Team Name: BioactiVT

University: Virginia Polytechnic Institute and State University

Team Members:

Jorge Cadena (Electrical Engineering-2015)

Charles Roco (Biological Systems Engineering-2015)

Emily Beauchamp (Engineering Science and Mechanics-2016)

Eddie Krutyanskiy (Mechanical Engineering-2016)

Eleanor Nave (Marketing Management, Management-2016)

Kerry Page (Mechanical Engineering-2016)

Nathan Roberson (Engineering Science and Mechanics-2016)

Amy Romero (Electrical Engineering-2016)

Priya Venkatraman (Materials Science and Engineering-2016)

Angad Verma (Mechanical Engineering-2016)

Gina Muan (Biological Systems Engineering-2017)

Mishu Barua (Mechanical Engineering-2018)

Parker Benzie (Mechanical Engineering-2018)

Andy Cohen (Mechanical Engineering-2018)

Taylor Donaghy (Mechanical Engineering-2018)

Problem Definition

Essential for monitoring pulse and blood oxygenation levels, pulse oximeters are nearly universal in operating rooms in developed nations, but they are scarce in much of the developing world. The World Health Organization (WHO) has declared closing this "pulse oximetry gap" to be a global health priority [1].

Approximately 77,700 operating rooms throughout the world lack pulse oximeters, and 31.5 million operations per year are conducted without them. This leads to 100-1000 times more deaths per capita in developing nations [1]. Extant devices fail to adequately address the challenges specific to limited-resource settings that contribute to the pulse oximetry gap, identified as follows:

1. Cost/quality trade-off: Hospital-grade pulse oximeters range from $200-4000, and fail to consider the costs of replacements and repairs that render many devices unusable [3,4].
2. Power unavailability: Much of the developing world lacks the consistent, abundant power required by current oximeters [6]. Even South Africa, the country with the second highest GDP in Africa, is threatened by periodic, unpredictable blackouts. [7] Though rechargeable batteries somewhat address the power issue, disposables are often difficult to obtain and risk having the machine shutting off during surgery [4].
3. Improper sanitation: Current fingertip devices are typically sanitized with rubbing alcohol, and often harbor bacteria due to incomplete cleaning by medical workers

Impact on Developing World

There are currently no pulse oximeters capable of operating without use of the electrical grid or batteries. However, in the market of supplying pulse oximeters to low resource hospitals, an organization called Lifebox has a product that costs $250 per unit. Lifebox has provided over

7,000 units distributed to over 90 countries Their device has been tested for accuracy and meets the FDA's specifications. Lifebox has conducted many research studies proving the need and effectiveness of supplying pulse oximeters to developing hospitals. Lifebox's groundwork enabled BioactiVT to identify the need for a better design. Future alternatives to a standalone device will be a mobile powered sensor and application. These devices have started to be developed but are not yet approved by the necessary organizations.

BioactiVT's pulse oximeter surpasses Lifebox's design because of the independent power sources and lower costs. The design incorporates the use of thermoelectric generators. These Peltier cells run off the the temperature differential of a person's skin. The use of thermoelectric generators enables the pulse oximeter to run independent of an unpredictable power grid.

Required Performance Specifications

There are 510(k) premarket notifications set forth by the FDA in regard to pulse oximeter devices. Although devices in developing countries may not be regulated by organizations like the FDA, the device must meet and exceed the most rigorous standards as there is no room for error and there are fewer resources to fix faulty equipment in developing countries [3]. Many of the requirements in this 510(k) are in compliance with regulations also outlined by the International Organization for Standardization (ISO). Some important specifications include acquiring an accurate SpO_2 reading within the 70% to 100% range, displaying an accurate pulse rate for extended periods of operation, using biocompatible materials, and the incorporation of an alarm at appropriate limits and ranges [8]. The team's device intends to meet or surpass all device specifications. Accuracy of SpO_2 readings and pulse rate, in addition to alarms, can be found in the fourth section. Biocompatibility of the aluminum pieces that will contact the skin has been confirmed by aluminum information available by the Center for Disease Control, who states that dermal contact may result in “very small” amounts of exposure, which would not lead to any adverse health effects [9].

Implementation of Prototype

The proposed solution is an adjustable reflectance pulse oximeter powered by a patient’s body heat. Once calibrated, the ratios of the red and infrared light can be used to calculate the percentage of blood that is oxygenated. The device takes advantage of hemoglobin’s ability to absorb and reflect light differently based on its oxygenation level. Blood oxygenation levels and pulse rate are acquired by passing red and infrared light through the patient's wrist with photodiode sensors enumerating the amount of reflected light. Every heartbeat will noticeably increase the oxygenated blood present, creating a peak. The device can determine the pulse rate by counting the amount of these peaks over time. The design will consist of Peltier cells that are capable of converting a temperature differential to electricity. One side of the Peltier cell will be exposed to the patient’s warm arm, while the other is attached to a heat sink that will maintain colder ambient temperatures. All parts that will contact the patient will be made of removable aluminum parts that can be easily sanitized by being placed in boiling water, alcohol wipes, or other means of sanitation.

Figure 1 shows the isometric view of the prototype, while Figure 2 shows the view from below, showing the plates which will contact the patient, as well as the LEDs and photodiode used for the pulse oximetry. Figure 3 shows a labeled, exploded assembly of the prototype.

Figure 1. Isometric View of Pulse Oximeter Prototype

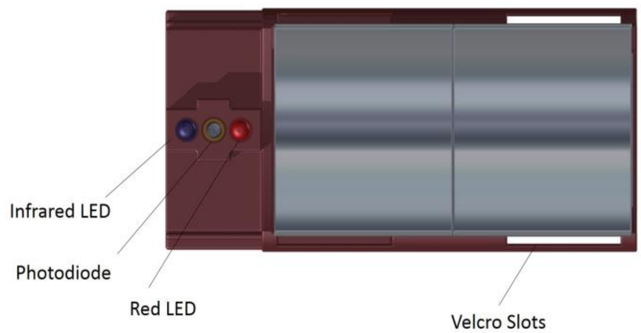

Figure 2. Bottom View of the Prototype

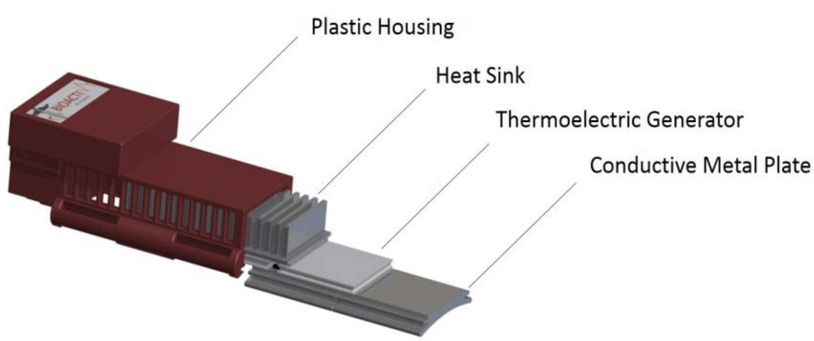

Figure 3. Exploded Assembly

Proof of Performance

The functionality of our design is supported by numerous experimental publications and research. Thermoelectric generators have been proven to produce enough power when in contact with human skin [5]; experimental data have concluded that these generators produce at least 100 microWatts per unit area, which is sufficient to power a pulse oximeter. Pulse oximetry itself is an older technology and is easily incorporated into current strategies for assessing patient health. The World Health Organization has extensively discussed the negative effects of not having a pulse oximeter in an operating room while a patient is under anesthesia. Both untethered and cost effective, this device which harnesses body heat to function will resolve the 'pulse oximetry gap' in developing nations.

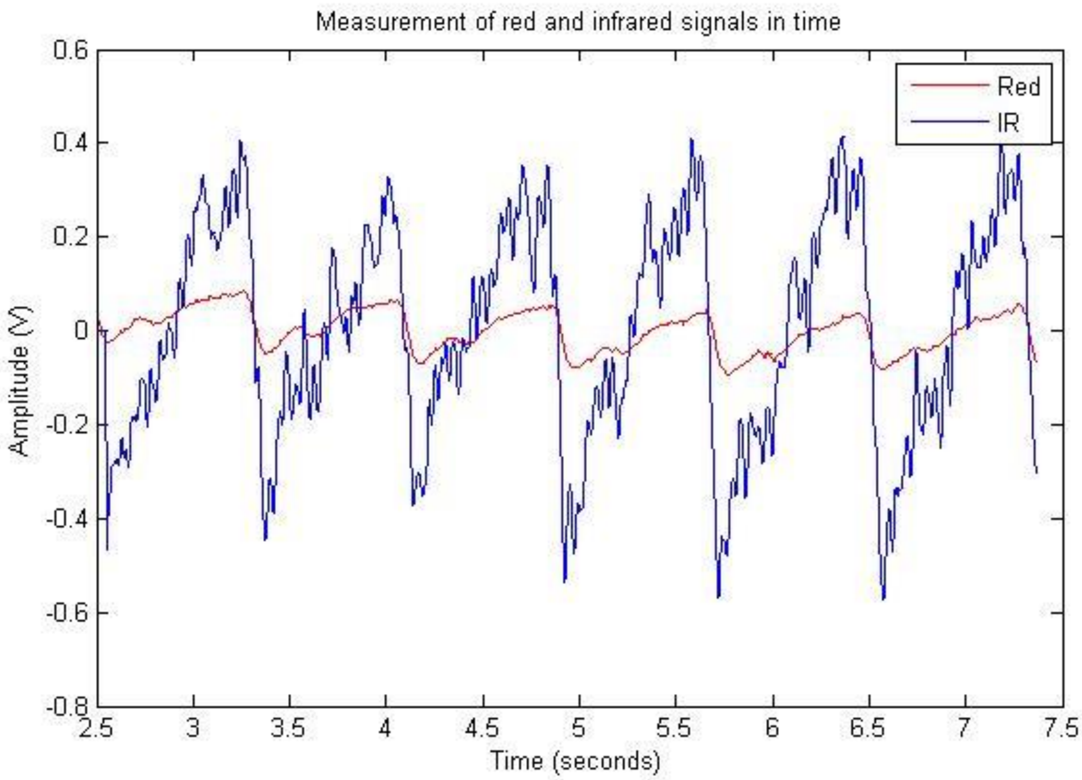

Figure 4. Measurement of signals in time

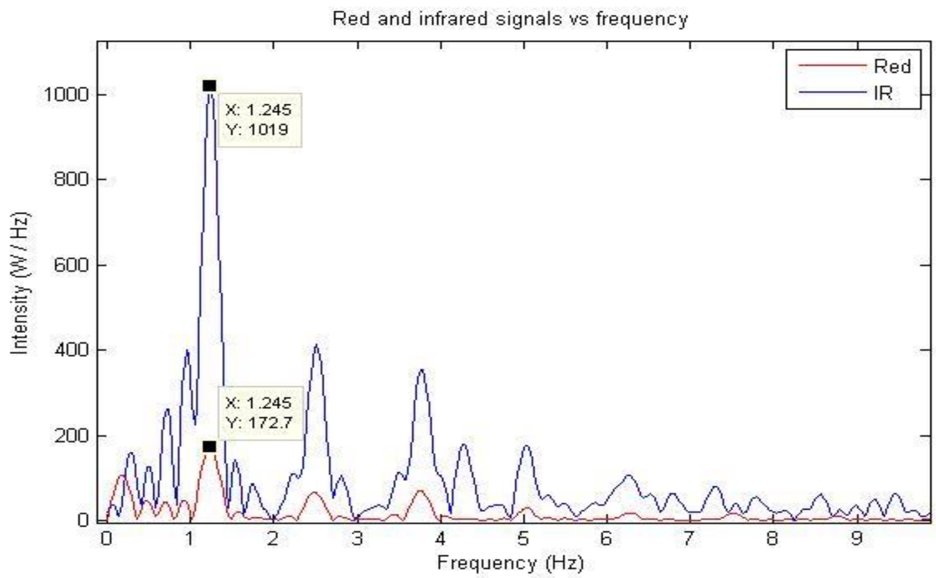

Figure 5. Frequency components of the signals

Figure 4 shows the heart rate of a healthy subject measured in time, using both red and infrared lights. Figure 5 shows the corresponding Fourier transform of the measurements. It can be seen that at the fundamental frequency of 1.245 Hertz (corresponding to 74 beats per minute) we get a ratio of close to 6 between infrared and red light intensities. With proper calibration and empirical testing, an equation to fully characterize a pulse oximetry curve can be obtained for this particular design. [*note*: the other bumps at other frequencies are part of the signals as well, but they are related to their shape and not to the intensity at the frequency of interest (the heart rate frequency)]

Patent Search Results

Currently, batteries power portable pulse oximeters. This solution is feasible only if those batteries can be replaced once they expire; the useful duration is approximately 72 hours. In the developing world, such a disposable power source is environmentally and economically wasteful. Instead, the solution presented is to incorporate thermoelectric generators into a pulse oximeter.

As of May 4, 2015, the results of a patent search reveal various components of the product, but none that are replicas. The results are as follows (in order of importance).

1. V.Leonov. “Thermoelectric generator for implants and embedded devices.” US 20090292335 A1 Nov. 26, 2009.

2. P. N. Cutchis, L. A. Pranger, D. G. Smith, W. P. Wiesman. “Emergency life support system.” US 6,848,444, Feb. 1, 2005.

3. P. Fiorini, V. Leonov, S. Sedky, C. Van Hoof, K. Baert. “Method of manufacturing a thermoelectric generator and thermoelectric generator thus obtained.” US 7,723,606. May 5, 2010.

Our design combines two previously patented technologies to solve a unique problem in a previously research domain. A similar design approach has been researched and published using a thermoelectric generator and a transmittance pulse oximeter [5]. Due to our global health approach, the proposed design and business idea is not planned to be a for profit company and thus unless further design improvements are made the team will not attempt to get a patent for this design. Previous research in the area focused on proving the technical feasibility as opposed to building, manufacturing and creating a sustainable ecosystem around the device.

Reimbursement

Because our design is aimed towards implementation in developing countries, it would not be reimbursable by Medicare or Medicaid. However, alternative programs exist that would address the monetary need. One such program is the Wellcome Trust which “bridges the gap between fundamental research and commercial application by funding projects to a stage where they are attractive to follow-on funders, such as venture capital firms, industry and public-private partnerships.” They support a wide spectrum of technologies and therapeutic projects; the key criterion for the ‘Pathfinder Award,’ one of their six main categories, is that the project addresses an unfilled medical need or is an enabling tool in healthcare research and development.

Similarly, the Bill and Melinda Gates Foundation has a Global Health Investment Fund which seeks to fund “clinical development of global health priorities and develop a vehicle to attract private sector capital.” Its co-investors include GSK, Merck and J.P. Morgan Social Finance. In the past this fund has provided considerable grants to universities involved in both research and on site testing of medical systems and devices.

Potential Market and Impact

Developing nations account for approximately 80 percent of the world’s total population, and also make up approximately 97 percent of global population growth. Due to high mortality rates, the low life expectancy and the increased awareness of healthcare need, the market for healthcare in developing countries is continuously growing.

The demographic the thermo-pulse oximeter is targeting are developing countries in need of improved healthcare services and equipment. When patients in these countries are going into surgery they should be monitored by pulse oximeters thereby increasing survival rates during the surgeries.

Our focus customer for the product is the healthcare facilities that exist in the third world countries already. We first want to center on ensuring that the existing structure of healthcare facilities have the proper pulse oximeters when entering the market. We can then move on to have non-profit organizations who provide healthcare in the developing countries using the product. Our first focus is ensuring that as many people in these countries have access to the product and ensuring that the quality of healthcare is increasing there.

The establishment of oversea distribution channels will be key to our allocation success. A partnership with nonprofit organizations such as PATH, USAID, or The Bill and Melinda Gates Foundation will open a path to distribution. Each of the partnerships are aimed to target organizations that currently have efforts based in developing countries that will help establish oversea connections. Partnerships can reinforce the low cost of the product. Eventually we would like to open up new channels to more developing countries once there is a more established product and method of distribution. Today's technology will be a key to our success by using the internet for online ordering and purchasing. In case of issues with delivery, product, etc. there will be a support/troubleshooting service from the online website.

References

[1] World Health Organization. “Global Pulse Oximetry Project.” Geneva: October 2008 [May 15, 2015]

[3] M. Miesen. “If a piece of equipement breaks in a hospital and there’s no one to fix it, does it make a sound?” Internet: http://www.whydev.org/if-a-piece-of-equipment-breaks -in-a-hospital-and-theres-no-one-to-fix-it-does-it-make-a-sound/, Feb. 19, 2014 [May 15 2015].

[5] T. Torfs, V. Leonov, C. Van Hoof. “Body-heat powered autonomous pulse oximeter.” *IEEE Sensors.* EXCO. 2006.

[7] P. Govender. “African power cuts hold off doomsday as sector seeks rescue.” Internet: http://www.reuters.com/article/2015/01/30/safrica-eskom-idUSL6N0V86CW20150130, Jan 30, 2015 [May 30, 2015].

[8] Food and Drug Administration. “Pulse Oximeters- Premarket notification submissions [510(k)s]: Guidance for industry and food and drug administration staff.” Internet: http://www.fda.gov/RegulatoryInformation/Guidances/ucm341718.htm#s4, Mar. 4, 2013 [May 15 2015].

[9] Agency for Toxic Substances & Disease Registry. “Toxic substances portal- Aluminum.” Internet: http://www.atsdr.cdc.gov/phs/phs.asp?id=1076&tid=34, Sept. 2008 [May 15 2015].

standards references: ISO 80601-2-61:2011

Letter of Support

To Whom It May Concern:

I would like to nominate our Virginia Tech Undergraduate BME Design Team ‘BioactiVT’ for consideration to the BMEStart competition. As the faculty advisor for this group, I can attest that these students are very dedicated to the implementation of their design and to making a global impact.

For their debut year as a design team on campus, BioactiVT has been involved in the process of developing a wearable pulse oximeter for distribution in third world countries. This device would monitor the pulse rate and blood oxygenation of patients undergoing anesthesia in the hopes of minimizing surgical accidents or casualties. The device is powered by thermoelectric generation from the wearer’s own body heat and outputs the necessary information on a display screen. The renewable aspects of its power source and sanitation process, among other components, serve to reduce cost of production.

If chosen for to participate in BMEStart, BioactiVT will deliver a high caliber pitch. Being a part of this competition will make a tremendous impact on the team and encourage the students to continue down the path of engineering design for global health issues. I hope you were given the sense that I feel very highly of the BioactiVT team and they have my full support.

Sincerely,

Dr. Pamela VandeVord