REB ID: 107952
Calibration and Validation of High Quality Low-Cost 3D Printed Pulse Oximeter

General

1. This study has been tabled as the Board has major concerns with the risks to healthy participants due to the cannulation of the radial artery (not described) and dropping the blood oxygen down to 70%. Please comment on whether there will be a full ICU monitoring system in place, how the participant will be protected and whether the study is done during the normal shift of the ED physician. Additionally, please comment on whether there has been agreement with the ER to carry out this study and who will monitor the participant to let the physician know if something happens

a. **There will be a full intensive care monitoring system in place**. The study will be carried out in the trauma bay of the Emergency Department of the Victoria campus of London Health Sciences Centre.

b. **Dr. Tarek Loubani, a licensed and experienced emergency physician, will be available exclusively for the trial participants.** He will oversee all participants involved. Other emergency physicians may be called into the trauma bay if they are needed on an on-call basis as per the usual flow of the emergency department, however Dr. Loubani and the nursing team dedicated to the trauma bay would be able to handle any resuscitation situations at gold standard levels of practice.

c. **The participant will be protected by continuous intensive care monitoring of vital signs.** The participant will be located in the highest acuity portion of the emergency department, the trauma bay. The participant will be watched continuously by Dr. Tarek Loubani for the entirety of her or his involvement and an observation period after the study. All monitoring will be done by Dr. Tarek Loubani.

d. **This project is carried out with the full approval and agreement of the Division of Emergency Medicine.** Dr. Tarek Loubani is a member of the Division of Emergency Medicine. Dr. Melanie Columbus is the research coordinator of the Division of Emergency Medicine, and oversees all research activity in the Division. Dr. Adam Dukelow (chair/chief of Emergency Medicine) and Dr. Vico Dagnone (Site chief of Victoria Campus Emergency Department) are both aware and fully support this project.

e. **Regarding arterial cannulation.** This is a very safe and common procedure in the emergency room, very similar to taking blood through an intravenous. I have attached a review article and a slide show explainer of the procedure showcasing its safety and efficacy as well as the procedure.

f. **Regarding the need for desaturation.** This is also a very safe procedure, and is **recommended by the FDA** for all pulse oximeters: “We recommend you follow Clause 201.12.1.101.2 and Annex EE.2 of ISO 80601-2-61:2011 *Procedure for invasive laboratory testing on healthy volunteers,* or equivalent method to validate the SpO_2 accuracy specifications of your pulse oximeter system by comparing each value from your system and a simultaneous value from co-oximetry of an arterial blood sample.”

Attached is section 4.1.1 of the guidance document “Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff”, as well as the entire document. An online version may be found here:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm341718.htm#s4

2. Please comment on any potential financial conflict of interest
The **primary investigator (Tarek Loubani)** has no real or perceived financial conflicts of interest. Research support staff **Melanie Columbus, Kevin Wood and Kristine Van Aarsen** have no real or perceived financial conflicts of interest.

Western Protocol
3. Section 1.4 indicates that this is not a student project but 1.3 indicates that funding is from a Summer Research Training Program for a research assistant medical student. Please clarify and comment on who will pay for human and material resources beyond the student

This project is by Dr. Tarek Loubani. Three research assistants (two medical students and one engineering student) will help with data collection, clerical work, data entry, etc. One student has a stipend paid by the Summer Research Training Program of the medical school. The other two students are volunteers.

All materials related to the study will be paid for personally by Dr. Tarek Loubani. This project is not being funded in any way by pharmaceutical or medical devices companies. The end goal is to release the project's results as open access hardware for wide use and dissemination.

4. Section 2.3: Section 2.2 indicates that the software needed to make the prototype still needs to be designed and written. Please comment on who, where, what testing, whether this is open or closed source code and the maintenance for this

Source code and all material related to this project is and will remain open source. A current version of the software to power the pulse oximeter is here, and attached to the application. It is currently ready for testing:

https://github.com/GliaX/oximeter/blob/master/oximeter_code.ino

Dr. Hanan Anis, professor of engineering at University of Ottawa, will be responsible for the quality of the source code. The source code will be tested using the Arduino software. Maintenance will be carried out by Dr. Hanan Anis and Dr. Tarek Loubani after release of the final pulse oximeter in collaboration with the open source community as per the accepted norms of open source software collaboration.

5. Section 2.6: Please indicate whether patients with pneumonia will be excluded

Patients with pneumonia or any other acute or chronic lung disease will be excluded from the first phase of the study.

6. Section 4.4 and 4.7: Please submit these to the REB once received. Please note that ethics approval will be withheld until the NCT# is received

Acknowledged.

7. Section 6.7: Please note that first patient contact should be made within the circle of care

This will be noted for Phase 2. Phase 1 consists of healthy volunteers. This has been modified in the resubmitted document as a tracked change.

8. Section 6.7: There are recruitment emails that are submitted to the REB for review. Please include this in this section and revise the confidentiality section accordingly

I believe this was intended to be Section 6.5. This has been ammended to read:
Phase 1: By poster or via email

Phase 2: In Person in the Emergency Department. First patient contact will be within the circle of care

9. Section 7.17, 7.20: This contradicts section 7.1 and 7.2 which indicates that no personal identifiers are being collected. Please clarify

No personal identifiers are collected from participants or patients, such as name, identification number, etc. Each patient will be assigned a unique serial number that is randomly assigned so that the patient's data can be tracked during data entry and analyzed at a later time. After data entry and validation, the original data collection material will be destroyed.

Section 7.17 has been rewritten as follows:
All data collected will be maintained on the LHSC "P" Drive in a password protected folder. Investigators will only look at or analyse data on LHSC computers. Data will only be passed between investigators on encrypted memory sticks or through the LHSC secure FTP sites. Hard copies will be stored in a locked filing cabinet and destroyed once the data has been electronically recorded. Data will be coded with unique identifiersserial numbers to facilitate data entry and validation. The serial number will in no way identify the patient.

Section 7.20 has been rewritten as follows:

Data will be coded with unique identifiersserial numbers to track data entry and validation.and the master list containing any identifiers will be stored separately from the collected data. After the relevant information is collected from the participant and recorded in a secure password protected databaseexcel spreadsheet, and data validation is complete, the original data collection form will be destroyed.

Letter of Information (phase 1)
All items noted below have been incorporated

10. Page 1: Please explain arterial catheter in lay terms

11. Page 1: “Two cubic centimetres of blood will be drawn for...” Please quantify this using ml or tsp/Tbsp
12. The device is called “high quality”. Please re-word this as this is coercive
13. Please explain external catheter, calibration and validation in lay terms
14. Please include information as to how blood pressure and heart rate will be monitored during the testing
15. Please indicate whether the participant can withdraw their data if they withdraw consent
16. Please include information on what will occur if there is a research related injury
17. Please include the risks of the arterial line ex. pain, thrombosis, hemorrhage etc.

Letter of Information (phase 2)
All items noted below have been incorporated

18. Please indicate whether the participant can withdraw their data if they withdraw consent
19. The device is called “high quality”. Please re-word this as this is coercive