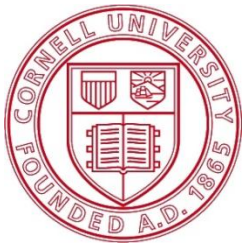
CHEST DISCOMFORT AID

A Design Project Report

Presented to the School of Electrical and Computer Engineering of Cornell University in

Partial Fulfillment of the Requirements for the Degree of

Master of Engineering, Electrical and Computer Engineering



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Degree Date: May, 2015

Acknowledgement

Our project would not have been possible without strong support from numerous sources. First and foremost, we would like to thank Professor Jonathan Black for his incredible insight, guidance, and feedback throughout the entire process. His mentorship was instrumental in all phases of the project, and his encouragement kept us going at key roadblocks. We would also like to give tremendous thanks to Ms. Pam Silverstein. Her guidance in the business aspects of the project was crucial to the formulation of our business plan and overall commercial strategy. Her encouragement helped us achieve major breakthroughs when we encountered significant pushback. We would like to thank Professor Bruce Land for his advice and assistance when we met technical challenges and Professor Robert Karpman for his input on medical regulations and physician perspective. We gained vital knowledge from these two experts, which were extremely important in the development phase. Finally, we would like to thank Long Island Technology Group for their industry support of the project.

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Abstract

Master of Engineering Program

School of Electrical and Computer Engineering

Cornell University

Design Project Report

Project Title: Chest Discomfort Aid
Author: Pooja Bangalore Ramachandra

Abstract: Globally, cardiovascular diseases account for approximately 17 million deaths a year, nearly one third of the total. Life threatening Cardiac events like Ventricular fibrillation, Angina, Arrhythmias as well as minor events like gastro intestinal disorder all cause similar symptoms like shortness of breath, dizziness ,palpitations etc. There is always an ambiguity among the patients when such symptoms are experienced - if they require immediate medical care or is it just a false alarm. To overcome this, this project aims at building a system of self assessment that is safe, usable and provides actionable advice for abnormal sensations in the chest. The product is aimed to be an over the counter, non-intrusive, inexpensive and easy to use diagnostic device that provides continues monitoring over a period of 24 hours. The resulting device consists of 2 main units- the sensor (patch) and the display unit. The false negatives should be less that 0.5% and should be regulatory complaint (FDA, IEC, UL). With this project, we aim to provide personalized health advice to the user by providing long-term monitoring that facilitates the capturing of sporadic events and produce actionable advice in real time.

Team: Literature Survey of the different causes of chest pain, Proposal of the design with different sensing modalities, Prior Art search, Competitor review, Proposal of different business models, Design and test of the components, Layout and the schematic of the design, Software algorithm for classification and Development of Android app.

My Part: Literature Survey of the different causes of chest pain, Literature Survey of the different causes of chest pain, Design and test of the components, Layout and the schematic of the design, Software algorithm for classification

Executive Summary

Heart disease is the leading cause of death in the US. Every year, about 600,000 people die of cardiac compilations and about 720,000 Americans have a heart attack. The coronary heart disease alone cost the US $108.9 billion each year. Cardiac complication can affect any age group and often occur without warning. We propose a device that provides continuous monitoring to maximize the potential of detecting critical events and gives user the power to self-assess any unusual sensations in the chest, informing users if they need to seek professional help or not. This device focuses on collecting the maximum amount of data through non-invasive methods to best guide the users with non-diagnostic advice their decision-making process.

The current standard of care for non-emergent medical situations is both costly and time-consuming, filled with different exams and personnel before finally reaching a decision. This tedious process sometimes deters individuals with mild/odd sensations to seek professional help, which may lead to serious complication later on. On the other hand, individuals anxious about their health are constantly visiting the ER from the slightest peculiar sensation, often clogging up the treatment of more serious patients and are an economic burden for hospitals. To address both categories of customers, this device provides continuous monitoring of four main non-invasive metrics, ECG, acoustic lung sounds, spirometer and infrared measurements, to better inform users when making health-related choices. A wearable component consists of continuous ECG and lung sound monitoring while the stationary component consists of a spirometer and infrared sensors. The system syncs with a smart phone and displays a list of parameters laying out risk indicators, which customers can use to make decisions. Any abnormalities noted by the device will be pushed to the user's smart phone notification center, warning the user of possible complications.

As a member of the seven member team, I worked with the whole team on the literature survey and the design proposal. At the initial stage, we considered every possible solution to the given problem and narrowed it down to include the most accurate and feasible measurements in our design. We decided to start with the wearable part of the project, as it is can be used as a standalone unit and as it was the minimum viable product to the market. Once the design was narrowed down and finalized, I was a part of subgroup who concentrated on testing the components, laying out the schematic and also working on the algorithm for classification of ECG and lung sounds.

We successfully tested the components, acquired the signals, designed the app and designed the layout of the PCB. The future work would be to fabricate the board and verify the algorithm. After this stage, all steps should be taken to receive full approval for the device by the FDA. Additionally testing will continue at every stage of development, both as part of the FDA approval process as well as to ensure quality and manufacturing readiness of the device.

1.0 Introduction

A wearable, continuous ECG as well as acoustic monitor that will capture all the signals and advices the user in terms of any abnormality has to be developed. This section will describe the problem, the objective, design specification and the prior art search.

1.1 Problem Definition

When people use health services, around 150 million each year suffer severe financial hardship because they have to pay out of their own pockets at the time they receive care, and 100 million are pushed into poverty as a result. The annual cost of asthma in the USA is estimated to be $18 billion. If one considers the lost productivity of family members and others caring for these individuals, the cost to society is far greater.Due to the Rural-Urban divide when it comes to access to health care system, the distance becomes a limiting factor that hinders/obviates rural folk, especially, from seeking timely medical interventions. And not being aware of the symptoms that manifest when one is having, say, an arrhythmia which could lead to potential cardiac complications, adds to the notion of I don't know what it means, so I don't care, which down the line could result in avoidable health complications, increased medical expenses and even loss of life.

Health care, in general, is therefore expensive, not easily accessible and user is unaware of his/her health status. Devices that currently exist such as a Holter Monitor and Spirometer, are expensive or prescription based, not easy or convenient to use, are not user-centric and don't apprise the user of the state of their heart and lung during use. Recently, we also have had a wave of fitness devices, such as Fitbit™, that monitor and apprise user of non-critical parameters such as steps taken, heart rate and calories burnt. But even these fail to address the gap that currently exists when it comes to monitoring critical health parameters. Therefore we aim to address these problem(s) by developing a system of self-assessment that is safe, usable and marketable for abnormal sensations in the chest.

1.2 Objective

The goal of this is project is to design and develop a wearable, continuous monitoring device that detects any abnormalities in the chest. The system should be able to acquire ECG data and lung sounds, process the data and analyze it. It should be used upon the detection of any odd sensation and should be worn up to 24 hours to catch any abnormalities in the measurements. The device must be able to withstand everyday physical activity and be as comfortable and unobtrusive as possible. The device must perform on par or better than the devices that exist today. It could be used as an alternative to clinically available monitors, but would give actionable advice as well as be more easy to use.

1.3 Design Specification

After extensive review of contemporary literature and technology on personalized medicine, e-medicine and wearable technology, we were able to establish a set of fundamental requirements for our device. In order to satisfy the needs of a wide range of demographics that vary by age, cultural background and gender, the device would have to adhere to a list of both very generic as well as very specific requirements. The generic requirements include qualities like accuracy, sensitivity, hardiness, environmental compatibility, repeatability and efficiency, while the specific requirements mostly focus on cultural acceptability across borders, user-friendliness, comfort of use and aesthetic qualities.

A conceptual design is essentially ideal while actual design considerations are beset by trade-offs. It is not possible to develop an ideal product while constraints are placed on time, cost, technology and skill. Hence, while designing a product it is important to evaluate what are the most essential characteristics the product or device needs to have, followed by other desirable characteristics that it ideally should have. This method of thinking helps designers achieve real goals while at the same time produce a high quality device. This analysis is also important because the addition or enhancement of one desired feature may lead to the loss of another. A good example for this is technology versus cost. In order to use the latest technology to prototype a product providing the greatest technical value, a high amount of investment is required. Here, cost becomes a constraint and hence a trade-off between technical enhancements versus cost must be established. This method of analysis enables the developers to place the desirable qualities in order of priority, which is a good guideline for design. Accordingly, while conceptualizing the design, we grouped the highest priority requirements of the device under "must-have" characteristics. The essential characteristics that under ideal conditions, will not be sacrificed, but can be designed flexibly, would fall under "should-have" characteristics. Finally, qualities that add to the value of the device but are not absolutely essential to the accurate functioning of the device come under "can-have" characteristics. Accordingly, a table of ideal device characteristics is presented here (Table 1):

Table 1

Must have	Should have	Could have
Regulatory Compliance	LED/LCD Display	Multi-Lingual
FDA Approval	3 Day Storage Capacity	Difficult To Reverse
IEC	Aesthetically Pleasing	Engineer
UL	Compact	Medical System Integration
Environmental Limits	Intuitive	User Specific Information
Temperature-20-60°C	Rechargeable	Cloud-Based Data
Humidity 0-100%	Comfortable	Continuous Monitoring
Waterproof to 10m	Adaptable: Non-User	Open Source Software
Drop-proof to 5m	Specific	Doctor Endorsement
Wearable Component	Wireless Sensor Network	Web App/Interface
ECG/Acoustic	Over-The-Counter	FDA Class II Compliant
Hypoallergenic	Works With Mobile Devices	
100g Total Mass		
Electrically Safe		

Can be worn up to 48hrs Wireless Non-wearable Component 500g Total Mass Electrically safe 2 Day Battery Life Life-threat warning within 30s DoD- Level encryption < 0.5% False Negative Rate < 2% False Positive Rate Noninvasive Visual/Audio Output <$100 Mfg. Cost Per Unit		

1.4 Prior Art Search

The recent surge in wearable devices has prompted companies and individuals to increase the number of patent fillings related to non-invasive health. However, these patents are usually targeted at a specific system in the body such as cardiac or respiratory, with little feedback to the user. Our device includes a wide range of parameters from different body systems to provide the most comprehensive analysis possible with non-invasive measurements. Currently, there is no patent that encompasses our product.

The following highlights relevant patents. These patents encompass parts of our product or have similar traits or measuring techniques. All patents were found on the USPTO website (http://www.uspto.gov/) with keywords: *chest, cardiac, portable, wearable, ECG, monitor*.

- *Patient-readable portable cardiac monitor (US 8774897)*
  - Abstract
    - Systems and devices to gather data from a subject's heart, analyze said data to determine whether the subject is experiencing cardiac arrhythmia, and display results of said determining. Use, and display of cardiac condition information, are preferably simple and unambiguous to untrained users
  - Assignee: Vernon N. Reaser, JR
  - Publish date: 7/8/2012

- *Wearable medical treatment device (US 8649861)*
  - Abstract
    - A wearable treatment device includes a cardiac sensing electrode, a treatment electrode, a user interface, and a sensor. The cardiac sensing electrode detects cardiac information, and the treatment electrode applies treatment to a subject. The user interface receives quality of life information from the subject, and the sensor detects subject activity and wellness information. A controller coupled with the cardiac sensing electrode, the treatment electrode, the user interface, and

the sensor receives the detected cardiac information, the quality of life information, and the detected subject activity and wellness information, and determines that treatment is to be applied to the body of the subject based upon the detected cardiac information. The controller can adjust the treatment based on at least one of the detected subject activity and wellness information and the quality of life information.

- Assignee: Zoll Medical Corporation
- Publish date: 2/11/2012

- *Health monitoring appliance (US 8747313 B2)*
  - Abstract
    - A heart monitoring system for a person includes one or more wireless nodes; and a wearable appliance in communication with the one or more wireless nodes, the appliance monitoring vital signs.
  - Assignee: Bao Tran
  - Publish date: 6/10/2014

- *Electronic skin patch for real time monitoring of cardiac activity and personal health management (US 8734339 B2)*
  - Abstract
    - A novel wearable electronic skin patch sensor device configured for the real time acquisition, processing and communicating of cardiac activity and other types of biological information within a wired or wireless network is disclosed. A system level scheme for networking the sensor device with client devices that include intelligent personal health management appliances, cellular telephones, PDAs, portable computers, personal computers, RFID Tags and servers is disclosed. The sensor device and the system enable distributed processing, archival and correlation of the biological information with biometrics, gastronomic information, user profiles and health factors that include height, weight, blood pressure and physical activity facilitating real time personal health management at any time and any place.
  - Assignee: Ip Holdings, Inc.
  - Publish date: 5/27/2014

- *Non-invasive cardiac monitor and methods of using continuously recorded cardiac data (US 8150502 B2)*
  - Abstract
    - Embodiments of the invention provide methods of obtaining continuous cardiac information from a mammal. First, attach a self-contained, wearable, portable continuous cardiac monitor to the mammal to create a chamber containing electrodes used to detect cardiac signals from the mammal. Next, continuously detect without analyzing the cardiac signals from the mammal for at least 24 hours. Next, store information related to substantially all detected cardiac signals in the cardiac monitor.
  - Assignee: Board of Trustees of Leland Stanford Junior University
  - Publish date: 4/3/2012

- *Systems and methods for processing and displaying patient electrocardiograph data (US 8798734 B2)*
  - Abstract
    - A method is disclosed for displaying patient ECG data. The method includes receiving ECG data including an ECG waveform; receiving analyzed ECG data including arrhythmic events; generating an indicia of the detected arrhythmic event; and displaying the indicia of the detected arrhythmic event in relation to the ECG waveform at a position associated with a time of the detected arrhythmic event. A system for displaying patient ECG data is also disclosed.
  - Assignee: Infobionic Inc.
  - Publish data: 8/5/2014

❖ Summary

Although wearable devices and personal health are gathering immense interest in the market, there is no existing product that addresses the central problem of modern healthcare. Consumers want to know more about their health and have actionable data to make health decisions. Medical devices do not provide user feedback and are difficult to gain access to without previous history. Fitness products give very little feedback with limited medical significance and only monitor a few metrics. Consumers need a hybrid device that provides actionable feedback and real health benefits. It should be safe, accessible, and easy-to-use. This gap in the market is what our device is trying to address. Our device seeks to provide users with understandable medical data that they can use to make informed decisions.

2.0 The Design Approach

Our design approach starts with a black box model. We first identified the problem and came up with a possible solution and based on our literature review and market needs, we came up with the baseline design which included all the measurements, all the outputs needed and all the functionalities required for the design. Hence the design process was evolutionary in nature and not the conventional approach. The proposed alternatives were combination of different modules of the baseline design and are not discreet designs by themselves. The different proposed alternative designs all have the same functionalities but different modules which were based on different factors like usability, costs etc.

2.1 Black Box Design

Figure 1: Black Box

The black box model of our design is as shown above. The inputs for the device will be the signals from the wearable component that is the ECG signal and the Acoustic Signal. These Signals are analyzed in the wearable part and then transmitted to the display and handheld unit. The other two inputs are Spirometer and Infrared Readings from the handheld device. The output of the device is the display of certain physiological parameters like the heart rate, the audio and visual alarm in case of emergencies and the transmission of data to cloud which can be accessed by the physician so that it can be monitored regularly.

Block Diagram

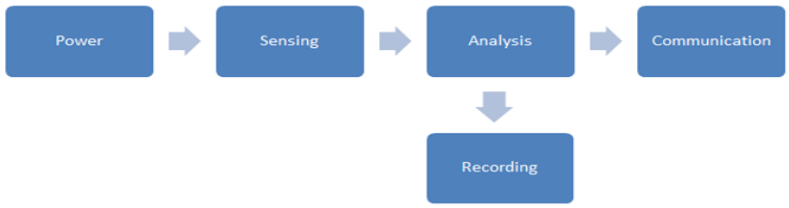

Figure 2: Block Diagram

The Block diagram of the system is as shown in Figure 2. The main components of the device are the power, sensing, analysis, communication and the recording units.

- **Power:** Since the design proposed has a continuous monitoring wearable unit, Power management will be crucial. The options considered are rechargeable batteries and disposable batteries that are compact like the Lithium Ion and Nickel Cadmium batteries.
- **Sensing unit:** The sensing units will have ECG electrodes and an electret microphone on the wearable unit and an LED and a compact spirometer on the handheld device.
- **Analysis:** The sensors reads the data, analyzes it and using this data, the physiological parameters are calculated by the algorithms running on an ARM-Cortex based

microcontroller. This data from the microcontroller is then transferred to the wrist display and the hand held device through a Bluetooth module.

- **Communication:** The communication between the sensor and the hand held device and the wearable unit will be through a Bluetooth module. Also, the data collected will be uploaded to a cloud storage which can be accessed by the physician.
- **Recording unit:** The microcontroller alone does not have enough capacity to hold all the important recorded information. For additional storage, there will be an SD card on the device which stores all the necessary information which can later be transmitted to a PC . In addition to this, the important information about the variations in the physiological parameters will be uploaded to cloud storage.

ECG and Acoustic data has to be monitored continuously to get accurate information and predict abnormalities like arrhythmias. It has to be on a wearable unit to get continuous readings. The blood Pressure measured by IR and the lung volume given by the spirometer does not give information about life threatening events and need not be monitored continuously[1]. Hence we propose three separate units for the device – The first one is the wearable unit that can be worn like a patch and consists of ECG and Acoustic sensors and the second is a sleek handheld device that has the ability to analyze, record, transmit and display the data and the third unit is a wearable wrist display unit that only displays the important parameters and gives out alarm in case of emergencies.

2.2 Design Alternatives

Based on the extensive literature Review and after considering many design alternatives, we shortlisted three different design concepts. They all have same functionalities but slightly differ in their specifications. They are - Concept one (The wrist display approach), Concept two (The two modules approach), Concept three (The smart phone approach). Fig 11, 12 and 13 are the mockups we designed and we visualize our end products to be similar. After designing these modules, we plan to fabricate them with a 3D printer or get it fabricated by an external manufacturer.

Table 2: Design Concepts

	Concept 1	Concept 2	Concept 3
POWER	[Wearable & Base Station] Rechargeable Battery	[Wearable & Base Station] Disposable Battery	[Wearable & Smartphone app] Rechargeable Battery
MEASUREMENT	[Wearable] ECG + Acoustic [Base Station] IR + Spirometry	[Wearable] ECG+ Acoustic [Base Station] IR + Spirometry	[Wearable] ECG + Acoustic
ANALYSIS	On-Board processing	On-Board & Cloud Based Processing	Processing in Smartphone & Cloud Based Processing
COMMUNICATION	Wrist Display + Audio	Display on Handheld Device Data transmission to physician	Smartphone Display + Data transmission to physician
RECORDING	Flash memory + SD card +Cloud Storage	Flash memory + SD card (on the handheld device) + Cloud storage	Flash memory + SD card +Cloud Storage

2.2.1 Concept 1: The Wrist Display Approach

Figure 3: Concept 1- The Wrist Display Approach

This proposed model will have 3 modules – the wearable sensor patch, the Wrist display and the Hand held device. This approach has an additional display module to make it more user-friendly and easy to move around. Considering various factors like it would be hard to move around with the hand- held device and it wouldn't be feasible to have a display on the wearable patch we came up with an idea of a wrist band display. This will be sleek band which can be worn on the hand and will display the essential parameters required and indicate the patients in case of emergencies. The sensor reads the data and sends it to the microcontroller for analysis. This data from the microcontroller is then transferred to the wrist display and the hand held device through a Bluetooth module. The display unit will display only the essential parameters like the heart rate and respiration rate; it also gives an alarm in case of emergency.

2.2.2 Concept 2: The two module approach

In this approach, the display is mounted on the handheld device. Advantage of this model is that there is no additional module like the wrist display unit as proposed earlier.

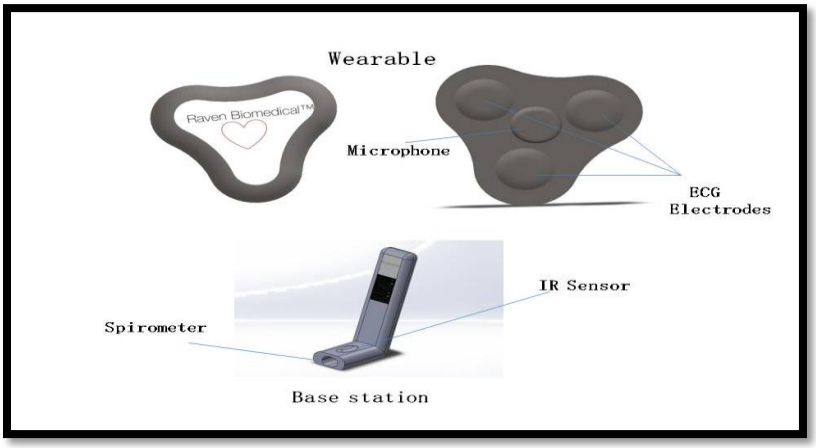

Figure 4: Concept 2-The Two module approach

The wearable unit will transfer the data to the handheld device. The hand held device will house the spirometer and the infrared sensors. The hand held device will also analyze the data and run the classification algorithms on it. The result will be displayed by the LCD unit on mounted on the handheld device. There is also an option of transferring the data to a PC through an USB port on this unit. In case of detection of abnormalities, the data is transferred directly to the cloud, so that a physician can access it quickly.

Since the display is on the hand-held device, the patient has to carry around the hand-held device to view and monitor the parameters. But it also gives information about the spirometer and the IR readings on the go, which can be useful for many patients. So there is a significant tradeoff between the first proposed model and this model.

2.2.3 Concept 3: The Smartphone approach

Figure 5: Concept 3 The Smartphone approach

This proposed model is a portable ECG and Acoustic monitor based on a Smartphone App. The wearable unit will collect the ECG and Acoustic readings and transmit it to the smart phone through a Bluetooth module for analysis and storage. The App designed for this purpose will run the filtering and detection algorithms to detect the variations in the parameters and detect abnormalities. In case of detection of any abnormalities, the app will transfer the data to the physician and also alert the patient[2].This model will have only one module that is the wearable unit. This model will be cost effective since it includes only the wearable unit. Since almost everyone is familiar with the use of the Smartphone, this model will be handy and very easy to use.

3.0 Design of the Wearable unit

The Wearable Unit

The wearable unit consists of a chest patch that acquires the ECG and the lung sounds and processes this data, classifies them and transmits it to a smart phone app over Bluetooth. The processing includes amplification of the low level signals, filtering out all the unwanted noise signals and passing it though an interpretative algorithm. The output of this stage is passed to a

Bluetooth low energy module (BLE) which, then wirelessly transmits the data to the smart phone app. This app displays the information to the user.

3.1 Hardware Design

The complete schematic of the wearable device is as shown below:

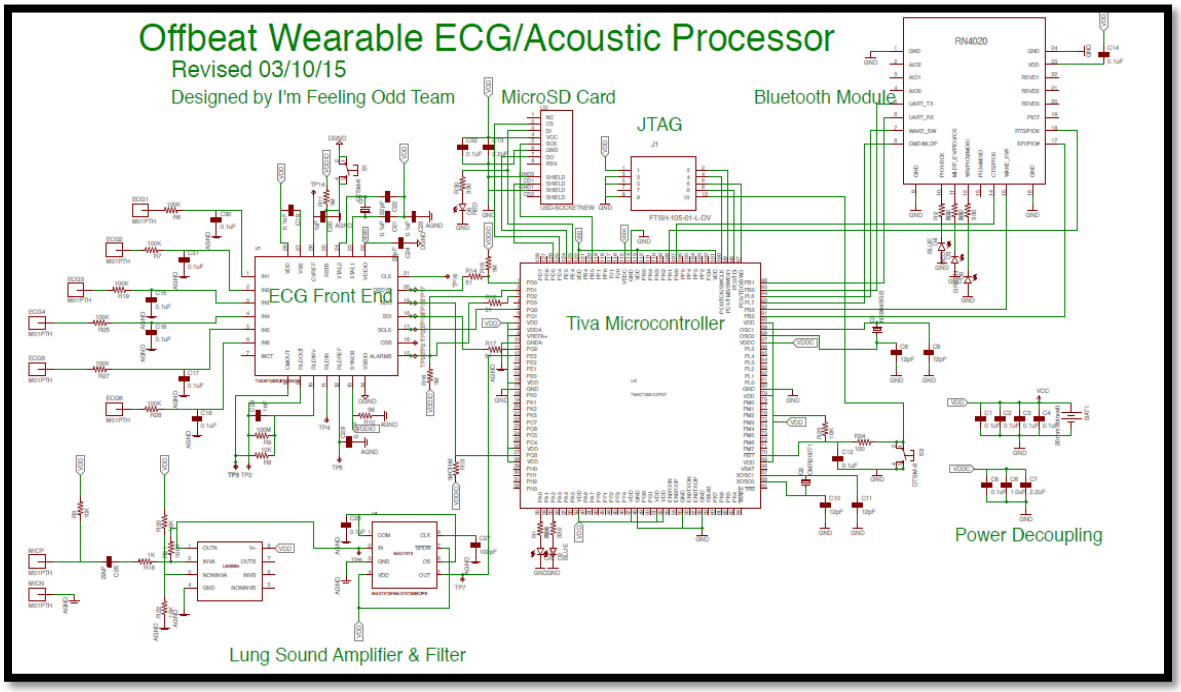

Figure 6: Schematic of the wearable unit

The wearable unit consists of mainly three parts, first is the analog circuitry for acquisition and filtering, second the digital microcontroller circuitry and third the Bluetooth module for transmission.

Analog Front End

The input is acquired with the three electrodes applied to the user's chest. The position of this electrodes should at 2 finger spacing from the center of the chest. Electrodes for recording biopotentials are composed of a metal (usually silver for ECG measurement), and a salt of the metal (usually silver chloride). This disposable foam-pad consists of an Ag-AgCl metal contact button at the top of a hollow column that is filled with a conductive gel. Most bioelectric measurements an interference level of 1 to 10μV peak-to-peak (pp) or less than 1% of the pp value of an ECG, is acceptable.

The second input is the lung sounds; this is acquired with the electret microphone encased in a plastic bell. This microphone operates with a voltage supply ranging from 1.3 to 10 V with a low

amplifier current drain of 50 µA, provides a flat frequency response between 50 and 3000 Hz, and offers advantages in terms of high durability compared to contact sensors[3].

Amplification and Filtering

The ECG signal acquired is filtered, amplified and converted to digital format in the Texas Instruments© ADS 1293[4].The amplification of the lung sounds is carried out using the traditional audio amplifier LM358N[5]. A fixed gain of 100x is applied to amplify the signals from mV to V for compatibility to the microcontroller. This signal will be further filtered to remove the electrode noise and the power line noise. A bandpass filter with cut off of 100Hz and 1500Hz was designed using the six order maxim filter.

Signal Processing

The amplified and filtered signal from the microphone and the digital signals from the ADS1293 are fed into the microcontroller through the ADC (analog to digital converter) and SPI (Serial Port Interface) respectively. The basic function of the microcontroller is to further amplify, digitize and filter the acquired signals. The TIVA© Driver library is used to program the microcontroller.

Bluetooth module

The transmission of the processed signal is done with the help of a Bluetooth low energy module. RN220© is used as the Bluetooth module[6]; this is chosen as the power consumption is minimum compared to other the Bluetooth devices[7].

Power supply unit

A Coin Cell - CR2032 lithium ion battery[8] is used to power the system. It has a capacity of 250 mAH at 3V and is 20mm by 3.2cm. The battery is placed at the bottom of the board and can be secured with medical tape during testing.

SD card and JTAG

A SD (Secure Digital) card is used to store the data for a period of time. SD card is used as opposed to a flash memory as it is flexible for expansion in the future.

A JTAG (Joint Test Action Group) port is added to the device for debugging purposes and is also used for programming the microcontroller as well the ADS 1293.

Output

The microcontroller transfers the data to the Bluetooth module using UART (Universal Asynchronous Receiver/Transmitter). The signal from the Bluetooth module is then transmitted to the Android app that alerts the user in case of any abnormalities.

3.2 Software Design:

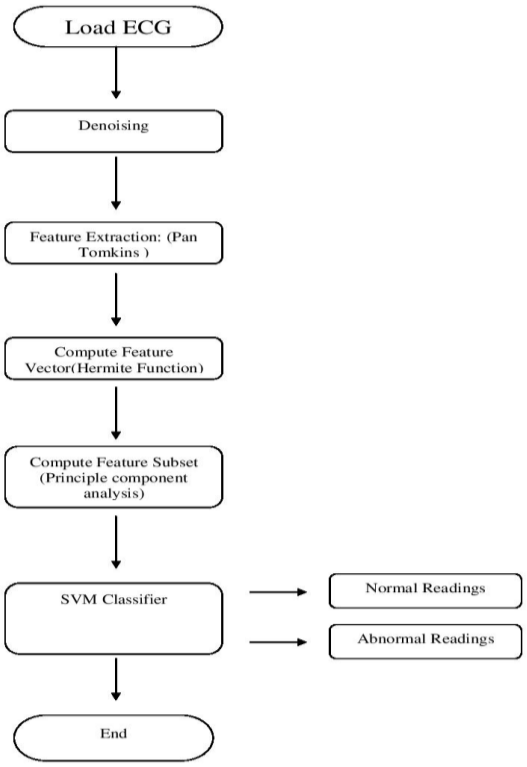

Figure 7: Software Implementation

The microcontroller acquires the input signals from its peripherals and in the next stage it performs additional digital filtering, feature extraction and then feeds it to the classification algorithm. When there is no data at the input, the microcontroller is put to 'Sleep' mode to reduce power consumption. A watchdog timer will look out for the inputs at its peripherals and 'wake' the microcontroller up when necessary.

Algorithm for classification:
The classification algorithm consists of 3 stages.
1. Preprocessing
2. Feature Extraction
3. Feature Reduction
4. SVM Classifier

We use the MIT Arrythmia database[10] to train the data we obtain. This source has over 4000 long term Holter recordings. Each of the records is slightly over 30 minutes long. This database is considered as the gold standard and has been proved very accurate in many research projects over the years[9].

Preprocessing

At the preprocessing stage, we filter out the additional noise with the appropriate cutoff values of the digital filters. The main categories of noise are: low-frequency baseline wander caused by respiration and body movements, high-frequency random noises caused by mains interference (50 Hz, 60 Hz) and muscular activity, and random shifts of the signal amplitude caused by poor electrode contact and body movements.

Feature Extraction

The important features of the signal that are used for classification are extracted from the raw signal. The Pan Tomkins algorithm[10] was used for the selection of QRS complex from the raw ECG signal. This algorithm gives us a pulse train of extracted features and this can be used for the classification purposes as the different conditions shows different characteristic features. The algorithm's source code is available as open source released under the clause-3 BSD license.

Feature Reduction

A large amount of data that is obtained from the feature extraction stage. This can be reduced by application of principle component analysis which reduces the number of features that is repeated over a period of time and gives out only the significant morphological variations of the signal.

SVM classification

Support vector machines are supervised learning models with associated learning algorithms that analyze data and recognize patterns, used for classification and regression analysis. Given a set of training examples, each marked as belonging to different categories, an SVM training algorithm builds a model that assigns new examples into one category or other, making it a non-probabilistic new examples into one category or the other, making it a non-probabilistic binary linear classifier[11].We use multiclass SVM which aims to assign various labels to instances by using support vector machines. This source code is available as open source released under the clause-3 BSD license.

At the end of this stage the output obtained is the classified data suggesting the category a particular signal. This is then transmitted to the app by the Bluetooth module. The user interface for this model is the android app. This app lets the user input the basic parameters required for establishing the baseline like age, weight, height, gender etc and provides an actionable advice to the user by indicating that something is wrong when an abnormality is detected.

3. 3 Design Rationale

The design of the device followed an evolutionary approach rather than by elimination. The first stage was identification of all measurements that detected discomfort in the chest. Next step was to verify how closely each of these measurements meets the design specification.

The most common non invasive measurements were

1. ECG
2. Lung sound
3. GI
3. Ultra sound
4. Infrared
5. Spirometry

The factors that affect our design are mostly – portability, feasibility of the measurement, cost, simplicity and the impact of measurements (the number of conditions each of these measurements can capture). Each of these factors was associated with a weight depending upon its influence on the design. Then each of the measurements were rated based on how closely it related to our desired design goal (A rating of 10 indicates that it matches our design goal completely). For example, cost of measuring ECG is around 40$, whereas cost of an Ultrasound unit will be around 150-300$. Hence ECG receives a rating of 9 on Cost and Ultrasound receives a 3 as we want the whole devices to cost under 200$. Similarly, this table was constructed for all the measurements and design requirements.

Table 3

Factors	Weight	Measurements (Rating form 1-10)					
		ECG	Lung sound	GI	Ultrasound	Infrared	Spirometry
Feasibility	0.20	8	8	1	3	10	6
Portable	0.20	9	9	2	3	10	8
Simplicity/Component Requirements	0.10	8	9	1	3	9	7
Cost	0.25	9	9	5	3	9	7
Impact of Measurement	0.25	9	9	5	5	7	8
Weighted Sum		9.1	8.5	3.25	3.8	8.9	7.05

Based on the numbers from the table, Ultrasound was eliminated as it was not feasible, not portable and it was difficult to implement and did not fit into the specification of the device. GI had mostly invasive techniques for measurements and did not meet the design specifications that

well, Hence it was also eliminated. Thus the 4 modalities – ECG, Lung sounds (Acoustic), Infrared and spirometry was chosen as it gave out the maximum information that was required to detect abnormalities in the chest, fitted into the specification of the device and also improved the accuracy of the device.

Initial Module

The Smartphone model of the 3 proposed models was chosen on the basis of its feasibility. It also gives out the most important information needed for the detection of abnormalities (ECG and Lung sounds). Also, it is the minimum viable product to the market. Based on the usability and user feedback, the complete, improved module can be developed in the later stage.

Sensor Selection

ECG sensors- Ag/Agcl are well known for its safety, accuracy and reliability[12].Hence this was most suitable for the device. For the acquisition of lung sounds, based on our literature survey, three most common types of sensors were used – Condenser microphone, Dynamic microphone and Piezo microphone[13]. The best sensor that met our end design goal had to be chosen.

Table 4

Factor	Weight	Microphone type (Ratings from 1-10)		
		Condenser Mic	Piezo Mic	Dynamic Mic
Size	0.25	6	2	5
Cost	0.40	9	3	4
Sensitivity/Fidelity	0.10	7	4	6
Simplicity/ Required components	0.45	7	8	8
Total	1.0	8.95	4.40	5.50

Based on the same rationale as the table5.0, we construct a table for the different types of microphones available in market and the desired qualities for the design. The most important parameter in this consideration is the sensitivity/fidelity because in order to have a successful classification, the sound that the mic produces must be as accurate as possible. Sensitivity of the condenser microphone was rated highest of the three because of its excellent transient response, coverage of a wide frequency band, and high output volume .The condenser microphone is commonly used with quieter sounds, because the external power allows for the signal to be amplified upon recognition. Size and simplicity were both rated second. Should the microphone be too large, portability of the device would be compromised, which would affect design of the device. The condenser microphone that is currently being implemented is 10.0mm in diameter,

by 5.0mm in depth, pretty small to maintain portability of the device. The Piezo Mic is the most expensive among the three and also it is least sensitive than the other two. Hence the numbers show that the condenser microphone is the best option for the device.

Algorithm

Compared to the other most commonly used algorithms for classification, like the MLP(Multilayer Perceptron) , Hybrid, TSK and SVM [14] . SVM (Support Vector Machine) was proven to be most accurate (97.3%) had least number of misclassification in many research papers[17]. In addition to this, the simplicity and the intuitiveness of the algorithm was the main reason for selection in the device[15,16].

Output

The way the information of the device is conveyed to the user plays a very important part in deciding which class the device will belong to according to the FDA classification. In order to avoid regulatory issues, the app was developed in such a way that it advices the user the degree of urgency in contacting the physician and the percentage of potential risk with respect to the chest. Based on this advice, the user can make a decision - if there is an immediate need to visit the physician. The physician will have access to all the data that is recorded, based on which he can take appropriate action. The app will have the same output universally until there is a scope of improvement which can be analyzed based on both user and physician feedback.

4.0 Evaluation

As the device complete prototype is being finalized, the testing of the hardware and the individual circuits is discussed in this section. The complete setup for the acquisition of the ECG signal and the Lung sound is as shown in the figure 8.

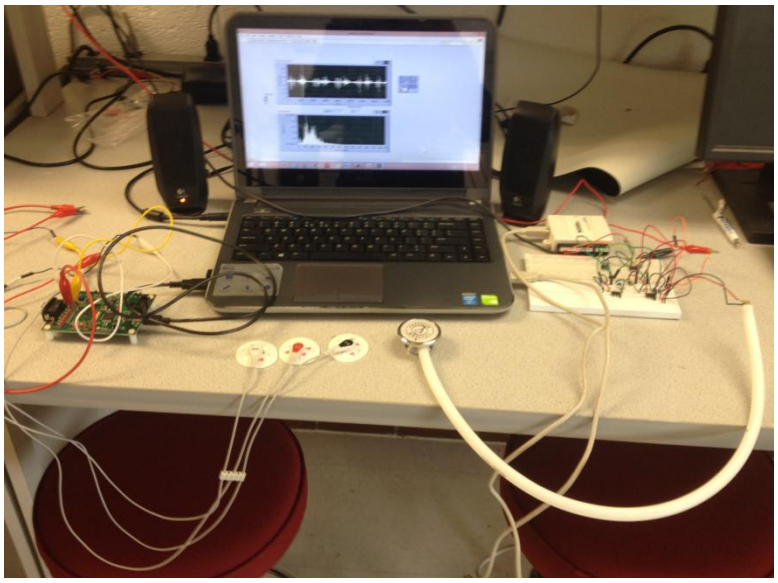

Figure 8. The Complete Setup

ECG Acquisition

We make use of the chip ADS1293[18] form Texas Instruments© which is an analog-front-end (AFE) IC. The TI AD1293 can support one to 5 leads with a single AFE. We acquire 3 lead signals in this design [appendix]. This is ideal chip for our device because of its size (5mm*5mm), low power consumption and cost. The functional block diagram of the chip as shown in the figure 9.

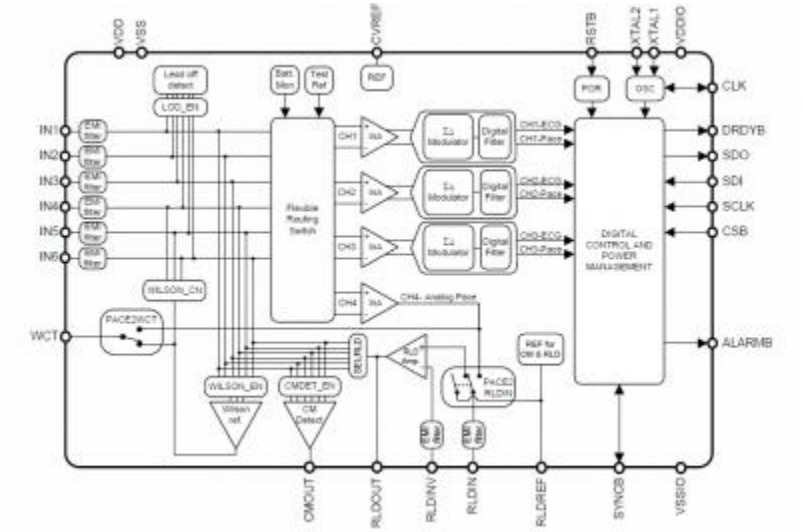

Figure 9. Block Diagram of ADS1293

This chip features three high – resolution channel with data rate upto 25.6 ksps capable of operating up to 25.6 ksps. In this configuration, the right-arm (RA), left-arm (LA), left-leg (LL) and right-leg (RL) electrodes are connected to the IN1, IN2, IN3 and IN4 pins. It incorporates EMI filters to reduce power line interference and an instrumentation amplifier and an ADC to amplify and convert the acquired ECG signal to Digital values. This data can be transmitted over Serial Port Interface. The acquired ECG signal was collected for about 10 seconds and around 15 heartbeats were observed with the signal to noise ratio of around 110 dB .The acquired ECG signals from the ADS1293 are as shown in figure 10.

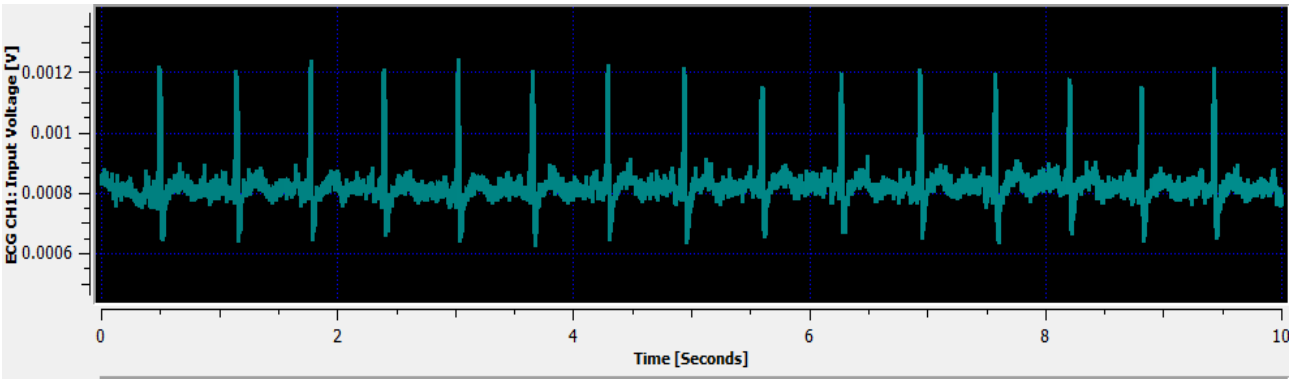

Figure 10. Acquired ECG signal (Texas Instruments Software)

Algorithm

As described earlier, we use Pan Tompkins Algorithm to separate the QRS complexes from the ECG signal. Pan and Tompkins[19] proposed a real – time QRS detection algorithm based on analysis of the slope, amplitude and width of QRS complexes. The MATLAB source code of the algorithm was used which is available for use under BSD License. The algorithm includes a series of filters and methods that perform lowpass, high-pass, derivative, squaring, integration, adaptive thresholding and search procedures. This algorithm has been tested with MIT Database and has been to proven to have an accuracy of 99.9%.[20]

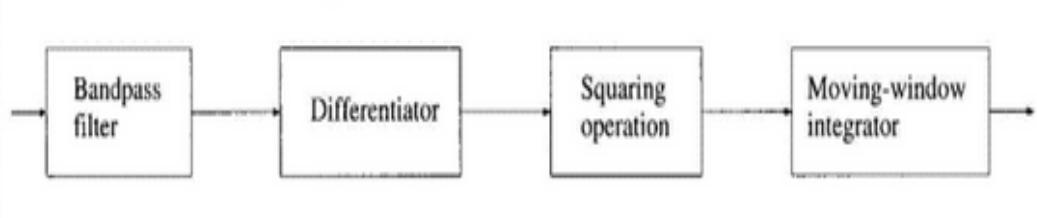

Fig 11 Block Diagram of Pan Tomkins Algorithm

Band pass filter – Consists of cascade of a Low pass filter and a High pass filter to isolate the predominant QRS energy centered at 10 Hz. Energy of the QRS complex is between 5Hz-15 Hz. Low pass filter eliminates the noise such as EMG and 50 Hz Power line noise. The cut off frequency will be 11 Hz. The high pass filter eliminates the motion artifacts, P wave and T wave. The Cut off frequency will be around 5 Hz.

Differentiator – This is to obtain information on slope and overcome the baseline drift problem. Accentuates QRS complexes relative to P and T wave.

Squaring Operation– Emphasizes the higher frequency component and attenuates the lower frequency component.

Moving Average filter – Acts as a smoother and performs a moving window integrator over 150ms

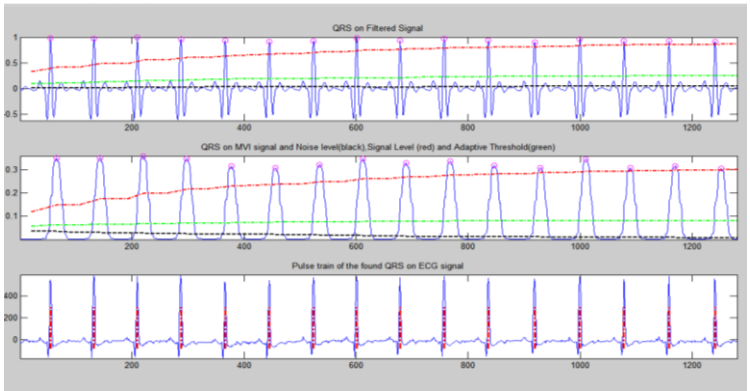

Figure 12 Output of Pan Tomkins Algorithm (MATLAB)

The output of the Pan Tomkins algorithm will give us a train of QRS complexes. The Hermite coefficients were then calculated to obtain the features for the training data of the SVM. Different labels will be then assigned to each of the different 17 conditions and the input will be trained against this data and output will correspond to the label of the input signals.

Lung sound Acquisition

The lung sounds were acquired with the help of a electrets microphone. This microphone was enclosed in a stethoscope tubing to reduce the effects of the atmospheric noise and amplify the signal. The input was taken from the trachea for testing purposes. This signal was then preamplified using LM358p and then the passed through the a bandpass filter with cutoffs 100Hz and 1000 Hz. This will filter out all the low frequency signals like the electrode noise , heart sounds and also the atmospheric high frequency signals. This signal is then passed through NI DAQ for further analysis in LabVIEW. The real time acquisition of the lung sounds is as shown in the figure 13.

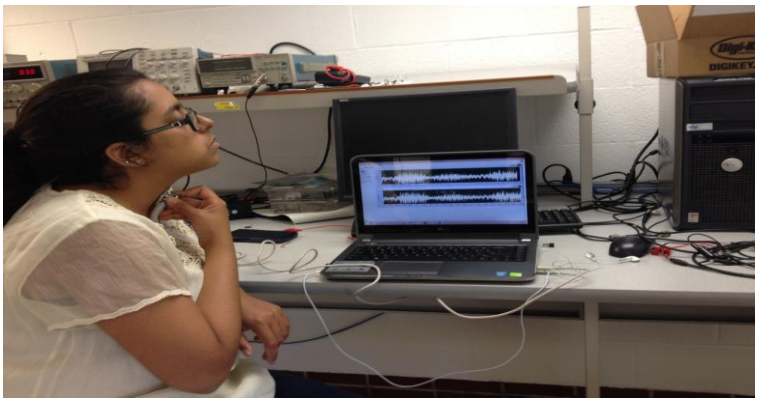

Figure 13. Acquisition of Lung sounds

This signal was then further amplified and filtered in LabVIEW and the frequency domain analysis was done to obtain the spectrograph of the lung sounds, with this we were able to analyze the dominant frequencies of each of the conditions and analyze their variations. The RALE repository was used to obtain the waveforms for different lung conditions like wheezes, crackles, ronchi and pneumonia The output spectrographs for each of the conditions is as shown in the following figures.

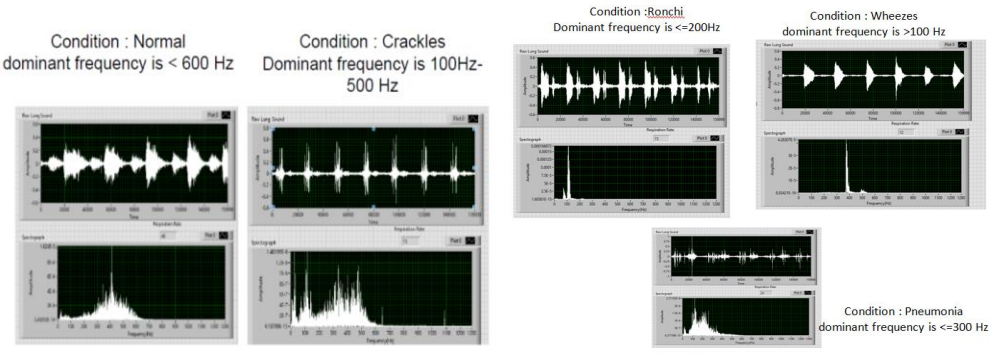

Figure 14. The lung conditions and their corresponding spectrographs (LabVIEW)

Summary

Our design is specifically targeted at a major problem in the healthcare chain. The healthcare system needs a device that helps users make the right decision when facing a medical situation, helps physicians prioritize their schedule and make doctor-user interaction easier, helps hospitals and insurance companies save cost on unnecessary visits. Our design targets all of the criteria necessary for optimizing the healthcare chain. We believe it benefits every party and does not try to exclude or bypass any stakeholder from the current chain.

The device gives users a third-party view in addition to what they might be experiencing and what their friends and family are suggesting, and it gives a peace of mind to the user when they know the device is monitoring them continuously throughout the night. The device give doctors the option of monitoring the user remotely rather than keeping them in the hospital overnight, and allow for preventative intervention when an abnormality is detected, even before the user calls the physician's office. Also, the doctors can now actively schedule their appointments based on real-data rather than a simple 6-month checkup with no user feedback in between. From an economical perspective, the device help hospitals and insurance companies save significant resources when dealing with individuals without medical coverage and healthy hypochondriacs. The team plans to make a commercial product under the company name Raven Biomedical after the initial prototype is complete -My contribution to the prototype being the hardware design and testing, schematic layout and the classification algorithm .With this product, the tedious process from diagnosis to treatment could be shorted significantly at lower costs to each party. This is the start of a new era in healthcare.

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Appendix

Justification and determination for 3-lead ECG in chest aid monitoring

ECG (electrocardiogram) is the current "gold standard" for cardiac event measurement and pathological diagnosis. Computer programs for interpretation of ECG signals have been optimized to yield accuracy and diagnostic value comparable to that of cardiologists [1]. In clinical evaluation setting, 12-lead ECG has been a routine method for clinicians to make the decision whether a patient shall be sent to the emergency room (ER) or not. The accuracy in pre-hospitalization diagnosis by ECG would help in saving time for determining the optimal treatment as well as directing more sophisticated diagnosis. Here we justify the necessity and reliability of using ECGs with reduced lead number (three) for pre-hospital diagnosis rather than anatomically applicable and skill-required 12-lead ECGs.

Introduction

The critical need for 12-lead ECG arises from its diagnostic value in ST elevation myocardial infarction (STEMI) [2], one major type of coronary artery disease (CAD, also termed ischemic heart disease). STEMI is now the no.1 killer in the U.S. as well as globally [3] and makes up for 25%~40% of the patients diagnosed with acute myocardium infarction (AMI) in U.S, slightly lower than NSTEMI annually [4]. Even with lower prevalence than angina pectoris, another subtype of CAD, AMI has a much higher morbidity, especially in males diagnosed with CAD [5]. Even though, STEMI has caused millions of death and is expected to continue to cause more patients to die in the coming future.

Discussion

The reason why some clinicians emphasize the importance of a 12-lead ECG for diagnosis is that if there is any possibility of STEMI in patients, it could lead to more accurate evaluation and prepare both the patients and the physicians for necessary acute treatment since not all the hospitals would be equipped with techniques to treat such disease [6,7]. Tough a 3-lead ECG can also detect abnormality ST segment elevation, decreased detection rate and duration of ST episode limits its diagnostic value in ischemia [11].

It is worth considering that even with a 12-lead ECG, additional tests such as X-ray are still required for diagnostic decision and improvement after the primary treatment [8]. And even for STEMI, a 12-lead ECG can still lead to measurement with false. For other cardiac conditions, a 12-lead ECG provided less consistency with the clinical findings in detecting abnormalities than a 3-lead ECG, suggesting a higher false positive or negative for 12-lead ECGs [8].

Moreover, when we target elder individuals, such as those who are over 55 or 60, a 12-lead ECG is expected to have decreased benefit. A 12-lead ECG requires more time is more difficult to determine and thus is hard for patients to self-administer [9]. Thus a 12-lead device appears to be less desirable (then a 3-lead design) for daily monitoring especially for elder people or people with certain disabilities.

From the prevalence use of 3-lead ECGs in portable medical devices and during patient transport to the ER, no technical problems having been reported in most medical diagnosis or tests and no clinical

difference has been observed between a 12-lead ECG and a 3-lead one. There are previous clinical researches studying the correlation between 3-lead and 12-lead ECG in diagnosis, which sometimes draw contrary conclusions[10 11 12 13]. However, after proper transformation and recovery of raw signals collected by the 3-lead ECG, a 12-lead ECG-similar output can be achieved in many studies [14].

Diseases that can be diagnosed by 3-lead ECG include right atrial enlargement, advanced interatrial block, advanced superoanterior hemi- and bifascicular block, inferior myocardial infarction, valve prolapse and some other common cardiac diseases [15]. According to the significant overlap of efficacy between 12-lead and 3-lead ECG in disease detection and diagnosis, using 3-lead ECG in Offbeat, for simplicity, seems a reasonable choice.

For commercialized cardiac monitors, the implanted ECGs with reduced leads are of much more convenience for customers in applying, adjusting and detaching the product. Many current cardiac monitoring (or diagnostic) products use single-lead ECG. In such case, the products are limited to detecting merely one disease [16]. Some other conditions including atrial fibrillate (which can be detected even by a 2-lead ECG), AV conduction block and etc. could be missed with these products.

Summary

A 3-lead ECG has multiple superiorities over the single-lead ECG and shows considerable competitiveness in monitoring cardiac events as a 12-lead ECG does (**Table 1**.). Accordingly, Offbeat uses 3-lead ECG for detecting and diagnosing for cardiac disorders.

ECG type	Pros	Cons
3-lead ECG	• Convenience to USE • Considerable diagnostic information for most cardiac diseases • Higher cost-efficiency *	• Poor performance in specifying MI subtypes • Less information
12-lead ECG	• Detailed information for pre-hospital diagnosis • Better performance in specifying MI subtypes	• Complexity for placing • More difficult in designing and manufacturing

Table 1. **Pros and cons of 3-lead and 12-lead ECG.**