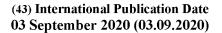


(19) World Intellectual Property Organization

International Bureau







(10) International Publication Number WO 2020/176206 A1

- (51) International Patent Classification: A61B 5/021 (2006.01) A61B 5/022 (2006.01)
- (21) International Application Number:

PCT/US2020/016845

(22) International Filing Date:

05 February 2020 (05.02.2020)

(25) Filing Language:

English

(26) Publication Language:

English

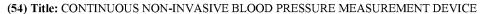
(30) Priority Data:

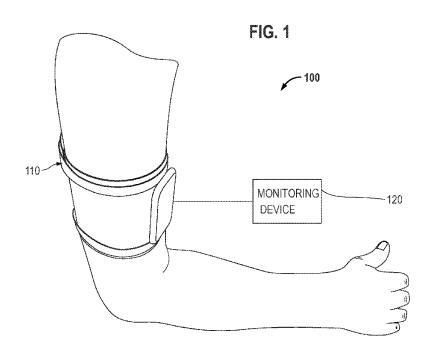
62/809,876

25 February 2019 (25.02.2019) US

- (71) Applicant: EDWARDS LIFESCIENCES CORPORATION [US/US]; One Edwards Way, Irvine, CA 92614 (US).
- (72) Inventors: AXELROD, Blake, W.; Edwards Lifesciences, One Edwards Way, Legal Department, Irvine, CA 92614 (US). SIEMONS, Alexander, H.; Edwards Lifesciences, One Edwards Way, Legal Department, Irvine, CA 92614 (US).

- (74) Agent: CRAPENHOFT, Michael et al.; Edwards Lifesciences, One Edwards Way, Irvine, CA 92614 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,





(57) **Abstract:** Disclosed is a method and apparatus for continuously monitoring the blood pressure of a patient with an arm cuff. The operations comprise: determining a baseline absolute blood pressure; continuously determining a photoplethysmogram associated with an arterial blood flow; determining a pulsatility waveform based on the photoplethysmogram; and continuously monitoring and determining the patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform.

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

CONTINUOUS NON-INVASIVE BLOOD PRESSURE MEASUREMENT DEVICE

BACKGROUND

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/809,876, filed February 25th, 2019, which is incorporated by reference herein in its entirety.

Field

[0002] Embodiments of the invention relate to non-invasive blood pressure measurement.

Relevant Background

[0003] Conventionally, absolute non-invasive blood pressure measurements are performed using external cuffs that apply pressure to one or more arteries and the response of the arteries is observed to determine the patient's blood pressure. Auscultatory and oscillometric blood pressure cuffs typically use this technique to obtain discrete (non-continuous) blood pressure measurements. A volume clamp method (e.g., typically used with a finger cuff) may relate to a technique for obtaining continuous blood pressure measurements.

[0004] Applying pressure to a patient's arteries has downsides. The large pressures required by auscultatory and oscillometric techniques are uncomfortable and may damage arteries if performed too frequently. Thus, use of these techniques is typically limited to a single measurement every 3-5 minutes. The volume clamp method applies lower but continuous pressure, which may result in venous pooling and uncomfortable numbness in the patient's finger.

[0005] "Cuff-less" blood pressure measurement techniques that do not require applying an external force to the arteries or require very low forces have been developed. Pulse wave analysis (PWA) techniques that obtain an arterial pulsatility waveform, extract amplitude and timing features, and track changes in those features over time that correlate with changes in blood pressure over time are the most successful class of cuff-less blood pressure measurement techniques. Examples of PWA techniques include photoplethysmography techniques developed by Centre Suisse d'Electronique et de Microtechnique (CSEM).

[0006] Unfortunately, these types of PWA techniques alone do not enable absolute blood pressure measurements.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. 1 is a diagram illustrating an example of an environment in which optional examples of the disclosure may be practiced.

[0008] FIG. 2 is a diagram illustrating another view of an example of an arm cuff according to optional examples.

[0009] FIGS. 3A and 3B are data plots illustrating data gathered and processed in the operation of an optional example of a device as described herein.

[0010] FIG. 4 is flowchart illustrating an optional example method for continuously monitoring the blood pressure of a patient with an arm cuff according to optional examples.

[0011] FIG. 5 is a block diagram illustrating an optional example device.

DETAILED DESCRIPTION

[0012] Various optional examples and aspects of the disclosures will be described with reference to details discussed below, and the accompanying drawings will illustrate the various optional examples. The following description and drawings are illustrative of the disclosure and are not to be construed as limiting the disclosure. Numerous specific details are described to provide a thorough understanding of various optional examples of the present disclosure. However, in certain instances, well-known or conventional details are not described in order to provide a concise discussion of optional examples of the present disclosures.

[0013] Reference in the specification to "one embodiment" or "an embodiment" or "optional example" means that a particular feature, structure, or characteristic described in conjunction with the embodiment or optional example can be included in at least one embodiment or optional example of the disclosure. The appearances of the phrase "in one embodiment" or "optional example" in various places in the specification do not necessarily all refer to the same embodiment or same optional example.

[0014] Optional examples of the disclosure may relate to method and apparatus for continuously monitoring the blood pressure of a patient with an arm cuff. Optional examples of the operations may comprise: determining a baseline absolute blood pressure; continuously determining a photoplethysmogram associated with an arterial blood flow; determining a

pulsatility waveform based on the photoplethysmogram; and continuously monitoring and determining the patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform.

[0015] Additional optional examples may relate to an arm cuff device comprising a light-emitting diode (LED) – photodiode (PD) assembly and a processor to: determine a baseline absolute blood pressure; continuously determine a photoplethysmogram associated with an arterial blood flow from the LED-PD assembly; determine a pulsatility waveform based on the photoplethysmogram; and continuously monitor and determine a patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform.

[0016] In particular, as will be described in more detail, one optional example may relate to combining a photoplethysmogram sensor (e.g., an LED-PD assembly) that obtains a pulsatility waveform from which changes in blood pressure may be estimated using pulse wave analysis (PWA) techniques in combination with an external arm cuff that measures discrete absolute blood measurements from which changes can be tracked.

[0017] With reference to Figure 1, a diagram illustrating an optional example of an environment 100 in which optional examples may be practiced is shown. As shown in Figure 1, an arm cuff 110 may be placed around a patient's upper arm. The arm cuff 110 may be of conventional shape – approximately circular and conical shaped with a cavity to accept the patient's arm. The arm cuff 110 may comprise components necessary for conventional oscillometric blood pressure measurement (e.g., pneumatic elements, pressure sensors, etc.). Arm cuffs to perform oscillometric blood pressure measurement are well known in the art. However, arm cuff 110, according to optional examples of the disclosure, may further include a photoplethysmogram sensor, such as an LED-PD assembly, as will be described in more detail hereafter. Although an LED-PD assembly is described as an optional example of the photoplethysmogram sensor, it should be appreciated that any suitable sensor may be utilized, such as, other optical sensors, light sensors, wave sensors, etc.

[0018] In one optional example, the photoplethysmogram sensor may include one or more LEDs and a PD. In this way, the photoplethysmogram sensor may illuminate a portion of the patient's arm with the LEDs, and measures the light reflected off of the arm with the PD. The light is absorbed by the blood in the patient's arm, and less light is reflected when more blood is passing through the arm, and vice versa. In other words, the light reflected off of the arm of the patient is inversely correlated with a blood flow volume. In different optional examples, LEDs that emit light with different frequencies (e.g., infrared, red, or

green light) may be utilized, so long as the light can be absorbed by the blood. Accordingly, a photoplethysmogram may be obtained. A pulsatility waveform suitable for pulse waveform analysis (PWA) can be derived from the photoplethysmogram with conventional methods. For example, the pulsatility waveform may be related to the AC portion of the photoplethysmogram.

[0019] In one optional example, an oscillometric blood pressure measurement may first be performed with the arm cuff 110 to obtain an absolute baseline blood pressure. In one optional example, the absolute baseline blood pressure may include systolic pressure, diastolic pressure, and mean arterial pressure (MAP). The oscillometric blood pressure measurement typically requires applying pressure to the patient's arm for a short period of time (e.g., approximately 30 seconds). It should be appreciated that in another optional example, a technique other than the oscillometric method may be utilized to obtain the absolute baseline blood pressure. Also, as has been described, arm cuffs to obtain oscillometric blood pressure measurements are known in the art.

[0020] According to an optional example of the disclosure, afterwards, the arm cuff 110 releases pressure and the photoplethysmogram sensor (e.g., the LED-PD assembly) continuously acquires the photoplethysmogram, and based upon that, the pulsatility waveform. According to one optional example, changes in the systolic, diastolic and mean arterial pressures from the initial oscillometric values may be continuously tracked by analyzing the pulsatility waveform with pulse waveform analysis (PWA) techniques. Also, in one optional example, a low pressure that does not meaningfully impede arterial blood flow may be retained in the arm cuff 110 during the continuous monitoring phase to bring the photoplethysmogram sensor close to the patient, or to keep the sensor at a fixed proximity of the patient.

[0021] Further, as an optional example, arm cuff 110 may be coupled to a patient monitoring device 120 through a power/data cable. The patient monitoring device 120 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, the power/data cable may transmit data to and from patient monitoring device 120 and also may provide power from the patient monitoring device 120 to the arm cuff 110. The patient monitoring device 120 may be mounted to or be a part of the arm cuff 110, itself, or may be remotely located. Also, in some optional examples the patient monitoring device 120 may not be connected by a cable and may be in

wireless communication with the arm cuff 110. It should be appreciated that these are just optional examples of the use of a patient monitoring device that may or may not be used with other optional examples.

[0022] With additional reference to Figure 2, a diagram illustrating another view of an example of an arm cuff 110 according to one optional example is shown. As described above, the arm cuff 110 may include components 210 utilized for conventional oscillometric blood pressure measurement (e.g., pneumatic elements, pressure sensors, etc.) and further, according to optional examples of the disclosure, may include a photoplethysmogram sensor 215. In one optional example, the photoplethysmogram sensor 215 can be an LED-PD assembly 215, and further may include one or more LEDs 220 and a PD 230. In one optional example, the photoplethysmogram sensor 215 may be on the inside of the arm cuff 110.

[0023] With this configuration, in one optional example, an oscillometric blood pressure measurement may first be performed with the arm cuff 110, particularly, with components 210, to obtain a baseline absolute blood pressure. Thereafter, in one optional example, in the continuous monitoring phase, the photoplethysmogram sensor 215 may continuously acquire the photoplethysmogram and therefore the pulsatility waveform. In particular, in one optional example, the LEDs 220 may illuminate a portion of the arm of the patient where the arm cuff 110 is worn and over which the photoplethysmogram sensor 215 is situated and the PD 230 may measure the light reflected off of the arm. In one optional example, once the pulsatility waveform is obtained, PWA techniques may be utilized to continuously track changes in the patient's blood pressure (e.g., systolic, diastolic, and mean arterial pressure values). In this way, by utilizing PWA techniques on the pulsatility waveform, the patient's blood pressure (e.g., systolic, diastolic, and mean arterial pressure values) can be tracked, determined, and displayed on the monitoring device 120. Thus, in optional example, the patient's blood pressure can be continuously monitored, tracked, determined, and displayed based on the baseline absolute blood pressure and the pulsatility waveform utilizing PWA techniques. Such PWA techniques may include any suitable PWA technique, such as techniques developed by Centre Suisse d'Electronique et de Microtechnique (CSEM).

[0024] As has been described, in one optional example, the arm cuff 110 obtains an absolute blood pressure measurement utilizing oscillometric blood pressure measurement techniques (e.g., from the patient's brachial artery), which is discrete and non-continuous, and then tracks the patient's blood pressure via analysis of the pulsatility waveform obtained

from the PD 230 by PWA techniques. In particular, in one optional example, the pulsatility waveform obtained by the PD 230, by utilizing PWA techniques, may be used to continuously monitor, track, update, and display the patient's blood pressure based on the previously measured baseline absolute blood pressure. Therefore, a periodic absolute blood pressure measurement may be taken that is then tracked via analysis of the pulsatility waveform by PWA techniques to continuously monitor, track, update, and display the patient's blood pressure. In one optional example, the use of photoplethysmogram sensor 215 offers the opportunity of obtaining a high quality pulsatility waveform from the brachial artery.

[0025] Referring to Figures 3A and 3B, data plots 300A, 300B according to optional examples of the disclosure are shown. Figure 3A shows a pulsatility waveform 300A obtained at the brachial artery using a photoplethysmogram sensor 215 integrated into a brachial arm cuff 110. Further, Figure 3B shows a power spectral density of the waveform 300A in the frequency range for PWA.

[0026] With additional reference to Figure 4, a flowchart illustrating an optional example method 400 for continuously monitoring the blood pressure of a patient with an arm cuff 110 according to one optional example is shown. At block 410, a baseline absolute blood pressure may be determined. At block 420, a photoplethysmogram associated with an arterial blood flow may be continuously determined. At block 430, a pulsatility waveform may be determined based on the photoplethysmogram. At block 440, the patient's blood pressure may be continuously monitored and determined based on the baseline absolute blood pressure and the pulsatility waveform. In one optional example, determining the baseline absolute blood pressure may be accomplished by applying an oscillometric blood pressure measurement technique. In one optional example, the baseline absolute blood pressure may include systolic pressure, diastolic pressure, and mean arterial pressure of the patient. As has been described, in one optional example, the photoplethysmogram associated with the arterial blood flow may be determined using a light-emitting diode (LED) – photodiode (PD) assembly 215 disposed in the arm cuff 110. In one optional example, the determining of photoplethysmogram comprises illuminating a portion of an arm of the patient with one or more LEDs 220 of the LED-PD assembly 215 and measuring light reflected off of the arm of the patient with a PD 230 of the LED-PD assembly 215. The patient's blood pressure may be continuously monitored and determined based on the baseline absolute blood pressure and the pulsatility waveform from the photoplethysmogram. As has been described, in one optional

example, tracking changes in the patient's blood pressure based on the pulsatility waveform may be accomplished by performing a pulse waveform analysis (PWA) on the pulsatility waveform. In particular, as has been described, in one optional example, the pulsatility waveform obtained by the PD 230, by utilizing PWA techniques, may be used to continuously monitor, track, update, and display the patient's blood pressure based on the previously measured baseline absolute blood pressure.

[0027] With reference to Figure 5, a block diagram illustrating an optional example device 500 is shown. It should be appreciated that the device 500 represents a non-limiting optional example of the patient monitoring device 120 in implementation with the arm cuff 110 to form a patient monitoring system. The optional example device 500 may comprise a processor 510, a memory 520, an input/output interface 530, and a storage device 540 connected with a bus 550. Under the control of the processor 510, data may be received from an external source through the input/output interface 530, or from the storage device 540, and stored in the memory 520, and/or may be transmitted from the memory 520 to an external destination through the input/output interface 530, or to the storage device 540. A nonlimiting implementation of the input/output interface 530 may comprise one or more of: a display, a touchscreen, a sensor connector port, a bidirectional communication port, etc. The storage device 540 may be implemented with one or more of: a hard disk drive, a flash drive, etc. The processor 510 may process, add, remove, change, or otherwise manipulate data stored in the memory 520. Further, code may be stored in the memory 520. Alternatively or additionally, code may be stored in the storage device 540, or received through the input/output interface 530, and then transferred to the memory 520. The code, when executed by the processor 510, may cause the processor 510 to perform operations relating to data manipulation and/or transmission and/or any other possible operations.

[0028] Therefore, one optional example of the disclosure is related to a patient monitoring system, comprising: an arm cuff 110; a memory 520; and a processor 510 coupled to the memory 520, the processor 510 to: determine a baseline absolute blood pressure; continuously determine a photoplethysmogram associated with an arterial blood flow; determine a pulsatility waveform based on the photoplethysmogram; and continuously monitor and determine a patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform. Further, processor 510 may command the display of the patient's blood pressure on the monitoring device 120 or at another device. It should be appreciated that many of the components of the device 500 (e.g., processor, memory, etc.)

may be implemented as part of the monitoring device 120, but may also be implemented at other parts of the arm cuff, or at other locations.

[0029] As one optional example, an oscillometric blood pressure measurement may first be performed with the arm cuff 110 to obtain a baseline absolute blood pressure. Thereafter, as one optional example, device 500 with implementation of functions by processor 510, may implement a continuous monitoring phase, in cooperation with the photoplethysmogram sensor 215 that continuously acquires the pulsatility waveform. In particular, in one optional example, the LEDs 220 may illuminate a portion of the arm of the patient where the arm cuff 110 is worn and over which the photoplethysmogram sensor 215 is situated and the PD 230 may measure the light reflected off of the arm. In one optional example, once the pulsatility waveform is obtained, PWA techniques implemented by the processor 510, may be utilized to continuously track changes in the patient's blood pressure (e.g., systolic, diastolic, and mean arterial pressure values). In this way, in one optional example, by utilizing PWA techniques on the pulsatility waveform, the patient's blood pressure (e.g., systolic, diastolic, and mean arterial pressure values) can be tracked, determined, and displayed on the monitoring device 120 or at another location. Thus, the patient's blood pressure can be continuously monitored, tracked, determined, and displayed based on the baseline absolute blood pressure and the pulsatility waveform utilizing PWA techniques. It should be appreciated that the previous description of the patient monitoring system, device, arm cuff, monitoring device, processor, etc., are just optional examples of a physical implementation to perform the functions, and any suitable physical implementation may be utilized. It should be appreciated that an arm cuff 110 utilizing an oscillometric blood measurement technique to obtain absolute blood pressure is only one optional example and that any suitable device at any suitable location utilizing any suitable technique may be utilized. Further, utilizing a photoplethysmogram sensor 215 that includes an LED-PD assembly that illuminates a portion of an arm of the patient with one or more LEDs 220 and measures light reflected off of the arm of the patient with a PD 230 to obtain a pulsatility waveform is only one optional example and other suitable devices and methods may be utilized. Moreover, utilizing PWA techniques on the pulsatility waveform is only one optional example and other suitable techniques may be utilized.

[0030] Therefore, optional examples of the disclosure relate to a brachial arm cuff with a photoplethysmogram sensor and a method for continuously monitoring a patient's blood pressure with a system comprising the brachial arm cuff. In one optional example, the

absolute baseline blood pressure is first obtained with a conventional oscillometric technique. In one optional example, the photoplethysmogram sensor is then utilized to generate a pulsatility waveform indicative of the arterial blood flow volume. In further optional examples, PWA techniques may thereafter be applied to the pulsatility waveform to continuously track changes in the patient's blood pressure.

[0031] It should be appreciated that the optional examples of the disclosure are associated with a number of benefits. A single device, i.e., the brachial arm cuff, has been described that can perform absolute blood pressure measurements and generate the pulsatility waveform as well. It is beneficial to use the brachial location to generate the pulsatility waveform because it is at the same phlebostatic level as the heart and existing medical process flows are well acquainted with brachial oscillometric devices. Further, recent advances in PD and LED technologies have increased the sensitivity of PDs and reduced the cost of large area PDs, thus increasing the sensitivity of photoplethysmogram sensors at lower costs. Accordingly, high quality waveforms can be obtained from the brachial location where the brachial artery can be buried beneath layers of fat and muscle. Therefore, examples of the disclosure enable accurate continuous blood pressure measurement and monitoring.

[0032] It should be appreciated that combining an optical sensor to obtain pulsatility waveforms for PWA BP tracking at the brachial location with a traditional oscillometric brachial arm cuff is beneficial because it combines both absolute measurement and tracking into a single device. Furthermore, the form factor is well understood and accepted in established usage spaces (e.g., hospitals and other healthcare settings). Moreover, the brachial location is at heart level and does not require compensation for hydrostatic changes between the hand and heart. Therefore, the optional examples described combine both absolute BP measurement with PWA BP tracking in a single device at a location that is ideal for both absolute BP measurements and human factors within the hospital setting.

[0033] It should be appreciated that the generic principles defined herein may be applied to other examples without departing from the spirit or scope of the invention. For example, in one optional example, a cuff may not be used over the upper arm, but may be located at the radial arteries or at the finger. In another optional example, in addition or as an alternative to the blood pressure, cardiac output or other hemodynamic parameters can be measured and tracked using similar techniques to those described herein. Further, it should

be appreciated that other techniques besides oscillometric techniques may be utilized to obtain absolute blood pressure measurements.

[0034] It should be appreciated that aspects of the disclosure previously described may be implemented in conjunction with the execution of instructions by processors, circuitry, controllers, control circuitry, etc. (e.g., processor 510 of Figure 5). As an example, a processor may operate under the control of a program, algorithm, routine, or the execution of instructions to execute methods or processes (e.g., method 400 of Figure 4) in accordance with embodiments 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.

[0035] 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.

[0036] 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.

[0037] 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.

[0038] The disclosure also includes the following clauses:

1. A method for continuously monitoring the blood pressure of a patient with an arm cuff, comprising:

determining a baseline absolute blood pressure;

continuously determining a photoplethysmogram associated with an arterial blood flow;

determining a pulsatility waveform based on the photoplethysmogram; and continuously monitoring and determining the patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform.

- 2. The method of claim 1, wherein determining the baseline absolute blood pressure comprises applying an oscillometric blood pressure measurement technique.
- 3. The method of any of the claims 1-2, wherein the baseline absolute blood pressure further comprises a systolic pressure, a diastolic pressure, and a mean arterial pressure.
- 4. The method of any of the claims 1-3, wherein the photoplethysmogram associated with the arterial blood flow is determined using a light-emitting diode (LED) photodiode (PD) assembly disposed in the arm cuff.
- 5. The method of any of the claims 1-4, wherein the determining of photoplethysmogram comprises illuminating a portion of an arm of the patient with one or

more LEDs of an LED-PD assembly and measuring light reflected off of the arm of the patient with a PD of the LED-PD assembly.

- 6. The method of any of the claims 1-5, wherein continuously monitoring and determining the patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform comprises tracking changes in the patient's blood pressure based on the pulsatility waveform.
- 7. The method of claim 6, wherein tracking changes in the patient's blood pressure based on the pulsatility waveform comprises performing a pulse waveform analysis (PWA) on the pulsatility waveform.
 - 8. A patient monitoring system, comprising:

an arm cuff;

a memory; and

a processor coupled to the memory, the processor configured to:

determine a baseline absolute blood pressure;

continuously determine a photoplethysmogram associated with an arterial blood flow;

determine a pulsatility waveform based on the photoplethysmogram; continuously monitor and determine a patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform; and command the display of the patient's blood pressure on a monitoring device.

- 9. The patient monitoring system of claim 8, wherein determining the baseline absolute blood pressure comprises applying an oscillometric blood pressure measurement technique.
- 10. The patient monitoring system of any of the claims 8-9, wherein the baseline absolute blood pressure further comprises a systolic pressure, a diastolic pressure, and a mean arterial pressure.

11. The patient monitoring system of any of the claims 8-10, wherein the photoplethysmogram associated with the arterial blood flow is determined using a light-emitting diode (LED) – photodiode (PD) assembly disposed in the arm cuff.

- 12. The patient monitoring system of any of the claims 8-11, wherein the determining of photoplethysmogram comprises illuminating a portion of an arm of the patient with one or more LEDs of an LED-PD assembly and measuring light reflected off of the arm of the patient with a PD of the LED-PD assembly.
- 13. The patient monitoring system of any of the claims 8-12, wherein continuously monitoring and determining the patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform comprises tracking changes in the patient's blood pressure based on the pulsatility waveform.
- 14. The patient monitoring system of claim 13, wherein tracking changes in the patient's blood pressure based on the pulsatility waveform comprises performing a pulse waveform analysis (PWA) on the pulsatility waveform.
 - 15. An arm cuff device, comprising:
 - a light-emitting diode (LED) photodiode (PD) assembly; and a processor configured to:

determine a baseline absolute blood pressure;

continuously determine a photoplethysmogram associated with an arterial blood flow from the LED-PD assembly;

determine a pulsatility waveform based on the photoplethysmogram; and

continuously monitor and determine a patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform.

16. The arm cuff device of claim 15, wherein determining the baseline absolute blood pressure comprises applying an oscillometric blood pressure measurement technique.

17. The arm cuff device of any of the claims 15-16, wherein the baseline absolute blood pressure further comprises a systolic pressure, a diastolic pressure, and a mean arterial pressure.

- 18. The arm cuff device of any of the claims 15-17, wherein the LED-PD assembly comprises one or more LEDs and a PD.
- 19. The arm cuff device of claim 18, wherein the one or more LEDs illuminate a portion of an arm of the patient, and the PD measures light reflected off of the arm of the patient.
- 20. The arm cuff device of claim 19, wherein the light reflected off of the arm of the patient is inversely correlated with a blood flow volume, and is used to generate the pulsatility waveform.
- 21. The arm cuff device claim 20, wherein a pulse waveform analysis (PWA) is performed on the pulsatility waveform to track changes in the patient's blood pressure.

WHAT IS CLAIMED IS:

1. A method for continuously monitoring the blood pressure of a patient with an arm cuff, comprising:

determining a baseline absolute blood pressure;

continuously determining a photoplethysmogram associated with an arterial blood flow;

determining a pulsatility waveform based on the photoplethysmogram; and continuously monitoring and determining the patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform.

- 2. The method of claim 1, wherein determining the baseline absolute blood pressure comprises applying an oscillometric blood pressure measurement technique.
- 3. The method of any of the claims 1-2, wherein the baseline absolute blood pressure further comprises a systolic pressure, a diastolic pressure, and a mean arterial pressure.
- 4. The method of any of the claims 1-3, wherein the photoplethysmogram associated with the arterial blood flow is determined using a light-emitting diode (LED) photodiode (PD) assembly disposed in the arm cuff.
- 5. The method of any of the claims 1-4, wherein the determining of photoplethysmogram comprises illuminating a portion of an arm of the patient with one or more LEDs of an LED-PD assembly and measuring light reflected off of the arm of the patient with a PD of the LED-PD assembly.
- 6. The method of any of the claims 1-5, wherein continuously monitoring and determining the patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform comprises tracking changes in the patient's blood pressure based on the pulsatility waveform.
- 7. The method of claim 6, wherein tracking changes in the patient's blood pressure based on the pulsatility waveform comprises performing a pulse waveform analysis (PWA) on the pulsatility waveform.

8. A patient monitoring system, comprising:

an arm cuff;

a memory; and

a processor coupled to the memory, the processor configured to:

determine a baseline absolute blood pressure;

continuously determine a photoplethysmogram associated with an arterial blood flow;

determine a pulsatility waveform based on the photoplethysmogram; continuously monitor and determine a patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform; and command the display of the patient's blood pressure on a monitoring device.

- 9. The patient monitoring system of claim 8, wherein determining the baseline absolute blood pressure comprises applying an oscillometric blood pressure measurement technique.
- 10. The patient monitoring system of any of the claims 8-9, wherein the baseline absolute blood pressure further comprises a systolic pressure, a diastolic pressure, and a mean arterial pressure.
- 11. The patient monitoring system of any of the claims 8-10, wherein the photoplethysmogram associated with the arterial blood flow is determined using a light-emitting diode (LED) photodiode (PD) assembly disposed in the arm cuff.
- 12. The patient monitoring system of any of the claims 8-11, wherein the determining of photoplethysmogram comprises illuminating a portion of an arm of the patient with one or more LEDs of an LED-PD assembly and measuring light reflected off of the arm of the patient with a PD of the LED-PD assembly.
- 13. The patient monitoring system of any of the claims 8-12, wherein continuously monitoring and determining the patient's blood pressure based on the baseline absolute blood

pressure and the pulsatility waveform comprises tracking changes in the patient's blood pressure based on the pulsatility waveform.

- 14. The patient monitoring system of claim 13, wherein tracking changes in the patient's blood pressure based on the pulsatility waveform comprises performing a pulse waveform analysis (PWA) on the pulsatility waveform.
 - 15. An arm cuff device, comprising:
 - a light-emitting diode (LED) photodiode (PD) assembly; and a processor configured to:

determine a baseline absolute blood pressure;

continuously determine a photoplethysmogram associated with an arterial blood flow from the LED-PD assembly;

determine a pulsatility waveform based on the photoplethysmogram; and

continuously monitor and determine a patient's blood pressure based on the baseline absolute blood pressure and the pulsatility waveform.

- 16. The arm cuff device of claim 15, wherein determining the baseline absolute blood pressure comprises applying an oscillometric blood pressure measurement technique.
- 17. The arm cuff device of any of the claims 15-16, wherein the baseline absolute blood pressure further comprises a systolic pressure, a diastolic pressure, and a mean arterial pressure.
- 18. The arm cuff device of any of the claims 15-17, wherein the LED-PD assembly comprises one or more LEDs and a PD.
- 19. The arm cuff device of claim 18, wherein the one or more LEDs illuminate a portion of an arm of the patient, and the PD measures light reflected off of the arm of the patient.

20. The arm cuff device of claim 19, wherein the light reflected off of the arm of the patient is inversely correlated with a blood flow volume, and is used to generate the pulsatility waveform.

21. The arm cuff device claim 20, wherein a pulse waveform analysis (PWA) is performed on the pulsatility waveform to track changes in the patient's blood pressure.

1/5

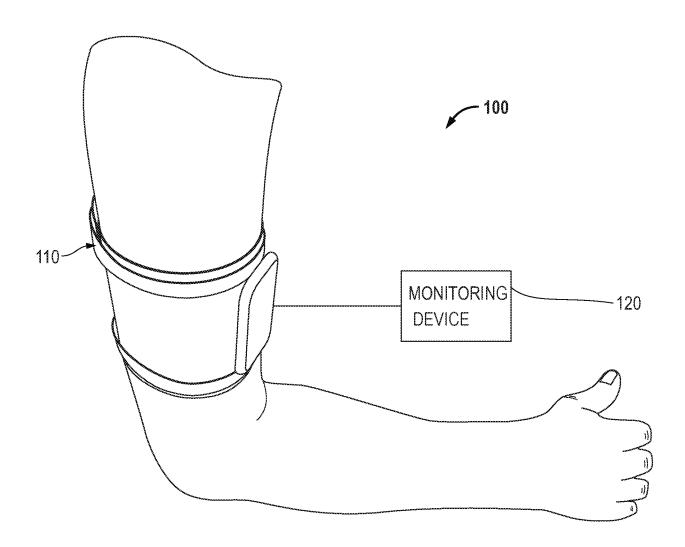


FIG. 1

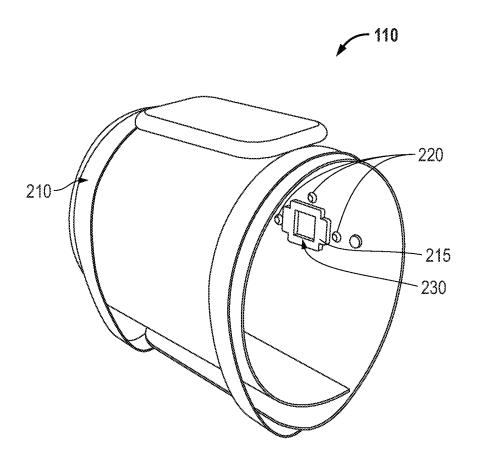


FIG. 2



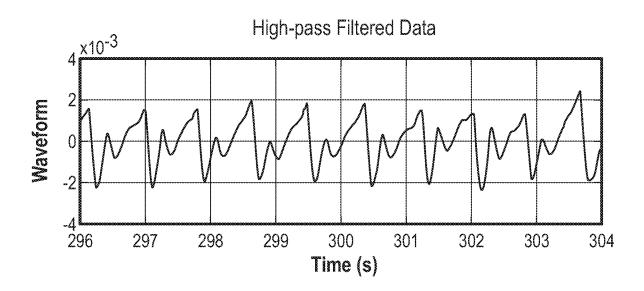


FIG. 3A

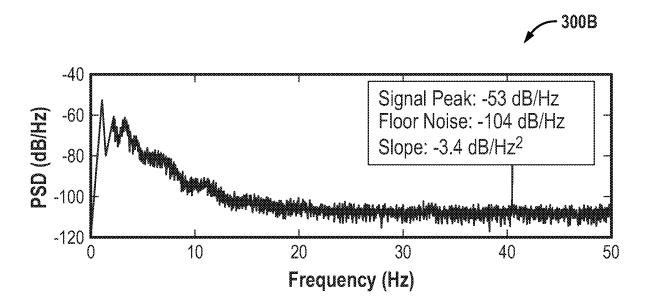


FIG. 3B

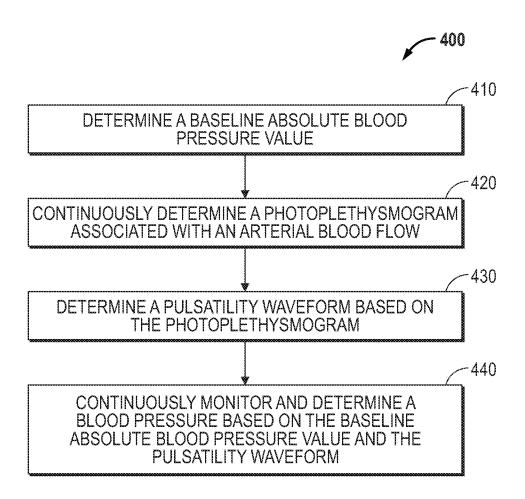


FIG. 4

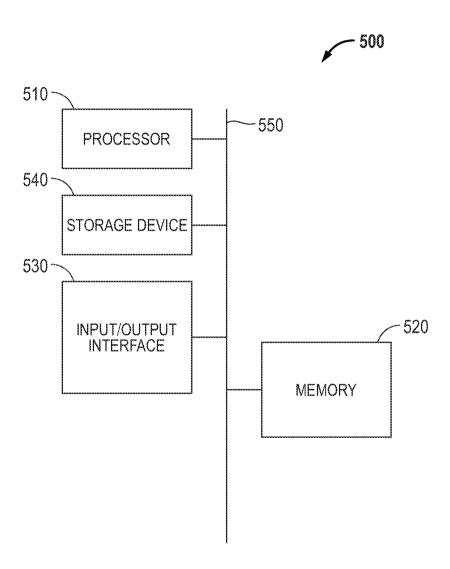


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/016845

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B5/021 A61B5 A61B5/021 A61B5/022 ADD. According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) A61B Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal C. DOCUMENTS CONSIDERED TO BE RELEVANT Category* Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. Χ US 2014/031638 A1 (JUNG SUN-TAE [KR] ET 1-21 AL) 30 January 2014 (2014-01-30) paragraphs [0025], [0027], [0030], [0033] US 2017/360314 A1 (PROENÇA MARTIN [CH] ET Χ 1-21 AL) 21 December 2017 (2017-12-21) paragraphs [0042], [0044], [0052] EP 0 426 572 A2 (TERUMO CORP [JP]) Α 1-21 8 May 1991 (1991-05-08) page 4, line 30 - line 31 Х Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents : "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "A" document defining the general state of the art which is not considered to be of particular relevance earlier application or patent but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be special reason (as specified) considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "O" document referring to an oral disclosure, use, exhibition or other document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 8 April 2020 21/04/2020 Name and mailing address of the ISA/ Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016 Knüpling, Moritz

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2020/016845

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2014031638 A1	30-01-2014	KR 20140013833 A US 2014031638 A1	05-02-2014 30-01-2014
US 2017360314 A1	21-12-2017	CN 107920758 A EP 3226758 A1 JP 6669409 B2 JP 2018517528 A US 2017360314 A1 W0 2016138965 A1	17-04-2018 11-10-2017 18-03-2020 05-07-2018 21-12-2017 09-09-2016
EP 0426572 A2	08-05-1991	DE 69026575 D1 DE 69026575 T2 EP 0426572 A2 JP H0763450 B2 JP H03143424 A US 5172696 A	23-05-1996 19-12-1996 08-05-1991 12-07-1995 19-06-1991 22-12-1992