

Requirements Specifications Document

for

Portable, Single-Lead ECG Monitor

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Wearable ECG

Requirements Specifications Document Concurrence

The undersigned acknowledge that they have reviewed and approve the Portable, One-Lead ECG Requirements Specifications Document. Changes to this document must be coordinated and approved by the undersigned of their designated representatives.

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1.0 General Information

1.1 Purpose

This document serves to provide a summary of the requirements specified for a Portable, Single-Lead ECG Monitor. This document also lists a number of constraints and assumptions made when designing this device.

1.2 Scope

This document entails an overall description of the device, the assumptions necessary for the construction of the device, implicated constraints for design, and finally the overall requirements of the device. These requirements include user requirements, system requirements (performance, software, and hardware), and interface requirements (input and output).

1.3 Referenced documents

- Customer Needs Document (2/11/2019)
- Requirements Traceability Matrix (3/4/2019)

1.4 Acronyms and Abbreviations

- AC – Alternating Current
- ECG – Electrocardiograph
- LCD – Liquid Crystal Display
- SD – Secure Digital
- USB – Universal Serial Bus

2.0 Overall Description

With cardiovascular disease remaining the number one killer in the United States, understanding cardiovascular health is more important than ever. The goal of this project is to build an easy to use, portable ECG device for patients with history of atrial fibrillation. Along with this, the venture aims to introduce low cost ECG technology to the general public, as well as improve ease of access for physicians to cardiographic data. The ECG will measure one or two leads rather than the traditional 12-lead ECG machines, thus allowing for the device to be compact while still maintaining accuracy and specificity comparable to that of a 12-lead device.

The aim of this endeavor is to make healthcare more accessible to the average consumer by providing a device capable of presenting ECG data in an easy to understand, aesthetic format. Consumers are expected to use the device multiple times as advised by physicians, requiring a lasting battery life throughout the day. The patient can expect to use our device to quickly and accurately monitor their ECG data.

2.1 Assumptions

- 2.1.1 DELETED
- 2.1.2 The touch sensing electrodes have sufficient sensitivity, such that ECG data can be collected.
- 2.1.3 The data is assumed to be secure since the device is only collecting information at the consumers discretion.
- 2.1.4 The frequency range of the normal human PQRST wave ranges between 0.5 and 20 Hz².

2.2 Constraints

- 2.2.1 DELETED
- 2.2.2 The device does not have wireless communication functionality.
- 2.2.3 The device shall serve as biometric data monitor for non-emergency monitoring use only, not as a diagnostic device.
- 2.2.4 The device shall require an SD card in order to share data.
- 2.2.5 The device has limited battery life.
- 2.2.6 The device shall require the user to remain stationary during use.

3.0 Requirements

3.1 User Requirements

- 3.1.1 The device shall be considered aesthetically pleasing to a panel of prospective users (both engineers and non-engineers).
- 3.1.2 The device shall be operable with included instructions.
- 3.1.3 The device shall cost under \$100.
- 3.1.4 The device shall produce ECG data.
- 3.1.5 The device shall have easily comprehensible data displayed on an LCD graphical interface (evaluated by a panel of both engineers and non-engineers).
- 3.1.6 The device shall weigh less than 100 grams.
- 3.1.7 The device shall be portable.
- 3.1.8 Data acquired by the device shall remain confidential to the user.

3.2 System Requirements

3.2.1 Performance Requirements

- 3.2.1.1 The device shall be able to perform for 24 hours with a 9V battery
- 3.2.1.2 The device shall have a minimum lifespan of 1 year.
- 3.2.1.3 The device microcontroller shall have a 16 GB SD card.
- 3.2.1.4 The device shall be able to withstand collisions at under 5 m/s.
- 3.2.1.5 The device shall output an ECG signal comparable to that of a 10 electrode, 12-lead ECG.

3.2.2 Software Requirements

- 3.2.2.1 Data acquired by the device shall be visible without additional required purchases.
- 3.2.2.2 The device shall have a processing speed of 16 MHz.
- 3.2.2.3 The device shall use Arduino-based software.
- 3.2.2.4 The ECG signal shall be made visible in less than 45 seconds.
- 3.2.2.5 The device shall include a programmed real-time clock to keep track of the date and time of recording sessions.

3.2.3 Hardware Requirements

- 3.2.3.1 The device shall use a 9V battery.
- 3.2.3.2 Data acquired by the device shall have a means of external storage (SD Card).
- 3.2.3.3 The device shall be housed in a 3D printed container.

3.3 Interface Requirements

3.3.1 Input Requirements

- 3.3.1.1 Voltage inputs shall occur through contact-based sensing electrodes.
- 3.3.1.2 DELETED
- 3.3.1.3 Input voltage shall be received by the device electrodes through interaction with the user's fingers.

3.3.2 Output Requirements

- 3.3.2.1 The device shall display an ECG wave on an LCD screen.
- 3.3.2.2 The device shall display date and time on an LCD screen.
- 3.3.2.3 The time between signal amplification/filtering and data representation shall occur in under 3 seconds.
- 3.3.2.4 Data shall be stored on an SD card in a file format readable on a PC/Mac.

References

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