UNIVERSITY OF WISCONSIN - MADISON

Pulse Oxi*tele*metry

Department of Biomedical Engineering

Adviser: Dr. Chris Brace
Client: Dr. Fred Robertson

Chris Fernandez (Team Leader)
Oliva Rice (Communicator)
Tony Prostrollo (BSAC)
Kaitlyn Laning (BWIG)

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Abstract

A pulse oximeter is a device that allows observation of basic respiratory function through noninvasive measurement of oxygen saturation in a person's arterial blood.[A] Traditional pulse oximetry devices require a patient to be tethered to a bedside monitor in a hospital where a healthcare provider monitors their readings continuously. In recent times, more mobile devices have been created. These oximeters are wireless in the sense that the patient is not bound to a bedside monitor, however, their oxygen saturation readings are neither saved and compiled for ongoing analysis, nor sent anywhere outside of their home. Dr. Fred Robertson proposed the idea of a device that would allow physicians, anywhere they might be, to receive their patient's oxygen saturation readings while the patient is elsewhere. This would allow hospitalized patients that do not require 24 hour care to return home while still being monitored. The proposed device would be free of wires, essentially transmitting time stamped oxygen saturation readings over the cellular network from the patient to the physician, for them to read on their computer or cellular device. Utilizing existing technology, a device was designed containing: a pulse oximeter sensor, BCI digital pulse oximetry board, a MICAz mote with integrated flash memory, Zigbee chip and an evolved 3rd generation cellular IP modem. These components allow for the transmission of pulse oximetry data through 3G networks to up to 5 health care providers simultaneously. Meta-analysis of contemporary research established that this concept is feasible. Therefore the team is in the process of integrating theses systems to build a marketable prototype.

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1.0 Problem Statement

It is vitally important to measure blood oxygen saturation data for patients with chronic diseases like congestive heart failure, chronic obstructive pulmonary disease or asthma. However many of these patients do not need to remain in a hospital setting. This pulse oxitelemetry device will collect real time blood oxygen saturation data from patients in a variety of environments made accessible by wireless data transmission. In doing so, the patient's quality of life will be increased due to freedom of mobility.

2.0 Background

2.1 <u>Characteristics of Pulse Oximetry</u>

Pulse oximetry is an essential practice for physicians to accurately assess a patient's health. If a patient's blood oxygen saturation drops below a certain threshold it can indicate that the patient's health is declining and that action by the physician should be taken. Without a sufficient amount of oxygen, a person's body does not function properly. This is because oxygen is necessary for the major biochemical reactions of all cells in the body to proceed.[B] When the oxygen saturation of a person falls below 90%, patients are considered hypoxic, or oxygen deprived.[C] In general terms, there is not enough oxygen in the patient's blood to fully oxygenate their surrounding tissues. Insufficient oxygen results in cellular dysfunction and damage. Studies have shown that a patient with oxygen saturation levels below 90% for an extended amount of time shows a significant correlation to an increased mortality rate.[C] When considering health and safety of the patient, it is highly recommended that they be admitted to the hospital when oxygen saturation levels have declined to 93%. For this reason, it is necessary for an accurate and robust method to retrieve pulse oximetric data. Figure 2.11 further illustrates this point through a graphical analysis of patient's time spent with a reduced oxygen saturation level that is at risk of acute heart failure.

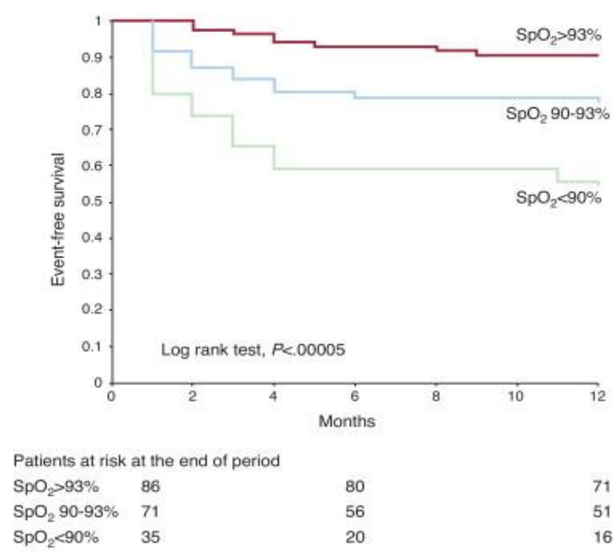

Figure 2.11. This graph analyzes the relationship between time and event-free survival of different levels of oxygen saturation. The trend illustrates that patient's with lower saturation percentages are more likely to experience an event such as death or heart failure within the first year.

Pulse oximetry utilizes the absorption wavelengths of oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) to determine the arterial oxygen saturation in a patient. To obtain this data, a sensor containing two LED lights on one side and a photo detector on the other, is typically placed in one of two areas on the body; the fingertip or the ear lobe.[D] Once the sensor is in place, red (660 nm) and infrared (940 nm) light are cast through the skin and are absorbed by hemoglobin in the bloodstream. Hb absorbs approximately ten times as much red light as HbO_2. In contrast, HbO_2 absorbs more infrared light than Hb.[D] The LED lights typically flash in an alternating fashion so a single photo detector is able to measure each of the light intensity levels. With a known absorption of both infrared and red light, a ratio of HbO_2 to Hb can be calculated. This ratio is what is commonly referred to as a patient's oxygen saturation percentage (SpO_2). In many cases, the raw data collected by the photo detector is transmitted to a monitor to be displayed. The output real time waveform is called a plethysmograph, which is primarily used to determine a patient's $SpO_{2.}$ In Figure 2.12, both the graphical and numerical display can be seen on a typical pulse oximeter.

Figure 2.11. Nonin's Avant 9700 pulse oximeter displays both a graphical and numerical data indicating an oxygen saturation of 96%.[E]

2.2 Contemporary Technology

There are many viable designs of pulse oximeters that are currently on the market. It is important to understand the contemporary technology that is being used before embarking on a journey of innovation. Therefore, detailed below are several contemporary pulse oximeters along with brief explanations of the innovation within each design.

Figure 2.12 shows an example of a basic, wired pulse oximeter, the Nonin 9700. The sensor, on the finger in this case, connects directly from the patient to the base station where the patient or physician can view the oximetric data. This device displays a numeric oxygen saturation reading as well as a plethysmograph for a physician to view. In addition to the Nonin 9700 model, Nonin also manufactures a 4000 model, which is a Bluetooth enabled pulse oximeter. The sensor, once again on the finger, is attached to a device wrapped around the wrist of the patient, that is capable of wireless transmission within a certain range.[E] The benefit of this design is that it allows the patient to move about the immediate area without being tethered down by wires connecting the pulse oximeter to its base station.

In addition to Nonin there are several other companies who manufactur reliable oximeters for mobile patients. For example, Philips Healthcare has designed the Philips Intellivue Transmitter for wireless telemetry.[F] When combined with a standard Philips' pulse oximeter wireless signal can be transmitted throughout hospital Wi-Fi networks. This allows the patient more freedom in a hospital setting.

Sensaris another medical device company based in France, has designed a patent pending product by the name of Zao. This device transmits SpO_2 percentage, blood glucose, heat rate, and temperature data, operating on the hospital's Wi-Fi network.[G] Unlike the Phillps device, Sensaris' device has the ability to interface with iPhones, Android Phones, iPads and computers.[G] The ability to interface with several mobile devices allows physicians, nurses and other hospital personnel to have patient data constantly at their fingertips within the hospital. Ultimately, this device has the capability to speed up reaction time of the hospital staff to a patient's sudden decrease in oxygen saturation levels.

2.3 Technical Limitations of Contemporary Technology

While several of the above examples provide robust, accurate signals of oximetric data in a wireless fashion, patients are either limited to a hospital or data must actively be retrieved or sent from the patient's home Wi-Fi network. This is an inconvenience for many patients who wish to carry out their daily activities and still require monitoring.

In addition to the limitations affecting the patient's ability to receive data, currently the physician has limited options for receiving oximetric data from a patient that is under a home care system. Currently, it is possible for the physician to see their patient's vitals while doing an in-home check-up, or receiving the information from the patient in a delayed manner. Even though Bluetooth technology allows for pulse oximetry readings to be sent to a base station, such as a computer within a patient's home, that data still must be actively sent to a physician via email or a communication system such as the Health Buddy telecommunication device. This device works through a phone land line and, after the patient has manually entered their vital readings, will send the data to a hospital for a physician to read.[H] This system aims to engage a patient in their health care, but requires patient cooperation to be effective. In a home setting, patients may forget to send their data to their physician or simply not comply to do so. This presents serious risk to the patient and limits the ability for the physician to respond promptly to sudden changes in the patient's vials. Patient care could be enhanced if physicians were able to remotely monitor patient's vitals without relying on patient compliance. This would more affectively allow the patient to be notified to seek medical attention or in more severe cases it could potentially contact EMTs to respond to the situation.

3.0 Design Motivation

The overall motivation behind this project is to make pulse oximetry data, collected inside a patient's home, accessible to their physician wherever they may be. While wireless pulse oximetry exists to an extent, no contemporary devices can send oximetry data beyond the boundaries of the patient's home. This data transmission would be useful to both patients and physicians. A wireless pulse oximeter that is able to transmit the data wirelessly straight from the device to a physician, will decrease the amount of responsibility the patient has and the time between oxygen saturation readings and data transmission. From a health care provider’s point of view, this innovation would allow them to essentially be anywhere in the world and still be updated on their patient’s vitals. For a patient, transmission of their oxygen saturation readings would require minimal cooperation and effort. This type of wireless data transmission is therefore a faster, more effective way of communicating blood oxygen saturation levels from mobile patients to their physicians.

4.0 Client’s Requirements

The final design prototype must be able to wirelessly transmit the data acquired from the device to a base station at predetermined intervals, such as every 30 seconds. Thus, the device does not have to provide continuous monitoring but the data collection intervals should be customizable to the second. The oxygen saturation percentage alarm threshold should also be adjustable. For example, a more high risk patient’s alarm would be set at a higher threshold compared to someone who is in better health. Another important requirement is that the battery should last at least a week while the device is undergoing discontinuous monitoring. Finally, an ear oximeter sensor is preferred and the design of the device should be light enough to be worn behind the ear, similar in size to a hearing aid. This would result in a device comfortable enough to wear at all times, as to not interfere with the patient's day-to-day activities.

5.0 Design Constraints

In order to ensure the device’s functionality and reliability, design constraints must be assessed. Since the patient will essentially be wearing the device 24/7 some safety requirements are essential. The thermal state of the device should not cause discomfort to the patient, therefore adequate insulation is required. Patients should not be exposed to any harmful currents or voltages from the device. The device should also follow current Radio Frequency (RF) Exposure thresholds set by IEEE and FCC of 1.6 Watts per Kilogram.[I] In order to ensure this, waterproofing the device is strongly preferred. The oximeter should also be thoroughly sterilized before distribution and should be able to be cleaned easily.

In order for this device to be considered reliable, precision and accuracy of the oxygen saturation readings should replicate the signal outputs of current pulse oximetry devices. Signals should be transmitted by the device at least every 15 minutes to ensure up to date oxygen saturation readings. Since this device will be worn by patients all the time, the size and weight will ideally be comparable to standard hearing aids. This would allow the device to fit comfortably on the ear and allow for minimal lifestyle disruption. Also the material of the sensor should not irritate the skin, or be functionally disrupted by bodily fluids and oils. Ideally the final product should be as close to the patients skin color as possible, in a shape that snugly fits behind the ear, with a smooth, comfortable, soft texture and finish.

On an ideal development timeline one prototype will be assembled by the end of the semester. Since this is a healthcare related device, FDA standards must be followed and approval is required. Since the data that is being transmitted is private health information, it would be necessary to encrypt the data that is sent to a physician over a secure network. A formal list of design specifications can be found in the appendix.

6.0 Design Alternatives

6.1 Common Factors

The five proposed transmission design alternatives share a few common characteristics. First, they will all be compatible with reusable pulse oximeter ear sensors. The current sensors being considered are BCI's ear oximeter sensor and Masimo's LNCS TC-1 reusable Tip-Clip ear sensor in shown Figure 6.11. Both of the sensors are current technologies that are used in hospitals and private practices around the country to determine patient's blood oxygen concentrations.

Figure 6.11 : The ear oximeter sensor by BCI (right) and the LNCS TC-1 Reusable ear senor(left) are used to transmit and collect light to determine the SpO2 levels. [JK]

Second they all will need to be compatible with BCI's Digital Micro Power Oximeter Board, and MEMSIC's MICAz mote since these components are necessary for the design. BCI's Digital Micro Power Oximeter Board is an OEM integrated board that has been validated by Harvard University, Boston University, University of Texas-Dallas, and Journal of American Medical Informatics Association a low power pulse oximetry component that is highly accurate on low perfusion tissues, and is suited for wireless application. It has the ability to read and interpret oxygen saturation and pulse rate data.[LMNO] The specific power and dimensional data can be found in Appendix A. It is also compatible with BCI's reusable sensors and MEMSIC's MICAz mote.[P]

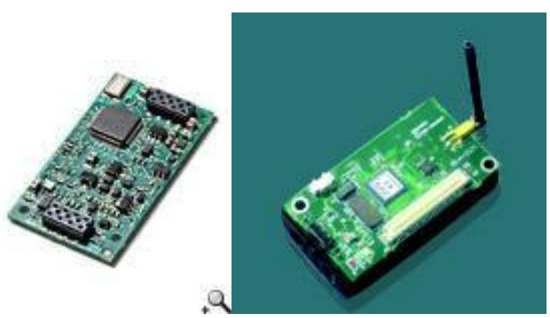

Figure 6.12: The Digital Pulse Oximeter Board (left) and the MICAz mote (right) are key features to our overall design.[PQ]

The MICAz mote is a "2.4 GHz Mote module used for enabling low-power, wireless sensor networks".[P] This device has very low power consumption and can transmit data up to 30 meters indoors. It comes with an attached battery pack for 2 AA batteries. It also contains LEDs to signal battery life, success of data transmission, and is compact.

6.2 Low Energy Bluetooth

The first proposed design is a device using Low Energy Bluetooth (BLE). Bluetooth 4.0 with low energy technology is the newest upgrade for Bluetooth. It has the ability to operate Bluetooth devices for a few years on one coin-cell battery[R]; making it appealing on the battery life front. It is a relatively low cost technology that is compatible with just about any type of receiver; cell phones, computers, PDAs, etc. However, BLE has limited indoor range at about 10 meters and uses the 2.4 to 2.485 GHz band to transmit data. This is an unlicensed band with 37 data channels and 3 advertising channels, increasing the reliability of the technology because the signal can transfer to unused channels. A typical Bluetooth chip uses an output power of 10mW that has a current of 15mA when running, and a current of 1 μA when in sleep mode. This form of current consumption is what allows BLE to have such a desirable battery life.

6.3 Ziggbee

The second design considered was Ziggbee. These wireless transceivers generally operate on the same 2.4 to 2.485 GHz band as BLE, however, use lower data rates (typically 250 kbps) than Bluetooth[P]. This is well suited for periodic data transmission from sensor inputs. These RF transceivers are also usually less expensive to purchase and simpler to configure. Additionally, they have lower power consumption and higher range than most Bluetooth devices, around 400m at 20 mA. Zigbee chips can join their network in approximately 30 milliseconds, while Bluetooth takes, on average, 3 seconds, making Zigbee more suitable for critical applications like vital signal transmission in an emergency care environment. Finally, unlike common 'star' wireless networks like Wi-Fi or other PANs like Bluetooth. Zigbee supports the capability for form ad hoc wireless mesh networks. This type of network allows for every full function device to act as a router to neighbor devices. The result of this is a more flexible wireless network with extended range through multi-hop topology, high reliability achieved through multiple network pathways, and decentralized data flow or network management.

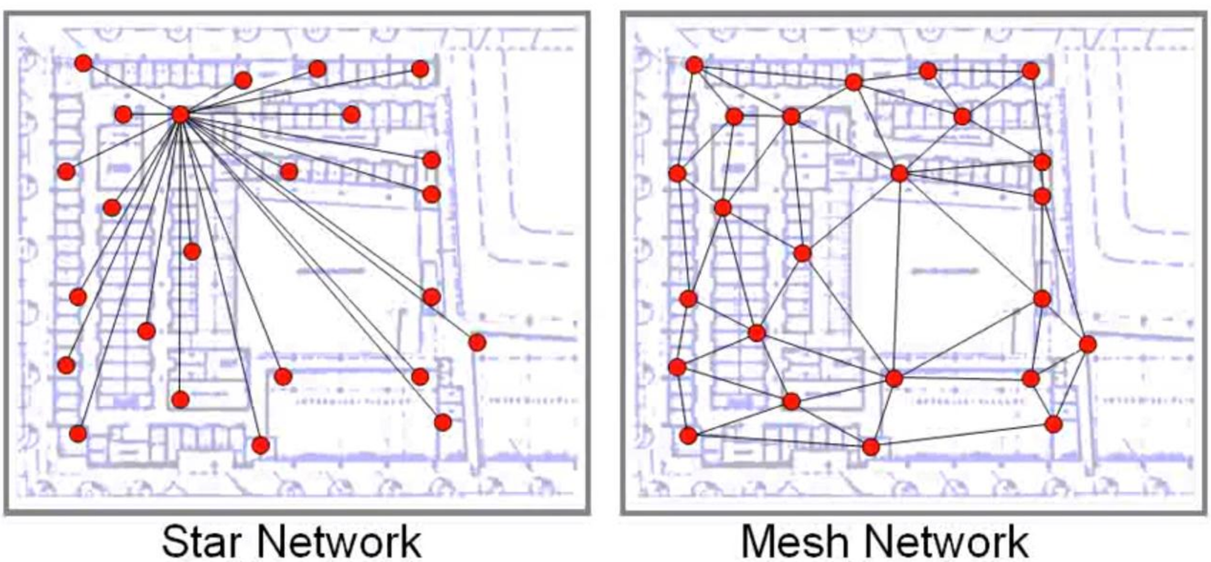

Figure 6.31. These images contrast star and Mesh network topologies. Full function devices are shown as red dots and network connections are shown as black lines.[S]

6.4 Wi-Fi

The third design that was considered in the comparative analysis was the use of Wi-Fi transmission. In general, Wi-Fi offers an adequate method to transmit data through a wireless network, as can be seen by any computer user connecting to the internet via Wi-Fi. However, considering the projects ultimate purpose, Wi-Fi fell short in several different factors. The biggest disadvantage of Wi-Fi is the transmission range. While Wi-Fi can provide on-site or intra-network transmission it has no ad hoc capabilities. In other words, its ability to transmit outside of a hospital or home is extremely limited.

Another area where Wi-Fi fell short was accuracy and robustness. The possibility for a computer or any Internet enabled device to become suddenly disconnected from the Wi-Fi network poses serious implications if that device is monitoring a patient's vitals. In general, all of the other design options provide a more efficient connection to the network.

On the other hand, Wi-Fi does hold its own in areas such as compatibility, battery life, cost, and size. In terms of compatibility, Wi-Fi integrates with several oximetry sensors and has the ability to transmit the data throughout the surrounding network. This method has in fact been utilized with products such as Sensaris' Zao as stated previously.[G] Regarding battery life, Wi-Fi has similar output power to Bluetooth (around 10mW), however, consumes more current since it does not employ the sleep mode that is seen in Bluetooth technology, thus decreasing its battery life. In general, cost and size do not present major issues for Wi-Fi technology since both can be adjusted based upon budget and design specifications.

6.5 3G Networks

The fourth design alternative uses 3G technologies to transmit data over a cellular network. 3G stands for third generation cell phone technology. The 3G network is a mobile broadband which cell phones also use. Cell phones send packets of digital information back and forth between cell phone radio towers via radio waves. For a phone call made by a cell phone, the packets of information carry voice data. For mobile broadband, aka 3G network, the packets of information would be other types of data, such as: e-mails, music files, Web pages, or in this case, oxygen saturation readings. WCDMA and EDGE are two of the most popular technologies today used to operate cell phone networks. The only difference between the two is the composition of algorithms that allow multiple user access to the same radio frequency without interference. Both WCDMA and EDGE have come up with innovative 3G technology solutions to communicate packets of data between cell phones.[T]

The main benefit of utilizing a 3G network in the design is the capability to send data beyond the walls of the patient's home. For this reason, the transmission range in the decision matrix received a 10. Another benefit to 3G networks is the speed and reliability of data transmission. Speeds between 400 and 700 Kbps are typical numbers for data transmission while content delivery is guaranteed while in range of cellular network.[T] For this reason 3G Cellular also received a 10 for accuracy and robustness. Regarding size and weight, the 3G processors are held within cell phones, which are now as light as 4.7 ounces and have dimensions as small as 4.5 inches by 2.4 inches by 0.48 inches.[U] The 3G chip itself is even smaller than the phone, therefore the size and weight aspect of the 3G Cellular received a 10 as well.

With high-speed data transmission, there are a few downsides regarding battery life and cost. Since data doesn't need to be collected continuously, battery life will be significantly larger than is typical for a phone sending data over a 3G network (8 hours),[V] but still not as optimal as low energy Bluetooth or Zigbee. Regarding cost, it can often be difficult to find 3G processing chips for purchase without incorporation into a cell phone thus, making purchasing more difficult and more expensive.

Overall, the 3G network received an 8.0 in the decision matrix making it a top contender among all of the design alternatives. As a side note, 4G cellular networks were also looked at. Since 4G cellular networks are still fairly new, focusing on 3G networks seemed like a safer option regarding technical accessibility and reliability of data transmission.

6.6 Zigbee with 3G

The fifth and final design incorporates Zigbee with 3G cellular technologies. This was proposed as a design alternative to capitalize on the strengths of each respective technology and to utilize the expanded wireless capabilities enabled by dual network access, similar to cell phones with 3G and Bluetooth. Zigbee is better suited for short distance, low power signal transmission. 3G cellular networks, as mentioned previously, enable global communication on a far more robust, existing network infrastructure. It is important to note, the Four-Faith IP modem offers integrated Zigbee and 3G capability without substantial cost increase. Additionally, the optimization of power usage and high sleep/wake configurability does not decrease battery life enough to trivialize this alternative.

7.0 Design Matrix

Factors	**Weight**	**BLE**	**ZigBee**	**WiFi**	**3G Cellular**	**3G Cellular & Zigbee**
Compatibility	24%	8	8	6	6	8
Battery Life	19%	10	10	8	8	8
Transmission Range	19%	3	6	6	10	10
Cost	14%	7	7	5	5	5
Accuracy/Robustness	14%	6	8	5	10	10
Size Weight	10%	10	10	6	10	9
Total	**100%**	**7.2**	**8.1**	**6.1**	**8.0**	**8.3**

Figure 7.01: The design matrix used to determine the final design.

To determine which design would be selected for this project, all of the designs were compared using a design matrix. The design matrix compares six factors that are considered to be the vital characteristics of a successful final design. Each factor was ranked a number between 1 and 5 depending on its importance. The total of these numbers was then added creating a total sum. Each factor's ranking was then dived by the total sum to produce the factors weighted percentage. The categories are: Compatibility with the MICAz mote and Pulse Oximeter board, Battery Life, Transmission Range, Cost, Accuracy/Robustness, and Size/Weight.

As seen in the matrix above compatibility with the MICAz mote and Pulse Oximeter board was considered the most important factor and therefore received a weight of 24%. A high score (7-10) for compatibility requires the technology to be compatible with little to no alterations or configuring necessary. Battery life and transmission range were both weighted at 19%. They were determined to be the second most important factors of the design. As mentioned above the patients will be mobile and it is imperative that the design requires little effort for the patient to change batteries at a reasonable frequency. A high score (7-10) for battery life requires the technology to last at least 7 days without having to replace the batteries.

Transmission range refers to the distance away from the transceiver the patient can travel. Ideally the patient could travel around the world and no matter where they are, their doctor could receive updated vital readings from them. However for this factor to receive a medium score (5-7) the technology has to produce a transmission range between 15 and 30 meters with walls. A high score (7-10) was reserved for technologies that contain the possibility to eventually allow the patient to travel outside of their home and still have their SpO_2 data collected in real time and sent to their health care provider.

Cost and accuracy/robustness were determined to be the 3rd most important factors with a weight of 14%. Cost is an important factor when considering manufacturing and distribution. A high score (7-10) in this category requires the technology to allow for the device to be feasibly manufactured and distributed for less than $100. Accuracy/robustness is an important factor and refers to how reliably the signal can be received and transmitted. A high score (7-8) was given to technologies with the ability to connect to more than one network. A top score of (9-10) was given to technologies that have very minimal “blind” locations where the signal could be lost or disturbed. The final factor is size/weight which weighed in at 10%. This factor refers to the overall size of the chip that would be required to use each type of technology in our design. The top score of (9-10) was given to technologies that were available in sizes less than 5 cubic centimeters.

After each design was analyzed based on the criteria of the matrix, the 3G Cellular with Zigbee design number 5 was chosen as the final design choice. This design has high scores in every category except cost, which is due to the fact that two different wireless technologies are being used. However, the better quality that will be obtained by combining the two different types of technology outweighs the slight cost difference.

8.0 Final Design:

A block diagram of the final design is shown on Figure 8.01, utilizing both Zigbee and WCDMA/EDGE wireless communication modules. The final project budget can be found in appendix C, and a table of relevant component parameters can be found in appendix B. For ease of understanding, the wall to wall device can be segmented into the following functions; signal acquisition and processing, intra-device data transmission, and end-user data reception.

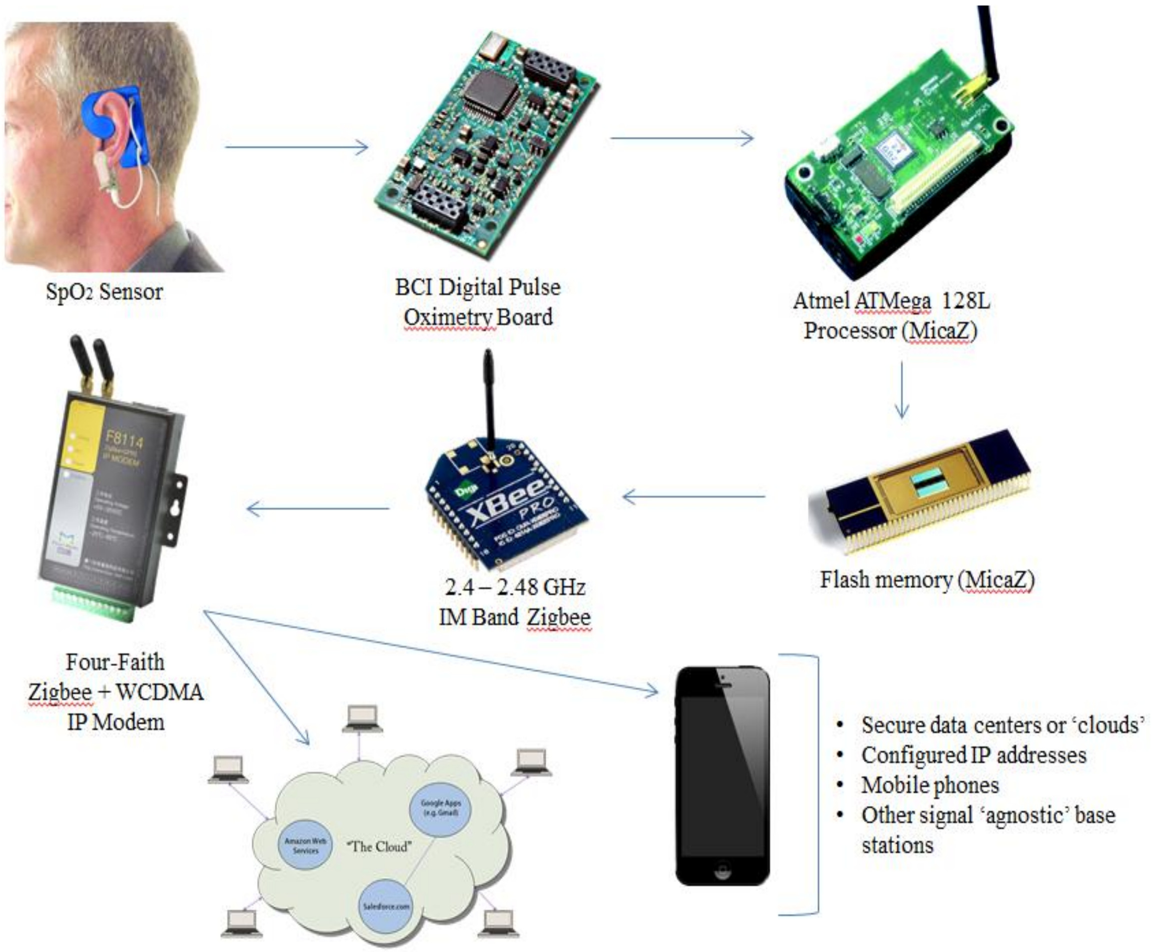

Figure 8.01: A high level, wall-to-wall of the pulse oxitelemetry device. Please note, the Atmel ATMega 128L Processor is directly connected to 8 ½ AA batteries with selective 3 – 5V outputs, which provide all components in the system power.

8.1 Signal Acquisition and Processing

The pulse oximetry sensor is embedded on an earlobe apparatus, which provides raw electrical input that varies proportionally with changes in light absorbance. This earlobe apparatus is equipped with a mechanical clamp on the earlobe and plastic limb that wraps behind the ear for improved sensor stability to minimize motion artifacts resulting from sensor movement and vibration.

This electrical input then passes into the BCI Digital Micro Power Oximeter board, which relates the optic information from the electrical signal into pulse waveforms. A series of pulse waveforms that can be complied to construct a photoplethysmogram(PPG)(Figure 8.11). The PPG is processed by the circuit elements of the BCI board and a SpO2 between 70 – 100% at a pulse rate between 20 and 300 bpm, averaged over a period of 10 seconds is constructed. This board also contains flags, audible beep or LED, that identify the patient if the sensor becomes unplugged, if there is no earlobe in the sensor, if it searches for a pulse for too long, or if the IR pulsatile signal is above or below programmable threshold levels.

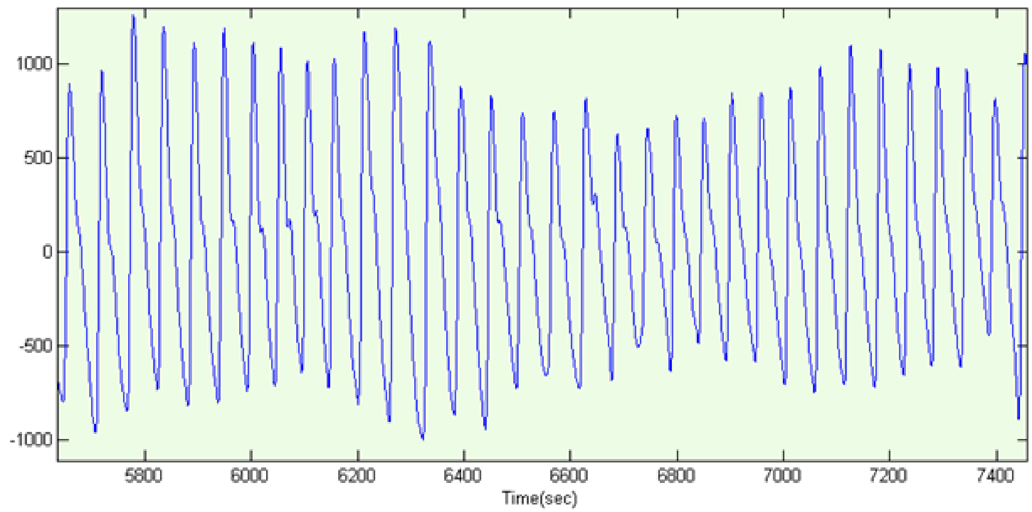

Figure 8.11: A pulse oximetric PPG in Matlab taken from a Nonan earlobe pulse oximetry sensor. Variation in amplitude is from respiratory induced variations.[W]

Data acquisition through the sensor and BCI board is managed by the MICAz mote. This mote contains an MPR2400CA processor platform based on the Atmel ATmega128L processor. It functions as a low-power microcontroller and runs MoteWorks software from its program flash memory. Additionally, this processor board has capacity to run sensor application processing and network communication stacks simultaneously (Figure 8.12). The BCI Digital Micro Power Oximeter board signal will output into a 10 bit ADC converter on a 51-pin expansion connector. Digital I/O, 12C, SPI, and UART input interfaces are also possible. Each 10 second averaged SpO_2 measurement will be collected at least once per minute and stored on an integrated 512 kb flash memory module, which could allow for up to 100,000 measurements in aggregate.

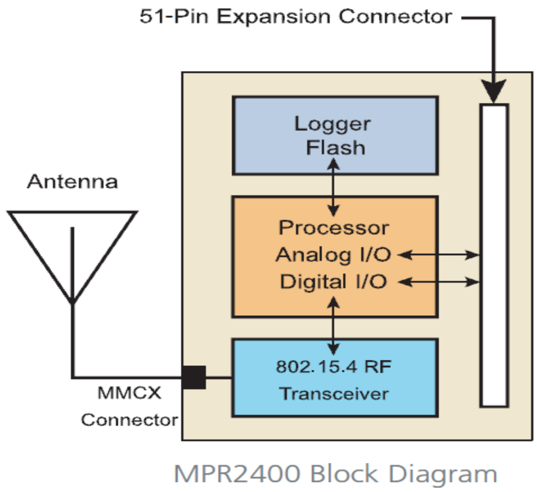

Figure 8.12. MICAz mote board block diagram showing the 51-Pin expansion connector, RF transceiver with antenna, flash memory module, and MPR2400CA processor platform.[P]

8.2 Intra-Device Data Transmission

Data transmission is enabled by Zigbee and WCDMA/EDGE 3G cellular wireless networks. As previously noted the MICAz mote will run sensor application processing and network communication stacks simultaneously. An integrated IEEE 802.15.4 compliant RF transceiver will send data on 2.4 – 2.48 GHz, globally compatible, ISM bands that can be programmed in 1 MHz steps. This allows for data transmission up to 100 m outdoors and 30 m indoors. This RF transceiver is managed by a TinyOS open source operating system that is also configured using MoteWorks software. Every 15 minutes the data stored of the integrated flash memory on the MICAz will transmit through this RF transceiver on the Four-Faith F8414 Zigbee + WCDMA IP modem (Figure 8.21).

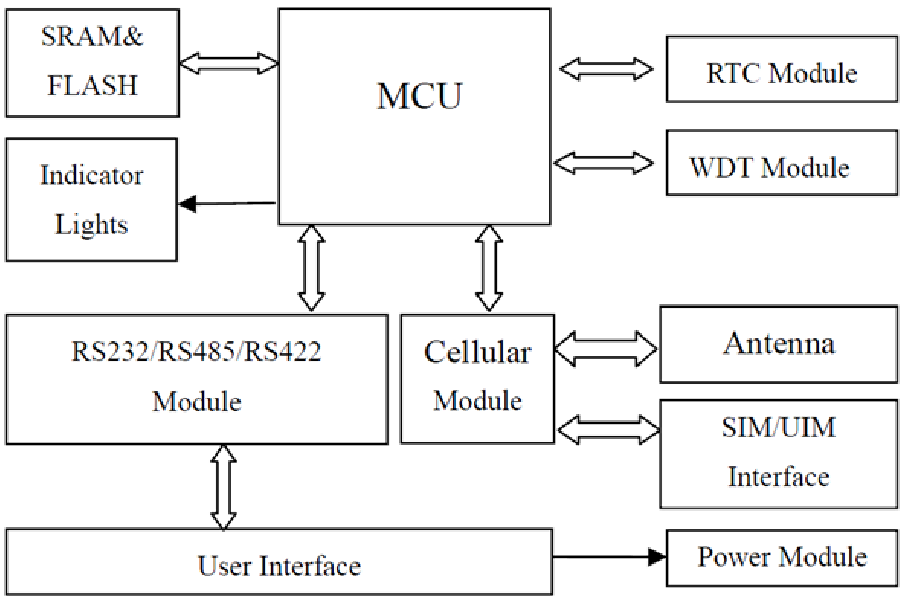

Figure 8.21. A Four-Faith F8414 IP modem block diagram displaying the 32 bit CUP, Zigbee module, cellular module, antenna, 3G SIM card interface, and indicator lights. Please note, the power module will be input from the onboard MICAz battery pack.

The F8414 IP modem can receive the IEEE 805.15.4 2.4 GHz ISM transmission up to 800 m outdoors and 90 m indoors. It has the capability to receive from 11 to 26 data channels at 1024 bytes, allowing for low power ad-hoc Zigbee to WCDMA mesh networking. The Zigbee data packet will temporarily be saved on a 512 kb extendable flash memory, regulated by a 32 bit CPU. This data is then transferred by F8414's high performance processing tools from Zigbee to one of many preconfigured cellular networks. This device is the largest power consumer in the wall-to-wall device.

8.3 End-User Data Reception

These pulse oximetric data packets can then be collected and received in by a wide variety of base stations. The F8414 IP modem supports Transmission Control protocol (TCP) server with multi TCP client connections, 5 I/O channels, multi online trigger ways (SMS, ring, and data), dynamic domain name (DDNS) and IP access to data centers, and APN/VPDN connectivity (Figure 8.31).[U] This modem also has the capability to send and receive with up to 5 double data centers (one main, another backup). This means that up to 5 preconfigured base stations can receive data from 1 pulse oxitelemeter simultaneously, with each base station referring to a preconfigured back-up base station if the primary address is inaccessible. This adds an additional layer of security to the design by providing controls to ensure the end-user receives data on schedule.

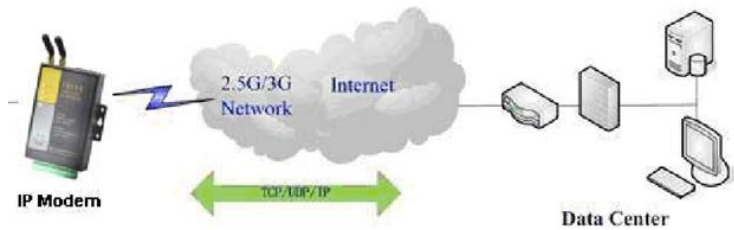

Figure 8.31: Illustration of F8414 IP modem cellular network connectivity to the internet, multiple data centers, and other 2.5G/3G cellular devices.[X]

All base station assignments are made using Four-Faiths proprietary IP Modem Configuration software programming tool. Therefore, this data can be directed to multiple sources simultaneously, including the patient's physician's personal computer, cell phone for emergency SpO_2 threshold crossing or pulse waveform abnormality, and to an anonymous data center for meta-analysis of global data from multiple patients.

9.0 Testing

9.1 Materials:

- Pulse Oxitelemter
- MicaZ Mote Base Station
- 3G IP Modem Base Station
- Criticare Hardwired Pulse Oximeter (provided by BME department)
- Oscilloscope with 2 input probes
- Signal and power generator
- Computer with Labview and 2 signal input channels
    - Pulse Oximetry DAQ interface
- Matlab
- 4 test subjects
- Stationary bicycle

9.2 Experiment #1 Method:

1. Attach the finger sensor of the hardwired pulse oximeter and the ear sensor of the pulse oxitelemeter to subject 1
2. Have subject 1 sit down in on the stationary bicycle and collect data using LabView simultaneously through both pulse oximeter outputs at a rate of 2 readings per second
3. After 2.5 minutes, have subject 1 begin peddling at a slow, comfortable pace
4. After 1.5 minutes, have subject 1 speed their pace significantly
5. Repeat steps 1 – 4 for subjects 2 – 4
6. After 5 minutes of data have been collected from 4 subjects, save the data and export into Microsoft Excel.

7. Using MATLab, calculate the difference between the pulse oxitelemetric data and the hardwired pulse oximeter data at each data point collected. These will be referred to as delta values.
8. Calculate the mean, standard deviation, maximum, and minimum SpO_2 saturations, and perform the same statistical calculations on the delta values. Using these delta values, calculate the pulse oxitelemetric tolerance vs. the positive control (Criticare pulse oximeter).
9. Create a scatterplot of SpO_2 saturations vs. delta values and identify under which state of physical excitation the delta values are the largest
10. Create fast-fourier transform plots and observe differences in the concentration of signal frequencies.

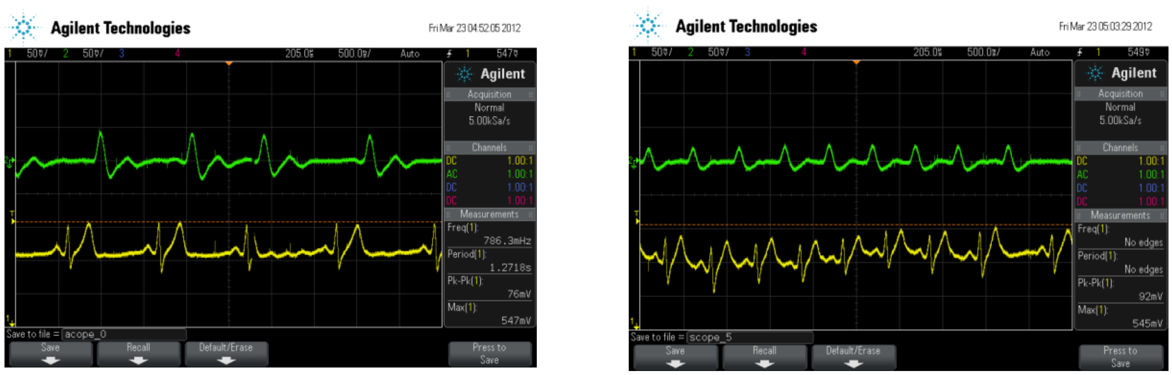

Figure 9.21. Criticare positive control pulse waveform (green) ECG signal (yellow) during rest (left) mild exercise (right).

9.3 Experiment #2 Methods:

1. Attach the finger sensor of the ear sensor of the pulse oxitelemeter to subject 1
2. Configure the pulse oxitelemeter device to 2 separate base stations:
    a. Configure base station 1 as be a Zigbee receiver within 5 m of subject 1
    b. Configure base station 2 as a 3G cellular receiver greater than 2 km away from subject 1
3. Instruct subject 1 to sit down in on a chair and collect data in LabView at a rate of 2 readings per second for 5 minutes, broadcasting to base stations 1 and 2 simultaneously
4. Repeat steps 1 – 4 for subjects 2 – 4, with each subject being <1 km away from each other subjects base station 2 location.
5. After 5 minutes of data have been collected from 4 subjects, save the data and export into Microsoft Excel.
6. Using MATLab, calculate the difference between the nearby Zigbee data and the 3G cellular data at each data point collected. These will be referred to as delta values.
7. Calculate the mean, standard deviation, maximum, and minimum SpO_2 saturations, and perform the same statistical calculations on the delta values.
8. Create a scatterplot of SpO_2 saturations vs. delta values and identify under which state of physical excitation the delta values are the largest
9. Create fast-fourier transform plots and observe differences in the concentration of signal frequencies.

10.0 Future Work

While tremendous progress has been made to this point, there is great deal of future work and opportunity ahead. First and foremost, the MICAz and F8414 hardware must be programmed and calibrated to exchange mutually compatible data parameters through the MoteWorks microcontroller and Four-Faith proprietary programming environments. Optimal data transmission rates and data packet resolution will iteratively be assessed by the team client, and through physician interviews. These factors, however, must be determined after optimization of a device ‘power budget’. Under current max power consumption considerations [appendix] the device will be able to save 900 time-stamped SpO_2 measurements per 15 minutes, and transmit this data package into 3G cellular networks continuously for 14 days using 9600 mAh of battery power.

Then, the end-user data receivers, referred to as base stations for the team’s purposes, must be configured through Four-Faith F8414 IP modem proprietary programming environment. Multi online trigger ways (SMS, ring, and data) will be utilized first to provide proof of concept. Next, group and client personal computer IP addresses will be configured to receive signal through LabView or Matlab/Simulink data acquisition interfaces. These interfaces will also facilitate the data acquisition needed for the accuracy and robustness testing experiments outlined above. Furthermore, open source adaptive filter algorithms for these interfaces, such as the exponentially weighted least squares (EWLS) or least mean squares (LMS) can be tested in a similar methodology to assess the benefits of virtually filtering signal noise.[Y]

Finally, there are many other directions in which the team could take the device, however, the following are viewed as particularly important. A setting enabling selective bypass of the Zigbee transceiver via hardware connection would allow for 3G cellular network accesses with significantly reduced power consumption. Next, due to aforementioned 3G transmission power consumption, pseudo-real time data transmission is impractical. If the 3G transmission device could also be selectively bypassed or hardwired to a power source, pseudo-real time Zigbee wireless data transmission would become practical. This setting would be particularly useful in ambulatory and intensive care environments, where real time pulse oximetric data is absolutely necessary. Furthermore, this Zigbee exclusive transmission network would benefit from the Zigbee capability to form optimized ad-hoc mesh networks and many nearby patients data could still be aggregated and introduced to cellular networks from a few, or even one, powerful 3G cellular module.

Lastly, the collection of this data poses a unique opportunity for large scale pulse oximetric analysis. As stated previously, patients with CHF, COPD and Asthma would benefit from more frequent physician monitoring, enabled by the pulse oxitelemeter. Inevitably, some population of these patients, if the device was widely adopted, will undergo congestive heart failure. If the device is collecting data at the time of heart failure, a unique pulse oximetric footprint will come into existence, that does not exist today due to the fact that this data is infrequently saved and more often un-collected during the time of crisis. By analyzing this data signature from a large population of patients, there is potential to uncover previously unknown indicators that are predictive of heart failure. If this hypothesis were to be true, this device could extend the time frame of proactive measures by physicians and greatly improve clinical prognosis for a disease that dramatically affects more than 27.1 million adults in the US alone and is the number one cause of death globally.[Z]

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Appendix A - PDS

BME 200/300
Pulse Oxitelemetry
Chris Fernandez
Olivia Rice
Tony Prostrollo
Kaitlyn Laning
12/12/12
Product Design Specifications

Function:

It is vitally important to measure blood oxygen saturation data for patients with chronic diseases like congestive heart failure, chronic obstructive pulmonary disease or asthma. However many of these patients do not need to remain in a hospital setting. This pulse oxitelemetry device will collect real time blood oxygen saturation data from patients in a variety of environments made accessible by wireless data transmission. In doing so the patient's quality of life will be increased due to freedom of mobility.

Client requirements:

- Wireless transmission from device to base station at predetermined intervals
- Comfortable design that will not burden day to day activities
- Battery life beyond 1 week for discontinuous monitoring
- Ability to customize data collection intervals and signal threshold notifications

Design requirements:

1. Physical and Operational Characteristics
a. *Performance requirements*: Primarily 24/7 monitoring, during day to day activities and while sleeping. Monitoring will consist of wireless signal transmission from the device to the cellular network and vice versa. Clinical and ambulatory settings would also be desirable.
b. *Safety*: The thermal state of the device cannot cause discomfort to the patient. Patients cannot be exposed to any harmful currents or voltages from the device. The RF exposure guidelines will be taken into account. Waterproofing the device to limit the likelihood of these events is strongly preferred. It needs to be thoroughly sterilized. Safety warnings will be included and Continua Healthcare Alliance standards will be considered.
c. Accuracy and Reliability: Precision and accuracy should very closely resemble the signal outputs of contemporary pulse oximetry devices. A specific signal tolerance from the wireless output relative to the wired output will be determined.
d. *Life in Service*: Signals must be transmitted by the device at least every 15 minutes, 24 hours a day, 365 days per year. Battery life must last longer than one week supporting these transmission intervals.
e. *Shelf Life*: Shelf life and life cycle of usage should be a minimum of 1 year.
f. *Operating Environment*: The device should not be exposed to temperature ranges, pressure ranges, humidity, shock loading, dirt or dust, corrosion from fluids, noise levels, insects, or

vibration beyond those of clinical outpatients. Due to this the device should be encased.
g. *Ergonomics*: The device usages will be restricted to the heights, reach, forces, and operation torques standard to clinical outpatients.
h. *Size*: Device size and weight will ideally be comparable to or smaller than standard hearing aids, in order to fit comfortably on the ear to allow for minimal lifestyle disruption.
i. *Materials*: Any materials used cannot irritate skin, or be functionally disrupted by bodily fluids and oils.
j. *Aesthetics, Appearance, and Finish*: The device should be as close to the patients skin color as possible, in shape that snugly fits behind the ear, with a smooth, comfortable, soft texture and finish.

2. Production Characteristics
a. *Quantity*: 1.
b. *Target Product Cost*: Less than $100.00 to purchase, manufacture, and distribute each device.

3. Miscellaneous
a. *Standards and Specifications*: FDA approval is required, IEEE wireless transmission certification is beneficial, and the Continua Healthcare Alliance certification is also beneficial.
b. *Customer*: Comfortability, mobility, reliability, device should be discrete as possible.
c. *Patient-related concerns*: Device will need to be sterilized on a monthly basis. Unprocessed patient pulse oximetry frequency responses must be transmitted over a secure network.
d. *Competition*: Masimo, Nonin, and Phillips pulse oximeters

APENDIX B – Summary of Relevant Component Parameters Table

Summary of Relevant Component Parameters

Device:	MicaZ	F8414 IP Modem	Digital MicroPower Oximetry Board
Electromechanical			
External Power	2.7 V - 3.3 V	5 V - 35 V	3.3 V
Size (mm)	58 x 32 x 7	91 x 58.5 x 22	38 x 20 x 6.1
Weight (g)	18	210	
Expansion Connector	51 - pin		
Processor Performance			
Program Flash Memory	128 KB	256 KB	
Measurement (serial) Flash	512 KB	512 KB	
Active Current Draw	8 mA	115 - 165 mA	14 mA
RF Transceiver			
Frequency Band	2400 MHz - 2483.5 MHz	2400 MHz - 2483.5 MHz	
Transmit (TX) Data Rate	250 Kbps	250 Kbps	
RF Power	-25 dBm - 0 dBm	0 dBm - 22 dBm	
Receive Sensitivity	-90 dBm to -94 dBm	-95 dBm to -104 dBm	
Outdoor Range	75 m to 100 m	100m to 800m	
Indoor Range	20 m to 30 m	60 m to 90 m	
Cellular Tranceiver			
Standard and Band		UMTS/WCDMA/HSDPA/HSUPA 850/1900/2100MHz GSM850/900/1800/1900MHz GPRS/EDGE CLASS 12	
Bandwith		HSUPA 5.76 Mbps HSDPA 7.2 Mbps UMTS 384 Kbps	
TX power		< 24 dBm	
RX sensitivity		< -109 dBm	
Wireless Power Consumption			
Communication	19.7 mA	115 - 165 mA	14 mA
Standby	20 µA	45 mA	
Sleep	1 µA	18 mA	
Timing Power Off	1 µA	1 mA	

APENDIX C - Budget Expenses

Final Budget and Expenses		
Device:	**Final Price**	**Quantity**
MicaZ	$0.00	2
Shipping	$50.00	-
F8414 IP Modem	$160	1
Shipping	$40.00	-
Digital MicroPower Oximetry Board	$255.00	1
Shipping	$0.00	-
Reusable Nortell Finger Sensor	$0.00	1
Disposable Nonin Ear Sensor	$0.00	1
AA Batteries	$0.00	4
Final Budgeted:	**$500.00**	-
Total Project Expenses:	**$505.00**	**10**