

Babykick: development of a wearable system for detecting fetal movements during pregnancy

by

Shayesteh Vefaghnematollahi
B.Sc., Azad University of Khomeinishahr, 2015

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ABSTRACT

Decreased fetal movement can indicate uncommon complication of labor; in response, we have developed a non-invasive, wearable monitoring tool to objectively assess fetal movement called the Babykick device. The novelty of this device is that it moves away from a traditional subjective assessment of fetal movement to an objective, quantitative measurement that remains low-cost. The designed tool refrains from utilizing expensive and less available monitoring modalities such as ultrasound imaging, Doppler velocimetry or cardiotocography. Instead, the wearable consists of a piezo-sensitive belt that is wirelessly connected to a phone or tablet. It can be used to record the frequency and amplitude of fetal movements perceived passively and non-invasively on the surface of the abdomen of the pregnant woman for a period of up to one hour while she is supine or seated in a reclined position. The findings from the Babykick device will be correlated with those from subjective maternal assessment and the observation of the Research Coordinator during the test. This low-cost, non-invasive wearable belt could potentially reduce negative outcomes such as still-birth, perinatal mortality and neonatal morbidity in low- to middle-income settings and is anticipated to be useful for long-term home monitoring.

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DEDICATION

I dedicate this work to my family.

Chapter 1

Introduction

1.1 Problem Discussion

The evolution of electronic components alongside the enhanced knowledge behind the design of medical devices has improved the quality of care that patients receive. Pregnancy monitoring devices, however, are the exception to these innovations; there have not been significant improvements in this field that focus on assessing the health of the pregnant woman and her fetus [1, 2].

The effects of hypoxemia make apparent the importance of tracking fetal movements. Lack of oxygen causes fetal distress, which results in a decrease in fetal movements as a compensatory behavioral response[3]. As the severity of hypoxemia increases, it can eventually lead to poor perinatal outcomes, including restricted fetal growth, pre-term birth, and stillbirth [4, 5, 3]. In addition, decreased fetal movement can be a sign of dysfunction, placental pathologies, nervous system changes or overall fetal health[3].

According to Lvchen Zhao, Wu Wei, Zeng Xianyi, Koehl, Ludovic and Tartare Guillaume [1], two of the most popular methods for detecting fetal movements are 1) the subjective perception of a pregnant woman and 2) ultrasound. The former method may yield unreliable measurement since it depends on a person's level of attention and the experience of women in detecting fetal movement. The current standard for measuring fetal movement indicates that a minimum of ten of "any discrete kick, flutter, swish or roll" every two hours is normal [6]. This methodology requires that women pay attention to the number of movements on a daily basis.

Diagnostic ultrasound, also called sonography or diagnostic medical sonography,

is an imaging method to produce images of soft tissue structures with the help of high-frequency sound waves. This technology facilitates doctors to diagnose different diseases and treat them in the best way possible. Ultrasound does not only create images from organs, it can also measure blood flow in the arteries. The biggest problems with using this device are that it requires highly skilled clinicians to perform and that the observation is only limited to the duration of the visit[5, 1].

The latter method - ultrasounds - are only achievable during clinic visits. Consequently, research shows that 40 percent of pregnant women become concerned about decreased fetal movement several times during their pregnancy [1, 4, 7]. Ultrasounds have been associated with increased maternal anxiety and unnecessary stress. Additionally, the length of time between ultrasound appointments can contribute to missing some vital signs regarding fetal health [1, 4, 2, 7].

The rate of stillbirths is another critical point for reassessing fetal monitoring practices and devices. Stillbirth rates have reduced more slowly than other maternal and pediatric survival indicators in low- and high-resourced settings [8]. All but 2 percent of the world's 2.6 million annual stillbirths occur in less-developed regions - 75 percent in sub-Saharan Africa and South Asia alone [8]. About 50 percent occur prior to the onset of labour, and 60 percent occur in either rural areas and/or in conflict and emergency zones. Therefore, families most under-served by health systems are disproportionately at risk[8]. Most pre-labour stillbirths are caused by poor function of the placenta. Of the 50 percent in-labour stillbirths, a significant proportion result from multiple insults related to placental function, infection and prolonged labour. However, due to passive fetal movement after death, women can continue to be aware of postmortem fetal movements. In well-resourced settings, high-risk fetuses are screened through ultrasound by using a combination of fetal weight estimation, assessments of amniotic fluid volume and fetal blood flow (umbilical and middle cerebral arterial, and ductus venous Doppler), as well as cardiotocography, and non-stress testing (NST) which is computerized [6]. Use of a biophysical profile in high-risk pregnancies, which incorporates ultrasound and NST, is associated with increased adverse perinatal outcomes[9, 10, 11, 12, 13].

These expensive technologies require highly-skilled clinicians to perform and interpret the tests and are limited to women with access to sophisticated levels of care. These facts indicate a significant need for a low-cost method to objectively measure active fetal movements in pregnant women. The proposed method enables pregnant women to engage with the health care system while further promoting reassurance

and the reduction of the global burden of stillbirth. Early recognition of decreased fetal movement may also provide physicians with an opportunity to intervene in fetuses identified at risk.

1.2 Background

Years before the modern ultrasound paved the way for screening, fetal movement gave women confirmation of their baby's existence; this method provided an estimation of their due date, premised on the time the baby had shown their viability through movement[14]. During this time, people believed the soul of the baby had formed by the time the mother felt the first movement [15]. Obstetricians of the nineteenth century considered a reduction in fetal movement as an ominous sign [16] - an indication of the importance of the presence of the movements. Interestingly, today fetal movement continues to be an avenue for confirming pregnancy [17].

As gestation progresses, fetal movement strengthens correlating with the growth of the fetus. Stronger fetal responses are associated with healthier fetal development and functionality [18, 19]. To emphasize this point, Luchinger et al. determined that structural abnormalities were preceded by abnormal fetal movement [20].

In the 1970s, a diagnosis of fetal jeopardy began with the consideration of the movements of the fetus. Research conducted by Sadovsky and Yaffe was carried out on a small group of pregnant women who tracked fetal movement daily. This study demonstrated that one day before the loss of the fetus, in a one to three day period, fetal movements were found to have decreased[21]. Based on a paper published by Pearson and Weaver, a 'movement alarm' of 10 kicks per day could be considered as a sign of a complicated pregnancy[22] with less counts an indication of an early delivery. Other research has found that monitoring fetal movement on a daily basis could prevent adverse fetal outcomes [23, 24]. In the 19th century, reduced and/or absent fetal movement in utero was recognized as a perilous indicator [22, 21]. Remarkably, in recent times, an absence of fetal movement is still regarded as a sign of intrauterine death [18].

A comparison of two studies indicates that there is a high correlation between maternal perception of fetal movement and capturing the movement by other devices such as ultrasound [25, 26, 27]. For improved survival rates in fetuses, it is recommended to monitor the fetal movements [25, 26, 27]. Insofar as a considerable number of methods for capturing fetal movements were mentioned in the papers, the

importance of monitoring fetal movements was apparent [25, 26, 27]. In the mentioned papers [25, 26, 27], there were a variety of promising methods to capture fetal movement with the aim of reducing the perinatal mortality in early studies, however, later high-quality studies contradicted these findings [28]. Findings from a 1989 randomized control trial, which was published in *The Lancet*, failed to show a benefit in counting the movements; as a result, there was a reduced utilization of fetal movements in antenatal screening in both low-risk and high-risk pregnancies [29]. It should be noted that the trial came under considerable criticism for the procedure used. The most notable criticism of this seminal work was the contamination between the control and experimental groups. For this reason, women from the experimental group - who were tracking fetal movement - often gave those women not counting fetal motion unsolicited advice, thus impacting the quality of the control group [27]. The importance of assessing fetal movement has been established by reviews, which have also recommended formalized methods of fetal movement monitoring. The Kick device is not the first to exist on hand; the current design for portable kick trackers is an outcome of several successful and unsuccessful progressive methods and products.

Until recently, one method - called "Cardiff Count to Ten" - was recognized as the most accurate mode. In this model, the pregnant woman counted ten movements and recorded the time in which those 10 movements occurred [30]. Many studies from the 19th century have suggested various patient-dependent methods to compute the movements as precisely as it was possible. Such a technique required astute focus for women to provide the right information to their care providers, and it consequently induced unnecessary anxiety for women. This method was superseded with passive and active methods. These methods, compared to the previous one, were easy to use and more precise. Although these general methods were useful for capturing different types of movement - four, in particular, were identified [31] - they required more engineering knowledge behind the scenes. The technological weaknesses of these devices still required that women still record by hand the number of kicks in a chart [32].

In the 1990s, there was a general consensus in healthcare that providing general information on fetal movements and methods for monitoring was likely beneficial for both pregnant women and the fetuses [27, 28]; thus an active method known as real-time ultrasound imaging was developed and more routinized. Health care providers made this screening compulsory for pregnant women. Since most women did not notice the reduction of their baby's movements on time [33, 34] - indeed, there were

many cases whereby mothers were deterred from seeking assessment which led to adverse outcomes [35] - ultrasound became popular. Despite the established recognition of the value of using ultrasound, it was not a suitable tool for a monitoring system utilized over longer periods of time [36]. Additionally, there was concern among clinicians regarding x-ray exposure, which leads to device modifications - i.e. engineers redesigned small, low-powered, sensitive, and robust devices that were also safe for long-term monitoring [37, 36]. A practical, low-cost screening tool was required for further evaluation. The alternative low-cost, passive methods required significant resource expenditure to execute, however, these devices exceeded previous ones as they had the ability to monitor fetal movement outside of hospitals [37]. Employing wearable accelerometers was one such method that not only was reliable but also supported pregnant women in their own spaces of comfort - they could use it in environments of their own choosing, also providing a level of safety, particularly considering their price [38, 39, 40, 41, 42]. Without a clinical definition for normal fetal activity, incorrect and inconsistent information was circulated [43] and designing these kinds of devices yielded the opportunity to capture the same quantified threshold for the types of fetal movement in various situations [38, 39], resolving the differential and inconstant information that was previously received by patients who had varying qualities of perception, in some instances even compromised [44, 45].

In 2011 an individual, accelerometer-based system was designed with four wires connected to the laptop [36]. One wire was placed on the mother's chest area to eliminate the artifacts (i.e. errors and noise that arise from a movement of a woman), and the rest were attached to the mother's abdomen around her belly button where the fetal movements mostly occur. An issue noted in the study was that despite the mother being asked to remain still, there was no observer to record maternal activities. Furthermore, this study was conducted on a mere three, individual subjects based on computing the root-mean-square [36]. The difference between accelerometer-based Fetal Movement Detection and the Baby Kick device is that the latter captures the movements with more than twice the number of sensors; in addition, the record of the maternal perception of the movements is corroborated with the presence of an observer. Furthermore, the number of sensors in Baby Kick is enough for sufficiently sampling most of the abdomen surface in which movements happen.

There is one fetal monitor on the market, which is instructive to compare. It is the MobiUSTMSP1 system - a device similar to an ultrasound imaging system. Although this device gives the pregnant person images of the fetus, the presence of an expert

is needed in order to best interpret the images.

There is another study presented in 2014 in which three recording systems were used in the set up for data acquisition and comparison[42]. The device itself consists of 4 sensors, which are controlled by a laptop, an ultrasound image and a maternal handheld. Although ultrasound is considered a gold standard, the tool has its own restrictions that limit its versatility. A failure of ultrasound is that it does not capture all movements when they occur outside the scanning probe area. Furthermore, moving the probe in and of itself can cause artifacts. In this way, some false reported movements occur when, in reality the ultrasound could not capture them[42]. The size of the system also makes it hard for portability for the pregnant woman.

Another feasibility study proposed a new way for low-risk pregnancy detection based on Electrocardiogram(ECG) recordings[46]. This study was rooted in the premise that the electrical impulse comes from heart's height and shape, which is detected from the abdomen of the mother-to-be, can indicate movements of the baby and also following that the fetal motility[47]. QRS wave represents the electrical impulse and in this study [47], the changes in shape and amplitude of the recorded fetal ECG are connected to the fetal movements.

Recently another belt was developed that uses piezoelectric sensors, which has proven its capability of detecting fetal movements and other biological signals[48]. This sensor converts the mechanical movements to voltage and vice versa. Although assigning one sensor in this belt makes this device cheaper and smaller than the Baby Kick device, the displacement of the belt for capturing movement from not only one area causes it to be inconvenient and also increases the probability of motion artifacts.

The most recent study in this field detects fetal movements with force sensing[49]. This developed device was tested on non-pregnant female volunteers. The volunteers were asked to wear the device and performed some movements - the movements were supposed to cause artifacts - such as laughing, breathing, bending and sitting up and so on. The performance of the device was compared to a simulator using servo motors. Although the error rate was only 3 percent, they had to eliminate the parts with lots of heavy movements like sitting up to use their algorithm. The number of sensors is the same as Baby Kick, but not examining the device on actual pregnant women calls into question the reliability of the algorithm.

The other technology which worth discussing is the fetal movement acceleration measurement (FMAM) recorder [50]. This device was tested on the maternal abdominal wall. The size of it is considerably small, and the detection recorded with two

accelerometer sensors. One advantage of the Baby Kick over the FMAM recorder is that it can count fetal movements over a longer time period as a result of consuming less battery. The second advantage is that the FMAM recorder is not wireless, which makes it hard to use.

Based on this literature review, it is clear that various studies have yielded diverse results due to the use of a different number of sensors in each device, the type of sensors, and the existence of the reference sensor. These criteria ascertain data analysis methods. Most of the studies used an accelerometer as the type of sensor, while in the Baby Kick device, piezoelectric sensors are paired along with accelerometer sensors in order to use both capabilities for better results. Although the comparison between the studies can be challenging due to the variety of factors, the proposed device attempts to use the best technology available at the lowest cost.

1.3 Motivations

Fetal movement is an important indicator of fetal well-being. Normal fetal movement is defined as ten or more movements in two hours, considered as “any discrete kick, flutter, swish or roll” [51]. The only established way to evaluate the health of fetuses is by using ultrasound. In order to ensure supportive pregnancy outcomes of pregnancy, pregnant women must go to a hospital facility to have access to professionals who perform ultrasounds and provide results on the health of the growing fetus which is not only expensive but can also be frustrating and painful for mothers-to-be due to the hormonal and physiological changes that come with pregnancy. This process will be repeated several times and possibly at higher than normal intervals based on the health of the fetus and status/situation of the pregnant woman. Typically, ultrasound is limited to 30 minutes of continuous monitoring, which is less than the average fetal sleep-wake cycle. One of the motivations of proposing this device is to give the opportunity to check the movements of the fetuses for extended periods. As mentioned, the duration of an ultrasound appointment is not sufficient to capture the movements before and after the appointment, and there is a chance of losing some critical data before and after the appointment, which can lead to irreparable consequences. The other motivation behind the development of Baby Kick is to send the device to developing counties where there is no other device for pregnant women to check their fetal movements. Additionally, a pregnant woman’s subjective perception for detecting fetal movements can be associated with increased maternal anxiety as

they have to keep count and pay attention to quantification. Ultrasound technology is expensive and requires highly-skilled clinicians to perform and interpret the tests, and also, a woman's subjective perception is limited to women accessing sophisticated levels of care. What is required is a low-cost method to objectively measure active fetal movements in women - wherever they encounter the health system - to promote reassurance and reduce the global burden of stillbirth.

The aforementioned issues provided the main impetus for developing the Baby Kick device. This investigation not only gives a definition to the fetal movement subject but can also pave the path for further directions in research.

1.4 Objective of study

The overall objective of this research is to propose a non-invasive wearable monitoring tool to assess fetal movement. The mentioned device is able to transfer a traditional the subjective assessment of fetal movement to an objective, quantitative, and yet low-cost measure of fetal movement without resorting to expensive and less available monitoring modalities.

The belt can be worn for extended periods compared to the time of ultrasound screening, for visualizing fetal movements in order to decrease outcomes such as stillbirth, perinatal mortality and neonatal morbidity. A combination of the detection algorithms of the device, clinically-relevant fetal movement indices and hardware configuration of the device will refine the accurate capture of fetal movement.

Main Objectives include the following:

- The findings from the KICK belt will be correlated with those from subjective maternal assessment. This will refine our detection algorithms, clinically-relevant fetal movement indices and hardware configuration to produce a device that can accurately capture fetal movement.
- To develop a low-cost, effective and easy-to-use tool to determine fetal movement.

1.5 Limitation of study

In this section, the focus is on the constraints that are necessary to take into account regarding developing the device.

- Inclusion criteria at the time of recruitment:
 - singleton pregnancy
 - known gestational age between 28 and 41 weeks of gestation
 - uncomplicated pregnancy
 - limited number of sensors

- Exclusion criteria at the time of recruitment:
 - Insufficient command of the English language to obtain consent
 - known major fetal anomaly
 - pre-pregnancy BMI more than 34
 - maternal medical conditions associated with intrauterine growth restriction (IUGR) and Uteroplacental insufficiency (UPI)

1.6 Advantages

The principal advantages of this device are its simplicity and objective measurement. The other advantage of the Baby Kick device is its small size, which is easy to use for the users; they do not need to sit with lots of wires attached to them. The primary goal of this device is to be low-cost and accessible for all people with a variety of outcomes. While the maternal perception of movements may be considered reasonable and free, relying on maternal perception of movement is predicated on a woman's ability to find time to focus on fetal movements and her ability to sense movements. If she is either obese or has an anterior placenta (as fetal movements are sensed in the stretch receptors under a woman's skin), this may become difficult. Compared to the gold standard screening test (ultrasound), which is expensive and rarely available to women at risk in less-developed countries, Baby Kick is affordable, making it ideal for sending to less-developed regions.

In high-resource countries, the most common indication for near- or at-term fetal assessment - with ultrasound and/or fetal heart rate monitoring - is maternal concern about decreased fetal movements and to the best of our knowledge, Babykick device is the first device that is in the process of getting to market to respond to this need of the mothers so they can check their fetal movements when they are worried.

Although this device has initially been designed for in-facility monitoring, once any issues with motion artifacts are resolved, this device has the potential to be used for long-term home monitoring, which makes it the first device in the market of this nature.

Once validated with normal ranges for gestational age (correcting for maternal weight distribution and placental location), Baby Kick will provide objective measurements that will be useful in all clinical settings. In more-developed settings, KICK's negative predictive performance to rule out perinatal risk will reduce the burden of antenatal fetal surveillance (this performance may require additional biomarker testing). In low-resource settings, Baby-kick device may be used to guide interventions such as referral to comprehensive emergency obstetric facilities and decisions around the timing of delivery[52].

1.7 Dissertation Organization

The content of this thesis concerns the development of an entire device to detect fetal movements. The data will be saved and compared to the mothers perception. As fetal movements is an important factor in utilizing the fetal well-being during pregnancy, the subject had started. After having discussed the background of the entire project in this first Chapter, the thesis is followed by four more chapters, with the ending chapter of conclusions to close the whole study. The rest of this thesis is organized as following:

Chapter 2 Deals with the development of the system hardware and gives information about different parts of hardware design. The purpose of the chapter is to describe the path from the first to the last in designing and developing the Babykick device. The chapter proceeds with the analog board design. Then analog components selection, schematic drawing and PCB design are detailed. After that, three generations of the wearable garment development is described. Also the design of the Babykick device is detailed.

Chapter 3 Explains the software design. In order to compare Babykick performance, mothers perception should be considered. The importance of application in comparing the result led the project to further step and the design of the application had started. In chapter three first the difference between android

and iOS is described and then all the steps for developing both application are detailed.

Chapter 4 The output of the second chapter and the third one is basically used as input of Chapter fourth. The data obtained from the device is reviewed in the chapter fourth with all the pictures.

Chapter 5 In chapter five, conclusions and recommendations for future studies are mentioned.

1.8 future study

This device initially designed for in-facility monitoring; once the problems with motion artifacts are resolved, this device could potentially be used for long-term home monitoring. The device uses machine learning to better learn the pattern of fetal movement for each pregnancy, which takes into account the different rate and rhythm of each unique fetus. As all fetuses are different in terms of their amount of movement, with this technology, there can be improved accuracy in tracking fetal movements (i.e. each one of them separately based on their own rhythm of movements). In this way, if a fetus moves less than the others the algorithm learns the behaviour of the fetus and does not compare it to the other fetuses. Another feature that has to be added to the Baby Kick device is a real-time application that offers immediate access to data to give health providers better odds of approaching any perceived abnormality on time.

Chapter 2

Hardware

A detailed description of all the purposes of the project was mentioned in the first chapter. In this chapter, a description of hardware phases which brought to develop the device is presented.

As the first step, the overview of this chapter is outlined with the help of the block diagram to determine the possible system which could be built to detect and illustrate the fetal motion. Figure 2.1 shows a schematic description of the device and other processes which could be used for data acquisition.

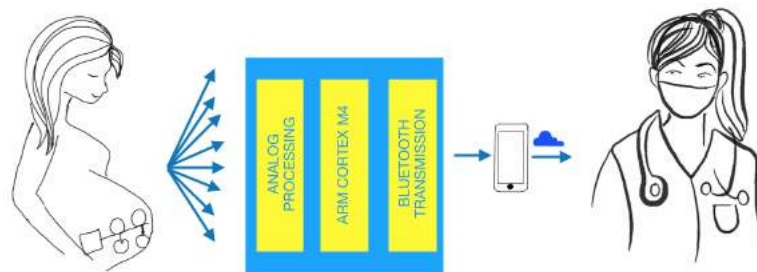


Figure 2.1: Overview of the device

2.1 Chapter Overview

The approach of using small devices in healthcare seeks to apply these innovations in a way to improve the system and make it more beneficial for both doctors and patients.

The Baby Kick device is aimed at quantifying fetal movement in the absence of ultrasound imaging, Doppler velocimetry or cardiotocography, which might help clinicians prevent the negative outcomes following the detection of reduced fetal movement. Similar to all the other devices developed, the development of this device combines a variety of fields: functional materials, data acquisition and processing, wireless communication networks (Bluetooth low energy) in the context of the human body, and monitoring and statistical methods for data analysis. The combination of all these will guarantee real-time and continuous fetal monitoring. The process begins with creating effective interfaces for data acquisition; this can change the entire scenario as the findings from the KICK device belt will be correlated with those from every individual maternal assessment. Storage of all the medical records can later be accessed by doctors; this is the last phase of the hardware.

In the previous version, When a pregnant woman senses the fetal movement, she had to press the button on the device, which is shown in figure 2.2. To make the artifacts minimum, "SNEEZE" button on the app is implemented (more information provided in the next chapter). The actual signal, which is captured by the device

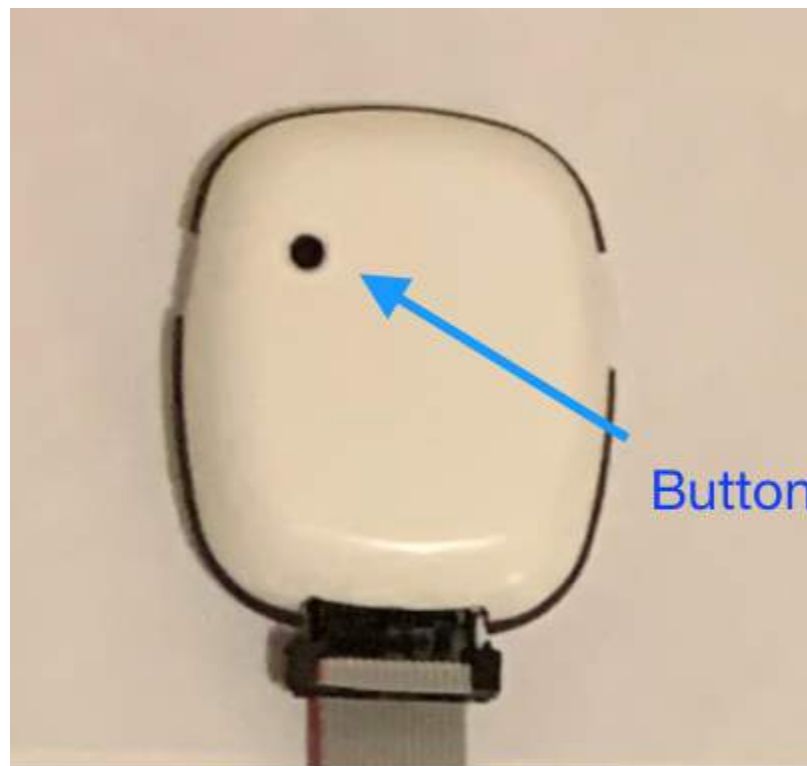


Figure 2.2: The Button of the device

is compared with the subjective maternal perception. Special attention is paid to show both the woman's recognition and the detected fetal movement at the same time. With the help of a designed app (explained in the next chapters), the device is connected to a phone or tablet. Figure 2.3 below shows the overall look of the system. The compact part of the device consists of four main parts: microcontroller



Figure 2.3: The overall look of the device on a pregnant woman

(MCU), Power Management, Storage, and an Analog front end. The relation between different parts is summarized in the following block. As the block scheme in figure 2.4 shows, the last prototype is able to record fetal movement with the wearable belt, pre-process the recordings thanks to an analog pre-processing stage designed and developed for this purpose, and digitally convert data and transmit them via Bluetooth low energy. To record fetal movement on the surface of the abdomen, a belt with piezoelectric sensors is used. These sensors presented as an appropriate

option to detect the movement not only for the circular shape of the sensors but also because of their number.

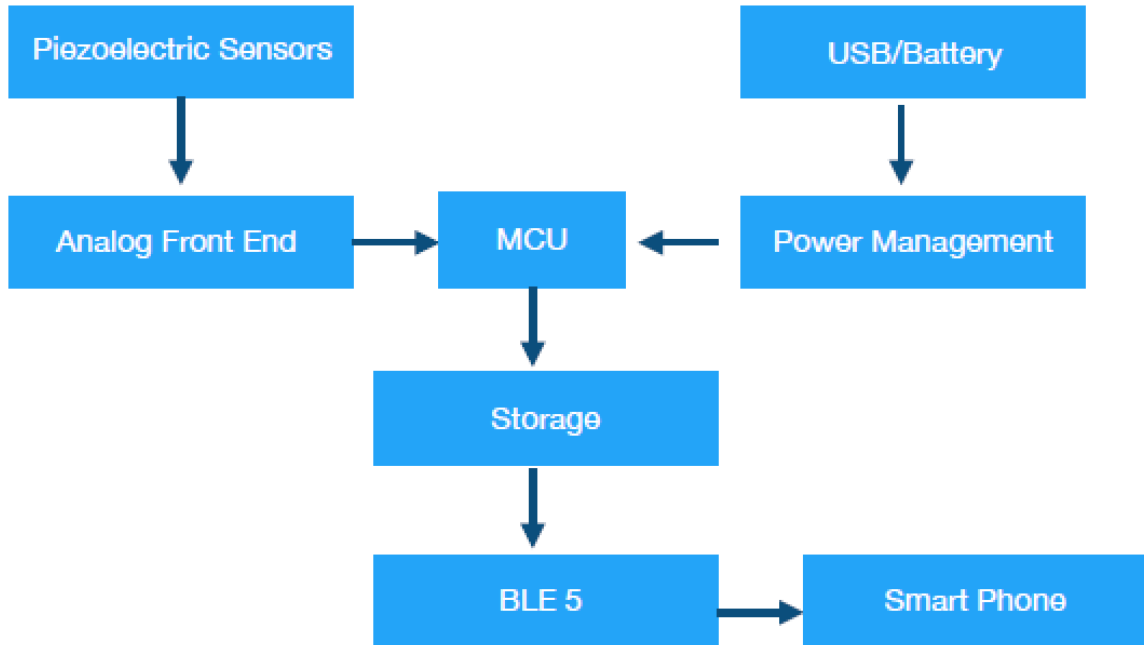


Figure 2.4: A simple illustration of the device block diagram

2.2 Component Selection

The objective of this project is to identify fetal movements in an accurate way. The movements sensor is based on eight piezoelectric sensors controlled by a low power microprocessor, which has its own Bluetooth Low Energy. When the data is captured by piezoelectric sensors, it will be converted to digital information and will be sent to the microprocessor. The microprocessor extracts the useful data and stores it on a microSD card(Secure Digital Card). The next step is to connect the card to a personal computer (PC) or mobile phone. Based on the features described above and the following requirements, the options narrow down to the listed components below.

2.2.1 Microprocessor

The ARM® Cortex®-M4 processor, nRF52832, is the micro-controller used in this device for its Bluetooth Low Energy, low power consumption and its memory (which contains Flash and RAM for both the code and data storage). Although it has

Digital signal processing (DSP) instructions, it is considered a relatively high speed MCU [53]. This microprocessor can be programmed using C/C++. This MCU is equipped with:

- Direct Memory Access (DMA) channels.
- a 12bit Analogue to Digital Converter (ADC) with eight channels
- independent timers.
- communication ports which can implement Universal Asynchronous Receiver Transmitter (UART)
- Serial Peripheral Interface (SPI) or Inter-Integrated Circuit

2.2.2 Piezoelectric Sensors

As the principle operation is premised on sensing pressure from fetal movements, the external part of the device - which houses the sensors - plays an essential role in this process. This 20mm diameter ceramic piezoelectric (CEB-20D64) is a low-cost sensor. This sensor happens to be light (Max 1.5g) and is made of brass, which is not harmful for the skin. Also, not having any sharp edges makes it comfortable to use[54]. The Babykick device belt with all its sensors was not tested in different temperatures but all its specifications measured at 5 to 35 celsius, humidity at 45 to 85 percentage, under 86 to 106kPa pressure based on its data sheet. Some of the other features are listed below, which contributed to selecting this sensor for the device:

- The dimensions of this round-shape sensor is 20 x 20 x 0.43 mm.
- It is connected with individual wires.
- It is not washable, but it will be cleaned with an alcohol wipe for every single subject.

2.2.3 Bluetooth Module

The design of every BL652 Series module is to add single-mode Bluetooth Low Energy (BLE) v5.0 to the devices that are small and portable. Due to its low-power consumption, users do not need to worry about the battery very often. This compact BL652

hardware gives the developers the opportunity to complete an embedded application via its Inter-Integrated Circuit, Serial Peripheral Interface, Universal asynchronous receiver-transmitter, Analog-to-digital converter or General Purpose Input Output interfaces. The ultra-low power consumption provides an outstanding wireless range. Powered by 4 dbm transmission, Nordic chipset technology enables bl652 modules to have both power efficiency and long-range wireless reach[55]. On the other hand, apart from the components, the developer needs to develop their device; BL652 requires no external components, which makes integration on prototype PCBs easy. Sustainable data rates of 100 kbps and 400 kbps are supported at transmitting/receiving powers. To make the device safe to try, it is better to send all the data after the data accusation with the help of Bluetooth low energy. All the mentioned features make it easy to choose this component regarding the purpose of the device. Figure 2.5 is a picture of the Bluetooth Module used in the Baby Kick device.

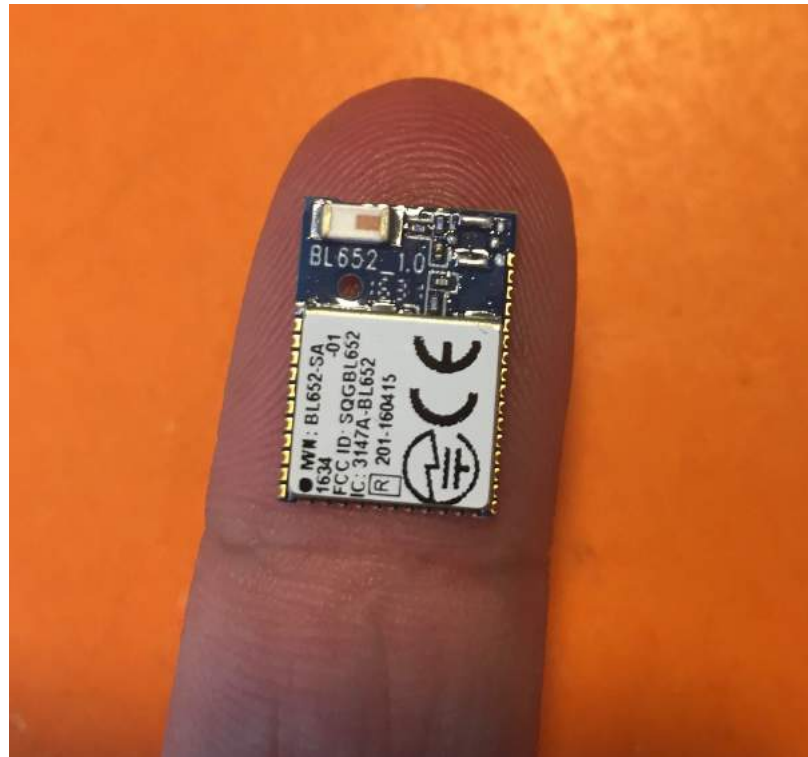


Figure 2.5: The Bluetooth Low Energy Component(BL652)

2.2.4 Power Requirements

This device has the ability to be charged with both USB and Li-ion battery. Power supply provided by a low noise 3.3V linear regulator as a digital supply and a 1.5V linear regulator as an analog voltage reference. The board is powered by a rechargeable battery, which guarantees up to 24 hours of battery life. A button controls switching the entire device on and off. This power management itself has four different parts inside to control the battery [53]. Figure 2.6 shows the parts.

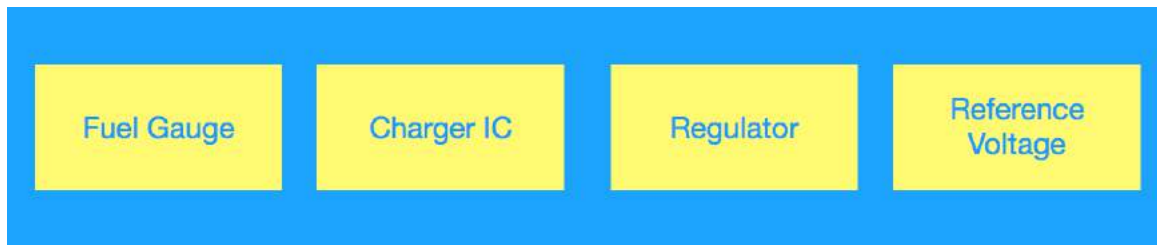


Figure 2.6: The package of Power Management

- Fuel Gauge: It is an instrument used to indicate the amount of battery that the device has.
- Charger IC: A battery charger forces an electric current through rechargeable battery to put energy into it. If the input charge is available, it will check the current situation of the device and decide to save the current or use it as a charge for the instant status of the device.
- Linear Regulator: It is a system used to maintain a steady voltage. This part has to provide the charge for MCU and other parts of the device.
- Ref Voltage: providing the reference voltage of 1.5v for analog.

2.2.5 Storage

Data plays an important role in all research, so the ability to store the data in every phase can give the device this chance to be comparable and usable. Once connected with smartphones, the recorded signals will be stored on the receiver (phone or the device itself) and, if needed, will be transmitted to the hospital. In the code, we have two parts: Fat file system (FatFs) and SAADC. FatFs gives the opportunity for Windows to save the data from the SD card(Secure Digital Card). This system helps

the computer to save the data, but the connection between MCU and SD card is with the serial peripheral interface. SPI is used for communicating with one or more peripheral devices quickly over short distances. This SPI has the clock, SCK, MISO, MOSI and ground. SAADC is the part to get the sample from ADC with adjusting the timer of the microcontroller. Every 50ms timer calls ADC to get the samples, and when the results finish call back, ADC function will be enabled. Due to this, features using SD card are essential[53].

2.3 Belt and Sensor Locations

In several studies performed in the area of fetal movements, the central part of the stomach was identified as a standard place to measure fetal movement, including heart rate [37, 49]. Not only did we pay attention to the most important area for capturing the data related to the fetus, we also located four other sensors further from the central part of stomach to capture a larger amount of the fetal movements. During master work, three generations of belts were developed. As mentioned, for all of them, the way the device makes the measurement is by eight piezoelectric sensors. Also, all generations of belts were completely designed and developed. Following is the explanation of both the dimensions and improvement of performance.

First generation of the belt

In the first generation, the sensors are located in a fabric textile in close contact with the pregnant woman's abdomen in two separate rows with four individual sensors equidistant from one another. On the other hand, the comfort of the sensors and their thickness make it easy to use for the pregnant women and do not impede a person's activities of daily living (for future usage of the device). The pregnancy belt is made of a soft texture with electrodes that are sewed into it. The flexible feature of the pregnancy belt, can guarantee efficient contact between the skin and the piezoelectric sensors without the usage of any gel[49, 37, 36, 50]. The belt that is used for the first generation is available at general stores for mothers-to-be to use in order to support their hips and lower backs. The following figure 2.7 indicates the first generation of the belt.



Figure 2.7: First generation of the belt

Second generation of the belt

The reason behind changing the first design is listed below.

- Removing the tape can be painful, especially for more sensitive skin.
- The placement of the sensors could be changed during the placement when another person is not available to help. The subject cannot be completely sure about the sensors' placements. The possibility of user doubt makes it not valuable enough for the consideration.
- The wires are not hidden, which can cause disconnection with the sudden movement.

To eliminate the weaknesses of the first design, the second generation belt was developed.

In the second generation, the fundamental novelty of the design is the process of injection molding for designing parts for holding the sensors. All the wires are hidden behind the design, which provides a cleaner look with more appeal for users.

The feature of molding is to empower engineers in a way to reproduce their product without any problems, especially on a large scale. Although every human being is surrounded by lots of plastic parts produced by injection molding, people are not familiar with this art base process. This design requires huge concentration to produce high-quality parts, and every mistake distinguishes the great from good product. The two-part silicone mold supports the shape of the design. For making Kick device custom two-part molded component, the following steps are required. The first step for making a silicon mold, which is also the essential step, is to have a part called the master, and provides the scaffold to take a mold from. Although making a master can be done in different ways, the quality of it can make its trace on the actual part using for molding. All the details are captured by the master, which is used for reproduction object[56]. Following are the list of methods for making the master.

- Clays
- 3D prints
- Paints

In the Kick device, a 3D printed prototype was printed first. The 3D print object was designed and printed by Fusion 360 and Original PRUSA I3 MK3S, respectively. Thermoplastic Polyurethane (TPU material) was the material that was used to 3d print the belt. Fusion 360 is a free software that works on both Mac and PC with a united platform. This software has multiple tools to accompany the designer from designing from scratch to create the finished product. Prusa 3D printer is a bridge for designing an object to an actual solid. Although most of the 3D printers have the same setup routines, they are divided from best to worst based on the accuracy of their final result. As Prusa is one of the most used printer, it was chosen to print the part of the belt.

Returning to the molding process, the next step after having the printed object is to figure out which side to mold first. Although the belt part is pretty flat and symmetric, it is better to start with the flat parts. The following step is to mount the master to a flat board. For securing the master to the board, the designer should have multiple options such as double-sided tape, super glue and modeling clay. In order to have the best outcome, it is most optimal to have a mixture of all the secure options.

The next step is to make the alignment keys. This step is to ensure the proper alignment of the two sides of the molds. For this reason, it is good to use some materials that can be easily found around a house, such as unused geometric pieces of plastics, bolts or screws. This method produces a lock system before the subsequent steps. Making a box for pouring the right amount of silicone around the master is necessary. This box is responsible for holding the silicone poured until it cures. Another material has to be used to make the surface clean and flat, and choosing this material is based on the silicone. In the Baby Kick belt, styrene was used to have a cleaner surface and reduce the probability of any mistakes. The master should be covered in the box, and so the estimation of the size is required. The more precise the measurement, the less silicon is poured. Again securing the box is the key in this step. It is better to use hot glue to bond the box to the surface of the board. As the process is also used in different fields, including The Film Industry, there are lots of types of silicone. In the Kick belt, Mold StarTM 15 SLOW was used for its mixture of 1A:1B by volume. The low viscosity of this product makes it easy to pour, and after curing, it still has its flexibility, which is a good candidate for our cause. Now the master is attached to a flat base in the box ready for the mixture of the silicone to be poured in. After mixing the right amount of silicon, the silicone should be poured slowly in one spot to flow slowly all over the master. The filling should be continued until it is level with the top of the box. After spending the exact amount of time mentioned on the instruction of the silicon box, the flat base that the belt is attached to should be removed gently along with the alignments. At this point, the first half of the mold is ready. Before pouring the other half of the mold, it is better to use the styrene spray again to release both sides of the silicone from each other in the last step.

The placements of acrylic rods is required in this step, which have the same diameter as plastic straws. After adjusting the firmed outer look, from the mixing silicone as it mentioned before will be repeated again. The result silicon is poured around the acrylic rods. After silicone is curing the the acrylic rods will be removed. When it is in this stage, it means the work is nearly done. The boxes and the master should be removed. Once again the molds from two parts should be attached and ready to use as an individual while the sensors are located in the surface of one of the sides. One way to understand if the mold is going through all is to see if it rises up through the plastic straws that are placed instead of the acrylic rods. Last step is to wait for the mold to be cured and removed from the frame mold[56]. Figure 2.8

is the second generation of the belt. This design is more comfortable than the other.

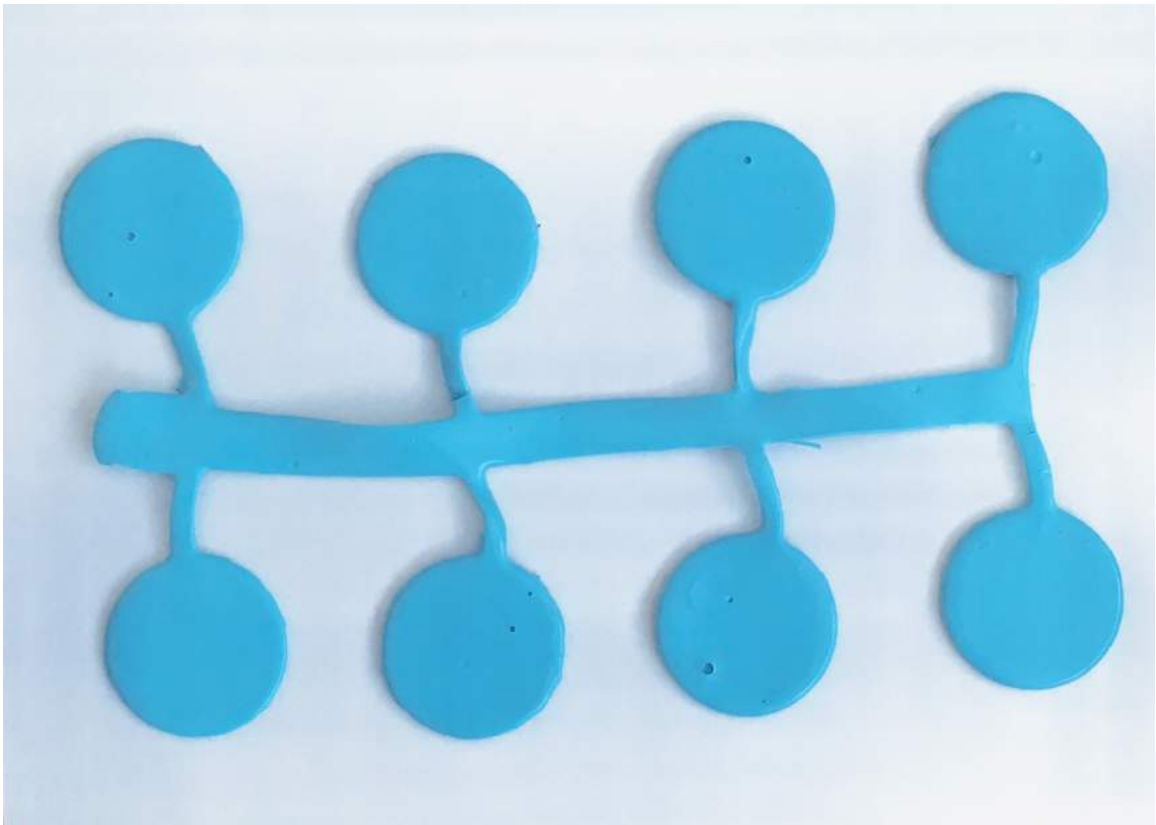


Figure 2.8: Second generation of the belt

The sensor wires are not crossed at any joints, which cause connectivity problems and cause discomfort for the woman. Also, the belt is a little bit heavy, which is not good for long term usage.

Although this design is better than the first one, in regards to the appearance and comfort, it has its own flaws.

Last generation of the belt

The reason behind not developing the second belt is that despite the better design, it is still heavy, which may be a problem for continuous monitoring. Also, the primary goal of the device is to be cheap, and we had to come up with new ideas to make it as cheap as possible. Thanks to the idea of pre-placement of the sensors in the second design, the concern of changing sensors placement was resolved. The last generation was designed in the Fusion 360 in the exact shape of the first belt with two rows of four sensors. All the wires are hidden in the routes between sensors. After examining

several designs and eliminating the problems, the final product is the one shown below in figure 2.9. The height of the design does not exceed two millimeters; this minimizes the required materials and ends up producing the most affordable device. It has its own flexibility and is lightweight for expectant mothers already bearing the weight of carrying a fetus. The hardware creates connectivity to acquire and transfer physiological signals and Bluetooth technology; this helps the additional belt wires. This lightweight belt also gives the subject good support for her back which makes it more desirable. She does not need to worry about the cleanliness of the belt since they are machine washable ones. The sensors receive both the movement of the woman's conscious and unconscious body movements. The piezo-sensitive belt will provide objective and accurate measures of the amplitude of fetal movements. Figure 2.9 is the picture of the third, and final, version of the belt.

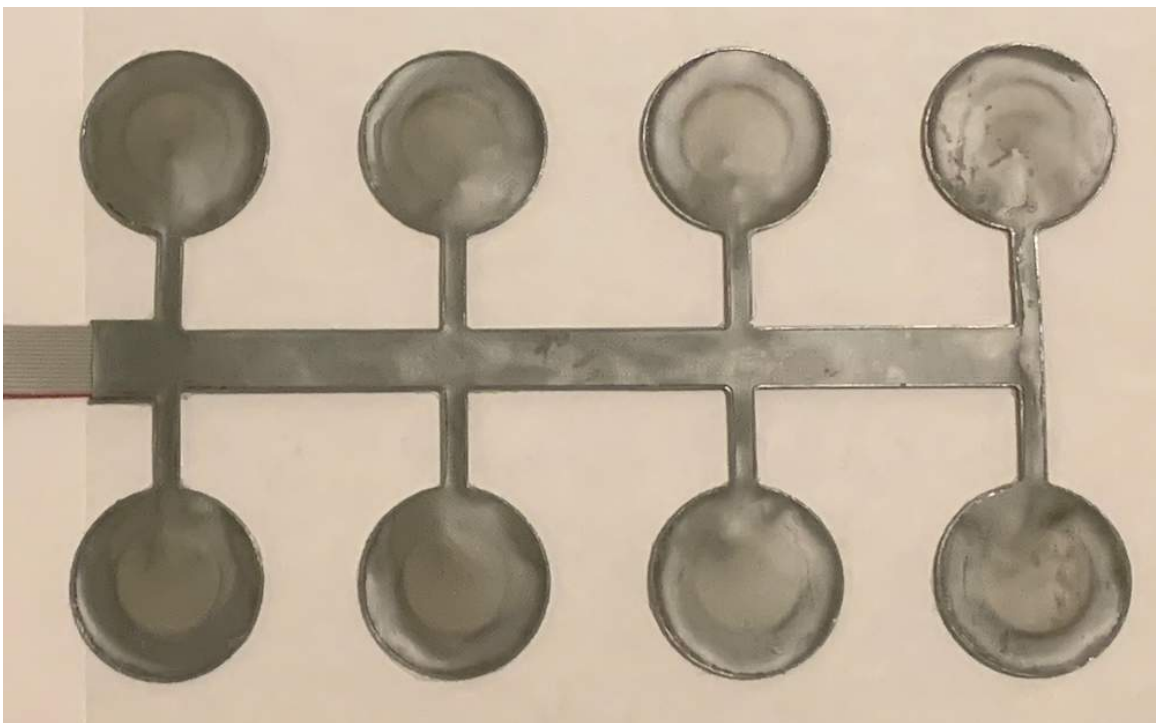


Figure 2.9: Last generation of the belt

2.4 Analog Board Design

The signal of interest, i.e. fetal movement, has very low amplitude; capturing the signal analog pre-processing is extremely essential. The circuit for the analog section,

which is shown in figure 2.10, is a 12-bit data acquisition system as a result of the usage of the device specific micro-controller. The input of the system is the signals from piezoelectric sensors with a 3.3 V supply. This circuit provides the best framework and connectivity to have an accurate, low-cost, reliable design.

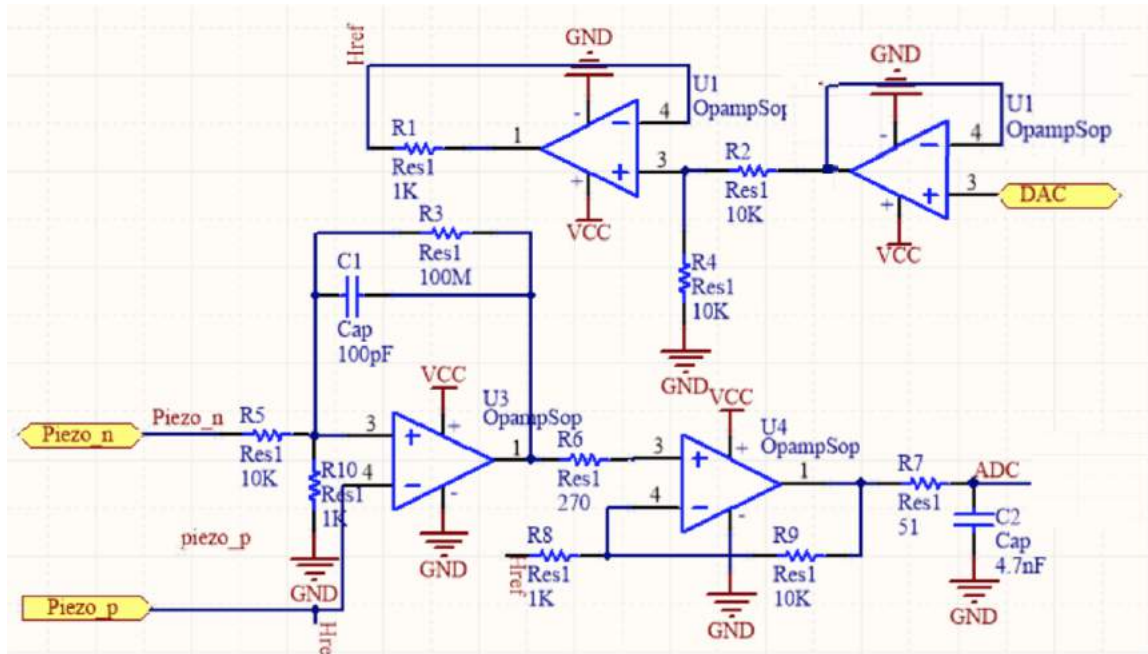


Figure 2.10: Connections of Analog part of the Babykick device

2.4.1 Circuit Description

The circuit of the analog part consists of an input signal conditioning stage, which makes it unique for data recording and transmission. This stage is characterized by an analog pre-processing stage, which consists of filters and amplification of an ADC stage. The current input signal is converted to a voltage by the charge-to-voltage converter, and amplified by a non-inverting amplifier, which consists of an op-amp and resistors as is shown in figure 2.12. The first stage of the circuit is an optional voltage divider; this implementation is to easily change the sensor. If the piezoelectric sensor produces a higher voltage range, the amount of resistors can be changed in order to control the result. The Baby Kick device data acquisition requires to be given voltage as an input, and as sensors output is current, an stage for converting the charge to voltage is needed.

Charge-to-voltage converter circuit

To decide the best circuit for converting the current to voltage was tested in two ways: first with Trans-impedance Amplifier and then with the charge amplifier. Both of these circuits are similar to each other but in the Babykick device the charge amplifier is the best option.

- The Trans-impedance Amplifier: The production of this circuit is an output voltage from the charge that is generated by the piezoelectric sensor. The circuit Trans-impedance Amplifier has an op-amp, a capacitor and a resistor. This converter is also known as the current control voltage source since by injecting an amount of current, the output voltage based on that current is certain. There are two ways to convert current to voltage:
 - Passive current-to-voltage: this is achieved by adding a resistor to the current source. The disadvantage of this solution is the change of voltage because of the load resistance. Figure 2.11 illustrates a Passive Current-to-Voltage Converter.

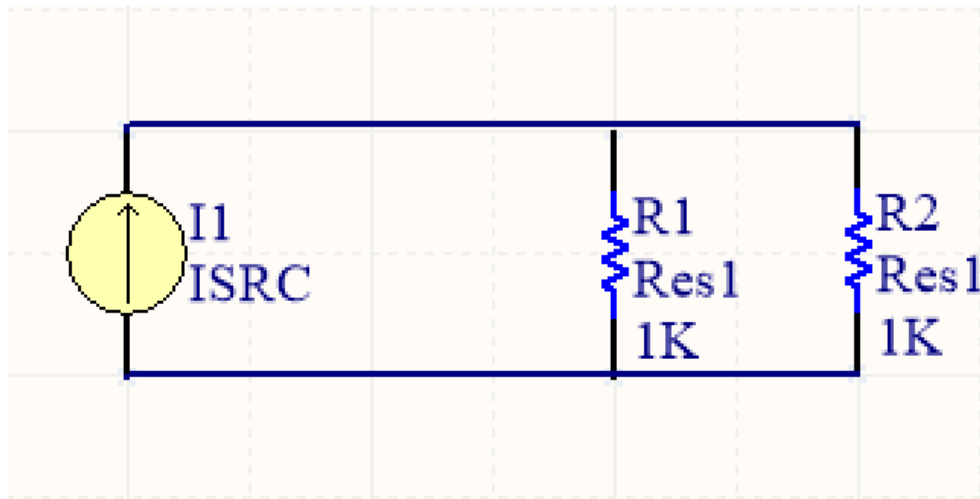


Figure 2.11: Passive current-to-voltage

- Active current-to-voltage: The limitation of the passive current-to-voltage converter can be avoided by using the active pathway. The current is connected to the inverting terminal (input) of the op-amp. This way, the current does not flow to the op-amp and the current terminals. The input current to the op-amp is equal to the current flows through the resistor.

- The charge amplifier: the charge amplifier is an integrator with a very high input insulation resistance. Installation of the resistance functionality is to prevent the waist of small amount that the piezoelectric sensor generates. The difference between these two circuits is that the trans-impedance amplifier has to multiply the current coming from the sensor by the resistance, which leads to an increase the amplitude and also converts the current into a voltage, but the output of the charge amplifier is proportional, and it is related to the accumulation of current over time. As the result, the charge amplifier is the best option for the Babykick device. The gain of the

Non-Inverting amplifier circuit

Figure 2.12 is the second stage that is used in the analog circuit. The simplest reason behind using this circuit is to amplify the output. In the Babykick analog design, the current is applied to the negative terminal, so the output signal will be 180 degrees out of phase of the input signal. The amplitude of the input and output of the signal is based on the amount of resistors applied (voltage gain). The two resistors attached to the inverting terminal control the level of feedback.

Buffer (Emitter Follower)

The buffer is an amplifier that passes signals along, which means the output is the same as the input inserted. The symbol for the buffer in digital logic is a triangle which has two input and output. Figure 2.13 shows the basic circuit of what is known as a buffer. The buffered and attenuated voltage reference from a point called DAC in the circute which is generated an offset of 1.5 V for conditioning the signal from the sensor. Both the buffer and the following circuit provide the half of the voltage comes from the DAC point, to be used in the HREF parts. The Op-amps are one quad TSZ124IQ4T. The TSZ124IQ4T is chosen for this application because of its high accuracy without calibration, low noise, and low offset voltage. Signals can be sampled up to 200Hz. Limiting the sample rate is because of the constraints imposed by the Bluetooth Low Energy bandwidth.

2.4.2 Board Layout

The Babykick device has a two-layer PCB; the second layer was determined for ground. All eight analog circuits are located in one side of the board, which takes the

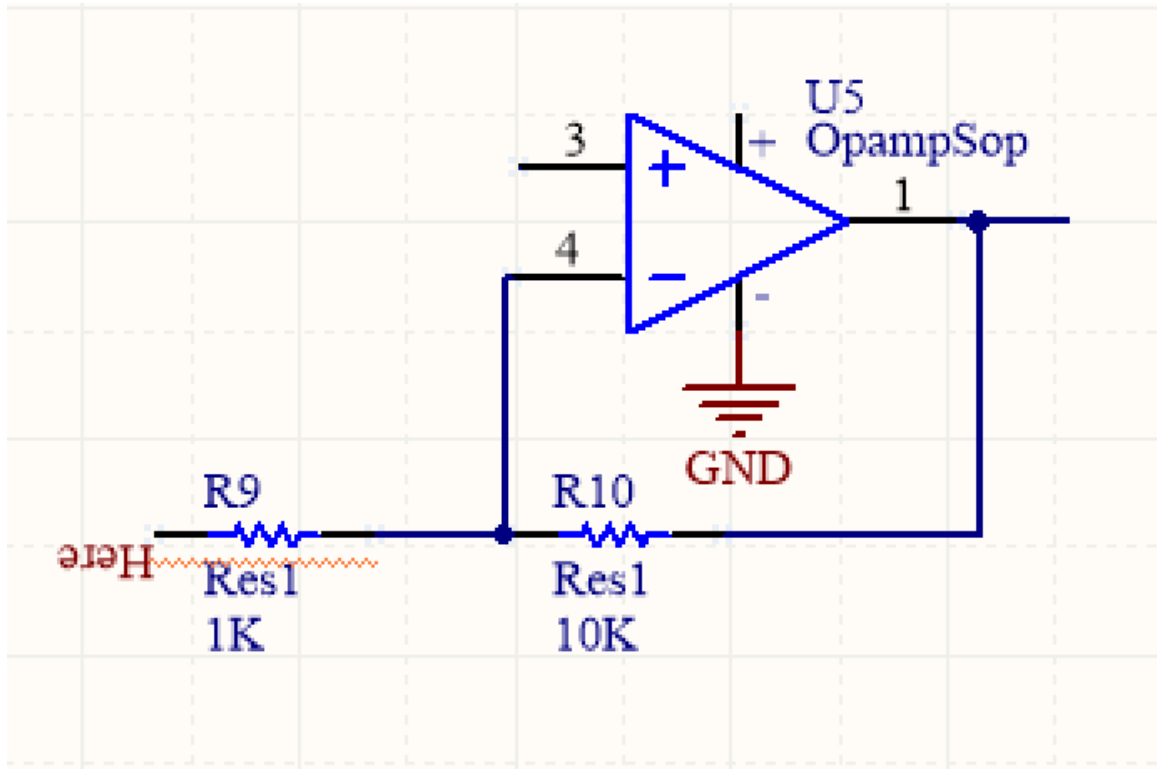


Figure 2.12: Non-inverting amplifier

signals from piezoelectric sensors attached to the board. All the steps were achieved by following specific rules of Printed Circuit Board design. The dimension of the board is 39.605mm*38mm. Figure 2.14 shows the size of the device. Figure 2.15 shows the boards obtained after PCB design, printing and components soldering.

2.5 Digital Board

The digital board of Baby Kick device consists of the micro SD memory card and Bluetooth low energy (microcontroller). The micro SD memory card saves data, and will be described further in the following sections.

2.5.1 Micro SD memory cards

SD cards have two main operating modes, one is using the SD mode commands and the other is Serial Peripheral Interface(SPI). Serial Peripheral Interface is used in the Baby Kick device.

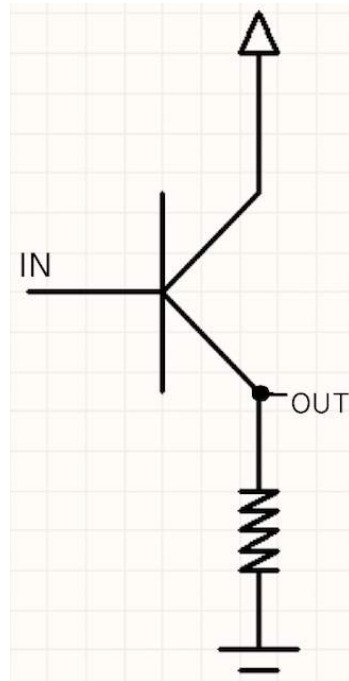


Figure 2.13: Buffer basic circuit

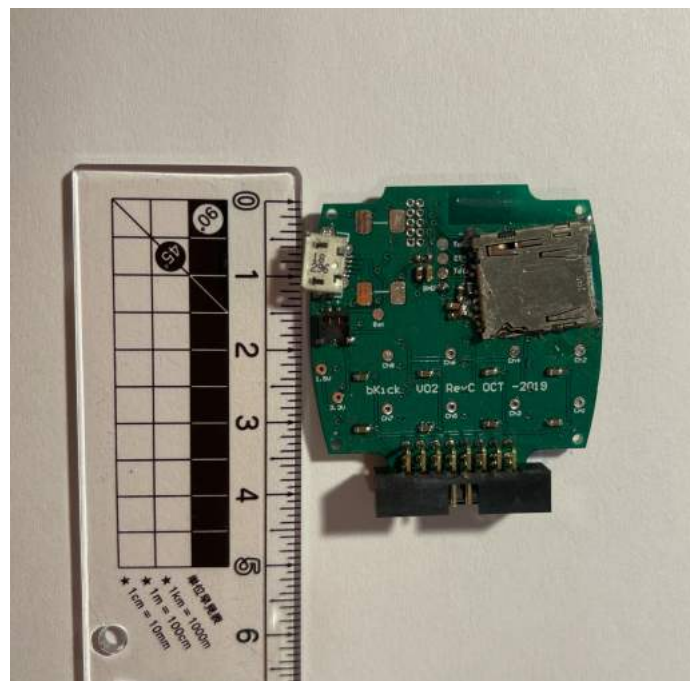


Figure 2.14: Size of the device

Serial Peripheral Interface(SPI)

Serial Peripheral Interface(SPI) is used as a short-distance communication. This mode runs based on master/slave setup. The microcontroller (master) communicates

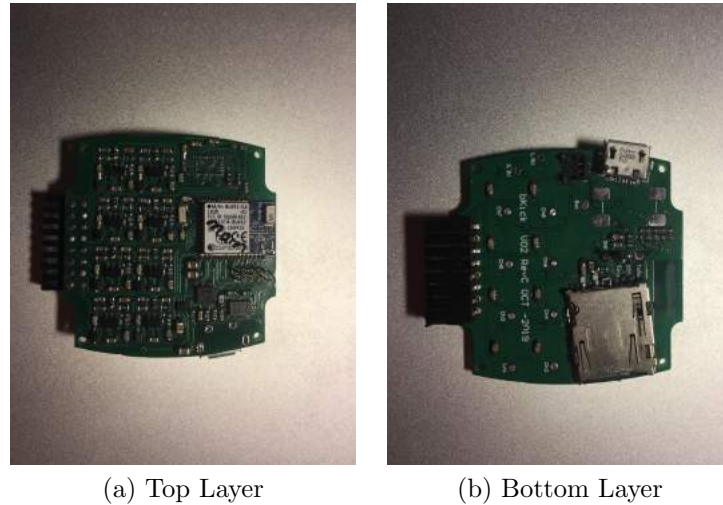


Figure 2.15: The board obtained after PCB design, printing and components soldering

with the SD card (the slave) with four signal lines, Chip select (CS), Serial Clock (SCLK), MISO (Master-In Slave-Out) and Master-Out Slave-In (MOSI). The communication starts with the master choosing the slave specific CS, and then as the clock changes its edge from low to high, the receiving device searches for the data[57]. The advantages of SPI over other types of bus, such as Inter-IC (I2C) is its simplicity and generality. Also, as the rate of transmission in SPI is greater than the others, it is used for Analog to Digital Converter (ADC) and Digital-to-Analog Converter (DAC) communication[57]. As mentioned before, SPI peripheral is used to communicate with the SD card but it also needs a software for data communication which is called file system driver (FAT)[58]. This FatFs module can be used for the specific SPI that is used in Babykick with just a few additional porting. The data on an SD card is organized as a file system. This organization is divided the memory into two parts. One part is allocated to how the data arrange and the remaining is used for storing the content[58].

2.5.2 Bluetooth Low Energy(BLE)

Bluetooth Low Energy (BLE) is a short-range, wireless technology that can talk to any modern platform concerning sending and receiving data. The first version was launched as Bluetooth 1.0, and after adopting some enhancement, it is now known as the Bluetooth 4.0 core specification [59, 60]. The most concern is for the coordination of connected devices around, which is served by The Bluetooth Special Interest Group

(SIG). This group is a universal community to develop the platform and structure for Bluetooth technologies. This way, developers should follow these specific roles which can make them sure that their devices will attach to the others easily [61].

Motivation of Bluetooth Low Energy

The idea of BLE came from the features that classic Bluetooth lacks. Despite the overlaps between the two technologies, they are used for different outcomes. The first option that classic Bluetooth cannot cover is to keep the battery from dying for extended periods. Developers used Bluetooth for transmitting a lot of data, which can consume battery life quickly. Using BLE provides this opportunity to developers to design devices to run on battery for a longer amount of time. This feature makes BLE a low-power version of the classic one. Portability is another excellent feature that accompanies devices that are powered by small batteries. These devices have witnessed the highest rate of growth due to consumer attraction and convenience amongst all wireless markets. One such example is the smartphone; others include medical devices, watches and remote controllers. The consequence of having BLE in the development is to minimize the cost of developing. Along with other features, connecting to the internet with more privacy and freedom over the data is another great feature that BLE can add to the device. This wireless technology is the best alternative for WiFi regarding the definition of security. The user has this option that rather or not receives data [62].

Key features of BLE

- **Interoperability:** The principal target is to implement a significant connection between the devices. Based on the variation of the methods and devices, it is an important fact to have excellent connectivities for devices that are from different manufacturers. For testing the connections, the Bluetooth SIG builds a structure and interoperability testing process[62, 60].
- **Prevention of noise:** This point can play a vital role when reliability matters. The transition of data should be valid even in the presence of other devices. This case, the developer designs devices that provides a better communication experience for the costumers[62, 60]..
- **Pairing:** Wireless devices need to be paired before they can make any connection

and share the data. The pairing has three phases which are listing below[62, 60]:

- In the first phase, two devices that are wanted to be connected, report their input and output capabilities. From this announcement, the determination of the next phase will be easy.
 - The second phase is to generate a short-term key (STK). STK is used in the next phase for the security of key distribution. The pairing devices first define the Temporary Key (TK) by using the out-of-band (OOB) method, Passkey Entry method or Just works.
 - The third Phase is the transportation of specific keys between master and slave. These keys are the Long Term Key (LTK), the Connection Signature Resolving Key (CSRK) and the Identity Resolving Key (IRK).
- Security: Data is confidential, and privacy is the most important concern in BLE devices. In the market, consumers need to be sure about the security of their data. The Bluetooth Core Specification for ensuring the protection of the consumer data provides two security modes called LE Security Mode 1 and LE Security Mode 2. Along with the modes, the privacy feature comes along to have a secure connection. Since BLE has this ability to change the Bluetooth device address on a frequent basis, trusted devices can understand the difference between the right and fake addresses. In this way, the device can use the address and change it frequently to prevent an unreliable way of connection[62, 60].
 - Signed Data: This means that if the communication channel is not encrypted, the device could still be sure to transmit the data securely. This can be done by signing the data with a Connection Signature Resolving Key (CSRK)[62, 60].

Architecture of Bluetooth Low Energy

Figure 2.16 shows the whole picture of the layers of Bluetooth Low Energy.

Generic Access Profile (GAP)

This layer's responsibility is to connect and advertise in the Bluetooth low energy devices. In other words, Bluetooth low energy devices can use GAP to make two devices communicate with each other. There are two ways that a device can join a

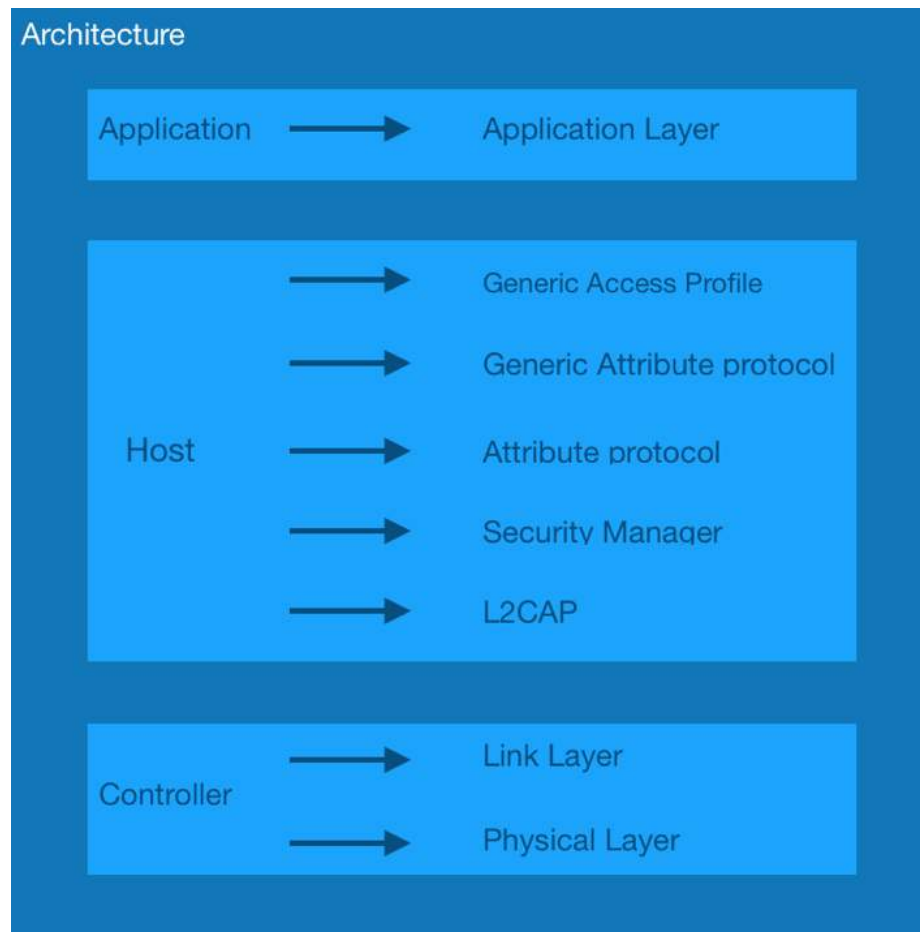


Figure 2.16: Architecture of Bluetooth Low Energy

BLE network and for both ways of connection, two sides are needed for sending and receiving the data[61].

- **Broadcaster/Observer:** Since devices do not have to explicitly connect to implement this role, this connection is known as the less-connection connectivity. Broadcaster and observer play the role here. One of the devices broadcast the package of advertisement, and the observer listens to the transmitted data.
- **Peripheral/Central:** This way of connectivity is more commonly used compared to the broadcasting method. Central and peripheral are the central concepts of transferring data in this way of connection. Peripheral shows its presence by sending advertising, and central makes the connection happen if it is interested in that kind of advertising package. Heart rate monitoring and tablets are examples of peripheral and central, respectively.

Along with the connection between one another, GAP also defines some procedures to make a secure path for transmitting data.

Generic Attribute Profile (GATT)

Devices with BLE operate as master and slave protocol based on how these devices are programmed. GATT comes along when the connection between central and peripheral has already established by GAP. GATT describes the transformation of data with the usage of characteristics and services[60]

Generic Attribute Profile rules

After the connection happens, the most important feature to remember is the uniqueness of the connections. It means that as long as a peripheral is connected to the central of the devices, other peripherals can not connect to it. This role is not followed by central devices since if it is needed, the central devices should connect to multiple peripherals to see what the peripherals have to offer. As long as peripherals connected to the central, other peripherals are no longer able to see the connection, or there is no way for other peripherals to link to its figure 2.17. This way, the security of the data will be guaranteed.

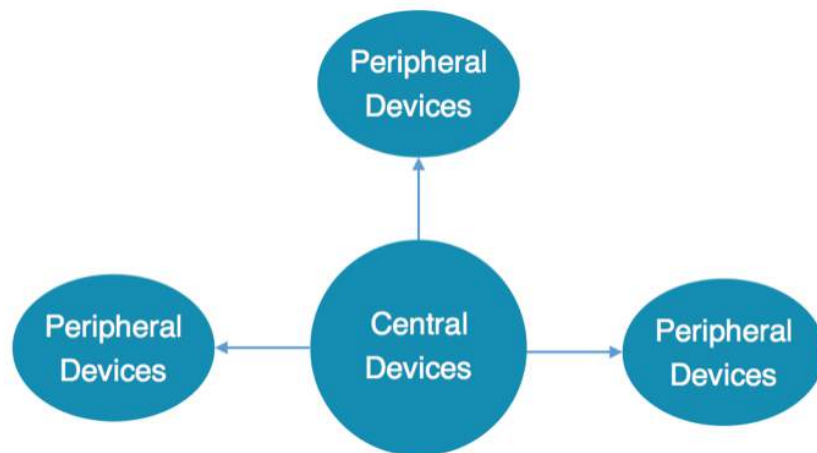


Figure 2.17: Rules of GATT

Generic Attribute Profile transactions

To understand GATT transactions, we need to be familiar with two major parts, Attribute Protocol (ATT) and peripheral/client relation which is mentioned before. The Attribute Protocol (ATT) is used by GATT as a mechanism to transport data and save related data in 16-bit IDs to prevent disorganization. When the connection is made, peripheral duty is to send a suggestion to central for interval connection. On the other hand, central needs to reconnect every connection for exploring new data. Sending suggestion from peripheral cannot guarantee the connection since the central devices are the ones which give priority to connect to different peripherals. As the figure, 2.18 shows, the general structure of GATT consists of the profile, services and characteristics. The profile is located on the top of the list, and it is composed of some services to perform GATT duties. The characteristic which is considered as the lowest part of the protocol helps with splitting the services' tasks to fulfill the schedule. A universally unique identifier (UUID) is a number which GATT is used for its uniqueness.

Universally Unique Identifier (UUID)

Universally unique identifier (UUID) makes the Characteristic individual. Each Characteristic is distinguished by a specific 16 or 128 bit. These IDs, which are known as the attribute, are broadcasted over the air. The short type (16-bit) is power and memory saving[60].

Project phases for implementing BLE

Bluetooth is anticipated to be utilized in the device. This implementation has two levels. One is to make an app and connect the user to the phone (Programming of the App), and the other is the connection of the phone with the hardware of the device (Recoding of the Microcontroller).

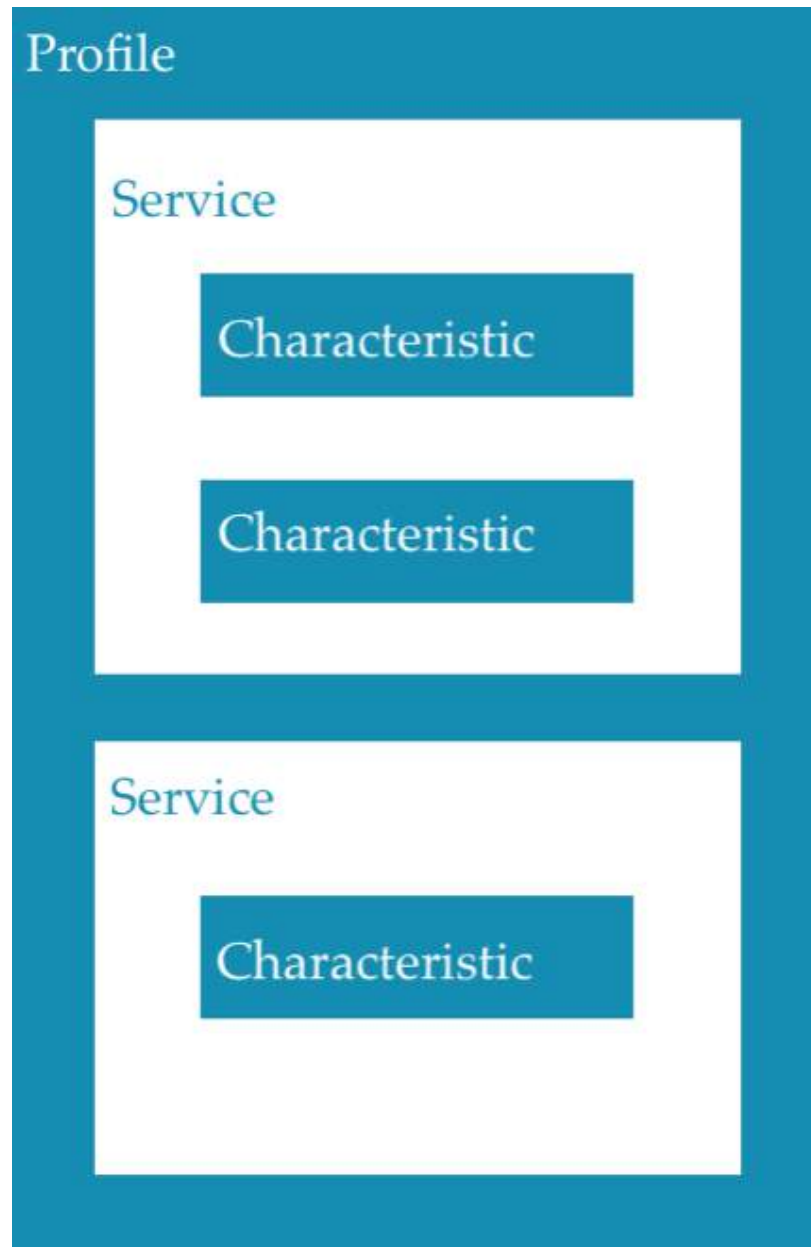


Figure 2.18: GATT Transactions

Chapter 3

The Software

3.1 Overview

The technological aspects of the device were the focus of previous chapters. In this chapter, the focus turns to the proprietary device, i.e. running Android and iPhone Operating System (iOS) development, style and the look of the software - i.e. where the human and computer interaction occur.

3.2 Project Requirements

In order to solve a problem, a need should be identified to address the problem. This matter can be thoroughly understood by experiencing the problems as an individual or group of people in need. Validation of the suggestions is key to provide insights on how to implement a better and more functional system. Weighing all the mentioned alternatives and prioritizing them based on the stage of the project is another challenging matter which needs to be accurately considered[63]. The development of this app began as an academic project and will hopefully expand to a fully functioning app able to serve the intended goals of the device in the real world. The minimum features in the application must enable the phone/tablet to perform in a way that enables a user to have a set of capabilities; these are listed bellow. At a minimum, the system must be able to detect the fetal movements. In this study, since the only way to check the result is through the woman's perception, the application should be able to save her subjective recordings for further correlation. There are two applications developed during the study. One for recruiting data and the other, which will

need some modifications, will be ready for further steps when the Baby Kick device is ready to be sent home. Bellow, there are some suggestions to make the application ready to be sent at home.

- Each woman needs to get with more than one set of data, so the application should be able to add information without any problems.
- The appearance of the application and its functionality can be changed in order to serve the user better. For example, if the app can remain running while the user rotates the phone or tablet, it is easier for the user to check a wider range of the data on the graph.
- For the desired functionality, it is better to add a list of emergency contacts in case the fetal movements do not match with the minimum standard of movements. The subject should also be given enough time to call in the event of a false alarm before the application sends the alarm.
- The other ideal function is to send a message to the doctor for quick advice in case of an emergency.

3.2.1 Selecting a Platform

In many cases, computers have been superseded by smartphones, which are more readily available and compact; handheld devices can be found in the majority of hands nowadays. Portability, price, and broad functionality further impact the shift from computers to mobile devices - possibly even contributing the making computers obsolete [64]. Despite the widespread distribution of mobile phones, specialists and professionals continue to believe in the utilization of desktop computers[64, 65]. As mobile technology is getting trendier, more powerful and continuously evolving, developers have shifted their work toward mobile development. Application developers are driven to endeavour to design and build new applications for mobile phone users to address their routine necessities[64]. Developing an application is one of the most important focuses of many companies as they want to make their product user friendlier[65, 64]. Based on how many people use their phones and also the importance of keeping the track of the data, it was decided to design an application for Baby Kick. The strong growth in the smartphone industry narrows researchers' options for developing an application for the convenience of the user[65]. In the case of

Baby Kick, the application was designed to be helpful for women seeking a sense of control and confidence[65]. They can start and stop the data recording with a touch of a button on the application, see their fetuses' movements easily, and the location of the movements. As it is becoming hard to ignore the role of smartphones in humans' lives, it is better to put the focus on the types of available smartphones. There are some mobile platforms of interest in the global forum such as iOS, Android and also platforms like Symbian (by Nokia) and Blackberry (by RIM), which have historically had large market shares, but recently these latter two have been superseded by iOS and Android[66]. As IOS AND ANDROID are used by a lot of people and also working with them is easier for users, there are the target platforms in the Baby Kick device.

3.2.2 User Experience

The design of the app should not only be simple and clean, but it should also be user friendly. This means the fonts, size, and other small details such as colour should be readable and constant. The overall style of buttons, check boxes or toggles with the same function have to be similar in terms of color, font and other features in order to help the user find a button and/or text easily. Consistent colour coding across the application will lend itself to easier accessibility and usability. Accessibility is another feature that makes the app more user friendly. This element refers to the importance of user navigation when confused and trying to find important information on pages of the application that are not the main page[63]. To avoid the confusion of the user, it is recommended to place the main features in the first pages[63]. In summary, the overall look should be pleasant and friendly enough for users (in our case, soon-to-be mothers) to feel comfortable enough to trust the application during its use. The longevity (battery life) is a requirement for most projects related to the performance of sensors and circuits. Battery life either for the device or the phone, is important. The battery will allow the woman to use the device for extended periods of time without charging problems during continuous monitoring. Finally, attention to the minor details that the developer has missed while developing code for the application is of great importance. Methodically going through every single detail ensures the success of the application in every aspect. The minor details may not seem to be significant at first glance, but the first impression plays a role in a successful release.

3.3 Development Environment Background (Android Operating System)

3.3.1 Software Development requirements

This section describes how to create Android applications from scratch. The development environment for developing applications, the programming language and other requirements.

Java

Java is an object-oriented language; this means that the focus of this language is on data. Objects and classes play an important role in this language to characterize the data. Classes are the characteristics that an object could have. The advantage of using object-oriented languages is the ability to write the program based on what the designer already has; they do not need to build everything from scratch in order to change something in their application. The next step is to write and test the program. In order to achieve this goal, developers need to have three tools[67, 68, 69].

- **Compiler or Java Development Kit:** The duty of compilers is to take a code (in this case, Java) and turn it into something understandable for computers.
- **Java Virtual Machine (JVM):** Running the codes on every platform is JVM's role. To prevent chaos from conflicting operating systems, there is Java byte-code, which is written by compilers. Then all data will be given to Java Virtual Machine (JVM). The next step is to distribute the result to systems by Java Virtual Machine. Figure 3.1 can make the explanations more understandable.
- **Integrated Development Environment (IDE):** IDE - such as Android Studio - is for managing the code (in this case, Java), and also gives the developer the chance to debug or run the code. In this way, changes will be more easily implemented and there is no need to open different windows to compile code as it was before. This well-organized environment makes the path for writing codes easier for developers. Android Software Development Kit (SDK) is another important thing that has tools and documents for developers to make their job easier and can be downloaded along with IDE.

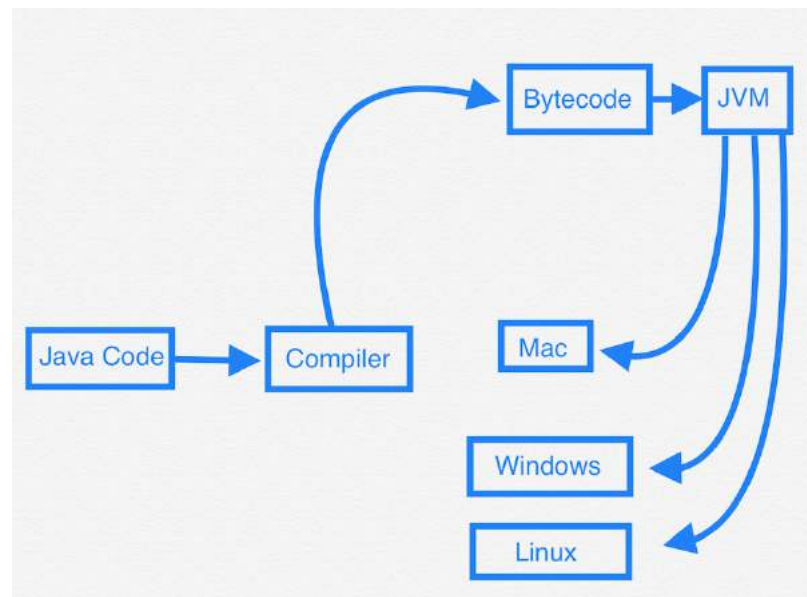


Figure 3.1: The road of the source code to different operating systems

Android Studio

Integrated development environment (IDE) is needed for developers to write the codes in. There are several integrated development environments to assist developers in writing their codes. Android Studio is one such tool that is developed by Google and also suitable for Android applications. This environment is offered for free and is for writing and running the code[70]. The features that are accompanied with this IDE include:

- Running and testing codes in simulators or an actual device
- Debugging the codes
- Tools for making the user interface more user friendly
- Giving the ability to make a local app or the one that can be used by others

Figure 3.2 illustrates an overview of the Android Studio integrated development environment[67, 64, 69]. The other important subject is the software development kit (SDK). This SDK will be installed during the Android Studio installation. SDK is a selection of tools that are vital for Android development; it can be used directly by the IDE or can be helpful in developing some tasks.

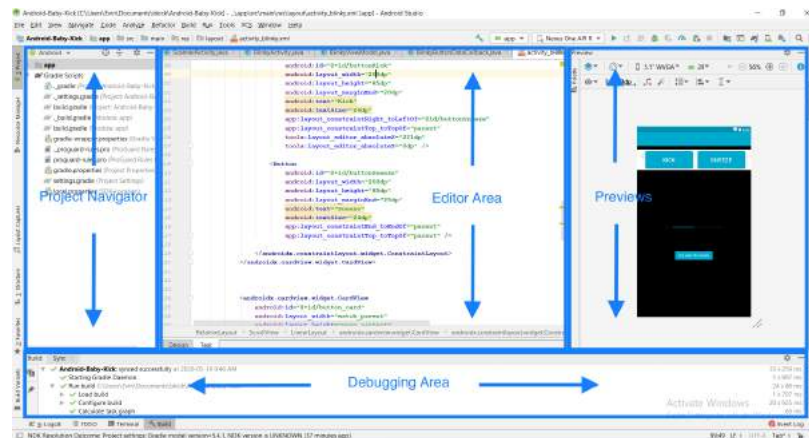


Figure 3.2: Android Studio Workspace Layout

Virtual Devices

One of the challenges developers face is to test the code on different devices to see if it works properly on every single, real device. Although it is recommended to at least buy one device to be sure about how the code appears, virtual devices give the developer the chance to test the code on every platform without spending money on purchasing all of them. As mentioned, having one real device gives the developer a proper sense of the difference between the emulator and the real device[67, 69, 68].

3.3.2 Android Layered Architecture

Android is based on Linux kernel. This kernel provides all low-level functionalities that the hardware needs and also the environment that Android programs need to be executed. Developers do not need to know the different layers of Android operating system in detail to design and run an application. However, knowing the application framework can be helpful for designing a better application. The application framework is a definition of the outer look of the application. The last layer is the app that is developed to be the answer for the users' necessities. Figure 3.3 shows all the layers that are existed for an application to run successfully. There are some programming languages for developers to achieve their goals. While C++ is the one which is used for programming lower-level drivers, it is used only for special purposes[69]. This part is not touched in the Baby Kick device.

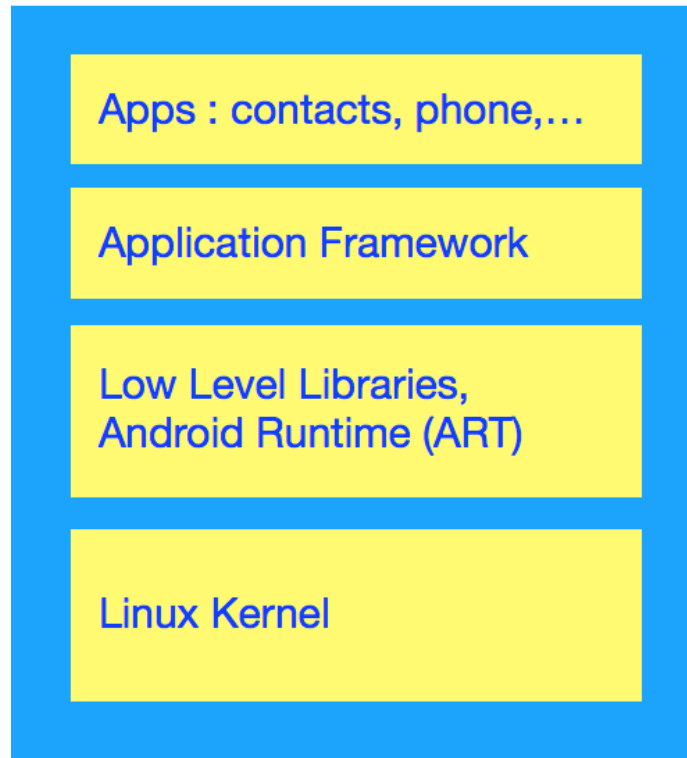


Figure 3.3: Android Operating System

Application

The first layer of the Android Architecture is Application. This top layer consists of the original application on Android and also the ones installed by a third-party [71].

Application Framework

The second, top layer is the Application Framework. It consists of an activity manager, content provider, resource manager, notification manager and view system. The activity manager is responsible for creating activities, maintaining them and also has to keep track of the activity interaction with device users[71]. The content provider establishes links between layers and provides data from one application to another. The resource manager has the ability to access non-code resources such as graphics. As the title of the notification manager shows, this part provides custom alerts in the status bar. Building an application user interface is the work of the view system such as adding button, text and etc.[71, 72, 70].

3.3.3 Designing Android Application

User Interface Layout

Before designing an application, the first task is to define all the features of the application and then to come up with a list for the needs and requirements that the app can solve, and then try to reach the goal by designing the outlook on a paper. Figure 3.4 shows all features that the application has to have for the first stage.

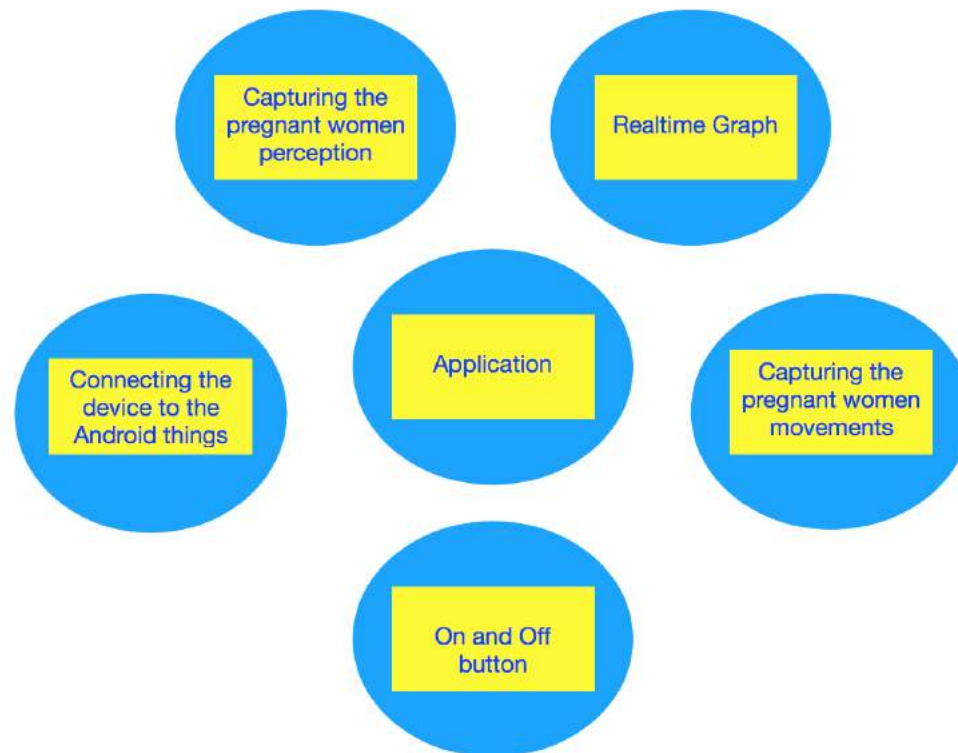


Figure 3.4: All features for the first application design for Android applications

Different pages of the android application

Different windows of the android application is summarized in figure 3.5

User Interface with Details

The following parts are the description of the development of the Baby Kick application on Android things. Opening the Android Studio and then creating a new project is the first step. The first window that the developer faces, is shown in figure 3.6.

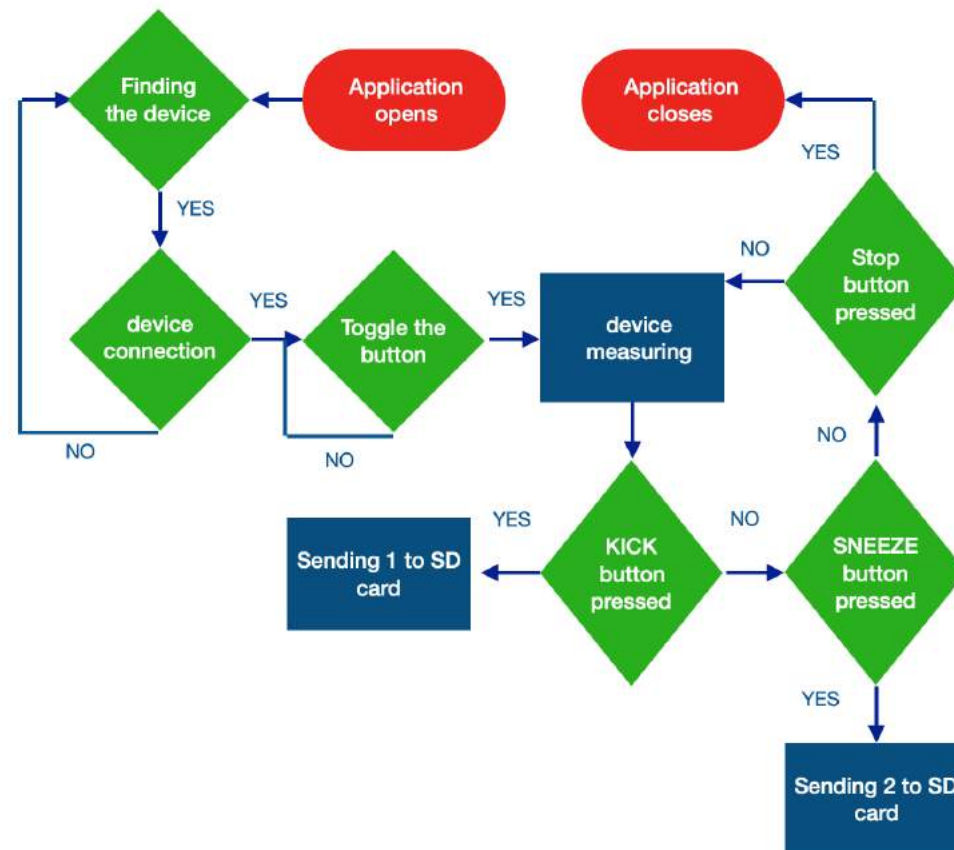


Figure 3.5: Different windows and their features

The configuration of the project and other form factors that the application will run on is the next step. Then it is time to choose the activity and finish the first set of configurations. However, the design is totally different from one developer to another. All settings and overall layout from the first step to the last happen in the editor area. The next step is to write the code based on the requirements of the application and attach the view with the code. The view contact in Android things has three pages, including the welcome page and result page. On the first page, all devices that are in its Bluetooth range pop up, and the user has to find the device and select it from the list, as shown in figure 3.7.

After selecting the device, the second window will be on the screen. In this window, the user has to select the button to start the recording. The presence of this button gives the user this feature to start the recording at their own time just with the click of a button. Figure 3.8 shows the second page of the application. As shown in figure 3.8, there are two buttons entitled "Kick" and "Sneeze". These buttons are

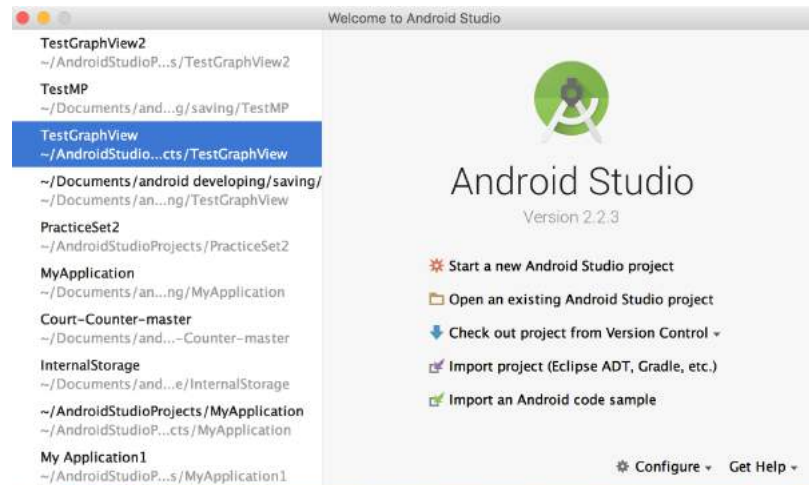


Figure 3.6: Welcome page of Android Studio

there to record the woman's perception of the fetal movements. After the pregnant woman senses a kick, she has to press the "Kick" button in the Android things; this way, a distinguishable line will be added to the data. If the device is able to get the kick around the time the mother senses the movement, this means the sensitivity of the sensors in the circuit works just fine. The other button is mostly for observers; if they observe that the pregnant woman moves or laughs or has any other movements that may cause artifacts in the data, they will press the "Sneeze" button. The result of both buttons will be added to the data and ready for the developer to go further in the study.



Figure 3.7: First window after turning the device on

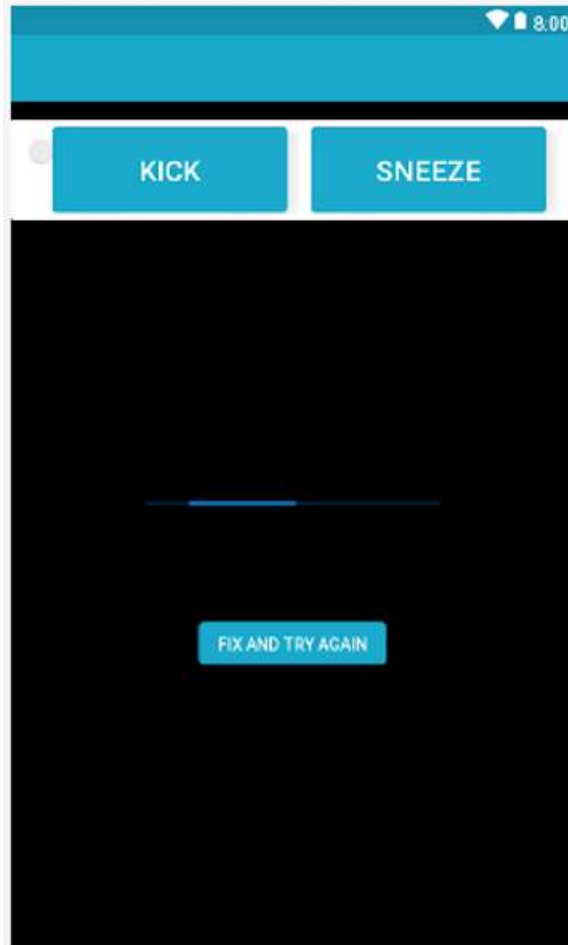


Figure 3.8: The second page

3.4 Android Things

Android things is an Internet of things operating system released by Google. Its ability to connect to the Internet to perform a function makes it an internet of things (IoT) operating system. The first reason behind designing this device is to give the developers with Java or Android the ability to make IoT devices through knowledge. The other unique feature of Android things - which makes it more appealing for use in the Baby Kick device - is that it exposes only one app to users. This way, the control of the application and also its security will be guaranteed; the user will not need to choose the application among other apps. The other feature is that as it starts, the app will be launched automatically; this reduces confusion for the user. As it can be connected to a device, it has to be accompanied with hardware. Saving power,

high degree functionality and additional expansion possibilities are the features that were important in selecting the hardware which narrows the options down to NXP i.MX7D. Figure 3.9 shows the Android things hardware.

3.5 Android Things Enclosure

The power in every device comes from their codes, hardware and all other parts that are hidden inside, but the first impression is influenced most by the device's outer shape. The outer shell can contribute to the adoption and attraction of the device, lending a user to spend more time with it, which is hard to do in this competitive market. The shell is of import when the decision to purchase the device is weighed against other available options. The enclosure was designed in an application called SOLIDWORKS. The first step in every design is to make a list of the requirements.

- The size of the board that has to be covered by the shell - the more precise the design, the better the outer shell. This way the box will hold the board better.
- The cutouts for interactions such as Wires and USB Connections.
- Imagining the whole concept to design the enclosure the best way possible in terms of time, material usage and supports for the print.

The first thing to do is to design the part for the inner components. In order to be sure about the dimensions, it is better to create the whole 3D models of the circuit into SOLIDWORKS program; this way, the designer can design the enclosure accurately around it. The model should not have all the detailed features. The dimensions should be considered in the model. Designing around the inner model makes the design more accurate, which leads the designer to get to the final version sooner. The other feature which is important to think about is the thickness of the shape. It has to be elegant and also printable based on printer ability. The important feature of designing the enclosure of the Android things in the Baby Kick device is that there is no bolt and nut in the design. All the parts click together without the use of any other parts. The whole enclosure has two parts for holding the circuit and the outer shell, which is shown in figure 3.9.

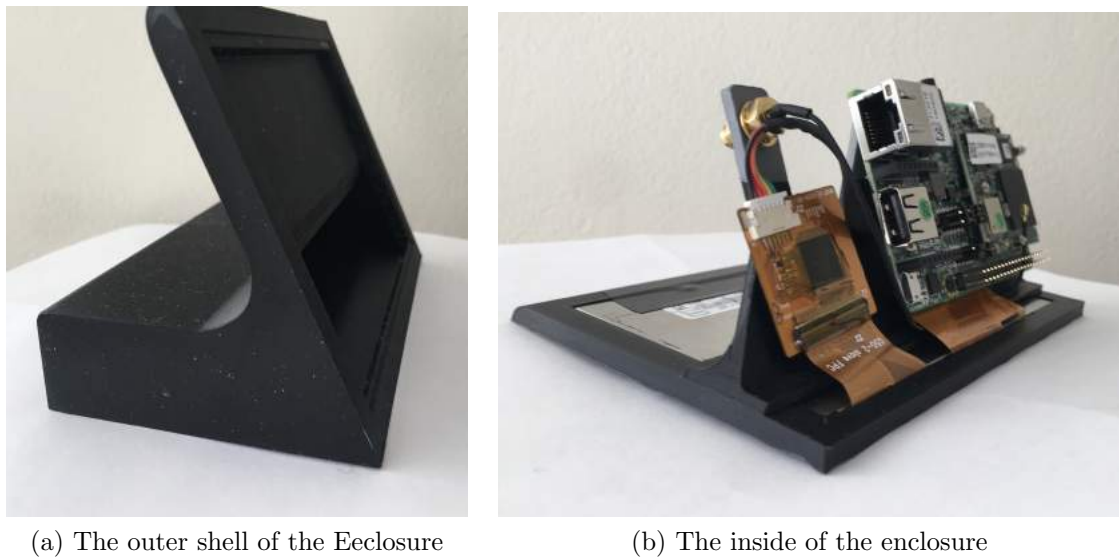


Figure 3.9: Enclosure Design

3.6 Development Environment background (iOS Applications)

3.6.1 Software Development Requirements

Following is the description of how to create iOS applications from scratch. The development environment for developing applications, the programming language and other requirements.

Swift

Swift is a programming language for all Xos, and it was rooted in objective-c. One of the reasons developers use it for developing their applications is that it has the power of both low-level programming languages and high-level languages such as JavaScript. The features that make this an intuitive language is its modernity, safety, speed and ability to be open source[73]. However, Swift is a new programming language; it is a type-safe language, which means that its features give the developer a chance to be clear about everything in the code. There are some features that are mostly used in the Kick application, which will be described with more details bellow [73, 74].

- Constants and Variables: Associating a name with a particular type. Using a file containing all constants is a huge help in order to save time. This way, the

developer only needs to look up the constant and its value without any trouble.

- **Collection Types:**
 - **Arrays:** This most used data type responsibility is to give a developer a list (collection) of different values.
 - **Sets:** Sets are in charge of Storing various values of a particular type.
 - **Dictionaries:** The association between a particular key with types and values is the dictionary obligation.
- **Control Flow:** Statements such as while, if and switch
- **Structures and Classes:** These two are the fundamental parts of every programming language. The beauty of Swift is that, unlike other programming languages, if a developer once defines a structure or class, it will be available for other interfaces.
- **Extensions:** Extending to an existing type to make it easier to identify functions related to a unique protocol. This way, the code gets organized and is easy to follow for further changes.

Xcode IDE (Integrated Developer Environment)

Xcode IDE is an integrated development environment developed by Apple Inc. for developing applications for all its products. This environment, which was first released in 2003, contains software development tools, including Interface Builder and Instruments. The features of this environment are its availability in the Mac App Store for free, which gives developers the chance to design and develop the app and even submit it to the App Store. The developer can find the latest version of Xcode in Google without any trouble. The other useful feature of Xcode IDE is the iPhone Simulator, which can be used to test iOS application codes and see the result right away. This way, the developer does not need to wait to see the result, and it can be run through the iOS Simulator[75, 73]. The Xcode workspace can be seen in figure 3.10.

Interface Builder

One of the most important tools which are offered by Xcode is Interface Builder (IB). IB makes developers able to design their one specific interface for their desired iOS

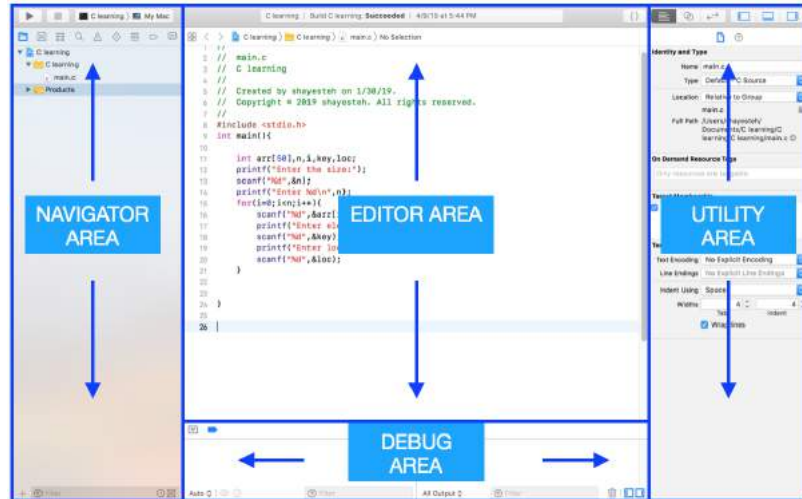


Figure 3.10: The Xcode workspace

app without ever writing a single line of a code[75]. Although the layout is similar to the Xcode workspace, upon a closer look, it has its own elements to be added to the view for better results. The left part is called the view hierarchy, and the right panel is the utility area in Xcode workspace. The figure of Interface Builder(IB) can be seen in figure 3.11.

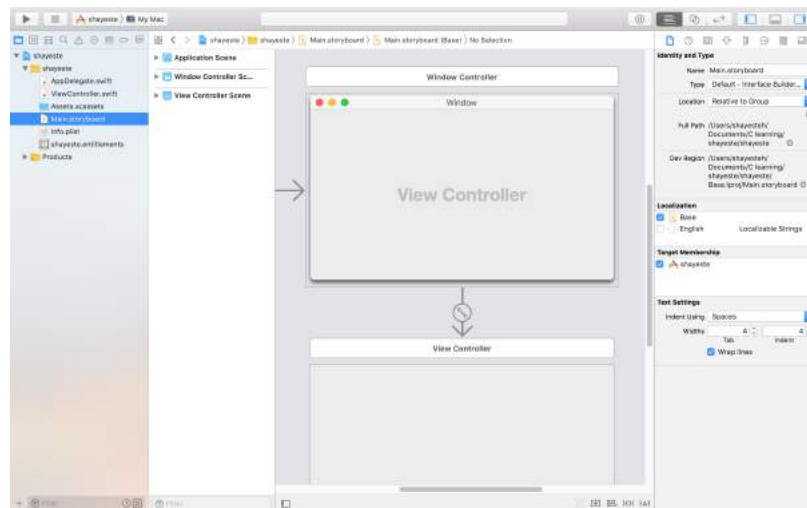


Figure 3.11: The Xcode Interface Builder workspace

iPhone Simulator

iPhone Simulator is a simulator for Mac OS X to test iOS applications and helps developers to visualize their design before uploading the application to a mobile device. The iPhone Simulator is considered as one of the fastest simulators[64]. Figure 3.12 shows an iPhone simulator.

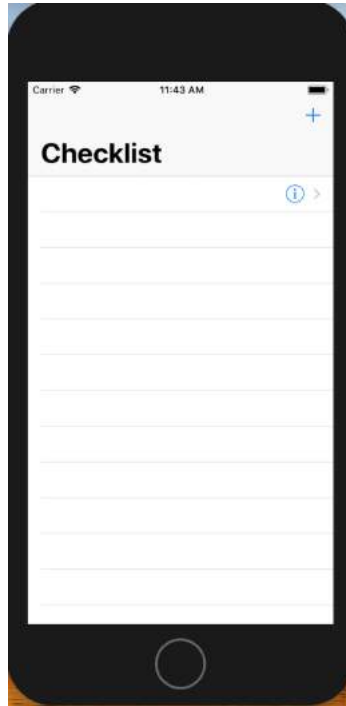


Figure 3.12: iPhone Simulator

Tools

There are some tools and resources for Swift to scale projects [76].

- Libraries: Swift library is a layer for fundamental basics swift programming. For adding new features, it is recommended to search for existing libraries to check if there is a library with the needed functionality.
- CocoaPods: CocoaPods has been used as a dependency manager in over a million apps. It also has thousands of libraries, which makes it a good candidate for solving a vast range of different problems. In other words, CocoaPods resolves the problem of adding the third library by adding the library and manage it

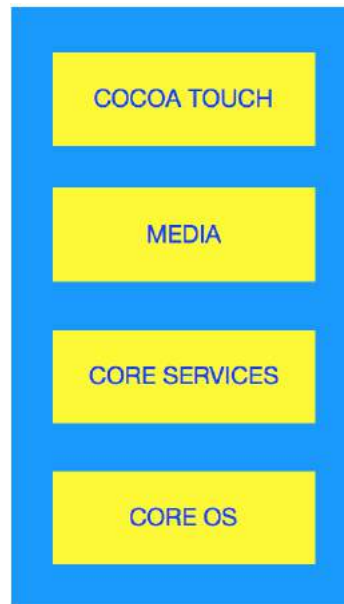


Figure 3.13: iOS's Layered Architecture

itself. While a CocoaPods file is added and executed to the project, a plain text file with some library automatically will be added to the whole project.

3.6.2 Layered Architecture of iOS

The iPhone Operating System was developed by Apple to run on their devices. After the Apple company unveiled various models of handheld devices such as their iPhone, iPad, iPod and Apple Watch, iOS became popular among developers[77]. Knowing what this technology is - and how to use it - requires understanding the development process in a little bit more detail. iOS layers from the lowest level of abstraction to highest are divided into four layers listed below, also shown in figure 3.13:

The Cocoa (Application) layer includes, the Media layer, the Core Services layer, the Core OS layer and the Kernel and Device Drivers layer[78]. The lower the layer is combined with the hardware; thus there is no need for its analysis given that the focus is not on this level. A description of every individual layer featured follows [78, 79].

- The Cocoa (Application) layer: This part includes all the information related to the user interface - the point where the app bridges the connection between the user and the hardware. As this app plays an important role in building

an app's user interface, it is necessary to explain one of its key features, storyboards. A storyboard is designed to illustrate screens of content. Its transition between view controllers is known as a segue. As designing the user interface for every application is crucial, Apple's integrated development environment (Xcode) provides a visual editor for developers to locate the buttons, view and other features in order to design their own applications. This feature adds a lot to Xcode as it is allowed to view all the views and view controllers and the correspondence between them[80].

- The Media layer: In this layer, the developer is allowed to work with images, videos, audios, animations, graphics and other kinds of media. Below are some frameworks which are accessed by the developer for developing an app.
 - Core Graphics: available for 2D drawing.
 - Image I/O: Importing and exporting images.
 - Core Text: text layouts and fonts.
- The Core Services layer: Although this layer has no direct connection with the user interface, all layers above are built on this service foundation. Generally, the quality of the application and the key technology behind all the apps depend on the lower layers. This layer also includes some high-level features such as Security Services, Social Media Integration, iCloud Storage and beyond[78]. Here are some frameworks which are used with the core services layer.
 - Core Data: Used for modelling the data.
 - Foundation: Available for core foundation.
 - Core Media: For low-level media.
- The Core OS layer: As this layer is placed above the final layer, it is responsible for the programming interfaces related to the hardware layer. This means that even developers do not deal with this part directly.
- The Kernel and Device Drivers layer: This layer is surrounded by low-level components and provides low-level environments to make a solid base for developers to develop software applications.

Patterns Design

The goal of designing patterns is to figure out the code and reduce the probability of probable errors when reusing similar codes in different situations. Several patterns exist which can be classified into three types[81]:

- **Creational:** The aim is to design a pattern in a way that is suitable for the particular situation. The Singleton Design Pattern is an example of a Creational pattern.
- **Structural:** This pattern is famous because of its simplicity. The purpose of this pattern is to give the developer better content to know the relation of the classes and objects, which lead to better design in terms of simplicity and intelligibility. The Model-View-Controller is considered as a structural architecture pattern.
- **Behavioural:** The identification of the communications between objects and classes responsibility of this pattern.

Model-View-Controller (MVC) is the most used design pattern of all[82]. This pattern has separated the object into three objects based on their roles: model objects, view objects, and controller objects[82]. Figure 3.14 illustrates the MVC relation and also some details about each one of them.

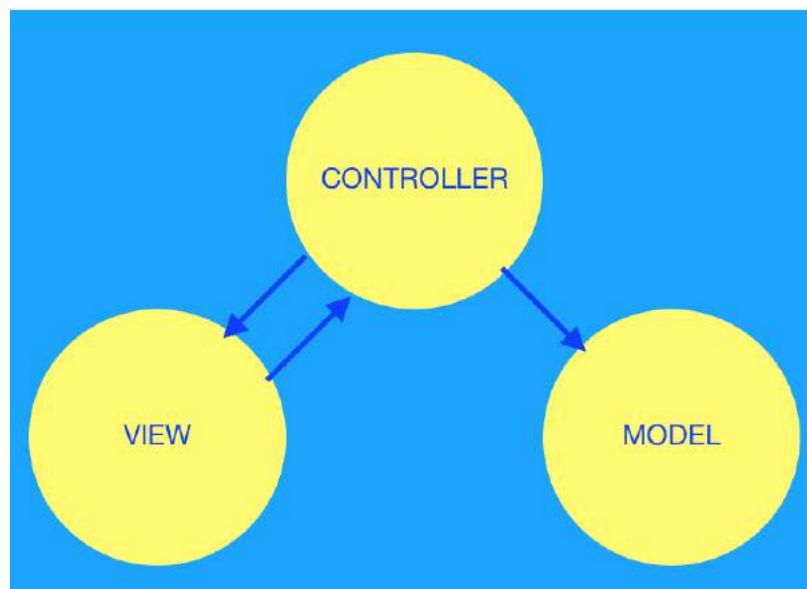


Figure 3.14: Model-View-Controller (MVC) Platform

- Model objects: This object is in charge of the application data and the basic behaviors.
- View objects: View object holds the parts related to the presentation to the user. In general, the control of all the visual representation, such as editing goes back to this object.
- Controller objects: The responsibility of this object is not summarized in one particular job. The control of the model and view are assigned to this object, and also access to other objects is part of Controller objects responsibility. In other words, this object is the head of this pattern. While an iOS app displays, based on the number of view controllers, the managing of what happens behind the scene is the role of the controller object.

3.7 Application Development

This section is a summary of the application and how it works. The next step is to explain this overall information and the path of designing the application step by step.

Applying the MVC model, Kick's app has the user interface as the view in which the user should input her own data. The controller processes the data, and the model is the software logic. The view content is four pages, including a welcome page, overall data page including weight and other variables and the result page. The user's inputs are stored as local variables, which will be processed by the controller at the end. Each of the four distinct user interfaces of this design carries out individual responsibilities. The first page of the design is the welcome page, which consists of the button to add a new set of data for different days. In this way, the user (in our case, pregnant women) can store different sets of data from the days the device has been used. The other feature that the app has for the first page is an editing tool to delete rows of data or edit the necessary information. On the second page, the user can provide a brief description of herself and the baby; she can also input her personal measurements, which can be critical elements for further assessments done by a doctor. After writing down every section of the required data by pressing the add item, all the information will be stored as a single row on the first page. All this information will be stored as static text in the text view object, and the user can choose from the page which day to follow. The last two pages have the same number

of objects and structures but different functionalities. One page is used to display the eight graphs - each one of them is related to one of the eight piezoelectric sensors of the device. The other page is responsible for saving every individual set of data. On this page, the user can add the new data by pressing the add "+" button.

3.8 Interface Creation with Details

The aforementioned was a summary of the application and the overall look of the application. The following sections outline the detailed descriptions of the developments.

Opening the Xcode and creating a new project is the first step to designing the application. The Xcode has to be installed, and figure 3.14 is the first window a developer will see.



Figure 3.15: Welcome Page Of Xcode

As mentioned before, Xcode IDE provides the developer code editing, compiling, debugging for an interface builder. These features are divided into four different areas: navigator, editor, debug, and utility areas. However, the design can be different from one developer to another, for setting up the overall layout, all designers use Interface Builder to design the first to last part of their application. Developers can take Interface Builder features into account and produce the best product suitable for the users' needs.

The first thing after opening the Xcode is to use the Auto layout. Auto layout is a combination of different constrains and measurements to provide developers with

a better platform to design. Figure 3.16 shows some features that an auto layout has. As it is time-consuming to design a unique layout for every single application,

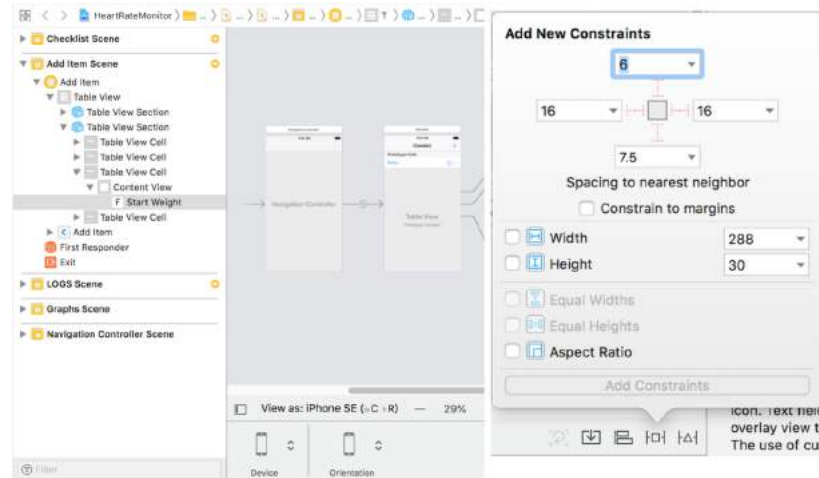


Figure 3.16: First Page after creating the project

Apple company introduces a stack view in order to reduce the amount of work that developers have to do. As a result of this stack view, developers are able to skip some steps and use reusable and common layouts instead of putting a huge amounts of work to design their own. UI stack view is a special non-rendering subclass of UI view and it manages the layout of the sub views. The stack view properties are axis, alignment, distribution and spacing, which, with the help of these stack view, combines different objects into one layer[83]. In the Baby Kick application, there are five objects in the view, including button, text views, labels and date picker in multiple table views. The button navigates between pages and gives the user this capability to change the whole data on the page. Text field disputes label is utilizable for receiving and processing users' input data, which gives the user the ability to write their own information in that particular area. Besides these objects, there are other adjustments to improve the look and usability of the app for the user.

The next step is to write a code based on the requirements of the application. There is a tool menu for adding a user interface component in the application. This menu makes the design easy by displaying the icons with their descriptions. After choosing the required icon, with an easy drag and drop it can be placed into the view window. Aligning different layouts, changing the size of them, and other outward looks occurs in this part of the Xcode. Hooking up the code with the related views is demanding to see the desired result after designing the view. The developer has to

attach the view to code to give the view a function. The interaction is accompanied by the keywords `IBAction` and `IBOutlet`. `IBAction` is contrary to `IBOutlet` and is declared when the UI components are called by an action. In the final step, the developer needs to connect the written code to the view. This way, the user will be able to use the application in a specified way that the developer had declared in the controller code. Figure 3.17 shows all pages, including in the iOS application. The segue between View Controllers is one of the most important parts in designing

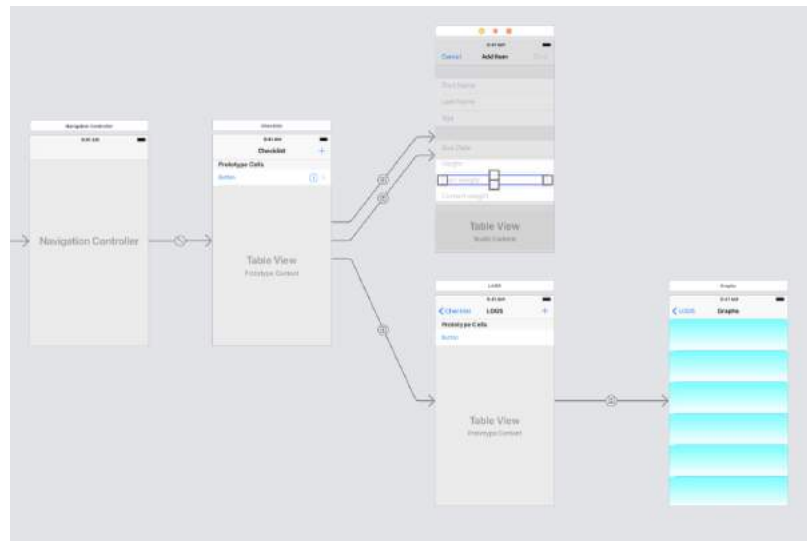


Figure 3.17: All the pages in the IOs application

an IOs Application. It is a transition data between two view controllers in the app's storyboard file [84]. Creating a Segue between view controllers in the same storyboard file is done by control-clicking the UI component and dragging to the target view controller. There are different kinds of segue which can be used to correspond to the transition required as listed below:

- Show
- Show Detail
- Present Modally
- Present as Popover

The outcome of this software meets the minimum requirements of both functionality and performance, and the application can be run with the least amount of errors.

Additionally, users can easily go back and forth between pages with the help of the titles of every UI components and pages. Combined all of these outcomes together, Kick application is successfully established as a complete iOS application, as shown in figure 3.18.

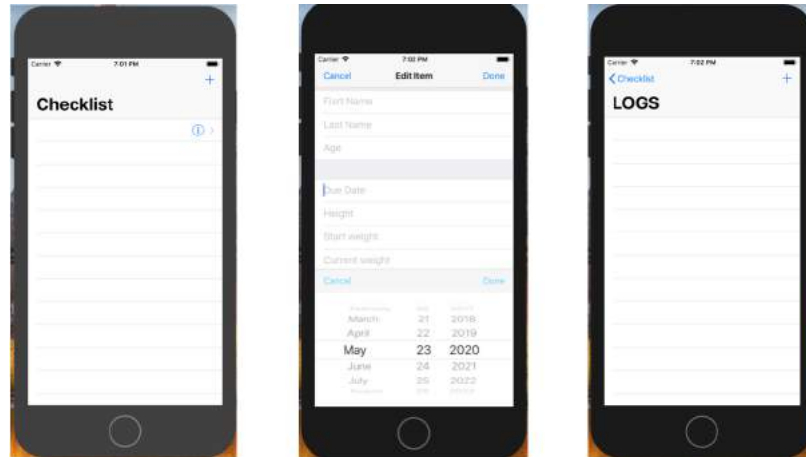


Figure 3.18: IOs Application

3.9 Limitations of iOS

Though iOS was considered the best option for the Kick device, it has its own limitations such as Running Application in Background. iOS requires specific permissions to let the application run tasks in the background. While it would be ideal if the application is running in the background while the user executes other apps or even she locks the screen for getting other stuff done, this permission is only given to some applications running specific services. Its safety prevents continuous monitoring in certain possible situations. Also, it was hard to maintain the best quality for the application for different[48]

Chapter 4

Data Analyse

In the previous chapters, the development of the device and the software were described. The Babykick device gets all the movements of a fetus caused and saves it on the SD card and will be compared with mothers perception. In this chapter, the user manual and one hour of data that was captured from a volunteer will be reviewed.

4.1 User manual

For data collection in COVID-19, the Babykick protocol was organized to be sent to probable volunteers. The purpose of the protocol was to reduce the error of data accusation and volunteer confusion. The summary of the user manual is summarized in the following part.

- There was a section with the summary of the device parts in non-technical language to be more comfortable for the person to get the whole point. Also, it was described the importance of mother cooperation. By having the users record when they feel the baby move while wearing the device, the data collected by the device will be compared to a reliable source(their perception).
- The second section in the user manual was assigned to the setup. It was described with all the detail possible, which is itemized in the following section.
 - First they have to turn the device on.
 - Then they should remove the white double-sided tape from both the device and the belt.

- The third thing is to place the belt on the front of their belly, with 4 nodes on the right side of their bellybutton and 4 nodes on the left side.
 - Then they have to turn the tablet on by plugging it into the battery pack using the white chord. It should turn on automatically.
 - After when the tablet has powered up, they have to select the device number “bkick number”, in order to connect the device to android things.
 - The mother has to wait for a few moments for the device and tablet to connect. When they are connected, the user will see a small toggle button on the top left of the screen, and two large buttons labeled “KICK” and “SNEEZE” on the top right.
- The next subject that was described in the user manual was about the way users have to seat and the instructions they have to follow after which are in the following points.
 - Once the device and tablet are ready, they have to find a comfortable seated/resting position where they can stay for the next 60 minutes.
 - At any point they wish to get up and/or move around, they have to simply press the button to stop measuring, and press it again when they are ready to resume
 - During the session, any time they feel their baby move, they have to press the “KICK” button on the tablet. If they happen to move in a way that would cause the device to detect a movement (such as a sneeze/-cough/laugh), they have to press the “SNEEZE” button on the tablet.
 - After data collection, they have to turn off the tablet and gently peel the device and belt off their stomach, then they have to place the double-sided tape back onto the sticky side of the device and belt.
 - The batteries of both the tablet and the device need to be charged after every use.

4.2 Volunteer Specifications

In the time of COVID-19, it was hard to forward the call for volunteers and in the case of Baby-kick device it was harder as the volunteers had to be pregnant and in

their their third trimester. Also as it was the first time testing the device the focus was on the constraints that are necessary to take into account regarding testing the device. Some features were expected in the volunteer in order to test the device. The features are listed bellow:

- singleton pregnancy: As it was important to capture the most accurate result from the data accusation and compare it to the mothers-to-be perceptions, singleton pregnancy was the first feature that was considered in accepting the volunteer. This way the data could be correlated with the mothers' input.
- uncomplicated pregnancy: Based on the information gathered from obstetricians, any complication may lead to not only get uncertain results from the Babykick device but also it could give the pregnant women anxiety as she does not see the result on the application. The base thought of developing Babykick was to help pregnant women in this terrifying and also most beautiful path not to make them more anxious.
- being familiar with pre-commercialized devices: Although the device was developed to be user friendly, it still needs modifications. People working on research do understand the process better and it is easier for them to follow the instructions.

Based on all the given specifications, there was a volunteer who participated in the study. The purpose of the test is to a better understanding of the device capacity to detect discreet fetal movements in women of varying weights and placental positions (the placenta can act as a shock absorber and alter maternal awareness of fetal movements [85].) Her general information is as follows.

- Body Mass Index (BMI): 23.4
- Gestational Age(GA) on the data accusation: 33.14
- Placenta Location: Posterior

This information was not considered in the data processing directly, and it was only gathered for future investigations. Also, as it was the first time testing the device, volunteers without any complications were accepted.

4.3 Data Visualization

As it is explained in previous chapters, in the development of the BabyKick device, the goal was not only to realize a device is able to record abdominal signals from the fetuses, but also to quantify the device performance and hopefully to help the clinicians and the pregnant women themselves in the detection of fetal movements. For this reason, a clinical study was started in order to evaluate which information can be depicted from the Babykick device and if the data captured from the device can be compared to the women perception. In order to compare the mothers' perception with the data captured from the device, a graph could be the best option to see the result visually and keep track of the changes over long periods of time. Between different kinds of graphs, a line graph was the best choice to illustrate when smaller changes exist in the data. After considering the line graph for the comparison, another code had to be written in order to perform simple changes that happens in the connection of each individual data point. Python was chosen for this part of the project.

4.3.1 Python

Python is one of the object-oriented programming languages. The reason behind choosing this language is that it is easy to learn and simple to use; therefore, the cost of program maintenance reduces compare to others available. Python boosts the productivity of developers compare to compiled languages such as c and c++. The size of this language is smaller than other languages (about one-fifth), which means developers need to put less effort into writing hundreds of lines of codes which leads to fewer errors and less debugs[86]. Python comes with an extensive collection of libraries, which helps developers reaching their goals faster. Python integration leads it to be called from c and c++ and product customization. The only downside to this language is its execution speed, which is sometimes slower than c and c++. After downloading the python package, a support library and an interpreter will be downloaded. Based on the codes the developer writes, the Python interpreter takes some libraries and all other materials it is needed to implement the code. Whatever forms it takes or other kinds of information, it has to be through a Python interpreter. Running Python code can be done in a variety of ways such as system command lines, the interactive prompt, icon clicks, module imports and also an integrated development environment (IDLE). IDLE is the environment that was chosen for Babykick device data Visualization. In short, IDLE provides a graphical user interface which is free

of charge and also it is part of the Python system, which makes it ideal to use[86].. To start writing the source code, a file under IDLE has to be created. The benefit of using the integrated development environment (IDLE) is to help the developer find the errors and spot them easily. To run the program, the developer has to save all the changes in the script first. Running the script this way will lead the result to be shown up in the Python shell window[86]. Another feature that IDLE has is that it can be customised and the developer can change the font and color easily to make spotting the errors easily. For saving the code and running the module, it is important to add “.py” to the name. Every module has to have some import operations on the top based on the script. These import operations guaranty access to that file’s contents. Although it is rare to have bugs in Python code, it can happen to some less fortunate developers. There are some ways to face this problem.

- Developers get very useful and readable errors message which is easy to Handel and the only way to resolve is to read errors carefully.
- If the error is not resolved, the next step is to insert print statements and rerun the code. This way if the correct print statement appear on the result means the problem came from another line of the code.
- For larger codes and especially the ones that the developers do not write it themselves, using IDE GUI debuggers is another way to solve the problem.

Python as an object oriented language has some object types to work with such as numbers, strings, lists, dictionaries and etc,. All the information in this section provides a summary of how Python works. In the next sections, the data and its graphs will be reviewed.

4.3.2 Babykick Device Graphs

As it mentioned before, to check the changes happen in the data, line graph is one of the best options. To review the data Python 3.8 was installed ,the newest major release, and all the graphs were figured with this version. Although Python is famous for being a general-purpose coding language, since the data captured from Babykick device was not complicated, lots of python features were not utilized and considered in the process of writing the code. As it mention in the chapter two, Babykick device consists of two major parts, hardware and software. The hardware is a mixture of

piezoelectric sensors and the actual device which should be attached to the pregnant woman stomach for data accusation. Babykick device makes the measurement is by eight piezoelectric sensors and therefore there are eight lines of data related to the number of piezoelectric sensors. In order to compare Babykick performance, mothers perception should be considered and viewed in the data. Comparing the result led the project to further step and the need of another button for the device got bold. Therefore in the android thing application there is an button to be pressed in case of mothers movements. This button can help the data analysing more accurate. The future study could be featuring the difference between the mothers-to-be artifacts and the fetal movements. This way the device can be though to figure the fetal movements and remove the mothers movements from the data itself. As the comparison of the device with the mothers' perception was the goal, there are three features that have to be shown in the graphs. first the data captured from the eight sensors of the Babykick device. The result of eight sensors are shown in figure 4.1. Second the mothers perception which is shown in the lower graph, separated from the Babykick device sensors and third the mothers artifacts which is also figured in the lower graph. Both mothers input for fetal movements and her own artifacts are shown in figure 4.2. As it shown in figure 4.2, the difference between the mother's perception and the fetal movements is the amplitude of the lines in the lower graph. If the line reaches number one, it means the mother feels a movement and if number two appears on the graph, it means the mother moves herself. Both mother and fetal movements are saved respectively with the numbers two and one, in the data during the data accusation and there is no need for additional attempt for distinguishing these two.

4.3.3 The volunteer data analyse

Beside all the specifications, as COVID-19 changed almost everything, another point had to be added to the specifications list for choosing the right volunteer. She had to be familiar with research as we could not reach her and observe the whole process. The volunteer had to test the device only with the information that was gathered for her. Although every step through the process was detailed with lines of instructions and lot of figures, she had to make it work and figure everything out herself. Therefore a person who is familiar with research could be better in testing the device. After sending out the information to find the best volunteer with all the mentioned specification that are necessary to take into account for testing the device, we could find

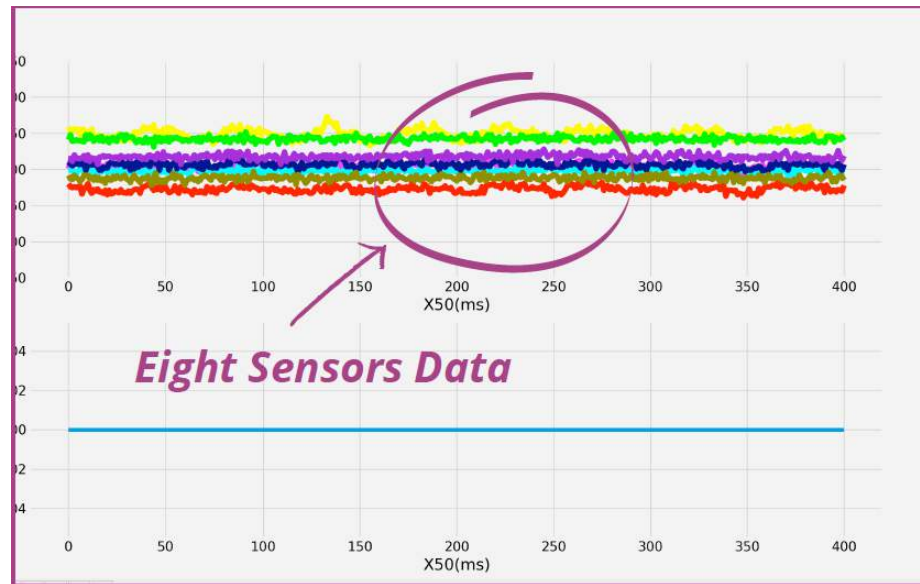


Figure 4.1: Babykick eight sensors data

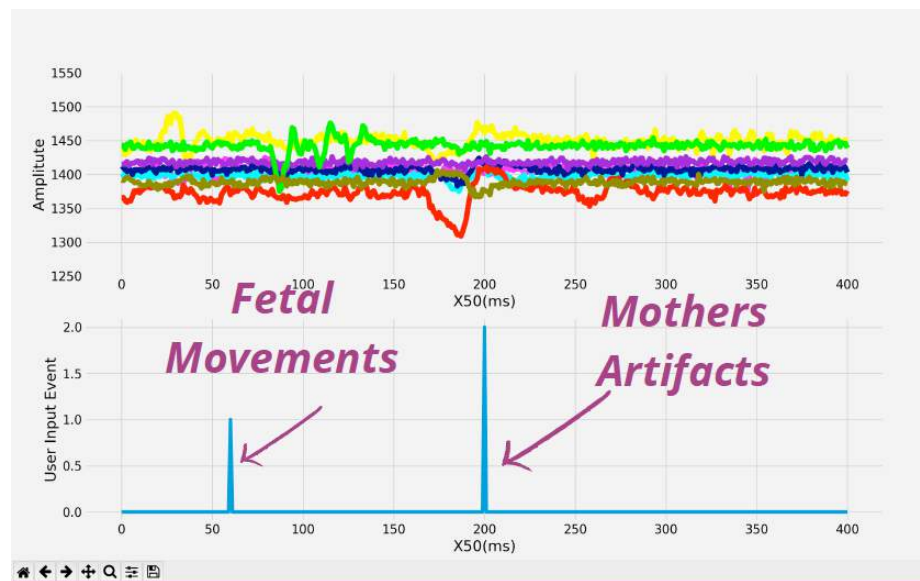


Figure 4.2: Mother's input for both fetal movement and her own artifacts

a kind enough volunteer to give the Babykick device a test. She had to be familiar with research as we could not reach her and observe the whole process.

Testing the device for the first time is hard enough, and also COVID-19 has happened with all its complications. Fortunately, with all the restrictions, we managed to recruit the data successfully. The volunteer was asked to wear the device for around one hour and sat in a comfortable position. She was supposed to press the “KICK”

button when she felt fetal movements. As it was mentioned, every button is attached to a certain number in the firmware of the device and then all of them were saved in the SD card. Data from eight sensors is shown in the first eight rows of data saved in an SD card. The ninth row of data belongs to the events that come from the user's input. The "KICK" button is recorded as number one in the ninth row of the data in the Sd card, and the "SNEEZE" button is correlated to number two in the last row of the data, which is the ninth row. The user input is illustrated as a line graph at the bottom part of every figure. In total, the volunteer pressed the "KICK" button thirty-seven times, which means the number of the movements that the woman felt during the data accusation session was thirty-seven. Also, she pressed the "SNEEZE" button ten times, which means she moved ten times herself during the data acquisition session. To compare the device performance, the mothers' perception was chosen. In order to compare the device with the users' input, is to divide the data into four sections.

- First set of figures 4.6, 4.7, 4.8, 4.9, 4.10 and 4.11 belongs to the parts of data that the mother felt her fetal movements, which was correlated as number one in the SD card.
- Second set of figures 4.14 and 4.15 belongs to the time that the mother moved herself during the data accusation. Number two in the last row of data in the SD card shows this set of figures.
- The third set of figures 4.12 and 4.13 belongs to the part that the mother did not feel any movements. The bottom part of this set of figures shows a constant zero as there is no number correlated to this part. And there is no particular changes has happened in the eight rows of data and the data should be smooth.
- The last set belongs to the parts that the device shows something but the mother did not press any button. This part can be explained as either the movements were so tiny that the mother could not feel or the mother was not pay attention enough at the time of as this can have three different explanations, first the movement could have been super small and as a result, the mother did not feel it to press the button; second the mother might have forgotten to record the movement, as she had to sit for one hour; or simply it might have been an error from the Babykick device.

Figures 4.3 and 4.4 are listed to indicate the different changes that happened in the graph as a result of the fetal movement and the user artifact. In figure 4.3, the blue line shows a strong event in the graph. In this part the only changes were not happened around the sensor which is shown with blue color, the pink line shows some movements near the related sensor. Although the movement near sensor shown with blue color is stronger, the movement near sensor shown in pink can not be ignored. As it is shown in figure 4.4, most of the lines were moved as the volunteer happened

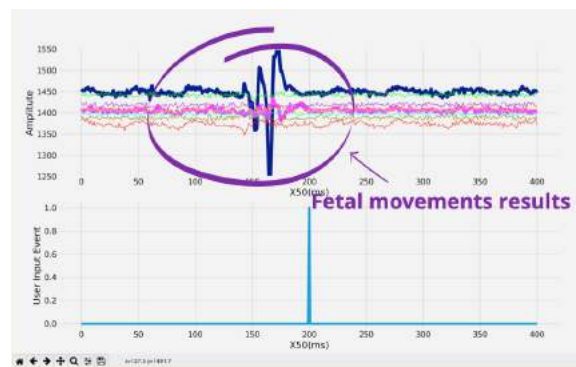


Figure 4.3: Feta movements

to move herself. The amazing feature for this part is the similarity of the changes in most of the lines in the graph. Labeling the events will be easier with the similarity in the graph. Figure 4.5, is shown the part that nothing happened in the data. In this

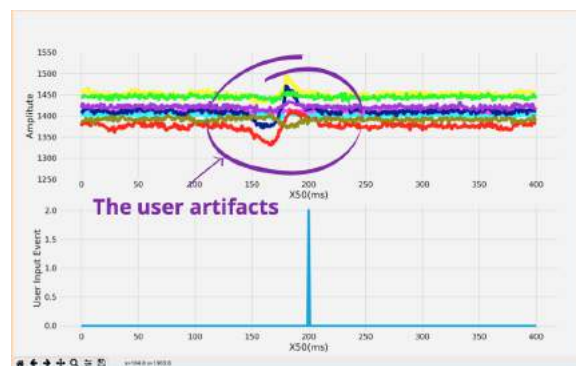


Figure 4.4: The user artifacts

part all the lines related to eight sensors have shown. All the lines are smooth and there is no sudden changes happened during this time. As in every figure, there are two parts for both the data and the users' input, in the bottom part of figure 4.5, the line stayed at zero which means the mother did not feel any movement and also she

did not moved herself. Based on the figures 4.3, 4.4 and 4.5 and all the explanations,



Figure 4.5: There is nothing happened in the data

following there are some figures from different sets which show how the device worked during the data acusation. The first twenty-four figures 4.6, 4.7, 4.8, 4.9, 4.10 and 4.11 are from the time that the mother felt the movements.

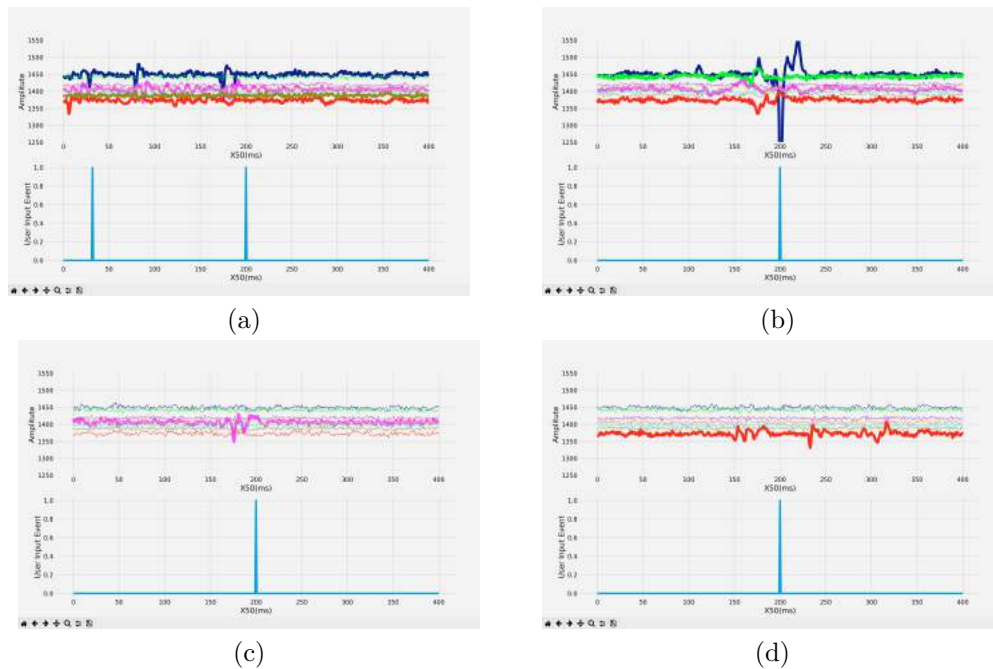


Figure 4.6: Mothers' perception and device data Capturing first set

As it is shown in figure 4.6(a), the mother felt the movements twice in the row and there are some changes happened in the blue, pink and red line. This means the Babykick device captured the movements perfectly. As it is shown in figure 4.6(b), the fetal movement was stronger compare to the first time, and the vibrations of this

kick moved almost all of the sensors. The amplitude of the blue line shows that the beginning of the movement was happened around the sensor which is correlated to the blue color. As the color of the line graphs shows the movements behind every sensor in the certain part of the pregnant woman stomach, the changes in different line graphs shows that all the sensors captured some movements during the test.

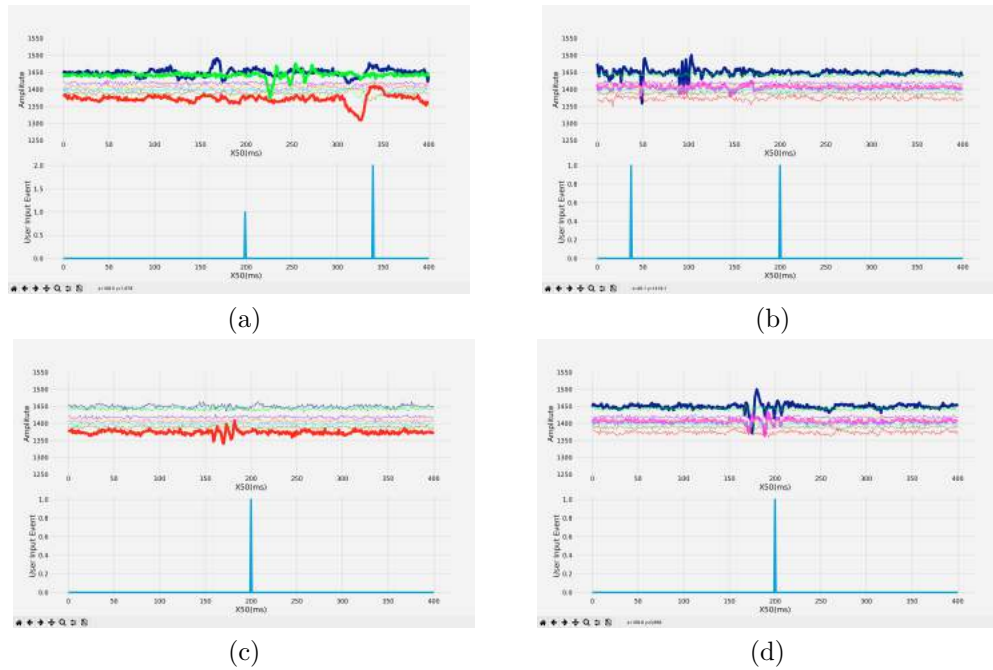


Figure 4.7: Mothers Perception and device data Capturing second set

In the figure 4.7, there are four different figures. In the figure 4.7(a), the mother felt a movement and also she had some artifacts herself. With paying attention to the lines of the graph, the blue and light green line of data picked the fetal movement as the changes of these two line are more sudden. The red line and also the last part of the blue line shows the mother movements, as in this part, the movement has a mountain shape and they happened exactly at the same time. In the figure 4.7(b), The volunteer felt two movements and it is shown in the part related to the mother's perception. In the mothers Perception and device data Capturing third set, figures 4.8(a), the movements were continuous and small, as the lines' amplitude is smaller compare to the other sets.

All the sixth set of data shows that the device found one hundred percent of the movements that the mother felt herself. As the device was required in order to limit the time of using expensive technologies which require highly-skilled clinicians to perform and also it was designed to help women with limited access to sophisticated

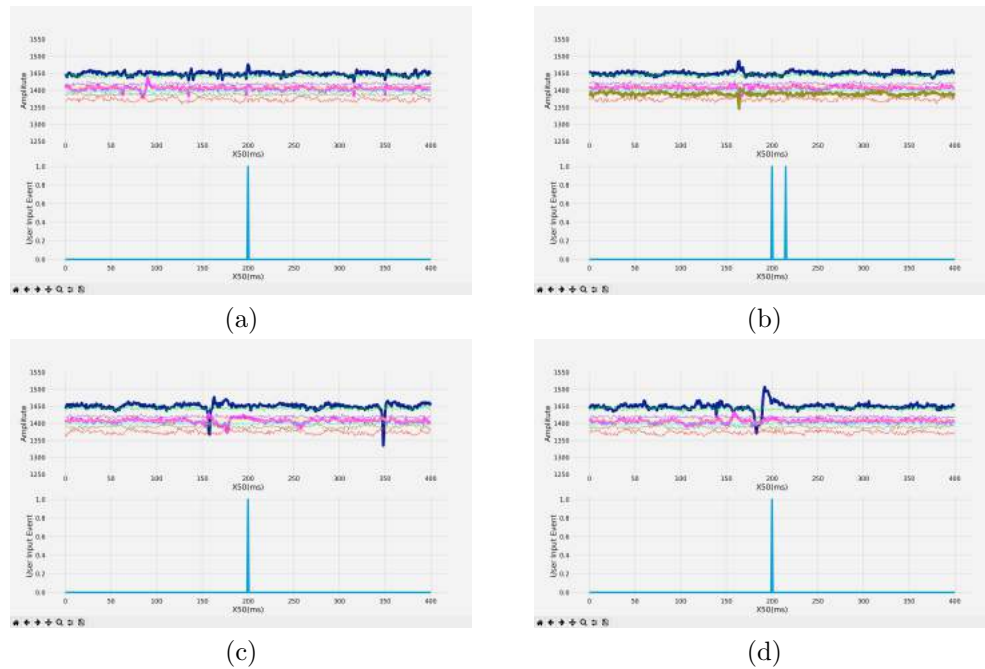


Figure 4.8: Mothers Perception and device data Capturing third set

levels of care, the performance of the device was really important. Based on the observation on all the data captured from the Babykick device, The device is shown that it can get all the movements that the mother felt. The Babykick device as a low-cost method to objectively measure active fetal movements in pregnant women was able to shows all the movements that happened during the data accusation.

The next section belongs to the data that was picked randomly in the parts that neither movements of the mother nor the baby’s movements happened. This means in these areas there is no user input event 4.12 and 4.13. As it is shown in figures 4.12 and 4.13, the lower part of the figure shows continues zero line which means the mother did not give the Babykick device any input. Also, the Babykick device did not get any movements that can changes the normal shape of the regular line graph. All the eight sensors’ input are smooth without any sudden changes.

This section is belonged to the data with mothers artifacts. The user should press “SNEEZE” button on the top right of the app when she moved herself in a way that would cause artifacts 4.14 and 4.15. An event with amplitude of two happens when the mother herself moves. The changes of the Babykick device is enough to be differentiate from the other parts of the graph.

With careful observation during the test, There were some parts that the device showed some changes in the data but there was no input from the mother. These

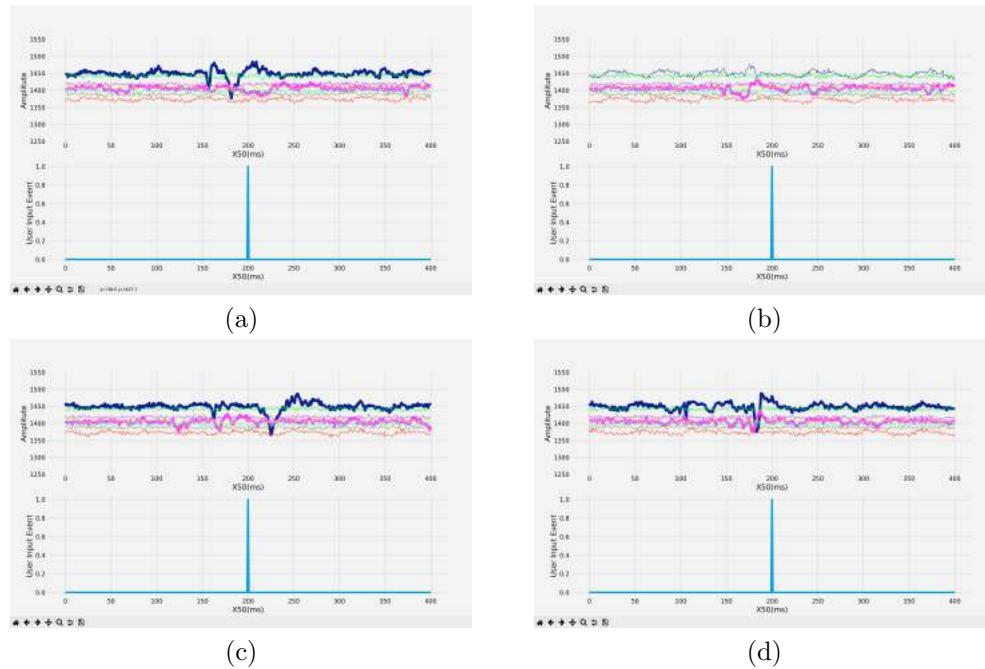


Figure 4.9: Mothers Perception and device data Capturing fourth set

changes were not captured with algorithm. This can have three different reason.

- the mother did not pay enough attention enough to press the button on the application, as the test was long enough for the mother to get distracted.
- the device could get a wrong movement
- the movement was small enough for the mother to not understand.

As the device was not compared with an ultrasound, every one of the mentioned list can be true. Figure 4.16 shows the parts that can be considered as a kick but the mother did not press any button for an input. In figure 4.16(a), both the light green line and dark blue had changed and this is a reason to pick this part as both lines have picked a movement. Also in figure 4.16(b) both the amplitude of both pink and green color have changed.

Table 4.1 shows the format of data which is captured with the Babykick device. All the data captured from the device are divided into nine rows. Eight rows for the eight sensors and the ninth row belongs to the mothers' perception. Based on the movements that happen during the test, the numbers of the first eight sensors can change. Every strong move will be saved with the larger number in the SD card. As the piezoelectric sensors have two-pole, the data is shown as a sin graph. It means the

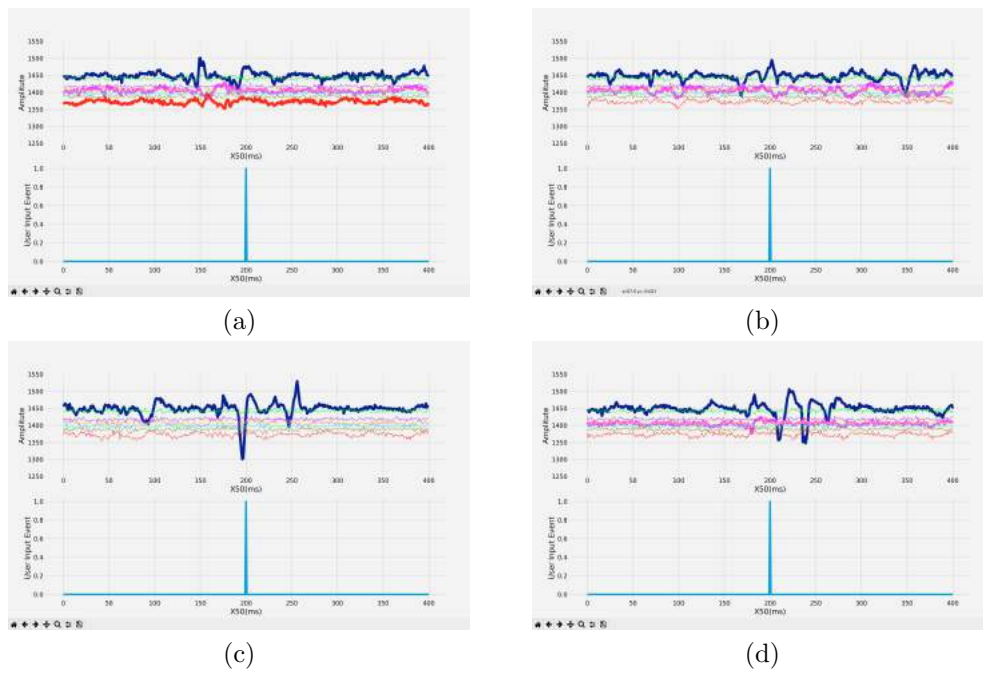


Figure 4.10: Mothers Perception and device data Capturing fifth set

graph with every movement can go higher and lower compared to the baseline. The numbers in the ninth row can be either zero, one and two. Number zero appears when the mother does not press any button on the android things application. Number one is for the time that the mother feels some movements, and number two is when the mother moves herself and makes some artifacts during the test.

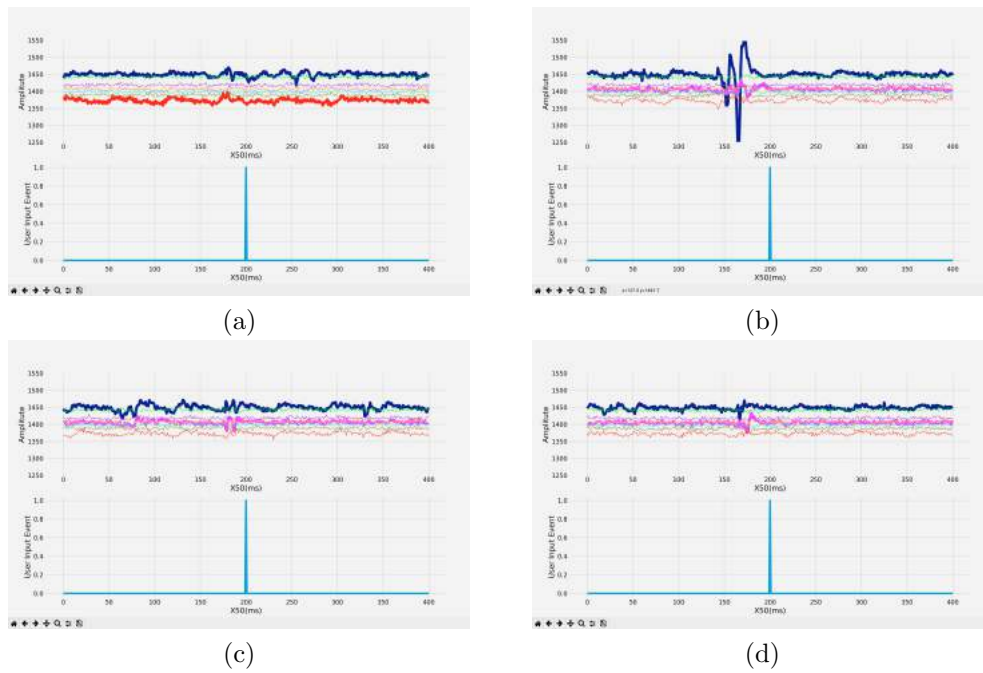


Figure 4.11: Mothers Perception and device data Capturing sixth set

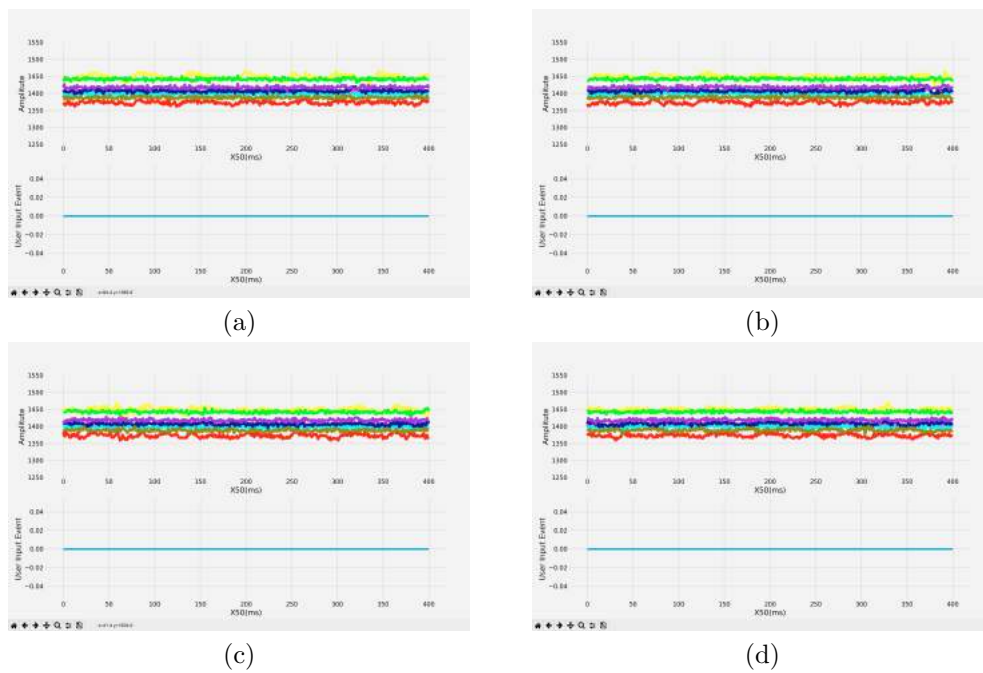


Figure 4.12: Data With NO User Input Event first set

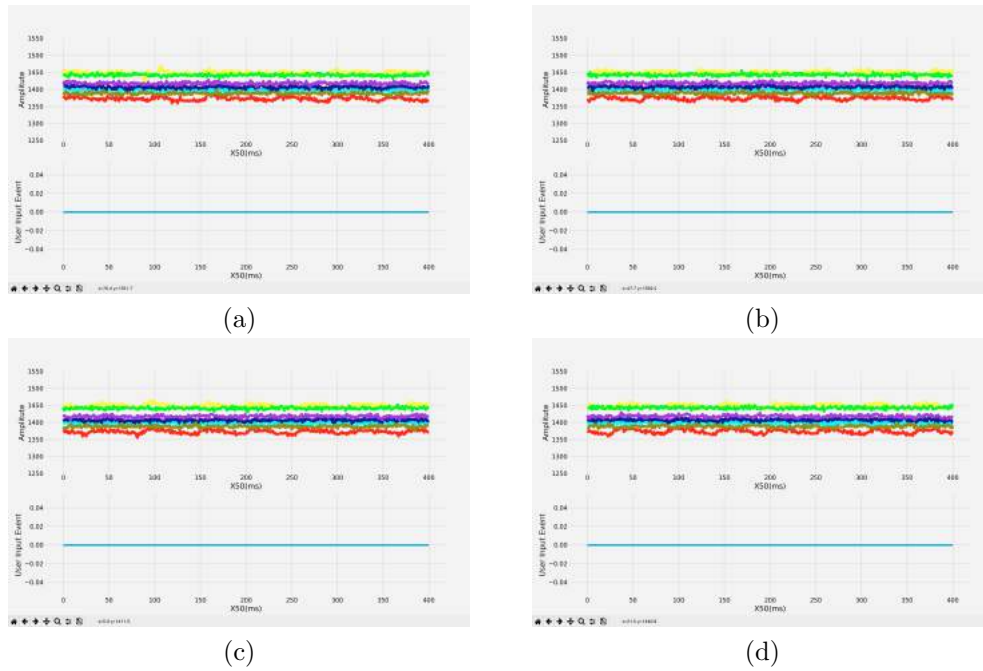


Figure 4.13: Data With NO User Input Event second set

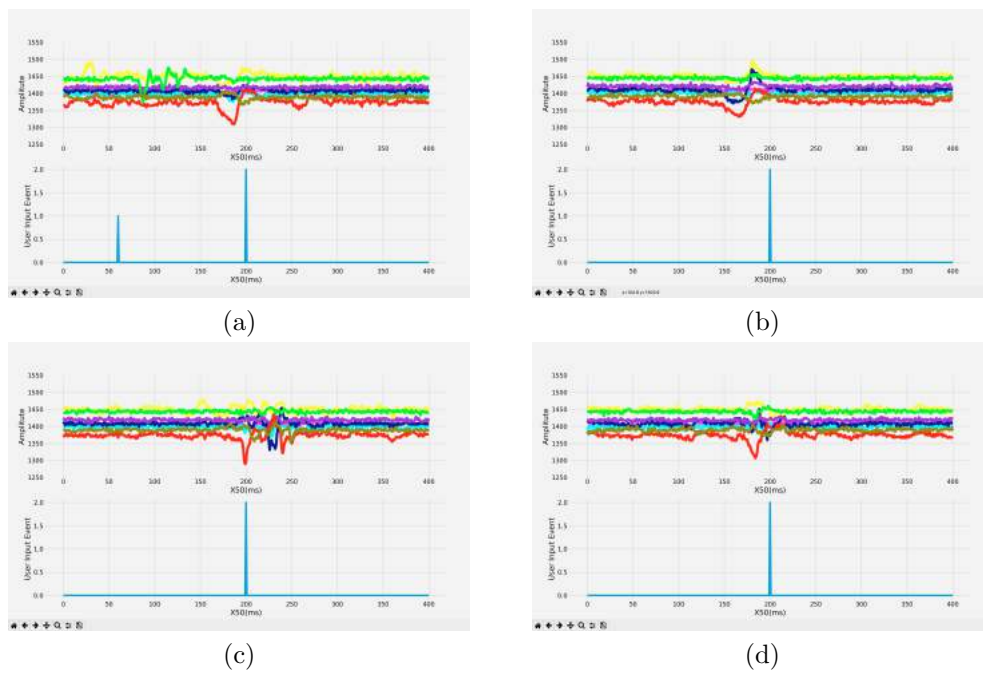


Figure 4.14: Data With mothers artifacts first set

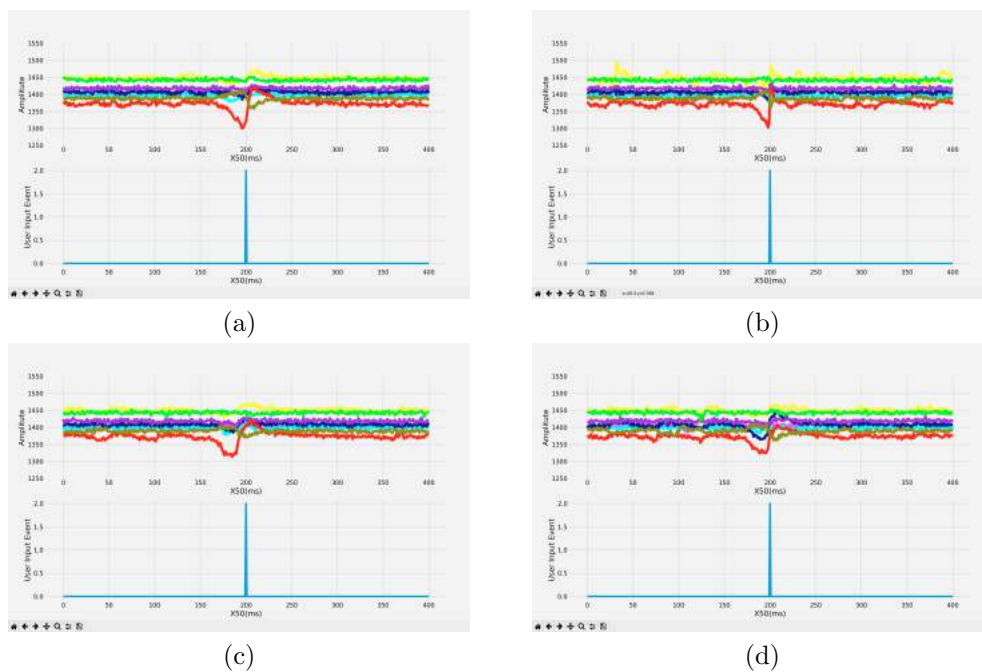


Figure 4.15: Data With mothers artifacts second set

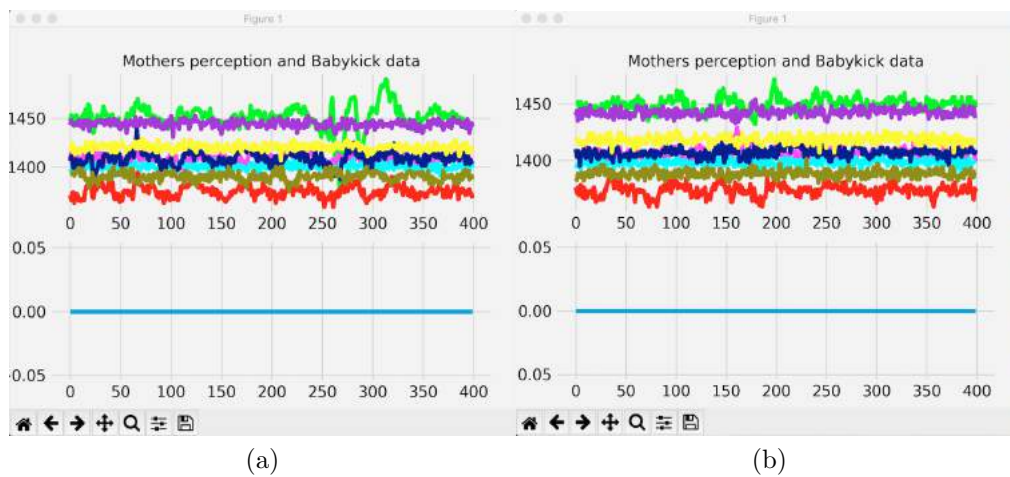


Figure 4.16: Not enough information to be labeled

Table 4.1: Table shows the eight columns of piezoelectric sensors data which come from the Babykick device and the ninth column is the user input. The result of the first sensor(first S) with all the other seven sensors are mentioned in different columns and the numbers are in millivolt(mv). The ninth column shows three different numbers which will be added to the SD card by the time the user press a certain button on the application. Number one means the mother pressed the "KICK" button when she felt the fetal movement. Number two means the mother pressed "SNEEZE" button when she moved herself during the test, and number zero means she did not press any button

First S	2end S	3rd S	4th S	5th S	6th S	7th S	8Th S	User Event
1446	1410	1391	1394	1410	1339	1444	1391	0
1011	1407	1402	1409	1424	1397	1433	1401	1
1469	1410	1400	1403	1419	1380	1443	1385	0
1463	1413	1400	1399	1416	1370	1441	1380	0
1468	1415	1403	1405	1421	1380	1442	1392	0
1221	1403	1398	1402	1419	1389	1433	1392	0
1438	1413	1399	1409	1417	1374	1444	1392	1
1435	1399	1411	1373	1423	1398	1450	1377	2
0999	1414	1391	1404	1424	1399	1435	1408	0
1507	1415	1402	1407	1421	1381	1441	1383	0
1494	1406	1397	1402	1417	1378	1440	1383	0
1496	1405	1397	1408	1417	1378	1442	1387	1
1491	1414	1399	1412	1422	1374	1439	1388	0
1481	1410	1400	1408	1424	1380	1442	1386	1
1477	1410	1397	1408	1421	1375	1442	1394	0
1459	1416	1398	1406	1421	1377	1438	1385	0
1459	1414	1399	1399	1422	1373	1440	1383	1
1463	1410	1398	1408	1419	1379	1445	1388	0
1464	1406	1402	1403	1420	1373	1440	1388	0
1455	1409	1394	1407	1418	1381	1444	1382	0
1435	1399	1411	1373	1423	1398	1450	1377	2
1496	1405	1397	1408	1417	1378	1442	1387	1

Chapter 5

Conclusion

The primary purpose of this master thesis was to develop a low-cost device to objectively measure active fetal movements in women, to reduce the global burden of stillbirth. Moreover, the research focused on helping women in more-resourced countries to be given this chance to use the device when they concern about the decreased fetal movements. The device is composed of a wearable device with eight piezoelectric sensors to record fetal movements from women's abdomen and further elaborations to extract this information.

5.1 Thesis main chapters

The research conducted by the author is divided into five chapters: the background, the technological(hardware) part, the software section, and the result with the ending chapter of the conclusion. The first chapter is allocated to the problem discussion. The problems that lack of oxygen can cause and reduced fetal movements can be a signal to avoid the problems. Also, the importance of tracking fetal movements and its effects were highlighted. Then the most popular ways to count the fetal movements were mentioned after providing some information about the importance of keeping track of the fetal movements. As it was described, the most popular ways to count fetal movements are the mothers-to-be perceptions and ultrasound. As the first method relies on different factors such as the pregnant person's level of attention or her experience in detecting fetal movements, it may yield unreliable measurement. Utilizing the second way has its own downsides; for instance, the usage of the device is limited to the clinic visits. Also, diagnostic medical sonographers are expected

to be in the ultrasound rooms, which makes these appointments more expensive. Another reason is related to the thirty minutes of every ultrasound session, which is less than a fetal sleep-wake cycle. This way, there is a chance to lose some critical information. The reason behind developing the Babykick device is to enhance the Chance of counting continuous fetal monitoring. The last important reason behind developing the Babykick device was to send the device to developing countries, where there are no hospitals with modern devices such as Ultrasound. The second chapter is about the development of the hardware part of the device with all its difficulties. While the overview of the chapter was outlined, all the details of developing the hardware part of the device to have the small, user-friendly and portable device were mentioned. The actual signal, which is captured from the device with the help of eight piezoelectric sensors, was sent to the micro-controller for further processing, and the data will be saved in the SD card of the device, and also it will be transmitted to the phone or tablet. The result will be compared with the mothers' perception. The components selection was another important stage in the hardware chapter since the features that were expected from the Babykick device had to be delivered. Choosing BL652 was one of the most important decisions as it has all the features of nRF52832 micro-controller, and also its Inter-Integrated Circuit gave the Babykick device a chance to be manufactured. One of the advantages of the Babykick device over its competitors is its battery performance. The battery can guarantee up to 24 hours of battery life even with the usage of Bluetooth Low Energy which consumes battery. The reason of Babykick being low power consumption is not only because of the components, the code and its programming plays an important role as well. The actual hardware of the device consists of two parts, one is the compact device and the other is the belt. Three generations were tested and the 3d-printed version was the winner as it was flexible and light-weighted. The preprocessing of the data is with the help of the analog circuit, which was described in the second chapter. In order to have a compact device, designing the PCB was another stage in the process of developing the device. The PCB had to be big enough to cover all the eight circuits of the analog part and also other components and also small enough to be considered as a portable device. To reduce the noise, the PCB has two layers. Bluetooth Low Energy was another advantage of the device. This feature gave the Babykick device a chance to send the data to the phone in real-time. The third chapter consists of the software part of the device, where human and computer interaction occurs. As the application gives the user the first impression, we had to be more careful. As iOS AND

ANDROID are used by a lot of people, and it could give the users a chance to be more familiar with these two, there were the target platforms in developing the Babykick device. The android application was considered for the data accusation and testing, and the other one was developed for future possibilities and commercialisation. As these two applications had to have their own specific features, the user interface of the applications was not similar. Swift and java were used to develop the applications. As the android things was chosen to be sent to the volunteers, the development of the device's outer shape was another necessity, which was done with the software called SOLIDWORKS. In the fourth chapter, the one hour of data that was captured from the volunteer with the Babykick device, and also the protocol that had to be followed in order to record the data, were described. The user manual had to be described in detail as the device had to be sent to their houses as COVID-19 happened with all its restrictions. In order to find the volunteer, some features had to be considered, as it was the first time that the Babykick device got tested. During the one hour of the data accusation, the mother had to sit, and she had to press the "KICK" button on the application when she felt any movements from the fetus. Another user input was the button called "SNEEZE", which had to be pressed when the mother made some motion artifacts herself. During the test, the mother felt thirty-seven movements, and the device could get all these movements. The pictures of this one hour of data are placed in the fourth chapter. The Babykick device also could get all the motion artifacts that happened during the test. In some parts of the device, we could see some sensitivity among some of the sensors; as the mother did not give us any input, it can not be considered as a kick or any fetal movements. To test the device in future, it is better to add ultrasound results to the mothers' perception.

5.2 In conclusion

The draft of this thesis has described the entire development from the beginning to the end. This compact wearable device is the smallest working device that can be used by mothers-to-be in the comfort of their own houses without the usage of any expensive technologies. This way, they will be more relaxed and it can be the best solution for their concern about decreased fetal movements Also, the circuit of the battery is designed in a way that can be used for more than couple of hours. Although the mother should not make sudden movements for now, she can use the device in their own comfortable spaces. Babykick device is not only the simplest and cheapest

way to capture the fetal movements, it also opens a window to the pregnant abdomens to give mothers and doctors extra information about the fetal in long term. Hopefully it can improve the existence of knowledge on fetal behaviours in total and give the doctors information to reduce the rate of still birth. As Babykick is a non-invasive device and does not have any danger for the user, it can be used several times and the user can increase the monitoring sessions without any fear. As mothers are more worried about the fetal situation in the final stage of gestation, Babykick can be considered as an extra option to give them tranquility. Moreover, the usage of cheap components makes Babykick device an affordable device for the majority of women. Users with average income can easily purchase the device and enjoy this amazing period of their lives more. Using this device also decreases the overall hospital visits especially in the COVID-19 crisis. The device could get all the fetal movements that the mother labeled during the one hour of data accusation and also it could get one hundred percent of the mother's motion artifacts. Overall, the Babykick device can improve the quality of care for both mothers and fetuses.

5.3 Future developments

Like every other research, there are a lot of work that can be done to make the device better, even if the result are interesting. This device initially designed for in-facility monitoring. To use this device the pregnant woman has to sit and perform the test. In future it is better to work on eliminating the motion artifacts and make it ready for long-term home monitoring. Another feature that has to be added to the Baby Kick device is a real-time application. Although the user can see the graphs on the application, there is no immediate access to the data. It is suggested to change the application in a way to have immediate access to data.

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