

Contract Book



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Biographies



Nicolle Jaurre is an undergraduate student at The Johns Hopkins University studying Biomedical Engineering with a focus on Instrumentation and Imaging Systems.



Qianqi Huang is a graduate student at The Johns Hopkins University studying Biomedical Engineering with a focus on Computational Medicine.



Xinyu Guan is an Electrical and Computer Engineering graduate student at JHU. He focuses on Signal Processing, Computer Vision, Machine Learning and VLSI design.

Abstract

StethoECG is a multi-functional heart monitoring system developed as an efficient and comprehensive solution for any possible concerns about heart attack or heart disease. It contains both detecting devices and telecommunication systems for real time communications and feedback between users and their personal doctors. Through patents and competitors research, we found that the existing products have problems that: hard to carry/use (wearable devices not acceptable for most patients), unclear market targeting, inefficient testing process, expensive payments, no in-time suggestions and non-digital report. Our StethoECG solves those problems at the same time by providing an online platform that allows users to set up their personal account and cloud to save their data or reports for communications with their personal doctors. Of course, their doctors will have in time access to their lastly updated health reports. Our “easy to use” device will provide a smart, efficient and comprehensive testing process and results to cooperate with our cloud platform system. In short, StethoECG will have a larger targeting market with better product competitiveness.

Introduction

In the US, heart disease is the leading cause of death with one in every four having some factor related to the heart. Approximately 121.5 million US adults have some form of heart diseases. Besides, between 2014 and 2015, heart diseases cost the United States \$351.2 billion in healthcare services, medicines, and lost productivity due to death. Researchers expect that CVD costs will rise to \$749 billion by 2035. The cardiac monitoring & cardiac rhythm management devices market size was valued at \$19.4 million in 2015 and is expected to reach \$32.3 million by 2022, growing at a Compound Annual Growth Rate of 7.6%. Regular examination is thus crucial to catching heart problems while they can still be treated, especially for patients with chronic issues. A precise and easy to use heart monitoring device to self-check is in demand, from which our product comes into being.

Our StethoECG is a multi-functional system including a heart signal detecting device, signal analysis software, and a telecommunication platform between clinicians and patients. When every heartbeat comes with a spreading wave of electrical activity, electronics can detect abnormalities even when the user may not be aware that something is wrong. Our smartphone app, in addition to providing an interactive and clear user interface, will use precise algorithms to process heart signals received from the device and provide comprehensive analysis using machine learning and AI. Results and analysis will be stored into a personal file for each patient. The software will also collect additional information like what kind of surgery patients have had before, helping the AI make more precise predictions. If any possible threat on their heart health appears, the system will warn users and inform doctors at the same time. Meanwhile, clinicians can also get a better understanding of patients' conditions and more accurately design personalized cardiac medical treatments according to the files. In addition, a platform will be built for real-time communication between doctors and patients, which can help with remote healthcare. In a world geared towards instant solutions and rapid results, we feel that healthcare should not lag behind. You take the wellbeing of your loved ones seriously, and so do we. We believe our solution presents a next generation upgrade to at-home heart health monitoring, and we would welcome the opportunity to prove this to you further.

Field Survey

Heart disease is a major cause of death in the US with nearly 655,000 Americans dying from heart disease each year. In most cardiac disorders, continuous cardiac monitoring is required and can well prevent death from heart issues. Increasing demand to enhance patients' lives and improve outcomes of heart disease, with advanced and minimally invasive technologies leads to our interest in the market of heart monitoring devices.

The heart monitoring devices market size was valued at \$19,397 million in 2015 and is expected to reach \$32,216 million by 2022, growing at a CAGR of 7.6%. From Figure[1] about the region growth rate, Asia region holds strong market potential, mainly driven by their large and growing populations as well as the increasing number of hospitals and clinics.

The COVID-19 outbreak also has an impact on the market. With the increasing preference to telemedicine of patients and clinicians and heart disease patients' higher vulnerability in case of infection, the peak demand for remote heart monitoring devices is anticipated to rise at an exponential rate in 2020.

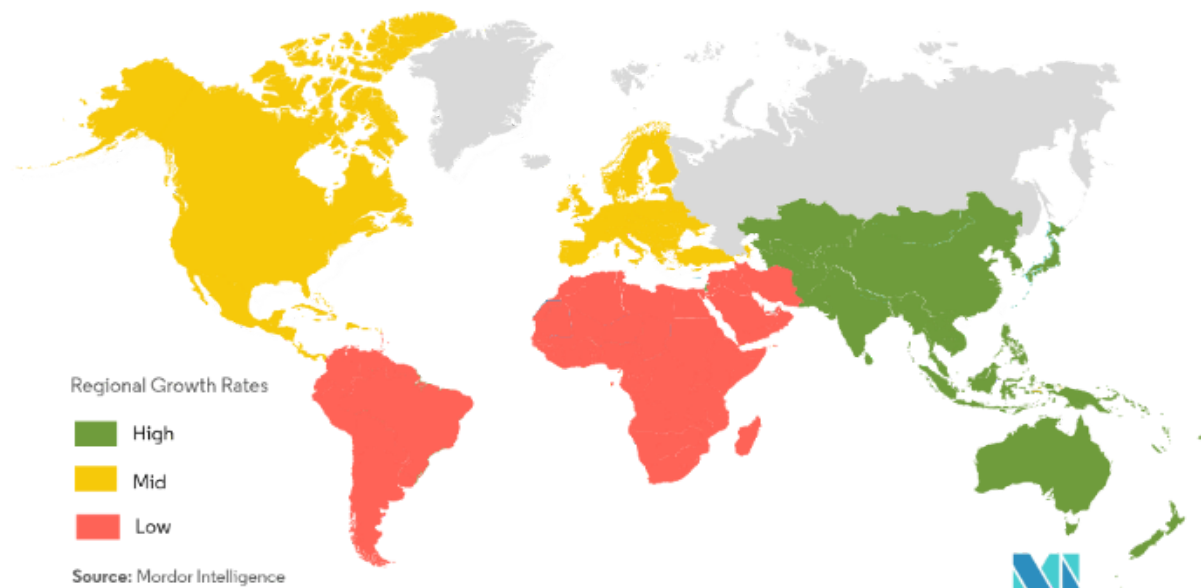


Figure 1 Region Growth Rates

Patent Survey

We conducted extensive searches for heart monitoring devices to evaluate the feasibility and innovation of our design. We break our design into two parts as hardware and software, and respectively searched relative patents as below.

- US20180028144A1: Electronic Acoustic Stethoscope with ECG
A noninvasive system for detecting and processing PCG and ECG waveforms includes an electronic acoustic stethoscope and a server computer.
- US20180055383A1: Multi-function health monitor
A system and method for a multi-function remote ambulatory cardiac monitoring system. The system includes a housing and a microprocessor disposed within the housing.
- US20170215755A1: Heart monitoring system usable with a smartphone or computer
A personal monitoring device has a sensor assembly configured to sense physiological signals upon contact with a user's skin.
- CN107714023A: Static ecg analysis method and apparatus based on artificial intelligence self study
The present embodiments relate to a kind of static ecg analysis method and apparatus based on artificial intelligence self study, realizing the automated analysis method of the static electrocardiogram of a complete fast process.
- KR20140037325A: Telemedicine system and method based ecg data using bio-signal meter and smart device

The present patents describe heart signal detection, transmission, and processing, which proves with current technology we can realize the combination of ECG and heart sound in one device. In addition, our product features connection with mobile smart devices for artificial intelligent analysis of signal, patient's individual health record and platform between clinicians, distinguishing our products from existing devices.

Intended Use

StethoECG is a multi-functional system including heart signal detecting device, signal analysis software and communication platform between clinicians and patients. This product is intended to aid users self-check their heart condition with ECG, heart sound data and artificial intelligence analysis. The platform system is also intended to provide heart health records and remote medicine service. This product is NOT intended to diagnose the user with specific disease with artificial intelligence analysis. The abnormal heart conditions will be identified and recommendation of seeking professional help will be given by this product.

Regulatory Issues

Since the StethoECG is an external medical monitoring device, we should only need to contact the Food and Drug Administration (FDA) and the US Patent and Trademark Office (USPTO). We should also not be required to do any human/animal tests because the device will only contact users externally. It is not designed to save or sustain lives in an emergency situation. As what we have claimed, the device should be a class 2 device with the same class of its competitors. Additionally, for our smart phone App, we may need to contact FCC and ONC.

Design

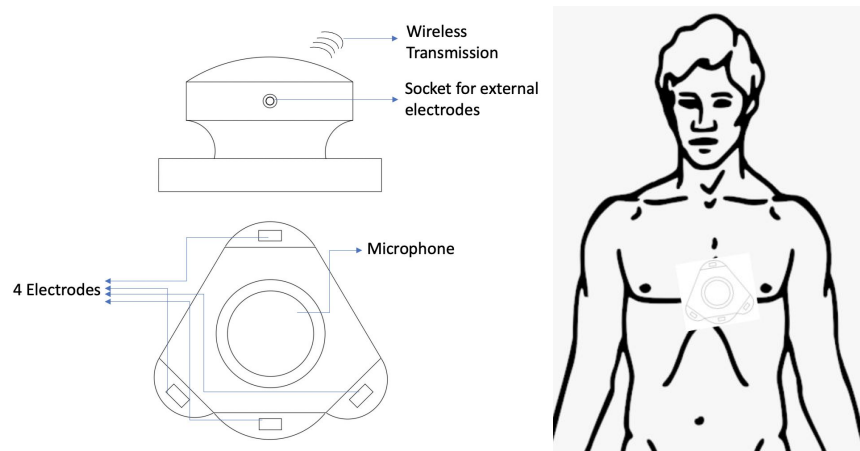


Figure 2 Simple Mode with 2 Leads

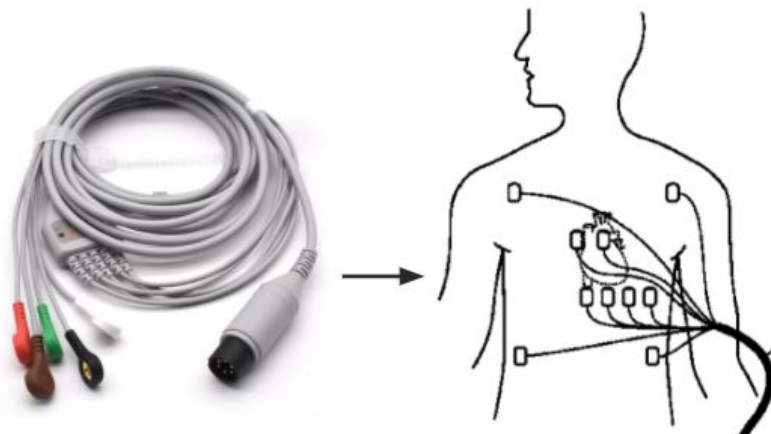


Figure 3 Precise Mode with 12 Leads

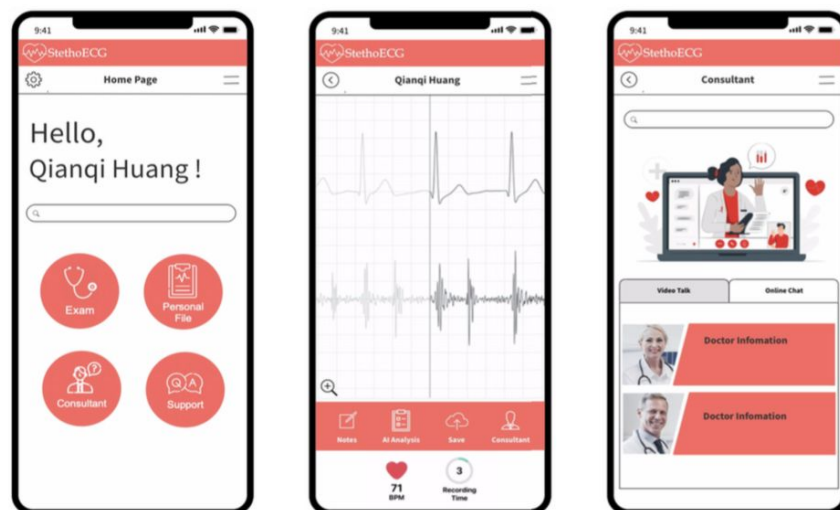


Figure 4 User Interface/Smartphone App

The detection device is designed like a chest piece of stethoscope. For different purposes, the device has two measurement modes as shown in Fig 2 and 3. In simple mode, users need to hold the rear of the device and stick it on the left chest to detect heart sound and ECG. The four electrodes on the bottom of the device will receive electrical signals and work as two-leads ECG system. The microphone on the bottom of the device will detect heart sound. Then signals will be wirelessly transferred to processors like smartphone or PC by bluetooth or WIFI. In precise mode, external electrodes will be connected to the device in order to establish a more accurate 12-lead ECG system. The ten electrodes need to be stuck on different places in the chest. Heart sound is detected in the same way as simple mode.

The smartphone App can process the signals from the detection device. Signals will be visualized in the app for easily reading. Using AI technology, the app can identify abnormal signals and make simple diagnostic predictions. In the app, examination results and medical information will be saved into personal files. Remote medicine is also available by video talking with professional clinicians in the app. Fig 4 shows the samples of our smartphone App user interface design.

System workflow:

Heartbeat Signal

Using Stethoscope/Electrode for ECG to convert heart signal to analog voltage.

Analog to Digital

Using Nonvolatile memory like EEPROM or flash to store the data with a real time clock. Then, transfer data to the processor(PC or Smartphone) by using bluetooth for wires.

Process Data

Extract data from the last step into a dataset, then start processing it into useful information for AI analysis. Data processing includes sampling, frequency domain processing, noise reduction or filtering, beats reconstruction and thresholding.

Opinions from AI

Train the data using machine learning to give a pre-analysis of abnormal heart signals that the user may have and deliver the result and data to Professional doctors.

Smartphone App

Allow patients to connect directly with their results and contact healthcare providers.

Business Strategy

In consideration of our company with innovative new products, research and development (or R&D) and innovation will be one focus in our business model, to ensure good user experience and build users' dependence on our product. Our target customers are patients with heart diseases in need of regular heart examination. We decided on two main sales channels. First is to sell directly to customers via both online and second is to sell in offline stores like pharmacies, specialty shops for medical devices, hospitals. And Since our first stage goal is to reach as many as possible target groups, We want to try multi-channel promotional approaches. First is online advertising, it also includes email marketing, search engine marketing, social media marketing. Online advertising has low cost compared to offline ads. In addition, geo-targeting and user's searching key words also help efficiently reach desired target groups. Secondly, we plan to sponsor or participate in relevant medical conferences and health expos in order to increase our product awareness. Thirdly, we want to cooperate with physicians, let them recommend our product to their patients. We believe their influence will offer more exposure opportunities of our product and increase public trust on our product's effectiveness.

Financial Plan (Years 1 and 2)

Expense	Unit Cost	Unit Number	Total Expense	Unit Number	Total Expense
Manufacturing Cost (85% of BOM)	\$54.31	1000	\$5,431	10,000	\$54,310
Office Space and Upkeep	\$48,000	1	\$48,000	1	\$48,000
RND and Product Development	\$10,000	1	\$10,000	3	\$30,000
Total Operating Costs Year 1			\$63,431	Total Operating Costs Year 2	\$132,310

Expense	Unit Cost	Unit Number	Total Expense	Unit Number	Total Expense
Patent Application/ Attorney	\$25,000	1	\$25,000	0.5	\$12,500
FDA Class II	\$10,000	1	\$10,000	0.25	\$2,500
FDA and Clinical Consultants	\$50,000	1	\$50,000	0.4	\$20,000
Total Regulatory Costs Year 1			\$85,000	Total Regulatory Costs Year 2	\$35,000

Expense	Unit Cost	Unit Number	Total Expense	Unit Number	Total Expense
Manufacturing Engineer	\$80,000	2	\$160,000	2	\$160,000
R & D Engineer	\$80,000	1	\$80,000	1	\$80,000
App Developer	\$100,000	1	\$100,000	1	\$100,000
Total Salary Costs Year 1			\$340,000	Total Salary Costs Year 2	\$340,000

Total Operating Costs Year 1	\$63,431
Total Operating Costs Year 2	\$132,310
Total Regulatory Costs Year 1	\$85,000
Total Regulatory Costs Year 2	\$35,000
Total Salary Costs Year 1	\$340,000
Total Salary Costs Year 2	\$340,000
Total Costs	\$987,741

Reimbursement

Though we believe our product is already very cost-effective to the customer, we do wish to apply for reimbursement codes to both encourage doctors to use StethoECG with their patients and increase accessibility to our product even more. First, we intend to apply for one of the new CPT codes 93XX0 – 93XX7 meant for long-term patient cardiac monitoring. In addition, we hope to have some of our telehealth features covered as well using codes such as CPT code 99490 which deals with reimbursement for clinical staff time and CPT code 99453 which deals reimbursement for patient education on how to use our product.

Summary

In summary, we believe that our device fills a gap in the cardiac health monitoring industry, provides a comprehensive and versatile option for patients concerned about their heart health, and can help give peace of mind to millions who currently lack the tools to know if something is wrong. Our app provides a user-friendly interface that makes heart health monitoring easier than it has ever been, and our highly competitive price and opportunities for reimbursement means that few will not have access to our product. In the future, we hope to streamline the features we currently have and add new ones to fit the needs of our customer base. Our goal, first and foremost, is to provide patients with as much information on their heart health as possible whenever and wherever they are. We hope to give families peace of mind and doctors the ability to perform more comprehensive health checks through telemedicine.

Plan Forward

Moving forwards, we are excited to begin both the first prototype of our product and the regulatory process. We hope to be able to expand our algorithm to detect a variety of different heart issues - arrhythmias, infarctions, murmurs etc. In addition, we want to gain more insight into what would become our working bill of materials and our manufacturing process - adjusting the price of our product from \$100 as we deem necessary to maintain our profitability. We also want to delve into the telehealth portion of our app, contact physicians who may wish to try it, and begin clinical testing. Through all of this, it is important that we begin the FDA pre-approval process and apply for a patent.

Appendix

- [1] Electronic stethoscope <https://patents.google.com/patent/EP2110080A1>
- [2] Electronic Acoustic Stethoscope with ECG
<https://patents.google.com/patent/US20180028144A1/en>
- [3] Multi-function health monitor <https://patents.google.com/patent/US20180055383A1>
- [4] Heart monitoring system usable with a smartphone or computer
<https://patents.google.com/patent/US20170215755A1>
- [5] Wireless ECG monitoring device and system
<https://patents.google.com/patent/US9706922B2/en>
- [6] System and method for classifying a heart sound
<https://patents.google.com/patent/US8992435B2>
- [7] Static ecg analysis method and apparatus based on artificial intelligence self study
<https://patents.google.com/patent/CN107714023A/>
- [8] Telemedicine system and method based ecg data using bio-signal meter and smart device
<https://patents.google.com/patent/KR20140037325A>
- [9] CMS Regulation for ECG Monitoring Systems
<https://www.acc.org/latest-in-cardiology/articles/2020/12/02/16/48/cms-releases-2021-medicare-physician-fee-schedule-final-rule>
- [10] Cardiac Arrhythmia Monitoring Devices Market-Growth, Trends, and Forecast(2020-2025)
<https://www.mordorintelligence.com/industry-reports/cardiac-arrhythmia-monitoring-devices-market>
- [11] Heart Disease Facts
<https://www.cdc.gov/heartdisease/facts.htm>