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(54) **SYSTEMS AND METHODS FOR PERFORMING DIAGNOSTIC PROCEDURES FOR A VOLUME CLAMP FINGER CUFF**

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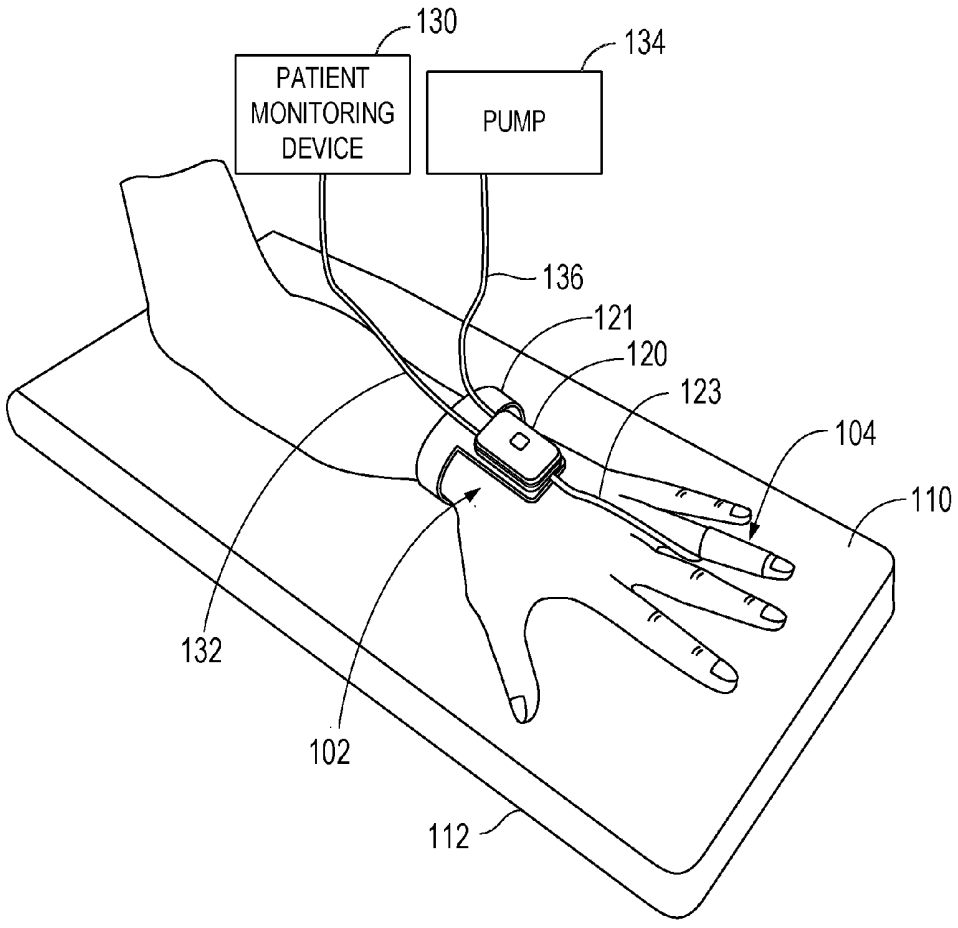
(57) **ABSTRACT**

Disclosed is a system to monitor a finger cuff connectable to a patient's finger to be used in measuring the patient's blood pressure by a blood pressure measurement system utilizing the volume clamp method and to measure the plethysmogram of the finger cuff. The system comprises the finger cuff that includes an enclosing portion that encloses a patient's finger. The enclosing portion includes a bladder and a light emitting diode (LED) and photodiode (PD) pair. The system further comprises a processor to: command applying pneumatic pressure to the bladder of the finger cuff from a low pressure to a high pressure; measure the plethysmogram of the finger cuff as the pressure increases from the low pressure to the high pressure; and determine fitness of the finger cuff on the patient's finger based on the measured plethysmogram. When the finger cuff is placed around the patient's finger, the bladder and the LED-PD pair aid the processor in measuring the plethysmogram.



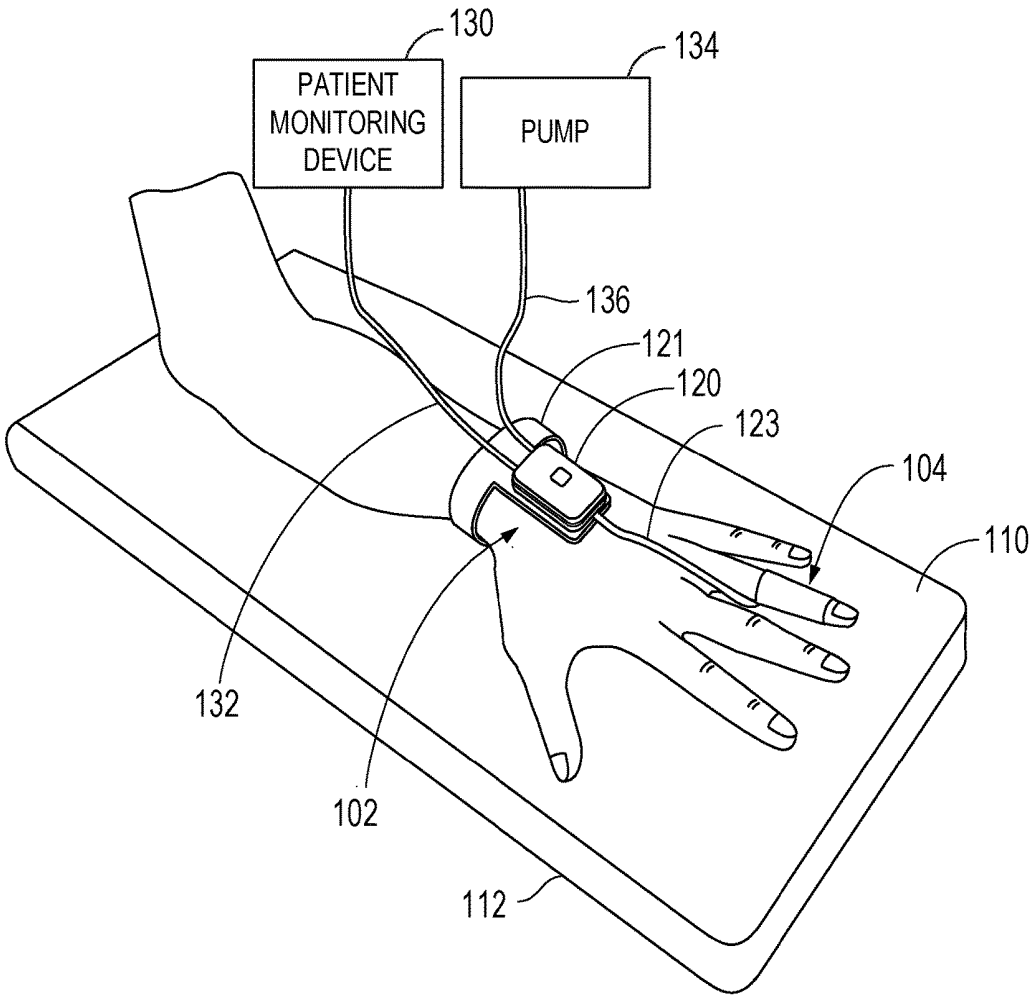

130
PATIENT MONITORING DEVICE
134
PUMP
136
121
120
123
104
110
132
102
112

FIG. 1

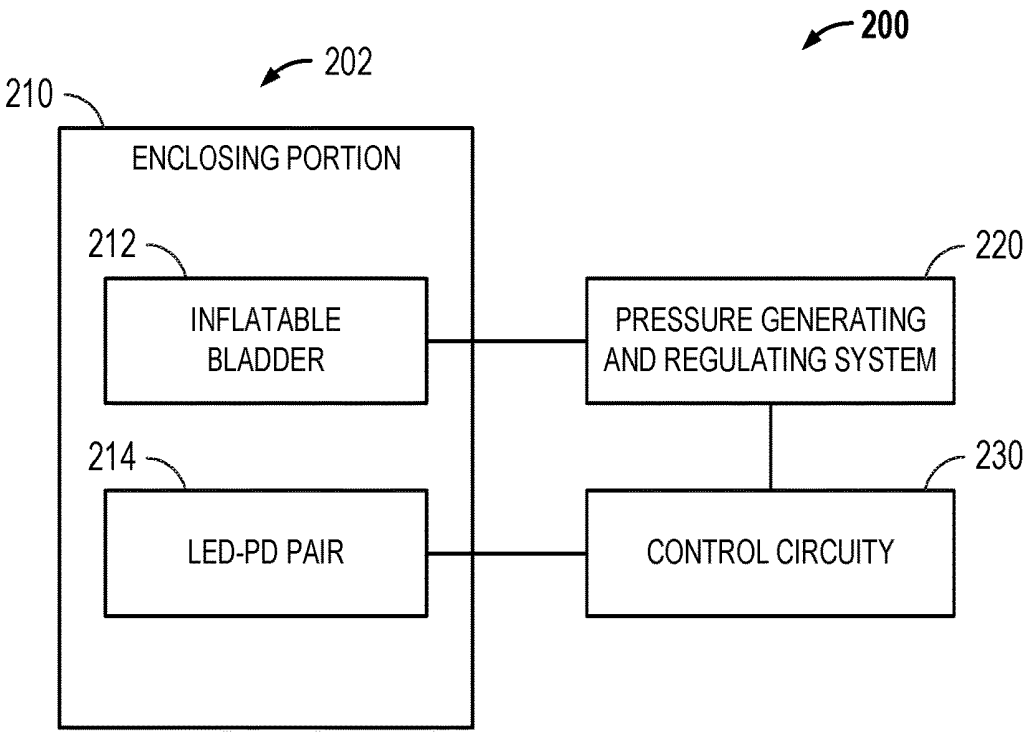

200
202
210
ENCLOSING PORTION
212
INFLATABLE BLADDER
214
LED-PD PAIR
220
PRESSURE GENERATING AND REGULATING SYSTEM
230
CONTROL CIRCUITY

FIG. 2

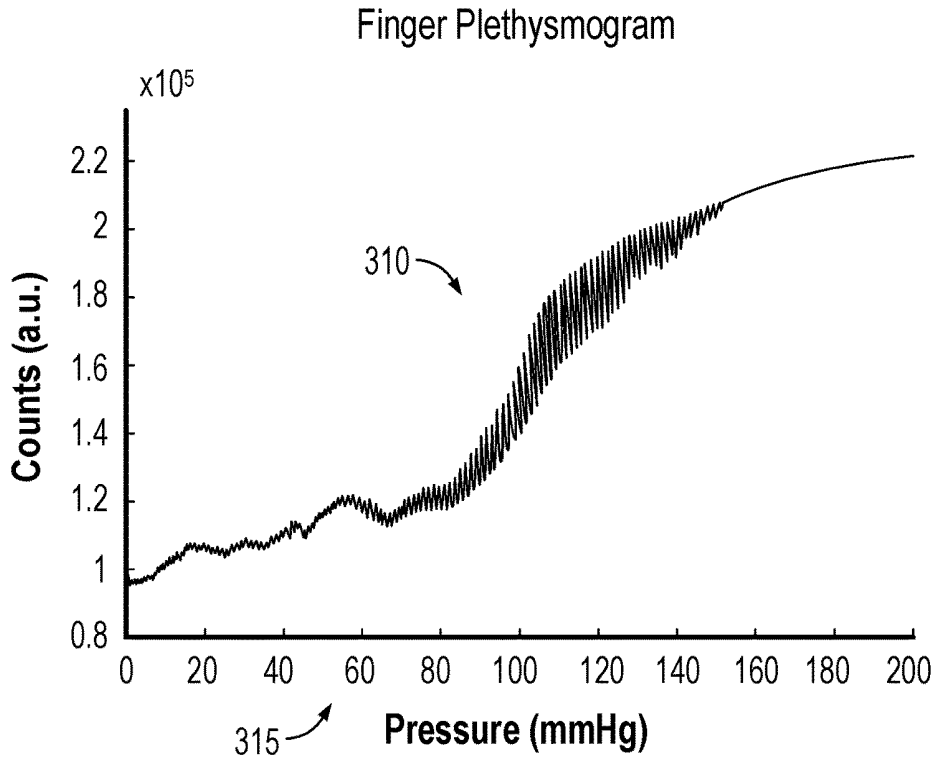

Finger Plethysmogram
x10^5
2.2
2
1.8
1.6
1.4
1.2
1
0.8
Counts (a.u.)
310
0
20
40
60
80
100
120
140
160
180
200
315
Pressure (mmHg)

FIG. 3A

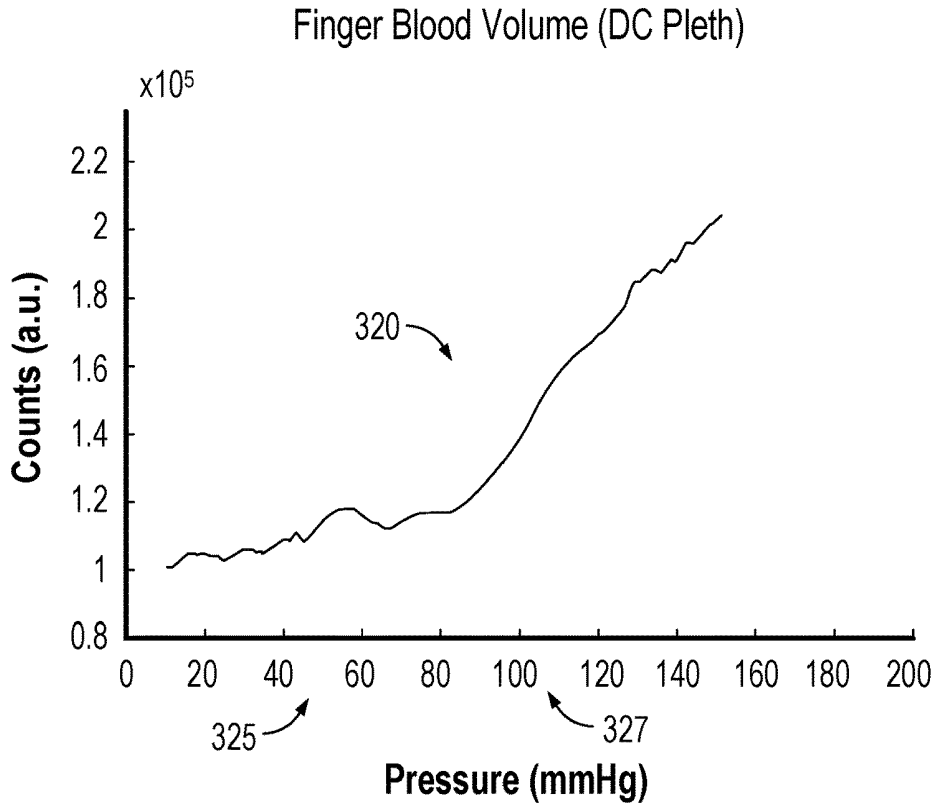

Finger Blood Volume (DC Pleth)
x10^5
2.2
2
1.8
1.6
1.4
1.2
1
0.8
Counts (a.u.)
320
0
20
40
60
80
100
120
140
160
180
200
325
327
Pressure (mmHg)

FIG. 3B

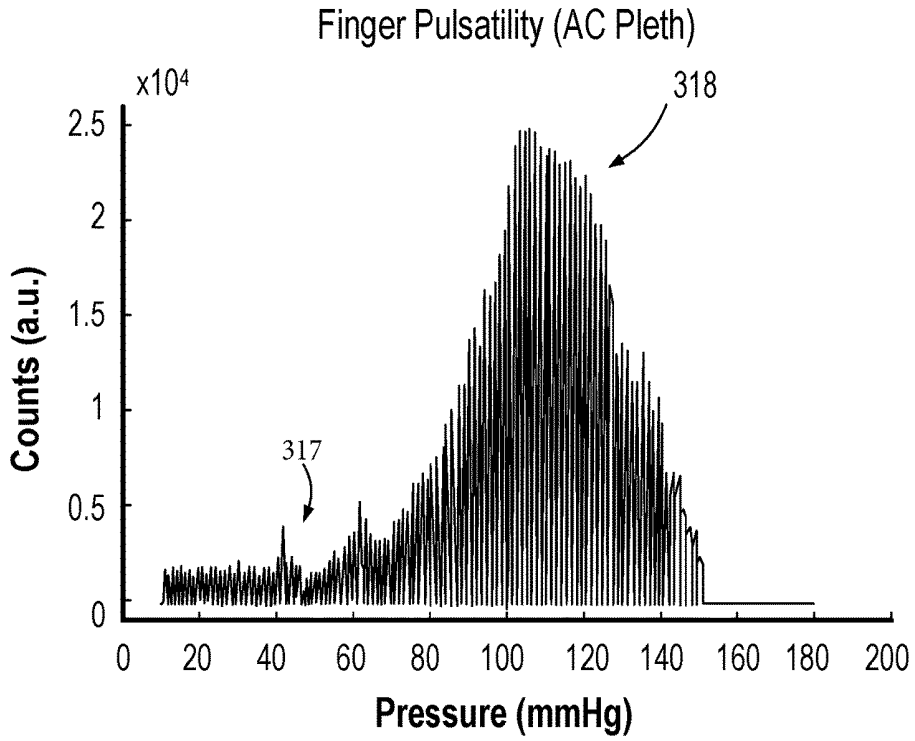

Finger Pulsatility (AC Pleth)
x10⁴
318
317
Counts (a.u.)
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
120
140
160
180
200
Pressure (mmHg)

FIG. 3C

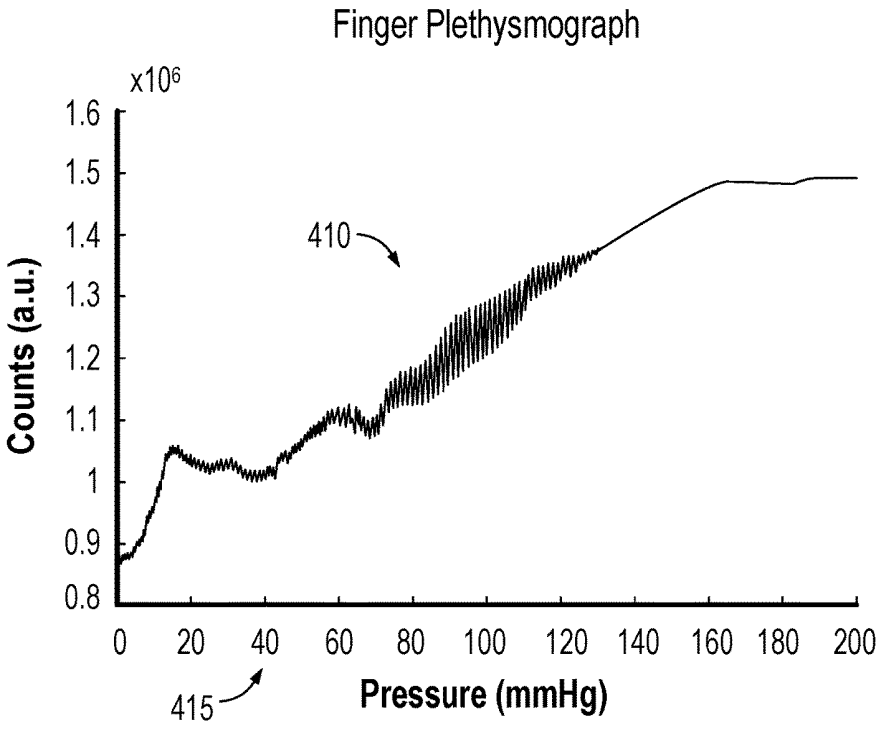

Finger Plethysmograph
x10^6
1.6
1.5
1.4
1.3
1.2
1.1
1
0.9
0.8
Counts (a.u.)
410
0
20
40
60
80
100
120
140
160
180
200
415
Pressure (mmHg)

FIG. 4A

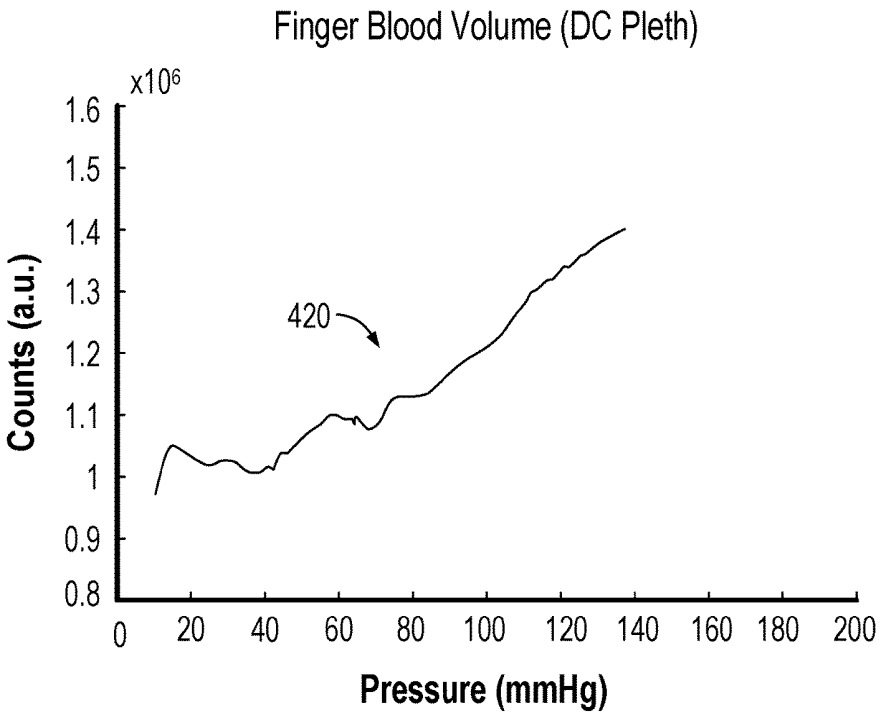

Finger Blood Volume (DC Pleth)
x10^6
1.6
1.5
1.4
1.3
1.2
1.1
1
0.9
0.8
Counts (a.u.)
420
0
20
40
60
80
100
120
140
160
180
200
Pressure (mmHg)

FIG. 4B

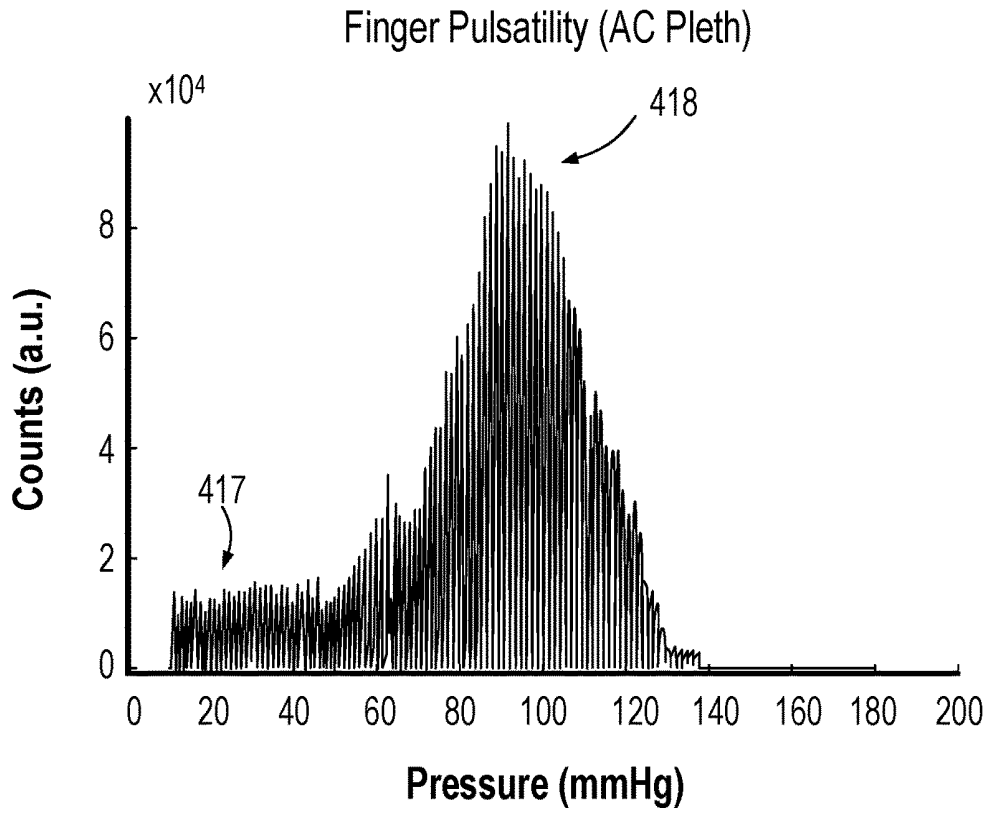

Finger Pulsatility (AC Pleth)
x10⁴
418
417
Counts (a.u.)
0
2
4
6
8
0 20 40 60 80 100 120 140 160 180 200
Pressure (mmHg)

FIG. 4C

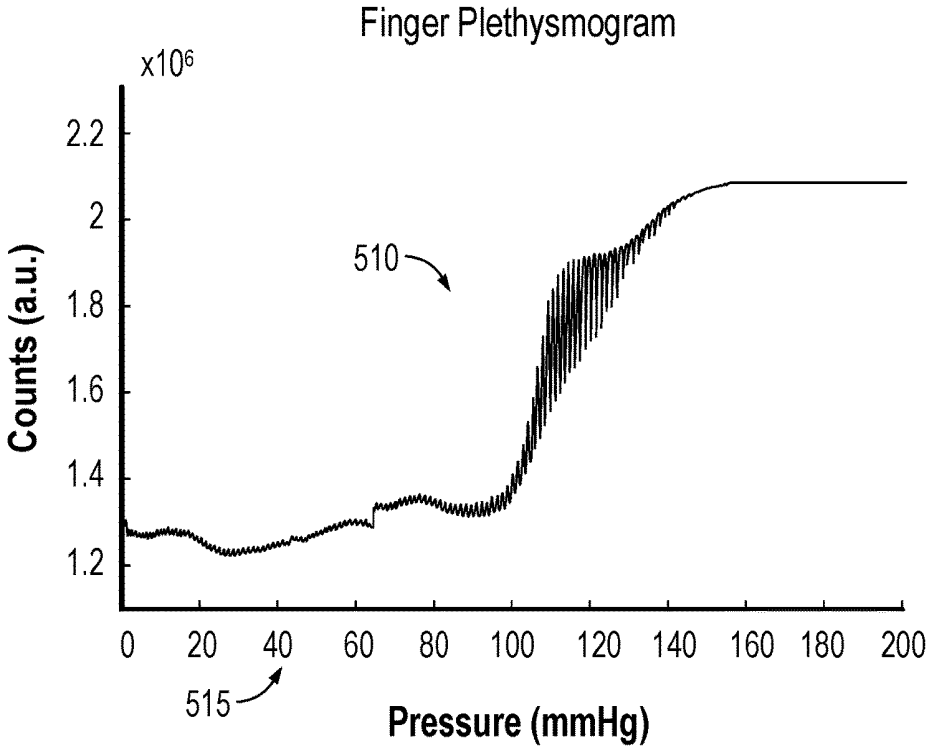

Finger Plethysmogram
x10^6
2.2
2
1.8
1.6
1.4
1.2
Counts (a.u.)
510
0
20
40
60
80
100
120
140
160
180
200
515
Pressure (mmHg)

FIG. 5A

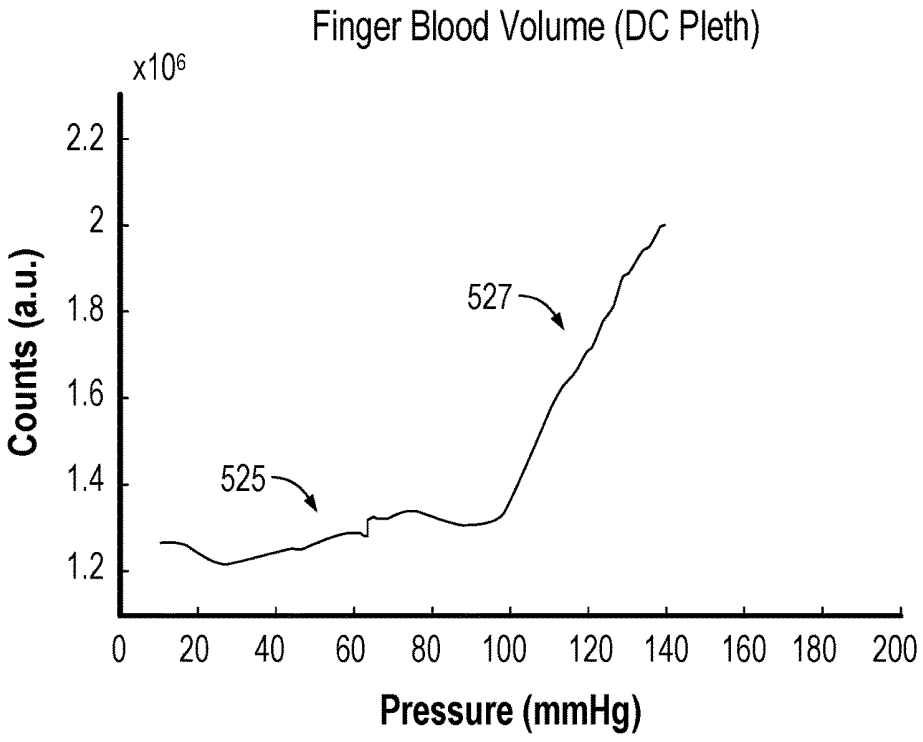

Finger Blood Volume (DC Pleth)
x10^6
2.2
2
1.8
1.6
1.4
1.2
Counts (a.u.)
527
525
0
20
40
60
80
100
120
140
160
180
200
Pressure (mmHg)

FIG. 5B

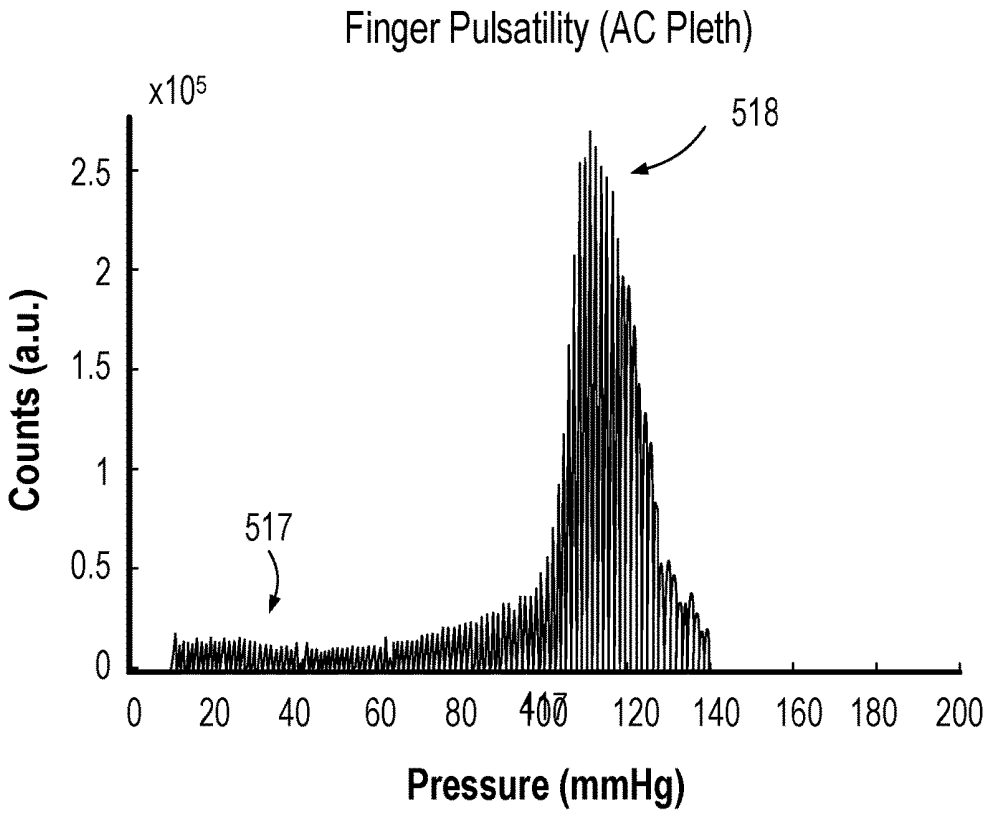

Finger Pulsatility (AC Pleth)
x10^5
518
517
Counts (a.u.)
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
120
140
160
180
200
Pressure (mmHg)

FIG. 5C

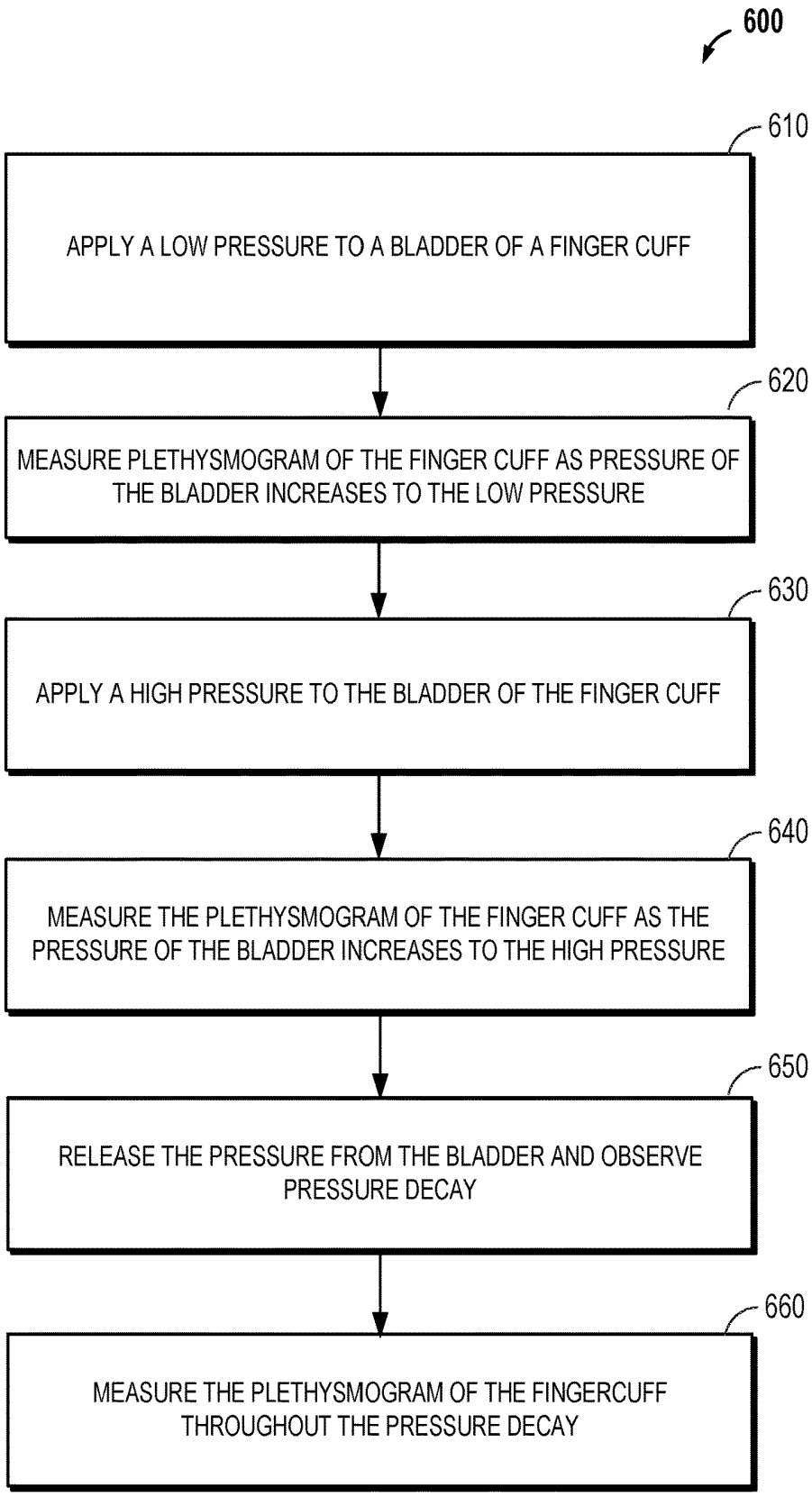

600
610
APPLY A LOW PRESSURE TO A BLADDER OF A FINGER CUFF
620
MEASURE PLETHYSMOGRAM OF THE FINGER CUFF AS PRESSURE OF THE BLADDER INCREASES TO THE LOW PRESSURE
630
APPLY A HIGH PRESSURE TO THE BLADDER OF THE FINGER CUFF
640
MEASURE THE PLETHYSMOGRAM OF THE FINGER CUFF AS THE PRESSURE OF THE BLADDER INCREASES TO THE HIGH PRESSURE
650
RELEASE THE PRESSURE FROM THE BLADDER AND OBSERVE PRESSURE DECAY
660
MEASURE THE PLETHYSMOGRAM OF THE FINGERCUFF THROUGHOUT THE PRESSURE DECAY

FIG. 6

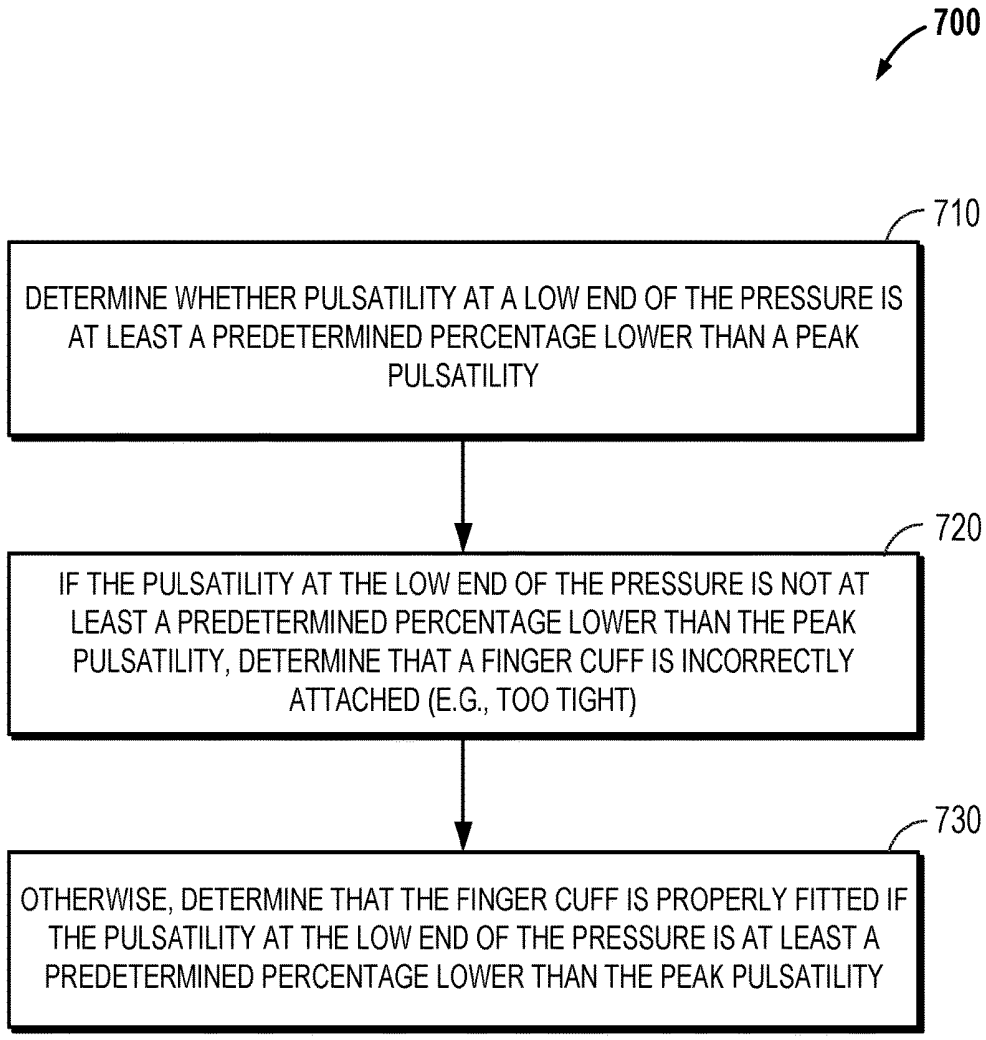

700
710
DETERMINE WHETHER PULSATILITY AT A LOW END OF THE PRESSURE IS AT LEAST A PREDETERMINED PERCENTAGE LOWER THAN A PEAK PULSATILITY
720
IF THE PULSATILITY AT THE LOW END OF THE PRESSURE IS NOT AT LEAST A PREDETERMINED PERCENTAGE LOWER THAN THE PEAK PULSATILITY, DETERMINE THAT A FINGER CUFF IS INCORRECTLY ATTACHED (E.G., TOO TIGHT)
730
OTHERWISE, DETERMINE THAT THE FINGER CUFF IS PROPERLY FITTED IF THE PULSATILITY AT THE LOW END OF THE PRESSURE IS AT LEAST A PREDETERMINED PERCENTAGE LOWER THAN THE PEAK PULSATILITY

FIG. 7

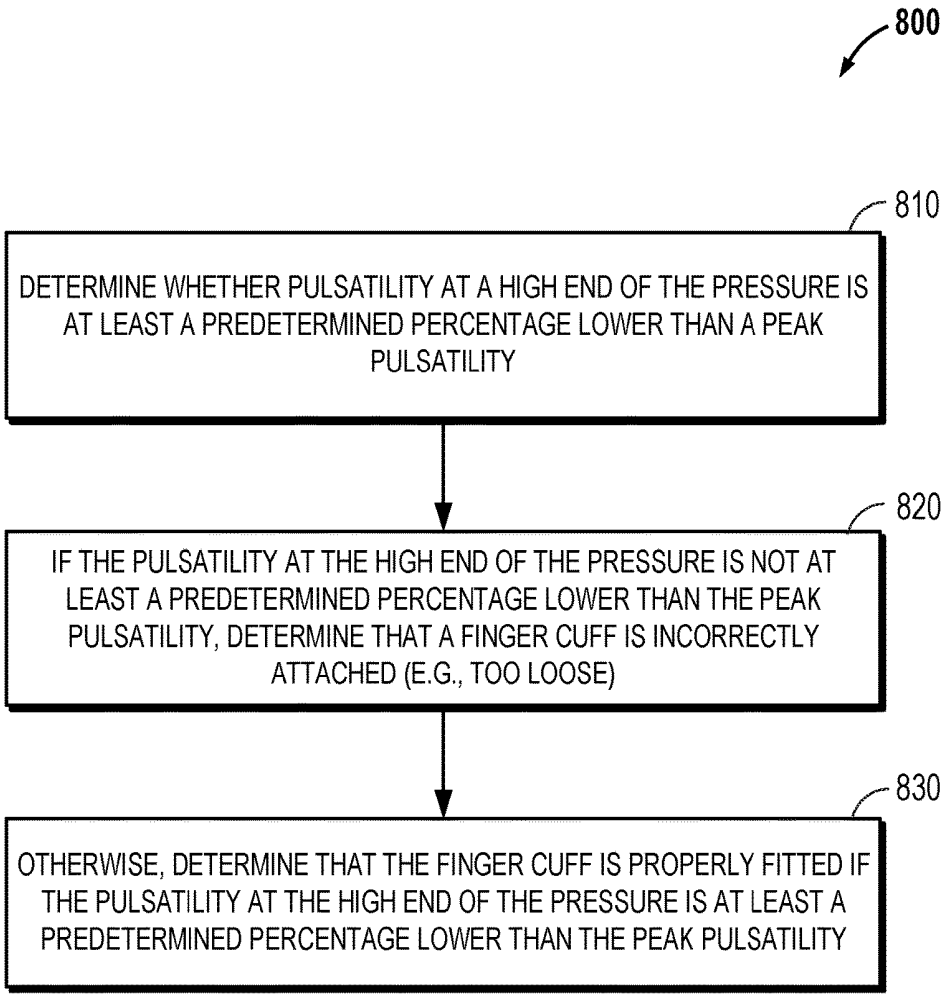

800
810
DETERMINE WHETHER PULSATILITY AT A HIGH END OF THE PRESSURE IS AT LEAST A PREDETERMINED PERCENTAGE LOWER THAN A PEAK PULSATILITY
820
IF THE PULSATILITY AT THE HIGH END OF THE PRESSURE IS NOT AT LEAST A PREDETERMINED PERCENTAGE LOWER THAN THE PEAK PULSATILITY, DETERMINE THAT A FINGER CUFF IS INCORRECTLY ATTACHED (E.G., TOO LOOSE)
830
OTHERWISE, DETERMINE THAT THE FINGER CUFF IS PROPERLY FITTED IF THE PULSATILITY AT THE HIGH END OF THE PRESSURE IS AT LEAST A PREDETERMINED PERCENTAGE LOWER THAN THE PEAK PULSATILITY

FIG. 8

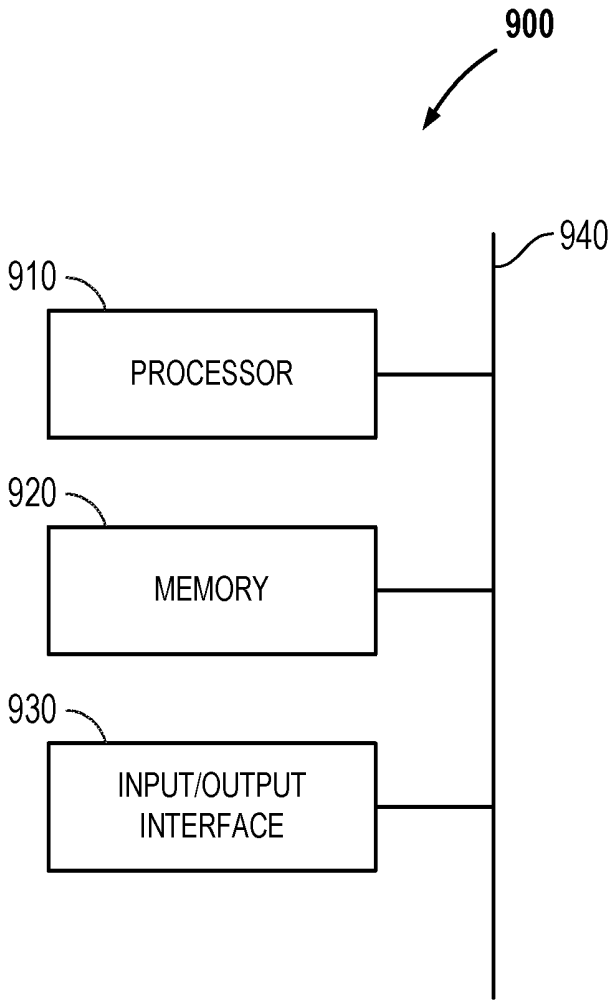

900
940
910
PROCESSOR
920
MEMORY
930
INPUT/OUTPUT
INTERFACE

FIG. 9

SYSTEMS AND METHODS FOR PERFORMING DIAGNOSTIC PROCEDURES FOR A VOLUME CLAMP FINGER CUFF

RELATED APPLICATION

[0001] This application claims priority to U.S. Provisional Application No. 62/594,111, filed Dec. 4, 2017, the contents of which are incorporated herein by reference in its entirety.

BACKGROUND

Field

[0002] Embodiments of the invention relate generally to non-invasive blood pressure measurement. More particularly, embodiments of the invention relate to the performance of diagnostic procedures for a volume clamp finger cuff.

Relevant Background

[0003] Volume clamping is a technique for non-invasively measuring blood pressure in which pressure is applied to a patient's finger in such a manner that arterial pressure may be balanced by a time varying pressure to maintain a constant arterial volume. In a properly fitted and calibrated system, the applied time varying pressure is equal to the arterial blood pressure in the finger. The applied time varying pressure may be measured to provide a reading of the patient's arterial blood pressure.

[0004] This may be accomplished by a finger cuff that is arranged or wrapped around a finger of a patient. The finger cuff may include an infrared light source, an infrared sensor, and an inflatable bladder. The infrared light may be sent through the finger in which a finger artery is present. The infrared sensor picks up the infrared light and the amount of infrared light registered by the sensor may be inversely proportional to the artery diameter and indicative of the pressure in the artery.

[0005] In the finger cuff implementation, by inflating the bladder in the finger cuff, a pressure is exerted on the finger artery. If the pressure is high enough, it will compress the artery and the amount of light registered by the sensor will increase. The amount of pressure necessary in the inflatable bladder to compress the artery is dependent on the blood pressure. By controlling the pressure of the inflatable bladder such that the diameter of the finger artery is kept constant, the blood pressure may be monitored in very precise detail as the pressure in the inflatable bladder is directly linked to the blood pressure. In a typical present day finger cuff implementation, a volume clamp system is used with the finger cuff. The volume clamp system typically includes a pressure generating system and a regulating system that includes: a pump, a valve, and a pressure sensor in a closed loop feedback system that are used in the measurement of the arterial volume. To accurately measure blood pressure, the feedback loop provides sufficient pressure generating and releasing capabilities to match the pressure oscillations of the patient's blood pressure.

[0006] Today, finger cuff based blood pressure monitoring devices generally use the same technology (e.g., photoplethysmography or similar technologies) to measure blood pressure. Unfortunately, such finger cuff devices may not be easily attachable to a patient's finger and may not be that accurate due to the finger cuff's positioning on the patient's finger. That is, attaching the finger cuff in a suboptimal way may negatively influence the measurement reliability and accuracy of the volume clamp system. For example, a loose finger cuff on the patient's finger may require the bladder to stretch in order to reach the finger. Therefore, this may lead to the additional consumption of energy and a reading of an artificially high blood pressure.

SUMMARY

[0007] Embodiments of the invention may relate to a system to monitor a finger cuff connectable to a patient's finger to be used in measuring the patient's blood pressure by a blood pressure measurement system utilizing the volume clamp method and to measure the plethysmogram of the finger cuff. The system comprises the finger cuff that includes an enclosing portion that encloses a patient's finger. The enclosing portion includes a bladder and a light emitting diode (LED) and photodiode (PD) pair. The system further comprises a processor to: command applying pneumatic pressure to the bladder of the finger cuff from a low pressure to a high pressure; measure the plethysmogram of the finger cuff as the pressure increases from the low pressure to the high pressure; and determine the fitness of the finger cuff on the patient's finger based on the measured plethysmogram. When the finger cuff is placed around the patient's finger, the bladder and the LED-PD pair aid the processor in measuring the plethysmogram.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. **1** is a diagram of an example of a blood pressure measurement system according to one embodiment.

[0009] FIG. **2** is a block diagram illustrating a finger cuff and a pressure generating and regulating system.

[0010] FIGS. **3**A-**3**C are diagrams illustrating the measured plethysmograms of a finger cuff according to embodiments of the invention.

[0011] FIGS. **4**A-**4**C are diagrams illustrating additional measured plethysmograms of the finger cuff according to embodiments of the invention.

[0012] FIGS. **5**A-**5**C are diagrams illustrating additional measured plethysmograms of the finger cuff according to embodiments of the invention.

[0013] FIG. **6** a flow diagram of a method for measuring the pulsatility of a finger cuff according to embodiments of the invention.

[0014] FIG. **7** is a flow diagram of a method for determining whether a finger cuff is properly fitted on a patient's finger according to embodiments of the invention.

[0015] FIG. **8** is a flow diagram of another method for determining whether the finger cuff is properly fitted on the patient's finger according to embodiments of the invention.

[0016] FIG. **9** is a block diagram illustrating example control circuitry.

DETAILED DESCRIPTION

[0017] With reference to FIG. **1**, which illustrates an example of a blood pressure measurement system according to one embodiment, a blood pressure measurement system **102** that includes a finger cuff **104** that may be attached to a patient's finger and a blood pressure measurement controller **120**, which may be attached to the patient's body (e.g., a patient's wrist or hand) is shown.

[0018] The blood pressure measurement system **102** may further be connected to a patient monitoring device **130**, and, in some embodiments, a pump **134**. Further, finger cuff **104** may include a bladder (not shown) and an LED-PD pair (not shown), which are conventional for finger cuffs.

[0019] In one embodiment, the blood pressure measurement system **102** may include a pressure measurement controller **120** that includes: a small internal pump, a small internal valve, a pressure sensor, and control circuity. In this embodiment, the control circuitry may be configured to: control the pneumatic pressure applied by the internal pump to the bladder of the finger cuff **104** to replicate the patient's blood pressure based upon measuring the pleth signal received from the LED-PD pair of the finger cuff **104**. Further, the control circuitry may be configured to: control the opening of the internal valve to release pneumatic pressure from the bladder; or the internal valve may simply be an orifice that is not controlled. Additionally, the control circuitry may be configured to: measure the patient's blood pressure by monitoring the pressure of the bladder based upon the input from a pressure sensor, which should be the same as patient's blood pressure, and may display the patient's blood pressure on the patient monitoring device **130**.

[0020] In another embodiment, a conventional pressure generating and regulating system may be utilized, in which, a pump **134** is located remotely from the body of the patient. In this embodiment, the blood pressure measurement controller **120** receives pneumatic pressure from remote pump **134** through tube **136** and passes on the pneumatic pressure through tube **123** to the bladder of finger cuff **104**. Blood pressure measurement device controller **120** may also control the pneumatic pressure (e.g., utilizing a controllable valve) applied to the finger cuff **104** as well as other functions. In this example, the pneumatic pressure applied by the pump **134** to the bladder of finger cuff **104** to replicate the patient's blood pressure based upon measuring the pleth signal received from the LED-PD pair of the finger cuff **104** (e.g., to keep the pleth signal constant) and measuring the patient's blood pressure by monitoring the pressure of the bladder may be controlled by the blood pressure measurement controller **120** and/or a remote computing device and/or the pump **134** and/or the patient monitoring device **130** to implement the volume clamping method. In some embodiments, a blood pressure measurement controller **120** is not used at all and there is simply a connection from tube **136** from a remote pump **134** including a remote pressure regulatory system to finger cuff **104**, and all processing for the pressure generating and regulatory system, data processing, and display is performed by a remote computing device.

[0021] Continuing with this example, as shown in FIG. **1**, a patient's hand may be placed on the face **110** of an arm rest **112** for measuring a patient's blood pressure with the blood pressure measurement system **102**. The blood pressure measurement controller **120** of the blood pressure measurement system **102** may be coupled to a bladder of the finger cuff **104** in order to provide pneumatic pressure to the bladder for use in blood pressure measurement. Blood pressure measurement controller **120** may be coupled to the patient monitoring device **130** through a power/data cable **132**. Also, in one embodiment, as previously described, in a remote implementation, blood pressure measurement controller **120** may be coupled to a remote pump **134** through tube **136** to receive pneumatic pressure for the bladder of the finger cuff **104**. The patient monitoring device **130** may be any type of medical electronic device that may read, collect, process, display, etc., physiological readings/data of a patient including blood pressure, as well as any other suitable physiological patient readings. Accordingly, power/data cable **132** may transmit data to and from patient monitoring device **130** and also may provide power from the patient monitoring device **130** to the blood pressure measurement controller **120** and finger cuff **104**.

[0022] As can be seen in FIG. **1**, in one example, the finger cuff **104** may be attached to a patient's finger and the blood pressure measurement controller **120** may be attached on the patient's hand or wrist with an attachment bracelet **121** that wraps around the patient's wrist or hand. The attachment bracelet **121** may be metal, plastic, Velcro, etc. It should be appreciated that this is just one example of attaching a blood pressure measurement controller **120** and that any suitable way of attaching a blood pressure measurement controller to a patient's body or in close proximity to a patient's body may be utilized and that, in some embodiments, a blood pressure measurement controller **120** may not be used at all. It should further be appreciated that the finger cuff **104** may be connected to a blood pressure measurement controller described herein, or a pressure generating and regulating system of any other kind, such as a pressure generating and regulating system that is located remotely from the body of the patient. Any kind of pressure generating and regulating system can be used, including but not limited to the blood pressure measurement controller, and may be described simply as a pressure generating and regulating system that may be used with a finger cuff **104** including an LED-PD pair and a bladder to implement the volume clamping method.

[0023] FIG. **2** is a block diagram illustrating a finger cuff and a pressure generating and regulating system. As an example, as shown in FIG. **2**, finger cuff **202** may include an enclosing portion **210**, an inflatable bladder **212** and an LED-PD pair **214**. The enclosing portion **210** may encircle or enclose a patient's finger and include inflatable bladder **212** and LED-PD pair **214**. The inflatable bladder **212** may be pneumatically connected to a pressure generating and regulating system **220**. The LED may be used to illuminate the finger skin and light absorption or reflection may be detected with the PD. The pressure generating and regulating system **220** and control circuitry (e.g., including a processor) **230** may generate, measure, and regulate pneumatic pressure that inflates or deflates the inflatable bladder **212**, and may further comprise such elements as a pump, a valve, a pressure sensor, and/or other suitable elements, as previously described. In particular, pressure generating and regulating system **220** in cooperation with control circuitry **230** may be configured to implement a volume clamp method with the finger cuff **202** by: applying pneumatic pressure to the inflatable bladder **212** of the finger cuff **202** to replicate the patient's blood pressure based upon measuring the pleth signal received from the LED-PD pair **214** of the finger cuff **202** (e.g., to keep the pleth signal constant); and measuring the patient's blood pressure by monitoring the pressure of the inflatable bladder **212** based upon input from a pressure sensor, which should be the same as patient's blood pressure, and may further command the display of the patient's blood pressure on the patient monitoring device.

[0024] In one embodiment, pressure generating and regulating system **220** and control circuitry **230** may automatically perform diagnostic procedures (e.g., a series of tests) to assess equipment statuses (e.g., pump performance, valve performance), finger cuff fitness (e.g., tightness, location and fit), and/or patient suitability (e.g., patient's perfusion) for the volume clamp method. In some embodiments, the diagnostic procedures may be performed at system start-up and/or during system run time of the pressure generating and regulating system **220** and/or control circuitry **230** to obtain and assess various metrics associated with the equipment statuses, finger cuff fitness, and patient suitability.

[0025] A plethysmogram, or pleth signal, obtained by the bladder **212** and LED-PD pair **214** contains two parts. The finger pulsatility, also known as the AC pleth, is the pulsation due to the subject's heart beats. The pulsatility can be changed by applying pressure to the finger, for example by the bladder **212**, that confine the artery's movement within the finger. The finger blood volume, also known as the DC pleth, excludes changes due to the subject's heart beats. Rather, it is the steady background level of light absorbing blood and tissue in the finger. The finger blood volume can be changed by applying pressure to the finger, for example by the bladder **212**, which squeezes blood, both arterial and venous, out of the finger. Both pulsatility and blood volume can be characterized as functions of external pressure applied by the bladder **212**. FIG. **3**A shows the plethysmogram as a function of pressure applied by a bladder, including both pulsatility and blood volume, for a typical finger. FIG. **3**B separates out just the steady state blood volume from **3**A, as pressure increases light absorbing blood is pushed out of the finger and the DC Pleth increases. FIG. **3**C separates out just the pulsatility from **3**A, at low pressures the artery is fully stretched by the subject's blood pressure resulting in low pulsatility, as the pressure increases the artery is compressed into a highly elastic state that yields large pulsations with each heartbeat, and at high pressure the artery is fully compressed and very little blood is able to enter the finger at each heartbeat. Thus both portions of the plethysmogram contain information relating to the interaction between subject's finger and the bladder.

[0026] In particular, pressure generating and regulating system **220** in cooperation with control circuitry **230** may apply pneumatic pressure to bladder **212** from a low pressure, e.g., 20-40 millimeter of mercury (mmHg), to a high pressure (e.g., 200 mmHg) and measure the plethysmogram of finger cuff **202** as the pressure increases from the low pressure to the high pressure. That is, in one embodiment, the pressure generating and regulating system **220** and control circuitry **230** (by way of bladder **212** and LED-PD pair **214**) may make continuous volumetric measurements (or plethysmogram) of arterial blood flows within the patient's finger as the pressure increases from the low pressure to the high pressure. Thus, pulsatility and blood volume in the finger may be detected based on the plethysmogram, which may be generated based on the pleth signal received from the PD of LED-PD pair **214**. Based on the measured pulsatility and/or blood volume of finger cuff **202**, the control circuitry **230** may determine the fitness of finger cuff **202** on the patient's finger. For example, the control circuitry **230** may determine whether finger cuff **202** is loose, properly fitted, or too tight on the patient's finger.

[0027] In some embodiments, in determining the fitness of finger cuff **202**, the pressure generating and regulating system **220** and control circuitry **230** may apply multiple pressure sequences to the finger cuff **202**, and the pleth signal received from LED-PD pair **214** may be acquired and analyzed. For example, a low pressure (e.g., 20-40 mmHg) may be applied to bladder **212**, and the pleth signal may be measured as the pressure of the bladder increases to the low pressure. A high pressure (200 mmHg) may then be applied to bladder **212** and held for a time period (e.g., 1 second), and during such time period, the pleth signal may again be measured. Subsequently, the pressure from bladder **212** may be released (e.g., by turning off the pump) and the pressure decay may be observed. The pleth signal may be measured throughout the pressure decay, and in some embodiments, for an additional time period (e.g., 3 seconds or any suitable amount of time) after the pump has been turned off. Based on the various measurements of the pleth signal, as previously described, the control circuitry **230** may determine whether finger cuff **202** is loose, properly fitted, or too tight on the patient's finger (as described in more detail with respect to FIGS. **3**A-**3**C, **4**A-C and **5**A-**5**C herein below). Further, based on the various measurements of the pleth signal, as previously described, the control circuitry **230** may perform various equipment status checks, as described below.

[0028] In some embodiments, with respect to equipment statuses, control circuitry **230** may check pump performance of the pressure generating and regulating system **220**. For example, control circuitry **230** may control a designated pneumatic pressure applied by the pump to the bladder **212** of the finger cuff **202**. Control circuitry **230** may then determine whether the pump has reached the designated pressure. If the pump does not reach the designated pressure, control circuitry **230** may determine that the pump is inoperable. Otherwise, control circuitry **230** may then determine whether the ratio of the designated pressure to the power of the pump during pressure impulse is within a desired ratio. If the ratio is not within the desired ratio, control circuitry **230** may determine that the pump is inoperable. In this case, an operator (e.g., healthcare provider) may be instructed to replace parts of the pump (e.g., servo unit).

[0029] In some embodiments, if a valve is present in pressure generating and regulating system **220**, the valve may be utilized to release pneumatic pressure from bladder **212**. In this case, control circuitry **230** may determine whether a leakage rate with the pump off and the valve closed is above a leakage threshold. If the leakage rate is not above the leakage threshold, control circuitry **230** may determine that a leakage exists in pressure generating and regulating system **220**. In this scenario, the operator may be instructed to check one or more connections between the servo and finger cuff **202**. If such condition occurs for a number of times (e.g., three times), the operator may be instructed to replace finger cuff **202**. If the condition continues to occur after the replacement of finger cuff **202**, control circuitry **230** may determine that the valve is inoperable and instruct the operator to replace, for example a servo unit associated with the valve.

[0030] In some embodiments, with respect to patient suitability, control circuitry **230** may check the patient's perfusion, which is the volume of blood flow through the finger. For example, control circuitry **230** may determine whether the blood volume measured at the end of recovery time, for example a DC Pleth magnitude, has returned to an initial value measured at the low pressure, thereby indicating that

blood has returned to the finger. If the blood volume measured at the end of the recovery time has not returned to the initial value (i.e., the blood has not fully returned), control circuitry **230** may determine that the patient's perfusion is too low for the volume clamp system to operate properly. In this case, the operator may be instructed to increase the patient's perfusion by warming the hand or to select a different pressure monitoring technology.

[0031] Referring to FIGS. **3**A-**3**C, diagrams illustrating measured plethysmogram of finger cuff **202** according to embodiments of the invention are shown. In some embodiments, FIGS. **3**A-**3**C illustrate the plethysmogram and its components, the finger pulsatility and finger blood volume, obtained by pressure generating and regulating system **220** and control circuitry **230**, as previously described, applying pressure to finger cuff **202** and measuring pleth signals. With reference to FIG. **3**A, the diagram illustrates a gradual pressure ramp response, and particularly, an example of the changing pleth signal as a function of pressure. As shown in the diagram, a trace **310** shows the measured plethysmogram in arbitrary units (a.u.) that corresponds to the pneumatic pressures (which may be measured in mmHg) applied to the patient's finger.

[0032] As can be seen on FIGS. **3**A-**3**C and **4**A-**4**C, diagrams illustrating additional measured plethysmogram of finger cuff **202** according to embodiments of the invention are shown. With reference to FIG. **3**A, the diagram illustrates a pressure ramp response, and particularly, an example of a changing pleth signal as a function of pressure. As shown in the diagram, trace **310** shows the plethysmogram that corresponds to the pneumatic pressures applied to the patient's finger. In this case, as can be seen on trace **310**, at a low end **315** of the pressure (e.g., approximately 50-80 mmHg), pulsatility **317** is low relative to the maximum pulsatility **318**, which may indicate that finger cuff **202** is properly fitted (FIG. **3**C). Similarly, with reference to FIG. **3**B, the diagram illustrates the finger blood volume, and particularly, another example of the changing pleth signal as a function of pressure. As shown, a trace **320** shows a finger blood volume at every pneumatic pressure level applied to the patient's finger. As can be seen on trace **320**, at a low end **325** of the pressure (e.g., approximately 30-60 mmHg), increase in DC pleth is gradual, whereas in the mid-range **327** of the pressure (e.g. approximately 80-120 mm Hg) the increase in DC Pleth is noticeably higher. The transition from gradual increase at low end **325** to rapid increase at mid-range **327** occurs between the low end of the pressure (approximately 30-60 mmHg) and the mid-range of the pressure (approximately 80-120 mmHg), which again may indicate that finger cuff **202** is properly fitted.

[0033] In contrast, referring to trace **410** of FIG. **4**A, at a low end **415** of the pressure (e.g., approximately 30-60 mmHg), pulsatility **417**, for example AC Pleth, is high compared to the peak pulsatility **418**, which may indicate that finger cuff **202** is too tight (FIG. **4**C). Similarly, with reference to FIG. **4**B, the diagram illustrates the blood volume, and particularly, the DC pleth signal as a function of pressure. As shown, a trace **420** shows a finger blood volume at every pneumatic pressure level applied to the patient's finger. As can be seen on trace **420** of FIG. **4**B, the increase in DC Pleth with pressure is roughly constant, that is, the trace **420** does not contain separate regions of low and rapid increase, in contrast to FIG. **3**B, which again may indicate that finger cuff **202** is too tight.

[0034] In another embodiment of the invention, referring to trace **510** in FIG. **5**A, at the low end **515** of the pressure (e.g. approximately 30-60 mmHg), the pulsatility **517** is low compared to peak pulsatility **518**, and furthermore, the pulsatility remains low well into the mid-range of the pressure (e.g. above 80 mm Hg), which may indicate the finger cuff **202** is too loose (FIG. **5**C). Similarly, with reference to **5**B, a region **525** of gradual increase in DC Pleth as a function of pressure and a separate region **527** of rapid increase in DC Pleth as a function of pressure are both present, similar to FIG. **3**B. Unlike FIG. **3**B, the transition from gradual increase of region **525** to rapid increase of region **527** occurs at a higher pressure (approximately 100 mm Hg), which may indicate the finger cuff **202** is too loose.

[0035] While FIGS. **3**A-**3**C, **4**A-**4**C, and **5**A-**5**C illustrate a gradual pressure ramp response for the observations of the plethysmogram change, in some embodiments, a stepped increase (or "staircase") and/or a large step response may be used for the observations of the plethysmogram change as a function of pressure.

[0036] FIG. **6** is a flow diagram of a method for measuring the pulsatility of a finger cuff according to embodiments of the invention. Process **600** may be performed by processing logic that includes hardware (e.g. circuitry, dedicated logic, etc.), software (e.g., embodied on a non-transitory computer readable medium), or a combination thereof. For example, process **600** may be performed by pressure generating and regulating system **220**, control circuitry **230**, or a combination thereof.

[0037] Referring to FIG. **6**, at block **610**, the processing logic applies a low pressure (e.g., 20-40 mmHg) to a bladder (e.g., inflatable bladder **212**) of a finger cuff (e.g., finger cuff **202**). At block **620**, the processing logic measures plethysmogram of the finger cuff as pressure of the bladder increases to the low pressure. At block **630**, the processing logic applies a high pressure (e.g., 200 mmHg) to the bladder of the finger cuff. At block **640**, the processing logic measures the plethysmogram, observing both the finger blood volume, or DC pleth, and the finger pulsatility, or AC pleth, of the finger cuff as the pressure of the bladder increases to the high pressure. At block **650**, the processing logic releases the pressure from the bladder and observes pressure decay. At block **660**, the processing logic measures the plethysmogram, observing both the finger blood volume, or DC pleth, and the finger pulsatility, or AC pleth, of the finger cuff throughout the pressure decay.

[0038] FIG. **7** is a flow diagram of a method for determining whether a finger cuff is properly fitted on a patient's finger according to embodiments of the invention. Process **700** may be performed by processing logic that includes hardware (e.g. circuitry, dedicated logic, etc.), software (e.g., embodied on a non-transitory computer readable medium), or a combination thereof. For example, process **700** may be performed by pressure generating and regulating system **220**, control circuitry **230**, or a combination thereof.

[0039] Referring to FIG. **7**, at block **710**, the processing logic determines whether pulsatility of a low end of the pressure (e.g., low end **315** of FIG. **3**A) is at least a predetermined percentage lower than a peak pulsatility (or AC pleth level). At block **720**, if the pulsatility at the low end of the pressure is not at least a predetermined percentage lower than the peak pulsatility (e.g., as shown in pulsatility **417** and **418** and in pulsatility **517** and **518**), the processing logic determines that the finger cuff (e.g., finger cuff **202**) is

incorrectly attached (e.g., too tight, rotated or offset from the phalanx center). In this case, an operator (e.g., healthcare provider) may be instructed, via patient monitoring device **130** for example, to remove and reapply (e.g., loosen) the finger cuff. In some embodiments, if the incorrect attachment of the finger cuff occurs for a predetermined number of times (e.g., three times), the operator may be instructed to select a larger finger cuff. Otherwise, at block **730**, the processing logic determines that the finger cuff is properly fitted if the pulsatility at the low end of the pressure is at least a predetermined percentage lower than the peak pulsatility (e.g., as shown in pulsatility **317** and **318**).

[0040] FIG. **8** is a flow diagram of another method for determining whether a finger cuff is properly fitted on a patient's finger according to embodiments of the invention. Process **800** may be performed by processing logic that includes hardware (e.g. circuitry, dedicated logic, etc.), software (e.g., embodied on a non-transitory computer readable medium), or a combination thereof. For example, process **800** may be performed by pressure generating and regulating system **220**, control circuitry **230**, or a combination thereof.

[0041] Referring to FIG. **8**, at block **810**, the processing logic determines whether pulsatility of a high end of the pressure is at least a predetermined percentage lower than a peak pulsatility (or pleth level). At block **820**, if the pulsatility at the high end of the pressure is not at least a predetermined percentage lower than the peak pulsatility, the processing logic determines that the finger cuff (e.g., finger cuff **202**) is incorrectly attached (e.g., too loose, rotated or offset from the phalanx center). In this case, the operator may be instructed, via patient monitoring device **130** for example, to remove and reapply the finger cuff (e.g., to reapply the finger cuff more tightly). In some embodiments, if the incorrect attachment of the finger cuff occurs for a predetermined number of times (e.g., three times), the operator may be instructed to select a smaller finger cuff. Otherwise, at block **830**, the processing logic determines that the finger cuff is properly fitted if the pulsatility at the high end of the pressure is at least a predetermined percentage lower than the peak pulsatility.

[0042] Referring to FIG. **9**, a block diagram illustrating example control circuitry **230** is shown. It should be appreciated that FIG. **9** illustrates a non-limiting example of a control circuitry **230** implementation. Other implementations of the control circuitry **230** not shown in FIG. **9** are also possible. The control circuitry **230** may comprise a processor **910**, a memory **920**, and an input/output interface **930** connected with a bus **940**. Under the control of the processor **910**, data may be received from an external source through the input/output interface **930** and stored in the memory **920**, and/or may be transmitted from the memory **920** to an external destination through the input/output interface **930**. The processor **910** may process, add, remove, change, or otherwise manipulate data stored in the memory **920**. Further, code may be stored in the memory **920**. The code, when executed by the processor **910**, may cause the processor **910** to perform operations relating to data manipulation and/or transmission and/or any other possible operations.

[0043] It should be appreciated that aspects of the invention previously described may be implemented in conjunction with the execution of instructions by processors, circuitry, controllers, control circuitry, etc. As an example, control circuity may operate under the control of a program, algorithm, routine, or the execution of instructions to execute methods or processes in accordance with embodiments of the invention previously described. For example, such a program may be implemented in firmware or software (e.g. stored in memory and/or other locations) and may be implemented by processors, control circuitry, and/or other circuitry, these terms being utilized interchangeably. Further, it should be appreciated that the terms processor, microprocessor, circuitry, control circuitry, circuit board, controller, microcontroller, etc., refer to any type of logic or circuitry capable of executing logic, commands, instructions, software, firmware, functionality, etc., which may be utilized to execute embodiments of the invention.

[0044] The various illustrative logical blocks, processors, modules, and circuitry described in connection with the embodiments disclosed herein may be implemented or performed with a general purpose processor, a specialized processor, circuitry, a microcontroller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field programmable gate array (FPGA) or other programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination thereof designed to perform the functions described herein. A processor may be a microprocessor or any conventional processor, controller, microcontroller, circuitry, or state machine. A processor may also be implemented as a combination of computing devices, e.g., a combination of a DSP and a microprocessor, a plurality of microprocessors, one or more microprocessors in conjunction with a DSP core, or any other such configuration.

[0045] The steps of a method or algorithm described in connection with the embodiments disclosed herein may be embodied directly in hardware, in a software module/firmware executed by a processor, or any combination thereof. A software module may reside in RAM memory, flash memory, ROM memory, EPROM memory, EEPROM memory, registers, hard disk, a removable disk, a CD-ROM, or any other form of storage medium known in the art. An exemplary storage medium is coupled to the processor such the processor can read information from, and write information to, the storage medium. In the alternative, the storage medium may be integral to the processor.

[0046] The previous description of the disclosed embodiments is provided to enable any person skilled in the art to make or use the present invention. Various modifications to these embodiments will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other embodiments without departing from the spirit or scope of the invention. Thus, the present invention is not intended to be limited to the embodiments shown herein but is to be accorded the widest scope consistent with the principles and novel features disclosed herein.

What is claimed is:

1. A system to monitor a finger cuff connectable to a patient's finger to be used in measuring the patient's blood pressure by a blood pressure measurement system utilizing the volume clamp method and to measure the plethysmogram of the finger cuff, the system comprising:

the finger cuff including an enclosing portion that encloses a patient's finger, the enclosing portion including a bladder and a light emitting diode (LED) and photodiode (PD) pair; and

a processor configured to:

command applying pneumatic pressure to the bladder of the finger cuff from a low pressure to a high pressure;

measure the plethysmogram of the finger cuff as the pressure increases from the low pressure to the high pressure; and

determine fitness of the finger cuff on the patient's finger based on the measured plethysmogram, wherein, when the finger cuff is placed around the patient's finger, the bladder and the LED-PD pair aid in measuring the plethysmogram.

2. The system of claim **1**, wherein the processor is further to command releasing the pressure from the bladder and to observe pressure decay, and to measure the plethysmogram of the finger cuff throughout the pressure decay.

3. The system of claim **1**, wherein determining the fitness of the finger cuff on the patient's finger comprises determining whether the finger cuff is loose, properly fitted, or too tight.

4. The system of claim **3**, wherein determining whether the finger cuff is loose comprises: determining whether the pulsatility at a high end of the pressure is at least a predetermined percentage lower than a peak pulsatility.

5. The system of claim **4**, wherein the processor is further to instruct an operator to reapply the finger cuff more tightly if the pulsatility at the high end of the pressure is not at least the predetermined percentage lower than the peak pulsatility.

6. The system of claim **3**, wherein determining whether the finger cuff is properly fitted comprises: determining whether the pulsatility at a low end of the pressure is low.

7. The system of claim **3**, wherein determining whether the finger cuff is too tight comprises: determining whether the pulsatility at a low end of the pressure is at least a predetermined percentage lower than a peak pulsatility.

8. The system of claim **7**, wherein the processor is further to instruct an operator to loosen the finger cuff if the pulsatility at the low end of the pressure is not at least the predetermined percentage lower than the peak pulsatility.

9. The system of claim **6**, wherein after the finger cuff is determined to be properly fitted, the finger cuff is used in measuring the patient's blood pressure by the blood pressure measurement system utilizing the volume clamp method.

10. The system of claim **1**, wherein the processor is further configured to:

determine whether blood volume of the patient's finger measured at the end of recovery time has returned to an initial value measured at the low pressure; and

in response to determining that the blood volume of the patient's finger measured at the end of the recovery time has not returned to the initial value:

determine that the patient's perfusion is too low for the blood pressure measurement system to operate properly, and

instruct an operator to increase the patient's perfusion by warming the hand or to select a different pressure monitoring technology.

11. A method to monitor a finger cuff connectable to a patient's finger to be used in measuring the patient's blood pressure by a blood pressure measurement system utilizing the volume clamp method and to measure the plethysmogram of the finger cuff, the finger cuff including an enclosing portion that encloses a patient's finger, the enclosing portion including a bladder and a light emitting diode (LED) and photodiode (PD) pair, the method comprising:

applying pneumatic pressure to the bladder of the finger cuff from a low pressure to a high pressure;

measuring the plethysmogram of the finger cuff as the pressure increases from the low pressure to the high pressure; and

determining fitness of the finger cuff on the patient's finger based on the measured plethysmogram, wherein, when the finger cuff is placed around the patient's finger, the bladder and the LED-PD pair aid in measuring the plethysmogram.

12. The method of claim **11**, further comprising: releasing the pressure from the bladder and observing pressure decay, and measuring the plethysmogram of the finger cuff throughout the pressure decay.

13. The method of claim **11**, wherein determining the fitness of the finger cuff on the patient's finger comprises determining whether the finger cuff is loose, properly fitted, or too tight.

14. The method of claim **13**, wherein determining whether the finger cuff is loose comprises: determining whether the pulsatility at a high end of the pressure is at least a predetermined percentage lower than a peak pulsatility.

15. The method of claim **14**, further comprising: instructing an operator to reapply the finger cuff more tightly if the pulsatility at the high end of the pressure is not at least the predetermined percentage lower than the peak pulsatility.

16. The method of claim **13**, wherein determining whether the finger cuff is properly fitted comprises: determining whether the pulsatility at a low end of the pressure is low.

17. The method of claim **13**, wherein determining whether the finger cuff is too tight comprises: determining whether the pulsatility at a low end of the pressure is at least a predetermined percentage lower than a peak pulsatility.

18. The method of claim **17**, further comprising: instructing an operator to loosen the finger cuff if the pulsatility at the low end of the pressure is not at least the predetermined percentage lower than the peak pulsatility.

19. The method of claim **16**, wherein after the finger cuff is determined to be properly fitted, the finger cuff is used in measuring the patient's blood pressure by the blood pressure measurement system utilizing the volume clamp method.

20. The method of claim **11**, further comprising:

determining whether blood volume of the patient's finger measured at the end of recovery time has returned to an initial value measured at the low pressure;

in response to determining that the blood volume of the patient's finger measured at the end of the recovery time has not returned to the initial value:

determining that the patient's perfusion is too low for the blood pressure measurement system to operate properly, and

instructing an operator to increase the patient's perfusion by warming the hand or to select a different pressure monitoring technology.

* * * * *

专利名称(译)	用于执行体积夹指套的诊断程序的系统和方法		
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摘要(译)

公开了一种系统，用于监测可连接到患者手指的手指套，该手指套用于通过利用体积钳方法的血压测量系统测量患者的血压并测量手指套的体积描记图。该系统包括指套，该指套包括封闭患者手指的封闭部分。封闭部分包括囊和发光二极管（LED）和光电二极管（PD）对。该系统还包括处理器，用于：从低压到高压向指套的囊施加气压;当压力从低压增加到高压时，测量指套的体积描记图;并且基于所测量的体积描记图确定手指套在患者手指上的适合度。当手指套被放置在患者手指周围时，膀胱和LED-PD对帮助处理器测量体积描记图。