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Telefetalcare: a first prototype of a wearable fetal electrocardiograph

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***Abstract*—Fetal heart rate monitoring is fundamental to infer information about fetal health state during pregnancy. The cardiotocography (CTG) is the most common antepartum monitoring technique. Abdominal ECG recording represents the most valuable alternative to cardiotocography, as it allows passive, non invasive and long term fetal monitoring. Unluckily fetal ECG has low SNR and needs to be extracted from abdominal recordings using ad hoc algorithms. This work describes a prototype of a wearable fetal ECG electrocardiograph. The system has flat band frequency response between 1-60Hz and guarantees good signal quality. It was tested on pregnant women between the 30th and 34th gestational week. Several electrodes configurations were tested, in order to identify the best solution. Implementation of a simple algorithm for FECG extraction permitted the reliable detection of maternal and fetal QRS complexes. The system will allow continuative and deep screening of fetal heart rate, introducing the possibility of home fetal monitoring.**

I. Introduction

Fetal monitoring during pregnancy is extremely important to reduce the incidence of fetal loss, perinatal morbidity and maternal distress. Continuous fetal monitoring is used in over 85% of labor episodes in the United States [1]. In particular, the analysis of heart rate variability (HRV) is commonly used to identify risky situations in fetal health. Pathological conditions as Intra Uterine Growth Restriction (IUGR), diabetes, infections and placental abruption can be diagnosed thanks to HRV analyses [2].

Several approaches can be used for the extraction of fetal heart rate (FHR). In standard fetal monitoring, the fetal heart rate is measured either by cardiotocography (CTG) or by ECG recordings using intrauterine electrodes directly placed on the fetal scalp [3]. The first approach combines fetal heart rate (FHR) measurement by Doppler ultrasound with uterine contraction recordings by a strain gauge band. CTG recording needs a hospital setting as it requires the repositioning and skillful placement of the ultrasound probe by specific medical personnel. Moreover it is not suitable for long term monitoring, because of the limited monitoring time allowed by the hospital stay for routine exams [4]. On the other hand, scalp ECG recording is extremely invasive and is feasible only during labor, after the rupture of the membranes.

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Fetal ECG recording performed by electrodes placed on the mother abdomen is a valuable alternative to standard approaches. It is absolutely non-invasive, thus allowing longer monitoring sessions. Moreover it provides additional information about fetal heart, e.g. morphology of P-wave, QRS-complex, QT duration measurement [5].

FECG signal is corrupted by many sources of noise, which make its detection and extraction very difficult [2]. The main source of noise is represented by the maternal ECG: the amplitude of the maternal QRS usually ranges from 100 to 150μV, the fetal QRS ranges from 5 to 60 μV. In addition, FECG signal is often covered by electrical noise from other sources. Common ECG noise sources, such as power line interference, muscle contractions, breathing, skin resistance interference, and instrumental noise, in addition to electromyogram and electrohysterogram due to uterine contractions, can corrupt FECG signals considerably[6].

The design principles and the general layout of a wearable fetal monitoring system, based on FECG extraction, were presented in [7]. The proposed system, named "*Telefetalcare",* was designed with the intention to build up a system that every pregnant woman could wear routinely at home during the last trimester (from the 30th gestational week). We hereby present the realization of the first

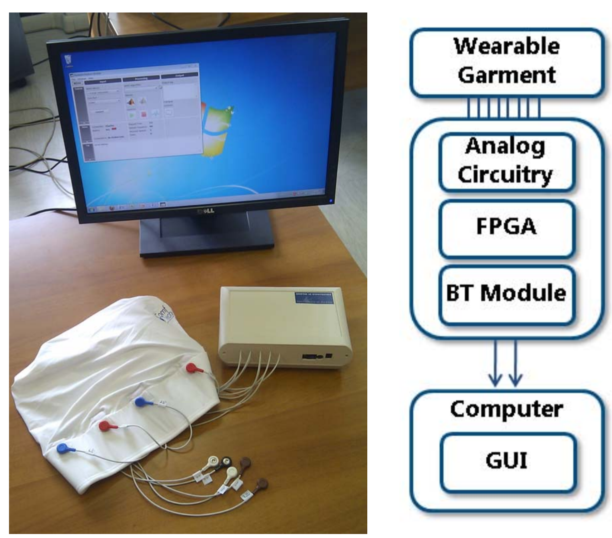

Fig. 1. The picture shows the first prototype of *Telefetalcare.* The wearable garment is provided by 9 textile electrodes for the recording of 8 abdominal ECG leads. A graphical user interface was developed for real time visualization of traces, extraction of FECG and detection of maternal and fetal QRS. The block scheme on the right is a schematic description of the prototype.

prototype and the preliminary results obtained after the acquisition of fetal ECG signals from pregnant volunteers. The device records 8 abdominal ECG leads using a comfortable and wearable garment which is placed on the mother abdomen. This unit is made of cotton and lycra and is characterized by 9 silver woven electrodes. A custom designed electronics preprocesses the signals which are transmitted to the laptop through Bluetooth connection. A graphical user interface (GUI) was developed to display signals in real time. It also allows the extraction of FECG from abdominal recordings, the identification of fetal QRS and the signals classification according to a quality index. Fig. 1 shows a schematic description and a picture of the system. The core of the device is the digital board, which is currently used to control signal sampling, quantization and transmission.

This is the first step of the overall project, described in [7]. The final goal is to realize a compact wearable device for home fetal monitoring. It will record data, extract FECG signals and RR series, select the most reliable FECG traces and send all the relevant information to a remote station through wireless connection. Everything will be performed on the wearable device, without linking it to a laptop.

Telefetalcare will reduce the number of required hospital visits and will allow comfortable fetal monitoring. At the same time, it will guarantee a deep and continuous screening of fetal wellbeing.

II. MATERIALS AND METHODS

A. *System Specifications*

The system is characterized by an analog preprocessing stage, which consists in a pass band filtering (0.08Hz – 110Hz), with a gain of 1740. Signals are sampled with a sampling frequency of 256 Hz. The 16 bit ADC has a voltage resolution of 50μV, corresponding to a 30nV resolution before amplification. The power supply is provided by a 3.6V battery. Fig. 2 shows a comparison between the frequency response of *Telefetalcare* (blue line)

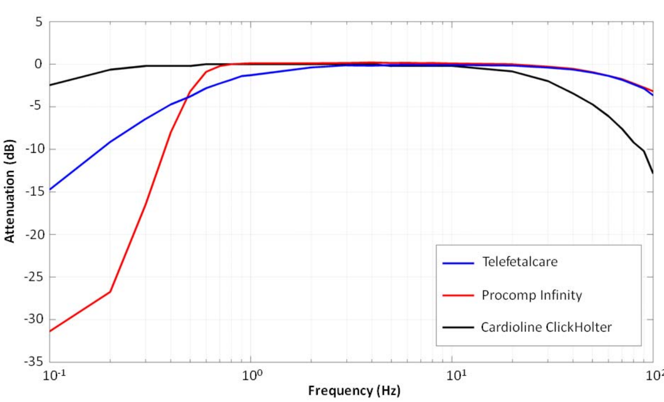

Fig. 2. A comparison between the frequency responses of *Telefetalcare* (blue line), Procomp Infinity (red line) and Cardioline ClickHolter (black line). *Telefetalcare* shows flat band behavior between 1 and 60Hz.

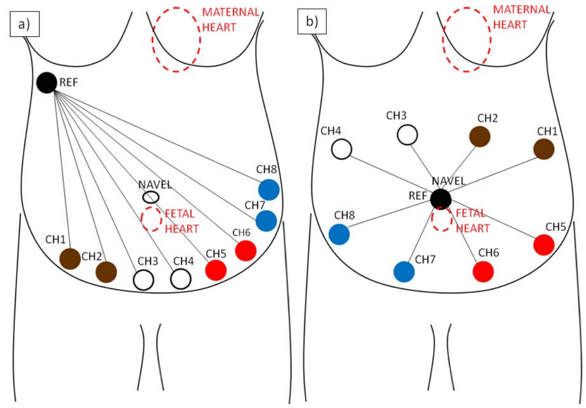

Fig. 3. Two of the several electrodes configurations under testing. In either case, the 8 ECG leads are obtained by computing the voltage difference between each of the 8 colored electrodes and the black reference one.

and the frequency responses of two commercial ECG recorders (Procomp Infinity [8] - red line - and Cardioline ClickHolter [9] - black line). To compute the frequency responses, 28 sinusoids of known amplitude were generated using a wave generator, with a frequency ranging from 0.1Hz to 100Hz. Fig. 2 shows the attenuation of the recorded sinusoids expressed in dB. The average cross correlation between the sinusoids recorded by *Telefetalcare* and sinusoids simulated in Matlab® (at the same frequencies) is 0.98 ± 0.02. *Telefetalcare* guarantees a flat band and very good performances between 1Hz and 60Hz.

B. *Configuration of abdominal electrodes*

Abdominal ECG signals are obtained by computing the differential voltage between each of the 8 abdominal electrodes and the reference, as Fig. 3 exemplifies. Several electrodes configurations were tested in order to identify the best solution. The configuration shown in Fig. 3a was used for preliminary recordings. It consists in a reference electrode placed on the right side of maternal chest, and 8 electrodes placed just below the abdomen. This configuration produces signals of big amplitude (up to 300 mVpp after amplification). Nonetheless, SNR between maternal and fetal ECG is not sufficiently good to guarantee a reliable FECG extraction.

For this reason, the configuration shown in Fig. 3b was proposed, which was selected for the realization of the wearable garment. It consists in a reference electrode placed on the navel, and 8 electrodes placed around it with radial symmetry. The recorded signals are characterized by smaller amplitude (up to 150 mVpp after amplification), but SNR between maternal and fetal ECG is good enough to allow efficient fetal QRS detection.

C. *Algorithm of FECG extraction*

Several methods for FECG extraction have been developed in the last decades. Methods based on adaptive filtering [10], subtraction [11] averaging [12] and independent component analysis (ICA) [13] are the most commonly used approaches.

A simple algorithm was developed in order to allow an easy on-board implementation in the future prototypes. At the moment, it has been completely developed and tested under Matlab® environment. The algorithm is inspired by Martens' algorithm for FECG extraction, described in [11].

Firstly, the 8 abdominal ECG recordings are filtered with a 50Hz digital FIR notch filter, in order to remove 50Hz interference. After AC removal, each signal is filtered with a 10th order moving-average low-pass filter:

$$x_{MAj}(i) = \frac{1}{10}\sum_{k=0}^{9} x_{50FILTj}(i+k)\ ,\ i = 1,\ldots,N-9\ ,\ j = 1,\ldots,8 \quad (1)$$

where x_{MAj} is the *j*-signal after MA filtering, $x_{50FILTj}$ is the *j*-signal after notch filtering and N is the length of the *j*-input signal. The difference between $x_{50FILTj}$ and x_{MAj} is computed:

$$y_j = x_{50FILTj} - x_{MAj}\ ,\ j = 1,\ldots,8 \quad (2)$$

For the localization of maternal QRS, the algorithm developed by Martens et al. [14] was employed. The approach is a QRS enhancement algorithm based on Principal Component Analysis (PCA). The input of the approach is X, a [8 x N] data matrix containing the eight y_j signals of N samples. The output of the PCA enhancement is first principal component c, which represents the linear combination of all the channels of X that yields maximum variance. In this way the large inter-channel correlation of the ECG components and the small inter-channel correlation of the noise are exploited. The QRS detection takes place on the signal c that is generated by the multi-channel QRS enhancement method. The QRS complexes are accurately detected by finding the maxima of the cross-correlation between the signal and a QRS template.

This approach permits the localization of maternal QRS complexes. After that, maternal QRS are removed from the y_j signals by means of an averaging and subtracting procedure. For each y_j signal, a window w_{QRS10j} of 10ms centered in the last detected maternal QRS is localized. A maternal QRS template t_{QRS10j} is obtained by averaging ten w_{QRS10j} windows of the y_j signal preceding the current QRS. The current maternal QRS is removed by subtracting from the y_j signal the t_{QRS10j} template, scaled by a constant a which minimizes the mean square difference between the current QRS and the template:

$$a_j = \min\left\| w_{QRS10j} - a_j \cdot t_{QRS10j} \right\|^2 \quad (3)$$

After the averaging and subtracting procedure, 8 $FECG_j$ signals are obtained. Finally, the fetal QRS complexes are detected on the $FECG_j$ by finding the maxima of the cross-correlation between the signal and a fetal QRS template. The QRS detector described in [14] was employed. QRS enhancement was not used for fetal QRS detection: fetal ECG is visible only in a small number (2 or 3) of abdominal recordings. For this reason, the fetal component would have not been present in the first principal component generated by the multichannel QRS enhancement.

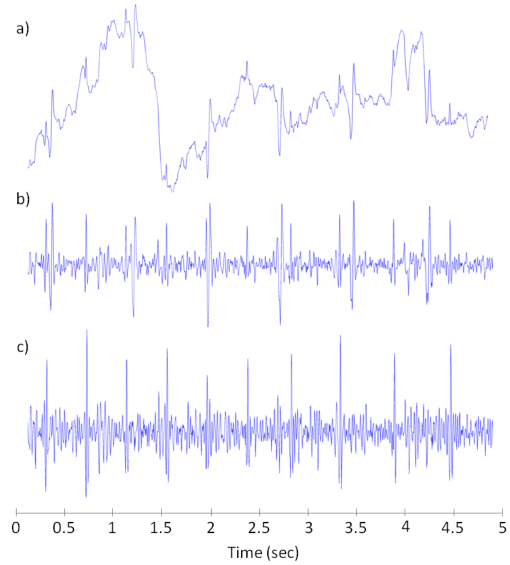

Fig. 4. (a) 5 sec abdominal ECG trace as recorded by *Telefetalcare*. (b) y_j signal, obtained after computing the difference between the notch-filtered signal and the MA-filtered signal. (c) *FECGj* trace, obtained after maternal QRS removal.

Only FECG signals obtained from an abdominal trace with clear fetal QRS complexes were considered for the successive analyses. A simple approach to classify the extracted FECG according to a quality index is presented in the following.

D. Selection of FECG traces

Fetal QRS detection is accomplished in each of the 8 $FECG_j$ traces obtained by the procedure previously described. Afterwards the quality of fetal QRS detection in the 8 channels is evaluated. The quality index q is computed in the following way:

$$RR_j(i) = QRS(i+1) - QRS(i)\ ,\ i = 1,\ldots,M_j - 1\ ,\ j = 1,\ldots,8 \quad (4)$$

$$q_j = mean\left(\sum_{i=1}^{M-1}\left\| RR_j(i+1) - RR_j(i) \right\|\right)\ ,\ j = 1,\ldots,8 \quad (5)$$

where RR_j is the series of the inter-beat distances for the *j*-signal, M_j is the total number of detected QRS for the *j*-signal and q_j is the quality index proposed to evaluate the fetal QRS detection. Finally, signals are sorted according to the q index: smaller q values correspond to better FECG traces and more reliable fetal QRS detection. Only FECG with q index < 0.1sec are considered for the successive analysis.

III. RESULTS

The prototype was tested on a limited number (4) of pregnant patients between the 30th and the 34th week of gestation, after informed consent. 8 abdominal ECG recordings were collected and stored, for a total acquisition time of approximately 20 minutes (298158 samples). The results were obtained using the electrodes configuration

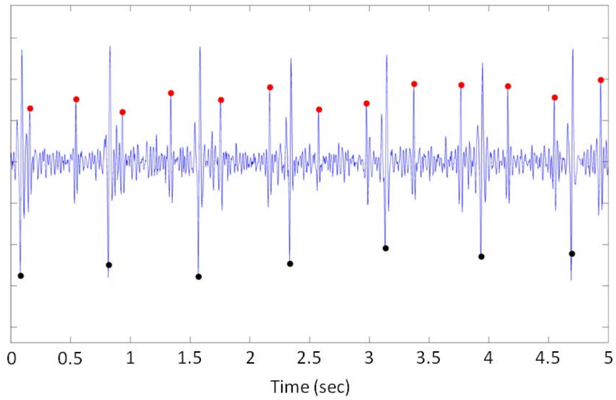

Fig. 5. Example of fetal and maternal QRS detection. Red dots highlight the detected fetal QRS, while black dots mark the detected maternal QRS.

shown in Fig. 3b. During the acquisition, the woman was sitting on a chair and she was asked to stay still.

Fig. 4 summarizes the quality of recorded signals and the different steps of the algorithm. Fig. 4a shows one abdominal ECG recording containing clear fetal components. The trace shown in the upper panel is a 5sec raw signal before any procedure of digital processing. Fig. 4b shows the y_j signal. It is the result of the difference between notch-filtered signal and MA-filtered signal. Fig. 4c shows the $FECG_j$ signal, obtained after maternal QRS removal. Fig. 5 shows the trace with the best quality score, with the detected fetal QRS (red dots) and the detected maternal QRS (black dots).

Accuracy and sensitivity of the entire system were quantified after fetal QRS detection. An expert clinician evaluated the 1st-ranked traces with q value < 0.1sec, by counting the number of (i) QRS correctly detected (TP); (ii) missed QRS (FN); (iii) QRS wrongly detected (FP). Accuracy and sensitivity were computed in the following way:

$$Acc = \frac{TP}{TP + FN + FP} \qquad Se = \frac{TP}{TP + FN} \tag{6}$$

For maternal QRS detection, we obtained an overall accuracy of 98.52% and sensitivity of 99.5% (TP = 1603, FP=16, FN=8). For fetal QRS detection, overall accuracy was 91,26% and sensitivity was 92,94% (TP=2684, FP=53, FN=204).

IV. DISCUSSION AND CONCLUSIONS

The prototype of a wearable fetal electrocardiograph was developed. *Telefetalcare* has been tested on few patients, showing good performances both in terms of acquired signals quality and fetal QRS detection. At the moment, the digital processing is performed offline, using a graphical user interface implemented in Matlab®.

To allow a good signal quality, it is very important to guarantee a tight contact between the wearable garment and the patient skin. The loss of contact causes a complete signal corruption. For this reason, the garment is very elastic and perfectly adheres to the abdomen. Different sizes will be realized to allow the optimal fit to pregnant women of different body builds.

The next step for the development of the final project is to implement the algorithms on the digital board embedded in the device. The package has to be miniaturized, reducing battery drain. Since the decrease of fetal QRS detection is often associated to signal corruption caused by patient movements, the system should be improved in order to reduce signal loss caused by mother movements. Data transmission to the remote station still has to be designed and developed.

The wearable system we are building up will permit an accurate and continuative monitoring of fetal wellbeing. The wearable garment, provided by textile electrodes, will allow pregnant women to monitor fetus health state without moving to the hospital or asking for clinicians support. The system will contribute to reduce costs in fetal monitoring, leading to a significant improvement in the quality of fetal wellbeing assessment.

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