Precision Lifestyle Technologies

School of Engineering Science • Burnaby, BC • V5A 1S6
www.precisionlifestyletech.com

The Heart of Medical Advances.

October 15, 2007
Dr. Andrew Rawicz
School of Engineering Science
Simon Fraser University
Burnaby, British Columbia
V5A 1S6

Re: ENSC 440/305 Functional Specification for a Wireless Heart Attack Detector

Dear Dr. Rawicz,

Enclosed please find a copy of the functional specification for a Wireless Heart Attack Detector, PULZE™ by Precision Lifestyle Technologies. The attached document outlines the requirements for PLT's proposed device. The company's primary objective is to implement a functioning device that would alert the emergency personnel when a person is having a heart attack in the shortest time possible in order for them to promptly receive medical assistance.

Our functional specification provides high level requirements not only for proof-of-concept prototype, but also for the production phase of development. Our project manager and design engineers will use this document for development and research activities.

PLT's talented and motivated team of senior engineering students includes Piraj Fozoonmayeh, Mojtaba Gharehbaghi and Sara Moghaddamjoo. If you have any questions or concerns, please do not hesitate to contact me by phone at (778) 883-2424 or by email at ensc440-psm@sfu.ca.

Sincerely,

Sara Moghaddamjoo
CEO
Precision Lifestyle Technologies Inc.

Functional Specification for:

Wireless Heart Attack Detector

Project Team:

Piraj Fozoonmayeh

Sara Moghaddamjoo

Mojtaba Gharehbaghi

Contact Person:

Sara Moghaddamjoo
sma22@sfu.ca

Submitted to:

Dr. Andrew Rawicz
Mr. Mike Sjoerdsma
School of Engineering Science
Simon Fraser University

Issue Date: October 15, 2007

Revision: 1.0

Executive Summery

According to the World Health Organization report of 2002, 59% of deaths were the result of non communal conditions. Of which, 29% of deaths were related to cardiovascular complications. To attain a better visual of this percentage, approximately 10 million people in a year die resulting from cardiovascular complications.

Most heart attacks could be somewhat maintained if the patient is to receive the needed medical attention in time. However, not everyone knows what a heart attack is like or what to do in case of such an emergency; hence a lot of heart attacks amount to death due to either the patient not being aware or not being able to seek medical attention in sufficient time.

The wireless heart attack detector, PULZE™, seeks to ease the element of surprise and give the users a better, healthier piece of mind. We at PLT are committed to design a reliable and cost effective device to detect and alert medical personnel in a timely manner to save lives.

Development of PULZE™ will occur in two phases. Upon completion of the first phase, PULZE™ will have the capability of detecting an acute heart attack type, and sending a signal to user's cell phone to alert emergency personnel.

The acute heart attack is chosen due to its popularity amongst adults. According to researches every 20 seconds a new heart attack occurs somewhere in America, whom 50% of them die due to not receiving prompt medical attention [1]. PULZE™ will have the ability to detect an acute heart attack and alert emergency personnel. The four month development cycle of our prototype is expected to be completed by Dec 15, 2007.

In the proof of concept phase PULZE™ will evaluate only one sign of acute heart attack. For the second phase of development, PULZE™ will also be capable of detecting heart attack more accurately by evaluating several characteristics of acute heart attack. Moreover, the device will alert emergency personnel in case of sudden discontinuity of movement due to an accident or falling down. Furthermore, PULZE™ will conform to the all pertinent standards and guidelines, including those of FDA and AAMI.

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Introduction

Telemedicine is a new advancement in delivery of clinical care through information technology and communication devices. This technology could be used immensely for disease detection and therapeutic purposes. It has been proven that early detection of a disease at its preliminary stages could profoundly reduce the risks and complications that may arise with time.

In the year 2004 United States statistical data recognizes coronary heart disease as the leading cause of death among American citizens. Each year 1,200,000 cardiac attacks are reported, from which 38 percent of these cases result in death [1]. This amounts to one in every three incidences of heart attack amounting to death. Considering the world population of more than six billion people, there are millions of people who are susceptible to death by heart attack. To reduce these horrific numbers we should concentrate our resources and technologies on improving early detection devices to further assist physicians to communicate with their patients on a daily basis since some heart complications may arise without prior warning.

An electrocardiogram (ECG), shown in **Error! Reference source not found.**, measures heart beat electrical activity which generates a wave or impulse through the heart muscles. This electrical impulse would constrict the cardiac muscles, which in turn causes blood to be pumped out of the heart into arteries. With patients with cardiac issues, an ECG allows the physician to know the length of time required for an electrical wave to travel through the heart. This information determines whether the electrical activity is normal, too fast/slow or irregular. An ECG can also give information about the size and health-state of the heart based on the amount of electrical activity that passes through the heart muscle. Based on these types of information, an ECG can detect a heart attack.

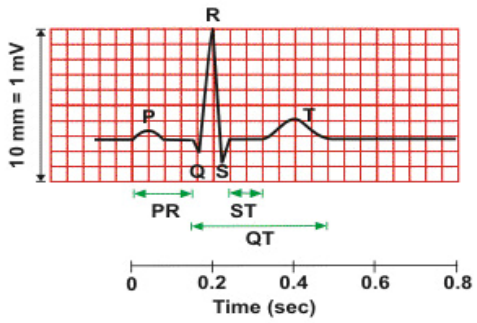


Figure 1: *Standard electrocardiogram (ECG)*

http://www.cvphysiology.com/Arrhythmias/ECG%20trace%20with%20grid.gif

The ECG technology has had an enormous impact for diagnostic purposes since its discovery; however, to further enhance ECG technology, improvements can be implemented. For instance, available ECG devices lack the advantage of being portal and hence they impose physical and spatial restrictions on the patient and the doctor. Moreover, an ECG device is able to detect a heart attack only after it has occurred, and by that time it may be too late to save the patient's life. To this date, little improvement on the ECG devices has been implemented to enable faster and better communication between the patient and the doctor. Therefore, the flaws that this technology is experiencing at this time should be recognized and actions should be taken to further improve its functionality to serve human lives more efficiently.

Our proposed system not only detects heart attacks for immediate assistance, but also could be used for various other applications:

1- The rate at which a heart beats plays an important role especially in catabolic exercises such as cardio exercises, so this device may also be used by athletes and people that would like to lose weight.

2- The design of the bio-sensors may be modified for other medicine applications such as using a respiratory sensor to detect respiratory problems.

Scope

The scope of this document covers the requirements and functionalities which need to be standardized for both the proof of concept and the final commercial product. Requirements for production may change as more product survey feed back are collected during the prototype design. The mentioned functional requirements represent the current vision of what customers demand and government regulations require. After through market studies and proof of concept testing the final modification of the device will be prepared for the production.

Glossary

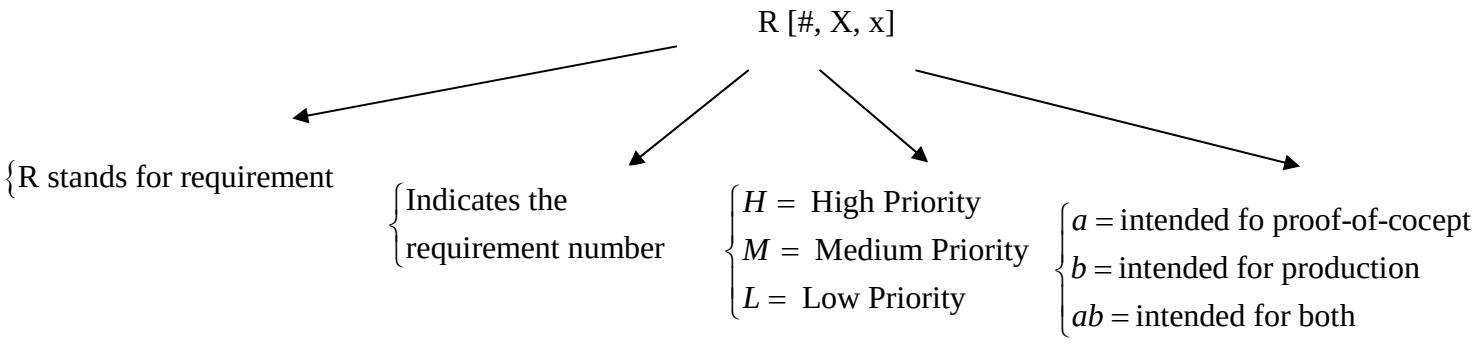
PLT: Precision Lifestyle Technologies Inc.
ECG: Electrocardiogram.
OS: Operating System
PDA: Personal Digital Assistant
AAMI: American Association of Medical Instruments
FDA: Food and Drug Administration

Intended Audience

The main purpose of this document is to act as a guideline to help the engineers in design, integration and quality assurance of PULZE ™. PLT's team members shall also use the functional specification document as a checklist to ensure that the development process is inline and to control and direct the progress toward the end users' expectations of the device. Another intended use of this document is to provide a reference to product features for future marketing phase of development.

Convention

The following notation is used throughout this document in order to illustrate each functional requirement:



By mid November the high priority requirements must be fulfilled and the medium priority requirements should be completed. However, the low priority requirements may be accomplished. In any case the requirements intended for proof of concept are to be completed by December 15, 2007.

System Requirements

System Overview

The aim of our project is to enhance the ECG technology to allow early detection of a cardiac heart attack before a patient experiences it. We believe this device can save millions of lives around the world by making it possible to detect a heart attack in advance, allowing the physicians sufficient time for patient care and treatment in hopes to prevent cardiac arrest and death. Our aim is to design and implement a device that can be easily worn as an accessory to monitor the heart beat. The data are monitored in this system in real time and as soon as an abnormality in heart beat is detected, a signal is transmitted to the patient's cell phone to alert an emergency unit provided by PLT. We believe our device is able to enhance life for patients prone to heart attack by providing them with the required medical attention promptly. Figure 3 illustrates the system block diagram.

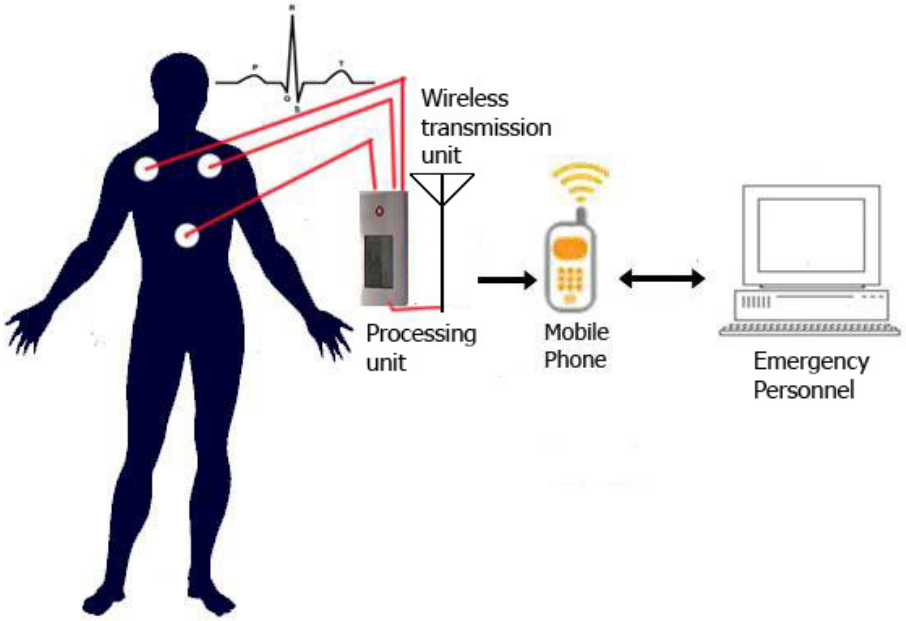


Figure 2: System Overview

Error! Reference source not found. demonstrates a block diagram of PULZE™ System.

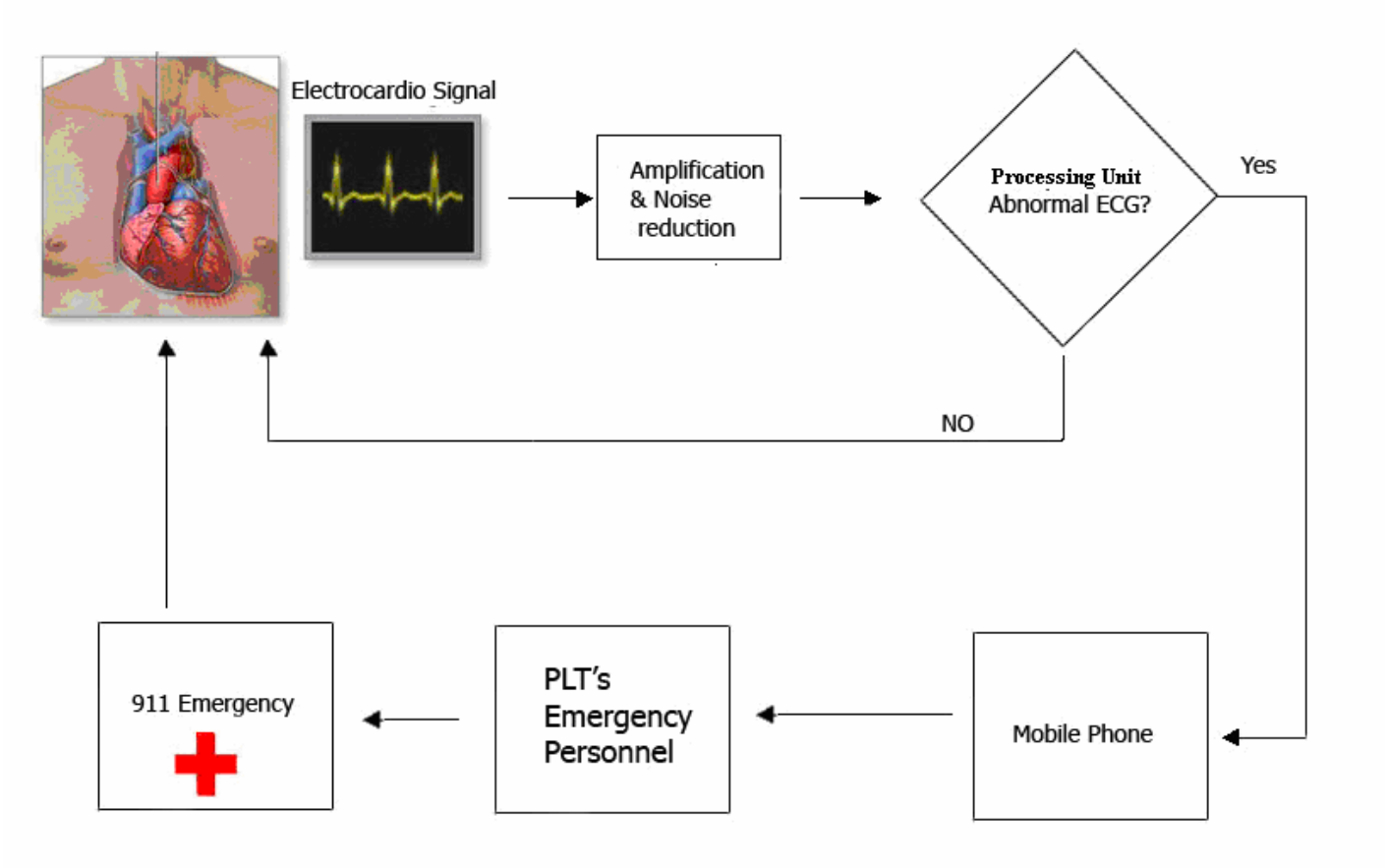


Figure 3: System Block Diagram

General Requirements

R [1, H, ab]: The device must operate under normal room temperature (20°C to 25°C) [2].

R [2, H, ab]: Different parts of the device must have high chemical stability to avoid any toxic contamination.

R [3, M, b]: The device must be water resistant.

R [4, H, b]: The weight of the device should not exceed 200 grams.

R [5, H, ab]: The device should operate under minimum amount of vibration.

R [6, H, ab]: The device shall not be under any electromagnetic influence.

R [7, M, b]: The retail price of the device shall not exceed $400.

R [8, H, ab]: The power supply of the device shall be rechargeable lithium ion battery, with 110V/120V re-charger, which is typical of North American wall outlets.

R [9, H, ab]: The user shall own a cell phone with wireless capabilities specified in transmission unit requirements.

Performance

R [10, H, ab]: The device shall detect Q-wave acute heart attack.

R [11, H, ab]: The device shall acquire a 5 mVolt signal from the heart, amplify it and send a clean signal to a processing unit.

R [12, L, b]: The device shall detect a sudden movement followed by a period of idleness.

Reliability and Serviceability

R [13, H, ab]: Total number of buttons on the device shall be limited.

R [14, M, ab]: The system shall report any errors encountered.

R [15, H, ab]: All the electrical parts of the device shall have proper isolation.

Compatibility

R [16, H, ab]: System power supply shall be stable and the circuitry shall be well-designed to avoid producing shock to the users.

R [17, H, b]: Power standards shall be compatible with the North American medical devices system.

Physical Requirements

R [18, M, a]: The device shall look sexy.

R [19, H, b]: The device's height shall not exceed 8 centimeters.

R [20, H, b]: The device's length and thickness shall not exceed 4 centimeter.

Data Acquisition unit Requirements

R [21, H, ab]: The data acquisition circuit must have high input impedance.

R [22, H, ab]: The data acquisition circuit will be able to take real-time samples of input signals.

R [23, H, ab]: The data acquisition circuit will have a high amplification gain.

R [24, H, ab]: The data acquisition circuit must apply a high frequency filter.

R [25, H, ab]: The data acquisition circuit must apply a low frequency filter.

R [26, H, ab]: The data acquisition circuit will have a high common mode rejection ratio.

R [27, H, ab]: The data acquisition circuit will require strong DC signal suppression.

Data Processing Unit Requirements

Figure 4 presents the normal ECG signal and Figure 5 illustrates the ST segment elevation caused by an acute heart attack.

R [28, H, a]: The device shall detect whether if the ST segment of the heart signal is elevated.

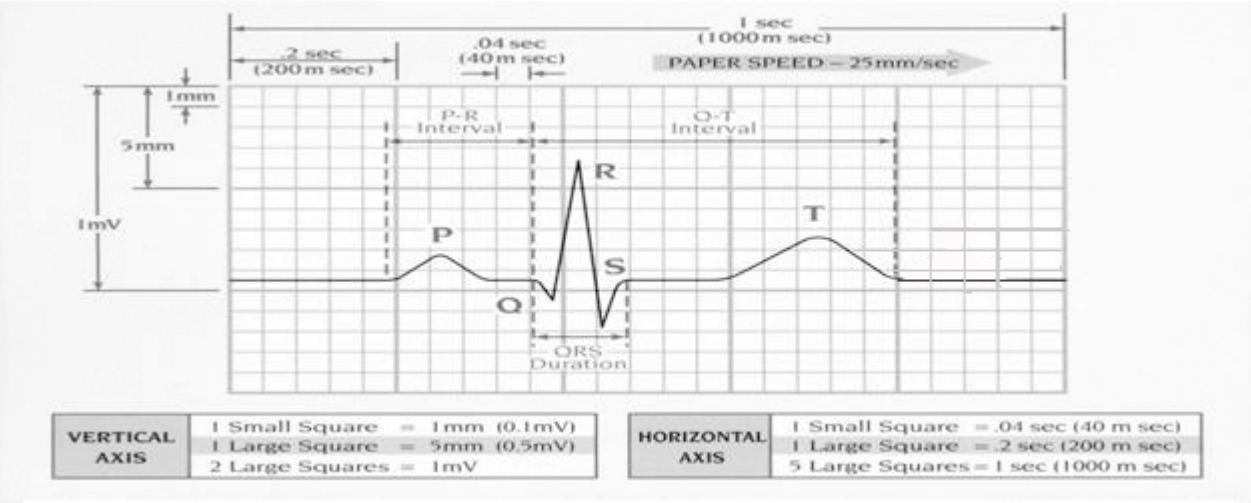


Figure 4: Normal ECG Signal

rnbob.tripod.com/electroc.htm

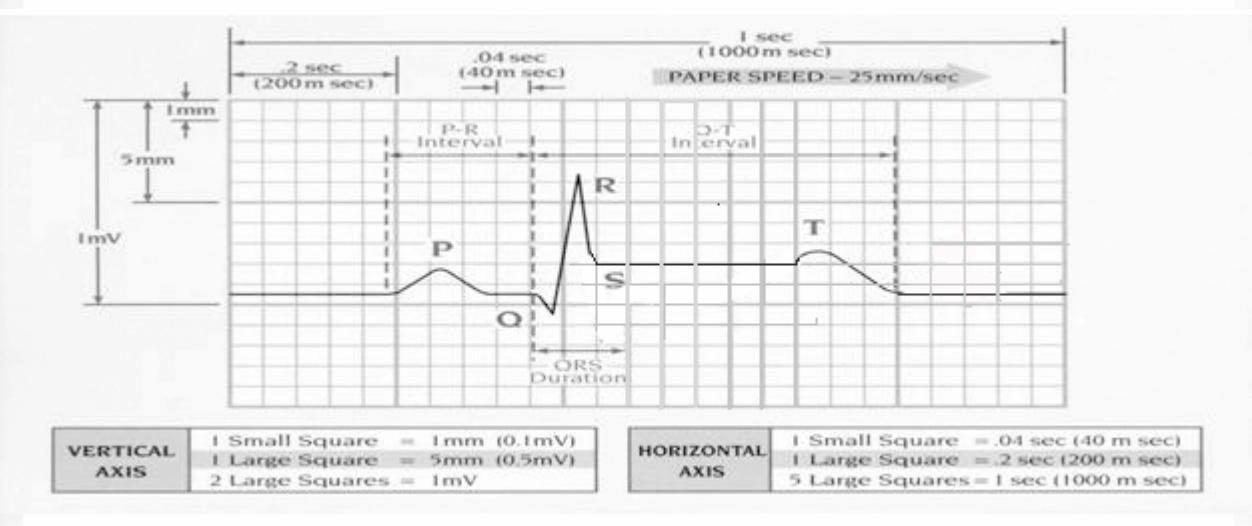


Figure 5: Acute Heart Attack Signal (ST Elevation)

R [29, H, ab]: The processing unit shall detect the R wave.

R [30, H, ab]: An alarm signal shall be transmitted if the signal does not return to baseline in certain amount of time.

Figure 5 presents the block diagram of the data processing unit of PULZE™.

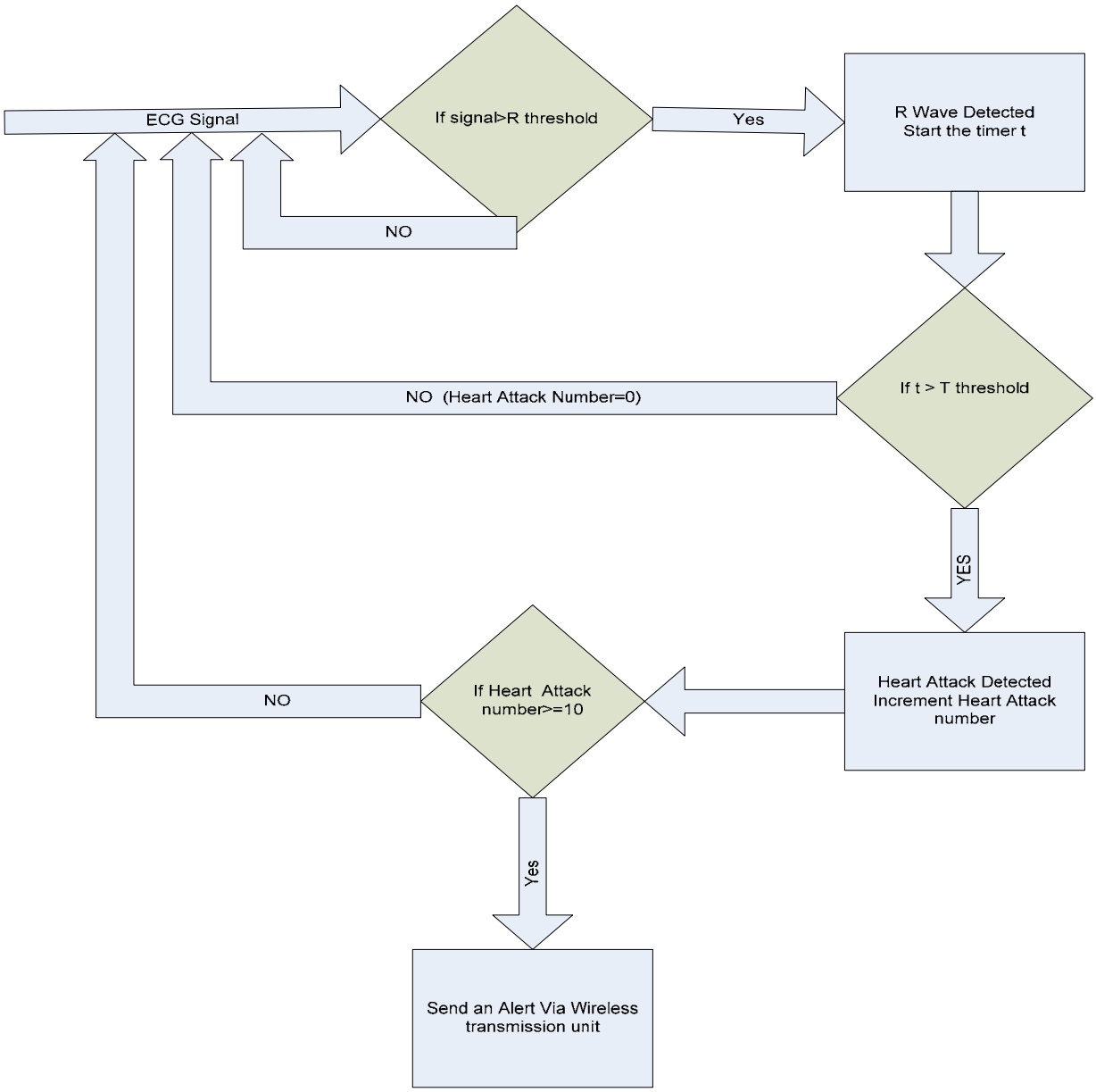


Figure 6: Data Processing Unit Block Diagram

R [31, H, ab]: The device shall acquire 4 samples in 0.04 seconds.

R [32, H, ab]: The device shall acquire one sample per 0.01 second at 100 Hz frequency.

R [33, H, ab]: Minimum sampling frequency shall be 200 Hz according to Nyquist theorem: "Exact reconstruction of a continuous-time baseband signal from its samples is possible if the signal is band limited and the sampling frequency is greater than twice the signal bandwidth."[3]

R [34, H, ab]: The processing unit requires at least 3 bits resolution or 8 steps to extract PQRST signals

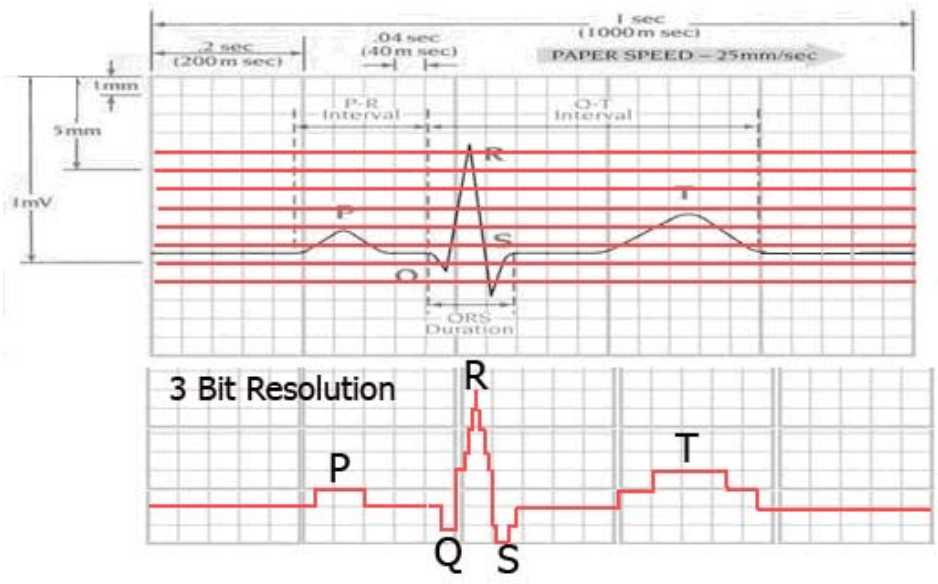


Figure 7: Reconstruction of the Signal with 3 Bit Resolution

rnbob.tripod.com/electroc.htm

$$\text{Size of Each Step} = \frac{\text{Peak to Peak Voltage}}{2^{(n-1)}}$$

* (minus one in the denominator is added to obtain more accuracy)

Transmission Unit Requirements

R [35, H, ab]: The wireless module shall support communication between the device and user's cell phone.

R [36, H, ab]: The data encryption for security shall be handled by user's cell phone.

R [37, H, ab]: Wireless communication shall use industrial, scientific and medical frequency band as standardized by the International Telecommunication Union [4]

R [38, H, ab]: The wireless communication channel of users' cell phone shall be available at all times.

Safety and Regulatory Requirements

FDA defines a medical device as "…an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary…intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes" [5].

Medical devices fall into three classifications assigned by the risk they impose. Classifications are: Class I, Class II and Class III and PULZE ™ falls into Class III of FDA medical devices. [5] Class III medical devices have the most strict regulatory controls because these types of devices usually support or sustain human life. All the relative FDA regulatory codes for PULZE™ have been presented below.

R [39, H, b]: The device shall conform to FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001 [6].

R [40, H, b]: The device shall conform to Item 2: AAMI EC53:1995, ECG cables and lead wires [7].

R [41, H, b]: The device shall conform to Item 41: AAMI / ANSI EC11:1991, Diagnostic electrocardiography [8].

R [42, H, b]: The device shall conform to Item 42: AAMI / ANSI EC13:1992, Cardiac monitors, heart rate meters, and alarms [9].

R [43, H, b]: The device shall conform to Item 45: AAMI / ANSI EC57-98, Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement [10].

R [44, H, b]: The device shall conform to Item 52: AAMI / ANSI EC12:2000, Disposable ECG [11].

R [45, H, b]: The device shall conform to CAN/CSA C22.2 No. 601.2.25: Electrocardiographs safety parameters and requirements [11].

R [46, H, b]: The device shall conform to CAN/CSA C22.2 No. 601.2.27: Electrocardiographs Monitoring Equipment safety parameters and requirements [11].

R [47, H, b]: The device shall conform to ANSI/AAMI EC11: safety and performance parameters for electrocardiography systems [11].

R [48, H, b]: The device shall conform to ANSI/AAMI EC12: safety and performance parameters, test parameters and terminology for electrocardiography electrodes [11].

R [49, H, b]: The device shall conform to ANSI/AAMI EC13: safety and performance parameters electrocardiography heat rate and waveform monitors [11].

R [50, H, b]: The device shall conform to IEC 60601 (1): Safety requirements, compatibility for medical electrical systems [12].

R [51, H, b]: The device shall conform to IEC 60601 (2): Safety, recording and analyzing of the electrographs [12].

Documentation and User Training Requirements

R [52, H, b]: User manual shall include a complete set of instructions on how to attach and use the device, written in English.

R [53, H, b]: A user friendly website should contain technical support information and a soft copy of the user manual, written in English.

R [54, H, b]: The user manual shall be written for an audience with no medical knowledge or electronics back ground.

R [55, H, b]: A detailed software and hardware installation guide shall be created for technicians and vendors.

R [56, H, b]: User manual shall be provided in French, Spanish, German, Simplified Chinese and Arabic to satisfy product language requirements for international marketing.

R [57, H, b]: Warranty shall be provided with the device.

R [58, H, b]: Company's contact information shall be provided with the package.

System Test Plan

R [59, H, a]: Simulation and signal processing will be investigated using MATLAB.

R [60, H, a]: Electrodes are to be tested individually. One electrode is tested individually to ensure its workability while avoiding interference from the neighboring electrodes.

R [61, H, a]: Minimum distortion should be seen when increasing the number of electrodes used.

R [62, H, a]: Signal is acquired and processed at the pre-amp and filtering module.

R [63, H, a]: The pre-amp and filtering module will first take in only 1 input signal at a time.

R [64, H, a]: After it is verified that all electrode signals can be obtained with minimal noise and distortion, all electrode signals will be multiplexed into the amplification and filtering module.

R [65, H, a]: The signal is tested and that maximum gain is achieved without clamping the signal

R [66, H, a]: A signal will be observed to ensure the output is expected.

R [67, H, a]: Signal display is obtained by MATLAB and Oscilloscope.

R [68, H, a]: All parts of connection to the system will be checked.

R [69, H, a]: The electrodes are placed on one of group members' heart.

Software Requirements

R [70, H, ab]: The software shall be available to users on a CD and on company's website.

R [71, H, ab]: The software shall be compatible with Microsoft® Windows Vista, Windows XP or Windows 2000.

R [72, M, b]: The software shall be compatible with APPLE® OS.

R [73, H, ab]: The software shall be able to initiate a call from user's cell phone to a number specified by the user at the time of installation.

R [74, H, ab]: The software shall allow users to change the specified number as many times they desire.

R [75, H, ab]: The software shall be programmed for small, resource-limited devices such as cell phones and PDAs. [13]

Marketing

According to FDA regulations three steps to market a medical device are as followed:

- First step is that the product shall comply with definition of the medical devices defined in section 201(h) of the FD&C.

- Second step is to classify the device according to the classification of FDA regulations.

- Third step is to submit a marketing application to FDA for revision.

Device Limitations

PULZE™ will undergo a series of development phases before it is commercialized. The device will not fulfill all the functional requirements as it is intended to serve as a proof-of-concept only. Once ST elevation of heart signal has been detected by the device, other acute heart attack signal characteristics will be evaluated by the device for the commercialized version. For example characteristics such as T wave inversion and Q wave depression.

Conclusion

The functional specification defines all the requirements for our wireless heart attack detector, PULZE™. The development of the product occurs in two phases. The first phase only focuses on proof of concept and the second phase will fulfill all the requirements mentioned in the document. The proof-of-concept phase is expected to be completed by December 15, 2007.

References

[1] www.americanheart.org/presenter.jhtml

[2] http://www.answers.com/topic/room-temperature

[3] http://ieeeexplore.ieee.org

[4] http://www.mobileinfo.com/Bluetooth/FAQ.htm#t1

[5] http://www.qrasupport.com/FDA_MED_DEVICE.html

[6]http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD__IDENTIFICATION_NO=388

[7]http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD__IDENTIFICATION_NO=5541

[8]http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD__IDENTIFICATION_NO=5607

[9]http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD__IDENTIFICATION_NO=8510

[10]http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD__IDENTIFICATION_NO=12429

[11] http://www.aami.org/publications/CD/cdchart.html

[12] http://www.601help.com/Other_601_Standards/other_601_standards.html

[13] http://www.webopedia.com/TERM/J/J2ME.htm

