



US010456074B2

(12) **United States Patent**
Penders et al.

(10) **Patent No.:** **US 10,456,074 B2**
(45) **Date of Patent:** **Oct. 29, 2019**

(54) **METHOD AND DEVICE FOR
CONTRACTION MONITORING**

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(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 130 days.

(21) Appl. No.: **15/523,072**

(22) PCT Filed: **Oct. 29, 2015**

(86) PCT No.: **PCT/US2015/058153**

§ 371 (c)(1),

(2) Date: **Apr. 28, 2017**

(65) **Prior Publication Data**

US 2018/0296156 A1 Oct. 18, 2018

Related U.S. Application Data

(60) Provisional application No. 62/072,348, filed on Oct.
29, 2014.

(30) **Foreign Application Priority Data**

Feb. 2, 2015 (BE) 2015/5056

(51) **Int. Cl.**

A61B 5/00 (2006.01)

A61B 5/11 (2006.01)

(Continued)

(52) **U.S. Cl.**

CPC **A61B 5/4356** (2013.01); **A61B 5/04012**
(2013.01); **A61B 5/0448** (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC **A61B 5/4356**
See application file for complete search history.

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Primary Examiner — Meredith Weare

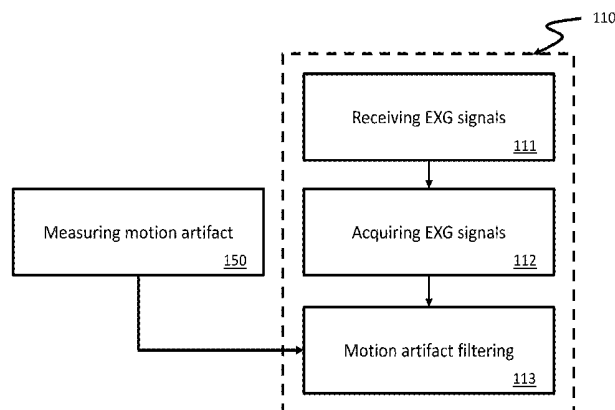
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(57) **ABSTRACT**

Described herein are systems and methods for contraction
monitoring. For example, a system for contraction monitor-
ing includes an electrode patch including at least two
electrodes, and a sensor module configured to be connected
to the electrode patch. In some embodiments, the sensor
module includes a signal acquisition module, a signal pro-
cessing module, a power management module, a sensor
control module, and a memory module and/or a data trans-
mission module. In some embodiments, a method for con-
traction monitoring includes measuring, using the signal
acquisition module, bio-potential signals by providing at
least two electrodes on the abdomen of a pregnant woman.

(Continued)

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In some embodiments, a method for contraction monitoring includes processing, using the signal processing module, the bio-potential signal to extract electrohysterogram signals, maternal electrocardiogram signals and fetus electrocardiogram signals, and processing, using the signal processing module, the individual signals to extract uterine contraction.

18 Claims, 30 Drawing Sheets

(51) Int. Cl.

A61B 5/0448 (2006.01)
A61B 5/16 (2006.01)
A61B 5/04 (2006.01)
A61B 5/024 (2006.01)

(52) U.S. Cl.

CPC *A61B 5/165* (2013.01); *A61B 5/6833* (2013.01); *A61B 5/721* (2013.01); *A61B 5/02411* (2013.01); *A61B 5/1107* (2013.01); *A61B 5/4362* (2013.01)

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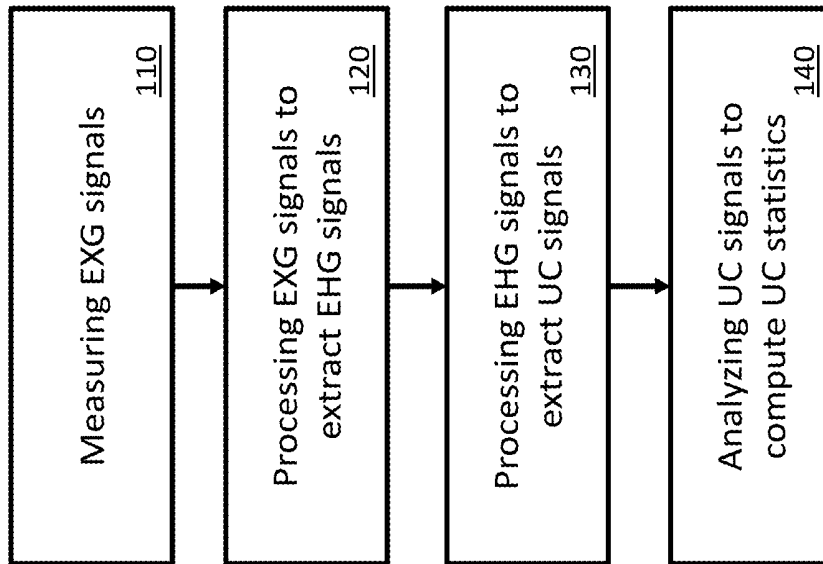
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FIG. 1

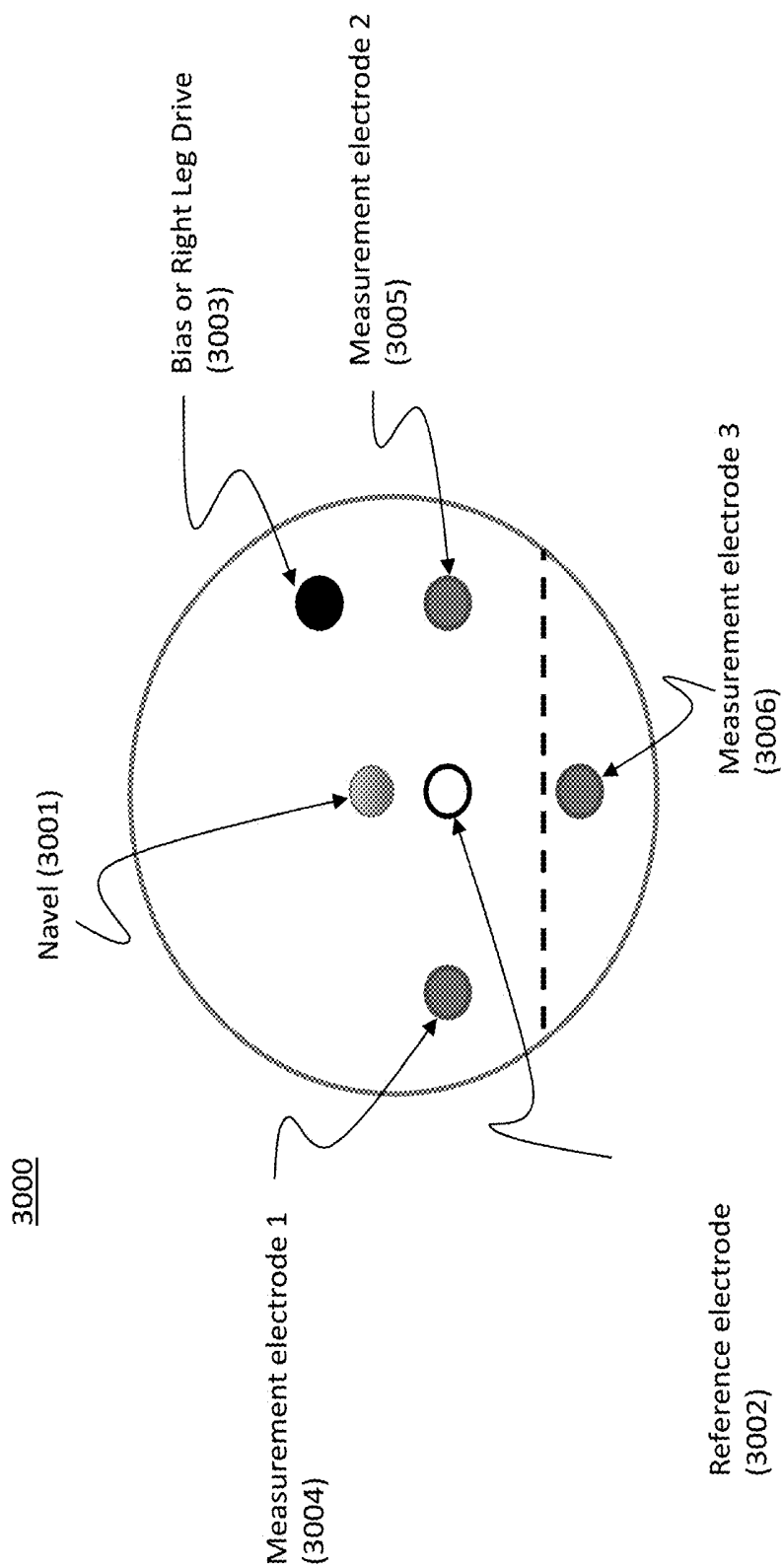


FIG. 2A

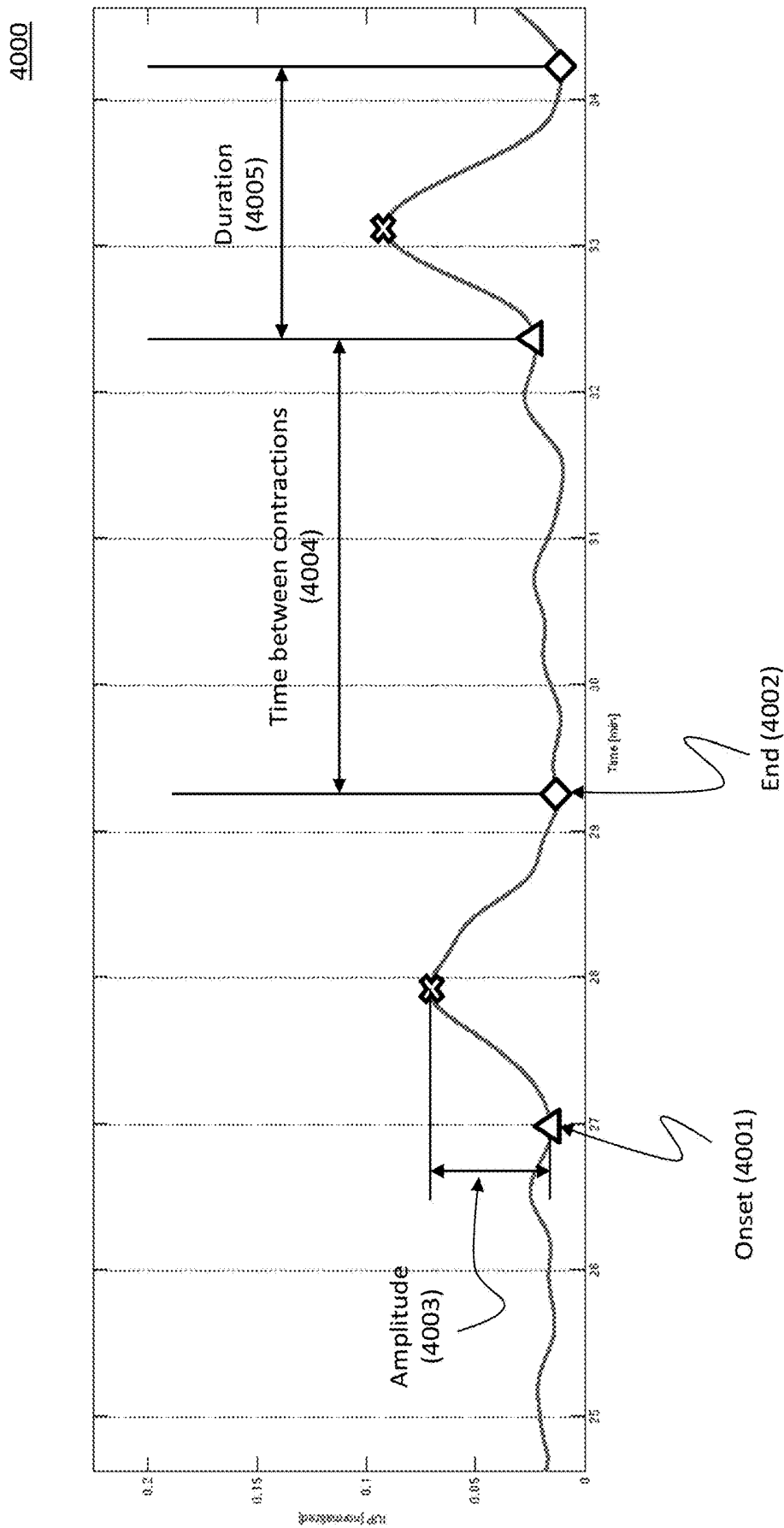


FIG. 2B

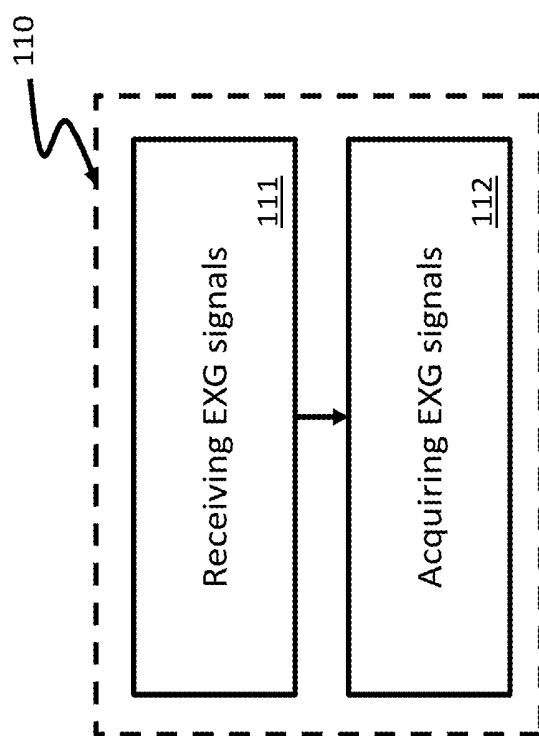


FIG. 3A

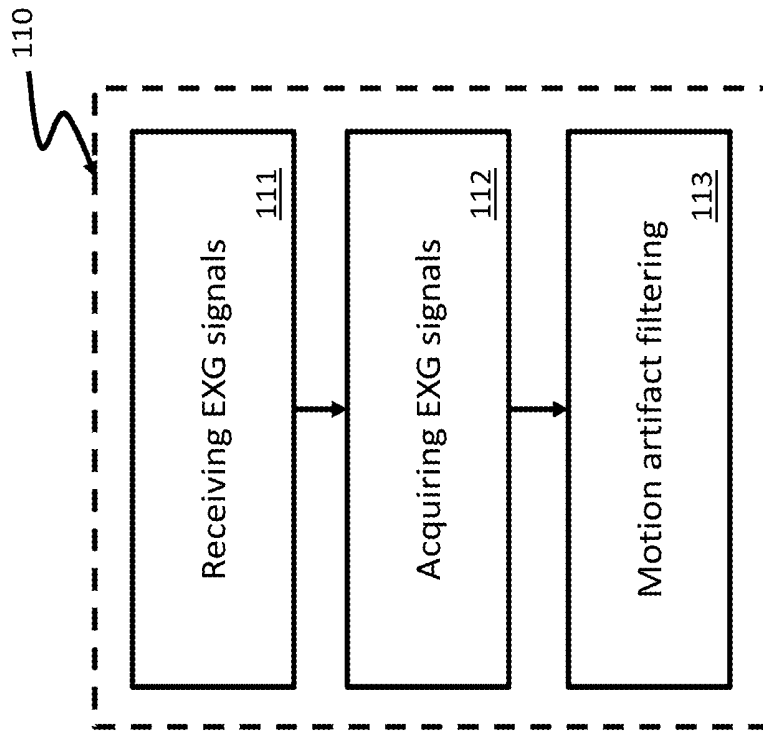


FIG. 3B

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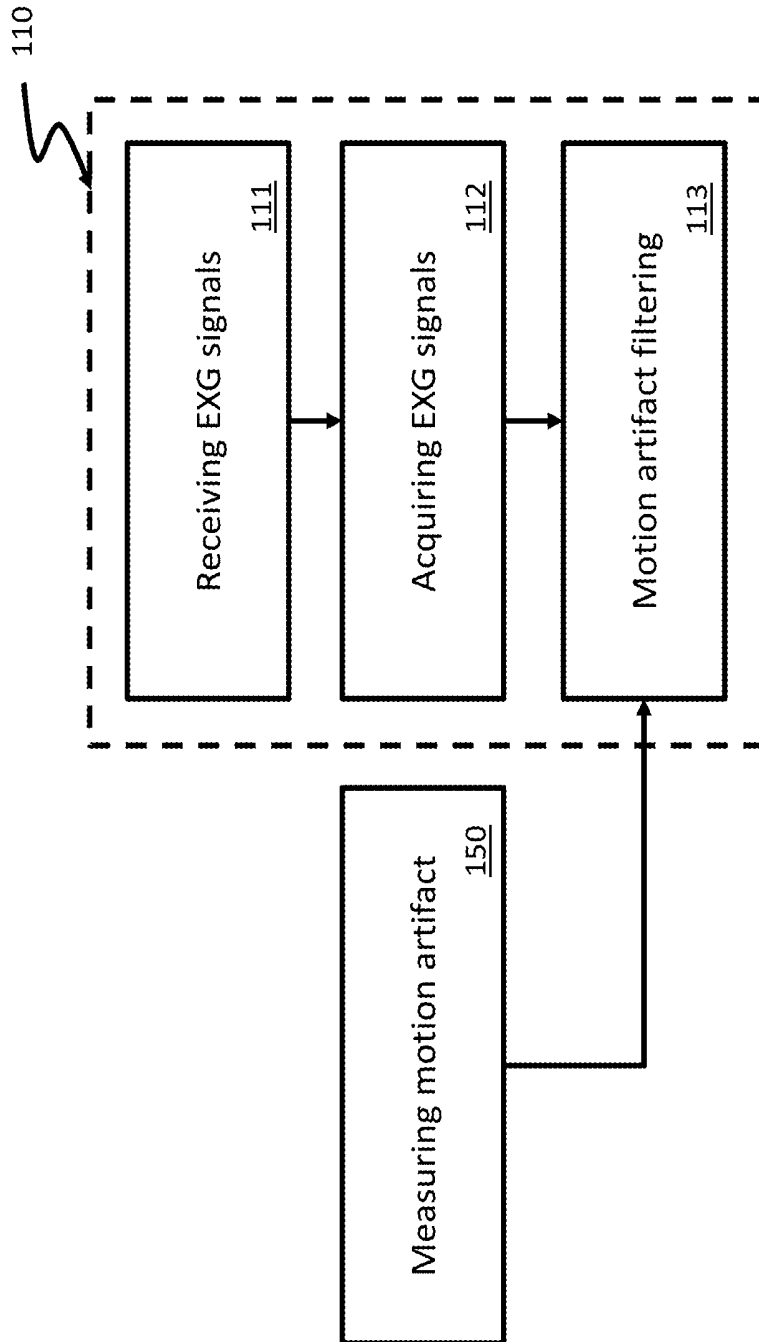


FIG. 3C

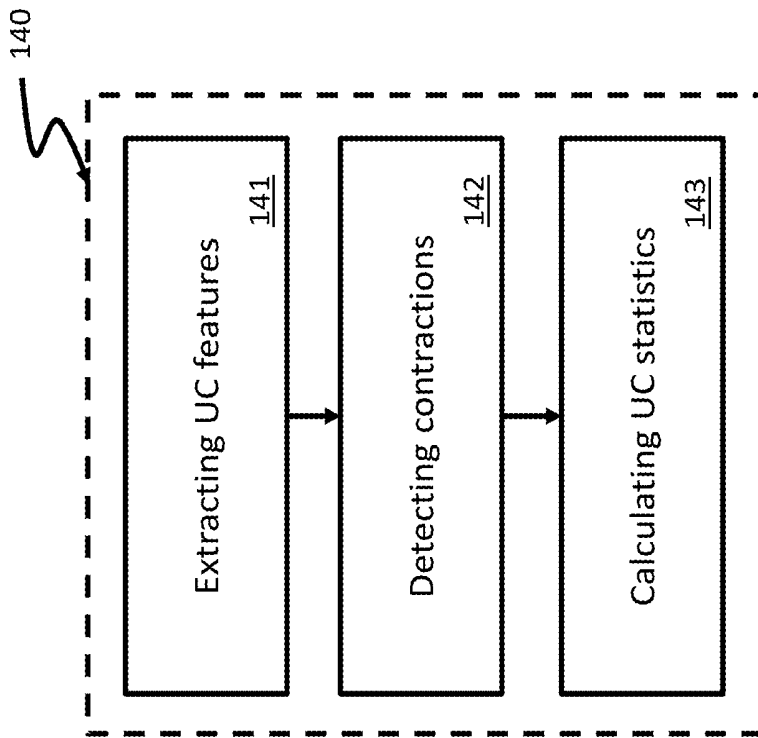


FIG. 4

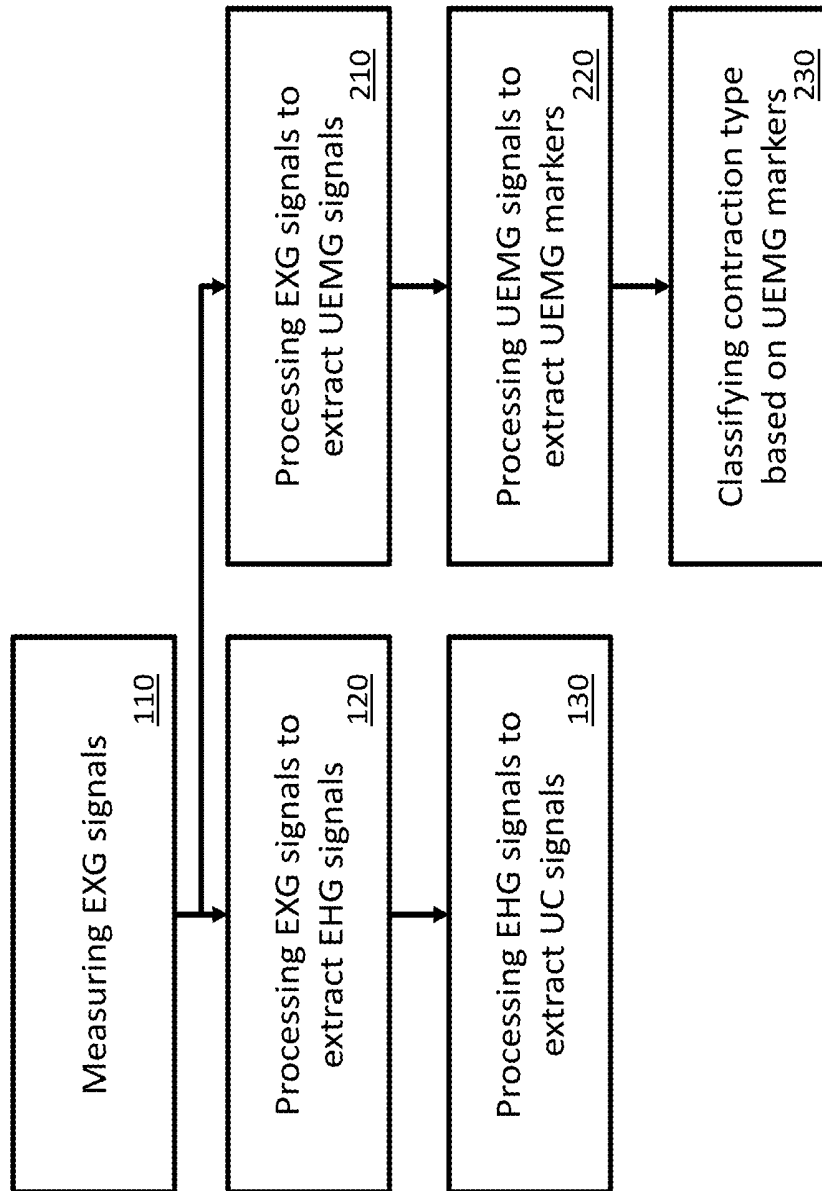
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FIG. 5A

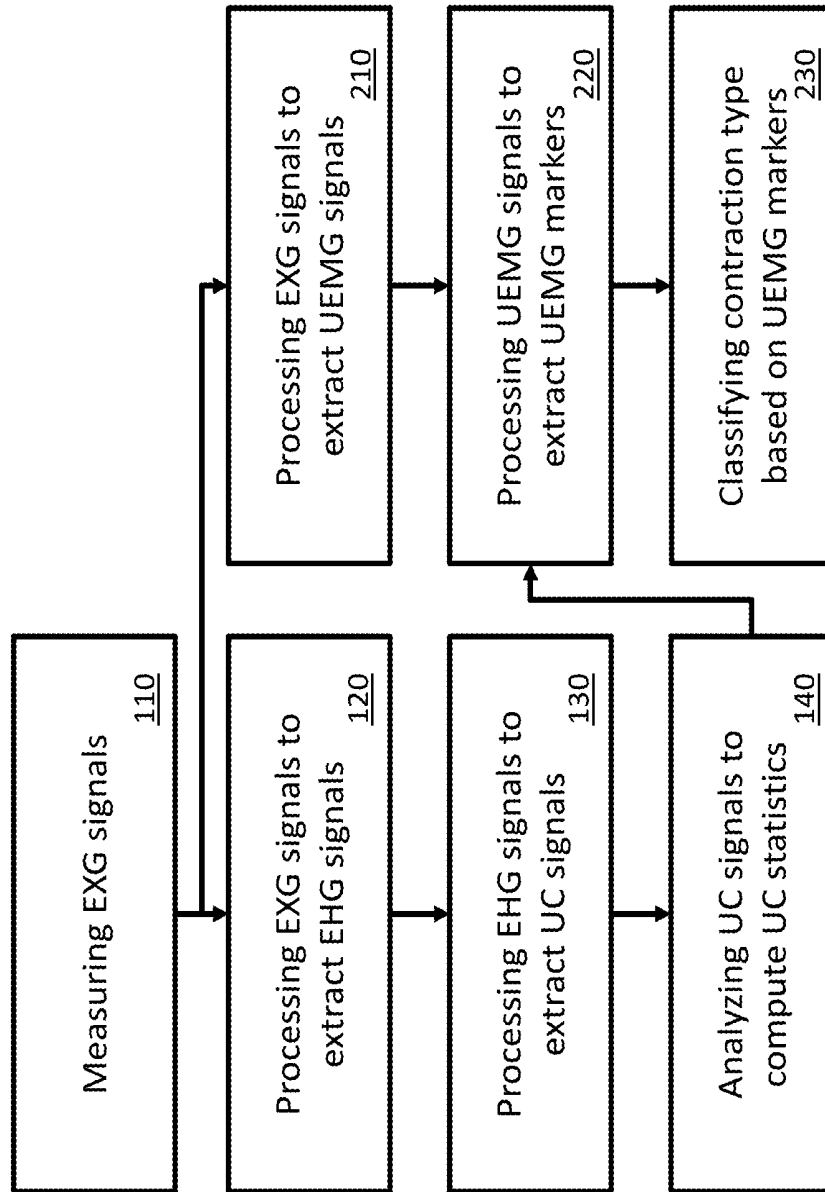
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FIG. 5B

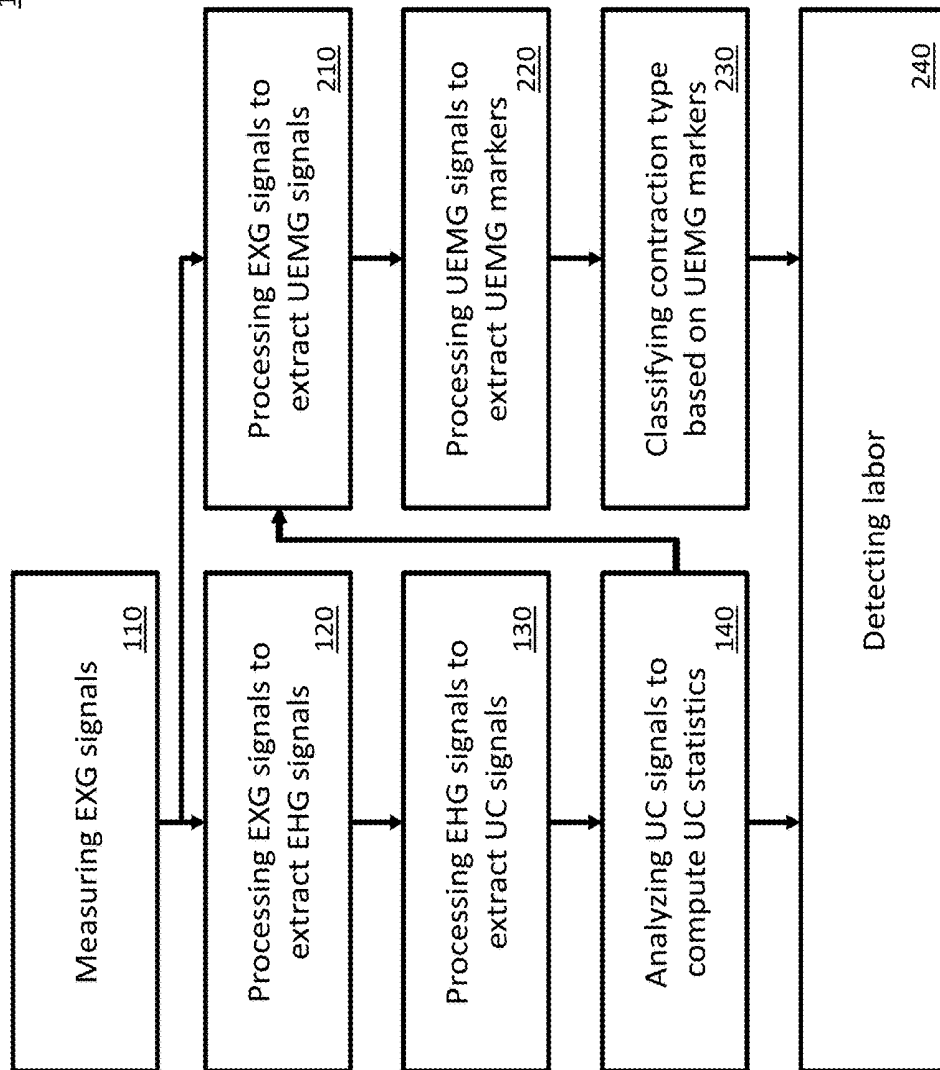
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FIG. 6

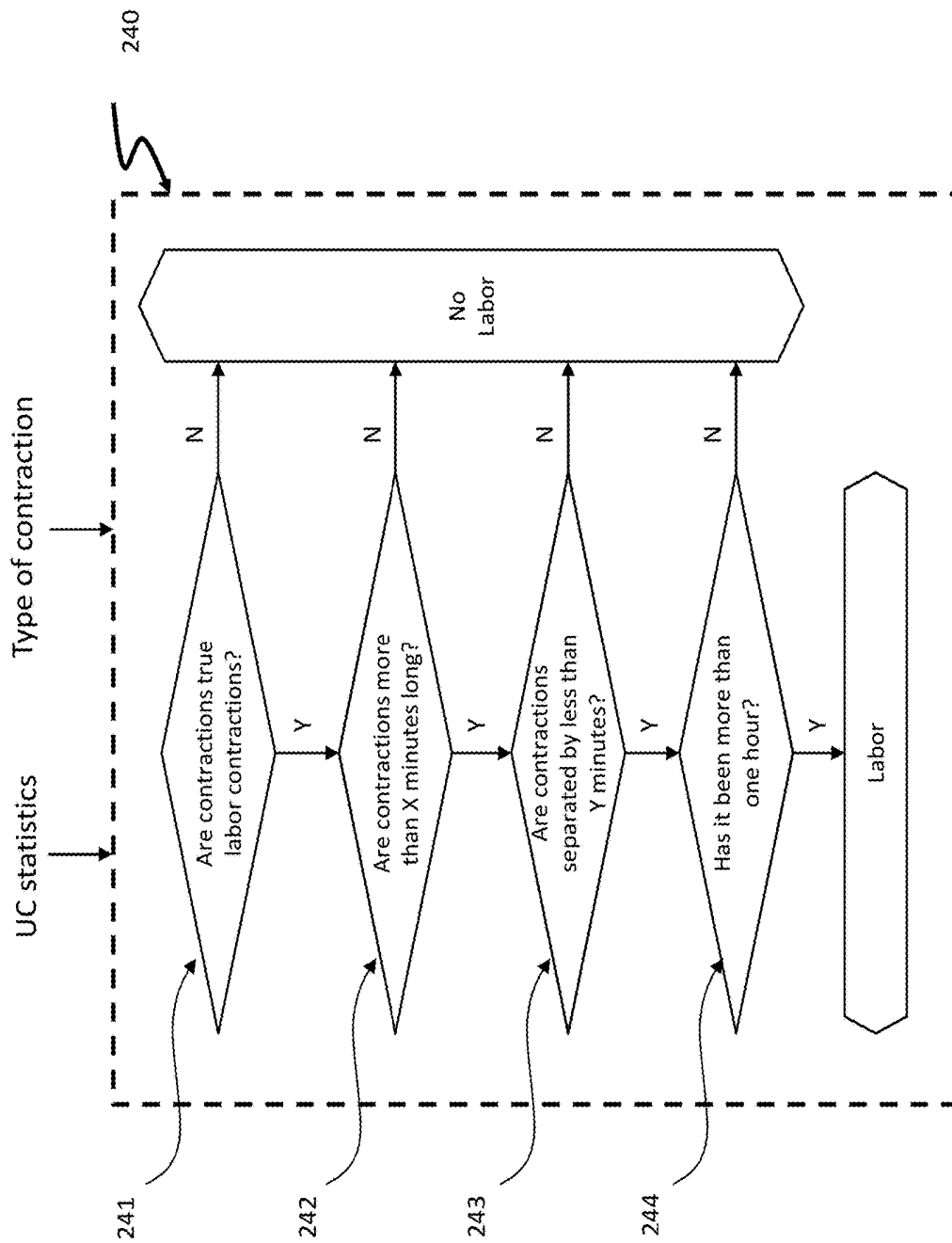


FIG. 7

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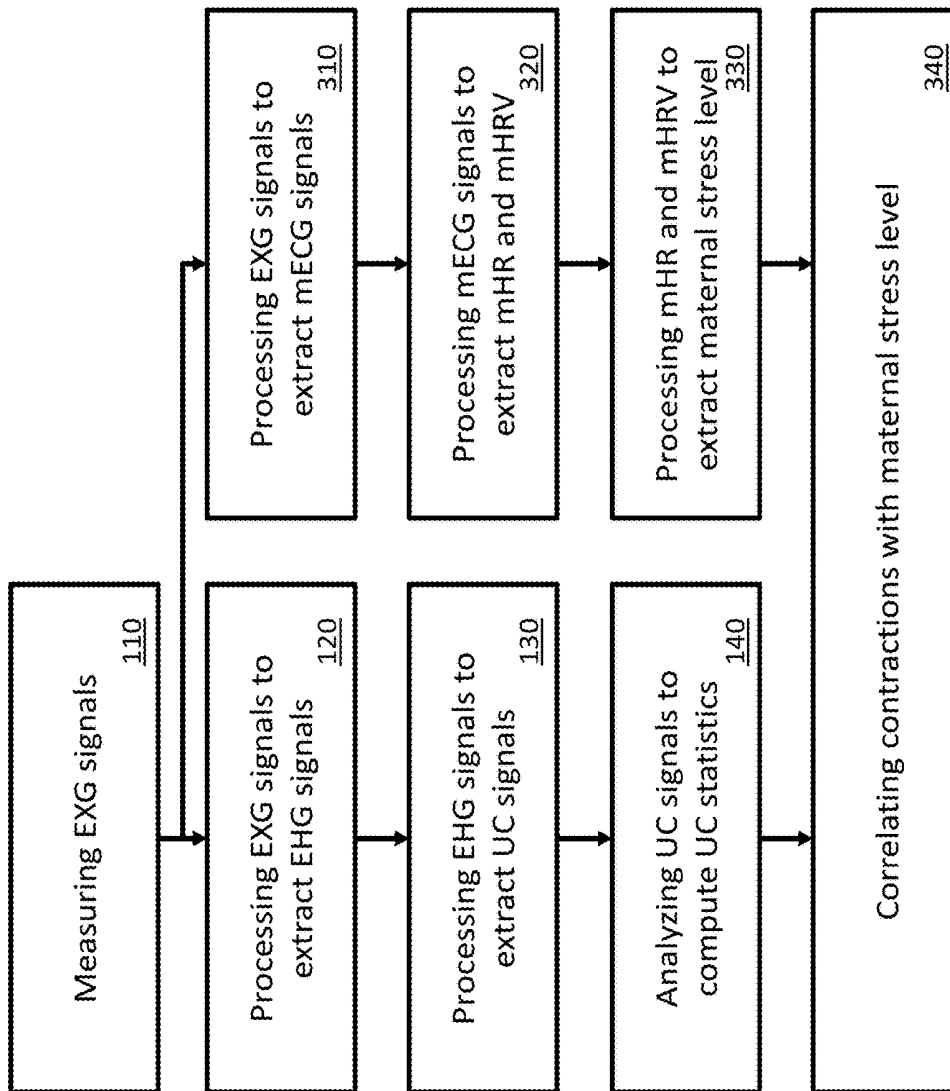


FIG. 8

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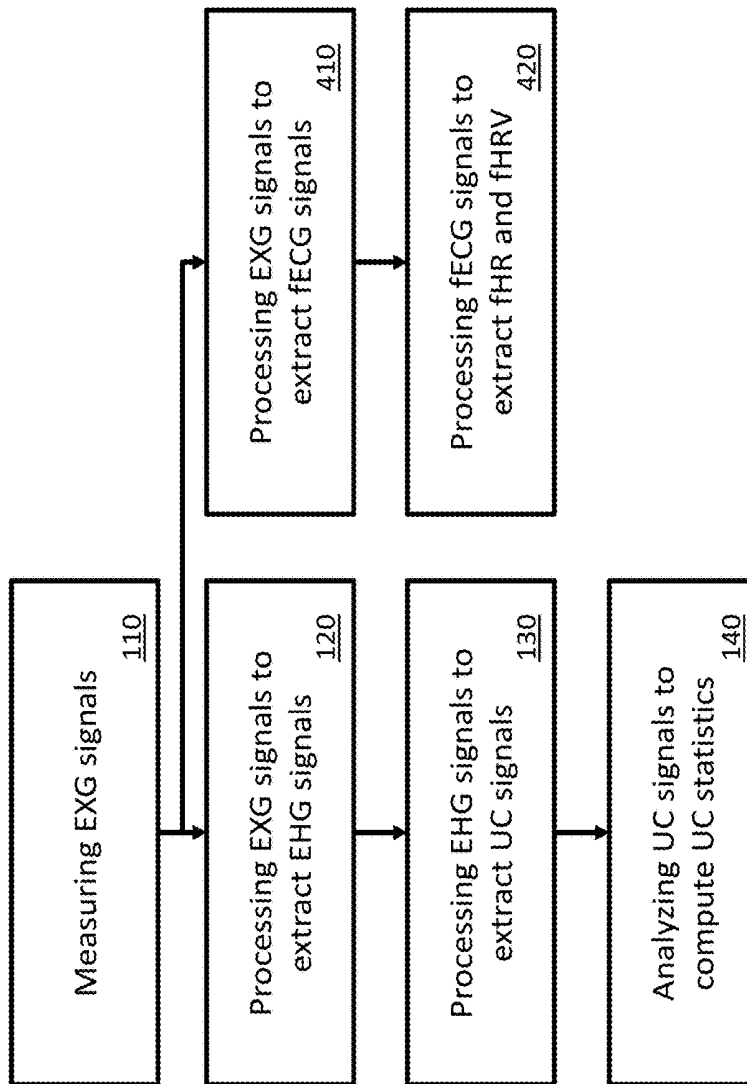


FIG. 9A

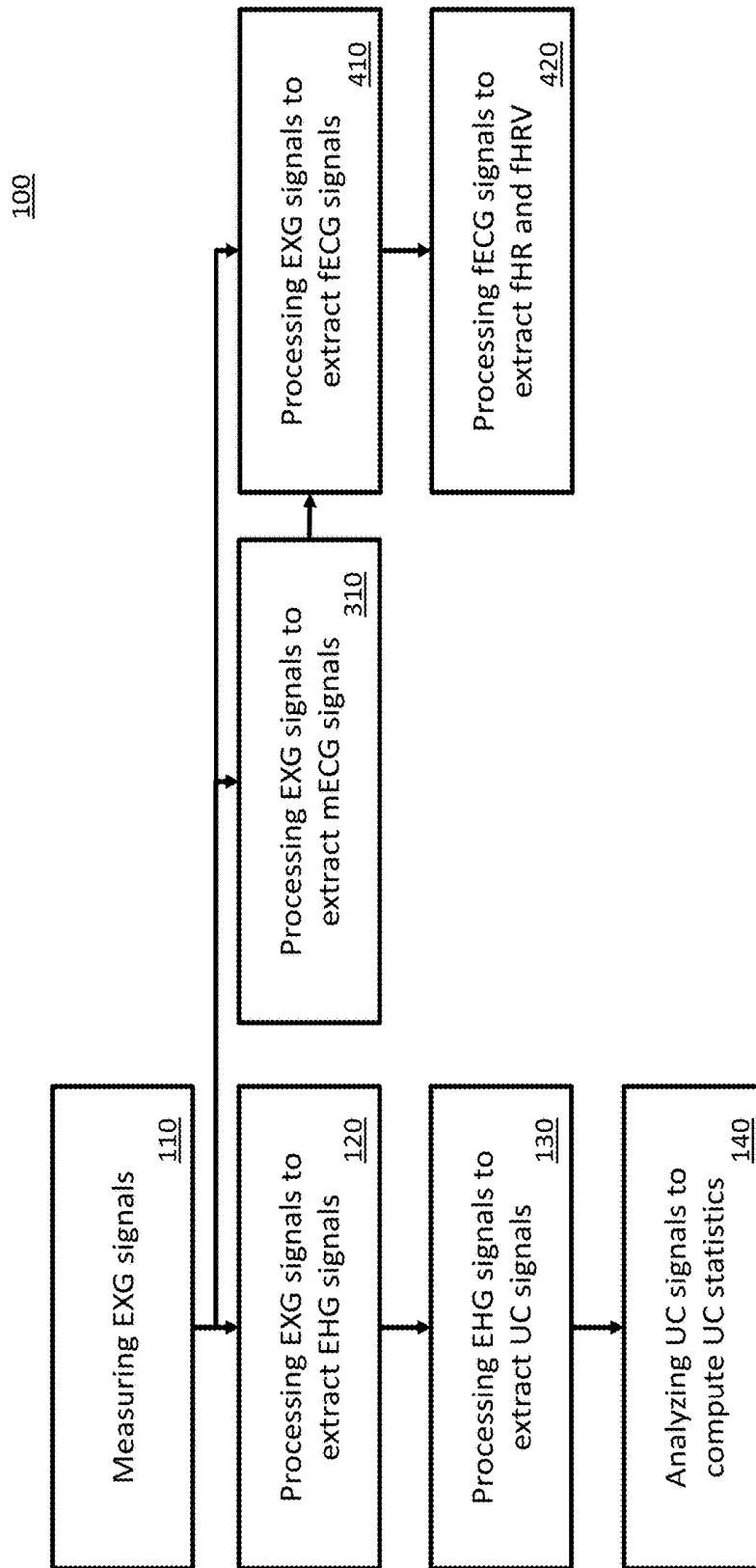


FIG. 9B

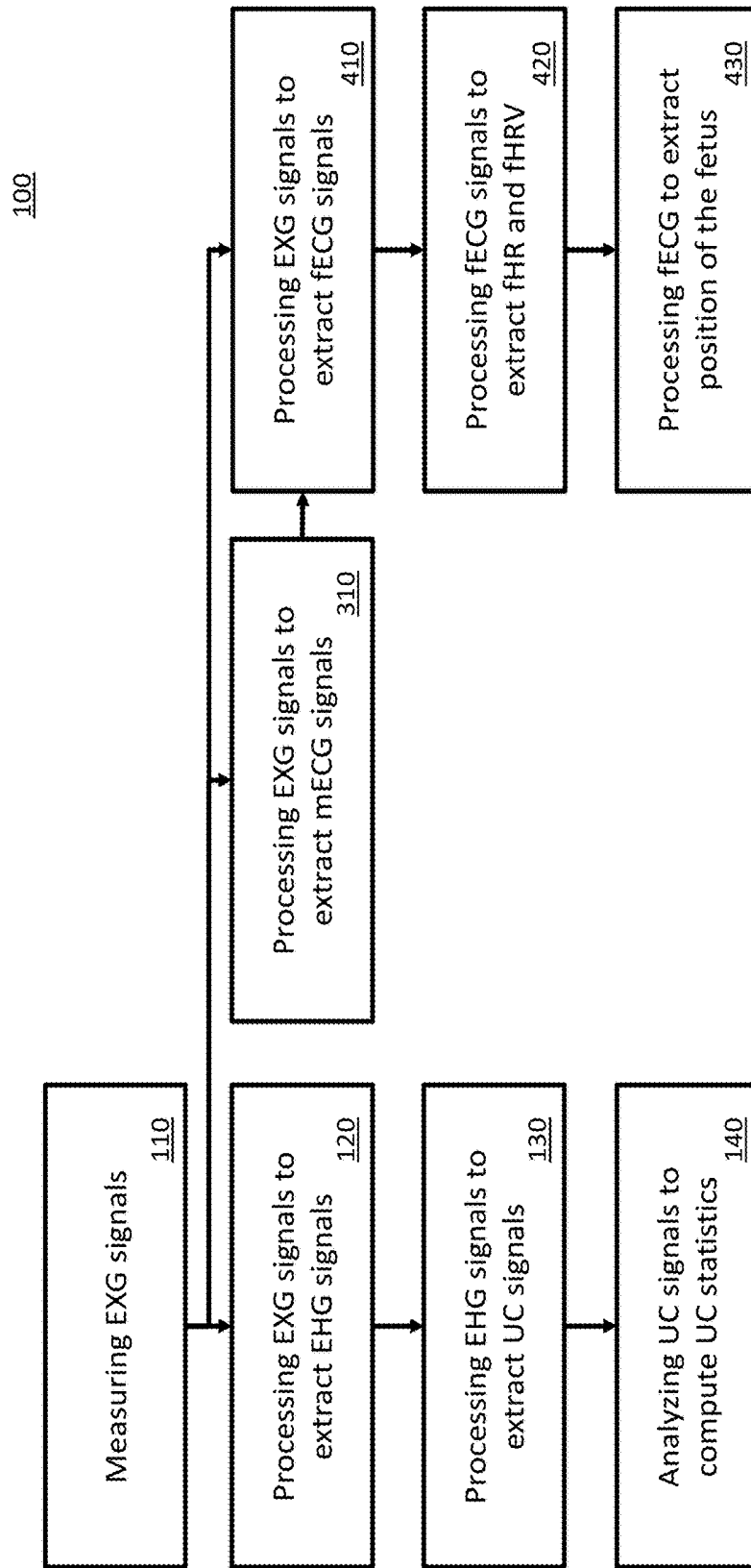


FIG. 9C

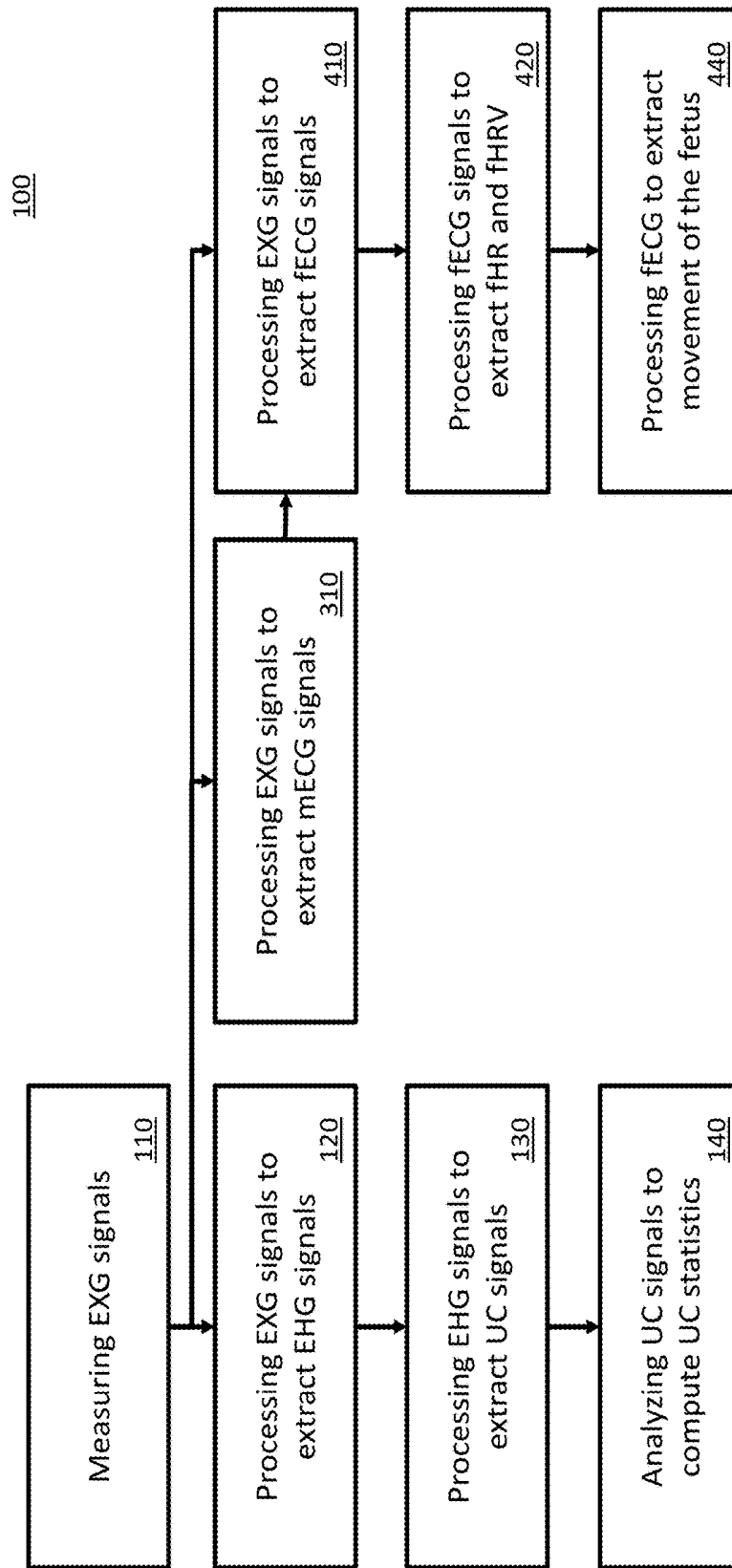


FIG. 9D

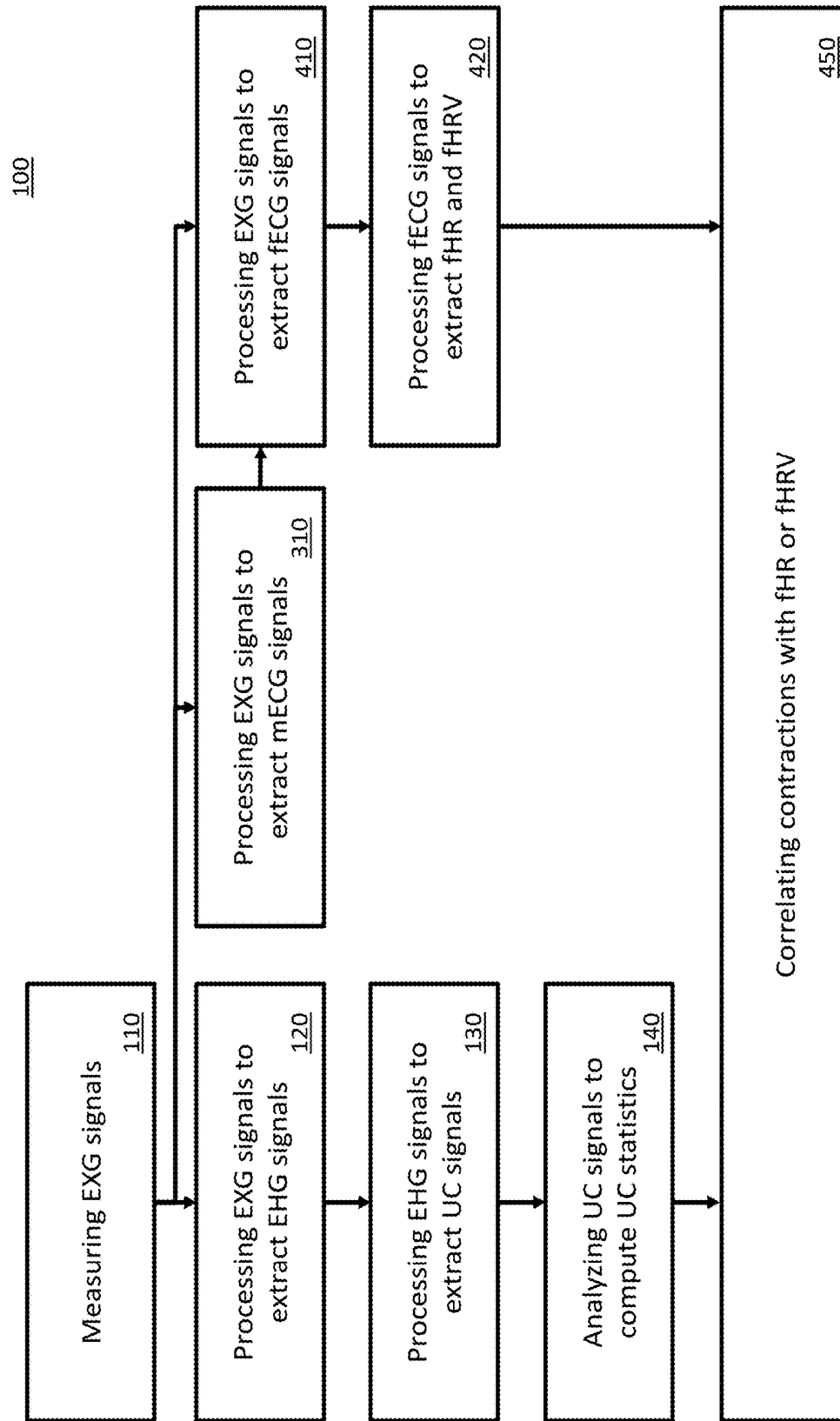


FIG. 10

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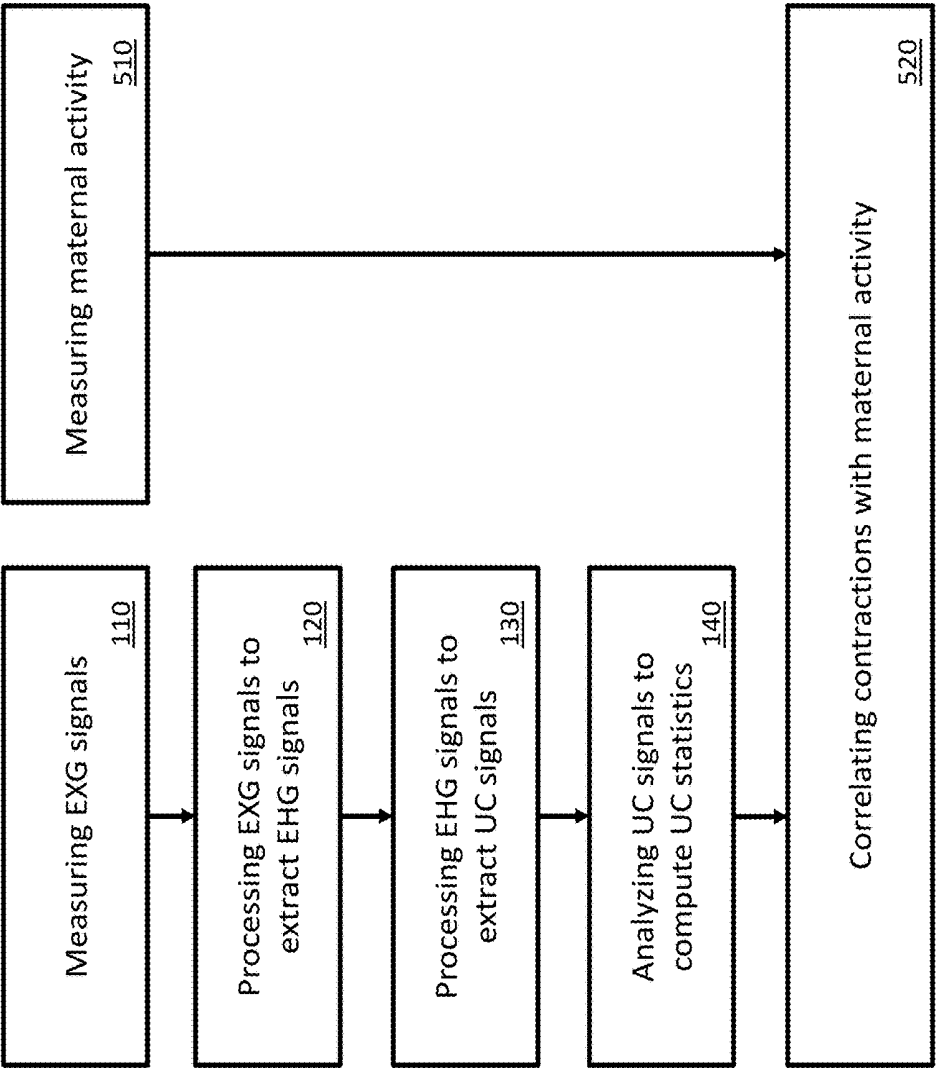


FIG. 11

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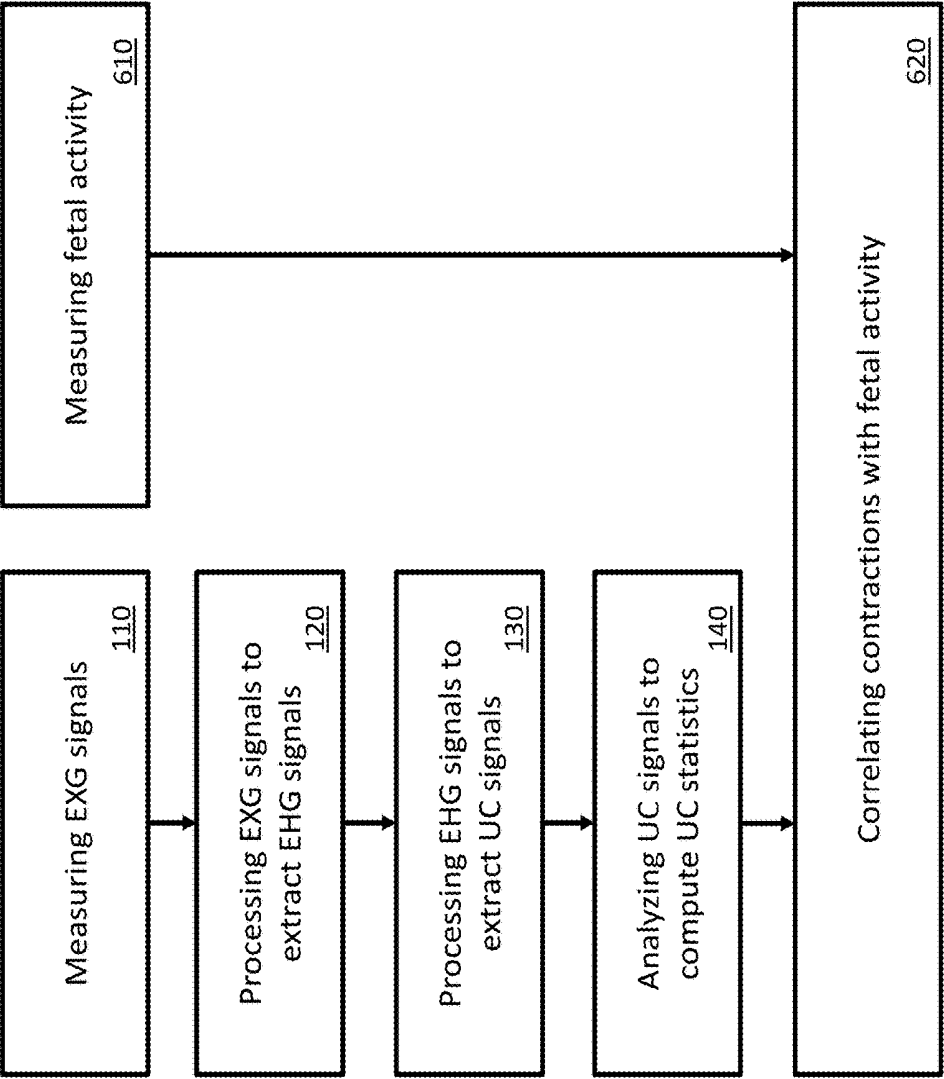


FIG. 12

2000

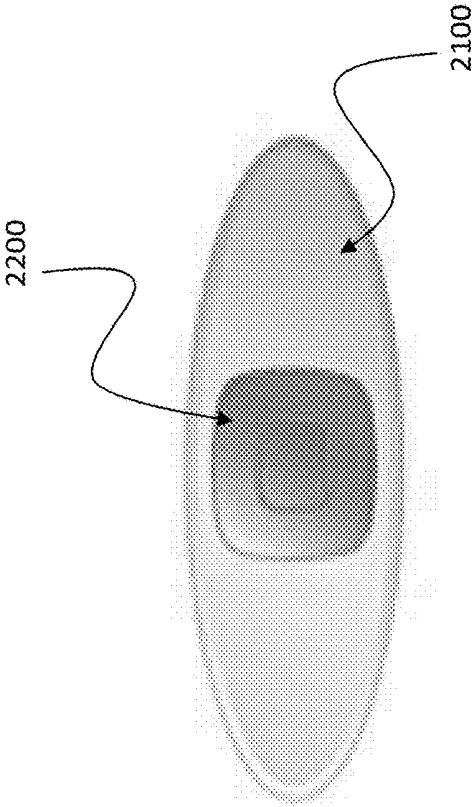


FIG. 13

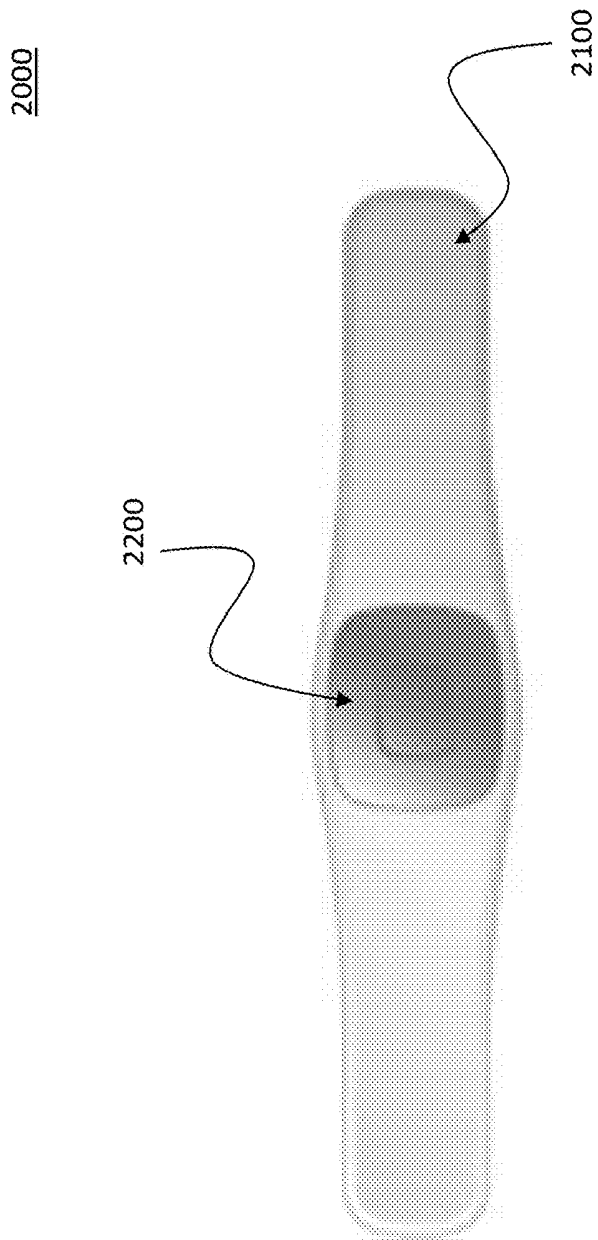
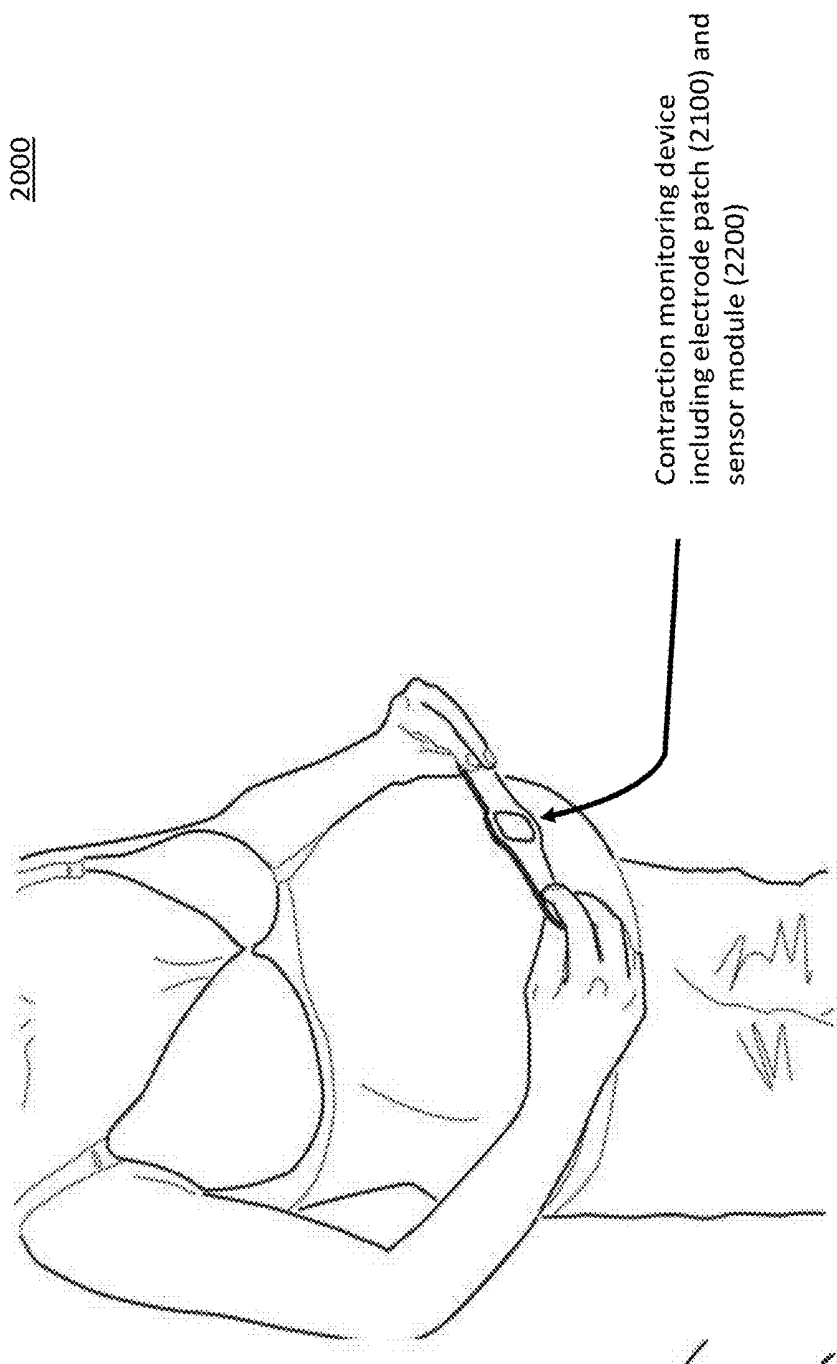


FIG. 14



2030

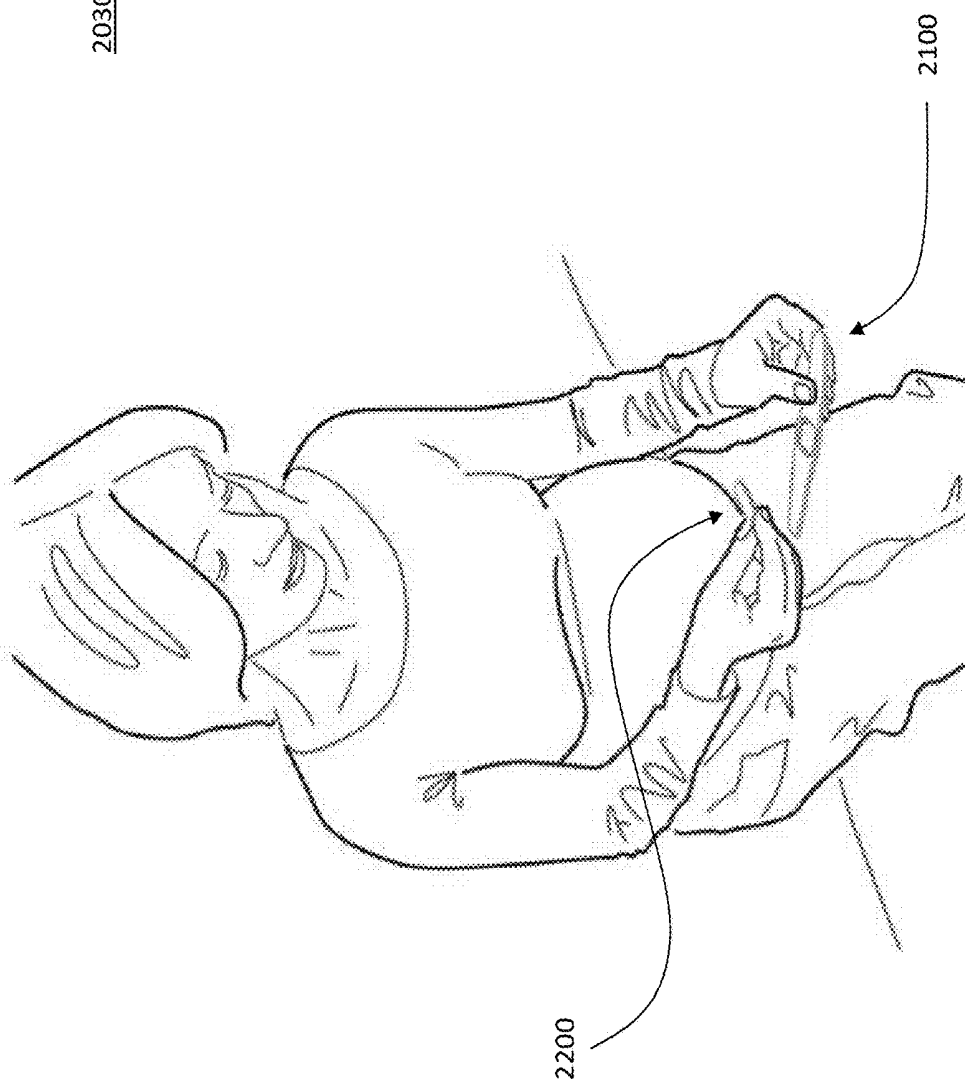


FIG. 16

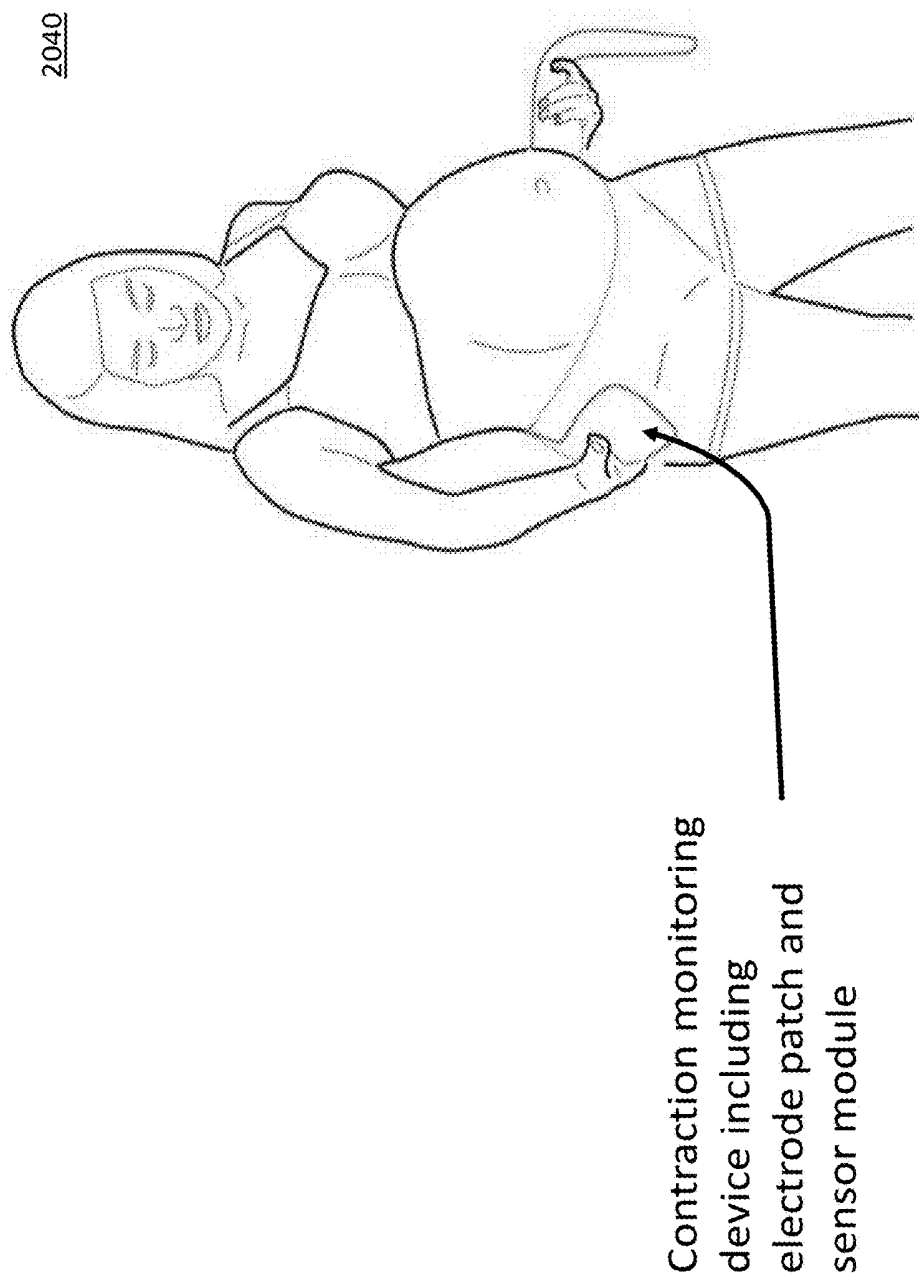


FIG. 17

2050

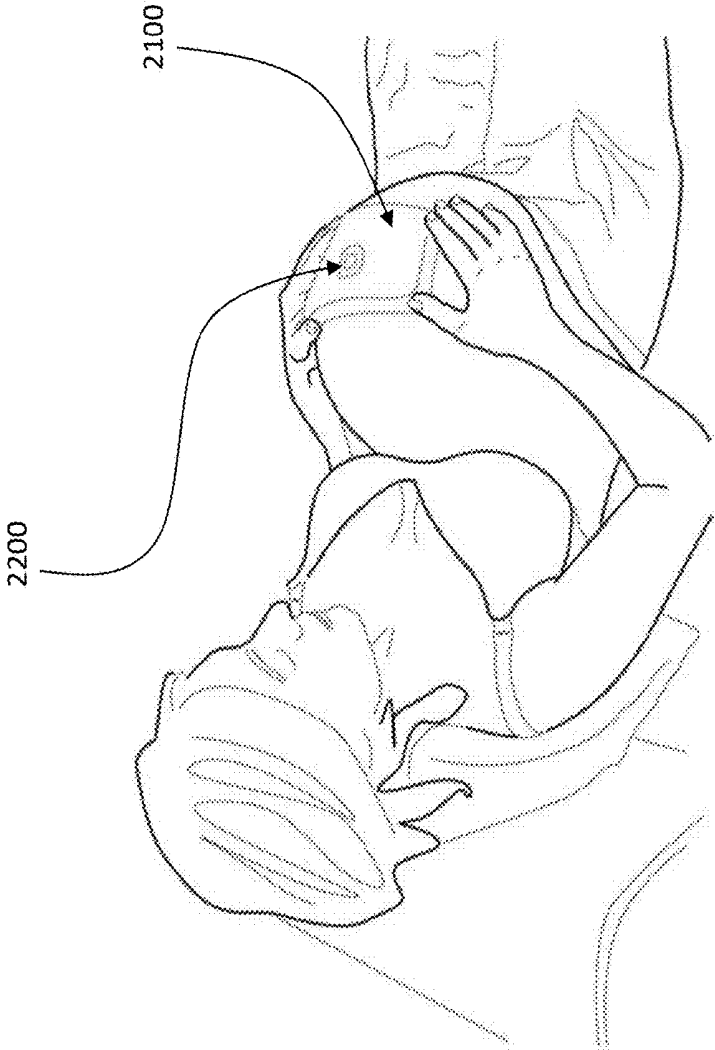


FIG. 18

2200

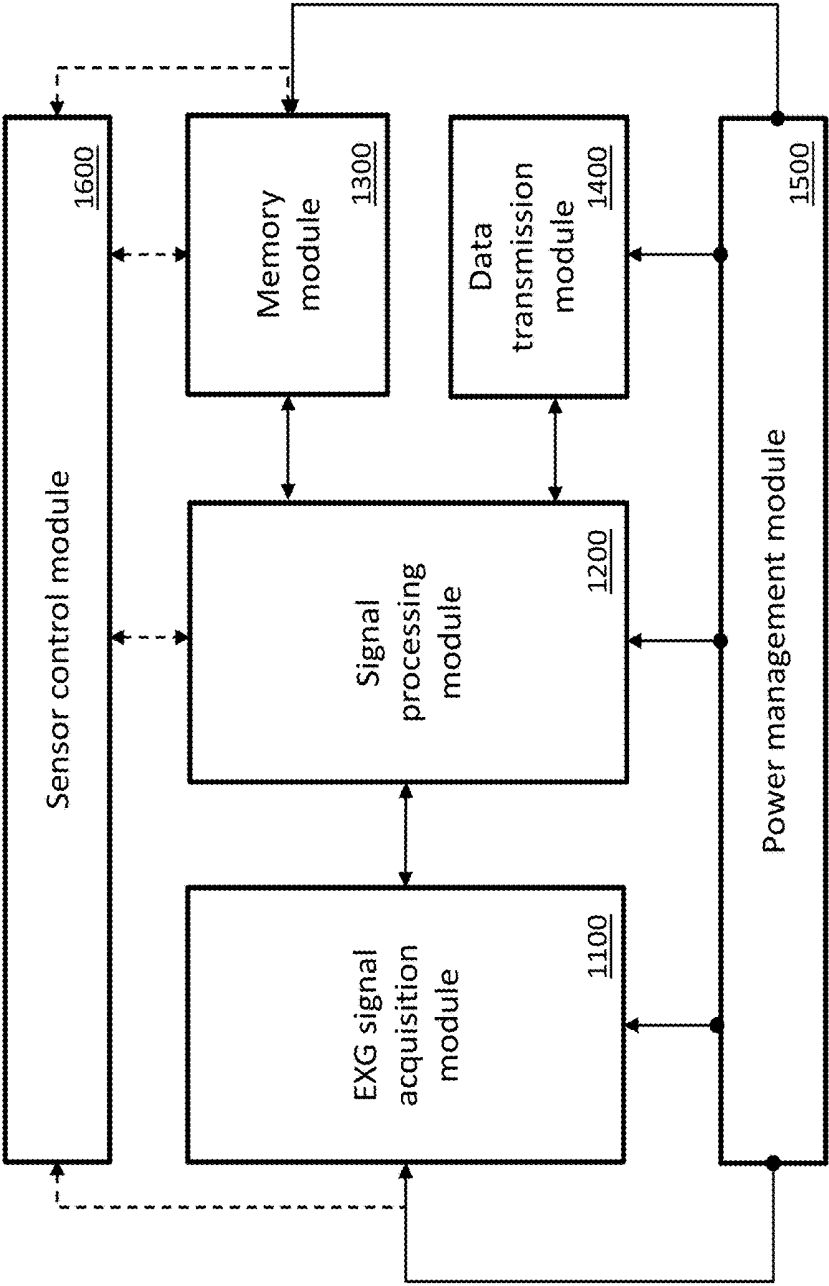


FIG. 19

2200

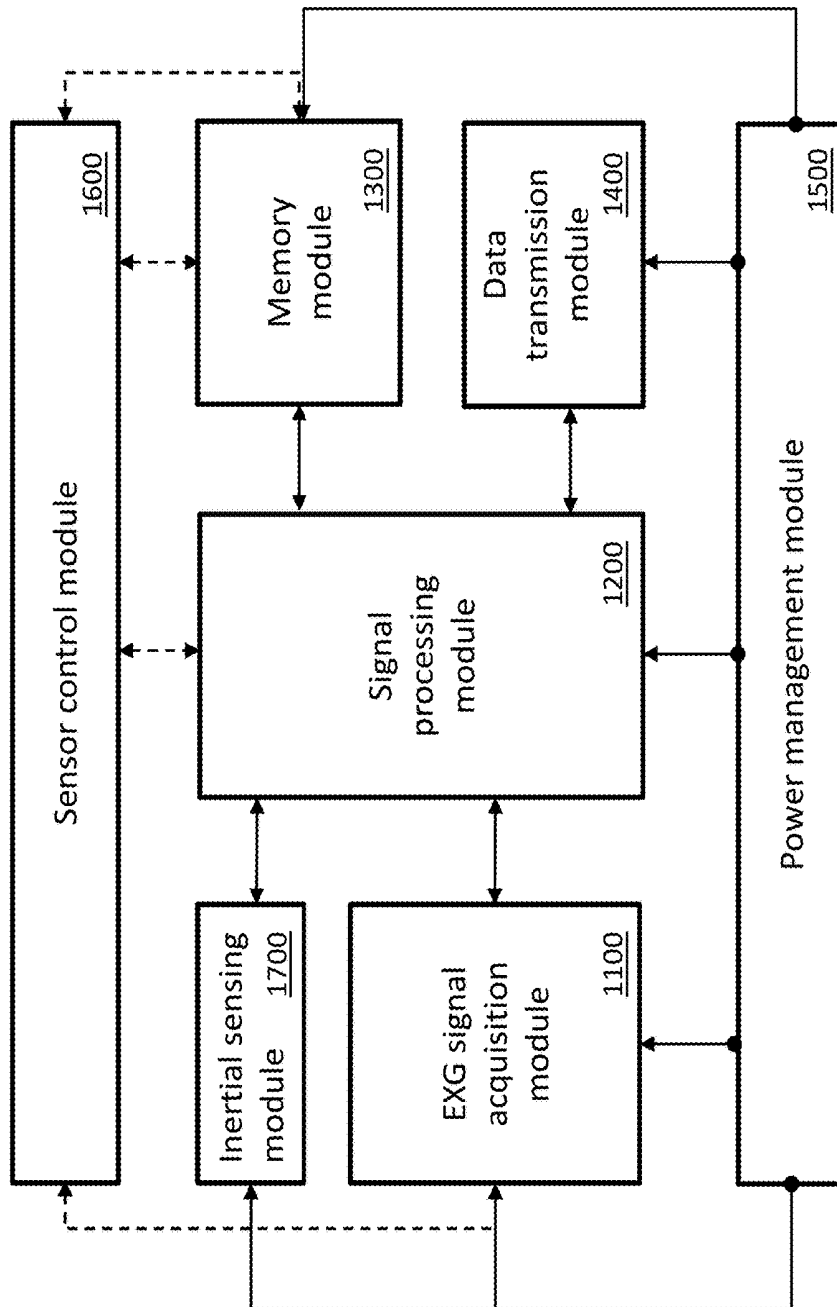


FIG. 20

2200

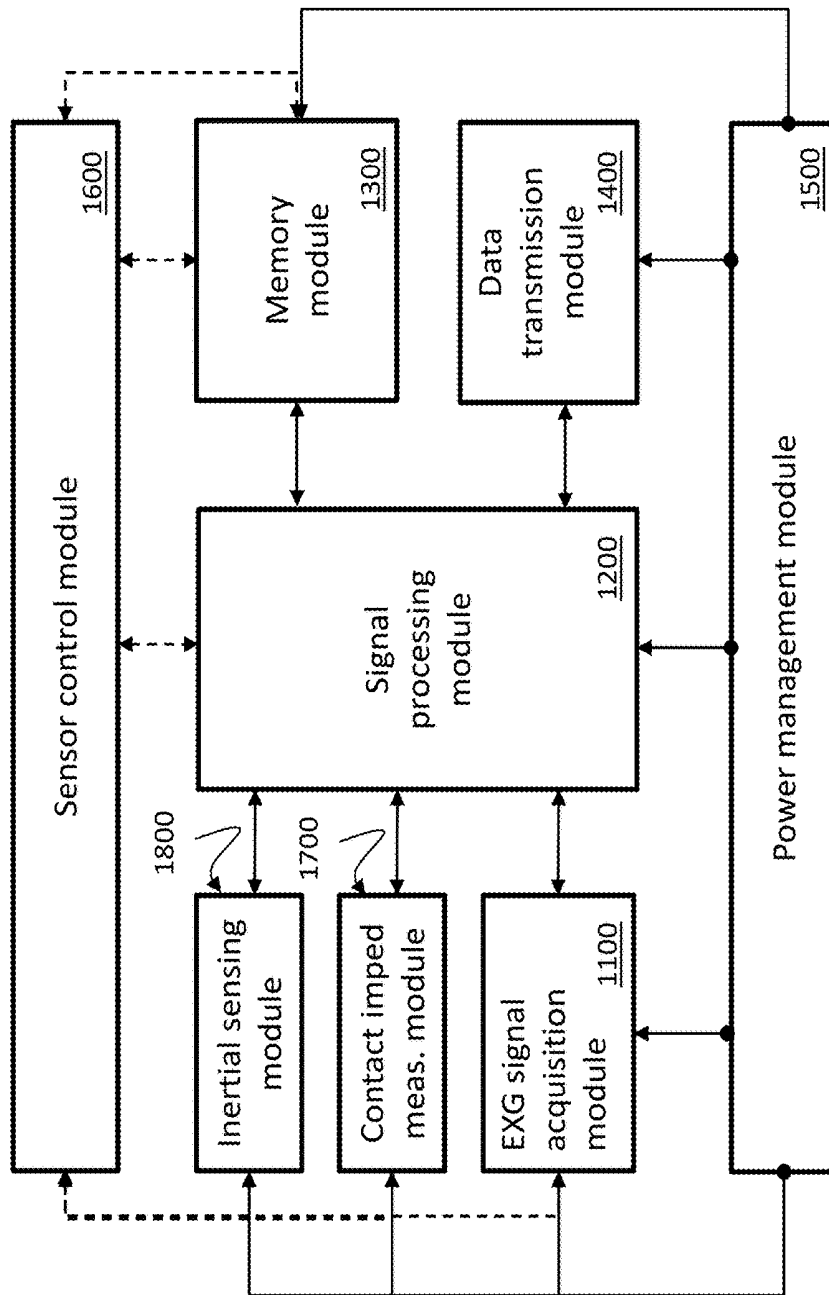


FIG. 21

2200

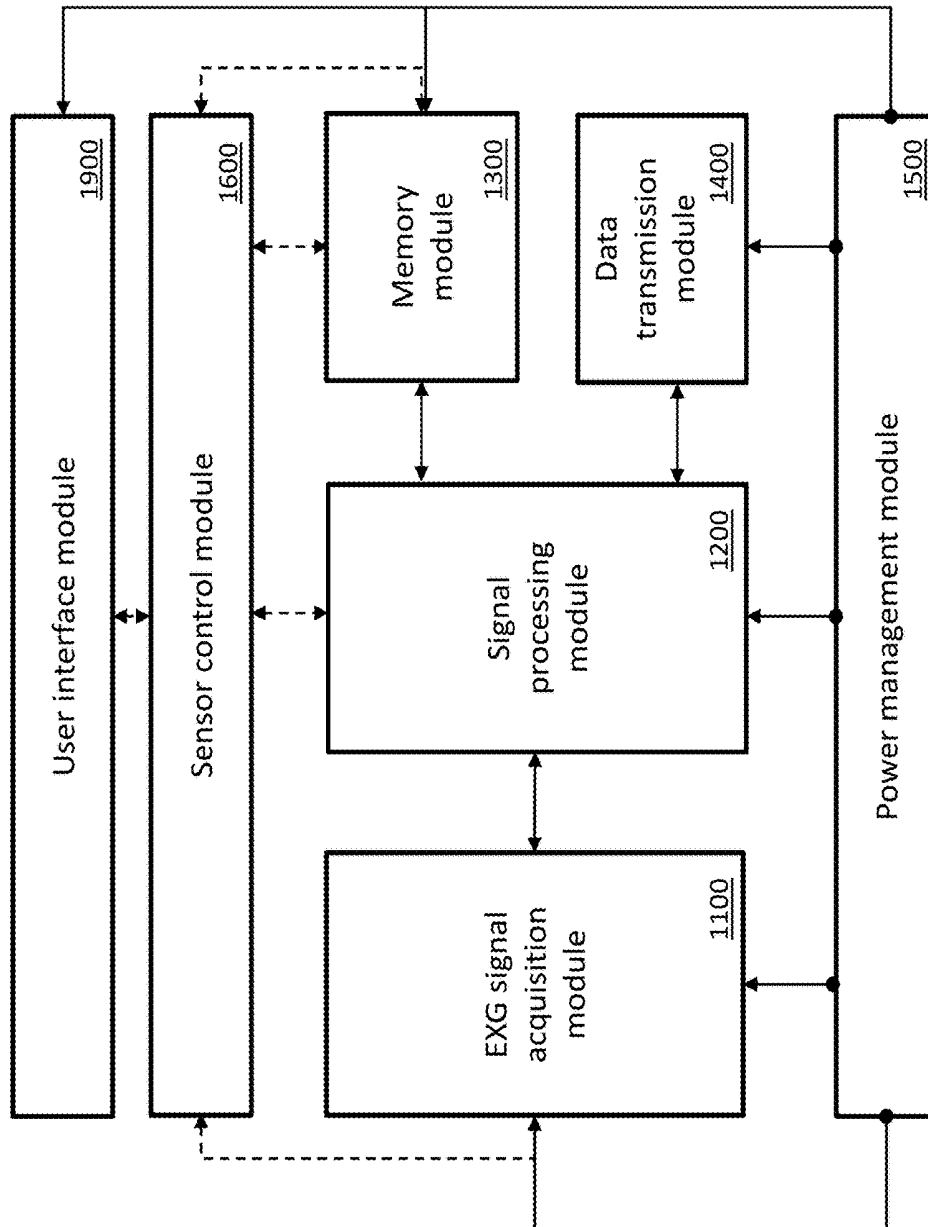


FIG. 22

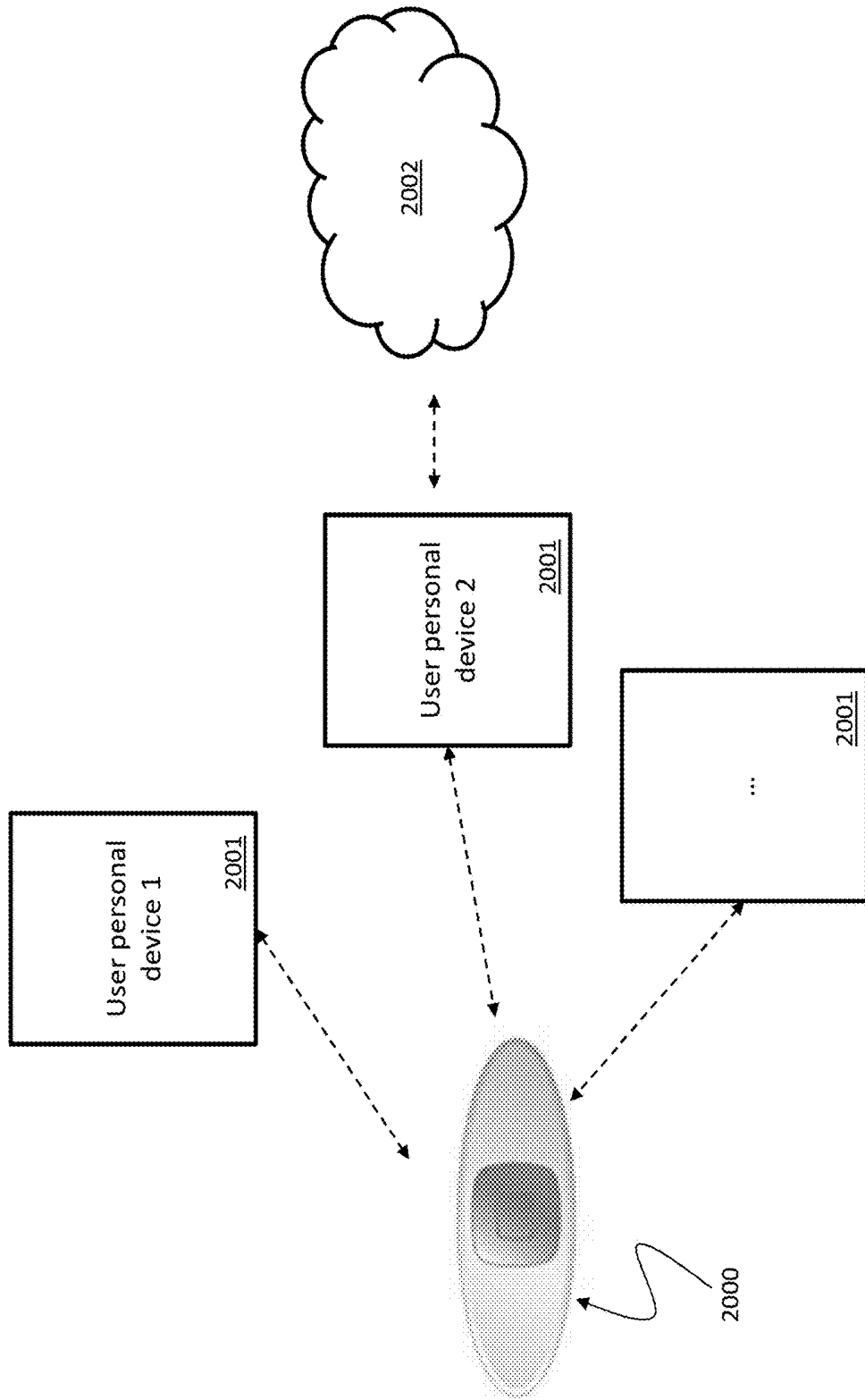


FIG. 23

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METHOD AND DEVICE FOR CONTRACTION MONITORING

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is the U.S. National Stage filing for PCT Application Ser. No. PCT/US2015/058153, now published as WO/2016/067101, titled "A Method and Device for Contraction Monitoring," filed Oct. 29, 2015, which is herein incorporated by reference in its entirety.

This application claims priority benefits to U.S. provisional patent application Ser. No. 62/072,348, titled "Method and Device for Contraction Monitoring", filed on Oct. 29, 2014, which is herein incorporated by reference in its entirety.

This application claims foreign priority benefits to Belgium patent application No. BE2015/5056, titled "Method and Apparatus for Monitoring Contractions in Pregnancy", filed on Feb. 5, 2015, which is herein incorporated by reference in its entirety.

FIELD

This invention relates to the field of pregnancy monitoring and more particularly to a method and device for contraction monitoring.

BACKGROUND

Pregnant women are full of questions about their pregnancy, their bodies, and their babies. One of the most stressful questions for late term women is am I having contractions? Answering this question is key to understand when labor is starting, allowing a pregnant couple to prepare for the imminent delivery and eventually leave, in a timely manner, for the hospital or the care institution where the delivery will happen. During the second and third trimester already, women may experience early contractions, also referred as Braxton Hicks contractions. Braxton Hicks contractions are the manifestation that the uterus is slowly preparing for the delivery. The feeling of a contraction is completely new and it is impossible for a woman to reliably identify a contraction from other abdominal physiological disturbances such as abdominal cramps or bowel disturbances. This is especially true for first time moms, but second and third time moms also report this problem, as they would often forget what a contraction feels like.

Next to pregnant women, clinicians have a vast interest in monitoring contractions. History of contractions is part of the clinical examination in most countries, and an OBGYN will typically ask her pregnant patient whether she has had contractions since her last visit, and how often. The answer to this question is inevitably inaccurate since a woman is not able to reliably report contractions.

Despite the importance of monitoring contractions outside the hospital or physician's office, from both a consumer and clinician perspective, there is to date no solution available for contraction monitoring outside controlled clinical settings. The best alternative solution available today for consumers is a stopwatch, physical and digital. Stopwatches rely on the woman's perception and feeling of a contraction, and are therefore intrinsically inaccurate and do not address the problem that woman cannot recognize or detect their contractions.

In healthcare practices, contractions are measured using a tocograph, which measures the pressure resulting from the

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contraction using a probe positioned on the woman's abdomen. The tocograph has several limitations. First, a tocograph is obtrusive, as it requires a woman to use a strap around her abdomen, a large pressure probe and gel. The obtrusiveness of a tocograph limits its applicability outside controlled clinical environments. Second, the position of the tocograph probes is important in getting a reliable measurement. As a consequence, the tocograph has to be operated by trained clinical staff and cannot be used by the pregnant woman herself. Third, a tocograph only measures the result of the contraction (a change in pressure on the surface of the abdomen), and not the actual physiological phenomena leading to the contraction. As a consequence, tocographs have shown low accuracy in characterizing contractions, especially the intensity of the contractions.

Physiologically, the contraction originates with the electrical activation of uterine cells, similar to the activation of muscle cells. Measuring the uterine electrical activity is a more accurate and more reliable way of measuring contractions called electrohysterography (EHG). US2012/0150010-A1 describes a device and method for monitoring uterine activity based on EHG. However, such devices are today limited to bulky devices with electrodes and wires, operated by clinically experienced staff, and limited to the clinical environment. Attempts have already been made to improve the ease of use and the bulkiness of such devices. US2007/0255184-A1 discloses a disposable labor detection patch using electromyogram signals of the uterus. However, such a concept of a disposable patch integrating all the electronics will inevitably be associated with a very high cost due to the cost of the electronic components, hindering its practicality and usability as a disposable system. Although the electrode part of the system needs to be often replaced for hygiene and signal quality reasons, the electronics can be used for hundreds or thousands of recordings without the need to be disposed or replaced. Furthermore, although a patch may be applicable for some pregnant women, attaching an adhesive on the abdomen of a pregnant woman often will be considered uncomfortable as it may lead to itching sensations, irritations, allergies or other disturbances. For such cases, considering other form factors than a patch would be advantageous.

Furthermore, the devices of US2012/0150010-A1 and US2007/0255184-A1 are limited in their functionality. These devices merely provide a measurement of the contraction signal, and do not perform any further analysis on the signal. As a result they are of limited value to the user directly, but require the intervention of a clinically experienced staff to interpret the results.

Electrodes placed on the abdomen of a pregnant woman are capable of measuring bio-potential signals that comprise various electrical signals generated by the body such as the maternal electro-cardiogram (mECG), the fetal electro-cardiogram (fECG) as well as the uterine electrohysterogram (EHG) and uterine electromyogram (UEMG) which is equivalent to the electrical signature of the uterine muscle contraction. The electrohysterogram can be seen as a high level view on the uterine electrical activity, looking at the slower waves that are generated by the common activation of a larger number of uterine cells. Complementarily, the uterine electromyogram can be seen as a fine view on the uterine electrical activity, looking at the fast paced electrical waves generated locally by smaller sets of uterine cells. EHG signals are usually analyzed in the time domain, using RMS, linear filters or other statistics, to come to an estimation of a contraction signal. UEMG signals are usually analyzed in the time frequency domain using Fourier trans-

forms, wavelet transforms, etc. EHG and UEMG signals are superposed to the maternal and fetal electro-cardiogram. Signal processing techniques are also required to isolate every physiological contributions to the bio-potential signals.

All these signals are monitored during long periods of time in the hospital during labor or in the last months of the pregnancy for monitoring and need to be further analyzed by a care specialist. These signals are usually displayed on a screen or printed on a sheet of paper while the signals are being recorded.

In view of the foregoing, a need exists in pregnancy monitoring for a device and a method for contraction monitoring that can be used by pregnant women in any environment, answering the most stressful questions that women have as they are progressing throughout pregnancy, while providing important clinical information that the healthcare practitioner can use during his clinical examination.

DISCLOSURE OF THE INVENTION

These aims are achieved according to the embodiments of the invention.

According to an aspect of the present invention, there is provided a contraction monitoring system comprising an electrode patch comprising at least two electrodes, including a measurement electrode and a reference electrode, and

a sensor module configured to be connected to the electrode patch, the sensor module comprising a signal acquisition module, a signal processing module, a power management module, a sensor control module and at least one of a memory module or a data transmission module, wherein

the signal acquisition module is configured to perform a method comprising the steps of measuring bio-potential signals by providing at least two electrodes on the abdomen of a pregnant woman, the signal processing module is configured to perform a method comprising the steps of

processing the bio-potential signal to extract electrohysterogram signals, processing the extracted signals to extract uterine contraction.

In an embodiment of the system according to the present invention, the method performed by the signal processing module further comprises the steps of processing the bio-potential signal to extract maternal electrocardiogram signals.

In another embodiment of the system according to the present invention, the method performed by the signal processing module further comprises the steps of processing the bio-potential signal to extract fetus electrocardiogram signals.

In a further embodiment of the system according to the present invention, the method performed by the signal processing module further comprises the steps of isolating from the electrohysterogram signals the part of the electrohysterogram signal that is relevant to the electrical activity of the uterus, and separating it out from the part of the electrohysterogram signal that is related to other physiological phenomena, noise, artifacts and any other contributions.

According to an embodiment of the present invention, the sensor module further comprises an inertial sensing module and the signal acquisition module further comprises the step of acquiring inertial sensing module data.

In a specific embodiment, the method performed by the signal processing module further comprises the steps of processing the inertial sensing module data to extract uterine contraction signals.

Advantageously, the method performed by the signal processing module further comprises the steps of processing the inertial sensing module data to measure motion artifact and wherein the step of processing the bio-potential signal to extract electrohysterogram signals, maternal electrocardiogram signals and fetus electrocardiogram signals, further comprises the step of applying motion artifact filtering to at least one of the extracted signals based on the measured motion artifact.

In an embodiment of the present invention, artifacts are detected by advantageously combining electrohysterogram signals and inertial sensing module data. Motion artifacts are made up of broad spectrum frequency components and artifacts which affect the signal of interest will also be visible outside of the specific band of interest. In general, motion artifacts are characterized by a short-time high-energy peak over a wide spectral range of the bio-potential signals. Detection of artifacts in bio-potential signals can hence be performed by calculating the energy of the signal outside of the band of interest, and setting a moving threshold (TA) to detect the instances in which a motion artifact distorts the signal of interest. The threshold for artifact detection is dynamically changed based on the moving baseline energy in the frequency band used for artifact detection. This method has proven successful in detecting strong motion artifacts, but is not sufficient in situations where the baseline energy level is high, or if the influence of the motion on the energy in the artifact detection band is low. In these cases, we can advantageously use of an inertial sensor to dynamically lower the threshold level during instances of increased motion of the sensor module. To this end, two features related to the rotational and translational energy of the inertial sensor are calculated and linearly combined as an indicator of the amount of sensor motion. When the amount of sensor motion exceeds a set minimum level (L_m), which can occur due to sensor noise of minor movements due to breathing, fetal movement, etc., the threshold TA, used to detect motion artifacts in the bio-potential signal, is lowered. The amount by which the threshold TA is lowered depends on the amount by which the sensor motion energy (E_m) exceeds the minimum level L_m . This way, the motion energy E_m can temporarily increase the sensitivity of the system in the detection of motion artifacts. Furthermore, as sharp motions often result in residual artifacts after the actual motion has subsided, a first order IIR filter is used to slowly return the threshold TA to its original value.

In an embodiment of the present invention, the method performed by the signal processing module further comprises the steps of

processing bio-potential signal to extract uterine electromyogram (UEMG),

processing the UEMG signals to extract UEMG markers, and

classifying the bio-potential signals into contraction types based on the UEMG markers.

In a preferred embodiment, UEMG markers comprise statistical features, such as at least one of average, mean, percentiles, standard deviation, kurtosis, any other statistical moments,

power spectrum features such as at least one of total power in the bandwidth, peak power, mean power, average power, power in certain frequency bands, entropy features and spatial propagation features such as at least one of laplacian, gradient, and higher order propagation features to indicate the rate, the pattern and the spatial distribution of the firing of the uterine contractile cells.

According to another embodiment of the present invention, the method performed by the signal processing module further comprises the step of analyzing the uterine contraction signals to compute uterine contraction statistics.

In a preferred embodiment of the present invention, the sensor module further comprises an inertial sensing module and/or is configured to interact with an activity sensor provided by another device, and wherein the method performed by the signal processing module further comprises the steps of

measuring maternal activity,
correlating maternal activity with uterine contraction signals and/or uterine contraction statistics.

According to a further embodiment of the present invention, the step of processing the individual signals to extract uterine contraction signals further comprises the steps of processing the mECG signals to extract a maternal heart rate (mHR) and maternal heart rate variation (mHRV), processing mHR and mHRV to extract maternal stress level, correlating contractions with maternal stress level.

In an embodiment of the system according to the present invention, the method performed by the signal processing module further comprises the step of providing user feedback.

According to a preferred embodiment of the present invention, the method performed by the signal processing module further comprises the steps of

processing the fECG signals to extract a fetal heart rate (fHR) and fetal heart rate variation (fHRV),
correlating contractions with fetal fHR and/or fHRV.

Advantageously, the method performed by the signal processing module further comprises the steps of extracting the position and movement of the fetus from the fECG, measuring fetal activity from the position and movement of the fetus.

Preferably, the method performed by the signal processing module further comprises the step of measuring fetal activity with the inertial sensing module.

According to an embodiment of the present invention, the method performed by the signal processing module further comprises the step of correlating uterine contraction signals and/or uterine contraction statistics with fetal activity.

In a preferred embodiment, the electrode patch further comprises a bias electrode and a second measurement electrode, wherein the first and second measurement electrodes are located on the two extremities of the electrode patch, and wherein the reference electrode is located substantially in the middle of the electrode patch.

In another preferred embodiment, the electrode patch further comprises a third measurement electrode, wherein the first and second measurement electrode and the reference electrode are positioned substantially on a line, and wherein the third measurement electrode is positioned below the reference electrode substantially perpendicular to the line.

According to another aspect of the present invention, there is provided an electrode patch for use in the system as described above, comprising a bias electrode, three mea-

surement electrodes and a reference electrode, wherein the first and second measurement electrode and the reference electrode are positioned substantially on a line, wherein the third measurement electrode is positioned below the reference electrode substantially perpendicular to the line.

According to another aspect of the present invention, there is provided a sensor module for use in the system as described above, configured to connect to the electrode patch described in the present patent application, comprising the signal acquisition module, the signal processing module, the power management module, the sensor control module and at least one of the memory module or the data transmission module.

It is a further aspect of the present invention to provide a contraction monitoring device for use in the system disclosed in this application, comprising an electrode patch and a sensor module configured to communicate with a user personal device configured to perform parts of the functions carried out by the signal processing module and/or by the signal acquisition module of the sensor module.

Advantageously, functions carried out by the user personal device further comprise

using context information coming from the user personal device to improve the accuracy and reliability of the user's uterine contraction activity estimation, maternal activity estimation, maternal stress estimation, fetal HR/HRV estimation, fetal movement estimation, fetal position estimation,
providing feedback to the user according to the measured parameters and estimated information to improve lifestyle and reduce risks related to pregnancy.

In an embodiment, a method for monitoring contractions is provided which comprises the steps of:

- measuring bio-potential signals by providing at least two electrodes on the abdomen of a pregnant woman,
- processing the bio-potential signals to extract EHG signals,
- processing the EHG signals to extract uterine contraction signals, and
- analyzing the uterine contraction signals to compute uterine contraction statistics.

This method allows the measurement of various types of bio-potential signals that carry information about the uterine activity of the pregnant woman. Each bio-potential signal can be processed and provide specific information related to the uterine activity of the pregnant woman. Combining the information corresponding to each type of bio-potential signal results in a more precise analysis of the uterine activity of the pregnant woman and allows a better and more precise diagnosis. Thanks to the uterine contraction statistics performed at step d) using the various contraction signals, this diagnosis is performed automatically by the method and no care specialist is required to interpret the various signals acquired. The uterine statistics computed are used to inform or alert the pregnant woman of the current status of her pregnancy and when she may need to go to the hospital. Such a device can therefore minimize risks of miscarriage, pre-term birth, and any complications related to pregnancy. Thanks to the method, the pregnant woman can be aware at all times of the current status of her pregnancy.

In embodiments of the invention, the processing of bio-potential signals comprises isolating and separating a part of the bio-potential signals that is relevant to the electrical activity of the uterus.

In embodiments of the invention, step b) comprises applying a filter having a bandpass of 0.3 Hz to 0.8 Hz to the biopotential signals.

In embodiments of the invention, the measured bio-potential signals comprise electrohysterogram signals, uterine electromyogram signals, maternal electrocardiogram signals and fetus electrocardiogram signals.

In embodiments of the invention, measuring bio-potential signals comprises providing at least three electrodes on the abdomen of the pregnant woman wherein the third electrode is used as a bias electrode or third leg electrode.

In embodiments of the invention, measuring bio-potential signals comprises three measurement electrodes, one reference electrode and one bias electrode.

In embodiments of the invention, the reference electrode is positioned slightly under the navel.

In embodiments of the invention, the three measurement electrodes are such that one is positioned to the right, one is positioned to the left and one is positioned below the reference electrode.

In embodiments of the invention, the distance between the reference electrode and each measurement electrode is between 3 to 10 centimeters.

In embodiments of the invention, the electrodes are integrated in one electrode patch, and wherein the step of measuring bio-potential signals comprises providing the electrode patch to the abdomen of the pregnant woman.

In embodiments of the invention, the step of processing the bio-potential signals comprises at least one of time-domain filtering, frequency-domain filtering, time-frequency-domain filtering or blind source separation.

In embodiments of the invention, the step of processing EHG signals comprises converting EHG signals into uterine contraction signals.

In embodiments of the invention, the step of processing EHG signals comprises at least one of root-mean-square, averaging, linear filters, integration operators, energy operators or entropy operators.

In embodiments of the invention, the step of analyzing uterine contraction signals comprises extracting uterine contraction features to calculate uterine contraction statistics.

In embodiments of the invention, the uterine contraction features comprises at least one of on-set, end or amplitude of a contraction.

In embodiments of the invention, the step of analyzing uterine contraction signals comprises determining the contraction on-set by determining the inflexion point of the uterine contraction signal, verifying if the inflection point corresponds to an ascending slope and determining the closest zero-derivative point in the uterine contraction signal prior to the inflexion point.

In embodiments of the invention, the step of analyzing uterine contraction signals comprises determining the end of a contraction by determining the inflexion point of the uterine contraction signals, verifying if this inflexion point corresponds to a descending slope and determining the closest zero-derivative point of the uterine contraction signals.

In embodiments of the invention, the step of analyzing uterine contraction signals further comprises determining the contraction amplitude by determining the local maximum between the contraction on-set and the end of a contraction.

In embodiments of the invention, the step of analyzing uterine contraction signals comprises identifying patterns in the uterine contraction signals by applying a wavelet transform to the uterine contraction signals wherein the on-set of the contraction is determined by the point at which the energy of the wavelet raises above a predetermined value

and the amplitude of the contraction is determined by the total power of the wavelet transform.

In embodiments of the invention, the step of analyzing uterine contraction signals comprises matching the uterine contraction signals with template signals stored in a database.

In embodiments of the invention, the database is user specific.

In embodiments of the invention, the uterine contraction statistics comprise at least one of frequency, duration or intensity of contraction.

In embodiments of the invention, the step of measuring bio-potential signals comprises receiving bio-potential signals, and conditioning and amplifying the received bio-potential signals.

In embodiments of the invention, the step of measuring bio-potential signals comprises filtering artifacts.

In embodiments of the invention, the filtering of artifacts comprises measuring a motion artifact signal in parallel to the bio-potential signals.

In embodiments of the invention, the motion artifact signal is measured by an accelerometer attached to the at least two electrodes.

In embodiments of the invention, the motion artifact signal is a contact impedance measured using the at least two electrodes.

In embodiments of the invention, the step of filtering artifacts comprises receiving measured motion artifact data.

In embodiments of the invention, the step of analyzing the uterine contraction signals comprises extracting uterine contraction features from the uterine contraction signals, detecting contractions, and calculating uterine contraction statistics.

In embodiments of the invention, the method further comprises

(e) processing the bio-potential signals to extract uterine electromyogram (UEMG) signals,

(f) processing the UEMG signals to extract UEMG markers, and

(g) classifying the bio-potential signals into contraction types based on the UEMG markers.

In embodiments of the invention, the step of processing UEMG signals comprises extracting UEMG features to extract the UEMG markers.

In embodiments of the invention, at least one of the uterine contraction statistics of step (d) are used as input for the processing of UEMG signals in step (f).

In embodiments of the invention, the method further comprises

(h) identifying bio-processing signals representing labor.

In embodiments of the invention, the step of identifying bio-processing signals representing labor is using at least one of a UC statistic of step (d) or a contraction type of step (g).

In embodiments of the invention, the method further comprises

(i) processing the bio-potential signals to extract maternal electro-cardiogram (mECG) signals,

(j) processing the mECG signals to extract a maternal heart rate (mHR).

In embodiments of the invention, the step of processing the mECG signals comprises analyzing the mECG signals to extract mECG R-waves.

In embodiments of the invention, the method further comprises

(k) processing the maternal heart rate to extract maternal stress level.

In embodiments of the invention, the method further comprises

- (l) processing the bio-potential signals to extract fetal electro-cardiogram (fECG) signals,
- (j) processing the fECG signals to extract a fetal heart rate (fHR).

In embodiments of the invention, the processing to extract fECG signals in step (1) uses the mECG signals of step (i) as input to filter the mECG signals from the fECG signals.

In embodiments of the invention, the processing of the fECG signals comprises determining the morphology of the fECG signals.

In embodiments of the invention, the method further comprises the step of simultaneously visualizing the UC signals and the fHR signals to determine fHR changes during a contraction.

In embodiments of the invention, the method further comprises measuring maternal activity using an activity sensor.

In embodiments of the invention, the method further comprises measuring fetal activity using an accelerometer positioned on the abdomen of the pregnant woman.

In embodiments of the invention, the method further comprises providing information to the pregnant woman based on at least one of a UC statistic of step (d) or a contraction type of step (g).

In an embodiment, a contraction monitoring device is provided which comprises

- an electrode patch comprising at least two electrodes, including a measurement electrode and a reference electrode, and
- a sensor module configured to be connected to the electrode patch, the sensor module comprising a signal acquisition module, a signal processing module, a power management module, a sensor control module and at least one of a memory module or a data transmission module.

While the electrodes are incorporated inside the electrode patch, there is no risk for the woman to misplace the various electrodes as their relative positioning is already correct on the electrode patch. The use of an electrode patch also improves the experience and the ease of use of contraction monitoring, as it does not require attaching multiple electrodes to the abdomen, but only requires attaching one single electrode patch. Also this electrode patch can be just positioned on the woman's abdomen. It can then be attached by an adhesive layer or incorporated in any piece of garment or textile. The woman can also continue her normal activities while wearing it and does not need to lie down as for most of today's contraction monitoring devices used in medical environments. The sensor module is configured to receive all the biopotential signals through the signal acquisition module, the signal processing module is responsible of transforming these signals into data understandable by the user, all these data being transferred to a user portable device thanks to the data transmission module or can also be kept in memory on the device itself. All these operations are coordinated by the sensor control module. The sensor module therefore enables the user to visualize all the signals and the information related to the uterus activity on a portable device and be accordingly informed.

In embodiments of the invention, the electrode patch comprises a sensor module receiving area to connect the sensor module to the electrode patch.

In embodiments of the invention, the electrode patch is disposable.

In embodiments of the invention, the electrode patch and the sensor module are in a garment, clothing, textile or belt.

In embodiments of the invention, the electrode patch comprises an adhesive layer to attached to the body of a user.

In embodiments of the invention, the electrode patch comprises electrode wires.

In embodiments of the invention, the electrode patch is connected to the sensor module by a magnetic connection, and wherein the magnetic connection is configured to provide an electrical contact between the sensor module and the electrode patch when connected.

In embodiments of the invention, the electrode patch is connected to the sensor module by mechanical connection, wherein the mechanical connection is configured to provide an electrical contact between the sensor module and the electrode patch when connected.

In embodiments of the invention, the electrode patch further comprises a bias electrode.

In embodiments of the invention, the bias electrode is located substantially in the middle of the electrode patch, and wherein the measurement electrode is located on one side of the bias electrode and the reference electrode on the opposite side than the one side with respect to the bias electrode.

In embodiments of the invention, the electrode patch comprises a second measurement electrode, wherein the first and second measurement electrodes is located on the two extremities of the electrode patch, wherein the reference electrode is located substantially in the middle of the electrode patch and wherein the bias electrode is located between one of the measurement electrodes and the reference electrode.

In embodiments of the invention, the electrode patch comprises a back electrode which is in use positioned at the back of a pregnant woman.

In embodiments of the invention, the electrode patch further comprises a third measurement electrode, wherein the first and second measurement electrode and the reference electrode are positioned substantially on a line, wherein the third measurement electrode is positioned below the reference electrode substantially perpendicular to the line, and wherein the bias electrode being located between a measurement electrode and the reference electrode.

In embodiments of the invention, the distance between the measurement electrode and the reference electrode is between three and ten centimeters.

In embodiments of the invention, the signal processing module is configured to perform any of the method embodiments provided.

In embodiments of the invention, the signal acquisition module comprises a conditioning module.

In embodiments of the invention, the signal acquisition module comprises an amplification module.

In embodiments of the invention, the signal acquisition module comprises an analog filter module.

In embodiments of the invention, the signal acquisition module comprises an analog-to-digital conversion module.

In embodiments of the invention, the memory module is configured to store data generated by the signal processing module.

In embodiments of the invention, the data transmission module is configured to transmit signals generated by the signal processing module to a user device.

In embodiments of the invention, the power management module is configured to deliver power to the contraction monitoring device.

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In embodiments of the invention, the sensor module further comprises an inertial motion sensing module.

In embodiments of the invention, the inertial sensing module comprises at least one of a one-axis accelerometer, a two-axis accelerometer or a tri-axis accelerometer.

In embodiments of the invention, the inertial sensing module further comprises at least one of a one-axis gyroscope, a two-axis gyroscope or a tri-axis gyroscope.

In embodiments of the invention, the inertial sensing module further comprises at least one of a one-axis magnetometer, a two-axis magnetometer or a tri-axis magnetometer.

In embodiments of the invention, the sensor module further comprises a contact-impedance measurement module.

In embodiments of the invention, the sensor module further includes a user interface module.

In embodiments of the invention, the user interface module comprises at least one LED.

In embodiments of the invention, the user interface module comprises at least one of a buzzer, a vibrating element, an audio speaker, or a display.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exemplary top-level flow diagram illustrating an embodiment of the method for measuring contractions based on bio-potential signals.

FIG. 2A is an exemplary diagram illustrating the position of the electrodes on the woman's abdomen.

FIG. 2B is an exemplary representation of a uterine contraction, uterine contraction features and uterine contraction statistics.

FIG. 3A is an exemplary flow diagram illustrating another alternative embodiment of the method for detecting uterine contractions of FIG. 1.

FIG. 3B is an exemplary flow diagram illustrating an alternative embodiment of the method for detecting uterine contractions of FIG. 3A.

FIG. 4 is an exemplary flow diagram illustrating yet another alternative embodiment of the method for detecting uterine contractions of FIG. 1.

FIG. 5A is an exemplary flow diagram illustrating yet another alternative embodiment of the method for monitoring uterine contractions of FIG. 1.

FIG. 5B is an exemplary flow diagram illustrating an alternative embodiment of the method for monitoring uterine contractions of FIG. 5A.

FIG. 6 is an exemplary flow diagram illustrating an alternative embodiment of the method for monitoring uterine contractions of FIG. 5A or FIG. 5B.

FIG. 7 is an exemplary flow diagram illustrating an alternative embodiment of the method for monitoring uterine contractions of FIG. 6.

FIG. 8 is an exemplary flow diagram illustrating yet another alternative embodiment of the method for monitoring uterine contractions of FIG. 1.

FIG. 9A is an exemplary flow diagram illustrating yet another alternative embodiment of the method for monitoring uterine contractions of FIG. 1.

FIG. 9B is an exemplary flow diagram illustrating an alternative embodiment of the method for monitoring uterine contractions of FIG. 9A.

FIG. 9C is an exemplary flow diagram illustrating an alternative embodiment of the method for monitoring uterine contractions of FIG. 9A or FIG. 9B.

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FIG. 9D is an exemplary flow diagram illustrating another alternative embodiment of the method for monitoring uterine contractions of FIG. 9A or FIG. 9B.

FIG. 10 is an exemplary flow diagram illustrating yet another alternative embodiment of the method for monitoring uterine contractions of FIG. 9A or FIG. 9B.

FIG. 11 is an exemplary flow diagram illustrating yet another alternative embodiment of the method for monitoring uterine contractions of FIG. 1.

FIG. 12 is an exemplary flow diagram illustrating yet another alternative embodiment of the method for monitoring uterine contractions of FIG. 1.

FIG. 13 shows an exemplary illustration of one embodiment of the device for contraction monitoring.

FIG. 14 shows an exemplary illustration of another embodiment of the device for contraction monitoring.

FIG. 15 shows an exemplary illustration of yet another embodiment of the device for contraction monitoring of FIG. 13.

FIG. 16 shows an exemplary illustration of yet another embodiment of the device for contraction monitoring of FIG. 13.

FIG. 17 shows an exemplary illustration of yet another embodiment of the device for contraction monitoring of FIG. 13.

FIG. 18 shows an exemplary illustration of yet another embodiment of the device for contraction monitoring of FIG. 13.

FIG. 19 is an exemplary an exemplary block-diagram of one embodiment of the sensor module of FIG. 13-18.

FIG. 20 is an exemplary an exemplary block-diagram of an alternative embodiment of the sensor module of FIG. 13-18.

FIG. 21 is an exemplary an exemplary block-diagram of another alternative embodiment of the sensor module of FIG. 13-18.

FIG. 22 is an exemplary an exemplary block-diagram of yet another alternative embodiment of the sensor module of FIG. 13-18.

FIG. 23 shows an exemplary illustration of yet another embodiment of the device for contraction monitoring of FIG. 14, wherein the contraction monitoring device is communicating with user personal devices.

MODES FOR CARRYING OUT THE INVENTION

The present invention will be described with respect to particular embodiments and with reference to certain drawings but the invention is not limited thereto but only by the claims. The drawings described are only schematic and are non-limiting. In the drawings, the size of some of the elements may be exaggerated and not drawn on scale for illustrative purposes. The dimensions and the relative dimensions do not necessarily correspond to actual reductions to practice of the invention.

Furthermore, the terms first, second, third and the like in the description and in the claims, are used for distinguishing between similar elements and not necessarily for describing a sequential or chronological order. The terms are interchangeable under appropriate circumstances and the embodiments of the invention can operate in other sequences than described or illustrated herein.

Moreover, the terms top, bottom, over, under and the like in the description and the claims are used for descriptive purposes and not necessarily for describing relative positions. The terms so used are interchangeable under appro-

prate circumstances and the embodiments of the invention described herein can operate in other orientations than described or illustrated herein.

Furthermore, the various embodiments, although referred to as “preferred” are to be construed as exemplary manners in which the invention may be implemented rather than as limiting the scope of the invention.

The term “comprising”, used in the claims, should not be interpreted as being restricted to the elements or steps listed thereafter; it does not exclude other elements or steps. It needs to be interpreted as specifying the presence of the stated features, integers, steps or components as referred to, but does not preclude the presence or addition of one or more other features, integers, steps or components, or groups thereof. Thus, the scope of the expression “a device comprising A and B” should not be limited to devices consisting only of components A and B, rather with respect to the present invention, the only enumerated components of the device are A and B, and further the claim should be interpreted as including equivalents of those components.

Since current solutions for contraction monitoring are only available to care professionals and for use in a controlled care environment, are constrained in their functionality, and are limited in their portability and accuracy, a method and a device for ambulatory contraction monitoring can prove desirable for allowing pregnant woman to monitor their contractions at any time and in any environment, to get new insights on how other health parameters can affect her contractions, or share this information with their partner, family, friends and healthcare practitioners during or in between visits. At least two cutaneous electrodes including a measurement electrode and a reference electrode, provided in a wearable system including an electrode patch and a sensor module, and placed on the pregnant woman’s abdomen, measure bio-potential (EXG) signals which comprise electrohysterogram (EHG), uterine electromyogram (UEMG), maternal electrocardiogram (mECG), fetus electrocardiogram (fECG), etc signals. This method allows to extract and isolate the required signals to improve the measurement of uterine contractions. The combination of the various signals improves the precision of the analysis of uterine contractions and all its implications for the mother and the fetus. Furthermore, the combination of the various signals provides new insights in the relation between the behavior of the mother and her contractions. The method is extremely robust and does not require a practitioner to position, operate or analyze the signals obtained. Furthermore, the method is suitable for being used directly by the pregnant woman.

The method advantageously monitors contraction based on bio-potential (EXG) signals measured on the abdomen of a pregnant woman. This can be achieved, according to one embodiment disclosed herein, by the method **100** for monitoring uterine contractions from EXG signals as illustrated in FIG. 1. As shown in FIG. 1, the method **100** for monitoring uterine contractions can include:

Measuring, at **110**, bio-potential (EXG) signals, comprising EHG signals,

Processing, at **120**, EXG signals to extract electrohysterogram (EHG) signals

Processing, at **130**, EHG signals to extract uterine contraction (UC) signals

Analyzing, at **140**, UC signals to compute relevant UC statistics

Measuring, at **110**, EXG signals can be achieved using at least two electrodes, yielding at least one channel EXG signal. In this configuration, one electrode can be referred as

the measurement electrode, whereas the second electrode can be referred as the reference electrode. In one embodiment, measuring EXG signals can be achieved using a third electrode, used as a bias electrode or as a right leg drive electrode, with the main objective to reduce the noise of the EXG measurement. In an alternative embodiment, measuring EXG signals can be achieved using additional electrodes, allowing the measurement of multiple channel EXG signals. The multiple electrodes can be positioned on different locations on the abdomen, advantageously providing multi-dimensional measurement of the uterine electrical activity.

In a preferred embodiment, illustrated on FIG. 2A, the method **100** for contraction monitoring of FIG. 1 uses three measurement electrodes (**3004**, **3005**, **3006**), one reference electrode **3002** and one bias electrode **3003**. The reference electrode **3002** is positioned slightly under the navel **3001**. The three measurement electrodes (**3004**, **3005**, **3006**) are positioned respectively to the right, to the left and below the reference electrode **3002**, as illustrated on FIG. 2A. Preferably, the distance between the reference electrode **3002** and each measurement electrode (**3004**, **3005**, **3006**) is comprised between three to ten centimeters. The bias or right leg drive electrode **3003** can be positioned anywhere on the abdomen, but not too close from the other electrodes. Preferably and advantageously, all electrodes can be integrated into an electrode patch. The electrode patch can significantly improve the reliability, the experience and use of the method **100** for monitoring contraction of FIG. 1. The use of an electrode patch improves the reliability of contraction monitoring, as it is not possible for a user to misplace the different electrodes relatively to each other, as they are always in the same relative position. The use of an electrode patch improves the experience and the ease of use of contraction monitoring, as it does not require attaching multiple electrodes to the abdomen, but only requires attaching one single electrode patch.

Referring to again to FIG. 1, processing, at **120**, EXG signals to extract EHG signals can consist in isolating from the EXG signals the part of the EXG signals that is relevant to the electrical activity of the uterus, and separating it out from the part of the EXG that is related to other physiological phenomena, noise, artifacts and any other contributions. Processing, at **120**, EXG signals to extract EHG signals can be achieved using signal processing techniques including but not limited to time-domain filtering, frequency-domain filtering, time-frequency-domain filtering and/or blind source separation. For example, and because physiology teaches us that EHG signals are known to have a frequency content contained within the 0.3 to 0.8 Hz bandwidth, each EHG signal can be extracted from the corresponding EXG signal by applying a filter with a bandpass of 0.3 Hz to 0.8 Hz. In another example, the multiple EXG channels are combined and processed using independent component analysis or other blind source separation technique to separate components of EXG signals with different variance. The components with the most variance in the low frequency band can then be retained as the EHG signals.

Processing, at **130**, EHG signals to extract UC signals can consist in converting the EHG signals into UC signals. Processing, at **130**, EHG signals to extract UC signals can be achieved using signal processing techniques including but not limited to root-mean-square, averaging, linear filters, integration operators, energy operators or entropy operators.

Advantageously, analyzing, at **140**, UC signals to compute relevant UC statistics can consist in further analyzing the UC signals to extract relevant UC features and calculate

relevant UC statistics. The UC signal is usually not intelligible for a person who does not have a clinical background. Therefore, although the UC signal can provide great information to the clinically trained expert, it can only provide very limited value to the non-clinically qualified user, like most pregnant women. Analyzing, at **140**, UC signals to compute relevant UC statistics advantageously analyze the UC signals to provide a set of features that are intelligible to the common user. Relevant UC features can include but are not limited to onset, end, amplitude of a contraction. In one embodiment, detecting the contraction on-set can be achieved by detecting the inflexion point in the UC signal, verifying that this inflexion point correspond to an ascending slope, and then finding the closest zero-derivative point in the UC signal prior to the inflexion point. The zero-derivative point can be used as an estimation of the contraction onset. Similarly, detecting the end of a contraction can be achieved by detecting the inflexion point in the UC signal, verifying that this inflexion point correspond to a descending slope, and then finding the closest zero-derivative point of the UC signal after the inflexion point. The zero-derivative point can be used as an estimation of the contraction end. Then the local maximum between the contraction on-set and end can be used as the measurement of the contraction amplitude. In another example, the amplitude underneath the UC signal and between the contraction on-set and end can be used as a measurement of the contraction amplitude. In another embodiment, a wavelet transform can be applied to the UC signal to identify patterns in the UC signal that correspond to a contraction. The onset (respectively the end) of the contraction can then be defined as the point at which the energy of the wavelet transform goes above (respectively below) a certain threshold. The amplitude of the contraction can then be computed as the total power of the wavelet transform between these two points, or as the local maximum in the time domain between the onset and the end of the contraction. In yet another embodiment, template matching can be used to recognize individual contraction. For example, a typical contraction template can be built from a database of contraction recordings. This database may or may not be user specific. Then the UC signal can be cross-correlated with the contraction template, and the maxima in the cross-correlation function can be considered to be the contraction. On-set, end and amplitude can then be calculated as described above. Relevant UC statistics can include but are not limited to frequency, duration or intensity of contractions. Frequency and duration can be directly calculated from the onset and the end of all contractions. The intensity of contractions can be calculated as the amplitude of the contraction. FIG. 2B shows an example of UC features and statistics extracted from a UC signal.

FIG. 3A shows another alternative embodiment of the method **100** for monitoring uterine contractions of FIG. 1, wherein measuring, at **110**, EXG signals can include: receiving, at **111**, EXG signals and acquiring, at **112**, EXG signals. Acquiring, at **112**, EXG signals can be achieved using electronics for conditioning and amplifying the EXG signals, and for converting the analog EXG signals into digital EXG signals (not shown).

EXG signals may be corrupted with movement artifacts, resulting in noise in the signal that can affect their interpretation. Movement artifacts are especially present in the case of ambulatory settings. Despite these artifacts, it is important to correctly and accurately measure the EXG signals. Preferably, the method comprises an automatic identification of motion artifacts. In fact, the presence of artifacts in the EXG

signal may lead to misinterpretations of the signal. Processing techniques to identify motion artifacts are therefore required to be able to exclude excerpts of the EXG signals that are corrupted with artifact. In a preferred and more advanced embodiment, processing techniques to remove such artifacts can be even more advantageous as the removal of motion artifacts from the EXG signals can avoid the need to exclude certain signal excerpts from the measurement. FIG. 3B shows an alternative embodiment of the method **100** for monitoring uterine contractions of FIG. 3A, wherein measuring, at **110**, EXG signals can further include motion artifact filtering, at **113**. Motion artifact filtering, at **113**, can be done in the analog domain before amplifying the EXG signals, and/or in the digital domain. Motion artifact filtering, at **113**, advantageously detects and removes artifacts from the EXG signals, in order to increase the quality and signal-to-noise ratio of the EXG signals. Motion artifact filtering, at **113**, can be achieved using a variety of signal processing techniques, including but not limited to: band-pass filters, linear filters, adaptive filters, wavelet filters, or blind source separation techniques.

Alternatively and advantageously, motion artifact filtering, at **113**, can be achieved using an additional motion artifact signal that is measured in parallel to the EXG signals and mainly carries information about the artifacts. For example the motion artifact signal can be measured using an accelerometer attached to the electrode patch. In another example, the motion artifact signal can be the contact impedance measured using the same electrodes than the ones used for measuring EXG signals. The motion artifact signal can be used as an input to the motion artifact filter. For example, the motion artifact signal can be used as the input to an adaptive filter representing an estimation of the noise. The adaptive filter, at **113**, can then function to remove the noise estimation from the EXG signals, yielding cleaner and more accurate signals. FIG. 3C shows an alternative embodiment of the method **100** for monitoring uterine contractions of FIG. 3B, wherein measuring motion artifact, at **150**, is used as an input to motion artifact filtering, at **113**. FIG. 4 shows another alternative embodiment of the method **100** for monitoring uterine contractions of FIG. 1, wherein analyzing, at **140**, UC signals to compute relevant UC statistics can preferably include extracting, at **141**, UC features, detecting, at **142**, contractions, and calculating, at **143**, UC statistics. Extracting, at **141**, UC features can comprise processing UC signals to yield a set of features that characterize the UC signals. Example of features may include but are not limited to time-domain features (zero-derivative points, inflexion points, local minima, local maxima), frequency-domain features, or time-frequency features. Detecting contractions, at **142**, can be performed using a set of thresholds and/or conditions on selected UC features. The thresholds or conditions can be manually set, or can automatically adapt based on the measured signal. For example, in the time domain, a contraction can be detected upon the identification of the following specific sequence: an inflexion point with ascending slope, followed by a local maximum, and followed by an inflexion point with a descending slope. In another example, in the time-frequency domain, a contraction can be detected when the energy of the wavelet transform in a predefined band corresponding to 0.3-0.8 Hz exceeds a certain threshold. Calculating, at **143**, statistics can be achieved by further analyzing the UC data for the contractions detected at **142**. For example, statistics such as average duration of contractions, time between

contraction, or average amplitude can be calculated based on the features extracted at **141** for a set of contractions detected at **142**.

EHG signals carry information about the UC signals. EHG signals are however limited in their frequency content. Stated somewhat differently, EHG signals provide a high level view on the electrical activity of the uterus. Next to the EHG, there is much more information contained in the EXG signals and that information pertains to the electrical activity of the uterus. Physiology teaches us that a contraction can be seen as the result of the common activation of thousands of uterus muscle cells. The rate at which the uterus contractile cells fire, the pattern at which they are firing, and the spatial distribution of their firing, all contain important information regarding the electrical activity of the uterus, that can be referred to as the fine information on the uterine electrical activity. Advantageously, the fine information can provide a greater detailed view on the contraction, and can be used to gather additional knowledge on the contraction. The fine information may for example be used to differentiate different types of contractions, or to provide greater insight on whether a contraction may induce labor or not. The fine information on the uterine electrical activity is not included in the EHG signals. Advantageously, this information can be extracted, next to the EHG signal, in a uterine electromyogram signal, or UEMG signal. FIG. 5A shows yet another alternative embodiment of the method **100** for monitoring uterine contractions of FIG. 1, wherein the method **100** for monitoring uterine contraction can further include:

Processing, at **210**, EXG signals to extract uterine electromyogram (UEMG) signals

Processing, at **220**, UEMG signals to extract UEMG markers

Classifying, at **230**, contraction type based on the UEMG markers

Processing, at **210**, EXG signals to extract UEMG signals can consist in isolating from the EXG signals the part of the EXG signals that is relevant to the uterine electromyogram, and separating it out from the part of the EXG that is related to other physiological phenomena, noise, artifacts and any other contributions. Processing, at **210**, EXG signals to extract UEMG signals can be achieved using signal processing techniques including but not limited to time-domain filtering, frequency-domain filtering, time-frequency-domain filtering and/or blind source separation. It will be noted that UEMG and EHG signals need not be mutually exclusive. In other words, the UEMG signals may partially overlap with the EHG signals.

Processing, at **220**, UEMG signals to extract UEMG markers can consist in analyzing the UEMG signals to extract relevant UEMG features that can be considered as UEMG markers. Examples of UEMG markers can include but are not limited to UEMG statistical features (average, mean, percentiles, standard deviation, kurtosis or any other statistical moments), power spectrum features (total power in the bandwidth, peak power, mean power, average power, power in certain frequency bands), entropy features, spatial propagation features (laplacian, gradient, and higher order propagation features), etc. The UEMG markers provide a quantification of the fine grained detailed of the uterine electrical activity. These markers can then be used to differentiate and classify different types of contractions.

Classifying, at **230**, contraction type based on the UEMG markers can consist in characterizing the specific type of a contraction based on the UEMG markers. Classifying, at **230**, can be done using supervised or unsupervised classification techniques. Examples of classification techniques

can include but are not limited to: decision trees, Bayesian networks, artificial neural networks, support vector machine, Markov chains, hierarchical models, etc. In a further embodiment, classifying, at **230**, contraction can consist in recognizing a Braxton Hicks contraction from a true labor contraction.

To improve the robustness of the method, FIG. 5B shows an alternative embodiment of the method **100** for monitoring uterine contractions of FIG. 1 and FIG. 5A, wherein the output of analyzing, at **140**, UC signals is used in Processing, at **220**, UEMG signals to extract UEMG markers. For instance, contractions detected through the analysis of UC signals can be used to define the excerpt of the UEMG signals on which the UEMG markers can be extracted. Processing, at **220**, the UEMG signals to extract the UEMG markers can then provide a finer and more detailed analysis of the contraction, wherein the finer time, frequency and time-frequency features can be extracted to provide a complete characterization of the contraction. Advantageously, the finer characterization can either provide new information, and/or be used to improve the accuracy and the robustness of classifying, at **230**, contraction type.

FIG. 6 shows another alternative embodiment of the method **100** for monitoring uterine contractions of FIG. 5A or FIG. 5B, wherein the method **100** for monitoring uterine contraction can further include detecting labor, at **240**. Detecting labor, at **240**, can use the UC statistics determined by analyzing, at **140**, UC signals and/or the contraction type determined by classifying, at **230**, contractions to detect whether a pregnant woman has gone into labor. Providing that an estimation of the gestational age can be available, detecting labor can also be used to detect onset of preterm labor, defined as labor starting before 37 weeks of gestational age.

Detecting labor, at **240**, can be achieved using analytics methods that include but are not limited to decision trees, conditional logic, support vector machines, artificial neural networks, Bayesian networks, Markov chains, hierarchical model, etc. In one example, detecting labor, at **240**, can be implemented according to common pregnancy practice such as the “411” rule, according to which a pregnant woman should go to the hospital for labor if she is having contractions at least every four minutes, of at least one minute duration and for at least one hour. Preferably, the “411” rule can be combined with an assessment of the type of contractions, to ensure that the contractions that are detected are true labor contraction and not Braxton Hicks contractions or any other physiological phenomena. FIG. 7 illustrates an exemplary embodiment of detecting labor, at **240**, of FIG. 6, wherein detecting labor, at **240**, can be achieved using a decision tree based on the UC statistics and contraction type. Turning to FIG. 7, the decision tree can take the UC statistics and the contraction type as input, to output the status of labor, namely “labor” or “no labor”. As illustrated on FIG. 7, detecting labor, at **240**, can include:

Checking, at **241**, if the contraction type corresponds to true labor contractions

Checking, at **242**, if contractions are at least X minute long

Checking, at **243**, if contractions are separated by at least Y minute

Checking, at **242**, if this has happened for at least Z hour

In one particular example, X=1, Y=4 and Z=1, implementing the “411 rule” well known to pregnancy care experts.

During pregnancy, contractions are known to prepare the body of the pregnant woman for labor and delivery. Painful

and frequent contractions may however be problematic as they may lead to early delivery and possibly to preterm birth, with dramatic consequence for the baby. There is today very limited knowledge available on the relationship between lifestyle behaviors of a pregnant woman and the number, frequency, duration and intensity of her contractions. Stated somewhat differently and more generally, there is limited information on the relation between lifestyle behaviors and the contraction profiles. An important lifestyle behavior known to have impact on pregnancy outcomes is maternal stress. Maternal stress can be extracted from heart rate variability. Information about heart rate variability is carried in the EXG signals measured according to the method 100 for contraction monitoring of FIG. 1. Therefore it is possible, by extending the method 100 for contraction monitoring of FIG. 1, to advantageously measure maternal stress and correlate the maternal stress with the contraction profile. FIG. 8 shows yet another alternative embodiment of the method 100 for monitoring uterine contractions of FIG. 1, wherein the method 100 for monitoring uterine contraction can further include:

Processing, at 310, EXG signals to extract maternal ECG (mECG) signals

Processing, at 320, mECG signals to extract maternal heart rate (mHR) and maternal heart rate variability (mHRV)

Processing, at 330, mHR and mHRV to extract maternal stress level

Correlating, at 340, contractions with maternal stress level

Processing, at 310, EXG signals to extract mECG signals can consist in isolating from the EXG signals the part of the EXG signals that is relevant to the maternal electrocardiogram, and separating it out from the part of the EXG that is related to other physiological phenomena, noise, artifacts and any other contributions. Processing, at 310, EXG signals to extract mECG signals can be achieved using signal processing techniques including but not limited to time-domain filtering, frequency-domain filtering, time-frequency-domain filtering and/or blind source separation.

Processing, at 320, mECG signals to extract mHR and mHRV can consist in analyzing the mECG signals to extract mECG fiducial points, in particular the mECG R-wave (also called R-peak), from which RR intervals, instantaneous mHR and mHRV can be calculated. Example of signal processing techniques to detect the R-wave from the mECG signals can include but are not limited to: averaging, derivative filters, linear filters, band-pass filters, continuous wavelet, discrete wavelet, template matching, etc. Instantaneous mHR can be computed from the distance between two successive R-waves. mHRV can then be computed from the variations in heart rate. mHRV can be calculated using time-based or frequency-based statistical features. Preferably, the R-waves can be detected using continuous wavelet transform, for example using a Mexican hat or Daubechies wavelet. The mECG signals can then be processed with a wavelet filter, and a threshold is applied on the output of the wavelet filter to detect possible R-wave candidates. All R-wave candidates are then filtered and only the one with the highest energy within a certain time window, for example 1 second, is kept as the R-wave.

Processing, at 330, mHR and mHRV to extract maternal stress can be achieved by combining mHR, mHRV, and/or trends and deviations in mHR or mHRV to obtain a measurement of the autonomic nervous system that are associated to stress. In a further embodiment (not shown), processing, at 330, mHR and mHRV to extract maternal stress using context information coming from a user device, e.g. a

smart phone, to improve the accuracy and reliability of the stress estimation. Accuracy can be improved by identifying context in which mHR and mHRV are most likely linked to the activation of the autonomic nervous system, as opposed to an increase in physical activity for instance. Context can be obtained from user activity and/or user daily routines. Daily routines can be estimated from the user low-level activity and/or location.

Correlating, at 340, contractions with maternal stress level can be achieved by looking at correlation between the maternal stress level on one end, and UC statistics and/or contraction type on the other end. Correlating, at 340, contractions with maternal stress level can advantageously provide new insights on how maternal stress level may affect contractions. For example, a woman may be able to discover that she has more contractions when her stress level is higher.

FIG. 9A shows yet another alternative embodiment of the method 100 for monitoring uterine contractions of FIG. 1, wherein the method 100 for monitoring uterine contraction can further include:

Processing, at 410, EXG signals to extract fetal ECG (fECG) signals

Processing, at 420, fECG signals to extract fetal heart rate (fHR) and fetal heart rate variability (fHRV)

Processing, at 410, EXG signals to extract fECG signals can consist in isolating from the EXG signals the part of the EXG signals that is relevant to the fetal electrocardiogram, and separating it out from the part of the EXG that is related to other physiological phenomena, noise, artifacts and any other contributions. Processing, at 410, EXG signals to extract fECG signals can be achieved using signal processing techniques including but not limited to template matching, averaging, time-domain filtering, frequency-domain filtering, time-frequency-domain filtering and/or blind source separation.

Processing, at 420, fECG signals to extract fHR and fHRV can consist in analyzing the fECG signals to extract fECG fiducial points, in particular the fECG R-wave (also called R-peak), from which RR intervals, instantaneous fHR and fHRV can be calculated. Example of signal processing techniques to detect the R-wave from the fECG signals can include but are not limited to: averaging, derivative filters, linear filters, band-pass filters, continuous wavelet, discrete wavelet, template matching, etc. Instantaneous fHR can be computed from the distance between two successive R-waves. fHRV can then be computed from the variations in heart rate. fHRV can be calculated using time-based or frequency-based statistical features.

FIG. 9B shows an alternative embodiment of the method 100 for monitoring uterine contractions of FIG. 9A, wherein processing, at 410, EXG signals to extract fetal ECG (fECG) signals can take the mECG signal as input. The mECG signals can be used in processing the EXG signals to filter the mECG signals from the fECG signals, therefore improving the signal-to-noise ratio on the fECG signals. Preferably, processing, at 410, EXG signals to extract fECG signals can include adaptive filtering, wherein the EXG signals and the mECG signals can be used as an input to the adaptive filter. The mECG signals can be used as the input to an adaptive filter representing an estimation of the noise on the fECG signals. The adaptive filter can then function to remove the noise estimation from the EXG signals, or in other words to remove the mECG from the EXG signals, yielding a cleaner version of the EXG signals with a reduced contribution of the mECG signals. The cleaner EXG signals can then be further processed using the method of FIG. 9A.

FIG. 9C shows an alternative embodiment of the method 100 for monitoring uterine contractions of FIG. 9A or FIG. 9B, wherein the method 100 for monitoring uterine contraction can further include processing, at 430, fECG to extract position of the fetus. Processing, at 430, fECG to extract

FIG. 9D shows an alternative embodiment of the method 100 for monitoring uterine contractions of FIG. 9A or FIG. 9B, wherein the method 100 for monitoring uterine contraction can further include processing, at 440, fECG to extract movement of the fetus. Processing, at 440, fECG to extract position of the fetus can be done advantageously by exploiting the fact that the morphology of the fECG is affected by the relative movement of the fetus from the measurement electrodes.

FIG. 10 shows yet another alternative embodiment of the method 100 for monitoring uterine contractions of FIG. 9A or FIG. 9B, wherein the method 100 for monitoring uterine contraction can further include correlating, at 450, contractions with the fHR or fHRV. Correlating, at 450, here can correspond to visualizing the UC signals and the fHR signals on two synchronized graphs positioned on top of each other. The fHR changes during a contraction can provide insights on the fetus response to the contractions and therefore can carry important information regarding the health status of the fetus. Advantageously, the method 100 for monitoring uterine contraction of FIG. 10 can simultaneously extract, from the only measurement of EXG signals, contractions and fHR, thus providing all the information necessary to perform the clinical standard non-stress test with an extreme simplicity of use that can be performed in any locations including the home. Preferably, this information can then be shared remotely with a clinical trained staff, who can interpret the data.

FIG. 11 shows yet another alternative embodiment of the method 100 for monitoring uterine contractions of FIG. 1, wherein the method 100 for monitoring uterine contraction can further include:

Measuring, at 510, maternal activity

Correlating, at 520, contractions with maternal activity

Measuring, at 510, maternal activity can be achieved using an activity sensor embedded in a smartphone, using a dedicated activity tracker or using an activity sensor embedded in the contraction monitor. Activity measures can include but are not limited to: steps, activity time, activity types, time spent in different activity types, energy expenditure, calorie burned, sleep duration, sleep quality. The activity sensor can track maternal activity over time, for specific recording sessions, or continuously and 24/7.

Correlating, at 520, contractions with maternal activity can be achieved by looking at correlation between maternal activity levels on one end, and UC statistics and/or contraction type on the other end. Correlating, at 520, contractions with maternal activity can advantageously provide new insights on how maternal activity may affect contractions. For example, a woman may be able to discover that she has more contractions when she is more active.

FIG. 12 shows yet another alternative embodiment of the method 100 for monitoring uterine contractions of FIG. 1, wherein the method 100 for monitoring uterine contraction can further include:

Measuring, at 610, fetal activity

Correlating, at 620, contractions with fetal activity

Measuring, at 610, fetal activity can be achieved using the method of FIG. 9D. Alternatively or additionally, fetal activity can be measured, at 610, using an accelerometer positioned on a woman's abdomen. Advantageously, fetal activity can be measured, at 610, using a combination of the method of FIG. 9D and accelerometers. This is advantageous because the method of FIG. 9D may be more accurate in detecting overall movement of the fetus, whereas accelerometer-based fetal activity measurement may be more accurate for localized fetus movement such as kicks. Combining both methods therefore can allow detecting both overall and local fetal movements. Fetal activity can be measured, at 610, during specific recording sessions, or continuously and 24/7.

Correlating, at 620, contractions with fetal activity can be achieved by looking at correlation between fetal activity levels on one end, and UC statistics and/or contraction type on the other end. Correlating, at 620, contractions with maternal activity can advantageously provide new insights on how fetal activity is related to contractions. For example, a woman may be able to discover that her baby is less active when she has contractions.

In yet another alternative embodiment (not shown) of the method 100 for monitoring uterine contractions of FIG. 5A, FIG. 5B, FIG. 6, FIG. 8, FIG. 9A, FIG. 9B, FIG. 9C, FIG. 9D, FIG. 10, FIG. 11 or FIG. 12, wherein the method 100 for monitoring uterine contraction can further include providing user feedback. Providing user feedback can provide recommendations or suggestions to the pregnant woman based on the UC statistics determined by analyzing, at 140, UC signals and/or the contraction type determined by classifying, at 230, contractions. User feedback can be provided to help woman reduce the pain associated to contractions, or to attempt to reduce the number or the frequency of contractions. User feedback can for example include recommendations for a better body position, for specific food, for specific activities (e.g. take a warm bath), etc. In a further embodiment, providing user feedback can provide recommendations or suggestions to the pregnant woman based on the correlation between contractions and maternal stress level, computed at 340. For example, if an elevated number of contractions and an elevated stress level are detected simultaneously, feedback can be provided to the woman to watch her stress level and to try to relax. The feedback can also include tips to help the user relax, or exercises that the user may be able to do to decrease her stress level. In a further embodiment, providing user feedback can provide recommendations or suggestions to the pregnant woman based on the correlation between contractions and maternal activity, computed at 520. For example, if an elevated number of contractions and an elevated activity level are detected simultaneously, feedback can be provided to the woman to reduce her activity and stay quiet for a few days. The user feedback can take the form of a message displayed in an App for smartphone, tablets, smart watch, or smart glasses, or a text message sent to the mother. Alternatively or additionally, the feedback can take the format of a message, graph, picture, figure, or any multimedia messages transmitted to the partner, family or friends of the pregnant women. Alternatively or additionally, the user feedback can take the form of a report with graphs, tables or text, sent to an OBGYN or a clinical trained staff for further interpretation.

According to the method 100 for monitoring uterine contractions of FIG. 5A, FIG. 5B, FIG. 6, FIG. 8, FIG. 9A, FIG. 9B, FIG. 9C, FIG. 9D, FIG. 10, FIG. 11 or FIG. 12, the data collected can include at least one of UC statistics, contraction type, mHR, mHRV, maternal stress, fHR, hHRV

or maternal activity. In yet another alternative embodiment, the data collected using the method 100 for monitoring uterine contractions can be used to stratify pregnant woman in different patient categories, based on their lifestyle and/or physiological profiles. In a further embodiment, the data collected using the method 100 for monitoring uterine contractions can be used identify possible risk factors for pregnancy complications or negative outcomes. Pregnancy complications may include hypertension, gestational hypertension, gestational diabetes, preeclampsia, etc. Negative pregnancy outcomes may include preterm birth, low birth weight, stillbirth, etc.

The method 100 for uterine contraction monitoring can be achieved, according to one embodiment disclosed herein, by the device 2000 for contraction monitoring illustrated in FIG. 13.

Turning to FIG. 13, the device 2000 for contraction monitoring comprises an electrode patch 2100 and a sensor module 2200, advantageously combined to monitor at least one channel of uterine contraction signals. The electrode patch 2100 and the sensor module 2200 may be in one part or may be made of two separate parts. The two separate parts can be provided with a mechanical and electrical system for attaching one to the other, such as a clipping system, a magnet. Other embodiments are described in the description. FIG. 14 illustrates another embodiment of the device 2000 for contraction monitoring. By comparing FIG. 13 and FIG. 14, one will easily understand that the electrode patch 2100 or the sensor module 2200 can take many different form factors.

Stated somewhat differently, the device 2000 for contraction monitoring can take many different shape, size, color, material and level of conformability to the body. The device 2000 may or may not take the form of a plaster. For example, the device 2000 may be integrated in a piece of garment. Or the device 2000 may take the form of a piece of clothing or textile. Or the device 2000 may take the form of a belt that is worn around the abdomen. For the last three examples, the electrode patch 2100 may be an integral part of the piece of garment, clothing or belt, or may be attached to such piece of garment, clothing or belt.

FIG. 15 shows an exemplary embodiment of the contraction monitoring device 2000, wherein the electrode patch 2100 and the sensor module 2200 can be integrated and encapsulated into one unique part solely making the device 2000. Preferably, the contraction monitoring device 2000 of FIG. 15 can have at least three electrodes, including one measurement electrode located on one extremity of the device, one reference electrode located on the other extremity of the device, and one bias electrode in the middle. Such configuration enables the measurement of one channel EXG signal, along the horizontal direction. More preferably, the device 2000 of FIG. 15 can have 4 electrodes, two measurement electrodes located on the two extremities, one reference electrode located in the middle of the device, and one bias electrode located between a measurement electrode and the reference electrode. Advantageously, a variant of the device 2000 of FIG. 15 (not shown) can have 5 electrodes, two measurement electrodes located on the two extremities of the device, one reference electrode located in the middle of the device, one additional measurement electrode located below the reference electrode, at 90 degrees from the line between the first three electrodes, and one bias electrode located between a measurement electrode and the reference electrode. Such configuration enables the measurement of two channels EXG signals, one along the horizontal direction and one along the vertical direction. In a further

exemplary embodiment, the device 2000 can be attached to the body using an adhesive layer. In another embodiment, the adhesive layer can be replaced by the user. In another exemplary embodiment, the device 2000 can be attached to the body using a strap or a piece of textile that can maintain the device 2000 in contact with the body.

FIG. 16 shows another exemplary embodiment of the contraction monitoring device 2000, wherein the electrode patch 2100 and the sensor module 2200 can be two separate parts of the device. The sensor module 2200 can be attached to the electrode patch 2100 before being used to monitor contraction. Preferably, the contraction monitoring device 2000 of FIG. 16 can have at least three electrodes, including one measurement electrode located on one extremity of the device 2000, one reference electrode located on the other extremity of the device 2000, and one bias electrode in the middle. Such configuration enables the measurement of one channel EXG signal, along the horizontal direction. More preferably, the device 2000 of FIG. 16 can have 4 electrodes, two measurement electrodes located on the two extremities, one reference electrode located in the middle of the device 2000, and one bias electrode located between a measurement electrode and the reference electrode. The electrode patch 2100 can be re-usable and washable. Alternatively, the electrode patch 2100 can be disposable, that is the user can change the electrode patch 2100 after each use of the contraction monitoring device 2000.

FIG. 17 shows an exemplary embodiment of the contraction monitoring device 2000, wherein the electrode patch 2100 and the sensor module 2200 can be integrated in a textile or clothing accessory. Examples of clothing accessory can include but are not limited to a shirt, T-shirt, belly-band, a pregnancy support belt or a belt. Preferably, the contraction monitoring device 2000 of FIG. 16 can have at least three electrodes arranged next to each other so that one measurement electrode is located on the right (respectively left) side of the abdomen, one reference electrode is located on the left (respectively right) side of the abdomen, and one bias electrode in the middle. More preferably, the device of FIG. 15 can have a fourth electrode positioned at 90 degrees from the linear arrangement, in the center of the abdomen. This 4th electrode can provide a measurement of the EXG signals in the vertical direction. More preferably, the device 2000 of FIG. 15 can have a fifth electrode positioned at the back of the woman, and providing a signal free of uterine activity but carrying physiological and recording artifacts, that can be used in processing the EXG signals to obtain cleaner and more accurate EHG, mECG and fECG signals.

FIG. 18 shows an exemplary embodiment of the contraction monitoring device 2000, wherein the electrode patch 2100 and the sensor module 2200 can be integrated in an accessory of every-day life that can be positioned on a woman's abdomen. For instance, the electrode patch 2100 and the sensor module 2200 can be integrated in a pillow or in a cover.

As it can be seen from FIG. 13, FIG. 14, FIG. 15, FIG. 16, FIG. 17 or FIG. 18, the device 2000 for contraction monitoring is integrated in a small and easy to use form factor that does not require to be operated by clinical staff. Stated somewhat differently, the device 2000 for contraction monitoring is advantageously implemented in such a way that a pregnant woman can operate it on her own. The small size and extreme miniaturization can be achieved thanks low-power electronics system design, that is a combination of low-power circuit design, low-power architecture design and firmware optimization. Low-power system design

allows minimizing the size of the battery and therefore can achieve very small size for the overall system. The ease of use can come from a combination of smart electronics and high level of integration. With smart electronics, the device **2000** can automatically turn on when it is positioned on the body, or the device **2000** can automatically detect contractions and trigger feedback accordingly, or the system can automatically detect a specific situation—for example the fact that the woman is moving—and adapt its signal processing accordingly. With high level of integration, the electrode patch **2100** can integrate all wires to the electrode, and provide a very simple way for the user to connect the sensor **2200** to the electrode patch. Connecting the electrode patch **2100** to the sensor **2200** can be done through magnetic interface, through a snap on mechanism, through a slide on mechanism, through a screw on mechanism, or any other mechanisms that provide a good mechanical and electrical contact between the sensor module **2200** and the electrode patch **2100**.

The use of an electrode patch **2100** improves the reliability of contraction monitoring as it is not possible for a user to misplace the different electrodes relatively to each other, as they are always in the same relative position. The use of an electrode patch **2100** improves the experience and the ease of use of contraction monitoring as it does not require attaching multiple electrodes to the abdomen, but only requires to attach one single electrode patch.

The device **2000** can be designed such that it is clear for the pregnant woman how to wear the device, and where to place it. The device **2000** can be designed such that it is very easy to put on. Preferably, the pregnant woman simply has to take the sensor module **2200**, attach it to the electrode patch **2100**, and wear it.

The electrode patch **2100** comprises at least two electrodes, referred to as the measurement electrode and the reference electrode, and allowing the measurement of one channel bio-potential (EXG) signal. In an alternative embodiment of the device, the electrode patch **2100** can include a third electrode, which can be used for biasing the signal acquisition electronics to the body voltage, or for applying a common mode voltage to the body in order to reduce the measurement noise, a measurement principle also known as right leg drive. In another alternative embodiment of the device **2000**, the electrode patch **2100** can include additional measurement electrodes, allowing the measurement of multiple channels of EXG signals, leading to multiple channels of uterine contraction signals. The multiple measurement electrodes can be positioned on different locations on the abdomen, advantageously providing multi-dimensional measurement of the uterine electrical activity. The electrodes may or may not include conductive gel.

Conductive gel may be used to improve the quality of the contact between the body and the electrodes. The electrode patch **2100** may or may not be adhesive.

In a preferred embodiment, and according to the method **100** for contraction monitoring of FIG. 1 and FIG. 2A, the electrode patch **2100** integrates three measurement electrodes, one reference electrode and one bias electrode. Turning to FIG. 2A, the reference electrode **3002** is positioned slightly under the navel **3001**. The three measurement electrodes (**3004**, **3005**, **3006**) are positioned respectively to the right, to the left and below the reference electrode **3002**. The distance between the reference electrode **3002** and each measurement electrode (**3004**, **3005**, **3006**) is between three to ten centimeters. The bias or right leg drive electrode **3003** can be positioned anywhere on the abdomen, but not too close from the other electrodes. Preferably and advantageously,

all electrodes can be integrated into an electrode patch **2100**. The electrode patch **2100** can significantly improve the reliability, the experience and use of the method for monitoring contraction of FIG. 1.

The sensor module **2200** can contain the electronic circuitry required to measure EXG signals and extract uterine contraction signals according to the method **100** for uterine contraction monitoring of FIG. 1.

FIG. 19 shows an exemplary block diagram of one embodiment of the sensor module **2200** of FIG. 13-18. Turning to FIG. 19, the sensor module **2200** includes:

- An EXG signal acquisition module **1100**,
- A signal processing module **1200**,
- At least one of a memory module **1300** or a data transmission module **1400**,
- A power management module **1500**, and
- A sensor control module **1600**.

The EXG signal acquisition module **1100** acquires the at least one channel EXG signals measured with the electrode patch **2100**. In another embodiment (not shown) of the sensor module **2200** of FIG. 19, the EXG signal acquisition module **1100** may further include: a conditioning module, an amplification module, an analog filter module and an analog-to-digital conversion module. Preferably, the conditioning module conditions the EXG signals before amplification. For instance, the conditioning system consists in removing the DC component from the EXG signals, or in filtering the EXG signals. In another, more advanced example, the conditioning module includes an analog artifact filter that filters out artifacts such as motion artifacts. Advantageously, the amplification module amplifies the EXG signals to a level that is compatible with the remaining of the sensor module electronics. More advantageously, the analog filter module further filters the amplified EXG signals, for instance to avoid aliasing during the analog-to-digital conversion. The analog-to-digital conversion module can convert the analog EXG signals to digital EXG signals. In another alternative embodiment, the EXG signal acquisition module **1100** can further include a digital motion artifact filter. The digital motion artifact filter system can further filter the digital EXG signals to specifically remove artifacts and improve the quality of the EXG signals.

More preferably, the signal processing module **1200** can process the EXG signals to extract the UC signals according to the method **100** for contraction monitoring of FIG. 1. In an alternative embodiment, the signal processing module **1200** is configured to process the EXG signals to extract the UC signals, at **120**, and compute the UC statistics, at **140**, according to the method **100** for contraction monitoring of FIG. 2. In another alternative embodiment, the signal processing module **1200** can process the EXG signals to extract the UC signals, and at least one of the UEMG signals, the mECG signals, the mHR, the mHRV, the fECG signals, the fHR or the fHRV. In another alternative embodiment, the signal processing module **1200** can include dedicated processing blocks to remove artifacts from the EXG signals after the EXG signals are acquired by the EXG signal acquisition module and before any further processing. The signal processing module **1200** can be implemented in a digital signal processor (DSP), in a micro-controller unit (MCU), in a field programmable gate array (FPGA), in an application specific integrate circuit (ASIC), in application specific processor (ASP), etc.

Preferably, the memory module **1300** stores the data corresponding to at least one of the signals generated by the signal processing module **1200**. The data can be stored on a volatile or non-volatile support. For example, the data can be

stored on FLASH memory. Advantageously, the data transmission module **1400** transmits at least one of the signals generated by the signal processing module **1200** to a user personal device. The user personal device can be a smart-phone, a tablet, a smart-watch, smart-glasses, a personal computer and/or any multimedia device that is equipped with wired, wireless or optical communication. Wired communication can be achieved using USB, Ethernet, HDMI, FireWire, Thunderbolt, RS232 or any other wired communication protocol. Wireless communication can be achieved using Bluetooth, Bluetooth low-energy, WiFi, Zigbee, NFC or any other wireless communication protocol.

The power management module **1500** can deliver power to the different modules of the contraction monitoring device **2000**. In an alternative embodiment, the power management module **1500** can include power management circuitry, a battery and on/off circuitry. The power management circuitry can convert the battery voltage to the right level of input voltage for the different modules of the device. The power management module **1500** can deliver an input voltage that is specific and may be different for every module. The battery can be rechargeable or alkaline, and can be of different chemistry and shape. In the case of a rechargeable battery, the power management circuitry can also include charging circuitry. The on/off circuitry can be a switch that allows the user to switch the device on and off. In another alternative embodiment, the on/off circuitry can advantageously include electronic circuitry to detect when the electrode patch **2100** is connected to the sensor module **2200**. The device **2000** can then automatically start upon detection of a connection between the sensor module **2200** and the electrode patch **2100**, and/or stop when the sensor module **2200** is detached from the electrode patch **2100**, thus greatly improving the user experience. In yet another alternative embodiment, the on/off circuitry can advantageously include electronic circuitry to detect when the contraction monitoring device **2000** is attached to the body. The device **2000** can then automatically start upon attachment of the contraction monitoring device **2000** on the body, and/or stop upon removal of the contraction monitoring device **2000** from the body, thus greatly improving the user experience.

The sensor control module **1600** controls the operation of the sensor module **2200** and ensures that the EXG signal acquisition module **1100**, the signal processing module **1200**, the memory module **1300** and the data transmission module **1400** can work together in an efficient implementation of the sensor module **2200**. Preferably, the sensor control module **1600** can be implemented in a micro-controller unit.

FIG. **20** shows an alternative embodiment of the sensor module **2200** of FIG. **19**, wherein the sensor module **2200** can further include an inertial motion sensing module **1700**. The inertial motion sensing module **1700** can include at least a one-axis accelerometer, a two-axis accelerometer or a tri-axis accelerometer. The inertial motion sensing module **1700** can also include a one, two or tri-axis gyroscope, and/or a one, two or tri-axis magnetometer. The inertial motion sensing module **1700** can be used to monitor the overall movement of the pregnant woman or the movements of the abdomen induced by fetus movement and kicks. Alternatively or additionally, the inertial motion sensing module **1700** can be used to measure the local movement of the sensor module. In a further embodiment, the data coming from the inertial motion sensing module **1700** can be used by the signal processing module **1200** to filter artifacts from the EXG signals. FIG. **21** shows an alternative embodiment of the sensor module **2200** of FIG. **19** or FIG. **20**, wherein the

sensor module **2200** can further include a contact-impedance measurement module **1800**. The contact-impedance measurement module **1800** can be used to continuously or intermittently measure the impedance of the contact of each electrode with the body. Accordingly and advantageously, the contact impedance can be used to provide an estimation of the quality of the contact, or to provide an estimation of motion artifacts. In a further embodiment, the contact impedance signals can be used by the signal processing module **1200** to filter artifacts from the EXG signals.

FIG. **22** shows an alternative embodiment of the sensor module **2200** of FIG. **19**, FIG. **20** or FIG. **21**, wherein the sensor module **2200** can further include a user interface module **1900**. The user interface module **1900** can be one or any combination of: a Light Emitting Diode (LED), a set of LEDs, a buzzer, a vibrating element, an audio speaker or a display. In the case of a set of LEDs, the individual LED can be arranged in a shape that is represent a specific shape such as a circle, a rectangle, a triangle or any other geometric shape. The LED color and/or activation pattern can be designed in order to communicate different message to the user. For example, the LED can be used to communicate start of the system, stop of the system, battery charge level, the detection of a contraction, the intensity of the contraction, the frequency of contraction, the duration between two contractions, etc. The LED can be controlled by the sensor control module **1600**.

FIG. **23** shows an alternative embodiment of the contraction monitoring device **2000** of FIG. **13-18**, wherein the contraction monitoring device **2000** is used in combination with at least one user personal device **2001**. The user personal device **2001** can be a smartphone, a tablet, a smart-watch, smart-glasses, a personal computer and/or any multimedia or digital device. In a further embodiment, the data monitored and transmitted by the contraction monitoring device **2000** to the user personal device **2001** can be displayed and/or stored on the user personal device **2001**. In yet a further embodiment, the data monitored and transmitted by the contraction monitoring device **2000** can be further transmitted, via the user personal device **2001**, to a cloud-based server or database **2002**.

In another alternative embodiment of the contraction monitoring device **2000** of FIG. **13-18**, the data from the contraction monitoring device **2000** can be combined with the data measured from a health or wellness monitoring device. For example, the data from the contraction monitoring device **2000** can be combined with data from a weight scale, an activity tracker, a heart rate chest-strap, a wrist-based pulse-rate monitor, a basal temperature sensor, or from any other ambulatory, wearable or portable monitoring system.

In yet another alternative embodiment, the contraction monitoring device **2000** of FIG. **13-18** can be used to monitor at least one UC signal and/or UC statistics, and visualize the at least one UC signal and/or UC statistics on the display of the user personal device **2001**. To achieve this task, the EXG signal acquisition module **1100** can acquire at least one EXG signals, and the signal processing module **1200** can process and analyze the EXG signals according to the method **100** of FIG. **1**, FIG. **2**, FIG. **3A**, FIG. **3B** or FIG. **4**. For example, turning to FIG. **1**, the EXG signals can be processed to extract EHG signals, at **120**, the EHG signals can be further processed to extract UC signals, at **130**, and UC signals can be analyzed to compute relevant UC statistics, at **140**. The data transmission module **1400** can then transmit the at least one UC signal to the user personal device **2001** for visualization.

In yet another alternative embodiment, the contraction monitoring device **2000** of FIG. **13-18** can be used to classify contraction, wherein the signal processing module **1200** of FIG. **15** can process and analyze the EXG signals according to the method **100** of FIG. **5A** or FIG. **5B**. Turning to FIG. **5A** or FIG. **5B**, the EXG signals can be processed to extract UEMG signals, at **210**, the UEMG signals can be further processed to extract UEMG markers, at **220**, and the UEMG markers can be used to classify contraction types, at **230**. In a further embodiment, the information about the contraction classification can be displayed to the user through the user interface module **1900** or on her user personal device **2001**. In a further embodiment, the contraction monitoring device **2000** of FIG. **13-18** can be used to distinguish between Braxton Hicks and true labor contractions.

In yet another alternative embodiment, the contraction monitoring device **2000** of FIG. **13-18** can be used to detect labor, wherein the signal processing module **1200** of FIG. **15** can further analyze the UC signals and/or the contraction type to detect labor, at **240**, according to the method **100** of FIG. **6**.

In yet another alternative embodiment, the contraction monitoring device **2000** of FIG. **13-18** can be used to monitor maternal stress level, wherein the signal processing module **1200** of FIG. **15** can process and analyze the EXG signals according to the method **100** of FIG. **8**. Turning to FIG. **8**, the EXG signals can be processed to extract mECG signals, at **310**, the mECG signals can be further processed to extract mHR and mHRV, at **320**, and mHR and mHRV can be further processed to extract maternal stress level, at **330**. In a further embodiment, the UC signals and/or UC statistics can be correlated with the maternal stress, at **340**, and according to the method **100** for contraction monitoring of FIG. **8**. The correlation between contractions and stress level can be visualized in one graph that overlays the UC statistics and the stress level over time. For example, the number of contraction per hour can be visualized together with the average stress level per hour. In another embodiment, the correlation between contractions and stress level can be summarized in a correlation score that summarizes in one number to what extent stress correlates with contractions for a certain user of the system. Thus, the contraction monitoring device **2000** of FIG. **13-18** can advantageously be used to correlate UC signals and/or statistics with maternal stress level, providing new insight on the relationship that may exist between maternal stress and contractions.

In yet another alternative embodiment, the contraction monitoring device **2000** of FIG. **13-18** can be used to monitor UC signals and at least one of fECG, fHR or fHRV, wherein the signal processing module **1200** of FIG. **15** can process and analyze the EXG signals according to the method of FIG. **9A** or FIG. **9B**. Turning to FIG. **9A** or FIG. **9B**, the EXG signals can be processed to extract fECG signals, at **410**, and the fECG signals can be further processed to extract fHR and fHRV, at **420**. In a further embodiment, the contraction monitoring device **2000** of FIG. **13** can be used to monitor the position of the fetus, according to the method **100** of FIG. **9C**. In a further embodiment, the contraction monitoring device of FIG. **13-18** can be used to monitor the movement of the fetus, according to the method **100** of FIG. **9D**.

In yet another alternative embodiment, the contraction monitoring device **2000** of FIG. **13-18** can be used to jointly visualize the UC signals and the fHR. The signal processing module **1200** can simultaneously extract the UC signals and the fHR, and can correlate UC signals with fHR according

to the method **100** of FIG. **10**. The fHR and the UC signals can be transmitted to the user personal device **2001** where they can be displayed on top of each other, alike the way signals are displayed on a cardiotocogram in hospital environment. Stated somehow differently, the contraction monitoring device **2000** of FIG. **18** advantageously provides similar information to a cardiotocogram with greatly improved user experience since the contraction monitoring device can be made much smaller and much more comfortable to use than traditional strapped cardiotocogram probes.

In yet another alternative embodiment, the contraction monitoring device **2000** of FIG. **13-18** can be used to monitor maternal activity, according to the method **100** for monitoring uterine contractions of FIG. **11**. In one embodiment, the maternal activity can be measured with the inertial sensing module **1800** of FIG. **21**. In another embodiment, the maternal activity can be measured using an activity sensor integrated in the user personal device **2001**, e.g. a smartphone. In yet another embodiment, the maternal activity can be measured using a separate activity tracker that can connect to the user personal device **2001**. In yet another embodiment, the UC signals and/or UC statistics can be correlated with the maternal activity, using correlating contractions with maternal activity, at **520**, according to the method **100** for contraction monitoring of FIG. **11**. The correlation between contractions and maternal activity can be visualized in one graph that overlays the UC statistics and the maternal activity over time. For example, the number of contraction per hour can be visualized together with the cumulated and/or average activity per hour. In another embodiment, the correlation between contractions and maternal activity can be summarized in a correlation score that summarizes in one number to what extent maternal activity correlates with contractions for a certain user of the system. Thus, the contraction monitoring device **2000** of FIG. **13-18** can advantageously be used to correlate UC signals and/or statistics with maternal activity, providing new insight on the relationship that may exist between maternal activity and contractions.

In yet another alternative embodiment, the contraction monitoring device **2000** of FIG. **13-18** can be used to monitor fetal activity, according to the method **100** for monitoring uterine contractions of FIG. **12**. In one embodiment, the fetal activity can be extracted from the fECG, using processing fECG to extract movement of the fetus, at **430**, according to the method **100** for monitoring contractions of FIG. **9D**. In another embodiment, the fetal activity can be measured with the inertial sensing module **1800** of FIG. **21**. In yet another embodiment, the UC signals and/or UC statistics can be correlated with the fetal activity, using correlating contractions with fetal activity, at **620**, according to the method **100** for contraction monitoring of FIG. **12**. The correlation between contractions and fetal activity can be visualized in one graph that overlays the UC statistics and the fetal activity over time. For example, the number of contraction per hour can be visualized together with the cumulated and/or average fetal activity per hour. In another embodiment, the correlation between contractions and fetal activity can be summarized in a correlation score that summarizes in one number to what extent fetal activity correlates with contractions. Thus, the contraction monitoring device **2000** of FIG. **13-18** can advantageously be used to correlate UC signals and/or statistics with fetal activity, providing new insight on the relationship that may exist between fetal activity and contractions.

In yet another alternative embodiment, the contraction monitoring device **2000** of FIG. **13-18** can provide feedback

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to the user, according to the method **100** for monitoring contractions of FIG. **13-18**. Feedback can include further information on the data recorded with the contraction monitoring device. Alternatively or additionally, feedback can include recommendations for adaptations in lifestyle or behavior based on the data measured by the contraction monitoring device. Feedback can be provided through the user interface module **1900** of FIG. **22**, through the user personal device **2001** of FIG. **19** and/or through any other communication tools to the user. Feedback can take the form of a noise, a certain LED pattern, a text message, a voice message or any other multimedia communication.

The disclosed embodiments are susceptible to various modifications and alternative forms, and specific examples thereof have been shown by way of example in the drawings and are herein described in detail. It should be understood, however, that the disclosed embodiments are not to be limited to the particular forms or methods disclosed, but to the contrary, the disclosed embodiments are to cover all modifications, equivalents, and alternatives.

The invention claimed is:

1. A contraction monitoring system comprising:
 - an electrode patch comprising at least two electrodes, including a first measurement electrode and a reference electrode, wherein the electrode patch is positionable on an abdomen of a pregnant woman; and
 - a sensor module configured to be connected to the electrode patch, wherein the sensor module is configured to perform a method comprising:
 - measuring a biopotential signal with the at least two electrodes,
 - acquiring inertial sensing data with an inertial sensing module,
 - automatically identifying the inertial sensing data that comprises one or more motion artifact signals resulting from the overall movement of the pregnant woman, movements of the abdomen induced by fetal movement, and local movement of the sensor module,
 - inputting the inertial sensing data and out of band energy for the biopotential signal into an artifact filter, wherein the input comprises adapting a threshold over time dependent on the out of band energy, dynamically adjusting the threshold by calculating a moving baseline energy such that the moving baseline energy adapts with time to follow changes in the inertial sensing data or the out of band energy signal, and dynamically changing the threshold based on the moving baseline energy,
 - dynamically adjusting the artifact filter by calculating a sensor motion energy from the inertial sensing data, establishing a set minimum level for the sensor motion energy, and lowering the threshold in proportion to the amount by which the sensor motion energy exceeds the minimum level,
 - filtering or excluding, with the artifact filter, the one or more motion artifact signals from the biopotential signal,
 - processing the filtered biopotential signal, with a signal processing module, to extract one or more electrohysterogram signals, and
 - processing the one or more electrohysterogram signals, with the signal processing module, to extract one or more uterine contraction signals.
2. The system of claim 1, wherein the method performed by the sensor module further comprises: processing the

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filtered biopotential signal to extract one or more of: maternal electrocardiogram signals (mECG) and fetus electrocardiogram signals (fECG).

3. The system of claim 2, wherein the method performed by the sensor module further comprises:

- processing the mECG signals to extract a maternal heart rate (mHR) and maternal heart rate variability (mHRV);

- processing mHR and mHRV to extract a maternal stress level; and

- correlating the one or more uterine contraction signals with the maternal stress level.

4. The system of claim 3, wherein the method performed by the sensor module further comprises: providing feedback to a user.

5. The system of claim 2, wherein the method performed by the sensor module further comprises:

- processing the fECG signals to extract a fetal heart rate (fHR) and fetal heart rate variability (fHRV); and
- correlating the one or more uterine contraction signals with one or more of: the fHR and the fHRV.

6. The system of claim 2, wherein the method performed by the sensor module further comprises:

- extracting one or more of: a position, a movement, and an orientation of a fetus from the fECG; and
- measuring a fetal activity from one or more of: the position, the movement, and the orientation of the fetus.

7. The system of claim 1, wherein the method performed by the sensor module further comprises:

- isolating from the one or more electrohysterogram signals a first part of the one or more electrohysterogram signals that is related to an electrical activity of a uterus; and

- separating the electrical activity of the uterus from a second part of the one or more electrohysterogram signals that is related to other physiological phenomena, noise, or artifacts.

8. The system of claim 1, wherein the method performed by the sensor module further comprises:

- processing the electrohysterogram signals to extract one or more electrohysterogram markers; and
- classifying the biopotential signal into contraction types based on the one or more electrohysterogram markers.

9. The system of claim 8, wherein the one or more electrohysterogram markers comprise:

- a statistical feature selected from the group consisting of: an average, a mean, a percentile, a standard deviation, a kurtosis, and a combination thereof;

- a power spectrum feature selected from the group consisting of: a total power in a bandwidth, a peak power, a mean power, an average power, a power in certain frequency bands, an entropy feature, and a combination thereof; or

- a spatial propagation feature selected from the group consisting of: a laplacian, a gradient, a higher order propagation feature to indicate a rate, a pattern, and a spatial distribution of a firing of one or more uterine contractile cells, and a combination thereof.

10. The system of claim 1, wherein the method performed by the sensor module further comprises: analyzing the one or more uterine contraction signals to compute uterine contraction statistics.

11. The system of claim 10, wherein the sensor module further comprises an inertial sensing module or is configured

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to interact with an activity sensor provided by another device, and wherein the method performed by the sensor module further comprises:

measuring a maternal activity; and

correlating the maternal activity with the one or more uterine contraction signals, the uterine contraction statistics, or a combination thereof.

12. The system of claim 10, wherein the method performed by the sensor module further comprises: correlating the one or more uterine contraction signals, the uterine contraction statistics, or combination thereof with a fetal activity.

13. The system of claim 1, wherein the electrode patch further comprises a bias electrode and a second measurement electrode, wherein the first and second measurement electrodes are located on two extremities of the electrode patch, and wherein the reference electrode is located substantially in a middle region of the electrode patch.

14. The system of claim 13, wherein the electrode patch further comprises a third measurement electrode, wherein the first and second measurement electrode and the reference electrode are positioned substantially on a line, and wherein the third measurement electrode is positioned below the reference electrode substantially perpendicular to the line.

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15. The system of claim 1, further comprising a user personal device configured to perform one or more functions performed by the sensor module.

16. The system of claim 15, wherein the one or more functions carried out by the user personal device further comprise:

using context information received by the user personal device to improve an accuracy and a reliability of measuring one or more of: a uterine contraction activity estimation, a maternal activity estimation, a maternal stress estimation, a fHR estimation, a fHRV estimation, a fetal movement estimation, and fetal position estimation; and

providing feedback to a user to promote a healthy lifestyle and reduce one or more risks related to pregnancy.

17. The system of claim 1, wherein filtering or excluding the one or more motion artifact signals from the biopotential signal slowly returns the threshold to an original value after sharp motions have subsided.

18. The systems of claim 1, wherein the out of band energy is outside of the frequency range of 0.2 Hz and 0.9 Hz.

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专利名称(译)	收缩监测的方法和装置		
公开(公告)号	US10456074	公开(公告)日	2019-10-29
申请号	US15/523072	申请日	2015-10-29
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CPC分类号	A61B5/0448 A61B5/165 A61B5/04012 A61B5/6833 A61B5/4356 A61B5/721 A61B5/4362 A61B5/02411 A61B5/1107 A61B5/0432 A61B5/0444 A61B5/0488 A61B5/1118 A61B2503/02		
优先权	2015005056 2015-02-02 BE 62/072348 2014-10-29 US		
其他公开文献	US20180296156A1		
外部链接	Espacenet		

摘要(译)

本文描述了用于收缩监测的系统和方法。例如，用于收缩监测的系统包括：电极片，其包括至少两个电极；以及传感器模块，被配置为连接至电极片。在一些实施例中，传感器模块包括信号采集模块，信号处理模块，电源管理模块，传感器控制模块以及存储器模块和/或数据传输模块。在一些实施例中，用于收缩监测的方法包括使用信号采集模块通过在孕妇的腹部上提供至少两个电极来测量生物电势信号。在一些实施例中，一种用于收缩监测的方法包括：使用信号处理模块来处理生物电势信号以提取心电图信号，母亲心电图信号和胎儿心电图信号，以及使用信号处理模块来处理单独的信号以提取信号。子宫收缩。

