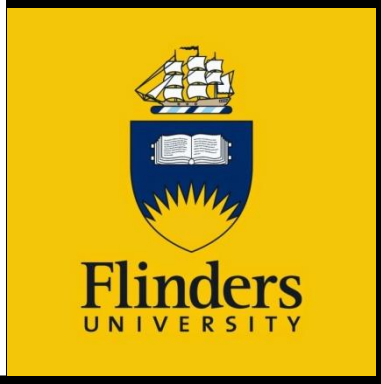

Ultrasound Based Blood Pressure Processing Monitoring and Acquisition

Master's Thesis

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16th October 2017

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5TH YEAR BACHELORS OF MECHANICAL (HONOURS), MASTERS OF BIOMEDICAL ENGINEERING
MASTERS THESIS

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This report was submitted on October 16, 2017 as partial fulfilment of the topics ENGR9700 (Masters Thesis) as required for completion of a degree of Bachelor of Mechanical Engineering (Honours)/ Master of Biomedical Engineering at Flinders University.

Created in Microsoft Word 2016

CAD Images in Autodesk Inventor 2017 (Student Edition), PCB Board and Circuit in Altium Designer 2016

Printed In Australia

EXECUTIVE SUMMARY

This thesis is a part of the Master of Biomedical Engineering presented to Flinders University and sponsored by Redarc Electronics (Automotive Engineering Company) in South Australia. The purpose of this thesis was to demonstrate a proof of concept in the use of ultrasound to measure blood pressure more accurately compared to existing technology.

The research undertaken in the initial phase of the project focused on the levels of inaccuracy present in existing devices in the market. These devices use manual Sphygmomanometers or digital oscillometric monitors. The manual devices' accuracy depends on the precision in the operators hearing of the Korotkoff sound [2]. Further, among the digital tools, studies conducted by Ruzicka [5], Wong [6], Shahbabu [7] and Menezes [8] have shown deviation in the accuracy and specificity of up to ±10 mmHg from the actual systolic (upper value) and diastolic (lower cost) pressure reading. According to the current standards set by British Hypertension Society and the European Society of Hypertension [9], for a digital monitor to be deemed accurate, it should have an error of ±3 mmHg and ±5% heart rate. These accuracy levels are not sufficiently achieved. Another aspect of blood pressure devices that needs to be addressed is the size of the cuffs used during readings. Currently marketed devices use three to four variations of sizes for use on the upper arm. Overestimation or underestimation of a measurement can occur if the cuff size is not a good fit; this has been the case in a number of studies [10], [11], [12] and [13]. Further ill-fitting cuffs induce pain during arm compression and hinder in-ambulatory monitoring of pressure readings.

The readings taken from digital blood pressure monitors are done by measuring the Mean Arterial Blood Pressure (MAPB). This is the pressure at which the cuff when wrapped around the wrist detects a significant change in the pressure. The systolic and the diastolic pressures are inferred from this. However, despite this technology, significant errors are made when estimate readings are taken.

The ultrasound concept devised here is based on placing the transducer on the wrist with the transmitted ultrasound signal reflecting from the source. The frequency of the reflected signal is different from the transmitted one. This change in the frequency is called the Doppler Shift.

Considering the limitations inaccurate recording of measurements in current devices, a proof of concept was undertaken to see whether blood flow could be analysed using ultrasound in order to find a relationship with the systolic and diastolic blood pressures. There was a requirement to design and construct a system which would analyse the ultrasound blood flow signal and the pressure applied to the wrist. These two signals can be overlapped to see the behaviour of the blood flow signal obtained through ultrasound or the Doppler shift in the frequency.

The system design includes three main components. First, a mechanical interface which would make the ultrasound transducer and pressure sensor sit on the wrist and apply pressure with a pumping mechanism. Second a valve to release the pressure after the occlusion of the radial artery. Finally, data acquisition to get the simultaneous reading of the pressure and the ultrasound for analysis. The significant part of the project was dedicated to building a proper acquisition system with driver circuit PCB for the pressure sensors and pump and a proper mechanical interface.

The signals were acquired and viewed in real-time using LabVIEW software. The post-processing of the signals was done using MATLAB. The MATLAB analysis incorporated a spectrogram analysis – a time and frequency overlapping analysis technique. Preliminary results showed a relationship between the ultrasound signal obtained and the occurrence of systolic and diastolic blood pressure, but confirmation of the results could not be satisfactorily justified due to time constraint. When the radial artery was completely occluded, there was no flow of blood which therefore caused no change in the Doppler shift or signal in the ultrasound. As the applied pressure was removed slowly, blood began to flow, producing high-frequency components in the spectrogram analysis. The magnitude of the high-frequency values increased to a point and then decreased as the pressure was reduced and blood flow became more laminar. The diastolic and systolic values were obtained from a standard BP monitor. When the results from the existing devices were compared to the ultrasound data, the SBP was predicted directly from the ultrasound signal. When the occlusion pressure was just enough to allow the flow of blood through the artery, there were changes in the time domain signal of ultrasound. In the frequency domain, it showed high-frequency components establishing a correlation between the occurrence of SBP and ultrasound. But in the DBP region, it was hypothesised that the magnitude of the high-frequency components would become constant but rather they followed a pattern where the high-frequency components started to decrease in the magnitude with each beat. The data collected showed such relation but could not be confirmed.

Based on the research, design and result outcome, it is recommended that further data collection from a larger population with better signal processing and further development of a more sophisticated device is undertaken. Limitations and sources of errors were present in this study due to use of an old ultrasound based Doppler system. Further research and development work to be undertaken will include further testing of this concept. This could provide a means of taking accurate pressure measurements in hospitals, healthcare departments, and defence and in ambulatory services.

DISCLAIMER

I certify that this thesis does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

Sitansu Sekhar

Date: 10th April 2018

ACKNOWLEDGEMENTS

I would like to acknowledge the CEO of Redarc Electronics, Mr. Anthony Kittel, for giving me the opportunity to undertake this project as a part of my Master's Thesis. His enthusiasm for the growth and development of the company into the medical field has helped in the research and development of innovative concepts.

Prof. Karen Reynolds, Dean (Research) of School of Computer Science, Engineering and Mathematics, for her valuable advice, insight and acceptance to undertake this industrial based project as a part of the Master's thesis.

The team of Prof. Karen Reynolds – Ms. Jodie Hobbs and Dr. Angus Wallace for their guidance and supervision on the project through the electronic design and signal processing. They provided support through each stage in the development of the project.

I am thankful to Mr. Jacob Brackenridge, manufacturing engineer, for his support and knowledge in the electronic and mechanical aspects of the project. Mr. Jacob Brackenridge, with his background in Biomedical Engineering, provided innovative ideas and helped in understanding many key concepts regarding the method of this project.

I would like to thank Mr. Wade Nathan, the procurement in-charge of Redarc Electronics for his support in procuring products and materials for the development of this project.

I would also like to extend my gratitude towards the help provided by a list of design and manufacturing engineers, Tom Cross, James Albrechtsen, Alain Baume, Kyle Dix and Neil Reynar at various stages of this project.

Finally, I would also like to acknowledge, Ms. Sai Lekshmi Chandramohan for helping with the editing of the thesis.

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ABBREVIATIONS

BP – Blood Pressure

HR – Heart Rate

BPM – Blood Pressure Monitor

SBP – Systolic Blood Pressure

DBP – Diastolic Blood Pressure

US – Ultrasound

DAQ – Data Acquisition

NI – National Instruments

PCB – Printed Circuit Board

MABP – Mean Arterial Blood Pressure

MAP – Mean Arterial Pressure

STFT – Short-Time Fourier Transform

FFT – Fast Fourier Transform

DFT – Discrete Fourier Transform

1. INTRODUCTION

Blood is pumped out of the heart at a certain pressure. The functioning of the heart is determined by the pressure values. Further, blood pressure helps in controlling the fluid-ion balance in the body. Blood pressure is one of the vital signs that are observed to determine whether the body is in homeostasis. It is also monitored for physio-pathological disorder purposes such as those associated with the renal and cardiovascular system. The importance of blood pressure measurement can be seen when visiting a medical practitioner, where the heart rate (pulse) and the blood pressure are two of the first parameters being measured. Variations of blood pressure outside of the normal range give insight and clues to various diseases. With growing education and awareness, there is a significant proportion of the population who invest in blood pressure monitors for home/personal use. On a global scale, the market of the blood pressure monitor is estimated to be around $2.6 billion as per a 2020 forecast from the Global Industry Analyst [14]. Omron Medical, one of the leading brands in the development of home blood pressure monitors, covers about 50% of global blood pressure monitor sales with 200 million blood pressure monitors sold thus far [15].

With the growing sales of these monitors around the world, accuracy and the efficiency of the measurements taken, especially in emergency and paramedic settings, are of crucial importance. Additionally, doctors require accurate readings of blood pressure in their practice, especially specialists in fields such as nephrology and cardiology. Existing devices such as the digital oscillometric monitor and sphygmomanometer have been used for a long period, owing to their simplicity in usage. Sphygmomanometers are based on listening to the Korotkoff sounds which occur due to the pulsatile laminar and turbulent flow of blood [2, 16]. Comparatively, digital blood pressure monitors work based on the oscillations caused due to the pulsation of flowing blood. These pulsations result in variation in the pressure in the cuff, which helps in observing the region where the mean arterial blood pressure occurs. The systolic and the diastolic pressures are mathematically modeled through an algorithm based on this pressure. The algorithm to deduce SBP and DBP from the MAP which involves in taking into consideration ratios above and below MAP [5, 17]. The processes involved in sphygmomanometer-based pressure measurement are subject to a high degree of error. This is

because the result depends on the operator's hearing capability. Considering this limitation, specialists and doctors require a technique to take measurements as accurately as possible. Stemming from this need, research has been carried out on ways to measure blood pressure more accurately, either by using optical laser technology, tonometry, ultrasound or electromagnetic radiation. Ultrasound consists of non-invasive, non-ionising, acoustic waves and has been extensively used in imaging technology. It has been implemented well in the development of blood velocity profiles. At present, ultrasound is used in the measurement of systolic blood pressure in veterinary science and practice. It has used in providing data from the regions where the flow of the blood can be detected and diastolic pressure not considered to be an important component [18]. Haberman et al. have provided significant comparisons in the uses and benefits of ultrasound measurement techniques over the oscillometric method. However, research in the use of ultrasound specific to human needs has not yet been researched and tested exhaustively. Based on the principles of ultrasound, an idea was developed by Dr. Kejur Fred, a nephrologist at the Women's and Children's Hospital, Adelaide, South Australia and Mr. Terrence Cody, an electronics engineer. Their idea was to measure blood pressure using the Doppler Ultrasound Blood Flow Monitor. Claims were made in a provisional patent regarding this device and its ability to measure systolic and diastolic blood pressure. But lack of proof led the two to pass on the idea to Redarc Electronics, a South Australian based electrical-automotive company to conduct further research and prove the concept. Redarc Electronics is the key sponsor of this project. Redarc has been involved in the research and development of innovative devices and competitive products over the last 20 years and is strong in its development of electronic based automated systems [19]. With their growing market and rapid growth in the world medical industry, Redarc accepted to invest in a simple, cutting-edge technology that could provide accurate readings of blood pressure.

Based on research reviews of the work which has been performed in the past on the accuracy of ultrasound, it is hypothesised for this proof of concept-based thesis that the direct interaction of the ultrasound signals with the flow of the blood would help in better prediction of the characteristics of the flow of blood under the change in the pressure in the cuff. This would further help in providing accurate where the SBP and DBP occur as supported by studies done on application tonometry using ultrasound [20-23].

Over the course of the proof of concept, there was a need for the development of a proper system which would help in the collection of data from people. This would assist in developing an algorithm to detect the SBP and DBP from the ultrasound profile obtained from candidates. The objective of the data collection was accuracy along with the reduction of any motion artifacts or interfering noises which might be caused during the process of acquisition. In the acquisition process, the development included the mechanical interface, electronics circuit development along with the acquisition programming and algorithm to detect the SBP and DBP. The detection of SBP and DBP depends on data collection which is touched by the Results and Post Processing section of the thesis but not wholly proved. An ethically aligned approach was followed at all times during the building of the data acquisition device, with safety being of utmost importance as well as an assurance of no inflicted pain.

1.1. PROJECT SCOPE AND CONSTRAINTS

1.1.1. INITIAL PROJECT JUSTIFICATION AND HYPOTHESIS

The measurement of the blood pressure is done using the Doppler Blood Flow Ultrasound Method. This method was expected to increase the accuracy of diastolic and systolic pressure. The existing blood digital pressure monitors use standard approximation algorithms which gives large errors in the readings of the SBP and DBP. To reduce the error, this project was based on looking into development of a system which would help in studying the ultrasound output when pressure is varied on the wrist. This would further enhance in obtaining SBP and DBP results using ultrasound with reduced errors as presented by the existing devices.

The hypothesis for this research is to study the effect of Doppler ultrasound frequency changes around the SBP and DBP regions and establish any correlation. It is expected that:

a. When the pressure is applied on the wrist, there would be no signal from the ultrasound when the blood is not flowing through the artery
b. When the pressure applied is enough to lead the blood flow through the artery, changes would be observed in the ultrasound signal in time and frequency domain
c. When the pressure has decreased to the level of diastolic pressure, the frequency changes from the ultrasound would become constant

1.1.2. PROJECT CHARACTERISTICS AND REQUIREMENTS

The focus of the project was to build and conduct signal processing using an ultrasound-based blood flow monitor which could obtain a very accurate blood pressure reading. The device would be aimed for those in the medical field in specialist centres and in defence organisations. The requirements enlisted below are taken into the consideration from a consumer perspective and developer perspective:

1. Collection of data to process SBP and DBP along with heart rate
2. Small cuff
3. Pain-less
4. Data acquisition system
5. Signal processing

1.1.3. PROJECT DELIVERABLES

The product development ideation was done through the support of Redarc Electronics and Dr. Kejur Fred, nephrologist, Women's and Children's Hospital who developed a set of requirements for the key development:

- *Ultrasound* for studying the detection of the SBP and DBP. This would incorporate the signal generated from the Ultrasound Doppler flow meter to possibly detect the systolic and diastolic pressure along with constant monitoring of the heart rate. The signal processing phase would include implementation of various filtering and detection circuits along with a micro-processor to digitally process the signal outcome and provide the results.
- *Micro-pumping mechanism* for application of pressure. To apply pressure to the wrist in a portable system, a piezo-electric driving circuitry was to be developed which would control pumping and release pressure accurately to detect signals.
- *System Development* to collect data from people to process the signals and establish a correlation with the data generated by the ultrasound blood flow meter and the pressure applied on the wrist.

1.1.4. PROJECT COMPLETION CRITERIA

The completion criteria for the project was based on successful completion with a proper data acquisition unit along with signals acquired from subjects for further processing. Few of the initial project requirements had to be modified as the present of time constraint. Further, the project continuation is dependent on the equalisation trends observed and verified among the data acquired.

1.1.5. CONSTRAINTS

- Time: Definite duration of the project
- Material Procurement: Fabrication required for biocompatible material of acceptable grades
- Design and development of PCB boards and mechanical components within the specified period

1.1.6. ASSUMPTIONS

Some of the assumptions developed at this point is to be researched upon to reach a definite set of conclusions:

- Availability of bio-compatible materials in the market can be used for the development of the mechanism of applying point pressure
- No such devices and patents have been manufactured or filed using a similar concept

1.2. BACKGROUND MOTIVATION AND PROVISIONAL PATENT

The project was initially termed by Dr. Kejur Fred, nephrologist at Women's and Children's Hospital, Adelaide. Being a nephrologist, the accurate measurement of blood pressure has always been a matter of concern, especially with infants whose blood flow is not in the audible range to be measured by a manual sphygmomanometer. Further adding to this, his idea was to help the defence sector where the measurement of the blood pressure accurately would not be possible in emergency using the manual technique. Digital oscillometric techniques pose greater inaccuracy as they are based on an estimation method rather than direct measurement of the SBP and DBP.

Another factor associated with the development of this project was that the current marketed sizes of cuffs provide an over-estimation or an under-estimation of the pressure recorded. Not only are there errors in the pressure readings but the compression of the ill-sized cuff on the arm inflicts momentary pain. Obese or overweight people, with a high level of fat content in the upper arm are hesitant if their pressure is required to be taken on a constant basis. Even the current digital monitors as stated by the doctor, are not only inaccurate but also inflict pain.

The two existing and popular techniques that measure blood pressure have been in the market for a long period, but with advancements in technology, their accuracy levels are being challenged. Based on these discussion points and based on the knowledge of use of ultrasound to observe the flow of the blood, a provisional patent was filed in 2015, under Artripress Ultrasound Blood Pressure Monitor. The patent document was submitted to Hills Innovation

Centre for further evaluation. Hills Innovation disregarded the document based on the claim that further research and proof of concept was required before a full patent could be issued on the device. The key points stated in the provisional patent and the reasons for it not able to prove the concept has been discussed under Chapter 1.

1.3. SUMMARY OF DOCUMENT

This document contains research and design work undertaken to develop a device which can collect ultrasound data of blood flow and the effect of the application of pressure to observe the changes in the Doppler signals received. In Chapter 2, an in-depth literature review has been undertaken which highlights the different types of devices available in the market, as well as the pros and cons of those devices based on the accuracy and ease of use. It also focusses on current research which is being undertaken for the use of ultrasound to measure different properties of blood flow. Many of these can be applied to the measurement of blood pressure. Further, the literature review discusses signal processing techniques which can be used in analysing the Doppler frequency shift received the pressure on the wrist is varied over the period. Processing techniques include the short-term Fourier transform (STFT) and spectrogram analysis method. A part of the literature review has also been dedicated to the consequences and benefits of measuring the pressure on the wrist and size of the bladder for the application of the pressure. A summary of the review has been presented under Appendix B, which looks over the different studies which have been carried out on the optimal size of the bladder and the accuracy of measuring the blood pressure on the wrist.

In Chapter 3 and 4, the design technique which has been undertaken has been discussed. It includes the design of a data acquisition system, including the mechanical interface on the wrist, consisting of the ultrasound transducer and the pressure sensor, along with the accurate placement of the sensors. The controller system incorporates the circuitry and the PCB which runs the pump and pressure sensor. In further design work, a PCB was developed which

consists of the amplification circuit for the pressure sensor and the driving circuit for piezoelectric micro-pump.

In Chapter 6, the signal acquisition has been explained where the signals from the pressure sensor and the ultrasound blood flow monitor are acquired and sent to the National Instruments DAQ USB based unit. From here the signals are processed in LabVIEW to observe real-time signals and the data is sent to MATLAB to obtain an accurate result. This is done by overlapping the signals from the two sources and seeing the occurrence of the systolic blood pressure and the diastolic blood pressure. For these purposes, a LabVIEW real-time acquisition program was developed.

The collection of the data done over the period, any equalisation trends observed, and the results inferred have been discussed in the later chapters, along with future work which is expected to be undertaken such as further testings to prove the concept, patent filing and the development of a commercial device.

2. LITERATURE REVIEW

The current literature review has been conducted to consider existing research being carried out in the field of ultrasound to detect blood flow and relate it to the blood pressure through the fluid flow characteristics of the blood.

This section has been divided into current research being carried out in the field of ultrasound blood flow measurement and the signal processing techniques. The review has been divided into sections which explains the background on the necessity of taking the blood pressure, the flaws in the existing devices which further includes the sources of errors given by the various sizes of cuffs used and the location of measurement, how ultrasound can be utilised, and current research being carried out using ultrasound. Finally, it explains the signal processing technique which can be utilised for analysing the ultrasound signals to give any correlation with the blood pressure or the flow of the blood. The scope of the search was limited to the articles presented after 1995 with some exceptions based on the reliability and usability of the research conducted prior to this period. Computerised searches were done from the following databases to find the relevant articles:

- PubMed
- Google Scholar
- Institute of Electrical and Electronics Engineering (IEEE)

2.1. BLOOD PRESSURE: PHYSIOLOGICAL SIGNIFICANCE

The heart is the organ which is responsible for the making the blood circulate the body in the systemic circulation and to lungs in the pulmonary circulation. When the heart compresses to pump the blood out, it reaches a maximum pressure level which is the systolic pressure. As the heart empties, the pressure at which the blood is being pumped decreases making it reach a minimum pressure level which is the diastolic pressure. The systolic pressure is measured at

120 mmHg while the diastolic pressure is estimated around 80 mmHg in a healthy individual [1].

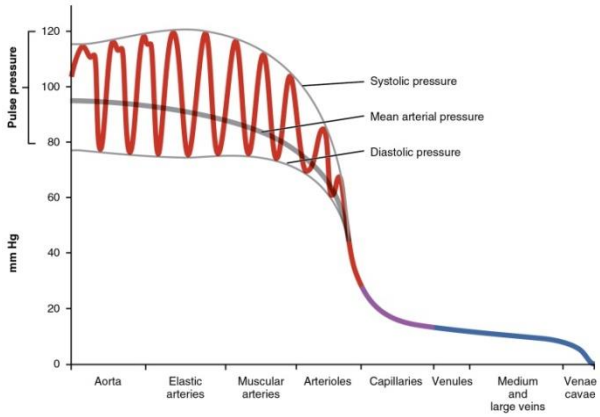


FIGURE 1: PRESSURE VARIATION IN BLOOD VESSELS FROM ARTERIES TO VEINS [1]

The pressure in the primary arteries increases approximately to 120mm Hg and then decreases to about 80mm Hg. In the cases of hypertension and hypotension, the systolic and diastolic blood pressure might be lower or higher than these standard values. Due to this change in pressure, the blood in the arteries flows in a pulsatile nature. Figure 1, shows the variation of the blood pressure in the arteries through the following vessels. As the blood flows through the vascular system, the pressure decreases due to frictional losses. Arteries have the highest pressure while there is a significant drop in the pressure in the arterioles because of the resistance they provide. Finally, the veins have the lowest pressure. The blood flow rate decreases considerably [1].

This rapid increase and decrease in the pressure is felt like a pulse generated when the left ventricle pushes the blood out into the aorta. A pressure wave rushes through the fluid arteries. This wave travels ten times faster than the blood itself. This pulse is felt in the wrist and neck. It tells the number of times the ventricles are contracting to eject the blood and the heartbeat is inferred. The amplitude of this pressure wave decreases with an increase in distance because of friction. This pulse pressure is mathematically given by:

$$Pulse\ Pressure = Systolic\ Pressure - Diastolic\ Pressure \ldots (1)$$

The significant part to focus on this project is the arterial pressure as that signifies the pressure at which the ventricles are pumping the blood out of the heart. It is the driving pressure. Ventricular pressure measurements are hard and invasive techniques would have to be used to do any analysis. Instead arterial pressure is used to reflect the ventricular chamber pressure. Due to the pulsatile nature of the blood flow, mean arterial blood pressure is used for the representation of the driving pressure.

Mathematically the mean arterial pressure is defined as the time average of arterial blood pressure, and the equation is given by [5]:

$$MAP = \frac{1}{T}\int_0^T P(t)dt \ldots (2)$$

Clinically it is expressed by the following formula or visually represented in figure 2:

$$MAP = P_{diastolic} + \frac{1}{3}\left(P_{systolic} - P_{diastolic}\right) \ldots (3)$$

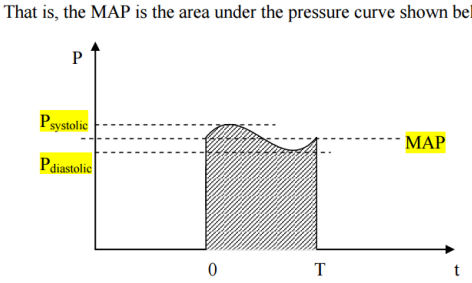


FIGURE 2: SYSTOLIC, DIASTOLIC AND MEAN ARTERIAL PRESSURE. SBP AND DBP ARE MEASURED USING APPROXIMATION FROM THE MAP [1]

2.2. COMPETING TECHNOLOGY

Several types of blood pressure monitors are available in the market. The gold standard mercury sphygmomanometer (being banned in European countries), aneroid sphygmomanometers, digital blood pressure monitors and the medical grade invasive catheters are the main categories of the devices which are being used extensively by healthcare professionals. With growing advancements in the technology, different methods are being developed to get highly accurate readings of measuring the blood pressure. This is especially needed by specialists such as the nephrologists and cardiologists where blood pressure plays a pivotal role in the diagnosis. Since the project is based on developing a portable blood pressure monitor using the concept of ultrasound, a comparison must be developed to the existing non-invasive portable techniques and other techniques available in the market.

2.2.1. INDIRECT BLOOD PRESSURE MEASUREMENT – ANEROID/MERCURY SPHYGMOMANOMETERS

Indirect measurement of blood pressure measures the intra-arterial pressure non-invasively. This measurement is done either through the palpation technique which involves feeling through the finger or auditory detection through a stethoscope. An inflatable cuff is used which is connected to an aneroid or mercury gauge and a rubber bulb for inflation of the cuff. When the cuff is inflated using the bulb, it applies pressure on location in which has been wrapped. As the pressure increases, it compresses the underlying blood vessel mainly the artery. The occlusive cuff is inflated until the pressure is well above the systolic pressure with no blood flowing through. This pressure is then slowly bled off. As the pressure at which the cuff is compressing the artery decreases, this leads to initiation of the flow of blood. Due to the pulsatile nature of the pressure waves, the blood pressure fluctuates between 80mm Hg and 120mm Hg, when the systolic peaks are higher than the occlusive pressure of the cuff, the blood spurts under the cuff causing a palpable pulse in the wrist (can be felt through the sensation of touch). If a stethoscope is being used audible Korotkoff sounds are generated by the flow of blood and vibrations of the vessel under the cuff [2, 6].

The manometer pressure at the first detection of the pulse is the systolic pressure. As the pressure in the cuff decreases, the audible sound goes through various phases. When there is a transition from muffling to silence, it is the diastolic pressure as shown in figure 3.

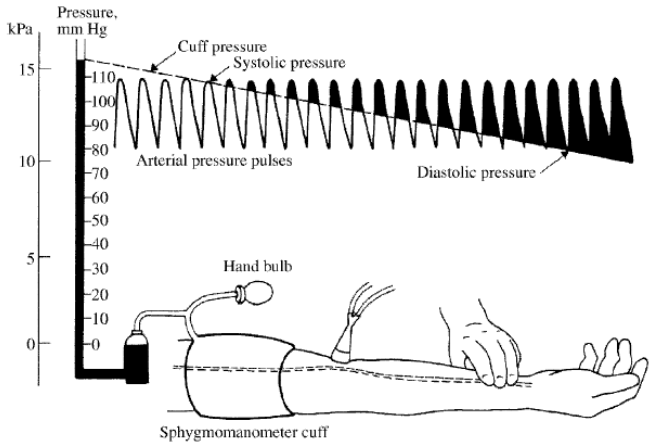


FIGURE 3: PULSE WAVE CREATES FLUCTUATION IN THE PRESSURE IN THE ARTERY WHICH FURTHER CREATES A FLUCTUATION IN THE CUFF HEARD THROUGH THE STETHOSCOPE AS KOROTKOFF SOUNDS [2]

Auscultation method is frequently used in the mercury or aneroid sphygmomanometer along with stethoscopes to listen to Korotkoff sounds has a lot of noises due to the low intensity and frequency of sound produced. In order to clearly hear these sounds, it is necessary to have a noise free environment along with the operator of having a hearing range as low as 5 to 32 Hz to hear the low-frequency flow sounds. Phase 1 sound signifying the turbulent flow and marks the SBP, phase 3 having the highest amplitude of the sound and marks the mean arterial blood pressure and finally phase 5 where the frequency of the sound is very low predicts the DBP [138]. Cuff sizes are essential as it might vary according to dimensions of the wrist and upper arm among the population and this technique is highly inaccurate in patients with hypotension and infants where the SBP and DBP are lower than the standard stated value [1, 137]. This causes a lower intensity Korotkoff sound to be produced making it inaudible [31].

2.2.2. Digital Blood Pressure Monitors vs. Aneroid/Mercury Sphygmomanometers

For the existing devices in the market, accuracy is one of the critical aspects which must be considered along with the repeatability of the results. As per a study conducted by Ruzicka et al. [7] to test the accuracy of the existing home blood pressure monitors, it was found that a high proportion showed inaccuracy in the systolic and diastolic pressure measurement when compared with a mercury sphygmomanometer. Another study conducted by Wong et al. [8] comparing automated devices showed an average error of 10mmHg from the actual systolic and diastolic pressure measured. Further supporting this according to Shahbabu et al. [9], sensitivity, accuracy and specificity of aneroid sphygmomanometers are higher than that of the digital blood pressure monitors with 89% of the aneroid types showed 5mmHg deviation error from the target pressure compared to 44% in digital blood pressure monitors. Menezes et al. [10] conducted a clinical test among 120 adolescents using an Omron wrist wearable device resulting in a difference of +8.1 mmHg DBP in boys and +5.7 mmHg in girls when compared to mercury sphygmomanometer.

As per Kazarowski et al. [11], three primary automated blood pressure monitors in the market, BpTRU, Microlife WatchBP Office and Omron 907 were tested for accuracy and showed to be highly accurate reducing the white coat effect among 25.3% of total subjects tested but it does not provide data on the variability of the readings from the actual measurement. These

devices are based on averaging six readings taken from the patients. But another study which analysed the accuracy of BpTRU on chronic kidney diseases by Brothwell et al. [12] showed a significant deviation in the systolic measurement of 117±14.1 mmHg when compared to the invasive monitoring of 143.8±15.5 mmHg. Under hypertension or any other chronic condition causing significant changes in blood pressure, digital monitoring techniques fail to establish accuracy.

Different protocols have been set to determine if a blood pressure monitor in the market is accurate or not. BHS (British Hypertension Society) 1993 and ESH (European Society of Hypertension) 2002 [9], have developed specific accuracy levels for blood pressure monitors to be considered suitable to be manufactured. A reading of 0-5 mmHg offset from the actual reading as measured using the aneroid/mercury sphygmomanometer is accurate and must meet these standards. From the extensive market analysis being done in table 1, various digital blood pressure monitors from Omron electronics, BPTru, Braun and different ambulatory blood pressure monitors had a specified accuracy of ±3 mmHg which is within the set standards. But these determined ranges of accuracy do not consider other sources of error which would be induced due to the varied size of the cuff. But these specified ranges of accuracy do not consider other sources of error which would be induced due to the varied size of the cuff. Also, oscillometric technique induces the device error due to a specific set of algorithms written to detect the systolic and diastolic pressures from the mean arterial blood pressure [26] as stated in equation 4:

$$MAP = P_{diastolic} + \frac{1}{3}\left(P_{systolic} - P_{diastolic}\right) \dots (4)$$

Based on this algorithm, the diastolic and systolic pressures are calculated. Again, this algorithm is pre-written into the microprocessor with some improvements based on the compliance of the cuff or statistical data collected by different companies and remains constant over different patients even when other factors such as varying blood flow rate, age and arteriosclerosis will affect the reading.

A more detailed review of the error which would be induced due to the varied sizes of the cuffs being used for the measurement has been integrated into the section 3 of the literature review. Even with a high ratio of errors being induced, the use of portable blood pressure monitors has been justified compared to other techniques such as the ambulatory blood pressure monitoring and sphygmomanometer as it reduces the white coat effect [27] and measurements can be taken

quickly without the presence of any professional. It has its further advantages being portable, non-invasive and cheaper prices as seen for the various digital monitors from the table 1 costings less than USD 100. But where accuracy is the prime factor these devices fail to deliver the result based on the simple algorithm written to detect the diastolic and systolic pressure as depicted in the equation 4.

2.2.3. Invasive Catheterisation vs. Non-Invasive Blood Pressure Monitors

Invasive catheterisation technique is by far the most accurate of all the devices. It is based on cannulation of the artery placing a fluid-filled catheter to an external pressure sensor or an internal pressure sensor at the tip of the catheter [2]. In the method of liquid-filled catheter and sensor, an insertion is made into the artery, with a proper supply of saline to ensure no coagulation or clotting occurs at the point of insertion. The pressure from the artery displaces the fluid-filled catheter further causing the diaphragm in the pressure sensor to move to detect the change in pressure. This method induces error due to the hydrostatic and hydrodynamic forces being generated by the fluid catheter. The intravascular pressure sensor method is helpful in eliminating this problem with the detection of the pressure occurring at the tip of the catheter [2].

Comparing the gold standard sphygmomanometers which gives an error in the readings of about ±2 mmHg provided the operator knows and can listen to the Korotkoff sounds accurately; invasive catheters which are specially designed to measure the blood pressure in relation to the flow rate invasively placing pressure catheter inside the artery are by far the state of art. Companies such as Phillips, Milar and Memscap develop these devices, but the cost is high compared to the portable non-invasive counterparts. Moreover, they come with the risk of causing infection hence can only be utilised in intensive care units (ICU) and emergency departments.

A study performed by Lehman et al. [13] compared the invasive with that of the non-invasive devices with a conclusion being NIBP devices give a higher systolic blood pressure in hypotension and lower than the actual value of hypertension. A further conclusion was developed from this study suggest that measurement of mean arterial blood pressure from an oscillometric method is same as that provided by invasive catheterisation. So, the problem

resides on the algorithm being used in the oscillometric method to calculate the systolic and diastolic blood pressure from the derived mean arterial pressures. This value would vary from patients to patients and yet again will be affected by the size of the cuff being used.

There still exist several pitfalls of using the invasive technique. Apart from it being non-portable, expensive and higher risks of infection making the use limited to the professional healthcare departments when the intra-arterial catheterisation is possible, the phenomena of under-damping and resonance are high which causes a high degree of inaccuracies

These are caused when oscillations generated by the pulsation of the cardio-vascular system overlaps the vibrations of the transducer causing constructive or destructive interference in the amplitude leading to the underestimation or overestimation of the pressure readings.

2.3. Occlusion Mechanism and Measurement Location

Research has been conducted into what the optimum size of any pressure application would be so accurate measurements are obtained. Further, the location of the analysis also plays a pivotal role as the blood pressure itself can be taken from sites such as the carotid artery in the neck, brachial artery in the upper arm, radial artery in wrist or fingers or femoral artery in the thigh. But the comfort of the patient, feasibility of measurement and the accuracy are the critical factors which have to be considered. In this section, the problem of the size of the pressure application and the location of the measurement to get the accurate reading of the blood pressure has been discussed. Since the focus of the project is to build a wrist wearable device, the search has been reduced to compare the measurements being taken from the wrist and comparing it to measures taken from other location with state of the art devices and obtain the accuracy of the set the data.

2.3.1. Blood Pressure Cuff and Mechanical Occlusion of Artery

Existing blood pressure devices, the aneroid as well as the digital oscillometric operate on the mechanism of occluding the blood flow in the location where the blood pressure is being measured as described in section 2.1. As per the requirement of the device, it is required that the cuff needs to be placed on the wrist where it would compress the artery to take the blood pressure from that region. Different studies have been conducted to measure the accuracy of obtaining the blood pressure using cuffs of various sizes over a wide range of subjects. Varying the dimensions of the cuffs because interferences in the reading leading to underestimation or the overestimation of the pressure recorded.

The circumference of the upper arm from where the blood pressure is usually being taken varies by the population. The existing devices come with standard sizes of cuffs recommended by the American Heart Association (AHA) [14, 15]. The cuff width is required to encircle 40% of the limb, and the length has to be 80-100% of the circumference of the limb. The standard ones available in the market come in three different sizes considering the measurement being taken from the forearm with child size of 8cm x 21cm, standard adult size of 27cm x 34cm and large adult size of 35cm x 44cm [16]. Most of the research conducted has been conducted using

quantitative and statistical analysis where the blood pressure is measured from many subjects. The results have been used to compare the blood pressure measured from the standard cuffs and that customised sizes based on the anatomical dimensions of the patients [14, 17-29]. When measured at the wrist, most of the authors agree with the standard size set by the AHA with 40% wrist circumference size being the cuff width. Larger sizes of the bladder would result in the underestimation of the pressure values while smaller size tends to give over-estimation of the readings. Study done by Kho et al. [28] has shown that using standard size cuffs for pregnant women has led to incorrect diagnosis of hypertension in quarter of the subjects, while utilizing the cuff larger sizes, assuming higher fat deposition in women in the upper arm during pregnancy reduce the error in diagnosis in the group of subjects. While Maxwell [24] and Sprafka [20] have shown use of larger cuff sizes would be beneficial as they would not over-estimate the pressure readings, the accuracy of obtaining the pressure reading is still a challenge.

Comparing the results being obtained in these studies to the actual scope of the project where a wrist wearable device must be developed, direct application of the pressure on the radial artery would be suitable with an excellent area so that the readings can be obtained. This would be like the tonometry (application of external pressure to match the pressure inside) method explained in section 2.5, where the artery is directly pressurised by the sensor [30-33]. The pressure from the device would push down on to the ultrasound transducer which would applanate the artery. This might overcome the problem of the varying sizes of the cuff to be used and reduce the error of the pressure measurement. Butterfield [34] and Boyer [35], have filed a patent which claims a mechanical mechanism can be used in conjunction with worm gear and springs mounted on the wrist which would be able to occlude the blood vessel providing means for the stress sensitive diaphragm sensor on the skin to measure the blood flow through the artery and interpret the pressure.

2.3.2. LOCATION OF BLOOD PRESSURE MEASUREMENT

The location of measurement of the pressure is another critical aspect which had to be considered. The pressure reading can be taken from any site with the major artery such as the upper arm (brachial artery), thig (femoral artery), neck (carotid artery), and fingers [36, 37]. Considering the comfort and feasibility, neck and thigh regions are neglected. Finger blood

pressure monitors provide similar results to other non-invasive monitoring [38, 39] but the implementation of the ultrasound technique on the finger would not be feasible due to lower flow rate and higher motion artefacts.

Based on the research from different sources for the pressure measurement from the radial artery in the forearm compared to the pressure in the brachial artery and intra-arterial, there are discrepancies obtained which is primarily because the pressure increases with the distance from the heart. There are changes in the diameter of the artery and height differences from the heart level cause higher pressure in the lower limbs. Brachial artery being on the same level as the heart, the pressure difference is not significant and represents an accurate site for obtaining proper results. But as mentioned previously in section 3.1, the size of the pressure application device plays a crucial role which becomes significant in deciding the location to take the measurements. Some of the researchers have favoured different techniques and compensation methods to obtain pressure from the radial artery. These compensation techniques involve taking the pressure measurement from the radial artery and adding the pressure difference between the heart and wrist [40-43]. As stated by BHS [44], any wrist wearable device must have an error of ±5 mmHg to be termed accurate enough to manufacture for the use by people. The errors obtained shown by the studies mentioned above claim to have errors lower than the BHS stated standard. Further authors from [45-47] have stated that any measurement of the pressure from the radial artery will be an overestimation comparing to the brachial artery. But these measurements being done are based again on a standard cuff size which adds to the errors in the experimental method. Carlsen et al. [45] have compared the findings of the systolic pressure from the subjects in healthy and chronic kidney disease from the radial artery with the readings provided by invasive catheterisation method with an error less than ±5 mmHg. This comparison has helped in establishing a benchmark for using the radial artery as the location of measurement of blood pressure.

The various statements made on the accuracy of the wrist wearable device to measure blood pressure, different ideas can be evaluated to compensate for these errors. Since the target market right now for the development of this device is primarily based for the healthcare sector and defence industry, the measurement can be done by making the wrist at the heart level [16] or implementing a standard compensation method to reduce the pressure reading to the original value.

2.4. ULTRASOUND

Transmission of the sound waves takes place as a sequential sine wave where the height of the wave is loudness. The number of cycles per second represents the frequency. The frequency of the ultrasound is more than a million cycles per second (1MHz). Use of ultrasound is justified in imaging or detection of signals through the human body because of very high frequency which can give high precision and spatial resolution.

Piezoelectric crystals produce the ultrasound waves in a transducer which vibrates when driven by a fluctuating voltage. The piezoelectric properties are those where any mechanical vibrations would generate alternating electrical voltage or vice versa. The fluctuating voltage causes the element to resonate at its natural frequency producing ultrasonic waves.

In medical ultrasound, either short burst of ultrasound pulses is generated as the transducer behaves as a transceiver where it first generates the pulses and then waits for receiving the reflected pulses. The time delay between the generation of the signal and the echo is the measure of the depth of the tissue. Or the pulses are continuous where the signals are generated by one transducer and received by another transducer [48].

Ultrasonic signals diminish as a function of distance, geometry and attenuation. As the sound waves propagate, there is attenuation of the energy through the medium which depends on the inverse square law and is given by equation 5:

$$I = \frac{I_0 e^{-\mu x}}{x^2} \dots (5)$$

Where, $I_0 = intensity\ of\ the\ incident\ signal$

$\mu = attenuation\ coefficient$

$x = distance$

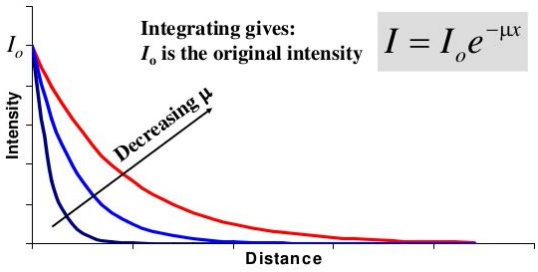


FIGURE 4: ATTENUATION OF ULTRASOUND SIGNAL WITH DISTANCE. THE ULTRASOUND SIGNAL IS HIGH SENSITIVE WHERE THE HIGH FREQUENCY SIGNAL CAN PROVIDE HIGHER RESULATION BUT CANNOT PENETRATE DEEPER [2]

The attenuation is dependent on the material and the frequency of the wave. The decrease in the intensity of the signal is measured through the thickness where the signal decreases in magnitude to half or the Half Value Layer (HVL). The HVL varies with different material. For instance, muscle has an HVL of 2.5 cm referring that the intensity is decreased to 50% when the wave has propagated 2.5cm [2, 49].

Low-frequency waves attenuate less until arriving at a deeper level than those of high-frequency ultrasound. Higher frequency ultrasound is used in the regions where resolution is essential, and the organs being viewed or information to be collected is superficial to the surface where the transducer is placed.

Ultrasound imaging techniques operate commonly at 3.5MHz at high speed of 1540m/second for soft tissues. The pulses are echoed back within microseconds to create visual images. The transmitting frequency related to the blood pressure measurement is around 8MHz, and the receiving frequency varies between 8MHz±f. A higher frequency is required to increase the spatial resolution due to a very minute size of the arteries with the mean diameter of 4.0 mm [49].

As the emitted sound waves enter the skin and deeper structures, some of the waves are reflected, transmitted and dissipated as heat. Most of the waves are either reflected at angles from the reflectors or pass through without returning directly to the transducer.

There are specular echoes which originate from relatively large regular shaped objects with smooth surfaces. They are intense and angle dependent. While others are scattered, echoes originating from relatively small, weakly reflective, irregularly shaped and less angle dependent. Only 1% of the sound waves are reflected directly which are responsible for the visual imaging or acquire the information for the flow of the blood [2].

Doppler flow mechanism is the change in the frequency obtained between the transmitted and received waves when there is a relative motion between the source and the receiver. Doppler flow mechanism can be seen in the transverse waves (electromagnetic waves) and longitudinal waves (acoustic waves). This change in frequency can be used to obtain the relative motion of the source [16].

Two different ultrasonic techniques can be used for the measurement of the blood pressure with one method being used for transcutaneous Doppler sensor which measures the motion of the arterial wall [16] and the other still under scrutiny with the research is the Doppler Blood Flowmeter.

2.4.1. ARTERIAL WALL MOTION BLOOD PRESSURE MEASUREMENT

The ultrasound transducer is placed in the inner lining of the pressure cuff, which generates 8-10 MHz ultrasonic wave. Reflected waves are detected by the receiver (acting as a microphone). The difference in the frequency between transmitted and received is proportional to the velocity of the wall motion and the blood velocity. With the increase in the cuff pressure above diastolic and below systolic, the blood vessel open and closes with the heartbeat, because of the pressure oscillation above and below the cuff pressure. Further, as the pressure in the cuff is also increased, the time between the opening and closing of the blood vessel decreases until they coincide. Reading at this point is systolic.

When the pressure in the cuff is reduced, the time between opening and closing increases until the closing signal from one pulse coincides with the opening signal from another. Reading at this point is diastolic [2] shown in figure 5.

This concept has been significantly used to see the diameter of the arterial wall and measure the blood pressure waveform as done in studies [50, 51]. But detecting the motion of the arterial wall induces errors due to the motion artefacts.

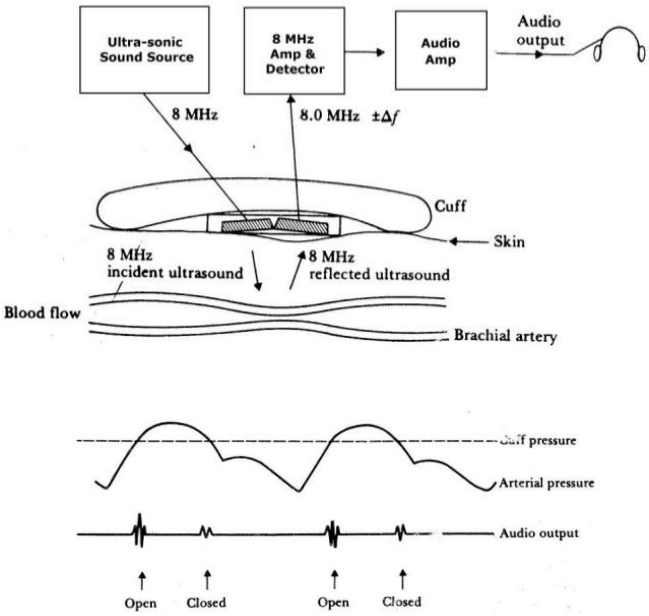


FIGURE 5: ARTERIAL WALL MOTION BLOOD PRESSURE MEASUREMENT USING ULTRASOUND [2]. THE ULTRASOUND DETECTS THE OPENING AND CLOSING OF THE ARTERY. AT HIGH PRESSURE, WHERE THE OPENING AND CLOSING COINCIDES IS TERMED AS SBP AND AS THE PRESSURE IS RELEASED, THE REGION WHERE THE ARTERY IS AT THE STATE OF OPEN AND THEN CLOSES REFERS TO DBP

2.4.2. DOPPLER BLOOD FLOW METER OVERVIEW

In blood flow meters, the ultrasound signal is transmitted into the vessel. This reflected signal is mixed with the transmitted signal. The difference in the transmitted and the received signal is processed to obtain the Doppler shift. This Doppler shift is then tuned to the audio range. As the heart pumps the blood, the pressure at which the blood is pumped goes from a minimum point (diastole of the heart) to the maximum point (systole of the heart). The blood flowing through a point in the artery increases in speed to a maximum value and then decreases to a minimum value. The change in the speed of the blood due to the pulsatile nature of the heart pumping out blood causes a change in frequency. This change is heard in the range of 20 Hz and 20 KHz through the speaker. As the speed of the blood flow keeps on changing, increasing to a maximum level and decreasing back, there is a spectrum of frequency heard from the speaker resembling ‘whooshing’ sound of blood. Figure 6 shows the incident and the reflected ultrasound signal when it hit the blood vessel.

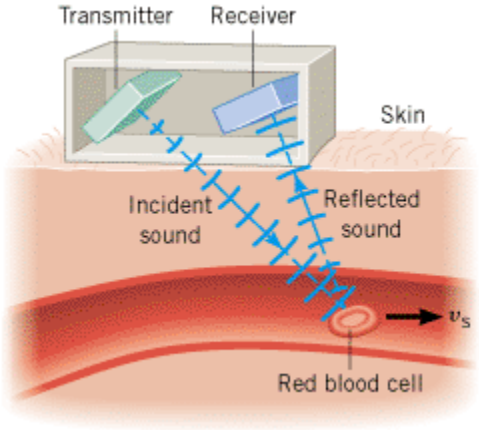


FIGURE 6: DOPPLER BLOOD FLOWMETER MECHANISM

Studies were carried out in [52, 53] have shown that ultrasound can be used to measure the blood pressure by assessing the flow of the blood. But with these research, there has not been significant development on how the measurement would be carried out and how accurate the results would be when compared to the current state of the art or the existing gold standard devices. A patent filed by [53], is closely correlated with the current research being carried out but there has not been any significant information on the device being provided. The patent focusses on the how the signals would be obtained from the flow velocity and the interpretations of the systolic and diastolic pressures. Another patent [54] from China focusses on using the ultrasound to develop a wrist wearable blood pressure monitor. But again, it depends on the opening and closing of the arterial wall as explained in section 2.4.1.

Kazamias [55] in 1971 conducted a similar study to compare the ultrasonic blood pressure measurement through transcutaneous flow meter with that obtained from the invasive catheterisation method. A close relationship was obtained between the results through the statistical analysis. The difference between the invasive pressure method and that of the ultrasonic method was less than 1% when compared to the 10% discrepancies obtained from the sphygmomanometers. Whyte [56] in 1975 conducted a similar experiment on children showing that systolic pressure can be accurately measured using the blood flow meters while diastolic pressure is over or underestimated. No further developments were made in this as the era of digital oscillometric blood pressure monitoring came into existence. Aaslid et al. [57] also performed experimental analysis to compare the systolic and diastolic pressure measured from the brachial artery using ultrasound transducer and cuff and compare the results in the intra-arterial device. The ultrasound unit did the velocity measurement and controlled the

pressure inside the cuff through the pneumatic servo system. But this mechanism assumed the velocity of the systolic and diastolic to be within a range and the measurement was being done proximal to the pressure application which would change the velocity signals.

2.4.3. ULTRASOUND VS. EXISTING TECHNOLOGY

The Doppler blood flow meter is used to detect the flow of the blood which can be compared to the motion of the arterial wall using ultrasound. Comparing this to the detection of the movement of the arterial walls and the opening and closing of the arterial lumen, a lower amount of noises would be induced due to the motion artefacts.

Advantages of the ultrasound technology over the existing aneroid meters would be, the processor would detect the Doppler change in the frequency which would occur for the diastolic and systolic, and the users do not have to listen to the Korotkoff sounds. Further, the frequency of the Korotkoff sounds in the diastolic range is lower than the human audible range which makes it impossible for the detection of accurate diastolic pressure. This makes it even harder to detect in the cases of infants who have a lower stroke volume producing low flow rate thus the lower intensity of sounds.

This technology would be non-invasive, and it is assumed that it would not be dependent on the size of the pressure cuff. The ultrasound transducer would be used to apply the pressure directly to the location of the radial artery to occlude the flow. This would significantly remove any errors which would have been induced by the varied sizes of the cuffs.

The direct interaction of the signals with the flow of the blood would enhance it to take a real-time reading without any probability based processing algorithm implemented by the oscillometric method where the mean arterial blood pressure is calculated through the vibration of the cuff, and systolic and diastolic pressure are inferred.

The table in Appendix B shows various market devices, patents and research. The extensive search has been done to compare the devices based on their accuracy and to see if there are any research being carried which are like the aim of this master's research.

2.5. CURRENT RESEARCH – ULTRASOUND DETECTING BLOOD VELOCITY AND PRESSURE

In this section, various research were analysed which used ultrasound to study the flow of the blood. In the next few paragraphs in this section, the studies describe the use of ultrasound to view the flow characteristics of blood being laminar or turbulent, applanation tonometry method to measure the pressure using ultrasound probes and their outcome and pulse wave velocity studies where the blood pressure waveform is obtained but failure in obtaining any diastolic pressures.

Blood Flow Characteristics Using Ultrasound

A close correlation exists between the flow of the blood and the systolic and diastolic pressure being measured. From a fluid flow perspective, when the systolic pressure is measured, the flow of the blood through the artery is entirely turbulent corresponding to high Reynolds Number, and when the diastolic pressure is being measured, the flow is altogether laminar with a low Reynolds Number [1, 58]. Here the Reynolds number is a parameter used in fluid mechanics to measure the characteristics of the blood flow is laminar or turbulent. Blood being a non-Newtonian fluid has a varying density and viscosity which changes over time and temperature. Lots of assumptions have been made in various studies on how the behaviour of flow varies over numerous blood vessels, and one of the most significant assumptions being larger arteries such as the carotid and femoral artery shows flow which is Newtonian [58, 59] compared to non-Newtonian flow in micro-circulation vessels [60]. Since the blood pressure measurement being taken is from the radial artery, a medium sized vessel, the effect of changing viscosity and density of the pulsatile blood flow will be prominent. The characteristic behaviour of blood flow and its profile would help in investigating the point where the flow would get laminar and turbulent. From a classical fluid mechanics perspective, flow through a tube is considered laminar when the Reynolds number which is the ratio of inertial forces to viscous forces is less than 2300 and turbulent when this ratio is higher than 4000. But implementing this in the quasi-static vascular system, these numbers fail to signify what would be the nature of the flow. A study performed by Li et al. [61] shows that the Reynolds number in the aorta in mammals is dependent on the body weight. It further explains that other factors such as heart rate, compliance of the artery and the entrance length are essential determinants

of the turbulence and cannot be compared to the standard range established for considering laminar-turbulence nature of the fluid. Great detail of dynamic fluid analysis has been conducted on modelling the flow of the blood, but it is not significantly relevant and does not provide good insight in detecting the pressure using ultrasound.

Further, an old 1976 based research by Stein et al. [62], has shown when the arteries are occluded, the Reynolds number of transition from laminar to turbulence can be as low as 500. This is affected by the geometry of the shape.

Ultrasound was being used to generate the flow waveforms in different arteries along with the computational fluid dynamics. Factors such as the flow rate, the wall shear stress and the velocity waveform were being calculated using the Womersley equation which provides the flow profile being parabolic or flat in nature [58, 63]. There is an increase in the over-estimation of the velocity during the systolic pressure. It has been observed that there was a decrease in the error when the speed was recorded from the radial artery with an over-estimation of 2.3% compared to the ulnar artery or other arteries, suggesting the lower error will help in obtaining proper signals for the flow of the blood [63].

Applanation Tonometry to Measure Pressure

Applanation tonometry technique is being utilised on the carotid and radial arteries where the application of pressure through an ultrasound probe occludes the vessel corresponding the external pressure being equal to the internal arterial pressure [30-33]. In these techniques, the waveform of the pressure was obtained from the changing diameter of the arterial walls due to the pulsatile wave and recorded through the brachial cuff. The calibration was done for the pressure measurement using standard sphygmomanometer. This has a close relationship using the Doppler blood flow meter to obtain the signal, high inaccuracies have been induced in these studies using a standard brachial cuff. Nelson et al. [32] have used radial artery to conduct results on a various group of patients under anti-hypertensive therapy, obstructive sleep apnoea, diastolic dysfunction, coronary and peripheral vascular diseases. No noteworthy results have been obtained which can be compared to the prior studies done correctly on the radial arteries. According to Greiwe et al. [64], the reliability of this method is still under scrutiny as it does not provide significantly accurate results with the mean percentage error can go as high as 23.5% for the mean arterial pressure (MAP). The current Doppler blood flow meter would be able to assess the changes in the blood velocity through the application of pressure on the radial artery rather than the requirement of monitoring change in the diameter of the arterial wall.

Pulse Wave Velocity Measurement using Ultrasound

Further investigation into studies [51, 65-70] conducted has used ultrasound primarily to detect the blood pressure waveform. The limitations of these experimental studies have been that the diastolic pressure measurement has been performed using invasive techniques to set boundary condition. These studies further have utilised two different ultrasound transducers with the different frequency with one measuring the motion of the arterial wall while the other measuring the pulse wave velocity (PWV). While [65] significantly provided insight into the filtering techniques which can be utilised in increasing the signal-to-noise ratio (SNR) and [51] has helped in providing details on data acquisition techniques discussed in the later section, but these studies have been based on entirely different approach compared to the currently assessed technique using single transducer blood flow meter.

2.6. SIGNAL PROCESSING

From the previous section 2.5, applanation tonometry and pulse wave velocity have shown considerable significance relating where the current project. It is necessary to understand what signals existing ultrasound blood flow meter provides, how they can be linked to obtaining the characteristics of the blood flow using proper signal processing techniques.

In this section, the focus is directed towards how the blood flow meter work in generating and receiving the signals, where the Doppler change effects come into play, how that Doppler change can be utilised in observing the characteristic flow change of the blood and the implementation of the signal processing technique to view any Doppler change received.

2.6.1. DOPPLER ULTRASOUND FREQUENCY SIGNALS

Doppler Ultrasound blood flow meter is based on generating ultrasound pulses which can be continuous or pulsed depending on the system being used. The existing flow meter devices tune down the signal from the ultrasonic range above 40kHz to the human audible hearing range level between 20Hz to 20kHz [1, 48]. The transmitted frequency f_0 from the generator undergoes Doppler frequency change and the phase and frequency shifted signal is being detected by the transducer [71]. The change in the Doppler frequency is shown by the equation

6 where f_t is the transmitted ultrasonic frequency, v is the speed of the moving particle, c is the speed of the sound in the medium and θ represents the insonation angle or the angle between the transducer and the direction of motion of the particle [72].

$$f_d = 2f_t cos\theta . \frac{v}{c} \dots (6)$$

The circuitry of the ultrasound includes an ultrasonic signal generator, signal receiver and multiplier. The generator emits a signal of desired frequency. The transmitted signal is back scattered from the moving particles (erythrocytes, leucocytes and platelets) and detected by the receiver. The signals from the transducer and the receiver are mixed using a multiplier chip [73] where f_0 is the transmitted signal and Δf being the Doppler shifted frequency shown in equation 7.

$$\cos(f_o + \Delta f) \times \cos(f_o) = \frac{1}{2}\cos(2f_o + \Delta f) + \frac{1}{2}\cos(\Delta f) \dots (7)$$

A Fourier analysis of this signal at a high sampling frequency would provide the change in the frequency where the Doppler signal occurs at lower frequency of less than 500Hz [72, 73]. The Doppler signal obtained can be changed or affected based on the insonation angle and the frequency of the ultrasound transmitter [72]. According to the study conducted based on the spectrum broadening [74], the bandwidth of the Doppler signal is also dependent on the insonation angle and the sample volume over which the target cells are studied.

2.6.2. SIGNAL PROCESSING TECHNIQUES

From the articles researched, blood flow meter has been used to process the change in Doppler signals to obtain the velocity of the blood. An approach has been thought of to be implemented in which the varying of the pressure on the radial artery as done by in [30-33]. Through the use of tonometry method and processing the output change in Doppler signals which has shown how velocity of the blood can be obtained and compare it to the study models for getting the velocity ranges where the flow characteristics of the blood will be entirely laminar for inferring the diastolic pressure and entirely turbulent for inferring as the systolic pressure. No significant

studies were found which predict the latter, on how the flow characteristic would behave when the artery is being occluded.

Solano et al. [75] developed a phantom model to analyse the effect of Doppler signals under different degree of stenosis of arteries and obtain the frequency spectrogram of the results. Comparing this to the region where the artery would be occluded to take the reading of the pressure, the flow would become highly turbulent generating high-frequency components. This model has provided insight into the use of spectrogram analysis at different frequencies. The change in the flow pattern studied by Solano is shown in figure 7, how the flow becomes turbulent. The study did not explain the signal processing technique. Further, developing a flow model of the blood using ultrasound data would be helpful, but within the limited time constraint the focus is to be implemented on viewing the changes in the Doppler frequencies when the pressure is being applied as stated in the approaches implemented in the tonometry technique.

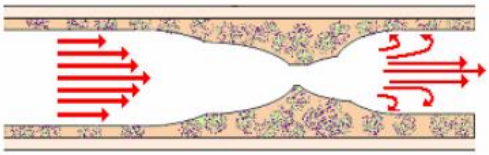


FIGURE 7: TURBULENT FLOW UNDER STENOSIS DETECTED USING ULTRASOUND. THIS STUDY HELPED IN DETECTING HOW TURBULENCE IS CHARACTERISED BY ULTRASOUND [83]

Spectrogram analysis or Short Time Fourier Transform (STFT) conducted in the study [73] shows the use of narrow and wide window lengths and the advantages of narrow windowing compared to the wider ones. This method was being implemented in MATLAB with the signals from the ultrasound obtained, and the processing results were the same as that shown in this study. Narrow window spectrogram would provide higher resolution in the time domain while a wider window will provide higher resolution in the frequency domain [76]. It also shows the implementation of digital low pass filter with cut-off frequency of 700Hz which would remove any high-frequency disturbances as observed in some of the current signal processing being done for the project. Further, in the digital signal processing done by Schlindwein et al. [77], they have analysed the motion of the arterial wall at the low frequency using short time window. Further, this study has provided some insight into the digital processing of the sound where a 20ms timing window has been stated to use while doing the Short-Time Fourier analysis. The signal processing conducted is like the one which has been thought to be devised

to determine the intensity of the sonograms and seeing the velocity change through the sonograms.

In the articles [78, 79], authors have compared different signal processing techniques namely the STFT spectrogram analysis with Autoregressive modelling (AR), Continuous Wavelet Transform (CWT) and S-Transform techniques. The STFT is a useful technique but has drawbacks being the resolution presented in the time and frequency domain, and it does not produce precise results with the shifting window leading to a significant amount of distortion and loss in the transient behaviour of the signal [80]. The Wavelet Transform is another technique for the time series function is parameterised into time and frequency components with a wavelet function of set scale shifting across the original function obtaining higher resolution results compared to STFT method [4].

$$W(a,b) = \int_{-\infty}^{\infty} y(t)\Psi_{a,b}(t)dt \ldots (8)$$

Here, y(t) is the continuous function whose wavelet transform is to be taken, Ψ is the mother wavelet function which transverses across the time domain function capturing the time and frequency components of the signal, while a is the scaling factor and b is the shifting factor.

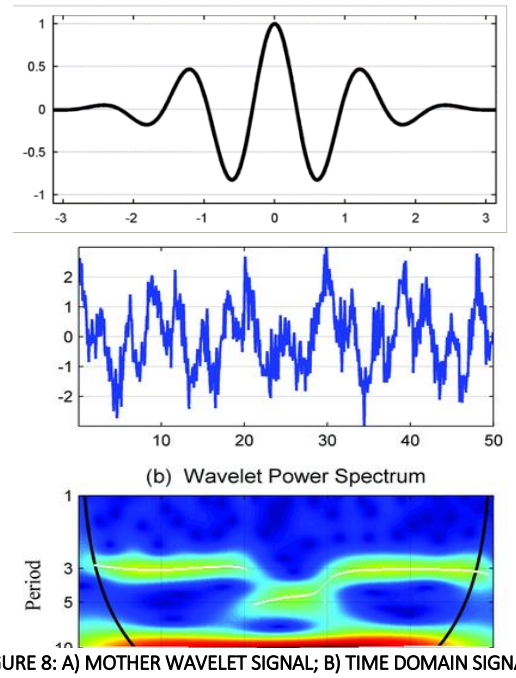


FIGURE 8: A) MOTHER WAVELET SIGNAL; B) TIME DOMAIN SIGNAL; C) WAVELET TRANSFORM [4]

Wavelet transforms provide better resolutions in time for high frequency and frequency resolution in the high frequency. An example of the outcome of the wavelet transform is shown in figure 8 which is similar to short time Fourier transform but uses more advanced technique of measurement. Since the Doppler signal obtained would be based on the low frequency ranges, a better time resolution can be attained signifying the changes in the events over time. Research conducted by Goncalves et al [81] on the various degrees of emboli in the blood and shown that continuous wavelet transform technique provides higher accuracy. Further the study shows that detection of emboli during diastole was easier due to lower velocity which was significantly shown in the wavelet transform compared to the systole.

2.7. PARAMETERS AFFECTING DOPPLER SIGNAL

2.7.1. MOTION ARTEFACTS

As stated above from [72-74], several parameters can affect the Doppler signal received by the flow meter. Adding upon these factors, the motion of the arterial wall and the process of breathing also affects the Doppler flow signal resulting in the changes in the Doppler flow velocity [82]. The study conducted on the effect of changes in the Doppler velocity signal from M-mode echocardiography states cardiac output [1] is underestimated when there is a motion of the vessel with respect to the transducer. This is because of the out of phase Doppler frequencies received by the transducer from the movement of the vessel and the blood which may result in destructive or constructive interferences. On the other hand, it can be overestimated when measured at the outer edge of the Doppler frequency spectrum, the measurement of velocity based on the upper and the lower bounds of the Doppler frequency bandwidth [74, 82].

The positioning of the transducer with respect to the flow direction affects the reading, inducing errors based on the region where the motion and micro-motion caused by the artefacts such as the breathing cycle would be higher or lower [83, 84]. These artefacts become crucial when the measurements are taken from the chest or brachial artery. The distal region of radial artery breathing has a significantly lower effect, and the motion due to the breathing lies in the lower

frequency region. Pozniak et al. [85] have discussed various artefacts which affect the spectral and colour Doppler measurement with one being the vascular motion relative to the transducer. Apart from the target artery observed for the blood flow other lymphatic vessels and veins which can be observed in the lower frequency band of the spectrum which can affect the Doppler signal. These lower frequency noises can be removed by the implementation of appropriate filtering techniques.

Doppler spectral broadening is another artefact common for Doppler signal processing. When a finite volume of the sample is measured is measured by the transducer in the artery, as the blood cell (target) moves across in the volume over the period, the backscattered Doppler angle will vary, producing a band of different frequencies [85]. A study by Vernon et al. [74], the bandwidth of the signal of the Doppler frequency is a function of velocity, and the study obtained the lower and upper limit of the bandwidths. This provides crucial information on the processing of the data to achieve these limits of the frequencies, but again the experiment was conducted on a thread moving through a tube rather than the actual blood vessel limiting the experiment.

2.7.2. INSONATION ANGLE

Insonation angle or the angle between the flow direction and the ultrasound signals is one of the crucial factors which affect the readings and the processing of the signals, depicted in the Figure 9.

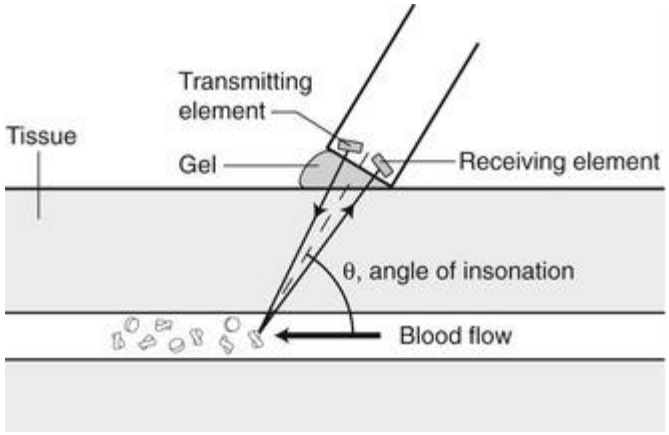


FIGURE 9: INSONATION ANGLE (ANGLE BETWEEN THE TRANSDUCER SIGNAL TRANSDUCTION PATH AND THE FLOW OF THE BLOOD) [3]

The dependence of the Doppler frequency change on the insonation angle from equation (2) shows a direct proportionality. Theoretically, placement of the transducers at 90^0 to the direction of the flow would provide no shift in the Doppler frequency while at 0^0, the maximum shift will be obtained. According to [86], a Doppler angle of 60^0 or less, must be taken into consideration but comparing this to the analytical implementation done in [72], a quantitative model where an insonation angle of about 60^0 results in minimisation of the fractional errors, due to noise but this is further dependent on the depth of the vessel and the centre frequency of the ultrasound device. A more realistic approach has been undertaken in [87-90], where Colour Duplex Ultrasound imaging has been used to analyse the effect of various angles on the flow velocity in haptic portal vein, intrarenal artery and reproductive tracts, entailing a range of 30^0 – 60^0 to obtain a true estimate of the flow. Angle above or below the range will provide an underestimation or overestimation of the flow velocity. The interference increases exponentially with the increase in the angle above 60^0 [89], with the cosine of angle reducing to lower values which cause the energy density of the noise to overcome the Doppler energy [72].

Investigations have been done which have strong disagreement of using of insonation angle of 60^0 as suggested in [72]. Assessment of the velocity in the middle cerebral artery in [91] shows uncorrected angle results are lower compared to the corrected angle results. This can get as low as 30-40% of the original results, suggesting an angle of 30^0 for precise velocity measurement. Further, [92] assesses foetal middle cerebral artery peak systolic velocity on 0^0 and 30^0 insonation angle, providing variance in the velocity measured. This signifies a 0^0 angle would be essential in obtaining the peak velocity, but placement of the transducer parallel to the vessel non-invasively cannot be achieved so correction angles should be utilised. An average error in the velocity of 25% would be obtained with the insonation angle of 42^0 [93], further contrasting the results as stated in most of the research. [93] showed that obtaining Doppler change frequency results with insonation angle lower than 30^0 has a lower probability, due to the anatomical feature of the artery but the error induced in the velocity measurement cannot be ignored. As per studies [94, 95] on the significance of insonation angle in detection of peak systolic velocity (PSV), a lowest possible angle is being advised. Due to the presence of the cosine term, the error in velocity measurement increases from 5.4% at 30^0 to 12% at 60^0 [95]. A phantom model was developed in [96] to measure the effect of the beam and flow angle.

This significantly disagrees with the standards of using 60^0 angle which resulted in 36% of peak velocity error in the study.

The angle at which the gel pads would be placed on the skin to obtain the ultrasound reading is an essential factor. As per [97], a perpendicular pad and a slanted pad provided significant differences in the PSV and the spectral broadening results. Increase in the angle of the gel pads causes a decrease in the beam flow angle (insonation angle) resulting in an accurate measurement of PSV.

From the various investigations done relating to the optimum insonation angle, when the transducer is to be placed on the wrist, one challenging factor is the curvature of the targeted blood vessel. Deviations in Doppler change can be observed from the flow in linear arteries compared to that through curved ones [98]. But it was assumed to be straight in [96] phantom model. Further a lot of authors have supported the use of insonation of angle of less than standardised 60^0 which would reduce the error in the velocity estimation. The currently used off-the-shelf continuous blood flow meter from Park Medical Electronics Model 811-B can be used to obtain the result at the insonation angle ranging from $30^0 – 60^0$ to further enhance the optimisation of the signals obtained.

2.8. Summary of Literature Review and Development of Hypothesis

In the review, various existing devices were compared based on their accuracy, induced errors and benefits of their usage. With the existing technology, it was observed that gold standard sphygmomanometers are by far considered the most accurate among the non-invasive devices, but they have high sources of errors, cannot be used for 24-hour pressure monitoring, requires the operator to listen to the Korotkoff sounds accurately and induce pain based on the compression through the cuff. Whereas the digital blood pressure monitors are being used extensively as they have automated signal processor to detect the region where the systolic and diastolic pressure would occur based on the vibration in the cuff as discussed in section 2.2. They provide a better edge on the portability and can be used for 24-hour monitoring. But compared to the accuracy provided by the aneroid or mercury sphygmomanometer, they have a standardised accuracy of ±5mmHg. But this accuracy is being affected under the conditions

of motion artefacts, cuff sizes, measurement location. Further different cuff sizes and measurement locations and the results obtained from these studies were analysed. This was done in order to obtain the minimal size bladder which can be used to compress the artery without compressing the entire limb to remove the factor of pain. The optimum size of the bladder for blood pressure measurement without over-estimating or under-estimating the pressure is given to be a width of 40% and length of 80%-100% the circumference of the measurement limb [14, 15].

Ultrasound can be used to measure the blood pressure will directly interact with the flow of the blood rather than depending on the listening to the Korotkoff sounds produced or the pressure change vibrations in the cuff. Several existing concepts and research work were being analysed to develop a proper technique where the ultrasound signal can be processed to obtain the blood pressure readings. The current idea of the use of Ultrasound to detect the opening and closing of the arterial wall [2, 51, 65] to identify where the systolic and diastolic pressure occurs is still under speculation as the arterial wall motion occurs at a very low frequency which is superimposed by the noise signals. Whereas the current technique under research for this project, the use of Doppler Blood Flow meter to process the signal provides the blood velocity which can be used to detect and study the flow characteristics. Primarily, some research was done into the use of the fluid flow characteristics of the blood based on the region where they would get turbulent or laminar. No significant results were obtained as the parameter Reynolds Number being used for the determining the fluid flow characteristics could not be applied based on the Doppler change frequency being obtained from the blood flow meter. This is because blood is a non-Newtonian fluid and does not obey the classical fluid mechanics principles.

In order to get a better understanding, the research work was extended into the processing the Doppler change in the ultrasound signal is obtained. This section of the review looked into the different processing mechanisms which can be used. Short Time Fourier Transform [73, 77] and Wavelet Transforms [78, 79] were the two processing technique being analysed which looks into the change in the frequency over a short time frame for the signal and creates a spectrogram view. This would help to analyse the signals during blood pressure survey from the patients. The systolic pressure can be easily obtained as under pressure, the artery would be occluded entirely, and no blood would be flowing through. When the threshold point is reached where the pressure from the blood forces itself out through the occluded region, the blood flow meter will generate signals detecting the flow. Monitoring of the flow through the pressure sensor would provide a means to read the systolic pressure at this point. To obtain the

diastolic blood pressure, it is being assumed that the spectrogram would change as the pressure is decreased. This would reach a point where there would be no change in the spectrogram signal with the magnitude of high-frequency components equal leading to the detection of the diastolic pressure.

3. ENGINEERING DESIGN PROCESS

The engineering design process involves several stages which must be considered. This project is based on developing a data acquisition and processing unit which can be used for data collection. It further includes the data processing and signal analysis to detect the appropriate values for the SBP and DBP. The device being developed is not a marketable product but rather a biomedical system which can be utilised for testing and studying people and in future whose principles can be embodied into an actual marketable device. According to Haik and Shahin, [99], detailed process has been entailed on approaching a design problem and implementing the design based on the requirements and specifications. The design processes involve several categories but, in this case, few of the major categories which would be involved in design of the system has been explained and documented which include:

1. Design Requirements
2. Functional Structure
3. Specifications
4. Identifying the needs
5. Conceptualisation or concept development
6. Concept evaluation
7. Design embodiment

Based on these principle sections, the design framework has been set to substantially carry out efficient design process work. The requirements and specifications were designed in order to make the acquisition system to be safe for the operator and the user and to reach an accurate data collection technique.

The research and design work which was carried out over the thesis included different parts which had to be considered to develop a proper data acquisition device which would enable collection of data safely from people and conduct appropriate signal processing and analysis. The list below shows the different components which were researched and worked on for the building of the device:

1. Mechanical Interface: This is the part which would be interfacing with the human body consisting of the transducers and the sensors to take appropriate measurements. This part would further incorporate appropriate mechanism to the lock the sensors in the position
2. Controller Unit: Consisting of the PCB and the microcontrollers for controlling the sensors and the actuators
3. Data Acquisition System: The data being received from the sensors and the ultrasound can be collected at different sampling frequencies and sent to the computer for signal processing and analysis
4. LabVIEW and MATLAB: The signal processing which was required to be carried out from the data received were conducted using these software

3.1. PROBLEM DEFINITION

Measurement of the blood pressure accurately is an essential need which would help in proper diagnosis and to undertake appropriate therapeutic procedures. The existing devices and their underlying concept have been under scrutiny due to their inaccuracy. Existing digital monitors have revolutionised the market for efficient, user-friendly and affordable measurement of the blood pressure even at home, but they have been posing significant challenges when it comes to take the readings accurately. This is a requirement in the hospitals and the emergency departments.

In order to reach a solution to this problem, ultrasound for detecting the flow of the blood is to be used whose data would be used to study any correlation to SBP and DBP. Using this concept, where the change in the ultrasound frequency or the Doppler frequencies can be used to measure the flow characteristic of the blood. This acquisition of the signals requires a prototype device which would be able to collect pressure and ultrasound data simultaneously which can then be processed to find any equalisation trend present.

Based on all these the problem definition was defined to be:

"Construction of a data acquisition system incorporating ultrasound and pressure sensor, to simultaneously receive the values and process it, in order to find any equalisation trend

present over the mass to verify the presence of Systolic and Diastolic Blood Pressures along with the heart rate".

3.2. CUSTOMER REQUIREMENTS

The customer in this case is the head nephrologist from the Women's and Children's hospital, Dr. Kejur Fred and other specialists and paramedics who would require accurate measurement of the blood pressure. Even though this is a biomedical testing device construction, the needs of the customers are required to be taken into the consideration. Some points which are stated by the Nephrologist which doctors would like to have in a blood pressure device is the accuracy. Apart from being accurate there are a list of few other requirements which was being stated by the customers:

1. Accuracy: As stated before, the entire objective of this project is to obtain accurate data for the measurement of the pressures.
2. Wrist Wearable: The customer requires a device which would be worn on the wrist and the signals be obtained from the wrist. Considering this, the device builds, and signal acquisition has been done on the wrist.
3. Portable: This is for the future requirement, where a portable device is to be created when the signal processing is deemed as successful. Portability has been taken as a requirement, but the importance of this requirement is not high but as stated by the stakeholders to be considered of importance once the proof of concept has been proven.
4. Data Transmission and Storage: The blood pressure data is required to be transmitted wirelessly to the general practitioners or health centres where a record can be kept for day to day blood pressure variation. Among other requirements, this has been kept for the future work.
5. Painless: Current devices which include cuff mechanism to occlude the wrist or the upper arm are painful. A device which would include a point pressure mechanism application only on a specified area where the artery is present is to be built.

Design requirements and specifications have been created based on the problem definition and the needs of the customer to create a data acquisition system.

3.3. EFFECT AND CAUSE DIAGRAM

Before getting into the device requirements, the effect and cause diagram in figure 10 had to be analysed to note where the project might face challenges and the reasons for the project to fail:

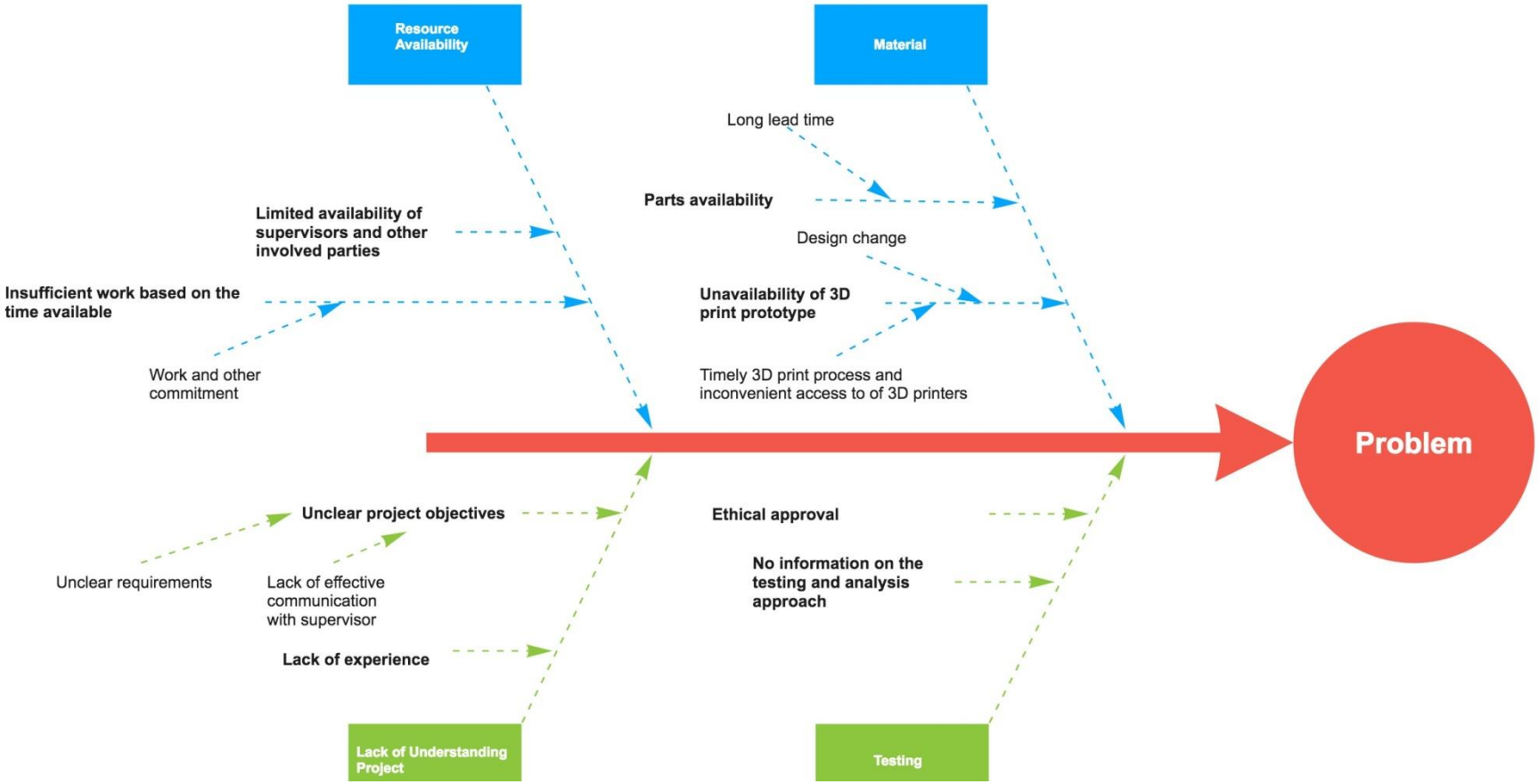


FIGURE 10: EFFECT AND CAUSE DIAGRAM FOR PROJECT FAILURE

While this effect and cause diagram in figure 11 is based on the process which needs to be undertaken in-order to successfully implement the project along with the design and result analysis:

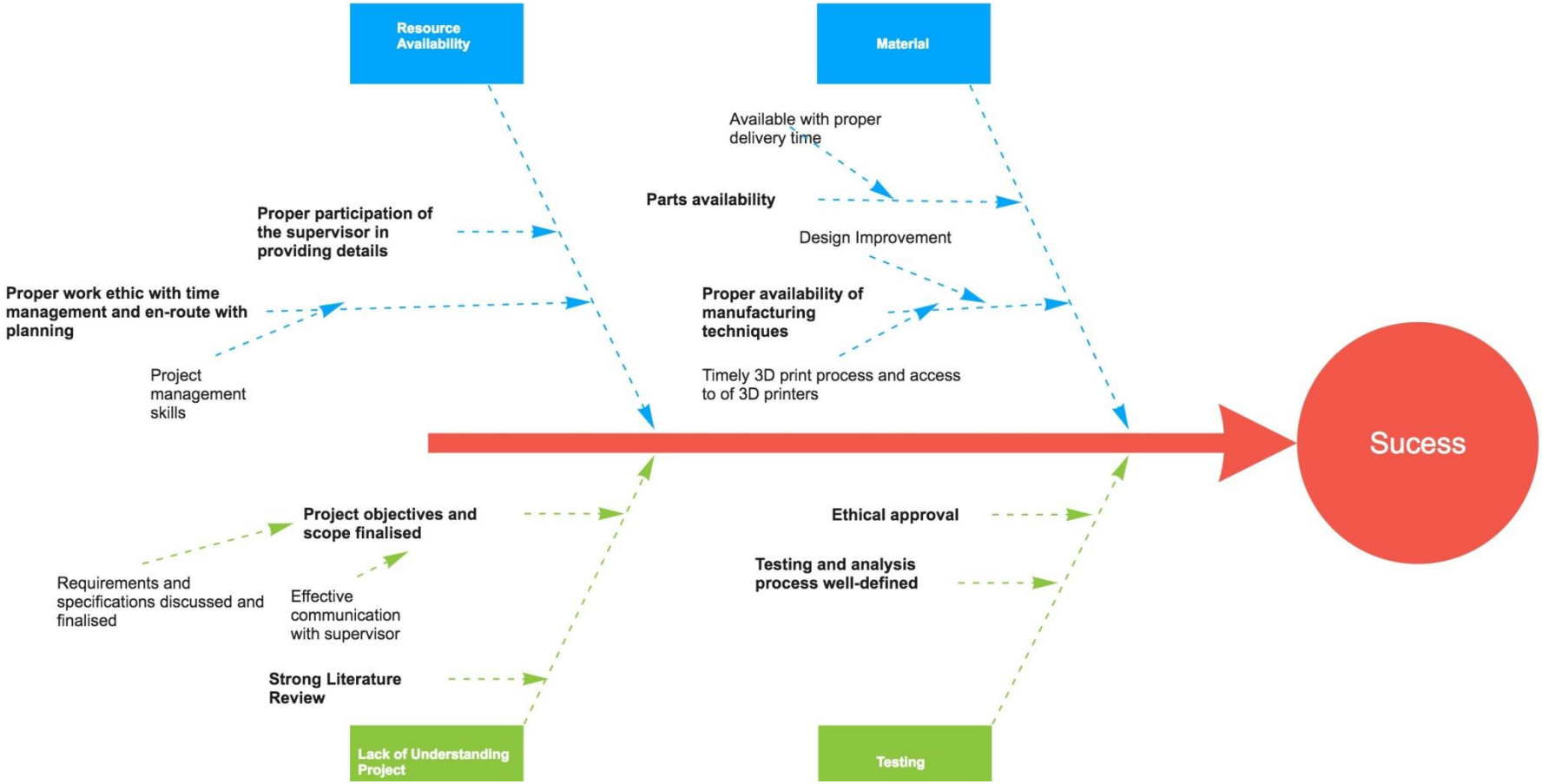


FIGURE 11: EFFECT AND CAUSE DIAGRAM FOR PROJECT SUCCESS

The project is based on the objective of undertaking signal processing on the data being collected. But collection of the data and the acquisition technique are significantly important to be built to obtain accurate data. It involves the mechanical and electronics aspects. Four of the key factors which have been considered in the problem and the success of the projects are as follows:

1. Resource Availability: The ideas and the guidance in the techniques of processing, knowledge and skills in the building of the device is key which must be kept in consideration. There are significant sections in the project where rigorous research had to be conducted such as the design of the PCB board which would facilitate in driving the sensors.

2. Material Procurement: This has always been a hindrance in projects where ordering and procurement takes longer time than usual. Ordering parts from manufacturers such as electronic components or ultrasound gel or getting parts manufactured such as the PCB boards always require changes in the scheduling. Availability of the parts is a key and had to be taken into consideration.

3. Understanding the project: There are times where the scope has to be modified in order to accommodate the possibilities of making the project effective. But there are times where getting off track the project is a high possibility.

4. Testing: The device constructed has to be tested based on the ethical approval. This project requires data collection where testing is one of the key objectives. It has to be ensured that proper testing protocols are being developed in order to test the people and collect data.

3.4. DEVICE REQUIREMENT

The device requirement is based on the problem definitions, customer requirements and the literature findings which was being done over the period. The requirements were set based on the need on how the data will be recorded, where the sensor will be placed, the sampling frequency at which the data will be recorded into the system and other components which would be required for the safe placement. The requirement covers from the mechanical wrist interface to the underlying electronics which would be used for the controlling and sensing of the signals and transmitting to the computer for post processing.

Data acquisition system	Description (Requirements)
Accurate	The main objective of the project is to obtain accurate results in the systolic and diastolic blood pressures along with the heart rate using the ultrasound Doppler flow meter
Painless	No pain to be induced on people while taking the reading when the transducer and the bladder compresses the wrist for the time period of the measurement being done ranging from 1-2 minutes.
Wrist mountable	Device is to be placed on to be placed on the wrist from where the readings would be taken. The main reason for this is the radial artery which would be used for monitoring the flow of the blood in the wrist is superficial compared to the brachial artery in the upper arm which is deep. Another reason being the fat deposition in the wrist is less compared to that on the upper arm

Accurate transducer placement	The ultrasound transducer must be placed in a fixed position. This would provide uniform signals reducing the probability of losing the signals
incorporated pressure sensor	A pressure sensor incorporated on the wrist would provide the pressure applied on the wrist using a cuff
Compatible, FDA grade rubber polymer	The bladder used to occlude the artery on the wrist. It is expected to be biocompatible, non-reacting, withstand up to 300 mmHg pressure
high sampling frequency data acquisition System	The data acquisition which is to be done for the signals from the pressure sensor and the ultrasound is expected to have a higher sampling frequency >5kHz to obtain a clear signal to observe the proper analysis results
Pumping mechanism	To inflate the bladder, different pumping mechanisms have been tried with existing blood pressure monitor automatic pump and micro-pump technology
Incorporate Emergency valve	In case of sudden overshoot of the pressure, it is required to have an emergency valve. In case the program fails, for safety of the user, the valve can be opened to release all the pressure

Incorporate Leak Valve	It is expected that the pump would inflate the bladder to a pressure well above the systolic pressure. Once, it has been inflated, the leak valves will be used to release the pressure slowly and see the change in the signals over the period
***Wireless Transducer position control**	A concept has been developed in which the ultrasound transducer attached to the mechanical interface can be controlled wirelessly with servo and Bluetooth module This would help in reducing the noise and error in the position when placing the transducer manually
***Wireless pressure data transmission**	The pressure data from the pressure sensor, can be wirelessly transmitted to the application
Incorporate Display Module	A display module would help in monitoring the pressure in the bladder along with the on/off of the pump and the emergency valve
Hard Ultrasound gel	Ultrasound gel are necessary as they reduce the impedance between the skin and transducer
Housing for transducer and ultrasound gel holder	A housing would hold the gel and the sensor in position over the wrist. This would ensure that the gel does not spill across the wrist while taking the measurement
Sensor Board Design	PCB design is required which would incorporate the pumping mechanism, pressure sensor amplifier and the LCD screen. It would

	communicate with the microcontroller to receive and send the data over to the data acquisition system
Safe	Safety being one the key factors while the measurement is taken so no electrical or mechanical damage is caused
Mechanical adjustable interface	Expected that the interface which would be sitting on the wrist is adjustable to different users.

3.4.1. OTHER DESIGN REQUIREMENTS

There have been several design requirements with the important ones which have been entailed above in the section of the device requirement 3.3. Among these there are several other requirements which must be taken into consideration in order to build a prototype model which would deliver the goals which have been stated in the problem definition and the customer requirements.

A further list of the requirements had to be considered along with the ones enlisted above as point listed below:

- **Safety:** To ensure that the design is safe to the operators with all the motion parts enclosed so it does not come directly in contact with the operator and pose any threat or damage.
- **Easy to Operate:** Must be easy to operate without with the program being uploaded which would be able to control the motion of the pins and the plate to generate appropriate pressure outcome.
- **Minimal Maintenance:** The device should be maintained easily and any change of the parts required must be easily replaceable.

- **Few Parts:** The number of parts in the device should be minimal to produce a reliability and easy maintenance over the course of time.
- **User Friendly:** Along with easy to operate, the device must be user friendly with proper module and graphical user interface (out of the scope of the current design project).
- **Power:** The power required to drive the device is based on the battery source of the ultrasound and the external batteries for driving the actuators and the sensors
- **Inexpensive Material:** Apart from the specimens involved for the testings, to keep the project under the budget, it is required to keep the cost of the materials lower.
- **Easy to repair:** If any damage incurs on the device through the process of testing, it is expected to be easily repaired without any major changes to the device setup.
- **Clean/Sanitisation:** The ultrasound lubricant is expected to be used for reducing the impedance between the transducer and the skin. This calls for a proper cleaning mechanism.
- **Constant Pressure Monitoring:** The pressure being applied on the wrist compared to the pressure inside the bladder should be constantly monitored
- **Visually Appealing Device:** The device should be visual appear to the clients with all the parts intact within specified dimension and shape.
- **Cost Effective:** The running cost of the device along with the maintenance and parts must be minimal.
- **Contingency Protocol:** A proper contingency protocol needs to be developed so that in case the plan in the designing process fails, another design is available which would be able to meet the same set of requirements.

3.4.2. PRIORITISING DESIGN REQUIREMENTS: PAIRED COMPARISON

A paired comparison was done based on the important requirements which has been tabulated in the section 3.4 under the device requirements and other important requirements which has been enlisted in the section 3.4.1. under the prioritising of the design requirements into a paired comparison. In this kind of comparison, a rating is being given to each requirement against another requirement. This is a means of quantifying how much more important the criteria letter is than the other, where the greater the number, the greater the importance. The overall

judgement of the important requirements is to be considered at the end based on the points given.

Paired Comparison of Ultrasound BP Monitor

		B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	Importance		
Safety	A	A1	A1	A1	A1	A1	A2	A1	I3	J2	A1	L1	A1	N3	O3	A1	A2	A1	*A=*	*14*	2.8
Easy to operate	B	B1	B1	B1	F1	B3	H1	I2	J1	B1	L1	B2	N3	O2	P2	B2	R1	B=	11	2.2
Low Maintenance	C	C1	E1	F1	C1	C1	I3	J2	C1	C1	M1	N2	O2	P1	C3	C1	C=	9	1.8
Few Parts	D	E2	F1	G1	H1	I2	J2	D1	L2	M2	N2	O2	P1	D2	R2	D=	3	0.6
User Friendly	E	F1	G1	H1	I2	J1	E1	L1	M1	N2	O2	P1	E2	R1	E=	6	1.2
Power	F	F1	H1	I3	F2	F1	L1	F2	N2	O2	P2	F2	F2	F=	14	2.8
Inexpensive Materials	G	H1	I1	J2	G2	L1	M1	N1	O1	P1	G2	G1	G=	7	1.4
Easy to repair	H	I1	J1	H1	H1	M1	N2	O1	P1	H1	H1	H=	9	1.8
Clean/Sanitisation	I	I1	I1	I1	I1	N1	O1	P1	I2	I2	I=	25	5
Constant Pressure Monitoring	J	J2	J1	J1	N1		P2	J2	J1	J=	18	3.6
Visually Appealing	K	L1	M1	N1	O1	P2	K1	K1	K=	2	0.4
Cost Effective	L	M1	N1	O1	L1	Q2	L1	L=	10	2
Contingency Protocol	M	N1	O1	P1	M3	M1	M=	12	2.4
Painless	N	N1	P1	N1	N2	N=	26	5.2
Accurate	O	O1	O1	O1	O=	23	4.6
Mechanical Adjustable Interface	P	P1	P2	P=	19	3.8
Light Weight	Q	Q2	Q=	4	0.8
Portable	R	R=	4	0.8

TABLE 1: PAIRED COMPARISON STATING THE RATING GIVEN TO THE REQUIREMENTS

In order to verify which of the requirements are important, a relative weighting graphical representation is being shown below in figure 12, which has been developed based on the importance score given to each of the criteria.

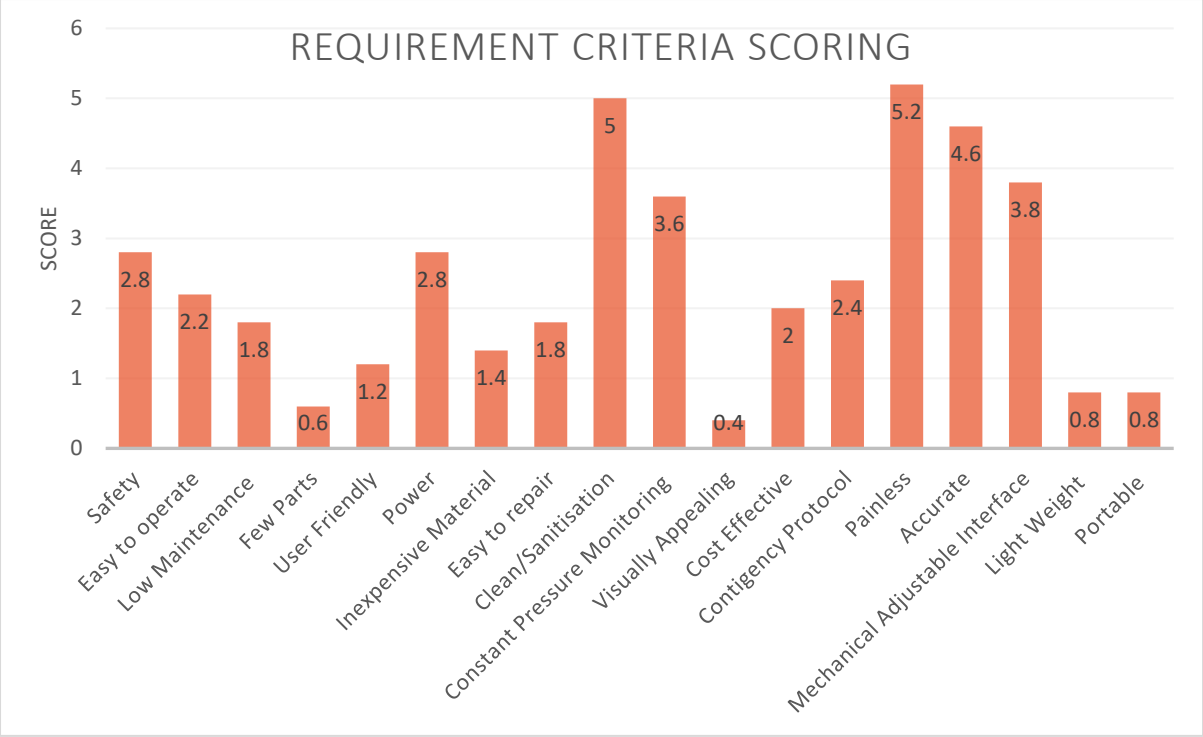


FIGURE 12: PAIRED COMPARISON RANKING GRAPH

From the requirement scoring criteria it is observed that some of the requirements hold a higher score compared to others. The few important ones which are essential and have been scored high have been listed below:

1. Painless
2. Clean/Sanitisation
3. Accurate
4. Adjustable Mechanical Interface
5. Constant Pressure Monitoring

These 5 requirements are key and pivotal. The device must be painless so in no means any pain is being induced. This is one of the safety factors which referring to the device requirements table in section 3.4, calls for an implementation of an emergency valve. Further, smoothened surfaces of the mechanical interface would provide a painless means of taking the readings from the device.

Since ultrasound gel is being expected to be used at the interface of the ultrasound transducer and the wrist, it is expected to have a proper mechanism to clean the system once the reading has been taken.

Accurate measurement is one of the key concerns with constant pressure monitor. The pressure being applied on the wrist has to be monitored accurately.

With different people expected to be tested, adjustable mechanical wrist mount is thought to be used or adjustable placement of the transducer in order to get the optimum location for taking the ultrasound reading.

3.4.3. OBJECTIVE TREE

The prioritising of the key requirements has led to the section where it is being required to evaluate the key design objectives. Based on the scores provided for the requirement criteria in section 3.4.2, 6 of the design objectives have been chosen as the key whose detailed design objective tree development is to be carried out. An objective tree would be helpful in dividing each section into sub-sections which would be followed in order to develop and design the concepts. The six important design objectives being:

1. Safety – 0.15
2. Accuracy – 0.2
3. Cleaning – 0.15
4. Adjustable Mechanical Interface – 0.1
5. Data Collection – 0.2
6. Pressure Monitoring – 0.2

Each has been provided with a score based on the importance. Since data collection, monitoring of the pressure and the accuracy with which the readings have been taken are the key objectives, they have been equally rated higher scores. While safety and cleaning being ethical aspect while using the device for data collection from the people, have been ranked second in the list. While adjustable mechanical interface would be good placement of the transducer, compared to others, it does not hold as high rank. But incorporation of adjustable wrist interface has been undertaken to provide better results in data collection process.

Further each section has been further divided and ranked based on the work which is to be conducted. Calibration being one of the key component which is included in the section of data collection, pressure monitoring and accuracy as the main objective of this project is to undertake accurate pressure measurement. The objective tree is shown below in figure 13.

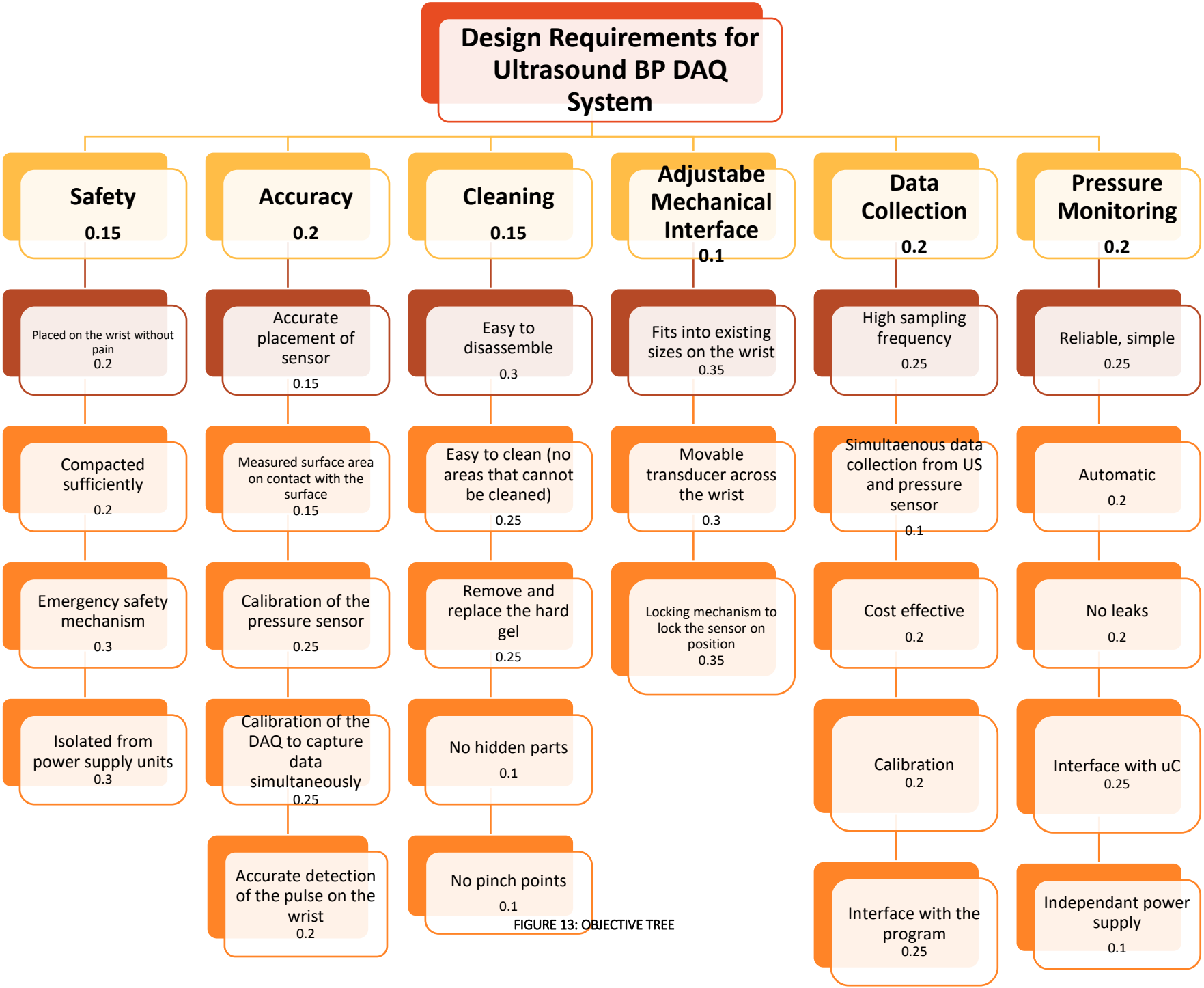


FIGURE 13: OBJECTIVE TREE

3.5. FUNCTIONAL STRUCTURE

The initial phases as described in the previous sections 3.1-3.4 have been dedicated to the requirements of the design development based on the needs and the problem definition. A list of requirements has been developed in order to undertake and focus on particular sections and subsections which would be essential. This section has been dedicated to the actual working of the device, the functional structure or the function tree as stated by Haik and Shahin [99]. Functional tree are used as they mark the input and the output of device. A detailed function tree also incorporates the internal 'black box' which have been decomposed to their respective function. A function tree in this project is essential as it marks the actual working of the device and also it has been used in the programming for the real-time data collection using the LabVIEW software.

The function tree in here describes:

1. Input and Output to the device
2. Decomposed internal functioning
3. Combination of the entire device operation

3.5.1. INPUT AND OUTPUT

The data acquisition device being built has the mechanical and electronic components. The user would be responsible in providing input. The idea of the development of the device has been done in such a way that, the two major outputs being:

1. Pressure Sensor data output, 0-5V
2. Ultrasound data output – frequency range 20Hz to 20kHz, ±1V

Apart from these output, other outputs being the display module which will show the pressure values and the state of the pump and the solenoid valve.

The major input to the system are from:

1. Pressure sensor: measuring the pressure being applied on the wrist

2. Ultrasound blood flow meter: the ultrasound signal measuring the flow of the blood – high frequency signals going into the body
3. Transducer position: two different concepts of automatic and manual user input for setting the position of the ultrasound transducer
4. Emergency valve: Opening and closing of the emergency valve to release the pressure when there is a sudden overshoot
5. Pump driving: User input to start and stop the pump
6. Leak valve: User input to set the leak rate

The figure 14 depicts the input/output scenario being used in the device:

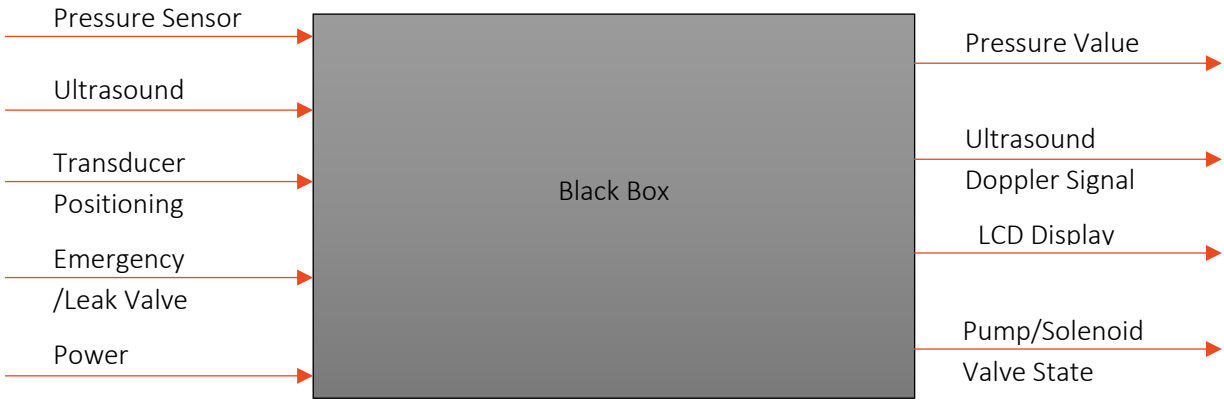


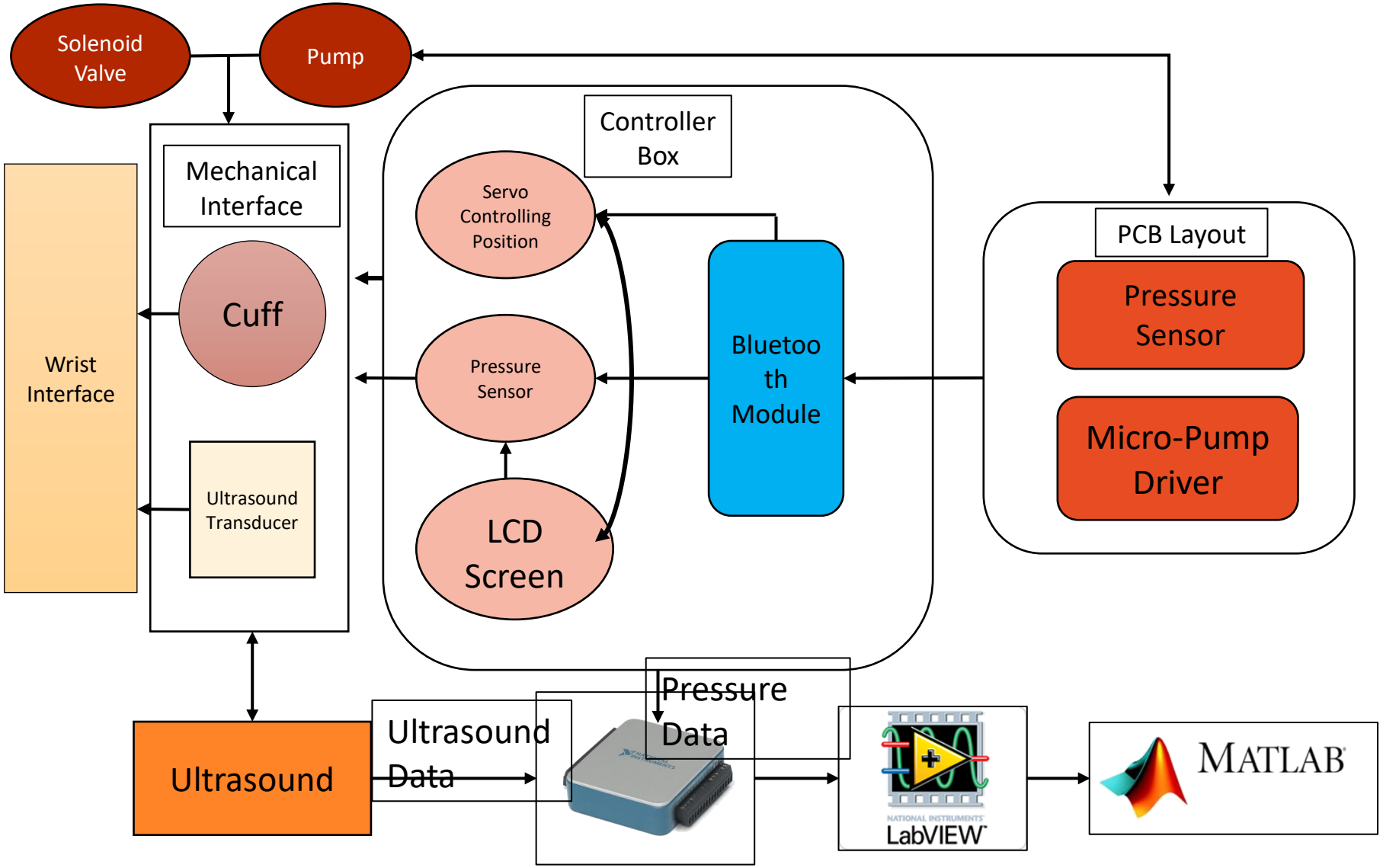
FIGURE 14: INPUT AND OUTPUT DIAGRAM

The black box is the processing box which contains the signal processing, controlling of the position of the transducer, amplification of the pressure sensor voltage, LCD module circuit and valve controller circuit along with the user input buttons to decide up on the state of the pump and solenoid valve.

The components inside the black box has been shown in the functional structure diagram below. A detailed functional block diagram has been shown in the next two pages in figure 15 and figure 16 indicating the various parts which has been included in the project. Figure shows the actual flow diagram of the signals from the input to the output which goes into the MATLAB and LabVIEW. The first block diagram in figure 15 is dedicated to the organisation of the device components. The prime outputs are the ultrasound and the pressure data which go for the signal processing. While the prime inputs are the pressure reading from the cuff and the ultrasound reading from the wrist along with the secondary inputs like user activation of the valves and the pump and positioning of the transducer on the wrist.

But figure 16 is more dedicated towards the actual input output block diagram with the detailed analysis inside the black box and the operations are interconnected.

FIGURE 15: FLOW DIAGRAM FROM INPUT TO OUTPUT



This detailed functional structure diagram shows two phases. The first input is provided to the system where the hardware is responsible for running the sensors and the actuators. The output shown in yellow is the data output from the primary system which is the input for the secondary system. The secondary system is involved in the processing and post processing done using the software which would provide the final processed data output.

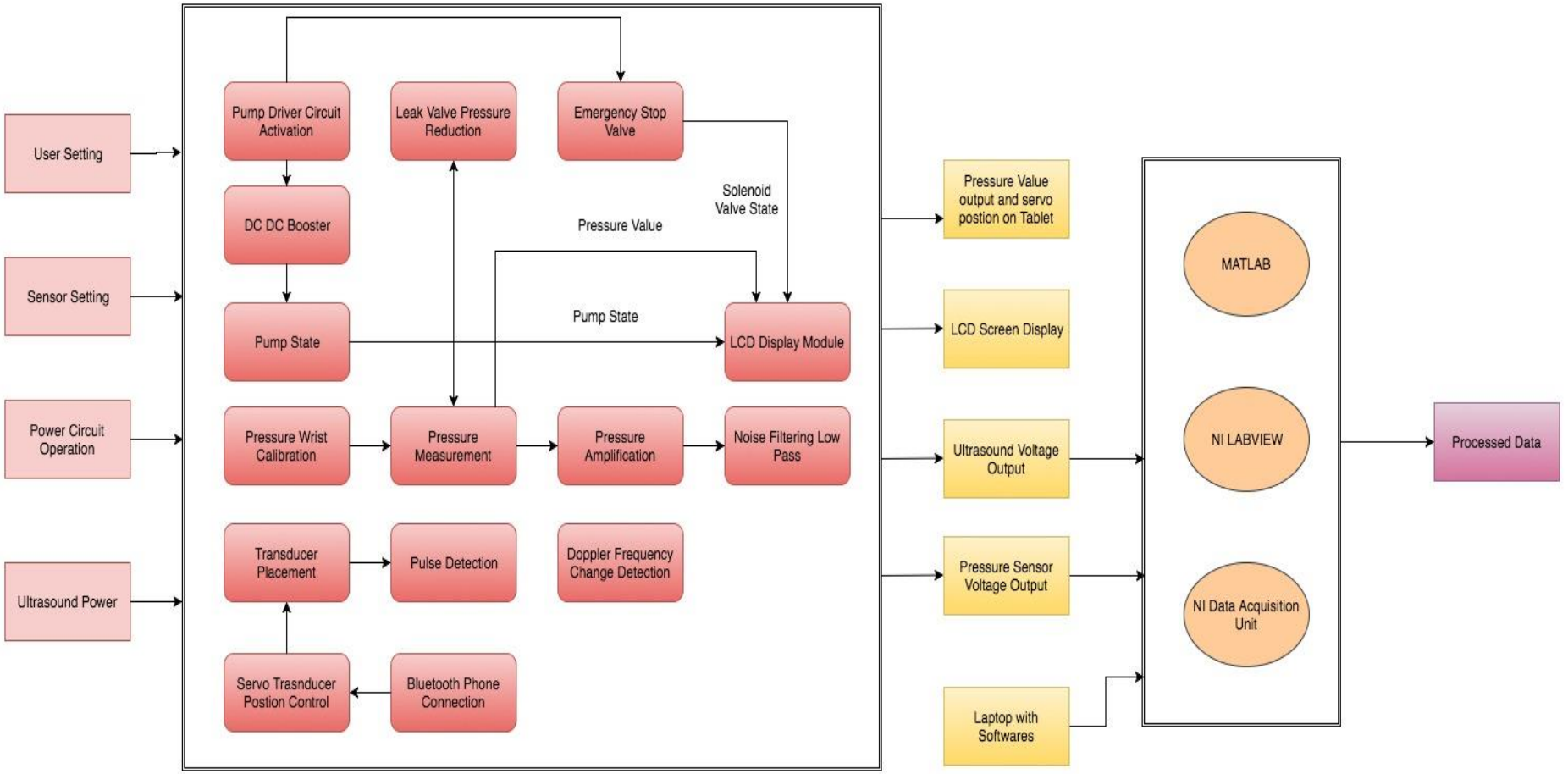


FIGURE 16: DETAILED FUNCTIONAL STRUCTURE

3.6. SPECIFICATIONS

3.6.1. OBJECTIVES

At this stage of the specifications, the provided requirements and the function of the device is to be utilised in order to conceptualise the device. This intermediate stage of specifications would provide with the quantitative values that would be required to develop a system. Using the development tools for the requirements which were namely the paired comparison, objective tree and the functional diagram, the key requirements which are needed to be considered have been obtained. This calls for narrowing the parameters which would go with these requirements which can be added to the device.

According to the need statement, the development of the data acquisition system would be able to collect the data but the added components to this system is the processing and post-processing techniques which are to be utilised in the collection of data. This extends the scope to be broadened to incorporate further signal processing.

3.6.2. DEVICE REQUIREMENTS AND SPECIFICATION INTER-RELATIONAL CHECKLIST

As stated in the sections of 3.2 and 3.4 regarding the requirements by the customer and the requirements which are adopted for the construction of the device, a general rule of parameters must be considered on which the specifications have to be laid down before considering the exact values of the specifications. The table 2 creates a checklist on which the actual specifications will be based up on. These are in correlation with the requirements:

Requirement	Expected Specification	Parameters
Safety	• Presence of emergency valve • User input type – switch, manual • Voltage if required for valve operation	Voltage Current Accessibility
Easy to operate	• User front end controls • Ease of access of data when processed • Ease of placement of the mechanical interface on the wrist	User Interface Display type Access mode
Low Maintenance	• Ease of repairing • Part availability if faulty • Low cost of parts	Repair/replacement time
Few Parts	• Mechanical parts expected to be kept low • Electronics part may vary in the quantity • Easy availability	Number of parts Description of parts
User friendly	• Front end accessibility	User Interface
Power	• Battery operated • Low voltage • Rechargeable	Voltage level Current supply
Inexpensive Materials	• Low cost • Ease of parts availability	Cost
Repairing	• Least time to repair and reassemble • Parts acquired • No long lead time on parts	Repair time Procurement time
Clean/Sanitisation	• Parts swapped around if required • Cleaning procedure	Replacement time
Constant Pressure Monitoring	• Pressure sensor accuracy levels	Pressure levels Voltage

	• Power supply to the sensor – constant • Driving circuit for reading of the voltage • Low voltage low current levels	Current supply
Visually appealing	• Not considered important at this stage	-
Cost Effective	• Low cost, within the budget	Cost Repair/replacement cost
Painless	• Measured dimension on the wrist • Smooth surfaces of the mechanical interface • Emergency valve • Insulated circuitry • Isolated battery and sources	Voltage level Accessibility Design dimension
Accurate	• Pressure sensor accuracy level • Data collection sampling frequency – High • Measured area pressure being applied • No leaks	Sampling frequency of DAQ Pressure sensor error levels
Mechanical Adjustable Interface	• Timely designed and assembled • Incorporate safety features	Parts design/assembly time Dimension
Light Weight	• Can be moved around for measurement • Intact parts	Weight Number of parts
Portable	*Specification same as the lightweight	Weight Number of parts

Contingency Protocol	• Plan B for failure of any of the current devised techniques	Backup plan

TABLE 2: EXPECTED SPECIFICATIONS AND PARAMETERS BASED ON THE REQUIREMENT

3.6.3. SUMMARISING INTERCONNECTION CHECKLIST

The list of the specifications to be considered provided in the previous section based on the requirements which have been previously considered, the key specifications which have to be considered while in the conceptualisation, design and development phases are:

1. Time – this would include the time for procurement of the parts, time for design and development and the time for the assembly. In case of any repairing needed, the lead time on it is essential to be considered as well.

2. Cost – procurement of the parts high of cost such as ultrasound have been considered in the early phases of the project. Other cost requirements include the parts which might be obtained over the course of the development and design

3. Weight – it is expected the device to be light weight or would be able to carry so it can be tested on people and readings could be obtained for the processing

4. Power – Providing power to the system to run includes the use of battery. The considerations being done for this section would be the power each component would require including the current draw and the voltage drop. Recharging the battery system has to be considered in order to avoid extra increase in the expenses

5. Dimension – the size of the mechanical interface constrained to the width of the wrist where the measurement is being taken has to be considered

6. Pressure accuracy – Highly accurate pressure sensor and the calibration method would signify how the data is being acquired. Procurement of highly accurate pressure sensor, the affecting parameters such as temperature and humidity, hysteresis and power levels must considered

7. Data acquisition sampling frequency – data collected from the pressure sensor and the ultrasound, the involved sampling frequency, effect of the Nyquist frequency and the memory it will acquire while processing needs to be considered

Figure 17 shows the key specifications parameter listing the points discussed above.

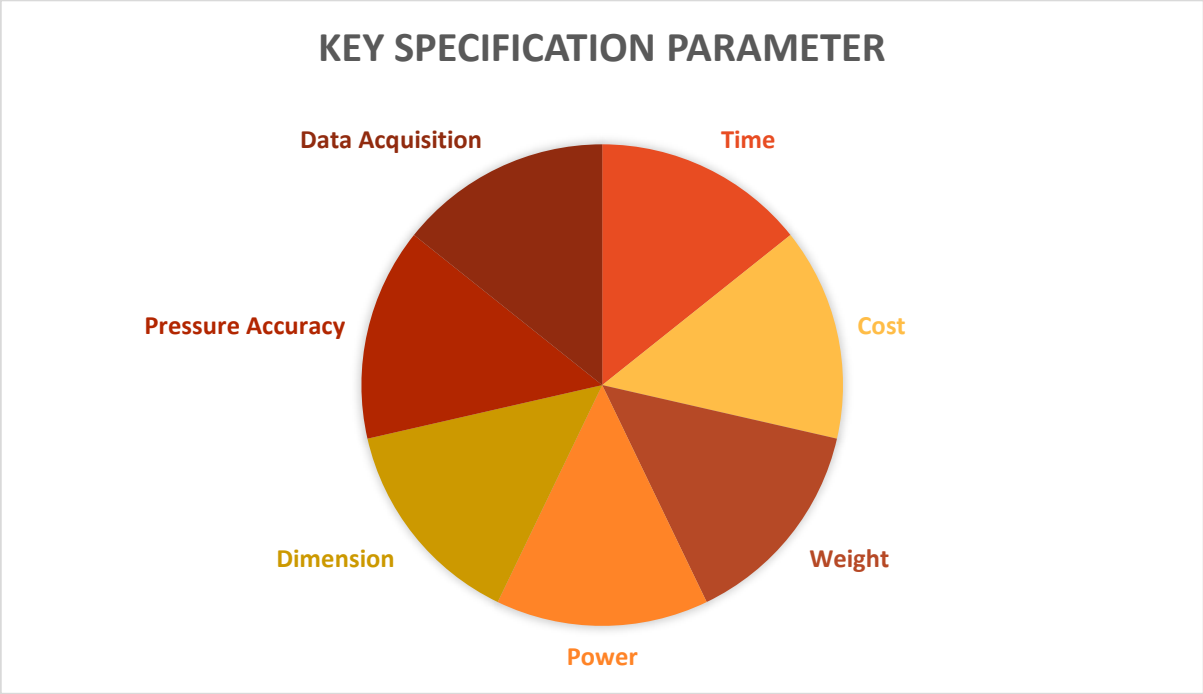


FIGURE 17: KEY SPECIFICATIONS PARAMETER

3.6.4. QUALITY FUNCTIONAL DEPLOYMENT METHOD

Quality function deployment technique evaluates the correlation between the requirement and the specification in the design process, quantitatively. It considers the human needs and base the specifications on that [100]. It also helpful in evaluating of the specifications ranking and seeing which specifications would be more important than the other. This section undertakes the quantitative measurement based on the qualitative values which have been obtained over the previous sections.

The QFD development has been done over the complete specifications section and the actual model is being shown at the end. It considers the following points:

1. Currently stated requirements
2. Specifications developed from the requirements
3. Target information or the objective which has to be attained to meet the specification
4. Importance based on the need of the project
5. Correlation matrix providing a rank based on the relation between the specifications and the requirements and how strongly the quantitative parameter needs to be considered

The model is based on the template shown below in figure 18. The QFD is presented in Appendix C. Here the focus is not the customer but a device which would be able to acquire data from people (subjects).

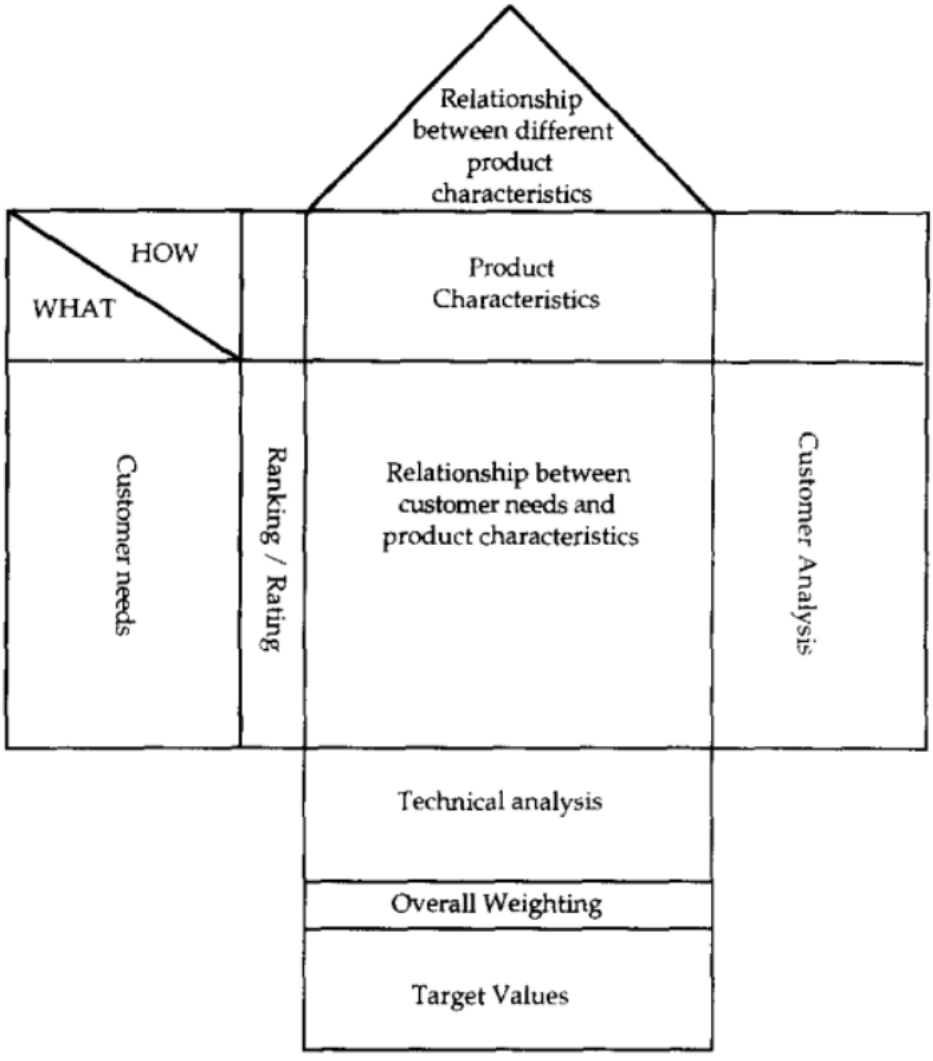


FIGURE 18: QUALITY FUNCTIONAL DEPLOYMENT MODEL EXAMPLE EXPAINING THE DIFFERENT SECTIONS

3.6.5. *Dimension of Pressure Application Area on Wrist*

An extensive research has been undertaken on the different sizes of the cuffs which are being used in the blood pressure devices, the error provided in the measurement and what the optimum size which must be utilised to obtain correct reading in the pressure. As per the discussion undertaken in the literature review section 2.3.1, various authors have suggested different sizes. A summary in table 3 has been generated based on the different sizes which have been recommended as shown below:

Author/Year	Recommended Cuff Width (cm)	Recommended Cuff Length (cm)	Wrist Circumference (cm)	Description	Check
[17]	12.5 – 13	35	< 33	British Hypertension Society	☒
	3	6	<6	American Heart Association. Based on 0.4 AC/CW ratio	☒
	5	15	6 – 15		
	8	21	16 – 21		
	10	24	22 – 26		
	13	30	27 – 34		
	16	38	35 – 44		
	20	42	45 – 52		
[14]	Arm Circumference/Width ratio = 0.4				☒
[18]	12	23		Standard	☒
	14	40		Special. Lower arterial pressure	☒
[19]	13	23		High SBP	☒
	13	36		Standard	☒
	16	23		Low SBP	☒
[20]	9	27	20.5 – 24.0		☒
	10	22	24.5 – 27.0		
	12	23	27.5 – 32.0		
	15	33	32.5 – 34.0		
[21]	Arm Circumference/Width ratio = 0.3 – 0.45				☒
[22]	14.3	27.8		Increased error	☒
	13.8	37.3			☒
[23]		21.5	<23	No information on the cuff width	☒
		27.5	23 – 32		
		35.3	>32		
[24]	Arm Circumference/Width ratio = 0.4 Length = 0.5 of circumference				☒
[25]	12	Length = 0.5 of circumference			☒
[26]	12	33.5		American Heart Association	☒
	14	Complete arm encirclement		WHO Expert Committee on Cardiovascular Diseases	
[27]	12	23		Higher error	☒

	15	34			☒
[28]	12	23		Higher error	☒
	16	34			☒
[29]	Arm Circumference/Width ratio = 0.4				☒

TABLE 3: LITERATURE BASED DIFFERENT CUFF SIZES SUMMARISED BY AUTHORS IN STUDIES

In the literature review it was considered according to the American Heart Association [14, 15], the set standard for the width of the cuff to be 40% the circumference of the wrist while the length has to be 80-100% circumference of the wrist. According to the research conducted and as summarised in the table above, 67% of the author have agreed to the standard of 40% width of the cuff to be used while 33% have stated a size greater or smaller than the standard specified size. Deciding on the minimum size of the cuff is also based on a simple experiment which was undertaken as stated in the Table 3. Based on the experiment where a point pressure was being applied on the wrist and measured where the ultrasound flow signal vanishes shown in Appendix A, with a pre-defined area where constant increments of weights were being applied, the smaller sizes provided an over-estimation of the pressure of occlusion or the systolic pressure. An area greater than 700mm^2 provided the pressure of occlusion value as recorded by the other devices for the measurement of the systolic pressure. This recommended that either the use of a cuff for occlusion based on the standard suggested by AHA of width being 40% the circumference of the wrist. The pie diagram in figure 19 below specifies the outcome of the research based on the studies which agree, disagree or are neutral:

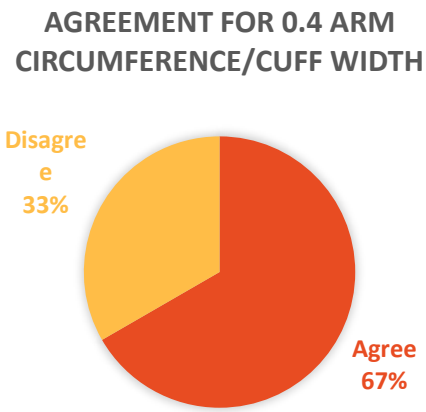


FIGURE 19: GRAPHICAL RESPRESENTATION OF THE STUDY FAVOURING (1) THE SIZE OF THE CUFF MUST BE 40% THE CIRCUMFERENCE OF THE WRIST

3.6.6. *Location of Measurement of Pressure*

In the section 2.3.2 of the literature review, which discusses the research being carried out for the location of the blood pressure measurement, commonly the measurement location is being taken on the upper arm where the brachial artery is present or on the wrist where the radial artery is present. The ultrasound transducers have an efficient penetration at high frequency for the vessels or targets which are superficial to the surface of the skin [2, 72].

Based on the research from different sources for the pressure measurement from radial artery in the forearm compared to the pressure in the brachial artery and intra-arterial, there are discrepancies obtained which is primarily because the pressure increases with the distance from the heart as there are changes in the diameter and height from the heart with higher pressure in the lower limbs. Brachial artery being on the same level as the heart, the pressure difference is not significant and represents an accurate site for obtaining proper results. Some of the researchers have favoured different techniques and compensation methods to obtain pressure from radial artery. The table 4 summarises the research findings for the cuff location and errors measured and if they are in the favourable range*:

Reference		Description	Favourable Location	Current Design Favourability
[40, 101]	Pre-operative State	Very low error	Wrist	☒
	Post-operative State	Not favourable for current device design	Upper-arm	☒
[40]	Comparison between radial artery pressure with oscillometric method	Very low error measured in the wrist	Wrist	☒
[41]	Conical cuff wrapping	Tied around wrist	Wrist	☒
	Cylindrical wrapping	Tied around upper arm		
	Forearm below elbow	Favourable low error result obtained		
[42]	Comparison between MAP and ABP	Within the standard error range	Wrist	☒
[102]	Comparison with ABP	Low errors for MAP and DBP but very high for SBP	Wrist	☒
[46]	Upper arm	Supports theory of very high pressure	Upper arm	☒
	Wrist			
[45]	Control	Can use wrist for measurement but will induce errors with condition of patients	Invasive catheterisation	☒
	Chronic Kidney Patients			

* Favourable range is based on the error of ±5 mm Hg from the brachial blood pressure measurement and if proper compensation can be done in order to obtain accurate readings if standard digital or aneroid system is used

[43]	Radial artery continuous compression device comparison with ABP and brachial cuff	Statistically accurate with high probability of staying in the range	Wrist	☒
[47]	Error between radial artery palpation and brachial auscultation	Changes in the age affects the readings, with compensation	Upper arm	☒

TABLE 4: LOCATION OF MEASUREMENTS

Based on the articles researched, the main two findings which have been concluded are that the placement of the cuff around the upper arm is preferred by the doctors as it is at the level of the heart. Based on the manometry rule and the guidelines set for the measurement of the blood pressure [103], pressure recording on the upper arm provides an error of up to ±2-5 mmHg while when the reading is taken from the radial artery, it can vary up to ±20 mmHg. These variations are due to the height difference from the heart and where the measurements are taken. From the table 4, studies have shown that [40-45] [46, 47, 101, 102] have favoured the measurements taken from the wrist do not vary significantly from the upper arm. They also favoured that in the cases where the measurements have to be taken from the wrist, a compensation technique can be utilised where, the difference can be subtracted based on the distance from the heart and the wrist.

Based on the research conducted, it is devised to build the mounting on the wrist and measure the pressure readings from there. The diagram in figure 20, shows the feasibility of the location of measurement on wrist based on the literature review, if the measurement from the wrist will be feasible or not.

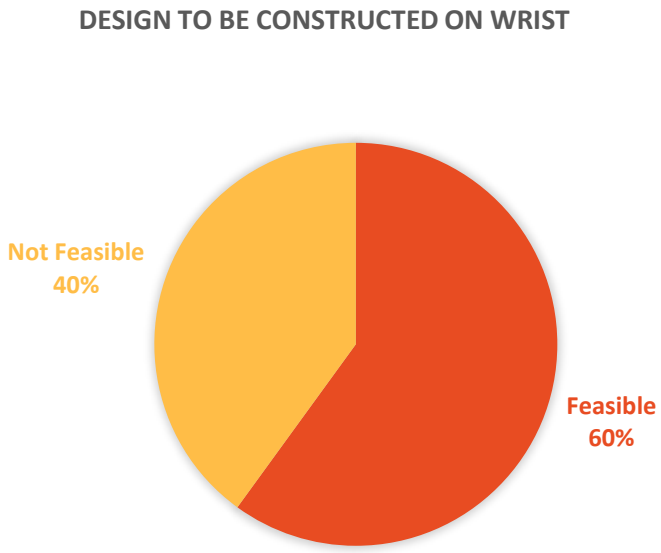


FIGURE 20: GRAPHICAL REPRESENTATION FOR FEASIBILITY OF SETTING THE LOCATION OF THE MEASUREMENT ON THE WRIST BASED ON THE LITERATURE REVIEW

3.6.7. Pressure Sensor Accuracy

Accuracy of the pressure sensor is the key to take accurate readings for further signal processing and device system to get close estimation of the systolic and the diastolic pressures. The measurements being taken from the pressure sensor is required to within very close accuracy levels. Marketed pressure sensors have accuracy as high as ±0.05% but they can be very expensive, and the dimensions come out to be a crucial factor when incorporating them in the design. Furthermore, the data output the pressure sensor is to provide must be within acceptable range which can be sent to the data acquisition unit in order to process the signals and acquire data. In such cases, high voltage or high current output must be considered and how it be affecting the data acquisition system. But on the other hand, if the output is low, amplification has to be considered to be read by the microcontroller. To bring the output to the acceptable range, development of external amplification or stepdown circuit is necessary. This adds up to the cost and the time.

There are various kinds of the pressure sensors in the market. Devising of the mechanical aspects are based on which pressure sensor would be suitable. Namely the two kinds of the

pressure sensors which have been investigated are the standard air pressure sensor and the force resistive sensors.

While the force resistive sensors are easy to drive and collect data with low level of circuitry and processing, the inaccuracy is high and deformation on the skin is very large. They operate as strain gauges.

The standard air pressure sensors which are commonly being used in the standard blood pressure monitors reads the pressure from the cuff or the bladder in which they have been embedded. The piezoelectric material inside deforms. The deformation is directly proportional to the pressure read from the cuff. The output is sent out as the voltage. The specifications of a proper pressure sensor are tabulated in table 5 below based on which research was conducted to decide which pressure sensor would be suitable for this purpose:

Parameters	Range (value)
Measurement Medium	Air
Pressure Range (mm Hg)	0 – 400
Maximum Allowable Pressure (kPa)	450
Maximum Output Voltage (REQURED)	0-5 V
Accuracy	±0.5 mm Hg
Hysteresis (Full scale)	0.5%
Operating Temperature	0^0C – 70^0C

TABLE 5: PRESSURE SENSOR SPECIFICATIONS

These are the specifications where the consideration has been provided to the range it can record. Most of the existing blood pressure devices can go up to 300mm Hg pressure. Voltage output would provide the transfer of the data from the pressure sensor which can be read by the micro-controller. As the microcontrollers can take variable voltage inputs, here a standard range is being considered. Finally, the accuracy is the most important parameter. It is required that the pressure reading to be as highly accurate as possible.

3.6.8. *POWER*

Power considerations has to be made as various components would be running from the battery. Power can be provided here either using AC mains power supply or by using batteries. The problem with the AC mains power supply is the safety. Different components would be requiring different levels of power which would call for development of a full wave voltage rectifier circuit along with voltage regulator. Further the requirement would be the use of step down converters. These all together would affect the size of the device further affecting the portability. The power usage of the pump, pressure sensor, microcontroller, servo-mechanism, emergency valves and the ultrasound itself will be different. Use of rechargeable lithium ion battery with proper current ratings would be able to provide proper supply. Recharging the batteries would be able to reduce the cost.

The ultrasound unit has its own dedicated battery power supply which can be recharged. The current can be used from this device to drive the entire system. The estimation of the voltage levels and current draw for each component has been specified below in table 6:

Components	Voltage (V)	Current Draw (mA)
Ultrasound	14	600
Pressure Sensor	10-20	<100
Pump	6 (Rotary), 18-28 (piezoelectric)	>200
Servo	3-6	<40
Microcontroller	3-6	<100
Valves	3-6	>100

TABLE 6: POWER UTILISATION SPECIFICATION

3.6.9. *PORTABILITY*

Another key specification is the weight of the device in order to make it portable. The portability of the device would be helpful in collecting data from different people without them have to come to a specific location to provide the data. It is expected that the device would be able to incorporate all the system including the ultrasound and the data acquisition unit at one location and be able to transfer the data to a laptop without. The constraint on setting the weight

is majorly dependent on the weight of the ultrasound device. But it is expected to keep the system weight as low as possible targeting a weight of <10kg.

Movement of the device around further required proper assessment based on the legislation set by the Australian OHS Professional [104]. It is based on the number of times the load is to be lifted and what the posture of the person would be while lifting the load. It was essential in carrying it around for the data collection purpose. In order to have a safe lifting it further is necessary to have all the components attached to a based plate to facilitate safe movement without the components falling. The legal limit of lifting the weight is dependent on the person so that in no sense any injury is being done [104].

In a long run it is expected that the entire unit would be wrist wearable blood pressure monitor which would be portable and light weight.

3.6.10. DATA ACQUISITION SYSTEM

Data acquisition process is essential in this case as collection and the transfer of the data is essential. The data collection and the choice of a data acquisition unit is based on the following parameters:

1. Number of channels: Requirement is that the data transfer to occur from the pressure sensor and the ultrasound unit simultaneously. At least 2 analogue channels are necessary

2. Sampling frequency: High sampling frequency would provide data at a rate in which the discretised values can be combined to produce a continuous smooth curve which can be utilised to interpret the information. An expected sampling frequency of >5kHz is desired.

3. Analog Resolution: Higher analogue resolution would be able to provide with higher AD conversion bits increasing the resolution of the readings obtained. Analog resolution higher than 8 bits is desired.

4. Analog Input Voltage: The key is to obtain the voltage reading from the source with high resolution. The ultrasound and pressure sensor peak to peak voltage have to be figured out in order to decide up on the input peak to peak voltage DAQ can measure.

Another important parameter to be considered in this case is the collection of the acquisition and the transfer of data to the computer for processing. Systems like National Instruments data acquisition units are helpful in directly acquiring and processing the real-time data using their dedicated software. Other acquisition systems such as the standalone ones from Agilent or Tektronix have high sampling frequency and internal storage but add up to the weight and constraining the portability. Oscilloscopes on the other hand can acquire data but have a set period of 8-12 seconds of data at a time with optimal sampling frequencies. But these fail to show the data real-time on a wider window and cannot directly transfer to be processed to software such as MATLAB.

3.6.11. HOUSE OF QUALITY

A house of quality has been deployed which states the comparison between the requirements and the specifications which has been set. Based on the specifications developed over the section 3.6, few of the major specifications were chosen along with the quantified values which is targeted to be achieved. The detailed house of quality matrix along with the correlation has been shown in the appendix section C.

The important specifications chosen in here are enlisted below along with the absolute and the relative ratings. These absolute ratings has been calculated based on the ratings for the requirements obtained in section 3.4.2 for the paired comparison. These ratings have been multiplied against the level rating which is 1,3 or 9 based on the importance and a summation is done for each specification against all the requirements. For instance, for the highest rated specification for the movement of the transducer across the wrist:

$$Absolute\ Rating = (9 \times 14) + (9 \times 11) + (3 \times 9) + (3 \times 3) + (3 \times 9) + (3 \times 10) + (9 \times 12) + (9 \times 26) + (9 \times 23) = 867 \ldots (9)$$

The calculation of the relative rating is done by, getting the maximum of all the absolute rating. Dividing the absolute rating of the specification for which the relative rating is to be calculated by the maximum absolute rating. Finally multiplying it by the highest correlational rate point given to the maximum rating, which in this case was 9. For instance, being light weight has an absolute rating of 395 while the maximum absolute rating is 867. The relative rating is given by:

$$Relative\ rating = \frac{395}{867} \times 9 = 4.10 \ldots (10)$$

The absolute and the relative rating for the calculation of the wrist ultrasound transducer placement is shown below in table 7:

Requirement	Requirement Ranking	Correlation rank
Safety	14	9
Easy to operate	11	9
Low maintenance	9	3
Few parts	3	3
Clean and sanitisation	3	3
Contingency protocol	3	3
Painless	9	9
Accurate	9	9
Mechanical adjustable interface	9	9
Absolute Importance (requirement rating*correlation rank)	867	

TABLE 7: ULTRASOUND TRANSDUCER PLACEMENT ON WRIST - QFD RATING BASED ON RELATION OF THE SPECIFICATION WITH THE REQUIREMENTS

The specifications stated in the house of quality covers the sections stated in the section 3.6.3 which includes the dimension, cost, time to build, weight, power usage and the features of the data acquisition system and ultrasound unit. The four important components of building this system is based on the wrist interface for the accurate placement of the transducer, the collection of the data and the characteristics of the data acquisition system, accuracy and the

resolution of the pressure sensor reading and the pumping system along with the flow rate and release rate.

It is required and essential to figure the way the system is going to lock the transducer on the wrist. For this it is being required that the mechanism for the movement across the wrist to be specified along with the width the transducer would be able to traverse across. Second it is also required to specify the area of contact of the mechanical component on the wrist which would help in calculating the pressure which would be applied on the wrist. The area is being calculated based on the literature review done in section 2.3.1 and analysis of the findings in section 3.6.5.

It is essential for the data acquisition system to be able to provide proper sampling frequency to avoid low resolution of the data. Further the collection of data from simultaneous sources requires multiple channels. Proper consideration has been provided to the ADC bits to incorporate the resolution of the data collected and the program which would acquire the data real-time.

Pressure sensor accuracy determines the accurate pressure reading on the wrist. The accuracy is further determined by the cost and the acquisition technique being utilised. It also incorporates the power supplied and the development of the driving boards.

Finally, pressurising the wrist with a proper pumping system and the flow rate it will deliver is important. The release rate if necessary would be able to determine the period, where the signal acquisition can occur and how slowly this release rate can be controlled to obtain more samples over the period. Table 8 lists the target values to be achieved, the absolute rating and the relative rating.

Specification	Target Values	Absolute Rating	Relative Rating
Light weight	< 10kg	395	4.10
Wrist radial artery measurement location		706	7.33
Surface area of pressure application	> 700 sq mm	676	7.02
Time to build	< 60 days	184	1.91
Cost	< $1,000	723	7.51
Sampling frequency	> 5K samples/second	315	3.27
DAQ channels	> 2 channels	21	0.22
DAQ ADC bits	> 8 bits	255	2.65
Power supply	> 12V	308	3.20
Wrist movement width	≈ 80 mm	867	9.00
Pressure sensor maximum range	0 < pressure < 350 mm Hg	597	6.20
Pressure sensor accuracy	≈ ±0.5 mm Hg	477	4.95
Emergency valve voltage	< 5V	564	5.85
Pump voltage supply	> 20V (piezo) < 6V (rotatory)	264	2.74
Flow rate (inflow)	< 500 ml/min	228	2.37
Release flow rate	> 200 ml/min	528	5.48
Ultrasound central frequency	> 8 MHz	527	5.47
Audible tune down range	20Hz < frequency < 20kHz	47	0.49
Signal acquisition period	< 1 minute	506	5.25

TABLE 8: TARGET SPECIFICATIONS, ABSOLUTE AND RELATIVE RATING (BASED ON THE RATING VALUE FROM THE POSITIONING OF THE TRANSDUCER ON THE WRIST)

3.7. CONCEPTUALISATION AND IDEATION

3.7.1. OBJECTIVES

With the deciding of the requirements and the specifications which would be necessary in setting up the platform for design and construction of the required device, at this stage it is necessary to come up with ideas which would be used in developing the concepts and working of the device. The function structure and the input/output diagrams in the section 3.5 helped in the understanding of the requirements of the device to be constructed. The assessment of the QFD (House of quality) helped in further understanding the specifications which would be necessary and the target values which would be required to develop the system.

The conceptualisation phase looks over the various aspects with prime focus being the mechanical interface which is required to be created which would be sitting on the wrist, the various kinds of pressure sensors and the pump system which can be utilised in meeting the specifications and the method in which the data acquisition must be done.

Focus has also been provided to the electronics and the construction of the circuitry for running the system. The data acquisition being done, and the program interface created which would be able to communicate with the device and capture the readings and the ideas being developed has been discussed further with proper morphological charts.

In this section, the focus has been provided to various ideas which were developed over the course for a better construction of the device. Preliminary prototypes were developed for the collection of the data and the associated problems and outcomes faced have also been discussed in this section. This sets the stage for the development of a proper working model which would be able to collect the data and provide the processing.

3.7.2. MECHANICAL DESIGN CONCEPTUALISATION

The development of the concepts included several aspects as discussed before. The first section where the mechanical devices are involved included the following:

1. Application of the pressure on the wrist: After evaluating the area for applying the pressure, it was required to develop a system which would be able to apply the pressure. Different techniques were thought of for this process which included:

    a. Spring piston mechanism
    b. Bladder pumping system
    c. Spring gear mechanism
    d. Servo mechanism

2. Pressure measurement: The pressure being applied on the wrist is required to be measured. The measurement is dependent by the means through which it is being applied. Few of the techniques which were thought and would be able to measure the pressure were:

    a. Force resistive pressure sensor (FSR) – can be implemented with a spring piston mechanism, spring gear mechanism, servo mechanism
    b. Strain gauge – similar to FSR
    c. Force capacitive pressure sensor – similar to FSR
    d. Fluid pressure sensor – Depending on the type of fluid, the pressure can be measured in gaseous state or liquid state. Most of the blood pressure monitors are based on using this technique

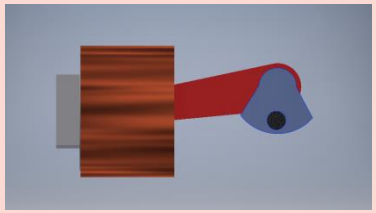
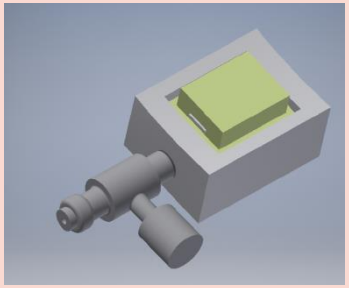
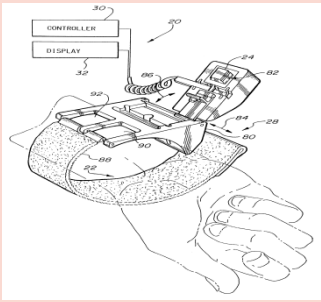
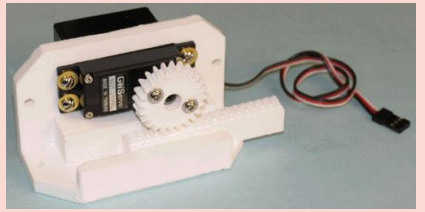
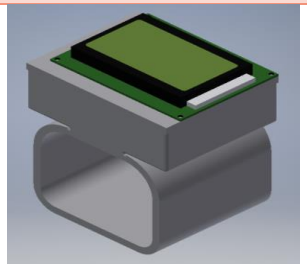
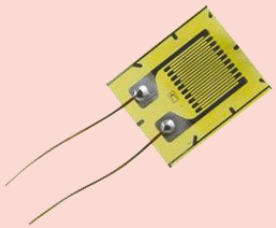
3. Placement of ultrasound transducer: Ultrasound transducers are required to be placed on the particular location on the wrist, above the blood vessel in order to obtain the Doppler changes in the signal. Placement required a proper framework which would lock itself in a position and when pressure is being applied, the transducer would be able to detect the changes in the signal with changing pressure value. Few techniques being thought included:

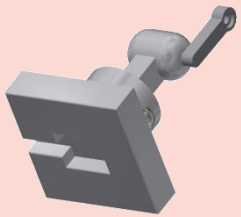
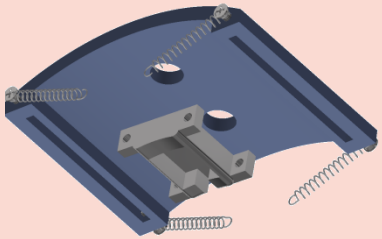
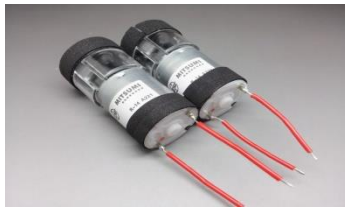
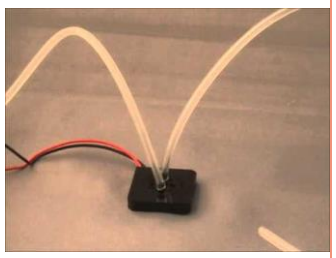
a. Manual placement on a fixed position
b. Servo controlled automatic placement – can be utilised in moving the transducer across the wrist using servo and additional external user control through Bluetooth or buttons
c. Manual movement and locking the sensor across the wrist

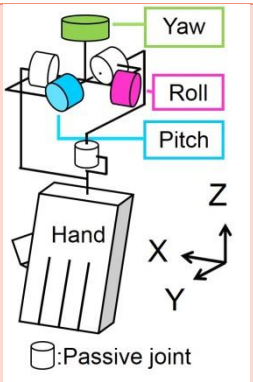
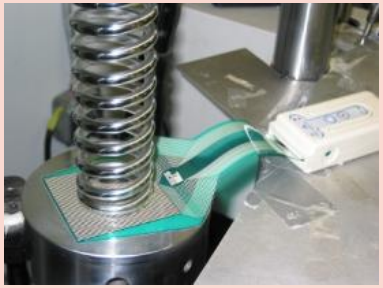
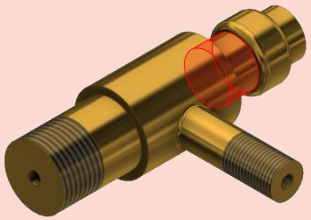
4. Framework: Placing the transducer, pressure application mechanism and pressure sensing mechanism further required a framework which would be able to hold the system at one position on the wrist. This further required deciding up on the previous three problems to develop a proper framework.

Ideas have been brainstormed across all these designs and have been presented in the subsequent pages in the form of morphological chart in table 9. In later sections, the evaluation has been done to obtain the design which will be best suited for the testing device.

TABLE 9: MECHANICAL CONCEPTUALISATION

	Option 1	Option 2	Option 3	Option 4
Pressure Application on wrist	 Slider Piston mechanism, the tip applying pressure on the wrist, drive by high torque motor	 Plastic cap on wrist, pumped with liquid or air to expand	 Tonometry [34]	 Linear rack pinion gear pressure application mechanism
	 Pressure application directly pushing the transducer on the wrist	 Inner lining of bracelet wrapped with bladder		
Pressure Measurement	 Force resistive sensor	 Strain gauge	 Capacitive force sensor	 Liquid pressure sensor

	 Manual blood pressure gauge	 Air pressure sensor		
Ultrasound Transducer placement on wrist	 Embedded with the pressure application device	 Spring based movement with the bladder	 Link based movement with bladder	 Transducer tied around the wrist with belt
Pumping Mechanism	 Manual pumping bladder with release valve (used in sphygmomanometers)	 Rotary blood pressure monitor pumps	 Piezoelectric micro liquid pump	 Air micro-pump

Framework	 Servo controlled motion	 Transducer pressure on the wrist	Links controlled movement 	 Spring pressure application
Bladder Material	 Helium balloon	 Rubber bladder	 Neoprene bladder	
Valve	 Needle valve	 Solenoid valve	 Leak valve	 Pressure release valve

3.7.3. ELECTRONIC DESIGN CONCEPTUALISATION

There are various electronic components which are required to be considered in order to undertake the build. The electronics would be able to read the signals from the device and communicate it to the computer in order to undertake the process of signal processing. In this conceptualisation phase, the controlling of the mechanical structures electronically have been brainstormed. The major components of the electronics have been listed below and tabulated ideas has been shown in table 10:

1. Data acquisition system – this would be essential and the key for capturing the data from the ultrasound unit and the pressure sensing device.

2. Microcontroller – the writing and the reading of the values into the microcontroller so as to communicate with other sensors such as the emergency valves or the pump.

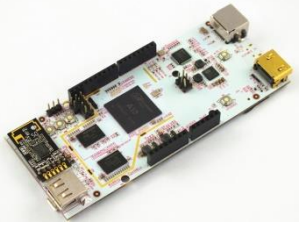
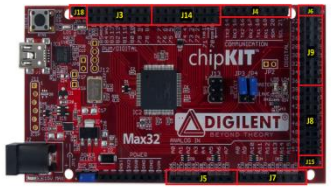
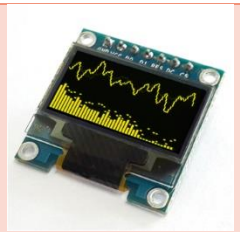
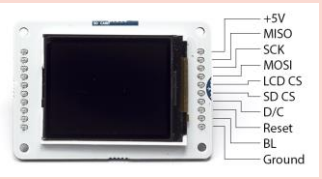
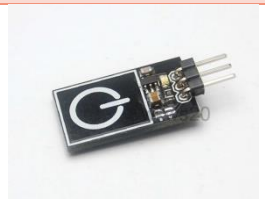
3. LCD screen – to provide the user a visual interface of the ongoing results such as the value of the pressure or the state of the valve

4. Ultrasound – the ultrasound itself is the key component to the entire project. The Doppler shift in the frequency which is recorded needs to be evaluated and observed. The collection of the data from the ultrasound would be helpful in the processing of the signals

5. User Interface – this includes the buttons and the potentiometer

6. DC DC Converter – various devices and sensors operating have different voltage and current requirements. It is required to have proper conversion system which would either step-up or step-down the voltage levels

7. Power supply – in order to provide power to the system, either through the AC source or the DC source

	Option 1	Option 2	Option 3	Option 4	Option 5
Data Acquisition System	 MCC DAQ	 NI DAQ	 Agilent Data logger	 Raspberry Pi DAQ	 Oscilloscope
Microcontroller (Appendix F)	 Arduino Uno	 Raspberry pi	 PC Duino	 Chipkit u32	 Arduino Mega
LCD Screen		 OLED	 TFT	 Touchscreen shield	 Raspberry Pi Display
User Interface				 Capacitive Touch Buttons	 Touch screen

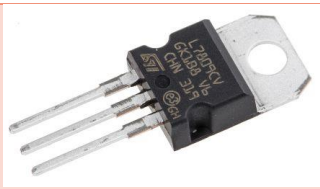
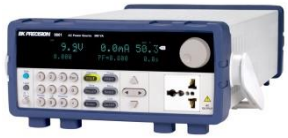
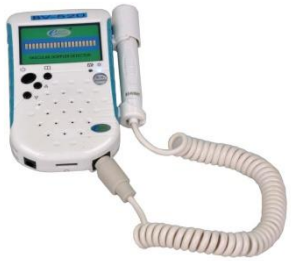
DC DC Converters	 Step up booster	 Boost IC	 Voltage regulator		
Power Supply			 DC Power Supply		 Lithium ion rechargeable
Ultrasound Units	 Bi-Directional Doppler [105]	 Doopler Vascular Bi-Directional [106]	 Bi-Directional [107]	 Peripheral uni-directional Doppler [108]	 Uni-directional blood flow meter [109]

TABLE 10: ELECTRONIC CONCEPTUALISATION

3.8. DESIGN EVALUATION

3.8.1. OBJECTIVES

In the previous section, different ideas were being put together for the development of the mechanical interface and the electronics. It is required to evaluate each concepts which has been thought of and deduce the most efficient and viable concept which can be physically embodied for the collection of the data.

It is further required to critically analyse each concept, with the results they will generate or the results which has been provided with the implementation and the improvement which had to be made for the final design.

This section goes through the following points:

1. Viability and non-viability of those ideas
2. Conceptualised and designed ideas
3. Outcomes of pre-prototyped design
4. Decision Matrix to select the best design

3.8.2. VIABILITY AND NON-VIABILITY OF IDEAS

In the section 3.7.2, various mechanical ideas were discussed for the placement of the ultrasound transducer and the measurement of the pressure. It is necessary to evaluate those ideas prior moving to discussing the conceptualised designs which have been developed. It is required to eliminate certain ideas prior to the development of the actual device concept. The table 11 below discusses the various ideas, the associated problems faced and the outcome for the improved design:

Function		Problem	Outcome
Pressure Application on wrist	1. Slider piston 2. Spring gear 3. Servo	Measurement of the stress induced on the surface of the wrist inaccurately measured due to deformation of the force resistive sensor or similar sensors	Not feasible to be used for the measurement of the pressure. Supports the use of standard bladder for pressurising the wrist
Pressure Measurement	1. Force resistive sensor 2. Strain gauge 3. Capacitive sensor	Deformation of the measurement area on the surface of the wrist, providing large errors in the readings Accuracy levels do not suit the specification set for < ±0.5 mm Hg	Not feasible Supports the use of electronic fluid pressure sensor
Pressure application medium	Liquid	High chances of spillage Risk of containment	Support the use of standard air pressurising mechanism
Valve	1. Needle 2. Mechanical pressure release	Do not meet the cost specification Dimensionally larger in size	Feasible use of solenoid valve or plastic leak valves
Material	Balloon Rubber Latex	Balloon having thin surface, high risk of breakage Latex not applicable based on the FDA [110]	Neoprene bladders are well suited and commercially available for the usage
		Electronic Components	
Data acquisition system	Agilent Data logger Oscilloscope	Increases the bulk Not supported for direct communication with MATLAB to acquire real time data	Use of portable USB based DAQ
User Interface	Touchscreen Capacitive touch buttons	Over the requirements, not within the scope Add to extra time and electronics for running the devices	Use of simple buttons and potentiometer
Power Supply	DC Power Supply AC Mains	Bulky DC power supply High risk as connection with the mains would require safety circuitry and fuse based systems to isolate the user from any electrical damage	Use of standard battery systems
Ultrasound blood flow meter		Devices procurement time high Real time monitoring not possible	Use of the existing Ultrasonic blood flow monitor Parks Medical

TABLE 11: VIALBILITY AND NON-VIABILITY OF THE CONCEPTS DEVELOPED

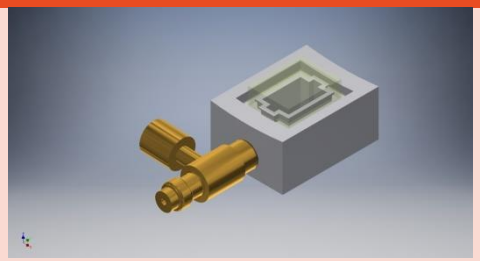
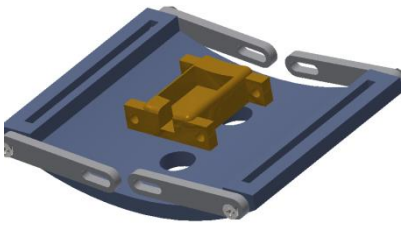
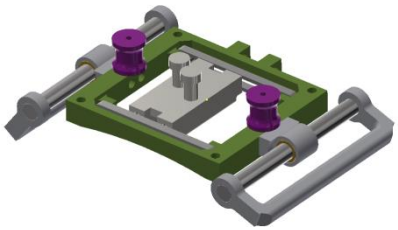
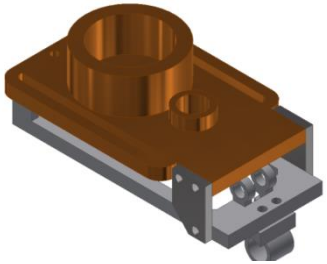
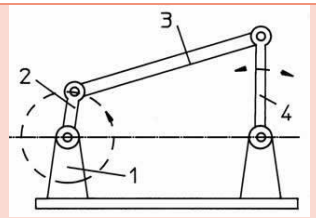
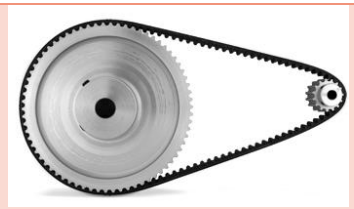
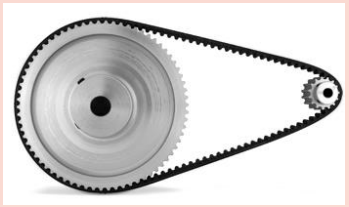
3.8.3. CONCEPTUALISED DESIGNS – MECHANICAL INTERFACE

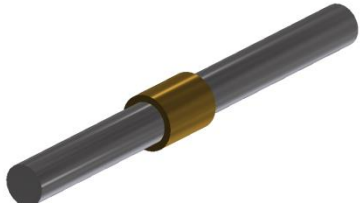
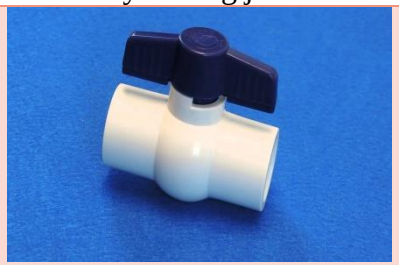
Various mechanical designs were conceptualised based on the pumping mechanism which has to be used, motion of the transducer on the wrist, method of application and reading of the pressure values. These needed the assessment based on how they will perform and if the specifications set are met for undertaking the readings or not. The major specifications on which the mechanical concepts have been based are:

1. Weight reducing factor
2. Efficient area of pressure application
3. Smooth movement of transducer across the wrist
4. Minimised Leakage

The mechanical design selection matrix with the components and their relevance to the major specifications are shown below in table 12:

TABLE 12: EVALUATION OF MECHANICAL CONCEPTS

Design	Weight Reduction	Efficient area of pressure application	Smooth movement of transducer across the wrist	Minimised Leakage
Holding of pressure	 Plastic Capped part	 Blood pressure cuff		 Blood pressure cuff
Placement of transducer on wrist designs	 3D printed part with transducer holder pressurised against cuff	 Vertical Movement with wrapped cuff	 Servo controlled movement	 Pump in proximity to the pressure application region
Transducer movement across wrist	 Links	 Belt pulley		

Wrapping around wrist			 Bush and dowel	
Pressure App.	 Micro-pump	 Rotary Pump	 Micro-pump	 Micro-pump
Running tubes	 Vinyl tubing joiner			 Rubber tubing
Valves	 Plastic leak valve			 Solenoid valve

3.8.4. CONCEPTUALISED DESIGNS – ELECTRONIC INTERFACE

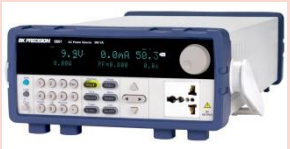
The electrical design included the microprocessor which would be able to control the pump, the pressure sensor and the emergency valve. The idea was also conceptualised to use the electronics for the controlling of the placement of the transducer on the wrist using a Bluetooth application using a phone or tablet. This was thought to be innovating along with the reduction of the interference caused due to manually adjusting the position. The decision points which were required to decide up on the electronic components which would be utilised are:

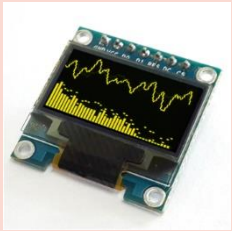
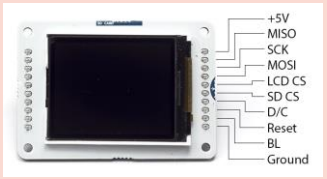
1. Accuracy of data collection
2. Layout of the electronics
3. Ease of Design
4. Maintenance and upgrading
5. User interface

It was a key to make the data collection to be accurate which also required the selection of the proper data acquisition system.

The evaluation of electronic components have been done in table 13.

TABLE 13: EVALUATION OF ELECTRONIC CONCEPTS

Function	Accuracy of data collection	Electronics Layout	Ease of design	Maintenance and Upgrading	User Interface
Data Acquisition	 National Instruments DAQ				 Agilent Data Logger
Micro-controller	 Raspberry Pi	 Arduino	 Arduino	 Arduino	 Arduino
Power Supply		 Lithium ion	 Standard AA/AAA		 DC Power Supply

User Control/Access	 Tactile Buttons			Upgrading is dependent on the microcontroller and can be upgraded to any of the system mentioned under the conceptualisation phase	 Touch Screen
User Interface	 OLED	 SPI based TFT	 Standard LCD screen	Upgrading is dependent on the microcontroller and can be upgraded to any of the system mentioned under the conceptualisation phase	 Arduino Touchscreen
Voltage Control		 PCB Desgin based	 Standard Booster		 Incorporated Voltage Display

3.8.5. EVALUATING CONCEPTUAL ALTERNATIVES

The electronics and the mechanical sections helped in evaluating the developed concepts for the controlling of the various functions for collection of the data. The mechanical concept included design selection criteria based on the specifications and the requirements which were evaluated from the sections 3.4 and 3.6.

The first section of evaluation considers the requirements and specifications based on which the electronics and mechanical functioning designs were required to be conceptualised.

In the second section, the matrix is based on the decision points used for the development of the conceptualised designs illustrated in the sections 3.8.3 and 3.8.4.

Further in this section, the pre-prototype being designed for the collection of the data has been discussed along with the variance in the results it provided as well in the Appendix D Section 3.

Mechanical		**Electronics**	
Criteria	**Scoring (%)**	**Criteria**	**Scoring (%)**
Weight	10	**Accuracy**	20
Cost	10	**Cost**	10
Assembly	10	**Maintenance**	5
Maintenance	10	**Performance**	15
Accuracy	20	**No. of Inputs**	10
Painless/Safe	15	**No. of Outputs**	10
Clean and Sanitisation	10	**Power Consumption**	15
Performance	10	**Assembly**	5
Ease of use	5	**Programming**	10
Total	100%		100%

TABLE 14: CRITERIA RANKINGS FOR MECHANICAL AND ELECTRONICS REQUIREMENTS

Based on the requirements for the device and the concepts evaluated, a decision matrix has been developed through a numerical approach. This numerical approach considers the various ideas and designs which were conceptualised mechanically. A rating has been provided based on the designing criteria to each. It is necessary to realise the mechanical approach required to be used and the electronics parts which would be suitable for the building of the system. The ranking has been tabulated in table 15 and 16. The graphical representation in figure 21 and 22 further provides the ranking which has helped in evaluating the best design decision.

Mechanical											
Decision Matrix											
Design Criteria		Weight	Cost	Assembly	Maintenance	Accuracy	Painless/Safe	Clean/Sanitisation	Performance	Ease of Use	SUM
Alternatives	Weighting	10	10	10	10	20	15	10	10	5	100
A	Weight Reduction	1	0.5	0.4	0.5	1	0.9	0.9	0.3	0.5	72
		10	5	4	5	20	13.5	9	3	2.5	
B	Efficient Area of Pressure Application	0.3	0.8	0.5	0.5	1	0.9	0.9	0.5	1	73.5
		3	8	5	5	20	13.5	9	5	5	
C	Smooth Movement of Transducer across wrist	0.3	0.4	0.2	0.6	0.9	0.7	0.9	0.6	0.9	63
		3	4	2	6	18	10.5	9	6	4.5	
D	Minimised Leakage	0.7	0.9	0.7	0.7	0.9	0.9	0.8	0.9	0.9	83
		7	9	7	7	18	13.5	8	9	4.5	

TABLE 15: DECISION MATRIX FOR 4 MECHANICAL CONCEPTS

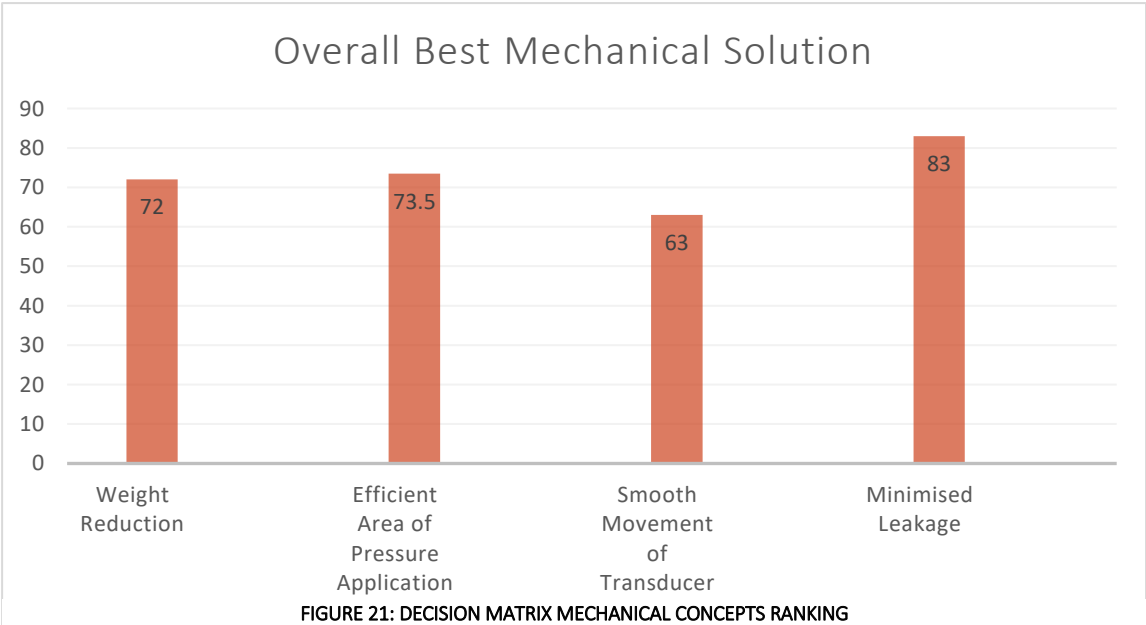


FIGURE 21: DECISION MATRIX MECHANICAL CONCEPTS RANKING

Electronics											
Decision Matrix											
Design Criteria		Accuracy	Cost	Maintenance	Performance	No. of Inputs	No. of Outputs	Power Consumption	Assembly	Programming	SUM
Alternatives	Weighting	20	10	5	15	10	10	15	5	10	100
A	Accuracy of data collection	1	0.5	0.6	0.7	0.9	0.9	0.6	0.5	0.8	68
		20	5	3	10.5	9	9	9	2.5	8	
B	Electronics Layout	0.7	0.8	0.5	0.5	0.9	0.9	0.7	0.4	0.8	70.5
		14	8	2.5	7.5	9	9	10.5	2	8	
C	Ease of design	0.7	0.9	0.5	0.3	0.9	0.9	0.4	0.6	0.8	65
		14	9	2.5	4.5	9	9	6	3	8	
D	Maintenance and Upgrading	0.7	0.3	0.4	0.6	0.9	0.9	0.2	0.3	0.4	54.5
		14	3	2	9	9	9	3	1.5	4	
E	User Interface	0.9	0.2	0.3	0.8	0.5	0.5	0.2	0.5	0.7	45.95
		18	1	0.9	8.4	4.5	4.5	1.8	1.25	5.6	

TABLE 16: DECISION MATRIX ELECTRONIC CONCEPTS

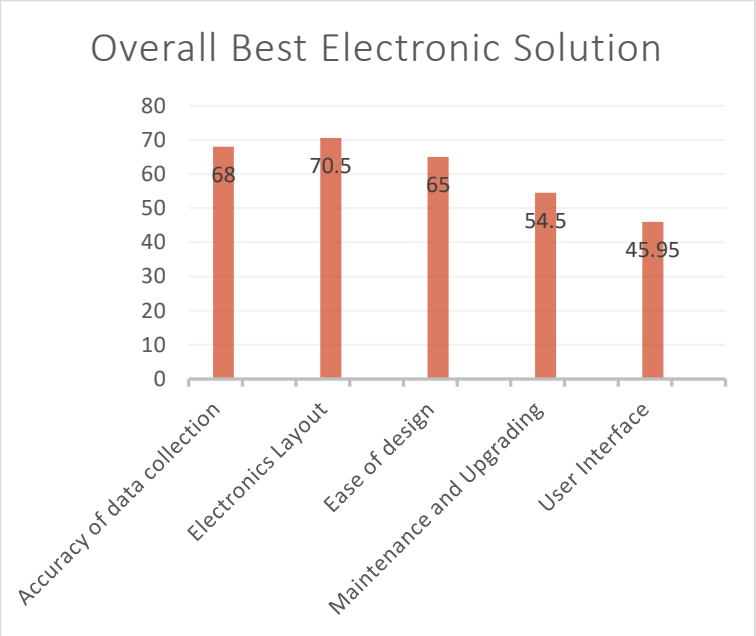


FIGURE 22: DECISION MATRIX ELECTRONICS RANKING

3.8.6. SUMMARY OF EVALUATION

The numerical evaluation done the section 3.8.5, provided the mechanical and the electronics design outcome. This sets the base for the actual detailed designing and embodiment of the design. From the mechanical design evaluation which covers the wrist interface, accurate pressure application and minimised leakage design specification showed a really close ranking. Based on the outcome provided through the design evaluation, prototypes were developed to test the one which would be better suited for the process.

Based on the electronics design it was important that the data being collected is accurate. But the use of electronic pressure sensor demanded not only accuracy but electronics layout to be developed which could be used for the process.

In the detailed design chapter 4, the following sections are discussed:

1. Pressure sensor – Circuit and PCB design
2. Pumping system – Circuit and PCB design
3. Data acquisition system procurement
4. Layout of sensors and actuators
5. Microcontroller programming
6. Data acquisition programming
7. Mechanical interface design

Appendix D Section 3 explains about the previous prototype which was being laid. It discusses further on the improvements which were required to be done in order to improve the accuracy of the data collection.

4. DESIGN DETAIL

4.1. OBJECTIVES

This section of the design detailing includes the design work which has been taken on to create a computer aided 3D device which would be able to collect the ultrasound signals from the wrist, apply the pressure to obtain the changes in the signal and sent the data for the data acquisition.

Market available devices has been considered in detail for the ultrasound device being used and the exact data acquisition device which is to be procured. It looks further into the pressure sensors which is to be used. Based on the market availability of the devices, the design detailing is done.

Further section incorporates the mechanical, electronics and the programming computer design work which has been undertaken over the course. The computer aided mechanical design has been done using Autodesk Inventor 2017. The mechanical interface uses two different solutions which were developed to automatically and manually control the positioning of the ultrasound sensor.

The electronics section has been dedicated to the circuits which were being designed to run the sensors and the pump, the circuit for the running of the servos, switches, LCD screen and the emergency valves. It also discusses on the PCB layout which was being done in order to minimise the area of the circuitry using Altium Designer 2016.

Finally, the data acquisition system being used to collect the data from the sensor and the ultrasound, is to be transferred to the computer for further signal processing. The program developed using LabVIEW 2016 has been explained on how the real-time signal acquisition is being done. It focusses on every section of the LabVIEW program and functions of each section in the development of the program.

4.2. MARKET AVAILABLE DEVICES

The four of the important sections to be considered in this case are the ultrasound device for obtaining the change in the signals of blood flow from the wrist, pumping mechanism to apply the pressure on the wrist, pressure sensor for the measurement of the pressure and finally the data acquisition system to send the data over to the computer for the processing.

4.2.1. ULTRASOUND

The objective of this entire project is to measure the change in the flow of the blood using the Doppler shift in frequencies when the pressure is being applied on the wrist to deduce the systolic and the diastolic blood pressure. Different ultrasound flow measurement devices are available in the market. Some of them have been tabulated in the section 3.7.3 and Appendix F Section 2.

The provisional patent which was filed, an ultrasound flow meter from Parks Medical Electronics, Doppler Ultrasound Flow Meter 811-B (Figure 23) operating at 9.5MHz frequency. The blood flowing through a point in the artery increases in speed to a maximum value and then decreases to a minimum value. The change in the speed of the blood due to the pulsatile nature of the heart pumping out blood causes a change in frequency. This change is tuned down to the audible range between 20Hz and 20KHz and heard through the speaker. As the speed of the blood flow keeps on changing, increasing to a maximum level and decreasing back, there is a spectrum of frequency heard from the speaker resembling to 'whooshing' sound of blood.

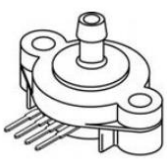
FIGURE 23: ULTRASONIC BLOOD FLOW METER BY PARKS MEDICAL ELECTRONICS MODEL 811-B

This device being used provided a base noise and the sensitivity of the transducer was very high. Any movement caused the signal to be lost. Different ultrasound devices in the market were researched. Most of them with the advanced features used data collection and in-built storage system. The problem with the new devices were, obtaining the real-time signal and sending it to the external DAQ system so it can be simultaneously compared with the pressure signal was not possible. Further the cost and the time of procurement of those devices was high, so it was decided to use the existing Doppler flow meter from Parks Medical Electronics. This further caused problems in the collection of the result due to the sensitivity and errors.

4.2.2. PRESSURE SENSOR

Two different pressure sensors were evaluated to be used which were based on the air pressure reading and had a range of pressure measurement which was within the required pressure range of 0-350 mm Hg. The important consideration here is the accuracy of the pressure sensor and the output voltage it provides. It is required and specified the accuracy to be ±0.5 mm Hg or less. The output voltage is necessary as the amplification circuit will be based on this. The pressure sensor specification is shown below in table 17.

TABLE 17: PRESSURE SENSORS SPECIFICATIONS COMPARISON

	MPX2050GSX	Omron 2SMPP-02
Measurement Medium	Air	Air
Pressure Range (kPa)	0 – 50	0 – 37
Maximum Allowable Pressure (kPa)	50	53
Maximum Output Voltage (mV)	41.5	31.0±3.1
Accuracy	± 0.5 mm Hg	Not mentioned
Offset Stability	±0.5%	0.5%
Operating Temperature	0^0C – 85^0C	0^0C – 50^0C
Images		

Omron 2SMPP-02 is being used in the Omron Wrist wearable blood pressure monitors. They are dimensionally small and provide the optimum range in which the blood pressure can be measured. But the accuracy is one of the key factors where they lack the efficiency. While MPX2050GSX has high accuracy level, they can be easily implemented using a simple instrumentation amplification circuit to amplify and read the data and send it over to microcontroller or to the data acquisition system. Hence the choice was to use MPX2050GSX for the prototype purpose.

4.2.3. PUMPING

Pumping of the bladder to apply the pressure on the wrist was essential. The pumping can be done either using the standard rotary air pumps used in the digital blood pressure monitors or using a micro-pump system. Micro-pump systems are based on piezoelectric material. Providing a driving voltage and proper frequency would cause the piezo to vibrate. This would lead to changes in the pressure levels on both sides of the piezo material, generating a flow of air. Micro-pumps are new to the market and it was essential to procure a micro-pump which can provide pressure levels from 0-300 mm Hg at least with internal valve. Further these pumps require driving circuits which are required to be designed. The two pumps which have been compared and tested are tabulated below in table 18:

	Murata Micro-pump	KOGE Micro-pump
Fluid	Air	Air
Pressure Range	0 – 1.2 kPa	0 – 300 mm Hg
Voltage (V)	20	28
Driving Frequency (kHz)	25 ± 0.5	21 ± 0.5
Internal Valve	No	Yes
Cost	$18.41	$20
Driving Circuit	Totem-pole	Square Wave, 50% DT
Flow Rate	700 cc/min	150cc/min
Images		

TABLE 18: PIEZOELECTRIC MICROPUMPS SPECIFICATIONS COMPARISON

KOGE Micro-pump has not been manufactured yet, but samples were acquired from the manufacturers for testing of the working. While Murata micro pump testings were done shown in the Appendix F Section 1, it failed to meet the specification due to the lack of the internal valve. Hence, KOGE micro-pump was chosen.

The reason of choosing a smaller pump was to incorporate the pump on the wrist while taking the reading. This would reduce any kind of leakages involved.

4.3. MECHANICAL CAD DESIGN

Various mechanical designs were tried with two were finalised, one which would be based on the automatic movement of the transducer across the wrist and the other being the manual adjustment of the transducer across the wrist.

4.3.1. AUTOMATIC PLACEMENT MECHANISM

The automatic transducer placement on the wrist design was based on the following idea:

1. The servo will control the movement of the transducer across the wrist. The control of the servo would be done by the user using a Bluetooth application.
2. The transducer would be sitting in the housing. The housing would be connected to the servo with a pulley belt mechanism
3. The bladder would be placed above the housing of the transducer. The idea is to apply the pressure directly on the transducer. The pump and the pressure sensor would be connected to the bladder, with the designed circuitry to run the pressure sensor and the pump sitting on the mount for the circuit. The dimension of the main frame design was based on the size of the bladder which was about 80 x 50 cm area.
4. An Arduino will be placed which would controlling the emergency valve and the movement of the transducer
5. The output from the pressure sensor will be sent out to the data acquisition system
6. The mount will be tied around the wrist using the Velcro tape mechanism

Figure 24-28 shows the automatic placement mechanism development for the placement of the transducer on the wrist.

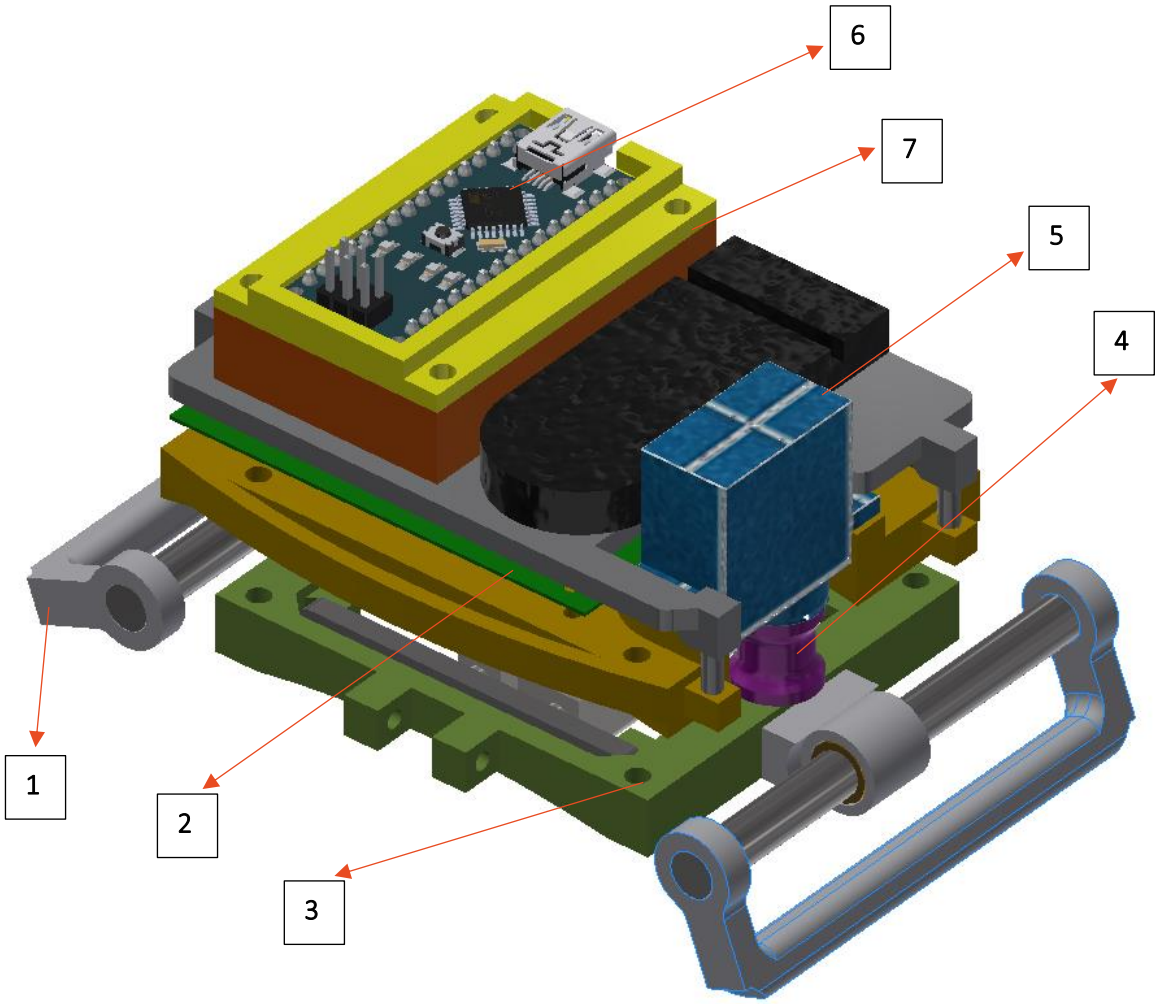


FIGURE 24: 3D CAD MODEL FOR THE AUTOMATIC PLACEMENT OF TRANSDUCER ON WRIST WITH SERVO AND EMBEDDED PRESSURE SENSOR AND PUMPING MECHANISM

1. Holder to strap the device around the wrist
2. PCB – Controlling the pump and the pressure sensor
3. Transducer housing
4. Driver pulley
5. Servo Motor
6. Arduino to control valves and motor
7. Housing for Bluetooth and wiring

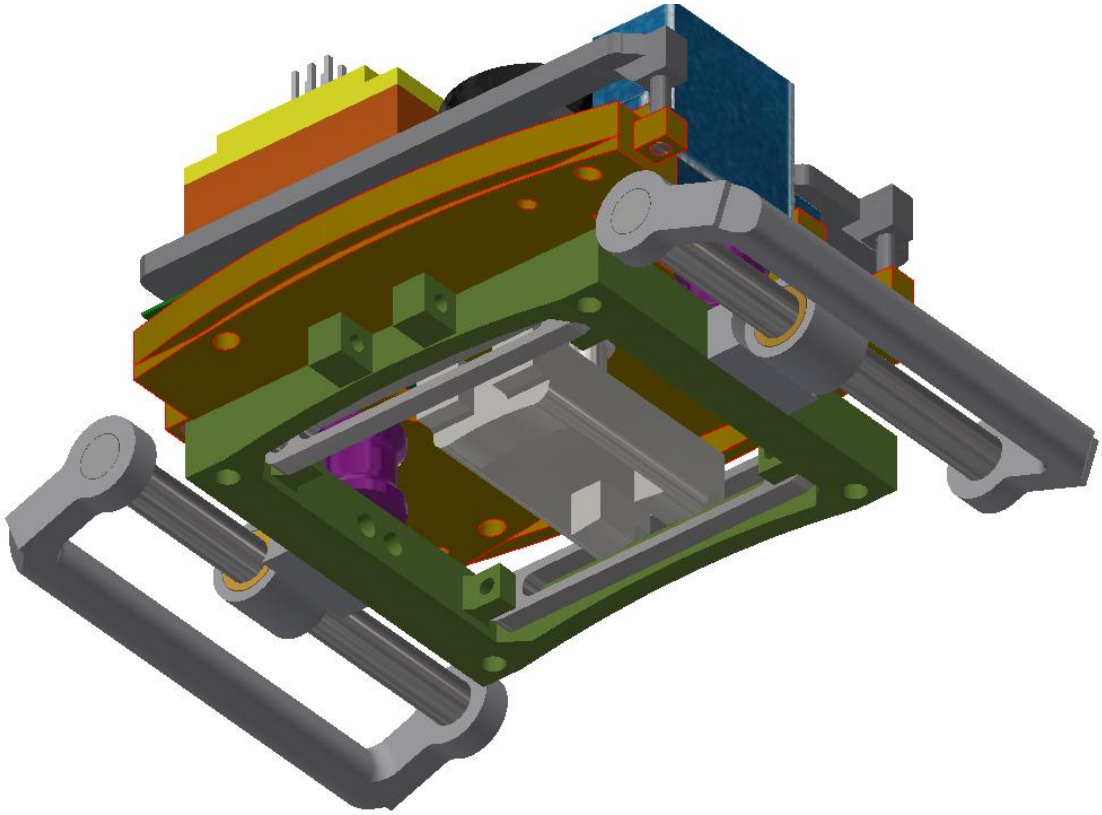


FIGURE 26: BOTTOM VIEW - HOUSING FOR THE TRANSDUCER

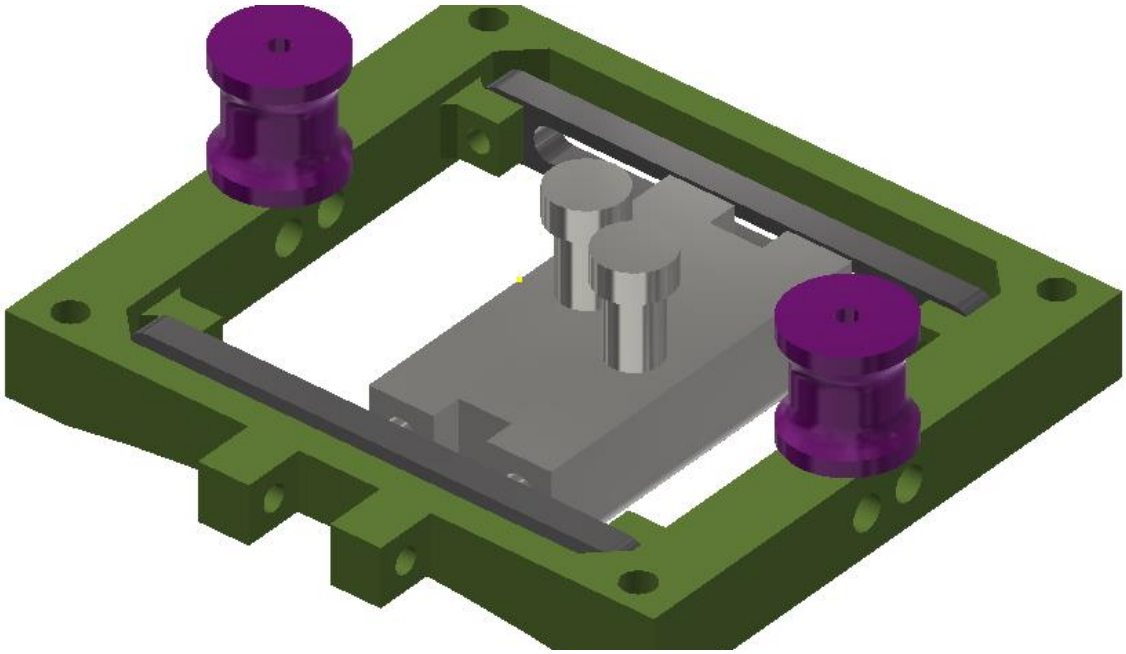


FIGURE 25: PULLEY MECHANISM TO MOVE THE TRANSDUCER HOUSING ACROSS

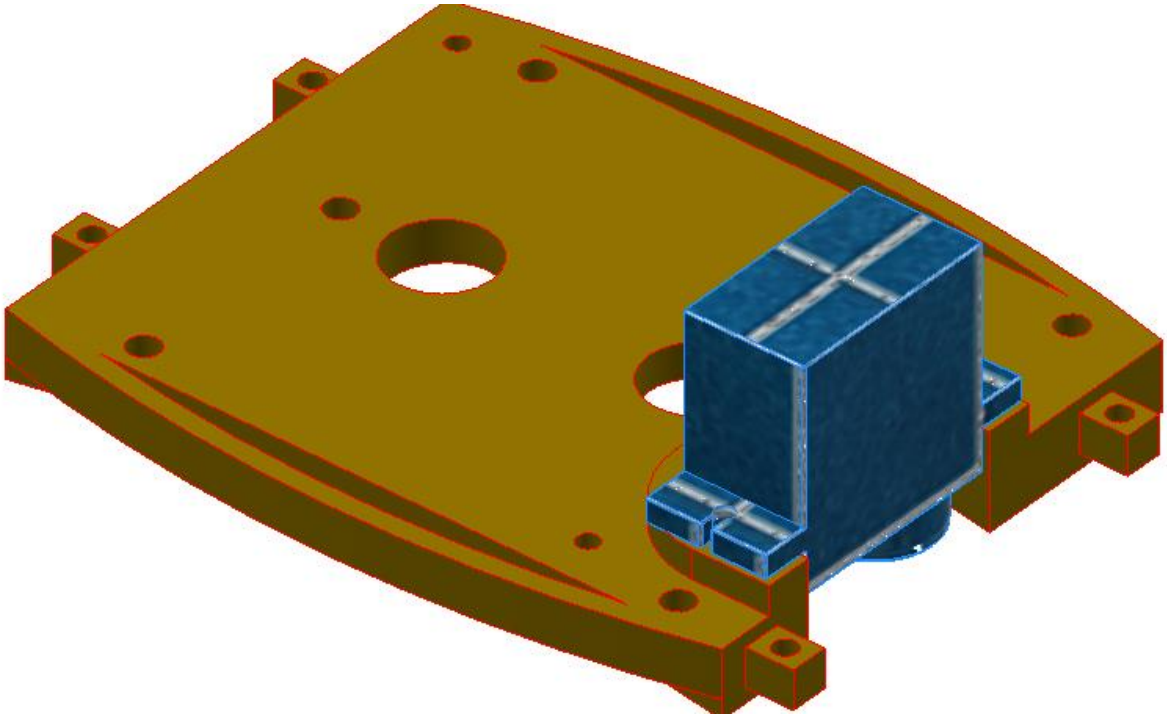


FIGURE 27: SERVO DRIVING

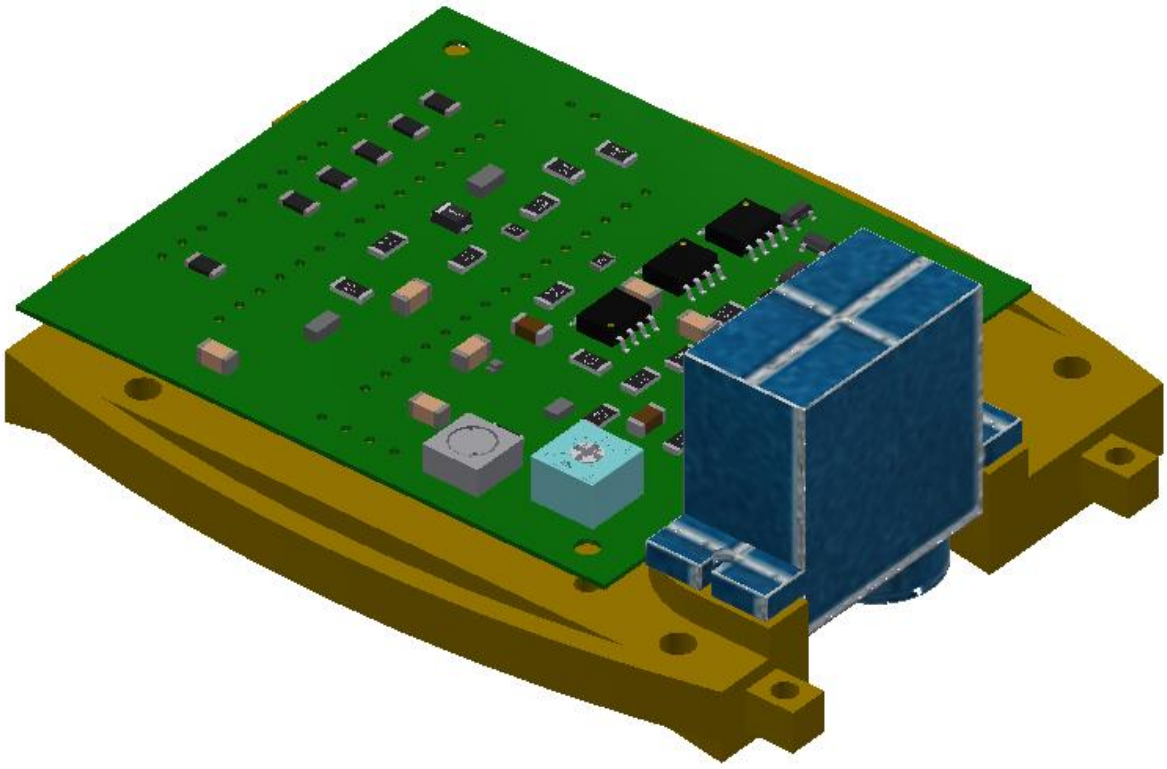


FIGURE 28: DESIGNED PCB BOARD ON HOUSING

4.3.2. *Manual Placement Of Transducer*

The manual placement of the transducer on the wrist was also implemented as a contingency plan. This would make the operator to move the transducer on to the position where the signals can be received. Again, this used the principle of belt pulley mechanism with a long shaft screw. Rotating the screw will move the transducer across the wrist. The pump and the pressure sensors are placed on the top holder.

The locking mechanism has been used with spring system. The top pump and the pressure sensor can be opened as they are pivoted to a point and can be locked back. Figure 29-31 shows the manual placement of the transducer on the wrist.

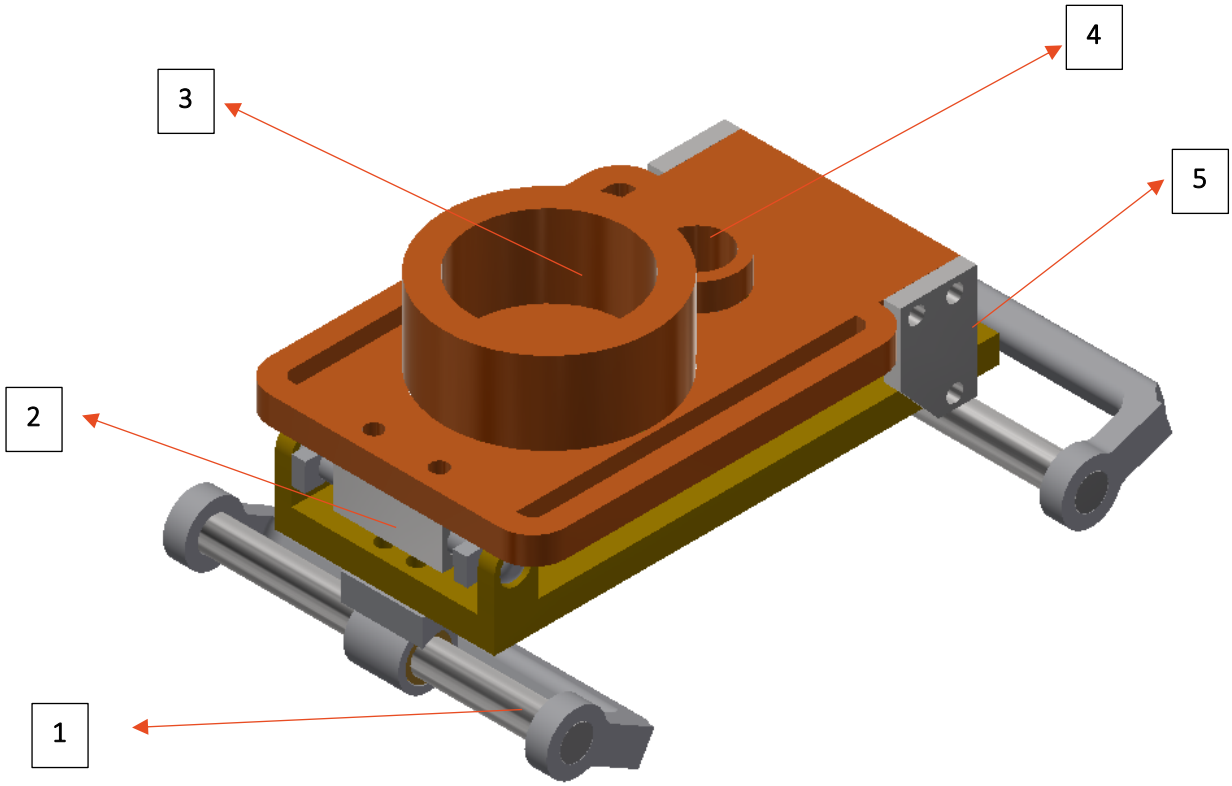


FIGURE 29: 3D CAD MODEL FOR MANUAL PLACEMENT OF TRANSDUCER ON THE WRIST

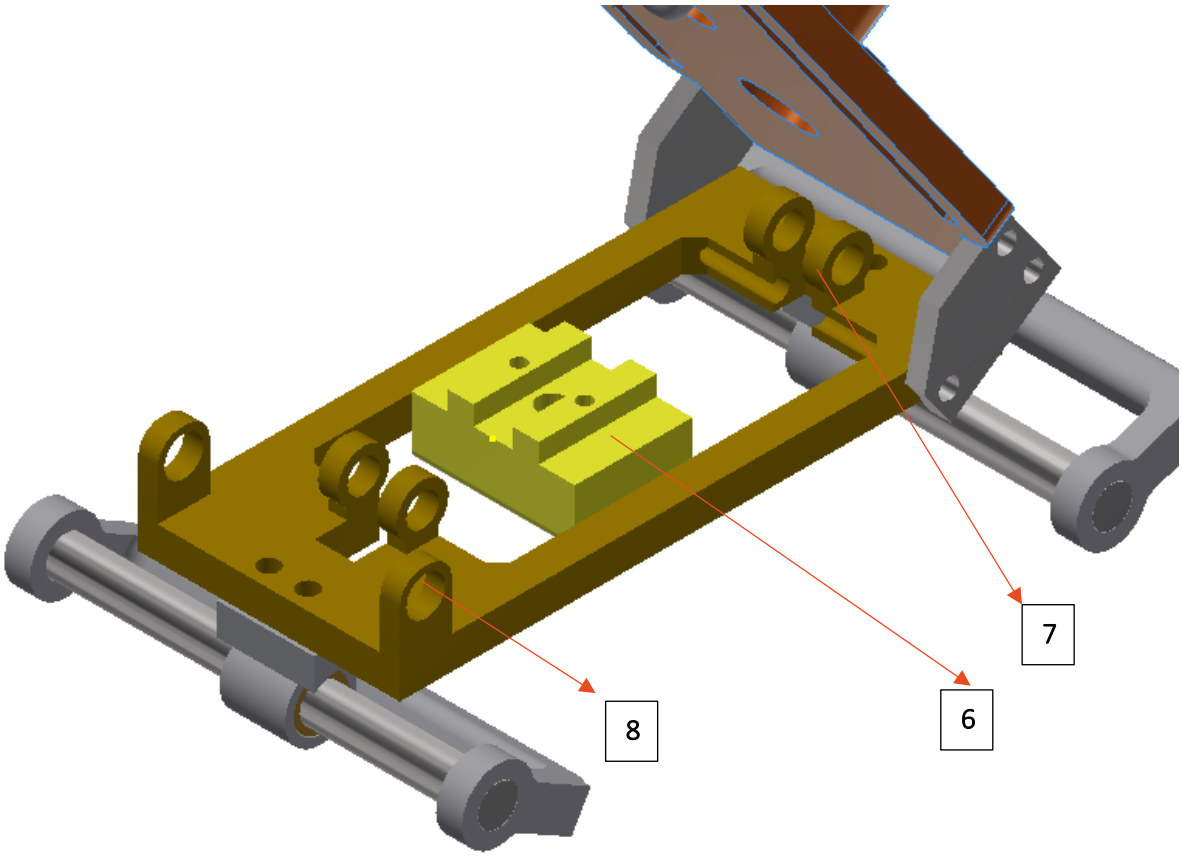


FIGURE 30: TRANSDUCER HOUSING

1. Wrist strap holder
2. Spring locking mechanism
3. Pump Holder
4. Pressure sensor holder
5. Pivot joints
6. Transducer housing
7. Pulley joints
8. Locking points

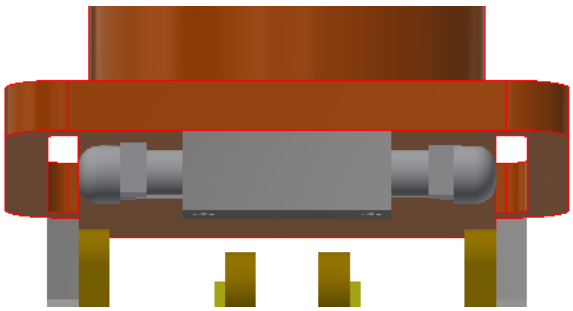


FIGURE 31: SPRING LOCKING MECHANISM

4.4. ELECTRONICS DESIGN – CIRCUIT AND PCB DESIGN

The driving of the pump and the amplification of the pressure sensor value required the designing of a proper PCB circuit which can be incorporated in the design shown in the section 4.3.1.

4.4.1. PRESSURE SENSOR AMPLIFICATION CIRCUIT

The pressure sensor being used is a MPX2050G has an output voltage range from 0-41.5 mV. The range being small requires an amplification. This was necessary, so the values could be read by the microcontroller such as Arduino and the output can be displayed on LCD. It was also necessary to amplify and send the signal over to the National Instruments data acquisition system. The Arduino ATMEGA 328P has a resolution of 10 bit with the input values from 0-1023 and the accurate readings are achieved only between 2.5V – 5V input, it was necessary to amplify the incoming signal from the pressure sensor. To do so an amplification as high as 100 was needed. This required designing an instrumentation amplifier circuit with an overall gain of >100.

An instrumentation amplifier circuit was designed. The pressure sensor required a specific dual rail low noise operational amplifier. Due to dual rail power supply to the operational amplifiers, it was necessary to create a reference voltage half way between supplied voltages which in this case were 5V. A reference of 2.5V was mapped to 0V in order to provide a virtual ground. A programmable reference TL431CD was used in order to set the reference voltage at 2.5V. A 10K potentiometer was also used to change the reference voltage.

Further in the design it was ensured to remove AC coupled by placing a capacitor between the ground and the non-inverting inputs of the amplifiers. This would make sure any frequency dependent changes such as AC signal from power input or any fluctuation from the DC power source are grounded without affecting the functionality of the circuit. The required gain had to be made to be around 130, when considering the maximum pressure value at 41.5mV, the value of 5V would be read by the Arduino. In order to achieve this, the equation mentioned below was calculated. The impedance of the circuit was tested using the LTSpice for the

programmable reference voltage in figure 32 which came out to be 19.6kΩ which was used in the equation 11 for the finding the gain below:

$$\frac{V_{out}}{V_{in}} = \left(1 + \left(\frac{2 * R_3}{R_4}\right)\right)\left(\frac{R_1}{R_2}\right) = \left(1 + \left(2 * \frac{2200}{100}\right)\right)\left(\frac{19600}{6800}\right) = 129.7 \ldots (11)$$

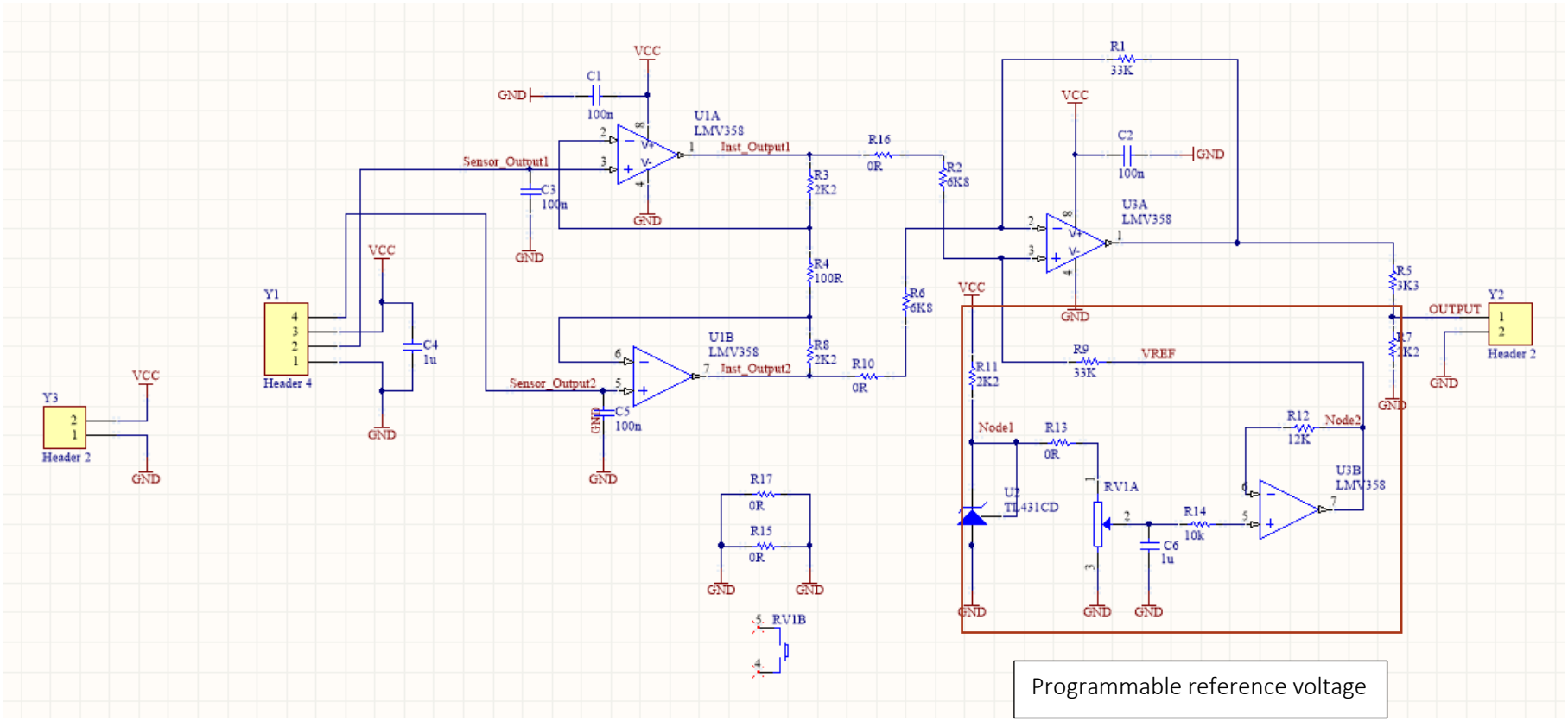


FIGURE 32: CIRCUIT DIAGRAM FOR PRESSURE SENSOR AMPLIFICATION

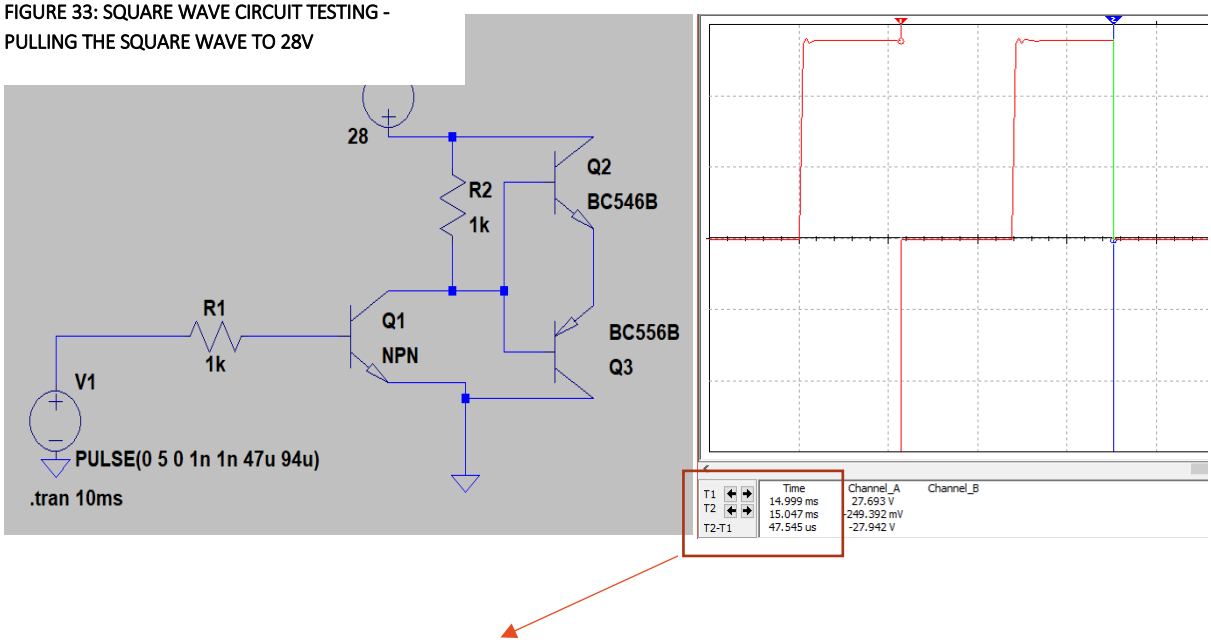
4.4.2. *MICRO-PUMP DRIVING CIRCUIT*

The micro-pump used in this case is KOGE micro-pump. The pump requires a square wave at 50% duty cycle, $28V_{pp}$. The driving circuit of the pump required the following sections:

1. Switching circuit – this would generate the square wave required by pushing-pulling the circuit
2. Microprocessor – the microprocessor would generate the square wave at 50% duty cycle at 21kHz
3. DC-DC Booster – the 5V square wave generated by the microcontroller needs to be amplified so it produces a $28V_{pp}$ square wave.

The circuit diagram in figure 33 shows the section for the implementation of the circuit along with the output graphs. The first graph shows the switching circuit supplied with a 28V power supply. It receives a $5V_{pp}$, 21kHz, 50% Duty cycle from the microcontroller simulator. The output generated is a $28V_{pp}$ square wave.

FIGURE 33: SQUARE WAVE CIRCUIT TESTING - PULLING THE SQUARE WAVE TO 28V



$$f = \frac{1}{T_2 - T_1} = \frac{1}{15.047ms - 14.999ms} = \frac{1}{0.047ms} = 21.276kHz \ldots (12)$$

Next it was necessary to develop the circuit which would be able to boost the voltage from 5V to 28V Market available DC-DC boosters such as the one from Arduino can boost from 5V to anything up to 65V. But the requirement in this case was to boost the voltage level to 28V. In order to develop a booster circuit, it was decided to use a Texas Instrument LM2733XMF/NOPB DC switching regulator which can go up to maximum of 40V from an input ranging from 2.7V-14V.

A Multisim simulation as shown in figure 34 was done to check the working of the circuit. In the simulation, a similar booster circuit was used corresponding to LM2733XMF as MC34063ADG. The output was successfully obtained to be 28V from a 5V input supply.

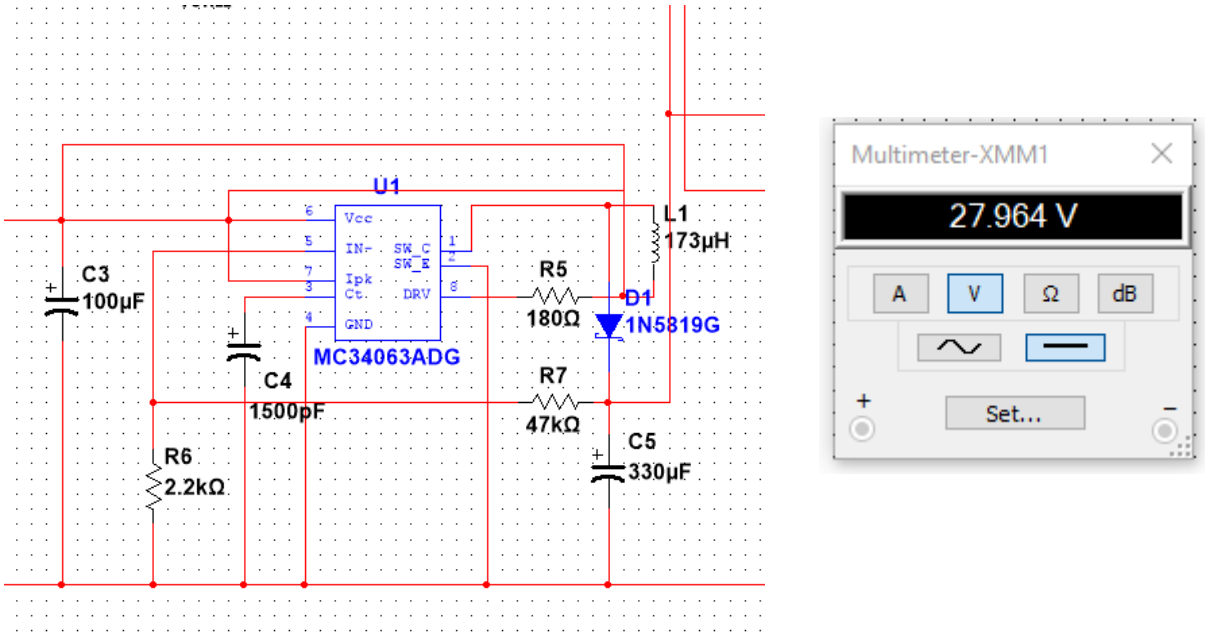


FIGURE 34: DC-DC BOOSTER 28V OUTPUT

The circuit implementation is obtained from the datasheet of the LM2733XMF shown below in figure 35:

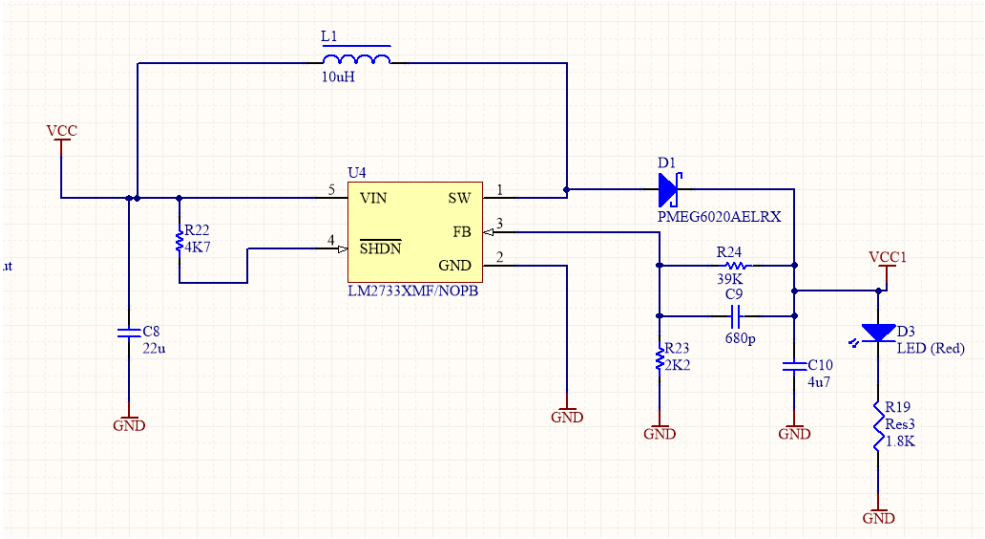


FIGURE 35: LM2733XMF DC-DC BOOSTER CIRCUIT LAYOUT

The output voltage was set based on the formula provided in the datasheet:

$$R24 = R23 \times \left(\frac{V_{out}}{1.23} - 1\right) \ldots (13)$$

$$V_{out} = 1.23 \times \left(\frac{R24}{R23} + 1\right)$$

$$V_{out} = 1.23 \times \left(\frac{39K}{2.2K} + 1\right) = 23.03V$$

The pump can operate in any range between 21V to 28V peak-peak. The voltage level was selected to be low at 23V. The resistors can be changed to obtain a higher voltage level as SMD 1208 package resistors were used.

The selection of the capacitor C9 in the circuit was based on the feed forward compensation provided in the datahseet given by:

$$Cf = \frac{1}{2 \times \pi \times R24 \times Fz} \ldots (14)$$

Where F_Z = 8kHz

$$Cf = \frac{1}{2 \times \pi \times 39K \times 8kHz} = 680pF$$

4.4.3. VOLTAGE REGULATION

The power supply requirement for the pressure sensor is DC 12-19V. There were two options, either to use another DC-DC switch converter to increase the voltage from 5V to 12V or use a

voltage regulator to regulate the voltage down from 23V to 12V. LM3480IM3X-12 is a 12V voltage regulator. This would regulate the voltage down from a maximum of 35V. The voltage regulator circuit was developed shown below in figure 36:

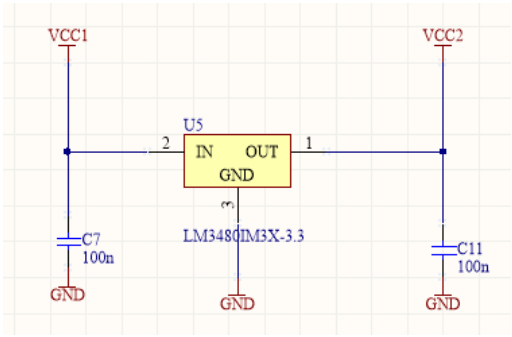


FIGURE 36: 12V VOLTAGE REGULATOR FOR PRESSURE SENSOR

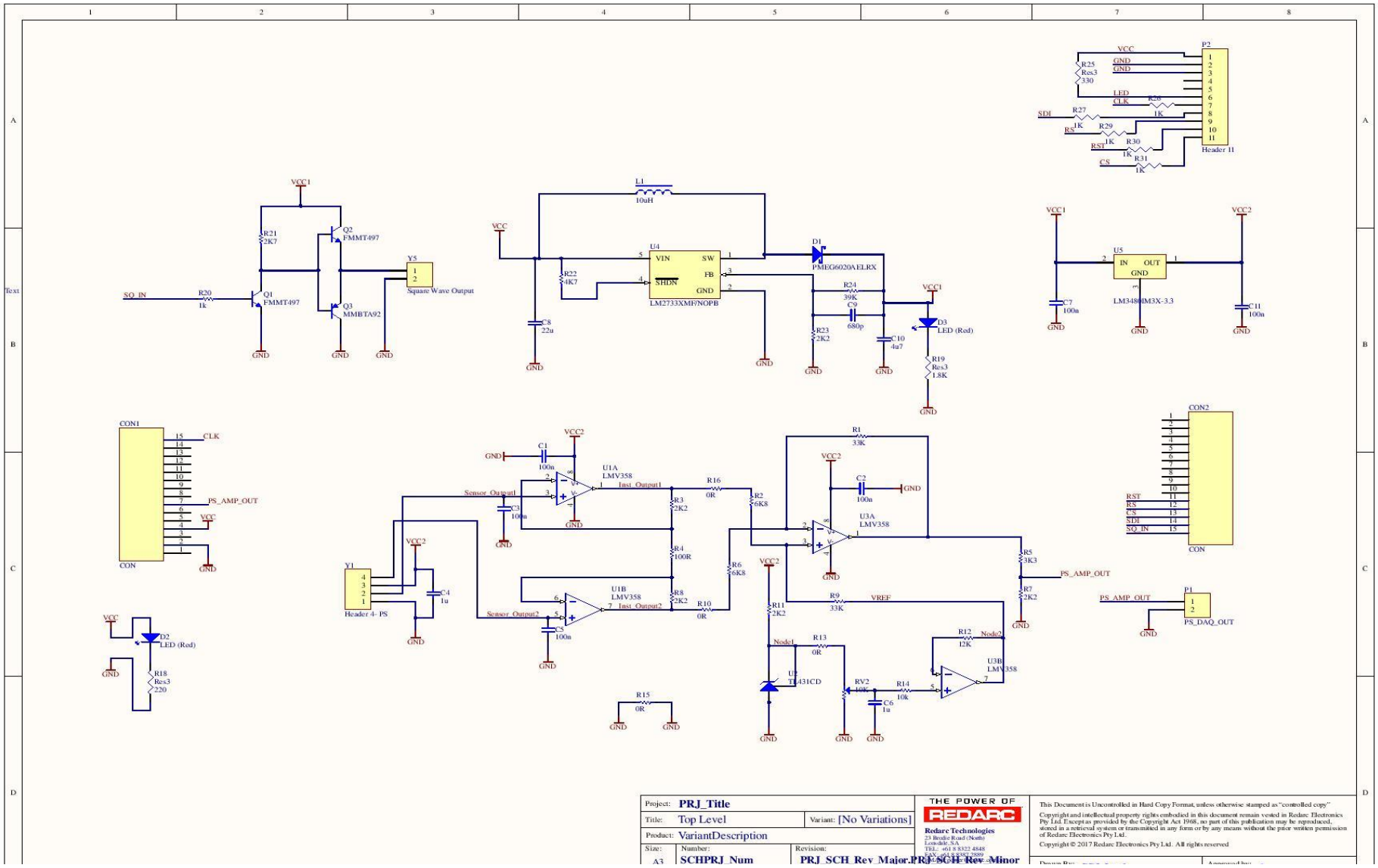


FIGURE 37: CIRCUIT DIAGRAM FOR PRESSURE SENSOR AMPLIFICATION, VOLTAGE REGULATOR, DC-DC BOOSTER AND SQUARE WAVE SWITCHING

4.4.4. PCB DESIGN

In this section, it was required to design a PCB which will include the pressure sensor amplification circuit, DC-DC booster, voltage regulator and the pump driving circuit. The design of the PCB required to set the rules. The table below shows some of the design specification of the board:

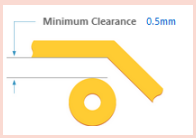
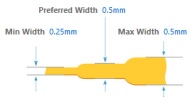
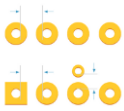
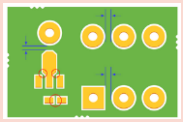
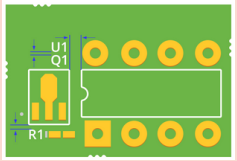
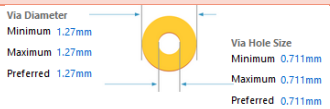
Parameters		Value/ Description
Clearance between adjacent tracks		0.5 mm
Track width		0.5 mm
On board ground plane	Polygon Pour Remove dead copper area	
Number of layers	Top Layer Middle Signal Layer Bottom Layer	3
Hole size		Minimum = 0.025mm Maximum = 2.54mm
Hole to Hole Clearance		0.254 mm
Minimum Solder Mask Silver		0.076 mm
Silk to Solder Mask Clearance		0.178 mm
Silk to Silk Clearance		0.254 mm
Routing Vias		Via Hole Size = 0.711 mm

TABLE 19: ALITUM DESIGN RULES

Based on the set design rules, the PCB design and routing was done for the components as shown in figure 38:

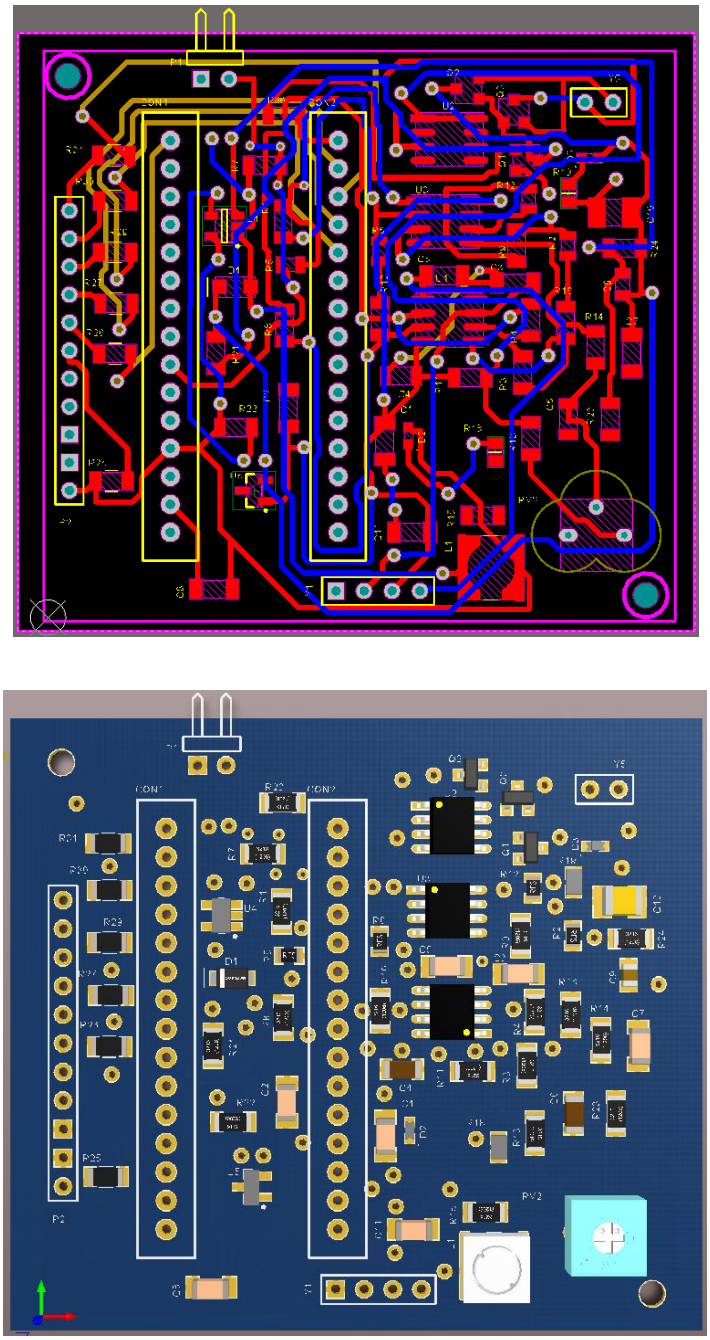


FIGURE 38: ALTIUM PCB DESIGN ROUTING LAYOUT AND 3D MODEL

The PCB board designed has a dimension of 61.49 mm x 54.26 mm. It has been designed to incorporate a TFT screen if required to be implemented. The 15 Pin connector added is meant to incorporate an Arduino Nano with ATMEGA 328P microcontroller. This would be generating the square wave, providing the power and receiving the pressure sensor data. The right-angled connector P1 at the top of the board is designed to send the data out from the pressure sensor to the data acquisition unit. A bill of materials is shown in Appendix G.

4.5. LabVIEW Program Design

4.5.1. Data Acquisition System

The collection of data from the ultrasound unit and the pressure sensor and sending it to the computer for further signal processing required a data acquisition unit which would be able to store the data. It was further required to monitor the real-time data being collected. This would enable the operator in seeing any disruptions caused by the movement of the transducer.

Data acquisition unit from National Instruments can interact with the dedicated LabVIEW program. The data received can be viewed and the signal processing can be conducted within the program to observe the changes in the Doppler shift in the frequency.

The data acquisition system being used is a National Instruments USB 6001 DAQ with the tabulated specifications in table 20:

Functions	Values	Specified Minimum
Analog Input Channels	8	2
Maximum Sampling Rate	10 kS/s	10 kS/s
Analog Input Resolution	14 bits	12 bits
Analog Input Absolute Accuracy	26 mV	
Electrical Signal Measured	Voltage	Voltage
Supported Power Input	Bus powered	
Maximum Update Rate	5 kS/s	

TABLE 20: DATA ACQUISITION SYSTEM SPECIFICATIONS

This section is dedicated to the programming which was developed and explains the front end and the back end of the programming, on the signals being received, processing done and the front-end output generated.

Front End Program

The program for the front-end LabVIEW is shown below in figure 39:

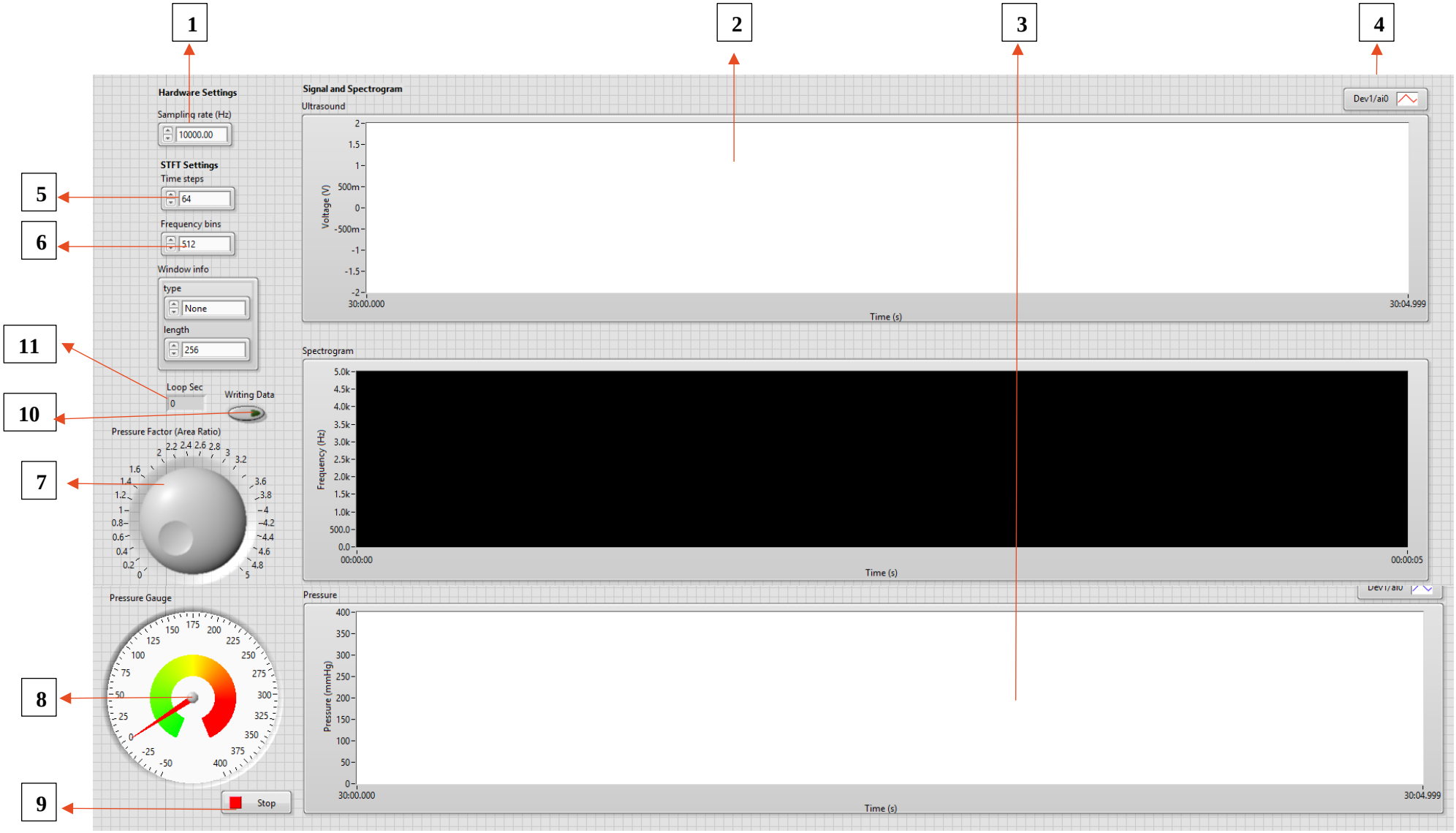


FIGURE 39: FRONT-END LAYOUT OF LABVIEW PROGRAMMING

1. Sampling frequency of the signal
2. Ultrasound time domain signal 5 second worth of data
3. Pressure sensor time domain signal 5 second worth of data
4. Spectrogram of ultrasound
5. Short-time Fourier Transform time steps
6. Short-time Fourier Transform frequency bins
7. Pressure calibration – application of pressure on wrist
8. Pressure gauge
9. Program Stop Button
10. Command to start taking the readings
11. Time to run each loop

The front end has been designed to set the sampling frequency of the data collected. Higher the sampling frequency – limited with the DAQ maximum rate – more space the data would need in the memory.

When the program it reads the ultrasound and pressure signal and displays the 5 second worth of data. The ultrasound signal is being processed to display spectrogram, which is an envelope of time-frequency components.

The pressure factor area ratio is a mathematical variable which is used to adjust the pressure being applied on the wrist to the pressure read from the bladder. This is dependent on the area of contact of the bladder with that of the ultrasound housing given by:

$$P_{bladder}A_{bladder} = P_{housing}A_{housing} \dots (15)$$

Finally, the gauge helps monitoring the calibrated pressure being applied on the wrist in mmHg. This program helps in real-time viewing of the spectrogram along with the backend processing which stores the data collected to a file.

Back End Program

The back-end program has been divided to multiple sections as follows:

1. Creating Channel – figure 40 shows the program of the data received from the data acquisition unit has to be read into the LabVIEW program. When the data collection is being done, two different channels are read at a time, one holding the pressure sensor value and one holding the information about the ultrasound. The read values are in the form of the voltage.

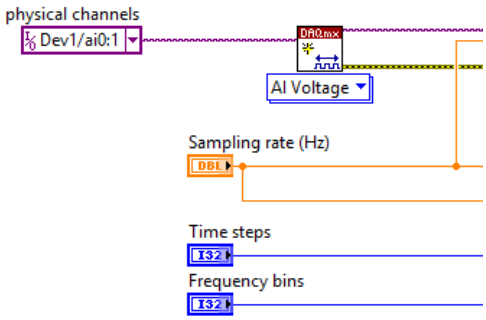


FIGURE 40: LABVIEW CHANNELS CREATIONS. THIS PART OF THE PROGRAM CREATED CHANNELS FOR THE CONNECTIO TO THE DATA ACQUISITION UNIT

2. Configuration of Channel – figure 41 shows the program section sets the sampling frequency which is fed by the user in the front end. It makes the data collection as continuous rather than discrete.

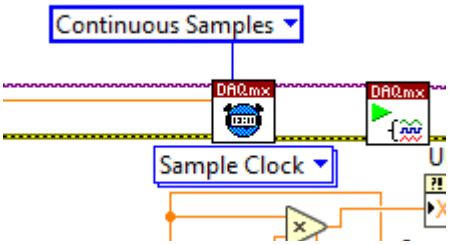


FIGURE 41: LABVIEW CHANNEL CONFIGURATION. CONFIGURED THE CHANNEL TO CONTINUOUS MODE WITH A SAMPLING FREQUENCY OF 10KS/SEC

3. Signal Division – figure 42 shows the signal coming from the DAQ is comprised of ultrasound and the pressure data. These two signals are split so appropriate processing can be done on each signal. This takes places in a loop.

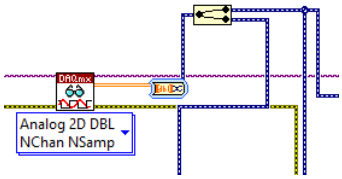


FIGURE 42: LABVIEW SPLITTING TWO SIGNALS FROM TWO CHANNELS

4. Pressure Calculation – The pressure sensor is connected to the bladder. The voltage reading acquired measures a voltage from range 0-5V. The pressure applied on the wrist using the ultrasound housing has a smaller surface area. The calibration was to be done within the program in such a way that the voltage received from the bladder corresponds to the pressure applied on the wrist using the housing. Measuring the area on which the pressure is being applied, the calibration equation came out to be (graphical program shown in figure 43):

$$Calibration\ equation = [\{87(voltage) - 83\} + 70] \times Area\ Ratio \ldots (16)$$

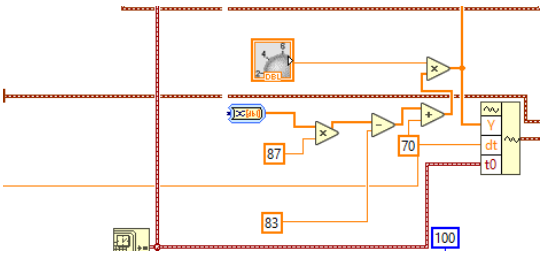


FIGURE 43: PRESSURE SENSOR CALIBRATION FROM VOLTAGE TO MM HG

5. Ultrasound Spectrogram – the ultrasound spectrogram output was generated using the TFA Online STFT Function. It required the parameters of the signal (ultrasound), time-frequency window information provided by the user in the front end as time steps and frequency bins and sampling frequency. The program of the STFT is shown below in figure 44:

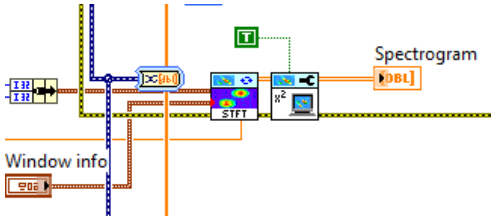


FIGURE 44: LABVIEW SPECTROGRAM GENERATOR, SHOWED A REALTIME SPECTROGRAM OF THE SIGNAL WHICH HELPED IN VIEWING ANY NOISES OR MOTION ARTEFACT

6. Data Acquiring – Finally the ultrasound and the pressure signals were written down into a text file when the user command for writing is being active. The location of the file storage can be programmatically changed. It writes the ultrasound voltage and calibrated pressure data with a ‘comma’ delimiter. If the program is stopped in between and restarted, the file is overwritten in order to save the space and remove the redundant data.

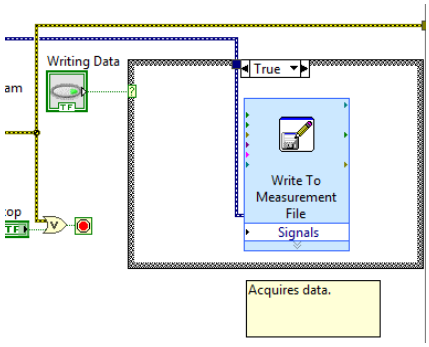


FIGURE 45: LABVIEW WRITING DATA TO TEXT FILE

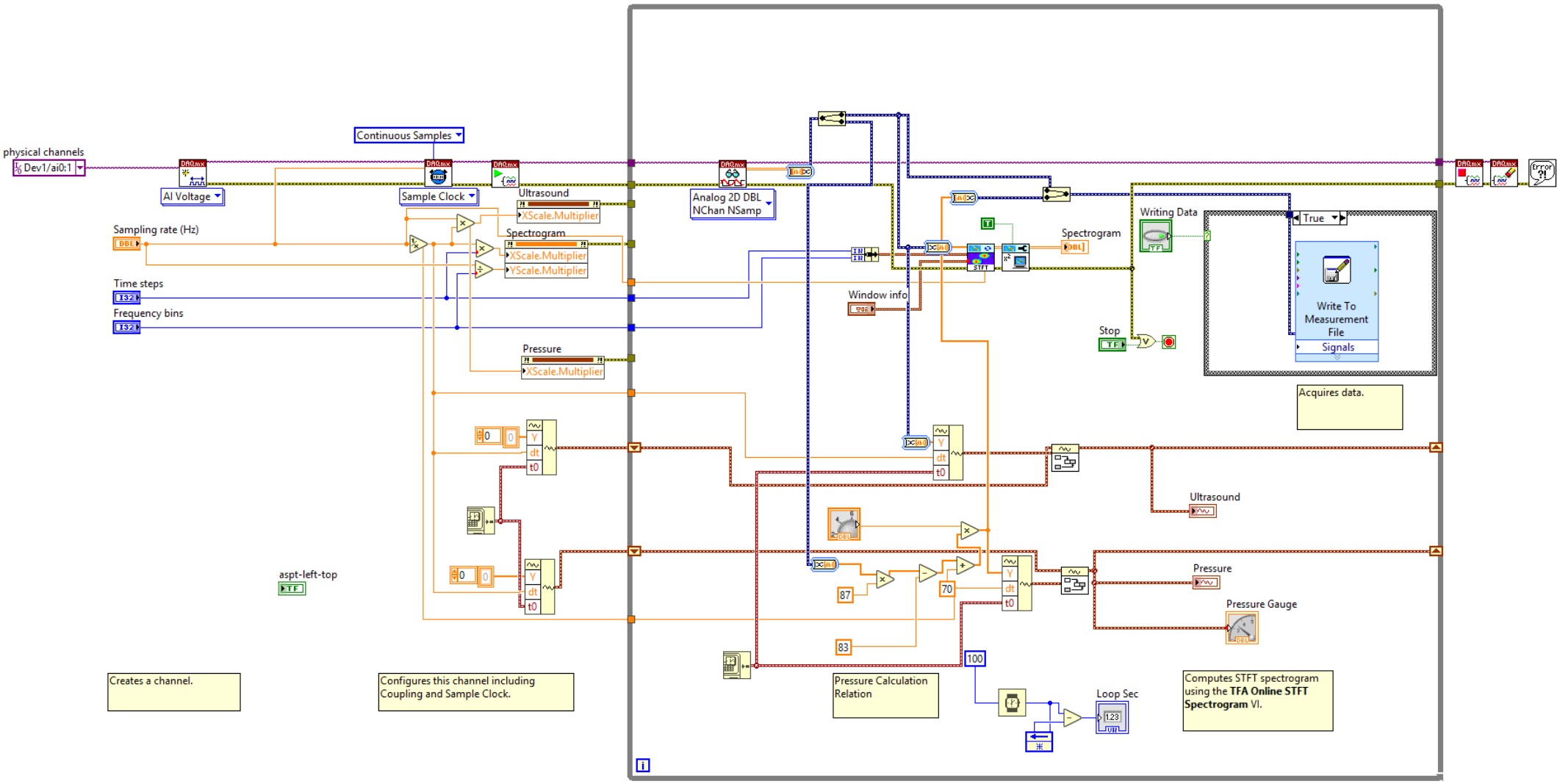


FIGURE 46: LABVIEW BACK-END PROGRAMMING

5. DESIGN EMBODIMENT

5.1. OBJECTIVES

In this section, after designing the computer aided design and developing the PCB and the program, the physical embodiment of the project needs to be done. The physical embodiment in this section includes the mechanical assembly, electronic assembly and testing and the physical assembly of the entire system.

The mechanical design section looks over the method of the implementation which was done for putting the transducer on the wrist and applying pressure to get the readings out. It also discusses on the method to keep the circuitry and the mechanical device at one location including the circuitry, ultrasound and the wrist interface.

The electronic design is based on the sensors being used, the control program implemented, and the working and design of the PCB board as discussed in the section 4.4.

5.2. MECHANICAL EMBODIMENT

One important thing to be noted, the two designs which were created, the manual and the automatic placement of the transducer, due to high lead time in the acquiring of the circuitry, automatic method was ignored and the focus was only kept on to the building of the manual mechanism where the ultrasound transducer could be manually adjusted and placed on the wrist.

5.2.1. BELT PULLEY DESIGN

The designs being developed in section 4.3 for the automatic and the manual placement of the transducer needed the mechanism to move the transducer across the wrist. The belt-pulley system mechanism was developed in which the belt either controlled by the transducer or by

manually would be moving the transducer across the wrist. The belt (figure 47) is based on the timing belt which would go around the pulley.

FIGURE 47: BELT 151MM, 2.038MM PITCH

The servo would drive the timing belt, which would in-turn drive the transducer placed on the wrist. The belt was required to be locked on to the transducer housing, for which the transducer was designed to incorporate a screw mechanism which would tighten the belt into the housing (figure 48).

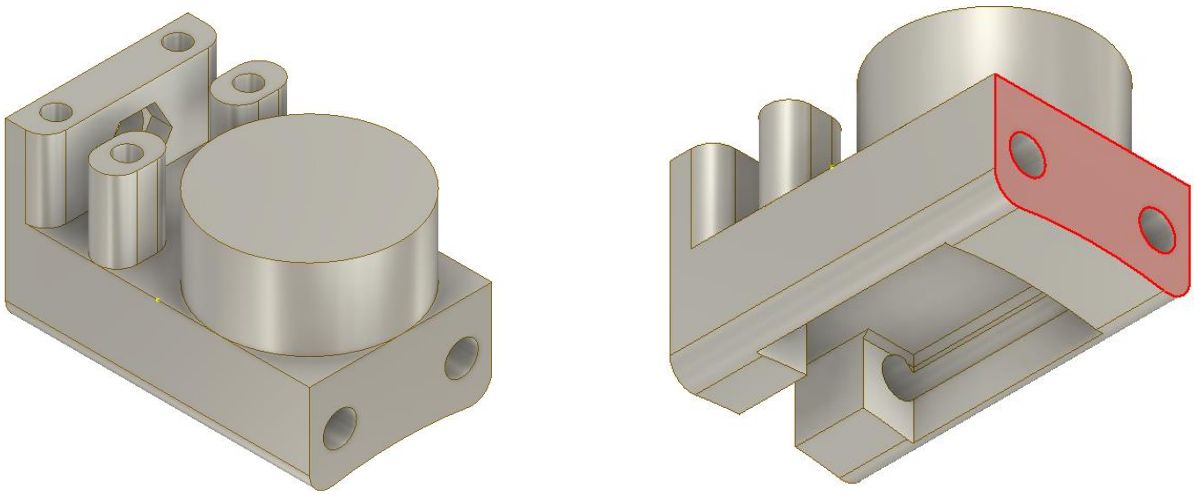


FIGURE 48: TRANSDUCER HOUSING

The design was done to be 3D printed using acrylic. The 3D printed mechanical design for the automatic movement is shown below in figure 49:

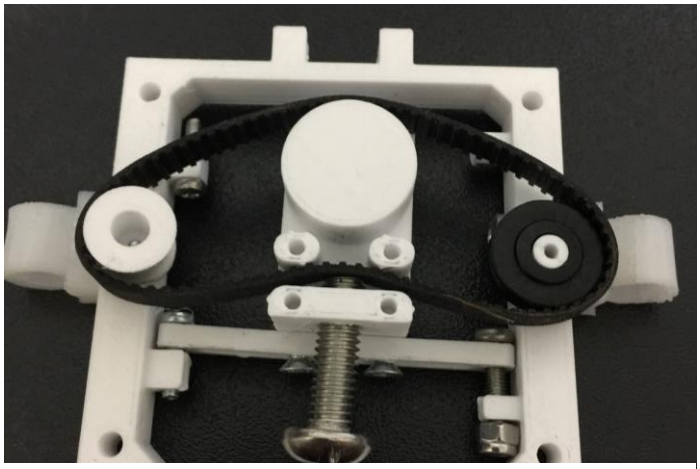


FIGURE 49: AUTOMATIC PLACEMENT OF TRANSDUCER

Various kinds of pulleys were available with specific to the belt acquired. The metallic based steel pulleys added to the weight. It was decided to use a 3D printable driver pulley attached to the servo and screwed with a washer onto the frame and a plastic pulley used in the curtain blinds which was the free rotating smooth pulley.

5.2.2. STRAP HOLDER DESIGN

The strap holder design was thought to be done in such a way which would reduce friction to move the entire interface back and forth on the wrist. The initial thinking was to incorporate linear bearing which would help in moving the system back and forth. But the smaller sized linear bearing of internal diameter less than 6mm and external diameter less than 10 mm, are expensive. Further they have a long lead time in procurement as they have to be custom built. Standard sizes of the bearing with the smallest one with internal diameter of 8 mm and external diameter of 14 mm shown in figure 50, used in the motion of the 3D printer nozzle added to bulk and size constraints of the design.

FIGURE 50: BALL BEARING - REDUCING FRICTION

It was decided to use bush and dowel pins. This would help in reducing the cost, time of manufacturing and light weight – designed according to the dimension provided. The side strap holder were machined dowel pins going through two brass bushes shown in figure 51.

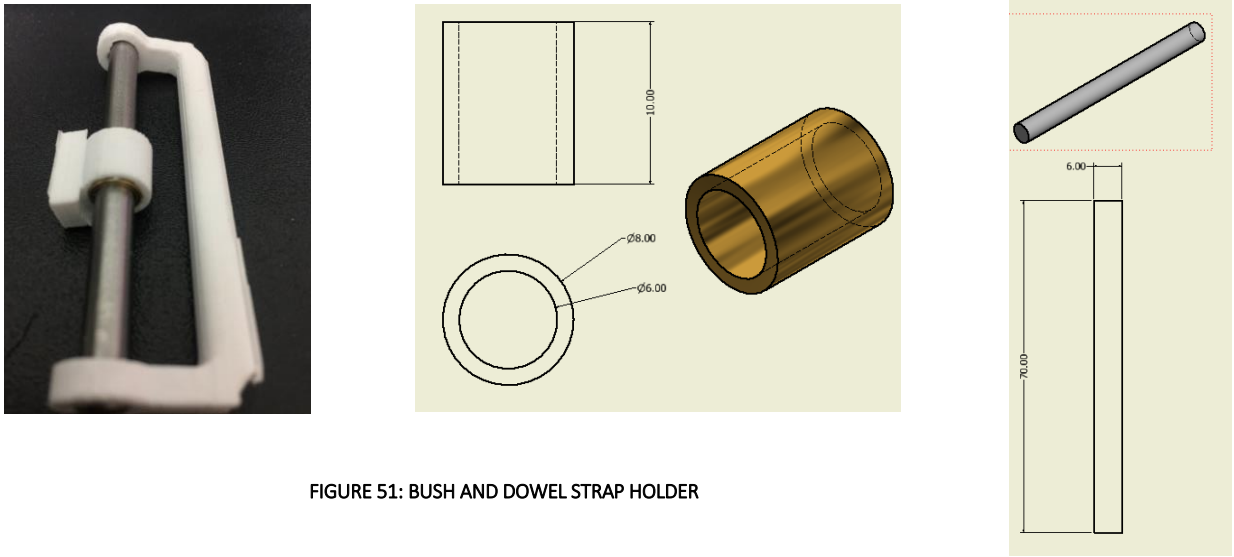


FIGURE 51: BUSH AND DOWEL STRAP HOLDER

5.2.3. *WRIST FRAME*

The wrist frame was designed for the automatic and the manual transducer placement methods. The effective width the transducer could move was kept to 80 mm. The frames were 3D printed using PLA as for the prototyping. It was required that the frame could hold the strap holder which would enable it to be tied around the wrist, and the transducer housing which can slide across the frame. The 3D printed holder is shown below in figure 52.

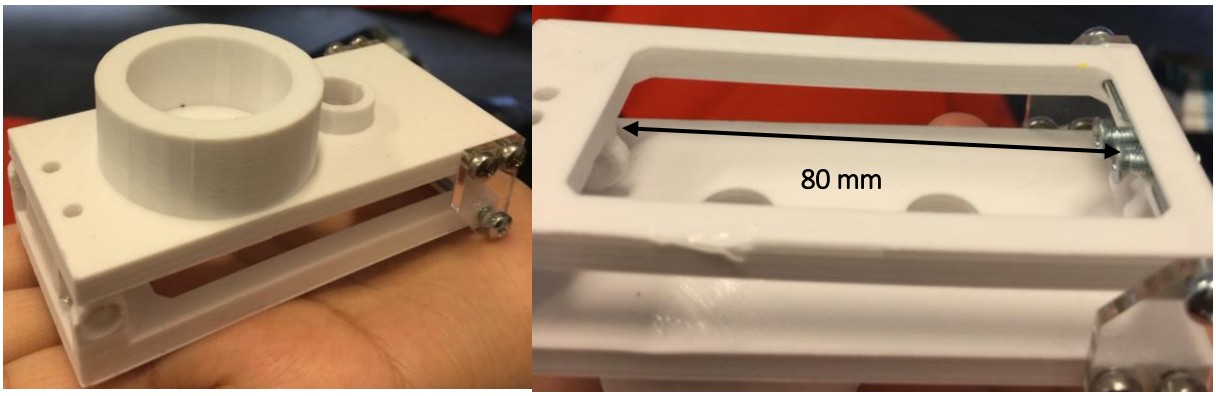


FIGURE 52: MANUAL PLACEMENT OF TRANSDUCER 3D PRINTED MODEL

5.2.4. MECHANICAL PLACEMENT OF THE SENSOR, VALVE AND MOTOR

The mechanical placement of the pressure sensor, valve and motor required no leakages into the external environment. In the initial prototype which has been discussed in the Appendix D section 3, plastic flexible vinyl tubing were used to connect the sensor and the pump. Another important point has to be noted, which was the use of micro-pump had to be avoided. The pumping system here was a rotary standard pump. The micro-pump acquired, manufactured by the Company failed to provide proper datasheet and the time constraint present in the project for testing and data collection lead to the decision of using a standard pump.

FIGURE 53: TUBING, PRESSURE CHAMBER AND LEAK VALVE

The leakages were high. Hence it was decided to change to rubber tubing used in the standard blood pressure monitors. The rubber tubing obtained from RS Components of external diameter 8mm and internal diameter of 3mm proved to be useful as it helped in preventing any leakages.

The pressure sensor was placed inside a plastic acrylic pressure chamber. This was connected to the tube which was directly connected to the bladder. A leak valve was present which was opened slightly to release the air over the period when the bladder reached a maximum value above the measured systolic pressure and no ultrasound signal was heard from the Doppler flow meter. One end of the tube was connected to a solenoid valve which was the emergency valve.

The bladder was connected to the frame. The bladder was a neoprene bladder from Omron blood pressure cuffs of extra small size 12-18 cm shown in figure 54. It was obtained from a wrist wearable blood pressure monitor for the prototype purposes.

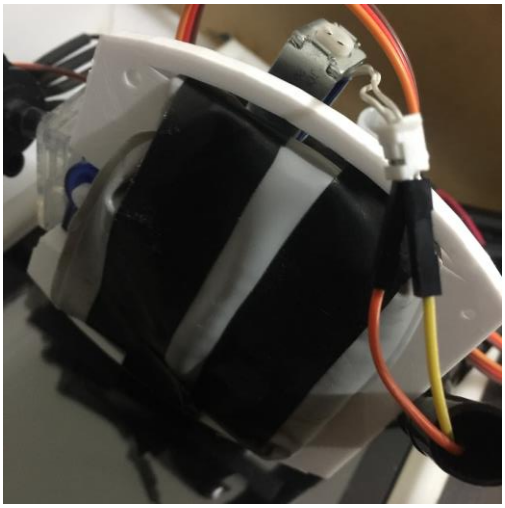


FIGURE 54: BLADDER FOR PRESSURE APPLICATION

5.2.5. *ULTRASOUND GEL*

Ultrasound gel was one of the important components required for taking the ultrasound measurement. It is used for reducing the impedance between the transducer and the skin providing a closed conductive medium. Initially the ultrasound gel used was from the Aquasonic, a water based liquid gel (figure 55).

FIGURE 55: LIQUID BASED ULTRASOUND GEL

The problem with the ultrasound liquid-based gel was that, it was required to apply a considerable amount before taking the measurements. Further, it made the transducer easily slip over the wrist. In order to improve the design, a hard ultrasound gel was decided to be used which would be embedded inside the housing of the transducer. The gel would not be required to be changed with every patient and reduced the motion artefacts created due to slippage of the transducer.

FIGURE 56: HARD ULTRASOUND GEL PAD

The gel pad from Aquaflex (figure 56) was cut into specific dimension so it would be able to fit into the transducer housing shown in figure 57.

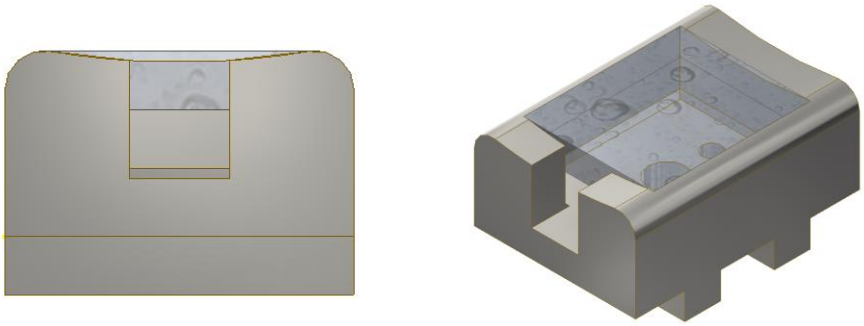


FIGURE 57: PLACEMENT OF ULTRASOUND GEL PAD IN TRANSDUCER HOUSING

5.3. ELECTRONIC DESIGNING

5.3.1. PRESSURE SENSOR PCB TESTING

1. Apply power (12V) and check that the current drawn is sensible (around 5-10mA.)
2. Set the reference potentiometer fully clockwise, and check that the reference voltage is close to 2.5V.
3. Connect the two differential inputs to the same voltage near 6V. The output voltage should be within +/-0.5V of the reference voltage (accounting for common mode errors.)
4. The following circuit in figure 58 was built. Nodes A and B was connected to the two differential inputs, and a signal generator outputting a 100Hz sine wave was connected to SIG_GEN. The peak-peak voltage that causes clipping was determined, and the measured gain compared to the designed gain.

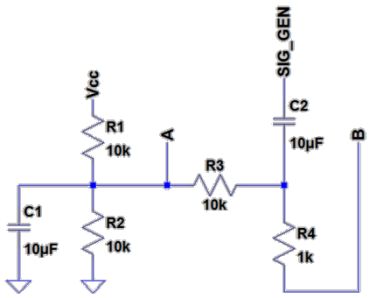


FIGURE 58: TEST CIRCUIT FOR PRESSURE SENSOR

The designed gain from the circuit was calculated to be 262. This helped in determining the actual gain obtained. The clipping VPP occurred at 10V.

In order to obtain the pressure-voltage relationship to justify the working of the pressure sensor module, a standard bulb was connected with a T-piece with one outlet going to a manual blood pressure gauge and the other end to the pressure sensor. The output of the pressure sensor was connected to the oscilloscope. Pressure was increased by pumping through the bulb. The obtained pressure was read in the pressure gauge and the corresponding voltage was read on the oscilloscope. A linear relationship was obtained between the pressure and the voltage shown below in figure 59:

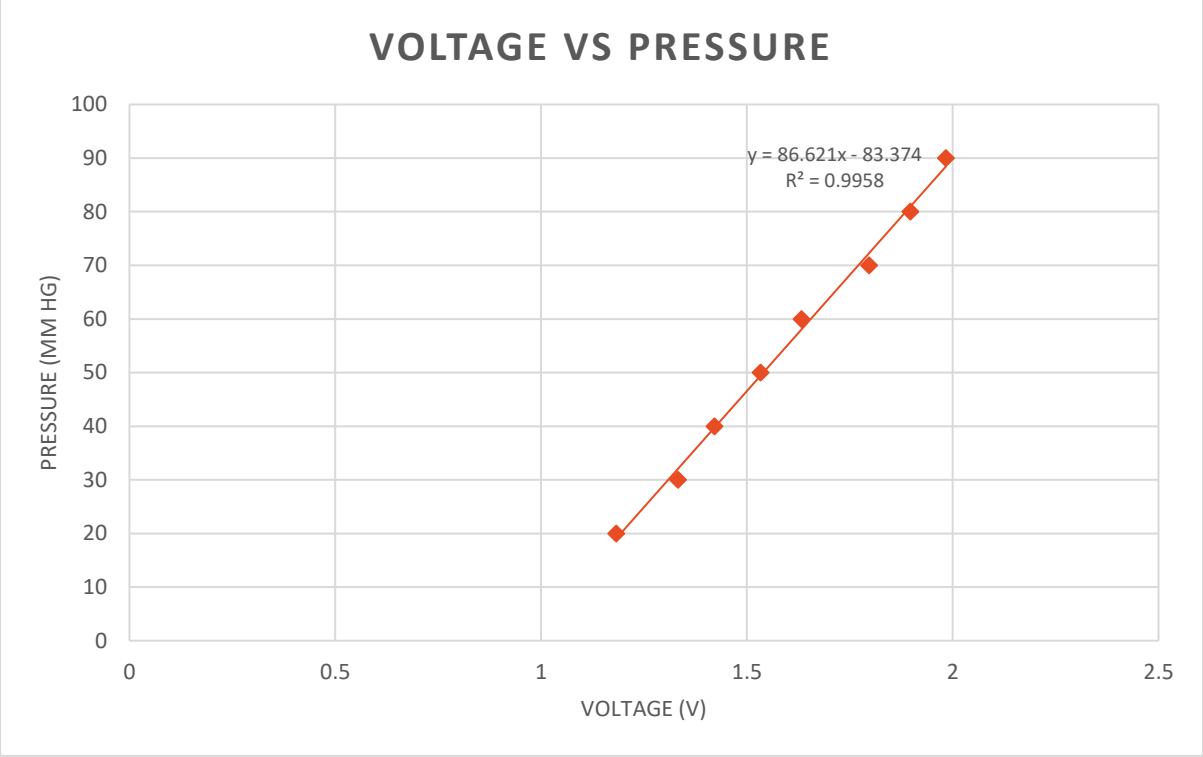


FIGURE 59: PRESSURE - VOLTAGE CALIBRATION CURVE

5.3.2. PUMP TESTING

The PCB designed for the micro-pump was required to be tested. The Arduino Nano with ATMEGA 328P chip was used to provide squares of 20.82 kHz at 50% duty cycle. The code is shown in Appendix H Section 1, pump code. Initially, the square wave was generated using the digitalWrite function in Arduino. The issue observed with this function was that, it produced an overshoot and undershoot of approximately 20%. The square wave was not clean and made the pump to produce a high frequency noise rather than vibrating the piezo. The code was developed to use the timer interrupt. This was used to generate the 21kHz frequency.

The compare match register, OCRA was required to set to a value so it would set the timer to overflow at when the set time was reached. The 8-bit Timer0 was used as the OCRA was less than the overflow value of 256 for the timer. The pre-scalar available for the timer0 is tabulated below in table 21:

CS02	CS01	CS00	Pre-Scalar	Test Frequencies
0	0	0	No Clock	
0	0	1	No Pre-scaling	20.3 KHz
0	1	0	8	20.6 KHz
0	1	1	64	21.05 KHz
1	0	0	256	21.3 KHz
1	0	1	1024	22.53 KHz

TABLE 21: PRESCALAR SETTING OF ARDUINO AND SQUARE WAVE FREQUENCY

Different pre-scalars were tried. The one closest to 21KHz was produced by pre-scalar 64.

$$OCRA_{Value} = \frac{[Arduino\ Clock\ Speed]}{Prescalar \times Desired\ frequency} - 1 \ldots (17)$$

$$OCRA_{value} = \frac{[16{,}000{,}000]}{64 \times 21000} - 1 \approx 5$$

The port manipulation was done rather than calling the digitalWrite function in Arduino. The PORTD which controls the digital pins 0-7 was used to make the pin HIGH and LOW. The generated square wave is shown below in figure 60:

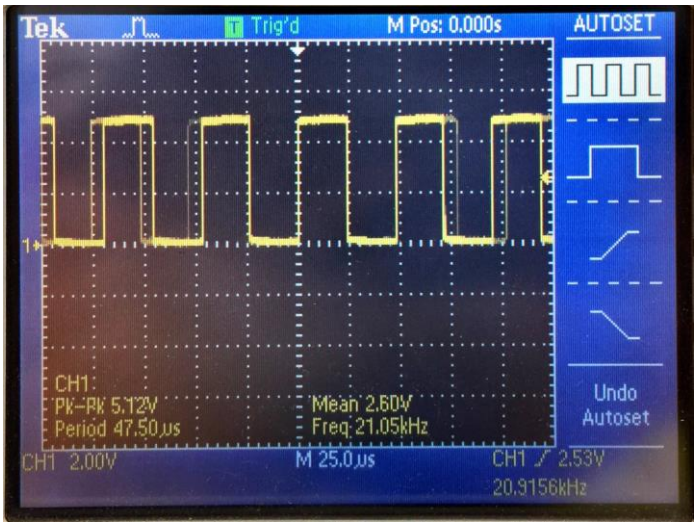


FIGURE 60: GENERATED SQUARE WAVE 21KHZ FREQUENCY 50% DUTY CYCLE

The square wave when passed through the push-pull switch circuit in section 4.4.2, micro-pump driving circuit, the square waves were pulled up to 23V and then pulled down to 0V. This triggered the pump to run as expected. The slow flow rate made the pump to increase the pressure in the bladder to a maximum of 200 mm Hg (after which the emergency valve was opened) in about 1.5 minutes. Unfortunately, this testing and development was done to check the feasibility of the micro-pump after the actual implementation of the system was done. The lead time in the PCB procurement and further assembling lead to exclusion of the pump from the device design.

The designed PCB along with the stencil was ordered from PCB Way as shown below in figure 61. A 4-layer (design based on 3 layer) board made of normal FR material, with tented vias and holes, thickness of 1.6 mm. The stencil designed is 550mm x 550mm one sided aluminium board.

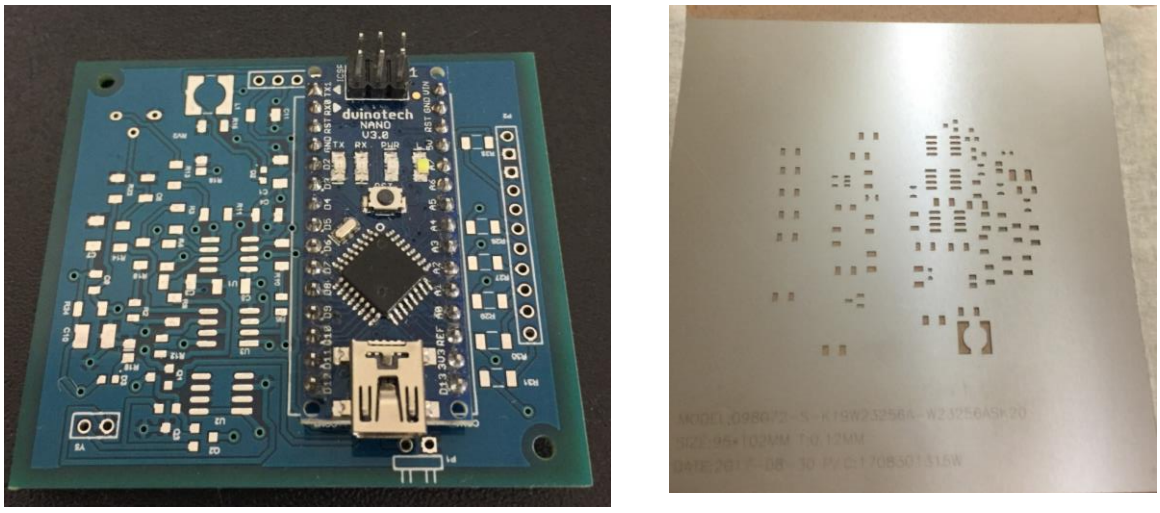


FIGURE 61: MANUFACTURED PCB AND STENCIL FOR REFLOW SOLDERING

5.4. DESIGN LAYOUT

The layout for the main components are divided into 4 main sections:

1. Holder for the Ultrasound, DAQ and Circuit
2. Design of controller box
3. Controller Circuit
4. Programming and User Interface

It was necessary to design a casing and a box which would hold the device at one place, making it portable. It was also necessary to design a controller box which will hold the PCB and controller circuitry and provide the user interface to control the system.

5.4.1. HOLDER - CASING

The design of the casing has been done in such a way that the plate would be able to hold ultrasound, the controller box, DAQ and a tablet. The use of the tablet is to control the positioning of the transducer using Bluetooth-Servo system if the automatic method of transducer placement is being used and to read the pressure value. The 3D model of the casing is shown below in figure 62:

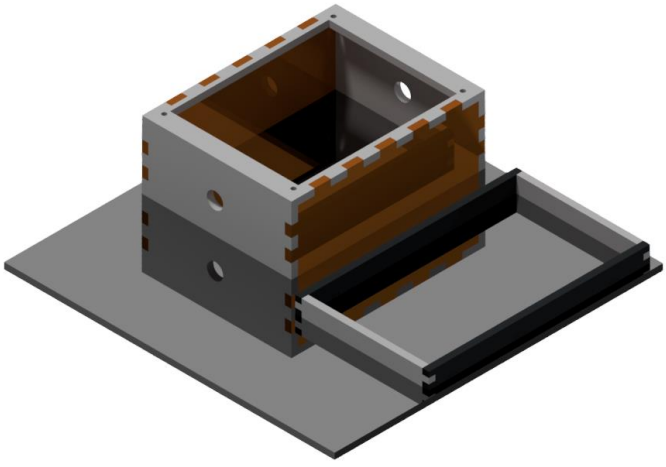


FIGURE 62: CAD MODEL FOR CASING

The fabrication was done using the laser cutting technique with 6 mm acetal being used for the holder. The fabricated unit is shown below in figure 63:

FIGURE 63: LASER CUT FABRICATED CASING FOR ULTRASOUD DAQ SYSTEM

5.4.2. CONTROLLER BOX

The controller box has been designed in such a way that, it will hold a breadboard along with the PCB circuit and other circuitry which are not included in the PCB design. It would provide an output for buttons for user interface as discussed and evaluated in the section 3.8.4. It provides an output for TFT screen which will show the state of the pump and readings taken for pressure. The CAD design is shown below in figure 64:

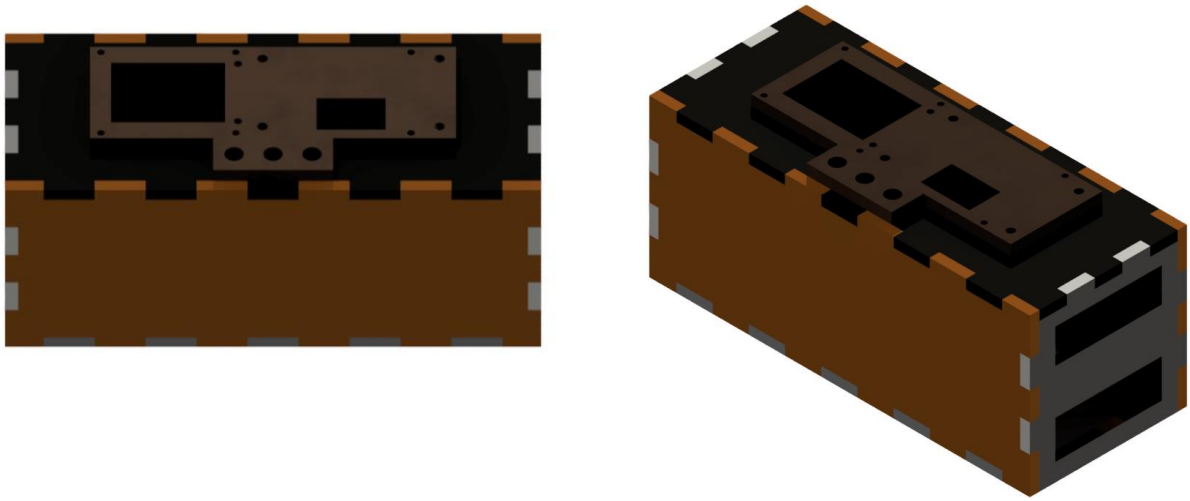


FIGURE 64: 3D MODEL FOR CONTROLLER BOX

The top cover holds the LCD and the buttons. The fabrication was done using 4.5 mm acrylic. The components were placed together using acrylic glue. The fabricated box is shown below in figure 65:

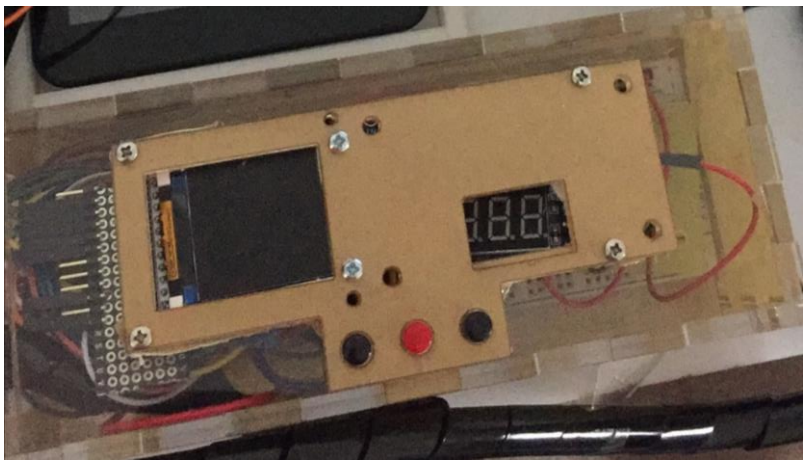


FIGURE 65: LASER CUT FABRICATED CONTROLLER BOX

The final assembled design is shown in figure 66:

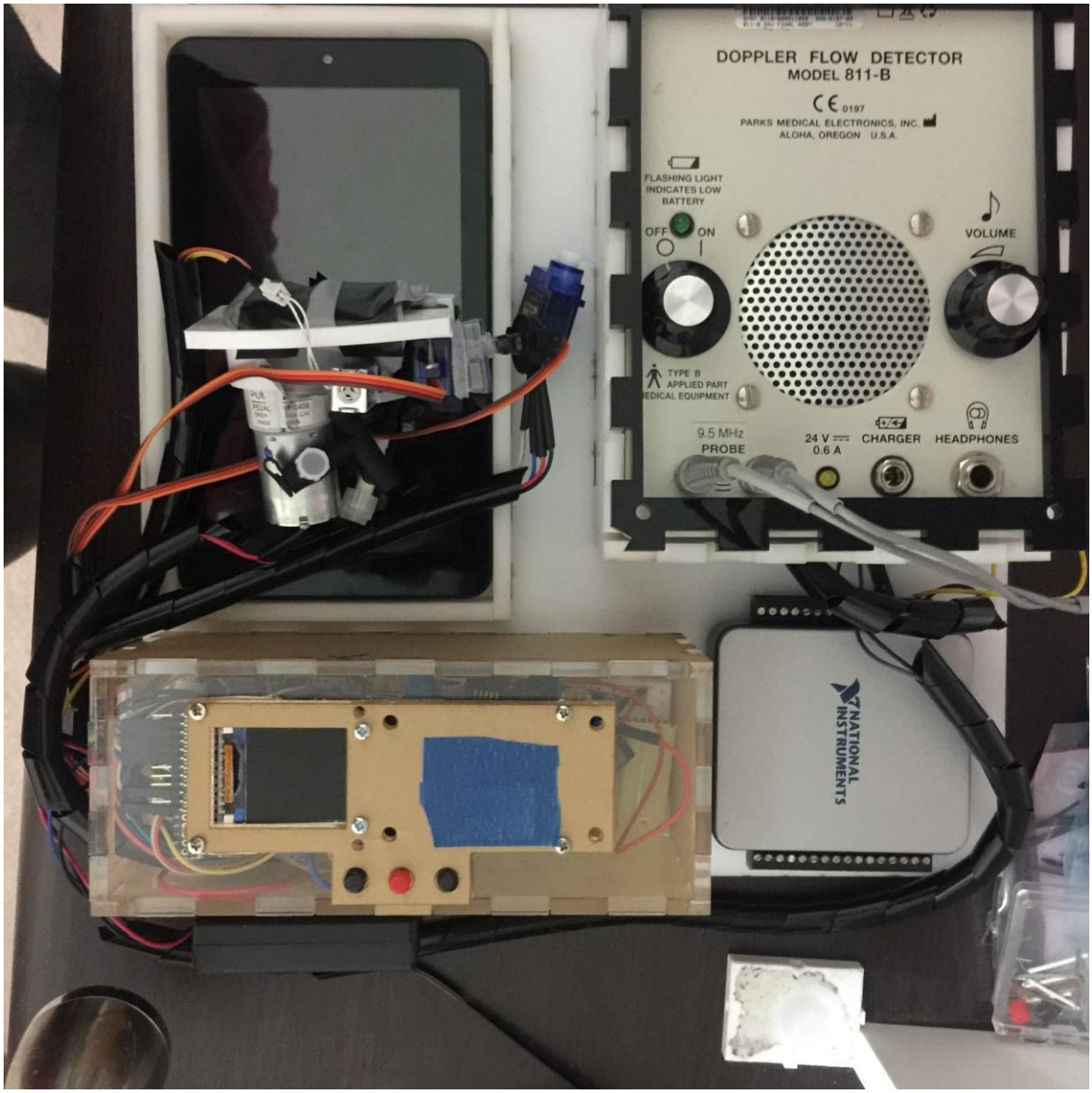


FIGURE 66: DAQ SYSTEM

5.4.3. CONTROLLER CIRCUIT

The controller circuit comprises of various parts:

1. Arduino – Microcontroller to read-write and control the sensors, display, Bluetooth and the pump. Arduino was chosen over other components as it was easier to program, availability of sensors compatible with Arduino such as Bluetooth module and solenoid valves.

2. Pressure sensor circuit – described in the section 4.4.1 and 4.4.4.

3. Pump Circuit – described in the section 4.4.2.

4. Display Unit – a 128 x 128 TFT Arduino display by Duinotech was used. The main purpose for the use of the display unit was to display the pressure value, state of the pump (if on or off) and state of the emergency valve

5. User Interface – tactile buttons used as the user interface to control the pump, emergency valve and resetting the circuit

6. DC-DC boost – even though the PCB was designed to incorporate the DC-DC booster, a variable DC-DC booster by Arduino was used as well boost the voltage required by the pressure sensor. This was not a necessary part but was done prior to acquiring the PCB board to start the prior testing

7. Bluetooth Module – a Bluetooth module was implemented inside controlled by Arduino which would receive data of the pressure sensor and send it to the Android device. It will also send data from the Android device for setting the position of the servo system to move the transducer to those positions.

8. Servo and Valve – Arduino fixed rotation servos were attached which would be able to control the position by rotating 180^{O}. The emergency valve is a solenoid valve which was controlled by a separate interrupt program by Arduino.

5.4.3.1. LCD Screen

The LCD screen used is TFT 128 x 128 Duinotech LCD. The pin connections are based on Serial Peripheral Interface connection. The pin outs went to the Arduino to the pins 13, 11, 10, 9 and 8 which corresponded to the SPI connections of the Arduino Nano. The table shows the Arduino and the LCD connections. Further each pin required a pull-up resistor. For this, using Veroboard, 1KΩ resistors were soldered on to the board so the connection between the Arduino

and the LCD be made. The pinout is shown in table 22 while the assembled LCD is shown in figure 67.

LCD Pin	Arduino Uno	SPI
CLK	13	SCK
SDI	11	MOSI
RS	9	DC
RST	8	RST
CS	10	CS
VCC	5V	5V

TABLE 22: LCD TO ARDUINO SPI CONNECTION PINS

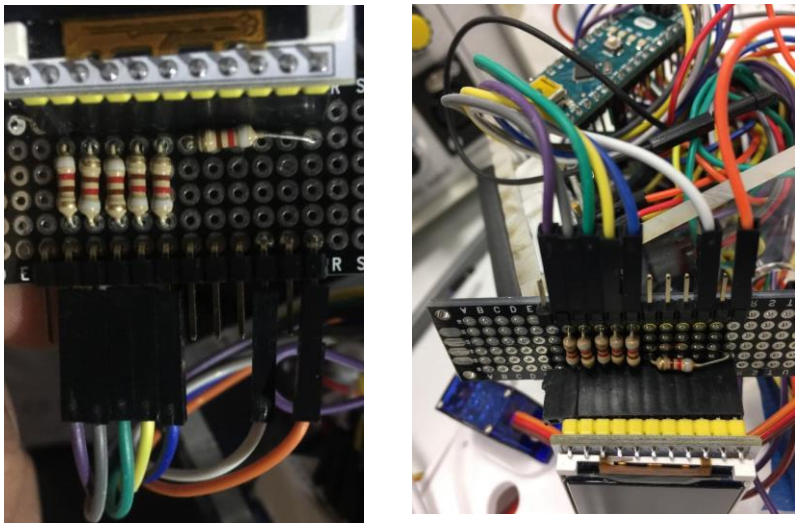


FIGURE 67: SOLDERING 1KOHM RESISTOR TO VEROBOARD FOR CONNECTION WITH ARDUINOOF THE TFT SCREEN

The Arduino program is based on reading the value obtained from the pressure sensor by converting the voltage reading which is read as a 10-bit value into pressure in mmHg and displaying on the screen. It further reads the state of the pump being on or off and displays on the screen.

A 128x128 screen is based on a coordinate system. The coordinate of the starting of the text which include the x-value and the y-value were required to be specified in the program along with the size of the text and the refresh rate and stroke colour.

5.4.3.2. User Interface

The user interface provided in this case are the buttons on the controller box which controls the pump, resetting of the Arduino and emergency solenoid valve. The second user interface was provided through the App developed which would read the pressure value and help in controlling the position of the transducer using the Bluetooth module.

Button Control

The button control here involved the reset of the Arduino. Arduino has its own reset button set on the board. It resets the program and re-initialises the setup and runs the main loop again. But accessibility of this button always not possible when the microcontroller is inside a case or device. In order to reset the program, the RESET pin of the Arduino was connected to a button. When this button was pressed, it triggered the same function as the Arduino's own on board reset button. This was essential in the case where the program got stuck or the reading had to be initialised to 0.

The solenoid valve button was connected to the digital pin 15 of Arduino. When this button was being pressed, the solenoid valve opened. When this button was pressed again, it closed the solenoid valve. This was done in order to release the pressure, if it exceeded a limit as a safety emergency valve. The state of the valve was programmed to be monitored on the LCD screen.

It was expected to use the micro-pump whose programming has been discussed in the previous section 5.3.2. A standard blood pressure monitor pump was connected to the device in order to pump the bladder in case the micro-pump got very slow and cumbersome in inflating the bladder. The standard blood pressure pump used is a 6V, 360 mA rating rotary pump. The pump was connected to the switch so that, when the button was pressed, the power from the battery system would flow into the pump and activate the system. Until the button was kept pressed, the pump stayed activated. The programmed LCD is shown in figure 68 which displays the state of the pump and the valve along with the pressure being measured.

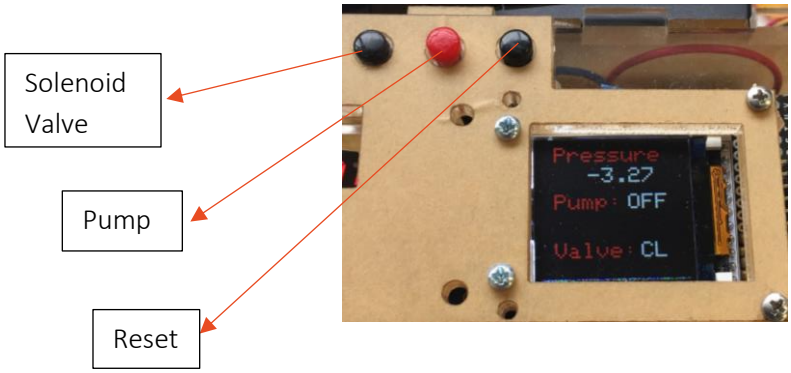


FIGURE 68: PROGRAMMED USER INTERFACE WITH SWITCH AND LCD OUTPUTING PRESSURE AND STATE OF PUMP AND SOLENOID VALVE

Bluetooth App Interface

The Bluetooth app interface was to provide a means to control the positioning of the servos in the automatic placement rather than direct interaction. This would reduce the noise due to movement when the wrist mechanical structure is placed.

Arduino has its own Bluetooth module HC-06 which works on the serial communication. It is a V2.0+EDR Bluetooth with BC417 chipset operating voltage of 3.3V shown below in figure 69.

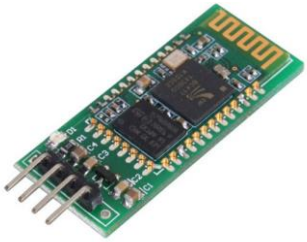


FIGURE 69: ARDUINO BLUETOOTH HC-06

The Bluetooth connection further required a means for connecting it to an application. MIT APP Inventor, an online programming application used for developing quick apps for Android devices. This was used for creating an app which would be able to read the data from the Arduino for the pressure value obtained. It would further be able to send the data from the application in an Android device to the Arduino. The data sent over the Bluetooth is converted to integer which would be fed to setting the position of the Servo.

The process in which the application would work is shown below in figure 70 with the user front-end interface and the back-end program.

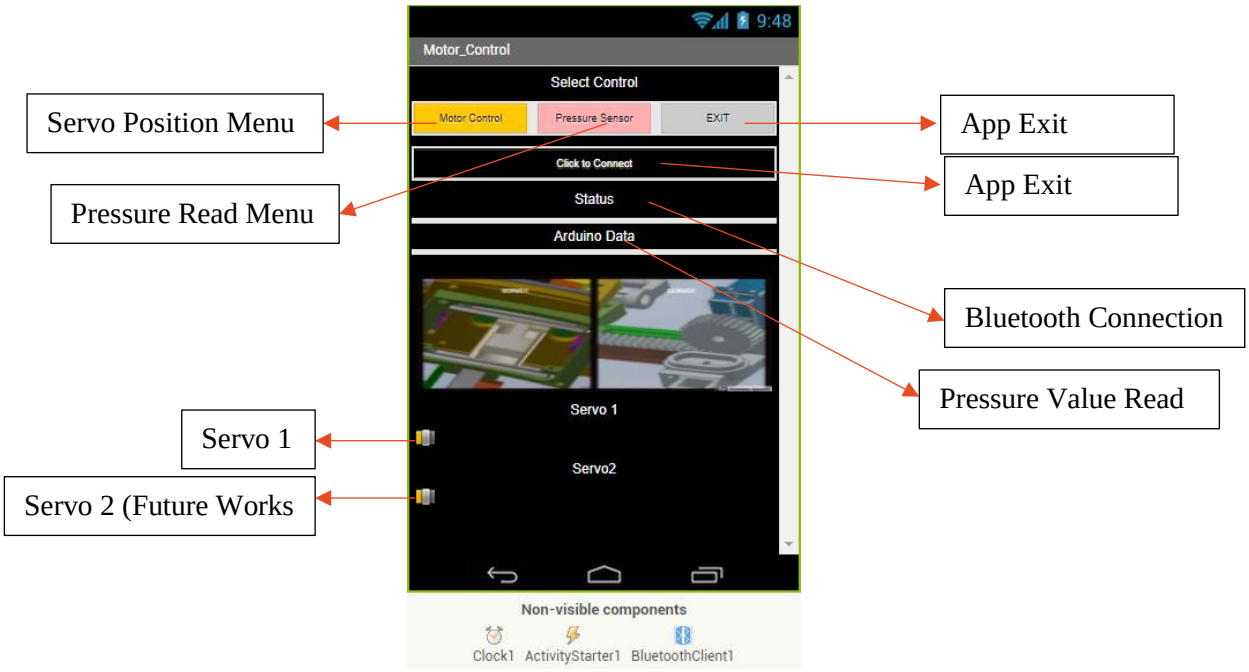


FIGURE 70: APP INVENTOR - ANDROID APP USER END

The front-end seen in the application controls the positioning of the servo and read the pressure value and send it to the phone. While the back-end program shown below is the actual programming which the MIT App-Inventor controls the sending and receiving of the data.

The programming has been divided into several components shown in the figure 72. When the 'Click to Connect' button is being pressed, the first component of the program reads the address name of the Bluetooth client from the list of the IDs of the Bluetooth provided on the app. Once the selection of the correct Bluetooth is being made, Bluetooth Client connects to the Bluetooth. If the button is pressed again, the Bluetooth is disconnected and the 'Disconnect' text is displayed to the User.

When the connection has been made, and button 1 is pressed or the 'Motor Control' button is pressed, the user is made available with two sliders, controlling the two servos. To be noted is, only one servo is being used for the lateral motion of the transducer. The second servo was implemented in a motivation to control the back and forth motion of the transducer making it to move in two dimensions. But due to time constraints, the second dimension was not implemented. When the slider in the main screen is moved, the value read from the position of the slider, such as the slider 1 can go from value 1000 to 1180. When it is placed at the position of 1000, a 2-byte number is sent through the Bluetooth to Arduino. The reason of sending 2-byte number was value of 1000 cannot be represented in a single byte. In the Arduino end, this

was read as 0 and the servo was fed with a value of 0. Making it move into a 00 position. A number, 1100 sent from the Bluetooth would be read as 1100-1000 = 100 which would be setting the servo to an angle of 1000.

Receiving data from Arduino into the application was done by using a function called Bluetooth.print(). This would send the serial data from Arduino to the RX port of the Bluetooth. In the program end, the Clock was set to 1 second. After every second, the app would read the data received and if received, it was displayed in the program.

Arduino Bluetooth Connection

The pin connection done between the Arduino and Bluetooth is shown below in figure 71:

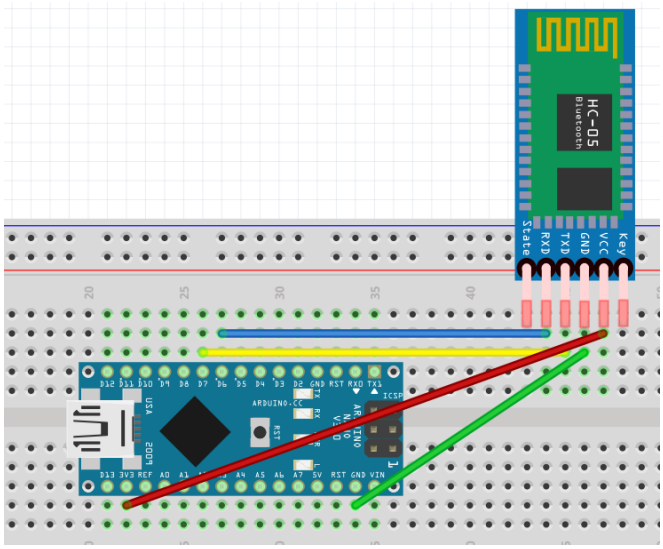


FIGURE 71: ARDUINO TO BLUETOOTH MODULE CONNECTION

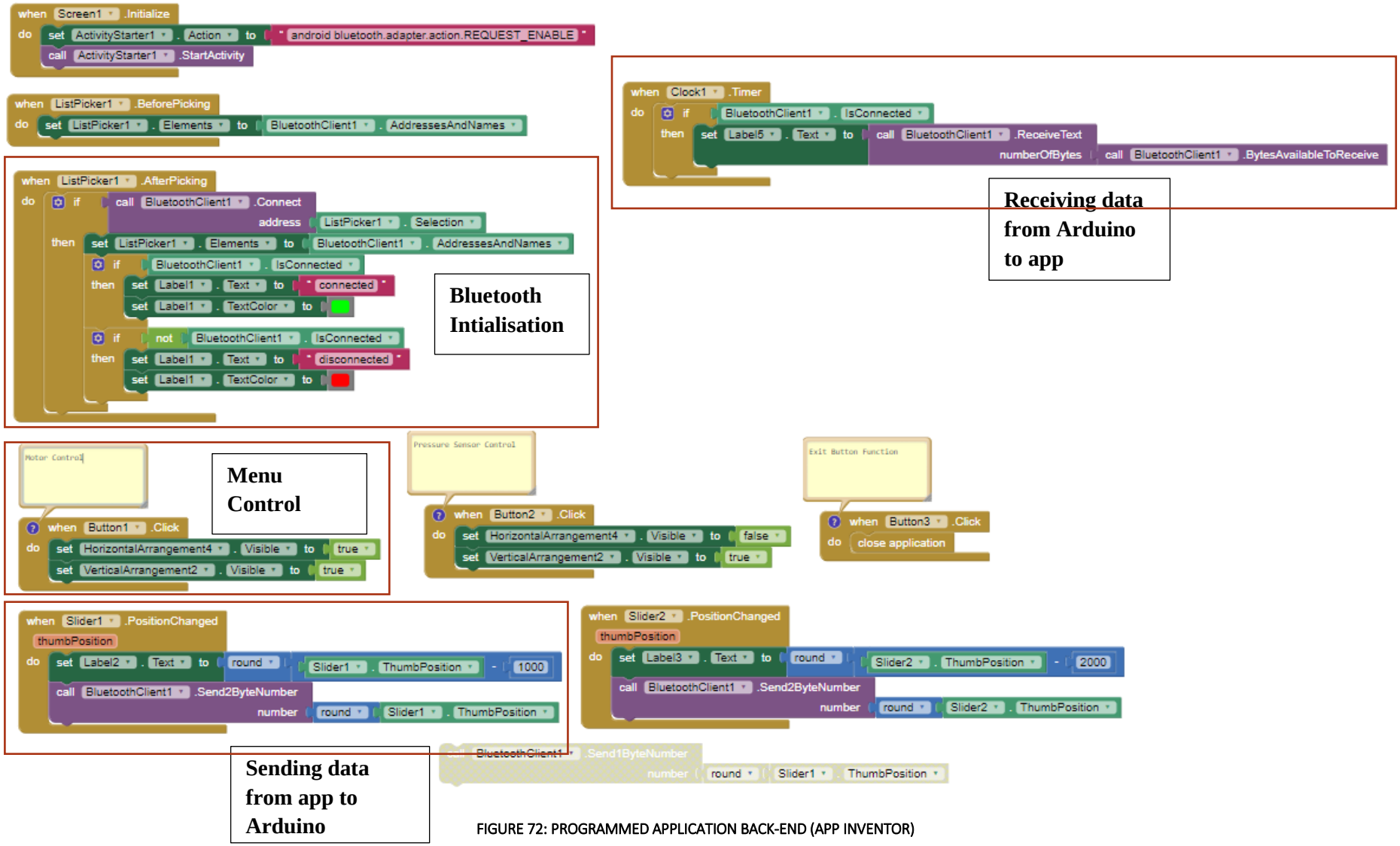


FIGURE 72: PROGRAMMED APPLICATION BACK-END (APP INVENTOR)

5.4.3.3. Programming

Arduino Nano with ATMEGA 328P chip was used for the programming. The programming done controls the pressure sensor, LCD, emergency valve, Bluetooth to receive and send data to the servo motor with the block diagram shown below in figure 73.

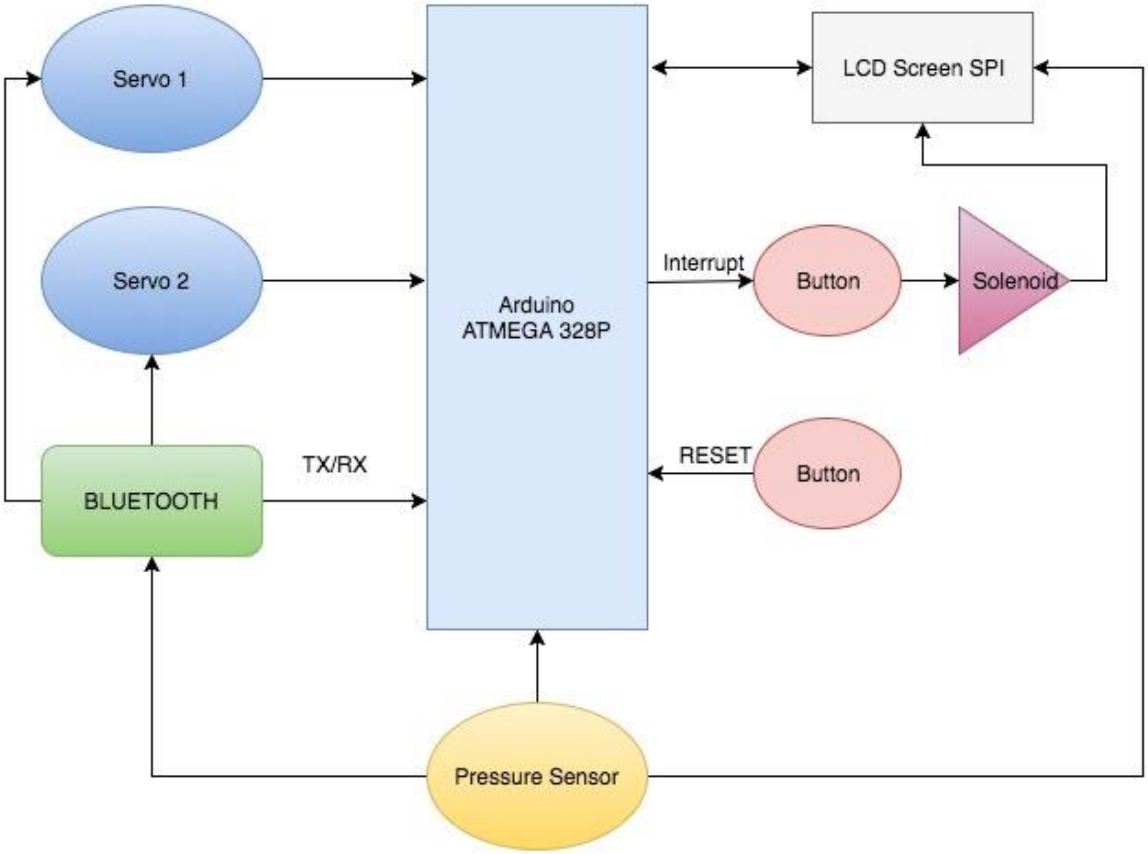


FIGURE 73: ARDUINO PROGRAMMING FLOW DIAGRAM

Pressure Sensor

The Arduino's analogue pin was connected to the pressure sensor. The pressure output a voltage value which was displayed as a 10-bit value in the Serial port. It was required to calibrate the pressure sensor value so the Arduino displayed the pressure value in mm Hg rather than 10-bit number. The calibration was done similar as done in section 5.3.1 for the pressure sensor calibration to be read by the LabVIEW. The calibration table and graph is shown in table 23 and figure 74. The equation fed into the Arduino program for the calibration is given by:

$$\text{Pressure} = 0.4068(x) - 95.99 \ldots (18)$$

10-bit value	Pressure (mmHg)
246	0
280	20
335	40
372	60
430	80
490	100

TABLE 23: PRESSURE TO 10-BIT CALIBRATION TABLE

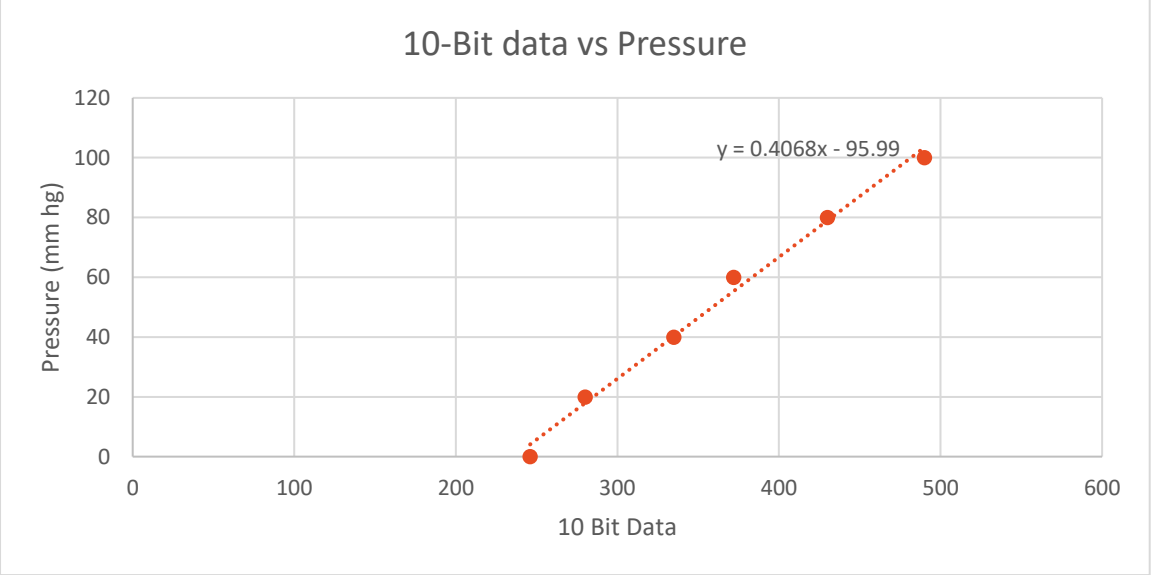


FIGURE 74: PRESSURE SENSOR CALIBRATION FOR DISPLAY MODULE (10 BIT-MM HG)

Bluetooth-Servo

The Bluetooth TX was connected to Arduino pin 7 and Bluetooth RX was connected to Arduino pin 6. The Bluetooth has an internal pre-defined baud rate of 9600. The baud rate was initialised in the program. When there was data available in the receiver of Bluetooth, the Arduino program checked it with the command line of:

$$bluetooth.available()$$

when the data was available, knowing the data sent from the app was a 2-byte data. The value was read from the Bluetooth transmitter as 1 byte and stored into 1 variable. The value was again read from the transmitter and second byte was stored in another variable (figure 75).

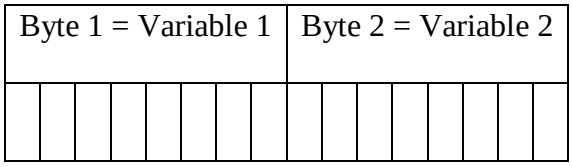


FIGURE 75: TWO 8-BITS VALUES STORED IN TWO VARIABLES IN ARDUINO

The data stored in the first variable was shifted by 8 bits to the MSB and the second byte was concatenated to form a 16-bit integer. The reason to concatenate the two 8-bit values was the fact that the programming done for the application would send a value either between 1000-1180 or 2000-2180. These numbers could not be represented in a single byte which goes from 0-255 decimal. A 2-byte value can go from 0 to 65535 as shown in figure 76:

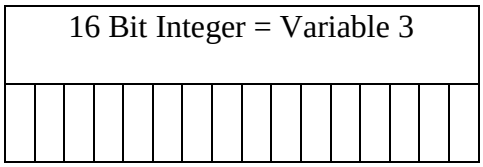


FIGURE 76: CONCATENATED TWO 8-BITS TO 16-BITS INTEGER

If the sent value is between 1000 and 1180, it is being mapped to 0 and 180 using the following the command line:

$$map(variable\ 3, 1000, 1180, 0, 180)$$

The mapped values were written into the Servos positioning to rotate them to fixed position in the automatic movement of the transducer.

Emergency Solenoid Valve

The emergency solenoid valve was present to be activated or opened by the user in case the pressure increases to very high value which might be painful to the subject who is being tested. The solenoid valve operating at 2.5V switching voltage was connected to the digital pin 15 or analogue pin A1 which was set to the digital mode.

The switch controlling the valve was connected to a button interrupt. Arduino Nano pin 2 and 3 are the interrupt pins. Attaching the interrupt would make these pins to change state based on the condition being provided. For instance, if the button is pressed and the command has been set to activate the corresponding function when the rising edge, falling edge or the change in the edge is being detected, only then the function associated will be executed.

The program has been developed in such a way, when the button is pressed once, the rising edge of the button is checked and the interrupt method for the solenoid is entered. The state is changed for the solenoid valve and the interrupt is ended. The state detects if the valve is HIGH (ON) or LOW (OFF).

5.4.4. *Ultrasound and Pressure Sensor Connection to DAQ*

The ultrasound output was generated from a wire soldered to the speaker as shown in figure 77. The output characteristics were between 20Hz – 8kHz, ±1V. It was connected to the analogue Port A0 of the NI DAQ.

The pressure sensor output was directly from the PCB. The instrumentation amplification circuit designed amplified the signal to the range between 0-5V. The connection was done with the analogue Port A1 of the DAQ.

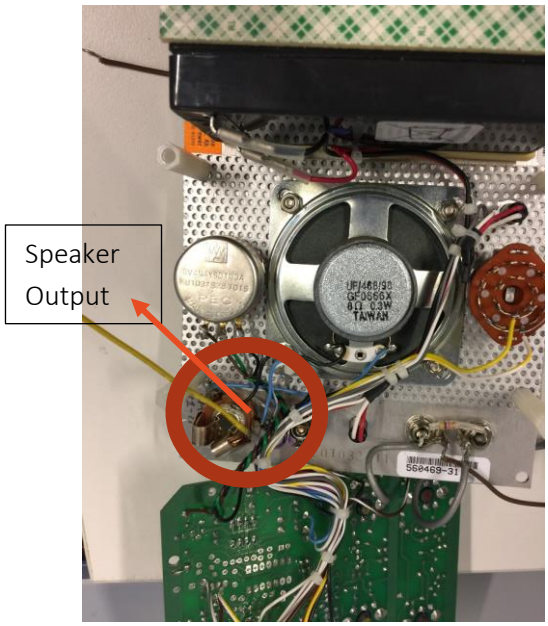


FIGURE 77: OUTPUT FROM ULTRASOUND BLOOD FLOW MONITOR

6. POST PROCESSING AND RESULTS

6.1. OBJECTIVES

The device construction was to collect data from people using the ultrasound and pressure sensor and to process the signal to obtain a relationship between the Doppler changes in the signal where the diastolic and the systolic pressure occurred. To collect the data, a proper test procedure had to be developed. This chapter discusses the testing done and the results collected. It also discusses the signal processing which has been conducted to overlap the pressure signal with the ultrasound spectrogram and generate the results.

Initially it was expected to do the testing and collection of data from a wide range of people including hypertensive, hypotensive and healthy groups. But as the project proceeded, the time constraint played an important factor which needed the reassessment of the data collection criteria. It was further required to develop proper testing protocol, so the data can be collected. The results obtained in the post processing in MATLAB could not be completely verified. The verification needed larger set of data from various people. It also required development of proper algorithm to look through the ultrasound data. The current results focus on viewing how the ultrasound signals behaves when pressure is being applied on wrist.

6.2. TESTING PROTOCOL

Study Design

The objective of this research is the collection of data from the ultrasound Doppler Blood flow meter to undertake signal processing spectrogram analysis. A randomised study was used to obtain the data for the hypothesis testing which followed that the application of the pressure on the radial artery would provide change in the Doppler frequencies which would facilitate the detection of the occurrence if the systolic and diastolic pressures.

Study Population

The study population would include volunteers of different age groups ranging from 21 years old to 55 years old working at Redarc Electronics. The size of the population was selected to be n = 20, males and females, with various health condition including hypertension and hypotension. Previous studies [56], [111], [70] have conducted similar trials using a small sample size between 15-40 subjects to test the effect of ultrasound Doppler change on the blood velocity. Further, the sample size has been kept smaller for this initial study design to obtain proper results so that improvements to the device can be made for proper clinical trials in future.

Exclusion Criteria

The study to acquire blood pressure signals was conducted on people based on their consent to participate. There were no significant exclusion criteria at this stage as consideration to various blood pressure levels and responses of the signals was to be gathered.

Method

1. Participation of the volunteers was asked based on different genders and age requirements for data collection. After candidates expressed interest, the procedure was explained to obtain their consent.
2. Once the required number of the volunteers (based on the sample size) was obtained, each volunteer was provided with a specific time to come for the testing.
3. Prior to the gathering of the signals, the age of the participant and any clinical complications experienced which could affect their normal blood pressure levels was asked for.
4. Standard digital wrist wearable blood monitors and upper arm blood pressure monitors by Omron Electronics was used to record the standard levels of the blood pressure.
5. The pulse on the radial region of the left wrist was obtained and the ultrasound gel was applied. The ultrasound transducer fixed in the housing was strapped around the wrist.
6. Turning on the Doppler Flow Meter provided the blood pressure signals. Any minor adjustments were made for the blood flow signal to appear clear.

7. The program written in LabVIEW was started so the National Instruments Data Acquisition Unit could start the collection of the ultrasound data from the Doppler flow meter and the pressure sensor reading the pressure applied on the wrist through the embedded bladder in the transducer housing.
8. The pump controlled by the Arduino microcontroller started increasing the pressure inside the bladder leading to the compression of the wrist by the transducer.
9. In the first run, no data collection was done but the signals were observed to see if the collection was accurate without the presence of any motion artefacts or inaccurate level of pressure being applied on the wrist.
10. As the pressure value reached above 250 mmHg (assuming higher than the actual systolic pressure), the pump was turned off and the pressure valve was opened so the pressure started to edge off slowly.
11. The pressure where the blood flow signals commenced would provide the systolic pressure as monitored by the gauge in the software in figure 78.

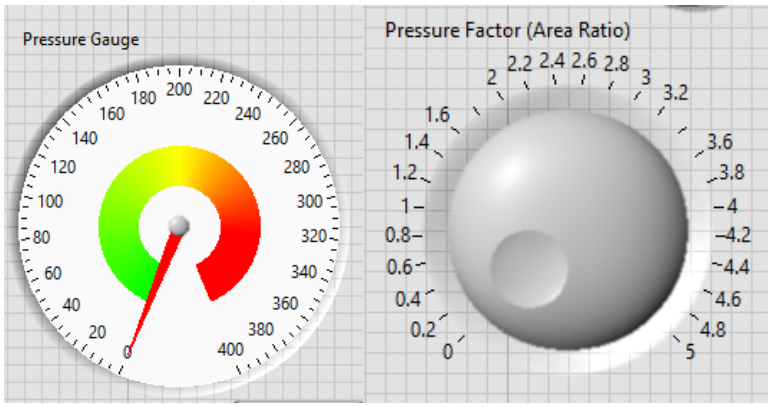


FIGURE 78: PRESSURE GAUGE AND CONTROL KNOB FOR CALIBRATING THE PRESSURE APPLIED ON THE WRIST BASED ON THE SURFACE AREAS OF CONTACT ON WRIST AND PRESSURE IN THE BLADDER

12. If the pressure values corresponded to the actual systolic value obtained from the digital blood pressure monitor, then the proper data collection was commenced. Otherwise the coefficients which control the pressure to pressure ratio due to different area of contact between the bladder and the transducer housing was adjusted to obtain accurate results.
13. After the adjustments were done, the actual data collection was commenced. The pressure value was increased to 250 mmHg and slowly bled off over time. The data was obtained through the DAQ and saved into the excel spreadsheet.
14. The collection of the data was continued until the pressure reduces to 0 mmHg.

15. The procedure was repeated 3 times to reduce the margin of error.

6.3. PRELIMINARY DATA

Initially the data collection was done with the objective of viewing the signals in the time domain. The signals were observed on an oscilloscope. Since the oscilloscope has a low storage memory for data, the signal obtained is shown below along with the processing done on the signal to obtain the spectrogram results as shown in figure 79.

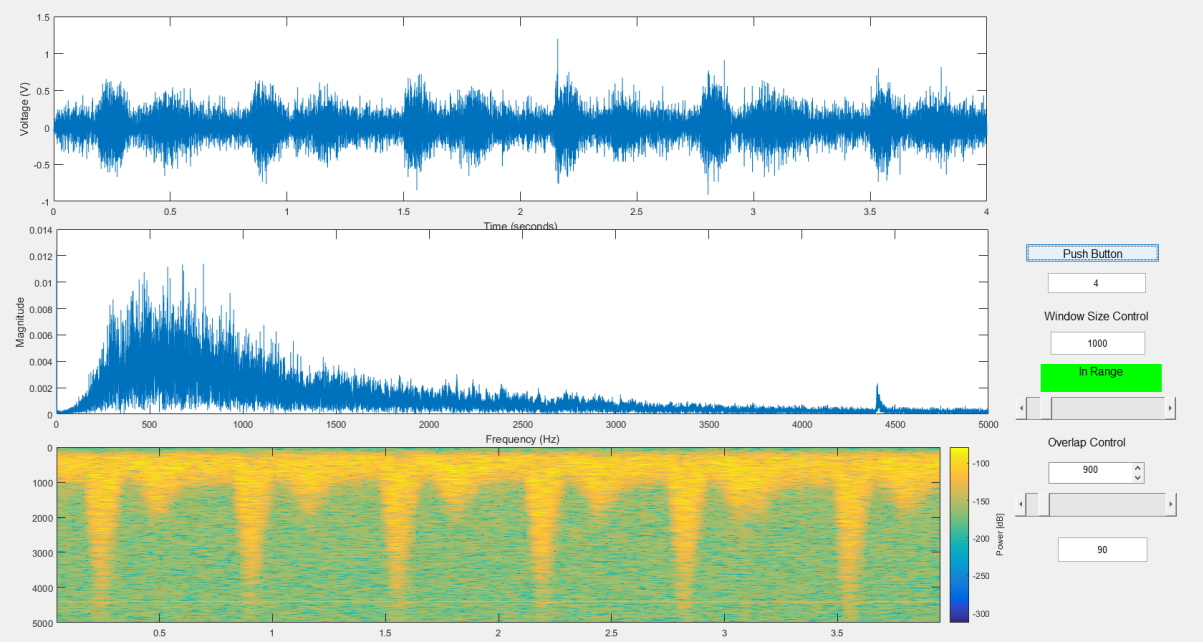


FIGURE 79: SPECTROGRAM SIGNAL WHEN NO PRESSURE APPLIED ON THE WRIST

The first graph shows the actual voltage versus time signal obtained. The high peaks can be seen when the Doppler change in the frequency is maximum and a 'whooshing' sound is heard from the speakers of the ultrasound. The second section of the graph shows the FFT of the overall signal. A constant noise was present from the speaker. The noise frequency is observed over the constant length of the signal. High magnitude components are seen around 300-1000 Hz. These components are due to the Doppler change in frequencies. Finally, the third section shows the spectrogram which was created to analyse the signal. A spectrogram is an overlap of frequency domain and the time domain signal. It shows the power density of different frequencies present at an instantaneous time.

In the spectrogram, different window size and signal overlap were tried. At an overlap of 90% of the signal which means, 90% of the data seen in the first sample is used in the second sample. A clear view of the spectrogram is observed. The high frequency values go up to 5kHz as the sampling frequency was set as 10kS/s. The Graphic User Interface developed in MATLAB, helped in analysing the varied sizes of the window and overlapping. Appendix H section 4 shows the output at different overlapping sizes.

When there was a flow of the blood heard from the ultrasound Doppler flow meter speakers, the high frequency components showed in the spectrogram shown in figure 80. During the time between which the blood flows, there were no high frequency components but a low frequency peak which was the due to the wave travel which occurs before the actual blood flows through the artery [112].

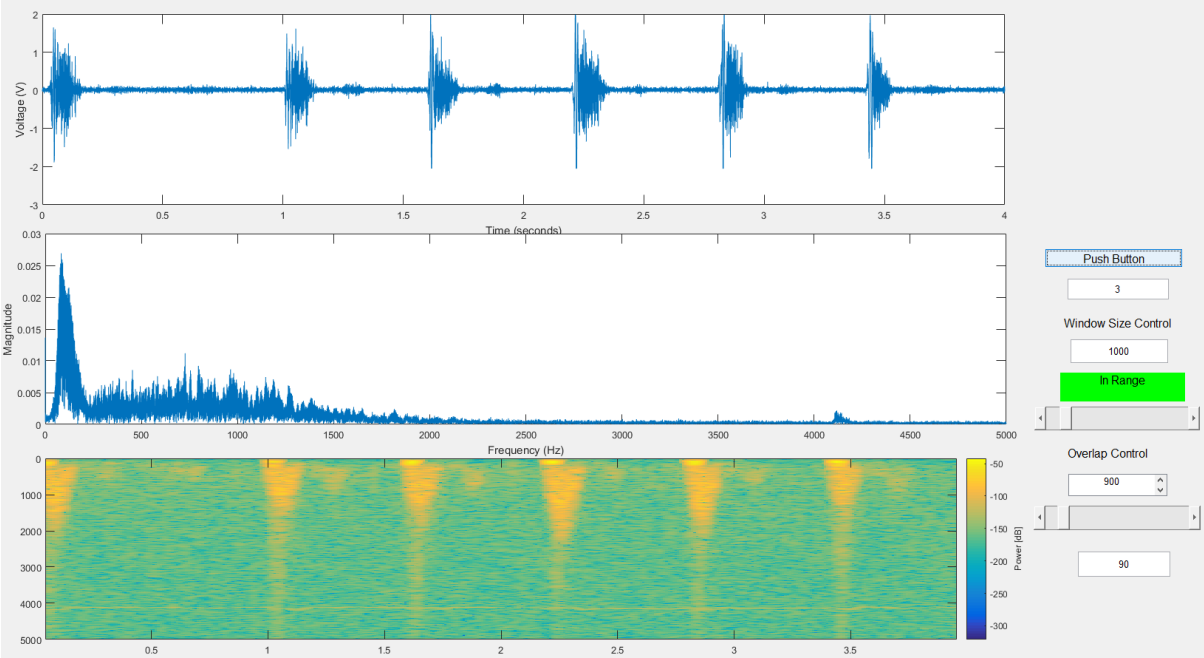


FIGURE 80: SPECTROGRAM SIGNAL WHEN INTERMEDIATE PRESSURE WAS APPLIED

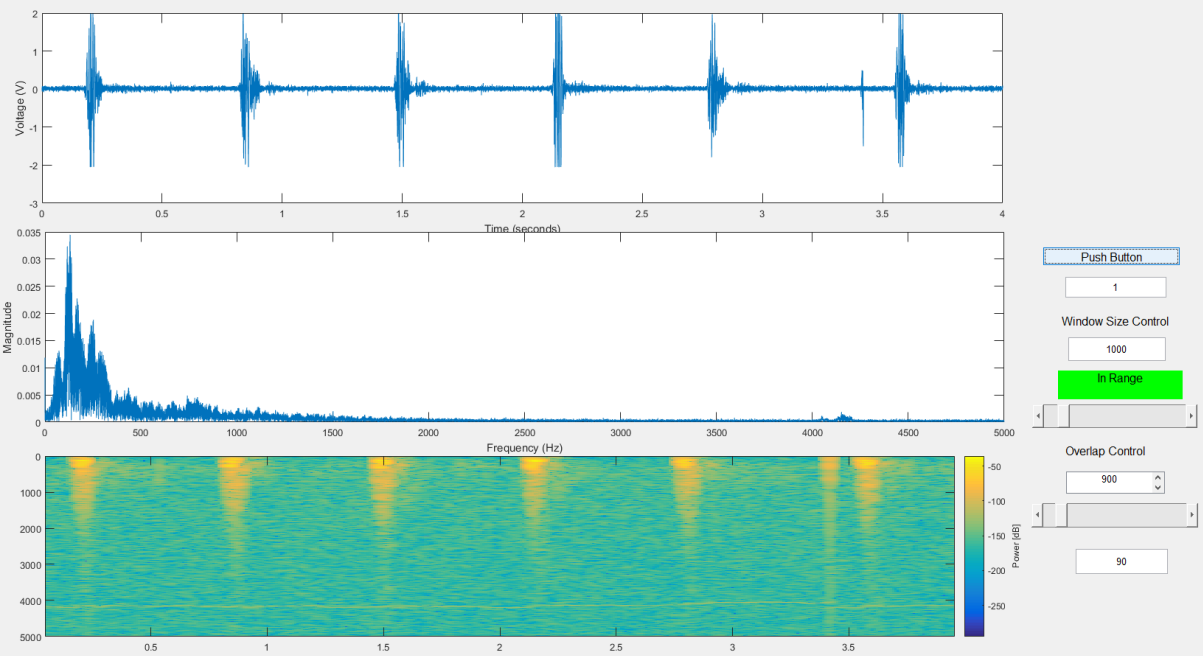


FIGURE 81: SPECTROGRAM SIGNAL WHEN PRESSURE JUST BELOW THE SYSTOLIC PRESSURE WAS APPLIED

As the pressure increased, there was a decrease in the high frequency components as shown in figure 81. A correlation can be seen at the point where systolic pressure is being taken, the blood flow is hindered due to the complete occlusion of the artery. It is expected that at the point of systolic pressure, no significant blood flow would be measured, the spectrogram would show peaks observed due to the turbulent flow. The blood would be forcing its way out through the small orifice of the artery.

6.4. DATA COLLECTION

6.4.1. PHYSICAL MEASUREMENT OF PRESSURE

In the next phase, after observing the differences in the preliminary data and what can be studied from those data, the actual data acquisition system was being used to collect ultrasound data along with the pressure data simultaneously. This would help in observing the behaviour of ultrasound with the increase or reduction of pressure.

In this case, the pressure reduction has been used as the pressure from the leak valve was being slowly released and the ultrasound data was seen. As stated in the section 6.2 under testing protocols, the actual blood pressure measurement was taken from existing two different digital blood pressure monitors. This was overlapped in the pressure signal to mark the points of systolic and diastolic points. The ultrasound signal behaviour change was observed around these points.

Due to time constraints the readings were taken from 3 volunteers and the signal processing was done. The table 24 below shows the parameters and the readings obtained from the 3 volunteers using two different digital blood pressure devices. Other parameters such as existence of any medical condition was asked as well.

A considerable variance was observed in the blood pressure measured from the wrist and the upper arm which is shown in table 25.

The data collected from the patients using the Omron Upper arm BP monitor and the wrist wearable BP monitor. 3 sets of values were collected from each device and the values were averaged out. Parameters such as medical conditions including hypertension, hypotension and any cardiovascular or renal conditions were also considered.

Vol	Volunteer's Name	Age	Weight		Omron Wrist BP			Omron Upper Arm BP			Hypertension	Hypotension	Medical Condition		Other Conditions	Comments
			(kg)		Systolic (mmHg)	Diastolic (mmHg)	Heart Rate	Systolic (mmHg)	Diastolic (mmHg)	Heart Rate	(Y/N)	(Y/N)	Cardiovascular	Renal		
1	Volunteer 1	23	84		123	79	61	110	81	59	N	N	Bradycardia	N	N	
					122	81	59	123	79	58						
					129	82	64	123	80	57						
				Average	125	81	61	119	80	58						
2	Volunteer 2	22	86		104	53	57	111	67	61	N	N	N	N	N	
					113	63	60	116	60	57						
					102	64	60	114	69	59						
				Average	106	60	59	114	65	59						
3	Volunteer 3	21	115		143	99	68	121	76	75	N	N	N	N	N	Physical exercise prior to test; placement of the device took longer time
					139	92	72	112	63	66						
					144	93	63	111	61	68						
				Average	142	95	68	115	67	70						

TABLE 24: MEASURED BLOOD PRESSURE FROM DIFFERENT VOLUNTEERS USING UPPER ARM AND WRIST WEARABLE BP MONITORS

Vol	SBP-W (mm Hg)	SBP-A (mm Hg)	Diff (mm Hg)	%Diff	DBP-W (mm Hg)	DBP-A (mm Hg)	Diff (mm Hg)	% Diff
1	125	119	6	4.8	81	80	1	1.234567901
2	106	114	-8	-7.547169811	60	65	-5	-8.333333333
3	142	115	27	19.01408451	95	67	28	29.47368421

TABLE 25: SBP AND DBP SUMMARY (DIFFERENCES AND % VARIANCE) BETWEEN UPPER ARM (A) AND WRIST (W)

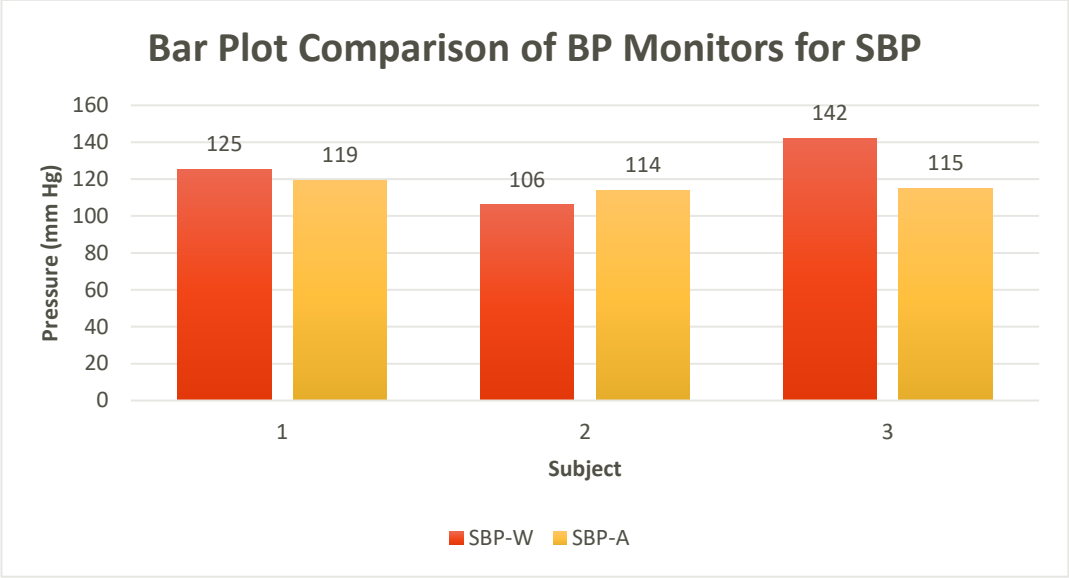


FIGURE 82: HISTOGRAM DISPLAYING SBP DIFFERENCES MEASURED FROM WRIST AND CUFF

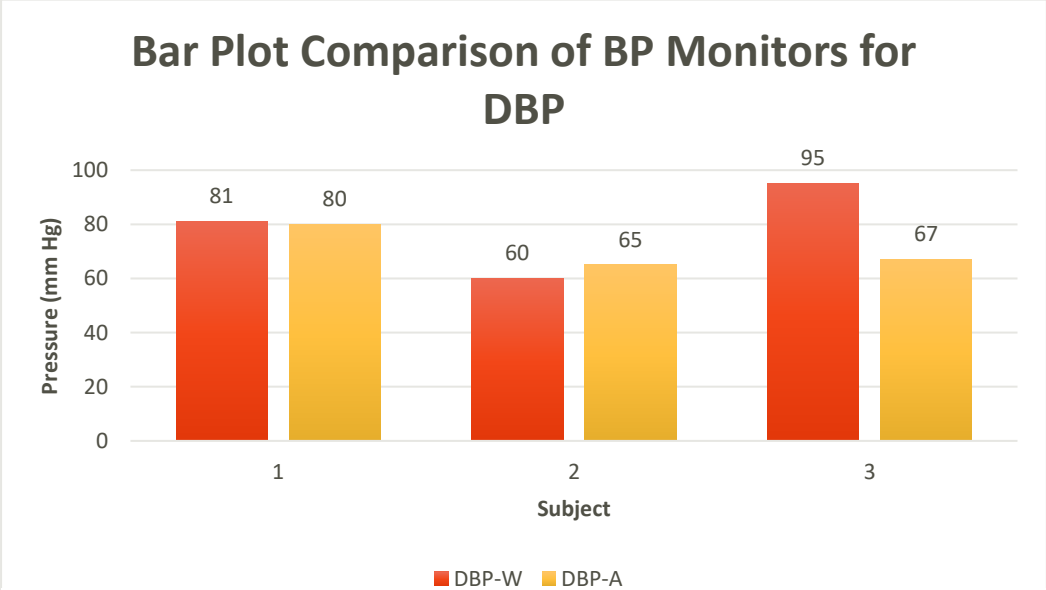


FIGURE 83: HISTOGRAM DISPLAYING DBP DIFFERENCES MEASURED FROM WRIST AND CUFF

From the figure 82, where the SBP has been measured, significant differences exist between the one measured from the upper arm and one measured from the wrist. These can be attributed to the inaccuracy of the devices as discussed in the section 2.2. Furthermore, the location of measurement also plays a pivotal role as the pressure measured on the wrist which at a height difference from the heart. The pressure measured is higher than usual. The accuracy is also dependent on the pressure sensor being used. Omron uses different grades of pressure sensors with different accuracy levels.

The readings taken from the wrist for the systolic and diastolic were used as references. These reference points have been used to analyse the ultrasound behaviour around these points to observe any changes.

6.4.2. LABVIEW DATA COLLECTION

The LabVIEW data collected as per the program developed explained in the section 4.5, generated the ultrasound voltage output and the calibrated pressure data in mm Hg. The collection was done at 10,000 Hz, sampling frequency. The real-time data was observed using the front-end window which showed the ultrasound time domain signal, spectrogram signal and the pressure signal shown below in figure 84.

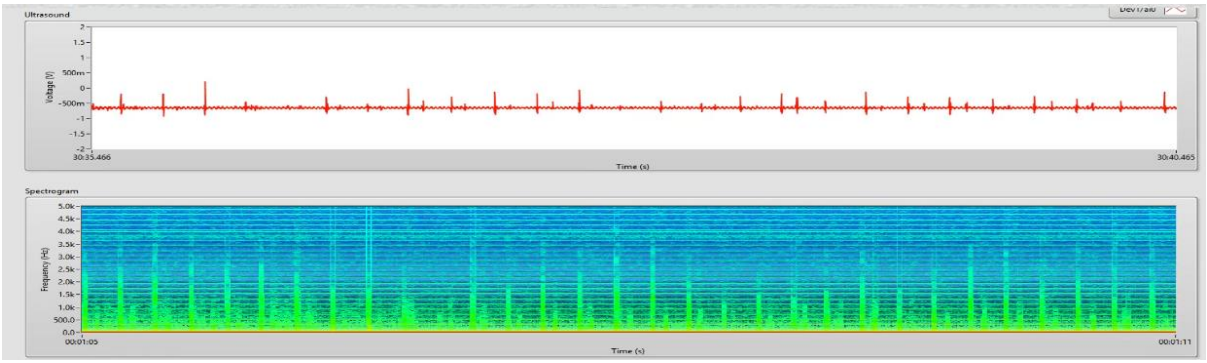


FIGURE 84: REAL-TIME ULTRASOUND TIME DOMAIN SIGNAL AND SPECTROGRAM

The data being collected was stored in a text file to be read in MATLAB for further signal processing.

Example of obtained signal from the LabVIEW in figure 85 shown below:

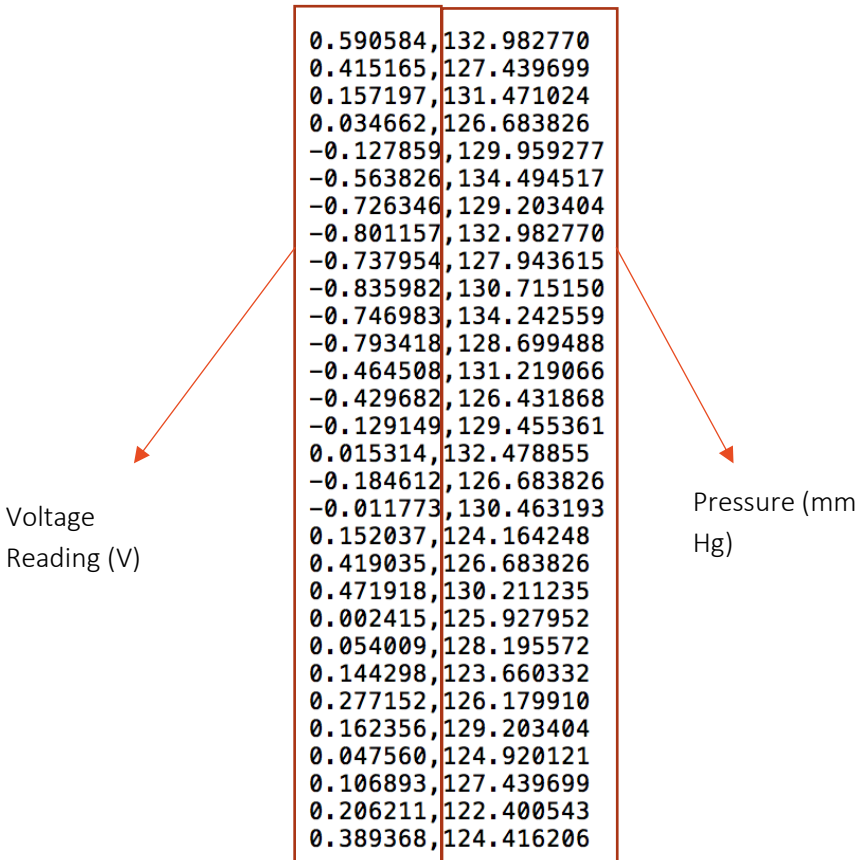


FIGURE 85: EXAMPLE READING OF DATA COLLECTED FROM LABVIEW

6.5. MATLAB DATA PROCESSING

The MATLAB code was written (shown in Appendix H) to read the data from the text file, plot the pressure signal and the ultrasound spectrogram signal. Initially the objective was to observe how the ultrasound frequency changes as the pressure is reduced. The output generated is shown below:

The overlapped pressure signal with the spectrogram can be observed. High noise can be seen in the pressure sensor value seen in figure 86 with pressure signal being shown in black. This noise is due to the signal being collected simultaneously with the ultrasound device. The ultrasound device had a base noise produced by the speaker. It was required to filter the pressure sensor signal to achieve a clean signal.

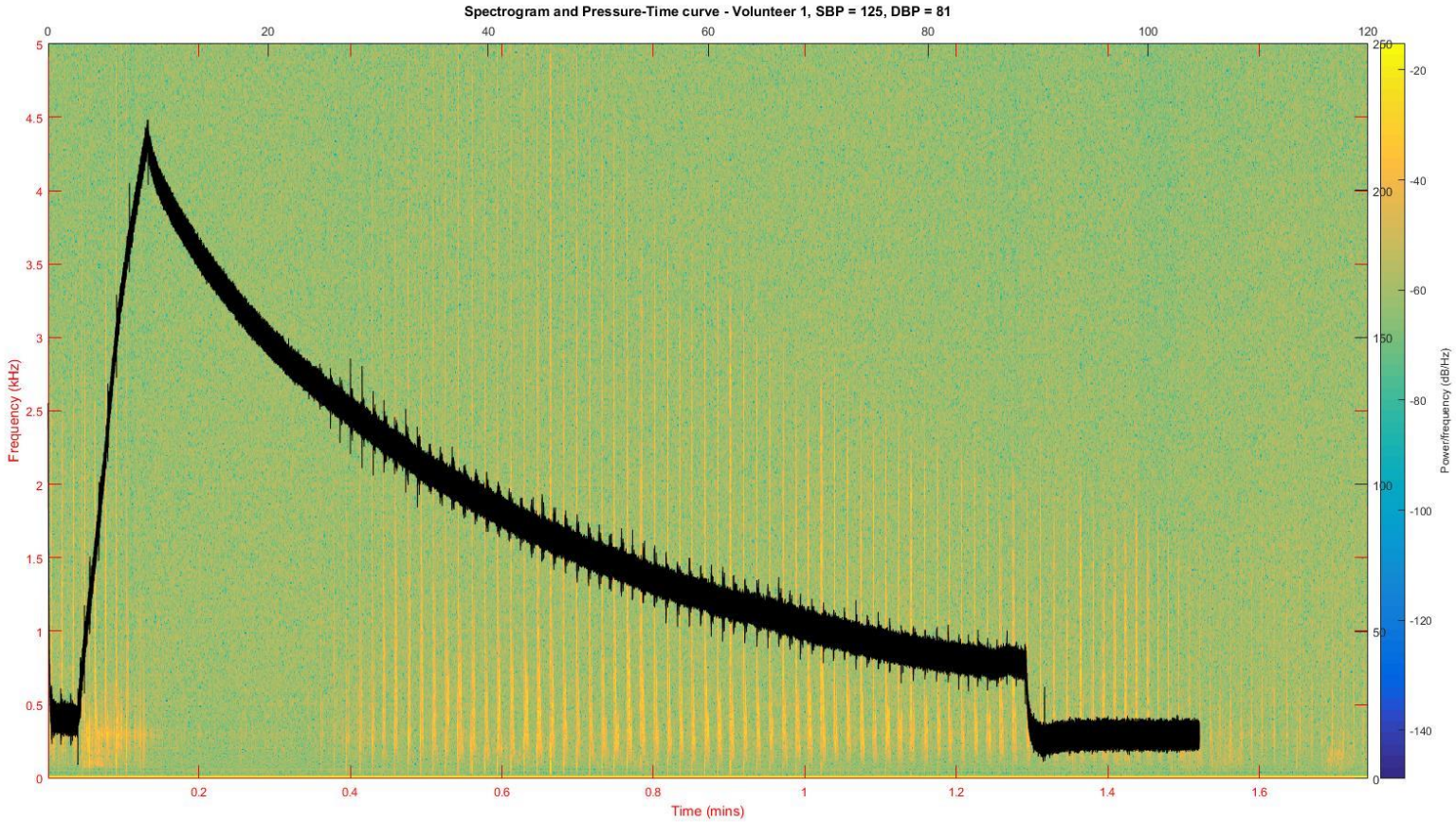


FIGURE 86: OVERLAPPED PRESSURE CURVE OVER SPECTROGRAM

6.5.1. FILTERING PRESSURE SENSOR DATA

The pressure signal as discussed required filtering. Before the filtering could be done, the cut-off frequency of the filter was required to be detected. The objective here was to obtain a clean pressure signal which could be used for comparison by plotting the SBP and DBP obtained from the oscillometric devices.

The signal FFT in figure 88 shows spikes at frequency 50Hz, 1.821kHz, 2.273kHz, 3.463kHz and 4.093kHz. The high frequency components do not correspond to the pressure signal data but the noise from the ultrasound and the pump vibration. These data were checked by using FIR filter around the peaks. The filtered pressure signal shows the noise components rather than the actual pressure data.

A high order lowpass FIR filter was developed with a cut-off frequency at 10 Hz. This would filter out all the high frequency noises from the ultrasound and the vibration created because of the pump. The filter frequency response is shown in figure 87. It is a 500th order low pass FIR filter. The reason for using such a high order value was that it was being required to obtain a smooth curve of the pressure signal, removing noise. At this stage, the objective was to obtain ultrasound and pressure data and to check if the blood pressure obtained here would show any relationship with that obtained using the existing blood pressure monitors. The final filtered signal is being shown in figure 89. The order was not necessary, a low value could have been chosen which would still consist of some noise embedded into it. A moving average filter would have helped as well in obtaining a smooth signal.

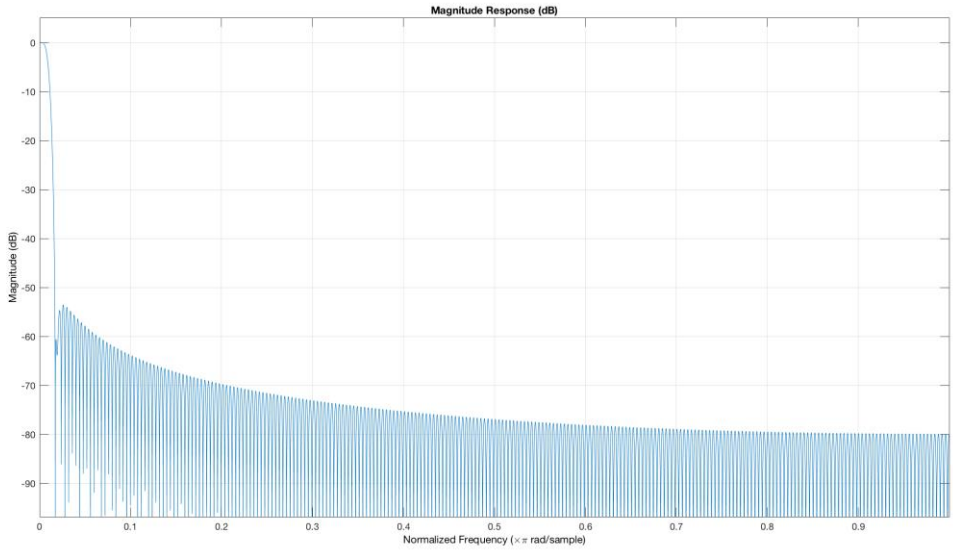


FIGURE 87: LOW PASS FIR FILTER 500TH ORDER CUT-OFF FREQUENCY = 10HZ

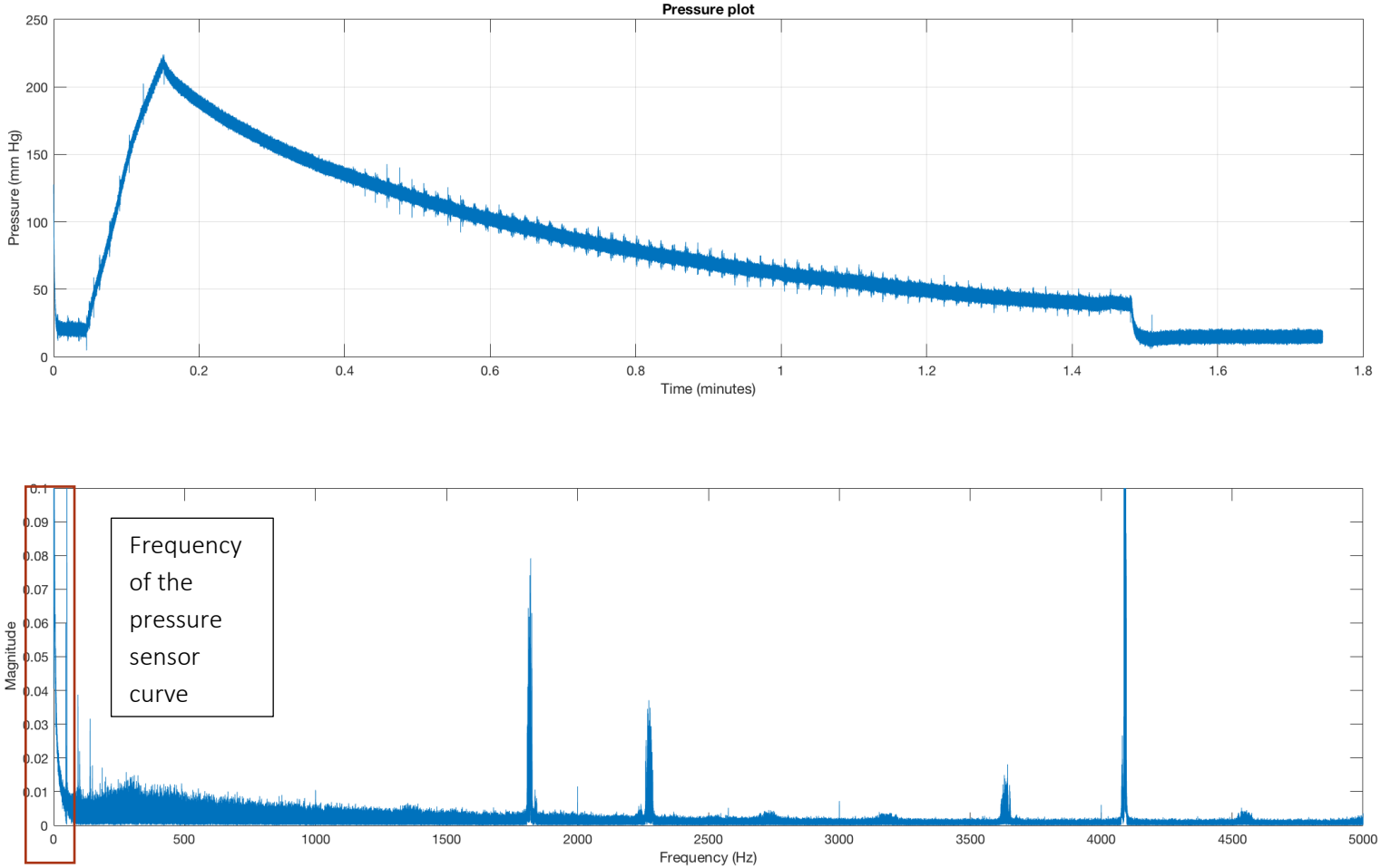


FIGURE 88: PRESSURE SIGNAL: TIME DOMAIN AND FFT

The filtered-out pressure signal is shown below:

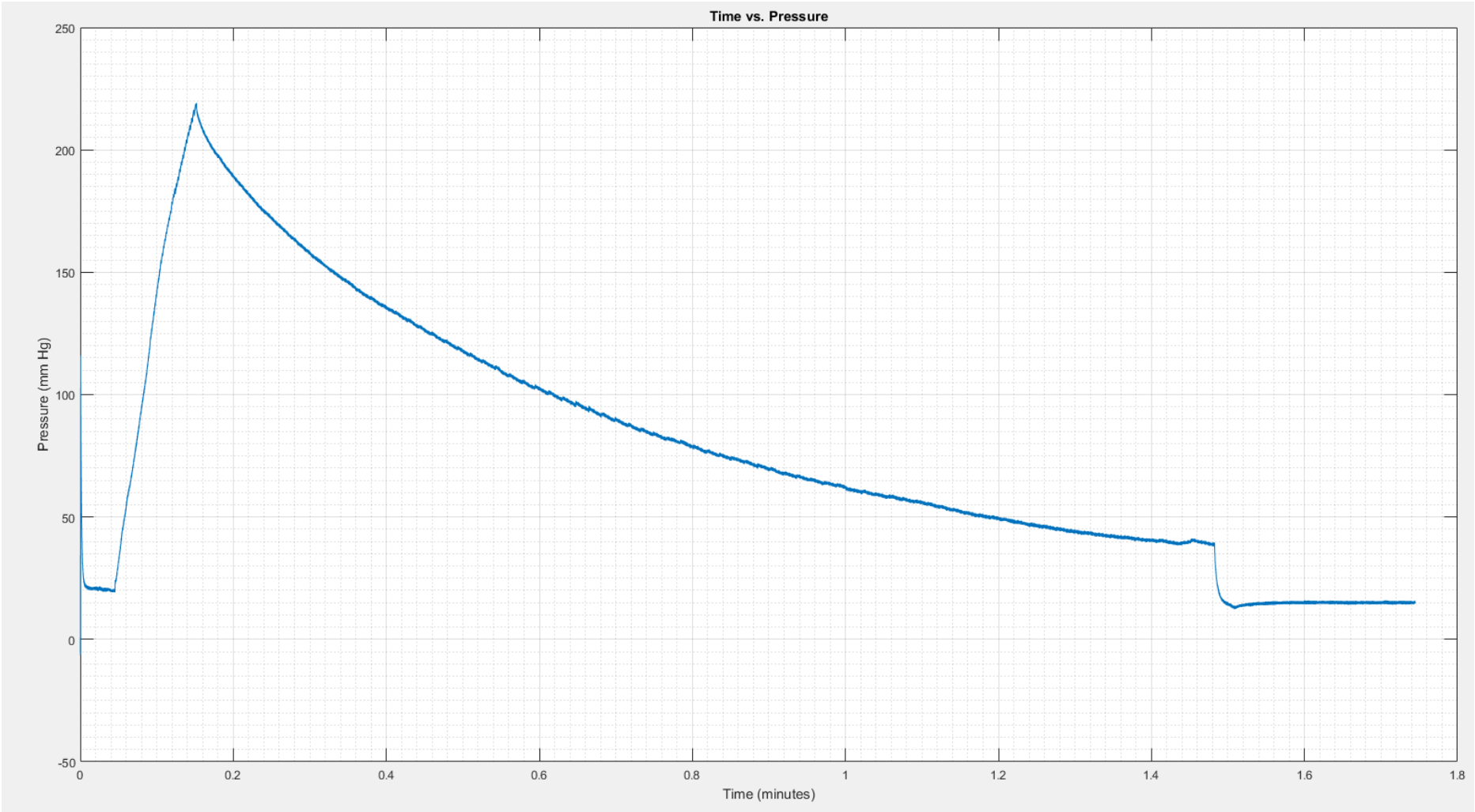


FIGURE 89: FILTERED PRESSURE SIGNAL

6.5.2. *ULTRASOUND SIGNAL*

The MATLAB code has been written has been divided into various sections. The flow diagram below in figure 90 explains the various sections in the programming which was involved.

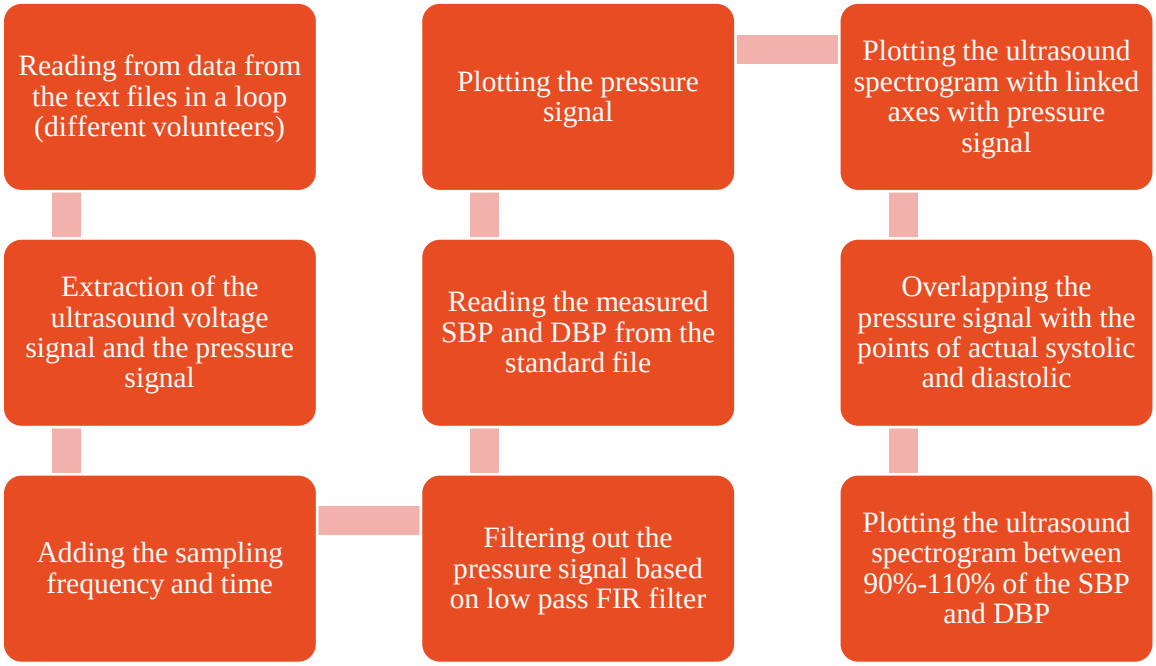


FIGURE 90: MATLAB PROGRAMMING

It was expected to read the pressure and voltage data from the text file generated by the LabVIEW. The program was written to generate the results for all the data obtained over different volunteers. It was also expected to overlap the points of the measured SBP and DBP with the actual pressure signal. This would help in correlating with the corresponding ultrasound signal.

In order to observe the changes in the ultrasound signal, the region around the SBP mark and the DBP mark were analysed. The spectrogram was plotted around this region.

The results obtained from the volunteers has been shown on the next 3 pages in figure 91-93.

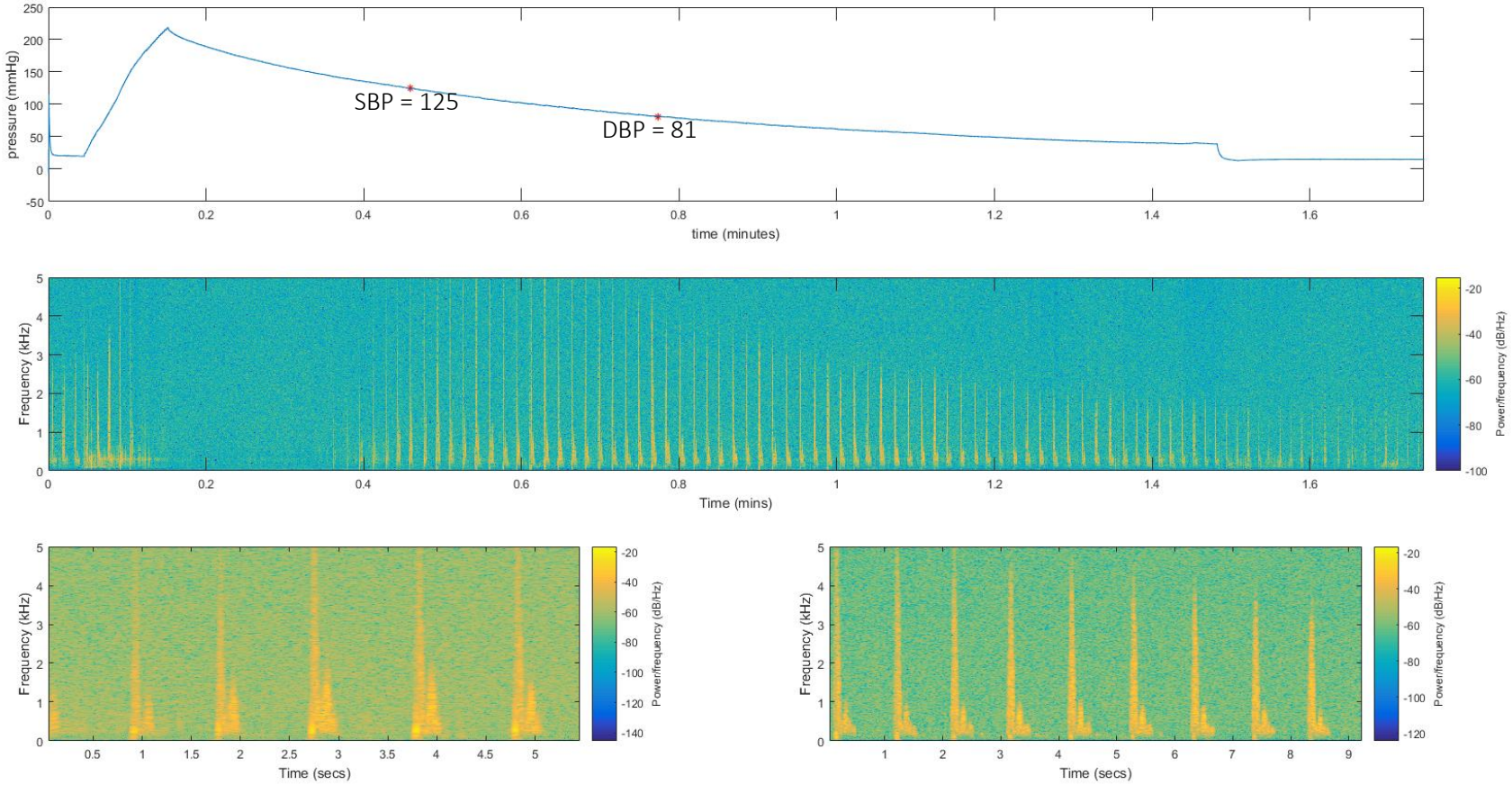


FIGURE 91: VOLUNTEER 1 RESULTS

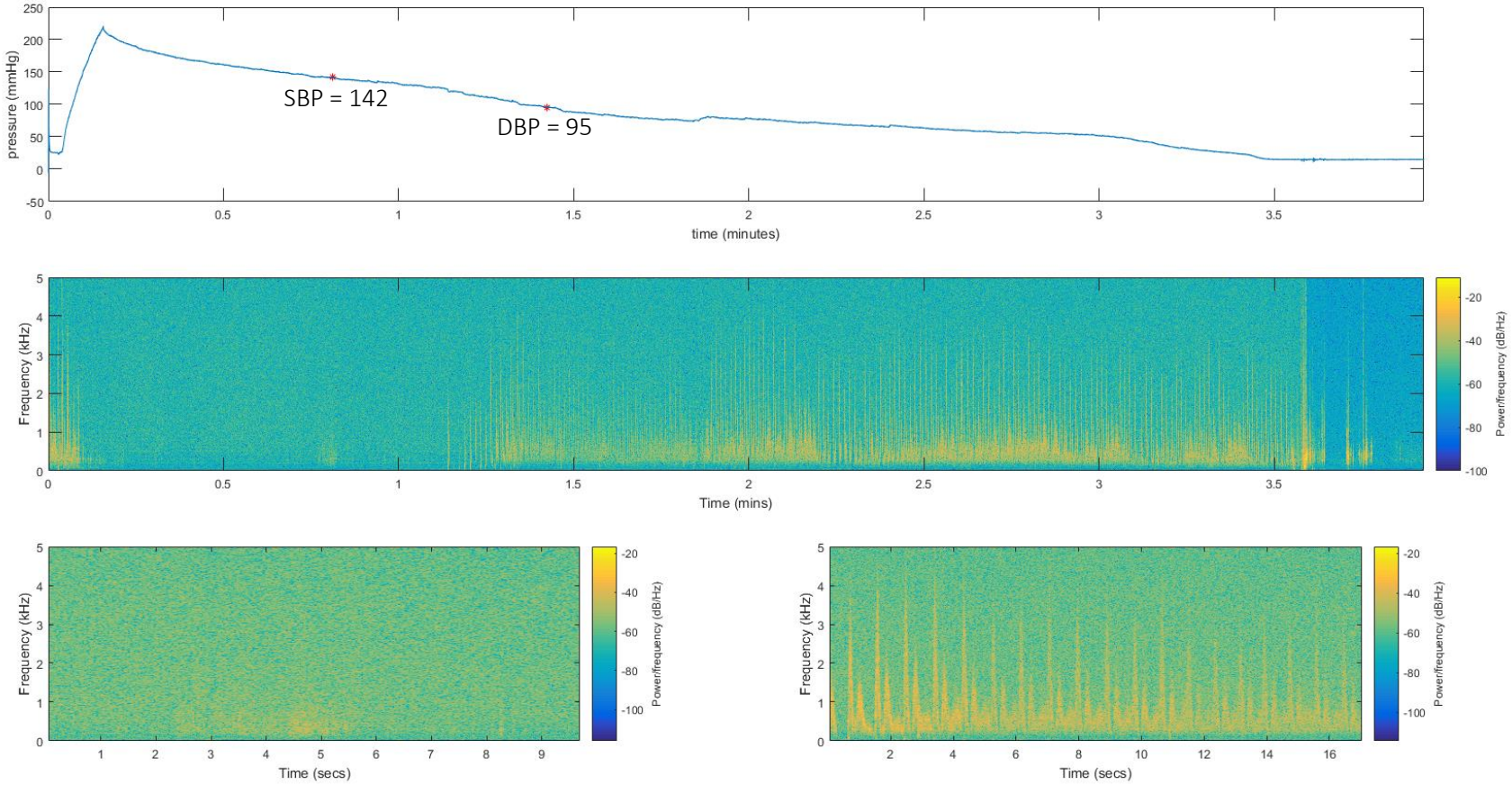


FIGURE 92: VOLUNTEER 2 RESULTS

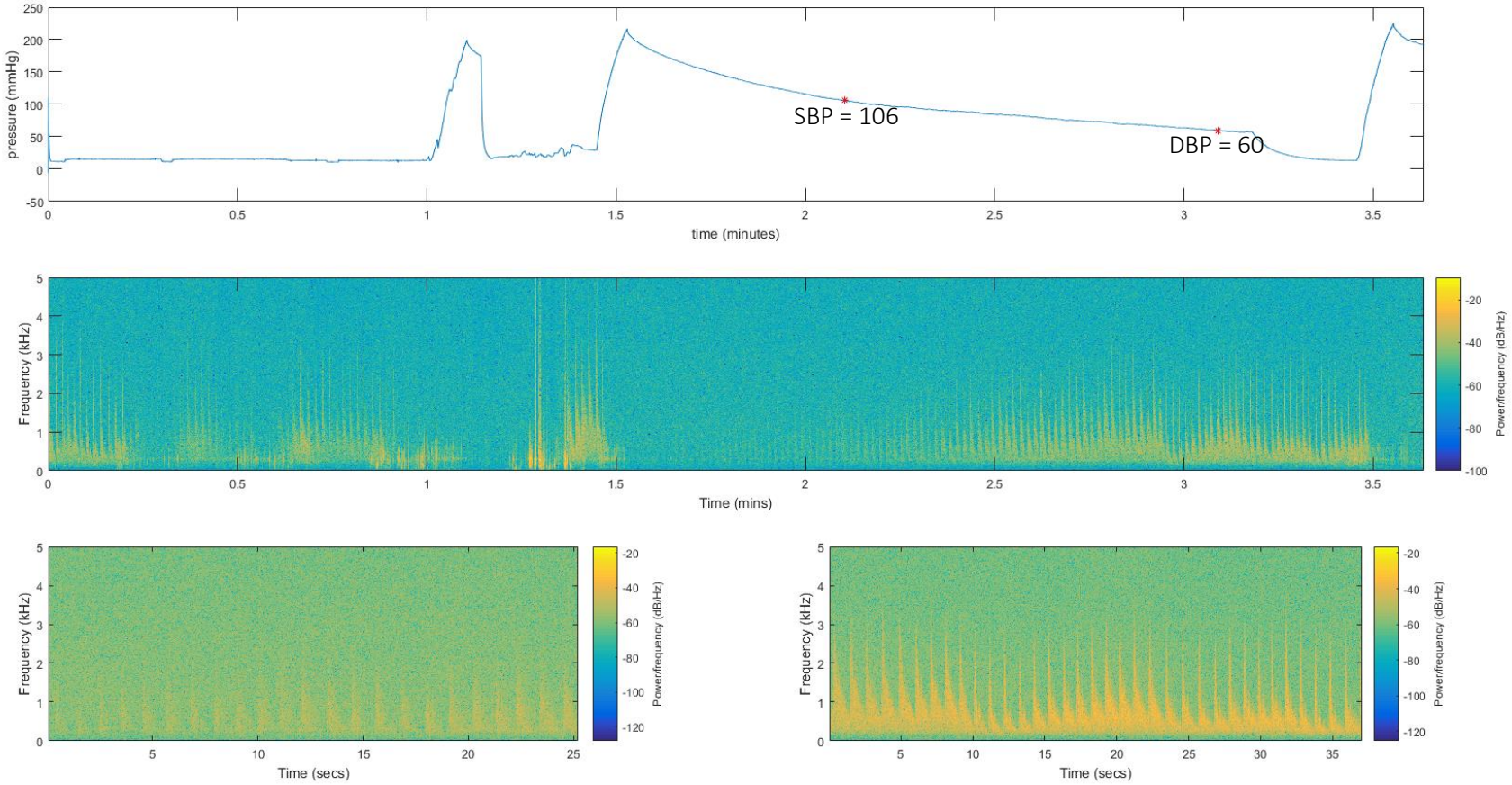


FIGURE 93: VOLUNTEER 3 RESULTS

7. DISCUSSION

The results obtained in section 6.5.2 from the ultrasound signal shows some correlation between the occurrence of the SBP and DBP. Seeing the signal in figure 94 from volunteer 1, the spectrogram shows when the pressure is very high, no blood flow occurs through the artery due to complete occlusion. When the pressure is slowly released as seen in the decrease in the pressure curve, the high frequency components start appearing.

The recorded SBP for volunteer 1 from the wrist wearable blood pressure monitor was 125 mmHg while seen from the ultrasound Doppler signal change. When the pressure was released, the flow of blood overcoming the occlusion started to occur at 143.5 mmHg.

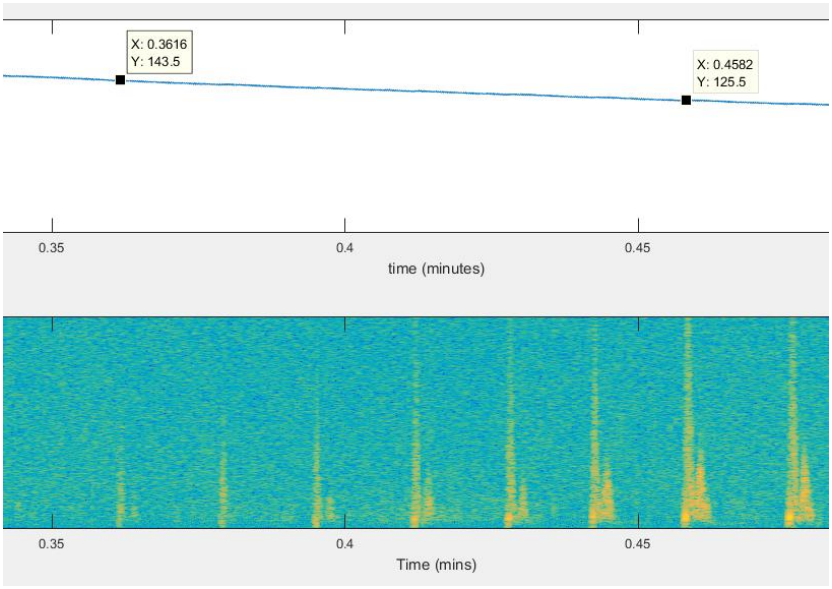


FIGURE 94: ULTRASOUND SIGNAL PREDICTED SBP AND MEASURED SBP

According to the literature, [8], [9] and [10] have stated significant errors observed when recording the SBP and DBP using digital BP monitors. In the diastolic region, a pattern was expected; the expectation was, as the pressure is significantly reduced and reached the DBP, there would not be any change in the Doppler shift frequencies magnitudes. The height of the high frequency components seen in the spectrogram would become constant. A constant magnitude spectrum of frequencies would be present as the flow of the blood becomes laminar. A pattern was observed in the figure 95. The actual recorded DBP was at 81 mmHg. But based

on what was hypothesised previously, as the region of DBP was crossed, the high frequency components started to reduce in the magnitude. The DBP from the ultrasound signal is predicted to be approximately 85 mmHg which was based on where the high frequency components start decreasing from the maximum value.

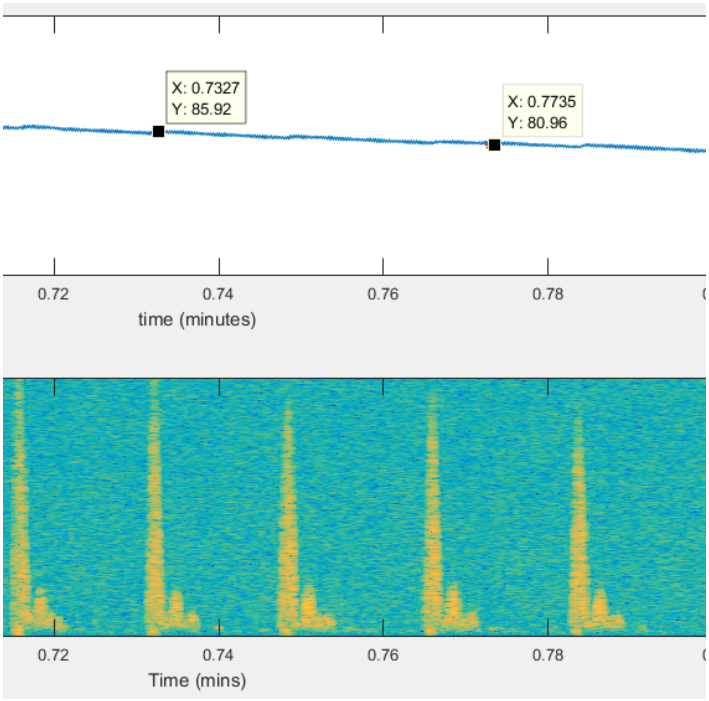


FIGURE 95: ULTRASOUND SIGNAL PREDICTED DBP AND MEASURED DBP

Further analysing if the pattern exists in the volunteer 2 and 3, the following results were obtained tabulated below:

Vol	Measured SBP	Calculated SBP	Pattern/ Comments	Measured DPB	Calculated DBP	Pattern/ Comments
2	142	120	Significant difference from the measured, SBP US signal occurs at lower pressure then measured	95	102	Similar to the change observed in volunteer 1, decrease in the height of high frequency components
3	106	127	A faint signal existed when the pressure was at the maximum	60	69	Not as meaningful change in the high frequency as observed in volunteer 1

TABLE 26: RESULT TABLE FOR MEASURED AND CALCULATED SBP AND DBP FROM SPECTROGRAM FOR VOLUNTEERS

The table 26, showed the differences in the SBP and DBP obtained from the device. It was required to conduct further processing over a larger mass to obtained better results.

The SBP can be accurately predicted. When the pulsatile pressure is enough to overcome occlusion pressure of the cuff, the blood starts to flow. This is shown as the changes in the high frequencies in the spectrogram compared to no presence of high frequency components when no blood is flowing. But the measurement of the diastolic being done is still under study which has been estimated with the data. With the progression of time and release of pressure, the magnitude of higher frequency increases to a certain point and then decreases. This also did not support the hypothesis where it was expected that once the DBP is attained, the magnitude of the high frequency components would become constant. This requires further signal processing and investigation which would include measuring the ultrasound data obtained in time domain as shown in figure 80 and 81. The time constraints has led to limitations in the design and analysis. Few of the limitations and sources of errors which impacted the results obtained are discussed below.

Limitations in Results:

There were expected sources of errors in the experimental design:

1. The calibration of the pressure sensor is crucial. It was calibrated using a manual pressure gauge. Further the pressure was applied on the wrist using a 3D printed part as shown in section 5.2.1. But the pressure was recorded from the bladder. The contact area between the bladder and the housing was calculated based on which the calibration was done in the LabVIEW program. This contact area may be affected by the change in stretching of the skin when compressed. A definitive way is required to be developed to keep the pressure application measurement to be exact.

2. The motion artefacts present added to the errors present in the signals. Any motion of the transducer would cause significant changes in the signals. This was not acceptable as it would cause error in the readings in blood pressure. This is clearly observable in the figure 93 where the subject initially moved the wrist, there were significant movement of the transducer on the wrist to find and adjust the transducer to an exact position.

3. The comparison of the pressure was done to that of the digital blood pressure monitors. The accuracy of the digital monitors was questionable due to significant variance obtained in the pressure measured using wrist wearable BP monitor and upper arm BP monitor.

4. Importantly, the relevance of the results can only be verified when tested among large group of people. Here the conclusion of the results had to be drawn using the results which were being obtained in the limited time available for the design, construction and analysis. The DBP obtained is not verified to be accurate and at the stage of processing of the results, a definite argument could not be made to support the findings. A definite result can be obtained in future where a proper, more accurate ultrasound unit can be constructed. This would help in developing proper algorithm directly from the ultrasound data.

The improvements which would make the system better in collection of the data has been discussed in the next chapter under future works.

8. FUTURE WORKS

8.1. DATA COLLECTION AND SIGNAL PROCESSING

A small sample size was used in the data collection to test the working of the device and observe the variation of the signals. The SBP and DBP can be detected using spectrogram analysis. But to verify the detection of the DBP and SBP accurately compared to the existing digital blood pressure monitor requires a larger sample size.

The previous standards set by the AHA have stated that the blood pressure measured using the digital oscillometric method can be ±5 mmHg but the current research expects a better result which can be estimated to be around ±1 mmHg of the target reading. A high sample size would be required of more than 100, if a better result is expected to be achieved. Higher sample size would also help in obtaining any correlation among different people have different levels of blood pressure.

But according to the previous studies in ultrasound, different sizes of samples have been used. A study by Whyte et al. [56] a sample size of 20 infants were used to do the study in detecting the trends occurring for SBP using the flow meter. While another study by Hernandez et al. [113] used a sample size of 13 children to study the arterial pressure using Doppler. A high sample size would be useful when proving the concept to be published and manufactured for the marketable use.

The signal processing which has been conducted uses a simple spectrogram analysis technique. Advanced signal processing analysing the Doppler signal to more accurately determine the location of the DBP would be required to be conducted. Technique of wavelets which was briefly explained in the literature review section 2.6.2 can be used to evaluate the analysis of the spectrogram signal. It would be required further to conduct in-depth signal analysis which would include obtaining the signals from larger number of people, viewing the changes in the time-domain signal and the frequencies of the signals and then to develop a proper algorithm which would determine the SBP and DBP from the ultrasound processed signals.

Furthermore, in future work, continuing from the data collection system developed, the time domain data can be used to see changes in the ultrasound signal in audio range or directly in

the ultrasound range. This can be then compared to the oscillometric fluctuation in the bladder. This would help in providing further details any correlation.

Further, the comparison of the ultrasound generated BP results can be done to invasive blood pressure readings as they would be highly accurate. Current comparison was done in the project with the non-invasive digital monitors for reducing the strong ethical influence, cost and time.

8.2. ELECTRONICS IMPROVEMENTS

The current acquisition system uses National Instruments DAQ system, an independent module for pressure sensor amplification and pump driver circuit. The control of the valves and LCD was done using the Arduino. It is expected in future an integration can be done for the PCB to control the entire system using a small circuit or chip.

The current ultrasound generation and reception is done using the Parks Medical Electronics Doppler Blood Flow Meter which produces an ultrasound with a central frequency of 9.5 MHz optimum for detecting the flow in vascular tissues. The device being manufactured in 1990s uses standard through hole components. With the advancements in current technology, the ultrasound can be controlled using a single chip or PCB designed with SMD components which would reduce the size and increase the accuracy of readings. The current device generates a background noise which can be eliminated in the construction of the new devices.

MATLAB and LabVIEW were used in the project to undertake the signal processing. Computers like Raspberry Pi can be designed to be used to undertake the signal processing. For instance, the *'scipy'* and *'matplotlib'* libraries in Raspberry Pi can generate spectrogram and undertake analysis in spectrogram. Further devices like FPGA (Field Programmable Gate Arrays) can be used to undertake signal processing such as wavelets if required in future.

This section shows the processing of the signal in the hardware. This was not a major part of the thesis, but the objective was to view how the signals would behave when it was filtered and rectified. The ultrasound signal obtained directly from the output of the speaker without any processing showed a fluctuation of the voltage from -1V to +1V. A full wave precision rectification circuit was built which would remove the negative voltages. The full description of the circuit design and analysis has been shown in the Appendix D section 4.

The rectified signal was filtered with a bandpass filter having a cut-off frequency between 200Hz and 1kHz. The purpose of this was to view the filtered signal which could be implemented in the hardware. When the pressure was released from a high pressure, the spikes in the signal was observed from this circuit. The SBP was inferred from there. The heart rate was inferred from the distance between the consecutive spikes. It was unable to detect the DBP.

This section is concerned more with the future works once the actual DBP has been verified over the range of people. Figure 96 shows the output of the processed signal using hardware.

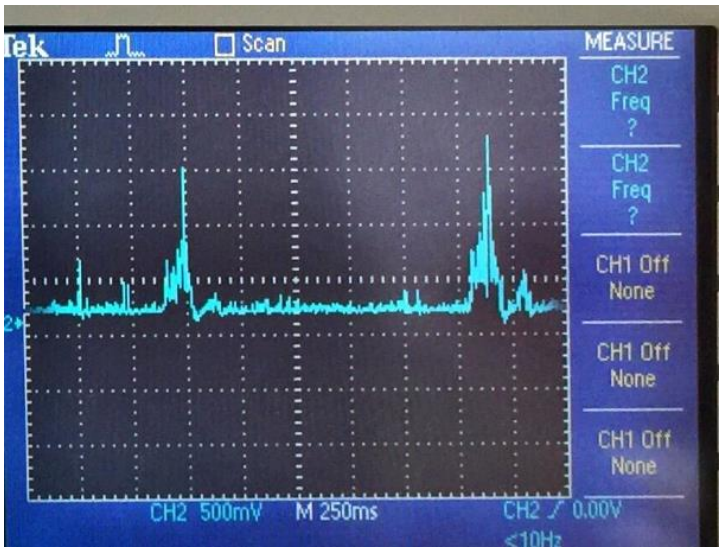


FIGURE 96: ELECTRONIC PROCESSED SIGNAL

8.3. MECHANICAL DESIGN

A simple mechanical design has been done to collect the data of the ultrasound from the wrist and apply pressure. It is expected that in future, a wrist wearable device is to be utilised. The device would be able to occlude the wrist with the bladder incorporated inside the wrist band. The custom sized bladder is required to be developed which would apply the pressure through the transducer on to the wrist rather than occluding the entire wrist itself.

The transducer used in the current ultrasound Doppler flow meter was a 9.5 MHz, infant piezoelectric transducer. It is expected to have an array of transducer sitting on the wrist. This would improve the accuracy of detection of the signal rather than positioning the transducer to first find the Doppler signal.

Future Vision

A vision as set by Redarc Electronics is to create a blood pressure monitor which would have the following features:

1. Use of Ultrasound: Revolutionise the measurement technique to directly interact with the flow of the blood to measure the pressure
2. Portable: A wrist wearable device to undertake continuous ambulatory monitoring
3. Accurate: Challenging the current levels of accuracy, a device highly accurate
4. Compact: Incorporate the ultrasound generation/reception, acquisition, processing of the signals within a single unit
5. Affordable: With all the advanced features, targeting a market where accuracy is pivotal i.e. in medical sector for proper diagnosis

An industrial based future works planning is shown in Appendix E as a SWOT analysis, which includes the various outcomes, strengths and weakness of the project. One key factor is the signal processing and obtaining values which would help to move forward into the testing phase where different people can be tested. This again goes back to development of proper algorithm predicting the diastolic pressure and minimising the errors and limitations.

9. CONCLUSION

The goal of the project was to undertake a proof of concept of measuring blood pressure using ultrasound. The initial idea of the project was developed by a South Australian nephrologist to consider the variation in the flow of the blood using imaging ultrasound process. Doppler changes in the signals or the shift in the transmitted and received frequencies when the ultrasound hits the target is used in the field of imaging. However, the use of ultrasound to detect the SBP and DBP has not been implemented widely and is used only for research purposes. Redarc Electronics' investment in the research and development of building innovative products led to involvement in the project with an interest in moving towards the biomedical sector.

With an idea for a proof of concept, data collection and signal processing were required to be undertaken. Collection of accurate data was crucial. Initially, the focus was done to develop a system which would be able to apply pressure on the wrist, measure the pressure and release the pressure over the period. Along with this, it was required to collect the ultrasound data simultaneously.

This led to the focus of building a mechanical interface which would sit on the wrist. The ultrasound blood flow meter used in the project was from Parks Medical Electronics. It is a uni-directional flow meter and had a set sized ultrasound transducer. To fixate the transducer on the wrist, a mechanical wrist interface was developed. Work was conducted to apply pressure on the wrist using a piezo-electric micro-pump and the pressure was measured using a pressure sensor. This required development of a PCB board which would incorporate the driver circuit and the amplification circuit.

Further it was required to develop a program which would be able to acquire the data from the pressure sensor and the ultrasound simultaneously. For this purpose, National Instruments DAQ was used along with LabVIEW programming. The program was developed to monitor the time domain ultrasound and the pressure signal. The real-time monitoring helped in reducing any error due to the movement of the transducer on the wrist. Further, the real-time spectrogram was viewed on LabVIEW to see for any high frequency or low frequency data obtained not a part of Doppler change in frequency but due to motion artefacts. The data was collected and stored into a text file to be processed using MATLAB.

The MATLAB processing had been conducted on the set of data which was obtained. A comparison was made to the actual blood pressure that was measured using existing digital blood pressure monitors. The reduction in the pressure and the change in the spectrogram results as the pressure was reduced was recorded. The occurrence of SBP was observed when the pressure applied on the wrist reached a point and the high frequency spikes in the spectrogram started to show. As the pressure was further reduced, around the DBP, the high frequency components started to decrease in magnitude with every beat. This was observed in the other sets of data obtained. While it was hypothesised that, as soon as the DBP is obtained, the magnitude of the high frequency observed at every beat would become constant. Further, the comparison with the digital monitors showed significant differences between the measured and calculated (ultrasound) pressure.

These differences can be attributed to either the limitations in the design or the data being provided by the ultrasound would be showing characteristics of the blood flow which would be more accurate. This theory is still unknown and requires further research in this field with advanced signal processing and larger set of data.

There were many challenges in the designing of the data acquisition system. These included sources of the noise due to movement of the transducer on the wrist or noise induced due to audio amplifier in the ultrasound unit. Further, due to the time constraints present, an in-depth analysis was required which could not be performed to compare the results obtained using the ultrasound method, the significance of the changing in frequency spectrum band and development of proper algorithm which would search through to find the SBP and DBP.

A larger sample size would help predict the exact relation where the DBP occurs and how the Doppler change behaves. It would also help in predicting the accuracy levels of the device.

Concluding on a positive note, a development of such device in future would provide many advantages if the limitations are overcome which include:

1. It is expected that it would provide ***higher accuracy*** compared to the existing digital and manual blood pressure monitors.
2. ***No requirement of different cuff sizes***, making it feasible to be used with people of different dimensions if the pressure is applied directly on the wrist through the ultrasound

3. Provides a means of measuring the ***inaudible low frequency DBP in infants*** through infants making it more accurate

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APPENDICES

APPENDIX A

POINT PRESSURE APPLICATION TESTING

According to the requirement of the physicians, they expect the design of the wearable blood pressure machine to be such that there is no cuff in the pumping mechanism rather a system so that it can apply pressure on to the point artery and occlude it. The application of pressure on a point would be significantly affected by the surface area of the pad resting on the wrist. The ultrasound transducer sitting on the wrist should not apply considerable pressure which would affect the flow of the blood. Different results were observed and as the surface area increased, higher amount of load had to be applied to stop the blood from flowing which was observed through the Doppler Flow meter.

Hypothesis

Smaller surface area would provide a better reading in the occlusion would be positive in the design development.

Aim

Check the effect of the surface area on the pressure at which the occlusion of the blood occurs, and interpret the suitable area for the design of the housing.

Variables

Independent Variable

- Surface area
- Loaded mass

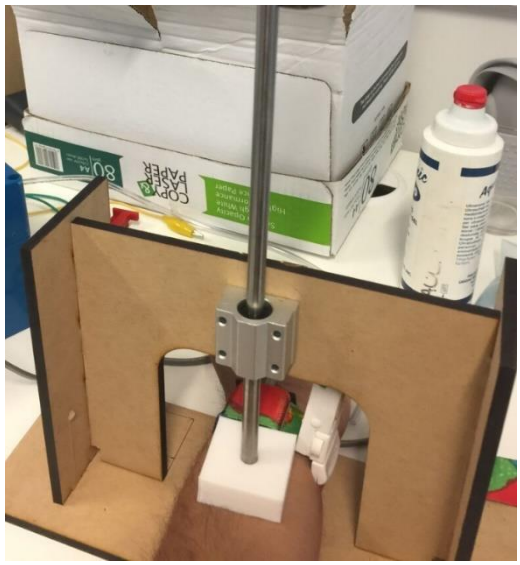
Dependant Variable

- Blood pressure

Method and Materials

In order to come up with a proper holder, a laser cut MDF stand was designed so that the hand can be placed into the holder. Ball bearings and rods were used in order to apply the pressure on the wrist when the weights were applied on the top end of the rod. The surface areas were varied using PLA Flex 3D printed pads.

The MDF stand was designed in such a way that the wrist of different people can be placed inside housing slot and pressure can be applied. This would have helped in observing the surface area effect in people having different wrist circumference and thickness. A prototype was designed through hand cut MDF which resulted in high instability. Finally the holder was decided to be laser cut so that the application of the weights would not let it to be structurally instable.



Different surface pads were designed of varying dimensions to ensure the surface area which is placed on the skin when the load is applied. The table below shows the various surface areas tested for the design.

Width (mm)	Length (mm)	Area (mm^2)
10	10	100
20	20	400
20	30	600
30	30	900
30	40	1200

40	40	1600

For the application of the loads, standard sized weights were tried to be found but due to unavailability locally, metal rods were used of 27cm long having weight of 621g. They were cut approximately into 4.5cm each of 103.5 g each using the metal cutting saw.

Doppler shift flow meter from Park Medical Electronics was used with the transducer was placed inside a designed housing. A strap was tied around the housing so that it is kept stable on the surface of the wrist with minimal motion artefacts.

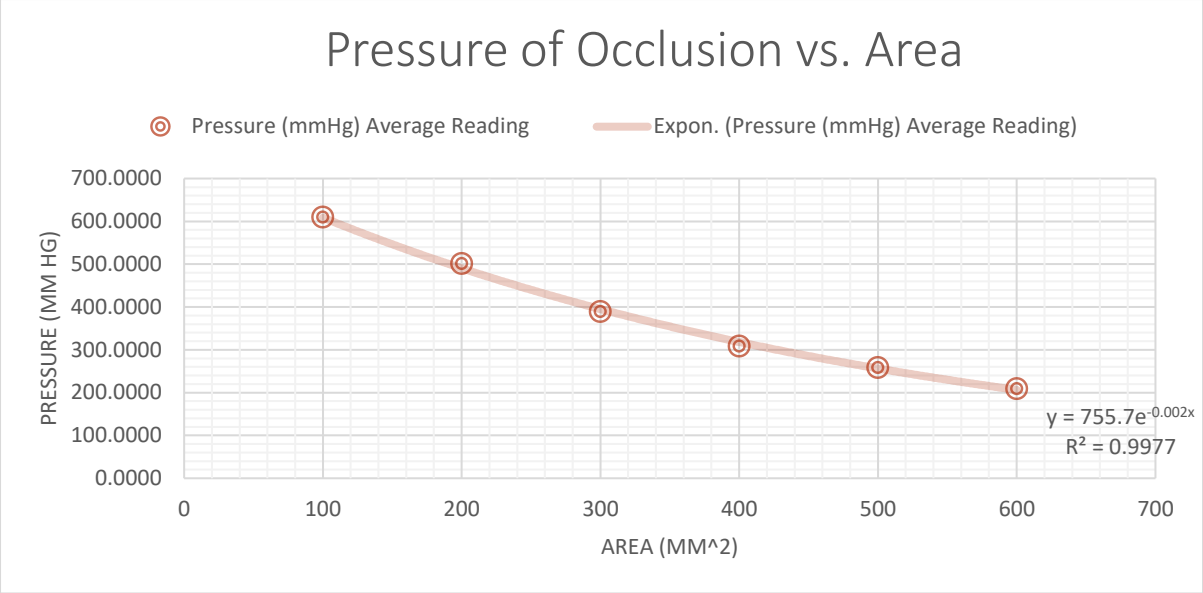
Three readings were taken for each surface area being tested for. Weights were added until the blood flow from the Doppler flow meter is not heard. The weight applied was used along with the known surface area to calculate the pressure.

Results and Outcome

As the surface area increased, larger amount of weight had to be applied in order to stop the flow of the blood as the pressure decreased. With smaller surface area, a pressure of over 600 mm Hg was produced when the blood flow stopped. This showed that smaller surface areas may not be accurate if a padding system had to be used for the occlusion of the blood flow. The table below shows the average pressure readings which were obtained at every surface areas being tested:

Area (mm^2)	Pressure (mmHg) Average Reading
600	209.03475
400	308.4631875
100	609.6915

A decaying pressure vs. area relationship was obtained from the results:



Discussion

A decaying relationship means that surface area cannot be directly related to the blood pressure. A linear relationship could have been used to predict the best surface area which would be applied on the wrist to obtain the pressure with the application of force.

There were significant amount of errors involved with the current experiment. First being standards weights were not present so small cut rods were used which were measured for the mass prior to the experiment. Any small change in the signal with the weights placed on the testing machine could not be observed.

Second, the ultrasound Doppler flow meter used a small infant transducer which had a high sensitivity. Slight change in the position would cause it to change the signal which either got distorted with the noise involved or go destroyed. Proper stability had to be maintained while testing for the surface area.

Third the test was carried out on one subject. Change in the wrist size and its effect on the surface area could not be studied as the experiment was not safe for loading high amount of weights at a height and had a risk of falling.

Suggested Improvement

Calibrated force resistive sensor would provide a better reading and with proper serial communication, the surface area at which occlusion would be occurring can be determined. This would remove the application of just weights reducing the safety risks.

APPENDIX B – MARKET ANALYSIS

Device Type	Company	Existing Patent Number	Year	Country Based	BP Measurement	Use of Ultra-sound	Use of Oscillometric Method	Invasive	Pressure Application Mechanism	Accuracy (%)	Portability	Location	Comment	Cost*
Finger Blood Pressure Monitor [36]		US 5025793 A	1988	USA	Y	N	Y	N		±2-30 mm Hg	Y	Index Finger		
Wearable BP Monitor Using Ultrasound [52]	MEMS Technologies		2012	Japan	Y	Y	N	N	Cuff	Not Specified	N	Wrist	Vessel Diameter	Research Based
Wrist Wearable Heart Rate Monitor [114]		US2014027 5852 A1	2014	USA	N	N	N	N	No Pressure	Not Specified	Y	Wrist	Photo-plethysmography	
BP Pump 2 NIBP Blood Pressure Simulator	Fluke Biomedical		2007	USA	Y	N	Y	N	Cuff	±5 mm Hg	Y	Upper Arm		
Wrist-mount blood pressure monitor [115]		US 2006011163 6 A1	2004	USA	Y	N	Y	N	Cuff	Not Specified	Y	Wrist		
Blood Pressure Monitor [116]	Omron Electronics	US 5687732 A	1997	USA	Y	N	Y	N	Cuff	Not Specified	Y	Wrist		
Cardiac Monitor Wristwatch [117]		US 4086916 A	1975	USA	N	Y	N	N		Not Specified	Y	Wrist	Arterial Pulse rate measurement using US	Concept
Wrist-worn high-accuracy pulsation measuring apparatus [118]	Casio	US 7341561 B2	2008	USA	N	N	N	N		Not Specified	Y	Wrist	Heart rate monitor through fluid sensor	Concept

Blood vessel diameter measuring apparatus [119]	Tokyo University of Agriculture and Technology	US 20170007210 A1	2016	Japan	Y	Y	N	N		Not Specified	N	Upper Arm	Blood Vessel Diameter Measurement	Research Based
Transcranial Doppler Ultrasound [120]	Harvard Medical School		2012	USA	N	Y	N	N		Not Specified	N	Multi-location	Occlusion in artery	Research Based
Doppler ultrasound method and apparatus for monitoring blood flow [121]	Spentech Inc	US 6196972 B1	2001	USA	N	Y	N	N		Not Specified	N	Radial Brachial	Blood flow measurement	
Wrist Blood Pressure Monitor	Omron Electronics		2013	USA	Y	N	Y	N	Cuff	±10 mm Hg	Y	Wrist		
H2	H2 Care		2017	Korea	Y	N	N	N	Cuff	Not Specified	Y	Wrist	Photo-plethysmography	
Wrist Blood Pressure Monitor with IMT	Micro Life		2015	USA	Y	N	Y	N	Cuff	±3 mmHg, ±5% HR	Y	Wrist		
Non-Invasive Arterial Blood Pressure Waveform [50]	MIT		2015	USA	Y	Y	N	N	N/A	±10mmHg	N	Radial Brachial	No Diastolic Measurement, Pulse Wave Velocity	Research Based
Assessing BP Waveform Using			2017	Iran	Y	Y	N	N	N/A	±6mmHg	N	Radial	Tonometry Method	Research Based

Ultrasound Image Processing [51]														
Exact Fit BP6200	Braun		2015	UK	Y	N	Y	N	Cuff	±3 mmHg, ±5% HR	Y	Brachial Artery	Size of cuff high error	$100
Digital Wrist Blood Pressure Monitor	Kogan		2013	USA	Y	N	Y	N	Cuff	±3 mmHg, ±5% HR	Y	Wrist	Size of cuff	$50
iHealth Sense	iHealth Labs		2016	USA	Y	N	Y	N	Cuff	±3 mmHg, ±5% HR	Y	Wrist	Bluetooth data transmit	$79.95
CK101	CK				Y	N	Y	N	Cuff	±3 mmHg, ±3% HR	Y	Wrist	Cuff Size Higher Error	$20
Aneroid BP Monitor	Reister			Germany	Y	N	N	N	Cuff	±2 mmHg	N	Upper Arm	Cuff Size Higher Error, Variability in operator's reading	$100
Mercury Sphygmomanometer	Reister			Germany	Y	N	N	N	Cuff	±2 mmHg	N	Upper Arm	Korotkoff, Gold Standard, Variability in operator's reading	$150

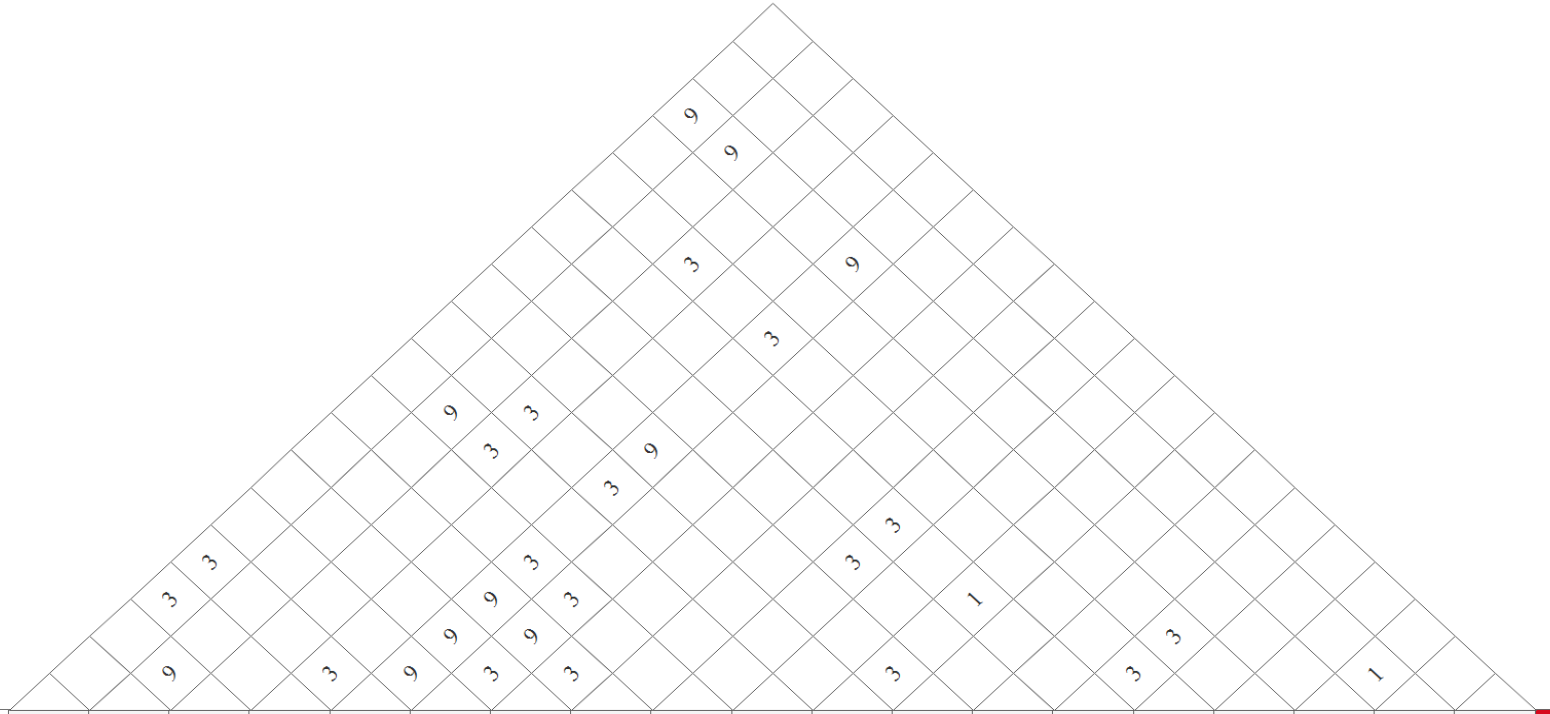
Anreoid Sphygmomanometer	eliteCare			Australia	Y	N	N	N	Cuff	±2 mmHg	N	Upper Arm/Wrist	Cuff Size Higher Error, Variability in operator's reading	$30
Dual Channel Pressure Control Unit	Millar			USA	Y	N	N	Y	N/A	0%	N	Intra-arterial	Invasive, High accuracy	>$10000
Pressure Transducers	Memscap			Norway	Y	N	N	Y	N/A	0%	N	Intra-arterial	Pressure sensor catheter	>$5000
Vital Sign Monitor	Welsch Allyn			USA	Y	N	Y	N	Cuff	±3 mmHg, ±5% HR	N	Upper Arm		$1700
Intellivue	Philips			USA	Y	N	N	Y	N/A	0%	N	Intra-arterial		>$3500
Generation Zero	Omron Electronics			USA	Y	N	Y	N	Band Cuff	Undetermined	Y	Wrist	Wearable, Micro-pumping technology	Undetermined
Doppler Probes Blood Pressure Measurement [53]		WO 2014074901 A1	2014	USA	Y	Y	N	N	Transducer Pressure	3%-7% of target reading	Not Specified	Major arteries	Close to the current research work	Concept
Ambulatory Blood Pressure Monitor	A&D Medical			Australia	Y	N	Y	N	Cuff	±3 mmHg, ±5% HR	Y	Upper Arm	Affected by the size of cuff	>$3200

Ambulatory Blood Pressure Monitor	Welsch Allyn			USA	Y	N	Y	N	Cuff	±3 mmHg	Y	Upper Arm	Affected by the size of cuff	>$4000
Ultrasonic Pulse Rate Monitor [122]	Salutron Inc		2009	USA	N	Y	N	N	N/A	Not Specified	Y	Wrist	Measurement of heart rate	Concept
Handheld Pocket Fetal Doppler	Sonoline		2013	Canada	N	Y	N	N	N/A	Not Specified	Y	Abdominal	Measurement of heart rate, accurate data processing	$100
Tonometry System for measuring blood pressure [34]	Alaris Medical Systems	US 6290650 B1	2001	USA	Y	N	N	N	Mechanical Occlusion	Not Specified	Y	Wrist	Electromagnetic stress sensors	Concept
Ultrasonic Continuous Non-Invasive Blood Pressure Monitoring [123]	General Electric Company	US 7425199 B2	2008	USA	Y	Y	N	N	Cuff	Not Specified	N	Upper Arm	Pulse wave velocity, arterial lumen diameter	Concept
Ultrasonic Blood Pressure Measurement Apparatus [124]	Seiko Epson Corporation	US 2016005840 9 A1	2015	Japan	Y	Y	N	N	N/A	Not Specified	N	Variable	Pulse wave velocity, arterial lumen diameter	Concept
Intelligent ultrasonic blood pressure monitoring bracelet [54]		CN 105662381 A	2016	China	Y	Y	N	N	Wrist Band	Not Specified	Y	Wrist	Doppler Mechanism	Concept

Non-invasive ultrasonic fetal heart rate monitoring [125]	General Electric Company	US 20080208057 A1	2008	USA	N	Y	N	N	N/A	Not Specified	N	Abdominal	Heart rate through Doppler frequency change	Concept
Device	**Company**	**Existing Patent Number**	**Year**	**Country**	**Power**	**Use of Ultrasound**	**Directional**	**Invasive**	**Measurement Frequency**	**Accuracy**	**Portability**	**Location**	**Comment**	**Price**
Doppler Blood Flow Monitor	Cook Medical			USA	12 V Lithium ion	Y	N	N	20MHz	<5%	N	Multi-location	Measuring the flow of the blood through Doppler Change in frequency	Based on quote
Uni-Directional Doppler Flow Meter	Park Medical Electronics		1998	USA	12V Lithium Ion	Y	N	N	8-9.5MHz	N/A	N	Radial Brachial Carotid Femoral	Uni-directional doppler flow meter velocity determination	$1400
Flow Coupler Device and System	Synovis			USA	Battery Powered	Y	N	Y	20MHz	Not Specified	N	Venous Flow Monitoring	Detection of anastomosis	Based on quote

OxyFlo	Oxford Optronix			UK	100-240V, 50-60Hz, 30W	N	Y	N	Electromagnetic	5% Stability	N	Multi-location	Laser Doppler mechanism	Based on quote
Ultrasonic Doppler Blood Flow Meter [126]	Matsushita Electric Industrial	US 4848355 A	1985	Japan	DC Power	Y	N	N	2-7MHz	Not Specified	N	Multi-location		

APPENDIX C – HOUSE OF QUALITY



	Light Weight <10kg	Wrist Radial Artery Measurement Location	Surface area of pressure application >700 sq.mm	Time to build >60 days	Cost <$1,000	Data acquisition system high sampling frequency >5K samples/second	Multiple channels DAQ >2	High ADC Bits >8	Power Supply >12V	Wrist Movement Dimension >80 mm across	Pressure Sensor max range >300 mm Hg	Pressure Sensor accuracy < +/-0.5 mm Hg	Emergency Solenoid valve operation voltage <5V	Pump Voltage supply >20 V	Flow Rate pump >500ml/min	Release rate < 200 ml/ min	Ultrasound central frequency >8MHz	Audible tune down range 20Hz<f<20kHz	Signal Acquisition Period <1 min	Importance Rating
Safety	9	9	3		3				9	9	3		9	3	9	9	1	1	9	14
Easy to operate	3	3		1	9				1	9			9					3		11
Low Maintenance			1	3	9				3	3			3						3	9

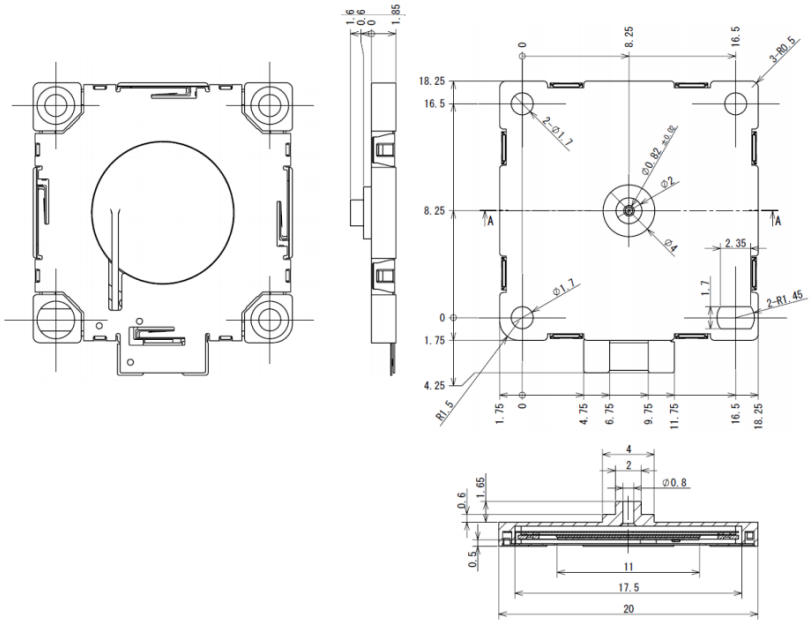
Few Parts	9	1	1	9	9					3			1	1						3
User Friendly	9	3	3																1	6
Power				1	3	3			9		3		9	9			9			14
Inexpensive Materials	9	1	1	3	9	3	3	3							3	3	9			7
Clean and Sanitisation		9	9		3					3										9
Constant Pressure Monitoring		3	3								9	9	3	3	3	9				25
Visually appealing	1	1		3	3															18
Cost Effective	1			9	9	9			9		9	9		9	3	3	9			2
Contingency Protocol		3	3							3										10
Painless		9	9							9	3		9			9			9	12
Accurate			9		9	9		9		9	9	9					9		9	26
Mechanical Adjustable Interface		9	3							9										23
Light Weight	9																9			4
Portable	9			3	9												9			4
Target Information	7kg		700 sq m	60 days	$1000	5k samp/ sec	2 chan	12 bits	12V	80 mm	350 mm Hg	+/- 0.5 mm Hg	2.5V	28 V	500 ml/ min	200 ml/ min	9.5M Hz	20Hz-20kHz	1min	
Absolute Importance	395	706	676	184	723	315	21	255	308	867	597	477	564	264	228	528	527	47	506	
Relative Importance	4.10	7.33	7.02	1.91	7.51	3.27	0.22	2.65	3.20	9.00	6.20	4.95	5.85	2.74	2.37	5.48	5.47	0.49	5.25	

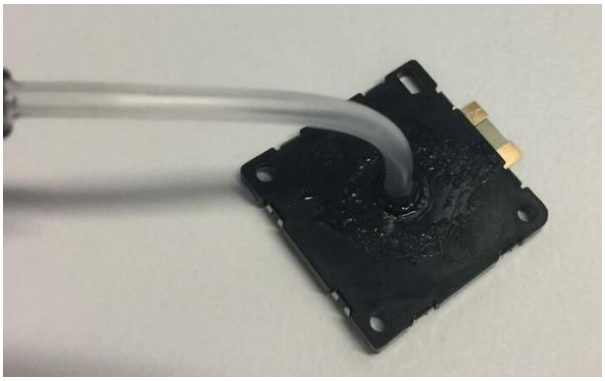
APPENDIX D

1. *PUMP*

The pump used in this project is a Murata Electronics micro-pump version MBZ1001T02, one of the micro-pumps designed to operate between 11-20V DC producing pressure of 1.2kPa at a resonant frequency of 25.1kHz. The size of the pump being very small, it is expected to be suitable for a micro design and can be used in a wrist watch band with ultrasonic flow meter.

The structural dimensions of the pump are shown below:





This is one of the pumps which were easily available from the company Mouser Electronics from where Redarc procures the electronic components.

Several doubts about the functioning of this system existed when it was purchased as listed below:

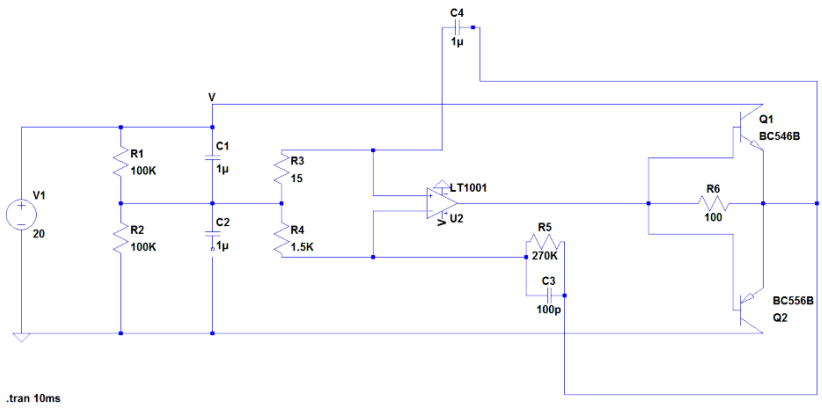
- The static pressure of the pump is about 1.2kPa and the flow rate being 0.70 L/min. The pressure required for occlude the artery ranges from 0-200 mm Hg or 0-26.66 kPa. If the pressure production would be enough or not was required to be tested.
- The back pressure of the pump was required to be measured as any absence of the check valve would cause the pressure to release and cannot be held inside the bladder. As per the schematics, the pump does not have any check valve attached to it.
- The capacity of the driver circuit was to be tested to find the operating frequency. The range of the frequency was between 24-27 kHz but it was required that the pump must be operated at its resonant frequency.
- Volumetric flow rate of the pump was 0.70L/min, the amount of time it will require to pump up the entire bladder before the deflation should occur.

Parts Procurement

Signal generator was used to test the pressure and flow of the pump at 25kHz. Due to no proper controlled oscillation, there was reverse current flow into the signal generator, making it go into a safety mode. This cu-off created a problem on the continuous operation of the bladder. To drive the pump effectively, the provided schematic circuit was used. The company Murata does not provide the Driver board so one had to be created.

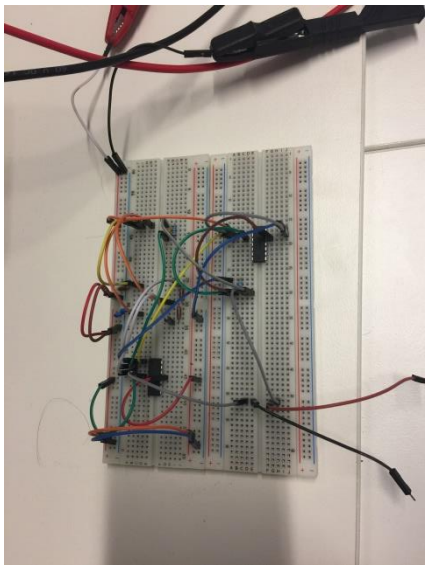
Building

The electronics was put down as per the schematics shown below:



The circuit is a piezoelectric oscillator circuit which would amplify the signal and make the voltage oscillate between ±4.5V at 25.12KHz. In order to test the working of the circuit, instead of a piezoelectric transducer, a capacitor was placed to see the oscillating behaviour of the circuit. This was chosen because the piezo is a capacitive material which vibrates when the voltage is applied. There is stored potential energy through voltage application which changes to mechanical energy.

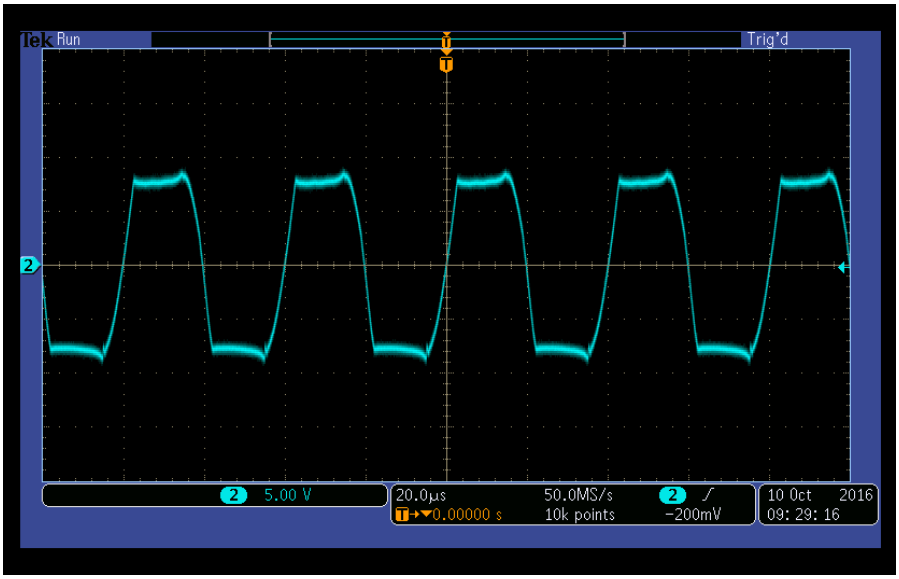
The setup on the prototyping board came out to be this:



The testing of this prototype was done first with a 1uF capacitor as modelled in the LT Spice for comparison to ensure the correct working of the circuitry. The output was checked on the oscilloscope and similar results were obtained. Then the piezoelectric micro-pump was attached and it worked as expected. When the voltage was varied, the flow rate changed.

The operating frequency of the pump came out to be 25.12kHz with the driver circuit which is the resonance frequency producing a flow rate of 1L/min as per the datasheet of the pump.

The oscilloscope output is shown below:



$$Frequency = \frac{1}{Period} = \frac{1}{T} = \frac{1}{39.18us} = 25.12kHz$$

The piezoelectric pump is running at resonant frequency for the maximum output.

Mechanical Sealing

The mechanical sealing was one of the key issues as the outlet outer diameter is only 4mm. In order to get a proper sealing some of the different pipe sizes were tried using super glue but problem being the low viscosity of the glue made it flow freely and if it came in contact with the outlet, it blocked the hole. The right size pipe was required to obtain the proper sealing so there are no leaks.

Bladder Inflation Testing Result

It was possible to inflate the bladder quickly with the micro-pump in 10-15 seconds with proper sealing. The bladder used was from the nurse staff manual sphygmomanometer, child size 18.4cm to 26.7cm range. When the bladder was tied around the wrist, there was a back flow of air causing it to escape from the piezo surface as the check valve was not strong enough to hold high back pressure. This called for trying to smaller check valve which can be added on to the piping system so the holding of the pressure can be tested.

According to the current tests, the maximum pressure recorded on the gauge at 20V is 20mm Hg and at 30V is 40mm Hg. Increasing the voltage certainly increases the pressure but to attain a pressure of 200-300 mm Hg, a very high voltage would be required which would not be safe or portable.

The check valves which are thought to be tried for:

- Soccer ball valve as it has very thin diameter to fit onto the current piping system. Associated concern with this valve is opening of the gate when the pressure on both the sides of the valve will be equal.
- Solenoid valve can be used programming with proper micro controller in order to release the pressure at the right time.

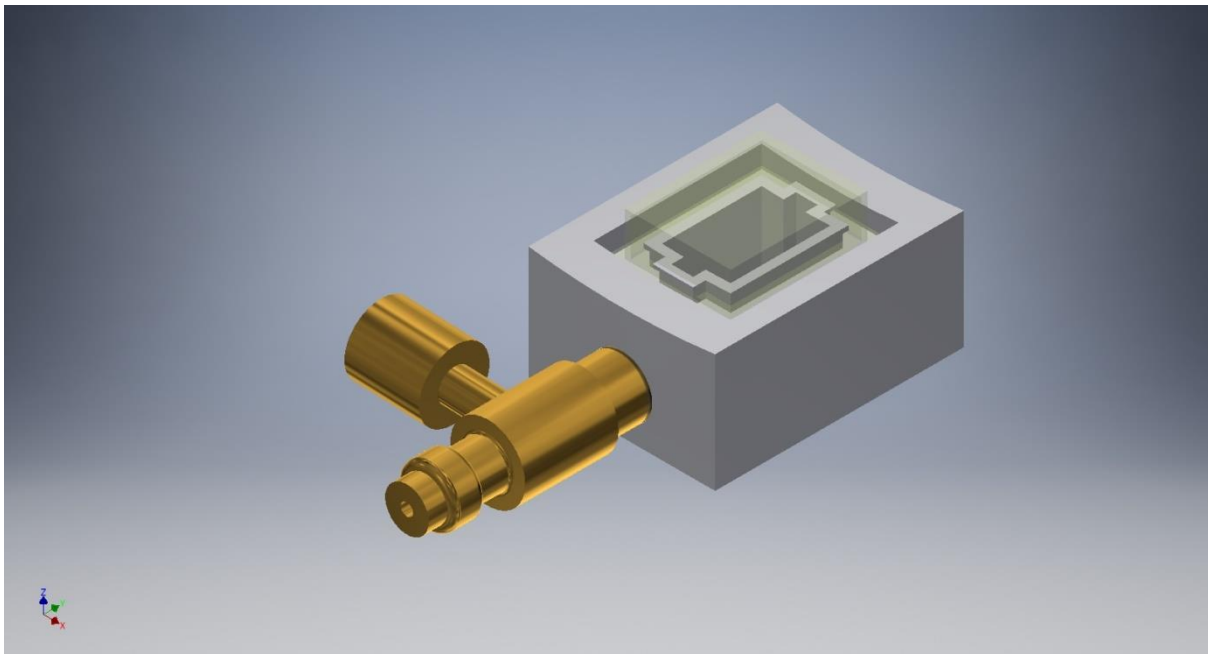
Both the valves were tried but both failed to work to attain higher pressure. The check valves had the problem being requiring an initial static pressure to open them up which were very large compared to the pressure which the micro-pump could generate.

Conclusion

The use of piezoelectric micro-pump by Murata Electronics is not possible as it lacks check valves to hold higher pressure greater than 30mm Hg. An increase in voltage would increase the pressure generated but it would not be feasible to use this technique pump.

2. *Mechanical Designs on Wrist*

Design 1: Pressure Holder



Material: ABS Plastic

Manufacturing: 3D Printing

Problem: No proper fitting of the silicon membrane on the top

Solution: Use of silicon paste. Waiting for 24 hours

Result: Pressure escaped. Failed in holding the pressure

Problem: Fitting the one way valve into the casing

Solution: Use of tube of same diameter

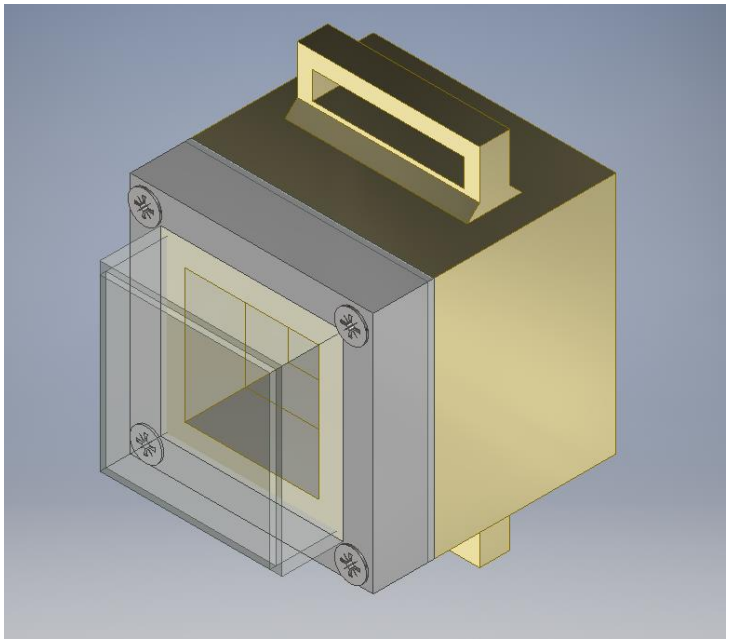
Result: Required sealing with silicon. Pressure still escaped.

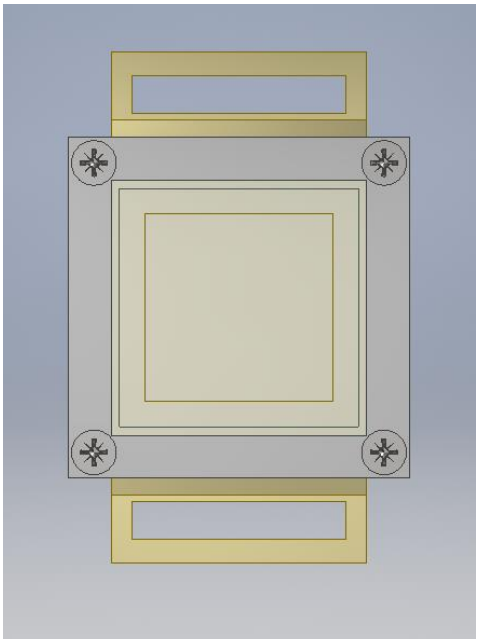
The silicon pasting needed to be removes as it was not able to hold the pressure. A different approach had to be used before trying the new design.

Problem: Fitting of the silicon membrane

Solution: Use of the super glue

Design 2: Pressure Holder





The idea was to use silicon sheet and attach it to a cover and then screw it with a cap. The problem with this design being that 3D printed casing would not be able to retain the pressure as tested with under water pumping test. In order to obtain a better design technique, the idea of retaining the pressure in the casing had to be changed.

Fabrication: 3D Printing ABS

Problem: Pressure escaping from the surface

Solution: Increase infill, layer height and density. Also needs to be coated with a layer of adhesive.

Implementation: Not implemented due to inaccuracy in the retaining the pressure within.

Improvement: Need a bladder inside the casing which would be able to retain the pressure and would inflate and deflate similar to the bladder used in the standard sphygmomanometers.

Design 3: Pressure Holder

The idea is to place a bladder/balloon in the rectangular slot so when the balloon expands, it compresses the wrist. The expansion of the balloon is to be done by the manual pumping system with attached mercury pressure gauge which would be able to monitor the pressure between 0-300 mmHg. An additional slot is present which would be able to hold the ultrasound transducer in place and the side flaps will hold the wrist band.

Problem

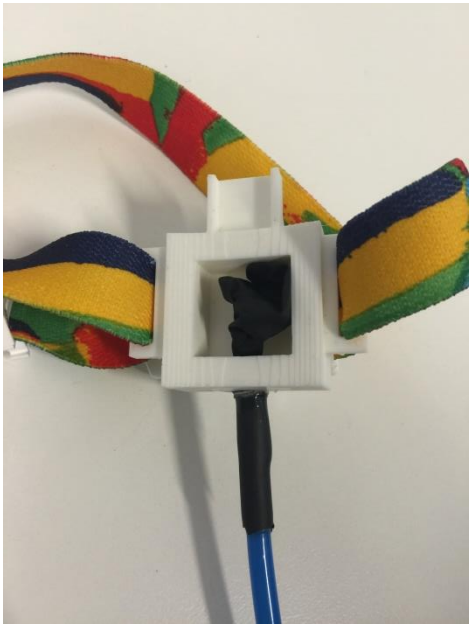
1. Bladder material: Two different materials were tested:
   a. Water balloon: Very thin and would not be able to attach to the hose. Prone to getting torn
   b. Silicon rubber glove: Good in holding pressure, but has leakages due to wide opening, cannot be concealed. Heat shrinks and glue damage the material

2. Leakage through pipes: Continuous piping required with proper valving to avoid leakages
   Solution: Used heat shrinks to avoid any leakage and worked successfully.

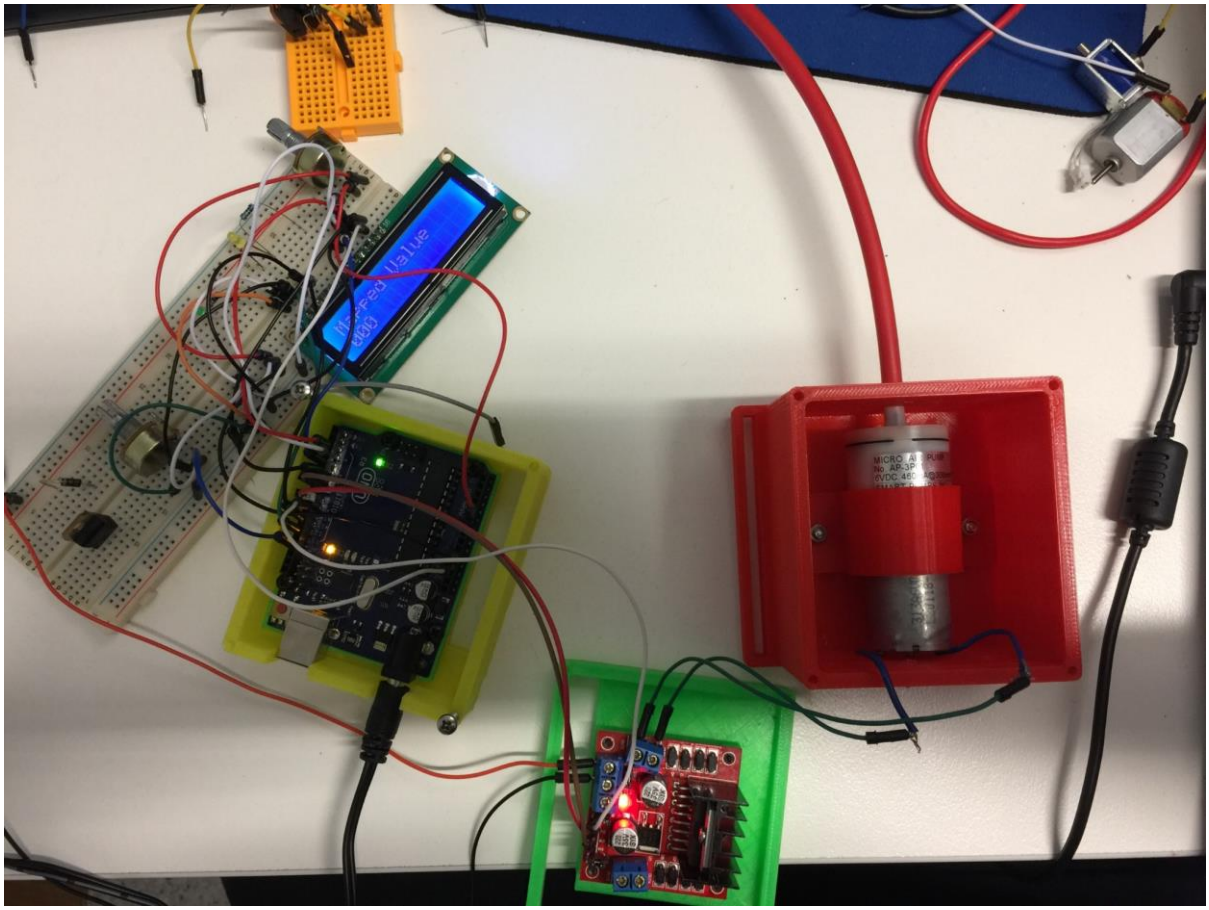
3. Pressure overshoot: Small bladder surface area resulted in higher pressure. Change in the bladder size.

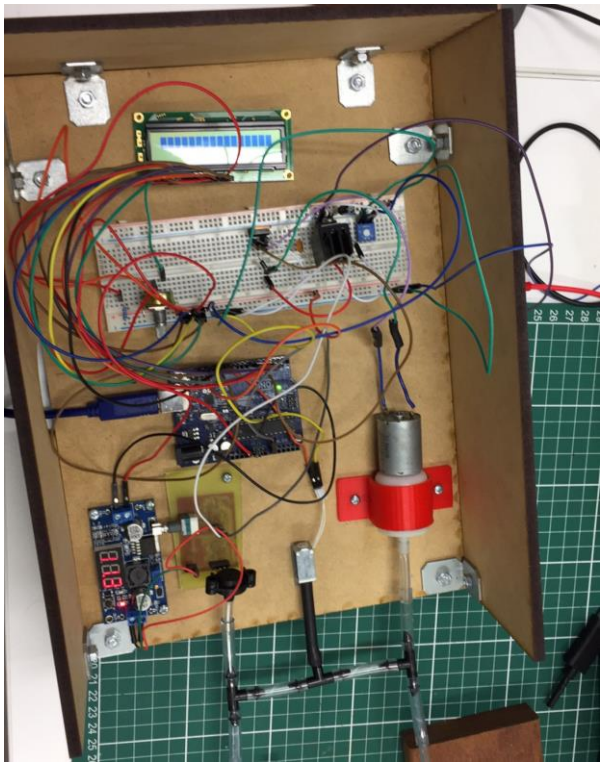
Required Improvement:

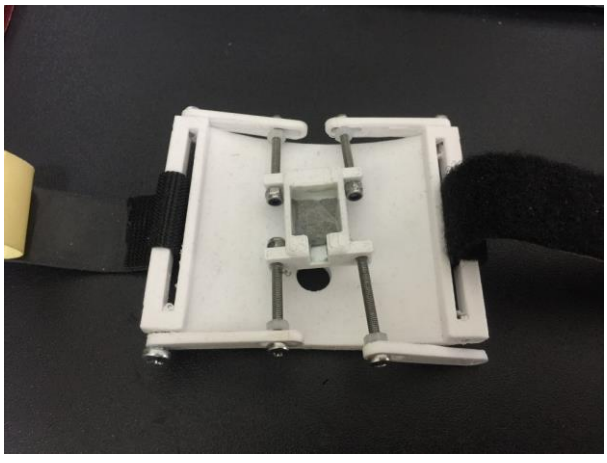
1. Change in the design of the casing so as to accommodate larger bladder, 40% of wrist width and 80% of wrist length. This would help in decreasing the pressure overshoot.
2. Proper material selection with expectation to test the pumping with bicycle inner tube.



3. *Prelim Prototype*







4. Initial Rectification Circuit Design

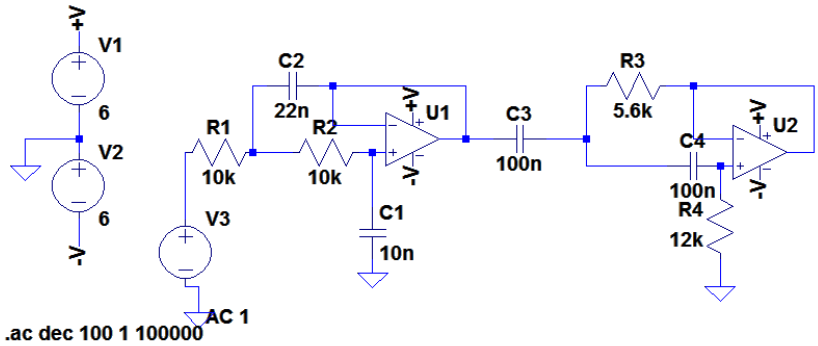
The noise signal required filtering of the signal but before filtering it was necessary to find out the range of frequencies the interest lies when the transducer is connected to the wrist. From the literature review done for the Doppler ultrasound change in frequency for detecting of blood pressure, for the systolic pressure the frequency change occurs between 200Hz to 1 kHz. Spikes were observed on oscilloscope when the blood flow sound was produced with the maximum frequency above 200 Hz.

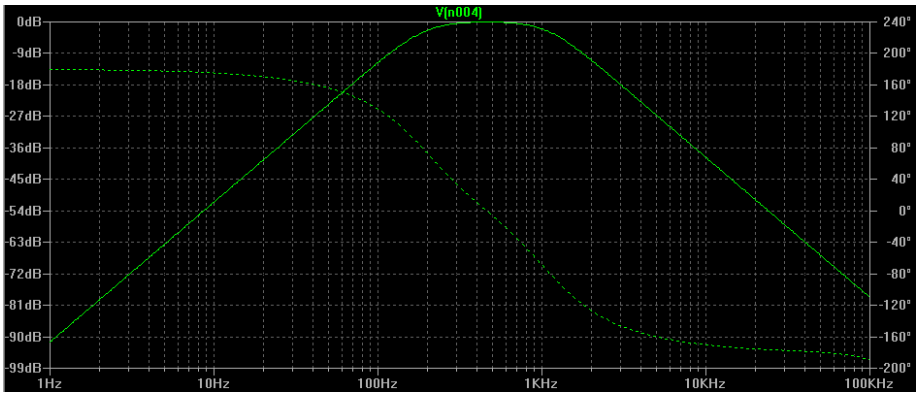
At this stage, it was assumed that the spikes observed were due to characteristic blood flow sound and not due to any external interfering signal.

Developing a filtering circuit required a band-pass filter construction with the lower end cut-off frequency at 200Hz and higher end cut-off frequency at 1 KHz. Before designing the filter, some considerations were kept in mind to get rid of the noises in the signal:

1. 50 Hz AC noise signal would act as the interfering noise due to no proper insulation in the ultrasonic device
2. Motion artefacts including the motion of wrist, internal tissue motion, blood flow in the veins can modify the signals

These motion artefacts are a part of the low frequencies noise and it is possible to get rid of these signals with the filtering circuit above 200 Hz. The filter designed was a 2nd order Sallen Key bandpass filter. The lower cut-off frequency of this filter is set to 194.15Hz and upper cut-off frequency was set to 1.073KHz. The circuit design along with the bode plot response is shown below:



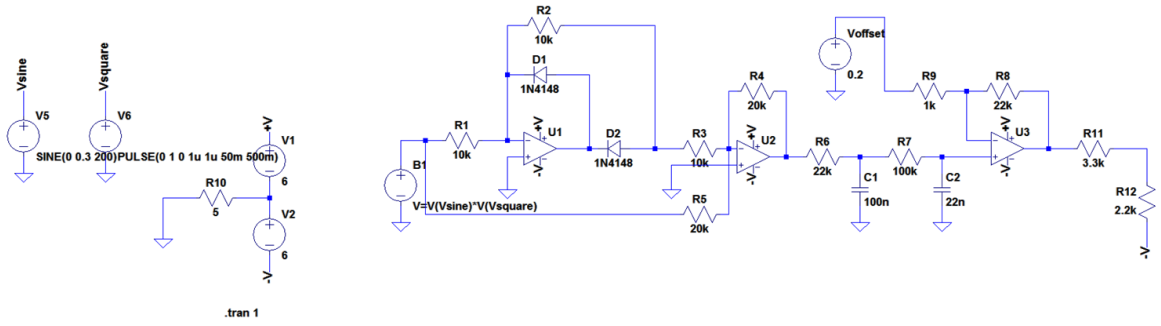


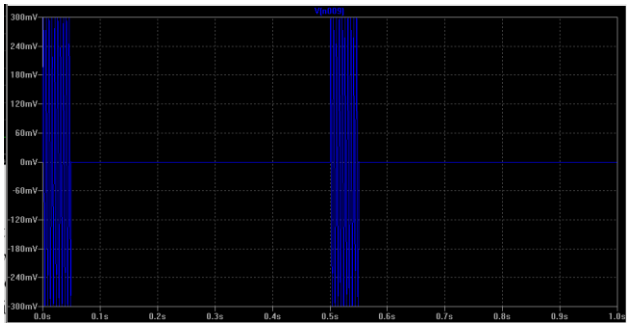
Rectification

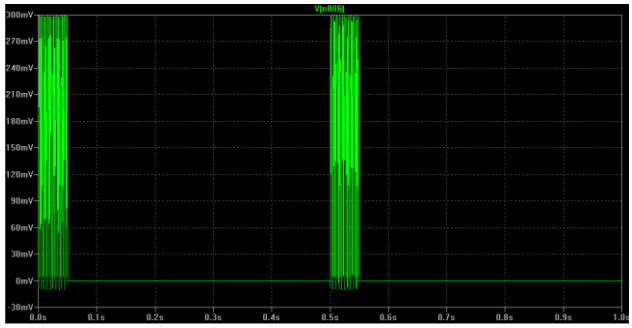
The signal coming from the output of the speaker in the Doppler Blood Flow meter is an oscillating signal. It was necessary to use a rectification circuit which would convert the oscillating signal into a rectified signal response. A thought was given to use a simple diode rectification circuit but the biggest drawback of such circuits is that the diodes require a forward voltage of about 0.7V to drive through the diode. The incoming signal from the flow meter was varying and tended to go lower than 0.7V which would not have been rectified.

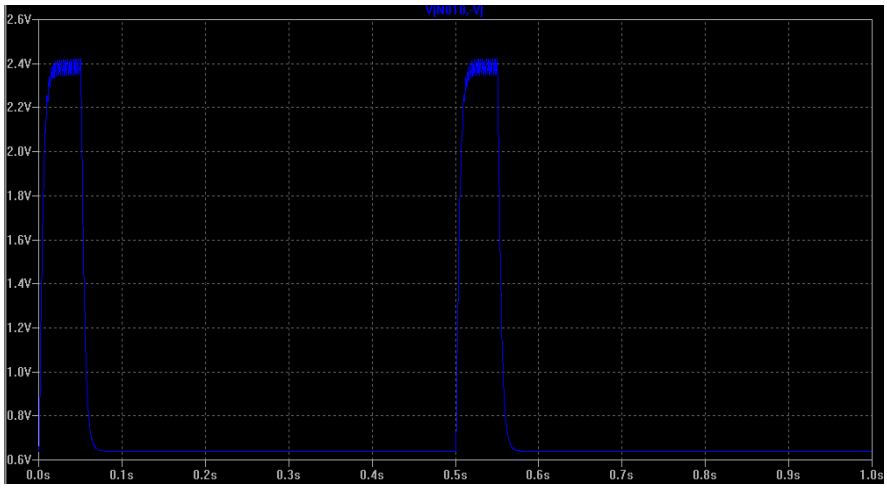
Amplification of the signal was also required as the signal generated during the peak sound pulse generated from the speaker was very low.

For these reasons, the precision rectification circuit was used. The designed circuit for the rectification is shown below along with the output after the rectification:







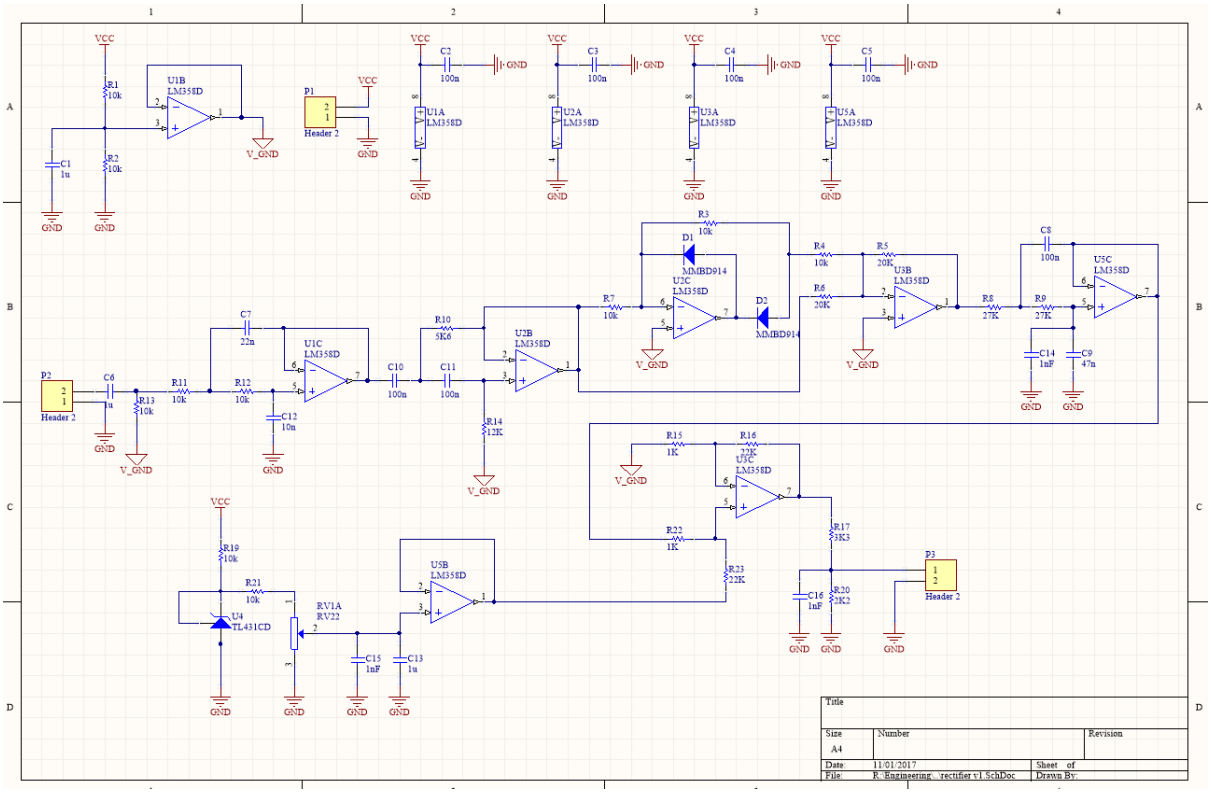


In the circuit, a sine wave signal of frequency 200Hz was induced as a noise component. A square wave signal was merged with the sine wave in order to model a signal which would correspond to the peaks achieved in the noise signal when the sound of blood flow is detected by the Doppler flow meter. This signal merged signal was passed through the diode rectification circuit which rectified the oscillating components. Finally it was passed through an amplification stage to amplify the signal about 300mV in the model to 2.4V so that it can be read by the Arduino.

Circuit Design

The circuits for the filtering and the precision rectification were combined in the Altium after proper test results were obtained in order to make a PCB layout. The circuit is divided into 4 important sections:

1. The output from the Doppler flow meter first goes through the bandpass filtering unit to attain the frequency between 200Hz and 1kHz.
2. The precision rectification circuit to obtain the rectified signal
3. Voltage reference to set a virtual ground at 2.5V as dual rail amplifiers were used
4. Amplification circuit



This circuit is designed to take the AC audio output from the ultrasonic blood flow detector and process the signal to output a 0-5V voltage indicating the strength of the AC audio input. This signal will then be connected to the ADC input of an Arduino microcontroller. It is designed to respond only to the 200-1000Hz frequency range of interest, rejecting low-frequency and high-frequency noise. It runs from a 12V nominal power supply voltage.

The circuit uses an op-amp (U1B) to provide a virtual ground midway between the supply voltage and ground. This is used as the ground reference for most of the signal processing circuitry in this circuit.

The signal is AC coupled via C6 and superimposed on the virtual ground voltage. U1C and U2B form low-pass and high-pass Butterworth Sallen-Key filters. These provide the 200-1000Hz bandpass characteristic required. Testing showed that these 2^{nd} order filters provided enough rejection of noise to get a good signal.

U2C and U3B form a full-wave precision rectifier circuit. U2C is a standard half-wave precision rectifier circuit, that outputs the positive half of the incoming signal, inverted. U3B is an inverting summing amplifier, that combines the original signal (with a gain of 1) and the inverted rectified signal (with a gain of 2) to produce a positive, full wave rectified version of the original signal.

U5C is a low-pass Butterworth filter with a cut-off of about 80Hz, which allows the average voltage of the rectified signal to pass while blocking the AC signal.

U4 and U5B provide an adjustable reference from 0-380mV.

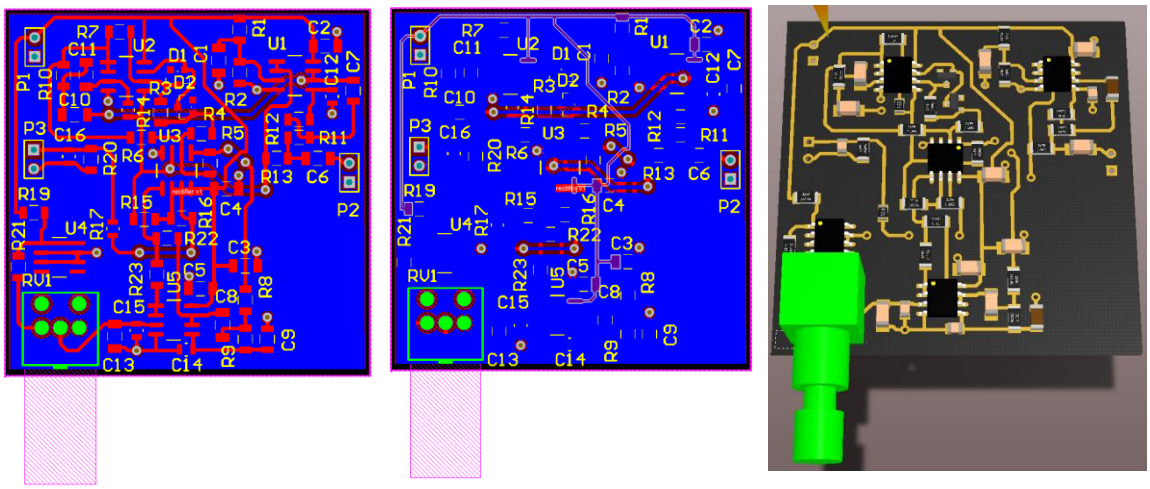
U3C provides amplification and level shifting of the rectified and filtered signal. The gain of 23 was chosen based on the desired 0-5V signal level and the measured signal strength from the ultrasound machine. The adjustable reference voltage allows the output voltage to be level shifted by -Vref*R16/R15. E.g. a Vref of 0.2V causes the output to be shifted down by 4.4V. The voltage divider formed by R17 and R20 divides the output down to match the 0-5V input required by the Arduino's ADC.

Because the microcontroller that is connected to this circuit is only concerned with the difference in amplitude between the peak and trough of this signal, the absolute offset of the output is unimportant, and no effort was made to ensure low offset voltages or drift.

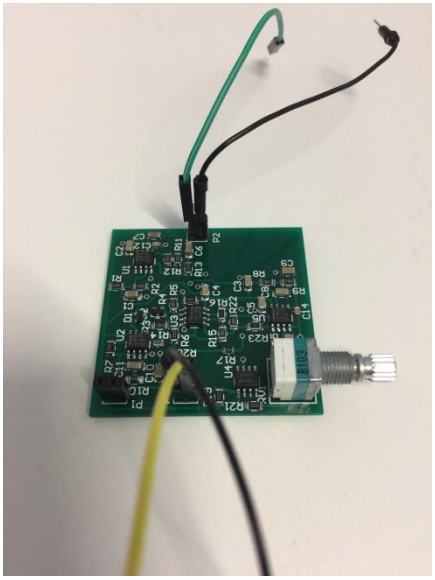
The LM358 was chosen for this circuit because its bandwidth is sufficient (even for the amplifier with a gain of 23) for the relatively slow signal, and because it is available.

PCB Design and Manufacture

The PCB design was done but this board was sent for manufacturing from a 3rd party PCB Way as design was not possible in one layer and required multiple layers with via. The design rules for this board followed were same as the one designed for the pressure sensor:



The designed board was sent for manufacturing and the final product is shown below after the surface mount soldering of the components were being done:



Testing of Rectification Board

The testing procedure was developed for this board as well:

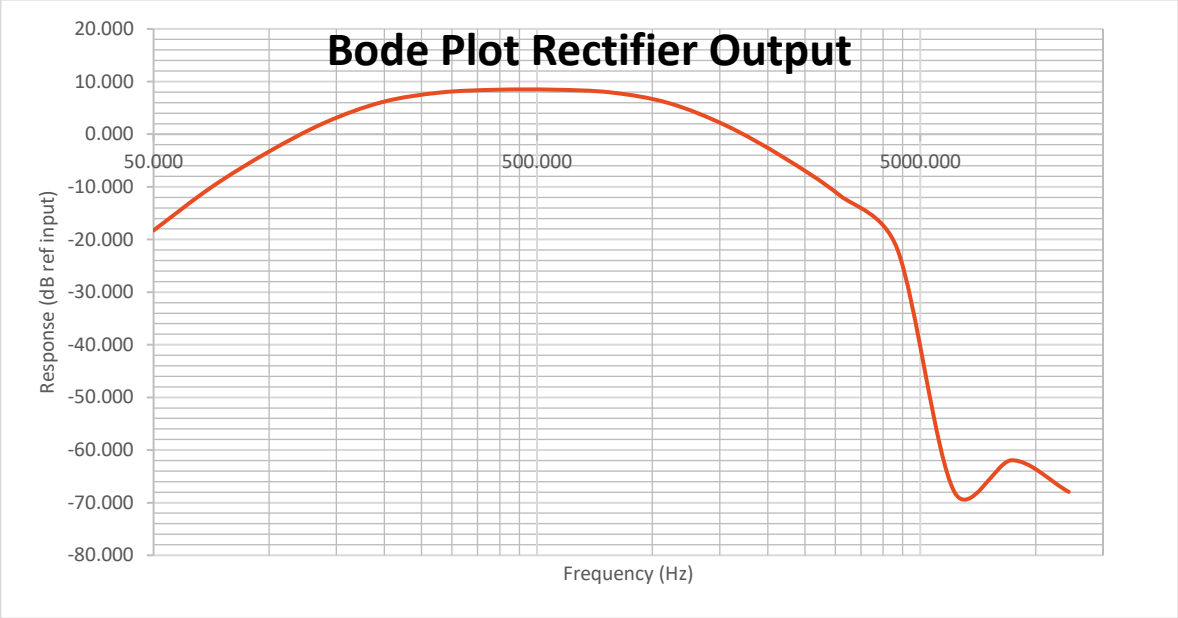
1. Apply 12V power to the circuit and measure the supply current. This should not exceed 10-15mA.
2. Check that the virtual ground voltage is roughly half the supply voltage.
3. Check that the reference voltage is 2.5V, and then adjust the potentiometer until the final circuit output is about 0.5V.
4. Apply a sine wave of 300mV amplitude with a frequency of 50Hz-10kHz to see that the frequency response is as expected (200-1000Hz.)
5. Apply a sine wave of 500Hz frequency and amplitude of 0-1V to test that there is a linear response between input and output voltage amplitude.

Result

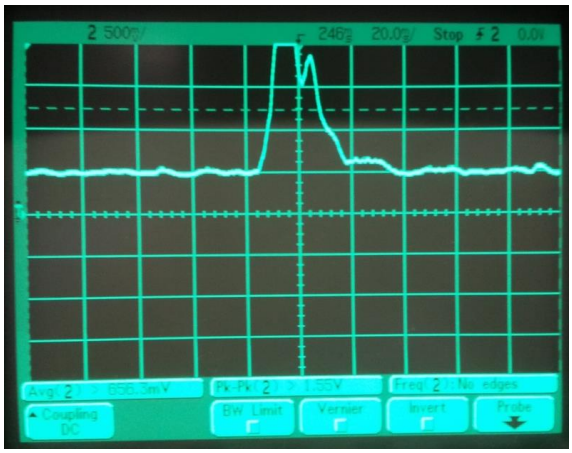
The table below shows the frequency response measured from the circuit using the function generator. Further to be noticed an offset voltage was recorded initially when a DC volt was applied which came out to be 506.8 mV. The sine wave function had amplitude of 250 mV_{PP}.

Frequency (Hz)	**Output (mV)**	**Corrected Output (mV) [w.r.t. offset voltage]**	**Output (dB ref. input in mVpp)**
50.000	537.3	30.5	-18.273
70.500	584.5	77.7	-10.150
99.405	675.6	168.8	-3.411
140.161	829.9	323.1	2.228
197.627	1012.1	505.3	6.112
278.654	1128	621.2	7.906
392.902	1168	661.2	8.448
553.992	1169	662.2	8.461
781.129	1130	623.2	7.934
1101.392	1002	495.2	5.937
1552.963	810.3	303.5	1.684
2189.678	658.8	152	-4.322
3087.446	572.2	65.4	-11.647
4353.299	527.2	20.4	-21.766
6138.151	506.9	0.1	-67.959
8654.793	507	0.2	-61.938
12203.258	506.9	0.1	-67.959

The obtained frequency response graph with the output (dB) is shown below. Comparing this to the one obtained in the circuit design phase of the filter, the correct cut-off frequencies are obtained approximately at 200 Hz and 1 kHz.

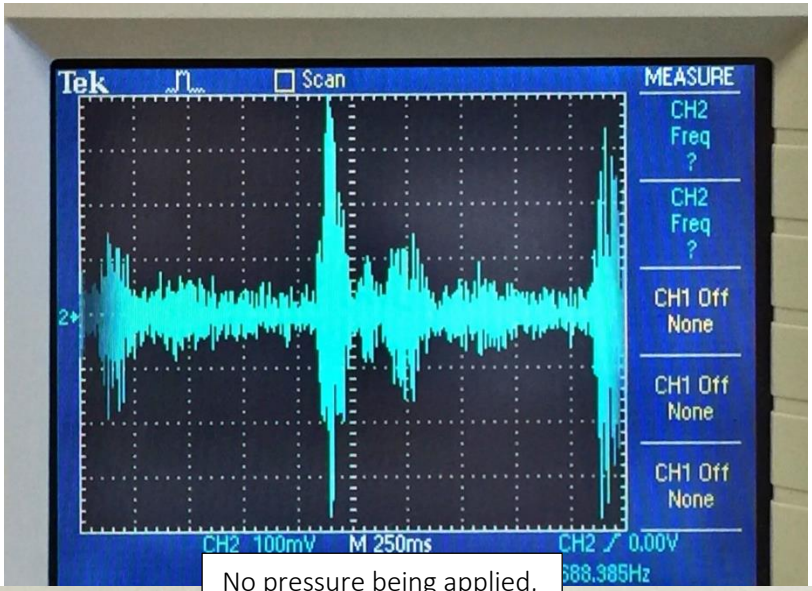


The board was connected to the speaker output of the Doppler Flow Ultrasound Meter. When the ultrasound probe was placed over the wrist with interfacing gel, 'whooshing' sound of blood flow was heard. The occurring of the sound marked a spike at the output of the rectifier circuit seen on the oscilloscope:

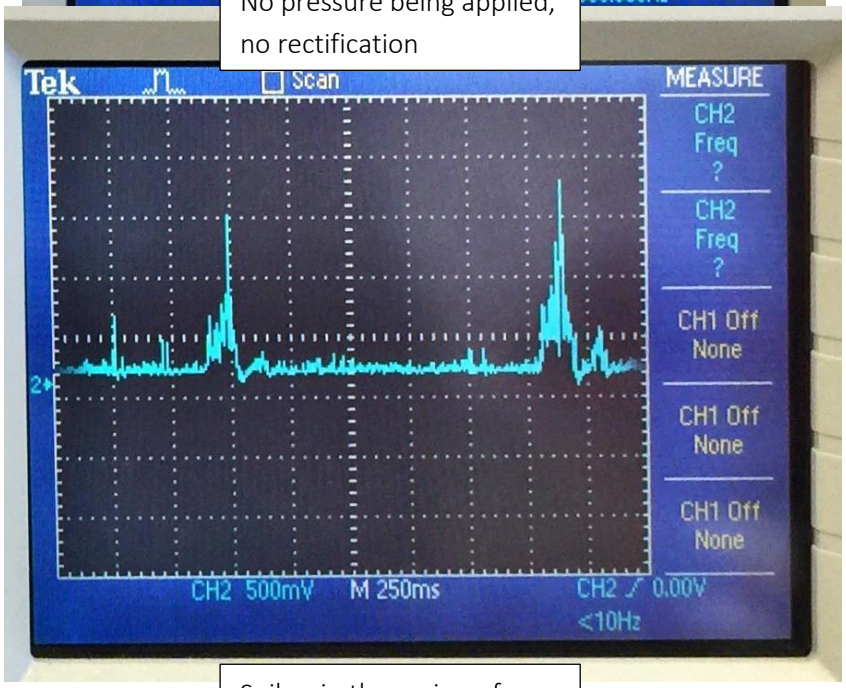


Raising the pressure above systolic gives no signal. Lowering it to the systolic boundary caused large pulses (as shown above) to appear very suddenly. These pulses will be very easy to measure on the microcontroller, as their amplitude is 1500-2000mVpeak and they last for 30-40ms.

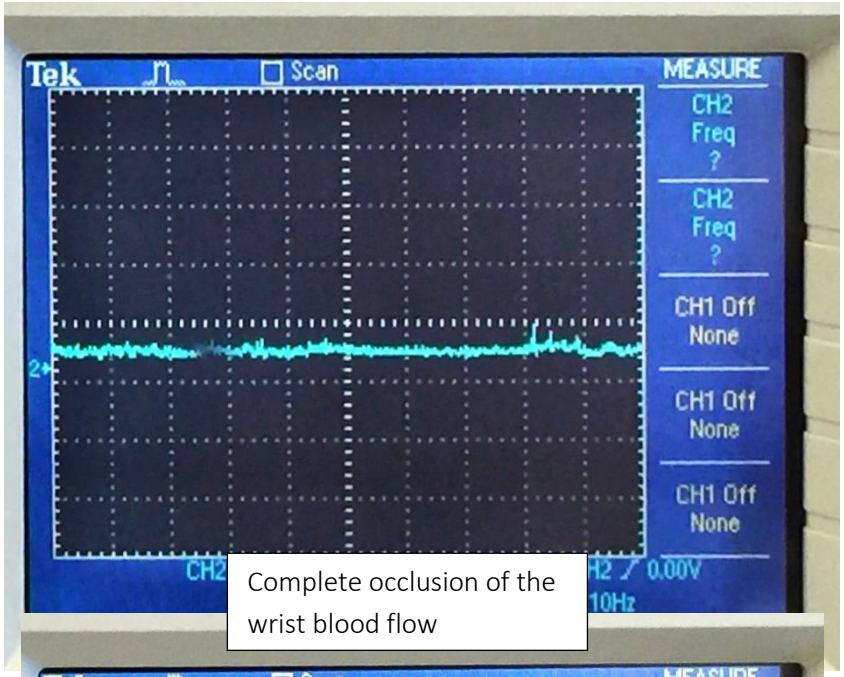
5. *Prelim Signals From Oscilloscope*



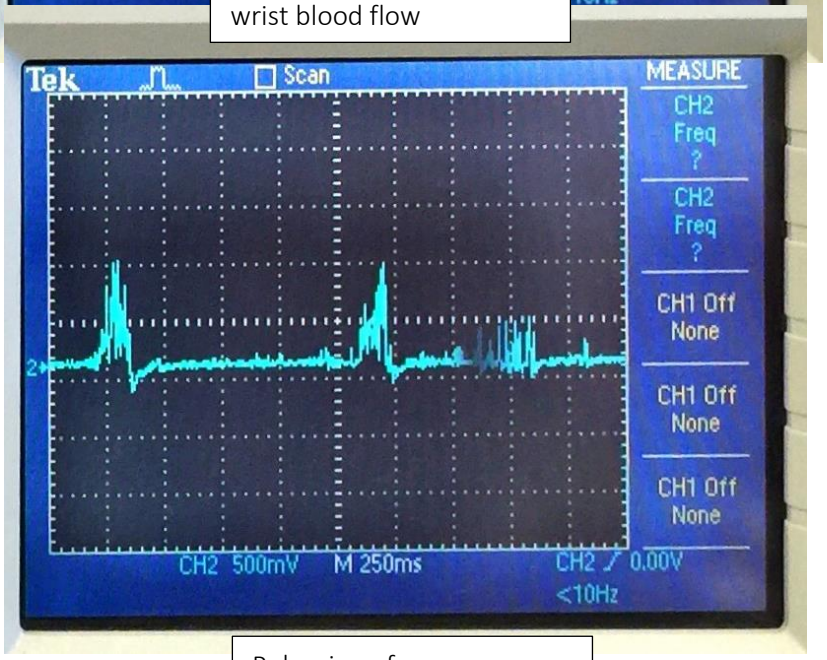
No pressure being applied, no rectification



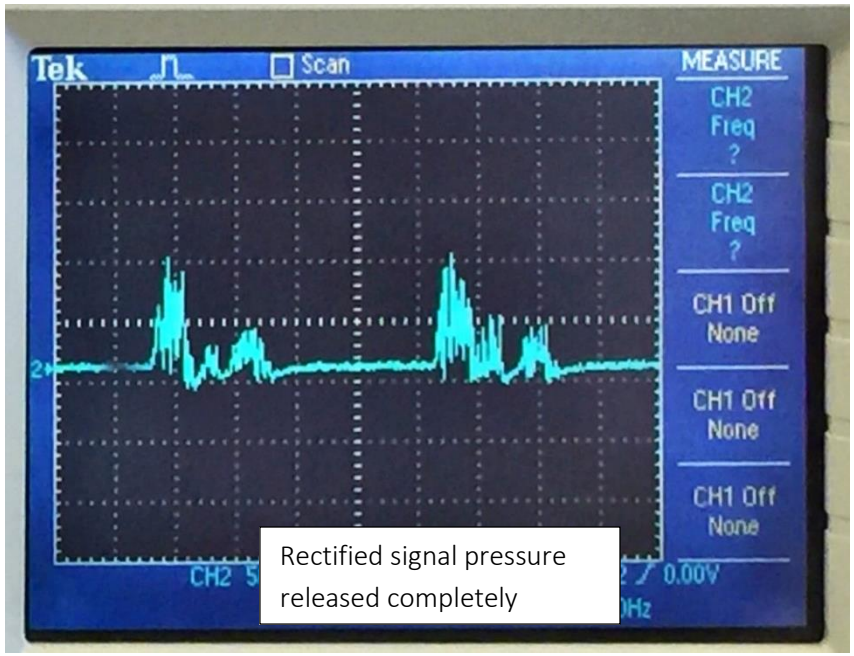
Spikes in the region of systolic pressure

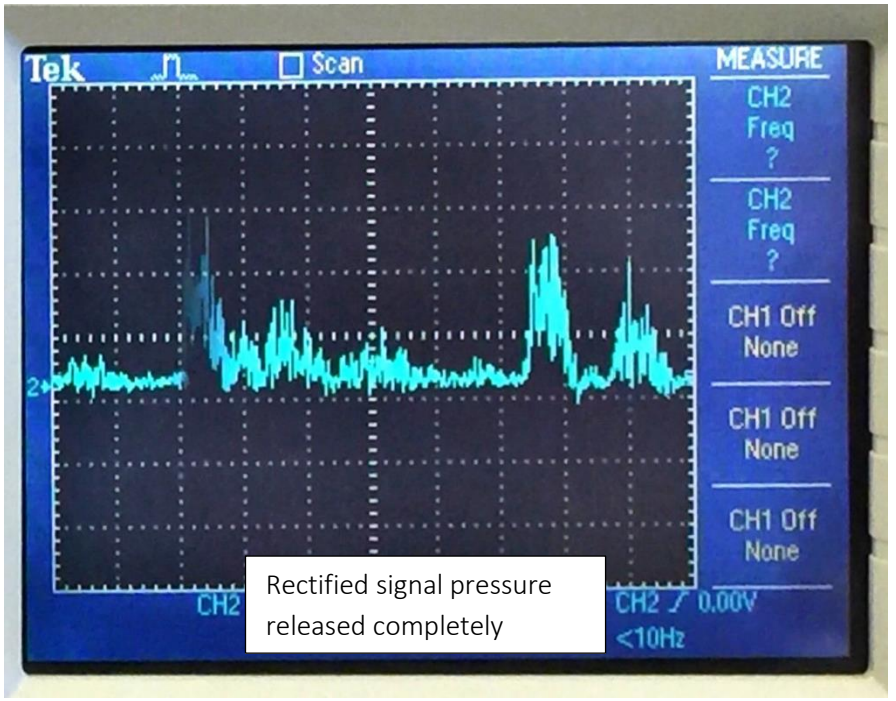


Complete occlusion of the wrist blood flow

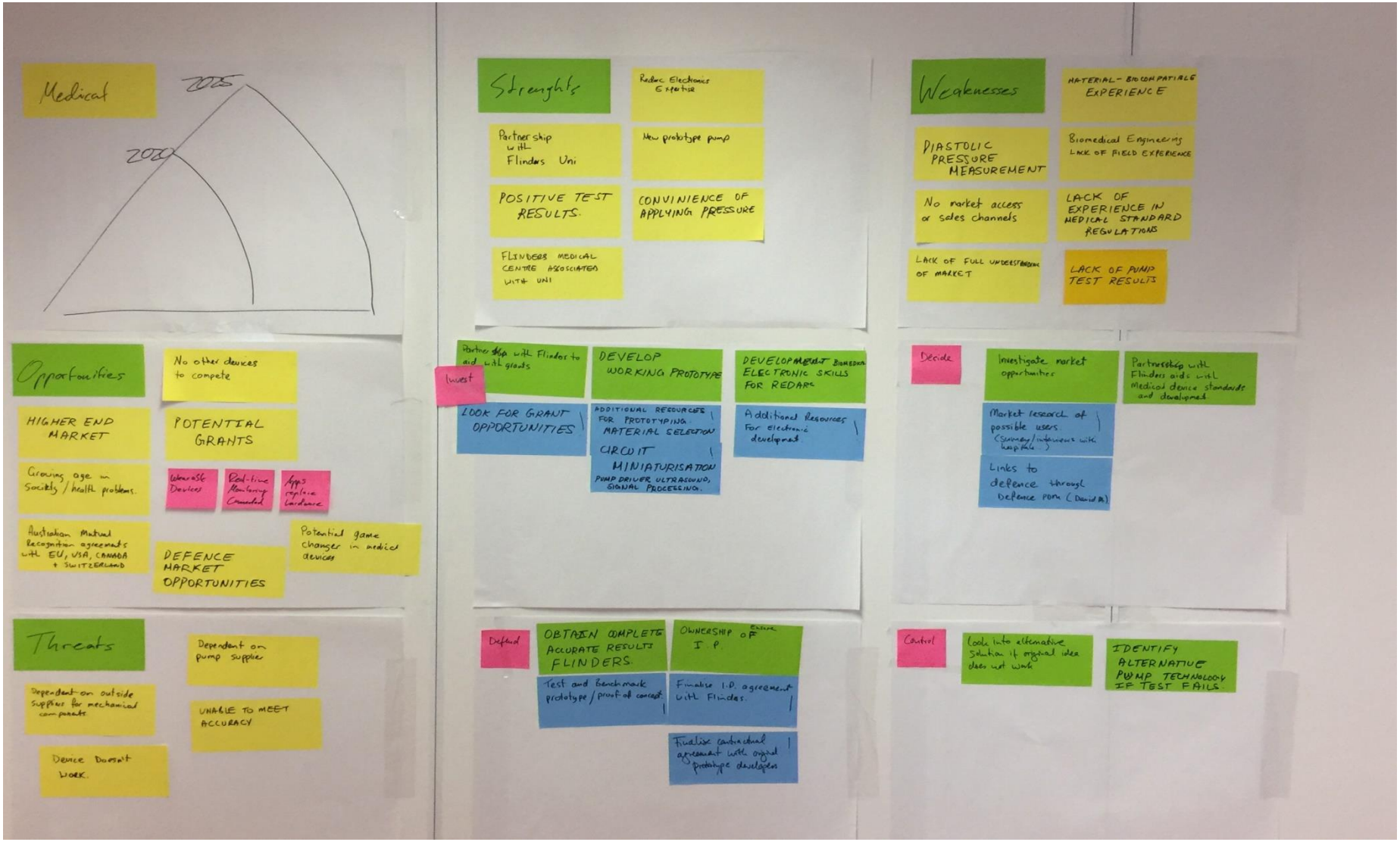


Releasing of pressure


Tek
Scan
MEASURE
CH2
Freq
?
CH2
Freq
?
CH1 Off
None
CH1 Off
None
CH1 Off
None
CH2
0.00V
Rectified signal pressure released completely


Tek
Scan
MEASURE
CH2
Freq
?
CH2
Freq
?
CH1 Off
None
CH1 Off
None
CH1 Off
None
CH2
CH2
0.00V
<10Hz
Rectified signal pressure released completely

APPENDIX E – SWOT ANALYSIS (FUTURE WORKS)



APPENDIX F –

1. *MICROCONTROLLER COMPARISON*

Microcontroller	Processor	Bits	Digital/Analog IO Pins	Operating Voltage/Input Voltage	DC Current I/O Pin	RAM	EEPROM	Clock Cycle	Programming Language	Connection	Board Dimension
Arduino Uno	ATMEGA 328P	8	14/6	5V, 7-12V	20mA	2KB	1KB	16MHz	C, C++	I2C, SPI, USB	68.6x53.4mm
Arduino Mega	ATMEGA 2560	8	54/16	5V, 7-12V	20mA	8KB	4KB	16MHz	C, C++	I2C, SPI, USB	101.52x53.3mm
Arduino Lily pad	ATMEGA 328V	8	14/6	2.7-5.5V, 2.7-5.5V	40mA	1KB	16KB	16MHz	C, C++	I2C, SPI, USB	Circular 5mm diameter
Raspberry Pi	Broadcom BCM2837 Arm7	32/64	40 pin GPIO	4.75-5.25V, 4.75-5.25V	2A	1GB LPDDR2	Micro-SD	900MHz	Python	I2C, SPI, USB	85x56mm
PCduino	Allwinner H3, Quad-core Cortex-A7	32/64	40 pin GPIO	5V, 5V	2A	1GB DDR3	Micro-SD	600MHz	Java, Python	UART, SPI, I2C	64x56mm
Chipkit uC32	Microchip PIC32MX-340F512H	32	42/12	3.3V, 7-15V	75mA	32KB	512KB	80MHz	C	UART, SPI, I2C	68x53mm

2. Probable Ultrasound Flow Meters

Device	Company	Frequency	Output Type	Other Features	Cost	Reference
Bi-directional Doppler ES-100V3	Hadeco		USB Interface	• Portable • Battery Operated • Blood Flow calculation • Realtime waveform display	On quote	[105]
Minidop ES-100VX	Hadeco	5,8, 10 MHz	Audio Speaker 300 mW	Portable Battery Operated	On Quote	
Smart Dop 45	Warner & Webster Pty LTd	2,4,8,10 MHz	Speaker Output: 200 mW	Portable Numerical Data Transfer to computer through USB Interface Battery Operated	$1,995 ex GST	[106]
DVM 4500	Hadeco	4, 5, 8, 10 and 20 MHz	Waveform storage	Spectrum formation Zero Cross Counter Measurable vessel diameter: 0.1-20mm FFT Analyser	On quote	[107]
BV 520	Bestman	8 MHz ± 10%	Speaker output	LCD TFT Displat	US $729	[108]
DP M350	Cook Medical	20 MHz	Speaker out	Variable transducer size	On quote	[127]

APPENDIX G – BILL OF MATERIALS

Electronic PCB Components

Comment	Description	Designator	Footprint	Quantity
100n	1206 100n 100V +10% -10% X7R 0mm	C1, C2, C3, C5, C7, C11	1206_CAP_1.6	6
1u	1206 1u 25V +10% -10% X7R 0mm	C4, C6	1206_CAP_1.2	2
22u	1206 22u 25V +20% -20% X5R	C8	1206_CAP_1.6	1
680p	0805 680p 50V +1% -0% 0mm	C9	0805_CAP > 1mm	1
4u7	1210 4u7 50V +10% -0% 0mm	C10	1210_CAP_2.5	1
CON	15 PIN INLINE THROUGH HOLE CONNECTOR	CON1, CON2	footprint	2
PMEG6020AELRX	DIODE SCHOTTKY 60V 2A	D1	SOD-123W_POL	1
LED (Red)	SMD LED RED 0603	D2, D3	LED_0603	2
10uH	INDUCTOR 10uH 30% SMD 5028	L1	IND-SRR5028	1
PS_DAQ_OUT	Header, 2-Pin, Right Angle	P1	HDR1X2H	1
Header 11	Header, 11-Pin	P2	HDR1X11	1
FMMT497		Q1, Q2	SOT23	2
MMBTA92	PNP MMBTA92 SOT-23	Q3	SOT23	1
33K	1206 33k 1.000% 0.250W	R1, R9	1206_RES	2
6K8	0805 6k8 1.000% 0.125W	R2, R6	0805_RES	2
2K2	1206 2k2 1.000% 0.250W	R3, R7, R8, R11, R23	1206_RES	5
100R	1206 100R 1.000% 0.250W	R4	1206_RES	1
3K3	0805 3k3 1.000% 0.125W	R5	0805_RES	1
0R	1206 0R 1.000% 0.250W	R10, R13, R15, R16	1206_RES	4
12K	0805 12k 1.000% 0.125W	R12	0805_RES	1
10k	1206 10k 1.000% 0.250W	R14	1206_RES	1
Res3	Resistor	R18, R19	6-0805_L	2
1k	RESISTOR 1206 1k 1% 0.25W	R20	1206_RES	1
2K7	1206 2k7 1.000% 0.250W	R21	1206_RES	1
4K7	1206 4k7 1.000% 0.250W	R22	1206_RES	1
39K	1206 39k 1.000% 0.250W	R24	1206_RES	1
Res3	Resistor	R25, R26, R27, R29, R30, R31	1206_RES	6
10K	1/4" SQUARE TRIMMING 10K POTENTIOMETER	RV2	RV17	1
LMV358	IC Dual Op-Amp	U1, U3	SO8	2
TL431CD	Programmable Precision Reference	U2	SO8	1
LM2733XMF/NOPB	0.6/1.6 MHz Boost Converters With 40V Internal FET Switch in 5-pin SOT-23, Pb-Free	U4	MF05A_N	1
LM3480IM3X-3.3	100 mA, Quasi Low-Dropout Linear Voltage Regulator, 3-pin SOT-23	U5	MF03A_N	1
Header 4- PS	Header, 4-Pin	Y1	HDR1X4	1
Square Wave Output	Header, 2-Pin	Y5	HDR1X2	1

Bill of Materials

Part	Quantity	Price	Source	Comment
Mechanical				
3D Printed Parts		$ 20.00	Bilby 3D	$15/250g
Dowel Pins	2		Machined	
Brass Bush	2		Machined	
Servo	2	$ 9.95	Jaycar	
Piezoelectric Micropump	5	$ 100.00	KOGE	
Blood Pressure Pump	1	$ 10.00	Alibaba	
Timing Belt	2	$ 10.89	RS Components	
Pulley (Blinds)	2	$ 4.50	Bunnings	
M2 Screws	100	$ 5.53	RS Components	Bag of 100
M3 Screws Zinc Plated	10	$ 3.87	RS Components	
M4 Screws	1	$ 0.05	RS Components	
Tubing	10	$ 10.00	Bunnings	
Solenoid Valve 12V	1	$ 12.00	Jaycar	
Pressure Chamber	1	$ 2.00	eBay	
Pressure Leak Valve	2	$ 5.00	eBay	
Velcro Tape	1	$ 10.39	Bunnings	
Wire Wound Insulation	1	$ 12.00	Jaycar	
Laser Cut Cover			University Fabrication Lab	
Aquaflex Ultrasound Pad	5	$ 53.00	eBay	
Electronics				
Pressure Sensor MPX2050	2	$ 37.20	Mouser	
PCB Board (Sensor Driver)	5	$ 127.00	PCB Way	
Jumper Wires		$ 20.00	Jaycar	
Arduino Nano	1	$ 29.95	Jaycar	
Bluetooth HC-06	1	$ 19.95	Jaycar	
Bread Board	2	$ 10.00	Jaycar	
Arduino TFT Display	1	$ 15.95	Jaycar	
Arduino DC-DC Booster	1	$ 19.95	Jaycar	
AA Li-Ion	1	$ 4.95	Jaycar	
AA Battery Cover	2	$ 12.00	Jaycar	
Veroboard	3	$ 10.00	Element 14	
NI DAQ USB 6001	1	$ 358.00	National Instruments	
Tactile Buttons	10	$ 13.95	Jaycar	
Tablet - Pendo Pad 7''	1	$ 50.00	Officeworks	
	Total	**$ 998.08**		

APPENDIX H – CODE

1. *PUMP CODE*

```
boolean toggle0 = 0;

void setup(){

  //set pins as outputs

  //pinMode(7, OUTPUT);
  DDRD = B01000000;
  cli();//stop interrupts

//set timer0 interrupt at 2kHz
  TCCR0A = 0;// set entire TCCR2A register to 0
  TCCR0B = 0;// same for TCCR2B
  TCNT0  = 0;//initialize counter value to 0
  // set compare match register for 2khz increments
  OCR0A = 5;// = (16*10^6) / (2000*64) - 1 (must be <256)
  // turn on CTC mode
  TCCR0A |= (1 << WGM01);
  // Set CS01 and CS00 bits for 64 prescaler
  TCCR0B |= (1 << CS01) | (1 << CS00);
  // enable timer compare interrupt
  TIMSK0 |= (1 << OCIE0A);

sei();//allow interrupts

}//end setup

ISR(TIMER0_COMPA_vect){//timer0 interrupt 2kHz toggles pin 8
  if (toggle0){
    PORTD = B01000000;
    //digitalWrite(7,HIGH);
    toggle0 = 0;
  }
  else{
    PORTD = B00000000;
    //digitalWrite(7,LOW);
    toggle0 = 1;
  }
}


void loop(){
  //do other things here
}
```

2. ARDUINO CODE

//declaring the libraries	Comments
#include <TFT.h> // Hardware-specific library #include <SPI.h> #include<Servo.h> #include<SoftwareSerial.h>	Declaring the libraries for the TFT display, SPI Control, Servo Control and Bluetooth communication

//Object definitions for the servos
Servo servo1; // servo for the lateral motion
Servo servo2; // servo for the proximal-distal motion
	Defining servo objects

int servo_1 = 6; int servo_2 = 19;	Defining Servo pins
//bluetooth control #define TX 4 //bluetooth transmitter #define RX 5 //bluetooth receiver SoftwareSerial bluetooth(TX, RX);	Declaring the pins for the Bluetooth communication for the Tx and Rx
//TFT screen #define CS 10 #define DC 9 #define RESET 8	Declaring the SPI pins for the communication with the LCD screen

int pressure_sensor = A0; //analog input pressure sensor
int solenoid_interrupt = 3; // digital input solenoid valve
int solenoid = 15;
//int button_pin = 2;
int pump_pin = 12; //pump control based on the signal received from pin 5
volatile byte state = LOW;
	Connecting the pressure sensor to the analogue pin A0
	Button and solenoid valve pin declaration

TFT myScreen = TFT(CS, DC, RESET); char printout[6]; char pump_output[3]; void setup() {	Defining the object for the TFT screen display

//setup for the lcd screen
myScreen.begin();
myScreen.background(0, 0, 0); // clear the screen with black
myScreen.stroke(255, 0, 0);
myScreen.setTextSize(2);
myScreen.text("Pressure", 15, 5);
myScreen.text("Pump: ", 15, 50);
myScreen.text("Valve: ", 15, 95);
delay(1000); // pause for dramatic effect
 	
Serial.begin(9600);
	Initialisation command for the screen display, begin command for the Bluetooth and the serial output with a baud rate of 9600

```
  bluetooth.begin(9600);

  servo1.attach(servo_1);
  servo2.attach(servo_2);
  pinMode(solenoid, OUTPUT);
  pinMode(pump_pin, INPUT);
  pinMode(solenoid_interrupt, INPUT_PULLUP);

attachInterrupt(digitalPinToInterrupt(solenoid_interrupt),
solenoid_method, RISING);
  //attachInterrupt(digitalPinToInterrupt(button_pin),
pump_state, RISING);

}

void loop() {

  //receiving data from the phone application to move it
into the servos
  if (bluetooth.available())
  {
    unsigned int servopos = bluetooth.read();
    //int servoposmap = map(servopos, 232, 155, 0, 255);
    //Serial.println(servopos);
    unsigned int servopos1 = bluetooth.read();
    unsigned int realservo = (servopos1 * 256) +
servopos;
    //Serial.println(realservo);

    if (realservo >= 1000 && realservo < 1180) {
      int servo_pos3 = realservo;
      //Serial.println(servo_pos3);
      servo_pos3 = map(servo_pos3, 1000, 1180, 0, 180);
      servo1.write(servo_pos3);
      //Serial.println("servo 1 ON");
      delay(10);
    }

    if (realservo >= 2000 && realservo < 2180) {
      int servo_pos2 = realservo;
      //Serial.println(servo_pos2);
      servo_pos2 = map(servo_pos2, 2000, 2180, 0, 180);
      servo2.write(servo_pos2);
      //Serial.println("servo 2 ON");
      delay(10);
    }
  }

  //sending data to the phone application
  else {
    if (digitalRead(pump_pin) == HIGH) {
      //Serial.println("Pump ON");
      //Serial.println(analogRead(pressure_sensor));
```

Attaching the pins for the servo declared to the servo object

Declaring solenoid pin as the output, and the button pins as the input
Solenoid button is declared as input pullup

Attaching the interrupt to the for the rising edge of the solenoid pin

Commencement of the main loop

Check condition if the Bluetooth is receiving anything in the receiver end.
If something is available then:

The 2- Bytes sent from the app is read

The 2-Bytes are read again to a different variable
Variable Servopos1 is shifted by 8 bits to the MSB and the initial value read is added to create a 16 bit value

If the value read is greater than 1000 or less than 1180 then, the mapping is done so that 1000 is read as 0^0 and 1180 is mapped as 180^0

This bit is for the second servo which was redundant for the time being
But here, if a value of 2000 to 2180 is available, only the value for second servo is mapped

If no data is available for the Bluetooth, then the pressure value which is being read from the pressure sensor is

float pressure_value = 0.4126 * (analogRead(pressure_sensor)) - 86.206;
 	
//add the pressure conversion factor to this
bluetooth.print(" ");
bluetooth.println(pressure_value);
//delay(1000);
 	
String pressure = String(pressure_value);
 	
pressure.toCharArray(printout, 6);
// print out and erase
 	
myScreen.stroke(255, 255, 255);
myScreen.text(printout, 45, 25);
myScreen.stroke(255, 255, 255);
myScreen.text("ON ", 80, 50);
 	
delay(1000);
 	
myScreen.stroke(0, 0, 0);
myScreen.text(printout, 45, 25);
myScreen.stroke(0, 0, 0);
myScreen.text("ON ", 80, 50);
}
	converted to mmHg from a 10-bit number
	
	The value is sent over the Bluetooth transmitter to be displayed in the application screen
	
	Here the array is set to fix a size on the screen area where the values will be printed
	
	The background colour is set to black
	The coordinates are set to printout the pressure value
	
	The coordinates are set to print the value of the state of the pump
	
	After a delay of 1 second
	The values are reset to 0 to be cleared off the screen so they don't overwrite the values

else if (digitalRead(pump_pin) == LOW) {
//Serial.println("Pump OFF");
Serial.println(analogRead(pressure_sensor));
float pressure_value = 0.4126 * (analogRead(pressure_sensor)) - 86.206;
 	
//add the pressure conversion factor to this
bluetooth.print(" ");
bluetooth.println(pressure_value);
//delay(1000);
 	
String pressure = String(pressure_value);
 	
pressure.toCharArray(printout, 6);
// print out and erase
 	
myScreen.stroke(255, 255, 255);
myScreen.text(printout, 45, 25);
myScreen.stroke(255, 255, 255);
myScreen.text("OFF", 80, 50);
 	
delay(1000);
 	
myScreen.stroke(0, 0, 0);
myScreen.text(printout, 45, 25);
myScreen.stroke(0, 0, 0);
myScreen.text("OFF", 80, 50);
}
	This section is for when the pump is not on to repeat the previous steps for displaying

}
 	
//add condition to check the emergency opening of the solenoid valve
//provided pressure is greater than 200mmHg
 	
}
 	
void solenoid_method() {
myScreen.stroke(0, 0, 0);
myScreen.text("CL", 90, 95);
 	
myScreen.stroke(0, 0, 0);
myScreen.text("OP", 90, 95);
state = !state;
digitalWrite(solenoid, state);
if (state) {
myScreen.stroke(255, 255, 255);
myScreen.text("CL", 90, 95);
 	
delay(1000);
// myScreen.stroke(255,255,255);
// myScreen.text("OPEN", 80, 95);
}
 	
else {
// myScreen.stroke(0,0,0);
// myScreen.text("CLOSE", 80, 95);
delay(1000);
myScreen.stroke(255, 255, 255);
myScreen.text("OP", 90, 95);
}
}
	A method checking the interrupt for printing the state of the solenoid valve

3. MATLAB CODE

```
function [plotting, data] = spectrogram_file(x)
plotting = getplot(x);                %plotting of the signal
data = getdata(x);           %processing the data
%processing = getprocessing(x);

%%
%plotting of the spectrogram and pressure curves
function plotting = getplot(x)
n = x;
for numberofsubs = 1
    sampling_time = 1/10000;
    sampling_frequency = 10000;

    formatSpec = '%C%f%f';           %format of reading the text file
    a = num2str(numberofsubs);
    concat_value = strcat(a,'.txt');  %combine the file value
    Table = readtable(concat_value,'Delimiter','tab','Format',formatSpec);
    Table(:,'Var1') = [];                %deleting first row of data
    Table = table2array(Table);              %creating double array out of
the table
    voltage = Table(:,1);
    pressure = Table(:,2);
    time = 0:sampling_time:(length(Table)-1)*sampling_time;
    time = time/60;                          %taking the transpose of the
matrix

    %%
    %Filtering the pressure signal output with low pass filter
    b = fir1(500,0.01, 'low');
    %wn = 5/(sampling_frequency/2);
    %fvtool(b,1,'Fs', fs)
    a = 1;
    y = filter(b,a,pressure);
    %plot(time, y);
    sampled_data = horzcat(time', voltage, y);

    %%
    %plotting the pressure
    figure(numberofsubs);
    ax(1) = subplot(3,2,[1,2]);

    %getting the values from the data function
    recorded_pressure = getdata(numberofsubs);
    SBP = recorded_pressure(1);
    DBP = recorded_pressure(2);

    index = y>SBP-0.001 & y<SBP+0.001;
    time_des = time(index);

    %plot(time_des, SBP,'r*');
    sbp_data_array = time_des';
    sbp_data_array(1:length(time_des),2:2) = (repmat(SBP, [1,
length(time_des)]))';

    index1 = y>DBP-0.001 & y<DBP+0.001;
    time_des1 = time(index1);
```

```
    %plot(time_des1, DBP,'r*');
    dbp_data_array = time_des1';
    dbp_data_array(1:length(time_des1),2:2) = (repmat(DBP, [1,
length(time_des1)]))';

    %sorting of the data
    sbpdbp = vertcat(dbp_data_array, sbp_data_array);
    sorted_time_index = sbpdbp(:,1);
    [sortedX, sortIndex] = sort(sorted_time_index);
    y_sorting = sbpdbp(:,2);
    sorted_Y_values = y_sorting(sortIndex);

    combined_pressure_points = horzcat(sortedX, sorted_Y_values);
    n = 1;
    while(n < length(combined_pressure_points+1))
        if(sorted_Y_values(n + 1) - sorted_Y_values(n) == DBP-SBP)
            ac_DBP_timestamp = sortedX(n+1);
            ac_DBP = sorted_Y_values(n+1);

            ac_SBP_timestamp = sortedX(n);
            ac_SBP = sorted_Y_values(n);
        end
        n = n+1;
    end
    measured_timestamps = vertcat(ac_DBP_timestamp, ac_SBP_timestamp);
    measured_pressures = vertcat(ac_DBP, ac_SBP);

    combined_measured_pressures = horzcat(measured_timestamps,
measured_pressures);

    plot(measured_timestamps, measured_pressures, 'r*');
    hold on
    plot(time,y);              %time domain plotting

    xlabel('time (minutes)');
    ylabel('pressure (mmHg)');
    xlim([0 length(time)/(60*10000)])

    hsp1 = get(gca, 'Position');          %getting the position components
of plot

    %spectrogram development
    ax(2) = subplot(3,2,[3,4]);
    window_size = 1000;
    noverlap = 900;
    [~,~,~] = spectrogram(voltage, window_size, noverlap, [],
sampling_frequency, 'yaxis');
    %spectrogram(voltage, window_size, noverlap, [], sampling_frequency,
'yaxis');
    spectrogram(voltage, window_size, noverlap, [], sampling_frequency,
'MinThreshold', -100, 'yaxis')
%     [~,~,~,pxx,fc,tc] =
spectrogram(voltage,window_size,noverlap,[],sampling_frequency, ...
%     'MinThreshold',-50);
%     plot(tc(pxx>0),fc(pxx>0),'.')
    hsp2 = get(gca, 'Position');         %getting the position components of
spectrogram

    set(gca, 'Position', [hsp2(1) hsp2(2) hsp1(3)  hsp1(4)])    %setting
```

```
same width
    %time1 = 0:sampling_time:(length(t)*sampling_time*100)+((length(time)-
length(t)*100)*sampling_time);
    linkaxes(ax, 'x');

    values = sampled_data;
    j1 = combined_measured_pressures(:,1);
    j2 = combined_measured_pressures(:,2);
    values(1:numel(j1), 4) = j1;
    values(1:numel(j2), 5) = j1;
    %values(1:numel(i),6) = i;

    %%
    %power spectrum around systolic and diastolic
    experimental_data = values;

    timestamps = experimental_data(:,4);
    diastolic_timestamp = timestamps(1);
    systolic_timestamp = timestamps(2);

    time_vector = experimental_data(:,1);
    voltage_vector = experimental_data(:,2);
    pressure_vector = experimental_data(:,3);

    %getting the range around the systolic and diastolic mark
    systolic_time_vector_indices = find(time_vector>0.9*systolic_timestamp
& time_vector<1.1*systolic_timestamp);
    systolic_time_vector = time_vector(systolic_time_vector_indices);

    systolic_voltage_vector = voltage_vector(systolic_time_vector_indices);

    %doing the fft of the function around 0.9-1.1 SBP
    Y_sys = fft(systolic_voltage_vector);
    %mag_Y_sys = abs(Y_sys);
    L_sys = length(systolic_voltage_vector);    %length of the signal
    P2_sys = abs(Y_sys/L_sys);          %two sided spectrum
    P1_sys = P2_sys(1:L_sys/2+1);
    P1_sys(2:end-1) = 2*P1_sys(2:end-1);

    %changing the bin values to frequency
    f_sys = 10000*(0:(L_sys/2))/L_sys;
    f_sys = f_sys';

    subplot(3,2,5);
    spectrogram(systolic_voltage_vector, window_size, noverlap, [],
sampling_frequency, 'yaxis')

%     plot(f_sys,P1_sys);
%     ylabel('Magnitude');
%     xlabel('Frequency (Hz)');
%     ylim([0 0.01]);
%     title('Systolic Spectrum Band')

    diastolic_time_vector_indices =
find(time_vector>0.9*diastolic_timestamp &
time_vector<1.1*diastolic_timestamp);
    diastolic_time_vector = time_vector(diastolic_time_vector_indices);

    diastolic_voltage_vector =
```

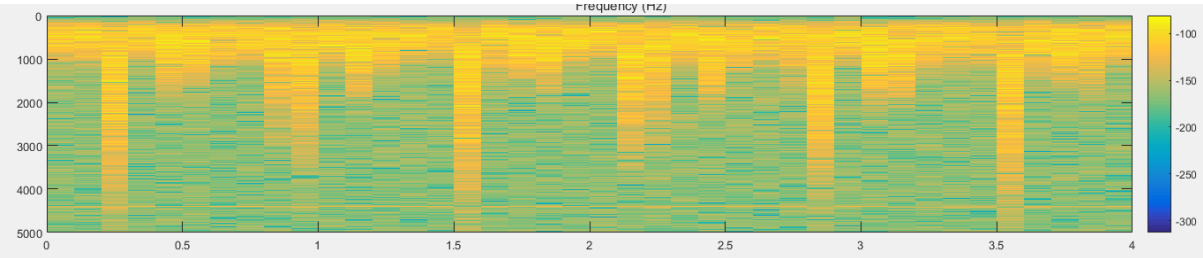
```
voltage_vector(diastolic_time_vector_indices);

    Y_dia = fft(diastolic_voltage_vector);
    %mag_Y_sys = abs(Y_sys);
    L_dia = length(diastolic_voltage_vector);    %length of the signal
    P2_dia = abs(Y_dia/L_dia);          %two sided spectrum
    P1_dia = P2_dia(1:L_dia/2+1);
    P1_dia(2:end-1) = 2*P1_dia(2:end-1);

    %changing the bin values to frequency
    f_dia = 10000*(0:(L_dia/2))/L_dia;
    f_dia = f_dia';

    subplot(3,2,6);
    spectrogram(diastolic_voltage_vector, window_size, noverlap, [],
sampling_frequency, 'yaxis')

%     plot(f_dia,P1_dia);
%     ylabel('Magnitude');
%     xlabel('Frequency (Hz)');
%     ylim([0 0.01]);
%     xlim([0 5000]);
%     title('Diastolic Spectrum Band')
end
plotting = combined_measured_pressures;
%%
%read standard blood pressure file and take the readings from there to
%localise the point on the pressure curve

function data = getdata(x)
numberofsubs = x;
for i = 1:numberofsubs
    filename = 'Testing.xlsx';
    indexnum = num2str(i);
    index_string = strcat(indexnum, ':', indexnum);
    read_file = xlsread(filename, 1, index_string); %reading systolic and
diastolic of people
    systolic = read_file(1);
    diastolic = read_file(2);
    data = [systolic diastolic];
end

%%
%processing function for generating the frequency domain output around the
%systolic and the diastolic pressure

% function processing = getprocessing(x)
% numberofsubs = x;
% for i = 2:numberofsubs
%     %measured_digital_pressure = getdata(i);
%
%     experimental_data = getplot(i);
%
%     timestamps = experimental_data(:,4);
%     diastolic_timestamp = timestamps(1);
%     systolic_timestamp = timestamps(2);
%
%     time_vector = experimental_data(:,1);
%     voltage_vector = experimental_data(:,2);
%     pressure_vector = experimental_data(:,3);
```

```
%
%     %getting the range around the systolic and diastolic mark
%     systolic_time_vector_indices =
find(time_vector>0.9*systolic_timestamp &
time_vector<1.1*systolic_timestamp);
%     systolic_time_vector = time_vector(systolic_time_vector_indices);
%
%     systolic_voltage_vector =
voltage_vector(systolic_time_vector_indices);
%
%     %doing the fft of the function around 0.9-1.1 SBP
%     Y = fft(systolic_voltage_vector);
%     mag_Y = abs(Y);
%     L = length(systolic_voltage_vector);    %length of the signal
%     P2 = abs(Y/L);          %two sided spectrum
%     P1 = P2(1:L/2+1);
%     P1(2:end-1) = 2*P1(2:end-1);
%
%     %changing the bin values to frequency
%     f = 10000*(0:(L/2))/L;
%     f = f';
%     processing = f;
%     processing(1:numel(P1),2) = P1;
% end
```

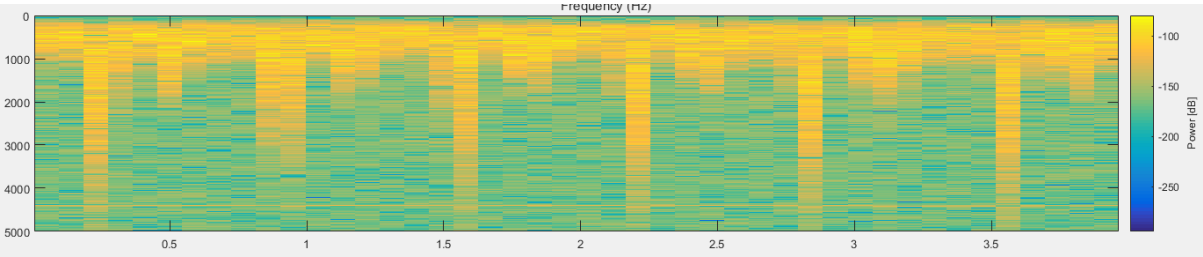
4. *Prelim Signals – Different sizes of Overlapping*

A clearer signal is obtained as the overlap was increased from 0% to 90%. This helped in the better analysis of the data.

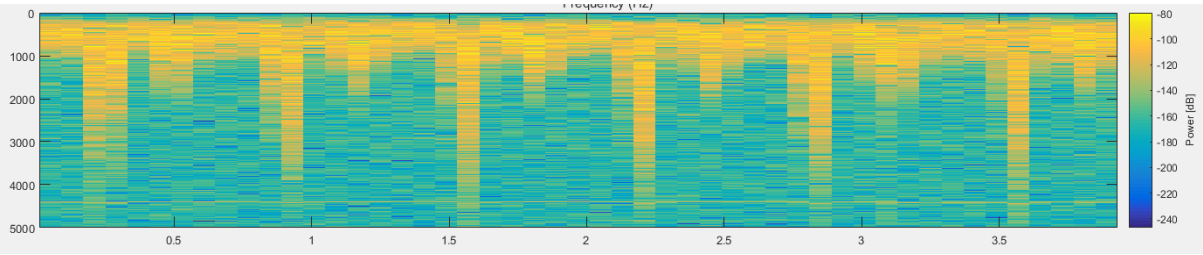
1. 0% Overlap



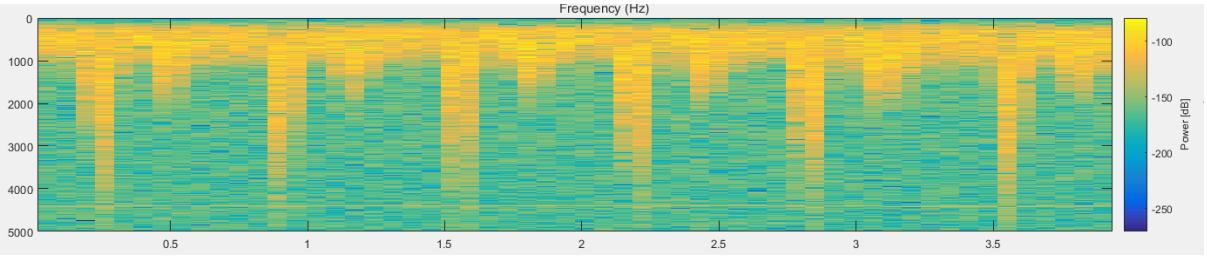
2. 10% overlap



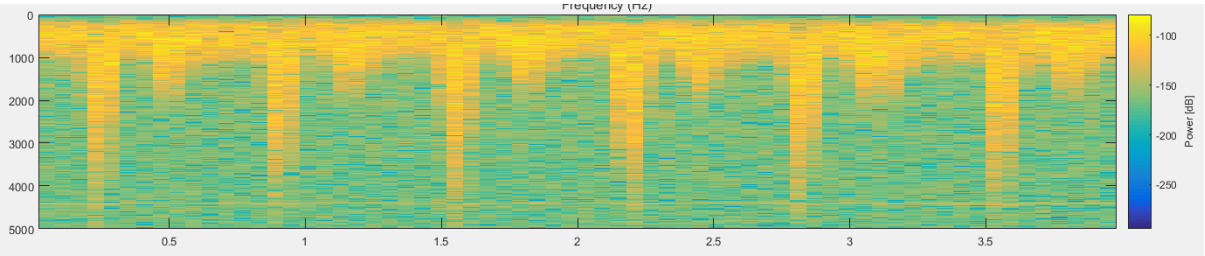
3. 20% overlap



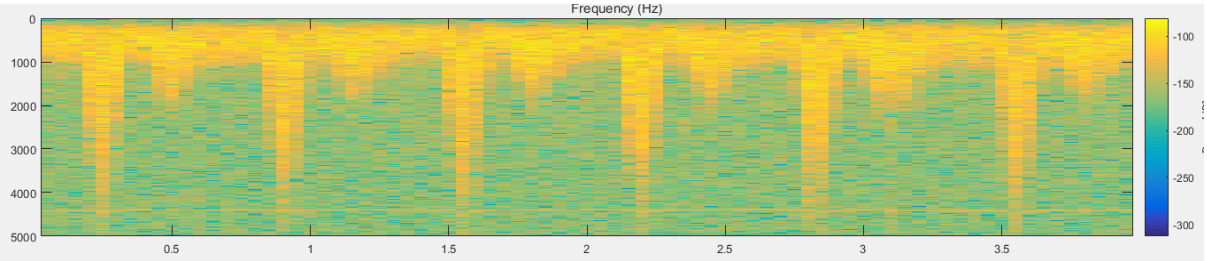
4. 30% overlap



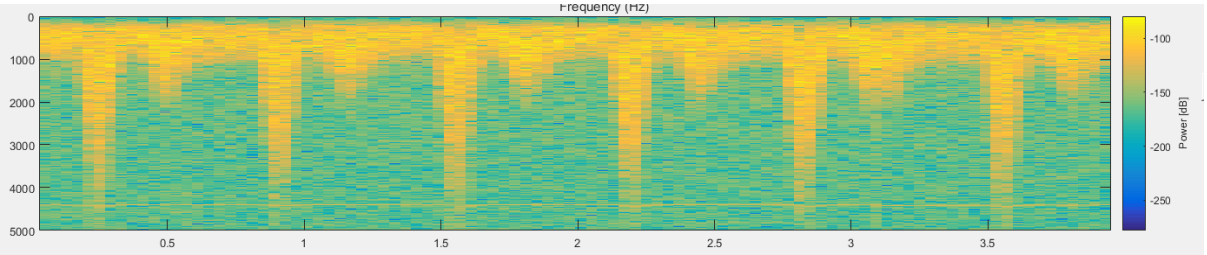
5. 40% overlap



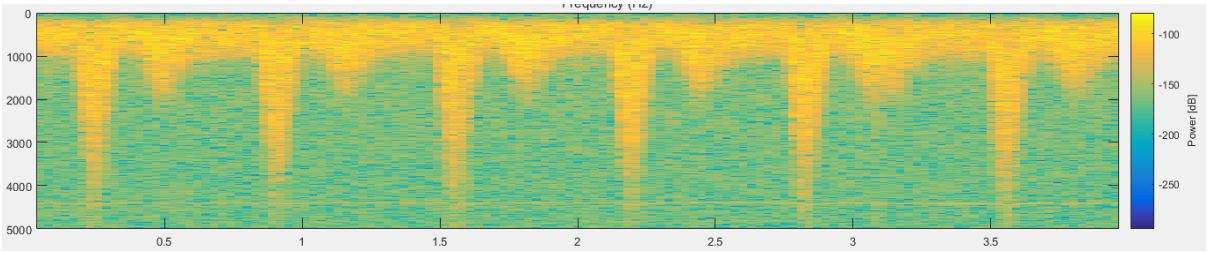
6. 50% overlap



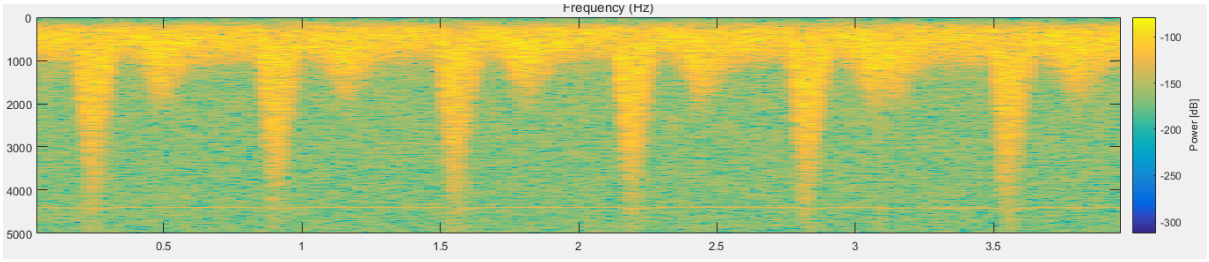
7. 60% overlap



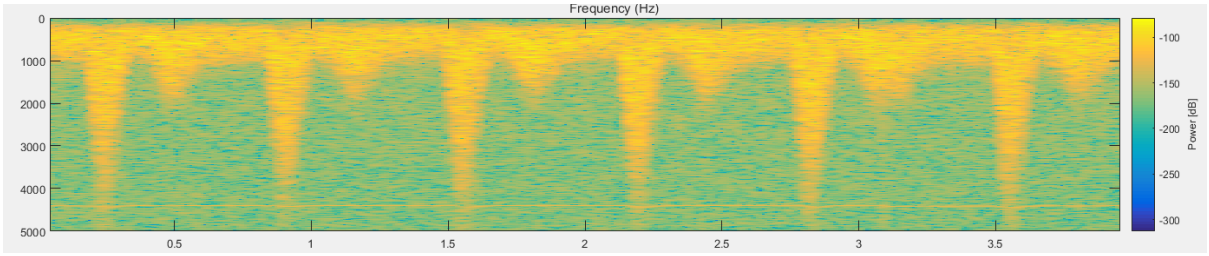
8. 70% overlap



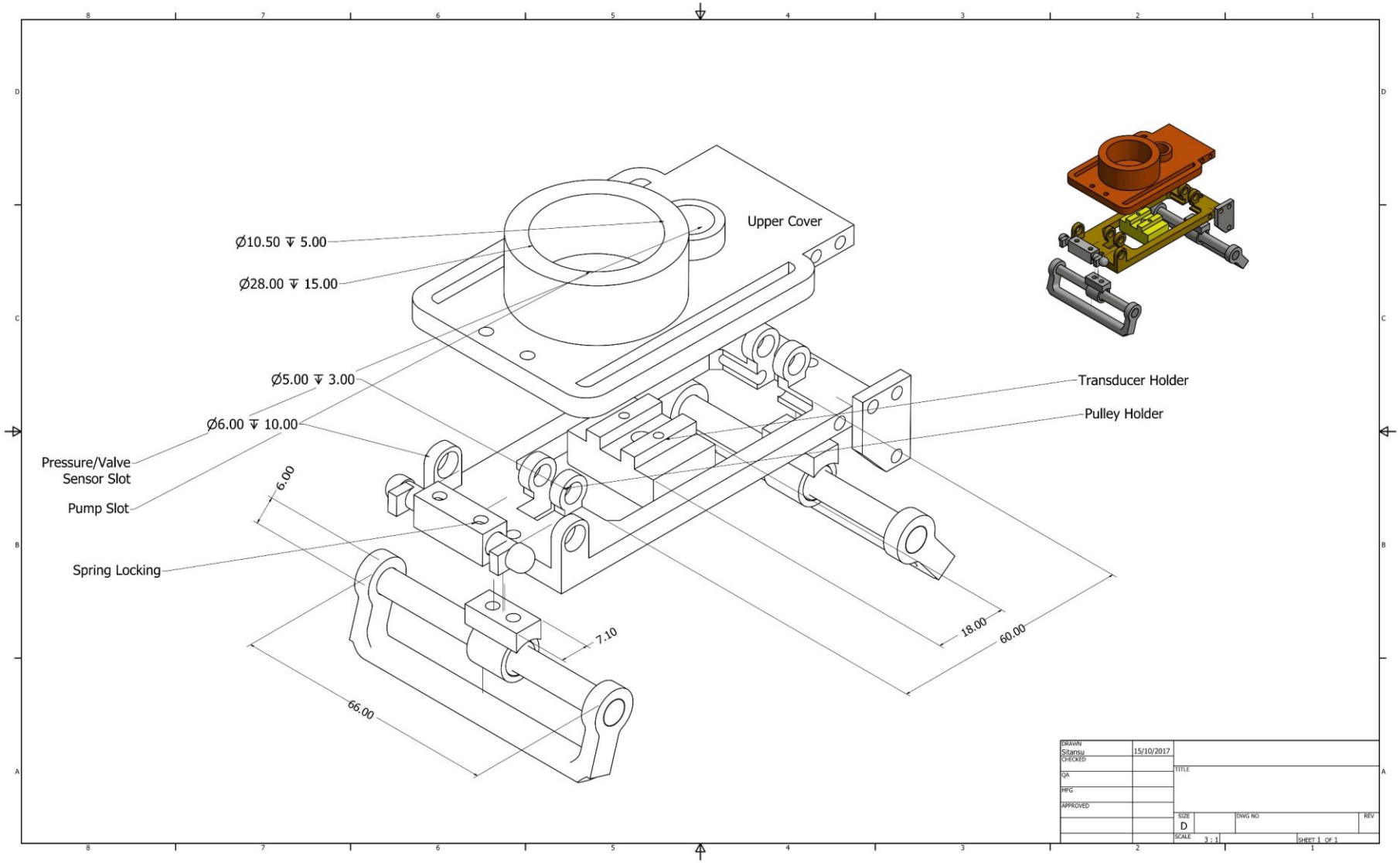
9. 80% overlap

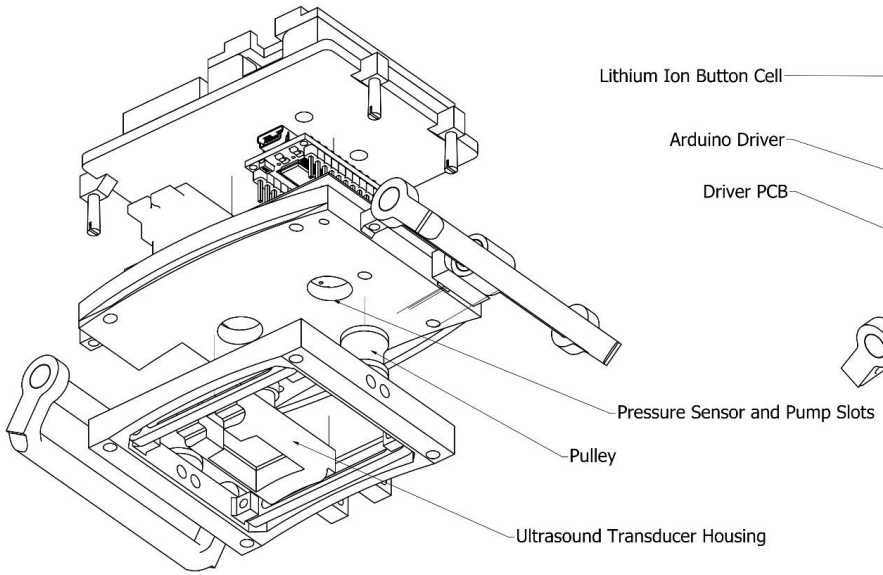


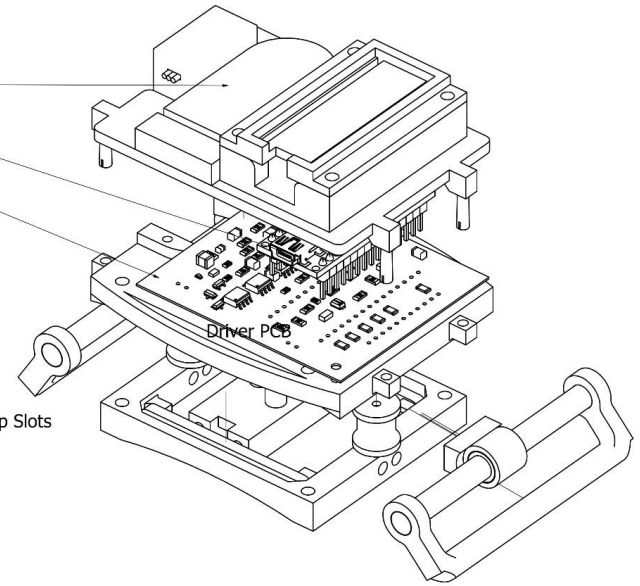
10. 90% overlap

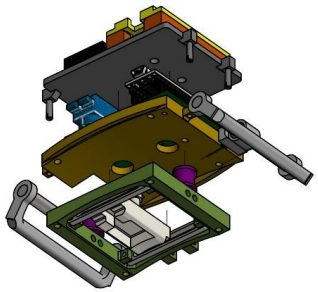


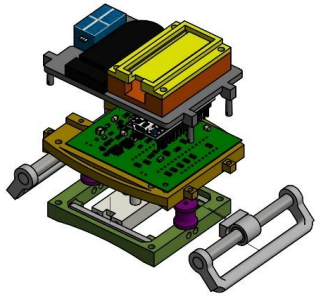
APPENDIX I – CAD DRAWINGS



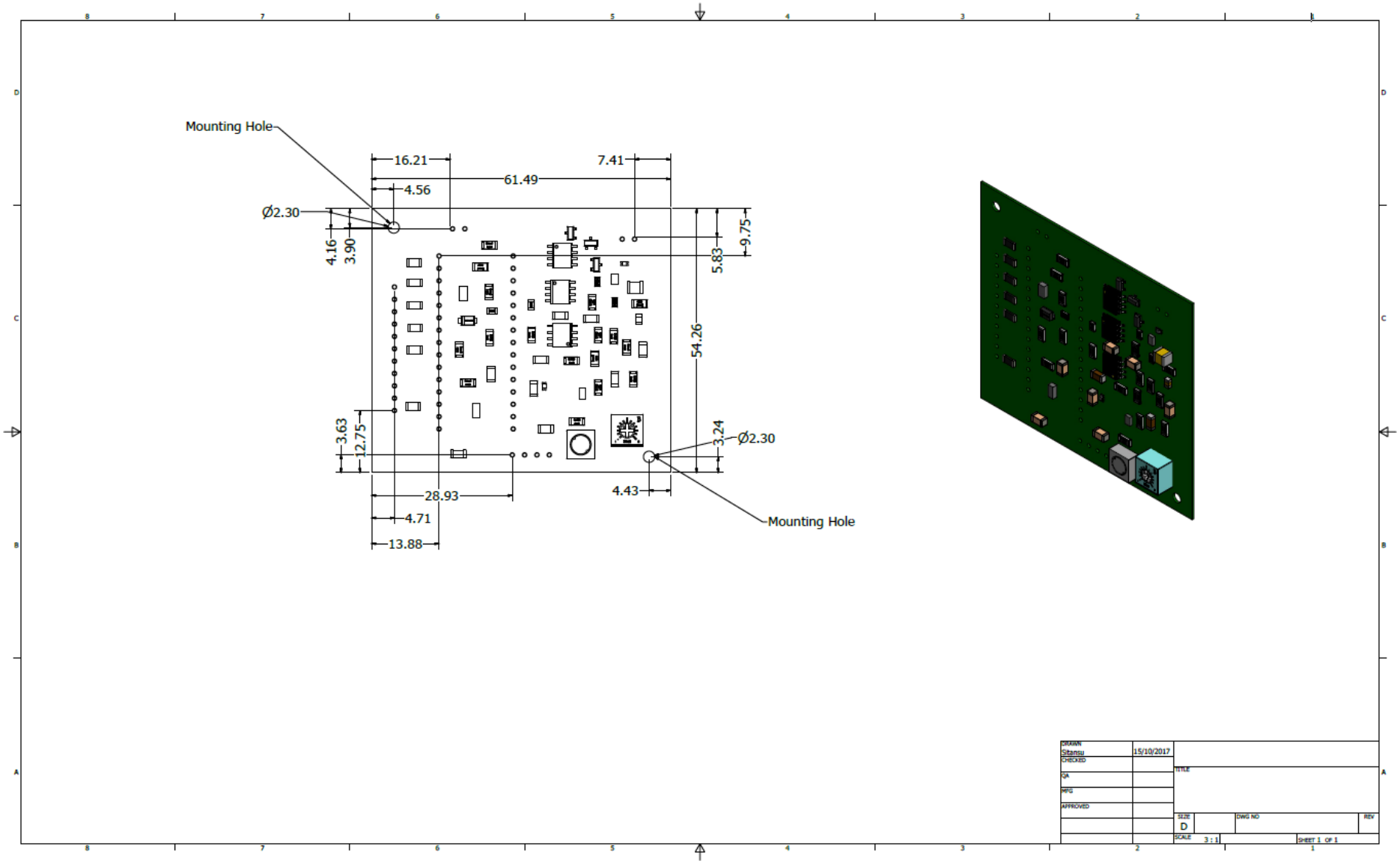


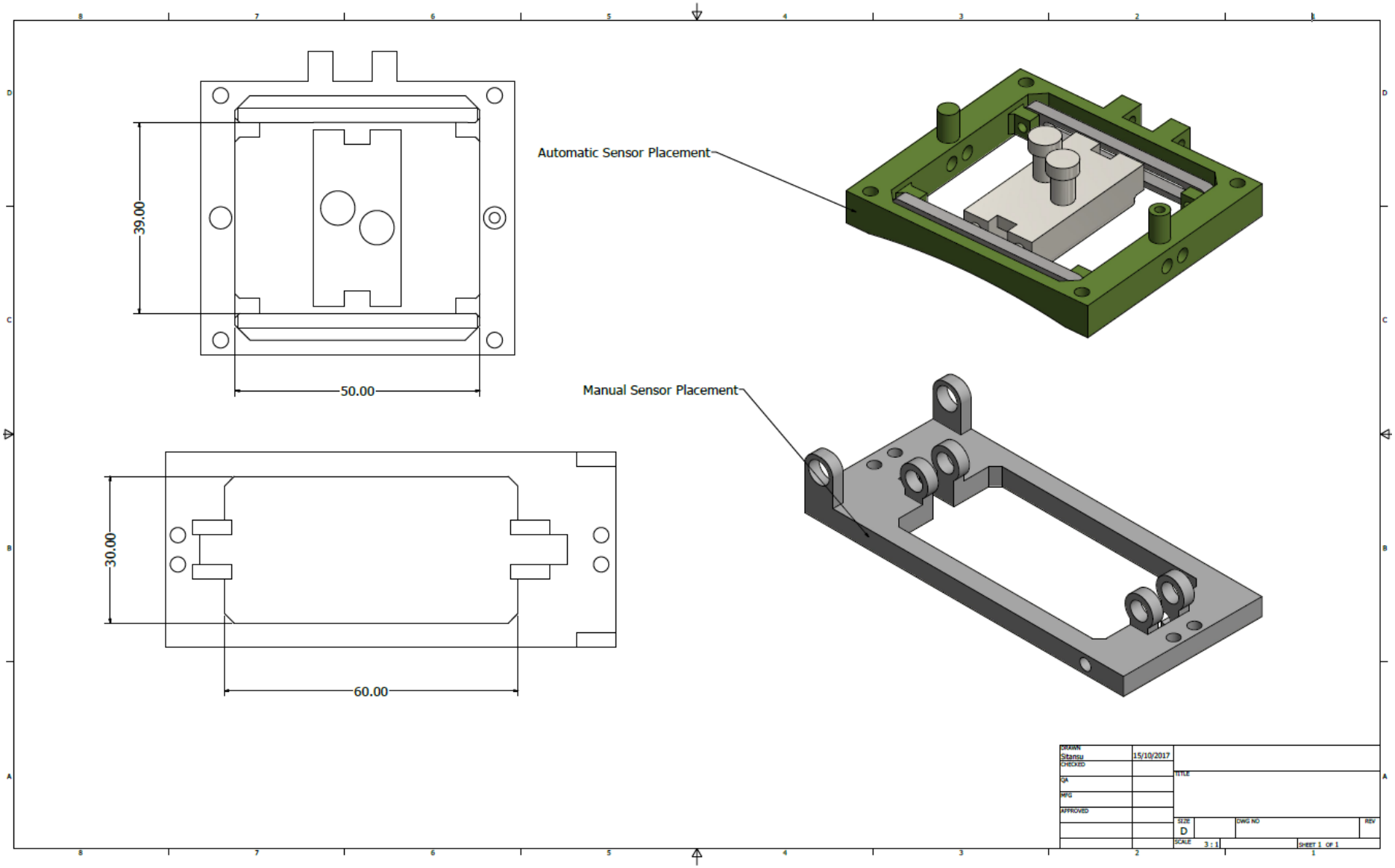






DRAWN Sitansu	15/10/2017		
CHECKED		TITLE	
QA			
MFG			
APPROVED		SIZE D	DWG NO / REV
		SCALE 2 : 1	SHEET 1 OF 1


Mounting Hole
16.21
61.49
7.41
4.56
Ø2.30
4.16
3.90
9.75
5.83
54.26
3.63
12.75
3.24
Ø2.30
28.93
4.43
4.71
13.88
Mounting Hole
DRAWN
Sitansu
15/10/2017
CHECKED
QA
MFG
APPROVED
TITLE
SIZE
D
DWG NO
REV
SCALE
3 : 1
SHEET 1 OF 1


39.00
50.00
Automatic Sensor Placement
Manual Sensor Placement
30.00
60.00
DRAWN
Sitansu
15/10/2017
CHECKED
QA
MFG
APPROVED
TITLE
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SCALE
3 : 1
SHEET 1 OF 1