ARM SIMULATOR FOR
BLOOD PRESSURE MEASUREMENT

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by

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M. Tech. Dissertation Approval

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ABSTRACT

Arm simulator is an instrument for simulating behavior of the arm during noninvasive measurement of blood pressure (BP). It is used for testing and calibration of BP monitor and can also be used to train healthcare personnel in making correct BP measurements on patients with wide ranging cardiovascular conditions. Objective of this project is to develop an arm simulator for both auscultatory and oscillometric methods of BP measurement and with the facility of setting heart rate, systolic and diastolic pressures, pulse volume, and level of arrhythmia, over a full clinical range. The instrument is in the form of a cylinder around which the cuff of the BP monitor is wrapped. A controller card inside the cylinder senses the air pressure in the cuff and mimics the behavior of an arm by generating Korotkoff sounds and oscillations in the air pressure inside the cuff at each heart beat. A PC based graphical user interface is used to set simulation parameters through a serial port. The controller card is designed using a 16-bit microcontroller with on-chip ADC and DAC. It has a pressure sensor and a force sensor for dynamically sensing the air pressure in the cuff. The pressure sensor provides an accurate sensing, but it requires connection to the cuff tubing using a T-connector. The force sensor is located on the cylinder surface and it measures the force exerted by the cuff wall on its sensing area. Its output is used to obtain the value of the cuff pressure. It does not require a connection to the cuff tubing, but the sensed values of the cuff pressure may be relatively less accurate. The cardiac pulses are generated at the set heart rate, with arrhythmia simulated by a random variation in the heart beat interval. For BP measurement using auscultatory method, the Korotkoff sound pulses, pre-stored in the program memory of the microcontroller, are output through a small speaker at each heart beat in accordance with the sensed value of the cuff pressure. For oscillometric method, a linear actuator is used to apply force pulse against the cuff wall and thereby to generate pressure oscillations in the cuff. The amplitude of the Korotkoff sound and pressure oscillations are scaled in accordance with the set value of the pulse volume and the sensed value of the cuff pressure.

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List of Abbreviations

Abbreviation	Term
ADC	analog-to-digital converter
AL	arrhythmia level (0 − 50 scale)
BP	blood pressure
CP	cuff pressure
DAC	digital-to-analog converter
DP	diastolic pressure
GUI	graphical user interface
HR	heart rate
ICU	intensive care unit
LFSR	linear feedback shift register
MAP	mean arterial pressure
N/A	not available
SOIC	small outline integrated circuit
PC	personal computer
PCB	printed circuit board
PW	pulse width
SSOP	shrink small outline package
SP	systolic pressure
UART	universal asynchronous receiver transmitter

Chapter 1
INTRODUCTION

1.1 Overview

Measurement of the blood pressure (BP) is a basic assessment of the functioning of a patient's cardiovascular system. Since hypertension (high blood pressure) and hypotension (low blood pressure) may not have any symptoms initially, it is very important to find these abnormal blood pressure conditions. Hypertension puts extra stress on the arteries. In case of hypotension, adequate amount of blood and oxygen may not reach the brain which may lead to shock and fainting [1]. For accurate BP reading, measurement must be carried out carefully using calibrated and tested measuring instruments. Testing of the instrument cannot be reliably carried out using human subjects because their pressure levels are influenced by physiological condition such as sleep, body position, smoking, emotional state, presence of drugs in the body etc. Taking multiple readings on the same subject may give different blood pressure readings. Measuring the blood pressure of a subject with multiple BP measuring instruments can also give different results. Further, we cannot get the full range of BP values with normal subjects. Abnormal cardiac conditions pose problems in BP measurement and a healthcare worker does not get exposure to these conditions by taking measurement on normal subjects. Therefore different types of arm simulators [2][3][4][5][6][7] have been developed, which mimic the behavior of the arm for BP measurement. These simulators can be used for testing and calibrating the noninvasive BP monitors and for providing training for BP measurement.

Several arm simulators have now become available commercially. Most of these simulators have the facility for testing the BP monitor based on oscillometric method but some also provide simulation of Korotkoff sound for auscultatory method [6]. These instruments often lack flexibility in selecting the simulation parameters and are generally expensive.

1.2 Project objective

The objective of the project is to design and build an arm simulator for BP measurement using auscultatory as well as oscillometric method. It is in the form of a cylinder around which the cuff of the BP monitor can be wrapped. For generating Korotkoff sound and pressure pulses, a 16-bit microcontroller with on-chip ADC and DAC is used. The simulator includes a PC based graphical user interface (GUI) for setting the simulation parameters through serial port. The Korotkoff sound pulses are pre-stored in the program memory and are output according to the set parameters and time-varying cuff pressure which is dynamically sensed. A pressure sensor, connected to the cuff tubing through a T-connector, provides an accurate sensing of the air pressure in the cuff. For a non-invasive sensing of the air pressure in the cuff, a force sensor is provided. It is located on the cylinder surface and it measures the force exerted on its sensing area by the cuff wall. Its output is used to obtain the cuff pressure. It does not require inserting a T-connector in the cuff tubing, but the sensed values may not be as accurate as those obtained using the pressure sensor. A linear actuator is used to generate pressure pulses in the cuff to simulate the heart beats during BP measurement by oscillometric method.

1.3 Report outline

The second chapter provides an overview of the basics of blood pressure, various BP measurement techniques and BP simulators. Chapter 3 describes the design approach. Chapter 4 describes the hardware. Chapter 5 describes microcontroller program and GUI software. Test results are presented in the next chapter. The last chapter summarizes the work done and provides some suggestion for improvement. Some of the commercially available BP arm simulators are described in Appendix A. Components used for the design are listed in Appendix B. The circuit diagram of the controller card is given in Appendix C.

Chapter 2

BLOOD PRESSURE MEASUREMENT AND ARM SIMULATORS

2.1 Physiology of heart

Cardiovascular system consists of the heart and the blood vessels which circulate blood throughout the body, for providing nutrients and oxygen to the cells and transporting away the waste products. Heart is a muscular organ which functions as a pump for blood circulation. As shown in the Figure 2.1, it consists of four chambers: the left atrium, the left ventricle, the right atrium, and the right ventricle [8][9][1]. Blood enters into the right atrium through the two venacava, superior venacava from the upper extremities such as head and neck, and inferior venacava from the lower extremities. The incoming blood fills the right atrium and the coronary vein also gets emptied into the right atrium. When the right atrium contracts it forces blood through the tricuspid valve into the right ventricle. When the ventricular pressure exceeds the atrial pressure, the tricuspid valve closes and pressure in the ventricle forces the semilunar pulmonary valve to open and the pulmonary artery circulates the deoxygenated blood into the lungs. In the lungs, the red blood cells give up carbon dioxide and are recharged with oxygen. The oxygenated blood enters into the left atrium through pulmonary vein and then it is pumped via mitral valve into the left ventricle by the contraction of the atrial muscle. As the left ventricular muscles contract, the mitral valve gets closed. Pressure build-up in the ventricle forces the aortic valve to open and the blood flows into the aorta and circulates inside the whole body. This cycle of blood circulation is repeated with each beat of the heart [8][9][1].

The sequence of events during a heart beat is known as the cardiac cycle as shown in Figure 2.2. It consists of two major periods, systolic and diastolic. The systolic period is defined as the period of contraction, specifically of the ventricle muscle. The diastolic period is the period of dilation of the heart chambers as they fill with blood. Each beat of the heart involves five major stages. The first two stages include the "ventricular filling" stage. The next three stages involve movement of blood from the ventricles to the pulmonary artery (in case of the right ventricle) and the aorta (in case of the left ventricle). Throughout the cardiac cycle, the blood pressure changes. The highest arterial pressure during the cycle is known as the systolic pressure (SP) and the lowest pressure is known as the diastolic pressure (DP). The physiological indications associated with different ranges of systolic and diastolic pressures are given in Table 2.1.

Table 2.1: Blood pressure ranges [10].

Systolic Pressure (mm Hg)	Diastolic Pressure (mm Hg)	Indication
50	30	Dangerously low BP
60	40	Too low BP
90	60	Borderline low BP
110	75	Low normal BP
120	80	Normal BP
130	85	High normal BP
140	90	Stage-1 high BP
160	100	Stage-2 high BP
180	110	Stage-3 high BP
210	120	Stage-4 high BP

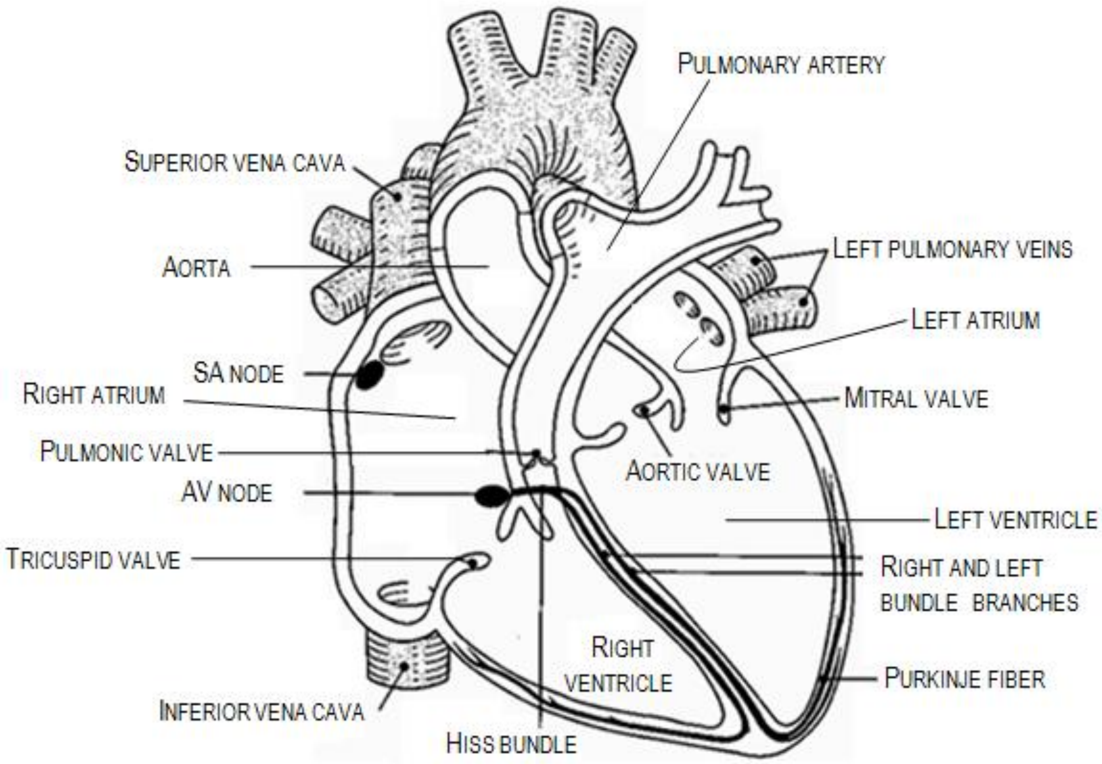


Figure 2.1 The heart, (adapted from [8]).

2.2 Techniques for blood pressure measurement

The blood pressure (BP) is measured either using invasive (direct) or non-invasive (indirect) methods. Direct method gives accurate BP measurement but it requires catheterization. This method is used for continuous BP monitoring in intensive care unit (ICU) and coronary care unit (CCU). A catheter or a needle type probe is inserted directly into the area of interest through arteries or vein [11]. Two types of probes are available, catheter tip probe and fluid filled probe. In the catheter tip probe, the sensor is mounted on the tip of the probe and the pressure exerted on the it is converted into a proportional electrical signal.

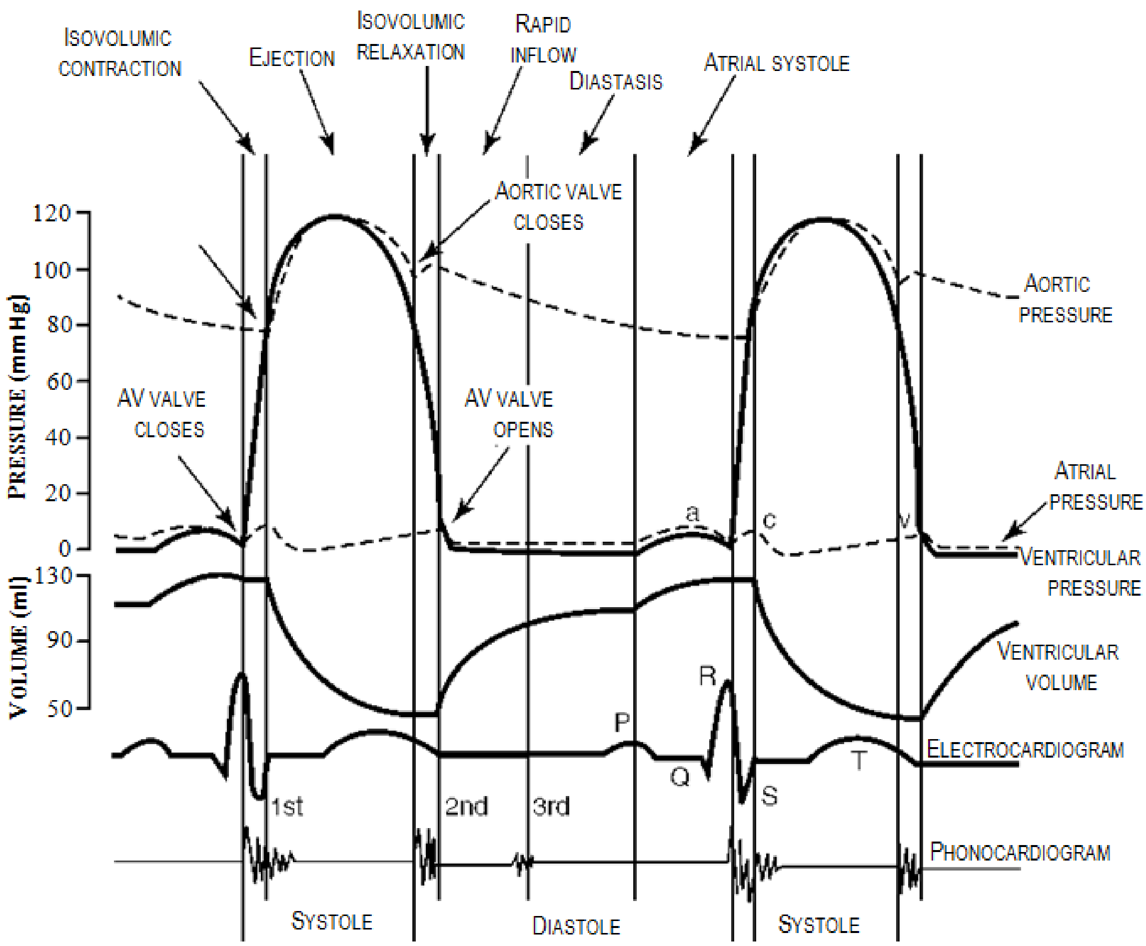


Figure 2.2: Various events during the cardiac cycle, (adapted from [12][9][1]).

In the fluid-filled catheter probe, the pressure is exerted by a fluid-filled column to the external transducer, which converts the pressure into the electrical signal, which is amplified and processed to give systolic, diastolic, and mean pressure values and may also be used for recording or display of the pulse waveform. The method gives continuous beat-to-beat BP, and hence it is very useful for monitoring a patient whose BP can change suddenly. It can be used for accurate measurement over an extended duration. The main drawback of this method is that arterial cannula can be a source of infection. This method requires expensive equipment and skilled staff.

For routine clinical measurement of BP, indirect methods are preferred. Although these are less accurate and the results obtained also depend on the patient position. Generally the measurement is carried out with the patient sitting quietly and comfortably with the back support for at least five minutes and the arm supported at the level of the heart. The commonly used non-invasive methods include (i) tonometry method, (ii) sphygmomanometer methods including auscultatory, oscillometric, and ultrasonic methods.

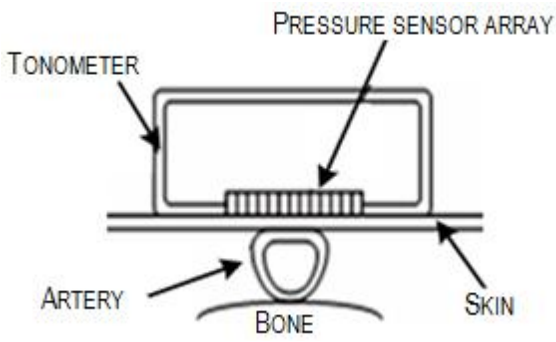


Figure 2.3: Tonometry method for blood pressure measurement, (adapted from [13][14]).

2.2.1 Tonometry method

In this method [13][14], the radial artery is used as a measuring point due to its larger diameter and easy accessibility, As shown in Figure 2.3, the superficial artery is compressed with an array of flat plates by placing it over skin surface. Each plate in the array is known as arterial rider. The artery is supported from below by a bone. An array of force sensors cylindrical in shape is used to sense the radial stress of the artery. Each force sensor is attached to arterial rider. Strain gauge sensor attached to arterial rider detects the arterial pulsation. The pressure is estimated by division of force by contact area of the arterial rider. A side plate is used to set the effect of skin tension to zero in vertical direction. This method is noninvasive and can be used to monitor blood pressure continuously. No cuff is required, but the instrumentation involves a relatively high cost. Wrist movement of the patient may result in inaccurate readings.

2.2.2 Sphygmomanometer method

In the sphygmomanometer method for indirect BP measurement [11][1], the blood pressure is measured using a cuff wrapped around the arm (which should be at about the heart level) and stethoscope is placed on the brachial artery. The instrument with a mercury manometer and a stethoscope is shown in Figure 2.4 [11]. The cuff is inflated by a squeeze bulb or an electrically operated pump, to a pressure above the expected value of SP so that the blood flow is occluded. The cuff is deflated slowly, and the stethoscope is used to hear the sound from the artery. The value of the cuff pressure at which the first sound is heard is taken as SP. This sound occurs because the blood flow under the cuff gets converted from laminar to turbulent form. As the pressure in the cuff is slowly decreased further, the flow in each cardiac beat increases and the sound gets more intense. As the cuff pressure is decreased further, the flow increases but it becomes less turbulent and sound gets weaker. The cuff pressure below which the sound disappears is taken as DP, because below this pressure the flow under the cuff is not turbulent. The sound heard with each heart beat when the cuff

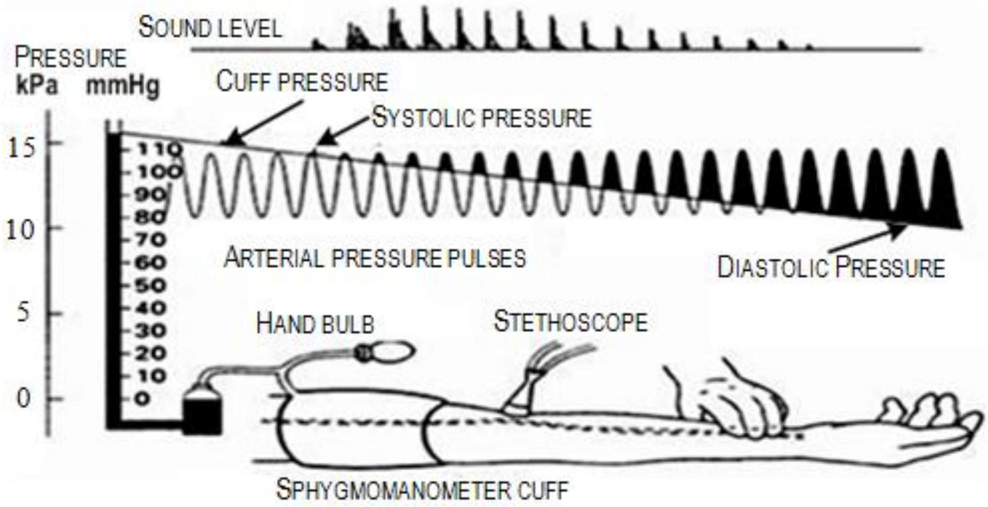
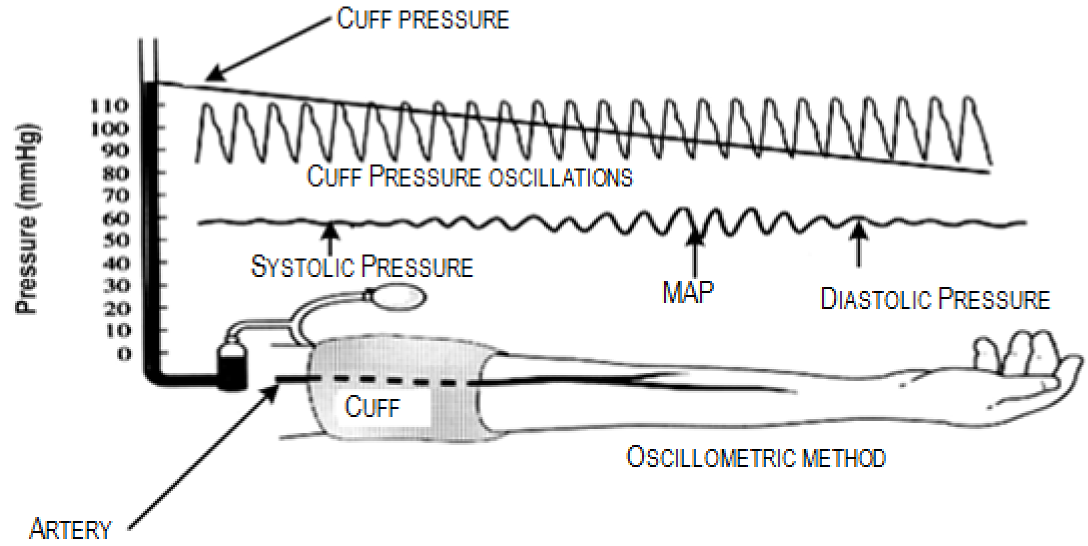


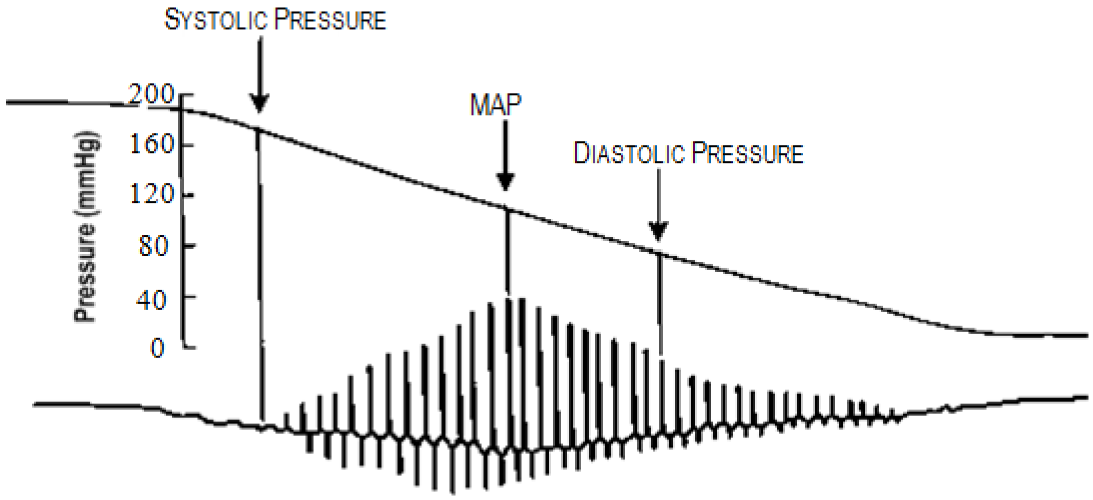
Figure 2.4: Auscultatory method for indirect blood pressure measurement, (adapted from [11][13]).

pressure is below the SP and above DP, is known as the Korotkoff sound [11][15]. The sound can be grouped in five types: (i) initial 'tapping' sound when the cuff pressure is just below the SP, (ii) sounds with increasing intensity as the cuff pressure is decreased, (iii) sounds with maximum intensity as the cuff pressure reaches near the mean arterial pressure (MAP), (iv) sounds getting muffled as the cuff pressure goes closer to DP, and (v) sounds disappear as the cuff pressure goes below DP. The cuff needs to be inflated to a pressure slightly above SP and it should be deflated at an appropriate rate to clearly hear the sounds in successive beats, without unduly extending the measurement time. Use of this technique requires experience in recognizing the sound and it cannot be used in noisy environment. It is prone to mechanical errors e.g. mercury leakage, air leakage, obstruction in the cuff etc. It may not give accurate results for infants and hypertensive patients.

The oscillometric method [11], as shown in Figure 2.5, works on the same principle as the auscultatory method, but it does not use a stethoscope. When the cuff pressure is in between SP and DP, each cardiac cycle causes a small change in the cuff pressure, which has the appearance of oscillations. These oscillations, caused by blood flow in the artery below the cuff, are sensed using a pressure transducer, ac coupled and amplified. The appearance and end of the oscillation indicate the time at which the cuff pressure equals SP and DP respectively. Figure 2.5(b) shows the oscillation in the cuff pressure. The point at which the oscillation begins to increase rapidly is SP. The point of maximum oscillation corresponds to the mean arterial pressure (MAP). The pressure at which oscillation decreases rapidly is the DP. The readings are not affected by environmental noise, such as those present in emergency and clinical rooms. Most of the automated electronic BP instruments use this technique. It is suited well for measuring MAP. Detection of the points of appearance and disappearance of



(a)



(b)

Figure 2.5 Oscillometric method of blood pressure measurement (a) Cuff placement (b) Oscillation in cuff pressure, (adapted from [11][13]).

oscillations is often difficult. SP and DP are estimated therefore by curve fitting from the plot of the oscillation amplitude vs. time. In this method, an excessive movement of patient or vibration during measurement may result in inaccurate readings.

In the ultrasonic method, as shown in Figure 2.6, a Doppler sensor is used to measure blood pressure by means of detecting motion of the blood vessel. For transmission and reception of the signal, 8 MHz crystals are placed over the arm with the help of a compression cuff [13]. An ultrasound source transmits signal to the blood vessel. The reflected signal is transduced by the receiving crystal and amplified. Difference in frequency (40 Hz to 500 Hz)

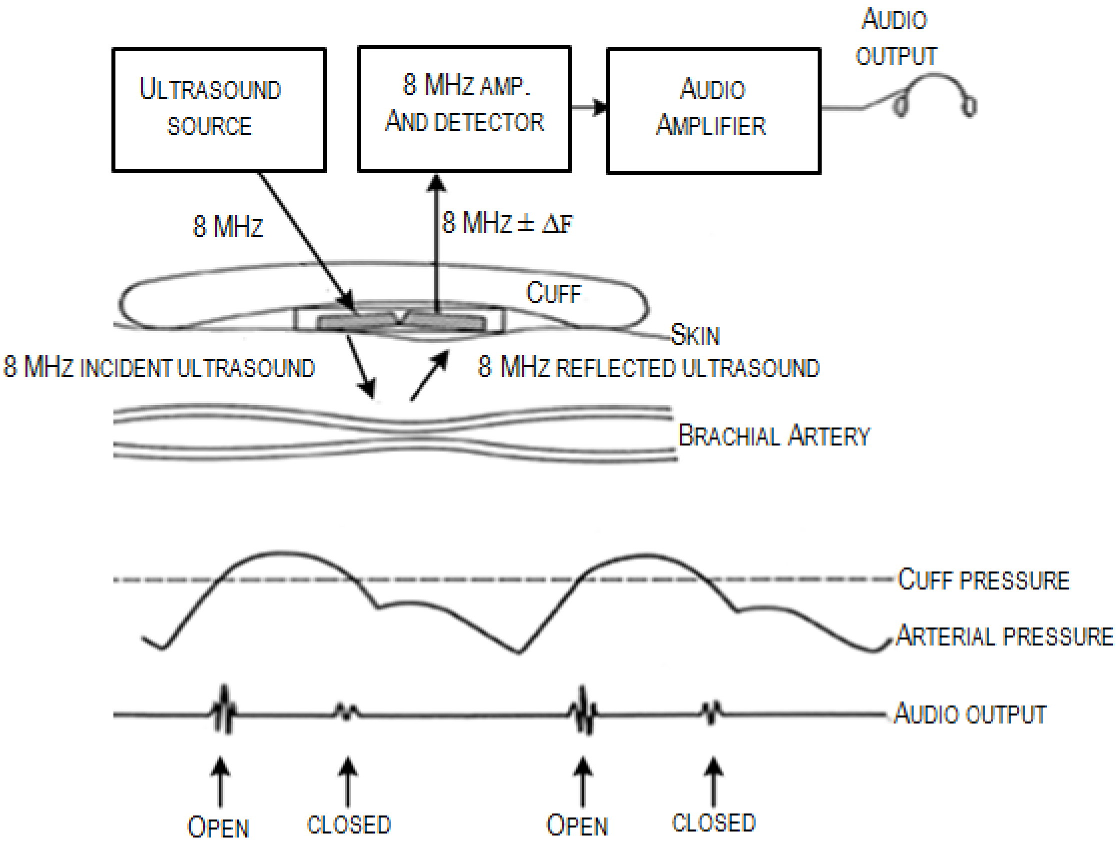
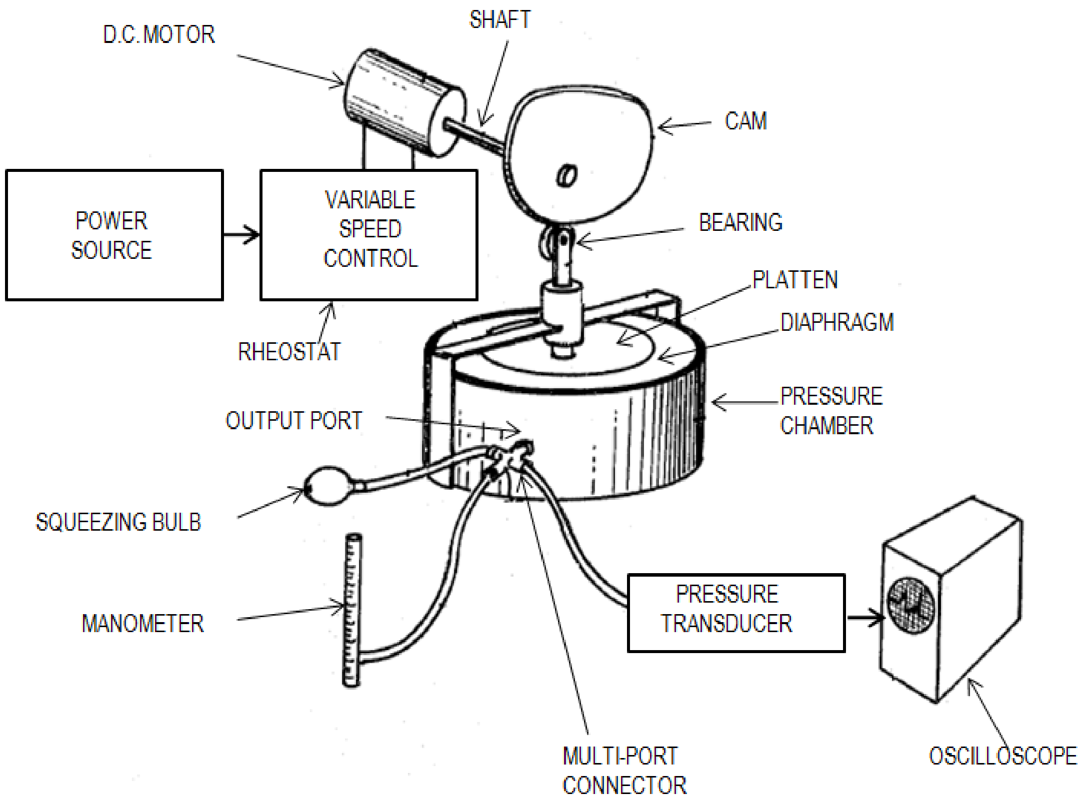


Figure 2.6 Ultrasonic method for indirect blood pressure measurement, (adapted from [13]).

between the transmitted and the reflected signals is proportional to the velocity of wall motion and blood cells. When cuff pressure is set between diastolic pressure and systolic pressure, the blood vessel opens and closes with each heart beat. As the cuff pressure is increased, the time between opening and closing of the artery decreases till it becomes zero. At this point, the reading of the cuff pressure is SP. As the cuff pressure is decreased, the time between opening and closing of the artery increases until the artery does not close at all. The reading of the cuff pressure at this point is DP. This method can be used in noisy environment and it can be used with infant and hypotensive subject. Movement by the patient may change the alignment between the sensor and vessel and the reflected signal may not give a correct reading. The auscultatory and ultrasonic methods detect SP and DP, and these can be used to estimate the mean arterial pressure. The oscillometric method detects MAP and then uses it in the estimation of the SP and DP.

2.3 BP arm simulators

BP arm simulators mimic the behavior of the arm during the process of BP measurement and are useful in testing and calibration of non-invasive BP monitors. Several of these have been



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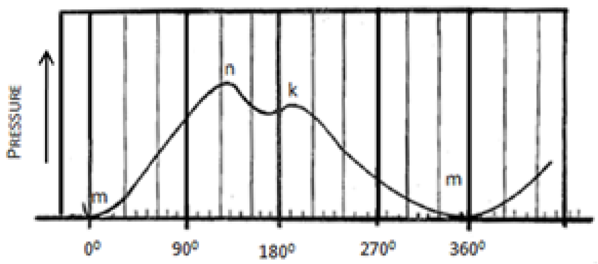

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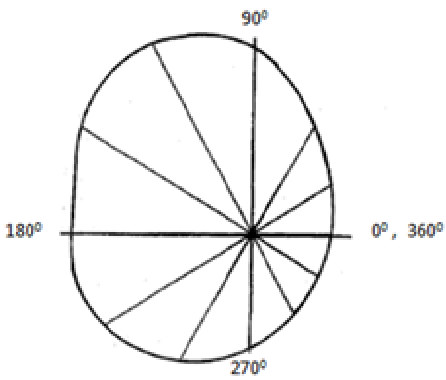


(c)

Figure 2.7: (a) dynamic arterial blood pressure simulator (adapted from [4]), (b) Arterial blood pressure waveform, (c) Shape of cam.

reported in the literature or described in patents and some of these simulators are reviewed in the following subsections. Some of the commercially available instruments are described in Appendix A.

2.3.1 Dynamic arterial BP simulator [4]

In 1975, Klein reported a dynamic arterial BP simulator [4] that can be used to calibrate or test a transducer before it can be put into the instruments. This simulator is designed to produce a blood pressure waveform as at the site of the reading device. The instrument as described in [4] is shown in Figure 2.7(a). It consists of a pressure chamber, a cam, a DC motor to drive the cam, and a manometer. The motor speed is controlled through a rheostat to simulate desired heart rate. The cam shape is designed to simulate the pressure variation during one cardiac cycle. The cam is attached to the motor shaft and it presses the platten with the help of a bearing. The to-and-fro motion of the platten causes variations in the pressure inside the chamber. Tubes along with a multiport connector are used to connect the pressure chamber to the blood pressure transducer, the squeezing bulb, and the manometer. The base-level pressure inside the chamber is adjusted by pressing the squeezing bulb, and is monitored by the manometer. A single cycle of an arterial blood pressure waveform is shown in Figure 2.7(b). The 'm' point shows the diastolic or minimum blood pressure level and the 'n' point indicates the systolic or maximum blood pressure level. Figure 2.7(c) is a graphical representation of the shape of the cam which is obtained by converting Cartesian coordinate of arterial blood pressure waveform into polar form. As the cam rotates, the arterial blood pressure waveform is generated inside the chamber and is fed to the pressure transducer and the sensed waveform can be seen on the oscilloscope. The instrument is bulky, and it lakes flexibility of setting an exact heart rate. Moreover the difference between SP and DP is fixed for a particular cam.

2.3.2 Arm simulator for an oscillometric BP monitor [2]

In 1984, Glover and Medero [2] reported an arm simulator for testing the performance of an oscillometric BP monitor with an inflatable pressure cuff. The schematic is shown in Figure 2.8(a), A processor accepts the inputs like SP, DP, MAP and HR. The pulse chamber has a diaphragm which can be actuated electrically to produce pressure pulses. The monitor to be tested has a pump for automatic inflation and deflation of the cuff via a tube with the help of a valve. A pressure transducer present in the monitor is connected to the cuff by a conduit.

A controllable pressure valve is used to balance the pressure across the diaphragm from the cuff, thus eliminating the need of variable pulses to compensate for applied cuff pressure levels. However, the valve is closed during the pressure pulses, consequently, the output pressure level of the pulse chamber is the sum of the pulse pressure created by the actuation of the diaphragm and the cuff pressure as it existed at the time of closing of the valve. Had there been a direct connection between the cuff and the transducer in the monitor, then the pressure pulses would have to be produced in the entire volume of the cuff, which would have required a large pressure chamber and large amount of power. The pressure

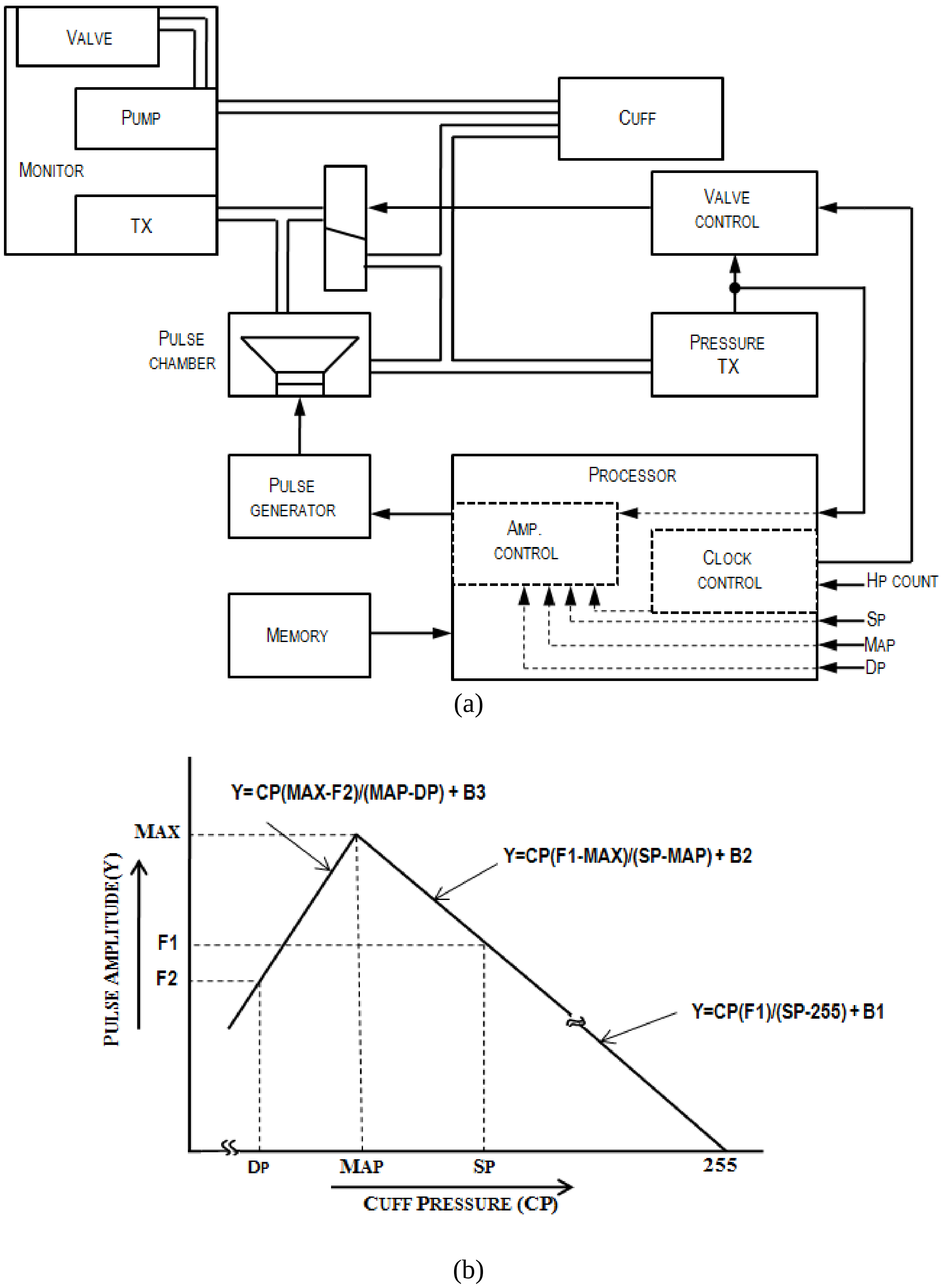


Figure 2.8: (a) Arm simulator for an oscillometric BP monitor (adapted from [2]), (b) Variation in pulse amplitude with cuff pressure.

sensor in the monitor senses the oscillation in the pressure chamber. After application of the pressure pulses, the valve is opened to connect the pressure chamber to the cuff, and the process is repeated at each simulated heart beat. As the pressure is decreased in steps, the amplitude of the pulses increases to a maximum value and then decreases, the pressure at which pulse amplitude is maximum is called Mean Arterial Pressure (MAP). The repetition rate of the actuation of diaphragm and amplitude of the pressure pulses are controlled by a processor according to the given input. The heart pulse rate input is directed to the clock control section of the processor, which divides the processor clock and uses it to time the operation of amplitude control portion. The timing signal from the heart pulse counter and signal from the transducer are fed to the valve control circuit. The automated BP monitors are generally designed to decrease the cuff pressure at a rate of 5 mmHg/s. Valve control circuit is set such that a change of less than 3 mmHg in pressure of pulse chamber will not cause the valve to open. The variation of pulse amplitude with cuff pressure is shown in Figure 2.8(b) indicating that as the cuff pressure becomes less than SP, the pulse amplitude starts increasing from F1 and reaches its maximum value at MAP. As the cuff pressure is further reduced, the pulse amplitude starts decreasing. When the cuff pressure reaches DP, the pulse amplitude becomes F2. The main feature of the simulator [2] is that pressure pulses can be produced with a smaller pressure chamber with less power consumption. The main drawback of the system is that the simulator requires modification of the tubing of the monitor and hence is suitable only for laboratory use. Further, it does not have provision for simulating arrhythmia and other abnormalities.

2.3.3 Compact oscillometric BP simulator [3]

In 2010, Ruiter and Ruiter reported a compact oscillometric BP simulator [3], as shown in Figure 2.9(a), using elastomeric coupling and a bidirectional actuator by generating pulses with settable parameters. The BP monitor under test consists of a pressure sensing unit with cuff, pressure regulator, and display unit. The cuff and BP monitor are connected pneumatically to the simulator via T-connector and extension hose. Using the pressure regulator of the BP monitor, the cuff can be inflated above SP of the patient and deflated in a stepwise manner. The pressure simulator consists of a bi-directional actuator operatively coupled to a pressure sensing system and actuator control mechanism. The bi-directional actuator includes a cam driven by a stepper motor. Motor drive control can rotate the motor shaft in clockwise or anti-clockwise direction. The cam is firmly attached to the shaft and can drive a cam follower via bearing. The cam follower is firmly attached to the slider. Displacement of the cam follower can move the slider only in vertical direction. Slider is used to serve as a piston to exert force on a pneumatic chamber, formed of rubber or latex hose and inserted in the cavity.

When the cam is turned, it compresses the pneumatic chamber causing change in pressure, which is coupled to the sensor on BP monitor through the extension hose. After the peak pulse pressure has been reached, the direction of rotation of cam is reversed and the pressure in the pneumatic hose and cuff is restored to test level. The pressure change in the

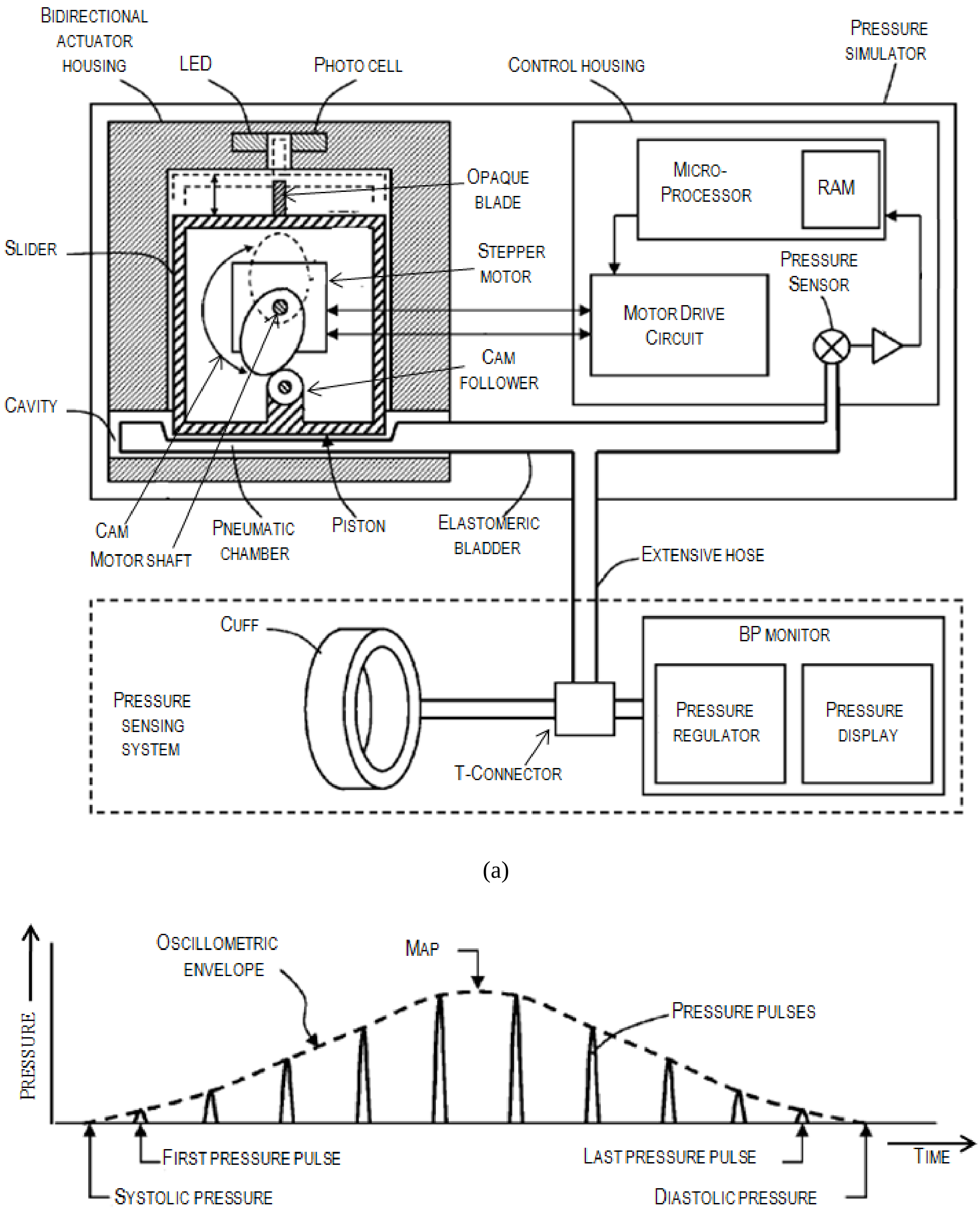


Figure 2.9: (a) Compact oscillometric BP simulator (adapted from [3]), (b) Pressure pulse waveform.

cuff is simultaneously measured by the pressure sensor and sensed signal is amplified and transmitted to the actuator control mechanism. Microprocessor monitors the instantaneous pressure reading, and calculate the amplitude of the pressure pulses and provides appropriate pulse to the actuator via motor drive circuit. The shape and amplitude of the predetermined pressure waveform can be pre-stored in the memory. The pressure pulse waveform in shown in Figure 2.9(b), the oscillometric envelope is characterized by mean pressure point and is bounded by simulated systolic and diastolic pressure point. The first pressure pulse is

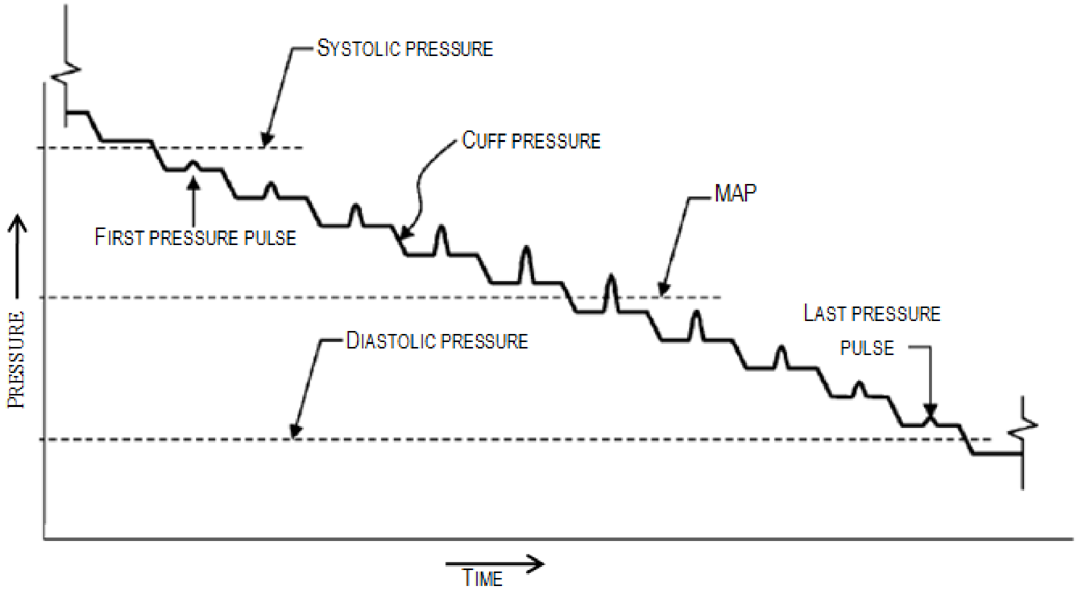


Figure 2.10: Cuff pressure as measured by BP monitor, (adapted from [3]).

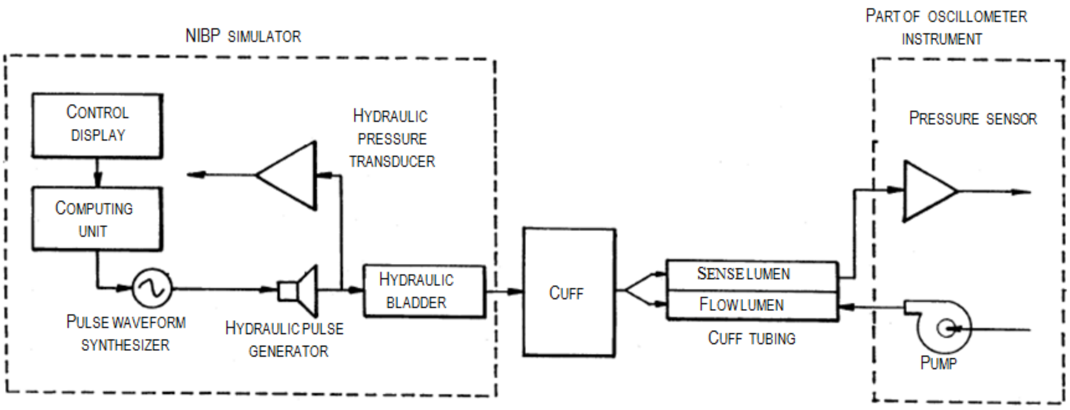


Figure 2.11: Oscillometric Non-Invasive BP simulator, (adapted from [5]).

introduced at or below SP point and the last pressure pulse is introduced at or above DP point. At the mean pressure point, cuff pressure matches the set value of MAP and the maximum pulse energy is transmitted through the cuff-patient interface. Figure 2.10 is a graphical representation of cuff pressure versus time during an oscillometric measurement cycle. The cuff is pressurized above the simulated systolic pressure, and pressure is reduced in a step-wise manner. As the cuff pressure becomes equal to simulated SP, the microprocessor drives the motor control circuit and causes cam to turn in counter-clockwise direction so that the piston deforms the pneumatic chamber, consequently introducing first pressure pulse. When the cuff pressure has been increased by the magnitude of first pressure pulse, the direction of cam is reversed. As the cuff pressure further decreases under the control of pressure regulator, the magnitude of pressure pulses introduced by actuator mechanism is increased according to the oscillometric envelope, until the cuff pressure equals the simulated mean pressure. Now if, cuff pressure is further reduced the magnitude of the pressure pulses also decreases, and finally the last pressure pulse is introduced when cuff pressure becomes equal to the simulated DP. To ensure that cam returns to the same position (home-position) at the onset of each pressure pulses, a photo-interrupt-detection mechanism is used. When the cam is away from the home position, the position of the opaque blade permits the photo cell to receive the light emitted by the LED. When the slider is moved upward, the opaque blade interrupts the passage of light from LED to the photo cell, thus confirming that cam is in home position.

The simulator [3] produces variable pressure pulses and provides greater control of the simulation parameters. Unlike the simulator in [2], the pulses are introduced in the cuff and the actuator takes more power. It is invasive in the sense that a T-connector is needed to pneumatically connect the simulator and the BP monitor under test. But unlike the simulator in [2], it does not require a separate pneumatic connector to the sensor of the monitor.

2.3.4 Non-invasive BP simulator for oscillometric method [5]

In 1991, Costello [5] reported an oscillometric BP simulator. Its schematic is shown in Figure 2.11. It is designed to be non-invasive to the BP monitor under test. The instrument consists of a microcomputing unit, control input and display for setting simulation parameters, a pulse waveform synthesizer, a hydraulic pulse generator, a hydraulic bladder and a hydraulic pressure sensor. The microcomputing unit delivers numerical samples of the desired waveform to the pulse waveform synthesizer which drives the hydraulic pulse generator which is connected to the hydraulic bladder. The hydraulic bladder is wrapped around the cylindrical housing, and cuff of the BP monitor is wrapped about the bladder. During simulation, the DC pressure under the cuff is transferred to the bladder and is sensed by a hydraulic pressure transducer. The pulse (or AC waveform) pressure generated is transferred to the cuff through the hydraulic bladder. This simulator is completely non-invasive to the oscillometric BP monitor under test. It does not require any pneumatic coupling to the BP monitor. However, cuff pressure cannot be accurately sensed using this method and also pulse amplitude cannot be accurately controlled.

2.3.5 Cardiological manikin auscultation and BP simulator [6]

In 1976, a BP simulator based on auscultation method was reported by Gordan and Patterson [6]. its schematic is shown in Figure 2.12. In this simulator, several sounds related to different cardiovascular diseases are stored in a magnetic tape or disc and can be played by a motor drive mechanism (not shown in Figure 2.12). A level detector circuit is attached to sense the discrete pressure level in mercury column in manometer tube. SP and DP values for different

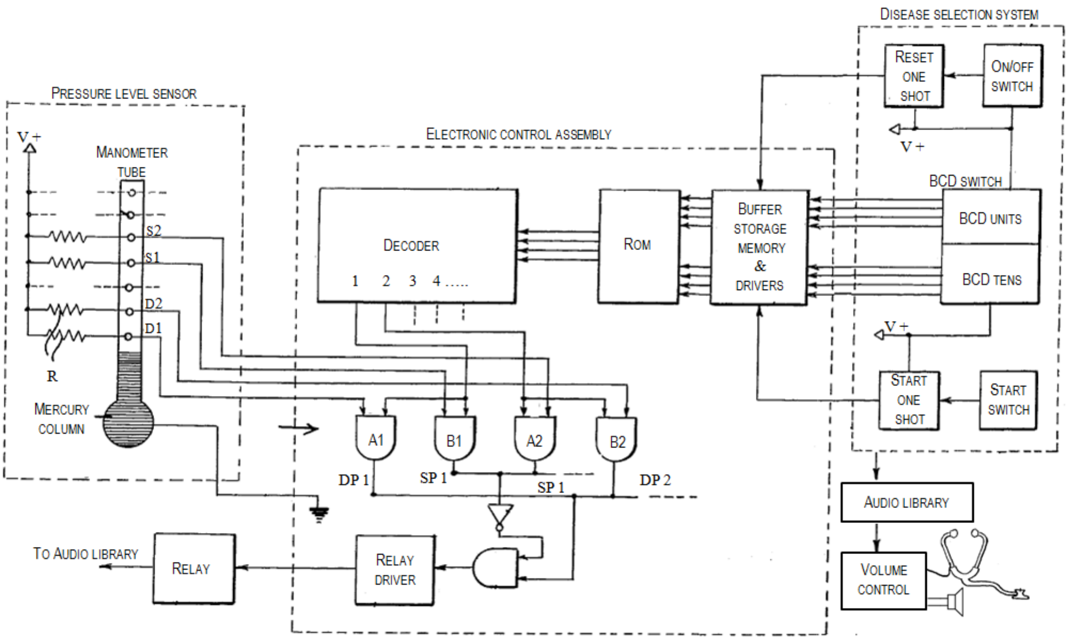


Figure 2.12: Auscultatory BP simulator, (adapted from [6]).

diseases are stored in the memory. The electronic control assembly selects a particular disease according to two digit BCD input and maps it to corresponding SP and DP. A cuff is wrapped around a simulated arm. Pressure is applied to the BP monitor cuff and depending upon the mercury level in the manometer, the corresponding electrical contacts in the level detector are shorted. The contactor outputs are used to find the value of cuff pressure and the corresponding sound is played. The sound can be heard on a stethoscope as well as on a speaker. When the pressure in the cuff reaches above the SP, no sound is heard, now if we start decreasing the cuff pressure, at SP and below SP sound is heard until pressure reaches below DP. This simulator [6] lacks in flexibility in setting the heart rate, SP and DP. It has no facility for simulation of arrhythmia. It uses mechanical system for rotating the disc or magnetic tape for playing heart sound which needs a lot of power.

2.3.6 Dynamic pulse simulator [7]

In a dynamic pulse simulator reported by Rosenthal *et al*.[7] in 2012, a pneumatic pulse is generated by twisting a flexible tube using a rotary actuator at one end with the other end of the tube held stationary. Twisting causes a decrease in volume and an increase in the pressure. The tube can be brought to its normal position by rotating the end in the opposite direction. A microcontroller can be used to control the duration of pulse, interval between the pulses, and magnitude of the pulse. The pulse shape can be changed by varying the rotation speed of stepper motor in clockwise and counter-clockwise direction. The authors reported that the pressure in the system may not be restored exactly after twisting back of the flexible tube.

Chapter 3
DESIGN APPROACH

3.1 Introduction

An arm simulator for BP measurement was earlier developed at IIT Bombay by Pushpa Gothwal as part of her M. Tech. project [16]. It consists of a hollow rigid cylinder placed horizontally and supported at the two ends. The left support has the battery and the controller card consisting of the pressure sensor and the electronic circuit board. A microcontroller based hardware along with software for auscultatory method was developed. The controller card has four keys through which simulation parameters can be set and are displayed on LCD. In this design, the pressure sensor is pneumatically connected to the cuff tubing of BP monitor via a T-connector. A Korotkoff sound pulse is stored in the processor memory. At each simulated heart beat, the sound pulse is output through the DAC of the microcontroller through an audio amplifier and speaker. The amplitude of the pulse is digitally scaled according to the sensed pressure to simulate the variation in the loudness of the Korotkoff sounds with the cuff pressure. The design has facility of setting SP, DP, arrhythmia level and pulse volume. A pseudo-random number generator can be used for introducing arrhythmia. The design also has provision for coupling pressure pulses, although actuator was not implemented. Efforts at non-invasive sensing of the cuff pressure were not successful.

After an examination and testing of the prototype developed in [16], the hardware design and the software has been revised. The simulation of arrhythmia and Korotkoff sound has been made more realistic. The hardware is modified, introducing the facility to sense the cuff pressure either invasively or non-invasively. BP simulation for oscillometric method is also implemented, and the designed instrument can be used either in auscultatory or oscillometric simulation mode. The simulation parameters can be set by a PC-based graphical user interface (GUI).

3.2 The instrument setup

The arm BP simulator setup, as shown in Figure 3.1(a), consists of a rigid cylinder placed vertically on a horizontal support. The computing unit of the simulator has a controller card consisting of a pressure sensor, a force sensor, a linear actuator, and its electronic circuit. The pressure sensor is used to sense the cuff pressure dynamically. Figure 3.1(b) shows manual BP monitor, it consists of cuff, manometer, and the cuff tubing. Figure 3.1(c) shows arm simulator setup with manual BP monitor. The cuff of the BP monitor is wrapped on the

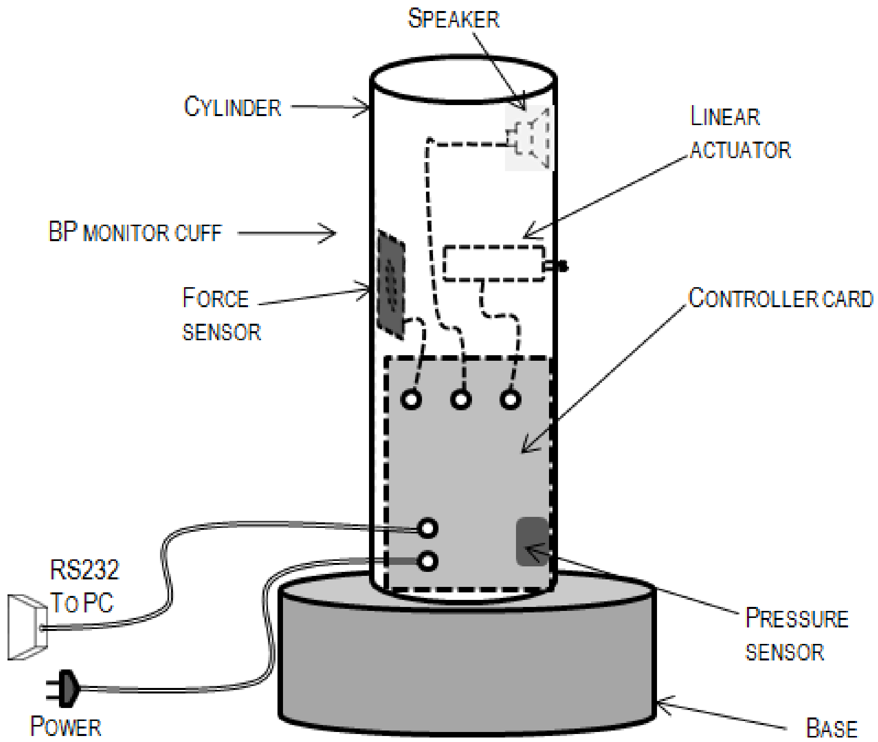


Figure 3.1(a): Arm simulator

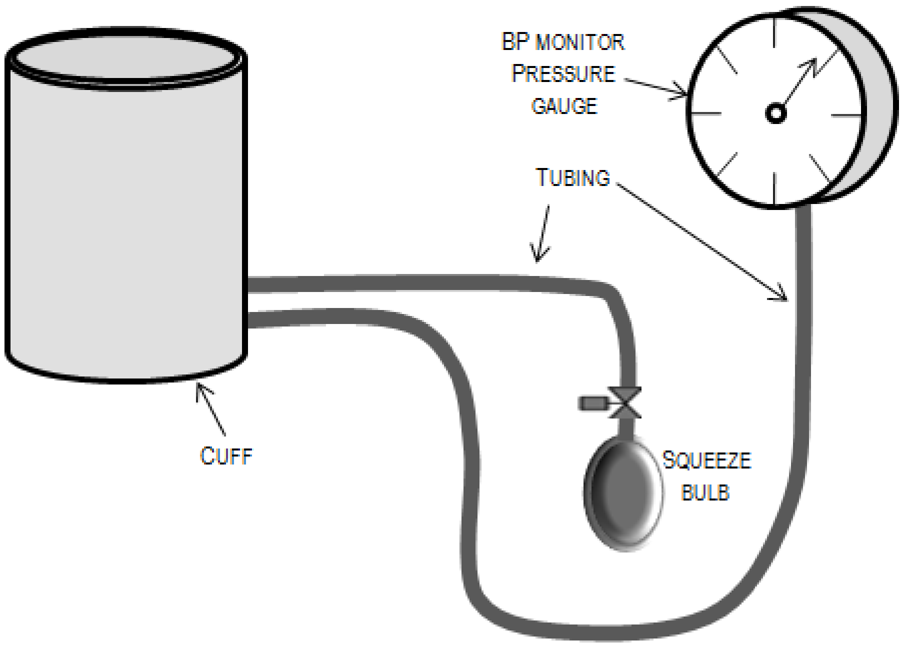


Figure 3.1(b): A manual BP measuring instrument

cylinder. It is connected between the cuff and the manometer of the BP monitor through a T-connector in the cuff tubing. The force sensor is mounted on the surface of the cylinder, to be in contact with the cuff wrapped around the cylinder. It senses the force exerted on its sensing

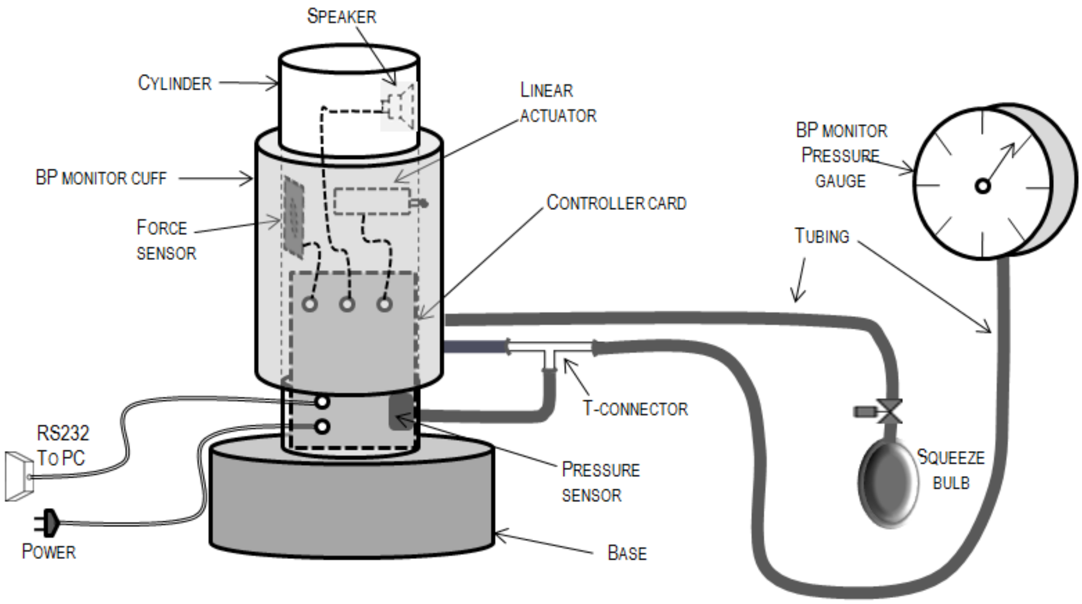


Figure 3.1(c): Measurement setup with Arm simulator and BP monitor

area by the cuff wall and the sensed value of the force is used to calculate the pressure inside the cuff. Thus it senses the pressure inside the cuff non-invasively without using a T-connector. A rectangular cut is made in the cylinder to fit the linear actuator in such a way that its plunger presses against the cuff surface to produce pressure pulses. The controller card is connected to a PC through serial port. The operation of simulator is controlled by a PC based GUI.

The simulation is carried out by generating the sounds and pressure pulses in accordance with the parameters set through GUI and the time-varying pressure in the cuff as dynamically sensed by the pressure sensor in case of invasive sensing, and by the force sensor in case of non-invasive sensing. The transducer for generating the Korotkoff sound and pressure pulses are kept inside the cylinder by making an appropriate cut in it.

3.3 Arm simulator schematic

A schematic representation of the arm simulator is shown in Figure 3.2. It consists of the heart beat generator, Korotkoff sound (K-sound) generation, oscillation generation, cuff pressure sensor, and amplitude calculator. For designing it as a low-cost and portable instrument, the design is realized using a single 16-bit microcontroller with on-chip ADC and DAC. A PC-based GUI is used for setting the simulation parameters including the heart rate, level of arrhythmia, pulse volume, systolic pressure, and diastolic pressure. The Korotkoff sounds and oscillations in the cuff are generated based on the set parameters and in response to time-varying pressure in the cuff.

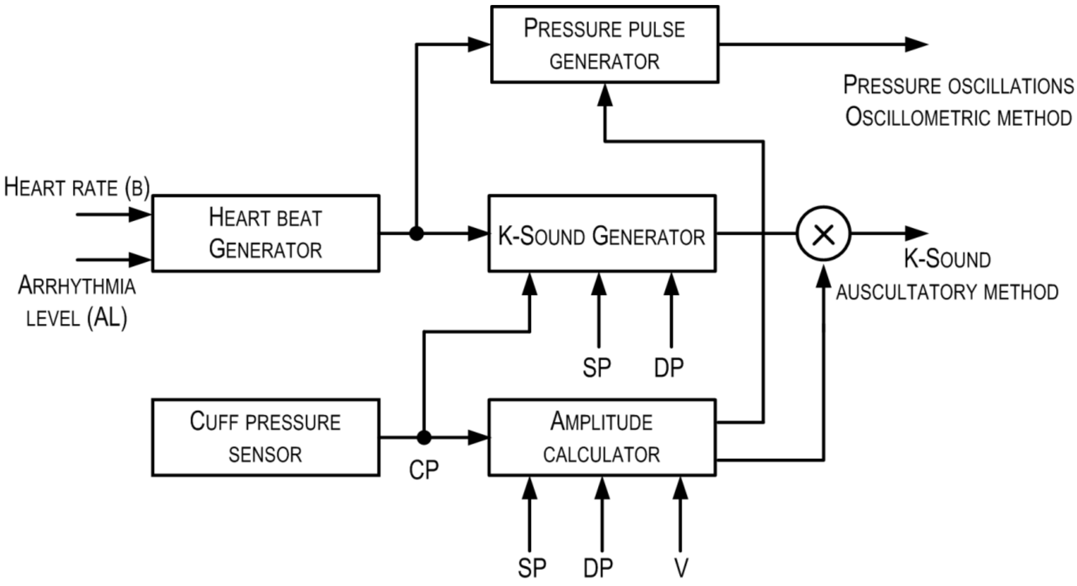


Figure 3.2: Schematic representation of the arm simulator [16]

3.4 Generation of heart beat and arrhythmia

In this design, the heart rate and level of arrhythmia are controlled by setting the control parameters over serial port from a GUI program on a PC. The heart beat is generated as a square wave, with a fixed on-time. The off-time is varied according to the selected heart rate. In arrhythmia, the heart has an irregular rhythm. It is simulated by varying the off period in accordance with a random number. The arrhythmia level (AL) can be set as 0, 1, 2, 3, 4, and 5. The arrhythmia level 0 corresponds to periodic heart beat. The arrhythmia levels of 1, 2, 3, 4, 5 correspond to peak variation of ±10 %, ±20 %, ±30 %, ±40 %, ±50 %, respectively, in the heart beat period with reference to the mean value as calculated from the heart rate.

To simulate arrhythmia, a pseudo-random generator [17] is used. It is realized using an 8-bit linear feedback shift register (LFSR), as shown in Figure 3.3. The feedback circuit provides maximum length of the bit sequence. The change in heart beat period is controlled by the value of random number represented in the shift register, with the mean value as set by the HR and the peak variations as set by AL. The value of bit 'b8' is taken as the sign for change in heart beat period, i.e. S = +1 if b_8= 0 and S = -1 if b_8 = 1. Plus sign indicates increase in time between the successive beats while the minus sign indicate decrease in time between the successive heart beats. The value represented by the remaining 7 bits ($b_7\ b_6$ .. b_1) is taken as the count W and is used to generate another random number C using the following equation

$$C = W \bmod (1 + 10\mathrm{AL}) \tag{3.1}$$

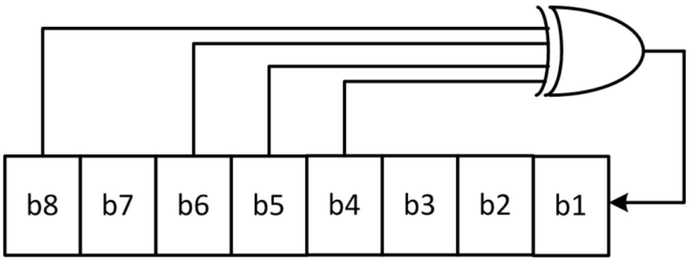


Figure 3.3: 8-bit LFSR for maximum bit sequence (as described in [17])

The value of C is an integer in the range [0, 10AL]. If the time between successive beats corresponding to the set by heart rate is T, then the actual time T' between successive beats for introducing arrhythmia is calculated as

$$T' = T[\,1 + (SC)/100] \quad (3.2)$$

For AL = 0, T' equals T, i.e. heart beat is perfectly regular. In operation mode, The on time is fixed as 200 ms, and therefore the off time for heart beat is calculated as

$$T'_{off} = T' - T_{on} \quad (3.3)$$

3.5 Generation of Korotkoff sounds

The Korotkoff sound is the arterial sound heard through a stethoscope placed on to the brachial artery, approximately 2 cm below the cuff of the sphygmomanometer [9]. In this design, two methods have been used for generation of Korotkoff sound. The first method generates the sound at each heart beat by amplitude scaling samples of a single pulse in accordance with the sensed value of the cuff pressure and the set values of systolic and diastolic pressures. The second method attempts to generate more realistic Korotkoff sounds by selecting a pulse from a set of pre-stored pulses according to the cuff pressure.

3.5.1 Generation of Korotkoff sounds using single K waveform

In this method [16], the Korotkoff sound at each heart beat is generated by scaling the samples of a single pulse from a recording of Korotkoff sound, stored in the processor memory as K-waveform. A representative sound pulse corresponding to MAP is captured and 1500 samples are stored at 8 kHz. The samples are output through the on-chip DAC of the microcontroller. The mean arterial pressure MAP [18] is calculated from the set values of the systolic pressure SP and the diastolic pressure DP as

$$\text{MAP} = \text{DP} + (\text{SP} - \text{DP}) / 3 \quad (3.4)$$

Amplitude of the sound is scaled according to the cuff pressure (CP) using the relation shown in Figure 3.4. The amplitude is zero for CP below DP. As the CP increases from DP to the MAP, the amplitude Amp increases linearly to the peak amplitude A_m. As CP further

Table 3.1: Relation between cuff pressure and selection of K-waveform

Diastolic pressure≤ Cuff Pressure ≤ Systolic pressure	Korotkoff Sound output
CP ≤ (DP+(((0.95)(MAP)-(DP))/3))	Wavefile1
CP ≤ (DP+((2)((0.95)(MAP)-(DP))/3))	Wavefile2
CP ≤ ((0.95)(MAP))	Wavefile3
(CP > ((0.95)(MAP))) && (CP < ((1.05)(MAP)))	Wavefile4
CP ≤ (((1)((SP-((1.05)(MAP)))/6)) + ((1.05)(MAP)))	Wavefile5
CP ≤ (((2)((SP-((1.05)(MAP)))/6)) + ((1.05)(MAP)))	Wavefile6
CP ≤(((3)((SP-((1.05)(MAP)))/6)) + ((1.05)(MAP)))	Wavefile7
CP ≤ (((4)((SP-((1.05)(MAP)))/6)) + ((1.05)(MAP)))	Wavefile8
CP ≤ (((5)((SP-((1.05)(MAP)))/6))+((1.05)(MAP)))	Wavefile9
CP ≤ (SP)	Wavefile10

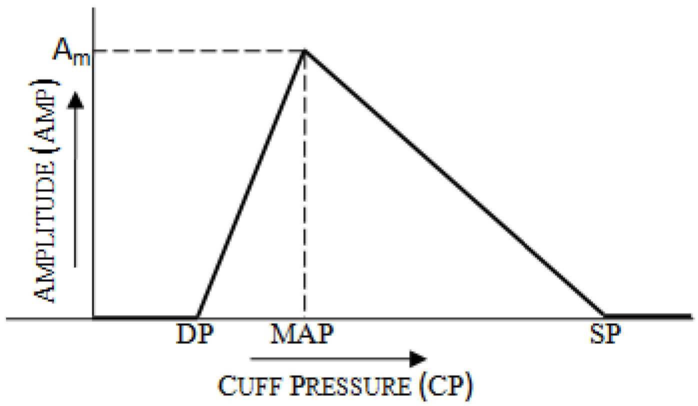


Figure 3.4: Korotkoff sound amplitude as a function of cuff pressure [16]

increases from MAP to SP, the amplitude linearly decreases to zero and remains zero for values higher than SP.

The relationship between CP and Amp can be written as,

$$\text{Amp} = \begin{cases} 0, & CP \leq DP \\ A_m (CP - DP) / (MAP - DP), & DP < CP \leq MAP \\ A_m (SP - CP) / (SP - MAP), & MAP < CP < SP \\ 0, & SP \leq CP \end{cases} \qquad (3.5)$$

The sound is further scaled in accordance with the set value of pulse volume (V). The DAC output is amplified by an audio amplifier and it drives a speaker to generate the Korotkoff sound pulses.

3.5.2 Generation of Korotkoff sound using pre-stored multiple sound pulses

In addition to change in the amplitude, the waveform of different beats of the Korotkoff sound varies as the cuff pressure varies. To simulate this effect, the sound pulse should be varied

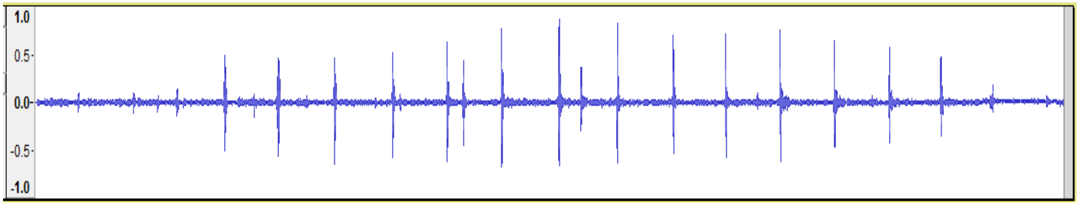
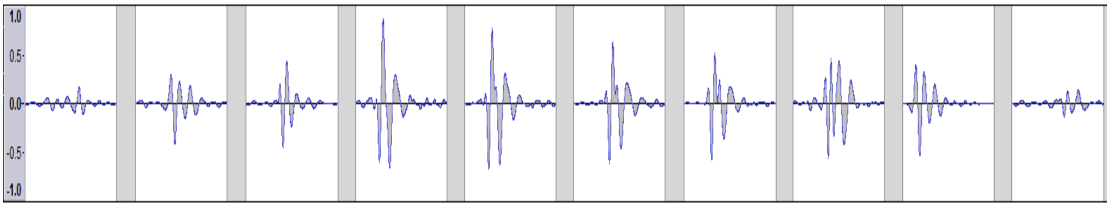


Figure 3.5: Korotkoff sound waveform for a normal person with cuff pressure changing from SP to DP, downloaded from [19]



(a) (b) (c) (d) (e) (f) (g) (h) (i) (j)

Figure 3.6: Ten representative sound pulses as extracted from the recording in Fig. 3.5 and stored as wavefile1 (a), wavefile2 (b), wavefile3 (c), wavefile4 (d), wavefile5 (e), wavefile6 (f), wavefile7 (g), wavefile8 (h), wavefile9 (i), and wavefile10 (j).

with the cuff pressure. A Korotkoff sound file was download from [19], and the waveform is plotted in Figure 3.5. Ten representative sound pulses were extracted, taking care to have no end discontinuities. These were stored in the program memory of the processor as 'wavefile1', 'wavefile2',......'wavefile10'. For each sound pulse, 1500 16-bit samples were stored at sampling frequency of 8 kHz. These sound pulses are shown in Figure 3.6. Due to memory constraints only ten waveforms are stored. With SP and DP set by the user through GUI, MAP is calculated using (3.4). When the sensed value of CP is in the range defined by set values of SP and DP, the Korotkoff sound is played at each heart beat in accordance with the relation in Table 3.1. Thus the waveform of the output and its scale factor both are varied in accordance with the sensed values of the cuff pressure and the set values of SP, DP and pulse volume.

3.6 Generation of pressure pulses in the cuff

A linear actuator with its forward and reverse motions controlled by the processor output pins can be used for generating oscillations in the cuff. The variation in amplitude of oscillation is achieved by varying the force exerted by linear actuator on the cuff surface wall by using pulse width modulation. For a given actuator, pulse width can be varied from minimum pulse width PW_{min} to maximum pulse width PW_{max}. The pulse width (PW) for a given SP and DP is calculated in ms as the following,

$$PW = \begin{cases} 0, & CP \leq DP \\ PW_{min} + (PW_{max} - PW_{min})(CP - DP) / (MAP - DP), & DP < CP \leq MAP \\ PW_{min} + (PW_{max} - PW_{min})(SP - CP) / (SP - MAP), & MAP < CP < SP \\ 0, & SP \leq CP \end{cases} \quad (3.6)$$

As CP decreases from SP to MAP, the amplitude of oscillation is increased. A further decrease in CP from MAP to DP results in a decrease in the amplitude of the oscillation. Finally at DP, amplitude of oscillation becomes zero. The final value of PW is also scaled in accordance with the set value of pulse volume.

Chapter 4
INSTRUMENT HARDWARE

4.1 Introduction

The arm simulator is designed for realizing (i) heart beat generation in accordance with the set heart rate and arrhythmia level, (ii) calculation of the oscillometric envelope, in accordance with the set values of systolic and diastolic pressures, (iii) outputting the Korotkoff sounds, (iv) outputting the pulses to the actuator for coupling oscillations in the cuff, and (iv) receiving the inputs for setting simulation parameters.

The simulator, as shown earlier in Figure 3.1, consist of a cylinder representing the patient arm for wrapping the cuff of the BP monitor, and a controller board for generating the Korotkoff sound through speaker and pressure oscillations in the cuff at each simulated heart beat in accordance with the set parameters. The cylinder is fitted with a sensor for dynamically sensing the pressure in the cuff and a mechanism for producing the Korotkoff sound and pressure pulses. The instrument can be operated in two modes, auscultatory simulation mode and oscillometric simulation mode. In auscultatory simulation mode, the waveform of the Korotkoff sound is generated in accordance with the set parameters and the pressure inside the cuff. In oscillometric simulation mode, an actuator produces oscillations in the air pressure in the cuff.

A block diagram of the hardware of the controller board is shown in Figure 4.1. It is designed using a microcontroller with on-chip ADC and DAC. ADC is used for sensing the cuff pressure. DAC is used for outputting the sound waveform through an amplifier and speaker. The internal timers of the microcontroller are used to generate cardiac pulses, in accordance with the set beat rate and arrhythmia. A computer based graphical user interface (GUI) is used for setting the simulation parameters through a serial port. It can be used to set simulation parameters: systolic pressure (SP), diastolic pressure (DP), heart rate (HR), arrhythmia level (AL), pulse volume (*V*), and simulation mode (auscultatory or oscillometric). A solenoid is fitted inside the cylinder on which the cuff of the BP monitor is wrapped, with the solenoid plunger just below the cylinder surface. It serves as a linear actuator to generate pressure pulses in the cuff. The cylinder also has a small speaker to produce the Korotkoff sounds. The instrument has a pressure sensor and a force sensor for sensing the pressure inside the cuff. Pressure sensor is used to sense the cuff pressure dynamically. It is pneumatically coupled to the cuff by inserting a T-connector in the cuff tubing. A force sensor is mounted on the surface of the cylinder, to dynamically sense the force exerted by the cuff wall on

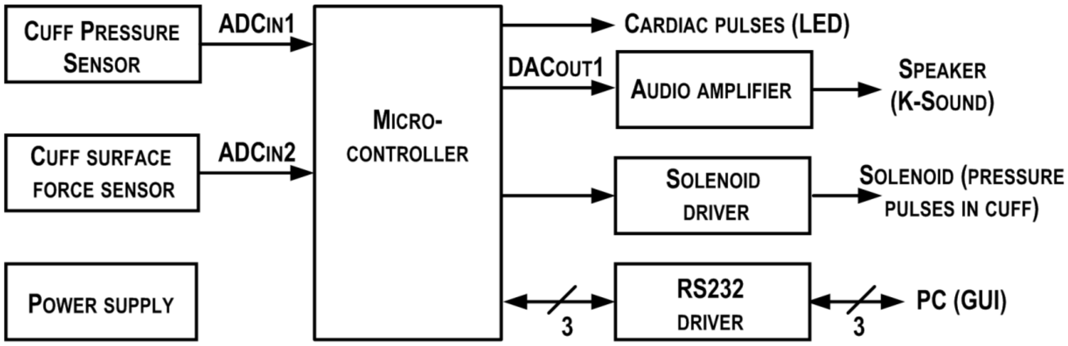


Figure 4.1: Block diagram of control board of the arm simulator

its sensing area. As the force is directly proportional to pressure, the force sensor can be used to non-invasively (without pneumatic coupling) sense the cuff pressure. The outputs of force sensor and the pressure sensor are given as inputs to on-chip ADC of the microcontroller. These two pressure sensing techniques are used for the initial development work, in which pressure waveform acquired by the two sensor can be compared with the pressure readings from the manometer. The objective is to have an instrument in which the sensing of the cuff pressure does not involve any modification of the cuff tubing.

4.2 Microcontroller

At the core of the circuit is the 16-bit microcontroller IC "Microchip DSPIC33FJ128GP802" [20]. It is available as 28-pin shrink plastic dual-in-line package (SPDIP) and small outline integrated circuit (SOIC) package. It has internal power-up reset and boots with its internal RC oscillator. It can be powered by 3 – 3.6 V supply. In our application, it is powered by 3.3 V. It has two I/O ports RA (RA.0 – RA.4) and RB (RB.0 – RB.15) and most of the port pins have multiple programmable functions. One of its two on-chip UART modules is used in our application for setting the simulation input parameter through a PC-based graphical user interface. The microcontroller has on-chip ADC with 10-bit resolution and maximum sampling frequency of 1.1 MHz. The ADC input range is 0 – 3.3 V. It has four channels CH0, CH1, CH2, and CH3. The channel CH0 can support up to 13 analog inputs. In our application two inputs of CH0 are used, one for pressure sensor and another for force sensor. It has two DAC outputs with 16-bit resolution and maximum sampling frequency of 100 kHz. In our application one DAC output is used for generating the Korotkoff sound at sampling frequency of 8 kHz. The microcontroller has five 16-bit timers, out of which two timers are cascaded and used for generation of cardiac pulses.

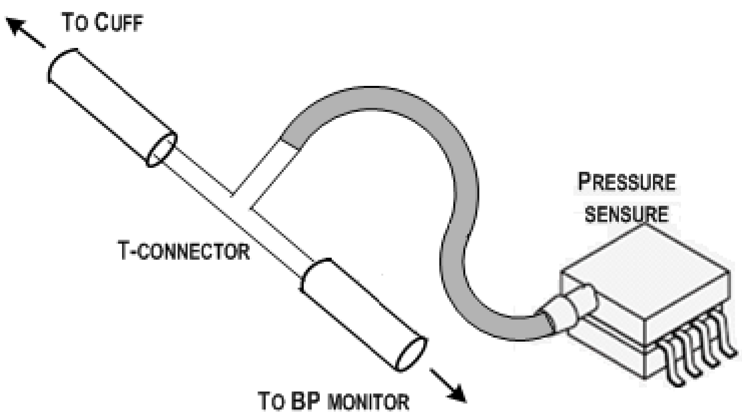


Figure 4.2: Coupling between cuff tube of BP monitor and pressure sensor (MPXV5050GP [21])

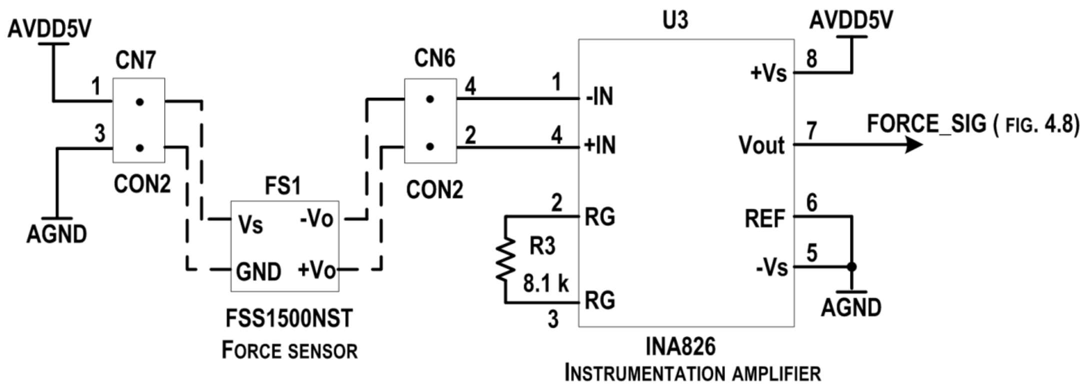


Figure 4.3: Force sensor and instrumentation amplifier for non-invasive sensing of cuff pressure

4.3 Sensing of the cuff pressure

A MEMS-based integrated pressure sensor, "Freescale semiconductor MPXV5050GP" [21], has been used for sensing the pressure in the cuff. It senses the gauge pressure, i.e. pressure above the atmospheric pressure, as coupled to its pressure port on its side as shown in Figure 4.2. It has a range of 0 – 50 kPa (0 – 375 mmHg), with a sensitivity of 90 mV/kPa (12 mV/mmHg) and pressure offset of 0.2 V. Thus, the cuff pressure of 0 – 210 mmHg results in output of 0.2 – 2.72 V. The output is directly connected to ADC input of the microcontroller without needing an amplifier. It has an accuracy of 2.5% V_{FSS}. The pressure sensor can be used with a supply voltage of 4.75 – 5.25 V, and has current drain of 10 mA. In our application, it is powered by 5 V. It is used for sensing the air pressure in the cuff by pneumatically coupling its sensing port to a T-connector placed between the cuff and the pressure gauge of the BP monitor. The coupling is made using a rubber tube with internal diameter of 4 mm, to match the outer diameter of the sensing port.

The coupling of the pressure sensor to the cuff requires disconnecting the cuff from BP monitor and inserting a T-connector. This is an invasive process and not easily feasible for all models of BP monitor. Attempts were made to sense the cuff pressure without using any direct coupling to it. In one such experiment, the cuff was wrapped with an air-filled rubber bulb placed between it and the cylinder, with a tube connecting the bulb to the pressure port of the sensor. The sensed pressure was found to vary with the cuff pressure. However, the offset and calibration factor varied with the material of the bulb and its location with respect to the cuff. Hence this method was considered to be unsuitable for an accurate sensing of the cuff pressure.

In another method of non-invasive sensing of the cuff pressure, a force sensor placed between the cylinder surface and cuff wall is used. The force applied on the sensor is equal to the integral of the pressure at the cuff surface over the area of contact between the cuff and the sensing surface. A piezoresistive force sensor "Honeywell FSS1500NST" [22] has been selected for this purpose. It works with 5 V supply and provides unamplified differential output. It has an input force range of 15 N (with safe limit of 45 N) and full-scale output voltage of 180 mV, i.e. sensitivity of 12 mV/N. Its sensing surface is in the shape of part of spherical ball, with an area of approximately 9.86 sq mm. In our application, we need to sense the pressure of 0 – 210 mmHg. Assuming a uniform sensitivity over the sensing surface and uniform contact between the cuff surface and the sensing surface, 210 mm Hg pressure corresponds to a force of 0.276 N. As this is only 1.8% of the full-scale range, we need a force scaling. This can be achieved by placing a plate of a much larger area above the sensor, with the scaling factor being equal to the ratio of the plate area and the sensing area. As the sensitivity of the sensor surface may not be uniform and force coupling from the cuff surface to the plate and that from the plate to the sensing surface also may not be uniform, the scaling factor for a given coupling plate needs to be empirically found. In our setup, a rectangular plate of area 120 mm^2 is placed between force sensor ball and the cuff. Using a scaling factor based on area ratio, cuff pressure of 210 mmHg should result in differential output of 40.3 mV. Measured value of the differential output from the force sensor was found to be 210 – 270 mV, with variations occurring for different wrappings of the cuff. An output value much larger than that calculated by scaling ratio indicates that the sensing surface has a non-uniform sensitivity, possibly much larger at the top of the spherical ball. The variations in the sensed output for the same applied cuff pressure may be caused by changes in the alignment of the coupling plate with sensor.

It was decided to provide a voltage gain of 7 for applying the output of the force sensor to the ADC input of the microcontroller which has range of 0 – 3.3 V. An instrumentation amplifier "TI INA826" [23] is used as U3 to amplify the differential output of the force sensor FS1to get a single ended output, as shown in Figure 4.3. The instrumentation amplifier can be operated with a single supply of 2.7 – 36 V. In our application, it is powered by 5 V. Resistor R3 of 8.1 kΩ is used to set the gain as 7. With this gain, the output for

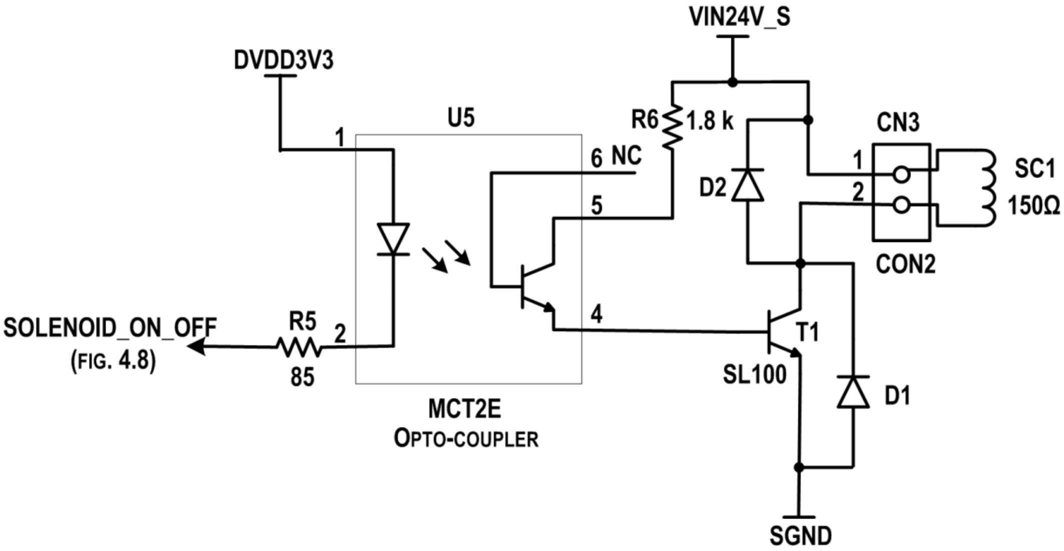


Figure 4.4: Driver for the linear actuator

pressure 210 mmHg was found to be 1.48 – 1.89 V, i.e. the sensitivity of sensor was found to be 7.0 – 9.0 mV/mmHg. The sensor output was measured to be well correlated with the cuff pressure as measured by a pressure gauge over a large range. The test results showed that we need to devise a method for maintaining a stable contact between the force scaling plate and the force sensor.

4.4 Pressure pulse generation

A 24 V solenoid is used as a linear actuator for producing pressure pulses in the cuff. With a coil resistance of 150 Ω, it takes a current of 160 mA. The driver for the linear actuator is shown in Figure 4.4. The on-off operation of the solenoid is controlled by microcontroller port pin RB.14. The variation in amplitude of oscillation is achieved by varying the force exerted by linear actuator on the cuff surface wall by using pulse width modulation. To provide isolation between solenoid coil current path and the microcontroller circuit, an opto-coupler "Vishay MCT2E" [24] has been used as U5. Switching of the solenoid current is carried out by an NPN power transistor "SL100" [25], shown as T1 in the figure. The power transistor has V_{CEOmax} of 50 V and I_{Cmax} of 500 mA. Diodes D1 and D2 ("1N4007" [26]) serve as snubber diodes and has peak reverse voltage rating of 1000 V and current rating of 1 A. When solenoid is actuated, its plunger presses against the cuff, thereby increasing pressure inside the cuff above its static pressure value. When it is deactivated, its spring restores the plunger back and the pressure in the cuff reduces to its static value. The pulse width controls the force of the actuator and thereby the amplitude of the oscillations of the pressure in the cuff. It was found that pulse width of less than 40 ms does not result in any noticeable oscillation in the cuff pressure and the amplitude of

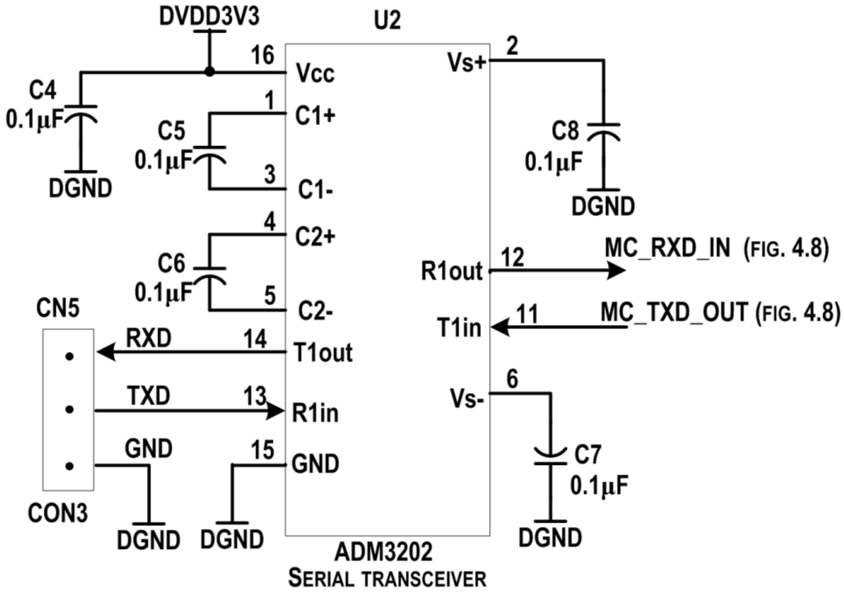


Figure 4.5: RS232 interface

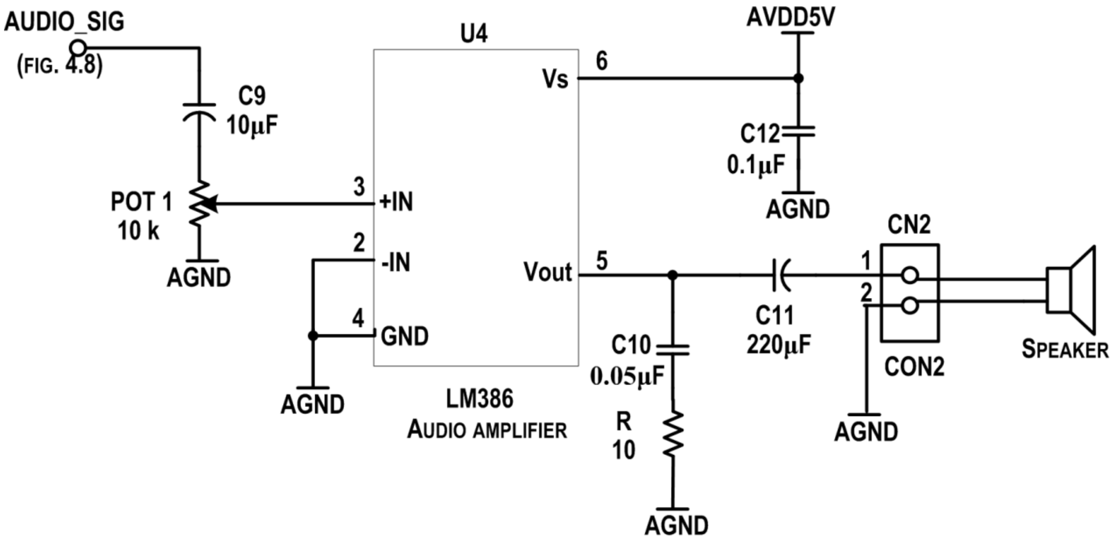


Figure 4.6: Circuit diagram of audio power amplifier

oscillation saturates at about 200 ms. Hence the minimum and maximum values of the pulse width are selected 40 and 200 ms, respectively.

4.5 Interface for parameter setting

Interfacing between computer and microcontroller is done using serial transceiver "Analog Devices ADM3202" [27], labeled as U2 in Figure 4.5. It is a logic level shifter for providing an interface between RS232 levels and 3.3 V microcontroller logic levels. Microcontroller's

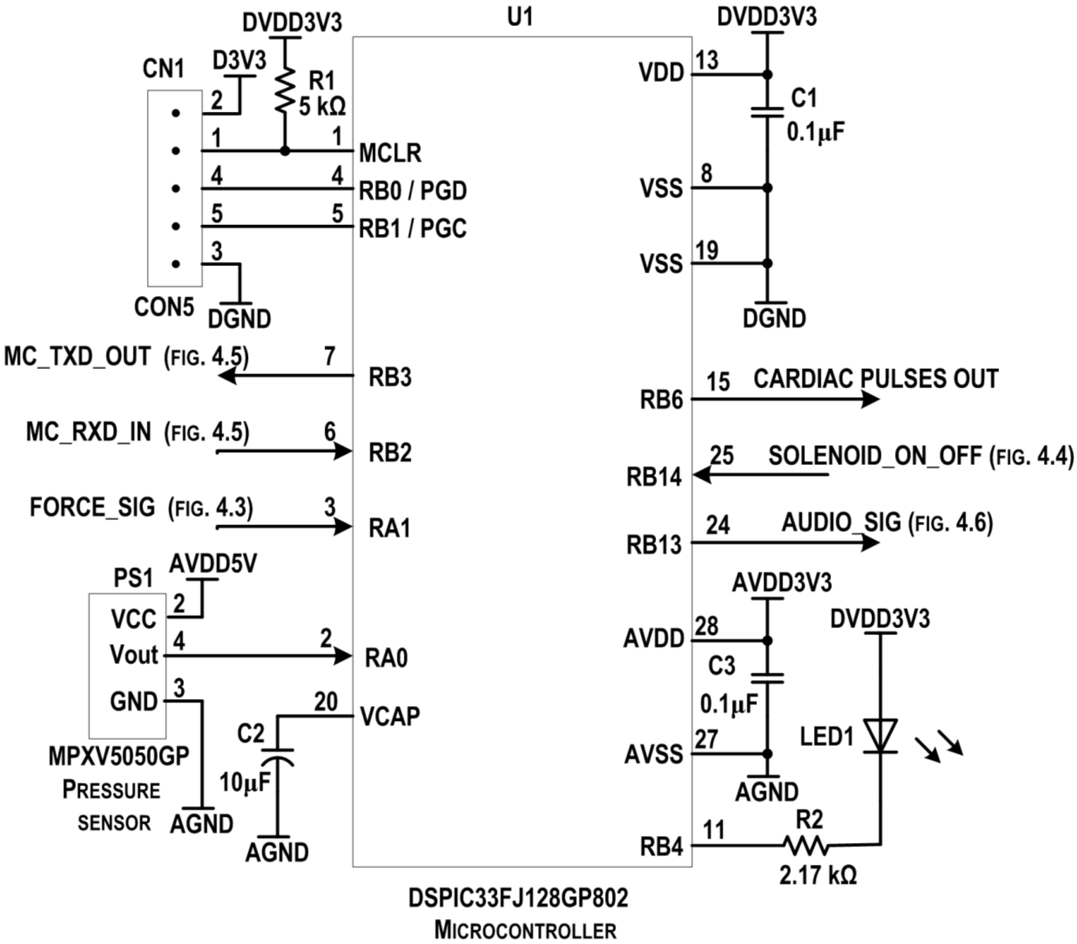


Figure 4.7: Microcontroller circuit

pin number 6 (RB.2) is configured as input pin to UART (receive), while the pin number 7 (RB.3) is configured as output pin from UART (transmit). U2 can be operated on 3.3 V, a maximum current of 12 mA, and supports maximum data rate of 460 kbps. CN5 is a 3-pin connector which is used for serial communication to PC or another computing device with RS232 port.

4.6 Korotkoff sound generation

The port pin RB.13 of the microcontroller is configured as DAC output to output Korotkoff sound pulses. As the DAC output cannot directly drive a speaker for generating audible sounds, a power amplifier IC "National LM386" [28] is used as U4 for driving the speaker. It can deliver 125 mW continuously into an 8 Ω load and can be used with 4 – 12 V supply. In our application, it is powered by 5V. For volume control, the input AUDIO_SIG is applied as input to U4 through a preset pot PT1 of 10 kΩ. The circuit with U4 connected in the RC coupled non-inverting amplifier mode with gain of 20 is shown in Figure 4.6.

Table 4.1: Assignment of the port pins of the 28-pin microcontroller U1 (DSPIC33FJ128GP802)

Pin label	Pin number	Function
MCLR	1	Active low reset
RA.0	2	ADC input for pressure sensor
RA.1	3	ADC input for force sensor
RB.0	4	PGD (for programming/debugging)
RB.1	5	PGC (for programming/debugging)
RB.2	6	UART input
RB.3	7	UART output
RB.4	11	Cardiac pulse out (LED indicator)
RB.6	15	Cardiac pulses (monitoring)
RB.13	24	DAC output for K-sound
RB.14	25	Linear actuator on/off

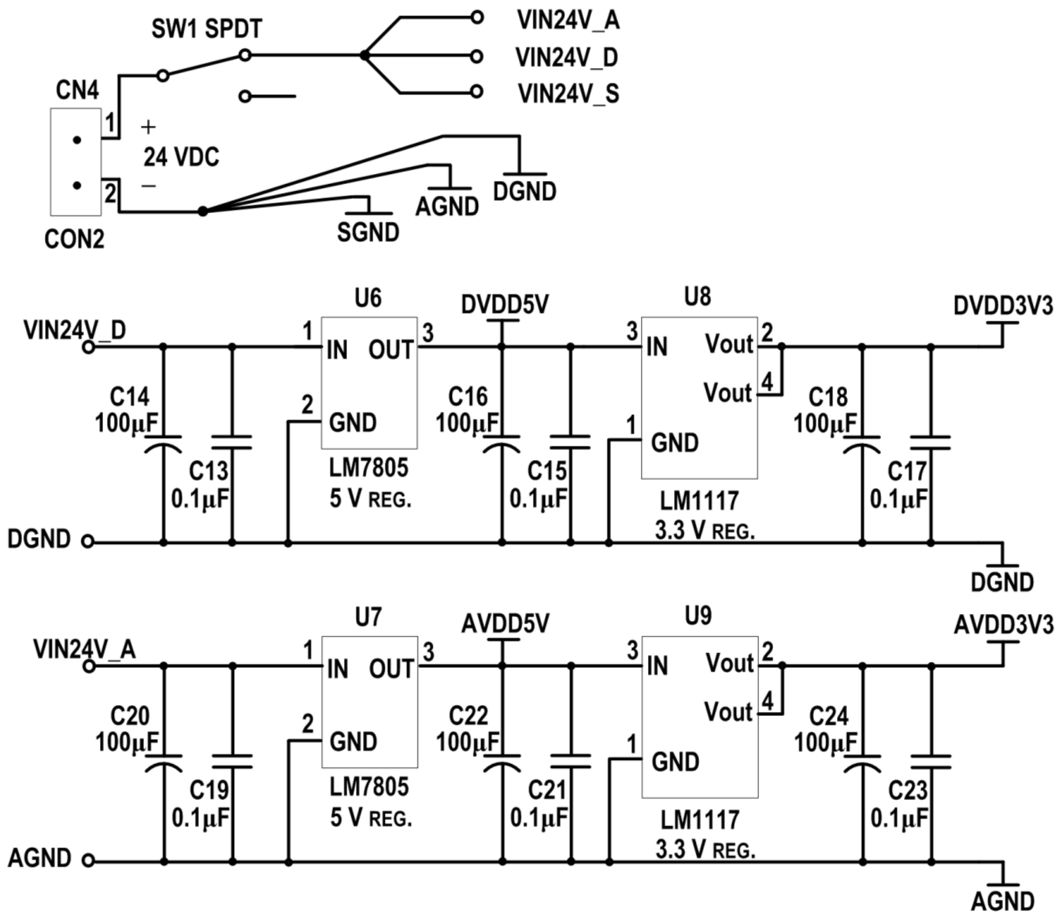


Figure 4.8: Power supply circuit

4.7 Microcontroller circuit

The microcontroller circuit of the arm simulator is shown in Figure 4.7, with the microcontroller "Microchip DSPIC33FJ128GP802" as its core component U1. It has internal program memory and is programmed to run using its internal clock generator. Connector CN1 is used for loading the program and for debugging the program operation using the development kit "Microchip PICkit^{TM}3". The assignment of port pins of U1 is given in Table

Table 4.2: Estimation of current consumption

Supply voltage	Block/Component	Current (mA)
DVDD3V3	U5 (MCT2E)	10.0
	U2 (ADM3202)	12.0
	U1 (DSPIC33FJ128GP802)	24.0
	LED1	1.2
	Total	47.2
DVDD5V	DVDD3V3	47.2
	U8 (LM117) quiescent	10.0
	Total	57.2
VIN24V_D	DVDD5V	57.2
	U6 (LM7805) quiescent	8.0
	Total	65.2
AVDD3V3	U1 (DSPIC33FJ128GP802)	5.0
AVDD5V	AVDD3V3	5.0
	LM117 (U9) quiescent	10.0
	FS1 (FSS1500NST)	1.6
	U3 (INA826)	16.0
	U4 (LM386)	8.0
	PS1 (MPXV5050GP)	10.0
	Total	50.6
VIN24V_A	AVDD5V	50.6
	U7 (LM7805) quiescent	8.0
	Total	58.6
VIN24V_S	SC1 (Solenoid)	160.0
VIN24V	VIN24V_D	65.2
	VIN24V_A	58.6
	VIN24V_S	160.0
	Total	283.8

4.1. LED1, connected to RB.4 of U1, is used to indicate the cardiac beats. The same output is also available at RB.6 for monitoring. As described earlier in Section 4.3, “Freescale semiconductor MPXV5050GP” is used as the pressure sensor as PS1. Its analog output is connected to the ADC input of U1 at pin RA.0. The output of the force sensor FS1 after amplification by U3, as shown in Figure 4.3, is connected to the ADC input at pin RA.1 for sensing the cuff pressure non-invasively. The port pin RB.14 is used to control the operation of solenoid as a linear actuator. The port pin RB.13 of U1 is configured as DAC output for generating Korotkoff sound.

A PC based graphical user interface (GUI), described in Chapter 5, is used to set simulation parameters through an RS232 connection. The PC and microcontroller are interconnected using serial transceiver IC "ADM3202". The port pin RB.2 is configured as input pin to UART of U1, while the pin RB.3 is configured as output pin from UART of U1.

4.8 Power supply

The instrument is designed to operate on 24 V DC which may be obtained from the mains using an AC to DC converter. The linear actuator SC1 (solenoid) is powered by 24 V, the audio power amplifier U4 (LM386 [28]), force sensor FS1 (FSS1500NST [22]), instrumentation amplifier U3 (INA826[U3]) and pressure sensors PS1 (MPXV5050GP [21]) are powered by 5 V, while the microcontroller U1 (DSPIC33FJ128GP802[20]) is powered by 3.3 V analog and digital supplies. The serial transceiver U2 (ADM3202 [27]) is powered by 3.3 V. All these voltages are obtained by using linear regulators as shown in Figure 4.8. The maximum current consumption of all components on the board is estimated to be $I_L \approx 283.8$ mA, as given in Table 4.2. The two voltage regulators U7 (LM7805 [29]) and U9 (LM1117 [30]) are used to supply the analog sections of the hardware with AVDD5V as regulated +5 V and AVDD3V3 as +3.3 V. The digital section is powered by DVDD5V as regulated +5 V and DVDD3V3 as +3.3 V from another set of regulators U6 (LM7805) and U8 (LM1117). Since we need a voltage regulator which can withstand 24 V and can supply a current of 57.2 mA, a regulator IC (LM7805 [29]) has been chosen because it can be operated up to 36 V, with maximum current capacity of $I_{MAX} = 1$ A, thus capable of handling the voltage and current requirement. To improve the stability of the regulator, a parallel combination of 100 µF and 0.1 µF is connected at the input and output of each regulators U6, U7, U8, and U9.

Chapter 5
SOFTWARE

5.1 Introduction

A PC based graphical user interface (GUI) is developed, using Visual Basic 2010, to set BP simulation parameters. A microcontroller program is written to receive these parameters through serial port and to carry out the operation of BP simulation accordingly. The program is developed in 'C' using the "Microchip MPLAB IDE, v8.84" and the development kit "Microchip PICkit^{TM}3" as programmer/debugger.

5.2 Graphical user interface (GUI)

The graphical user interface for setting of simulation parameters is shown in Figure 5.1.The user can select systolic pressure (SP), diastolic pressure (DP), heart rate (HR), pulse volume and arrhythmia level (AL). The selection ranges of simulation parameters are given in Table 5.1.The user can select auscultatory mode or oscillometric mode for BP simulation. For sensing the cuff pressure, either invasive sensing (using pressure sensor) or non-invasive sensing (using force sensor) can be selected. The program opens a serial port on the PC with 9600 baud, 1 start bit, no parity, and 1 stop bit. The simulation can be started by pressing "Start Simulation" button on the GUI. The pressing of "Start Simulation" button sends an eight byte code word to microcontroller through serial port. The microcontroller receives the code and starts the simulation according to the set parameters. The details of eight-byte code word for setting the simulation parameters is given in Table 5.2. A one-byte code corresponding to the cuff pressure is sent periodically from the microcontroller to the PC and the cuff pressure is displayed on the GUI. The simulation can be stopped by pressing the "Stop Simulation" button on the GUI as shown in Figure 5.2. The outline of the working of GUI is shown in Figure 5.3.

Table 5.1: Parameter settings

Parameter	Min	Max	Default	unit	Remark
SP	20	210	120	mmHg	Step size: 5 mmHg, Min = min (20, DP)
DP	0	140	80	mmHg	Step size: 5 mmHg, Max = max (SP, 140)
Arrhythmia (AL)	0	50	0	-	0: no variation, 50: 50% peak variation in period of heart beat. Step size: 10
Heart Rate (HR)	20	150	70	bpm	Step size: 5 bpm
Pulse volume (*V*)	0	100	100	-	0: no volume, 100: maximum. volume. Step size: 20

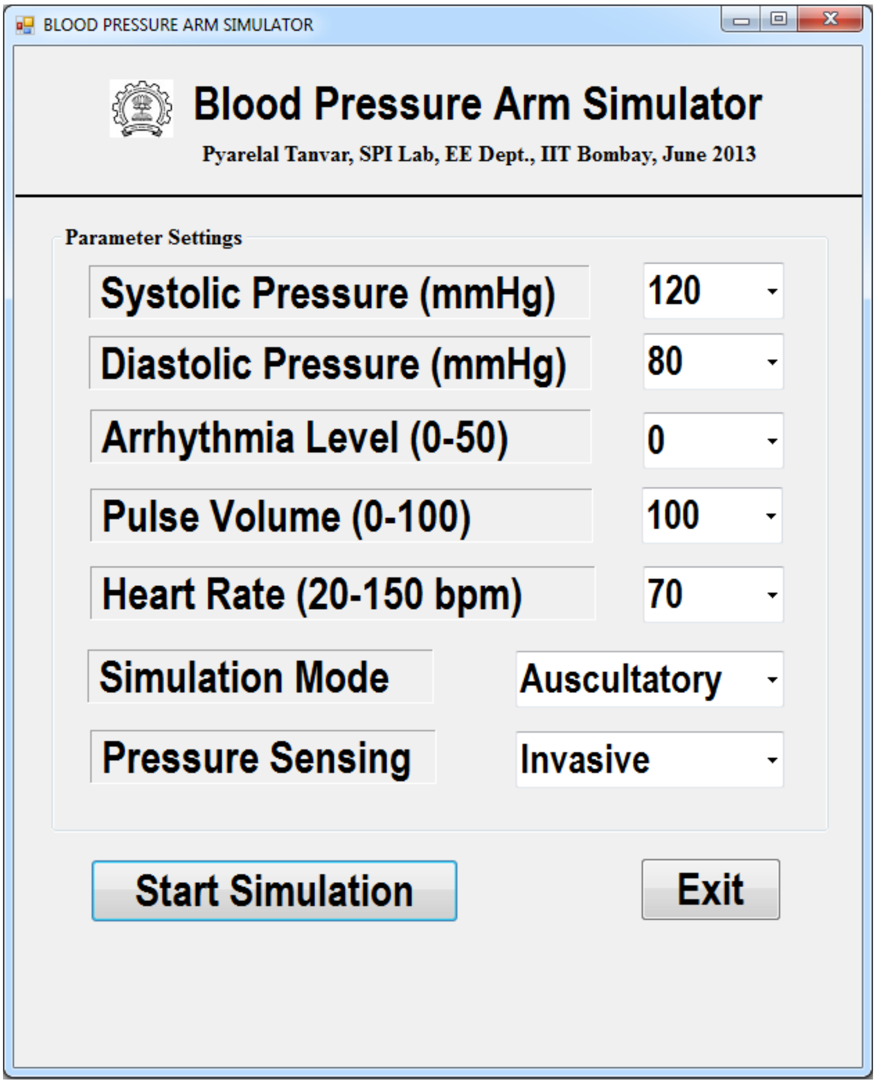


Figure 5.1: An example of GUI screen for setting the simulation parameter.

Table 5.2: Eight-byte code for parameter setting

Byte No.	Parameters	Values	Remark
1	SP	20 − 210	Ex.: d120 or 0x78 for SP = 120 mmHg
2	DP	0 − 140	Ex.: d80 or 0x50 for DP = 80 mmHg
3	Arrhythmia level	0 − 50	0: 0 %, 1: 10 %, 2: 20 %, 3: 30 %, 4: 40 %, 5: 50 %
4	Pulse volume	0 − 100	0: 0 %, 1: 20 %, 2: 40 %, 3: 60 %, 4: 80 %, 5: 100 %
5	HR	20 − 150	Ex.: d70 or 0x46 for HR = 70 bpm
6	Simulation mode	0, 1	0: auscultatory, 1:oscillometric mode
7	Simulation start/stop	0, 111	0: Stop simulation, 111: Start simulation
8	Type of pressure sensing	0, 1	0: Pressure sensor, 1: Force sensor

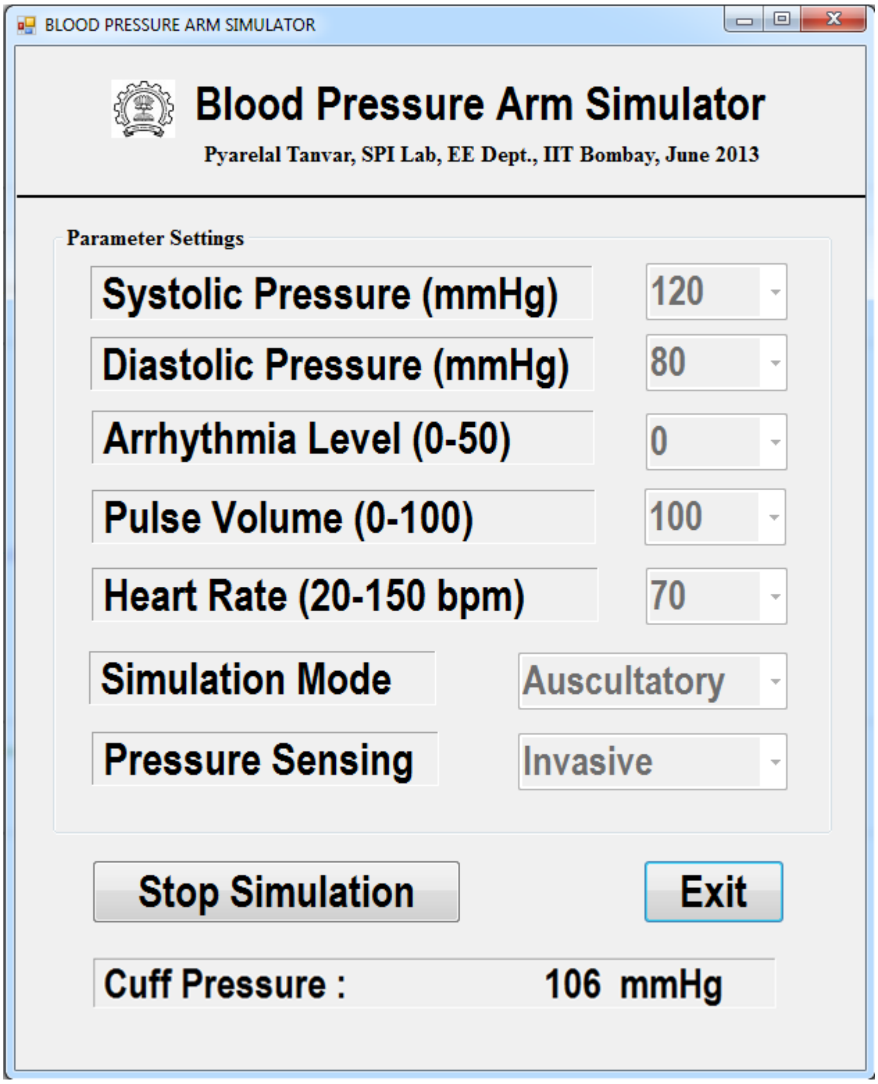


Figure 5.2: An example of GUI screen during simulation.

5.3 Microcontroller software

The complete flowchart of BP simulation is shown in Figure 5.4(a) and Figure 5.4(b), After power ON, the microcontroller initializes the port pins, ADC, DAC, and UART. It continuously polls the UART for the data to be received from GUI. The microcontroller sets the simulation parameters SP, DP, HR, PV, and AL in accordance with the received data. If the sixth byte is "0", then it sets simulation mode to be auscultatory, otherwise simulation mode is set to be oscillometric. If the eighth byte is "0" then pressure sensor will be selected for cuff pressure sensing, otherwise force sensor will be selected. If the value of seventh byte is "111" then BP simulation will start. The cuff pressure is dynamically sensed and sent to PC through serial port to be displayed on GUI. In auscultatory mode of BP simulation, as long as the cuff pressure is between systolic and diastolic pressure, the Korotkoff sound pulses are output at the DAC, otherwise no sound is heard. In oscillometric mode of BP simulation

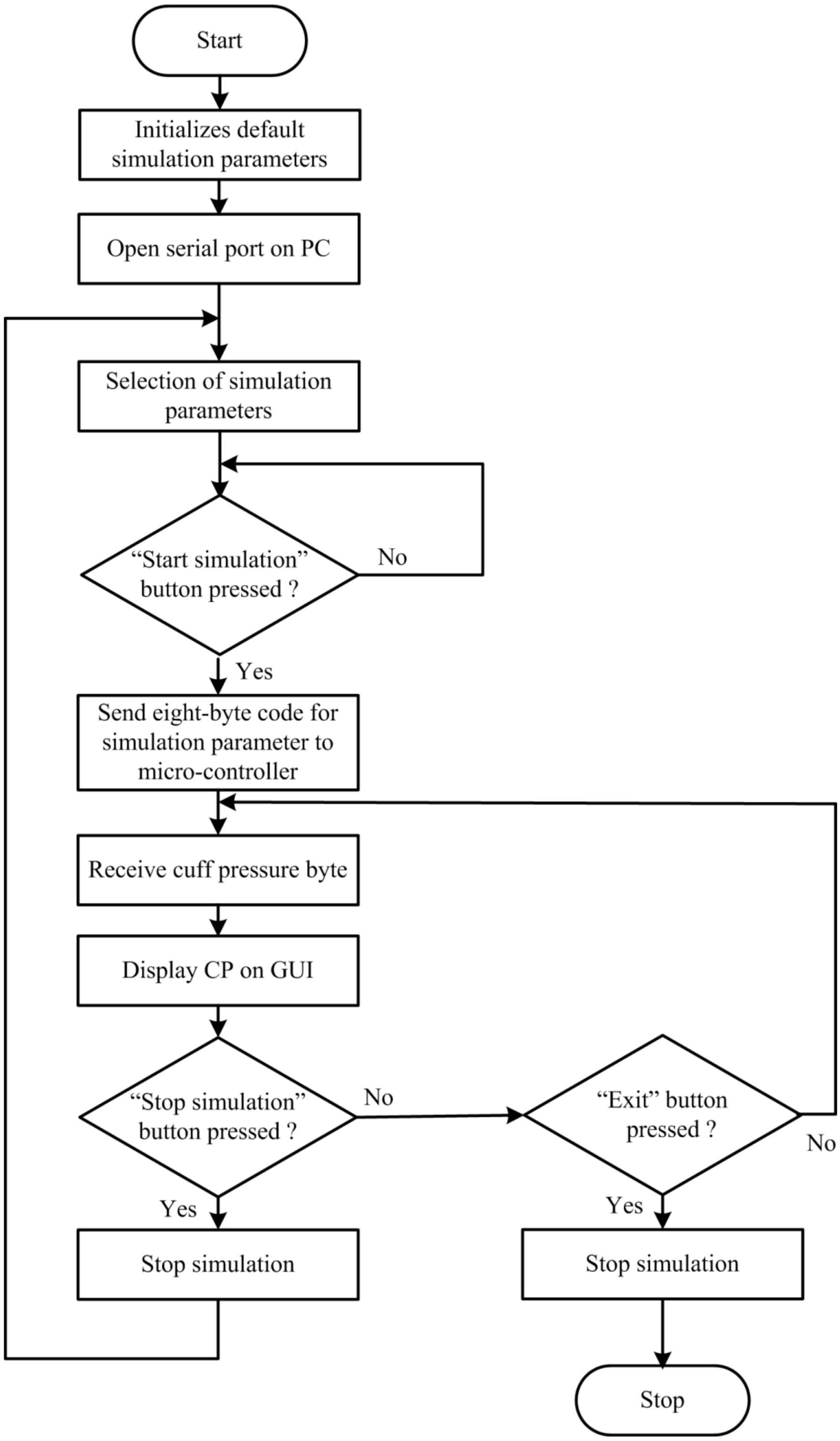


Figure 5.3 Flowchart for PC-based GUI program.

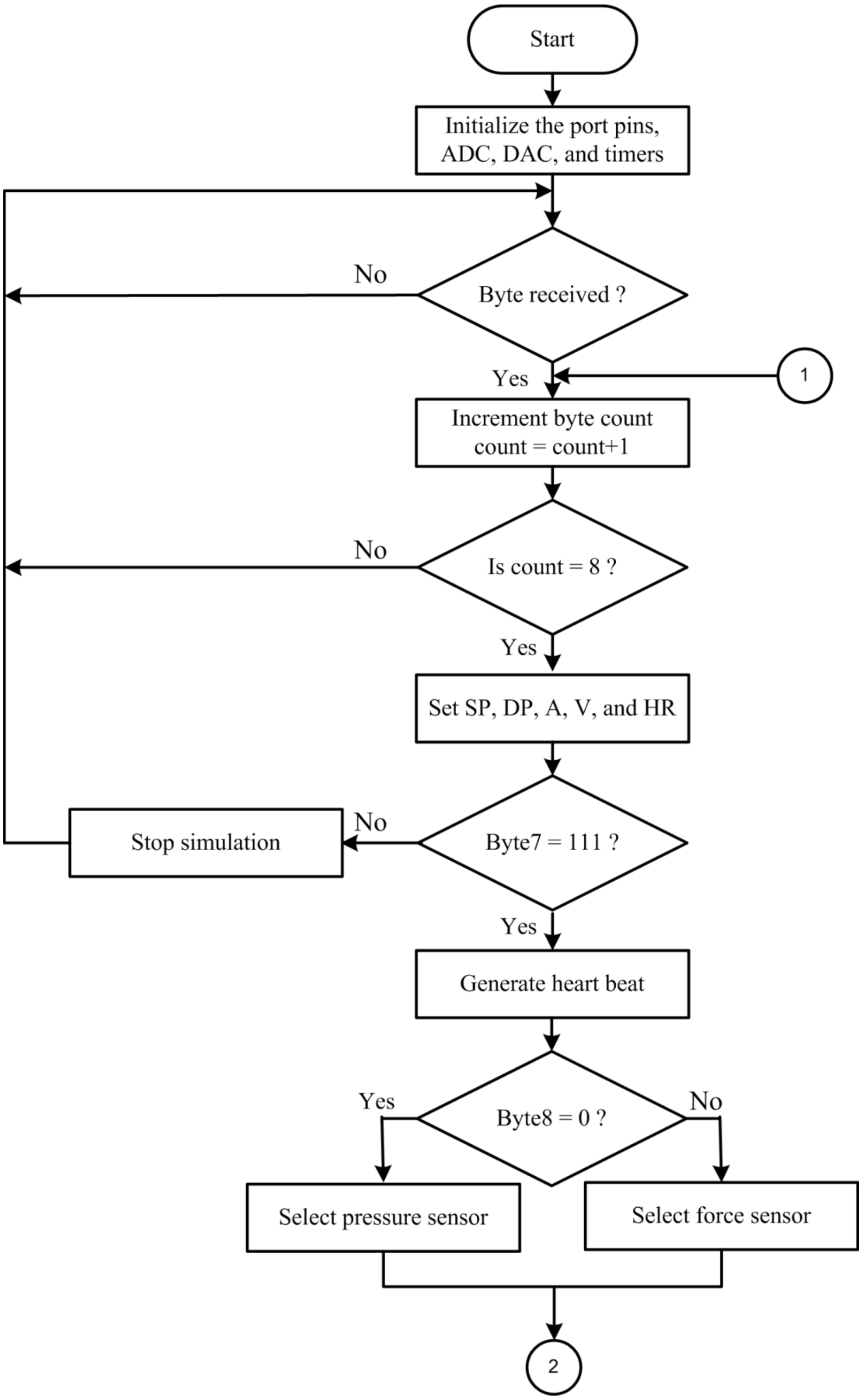


Figure 5.4(a) Flowchart for microcontroller program: initialization and parameter setting.

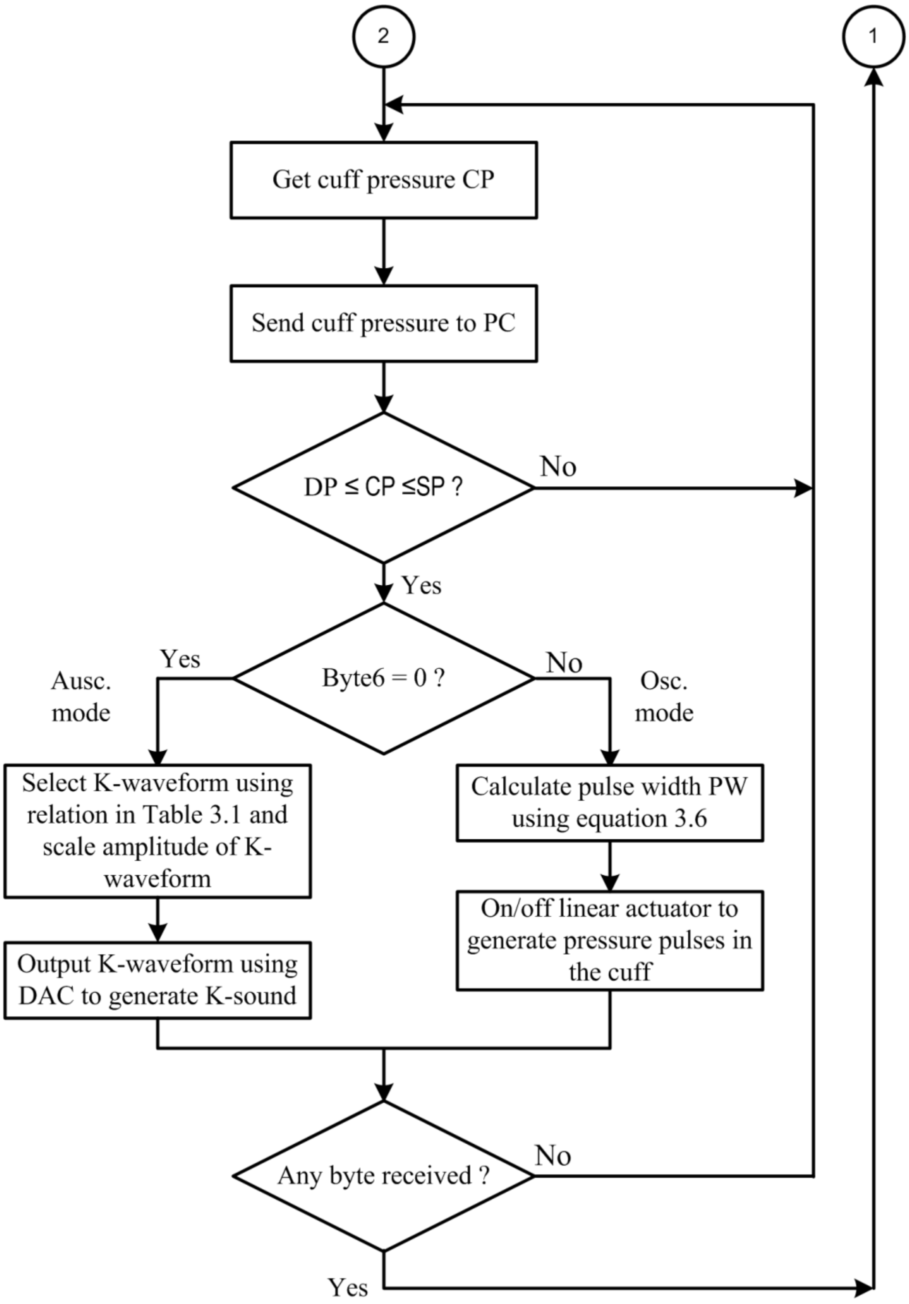


Figure 5.4(b) Flowchart for microcontroller program: Operation.

as long as the cuff pressure is between systolic and diastolic pressure, the pressure pulses are generated in the cuff using linear actuator. The simulation is stopped if GUI again send eight byte codeword data, and the seventh byte happen to be "0".

Chapter 6
SYSTEM ASSEMBLY AND TEST RESULTS

6.1 System assembly

The simulator consists of: cylinder, solenoid, force sensor, pressure sensor, electronic circuit, speaker, and GUI. The instrument is in the form of a rigid cylinder placed vertically on a horizontal support. The cuff of the BP monitor is wrapped on the cylinder. A pressure sensor is connected between the cuff and the manometer of the BP monitor through a T-connector. The force sensor is mounted on the surface of the cylinder, to be in contact with the cuff wrapped around the cylinder. A rectangular cut is made in the cylinder to fit the solenoid in such a way that its plunger presses against the cuff surface to produce pressure pulses. Another cut is made in the cylinder to fit a speaker. A PC on which GUI runs is connected to the instrument through a serial port for setting of simulation parameters. The entire circuit is assembled on a bread board and simulation results are obtained. After designing a PCB for the controller card, the components can be mounted on it and this controller card can be fitted inside the cylinder, to realize a compact prototype.

Figure 6.1(a) shows arm simulator prototype. Figure 6.1(b) shows arm simulator prototype with circuit on bread board and speaker. Figure 6.2 shows arm simulator pneumatically connected to manual BP monitor via a T-connector, and the cuff of the BP monitor is wrapped around the cylinder. Figure 6.3 shows arm simulator pneumatically connected to automatic BP monitor via a T-connector, and the cuff of the BP monitor is wrapped around the cylinder. Figure 6.4 shows arm simulator coupled to cuff of the manual BP monitor non-invasively (i.e. without a T-connector), and the cuff of the BP monitor is wrapped around the cylinder. Figure 6.5 shows arm simulator coupled to cuff of the automatic BP monitor non-invasively, and the cuff of the BP monitor is wrapped around the cylinder.

6.2 Test results for the pressure sensor

The operation of the pressure sensor was tested by measuring its output for different values of air pressure in the cuff. These readings were taken for three different wrappings of the cuff on the cylinder and with the cuff pressure increasing and decreasing. The reference values of the pressure were taken using the mercury manometer of the manual BP monitor "Diamond BP apparatus". The results are given in Table 6.1. No significant hysteresis is obtained and the standard deviation is very small. The mean and standard deviation of pressure sensor output

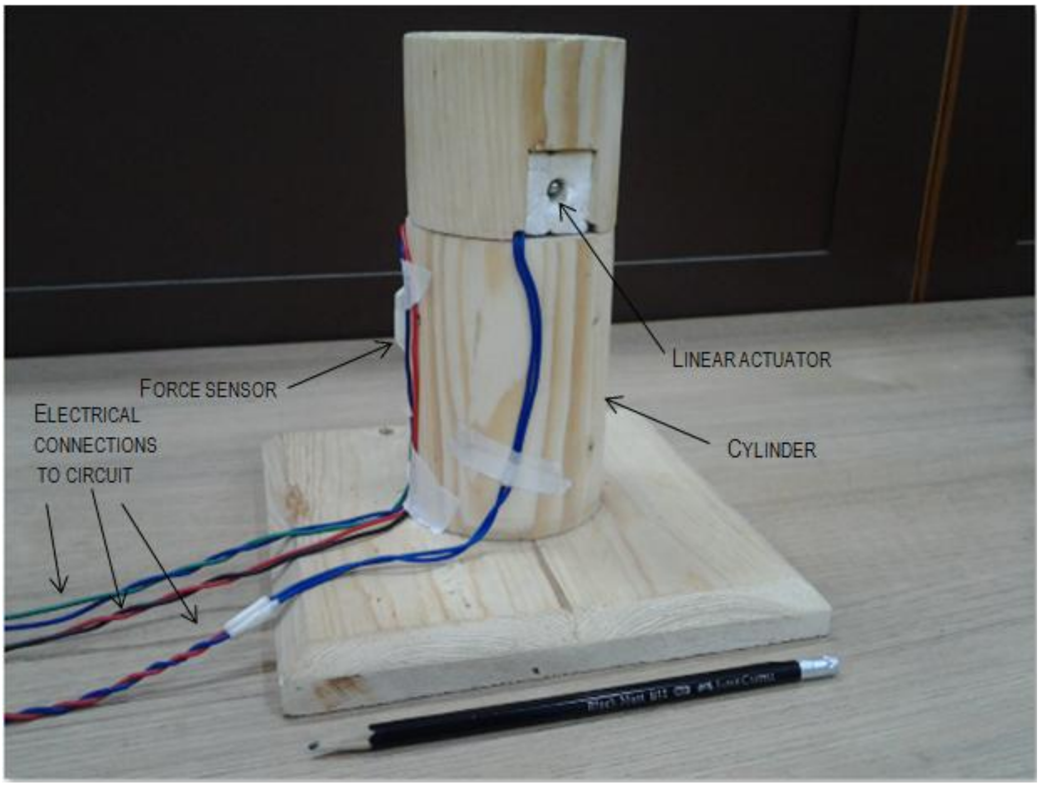


Figure 6.1(a): Mechanical assembly of the BP arm simulator

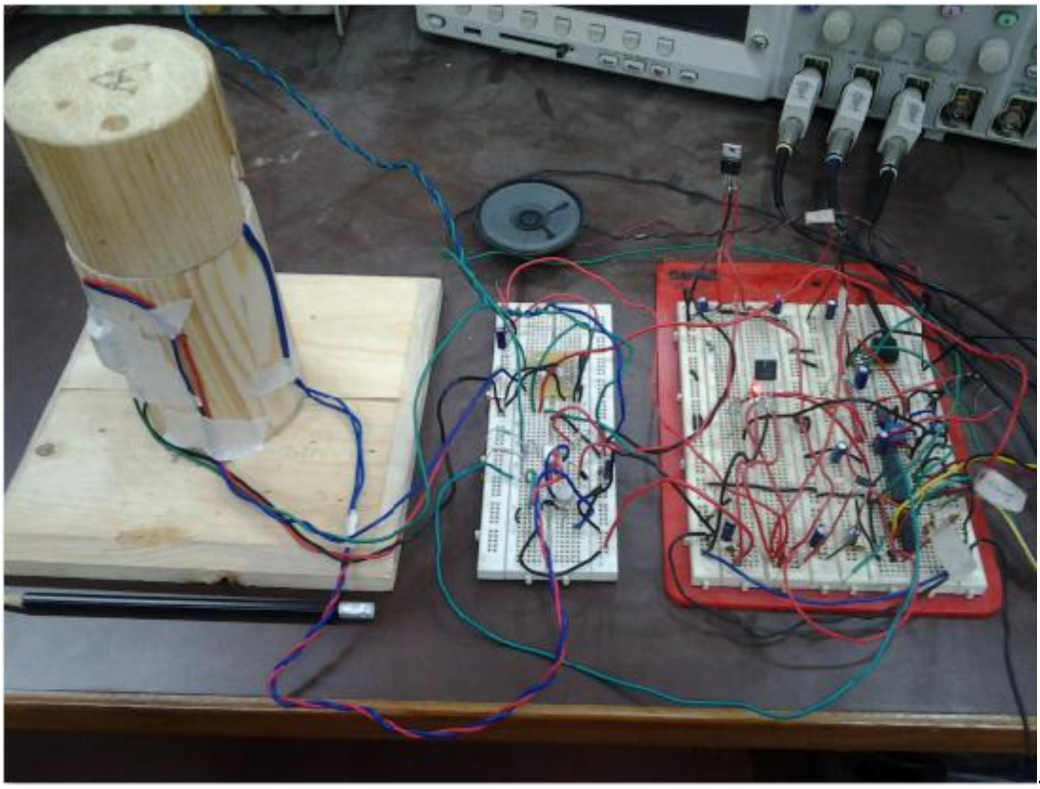


Figure 6.1(b): BP arm simulator prototype with its circuit board

vs. the cuff pressure are plotted in Figure 6.6. It shows a nearly linear relationship with an offset of 0.2 V, and sensitivity of 12 mV/mmHg, as given in the datasheet.

Figure 6.2: BP arm simulator connected to a manual BP monitor via T-connector

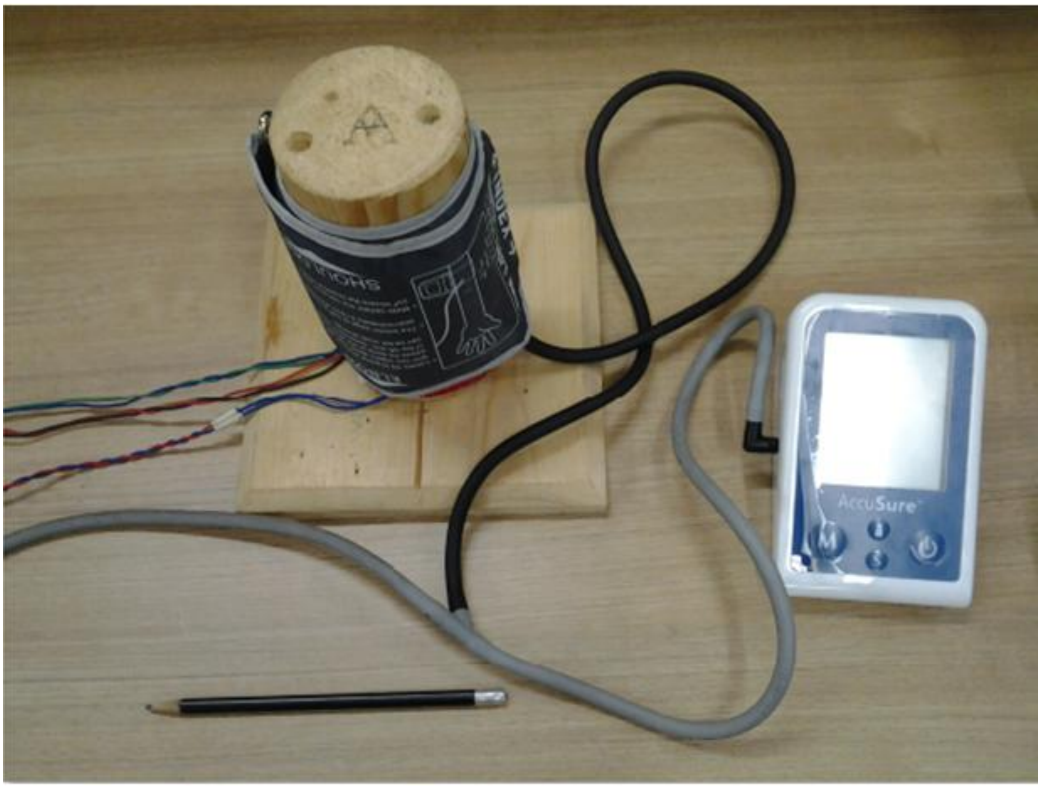


Figure 6.3: BP arm simulator connected to an automatic BP monitor via T-connector

Figure 6.4: BP arm simulator connected non-invasively to a manual BP monitor

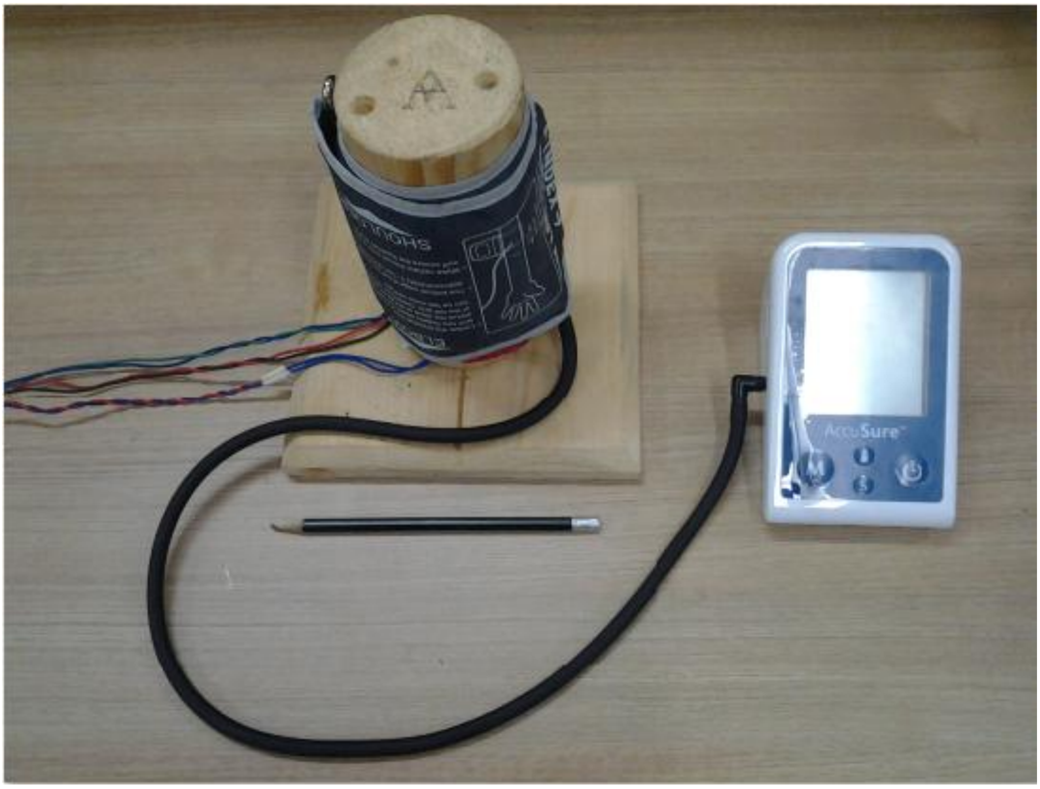


Figure 6.5: BP arm simulator connected non-invasively to an automatic BP monitor

Table 6.1: Test results for pressure sensor

Input	Pressure sensor output (V)							
Pressure (mmHg)	Wrap1 Incre.	Wrap1 Decre.	Wrap2 Incre.	Wrap2 Decre.	Wrap3 Incre.	Wrap3 Decre.	Mean	Std. Dev.
0	0.220	0.220	0.220	0.220	0.220	0.220	0.220	0.000
10	0.300	0.300	0.360	0.360	0.350	0.310	0.330	0.030
20	0.460	0.460	0.480	0.460	0.460	0.460	0.463	0.008
30	0.580	0.580	0.580	0.580	0.580	0.580	0.580	0.000
40	0.700	0.700	0.700	0.700	0.700	0.700	0.700	0.000
50	0.820	0.820	0.820	0.820	0.800	0.800	0.813	0.010
60	0.920	0.940	0.940	0.940	0.940	0.940	0.937	0.008
70	1.060	1.060	1.060	1.060	1.060	1.000	1.050	0.024
80	1.200	1.200	1.120	1.180	1.180	1.160	1.173	0.030
90	1.300	1.300	1.300	1.300	1.280	1.280	1.293	0.010
100	1.400	1.420	1.420	1.420	1.400	1.400	1.410	0.011
110	1.520	1.520	1.500	1.550	1.520	1.520	1.522	0.016
120	1.650	1.650	1.650	1.650	1.650	1.650	1.650	0.000
130	1.700	1.750	1.800	1.800	1.800	1.800	1.775	0.042
140	1.900	1.900	1.900	1.900	1.900	1.900	1.900	0.000
150	2.000	2.000	2.000	2.000	2.000	2.000	2.000	0.000
160	2.150	2.100	2.150	2.150	2.100	2.100	2.125	0.027
170	2.250	2.250	2.250	2.250	2.250	2.250	2.250	0.000
180	2.350	2.350	2.400	2.400	2.350	2.350	2.367	0.026
190	2.500	2.500	2.500	2.500	2.500	2.500	2.500	0.000
200	2.600	2.600	2.600	2.600	2.600	2.600	2.600	0.000
210	2.700	2.700	2.700	2.700	2.700	2.700	2.700	0.000

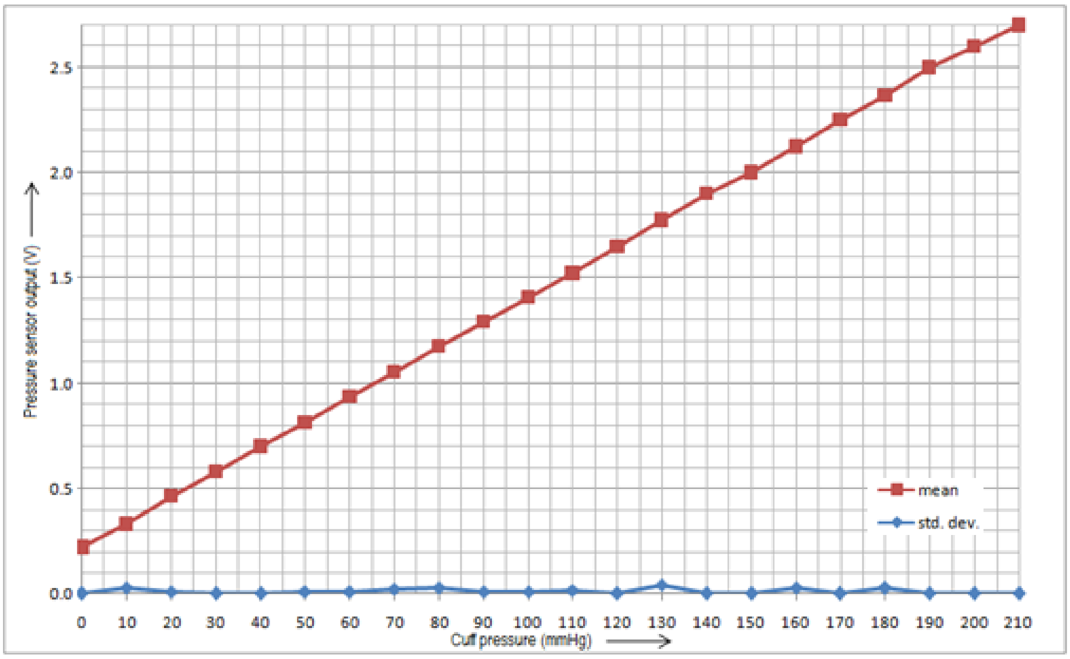


Figure 6.6: Pressure sensor output (V) vs. cuff pressure (mmHg)

6.3 Test results for the force sensor

Force sensor was tested in the same manner as the pressure sensor for three different wrapping (wrap1, wrap2, and wrap3) of the cuff on the cylinder. The differential amplifier

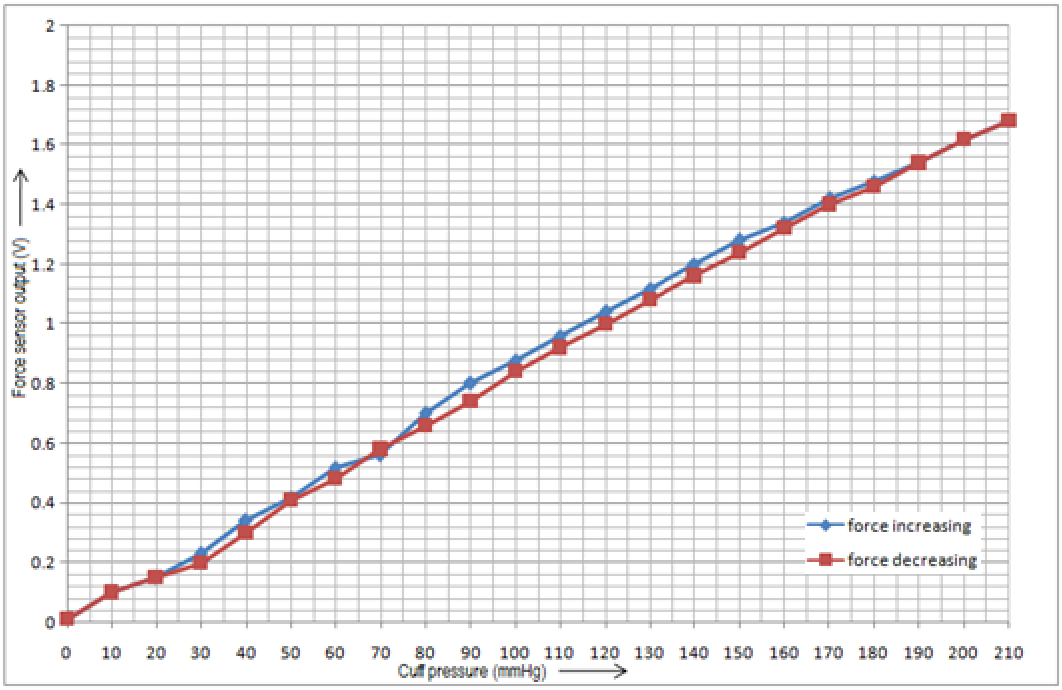


Figure 6.7: Force sensor output (V) vs. cuff pressure (mmHg) with wrap1

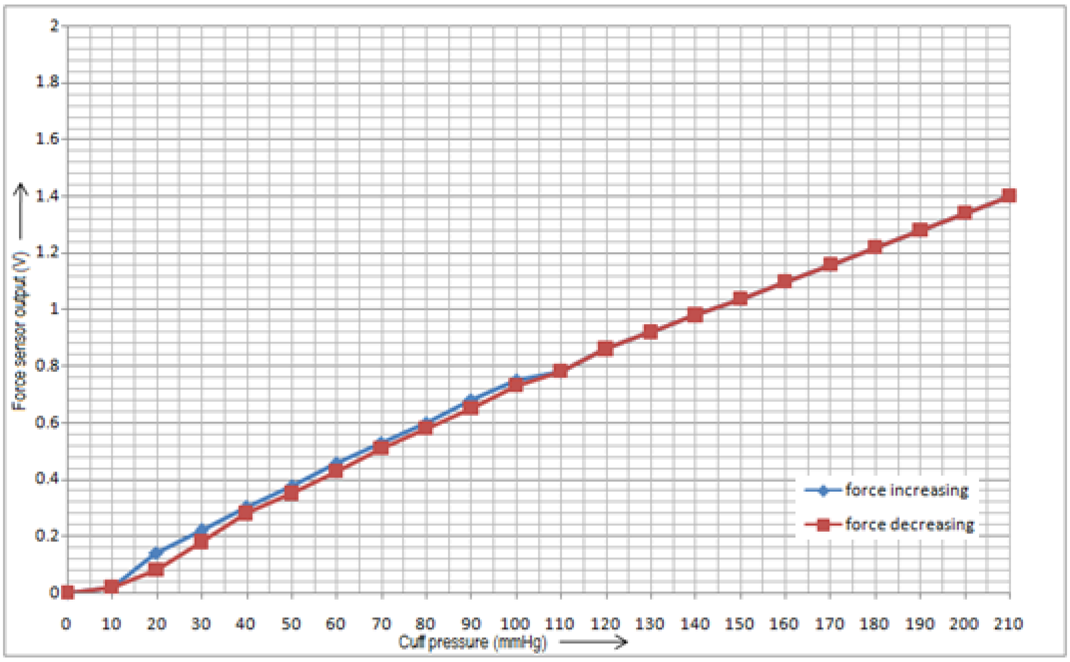


Figure 6.8: Force sensor output (V) vs. cuff pressure (mmHg) with wrap2

output values vs. the cuff pressure are given in Table 6.2. The values are also plotted separately for three different wrappings in Figures 6.7, 6.8, and 6.9, for ascending and descending change in the pressure. No significant hysteresis is seen in the readings for ascending and descending pressures shows, a maximum mismatch of 60 mV (corresponds to

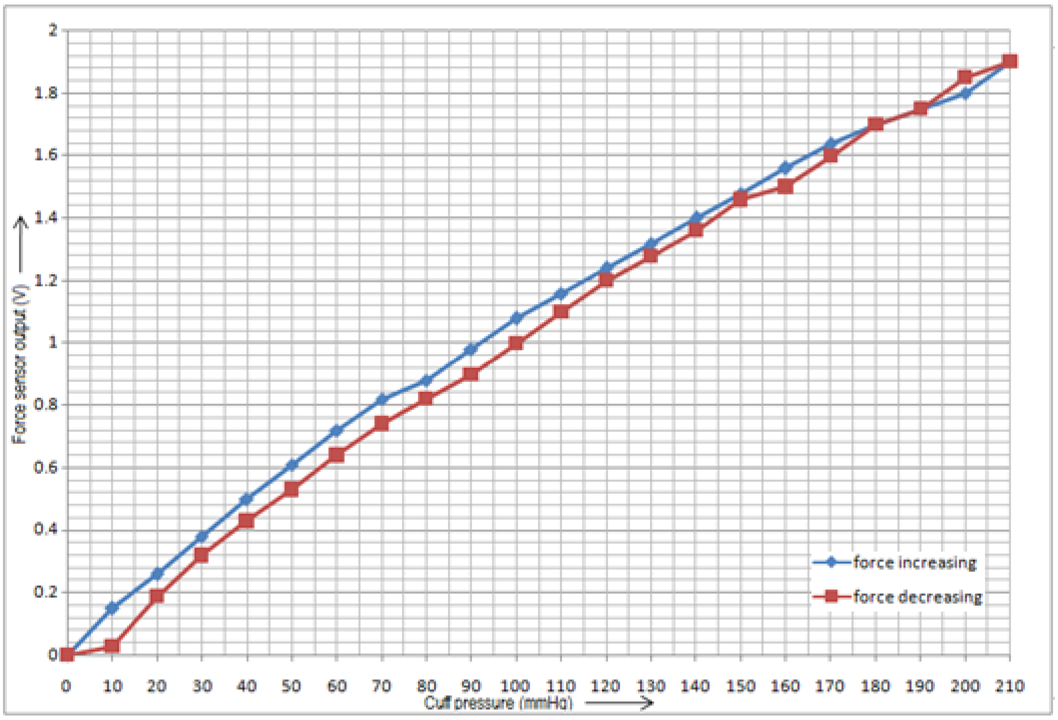


Figure 6.9: Force sensor output (V) vs. cuff pressure (mmHg) with wrap3

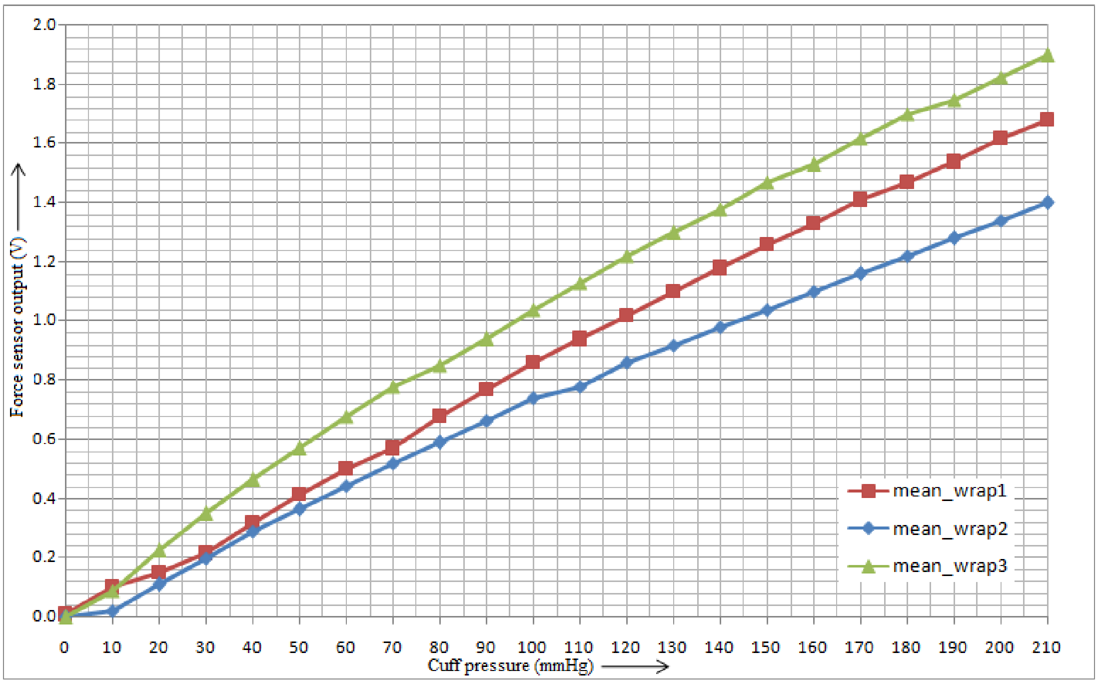


Figure 6.10: force sensor output (V) vs. cuff pressure (mmHg) with three different wrappings, mean of the readings with increasing and decreasing pressure.

8.57 mmHg). However, the values for different wrapping show a significant mismatch. Figure 6.10 shows the mean values (ascending and descending pressure) for the three wrappings. There are deviations from a linear relationship. It may be noted that linearity is better at higher pressures. Thus the force sensor output varies with wrapping of the cuff. The changes

Table 6.2: Force sensor output after amplification vs. cuff pressure.

Input	Force sensor output (V)								
Pressure (mmHg)	Wrap1 Incre.	Wrap1 Decre.	Mean wrap1	Wrap2 Incre.	Wrap2 Decre.	Mean wrap2	Wrap3 Incre.	Wrap3 Decre.	Mean wrap3
0	0.010	0.010	0.010	0.000	0.000	0.000	0.000	0.000	0.000
10	0.100	0.100	0.100	0.020	0.020	0.020	0.150	0.030	0.090
20	0.150	0.150	0.150	0.140	0.080	0.110	0.260	0.190	0.225
30	0.230	0.200	0.215	0.220	0.180	0.200	0.380	0.320	0.350
40	0.340	0.300	0.320	0.300	0.280	0.290	0.500	0.430	0.465
50	0.420	0.410	0.415	0.380	0.350	0.365	0.610	0.530	0.570
60	0.520	0.480	0.500	0.460	0.430	0.445	0.720	0.640	0.680
70	0.560	0.580	0.570	0.530	0.510	0.520	0.820	0.740	0.780
80	0.700	0.660	0.680	0.600	0.580	0.590	0.880	0.820	0.850
90	0.800	0.740	0.770	0.680	0.650	0.665	0.980	0.900	0.940
100	0.880	0.840	0.860	0.750	0.730	0.740	1.080	1.000	1.040
110	0.960	0.920	0.940	0.780	0.780	0.780	1.160	1.100	1.130
120	1.040	1.000	1.020	0.860	0.860	0.860	1.240	1.200	1.220
130	1.120	1.080	1.100	0.920	0.920	0.920	1.320	1.280	1.300
140	1.200	1.160	1.180	0.980	0.980	0.980	1.400	1.360	1.380
150	1.280	1.240	1.260	1.040	1.040	1.040	1.480	1.460	1.470
160	1.340	1.320	1.330	1.100	1.100	1.100	1.560	1.500	1.530
170	1.420	1.400	1.410	1.160	1.160	1.160	1.640	1.600	1.620
180	1.480	1.460	1.470	1.220	1.220	1.220	1.700	1.700	1.700
190	1.540	1.540	1.540	1.280	1.280	1.280	1.750	1.750	1.750
200	1.620	1.620	1.620	1.340	1.340	1.340	1.800	1.850	1.825
210	1.680	1.680	1.680	1.400	1.400	1.400	1.900	1.900	1.900

in the output voltage may be caused by changes in the effective contact area between the cuff wall and the sensing surface.

6.4 BP simulation results for auscultatory method

With different settings of simulation parameters with cuff pressure, variation during inflation and deflation, waveform were recorded. To show satisfactory operation of the simulator the results are given in Figure 6.11 to 6.20. Figure 6.11 shows Korotkoff sound waveform along with the heart beats as the pressure in the cuff is between SP and DP. Figure 6.12 shows regular heart beat and generated Korotkoff sound waveform on each heart beat. Figure 6.13 shows Korotkoff sound waveform and irregular heart beat and with ±30 % arrhythmia introduced. Figure 6.14 shows Korotkoff sound waveform and irregular heart beat and with ±50 % arrhythmia introduced. Figure 6.15 shows Korotkoff sound waveform and irregular heart beat with cuff pressure varying from SP to DP with ±50 % arrhythmia introduced. Note that the shape of amplitude envelop is in accordance with (3.5). Figure 6.16 shows that most of Korotkoff sound waveforms are missed when cuff pressure is decreased very fast. Figure 6.17 shows some of the Korotkoff sound waveforms are missed with fast decrease in cuff pressure. Figure 6.18 shows Korotkoff sound waveforms with irregular fast heart beats and ±50 % arrhythmia level, when cuff pressure is decreased slowly. Figure 6.19 shows Korotkoff sound waveforms with irregular fast heart beats and ±50 % arrhythmia level, when cuff

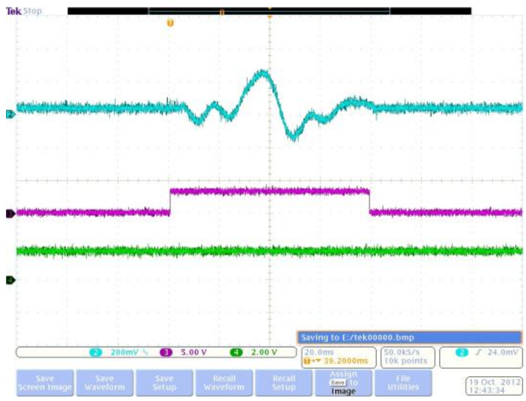


Figure 6.11 DSO recording of single cycle of simulator waveforms with a small and slow variation in the cuff pressure, with SP=120, DP=80, HR=75, A=0, V=100. Ch.1: Korotkoff sounds (top), Ch.2: Cardiac pulses (middle), Ch.3: cuff pressure (bottom)

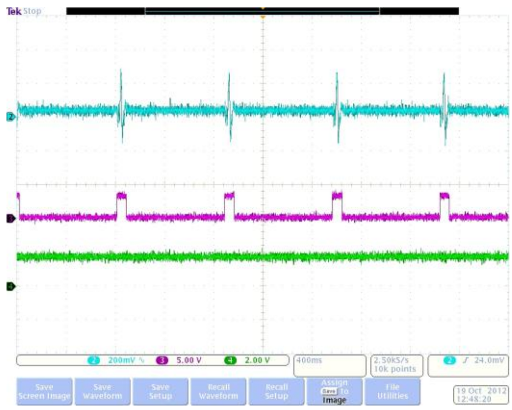


Figure 6.12 DSO recording of multiple cycle of simulator waveforms showing regular heart beat variation in the cuff pressure, with SP=120, DP=80, HR=75, A=0, V=100. Ch.1: Korotkoff sounds (top), Ch.2: Cardiac pulses (middle), Ch.3: cuff pressure (bottom)

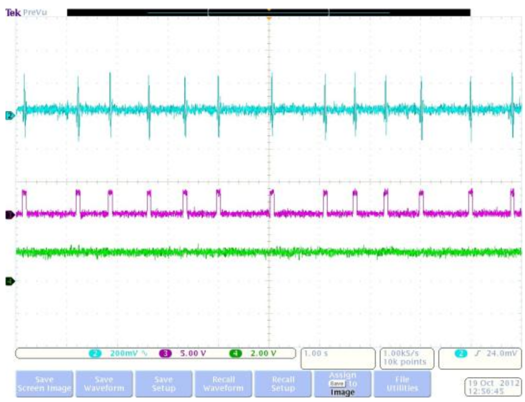


Figure 6.13 DSO recording of multiple cycle of simulator waveforms showing irregular heart beat with a small and slow decrease in the cuff pressure, with SP=120, DP=80, HR=75, A=30, V=100. Ch.1: Korotkoff sounds (top), Ch.2: Cardiac pulses (middle), Ch.3: cuff pressure (bottom)

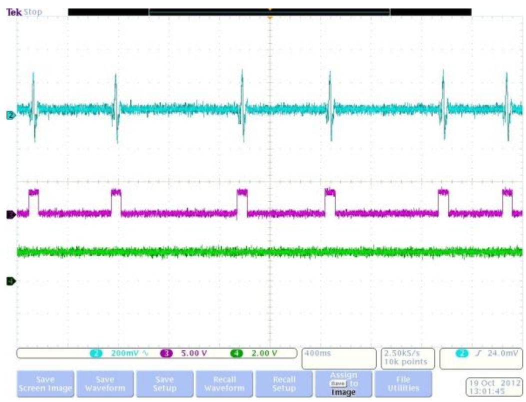


Figure 6.14 DSO recording of multiple cycle of simulator waveforms showing irregular heart beat with slow decrease in the cuff pressure, with SP=120, DP=80, HR=75, A=50, V=100. Ch.1: Korotkoff sounds (top), Ch.2: Cardiac pulses (middle), Ch.3: cuff pressure (bottom)

pressure is decreased from SP to DP. Figure 6.20 shows Korotkoff sound waveforms and regular heart beats with inflation and deflation of the cuff. It indicates that when cuff pressure is being increased from DP to SP, some sound may be heard, and after SP no sound is present. Now when cuff pressure is decreased to SP, Korotkoff sound waveform is heard on each heart beat and disappears as the pressure goes below DP.

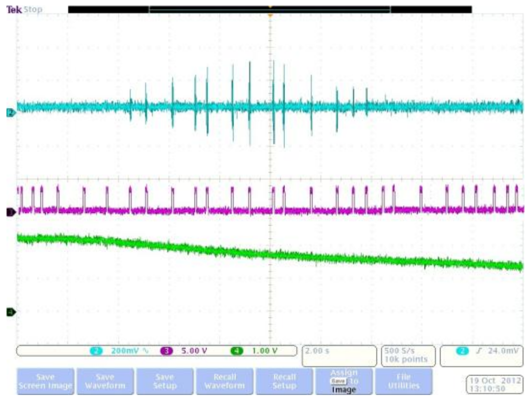


Figure 6.15 DSO recording of multiple cycle of simulator waveforms showing irregular heart beat with decrease in the cuff pressure, with SP=120, DP=80, HR=75, A=50, V=100. Ch.1: Korotkoff sounds (top), Ch.2: Cardiac pulses (middle), Ch.3: cuff pressure (bottom)

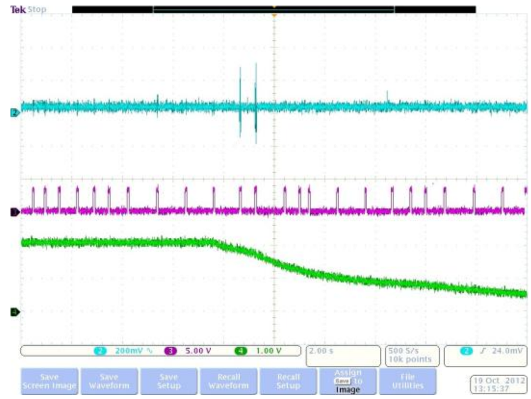


Figure 6.16 DSO recording of multiple cycle of simulator waveforms showing irregular heart beat with fast decrease in the cuff pressure, with SP=120, DP=80, HR=75, A=50, V=100. Ch.1: Korotkoff sounds (top), Ch.2: Cardiac pulses (middle), Ch.3: cuff pressure (bottom)

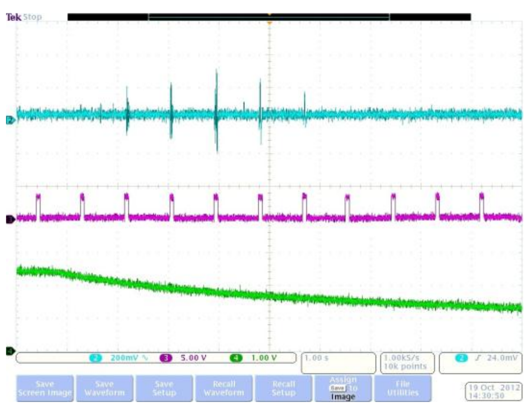


Figure 5.17 DSO recording of multiple cycle of simulator waveforms with fast decrease in the cuff pressure, with SP=120, DP=80, HR=75, A=0, V=100. Ch.1: Korotkoff sounds (top), Ch.2: Cardiac pulses (middle), Ch.3: cuff pressure (bottom)

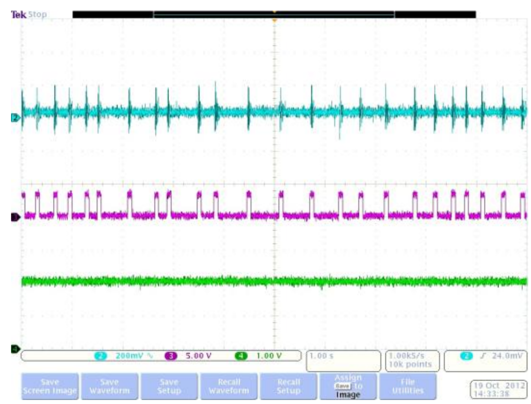


Figure 5.18 DSO recording of multiple cycle of simulator waveforms showing irregular fast heart beat, with a slow decrease in the cuff pressure, with SP=120, DP=80, HR=140, A=50, V=100. Ch.1: Korotkoff sounds (top), Ch.2: Cardiac pulses (middle), Ch.3: cuff pressure (bottom)

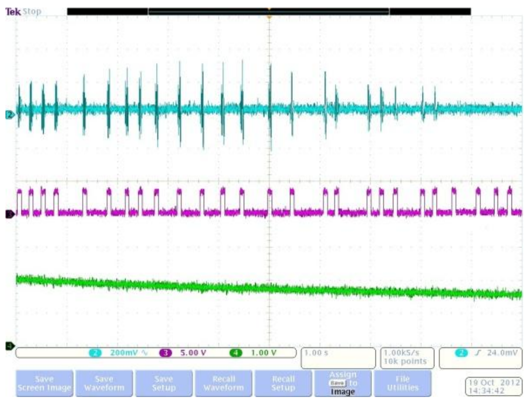


Figure 6.19 DSO recording of multiple cycle of simulator waveforms showing irregular fast heart beat, with fast decrease in the cuff pressure, with SP=120, DP=80, HR=140, A=50, V=100. Ch.1: Korotkoff sounds (top), Ch.2: Cardiac pulses (middle), Ch.3: cuff pressure (bottom)

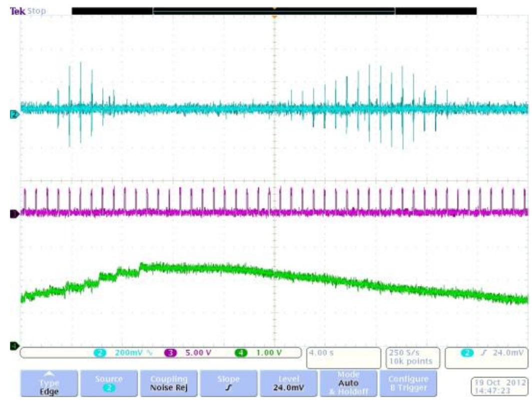


Figure 6.20 DSO recording of multiple cycle of simulator waveforms with fast increase and slow decrease in the cuff pressure, with SP=120, DP=80, HR=70, A=0, V=100. Ch.1: Korotkoff sounds (top), Ch.2: Cardiac pulses (middle), Ch.3: cuff pressure (bottom)

Table 6.3: BP simulation results for oscillometric method with zero arrhythmia, SP = 120 mmHg, DP = 80 mmHg, pulse width modulation.

Set.	Observed SP (mmHg)			Observed DP (mmHg)			Observed HR (bpm)		
HR	SP1	SP2	SP3	DP1	DP2	DP3	HR1	HR2	HR3
20	–	–	–	–	–	–	–	–	–
30	–	–	–	–	–	–	–	–	–
40	–	–	–	–	–	–	–	–	–
50	116	–	113	79	–	86	49	–	50
60	114	117	118	79	97	84	60	60	60
70	118	110	122	92	80	93	70	70	71
80	123	111	121	101	85	96	78	79	81
90	118	110	119	91	81	94	91	90	91
100	112	113	122	80	88	78	100	100	97
110	106	117	120	78	82	94	110	110	111
120	109	119	118	83	93	78	119	121	120
130	113	105	111	85	76	85	131	129	131
140	104	116	113	78	88	83	139	141	141
150	117	117	106	80	93	78	151	150	150

6.5 BP simulation results for oscillometric method

The instrument is tested to simulate BP for oscillometric method using an automatic BP monitor "AccuSure" with SP/DP set to 120/80 and HR variation from 20 bpm to 150 bpm and pulse width modulation. The results obtained are presented in Table 6.3. It can be noted that results indicate correct detection of the heart rate, but the SP values were under-estimated and DP values were over-estimated and there were inconsistencies in value of repeated measurements. These results indicate that the magnitude of the pressure pulses in the arm cuff introduced by

Table 6.4: BP simulation results for oscillometric method with zero arrhythmia, SP = 120 mmHg, DP = 80 mmHg, fixed pulse width of 200 ms.

Set.	Observed SP (mmHg)			Observed DP (mmHg)			Observed HR (bpm)		
HR	SP1	SP2	SP3	DP1	DP2	DP3	HR1	HR2	HR3
20	–	–	–	–	–	–	–	–	–
30	–	–	–	–	–	–	–	–	–
40	–	–	–	–	–	–	–	–	–
50	113	133	114	77	91	81	50	50	49
60	128	119	112	104	78	84	58	59	59
70	121	121	119	94	88	77	69	70	69
80	118	125	112	82	94	81	80	81	80
90	120	126	120	91	79	90	89	91	90
100	121	111	122	81	89	92	99	100	99
110	111	110	123	86	84	96	110	111	110
120	104	119	105	82	89	78	121	120	121
130	125	125	101	83	88	77	129	130	132
140	111	128	109	81	92	80	141	140	141
150	115	122	109	88	97	82	151	150	151

Table 6.5: BP simulation results for oscillometric method with arrhythmia 0 % to 50 %, SP = 120 mmHg, DP = 80 mmHg, pulse width modulation

AL	Observed SP (mmHg)			Observed DP (mmHg)			Observed HR (bpm)		
(%)	SP1	SP2	SP3	DP1	DP2	DP3	HR1	HR2	HR3
0	102	117	118	85	82	92	80	79	81
10	109	119	115	82	92	81	77	81	80
20	116	115	116	84	86	87	72	75	69
30	117	116	118	90	81	79	76	−	74
40	114	118	116	82	88	80	92	95	90
50	113	121	116	81	94	82	60	−	79

Table 6.6: : BP simulation results for oscillometric method with arrhythmia 0 % to 50 %, SP = 120 mmHg, DP = 80 mmHg, fixed pulse width of 200 ms

AL	Observed SP (mmHg)			Observed DP (mmHg)			Observed HR (bpm)		
(%)	SP1	SP2	SP3	DP1	DP2	DP3	HR1	HR2	HR3
0	108	121	115	81	91	79	80	−	−
10	107	−	−	78	−	−	81	−	−
20	126	−	−	78	−	−	74	−	−
30	−	−	122	−	−	105	−	50	49
40	120	−	121	96	−	86	65	59	59
50	−	108	96	−	88	28	−	70	69

the linear actuator needs to be increased. In another experiment, SP/DP set to 120/80, the pulse width was fixed at 200 ms and HR was varied from 20 bpm to 150 bpm. The results obtained are presented in Tables 6.4. It can be noted that HR was detected correctly, but SP values in some instances were under-estimated and in some instances were over-estimated. The same is true with DP values.

In another experiment SP, DP and HR, set to 120, 80 and 80, respectively, With pulse width modulation and arrhythmia level was varied from 0 % to 50 %. The results obtained are shown in Table 6.5. The results indicate that HR values in some instances are under-estimated and in some instances are over-estimated. The SP values are under-estimated and DP values are over-estimated.

In another experiment SP, DP and HR, set to 120, 80, and 80, respectively, with fixed pulse width of 200 ms, and arrhythmia level is varied from 0 % to 50 %. The results obtained are shown in Table 6.6. Most of the time, the automatic BP monitor gave an indication , as indicated by dashes in the table. Even if the values were shown, they were generally not correct.

Chapter 7
SUMMARY AND CONCLUSION

The project objective was to develop a portable arm simulator for non-invasive BP measurement with settable values of SP, DP, HR, pulse volume, and arrhythmia likely to occur under clinical conditions. It should facilitate calibration and testing of BP monitors and should also be usable for training healthcare professional in taking correct measurement of blood pressure on patients with different cardiovascular conditions. A microcontroller based instrument with a serial interface for PC-based GUI for setting the simulation parameters has been designed, assembled, and tested.

The instrument is in the form of a cylinder around which the cuff of the BP monitor is wrapped. A controller card inside the cylinder senses the air pressure in the cuff and mimics the behavior of an arm by generating Korotkoff sounds and oscillations in the air pressure inside the cuff at each heart beat, when the sensed value of the cuff pressure is between the set values of the diastolic and systolic pressures. The controller card is designed using a 16-bit microcontroller with on-chip ADC and DAC. Cuff pressure is sensed dynamically by either a pressure sensor or a force sensor. The pressure sensor provides an accurate sensing of the air pressure in the cuff, but it requires pneumatic coupling to the cuff tubing using a T-connector. The force sensor is placed between the cuff and the cylinder. It senses the force on its active sensing area in contact with the cuff wall. It is noninvasive in the sense that it does not require a modification in the cuff tubing, but the sensed values of the cuff pressure may be relatively less accurate.

The cardiac pulses are generated at the set heart rate, with arrhythmia simulated by a random variation in the heart beat interval. For BP measurement using auscultatory method, the Korotkoff sound pulses, pre-stored in the program memory of the microcontroller, are output through a small speaker at each heart beat in accordance with the sensed value of the cuff pressure. For oscillometric method, a linear actuator is used to apply force against the cuff wall and thereby to generate pressure pulses in the cuff. The amplitude of the Korotkoff sound and pressure oscillations are scaled in accordance with the set value of the pulse volume.

Examination of the waveforms showed satisfactory operation of the instrument for auscultatory and oscillometric methods of noninvasive BP monitoring. Use of an automatic BP monitor for BP measurement on the arm simulator showed correct detection of the heart rate, but the SP values were under-estimated and DP values were over-estimated, indicating that the magnitude of the pressure pulses in the arm cuff introduced by the linear actuator needs to be increased.

Some suggestions for further work for developing the arm simulator from as a fully functional prototype and subsequently as a commercially available instrument are as the following:

1) A compact PCB for the controller card needs to be designed and assembled. The controller card along with the power supply, sensor, speaker, and linear actuator has to be fitted inside the cylinder. Product design from the user perspective needs to be completed.

2) Mechanism for fixing the force sensor for a repeatable and accurate sensing of the cuff pressure has to be developed. Once this is done, the instrument will become very convenient to use as there will be no need to insert the T-connector in the cuff tubing.

3) The instrument needs to be tested with several models of automatic BP monitors to identify the problems related to BP simulation for measurement by oscillometric method and to devise appropriate solutions.

4) The GUI can be enhanced to make it more user friendly and to provide a dynamic plot of the sensed pressure.

5) The versatility of the instrument can be enhanced by developing the GUI to run on handheld computing devices. The controller board design needs to be modified to provide USB and Bluetooth connectivity between the instrument and PC or other computing devices.

Appendix A
COMMERCIALLY AVAILABLE BP SIMULATORS

Some of the commercially available BP simulators are briefly discussed here with their important specifications summarized in Table A.1. All the BP simulators available till date are based on invasive sensing of cuff pressure using a T-connector.

A.1. Fluke Biomedical "CuffLink non-invasive BP simulator" [31]

CuffLink NIBP Analyzer provides BP simulation for oscillometric method. It can simulate BP waveforms for seven adult, five neonate and five arrhythmias to evaluate the performance of oscillometric BP monitors. It can generate various rhythms like normal, tachycardia (fast heart beat), and bradycardia (slow heart beat) for up to 99 cycles. It can generate normal, hypertensive, and hypotensive BP waveforms for adult and neonate patients. When arrhythmia options is selected, the SP/DP is set to 120/80 and HR is set to 80 bpm. The instrument has an internal pump to pressurize the NIBP system under test. It can measure inflate/deflate timing. It includes cuffs with different circumferences 39.5 cm, 33 cm, 26.6 cm, and 20 cm for large adult, adult, small adult, child, respectively and three small cuffs 14 cm, 10 cm, and 7.6 cm circumference for neonates. It has an alphanumeric display of 8 lines x 40 characters to display instantaneous cuff pressure, peak cuff pressure, inflate/deflate time, inflate/deflate rate, selected heart rate. It has RS232 interface to download cuff measurement data and control test features. It can also be used for leakage testing and relief valve testing. It has eight options for HR, and thus lakes flexibility in setting HR. No independent selection of SP and DP is provided.

A.2. BC Biomedical "NIBP simulator" [32]

NIBP simulator 1000 series from BC biomedical has three models NIBP-1010, NIBP-1020 and NIBP-1030. NIBP-1010 is the basic model and can be used to test NIBP monitors. It has option for adult and neonatal hypotensive and hypertensive modes, and supports heart rate of 80 and 94 bpm. NIBP-1020 model has features of NIBP-1010 and can display ECG waveform with full QRS segments. It supports heart rate of 30, 60, 120 and 240 bpm. NIBP-1030 model supports ECG arrhythmia with NIBP simulation disabled. Arrhythmia sequence includes premature ventricular contraction, ventricular fibrillation and ventricular tachycardia. It can display leak rate in mmHg per minute. NIBP-1000 series supports systolic and diastolic shift to compensate for different methods of measuring oscillometric NIBP by various manufacturers and models of device under test. It has selectable display with five main screens for pressure, output selection, pressure waveform, pressure graph, ECG output screen and battery life indicator screen. With battery life remaining 10%, the BP simulation mode is automatically be disabled, but ECG operation can be continued. When battery life is 0%, system automatically turns off. It supports only few systolic/diastolic pairs for simulation and has limited options for HR selection.

A.3. Fluke Biomedical "BP Pump-2 NIBP simulator and tester" [33]

It can be used to test NIBP monitors for both arm and wrist cuff types. The tester can be used to verify the performance of different blood pressure monitors based on oscillometric technique. User can select input parameters like systolic pressure, diastolic pressure, heart rate and pulse volume. Pressure can be generated in selectable increment of 1 mmHg. It can simulate arrhythmia including, premature atrial contraction, premature ventricular contraction and atrial fibrillation. It has an internal pump that can be used for high-low pressure release verification and leak testing on cuff, tubing and connections. It can pressurize the pressure port from 0 mmHg to 400 mmHg and keeps track of pressure loss over a time period. The peak pressure, present pressure and leak rate are displayed continuously. It has RS232 serial interface. Tester capabilities can be extended with the optional accessories for ECG synchronization with non-invasive output and external wrist cuff simulation. ECG signals are available for arrhythmia, and for all standard BP. Two models are available: BP Pump 2L is the standard model and BP Pump 2M is the high accuracy one.

A.4. Rigel Medical "BP-SIM Handheld simulator for NIBP monitors" [34]

It simulates oscillometric waveform for calibration of NIBP monitors. It is a handheld simulator and has full keyboard for easy data capturing and assets management. User can set NIBP pressure, pulse volume, heart rate and manufacturer-specific envelope (O-curves). It has large capacity internal memory for test results and record keeping purposes. The information regarding performance of NIBP monitor, make, model, serial number, site and location can be stored in the onboard memory. It uses Bluetooth-enabled technology to facilitate wireless connectivity between tester and PCs, for fast downloading of performance data and the uploading of manufacturer's O-curves. It has built in pump to generate user defined pressure for leak tests and over pressure tests. Internal digital manometer allows pressure measurement using a wide range of units like mBar, mmHg, inHg, kPa etc.

A.5. Gaumard "S270 Blood pressure arm simulator" [35]

This simulator is developed to train healthcare professionals in making blood pressure measurement using auscultation method. It has BP arm with internal speaker, BP cuff and Stethoscope, and BP auscultation tutor. It has options for parameter settings like pulse rate, systolic pressure, diastolic pressure, and auscultatory gap. The Korotkoff sound will be heard when the cuff pressure is between SP and DP. Current cuff pressure can be seen on the display. It does not have any option of arrhythmia simulation.

A.6. NASCO “Life/form Blood Pressure Simulator (LF01095U)” [36]

The NASCO Life/form BP simulator can be used for the demonstration of the 5 phases of Korotkoff sound including an auscultatory gap (absence of audible pulse). This simulator produces digitally recorded sound with settable pulse rate and volume. Its main features are calibration of simulator, setting of palpation, extra speaker to hear Korotkoff sound, and settable systolic pressure, diastolic pressure, pulse rate, and pulse volume. Battery status can be seen on the display. Palpation can be felt upon start up, pupations continue during inflation until cuff pressure reaches to SP point and it occurs again when the cuff pressure is at SP point or below it during deflation. It does not have any option of arrhythmia simulation.

A.7. Datrend Systems Inc. "AccuSim-BP Handheld simulator for NIBP monitors" [37]

AccuSim-BP can be used for testing of NIBP monitors based on oscillometric method. It's features include adjustable pulse rate, pulse amplitude, preset calibration tables from various NIBP monitor manufacturers. It supports BP presets for 7 adult and 6 neonatal with BP envelope shift. It can simulate arrhythmia with delay of 2 – 8 s in increment of 0.5 s. It supports leak test and overpressure tests of the NIBP monitor's cuff and hoses. It has an internal pressure pump, RS232 interface for external control, USB port for web-based up-gradation. It lakes flexibility in setting SP and DP independently.

A.8. Pronk Technology "SimCube NIBP simulator" [38]

The SimCube NIBP simulator is based on oscillometric method. It has five models SC-1, SC-2, SC-3, SC-4, SC-5. It can be used to calibrate the NIBP monitors. It can simulate hypertensive and hypotensive BP for adult and neonatal. It can perform leak test for NIBP monitor's cuff and hoses (SC-5 only). Models SC-2,SC-4, SC-5 support ECG simulation while ECG arrhythmia simulation is available only in SC-5. Models SC-3, SC-4, SC-5 can be operated on battery power. This simulator lakes flexibility in setting up SP/DP values and heart rate independently.

Table: A.1: Summary of commercially available BP simulators

Sr. No.	Manufacturer	Model	Cost (US $)	Features and speccifications
1	Fluke Biomedical	CuffLink NIBP Simulator [31]	N/A	Technique: Oscillometic Pressure range: 0 – 300 mmHg Peak cuff pressure: 500 mmHg No. of Cuffs: 7 (different circumferences) Heart Rate (bpm): 30, 40, 60, 80, 120, 160, 200 and 240. Adult Sys/Dis: 60/30, 80/50, 100/65, 120/80, 150/100, 200/150, 255/195. Neonatal Sys/Dis: 60/30, 80/50, 100/65, 120/80, 150/100 Arrhythmias: PAC, PVC, AF, Missed Beat. RS232 Interface Inflate/Deflate time: 0.1 – 999.9 s Inflate/Deflate rate: 0.1 – 999.9 mmHg/s Leakage and relief valve testing Supply V: 120/230 V, 50/60 Hz Weight: 6.82 kg
2	BC Biomedical	NIBP-1010 NIBP-1020 NIBP-1030 [32]	$1,995 N/A N/A	Technique: Oscillometic Pressure range: 0 – 500 mmHg Accuracy: ± (1% of Reading + 0.5 mmHg) Heart rate: 80, 94 bpm Simulation mechanism: stepper motor with piston assembly. RS-232 interface. NIBP-1010 features + ECG waveforms NIBP-1020 features + ECG arrhythmia waveforms, leak rate test.

				Sensitivity: selectable 5 µV/V/mmHg and 40 µV/V/mmHg Supply V: 12 VDC, 500mA Weight: 1.36 kg
3	Fluke Biomedical	BP Pump 2L(Basic Model) BP Pump 2M (High-Accuracy Model) [33]	N/A	Technique: Oscillometic Pressure range (2_L): 0 – 300 mmHg Pressure range (2_M): 0 – 400 mmHg Resolution : Basic model: 1 mmHg High accuracy model: 0.1mmHg Accuracy: ± 0.5% (0 – 300 mmHg) ± 1mmHg ± 2% (301 – 400mmHg) <0.8mmHg (High accuracy model) Heart Rate (bpm): 30 – 250 in step of 1 Systolic Pressure: 20 – 250 mmHg Diastolic Pressure: 10 – 200 mmHg ECG Interface: RA, RL, LA, LL, V. Supply:100-240 V, 50/60 Hz Weight: 3.4 kg
4	Rigel Medical	BP-SIM Handheld NIBP Simulator [34]	N/A	Technique: Oscillometic Heart rate (bpm): 1 – 300 Integrated pump: 0 – 350 mmHg (user conf.) Pulse volume: high, low, medium. Communication : Bluetooth Leak test: 0 – 350mmHg (user conf.) Overpressure: automatic (max. 410 mmHg) Digital manometer: 0 – 410 mmHg Accuracy: ±0.5% Full Scale Supply: Battery operated and can be charged with 120/230 VAC, 50 Hz. Weight: Less than 1 kg.
5	Gaumard	S270 Blood Pressure Arm [35]	$745	Technique: Auscultatory Factory setting: SP: 150 DP: 90 HR: 70 Range of SP/DP and HR is not available. Supply: 110 – 240 VAC
6	Nasco	LF01095U Blood Pressure Simulator [36]	$845.53	Technique: Auscultatory Heart rate (bpm): 0-300 SP/DP range: not available Option for setting Auscultatory gap. Power supply DC: 9 V
7	Datrend Systems Inc.	AccuSim-BP Hand Held NIBP Simulator [37]	N/A	Technique: Oscillometric Pressure range (mmHg): 0.0 – 400.0 Manometer accuracy : ± 0.5 mmHg Heart rate (bpm): 15 – 330 HR accuracy: ± 1 bpm SP/DP (mmHg) Adult: 240/190, 200/150, 150/100, 120/80, 100/65, 80/50, 60/30.

				SP/DP (mmHg) Neonatal: 150/120, 120/90, 100/70, 80/50, 60/30, 35/15. BP envelope shift : ± 50 mmHg. Communication: RS232, mini-USB Supply: DC: 16.5 V (Li-ion battery) AC: 100 – 240 VAC Weight: 0.86 kg.
8	Pronk Technologies	SC-1 SC-2 SC-3 SC-4 SC 5 Sim Cube NIBP Simulators [38]	N/A	Technique: Oscillometric Pressure range: 0–480 mmHg Pressure range:- 400 to +400 mmHg (SC-5) Accuracy: ±3 mmHg or 2% of reading SP/DP with HR: adult (120/80 mmHg, 70 bpm), Neonatal (70/40 mmHg, 95 bpm), Hyper (190/120 mmHg, 70 bpm), Hypo (80/40 mmHg, 70 bpm). Leak test (SC-5 only) SC-5: ECG arrhythmia simulation HR(bpm): 30,60, 90,120, 45, 60, 160,220
9	Simulaids	No 600 LF01129 LF01095 LF03204 [39]	$802.95	Technique: Auscultatory Pressure range: 0–300 mmHg in two mm increments Supply: Battery or 110 VAC adapter

Appendix B
COMPONENT LIST

Table B.1: Component list of the "Arm Simulator for BP measurement"

Component designator	Component description	Part number / Value	Quantity
C10	Capacitor, ceramic, surface mounted	0.05 µF	1
C1, C3, C12, C13, C15, C17, C19, C21, C23	Capacitor, ceramic, surface mounted	0.1 µF	9
C4, C5, C6, C7, C8	Capacitor, ceramic, surface mounted	1.0 µF	5
C2, C9	Capacitor, ceramic, surface mounted	10 µF	1
C14, C16, C18, C20, C22, C24	Capacitor, electrolytic, surface mounted	100 µF	6
C11	Capacitor, electrolytic	220 µF	1
R4	Resistor, surface mounted	10 Ω	1
R5	Resistor, surface mounted	85 Ω	1
R6	Resistor, surface mounted	1.8 kΩ	1
R2	Resistor, surface mounted	2.17 kΩ	1
R1	Resistor, surface mounted	5 kΩ	1
R3	Resistor, surface mounted	8.1 kΩ	1
POT1	Resistor, surface mounted	10 kΩ	1
LED1	LED, surface mounted	RED	1
D1,D2	Diode, surface mounted	1N914	2
T1	Transistor, surface mounted	SL100	1
SW1	SPDT	SW1	1
SC1	Solenoid	10 N	1
CN1	Connector, 5-pin	CON5	1
CN5	Connector, 3-pin	CON3	1
CN2, CN3, CN4, CN6, CN7, CN8	Connector, 2-pin	CON2	5
PS1	Pressure sensor	MPXV5050GP	1
FS1	Force sensor	FSS1500NST	1
U1	IC, microcontroller, 28-pin, SOIC	DSPIC33FJ12-8GP802	1

Component designator	Component description	Part number / Value	Quantity
U2	IC, serial transceiver, 16-pin, SSOP	ADM3202/ SP3232ECA	1
U3	IC, instrumentation amplifier, 8-pin, SOIC	INA826	1
U4	IC, audio amplifier, 8-pin, DIP	LM386	1
U5	IC, opto-coupler, 6-pin, DIP	MCT2E	1
U6, U7	IC, voltage regulator, 3-pin	7805C	2
U7, U9	IC, voltage regulator, 4-pin	LM1117	2

Appendix C
SCHEMATIC OF ARM SIMULATOR FOR BP MEASUREMENT

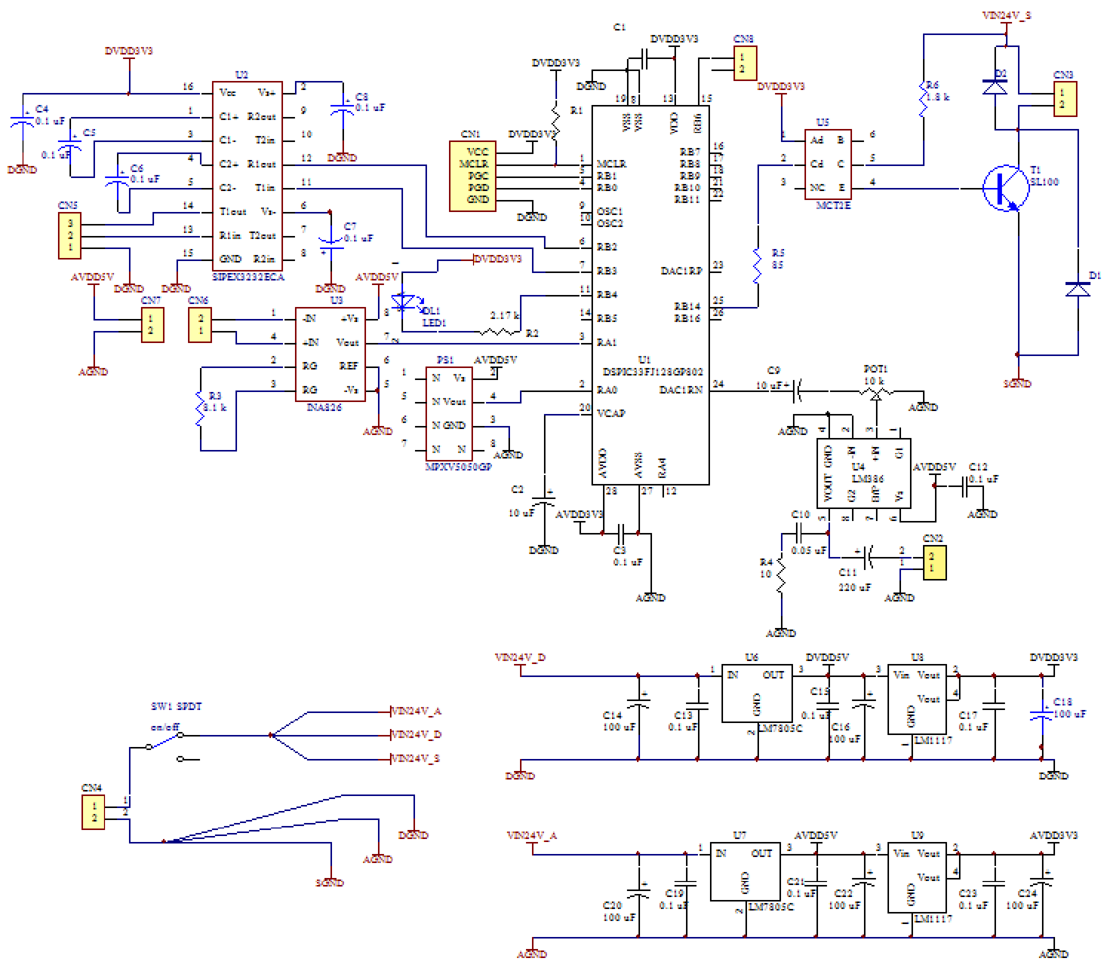


Figure C.1: Circuit diagram of the controller card

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