PulseMobile
A novel wireless pulse oximetry device and cloud platform for remote monitoring

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Abstract—**We present the development of a novel chronic illness patient management system for physicians, nurses and other critical care team members. This system combines a cellular network based pulse oximeter with automated transmissions and a web based dashboard application that can be viewed by authorized care team members. This management tool will help improve the communication between physicians and remote patients with chronic illnesses such as congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD), while they are outside of the hospital. A first iteration prototype and web application were developed and tested showing 100% transmission success between the device and web application. A second iteration of both the oximeter device and cloud based dashboard application are currently underway in order to improve the form factor of the device and the robustness of the web application. Ultimately this monitoring system could reduce patient mortality rates, hospital readmissions and emergency room visits and thus, significantly decrease the costs associated with those events while improving patient quality of life.**

I. INTRODUCTION

Patients with chronic diseases such as congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD) do not require continuous monitoring in a hospital, however, they could greatly benefit from periodic oxygen saturation and heart rate monitoring to determine their current state of health. Effective monitoring is challenging in a home setting with current technologies due to range limitations of current devices and issues with patient compliance. There are currently many Bluetooth pulse oximeters on the market[1] that patients can use to take their own oxygen saturation reading and sync it to a base station within 33 feet[2] of the device such as their smart phone or personal computer. These readings are not automatically sent anywhere; they are simply stored on the user's base station. Similarly there are many Bluetooth personal wearable fitness devices on the market such as the Fitbit that can additionally sync the user's information from their smart phone to a cloud database where it can be accessed through the web. However, a clinical grade wearable biosensor system has yet to be developed. With healthcare costs on the rise and shifts in healthcare regulation, remote monitoring development and studies have been rapidly progressing[3].

In particular, the United Kingdom Department of Health began a study titled The Whole System Demonstrator Programme in 2008. They completed a 12 month randomized control trial of telehealth remote monitoring with CHF, COPD and diabetes patients. The study compared a group of telehealth-equipped patients using technology for remote monitoring to a control group whom only used standard health care practices. The overall goal of the study was to see if using telehealth technologies as a remote intervention tool reduced hospital readmissions among other things. The findings indicate that if this type of remote monitoring technology is used correctly, telehealth can deliver a 20% reduction in emergency admissions, a 14% reduction in elective admissions and a 14% reduction in bed days. Additionally they showed a 45% reduction in mortality rates with the patients using telehealth monitoring. These results demonstrate that constant communication between a physician and patient can drastically improve patient quality of life and in addition reduce costs associated with readmissions. The type of telehealth monitoring that this study employed was in fact extremely basic. The patients were asked to take a clinical reading at the same time each day and communicate that reading to the researchers. Symptom questions and educational messages were also sent to the patient. The readings and symptom data were then entered into an electronic health record where the information could be monitored and analyzed by health care professionals whom could contact the patients if needed[4]. This study proved the major impact telehealth technologies could have on health care. However, this type of monitoring is not realistic in an uncontrolled environment since patients may choose not to comply with the requests. Additionally, it requires tedious data entry into the electronic health care record, which clinicians in U.S. simply don't have time for.

While there are 'newer' and 'hotter' vital sensing technologies available today, pulse oximetry has proved over and over to be a reliable and robust measurement tool especially for HF patients. Heart failure isn't an event that occurs suddenly but instead a person's heart will decompensate over time. In a study done by Dartmouth in 2009, they hooked up all of their ICU patients inside the hospital in order to continuously monitor their pulse oximetry data. From this data the physicians were able to diagnose and foresee multiple conditions associated with heart deterioration they were otherwise unable to. We propose to take this type of continuous monitoring outside the hospital, and incorporate a seamless data transmission and entry system. Patients will go about their daily lives as their automated pulse oximetry readings are sent to care team members for them to monitor and analyze.

II. Hardware Design

Fig. 1. Fully operational pulseMobile device. SeeedStudio GSM Shield and Smith's Medical BCI board/sensor integrated with an Arduino Mega ADK powered by 9V battery.

The pulseMobile device is provided to the CHF patient when they leave the hospital. At home, the patient is expected to wear the hands free device during waking hours while it automatically collects and sends clinical grade SpO2 and heart rate data through the cellular network to an encrypted online database. Sending through the cellular network with a built in GSM shield allows the user to go about their everyday lives by eliminating the necessity of owning a cellular phone and the limitation of staying within 30 feet of a Bluetooth base station. While the patient is wearing the pulseMobile, the critical care team receives real-time data that can be used to administer preventative care before potentially fatal decompensations.

The first iteration of the pulseMobile device is powered by a 9V battery and controlled with an Arduino Mega ADK. Sitting on the Arduino is an integrated circuit that handles all the connections between the Smith's Medical BCI Pulse Oximetry module, the BCI sensor, and the Arduino, including level shifting the 5V TTL Arduino logic to 3.3V CMOS logic for the BCI board. Also sitting on top of the Arduino is the SeeedStudio wireless GSM transmission module to send data through the cellular network. The entire device fits inside a 3D printed case with a belt loop for protection and hands free integration.

During regular daytime operation, the device is in a low power consumption mode collecting pulse oximetry data every 10 seconds and saving an averaged value every minute. In this phase, the device consumes between 3 and 5 mAh (milliamp hours). Every 15 minutes, the device turns on the GSM shield and transmits the 15 minutes of collected data. In this phase, the device consumes between 80 and 100 mAh. In the case that the user is temporarily in an area with no cellular reception, the device powers the GSM shield down after attempting to send for one minute and continues saving data in order to send all 30 minutes of data at the during the next attempt. The device has enough memory to save 1.5 years worth of data in worst-case scenarios. This is should never happen because lack of cellular reception is usually a temporary issue.

The second iteration of pulseMobile will be the first step in the miniaturization stage for patient comfort/portability and power usage efficiency for battery life. We have already developed the base of the integrated circuit using open hardware EAGLE files from Seeedstudio and Arduino as well as the knowledge we already gained from implementing the BCI board and sensor. We included a simple USB interface to debug and program the ATMega32U4 microcontroller, which has replaced the bulky Arduino from the first iteration of pulseMobile. Furthermore, we plan on replacing the 9V battery with a more powerful dime-sized lithium ion battery.
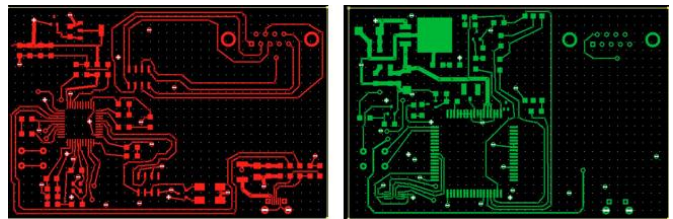

Fig. 2. Initial integrated circuit board layout of second iteration pulseMobile device designed using Eagle PCB design software.

III. Software Design

The pulseMobile cloud application effectively overcomes the disruption to EHR workflow associated with current telehealth methods. It will be used as a clinical decision making tool for physicians and care-team members, allowing them to view their patients' most recent pulse oximetry readings as well as their history as seen in Figure 3b. The application is accessible through any authenticated, client-side web browser on an Internet enabled device. It includes an automated alert system that sends notifications to care teams and physicians when a patient's data falls below their personalized pre-defined threshold of SpO_2 and HR for a certain period of time. A green, yellow, red threshold system on the application dashboard (Figure 3a) tells the clinician how many patients are in good, mild, or severe shape according to their specific threshold levels. Thus, they will be able to see which patients are at risk and make an early intervention decision to try and prevent an emergency readmission.

The Ruby on Rails framework was selected as the back-end platform for development because it offers a stable server side implementation that can handle HTTP requests from client interactions with ease. There are also a variety of add-ons called 'gems' that allow for the addition of various features to the application. One such 'gem', called Devise, was used to create an authentication and authorization system to allow care team members to register for our application and then access their patients' data once registered. As for the front-end platform, users interact with the application in their browser through a front-end framework called Bootstrap with incorporated HTML5, CSS, and JavaScript functionalities.
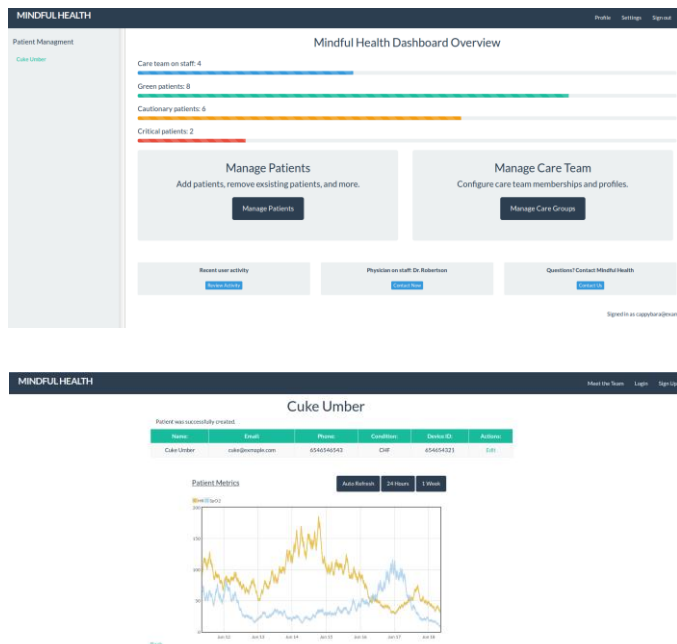
Figure 3. The main dashboard accessed by physicians and care teams (above) and a full week data view for an individual patient (below). Note that the dashboard prioritizes patients into green, cautionary, and critical health statuses based on physician set vital thresholds. Also note the increase in heart rate that corresponds to a steep decrease in SpO2 in the sample plot.

IV. HARDWARE TESTING: MATERIALS & METHODS

The most critical feature of the pulseMobile solution is the clinical grade quality and accuracy of the devices output pulse oximetry data. As such, SpO2 and Heart Rate data collected from pulseMobile device was tested for accuracy against control data, specifically from a calibrated CasMed 740 finger pulse oximeter that was provided by the Madison VA Hospital. $n = 5$ test subjects wore pulseMobile device concurrently with the CasMed. Simultaneous measurements were recorded from the pulseMobile and the control every second for one minute.

V. SOFTWARE TESTING: TOOLS & METHODS

To ensure the proper functionality of our software system, the test-driven development paradigm, a standard among current web development techniques, will be used. This style of testing takes advantage of an incorporated testing suite called Rspec on the Rails platform. Each test is written to define key functionality requirements for the application and all tests are written before any of the code for the actual web application. At this point, all the tests will fail. Now the developer writes the code for the web application with the goal of making the entire testing sutie pass. This ensures that the web application has all of the desired functionality requirements previously defined. In total, 72 tests have included in the current pulseMobile cloud application that validate data models, controllers, features, among other aspects of the application. Currently, all 72 tests are passing.

Testing data integrity will also be important as patient information passes from the database to our front-end visualization. This will be accomplished once we have integrated a HIPPA compliant patient data security system. We are currently in the process of collaborating with start-up companies in Madison that provide these capabilities as a service.

VI. RESULTS & DISCUSSION

Collected pulseMobile and control SpO2 and Heart Rate data from two of the five participants is shown in figure 4. Of the five participants, four were healthy adults and one was a volunteer CHF patient. Compared to the healthy adults, the highest variance in control SpO2 and HR was observed in this CHF patient; this variability can also be observed in figure 4. It is hypothesized that this increased variability is due to the patient's condition, specifically regarding the individuals less consistent ability to supply adequate oxygen to peripheral organs.

To analyze these data, the difference between the pulseMobile and control SpO2 and HR was calculated, leaving 300 pulseMobile – control measurements for each vital respectively. The differences between the 300 collected SpO2 and HR values can be visualized in figure 5 respectively. The null hypothesis was stated as the difference between pulseMobile and control measurements is zero, with a non-zero difference as the alternative hypothesis. To test this hypothesis, a non-directional dependent t-test for paired samples was used separately for SpO2 and HR respectively. The outputs of these statistical tests were a p-value of 0.9955 for SpO2, and a p-value of 0.99775 for HR. Therefore, we retain the null hypothesis, indicating evidence for zero difference between pulseMobile and control pulse oximetry data samples.

Confounding variables are hypothesized to have impacted these results. More specifically, there is statistically significant evidence that data output from ear oximeters can be different than data output from finger oximetry sensors, which the CasMed oximeter utilized [5][6]. In addition, differences in photoplethysmogram processing algorithms implemented in the pulseMobiles BCI system and the CasMed processer also account for variation in output. Despite these confounding factors, these findings suggest that pulseMobile is nonetheless statistically accurate, and could be substituted for a CasMed finger oximeter system with further testing.
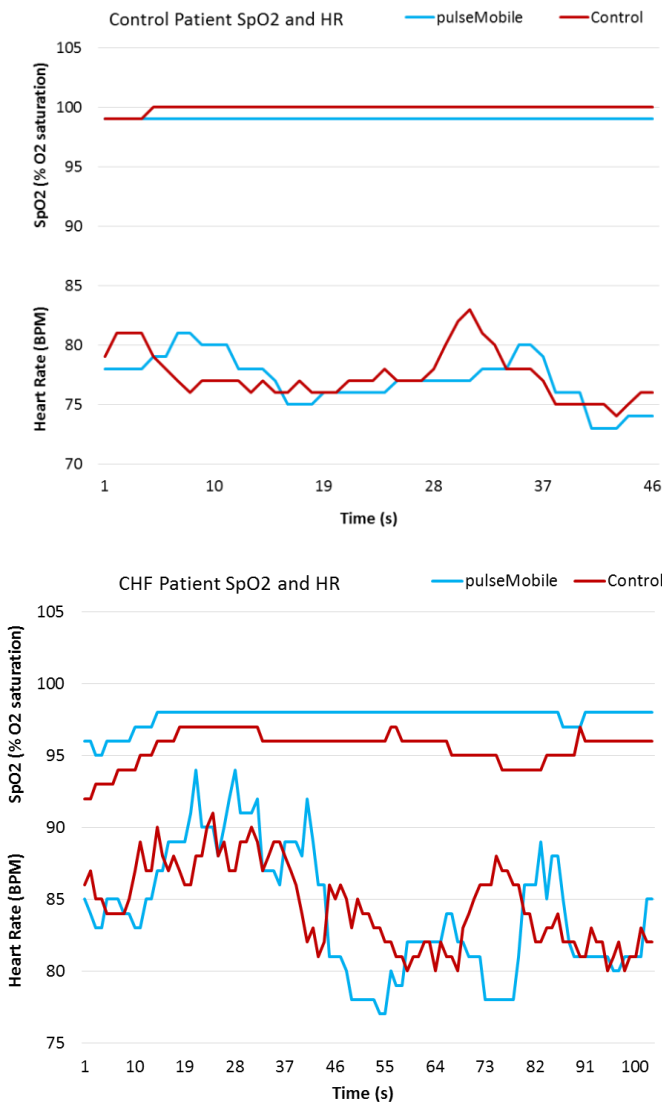
Fig. 4. Plots of Heart Rate (beats-per-minute) and SpO2 (% O2 saturation) for pulseMobile (blue) and CasMed 740 control (red) devices versus time. The similarity in the output vitals between both systems over time can be noted. In addition, increased HR and SpO2 variability can be observed in the CHF patient versus the healthy patient data.
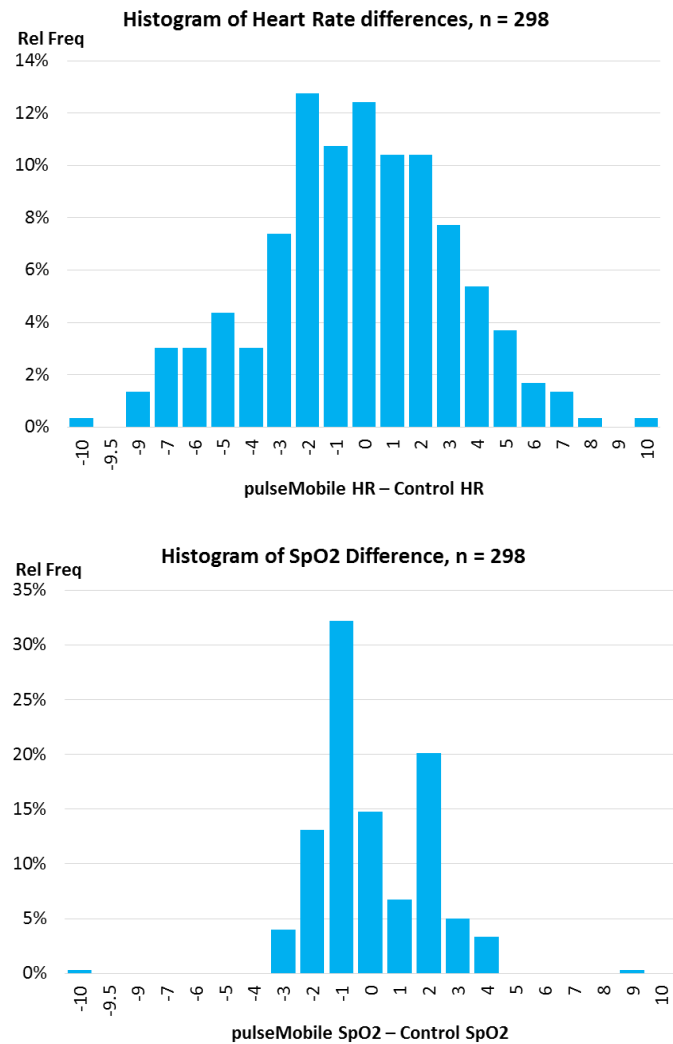
Figure 5. Histograms of the calculated difference between pulseMobile and CasMed740 Heart Rate (above) and SpO2 (below) values. Note that each histogram contains >99% of the total values collected. A slight left skew is observed in both HR and SpO2 data, representing a time-delay in output values attributable to the pulseMobile ear sensors later perfusion.

FUTURE WORK & TESTING

Further research is needed to asses if pulseMobile can effectively reduce avoidable hospitalizations for CHF and COPD patients. First, additional network integration testing is needed to assess the performance of GSM data transmissions in regions with variable network strength. This will be accomplished by collecting and transmitting data in areas that are stratified from strong to weak GSM network strength.

Next, patient compliance must be tested. In order for this data to be actionable, it must be collected from patients in adequate volume. This can be studied by implementing accelerometer-only pulseMobile systems through home health providers. By collecting accelerometer data from CHF and COPD patients over a period of weeks, we can establish whether or not the pulseMobile device supplies caregivers enough data to enable actionable interventions and address the current compliance issue. We are interested additionally in optimizing user experience and usability of the pulseMobile cloud software.

Finally, the pulseMobile must be implemented in the clinical setting to assess the impact of this platform on patient mortality rates, number of bed days, hospitalizations, and interventions, as well as patient and care team satisfaction. This study involves utilizing the pulseMobile system on a minimum of 25 patients from one or more hospitals over a period of 6 months to 1 year. The outcome of this study will provide early insight to the efficacy of the pulseMobile platform versus the current methods of CHF patient management. The pulseMobile aims to decrease in mortality rate, hospitalizations, and bed days, with an accompanying increase in early interventions, and patient and care team satisfaction.

VII. CONCLUSION

The results for the pulseMobile hardware and software tests respectively are representative of a platform that produces accurate, clinical-grade pulse oximeter data, which can be consistently and reliably provided to healthcare professionals via the GSM network with through easy-to-use web software.

In effect, the pulseMobile platform will potentially allow care teams and patients to be connected at all times, from nearly any US location, providing a sense of safety and security to patients and care teams alike. By enabling earlier detection of disease related exacerbations, quality of care can be improved as care teams deliver preventative treatments earlier in the symptomatic lifecycle, avoiding hospitalizations that would potentially occur if conditions grow in severity without treatment. Furthermore, it is anticipated that the combination of preventative treatments in non-hospital or emergency room settings and the potential reduction in hospital bouncebacks and bed days provide a significant reduction in the cost-of-care for these patient groups. If successful, the pulseMobile platform could be implemented clinically and deliver these benefits for patients across the US and globally.

An important feature of the pulseMobile platform is the potential for very large volumes of longitudinal patient data to be analyzed, allowing for a better understanding of the evolution CHF and COPD diseases over time. Using modern machine learning and neural network techniques, these insights could be applied and refined in the pulseMobile platform for alert generation and prognosis prediction as well. It is also important to note that the core wearable GSM and software technologies can be applied to better understand and manage a variety of other diseases, including wearable EEG for Epilepsy related disorders, connected Blood Glucometers for Diabetes, and many others.

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