UNIVERSITY OF WISCONSIN - MADISON

Pulse Oxi*telemetry*

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Abstract

Traditional pulse oximetry sensors require a patient to be tethered to a bedside monitor in a hospital were a healthcare provider monitors readings continuously. This presents a huge disadvantage to patients who do not necessarily need to be in the hospital, but do have a need for pulse oximetric data monitoring. A common example of this situation would be a person who suffers from congestive heart failure. It is important for this type of patient to be monitored; however it is not always necessary for that patient to remain in the hospital. While, the healthcare industry has been working on possible improvements to the tethered device and has provided alternative pulse oximetry sensors to the tethered system such as a mobile wrist watch design or wireless systems operating on the hospital network, much improvement is needed.

Dr. Fred Robertson has an idea for another improvement that would allow the hospitals to send patients that do not require hospitalization home and still allow the healthcare providers to monitor these patients pulse oximetric data. This would ultimately create a comfortable, mobile pulse oximetry unit with the ability to transmit the SpO_2 data to a healthcare provider’s cell phone or computer no matter where the patient or their provider is located. This would allow for current patients being monitored to return to their own homes and resume normal daily activities instead of being confined to the hospital.

In order for this device to have an unlimited range of transmission, a pulse oximetry ear sensor needs to be integrated with a MICAz mote, a digital pulse oximeter board as well as a Four-Faith ZigBee to EDGE converter. Throughout the remainder of the semester, the separate components of this oxitelemetric device will be programed and assembled to be capable of monitoring SpO_2 data in real-time and transmitting said data to a predetermined healthcare provider.

1.0 Problem Statement

The pulse oxitelemetry sensor will collect real time blood oxygen saturation data from patients in a variety of environments made accessible by wireless data transmission. These unprocessed signals will be periodically stored in a base-station 'agnostic' database for analysis and evaluation by healthcare providers. Contemporary technologies are most often wired instruments, which cause mobility limitations that make real time data collection unrealistic for patients.

2.0 Background

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

Pulse oximetry utilizes the absorption wavelengths of two different types of hemoglobin to monitor the arterial oxygen saturation in a patient. In order to obtain this data, a sensor containing two LED lights and a photodetector is usually placed in one of two areas on the body of the patient: the fingertip or the ear lobe.[1] Once the sensor is in place, red (660 nm) and infrared (940 nm) light is cast through the finger or earlobe. The amount of transmitted light is then collected by the photodetector which ultimately yields a ratio between oxygenated hemoglobin and deoxygenated hemoglobin. This ratio is what is commonly referred to as a patient's oxygen saturation (O2 sat.).

In order to fully understand the process of retrieving a patient's oxygen saturation levels, it is necessary to discuss the specific absorbance patterns of hemoglobin and how this translates to a ratio communicated by the photodetector. When the red and infrared light pass into the bloodstream, they are absorbed by oxygenated and deoxygenated hemoglobin. The difference however, is deoxygenated hemoglobin absorbs approximately ten times as much red light as oxygenated hemoglobin. In contrast, oxygenated hemoglobin absorbs more infrared light than deoxygenated hemoglobin.[1] Once these two pieces of information are known, the photodetector can calculate the ratio that becomes the patient's oxygen saturation based upon the amount transmitted through the bloodstream unabsorbed.

In many cases, the raw data collected by the photodetector is transmitted to the patient's bedside monitor and displayed in a graphical and numerical analysis. The graphical analysis is called a plethysmograph and it also shows the pulsating nature of the blood flow through the human body. In Figure 1.11 below, both the graphical and numerical analysis can be seen.

Figure 1.11. Nonin's Avant 9700 pulse oximeter displays both a graphical

and numerical data indicating an oxygen saturation of 96%.[2]

2.2 Contemporary Technology

There are many viable designs of pulse oximeters that are currently on the market and to list them all would be unproductive. In any case, 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.

To begin, Figure 1.11 above shows the Nonin 9700 pulse oximeter. This is an example of a basic, wired pulse oximeter. 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 supplies a robust and accurate signal so the physician is able to make informed decisions about the patient’s treatment. In addition to the Avant 9700 model, Nonin also manufactures an Avant 4000 model which is a Bluetooth enabled pulse oximeter. The sensor, once again on the finger, is attached to a device capable of wireless transmission that wraps around the wrist of the patient.[2] The benefit of this design is that it allows the patient to move about the immediate area without being tethered down by wires connecting to the base station.

While Nonin is an industry leader in pulse oximetry, there are several other manufacturing companies that have designed viable options for mobile pulse oximetry patients. For example, Philips Healthcare has designed the Philips Intellivue Transmitter for wireless telemetry.[3] This system allows for the patient to broadcast a wireless signal from one of Philips’ pulse oximetry devices throughout the hospital network. This allows the patient more freedom and capability than either of the two previously mentioned devices.

In addition to the Nonin and Philips devices illustrated above, Sensaris, a medical device company based in France, has designed a patent pending product by the name of Zao. As seen in Figure 1.21 below, Zao is an “all in one” device that operates on the hospital’s Wi-Fi network similarly to the Philips system.[4]

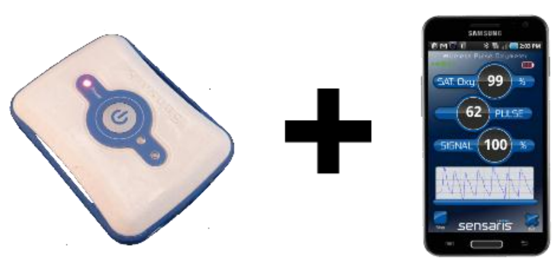

Figure 2.21. The Zao device provides glucose, temperature, oximetry, and blood pressure data to the physician in real time.[4]

However, the twist that Sensaris has placed on their device is the ability for the device to interface with iPhones, Android Phones, iPads and computers. The ability to interface with several mobile devices allows physicians, nurses and other hospital personnel to have patient data at their fingertips at all times. Ultimately, this device has the capability to speed up reaction time of the hospital staff to a patient’s sudden decrease in vitals.

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 essentially limited to the hospital or home environment to which they are receiving treatment. This poses a problem for many patients who are in need of vitals monitoring but still carrying on daily activities. With the current technologies as illustrated above, a trip to the grocery store, post office, or a nearby restaurant, would leave the patient without the data that is so important to their health and well-being.

In addition to the limitations affecting the patient's ability to receive data, the physician has no way of receiving oximetric data from a patient that is under a home care system. It is possible for the physician to see the vitals of their patient when they are doing an in-home visit or check-up, however, any time when the physician is not within the wireless network of the patient's home, they are completely in the dark as to the condition of their patient. This presents serious risk to the patient and limits the ability for the doctor to respond to sudden changes in the patient's vials.

3.0 Design Motivation

The overall motivation behind our project is to make pulse oximetry data, collected inside a patient's home, accessible to their physician wherever they may be. Many current pulse oximeters have been fabricated in a more mobile fashion in recent times.[1] However, nothing has been created to send the data the oximeter collects to a base-station 'agnostic' database via wireless transmission that can then be sent beyond the boundaries of the patient's home. This data transmission would be useful to both patients and physicians. Currently the at home patient would has to manually enter readings into a communication system in order to send their vitals to a physician. One such system is 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.[5] A wireless pulse oximeter that is able to transmit the data wirelessly straight from the device will decrease the amount of responsibility the patient has, and also decrease time between oxygen saturation readings and data transmission to the physician. From a health care provider's point of view, if data transmission of their patient's oxygen saturation levels were wireless, it would allow for them to essentially be anywhere in the world and still be kept up to date on their patient's vitals. This type of wireless data transmission is therefore a faster, more effective way of communicating blood oxygen saturation levels from at home patients to their physicians.

4.0 Client's Requirements

After first meeting with Dr. Fred Robertson, he made it clear that the majority of this project was up to us to decide upon. However, he did list a few requirements regarding the final device. First off, the final design prototype must be able to wirelessly transmit the readings from the device to a base station at predetermined intervals. The device does not have to be constantly monitoring but the data collection intervals, along with the signal threshold should be customizable. Another important feature of the final design product is battery life. The battery should last at least a week while the device is performing discontinuous monitoring. Finally, the design of the device should be comfortable and light, as to not interfere with the patient's day to day activities.

5.0 Design Constraints

Subsequently to learning the client's desires for the device, some more design constraints were brainstormed to ensure the device's functionality and reliability. Since the patient will essentially be wearing the device 24/7 some safety requirements needed to be addressed. The thermal state of the device should not cause discomfort to the patient. Patients should not be exposed to any harmful currents or voltages from the device. In order to ensure this, waterproofing the device is strongly preferred. The oximeter should also be safely 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 very closely resemble 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, or smaller than, standard hearing aids. This would allow it 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.

To successfully meet our client's wants, only one prototype needs to be completed 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 also be useful to encrypt the data and be 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 a reusable pulse oximeter ear sensor. The current sensors being considered are BCI's ear oximeter sensor and Masimo's LNCS TC-1 reusable Tip-Clip ear sensor seen below in Figure 6.1. Both of the sensors are current technologies that are used in hospitals and private practices around the world to determine patients pulse 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[6 7].

Second they all will need to be compatible with BCI's Digital Micro Power Oximeter Board, and MEMSIC's MICAz mote. BCI's Digital Micro Power Oximeter Board is an OEM integrated Board that has been validated as accurate, low power pulse oximetry components suited for wireless application by Harvard University, Boston University and Journal of American Medical Informatics Association. It has the ability to read and interpret SpO2 data and pulse rates. This board has a power consumption of 22 mW with a need of a single 3.3V voltage source. Its small size is also an advantage with dimensions of 39mm x 2 mm x 5.6 mm. It is also compatible with BCI's reusable sensors and MEMSIC's MICAz mote.[8]

Figure 6.12: The Digital Pulse Oximeter Board (left) and the MICAz mote (right) are key features to our overall design.[8 9]

The MICAz mote is a "2.4 GHz Mote module used for enabling low-power, wireless sensor networks"(MICAz datasheet). This device has very low power consumption and can transmit data up to 30 meters indoors. It comes with an attached battery pack for 4 1/2 AA batteries. It also contains LEDs to signal battery life and the success of transmitting data and is compact with dimensions of 58mm x 32mm x 7mm.

6.2 Low Energy Bluetooth

The first proposed design to meet the needs of the client is Low Energy Bluetooth (BLE). Bluetooth 4.0 with low energy technology is the newest upgrade to Bluetooth. It has the ability to operate Bluetooth devices for up to a few years on one coin-cell battery[10]; making it very 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. BLE also 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 is what allows the technology 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[8]. This is well suited for period 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 20 mA at 400 m. Finally, Zigbee chips network join time is approximately 30 milliseconds, while Bluetooth is on average, 3 seconds, making Zigbee more suitable for critical applications like vital signal transmission in an emergency care environment.

6.4 WiFi

The third design that was considered in the comparative analysis was the use of WiFi. In general, WiFi provides an accurate method to transmit data through a wireless network. However, considering the projects ultimate purpose, WiFi fell short in several different factors. The biggest disadvantage of WiFi illustrated in the design matrix below is the transmission range. While WiFi can provide on-site or in-network transmission, it has no ad hoc capabilities. In other words, its ability to transmit outside of the hospital or home is extremely limited.

Another area where WiFi fell short of the competition was accuracy and robustness. The ability for a computer or any internet enabled device to become suddenly disconnected from the WiFi network poses serious implications if that device is monitoring a patient in need of data acquisition. In general, all of the other design options provide a more robust and accurate connection to the network.

In addition to these factors, WiFi does hold its own in areas such as compatibility, battery life, cost, and size. In terms of compatibility, WiFi 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 [4]. On the topic of battery life, WiFi is similar to the output power of Bluetooth (around 10mW) however does not employ the sleep mode that is seen in Bluetooth technology. In general, cost and size to not present major issues for WiFi technology as both are able to be adjusted based upon budget and design specifications.

6.5 3G Networks

The fourth design is to use 3G technologies to transmit data over a cellular network. 3G stands for third generation cell phone technology. The 3G network is the same thing as mobile broadband which essentially works the same way a cell phone does. 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. CDMA and GSM 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 for multiple user access to the same radio frequency without interference. Both CDMA and GSM have come up with innovative 3G technology solutions to communicate packets of data between cell phones[11].

The main benefits of a 3G network for our 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[11]. For this reason 3G Network 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 inch[12]. The 3G chip is even smaller than the phone therefore the size and weight aspect of the 3G network received a 10 as well.

Of course with high speed data transmission there are a few downsides regarding battery life and cost. Since we won't need to collect data continuously, battery life will still be significantly larger than is typical for a phone sending data over a 3G phone, which is around 8 hours[13], 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 most likely more expensive, especially when only one chip needs to be purchased for the final prototype.

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 networks utilizing EDGE technologies 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 assurance of transmission delivery.

6.6 Zigbee with 3G

The fifth and final design is Zigbee with 3G cellular technology was also 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, as mentioned above, enables global communication on a far more robust, existing network infrastructure. It is important to note, the MICAz system offers integrated Zigbee capability without any incremental cost increase, therefore making 3G connectivity the only substantial cost factor for this design alternative. Additionally, the optimization of power usage and high sleep/wake configurability allows the battery life not to increase substantially 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 the final design for this project, all of the designs were compared using a design matrix. The design matrix compares six categories or factors that are considered to be the vital characteristics of a successful final design. The categories are Compatibility with the MICAz mote and Pulse Oximeter board, battery life, transmission range, cost, accuracy/robustness, and size/weight. Each factor was then weighted based on its importance in the overall design.

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 would require the technology to be compatible with little to no altering 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 client will be in their own home 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 would require the technology to last at least 7 days without having to replace the batteries. A top score (9-10) would require the technology to last more than 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 updates. However for this factor to receive a medium score (5-7) the technology would have to have a transmission range between 15 and 30 meters with walls. A high score (7-10) was reserved for technologies that may have the power to eventually allow the patient to travel outside of their home and still have their SpO2 data sent in real time 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 would require 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 well the signal can be received and transmitted with reliability. A high score (7-10) 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 disturbed. The final factor is size/weight and 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 determined to be the final design choice. This design has high scores in every category except cost, and this is due to the fact of two different types of technology need to be purchased. But the better quality that will be obtained by having 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 5, utilizing both Zigbee and WCDMA/EDGE wireless communication modules. 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.

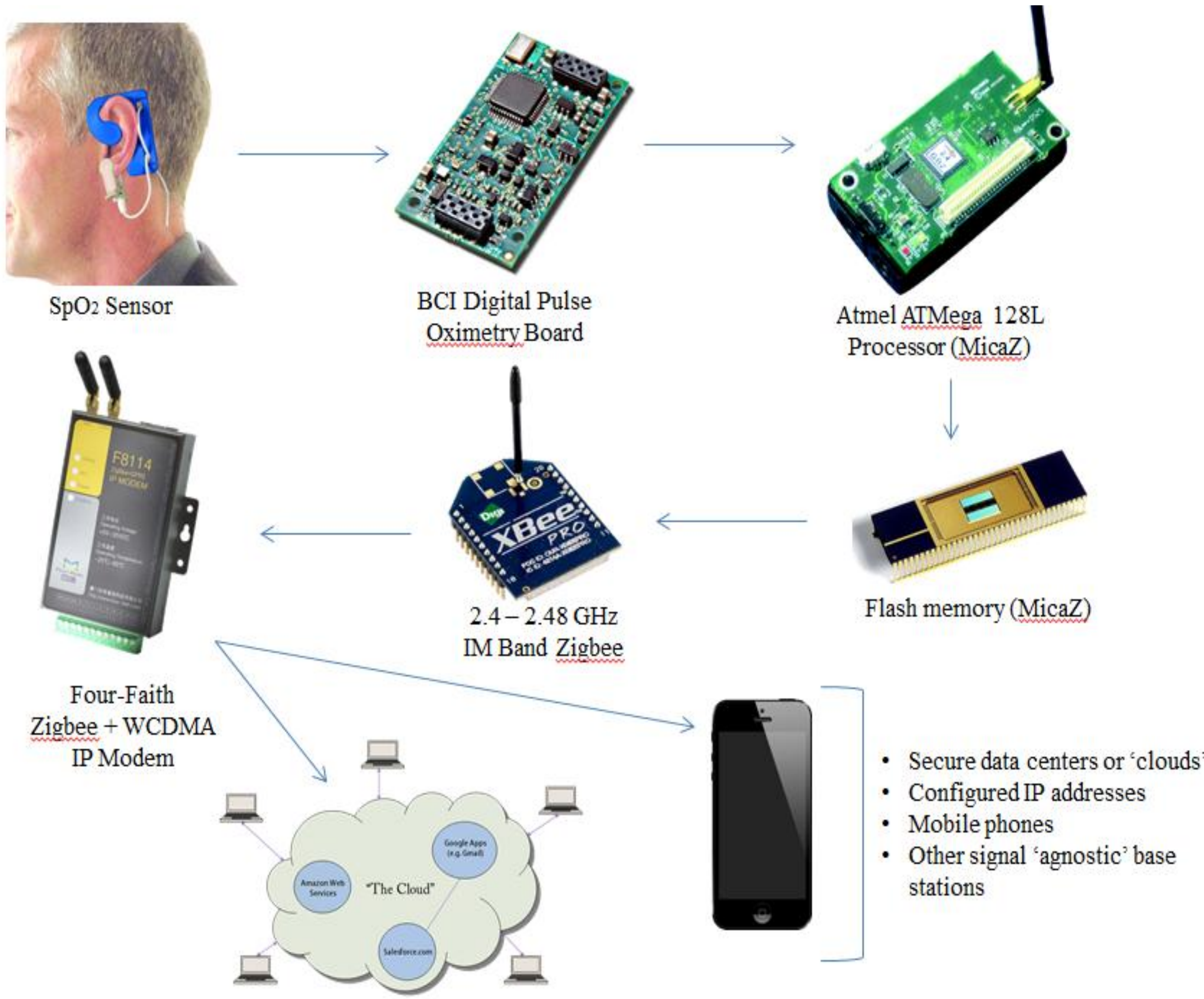

Figure 8.01: A high level, wall-to-wall of the pulse oxitelemetry device. Please note, the Atmel ATMega 128L Processor is directly connected to 8 ½ AA batteries with selective 3 – 5V outputs, which provide all components in the system power.

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 volumetric measurements. These measurements are compiled to create a photoplethysmogram (PPG) (Figure 5). 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. An input voltage of +3.3 V is required with an average current draw of 14 mA [46 mW].

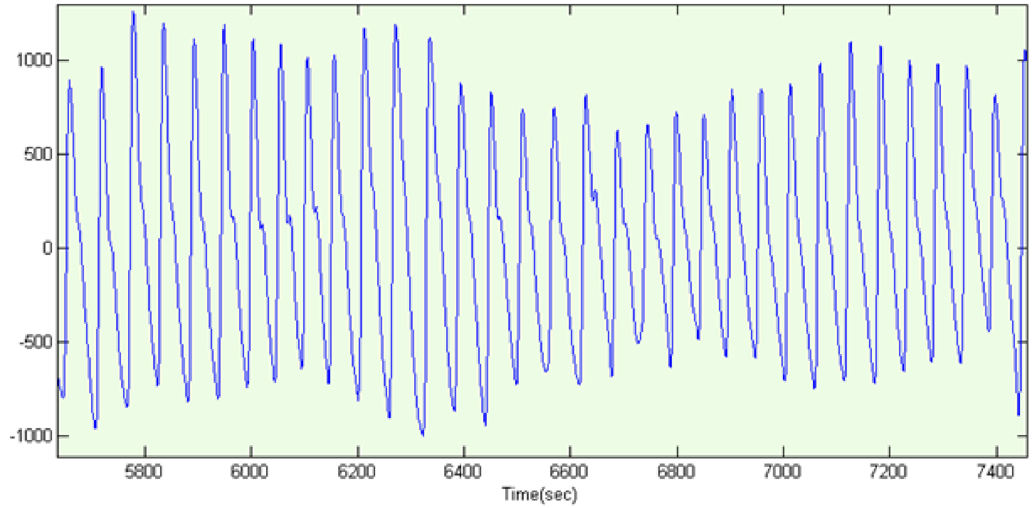

Figure 8.11: A pulse oximetric PPG in Matlab taken from a Nonan earlobe pulse oximetry sensor. Variation in amplitude is from respiratory induced variations.[14]

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 128 kb program flash memory. Additionally, this processor board has capacity to run sensor application processing and network communication stacks simultaneously (Figure 6). 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 SpO2 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. These signal acquisition and processing components of the MICAz require an external power source between 2.7 – 3.3V at a current draw of 8 mA in active mode and <15 µA in sleep mode.

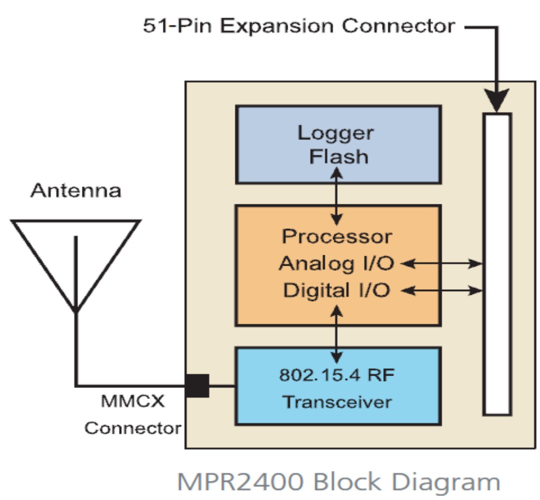

Figure 8.12: MICAz mote board block diagram showing the 51-Pin expansion connector, RF transceiver with antenna, flash memory module, and MPR2400CA processor platform.[8]

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 at 250kbps up to 100 m outdoors and 30 m indoors. This transceiver has a receive sensitivity of -90 dBm (min) and -94 dBm (typ), with an adjacent channel rejection of from 38 dB – 47 dB. Current draw is 19.7 mA in receive mode, 11 mA in transmission mode, 20 µA idle, and 1 µA when in sleep mode. This RF transceiver is managed by a TinyOS open source operating system that is also configured using MoteWorks software. Every 15 minutes, the contents of the integrated flash memory on the MICAz will transmit all of its data contents through this RF transceiver the Four-Faith F8414 Zigbee + WCDMA IP modem (Figure 7).

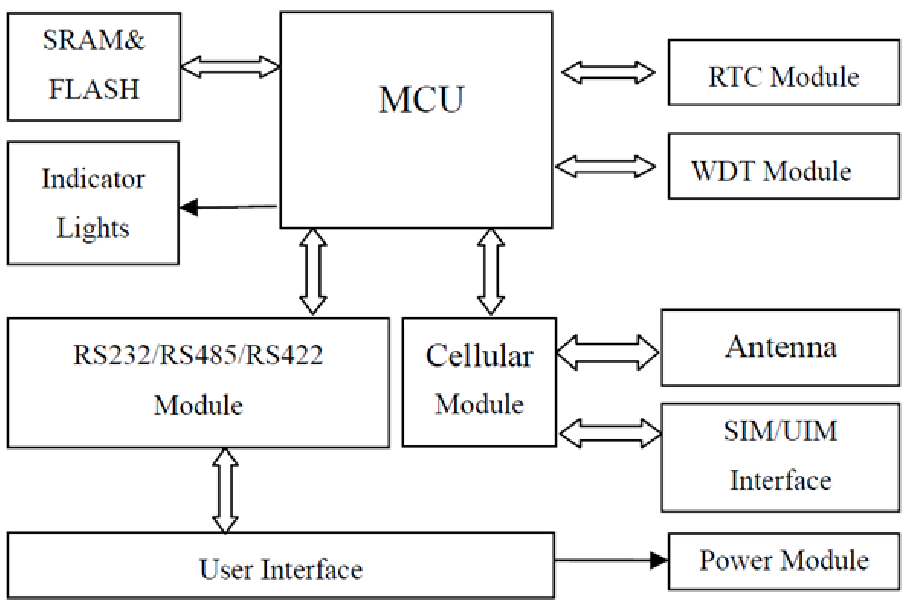

Figure 8.21: A Four-Faith F8414 IP modem block diagram displaying the 32 bit CUP, Zigbee module, cellular module, antenna, 3G SIM card interface, and indicator lights. Please note, the power module will be input from the onboard MICAz battery pack.[15]

The F8414 IP modem will 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 if desired. 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 F8414s high performance processing tools from Zigbee to UMTS/WCDMA/HSDPA/HSUPA/GSM/GPRS/EDGE 850/1900/or 2100 MHz cellular networks. This device is the largest power consumer in the wall-to-wall device; 115-165 mA at 5V communicating, 45mA at 5V standby, 18mA at 5V sleeping, and 1mA at 5V power off.

8.3 End-User Data Reception

These period data packets can then be collected and received in by a wide variety of base stations. The F8414 IP modem supports TCP server with multi TCP client connections, up to 5 double data centers (one main, another backup), 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.[12]

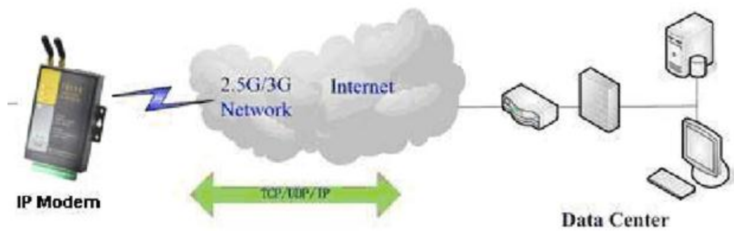

Figure 8.31: Illustration of F8414 IP modem cellular network connectivity to the internet, multiple data centers, and other 2.5G/3G cellular devices. [17]

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 patients physicians personal computer, cell phone for emergency SpO_2 threshold crossing, and to an anonymous data center for meta-analysis of global data from multiple patients.

9.0 Testing

The pulse oxitelemeter will undergo signal accuracy testing versus a positive control pulse oximeter and signal robustness testing at varied distances. Most importantly, the accuracy of the data output of this prototype must be within a certain tolerance of contemporary pulse oximetric technology to be considered valid or useful. This test will be performed by collecting SpO2 data in vivo, from the 4 design team members, simultaneously through the pulse oxitelemeter and a pulse oximeter provided by the UWSMPH. The wired pulse oximeter will function as a positive control and delta values will be calculated in reference to this signal output. Data will be collected at over a period of 5 minutes per person, at varied levels of physical exertion.

Next, the signal robustness will be tested by calculating the loss of signal over increasing distance. This test will also be performed by collecting SpO2 data in vivo, from the 4 design team members, simultaneously through the pulse oxitelemeter and a pulse oximeter provided by the UWSMPH. The methodology of this experiment is similar to that of the last - the wired pulse oximeter will again function as a positive control and delta values will be calculated in reference to this signal output. Data will be collected at over a period of 5 minutes per person, at varied distances from the base station. The wired pulse oximeter will travel with the patient and always be treated as 0 meters from the patient. Data will be collected at multiplicatively increasing distances and the loss of resolution will be determined by evaluating the deviation from the positive control data. Additionally, delta values will be calculated between the frequency domain data at each pulse oxitelemetric signal distance. This will help quantify to what extent signal interference is present or increases at increasing distances. For example, while the pulse oxitelemetric signal may broadly resemble the positive control signal at key values, signal frequencies that were minor at near distance and more frequently reoccurring relative to the most concentrated signal frequencies would be indicative of increasing interference or noise, if said concentrated frequencies show minor alteration in their presence.

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, all circuit boards must be acquired from their respective companies. A budget of $500.00 was approved by the UW – Madison Medical School Department of Anesthesiology. Price quotes have been received on the Four-Faith F8414 and Smiths Medical for the BCI Digital Micro Power Oximeter board, which comes with a reusable sensor, and the team is still under budget. No price quote has been received from MEMSIC as of yet, which is prerequisite to finalizing purchase orders with all companies.

Next, 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 other physician interviews. These factors, however, must be determined after optimization of a device 'power budget'. As the device must operate for a minimum of 1 week before exchanging batteries, the assignment of a likely maximum of 9600 mAh (8 ½AA lithium batteries), will determine the most effective frequency at which data can be transmitted into the cellular network, the most power consumptive operation of the device.

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.

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 selectively bypassed or hardwired to a power source, pseudo-real time Zigbee wireless data transmission would become practical. This setting would be particularly 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 ad-hoc mesh networks and many physically 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 pulse oximetric large scale analysis. As stated previously, patients with high risk of congestive heart failure 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 key indicators that are predictive of heart failure. If this were true, this device could extend the time frame of proactive measures by physicians and greatly improve clinical prognosis for a disease that traumatically affects more than 2% of the adult population.

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Appendix - PDS

BME 200/300
Pulse Oxitelemetry
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9/21/12
Product Design Specifications

Function:
The pulse oxitelemetry sensor will collect real time blood oxygen saturation data from patients in a variety of environments made accessible by wireless data transmission. These unprocessed signals will be periodically stored in a base-station 'agnostic' database for analysis and evaluation by healthcare providers. Contemporary technologies are most often wired instruments, which cause mobility limitations that make real time data collection unrealistic for patients.

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 home monitoring, during day to day activities and while sleeping. Monitoring will consist of wireless signal transmission from the device to the base station 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. Waterproofing the device to limit the likelihood of these events is strongly preferred. Needs to be safely 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 has not yet been 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.

g. *Ergonomics*: The device usages will be restricted to the heights, reach, forces, and operation torques standard to clinical outpatients.
h. *Size*: Device size 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. *Weight*: Device 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.
j. *Materials*: Any materials used cannot irritate skin, or be functionally disrupted by bodily fluids and oils.
k. *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 and Nonin pulse oximeters.