Development of Performance and Safety Monitoring System for Low Cost Ultrasound Medical Devices for Prenatal Diagnosis

Research

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Dedication

This project would not have been possible without considerable guidance and support. I would to acknowledge those who have enabled me to complete this work.

Firstly, I would like to express my gratitude to my respectful Research Management Center of Universiti Teknologi Malaysia, for their support and approval of this project.

To Head of medical electronics Laboratory, Dr. Norlaili, Seow Siew Chin, Lau Eng Xiang, Indra Hardiyan Mulyadi and Murni Norestri Binti Mohd Nordin for hardware and software development on low cost ultrasound improvement.

Finally yet importantly, for all support from persons which could not be mentioned it one by one.

Executive Summary

Development of performance and safety monitoring system for low cost ultrasound medical devices for prenatal diagnosis

Ultrasound is widely used in prenatal diagnosis. This is due to the easier, safer and lower cost compared to other medical imaging modalities such us CT – scan, MRI and gamma ray. The advancement of microelectronic technology according to Moore law has enabled the production of low cost ultrasound machines. In 2007, there were about 200.000 low cost ultrasound machines worldwide. It is predicted that the number of these machines will increase and achieve 500.000 machines in year 2011. Survey result shows the most low cost ultrasound machines have lacking in performance and safety. This may cause an undesired diagnostic result that may be danger for patients.

In order to reduce the undesired effect of ultrasound for patient diagnostic, a performance and safety monitoring system has been developed. The system is focused to improve the quality of service in prenatal diagnosis using ultrasound B scanning mode. According to the clinical survey and the draft of code of ultrasound in medical diagnostic there are two safety parameters to be monitored or tested before using ultrasound for medical diagnostic, they are the electrical leakage current and ultrasound intensity. Beside safety parameters, it is also required to monitor or test the performance of ultrasound. The performance parameters include dead zone, uniformity, depth of penetration, axial and local resolution, high scatter object diameter, vertical and horizontal distance.

This project developed hardware and software to monitor the electrical leakage current called “leakage current meter” and a device to test ultrasound power and intensity called “ultrasound power meter”. Improvement and measurement of ultrasound performance has

been done by development of additional hardware and software device called "sonoimprometer".

The leakage current meter has been developed according to IEC 60601-1. The meter can measure the patient, enclosure and earth leakage current with resolution of 1 µA with range of 0 to 500 µA. The meter consists of current electrode, amplifier, ADC, microcontroller and computer with monitor. The measurement result can be seen in computer display.

The ultrasound power mater has been developed by using double polymer sensor called *polyvinylidene fluoride* (PVDF). The meter has been designed according to IEC 60601-2-37 and IEC 60601 of the safety requirement for ultrasound in medical diagnostic and therapeutic. The meter is able to measure the ultrasound power from therapeutic and diagnostic machine with frequency range of 20 kHz to 10 MHz and power range of 0 to 30 W with resolution of 30 mW. The output is displayed on LCD and transferred to PC through USB for further analysis.

The *sonoimprometer* has been created to measure and improve the ultrasound image quality. The meter is connected to ultrasound machine through USB and BNC connector. This system can capture the ultrasound image from low cost ultrasound machine. The captured image is stored in *sonoimprometer* and processed in order to have the value of some image quality parameter according to American Association of Physicist in Medicine. The meter is able to improve the resolution, contrast and geometry accuracy of measured images.

All of developed device has been tested in laboratory and clinic to characterize the functionality, safety, stability and reliability. The test result shows that the *sonoimprometer* can be used by most low cost ultrasound machines to test their safety and performance. This *sonoimprometer* has been also presented in two competitions; they were NRIC and INATEX 2008, and won gold medal and special award. The products have been also registered to patent agent approval as novel products. The developed product is low cost, small in size, user friendly and has big market potential. The system

not only can monitor the performance, it is also capable to measure the safety of ultrasound machine. This machine can be used in private clinics, healthcare centres, home, research centres and ultrasound machine manufacturer, distributor and maintenance companies. It is estimated that about 400 products required yearly in Malaysia only.

In order to penetrate Malaysia and international market, certifications of the product are required such as SIRIM, MOH and TUV. A business plan proposal for pre commercialization is recommended to be created and applied to MOSTI, such as TECHNOFUND or INNOFUND. Cooperation with companies is required for development, product commercialization and marketing.

Abstrak

Peranti Ultrabunyi telahpun diguna pakai secara meluas di seluruh dunia terutamanya untuk diagnostik prakelahiran. Namun begitu, peranti ultrabunyi kos rendah yang terdapat di pasaran pada hari ini masih lemah dari aspek pencapaian kualiti dan keselamatannya. Justeru itu, bagi menambahbaik pencapaian kualiti dan keselamatan peranti tersebut, satu sistem pemantauan pencapaian kualiti dan keselamatan bagi peranti ultrabunyi kos rendah telah dibangunkan. Sistem pemantauan ini terdiri daripada unit pengukuran dan pembaikan kualiti imej (Ultrasound *image quality measurement improvement*) serta unit pengukur kuasa luaran ultrabunyi (*ultrasound power meter*).

Unit pengukuran dan pembaikan kualiti imej ini dipanggil "*sonoimprometer*". Ia dibangunkan untuk menambahbaik beberapa parameter kualiti imej seperti kejelasan (*resolution*), kontras (*contrast*) dan ketepatan geometri (*geometric accuracy*). Pengukur ini juga mampu mengukur beberapa parameter kualiti imej tambahan seperti zon mati (*dead zone*), keseragaman (*uniformity*), kedalaman (*depth of penetration*), kejelasan setempat dan searah (*axial and local resolution*) , diameter objek terpancar tinggi (high scatter object) dan juga jarak menegak dan melintang (*vertical and horizontal distance*) yang memenuhi standard AAPM (*American Associataion of Physics in Medicine*) dan Kod cara kerja bagi peranti ultrabunyi untuk diagnostik perubatan. Sonoimprometer ini hanya perlu disambungkan ke port video (*video port*) yang terdapat pada hampir semua peranti ultrabunyi kos rendah.

Unit pengukur kuasa luaran ultrabunyi pula telah dibangunkan untuk mengukur kuasa ultrabunyi yang diterima oleh tisu-tisu badan. Filem PVDF telah digunakan sebagai komponen pengesan ultrabunyi. Unit pengukur kuasa ini boleh mengukur kuasa ultrabunyi sehingga 10 W/cm^2 dan memenuhi piawaian keperluan FDA dan IEC sebagai peranti pengukur ultrabunyi perubatan.

Meter kebocoran arus juga telah dibangunkan untuk memantau kebocoran arus pada pesakit dan pada dawai pembumian. Meter tersebut mampu mengukur kebocoran arus sehingga 500 µA dan turut memenuhi keperluan keselamatan IEC-60001-1 untuk peranti perubatan.

Kesemua unit-unit pengukuran yang dibangunkan tadi telah pun diintegrasikan dan diuji pada beberapa peranti ultrabunyi kos rendah di makmal dan pusat perubatan. Hasil kajian mendapati bahawa sistem ini mampu memantau dan menambah baik kualiti imej bagi peranti ultrabunyi untuk diagnostik prakelahiran, memantau kuasa luaran dan mengukur kebocoran arus dari peranti ultrabunyi dan terbukti telah menambahbaik kualiti imej dan aspek keselamatan peranti ultrabunyi kos rendah.

Adalah diharapkan, pada masa hadapan agar model ini dapat dibangunkan dan produk ini menjadi sebahagian daripada komponen tambahan bagi peranti ultrabunyi kos rendah yang mungkin digunakan oleh institusi-intitusi kesihatan di seluruh negara.

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List of Abbreviations

2D	: Two Dimensional
3D	: Three Dimensional
AAPM	: American Associataion of Physics in Medicine
ADC	: Analog Digital Converter
AIUM	: American Institute of Ultrasound in Medicine
ALARA	: as low as reasonably achievable principle
DSP	: Digital Signal Processing
FIR	: Finite Impulse Response
FPGA	:Field-programmable gate array
ISO	: International Organization for Standardization
IC	: Integrated Circuit
IEC	: International Electrotechnical Commission
LCD	: Liquid Crystal Display
MS IEC	: Malaysia Standard International Electrotechnical Commission
MS ISO	: Malaysia Standard International Organization for Standardization
MI	: Mechanical Index
PVDF	: Polyvinylidene Fluoride
TI	: Thermal Index
TIB	: Thermal Index of Bone
TIC	: Thermal Index of Cranial Bone

1 Introduction

Low cost ultrasound medical devices have a big market worldwide. One of possible applications is prenatal diagnosis. However, the current devices have still lack in quality and safety. In order to improve the performance and safety of these devices, a monitoring system is necessary. The system consists of hardware and software and has function to monitor the safety parameter of devices such as leakage current and ultrasound intensity as well as performance parameter such as image quality.

The first phase of the research project is identification of the requirement of performance and safety for low cost ultrasound medical devices for prenatal diagnosis. In this phase, the survey of some low cost ultrasound medical devices has been done. The survey includes the measurement of image quality using ultrasound phantom and measurement of electrical safety parameter using electrical safety analyzer complies IEC 60601. Besides that, the measurement of signal on board and redrawing the block diagram has been done. After reverse engineering, the performance and safety requirement of devices are identified based on IEC standard, FDA / AIUM requirement and draft of code of practice for Malaysia.

The second phase is the development of software and hardware for monitoring of the devices performance and safety. In this phase, the lack of quality and safety of devices has been reduced with adding software and hardware to the devices. The software may have function to display the safety parameter and image quality parameter. The hardware is capable to measure the electrical parameter such as leakage current, and also temperature changing and ultrasound power. The hardware and software are connected to devices through USB or integrated direct with CPU from devices.

1.1 Objective

The objective of research is to identify the performance and safety requirement of low cost ultrasound medical devices for prenatal diagnosis and to develop software and hardware for monitoring of the performance and safety of devices.

1.2 Scope

In this research, we concentrated to find out the requirement of performance and safety of low cost ultrasound medical devices for prenatal diagnosis. Those requirements derived the system design and realization of the system to improve the low-cost ultrasound performance and safety. System testing was performed by testing the ultrasound in clinics. The testing result was analyzed by comparing the results with and without the improved devices. Optimization has been performed to improve the testing result.

2 Methodology

2.1 Flow Chart

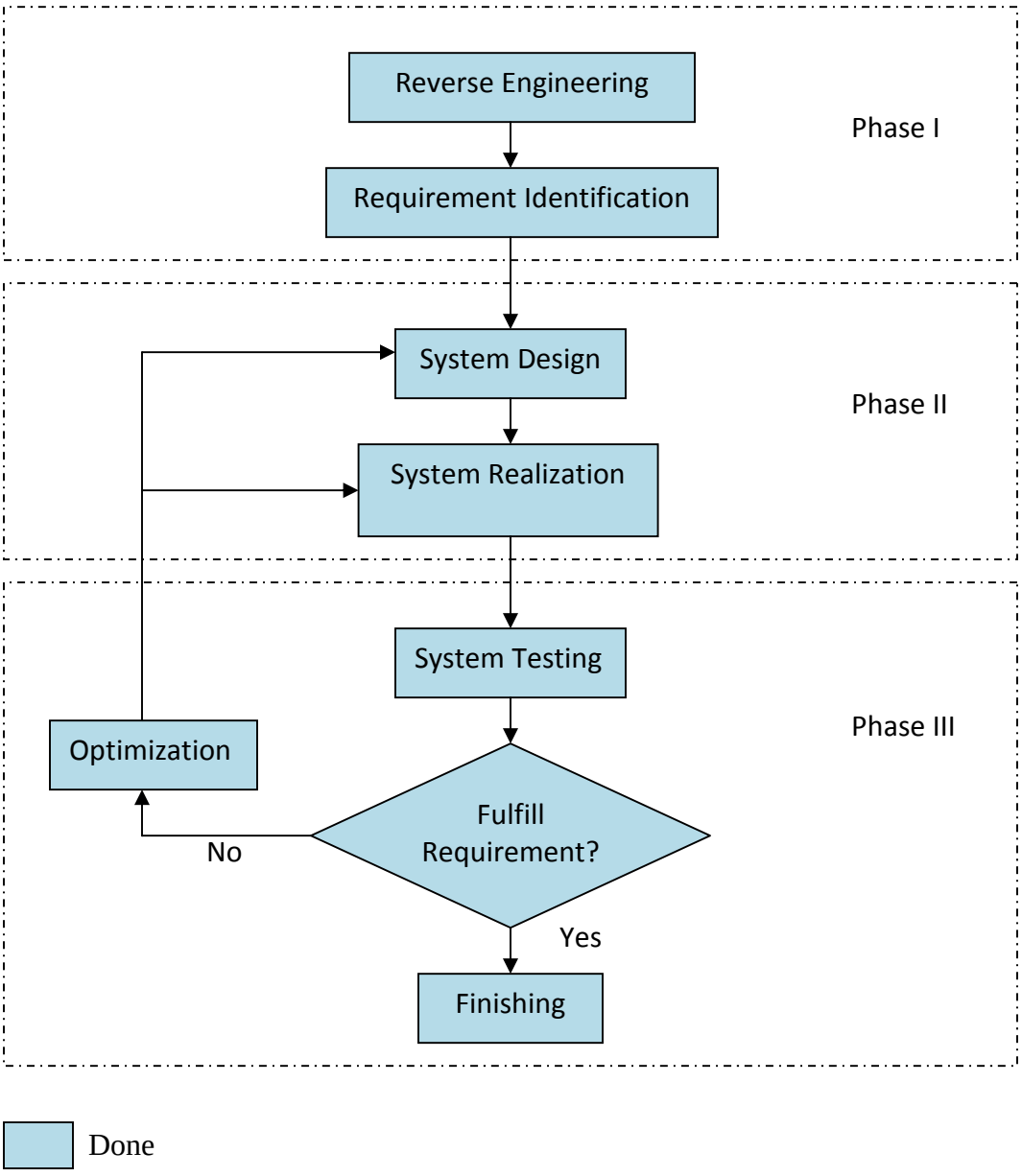

Figure 2-1 Flowchart of the methodology

2.2 Gantt chart

	Month											
Activities	I	II	III	IV	V	VI	VII	VIII	IX	X	XI	XII
Reverse Engineering												
Requirement Identification												
System Design												
Hardware Realization												
Software Realization												
System Testing												
Optimization												
Final Report												

	Planned Timeline
	Actual Timeline

2.3 Milestones

	Month											
Milestone	I	II	III	IV	V	VI	VII	VIII	IX	X	XI	XII
Report I Completion												
Specification Identification Completion												
Report II Completion												
System Completion												
Report III Completion												
Testing Completion												
Final Report Completion												

	Planned Milestone
	Completed Milestone

3 Survey of Ultrasound Machines

In this phase, the study of Echo Blaster 64 and UTM clinic's low cost ultrasound machines has been done. Literature review of ultrasound machine was performed in this phase.

3.1 Portable-Ultrasound Machine at UTM Clinic

UTM clinic has two portable ultrasounds, which is used for human-diagnostic. The ultrasound was made by Shantou Institute of Ultrasonic Instruments (SIUI) China. The device type is CTS-385, produced in 2001. The CTS-385 is designed for the diagnosis of liver, gallbladder, kidney, pancreas, thyroid, breast, uterus, bladder, ovary, etc. The system is a portable linear and convex unit for general application.

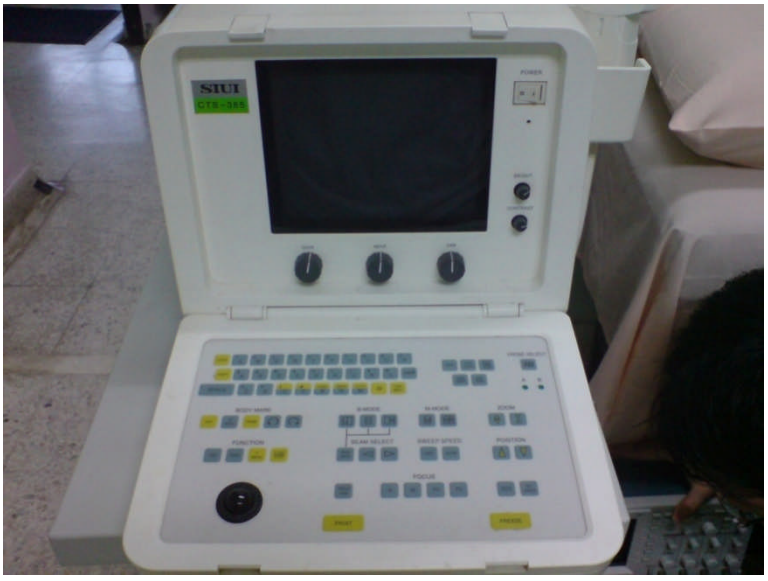

Figure 3-1 Portable Ultrasound at UTM Clinic

3.1.1 Main Specifications

Scanning System	Convex and linear
Scanning Mode	B, B/M, M
Probe Frequency	3.5 MHz convex probe of broadband and 3-step multi-frequency
Focusing Method	4-step focusing with variable aperture
Image Magnification	x1, x1.2, x1.5, x2 as well as depth shift
Image Processing	Pre-processing, correlation-processing, interpolation
Measurement Functions	Distance, area, volume, heart rate, gestational weeks, etc.
Body Marks	8 kinds with probe mark display
Character Display	Date, time, frequency, gain, magnification, focus, etc.
Power Consumption	110 V/220 V, 140 VA
Net Weight	Approximately 13 kg
Cineloop	64 frames for B mode, 256 seconds for M mode

The portable ultrasound provides minimal function of ultrasound device for diagnostic. The CTS-385 has B, B/M, and M of black and white scanning model. Based on the analysis of this ultrasound device, we conclude the block diagram of the system in Figure 3-2.

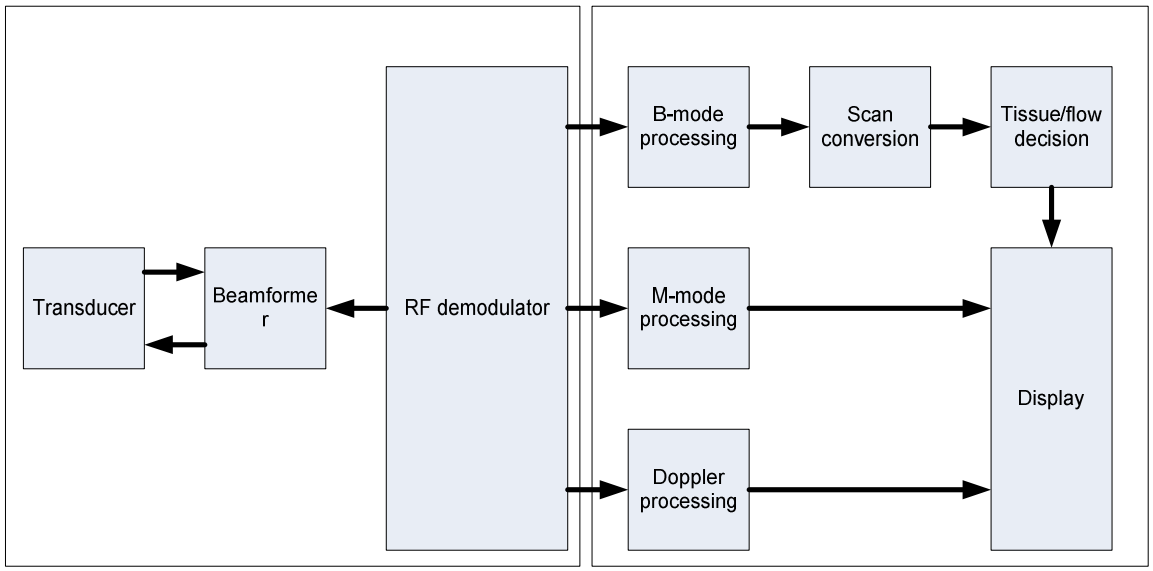

Figure 3-2 Portable Ultrasound Block Diagram

3.2 Low Cost Ultrasound Machine (Echo Blaster 64)

Figure 3-3 Portable ultrasound machine

Echo Blaster 64 can be connected to any modern personal computer via USB 2.0 interface. It has advanced software scan-converter, capable to process up to 120 frames per second. User interface built on Echo Wave software provides new capabilities, which earlier was not achievable for entry–level systems, they are:

1. Extended measurement package including cardiology, urology, Ob/Gyn and special veterinary calculation
2. Movie clips as long as 2 minutes (read more) can be recorded and stored in the files
3. New wide-bandwidth probes for any application
4. Possibility to work with 3DView, PanoView and ClearView plug-in modules adds new diagnostic value
5. Ready-to-Telemedicine concept allows remote diagnostic
6. Multiline technology for scanning without “black dots” artefacts provides noticeable improvement of image quality
7. Attractive price

3.2.1 System Specification

Imaging Modes	B B+B B+M M "FREEZE" mode scan angle changing in 6 steps for frame rate maximizing
Scanning Method	Linear convex microconvex
Probes	7 available probes 64 elements probes : from 2,0 MHz to 7,5 MHz; triple frequency automatic probe recognition 1 probe port
Focusing	16 Channel Analog Beamformer digital transmit focusing multi lines technology, 192 real ultrasound lines multi focus mode:

	transmit/receive focusing, max 4 points; programmable focus area presets
Signal Processing	pre-processing TGC Control, 5 zones for each depth dynamic range control, 8 steps overall gain control, 16 steps M - mode sweep speed control, 1-16 sec acoustic power control, 256 levels, 10-100% post-processing variable frame averaging color processing brightness, contrast, gamma control scan direction and up / down orientation control negative / positive control real time Intelligent Zoom and Free Hand Zoom bi-linear interpolation echo enhancement control, 5 values rejection function, 32 values
Ultrasound Software	Echo Blaster 64 drivers package for beamformer and probes Echo Wave software Echo Wave II software ClearView plug-in (optional) 3DView plug-in (optional) PanoView plug-in (optional) SDK documentation / sample code (available by agreement)
Ultrasound imaging	512*512 pixels true 256 gray shades full motion and full size real-time ultrasound imaging, up to 120 fps
Cineloop	recording up to 2048 frames to memory Play / Pause / Stop / frame selection saving ultrasound video file to disk size optimized (lossy compression) not size optimized (full quality) loading ultrasound video file from disk
Depth Selection, cm	3 4.5 6 9 12 15 18 21 23.5
Measurements	B-mode

and Calculations	4 distance measurements 2 area measurements: Ellipse (area, perimeter, long axis, short axis and volume of the ellipsoid are calculated); Freehand (area and perimeter are calculated). 2 angle calculations (based on 3 linear markers). GYN package: GW Indication (based on LMP, BBT or KED); GW estimation based on various parameters (USA, Hansmann, Campbell, Tokyo and Osaka methods); Fetus Weight calculation (USA, Hansmann, Tokyo and Osaka methods); GW estimation for animals (bovine, equine, canine, feline). Urology volume calculation (based on object's height, width and length). M-mode 2 linear measurements (distance, time, speed and heart rate are calculated). Cardio package: Left Ventricle measurements (HR, IVSTD, LVIDD, PWTD, IVSTS, LVIDS, PWTS) and calculations (EDV, ESV, SV, EF, CO, FS). Three methods of volume calculations (Cubed, Pombo, Teichholz) are realized; Aortic Valve measurements (AOD, LAD) and calculation of the LA/AO ratio.
Functions	mouse / trackball / keyboard operation image comment / save / recall browsing unlimited programmable presets for clinically specific imaging anatomical Icons with probe position indicator, 10 icons the set of predefined color schemes for software interface, possibility to create custom schemes direct e-mail sending function with image or video attachment via Internet printing on system printer user-friendly pop-up menus and dialogue boxes standard TV output using computer's display adapter (option) view / recall / save any from last 16 early freezed images multi-language support: English, French, German, Polish, Romanian, Russian, Spanish
Computer Requirements	IBM PC compatible Desktop/Notebook/Tablet PC CPU 1.0 GHz or better 256 Mb of RAM or better USB 2.0 interface Windows® XP / Windows® Vista

3.2.2 Block Diagram

As shown in Figure 3-3, the PC Based Ultrasound that we have investigated has four main components. The probe transducer generates and retrieves the ultrasound signal. It consists of 64 parallel ultrasound transducers. The Signal Processing Box is the processing part outside the PC. It performs signal processing and controls the probe power. The PC or CPU is interface of control, processing and display. In CPU, the driver as the communication frame and the imaging software for ultrasound as the general user interface for the PC-based Ultrasound are installed. The end-output is the display monitor of the user interface.

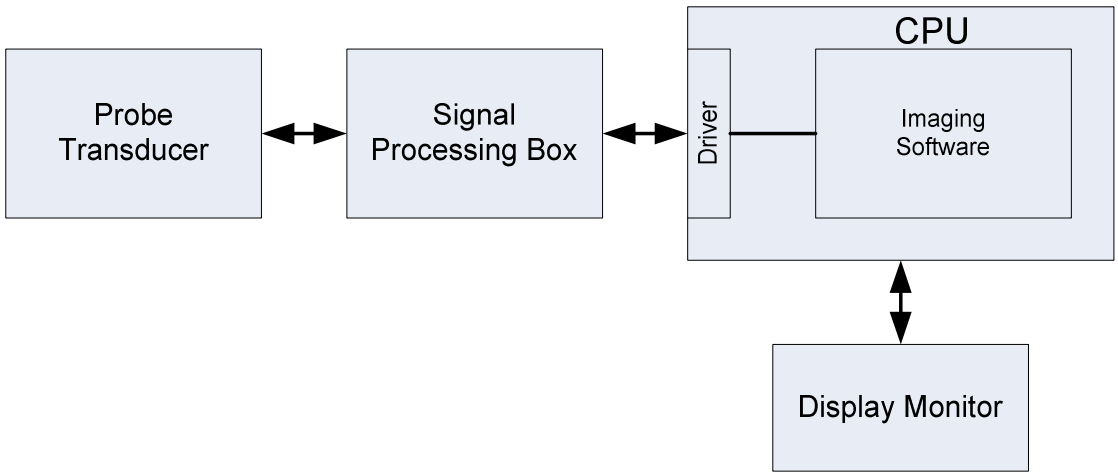

Figure 3-3 Component on PC based Ultrasound Device

3.2.3 Components

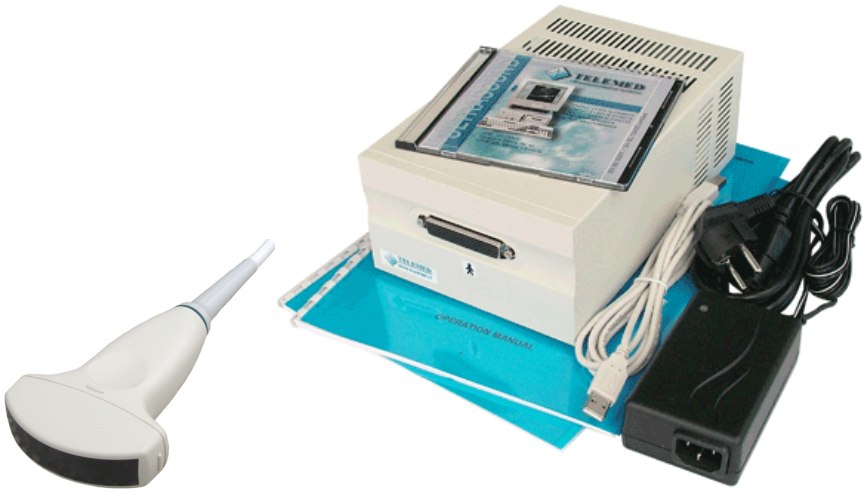

Figure 3-4 Probe transducer and signal processing box

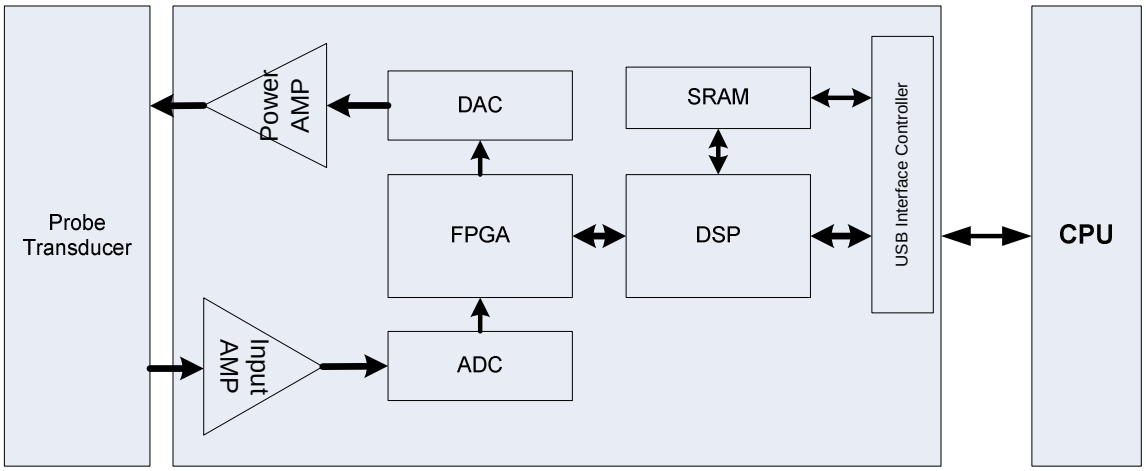

Figure 3-5 Block Diagram of Signal Processing Box of PC based Ultrasound

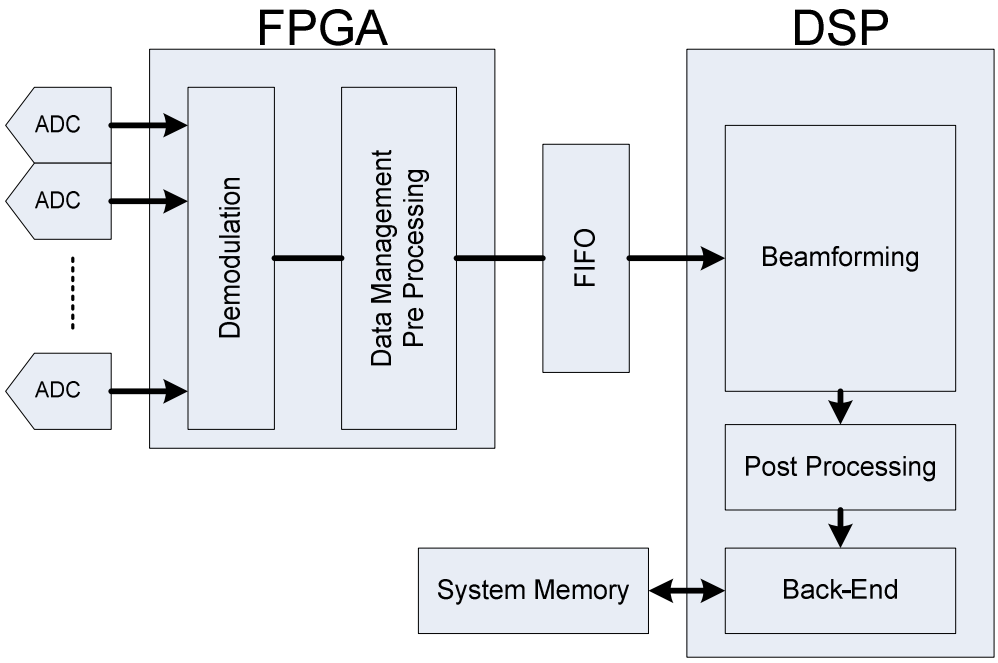

Figure 3-6 Ultrasound Signal Processing Process Diagram

3.3 Summary of Survey

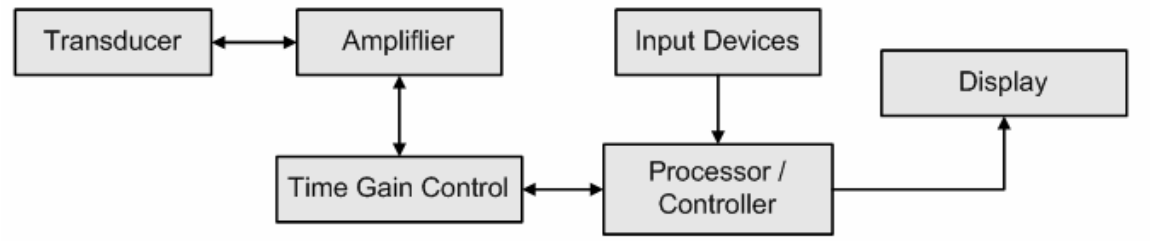

Figure 3-7 Ultrasound machine diagram block

Ultrasound machine consists of transducer, amplifier, time gain control, processor and display.

4 Literature Review of Ultrasound Machine

Most commercial ultrasound machines are capable to support various modes; each mode has different type of information presented to the clinician. Due to the large computing power required, many commercial ultrasound machines have been designed using fixed-function circuit boards. Although the hard-wired approach has met the high computational requirement, but these modern ultrasound machines do not allow the researcher to acquire internal data, modify the signal processing algorithms or test a new clinical application.

A software-based ultrasound machine could offer the needed flexibility to modify the ultrasound processing algorithms and evaluate new ultrasound applications for clinical efficacy (Vijay Shamdasani and Yongmin Kim, 2003). An ultrasound machine in which all of the back-end processing is performed in software rather than in hardware had been designed. A programmable ultrasound machine supports all the core ultrasound processing in software without sacrificing the performance and capability of an ultrasound machine. The high-level block diagram of an ultrasound system is shown in Figure 4-1. The front end controls the formation of acoustic beams and produces a collection of digital samples along each beam, henceforth referred to as a vector. In color-flow and Doppler imaging, multiple vectors are acquired along each beam line. Multiple samples from the same spatial location along a beam line are called an ensemble size. They are equal the number of vectors along the same beam line. The acquired samples are processed in the back-end depending on the ultrasound mode selected. For example, the shaded blocks in Figure 4-1 are the back-end processing modules used in color-flow mode. Figure 4-2 shows the block diagram of the programmable ultrasound system. The front-end electronics used in the system are from a commercial ultrasound machine (Hitachi Medical Corporation's EUB-6000). Equator Technologies' MAP processor is the main processing engine of the ultrasound system. It receives the in-phase (I) and quadrature (Q) data from the demodulation and decimation board then processes them

and transfers the image to be displayed to the PC host. The PC host provides the user interface and acts as a master controller of the system.

4.1 Block Diagram

The main blocks in the B-mode processing module in Figure 4-3 are shown in Figure 4-4. B-mode imaging computes the envelope of complex vector in the envelope detection block. The dynamic range of the envelope is therefore logarithmically compressed. Envelope detection and dynamic range compression operate on multiple vectors to create a frame of B-mode data. Spatial filtering is performed on the frame to remove noise and enhance edges. The spatial filter is a 2D filter with a 16 x 16 kernel in the lateral and axial directions. Persistence processing performs temporal filtering with two consecutively acquired frames to reduce noise and speckle. Scan conversion as shown in Figure 4-4 transforms the frame to Cartesian coordinates of the raster display.

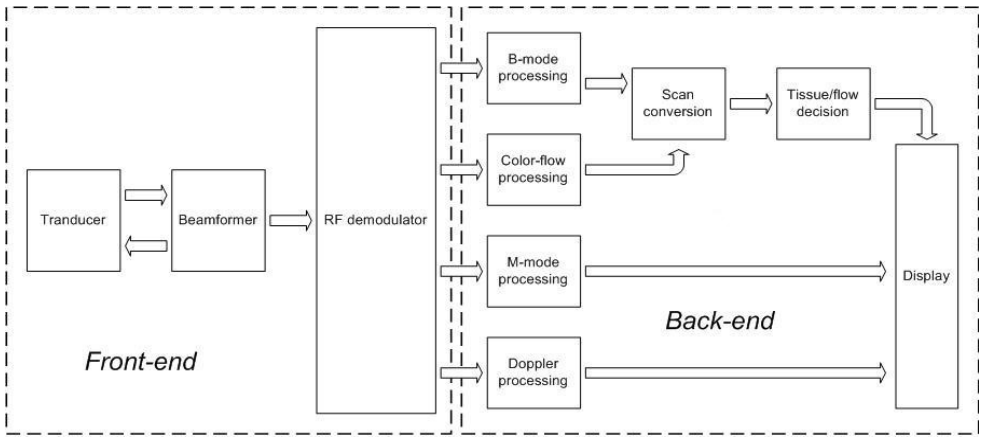

Figure 4-1 Block diagram of a typical ultrasound machine where the shaded area represents the back-end blocks used in color-flow mode.

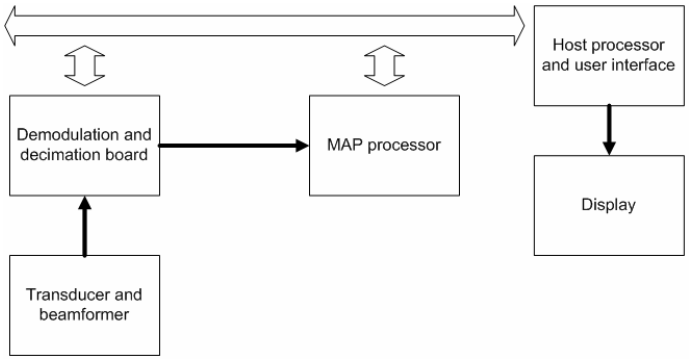

Figure 4-2 Block diagram of software-based ultrasound machine

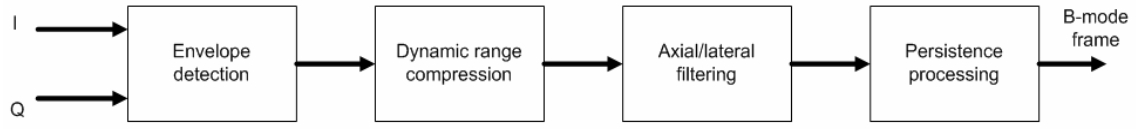

Figure 4-3 Block diagram of B-mode processing

A color-flow image consists of a pseudo-color flow image that is overlaid on top of a 2D B-mode image. Thus, the ultrasound system needs to simultaneously acquire and process the B-mode data as well as color-flow data. The main computing blocks for color-flow processing include the wall filter, flow autocorrelation, flow arctangent, flow power estimation, 2D angular and linear filters and persistence as shown in Figure 4-4. The received ultrasound data contain large undesired clutter (low-frequency reflections from stationary/slow moving tissues, typically vessel walls) in addition to the desired small signals generated by the moving blood cells. The wall filter is employed to remove the clutter. A high pass FIR filter is used to attenuate the clutter from the demodulated signal, I and Q. Since the characteristics of the cluster and flow signals depend on the anatomical region of the body being scanned, the number of taps and cut off frequency of this filter are need to be varied.

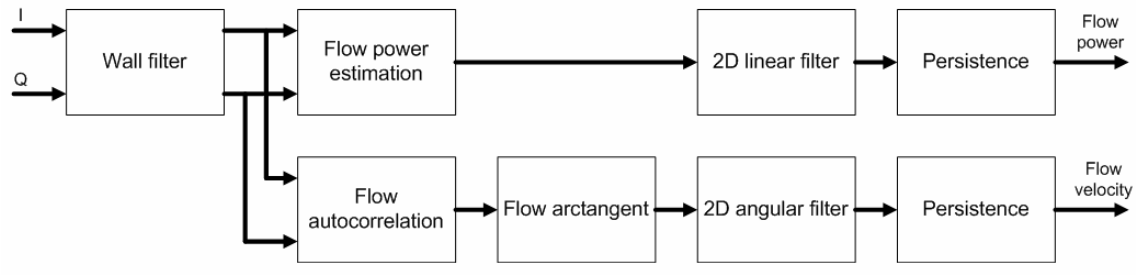

Figure 4-4 Block diagram of color-flow processing

Autocorrelation method is used to estimate the velocity. The phase of the first lag of autocorrelation of an ensemble can be used in estimating the flow velocity. Flow autocorrelation and flow arctangent estimate the flow velocity from wall-filtered data. The flow power is also estimated from the wall-filtered data. Noise is reduced by 2D filtering and persistence processing. The 2D linear filter is 3 x 3 in the axial and lateral directions while the 2D angular filter is 7 x 7. Persistence produces a weighted average of pixel values from two consecutively acquired velocity or power images for the corresponding output image. The scan conversion block converts the B-mode, velocity and power data from polar coordinates to Cartesian coordinates for raster display.

5 Requirement Identification

Survey of ultrasound machine derived the requirement identification. The identification derived the identification of performance and safety requirement of ultrasound machine. The image quality of ultrasound machine is identified based on AIUM and AAPM standard. The electrical safety is based on IEC standard while ultrasound power is based on IEC and FDA standard.

5.1 Performance of Ultrasound machine

5.1.1 Ultrasound Image Quality

For ultrasound imaging, there are some specified parameters to define the quality. As proposed by the AAPM and AIUM, these parameters include detail resolution, contrast resolution, image uniformity and distance accuracy.

Detail resolution refers to the ability to visualize and distinguish small structures in a clear and precise manner. Lateral resolution and axial resolution are aspects of detail resolution. Lateral resolution is the ability to separate and define small structures perpendicular to the beam axis. This resolution is measured in millimeters and is a function of beam width. Meanwhile, axial, or longitudinal, resolution is the measure of the transducer's ability to separate and define two structures along the axis of the beam. This is a function of pulse width, and is optimized by damping the crystal and increasing frequency. Detail resolution is important, however, not only to be able to separate close objects, but also be able to identify them as well.

Contrast resolution is the ability of picking out subtle differences in the presence of bright reflectors. A good contrast resolution ultrasound image is able to differentiate several

similar types of tissues, and visualize subtler structural differences. This is important in differentiating soft tissue structures in the presence of bones.

Ultrasound image distance accuracy consists of vertical distance accuracy and horizontal distance accuracy. Vertical distance accuracy refers to the ability of display accurate distances or measurements along the beam's axis. Horizontal distance accuracy, on the other hand, refers to the ability of display accurate distances or measurements perpendicular to the beam axis. If the detail resolution, contrast resolution and distance accuracy are to be of any diagnostic use to the interpreter, image uniformity refers to the ability to maintain high value in these parameters throughout the entire field of view.

5.1.2 Ultrasound Image Quality Measurement

The most objective way of assessing the image quality of an ultrasound system is to use the operator receiving characteristics (ROC) curves (Shung et al., 1992), in which human involvement is included. To be meaningful statistically, many subjects need to be studied to obtain a measurement in which inter and intra observer variations are considered. Although this approach is the most desirable, it is very complicated and expensive. Simpler but quantitative measures such as spatial resolution and contrast resolution are often preferred. The spatial resolution can be assessed by imaging standardized targets or phantoms consisting of point or wire targets embedded in water or tissue mimicking gets. The spatial resolution measured this way depends strongly upon the instrument settings. A more convenient approach is to determine the point spread function of the system. The point spread function of an imaging system is the spatial point response (Shung et al., 1992), which is the inverse spatial Fourier transform of the spatial transfer function of an imaging system if it can be treated as a linear system. Suppose that the point spread function and the spatial transfer function of an imaging system can be denoted as $h(\mathbf{x})$ and $H(\mathbf{v})$, respectively, where $\mathbf{x}$ and $\mathbf{v}$ are vectors representing spatial distance with a unit of cm and spatial frequency with a unit of cycles per cm. The input, S, which is the object to be imaged and output, O, which is the image acquired by the imaging system are related by the following equation in the spatial frequency domain:

$$O(\mathbf{v}) = H(\mathbf{v})S(\mathbf{v})$$

In the spatial domain, their relationship is given by

$$o(\mathbf{x}) = h(\mathbf{x}) * s(\mathbf{x}) = \int_{-\infty}^{\infty} s(\mathbf{x})h(\mathbf{x} - \chi)d\chi$$

where *denotes convolution.

The point spread function of an ultrasound system can be assessed by imaging a small point target embedded in homogeneous gel medium or a point target suspended in a water bath and mapping the grey level of the image. Figure 5-1 shows the grey level of such an image as a function of one dimension of the spatial vector, **x**, represented by $x1$. System I, which has a sharper point spread function, should have a better resolution than system II.

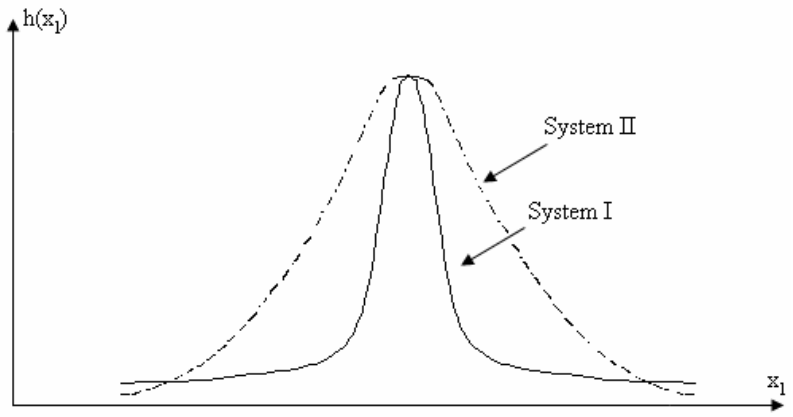

Figure 5-1 Point spread function of two imaging systems represented by grey-scale distributions as a function of one spatial dimension. System I has a narrow point spread function and therefore better spatial resolution than system II

AAPM, on the other hand has suggested action levels for ultrasound image quality indicators. Table 1 provides suggested defect and action levels for ultrasound diagnostic machine.

Table 1 defect and action levels for ultrasound diagnostic machine.

Image quality indicator	Suggested defect level	Suggested action level
Image uniformity	In general, nonuniformity >6 dB or, any consistent measurable change from baseline.	In general, nonuniformity >4 dB or, any consistent measurable change from baseline
Depth of visualization	Change >1 cm from baseline	Change >0.6 cm from baseline

Vertical distance accuracy	Error >2 mm or 2%	Error >1.5 mm or 1.5%
Horizontal distance accuracy	Error >3 mm or 3%, whichever is greater	Error >2 mm or 2%, whichever is greater.
Axial resolution	In general .1 mm, or any consistent measurable change from baseline	1 mm, or 2 mm if freq,4 MHz, or any consistent measurable change from baseline
Lateral resolution	3.53 focal length/~freq in MHz3 aperture diameter in mm! or change ,1.5 mm from baseline value	2.53 focal length/~freq in MHz3 aperture diameter in mm! or change .1 mm from baseline value
Dead zone	10 mm for *f*,3 MHz 7 mm for 3 MHz,*f*,7 MHz 4 mm for *f* >7 MHz or any consistent measurable change from baseline	7 mm for *f*,3 MHz 5 mm for 3 MHz,*f*,7 MHz 3 mm for *f* >7 MHz or any consistent measurable change from baseline

5.2 Safety of Ultrasound Machine

One of the well-promoted advantages of ultrasound in diagnostic system is its apparent safety. This makes the applications of ultrasound in medical diagnostic have experienced considerable growth during the past few years.

Ultrasound produces heating, pressure changes and mechanical disturbances in tissue. Diagnostic levels of ultrasound can produce temperature rises that are hazardous to sensitive organs and the embryo/fetus. Particular care should be taken to reduce the risk of thermal and non-thermal effects during investigations of the eye and when carrying out neonatal cardiac and cranial investigations.

Minimum safety requirements based of Thermal Index (TI) and Mechanical Index (MI) are important indicators to identify the degree of thermal and mechanical effect of ultrasound.

Ultrasound diagnostic devices shall display on screen the thermal and mechanical index. Operators should regularly check both indices while scanning and should adjust the machine controls to keep them as low as reasonably achievable (ALARA principle) without compromising the diagnostic value of the examination. Where low values cannot be achieved, examination times should kept as short as possible.

Ultrasound operators should receive more education in evaluating risks and benefits. This training should be part of the process of ultrasound laboratory accreditation. The requirements for the safe use of ultrasound therapy devices may be divided into the following four areas:

a) Indicators
b) Labeling
c) Output control
d) Timer specifications

The maximum temporal average effective ultrasonic intensity shall not exceed 3 W/cm^2. This value was chosen for several reasons:

- Higher intensities do not seem to be required for efficacy. Survey data indicate that 3 W/cm^2 is commonly found as the maximum nominal intensity available for most devices. This intensity value has been accepted by European manufacturers for many years as the maximum necessary for therapy.

- Higher intensities may be painful or damaging. It was proven by many studies. In order to maintain the safety of ultrasound devices, the routine testing and calibration by suitably trained personnel is required. The routine testing includes visual inspection, general electrical safety testing and performance testing.

5.2.1 Electrical Safety of Ultrasound Machine

Safety of Ultrasound Machine Power

The calibration should be done to ensure the accuracy of ultrasonic power, beam and exposure time as indicated in therapeutic devices, as well as image quality, thermal and mechanical index as indicated in diagnostic devices. The equipment shall comply with general electrical safety requirement specified in MS ISO 13485, MS IEC 60601-1, MS IEC 60601-1-2, IEC 60601-1-4 and IEC 60601-2-37.

The current regulatory limit for ultrasound diagnostic applications is 720 mW/cm^2 of intensity, estimated at the tissue of interest, i.e. attenuated according to the beam path length in tissue. For this intensity, it has been estimated that the maximum temperature in the conceptus may exceed 2^oC. Maximum allowable output of ultrasound medical devices for diagnostic purposes should meet the requirements specified in Table 2.

Table 2 Maximum allowable output of ultrasound medical devices for diagnostic purposes

Application	Intensity, mW/cm^2	MI	TI
Peripheral Vessel	720	1.9	4
Cardiac	720	1.9	4
Fetal, Neonatal	720	1.9	4
Ophthalmic	50	0.23	0.2

The production of unintended or uncontrolled motion of transducer assemblies intended for intra-corporeal use. The spatial peak temporal intensity of unwanted ultrasound radiation from a treatment head intended for hand-held use shall be less than 100 mW/cm^2 when measured as follow:

- The front face of the treatment head is immersed in degassed water in the temperature of 22 ± 3 ^{o}C.
- The equipment is operated at the rated output power specified for the treatment head.

The unwanted ultrasound radiation is measured by scanning, by hand, the side walls of the treatment head by means of a calibrated hydrophone coupled to the sidewalls using a coupling gel. The treatment head shall meet the requirement of drip-proof equipment (ingress of liquids). Quantitative indicators shall be provided on the control panel in the form of a meter or a calibrated output control. It must be directly readable, and show output power and effective Intensity in the case of continuous wave mode of operation and temporal maximum intensity and Temporal maximum output power in the amplitude modulated wave mode of operation.

Any power displayed shall not differ from the actual value more than ± 20% of the actual value. The maximum effective intensity shall not exceed 3 W/m^2 with any treatment head or attachment head provided by the manufacturer. The ultrasound equipment shall incorporate a means (an output control) to enable the output power to be reduced to not more than 5 % of the rated output power. The output power shall not vary by more than ± 20% for variations of the mains voltage of ± 10%. Compliance shall be checked by measurement of the output power at 90 %, 100 % and 110% of the rated value of the mains voltage. Equipment shall be provided with an adjustable timer that de-energizes the output after a pre selected operating period. The timer shall range not exceeding 30 min and the following accuracy:

- Less than 5 min (± 30 s)
- min to 10 min (± 10 % of setting)
- more than 10 min (± 1 min)

The beam non-uniformity ratio shall not exceed 8.0 with any treatment head or attachment head provided by manufacturer. During one hour of continuous operation at

maximum output power and at rated mains voltage, in water at $22^{o}C \pm 3$ °C, the output power shall remain constant within ± 20 % of its initial value. The connecting cord of the treatment head shall be protected against excessive bending at the entries into the treatment head and into the equipment to the pertaining connection plug, respectively.

5.2.2 Power of Ultrasound

Mechanical Index

A Mechanical Index (MI) is selected as the value to be calculated as an indicator related to mechanical effects. The index is intended to estimate the potential for mechanical bio-effects. Mechanical effects are including motion (or streaming) around compressible gas bubbles as ultrasound pressure waves pass through tissues and energy released in the collapse, via cavitations of transient gas bubbles. While no adverse mechanical bio-effects have been reported to date in humans from exposure to ultrasound output levels typical of ultrasound diagnostic equipment, several observations have contributed to the development of the MI. In lithotripsy, mechanical bio-effects are induced by ultrasound with peak pressures in the same range as are sometimes used in diagnostic imaging, albeit at markedly different frequencies. Besides, in vitro experiments and observations with lower organisms have demonstrated the possibility of cavitations at ultrasound pressures and frequencies in range in some ultrasound diagnostic equipment. Next, Lung hemorrhage has been demonstrated in mice exposed to levels of pulsed ultrasound similar to those used in ultrasound diagnostic equipment. (Although this has been demonstrated in adult mice, similar effects have been found in fetuses). Unclear conclusion has been drawn on the relevance of these laboratory studies to human exposure to diagnostic ultrasound. However, the result raise sufficient concern that the calculation of a MI will raise in users' minds an appropriate awareness of the possibility of mechanical effects and of the condition in which the possibility is more likely. The conditions that affect that likelihood of mechanical effects are not well understood yet.

However, it is generally agreed that the likelihood increases as peak rare factional acoustic pressure increases and decreases as the ultrasound frequency increases. Further,

it is generally believed to be a threshold effect such that no occurs unless a certain output level is exceeded. While the existing limited experimental data suggest a linear frequency relationship, a more conservative root-frequency relationship is selected. The MI is defined as

$$MI = \frac{p_{ra} f_{awf}^{-\frac{1}{2}}}{C_{MI}} \quad \text{for } f_{awf} < 4 \text{ MHz}$$

Where $C_{MI} = 1$ MPa $MHz^{-1/2}$ and

$$MI = \frac{p_{ra}}{2C_{MI}} \quad \text{for } f_{awf} \geq 4 \text{ MHz}$$

where $C_{MI} = 1$ Mpa, pra is the Attenuated Peak-Rarefactional Pressure in megapascals, f_{awf} is the Acoustic-Working Frequency in megahertz.

The choice of a homogeneous tissue model and a derating factor of 0.3 dB cm-1 MHz-1 is compromise. Other attenuation models were evaluated and rejected, such as fixed distance 0.5 dB cm-1 MHz-1, a value more representative of many radiological and cardiac imaging applications. However, use of more than one attenuation model would entail an increase in equipment complexity and could create a further need for user input to select appropriate attenuation schemes. It is not felt that extra complexity in attenuation modelling is justified given the level of understanding of the conditions required to produce mechanical bio-effects. With the selected compromise attenuation model, the MI is simple to implement and use and most importantly, sufficient to allow users to minimize acoustic output and any corresponding potential mechanical bio-effects.

Thermal Index (TI)

The relationship between thermal rise and tissue bio-effects is well established (numerous studies) and while present acoustic output measurement parameters, such as:

- P = Output power
- Ita = Temporal-Average Intensity
- Ispta = Spatial-Peak Temporal-Average Intensity

are not individually suitable as indicators or estimators of ultrasound-induced temperature rise, combinations of these parameters, along with specific geometric information, can be used to calculate indices which provide an estimate of temperature rise in soft tissue or bone. Because of the difficulties of anticipating and thermally modelling the many possible ultrasound scan planes of the human body, simplified models based on average conditions are used. Three user-selectable TI categories corresponding to different anatomical combinations of soft tissue and bone encountered in imaging applications are defined. Each category uses one or more TI models that are calculated based on information on the equipment, including transducer aperture or acoustic beam dimensions and the imaging mode.

Table 3 Thermal Index categories and models.

Thermal Index Category	Thermal Index Models	
	Scanned Mode	Non-scanned Mode
TIS (soft tissue)	A. Soft tissue at surface	B. Large aperture C. Small aperture
TIB (bone at focus)	A. Soft tissue at surface	D. Bone at focus

TIC (bone at surface)	E. Bone at surface

The Soft-tissue Thermal Index (TIS) is based on three soft tissue models. Two models cover small and large aperture cases for non-scanning modes, such as Doppler and M-mode. The remaining model covers scanned modes, such as colour flow mapping and B-mode. The Bone Thermal Index (TIB) uses, for non-scanning modes, a model in which bone is located in a focal region (such as may occur in second and third trimester foetal applications). For scanned modes, the soft tissue model is used because the temperature increase at the surface is typically greater than, or about the same as with the bone at the focus. The Cranial Bone Thermal Index (TIC) is based on a model with bone located close to the surface. The cranial bone is used with both the non-scanning mode and the scanned mode.

In this annex, the Thermal Index, TI is defined by the relationship

$$TI = \frac{P_p}{P_{deg}}$$

Where P_p is the Power Parameter as defined in this annex and P_{deg} is the estimated power necessary to raise the target tissue 1^oC, based on the thermal models discussed in this annex.

The derivation of the temperature rise estimation models requires the understanding of four key concepts/parameters.

6 Realization

6.1 Sonoimprometer

For ultrasound imaging, there are some specified parameters to define the quality. As proposed by the American Association of Physics in Medicine (AAPM), these parameters include detail resolution, contrast resolution, image uniformity and distance accuracy.

Detail resolution refers to the ability to visualize and distinguish small structures in a clear and precise manner. Lateral resolution and axial resolution are aspects of detail resolution. Lateral resolution is the ability to separate and define small structures perpendicular to the beam axis. This resolution is measured in mm and is a function of beam width. Meanwhile, axial, or longitudinal, resolution is the measure of the transducer's ability to separate and define two structures along the axis of the beam. This is a function of pulse width, and is optimized by damping the crystal and increasing frequency. Detail resolution is important, however, not only to be able to separate close objects, but also be able to identify them as well.

Contrast resolution is the ability of picking out subtle differences in the presence of bright reflectors. A good contrast resolution ultrasound image is able to differentiate several similar types of tissues, and visualize subtler structural differences. This is important in differentiating soft tissue structures in the presence of bones.

Ultrasound image distance accuracy consists of vertical distance accuracy and horizontal distance accuracy. Vertical distance accuracy refers to the ability of display accurate distances or measurements along the beam's axis. Horizontal distance accuracy, on the other hand, refers to the ability of display accurate distances or measurements perpendicular to the beam axis.

If the detail resolution, contrast resolution and distance accuracy are used to the interpreter, then image uniformity refers to the ability to maintain high value in these parameters throughout the entire field of view.

To overcome standard requirements, low cost ultrasound needs an improvement. Although we brew from the scratch of ultrasound machine, the additional system was made to improve the ultrasound machine. The additional system is called "sonoimprometer". It is a portable system that can process the ultrasound diagnostic images just by plugging to the video output port of the ultrasound diagnostic machine. In addition, measurement of cyst diameter, vertical and horizontal distances can be done also within the system either manually or automatically.

As shown in Figure 6-1, the Sonoimprometer consist of hardware and software part. The hardware part is mainly the system configuration that includes the processor and the video grabber. The software part consists of image processing for enhancement of ultrasound images, measurement of certain image quality parameters and design of user-friendly GUI. MATLAB software is used to simulate the result of the implementation of software part.

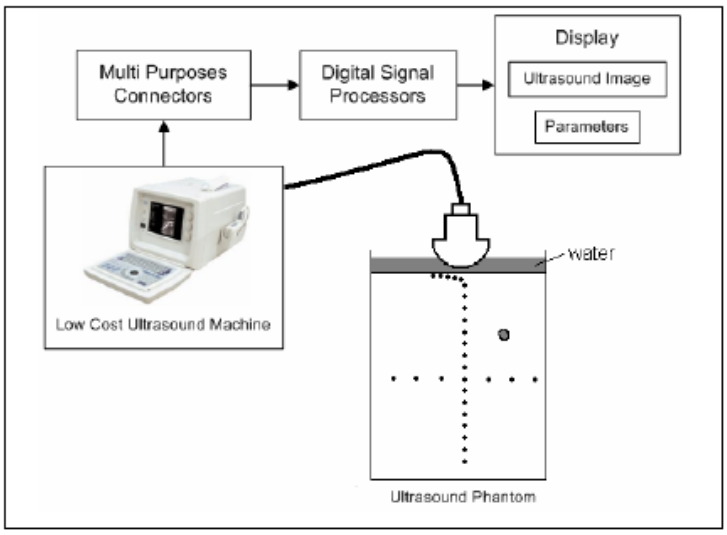

Figure 6-1 Block diagram of Sonoimprometer

6.1.1 Image Processing Algorithm

The main purpose of image processing is to enhance the ultrasound image so that ultrasound image is easier to read. Several image-processing techniques are used to enhance the image. This includes image merging to retain some details of the ultrasound image, scaling to smooth the images and finally some simple mathematical operations are performed to control the intensity of the image. Figure 6-2 shows the flow of the applied image processing techniques.

6.1.2 Images Merge

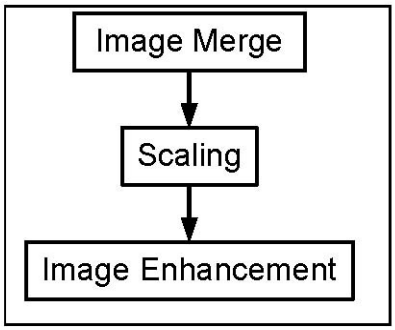

Figure 6-2 Flow of image processing algorithm

In this system, there are two input images will be merged. The main purpose of images merging is to retain some information of the ultrasound image. Due to some limitations of the ultrasound probe, some structure may not be captured during scan. Therefore, a second image on the small shift of the first position is captured by hoping that the detail that is not captured on the first image may be captured on the second image. Merging of these two images may over the limitations since the information may be retained. Figure 6-3 illustrates the limitations of the ultrasound probes and Figure 6-4 shows how images merge may overcome this problem.

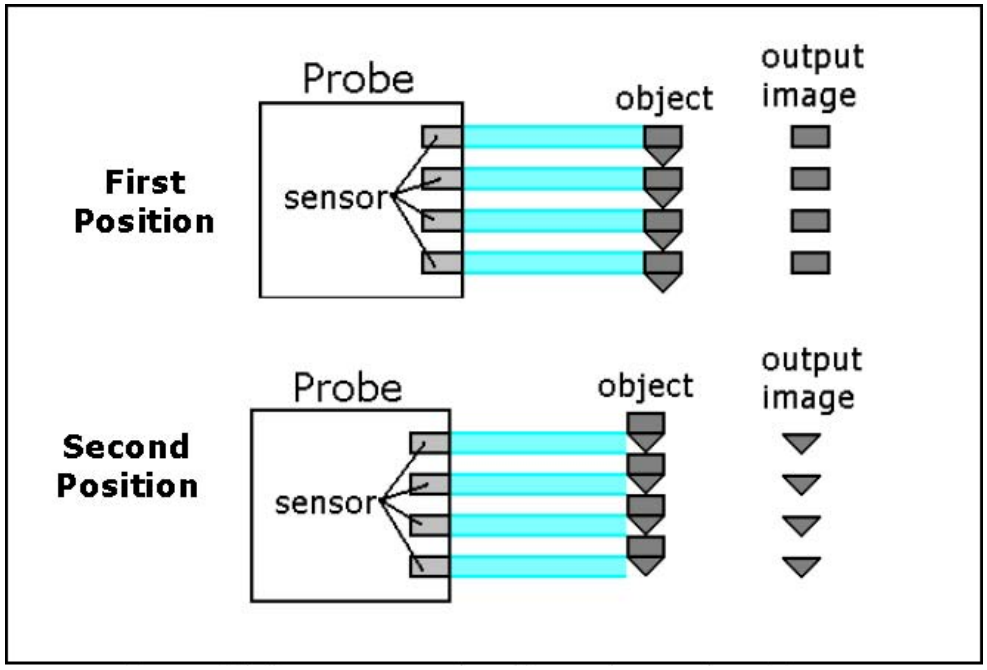

Figure 6-3 Image captured on first and second position

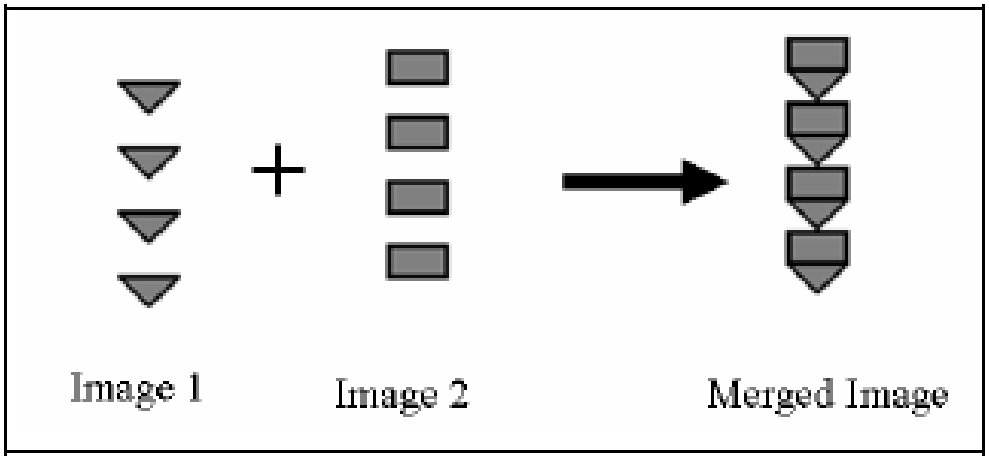

Figure 6-4 Image after images merge

Scaling

Scaling is the process of changing the dimensions of an image. It is accomplished by changing the number of pixels in the x- and y- directions. It is obvious that we can also use this process to display the same image on a device with different resolution and keep a unity scale factor. Scaling can be the same in the vertical and horizontal directions, but not have to. So, anamorphic (distorted) scaling can be used to create special effects or fit an image into a defined area. The proposed system uses the B-Spline image interpolation for the scaling.

Image Enhancement

For image enhancement, the main purpose is to enhance the contrast so that the object being scanned is clearer or more obvious. In order to enhance the contrast, simple mathematical operations are performed. Firstly, multiplication is done to make the higher value pixels getting higher value. In other hand, this makes bright pixels getting brighter but dark pixels stay dark. The difference between dark and bright pixels can be obviously seen. Secondly, deduction is being performed to control the intensity of the image so that the bright pixels are not getting too bright and look unreal.

6.1.3 Measurement

The developed system is designed to be able to do measurement automatically and manually. Firstly, in order to do measurement, calibration has to be performed. User is prompted to perform calibration by enter a desired calibration distance value. Then the user can shows the calibration distance by clicking two points on the picture. The distance is calculated using the distance formula:

$$d = \sqrt{(i_1 - i_2) + (j_1 - j_2)}$$

Where *d* is the distance calculated, *i* and *j* are the coordinates of the two points.

By calculating the calibration value, the real value of the distance can be calculated instead of in the unit of pixels. The real distance of unit pixel is then calculated by dividing the calibration distance value with the distance on the image in the unit of pixel. Conversion of distance in unit pixel to distance in mm can be done easily by multiply it to the reference value. For manual measurement, user is prompted to click on the two points that to be measured the distance. The distance between two points is calculated using the formula above and the converted to mm unit.

The developed system is designed to be able to do measurement on cyst diameter, vertical distance and horizontal distance of a phantom automatically. The user has to first load an image focusing the part measured.

Measurement on cyst diameter, vertical and horizontal distance of a phantom then runs automatically. For automatic measurement, the reference value is also taken from the calibration mentioned. Figure 6-5 shows the flow of automatic measurement.

For all measurement, the program first crops the region that the objects that to be measured may take place. Therefore, the image load should be focusing the measure part so that the objects to be measured are within the crop region. Then, the enhancement on the crop region is done before the edge detection.

Edge detection is a terminology in image processing and computer vision, particularly in within the areas of feature detection and feature extraction, to refer to algorithms that aim at identifying points in a digital image at which the image brightness changes sharply or more formally has discontinuities.

The result of applying an edge detector to an image may lead to a set of connected curves that indicate the boundaries of objects, the boundaries of surface markings as well curves that correspond to discontinuities in surface orientation.

Thus, applying an edge detector to an image may significantly reduce the amount of data to be processed and may therefore filter out information that may be regarded as less relevant, while preserving the important structural properties of an image.

Applying Canny edge detection to the region cropped bounds the objects within that area with white boundary. The region cropped is now in binary format, which is in term of '0' (black) and '1' (white). The objects are then filled with '1' (white). After that, any object in the region can now be recognized as an object by the system. The system then labels all the objects in the area with a unique number starting with one.

For all the objects in the cropped region, the areas of those objects are calculated in pixels. For cyst diameter measurement, the object with the highest value of area is the cyst. On the other hand, for horizontal and vertical distance measurement, the two highest value of area objects are the objects that to be used as reference points for measurement. Therefore, the objects to be measured can be identified. The other objects in the region are considered as noise and then ignored during any measurement.

For cyst diameter measurement, the centroid of the cyst is calculated. Centroid is defined as the center of mass of the region. Therefore, the centroid of the cyst is the center for nicely bound cyst. With the centroid or the point within the cyst, iteration can be done in order to get some points on the boundaries of the cyst. The flow of the iteration is shown in the following flowchart. According to the iteration, points with less than 3 pixels are considered as noise and then ignored. Figure 6-6 shows the flow for iteration of point 1 and point 2. Meanwhile, Figure 6-7 shows the iteration for point 3 and 4. Figure 6-8 shows the iteration for point 5 and 6 and Figure 6-9 shows the iteration flow for point 7 and 8. As a result, some points on the boundary of the cyst can be obtained. Figure 6-10 illustrates the distribution of the points on the boundary of the cyst. Distances between those points are the diameters for the cyst. Diameters for the cyst are calculated and average diameter can be obtained.

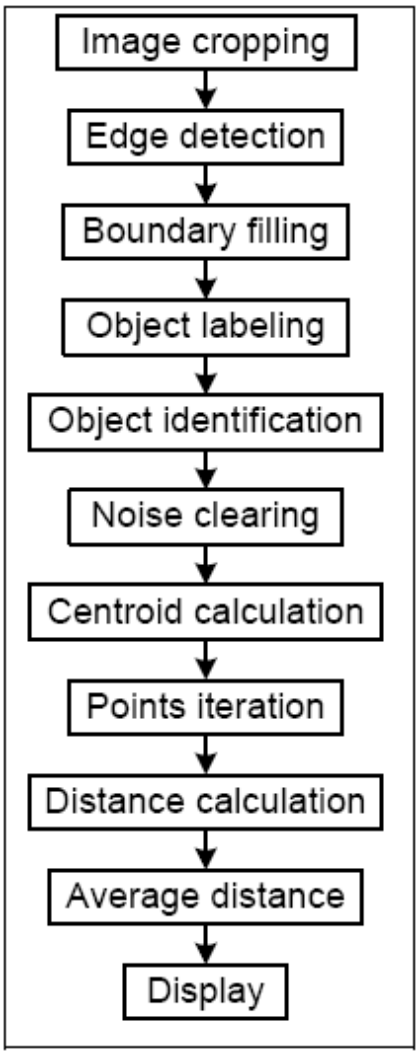

Figure 6-5 Flow of automatic measurement

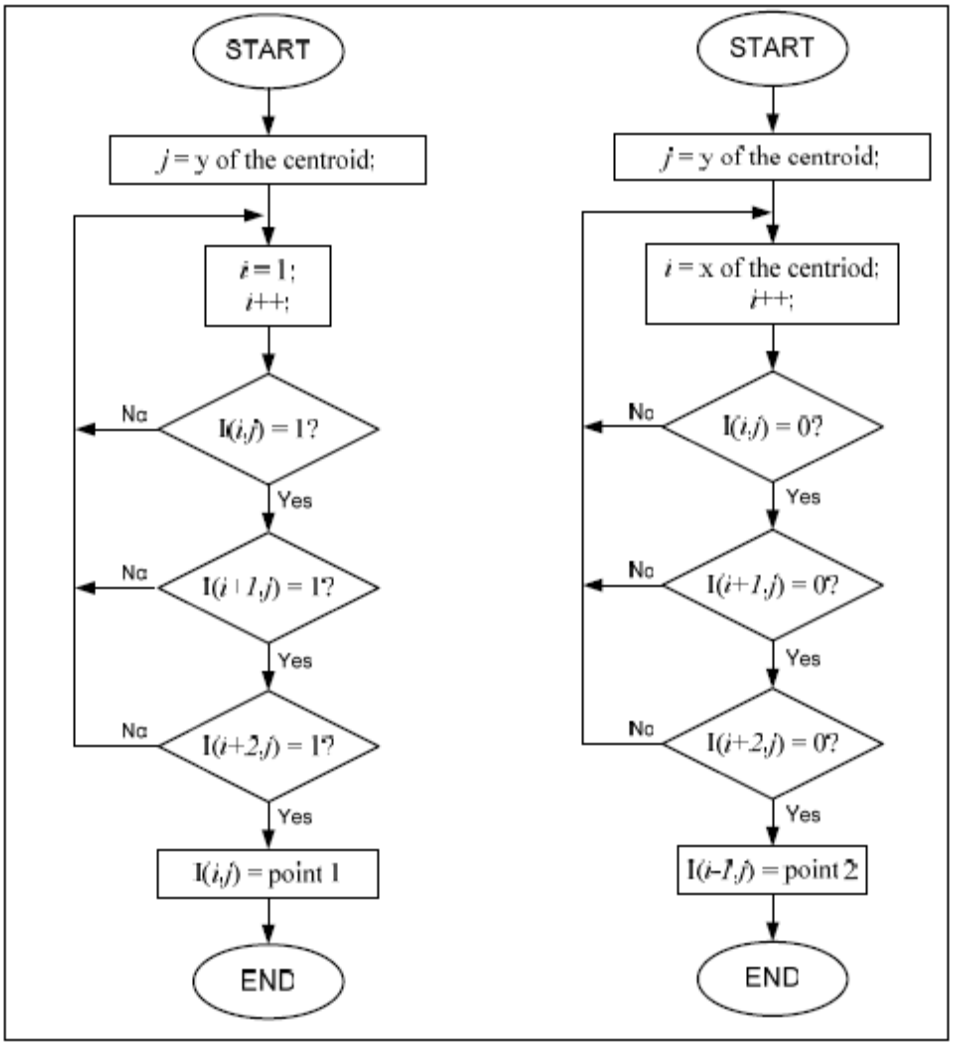

Figure 6-6 Iteration flow for point 1 and 2

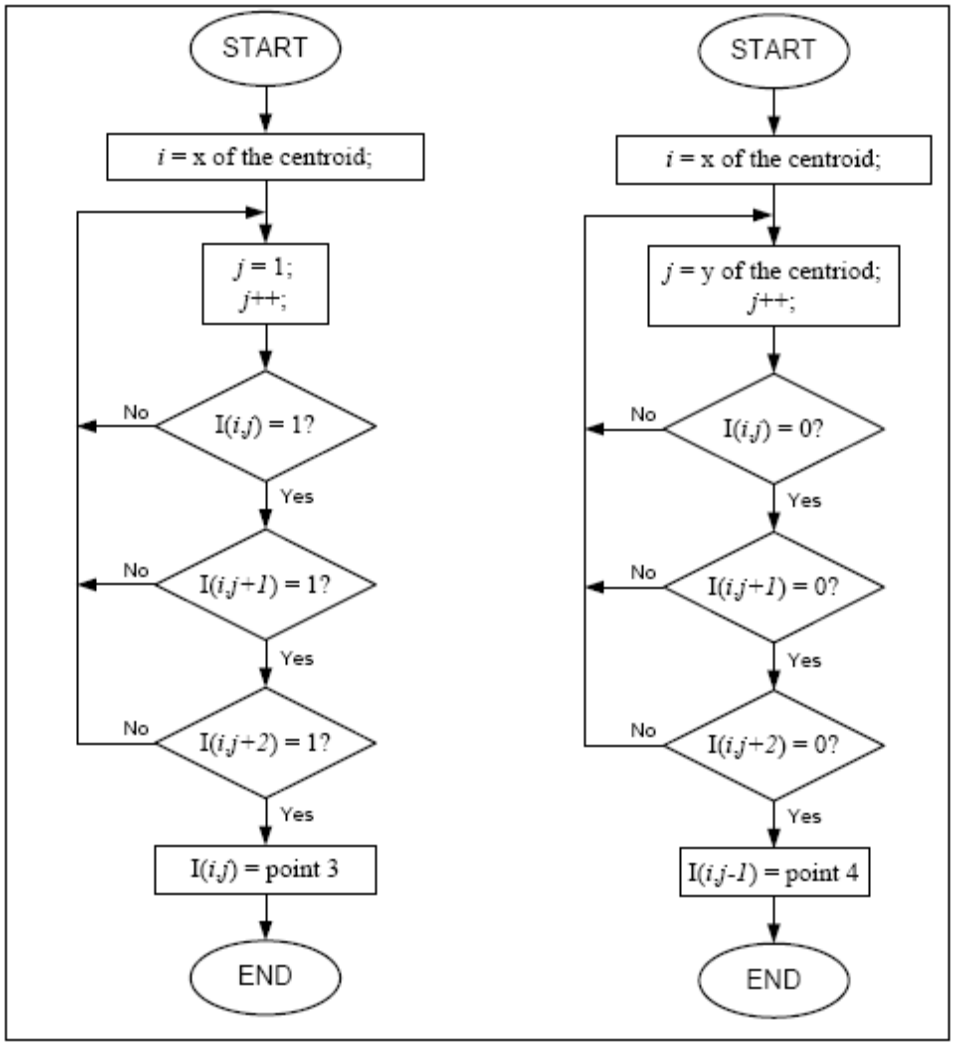

Figure 6-7 Iteration flow for point 3 and 4

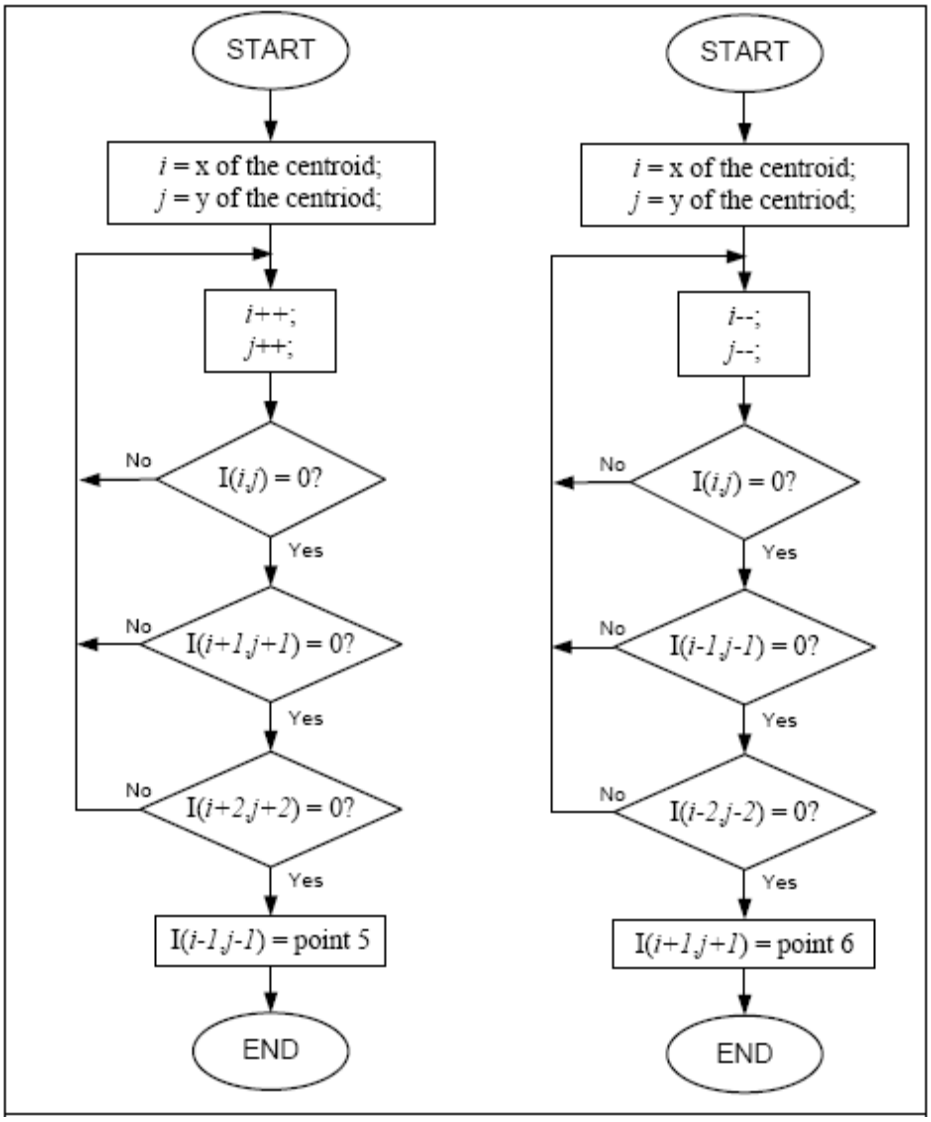

Figure 6-8 Iteration flow for point 5 and 6

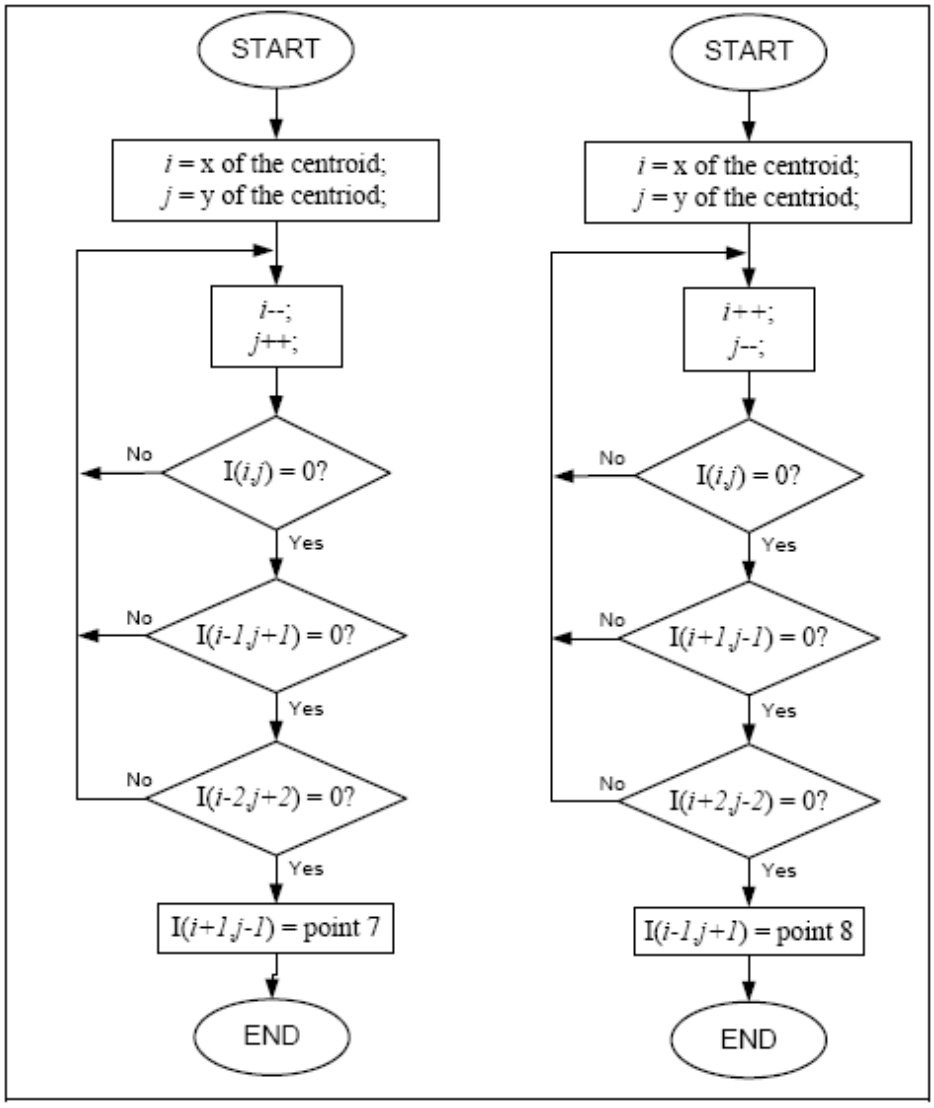

Figure 6-9 Iteration flow for point 7 and 8

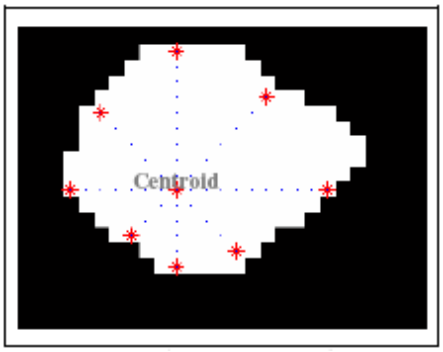

Figure 6-10 Illustration of distribution of points in the cyst

For horizontal and vertical distance measurement, iteration of points is also done. The distance between points can be calculated. Figure 6-11 and Figure 6-12 illustrate the distribution of points for vertical and horizontal distance measurement respectively.

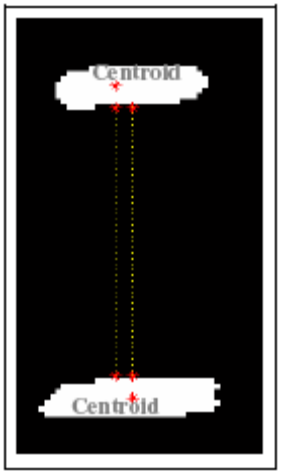

Figure 6-11 Illustration of distribution of points for vertical distance measurement

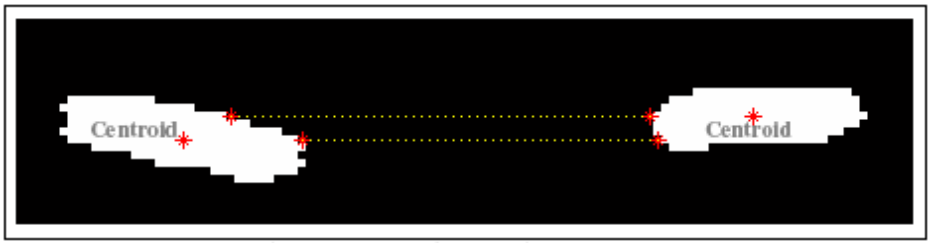

Figure 6-12 Illustration of distribution of points for horizontal distance measurement

6.1.4 Graphical User Interface (GUI)

Since Matlab is used for the implementation of image processing algorithm, the Graphical User Interface (GUI) designed is also created from Matlab. The Matlab GUI function is able to create all kind of GUI. A user friendly GUI was created for the implementation of the software.

In order to create the GUI, the GUIDE window of Matlab was called. The GUIDE window is the workplace where the interface is created. The operation for each function is written in the callback of GUIDE. Finally, the GUI designed can be complied to create Windows Standalone File by using Matlab Development Tool where the Matlab Compiler can be called here. Figure 6-13 shows the GUIDE windows where the interface can be designed.

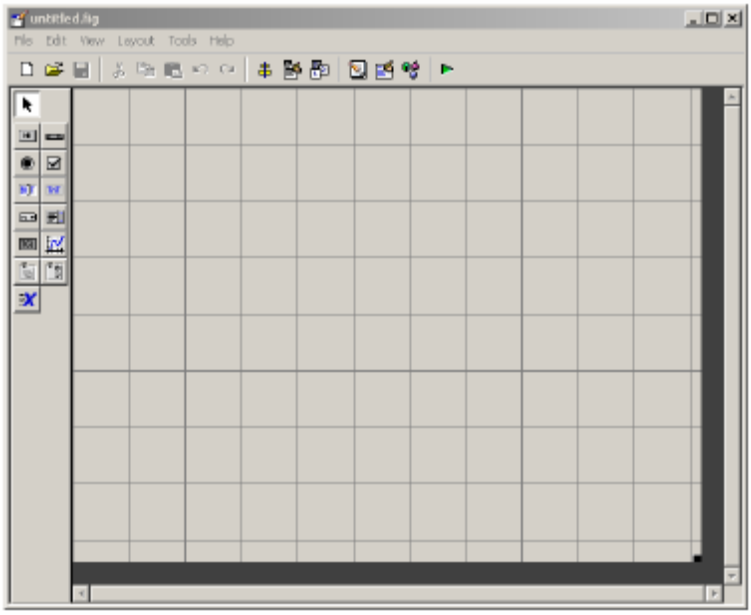

Figure 6-13 GUIDE window of Matlab for GUI design

For the developed system, the GUI of the system is shown in Figure 6-14. It is a simple and user friendly GUI since all the buttons is big and the labels are clear enough. The function of each button is clearly labelled. User can click the button to perform the desired operation. Warning and error dialogs are used to prompt user in case of wrong operation such as wrong flow of operation. There is a big display to display the image after operation. Loading bar is used to inform the user the processing percentage.

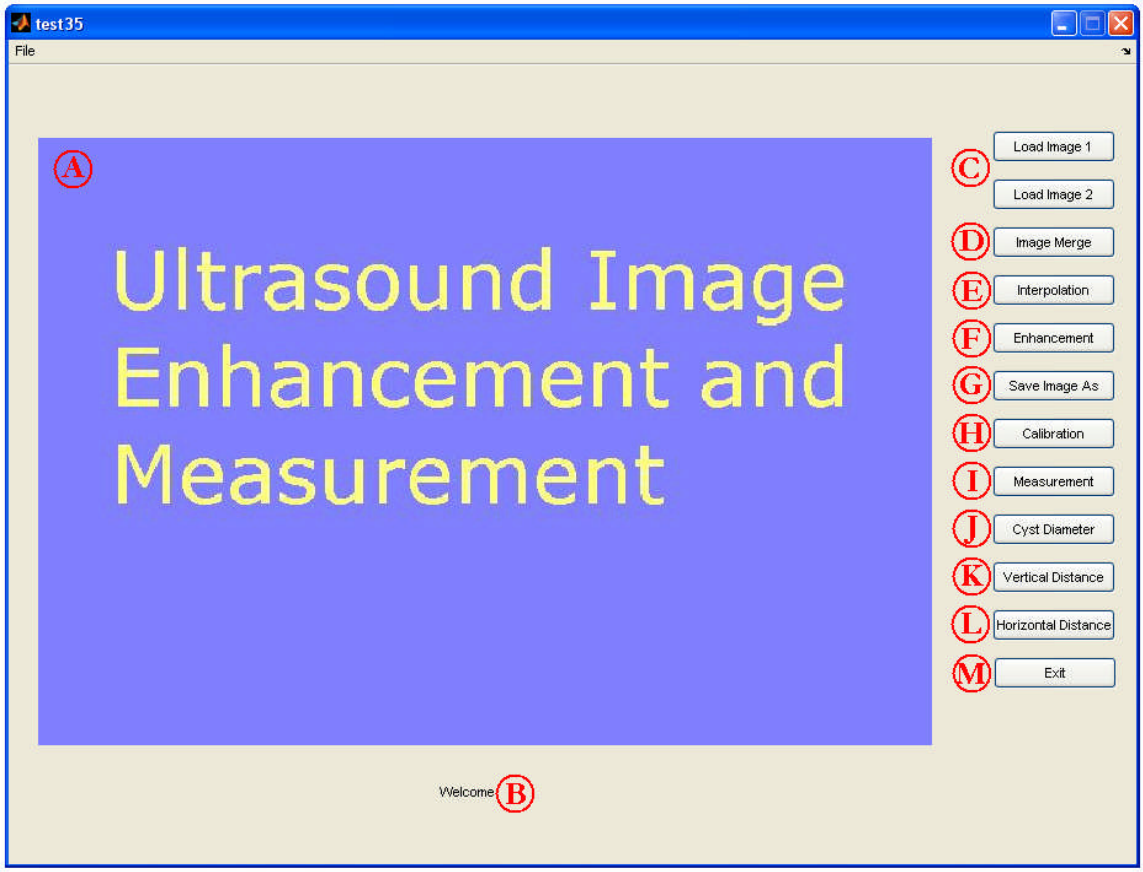

Figure 6-14 GUI of the developed system

Table 4 The function of each part of the GUI

Label	Functions
A	Image display
B	Status indicator
C	Button for loading images for processing and measurement
D	Button for image merge operation
E	Button for Bicubic Spline Interpolation operation
F	Button for image enhancement operation
G	Button for saving image (as JPEG file)
H	Button for calibration of scale for measurement

I	Button for manual measurement
J	Button for automatic cyst diameter measurement
K	Button for automatic vertical distance measurement
L	Button for automatic horizontal distance measurement

6.2 Ultrasound Power Meter

The ultrasound power meter uses the PVDF sensor to measure the ultrasound power. Then it needs peripheral circuits to display the measurement of the measurement. First, we need to choose the appropriate material and electronic components to construct this project. Then, the aquarium water tank is used in which can put about 2 litres of water. The chosen of the aquarium water tank is due it has the transparent surface. It makes the writer easy to allocate the PVDF sensor inside the water tank. Then, at the bottom of the water tank, some of the stereo foam is put as ultrasound absorbing material. This is used to prevent the bottom of the water tank become a hot spot area. The water inside the water tank used as propagation medium for ultrasound transmits the energy. The Figure 6-15 shows the prototype of the designed hydrophone with PVDF sensor. Then the electrode of the PVDF sensor is connected to the peripheral circuits. The peripheral circuits is build by the amplifier circuit, peak detector circuit, build in ADC inside the microcontroller and microcontroller circuit to drive the LCD display

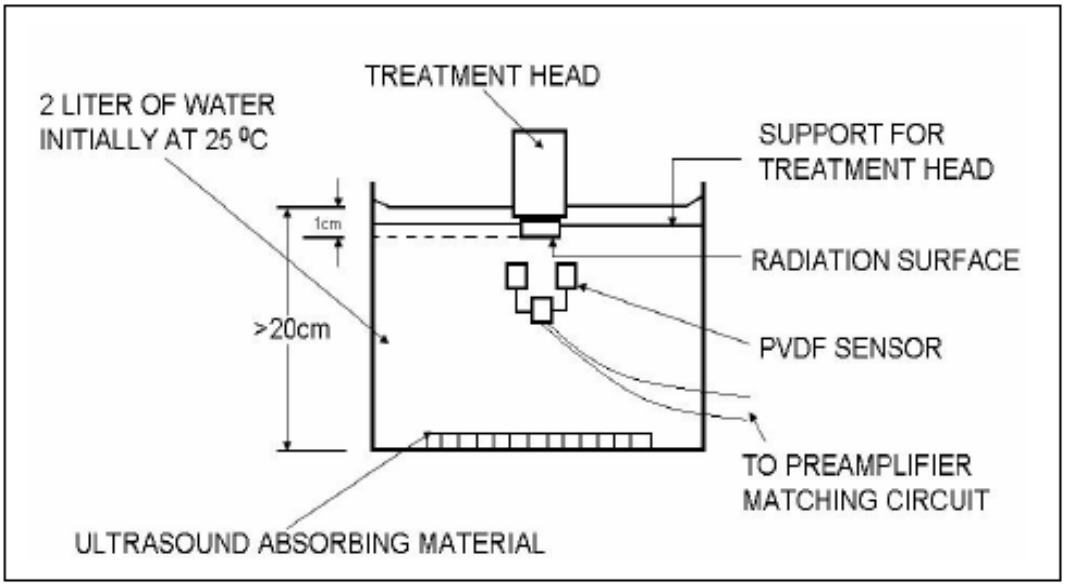

Figure 6-15 The designed of hydrophone

6.2.1 Flow of the design block diagram

Figure 6-16 shows the flow of the designed system. The ultrasound therapeutic device generates the ultrasound wave. This wave is be emitted by a treatment head in which connected to the machine with a probe. The treatment head puts inside the hydrophone power meter immersed about 1 cm in the water. The treatment head emitted the ultrasound by using the water as propagation medium to transmit energy. The PVDF sensors hand hang inside the water tank detects the ultrasound energy. The heat explore on the surface of the PVDF sensor transforms to the electrical energy. Then the electrode of the sensors is connected to the preamplifier matching circuit.

Before the preamplifier matching circuit build, it may need to measure the raw voltage of the sensors. These because I need to find out the amplify gain that I needed to amplify the measurement in the desired range. Then we also needed to measure the electrical impedance of the PVDF sensors. This is needed to ensure the sensors impedance is close match with the amplifier circuit to obtain the optimum results. The component in the

preamplifier matching circuit should in the range of 40 MHz. Apart from this; this circuit also is the interface between the hydrophone and the microprocessor.

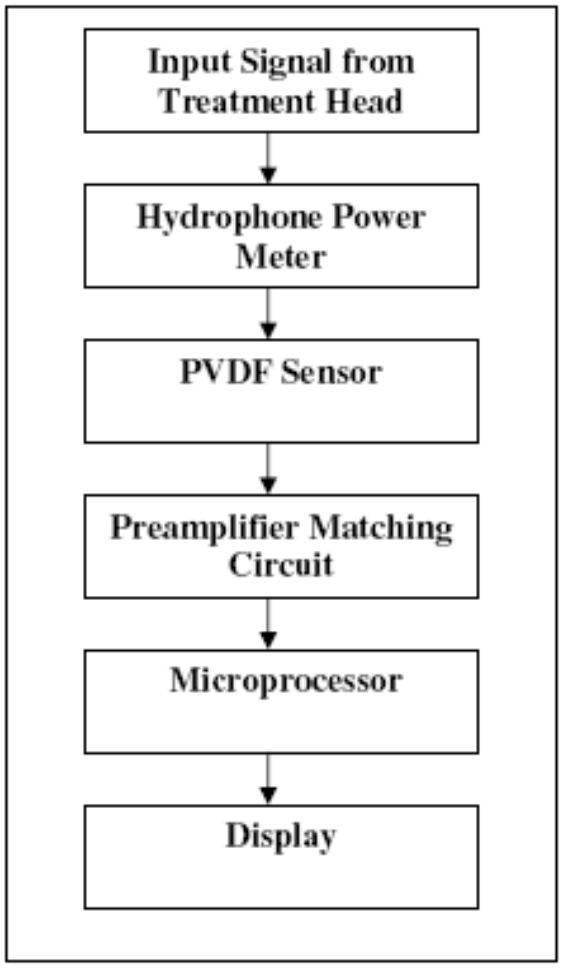

Figure 6-16 Block diagram of the designed system

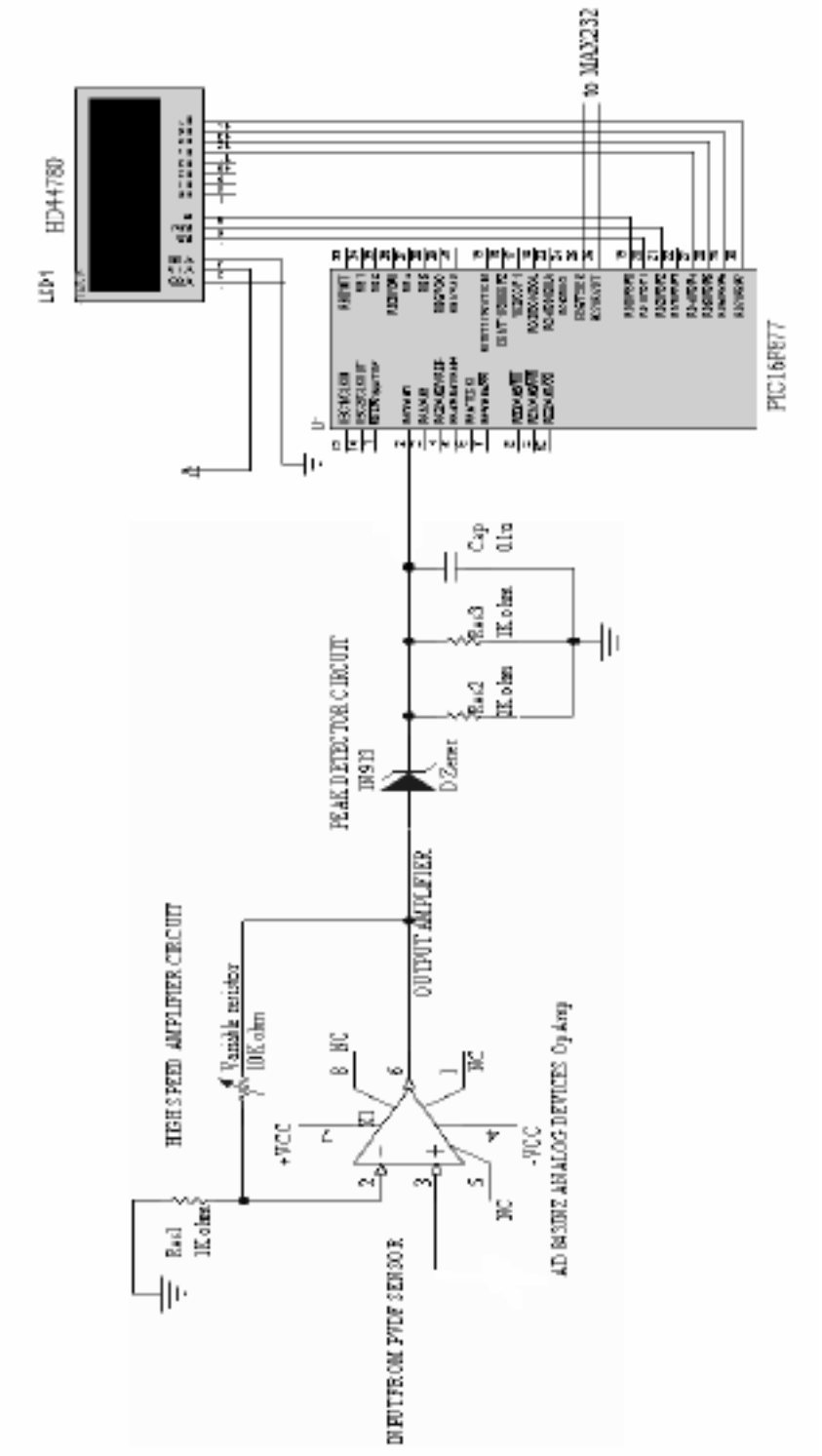

Figure 6-17 The process and control circuit for the design system

After the signal amplifier by the circuit, it is connected to the microprocessor. Figure 6-17 shows the process and control circuit for the preamplifier, microcontroller and LCD display circuit. This part includes two main components such as ADC and the microcontroller. The converter is used to digitalizing the signal to process by the microcontroller to display the measurement with a LCD display a JHD162A (with backlight) 2 x16 characters LCD which has the same pin configuration with Hitachi HD44780 (without backlight). Meanwhile for the microprocessor is the PIC16F877 in which the ADC is build inside the chip.

6.2.2 Hardware Approach

The hardware approach is include the PVDF sensor, the design of the amplifier matching circuit by using the AD 843 IC, the implementation of the peak detector circuit, the Microcontroller PIC16F877 and the implementation of the LCD display.

The PVDF sensor

The PVDF sensor that used in this project is named as Student Starter Kit and illustrated at Figure 6-18. This product comes from the Precision Acoustic Company located in United Kingdom. The PVDF and its co-polymers are the two most widely known piezo-polymers. PVDF exhibits strong piezo- and pyro-electric response, and has acoustic impedance that is much closer to water than conventional piezo-ceramic materials. These properties have made it highly desirable for the productions of ultrasonic sensors.

PVDF is chemically resistant, and mechanically resilient. Generally, PVDF should be kept and used below 60°C. An exposure to temperatures above 100°C is likely to remove the majority of piezo-electric behaviour. The sensor is a co-polymer of PVDF with Trifloroethylene. It has greater piezoelectric output than PVDF and has better thermal stability with reported operating temperatures as high as 100°C. The disadvantage with co-polymer is that it tends to be a more difficult material to fabricate and stress cracks/fractures can be problematic. Meanwhile the electromechanical coupling coefficient is 14% and the relative dielectric constant is 10 to 12.

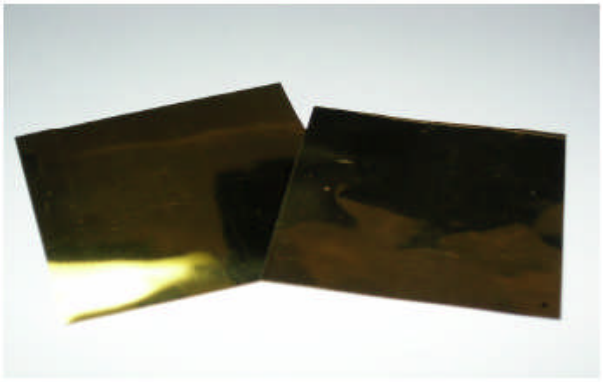

Figure 6-18 PVDF Sensor

Preamplifier matching amplifier and peak detector circuit

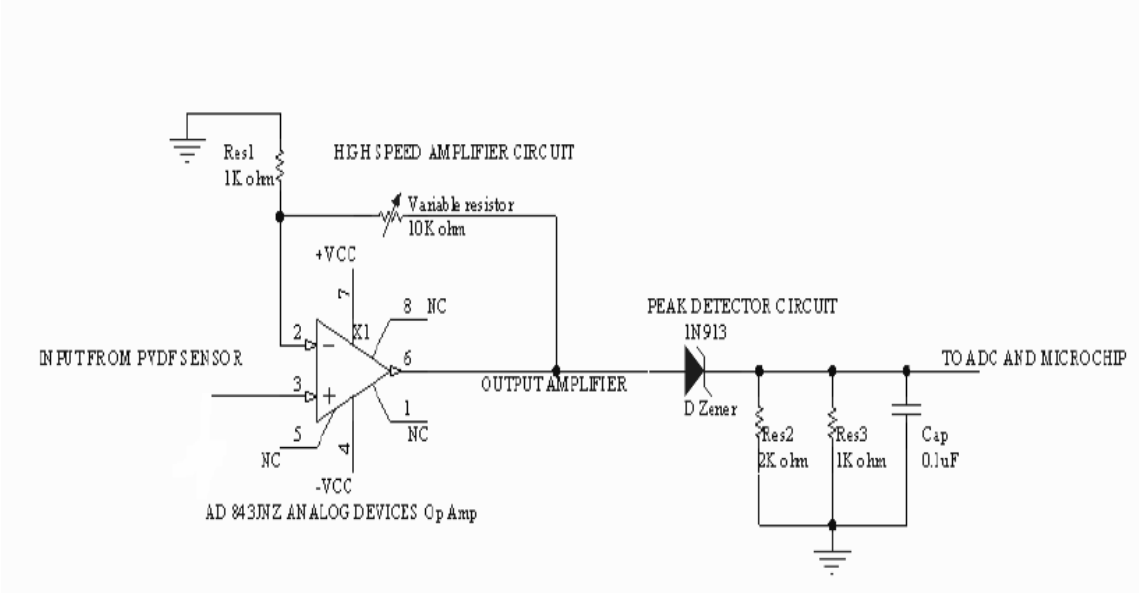

Figure 6-19 Preamplifier matching amplifier and peak detector schematic circuit

The Figure 6-19 shows that preamplifier-matching circuit is build by using the AD843 JNZ Op-amp integrated circuit. The AD843 is a fast settling, 34 MHz, CBFET input op amp. The AD843 combines the low (0.6 nA) input bias currents characteristic of a FET

input amplifier while still providing a 34 MHz bandwidth and a 135 ns settling time (to within 0.01% of final value for a 10 volt step). The AD843 is a member of the Analog Devices' family of wide bandwidth operational amplifiers.

These devices are fabricated using Analog Devices' junction isolated complementary bipolar (CB) process. This process permits combination of dc precision and wideband ac performance previously unobtainable in a monolithic op amp. The 250 V/ms slew rate and 0.6 nA input bias current of the AD843 ensure excellent performance in high speed sample-and-hold applications and in high speed integrators. This amplifier is also ideally suited for high bandwidth active filters and high frequency signal conditioning circuits. The amplifier circuit is function to amplify the signal come from the PVDF sensor. The Figure 6-20 showed the pin diagram for the AD843 IC.

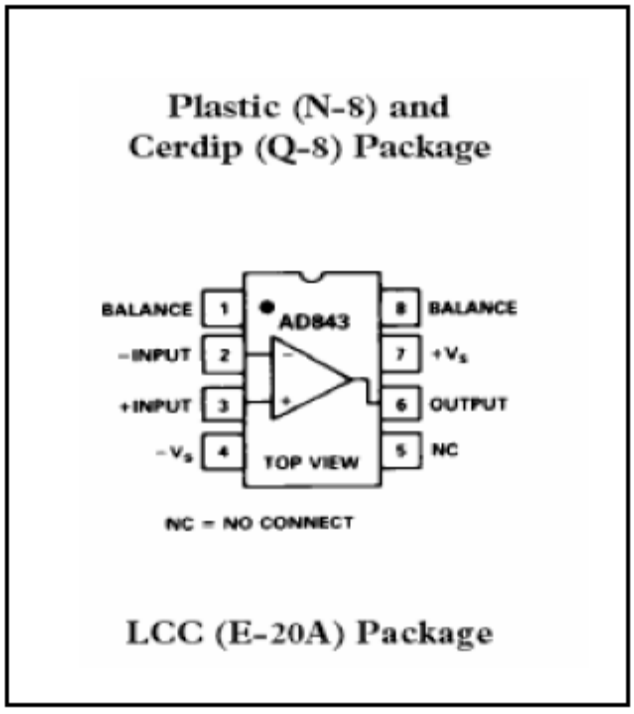

Figure 6-20 Pin diagram for the AD843 IC

Since the AD843 is a high-speed op amp, so it is able to process the signal with low noise output. In designing practical circuits using the AD843, the user must keep in mind that some special precautions are needed when dealing with high frequency signals. Circuits

must be wired using short interconnect leads. Ground planes should be used whenever possible to provide both a low resistance, low inductance circuit path and to minimize the effects of high frequency coupling. IC sockets should be avoided; since their increased interplead capacitance can degrade the bandwidth of the device.

Power supply leads should be bypassed to ground as close as possible to the pins of the amplifier. Again, the component leads should be kept very short. As shown in Figure 6-21, a parallel combination of a 2.2 mF tantalum and a 0.1 mF ceramic disc capacitor is recommended.

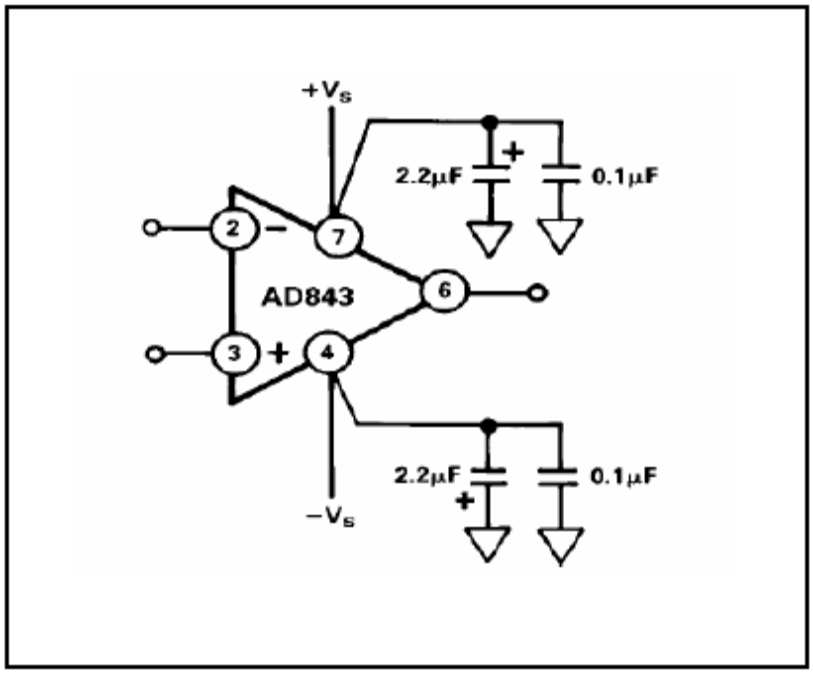

Figure 6-21 Recommended Power Supply Bypassing for the AD843

The peak detector circuit is used to generate the output from the amplifier circuit corresponds to the peak value of the envelope instead of individual modulating waveform cycles. This is shown in Figure 6-22. The output of the peak detector circuit is connected to the A/D converter of Microcontroller PIC16F877 to be digitalized and displayed by LCD. Beside that, the peak detector circuit is used to eliminate the negative phase signal because the Microcontroller PIC16F877 cannot digitalize the negative phase signal.

Negative value can make the microcontroller blow up, so this is the precaution step we should know. As we can see though the Figure 6-22**,** the negative phase has been eliminated and look like an envelope signal. The high-speed zener diode 1N913 is used for that circuit.

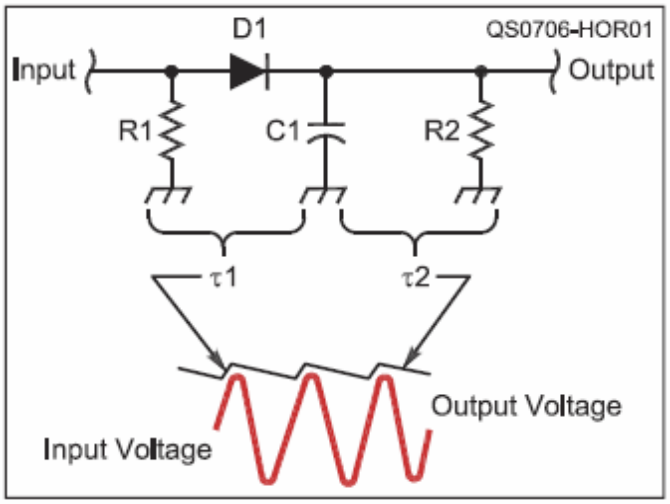

Figure 6-22 Signal generated by peak detector circuit

Microcontroller PIC16F877

The PIC16F877 is one of the most commonly used microcontrollers especially in automotive, industrial, appliances and consumer applications. In Figure 6-23, the block diagram of the PIC16F877 is illustrated. Due to the core feature of this microcontroller in which have the build in high speed analog to digital converter with frequency of 20 MHz, this microcontroller have been chosen to digitalize the signal of the peak detector circuit and drive the LCD display. The implementation of this circuit is illustrated at Figure 6-23 by connected to the input from peak detector circuit by using the pin 2.

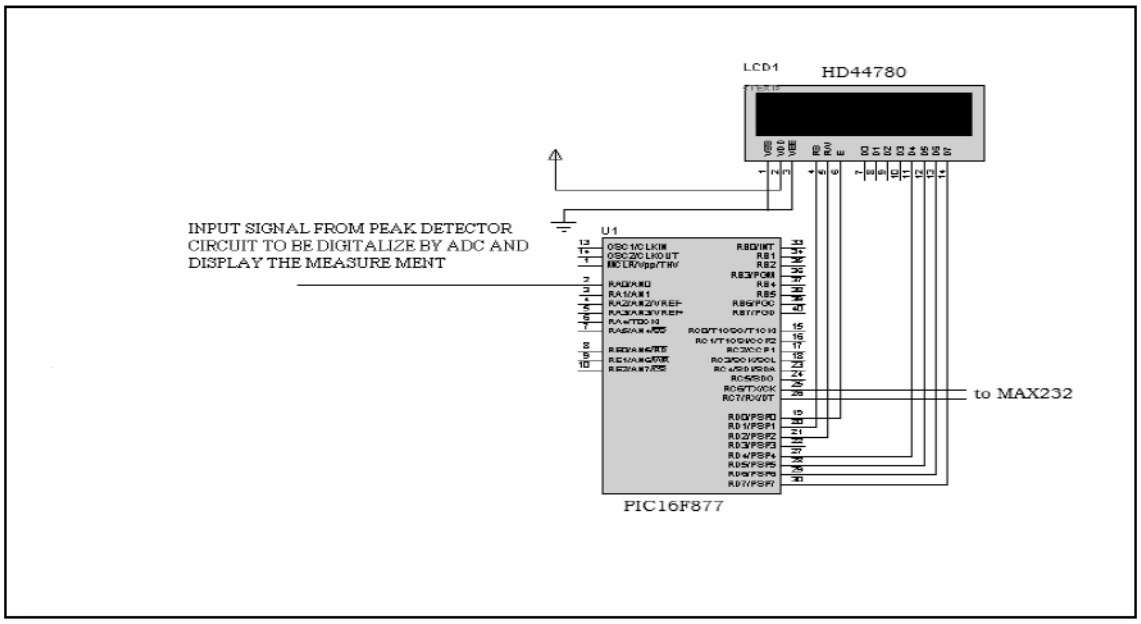

Figure 6-23 Connection between the microcontroller and peak detector circuit

LCD Display

HD44780 is a main controller to the LCD Character Display. This controller is located at the back of it. Since it is a controller, it has several instruction sets for user to control digital data interaction. We can control the LCD using 8-bit or 4-bit data. The pin 15 and 16 is for LCD backlight. They are optional. Switching on the backlight of LCD causes battery to dry up rapidly. The third pin (VEE) needs to be connected to a variable resistor to control the LCD contrast, while the R/W (read or write) pin is connected to the ground. R/S and E are connected to RD2 and RD3 to PIC respectively. For data communication pins, D0-D7 (8-bit) is connected directly to RB0-RB7 of the PIC.

6.2.3 Software Approach

In the software approach section, two softwares were used, they are the CCSC compiler and PICkit Programmer. The CCSC compiler is used to writing the source code to setup the ADC and drive the LCD display to display the measurement. Meanwhile, the PICkit programmer is used to program the hex file of the source code to the Microcontroller PIC16F877A.

The programming important parts of this project are in using the character LCD display and the A/D converter from the Microcontroller PIC16F877.

Character LCD Display

The flowchart below shows the basic programming algorithm of how to use the character display.

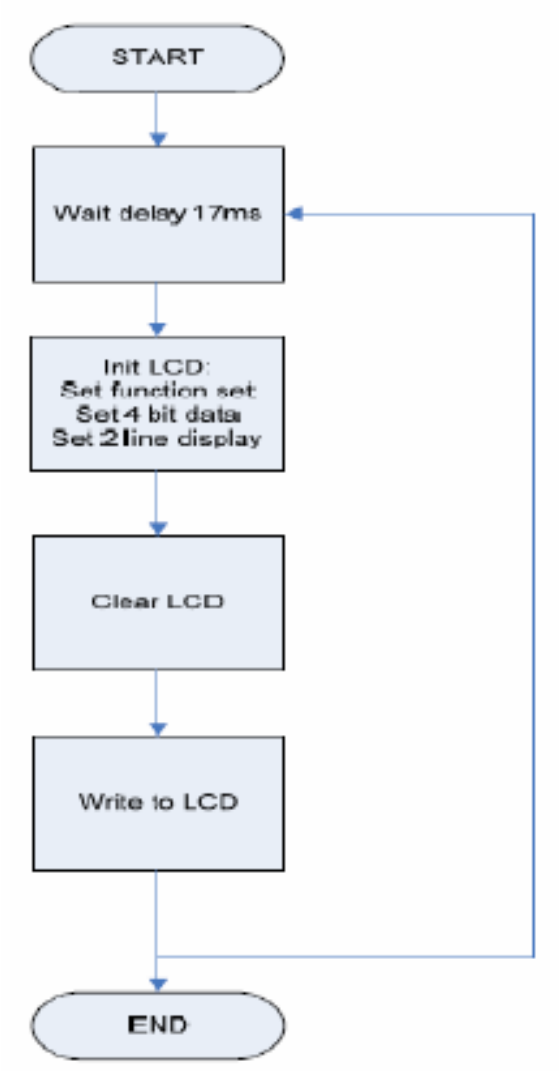

Figure 6-24 LCD set up

A/D Converter of PIC16F877

Flowchart below shows how to setup A/D converter and to read value of ADC from the Microcontroller PIC 16F877.

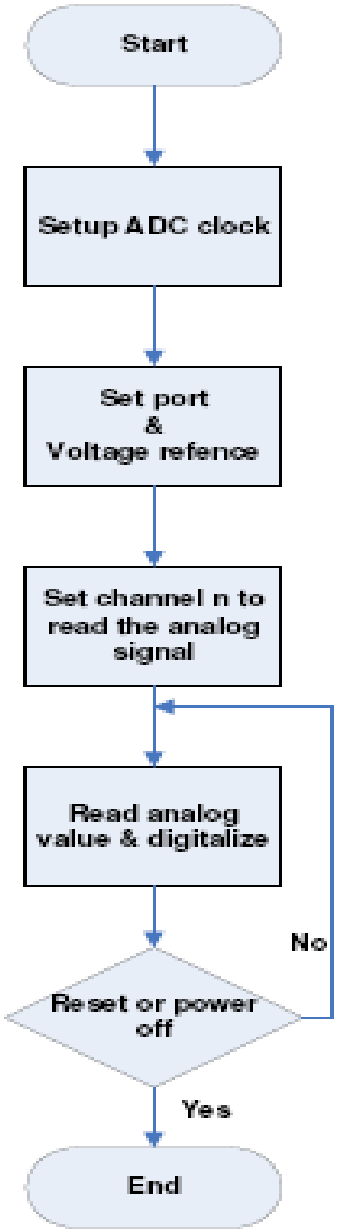

Figure 6-25 ADC setup

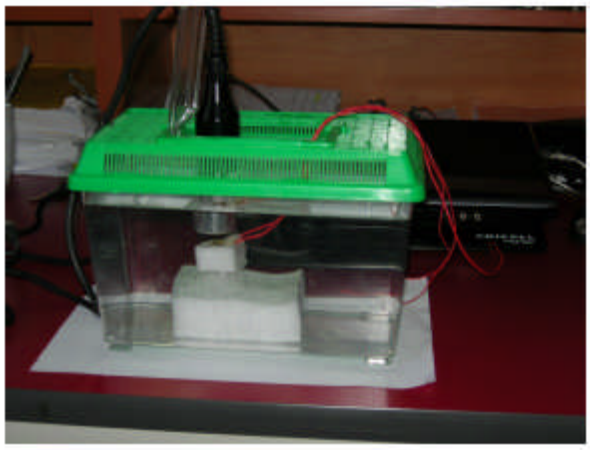

Figure 6-26 Hydrophone tank

Figure 6-26 shows the casing and the PVDF sensor which is the hydrophone. The casing is made by the aquarium plastic tank. The PVDF sensor and water are put inside the tank. As mention before, the water as a medium for the ultrasound transmits the energy to the sensor by emitted from the ultrasound therapy transducer. Then some of the ultrasound adsorbing material have put at the bottom of the water tank the prevent hot spot occur at bottom and prevent the reflection from the bottom. Then, two of the electrodes are connected to the preamplifier matching circuit.

6.3 Leakage Current Monitoring

One of the project objectives is to develop the real time leakage current monitoring system. This system is used to show the value of the leakage current in certain devices and alert the user who is handles the devices take a precaution steps before any kind of accident happens. Through this project, the better understanding of how to use the medical devices in safe condition has been achieved based on IEC 601 (International Electro-technical Commission). Then, this project also guides to the general principles of electrical safety testing of medical devices and to ensure that the operation of medical devices that used electrical power are in safe working order, and that is well tested on a regular basis to ensure its safety.

Leakage Current Monitoring is a system that measures the value of leakage current produce by the ultrasound diagnostic devices. The basic idea of the design is to increase the value of the leakage current in order to display it on the computer or LCD display.

6.3.1 Block Diagram

The core of designing the leakage current monitoring system is actually to design its leakage current meter. The figure 6-27 shows the block diagram of a leakage current meter.

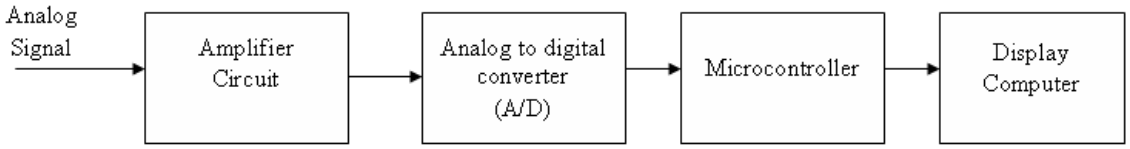

Figure 6-27 Block Diagram of the leakage current meter

There are four main parts needed to design the leakage current meter, they are current amplifier, analog to digital converter, microcontroller and display. Leakage current is an analog signal. Before converting the analog signal to digital signal, the leakage current is amplified by a current amplifier. Actually, the reason of doing this is the leakage current is too small to be detected by the microcontroller, it is need to amplify the leakage current so it can be detect by the microcontroller. After increase the leakage current, it goes to the ADC to convert the analog signal of leakage current to the digital signal. From the design, the leakage current meter is expected to detect the value between 10 nA to 10 mA. Therefore, in the analog to digital converter, we have set the appropriate frequency sampling that can convert the entire signal to digital signal.

The output of the analog to digital signal is then captured by the microcontroller. The function of the microcontroller is as interface to display the value of the leakage current measured. In the microcontroller, there is a short of programming. The programming does a task to send the level of the leakage current to the display. To display the leakage current there are two choices, seven-segment display and LCD display. The display must have at least seven digits for a high accuracy measurement. The easier way to know the

measurement result is displaying it to the PC. To display the value of the leakage current that have been measured on the computer, it needs more components for buffering and serial port communication. However, these components are not included in the design.

The Real Time Leakage Current monitoring system has been designed. This Real Time Leakage current monitoring system considers the International Electric Commission (IEC 60601) in the design. The Figure 6-28 shows the Real Time Leakage Current Monitoring System.

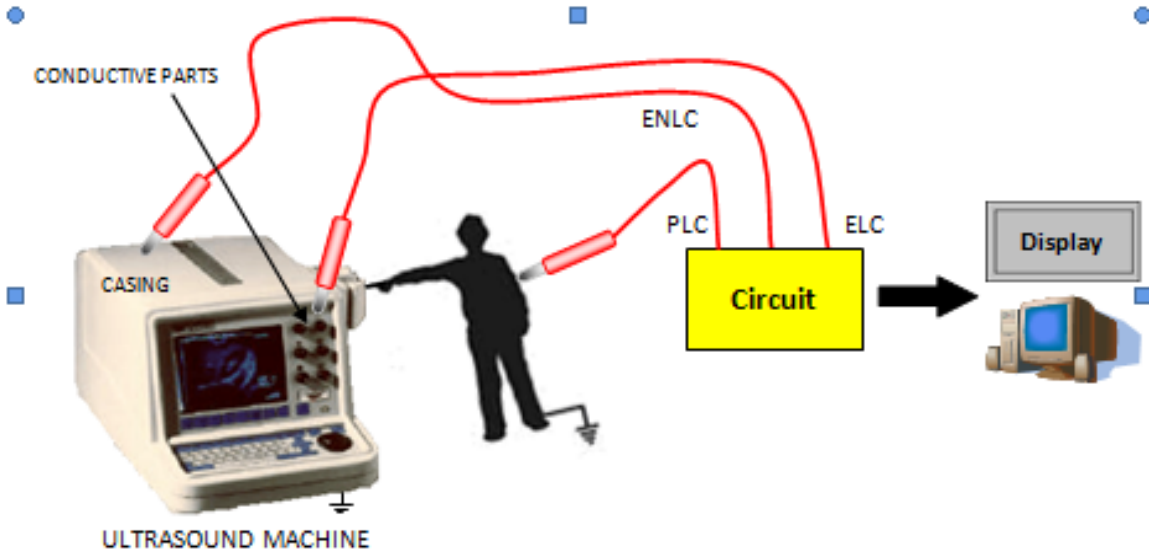

Figure 6-28 Real Time Leakage Current Monitoring System

The Real Time Leakage Current Monitoring consists of three main parts; they are ultrasound diagnostic devices, leakage current meter and the display. The ultrasound diagnostic machine is the equipment tested. This means that the leakage current produced by the ultrasound is be measured by the system. Then, the leakage current meter measures the leakage current and sends the measurement result to the display.

The Real Time Leakage Current Monitoring System is the design that measures three types of leakage current meter. The leakage currents that are measured by the system are earth leakage current, enclosure leakage current and Patient Leakage Current.

Earth Leakage Current

Earth leakage current is a very critical current. Earth leakage current measures the current flowing back to earth ground through the ground conductor of the line cord. To measure the earth leakage current, the probe from the circuit leakage current meter must touch the conductive parts of the ultrasound diagnostic devices that connected to the ground. Maximum measured current reading that should be appear on the display must be less than 500µA

Enclosure Leakage Current

Enclosure leakage current is essentially the leakage that a person would be subjected to when they were touching the certain device. Enclosure leakage current is measured between an exposed part of the device that is not intended to be protectively earthed and true earth. This kind of measurement measures the leakage to ground from exposed conductive parts of the enclosure such as connectors, exposed metal, knobs, shafts, etc. To measure the enclosure leakage current, the probe from the leakage current meter must touch the enclosure part of the ultrasound diagnostic devices such as connectors, exposed metals like screw or etc. Maximum measured current reading that should appear on the display must be less than 500µA.

Patient Leakage Current

Patient Leakage Current is the most critical of all safety measurements because the patient leads are directly contacted to the patient. For invasive devices, the leads are under the skin where the resistance is low. This measurement requires a very sensitive and accurate measurement device. The patient leakage current is also the most complicated and time-consuming of all the safety tests because of the number of possible combinations required to measure. Patient leakage current is measured between true earth and all patient applied parts, with tester connected to each applied parts in turn. To measure the patient leakage current, the probe from the leakage current meter must touch the human body. The patient must touch the ultrasound diagnostic devices. Maximum measured current reading must be less than 100µA for B, BF and 10µA for CF.

6.3.2 Component

In this project design, three components are used. The three main components are:

Amplifier Circuit

Current amplifier can be found in wide applications, particularly in a system that requires a low power supply voltage in communication system, instrumentation system, biomedical system, etc. Recently, many current amplifiers have been developed. The basic principle of the current amplifier is same like voltage amplifier, to increase the signal current level. In this project, the minimum input that can be detected by the amplifier is 1µA. The current goes through a 10 Ω resistor and converted into voltage. Then, the voltage is amplified by the amplifier to minimum voltage that can detect by the analog to digital converter. The minimum input can be detected by the analog to digital converter is 19.61mV, that means the gain of amplifier must be 1961. The following figure 6-29 shows the amplifier circuit.

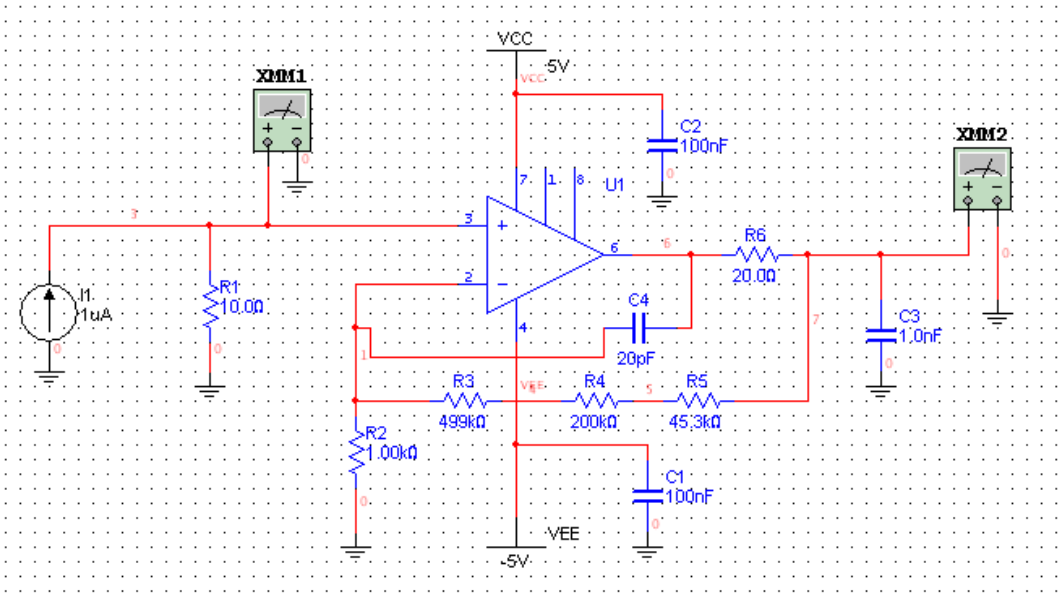

Figure 6-29 The amplifier circuit

Analog to Digital Converter

An analog-to-digital converter is a device that converts analog signals into digitalsignals. Analog information is transmitted by modulating a continuous transmission signal by amplifying a signal's strength or varying its frequency to add or take away the data. Digital information describes any system based on discontinuous data or events.

Computer that handles data in digital form requires analog-to-digital converters to convert signals from analog to digital before it can be read. One example is a modem that turns signals from digital to analog before transmitting those signals over communication lines such as telephone lines that carry only analog signals. The signals are turned back into digital form (demodulated) at the receiving end so that the computer can process the data in its digital format.

In this project, the analog to digital converter is already built in the microcontroller. Therefore, this can save money and space to use one single analog to digital converter. The resolution of the analog to digital converter is 8 bits. The reference voltage to generate analog to digital converter is 5V. The minimum voltage that can be detected by the analog to digital converter is 19.61mV. The maximum voltage that can be detected by the analog to digital converter is 5V. It means that the minimum input detected by the amplifier circuit is 1µA and the maximum input can be amplified by the amplifier circuit is 255µA or 0.255mA.

Microcontroller

The Microcontroller is the core component of the project. The microcontroller used in this project is PIC 16F877A. This microcontroller is produced by the Microchip Company. There are many several reasons why this chip is chosen:

a) Its size is small and equipped with many input and output ports without having to use a decoder or multiplexer.

b) It has low-power, high-speed Flash/EEPROM technology, wide operating voltage range (2.0V to 5.5V), commercial and Industrial temperature ranges, and Low-power consumption.

c) It is very simple and useful microcontroller because only 35 single-word instructions to learn. All single-cycle instructions except for program branches, which are two-cycle. The Operating speed for DC is 20 MHz clock input.

d) It can be programmed and reprogrammed easily because it has 100,000 erase/write cycles Enhanced Flash program memory typical and 1,000,000 erase/write cycles Data EEPROM memory typical.

e) Data EEPROM Retention lasts more than 40 years it is self-reprogrammable under software control.

f) It also has the Analog-to-Digital (A/D) Converter module on itself. Therefore, if the design needs a lot of ADC, it can be useful for design.

Figure 6-30 shows the pin description of the microcontroller PIC 16F77A.

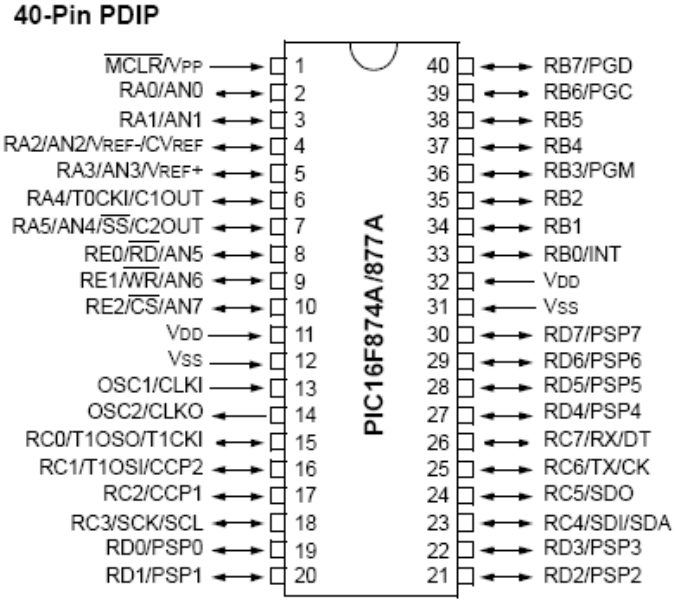

Figure 6-30 Pin description of PIC16F77A

In this project, only a few pins are used which are pin 1, 2, 11, 12, 13, 14, 25, 26, 31, and 32. Pin 1 is used to reset the PIC microcontroller. The analog signal from the amplifier circuit goes through input pin 2. Pin 2 purpose is to capture the analog signal before converting it to digital signal. Pins 11 and 32 are connected to the 5V VDD in order to generate the PIC microcontroller. Pins 12 and 31 are signal ground. Pin 13 and 14 are connected to the oscillator to generate clock. Pin 25 and 26's function is to transfer the data generate by the PIC microcontroller to the computer. The following figure 6-31 shows the pins used in the PIC microcontroller.

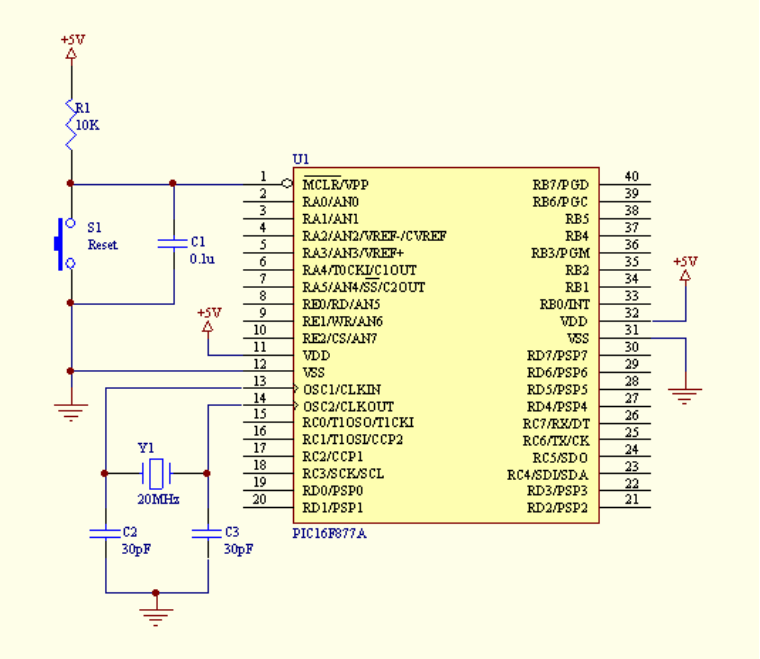

Figure 6-31 The PIC16F77A microcontroller circuit

Power Supply 5V

Most digital logic circuit and processor need a 5 V power supply. In order to get the 5V voltage, it needs to build a regulated 5V volt source. Usually we get the 5V voltage from the unregulated power supply from 9 volts to 24 volts DC. The following figure 6-32 shows the circuit to generate 5V voltage from the 9V battery.

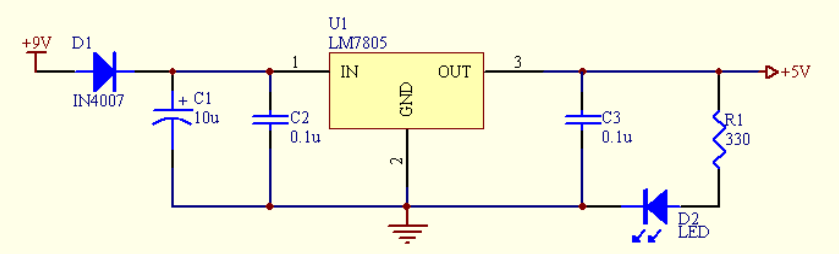

Figure 6-32 The Voltage Regulator circuit

LM7805 is a voltage regulator that generates regulated 5 V. The LM7805 can take input from range 7V until 30V. Then, it regulates the input voltage to be 5 V. Diode used in this circuit is used for voltage polarity and brownout protection. The function of the capacitor is to stabilize the voltage or as a ripper filter. LED is an indicator to show that the circuit is on. The resistor function is to limit the current through the LED.

MAX232 and RS232 Serial Communications

SCI is an abbreviation for Serial Communication Interface and as a subsystem of PIC 16F877A microcontroller. It provides RS232 serial communications with PC.

Same with the hardware communication, standard NRZ (Non Return to Zero) format also known as 8 or 9 data bits without and with parity bit. One stop bit is used. Free line is defined as the status of logic one. Start bit has the status of logic zero. The data bits follow the start bit. After the data bits, stop bit is placed with logic one. The duration of the stop bit depends on the transmission rate. It is adjusted according to the needs of the transmission. For the transmission speed of 9600 bps, the duration of the stop bit is 104µs.

In order to connect a PIC microcontroller to a serial port on a computer, it needs to adjust the level of the signals. The signal level on a PC is -10V for logic zero and +10V for logic one. Since the level signal on the PIC microcontroller is +5V for logic one and 0V for logic zero, we need intermediate stage that makse the level of voltage same. MAX232 is one chip designed to converts the signal from of -10V to +10V into the 0V and 5V.

Figure 6-33 and 6-34 show the schematic for MAX232, connection of RS232 and the circuit between MAX232, RS232 and the PIC microcontroller.

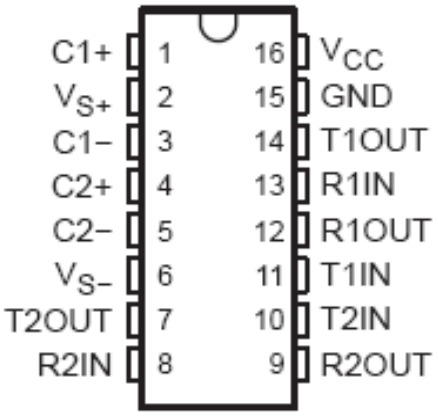

Figure 6-33 The MAX232 schematic diagram

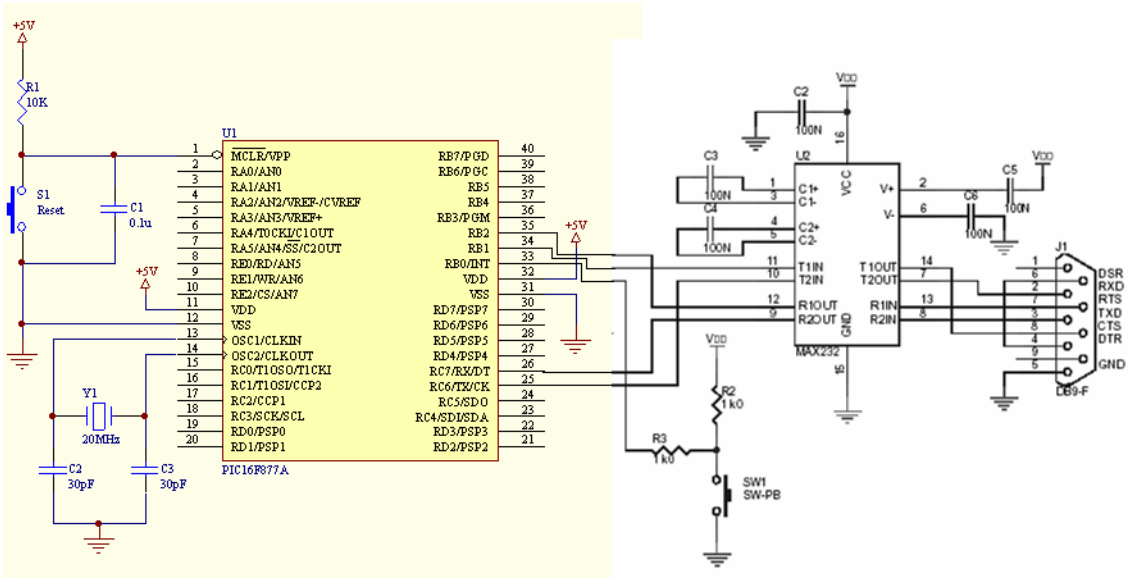

Figure 6-34 The connection circuit between MAX232, RS232 and the PIC microcontroller

6.3.3 Programming Implementation

In this project, there are two parts of programming implementations:

- Programming the PIC microcontroller in order to get the data from amplifier circuit and converting it into the digital signal
- Programming the PC to display the leakage current measurement result

PIC microcontroller programming

The compiler that is being used to program the Microchip PIC microcontroller is CCS-PICC C compiler. CCS- PICC C compiler is just one of many C compilers available to program the PIC. To start using CCS- PICC C compiler, the device type needs to be selected. Then, the analog input pin used in the circuit is selected. After that, the program is written. Figure 6-35 shows the flow chart of the making a program for the PIC microcontroller.

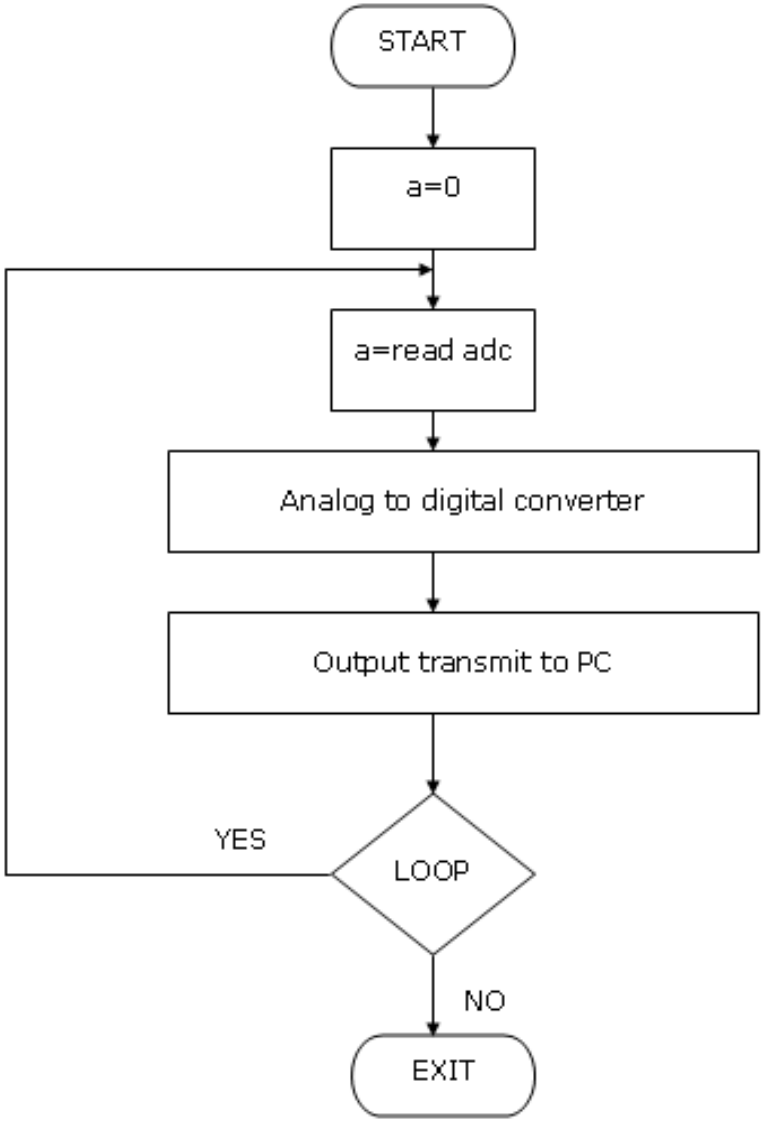

Figure 6-35 Flow chart of the PIC microcontroller

Start by declared a char which is a = 0. Then, set the char as read from the ADC in the PIC that means that read the analog signal. After that, convert the analog signal to digital signal. Lastly, transmit the data to computer. The super loop is used to set that condition is always TRUE. It means that the PIC keeps reading the input signal and transmit it to the computer.

PC Display

Visual basic 6.0 is used to display the data on the computer screen from the PIC microcontroller. The data from PIC microcontroller is transmit using RS232 cable to the communications port of the computer. The following Figure 6-36 shows the flowchart of the visual basic programming.

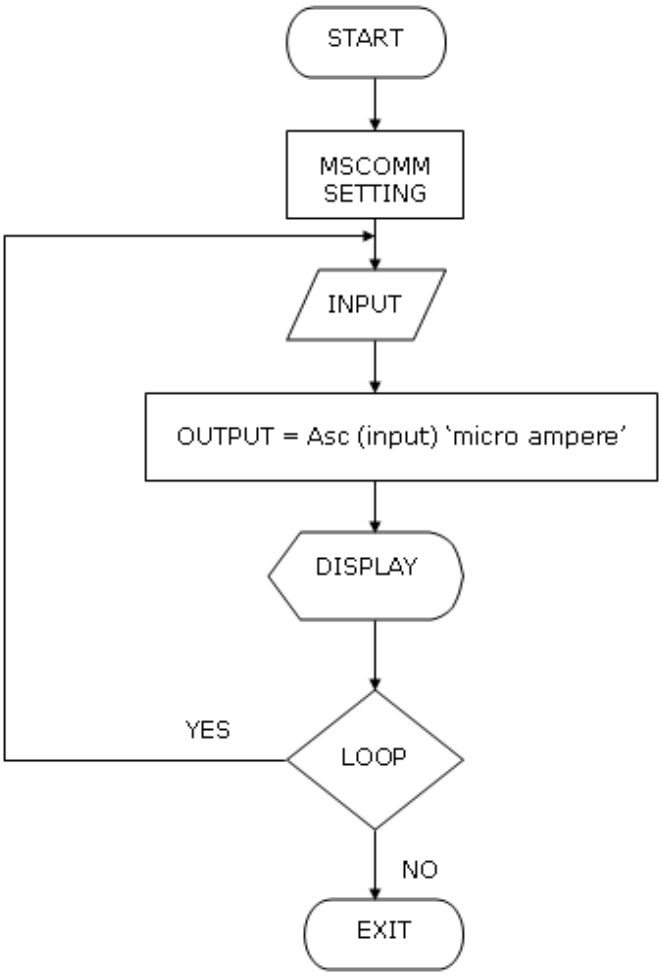

Figure 6-36 Flow chart of the Visual Basic Programming

First the MSCOMM setting need to been done first as a requirement to send data to the computer. Then, program gets the input data from the microcontroller. The second step is calculating. Lastly, it displays the data on the screen. The loop on the flowchart is always

TRUE which mean that the program keeps on update the data sent by the PIC microcontroller and display in.

Figure 6-37 shows the display of leakage current monitoring system for ultrasound diagnostic device on the PC.

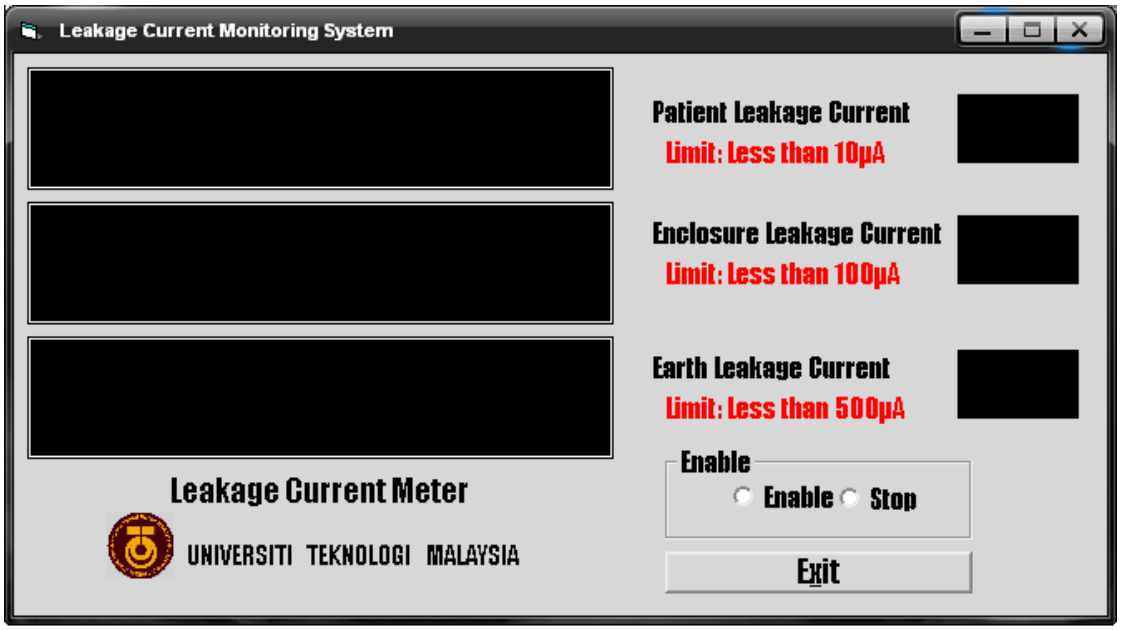

Figure 6-37 The display of leakage current monitoring system

As shown in Figure 6-37, there are three types of leakage current measured, they are patient leakage current, enclosure leakage current and earth leakage current. In the window, there is enable button to start the measurement and stop button to stop the measurement. Then, there also exit button if the user want to exit from the program.

If the user want to measure the patient leakage current, the system also show the limit of the patient leakage current, 10 microampere. On the left side of the limit, there is a leakage current meter for patient leakage current measurement and the right side of the patient leakage current is a condition for the patient leakage current measurement whether is exceed the limit or not.

For the earth leakage current measurement and enclosure leakage current, there is also same with the patient leakage current measurement. The left side of the measurement is the leakage current of each measurement. The right side of the measurement is made to check each measurement whether it exceeds the limit or not. As a conclusion, the display alerts the user to be aware of the leakage current when using the ultrasound device.

7 Conclusion

Low cost ultrasound machines for prenatal diagnosis have big market potential worldwide. Current low cost ultrasound machines are still lack in performance (quality) and safety. In order to improve the safety and quality of low cost ultrasound machines, a monitoring system has been developed. The monitoring system consists of ultrasound image quality measurement and improvement unit, leakage current measurement unit and ultrasound power meter.

The ultrasound image quality improvement and measurement unit called "sonoimprometer" has been developed to improve the image quality parameters including resolution, contrast and geometry accuracy. This meter is also able to measure some image quality parameters according to AAPM standard and the coming Malaysian code of practise for ultrasound in medical diagnostic. The parameters include dead zone, uniformity, depth of penetration, axial and local resolution, high scatter object diameter and vertical and horizontal distance. The sonoimprometer can be connected to the most low cost ultrasound machines which have video port.

Ultrasound power meter has been developed to measure the ultrasound power received by human tissue. We used PVDF polymer thin film as ultrasound sensor. The power meter is able to measure the ultrasound intensity up to 10 W/cm^2 with resolution of 1 mW/cm^2. It meets FDA and IEC requirement of ultrasound in medical diagnostic.

Leakage current meter has also been developed to monitor the patient enclosure and earth leakage. The meter is able to measure the electrical leakage current up to 500 µA with resolution of 1 µA. It meets IEC-60001-1 safety requirement of medical devices.

The developed system has been integrated and tested with several ultrasound machines available in clinic and laboratory. Test result shows that the system is able to monitor the image quality of ultrasound machine for prenatal diagnostic, monitor the ultrasound

power output and monitor leakage current as well as to improve the image quality of low cost ultrasound machines.

It is recommended in the near future to integrate the developed prototypes into one unit and propose this product as additional part of low cost ultrasound machine to be used in health care institutions in Malaysia.