DESIGN AND DEVELOPMENT OF A COST-EFFECTIVE DIGITAL STETHOSCOPE

BY

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A thesis submitted in partial fulfillment of the requirement for the degree of

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In

Biomedical Engineering

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DECLARATION

It is hereby declared that this research study has been done for partial fulfillment of requirements for the degree of Master of Sciences in Biomedical Sciences. This work has not been taken from any publication. I hereby also declare that no portion of the work referred to in this thesis has been submitted in support of an application for another degree or qualification in this university or other institute of learning.

MUHAMMAD WAQAR

To

My Family and all the people around me

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List of Abbreviations

ECG	Electrocardiography
MS	Mitral Stenosis
MR	Mitral Regurgitation
AS	Aortic Stenosis
AR	Aortic Regurgitation
TS	Tricuspid Stenosis
TR	Tricuspid Regurgitation
PS	Pulmonary Stenosis
PR	Pulmonary Regurgitation
MVP	Mitral Valve Prolapses
VSD	Ventricular Septal Defect
PDA	Patent Ductus Arteriosus
HOCM	Hypertrophic Cardiomyopathy
SNR	Signal to Noise Ratio
FFT	Fast Fourier Transform
LCD	Liquid Crystal Display
MEMS	Micro Electromechanical System
ANC	Adaptive Noise Cancellation
STFT	Short Time Fourier Transform
WT	Wavelet Transform
DWT	Discrete Wavelet Transform

List of Abbreviations

ILSA	International Lung Sounds Association
FDA	The Food and Drug Administration
PMA	Premarket Approval
NAICS	The North American Industry Classification System
EC	European Commission
MDD	Medical Devices Directive
ADC	Analog to Digital Converter
DAC	Digital to Analog Converter
PCB	Printed Circuit Board
BPM	Beats Per Minute

ABSTRACT

Background:

The medical device used for auscultation purpose is known as a stethoscope. There are two types of stethoscopes available in the market; an ordinary or acoustic stethoscope and an electronic or digital stethoscope. The acoustic stethoscope is widely used by physicians due to its cost-effectiveness but it has a poor sound quality especially in the in noisy environment. A digital stethoscope can be used to overcome this problem but due to its expansive nature it is rarely used. The objective of this thesis was to give a better and cost-effective solution.

Methodology:

An Arduino DUE based digital stethoscope was designed that used the chest-piece of an ordinary stethoscope for detecting the acoustic sounds from the body. A high sensitive studio speech microphone was inserted inside the pipe attached near the end of chest-piece for converting the acoustic sounds into electrical signal. Due to low amplitude, the sounds were amplified by the first low noise operational amplifier. The signal was then passed to a second order Sallen-key low pass antialiasing filter, digitized by built-in 12-bits analog to digital converter (ADC) of Arduino DUE and processed to calculate the beats per minute (BPM) and displayed over a serial TFT graphic LCD. The digital signal was converted to analog signal by means of built-in 12 bits digital to analog converter (DAC) and post-amplified by a low noise power amplifier and fed to the headphones.

Results:

The device was tested on five subjects in different environmental conditions. The heart sounds were recorded in wav format by Thinkslab one Phonocardiogram software and read in MATLAB. The signal to noise ratio (SNR) was calculated and compared with recorded sounds of a standard commercially available Litmann 3200 digital stethoscope. The beats per minute along with real time heart sounds (S1 and S2) were clearly detected on TFT graphic LCD. The cost analysis of the device was also presented.

Keywords:

Acoustic and digital stethoscope, High sensitive studio speech microphone, Sallen-key antialiasing filter, Arduino DUE, LM386 IC, Thinks Lab One Phonocardiogram, MATLAB, signal to noise ratio (SNR), TFT graphic LCD, Litmann 3200.

PART I

INTRODUCTION & LITERATURE REVIEW

1.1. Overview

Auscultation is the process of listening to internal body sounds and it is achieved by using a device known as stethoscope [1]. There are two types of stethoscope available in the market; an ordinary or acoustic stethoscope and an electronic or digital stethoscope. The first stethoscope is widely used by doctors for auscultation due to its cheapness. But, it is unable to provide better sound quality that creates difficulties in the auscultation process in noisy environment. It contains a chest piece or diaphragm that detects the acoustic sounds from the body that travel across two tubes to the listening ears. The second type is the advanced version of stethoscope that detects the acoustic sounds exactly in the same manner as did with ordinary stethoscope. It electronically amplifies the acoustic sounds after converting them into electrical voltages. These amplified sounds are then digitized and processed with a microcontroller or DSP processor for further signals processing. It is particularly used for hearing the internal sounds of infants or small babies that is difficult to achieve by means of an acoustic stethoscope. The second advantage of an electronic or digital stethoscope is that processed sounds can be recorded in the computer or external memory devices for future analysis. But, the current models of digital stethoscope available in the market are highly expansive that creates limitations in its clinical use by doctors.

1.2. Internal Body Sounds

There are various internal body sounds in the human body such as heart sounds, lung sounds, and murmurs. This thesis focused only on the detection and analysis of heart sounds.

1.2.1 Heart Sounds

Heart has four chambers; the two upper chambers known as atria or auricles and two lower chambers called as ventricles. The squeezing of blood from chamber to chamber is done by the contraction of cardiac muscles. This squeezing opens the valves that enables the blood flow from one chamber to the other. Similarly, after blood is received by the corresponding chamber the valves get closed that prevent the backward flow of blood. This process of cardiac muscles contraction and relaxation gives the efficient blood flow throughout the heart as well as to rest of the body. There are two types of sounds produced under normal heart conditions; the first sound is S1 that corresponds to mitral and tricuspid valves closure after receiving blood from lungs and body. This initiates the systolic process. The second sound is S2 that shows the initiation of diastolic process and termination of systole, and is produced by the aortic and pulmonic valves closure after pumping blood to the body and lungs [2]. The frequency ranges of S1 and S2 sounds is between 20 to 175 Hz [3]. According to [4], The peaks of S1 sound like in the lower frequency range (10 to 50 Hz) and medium frequency range (50 to 140 Hz), where the S2 peaks are observed in lower frequency range (10 to 80 Hz), medium frequency range (80 to 200 Hz), and higher range of frequency (220 to 400 Hz). Similarly, there are also two other sounds; S3 sound is obtained by the passive filling of ventricles known as early diastolic process, and S4 sound by active filling of ventricles known as late diastolic process. The peaks of S3 and S4 sounds are usually observed within the frequency range (20 to 70 Hz). These sounds should be carefully observed because they may suggest the heart abnormalities [5]. Most of the Heart sounds lie in the frequency range (35 to 400 Hz) [3].

1.2.1. Heart Sounds Characteristics

As the beating of heart and blood flow through it results in the generation of Heart sounds [6]. There are two normal heart sounds in healthy adults: the first S1 that is produced by the closure of atrioventricular valves; and the S2 sound produced by the closing of semilunar valves. The normal S1 and S2 sounds are shown in Figure 1.1.

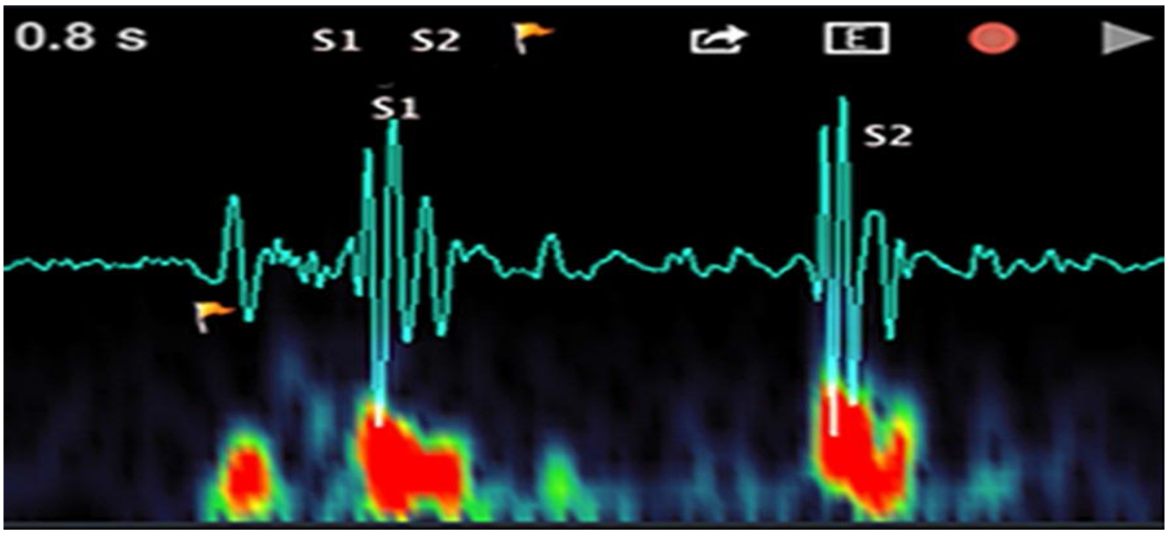

Figure. 1.1. Normal S1 and S2 sounds in a healthy adult

Similarly, in abnormal cases, there might be additional signal activities between S1 and S2 sounds e.g. S3, S4, and murmurs. The S3 sound is produced when there is a sudden deceleration of blood flow from atrium into left ventricle. This sound behaves like normal heart sounds in children and adults up to 35 to 40 years. But, after 40 years, this sound acts like an abnormal hear sound and is correlated with the dysfunction and volumetric overloading of ventricles [7]. The vibration of valves, supporting structures, and walls of ventricles cause the S4 sound. It has been proved that S4 during the diastolic period is the symptom of heart failure [8]. Generally, the frequency of S1 sound is smaller than S2 but its duration is greater than S2 sound. After 0.1 to 0.2 s of S2, S3 occurs whereas S4 occurs before 0.07 to 0.1 s of S1- both are low pitched sounds. Additionally, heart problems or diseases may cause numerous heart murmurs that are extra or unusual sounds heard during the beating of heart and are classified as systolic, diastolic and continuous murmurs [9].

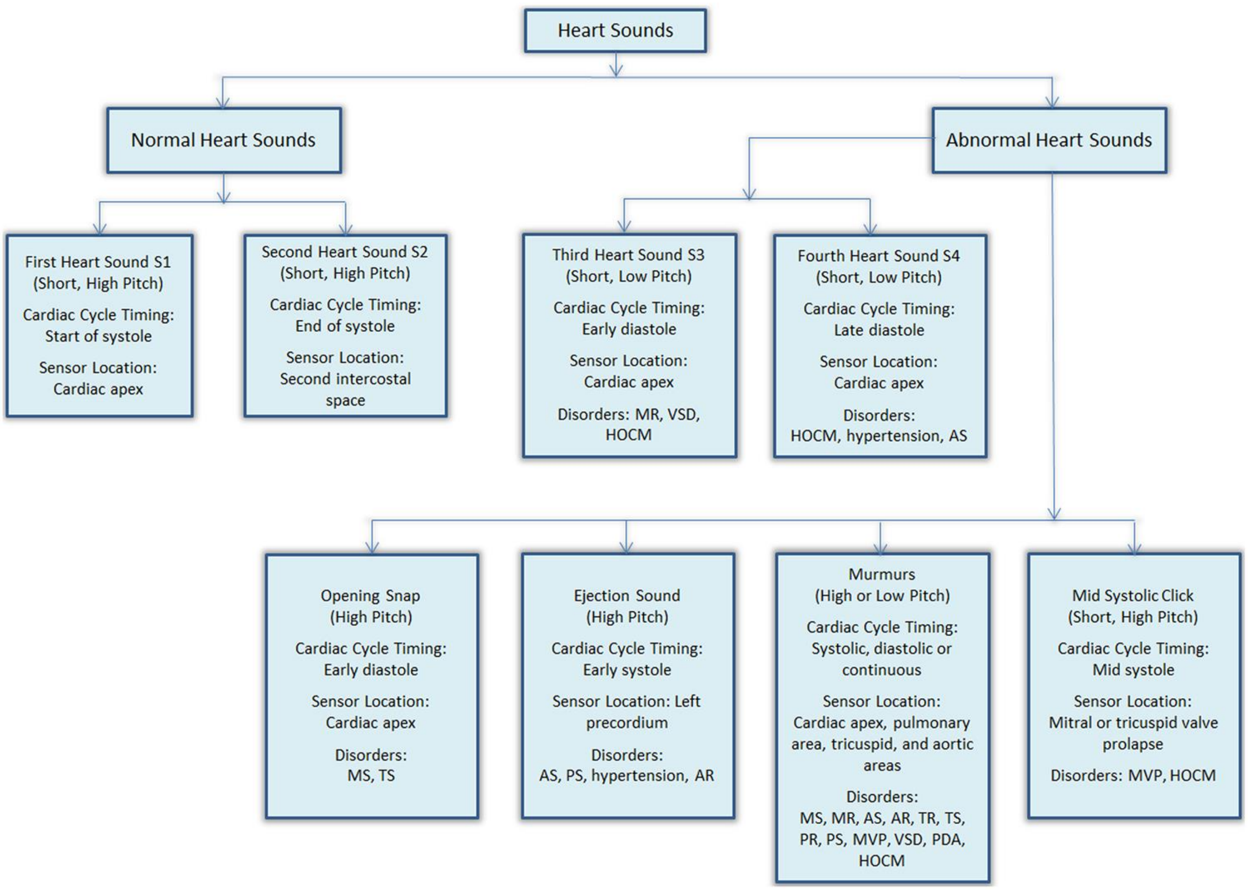

Figure 1.2. Types and Characteristics of Heart Sounds [6]

The association of each cardiac disorder depends in the abnormality of one or more heart sounds. Figure 1.2 also gives depiction of the cardiac disorders associated with each heart sound. The characteristics of cardiac murmurs are summarized in Table 1.1.

Table.1.1. Cardiac Murmurs with Characteristics [6]

Type of Murmur	Location	Timing	Quality	Pitch
Mitral stenosis (MS)	Apex	Diastolic	Rumbling	Low
Mitral regurgitation (MR)	Apex	Systolic	Blowing	High
Aortic stenosis (AS)	Apex/right upper sternal border	Systolic	Harsh	High
Aortic regurgitation (AR)	Right upper sternal border/left third/ fourth intercostal space (ICS)	Diastolic	Blowing	High
Tricuspid stenosis (TS)	Lower right and left sternal borders	Diastolic	Rumbling	High
Tricuspid regurgitation (TR)	Left fourth ICS	Diastolic	Blowing	High
Pulmonary stenosis (PS)	Left second ICS	Systolic	Blowing	High
Pulmonary regurgitation (PR)	Second/third ICS	Diastolic	Blowing	High
Mitral valve prolapses (MVP)	Apex	Mid-late systolic	Blowing	High

Ventricular septal defect (VSD)	Left lower sternal border	Systolic	Harsh	High
Patent ductus arteriosus (PDA)	Left upper sternal border	Continuous	Harsh	High
Hypertrophic cardiomyopathy (HOCM)	Left lower sternal border	Mid-late systolic	Harsh	High

Some of the miscellaneous sounds have a high-pitched diastolic opening snap sound that is produced by mitral valve rapid opening in mitral stenosis (MS) or tricuspid stenosis (TS). The most common early systolic sound is the ejection sound (ES) produced by the sudden halting of semilunar cusps as they open during early systolic process. During the mid-systolic process, a high frequency sound named as mid-systolic click (MSC) is produced by the abrupt halting of prolapsing mitral valve's leaflets excursion into the atrium by chordae [10]. During the process of heart sounds auscultation, the abnormal sounds and murmurs are the interested things to be detected by the physicians that might suggest the cardiac pathology presence and also provide information for diagnosis.

1.3. System Review

One of the state-of-art example of electronic stethoscopes is shown in Figure 1.3 that contains a bell, diaphragm and wide mode for picking the right frequency for better auscultation of body sounds. This stethoscope has the ability to record the patient's heart sounds on the computer for further analysis. This property provides the better understanding and interpretation of heart sounds to the doctors for better health services. A computer based cardiac dysfunction system utilizing an electronic stethoscope has three main modules i.e. data acquisition, preprocessing and signal processing modules as shown in Figure 1.4.

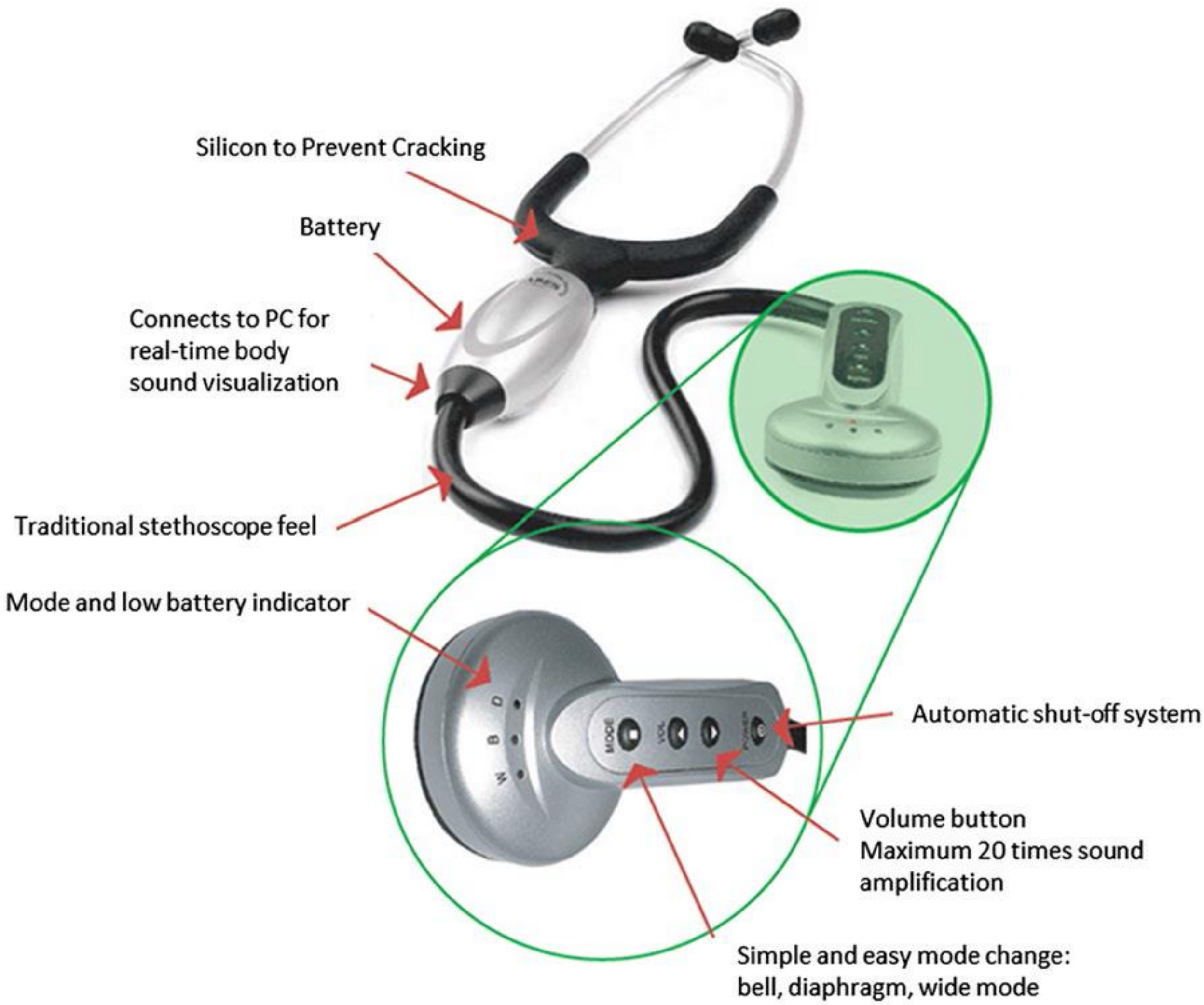

Figure 1.3. An example of Electronic Stethoscope [11]

The data acquisition module detects the heart sounds from the body, converts it into digital signals and sends to the preprocessing module. The preprocessing module filters the hear sounds and reduce interference of noise by normalization and segmentation techniques. The signal processing module extracts and classifies the features in heart sounds. After classification, the results obtained are utilized for clinical use and decision making diagnosis [12].

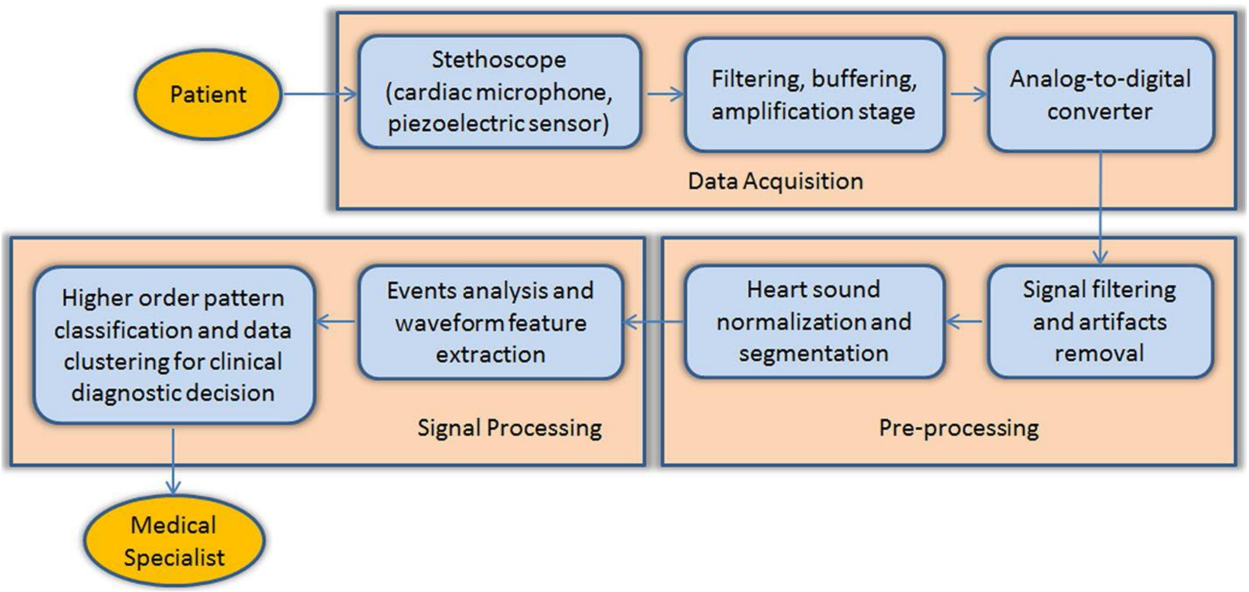

Figure 1.4. A Typical Flow Chart of a Heart Sound Acquisition System [12]

1.3.1. Heart Sounds Acquisition

The heart sound acquisition process is done in three stages; electronic stethoscope sensor, amplification and antialiasing filtering, and analog to digital conversion (ADC). The electronic stethoscope sensor directly collects the heart sounds from the patient and converts it into electrical signal that is to be processed by the electronic circuit. Some commonly used sensors are electret condenser microphones, piezoelectric sensors etc. As the heart sounds electrical signal has very low amplitude, therefore, they are given to an amplifier circuit for amplification. The antialiasing filter normally removes the 50 Hz sound and doubles the frequency of the heart sounds. The filtering is done in such a way that the signal can be converted by ADC. The ADC converts the analog signal into digital signal. The designer has a choice of choosing the sampling rate and bit resolution. Normally, the high rate of sampling and bit resolution provide higher accuracy by consumer larger bandwidth and power consumption.

1.3.2. Heart Sounds Preprocessing

This process is done in three steps; Noise reduction, normalization and segmentation. The noise reduction process is done by applying a digital filter after extracting the desired frequency band from the noisy heart sound signal. To make the system more efficient, advanced artifacts removal methods are utilized for achieving the better Signal-to Noise ratio (SNR). During the data acquisition process, different sampling rates produce variations in heart sounds. Therefore, it is necessary to normalize heart sounds signal up to a certain level for avoiding the variations occurred by data acquisition at different samples. Once the signal is normalized, it is ready for segmentation process for extracting the desired features from it.

1.3.3. Heart Sounds Signal Processing

The signal process is done by extraction of features and classification of heart sounds. The feature extraction step involves the conversion of raw data into parametric form. The parametric form is known as feature that is later on utilized for further processing and analysis. Using certain classifiers trained with the features extracted are utilized for characterization of data and help the doctors for clinical decision making diagnostic process.

1.4. Heart Sounds Recording Sensors

As discussed before, there are two types of stethoscopes; an ordinary or acoustic stethoscope and an electronic or digital stethoscope. The ordinary stethoscope operation is based on the sound transmission via air-filled tubes from the chest piece to the ears of listener. There two parts of chest piece; the bell that is particularly used for transmitting low frequency sounds and the diaphragm that usually transmits higher frequency sounds. The major problem in acoustic stethoscope is its extremely low sound level. This problem is efficiently tackled by electronic or digital stethoscope because the low level of sounds can be amplified by operational amplifiers for optimal listening. The amplified sounds are then digitized for further signal processing and transmission purposes. It had been observed that electronic stethoscopes are much better than the traditional acoustic stethoscopes for heart sounds auscultation, even though not suitable for lung sounds [13].

The sensors or transducers used in electronic stethoscope vary widely. The simplest way of detecting heart sounds from the body is done through placing a microphone in the chest piece. The microphone is mounted behind the diaphragm, capable of picking the sound pressure created by the diaphragm of stethoscope, and ultimately converts it into electrical voltage. The microphone also has a diaphragm, and thus the whole acoustic transmission path consists of the stethoscope diaphragm, air within the housing of stethoscope, and lastly the diaphragm of microphone. The presence of two diaphragms and the air's intervening path lead to the picking up of excess ambient noise by microphone along with inefficient transfer of acoustic energy [14].

The principle of operation of piezoelectric sensors is quite different than the microphones. The electrical energy is produced by them through a crystal substance's deformation. The motion of diaphragm in one case deforms crystal of piezoelectric sensor that is coupled to the stethoscope diaphragm in a mechanical manner and results in an electrical signal. The mechanism of conversion results in the distortion of signal compared with the pure diaphragm motion's sensing is the main problem with this sensor. Thus, the sound detected by this sensor has different tone with distortion as compared to sounds obtained by traditional stethoscope [15].

The micro-electro-mechanical system (MEMS) based capacitive sensors are utilized that are capable of detecting acoustic pressure by changing its minimal value of capacitance. The working of capacitive MEMS based sensors is shown in Figure 1.5.

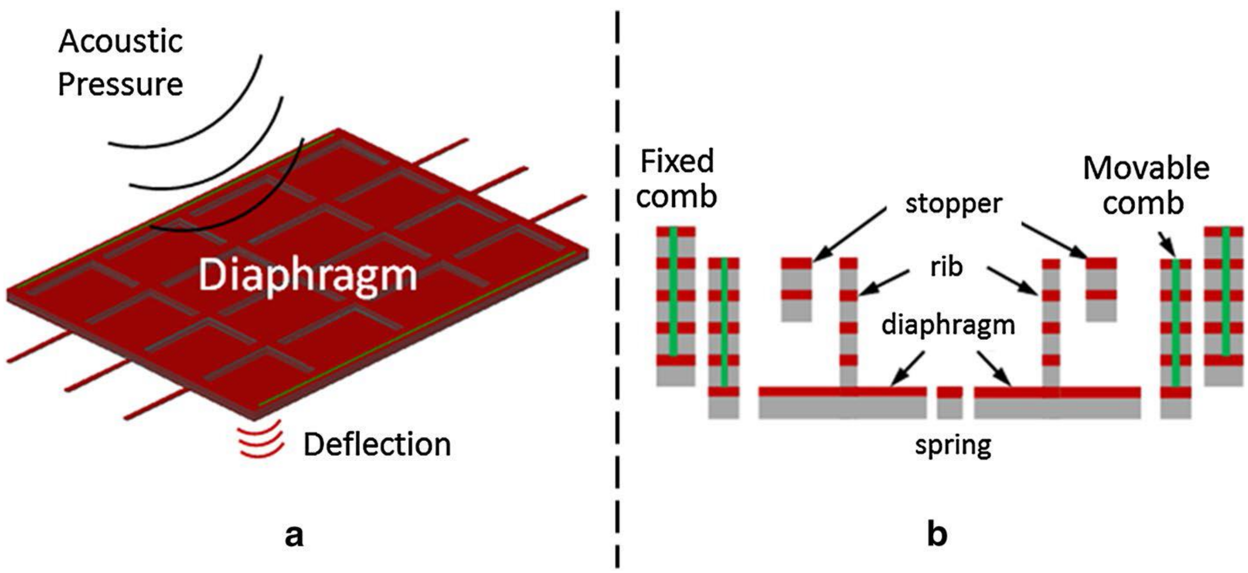

Figure 1.5. MEMS Based Capacitive Sensor [16]

The suspended weight is the diaphragm located at the center and is free to move. This diaphragm is electrically isolated from the static comb like structure, thus having a nominal value of capacitance between them. When acoustic pressure is applied on the diaphragm, it will start moving in harmony with the acoustic pressure source thus producing variations in the nominal value of capacitance. The MEMS based capacitive sensors have various advantages; smaller in size, mass production and better stability to temperature. Additionally, these sensors are compatible with complementary metal oxide semiconductor (CMOS) technology; therefore, combination with integrated circuits can result in the development of high performance heart sound sensor systems [17]. The specifications of sensors utilized by researchers for electronic stethoscopes and the proposed design sensor are shown in Table 1.2.

Table 1.2. Specifications of Various sensors used in Electronic Stethoscopes

Sensor Type	**Sensitivity (dB)**	**Bandwidth (Hz)**	**Impedance (Ω)**	**Operating Voltage (V)**	**Temperature Sustainability (C)**
Electret Condenser Microphone	-46 +/- 3	40-10 kHz	5 k	5-9	-20-70
Piezoelectric Sensor	-55 +/- 5	10-20 kHz	1 k	8-15	-100-275
MEMS based Capacitive Sensor	-65 +/- 5	0.1-35 kHz	100	1-15	-150-400
High Sensitive Studio Speech Microphone (Proposed)	-52 +/- 5	20-20 kHz	2.2 k	2-15	-60-300

1.5. Heart Sounds Denoising

Various factors are involved in disturbing the heart sounds that can prohibit their analysis. Generally, the noise in heart sounds can be either external or internal [18]. The external disturbances have a wide spectrum band and are caused by speech and motion, whereas digestive and respiratory processes mainly result in internal noise. Also, there are also other types of noise that occur during vocal (laughing, coughing etc.), physiology (swallowing, chewing, muscle movements etc.), sensor or transducer (rubbing) and environmental (door knocking, playing music, ringing phones, footsteps etc.) [19]. Because of the existence of such noises, it is difficult to hear some heart sounds components particularly heart murmurs that have very low amplitude and characteristics similar to noise. Thus, the development of efficient algorithms for noise removal for working in noisy surrounding is really important aspect of researchers.

Generally, the algorithms for heart sounds detection can be divided into two groups; time domain denoising and frequency domain denoising. Adaptive noise cancellation (ANC) is a technique used for noise removal in time domain that consists of two sensors. The first sensor is used for picking up the noise corrupted heart sounds and the second sensor picks up the environmental noise. The second input is first filtered and then subtracted from the first input for obtaining the estimated signal [20]. The ANC algorithm is shown in Figure 1.6.

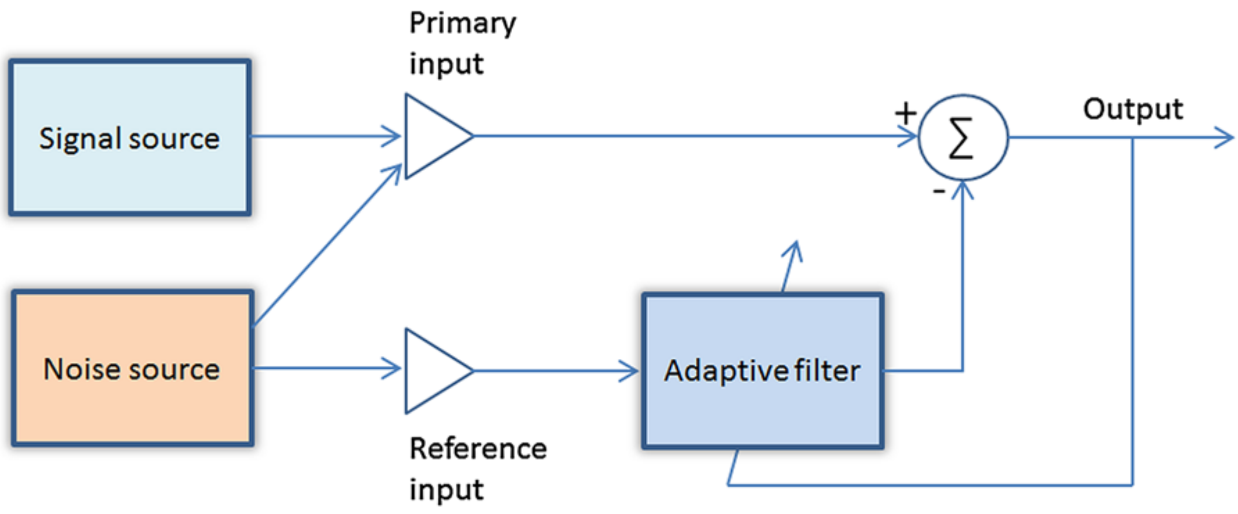

Figure 1.6. Adaptive Noise Cancellation (ANC) in Electronic Stethoscope [20]

As both the heart sounds signal and environmental noise vary with time, the filter utilized should have an adaptive algorithm for changing the filter coefficients value for better approximation after every iteration. The least mean square (LMS), normalized least mean square (NLMS), sub-band least mean square (SLMS), sub-band normalized least mean square (SNLMS), and recursive least square (RLS) are the most popular adaptive noise cancelling algorithms. Additionally, Chebyshev infinite impulse response (IIR) filter can also be used for further enhancement in heart sounds by filtering high and low frequency bands and only keeping the band of interest [21].

The second denoising technique can be called as frequency or transform domain denoising in which the signal is transformed to frequency domain for analyzing the frequency components of the heart sounds that are not readable in time domain. The Fourier analysis the best method for analyzing the frequency contents of the signal. The conversion of a time series from time domain to frequency domain is usually done by Fourier Transform (FT). Fast Fourier Transform (FFT) algorithm is the usual implementation of FT. One of the major drawback of FT is that it is unable to reveal the frequency contents of a stationary signal and also do not give information about the variation in signal with time. For this purpose, a new signal processing technique is adopted known as Short-Time Fast Fourier Transform (STFT) [22]. The STFT follows the process of windowing that analyzes a small section of stationary or nonstationary signal at a particular time by decomposing a time domain signal in 2D time-frequency representation. The STFT has very low frequency resolution. For getting better frequency resolution, the size of the window should be larger and it is achieved by wavelet transform (WT) that utilizes a variable length window. WT is used for getting better resolution in both time and frequency domains. The most commonly used WT is discrete wavelet transform (DWT) in which the wavelets are sampled discretely [23]. The catalog of researchers worked on time domain and frequency domain denoising of heart sounds is depicted in Table 1.3.

The proposed design utilizes a moving average filtering technique that takes ten samples and averages them continuously. This smoothen the signal and the SNR is improved by 9.16 dB.

Table 1.3. Denoising Techniques for Heart Sounds Detection in Electronic Stethoscope

Authors	**Denoising Technique**	**Type of Sensor**	**No. of sensors**	**Method**	**Results**
[24]	Time	Electret Condenser MIC	2	LMS-ANC	SNR improved by 12.11 to 16.11 dB
[25]	Time	Electronic Stethoscope	1	Single input ANC	Lungs murmurs and Noises removed
[26]	Time	Microphone	1	LMS, RLS	LMS improved heart

					sounds by 95-97 percent and RLS 90-92 percent
[27]	Time	-	-	LMS-ALE	SNR is improved by 7.89 dB
[28]	Frequency	Audicor System	2	STFT	S3 and S4 Sounds are efficiently detected
[26]	Frequency	Electret Condenser MIC	1	DWT, Hilbert Transform	Optimal selection of parameters suggested
[29]	Frequency	Microphone	1	DWT, RLS-ALE	DWT and RLS-ALE gave better outcomes
[30]	Frequency	-	-	EMD	EEMD gave better heart sounds noise removal
[31]	Frequency	-	-	DWT	Accurate extraction of S1 and S2 sounds
Proposed	Time	High Sensitive Studio-speech MIC	1	Moving Average Filtering	SNR is improved by 9.16 dB

1.6. Lungs Sounds Auscultation

There is some imprecision found from the traditional nomenclature for the lung sounds. Thus, this section presents a terminology developed by the ad hoc committee of the International Lung Sounds Association (ILSA) [32]. This classification has replaced the term "rale" by "crackle", since the adjectives utilized for qualifying rales (i.e. dry or moist) could be misleading with regards to the processes through which rales or crackles are produced. The sounds that are produced acoustically and does not suggest any site or means of generation are called crackles. Table 1.3 shows the clinical characteristics of normal and abnormal lung sounds along with their clinical correlations.

Table 1.4. Summary of Lung Sounds, Clinical Characteristics and Clinical Correlations [33]

Lung Sounds	**Clinical Characteristics**	**Clinical Correlations**
Normal Tracheal Sound	Clinically hearable sounds in both phases of respiratory cycle with hollow and nonmusical nature	Intrapulmonary sounds transportation by indicating the upper airway patency; If the upper airway patency is altered leads to the disturbance of these sounds. These sounds are used for monitoring sleep apnea and are considered as a good model for bronchial breathing.
Normal Lung Sound	These sounds are hearable only during inspiration and early	These sounds are diminished by hypoventilation, airway

	expiration with soft and nonmusical nature.	narrowing, lung destruction, pneumothorax, and effusion. These sounds are assessed as an aggregate source with normal breath sounds and ruled out clinically important airway obstruction.
Bronchial Breathing	These sounds most probably mimic tracheal sounds and are soft, nonmusical, and hearable during both phases of respiratory cycle.	These sounds normally indicate the patent airway surrounded by consolidated tissue of lungs during pneumonia or fibrosis.
Stridor Sound	Theses sounds might be heard over the upper airways or at a distance without using stethoscope and have a high pitch and musical nature.	These sounds indicate the obstruction in upper airway associated with larnygomalacia, lesion in vocal cord, post-extubating lesion during inspiration, and associated with tracheomalcia, bronchomalacia, and extrinsic compression during expiration. These sounds also have association with fixed lesions when biphasic.

Wheeze Sound	These sounds are heard on both inspiration and expiration with a high pitch and musical nature.	These sounds suggest narrowing in airway or localized blockage during foreign body or tumor and are associated with asthma and chronic obstructive lung disease. The limitation degree of airflow is directly proportional to the number airways generating wheezes and might be absent when there is very low airflow during severe asthma and destructive emphysema.
Rhonchus Sound	These sounds might be heard during both the inspiration and expiration and have a low pitch and musical nature similar to snoring.	These sounds are associated with abnormal airway collapsibility an d rupture of fluid films and are cleared with coughing, suggesting a role for secretions in larger airways. These are also common with narrowing of airway caused by thickening of mucosa, edema, and bronchospasm.

Fine Crackle Sound	These sounds are heard during mid-to-late inspiration and incidentally during expiration probably unaffected by cough, gravity dependent, not transmitted by mouth and have short, explosive, and nonmusical nature.	These sounds are not related to secretions and associated with interstitial lung fibrosis, congestive heart failure, pneumonia, idiopathic pulmonary fibrosis, asbestosis, and might be present before radiological detection changes.
Coarse Crackle Sound	These sounds are heard only during inspiration and throughout the process of expiration probably effected by cough, transmitted through mouth and have short, explosive, and nonmusical nature.	These sounds indicate the intermittent opening of airway and might be related to secretions particularly in chronic bronchitis.
Pleural Friction Rub Sound	These are usually biphasic sounds and heard over basal regions with having explosive and nonmusical nature.	These sounds are particularly associated with pleural tumors or pleural inflammations.
Squawk Sounds	These sounds are accompanied by crackles and having mixed and short musical nature.	These sounds are associated with distal airways, might suggest hypersensitivity pneumonia and other interstitial diseases of

		lungs in non-acute ill patients, and also indicate the disorder of pneumonia in in acute ill patients.

1.7. Normal Lung Sounds

The fundamentals of lung auscultation are shown in Figure 1.7.

1.7.1. Tracheal Sounds

The tracheal sounds and their auscultation are performed infrequently, but in some situations they can give significant clinical information. When auscultation is performed over suprasternal notch or the lateral neck, they have a huge amount of energy and are heard easily during the both phases of respiratory cycle. The frequency range of normal tracheal sounds is between 100 to 5000 Hz with a sharp drop in energy at about 800 Hz and smaller energy above 1500 Hz. These sounds are produced by turbulent flow of air in glottis, pharynx, and subglottic region [34].

The auscultation of tracheal sounds is very useful in many situations. Firstly, sound is carried from trachea to lungs, allowing auscultation of other sounds without filtration from the chest cage. Secondly, the tracheal sounds characteristics are identical in quality to the abnormal bronchial breathing heard in those patients having consolidation in lungs. Thirdly, in those patients having obstruction in upper-airway, these sounds have musical nature characterized as a typical stridor or a localized, in tense wheeze. The recognition of tracheal wheeze has a significant importance because when auscultation is done over the lungs, it is incorrectly taken for the asthma wheeze. Lastly, tracheal sounds monitoring is a technique in which patients are monitored noninvasively for the sleep apnea syndrome, hence practically the auscultation of these sounds cannot be done by stethoscope [35]. On the other hand, a child's stridorous breathing with croup can easily be recognized, stridor in adults, when occurred due to bronchial or tracheal stenosis or through a tumor in the airway located at the center, is subtler. In the examination of lungs, it might be missed but when auscultation is done over the larynx or trachea it could be heard [36].

1.7.2. Vesicular Sounds

The surface of chest is mainly used for auscultation of normal breathing that is mainly influenced by the anatomical structures between the sound generation's site and the auscultation's site. During the analysis of sounds, the frequency ranges of vesicular sounds are narrower as compared to the tracheal sounds, extending from 100 Hz to 1000 Hz, with a sharp drop at about 100 Hz to 200 Hz [37]. The idea of vesicular sound generation after entering the air within alveoli is not correct. The modern concepts of physiology show that gas molecules move from one part to other in lungs by the process of diffusion in a bulk flow manner, which is a silent process. Most importantly, various studies support the double origin's idea, with the component of inspiration generated within the lobar and segmental airways and the component of expiration coming from more central sources [38].

There are various mechanisms suggested for vesicular sounds such as turbulent flow, vortexes, and other unknown hitherto mechanisms [39]. On medical point view, the decrease in the intensity of sound is the most common abnormal factor. The decrease in the intensity level of sound might be due to the loss in its energy at the site where the sound is generated, impaired transmission or both. When there is a drop in the airflow during inspiration, the generation of sound can be decreased that results from various conditions ranging from the poor cooperation to the central nervous system (CNS) depression. The blockage in airway conditions include the narrowing that happens in obstructive airways disorders such as asthma and chronic obstructive pulmonary disorder (COPD). There might be permanence in the decrease in the breath sounds in cases such as pure emphysema, or reversible in asthma [40].

The intrapulmonary and extra-pulmonary factors are involved in the sound transmission impairment. The extra-pulmonary factors involve obesity, deformities in chest, and distention in abdomen due to ascites. Similarly, the intrapulmonary factors include lung's mechanical properties disruption or the interposition of a medium between sound generation source and the stethoscope that has a different acoustic impedance from that of normal parenchyma. By the way, in pneumonia the lung consolidation development occurs in lower breath sounds only if there is blockage in the embedded airways due to viscous secretions or inflammation. If there is patency in the airways, improvement in transmission of sounds actually happened, lead to the increase in the component of expiration due to bronchial breathing that corresponds to the air bronchogram or radiographs.

1.8. Abnormal Lung Sounds

1.8.1. Stridor

It is the abnormal sound having a pitched and musical nature produced after the turbulent airflow passes across a narrow segment of the upper respiratory tract. It is sometimes such an intense sound and can be heard without using any stethoscope. These sounds are characterized by regular sinusoidal function having fundamental frequency of about 500 Hz and contain several harmonics. The evaluation of stridor is especially useful in patients in the intensive care units who have undergone extubating, when its appearance can be a sign of exathoraxic obstruction in airway needing quick intervention.

In situations of such obstruction, stridor sound could be easily distinguished from wheeze sound because it can be easily heard during inspiration than expiration and its prominence is more at neck than over the chest. However, stridor is normally inspiratory sound but it can also be biphasic or expiratory. In adult individuals, the other causes of stridor include epiglottis, airway edema after removal of device, anaphylaxis, dysfunction of vocal cords, foreign body inhalation, laryngeal tumors, tracheal carcinoma, and thyroiditis [41].

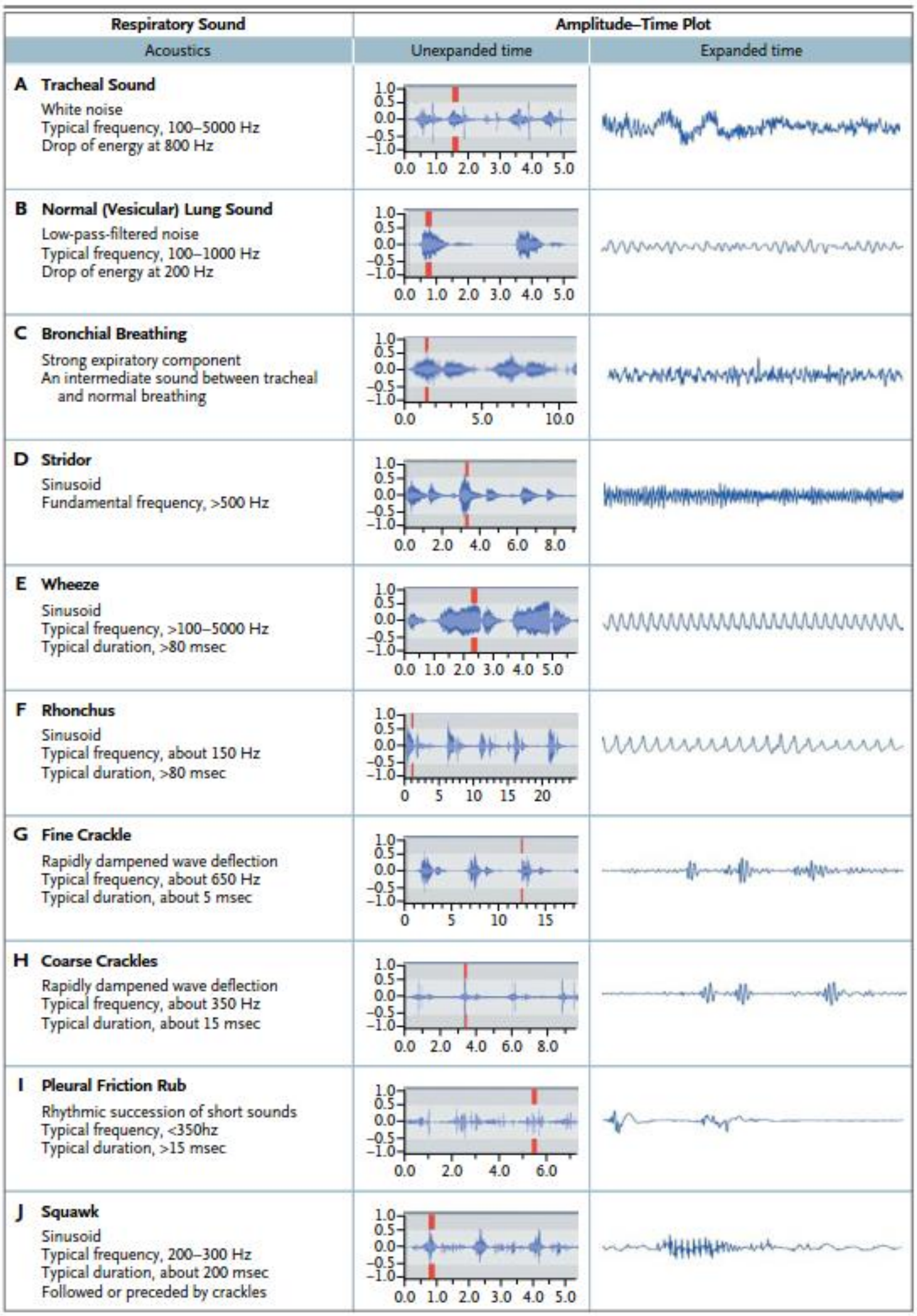

Figure 1.7. Fundamentals of Lung Auscultation [32]

1.8.2. Wheeze

This is the most easily recognized abnormal lung sound. Its duration is longer than 100 ms and its musical quality allows to be discerned by the human ear. During the analysis of sound, wheeze have sinusoidal appearance with energy range between 100 Hz to 1000 Hz and its harmonics exceed 1000 Hz on time [42]. It is most likely inaccurate to credit high-pitched wheezes to the narrowing of peripheral airways routes and low-pitched wheezes to the narrowing of central airways. Supposedly, wheezes are shaped in the branches between the second and seventh production of the airway tree by the coupled oscillations of gas and walls of airways that have been contracted to the point of pairing by an assortment of mechanical forces. Additionally, there are two principals incorporated in the model: first, that in spite of the fact that wheezes are constantly related with limitation of airflow, airflow can be restricted without wheezes, and second, that the pitch of an individual wheeze is resolved not by the diameter of the airway but rather by the air wall thickness, twisting stiffness and longitudinal tension [43].

Wheezes can be inspiratory, expiratory, or biphasic. However, normally occur in obstructive diseases of airways, particularly asthma, they are definitely not pathognomonic of a specific illness. In asthma and COPD, wheezes can be heard all over the mid-section, making their number hard to assess. Local wheeze is regularly identified with a nearby process, more often than not an impediment by a remote body, mucous attachment, or tumor. Inability to perceive this sort of wheeze can have serious consequences for patients, who regularly get a misdiagnosis of 'hard to-treat asthma' and are not alluded to fitting masters for months or even years after the underlying assessment. Wheezes might be truant in patients with serious obstruction of airway. Indeed, the model referred to above predicts that the more serious the obstruction, the lower the probability of wheeze. The normal example is the attack of serious asthma, a condition in which the low respiratory flows can't give the power required to produce wheezes. As an outcome, the going with normal breath sound is additionally extremely lessened or even truant, making a clinical picture known as ‘silent lung’. As the obstruction is assuaged and airflow increments, both the wheeze and ordinary breath sounds reappear [44].

At last, a word must be said in regards to the rhonchus. This sound is thought to be a variation of the wheeze, contrasting from the wheeze in its lower pitch regularly almost 150 Hz which is in charge of its similarity to the sound of wheezing on auscultation. The rhonchus and the wheeze presumably have a similar generation mechanism, however the rhonchus, not at all like the wheeze, may vanish subsequent to coughing, which recommends that secretions play a role. Though numerous doctors still utilize the term rhonchus, some want to allude to the trademark musical sounds just as high or low-pitched wheezes.

1.8.3. Crackle

Crackles are explosive and short sounds with nonmusical nature and are heard during the process of inspiration and sometimes during expiration. There are two types of crackles: fine and coarse crackles. The fine crackles are heard during mid-to-late inspiration and are finely perceived in dependent regions of lung as well as not transmitted by mouth. The fine crackles are not influenced by cough but altered by gravity, varying or diminishing with variations in body position. On the other hand, coarse crackles are produced during inspiration and throughout expiration with having a quality of popping. They are heard over any region of lung, usually transmitted to the mouth, can alter or diminish with coughing, and uninfluenced by changes in the positions of body. During sound analysis, crackles are rapidly damped sounds with a repetitive pattern. The duration of fine crackles is shorter than coarse crackles (5ms vs 15 ms) and higher frequency (650 Hz vs 350 Hz) [45]. Fine crackles are produced by sudden inspiratory opening of small airways closed by surface forces during the last expiration process. Similarly, the production of coarse crackles is due to gas boluses passing through airways by intermittent opening and closing [46].

1.8.4. Pleural Friction Rub

There is silent sliding of parietal and visceral pleura over each other in healthy individuals. People with numerous lung diseases have the rough visceral pleura such to an extent that its passage over the parietal pleura generates crackles that are heard as a friction rub. On auscultation, this sound is more prominent on the basal and auxiliary regions as compared to upper regions. This is because the basal regions lie on the steeper portion of the static pressure volume curve, whereas the upper regions lie on the plat portions of the curve. Therefore, the basal regions undergo greater expansion for a given trans pulmonary pressure. Usually, the nature of pleural friction hub is biphasic, and the expiratory sequence mirrors the inspiratory sequence [47]. The waveform of pleural friction rub is similar to crackles but have longer duration and lower frequency components. These sounds are usually produced by sudden tangential release of energy from lungs surface, which is prevented temporally from sliding due to a frictional force among the two layers of pleura. These sounds are normally heard in inflammatory diseases such as pleuritis or mesothelioma.

1.8.5. The Squawk Sound

This is a mixed sound that has components of both musical and nonmusical nature. The squawk contains sinusoidal oscillations with duration less than 200 ms and its fundamental frequency lies between 200 to 300 Hz. The mechanism of squawk sound is unknown but according to one theory, it is produced by the peripheral airways oscillations having walls remain in apposition longer enough for oscillating under airflow action during inspiration. It is heard in patients having hypersensitivity pneumonitis [48].

PART II

DESIGN
&
METHODOLOGY

2.1.Medical Standards

Medical standards are regulations that control the use of medical devices while applying them on patients during any clinical practice. They also known as medical devices regulations.

2.2.Definition and Scope of Medical Devices

According to the Federal Food Drug & Cosmetic Act, medical devices are implements, apparatuses, in-vitro reagents, contrivances, implants, or other analogous products that are utilized in diagnosis, cure, treatment, prevention, or mitigation of diseases both in animals and humans and are listed in the US Pharmacopoeia, legitimate Formulary, or any addenda to these. These devices can assist change animals or humans' functions of body or structures, but have no effect through their metabolism or chemical reactions [49].

Unlikely drugs, medical devices do not undergo any metabolism in the body or mediate chemical reactions. Accessories utilized in the hospitals are not medical devices except where the manufacturer has planned it for combining with medical device in order to facilitate the objective of device [50]. The designation of certain items as medical devices in different countries has certain variations. These items include spare parts for medical devices that assist the devices in their disabled form and are utilized in treating the diseases and injuries in animals, and gadgets in which animal or human tissue is integrated that might adhere to the above definition are regulated by different rules.

Similarly, a medical device defined by European Commission MDD 92/ 42/ EEC as an object, implement, machine, apparatus, or any other item that is combined or singly used for humans in order to diagnose, monitor, cure, prevent or alleviate a disease or control, examine, replace, modify a physiological or an anatomical attribute. The medical device should not attain any intended action via immunological, pharmacological or metabolic effects. In-vitro devices for diagnostic purposes and custom made devices also include in the category of medical devices [51]. Today, there is versatility in the medical device sector and besides the more common products such as bandages and syringes, it now encompasses the novel new era cutting edge techniques in the grounds of nanotechnology, tissue engineering, and bioinformatics [52].

2.3. Medical Devices Classification

2.3.1. FDA Classification Schemes

Medical devices are classified into three classes by The Food and Drug Administration (FDA); Class-I, Class-II, and Class-III. The classification is based on the health risks probably associated with medical devices containing software and are meant for ensuring the fact that the medical devices are safe as well as effective [53]. General controls are used for governing Class-I medical devices whereas special controls and strict regulatory controls are applied on Class-II medical devices. A premarket approval (PMA) is needed for beginning the marketing of Class-III devices. To ensure their safety and effectiveness, the data available is inadequate. These devices are associated with certain risk of serious injury or illness and they can give harm to the health of an individual [54].

The classification of devices is done in categories by FDA. The medical specialty of product is associated with code of these categories. The advisory committee supervise the device regulations and the specialties are related to it. Product codes are also included in it that relate to the devices features and functions. There are 19 specialties are defined by FDA i.e. Radiology, Dental, Pathology, Hematology, or Anesthesiology.

2.3.2. The North American Industry Classification System (NAICS)

FDA classification system of medical devices is not used by The U.S Census Bureau and they use NAICS. Based on the economic activity, the manufacturers and government in the U.S use NAICS for classifying business in American medical industry. There are eight classes of medical devices in this system of classification and are shown in Table 2.1.

Table 2.1. Classification of Medical Devices under The North American Industry Classification System (NAICS) [56]

Serial No.	Class	Code	Examples
1	Surgical appliances and supplies	NAIC 339113	wheelchairs, artificial joints and limbs, surgical dressings, surgical kits, orthopedic appliances, surgical gloves, hydrotherapy appliances, rubber medical gloves, stents, and disposable surgical drapes
2	Surgical and medical instruments	NAIC 339112	catheters, syringes, blood transfusion devices, anesthesia apparatus, hypodermic needles, and optical diagnostic apparatus
3	Dental goods	NAIC 339114	dental chairs, drills, dental hand instruments, amalgams, sterilizers, and cements
4	Dental laboratories	NAIC	orthodontics, crowns, bridges, and

		339116	dentures
5	Irradiation equipment	NAIC 334517	CT, X-ray, and diagnostic imaging equipment
6	Ophthalmic goods	NAIC 339115	lenses, frames for eyeglasses, and other magnification and optical products
7	Substances for carrying out in vitro diagnosis	NAIC 325413	Petri dishes, test tubes, and other devices for diagnostic tests
8	Electro-medical equipment	NAIC 334510	pacemakers, ultrasonic scanning devices, MRI machines, patient-monitoring equipment, and patient-monitoring systems

2.3.3. European Classification Scheme

Based on the risks to the safety of consumers, European system classifies medical devices into four classes: Class-I, Class-II A, Class-II B, and Class-III. There is no need of PMA process for Class-I devices but they are necessary to meet all efficacy and safety guidelines during their design, manufacturing, and labeling. Medical devices belonging to Class-II, Class-III or Class-I that require sterile environment are needed to send a Conformity Declaration to the relevant directives of European Commission (EC) before their PMA process. For conformity assessment, they are needed to submit particulars about the used procedure. An additional EC certificate is required to submit for high risks devices by the manufacturers.

2.4. Documentation of the Proposed Digital Stethoscope

2.4.1. Introduction

The product is a Digital Stethoscope, with model: HSL Digital Stethoscope is an active medical device particularly use for diagnostic purposes. It is aimed for listening, analyzing and monitoring the sounds of heart, lungs, and other body parts. The HSL Digital Stethoscope is capable to analyze the sounds frequencies from 35 Hz to 1000 Hz.

This instrument contains an acoustic stethoscope's chest piece for the detection of the sounds. There is a high sensitive studio speech microphone with sensitivity of -52dB ±5dB that converts the acoustic signal into electrical signal. The signal is amplified and filtered, and then digitized and processed by Arduino DUE board. The beats per minute and the real time signal are displayed over a 2.4 inches serial TFT graphic LCD. The system is powered by two 3.7 V/ 400 mAh rechargeable Lipo batteries.

2.4.2. Intended Use of Device

The HSL Digital Stethoscope is an active medical device used for listening, analyzing and monitoring of the sounds of heart, lungs, and other body parts.

2.4.3. Device Classification

The HSL Digital Stethoscope is classified by the designer according to the **Annex IX** of the **Directive of the Medical Devices 93/42/EEC** as device belonging to the **Class II a**. This device is operated at non-sterile conditions.

2.5. Device attributes conformity with necessities provided by regulations

2.5.1. Applicable regulations

Functionality and safety of this device shall match the important necessities given by the Council Directive 93/42/EEC (Medical Devices Directive MDD).

The needs of the above directive are estimated into national legislation of Czech Republic by the virtue of Government order number 336/2004 Coll. The conformity to this order number means also the conformity to the suitable directive and vice versa.

In situation of the accessible corresponding European Standards, the obedience of standard of EN provides an assumption of conventionality.

2.5.2. Technical specifications and standards

The list of technical specifications and standards showing the important necessities of the directive related to the device is shown in Table 2.2.

Table 2.2. Technical specifications and standards

Serial No.	Number of Document	Name of the Document
1	EN ISO 14971:2007	Medical devices-medical devices and risk management application
2	EN 1041:1998	Medical devices with information provided by the designer
3	EN ISO 13485:2003	Quality management systems required for regulatory purposes

		of the medical devices
4	EN 980:2008	Labeling of medical devices with graphical symbols
5	EN 60601-1:1990	Part 1: General needs for safety of medical electrical device
6	EN 60601-1-2:2001	Part 1-2: General needs for safety of medical electrical device. Collateral standard: Electromagnetic compatibility. Tests and requirements
7	EN 60601-1-4:1999	Part 1-4: General needs for safety of medical electrical device. Collateral standard: Programmable electrical medical systems
8	EN ISO 10993-5:2009	Part 5: Cytotoxicity invitro tests for biological evaluation of medical device
9	EN ISO 10993-10:2002	Part 10: in irritation and delayed type hypersensitivity tests for biological evaluation of the device
10	MDD 93/42/EEC	Council directive concerning medical devices

2.6.Materials and Methods

The block diagram of the digital stethoscope system is presented in Figure 2.1.

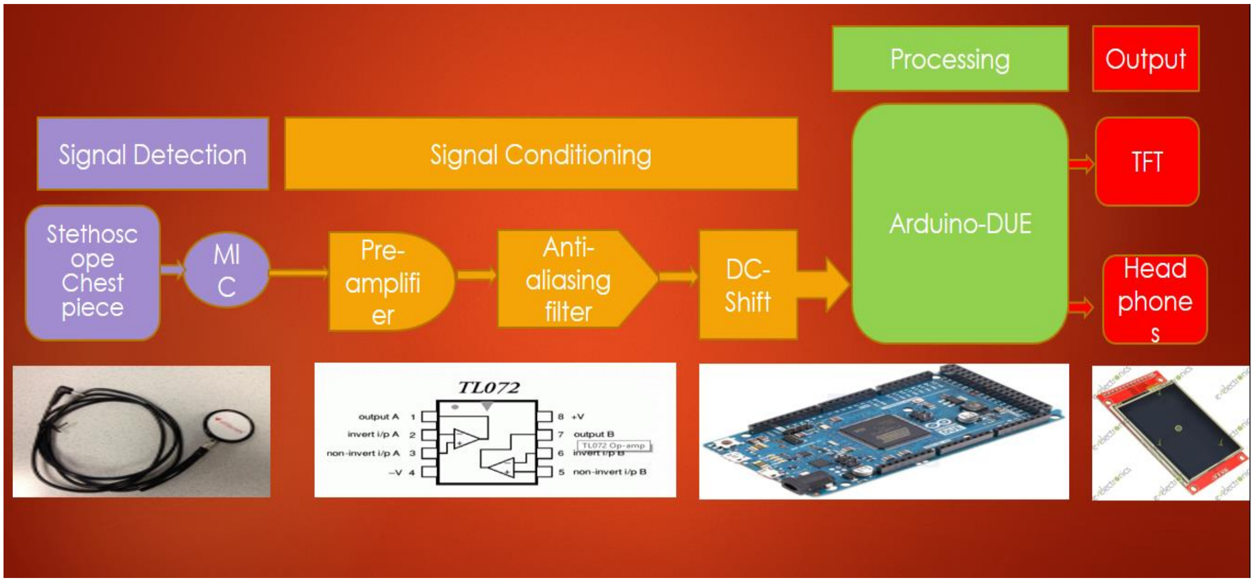

Figure 2.1. Block Diagram of Proposed Digital Stethoscope System

The entire methodology is divided into four sections;

- Signal Detection
- Signal Conditioning
- Signal Processing
- Output

2.6.1. Signal Detection

The signal detection part consists of the chest-piece of an ordinary stethoscope that detects the acoustic heart sounds from the body. A high sensitive 3.5 mm studio speech microphone is attached inside the pipe near the end of the chest-piece as shown in Figure 2.2.

Figure 2.2. Assembly of High Sensitive Microphone Attached with Chest-piece

The microphone has a sensitivity of -52 dB +/- 5 dB, impedance is 2.2 kΩ, and its frequency range is between 20 Hz to 15 kHz. The microphone biasing circuit is shown in Figure 2.3.

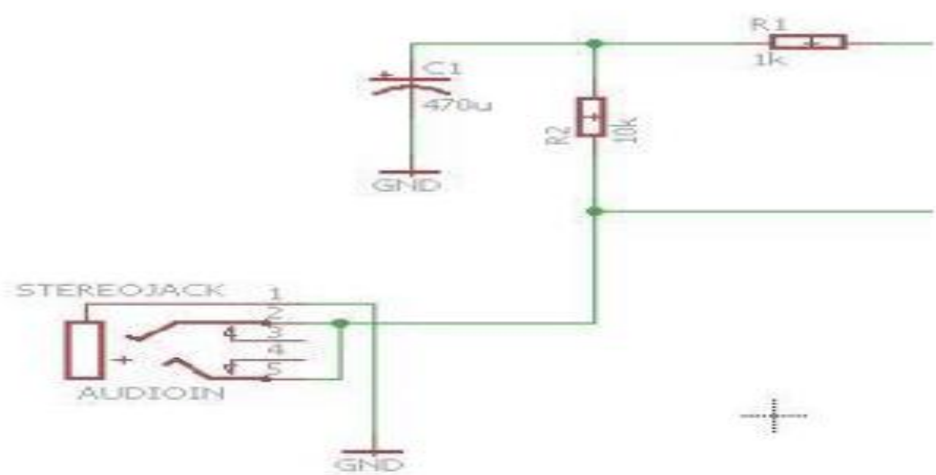

Figure 2.3. Microphone Biasing circuit powered by 3.7 V Lipo Battery

2.6.2. Signal Conditioning

The second part is the signal conditioning part composed of preamplifier, antialiasing filter, and DC shifting. The microphone converts the acoustic signal detected by chest-piece into electrical signal. This signal has very low amplitude lies between 35 mV to 50 mV. It is given to the preamplifier circuit that is composed of a TL072 IC. This is a dual operational amplifier IC and its first op-amp is used as an inverting preamplifier. The preamplifier circuit is shown in Figure 2.4.

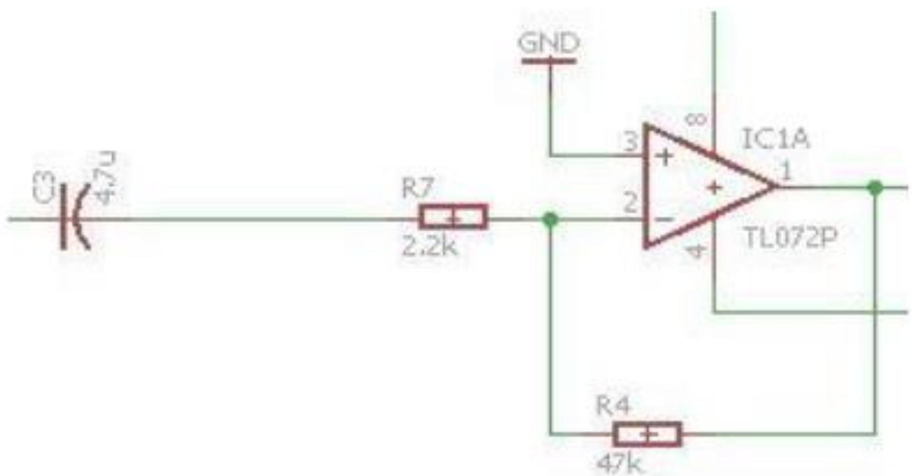

Figure 2.4. The Inverting Preamplifier Circuit

The gain of the preamplifier is 21.36 and it is calculated by using formula;

$$G = -R2/R1 \quad (4.1)$$

The amplified signal from the preamplifier is subjected to the second op-amp of the Tl072 IC and it is used as an active second order Sallen-Key antialiasing filter. The circuit for this filter is shown in Figure 2.5.

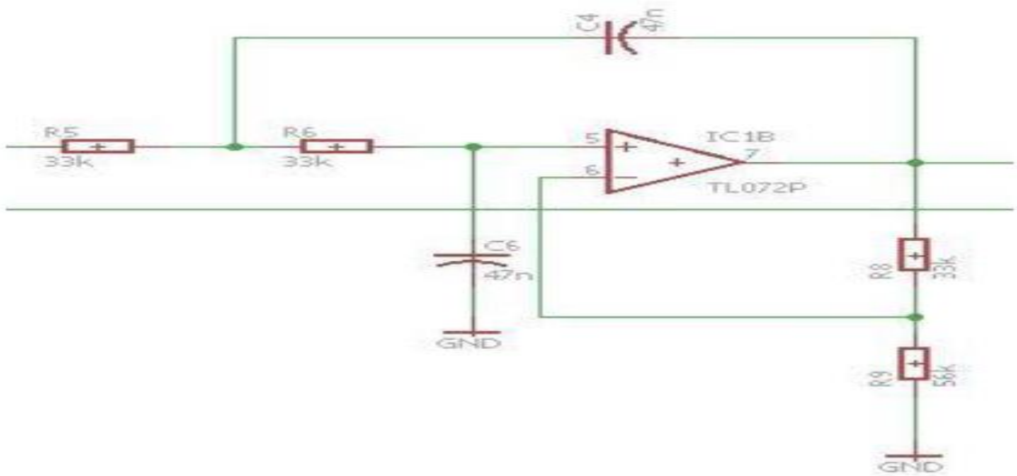

Figure 2.5. 2nd Order Active Sallen-Key Low Pass Filter

The cutoff frequency of the filter is 1026 Hz and it is calculated by using formula;

$$fc = \sqrt{R1R2C1C2} \qquad (4.2)$$

A DC shift of 1.67 V is added in the filtered signal that is provided by 3.3 V pin of Arduino through a voltage divider. It is necessary because Arduino cannot read negative portion of the alternating heart sounds signal. The circuit is shown in Figure 2.6.

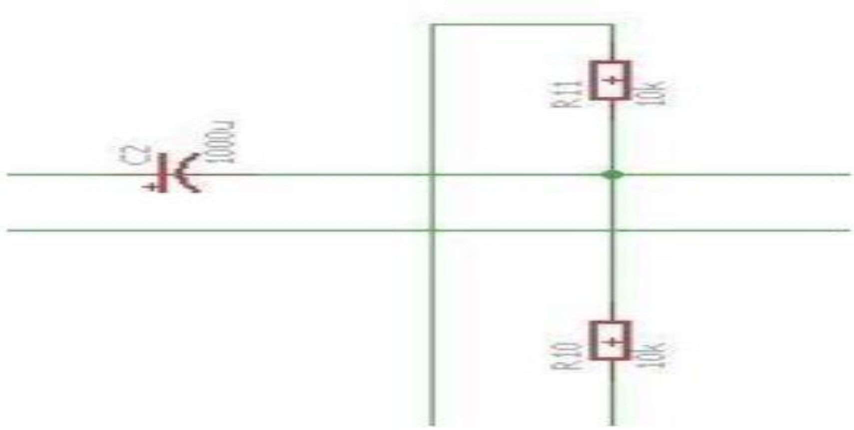

Figure 2.6. DC Shift added by Arduino DUE 3.3 V pin through a voltage Divider Circuit

2.6.3. Signal Processing

The third part of the methodology is the signal processing and it is done by Arduino DUE Board shown in Figure 2.7. The specifications of Arduino DUE are as under:

- It is the first Arduino with an ARM-based microcontroller.
- It contains Atmel SAM3X8E ARM Cortex-M3 CPU for high performance.
- There are 54 digital input/output pins. 12 pins can be used as PWM outputs.
- It has 12 analog inputs, 4 UARTs (hardware serial ports) and a clock of 84 MHz
- It also has a USB OTG capable connection and two built-in 12-bits DAC (digital to analog converters)
- It contains a power jack, an SPI header, a JTAG header, and reset and erase buttons.

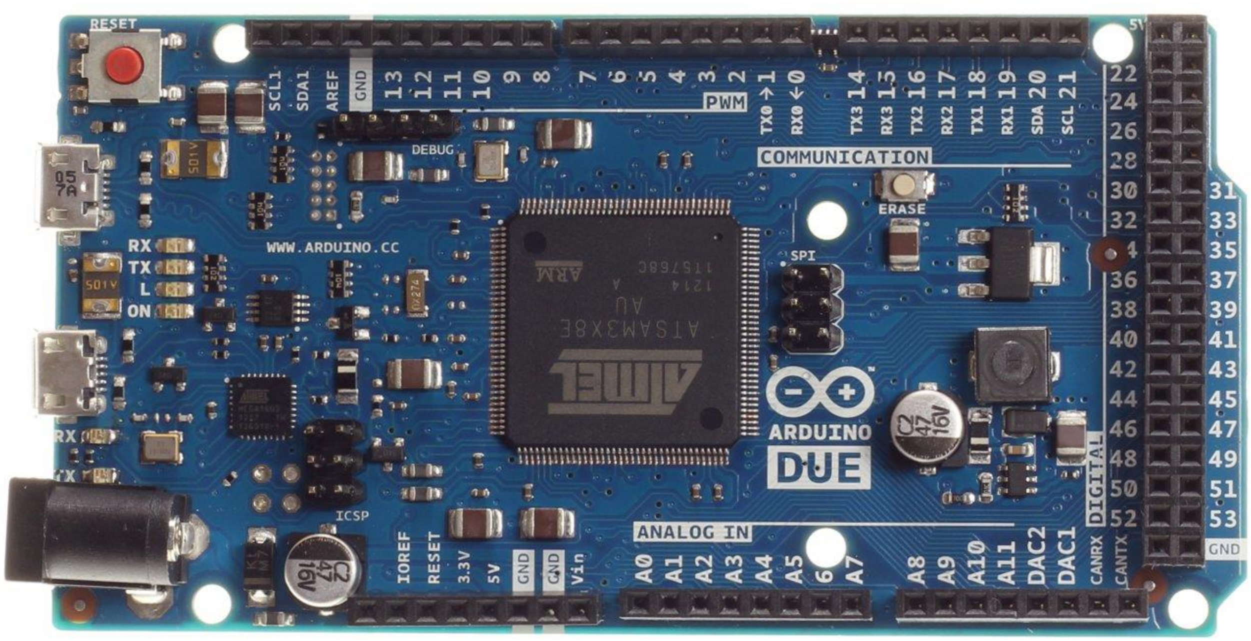

Figure 2.7. A typical Arduino DUE Board

The first step is to digitize the signal and it is done by analog 12-bit A1 pin of the Arduino DUE board. The second step is to apply a simple moving average filter for removing noise from the signal. The third step is to set the threshold for beats count. A threshold of 2400 is set. The beats are defined in such a way that it will always be greater than the corresponding neighbors to it. After counting the beats, the calculation of beats per minutes (BPM) are done and a real time heart sounds along with BPM are displayed over a serial 2.5 inch TFT graphic LCD (240 x 320). The pin configuration of TFT LCD with Arduino DUE board is shown in Table 2.3.

Table 2.3. Pin Configuration of TFT Graphic LCD with Arduino

TFT Pins	Vcc	GND	CS	RST	DC	MOSI	SCK	LED	MISO
Arduino Pins	3.3 V	GND	D-10	-	D-9	SPI-2	SPI-5	-	SPI-6

The algorithm applied in Arduino Software is shown in Figure 2.8.

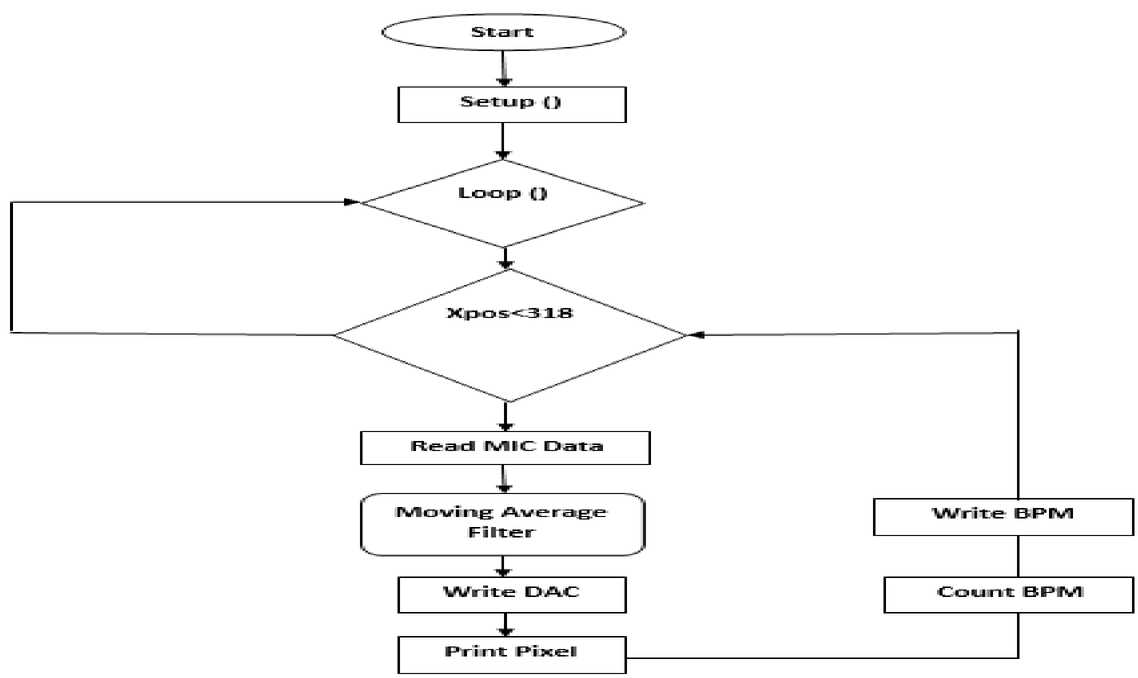

Figure 2.8. Algorithm Applied in Arduino Software

2.6.4. Output of System

The fourth part is the output part. The first output is the digital output that is in the form of BPM and real time heart sounds over TFT graphic LCD. The digital output is shown in Figure 2.9.

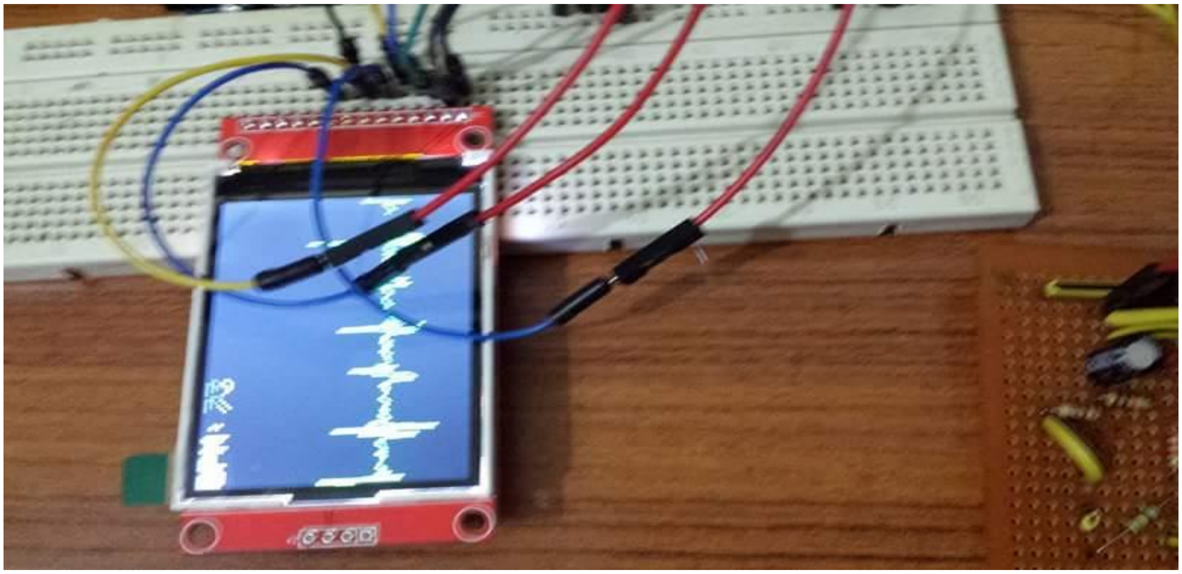

Figure 2.9. BPM and Real time heart sounds over TFT Graphic LCD

The second output is analog that is obtained after converting it through built-in 12 bit DAC0 pin of Arduino DUE board. This signal is then given to a low noise LM386 power amplifier. A speaker or earphones can be connected with 3.5 mm stereo audio jack for listening the analog heard sounds. The power amplifier circuit is shown in Figure 2.10.

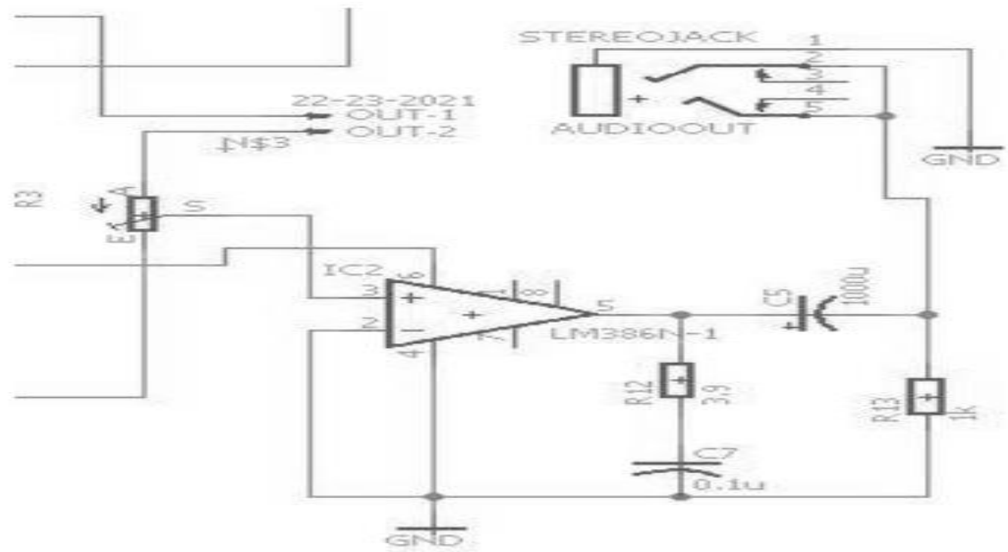

Figure 2.10. Low Noise Power Amplifier Circuit

The complete Proteus schematics of the circuit is shown in Figure 2.11.

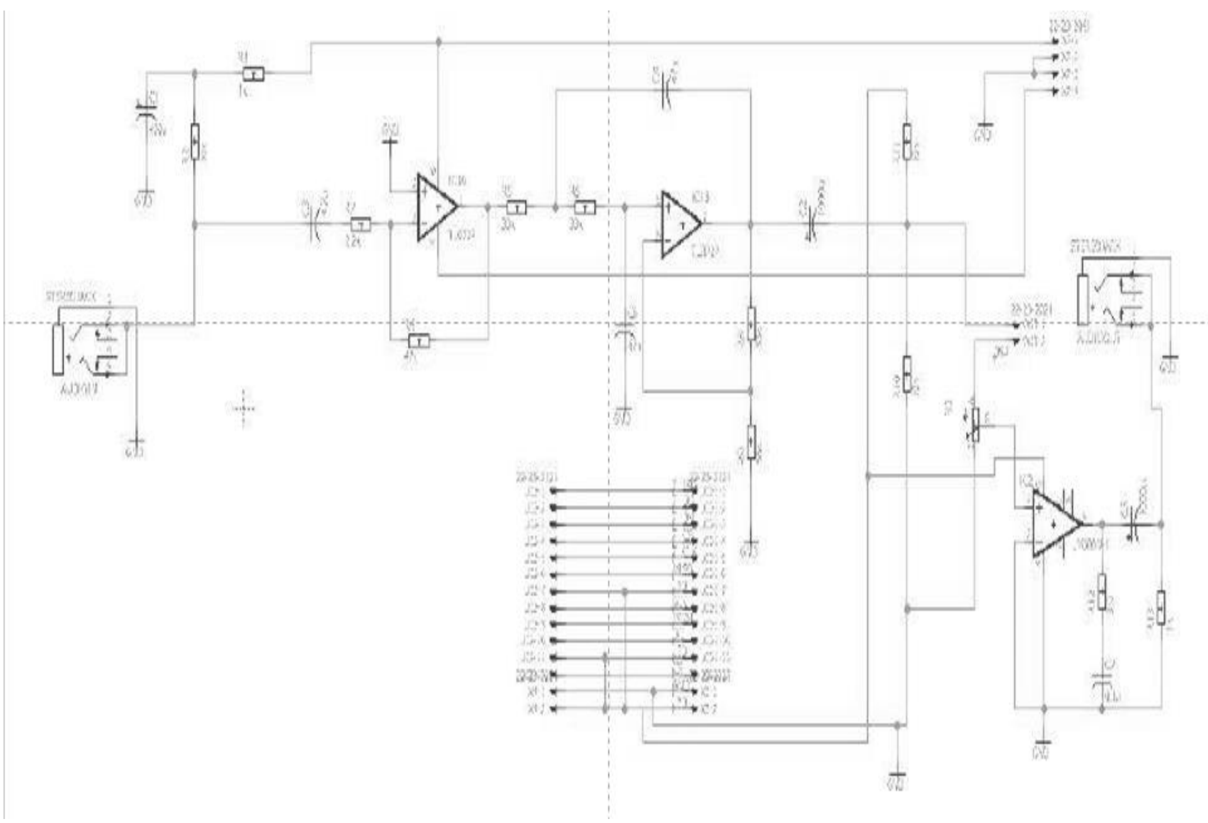

Figure 2.11. Proteus Schematics of Circuit

PART III

RESULTS
&
ANALYSIS

3.1. Results

The circuit is designed in Proteus and its PCB layout is designed in Dip trace software. The PCB layout front and back are shown in Figure 3.1 and the hardware implementation is shown in Figure 3.2.

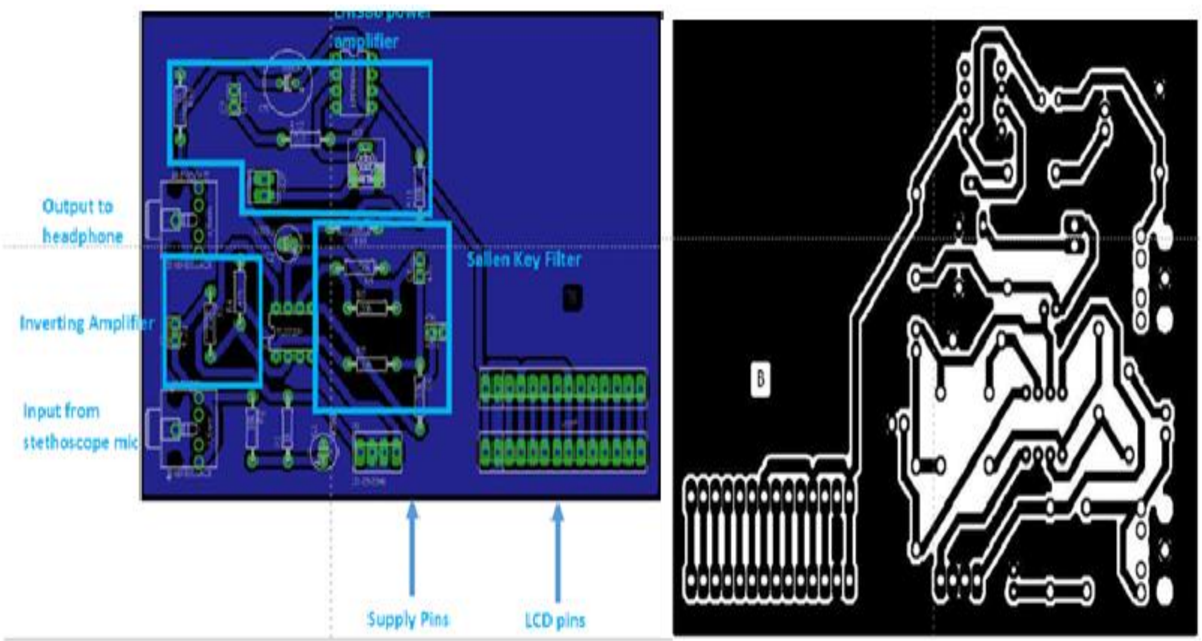

Figure 3.1. PCB Design in Dip trace software (Front and Back View)

3.1.1. Software Results

3.1.1.1. Proteus Simulations

As mentioned before that circuit was designed in Proteus 8.1 software. At early stages of design, the circuit was tested in Proteus and its simulations were performed. A wave file was given as an input to the circuit and each stage of the circuit i.e. pre-amplification, Sallen-Key filter and Power amplifier were tested. Figure 3.3 shows the actual wave sound that was given as an input to the circuit.

Figure 3.2. Hardware Implementation of Circuit on PCB Sheet

This signal was then amplified by means of first operational amplifier of TL072 IC.

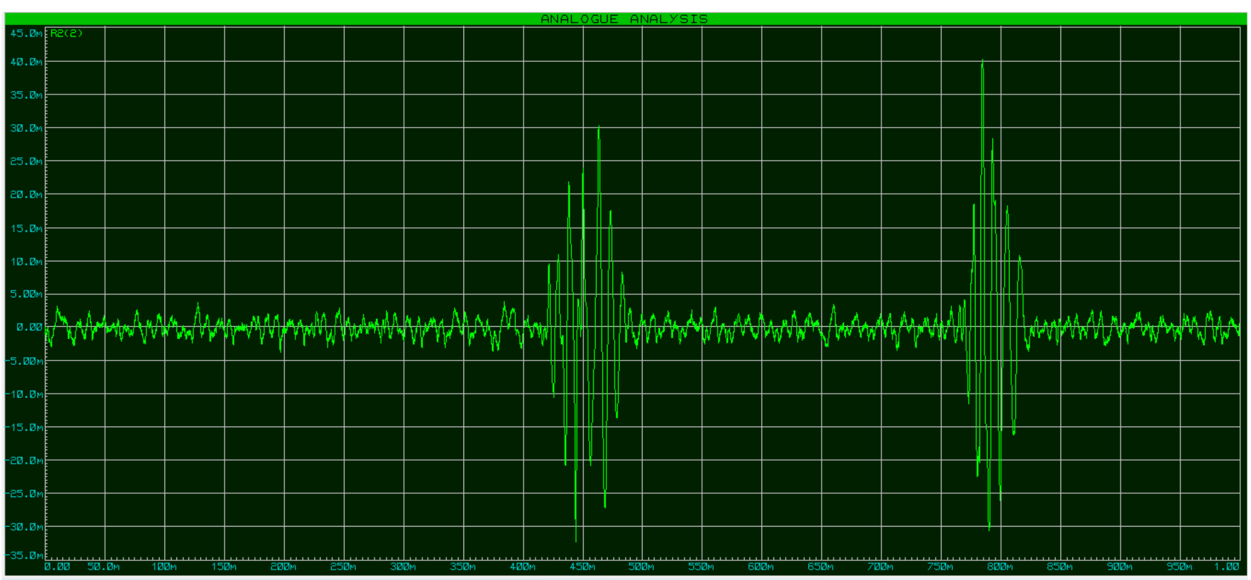

Figure 3.3. Normal Audio signal input of the system with 45 mV amplitude

Figure 3.4 shows the amplified output of the amplifier circuit.

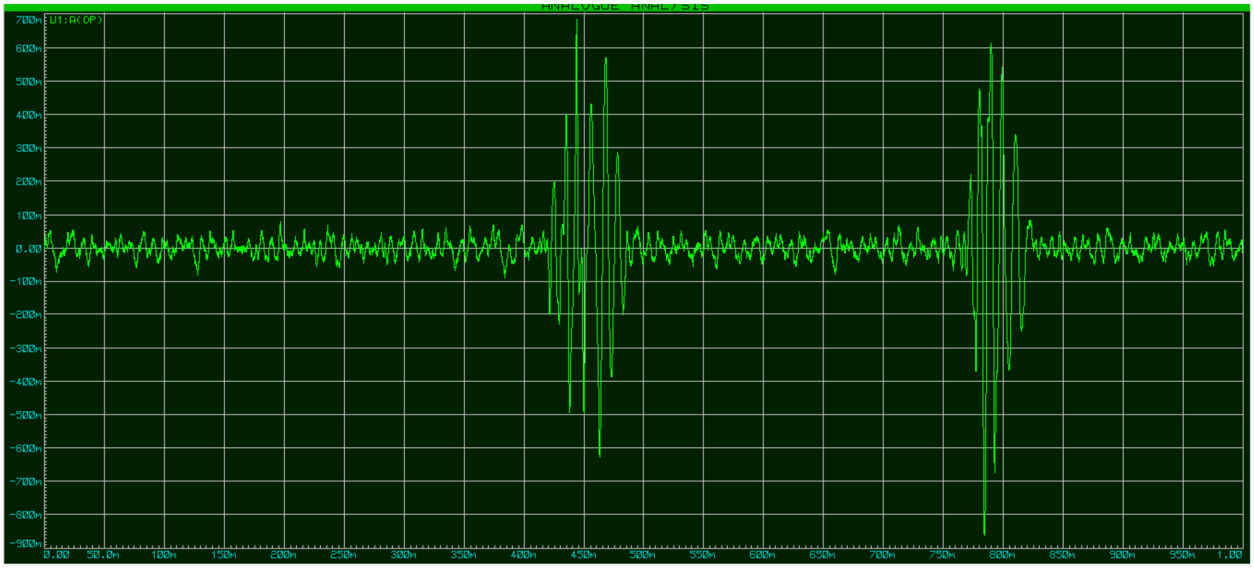

Figure 3.4. Amplified signal by TL072 with amplitude of 700 mV

The amplified signal is given to the second operational amplifier of TL072, which a 2nd order active Sallen-key antialiasing low pass filter. The simulated results of this stage is shown in Figure 3.5.

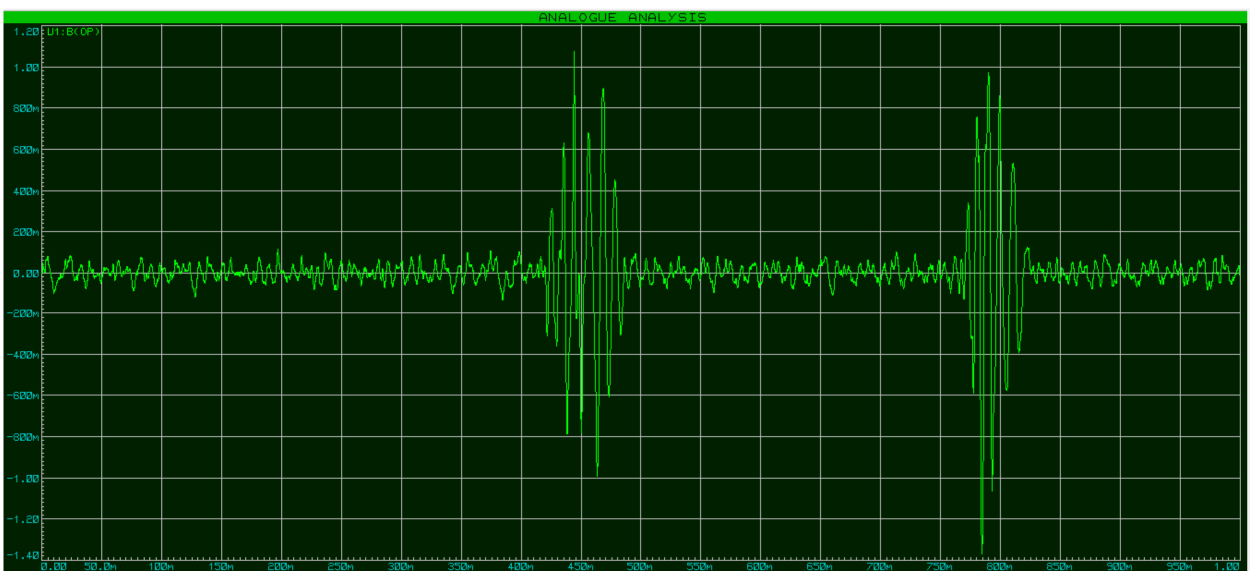

Figure 3.5. 2nd Order Sallen-Key Antialiasing Low Pass Filter with Cut-off Frequency 1026 Hz

3.1.1.2. 2nd Order Sallen-Key Low Pass Filter Characteristics

To find the characteristics of Sallen-Key filter an online WEBENCH® Filter Designer tool was used. Figure 3.6 shows the magnitude response in dB and phase response of the filter and Figure 3.7 Shows the group delay and step response. The filter characteristics are shown as under:

- **Transfer Function**

$$G(s) = 41569653.487839/(s\hat{}2 + 12894.906511928s + 41569653.487839)$$

- **Cutoff Frequency**

$$fc = 1026.1440560406$$

- **Quality Factor**

$$Q=0.7$$

- **Damping Ratio**

$$\zeta = 1$$

- **Step Response**

$$g(\infty) = 1.05$$

- **Impulse Response**

  The transient waveform is not detected

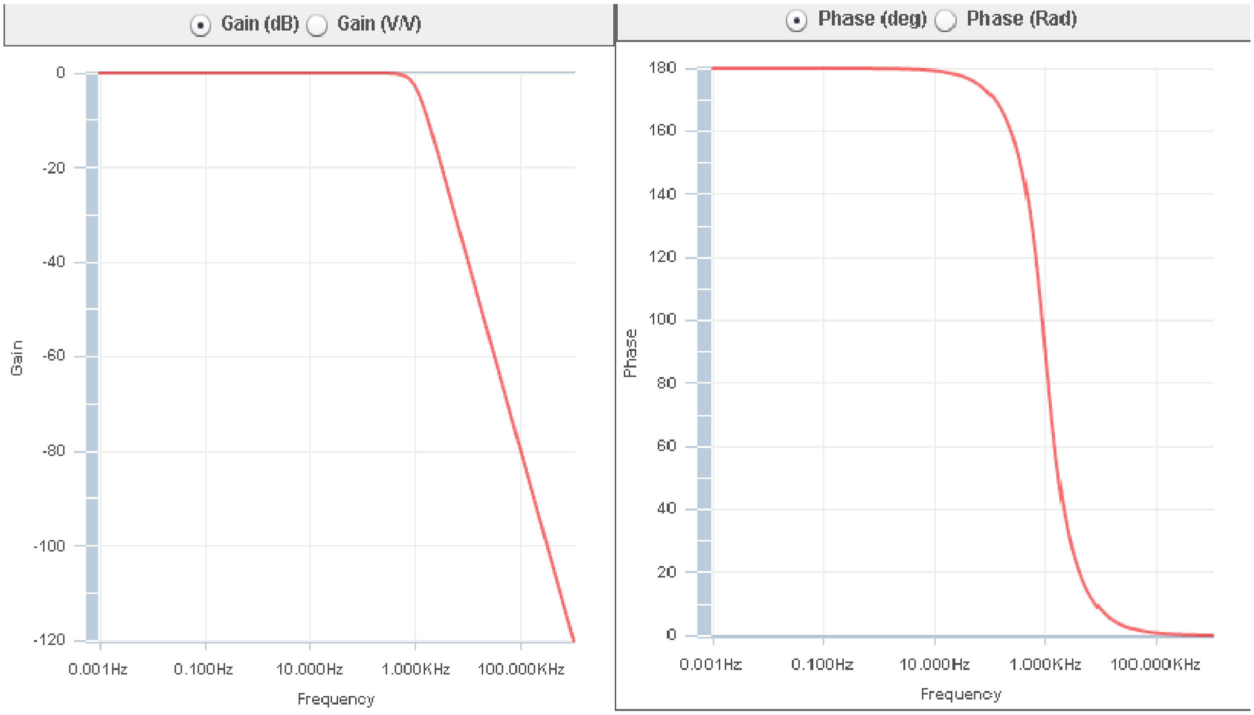

Figure 3.6. Magnitude and Phase Response of Sallen-Key filter using Workbench Tool

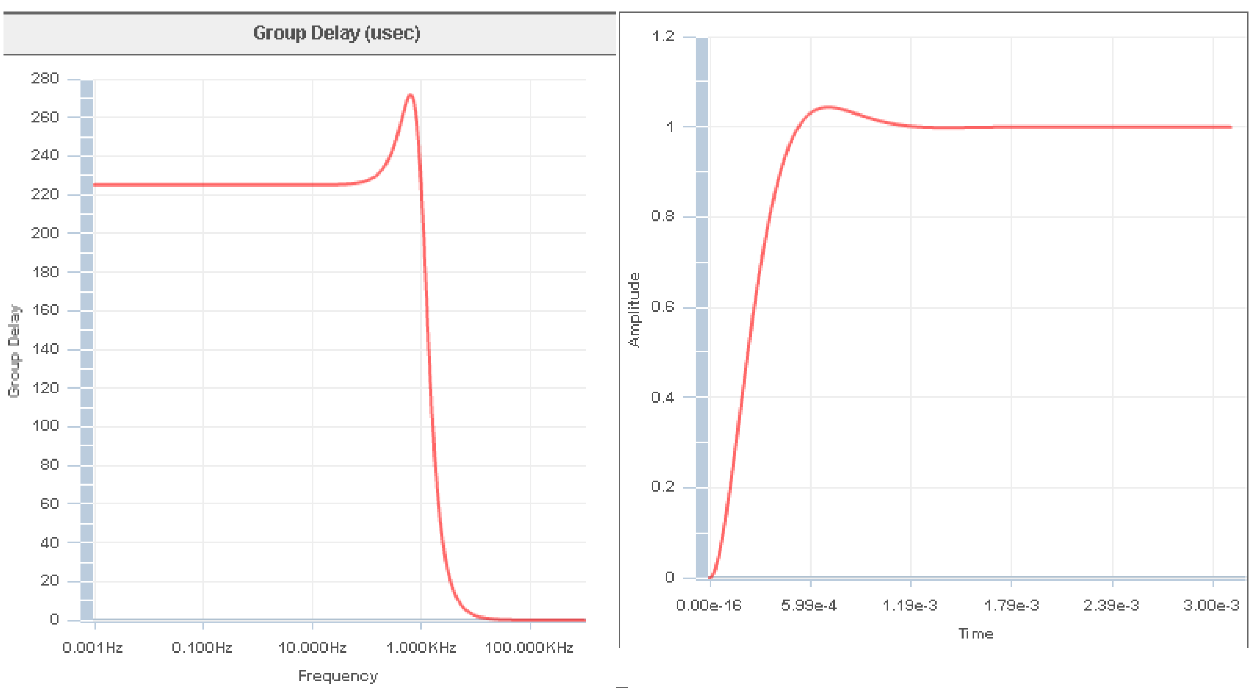

Figure 3.7. Group Delay and Step Response of Sallen-Key filter using Workbench Tool

3.1.1.3. Heart Sounds Analysis

To analyze the heart sounds detected by the proposed device were converted into .wav format using the thinks lab one phonocardiogram software. The heart sounds were recorded at a rate of 44,100 bps. The recorded audio file was read in MATLAB and its FFT and Signal to Noise Ratio (SNR) was calculated. The SNR of the recorded signal was compared with the heart sounds recorded by Littman 3200 Digital stethoscope. The FFT of the recorded heart sounds is shown in Figure 3.8.

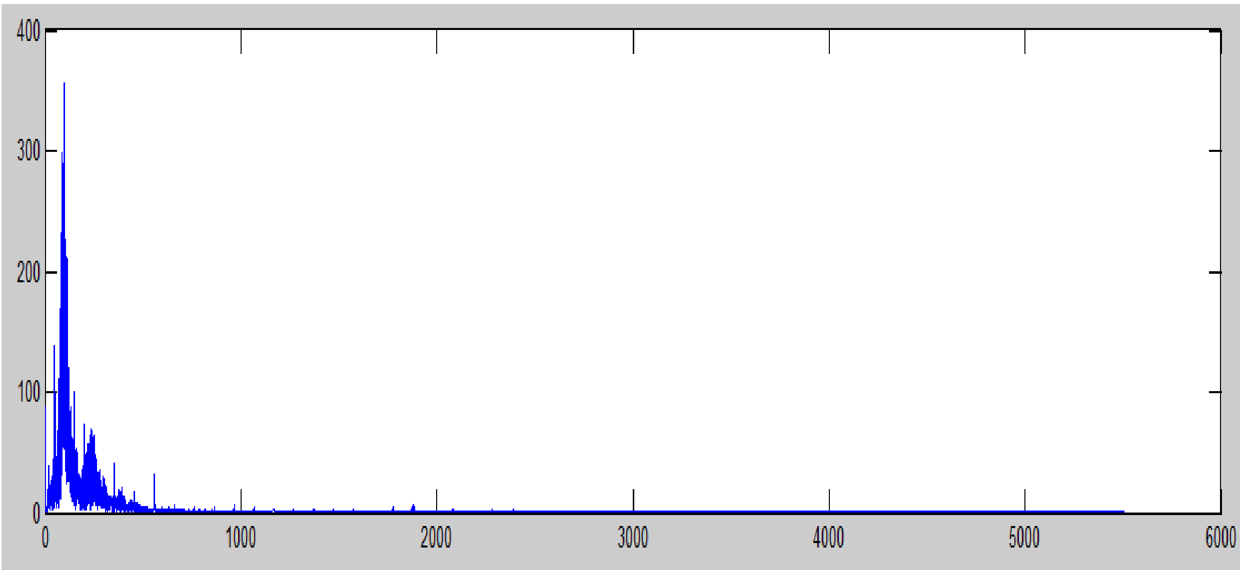

Figure 3.8. FFT of Recorded Heart Sounds in MATLAB

Firstly, the .wav file was extracted in MATLAB. The Sampling Rate was kept as 22050. Three frequency ranges selected in the signal; 0-35 Hz, 35-400 Hz, and 400- 1000 Hz. The correct heart sounds lie in the second range i.e. 35-400 Hz. The sounds that appeared at other frequency ranges were considered as noise. A built-in Trapezoidal function was used that calculates the area under each of the three sections of the FFT graph. The resulted integrals of the three sections were obtained. Then, these integrals were divided by their corresponding frequency ranges to get the average area (Area/ Hz) for each of the three portions. The relative noise was calculated by summing the first and third integrals, whereas the second integral defines a relative value for heart sounds. The flow chart of SNR is shown in Figure 3.9.

$$SNR = (Signal\ Power)/(Noise\ Power)$$

Also, The SNR in dB was calculated as

$$SNR_{dB} = -20log_{10}(SNR)$$

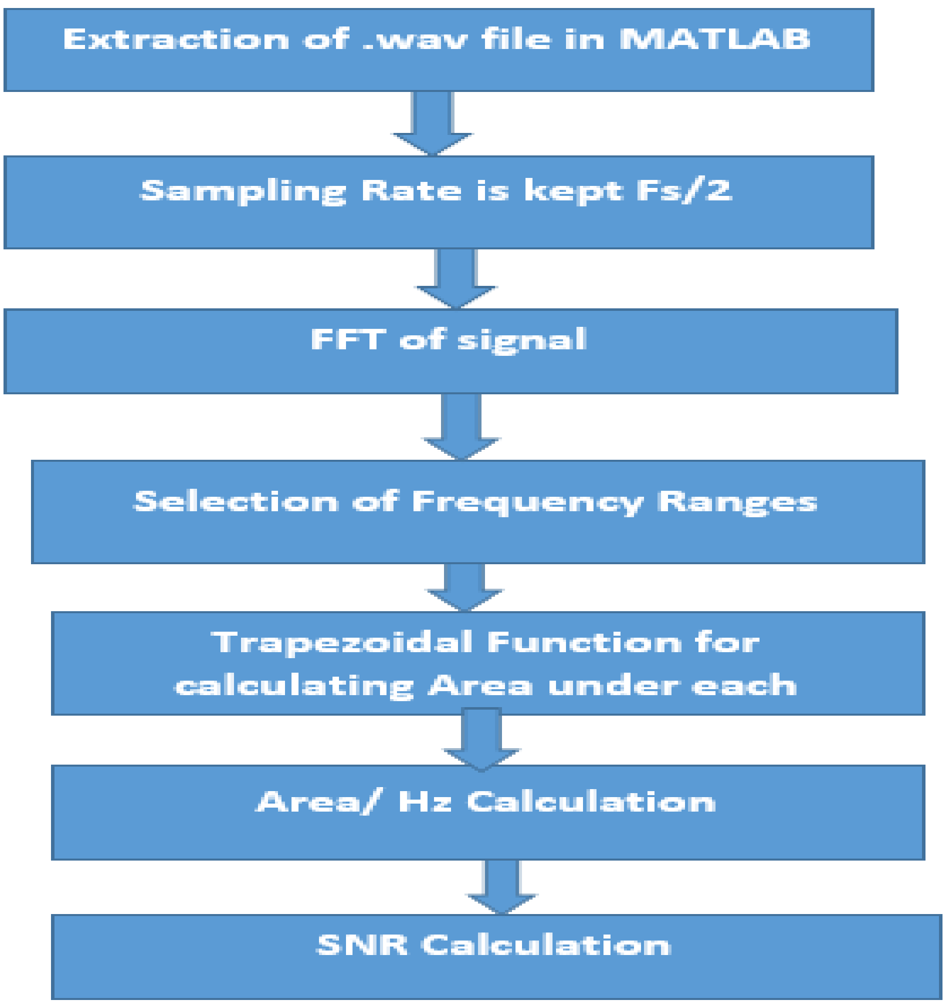

Figure 3.9. Flow Chart of Signal to Noise Ratio (SNR) Calculation in MATLAB

The complete results of the proposed systems are summarized in Table 3.1.

Table 3.1. Subjects BPM, SNR, and Comparison with Litmann 3200 Digital Stethoscope

No. of Subjects	Age (Years)	Beats Per Minutes (BPM)	Normal BPM	Average Linear SNR (Ls)	Average SNR in dB	Litmann 3200 Linear SNR (Lt)	Difference D= Lt-Ls
1	48	76	60-100	2.873∓ 0.083	-9.16	3.202	0.329
2	23	82	60-100	2.612∓ 0.262	-8.33	3.202	0.590
3	78	93	60-100	2.345∓ 0.157	-7.40	3.202	0.857
4	39	73	60-100	2.414∓ 0.367	-7.64	3.202	0.788
5	3	115	80-120	1.634∓ 0.242	-4.26	3.202	1.560

3.2. Hardware Results

As mentioned before that there are two outputs of the system; one digital output in the form of BPM and real time signal on TFT graphic LCD and the other the analog output heard on speaker or headphones. Heart sounds are clearly detected and realized over TFT graphic LCD. The hardware results are shown in Figure 3.10, where S1 and S2 sounds were clearly detected on breadboard as well as on actual hardware implemented on PCB sheet.

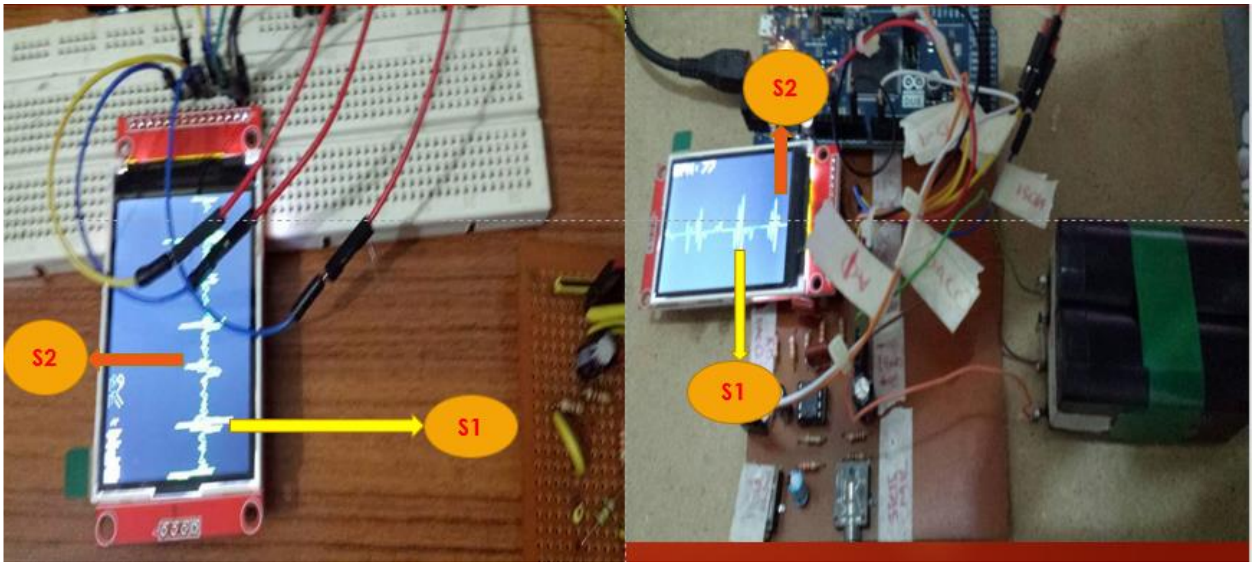

Figure 3.10. Heart Sounds S1 and S2 detection on both Breadboard and PCB

3.3. Cost Analysis

The cost analysis of the device is shown in Table 3.2.

Table 3.2. Cost Analysis of Digital Stethoscope

Serial Number	Component Name	Component Price
1	Acoustic Stethoscope	Rs. 3,000 /-
2	Studio Speech Microphone	Rs.1200 /-
3	TL072 IC	Rs. 270 /-

4	Arduino DUE	Rs. 3,500 /-
5	TFT Graphic LCD	Rs. 2,000 /-
6	LM386 Power Amplifier	Rs. 20 /-
7	Lipo Batteries	Rs. 700 /-
8	MIscelleneous	Rs. 200 /-
	Total	Rs. 10,890 /-

PART IV

Discussion

&

Conclusion

4. Discussion

4.1. Summary

The aim of the study was to develop a cost-effective and simple design for digital stethoscope system that should be able to detect the internal body sounds along with their real-time realization.

Heart diseases are thought to be the most leading cause of mortality and morbidity throughout the world. After getting the detailed history of cardiovascular system, one of the first step is the physical examination. Heart auscultation is making the core of heart physical examination. Despite important variability of inter-observer and habituation and training need, auscultation of heart gives significant patient's initial clues in his evaluation and acts a guide for further testing and diagnosis.

The mechanisms that are involved in the generation of heart sounds include: heart valves opening and closing, blood flow through the orifice of valve, blood flow into the chambers of ventricles, and heart surfaces rubbing. Similarly, the initial evaluation of heart sounds is to focus in the anatomic areas include apex of heart, the tricuspid area, the pulmonary area and the aortic area. Additionally, the auscultation of left axilla, heart base, interscapulum area, and carotid arteries should be done to examine for radiation of cardiac murmurs and sounds.

Auscultation is done by means of a stethoscope. Currently, two types of stethoscopes are available in the market and used by physicians. The first form is the traditional acoustic stethoscope that is mostly used by doctors to listen the internal body sounds and the other is the modern form of stethoscope called as electronic or digital stethoscope. Digital stethoscope is expansive than the ordinary acoustic stethoscope but is capable to overcome the limitations observed in the acoustic stethoscope.

4.2. Why Digital Stethoscope?

The major objective of a digital stethoscope is to retain the look and feel of an ordinary stethoscope but to improve the low sound quality observed in acoustic stethoscope. Additionally, better quality digital stethoscopes provide sophisticated abilities such as recording audio and playback. They also give the real-time graphs and results by interacting with computers or graphic LCDs. Such kind of advanced functionality enhances the diagnostic abilities of a physician. Retaining the current form of existing acoustic stethoscopes (look and feel) while increasing the performance in a digital way needs some smaller, low-power and cost-effective solutions.

4.3. Methodology

4.3.1. Why Lipo-Batteries?

The circuit was powered by two 3.7 V and 440 mAh lipo-batteries. These were selected for two reasons: first, making the circuit less power consuming; and second, these batteries are small sized and rechargeable.

4.3.2. Why Studio Speech Microphone

As discussed in the literature that most of the researchers used electret condenser microphone for detecting the acoustic signal from the body. There are two problems with this microphone: one is its low sensitivity (-44dB $\pm$ 3 dB) and other the frequency band covered by this microphone (45 Hz to 4 kHz). As heart sounds are very low frequency signals, therefore, a high sensitive microphone should be used for their proper detection. To achieve proper detection, a high sensitive studio speech microphone of sensitivity (-52dB± 5dB) was used that had the ability to detect signals between 20 Hz to 20 kHz. As this is not efficient but it was chosen after finding it the best choice available in the local market.

4.3.3. Why Amplification and Antialiasing Filtering with TL072 IC?

Amplification is the most necessary part of a digital stethoscope circuit because the detected heart sounds have very low amplitude of about 35mV to 50mV. To make this signal readable by ADC of microcontroller, this signal needs to be amplified. Most of the researchers discussed in the literature used more than one ICs for achieving amplification and antialiasing filtering. This makes the circuit bulky that leads to increase power consumption. The second important aspect should be kept in mind while using an IC is that it should be low-noise chip. TL072 is a low-power (2V to 15V with 10 mA), low-noise, and dual operational amplifier IC. The first operational amplifier was used for amplification and the antialiasing filtering was achieved by second operational amplifier. Hence, it gave the operation of two different tasks in a single chip.

4.3.4. Why Arduino DUE for Digitization and Signal Processing?

Digitization and signal processing is the core part of a digital stethoscope. This requires analog to digital conversion of analog acoustic heart sounds first and then signal processing is done. Arduino DUE was selected for this purpose for several reasons. The first important reason is that it has built-in 12-bits ADCs that other traditional microcontrollers (e.g. ATmega16, Atmega32, PIC16F877A etc.) lack. The ADCs of these microcontrollers are usually 8 to 10-bits that gives lower resolution. Arduino DUE gives the best resolution after having 12-bits ADCs. Secondly, Arduino DUE is the first one that contains ARM-based microcontroller. For achieving high performance, it has Atmel SAM3X8E ARM Cortex-M3 CPU. Thirdly, the digital to analog conversion is done by digital to analog converter (DAC). The literature shows that digital to analog conversion is done by separate 8 to 10-bits DACs that increases the size of circuit and ultimately power consumption. Arduino DUE contains two built-in 12-bits DACs for this purpose. Fourthly, most of the microcontrollers used in the literature are operated by 5 V that needs a separate 5V regulator. On the other hand, Arduino contains built-in 3.3 V and 5V regulators and it also provides the availability of separate ground pins. Finally, Arduino DUE has a clock frequency of 84 MHz that is much more than other traditional microcontrollers.

4.3.5. Why Serial TFT Graphic LCD?

A serial TFT graphic LCD was used for displaying BMP and real-time heart sounds. This was used because it uses 3.3V of Arduino, and hence, does not need additional power supply for its operation. Secondly, it was selected for making the whole system a standalone and diminishes the use of computer or laptop for realization of heart sounds.

4.4. Limitations and Implications

Although, the main objectives of thesis are achieved that include noise-free heart sounds auscultation and their realization in real-time. But, this project has various limitations that are as under:

- The high sensitive studio speech microphone has a bandwidth of 20 Hz to 20 kHz and the heart sounds frequency varies in patients. Most of the researchers have observed heart sounds in the frequency range 35 to 400 Hz but some also have observed heart sounds starting from 10 Hz and reaching 400 Hz. Therefore, making the system more efficient, a sensor should be used that has the capability of detecting frequencies less than 10 Hz.

- However, TL072 is a low-power and low-noise IC but it requires two separate batteries for its operation: one for giving +Vcc and the other for -Vcc. Therefore, another IC should be used that is low-power, low-noise and operates by single battery.
- As the system gives both audio and digital outputs on headphones and TFT graphic LCD. The heart sounds are recorded in computer by using Thinks Lab One Phonocardiogram software for converting them into wav file and SNR is calculated in MATLAB. The system needs to be improved by installing a separate read only memory (RAM) for heart sounds recording in order to make them feasible for further signal processing in future.
- More efficient algorithms and circuit designing are required to be developed for making the system noise-free and increasing the overall performance.
- The system consumes power but to overcome this problem, a wireless system should be designed that receive the heart sounds in an android application for their detection and analysis.

4.5. Conclusion

This thesis presented a cost-effective digital stethoscope system that is capable of detecting and analyzing noise-free heart sounds both on headphones and TFT graphic LCD. Being a cost-effective real-time system, this system provides better cardiac sounds auscultation instantly.

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