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(71) Applicant *(for all designated States except US)*: **GLAXO GROUP LIMITED** [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford Middlesex UB6 ONN (GB).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **WALKER, Dwight** [US/US]; c/o GlaxoSmithKline, Global Patents, Five Moore Drive, PO Box 13398, Reserch Triangle Park, NC 27709 (US).

(74) Agent: **STRICKLAND, J., Michael**; GlaxoSmithKline, Corporate Intellectual Property Department, Five Moore Drive, PO Box 13398, Research Triangle Park, NC 27709 (US).

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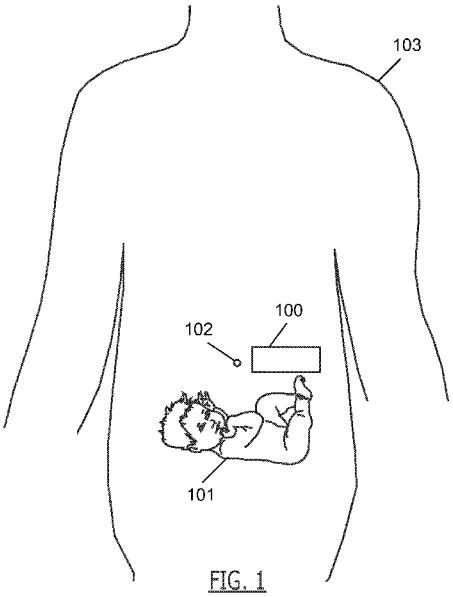

FIG. 1

(57) Abstract: Systems and methods of monitoring the fetal heart rate in a human subject are described. The subject's umbilicus defines a point on an umbilicus axis length perpendicular to the subject's body. The axis is oriented on an umbilicus plane perpendicular to the subject's length. The system includes at least one sensor mountable in an ellipse defined by the subject's length and width. The width is the umbilicus plane's longest chord. The sensor senses acoustic energy and generates a signal. A processing unit receives the signal to determine average fetal heart rate frequency.

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Heart Rate Monitor

Field of the Invention

10 The present invention relates to the field of monitoring fetal heart rate.

Background of the Invention

The monitoring and analysis of the heart rate has been a useful technique for
15 diagnosis of cardiac disease for several decades. There are two significant measurements of this signal: the waveform profile and the rate. Both can be useful in clinical diagnoses. During pregnancy, the well-being and condition of a fetus can be assessed by monitoring both properties of the fetal heart rate. For example, the fetal heart rate can often reveal important information for an arrhythmia diagnosis.

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Typically, during gestation, the only time a pregnant woman hears her baby's heart beat is during prenatal check-ups. However, women who have experienced miscarriages or complications in previous pregnancies are often more anxious in subsequent pregnancies. Thus, waiting between prenatal appointments for up-dates on
25 their baby's health can be a source of stress to the parents. This need is often compounded in instances where there are complications with a pregnancy. In such situations, parents may find themselves making frequent trips to the emergency room. Monitoring their baby's heart rate using a fetal heart rate monitor may also help reduce the number of hospital trips that parents have to make. Moreover, fetal heart rate
30 monitors place no stress on the baby so it is safe to use during pregnancy.

Current technology used to follow fetal heart rate is based on Doppler ultrasound. The Doppler device is placed on the maternal abdomen with a coupling gel to find the fetal heart rate. This is typically done by a doctor or ultrasound technician and requires

some degree of training and skill. These types of monitors can be purchased or rented for use as at-home fetal heart rate monitors. Both choices can be fairly expensive.

Summary of the Invention

In one aspect, embodiments of the present invention are directed to a system for monitoring the heart rate of a fetus in a female human subject having an umbilicus, the umbilicus defining a point on an umbilicus axis oriented perpendicular to the length of the subject's body, the umbilicus axis oriented on an umbilicus plane that is perpendicular to the length of the subject's body. The system includes at least one sensor mountable on the subject in an area defined by:

$$\text{Area} = \pi * (0.05 * l_{\text{subject}}) * (0.1 * w_{\text{subject}})$$

where l_{subject} is the length of the subject and w_{subject} is the width of the subject. The width of the subject is equal to the longest chord swept out by the umbilicus plane. The area defines an ellipse such that the major axis is perpendicular to the umbilicus axis and the lower focus of the area is oriented along the umbilicus axis. The sensor is adapted to sense acoustic energy and generate at least one acoustic energy signal representing the acoustic energy. A processing unit is adapted to receive the acoustic energy signal, with the processing unit being further adapted to process the acoustic energy signal and determine average fetal heart rate frequency as determined by:

$$f_{FHR}^{average}(T) = \frac{1}{T}\int_0^T \left(m * f_{R_2} + n * \{ f_{R_3} - f_{R_4}^{\text{maternalamplitudethreshold}} \} \right) dT$$

where R_1 is a frequency between 50 and 250 Hz and R_2, R_3 and R_4 are independently frequency ranges within which R_1 falls, T is T_p and is a time between 10 milliseconds and 28 days, $f_{FHR}^{average}(T)$ is the average fetal heart rate frequency, m is 0 or 1, n is 0 or 1, where m+n is at least 1, f_{R_2} is the current fetal heart rate within R_2, f_{R3}

is the current fetal heart rate within R_3 and $f_{R4}^{maternalamplitudethreshold}$ is the maternal amplitude threshold within R_4.

In a further aspect, embodiments the present invention is directed to a system for monitoring the heart rate of a fetus in a female human subject having an umbilicus , the umbilicus defining a point on an umbilicus axis oriented perpendicular to the length of the subject's body, the umbilicus axis oriented on an umbilicus plane that is perpendicular to the length of the subject's body. The system includes at least one sensor mountable on the subject in an area defined by:

$$\text{Area} = \pi * (0.05*l_{\text{subject}}) * (0.1*w_{\text{subject}})$$

where l_{subject} is the length of the subject and w_{subject} is the width of the subject. The width of the subject is equal to the longest chord swept out by the umbilicus plane. The area defines an ellipse such that the major axis is perpendicular to the umbilicus axis and the lower focus of said area is oriented along said umbilicus axis. The sensor is adapted to sense acoustic energy and generate at least one acoustic energy signal representing the acoustic energy. A processing unit is adapted to receive the acoustic energy signal, with the processing unit being further adapted to process the acoustic energy signal and determine an aspect average fetal heart rate waveform profile, the profile comprising a leading edge, a trailing edge and a translational edge as determined by:

$$slope_{FHR}^{average}(T) = \frac{1}{T}\int_0^T \left(m*slope_{R8} + n*\{slope_{R9} - slope_{R10}^{\text{maternalamplitudethreshold}}\} \right) dT$$

where R_1 is a frequency between 50 and 250 Hz and R_8, R_9 and R_{10} are independently frequency ranges within which R_1 falls, T is T_p and T_p is a time between 10 milliseconds and 28 days, $slope_{FHR}^{average}(T_p)$ is the slope of the leading edge of the average fetal heart rate waveform profile, m is 0 or 1, n is 0 or 1, where m+n is at least 1,

5 $slope_{R_8}$ is the current average fetal heart rate waveform profile R_8, $slope_{R_9}$ is the current average fetal heart rate waveform profile within R_9 and $slope_{R_{10}}^{maternalamplitudethreshold}$ is the maternal amplitude threshold average heart rate waveform profile within R_{10}.

In yet a further aspect, embodiments the present invention is directed to a system
10 for monitoring the heart rate of a fetus in a female human subject having an umbilicus , the umbilicus defining a point on an umbilicus axis oriented perpendicular to the length of the subject's body, the umbilicus axis oriented on an umbilicus plane that is perpendicular to the length of the subject's body. The system would includes at least one sensor mountable on said subject in an area defined by:

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$$\text{Area} = \pi * (0.05*l_{\text{subject}}) * (0.1*w_{\text{subject}})$$

where l_{subject} is the length of the subject and w_{subject} is the width of the subject. The width of the subject is equal to the longest chord swept out by the umbilicus plane. The
20 area defines an ellipse oriented such that the major axis is perpendicular to the umbilicus axis and wherein the lower focus of the area is oriented along said umbilicus axis. The sensor is adapted to sense acoustic energy and generate at least one acoustic energy signal representing the acoustic energy. A processing unit adapted to receive said acoustic energy signal, and the processing unit is further adapted to process the acoustic energy
25 signal and determine the average fetal heart rate frequency as determined by:

$$f_{FHR}^{average} = \frac{1}{T}\int_0^T \left(m*f_{R11} + n*\{f_{R12} - f_{R_{13}}^{\text{maternalamplitudethreshold}}\} \right) dT$$

where R_1 is a frequency between 50 and 250 Hz and R_{11}, R_{12} and R_{13} are
30 independently frequency ranges within which R_1 falls, wherein T is T_p and T_p is a time between 0.01 minutes and 28 days, $f_{FHR}^{average}$ is the average fetal heart rate frequency, m is 0 or 1, n is 0 or 1, wherein m+n is at least 1, $f_{R_{11}}$ is the current fetal heart rate within

R_{11}, f_{R12} is the current fetal heart rate within R_{12} and $f_{R13}^{maternalamplitudethreshold}$ is the maternal amplitude threshold within R_{13}. The processing unit is also adapted to receive the acoustic energy signal, and is further adapted to process the acoustic energy signal and determine the average fetal heart rate waveform profile as determined by:

$$slope_{FHR}^{average} = \frac{1}{T}\int_0^T \left(m * slope_{R14} + n * \{ slope_{R15} - slope_{R16}^{\text{maternalamplitudethreshold}} \} \right) dT$$

where R_1 is a frequency between 50 and 250 Hz and R_{14}, R_{15} and R_{16} are independently frequency ranges within which R_1 falls, wherein T is T_p and T_p is a time between 0.01 minutes and 28 days, $slope_{R14}$ is the current average fetal heart rate waveform within R_{14}, $slope_{R15}$ is the current average fetal heart rate waveform profile within R_{15} and $slope_{R16}^{maternalamplitudethreshold}$ is the maternal amplitude threshold average heart rate waveform profile within R_{16}.

Brief Description of the Figures

Figure 1 shows an embodiment according to the present invention for the placement of a sensor in relationship to the fetus and the umbilicus;

Figure 2 shows an embodiment according to the present invention of a plan view of the subject's umbilicus plane;

Figure 3 shows a signal flow for the fetal heart rate determination according to an embodiment of the invention;

Figure 4 shows another signal flow for the fetal heart rate determination according to an embodiment of the invention;

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Figure 5 shows another signal flow for the fetal heart rate determination according to an embodiment of the invention; and

Figure 6 shows a fetal heart rate waveform profile according to an embodiment
10 of the present invention.

Detailed Description of the Invention

As discussed in detail below, the fetal heart rate monitoring system of the
15 invention generally includes at least one sensor mounted on a subject, the sensor being adapted to sense acoustic energy and generates at least one acoustic energy signal. This acoustic energy signal is subsequently received by a processing unit adapted to process the acoustic energy signal and determine at least the average fetal heart rate frequency.

20 As will be appreciated by one having ordinary skill in the art, the processing unit of the invention can be readily employed in conjunction with a multitude of sensors and would be capable of determining a number of parameters. Potential applications thus include, for example, the following: fetal tachycardia; fetal bradycardia; saltatory variability; variable decelerations associated with a nonreassuring pattern; and late
25 decelerations with preserved beat-to-beat variability.

Repeat use of reference characters herein and in the figures is intended to represent same or analogous features or elements of the invention.

30 It is to be understood that this invention is not limited to particularly exemplified materials, methods or structures as such may, of course, vary. Thus, a number of materials and methods similar or equivalent to those described herein can be used in the practice of the present invention.

5 It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments of the invention only and is not intended to be limiting.

Unless defined otherwise, all technical and scientific terms used herein have the 10 same meaning as commonly understood by one having ordinary skill in the art to which the invention pertains. Further, all publications, patents and patent applications cited herein, whether supra or infra, are hereby incorporated by reference in their entirety.

As used in this specification and the appended claims, the singular forms "a", 15 "an" and "the" include plural referents unless the content clearly dictates otherwise.

Implementation of the methods and systems of embodiments of the present invention, as described herein, can involve performing or completing selected tasks or steps manually, automatically, or a combination thereof. In some embodiments of the 20 present invention, several selected steps could be implemented by hardware or by software on any operating system or any firmware or a combination thereof. For example, as hardware, selected steps of embodiments of the invention could be implemented as a chip or a circuit. As software, selected steps of embodiments of the invention could be implemented as a plurality of software instructions being executed by 25 a computer using any suitable operating system. In any case, selected steps of the method and system of the invention could be described as being performed by a data processor, such as a computing platform for executing a plurality of instructions.

Reference will now be made in detail to embodiments of the invention, one or 30 more examples of which are illustrated in the accompanying figures.

Figure 1 shows and illustrates a sensor (100) for monitoring the fetal heart rate of a fetus (101). The sensor (100) is located proximate to the umbilicus (102) on a subject's body (103).

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Figure 2 illustrates a human subject (203). The umbilicus (202) defines a point on an umbilicus axis oriented perpendicular to the length direction of the subject's body (205). The umbilicus axis is oriented on an umbilicus plane (204) that is perpendicular to the length of the subject's body.

The fetal heart rate system comprises at least one sensor mountable on the subject in an area defined by:

$$\text{Area} = \pi * (0.05*l_{\text{subject}}) * (0.1*w_{\text{subject}})$$

where l_{subject} is the length (i.e., height) of the subject and w_{subject} is the width of the subject. The width of the subject is equal to the longest chord (206) swept out by the umbilicus plane. The resulting area defines an ellipse (207) such that the major axis is perpendicular to the umbilicus axis. The lower focus (209) of the area is oriented along the umbilicus axis and the upper focus (208) lies along the direction of the subject's body (205).

The sensor (100) is adapted to sense acoustic energy and generate at least one acoustic energy signal representing the acoustic energy as depicted in Figure 3. A processing unit (309) is adapted to receive the acoustic energy signal (308) with the processing unit (309) being further adapted to process the acoustic energy signal (308). The processing unit (309) is capable of determining a number of fetal heart rate parameters (301-305, 309). In one embodiment, the processing unit (309) would determine average fetal heart rate frequency as determined by:

$$f_{FHR}^{average}(T) = \frac{1}{T}\int_0^T \left(m*f_{R_2} + n*\{f_{R_3} - f_{R_4}^{\text{maternalamplitudethreshold}}\} \right) dT$$

where $f_{FHR}^{average}(T)$ is the average fetal heart rate frequency, m is 0 or 1, n is 0 or 1, m+n is at least 1, f_{R_2} is the current fetal heart rate within R_2, f_{R_3} is the current fetal

heart rate within R_3 and $f_{R4}^{maternalamplitudethreshold}$ is the maternal amplitude threshold within R_4

In some embodiments, R_1 is a frequency between 50 and 250 Hz and R_2, R_3 and R_4 are independently frequency ranges within which R_1 falls. In other embodiments, R_1 is a frequency between 80 and 230 Hz and R_2, R_3 and R_4 are independently frequency ranges within which R_1 falls. In further embodiments, R_1 is a frequency between 90 and 200 Hz and R_2, R_3 and R_4 are independently frequency ranges within which R_1 falls.

In some embodiments, T is T_p and is a time between 10 milliseconds and 28 days. In other embodiments, T is T_p and is a time between 12 hours and 14 days. In further embodiments, T is T_p and is a time between 5 minutes and 24 hours.

One of skill in the art will appreciate that various sensors can be employed within the scope of the present invention, such as the one disclosed in U.S. Patent No. 6,512,830.

In one embodiment, the fetal heart rate system uses at least one sensor mountable laterally in the same transverse plane as the umbilicus.

In one embodiment, at least one sensor is mountable laterally the transverse plane opposite the umbilicus.

In one embodiment, the sensor generates a plurality of acoustic energy signals representing the acoustic energy. The plurality can be 2, 3, 4, 5, 6 or more acoustic energy signals representing multiple fetal heart rates.

In one embodiment, the processing unit is further adapted to determine a number of additional fetal heart rate parameters such as an average fetal heart rate (303) determined by:

$$f_{\mathrm{BPM}}^{\mathrm{average}} = f_{FHR}^{average}(T) * 60 .$$

In some embodiments of average fetal heart rate, T is a time between 10 milliseconds and 28 days. In other embodiments of average fetal heart rate, T is a time between 12 hours and 14 days. In a further embodiment of average fetal heart rate, T is a time between 5 minutes and 24 hours.

In one embodiment, the processing unit is further adapted to determine a number of additional fetal heart rate parameters such as a prolonged rapid heart rate (305) by:

$$\left(\frac{1}{T_1} \int_0^{T_1} \left(f_{FHR}^{average}(T_p) - f_{FHR}^{average}(T_1) \right)^2 dT_1 \right)^{1/2}$$

where $f_{FHR}^{average}(T_1)$ is calculated using:

$$f_{FHR}^{average}(T_1) = \frac{1}{T_1} \int_0^{T_1} \left(m * f_{R_2} + n * \{ f_{R_3} - f_{R_4}^{\mathrm{maternalamplitudethreshold}} \} \right) dT_1 .$$

In some embodiments, T_1 is a time between 10 milliseconds and 28 days. In other embodiments, T_1 is a time between 12 hours and 14 days. In a further embodiment, T_1 is a time between 5 minutes and 24 hours.

In one embodiment, the processing unit is further adapted to determine a number of additional fetal heart rate parameters such as a prolonged slow heart rate (304) by:

$$\left(\frac{1}{T_2} \int_0^{T_2} \left(f_{FHR}^{average}(T_p) - f_{FHR}^{average}(T_2) \right)^2 dT_2 \right)^{1/2}$$

where $f_{FHR}^{average}(T_2)$ is calculated using:

$$f_{FHR}^{average}(T_2) = \frac{1}{T_2} \int_0^{T_2} \left(m * f_{R_2} + n * \{ f_{R_3} - f_{R_4}^{\mathrm{maternalamplitudethreshold}} \} \right) dT_2 .$$

In some embodiments, T_2 is a time between 10 milliseconds and 28 days. In other embodiments, T_2 is a time between 12 hours and 14 days. In a further embodiment, T_2 is a time between 5 minutes and 24 hours.

In one embodiment, the processing unit is further adapted to determine a number of additional fetal heart rate parameters such as a long-term variability (302) by:

$$\text{Long term variability} = \sum_{0}^{T_3}\left(f_{FHR}^{average}(T_p) - f_{FHR}^{average}(T_3)\right)$$

where $f_{FHR}^{average}(T_3)$ is calculated using:

$$f_{FHR}^{average}(T_3) = \frac{1}{T_3}\int_0^{T_3}\left(m * f_{R_2} + n * \{f_{R_3} - f_{R_4}^{\text{maternalamplitudethreshold}}\}\right)dT_3 .$$

In some embodiments, T_3 is a time between 10 milliseconds and 48 days. In other embodiments, T_3 is a time between 1 second and 60 minutes. In a further embodiment, T_3 is a time between 1 second and 10 minutes. In a further embodiment, T_3 is a time between 1 second and 3 minutes.

In one embodiment, the processing unit is further adapted to determine a number of additional fetal heart rate parameters such as an accelerated heart rate (301) is determined by:

$$\left(\frac{1}{900}\int_0^{900}\left(f_{FHR}^{average}(T_p) - f_{FHR}^{average}(T_4)\right)^2 dT_4\right)^{1/2}$$

where $f_{FHR}^{average}(T_4)$ is calculated using:

$$f_{FHR}^{average}(T_4) = \frac{1}{T_4}\int_0^{T_4}\left(m * f_{R_2} + n * \{f_{R_3} - f_{R_4}^{\text{maternalamplitudethreshold}}\}\right)dT_4 .$$

In some embodiments, T_4 is a time between 10 milliseconds and 60 minutes. In other embodiments, T_4 is a time between 1 second and 30 minutes. In a further embodiment, T_4 is a time between 1 second and 3 minutes.

In other embodiments, the processing unit is further adapted to display a variable and sound an alarm. As will be appreciated by one having ordinary skill in the art, the display and alarm can also be an integral component or feature of the processing unit.

Figure 3 illustrates a processing unit (309) that is configured to activate an alarm (306) or display (307) a message if a condition requires an alert, for example. As illustrated in Figure 3, these alert conditions include accelerated heart rate (301), long term variability of heart rate (302), fetal heart rate average (303), prolonged slow heart rate (304) and prolonged rapid heart rate (305); however, one of ordinary skill in the art will appreciate that the alert conditions can include one or more of the foregoing.

In one embodiment, the processing unit is adapted to receive and process a plurality of acoustic energy signals and determine at least one average fetal heart rate frequency therefrom. In another embodiment, the processing unit is adapted to receive and process the plurality of acoustic energy signals and determine two average fetal heart rate frequencies as determined by:

$$f_{FHR}^{average}(T_{p1}) = \frac{1}{T_{p1}} \int_0^{T_{p1}} \left(m * f_{R_2} + n * \{ f_{R_3} - f_{R_4}^{\text{maternalamplitudethreshold}} \} \right) dT_{p1}$$

and

$$f_{FHR}^{average2}(T_{p2}) = \frac{1}{T_{p2}} \int_0^{T_{p2}} \left(m * f_{R5}^{2} + n * \{ f_{R_6}^{2} - f_{\mathrm{R}_7}^{\text{maternalamplitudethreshold}} \} \right) dT_{p2} \ .$$

where $f_{FHR}^{average}(T_{p1})$ is the first average fetal heart rate frequency, $f_{FHR}^{average2}(T_{p2})$ is the second average fetal heart rate frequency, m is 0 or 1, n is 0 or 1, m+n is at least 1, f_{R_2} is the first current fetal heart rate and is within R_2, $f_{R_5}^{2}$ is the second current fetal

heart rate and is within R_5, f_{R_3} is the first current fetal heart rate and is within R_3, $f^2_{R_6}$ is the second current fetal heart rate and is within R_6, $f^{\text{maternalamplitudethreshold}}_{R4}$ is the maternal amplitude threshold frequency and is within R_4 and $f^{\text{maternalamplitudethreshold}}_{R7}$ is the maternal amplitude threshold frequency within R_7.

In some embodiments, R_1 is a frequency between 50 and 250 Hz and R_2, R_3, R_4, R_5, R_6 and R_7 are independently frequency ranges within which R_1 falls. In some embodiments, T_{p1} and T_{p2} are independently times between 10 milliseconds and 28 days. In other embodiments, T_{p1} and T_{p2} and are independently times between 12 hours and 14 days. In a further embodiment, T_{p1} and T_{p2} and are independently times between 5 minutes and 24 hours.

It is to be understood by one having ordinary skill in the art that the processing unit could be adapted to receive and process the plurality of acoustic energy signals and determine 3, 4, 5, 6 or more average fetal heart rate frequencies.

In one embodiment, a system for monitoring the fetal heart rate of a human subject can be adapted to receive the acoustic energy signal, the processing unit being further adapted to process the acoustic energy signal and determine an aspect average fetal heart rate waveform profile. The profile includes a leading edge (601), a trailing edge (603) and a translational edge (602) as determined by:

$$slope^{average}_{FHR}(T) = \frac{1}{T}\int_0^T \left(m*slope_{R8} + n*\{slope_{R9} - slope^{\text{maternalamplitudethreshold}}_{R10}\} \right) dT$$

where $slope^{average}_{FHR}(T)$ is the slope of the leading edge of the average fetal heart rate waveform profile, m is 0 or 1, n is 0 or 1, m+n is at least 1, $slope_{R8}$ is the current average fetal heart rate waveform profile R_8, $slope_{R9}$ is the current average fetal heart

rate waveform profile within R_9 and $slope_{R_{10}}^{maternalamplitudethreshold}$ is the maternal amplitude threshold average heart rate waveform profile within R_{10}.

In some embodiments, R_1 is a frequency between 50 and 250 Hz and R_8, R_9 and R_{10} are independently frequency ranges within which R_1 falls. In some embodiments, T is T_p and T_p is a time between 10 milliseconds and 28 days.

Figure 4 illustrates a processing unit (411) adapted to receive the acoustic energy signal (410) with the processing unit (411) being further adapted to process the acoustic energy signal (410). The processing unit (411) is capable of determining a number of fetal heart rate parameters (401 and 402).One skilled in the art would also recognize that processing unit (411) could be configured to activate an alarm (408) or display (409) a message if a condition required an alert.

In one embodiment, the processing unit (411) can further be adapted to determine a fetal heart rate waveform deviation (401) by:

:

$$\left(\frac{1}{T_5}\int_0^{T_5}\left(slope_{FHR}^{average}(T_p)-slope_{FHR}^{average}(T_5)\right)^2 dT_5\right)^{1/2}$$

In one embodiment, $slope_{FHR}^{average}(T_5)$ is calculated by:

$$f_{FHR}^{average}(T_5)=\frac{1}{T_5}\int_0^{T_5}\left(m*f_{R_2}+n*\{f_{R_3}-f_{R_4}^{\text{maternalamplitudethreshold}}\}\right)dT_5 .$$

In a further embodiment, T_5 is a time between 10 milliseconds and 60 minutes. In other embodiments, T_5 is a time between 1 second and 10 minutes. . In yet other embodiments, T_5 is a time between 1 second and 3 minutes. In yet other embodiments, T_5 is a time between 1 second and 1 minute.

In one embodiment, the processing unit (411) can be adapted to receive and process a plurality of acoustic energy signals and determine two fetal heart rate shape profiles (402) as determined from equations by:

$$slope_{FHR}^{average}(T_{p1}) = \frac{1}{T_{p1}} \int_{0}^{T_{p1}} \left(m*slope_{R8} + n*\{slope_{R9} - slope_{R10}^{maternalamplitudethreshold}\} \right) dT_{p1}$$

and

$$slope_{FHR}^{average2}(T_{p2}) = \frac{1}{T_{p2}} \int_{0}^{T_{p2}} \left(m*slope^{2}{}_{R8} + n*\{slope^{2}{}_{R9} - slope_{R10}^{maternalamplitudethreshold}\} \right) dT_{p2}$$

.

where $slope_{FHR}^{average}(T_{p1})$ is the first average fetal heart rate waveform profile, $slope_{FHR}^{average2}(T_{p2})$ is the second average fetal heart rate waveform profile, m is 0 or 1, n is 0 or 1, m+n is at least 1, $slope_{R_2}$ is the first current fetal heart rate waveform profile and is within R_2, $slope_{R_5}^{2}$ is the second current fetal heart rate waveform profile and is within R_5, $slope_{R_3}$ is the first current fetal heart rate waveform profile and is within R_3, $slope_{R_6}^{2}$ is the second current fetal heart rate waveform profile and is within R_6, $slope_{R4}^{maternalamplitudethreshold}$ is the maternal amplitude threshold frequency and is within R_4 and $slope_{R7}^{maternalamplitudethreshold}$ is the maternal amplitude threshold frequency within R_7.

In one embodiment, R_1 is a frequency between 50 and 250 Hz and R_2, R_3, R_4, R_5, R_6 and R_7 are independently frequency ranges within which R_1 falls.

In some embodiments, T_{p1} and T_{p2} are independently times between 10 milliseconds and 28 days. In other embodiments, T_{p1} and T_{p2} and are independently times between 12 hours and 14 days. In further embodiments, T_{p1} and T_{p2} are independently times between 5 minutes and 24 hours.

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Figure 5 illustrates a processing unit (511) adapted to receive the acoustic energy signal (510) with the processing unit (511) being further adapted to process the acoustic energy signal (510). The processing unit (511) is capable of determining a number of fetal heart rate parameters (501-507).One skilled in the art would also recognize that
10 processing unit (511) could be configured to activate an alarm (508) or display (509) a message if a condition required an alert.

A person or ordinary skill in the art would understand that these conditions could include accelerated heart rate profile (501), long term variability of heart rate profile
15 (502), fetal heart rate average profile (503), fetal heart rate shape profile (504), fetal heart rate profile deviation (505), prolonged slow heart rate profile (506) and prolonged rapid heart rate profile (507), each of which can be determined using methodology similar to that described above with respect to Figures 3 and 4. Such conditions have been discussed in "Fetal heart rate patterns: monitoring, interpretation, and management",
20 American College of Obstetricians and Gynecologists technical bulletin no. 207. Washington, D.C.: ACOG, 1995. One of ordinary skill in the art will appreciate that the alert conditions can include one or more of the foregoing.

As will be appreciated by one having ordinary skill in the art, the displays and
25 alarms of the aforementioned embodiments can also be an integral component or feature of the processing units, separate or remotely located components of the processing units, or any combination thereof.

In one embodiment, a system for monitoring the fetal heart rate of a human
30 subject includes at least one sensor (100) mountable on the subject (103) in an area defined by:

$$\text{Area} = \pi * (0.05*l_{\text{subject}}) * (0.1*w_{\text{subject}}); \text{ and}$$

In another embodiment, a system for monitoring the heart rate of a fetus in a female human subject includes a processing unit (309) adapted to receive the acoustic energy signal (308). In a further embodiment, the processing unit (309) is further adapted to process the acoustic energy signal (308) and determine the average fetal heart rate frequency as determined by:

$$f_{FHR}^{average} = \frac{1}{T}\int_0^T \left(m * f_{R11} + n * \{ f_{R12} - f_{R13}^{\text{maternalamplitudethreshold}} \} \right) dT .$$

where $f_{FHR}^{average}$ is the average fetal heart rate frequency, m is 0 or 1, n is 0 or 1, m+n is at least 1, $f_{R_{11}}$ is the current fetal heart rate within R_{11}, f_{R12} is the current fetal heart rate within R_{12} and $f_{R13}^{maternalamplitudethreshold}$ is the maternal amplitude threshold within R_{13}.

In one embodiment, R_1 is a frequency between 50 and 250 Hz and R_{11}, R_{12} and R_{13} are independently frequency ranges within which R_1 falls.

In a further embodiment, T is T_p and T_p is a time between 0.01 minutes and 28 days.

In one embodiment, a system for monitoring the heart rate of a fetus in a female human subject also includes a processing unit (309) adapted to receive the acoustic energy signal (308), the processing unit (309) being further adapted to process the acoustic energy signal (308) and determine the average fetal heart rate waveform profile as determined by:

$$slope_{FHR}^{average} = \frac{1}{T}\int_0^T \left(m * slope_{R14} + n * \{ slope_{R15} - slope_{R16}^{\text{maternalamplitudethreshold}} \} \right) dT$$

where $slope_{FHR}^{average}(T)$ is the slope of the leading edge of the average fetal heart rate waveform profile, m is 0 or 1, n is 0 or 1, m+n is at least 1, $slope_{R_{14}}$ is the current average fetal heart rate waveform within R_{14}, $slope_{R_{15}}$ is the current average fetal heart rate waveform profile within R_{15} and $slope_{R_{16}}^{maternalamplitudethreshold}$ is the maternal amplitude threshold average heart rate waveform profile within R_{16}.

In one embodiment, R_1 is a frequency between 50 and 250 Hz and R_{14}, R_{15} and R_{16} are independently frequency ranges within which R_1 falls. In one embodiment, the frequency of interest is where R_{11} is equal to R_{14}. In another embodiment, the frequency of interest is where R_{12} is equal to R_{15}. In another embodiment, the frequency of interest is where R_{13} is equal to R_{16}. In a further embodiment, the frequency of interest is where R_{11} is equal to R_{14}, R_{12} is equal to R_{15}, R_{13} is equal to R_{16}.

In yet a further embodiment, T is T_p and T_p is a time between 0.01 minutes and 28 days.

Method and system embodiments of the present invention can thus be effectively employed in numerous applications. The applications include, without limitation, the ability to monitor fetal heart rate during pregnancy, labor and/or birth; to monitor fetal heart rate waveform profile during pregnancy, labor and/or birth; to monitor fetal heart rate and fetal heart rate waveform profile during pregnancy, labor and/or birth; to monitor fetal heart rate and fetal heart rate waveform profile during pregnancy, labor and/or birth and to detect fetal distress; to monitor fetal heart rate and fetal heart rate waveform profile during pregnancy, labor and/or birth and to detect fetal distress and provide an electrical output; to monitor fetal heart rate and fetal heart rate waveform profile during pregnancy, labor and/or birth and to detect fetal distress and provide an electrical output consisting of an acoustic, visual, mechanical, electrical indicator and combinations thereof; transporting the system to monitor fetal heart rate and fetal heart rate waveform profile during pregnancy, labor and/or birth a distance of at least 5 miles from location A

5 to location B; transporting the system to monitor fetal heart rate and fetal heart rate waveform profile during pregnancy, labor and/or birth a distance of at least 5 miles from location A to location B by driving across land, sailing across water and/or flying through air; transporting the system to monitor fetal heart rate and fetal heart rate waveform profile during pregnancy, labor and/or birth a distance of at least 5 miles from location A
10 to location B where A and B are in different countries.

Although specific embodiments of the present invention are herein illustrated and described in detail, the invention is not limited thereto. The above detailed descriptions are provided as exemplary of the present invention and should not be construed as
15 constituting any limitation of the invention. Modifications will be obvious to those skilled in the art, and all modifications that do not depart from the spirit of the invention are intended to be included with the scope of the appended claims.

20

5 What is claimed is:

1. A system for monitoring the heart rate of a fetus in a female human subject having an umbilicus , the umbilicus defining a point on an umbilicus axis oriented
10 perpendicular to the length of the subject's body, the umbilicus axis oriented on an umbilicus plane that is perpendicular to the length of the subject's body, comprising:

at least one sensor mountable on said subject in an area defined by equation (1);

15 $$\text{Area} = \pi * (0.05 * l_{\text{subject}}) * (0.1 * w_{\text{subject}}) \qquad (1)$$

wherein l_{subject} is the length of the subject and w_{subject} is the width of the subject, wherein the width of the subject is equal to the longest chord swept out by the umbilicus plane, said area defining an ellipse such that the major axis is perpendicular
20 to the umbilicus axis and wherein the lower focus of said area is oriented along said umbilicus axis; and

said sensor being adapted to sense acoustic energy and generate at least one acoustic energy signal representing said acoustic energy; and

a processing unit adapted to receive said acoustic energy signal, said processing
25 unit being further adapted to process said acoustic energy signal and determine average fetal heart rate frequency as determined by equation (2);

$$f_{FHR}^{average}(T) = \frac{1}{T}\int_0^T \left(m * f_{R_2} + n * \{ f_{R_3} - f_{R_4}^{\text{maternalamplitudethreshold}} \} \right) dT \qquad (2)$$

30 wherein R_1 is a frequency between 50 and 250 Hz and R_2, R_3 and R_4 are independently frequency ranges within which R_1 falls, wherein T is T_p and is a time between 10 milliseconds and 28 days, $f_{FHR}^{average}(T)$ is the average fetal heart rate frequency, m is 0 or 1, n is 0 or 1, wherein m+n is at least 1, f_{R_2} is the current fetal

heart rate within R_2, f_{R3} is the current fetal heart rate within R_3 and $f_{R4}^{maternalamplitudethreshold}$ is the maternal amplitude threshold within R_4.

2. The system of Claim 1, wherein said processing unit is further adapted to determine an average fetal heart rate by equation (3);

$$f_{\mathrm{BPM}}^{\mathrm{average}} = f_{FHR}^{average}(T) * 60 \qquad (3).$$

3. The system of Claim 1, wherein said processing unit is further adapted to determine a prolonged rapid heart rate by equation (4);

$$\left(\frac{1}{T_1} \int_0^{T_1} \left(f_{FHR}^{average}(T_p) - f_{FHR}^{average}(T_1) \right)^2 dT_1 \right)^{1/2} \qquad (4)$$

wherein $f_{FHR}^{average}(T_1)$ is calculated using equation (2) wherein T is T_1, and T_1 is a time between 10 milliseconds and 28 days.

4. The system of Claim 1, wherein said processing unit is further adapted to determine a prolonged slow heart rate by equation (5);

$$\left(\frac{1}{T_2} \int_0^{T_2} \left(f_{FHR}^{average}(T_p) - f_{FHR}^{average}(T_2) \right)^2 dT_2 \right)^{1/2} \qquad (5)$$

wherein $f_{FHR}^{average}(T_2)$ is calculated using equation (2) wherein T is T_2, and T_2 is a time between 10 milliseconds and 28 days.

5. The system of Claim 1, wherein said processing unit is further adapted to determine a long term variability by equation (6);

$$\text{Long term variability} = \sum_{0}^{T_3}\left(f_{FHR}^{average}(T_p) - f_{FHR}^{average}(T_3)\right) \quad (6)$$

wherein $f_{FHR}^{average}(T_3)$ is calculated using equation (2) wherein T is T_3 and T_3 is a time between 10 milliseconds and 48 days.

6. The system of Claim 1, wherein acceleration is determined by equation (7);

$$\left(\frac{1}{900}\int_{0}^{900}\left(f_{FHR}^{average}(T_p) - f_{FHR}^{average}(T_4)\right)^2 dT_4\right)^{1/2} \quad (7)$$

wherein $f_{FHR}^{average}(T_4)$ is calculated using equation (2) wherein T is T_4 and T_4 is a time between 10 milliseconds and 60 minutes.

7. The system of Claim 3, wherein T_1 is between 12 hours and 14 days.

8. The system of Claims 3, wherein T_1 is between 5 minutes and 24 hours.

9. The system of Claims 4, wherein T_2 12 hours and 28 days.

10. The system of Claims 4, wherein T_2 is between 5 minutes and 24 hours.

11. The system of Claim 5, wherein T_3 is between 1 second and 60 minutes.

12. The system of Claim 5, wherein T_3 is between 1 second and 10 minutes.

13. The system of Claim 5, wherein T_3 is between 1 second and 3 minutes.

14. The system of Claim 6, wherein T_4 is between 1 second and 30 minutes.

15. The system of Claim 5, wherein T_4 is between 1 second and 3 minutes.

16. The system of Claim 1, wherein said at least one sensor is mountable laterally in the same transverse plane as the umbilicus.

17. The system of Claim 1, wherein said at least one sensor is mountable laterally in the same transverse plane opposite the umbilicus.

18. The system of Claim 1, wherein said sensor generates a plurality of acoustic energy signals representing said acoustic energy.

19. The system of Claim 18, wherein said processing unit is adapted to receive and process said plurality of acoustic energy signals and determine at least one average fetal heart rate frequency rate therefrom.

20. The system of Claim 18, wherein said processing unit is adapted to receive and process said plurality of acoustic energy signals and determine two average fetal heart rate frequencies as determined from equations (2) and (8);

$$f_{FHR}^{average2}(T^2) = \frac{1}{T^2}\int_0^{T^2}\left(m * f_{R5}^2 + n * \{f_{R_6}^2 - f_{R_7}^{\text{maternalamplitudethreshold}}\}\right)dT^2 \qquad (8)$$

wherein R_1 is a frequency between 50 and 250 Hz and R_2, R_3, R_4, R_5, R_6 and R_7 are independently frequency ranges within which R_1 falls, wherein T is T_p and T^2 is T_{p2}, T_p and T_{p2} are independent times between 10 milliseconds and 28 days, $f_{FHR}^{average}(T_p)$ is the first average fetal heart rate frequency, $f_{FHR}^{average2}(T_{p2})$ is the second average fetal heart rate frequency, m is 0 or 1, n is 0 or 1, wherein m+n is at least 1, f_{R_2} is the first current fetal heart rate and is within R_2, $f_{R_5}^2$ is the second current fetal heart rate and is within R_5, f_{R_3} is the first current fetal heart rate and is within R_3, $f_{R_6}^2$ is

the second current fetal heart rate and is within R_6, $f_{R4}^{\text{maternalamplitudethreshold}}$ is the maternal amplitude threshold frequency and is within R_4 and $f_{R7}^{\text{maternalamplitudethreshold}}$ is the maternal amplitude threshold frequency within R_7.

21. A system for monitoring the heart rate of a fetus in a female human subject having an umbilicus , the umbilicus defining a point on an umbilicus axis oriented perpendicular to the length of the subject's body, the umbilicus axis oriented on an umbilicus plane that is perpendicular to the length of the subject's body, comprising:

at least one sensor mountable on said subject in an area defined by equation (9);

$$\text{Area} = \pi * (0.05*l_{\text{subject}}) * (0.1*w_{\text{subject}}) \qquad (9)$$

wherein l_{subject} is the length of the subject and w_{subject} is the width of the subject, wherein the width of the subject is equal to the longest chord swept out by the umbilicus plane, said area defining an ellipse such that the major axis is perpendicular to the umbilicus axis and wherein the lower focus of said area is oriented along said umbilicus axis; and

said sensor being adapted to sense acoustic energy and generate at least one acoustic energy signal representing said acoustic energy; and

a processing unit adapted to receive said acoustic energy signal, said processing unit being further adapted to process said acoustic energy signal and determine an aspect average fetal heart rate waveform profile, said profile comprising a leading edge, a trailing edge and a translational edge as determined by equation (10);

$$slope_{FHR}^{average}(T) = \frac{1}{T}\int_0^T \left(m*slope_{R8} + n*\{slope_{R9} - slope_{R10}^{\text{maternalamplitudethreshold}}\} \right) dT \quad (10)$$

wherein R_1 is a frequency between 50 and 250 Hz and R_8, R_9 and R_{10} are independently frequency ranges within which R_1 falls, wherein T is T_p and T_p is a

time between 10 milliseconds and 28 days, $slope_{FHR}^{average}(T_p)$ is the slope of the leading edge of the average fetal heart rate waveform profile, m is 0 or 1, n is 0 or 1, wherein m+n is at least 1, $slope_{R_8}$ is the current average fetal heart rate waveform profile R_8, $slope_{R_9}$ is the current average fetal heart rate waveform profile within R_9 and $slope_{R_{10}}^{maternal\,amplitude\,threshold}$ is the maternal amplitude threshold average heart rate waveform profile within R_{10}.

22. The system of Claim 21, wherein said processing unit is further adapted to determine a fetal heart rate wave form deviation is determined by equation (11);

$$\left(\frac{1}{T_5}\int_0^{T_5}\left(slope_{FHR}^{average}(T_p)-slope_{FHR}^{average}(T_5)\right)^2 dT_5\right)^{1/2} \qquad (11)$$

wherein $slope_{FHR}^{average}(T_5)$ is calculated by equation (10) wherein T is T_5, and T_5 is a time between 10 milliseconds and 60 minutes.

23. The system of Claim 21, wherein T_p is between 1 second and 10 minutes.

24. The system of Claim 21, wherein T_p is between 1 second and 3 minutes.

25. The system of Claim 21, wherein T_p is between 1 second and 1 minute.

26. The system of Claim 21, wherein said sensor generates a plurality of acoustic energy signals representing said acoustic energy.

27. The system of Claim 26, wherein said processing unit is adapted to receive and process said plurality of acoustic energy signals and determine at least one fetal heart rate shape profile therefrom.

28. The system of Claim 26, wherein said processing unit is adapted to receive and process said plurality of acoustic energy signals and determine two fetal heart rate shape profiles as determined from equations (10) and (12);

$$slope_{FHR}^{average2}(T^2) = \frac{1}{T^2}\int_0^{T^2}\left(m*slope^2{}_{R8} + n*\{slope^2{}_{R9} - slope_{R10}^{maternalamplitudethreshold}\}\right)dT^2 \quad (12)$$

wherein R_1 is a frequency between 50 and 250 Hz and R_2, R_3, R_4, R_5, R_6 and R_7 are independently frequency ranges within which R_1 falls, wherein T is T_p and T^2 is T_{p2}, T_p and T_{p2} are independent times between 10 milliseconds and 28 days, $slope_{FHR}^{average}(T_{p2})$ is the first average fetal heart rate waveform profile, $slope_{FHR}^{average2}(T_{p2})$ is the second average fetal heart rate waveform profile, m is 0 or 1, n is 0 or 1, wherein m+n is at least 1, $slope_{R_2}$ is the first current fetal heart rate waveform profile and is within R_2, $slope_{R_5}^2$ is the second current fetal heart rate waveform profile and is within R_5, $slope_{R_3}$ is the first current fetal heart rate waveform profile and is within R_3, $slope_{R_6}^2$ is the second current fetal heart rate waveform profile and is within R_6, $slope_{R4}^{maternalamplitudethreshold}$ is the maternal amplitude threshold frequency and is within R_4 and $slope_{R7}^{maternalamplitudethreshold}$ is the maternal amplitude threshold frequency within R_7.

29. A system for monitoring the heart rate of a fetus in a female human subject having an umbilicus , the umbilicus defining a point on an umbilicus axis oriented perpendicular to the length of the subject's body, the umbilicus axis oriented on an umbilicus plane that is perpendicular to the length of the subject's body, comprising: at least one sensor mountable on said subject in an area defined by equation (13);

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$$\text{Area} = \pi * (0.05*l_{\text{subject}}) * (0.1*w_{\text{subject}}) \qquad (13)$$

wherein l_{subject} is the length of the subject and w_{subject} is the width of the subject, wherein the width of the subject is equal to the longest chord swept out by the umbilicus plane, said area defining an ellipse oriented such that the major axis is perpendicular to the umbilicus axis and wherein the lower focus of said area is oriented along said umbilicus axis; and

said sensor being adapted to sense acoustic energy and generate at least one acoustic energy signal representing said acoustic energy; and

a processing unit adapted to receive said acoustic energy signal, said processing unit being further adapted to process said acoustic energy signal and determine the average fetal heart rate frequency as determined by equation 14;

$$f_{FHR}^{average} = \frac{1}{T}\int_0^T \left(m*f_{R11} + n*\{f_{R12} - f_{R13}^{\text{maternalamplitudethreshold}}\} \right) dT \qquad (14)$$

wherein R_1 is a frequency between 50 and 250 Hz and R_{11}, R_{12} and R_{13} are independently frequency ranges within which R_1 falls, wherein T is T_p and T_p is a time between 0.01 minutes and 28 days, $f_{FHR}^{average}$ is the average fetal heart rate frequency, m is 0 or 1, n is 0 or 1, wherein m+n is at least 1, $f_{R_{11}}$ is the current fetal heart rate within R_{11}, f_{R12} is the current fetal heart rate within R_{12} and $f_{R13}^{maternalamplitudethreshold}$ is the maternal amplitude threshold within R_{13}; and

a processing unit adapted to receive said acoustic energy signal, said processing unit being further adapted to process said acoustic energy signal and determine the average fetal heart rate waveform profile as determined by equation (15);

$$slope_{FHR}^{average} = \frac{1}{T}\int_0^T \left(m*slope_{R14} + n*\{slope_{R15} - slope_{R16}^{\text{maternalamplitudethreshold}}\} \right) dT \qquad (15)$$

wherein R_1 is a frequency between 50 and 250 Hz and R_{14}, R_{15} and R_{16} are independently frequency ranges within which R_1 falls, wherein T is T_p and T_p is a time between 0.01 minutes and 28 days, $slope_{R14}$ is the current average fetal heart rate waveform within R_{14}, $slope_{R15}$ is the current average fetal heart rate waveform profile within R_{15} and $slope_{R16}^{maternalamplitudethreshold}$ is the maternal amplitude threshold average heart rate waveform profile within R_{16}.

30. The system of Claim 29, wherein R_{11} is equal to R_{14}.

31. The system of Claim 29, wherein R_{12} is equal to R_{15}.

32. The system of Claim 29, wherein R_{13} is equal to R_{16}.

33. The system of Claim 29, wherein R_{11} is equal to R_{14}, R_{12} is equal to R_{15}, R_{13} is equal to R_{16}.

34. A method for monitoring the heart rate of a fetus in a female human subject having an umbilicus , the umbilicus defining a point on an umbilicus axis oriented perpendicular to the length of the subject's body, the umbilicus axis oriented on an umbilicus plane that is perpendicular to the length of the subject's body, comprising:

mounting at least one sensor on said subject in an area defined by equation (16);

$$\text{Area} = \pi * (0.05*l_{\text{subject}}) * (0.1*w_{\text{subject}}) \qquad (16)$$

wherein l_{subject} is the length of the subject and w_{subject} is the width of the subject, wherein the width of the subject is equal to the longest chord swept out by the umbilicus plane, said area defining an ellipse such that the major axis is perpendicular

to the umbilicus axis and wherein the lower focus of said area is oriented along said umbilicus axis;

sensing an acoustic energy;

generating at least one acoustic energy signal representing said acoustic energy;

processing said acoustic energy signal; and

determining an average fetal heart rate frequency as determined by equation (17);

$$f_{FHR}^{average}(T) = \frac{1}{T}\int_0^T \left(m * f_{R_2} + n * \{ f_{R_3} - f_{R_4}^{\text{maternalamplitudethreshold}} \} \right) dT \qquad (17)$$

wherein R_1 is a frequency between 50 and 250 Hz and R_2, R_3 and R_4 are independently frequency ranges within which R_1 falls, wherein T is T_p and T_p is a time between 10 milliseconds and 28 days, $f_{FHR}^{average}(T_p)$ is the average fetal heart rate frequency, m is 0 or 1, n is 0 or 1, wherein m+n is at least 1, f_{R_2} is the current fetal heart rate within R_2, f_{R_3} is the current fetal heart rate within R_3 and $f_{R_4}^{maternalamplitudethreshold}$ is the maternal amplitude threshold within R_4.

35. A method for monitoring the heart rate of a fetus in a female human subject having an umbilicus , the umbilicus defining a point on an umbilicus axis oriented perpendicular to the length of the subject's body, the umbilicus axis oriented on an umbilicus plane that is perpendicular to the length of the subject's body, comprising:

mounting at least one sensor on said subject in an area defined by equation (18);

$$\text{Area} = \pi * (0.05 * l_{\text{subject}}) * (0.1 * w_{\text{subject}}) \qquad (18)$$

wherein l_{subject} is the length of the subject and w_{subject} is the width of the subject, wherein the width of the subject is equal to the longest chord swept out by the umbilicus plane, said area defining an ellipse such that the major axis is perpendicular

to the umbilicus axis and wherein the lower focus of said area is oriented along said umbilicus axis;

sensing an acoustic energy;

generating at least one acoustic energy signal representing said acoustic energy; and

processing said acoustic energy signal; and

determining an aspect average fetal heart rate waveform profile, said profile comprising a leading edge, a trailing edge and a translational edge as determined by equation 19;

$$slope_{FHR}^{average}(T) = \frac{1}{T}\int_0^T \left(m * slope_{R8} + n * \{ slope_{R9} - slope_{R10}^{\text{maternalamplitudethreshold}} \} \right) dT \quad (19)$$

wherein R_1 is a frequency between 50 and 250 Hz and R_8, R_9 and R_{10} are independently frequency ranges within which R_1 falls, wherein T is T_p and T_p is a time between 10 milliseconds and 28 days, $slope_{FHR}^{average}(T_p)$ is the slope of the leading edge of the average fetal heart rate waveform profile, m is 0 or 1, n is 0 or 1, wherein m+n is at least 1, $slope_{R8}$ is the current average fetal heart rate waveform within R_8, $slope_{R9}$ is the current average fetal heart rate waveform profile within R_9 and $slope_{R10}^{maternalamplitudethreshold}$ is the maternal amplitude threshold average heart rate waveform profile within R_{10}.

36. A method for monitoring the heart rate of a fetus in a female human subject having an umbilicus , the umbilicus defining a point on an umbilicus axis oriented perpendicular to the length of the subject's body, the umbilicus axis oriented on an umbilicus plane that is perpendicular to the length of the subject's body, comprising:

mounting at least one sensor on said subject in an area defined by equation (20);

5

$$\text{Area} = \pi * (0.05*l_{\text{subject}}) * (0.1*w_{\text{subject}}) \qquad (20)$$

wherein l_{subject} is the length of the subject and w_{subject} is the width of the subject, wherein the width of the subject is equal to the longest chord swept out by the umbilicus plane, said area defining an ellipse such that the major axis is perpendicular to the umbilicus axis and wherein the lower focus of said area is oriented along said umbilicus axis;

sensing an acoustic energy;

generating at least one acoustic energy signal representing said acoustic energy; and

processing said acoustic energy signal;

determining an average fetal heart rate frequency as determined by equation (21);

$$f_{FHR}^{average}(T) = \frac{1}{T}\int_0^T \left(m * f_{R_{11}} + n * \{ f_{R_{12}} - f_{R_{13}}^{\text{maternalamplitudethreshold}} \} \right) dT \qquad (21)$$

wherein R_1 is a frequency between 50 and 250 Hz and R_{11}, R_{12}, R_{13}, R_{14}, R_{15} and R_{16} are independently frequency ranges within which R_1 falls, T is T_p and T_p is a time between 10 milliseconds and 28 days, $f_{FHR}^{average}(T_p)$ is the average fetal heart rate frequency, m is 0 or 1, n is 0 or 1, wherein m+n is at least 1, $f_{R_{11}}$ is the current fetal heart rate within R_{11}, $f_{R_{12}}$ is the current fetal heart rate within R_{12} and $f_{R_{13}}^{maternalamplitudethreshold}$ is the maternal amplitude threshold within R_{13};

determining an aspect average fetal heart rate waveform profile, said profile comprising a leading edge, a trailing edge and a translational edge as determined by equation (22);

$$slope_{FHR}^{average}(T) = \frac{1}{T}\int_0^T \left(m*slope_{R14} + n*\{slope_{R15} - slope_{R16}^{maternalamplitudethreshold}\} \right) dT \quad (22)$$

wherein T is T_p and T_p is a time between 0.01 minutes and 28 days, $slope_{FHR}^{average}(T_p)$ is the slope of the leading edge of the average fetal heart rate waveform profile, m is 0 or 1, n is 0 or 1, wherein m+n is at least 1, $slope_{R8}$ is the current average fetal heart rate waveform within R_8, $slope_{R9}$ is the current average fetal heart rate waveform profile within R_9 and $slope_{R10}^{maternalamplitudethreshold}$ is the maternal amplitude threshold average heart rate waveform profile within R_{10}.

37. The method of Claims 34, 35 or 36, wherein said fetal heart rate frequency comprises an event associated with a fetal heart rate, said fetal heart rate being selected from the group consisting of baseline beats per minute, prolonged rapid heart rate, prolonged slow heart rate, transients and constant variation from the baseline.

38. The method of Claim 37, wherein said processing unit is further adapted to detect fetal distress, and upon detection of said fetal distress provides an electrical output.

39. The method of Claim 38, wherein said electrical output is a human sensible output, said human sensible output consisting of an acoustic, visual, mechanical, electrical indicator and combinations thereof.

40. A method for transporting the processing system of any of Claims 1-29, said method comprising moving the system a distance of at least 5 miles from location A to location B.

41. The method of Claim 40, wherein said moving comprises at least one mode of transportation from the group consisting of driving across land, sailing across water and flying through air.

5

42. The method of Claim 40, wherein location A is in one country and location B is in another country.

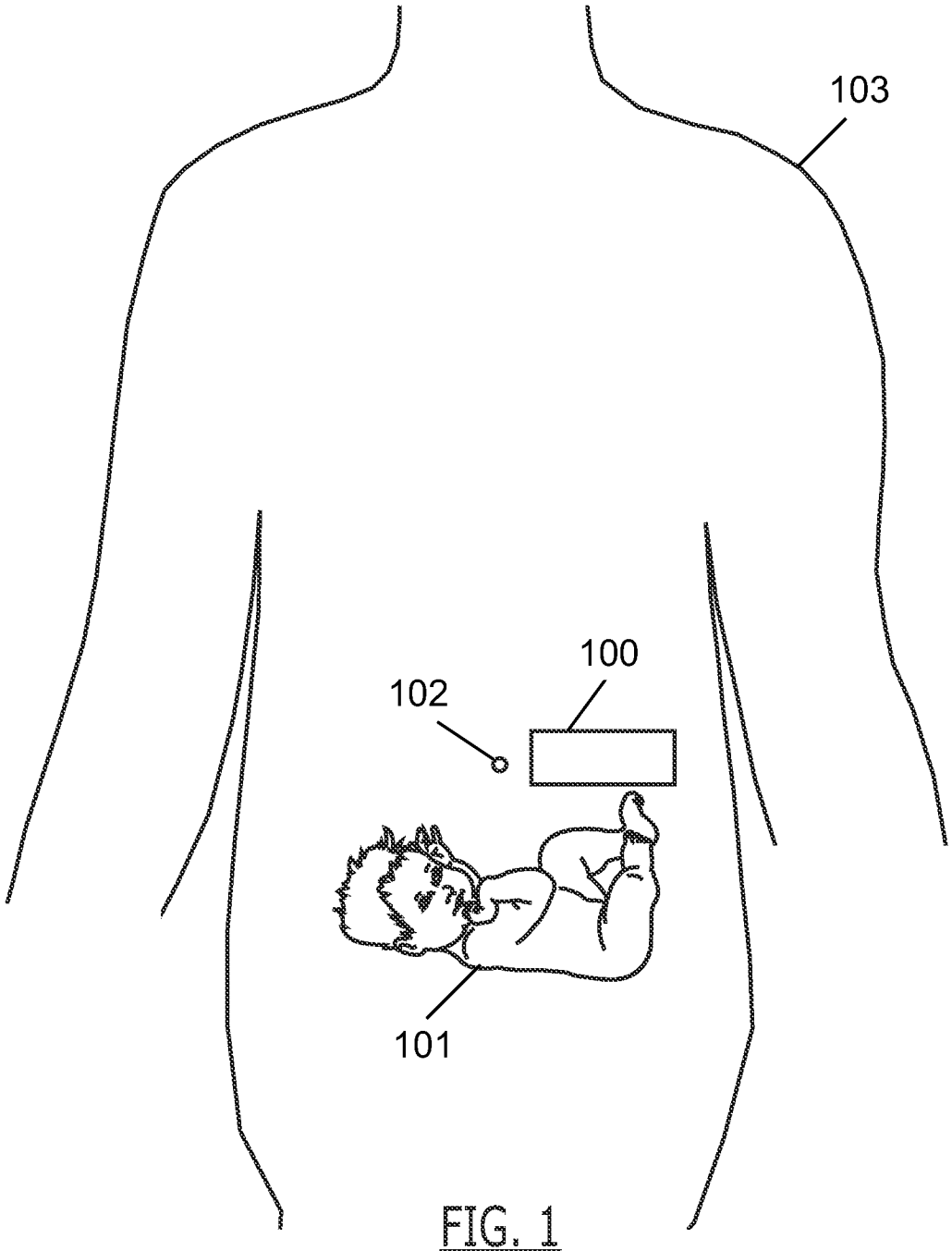

FIG. 1

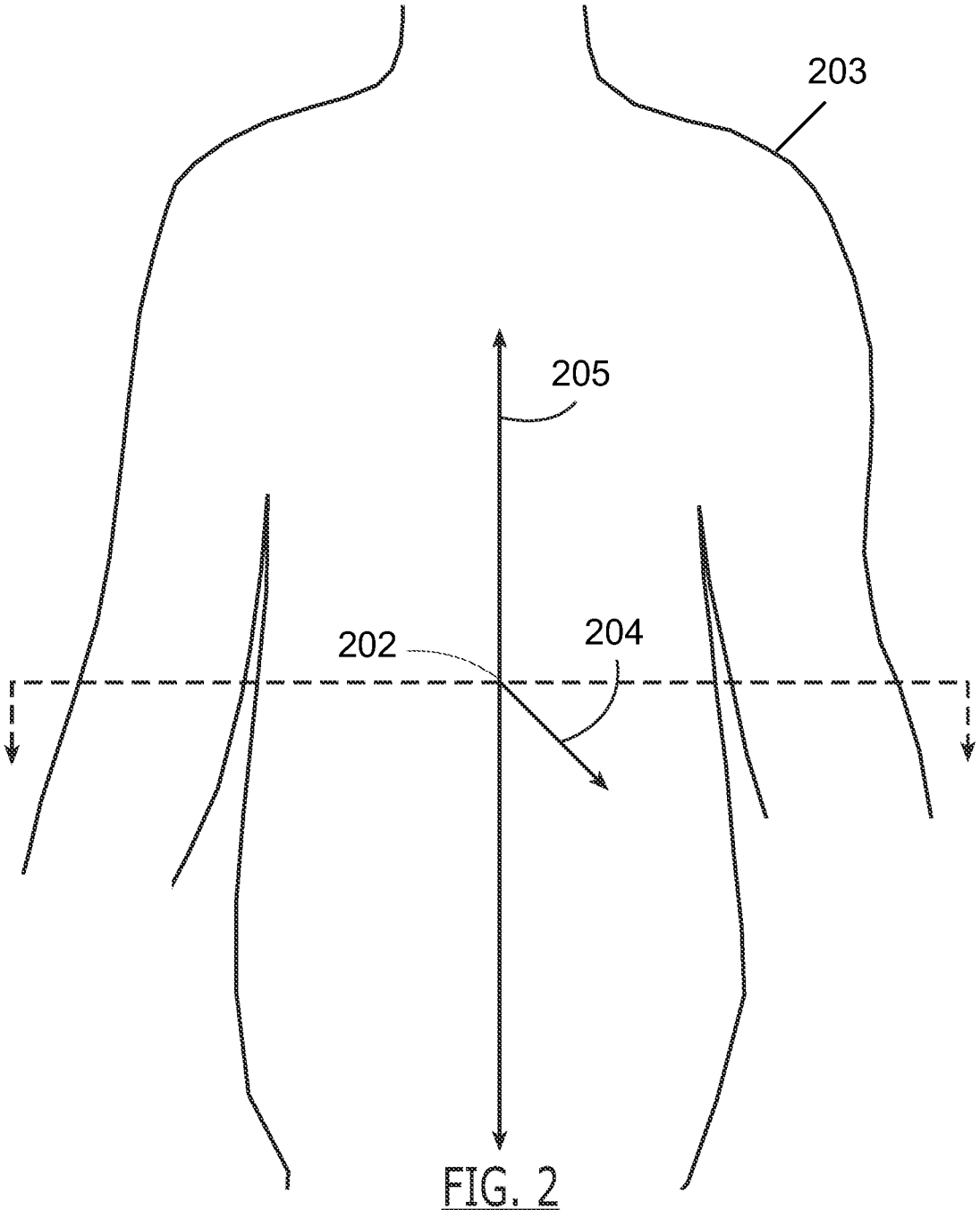

FIG. 2

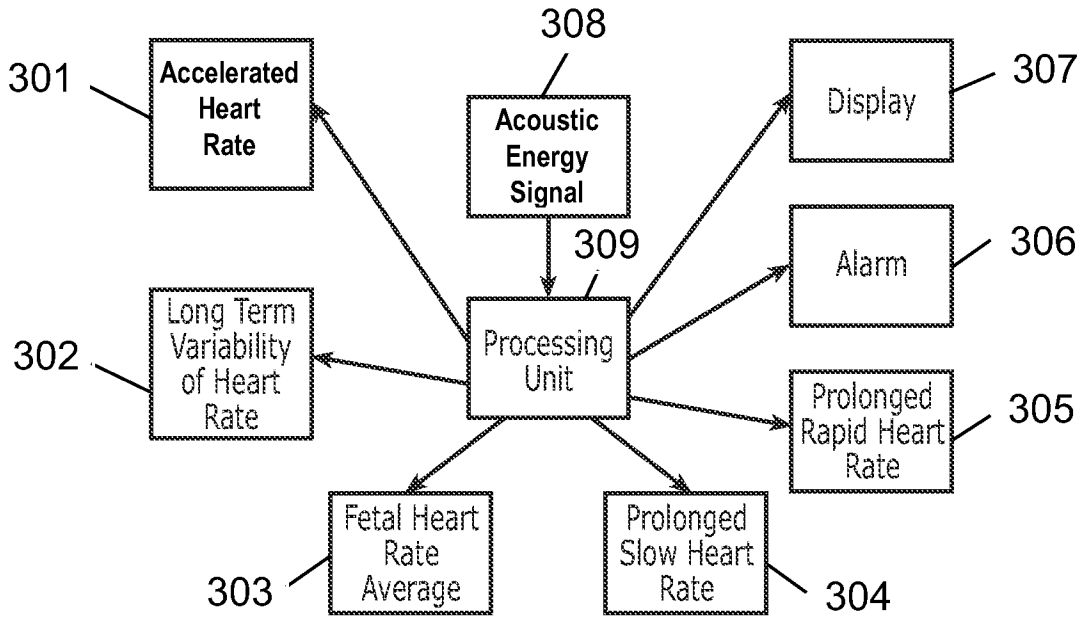
308
301
Accelerated Heart Rate
Acoustic Energy Signal
Display
307
309
Alarm
306
302
Long Term Variability of Heart Rate
Processing Unit
Prolonged Rapid Heart Rate
305
Fetal Heart Rate Average
Prolonged Slow Heart Rate
303
304

FIG. 3

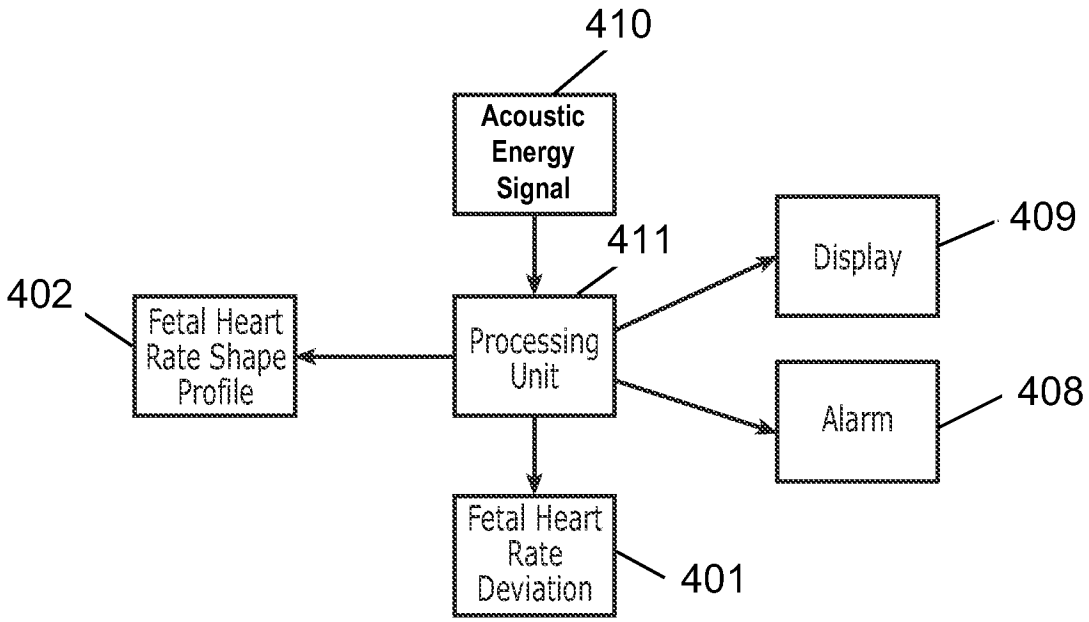
410
Acoustic Energy Signal
411
Display
409
402
Fetal Heart Rate Shape Profile
Processing Unit
Alarm
408
Fetal Heart Rate Deviation
401

FIG. 4

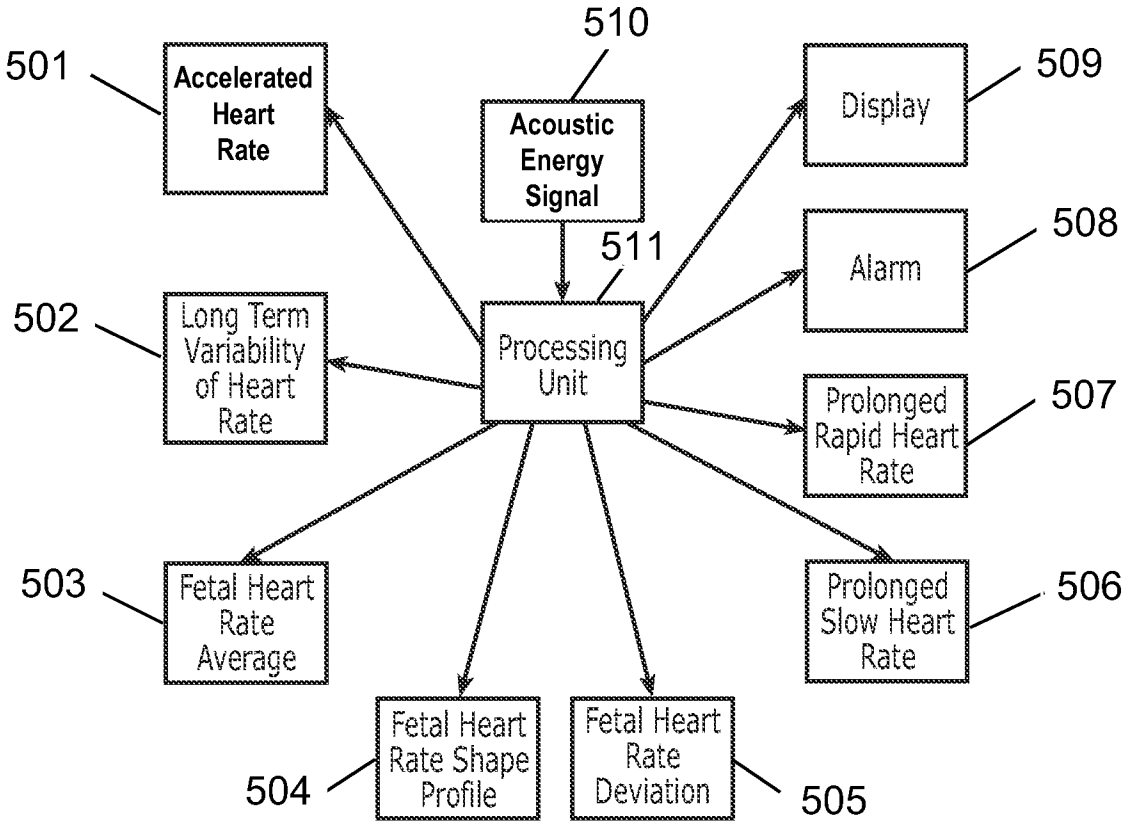
510
501
Accelerated Heart Rate
Acoustic Energy Signal
Display
509
511
Alarm
508
502
Long Term Variability of Heart Rate
Processing Unit
Prolonged Rapid Heart Rate
507
503
Fetal Heart Rate Average
Prolonged Slow Heart Rate
506
Fetal Heart Rate Shape Profile
Fetal Heart Rate Deviation
504
505

FIG. 5

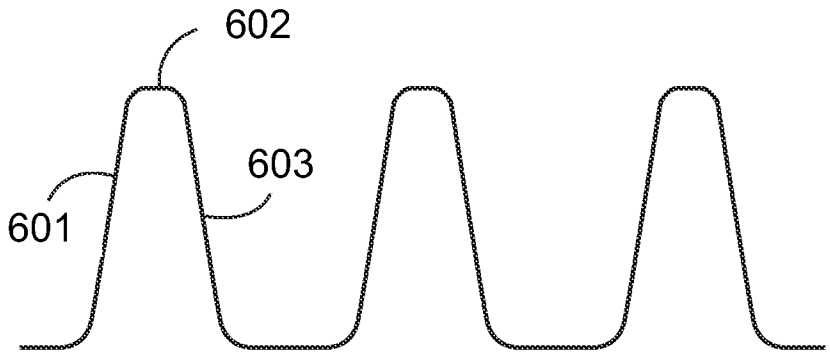
602
603
601

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/055450

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 8/00 (2010.01)
USPC - 600/437
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)
IPC(8) - A61B 5/00; A61B 5/024; A61B5/0245; A61B 5/0402; A61B 8/02; A61B 8/00; A61B 8/08 (2010.01)
USPC - 327/552; 333/175; 345/440.1; 600/300; 600/437; 600/511

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)
PatBase, Google Scholar, Google Patents, Scitopia, IEEE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/0124878 A1 (SHARONY) 09 June 2005 (09.06.2005) entire document	1-42
A	US 2007/0260133 A1 (MEYER) 08 November 2007 (08.11.2007) entire document	1-42
A	US 5,724,032 A (KLEIN et al) 03 March 1998 (03.03.1998) entire document	1-42
A	US 5,088,497 A (IKEDA) 18 February 1992 (18.02.1992)	1-42

☐ Further documents are listed in the continuation of Box C. ☐

* 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
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"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
17 December 2010	23 DEC 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774