Garment design for an ambulatory pregnancy monitoring system

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Garment design for an ambulatory pregnancy monitoring system

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Abstract. Constant pregnancy monitoring is a promising alternative to reduce the number of stillbirths and preterm delivery due to false alarms. Tele-monitoring systems can provide regular, accurate and timely monitoring to reduce risks, costs and the time the mothers-to-be spend at hospitals. A smart garment integrated with sensors and a flexible printed circuit board for ambulatory pregnancy monitoring is proposed. A study was conducted to gather user requirements to ensure comfort during long registrations of Fetal Heart Rate (FHR) and Electrohysterogram (EHG). Based on those requirements, several garment alternatives for the monitoring system are proposed and evaluated.

Keywords: Pregnancy monitoring, user research, body area networks.

1 Introduction

Assessing fetal well-being during pregnancy and labor is a priority to reduce the number of stillbirths and preterm deliveries due to false alarms. Around 3 million annual third-trimester stillbirths occur around the world [1]. Moreover, the counts might be underestimated, as stillbirths are often not counted nor included in the Global Burden of Disease. Most of these stillbirths occur in low-income countries where interventions in the maternity care are not enough. In high-income countries the rates of stillbirths have been reduced in since 1940, but the improvements have decreased in recent years [2]. To effectively identify fetal distress and to ensure timely interventions, screening tools for fetal well-being can be used. These tools include fetal movement, heart rate, fetal growth, among others. Currently, pre-existing or pregnancy related medical conditions are predictors of high-risk pregnancies [1]. In the Netherlands, obstetric care differs for low- and high-risk mothers. Low-risk pregnancies are handled by the primary care system, with the help of midwives. As soon as a high-risk situation is identified, mothers-to-be are referred to the secondary care. Most pregnant women are scheduled for regular screenings, regardless of their status. If complications arise, they are referred to secondary care for additional checkups. Within this system, women at low-risk in the primary care have a greater risk of prenatal dead than those at high-risk who deliver in the secondary care. Furthermore, mortality increases with transfers between primary and secondary care. A potential explanation is that fetal distress is not detected on time [1], [3]. Hence, tele-monitoring might prove to be a good solution to provide a timely alert of fetal distress by letting future mothers monitor the progress of their babies at home, without increased risk or discomfort.

Previous work has proven the feasibility of such tele-monitoring systems. First, tele-monitoring of pregnancies at risk would imply a considerable cost-reduction per year [4]. Second, patient-directed FHR monitoring and transmission is successful with high level of satisfaction from the patients [5]. There are even some commercial wireless pregnancy monitors, such as the Avalon CTS Cordless Fetal Transducer System [6], the Monica AN24 monitor [7], and the Remote Fetal Monitor [8]. From these, only the last two aim at home usage. They consist of a big and cumbersome-to-carry handheld device to which the sensing electrodes are attached using wires. Ideally, the monitoring device is not only to provide accurate monitoring and timely identification of possible complications, but also, to ensure the comfort of the mother while doing so. In this sense, the Telefetalcare monitor [9] improved the user experience by using a textile belt with eight ECG leads attached to the fabric. However, its battery life is still limited and the garment is prone to motion artifacts. Therefore, there is still room for improvement in the development of a portable monitoring system.

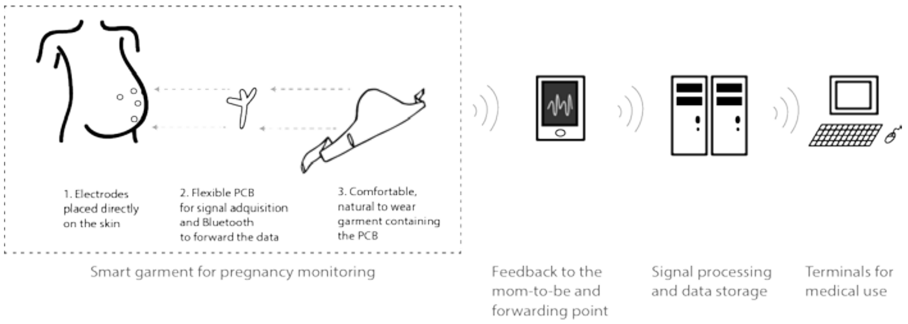

Figure 1. Diagram of the system architecture

2 System concept

Smart Energy Body Area Sensor Network (SEBAN) is an ongoing project. Its goal is to create a wearable with an integrated fully wireless electronic system (Figure 1) which continuously monitors the progress of pregnancy at home. Its safety will be ensured by keeping the wireless communication within the recommended Specific Absorption Rate (SAR) levels[10], and using it only on battery power. It will use an energy efficient amplifier as described by [11]. The data gathered will be sent to the mobile phone of the users with low-power Bluetooth 4.0. On the phone, moms-to-be will get information about the status of the unborn baby. Furthermore, the phone will be used as forwarding point for the data. The data will be transferred to a back-end server where additional signal processing will be performed. The outcome of the monitoring will be accessible by terminals at the hospital, so that caregivers can assess it and take the necessary actions in case of an emergency. Moreover, five electrodes placed directly on the pregnant belly skin will be used. Solid-gel sticky electrodes are chosen to have a good electrode-skin contact, and thus, reduce motion artifacts. They will be optimally arranged [12] for measurement of FECG and EHG during the last weeks of pregnancy. With this, the system aims to have an increased robustness against signal loss due to constant changes in the fetal position.

3 User requirements

Several user needs were identified by user research. The main goals were to (1) identify opportunities of improvement in the current monitoring process; and (2) elicit the experiences they have with garments for pregnancy such as support belts. Finally, it was also asked (3) feedback about initial prototypes, and the (4) type of wearable they would like to have. This information led to several user requirements.

3.1 Methods

Participants
Six pregnant women (average gestational age = 31.8 weeks, SD = 5.17) and two women who recently had a child (less than 3 months after delivery) were interviewed. The average age of the participants was 31 years (SD = 3.4).

Procedure and analysis
To help participants elicit their previous experiences and better imagine the possible use of the monitoring system at home, in contrast with the hospital, a semi-structured contextual inquiry was conducted. Five women were interviewed at their home, and three were interviewed at the hospital, where they were admitted for diverse reasons. Hospitalized women had Cardiotocographs (CTG) at least once a day, and the interviews took place during this monitoring time. Techniques proposed by the co-constructing-stories method were also used. In the sensitization part of the interviews, the questions addressed goals 1 to 3. In the elaboration phase, the concept of the ambulatory monitoring system was introduced and illustrated with paper and fabric prototypes. The questions encouraged participants to provide feedback on the concept and to propose desired solutions. The analysis was done with affinity diagrams.

3.2 Results

The results indicate that the current monitoring system is satisfactory for low-risk pregnant women. They go to their scheduled checkups, which include Ultrasound and FHR monitoring. In case of an unusual event, they are referred to the hospital, where CTGs are more common. The monitoring devices are, in general, comfortable. Women appreciate the information provided by their caregiver and the opportunity to make questions. Also, they expressed that looking at the baby through the ultrasound is pleasant, and it is always reassuring to know that the baby is healthy.

> *"It is a long time between the 8, 12 and 20 weeks ultrasound. For me it would be more comforting if I had this visual image [of the baby]more often." - Participant 3*

On the other hand, they dislike the coldness of the gel used to improve conductivity; the tightness of the CTG bands; difficulty to find a moving baby with the CTG; and the long time it takes to make a good registration.

> *"The CTG would be better if the monitoring times were shorter. I do not like to lie down without moving. If I want to go to the toilet I have to call the nurse to unplug me." - Participant 7*

Most of the participants experience uncertainty about what is happening to their body. They constantly seek more information with relatives, caregivers, online or in books. Women, who had complications in this or previous pregnancies, also expressed that they would like to have extensive checkups more regularly to be sure the baby is alright. However, the low-risk mothers-to-be were also aware that excessive information can cause more worries than needed.

Required characteristic for the monitoring system were that it should: prevent uncertainty; provide a sense of safety and control; increase the bond between mother and baby; and reduce time at the hospital for monitoring. The system feedback should include information about: correct position of the sensors; auditory feedback with the sound of the FHR; a visual image of the baby and his/her status; differences between sensors in case of twins; fetal movement levels; the correct registration of the measurements and their transmission to the hospital; and have timely, noticeable alarms in case of fetal distress. Finally, the wearable should be: unnoticeable to other people; easy to combine with other clothes; a shirt or a belt; soft, elastic, not warm or "sweaty", non-sticky, and not heavy. The wearable also should: allow movement of the mother; provide clear instructions for use; allow to easily find a moving baby; have non-sticky electrodes; and have the ability to grow with the belly.

4 Garment Design, Prototyping and Evaluation

The garment consists of two parts: the soft-fabric wearable and a flexible Printed Circuit Board (PCB). The PCB contains five female Anorak snaps to plug the electrodes without wires; and the electronic system to filter, amplify and transmit the data to a mobile device. The fabric wearable aims at providing a comfortable, natural wear whilst ensuring that the sensors are firmly in place, therefore reducing possible motion artifacts. The integration between the PCB and the garment should reduce movement in the sensor-skin contact and let the user remove the PCB during washing.

4.1 Printed Circuit Board

The PCB was designed to meet the sensor distribution requirements [12]. Its substrate (DuPont Kapton polyimide film) is flexible only in one direction, which makes it difficult to adapt a squared PCB to the round pregnant belly shape. Therefore, a star-like shape was designed (Figure 2a). Its advantages are that (1) the shape can be bent to follow a round surface; (2) it is less uncomfortable and noticeable to third persons; (3) the electrodes connect directly to the PCB with the correct distribution; (4) the filters/amplifiers can be placed near to each electrode to reduce environment noise; and (5) there is enough area to place all the required electronic components.

Figure 2. (a) The PCB shape in a Kapton polyimide film, attached to fabric using Anorak snaps. (b) Double layer with mesh fabric to adjust the PCB in the Wrap top.

4.2 Garment

Based on the requirements, four prototypes were developed and evaluated (Figure 3).

Figure 3. Garments, from left to right: Belly band, Belly belt, Wrap top and Shirt.

Garment	Garment type	Adjustment type	Material	Color
Belly band	Band	Closed garment	Cotton span	White
Belly belt	Band	Open garment with wrapped closure secured by a knot	Lycra	Black
Shirt	Shirt	Closed garment	Knitted cotton structure	White
Wrap top	Shirt	Open garment with wrapped closure secured by hooks	Lycra	White

Table 1. Garment description

The type of garment and the type of adjustment for different sizes were varied among shirt, band, open, and closed, to test which one was preferred (Table 1). Shirts are more natural to wear, whereas bands are easier to fit different belly sizes. In contrast, open garments allow tightness adjustment according to the gestational age, while closed garments are easier to put on. Another advantage of open, wrapped garments is that they provide multiple layers of fabric. Thus, the PCB can be placed in between them to prevent its contact with the skin. A mesh fabric was used in the inner layer to let the electrodes be placed directly on the skin, followed by the mesh fabric layer, the PCB, and finally, by a layer of regular fabric. This was also implemented in closed garments using bags (Figure 2b).

4.3 Evaluation

The aforementioned prototypes were evaluated to select the best features of each one, their comfort and their usability.

Methods

Participants
Five pregnant women (average gestational age = 27.8 weeks, SD=2.38, average age = 32.2, SD=2.78) participated in the evaluation. Four of them evaluated the prototypes at the hospital (high-risk), and one of them (low-risk) did the evaluation at home.

Procedure and analysis
The low-risk participant was considered as a pilot, and therefore she tested only one prototype: the shirt. The rest tried three prototypes (i.e., Belly band, Belly belt, and Wrap Top). Each prototype was provided with a set of instructions (Figure 4) on how to wear it. They were asked to wear the garment without help from the facilitator, and to think aloud during the process. After the task, a semi structured interview was conducted. It covered questions about wearable features (fabric, color, type of wearable, PCB – garment integration, usability, and desired frequency of use).

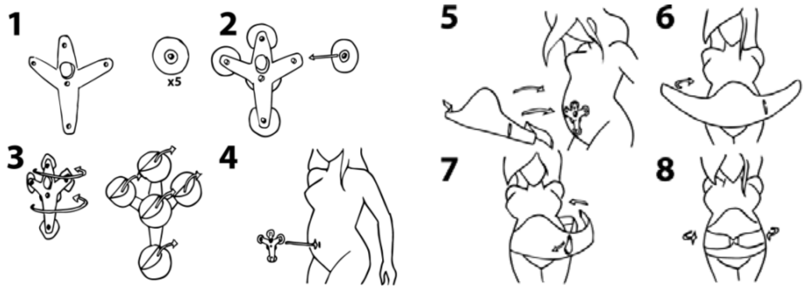

Figure 4. Example of the instructions followed by the participants (Wrap top).

Results
In general, electrode placement was easily understood by the participants. The PCB is light and after its placement, most women did not feel it anymore. However, they did not appreciate the metallic look and the sharp edges of the PCB.

The instructions to wear the garments were quickly understood. Yet it did not mean that the garments were easy to use. The main difficulty was that the size of the garment was inappropriate for most women, i.e., it was either too big or too small. Especially the Wrap was not easy to close. The hooks were not easy to see or reach. Furthermore, only two participants understood the concept of using the mesh fabric in between the PCB and the electrodes. However, this was not their first interpretation of the instructions. In the case of the Belly band, the mesh pocket was rather confusing.

The preferred type of garment was the Belly band because it was the easiest to put on and the prototype size fitted better most of the women. Nevertheless, several participants mentioned that if the shirt fitted them better, they would prefer it. As for the fabric, participants preferred cotton than Lycra, as the latter is perceived as a “sweaty” material. The preferred color was black, as white was often called “hospital white”.

Four participants would recommend the system. They liked that it is user friendly and that they can move around while wearing it. However, they would miss the contact with the doctor and they suggested providing different sizes of the garment.

5 Discussion and Conclusions

A novel concept for a wearable for pregnancy monitoring was presented and developed through user research. In general, it was liked by all participants, especially if their baby would benefit from it. The proposed garments and the PCB shape have been rated as comfortable, and relatively easy to use. However, features such as the mesh fabric layer have to be revised and improved.

None of the participants complained about the possibilities to combine the garments with other clothes. In this evaluation, the most preferred garment was the Belly band, but this outcome has to be considered carefully. This result might be because the Belly band fitted best most of the participants and not because it is their preferred garment type. Future versions of the garment should address the fitting issue more carefully, either by providing different garment sizes, improving the fitting technique in open garments or by designing a one-size-fits-all closed garment.

Feature	**Band**	**Belt**	**Shirt**	**Wrap-top**
Combination with PCB	-	+	-	+
Preference for wear	+	-	+	-
Easiness to understand (affordances)	+	-	+	-
Easy to adjust PCB	+	+	-	-
Tightness	+	++	+	++
Less Movement Artifacts	++	++	+	+
Natural to wear	-	-	+	+
Unnoticeable	+	+	+	+
Total positive scores	**7**	**7**	**6**	**6**

Table 2. Summary of the advantages and disadvantages of each garment type. + means good, and – bad.

Table 2 provides an overview of the advantages and disadvantages of each garment type. The scores for the types of garment are very close to each other. The main cause is that they have complementary advantages. To make a decision, an extra weight factor was given to those aspects related to tightness and less movement artifacts. These were considered most important as they might influence the accuracy of the measurements. Thus, they are critical to keep the core functionality of the system.

The PCB shape was rated as comfortable. However, the current prototype was tested only with the substrate. Adding the electronic components might change how comfortable it is. Even though it is a technical requirement for improved registrations, the size of the PCB is still big. Women tend to shrink or fold the fabric-metal integration region when they do not see the metal part, which can eventually lead to breaking of the PCB. In contrast, when the PCB is visible, women are afraid of getting cut by the sharp edges. Future work should improve the PCB-Garment integration.

Finally, the SEBAN pregnancy monitor differs from other systems because it improves energy management to provide long-term usage; the data acquisition garment is optimized for robust data acquisition (i.e., optimal arrangement of electrodes, no wires, sensors next to the amplifier); it is completely wireless; it uses a common device as a mobile phone to give feedback and forward the data; and the wearable design considers comfort and usability. Nevertheless, it still uses sticky electrodes to ensure good electrode-skin contact, which might cause skin irritation.

The garment design can be further improved: first, by considering several options for the garment-PCB integration; a complete evaluation of the garment and the performance of the monitoring; and the design of other elements of the system architecture, such as the App to provide feedback to mothers-to-be, and the software for the caregivers. Furthermore, as technology advances, regular electrodes could be replaced with textile electrodes to improve even more the comfort of the mother.

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7 References

[1] R. Haws, M. Y. Yakoob, T. Soomro, E. Menezes, G. Darmstadt, and Z. Bhutta, “Reducing stillbirths: screening and monitoring during pregnancy and labour.,” *BMC Pregnancy Childbirth*, vol. 9, Jan. 2009.

[2] V. Flenady, P. Middleton, G. C. Smith, W. Duke, J. J. Erwich, T. Y. Khong, J. Neilson, M. Ezzati, L. Koopmans, D. Ellwood, R. Fretts, and J. F. Frøen, “Stillbirths: the way forward in high-income countries.,” *Lancet*, vol. 377, no. 9778, pp. 1703–17, May 2011.

[3] A. Evers and H. Brouwers, “Perinatal mortality and severe morbidity in low and high risk term pregnancies in the Netherlands: prospective cohort study,” *BMJ*, vol. 341, pp. 1–8, 2010.

[4] H. Buysse, G. De Moor, G. Van Maele, E. Baert, G. Thienpont, and M. Temmerman, “Cost-effectiveness of telemonitoring for high-risk pregnant women.,” *Int. J. Med. Inform.*, vol. 77, no. 7, pp. 470–6, Jul. 2008.

[5] R. Kerner, Y. Yogev, a. Belkin, a. Ben-Haroush, B. Zeevi, and M. Hod, “Maternal self-administered fetal heart rate monitoring and transmission from home in high-risk pregnancies,” *Int. J. Gynecol. Obstet.*, vol. 84, no. 1, pp. 33–39, Jan. 2004.

[6] Philips, “Avalon CTS.” [Online]. Available: http://www.healthcare.philips.com/nl_nl/products/patient_monitoring/products/avalon/. [Accessed: 05-Sep-2014].

[7] MonicaHealthcare, “Monica AN24.” [Online]. Available: http://www.monicahealthcare.com/products/index.php. [Accessed: 05-Sep-2014].

[8] CIDESI, “Monitor Fetal Remoto.” [Online]. Available: http://www.conacyt.mx/agencia/index.php/innovacion/103-cidesi-desarrolla-monitor-fetal-remoto-tecnologia-para-el-cuidado-de-la-salud-prenatal. [Accessed: 05-Sep-2014].

[9] A. Fanelli, M. G. Signorini, M. Ferrario, P. Perego, L. Piccini, G. Andreoni, and G. Magenes, “Telefetalcare: a first prototype of a wearable fetal electrocardiograph.,” in *IEEE Engineering in Medicine and Biology Society. Annual Conference*, 2011, vol. 2011, pp. 6899–902.

[10] I. Std, I. Standards, C. Committee, N. R. Hazards, and I. S. Board, *IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields , 3 kHz to 300 GHz*. 1999.

[11] S. Song, M. J. Rooijakkers, C. Rabotti, M. Mischi, a. H. M. van Roermund, and E. Cantatore, “A low-power noise scalable instrumentation amplifier for fetal monitoring applications,” *2013 IEEE Int. Symp. Circuits Syst.*, pp. 1926–1929, May 2013.

[12] M. J. Rooijakkers, S. Song, C. Rabotti, S. G. Oei, J. W. M. Bergmans, E. Cantatore, and M. Mischi, “Influence of electrode placement on signal quality for ambulatory pregnancy monitoring.,” *Comput. Math. Methods Med.*, vol. 2014, p. 960980, Jan. 2014.