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Executive Summary

High Risk Pregnancy, a condition that affects almost 10% of pregnancies, is when the mother has a pre-existing condition, that puts the mother or fetus at an increased risk. These conditions include: heart disease, high blood pressure, autoimmune disorders, diabetes, women under the age of 17 or over 35, etc. High risk patients must receive extra care from their physicians, through extra doctor's visits., which can increase the financial burden.

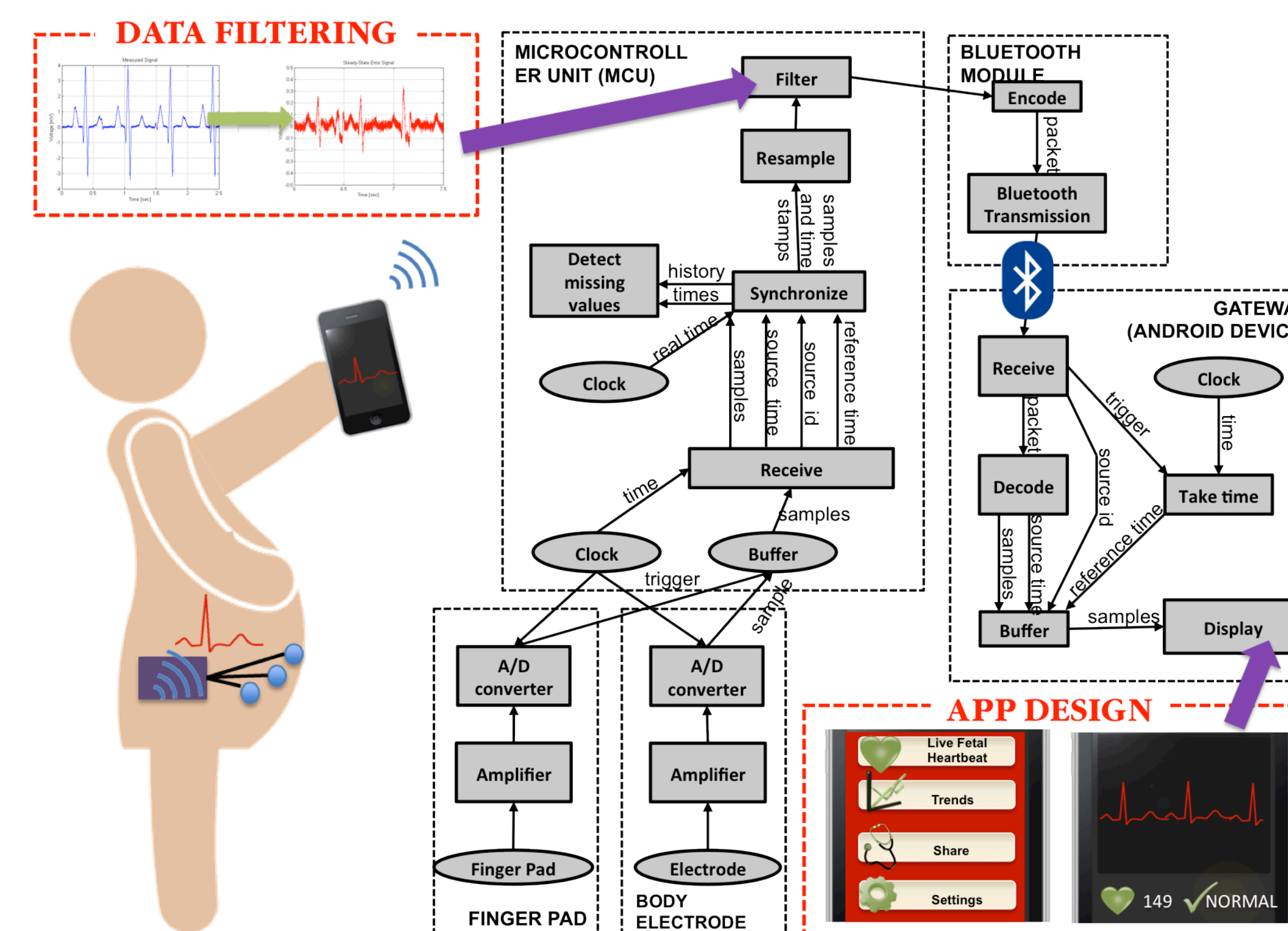
Currently, internal and external fetal heart monitoring does exist, however there are significant issues with both. Internal monitoring is invasive and risky, so doctor's only perform this procedure when necessary. External monitoring, such as a Doppler, is only capable of providing an audible heartbeat, not an ECG pattern.

Our device is mobile and easy to use at home. With ECG leads attached to the mother's stomach, an ECG signal is transmitted to a microcontroller, and then to a mobile device application. The user is able to look at their fetus's heart rate on the screen, save the data for their doctor's viewing later, and be alerted if the fetus's heart rate is abnormal.

The device is very safe as it uses only standard components: ECG leads, Bluetooth, and Mobile technology. This device is ideal for mothers with high risk pregnancy who want an added monitoring system for their child.

Description of Design

Overview:



Novelty

Current Fetal Heartbeat Monitor

- Internal and External (Doppler) Monitor:
- External only displays a beat per minute [1] and does not show actual EKG signal
- Internal does provide more accurate data but is very risky and can only be used when the cervix has dilated and the amniotic sac has been ruptured[2]
- Only can be done in doctor's office; inconvenient to do regularly
- Devices are bulky
- Monica AN24 Device:
- Semi-wireless
- Collects real-time electrical signals using ECG-style electrodes [3]
- Only can be done in doctor's office; inconvenient to do regularly
- Mainly uses during labor and delivery

Baby Beats

- Collects real-time baby's heartbeat signal using 3-lead ECG-style electrodes
- Can be used after two months of pregnancy
- Reports any abnormalities or deviations from common trends
- Non-invasive
- Accuracy
- Sufficient alert time
- Mobility
- Physically convenient
- User Friendly

Problem and Clinical Need

Problem: There is currently no convenient way to monitor a fetus's vital signs without going into the doctor's office. This can cause stress & anxiety for the mother, which can lead to other complications within the pregnancy.

Intended Patients: 'High-risk' pregnancy patients. Currently in the US alone, at least twenty percent of pregnancies fall under this demographic.

Advantages:

- Security of knowing the fetus's heart is developing properly
- Allows mother to avoid pricey & out of the way doctor's visits
- Easy to understand user interface, available for use at the mothers convenience

Market Description

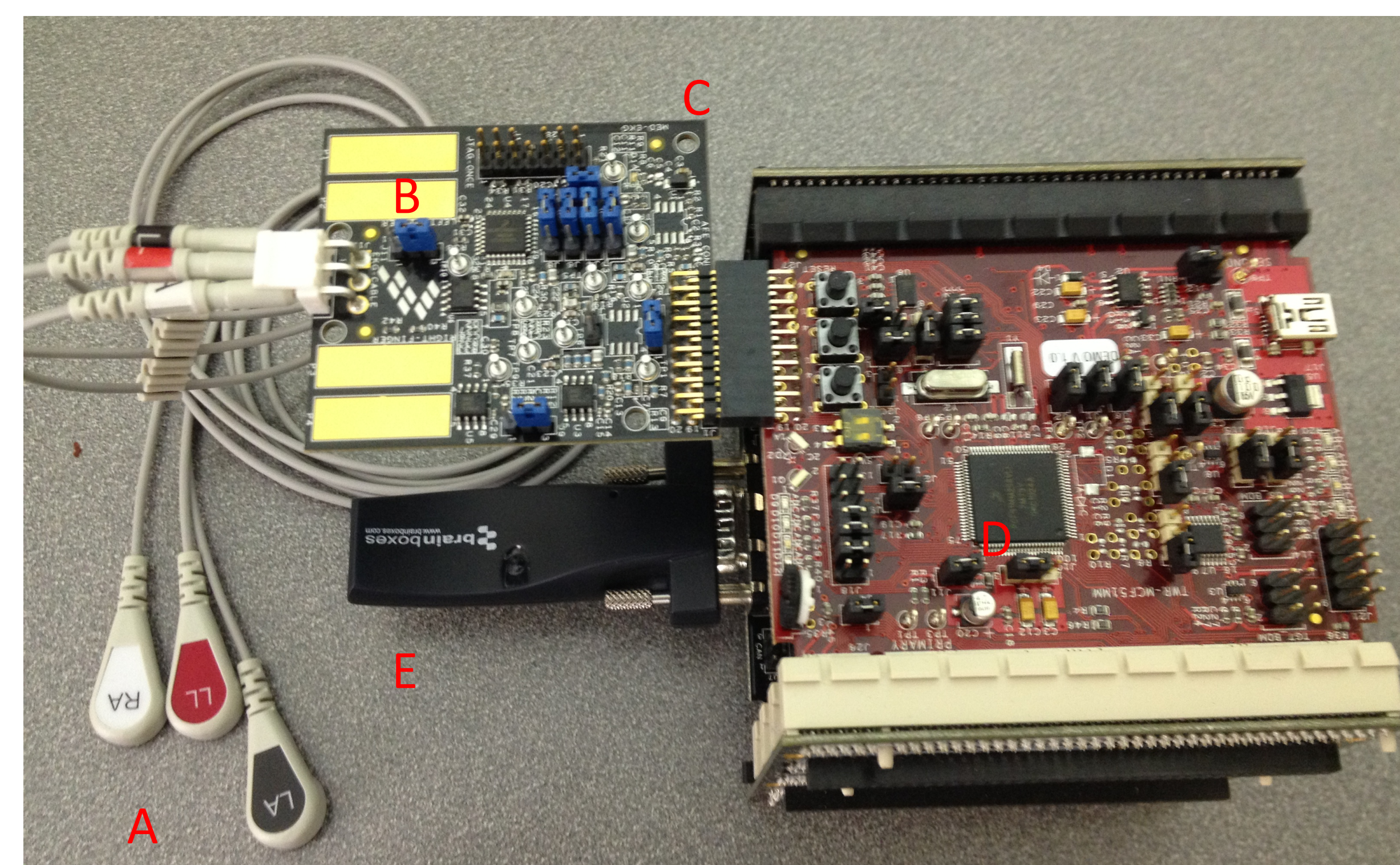
With over 80% of women pregnant at some time in their lives, in the United States alone there are an estimated 4,000,000 pregnancies every year. The Center for Disease Control says that "at least one in five women are obese when pregnant." [1] Other factors that classify woman as high-risk include: heart disease, high blood pressure, autoimmune disorders, diabetes, woman under 17 or over 35, woman who have had 3 or miscarriages, along with various other ailments.

Almost three-fourth of women surveyed responded positively to the thought of an at-home monitoring system, describing interest is using this device if it were to be on the market. One woman even commented to the thought of the device by saying "I would have no hesitations. Although, I would have used it non-stop! It would have prevented my need for stress tests at the doctor's office. I had them quite a few times because my son hardly moved." [2] The potential market for an at-home monitoring system could not only target woman in the USA but around the world. In this day and age, smart tablets and phones are becoming the forefront of medical technology and could help millions of people.

Estimation of Product Costs

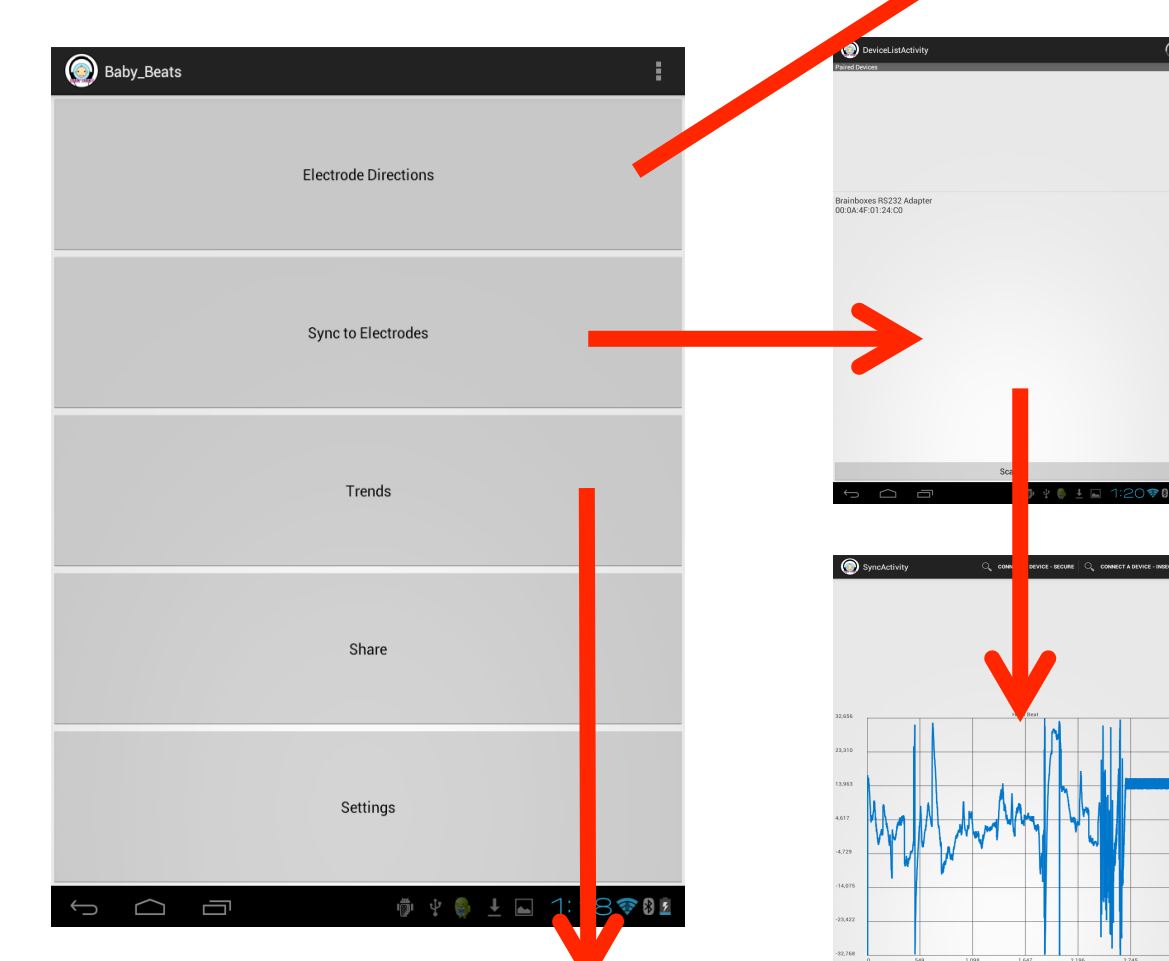
Part	Required Amount per device	Bulk Cost	Cost/Unit
3-lead Electrodes	1/device	\$120.00/10	\$2.00
MCU Circuit Board	2/device	-	\$4.00
Fabricating the circuit board	1/device (5cm x 5cm)	\$200.00/150 of 25cm ²	\$1.33
		Total Cost per device (w/o Labor)	\$11.33

Hardware:



A	ECG Leads	Attach to the mother's abdomen to collect the analog voltage, which include the mother's heart beat, fetal heart beat, and noise
B	Finger Sensing Pads	Mother presses her thumbs against these pads to collect the analog voltage of the mother's heartbeat and noise.
C	Analog Front End	Grabs analog signal from A and B (above), converts it into a digital signal, and sends it to the Digital Signal Controller on the MCU.
D	Microcontroller Unit	MCU completes noise removal, adaptive filtering to find the fetal heart rate and then sends the signal to the Bluetooth Module.
E	Bluetooth Module	Establishes the Serial Port Profile (SPP) connection with the user's Android device, and signal's sent in 64 byte packets

Software:



As the data is read from the input stream it is written to a file which is saved on the application. When the user navigates to "Trends" they will be able to view the last recorded data session.

Gives the user instructions for applying electrodes and using device

User is prompted to select a device to connect to. The first time the user connects to the bluetooth module on the heart rate device, they will be prompted to enter a device-specific pin. After that, the device will be "paired" and the user can easily sync to it.

Once the application is connected to the device (through Serial Port Profile), it creates a "Connected Thread" and reads bytes from the stream. A buffer reads the bytes into short integers and adds them to an array of GraphViewData which will be displayed on the screen live. The data visually scrolls across the screen.

Anticipated Regulatory Pathway

•Class II Medical Device

•The device utilizes safe technologies already in existence: Mobile and Bluetooth

•Baby Beats is similar to a device that already exist in the market: Monica AN24, therefore a 510(k) process is appropriate.

•Needs FDA Clearance

•Requires Clinical Studies

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