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(54) **DOPPLER ULTRASOUND BASED FETAL MONITORING**

AUF DOPPLER-ULTRASCHALL BASIEREND FETALE ÜBERWACHUNG

SURVEILLANCE FOETALE BASÉE SUR LES ULTRASONS DOPPLER

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EP 2 629 672 B1

Description

FIELD OF THE INVENTION

[0001] The following belongs to the field of Doppler ultrasound and to the field of Doppler ultrasound based fetal monitoring.

BACKGROUND OF THE INVENTION

[0002] With advances in ultrasound technologies, ultrasound monitoring devices are increasingly available for home use. With this, the risk of exposure to doses of ultrasound higher than recommended is also increasing. Home ultrasound devices with automatic time out and those that measure the dosage and automatically lock themselves are known. The principle behind safe exposure to any radiation, in the present case to ultrasound radiation, is known as ALARA - As Low As Reasonably Achievable.

[0003] The published European patent application EP 1852058 A1 titled "Fetus Movement Monitoring System and Fetus Movement Information Collecting Device" describes a device for sensing fetal movements that uses a passive sensor. It states that in hospitals, the image of a fetus in the uterus of the mother's body is generally monitored by an ultrasonic wave echo device. But, because this type of device is a so-called active sensor type which applies an ultrasonic wave to a fetus in the uterus of the mother's body and receives its reflected wave, it is undesirable to use this type of device for monitoring fetal movements over a long time in consideration of an adverse influence to the fetus. Furthermore, there is a problem that an ultrasonic wave echo device is configured to be used by a specialist such as a doctor or midwife, and cannot be used easily by a pregnant woman herself at home.

[0004] Karlsson B et al. "The DopFet system: a new ultrasonic Doppler system for monitoring and characterization of fetal movement", Ultrasound in Medicine and Biology, New York, NY, US, vol. 26, No. 7, 1 September 2000 (2000-09-01), pages 1117-1124, discloses a Doppler ultrasound device for monitoring a fetus in a subject comprising a pair of miniature sensors, a 2-MHz continuous-wave directional Doppler electronic module and a laptop personal computer, wherein one of the sensors is aimed at the fetal limbs and the other at the thorax to detect heart and upper body movements.

[0005] Recent advances in ultrasound technologies have enabled the use of Doppler Ultrasound for fetal movement monitoring at home. However the danger of unintended exposure to ultrasound radiation beyond recommended doses still exists.

SUMMARY OF THE INVENTION

[0006] It is preferable to have a Doppler ultrasound device and method and a computer program to execute such a method, for fetal monitoring at home that limits the ultrasound dosage to the recommended maximum daily dosage. It is also preferable to have such a device that also follows the ALARA principle and. The disclosed device and method are defined by the independent claims. The dependent claims define advantageous embodiments.

[0007] According to an aspect of the present invention a Doppler ultrasound device for monitoring a fetus in a subject and limiting ultrasound radiation to the fetus is proposed as defined in claim 1.

[0008] This device provides the advantage of being safe for use by the mother-to-be herself in the comfort of her home. It may further have the advantage of providing information about the movements of the fetus along with the information whether the movements are within the normal range or not. What is normal is based on available clinical data on the number of fetal movements in a given time duration. It may have the further advantage that the method follows the 'ALARA' principle and is safe for the mother-to-be and the fetus and, at the same time, provides information about fetal movements.

[0009] According to another aspect of the present invention a method of Doppler ultrasound limiting ultrasound radiation to a fetus in a subject while monitoring the fetus is proposed as defined in claim 13.

[0010] A computer program is also disclosed. The program comprises computer executable instructions for carrying out the disclosed method when the computer program is run on a computer.

[0011] A computer readable storage medium in which the disclosed computer program is stored is also disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] These and other aspects will be described in detail, by way of example, on the basis of the following embodiments and implementations, with reference to the accompanying drawings, wherein:

Fig. 1 is a diagrammatic representation of the device disclosed
Fig. 2 is a table showing the functional details of the device disclosed;
Fig. 3 is a diagrammatic representation of an embodiment of the disclosed device; and
Fig. 4 is a diagrammatic representation of the method disclosed;

DETAILED DESCRIPTION OF EMBODIMENTS

[0013] The disclosed device and method are described below in detail with reference to the figures.

[0014] With reference to Fig. 1, a Doppler ultrasound device 100 for assessing wellbeing of a fetus in a subject based on fetal movements is described. An ultrasound transducer 101 is used to radiate a subject with ultra-

sound of suitable characteristics and to receive the reflected ultrasound waves. The device comprises a estimator unit 103 for estimating whether the acoustic coupling between the transducer and the subject (not shown) is adequate or not. A accumulator unit 105 accumulates a time duration of ultrasound radiation. A first comparison unit 107 compares the accumulated time duration with a reference time duration. A detector unit 109 detects movements of the fetus based on reflected ultrasound radiation. A counter unit 111 counts the number of fetal movements detected by the detector unit 109. A second comparison unit 113 compares the number of counted fetal movements with a reference number. A decision unit 115 decides on at least one of a further action of the device, the state of wellbeing of the fetus and an action recommended to the subject based on the comparison. A user interface 117 conveys the decision or decisions of the decision unit to the subject. The user interface 117 may also be used to convey to the user the estimate of the acoustic coupling from the estimation unit 103.

[0015] The various decisions and conditions under which those decisions are reached are now described. These conditions and decision are shown in tabular form in columns 1 to 5 of Fig. 2. If the number of counted movements reaches the reference number before the accumulated time duration for which ultrasound is radiated reaches the reference time duration, further counting of fetal movements is stopped. That is to say, ultrasound radiation is stopped and further ultrasound radiation is disabled for a predetermined time duration. This ensures that the exposure to ultrasound is limited according to the principle of ALARA. If the number of counted fetal movements does not reach the reference number before the accumulated time duration reaches the reference time duration, the following are done. The radiation of ultrasound and counting of the fetal movements is continued for a predefined extended time duration, say 30 minutes. The information that the fetal movement is being counted for the predefined extended time duration is conveyed to the subject. The counting is continued from the number that was reached when the reference time duration was reached. Whenever the number of counted fetal movements reaches the reference number at any time within the predefined extended time duration, it is conveyed to the subject that the number of fetal movements is within normal limits and further ultrasound radiation is disabled for the predetermined time duration. And if the number of counted fetal movements does not reach the reference number even at the end of the predefined extended time duration, the information is conveyed to the subject that the reference number has not been reached and the subject is recommended to consult a medical practitioner at the earliest and further ultrasound radiation is disabled for the predetermined time duration.

[0016] In an extreme case where not a single movement of the fetus is recorded when the accumulated time duration has reached the reference time duration, further radiation is disabled for the predetermined time duration and it is recommended to the subject to consult a medical practitioner at the earliest.

[0017] As described earlier, accumulator unit 105 starts accumulating the time duration of ultrasound radiation only when the estimator unit 103 has estimated that the acoustic coupling is adequate. Since the ultrasound transducer should be coupled adequately to the surface of the subject's abdomen, and an adequate amount of a gel between the surface of the abdomen and the transducer is needed to ensure adequate acoustic coupling, there are chances that the acoustic coupling is not adequate. Methods to determine whether the acoustic coupling is adequate or not, are known. They may utilize detection of ringing in the transducer when the acoustic coupling is inadequate, for instance.

[0018] Even though, in the description above, the time is said to be accumulated upwards, it is obvious that time can be counted downwards and when the remaining time reaches zero it is equivalent to the output of the first comparator indicating that the reference time duration has elapsed. The remaining time being greater than zero, conversely, is equivalent to the comparator indicating that the reference time duration has not elapsed. Thus the description is only to describe the method in an easily understandable manner. There may be many different ways of achieving the desired result and all such equivalent variations are assumed to fall under the scope of the disclosed method.

[0019] The conditions under which various actions are taken by the device, the indications to be conveyed to the subject and the recommendations to be made to the subject are listed in tabular form in Fig. 2. In this table, under the first two columns, the comparator output '1' means that the value of the corresponding compared quantity has reached or crossed the reference values of the respective comparators. Conversely the comparator output '0' indicates that the compared quantity is below the reference value. It is evident that this is only one way of describing the outputs and what is meant is a binary logical output.

[0020] The sixth column of the table in Fig. 2 shows the recommendations to be made to the subject under the various conditions described hitherto. The sixth column of Fig. 2 shows one of the exemplary ways of conveying information to the subject. Colored lights, LEDs for instance, are used to indicate various conditions and recommendations. However, other means of conveying information and recommendations to the subject could be thought of, for instance LED or LCD alphanumeric display units, for instance.

[0021] The disclosed device thus gives the subject information and recommends action to ensure the safety of the fetus and the subject. At the same time, it ensure that the subject cannot use the device further with the hope that if monitored further, the device may detect fetal movements and thereby wasting precious time in consulting a medical practitioner and/or endangering the subject and the fetus with radiation beyond the recom-

mended maximum daily dosage.

[0022] In the description above, the reference number has been treated as a constant. However, it is known that as the pregnancy advances, the number of movements of the fetus per day, and hence the number of movements in the predetermined time duration tends to fall. Thus, the reference number reduces as the age of the pregnancy increases. The reference numbers may be updated as the age of the pregnancy increases. Reference numbers may be stored in a look up table, for instance, mapped to the age of the pregnancy and the reference number updated every time the device is used by the subject. Alternatively the reference number may be updated every week, once the age of the pregnancy has been entered at the time of the first use of the device.

[0023] It is contemplated that the disclosed device is in the form of or comprises or adapted into a belt as shown in Fig. 3, which when worn around the waist or abdomen of the subject, positions the ultrasound transducer 315 on the surface of the subject's abdomen. However, the subject may have to ensure that gel is applied at the right place so that there is adequate acoustic coupling between the transducer and the subject. With this the subject can go about her work while the device is in operation.

[0024] Fig. 4 is a diagrammatic representation of the disclosed method of Doppler ultrasound. It is known that ultrasound is radiated into a subject and the reflected waves are received and analyzed for imaging the part of the subject's body that reflects the ultrasound. If there are parts of the body that are moving inside the patient's body, the reflected ultrasound will have a shift in its frequency depending on the speed and direction of the movement of the part of the body. Such a shift is known as the Doppler shift. An analysis of the shift in the frequency, the Doppler shift, of the reflected ultrasound provides information on the movement of the parts of the subject's body.

[0025] According to the disclosed method 400, the abdomen of the subject is radiated with ultrasound and it is ascertained that the acoustic coupling between the ultrasound transducer and the abdomen of the subject is adequate in an estimation step 419. The duration of ultrasound radiation is measured and accumulated in an accumulation step 421 only when the estimate is that the acoustic coupling is adequate. This estimation is carried out periodically to ensure that the acoustic coupling remains adequate throughout the duration of the assessment. If the acoustic coupling is estimated to be inadequate at any time, the accumulation is stopped. It is continued only after the acoustic coupling has been set right. The accumulated time duration is compared with a reference time duration, one hour for instance, in a first comparison step 423. Simultaneously, the reflected ultrasound is received and analyzed to detect fetal movements in a detection step 425. The fetal movements sensed are counted in a counting step 427. The number of counted fetal movements is compared in a comparison step 429 with a reference number. Based on the results of the two comparisons, a decision is made in a decision making step 431. One of the decisions is whether to continue the process or not. The other decision is an estimate about the wellbeing of the fetus based on the number of counted fetal movements. One or more of these may be conveyed to the subject in a conveying step 433.

[0026] When this method is employed on a pregnant woman, with appropriate choice of the frequency of the ultrasound and the application of the ultrasound to the abdomen, information about the movements of the fetus may be obtained. This information may be about movements of the fetus, fetal heartbeat, maternal heartbeat blood flow in maternal or fetal blood vessels or both for instance.

[0027] Since the characteristics of the fetal movements are known, the signals corresponding to them can be recognized and counted. Although there are variations in the number of fetal movements from one mother-to-be to another, data on such movements collected over a large number of pregnant women has shown the normal evolution of the number of fetal movements over the gestation period. The trend of movements in a pregnancy is therefore relevant and any decrease of movements more than expected from the normal trend over the gestation period may be indicative of fetal compromise. Thus these movements may be counted to assess if the number of fetal movements in a given time duration is within the normal range or not.

[0028] However, if the number of fetal movements is below the normal count but is close to it, an ambiguity exists since the number of fetal movements is not uniform over the day. In such cases, the monitoring of the subject for fetal movements for an extended time is recommended. However, it is not recommended that the subject and the fetus be exposed to ultrasound over long periods of time. A method of Doppler ultrasound based fetal movement monitoring that avoids such exposure beyond the recommended dosage and still provides useful information about the fetal movement is disclosed.

[0029] A computer program product is also disclosed. Such a computer program product comprises computer executable instructions for carrying out the method disclosed herein, when the computer program is run on a computer. The computer program has computer executable instructions to carry out the various steps of the disclosed method. The term computer is used in a general sense. This could by any of the various digital circuits such as a microprocessor, microcontroller, a Digital Signal Processor (DSP) or any other dedicated or generally purpose electronic component with computing ability.

[0030] Computer readable media carrying the disclosed computer program is also disclosed. Such a computer program may be burnt or otherwise stored in computer readable media such as a CD, DVD, or a plug-in semiconductor memory device commonly called a USB device. The program may be made available on the internet for download and installed on the disclosed device before using the device. Such a program has all the nec-

essary computer executable instructions to carry out the method either on a dedicated device such as the one disclosed above or on a general purpose Ultrasound device that could run the said program to carry out the various steps of the method disclosed.

[0031] While the embodiments and implementations have been described in detail in the drawings and description, such drawings and description are to be considered exemplary and not restrictive; the invention is not limited to the disclosed embodiments. Variations and combinations will occur to a practitioner and all such variations are deemed to be within the scope of the disclosed methods.

[0032] In the descriptions above, since the device and method are for use by a pregnant lady for monitoring herself, the term subject has been used everywhere. However it is conceivable that someone else may assist the lady and in that case, the information conveyed may be for that person. This however does not affect the descriptions in a significant manner.

[0033] Other variations to the disclosed embodiments can be understood and effected by those skilled in the art, in practicing the claimed invention, from a study of the drawings, the disclosure, and the appended claims. In the claims, the word "comprising" does not exclude elements or steps other than those mentioned, and the indefinite article "a" or "an" does not exclude a plurality. A single processor or other unit may fulfill the functions of several items recited in the claims. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage. A computer program may be stored or distributed on a suitable medium, such as an optical storage medium or a solid-state medium supplied together with or as part of other hardware, but may also be distributed in other forms, such as via the Internet or other wired or wireless telecommunication systems. Any reference signs in the claims should not be construed as limiting the scope of the claims.

Claims

1. A Doppler ultrasound device (100) for monitoring a fetus in a subject and limiting ultrasound radiation to the fetus, the device comprising:

an accumulator unit (105) for accumulating a time duration for which ultrasound is radiated into the subject;
a first comparison unit (107) for comparing the accumulated time duration with a reference time duration;
a detector unit (109) for detecting a movement of the fetus based on reflected ultrasound radiation;
a counter unit (111) for counting the number of detected fetal movements;
characterized by
an estimator unit (103) for estimating an adequacy of acoustic coupling between an ultrasound transducer and the subject, wherein the accumulation unit (103) starts accumulating when the acoustic coupling has been estimated to be adequate;
a second comparison unit (113) for comparing the number of counted fetal movements with a reference number;
a decision unit (115) for making at least one decision based on at least one of an output of the first comparison unit and an output of the second comparison unit, said decision being related to at least one of a further action of the device, the state of wellbeing of the fetus and an action recommended to the subject; and
a user interface (117) for conveying an information to the subject based on the at least one decision.

2. The device of claim 1 wherein the device is adapted for being operational when worn on the subject's abdomen.

3. The device of claim 1 wherein the counter unit (111) is for counting fetal movements above a predefined threshold of at least one parameter of the movement of the fetus out of a set of parameters including but not limited to a magnitude, a velocity, an acceleration and a force.

4. The device of claim 1 wherein the reference number is dependent on an age of the pregnancy of the subject.

5. The device of claim 1 wherein:

when the accumulated time duration is less than the reference time duration and the number of counted fetal movements is less than the reference number, the decision of the decision unit (115) is to continue the accumulating and the counting; and
the user interface (117) conveys to the user that the assessing is continuing.

6. The device of claim 1 wherein:

when the accumulated time duration is less than the reference time duration and the number of counted fetal movements equals the reference number, the decision of the decision unit (115) is to disable the ultrasound radiation for a predetermined time duration; and
the user interface (117) conveys to the subject that the movement count is normal.

7. The device of claim 1 wherein:

when the accumulated time duration is equal to the reference time duration and the number of counted fetal movements is zero, the decision of the decision unit (115) is to disable the ultrasound radiation for the predetermined time duration; and
the user interface (117) conveys a recommendation to the subject.

8. The device of claim 1 wherein:

when the accumulated time duration is equal to the reference time duration and the number of counted fetal movements is less than the reference number and not zero, the decision of the decision unit (115) is to continue the accumulating and the counting for a predefined extended time duration; and
the user interface (117) conveys to the user that the ultrasound radiation is being continued for the predefined extended time duration.

9. The device of claim 8 wherein:

when the accumulated time duration is equal to the sum of the first reference time duration and the predefined extended time duration, and the number of counted fetal movements is less than the reference number, the decision of the decision unit (115) is to disable the ultrasound radiation for the predetermined time duration; and
the user interface (117) conveys a recommendation to the subject.

10. The device of claim 8 wherein:

when the accumulated time duration is less than the sum of the first reference time duration and the predefined extended time duration, and the number of counted fetal movements is equal to the reference number, the decision of the decision unit (115) is to disable the ultrasound radiation for the predetermined time duration and user interface (117) conveys to the subject that the number of fetal movements is normal; or
when the accumulated time duration is equal to the sum of the first reference time duration and the predefined extended time duration, and the number of counted fetal movements is less than the reference number, the decision of the decision unit (115) is to disable the ultrasound radiation for the predetermined time duration and the user interface (117) conveys a recommendation to the subject.

11. The device of claim 1 further comprising a memory unit for storing the number of counted fetal movements; and
the decision unit is configured for making a decision based on the number of counted fetal movements at the end of an assessment and the number of counted fetal movements at the end of the preceding assessment.

12. The device of claim 11 configured to additionally store the accumulated time duration at the end of an assessment; and
the decision unit is configured for making a decision based on a ratio of counted fetal movements at the end of an assessment and the accumulated time duration at the end of the assessment and the ratio of counted fetal movements at the end of the preceding assessment and the accumulated time duration at the end of the preceding assessment.

13. A method of limiting ultrasound radiation to a fetus in a subject while monitoring the fetus, the method comprising the steps of:

an accumulation step of accumulating a time duration for which ultrasound is radiated into the subject;
a first comparison step of comparing the accumulated time duration with a first reference time duration;
a detection step of detecting a movement of the fetus based on reflected ultrasound radiation;
a counting step of counting the number of detected fetal movements;
characterized by
an estimation step of estimating acoustic coupling between an ultrasound transducer and the subject, wherein the accumulating is started when the acoustic coupling has been estimated to be adequate, and in that it further comprises:

a second comparison step of comparing the number of counted fetal movements with a reference number;
a decision step of making at least one decision based on at least one of the first comparison and the second comparison, said decision being related to at least one of a further action of the device, the state of well-being of the fetus and an action recommended to the subject; and
a conveying step of conveying an information to the subject based on the decision.

14. A computer program comprising computer executable instructions for carrying out the method of claim 13 when the computer program is run on a computer.

15. A computer readable storage medium carrying the

computer program according to claim 14.

Patentansprüche

1. Doppler-Ultraschallvorrichtung (100) zum Überwachen eines Fötus in einer Person und Begrenzen der Ultraschallstrahlung für den Fötus, wobei die Vorrichtung Folgendes umfasst:

   eine Akkumulatoreinheit (105) zum Kumulieren einer Zeitdauer, während der Ultraschall in die Person gestrahlt wird;
   eine erste Vergleichseinheit (107) zum Vergleichen der kumulierten Zeitdauer mit einer Referenzzeitdauer;
   eine Detektoreinheit (109) zum Detektieren einer Bewegung des Fötus basierend auf reflektierter Ultraschallstrahlung;
   eine Zählereinheit (111) zum Zählen der Anzahl von detektierten fetalen Bewegungen;
   gekennzeichnet durch
   eine Schätzeinheit (103) zum Einschätzen einer Adäquatheit der akustischen Kopplung zwischen einem Ultraschallwandler und der Person, wobei die Akkumulatoreinheit (105) mit dem Kumulieren beginnt, wenn die akustische Kopplung als adäquat eingeschätzt wurde;
   eine zweite Vergleichseinheit (113) zum Vergleichen der Anzahl von gezählten fetalen Bewegungen mit einer Referenzanzahl;
   eine Entscheidungseinheit (115) zum Treffen mindestens einer Entscheidung basierend auf mindestens einem von einer Ausgabe der ersten Vergleichseinheit und einer Ausgabe der zweiten Vergleichseinheit, wobei sich die genannte Entscheidung auf mindestens eines von einer weiteren Aktion der Vorrichtung, dem Status des Wohlbefindens des Fötus und einer der Person empfohlenen Aktion bezieht; und
   eine Benutzerschnittstelle (117) zum Übermitteln einer Information an die Person basierend auf der mindestens einen Entscheidung.

2. Vorrichtung nach Anspruch 1, wobei die Vorrichtung dafür ausgelegt ist, betriebsfähig zu sein, wenn sie auf dem Abdomen der Person getragen wird.

3. Vorrichtung nach Anspruch 1, wobei die Zählereinheit (111) vorgesehen ist zum Zählen von fetalen Bewegungen über einem vordefinierten Schwellenwert von mindestens einem Bewegungsparameter des Fötus aus einem Satz von Parametern einschließlich - aber nicht begrenzt darauf - einer Magnitude, einer Geschwindigkeit, einer Beschleunigung und einer Kraft.

4. Vorrichtung nach Anspruch 1, wobei die Referenzanzahl von einem Alter der Schwangerschaft der Person abhängt.

5. Vorrichtung nach Anspruch 1, wobei:

   wenn die kumulierte Zeitdauer kürzer ist als die Referenzzeitdauer und die Anzahl der gezählten fetalen Bewegungen kleiner ist als die Referenzanzahl, die Entscheidung der Entscheidungseinheit (115) darin besteht, mit dem Kumulieren und dem Zählen fortzufahren; und
   die Benutzerschnittstelle (117) dem Benutzer übermittelt, dass die Beurteilung fortgesetzt wird.

6. Vorrichtung nach Anspruch 1, wobei:

   wenn die kumulierte Zeitdauer kürzer ist als die Referenzzeitdauer und die Anzahl der gezählten fetalen Bewegungen gleich der Referenzanzahl ist, die Entscheidung der Entscheidungseinheit (115) darin besteht, die Ultraschallstrahlung für eine vorgegebene Zeitdauer zu deaktivieren; und
   die Benutzerschnittstelle (117) der Person übermittelt, dass der Bewegungszählwert normal ist.

7. Vorrichtung nach Anspruch 1, wobei
   wenn die kumulierte Zeitdauer gleich der Referenzzeitdauer ist und die Anzahl der gezählten fetalen Bewegungen null ist, die Entscheidung der Entscheidungseinheit (115) darin besteht, die Ultraschallstrahlung für die vorgegebene Zeitdauer zu deaktivieren; und
   die Benutzerschnittstelle (117) der Person eine Empfehlung übermittelt.

8. Vorrichtung nach Anspruch 1, wobei
   wenn die kumulierte Zeitdauer gleich der Referenzzeitdauer ist und die Anzahl der gezählten fetalen Bewegungen kleiner ist als die Referenzanzahl und nicht null, die Entscheidung der Entscheidungseinheit (115) darin besteht, das Kumulieren und Zählen für eine vorgegebene verlängerte Zeitdauer fortzusetzen; und
   die Benutzerschnittstelle (117) dem Benutzer übermittelt, dass die Ultraschallstrahlung für die vorgegebene verlängerte Zeitdauer fortgesetzt wird.

9. Vorrichtung nach Anspruch 8, wobei
   wenn die kumulierte Zeitdauer gleich der Summe der ersten Referenzzeitdauer und der vordefinierten verlängerten Zeitdauer ist und die Anzahl der gezählten fetalen Bewegungen kleiner ist als die Referenzanzahl, die Entscheidung der Entscheidungseinheit (115) darin besteht, die Ultraschallstrahlung für die vorgegebene Zeitdauer zu deaktivieren; und
   die Benutzerschnittstelle (117) der Person eine

Empfehlung übermittelt.

10. Vorrichtung nach Anspruch 8, wobei
wenn die kumulierte Zeitdauer kürzer ist als die Summe der ersten Referenzzeitdauer und der vordefinierten verlängerten Zeitdauer und die Anzahl der gezählten fetalen Bewegungen gleich der Referenzanzahl ist, die Entscheidung der Entscheidungseinheit (115) darin besteht, die Ultraschallstrahlung für die vorgegebene Zeitdauer zu deaktivieren, und die Benutzerschnittstelle (117) der Person übermittelt, dass die Anzahl der fetalen Bewegungen normal ist; oder
wenn die kumulierte Zeitdauer gleich der Summe der ersten Referenzzeitdauer und der vordefinierten verlängerten Zeitdauer ist und die Anzahl der gezählten fetalen Bewegungen kleiner ist als die Referenzanzahl, die Entscheidung der Entscheidungseinheit (115) darin besteht, die Ultraschallstrahlung für die vorgegebene Zeitdauer zu deaktivieren, und die Benutzerschnittstelle (117) der Person eine Empfehlung übermittelt.

11. Vorrichtung nach Anspruch 1, weiterhin umfassend eine Speichereinheit zum Speichern der Anzahl von gezählten fetalen Bewegungen; und
wobei die Entscheidungseinheit konfiguriert ist, um eine Entscheidung basierend auf der Anzahl der gezählten fetalen Bewegungen am Ende einer Beurteilung und der Anzahl der gezählten fetalen Bewegungen am Ende der vorhergehenden Beurteilung zu treffen.

12. Vorrichtung nach Anspruch 11, die konfiguriert ist, um zusätzlich die kumulierte Zeitdauer am Ende einer Beurteilung zu speichern; und
wobei die Entscheidungseinheit konfiguriert ist, um eine Entscheidung basierend auf einem Verhältnis der gezählten fetalen Bewegungen am Ende einer Beurteilung und der kumulierten Zeitdauer am Ende der Beurteilung und dem Verhältnis der gezählten fetalen Bewegungen am Ende der vorhergehenden Beurteilung und der kumulierten Zeitdauer am Ende der vorhergehenden Beurteilung zu treffen.

13. Verfahren des Begrenzens von Ultraschallstrahlung für einen Fötus in einer Person während der Überwachung des Fötus, wobei das Verfahren die folgenden Schritte umfasst:

einen Akkumulationsschritt zum Kumulieren einer Zeitdauer, während der Ultraschall in die Person gestrahlt wird;
einen ersten Vergleichsschritt zum Vergleichen der kumulierten Zeitdauer mit einer ersten Referenzzeitdauer;
einen Detektionsschritt zum Detektieren einer Bewegung des Fötus basierend auf reflektierter Ultraschallstrahlung;
einen Zählschritt zum Zählen der Anzahl von detektierten fetalen Bewegungen;
gekennzeichnet durch
einen Schätzschritt zum Einschätzen der akustischen Kopplung zwischen einem Ultraschallwandler und der Person, wobei mit dem Kumulieren begonnen wird, wenn die akustische Kopplung als adäquat eingeschätzt wurde; und
dadurch, dass es weiterhin Folgendes umfasst:

einen zweiten Vergleichsschritt zum Vergleichen der Anzahl von gezählten fetalen Bewegungen mit einer Referenzanzahl;
einen Entscheidungsschritt zum Treffen mindestens einer Entscheidung basierend auf mindestens einem von dem ersten Vergleich und dem zweiten Vergleich, wobei sich die genannte Entscheidung auf mindestens eines von einer weiteren Aktion der Vorrichtung, dem Status des Wohlbefindens des Fötus und einer der Person empfohlenen Aktion bezieht; und
einen Übermittlungsschritt zum Übermitteln einer Information an die Person basierend auf der Entscheidung.

14. Computerprogramm umfassend computerausführbare Anweisungen zum Durchführen des Verfahrens nach Anspruch 13, wenn das Computerprogramm auf einem Computer ausgeführt wird.

15. Computerlesbares Speichermedium, auf dem das Computerprogramm nach Anspruch 14 gespeichert ist.

Revendications

1. Dispositif d'échographie Doppler (100) permettant de surveiller un foetus chez un sujet et de limiter le rayonnement ultrasonore en direction du foetus, le dispositif comprenant :

une unité d'accumulateur (105) permettant d'accumuler une durée pendant laquelle des ultrasons sont mis à rayonner dans le sujet ;
une première unité de comparaison (107) permettant de comparer la durée accumulée avec une durée de référence ;
une unité de détecteur (109) permettant de détecter un mouvement du foetus en se basant sur un rayonnement ultrasonore réfléchi ;
une unité de compteur (111) permettant de compter le nombre de mouvements foetaux détectés ;

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une unité d'estimateur (103) permettant d'estimer une adéquation de couplage acoustique entre un transducteur ultrasonore et le sujet, l'unité d'accumulation (105) démarrant l'accumulation lorsque le couplage acoustique a été estimé comme étant adéquat ;
une seconde unité de comparaison (113) permettant de comparer le nombre de mouvements foetaux comptés avec un nombre de référence ;
une unité de décision (115) permettant de prendre au moins une décision en se basant sur au moins l'une d'une sortie de la première unité de comparaison et une sortie de la seconde unité de comparaison, ladite décision étant relative à au moins l'une d'une action supplémentaire du dispositif, de l'état de bien-être du foetus et d'une action recommandée au sujet ; et
une interface utilisateur (117) permettant de transmettre une information au sujet en se basant sur la au moins une décision.

2. Dispositif selon la revendication 1, dans lequel le dispositif est adapté pour être opérationnel lorsqu'il est porté sur l'abdomen du sujet.

3. Dispositif selon la revendication 1, dans lequel l'unité de compteur (111) est destinée à compter des mouvements foetaux au-delà d'un seuil prédéfini d'au moins un paramètre du mouvement du foetus parmi un jeu de paramètres incluant, sans s'y limiter, une grandeur, une vitesse, une accélération et une force.

4. Dispositif selon la revendication 1, dans lequel le nombre de référence est dépendant d'un âge de la grossesse du sujet.

5. Dispositif selon la revendication 1, dans lequel :

lorsque la durée accumulée est inférieure à la durée de référence et que le nombre de mouvements foetaux comptés est inférieur au nombre de référence, la décision de l'unité de décision (115) est de continuer l'accumulation et le comptage ; et
l'interface utilisateur (117) transmet à l'utilisateur que l'estimation se poursuit.

6. Dispositif selon la revendication 1, dans lequel :

lorsque la durée accumulée est inférieure à la durée de référence et que le nombre de mouvements foetaux comptés est égal au nombre de référence, la décision de l'unité de décision (115) est d'interrompre le rayonnement ultrasonore pendant une durée prédéterminée ; et
l'interface utilisateur (117) transmet au sujet que le décompte de mouvement est normal.

7. Dispositif selon la revendication 1, dans lequel :

lorsque la durée accumulée est égale à la durée de référence et que le nombre de mouvements foetaux comptés est de zéro, la décision de l'unité de décision (115) est d'interrompre le rayonnement ultrasonore pendant la durée prédéterminée ; et
l'interface utilisateur (117) transmet une recommandation au sujet.

8. Dispositif selon la revendication 1, dans lequel :

lorsque la durée accumulée est égale à la durée de référence et que le nombre de mouvements foetaux comptés est inférieur au nombre de référence et non pas de zéro, la décision de l'unité de décision (115) est de continuer l'accumulation et le comptage pendant une durée prolongée prédéfinie ; et
l'interface utilisateur (117) transmet à l'utilisateur que le rayonnement ultrasonore est poursuivi pendant la durée prolongée prédéfinie.

9. Dispositif selon la revendication 8, dans lequel :

lorsque la durée accumulée est égale à la somme de la première durée de référence et de la durée prolongée prédéfinie, et que le nombre de mouvements foetaux comptés est inférieur au nombre de référence, la décision de l'unité de décision (115) est d'interrompre le rayonnement ultrasonore pendant la durée prédéterminée ; et
l'interface utilisateur (117) transmet une recommandation au sujet.

10. Dispositif selon la revendication 8, dans lequel :

lorsque la durée accumulée est inférieure à la somme de la première durée de référence et de la durée prolongée prédéfinie, et que le nombre de mouvements foetaux comptés est égal au nombre de référence, la décision de l'unité de décision (115) est d'interrompre le rayonnement ultrasonore pendant la durée prédéterminée ; et
l'interface utilisateur (117) transmet au sujet que le nombre de mouvements foetaux est normal ; ou
lorsque la durée accumulée est égale à la somme de la première durée de référence et de la durée prolongée prédéfinie, et que le nombre de mouvements foetaux comptés est inférieur au nombre de référence, la décision de l'unité de décision (115) est d'interrompre le rayonnement ultrasonore pendant la durée prédéterminée et l'interface utilisateur (117) transmet une recommandation au sujet.

11. Dispositif selon la revendication 1, comprenant en outre une unité de mémoire permettant de stocker le nombre de mouvements foetaux comptés ; et
l'unité de décision est configurée pour prendre une décision en se basant sur le nombre de mouvements foetaux comptés à la fin d'une estimation et le nombre de mouvements foetaux comptés à la fin de l'estimation précédente.

12. Dispositif selon la revendication 11, configuré pour stocker de surcroît la durée accumulée à la fin d'une estimation ; et
l'unité de décision est configurée pour prendre une décision en se basant sur un rapport entre des mouvements foetaux comptés à la fin d'une estimation et la durée accumulée à la fin de l'estimation et le rapport entre des mouvements foetaux comptés à la fin de l'estimation précédente et la durée accumulée à la fin de l'estimation précédente.

13. Procédé de limitation du rayonnement ultrasonore en direction d'un foetus chez un sujet pendant la surveillance du foetus, le procédé comprenant :

une étape d'accumulation consistant à accumuler une durée pendant laquelle des ultrasons sont mis à rayonner dans le sujet ;
une première étape de comparaison consistant à comparer la durée accumulée avec une première durée de référence ;
une étape de détection consistant à détecter un mouvement du foetus en se basant sur un rayonnement ultrasonore réfléchi ;
une étape de comptage consistant à compter le nombre de mouvements foetaux détectés ;

caractérisé par

une étape d'estimation consistant à estimer un couplage acoustique entre un transducteur ultrasonore et le sujet, l'accumulation étant démarrée lorsque le couplage acoustique a été estimé comme étant adéquat, et en ce qu'il comprend en outre ;
une seconde étape de comparaison consistant à comparer le nombre de mouvements foetaux comptés avec un nombre de référence ;
une étape de décision consistant à prendre au moins une décision en se basant sur au moins l'une de la première comparaison et de la seconde comparaison, ladite décision étant relative à au moins l'une d'une action supplémentaire du dispositif, de l'état de bien-être du foetus et d'une action recommandée au sujet ; et
une étape de transmission consistant à transmettre une information au sujet en se basant sur la décision.

14. Programme d'ordinateur comprenant des instructions exécutables par ordinateur permettant de réaliser le procédé selon la revendication 13, lorsque le programme d'ordinateur est réalisé sur un ordinateur.

15. Support de stockage lisible par ordinateur portant le programme d'ordinateur selon la revendication 14.

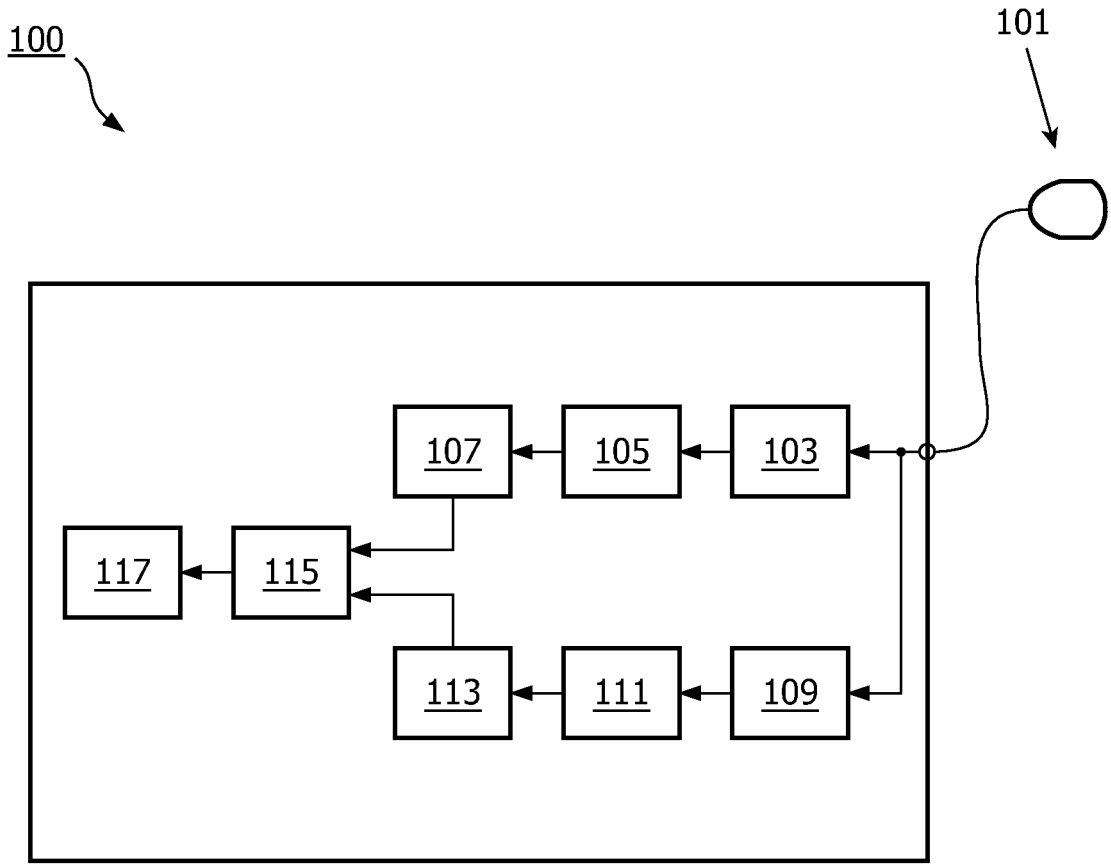

FIG. 1

Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7
Result of the first comparison (accumulated time < reference time > 0)	Result of the second comparison (COUNT*< reference count > 0)	Further action	Count normal or not	Recommendations to the subject	Example indication with a light source. For instance colored LED	Status of the device to be indicated to the subject
0	0	Continue counting movements	None	None	Blue/white	In use within first time slot
0	1	Stop US radiation and counting of movements	Normal	None	Green	Stopped
1	0 (COUNT≥1)	Continue count	None	None	Amber	In extended time period
1	0 (COUNT=0)	Stop counting movements	No fetal movement	Consult doctor	Red	Stopped
1	1	Stop counting	Normal	None	Green	Stopped
In the extended time period						
(accumulated time < (reference time + extended time) > 0)						
0	1	Stop counting movements	Normal	None	Green	Stopped
1	0	Stop counting movements	Fetal movement count below normal	Consult your doctor immediately	Red	Stopped
1	0	Stop counting	Normal	None	Green	Stopped

*: COUNT = Counted number of movements

FIG. 2

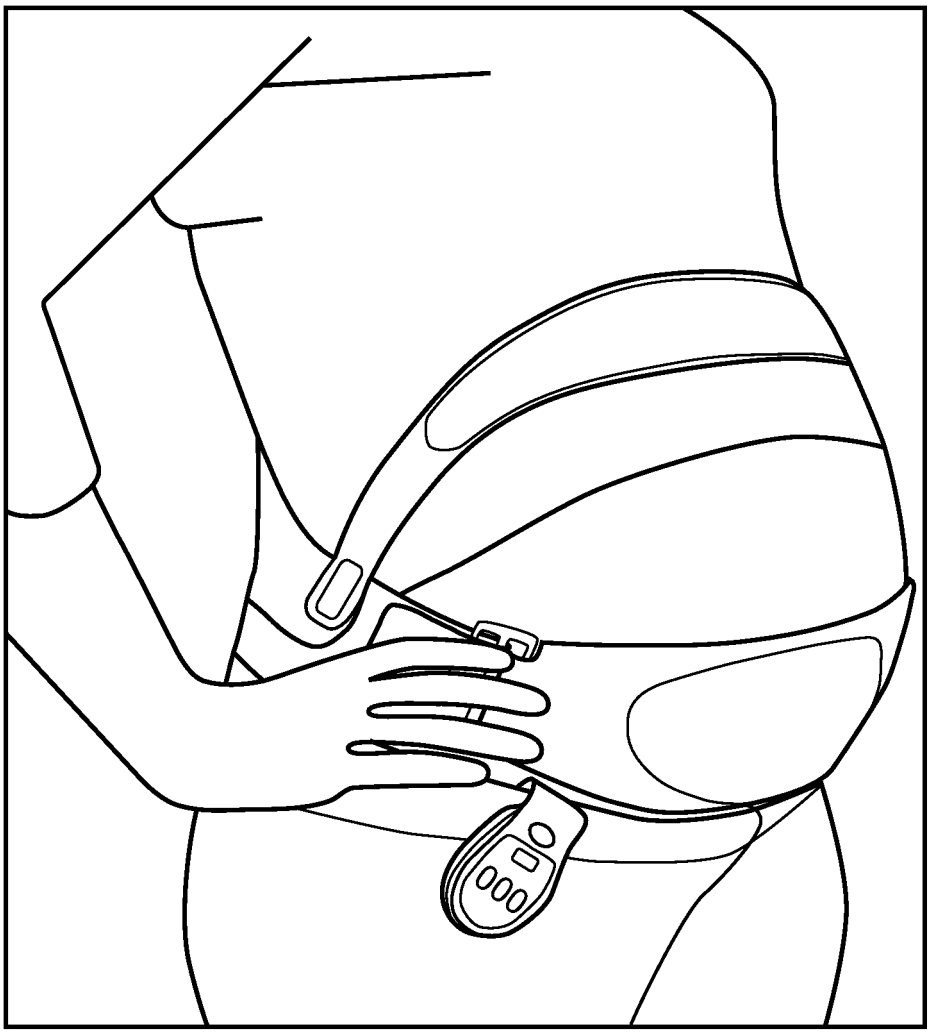

FIG. 3

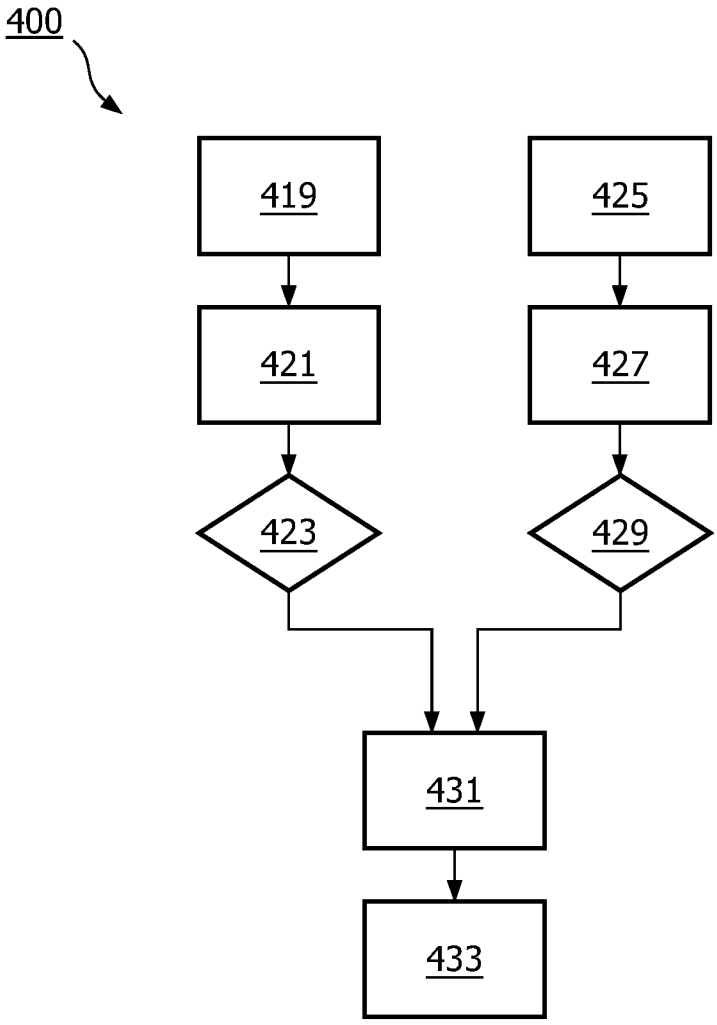

FIG. 4

REFERENCES CITED IN THE DESCRIPTION

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- EP 1852058 A1 **[0003]**

Non-patent literature cited in the description

- **KARLSSON B et al.** The DopFet system: a new ultrasonic Doppler system for monitoring and characterization of fetal movement. *Ultrasound in Medicine and Biology, New York, NY, US,* 01 September 2000, vol. 26 (7), 1117-1124 **[0004]**

专利名称(译)	基于多普勒超声的胎儿监护		
公开(公告)号	EP2629672B1	公开(公告)日	2016-12-21
申请号	EP2011781636	申请日	2011-10-17
[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
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其他公开文献	EP2629672A1		
外部链接	Espacenet		

摘要(译)

公开了一种将超声辐射限制在安全水平并符合ALARA原理的胎动监测方法。所公开的通过多普勒超声监测胎儿运动的方法包括累积超声辐射到受试者中的时间，将累积时间与第一参考总时间进行比较，计算受试者中胎儿运动的数量，比较运动的数量与参考数字，决定设备的进一步动作和要向对象推荐的动作中的至少一个，并且传达设备的进一步动作中的至少一个，向受试者提供关于计数的胎动和动作的信息。推荐给主题。还公开了一种用于监测受试者中胎儿运动的多普勒超声装置。

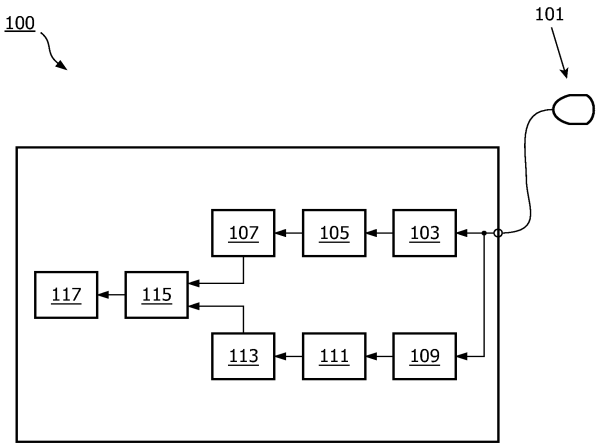

FIG. 1