

Verification and Validation Report
Data Acquisition System in Low Resource Settings

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1. Overview

The Blantyre Malaria Project (BMP) is researching treatment interventions for cerebral malaria in low-resource settings (LRS). The disease primarily affects African children, and a hallmark in its progression is brain swelling.¹ The research site, the Queen Elizabeth Central Hospital in Blantyre, Malawi, has one of few MRI units in Africa. To improve cerebral malaria (CM) outcomes, the BMP is researching disease progression indicated by heart rate variability analysis (HRV).² In conjunction with Etiometry Inc., a healthcare technology company based in Boston, data from ECG waveforms, blood pressure, and pulse oximetry will be used to create predictive algorithms for early disease intervention. This project aims to build a data acquisition system that will collect and archive high resolution data to a remotely accessible server for researchers in the U.S. The designed system will be cost-effective, maintain resolution fidelity, and support remote access.

2. Updates from Progress Report

2.1 Need

There have been no changes to the need statement.

2.2 Scope

There have been some changes made to the scope. Specifically, the device will only need to collect ECG data and heart rate (HR) for heart rate variability (HRV) analysis. Real-time monitoring of the collected data is no longer required. The other additional biomarker information, such as pulse oximetry and invasive blood pressure, are no longer required.

2.3 Design Specifications

The changes made to the design specifications are as follows: invasive blood pressure and pulse oximetry are no longer required measurements and data transmission no longer

needs to be between buildings or across brick and steel walls. Full project design specifications are shown in Table A.1 with changed parameters striked through.

2.4 Design Schedule

There have been no changes to the design schedule.

2.5 Team Responsibilities

There have been no changes to team responsibilities.

3. Verification Plan

To ensure that the device works according to the design specifications, it will need to collect accurate ECG waveforms at a high signal fidelity. Once the data is collected, it will need to be written into a file that can be manipulated and stored. To make sure the data collected is in fact useful and shows accurate biomedical information, this file will be put into a HRV analysis software and the results will be analyzed. Finally, the data will be uploaded onto a physical server and a cloud server for storage.

3.1 High Frequency Data

The first step of verification testing is to ensure that the ECG data is collected at a frequency of 200 Hz, which is needed for advanced ECG analysis. To collect the test data, a human subject will be monitored with a patient monitor (GE Solar 8000M with 650SL Tram module) using a 4-lead ECG, with placements depicted in Figure A.1.³ The analog output of the patient monitor will be connected to a 16-bit analog-to-digital converter (ADC, ADS1115) and encoded by a Raspberry Pi (RPi). The data will be collected continuously for 10 seconds at 200 samples per second. This data will then be displayed in the terminal of the RPi software.

3.2 Writing Files

The next step in the verification process is to make sure the device can write the high frequency data into files that can be easily accessed, stored, and analyzed. These will be simple text files which are compatible with both RPi software and the other analysis software that will process the data post-collection. To verify this step, data will be collected for a longer period of time, since the device is supposed to run 24/7. An adequate time period for this initial testing phase will be 5 minutes. The device will then run its code and produce a text file that should be readable by the HRV analysis software.

3.3 Biomedical Signal Analysis Software (Kubios)

After collecting the data file, it is important then to verify that it is the correct signal. This will be done by running the data through a biomarker analysis software and reviewing the final results. The analysis software that will be used to analyze the data files is called Kubios, a medical software used by physicians and researchers to do HRV analysis.⁴ It is free for download, and comes complete with instructions on its website. To test whether Kubios can read the data collected, the data file will need to be manipulated slightly before it is inputted into the software. The software only reads certain kinds of files, and one of these is RR interval ASCII text files.⁵ Thus, the RR interval will need to be calculated from the original ECG data.^{6,7}

Once the RR interval is constructed and analyzed, Kubios will provide detailed report with the appropriate HRV analysis for a given situation. One of these situations will be the test subject running in place for enough time to put stress on their system. This will lead to a change in HR that will be detectable by Kubios. Being able to see this change in the analyses will be sufficient for verifying the device's accuracy.

3.4 Server and Cloud Storage

The last step of verification involves storing the data onto a physical server (like a computer) and a cloud server. A file transfer protocol (FTP) can be used to move files from the RPi to another computer.⁸ The RPi can also upload the data onto a cloud server like Google Drive or DropBox through a Wi-Fi connection.^{9,10,11} Checking that the file is saved on the computer and on the cloud server is enough to see if the file transfer has worked, however, Kubios can also be used to ensure that the file has been transferred properly to both servers.

4. Final Validation Testing Plan

The validation process will assess the implementation of the system in the intended site. Validation testing will address the following steps: full system integration, remote software updates, and customer satisfaction.

4.1 Full System Integration

BMP is expecting an automated system that will continuously collect and archive from eight patient monitors in the Queen Elizabeth Central Hospital. The data acquisition unit, consisting of the RPi and the ADC, will be wired together in a single, user-friendly housing. Specifically, it will be wired to receive analog inputs from one patient monitor via a standard 15 pin connection and powered by 230 V wall power. The RPi will automatically collect and transmit ECG and HR signals. These signals will be continuously collected and wirelessly archived to a remotely accessible server once a day. To test the full system, without prompting the RPi, physiological signals will be collected for 10 minutes and archived onto a cloud server.

4.2 Software Updates

The next part of the validation testing plan would be to allow for the RPi to be accessed by Etiometry Inc. so that they can update the software and make changes to the data collection

process, if necessary. The RPi's software can be automatically updated through the unattended upgrades package.¹² As for the physical server, the software to manipulate data collection can be accessed via remote access using VNC connect.¹³ As long as the VNC connect application is downloaded onto both devices, a remote access link can be made to update the RPi software.¹³

4.3 Product Accessibility and Reproducibility

For the final part of the validation process, the data acquisition system will also need to be easily assembled by the group of researchers in Blantyre. A list of materials and a user manual, detailing the connections between the parts of the system and RPi code, will be provided to the client.

5. FDA Process

The data acquisition unit's main function is to obtain data from a patient monitor and convert it to a digital signal, and then transfer the data at a high fidelity to a server to be archived. Since the process does not involve a patient being directly connected to the device, there should be no issues with the device complying with Food and Drug Administration (FDA) regulations.

The device does, however, involve the usage of patient biomarker data to analyze HRV. Therefore, the protection of patient confidentiality needs to be considered. The Health Insurance Portability and Accountability Act (HIPAA) is a personal health information protection law that only applies to U.S. physicians and patients.¹⁴ In addition, Malawi does not have its own data privacy law.¹⁵ Therefore, there should also be no issues with patient confidentiality.

6. Overall Status of the Project

The RPi has been equipped with Raspbian, a git repository, configured with the I²C protocol, and wired with the ADC. Random test data has been successfully read by the RPi and saved as a .csv file on the RPi's internal memory, shown in Figure A.2. In an attempt to collect physiological data using a GE Solar 8000M patient monitor, the output signal from one ECG trace was connected to the ADC and RPi. This test showed that the analog signal was successfully encoded at 200 samples per second, but the recorded voltages were not as expected. The next steps are to verify the collection of accurate ECG and HR signals, perform a test analysis with Kubios, and implement a protocol to wirelessly upload the data to a cloud server.

7. Appendix

Specification	Metric	
Data Acquisition Unit		
Compatibility	GE Solar 8000i Patient Monitor and related hardware	
Safety	No harm to patient or staff.	
Cost	< \$500 for eight units	
Size and Weight	Portable. Fits on medical cart. Less than 10x20x8" and 15 lbs.	
Power	Wall Power: 230 V, 50 Hz, single phase	
	Backup generator	
Mode of Operation	Continuous during length of stay	
Measurement	Waveform: ECG (4 lead), Invasive Arterial Blood Pressure	
	Discrete: Non-Invasive Blood Pressure, Pulse Oximetry	
Frequency	min: 100 Hz	ideal: 200 Hz
Sampling Amplitude	16-bit	
Resolution Range	ECG: 0.5 - 5 V	BP: 0.0V +/- 0.025 V
Transmission	Wireless. Real-time. Digital output to server.	
	Between buildings. Across brick & steel walls. 200 - 300 yards.	
Software	User-friendly interface	
Server Unit		
Storage	Flexible. Will depend on data format and remote storage by client	
Power	Wall Power: 230 V, 50 Hz, single phase	
Software	Receives and archives data in real-time from multiple monitors	
Accessibility	Remotely view and download real time data archived data	
Maintenance	Remote access of software code for maintenance and updates	

Table A.1. Updated design specifications for the data acquisition system. Changes to initial specifications indicated with strikethrough.

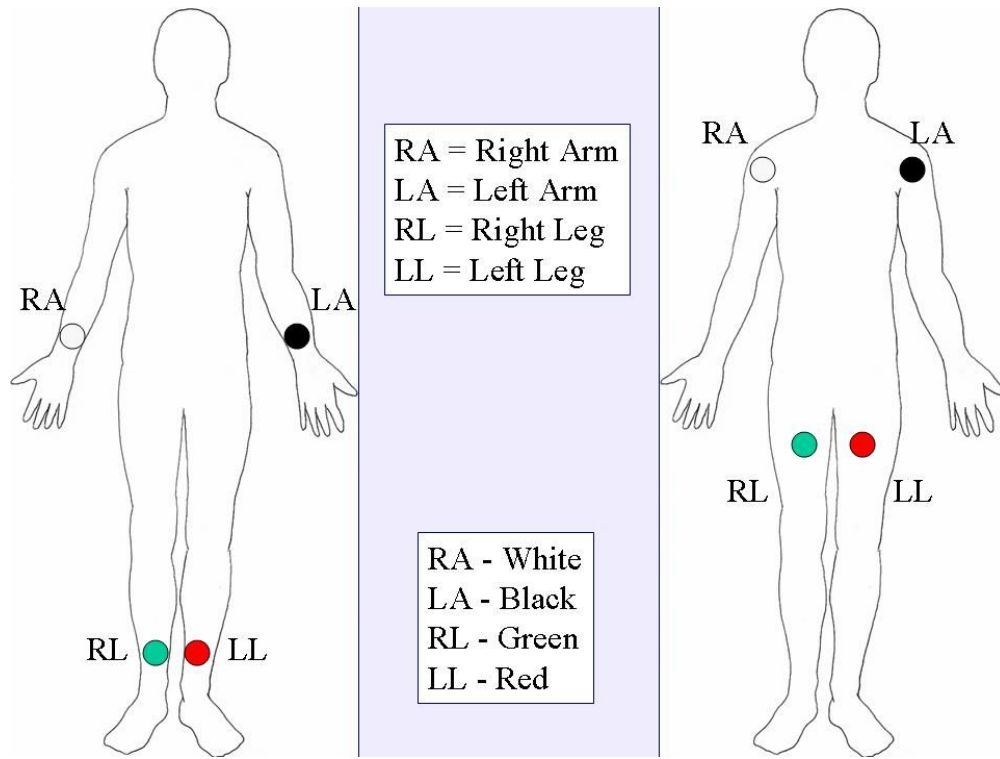


Figure A.1. ECG lead placements on the human test subject.³

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Figure A.2. Screenshot of the test data.

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