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(54) **METHOD FOR USE IN AN OPTIMIZATION OF A NON-INVASIVE BLOOD PRESSURE MEASUREMENT DEVICE**

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(57) **ABSTRACT**

The invention relates to an improved method for use in a optimization of a non-invasive blood pressure measurement device. The invention thereto provides a method for use in a optimization of a non-invasive blood pressure measurement device, comprising the steps of a) measuring a blood pressure related parameter with a non-invasive blood pressure measurement device, which device comprises at least one servo controller in a first configuration; b) changing the settings, in particular the gain, of the servo controller; c) monitoring the change of the blood pressure related parameter under the influence of the changing settings of the servo controller; d) determining a match between the servo controller configuration and the body part being measured based on the monitoring of the change of the blood pressure related parameter and e) adjusting the servo controller so that it matches the physiological characteristics of the measured body part.

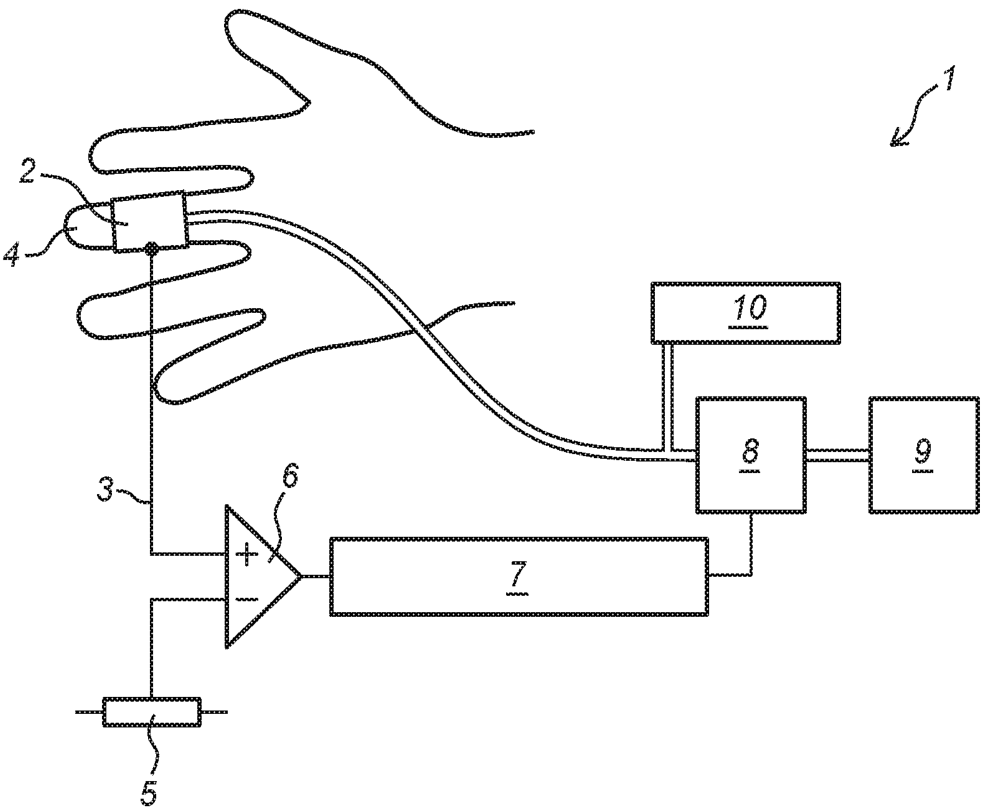


Fig. 1

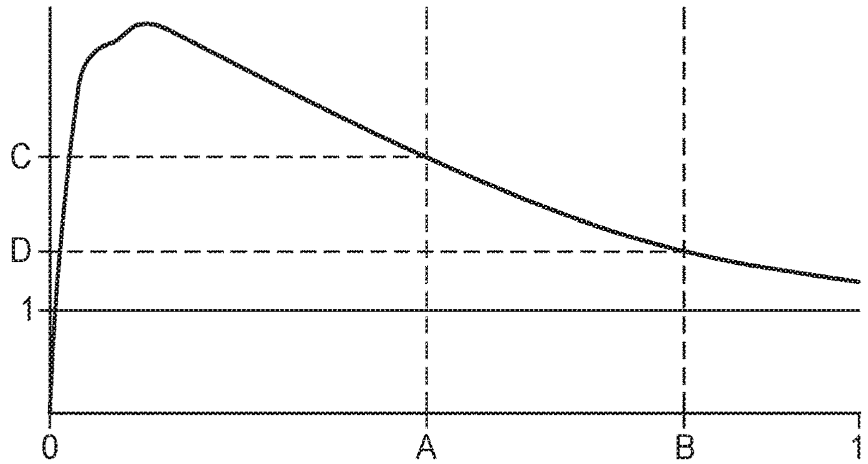


*Fig. 2A*

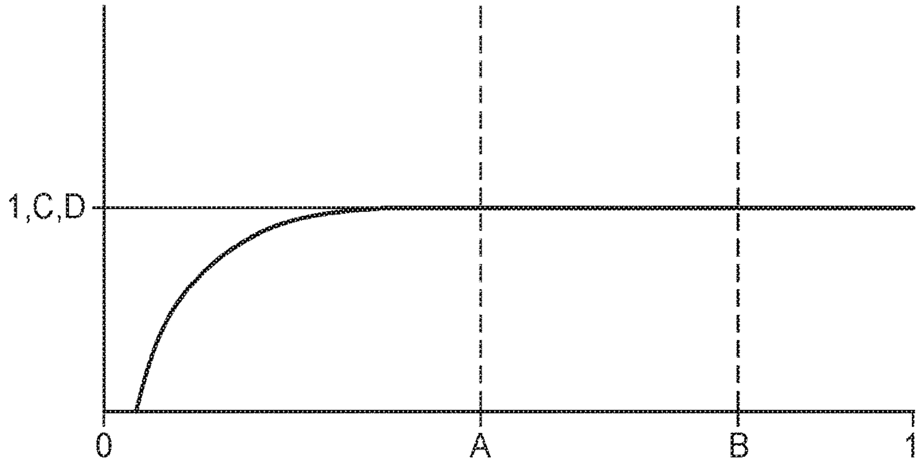


*Fig. 2B*

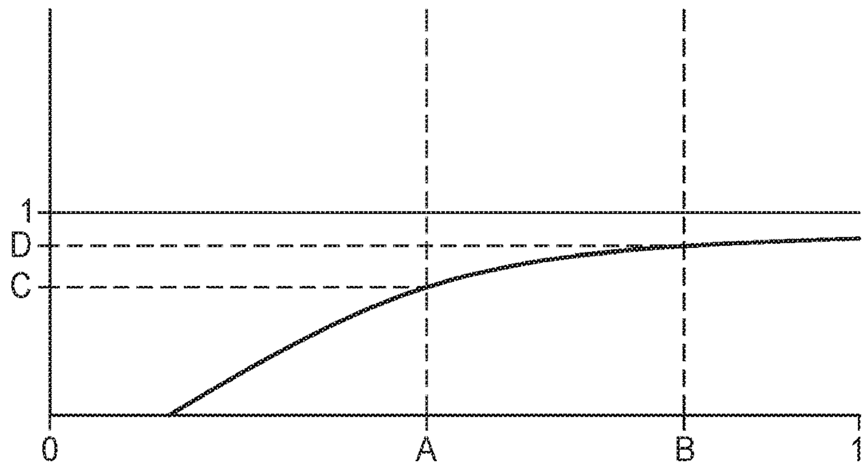


*Fig. 2C*

# METHOD FOR USE IN AN OPTIMIZATION OF A NON-INVASIVE BLOOD PRESSURE MEASUREMENT DEVICE

## CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims priority to U.S. Provisional Application No. 62/582,160, filed Nov. 6, 2017, the contents of which are incorporated herein by reference in its entirety.

## TECHNICAL FIELD

**[0002]** The present invention relates to method for use in an optimization of a non-invasive blood pressure measurement device.

## BACKGROUND OF THE INVENTION

**[0003]** It has been known for several years how to measure non-invasive blood pressure waveform continuously wherein a pressure cuff is placed around a body extremity, such as a finger. EP 0 048 060 for instance describes that the pressure of a fluid inside the cuff is controlled on the basis of a signal of a plethysmograph by a pressure valve, in turn controlled by a servo control feedback loop.

**[0004]** The signal of the plethysmograph is representing the volume of blood inside the blood vessels of the finger under the cuff. The more blood, the more light from a light source of the plethysmograph is absorbed, which results in a lower signal of the plethysmograph (and vice versa). During every heartbeat, blood is transported through the blood vessels in the finger. This causes a blood pressure and volume increase of the vessels, and thus a signal decrease of the plethysmograph.

**[0005]** In the known method, the cuff pressure of the pressure cuff is servo controlled using a valve, such that the signal of the plethysmograph, and thus the volume of blood inside the blood vessels under the cuff, is kept constant. The pressure exerted on the blood vessel walls from the inside by the heart pulsations is continuously counteracted by a pressure exerted by the pressure cuff, which results in a constant diameter of the blood vessels and, if the set point of the servo is chosen correctly, in an unloading of the vessels. In this case, the counter pressure exerted by the cuff is a direct measure for the actual blood pressure inside the blood vessel, and allows for a continuous non-invasive blood pressure measurement. Ideally, the speed in which the counter pressure exerted by the pressure cuff changes matches the speed in which the blood pressure inside the blood vessels under the cuff changes.

**[0006]** It is therefore an objective of the present invention to provide an improved method for use in an optimization of a non-invasive blood pressure measurement device.

## SUMMARY

**[0007]** The invention provides a method for use in an optimization of a non-invasive blood pressure measurement device, comprising the steps of a) measuring a blood pressure related parameter with a non-invasive blood pressure measurement device, which device comprises at least one servo controller in a first configuration; b) changing the settings, in particular the gain, of the servo controller; c) monitoring the change of the blood pressure related parameter under the influence of the changing settings of the servo controller; and d) determining a match between the servo controller configuration and the body part being measured based on the monitoring of the change of the blood pressure related parameter. The match may be optimal, such that the controller configuration and the body part are matched, or the match may be sub-optimal or off, such that a mismatch is determined. The controller may for instance be a PID controller.

**[0008]** It has been found that the servo controls can be optimized for each measured body part, in particular each body extremity, such as the fingers. For example the optimal servo control differs for warm and cold body parts, or fingers. In a cold finger for example the smooth muscles around the arteries inside the finger are contracted more compared to in warm fingers, which contraction limits blood flow to the fingers. This contracted state firms up the fingers, wherein the arteries change or expand relatively slow as well, such that a for slow responding arteries optimised servo system should be used to match this behaviour. The same applies vice versa, for warmer fingers and rapid responses.

**[0009]** One of the parameters in the servo control is the gain. Gain is a proportional value that shows the relationship between the magnitude of the input and the magnitude of the output signal at steady state. By altering the gain one can provide more or less "power" to the system. However, increasing gain or decreasing gain beyond a particular safety zone can cause the system to become unstable, since an increase in signal also increases error margins on the signals.

**[0010]** It has been found that variations in the gain in the servo control have little effect on the servo control when the servo control is matched to the body part that is measured, whereas variations in the gain have large effects on the servo control when the control is not matched. When the gain is changed during measurements, for instance during continuous non-invasive blood pressure measurements, and the change in gain does not particularly affect the results, it may be determined that the servo control is tuned, or matched, to the measured body part. On the other hand, if the change in gain causes a change in the measurement, it may be determined that the servo control is not tuned to the measured body part, and could be improved. Matching in the context of the invention means that the control is optimized for the specific body part characteristics, and that the servo controller is at the right configuration.

**[0011]** The blood pressure related parameter may be chosen from the group of pulse pressure, blood pressure or derivatives thereof. Derivatives for instance include changes in pressures over time. The group may further include parameters like controller errors, indicative of the performance of the control, which in turn are based on blood pressure related parameters or combinations of the parameters.

**[0012]** The method may further comprise the step of e) adjusting the configuration of the servo controller in relation to the determination of step d). This step is typically taken if the determination of the match, in step d), indicated that there is no (complete) match between the controls of the system and the body parts to be measured. By adjusting the configuration of the servo control, the match between the settings and the characteristics of the body part may be improved. One could for instance adapt the frequencies used or modify other servo controller characteristics or parameters to match the body part characteristics.

[0013] During step b) the settings may be changed for at least one heartbeat, in particular about 2 heartbeats. In order to be able to determine the effect of the change on the blood pressure related parameter, at least one single heartbeat should pass in the changed configuration. Since the blood pressure is variable by nature, the influence of changed servo settings can only be determined statistically, by for example measure one beat with current settings, measure the next beat with some changed servo settings, then again one beat with current settings and repeat this alternation for some period to accumulate sufficient data to determine the influence of the changed servo settings.

[0014] During step b), the settings may be changed to a value above the original setting as well as to a value below the original setting. This way, the change in blood pressure related parameters may be seen along both ways of the original setting, which could indicated whether or not an increase or a decrease of the original setting could result in an improved configuration, or a configuration which results in a better match with the characteristics of the body part which is measured.

[0015] Step d) may comprise the steps of calculating the optimal configuration of the servo controller based on the change in settings and resulting change of the blood pressure related parameter and comparing the optimal configuration with the current configuration of the servo controller. When the optimal configuration is calculated from the change in settings, an empirically determination of the best settings can be avoided, which saves time. The method according to the invention may thus include the steps of: f) calculating the optimal configuration of the servo controller based on the change in settings and resulting change of the blood pressure related parameter; and g) adjusting the configuration of the servo control to the calculated optimal configuration.

[0016] Steps b) and c) may be repeated until the change in settings, in particular the gain, does not result in a change in the blood pressure related parameter, wherein in step d) a match is established. When the change in the settings of the servo control does not influence or change the measured parameter, the servo configuration match the characteristics of the measured body part.

[0017] The steps may be repeated during measurement with the non-invasive blood pressure measurement device, in particular periodically. This enables a constant monitoring and adjustment of the match between the servo control configuration and the measured body part. For instance, when the muscle contraction in a measured finger changes during the measurement, the periodic check of the match between the finger and the servo settings will indicate that that the characteristics of the finger have changed, and the servo control may be changed because of this.

[0018] The settings, in particular the gain, of the servo controller may be normalized before changing. The normalizing may be used to consider the settings to be changed in a safe area, for instance an area which is stable. In particular when the gain is increased, high gains (so high amplifications of the signals) results in oscillation of the signal. In the normalized settings, the highest gain which is stable, and does not result in oscillation, is set to value 1. This normalized gain may for instance be used to determine a starting point for the measurements. One could for instance start the measurement at a normalized gain between 0.4 and 0.6. In turn, the change in the settings of the servo controller may be expressed in normalized gain as well, for instance by increasing or decreasing the gain by 0.1 in normalized gain.

[0019] The invention further relates to a non-invasive blood pressure measurement device configured for use in a method according to the invention, comprising at least one servo controller; and at least one blood pressure measurement tool.

[0020] The non-invasive blood pressure measurement device may comprise at least two blood pressure measurement tools, wherein a first blood pressure measurement tool may be configured for optimization of a non-invasive blood pressure measurement device, and wherein a second blood pressure measurement tool may be configured to measure blood pressure, preferably also during optimization of the device. The two tools are typically arranged on different body parts, for instance different fingers, which are comparable. This allows a continuous measurement of the blood pressure related parameter, and a continuous optimization of the servo control settings. The optimization therefore does not negatively influence the measurement of the blood pressure related parameter.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0021] The invention will be explained by means of the non-limiting working examples depicted in the following figures. Specifically:

[0022] FIG. **1** schematically shows a device for non-invasive blood pressure measurements according to the prior art; and

[0023] FIGS. **2**A-**2**C schematically show the results of different gains on a modelled finger;

## DETAILED DESCRIPTION

[0024] FIG. **1** schematically shows a device **1** for non-invasive blood pressure measurements according to the prior art, comprising a pressure cuff **2**, which generates a signal **3**, the plethysmogram, based on the detected light. This signal **3**, representative for the volume of blood in the finger **4** is compared to a set-point **5** by a comparator **6**, which comparison is then communicated to a servo controller **7**. Based on the information, the servo controller **7** in turn controls a control valve **8**. The valve **8** regulates the pressure supplied to the pressure cuff **2** by a pump **9**. The pressure supplied to the pressure cuff **2** is measured by a transducer **10**. The present invention may be used with a similar device for non-invasive blood pressure measurements, but with an improved method.

[0025] FIG. **2**A schematically shows a modelled relation between blood pressure related parameter (in this case pulse pressure) and a servo setting (in this case gain) at a first configuration, or first match. The gain of the servo is plotted on the X axis; on the Y axis the pulse pressure is depicted. The line at Y=1 represents the true pulse pressure (as used in the simulation). The curves show the measured pulse pressure (as measured with an instance of a servo with specific settings). The first configuration is a configuration in which the body part is a finger, wherein the finger artery is modelled as a first order Butterworth filter at a −3 dB frequency at 1 Hz. FIG. **2**B shows the same modelled relation with a finger with a −3 dBfrequency at 10 Hz and FIG. **2**C shows the relation with a finger with a −3 dB frequency at 100 Hz. In this example, the servo is optimised for a finger with a transfer function similar to a simple first order filter with a −3 dB point at 10 Hz. FIG. **2**B shows that, if the servo is optimised to the finger characteristics changes in gain do not alter the morphology of the blood pressure waveform. FIGS. **2**A and **2**C are examples of a mismatch between servo settings and finger characteristics, and changes in gain influence the measured pulse pressure.

**[0026]** On the X-axis of FIG. **2** a normalized gain is shown, in which the value 1, on the far right, indicates a gain at which the system becomes unstable. On the Y-axis a pulse pressure is shown in arbitrary units. On the X-axis two values (A, B) of normalized gain are indicated, and the corresponding values of the pulse pressure, on the Y-axis are indicated by two other values (C, D) respectively. As can be seen from the FIGS. **2**A-**2**C, the change in gain has significant influence on the Y-axis values in FIG. **2**A (a 1 Hz setting) and FIG. **2**C (a 100 Hz setting) and the smallest influence on these values in FIG. **2**B (a 10 Hz setting).

**[0027]** It will be apparent that the invention is not limited to the exemplary embodiments shown and described here, but that within the scope of the appended claims numerous variants are possible which will be self-evident to the skilled person in this field.

**1**. A method for use in optimization of a non-invasive blood pressure measurement device, comprising the steps of:

a. measuring a blood pressure related parameter with a non-invasive blood pressure measurement device, which device comprises at least one servo controller in a first configuration;

b. changing the settings, in particular the gain, of the servo controller

c. monitoring the change of the blood pressure related parameter under the influence of the changing settings of the servo controller; and

d. determining a match between the servo controller configuration and the body part being measured based on the monitoring of the change of the blood pressure related parameter.

**2**. A method according to claim **1**, further including the step of:

e. adjusting the configuration of the servo controller in relation to the determination of step d).

**3**. A method according to claim **1**, wherein the blood pressure related parameter is chosen from the group of consisting of pulse pressure, blood pressure and derivatives thereof.

**4**. A method according to claim **1**, wherein during step b) the settings are changed for at least one heartbeat.

**5**. A method according to claim **1**, wherein during step b), the settings are changed to a value above the original setting as well as to a value below the original setting.

**6**. A method according to claim **1**, wherein step d) comprises the steps of calculating the optimal configuration of the servo controller based on the change in settings and resulting change of the blood pressure related parameter, and comparing the optimal configuration with the current configuration of the servo controller.

**7**. A method according to claim **1**, and further comprising the steps of:

f. calculating an optimal configuration of the servo controller based on the change in settings and resulting change of the blood pressure related parameter; and

g. adjusting the configuration of the servo controller to the calculated optimal configuration.

**8**. A method according to claim **1**, wherein steps b) and c) are repeated until the change in settings, in particular the gain, does not result in a change in the blood pressure related parameter, and wherein in step d) a positive match is established.

**9**. A method according to claim **1**, wherein the steps are repeated during measurement with the non-invasive blood pressure measurement device, in particular periodically.

**10**. A method according to claim **1**, wherein step b) comprises the steps of normalizing the settings, in particular the gain, of the servo controller.

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| 专利名称(译) | 用于优化无创血压测量装置的方法 | | |
| 公开(公告)号 | US20190133466A1 | 公开(公告)日 | 2019-05-09 |
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| 外部链接 | Espacenet USPTO | | |


摘要(译)

本发明涉及一种用于优化无创血压测量装置的改进方法。本发明提供了一种用于优化无创血压测量装置的方法，包括步骤：a）利用无创血压测量装置测量血压相关参数，该装置包括至少一个伺服装置控制器处于第一配置; b）改变伺服控制器的设置，特别是增益; c）在伺服控制器的设置变化的影响下监测血压相关参数的变化; d）基于血压相关参数的变化的监测确定伺服控制器配置和被测量的身体部位之间的匹配，以及e）调整伺服控制器使其匹配测量的身体部位的生理特征。


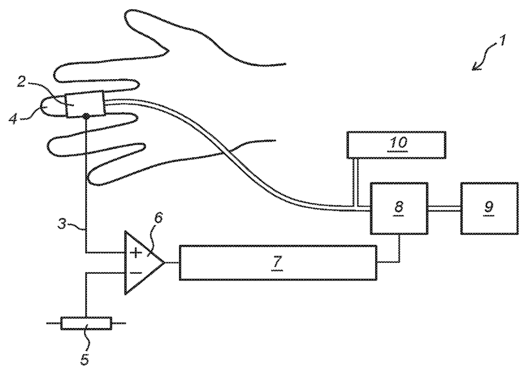

Fig. 1