The University of Texas at Austin

Engineering World Health

# FreePulse: A Low-Cost Patient Monitor

## Design Team

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May 30, 2015

# 1 Problem Definition

A patient monitor is a mechanical and electrical medical device designed to continually monitor a patient's vital signs in order to identify respiratory or cardiac distress. Patient monitors play a crucial role in virtually all aspects of medical care, including emergency and surgical units, intensive and critical care units, and other non-critical units. Patient monitors are a staple item in developed world hospitals; however, in crowded developing world hospitals, a low patient-monitor-to-patient ratio prevents doctors from performing a sufficient number of surgeries to meet the needs of the local population as well as effectively treat patients in critical care. The reason for this shortage of patient monitors can be primarily attributed to cost of current market models, ranging anywhere from $1,000 to $10,000 [1, 2]. This high cost forces developing hospitals to largely depend on outside donations for new devices, an infrequent and unreliable source of critical equipment. There is a clear and demonstrated need for a low-cost patient monitor that can be purchased in bulk by developing world hospitals, thus giving many more patients the monitoring they need.

In a case study of a large public hospital in Gitarama, Rwanda, one of our team members working with Engineering World Health found that although the hospital had over 400 beds for patients, only five patient monitors could be accounted for in the hospital's inventory. In the emergency care ward, only one monitor was available to keep track of three intensive care beds; when multiple patients in the emergency care ward were unstable, the nurses continually cycled the patient monitor between the three beds. Furthermore, although the hospital had multiple rooms and anesthesia machines in the surgery ward, only two surgeries could be performed at a time due to a lack of monitoring equipment. This bottleneck meant that patients waited for days before undergoing crucial surgeries, thus slowing the flow of patients and, inevitably, creating more patients whose condition needed to be monitored constantly. This problem is not by any means isolated to this one public hospital, and due to this shortage of patient monitors, hospitals cannot effectively take care of their patients. Clearly, the lack of accessible monitoring equipment is a crippling issue for developing world healthcare systems.

## 2 Impact in the Developing World

In response to this problem, we developed FreePulse, a low-cost patient monitor that serves as an accessible and affordable alternative to conventional patient monitor technologies. FreePulse provides the same critical services as existing patient monitors, including electrocardiogram data (ECG), peripheral capillary oxygen saturation ($SpO_2$), and heart rate, while costing substantially less than currently existing market equivalents [1, 2]. Furthermore, it is designed with developing world hospital environments in mind; a rugged plastic case allows the device to endure rough and consistent usage, while a 1200 mAh rechargeable battery with uninterrupted power supply keeps the monitor running even in inconsistent power conditions. It is common for devices to be used by untrained or overworked staff, especially in larger public hospitals in developing countries, and as a result, overly-complex devices are often abandoned or marked as broken and never see use on the hospital floor; FreePulse takes this into account by using an extremely intuitive touch screen interface, requiring virtually no training to begin using the device. With these features and an approximate manufacturing price point of $72, FreePulse offers the consistent monitoring that patients require at a cost that developing world hospitals can afford in bulk.

Given the widespread need for this technology, even a small distribution of FreePulse monitors can make an enormous difference in the lives of patients in developing world hospitals. Take our case study in Rwanda for example: there are 47 district hospitals and 500 health care centers that service about 7.65 million people annually, according to the Demographic and Health Surveys Program [7, 8, 9]. If we can provide at least 12 monitors per hospital and 8 monitors per health care center, we could immediately help millions of people in Rwanda. Twelve more monitors in a hospital means that nurses wouldn't have to switch monitors between patients in intensive care, reducing the risk of infection; it means that there would be more monitors available for surgery wards and faster patient turnover, helping people recover more quickly and return to supporting their families. As production of FreePulse monitors scales up, so will the impact, and given the breadth and depth of harm that is caused by a lack of patient monitoring, this impact is desperately needed.

# 3 Required Performance Specifications

In order to be effective in a developing world hospital environment, FreePulse must satisfy a particular set of performance specifications regarding its measurements, power usage, and durability. FreePulse's achievement of these specifications will be expounded upon in the "Implementation of Prototype" and "Proof of Concept" sections.

## 3.1 Durability

The patient monitor must be able to withstand a variety of outside forces that it may come in contact with. This includes drops, requiring an internal design that will not break upon impact; water exposure, requiring a waterproof internal design or sealed case; power outages, requiring at least two hours of backup battery life to give time for wall power to be restored or generator power engaged; and climate extremes, requiring that a circuitry design will function as intended in extreme temperatures and humidities.

## 3.2 User Interface

Devices built for the developing world should be effective in their function but also intuitive to use, requiring minimal or no training. Due to the high demands of emergency care in the developing world, doctors and nurses will reject or discard devices that require too much time to understand or operate. No matter the internal complexity of the device, the user's black box view must be clean, simple, and intuitive.

## 3.3 Hardware

To function at the level of current market competitors, FreePulse must be able to measure an ECG signal using the 3-lead method as well as determine the user's heart rate and $SpO_2$. The sampling rate provided by the hardware must be at least faster than the limit determined by Nyquist's theorem, which is two times the highest component frequency of the signal to be measured. Preliminary Fourier transform analysis of patient ECG signals suggests this absolute minimum baseline frequency is approximately 1000 Hz, and in order to consistently acquire high-quality signals, higher sampling rates are required.

## 3.4 Software

In order to minimize user frustration, software must be fast and responsive at all times. Since a microcontroller is proposed as the computational centerpiece of the design, the software must be written to be memory efficient, or as minimally computationally expensive as possible, but still provide all the necessary features that FreePulse has set out to have. This includes ECG and SpO2 tracing, heart rate calculation, and alarm settings, among other things.

# 4 Implementation of Prototype

The FreePulse patient monitor was designed with these performance specifications in mind. Its portable and durable casing and design makes it an excellent fit for a wide variety of medical applications. While prototyping FreePulse, some key user experiences were assessed.

## 4.1 Durability

A sliding latch with an O-ring seal is one of the key features that contribute to the durability of the FreePulse monitor. The O-ring makes the monitor and interior circuit components waterproof and improves the durability of the monitor. Additionally, the latch allows easy access to these interior components, thus eliminating the need for screws in the FreePulse design. This lack of screws is a major plus for use in the developing world due to the tendency of screws to strip or break under stress.

Another design choice that improves the durability of the FreePulse monitor is the use of ABS plastics on the exterior. The use of ABS plastics make the FreePulse casing very resistant to chemical corrosion, increasing the device's overall life span. These same plastics allow ergonomic and portable design. If the casing were to deteriorate, a new one could be printed using an ABS 3D printer and models downloaded from a publicly available server.

Finally, the production model of FreePulse will include resin-coated electrical components, greatly increasing the durability and life span of the monitor. As a result of the resin coating on our electrical components, fluctuations in humidity will have negligible effects on the circuit components. This feature combined with the O-ring design provides a fail-safe mechanism for protection from accidental water exposure.

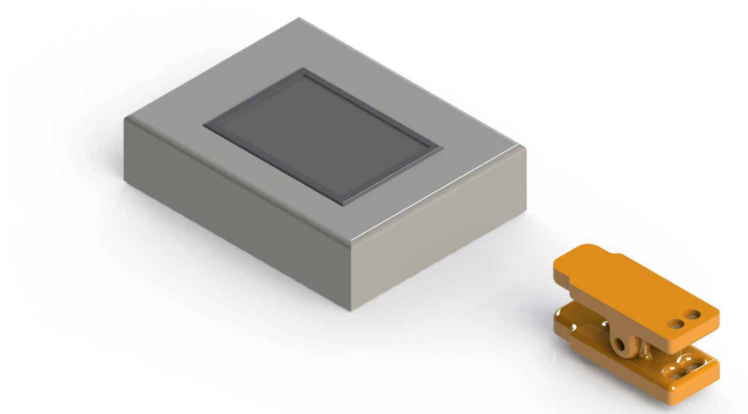


Figure 1: The FreePulse monitor uses only a touchscreen for user interaction and is surrounded by an enclosure made of ABS plastics.

## 4.2 User Experience

The limited number of user input mechanisms on the FreePulse monitor simplifies the user learning curve. The lack of mechanical devices greatly increases the monitor's durability and reduces mechanical complexity. The simplicity of a single touch screen allows the monitor to have an intuitive

UI that is also easily extensible. Text can be translated into the native language of the user, colors can be changed to suit the user's preference, alert systems can be tailored to the user's tastes, and all of these capabilities come from a simple buttonless interface.

Furthermore, the modular design in the production model of the FreePulse monitor adds tremendous value to it as a product and as a platform. Currently, the monitor supports $SpO_2$ and ECG readings. However, the same circuit can be expanded to monitoring muscle activation, analyzing patient temperature fluctuations, and body imaging capabilities. This extensible design allows for damaged modules to be swapped out easily and effectively. It also allows seamless hardware upgrades, preventing the user from having to replace the entire system. This key feature of the FreePulse monitor reduces waste and emphasizes sustainability.

## 4.3 Hardware

The Teensy microcontroller is the heart of the FreePulse circuit. Its low cost coupled with its 74 MHz processing speed gives FreePulse the sampling rate of a state-of-the-art monitor without the price point. This processing power is used to manage the sampling rates for both the ECG and $SpO_2$ probes as well as run the display and power all of the connected peripheral circuits. Furthermore, low-cost miniaturized voltage regulators are used to run the entire circuit from a single voltage source despite differing components and even differing grounds. The ECG circuit uses an active low-pass filter to amplify physiological signals up to 5000 times, while both passive and active filters were used to reject noise and extract a clear waveform to display on the screen. Overall, these disparate hardware components communicate smoothly through the GPIO pins of the Teensy microcontroller, producing a quality signal that rivals the functionality of current market competitors, but at a fraction of the cost.

## 4.4 Software

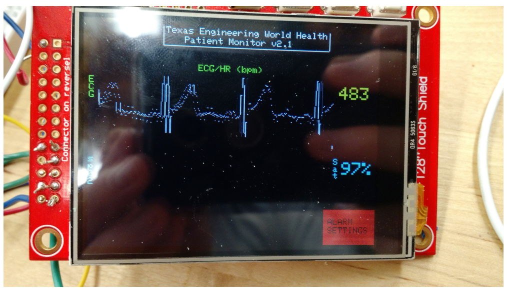
Mirroring the modularity of the hardware design, the software for FreePulse was written with extensibility and speed in mind. The interface's components are written as block items, meaning that they can be stretched and rearranged depending on the screen needs for that iteration of the product. Template classes for signal traces and efficient input buffer systems already exist for the ECG and $SpO_2$ and can be easily extended to be used with any medical input probe. In order to keep the memory footprint of the program as small as possible and optimize operations for this product's use case, custom classes were written for standard library constructs such as vectors. By keeping low-level control over the transfer and storage of data, we were able to maximize the memory and processing resources of the Teensy and create a fluid, responsive, and versatile system. Furthermore, having a total binary file size of 57.9 KB and efficiently using the 64 KB of RAM on the Teensy ensures that the software is both space and time efficient.

# 5 Proof of Concept and Performance

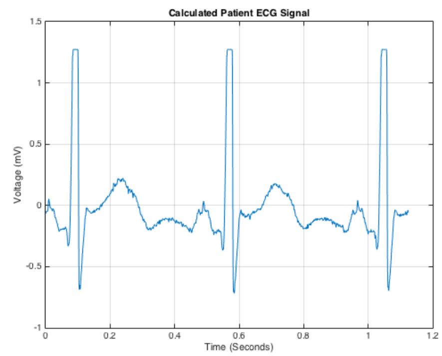
We have demonstrated proof of concept for FreePulse through stage-by-stage testing of our prototype.

## 5.1 ECG Testing

The most complex hardware component of our design is the filtering and amplification circuit for an ECG signal. Critical to the success of signal acquisition is a sampling rate that allows for clear visualization of the input signal; we have set the sampling rate at a controlled 6.67 kHz to achieve optimal signal clarity while retaining a smooth and responsive user interface.




(a) FreePulse capturing and filtering an ECG.




(b) Data read directly from FreePulse's input buffer for the ECG signal. All features of the P-QRS-T complex are clearly distinguishable.

## 5.2 Peripheral Capillary Oxygen Saturation

Our current prototype utilizes both visible and IR LEDs paired with phototransistors to measure the amount of light transmitted through a user's tissue. The LEDs and diodes are housed in a plastic case similar in form factor to traditional finger clip pulse oximeters, and the output of the phototransistors is filtered by a passive low-pass filter. We are currently still developing our calibration algorithm for calculating oxygen saturation from this curve, as it is a very hardware-dependent process; however, initial signal processing is already showing a clear view of the transmittance waveform.

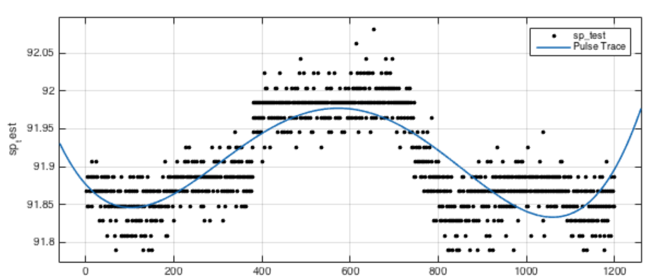



Figure 3: Signal processing allows us to extract the pulse curvature in the transmittance signal.

## 5.3 Battery Capacity

In order to be useful in an inconsistent power environment, FreePulse must be able to run on battery power for a reasonably long time frame. The lithium ion battery in FreePulse has a capacity of 1200 mAh; we also have measured it to have an average power draw of 185 mA with all LEDs illuminated and probes running, meaning the system can run for approximately 6 hours on a single charge. This capacity means that FreePulse is more than capable of continuing to monitor patients during a power outage and can last long enough for the backup power to be initiated or the power grid restored.

## 5.4 Form Factor

Finally, we have tested the feasibility of our product design by producing PCBs and casing for the monitor. Using circuit layout software, we designed a PCB that was small enough to fit neatly behind the touch screen while remaining two layers, reducing manufacturing cost. This circuitry is completely self-contained, running solely on the rechargeable battery due to the use of voltage regulators; this allows FreePulse to be handheld in size.

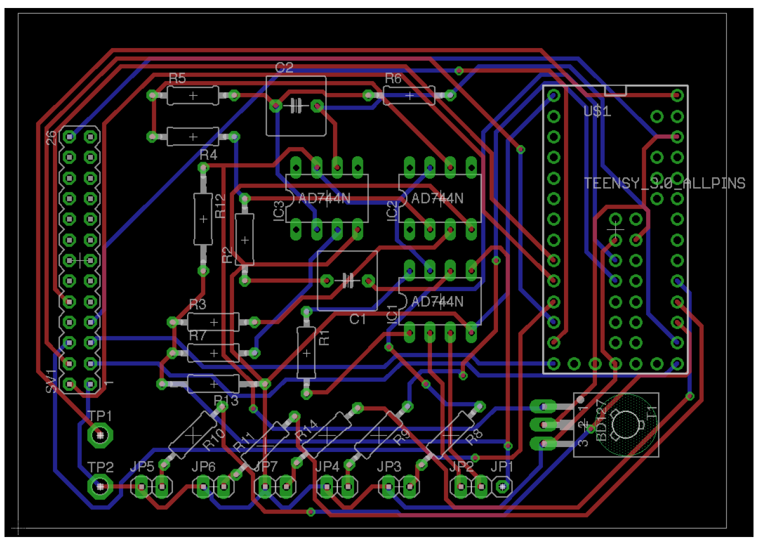



Figure 4: All of the hardware required for the FreePulse patient monitor is organized into a small two-layer PCB.

The data from our prototype serves as a proof of concept that FreePulse can indeed fulfill its core purpose: to provide quality patient monitoring at a cost that is affordable to developing world hospitals. Its high-resolution signal acquisition, six hour battery life, and compact shape suit it perfectly for working in developing world hospitals.

To hear more about the FreePulse patient monitor and its importance for developing world healthcare, watch the following video at:
**https://www.youtube.com/watch?v=NApNLTBnjBY**

# 6 Business Plan for Manufacturing and Distribution

## 6.1 Patent Assessment & Patentability

After analyzing the current medical market in the third world, we discovered that there are no products specifically designed to address the need for a low cost portable patient monitor in the third world. Two major companies dominate the current market: GE Healthcare and Philips Healthcare. One of the most common patient monitors is the Philips IntelliVue MP50, whose baseline specifications include 4 inputs slots, wireless connectivity, a touchscreen and a 5-hour battery life with a price of $4,500 for the baseline version [1]. The market rival for this is the GE Healthcare GE Carescape V100 Monitor, which can determine blood pressure, temperature and $SpO_2$ with price of $2,595 [2]. However, our product is unique in that FreePulse is able to provide ECG and $SpO_2$ readings for a fraction of the price of our competitors. This is one of our major selling points and our biggest advantage since we are submitting a product similar to the many on the market. Additionally, for this reason, we can bypass a majority of the cost of FDA approval and keep our selling price low.

We believe that certain portions of our product are patentable and not exactly similar to certain existing patents. Furthermore, all technologies developed by our team have been documented and verified by an unbiased third party. In order to understand the patentability and the patent landscape for our project we need to first understand where knowledge about different parts of the project has been discovered. The technological section of the device can be broken down into three sections, the ECG amplification and filtering circuit, the Teensy microcontroller, and the $SpO_2$ circuitry. The ECG amplification system was formatted after a circuit from the University of Texas Biomedical Engineering Junior Lab Manual. This manual was created by Dr. Stephen Marek, and with his permission, we are using a modified version of this circuit. Our current patent search has yet to discover a patent that specifically follows our design, but patent number US69670737 B1 has a circuit that is slightly similar to our design. It is very risky to patent this section of the project because this concept is widely used in medical devices. The Teensy microcontroller, which is the primary computational and operational heart of the FreePulse monitor, was purchased; in developing the software for FreePulse, we utilized open source libraries released under the MIT open source license. Under this license we are able to patent any of the code we have created for the user interface and the system alerts as well as the operating code for the functionality of the FreePulse monitor. This code development has been recorded and documented via GitHub, a third party code hosting service. This will allow us to properly patent the code after it has been finalized. The $SpO_2$ circuit was completely developed from a base understanding of how to detect blood oxygen levels via infrared LED and red LED detection. This entire section was developed independently by our team and this code and circuitry behind may be patentable. Patent number US7136704 "Blood Oxygen Monitoring System" and US8583203 "Finger Type Pulse and Blood Oxygen Measuring Device" are similar in purpose but different in design and therefore do not pose any opposition to this section of the project.

## 6.2 Anticipated Regulatory Pathway

FreePulse is considered a Class I device by FDA regulations. Many developing world countries use FDA approval as a guideline for what to allow in their country; in addition to this, government and private organizations within the United States have also expressed interest in the project. Therefore, we will outline our regulatory pathway procedures in terms of FDA approval, which would maximize the impact of our project.

The FreePulse patient monitor has already made progress towards FDA approval during our development cycle. We have already filled out a 510K document, strengthening our market feasibility in third world countries and bringing us one step closer to making our product available for consumers in the United States. The cost to submit the 510K for approval is $2,509, after which there is a waiting period of at least four months. Since our device is classified as Class I, we do not have to file for a premarket approval document, simplifying the approval process [3].

## 6.3 Anticipated Manufacturing Costs

The total manufacturing cost of this product will be approximately $71.73 in bulk, $118.42 individually. This price does not include the soldering and setting of the product or shipping. The assembly of the monitor will be free for now, as the members of the team will assemble it. Once mass production begins we will see this cost increase, but this cost will not be propagated to the consumer. A potential solution will be to purchase floor space and machinery to help assemble this product. The quality assurance will be done upon every completed monitor. This step is considered part of the assembly process and thus currently will not cost us anything except time. Due to the fact that our product will be shipped around the globe, shipping prices will vary depending on location. Overall, we hope to manufacture this product at its bulk price of $71.73.

Table 1: Item Cost, Per Unit.

| Component | Number Required | Price Per Unit (USD) | Bulk Price Per Unit (USD) |
|---|---|---|---|
| Teensy 3.1 | 1 | $20.00 | $5.00 |
| Lithium-ion Charger | 1 | $12.50 | $12.50 |
| Lithium-ion Battery | 1 | $9.95 | $7.50 |
| Op-Amp | 2 | $0.91 | $0.24 |
| Instrumentation Amp | 1 | $8.38 | $8.38 |
| 1000pf Capacitor | 1 | $0.47 | $0.47 |
| 510Ω Resistor | 2 | $1.18 | $1.18 |
| 465kΩ Resistor | 4 | $0.40 | $0.40 |
| Voltage Regulator | 1 | $3.95 | $3.95 |
| PCB Sheet | 1 | $9.00 | $6.00 |
| LCD Display | 1 | $29.99 | $25.00 |
| Soldering Wire | 1 | $10.00 | $6.00 |
| Case | 1 | $10.00 | $6.00 |
| Total Cost | | $118.42 | $71.73 |

## 6.4 Potential Market and Impact

The target market for FreePulse is the third world's healthcare market and third parties' health care product distributors. As of last year, the African health care industry made $850.1 billion in 2014 [4]; more specifically, the Rwandan market was valued at $33 million [5]. Rwanda was chosen as the introductory market because it is the nation in which we initially discovered the need; furthermore, we have many contacts on the ground who have demonstrated that they are willing to work with

Table 2: Assembly Cost.

| Item or Service | Cost (USD) | Cost Per Unit (USD) |
|---|---|---|
| 50-watt Soldering Iron | $26.95 | $0 |
| DE Soldering Iron | $35.95 | $0 |
| Assembly of Product | $0 | $0 |
| Quality Assurance | $0 | $0 |

us to make this become a reality. Once our product has proven its success in Rwanda, we will expand to neighboring African healthcare markets; however, our marketing vision is not limited to Africa. We also have many contacts that will allow us to expand into south Asian healthcare markets, primarily in India. The Indian healthcare market is currently valued at $80 billion and is projected to grow to $160 billion, making it a promising industry to introduce FreePulse into [6]. Due to a clear and present need for low-cost healthcare, the large number of medical practitioners operating in low-income areas, and our contacts within local medical associations, we believe this also can prove to be a very promising market.

The base selling price of the monitor will be $125 in order to clear operational expenses as well as cover the manufacturing and distribution costs, approximately determined to be $71.73. In order to uphold the social goal of providing this patient monitor to as many individuals as possible, we will have a target net profitability of 55%. To provide the lowest possible cost to developing world hospitals, our current plan is to develop a mark I version and mark II version of our product; the mark II version will target developed world consumer use and will contain more user features like smartphone connectivity via bluetooth, and the profits from these sales will allow us to lower the cost of the mark I devices and provide them to developing world hospitals at an even more discounted price than $125.

As mentioned in the analysis of the potential market, our initial target customer will be healthcare medical distributors and hospitals in Rwanda. Most African hospitals receive their medical devices through large medical distributing companies; two of these potential distributors are Misreya Medical, located in Cairo, and Setema Limited, located in Rwanda. After these distributors purchase a bulk order of FreePulse monitors, they will distribute the monitors to various medical practices across their respective regions. The second target market will be hospitals and medical associations. These entities will be directly using the product, and in selling to these groups we will cut out the medical distributors at the expense of an increased shipping cost. These entities may receive support from charities or countries; for instance, St. Consulata, a hospital based in Rwanda, receives support from the UK. Since some hospitals do not know when they will receive financial support or how much, they have to strategize to make the most of their current resources. Since our product is much cheaper than what is currently on the market and provides the same features, these hospitals will prefer our product over competitors. In the end, we hope to see this monitor serving as many people as possible. Given the incredible potential for impact explained previously in the "Impact in the Developing World" section, it is clear that FreePulse will be able to make a significant difference in the healthcare industry of the developing world and achieve its primary goal of providing better care to those who need it most.

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