Ergonomics of Cardiotocography

By Pengxiang Hu, ECE '16

Medical devices are designed for myriads of purposes: many are used to monitor body metrics, while others are used to perform surgical operations. Cardiotocography (CTG) is a diagnostic technique used to monitor a pregnant mother's uterine contractions and the heart rate of her fetus. CTG-based devices must adhere to an exceptionally stringent set of requirements, involving safety for both mother and fetus, comfort, and privacy. Such devices also must enable physicians to diagnose fetal health remotely and to provide medically-sound advice to mothers; thus the presentation of information is also an important design consideration. The Azure Team considered all these factors in its design of a fetal monitoring wearable device.

Introduction

Cardiotocography (CTG) is a technical means of recording fetal heartbeats and uterine contractions during pregnancy, especially during the third trimester and labor, in order to assess patients with certain high-risk conditions for which antepartum fetal surveillance is indicated. The goal of this antepartum fetal surveillance is to prevent fetal death. Combining both the measurements of uterine contraction and responsive fetal heart rate, CTG can help medical practitioners deduce the adequacy of fetal oxygenation, potential congenital heart malformation, maternal fever, and fetal infection (Figure 1).

The Importance of CTG Ergonomics

With regards to the ergonomics of CTG, we are talking about the integration of design principles from a variety of disciplines. A good design with thorough ergonomics consideration not only enhances the utility and usability of CTG but also improves the fundamental functionality of the device. Before delving into the details of CTG ergonomics design, we need to clarify that all design must focus on the *functional* purpose of the device: in this case, to monitor the fetal heart rate and uterine contraction accurately and efficiently.

Thus the first principle of CTG ergonomics is accuracy. Traditionally, CTG fetal monitoring is done via an abdominal Doppler on the mother or fetal scalp electrode on the baby. Even though this technique is highly sensitive and good at detecting true positives, it also generates many false positives. As a result, CTG needs to be complemented with other techniques such as fetal blood sampling to identify metabolic acidosis in the baby. These additional processes are intrusive and add risks of fetal infection. Thus the first design principle is to enhance the ratio of true to false positives and to give more accurate evaluations of the health status of the fetus.

Second, patient psychology should be emphasized. Since a CTG device deals with a very sensitive and important topic, namely the health and safety of the fetus, parents

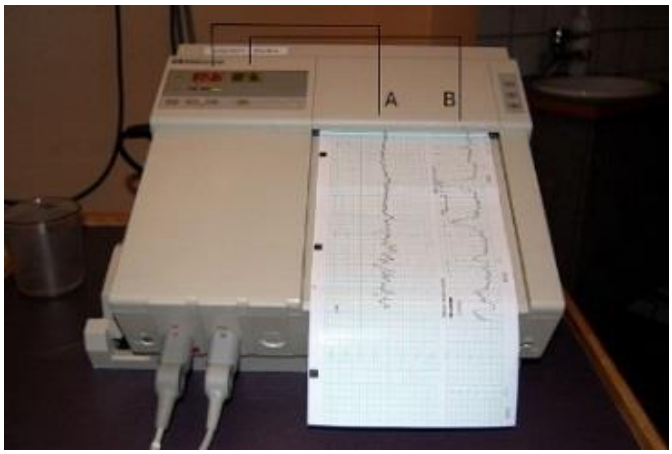

Figure 1: CTG reading print-out. A is the fetal heart rate, B is the uterine contraction signal. Both signals are plotted in the time domain

would naturally consider any related issues with tremendous seriousness. Thus, when rendering detected fetal information on the graphical user interface (GUI), we engineers must present the information carefully and with a view to deterring panic. A misleading interface exposes the device manufacturer to liability.

Another important ergonomics issue is the physical design of the device and its impact on the patient's physiology. Considering the inherent nature of CTG, pregnant women will be wearing our device for a significant amount of time every day. Long durations of consistent skin contact can be a huge challenge for wearable device users. First, the device shouldn't cause physical discomfort or else patients will be repulsed by putting it on and then its entire purpose would fail; Second, skin in the abdominal areas can be very sensitive and prone to developing allergic rashes when they have contact with unfriendly materials for even only a while; Third, the human body secretes grease and sweat that can corrode CTG devices and shorten their life span.

While many other such as mobile device communications and custom user behavior are important, for the purposes of illustration, our discussion here focuses on the two main stakeholders: mother and doctor.

Ergonomics of CTG for Patients

As mentioned earlier, patient psychology bears great importance in CTG design. As the owners of their own medical data, patients normally should granted access to their own vitals and diagnosis. However, because people aren't always rational during emergencies, the presentation aspect of CTG data should be carefully designed. According to Ross (2003), promoting patient access to medical records can lead to side effects such as increasing anxiety or confusion. In fact, 11% of medical outpatients reported "upsetting feelings" after reading their records. For obstetric patients especially, a nonrandomized controlled trial reported that 23% found the records "difficult to understand or worrying." In the Azure Team's experiments with real time fetal data, the attention that expectant mothers pay to their fetuses only increases their concerns. Thus it is advised that once a potential emergency is detected through a CTG device, medical professionals should contact prospective parents immediately to explain the situation and offer guidance or else encourage more frequent visits and tests.

Despite the negative reactions to reading their own data, the majority of patients in Ross's study reported that reading their medical records educated them about their medical condition and improved their communication with their doctors (Ross & Lin, 2003). In fact, 80% of the patients reported that access to records gave them more confidence in their doctors and made them feel better understood.

The Azure Team can translate the above results to a more sophisticated mechanism for our CTG device. Instead of blocking patients from the stern diagnostic result, doctors can be granted power to release the patient access to their records if doctors can make sure that the mothers are well educated on the topic and can respond calmly and perfectly to the specific type of medical emergency.

Physical comfort is an equally important aspect in ensuring the efficacy of a CTG device. This includes the material of the touching device and orientation of the sensor on mother's abdominal area. The EMG and FECG sensor should be enclosed in a smooth and flat shaped closure and close to abdomen to ensure that the weight of the device is equally distributed. As for contact material, electrode gel pads are responsible for picking up signal from the surface of abdominal skin. The pads are designed to work with human skin and should not cause any allergic reaction. Moreover, they are designed to last around 30 days once taken from the sealed packaging they arrive in (*3M Red Dot Multi-Purpose Monitoring Electrode, Foam, 50/bg*, n.d.). Thus theoretically, people should be able to take accurate sensor readings for as long as 30 days with one set of pads. However, regular replacement of the gel pads is recommended because continuous wear and damage can cause the electrodes to pick up more artifacts.

The taping of sensors on mother's abdominal area should maximize the comfort and minimize the noise interference. Since this device is applied to pregnant

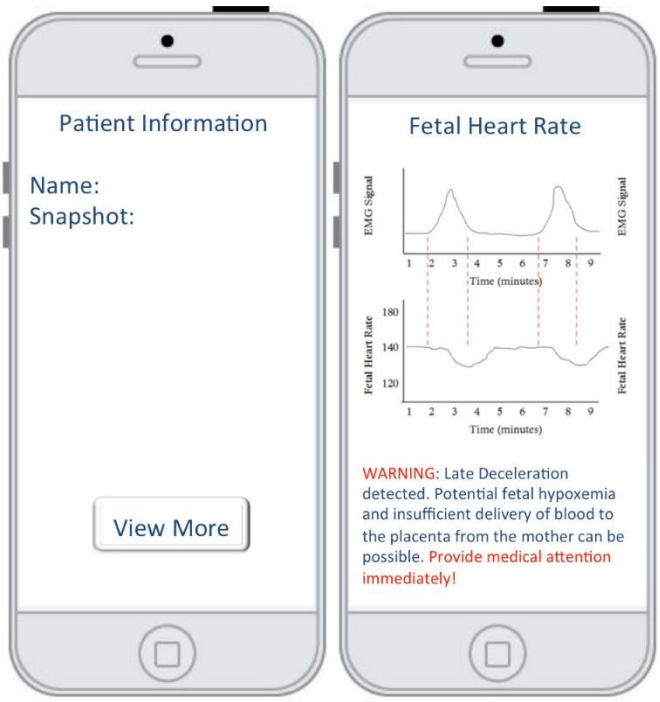

Figure 2: Device interface for fetal monitoring.

mothers in their third trimester (between week 27 and the onset of labor), the fetus usually is of significant size and prospective mother's abdominal protuberance is very specific to work with. The most common fetal position during third trimester pregnancy and before labor is the head facing downward position (Mayo Clinic, n.d.). This implies that the heart of the fetus is also located on the lower part of the abdomen and around navel area. However, based on the specific baby settling position, we recommend mothers to place the electrodes closest to babies' hearts for most accuracy. The ground reference should be around the side pelvis bone because it has the least amount of muscle electric potential interference.

Ergonomics of CTG for Doctors

The Azure Team's device should give doctors full access to all medical data to help the diagnosis. First of all, summaries of the data should be available to give snapshots of the medical situation. Along with the summaries, data details and highlights should be presented to support the diagnosis. This will free up precious time for making sound judgments by avoiding dig through all the minute details. Doctors will also be better informed about medical situations or emergencies before encountering patients and this will reduce the delay time in starting secondary testing and medical treatment.

The device will also provide doctors with the option to view only factual data from the sensor detection if they want to avoid the preconceptions that an automatically generated diagnosis might induce.

CTG software for doctors should present diagnostic data in a clean and concise interface to facilitate doctors' decision making. The software should present the highlights of heart rate and uterine contraction waveform as well as access to all recorded data in case the doctors need more confirmation. The waveform presentation should be constructed to mimic the presentation generated by current CTG technology (Figure 2) so as to encoruage doctors to adopt this new technology. The software design should follow Apple's Human Interface Guidelines in order to make the inferface as intuitive as possible.

References

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