Summer Research Training Program
2018 Project Description

Name of Supervisor: Tarek Loubani
Department: Division of Emergency Medicine, Department of Medicine
Office Address: 800 Commissioners Rd E, London, ON N6A 5W9
Email: tarek@tarek.org
Phone: 519-488-6475
Supervisor's homepage (if available): https://github.com/gliax

---

Project Title: Validation and documentation of a High-Quality, Open-Access Electrocardiogram

Project Description – include background, hypothesis, proposed methodology, and expected outcomes (one page maximum; you may attach a page to this form):

Background

The Electrocardiogram (ECG) is a medical device that is the standard of care in the developed world for detecting cardiac pathologies such as arrhythmias, ischemia, and hypertrophy with high sensitivity. Although a vital tool in the emergency department, operating room and ward settings, many rural hospitals and solo clinics do not have access to this piece of equipment. In low-and middle-income countries, ECG's are unattainable due to high costs and the complex nature of ECG interpretation. The initial investment of an premium brand ECG is several thousand dollars. However, following the initial purchase, tests are inexpensive and non-invasive.

Using current rapid prototyping technologies such as 3D printing, it is possible to create an inexpensive electrocardiogram that meets or exceeds the gold standard.

The goal of this project is to design, validate and calibrate an ECG device that costs less than USD$500 to build and is approved by Health Canada. The completed device will be released under Open Hardware License (OHL), such that hospitals and ministries of health in rural and impoverished communities in Canada and internationally would have easy access to these devices.

Hypothesis

This project relies on two pillars: the use of 3D printers and other rapid prototyping technology; and leveraging Open Access and Open Source principles and devices to decrease development costs and disseminate results to stakeholders.

This model has been proved with a simple medical device (the stethoscope) and a more complex device (pulse oximeter). The main question of our research is: Can the successful model that developed, validated and deployed a low-cost stethoscope also be used to develop more complex devices such as an electrocardiogram?

Methodology

Hardware. Design considerations include: cost, availability of parts, ease of construction, quality, ease of maintenance, and ease of use. Preliminary engineering work has been carried out for the

electrocardiogram by Institute for Development of Advanced Applied Systems Rače (IRNAS), an engineering firm located in Solvenia that specializes in creating effective and affordable systems using an open-source model. The electrocardiogram device prototype is currently in production and should be completed by the end of first quarter 2018. A testable prototype should be ready by the beginning of third quarter 2018.

Software. Software is also an important piece of the overall functioning of the electrocardiogram. The software involved in the electrocardiogram involves three aspects: Firmware, descriptive calculations, and interpretation algorithms.

Firmware is the software necessary for the device to function and display the electrical signals of the heart. Descriptive calculations are those calculations of parts of the waveform such as heartrate, PR intervals, QT intervals, etc. Interpretation algorithms are those algorithms that give a clinical prediction of the patient's state based on electrical signals (e.g., ST-elevation MI). The first release of the electrocardiogram will include descriptive calculations. A future version will incorporate interpretation algorithms.

Laboratory calibration.
Design. Calibration study.
Population. None. Calibration will involve devices that behave as phantoms of electrical heart activity.
Exclusion criteria. None
Method. A spectrum of electrical activity will be transmitted through both the prototype device and the gold standard premium device. Data will be collected from both electrocardiograms and compared statistically against the source signal to determine accuracy of transmission of the electrical activity spectrum.

Device validation.
Design. Equivalence study. Blinded.
Population. Consecutive visitors to a tertiary center emergency department.
Sample size. 250 patients are required to ensure equivalence between a gold-standard ECG and our experimental ECG.
Procedure. Standard 12-lead electrocardiograms will be taken using the prototype electrocardiogram and a gold standard premium device. Data will be compared by a cardiologist to ensure that the prototype is equivalent to the premium device.

Timeline
Final construction of hardware and software: June 2018
Ethics approval: June - December 2018
Calibration Study: June – December 2018
Validation Study: July – August 2019
Write-up and submission: September – December 2019

Expected Outcomes

This project will impact the availability and quality of electrocardiograms in Ontario, especially in solo clinics, rural hospitals and remote outposts. It will also encourage the repair of devices on site, reducing equipment downtime and repair costs.
Glia's stethoscope has already made a significant impact. Replicating this success with electrocardiograms will lead to the wide availability of devices. The availability of specifications for generic manufacturers to

manufacture devices and the subsequent downward price pressure on premium brand manufacturers will increase the standard of care for all patients in Ontario. It will also allow LHINs to save costs while maintaining equivalent quality of care.
In the developing world, these low-cost electrocardiograms will allow ministries of health and hospitals to forgo rationing of these devices and provide them to hospitals and clinics, multiplying the availability dramatically.

Research Environment - Description of the number of research personnel, size of lab, etc.:

Tarek Loubani, Associate Professor in the Division of Emergency Medicine, Department of Medicine.
Carrie Wakem, Project Manager
Melanie Columbus, Research Coordinator
Alex Pavlosky, Research Assistant
Luka Mustafa, Engineer, Inštitut za razvoj naprednih aplikativnih sistemov Rače (IRNAS)

This research will be based in the Emergency department at LHSC, primarily at the Victoria campus. Research in the emergency department is conducted via the Western Emergency Centre for Academic and Research Excellence (WECARE), which is coordinated by Dr. Melanie Columbus and directed by Dr. Jon Dreyer.

Expected Objectives/Accomplishments for Student for Year 1:

- Review literature regarding electrocardiogram
- Understand and familiarize oneself with the philosophy of Free/Open hardware as a model of improving access to health
- Help in the Research Ethics Board application
- Help in the setup of a calibration experiment for the device
- Provide support to users and feedback to the engineering team to improve the device

Expected Objectives/Accomplishments for Student for Year 2:

- Participate in the calibration study and collect and preliminarily interpret data
- Participate in the validation study and collect and preliminarily interpret data
- Participate in reliability testing
- Help to prepare submission to Health Canada for final approval of the device
- Help to prepare publication of the device

REB approval is still pending, but no obstacles are expected for the routine calibration of the device. No REB approval the first part of this project.