Unobtrusive Continuous Monitoring of Fetal Cardiac Electrophysiology in the Home Setting

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***Abstract*— The current home fetal heart rate (fHR) measurement devices and clinical cardiotocography (CTG) use ultrasound Doppler detectors that are highly position and movement dependent making it difficult to capture the fHR, often causing unnecessary alarm and concerns. The U.S. Food and Drug Administration (FDA) has also been concerned about the unknown rate of repeat and prolonged use of ultrasound detectors. Fetal electrocardiogram (fECG) and HR monitoring devices based on bio-potential acquisition have been developed; however, they are bulky and intrusive, thus not widely accepted. Here, we present innovative non-contact electrode ECG sensors on a small unobtrusive patch which could be attached to the abdomen, or inside garment, incorporated with Bluetooth low energy (BLE) wireless communication, to transfer the acquired data to a smartphone. An Android app was developed to extract the mixed maternal/fetal ECG (f/mECG) signals. In this paper, we demonstrate a simple and robust scheme to provide accurate 24/7 monitoring of f/mHR, with the potential to expand to f/mECG monitoring in the home setting.**

Keywords—Bluetooth low energy, home setting, fetal ECG, fetal HR, maternal ECG/HR.

I. INTRODUCTION

Expectant mothers often worry about the baby's wellbeing, especially when they notice a decrease in fetal movements. A review showed that 50% of the pregnant women in a study from Norway were sometimes worried about decreased fetal movement, and between 4-15% of pregnant women consult healthcare because of a decrease in fetal movement in third trimester [1]. The challenge is to minimize unnecessary clinical consultation while not missing the opportunity to intervene if the fetus is actually at risk. There is no reliable way to assess fetal heart rate (fHR) at home except with a home-used consumer ultrasound Doppler fHR device that is notorious in in difficulty to finding the fetal heart beats, often causing even more alarm to the other. Also importantly, we still do not know if there are any risks to the fetus with prolonged ultrasound exposure, as warned by the FDA especially over home fHR devices (FDA 2014) [2].

From a clinical practice perspective, a recent national study reported by the CDC showed that the U.S. fetal mortality rate remained unchanged from 2006 through 2012 at 6.05 per 1,000 births [3]. A key fetal monitoring measure - fHR monitoring using cardiotocography (CTG), in spite being used in 85% of all labors in the US, and with comparable frequency during the antepartum period for monitoring, has not unequivocally showed that it can reduce perinatal morality. The 2015 Cochrane review of antenatal CTG for fetal assessment showed no clear evidence that it improves perinatal outcome [4]. However, there is certainly a general confidence of the healthcare professionals in and general expectation of the pregnant women that fHR monitoring with CTG being used in labor and during the antepartum period, even in the non-high-risk cases. This is a clinical dilemma that needs to be addressed. FHR monitoring needs to be improved, after being used traditionally over 40 years, in an improved way that could be more relevant in improving perinatal outcome. Currently there is no device that can display fHR on a mobile continuous basis using a compact, unobtrusive and comfortable device. The *Pregsense* belt and other similar ones for mobile fHR monitoring are bulky and costly. Others include home ultrasound Doppler fHR monitors such as those by Sonoline or VTech, costing about $50 each basic unit as a consumer product. They all require active scanning over the abdomen coupling with ultrasound gel to locate the fetal heart to obtain the fHR.

In this context, we have been developing unobtrusive abdominal patches using non-contact electrodes (NCE) to acquire fetal/maternal electrocardiogram (f/mECG) and algorithms to extract the fECG and mECG as well as their derivatives like heartrate [5]. The patch operation as well as the algorithms were validated with the public online data from Database for the Identification of Systems (DaISy). The extraction of full-feature fECG would pave the way to the early detection of heart disease in fetus; however, extensive efforts would be needed to overcome the challenges in dealing with interferences in practical scenarios. Here, we aim to develop a simple and robust system, offering reliable fHR monitoring in the home setting, in order to reassure expectant mothers in the daily life. If successful, this indeed makes a big stride already. To validate the system, we simulated the mixed f/mECG data by recording simultaneously from two subjects, mimicking the f/mECG scenario. A real-time Android application was developed with algorithms to process and extract fHR.

II. DESIGN AND IMPLEMENTATION

The conceptual design of the entire system is illustrated in **Fig. 1.** The system is comprised of an Android application, a NCE ECG patch [5], a Bluetooth Low Energy (BLE) module and power management fabricated on flexible substrate

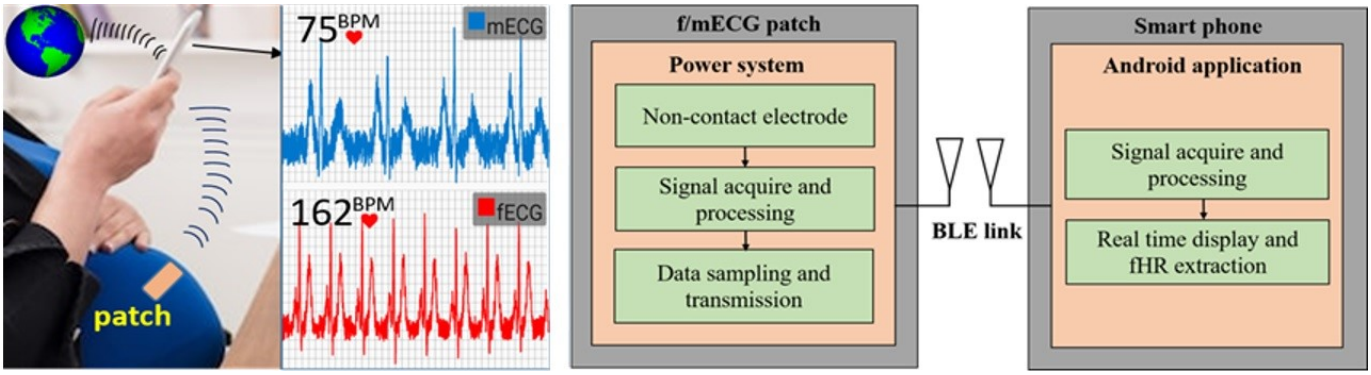

Fig. 1. The conceptual design and block diagram of the fetal/maternal ECG/HR monitoring system.

(single-ply FR-4, *Lenthor Engineering, Milpitas, CA*). In the patch, NCEs are used to collect the abdominal ECG signal of pregnant women. The processed and amplified data are then transmitted to a smartphone. In the Android app, the collected signal will be further processed by digital filters before the fHR is extracted, displayed and logged.

A. NCE f/mECG patch acquisition

1) Non-contact electrode

Along with the conventional electrodes, such as Ag/AgCl electrodes, non-contact electrode (NCE) is an alternative option for biopotential acquisition, which is immune to signal degradation for long-term monitoring applications. Moreover, it does not require skin preparation before collecting the signal, which tremendously reduces setting up time and increases the ease of use. Previously, we utilized NCE electrodes as a combination of a metal plate with various materials (copper or silver) and a buffer with a unity gain in attempt to reduce the skin-electrode impedance before driving the signal to a differential amplifier [6, 7]. However, the acquired signal is still susceptible to motion artifacts and other interferences, possibly due to the bias current path [8]. Since the bias current cannot flow through human body, it may cause high input impedance as well as amplifier saturation. Here, in addition to inheriting the previous design, a resistor network was added to allow a path for currents to flow to ground (**Fig. 2a**). The NCEs were designed with a circular shape as shown in **Fig. 2b**.

2) Analog signal processing circuitry

The collected signal through NCEs is passed to a differential amplifier (INA333, *Texas Instruments, TX*) with a gain of 50. The reference pin of INA333 is connected to a reference voltage which is a half of the supplied voltage of the system so that the output of INA333 is shifted to above 0 V. Subsequently, the signal is fed through a third order active low-pass Butterworth filter with a cutoff frequency of 150 Hz. An active notch filter was designed to eliminate the ambient 60 Hz. A twin T parallel resistor and capacitor network is used to obtain a deep notch, improving 60-Hz elimination. Finally, the filtered signal is amplified with a gain of 6, resulting in a total gain of 300 for the system.

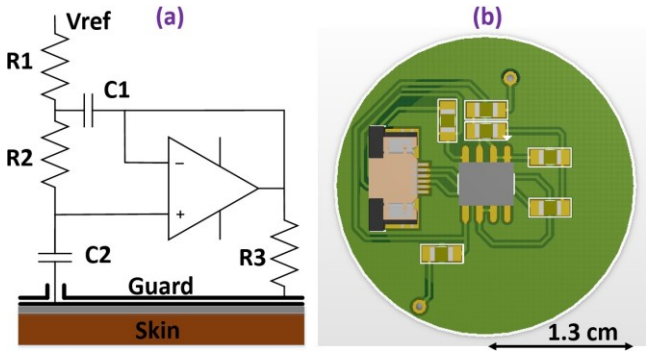

Fig. 2. (a) NCE circuit and **(b)** layout.

B. Mobile application

Fig. 3 shows the flow chart of our mobile application. First, the application interrogates the availability of BLE in device and then enables the communication. Since the BLE module integrated on the f/mECG patch plays as a slave, the connection would be established if the app scans and finds the f/mECG patch. Once successful, the processed mixed ECG signal will be sampled and transmitted via the nRF51422 (*Nordic Semiconductor*) BLE transmitter. A data buffer is initialized and waiting for the coming data. The data then are converted to the ECG data flowed by real-time digital signal processing. A fetal heartrate (fHR) detection scheme will extract, display the fHR and mHR in real time, as well as log them into the system.

C. Fetal heart rate detection

The heartrate detection scheme provides continuously

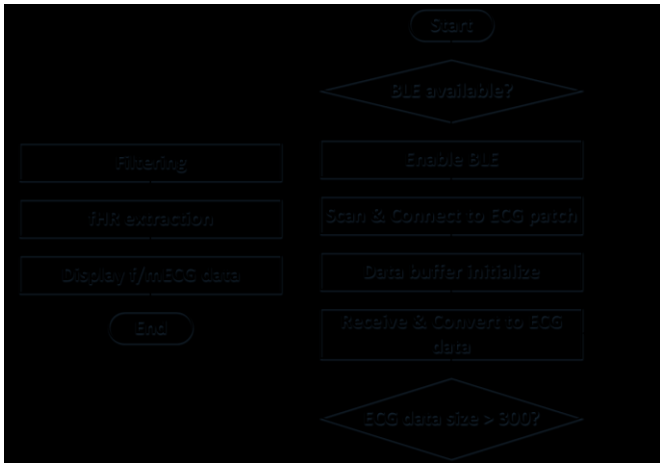

Fig. 3. Operation flow chart.

updated readings of fHR and mHR. The filtered signal is run through a peak detector. After the correct signal peaks are identified, the signal is scaled to the largest peaks. This step ensures that overall ECG signal strength will not adversely impact the ability of the system to give accurate HR readings. The R-peak amplitudes of fECG were assumed to be within 30 -50 percent range of the average R-peak amplitude of the mECG. In addition to that, in order to differentiate the larger of the maternal P and T waves from the fetal R peaks, the abdominal ECG signal was analyzed under the second order derivative. Since the interval of fECG signal complex QRS is narrower than that of the maternal P and T waves, the fECG peak will be detected as the highest peaks of the derivative signal.

III. Experiment and Results

The f/mECG patch should be able to collect both maternal and fetal ECG signals. In this experiment, in order to mimic practical scenarios, we collected ECG signals from two people simultaneously using one device. The fHR algorithm then was validated for peak detaction of fECG through seven sets of mixed ECG signals. Several parameters were defined for the binary classification test 1) True Positive (TP): there is an R peak of fECG and it is correctly detected by algorithm; 2) False Positive (FP): there is not an R peak in fECG, but it is detected as an R peak by algorithm; 3) True Negative (TN): there is not an R peak of fECG and it is correctly detected as not an R peak by the algorithm; and 4) False Negative (FN): there is an R peak of fECG, but it failed to detect by algorithm. The value of positive predictive value (PPV), sensitivity and accuracy can be calculated as follows:

$$PPV = \frac{TP}{TP + FP}$$

$$Sensitivity = \frac{TP}{TP + FN}$$

$$Accuarcy = 1 - \frac{FP + FN}{NumberOfTotal}$$

The results for detecting R peaks are showed in TABLE I. The values of PPV, sensitivity, and accuracy of fHR detection algorithm by using the device are about 97.5%, 98.68%, and 98.04%, respectively.

Fig. 4 displays the acquired mixed ECG signal with two people. It is obvious that the ECG signal of each person was successfully extracted.

TABLE I Performance of FHR Detection Alogrithm

Actual R Peak	Output of fHR detection algorithm		
	R Peak	***Not R Peak***	***Total***
R Peak	975	13	988
Not R Peak	25	7	32
Total	1000	20	1020

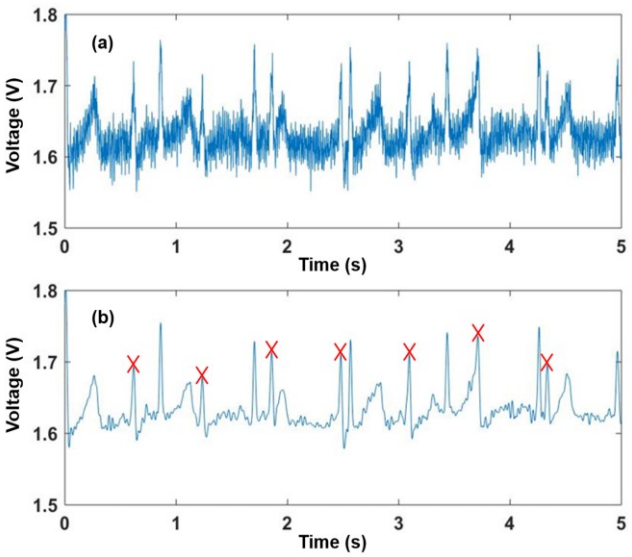

Fig. 4. (a) A simulated mixed ECG signal with fECG and mECG components; (**b**) The R peaks of fECG were successfully detected.

IV. Discussion and Conclusions

We have successfully demonstrated a robust fHR monitoring system which could be used for expectant moms in the daily life. The modified design of the NCE circuit helped enhance the signal quality. The NCE feature would make it feasible to integrate this system inside garment or accessories, showing promise to be widely used by a large population. In the future, in addition to improving the hardware of the system and further extracting the full-feature fECG for study and diagnosis purposes, we also aim to upgrade the software components. First, we consider to establish cloud-based storage and computing thus advanced pattern recognition via machine learning can be implemented. Second, other parameters can be measured along with ECG such as motion and SpO2, by integrating additional sensors into the current system. These parameters may help improve the signal processing scheme as well as provide an overview of the expectant mother and her future baby, supporting better monitoring and diagnosis, by distant caregivers and/or some novel artificial intelligence-based smart system

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