Android-Based Tocodynamometer and Fetal Heart Rate Monitor

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tocotronics

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Executive Summary

A tocodynamometer is a medical device used to measure the frequency and duration of uterine contractions. A fetal heart rate monitor is a medical device used to monitor the heart rate of the fetus. Both are used in hospitals to monitor the condition of a woman's pregnancy.

Both tocodynamometers (tocos) and the fetal heart rate monitors suffer from usability issues. The devices are bulky (~1' x 1' x 0.5'), expensive (~$10,000), and difficult to use, meaning that they are confined to specialized hospitals [1]. Many low resource hospitals do not have tocos, and, in general, the toco device is not portable or convenient.
Our solution is an Android application and small embedded system that will take the place of both of these devices. It is a low cost, portable, easy to use alternative to typical tocos and fetal heart rate monitors. We believe that it will fill a need for low resource hospitals and provide an opportunity for in-home care.

Electrodes are currently the only accepted alternative to the pressure sensing buttons of tocos [2]. Therefore, competitors of our product may involve electrodes but provide the app in a platform other than a tablet.

This solution is advantageous to other solutions because it integrates fetal heart rate monitors and tocodynamometers. The device is also portable and easy to use. Moreover, tablets are becoming increasingly popular, so a tablet-based application will be favored by consumers.

We have been able to obtain EMG and ECG data using the device. We believe that obtaining EHG data will be a natural extension to the process necessary for obtaining EMG data, making our device technical feasible for our relevant application.

FDA approval for such an app that is involved in diagnosis is required [3]. Similar mobile applications have typically applied for a 510 (k). We believe that our device will be supported by Medicare/ Medicaid because it provides a more cost-effective alternative to existing tocodynamometers and fetal heart rate monitors.

The estimated size of the market was considered to be all pregnant women. This is a very liberal assumption as only a fraction of these pregnant women may have tablets or may consider purchasing a tablet. We plan on selling our device anywhere between \$300 to \$400. This initial elevated price will allow us to support the extensive user testing of our device we plan on conducting.

Description of the Problem

A tocodynamometer is a medical device used to measure the frequency and duration of uterine contractions. It is used quite often in hospitals to monitor the condition of a woman's pregnancy. It uses a pressure sensing button that must be strapped tightly to the patient by the nurse or other assistant [4].

Another component of pregnancy care is a fetal heart rate monitor. Specialized equipment must be used due to the inherent challenges of filtering the relatively small fetal heart rate signal from the more prominent electrical signals present in a pregnant woman. Consideration of this device is important because the fetal heart rate monitor is often used in conjunction with a toco to help doctors understand the state of the pregnancy and make important decisions.

Problem Description

The problems with these devices are simple and well-defined. For the tocodynamometer, the patient must remain still to ensure that the reading is based on contractions and not on any shifting of position that may occur while the patient is in pain [5]. Furthermore, both tocos and fetal heart rate monitors are bulky (~1′ x 1′ x 0.5′), expensive (~$10,000), and difficult to use.

Project Objective

Our goal is to create an Android application that acts as both a tocodynamometer and a fetal heart rate monitor. The relevant electrohysterogram (EHG) and electrocardiography (ECG) data can be obtained using electrodes. The signal is amplified on a dedicated board (Muscle Sensor v3) and then passed through an analog to a digital converter on an Arduino Uno. The digital signal is then packaged into bytes and shipped out over a serial connection to the microUSB port of the Android device, a Google Nexus 7. The App receives the data, filters it in real time, plots the signals for viewing purposes, and calculates useful metrics such as contractions per minute and fetal heart rate.

Documentation of the Problem

There are not many risks associated with our device. The only parts of our device that are in close proximity to the mother is the electrodes. The signals are obtained using silver chloride electrodes. Silver chloride electrodes have been used on pregnant women for various different applications, such as in quantitatively characterizing uterine contractions [6]. Therefore, we do not believe there are any risks associated with this aspect of our device. However, in obtaining IRB approval, a more in depth risk analysis of the device and its potential risk to the mother and the fetus must be conducted.

Problem Documentation

To gauge the accuracy of our device, we have to test the device on real patients after obtaining IRB approval. The results can be compared to hospital tocodynamometer and fetal heart rate monitor under the supervision of a tocodynamometer. Using our device when a patient is undergoing labor will allow us to gauge the feasibility of our device.

Prototype of Design

APPLICATION ARCHITECTURE

As seen in Figure 1, there are four main flows in the application architecture:

1. Electrodes plug directly into the Muscle Sensor v3.
2. The Muscle Sensor v3 takes in an analog value (voltage), amplifies it, and passes it (via a wire) to the Arduino Uno.
3. The Arduino Uno converts the analog signal to a digital value that it packages and sends over a serial connection to the Google Nexus 7 tablet via a USB adapter.
4. The Tocotronics Android Application filters the input signal, plots the data, and calculates useful metrics.

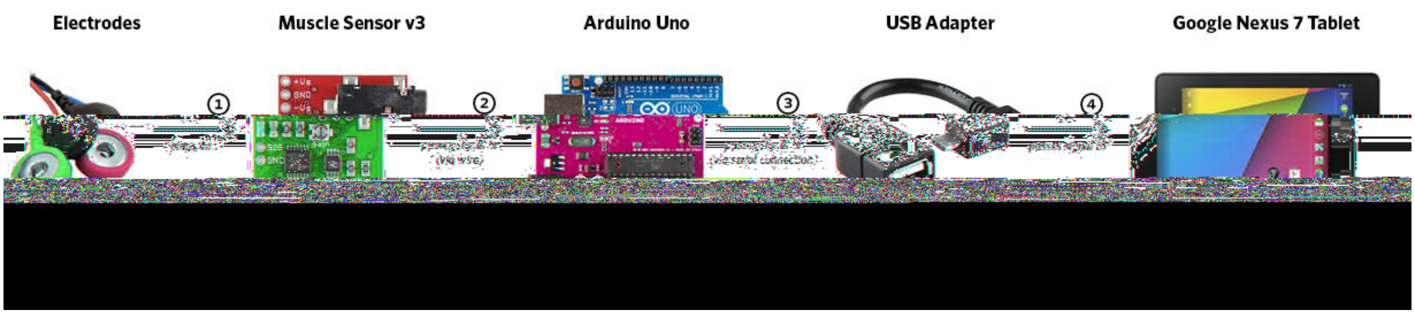

FIGURE 1. APPLICATION ARCHITECTURE FOR TOCOTRONICS TOCODYNAMOMETER AND FETAL HEART RATE MONITOR

SIGNAL FILTERING

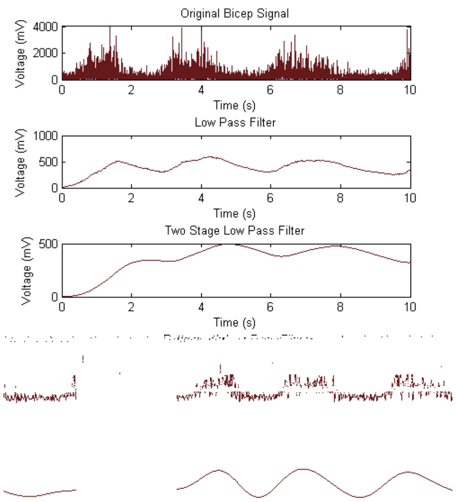

FIGURE 2. DEMONSTRATION OF DIFFERENT FILTERS APPLIED TO EMG DATA

Because EHG data was not available, signal filtering was conducted on EMG data. In choosing the most appropriate filter for uterine contractions, sample data was collected from the bicep (Figure 2), quadricep, and abdominal muscles, all at 960 Hz. Various signal processing techniques were applied to the EMG data, as shown in Figure 2. The wavelet filter was found to best represent the input signal and was our first choice for processing the EMG data. However, even though wavelet analysis worked best on the stationary signal, it did not allow for real-time analysis. Therefore, we decided to switch to using a low pass filter.

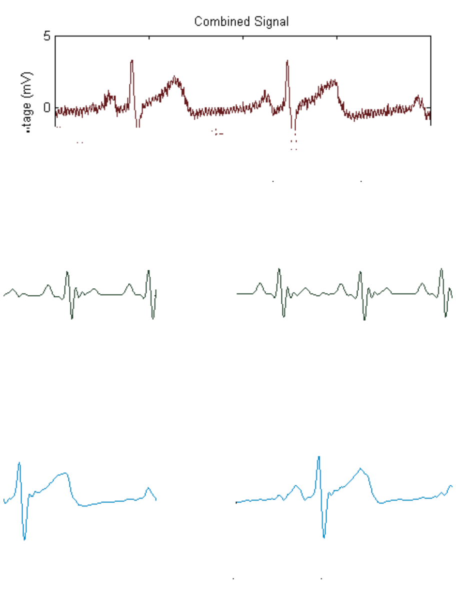

FIGURE 3. DEMONSTRATION OF ADAPTIVE NOISE CANCELLING FILTER ON THE FETAL ECG SIGNAL

The fetal ECG data was obtained using an adaptive noise cancelling filter (Figure 3). The fetal heart signal is distinct from the maternal signal in two ways: the amplitude of the wave is smaller and the frequency of the heart beats is faster. In extracting the fetal signal from the combined signal of mother and fetal heart rate, we chose an adaptive filtering technique called adaptive noise cancelling. In this approach, the filter utilizes a primary input (the combined signal), and a reference input (the maternal signal). The filter tries to match the primary and reference inputs, while storing any discrepancies as an error signal. In this application, the error that is being removed from the primary input is actually the signal of interest; it represents the fetal heart rate.

GRAPHICAL DATA PRESENTATION

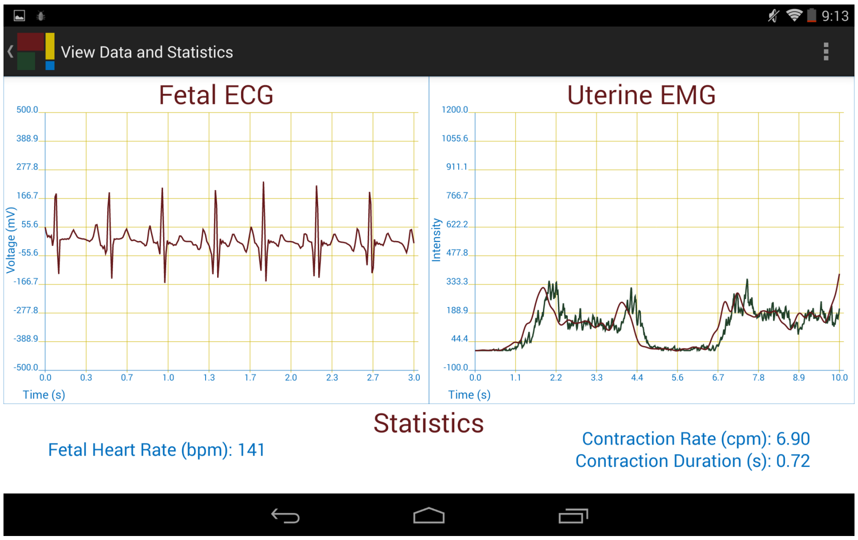

FIGURE 4. APPLICATION SCREENSHOT OF MONITORING PAGE

Figure 4 shows the monitoring page of the application. The graph on the left shows a visual representation of the fetal heart signal. The graph on the right shows the uterine muscle signal. Below the plots, the fetal heart rate, contraction frequency, and contraction duration are calculated and displayed.

PROOF OF DESIGN

After visiting the Magee-Womens Hospital of UPMC, our team determined that tocos are bulky, making them inconvenient for both patients and healthcare professionals. The nurse we corresponded with indicated that she preferred EHG data obtained through electrodes to the pressure data obtained used current tocos. Electrodes would allow the patient more freedom to move about and would be more convenient for the nurse to put or remove. We also believe that tablets are small and more convenient to use than the current bulky tocos [6]. However, to truly determine the use of such a device, we would have to obtain IRB approval and collaborate with OBGYNs, nurses, and nurse assistants to conduct user testing of our device in a clinical setting.

Current Patents

Current apps for monitoring fetal heart rate include the FetalBeats App, which uses ultrasound technology. However, this app requires a lot of additional components such as the FetalBeats heart monitor, mini speakers, connecting wires, and ultrasound jelly [7]. The app and the additional components cost about $150. The app is sold at various stores such a Babies "R" Us. Various studies have shown that compared abdominal fetal ECG is more reliable and accurate than ultrasound. Moreover, it abdominal fetal ECG is less likely than ultrasound to display the maternal heart rate in place of the fetal heart rate [8]. In contrast to the array of apps found for measuring fetal heart rate, no app for measuring uterine contractions was found.

We believe that our product is providing a novel solution by integrating fetal heart rate monitors and tocos to provide reliable information regarding the status of a woman's pregancy. Doctors prefer both information of the fetal heart rate and the uterine contractions in determining the status of the labor and pregnancy. In a hospital labor room, a woman is connected to two monitors: the tocodynamometer and fetal heart monitor. The two monitors simultaneously produce a graph of the two waveforms on a labor strip. The graph that simultaneously shows mother's contractions and the fetal heart tones can be used to see how the baby is responding to the mother's contractions and to make sure that the baby is obtaining sufficient oxygen and to differentiate between late decelerations, early decelerations, and variable decelerations.

Anticipated Regulatory Pathway

The FDA explicitly differentiates between mobile applications that promote wellness and those that are involved in diagnosis and treatment. Mobile applications such as the medical reference app Physician's Desk Reference do not require approval. However, applications that are involved in diagnosis and treatment require FDA approval. In 2011, the FDA released draft guidance for mobile medical applications [9].

Mobile medical apps transform a mobile platform into a regulated medical device. This mobile app is a medical device. Medical mobile applications may require premarket Approval Application (PMA) or (510)k approval. PMA is the most stringent marketing application for devices required. PMA requires providing sufficient scientific evidence that the device is safe and effective for its specific use. A 510(k) involves demonstrating that the device is safe and effective and substantially equivalent to a legally marketed device not subjected to PMA.

Several 510(k) applications have been cleared by FDA for mobile medical applications, associated with ipod or ipad. A 510(k) application requires various software related arguments such as Level of Concerns & Description, Software Requirements & Design specifications, Product & Software Risk Analyses, Verification & Validation, and Revision History & Anomalies [10]. For our final product, we would have to obtain (510)k approval.

Reimbursement

Because our device is so inexpensive, we would expect most hospitals to buy it outright without assistance from insurance companies or the government. Since the device has a shorter setup time and only requires electricity and fresh electrodes, it would likely cost less than a session with a traditional tocodynamometer. This means traditional sessions with tocodynamometers and fetal heart rate monitors that are reimbursed by Medicare, Medicaid, or private insurers would likely be replaced by the use of our device [11]. Therefore, we expect that our device will be well received because it is a more cost-effective alternative to existing tocodynamometers and fetal heart rate monitors.

Estimated Manufacturing Costs

PRODUCTION PART	QUANTITY	COST/UNIT	TOTAL COST
Android Tablet	1	$259.99	$259.99
Tablet Adapter	1	$5.95	$5.95
Electrodes	3	$0.47	$1.42
Arduino Uno	1	$13.13	$13.13
Medical EMG Board	2	$56.49	$112.98
Storage Box	1	$10.00	$10.00
		Total Cost	$403.47
		Total Cost (without tablet)	$143.48

Tablet Adapter: Currently tablet adapters cost about $2 to $6 each, when purchased individually. A larger order of these tablet adapters is expected to cost much less if this device is to be commercialized.

Estimated Cost

Electrodes: The silver chloride electrodes are fairly cheap (approximately $0.47 per electrode). However, these electrodes must be replaced after use.

Arduino Uno: This unit is one of the most likely parts to change prior to the release of our final product. Currently it provides a good environment for developing our prototypes. However, its I/O ports and features are more advanced than what would be needed for our final product (I/O ports and features). Therefore, the arduino will be replaced by a stripped-down version that is constructed with the same atmel microprocessor and has a PCB circuit containing the ports we desire.

Medical EMG Board: The medical EMG board is the most expensive part of our current device. Buying the board in bulk can bring down the cost to $40 per unit. A potential solution to drive down the cost further would be to build a signal mux that would flash rotate through each of the needed electrodes.

Potential Market

One of our device's strongest aspects is its potential market size. Because traditional tocodynamometers are so expensive, many small or low resource hospitals are unable to purchase them. Our device would put tocodynamometers within reach of nearly every hospital. According to the American Hospital Association, there are 5,723 hospitals in the United States. That means that from hospitals in the United States alone, our device would have nearly 6,000 clear potential clients. This does not factor in the global market or smaller clinics that could now afford tocodynamometers.

Potential Market

Our product cost at the moment is about $200. However, we believe that this price can be decreased further during commercialization of our final product. We believe that a good range for our starting price is between $300 and $400. This cost will allow us to fund user testing to assess the reliability of our final product. Consumers can purchase the product in the appstore. While the app can be immediately downloaded, the various attachments to the device can be mailed to the consumer following purchase.

We will try to enter the market working with low resource hospitals. If we were able to meet with hospital representation, we would demonstrate our low cost solution to fetal monitoring. With some success in low resource hospitals, we could try to expand to in-home use distribution.

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