

AN APPARATUS FOR ACQUIRING SIGNALS FROM A PREGNANT SUBJECT

Cross-Reference to Related Applications

- 5 Divisional status is claimed from Singapore parent application No. 10201901341V the entire contents of which is incorporated herein by reference.

Field of the Invention

- 10 The present invention relates to an apparatus for acquiring signals from a pregnant subject.

Background of the Invention

- 15 Prenatal care is important throughout the course of pregnancy in order to minimize the risk of complications. This typically includes regular check-ups with a healthcare professional of which prenatal examinations are usually carried out. One of the parameters that is typically measured during these check-ups is fetal heart rate. Before labour, this is typically done by means of cardiotocogram (CTG) which consists
20 of a cardio and toco transducer. The cardio transducer, which utilises Doppler ultrasound technology, is used to monitor the fetal heart rate pattern as a function of time, allowing monitoring of the fetal wellbeing and the evaluation of any signs of fetal distress. The toco transducer, utilizing pressure sensors, measures the mechanical force exerted by the uterine muscle allowing for observation of patterns of uterine
25 activity. This can also be done relatively cheaply with a stethoscope.

- However, Doppler ultrasound devices are typically expensive and are preferably used by a trained health care professional to ensure correct operation. The Food & Drug Administration in the United States of America issued a formal statement
30 recommending against at-home use of fetal doppler systems due to the risks of system misuse which could result in misinterpretation of fetal heart rate, over-heating fetal tissue and introducing stress on the fetus.

- Another method, using electrophysiological signals such as electrocardiogram (ECG)
35 and electrohysterogram (EHG), has the potential to address the above issues of

usability and diagnostic. The recording of abdominal fetal electrocardiogram (AFECG) is a simple and non-invasive method for monitoring the electrical activity of the fetus heart. Like the standard ECG, which reflects cardiac and metabolic activity, FECG is a potentially more sensitive indicator of fetal health state compared to Doppler
5 ultrasound given the higher resolution of heart rate and heart rate variability data that can be obtained.

Such recordings of AFECGs are typically complicated by the existence of noise, which deteriorates the signal's quality decreasing the signal-to-noise ratio (SNR). The
10 sources of interference when acquiring the abdominal signals are: the maternal ECG, the myographic noise, the powerline interference, the fluctuation of the baseline and factors related to the gestation week. Furthermore, the fetal signal is rather small due to the size of the fetal heart and the intervening tissue.

15 It is possible to hear fetal heartbeat by means of a fetal stethoscope, sometimes referred to as a pinard horn. However, this is cumbersome because to obtain the fetal heart rate, the user would have to count the number of heart beats per minute. This may often result in inaccurate readings and users who are unfamiliar with operating a stethoscope may not be able to locate the appropriate placement of the stethoscope
20 to obtain an accurate and constant reading. Additionally, the stethoscope only provides a snapshot of the fetal heart rate, and is unable to provide critical information about fetal distress.

In addition, uterine activity is typically monitored using pressure sensors positioned
25 over the abdomen. Pressure sensing methods include the use of tocodynamometers (toco) or simple manual palpation. Tocodynamometers measure the frequency and duration of uterine contractions but have limited sensitivity of the intensity of the contractions. Typically, these devices need to be sufficiently secured on the subject's abdomen to ensure minimum sensitivity to external disturbances, which usually
30 requires a medical professional to ensure accurate positioning.

Therefore, most parents and healthcare professionals only have access to fetal heart rate and uterine contractions data during routine check-ups. The frequency of the check-ups may not be regular enough to pick up irregularities with the pregnancy
35 which may only present themselves intermittently and therefore not necessarily during

the check-up. Any signs of risk during the pregnancy may increase the need for more frequent check-ups at a hospital, for example, and if the check-up is inconclusive, may require hospitalization for further observation.

- 5 In certain remote locations, access to healthcare providers may be problematic and as such, pregnant women may not have access to regular check-ups. This may be due to the distance to the nearest hospital being too far or a lack of funds to afford a pre-natal check-up.
- 10 It is generally desirable to overcome or ameliorate one or more of the above described difficulties, or to at least provide a useful alternative.

Summary of the Invention

- 15 In accordance with the present invention, there is provided an apparatus for acquiring signals from a pregnant subject, the apparatus including a flexible portion that is conformable to an abdomen of the subject, the flexible portion including a plurality of signal acquisition points, each signal acquisition point comprising a contact adapted to electrically couple to a respective electrode and signal acquisition circuitry, wherein
- 20 the flexible portion includes:
- a first linear section that is generally aligned along a first axis; and
 - a second linear section extending from the first linear section, the second linear section being generally aligned along a second axis that is perpendicular to the first axis;
- 25 wherein a first group of the signal acquisition points is located along the first axis and a second group of the signal acquisition points is located along the second axis.

Brief Description of the Drawings

- 30 Preferred embodiments of the invention are hereafter described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

- Figure 1a is a back view of an apparatus for acquiring signals from a pregnant subject;
- 35 Figure 1b is a front view of the apparatus shown in Figure 1a;

- Figure 2a is a back perspective view of the apparatus shown in Figure 1a;
Figure 2b is a front perspective view of the apparatus shown in Figure 1a;
Figure 3a is an exploded view of the assembly mechanism of the apparatus shown in Figure 1a;
5 Figure 3b is a left view of the apparatus shown in Figure 1a;
Figure 3c is a top view of the apparatus shown in Figure 1a;
Figure 4a is a schematic view of an initial pattern used to assess electrode placement of the apparatus of Figure 1a;
Figure 4b is a schematic view of an example placement of electrodes on the apparatus
10 as shown in Figure 1a;
Figure 5a is a schematic view of the example placement of electrodes as shown in Figure 4b;
Figure 6a is a perspective top view of the apparatus of Figure 1a in use;
Figure 6b is a perspective front view of the apparatus of Figure 1a in use;
15 Figure 7a is a perspective view of the apparatus of Figure 1a being placed on a curved surface;
Figure 7b is a perspective view of the apparatus of 7a placed on a curved surface;
Figure 8a is a bottom perspective view of the apparatus of Figure 1a in position to be coupled to a signal processing module;
20 Figure 8b is a top perspective view of the apparatus of Figure 1a in position to be coupled to a signal processing module;
Figure 9a is a back view of the apparatus of Figure 1a coupled to a signal processing module;
Figure 9b is a front view of the apparatus of Figure 1a coupled to a signal processing
25 module;
Figure 10a is a perspective back view of the apparatus of Figure 1a coupled to a signal processing module;
Figure 10b is a perspective front view of the apparatus of Figure 1a coupled to a signal processing module;
30 Figure 11a is a side view of the apparatus of Figure 1a coupled to a signal processing module;
Figure 11b is a section view of the apparatus of Figure 1a coupled to a signal processing module;
Figure 11c is a top view of the apparatus of Figure 1a coupled to a signal processing
35 module.

- Figure 12a is a front view of a signal processing module;
Figure 12b is a back view of the signal processing module of Figure 12a;
Figure 13a is a front perspective view of a signal processing module of Figure 12a;
Figure 13b is back perspective view of a signal processing module of Figure 12a;
5 Figure 14a is a top view of the signal processing module of Figure 12a;
Figure 14b is a bottom view of the signal processing module of Figure 12a; and
Figure 14c is a side view of the signal processing module of Figure 12a.

Detailed Description of Embodiments of the Invention

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The apparatus 10 shown in Figures 1a and 1b allows for non-invasive monitoring of maternal and fetal health by acquiring signals from a pregnant subject 16. Preferably, apparatus 10 is wireless and/or a wearable device. As shown in Figures 6b, 7a and
15 7b, the apparatus 10 is for acquiring signals from a pregnant subject 16, the apparatus 10 including a flexible portion 204 that is conformable to an abdomen 17 of the subject 16, the flexible portion 204 including a plurality of signal acquisition points 202, each signal acquisition point 202 comprising a contact adapted to electrically couple to a respective electrode 206 and signal acquisition circuitry, wherein the
20 flexible portion 204 includes:

- a first linear section 204b that is generally aligned along a first axis A_H ; and
- a second linear section 204a extending from the first linear section 204b, the second linear section 204a being generally aligned along a second axis A_V that is perpendicular to the first axis A_H ;
- 25 wherein a first group of the signal acquisition points is located along the first axis A_H and a second group of the signal acquisition points is located along the second axis A_V .

The apparatus 10 makes monitoring maternal and fetal health status simpler, faster
30 and more convenient. Maternal and fetal health can be monitored by parameters such as maternal heart rate, fetal heart rate and uterine activity.

For example, the signal acquisition points 202, are integrated into the flexible portion 204 to ensure the correct positioning of the apparatus 10 when placed on the
35 abdomen 17 of the subject 16. In some embodiments, the signal acquisition points

202 are the female side of standard ECG snap buttons, and snap to the male connection of electrodes 206 using a press-push mechanism. The signal acquired by the electrodes 206 includes but is not limited to ECG and EHG signals from unipolar leads and measurement of the signal may be relative to a common reference for multiple leads, for example a signal measured at reference signal acquisition point 202e (when connected to electrode 206e).

For example, the signal acquisition points of the first group may be located symmetrically about the first axis V_H . As shown in Figure 1a, flexible portion 204 includes 5 signal acquisition points 202, with 3 signal acquisition points 202a, 202b, 202c being arranged along the first axis A_H and 3 signal acquisition points 202d, 202e being arranged along the second axis A_V . In this embodiment, one of the 5 signal acquisition points is a central signal acquisition point 202b and is located at the intersection of the first axis A_H and the second axis A_V . Figure 5a shows a configuration of signal acquisition points 202 along the second axis A_V and first axis A_H . In some embodiments, more than 5 signal acquisition points 202 are arranged on the flexible portion 204 and in other embodiments, fewer than 5 signal acquisition points 202 may be arranged along the axes of flexible portion 204.

As shown in Figure 5d electrodes 206a, 206b, 206c, 206d and 206d are positioned and coupled to signal acquisition points 202a, 202b, 202c, 202d and 202e in the configuration as shown. For example, an electrode 206 may be a disposable wet adhesive electrode such as, per example, electrodes developed by 3M™ Red Dot™ 2238 or 2239.

In some embodiments, the first group includes three signal acquisition points 202a, 202b, 202c located along the first axis and spaced from each other by about 6 cm as shown in Figure 4a. Advantageously, the one or more signal acquisition points are configured, when coupled to respective electrodes and signal acquisition circuitry, to acquire unipolar signals.

In some embodiments, a uterine activity signal acquisition point 202d is positioned along the second axis A_V to acquire signals associated with the pregnant subject's uterine activity. As shown in Figure 4b, the uterine activity signal acquisition point

202d is spaced about 8 cm from the intersection between the first axis A_H and the second axis A_V .

As shown in Figure 4b, a reference signal acquisition point 202e is located along the second axis A_V to acquire reference signals. For example, the reference signal acquisition point 202e is located about 18 cm from the intersection between the first axis A_H and the second axis A_V .

In some embodiments, the flexible portion 204 has a channel 208 defined therethrough for aligning the apparatus 10 along the abdomen 17 of the subject 16. This provides a physical reference to a non-expert user, for example, in order to position easily the apparatus 10 on the abdomen 17 in a manner which minimizes noise within the signals acquired by the electrodes 206. Advantageously, the channel 208 is shaped to allow a user to align the channel 208 to a navel 18 of the pregnant subject 16 by visual or tactile means, as shown in Figures 7a and 7b.

Advantageously, the channel 208 is positioned along the second axis A_V . As shown in Figure 5a, the channel 208 is positioned between the uterine activity signal acquisition point 202d and the intersection between the first axis A_H and the second axis A_V . This means that the channel 208 may be readily aligned over the navel of the subject 16 to ensure that signals are acquired both above (by signal acquisition point 202b) and below (by signal acquisition point 206d) the navel. In some embodiments, the channel defines a longitudinal axis that is mutually orthogonal to the first axis A_H and the second axis A_V .

As shown in Figures 1b, 2b, 3a, 3b and 3c and 5, the flexible portion 204 includes a cable hub 212 attached to the flexible portion 204 for feeding signals from the signal acquisition points to signal acquisition circuitry and/or signal processing circuitry. Cable hub 212 is coupled to second section 204b of flexible portion 204 by means of a distributor 213, for example. Cables (not shown) may be embedded in flexible portion 204 and extend from respective signal acquisition points 202 to termination points of the distributor 213, which in turn are in electrical communication with respective output terminals 203a, 203b, 203c, 203d, 203e (collectively referred to hereafter as connectors 203) of the cable hub 212.

Advantageously, cable hub 212 is formed from a rigid material, for example ABS or any other hard polymer, and forms a single body with the flexible portion 204 for providing structural integrity to apparatus 10. Preferably, the cable hub 212 houses connectors 203 which are coupled to the signal acquisition points 202.

5 Advantageously, cable hub 212 is the male component of the connector providing electrical connection to the electrodes 206. Advantageously, the cable hub has a channel 208' extending therethrough, the channel being aligned with the channel 208 of the flexible portion 204. In some embodiments, the channel of the cable hub 212 has a chamfered entry portion 209 for receiving a finger of a user (such as subject

10 16). The chamfered entry portion 209 makes it easier for a user to insert their finger into the channel 208, 208' for tactile alignment with the subject's 16 navel, and moreover, allows the apparatus 10 to be more easily manoeuvred in that the user's finger is disposed at an angle rather than being constrained to be vertical.

15 In some embodiments, the apparatus 10 includes a signal processing module 210 attached to the cable hub 212, as shown in Figures 12a, 12b, 13a, 13b, 14a, 14b and 14c. As shown in Figures 6a and 6b, the signal processing module 210 is coupled to the flexible portion 204, for example via cable hub 212. In some embodiments, the signal processing module 210 is detachable from the cable hub 212. The signal

20 processing module 210 includes a housing 211 within which is housed the signal processing circuitry and preferably also at least part of the signal acquisition circuitry. Advantageously, cable hub 212 allows a secure coupling between section 204b and signal processing module 210 to maintain the stability of the device and rigidity of the connections. The housing 211 contains at least one printed circuit board (PCB) (not

25 shown) carrying the signal processing circuitry and/or the signal acquisition circuitry, and one or more cables in communication with the one or more respective signal acquisition points 202, via ports 223a, 223b, 223c, 223d and 223e which couple to respective connectors 203 of the cable hub 212. The signal processing module 210 is preferably rigid, for example made of a like ABS or any other hard polymer, to store

30 the electronic components for apparatus 10.

Signal processing module 210 is the female component providing electrical connection to the PCB, for example. Advantageously, housing 211 for the electronics provides rigidity to the signal acquisition points.

The first linear section 204b and s section 204a of the flexible portion 204 are made of a flexible material that is deformable for conforming to the abdomen 17 of the subject 16. For example, the flexible material is a flexible polymer such as Thermo plastic material (TPE), TPU or silicone rubber.

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Advantageously, the one or more electrodes acquire electrocardiogram (ECG) and electrohysterogram (EHG) signals from the skin of the abdomen 17 of the subject 16. In some embodiments, the signal acquisition circuitry includes an analog front end which contains a biosignal amplifier, unipolar input for 8 channels with a minimum acquisition of 1.5 mV, for example. Further, an analog-digital convertor (ADC) and processor is provided for converting and processing the signals received by the electrodes 206. Advantageously, the ADC and processor have the following specifications: minimum resolution of 24-bits and 1 μ A, (ECG), 6 μ A (EHG); minimum sampling rate of 250Hz (ECG), 100 Hz (EHG); ideal sampling rate = 1000 Hz (ECG), 1000Hz (EHG).

The signals acquired by the one or more electrodes 206 may be sent wirelessly to a transceiver of a mobile computing device (not shown) running a software application that displays, and may optionally perform post-processing on, the acquired signals. Advantageously, wireless communication may be by Bluetooth™. In this embodiment, apparatus 10 includes a Bluetooth transmitter for communicating with the mobile computing device.

Apparatus 10 includes a battery (for example, located in housing 211) for powering the components of the apparatus 10. Preferably, the battery is a lithium-ion rechargeable battery. Advantageously, the level of charge in the battery is displayed as an indicator to the user.

Process for selection of the contacts position

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Using unipolar ECG leads where the reference is sufficiently far away from the measuring electrode may improve AFECG SNR. A unipolar lead implies that the collected signal is single-ended and is a substitution of one reference electrode from one measuring electrode. However, unipolar leads may be affected by larger sensitivity to background noise such as power line interferences and physiological

artifacts such as electromyogram (EMG) signals and maternal ECG. Therefore, it may be beneficial to identify the appropriate distance between the reference and measuring electrodes.

5 During pregnancy, the uterus size typically increases from about 10 cm to about 60 cm. The average uterus size is determined by the gestational age (GA), which is determined in weeks, where GA of 37 weeks and above is at term. Additionally, the fetus position is variable as the fetus is mobile and changes position regularly within the womb. Furthermore, mothers may have different body mass index (BMI) and
10 abdomen size. Therefore, it is important to design the shape of apparatus 10 and the placement of the signal acquisition points 202 which can acquire accurate signals despite various abdomen sizes depending on the size of the uterus, mobility of the fetus, and a wide range of BMI values.

15 To minimize patient discomfort, the total number of electrodes should be kept at a minimum. Additionally, this may result in a more compact device which is simpler to use. An ideal electrode position pattern should consider all three aspects: a large fetal ECG SNR, assurance of effective signal detection for various fetal position, GA, and BMI, and minimal cover of the abdomen for patient's comfort.

20 Uterine activity (UA), or contractions, can be obtained by measuring the uterine EMG signal, also known as electrohysterogram (EHG). The EHG can be measured using a unipolar lead where the reference and the measuring electrodes are close to each other. In this case, it is important that the measuring electrode is placed directly on
25 the uterine muscle, or as close to as possible, over the diastasis of the rectus abdominis, with minimal interferences from other abdominal muscles to avoid strong physiological artifacts.

An initial contact pattern was selected (Figure 4a). The initial pattern is designed to
30 use a single reference electrode 402ref at the bottom of the abdomen, for example 2 to 5 cm over the symphysis pubis. The pattern of the measuring electrodes 402a, 402b, 402c, 402d, 402e, 402f was determined following an initial clinical study where electrodes were systematically positioned around the navel at various distances and angles. The position of the uterine contraction electrode 402ua was determined
35 following the criteria described above.

Preferably, off-the-shelf wet gel electrodes developed for sensitive skin, such as 3M Red Dot electrodes 2238 or 2239 is used. For example, the wet gel electrodes are circular with a 3 cm diameter.

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A clinical study was performed using the initial pattern as shown in Figure 5a and involved n=30 patients with BMI ranging between 22 and 61 and GA between 25 to 41 weeks. For each measurement, the fetus position and presentation were measured using ultrasound and were statistically representative of reported world distribution.

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A Signal Quality Index (SQI) was used to evaluate each electrode position on the initial pattern, similar to the SQI method used by Behar *et al.* (Behar *et al.*, *Physiol. Meas.*, 37 (2016) R1). The SQI provides a relative measure of signal quality within a single dataset and relies on dataset-dependent parameters. For each dataset, the electrodes positions were ranked from 1 to 6, corresponding to the highest to lowest calculated SQI values, respectively. This provided a robust classification method of electrode positions A to F for statistical comparison between the datasets (Table 1).

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Table 1: Statistical ranking of the electrode position according to their SQI values across n=30 datasets.

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Electrode Position	A	B	C	D	E	F
SQI rank	5	6	1	4	3	2

Positions C, D, E, and F were identified with the highest ranks. Ranking of position F decreases with earlier GA, and any electrode placement between position D and F would be acceptable for AFECG acquisition. Therefore, the exemplary electrode placement for AFECG and UA acquisition resembles the pattern of Figure 4b.

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The 3 fetal ECG electrodes 202a, 202b, 202c selected were the 3 side-by-side located just above the navel 18. This configuration satisfies the criteria of high SNR, various fetal position, GA, and BMI, and provides a compact and usable pattern for an improved patient comfort.

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The selected shape for the present invention resembles the one of a "T", where the navel 18 is centrally located and provides an adequate referral for positioning and placement.

- 5 Throughout this specification, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.
- 10 The reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form of suggestion that the prior art forms part of the common general knowledge.

Claims Defining the Invention

1. An apparatus for acquiring signals from a pregnant subject, the apparatus including a flexible portion that is conformable to an abdomen of the subject, the
5 flexible portion including a plurality of signal acquisition points, each signal acquisition point comprising a contact adapted to electrically couple to a respective electrode and signal acquisition circuitry, wherein the flexible portion includes:
 - a first linear section that is generally aligned along a first axis; and
 - a second linear section extending from the first linear section, the second linear
10 section being generally aligned along a second axis that is perpendicular to the first axis;wherein a first group of the signal acquisition points is located along the first axis and a second group of the signal acquisition points is located along the second axis.
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2. The apparatus of claim 1, wherein the signal acquisition points of the first group are located symmetrically about the second axis.
3. The apparatus of claim 1 or claim 2, including a central signal acquisition point
20 located at the intersection of the first axis and the second axis.
4. The apparatus of any one of claims 1 to 3, wherein the first group includes three signal acquisition points located along the first axis and spaced from each other by about 6 cm.
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5. The apparatus of any one of claims 1 to 4, wherein the signal acquisition points are configured, when coupled to respective electrodes and signal acquisition circuitry, to acquire unipolar signals.
- 30 6. The apparatus of any one of claims 1 to 5, including a uterine activity signal acquisition point positioned along the second axis to acquire signals associated with the pregnant subject's uterine activity.
7. The apparatus of claim 6, wherein the uterine activity signal acquisition point is
35 spaced about 8 cm from the intersection between the first axis and the second axis.

8. The apparatus of any one of claims 1 to 7, including a reference signal acquisition point located along the second axis to acquire reference signals.
- 5 9. The apparatus of claim 8, wherein the reference signal acquisition point is located about 18 cm from the intersection between the first axis and the second axis.
- 10 10. The apparatus of any one of claims 1 to 9, wherein the flexible portion has a channel defined therethrough for aligning the apparatus along the abdomen of the subject.
11. The apparatus of claim 10, wherein the channel is positioned along the second axis.
- 15 12. The apparatus of claim 11, wherein the channel is positioned between the uterine activity signal acquisition point and the intersection between the first axis and the second axis.
- 20 13. The apparatus of any one of claims 10 to 12, wherein the channel defines a longitudinal axis that is mutually orthogonal to the first axis and the second axis.
- 25 14. The apparatus of any one of claims 10 to 13, wherein the channel is shaped to allow a user to align the channel to a navel of the pregnant subject by visual or tactile means.
15. The apparatus of any one of the preceding claims, including a cable hub attached to the flexible portion for feeding signals from the signal acquisition points to signal acquisition circuitry and/or signal processing circuitry.
- 30 16. The apparatus of claim 15, wherein the cable hub is formed from a rigid material.
- 35 17. The apparatus of claim 15 or claim 16, wherein the cable hub has a channel extending therethrough, the channel being aligned with the channel of the flexible portion.

18. The apparatus of claim 17, wherein the channel of the cable hub has a chamfered entry portion for receiving a finger of a user.

5 19. The apparatus of any one of claims 15 to 19, including a signal processing module attached to the cable hub.

20. The apparatus of claim 19, wherein the signal processing module is detachable from the cable hub.

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21. The apparatus of any one of claims 15 to 20, wherein the signal processing module houses the signal acquisition circuitry and the signal processing circuitry.