Development and evaluation of a uterine contraction monitoring device: a home monitoring device

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Abstract

Preterm labor is one of the major public health problems in the developing countries, where accessibility to health facilities is low in some areas. Home monitoring devices could be good options in this situations. Therefore, we developed a tool for early detection of contractions. The type of signal, artifacts removing way, a method for sending signals safely, detecting abnormal contractions method, and evaluation methods were determined. EHG signals were applied to send contractions to mobile application. Alarms were displayed if abnormal contraction is detected. Relative Error and Co-efficient of variation were calculated for evaluation of accuracy and repeatability of device, respectively, which were acceptable. This portable, low weight, low cost and easy to use uterine contraction-monitoring device could be used in urban and rural health centers, at home and by pregnant women who are living in hard-to-reach places. This may help early awareness and take action to prevent premature birth.

Introduction

Preterm Labor (PTL) is one of the most important problems of obstetricians and the most common cause of infant mortality. A premature labor is a labor whose pregnancy lasts less than 37 weeks (1). In different regions, the prevalence of PTL is about 5-10% of all pregnancy cases. Studies in different countries show that, despite a decrease in infant mortality over the past 20 years, PTL has a high prevalence, so that it is between 12-13% in the United States and 5-7% in Europe (2). The majority of preterm labors in the world occurs in South Asia and sub-Saharan Africa (3). In Iran, the prevalence of preterm labor is high, and it has been reported as about 4.39 to 6.5 in various studies (4).

PTL has different influencing risk factors (5). Preeclampsia and/or fetal growth restriction (FGR) are mainly medical reasons for one-third of PTLs, and spontaneous preterm labor is two-thirds of PTLs. Prevention of PTL is one of the most important purposes of birthing specialist care (6). Because there are many reasons for this problem, different types of scientific search and clinical strategies are needed to prevent it (7). For a desirable PTL prevention method, a combination of three items including maternal risk factors, obstetric history, and screening tools should be considered for stratification of risk (5).

Contractions of the uterine during pregnancy are monitored to evaluate PTL threat. External measurement of uterine electrical activity is known as a substitute way of monitoring and analyzing uterine contractions. Tocodynamometry (TOCO) is the most common tool (8). Besides the benefits, TOCO has some disadvantages that negatively affect correct identification of PTL (9). So, a more accurate method is needed. Another method is electrohysterogram (EHG), which was developed in the 1960s (10). It is a signal related to electrical waves emitted by smooth muscle cells of the uterus, which is also known as the uterine contraction signal

(11). EHG provides better results in aspects of accuracy and reliability compared with tocodynamometry (12).

Because uterine activity related to PTL often cannot be identified by patients, home uterine activity monitoring can be suitable for early detection of uterine contractions without hospitalization. Various devices for this purpose were created and studies performed to evaluate their efficacy. Some studies show that using a home uterine activity monitoring device can increase the length of pregnancy in women with high PTL risk (13). This leads to a decrease in infant mortality, because gestational age has an inverse relationship with the risk of neonatal morbidity and mortality (14).

In Iran, the prevalence of PTL is high, and accessibility to health facilities in some regions is low. A home monitoring device could be a good option. Regarding this, we decided to develop a tool to monitor uterine activity at home for pregnant women. Also, the noises of EHG signals were removed by the composition of filters and amplifiers.

Materials and Methods

In this study, for development, some prerequisites were important to be determined before development of device. signal receiving method then removing artifacts from signals considered firstly. Then determining the most important factors in evaluation, and detecting way of abnormal contractions. Details of development are described below.

For continuously monitoring, dry contact electrodes are used by people (15). In this research, we used dry contact electrodes. In order to receive uterine contraction signals and remove noises of EHG signals, we combine amplifiers and filters.

Amplifier

We needed an Amplifier that could convert an EHG signal that has an amplitude of mv into output with a voltage range of several volts. Because it should be able to receive and convert to a digital signal. So, several layers of amplifiers are needed. Amplification layers with required filters are developed to get the maximum signal-to-noise ratio (SNR) at output. It is considered as an important factor because higher SNR value lead to resolution. SNR is defined as 20 log10(s/σ). The maximum amplitude in the averaged time period signal is s (16).

Operational Amplifier

The main task of an operational amplifier with AC number (AD620NA) is to amplify low amplitude signals received from the abdomen so that the signal can be used in the filter layer. Generally, operational amplifiers are differential amplifiers with wide bandwidth, high input impedance, stable and adjustable gain, and high common mode rejection ratio. Furthermore, features include low noise, low input bias current and low power of the AD620 make it suitable for medical applications and instrumentation (17). This IC is an 8-pin piece, with low power consumption, low offset, and high precision, which has adjustable and high gain (figure 1,2).

Electronic filters

They are electronic circuits that do signal processing, especially when we want to eliminate unwanted signals from elements or increase them (unwanted signals). Electronic filters can be as follows:

1. Active or inactive (18)
2. Analogue or digital
3. Linear or non-linear
4. Infinite Impulse Response (IIR) or Finite Impulse Response (FIR) (19)
5. Time discontinuity or time continuity

In this study, high-pass filter, active filters, Low Pass Filter with amplification (LPF & AMP), and Notch Filter were used. Regarding the frequency spectrum of EHG signal in the range of 0.1 to 3-5 Hz (20), a high-pass filter of RC type with a cutoff frequency of 0.1 Hz has been selected (figure 3,4).

For active filters, a combination of active and inactive components (amplification) and an external power source were used. Amplifiers that are frequently used in active filter designs can have a high Q factor. They can reach resonance and this occurs without using an inductor. However, the bandwidth of used amplifiers limits their upper frequency limit (21).

Low Pass Filter with amplification (LPF & AMP) is to remove signals with a frequency higher than 3 Hz. Due to the great advantage of the Sallen-Key type active filter (22), the same type of filter with amplification has been used in the design of the low-pass filter. (figure 5).

Notch Filter can be used to eliminate urban electricity artifact signals in this electrocardiogram device. Because the urban electricity frequency is 50 Hz in Iran, we must use a low-pass filter that is set to a frequency of 50 Hz to remove the noise caused by urban electricity frequency. For this purpose, we use a Twin-T Notch type filter and then an amplifier to amplify the signal without noise. The designed filter is passive. Due to the loss of another IC, the passive T-Notch filter effectively removes noise from urban electricity.

Power supply

Based on our purpose, the device should be portable. So, a rechargeable lithium battery was used. Due to the need for negative polarity in powering operational amplifiers, IC 7660, which produces negative voltage, has been used.

Sending signals

Because of the necessity for easy use of devices by pregnant women, data must be transmitted wirelessly. The HC-05 data transfer module, which is a Bluetooth to serial interface, is used for sending data to smartphones.

Device Evaluation

At first, we evaluated the accuracy of the device with an ECG Signal Simulator. ECG signals were entered into the device, and the device output was recorded. The average of four repeated tests was calculated in this section.

$$CV = \frac{\sigma}{|\mu|} * 100\% \; that \; \sigma = \sqrt{\frac{1}{N}\sum_{i=1}^{N}\left(A_{\mathrm{ti}} - \mu\right)^2} \; and \; \mu = \frac{1}{N}\sum_{i=1}^{N} A_{\mathrm{ti}} \backslash n$$

Smartphone Application

The application was designed for patients with the aim of providing easy access to uterine data and informing pregnant women about contractions. Features of the application are determined with regard to the basic needs of users. Data is saved on mobile phones. The application was developed on Android.

Results

The overall design of the uterine contraction monitoring tool consists of receiving signals, amplifying, filtering and sending them to smartphone applications. Below the block diagram, show this process (Figure 6) in which a signal will amplify after receiving from the body. Then, through suitable filters, the target signal is extracted and de-noised. Finally, data was extracted from an analog-to-digital converter and sent via Bluetooth.

The developed device is portable, has a low weight, and can detect uterine contractions without interfering with noise (Figure 7). The usability of the device is easy, so that three electrodes receive signals from the body. While sending signals, the LED, besides the Bluetooth icon, is flashing light. After analysis, contraction signals show on the smartphone. The battery of the device is chargeable and located behind the device.

Sample contraction signals received from the device are shown in Figure 8. For device tuning, applying devices by pregnant women is needed.

Table 1 shows the results of the device evaluation. Two criteria for the accuracy (RE) and repeatability (CV) of the device are calculated. The numbers in the table showed that they were acceptable.

The smartphone application was developed in several sections (Figure 9). It consists of a login section, a profile section includes age, pregnancy age in weeks, number of deliveries, and type of delivery includes cesarean or vaginal delivery in a previous pregnancy. Previous uterine contraction tests, start new session and help. Abnormal contractions are identified using strength, duration and frequency of contractions, but this is the difference between women with or without history of cesarean delivery. For preterm patterns, the application shows warning notifications to users.

Discussion

This study was done to develop a uterine contraction-monitoring tool. A portable device with a smartphone application that pregnant women can use easily was the output of our research. Cost, energy consumption, removing noise and weight were taken into account for more usefulness. This tool is a sample of telemedicine devices that can be used for pregnant women with a high-risk of PTL or for other pregnant women with a physician's diagnosis. Unlike the Toco device, it is possible to use this product at home in remote areas.

In this device, EHG was used to receive the uterus signals for some reason. The first was that the tocodynamometer must be properly held by a guard to distinguish uterine contractions (24). While using EHG electrodes that are attached to a woman's skin, avoid the problems of electrode displacement. This means that a pregnant woman can move during the recording signals. Another reason was the power of the device to distinguish between labor contractions and Braxton-Hicks contractions (25). EHG analysis during pregnancy can be used to predict the risk of labor.

The third reason was the evaluation criteria of existing tools. Several studies have calculated the sensitivity, specificity, and predictive values of CTG. Based on most of them, specificity (>90%) was relatively high, but sensitivity (averaging 50%) was low (26). Also, based on Thijsse's study (27), the accuracy and sensitivity of the EHG are higher than the tocodynamometer. In addition, sensitivity in obese women was 46 to 51% by tocodynamometer and 82 to 97% by EHG. The intrauterine pressure catheter (IUPC) is the more accurate method (27). Especially in obese women, it is more accurate than external tocodynamometry in detecting the power and frequency of uterine contractions (28). However, this method is invasive and has some side effects (29). Nevertheless, Electrohysterography is a non-invasive method to monitor FHR and uterine contractions (12).

The study by Marque et al. (30) has proved that it is possible to detect the risk of PTL as early as the 27th week of pregnancy with a non-invasive method. Other studies (25, 31-33) on pregnant women showed that EHG analysis is a promising and non-invasive diagnostic tool for the diagnosis of PTL.

EHG has some disadvantages. For example, recordings of EHG include some physiological interferences such as abdominal muscle activity, and motion artifacts (34). We used operational amplifiers and filters (low-pass filter, high-pass filter and notch filter) to remove abdominal muscle activity noises.

In the world, multiple home pregnancy monitoring systems have been produced. For example, Bloomlife (35) acquires EHG signals with one channel for capturing uterine contractions (UC). It provides the frequency, pattern, and duration of UC. Invu (36) captures FHR and maternal HR. However, this device does not provide information about UC. Monica Novii wireless patch system (37) captures fetal ECG and UC waveforms in one channel. The device developed in this study was the first device of this type in Iran and can capture UC using EHG signals with three electrodes. In the application, the duration, power and frequency of UC are shown. Also, the application makes an alarm if it detects a contraction other than Braxton Hicks. The facilities in the application are basic. In the future, new features such as an education section for patients, a version of software for nurses and obstetricians, and sending messages to nurses, obstetricians and relatives of pregnant women will be added.

Conclusion

With new technologies, uterine contractions could be recorded and analyzed more efficiently. The developed low-cost portable device could be used by pregnant women, nurses, and obstetricians easily. It can be used for UC monitoring and PTL prediction. This monitoring could not prevent PTL, but it provides a possibility for early intervention, and may increase the length of pregnancy.

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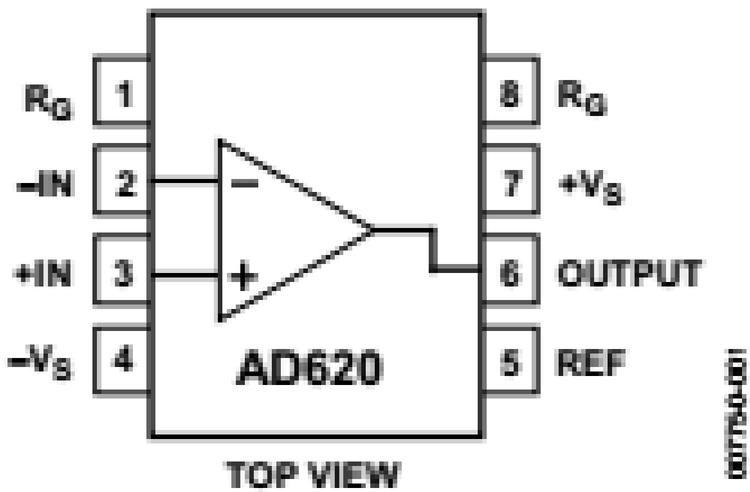

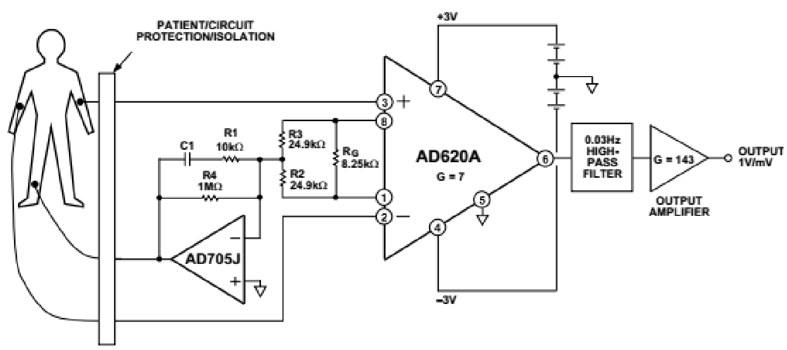

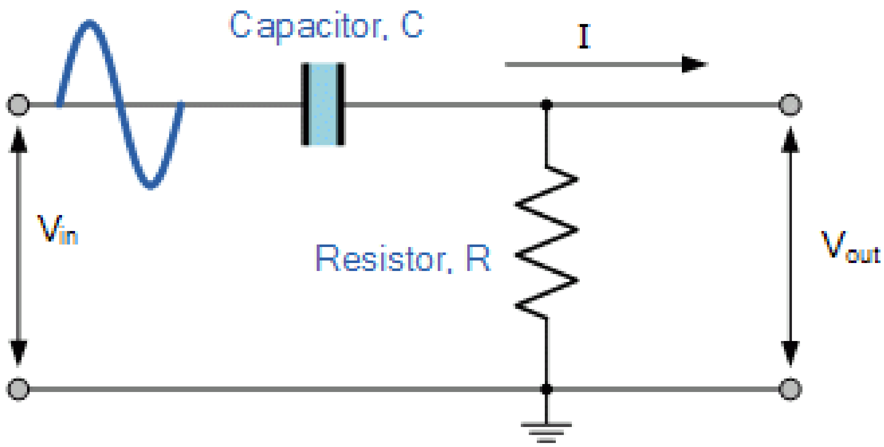

Figure 3: RC high pass filter

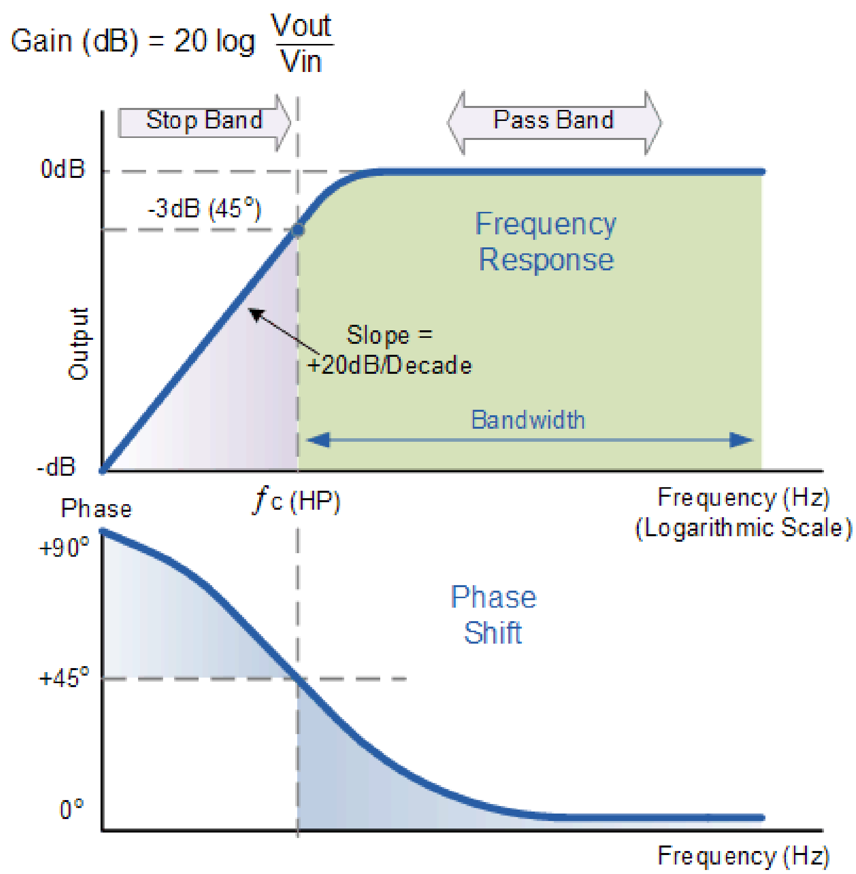

Figure 4: High pass filter amplitude and phase diagram

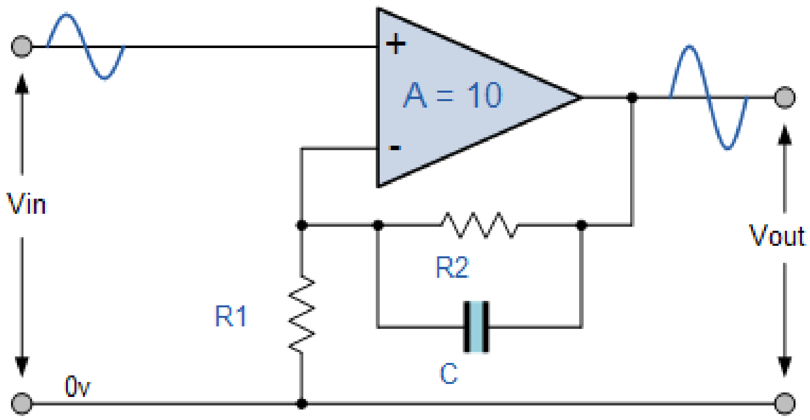

Figure 5: Implemented low-pass filter of Sallen-Key type with amplification

Figure 6: Device Block Diagram

Figure 7: home uterine contraction monitoring

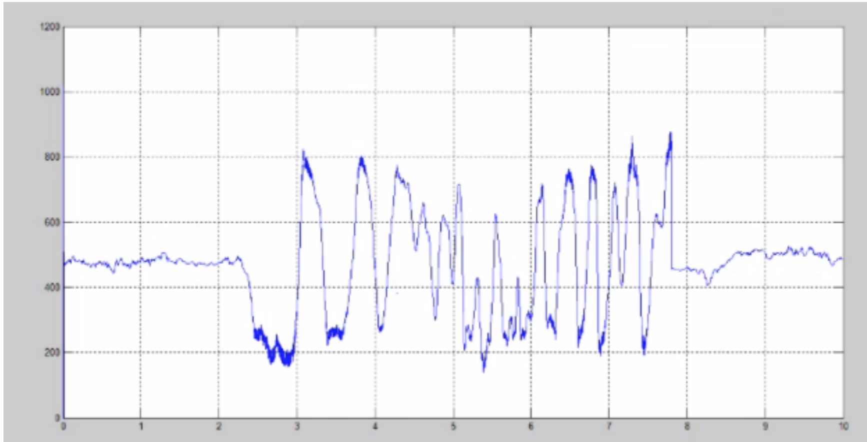

Figure 8: contractions signals

	1	2	3	4	5
A_t	0.047	0.468	0.933	1.405	1.875
A_e	0.05	0.5	1	1.5	2
RE	6	6.4	6.7	6.3	6.2
CV	0.022	0.013	0.011	0.022	0.014

Table 1: Evaluation of the device