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Development of a Home-based Fetal Electrocardiogram (ECG) Monitoring System

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***Abstract*—We develop a novel wearable fetal electrocardiogram (fECG) monitoring system consisting of an abdominal patch that communicates with a smart device. The system has two main components: the fetal patch and the monitoring app. The fetal patch has electronics and recording electrodes fabricated on a hybrid flexible-rigid platform while the Android app is developed for a wide range of applications. The patch collects the abdominal ECG (aECG) signals that are sent to the smart device app via secure Bluetooth Low Energy (BLE) communication. The app software connects to a cloud server where processing and extraction algorithms are executed for real-time fECG extraction and fetal heartrate (fHR) calculation from the collected raw data. We have validated the algorithms and real-time data recordings on pregnant subjects yielding promising results. Our system has the potential to transform the currently used fetal monitoring system to an effective distanced and tele-maternity care.**

I. Introduction

The infant mortality rate in the United States shows no improvement in the care system with 6.20 per 1,000 live births in 2004 and 6.23 in 2003 [1]. Fetal heartrate monitoring is an essential component of perinatal care by recognizing elements that might imperil the life of the fetus and mother. Fetal monitoring may helptriage and/or diagnose preterm contractions and fetal well-being [2]. While the gold standard antenatal cardiotocography (CTG) showed no significant difference in identifying perinatal risk compared with no CTG, computerized CTG showed a significant reduction in perinatal mortality, indicating further deployment of cutting-edge tools and advanced analytics may help enhance the outcomes [3].

In recent years, home-based devices for fetal monitoring have been introduced. These include Doppler-ultrasound fetal heart rate (fHR) monitors which require active scanning over the abdomen using gel to locate the fetal heart. The measurement is especially challenging for non-medical persons. Additionally, the Food and Drug Administration (FDA) issued a warning in 2014 against the use of such ultrasound-based fHR home monitors [4]. Further, it provides only fHR, which cannot be used to monitor abnormal development of the heart, in contrast to fetal electrocardiogram (fECG), which depicts PQRST features in the signal that helps evaluate the functional status of the heart [5]. fECG provides vital information about fetal well-being, fetal development, and maturity, or non-reassuring fetal status during pregnancy and labor [2]. Some home-based fECG systems were developed and introduced; nevertheless, they are bulky, costly, and intrusive, thus have not been widely used. The abdominal ECG (aECG) consists of several bioelectric potentials such as maternal heart activity (mECG), fECG, maternal muscle activity (mEMG), fetal movement activity, and noise. Continuous fECG monitoring has remained a challenging problem in the research community [6].

In this work, a home-based fetal and maternal monitoring system, including a fetal patch, a mobile application, and a cloud server is designed and implemented (**Fig. 1**). We developed hardware and software components to create a remote prenatal care system. The abdominal ECG signals are collected by a wearable patch, and then the collected data are sent to the Android app via Bluetooth Low Energy (BLE) communication. The pre-processing and extraction algorithms are performed through the connected cloud server from the app to separate the fECG and mECG. Then, fHR calculation is

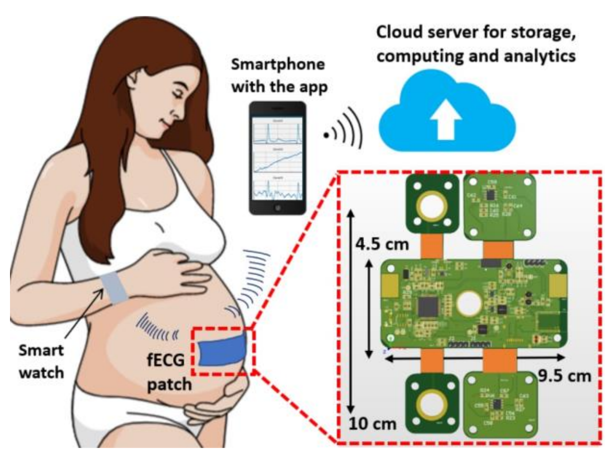

Figure 1. Fetal ECG monitoring patch and system.

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performed to assess the performance of the device. Finally, the fECG and fHR are displayed in real-time on the app. Users will be warned to visit the hospital when a critical event, or better yet, a pre-critical event, occurs.

II. Methods and Implementation

A. *The fetal patch*

The patch is made of a flexible-rigid printed circuit board with dimensions of 4.5 cm × 9.5 cm. Two wings having electrodes measured 10 cm apart are designed with a flexible material (highlighted in orange – **Fig. 1**), which increases the contact surface between the electrode and abdominal area. It contains two types of electrodes (*i.e.*, Ag/AgCl wet electrode and non-contact electrode) for validation and comparison. While the wet electrodes can provide high signal to noise ratio (SNR) by having the electrolyte gel, it was known to cause skin irritation for long-term measurement [7]. Thus, we deployed the non-contact electrode (NCE) as an alternative on the patch. The dual-channel design is to characterize and compare the performance of the contact and non-contact approaches. The patch's circuitry comprises an ADS1299 chip (*Texas Instrument*) with 24-bit analog-to-digital converter specifically designed for biomedical signal measurement and a system-on-chip nRF82832 (*Nordic Semiconductor, Trondheim, Norway*) powered with Arm Cortex-M4 CPU running at 64 MHz. The nRF5282 is used to transmit data from ADS1299 to the Android application through BLE.

B. *Fetal ECG Extraction Algorithm*

fECG extraction algorithms can be classified into three groups: blind source separation (BSS), template subtraction, and filtering techniques. The BSS methods assume that the abdominal signal is a mixture of independent signals, consisting of fECG, mECG, and noises [8]. In our first-generation system, we utilized the least-mean square adaptive filtering [9]. Further, we implemented the BSS method via the independent component analysis (ICA), FastICA and RobustICA, and validated and compared them with the online data [10]. In our recent report, we implemented and tested various techniques, including Extended Kalman Filter (EKF), template subtraction (TS), ICA and their combination using the PhysioNet 2013 Challenge data bank as well as the data with added Gaussian and motion noise, to mimic daily life situations with wearable devices [11].

Among these, EKF is a powerful approach for single-channel fECG extraction [12]. The celebrated Kalman Filter (KF) is an optimal algorithm for estimating parameters of linear and Gaussian dynamic models [13]. EKF is used for nonlinear problems, which is based on local linearization of the nonlinear model by using the Jacobian operator [14]. The dynamic model for a discrete nonlinear system is typically formulated as follows:

$$\begin{cases} \underline{x}_{k+1} = f(\underline{x}_k, \underline{w}_k, k) \\ \underline{y}_k = g(\underline{x}_k, \underline{v}_k, k) \end{cases} \tag{1}$$

where g is the observation function that maps state space into the observed space. f is the state transition function that describes the evaluation of the state variable $\underline{x}_k$, $\underline{w}_k$, and $\underline{v}_k$ denote the process and observation noises and $\underline{y}_k$ is observation vector [15]. The linear approximation near a desired reference point $(\hat{\underline{x}}_k, \hat{\underline{w}}_k, \hat{\underline{v}}_k)$ will lead to the following linear estimates:

$$\begin{cases} \underline{x}_{k+1} \approx f(\hat{\underline{x}}_k, \hat{\underline{w}}_k, k) + A_k(\underline{x}_k - \hat{\underline{x}}_k) + F_k(\underline{w}_k - \hat{\underline{w}}_k) \\ \underline{y}_k \approx g(\hat{\underline{x}}_k, \hat{\underline{v}}_k, k) + C_k(\underline{x}_k - \hat{\underline{x}}_k) + G_k(\underline{v}_k - \hat{\underline{v}}_k) \end{cases} \tag{2}$$

where

$$A_k = \frac{\partial f(\underline{x}, \hat{\underline{w}}_k, k)}{\partial \underline{x}}\Big|_{\underline{x} = \hat{\underline{x}}_k} \qquad F_k = \frac{\partial f(\hat{\underline{x}}_k, \underline{w}, k)}{\partial \underline{w}}\Big|_{\underline{w} = \hat{\underline{w}}_k}$$

$$C_k = \frac{\partial g(\underline{x}, \hat{\underline{v}}_k, k)}{\partial \underline{x}}\Big|_{\underline{x} = \hat{\underline{x}}_k} \qquad G_k = \frac{\partial g(\hat{\underline{x}}_k, \underline{v}, k)}{\partial \underline{v}}\Big|_{\underline{v} = \hat{\underline{v}}_k}$$

Here, before running the extraction algorithm, the acquired data are filtered to remove the baseline wander and powerline interference noise. The baseline wandering is removed by using a lowpass filter, and the power-line interference noise is suppressed by a notch filter. Then, the EKF algorithm is used to estimate the mECG signal, which is used to remove the mECG signal by subtracting it from aECG. The residual signal consists of fetal ECG and noise. Another EKF is used to filter out the fECG from the noise. Finally, the fetal QRS complexes (fQRS) are detected by using the Pan-Tompkin algorithm [11, 12].

C. *Android Smartphone App Software*

We developed an Android smartphone application in Java that connects to the patch via BLE communication for data collection, displaying, and logging. Through BLE protocols, the app connects to the fetal patch and reads in multiple data channels at a rate of 500 Hz. After accumulating at least 1,000 data points, the input data are sent to a cloud server to extract the fetal and maternal ECG through the algorithm described in Section II.A. This would provide sufficient data to detect peaks and extract the fECG with higher accuracy. The results will start appearing on the application interface after ~10 seconds of initially starting in the form of dynamic graphs as well as numerical values for the fHR. The user can disconnect the patch at any time and save the raw data with associated time points they are received in the application to a text file with a customizable name in the phone's external storage. The results of the algorithm will also be saved in the cloud. The user also can load past text files to view the raw data and process fECG and fHR. This process is depicted in the flow chart in **Fig. 2**.

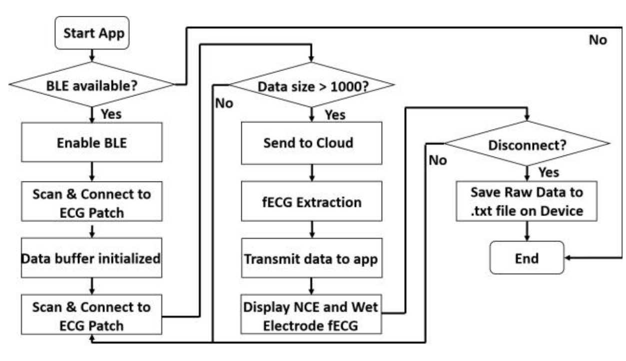

Figure 2. Android application operation flow chart.

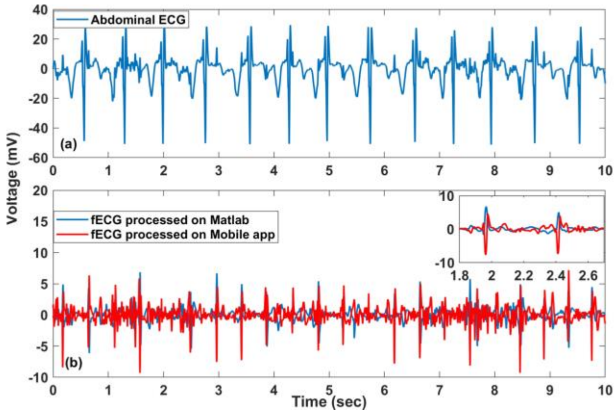

Figure 3. Results of fetal ECG Extraction by using the Mobile app and MATLAB. (**a**) A signal from PhysioNet 2013 Challenge databank; and (**b**) the fECG signal on Mobile app and MATLAB.

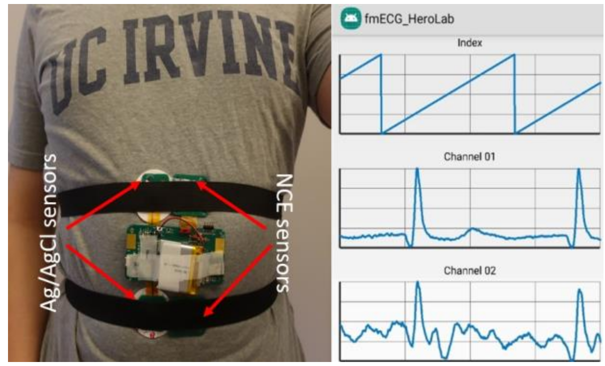

Figure 4. The fetal patch setup and experiment.

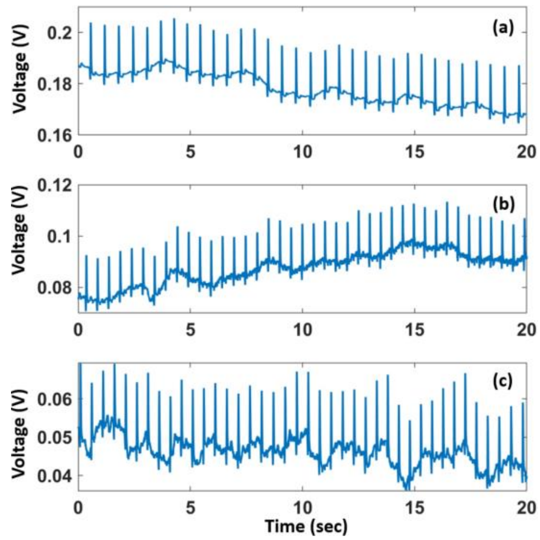

Figure 5. ECG signals recorded from the patch: (**a**) sitting position, (**b**) standing position, (**c**) walking position.

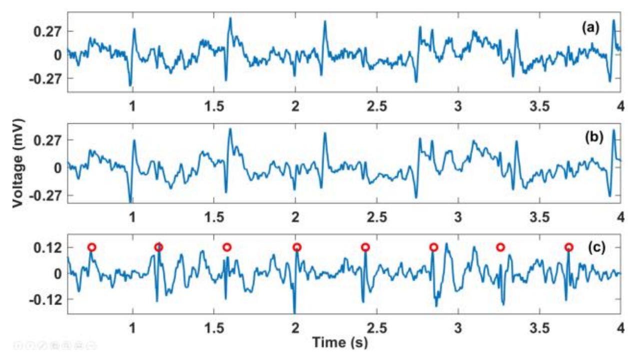

Figure 6. Results of fetal ECG extraction by using the Android application. (**a**) recorded data from maternal abdominal; (**b**) filtered data; and (**c**) Fetal ECG extracted and fetal QRS detected.

III. Experiments and Results

All experiments comply with protocols approved by the Institutional Review Board (IRB) committee at UC Irvine (IRB#2020-6342).

A. *Algorithm Validation*

The EKF algorithm described in the previous section is implemented on mobile app for real-time fECG extraction (**Fig. 3**). To evaluate the accuracy of the mobile app, we tested it with the PhysioNet 2013 Challenge databank which consists of a collection of one-minute abdominal ECG recordings, as all these data are annotated [16]. To implement the mobile app, the MATLAB code must be converted to Java. In this conversion, because all functions must be rewritten, the application may not have the same accuracy of MATLAB code. The mobile app were compared in terms of the F1 score and evaluated against MATLAB. F1 score is accuracy measure and can be obtained from the following equation:

$$F1=\frac{2*TP}{2*TP+FN+FP} \tag{2}$$

where TP, FP and FN are true positive, false positive and false negative in fECG peak detection, respectively. **Table 1** presents the average F1 score results in the 68 aECG records using the mobile app and MATLAB code. It can be seen that the mobile app is reliable as the results are comparable to that of MATLAB.

TABLE I. Average F1 score (%) with mobile app and MATLAB code for all records

	Table Column Head	
	Mobile app	***MATLAB***
F1 Score	84.8	86.7

B. *Device Validation*

The fetal patch was first validated on a healthy subject in different postures (*e.g.*, siting, walking, and standing). **Fig. 4** describes the patch setup and mobile application user interface. Specifically, two flexible belts were used to attach the patch on abdominal area. The volunteer was asked to perform different activities such as sitting on the chair, walking slowly, and standing. The mobile application was then turned on connecting with the patch. The index graph showed the data transmit package, checking if there is any data lost during the transmission. The data were then collected in 5 minutes for each posture. **Fig. 5** illustrates the ECG data (plotted in the first 20 seconds) from the first experiment. It can be seen that the ECG signal in the sitting position is clean and more stable than those recorded by standing and walking position. Especially, motion artifacts were found in the signal with walking position.

C. Entire System Validation

The entire system was further validated on 10 pregnant women between 28 and 34 weeks of gestation in the UCI Medical Center. The patch was embedded inside a maternity belt. The pregnant subjects were asked to perform a transabdominal ECG recording within 5 minutes. Each subject was laid on the chair and the belt with the fetal patch was attached on the abdominal area. **Fig. 6** illustrates the collected ECG and processed fECG of a pregnant woman. The obtained ECG was filtered to remove DC noise and interference and applied to the fECG extraction algorithm as described in Section II.B. As can be seen, our system can successfully collect the abdominal ECG and extract the peaks of fECG (highlighted in red in **Fig. 6c**). For this pregnant woman, the fHR is measured at 100 beats per minute which is normal for this stage of pregnancy.

IV. Discussion & Conclusion

In this paper, we have developed a fetal ECG monitoring device and extraction algorithms implemented on an Android smartphone which is capable of providing real-time and continuous fetal monitoring. We rigorously conducted several experiments to validate the operation of all components. The Android smartphone application was compared in terms of the F1 score and evaluated against offline processing using MATLAB. The results indicate that mobile app is reliable on its own. The entire system was tested with 10 pregnant subjects, demonstrating its feasibility. Specifically, the aforementioned device has been successfully applied to collect and extract fECG from aECG, and the efficacy of the proposed system has been carried out with real-time data recordings on pregnant subjects. Our Android application provides graphical and numerical information of fECG to assess fetal wellbeing. The fHR was calculated, and the fECG and fHR were displayed in real-time. Examination of patterns and fHR obtained would indicate the need to take the appropriate medications during labor.

Through numerous experiments, and a pilot study with pregnant subjects, we notice that electrode placement has a significant effect on the fECG signal quality. This was anticipated as the fetus location and orientation vary person to person and also at different gestational ages. We plan to incorporate accelerometric sensors and additional algorithms to detect and extract other signals such as uterine contraction and fetal movement. Regarding the long-term usage of the patch, with the non-contact technology deployed, it would bring comfort to users, avoiding unwanted side effects [4] due to the use of conventional contact electrodes.

In the future, we will improve the entire system with more miniaturized patches, optimized Android and iOS apps, real-time and pseudo-real time analytics with cloud computing. We will also conduct more experiments on the pregnant subjects, including subjects with twins, to validate the system and the fECG extraction algorithms.

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References

[1] M. F. MacDorman and S. Kirmeyer, "Fetal and perinatal mortality: United States, 2005," 2009.

[2] R. Jaros, R. Kahankova, R. Martinek, J. Nedoma, M. Fajkus, and Z. Slanina, "Fetal phonocardiography signal processing from abdominal records by non-adaptive methods," in *Photonics Applications in Astronomy, Communications, Industry, and High-Energy Physics Experiments 2018*, 2018, p. 108083E.

[3] Z. Alfirevic, G. M. Gyte, A. Cuthbert, and D. Devane, "Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour," *Cochrane database of systematic reviews,* 2017.

[4] T. Le, A. Moravec, M. Huerta, M. P. Lau, and H. Cao, "Unobtrusive continuous monitoring of fetal cardiac electrophysiology in the home setting," in *2018 IEEE SENSORS*, 2018, pp. 1-4.

[5] G. D. Clifford, I. Silva, J. Behar, and G. B. Moody, "Non-invasive fetal ECG analysis," *Physiological measurement,* vol. 35, p. 1521, 2014.

[6] D. Jagannath and A. I. Selvakumar, "Issues and research on foetal electrocardiogram signal elicitation," *Biomedical signal processing and control,* vol. 10, pp. 224-244, 2014.

[7] E. Graatsma, B. Jacod, L. van Egmond, E. Mulder, and G. Visser, "Fetal electrocardiography: feasibility of long-term fetal heart rate recordings," *BJOG: An International Journal of Obstetrics & Gynaecology,* vol. 116, pp. 334-338, 2009.

[8] J.-F. Cardoso, "Blind signal separation: statistical principles," *Proceedings of the IEEE,* vol. 86, pp. 2009-2025, 1998.

[9] M. Sharma, P. Ritchie, T. Ghirmai, H. Cao, and M. P. Lau, "Unobtrusive acquisition and extraction of fetal and maternal ECG in the home setting," in *2017 IEEE SENSORS*, 2017, pp. 1-3.

[10] T. Le, J. Fortunato, N. Maritato, Y. Cho, Q.-D. Nguyen, T. Ghirmai*, et al.*, "Home-based mobile fetal/maternal electrocardiogram acquisition and extraction with cloud assistance," in *2019 IEEE MTT-S International Microwave Biomedical Conference (IMBioC)*, 2019, pp. 1-4.

[11] S. Sarafan, T. Le, A. M. Naderi, Q.-D. Nguyen, B. T.-Y. Kuo, T. Ghirmai*, et al.*, "Investigation of Methods to Extract Fetal Electrocardiogram from the Mother's Abdominal Signal in Practical Scenarios," *Technologies,* vol. 8, p. 33, 2020.

[12] R. Sameni, M. B. Shamsollahi, C. Jutten, and G. D. Clifford, "A nonlinear Bayesian filtering framework for ECG denoising," *IEEE Transactions on Biomedical Engineering,* vol. 54, pp. 2172-2185, 2007.

[13] R. E. Kalman, "A new approach to linear filtering and prediction problems," *Journal of basic Engineering,* vol. 82, pp. 35-45, 1960.

[14] A. H. Jazwinski, *Stochastic processes and filtering theory*: Courier Corporation, 2007.

[15] M. Ungureanu, W. M. Bergmans Johannes, G. Oei Swan, and R. Strungaru, "Fetal ECG extraction during labor using an adaptive maternal beat subtraction technique," in *Biomedizinische Technik* vol. 52, ed, 2007, p. 56.

[16] I. Silva, J. Behar, R. Sameni, T. Zhu, J. Oster, G. D. Clifford*, et al.*, "Noninvasive fetal ECG: the PhysioNet/computing in cardiology challenge 2013," in *Computing in Cardiology 2013*, 2013, pp. 149-152.