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(54) **PULSE WAVE VELOCITY-TO-BLOOD PRESSURE CALIBRATION PROMPTING**

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(57) **ABSTRACT**

A system and method are provided for prompting blood pressure-related calibrations. The method relies on statistical hypothesis tests over a current measurement and an accumulated set of calibration points to determine whether the benefit of calibration, in terms of calibration diversity, outweighs the cost to the patient. The algorithm uses statistical methods to predict calibration effect without actually performing the calibration, hence, reducing the calibration 'cost' to the patient and increasing the diversity of calibration points and thereby improving PWV-BP transform quality. The method is applicable to both manual and automatic calibration modes.

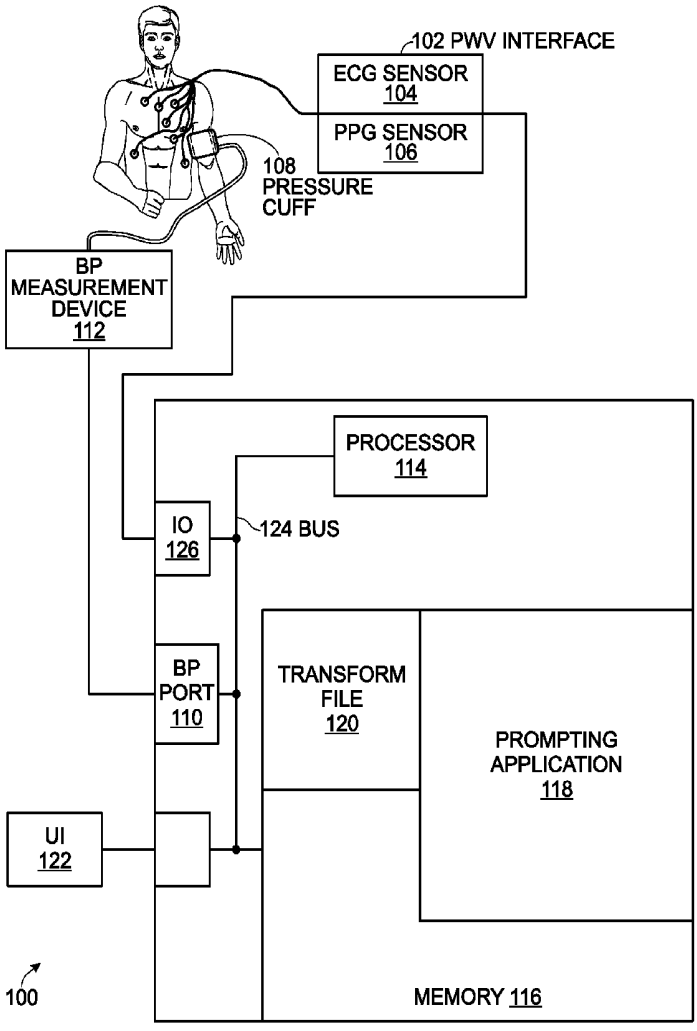


Fig. 1

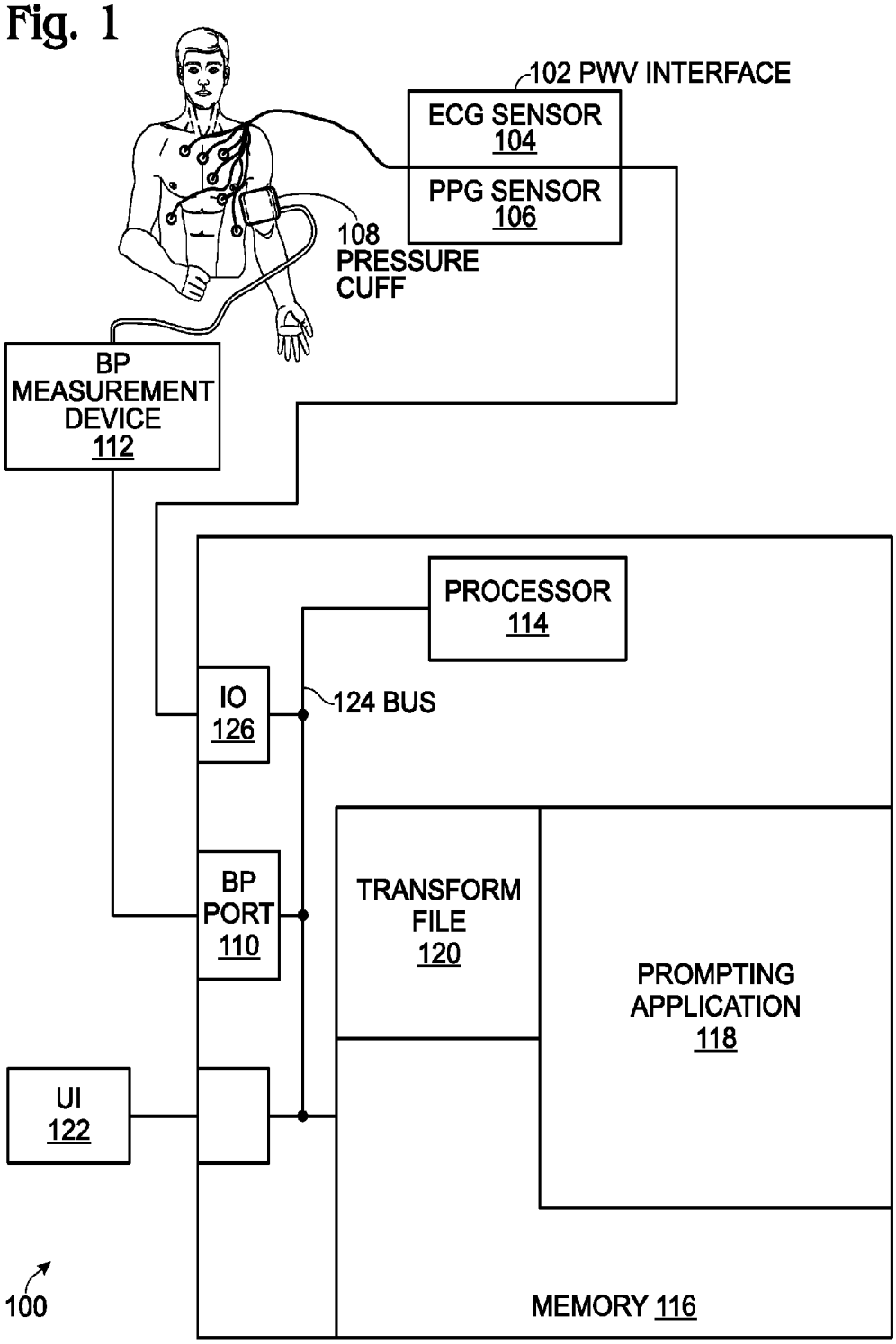

102 PWV INTERFACE
ECG SENSOR
104
PPG SENSOR
106
108
PRESSURE
CUFF
BP
MEASUREMENT
DEVICE
112
PROCESSOR
114
IO
126
124 BUS
BP
PORT
110
TRANSFORM
FILE
120
PROMPTING
APPLICATION
118
UI
122
100
MEMORY 116

Fig. 2

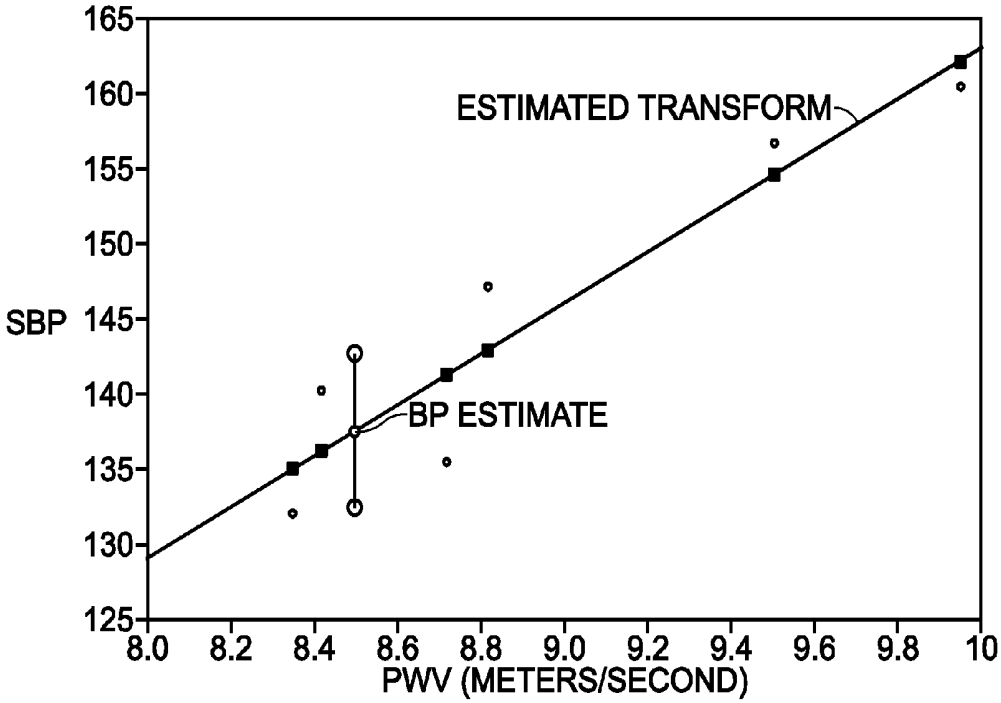

165
160
155
150
SBP 145
140
135
130
125
ESTIMATED TRANSFORM
BP ESTIMATE
8.0 8.2 8.4 8.6 8.8 9.0 9.2 9.4 9.6 9.8 10
PWV (METERS/SECOND)

Fig. 3

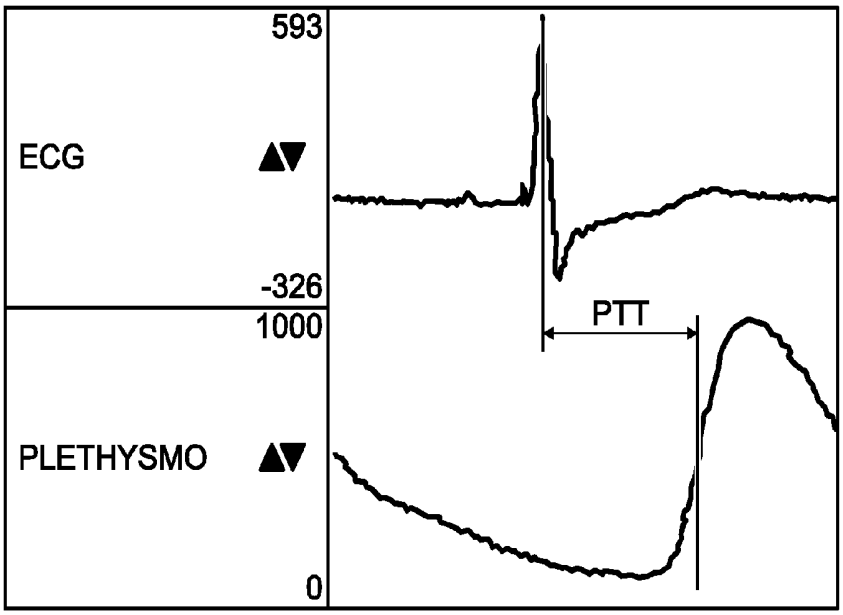

593
ECG
-326
1000
PLETHYSMO
0
PTT

Fig. 4

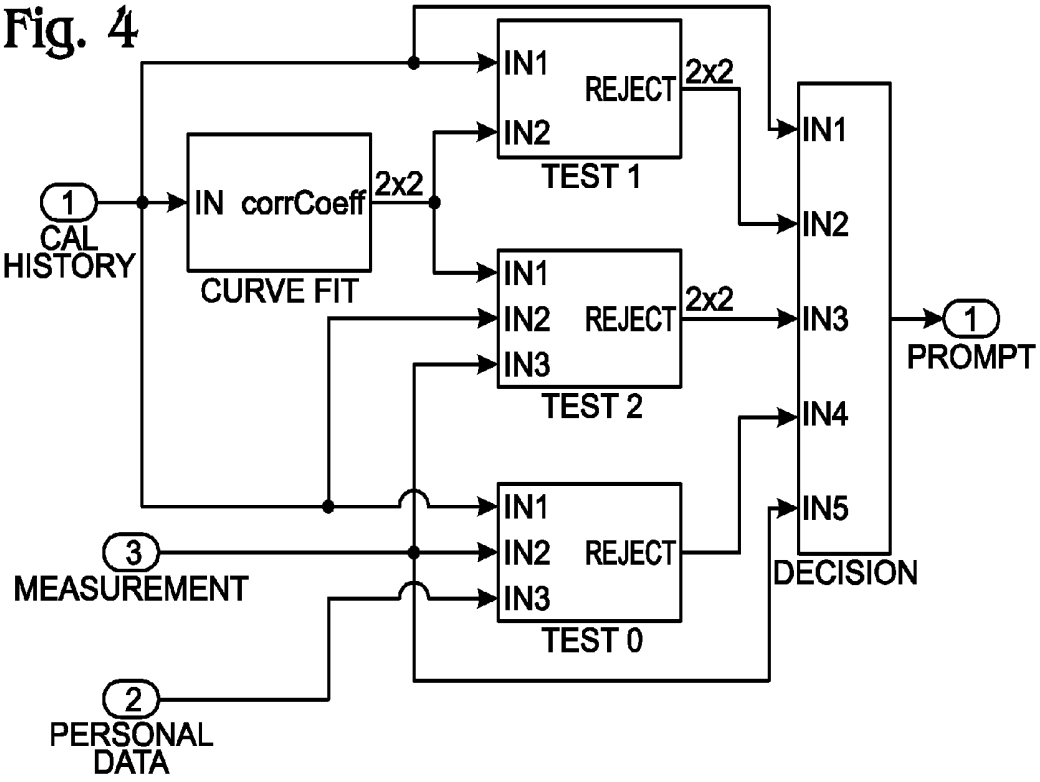

1
CAL
HISTORY
IN corrCoeff
2x2
CURVE FIT
IN1
IN2
REJECT
2x2
TEST 1
IN1
IN2
REJECT
IN3
2x2
TEST 2
IN1
IN2
REJECT
IN3
TEST 0
3
MEASUREMENT
2
PERSONAL
DATA
IN1
IN2
IN3
IN4
IN5
DECISION
1
PROMPT

Fig. 5

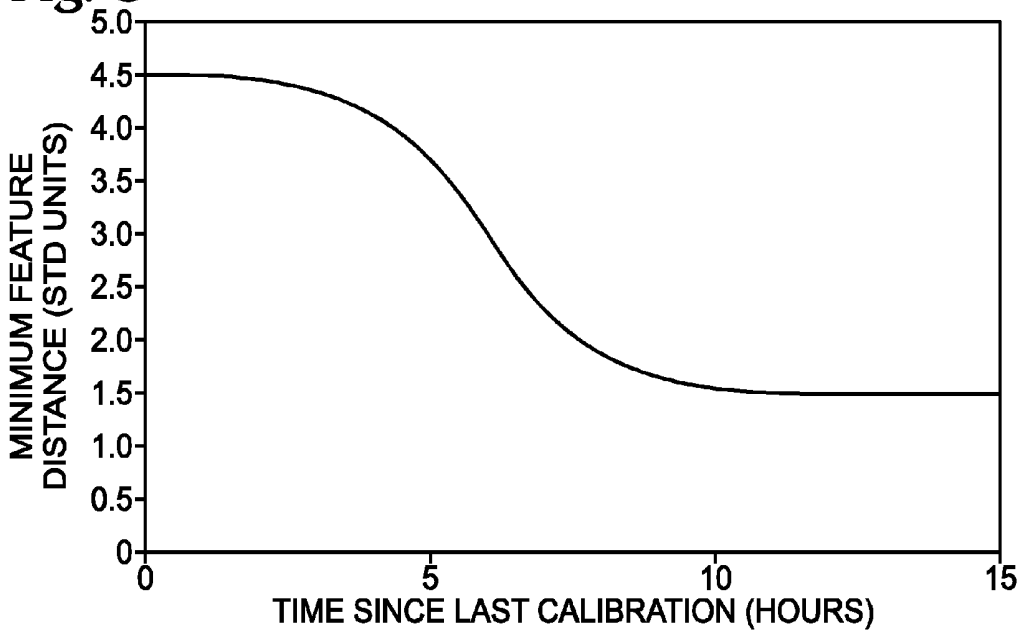
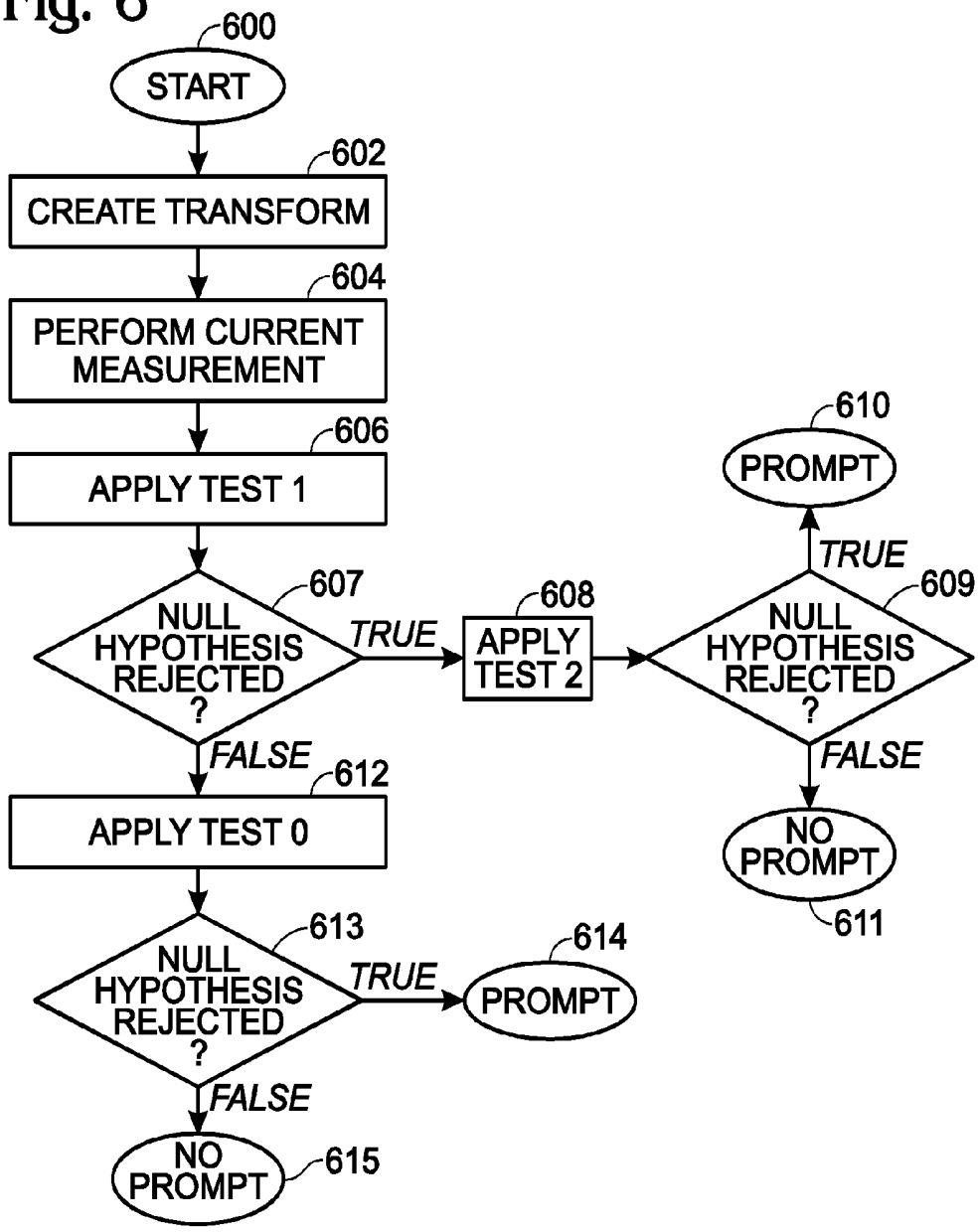

MINIMUM FEATURE
DISTANCE (STD UNITS)
5.0
4.5
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0
0
5
10
15
TIME SINCE LAST CALIBRATION (HOURS)

Fig. 6


600
START
602
CREATE TRANSFORM
604
PERFORM CURRENT MEASUREMENT
606
APPLY TEST 1
607
NULL HYPOTHESIS REJECTED ?
TRUE
608
APPLY TEST 2
609
NULL HYPOTHESIS REJECTED ?
TRUE
610
PROMPT
FALSE
NO PROMPT
611
FALSE
612
APPLY TEST 0
613
NULL HYPOTHESIS REJECTED ?
TRUE
614
PROMPT
FALSE
NO PROMPT
615

PULSE WAVE VELOCITY-TO-BLOOD PRESSURE CALIBRATION PROMPTING

RELATED APPLICATIONS

[0001] This application incorporates by reference an application entitled, SYSTEM AND METHOD FOR DERIVING A PULSE WAVE VELOCITY-BLOOD PRESSURE TRANSFORM, invented by Fredrick Hill, Ser. No. 14/932,019, filed Nov. 4, 2015, Attorney Docket No. SLA3572.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention generally relates to blood pressure measurement and, more particularly, to a system and method for determining when pulse wave velocity-to-blood pressure calibration is advantageous.

[0004] 2. Description of the Related Art

[0005] In recent years, consensus has developed that a strong correlation exists between arterial pulse wave velocity (PWV) and systolic and diastolic blood pressure [1]. A PWV measurement involves a combination of simultaneous electrocardiography (ECG or EKG) and photoplethysmography (PPG) measurements. Electrocardiography is the process of recording the electrical activity of the heart over a period of time using electrodes placed on a patient's body. These electrodes detect the tiny electrical changes on the skin that arise from the heart muscle depolarizing during each heartbeat. During each heartbeat, a healthy heart has an orderly progression of depolarization that starts with pacemaker cells in the sinoatrial node, spreads out through the atrium, passes through the atrioventricular node down into the bundle of His and into the Purkinje fibers spreading down and to the left throughout the ventricles. This orderly pattern of depolarization gives rise to the characteristic ECG tracing.

[0006] Photoplethysmography is a method of measuring the perfusion of blood to the dermis and subcutaneous tissue by illuminating the tissue at the surface and observing variations of the light. With each cardiac cycle the heart pumps blood to the periphery. In recent practice, the change in blood volume caused by the pressure pulse of the cardiac cycle is detected by illuminating the skin with a light-emitting diode (LED) and measuring the amount of light either transmitted or reflected to a photodiode. The resulting waveform characterizes the relative blood volume of the tissue over time.

[0007] A blood pressure (BP) measurement based on PWV has many appealing qualities. The measurement requires no arterial compression and no recovery period. The measuring device can be small and inconspicuous and might even be worn for long periods. The measurement is very fast, producing a new blood pressure estimate on every heartbeat. As such, it is possible to estimate measurement uncertainty and reduce measurement error by methods like time averaging, uncertainty weighting, and median filters. A key challenge to the PWV-BP measurement is producing an accurate transform from PWV to BP. Characterization of the transform from PWV-to-BP can be performed by fitting a transform curve to pairs of PWV and BP samples collected from a patient. This fit effectively calibrates the transform curve to a specific patient and, as such, the (PWV, BP) pairs might be called calibration points.

[0008] Multipoint calibration can improve BP estimation significantly over single point [1]. A high quality calibration set reflects diversity in the patient state and exhibits a wide range on the measurement axes, which serves to guard against extrapolation. In currently available PWV-BP products, recalibration (if addressed at all) is triggered solely on the passage of time. Yet, passage of time does not ensure range or diversity in the calibration set. One innovative product for hospital use [11, 12] uses an integral pressure cuff to induce diversity in the calibration measurement. Recalibration is required every 4-8 hours and calibration measurements are discarded on the following calibration. This mode of operation is not appropriate for the general home-use case. Calibration is associated with a cost to the patient (e.g., time, distraction, discomfort). That cost must be considered in the calibration process, especially in the home use case where calibration is typically be performed manually and the cost may be especially high in the context of a busy patient schedule. So the challenge presented by the home use case is to balance the goal of collecting a diverse calibration set representative of recent patient state with the cost of calibration.

[0009] It would be advantageous if there existed a PWV-BP calibration prompting method able to collect a diverse calibration sets with a minimum of bother to the user, and had the capability of predicting calibration effect without actually performing the calibration.

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[0011] 2. SYSTEM AND METHOD FOR DERIVING A PULSE WAVE VELOCITY-BLOOD PRESSURE TRANSFORM, invented by Fredrick Hill, Ser. No. 14/932,019, filed Nov. 4, 2015, Attorney Docket No. SLA3572.

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SUMMARY OF THE INVENTION

[0025] A blood pressure (BP) measurement based on Pulse Wave Velocity (PWV) has many appealing qualities. The measurement requires no arterial compression and no recovery period. The measuring device can be small and inconspicuous and might even be worn for long periods. The measurement is very fast, producing a new blood pressure estimate on every heartbeat. As such, it is possible to estimate measurement uncertainty and reduce measurement error by methods like time averaging, uncertainty weighting, and median filters.

[0026] A PWV-BP device typically monitors the electrocardiography (ECG) and photoplethysmography (PPG) signals as the basis of its measurement. Specifically, the device measures the time interval between the ECG R-wave and the foot of the perfusion pulse [4] acquired through PPG and derives the PWV as a function of the distance from the heart to the PPG measurement site.

[0027] As disclosed herein, the short-term sample statistics of the PWV-BP measurement can be leveraged with an approach that at least ensures that 1) calibrations are reasonably spaced from previous calibrations along some meaningful dimension, 2) the spacing reflects the time from the last calibration, and 3) the calibration set evolves with the patient state. The second requirement reflects the use case and the cost of calibration. If a calibration was recently requested, the diversity payoff should be high before requesting again.

[0028] The calibration prompting algorithm rests on three statistical hypothesis tests, labeled Test 0, Test 1, and Test 2, for simplicity. These are known in inferential statistics [15] as null hypotheses.

[0029] Accordingly, a method is provided for prompting blood pressure-related calibrations. The method creates a transform of a calibration set that includes a plurality of sample pairs. Each sample pair includes a mean measurement of pulse wave velocity correlated to a measured reference blood pressure value, and each mean PWV measurement is derived from a plurality of PWV observations. After taking a current mean PWV measurement a model utility test is performed comparing an estimated slope of the transform to an estimated standard deviation of the slope (Test 1). If a null hypothesis of the model utility test is rejected, a first normalized mean difference test is performed comparing a current blood pressure estimate with a mean calibration reference blood pressure over the calibration set (Test 2). If a null hypothesis of the first normalized mean difference test is rejected, a calibration of the transform is prompted. The calibration includes augmenting the calibration set with actual BP measurements correlated to the current mean PWV measurement. If the null hypothesis of the model utility test is not rejected, a second normalized mean difference test is performed comparing the mean of the PWV over the calibration set with the current mean PWV measurement (Test 0). If the null hypothesis of the second mean difference test is rejected, a calibration of the transform is prompted.

[0030] More explicitly, performing the model utility test (Test 1) includes finding a test statistic value of t less than a first predetermined value,

$$t = \frac{\hat{\beta}_1 - \beta_{10}}{s_{\hat{\beta}_1}}$$

[0031] where $\hat{\beta}_1$ is the estimated transform slope;

[0032] where β_{10} is the hypothesis transform slope; and,

[0033] where $s_{\hat{\beta}_1}$ is the estimated standard deviation of the transform slope.

[0034] Performing the first normalized mean difference test (Test 2) includes finding the difference between the mean calibration reference blood pressure and the current blood pressure estimate normalized by a standard deviation product over the calibration set. Performing the second normalized mean difference test (Test 0) includes finding the difference between the current PWV estimate and the mean PWV over the calibration set normalized by a PWV standard deviation product.

[0035] In one aspect, performing the first normalized mean difference test (Test 2) includes adjusting the confidence threshold of the first normalized mean difference test as a function of time since the last-occurring previous calibration. Likewise, performing the second normalized mean difference test (Test 0) may also include adjusting the confidence threshold of the second normalized mean difference test as a function of time since the last-occurring previous calibration. In another aspect, performing the model utility test (Test 1), performing the first normalized mean difference test (Test 1), and performing the second normalized mean difference test (Test 0) may all, or individually include deleting the oldest elements of the calibration set as a function of time since the last-occurring previous calibration.

[0036] Additional details of the above-described method and a system for prompting blood pressure-related calibrations are presented below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] FIG. **1** is a schematic block diagram of a system for prompting blood pressure-related calibration.

[0038] FIG. **2** is a graph of systolic blood pressure (SBP) vs. PWV measurements depicting a calibration set (dots), estimated PWV-to-BP transform, BP estimates (squares), and BP estimate with a confidence interval.

[0039] FIG. **3** illustrates waveforms of an exemplary PWV measurement that may be acquired on every arterial pulse.

[0040] FIG. **4** shows a block diagram of the tests, the final prompt generation, and a curve fit block, which provides inputs to Test 1 and 2.

[0041] FIG. **5** is a graph depicting a continuous gating function.

[0042] FIG. **6** is a flowchart illustrating a method for prompting calibration based upon the above-described tests.

DETAILED DESCRIPTION

Definitions

[0043] Calibration Prompt—May be an audio tone, an active icon on a display, a voice prompt, or any indication which serves to entice the patient to calibrate the pulse wave velocity-to-blood pressure (PWV-BP) device. If a pliant patient is assumed who calibrates when (and only when) prompted, then the terms "calibrate" and "prompt" may be used interchangeably. On a worn PWV-BP device, with an integral electronically-actuated cuff measurement device, the prompt might be the cuff actuation trigger.

[0044] Feature—A characteristic of the photoplethysmography (PPG) and/or electrocardiography (ECG) signals.

[0045] Measurement—The result of an estimator (e.g., mean or median) over k observations of the PWV feature. A measurement is associated with a standard deviation over the observations and a timestamp representing the time and date of the observations. Observations typically occur once per arterial pulse. The number of observations (i.e., k) is stipulated to be greater than some minimum to improve significance of the sample statistics.

[0046] Transform Model—a linear model is typically assumed between PWV and BP or some linearizing function of the PWV and BP. The model has two parameters β_0 and β_1, representing the intercept and slope of the model equation.

[0047] FIG. **1** is a schematic block diagram of a system for prompting blood pressure-related calibration. The system **100** comprises a PWV measurement interface **102** comprising an electrocardiogram (ECG) sensor **104** and a photoplethysmography (PPG) sensor **106** for measuring ECG and PPG signals. As noted above, the PWV feature is derived from ECG and PPG measurements. Typically, the PPG sensor **106** comprises a light emission device and a light sensing device (not shown) for detecting changes in optical transmittance of an illuminated test subject body. Typically, the ECG sensor **104** comprises at least two electrodes. The system **100** also includes a BP port **110** to accept BP measurements. As shown, a BP measurement device **112** may be connected to the BP port **110** to supply BP measurements, however taken. In one aspect, the BP measurement device **112** collects BP measurements when connected to a pressure cuff **108**. As system **100** is typically used, the collection of BP measurements occurs more infrequently than PWV measurements, and in some aspects the BP port **110** is not always connected. The device further comprises a processor **114**. A non-transitory memory **116** includes a prompting application **118** and a transform file **120**.

[0048] For the sake of simplicity the system **100** is described in the context of a single (PWV) feature. However, as explained in more detail below, multiple features may be measured in addition to, or as an alternative to PWV. In that case, other measurement devices (not shown) may be connected to the system. The transform file **120** comprises a calibration set including a plurality of sample pairs. Each sample pair includes a mean measurement of pulse wave velocity correlated to a measured reference blood pressure values, and each mean PWV measurement is derived from a plurality of PWV observations.

[0049] The prompting application **118** is enabled as a sequence of processor instructions for accepting a current mean PWV measurement, performing a model utility test comparing the difference between an estimated slope of the transform and its hypothesis value to an estimated standard deviation of the slope (Test 1). If the null hypothesis of the model utility test is rejected, a first normalized mean difference test is performed comparing a current blood pressure estimate with a mean calibration reference blood pressure over the calibration set (Test 2). If the null hypothesis of the first normalized mean difference test is rejected, the prompting application **118** determines that the transform would benefit from calibration and issues a calibration prompt. In that case, the prompting application **118** accepts BP measurements using the cuff **108**, BP measurement device **112**, and BP port **110** in response to the prompt, modifies the transform by augmenting the calibration set with actual BP measurements correlated to current mean PWV measurements.

[0050] The prompting application **118** performs a second normalized mean difference test when the null hypothesis of the model utility test is not rejected, comparing the mean of the PWV over the calibration set with the current mean PWV measurement (Test 0). If the null hypothesis of the second mean difference test is rejected, a calibration of the transform is prompted.

[0051] In one aspect, the prompting application **118** performs the model utility test (Test 1) by finding a test statistic value of t less than a first predetermined value,

$$t = \frac{\hat{\beta}_1 - \beta_{10}}{s_{\hat{\beta}_1}}$$

[0052] where $\hat{\beta}_1$ is the estimated transform slope;

[0053] where β_{10} is the hypothesized transform slope; and,

[0054] where $s_{\hat{\beta}_1}$ is the estimated standard deviation of the transform slope.

[0055] The prompting application **118** calculates the estimated standard deviation of the slope ($s_{\hat{\beta}_1}$) as follows:

$$S_{\hat{\beta}_1} = \frac{s}{\sqrt{S_{xx}}} = \frac{\sqrt{\frac{SSE}{N-2}}}{\sqrt{\sum (x_i - \bar{x})^2}}$$

[0056] where SSE(sum of the squared errors) is defined as:

$$SSE=\Sigma(y_i-\hat{y}_i)^2;$$

[0057] wheres s is

$$\sqrt{\frac{SSE}{N-2}};$$

[0058] where S_{xx} is $\Sigma(x_i-\bar{x})^2$;

[0059] where x_i is a PWV measurement in the calibration set;

[0060] where $\bar{x}$ is the mean PWV over the calibration set;

[0061] where N is the number of PWV measurements within the calibration set;

[0062] where y_i is a reference blood pressure measurement in the calibration set; and,

[0063] where $\hat{y}_i$ is an estimated blood pressure resulting from transforming PWV measurement x_i.

[0064] The prompting application **118** performs the first normalized mean difference test (Test 2) by finding the difference between the mean calibration reference blood pressure and the current blood pressure estimate normalized by a standard deviation product over the calibration set. More explicitly, the prompting application **118** performs Test 2 by finding a test statistic (t) as follows:

$$t = \frac{\overline{Y} - \mu_0}{\partial / \sqrt{N}}$$

[0065] where $\overline{Y}$ is the blood pressure mean over the N calibration measurements;

[0066] where μ_0 is the Test 2 hypothesis mean, which is taken as the current blood pressure estimate produced by applying the transform to the current mean PWV measurement;

[0067] where ∂ is a sample standard deviation of the reference blood pressure over the calibration set.

[0068] In one aspect, the prompting application **118** performs the second normalized mean difference test (Test 0) by finding the difference between the current PWV estimate and the mean PWV over the calibration set normalized by a PWV standard deviation product. More explicitly, the prompting application **118** performs Test 0 by finding a test statistic (t) as follows:

$$t = \frac{\overline{X} - \mu_0}{\partial / \sqrt{N}}$$

[0069] where $\overline{X}$ is the PWV mean over the N calibration measurements;

[0070] where μ_0 is the Test 0 hypothesis mean, which is taken as the current mean PWV measurement; and,

[0071] where ∂ is estimated as a population-based standard deviation over the patient's demographic group.

[0072] In another aspect, the prompting application **118** performs the first normalized mean difference test (Test 2) by adjusting a confidence threshold of the first normalized mean difference test as a function of time since the last-occurring previous calibration. Likewise, the prompting application **118** may perform the second normalized mean difference test (Test 0) by adjusting the confidence threshold of the second normalized mean difference test as a function of time since the last-occurring previous calibration.

[0073] In one aspect, the prompting application **118** performs the model utility test (Test 1) by deleting the oldest elements of the calibration set as a function of time since the last-occurring previous calibration. In addition, the prompting application **118** may perform the first normalized mean difference test (Test 2) by deleting the oldest elements of the calibration set as a function of time since the last-occurring previous calibration. Further, the prompting application **118** may perform the second normalized mean difference test (Test 0) by deleting the oldest elements of the calibration set as a function of time since the last-occurring previous calibration.

[0074] The system **100** may also include a bus **124**, input/output (IO) port **126**, and user interface (UI) **122**. The communication bus **124** may, for example, be a Serial Peripheral Interface (SPI), an Inter-Integrated Circuit (I^2C), a Universal Asynchronous Receiver/Transmitter (UART), and/or any other suitable bus or network. Although the drawing implies that the components of the system are essentially collocated in the same device, in some aspects various components may be located outside the device, communicating with other components via a wired or wireless connection.

[0075] The memory **116** may include a main memory, a random access memory (RAM), or other dynamic storage devices. These memories may also be referred to as a computer-readable medium. Such a medium may take many forms, including but not limited to, non-volatile media, volatile media, and transmission media. Non-volatile media includes, for example, optical or magnetic disks. Volatile media includes dynamic memory. Common forms of computer-readable media include, for example, a floppy disk, a flexible disk, hard disk, magnetic tape, or any other magnetic medium, a CD-ROM, any other optical medium, punch cards, paper tape, any other physical medium with patterns of holes, a RAM, a PROM, and EPROM, a FLASH-EPROM, any other memory chip or cartridge, or any other medium from which a computer can read. The execution of the sequences of instructions contained in a computer-readable medium (i.e. screening application **120**) may cause the processor **114** to perform some of the steps of determining PWV-BP transform validity. Alternately, some of these functions may be performed in hardware (not shown). The practical implementation of such a computer system would be well known to one with skill in the art. In one aspect, the processor **114** is an ARM processor using a reduced instruction set computing (RISC) architecture.

[0076] The user interface **122** and IO port **126** may incorporate a display, a modem, an Ethernet card, or any other appropriate data communications device such as USB. The physical communication links may be optical, wired, or wireless. The user interface **122** may incorporate a keypad or a cursor control device such as a mouse, touchpad, audio speaker or alarm, touchscreen, trackball, stylus, or cursor direction keys. In one aspect of the system, the UI **122** is the component of the system delivering the calibration prompting messages to the user.

[0077] The system **100** may include a special purpose computing system, and as such, can be programmed, configured, and/or otherwise designed to comply with one or more networking protocols. According to certain embodiments, the system **100** may be designed to work with protocols of one or more layers of the Open Systems Interconnection (OSI) reference model, such as a physical layer protocol, a link layer protocol, a network layer protocol, a transport layer protocol, a session layer protocol, a presentation layer protocol, and/or an application layer protocol. For example, IO **126** may include a network device configured according to a Universal Serial Bus (USB) protocol, an Institute of Electrical and Electronics Engineers (IEEE) 1394 protocol, an Ethernet protocol, a T1 protocol, a Synchronous Optical Networking (SONET) protocol, a Synchronous Digital Hierarchy (SDH) protocol, an Inte-

grated Services Digital Network (ISDN) protocol, an Asynchronous Transfer Mode (ATM) protocol, a Point-to-Point Protocol (PPP), a Point-to-Point Protocol over Ethernet (PPPoE), a Point-to-Point Protocol over ATM (PPPoA), a Bluetooth protocol, an IEEE 802.XX protocol, a frame relay protocol, a token ring protocol, a spanning tree protocol, and/or any other suitable protocol.

[0078] The system **100** may provide a direct connection to a remote server via a direct link to a network, such as the Internet. Connection may be provided through, for example, a local area network (such as an Ethernet network), a personal area network, a wide area network, a private network (e.g., a virtual private network), a telephone or cable network, a cellular telephone connection, a satellite data connection, or any other suitable connection.

[0079] In certain embodiments, a host adapter is configured to facilitate communication between system **100** and one or more network or storage devices via an external bus or communications channel. Examples of host adapters include, without limitation, Small Computer System Interface (SCSI) host adapters, Universal Serial Bus (USB) host adapters, IEEE 1394 host adapters, Advanced Technology Attachment (ATA), Parallel ATA (PATA), Serial ATA (SATA), and External SATA (eSATA) host adapters, Fibre Channel interface adapters, Ethernet adapters, or the like.

[0080] FIG. **2** is a graph of systolic blood pressure (SBP) vs. PWV measurements depicting a calibration set (dots), estimated PWV-to-BP transform, BP estimates (squares), and BP estimate with a confidence interval. Characterization of the transform from PWV to BP can be performed by fitting a transform curve to pairs of PWV and BP samples collected from a patient. This fit effectively calibrates the transform curve to a specific patient and, as such, the (PWV, BP) pairs might be called calibration points.

[0081] FIG. **3** illustrates waveforms of an exemplary PWV measurement that may be acquired on every arterial pulse. The PWV-BP system **100** typically monitors the ECG and PPG signals as the basis of its measurement. Specifically, the device measures the time interval between the ECG R-wave and the foot of the perfusion pulse [4] acquired through PPG as derives the PWV as a function of the distance traveled from the heart to the PPG measurement site.

[0082] FIG. **4** shows a block diagram of the tests, the final prompt generation, and a curve fit block, which provides inputs to Test 1 and 2. The calibration prompting algorithm rests on three statistical hypothesis tests, labeled Test 0, Test 1, and Test 2, for simplicity. These are known in inferential statistics [15] as null hypotheses.

Test 0—Significance of PWV Difference

[0083] Test 0 is the most rudimentary of the three tests. Its null hypothesis is that the normalized difference between the mean calibration PWV and the current PWV measurement is insignificant. Hence, calibration should not be prompted. It relies only on the personal data, the current measurement, and the PWV values in the calibration history. If the calibration history is empty, the Test 0 null hypothesis is rejected (ultimately leading to a calibration prompt). Otherwise, the following test statistic is used:

$$t = \frac{\overline{X} - \mu_0}{\partial / \sqrt{N}} \tag{0}$$

and has approximately standard normal distribution. $\overline{X}$ is the PWV sample mean (or median) over the N calibration measurements and μ_0 is the hypothesis mean, which is taken as the current PWV measurement. (Recall that each measurement is the mean over many observations.) The parameter a (PWV standard deviation) is interpolated from published population values (e.g., [14]) based on the patient's personal data (e.g., age and gender).

[0084] The notion of p-value provides the basis for stating the test criterion. A p-value is a statistical mechanism used in hypothesis testing. It provides a frame of reference in probability for setting test limits. Specifically, the p-value is the probability of obtaining a result in the test statistic equally or more adverse to the null hypothesis than the value given by the current measurement. This probability is taken under the assumption that the test hypothesis holds. For example, assume that the current PWV is 7.0 m/s and there are two calibration points whose mean value is 6.5. The patient's age is 35, for which is derived a population-based PWV standard deviation of 2.7. This gives a t-value of

$$t = \frac{\overline{X} - \mu_0}{\partial / \sqrt{N}} = \frac{6.5 - 7.0}{2.7 / \sqrt{2}} = -0.2619 \tag{1}$$

PWV measurements greater than or equal to 7.0 or less than or equal to 6.0 would be "equally or more adverse", yielding limits on t of ±0.2619. The probability of a t-value "equally or more adverse" is "two-sided" and (given the standard normal distribution of t) is calculated as:

$$p(|t| \geq t_0) = 2*(1-\phi(t_0)) \tag{2}$$

where $\phi(t)$, is the standard normal cumulative density function. For the example above:

$$p(|t| \geq 0.2619) = 2*(1-\phi(0.2619)) = 79\% \tag{3}$$

[0085] So, the likelihood of a PWV with greater diversity (more adverse to the null hypothesis) is quite high. Assuming a significance limit at 35% (i.e., $H_0 \equiv p(|t| \geq t_0) > 0.35$), then the Test 0 hypothesis would "fail to reject" (because $p(|t| \geq 0.2619) > 35\%$). Now assume μ_0 is 8.4 m/s. Then t and the corresponding p-value are:

$$t = \frac{\overline{X} - \mu_0}{\partial / \sqrt{N}} = \frac{6.5 - 8.4}{2.7 / \sqrt{2}} = -0.9952 \tag{4}$$

$$p(|t| > 0.9952) = 2 * (1 - \varphi(0.9952)) = 32\% \tag{5}$$

[0086] The null hypothesis would then be rejected. This result means that the difference in (1) is statistically significant, relative to the p-value threshold of 35%.

[0087] The algorithm uses a p-value threshold that is dependent on the time since the previous calibration and is decreasing. As such, the method ensures a statistical premium for more frequent calibrations and balances the cost of calibration (to the user) with its statistical advantage and

utility in gathering a diverse calibration set. The calibration history over which the t-value is calculated is limited to a fixed time window.

[0088] This forces evolution of the calibration set to reflect recent patient state.

Test 1 and 2—Difference Significance in Terms of Blood Pressure

[0089] Test 0 ensures meaningful calibration when few calibration points have been collected or any time when the calibration points fail to conform to the transform model. However, once the personal PWV-BP transform has been established, much of the mechanism for screening the personal transform (described in [2]) may also serve to determine calibration prompts.

[0090] From a wide perspective, Test 1 serves to establish the utility of the linear regression model in characterizing the calibration set. Test 2 assumes model utility and establishes the significance of the difference between the current BP estimate (from transformed PWV) and the mean calibration BP. Both Test 1 and Test 2 require a curve fit of the calibration parameters—a linear regression with appropriate linearization of the parameters.

[0091] Test 1 determines the 'utility' of the model relative to the calibration set. A small number of calibration points or a calibration set lacking diversity tends to confirm the null hypothesis that the model does not offer a useful characterization of the PWV-BP transform. Greater diversity and point count in the calibration set tends to reject the Test 1 null hypothesis and indicate that the model is useful for characterizing the relationship between PWV and BP.

[0092] Specifically, following [2] with equations renumbered:

[0093] Specifically, the Test 1 null hypothesis is confirmed when the calibration set is empty (e.g., N=0). Otherwise, Test 1 relies on the standardized variable:

$$t = \frac{\hat{\beta}_1 - \beta_1}{s_{\hat{\beta}_1}} \tag{6}$$

[0094] where β_1 is the true (and unobservable) regression slope, $\hat{\beta}_1$ is the estimated slope, and $s_{\hat{\beta}_1}$ is the estimated standard deviation of the slope. The quantity $\hat{\beta}_1-\beta_1$ is an estimate residual, the difference between an estimated value and its true value. The hypothesis assumes β_1 to be a small positive value less than the smallest slope expected (e.g., 8)

[0095] The estimated standard deviation of the slope ($s_{\hat{\beta}_1}$) is calculated as:

$$S_{\hat{\beta}_1} = \frac{s}{\sqrt{S_{xx}}} = \frac{\sqrt{\frac{SSE}{N-2}}}{\sqrt{\sum (x_i - \bar{x})^2}} \tag{7}$$

[0096] where SSE is defined as:

$$SSE=\Sigma(y_i-\hat{y}_i)^2 \tag{8}$$

[0097] The numerator of (7) is the sample standard deviation of the estimate. The term (N−2) represents the degrees of freedom associated with the sum of squared errors (SSE) of the transform applied to the calibration set. The SSE is simply a squaring and summing of the residuals of the transform over the calibration set.

[0098] The Test 1 hypothesis states that

$$t<t_{\alpha/2,n-2} \tag{9}$$

[0099] where t_{an-2} is the value of the Student's T distribution CDF at a for n−2 degrees of freedom. The quantity t has a Student T distribution with n−2 degrees of freedom. The statistical interpretation is that over many trials, the true (unobservable) value of t lies within the stated interval with probability 1−α (e.g., 99%). Since the hypothesis is stated with a wide margin, the failure of (9) provides strong evidence that the slope of the transform is non-zero, which implies the utility of the linear model in characterizing the calibration set and implies the inferential validity of the resulting transform. Furthermore, the assumption of small positive β_1 ensures that the hypothesis is rejected only on strong evidence of a positive slope.

[0100] Test 2 depends on the rejection of the Test 1 null hypothesis. That is, Test 2 depends on model utility and, like Test 0, it is structured as a p-test. While Test 0 compares the mean calibration PWV to the current PWV measurement normalized to a population-derived PWV standard deviation, Test 2 compares the mean calibration blood pressure to the current BP estimate normalized by a product of the BP standard deviation in the calibration set. The test statistic is identical to that used for Test 0. From (0) above:

$$t = \frac{\bar{Y} - \mu_0}{\partial / \sqrt{N}} \tag{10}$$

[0101] where t has approximately standard normal distribution. $\bar{Y}$ is the blood pressure mean over the N calibration measurements and μ_0 is the hypothesis mean, which is taken as the current blood pressure estimate (i.e., $\hat{Y}=\hat{\beta}_0+\hat{\beta}_1 x^*$). The parameter ∂ is estimated as the blood pressure sample standard deviation over the calibration set.

[0102] For example, if the current systolic BP is assumed to be 122.0 mmHg, there are eight calibration points whose mean value is 120.0 and the calibration set SBPs have a standard deviation of 5.0 mmHg.

[0103] This gives a t-value of

$$t_0 = \frac{\bar{X} - \mu_0}{\partial / \sqrt{N}} = \frac{120 - 122}{5.0 / \sqrt{8}} = -1.1314 \tag{11}$$

[0104] The probability of a t-value "equally or more adverse" is:

$$p(|t|\geq 1.13)=2*(1-\phi(1.13))=26\% \tag{12}$$

[0105] In this case, a reasonable likelihood of getting a "better", more diverse, estimate may be inferred. If the current BP estimate was 128, then:

$$t_0 = \frac{\bar{X} - \mu_0}{\partial / \sqrt{N}} = \frac{120 - 128}{5.0 / \sqrt{8}} = -4.5253 \tag{13}$$

$$p(|t| \geq 4.5253) = 2 * (1 - \varphi(4.5253)) < 0.00001 \tag{14}$$

[0106] Here, the likelihood of a more adverse estimate is 0.001%. It is quite unlikely that a subsequent measurement

will be more adverse to the null hypothesis. As with Test 0, the null hypothesis for Test 2 sets a significance threshold on the p-value and assumes the p-value is greater than that threshold (hence, no prompt is needed).

[0107] While Test 2 is very similar to Test 0, Test 2 operates in the domain of blood pressure and builds both the mean and standard deviation values on actual reference measurements. Furthermore, the blood pressure estimate is based on a transform which has a verified inferential basis, courtesy of the model utility test.

[0108] Since the calibration set is composed of both systolic and diastolic measurements (two per calibration point), Test 1 and Test 2 are applied to both systolic and diastolic measurements and yield an output for each.

Prompt Generation

[0109] FIG. **6** is a flowchart illustrating a method for prompting calibration based upon the above-described tests. Given the hypothesis tests described above, prompt generation is straightforward. At most two hypotheses must be tested. The method begins at Step **600**. A transform is derived from the calibration set in Step **602** and the current PWV measurement is collected in Step **604**. Step **606** applies Test 1. If Test 1 fails to reject the null hypothesis in Step **607**, then the linear model is not applicable to the calibration set. Step **612** applies Test 0. Otherwise, the linear model is established, and Step **608** applies Test 2. If Test 0 fails to reject in Step **613**, no prompt is warranted (Step **615**). Otherwise, Step **614** triggers a calibration prompt. If Test 2 fails to reject in Step **609**, no prompt is warranted (Step **611**). Otherwise, Step **610** triggers a calibration prompt.

[0110] Note that all three tests depend on the calibration history. For Test 1 and Test 2, if the history is empty, the null hypothesis for each is confirmed. For Test 0, the interpretation is different. An empty history causes the null hypothesis to reject, supporting prompt generation in cases where the calibration history is empty.

[0111] Two reference blood pressure measurements exist for each calibration measurement—systolic and diastolic. As such, the logic of FIG. **6** is applied once for systolic blood pressure and once for diastolic. A prompt is triggered to the patient if either systolic or diastolic prompts are indicated.

Gating Function

[0112] A key goal of calibration prompting is to balance the cost of the calibration with its statistical advantage. If a calibration was recently requested, a statistical advantage (e.g., the diversity payoff) should be high before requesting again. Both Test 0 and Test 2 have thresholds that may vary to increase or decrease the level of confidence in the rejection outcome. A gating function is used to alter these thresholds as a function of time since the last calibration measurement.

[0113] For Test 0 the threshold is a p-value. For example, 35% might be used normally and a value of 10% immediately following calibration. One realization is the simple step function:

$$\text{if}(\Delta t > t\text{Thresh}) p\text{Thresh}=35\%;\ \text{else}\ p\text{Thresh}=10\%;\text{end}$$

[0114] where Δt is the time since the last calibration, tThresh is a threshold on that time, and pThresh is the Test 0 p-value threshold below which, the null hypothesis is rejected.

[0115] For Test 2, the confidence interval threshold is chosen as a clinically insignificant range. Rather than alter that range, the interval confidence is adjusted:

$$\text{if}(\Delta t > t\text{Thresh})\alpha=15\%;\ \text{else}\ \alpha=5\%;\ \text{end}$$

[0116] These gating functions are simple step functions. If more detailed control is needed, a continuous function of time might be used. For example, the logistic function, with appropriate multipliers (m), offsets (b), and time shifts (s) might be useful:

$$g(t) = b + m \times \left(1 - \left(\frac{e^{t-s}}{1+e^{t-s}}\right)\right) \tag{15}$$

[0117] FIG. **5** is a graph depicting a continuous gating function for b=1.5, m=3, and s=6.

[0118] The algorithm is grounded in statistical methods. Its novelty derives from its capability to predict calibration effect without actually performing the calibration, hence, reducing the calibration 'cost' to the patient and increasing the diversity of calibration points and improving PWV-BP transform quality. The method is applicable to both manual and automatic calibration modes. It may be used in conjunction with the method described in [2] to yield a comprehensive and coherent approach to PWV-BP calibration for the home use case.

[0119] Returning to FIG. **6**, as noted above, Step **602** creates a transform. The transform comprises a calibration with sample pairs including a mean measurement of pulse wave velocity correlated to a measured reference blood pressure value. Each mean measurement is derived from a plurality of feature (PWV) observations. Step **604** performs a current PWV mean measurement. Step **606** performs a model utility test comparing an estimated slope of the transform to an estimated standard deviation of the slope (Test 1). If a null hypothesis of the model utility test is rejected, Step **608** performs a first normalized mean difference test comparing a current blood pressure estimate with a mean calibration reference blood pressure over the calibration set (Test 2). If a null hypothesis of the first normalized mean difference test is rejected, Step **611** prompts a calibration of the transform, where the calibration includes augmenting the calibration sets with actual BP measurements correlated to the current mean PWV measurement.

[0120] If the null hypothesis of the model utility test is not rejected, Step **612** performs a second normalized mean difference test comparing the mean of the PWV over the calibration set with the current mean PWV measurement (Test 0). If the null hypothesis of the second mean difference test is rejected, Step **614** prompts a calibration of the transforms.

[0121] In one aspect, performing the model utility test (Test 1) in Step **606** includes finding a test statistic value of t less than a first predetermined value,

$$t = \frac{\hat{\beta}_1 - \beta_{10}}{s_{\hat{\beta}_1}}$$

[0122] where $\hat{\beta}_1$ is the estimated transform slope;

[0123] where β_{10} is the hypothesized transform slope; and,

[0124] where $s_{\hat{\beta}_1}$ is the estimated standard deviation of the transform slope.

[0125] where the estimated standard deviation of the slope ($S_{\hat{\beta}_1}$) is calculated as:

$$s_{\hat{\beta}_1} = \frac{s}{\sqrt{S_{xx}}} = \frac{\sqrt{\frac{SSE}{N-2}}}{\sqrt{\Sigma(x_i-\bar{x})^2}}$$

where SSE(sum of the squared errors) is defined as:

$$SSE=\Sigma(y_i-\hat{y}_i)^2;$$

[0126] where s is

$$\sqrt{\frac{SSE}{N-2}};$$

[0127] where S_{xx} is $\Sigma(x_i-\bar{x})^2$;

[0128] where x_1 is a PWV measurement in the calibration set;

[0129] where $\bar{x}$ is the mean PWV over the calibration set;

[0130] where N is the number of PWV measurements within the calibration set;

[0131] where y_i is a reference blood pressure measurement in the calibration set; and,

[0132] where $\hat{y}_i$ is an estimated blood pressure resulting from transforming PWV measurement x_i.

[0133] In another aspect, performing the first normalized mean difference test (Test 2) in Step **608** includes finding the difference between the mean calibration reference blood pressure and the current blood pressure estimate normalized by a standard deviation product over the calibration set. Test 2 finds a test statistic (t) as follows:

$$t = \frac{\bar{Y}-\mu_0}{\partial/\sqrt{N}}$$

[0134] where Y is the blood pressure mean over the N calibration measurements;

[0135] where μ_0 is the Test 2 hypothesis mean, which is taken as the current blood pressure estimate produced by applying the transform to the current mean PWV measurement; and,

[0136] where ∂ is a sample standard deviation of the reference blood pressure over the calibration set.

[0137] In one aspect, performing the second normalized mean difference test (Test 0) in Step **812** includes finding the difference between the current PWV estimate and the mean PWV over the calibration set normalized by a PWV standard deviation product. Test 0 finds a test statistic (t) as follows:

$$t = \frac{\bar{X}-\mu_0}{\partial/\sqrt{N}}$$

[0138] where $\bar{X}$ is the PWV mean over the N calibration measurements;

[0139] where μ_0 is the Test 0 hypothesis mean, which is taken as the current mean PWV measurement; and,

[0140] where ∂ is estimated as a population-based standard deviation over the patient's demographic group.

[0141] In another aspect, performing the first normalized mean difference test (Test 2) in Step **608** includes adjusting the confidence threshold of the first normalized mean difference test as a function of time since the last-occurring previous calibration. Likewise, performing the second normalized mean difference test (Test 0) in Step **612** includes adjusting the confidence threshold of the second normalized mean difference test as a function of time since the last-occurring previous calibration.

[0142] In another variation, performing the model utility test (Test 1) in Step **606** includes deleting the oldest elements of the calibration set as a function of time since the last-occurring previous calibration. In the same manner, performing the first normalized mean difference test (Test 2) in Step **608** may include deleting the oldest elements of the calibration set as a function of time since the last-occurring previous calibration. Further, performing the second normalized mean difference test (Test 0) in Step **612** may include deleting the oldest elements of the calibration set as a function of time since the last-occurring previous calibration.

[0143] A system and method have been provided for deriving BP-related calibrations. Examples of particular statistical processes have been presented to illustrate the invention. However, the invention is not limited to merely these examples. Other variations and embodiments of the invention will occur to those skilled in the art.

We claim:

1. A method for prompting blood pressure (BP)-related calibrations, the method comprising:

creating a transform comprising a calibration set including a plurality of sample pairs, where each sample pair includes a mean measurement of pulse wave velocity (PWV) correlated to a measured reference blood pressure value, where each mean PWV measurement is derived from a plurality of PWV observations;

performing a current mean PWV measurement;

performing a model utility test comparing an estimated slope of the transform to an estimated standard deviation of the slope (Test 1);

when a null hypothesis of the model utility test is rejected, performing a first normalized mean difference test comparing a current blood pressure estimate with a mean calibration reference blood pressure over the calibration set (Test 2); and,

when a null hypothesis of the first normalized mean difference test is rejected, prompting a calibration of the transform, where the calibration includes augmenting the calibration set with actual BP measurements correlated to the current mean PWV measurement.

2. The method of claim **1** further comprising:

when the null hypothesis of the model utility test is not rejected, performing a second normalized mean difference test comparing the mean of the PWV over the calibration set with the current mean PWV measurement (Test 0); and,

when the null hypothesis of the second mean difference test is rejected, prompting a calibration of the transform.

3. The method of claim 1 wherein performing the model utility test (Test 1) includes finding a test statistic value of t less than a first predetermined value,

$$t = \frac{\hat{\beta}_1 - \beta_{10}}{s_{\hat{\beta}_1}}$$

where $\hat{\beta}_1$ is the estimated slope;
where β_{10} is the hypothesis slope; and,
where $s_{\hat{\beta}_1}$ is the estimated standard deviation of the slope.

4. The method of claim 3 wherein the estimated standard deviation of the slope ($S_{\hat{\beta}_1}$) is calculated as:

$$s_{\hat{\beta}_1} = \frac{s}{\sqrt{S_{xx}}} = \frac{\sqrt{\frac{SSE}{N-2}}}{\sqrt{\Sigma(x_i - \bar{x})^2}}$$

where SSE(sum of the squared errors) is defined as:

$SSE=\Sigma(y_i-\hat{y}_i)^2$;

where s is s

$$\sqrt{\frac{SSE}{N-2}};$$

where S_{xx} is $\Sigma(x_i-\hat{y}_i)^2$;
where x_i is a PWV measurement in the calibration set;
where $\bar{x}$ is the mean PWV over the calibration set;
where N is the number of PWV measurements within the calibration set;
where y_i is a reference blood pressure measurement in the calibration set; and,
where $\hat{y}_i$ is an estimated blood pressure resulting from transforming PWV measurement x_i.

5. The method of claim 1 wherein performing the first normalized mean difference test (Test 2) includes finding the difference between the mean calibration reference blood pressure and the current blood pressure estimate normalized by a standard deviation product over the calibration set.

6. The method of claim 5 wherein Test 2 finds a test statistic (t) as follows:

$$t = \frac{\bar{Y} - \mu_0}{\partial/\sqrt{N}}$$

where $\bar{Y}$ is the blood pressure mean over the N calibration measurements;
where μ_0 is the Test 2 hypothesis mean, which is taken as the current blood pressure estimate produced by applying the transform to the current mean PWV measurement; and,
where ∂ is a sample standard deviation of the reference blood pressure over the calibration set.

7. The method of claim 2 wherein performing the second normalized mean difference test (Test 0) includes finding the difference between the current PWV estimate and the mean PWV over the calibration set normalized by a PWV standard deviation product.

8. The method of claim 7 wherein Test 0 finds a test statistic (t) as follows:

$$t = \frac{\bar{X} - \mu_0}{\partial/\sqrt{N}}$$

where $\bar{X}$ is the PWV mean over the N calibration measurements;
where μ_0 is the Test 0 hypothesis mean, which is taken as the current mean PWV measurement; and,
where ∂ is estimated as a population-based standard deviation over the patient's demographic group.

9. The method of claim 2 wherein performing the first normalized mean difference test (Test 2) includes adjusting a confidence threshold of the first normalized mean difference test as a function of time since a last-occurring previous calibration; and,
wherein performing the second normalized mean difference test (Test 0) includes adjusting a confidence threshold of the second normalized mean difference test as a function of time since a last-occurring previous calibration.

10. The method of claim 2 wherein performing the model utility test (Test 1) includes deleting oldest elements of the calibration set as a function of time since a last-occurring previous calibration;
wherein performing the first normalized mean difference test (Test 2) includes deleting oldest elements of the calibration set as a function of time since the last-occurring previous calibration; and,
wherein performing the second normalized mean difference test (Test 0) includes deleting oldest elements of the calibration set as a function of time since the last-occurring previous calibration.

11. A system for prompting blood pressure (BP)-related calibrations, the system comprising:
a PWV measurement interface comprising an electrocardiogram (ECG) sensor and a photoplethysmography (PPG) sensor for measuring ECG and PPG signals;
a processor;
a non-transitory memory including:
a transform file comprising a calibration set including a plurality of sample pairs, where each sample pair includes a mean measurement of pulse wave velocity (PWV) correlated to a measured reference blood pressure values, where each mean PWV measurement is derived from a plurality of PWV observations;
a prompting application enabled as a sequence of processor instructions for accepting a current mean PWV measurement, performing a model utility test comparing a difference between an estimated slope of the transform and its hypothesis value to an estimated standard deviation of the slope (Test 1), and when a null hypothesis of the model utility test is rejected, performing a first normalized mean difference test comparing a current blood pressure estimate with a mean calibration reference blood pressure over the calibration set (Test 2), and when

a null hypothesis of the first normalized mean difference test is rejected, prompting a transform calibration.

12. The system of claim **11** further comprising:

a BP measurement interface comprising a BP cuff for measuring BP signals; and,

wherein the prompting application accepts BP measurements in response to prompting the transform calibration, and modifies the transform by augmenting the calibration set with actual BP measurements correlated to current mean PWV measurements.

13. The system of claim **12** wherein the prompting application performs a second normalized mean difference test when the null hypothesis of the model utility test is not rejected, comparing the mean of the PWV over the calibration set with the current mean PWV measurement (Test 0), and when the null hypothesis of the second mean difference test is rejected, prompting a calibration of the transform.

14. The system of claim **12** wherein the prompting application performs the model utility test (Test 1) by finding a test statistic value of t less than a first predetermined value,

$$t = \frac{\hat{\beta}_1 - \beta_{10}}{s_{\hat{\beta}_1}}$$

where $\hat{\beta}_1$ is the estimated transform slope;

where β_0 is the hypothesized transform slope; and,

where $s_{\hat{\beta}_1}$ is the estimated standard deviation of the transform slope.

15. The system of claim **14** wherein the prompting application calculates the estimated standard deviation of the slope ($S_{\hat{\beta}_1}$) as follows:

$$s_{\hat{\beta}_1} = \frac{s}{\sqrt{S_{xx}}} = \frac{\sqrt{\frac{SSE}{N-2}}}{\sqrt{\Sigma(x_i - \bar{x})^2}}$$

where SSE(sum of the squared errors) is defined as:

$SSE=\Sigma(y_i-\hat{y}_i)^2$;

where s is

$$\sqrt{\frac{SSE}{N-2}};$$

where S_{xx} is $\Sigma(x_i-\bar{x})^2$;

where x_i is a PWV measurement in the calibration set;

where $\bar{x}$ is the mean PWV over the calibration set;

where N is the number of PWV measurements within the calibration set;

where y_i is a reference blood pressure measurement in the calibration set; and,

where $\bar{y}_i$ is an estimated blood pressure resulting from transforming PWV measurement x_i.

16. The system of claim **12** wherein the prompting application performs the first normalized mean difference test (Test 2) by finding the difference between the mean calibration reference blood pressure and the current blood pressure estimate normalized by a standard deviation product over the calibration set.

17. The system of claim **16** wherein the prompting application performs Test 2 by finding a test statistic (t) as follows:

$$t = \frac{\bar{Y} - \mu_0}{\partial/\sqrt{N}}$$

where $\bar{Y}$ is the blood pressure mean over the N calibration measurements;

where μ_0 is the Test 2 hypothesis mean, which is taken as the current blood pressure estimate produced by applying the transform to the current mean PWV measurement;

where ∂ is a sample standard deviation of the reference blood pressure over the calibration set.

18. The system of claim **13** wherein the prompting application performs the second normalized mean difference test (Test 0) by finding the difference between the current PWV estimate and the mean PWV over the calibration set normalized by a PWV standard deviation product.

19. The system of claim **18** wherein the prompting application performs Test 0 by finding a test statistic (t) as follows:

$$t = \frac{\bar{X} - \mu_0}{\partial/\sqrt{N}}$$

where $\bar{X}$ is the PWV mean over the N calibration measurements;

where μ_0 is the Test 0 hypothesis mean, which is taken as the current mean PWV measurement; and,

where ∂ is estimated as a population-based standard deviation over the patient's demographic group.

20. The system of claim **13** wherein the prompting application performs the first normalized mean difference test (Test 2) by adjusting a confidence threshold of the first normalized mean difference test as a function of time since a last-occurring previous calibration; and,

wherein the prompting application performs the second normalized mean difference test (Test 0) by adjusting diminishing a confidence threshold of the second normalized mean difference test as a function of time since a last-occurring previous calibration.

21. The system of claim **13** wherein the prompting application performs the model utility test (Test 1) by deleting oldest elements of the calibration set as a function of time since a last-occurring previous calibration;

wherein the prompting application performs the first normalized mean difference test (Test 2) by deleting oldest elements of the calibration set as a function of time since the last-occurring previous calibration; and,

wherein the prompting application performs the second normalized mean difference test (Test 0) by deleting oldest elements of the calibration set as a function of time since the last-occurring previous calibration.

* * * * *

专利名称(译)	脉搏波速度 - 血压校准提示		
公开(公告)号	US20170119264A1	公开(公告)日	2017-05-04
申请号	US14/983348	申请日	2015-12-29
[标]申请(专利权)人(译)	AMERICA SLA夏普LAB		
申请(专利权)人(译)	AMERICA（SLA），INC夏普实验室.		
[标]发明人	HILL FREDRICK		
发明人	HILL, FREDRICK		
IPC分类号	A61B5/021 G01L27/00 A61B5/022 A61B5/00 A61B5/0452		
CPC分类号	A61B5/02125 A61B5/7221 A61B5/7253 G01L27/005 A61B5/0059 A61B5/02233 A61B5/0452 A61B5/02416 A61B5/0456 A61B2560/0223		
外部链接	Espacenet USPTO		

摘要(译)

提供了一种用于提示与血压相关的校准的系统和方法。该方法依赖于对当前测量和累积校准点集合的统计假设检验，以确定校准的好处在校准多样性方面是否超过患者的成本。该算法使用统计方法来预测校准效果而无需实际执行校准，因此，降低了对患者的校准“成本”并增加了校准点的多样性，从而提高了PWV-BP变换质量。该方法适用于手动和自动校准模式。