDs (which will result in a much lower production cost) the electronics is being redesigned. New printed circuit boards, analog electronics, a/ds and timing chips are needed. This results in a temporary setback in order to achieve a better final result.

The software used for CCD/lens distortion correction (camera correction) and image segment (mosaic) reconstruction or stitching has been refined to make it better suited to computer aided diagnosis programs, a likely future application. Basically it is working well but will need to be modified somewhat to fit the new low-cost (CMOS CCD) design.

3. Desirability of Redesign for Low-Cost Production

The introduction of low-cost, better geometry CCDs and other electronics which made a low-cost imager with conventional screen feasible together with the commercial competition which made our original higher cost/performance design less marketable, and the delay in the development of the XLV led us to the decision that our intermediate goal would be the design and fabrication of a low-cost digital imager using a conventional screen (with lens-coupled CCDs). This is our main focus at present.

List of Publications

1. 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.

2. 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.

3. 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.

4. 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.

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9. Kutlubay, M., R. Wasserman, D. Wobschall, R. Acharya, S. Rudin, and D. Bednarek, "Cost Effective, High-Resolution, Portable Digital X-ray Imager," SPIE Vol. 2432, (p 554), (San Diego, Feb. 1995).

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Appendix A Imager Design Summary

The high resolution, high sensitivity, low cost x-ray imager is a combination of two innovative x-ray imager techniques previously developed by the participants, specifically the segmented imager screen and the x-ray light valve (XLV). The segmented approach allows multiple, standard CCD and optical components to achieve system high resolution. The XLV allows moderate cost, standard CCDs to be used without adversely effecting the sensitivity and noise level because the light level is determined by the optical source and not by the x-ray intensity. Additionally the XLV has a high resolution and contrast sensitivity which makes this technique particularly well suited for mammography.

The system consists of a blue LED light source, the XLV, optics, red light source, charge-coupled device (CCD) as the photodetector, data acquisition electronics, computer (with interface and software), and CRT display. The system being developed is the digital x-ray imager portion of a complete x-ray mammography instrument.

<u>Relevance*</u>(old and new versions compared)

Screening mammography has been shown to be effective in increasing early detection and decreasing the mortality rate of breast cancer. Barriers to increased utilization of mammography include:

- Deficiencies in image quality and interpretation.
  A facility for image enhancement and improved contrast resolution through digital methods could decrease both false negative and false positive rates.
- Radiation risk.
  A reduction in the x-ray dose per mammogram would improve the risk versus benefit ratio and allow more frequent screening and at an earlier age.
- Cost and convenience.
  A decrease in cost and an increase in convenience would attract more women to the screening programs.

Digital x-ray images as a replacement for film/screen are widely regarded as having excellent potential for reducing these barriers as evidenced by extensive research, development and commercial efforts underway. While regarded as the technology of the future, existing x-ray digital imagers do not live up to this potential because they require undesirable compromises between cost and performance goals. Cost aside, digital images also normally cannot achieve large area, and high resolution at the same time as low noise.

[By combining the previously demonstrated segmented-image and selenium/liquid-crystal light valve technologies, we are developing (and expect to manufacture) a digital x-ray imager without the compromises which are characteristic of other digital imagers.] NEW: **By using our previously developed mosaic image technology and taking advantage of newer CCDs and other electronic devices, we are developing a low cost, high resolution x-ray imager as a**

second goal. Specifically we expect to achieve excellent spatial resolution, higher sensitivity, and superior contrast compared to film/screen. Also the cost will be significantly lower than competitive digital imager technologies. System cost is expected to be less than film/screen systems when image storage/retrieval/transmission factors, and especially the cost of misdiagnosis due to poor image quality, are taken into account. Thus we believe that we can achieve:

- Demonstrated full size image quality [better] comparable to than film/screen/screen
- Convenience of digital imaging, including rapid viewing and image enhancement.
- Potentially lower x-ray dose per mammogram than film/screen/screen
- Lower cost per mammogram

In common with other digital imagers, image enhancement/zoom capability, computer aided diagnosis, tele-radiography, and rapid image storage/retrieval are available options. Our stress will be an objective demonstration of high image quality resulting in clinical trials leading to FDA approval.

The major focus of this development is the reduction of observational and interpretational errors in breast diagnostics by providing high spatial resolution and significantly improved contrast resolution in the image, specifically through (1) an improved image acquisition (detector) system and (2) improved image processing.

In the more distant future, active element digital imagers may offer the performance goals stated here but in the near term we believe that this imager has the best chance of providing the desired cost and performance.

CMOS Image Sensor Mosaic and Imager Electronics Redesign

The CMOS image sensor chosen for the redesign is the VV5850 from VLSI Vision Limited. This high resolution sensor has desirable parameters to perform mosaic imaging for X-ray applications. The most vital characteristics to ensure performance are as follows:

VV5850 Monochrome CMOS Image Sensor	
Image Format	992x800 pixels
Pixel Size	10.8 μm x 10.8 μm
Package Size	23.37 mm x 23.37 mm
S/N Ratio	66 dB
Power	125 mW
Quantum Efficiency (@ 500-600 nm)	50-60%
Pixel Rate	5M pixel/s
Correlated Double Sampling	On chip

Table 3 - Characteristics of the VV5850 CMOS image sensor

The imager signal-to-noise, and thus the X-ray dose needed for an adequate image, is strongly dependent on the lens demagnification factor. The demagnification factor of the optical system depends on the physical constraints which determines the minimum distance obtainable between image sensors. Using the above characteristics, the following demagnification factor is calculated:

$$m\_1x = \frac{s_x + d + 20_x}{x}$$

$$X = 6(s_x + d + 20_x)$$

$$s_x = 15mm$$

$$m^{-1}x = 3.87$$

$$Y = 6(s_y + d + 20_y)$$

$$s_y = 6.5mm$$

X = overall width of imaging area = 10" = 254 mm
Y = overall height of imaging area = 8" = 203.2 mm
s_x = spacing between sensors in x direction
s_y = spacing between sensors in y direction
d = detector width and height = 23.37 mm
O_x = image overlap in x direction = 2 mm
O_y = image overlap in y direction = 2mm
x = length of pixels in one row = 10.951 mm
y = length of pixels in one column = 8.64 mm
m^{-1} = demagnification factor

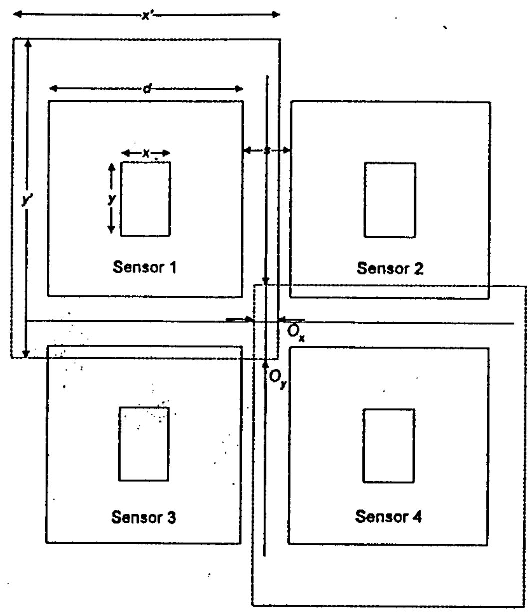

Fig. 17 Mosaic Image Segment Overlap Geometry

Note that the minimum demagnification factor is obtained by calculating the minimum spacing required to achieve a desired overlap of the imaging area in the image plane. The resulting pixel size at the image plane becomes 41.8 um x 41.8 um. With a small pixel size it is possible to average adjacent pixels to effectively increase the signal-to-noise ratio of the system. This is discussed in the following section.

CMOS Mosaic Signal-to-Noise Ratio

A standard phosphor X-ray screen will be used to convert X-ray's to light. Typical conversion gain of 1200 photons per X-ray quanta results from these screens. A 6x6 array of lenses will focus the converted light to the CMOS detectors. To collect the light output from the screen, the lenses must have a high transmission efficiency. The following equation approximates the efficiency for lens coupling:

$$\eta = \frac{T(\lambda)}{1 + 4f^2(1-m^{-1})^2}$$

where

η = lens coupling efficiency
$T(\lambda)$ = transmission factor of lens
m^{-1} = demagnification factor
$f_{\#}$ = f/D, f-number

Note that the lens coupling efficiency decreases rapidly as either the f-number or demagnification factor increase. Since the f-number is difficult to decrease beyond 1.5 to 1.2, the main factor in improving efficiency is the demagnification factor. This factor depends on the spacing between the CMOS sensors in the array. The demagnification was derived in the previous section and was optimized as 3.87 for the VV5850 CMOS sensor. Assuming a typical transmission factor of 0.75 for the lens and an f-number of 1.2 the efficiency is approximated as:

$$\eta = 1.55\%$$

With this efficiency, the system gain, G, may be calculated as:

$$G = g_{scr} \bullet \eta_{CMOS} \bullet \eta$$

$$g_{scr} = \text{conversion screen gain}$$

$$\eta_{CMOS} = \text{quantum efficiency of CMOS detector}$$

The signal generated in terms of electrons at the CMOS sensor for a typical X-ray exposure is calculated as:

$$S_e = \alpha \bullet Q \bullet R \bullet G \bullet A_{pxl}$$

where

α = screen absorption
Q = x-ray output in quanta per mm² per mR
R = x-ray exposure in mR
A_{pxl} = area of CMOS pixel

The following table displays typical values for the above parameters and estimates the signal-to-noise ratio:

Parameter	Value
X-ray energy, E	50keV
X-ray output, Q	270,000
Screen absorption, α	0.5
Exposure, R	1mR
Screen gain, g_{scr}	1200
Quantum efficiency of CMOS sensor, η_{CMOS}	50%
Pixel area in mm² at image plane, A_{pxl}	1.64×10^{-3} mm²
Lens coupling efficiency, η	1.7%
CMOS sensor noise floor, η_e	30 e^- rms

Table 2 - Typical values for digital X-ray imaging using lens coupling

Substituting the above parameters into equations above gives a signal value at the CMOS detector in terms of electrons as:

$$S_e \approx 2060\ e^-$$

By summing adjacent pixel values as mentioned, the overall signal may be increased while the effective resolution is decreased. The pixel size of 42 um at the image plane may be increased to 126 um by averaging the pixel values of 9 adjacent pixels. The noise increases as the square root of the number of pixels averaged. Thus, overall signal-to-noise ratio becomes:

$$S/N = \frac{3S_e}{n_e}$$
$$S/N \approx 206$$

The CMOS sensor prototype imager will be used to measure the actual S/N ratio and compare this value to the calculated. The above calculation shows the potential to provide approximately 8-bit grayscale images, which is the same as film/screen, and is our goal for this portion of the imager redesign. As indicated below, the A/D is 12-bits so that the data acquisition will not be a limiting factor.

Electronics

The electronic design of the 6x6 CMOS imager will be similar to existing hardware developed for the CCD mosaic except a single DSP processor architecture will be used to save cost. The following block diagram shows the basic sections of the electronic hardware:

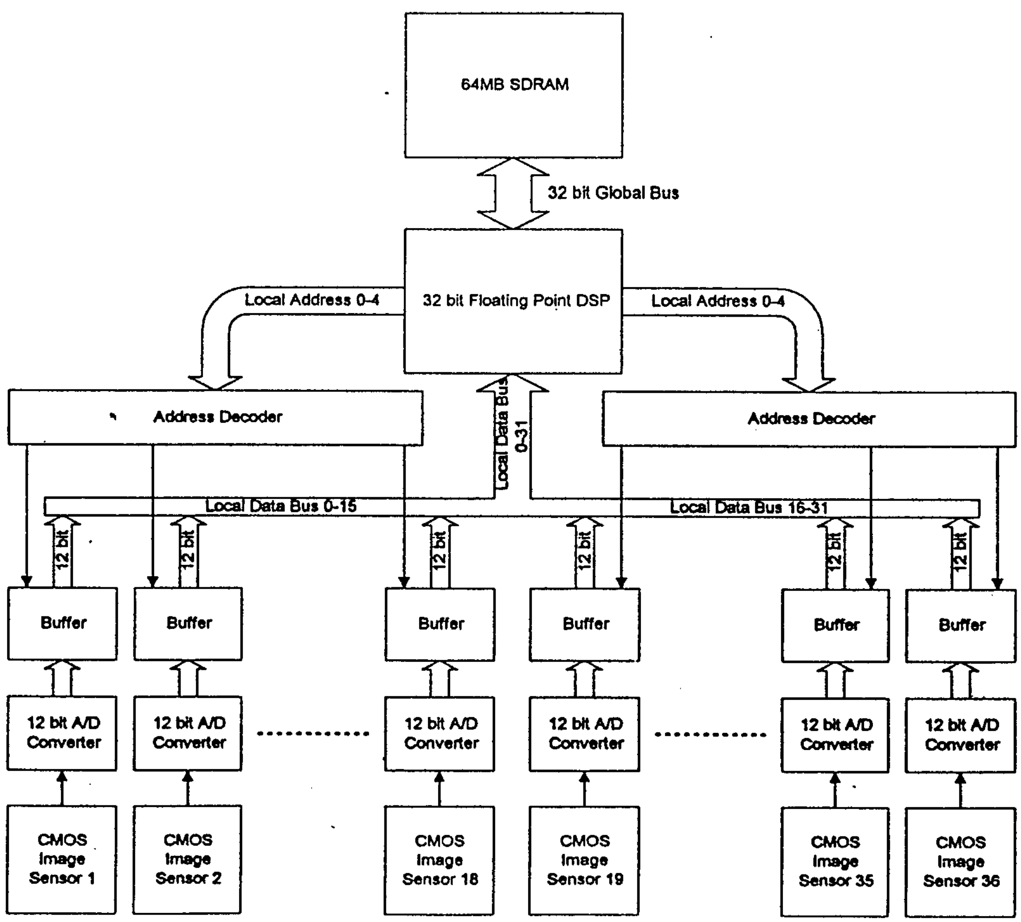

Fig. 18 Block Diagram of Electronics

There will be a single programmable logic device, PLD, that will control the image sensor timing and A/D converter timing (not shown above). The 12 bit digital data from the A/D is latched to a series of buffers with individual addresses on the DSP. Each pixel from all 36 sensors are latched in simultaneously and then read at high speed into the memory of the DSP system. The pixel rate for the system will be 1MHz which results in a total data throughput of 18M words/s for the DSP.

Since the Visual VLSI Ltd. VV5850 operates on a single 5V power supply, all the electronics will also operate at this voltage to simplify the electronics. The CMOS sensor also integrates correlated double sampling on chip so that external analog processing is not necessary.

Cost Comparison and Performance Tradeoffs

The following table compares the costs associated with the original CCD mosaic design and the CMOS sensor redesign:

Electronics	8x9 CCD Mosaic	6x6 CMOS Mosaic
Image Sensors	$28,800	$3,600
Analog Processing	$14,000	$500
Digital Processing	$30,000 (18 DSP system)	$5000 (1 DSP on board and 1 DSP on PC)
Lenses	$28,000 (custom)	$3,600 (off the shelf)
Total	$100,800	$12,700

The basic component cost of $12,700 will allow a selling price of about $60,000. As discussed above, the selling price of commercial full scale digital mammography units are estimated to be $250,000 to $500,000. Of course there are some tradeoffs in terms of imaging performance and image reconstruction time by shifting to the lower cost design. The table below compares the most important characteristics in terms of performance for both designs:

Parameter	8x9 CCD Mosaic	6x6 CMOS Mosaic
Calculated System S/N Ratio	280 (100 um pixels)	206 (125 um pixels)
RMS Noise Floor in e^- rms	15 e^-	30 e^-
Max. Integration Time	1 s	200 ms
Max. Dynamic Range of sensors	76 dB	66 dB (with FPN noise cancellation)
Acquisition-to-display time	20 seconds	3-5 minutes
Power Consumption	250-300W	10-20W

Appendix C Original Task Schedule (end of Year 1)

Task 1. Build Prototype (low resolution)

A. Fabricate Small Area X-ray Light Valve
   A XLV with a size between 80 x 80 mm (3x3 inch) and 200 x 200 mm (8 x 8 inch), will be fabricated. The device will be similar to that previously made.
B. Test of X-ray Light Valve
   The XLV fabricated above will be characterized by Sunnybrook and methods of improvement suggested. A moderate resolution of 3 > to 10 lp/mm is anticipated.
C. Fabricate Optics*
   The optical system was fabricated by Sensor Plus subcontractors. Segment area is 24x36mm and the array size is 2 x 2 initially, and then 2x4.
D. Electronics Computer, and Interface*
   A new design for the CCD input electronics and a/d converter was devised, and fabricated. One CCD channel was tested.
E. System Test
   The system response will be measured at SUNY/Buffalo (ECMC) using phantoms.

Task 2. System Design

A. XLV
   The XLV side illumination screen was designed by Sunnybrook.*
B. Optics
   The optics was designed by Sensor Plus and J.A. Optics, a subcontractor.*
C. Video Data Acquisition and Interface
   The electronics is being designed by Sensor Plus. One channel is being tested, further versions are planned.*

*completed first year

D. Image Reconstruction Software
   The reconstruction software was done Sensor Plus.
E. Radiographic Workstation Software
   The radiographic will be designed by InfiMed.
F. Adapt to x-ray Unit
   The Bucky grid and interface will be added to a commercial x-ray source by SUNY/Buffalo.
G. Test Methods and Equipment
   Test methods and equipment will be planned by SUNY/Buffalo (ECMC).

Task 3. Fabricate and Evaluate Small Area, High Resolution Prototype

A. Fabricate Hi-Resolution X-ray Light Valve (XLV)
   An improved XLV will be made by a subcontractor to be determined. 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 (as above) and methods of improvement suggested, as required.

C. Fabricate Optical System
Based on the results of Task 1, design the final optical system (including case and mounting) and construct a portion (2 x 4 array) at Sensor Plus. It will have provision for, but not include, the tilt plates needed to improve the resolution to 25 μm. Preliminary tests will be done with the Task 1 prototype.

D. Fabricate and Test Video Electronics Section
One segment of the video data-acquisition system consisting of the CCD, analog input, 12-bit A/D and digital signal processor has been designed, constructed, and tested. It was done on a printed circuit board with the same size as the final, multi-segment version. The memory will be sufficient for the 25 μm image but the software will be written for the nominal 50 μm pixel. The objective is to demonstrate that the effective noise level does not exceed 2 LSB out of a 12-bit full scale range.

E. Fabrication and Test of Workstation Interface
The control (DSP or microprocessor) which combines the outputs of the individual DSP segments and transfers the data in a block to the computer (workstation) will be fabricated.
The tests will include a checkout of the workstation hardware and basic software. Software from the previous DOS-based system will be converted to the workstation and tested.

F. Test of Imager Segment
The performance of the imager will be tested at SUNY/ECMC using phantoms with a stress on resolution contrast sensitivity and noise measurements.

<u>Task 4.</u> <u>Fabricate and Test Full Size Imager</u>

A. Fabricate Full Size, High Resolution XLV
The XLV similar to that made in Task 3A will fabricated except that it will be full size (8.5" x 11.5") and will incorporate improvements indicated by previous testing.

B. Test of XLV
Tests similar to Task 3B will be made by Sunnybrook.

C. Fabricate Optical System
The optical system will be designed by Sensor Plus, based on the results of Task 3C, and fabricated by outside vendors.

D. Fabricate Image Acquisition Electronics
The final size printed circuit boards will be laid out, built and tested at Sensor Plus. The DSP software will be programmed at Sensor Plus.

E. Refinement and Test of Image Processing Software
Two high performance Pentium computers will be purchased (one at InfiMed and one at Sensor Plus). The image transmission software between the DSP and computer will be tested by Sensor Plus and InfiMed.

Task 5. System Performance Test

A. Test of Imager
The imager will be tested at SUNY (ECMC) using phantoms and specimens for Roswell Park Cancer Institute RPCI if appropriate. In addition to resolution and noise, image distortion or discontinuities between segments will be examined.

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.

C. Clinical Trial Planning
Planning for future clinical trials will be made primarily by SUNY (ECMC) and the consultants.

Task 6. Preparation, Radiographic Workstation Software

A. Implementation of Standard Viewing Software
Software features required by users will be implemented by InfiMed.

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.

C. Environmental Tests
Tests will be made of the image quality under moderate vibration, humidity, and temperature variations by Sensor Plus and InfiMed.

D. Image Compression
A method of image compression and storage will be selected and implemented at InfiMed.

E. Display Tests
The quality of the display will be evaluated at InfiMed, SUNY (ECMC and RPCI).

Task 7. Implementation and Test of Double Resolution Sampling Feature

A. Fabricate Tilt Plates
The tilt plates (Fig. 17) and electronic drivers will be fabricated and tested using first the small area imager (Task 3) and then the full area (Task 4). Also the software needed to capture the shifted images will be prepared.

B. Test with Optical Targets
The resolution will be tested using a transparent film/screen test pattern with features as down to 10 μm in size. The resulting reconstructed images will be verified with the known pattern.

C. System Test
A test of the system with the XLV and x-ray source (using phantoms) will be made. The objective is to verify the 25 μm spatial resolution, and high contrast resolution, over the full image areas (8" x 11").

Statement of Work

This statement is taken from the original proposal.

I. Perform the following tasks described under TASK SCHEDULE in the original proposal:

Task 1. Build Prototype
- Fabricate Small Area X-ray Light Valve
- Test of X-ray Light Valve
- Fabricate Optics
- Electronics Computer, and Interface
- System Test

Task 2. System Design
- XLV
- Optics
- Video Data Acquisition and Interface
- Image Reconstruction Software
- Radiographic Workstation Software
- Adapt to x-ray Unit
- Test Methods and Equipment

Task 3. Fabricate and Evaluate Small Area, High Resolution Prototype
- Fabricate Hi-Resolution X-ray Light Valve (XLV)
- Test of XLV
- Fabricate Optical System
- Design and Test Video Electronics Section
- Fabrication and Test of Workstation Interface
- Test of Imager Segment

Task 4. Fabricate and Test Full Size Imager
- Fabricate Full Size, High Resolution XLV
- Test of XLV
- Fabricate Optical System
- Fabricate Image Acquisition Electronics
- Refinement and Test of Image Processing Software

Task 5. System Performance Test
- Test of Imager
- Comparison with Film/screen
- Clinical Trial Planning

Task 6. Preparation, Radiographic Workstation Software
- Implementation of Standard Viewing Software
- Verification of Image Quality Robustness
- Environmental Tests
- Image Compression
- Display Tests

Task 7. Implementation and Test of Double Resolution Feature
- Fabricate Tilt Plates

Test with Optical Targets
System Test

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

* 8x10 inch active area (minimum)
* Pixel size approximately 50 microns over full image size and 25μm in restricted areas.
* 12 bit effective dynamic range (gray scale)
* The border on one side of the imager must be under 3mm and preferably 1mm.
* The work station must have the capability to acquire complete radiographs at high resolution (4000 x 5000 pixel minimum, and 8000 x 10,000 preferred). 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.