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(54) **METHODS AND SYSTEM FOR ASSESSMENT OF PERIPHERAL PERFUSION**

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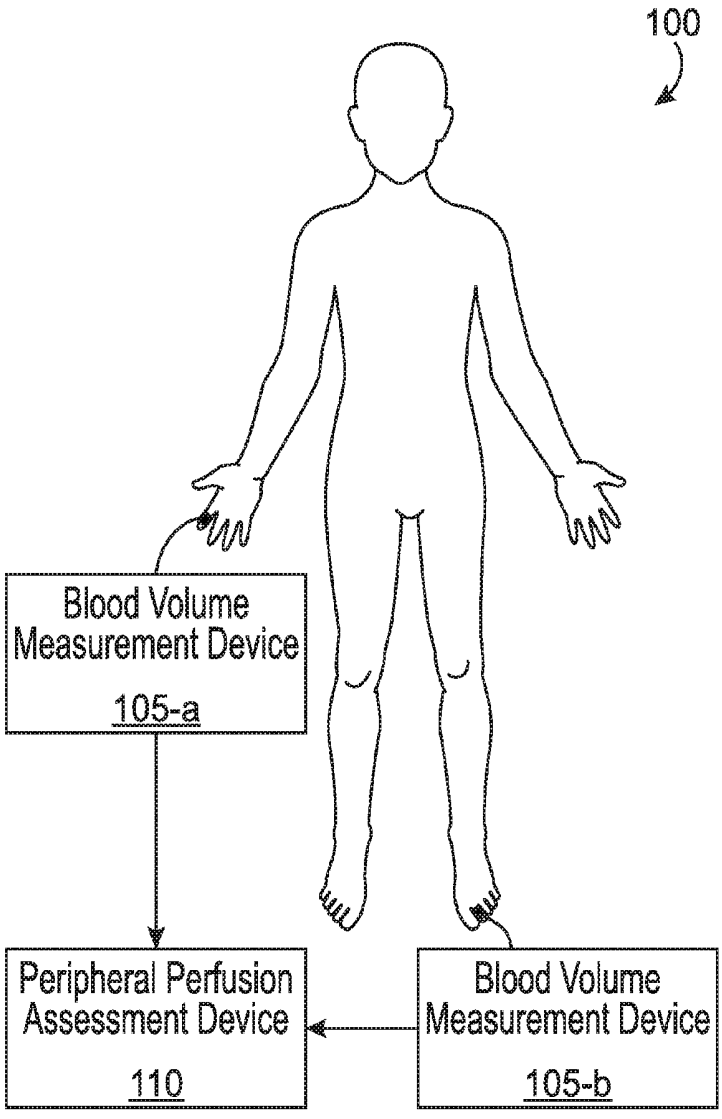
(57) **ABSTRACT**

The present technology is directed to apparatuses, systems, and methods for assessing absolute and relative peripheral perfusion. In various embodiments, two blood volume measurement devices measure the blood volume at a patient's extremities either simultaneously or in series. Distortions between the waveforms generated by the two blood volume measurement devices are detected, and an assessment of the patient's perfusion is determined based on the degree of distortion.



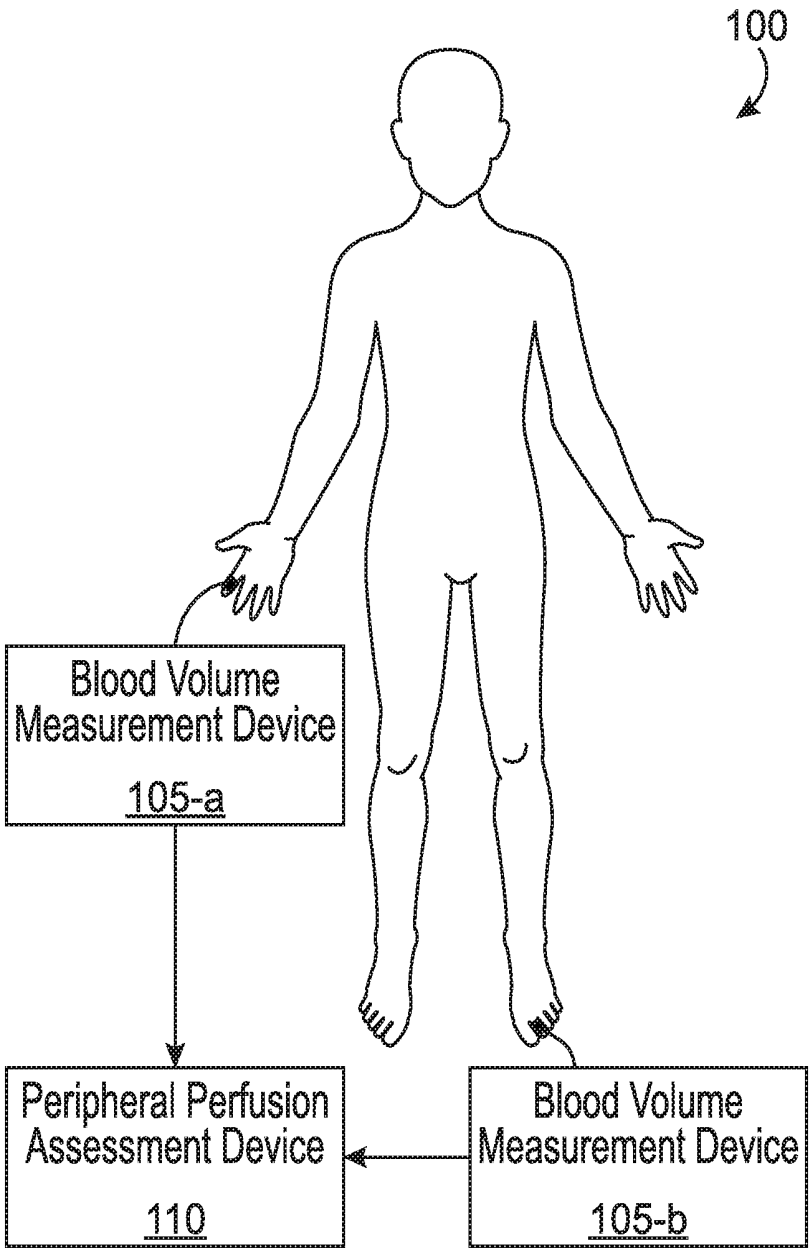

100
Blood Volume Measurement Device 105-a
Peripheral Perfusion Assessment Device 110
Blood Volume Measurement Device 105-b

FIG. 1A

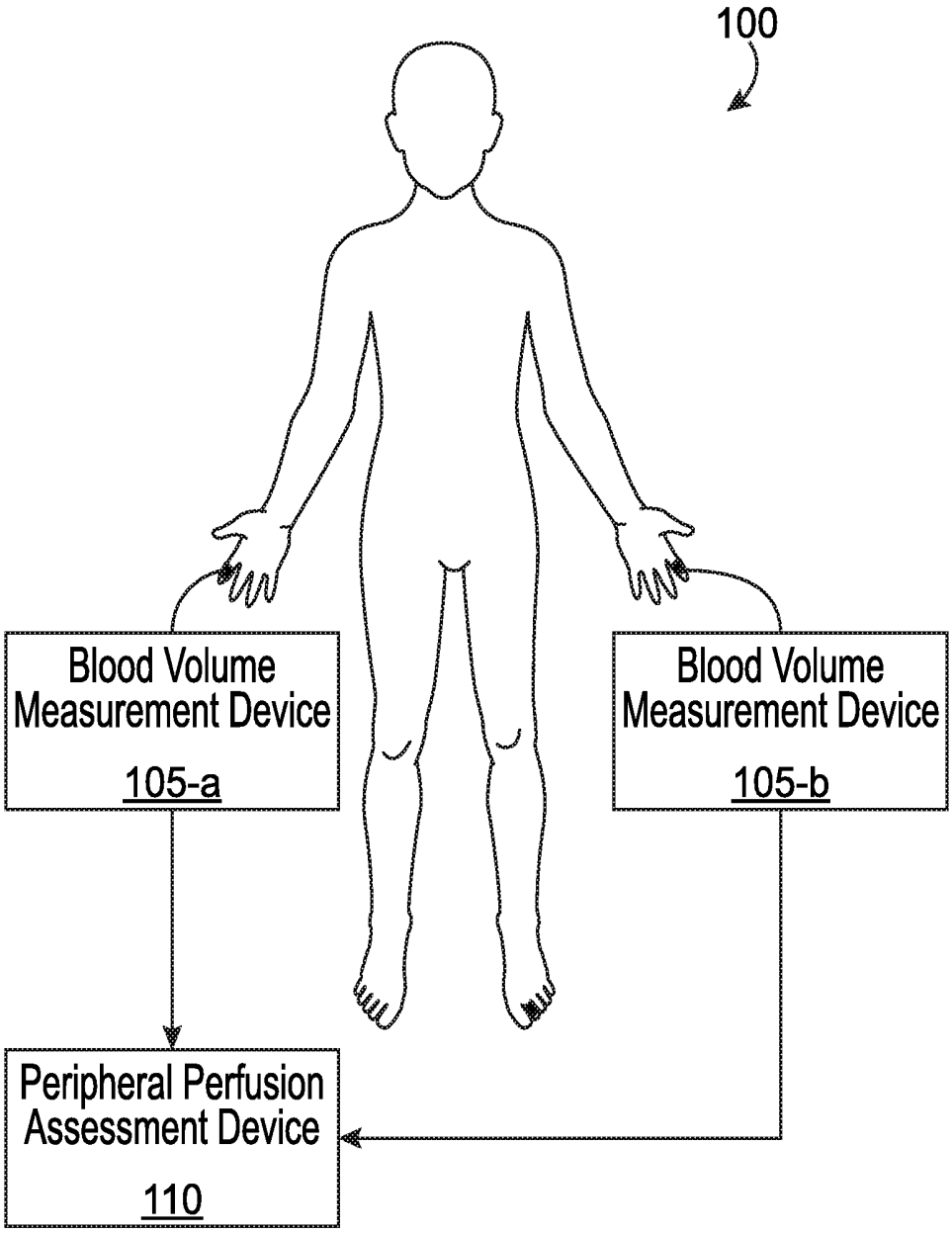

100
Blood Volume Measurement Device 105-a
Blood Volume Measurement Device 105-b
Peripheral Perfusion Assessment Device 110

FIG. 1B

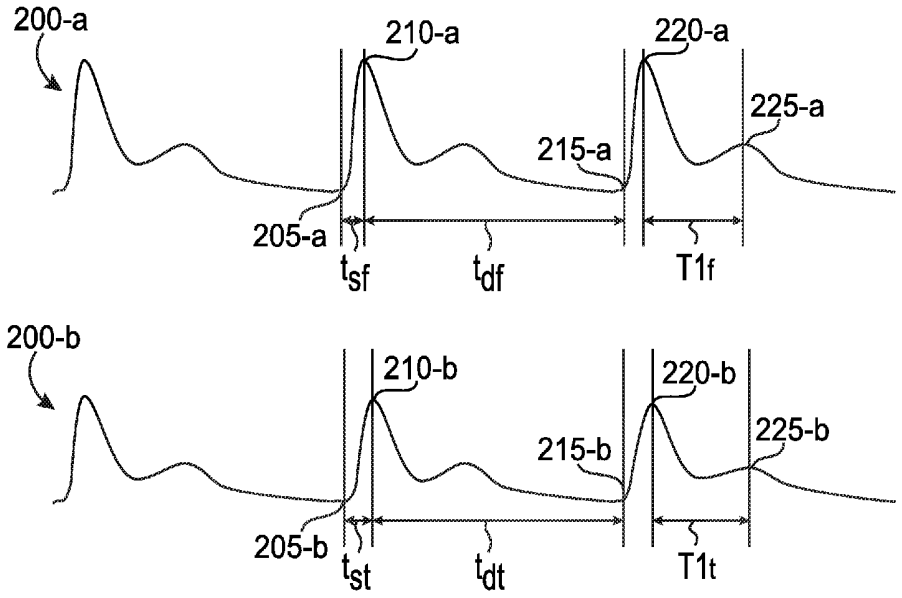

200-a
210-a
220-a
225-a
215-a
205-a
t_{sf}
t_{df}
T1f
200-b
210-b
220-b
225-b
215-b
205-b
t_{st}
t_{dt}
T1t

FIG. 2

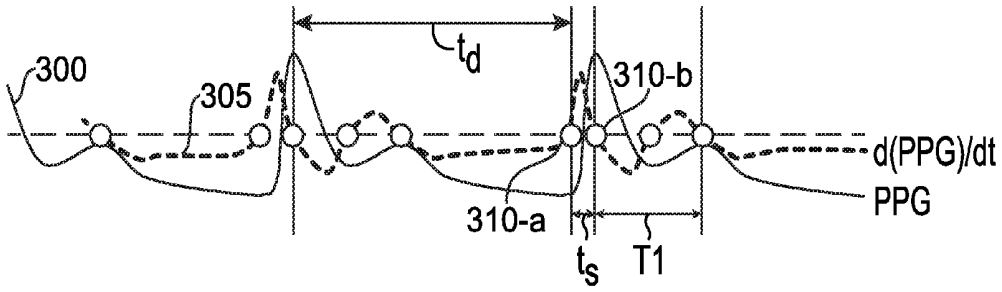


FIG. 3

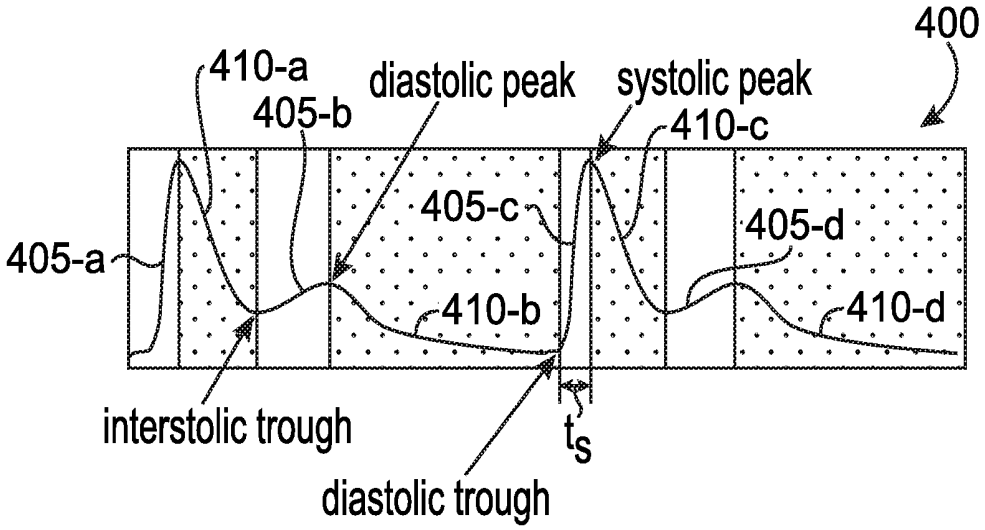

400
410-a
405-b
diastolic peak
systolic peak
410-c
405-a
405-c
405-d
410-b
410-d
interstolic trough
t_s
diastolic trough

FIG. 4

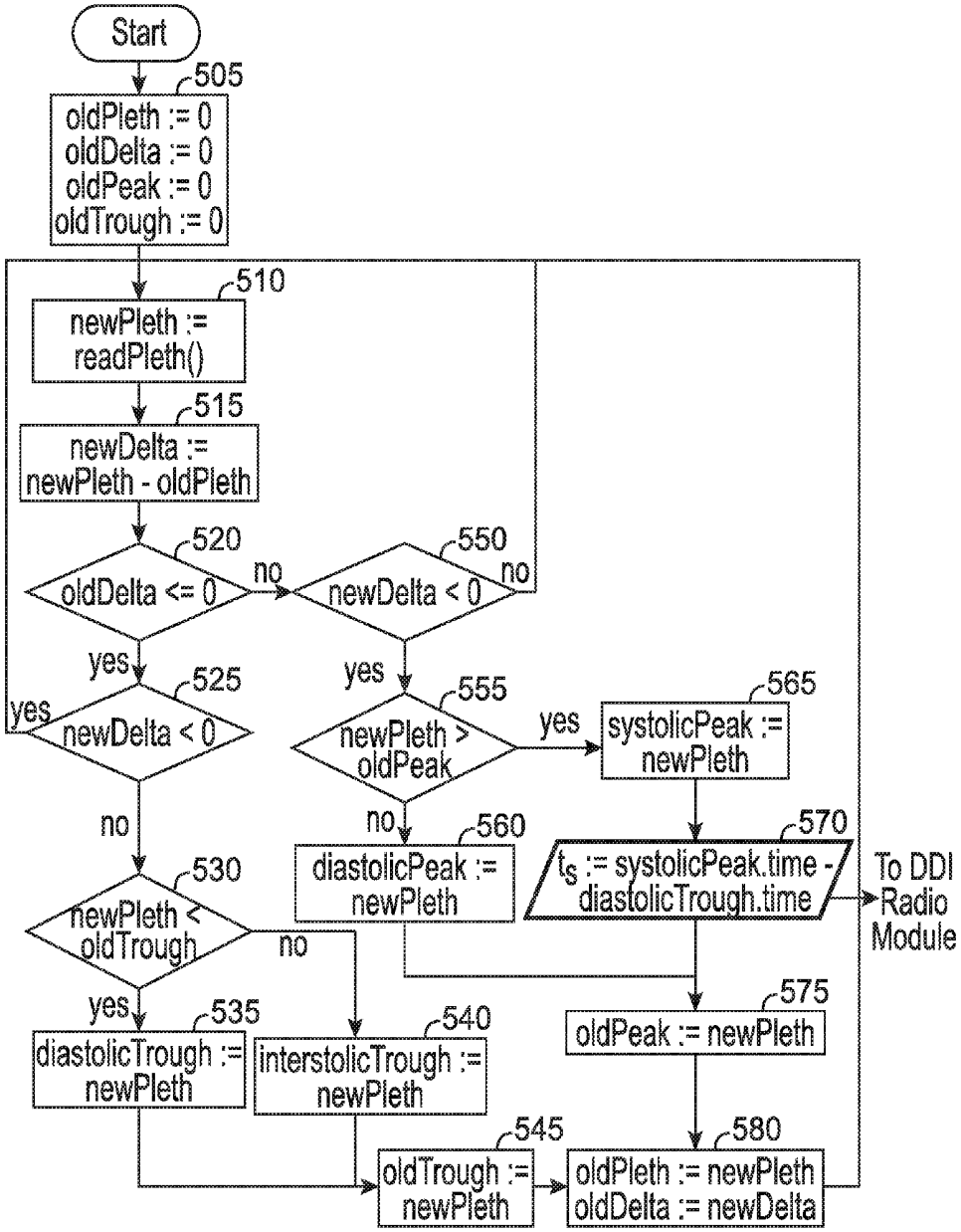

Start
505
oldPleth := 0
oldDelta := 0
oldPeak := 0
oldTrough := 0
510
newPleth := readPleth()
515
newDelta := newPleth - oldPleth
520
oldDelta <= 0
no
550
newDelta < 0
no
yes
525
newDelta < 0
yes
yes
555
newPleth > oldPeak
yes
565
systolicPeak := newPleth
no
560
diastolicPeak := newPleth
570
t_S := systolicPeak.time - diastolicTrough.time
To DDI Radio Module
no
530
newPleth < oldTrough
no
yes
535
diastolicTrough := newPleth
540
interstolicTrough := newPleth
575
oldPeak := newPleth
545
oldTrough := newPleth
580
oldPleth := newPleth
oldDelta := newDelta

FIG. 5

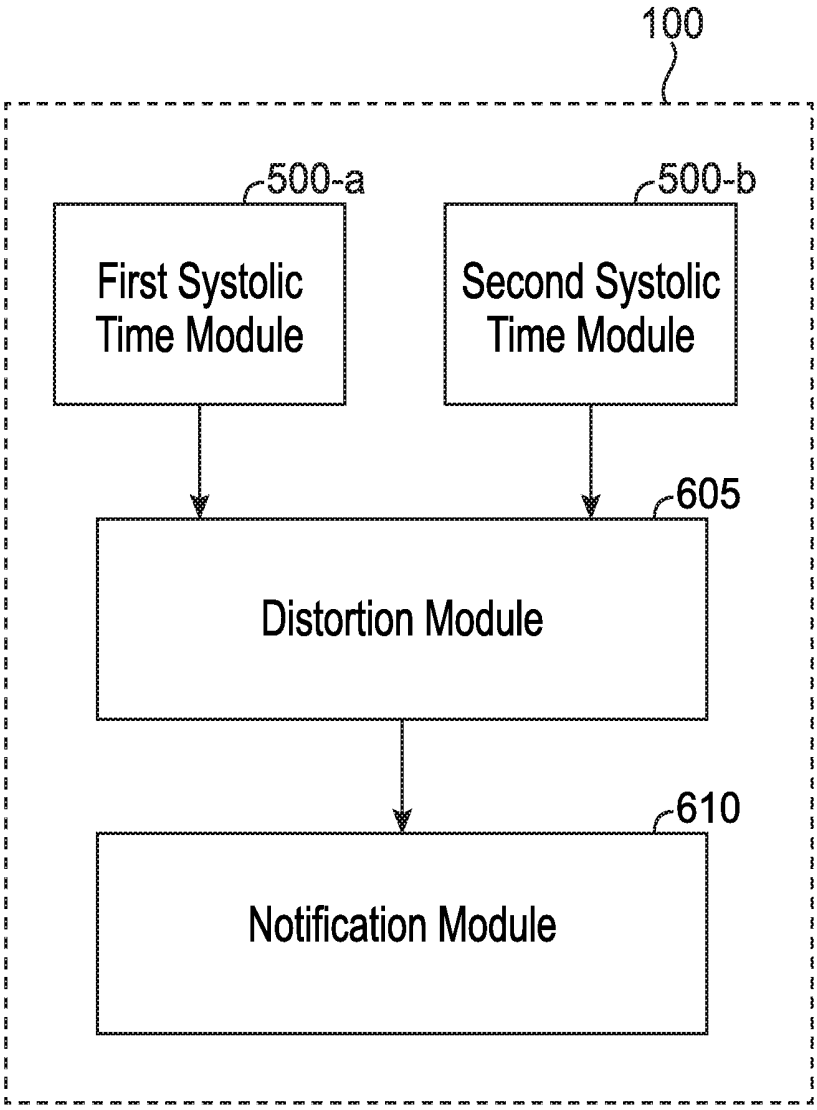

100
500-a
First Systolic Time Module
500-b
Second Systolic Time Module
605
Distortion Module
610
Notification Module

FIG. 6

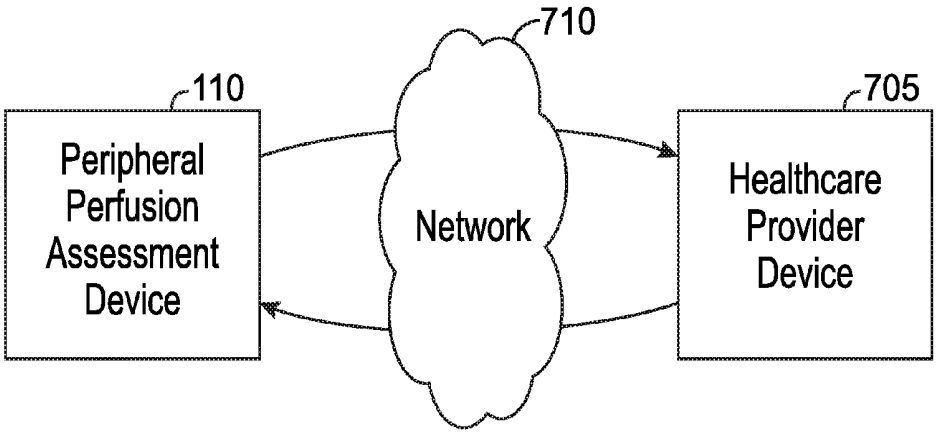

710
110
705
Peripheral Perfusion Assessment Device
Network
Healthcare Provider Device

FIG. 7

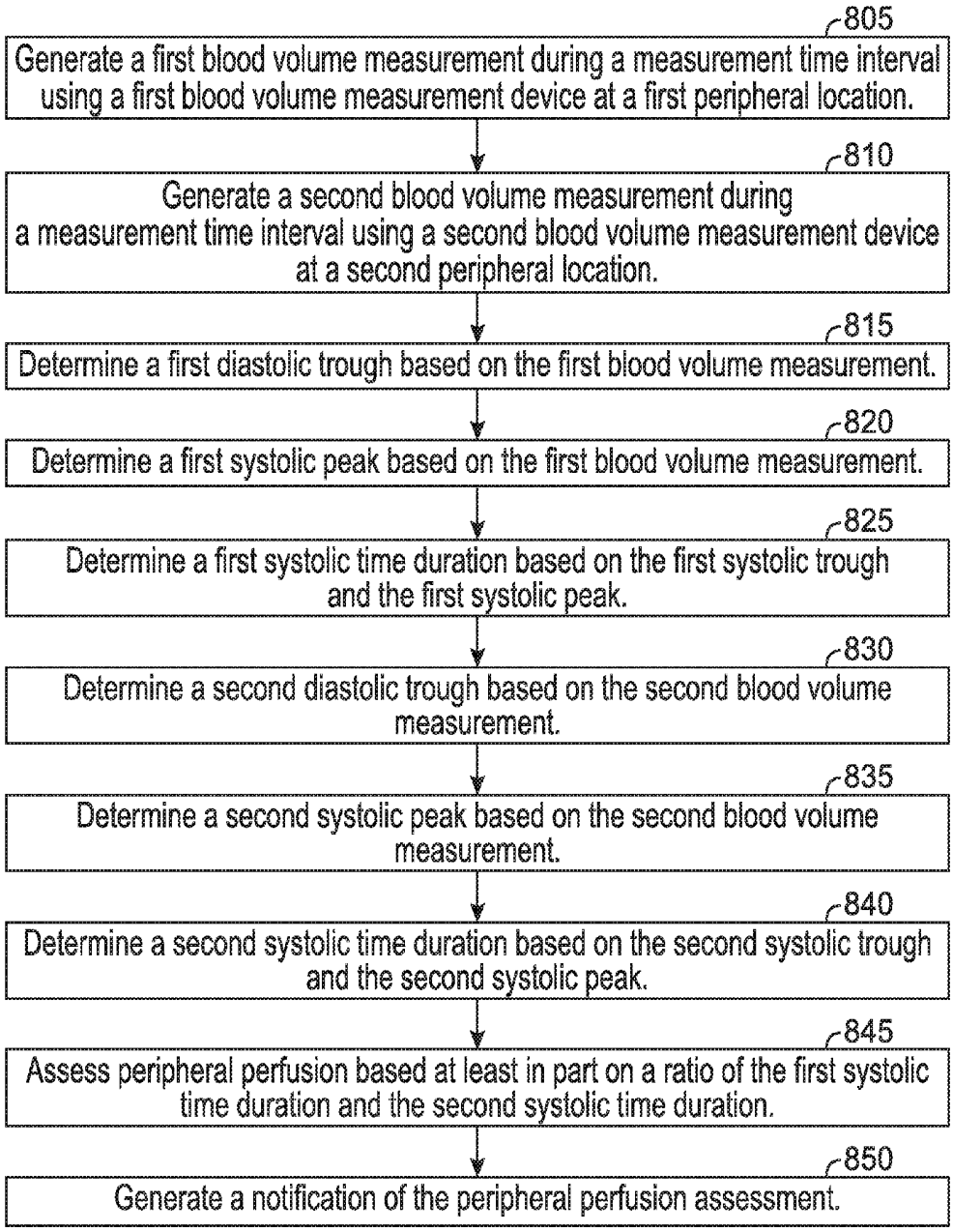
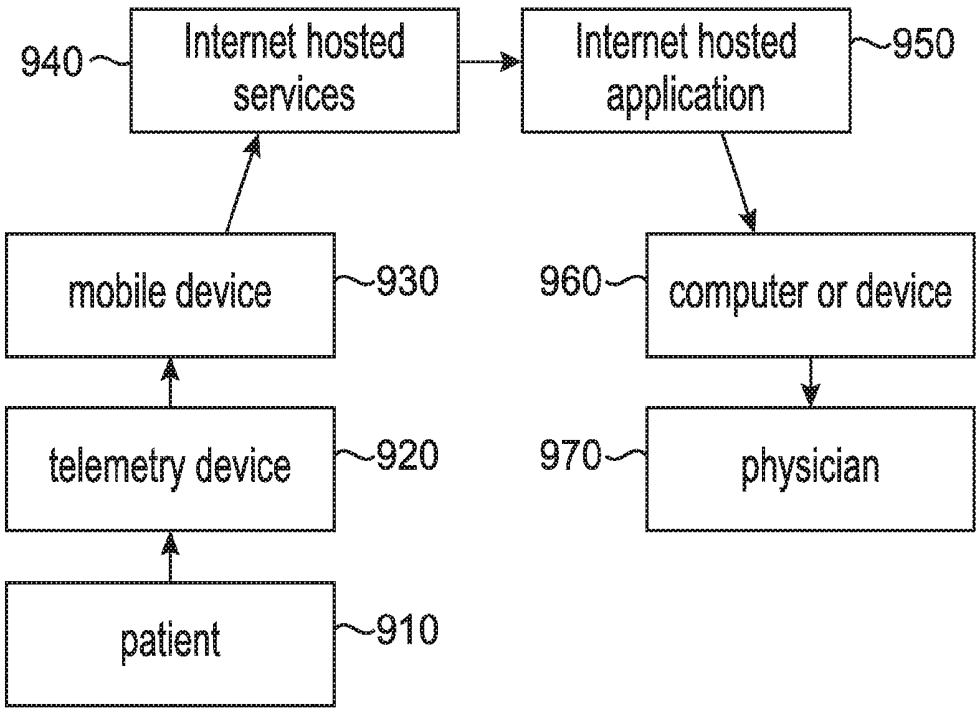
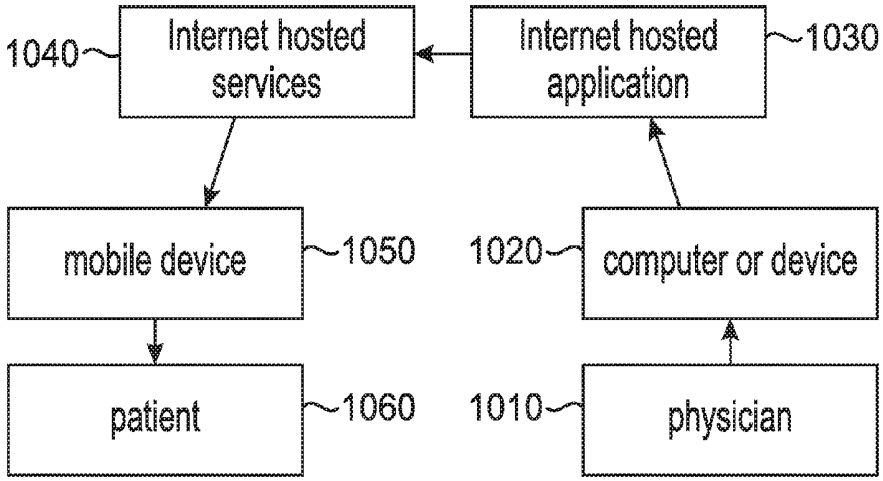

805
Generate a first blood volume measurement during a measurement time interval using a first blood volume measurement device at a first peripheral location.
810
Generate a second blood volume measurement during a measurement time interval using a second blood volume measurement device at a second peripheral location.
815
Determine a first diastolic trough based on the first blood volume measurement.
820
Determine a first systolic peak based on the first blood volume measurement.
825
Determine a first systolic time duration based on the first systolic trough and the first systolic peak.
830
Determine a second diastolic trough based on the second blood volume measurement.
835
Determine a second systolic peak based on the second blood volume measurement.
840
Determine a second systolic time duration based on the second systolic trough and the second systolic peak.
845
Assess peripheral perfusion based at least in part on a ratio of the first systolic time duration and the second systolic time duration.
850
Generate a notification of the peripheral perfusion assessment.

FIG. 8



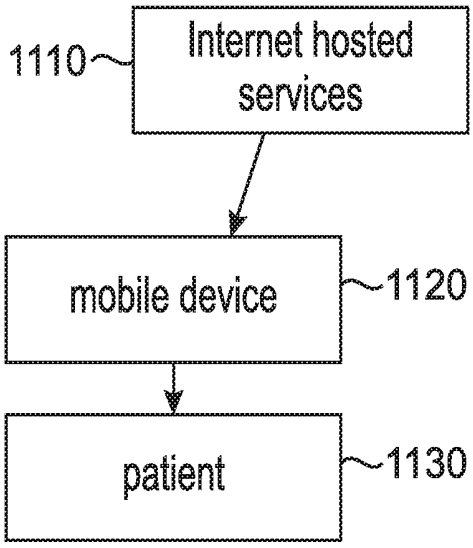
Telemetry Data Flow
900

FIG. 9



Notice to Patient from Physician
1000

FIG. 10



Notice to Patient from System
1100

FIG. 11

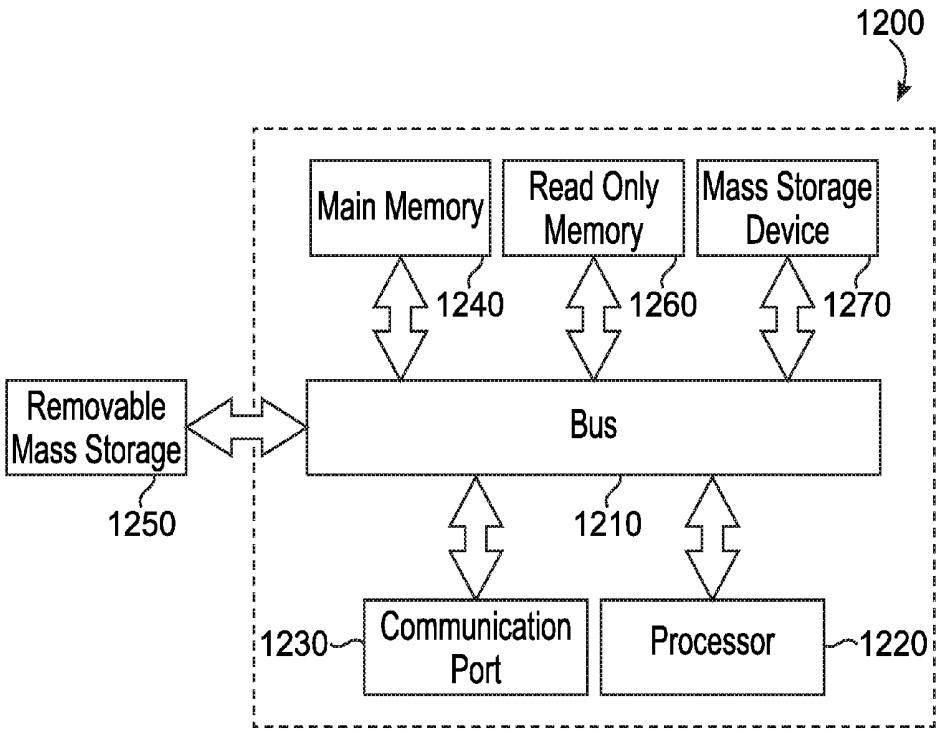

1200
Main Memory
Read Only Memory
Mass Storage Device
1240
1260
1270
Removable Mass Storage
Bus
1250
1210
1230
Communication Port
Processor
1220

FIG. 12

Harbor Vascular, Inc. Home Perfusion Index Sample Report
www.harborvascular.com
888-888-8888 tel.
888-888-8888 fax.

Name: Test, Patient
Date: 00/00/0000 00:00
Phone Location I.D.#: 0000-00
Patient I.D.#: 00-000-000
Provider I.D.: 00-000

Procedure Code: CPT 99490, 99091
Indications: Claudication, Limb Pain, Tobacco Use Disorder, Hypertension, Peripheral Vascular Disease

ICD-9 coding: 729.5, 443.9, 440.22, 305.1, 401.1, 436

Date	RIGHT MPulse P.I.	LEFT MPulse P.I.
8/4/15	0.93	0.97
8/12/15	**0.66**	0.97
8/12/15	**0.68**	0.96
9/4/15	**0.65**	0.93

ALERT SENT TO PHONE I.D.#: 0000-00 00:00:01/CONFIRMED RECEIPT 00:00:02
ALERT SENT TO PROVIDER I.D.#: 00-000 00:00:01/CONFIRMED RECEIPT 00:00:03

TEST INTERPRETATION:
1. ABNORMAL ANKLE-BRACHIAL INDEX RIGHT LEG, WITH INTERVAL DECREASE IN PERFUSION SINCE LAST TESTING
2. NO CHANGE IN PERFUSION INDEX, LEFT LEG
3. ATHEROSCLEROTIC RISK FACTOR MODIFICATION ADVISED
4. RECOMMEND FOLLOW-UP APPOINTMENT WITH VASCUAR SPECIALIST (ALERT SENT AND CONFIRMED)
5. 20+ MINUTES OF PROVIDER TIME SPENT ON INTERPRETATION AND MANAGEMENT

Signed, Interpreting Provider, MD 00:00:08

FIG. 13

METHODS AND SYSTEM FOR ASSESSMENT OF PERIPHERAL PERFUSION

PRIORITY

[0001] This application claims priority to U.S. provisional application Ser. No. 62/146,869 filed on Apr. 13, 2015, the entirety of which is incorporated herein.

TECHNICAL FIELD

[0002] The present technology relates generally to blood volume measurement and, more particularly, to techniques for utilizing blood volume measurements to assess peripheral perfusion. Additionally, the present technology relates to the delivery of these measurements to a physician for the purpose of remote monitoring the patient.

BACKGROUND

[0003] Peripheral perfusion, or the adequacy of blood flow through the peripheral vasculature, can be assessed to detect deficits and potentially prevent limb or life threatening situations. Techniques for measuring for peripheral perfusion currently require a patient to visit a healthcare provider wherein the healthcare provider takes multiple blood volume or blood pressure measurements using a single measurement device. For example, the healthcare provider may measure blood pressure at a patient's arm. The healthcare provider may then measure blood pressure at the patient's ankle. The two blood pressures can then be analyzed to assess the patient's peripheral perfusion. These and other healthcare provider assessments, however, tend to have significant limitations including requiring costly and time-consuming in-facility testing by trained medical personnel using expensive equipment, infrequent testing for at-risk patients, and accuracy and repeatability issues. For example, the blood pressure measurements require the sequential use of blood pressure cuffs by a skilled technician in order to ensure accuracy of the measurements.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] Many aspects of the present disclosure can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0005] FIG. **1**A illustrates an example of a peripheral perfusion assessment system, in accordance with various aspects of the present disclosure.

[0006] FIG. **1**B illustrates another example of the peripheral perfusion assessment system, in accordance with various aspects of the present disclosure.

[0007] FIG. **2** illustrates examples of waveforms generated by blood volume measurement devices, in accordance with various aspects of the present disclosure.

[0008] FIG. **3** illustrates a technique for determining features of a blood volume waveform, in accordance with various aspects of the present disclosure.

[0009] FIG. **4** illustrates another technique for determining features of a blood volume waveform, in accordance with various aspects of the present disclosure.

[0010] FIG. **5** illustrates a systolic time calculation module, in accordance with various aspects of the present disclosure.

[0011] FIG. **6** illustrates modules of a peripheral perfusion assessment device, in accordance with various aspects of the present disclosure.

[0012] FIG. **7** illustrates an example of a networked-based environment in which some aspects of the present technology may be utilized.

[0013] FIG. **8** is a flowchart illustrating a set of operations for assessing peripheral perfusion, in accordance with various aspects of the present disclosure.

[0014] FIG. **9** is a diagram showing the flow of data from the measuring device used on the patient ultimately arriving to the monitoring physician.

[0015] FIG. **10** is a diagram showing how the monitoring physician can send notifications to the patient through the system according to one embodiment.

[0016] FIG. **11** is a diagram showing how the system automatically can send notifications to the patient according to one embodiment.

[0017] FIG. **12** is an example of a computer system with which embodiments of the present technology may be utilized.

[0018] FIG. **13** is an example of a report generated indicating device output data analysis in interpretable form for the monitoring medical provider. This report allows for interpretation and affords the medical provider to recommend further evaluation and management if necessary. This report is generated in billable form for the provider after interpretation is complete.

DETAILED DESCRIPTION

[0019] The present technology is directed to apparatuses, systems, and methods for assessing absolute and relative peripheral perfusion. As discussed in greater detail below, two blood volume measurement devices may measure the blood volume at a patient's extremities either simultaneously or in series. Distortions between the waveforms generated by the two blood volume measurement devices are detected, and an assessment of the patient's perfusion is determined based on the degree of distortion. The patient and/or a healthcare provider may be notified if the degree of distortion indicates that the patient is at risk of a peripheral arterial disease.

[0020] Some embodiments of the present technology provide for fast and accurate techniques to assess peripheral perfusion in an "at-home" or "out-of-facility" (e.g., telemetric) environment without the use of cuffs. Certain aspects of the present technology provide for continuous measurements of relative peripheral perfusion to detect perfusion deficits and potential limb or life threatening situations.

[0021] Blood volume measurement devices, such as plethysmography and photoplethysmography devices, measure changes in the volume of an organ caused by fluctuations in the amount of blood the organ contains. For example, a photoplethysmography device may measure blood volume in the arteries and arterioles of a patient's subcutaneous tissue by illuminating the patient's skin and measuring changes in light absorption. The changes in blood volume may correspond to the cardiac cycle. As the heart pumps blood to the periphery, the arteries and arterioles in the subcutaneous tissue are distended. Thus, blood volume measurement devices can be useful in assessing the peripheral perfusion of a patient. A peripheral perfusion assessment using the blood volume measuring systems and

devices disclosed herein can also serve as a surrogate for overall cardiovascular risk assessment.

[0022] Specific details of several examples of the present technology are described below with reference to FIGS. **1-12**. Additionally, several other embodiments of the technology can have different configurations, components, or procedures than those described herein. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements and that the technology can have other embodiments without several of the features shown and described below with reference to FIGS. **1-12**.

[0023] The techniques introduced herein can be embodied as special-purpose hardware (e.g., circuitry), as programmable circuitry appropriately programmed with software and/or firmware, or as a combination of special-purpose and programmable circuitry. Hence, embodiments may include a machine-readable medium having stored thereon instructions that may be used to program a computer (or other electronic devices) to perform a process. The machine-readable medium may include, but is not limited to, floppy diskettes, optical discs, compact disc read-only memories (CD-ROMs), magneto-optical discs, ROMs, random access memories (RAMs), erasable programmable read-only memories (EPROMs), electrically erasable programmable read-only memories (EEPROMs), application-specific integrated circuits (ASICs), magnetic or optical cards, flash memory, or other type of media/machine-readable medium suitable for storing electronic instructions.

TERMINOLOGY

[0024] Brief definitions of terms and phrases used throughout this application are given below.

[0025] The terms "connected" or "coupled" and related terms are used in an operational sense and are not necessarily limited to a direct physical connection or coupling. Thus, for example, two devices may be coupled directly, or via one or more intermediary media or devices. As another example, devices may be coupled in such a way that information can be passed there between, while not sharing any physical connection with one another. Based on the disclosure provided herein, one of ordinary skill in the art will appreciate a variety of ways in which connection or coupling exists in accordance with the aforementioned definition.

[0026] The phrases "in some embodiments," "according to some embodiments," "in the embodiments shown," "in other embodiments," and the like generally mean the particular feature, structure, or characteristic following the phrase is included in at least one implementation of the present technology, and may be included in more than one implementation. In addition, such phrases do not necessarily refer to the same embodiments or different embodiments.

[0027] If the specification states a component or feature "may", "can", "could", or "might" be included or have a characteristic, that particular component or feature is not required to be included or have the characteristic.

[0028] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded.

[0029] The term "module" or "engine" refers broadly to general or specific-purpose hardware, software, or firmware (or any combination thereof) components. Modules and engines are typically functional components that can generate useful data or other output using specified input(s). A module or engine may or may not be self-contained. Depending upon implementation-specific or other considerations, the modules or engines may be centralized or functionally distributed.

GENERAL DESCRIPTION

[0030] FIG. **1**A illustrates an example of a peripheral perfusion assessment system **100**, in accordance with various aspects of the present disclosure. The system **100** includes two blood volume measurement devices **105**-*a* and **105**-*b*. The blood volume measurement devices **105**-*a* and **105**-*b* are configured to measure blood volume at two extremities of a patient. For example, as shown in FIG. **1**A, blood volume measurement device **105**-*a* is configured to measure blood volume at a finger of the patient, and blood volume measurement device **105**-*b* is configured to measure blood volume at a toe of the patient. The blood volume measurement devices **105**-*a* and **105**-*b* may be plethysmography devices, photoplethysmography devices, or other types of devices for measuring changes in blood volume or blood pressure over time.

[0031] The blood volume measurement devices **105**-*a* and **105**-*b* generate continuous waveforms of the blood volume in each extremity. These continuous measurements at each extremity may be taken simultaneously so that the waveforms are aligned in time. The blood volume measurement devices **105**-*a* and **105**-*b* transmit the waveforms of blood volume over time to a peripheral perfusion assessment device **110**. In some examples, the peripheral perfusion assessment device **110** may be a component of one or both of the blood volume measurement devices **105**-*a* and **105**-*b*. In other examples, the peripheral perfusion assessment device **110** may be remote from the blood volume measurement devices **105**-*a* and **105**-*b*. The blood volume measurement devices **105**-*a* and **105**-*b* may transmit the waveforms of blood volume over time to the peripheral perfusion assessment device **110** via a wired or wireless connection.

[0032] The peripheral perfusion assessment device **110** detects distortions in specific features of the waveforms from the blood volume measurement devices **105**-*a* and **105**-*b*. Based on the distortions, the peripheral perfusion assessment device **110** may identify limb-threatening or life-threatening conditions in peripheral perfusion in the patient. Distortions in peripheral perfusion may be side effects of revascularization with stents, arterial bypass surgery, or other cardiovascular procedures and/or conditions. These distortions can be detected through the continuous analysis techniques described herein, and, in some embodiments, can direct limb-saving medical management for the patient.

[0033] FIG. **1**B illustrates another example of the peripheral perfusion assessment system **100**, in accordance with various aspects of the present disclosure. In this example, blood volume measurement device **105**-*a* is configured to measure blood volume at a first finger of the patient (e.g., a right-hand finger), and blood volume measurement device

105-*b* is configured to measure blood volume at a second finger of a contralateral upper extremity of the patient (e.g., a left-hand finger). The blood volume measurement devices **105**-*a* and **105**-*b* generate waveforms of the blood volume in each finger, and transmit the waveforms to the peripheral perfusion assessment device **110**. The peripheral perfusion assessment device **110** may then detect distortions and identify changes in peripheral perfusion as described in reference to FIG. **1**A.

[0034] FIG. **2** illustrates examples of waveforms generated by the blood volume measurement devices **105**-*a* and **105**-*b*, in accordance with various aspects of the present disclosure. For example, blood volume measurement device **105**-*a* may generate waveform **200**-*a*, and blood volume measurement device **105**-*b* may generate waveform **200**-*b*. The waveforms **200**-*a* and **200**-*b* may correspond to blood volume measurements taken simultaneously or in close temporal proximity at two different extremity locations of the patient, for example at a patient's finger and toe, respectively. Alternatively, the waveforms **200**-*a* and **200**-*b* may correspond to blood volume measurements taken simultaneously or in close temporal proximity at a patient's right-hand finger and left-hand finger, respectively.

[0035] Features of each waveform **200**-*a* and **200**-*b* may correspond to parts of the patient's cardiac cycle. For example, waveform **200**-*a* may include a first diastolic trough **205**-*a*, a first systolic peak **210**-*a*, a second diastolic trough **215**-*a*, a second systolic peak **220**-*a*, and a diastolic peak **225**-*a*, as measured at a patient's finger. A systolic time interval (t_{sf}) may be determined as the time between the first diastolic trough **205**-*a* and the first systolic peak **210**-*a*. A diastolic time interval (t_{df}) may be determined as the time between the first systolic peak **210**-*a* and the second diastolic trough **215**-*a*. An interstolic time interval ($T1_f$) may be determined as the time between second systolic peak **220**-*a* and the diastolic peak **225**-*a*. The waveform **200**-*b* may include similar features, as measured simultaneously or in temporal proximity at a patient's toe.

[0036] Relative differences in the systolic time measured at the patient's finger (t_{sf}) and the systolic time measured at a patient's toe (t_{st}) may indicate a peripheral arterial disease in the patient. Similarly, differences in the systolic time measured at the patient's right-hand finger and the systolic time measured at a patient's left-hand finger may also indicate a peripheral arterial disease in the patient.

[0037] In one embodiment, the presence and degree of severity of peripheral arterial disease may be determined by comparing waveform features measured at two extremities. This comparison may be mapped to a digital-digital index (DDI). The value of this DDI relative to a "normal range" may indicate the presence and degree of severity of peripheral arterial disease. In such a case, this may prompt the patient to undergo medical evaluation, confirmatory diagnostic testing and possible therapeutic interventions.

[0038] In another embodiment, the degree to which this DDI changes over time may indicate the presence, progression and degree of severity of the disease. This change may be measured in absolute or relative terms. For instance, an absolute drop of about 0.10, about 0.15 or about 0.20 or more, or a relative change of about fifteen percent, about twenty percent, about 25 percent or more over a period of 6 months or more (e.g. about 6 months, about 8 months, about 12 months, or about 24 months) may indicate a severe progression of the disease. It may also be measured in relative terms. Moreover, this relative change over a longer period may indicate significant progression of the disease. In such a case, the patient may need to undergo further testing to determine if any medical therapeutic intervention is required.

[0039] In another embodiment, the presence and degree of severity of peripheral arterial disease may be determined by calculating a ratio between the systolic times measured at the two extremities of the patient. For example, a digital-digital index (DDI) ratio may be calculated as

$$DDI = \frac{p_1 t_{s1} + k_1}{p_2 t_{s2} + k_2} + k_3,$$

where the p coefficients and the k constants are drawn from empirical studies of peripheral arterial diseases (similar to a toe-brachial index—TBI). For measurements taken simultaneously or in temporal proximity at a toe and a finger ("toe-to-finger"), a DDI ratio between 0.65 and 1.0 may indicate low distortion between the two systolic time measurements, and thus a low likelihood of peripheral arterial disease. A toe-to-finger DDI ratio less than 0.35 may suggest, for example, a critical vascular occlusive disease. For measurements taken at a right-hand finger and a left-hand finger ("finger-to-finger"), a DDIf ratio less than 0.9 may suggest, for example, perfusion deficits between the patient's upper extremities, which may signify occlusive disease or a post-surgical arterial steal syndrome. In such a case, the patient may need to undergo further medical evaluation and confirmatory testing to determine if any action should be taken. In one embodiment, if peripheral arterial disease is confirmed, the subject is treated. Treatment can include counseling on lifestyle changes (e.g. smoking, diet, exercise), cholesterol-lowering medications (e.g. statins) to reduce LDL-C to less than 100 mg/dL, blood pressure medication, medication to prevent clot formation (e.g. daily asprin or clopidogrel), or medications to increase blood flow to the limbs such as cilostazol or pentoxifylline. Treatment can also include angioplasty, graft bypass or thrombolytic therapy.

[0040] FIG. **3** illustrates an embodiment of a technique for determining features of a blood volume waveform **300**, in accordance with various aspects of the present disclosure. A first derivative of the blood volume waveform **300** is calculated, and a derivative waveform **305** is generated. Each of the zero-crossings of the derivative waveform **305** may then be determined. Zero-crossing **310**-*a* corresponds to a diastolic trough of the blood volume waveform **300**, and zero-crossing **310**-*b* corresponds to a systolic peak of the blood volume waveform **300**. A systolic peak is always higher than a diastolic peak, and a diastolic trough is always lower than a interstolic trough. The systolic time (t_s) of the blood volume waveform **300** may then be determined as the time interval between zero-crossing **310**-*a* and zero-crossing **310**-*b*.

[0041] FIG. **4** illustrates another embodiment of a technique for determining features of a blood volume waveform **400**, in accordance with various aspects of the present disclosure. The blood volume waveform is divided into increasing segments **405** (light background), and decreasing segments **410** (gray backgrounds). The increasing segments **405** correspond to segments where the first derivative of the blood volume waveform **400** is positive. The decreasing

segments **410** correspond to segments where the first derivative of the blood volume waveform **400** is negative. The peaks of the blood volume waveform **400** occur where the first derivative changes from positive to negative. For example, a systolic peak occurs between increasing segment **405**-*a* and decreasing segment **410**-*a*, and a diastolic peak occurs between increasing segment **405**-*b* and decreasing segment **410**-*b*. The troughs of the blood volume waveform **400** occur where the first derivative changes from negative to positive. For example, an interstolic trough occurs between decreasing segment **410**-*a* and increasing segment **405**-*b*, and a diastolic trough occurs between decreasing segment **410**-*b* and increasing segment **405**-*c*. Thus, the primary features of a blood volume waveform **400** may be determined using the sign changes of a first derivative of the blood volume waveform **400**. The actual values of the first derivative may be ignored. The systolic time of the blood volume waveform **400** may then be determined as the time interval between the diastolic trough and the systolic peak.

[0042] FIG. **5** illustrates an embodiment of a systolic time calculation module **500**, in accordance with various aspects of the present disclosure. The systolic time calculation module **500** determines the systolic time from an input blood volume waveform (also referred to as a plethysmograph). The systolic time calculation module **500** may be anywhere in the system including but not limited to a component of the peripheral perfusion assessment device **110**, the mobile device, internet service, internet application or computer or device used by the physician. The systolic time calculation module **500** calculates the systolic time of the input blood volume waveform by determining where the waveform changes from an increasing segment to a decreasing segment, or changes from a decreasing segment to an increasing segment, as described in reference to FIG. **4**. If the value of the blood volume measurement where the waveform changes from an increasing segment to a decreasing segment is larger than other increasing-to-decreasing values, then the systolic time calculation module **500** determines that value to be a systolic peak, and notes the time when the systolic peak occurred. If the value of the blood volume measurement where the waveform changes from a decreasing segment to an increasing segment is lower than other decreasing-to-increasing values, then the systolic time calculation module **500** determines that value to be a diastolic trough, and notes the time when the diastolic trough occurred. The systolic time calculation module **500** may then determine the time interval between the systolic peak and the previous diastolic trough, and output the time interval as the systolic time of the input blood volume waveform.

[0043] The flowchart of FIG. **5** further illustrates a method by which the systolic time calculation module **500** determines the systolic time of an input blood volume waveform in accordance with an embodiment of the present disclosure. At step **505**, the values oldPleth, oldDelta, oldPeak, and oldTrough used by the module **500** are initialized to zero. At step **510**, the module **500** reads a blood volume value from the input waveform, and stores it as newPleth. The module **500** then calculates the difference between newPleth and oldPleth, and stores the result as newDelta at step **515**. At step **520**, the module **500** determines if the value oldDelta is less than or equal to zero. If yes, then the module **500** determines if newDelta is less than zero at step **525**. If yes, the module **500** returns to step **510** to read another blood volume value and store it as newPleth. If newDelta is greater than or equal to zero at step **525**, then the module **500** determines if newPleth is also less than oldTrough at step **530**. If not, then the module **500** stores the value of newPleth as interstolicTrough at step **540**, and also stores the value of newPleth as oldTrough at step **545**. At step **580**, the module further stores the value of newPleth as oldPleth and the value of newDelta as oldDelta. The module **500** then returns to step **510** to read another blood volume value and store it as newPleth. Returning to step **530**, if newPleth is less than oldTrough, then the module **500** proceeds to step **535** and stores the value of newPleth as diastolicTrough. The module **500** then proceeds to step **545** and continues as described above.

[0044] Returning to step **520**, if oldDelta is greater than zero, then the module **500** proceeds to step **550** and determines if newDelta is less than zero. If not, then the module **500** returns to step **510** to read another blood volume value and store it as newPleth. If newDelta is less than zero in step **550**, then module **500** determines if newPleth is greater than oldPeak in step **555**. If yes, then the module **500** stores the value of newPleth as systolic Peak at step **565**. The module **500** then determines the time corresponding to the diastolicTrough value and the time corresponding to the systolicPeak value, and calculates the difference between the two times. The module **500** then outputs the difference as the systolic time (t_s) of the input blood volume waveform. The module **500** then stores the value of newPleth as oldPeak at step **575**. At step **580**, the module **500** further stores the value of newPleth as oldPleth and the value of newDelta as oldDelta. The module **500** then returns to step **510** to read another blood volume value and store it as newPleth.

[0045] Returning to step **555**, if newPleth is less than or equal to oldPeak, then module **500** proceeds to step **560** and stores the value of newPleth as distolicPeak. At step **575**, the module also stores the value of newPleth as oldPeak, and then further stores the value of newPleth as oldPleth and the value of newDelta as oldDelta at step **580**. The module **500** then returns to step **510** to read another blood volume value and store it as newPleth. The module **500** continues reading in new blood volume values until a predetermined number of blood volume values have been processed, a predetermined time interval of the blood volume waveform has been processed, or all values of the blood volume waveform have been processed.

[0046] FIG. **6** illustrates modules of a peripheral perfusion assessment device **110**, in accordance with various aspects of the present disclosure. A first systolic time module **500**-*a* may receive a first blood volume waveform from a first blood volume measurement device **105**-*a*. A second systolic time module **500**-*b* may receive a second blood volume waveform from a second blood volume measurement device **105**-*b*. The first and second blood volume waveforms may correspond to blood volumes measured simultaneously at two extremities of a patient. The first systolic time module **500**-*a* determines a systolic time of the first blood volume waveform, and the second systolic time module **500**-*b* determines a systolic time of the second blood volume waveform. The first and second systolic time modules **500**-*a* and **500**-*b* may determine the systolic times using the method illustrated in FIG. **5**, or using other systolic time calculation methods. In some examples, the peripheral perfusion assessment device **110** may include a single systolic

module **500**, and may calculate both the systolic time of the first blood volume waveform and systolic time of the second blood volume waveform.

[0047] A distortion module **605** receives the two systolic times from the systolic time modules **500**-*a* and **500**-*b*, and determines a degree of distortion between the first blood volume waveform and the second blood volume waveform. The degree of distortion may be determined using the DDI ratio described in reference to FIG. **2**, or may be determined using other comparison methods. Based on the degree of distortion between the first and second blood volume waveforms, the distortion module **605** assesses the patient's peripheral perfusion. Based on the assessment of the distortion module **605**, a notification module **610** may notify the patient, a healthcare provider, or both of the assessment. If the distortion module **605** assesses that the patient is at risk of a peripheral arterial disease, then the notification may instruct the patient and/or healthcare provider of the need for medical attention. If the distortion module **605** assesses that the patient is not at risk of a peripheral arterial disease, then the notification may instruct the patient and/or healthcare provider of the current status of the patient's peripheral perfusion. The notification module **610** may also store and/or transmit the blood volume waveforms, the systolic times, the DDI ratio, and/or other measurements for further processing and/or analysis. The notification module **610** may notify the patient of the assessment via a display, an alarm, a haptic interface, or other types of notifications. The notification module **610** may notify the healthcare provider via a wired or wireless connection to a healthcare provider device.

[0048] In some examples, the notification module **610** may directly receive the blood volume waveforms from the first and second blood volume measurement devices **105**-*a* and **105**-*b*. The notification module **610** may then transmit the blood volume waveforms to another device for analysis and assessment of the patient's peripheral perfusion. For example, the notification module **610** may transmit the blood volume waveforms to a healthcare provider device.

[0049] FIG. **7** illustrates an example of a networked-based environment in which some aspects of the present technology may be utilized. As shown in FIG. **7**, a peripheral perfusion assessment device **110** communicates with a healthcare provider device **705** via a network **710**. The peripheral perfusion assessment device **110** and healthcare provider device **705** may be conventional computer systems (e.g., a desktop or laptop computer), mobile devices having computer functionality (e.g., a mobile telephone, a smartphone, wearable computer, etc.), or purpose-built computing devices for communicating peripheral perfusion assessments.

[0050] The peripheral perfusion assessment device **110** and healthcare provider device **705** can be configured to use network **710** to communicate. In accordance with various embodiments, network **710** can include any combination of local area and/or wide area networks, using both wired and wireless communication systems. In one embodiment, network **710** uses standard communications technologies and/or protocols. Thus, network **710** may include links using technologies such as Ethernet, 802.11, Bluetooth, near-field communications (NFC), worldwide interoperability for microwave access (WiMAX), 3G, 4G, CDMA, digital subscriber line (DSL), etc. Similarly, the networking protocols used on network **710** may include multiprotocol label switching (MPLS), transmission control protocol/Internet protocol (TCP/IP), User Datagram Protocol (UDP), hypertext transport protocol (HTTP), simple mail transfer protocol (SMTP) and file transfer protocol (FTP). Data exchanged over network **710** may be represented using technologies and/or formats including hypertext markup language (HTML) or extensible markup language (XML). In addition, all or some links can be encrypted using conventional encryption technologies such as secure sockets layer (SSL), transport layer security (TLS), and Internet Protocol security (IPsec).

[0051] In some embodiments, the peripheral perfusion assessment device **110** and healthcare provider device **705** can retrieve or submit information to one another. For example, the peripheral perfusion assessment device **110** may transmit a notification of a peripheral perfusion assessment, a DDI ratio, blood volume waveforms, and/or other measurements from the blood volume measurement devices **105**-*a* and **105**-*b* to the healthcare provider device **705**. The healthcare provider device **705** may transmit a notification of a peripheral perfusion assessment, warning, and/or other instructions from the healthcare provider to the peripheral perfusion assessment device **110**. In these examples, the peripheral perfusion assessment device **110** may notify the patient of the assessment, warnings, and/or instructions from the healthcare provider device **705**. In some examples, the healthcare provider device **705** may store historical records of the peripheral perfusion assessments, DDI ratios, blood volume waveforms, and/or other measurements from one or more patients in a database. The healthcare provider device **705** may use the historical records database for further analysis of one or more patients' health data. The database may include various database components that can be implemented in the form of a database that is relational, sequential, hierarchical, scalable, secure, and/or featuring other attributes. Examples of such database include, but are not limited to, DB2, MySQL, Oracle, Sybase, and the like. Alternatively, these databases may be implemented using various standard data-structures, such as an array, hash, list, struct, structured text file (e.g., XML), table, binary, and/or the like. Such data structures may be stored in memory and/or in structured files.

[0052] FIG. **8** is a flowchart illustrating a set of operations for assessing peripheral perfusion, in accordance with various aspects of the present disclosure. The operations illustrated in FIG. **8** may be executed by a blood volume measurement device **105**, a peripheral perfusion assessment device **110**, a healthcare provider device **705**, and/or a combination of devices. The devices may include a memory and one or more processors. These components are examples of various means for performing some of the operations illustrated in FIG. **8**.

[0053] At block **805**, the set of operations include generating a first blood volume measurement during a measurement time interval using a first blood volume measurement device at a first peripheral location. For example, the first peripheral location may be a toe of a patient. At block **810**, the set of operations include generating a second blood volume measurement during a measurement time interval using a second blood volume measurement device at a second peripheral location. For example, the second peripheral location may be a finger of the patient. The first blood

volume measurement device and the second blood volume measurement device may include plethysmography or photoplethysmography devices.

[0054] At block **815**, the set of operations include determining a first diastolic trough based on the first blood volume measurement. At block **820**, the set of operations include determining a first systolic peak based on the first blood volume measurement. The first systolic peak and the first diastolic trough may be determined based on a first derivative of the first blood volume measurement. At block **825**, the set of operations include determining a first systolic time duration based on the first diastolic trough and the first systolic peak. At block **830**, the set of operations include determining a second diastolic trough based on the second blood volume measurement. At block **835**, the set of operations include determining a second systolic peak based on the second blood volume measurement. The second systolic peak and the second diastolic trough may be determined based on a first derivative of the second blood volume measurement. At block **840**, the set of operations include determining a second systolic time duration based on the second diastolic trough and the second systolic peak. At block **845**, the set of operations include assessing peripheral perfusion based at least in part on a ratio of linear functions of the first systolic time duration and the second systolic time duration. At block **850**, the set of operations include generating a notification of the peripheral perfusion assessment. The notification may then be transmitted to a healthcare provider.

Flow of Telemetry Data to Physician Overview

[0055] Embodiments of the present technology include paths along which the patient's measurements and other data travel on the way to a monitoring physician. These paths include various way points where the data may be stored, transformed, formatted or aggregated with other data and/or transmitted. FIG. **9** is an example of such a path. The number of waypoints and the actions taken at each way point may vary from that described in FIG. **9**. According to the present example, one or more telemetry devices **920** is applied to the patient **910**. The telemetry device captures patient data and sends them to a mobile device **930**. The mobile may store these data, perform calculations on them, format them, aggregate them with other data, etc. and send data to Internet hosted services **940**, which also may store the data, transform them, aggregate them, etc. Internet hosted applications **950** may serve these resulting data to a computer or device **960** used by a monitoring physician **970**.

[0056] Embodiments of the present technology include paths along which the physician may notify the patient for reasons including but not limited to a reminder to take a new reading. These paths include various way points where the notification may be stored, transformed, formatted or aggregated with other data and/or transmitted. FIG. **10** is an example of such a path. The number of waypoints and the actions taken at each way point may vary from that described in FIG. **10**. According to the present example, a monitoring physician **1010** uses a computer or device **1020** to initiate a notification to the patient. This computer or device sends the request to an internet hosted application **1030** which sends a request to an internet hosted service **1040** which, in turn, delivers a notification to a mobile device **1050** which reaches the patient **1060**.

[0057] Embodiments of the present technology include paths along which the system may automatically notify the patient for reasons including but not limited to a reminder to take a new reading. These paths include various way points where the notification may be stored, transformed, formatted or aggregated with other data and/or transmitted. FIG. **11** is an example of such a path. The number of waypoints and the actions taken at each way point may vary from that described in FIG. **11**. According to the present example, an internet hosted application **1110** decides to initiate a notification to the patient based on some criteria possibly including but not limited to the last known telemetry reading from that patient. This internet hosted service sends a notification to a mobile device **1120** which reaches the patient **1130**.

Computer System Overview

[0058] Embodiments of the present technology include various steps and operations, which have been described above. A variety of these steps and operations may be performed by hardware components or may be embodied in machine-executable instructions, which may be used to cause a general-purpose or special-purpose processor programmed with the instructions to perform the steps. Alternatively, the steps may be performed by a combination of hardware, software, and/or firmware. As such, FIG. **12** is an example of a computer system **1200** with which embodiments of the present technology may be utilized. According to the present example, the computer system includes a bus **1210**, at least one processor **1220**, at least one communication port **1230**, main memory **1240**, a removable storage media **1250**, a read only memory **1260**, and a mass storage **1270**.

[0059] Processor(s) **1220** can be any known processor, such as, but not limited to, Intel® lines of processor(s); AMD® lines of processor(s); ARM® lines of processors, or other application-specific integrated circuits (ASICs). Communication port(s) **1230** can be any communication port, such as, but not limited to, an RS-232 port for use with a modem-based dialup connection, a 10/100 Ethernet port, a Gigabit port using copper or fiber, wireless antennas, etc. Communication port(s) **1230** may be chosen depending on a network such as a Local Area Network (LAN), Wide Area Network (WAN), cellular network, or any network to which the computer system **1200** connects.

[0060] Main memory **1240** can be Random Access Memory (RAM) or any other dynamic storage device(s) commonly known in the art. Read only memory **1260** can be any static storage device(s) such as Programmable Read Only Memory (PROM) chips for storing static information such as instructions for processor **1220**.

[0061] Mass storage **1270** can be used to store information and instructions. For example, hard disks such as the Adaptec® family of SCSI drives, an optical disc, an array of disks such as RAID or such as the Adaptec family of RAID drives, or any other mass storage devices may be used.

[0062] Bus **1210** communicatively couples processor(s) **1220** with the other memory, storage and communication blocks. Bus **1210** can be any system communication bus, such as, but limited to, I2C, PCI, PCI-Express, UMI, DMI, QPI, etc.

[0063] Removable storage media **50** can be any kind removable storage, such as, but not limited to, external hard-drives, flash memory cards, floppy drives, Compact

Disc-Read Only Memory (CD-ROM), Compact Disc-Re-Writable (CD-RW), Digital Video Disk-Read Only Memory (DVD-ROM), Blu-Ray, etc.

[0064] The components described above are meant to exemplify some types of possibilities. In no way should the aforementioned examples limit the scope of the technology, as they are only embodiments.

[0065] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology, as those skilled in the relevant art will recognize. For example, while steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments. All references cited herein are incorporated by reference as if fully set forth herein.

[0066] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0067] Further, while advantages associated with certain embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

We claim:

1. A method for assessing peripheral perfusion in a subject, comprising:

generating a first blood volume measurement during a measurement time interval using a first blood volume measurement device at a first peripheral location of the subject;

generating a second blood volume measurement during a measurement time interval using a second blood volume measurement device at a second peripheral location of the subject;

determining a first diastolic trough based on the first blood volume measurement;

determining a first systolic peak based on the first blood volume measurement;

determining a first systolic time duration based on the first diastolic diastolic trough and the first systolic peak;

determining a second diastolic trough based on the second blood volume measurement;

determining a second systolic peak based on the second blood volume measurement;

determining a second systolic time duration based on the second diastolic trough and the second systolic peak; and

assessing peripheral perfusion based at least in part on a ratio of linear functions of the first systolic time duration and the second systolic time duration.

2. The method of claim **1**, wherein:

determining the first diastolic trough and the first systolic peak comprises determining a first derivative of the first blood volume measurement, and

determining the second diastolic trough and the second systolic peak comprises determining a first derivative of the second blood volume measurement.

3. The method of claim **2**, wherein the first diastolic trough and the first systolic peak are determined based on a sign of the first derivative of the first blood volume measurement, and the second diastolic trough and the second systolic peak are determined based on a sign of the first derivative of the second blood volume measurement.

4. The method of claim **1**, wherein the first blood volume measurement device and the second blood volume measurement device comprise plethysmography devices.

5. The method of claim **1**, wherein the first blood volume measurement device and the second blood volume measurement device comprise photoplethysmography devices.

6. The method of claim **1**, wherein the first peripheral location comprises a toe of a patient, and the second peripheral location comprises at least one of a finger of the patient or a finger of the contralateral upper extremity of the patient.

7. The method of claim **1**, assessing peripheral perfusion comprises:

determining the ratio of the first systolic time duration and the second systolic time duration indicates one or more of a peripheral arterial disease and a perfusion deficit.

8. The method of claim **7** further comprising recommending for treatment for or treating the subject for peripheral arterial disease or a perfusion deficit or conducting further tests to confirm peripheral arterial disease or a perfusion deficit.

9. The method of claim **8** wherein the treatment is selected from cholesterol-lowering medication, blood pressure medication, medication to prevent clot formation, medication to increase blood flow to the limbs, angioplasty, graft bypass or thrombolytic therapy.

10. The method of claim **1**, further comprising:

generating a notification of the peripheral perfusion assessment.

11. The method of claim **10**, further comprising:

displaying the notification.

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

transmitting the notification to a healthcare provider.

13. A system for assessing peripheral perfusion, comprising:

a first blood volume measurement device for generating a first blood volume measurement during a measurement time interval at a first peripheral location;

a second blood volume measurement device for generating a second blood volume measurement during a measurement time interval at a second peripheral location;

a peripheral perfusion assessment device for receiving the first blood volume measurement and the second blood volume measurement, wherein the peripheral perfusion assessment device:

determines a first diastolic trough based on the first blood volume measurement;

determines a first systolic peak based on the first blood volume measurement;

determines a first systolic time duration based on the first diastolic trough and the first systolic peak;

determines a second diastolic trough based on the second blood volume measurement;

determines a second systolic peak based on the second blood volume measurement;

determines a second systolic time duration based on the second diastolic trough and the second systolic peak; and

assesses peripheral perfusion based at least in part on a ratio of linear functions of the first systolic time duration and the second systolic time duration.

14. The system of claim **13** further configured to deliver patient-related telemetry data to a physician.

15. The system of claim **14** further configured to deliver notifications to the patient when initiated by the physician.

16. The system of claim **15** wherein the notifications are automatically initiated.

* * * * *

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摘要(译)

本技术涉及用于评估绝对和相对周围灌注的装置，系统和方法。在各种实施例中，两个血液体积测量装置同时或串联地测量患者四肢处的血液体积。检测由两个血液体积测量装置产生的波形之间的失真，并且基于失真的程度来确定患者的灌注的评估。