Self-Administering Pediatric Vital System
May 23rd 2018

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Abstract
The objective of this project is to create a device for pediatric divisions in hospitals to improve gathering vital signs of their patients by incorporating biometric sensors into a stuffed animal. Children tend to be extremely difficult patients because they are scared of being in a hospital, being sick, and feeling unsafe. Giving a child a stuffed animal that acts as a medium for both comforting the child and taking vitals not only frees up doctors and nurses but gives the child something safe in a foreign world.

Currently on the market there are similar devices but they do not record all vital signs. The current versions only measure one or two different vital signs. In our design we would be implementing a version that can measure pulse rate, body temperature, O₂ saturation, and respiration rate. These vital signals are then transmitted wirelessly to a nurses station. The device contains a microprocessor that controls all of the digital signals coming back from the sensors. This device will simplify a process that is very difficult for doctors and will ultimately make kids in hospitals feel safer. In addition, this emotional support makes the hospital visit a pleasant experience for the patient. Ultimately, promoting patient health and recovery through a positive attitude towards the process. The major benefit of this device is that it incorporates multiple sensors whereas competing designs only offer one or two, and could change the way pediatric divisions of hospitals operate for the better.
Chapter 1. Introduction

Problem Statement
Hospitals are a stressful place for both patients and the doctors and nurses that run them. In pediatric hospital wings where all the patients are children, who are notoriously tricky patients, nurses tasked with taking vitals have one of the more stressful jobs.

One current solution on the market is to use biometric sensors within stuffed animals to take the vitals of young patients without them even knowing. This solution is a product developed by ID Guardian, a company headquartered in Croatia that sells most of its products in the United Kingdom (Figure 1).[1] One issue with this solution is that only one sensor is incorporated into each stuffed animal, and each product is sold at a price that may be too steep for some hospitals to order, especially considering that most hospitals would need to buy 25+ devices.

Our Approach
The goal of our project will be to incorporate multiple sensors into a single stuffed animal and offer it at a price cheaper than buying multiple devices of our competitor’s product. One of the reasons for incorporating multiple sensors into one device is so that all the necessary vitals can be taken with one single stuffed animal instead of making the patient hold different animals. This would reduce resources spent to administer multiple tests and also possibly provide emotional comfort to the patient by allowing them to hold the same animal for the duration of the vital testing. Another reason for our device is to save the time of nurses whose time can be better used elsewhere.
Preliminary research suggests that the most important sensors to have in our device are pulse rate, body temperature, O₂ saturation, and respiration rate.[2] Our plan is to incorporate all of these sensors using an Arduino Uno board as the controller (Figure 3).

**Product Description**

Our customer base is primarily populated by hospitals that have limited staff. Our product alleviates the stress on staff by supplementing a self-administered test that allows hospital staff to tend to more immediate tasks. This product allows hospitals to allocate doctors and nurses to other tasks, which to most hospitals is an invaluable asset. Hospitals would be the target market with an emphasis on pediatric hospitals. This device is currently in the home market throughout Europe. Our product is an improved version of this device and making an introduction in the U.S. market.

![Figure 2 Doctor checking vitals on a pediatric patient [3]](image)

This product accurately records vitals of pediatric patients and provides the patients with a sense of security. The goal of this device is to combine medical procedures with the comfort of home. This provides the patient with a emotional comfort while also recording and administering vitals testing. Hospitals currently take high volumes of donated stuffed animals to comfort pediatric patients both outpatient and in emergency room settings.[4][5]
This product is a customer need due to the fact that hospitals are increasingly becoming more understaffed and as a product that alleviates this stress in hospitals.[7] Furthermore, in-home care is increasing across the country and this product will allow constant monitoring and quarantine from the various diseases within hospitals. Hospitals are seeking products to automate medicine at a rate that doctors and nurses stand a chance to keep up with the increasing volume of patients. Sensor technology has increased rapidly with the large leaps in electronics technology. Most readings can now be taken non-invasively. Pairing non-invasive sensors together to create a virtual doctor is the future of this device.

**Report Summary**

Chapter 2 will focus on the current solutions available and the research showing the value of the product. In chapter 3, the technical background will be presented, as well as and preliminary component research. Our design approach and results will be presented in chapter 4 and chapter 5 will be the conclusions and future works. Math derivations and microcontroller code will be in the appendix.
Chapter 2. Existing Solutions & Market Research

*Market Research*
This product is a continuation of the movement from the medical community to make hospital practices less invasive. However, this is one of the first products that also automates the process without the need for a doctor or nurse. The global market for Advanced Patient Monitoring Systems has a projected Compounded Annual Growth Rate (CAGR) of 7.00% (Figure 4). [8]

![Figure 4 Tabulated Data of Global Market Growth](image)
This market is primarily dominated by Biomedical juggernauts such as Johnson & Johnson, Medtronic, GE Healthcare, etc. These companies dominate over half of the global market due to their processes implemented to get FDA approval with new devices (Figure 5).[10]

<table>
<thead>
<tr>
<th>Market Position</th>
<th>Supplier</th>
<th>Share of Total Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Medtronic</td>
<td>14.2%</td>
</tr>
<tr>
<td>2</td>
<td>Philips Medical</td>
<td>8.2%</td>
</tr>
<tr>
<td>3</td>
<td>St. Jude Medical (Now Abbott)</td>
<td>7.3%</td>
</tr>
<tr>
<td>4</td>
<td>Boston Scientific</td>
<td>6.2%</td>
</tr>
<tr>
<td>5</td>
<td>GE Healthcare</td>
<td>3.1%</td>
</tr>
<tr>
<td>6</td>
<td>Roche</td>
<td>2.6%</td>
</tr>
<tr>
<td>7</td>
<td>All Others</td>
<td>58.4%</td>
</tr>
</tbody>
</table>

The goal of this product is to overtake the pediatric market specifically targeting advanced vital monitoring systems. By moving into a niche market using legacy sensors and technology that are already FDA approved. The closest competitor that is directly in this product niche is Scanadu which developed a device for the at home market.[11] They had a major shortcoming when attempting to acquire the proper FDA approval. This is a large market that has the potential to continue to foster niche aspects of advancements in patient monitoring systems and easily allows our product to plant itself in this market.

**Existing Solution Issues**
The present solution has two main issues: only taking one vital sign with each animal and not being FDA approved. The competitor product only takes one or two vital signs and needs three different stuffed animals to take all the same vital signs our product would be able to. Also, the competitor product is not approved by the FDA and as such is not approved for use in the United States.

The area of the market we are attempting to serve is busy nurses and doctors that could use their time to serve other functions in a busy hospital. The window of opportunity of this product is as long as nurses are needed to test patient’s vital signs. Once technology is advanced enough where vital signs can be taken without a nurse by just sitting on a bed, our product will be mostly obsolete.
Entering the market could be relatively expensive depending on the FDA approval process. Our device would most likely be classified as a Class II medical device meaning that it would need to meet certain regulations to receive FDA clearance. Our product will require a 501(k) application to be submitted to the FDA (Figure 5). This application is for devices that are ‘substantially equivalent’ to existing devices on the market, and we will be using sensors that are already FDA approved.[12]

![Figure 5 510(k) application process for the FDA.[12]](image)

The key partners would be Build-a-Bear Workshop (if a strategic partnership could be formed) and Medtronic (Figure 12). A partnership with Build-a-Bear could benefit both sides; allowing us to have someone to supply teddy bears and help with the production, and allowing Build-a-Bear to get their company some good PR and marketing to young children and parents. The key customer on the other hand would be the Children’s Hospital Association, the association that is responsible for running the 220 children’s hospitals across the country.
Marketing Requirements

Medicine in today’s world is nothing like what it was even ten years ago. There are now new markets with new customer needs in mind. The term “telehealth” refers to methods of medicine that are remote and self-sufficient without the need for a doctor. Our product is breaking into this market with a specific archetype patient and customer. By tapping into a specific niche market within the global sphere of advanced patient monitoring technologies we hope our product will be a stand out product acting as a startup emerging into a new market.

![Telehealth Patients by Year, United States](image)

*Figure 6 Graph Demonstrating Increase in Remote Medicine [13]*

In order to succeed where other companies fell short is to become an FDA approved device. This will be expedited by the FDA’s 510(k) application process. By getting FDA approval it will open doors to be put into hospitals around the country. This device is going after a target market that has more than just monetary value but also emotional security value. By selling this point to pediatric departments it ultimately conquers just standalone devices due to the inherent benefit that a stuffed animal is to a scared child. The added benefit of our device is that it is an all-in-one system. This is a concept that has been implemented in the U.S. with limited success. In the U.K. the comparable system only achieves one vital measurement per system. With the market growing towards an increase in remote medicine and our device targeting a small market of customers with specific needs, our device can accomplish a takeover in the field of remote pediatric vitals with little resistance from market competitors. Our customers have 2 major reservations when it comes to our product; FDA approval and cost. Our product will come at a price point that is able to withstand the costs of FDA approval and also maintain the proper cost benefit to hospitals. Time is an invaluable resource to hospitals and our product offers this at a fair market price with intrinsic value going above science and technology and ultimately making life stress free for pediatric patients.[14]
<table>
<thead>
<tr>
<th>Requirement Number</th>
<th>Marketing Requirement</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Low Cost</td>
<td>In order for this product to be marketable it has to be cost effective to hospitals for them to replace doctors and nurses time.</td>
</tr>
<tr>
<td>2</td>
<td>Captures Primary Vitals</td>
<td>To functionally replace a doctor this device must be able to capture all vital signs. This product takes all vital signs that must be taken frequently by doctors.</td>
</tr>
<tr>
<td>3</td>
<td>Doctor Comparable Accuracy</td>
<td>Accuracy is extremely important in biomedical devices and this device needs to have extremely small margins of error.</td>
</tr>
<tr>
<td>4</td>
<td>Wireless Data Transfer</td>
<td>Once the data is recorded of each patient this data would be integrated into digital hospital records for real-time monitoring and analysis.</td>
</tr>
<tr>
<td>5</td>
<td>Emotional Support</td>
<td>Using stuffed animals in hospitals has been a time proven method for alleviating stress in pediatric patients. The comfort received by a stuffed animal to a child in distress is dual functionality that is essentially priceless to pediatric hospitals.</td>
</tr>
</tbody>
</table>
Chapter 3. Technical Background

Sensor Overview
In this device there are four non-invasive sensors that measure vitals with accuracy comparable to a doctor. Starting with a body temperature sensor, this sensor uses the method of superficial temporal artery to detect temperature within 0.1°C. Temperature determined from the temporal artery is the most accurate means of temperature readings outside the “golden” standard of a rectal administered reading. Teddy the Guardian as seen in Figure 2 uses a body temperature sensor that uses the patient's hand to take the vital reading.[1]

![Temporal Artery Temperature Sensor](image)

Figure 7 Temporal Artery Temperature Sensor [15]

For O₂ saturation monitoring, a pulse oximetry sensor is an ideal candidate for a sensor because of its non-invasive readings and dual functionality. These sensors work by shining visible red and infrared light through areas on the body with capillaries close to the surface of the skin, such as a finger, earlobe, or toe.[15] When this light passes through the skin some of the light is absorbed and some is left to pass. By monitoring how much light is absorbed the sensor determines the amount of O₂ saturation in the body.[16] This sensor also monitors pulse rate giving the pulse oximetry sensor dual functionality.
There are multiple methods to measure respiratory rate. The two methods that fit best with this product are the use of a pulse oximetry sensor, which is already needed, or an Electrocardiogram (ECG) sensor. With improvements in noncontact ECG sensors there are now capacitive sensors that are integrated into fabrics that can sense electrical impulses of the heart to measure respiratory rates. Although this fabric method would be ideal for our product it would make more sense to just use the pulse oximetry sensor in order to minimize cost and system complexity.

Top Level Design

This device will be using an Arduino Uno microcontroller to interpret the individual signals from the biomedical sensors. Each sensor will record a separate vital sign and return either a digital or analog signal. Within the software, the signals will be converted into the various metrics being measured (i.e. taking pulse data and converting it to BPM). Once data is collected the device will transfer the data via a bluetooth link to an app that tracks patient vitals for nurses and doctors to monitor. This process of data collection and data transfer will be repeated as prescribed by a physician to mimic the same process a doctor would follow. While the device is not collecting or transferring data the device should power down into a low power mode to promote long battery life. Functional block diagrams of high level and subsystem level designs show how this device will function.

The temperature sensor and pulse oximetry sensor will be connected using Inter-Integrated Circuit (I²C) and Serial Peripheral Interface (SPI) communication for high speed data acquisition. This data will be recorded in the microcontroller and as the measurements are been verified the system will then use the bluetooth communication interface to upload the data in real time.
In all there will be five subsystems. One for each of the two biomedical sensors, one for the bluetooth adapter, one for the charging subsystem, and lastly the microcontroller subsystem. Each of the biomedical sensors will output a digital signal that represents the data collected over time. The microcontroller subsystem is the main subsystem in this device. The microcontroller is tasked with recording and analyzing all data recorded by the sensors and delivering them via bluetooth to doctors and nurses. To start, the microcontroller has to decode the acquired data and determine the proper metric. Accuracy and reliability will be greatly increased by taking multiple measurements and comparing data taken at various times to ensure the data is suitable for interpretation. Specifically for the pulse oximetry sensor the microcontroller will control the Light Emitting Diodes (LEDs) that are used in determining pulse and O₂ saturation. Once all three vitals are verified and recorded the vitals are uploaded through the bluetooth link. Lastly, the charge controller will allow the battery to charge with a USB connection to eliminate the need for an AC/DC converter. This USB connection will double as an alternate method to retrieve medical data in an instance where bluetooth communication is not an option. The subsystem design can be seen below in Figure 11.
Figure 10 Block Diagram

Figure 11 Arduino Software Block Diagram
### Table III. Engineering Requirements

<table>
<thead>
<tr>
<th>Engineering Requirement</th>
<th>Engineering Specification</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Cost</td>
<td>Device Cost &lt; $100</td>
<td>Sourcing sensors that are cheap yet still fulfill the accuracy and reliability needs</td>
</tr>
<tr>
<td>Multiple Biometric Capabilities</td>
<td>Vital Signs Measured &gt; 2</td>
<td>Device should measure more than 2 vital signs to stand out from competitor product.</td>
</tr>
<tr>
<td>High Accuracy</td>
<td>95.0% Accuracy*</td>
<td>Accuracy needs to be comparable to a Doctor for this device to be in hospitals</td>
</tr>
<tr>
<td>Wireless Data Transfer</td>
<td>Programmable refresh rate and error checking on data transfer</td>
<td>Error checking resolves issues of corrupted data and programmable refresh rate allows for a patient specific plan</td>
</tr>
</tbody>
</table>

*Accuracy is based off percent error from a commercial biometric device. It is calculated with the following formula: \[\text{Accuracy} = 1 - \%\ error = \left(1 - \frac{\text{Experimental Reading} - \text{Commercial Reading}}{\text{Commercial Reading}}\right) \times 100\]

### Table IV. Testing Requirements

<table>
<thead>
<tr>
<th>Acceptance Test</th>
<th>Test Requirement</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Oximetry Sensor Accuracy</td>
<td>(O_2) Saturation and Pulse (\leq 5%) deviation from median</td>
<td>This ensures the data recorded is accurate and reliable as data can change with patient position, placement of sensor, etc.</td>
</tr>
<tr>
<td>Temporal Artery Temperature Sensor Accuracy</td>
<td>(\leq 0.1^\circ\text{C}) deviation from a rectal temperature</td>
<td>Rectal temperature is defined as the “golden” standard for body temperature</td>
</tr>
<tr>
<td>Bluetooth Link - Data Corruption Test</td>
<td>(\leq 0.001%) transmission error**</td>
<td>Less than 1 in 10000 samples transferred can deviate from the recorded data.</td>
</tr>
<tr>
<td>Programmable Refresh Rate</td>
<td>Refresh rate varied between 5 seconds and 30 minutes</td>
<td>Doctors may need to vary how often vitals are taken depending on the patient.</td>
</tr>
<tr>
<td>Charge Controller Reliability</td>
<td>Charger does not exceed rated battery voltage</td>
<td>This prolongs battery life and limits damage to patient and device.</td>
</tr>
</tbody>
</table>
**Using an even parity error detection scheme we attempted to achieve 1 in 1000 samples to be corrupted. This was partially due to the fact that transmitting in real-time did not allow us to use stronger error detection strategy such as checksum. We felt this was a good starting point to base our transmission error. The data word being transmitted is a 16 bit word for each of the metrics (pulse, body temperature, O2 saturation, and respiratory rate). By transmitting the same word that is received from the sensor the Arduino Uno has less arithmetic to solve.**

Acceptance testing of this device is primarily focused on the accuracy of the biomedical sensors. Secondly, the data transfer via bluetooth with the programmable refresh rate must be tested for data corruption and proper time intervals on recorded data. Lastly, the charge controller must be tested to correctly charge the lithium ion battery to avoid over charging and damage of the battery.

**Preliminary Sensor Selection Process**
Currently the main focus is centered on the pulse oximetry sensor and algorithm. The MAX30101 designed by Maxim integrated contains features such as ambient light rejection which is beneficial because it eliminates the need for a digital signal algorithm on the Arduino Uno. Additionally, there is an on chip processing component that eliminates fast transient noise during operation. The device also has regulated current draw when inactive or conditions are appropriate for lower light levels to achieve relative low power draw thus maximize battery life.

![Figure 12 MAX30101 block diagram](image-url)
The next step of integration is focused on the body temperature sensor. The MAX30205 is already approved by the FDA per the ASTM E1112 standard. This sensor also has an extremely high level of sensitivity of 0.1°C. This coupled with the application of the sensor on the temporal artery will yield the highest results of any clinical setting.

Figure 13 MAX30205 block diagram
Figure 14 Schematic of the Temperature and Pulse Oximetry Sensors
Chapter 4. Design Process

Approach
Currently we are implementing pseudo code provided by Maxim along with our previous heart rate monitor algorithm. Building in I2C interface for the sensors is necessary for proper data acquisition. Both sensors also run on the same clock which will need to be properly tuned. The MAX30205 temperature sensor reads out a 16 bit two’s complement message. The MAX30101 pulse oximetry sensor utilizes a adjustable 16-18 bit data bus which represents the quantized information from the sensor. Once the data is converted to the appropriate vital sign the data will be transmitted via bluetooth. The data will be transmitted real time as the transmission from the device will be constant at the rate the conversion rate of our algorithm. With these sensors, the bulk of the raw data conversion is taken care of with noise cancellation the data and the proper vital conversion. The main job of the Arduino is to decode the data busses with the sensors and send a real time message with the vitals via bluetooth to a computer.

The major design choice in our device is the type of sensors we choose. By choosing low cost sensors that already have obtained FDA approval in some form will greatly improve our design process. Additionally, the type of sensor we go with will govern which communication interface we choose. The level of complexity in a sensor we choose also influences how complex the DSP programming will be. All in all, complexity and price of the sensor are proportional to how much more complex and expensive the microcontroller software is. This is what makes the sensor choice the most critical design decision.

System Housing Prototype

Figure 15 3D model and 3D print of the Arduino housing
Cost
The estimated cost for our project was about $94, well below the $200 allowance provided by the EE department. In order to finance this project within a company the full cost would be closer to $2000 in order to have key testing equipment available such as an oscilloscope.

Prototype
We designed a prototype board to evaluate the sensors. Designed using the IEEE PCB printer we were able to generate a break out board for debugging the two sensors. The body temperature sensor requires much less initialization and tuning thus we moved forward with the MAX30205 sensor first. This sensor requires a hysteresis to be set which we have chosen to be 32°C to 44°C. These limits were specifically chosen because those are the limits of the human body. Once the hysteresis is set the MAX30205 can read temperatures that fall within the range the Arduino will

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**Figure 16 Bill of Materials**

<table>
<thead>
<tr>
<th>Sub</th>
<th>Sub</th>
<th>Sub</th>
<th>Sub</th>
<th>Description</th>
<th>Qty</th>
<th>P/N</th>
<th>Total Cost (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Final Assy - Pediatric Vitals Teddy Bear</td>
<td>1</td>
<td>1001</td>
<td>Instr</td>
<td>6</td>
<td>1000</td>
<td>1000.00</td>
</tr>
<tr>
<td>1</td>
<td>Microcontroller &amp; Sensors</td>
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<td>1002</td>
<td>Instr</td>
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<tr>
<td>1</td>
<td>Arduino Uno Microcontroller</td>
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<td>1004</td>
<td>Spec</td>
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</tr>
<tr>
<td>1</td>
<td>Pulse Oximetry Sensor</td>
<td>1</td>
<td>1005</td>
<td>Spec</td>
<td>2</td>
<td>8.00</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>Temporal Artery Sensor</td>
<td>1</td>
<td>1006</td>
<td>Spec</td>
<td>2</td>
<td>11.00</td>
<td>11</td>
</tr>
</tbody>
</table>

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“ask” the for the temperature reading. Because the temperature sensor and pulse oximetry sensor will be read over the same bus, the timing of the read cycles is incredibly important. The first step of troubleshooting after setting the hysteresis is figuring out how many readings are needed to produce a stable temperature value. Moving into the MAX30101, the most important part is the timing, and reading of the LED values. Because there are three different LEDs the timing has to be extremely accurate to coincide with the temperature sensor readings as efficiently as possible to minimize delay in readings. See Appendix II for the pseudo code architecture being implemented for the MAX30101. The pulse-oximetry sensor, MAX30101 requires three separate voltage sources: LED driver voltage, Operating voltage, and I²C pull up voltage. These are respectively, 5V, 1.8V, and 3.3V. This will require two linear regulators to step down from 5V to 3.3V and then again to 1.8V.

![Figure 17 PCB breakout board for MAX30205](image)

*Figure 17 PCB breakout board for MAX30205*

![Figure 18 PCB breakout board for MAX30101](image)

*Figure 18 PCB breakout board for MAX30101*
As can be seen in Table V above, the results from the pulse oximeter were less accurate than desired. The results from the arterial temperature sensor were within our original design goals. Since our temperature sensor IC arrived first, we were able to get the PCB for it printed on schedule and were also able to calibrate it on schedule. The biggest difficulty with calibrating the temperature sensor was that it was hard to get separate data points since neither of us had a fever or cold while testing. We tried artificially warming up our forehead to get a wider range of data points but the temperature sensor we were using to calibrate with did not show much deviation from the standard 98.6°F.
The microcontroller code for the pulse oximeter was more complicated than the temperature sensor code since we were getting multiple readings from the same sensor. Also, since we got our pulse oximeter after our temperature sensor we had less time to calibrate it. The biggest difficulty was getting the respiratory rate measurement within design goals. Since the average respiratory rate for most people ranges from 12-20 breaths per minute any deviation from this number had a larger effect of the error than the other vital sign measurements.

Final Product

![Figure 20 Final Product (Front View on Left, Back View on Right)](image)

Seen above in Figure 20 is the final product. Black lines represent wired connections from microcontroller to external devices. Back view is shown unstitched but was restitched after testing stage.
Chapter 5. Conclusion & Future Works

Conclusions
There were multiple issues that were encountered during the design and build process. First off, keeping up with our own Gantt chart proved to be more difficult than expected. A combination of midterms, other projects, and work put us slightly behind schedule. All of our sensors were surface-mount components which required the design and order of a printed circuit board (PCB), which we did not originally plan for. We made up for this by working on PCB designs over spring break, which we had set aside as an open week to work on whatever was needed to be done to get back on schedule.

The size of the surface mount components was also much smaller than expected. Both integrated circuits had a surface area less than 5mm²; this made soldering the components more difficult than anticipated. In order to accomplish this solder paste had to be used in a reflow oven.

The main technical issues that we encountered was calibrating all of our sensors with our microcontroller in order to achieve the desired accuracy of 95%. We initially calibrated our sensors not enclosed in the stuffed animal but when the sensors were placed in the stuffed animal, the accuracy of our readings decreased and we had to recalibrate the sensors. Another issue was calibrating the temperature sensor. Since most humans have a temperature of 98.6°F it was a hard to get a wide range of temperatures to calibrate over.

Future Works
The next step in taking our product to the next stage of actually being used in hospitals would be to improve the accuracy to at least 99%. To have any chance of our product being used in a real hospital would require it to have comparable accuracy to an actual medical device. More data measurements would need to be taken in order to more accurately calibrate our sensors.

After achieving an acceptable accuracy level, the next step would be to begin working towards FDA approval via the 510(k) approval process. Since all of our sensors are individually FDA approved this process should not be too difficult. The process takes on average 3-6 months. After gaining FDA approval the next step would be to perform test trials within a hospital. This would require contacting several hospitals and also producing at least two more test products. It would be difficult to gather quantitative data on the emotional support aspect of the product due to the qualitative nature of emotion. One method would be to survey nurses after using our product on whether or not it had a positive effect on the happiness/calmness of the patient. This data would be collected in addition to data regarding the accuracy of our products readings.
After achieving proper FDA approval the next step in the process would be to begin larger scale manufacturing of multiple products. Our original goal was to have one of our devices in each patient room at a pediatric hospital. Since some pediatric hospitals in bigger cities can have upwards of 500 beds, it would make more sense to produce a small sample of devices for testing before going ahead and manufacturing such a large quantity of devices. For preliminary trial runs, at least 50 devices can be produced and used.

After producing the proper number of devices for a hospital test run, the next stage in our process would be to get in contact with hospitals and find one that would like to test our product. Our product would have to be offered at a discounted rate since we will have no brand recognition and minimal reputation built up. If after a successful trial period in a test hospital we could increase production to have enough devices to serve the whole hospital. From here, the last step would be to start reaching out to more and more hospitals to sell more devices. Our product was originally planned to be sold primarily in the United States but if enough positive feedback ensued it would be taken to an international stage, most likely starting in Canada before branching overseas.
References


Appendix I. ABET Senior Project Analysis

Functional Requirements
Our project is a biometric monitoring system housed inside a stuffed animal for use in pediatric hospitals. Our system measures heart rate, respiratory rate, O₂ saturation, and body temperature and reports all the measurements wirelessly via SPI communication protocol.

Primary Constraints
The first significant challenge was the fabrication of our PCBs and subsequent soldering of our ICs. All our ICs were surface mount components and had a surface area of less than 12mm². Our first attempt at printing a PCB for our arterial temperature sensor produced a board with overlapping traces and required a second print. All of our ICs had to be soldered on using solder paste and a reflow oven, which we had not originally planned for.

Furthermore, the second biggest challenge we came across was the calibrating of our sensors. When testing our sensors normally (not enclosed in the stuffed animal) relatively precise results were readily obtained. But after placing our system within the stuffed animal all the sensors needed to be recalibrated to account for the difference in medium between patient and sensor.

Economic
Originally we estimated that our components would cost less than $100 and by the end of the project we actually spent $93.83. A final bill of materials can be seen in the above report (Figure 16). Additional equipment costs consisted of a PCB mill from IEEE to print the circuit boards, a reflow oven for soldering our ICs, and an oscilloscope for sensor verification and calibration. Our original estimated development time was 19 weeks and our actual development time ended up being 20 weeks.

Commercial Manufacturing
Not applicable as we only made one device.

Environmental
Major environmental impacts associated with our device would be based on future plans to manufacture multiple devices. The impact from one device comes from the use of silicon in the microcontroller, PCBs, and ICs. Another considerable impact is from the wireless communication system. There are already so many wireless devices being used today and the health effects of being surrounded by high-frequency waves in our everyday lives will start to be seen in the next few decades.

Manufacturability
See above in primary constraints.
**Sustainability**
The sustainability of our product is closely tied to the sustainability of our ICs: the arterial temperature sensor and the pulse oximeter. Both ICs are built by Maxim Integrated and have an estimated lifetime of over 5 years. The other component to consider is the stuffed animal. Overtime the stuffed animal will show signs of wear and tear and eventually need to be replaced before the rest of the system. This is the only maintenance that will need to be upkept for our product.

An upgrade that could improve the product would be a custom built stuffed animal that was medical grade with premade housings for the sensors. For our product we just used a normal teddy bear and carefully unstitched it to place our system within and then restitched it shut. This would most likely require adding a manufacturing engineer to the product team to deal with the design and fabrication of the custom built stuffed animal.

**Ethical**
Since our product will be primarily for pediatric hospital patients cost is a major ethical consideration. Most families dealing with hospital costs for a child are usually financially burdened and as a result our product needs to be reasonably priced to not put an additional hardship onto the family. Also since our product will be coming in contact with sick children it will have to be as safe as realistically possible.

**Health and Safety**
Since our device will be used in hospitals it will have to be FDA-approved which will require rigorous attention to safety and regulations. Our product will be coming in contact with different pediatric patients and will require a cleaning protocol to adhere to in between patient uses. Taking apart the device and washing the entire stuffed animal would be time consuming, while the alternative of just cleaning the surface of the stuffed animal has a small possibility of contamination from leftover bacteria and germs.

**Social and Political**
Not applicable to our device.

**Development**
New tools for us that we used during this product was the PCB mill from the IEEE department at Cal Poly and the reflow oven in the capstone room. Also both sensors we used were new to us but the concepts needed to operate them were covered in the microprocessor based system design class at Cal Poly.
Appendix II. Oximeter Code

// Authors: Ryan Brown & Matthew Rochford
// Project: MAX30101 Pulse-Oximeter Reader
// Description: This code reads the values from 3 different LEDs
// to determine heart rate, respiratory rate, and
// O2 saturation. The values of each are read on the
// FIFO data bus, in a successive order.

#include <Wire.h>

void setup() {
  // put your setup code here, to run once:

  Wire.begin();  //join i2C bus as master

  // SETUP
  Wire.beginTransmission(0xAE);       // WRITE Addr. for MAX30101
  Wire.write(0xAE);                   // send addr. of MAX30101
  Wire.write(0x04);                   // send FIFO_WR_PTR addr.
  delay(0.01);
  Wire.write(0xAE);                   // send addr. of MAX30101
  Wire.write(0x04);                   // send FIFO_WR_PTR addr.
  Wire.endTransmission();
}

void loop() {
  // put your main code here, to run repeatedly:

  Wire.beginTransmission(0xAE);       // WRITE Addr. for MAX30101
  Wire.write(0xAE);                   // send addr. of MAX30101
  Wire.write(0x07);                   // send addr. of FIFO_DATA
  Wire.endTransmission();

  for(i=0; i < 3; i++)
  {
      Wire.requestFrom(0xAF, 16);
      int FIFO_data = Wire.read();
      Wire.requestFrom(0x0C, 8);
      int LED1_0;
      Wire.requestFrom(0xAF, 16);
      int FIFO_data = Wire.read();
      Wire.requestFrom(0x0C, 8);
      int LED1_1;
      Wire.requestFrom(0xAF, 16);
      int FIFO_data = Wire.read();
      Wire.requestFrom(0x0C, 8);
      int LED1_2;
  }
}
int FIFO_Data_bpm = FIFO_data * 60;
Serial.print("Heart rate = %d Beats/min", FIFO_data_bpm);

Wire.requestFrom(0xAF, 16);
int FIFO_data = Wire.read();
Wire.requestFrom(0x0D, 8);
int LED2_0;
Wire.requestFrom(0xAF, 16);
int FIFO_data = Wire.read();
Wire.requestFrom(0x0C, 8);
int LED2_1;
Wire.requestFrom(0xAF, 16);
int FIFO_data = Wire.read();
Wire.requestFrom(0x0C, 8);
int LED2_2;
int FIFO_Data_respir = FIFO_data * 60;
Serial.print("Respiration Rate = %d breathes/min", FIFO_respir);

Wire.requestFrom(0xAF, 16);
int FIFO_data = Wire.read();
Wire.requestFrom(0x0C, 8);
int LED3_0;
Wire.requestFrom(0xAF, 16);
int FIFO_data = Wire.read();
Wire.requestFrom(0x0C, 8);
int LED3_1;
Wire.requestFrom(0xAF, 16);
int FIFO_data = Wire.read();
Wire.requestFrom(0x0C, 8);
int LED3_2;
Serial.print("Oxygen Saturation = %d %", FIFO_data)
Appendix III. Body Temperature Code

// Authors:      Ryan Brown & Matthew Rochford
// Project:      MAX30205 Temperature Reader
// Description:  This code sets up the MAX30205 temperature sensor to
//                read body temperatures within the range of 95 to 113
//                degrees Fahrenheit. The temperature is read out as a
//                16bit binary number that is then converted to an
//                integer. These values are then taken 500ms.

#include <Wire.h>

void setup() {
  Wire.begin(); // join i2c bus as master

  //Setup
  Wire.beginTransmission(0x90); // Sets up I2C Bus with MAX30205 address
  Wire.write(0x90); // MAX30205 Slave Address
  delay(0.01); // clock cycle
  Wire.write(0x01); // Pointer Configuration Addr. Reg.
  delay(0.01); // clock cycle
  Wire.write(0x02); // Configuration byte
  Wire.endTransmission(); // end transmission

  //Set up Thermometer [35<Tc<45] or [95<Tf<113]
  //T_Hyst Write function
  Wire.beginTransmission(0x90); // Sets up I2C Bus with MAX30205 address
  Wire.write(0x90); // MAX30205 Address
  delay(0.01); // clock cycle
  Wire.write(0x02); // T_hyst address Register = 0x02
  delay(0.01); // clock cycle
  Wire.write(0x23); // T_hyst MSB => 35C = 0x23
  delay(0.01); // clock cycle
  Wire.write(0x00); // T_hyst LSB => 0x00
  delay(0.01); // clock cycle
  Wire.endTransmission(); // end transmission

  //T_Hyst Write function
  Wire.beginTransmission(0x90); // Sets up I2C Bus with MAX30205 address
  Wire.write(0x90); // MAX30205 Address
  delay(0.01); // clock cycle
  Wire.write(0x03); // T_os address Register = 0x02
  delay(0.01); // clock cycle
  Wire.write(0x2D); // T_hyst MSB => 45C = 0x2D
  delay(0.01); // clock cycle
  Wire.write(0x00); // T_hyst LSB => 0x00
  delay(0.01); // clock cycle
  Wire.endTransmission(); // end transmission
Serial.begin(9600); // start serial for output (baud rate = 9600)
}

void loop() {

  // Read Temperature
  Wire.requestFrom(0x90, 8);  // top 8 bits from MAX30205
  int addr_30205 = Wire.read(); // Receive addr_30205 as an integer
  delay(0.01); // clock cycle
  Wire.requestFrom(0x90, 8); // Read next 8 bits from MAX30205
  int MSB = Wire.read(); // receive LSB as an integer
  delay(0.01); // clock cycle
  Wire.requestFrom(0x90, 8); // low 8 bits from MAX30205
  int LSB = Wire.read(); // receive LSB as an integer
  int temp = MSB; // convert to temperature with 1C tolerance
  Serial.print(MSB); // print character
  delay(500);

}