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(54) **Title**: FETAL HEART RATE EXTRACTION FROM MATERNAL ABDOMINAL ECG RECORDINGS

(57) **Abstract**: System (10) for extracting a fetal heart rate from at least one maternal signal using a computer processor(26). The system includes sensors(12-18)attached to a patient to receive abdominal ECG signals and a recorder and digitizer(20)to record and digitize each at least one maternal signal in a maternal signal buffer(22A-22D). The system further includes a peak detector(40)to identify candidate peaks in the maternal signal buffer. The signal stacker(42)of the system stacks the divides at least one maternal signal buffer into a plurality of snippets, each snippet including one candidate peak and a spatial filter(44)to identify and attenuate a maternal QRS signal in the plurality of snippets of the maternal signal buffer, the spatial filter including at least one of principal component analysis and orthogonal projection, to produce a raw fetal ECG signal which is stored in a raw fetal ECG buffer. The system further includes a fetal QRS identifier(46)for identifying peaks in the raw fetal ECG buffer by at least one of principal component analysis and a peak-detector followed by rule based fQRS extraction and a merger(48)to calculate and merge the fetal heart rate from the identified peaks.

Fetal Heart Rate Extraction from Maternal Abdominal ECG Recordings

The present application relates generally to extracting a fetal heart rate from maternal abdominal electrocardiogram (ECG) recordings. It finds particular application in conjunction with the usage of spatial filtering and adaptive rule-based fetal QRS detection and will be described with particular reference thereto. However, it is to be understood that it also finds application in other usage scenarios and is not necessarily limited to the aforementioned application.

Heart defects are among the most common birth defects and the leading cause of birth defect-related deaths. Every year, about one out of 125 babies are born with some form of congenital heart defects. Congenital heart defects originate in early stages of pregnancy when the heart is forming and they can affect any of the parts or functions of the heart. Cardiac anomalies may occur due to a genetic syndrome, inherited disorder, or environmental factors such as infections or drug misuse. However, except for during labor, fetal electrocardiography has not proved an effective tool for imaging specific structural defects.

Detection and analysis of fetal cardiac signals are essential components of fetal health monitoring and have various applications in monitoring of fetal arrhythmia, fetal behavioral state and etc., but fetal electrocardiography has been confined to more global issues such as general ischemia due to specific fetal positioning that chokes the umbilical cord. The reason for this limitation is that the noninvasive fetal electrocardiogram (ECG) is contaminated by fetal brain activity, myographic (muscle) signals (from both the mother and fetus), movement artifacts and multiple layers of different dielectric biological media through which the electrical signals must pass. Fetal ECG is much weaker than the other interfering bio-signals (maternal cardiac signals, uterine contraction) and often contaminated by fetal brain activity, myographic (muscle) signals (from both the mother and fetus), and movement artifacts. Continuous fetal heart rate (FHR) monitors are hoped to reduce undiagnosed fetal hypoxia, but the outputs are often unreliable and difficult to interpret, resulting in increased Caesarean section rates of deliveries of healthy infants.

The most accurate method for measuring FHR is direct fetal electrocardiographic (FECG) using a fetal scalp electrode which is only possibly used in labor but not commonly used in clinical due to its associated risk. Non-invasive FECG monitoring is measured through electrodes placed on expecting mother's abdomen. This method can be used after the middle of the fourth month of pregnancy with negligible risk.

However, it is often difficult to detect the FHR in the abdominal ECG signal, since the maternal ECG is usually of greater amplitude in them and R-peaks of maternal ECG often overlap with the R-peaks of fetal ECG. Using sophisticated signal processing techniques have improved accuracy in FHR estimation. There are still great deals of room for improvement.

Fetal monitoring today is based on the fetal heart rate and does not incorporate characteristics of the fetal ECG (fECG) waveform characteristics that are the cornerstone of cardiac evaluation of both children and adults. The primary reason for the exclusion of this most critical source of information from clinical practice is that the technology to reliably measure fECG is largely unavailable. As a consequence, research correlating ECG characteristics to neonatal outcomes has not been done on a large scale.

The maternal ECG as discussed is a potential noise, which corrupts fetal ECG.

Existing ECG analysis techniques are generally tuned for situations where the ECG signal dominates the noise present in a recording channel. In situations where this is not the case, for example when using lower-cost ECG equipment or when attempting to record fetal heart beat from abdominal electrodes placed on the mother, the signal deviations due to noise can become indistinguishable from signal deviations due to the electrical activity of the heart.

Extraction of a reliable fetal heart rate and fetal ECG signals would enable the clinicians in an early detection of cardiac abnormalities and help them to prescribe proper medications in time, or to consider the necessary precautions during delivery or after birth. Despite advances in adult electrocardiography and signal processing techniques, the analysis of fetal ECGs is still in its infancy. The clinical potential of abdominal fECG monitoring by placing electrodes over mother's abdomen in antepartum (prior to labor) has been hampered by difficulties in obtaining a reliable fECG. There is a need for a method of extracting the fECG from the maternal ECG.

The present application provides new and improved methods, which overcome the above-referenced problems and others.

In accordance with one aspect, a system for extracting a fetal heart rate from at least one maternal signal using a computer processor is provided. The system includes sensors attached to a patient to receive abdominal ECG signals and a recorder and digitizer to record and digitize each at least one maternal signal in a maternal signal buffer. The system further includes a peak detector to identify candidate peaks in the maternal signal buffer. The signal stacker of the system stacks and divides at least one maternal signal buffer into a

plurality of snippets, each snippet including one candidate peak and a spatial filter identifies and attenuates a maternal QRS signal in the plurality of snippets of the maternal signal buffer, the spatial filter including at least one of principal component analysis and orthogonal projection, to produce a raw fetal ECG signal which is stored in a raw fetal ECG buffer. The system further includes a fetal QRS identifier for identifying peaks in the raw fetal ECG buffer by at least one of principal component analysis and a peak-detector followed by rule based fQRS extraction and a merger to calculate and merge the fetal heart rate from the identified peaks.

In accordance with another aspect, a method of extracting a fetal heart rate from at least one maternal signal is provided. The method includes recording and digitizing at least one maternal signal in a maternal signal buffer and identifying candidate peaks in the maternal signal buffer. The method divides the at least one maternal signal buffer into a plurality of snippets, each snippet including one candidate peak. A maternal QRS signal is identified and attenuated by spatial filtering in the plurality of snippets of the maternal signal buffer. The spatial filter includes at least a principal component analysis or orthogonal projection and produces a raw fetal ECG signal, which is stored in a raw fetal ECG buffer. The peaks in the raw fetal ECG buffer are identified by principal component analysis or a peak-detector followed by rule based fQRS extraction and the fetal heart rate is identified from the peaks.

In accordance with another aspect, a module for extracting a fetal heart rate from at least one maternal signal is provided. The module includes a recorder and digitizer which records and digitizes at least one maternal signal in a maternal signal buffer. The module also includes a processor configured to identify candidate peaks in the maternal signal buffer and divide the at least one maternal signal buffer into a plurality of snippets, each snippet including one candidate peak. The processor is further configured to identify and attenuate, by spatial filtering, a maternal QRS signal in the plurality of snippets of the maternal signal buffer with the spatial filter including at least one of principal component analysis and orthogonal projection wherein the spatial filtering produces a raw fetal ECG signal which is stored in a raw fetal ECG buffer. The processor then identifies peaks in the raw fetal ECG buffer by at least one of principal component analysis and a peak-detector followed by rule based fQRS extraction and a calculator calculates the fetal heart rate from the identified peaks.

One advantage resides in improved fetal ECG readings from abdominal ECG recordings using orthogonal projection or principal component analysis.

Another advantage resides in improved reliability of continuous fetal heart rate monitoring and reading interpretation.

Another advantage resides in improved identification of cardiac signals in a low signal-to-noise ratio ECG such as a fetal heart beat detection.

Another advantage resides in improved clinical workflow.

Another advantage resides in improved patient care.

Still further advantages of the present invention will be appreciated to those of ordinary skill in the art upon reading and understanding the following detailed description.

The invention may take form in various components and arrangements of components, and in various steps and arrangement of steps. The drawings are only for purposes of illustrating the preferred embodiments and are not to be construed as limiting the invention.

FIGURE 1 illustrates a fetal heart rate extraction system.

FIGURE 2 illustrates a flowchart diagram for detecting a fetal heart rate from an abdominal fECG.

FIGURE 3 illustrates a flowchart diagram for maternal QRS detection.

FIGURE 4 illustrates a continuation flowchart diagram of Figure 3 showing the peak detection and auto correction of maternal QRS detection.

FIGURE 5 illustrates the data matrix constructed using the abdominal ECG (AECG) data corresponding to approximately ~200 samples before the maternal QRS peaks and ~450 samples after the maternal peaks.

FIGURE 6 illustrates the data matrix with the maternal QRS subtracted.

FIGURE 7 illustrates before and after maternal attenuation data of a single row in a data matrix when the PCA technique is applied.

FIGURE 8 illustrates a fetal heart beat preserved after attenuation of maternal QRS even when the fetal heart beat overlaps with a maternal QRS.

FIGURE 9 illustrates shows a fetal ECG (fECG) trace extracted by PCA with the fetal QRS peaks marked with triangles

FIGURE 10 illustrates the attenuation of a maternal ECG using orthogonal projection technique with the maternal QRS projected out.

FIGURE 11 illustrates the abdominal ECG and fetal ECG trace extracted with the black dot representing the fetal QRS location as annotated based on fetal scalp electrode

FIGURE 12 illustrates the comparison of the fetal heart obtained from fetal ECG (after spatial filtering) to the fetal heart rate obtained from scalp electrode.

FIGURE 13 illustrates a schematic representation of the method for determining heartbeat assignment and certainty assessment information.

FIGURE 14 illustrates the input to a baseline wander removal algorithm.

FIGURE 15 illustrates the output to a baseline wander removal algorithm.

FIGURE 16 illustrates the threshold found by the optimized thresholding routine on a 60s long segment of ECG signal.

FIGURE 17 illustrates the compilation of signal snippets surrounding the threshold crossings.

FIGURE 18 illustrates the signal snippets represented in principal component analysis (PCA) space.

FIGURE 19 illustrates the certainty of each heart beat based upon the original ECG trace.

FIGURE 20 illustrates finding the best combination of channels by considering the number of peaks and the resulting heart rate variability.

FIGURE 21 illustrates an RR interval before and after correction.

FIGURE 22 illustrates an RR interval denoting where missing beats are likely.

FIGURE 23 illustrates an RR interval denoting where peaks are misidentified.

FIGURE 24 illustrates a flowchart diagram depicting a merge process for the different signals or different results of processing the signals that is used to combine the output to get an accurate fetal QRS location.

FIGURE 25 illustrates four simultaneously-recorded Fetal ECG signals (see top four plots) and a combined confidence signal output (see bottom plot).

The present application is directed to a method for improved fetal heart rate extraction and interpretation. The invention disclosure is inspired by the insight that current methods for monitoring fetal heart rates are unreliable and difficult to interpret resulting in increased caesarean sections for health infants. Presently, the most accurate method for measuring fetal heart rates is direct fetal electrocardiographic using a fetal scalp electrode, which is only typically used during labor due to its associated risks during a routine pregnancy exam. Non-invasive fetal electrocardiographic monitoring is measured through electrodes placed on the mother's abdomen, however, it is often difficult to detect the fetal heart rate since the maternal ECG is usually more prevalent.

The present application presents an improved algorithm for fetal heart rate extraction from abdominal fECG recording using spatial filtering, such as Principal component analysis and orthogonal projection techniques for maternal ECG attenuation and

PCA clustering. Additionally, the present invention utilizes adaptive rule based fetal QRS detection for the extraction of the fetal heart rate.

With reference to FIGURE 1, a fetal heart rate extraction system **10** receives abdominal ECG signals from sensors **12-18** attached to a patient (e.g., a pregnant woman). The sensors **12-18** provide signals, which are digitized by an A/D converter digitizer **20** and stored in buffers **22A-22D.** Each sensor may provide a signal stored in its own respective buffer. The buffers **22A-22D** are part of a memory **24**. The system **10** includes a computer-processing device **26** (or "processor") to execute instructions stored in an instruction memory **28**. The instruction memory **28**, the data memory **24**, the digitizer **20**, and the processor **26** are connected by a data bus **30**.

The system **10** may include one or more dedicated or general-purpose computing devices, such a server computer or a laptop computer with an associated display device and a user input device, such as a keyboard and/or cursor control device (not shown). The memories **24, 28** may be separate or combined and may represent any type of computer readable memory such as random access memory (RAM), read only memory (ROM), magnetic disk or tape, optical disk, or flash memory. The processor can be variously embodied, such as by a single-core processor, a dual-core processor (or more generally by a multiple-core-processor), a digital processor and cooperating math coprocessor, a digital controller, and the like.

The term "software" as used herein is intended to encompass any collection or set of instructions executable by a computer or other digital system so as to configure the computer or other digital system to perform the task that is the intent of the software. The term "software" as used herein is intended to encompass such instructions stored in the storage medium such as RAM, a hard disk, optical disk, or so forth, as is also intend to encompass so-called "firmware" that is software stored on a ROM or so forth. Such software may be organized in various ways, and may include software components organized as libraries, Internet-based programs stored on a remote server or so forth, source code, interpretive code, directly executable code, and so forth. It is contemplated that the software may invoke system-level code or calls to other software residing on a server or other location to perform certain functions.

In one embodiment, the system **10** is configured by instructions in the memory **28** to embody a peak detector **40**, a signal stacker **42** , a spatial filter **44** (including a principal component analyzer and a orthogonal projection analyzer), a fetal QRS identifier **46**

(including a second principal component analyzer and adaptive rule based analyzer), and a merger **48** .

FIGURE 2 shows a method in accordance with one embodiment. The steps are, in one embodiment, performed by the computer processor **26** under control of the instructions stored in the memory **28**. The method or software modules starts at S100.

At S102, a maternal heart rate is detected in at least one maternal ECG channel. This includes recording and digitizing each ECG channel, storing the digital information in a buffer, filtering the signal in the buffer, and then detecting peaks. Step S102 is explained in greater detail with respect to FIGURE 3.

At S104, for each channel (buffer), a fixed n-length window is applied around each of the m maternal QRS complexes (each peak detected in step S102). In one embodiment, the window size is 110% of the median RR interval for that channel, with 35% before the R peak and 75% after the R peak. Each channel results in an m x n matrix. This construction increases the spatial resolution even for a single channel data and aids the spatial filtering techniques of PCA and orthogonal projection (OP) to better attenuate maternal QRS.

At S106, spatial filtering is applied to each channel (or to just one channel if only one channel was recorded) to attenuate the maternal QRS. The spatial filtering uses at least one of principal component analysis and orthogonal projection, explained in further detail below. One channel may be processed using both principal component analysis and orthogonal projection to produce two output buffers.

At S108, the fetal QRS is extracted from the buffer. At least one of adaptive rule based fQRS detection and PCA clustering based fQRS detection are used to extract the fetal QRS. Either technique may be applied to the output of S106, yielding four "paths" through S106 and S108. For example, any one signal may be processed using: Maternal ECG attenuation using PCA followed by fetal ECG detection using PCA, Maternal ECG attenuation using PCA followed by fetal ECG detection using adaptive rule based detection, Maternal ECG attenuation using orthogonal projection followed by fetal ECG detection using PCA, and Maternal ECG attenuation using orthogonal projection followed by fetal ECG detection using adaptive rule based detection. These methods of processing may produce four different results for each signal, although, in a preferred embodiment, only three of the paths are used, as explained below.

At S110, the different signals or different results of processing the signals are merged. Because S104 and S106 may produce multiple output buffers, and multiple signals

may have been input, merge fQRS is used to combine the output to get an accurate fetal QRS location and hence an accurate fetal heart rate. This step is explained in further detail below.

At S112, the method ends. To summarize FIGURE 2, the raw ECG is first filtered and then subjected to maternal ECG attenuation. Maternal ECG attenuation consists of extraction of the maternal QRS signal, signal stacking around the detected maternal QRS, and application of spatial filtering techniques to attenuate the maternal ECG. Maternal ECG attenuation produces a raw fetal ECG signal, which is processed to detect the fetal ECG signal. Adaptive rule based fQRS detection and PCA clustering are used to extract the fetal QRS from the raw fetal ECG system. Each signal may be processed using different combinations of techniques, or multiple signals may be processed.

MATERNAL QRS DETECTION

FIGURES 3 and 4 show the sub-steps or sub-modules of S102 of FIGURE 2.

At S200, step or module S102 of FIGURE 1 starts.

At S202, at least one maternal ECG signal is recorded, digitized, and stored in a buffer. In one embodiment, four maternal signals are recorded, though more or fewer are contemplated. In another embodiment, only one maternal signal is recorded. In one embodiment, the maternal ECG is stored in 1 minute buffers. In another embodiment, the buffers may be shorter, e.g., 5, 10, 15, or 30 seconds.

At S204, the raw ECG data is first band-pass filtered between 2-50 Hz (or other filter range, e.g., from 1 Hz to 100 Hz) to remove any baseline-wander and other low-frequency movement artifacts. A median filter could also be used.

At S206, preprocessing begins.

At S208, data for each channel is split into segments of 0.5 sec duration. The duration may be longer or shorter.

At S210, any linear trends are removed.

At S212, the detrended segments are concatenated back together.

At S214, in an embodiment with multiple channels, the channels of pre-processed fECG data are ranked based on 1) the power spectrum of a Fourier transform in descending order with high weight, 2) power of a Hilbert transform in descending order with medium weight, and 3) a standard deviation in ascending order with low weight, respectively. As mentioned before, in one embodiment, there are four channels.

At S216, the polarity of each channel is detected. If the maximum amplitude of the channel is smaller than the absolute value of the minimum amplitude of the channel, then the channel is flipped. The method continues on FIGURE 4.

With reference to FIGURE 4, at S218, a peak detector is used to detect peaks in the channel. In one embodiment, the peak detector is based on one threshold for searching the channel at local maximums of ECG amplitude and 3 thresholds for derivatives of those indexes of local maximums in which the 3 thresholds partly represent R-R intervals in low, normal and high levels.

At S220, the peaks found in S218 are corrected by searching for a local maximum in a narrow window around the auto-detected peak found in S218.

At S222, the peaks are optionally auto-corrected. In embodiments with multiple channels, the channels are selected which indicate a heart rate (HR, peak numbers of the channel) in a reasonable range (corresponding to 20-150 bpm or preferably 30-132 bpm) and match the other channels with a difference less than 1 bpm. The selected channels are then compared to match the weighted rank in which the highest ranked channel is chosen. At S223, if no channel is selected, the method proceeds to step or module S224. If a channel was selected, the method proceeds to step or module S234.

At S224, the buffer is segmented into shorter ECGs for each channel, e.g. 10.

At S226, the factor of the threshold is reduced.

At S228, auto-detection, similar to S218, is reapplied.

At S230, if the channels which are selected indicate a heart rate (HR, peak numbers of the channel) in a reasonable range (corresponding to 20-150 bpm or preferably 30-132 bpm), processing proceeds to S232. If not, the channels are segmented again at S224.

At S232, the channels are desegmented and processing continues at S234.

At S234, once the channel and correct peak number have been detected, a heart rate is computed from the peak number. A first derivative is also computed from the heart rate. If the absolute value of the first derivative is higher than a threshold, a misplaced peak in will be corrected.

At S236, the method ends. The maternal R peaks in each buffer have been detected. Processing continues at S104 of FIGURE 2.

SPATIAL FILTERING: PCA

After the auto-correction of the step or module S102, the signals are stacked at S104, described above. At S106, the stacked buffers are spatially filtered by principal component analysis (PCA) or orthogonal projection. This section describes PCA.

PCA has been used to separate ventricular and atrial components of an adult ECG for estimation of atrial fibrillatory waves. Fetal components can be extracted by applying PCA to the stacked matrix M of maternal beats and subtracting the maternal

contributions. The most significant components are related to the main maternal QRST waveform and the interbeat variability that exist in maternal QRST waveform. The remaining components correspond to fetal ECG and sources of contamination. To estimate the fetal ECG (fECG), a mean of the matrix M and the contributions of the top three principal components to that row are subtracted from each row of the matrix M. This removes the maternal ECG. Unstacking the matrix M gives the fetal ECG. A low pass filter can be applied to remove any discontinuity that may have resulted from windowing.

In one embodiment, the abdominal ECG (AECG) data corresponds to approximately ~200 samples (0.35* mean (RR interval)) before the maternal QRS peaks (detected at step S102) and ~450 samples (0.75* mean (RR interval)) after the maternal peaks. The samples are extracted and stacked in the step or module S104 in a matrix with dimension m x n where m is a number of maternal QRS locations and n is ~650 samples. This construction enables increasing the spatial resolution for each channel and hence enables any spatial filtering technique to better attenuate the maternal QRS. The matrix of stacked beats is shown graphically in FIGURE 5.

The data of stacked maternal beats is subjected to PCA to attenuate the maternal ECG. In one embodiment, the mean of the stacked beats along with the next 3 principal components are identified as maternal components. In other embodiments, the mean by itself or the mean plus one or two principal components may be used. In one embodiment, the mean plus three components is used because of the structure of the QRS. A low pass filter may optionally be applied to smooth out any discontinuities resulting from windowing. A set number of principal components are used here to filter out the maternal ECG. However, in another embodiment, one can identify the correct number of components to use for an individual record by looking at how many components represent most of the energy within the signal. Using a smaller number of principal components minimizes attenuation of fetal QRS while using a large number of principal components maximizes removal of maternal QRS. FIGURE 6 shows successful attenuation of maternal QRS. FIGURES 7 and 8 show single rows in the data matrix before (dashed) and after (solid) maternal attenuation. FIGURE 8 shows that fetal QRS can be preserved even when it overlaps with a maternal QRS complex. Once the maternal components are attenuated via PCA, the remaining components are used to reconstruct the fetal ECG in the step or module S108.

The above procedure is repeated for all four channels of AECG data. FIGURE 9 shows examples of a fetal ECG (fECG) trace extracted by PCA. The fetal QRS peaks (provided for this dataset) are marked with triangles. It can be observed that the proposed

approach extracts a clean fECG and hence would enable a robust fetal heart rate extraction and fetal cardiac waveform analysis for in-utero diagnosis. Once the fetal ECG has been extracted for all 4 channels, a rule-based fetal QRS detector or PCA can be used in the step or module S108 to detect fetal heart rates. The results of PCA followed by adaptive rule based filtering are show in Table 1, at the end of this specification, in the row labeled PCA-Adaptive, and for PCA followed by PCA in the row labeled PCA-PCA.

SPATIAL FILTERING: ORTHOGONAL PROJECTION

Orthogonal Projection has been used in attenuation of maternal and fetal Mangenocardiogram (MCG) from fetal Magentoencephalogram (fMEG) and is based on Gram-Schmidt orthogonalization. In the step or module S106 of FIGURE 2, the OP is applied to the stacked matrix M to remove maternal contributions. That is, in both OP and PCA, the data is first stacked in the step or module S104. A data point at which the matrix M attains the largest amplitude is chosen as the first maternal ECG signal space vector of dimension m x 1, where m is the number of maternal QRS complexes. The choice of the largest amplitude signal space vector can be based on the root mean square (rms) estimate. This vector is projected out from the matrix M. The procedure is then repeated on the residual, and the next signal space vector is selected and projected out, and so on. The vector selection procedure is stopped when the residual drops below a specified threshold, for example, a multiple of the rms noise estimate. As with PCA, the matrix M with maternal contributions removed is un-stacked to give the fetal ECG.

As with PCA, the abdominal ECG (AECG) data corresponds to approximately ~200 samples (0.35* mean (RR interval)) before the maternal QRS locations and ~450 samples (0.75* mean (RR interval)) after the maternal QRS locations, producing 650 samples, shown in FIGURE 4, as discussed above.

This data is then subjected to orthogonal projection (OP), based on Gram-Schmidt orthogonalization, to attenuate the maternal ECG. The norm of the maximum vector in the data constructed is extracted and termed as a U matrix with dimension m x 1. The constructed data is termed as Avg with dimension m x n. With the application of Gram-Schmidt orthogonalization as described in the equation below, the vector U is projected out of the Avg. In one embodiment, this procedure is repeated until the maximum vector amplitude is less than 5 μvolts. Other thresholds are possible, such as 1, 2, or 10 μvolts.

$$Avg = Avg - \left(\frac{Avg \times U}{U^2} \right) \times U \longrightarrow (1)$$

The result of this procedure applied to the data of FIGURE 4 is shown in FIGURE 10. In an embodiment with four channels, the OP is repeated for all four channels of AECG data. Once the fetal ECG has been extracted for all 4 channels, one of PCA and adaptive rule-based fetal QRS detector is used to extract the fetal heart rate. The results shown below in TABLE 1 indicate that OP followed by an adaptive rule based approach (capable of filling the missing fetal QRS locations and also shifting the fetal QRS locations) yields a fetal RR interval measurement of less than 20 across the different datasets. In another embodiment, the OP is followed by PCA.

FIGURE 11 show the abdominal ECG **122** and fetal ECG trace **120** extracted by the proposed approach and the black dot represents the fetal QRS location as annotated based on fetal scalp electrode (used to check the performance of the fetal ECG). Note that the alignment is quite close. FIGURE 12 shows the fetal heart rate extracted from the buffers after spatially filtering to remove the maternal QRS, leaving a raw fetal ECG in the buffer. FIGURE 12 also includes a fetal heart rate obtained with the fetal scalp electrode, which serves as the gold standard. The PCA or OP method can be used to extract a clean fECG and enable a robust fetal heart rate extraction in the step or module S108.

PCA CLUSTERING TO IDENTIFY FETAL QRS (STEP or MODULE S108 of FIGURE 2)

The sub-steps of the PCA method of the step or module S108 of FIGURE 2 are shown in FIGURE 13.

At S300, the method starts.

At S302, the data with the maternal QRS attenuated from the step or module S106 is received.

At S304, a baseline wander removal technique is applied. This may be either a median filter or a band-pass filter (e.g. from 1 Hz to 100 Hz), or other equivalent technique of baseline wander removal. The input (maternally attenuated ECG from S106) is shown in FIGURE 14, and the output of such a filter is depicted in FIGURE 15.

At step or module S306, the filtered signal is passed to an automatic thresholding module. The optimized thresholding routine chooses a threshold to minimize the variance of intervals between threshold crossings while constraining the number of threshold crossings to remain in a physiologically plausible range for a fetal heart beat. The threshold level is varied from zero to the maximum signal value, then from zero to the minimum signal value. At each threshold value the number of threshold crossings is recorded, along with the times between threshold crossings and standard deviations of times between threshold crossings. The assumption behind this method is that the R peaks of the desired cardiac

components will deviate from baseline more than the majority of the contributions from a normally distributed noise signal. In this case, an optimal threshold value is one where the standard deviation of threshold-crossing intervals is minimized (threshold crossing intervals that are primarily from noise will have larger standard deviations than those from a regular heart beat), with the constraint that the number of threshold crossings is within a physiologically plausible range (e.g., representing heart rates of between 30 and 200 beats per minute). Furthermore, in the case where there are many threshold values with similar crossing counts and variability statistics, the threshold with minimum absolute value is chosen, as this will tend to preserve low-amplitude true beats while possibly allowing a minimal amount of noise, which will be separated at later stages. FIGURE 16 demonstrates the threshold **84** found by this algorithm on a 60 seconds long segment of ECG signal and several above-threshold beats **82**.

At S308, snippets of the filtered ECG are taken and list of threshold crossing **82** timings. For each threshold crossing, the portion of the signal immediately before and after the crossing (in these plots, this duration is 50ms before to 50ms after threshold crossing) is appended to a matrix, with each matrix row representing a potential PQRS cardiac complex, and aligned to the threshold crossing point. This is illustrated in FIGURE 17, where each signal snippet surrounding a threshold crossing is plotted in time. In this plot one can see that many of the snippets have similar shapes – these are the desired cardiac complexes the algorithm is designed to isolate. In the embodiment, these crossing points **82** are used to capture 100ms signal snippets. Other lengths of snippets are contemplated (e.g. 50ms, 200 ms, 500ms, and 1 sec).

These f signal snippets (where f is the number of snippets) are used as rows in an f x g matrix, to which PCA is applied. The first n components are used to separate cardiac complexes from noise (in this embodiment, n=3, but other values are contemplated). This finds the ordered dimensions of maximum variation. FIGURE 18 displays the signal snippets from FIGURE 17 as points in this new PCA space. There should be a dense cluster representing true fQRS complexes that are similar to each other, and a more distributed set of points representing noise, which will tend to have large variation. The assumption for this analysis is that cardiac components will be more similar to each other than to noise, and that noise contributions will all be different. In this case, when cast into “PCA-space,” the cardiac contributions form a discrete cluster **86** of a physiologically plausible number of units; whereas, the noise contributions will be distributed throughout the space.

At S310, the method proceeds with K-Means clustering to find the cluster that represents the fQRS complexes. The center of this cluster is used to assign a confidence value to each snippet by measuring the distance from the snippet to the center of the cluster. Snippets with points closer to the center of this cluster **86** are deemed more likely to be fQRS complexes than points farther away. That is, in one embodiment, the confidence is proportional to the inverse of the distance. This list of signal snippet times and confidences from each channel is then passed to the merging algorithm described below.

In one embodiment, k-means clustering is used, but other techniques such as hierarchical clustering, density-based, or distribution-based clustering could equivalently be employed. In the k-means case, the number of potential groups is varied from 1 to n (in this case 5). As this is a probabilistic technique, at each step number of groups the technique is repeated multiple times. At each iteration, each found cluster is evaluated based on the final heart rate, mean inter-R interval, and standard deviation of inter-R interval if the cluster were to represent true heart beats. At the end of this process, the cluster selected as the “true” cluster is the one that minimizes the standard deviation of inter-R intervals and is physiologically plausible (e.g., a heart rate between 30-200 bpm, or a more narrowly defined range if subject age is known). FIGURE 18 displays the cluster that was determined to represent the cardiac complexes, where the circle **86** indicates highest density of points representing a true cardiac complex.

At step or module S312, the cluster is used to identify which threshold crossings could be caused by heart beats and assign a confidence indication to each beat. This step makes use of the PCA clustering result in the following manner. The threshold crossings that have PCA representations near the center of the “true beat” cluster **86** are assumed to be true beats, and the distance from the center of that cluster is used as an indicator of reliability. Using the k-means based beat assignment, all beats assigned to the “true beat” cluster are included as potential beats. The standard deviation of the distances of these points from the center of the cluster is calculated, and this number is used to calculate a z-score of each point – each point’s distance from the cluster center, normalized by the standard deviation of the cluster distances. This z-score is used as a reliability index, with lower z-scores (representing beats closer to the cluster center, and thus more stereotypical) indicating high-confidence beats. A top trace **90** of FIGURE 19 shows the original ECG trace, now with potential heart beats identified. A bottom trace indicates **92** the confidence associated with each classification, where taller lines correspond to greater confidence.

ADAPTIVE RULE BASED FETAL QRS IDENTIFICATION (STEP or MODULE S108 of FIGURE 2)

The best combination of channels or the polarity of the channel (direction of the R peak) can differ among recordings. To detect the R peaks, a basic peak detector is first applied to different combinations of channels and polarities. The different combinations are then ranked based on the number of peaks detected and heart rate variability. The combination of channel(s) with the most peaks detected and least heart rate variability is designated the winning combination whose peaks are then output as the fetal QRS locations. Possible combinations of channels are:

$$a*ch1 + b*ch2 + c*ch3 + d*ch4$$

where a, b, c, and d can take on the values of 0, 1, and -1 resulting, for a four channel system, in 80 possible unique combinations, excluding [a,b,c,d] = [0, 0, 0, 0] since at least one channel must be used. The leading coefficient can be 1 and -1 because it is not known whether R peaks are going upward or downward (the polarity of the channel). One can decrease the set of possible combinations if there is confidence about the polarity of some of the channels. Peak detection is done on each combination of channels. To rank the different combinations, the number of peaks detected and the resulting heart rate variability (standard deviation of RR intervals) is measured. If the wrong polarity is used or if only channels with poor SNR are used, the resulting number of peaks and heart rate variability are likely to be poor. The winning combination should have a large number of peaks detected along with low heart rate variability, subject to biological constraints. These constraints could be different for maternal and fetal heart beats. FIGURE 20 shows an example of this technique and how ranking of channel combinations are done. Each point 128 in FIGURE 20 is projected onto the best fit line. The channel combination **130** resulting in the highest projected magnitude is the winning combination. In this particular record, the best combination of channels is (Ch1 + Ch2 + Ch3 – Ch4) which means all channels contribute to a better peak detection. Channel 3 has low SNR but still provides some useful information. Removing channel 3 from the mix provides the second best solution. The best solution reverses the polarity of channel 4.

Calculating the required metrics for each channel can be computationally intensive. Less computationally intensive embodiments are contemplated. One can use shorter recordings (10 seconds instead of 1 minute recordings) to determine the best combination of channels and then apply the detected polarity to the entire record. One can use a subset of the 80 combinations such as only considering any combination of 2 channels. A simpler version of picking one out of 4 channels also yielded good results. In this case, the

channel polarity is determined by applying peak detection to both the signal x and its negation –x and choosing the polarity that gives the largest median peak amplitudes. The best channel is then chosen as the one which gives the smallest heart rate variability.

Because fECG is often weak in abdominal recordings, almost all peak detectors will misplace some peaks or miss peaks completely. Therefore, it can be beneficial to make corrections to the output of peak detectors by estimating missing beats and shifting location of detected peaks. Applying the following two rules makes conservative corrections to the detected peaks with minimal alteration of peaks already correctly identified:

1) Missing beats are identified when the RR interval is greater than 1.3 times the median RR interval of the entire record. One or more new beats are then placed equally spread within neighboring peaks.

2) A peak is misplaced when a pair of RR intervals (RRk, RRk+1) shows one of the following patterns: (a) RRk $\leq$ 0.9 x medianRR followed by RRk+1$\geq$ 1.1 x medianRR or (b) RRk $\geq$ 1.1 x medianRR followed by RRk+1 $\leq$ 0.9 x medianRR. Misplaced peaks are shifted to midway between neighboring peaks.

These two rules make conservative corrections to the detected peaks with minimal alteration of peaks already correctly identified. A similar approach can be used to remove extra peaks. However, in the illustrated embodiment, extra peaks were not removed because not many extra beats were detected. FIGURES 21-23 provides an example of how these rules can improve peak detection.

FIGURE 21 shows an RR interval before and after correction. Peaks **134** are possibly misplaced and peaks **132** are possibly missing. FIGURE 22 shows an RR interval when missing beats are likely (upper chart) and the lower diagram shows the beat filled in. FIGURE 23 shows the RR interval when peaks are misidentified (upper) and the peak shifted to a more likely location (lower). The dashed vertical lines in the upper charts denote estimates of fetal peak locations before correction. The dashed vertical lines denote estimates of fetal peak locations after correction in the lower chart.

The list of peak times may be assigned a standard confidence based on past performance of the method and then passed to the merging algorithm described below, with or without peaks from the PCA algorithm.

MERGE Fetal QRS

Merge fQRS is designed to account for the fact that no single channel or method will be the best in all situations. Given a list of proposed fQRS locations from multiple sources, Merge fQRS implements a modified voting routine to determine likely

fQRS complexes, which it then analyzes for likely missed and misplaced complexes. The first step in the algorithm is to create a zero-filled vector of the same duration as the ECG recordings (e.g., one minute each). Each input beat list is considered in turn, through a process in which the beat with the maximum certainty is chosen and its confidence metric is added to the vector. Chosen beats are removed from the channel's list until no beats remain, and the next list is added in the same manner to the vector. Strong fetal complexes should be recorded by multiple channels, and so contributions in corresponding bins should add. To account for timing variations, the signal is filtered by a Gaussian window prior to further analysis. The next step proceeds as the first – the tallest peak in the recording is held as the location of the highest confidence of a complex and is chosen first, its time is added to a list, and the region surrounding it is set to zero. The next highest peak is chosen and similarly added. This process repeats until the maximum peaks are less than 50% of the original maximum. After that point, a filling and shifting process similar to that described in Adaptive Rule Based fQRS is employed to bring the record in line with physiological statistics.

FIGURE 24 illustrates the sub-steps or sub-modules of step or module S110 of FIGURE 2.

Step S110 starts at sub-step S400.

At S402, proposed timings of cardiac complexes from a recording session are received from the result of the multiple methods of step or module S108 (PCA-based or rule based beat detection) analyzing the same ECG trace. A more traditional beat detection algorithm such as "Local Max" may also be used as an input. The output may also be from the same method (e.g., PCA) being applied to multiple simultaneously recorded ECG channels. In one embodiment, a combination of these approaches is the input: multiple algorithms (PCA and rule based) are each applied to multiple ECG channels.

If the input algorithm provides a metric of confidence in each beat, that can be used. In the absence of such metrics, then, at S404, a confidence metric is assigned. This may be done three ways. A constant metric for all proposed beats from that source channel/algorithm, based either on a channel reliability metric (e.g. power spectrum analysis), or on relative performance of the analysis algorithm on existing training datasets may be assigned. A varying beat-by-beat metric where high confidence values are assigned to beats found in relatively low-noise segments, and lower confidences assigned to beats proposed in high-noise signal segments may be assigned. A combination of the two approaches may be used where a beat-by-beat confidence is assigned, but a maximum confidence possible is set

by the expected reliability of the analysis technique or by the overall channel signal-to-noise ratio.

At S406, a combined confidence record that reflects the information from all input channels is initialized to zero. One input record is chosen (for example, at random) and the highest assigned confidence is added to the combined record at the corresponding time. The beat time that was added is removed from the input record, along with any nearby beat time. Here, nearby is set to the longest physiologically plausible interval, normally any beat time with 25 ms of the chosen beat time, corresponding to a heart rate of 40 bps. This interval can be tuned based on the statistics of the patient. In one embodiment, the interval is set to 12.5 ms, reflecting the fact that fetal heart rates are faster than adult heart rates. The next highest confidence is found and is added to the combined record, and it and nearby beat times are again removed. This process is repeated until no beats remain in the record. Once a record is empty, another input record is chosen at random and similarly added to the combined confidence record.

The newly created combined confidence record now consists of zeros where no input record assigned beat times, and non-zero values where input records assigned beats. At this point there can be some sections of the record that have only single proposed beats, and other regions with several nearby values where multiple input records proposed beats.

In order to accommodate imprecise timing between the different records, a Gaussian window is convolved against the combined record. This has the effect of creating a smooth confidence signal, where the height of the signal reflects increasing certainty of a true beat at this location. This is shown plot **110** of FIGURE 25. This can be thought of as a voting procedure – areas of the record where multiple channels discovered a potential cardiac complex will have higher values than areas where only a single channel proposed as a beat location Similarly, the greater the temporal coincidence between beat proposals, the higher the summed Gaussian bumps.

At S408, this combined confidence signal is analyzed to discover beat locations that have either high confidence or high agreement between the channels. Similarly to how the combined record is constructed, the maximum point in the confidence signal is chosen as the first point to add to the proposed combined output record Once this point is chosen and added, the area near to the point is set to zero (following the interval width guidelines as described earlier). The next highest point in the combined confidence signal is chosen and added to the proposed combined output record, and the combined confidence signal is again zeroed near the chosen point. This process repeats, with the added constraint

that when the algorithm attempts to add a point to a region of signal with more than 20 existing proposed beats in a minute segment, the added beat must be an approximate even multiple of the median inter-beat-time from the existing beats. A threshold of more or less than 20 may be used. The purpose of this constraint is to prevent the technique from adding low-confidence beats to the output record that are not physiologically plausible. Once the maximum of the confidence signal is less than 30% of the original maximum, this phase is complete.

At this point the maximum amount of information, has been extracted from each individual trace, but can still improve the output record by using common physiological assumptions.

At S410, by taking into account normal heart rate ranges and heart rate variability statistics, the technique finds violations of these statistics in its record and can optionally either provide an alert, annotate a likely error, or quietly correct the record, as appropriate in the application context. In one embodiment, the technique, similarly to the adaptive rule based step or module S108, searches for two main violations: record gaps, and beat misplacements. Record gaps occur when cardiac complexes are not detected by any of the input records. These gaps are found by measuring the median beat-to-beat interval of local sections of the signal, and then searching for areas of the signal that have a lack of beats over an interval approximately equal to an integer multiple of the local median beat-to-beat interval. These are marked as missing beats. The gap interval is used to assess the likely number of beats missed. The appropriate number of beats can be added to the record at the appropriate times. Beat misplacements can occur when beat timing is slightly off from where the true beat occurred. The signature of this type of error is when one beat-to-beat interval is greater (or less) than the local median interval time by a percentage, and the subsequent interval is less (or greater) than the median by the same percentage. The record is searched for this signature, and can adjust the beat timing in the appropriate direction to correct the issue.

At S412, the step or module S110 ends. The final output of S412 (and step or module S110) includes of the record of proposed times of cardiac complexes, along with the certainty associated (from the combined confidence signal), the input record identification with the “best version” of the beat, and indications of which beats have been added to fill gaps, or which beats have been adjusted to correct for timing errors. This final output is used to render display a heartbeat to a user. The bottom trace **110** of FIGURE 25 shows the output

record with solid vertical lines, which align closely with a cardiologist's annotations of true fetal cardiac complex locations, marked by dashed lines.

In this embodiment of FIGURE 25, the technique was used for to create an output of one method (PCA-based beat detector) applied to 4 signals **108** of an input maternal (abdominal) ECG. The method could also combine the output from a PCA based beat detector with the output from alternate algorithms to provide a final combined beat record. The combined output of PCA and rule based detection (following PCA and OP maternal attenuation) generally out-performs the outputs of the component methods.

RESULTS AND DISCUSSION

The results of three different techniques on sample data sets are shown in Table 1. A combination of these three algorithms yielded improved scores on the training datasets. Thus merging the three methods would be expected to improve performance on the validation set B, which did indeed yield improved results: 52.49 and 10.61 for Events 4 and 5 respectively. The methods used where PCA-PCA (PCA-maternal attenuation followed by PCA-clustering based fQRS), PCA-Adaptive (PCA-maternal attenuation followed by Adaptive rule based fQRS), and OP-Adaptive (OP-maternal attenuation followed by Adaptive rule based fQRS detection). Though the proposed spatial filtering techniques (PCA and OP) attenuate the maternal ECG, there could still be scenarios of maternal cardiac residues. The process of filling and shifting fetal QRS locations is meant to produce heart rate estimates that are physiological. However, this process may not produce true fetal QRS locations.

Table 1:

	Sample A		Sample A-ext	
	Event 4	Event 5	Event 4	Event 5
PCA-PCA	64.35	9.94	248.27	18.68
PCA-Adaptive	7.02	4.29	165.28	14.11
OP-Adaptive	12.70	6.82	243.55	17.91
Merge	5.00	4.05	146.76	14.65

The invention has been described with reference to the preferred embodiments. Modifications and alterations may occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be constructed as including all such modification and alterations insofar as they come within the score of the appended claims or the equivalents thereof.

CLAIMS:

1. A system (10) for extracting a fetal heart rate from at least one maternal signal, using a computer processor (26), the system configured to:

receive abdominal ECG signals sensors (12-18) attached to a patient;

record and digitize (20) each at least one maternal signal in a maternal signal buffer (22A-22D); and

execute instructions stored in an instruction memory (28) including:

a peak detector (40) to identify candidate peaks in the maternal signal buffer;

a signal stacker (42) that stacks and divides at least one maternal signal buffer into a plurality of snippets, each snippet including one candidate peak;

a spatial filter (44) to identify and attenuate a maternal QRS signal in the plurality of snippets of the maternal signal buffer, the spatial filter including at least one of principal component analysis and orthogonal projection, to produce a raw fetal ECG signal which is stored in a raw fetal ECG buffer;

a fetal QRS identifier (46) for identifying peaks in the raw fetal ECG buffer by at least one of principal component analysis and a peak-detector followed by rule based fQRS extraction; and

a merger (48) to calculate and merge the fetal heart rate from the identified peaks.

2. The system according to claim 1, wherein the peak detector to identify candidate peaks includes:

identifying a plurality of local maxima, optionally eliminating local maxima having a derivative below a threshold, and optionally checking a rate of the candidate peaks for physiological plausibility as a maternal heart rate.

3. The system according to claim 1, wherein, the digitized maternal signal is preprocessed (S206) by at least one of:

a band-pass filter (S204) of the at least one maternal signal in a range of 2-50 Hz;

splitting the maternal signal into segments of .5 seconds (S208), removing linear trends (S210), and concatenating the de-trended segments (S212); and

ranking (S214) the at least one maternal signal and at least one second

maternal signal in descending order based on a power spectrum of a Fourier transform, descending order of power of a Hilbert transform, and ascending order of standard deviation.

4. The system according to anyone of claims 1-3, wherein the candidate peaks are auto-corrected (S222) by selecting, from a plurality of maternal signals including the at least one maternal signal and the at least one second maternal signal, channels having candidate peaks (S223) which are physiologically plausible as a maternal heart rate and, from the selected channels, identifying a highest ranked channel, the system further comprising:

using the candidate peaks of the highest ranked channel as candidate peaks if at least one channel is physiologically plausible;

if no channel is physiologically plausible:

segment (S224) each of the plurality of channels to create segments;

auto-detect a second plurality (S228) of candidate peaks in the segments;

concatenate the segments (S232); and

use the second plurality of candidate peaks as candidate peaks (S234).

5. The system according to claim 1, wherein the spatial filter includes principal component analysis (S106), the identify and attenuate of the maternal QRS including:

stack the snippets (S104);

calculate the mean of the snippets and, optionally calculate one, two, or three of the next principal components;

identify the mean of the snippets as a main maternal component and, optionally, identify the next one, two, or three principal components as other maternal components.

attenuate the main maternal component and optionally attenuate the other maternal components.

6. The system according to claim 1, wherein the spatial filter includes orthogonal projection (S106), the identify and attenuate the maternal QRS including:

repeat, until the maximum amplitude of the plurality of snippets is less than background:

extract a norm vector of a maximum vector in the snippets; and

project the norm vector out of the snippets by orthogonalization.

7. The system according to claim 1, wherein the peaks in the raw fetal ECG are identified by principal component analysis, the identifying including:

compute a plurality of thresholds from zero to a maximum value of the raw fetal ECG (S306);

for each of the plurality of thresholds, identify a plurality of threshold crossings, a number of the plurality of threshold crossings, a plurality of intervals between adjacent threshold pairs of the plurality of threshold crossings, a rate of threshold crossings, and a standard deviation of the plurality of intervals;

eliminate threshold values corresponding to a physiologically implausible rate of threshold crossings;

select a threshold based on the standard deviations, selecting a low standard deviation and, if at least two of the plurality of thresholds have similar standard deviations, selecting a low threshold of the at least two thresholds;

for each threshold crossing corresponding to the selected threshold, constructing a window around the threshold crossing, forming a plurality of windows;

perform principal component analysis (S308) on the plurality of windows to identify at least a first principal component and, optionally, an additional principal component;

cast the plurality of windows into a principal component analysis space and clustering the plurality of windows into a principal component analysis space and comparing the plurality of clusters based on a number of threshold crossing in the cluster, a mean interval between threshold crossings, and a standard deviation of the intervals between adjacent threshold crossings in the cluster to select a most likely cluster (S310);

assign a confidence indication (S312) to each threshold crossing in the most likely cluster, the confidence interval based on how far the window corresponding to the threshold crossing is from the center of the most likely cluster in the principal component analysis space;

optionally, select as fetal heart beats a plurality of threshold crossing as having high confidence indications;

optionally, compare the plurality of clusters by assessing a physiological plausibility of the threshold crossing as a heartbeat;

optionally, process the raw fetal ECG to remove a baseline wander (S302)from the raw fetal ECG.

8. The system according to claim 1, wherein the identifying of the peaks in the raw fetal ECG includes using a peak detector followed by rule based fQRS extraction (Fig. 20), the identifying including:

identify peaks and an RR interval with a peak detector;

identify, as a missing peak (132), an adjacent pair of peaks which are separated by an interval greater than the RR interval multiplied by a missing peak factor, the missing peak factor between 1.1 and 1.9;

insert a beat between the adjacent pair of peaks;

identify sets of three peaks, including a first, second, and third peak in which the first and second peaks are separated by an interval which is RR times alpha and the second and third peak are separated by an interval which is RR times the quantity two minus alpha, where alpha is between .7 and .95 or between 1.05 and 1.3;

move the second of the three identified peaks so that the interval between the first and second peak is RR and the interval between the second and third is RR.

9. A method (Fig. 2) of extracting a fetal heart rate from at least one maternal signal, the method comprising:

recording and digitizing each at least one maternal signal in a maternal signal buffer (S202);

identifying candidate peaks (S102) in the maternal signal buffer;

dividing the at least one maternal signal buffer into a plurality of snippets, each snippet including one candidate peak;

identifying and attenuating by spatial filtering a maternal QRS signal in the plurality of snippets of the maternal signal buffer, the spatial filter (S106) including at least one of principal component analysis and orthogonal projection, the spatial filtering producing a raw fetal ECG signal which is stored in a raw fetal ECG buffer;

identifying peaks in the raw fetal ECG buffer by at least one of principal component analysis and a peak-detector followed by rule based fQRS extraction (S108); and

calculating the fetal heart rate from the identified peaks (S110).

10. The method according to claim 9, wherein identifying the candidate peaks includes:

identifying a plurality of local maxima, optionally eliminating local maxima having a derivative below a threshold, and optionally checking a rate of the candidate peaks for physiological plausibility as a maternal heart rate.

11. The method according to claim 9, wherein, after digitizing the at least one maternal signal, the maternal signal is preprocessed (S206) by at least one of:

band-pass filtering (S204) the at least one maternal signal in a range of 2-50 Hz;

splitting the maternal signal into segments of .5 seconds, removing linear trends, and concatenating the de-trended segments (S208); and

ranking the at least one maternal signal and at least one second maternal signal in descending order based on a power spectrum of a Fourier transform, descending order of power of a Hilbert transform, and ascending order of standard deviation (S214).

12. The method according to anyone of claims 9-11, wherein the candidate peaks are auto-corrected (S220) by selecting, from a plurality of maternal signals including the at least one maternal signal and the at least one second maternal signal, channels having candidate peaks which are physiologically plausible as a maternal heart rate and, from the selected channels, identifying a highest ranked channel, the method further comprising:

using the candidate peaks of the highest ranked channel as candidate peaks if at least one channel is physiologically plausible;

if no channel is physiologically plausible (S223):

segmenting each of the plurality of channels to create segments (S224);

auto-detecting a second plurality of candidate peaks in the segments (S228);

concatenating the segments; and

using the second plurality of candidate peaks as candidate peaks.

13. The method according to claim 9, wherein the spatial filtering includes principal component analysis (S106), the identifying and attenuating of the maternal QRS including:

stacking the snippets (S104);

calculating the mean of the snippets and, optionally calculating one, two, or three of the next principal components;

identifying the mean of the snippets as a main maternal component and, optionally, identifying the next one, two, or three principal components as other maternal components.

attenuating the main maternal component and optionally attenuating the other maternal components.

14. The method according to anyone of claims 9, wherein the spatial filtering includes orthogonal projection (S106), the identifying and attenuating of the maternal QRS including:

repeating, until the maximum amplitude of the plurality of snippets is less than background:

extracting a norm vector of a maximum vector in the snippets; and

projecting the norm vector out of the snippets by orthogonalization.

15. The method according to claim 9, wherein the peaks in the raw fetal ECG are identified by principal component analysis, the identifying including:

Computing (S306) a plurality of thresholds from zero to a maximum value of the raw fetal ECG;

for each of the plurality of thresholds, identifying a plurality of threshold crossings, a number of the plurality of threshold crossings, a plurality of intervals between adjacent threshold pairs of the plurality of threshold crossings, a rate of threshold crossings, and a standard deviation of the plurality of intervals;

eliminating threshold values corresponding to a physiologically implausible rate of threshold crossings;

selecting a threshold based on the standard deviations, selecting a low standard deviation and, if at least two of the plurality of thresholds have similar standard deviations, selecting a low threshold of the at least two thresholds;

for each threshold crossing corresponding to the selected threshold, constructing a window around the threshold crossing, forming a plurality of windows;

performing principal component analysis on the plurality of windows to identify at least a first principal component and, optionally, an additional principal component;

casting the plurality of windows into a principal component analysis space and clustering the plurality of windows into a principal component analysis space and comparing the plurality of clusters based on a number of threshold crossing in the cluster, a mean interval between threshold crossings, and a standard deviation of the intervals between adjacent threshold crossings in the cluster to select a most likely cluster (S312);

assigning a confidence indication (S312) to each threshold crossing in the most likely cluster, the confidence interval based on how far the window corresponding to the threshold crossing is from the center of the most likely cluster in the principal component analysis space;

optionally, selecting as fetal heart beats a plurality of threshold crossing s having high confidence indications;

optionally, compares the plurality of clusters by assessing a physiological plausibility of the threshold crossing as a heartbeat;

optionally, processes the raw fetal ECG to remove a baseline wander (S304) from the raw fetal ECG.

16. The method according to claim 9, wherein the identifying of the peaks in the raw fetal ECG includes using a peak detector followed by rule based fQRS extraction, the identifying including:

identifying peaks and an RR interval with a peak detector;

identifying, as a missing peak, an adjacent pair of peaks which are separated by an interval greater than the RR interval multiplied by a missing peak factor, the missing peak factor between 1.1 and 1.9;

inserting a beat between the adjacent pair of peaks;

identifying sets of three peaks, including a first, second, and third peak in which the first and second peaks are separated by an interval which is RR times alpha and the second and third peak are separated by an interval which is RR times the quantity two minus alpha, where alpha is between .7 and .95 or between 1.05 and 1.3;

moving the second of the three identified peaks so that the interval between the first and second peak is RR and the interval between the second and third is RR.

17. The method according to claim 9, wherein the at least one maternal signal includes at least a first and a second maternal signal which are processed according to the method of claim 1 to produce at least a first and a second raw fetal ECG buffer, the identifying peaks in the first and second raw fetal ECG signal buffer using a peak detector followed by rule based fQRS extraction including:

assigning a coefficient to each of the at least one raw fetal ECG signals;

assigning a value of one 0, +1, and -1 to each coefficient, multiplying each signal by its respective coefficient, and summing the channels to produce a summed channel, and repeating the assigning and summing for all combinations of coefficients, omitting a combination of all zero coefficients, to produce a plurality of summed channels;

identifying peaks in the plurality of summed channels with a peak detector; and

ranking the plurality of summed channels by greatest number of peaks and lowest standard deviation, and selecting a beset combination of the plurality of summed channels based on the greatest number of peaks and lowest standard deviation.

18. The method according to claim 9, wherein a plurality of raw fetal ECGs are processed to identify a plurality of sets of possible peaks, the method further including:

assigning a confidence to each peak (S404);

summing the confidence of peaks (S406) which overlap in time from different raw fetal ECGs;

picking a plurality of peaks as actual fetal beats based on the summed confidences (S408); and

calculating the fetal heart rate from the actual fetal beats (S410).

19. A non-transitory computer readable medium carrying software which controls one or more processors to perform the method according to any one of claims 9-18.

20. A module for extracting a fetal heart rate from at least one maternal signal, the module comprising:

a processor (26) configured to:

identify candidate peaks in the maternal signal buffer (22A-22D);

divide the at least one maternal signal buffer into a plurality of snippets, each snippet including one candidate peak;

identify and attenuate by spatial filtering a maternal QRS signal in the plurality of snippets of the maternal signal buffer, the spatial filter including at least one of principal component analysis and orthogonal projection, the spatial filtering producing a raw fetal ECG signal which is stored in a raw fetal ECG buffer; and

identify peaks in the raw fetal ECG buffer by at least one of principal component analysis and a peak-detector followed by rule based fQRS extraction;

a recorder and digitizer (20) which records and digitizes at least one maternal signal in a maternal signal buffer; and

a calculator for calculating the fetal heart rate from the identified peaks.

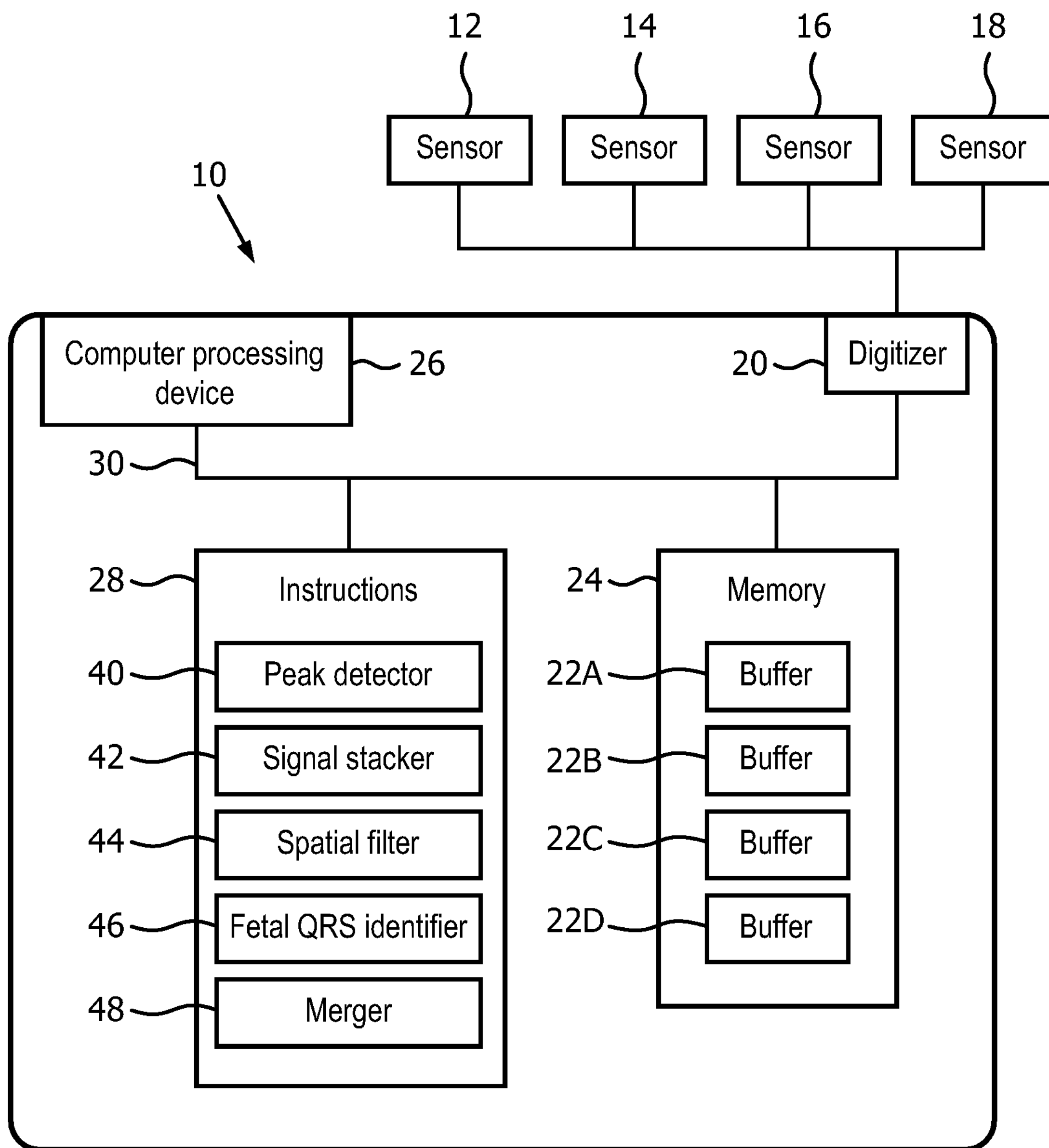

FIG. 1

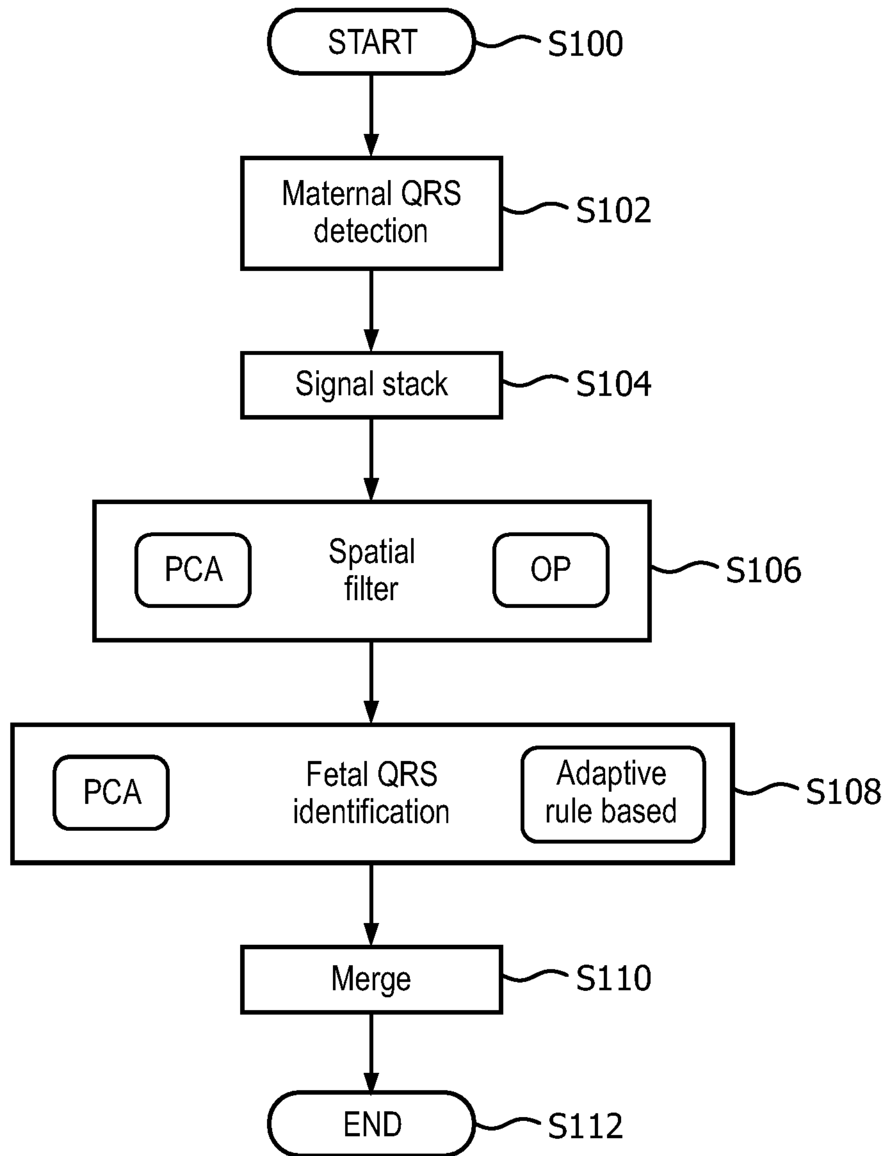

FIG. 2

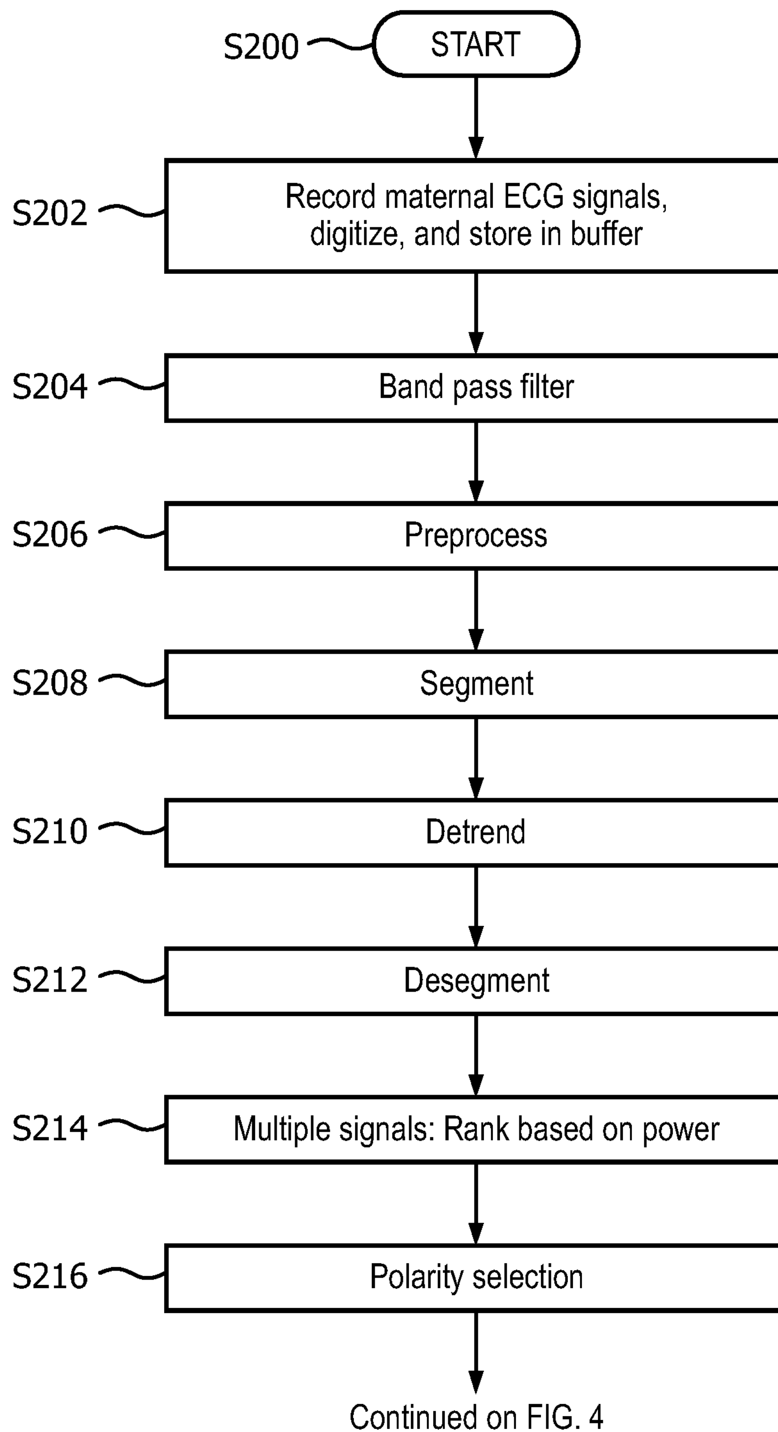

FIG. 3

Continued from FIG. 3

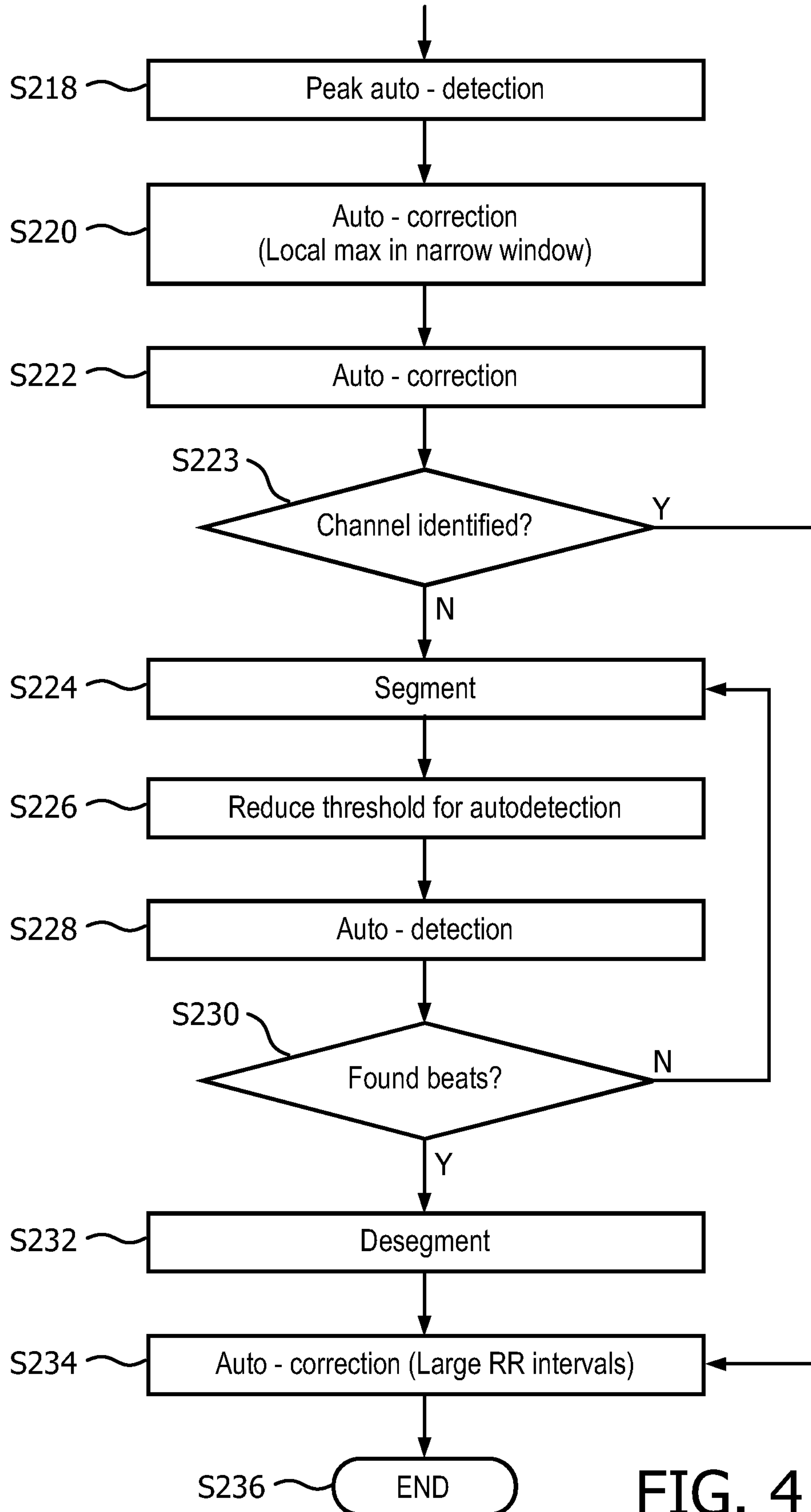

FIG. 4

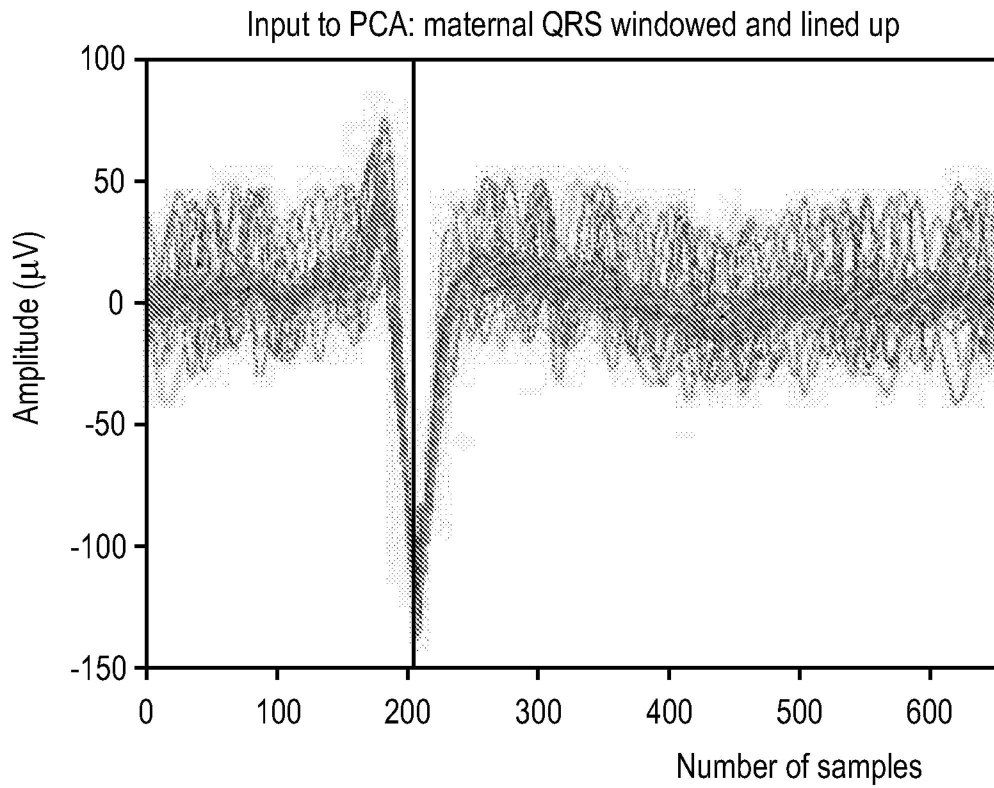

FIG. 5

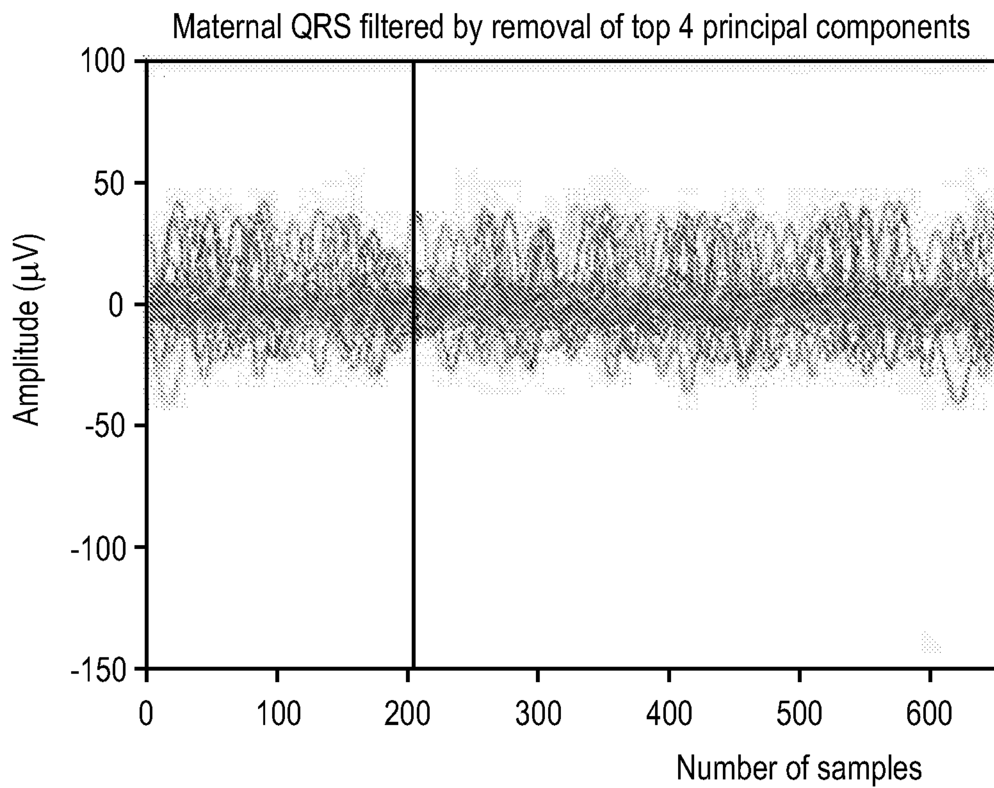

FIG. 6

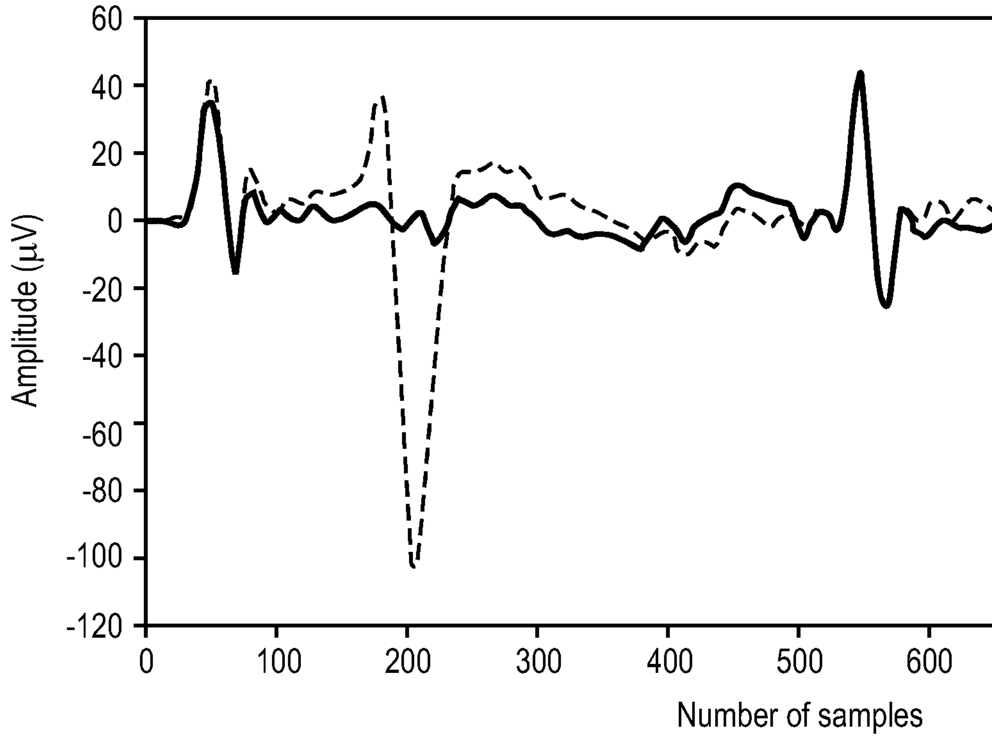

FIG. 7

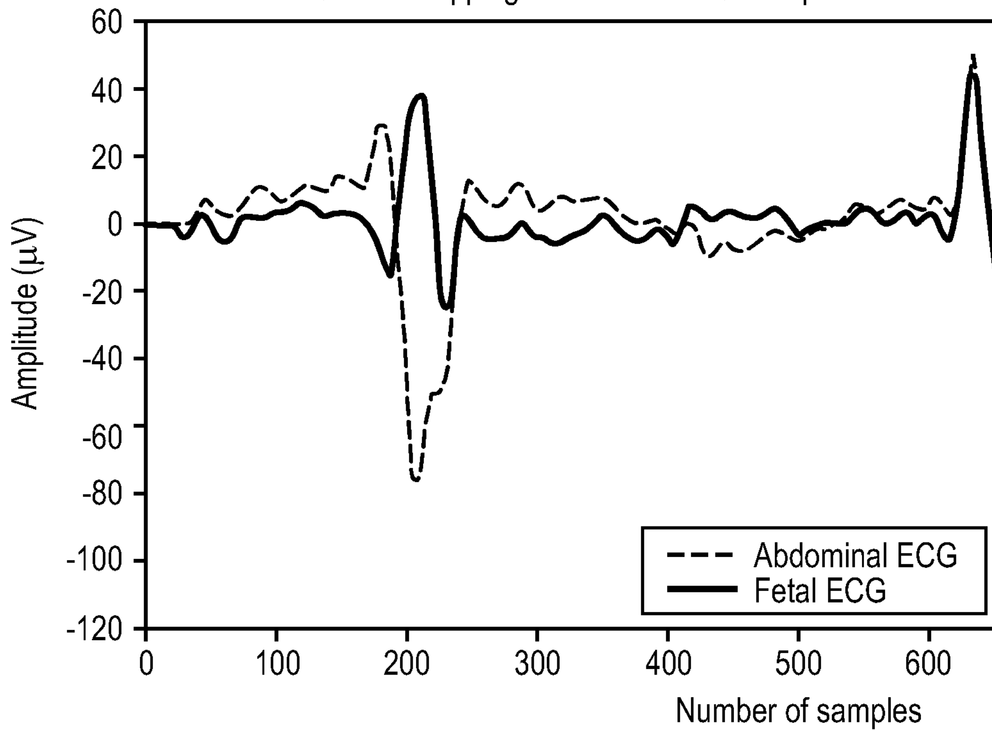

FIG. 8

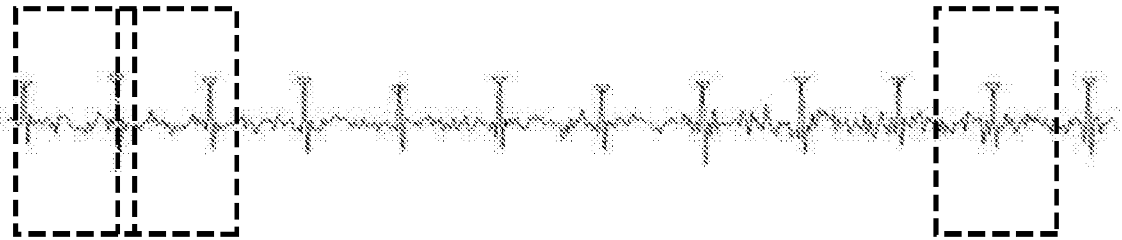

FIG. 9

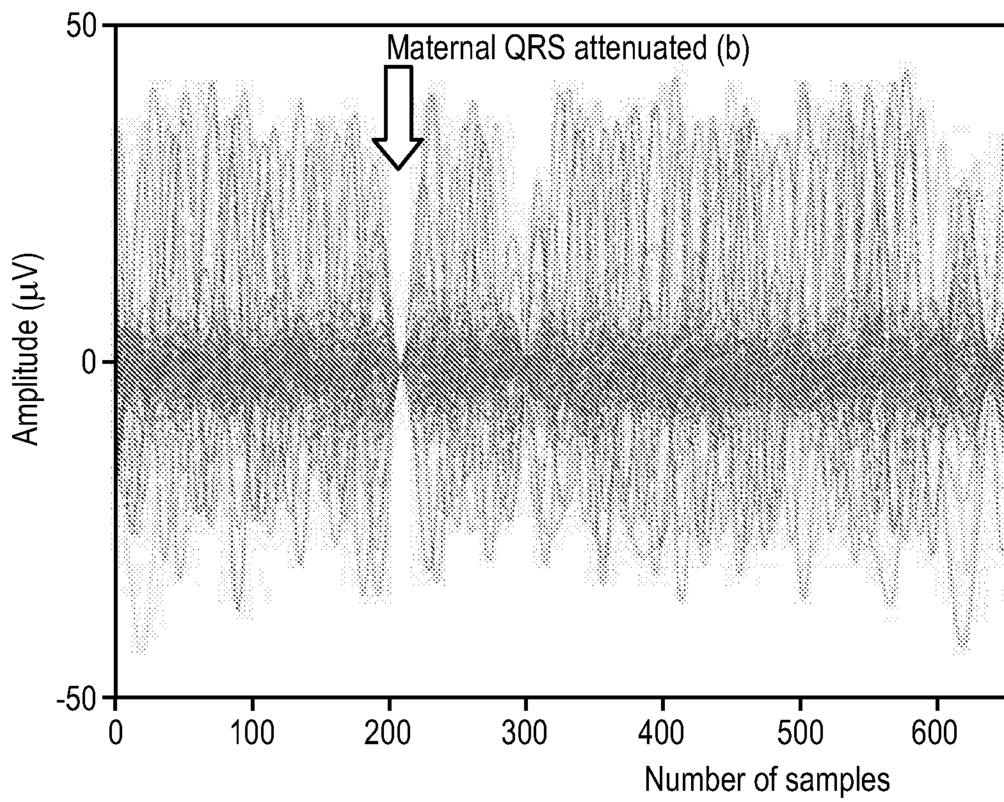

FIG. 10

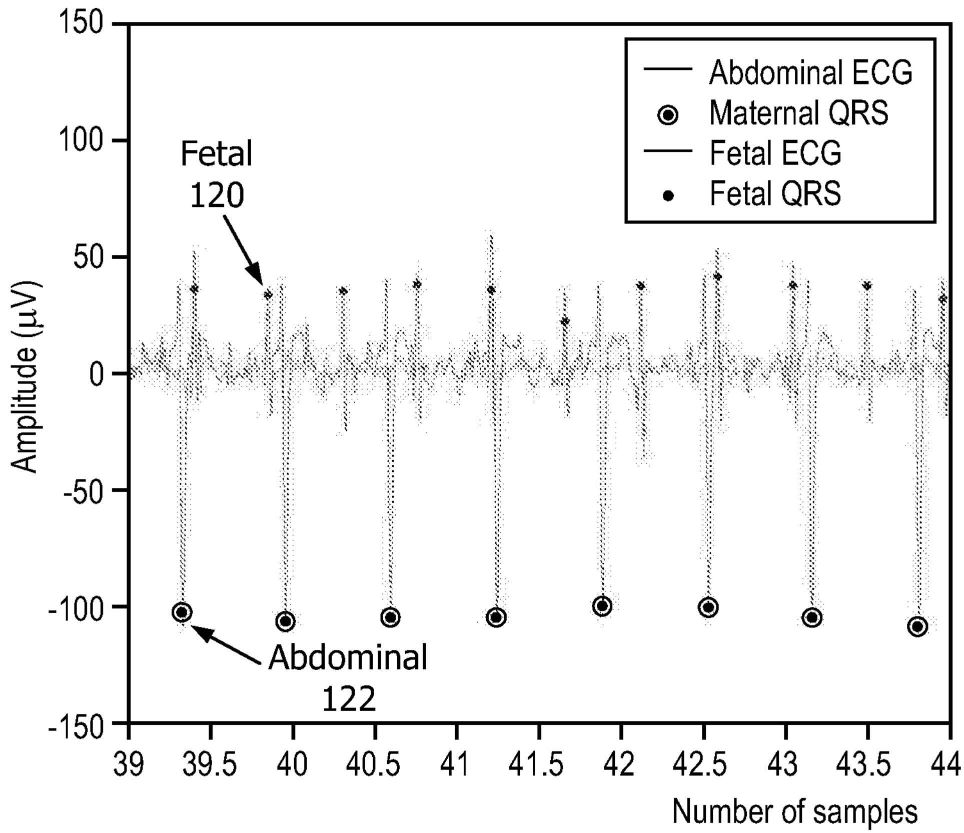

FIG. 11

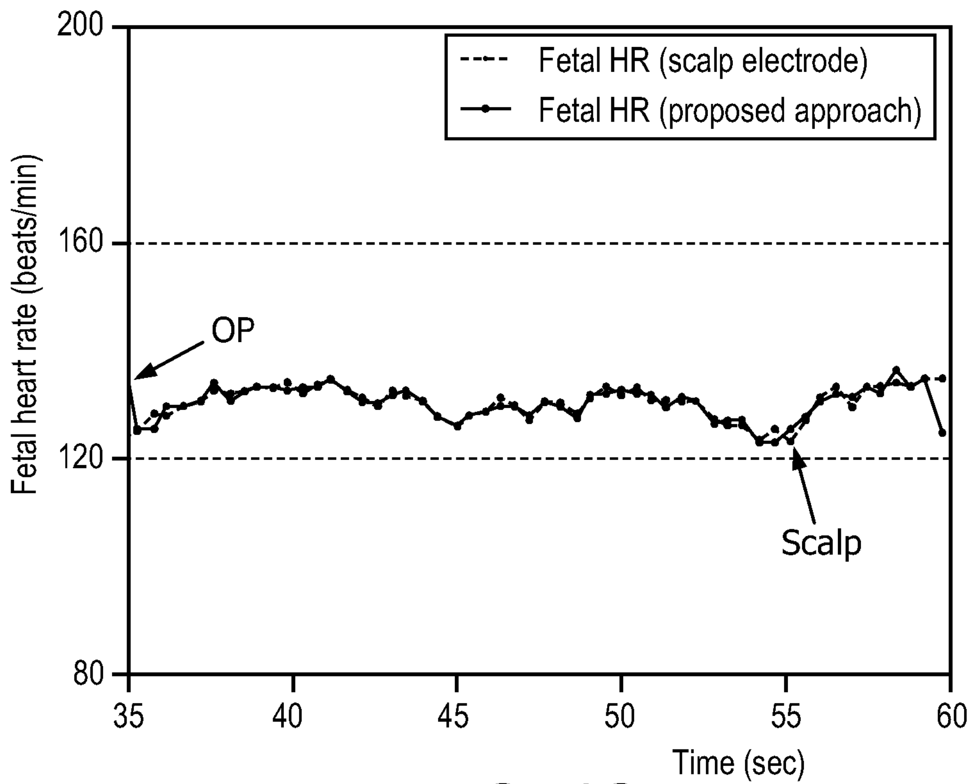

FIG. 12

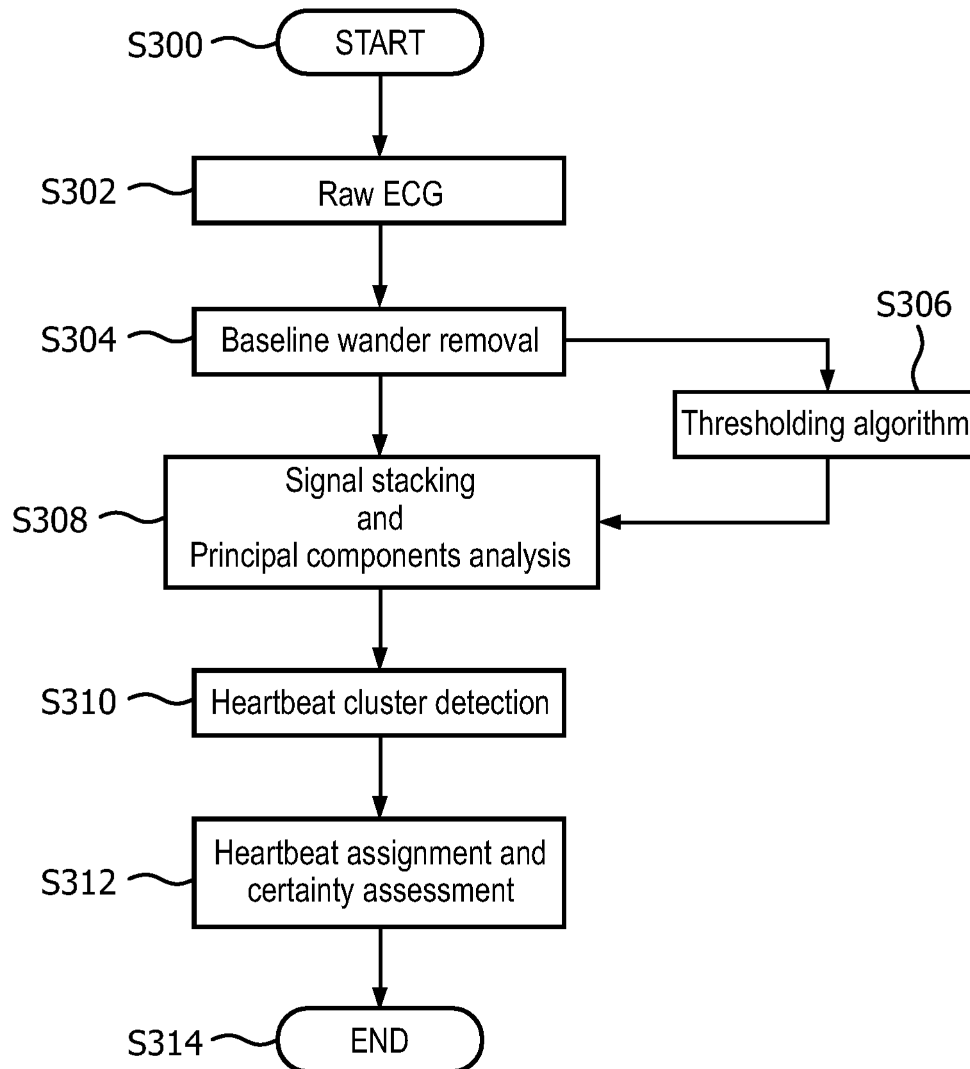

FIG. 13

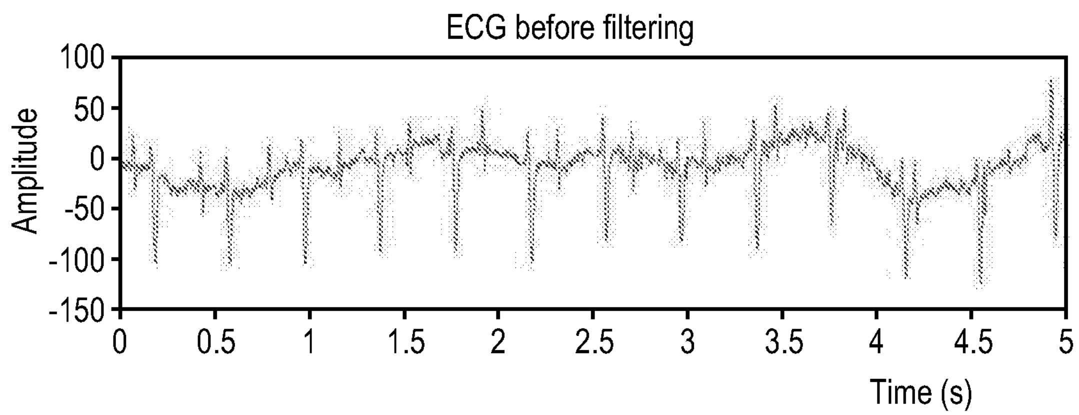

FIG. 14

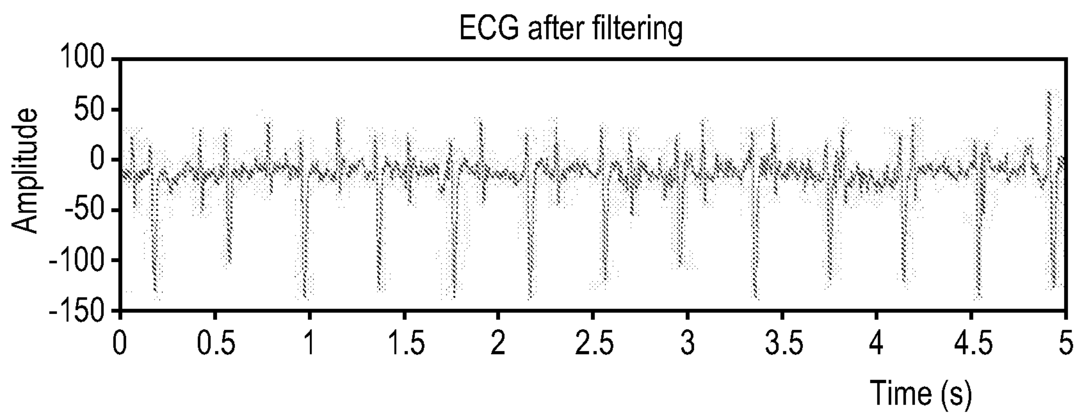

FIG. 15

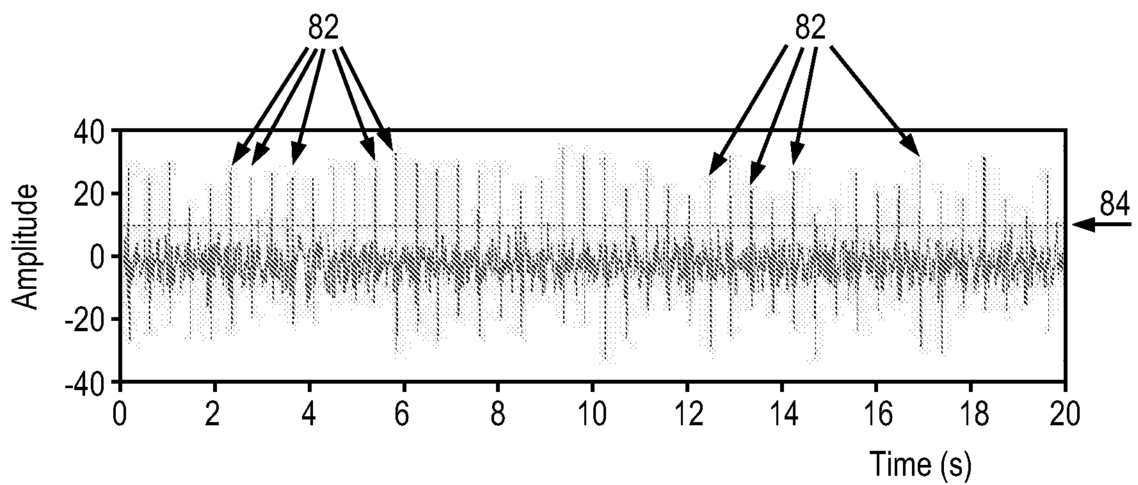

FIG. 16

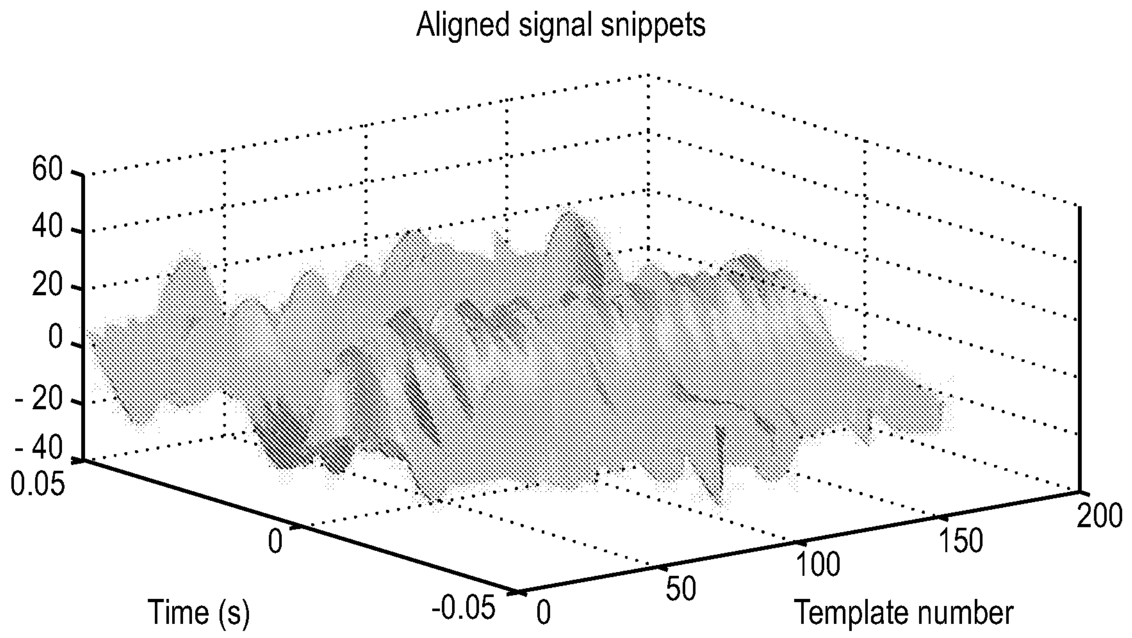

FIG. 17

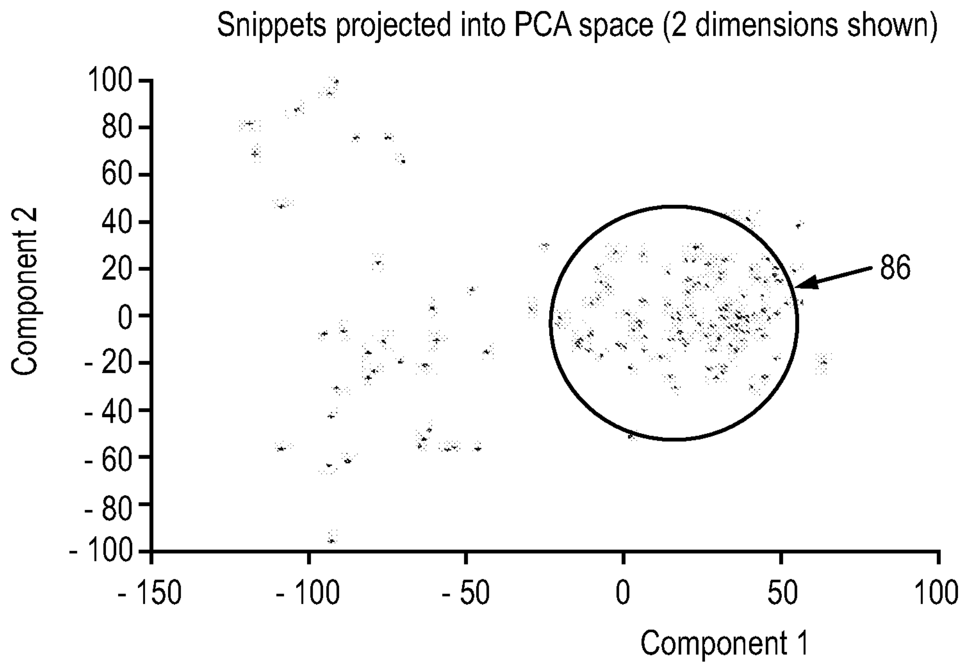

FIG. 18

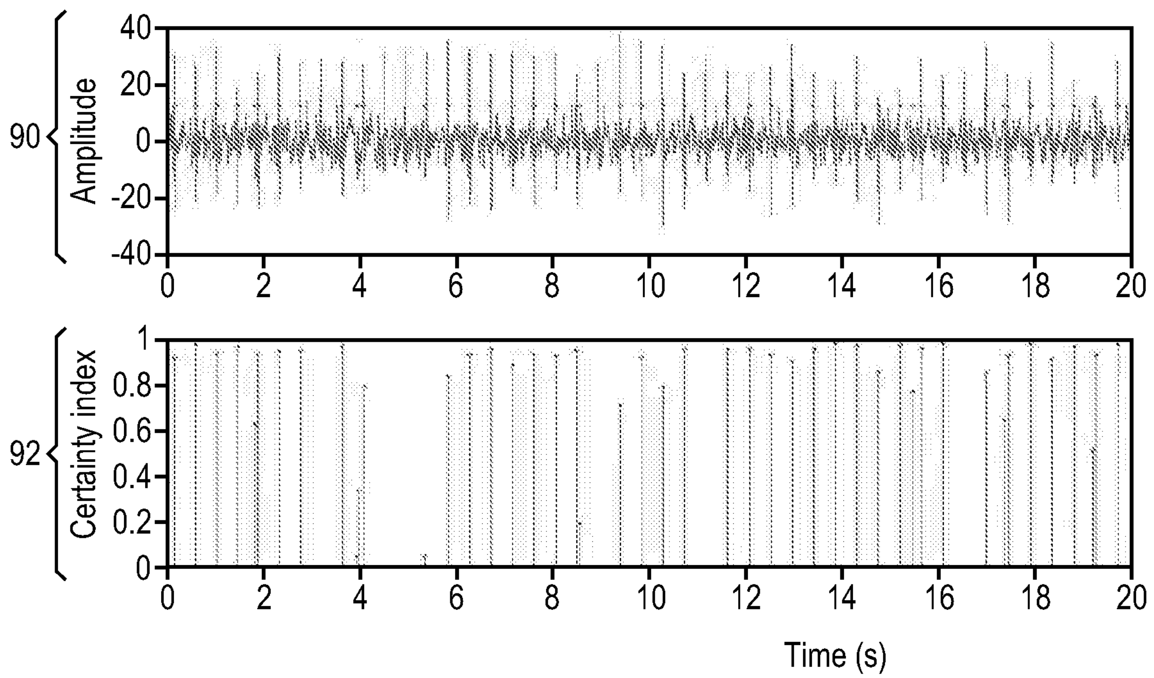

FIG. 19

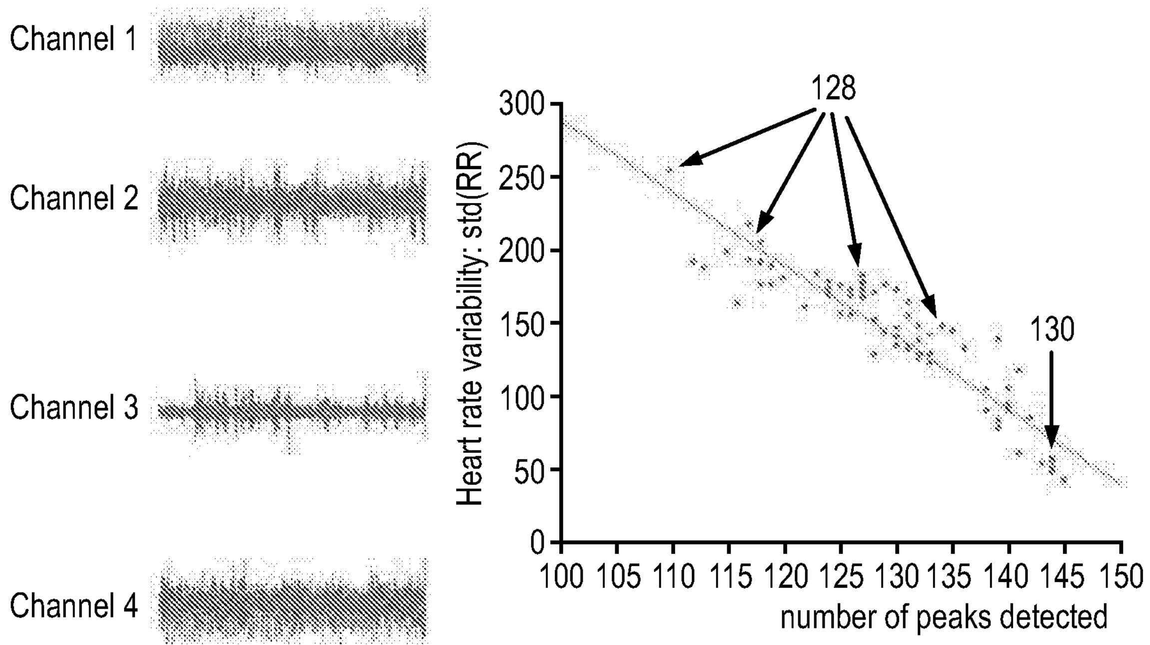

FIG. 20

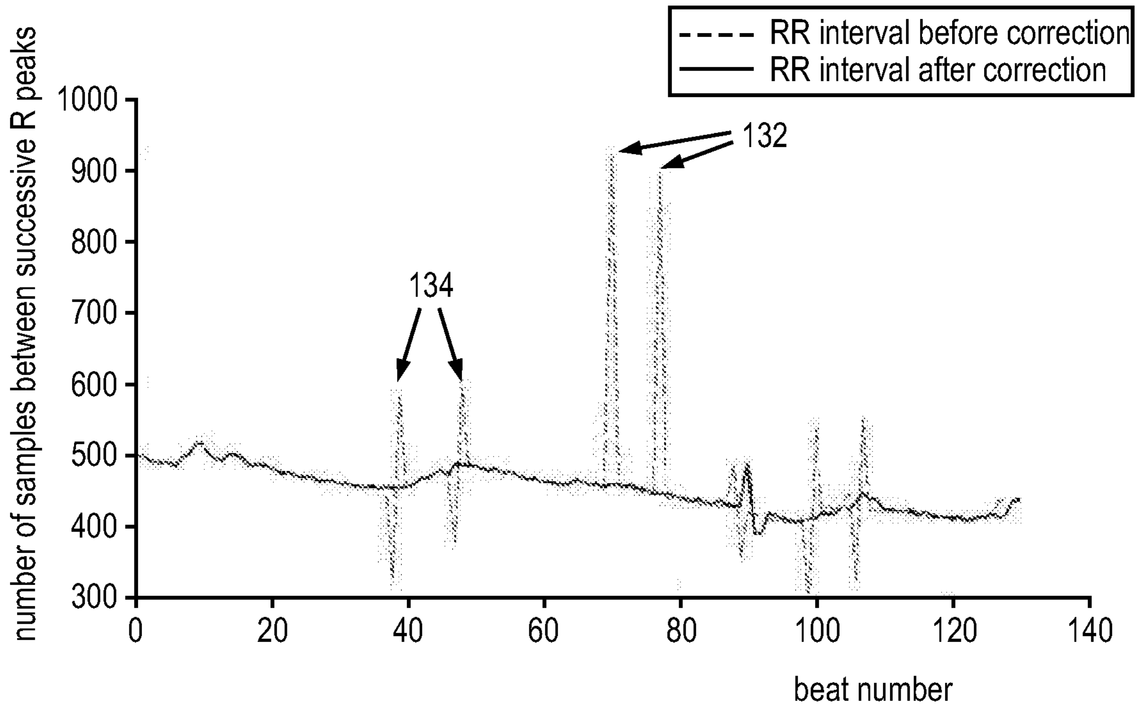

FIG. 21

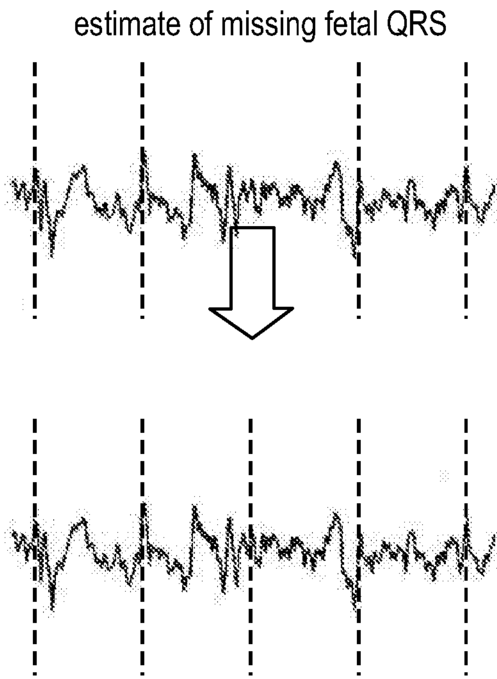

FIG. 22

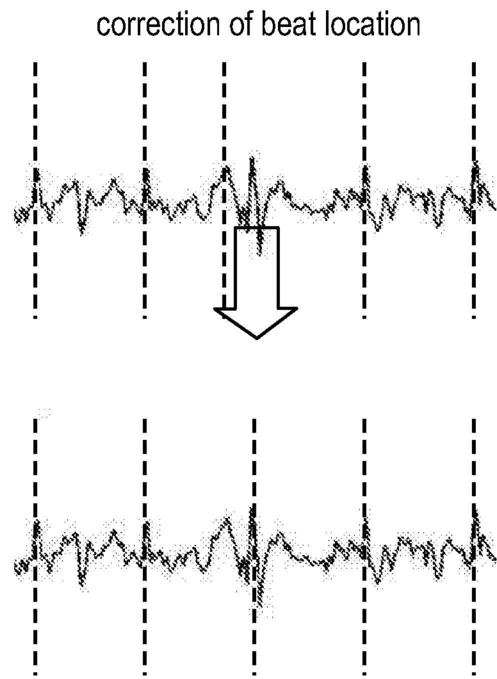

FIG. 23

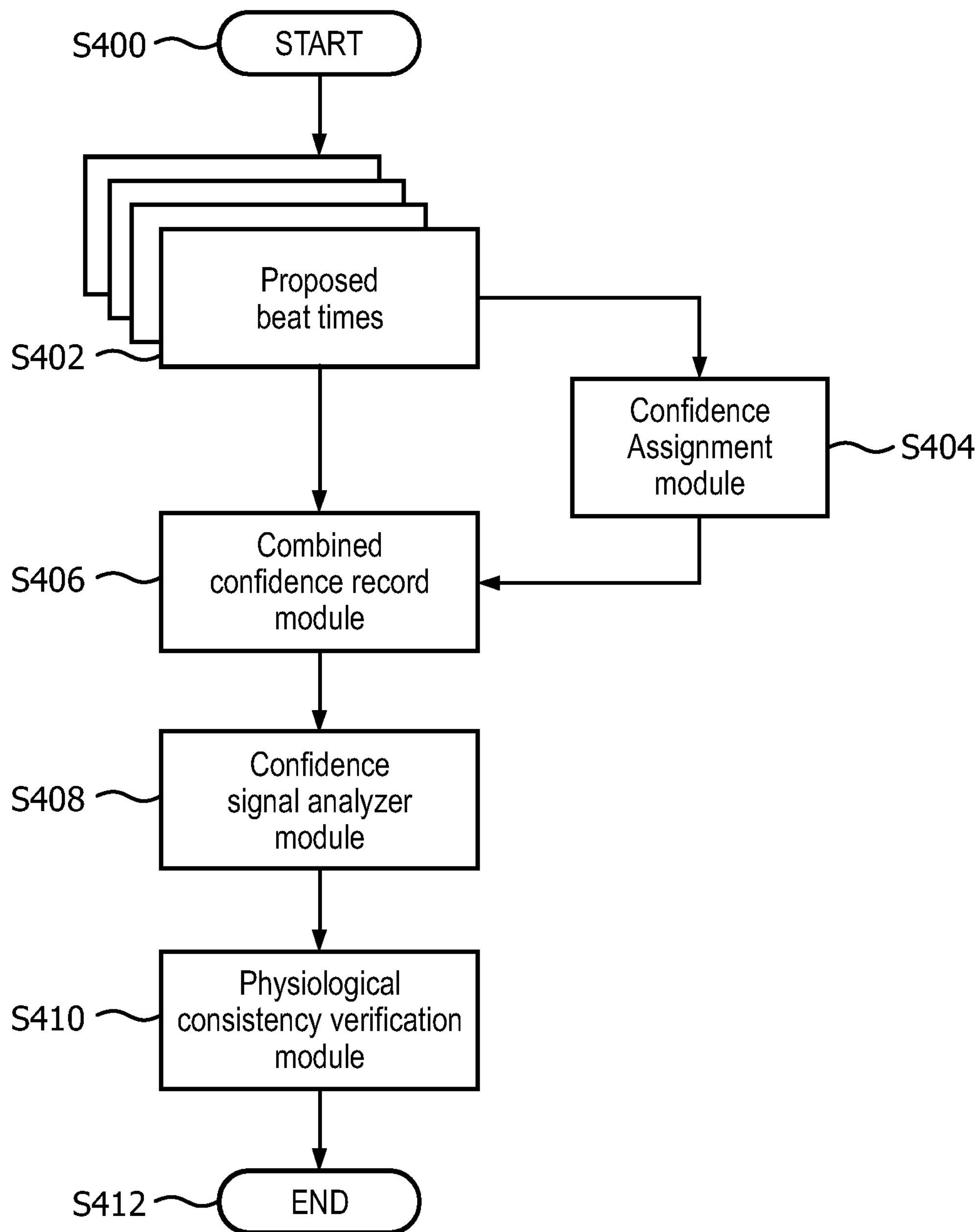

FIG. 24

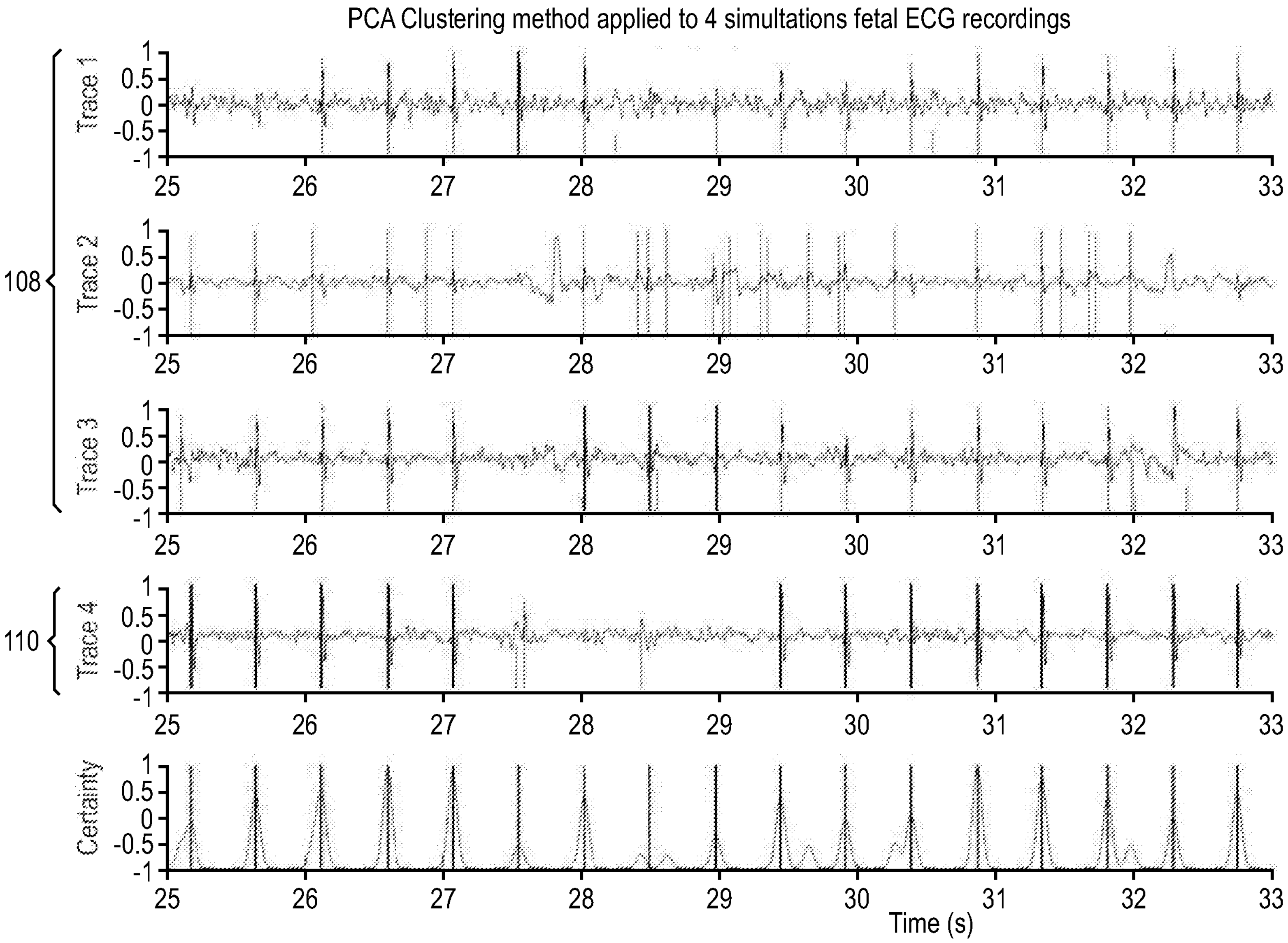

FIG. 25

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2014/063984

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/024 A61B5/0444 A61B5/00 A61B5/0255
ADD. A61B5/0402 A61B5/0468

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	ABBOUD S ET AL: "Real-time abdominal fetal ECG recording using a hardware correlator", COMPUTERS IN BIOLOGY AND MEDICINE, NEW YORK, NY, US, vol. 22, no. 5, 1 September 1992 (1992-09-01), pages 325-335, XP026186881, ISSN: 0010-4825, DOI: 10.1016/0010-4825(92)90021-E [retrieved on 1992-09-01] figures 1, 2, 4, 9, 10 page 326, lines 20-22, 25-26, 38, 40 page 327, line 11 page 328, line 5 page 329, lines 13, 16-19, 26-29, 32, 33, 37, 38, 40, 45, 46, 49 page 330, lines 1-6 page 331, lines 18-20 -/--	1-20

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 December 2014	22/12/2014

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Meyer, Wolfgang

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Chapters C. and D. -----	
A	WO 2011/003132 A1 (HEARD SYSTEMS PTY LTD [AU]; TAPSON JONATHAN CRAIG [ZA]; GARGIULO GAETA) 13 January 2011 (2011-01-13) page 5, line 2 page 8, lines 10, 11 page 9, line 19 page 11, lines 9, 13 page 12, lines 9, 20-22, 26, 28, 29 page 13, lines 3, 4-6 -----	1-3,5,6, 9-11,13, 14,19,20
A	KARVOUNIS E C ET AL: "A Method for Fetal Heart Rate Extraction Based on Time-Frequency Analysis", COMPUTER-BASED MEDICAL SYSTEMS, 2006. CBMS 2006. 19TH IEEE INTERNATION AL SYMPOSIUM ON SALT LAKE CITY, UT, USA 22-23 JUNE 2006, PISCATAWAY, NJ, USA,IEEE, PISCATAWAY, NJ, USA, 1 January 2006 (2006-01-01), page 347, XP031668663, ISBN: 978-0-7695-2517-4 abstract figure 4 -----	4,12
A	KOTAS M ET AL: "Towards noise immune detection of fetal QRS complexes", COMPUTER METHODS AND PROGRAMS IN BIOMEDICINE, ELSEVIER, AMSTERDAM, NL, vol. 97, no. 3, 1 March 2010 (2010-03-01), pages 241-256, XP026914967, ISSN: 0169-2607, DOI: 10.1016/J.CMPB.2009.09.005 [retrieved on 2009-10-09] chapter 4.3 equations (12) and (19) page 248, left-hand column, lines 5, 6 -----	7,15
A	XUEYAN XU ET AL: "Automatic detection of artifacts in heart period data", JOURNAL OF ELECTROCARDIOLOGY, vol. 34, no. 4, 1 October 2001 (2001-10-01), pages 205-210, XP055157903, ISSN: 0022-0736, DOI: 10.1054/jelc.2001.28876 the whole document page 206, left-hand column, lines 22-27 -----	8,16

-/--

1

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	VULLINGS R ET AL: "Dynamic segmentation and linear prediction for maternal ECG removal in antenatal abdominal recordings; Maternal ECG removal in abdominal recordings", PHYSIOLOGICAL MEASUREMENT, INSTITUTE OF PHYSICS PUBLISHING, BRISTOL, GB, vol. 30, no. 3, 1 March 2009 (2009-03-01), pages 291-307, XP020153663, ISSN: 0967-3334, DOI: 10.1088/0967-3334/30/3/005 chapter 3.1 -----	17
A	US 2005/267376 A1 (MAROSSERO DOROTHEE [US] ET AL) 1 December 2005 (2005-12-01) paragraphs [0105] - [0107], [0122], [0135] - [0146] -----	18
A	WO 03/028550 A2 (QINETIQ LTD [GB]; SMITH MARK JOHN [GB]; PENNEY RICHARD WILLIAM [GB]) 10 April 2003 (2003-04-10) the whole document -----	1-20
A	ABBOUD S ET AL: "Quantification of the fetal electrocardiogram using averaging technique", COMPUTERS IN BIOLOGY AND MEDICINE, NEW YORK, NY, US, vol. 20, no. 3, 1 January 1990 (1990-01-01), pages 147-155, XP026186788, ISSN: 0010-4825, DOI: 10.1016/0010-4825(90)90001-6 [retrieved on 1990-01-01] the whole document -----	1-20
A	RUBEN MARTI N-CLEMENTE ET AL: "Fast Technique for Noninvasive Fetal ECG Extraction", IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING, IEEE SERVICE CENTER, PISCATAWAY, NJ, USA, vol. 58, no. 2, 1 February 2011 (2011-02-01), pages 227-230, XP011372864, ISSN: 0018-9294, DOI: 10.1109/TBME.2010.2059703 the whole document -----	1-20
	-/--	

1

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CHRISTOPHER J JAMES ET AL: "TOPICAL REVIEW; Independent component analysis for biomedical signals; Review: Independent component analysis for biomedical signals", PHYSIOLOGICAL MEASUREMENT, INSTITUTE OF PHYSICS PUBLISHING, BRISTOL, GB, vol. 26, no. 1, 1 February 2005 (2005-02-01), pages R15-R39, XP020092142, ISSN: 0967-3334, DOI: 10.1088/0967-3334/26/1/R02 the whole document -----	1-20
A	MASOUMEH HAGHPANAHI ET AL: "Fetal ECG extraction from abdominal recordings using array signal processing", 2012 COMPUTING IN CARDIOLOGY, 1 January 2013 (2013-01-01), pages 173-176, XP055156829, ISSN: 2325-8861 ISBN: 978-1-46-732076-4 the whole document -----	1-20

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2014/063984

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
WO 2011003132	A1	13-01-2011	AU	2010269114	A1	02-02-2012
			EP	2451347	A1	16-05-2012
			NZ	597459	A	31-01-2014
			US	2012108989	A1	03-05-2012
			WO	2011003132	A1	13-01-2011
US 2005267376	A1	01-12-2005	EP	1776041	A2	25-04-2007
			US	2005267376	A1	01-12-2005
			US	2005267377	A1	01-12-2005
			WO	2005117692	A2	15-12-2005
WO 03028550	A2	10-04-2003	AT	330539	T	15-07-2006
			AU	2002329426	A1	14-04-2003
			DE	60212666	T2	24-05-2007
			EP	1432349	A2	30-06-2004
			EP	1700564	A2	13-09-2006
			EP	1941830	A2	09-07-2008
			ES	2262834	T3	01-12-2006
			JP	2005503883	A	10-02-2005
			MY	129068	A	30-03-2007
			TW	568770	B	01-01-2004
			US	2004243015	A1	02-12-2004
			US	2008183092	A1	31-07-2008
			WO	03028550	A2	10-04-2003

patsnap

专利名称(译)	从孕妇腹部心电图记录中提取胎儿心率		
公开(公告)号	EP3043699A1	公开(公告)日	2016-07-20
申请号	EP2014790305	申请日	2014-08-20
[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
申请(专利权)人(译)	皇家飞利浦N.V.		
当前申请(专利权)人(译)	皇家飞利浦N.V.		
[标]发明人	CHENG LIMEI CARLSON ERIC THOMAS VAIRAVAN SRINIVASAN XU MINNAN		
发明人	CHENG, LIMEI CARLSON, ERIC THOMAS VAIRAVAN, SRINIVASAN XU, MINNAN		
IPC分类号	A61B5/024 A61B5/0444 A61B5/00 A61B5/0255 A61B5/0402 A61B5/0468		
CPC分类号	A61B5/02405 A61B5/02411 A61B5/0255 A61B5/04028 A61B5/0444 A61B5/0468 A61B5/4362 A61B5/7203 A61B5/725 A61B5/7253 A61B5/04017 A61B5/0456 A61B5/0472		
优先权	61/875209 2013-09-09 US 61/918960 2013-12-20 US		
外部链接	Espacenet		

摘要(译)

系统（10），用于使用计算机处理器（26）从至少一个母体信号中提取胎儿心率。该系统包括连接到患者以接收腹部ECG信号的传感器（12-18）和记录器和数字转换器（20），以记录和数字化母体信号缓冲器（22A-22D）中的每个至少一个母体信号。该系统还包括峰值检测器（40），用于识别母体信号缓冲器中的候选峰值。系统的信号堆叠器（42）堆叠将至少一个母体信号缓冲器分成多个片段，每个片段包括一个候选峰值和空间滤波器（44）以识别和衰减多个片段中的母体QRS信号。在母体信号缓冲器中，空间滤波器包括主成分分析和正交投影中的至少一个，以产生存储在原始胎儿ECG缓冲器中的原始胎儿ECG信号。该系统还包括胎儿QRS标识符（46），用于通过主成分分析和峰值检测器中的至少一个来识别原始胎儿ECG缓冲液中的峰值，然后进行基于规则的fQRS提取和合并（48）以计算和合并胎儿心率来自已识别的峰值。