(57) Abstract: A method for monitoring the blood pressure of a patient, comprising the following steps: determining a pulse arrival time signal from the patient 2 based on the pulse wave velocity method; determining an accelerometer signal from the patient 2; and triggering an additional measure or deriving a blood pressure value, taking into account the pulse arrival time signal and a DC component of the accelerometer signal. In this way, a possibility for monitoring the blood pressure of a patient is provided with which false alarms and/or unnecessary additional cuff-based blood pressure measurements can be avoided.
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, Published: ML, MR, NE, SN, TD, TG). — with international search report (Art. 21(3))
MONITORING THE BLOOD PRESSURE OF A PATIENT

FIELD OF THE INVENTION

The invention relates to the field of monitoring the blood pressure of a patient, and especially to avoiding false alarms when monitoring the blood pressure.

BACKGROUND OF THE INVENTION

Blood pressure measurements in clinical setting are conventionally mainly based on the sphygmo-manometric occlusive arm-cuff, which is clumsy, uncomfortable and only allows for intermittent measurements at intervals of several minutes. Hence, there is a strong interest by the medical community in new technologies, which provide timely detection of critical changes of a patient's blood circulation status.

A technical approach for early detection of critical blood pressure changes is based on the pulse wave velocity (PWV) technique, where surrogate markers of blood pressure are typically derived from a continuously monitored ECG waveform and plethysmograph like the signal of a single wavelength of from a SpO2 sensor. The measurement of the pulse wave velocity offers the opportunity to derive significant changes of arterial blood pressure at heart-beat frequency without applying an external pressure. It is common practice to use the pulse arrival time (PAT), which is defined as the time-delay between the R-peak of the QRS wave from the ECG and the arrival of the arterial pulse wave at the periphery, e.g. measured by a plethysmographic sensor.

Conventionally, whenever a significant change in blood circulation is identified based on a measurement of the pulse arrival time from the ECG and the plethysmograhic sensor, a standard cuff-based blood pressure measurement is triggered automatically to confirm the change in blood pressure and to let the practitioner know it, when the patient's blood pressure is falling/increasing to critical level. However, in this way still a great number of cuff-based blood pressure measurement is triggered which would not have been necessary since actually no severe change in blood pressure of the patient has occurred.
SUMMARY OF THE INVENTION

It is an object of the invention to provide a method and a system for monitoring the blood pressure of a patient with which false alarms and/or unnecessary additional cuff-based blood pressure measurements can be avoided.

This object is achieved by a method for monitoring the blood pressure of a patient, comprising the following steps:

- determining a pulse arrival time signal from the patient based on the pulse wave velocity method;
- determining an accelerometer signal from the patient; and
- triggering an additional measure or deriving a blood pressure value, taking into account the pulse arrival time signal and a DC component of the accelerometer signal.

This means that, according to the invention, a DC component of the accelerometer signal is determined. In this way, effects on the pulse arrival time which are due to different postures and not because of a changing circulatory state of the patient can be taken into account. Especially, according to the invention, a blood pressure value can be derived on the basis of the determined pulse arrival time and a DC component of the accelerometer signal which means that a blood pressure value is determined which is corrected by the posture effect on the pulse arrival time detected by the DC component of the accelerometer signal. Alternatively, based on the pulse arrival time and the DC component of the accelerometer signal, an additional measure can be triggered which means that in case the pulse arrival time and/or the DC component of the accelerometer signal fulfill a predefined condition, further measures can be taken. What such additional measures can be, is set out in detail in the following.

With respect to taking an additional measure, according to a preferred embodiment of the invention, before triggering the additional measure, the value of the pulse arrival time signal is compared with at least one predefined pulse arrival time threshold value, and the additional measure is only taken if the value of the pulse arrival time signal exceeds or under-runs the predefined pulse arrival time threshold value.

This means that an additional measure is only taken when the pulse arrival
time becomes longer or shorter than a predefined threshold value, respectively, which means that the blood pressure might have fallen or risen over an acceptable value, respectively. With respect to this, it is possible to have only one threshold value, which then is an upper or a lower threshold value. However, it is preferred that two threshold values are used, i.e. an upper threshold value and a lower threshold value. Furthermore, according to a preferred embodiment of the invention, the upper threshold value and/or the lower threshold value is dependent on the heart rate.

With respect to this, it is further preferred that the additional measure is checking for a posture change based on a change of a DC component of the accelerometer signal. This provides for the following possibility:

In case a posture change is actually detected since a DC component of the accelerometer signal has changed, it is waited for an equilibration of the blood pressure regulation of the patient in this new posture. After equilibration, a new threshold value for the pulse arrival time can be determined, taking into consideration the effects of the new posture on the blood pressure.

However, should no posture change be detected, the change of the value of the pulse arrival time is probably due to an actual change of the blood pressure. In this case, according to a preferred embodiment of the invention, the additional measure is a cuff-based measurement of the blood pressure of the patient. In this way, the blood pressure can be detected in an even more reliable way. Especially, in case the blood pressure value of the cuff-based blood pressure measurement exceeds a predefined blood pressure threshold value, according to a preferred embodiment of the invention, a subsequent alarm is triggered.

Though above mentioned method might be more reliable, according to another preferred embodiment of the invention, the additional measure is a direct alarm which means that in case that the value of the pulse arrival time signal exceeds or under-runs the predefined pulse arrival time threshold value and no posture change is detected based on the DC component of the accelerometer signal, an alarm is directly triggered without further performing a cuff-based blood pressure measurement.

Moreover, according to another preferred embodiment of the invention, the step of deriving the blood pressure value taking into account the pulse arrival time signal and the DC component of the accelerometer signal further comprises the step of
determining the blood pressure value based on pre-calibrated values for pulse arrival
time signal vs. DC component of the accelerometer signal. With respect to this, it is
especially preferred that pre-calibrated values of the blood pressure for pulse arrival time
signal vs. DC components of the accelerometer signal is provided in a look-up table
which has been generated in a preceding calibration procedure. Alternatively, an
analytical correction function for the blood pressure on the basis of values for pulse
arrival time signal vs. DC component of the accelerometer signal can be provided. This
preferred embodiment of the invention provides for an absolute determination of the
blood pressure of the patient corrected by the effects of different postures of the patient
on the PAT measure.

Further, according to a preferred embodiment of the invention, the step of
deriving a blood pressure signal from the patient based on the pulse wave velocity-
method comprises the steps of deriving an ECG signal from the patient, and deriving a
pulse wave signal from the patient. With respect to this, it is especially preferred that the
step of deriving a pulse wave signal from the patient comprises the step of deriving a
pulse wave signal from the patient, preferably a plethysmographic signal e.g. by optical
or bioimpedance means.

Above-mentioned object is further addressed by a system for monitoring
the blood pressure of a patient, comprising:

- a pulse wave velocity unit adapted for determining a pulse arrival time
  signal from the patient based on the pulse wave velocity method;
- an accelerometer adapted for determining an accelerometer signal from
  the patient; and
- a monitoring device adapted for triggering an additional measure or
deriving a blood pressure value, taking into account the pulse arrival time
signal and a DC component of the accelerometer signal.

Preferred embodiments of the system according to the invention relate to
the preferred embodiments according to the method as described above.

In detail, according to a preferred embodiment of the invention, the
system comprises a comparator which is adapted for comparing the value of the pulse
arrival time signal with a predefined pulse arrival time threshold value. Further,
according to a preferred embodiment of the invention, a cuff is provided which is
adapted for a cuff-based measurement of the blood pressure of the patient.

Furthermore, according to a preferred embodiment of the invention, an alarm unit is provided which is adapted for triggering an alarm in case the blood pressure value of the cuff-based blood pressure measurement exceeds or falls below a predefined blood pressure threshold value or the pulse arrival time signal under-runs a predefined pulse arrival time threshold value.

Moreover, according to a preferred embodiment of the invention, a storage device is provided in which pre-calibrated values for pulse arrival time signal vs. DC component of the accelerometer signal are stored. Such pre-calibrated values can be provided in form of a look-up table or in form of an analytical function. According to another preferred embodiment of the invention, the pulse wave velocity unit comprises an ECG sensor and a pulse sensor, preferably adapted for deriving a plethysmographic signal from the patient.

In order to detect the posture of the patient, an additional sensor on the patient can be used. In this case, a separate acceleration sensor is attached to the patient and connected to the monitoring device. However, according to a preferred embodiment of the invention, an ECG-electrode with an integrated acceleration sensor is used.

According to another preferred embodiment, an ECG-electrode connector with an integrated acceleration sensor is provided.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other aspects of the invention will be apparent from and elucidated with reference to the embodiments described hereinafter.

In the drawings:

Fig. 1 is a schematical depiction of an embodiment of the invention; and

Fig. 2 is a flow diagram of another embodiment of the invention.

DETAILED DESCRIPTION OF EMBODIMENTS

As already stated above, PWV measurement is a promising approach, which offers the opportunity to derive significant changes of arterial blood pressure at a
heart-beat frequency without applying an external pressure. For that, the pulse arrival time is determined, which is defined as the time-delay between the R-peak of the QRS wave from the ECG and the arrival of the arterial pulse wave at the periphery. This comprises the sum of the pre-ejection period (PEP) and the pulse transit time (PTT), both representing different underlying cardiovascular mechanisms:

\[ PAT = PEP + PTT. \]

More precisely, the PEP is a cardiac component covering the iso-volumic ventricular contraction stage while the PTT is a purely vascular component that can only be defined after the aortic valve opening. It was found that PEP is a good marker for blood pressure changes induced by physical stress. However, PEP is also sensitive to fluid shifts within the body induced by posture changes at constant blood pressure, which has to be taken into account for detecting accurately significant blood pressure changes. Further, it has been found that the known PEP effect causes a significant PAT change that is not associated with a blood pressure change. The observed PAT change for different postures is covered almost completely by the PEP changes. In order to compensate this effect, according to an embodiment of invention, the posture of the patient is detected.

In order to detect the posture of the patient, according to this preferred embodiment of the invention, an acceleration sensor 1 is attached to the patient 2 and connected to a monitoring device 3, which is schematically depicted in Fig. 1. The connection of the acceleration sensor 1 with the monitoring device 3 is a wireless connection 6. The patient's 2 posture is inferred from the DC-components, i.e. averages, of the acceleration signals, which contain information of the acceleration sensor's 1 orientation with respect to the earth gravity axis.

Since earth gravity creates a constant acceleration towards ground, its projection on the axis of the acceleration sensor 1 unveils the orientation of this axis and, hence, of the acceleration sensor 1. Thus, the patient 2 is considered to be standing when its trunk is upright, sitting when its trunk is slightly tilted backward, and lying when its trunk is roughly parallel to the ground. For a correct classification of the patient's 2 posture it is preferred to calibrate the system with a known posture. Further, for the actual blood pressure monitoring, according to the embodiment of the invention shown in Fig. 1, an ECG sensor 4 and a pulse wave sensor 5 for a plethysmographic
measurement are provided in a conventional way for enabling a PWV measurement, the ECG sensor 4 and the pulse wave sensor 5 forming a pulse wave velocity unit 7. The ECG sensor 4 and the optical sensor 5 are both connected with the monitoring device via the wireless connection 6, too. Further, a cuff 8 for a conventional cuff-based blood pressure measurement is provided.

As shown in Fig. 1, a separate acceleration sensor 1 can be provided on the patient 2 in order to detect his posture. According to another embodiment, an ECG electrode with an integrated acceleration sensor can be used. Further, it is also possible to use an ECG-electrode connector with an integrated acceleration sensor.

Moreover, according to still another preferred embodiment of the invention, an automated normalization of the pulse arrival time (PAT) after detecting a posture change is applied: After a posture change has been detected, the continuously measured pulse arrival time is normalized for the new posture. This is done automatically, triggered by the detected posture change via the acceleration sensor signal, and a new reference PAT is determined. An according flow diagram for this embodiment of the invention is shown in Fig. 2.

According to the embodiment of the invention shown in Fig. 2 exemplified for detection of a critical blood pressure increase, at the beginning of the monitoring, a threshold value for the pulse arrival time (PAT₀) is determined, e.g. on the basis of the detected pulse arrival time average over a predefined duration. Further, when such a pulse arrival time value is observed which falls below the predefined threshold value, it is checked if a posture change of the patient was detected. If such a posture change was actually detected, it is waited until the blood pressure regulation process has equilibrated. Then, a new threshold value is defined based on an average of monitoring the pulse arrival time for a predefined duration. Then, it is further checked if the actual pulse arrival time observed under-runs the new threshold value. Then, the process described above may continue.

In case that, when checking for a posture change of the patient, it is detected that no posture change has occurred since the DC component of the accelerator signal has not changed, a cuff-based blood pressure measurement is triggered. If this cuff-based blood pressure measurement results in a critical blood pressure which exceeds a predefined threshold value, an alarm is generated. In case the cuff-based blood
pressure value is not determined to be critical, it is continued with checking the actual pulse arrival time as described before.

Further, according to still another embodiment of the invention, before a monitoring period is started, a calibration procedure is performed for different postures of the patient providing the relation of PAT vs. postures, e.g. at several different angles. A look up-table is created by this procedure, which can be used in the monitoring period to compensate for PAT changes caused by posture changes. In addition, the blood pressure can be measured with a cuff to assess the blood pressure changes associated with the different postures, which allows a further refinement of the posture-related PAT corrections. Alternatively, PEP can be measured directly in different postures using for example a stethoscope for heart sound analysis or impedance cardiography.

While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive; the invention is not limited to the disclosed embodiments.

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 other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality. 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. Any reference signs in the claims should not be construed as limiting the scope.
CLAIMS:

1. A method for monitoring the blood pressure of a patient, comprising the following steps:
   determining a pulse arrival time signal from the patient (2) based on the pulse wave velocity method;
   determining an accelerometer signal from the patient (2); and
   triggering an additional measure or deriving a blood pressure value, taking into account the pulse arrival time signal and a DC component of the accelerometer signal.

2. The method according to claim 1, wherein before triggering the additional measure, the value of the pulse arrival time signal is compared with at least one predefined pulse arrival time threshold value, and the additional measure is only taken if the value of the pulse arrival time signal exceeds or under-runs the predefined pulse arrival time threshold value, the predefined pulse arrival time threshold value preferably being dependent on the heart rate.

3. The method according to claim 1 or 2, wherein the additional measure comprises checking for a posture change of the patient (2) based on a change of the DC component of the accelerometer signal.

4. The method according to any of claims 1 to 3, wherein the additional measure comprises a cuff-based measurement of the blood pressure of the patient (2).

5. The method according to claim 4, wherein a subsequent alarm is triggered in case the blood pressure value of the cuff-based blood pressure measurement exceeds or under-runs a predefined blood pressure threshold value.
6. The method according to any of claims 1 to 5, wherein the step of deriving the blood pressure value taking into account the pulse arrival time signal and the DC component of the accelerometer signal further comprises the step of determining the blood pressure value based on pre-calibrated values for pulse arrival time signal vs. DC component of the accelerometer signal.

7. The method according to any of claims 1 to 6, wherein the step of deriving a blood pressure signal from the patient based on the pulse wave velocity-method comprises the steps of deriving an ECG signal from the patient (2), and deriving a pulse wave signal from the patient.

8. The method according to claim 7, wherein the step of deriving a pulse wave signal from the patient comprises the step of deriving a pulse wave signal from the patient (2), preferably a plethysmographic signal.

9. A system for monitoring the blood pressure of a patient, comprising: pulse wave velocity unit (7) adapted for determining a pulse arrival time signal from the patient (2) based on the pulse wave velocity method; an accelerometer (1) adapted for determining an accelerometer signal from the patient (2); and a monitoring device (3) adapted for triggering an additional measure or deriving a blood pressure value, taking into account the pulse arrival time signal and the DC component of the accelerometer signal.

10. The system according to claim 9, wherein the monitoring device (3) is adapted for comparing the value of the pulse arrival time signal with a predefined pulse arrival time threshold value.

11. The system according to claim 10, wherein a cuff adapted for a cuff-based measurement of the blood pressure of the patient is provided.
12. The system according to claim 10 or 11, wherein the monitoring device is adapted for triggering an alarm in case the blood pressure value of the cuff-based blood pressure measurement exceeds a predefined blood pressure threshold value or the pulse arrival time signal under-runs or exceeds a predefined pulse arrival time threshold value.

13. The system according to any of claims 10 to 12, wherein the monitoring device (3) is adapted for storing pre-calibrated values for pulse arrival time signal vs. DC component of the accelerometer signal.

14. The system according to any of claims 10 to 13, wherein the pulse wave velocity unit (7) comprises an ECG sensor (4) and a pulse sensor, preferably an optical sensor (5) adapted for deriving a plethysmographic signal from the patient (2).

15. The system according to any of claims 10 to 14, wherein an ECG-electrode with an integrated acceleration sensor or/and an ECG-electrode connector with an integrated acceleration sensor is provided.
FIG. 1

Start

Define PAT₀

|PAT/PAT₀| < Th?

Posture change?

Wait

Define new PAT₀

FIG. 2

Trigger cuff measurement

Critical BP

Alarm
A. CLASSIFICATION OF SUBJECT MATTER

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

INV. A61B5/0285

B. FIELDS SEARCHED

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

A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C.

See patent family annex.

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Name and mailing address of the ISA:

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Authorized officer:

Pohjamo, Terhi
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Abstract

Form PCT/ISA/210 (continuation of second sheet) (April 2005)
## INTERNATIONAL SEARCH REPORT

**Information on patent family members**

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