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(54) **BLOOD PRESSURE DIAGNOSTIC DEVICE PROVIDING ENHANCED VASCULAR CONDITION DETECTION FEATURES AND RELATED METHODS**

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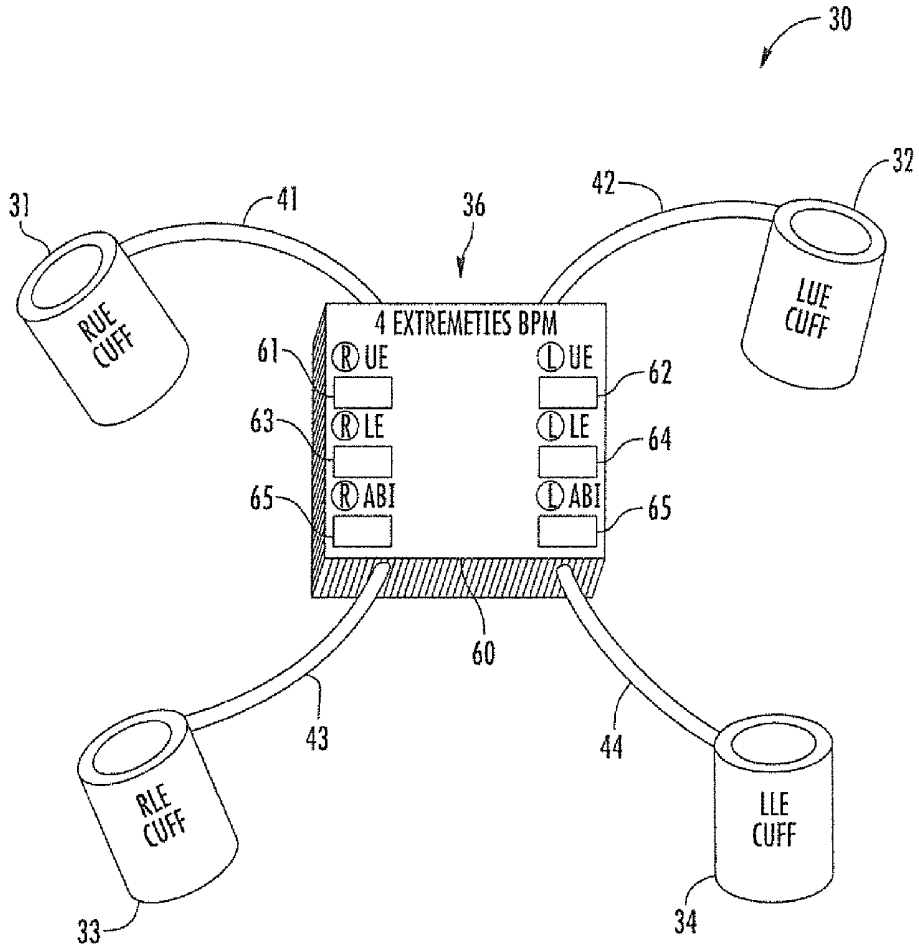
(57) **ABSTRACT**

A medical diagnostic system may include a plurality of blood pressure measuring devices each configured to measure blood pressure of a respective extremity from among a plurality of extremities of a patient, and a blood pressure diagnostic device including at least one input device and a controller. The controller may cooperate with the at least one input device to determine blood pressure measurements for the respective patient extremities based upon the plurality of blood pressure measuring devices, receive an indicator of at least one symptom of the patient via the input device, and determine statistical probabilities that a condition of the patient is within a first group of vascular conditions requiring a first course of treatment, and a second group of vascular conditions requiring a second course of treatment different than the first course of treatment, based upon the determined blood pressure measurements and the indicator of the at least one symptom.



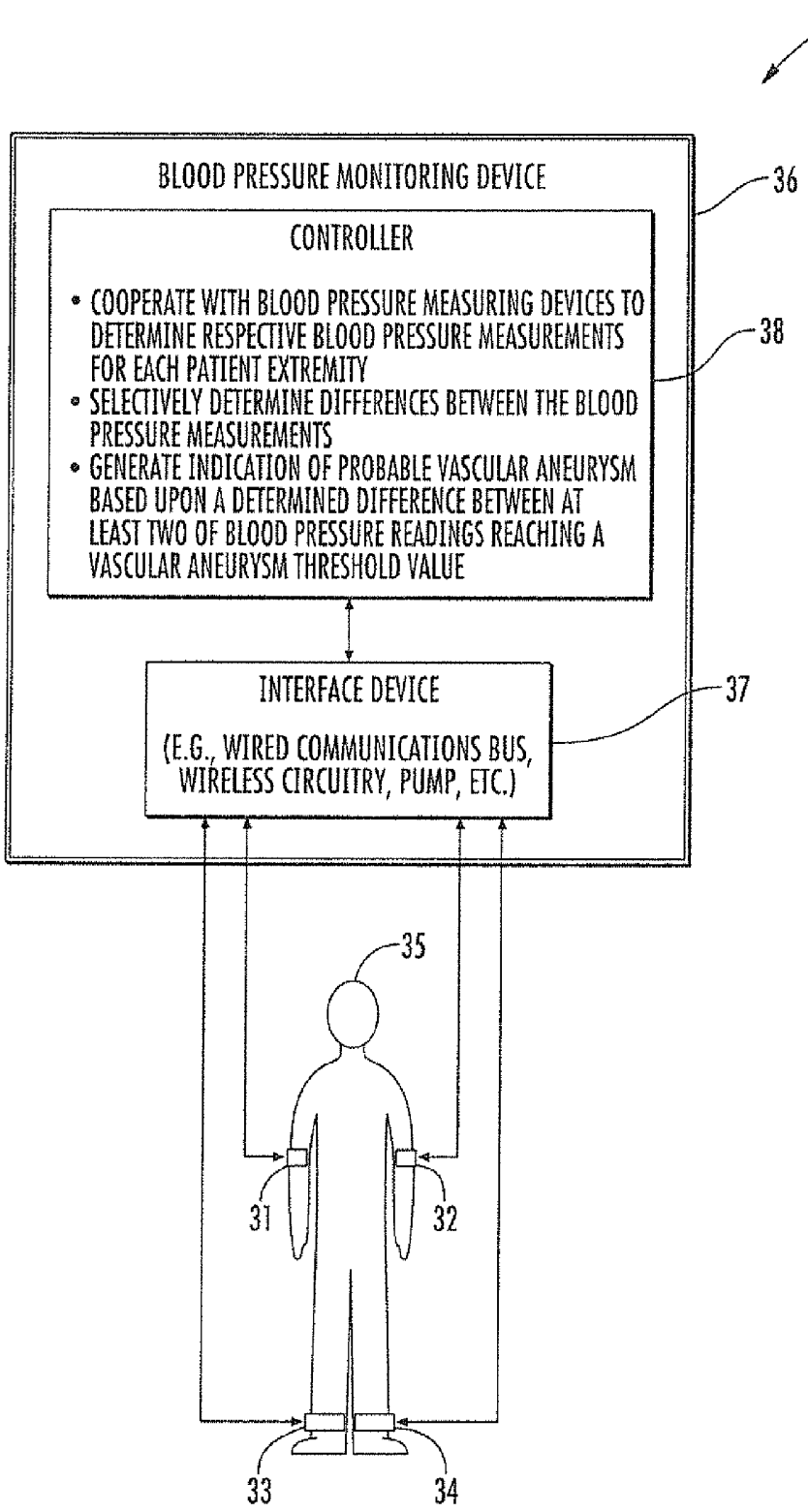

30
BLOOD PRESSURE MONITORING DEVICE
36
CONTROLLER
• COOPERATE WITH BLOOD PRESSURE MEASURING DEVICES TO DETERMINE RESPECTIVE BLOOD PRESSURE MEASUREMENTS FOR EACH PATIENT EXTREMITY
• SELECTIVELY DETERMINE DIFFERENCES BETWEEN THE BLOOD PRESSURE MEASUREMENTS
• GENERATE INDICATION OF PROBABLE VASCULAR ANEURYSM BASED UPON A DETERMINED DIFFERENCE BETWEEN AT LEAST TWO OF BLOOD PRESSURE READINGS REACHING A VASCULAR ANEURYSM THRESHOLD VALUE
38
INTERFACE DEVICE
(E.G., WIRED COMMUNICATIONS BUS, WIRELESS CIRCUITRY, PUMP, ETC.)
37
35
31
32
33
34

FIG. 1

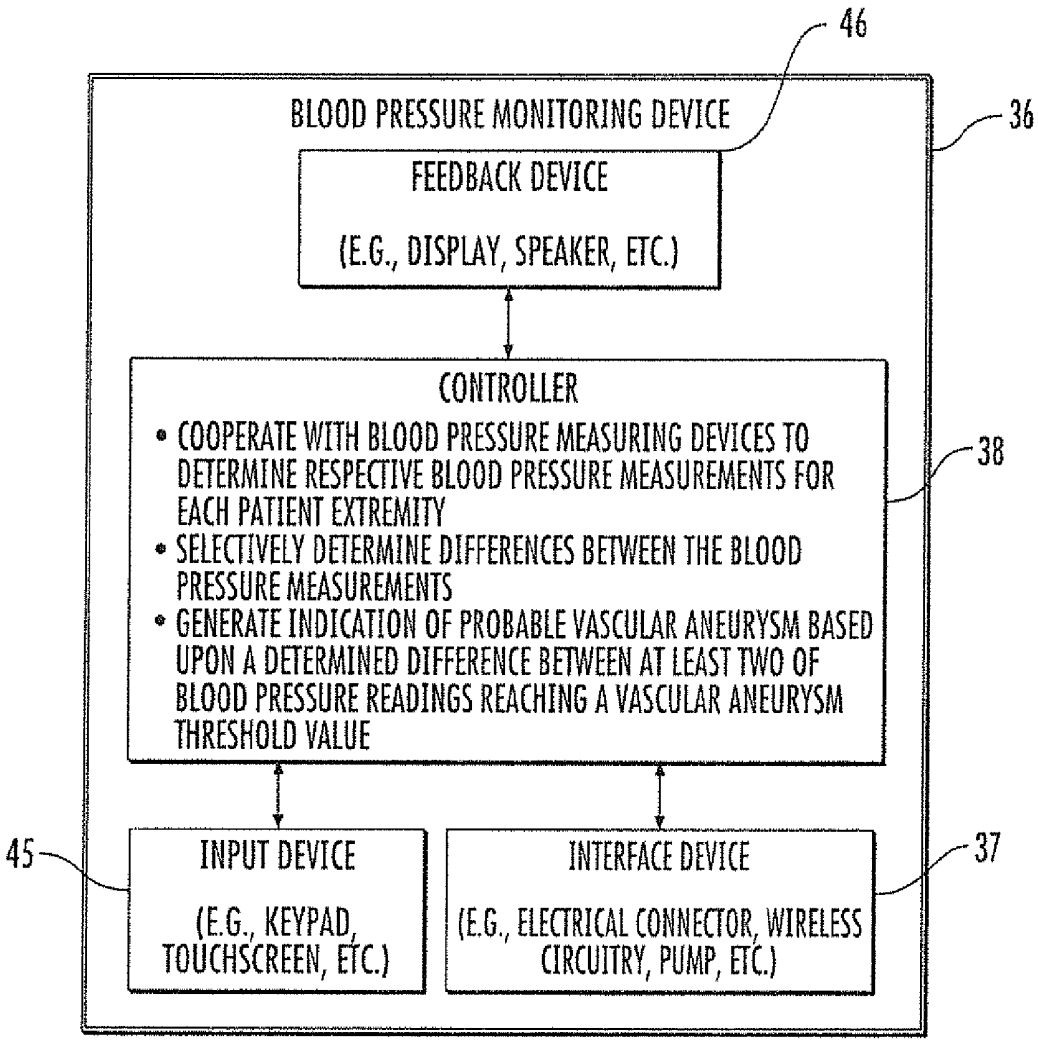

46
BLOOD PRESSURE MONITORING DEVICE
36
FEEDBACK DEVICE
(E.G., DISPLAY, SPEAKER, ETC.)
CONTROLLER
• COOPERATE WITH BLOOD PRESSURE MEASURING DEVICES TO DETERMINE RESPECTIVE BLOOD PRESSURE MEASUREMENTS FOR EACH PATIENT EXTREMITY
• SELECTIVELY DETERMINE DIFFERENCES BETWEEN THE BLOOD PRESSURE MEASUREMENTS
• GENERATE INDICATION OF PROBABLE VASCULAR ANEURYSM BASED UPON A DETERMINED DIFFERENCE BETWEEN AT LEAST TWO OF BLOOD PRESSURE READINGS REACHING A VASCULAR ANEURYSM THRESHOLD VALUE
38
45
INPUT DEVICE
(E.G., KEYPAD, TOUCHSCREEN, ETC.)
INTERFACE DEVICE
(E.G., ELECTRICAL CONNECTOR, WIRELESS CIRCUITRY, PUMP, ETC.)
37

FIG. 2

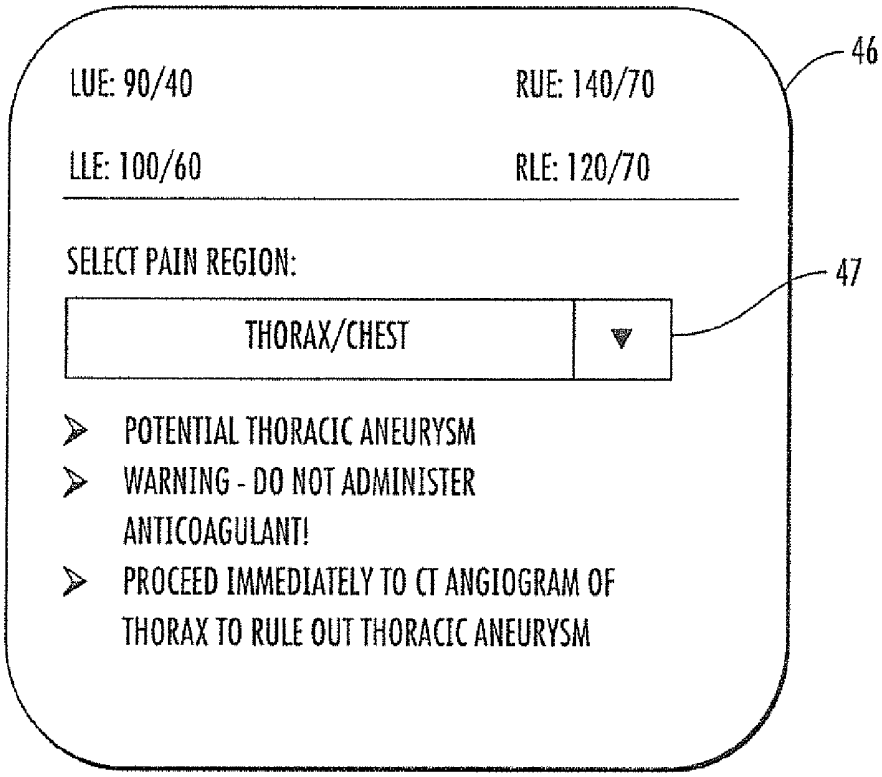

LUE: 90/40
RUE: 140/70
LLE: 100/60
RLE: 120/70
SELECT PAIN REGION:
THORAX/CHEST
POTENTIAL THORACIC ANEURYSM
WARNING - DO NOT ADMINISTER ANTICOAGULANT!
PROCEED IMMEDIATELY TO CT ANGIOGRAM OF THORAX TO RULE OUT THORACIC ANEURYSM
46
47

FIG. 3

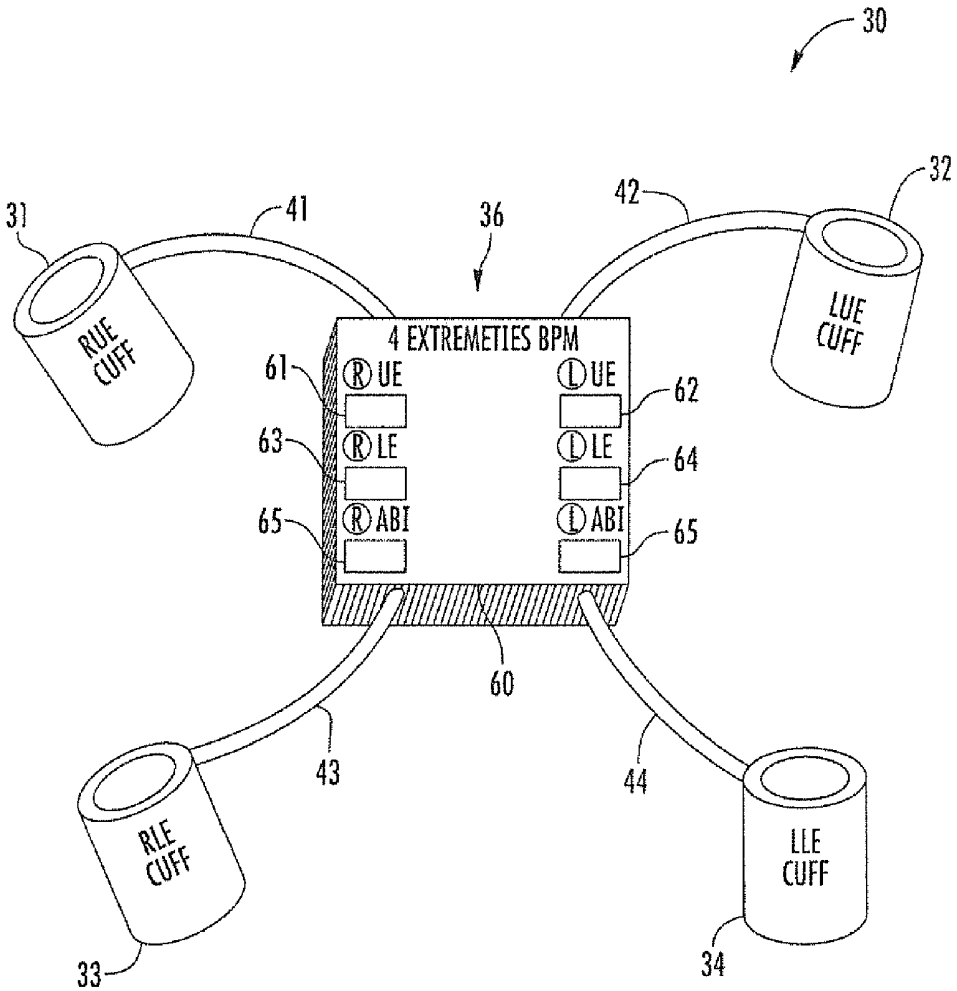

30
31
41
36
42
32
RUE CUFF
4 EXTREMETIES BPM
LUE CUFF
61
Ⓡ UE
Ⓛ UE
62
63
Ⓡ LE
Ⓛ LE
64
65
Ⓡ ABI
Ⓛ ABI
65
60
43
44
RLE CUFF
LLE CUFF
33
34

FIG. 4

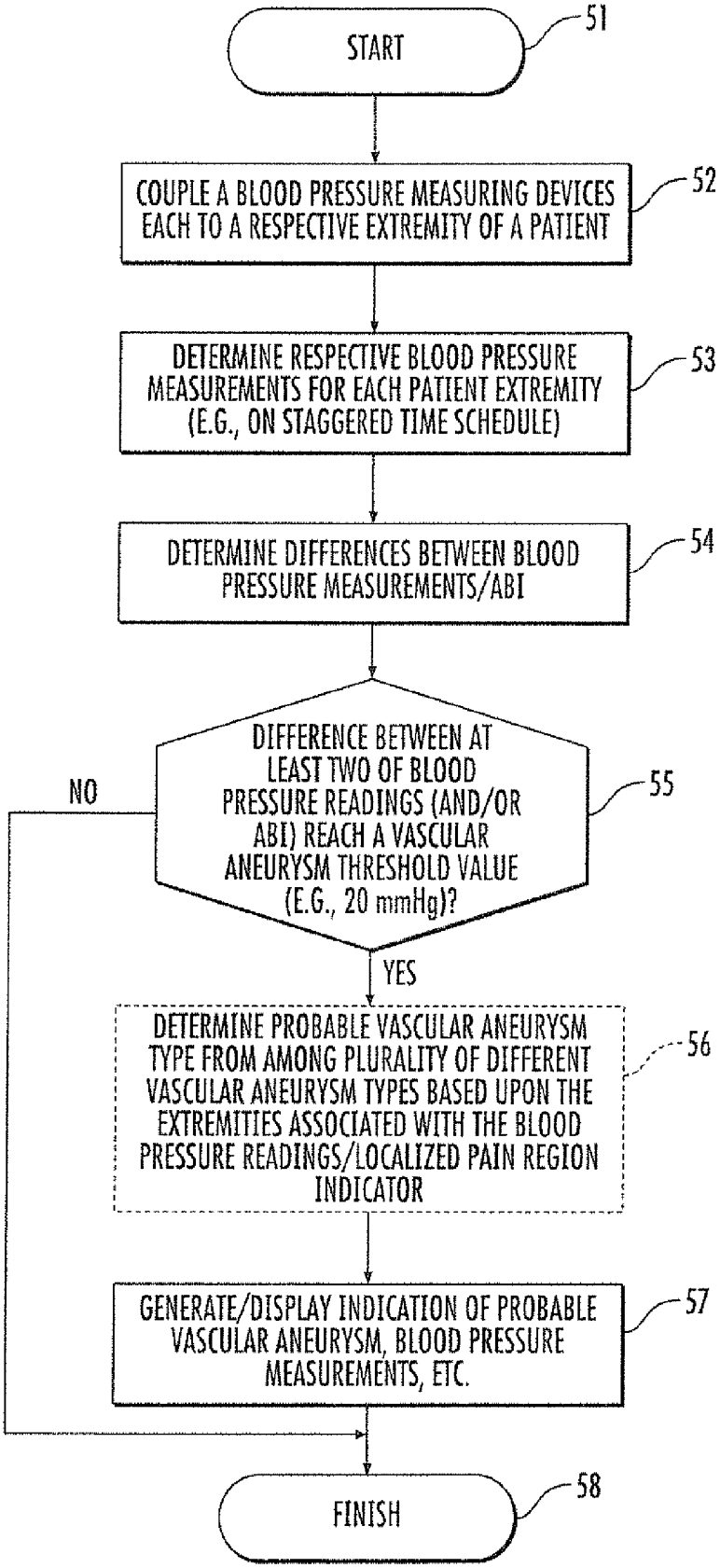

START
51
COUPLE A BLOOD PRESSURE MEASURING DEVICES EACH TO A RESPECTIVE EXTREMITY OF A PATIENT
52
DETERMINE RESPECTIVE BLOOD PRESSURE MEASUREMENTS FOR EACH PATIENT EXTREMITY (E.G., ON STAGGERED TIME SCHEDULE)
53
DETERMINE DIFFERENCES BETWEEN BLOOD PRESSURE MEASUREMENTS/ABI
54
DIFFERENCE BETWEEN AT LEAST TWO OF BLOOD PRESSURE READINGS (AND/OR ABI) REACH A VASCULAR ANEURYSM THRESHOLD VALUE (E.G., 20 mmHg)?
55
NO
YES
DETERMINE PROBABLE VASCULAR ANEURYSM TYPE FROM AMONG PLURALITY OF DIFFERENT VASCULAR ANEURYSM TYPES BASED UPON THE EXTREMITIES ASSOCIATED WITH THE BLOOD PRESSURE READINGS/LOCALIZED PAIN REGION INDICATOR
56
GENERATE/DISPLAY INDICATION OF PROBABLE VASCULAR ANEURYSM, BLOOD PRESSURE MEASUREMENTS, ETC.
57
FINISH
58

FIG. 5

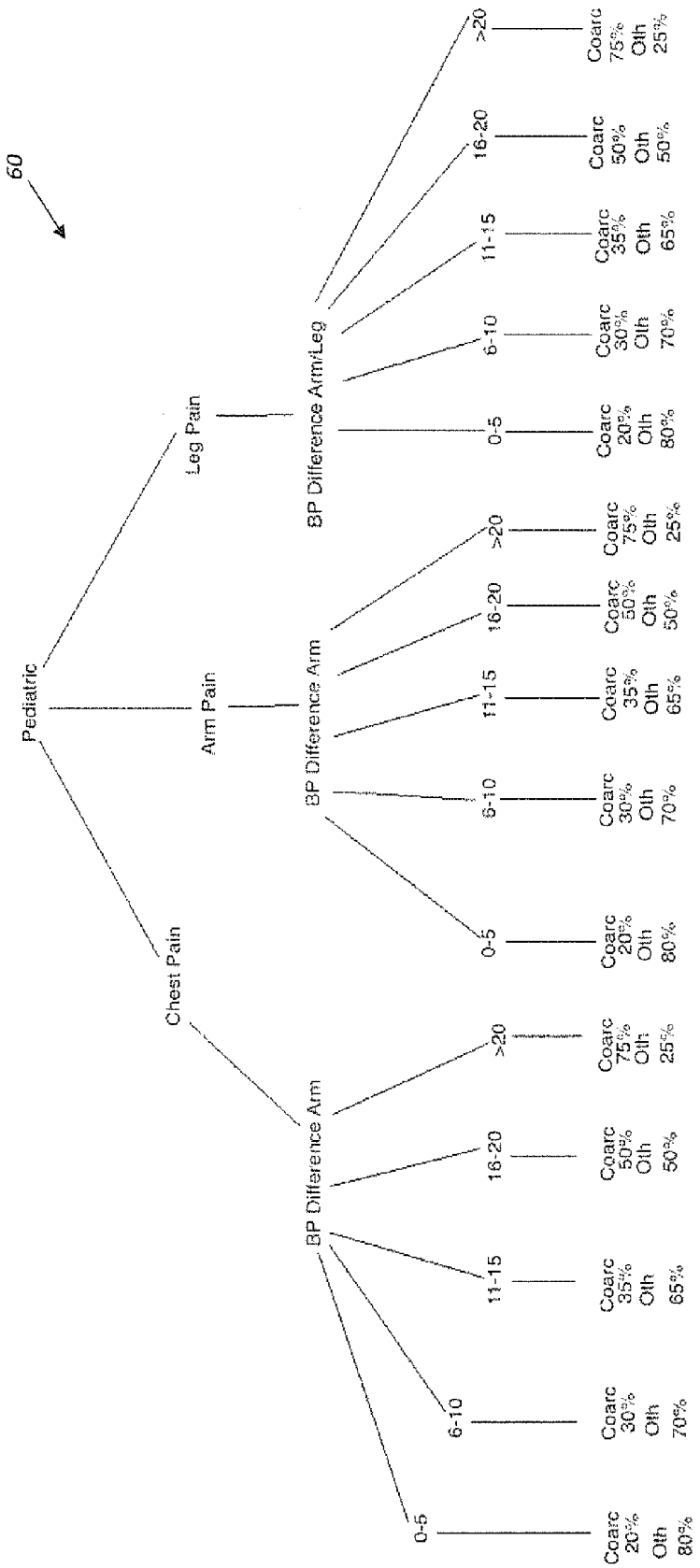

60
Pediatric
Leg Pain
Arm Pain
Chest Pain
BP Difference Arm/Leg
BP Difference Arm
BP Difference Arm
0-5
6-10
11-15
16-20
>20
Coarc 20% Oth 80%
Coarc 30% Oth 70%
Coarc 35% Oth 65%
Coarc 50% Oth 50%
Coarc 75% Oth 25%

FIG. 6

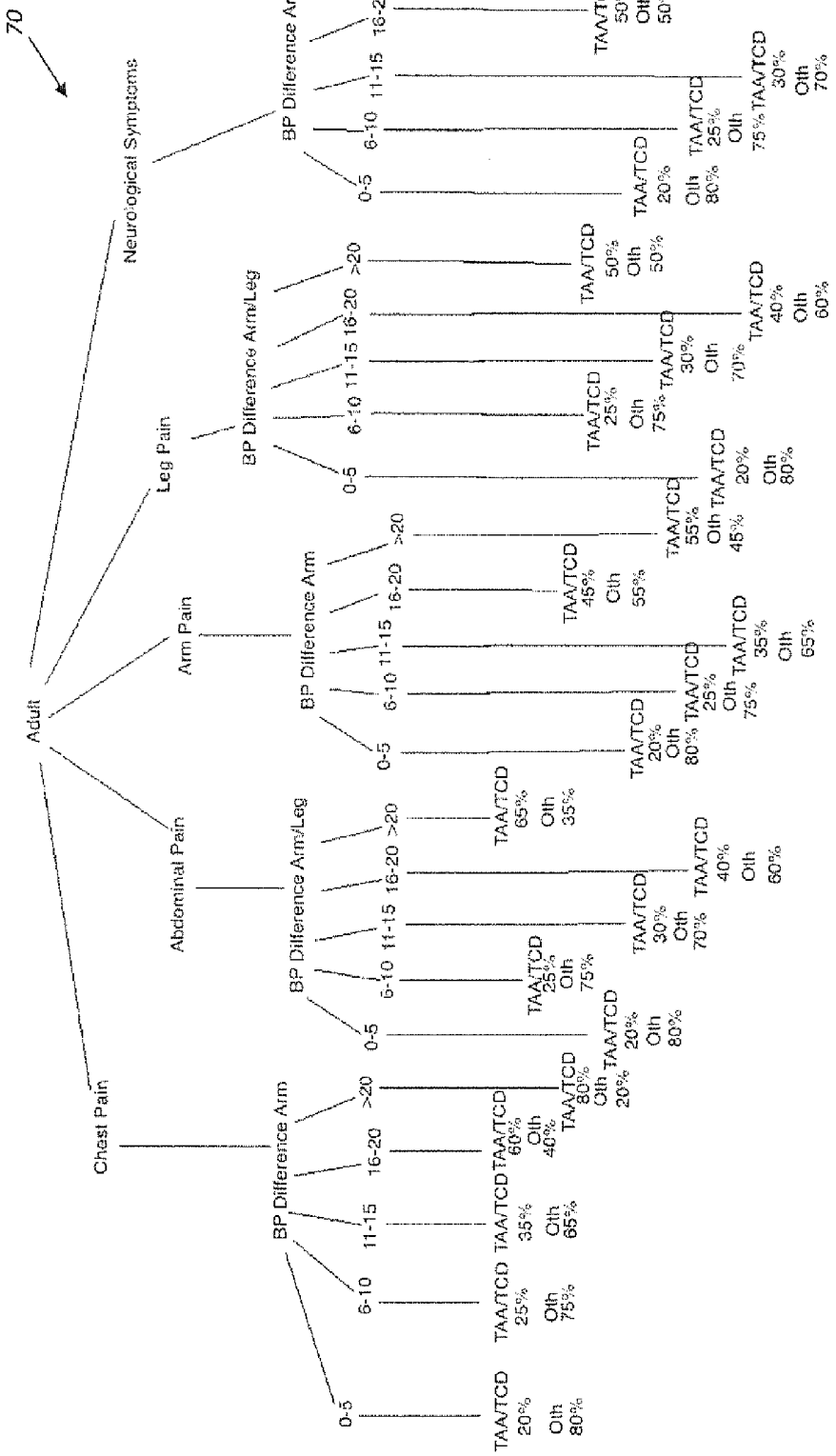

70
Adult
Chest Pain
Abdominal Pain
Arm Pain
Leg Pain
Neurological Symptoms
BP Difference Arm
BP Difference Arm/Leg
0-5
6-10
11-15
16-20
>20
TAA/TCD
Oth

FIG. 7

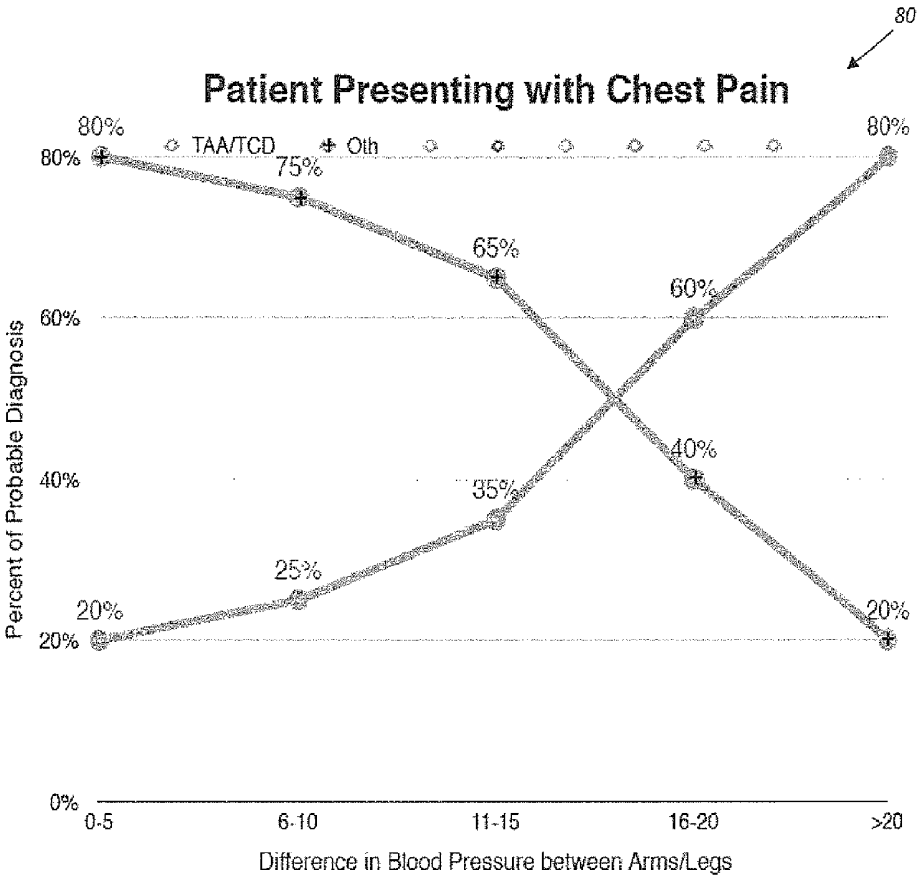

80
Patient Presenting with Chest Pain
TAA/TCD
Oth
80%
80%
75%
65%
60%
60%
40%
40%
35%
25%
20%
20%
20%
0%
0-5
6-10
11-15
16-20
>20
Percent of Probable Diagnosis
Difference in Blood Pressure between Arms/Legs

FIG. 8

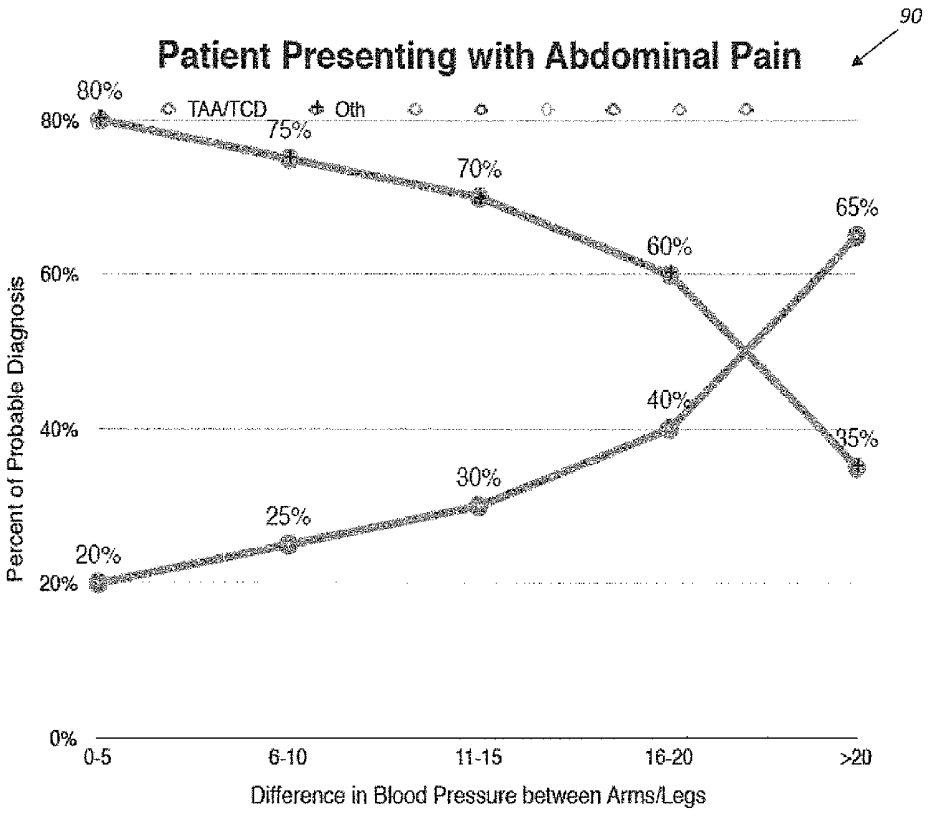

90
Patient Presenting with Abdominal Pain
TAA/TCD
Oth
80%
75%
70%
60%
65%
40%
35%
30%
25%
20%
Percent of Probable Diagnosis
0%
0-5
6-10
11-15
16-20
>20
Difference in Blood Pressure between Arms/Legs

FIG. 9

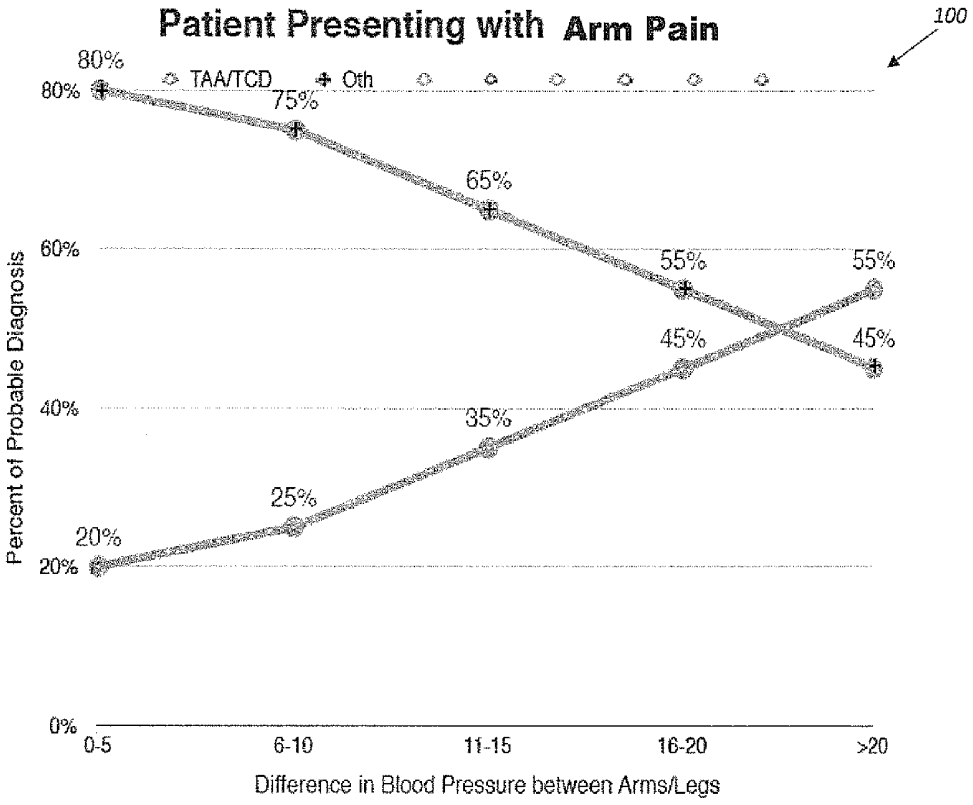

Patient Presenting with Arm Pain
100
TAA/TCD
Oth
80%
75%
65%
55%
55%
45%
45%
35%
25%
20%
20%
60%
40%
0%
Percent of Probable Diagnosis
0-5
6-10
11-15
16-20
>20
Difference in Blood Pressure between Arms/Legs

FIG. 10

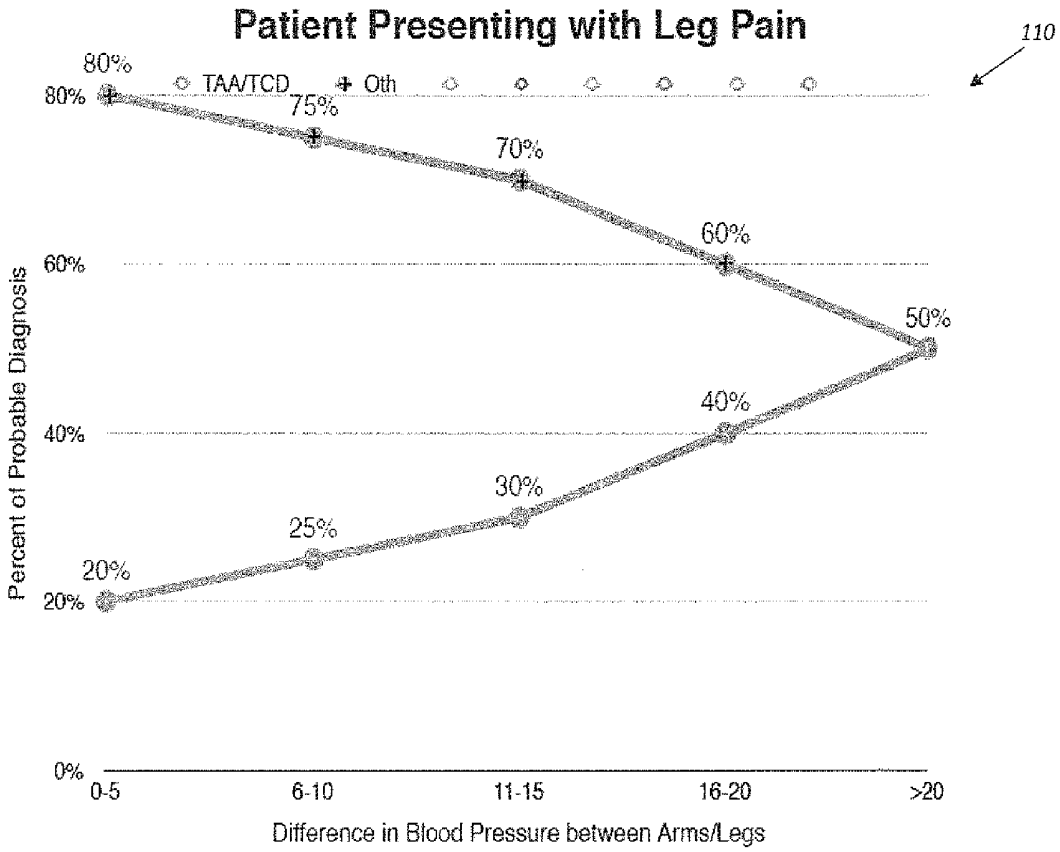

Patient Presenting with Leg Pain
110
TAA/TCD
Oth
80%
75%
70%
60%
50%
40%
30%
25%
20%
Percent of Probable Diagnosis
0%
0-5
6-10
11-15
16-20
>20
Difference in Blood Pressure between Arms/Legs

FIG. 11

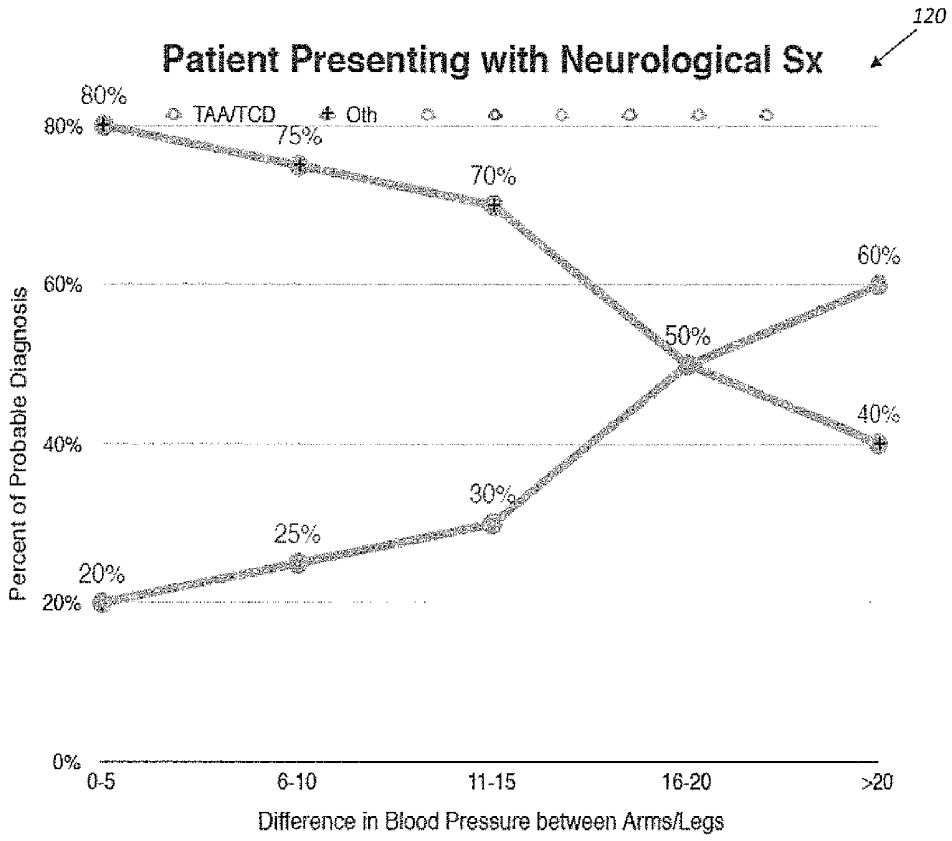

120
Patient Presenting with Neurological Sx
TAA/TCD
Oth
80%
75%
70%
60%
50%
40%
30%
25%
20%
Percent of Probable Diagnosis
0%
0-5
6-10
11-15
16-20
>20
Difference in Blood Pressure between Arms/Legs

FIG. 12

BLOOD PRESSURE DIAGNOSTIC DEVICE PROVIDING ENHANCED VASCULAR CONDITION DETECTION FEATURES AND RELATED METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. application Ser. No. 13/087,684 filed Apr. 15, 2011, which claims the benefit of provisional application No. 61/324,527, filed Apr. 15, 2010, the contents of which are hereby incorporated herein in their entireties by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to the field of medical devices, and, more particularly, to blood pressure monitoring systems, devices, and related methods.

BACKGROUND OF THE INVENTION

[0003] Various approaches have been developed for determining blood pressures of patients. One such example is disclosed in U.S. Pat. No. 7,608,045 to Mills, which is directed to a method for noninvasively monitoring physiological characteristics of a patient's blood. Determinations of blood constituent concentrations may be made by comparing absorbance of radiation at varying parameters, such as path length and blood pressure. Changes in pressure may be effected by changing the height of the probes relative to the patient's heart. Determinations of blood pH may be made by comparing absorbance of the blood at different wavelengths. The temperature of the blood, and thus of the patient's core, may also be accurately determined. Further, cardiac output characteristics and blood pressures may be noninvasively determined using the methods of the invention.

[0004] A related ankle brachial pressure index system is disclosed in U.S. pub. no. 2009/0036786 to Gough et al. The system includes two cuffs for each ankle and two cuffs for each arm of a patient. Each cuff has chambers. The four cuffs are applied to each limb (or finger or toe), and each chamber is inflated simultaneously to a pressure until a Pneumo Arterial Plethysmography (PAPG) signal related to the arterial flow in the limb is detected at the chambers. The chambers are then simultaneously inflated until the PAPG signals are extinguished in each limb, the inflation of chambers continuing for 10 mmHg to 20 mmHg above that pressure. The chambers are then deflated and the pressure at which the PAPG signal returns in the first chamber is recorded for each limb and this value of the pressure is used to calculate the ABPI. The ABPI is displayed or sent to a remote site.

[0005] Despite the advantages of such systems, further enhancements may be desirable in blood pressure monitoring systems, such as to provide enhance diagnostic capabilities, for example.

SUMMARY OF THE INVENTION

[0006] A medical diagnostic system may include a plurality of blood pressure measuring devices each configured to measure blood pressure of a respective extremity from among a plurality of extremities of a patient, and a blood pressure diagnostic device including at least one input device and a controller. The controller may cooperate with the at least one input device to determine blood pressure measurements for the respective patient extremities based upon the plurality of blood pressure measuring devices, receive an indicator of at least one symptom of the patient via the input device, and determine statistical probabilities that a condition of the patient is within a first group of vascular conditions requiring a first course of treatment, and a second group of vascular conditions requiring a second course of treatment different than the first course of treatment, based upon the determined blood pressure measurements and the indicator of the at least one symptom.

[0007] More particularly, the controller may determine the statistical probabilities based upon differences between the blood pressure measurements for the respective patient extremities and the indicator of the at least one symptom. By way of example, the at least one symptom may comprise a localized pain center in the patient's body, a neurological symptom, etc.

[0008] In accordance with one example, the first course of treatment may comprise a chest pain protocol including administration of an anti-coagulant to the patient, and the second course of treatment may comprise an aneurysm and dissection protocol excluding administration of an anti-coagulant to the patient. The blood pressure diagnostic device may further include an output device cooperating with the controller to output the statistical probabilities, and/or to output the first course of treatment or the second course of treatment as a recommended course or treatment for the patient based upon the determined statistical probabilities.

[0009] A related blood pressure diagnostic device, such as the one described briefly above, and a related medical diagnostic method are also provided. The method may include coupling a plurality of a blood pressure measuring devices each to a respective extremity of a patient, and using a blood pressure monitoring device to determine blood pressure measurements for the respective patient extremities based upon the plurality of blood pressure measuring devices, and receive an indicator of at least one symptom of the patient. The blood pressure diagnostic device may be further used to determine statistical probabilities that a condition of the patient is within a first group of vascular conditions requiring a first course of treatment, and a second group of vascular conditions requiring a second course of treatment different than the first course of treatment, based upon the determined blood pressure measurements and the indicator of the at least one symptom.

[0010] A related non-transitory computer-readable medium may have computer-executable instructions for causing a blood pressure diagnostic device to perform steps including determining blood pressure measurements for the respective patient extremities based upon a plurality of blood pressure measuring devices each coupled to a respective extremity of a patient, and receiving an indicator of at least one symptom of the patient via the at least one input device. A further step may include determining statistical probabilities that a condition of the patient is within a first group of vascular conditions requiring a first course of treatment, and a second group of vascular conditions requiring a second course of treatment different than the first course of treatment, based upon the determined blood pressure measurements and the indicator of the at least one symptom.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. **1** is schematic block diagram of a blood pressure monitoring system in accordance with an exemplary embodiment.

[0012] FIG. **2** is a schematic block diagram of the blood pressure monitoring device of the system of FIG. **1** illustrating additional optional features thereof.

[0013] FIG. **3** is a front view of an example feedback device of the blood pressure monitoring device of FIG. **2**.

[0014] FIG. **4** is a perspective view of another example embodiment of the blood pressure monitoring system of FIG. **1**.

[0015] FIG. **5** is a flow diagram illustrating method aspects associated with the systems and devices of FIGS. **1-4**.

[0016] FIGS. **6** and **7** are decision tree flow diagrams illustrating an approach for determining statistical probabilities of vascular conditions for pediatric and adult patients, respectively, in accordance with an example embodiment.

[0017] FIGS. **8-12** are graphs illustrating the statistical probabilities of first and second groups of vascular conditions for different pain centers from the diagram of FIG. **7**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0018] The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which exemplary embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

[0019] Referring now to FIGS. **1** through **5**, a blood pressure monitoring system **30** and related method aspects are first described. The system **30** illustratively includes a plurality of a blood pressure measuring devices **31-34**, each of which is configured to measure the blood pressure of a respective extremity of a patient **35**. Beginning at Block **51** (FIG. **5**), in the illustrated example, the blood pressure measuring devices **31-34** are respectively associated with or coupled to (Block **52**) the following extremities: right upper extremity (RUE) or right arm; left upper extremity (LUE) or left arm; right lower extremity (RLE) or right leg; and left lower extremity (LLE) or left leg. In the example of FIG. **4**, the blood pressure measuring devices **31-34** are cuffs, but other suitable types of blood pressure measurement devices (e.g., finger/toe probes, etc.) may also be used. Moreover, in the case of blood pressure cuffs, these may be reusable cuffs or disposable cuffs (or a combination thereof).

[0020] The system **30** further illustratively includes a blood pressure diagnostic or monitoring device **36**. More specifically, the blood pressure monitoring device **36** illustratively includes one or more interface devices **37** configured to interface with the blood pressure measuring devices **31-34**, and a controller **38** coupled to the interface device. By way of example, in some embodiments where blood pressure cuffs are used, the interface device **37** may comprise one or more air pumps or compressors (not shown) with attachments for fluid lines **41-44** (see FIG. **4**), which in turn are respectively coupled or connected to the blood pressure measuring devices **31-34** (i.e., cuffs). In this way, the blood pressure monitoring device **36** may be used to pneumatically inflate/deflate the cuffs for blood pressure measurements. Also by way of example, the controller **38** may be implemented using appropriate hardware components, such as a processor, memory, etc.

[0021] The interface device **37** may further include one or more input and/or output devices such as electrical connectors (e.g., a communications bus plug, such as for a USB bus, measurement probe plug, etc.) for wired connections to the blood pressure measuring devices **31-34**. This allows control or measurement data to be communicated to or from the blood pressure measuring devices **31-34**. However, in some embodiments, the interface device **37** may in addition, or instead, include a wireless communications circuitry (e.g., cellular, WiFi, Bluetooth, near field communication (NFC), etc.) for wirelessly communicating with the blood pressure measuring devices **31-34**. In the case of a wireless blood pressure cuff, the cuff may include a respective pump for inflating the cuff, along with its own wireless communications circuitry for communicating with the interface device **37**. In embodiments where disposable cuffs are used, the pump and wireless communications circuit may be enclosed or carried by a housing that may be releasably connected in fluid/electrical communication with the cuff, so that the cuff may be disposed of, but the housing may be readily re-used for another (or the same) patient, for example.

[0022] The controller **38** is configured to cooperate with the blood pressure measuring devices **31-34** to determine respective blood pressure measurements for each patient extremity, at Block **53**, and selectively determine differences between the blood pressure measurements, at Block **54**. It should be noted that differences between all of the blood pressure measurements need not be determined or used in all embodiments. In addition, the controller **38** may also advantageously generate an indication of a probable or potential vascular aneurysm based upon a determined difference between at least two of the blood pressure measurements reaching a vascular aneurysm threshold value, at Blocks **55** and **57**, which illustratively concludes the method shown in FIG. **5** (Block **58**), although it should be noted that continued blood pressure measurement and monitoring may be performed by the system **30**, if desired.

[0023] By way of example, a systolic pressure difference of greater than about ten mmHg may be indicative of a vascular aneurysm. More particularly, a threshold range of about twenty to forty mmHg difference (or higher) in systolic pressure may provide a relatively good indication of a potential aneurysm, as will be discussed further below.

[0024] A vascular aneurysm is a localized, blood-filled bulge in the wall of a blood vessel, such as an artery or vein. As the size of an aneurysm increases, there is a significant risk of rupture, resulting in severe hemorrhage, other complications, or even death. Acute aneurysms may result in severe localized pain (e.g., in the chest, back, leg, etc.) depending upon their location in the patient's body. However, this may cause first responders (e.g., paramedics, etc.) and even triage providers (e.g., emergency room personnel) to initially misdiagnose the problem. For example, chest pains resulting from a thoracic aneurysm might initially be misdiagnosed as angina or a heart attack. As a result, an emergency care provider may initiate a course of treatment that worsens the aneurysm, such as administering a blood thinner/anticoagulant (e.g., heparin, aspirin, etc.), or sending a patient out for the wrong set of tests/treatment that may prolong the ultimate detection and appropriate treatment for the aneurysm. However, time is typically of the essence in avoiding rupture or other complications from acute aneurysms, and such delays may therefore prove hazardous to the patient.

[0025] Yet, the system **30** may advantageously be used by emergency responders or triage providers to quickly and accurately help assess the potential of a vascular aneurysm in a patient. This may potentially help expedite obtaining appropriate follow-up treatment in time to help avoid serious injury or death, and to avoid administering potentially harmful medications to the patient.

[0026] As will be discussed further below, the blood pressure monitoring device **36** may be further configured to advantageously determine a probable vascular aneurysm type from among a plurality of different vascular aneurysm types (e.g., thoracic aortic aneurysm, abdominal aortic aneurysm, peripheral arterial aneurysm, etc.) based upon the respective extremities associated with the blood pressure measurements, at Block **56**. More particularly, in the embodiment illustrated in FIG. **2**, the blood pressure monitoring device **36** further includes an input device **45** coupled to the controller **38**. By way of example, the input device **45** may comprise one or more of a keyboard or keypad, touch screen, menu buttons, a mouse, etc. The input device **45** may advantageously be used by a first responder, etc., to input an indicator of a localized pain region where the patient **35** is experiencing pain (e.g., chest, back, leg, arm, etc.). In some embodiments, the input device may take the form of a wireless communications device (e.g., Bluetooth, NEC, WiFi, etc.) which receives input indicators or information from a mobile computing device, such as a smart phone, tablet computer, laptop computer, etc. In this regard, in some embodiments the blood pressure monitoring device may be implemented using such a mobile device, such as through an application or app installed on the device which performs the noted operations described herein based upon the input it receives from the blood pressure measuring devices **31-34**, and via the input device (e.g., keypad, touch screen, etc.) associated with the mobile computing device, as will be appreciated by those skilled in the art.

[0027] As such, the controller **38** may be further configured to receive the indicator of the localized pain region via the input device **45**, and determine the vascular aneurysm type also based upon the localized pain region indicator. That is, by comparing the differences in blood pressure readings in combination with knowing the region where the pain is located, this may allow the controller **38** to provide even more accurate assessments of potential vascular aneurysms. In the example of FIG. **3**, in which the feedback device **46** comprises a display, a pull down menu box **47** is provided for selecting the appropriate localized pain region, although other suitable approaches for inputting such data may also be used in different embodiments. For example, symptoms and other patient information may be communicated to the blood pressure monitoring device **36** (e.g., via a wireless communication link, etc.) from a central record keeping system (e.g., a screener initially inputs patient information and symptoms into a patient database upon arrival at ER, etc.). Conversely, symptom information entered directly into the blood pressure monitoring device **36** (e.g., by a paramedic, etc.), as well as measurement and diagnostic data, may be uploaded to the central record keeping system over the air, etc.

[0028] The controller **38** may be further configured to determine at least one ankle brachial pressure index (ABI) value based upon the blood pressure measurements (Block **54**), and generate the indication of a probable vascular aneurysm (or other vascular condition) also based upon the at least one ABI (Block **55**). ABI is the ratio of the blood pressure in the lower legs to the blood pressure in the arms, and is typically calculated by dividing the systolic blood pressure in the leg (e.g., at the ankle) by the systolic blood pressure in the arm. The ABI may also help to further enhance the accuracy of a potential vascular aneurysm determination, as well as to diagnose other vascular problems, as will be discussed further below. In some embodiments, a "cross-body" (i.e., from left arm to right leg, or right arm to left leg) ABI may also be determined and used for diagnostic purposes.

[0029] In the example of FIG. **4**, the blood pressure monitoring device **36** further includes a housing **60**, and a plurality of display windows **61-66** carried by the housing and coupled to the controller **38** (not shown in FIG. **4**). The display windows **61-66** are configured to conveniently display RUE blood pressure, LUE blood pressure, RLE blood pressure, LLE blood pressure, right-side ABI, and a left-side ABI, respectively. As such, the blood pressure monitoring device **36** may advantageously provide blood pressure measurements or readings for up to all four patient extremities, as compared to traditional blood pressure measuring devices which require a practitioner to measure blood pressure one extremity at a time.

[0030] The input device **45** may advantageously be used to set a particular measurement type, sequence, etc. For example, an option to measure one or more blood pressures at a time may be provided. More particularly, the controller **38** may further be configured to cooperate with the blood pressure measuring devices **31-34** to determine respective blood pressure measurements for one or more patient extremities on a staggered time schedule (e.g., fifteen seconds apart or greater), if desired. That is, the blood pressure measuring devices **31-34** may be actuated at different times, which may provide more accurate readings for determining particular vascular conditions in some circumstances. Moreover, this may be done to cause less stress (i.e., afterload) on the heart, which may be important if a heart attack is a possible or suspect condition (i.e., if a heart attach has not previously been ruled out). Another option is to obtain ABI readings on one or both sides of the patient **35** (or cross-body ABI's). Further, a diagnostic mode may be entered to determine potential vascular aneurysms or other conditions, as discussed above.

[0031] In some embodiments, a single blood pressure monitoring device **36** may be used with additional sets of blood pressure measuring devices **31-34** to monitor blood readings and perform diagnoses for more than one patient **35**. This may potentially provide several benefits, including reduced storage space requirements, enhanced portability, and reduced cost, for example. While this embodiment may be particularly advantageous where wireless measuring devices **31-34** are used, it may be implemented with "wired" measuring devices as well (or a combination of wired and wireless), in some embodiments.

[0032] In this regard, the above-noted features may advantageously be embodied in a non-transitory computer-readable medium having computer-readable instructions for causing a computing device to perform the operations described herein. More particularly, this allows computing devices such as desktop computers, laptop computers, tablet computers, smart phones, personal digital assistants (PDA's), etc. to conveniently interface with the measuring devices **31-34** (e.g., via a cellular, WiFi, Bluetooth, NFC, wired, or other communications link), and receive operator input or provide output through the existing input or output devices thereof, respec-

tively. Thus, by installing an appropriate application or "app" on such devices, they may serve as the blood pressure monitoring device, which not only provides for enhanced convenience of use, it may also result in reduced equipment costs, for example. Moreover, different computing devices may be coupled together in a network, such that one or more central computing devices (e.g., server, desktop or laptop computer, etc.) interface with the measuring devices **31-34**, while other portable devices (e.g., tablet computer, smart phone, PDA) obtain feedback data from the central computing device(s).

[0033] Referring again to FIG. **3**, the controller **38** may be further advantageously configured to selectively output, via the feedback device **46** (i.e., a display in the illustrated example), a warning not to administer a blood thinner or anticoagulant (e.g., aspirin, heparin, etc.) to the patient **35** based upon the determined difference between the at least two of the blood pressure measurements reaching the vascular aneurysm threshold value (i.e., based upon the given likelihood that the patient may in fact have an aneurysm). In the illustrated example, the warning reads "WARNING—DO NOT ADMINISTER ANTICOAGULANT." In addition, the controller **38** may be similarly configured to cause the display **46** to display a visual indication of the probable vascular aneurysm, which in this example reads "potential thoracic aneurysm." Further instructions to the care provider are also given in this example, which read "proceed immediately to CT angiogram of thorax to rule out thoracic aneurysm." The controller **38** is also configured to cause the display **46** to display the blood pressure measurements for each of the extremities, similar to the example of FIG. **4**. Here, the extremity blood pressure readings are as follows: LUE=90/40; RUE=140/70; LLE=100/60; and RLE=120/70. Of course, ABI's may similarly be displayed, as described with reference to FIG. **4**.

[0034] The foregoing will be further understood with reference to several use case scenarios. The first scenario is for a potential thoracic aneurysm, in which the blood pressure readings are those shown in FIG. **3** and set forth above. The patient presents with chest pain or a "ripping" chest pain, and the emergency care provider initiates an immediate blood pressure check for all of the patient's extremities using the system **30**. Because the of the difference between the upper and lower systolic blood pressures (right side) is twenty mmHg, an immediate CT (i.e., X-ray computed tomography) angiogram of the thorax is recommended to rule out a thoracic aneurysm. It should be noted that diastolic or mean blood pressure comparisons may also be used in some embodiments. Moreover, cross-body blood pressures may also be compared.

[0035] By way of contrast, if the emergency care provider were to use a single-extremity measuring device and only one of the patient's extremities were checked, a misdiagnosis of unstable angina or a potential heart attack, etc., may be reached, and the patient may be sent directly to a heart catheter lab. Generally speaking, blood pressure measurements should be taken on all patient extremities when a patient presents with chest pain or extremity pain. However, because blood pressure measurements are typically performed one extremity at a time in most ER's, urgent care centers, etc., this is very time consuming and may possibly be delayed or even skipped when caregivers are extremely busy or rushed. Moreover, it is common to administer an anticoagulant as a "precaution" when a patient presents with chest pain. Either the delay from the misdiagnosis or the anticoagulant may unfortunately cause the aneurysm to rupture, potentially risking severe injury or death.

[0036] In a second use case scenario, where the patient **35** experiences abdominal pain radiating to the back or severe back pain, an immediate blood pressure check of all extremities is performed using the system **30**. If there is a blood pressure differential from the upper to the lower extremities of twenty to forty mmHg (e.g., systolic), for example, where the upper pressure is greater than the lower, the blood pressure monitoring device **36** may advantageously diagnose a potential abdominal aortic aneurysm, and recommend an abdominal aortic ultrasound or CT angiogram of the abdominal aortic to rule out an abdominal aortic aneurysm.

[0037] In accordance with a third use case scenario pertaining to a suspect peripheral aneurysm, the patient **35** presents with severe leg pain, numbness, or cramping. An immediate blood pressure check of all extremities is again performed using the system **30**. On the unilateral (i.e., same) side, an upper blood pressure that is greater than the corresponding lower blood pressure by twenty mmHg or more may be indicative of a femoral or popliteal artery aneurysm. Here, the course of action provided by the blood pressure monitoring device **36** may be to obtain an immediate arterial Doppler scan of the affected lower extremity, and not to administer an anticoagulant.

[0038] In a fourth use case scenario pertaining to a peripheral arterial vascular disease (PAD), the patient **35** presents with severe leg pain, cold feet, or a pain with exertion (i.e., exercise). Generally speaking, exemplary ranges for PAD classification may be 0.8-1 for mild disease, 0.5-0.8 for moderate disease, and 0.0-0.5 for severe disease. As such, if the blood pressure monitoring device **36** determines an ABI of less than 0.6, this may be used as the threshold or trigger point for a diagnosis of potential claudication. Accordingly, the blood pressure monitoring device **36** may recommend obtaining an arterial Doppler scan of the affected leg, and may note that there is a low risk associated with administering an anticoagulant (provided that the patient is not allergic to aspirin, heparin, etc.).

[0039] In addition to the foregoing examples, the blood pressure monitoring device **36** may also provide potential diagnoses and a recommended treatment or course of action for other vascular conditions. By way of example, such conditions may include the following: dissecting thoracic aneurysm; coarctation of the aorta; tetralogy of fallot; transposition of the great vessels; subclavian artery stenosis; subclavian steal syndrome; Marfan's syndrome; common iliac artery stenosis; external iliac artery stenosis; auxiliary artery stenosis; congenital diseases; aortic dissections; acute coronary syndromes; chest trauma from a motor vehicle accident or other blunt chest wall trauma; etc. In such instances, measured blood pressure and/or ABI values, patient symptoms, etc., may be used by the controller **38** to determine a potential diagnosis for these various conditions based upon appropriate respective blood pressure and/or ABI suspect ranges, as will be appreciated by those skilled in the art, similar to the examples provided above.

[0040] The system **30** may therefore provide enhanced blood pressure monitoring and diagnostic features in numerous clinical settings, including primary care, urgent care, pediatrics, cardiology, ER/hospitals, first responders (e.g., paramedics), etc. In the case of first responders, the system **30** may be of particular advantage because it may help prevent

administering of an anticoagulant when this may be detrimental, and also to provide advance notice to a hospital, ER, etc., of what test facilities need to be made immediately available for the patient upon arrival (e.g., ultrasound, CT, etc.). In an example pediatric application, coarctation of the aorta is a congenital condition in which the aorta narrows in the area of the ductus arteriosus, typically resulting in diminished blood pressure in the LUE. However, due to time constraints, etc., a care provider may typically only subjectively palpate for blood pressure differences. Yet, use of the blood pressure monitoring system **30** may advantageously allow for a more accurate assessment or diagnosis of this potential condition (or others) in newborns or children (along with a corresponding recommendation of the appropriate follow-up testing or procedures), which might otherwise be missed by subjective palpation alone.

[0041] In accordance with another aspect described now with reference to FIGS. **6-12**, the blood pressure measurement device **36** may be particularly beneficial for first responders (e.g., paramedics, etc.) and/or medical triage personnel (e.g., in an ER, etc.) to help determine the appropriate treatment path for a given patient and avoid a misdiagnosis that may lead to a wrong decision regarding the administration of an anti-coagulant, or the medical imaging test that should be expedited for the patient. More particularly, the controller **38** may advantageously cooperate with the interface device **37** to determine blood pressure measurements for the respective patient extremities based upon the plurality of blood pressure measuring devices **31-34**, and receive an indicator of at least one symptom of the patient via the input device **45**, as discussed earlier. However, based upon the blood measurements and the symptom indication(s) provided by the medical attendant, the controller **38** may determine statistical probabilities that a condition of the patient is within a first group of vascular conditions requiring a first course of treatment, and a second group of vascular conditions requiring a second course of treatment different than the first course of treatment.

[0042] More particularly, the controller **38** may determine the statistical probabilities based upon differences between the blood pressure measurements for the respective patient extremities (e.g., differential pressure between left/right arms, left/right legs, left arm/right leg, right art/left leg) and the noted symptom(s). Generally speaking, with respect to vascular conditions, symptoms may be grouped into two different types, namely localized pain center or regions in the patient's body, and neurological conditions being experienced by the patient (e.g., numbness, weakness, dizziness, faintness, etc.). For the following examples, the first group of vascular conditions includes those for which no anti-coagulant (e.g., heparin) should be administered to the patient, and instead the patient should initially be sent for an expedited imaging analysis, such as a CT scan, as discussed above. Such conditions may include an aneurysm (e.g., a thoracic aortic aneurysm (TAA) or an abdominal aortic aneurysm (AAA)), or a dissection (e.g., a thoracic dissection (TCD)). Again, a misdiagnosis of heart disease and administration of an anti-coagulant to a patient with such a condition can be not only harmful but potentially fatal to the patient, either from a premature rupture caused by the anti-coagulant, or prolonging of a correct diagnosis and surgical intervention.

[0043] On the other hand, the second group or category of vascular conditions may be those for which a "chest pain protocol" may be appropriate, including the administration of an anti-coagulant, for example. In fact, prolonging of an anti-coagulant can be harmful or potentially fatal to a patient in some circumstances. Such conditions may include coronary artery disease (CAD), arterial sclerosis (ART) (including plaque build up in the arteries), subclavian stenosis (SS), peripheral arterial disease (PAD), etc.

[0044] In the illustrated example, the controller **38** is configured to determine a statistical likelihood or probability that the vascular condition being suffered by the patient is in the first group or second group based upon differential blood pressure measurements based upon the patient's age and symptom(s), as well as differential blood pressure measurements. More particularly, differential measurements used in this example are those between the measured arm pressures and/or the cross-body differences between arms and legs (e.g., left leg/right arm and right leg/left arm), although in other embodiments differential leg/leg pressures or same side arm/leg differentials may also be used.

[0045] As seen in FIGS. **6** and **7**, the processing steps performed by the controller **38** are shown in a decision tree or algorithm flow path for clarity of explanation. A first determination or discriminator may be the age of the patient, i.e., whether the patient is a juvenile (pediatric) patient, for which the diagnostic flow path **60** of FIG. **6** would be followed, or an adult patient, for which the diagnostic flow path **70** of FIG. **7** would be followed. However, in some embodiments age need not be considered (e.g., the controller **38** may be configured for adult use only, etc.) The determination as to whether the patient is an adult or child may simply be a menu selection option for "adult" or "pediatric" patient, for example, or it may be more sophisticated, such as by allowing for the patient's age to be input via the input device **45**, for example, at which point the controller **38** may be configured to determine the appropriate diagnostic path based upon the patient's age. It should also be mentioned that, while a single adult diagnostic path is used in the present example, this could be broken up into different diagnostic paths for different ages of adults (e.g., 20-30, 30-40, 40-50, 50+, etc.).

[0046] More particularly, for a pediatric patient certain assumptions may be made based upon the relatively low occurrences of certain diseases in minors (e.g., coronary artery disease, etc.), and the low likelihood that a neurological condition experienced by a minor is the result of a vascular condition. Thus, in this decision tree, the controller **38** may be configured to consider only pain regions (e.g., chest pain, arm pain, leg pain, etc.) and differential pressures, and determine a statistical likelihood of a coarctation group (i.e., coarctation of the Aorta, or coarc), in which magnetic resonance angiography or CT angiogram should be expedited, or a group of "other" possible conditions the pediatric patient may be suffering and requiring a different course or treatment. More particularly, based upon the selected pain center (which may be the predominant pain center if multiple pain centers are being experienced, for example), and the differential pressures measured by the controller **38** and measuring devices **31-34**, the statistical probabilities of being in a coarctation group versus an "other" vascular condition group for which a different course of treatment is appropriate may be determined as shown. In the given example, the statistical probabilities provided have been determined based upon case studies and doctor experience, and may be stored in a lookup table or database. Another option is that the statistical probabilities may be calculated by the controller **38** using appropriate algorithms or formulas and the data collected via the

input device **45** and measuring devices **31-34**, as will be appreciated by those skilled in the art.

[0047] Turning to the adult diagnostic path **70** of FIG. **7**, it may be appropriate to consider more symptoms in this diagnostic path, since there are more vascular conditions that are statistically likely to be experienced by an adult versus a child. The graphs **80**, **90**, **100**, **110**, and **120** of FIGS. **8-12** respectively illustrate the portions of the diagnostic tree for determining statistical probabilities of vascular conditions for adults based upon a symptom of chest pain, abdominal pain, arm pain, leg pain, and neurological symptoms. In the illustrated example, the first group is labeled as the "TAA/TCD" group, which again is the group including aneurysms, dissections, etc., for which a chest pain protocol is not appropriate (i.e., an anti-coagulant should not be administered). The second group of vascular conditions is labeled as "other" (oth), which would include the other above-noted conditions for which a chest pain protocol is appropriate.

[0048] The controller **38** may cause the feedback or output device(s) **46** to output the determined statistical probabilities for the first and/or second groups. In addition, or in place of outputting the probability values, the controller **38** may instead cause the appropriate course of treatment to be output, which for the first group would be to proceed immediately to medical imaging (e.g., CT, MRI, etc.) to determine if emergency vascular surgery is appropriate for an aneurysm, etc., while the second course of treatment would be to begin a chest pain protocol in which heparin, etc., is administered to the patient. As described above, a warning may also be provided along with the prescribed course of treatment (e.g., not to administer an anti-coagulant, etc.).

[0049] By having the blood pressure diagnostic or monitoring device **36** automatically make determinations of the statistical probabilities of likelihoods that the vascular condition being suffered by a patient requires a chest pain protocol procedure or not, this advantageously helps first responders and triage personnel to get the patient started or directed to the correct course of treatment as early as possible in the treatment process, and thereby increases the chances that the patient will not suffer further harm or death. For example, based upon a determination by the blood pressure monitoring device **36** of a high statistical likelihood that the patient is suffering from an aneurysm/dissection by a paramedic at the time of first response or en route to the hospital, the paramedic or consulting physician may determine that the patient needs to be routed to a different hospital where the appropriate medical imaging (CT, etc.) equipment and/or surgical personnel are available, such as at a larger metropolitan hospital. Otherwise, routing the patient to a smaller rural hospital where such facilities or personnel are not available may result in the death of the patient due to a prolonged time to diagnosis of the actual condition, and then the subsequent time necessary to transport the patient to the location where the proper equipment/personnel are available.

[0050] On the other hand, if the first responder learns that there is a high statistical probability or likelihood that the patient is suffering from a vascular condition that requires a chest pain protocol, this may allow the first responder (e.g., paramedic) to administer the anti-coagulant en route to the hospital with a greater confidence level that this is beneficial to the patient and can help avoid a further heart attach, stroke, etc.

[0051] It should be noted that while the above examples are provided with respect to first and second groups of vascular conditions, more than two groups may be used in certain embodiments and, as seen with the pediatric example of FIG. **6**, a group may correspond to a singular condition. That is, the above-described approach may also be used to find the statistical probabilities of a given one of a plurality of different vascular conditions, as will be appreciated by those skilled in the art. More particularly, the controller **38** may be configured to determine the statistical probability that the patient has a specific condition, for example. Moreover, it should be noted that in some embodiments, the controller **38** may consider one or more other symptoms, including age, weight, gender, medical history, etc. Further, the controller **38** may employ weighted calculations to give certain input factors more influence in the statistical probability calculation as appropriate.

[0052] Many modifications and other embodiments of the invention will come to the mind of one skilled in the art having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is understood that the invention is not to be limited to the specific embodiments disclosed, and that modifications and embodiments are intended to be included within the scope of the appended claims.

That which is claimed is:

1. A medical diagnostic system comprising:

a plurality of a blood pressure measuring devices each configured to measure blood pressure of a respective extremity from among a plurality of extremities of a patient;

a blood pressure diagnostic device comprising

at least one input device, and

a controller cooperating with said at least one input device to

determine blood pressure measurements for the respective patient extremities based upon said plurality of blood pressure measuring devices,

receive an indicator of at least one symptom of the patient via said input device, and

determine statistical probabilities that a condition of the patient is within a first group of vascular conditions requiring a first course of treatment, and a second group of vascular conditions requiring a second course of treatment different than the first course of treatment, based upon the determined blood pressure measurements and the indicator of the at least one symptom.

2. The medical diagnostic system of claim **1** wherein said controller determines the statistical probabilities based upon differences between the blood pressure measurements for the respective patient extremities and the indicator of the at least one symptom.

3. The medical diagnostic system of claim **1** wherein the at least one symptom comprises a localized pain center in the patient's body.

4. The medical diagnostic system of claim **1** wherein the at least one symptom comprises a neurological symptom.

5. The medical diagnostic system of claim **1** wherein the first course of treatment comprises a chest pain protocol including administration of an anti-coagulant to the patient.

6. The medical diagnostic system of claim **1** wherein the second course of treatment comprises an aneurysm and dissection protocol excluding administration of an anti-coagulant to the patient.

7. The medical diagnostic system of claim **1** wherein said controller further cooperates with said at least one input

device to receive an indicator of whether the patient is a pediatric or adult patient, and determine the statistical probabilities also based upon the indicator of whether the patient is a pediatric or adult patient.

8. The medical diagnostic system of claim **1** wherein said blood pressure diagnostic device further comprises an output device cooperating with said controller to output the statistical probabilities.

9. The medical diagnostic system of claim **1** further comprising an output device cooperating with said controller to output the first course of treatment or the second course of treatment as a recommended course of treatment for the patient based upon the determined statistical probabilities.

10. A blood pressure diagnostic device for use with a plurality of a blood pressure measuring devices each configured to measure blood pressure of a respective extremity from among a plurality of extremities of a patient, the blood pressure diagnostic device comprising:

at least one input device; and

a controller cooperating with said at least one input device to

determine blood pressure measurements for the respective patient extremities based upon the plurality of blood pressure measuring devices,

receive an indicator of at least one symptom of the patient via said at least one input device, and

determine statistical probabilities that a condition of the patient is within a first group of vascular conditions requiring a first course of treatment, and a second group of vascular conditions requiring a second course of treatment different than the first course of treatment, based upon the determined blood pressure measurements and the indicator of the at least one symptom.

11. The blood pressure diagnostic device of claim **10** wherein said controller determines the statistical probabilities based upon differences between the blood pressure measurements for the respective patient extremities and the indicator of the at least one symptom.

12. The blood pressure diagnostic device of claim **10** wherein the at least one symptom comprises at least one of a localized pain center in the patient's body and a neurological symptom.

13. The blood pressure diagnostic device of claim **10** wherein the first course of treatment comprises a chest pain protocol including administration of an anti-coagulant medicine to the patient, and wherein the second course of treatment comprises an aneurysm and dissection protocol excluding administration of an anti-coagulant medicine to the patient.

14. A medical diagnostic method comprising:

coupling a plurality of a blood pressure measuring devices each to a respective extremity of a patient; and

using a blood pressure monitoring device to

determine blood pressure measurements for the respective patient extremities based upon the plurality of blood pressure measuring devices,

receive an indicator of at least one symptom of the patient, and

determine statistical probabilities that a condition of the patient is within a first group of vascular conditions requiring a first course of treatment, and a second group of vascular conditions requiring a second course of treatment different than the first course of treatment, based upon the determined blood pressure measurements and the indicator of the at least one symptom.

15. The method of claim **14** wherein determining the statistical probabilities comprises determining the statistical probabilities based upon differences between the blood pressure measurements for the respective patient extremities and the indicator of the at least one symptom.

16. The method of claim **14** wherein the at least one symptom comprises at least one of a localized pain center in the patient's body and a neurological symptom.

17. The method of claim **14** wherein the first course of treatment comprises a chest pain protocol including administration of an anti-coagulant medicine to the patient, and wherein the second course of treatment comprises an aneurysm and dissection protocol excluding administration of an anti-coagulant medicine to the patient.

18. A non-transitory computer-readable medium having computer-executable instructions for causing a blood pressure diagnostic device to perform steps comprising:

determining blood pressure measurements for the respective patient extremities based upon a plurality of blood pressure measuring devices each coupled to a respective extremity of a patient;

receiving an indicator of at least one symptom of the patient; and

determining statistical probabilities that a condition of the patient is within a first group of vascular conditions requiring a first course of treatment, and a second group of vascular conditions requiring a second course of treatment different than the first course of treatment, based upon the determined blood pressure measurements and the indicator of the at least one symptom.

19. The non-transitory computer-readable medium of claim **18** wherein determining the statistical probabilities comprises determining the statistical probabilities based upon differences between the blood pressure measurements for the respective patient extremities and the indicator of the at least one symptom.

20. The non-transitory computer-readable medium of claim **18** wherein the first course of treatment comprises a chest pain protocol treatment including administration of an anti-coagulant medicine to the patient, and wherein the second course of treatment comprises an aneurysm and dissection protocol excluding administration of an anti-coagulant medicine to the patient.

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专利名称(译)	血压诊断装置提供增强的血管状况检测特征和相关方法		
公开(公告)号	US20140343441A1	公开(公告)日	2014-11-20
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[标]申请(专利权)人(译)	阿拉特里斯特ANTHONY		
申请(专利权)人(译)	阿拉特里斯特，ANTHONY		
当前申请(专利权)人(译)	阿拉特里斯特，ANTHONY		
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摘要(译)

医疗诊断系统可以包括多个血压测量装置，每个血压测量装置被配置为测量患者的多个肢体中的相应肢体的血压，以及血压诊断装置，其包括至少一个输入装置和控制器。控制器可以与至少一个输入设备协作以基于多个血压测量设备确定各个患者肢体的血压测量值，通过输入设备接收患者的至少一个症状的指示符，并确定统计基于确定的血压测量值，患者的状况在需要第一疗程的第一组血管状况内的概率，以及需要与第一疗程不同的第二疗程的第二组血管状况的概率和至少一种症状的指标。