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(54) **VASCULAR FLOW DIAGNOSTIC SYSTEM**

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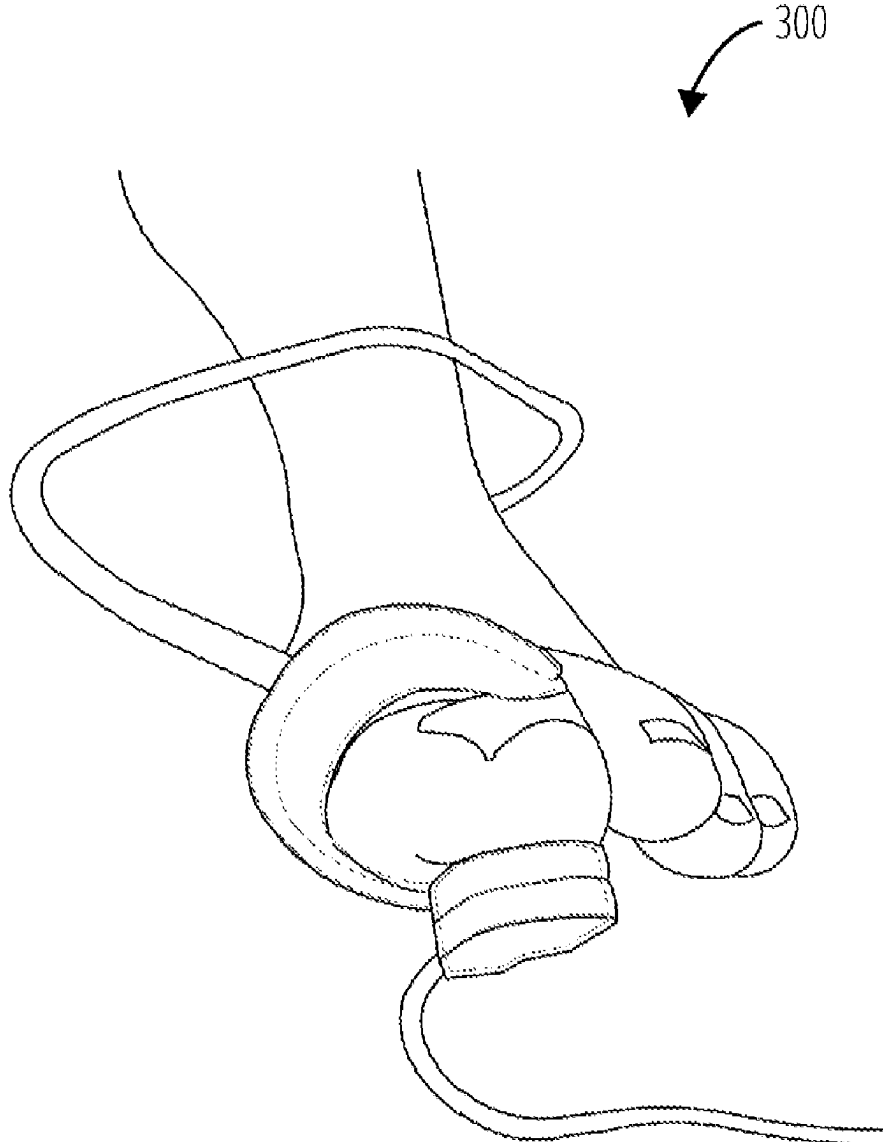
Related U.S. Application Data

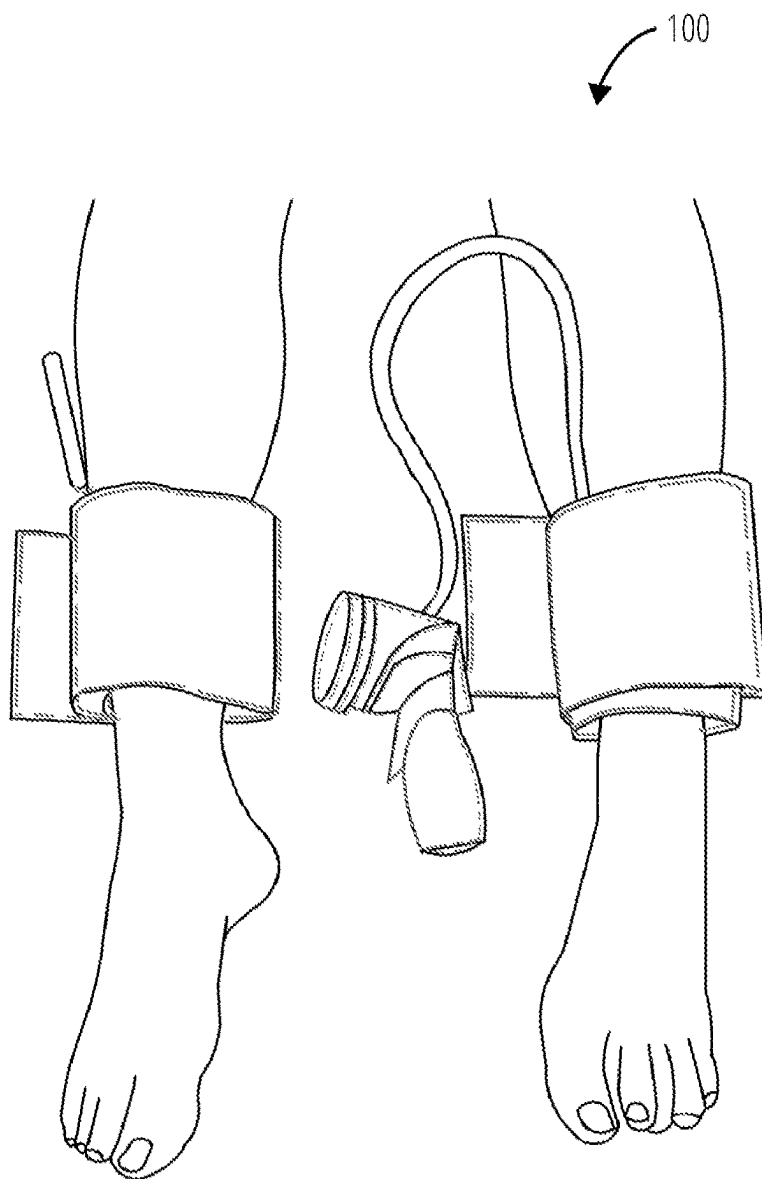
(63) Continuation of application No. 16/785,398, filed on Feb. 7, 2020, now Pat. No. 11,903,688, which is a continuation of application No. PCT/US18/53700, filed on Oct. 1, 2018.

(60) Provisional application No. 62/566,760, filed on Oct. 2, 2017.

(57) **ABSTRACT**

A diagnostic system includes one or more blood flow sensors adapted to contact but not penetrate the skin of the pedal arch and aligned with blood vessels of the pedal arch. Readings from the blood flow sensors are transformed into blood flow acceleration times, and the blood flow acceleration times are used to identify a blood flow pathology.





PRIOR ART

FIG. 1

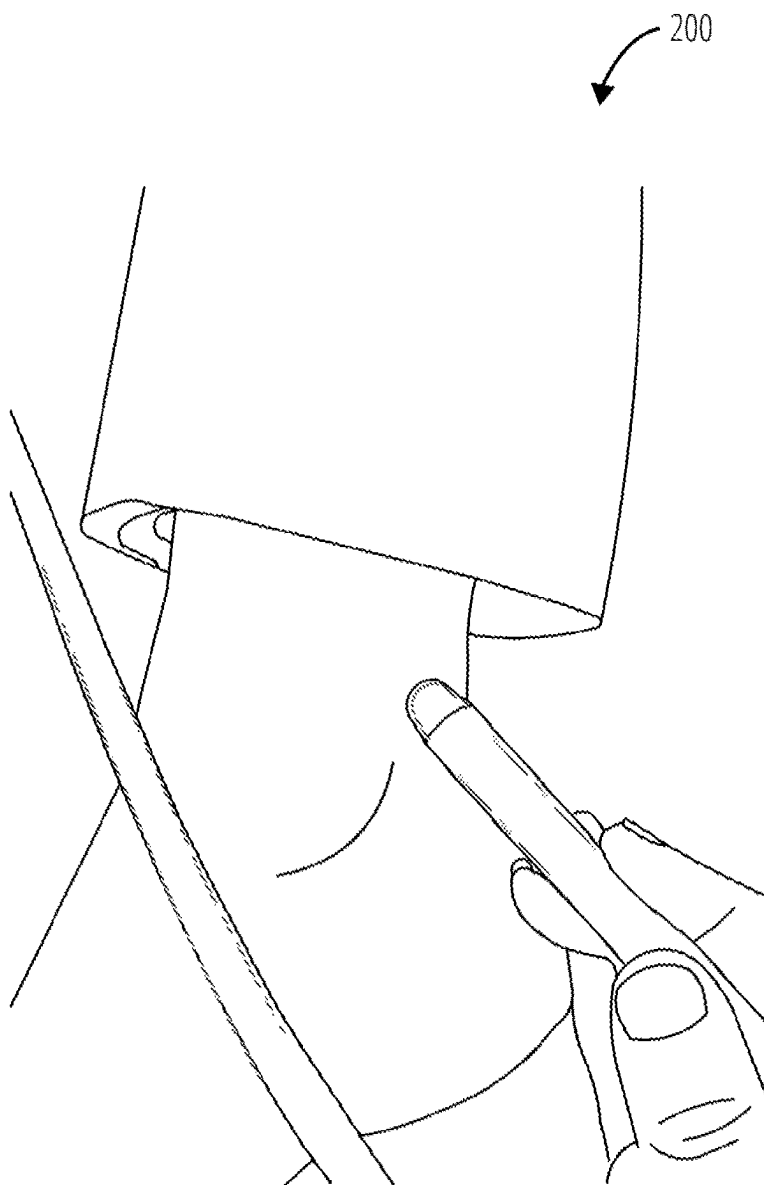


FIG. 2

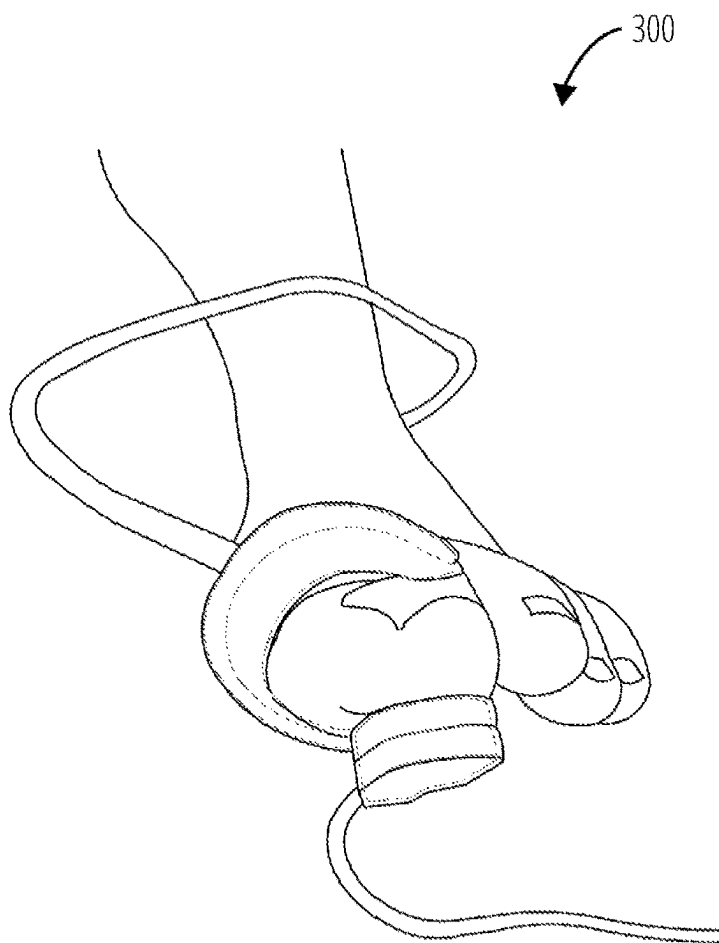


FIG. 3



FIG. 4

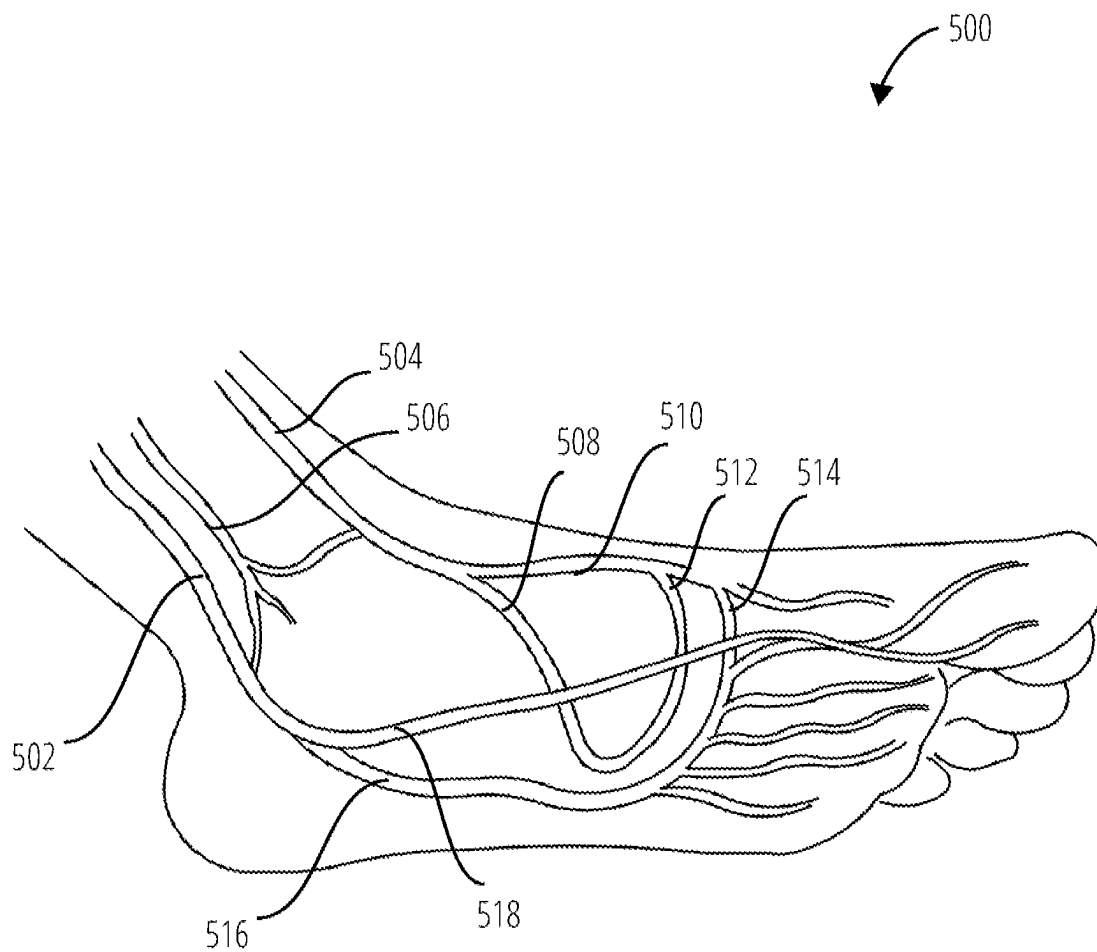


FIG. 5

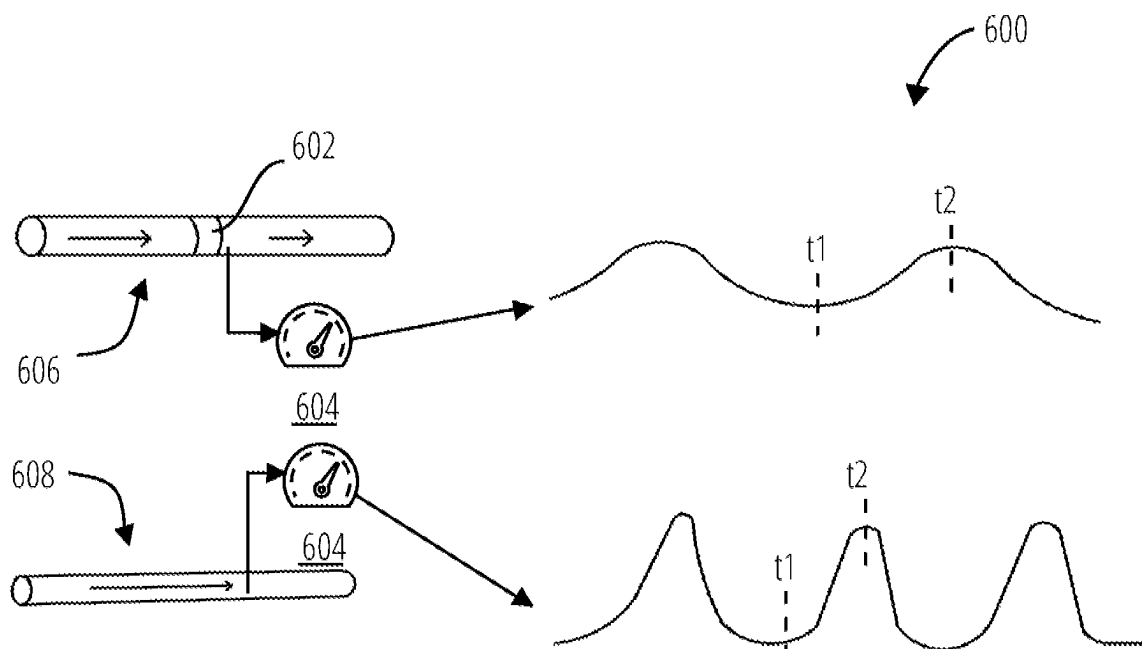


FIG. 6

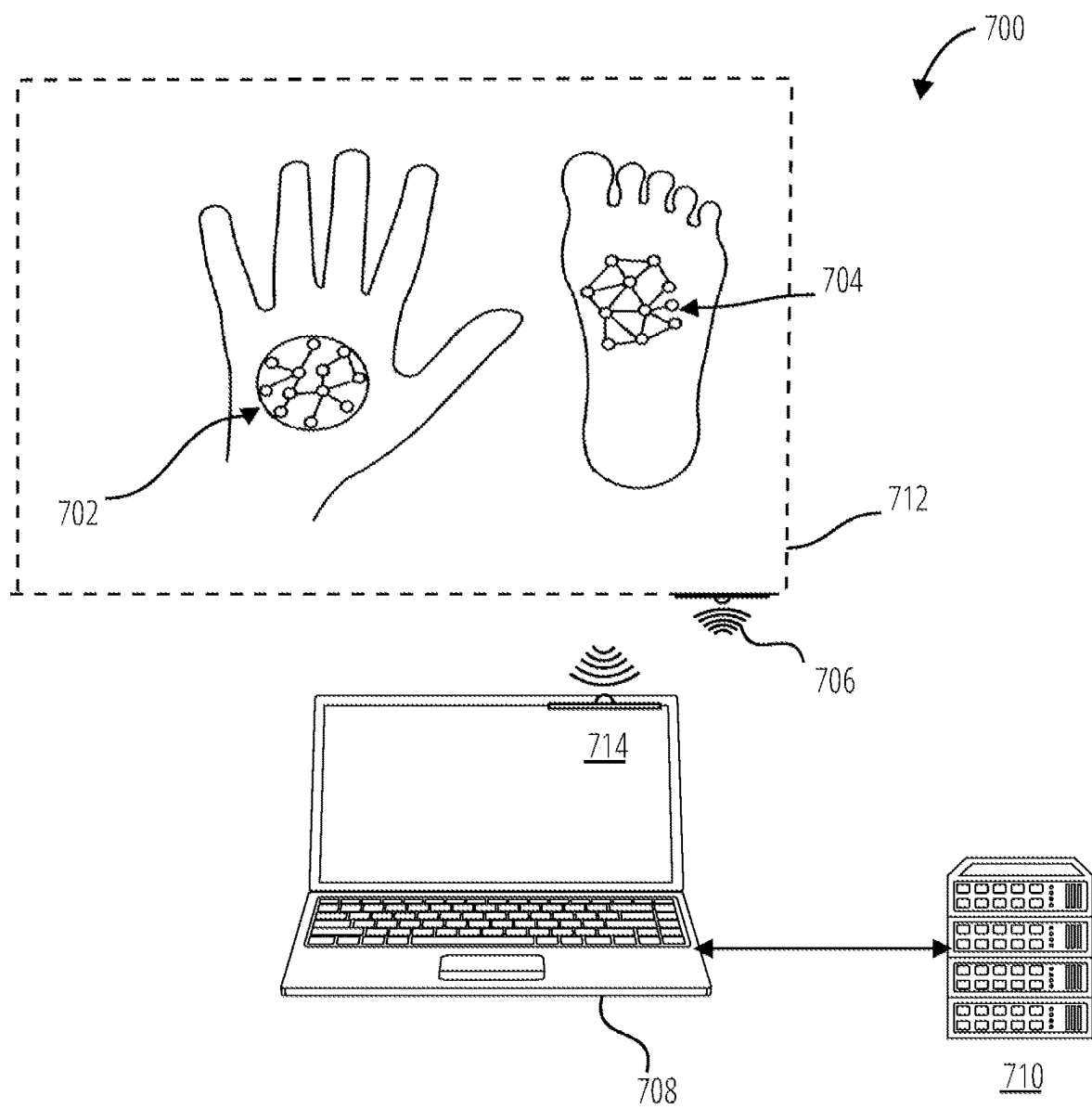


FIG. 7

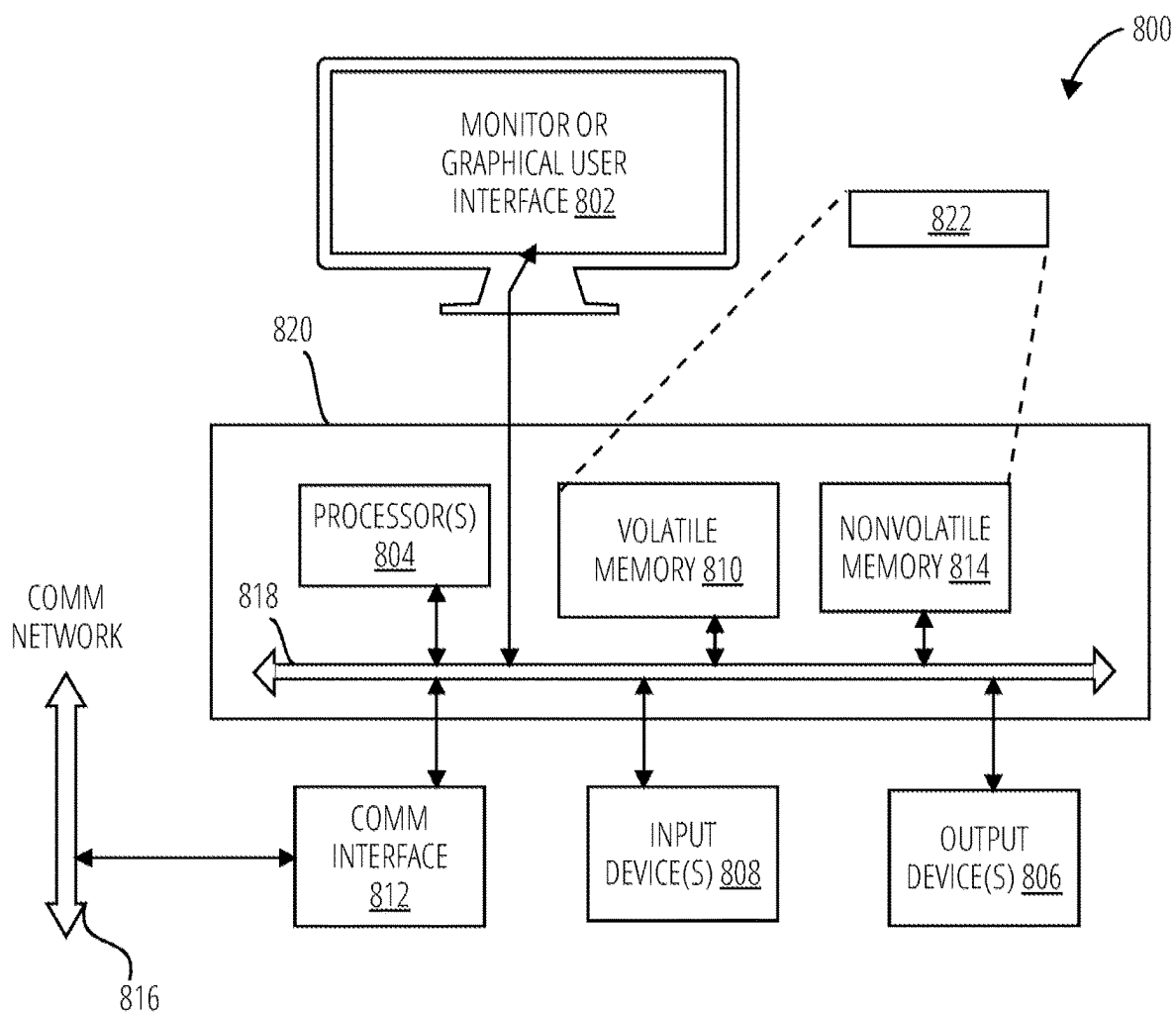


FIG. 8

900



Normal	Mild Claudication	Severe Claudication	CLI – rest pain, tissue loss
0-120	121-180	181-224	>225
<u>ABI 0.9-1.2</u>	0.89-0.69	0.68-0.40	0.39-0.00
TBI >0.70	>0.70	0.69-0.50	0.49-0.00

TABLE 1

FIG. 9

VASCULAR FLOW DIAGNOSTIC SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority and benefit as a National Stage application under 35 U.S.C. 371 to international application serial no. PCT/US17/2953700, filed on Oct. 1, 2018, titled “VASCULAR FLOW DIAGNOSTIC SYSTEM”, which claims priority to U.S. application Ser. No. 62/566,760, filed on Oct. 2, 2017, each of which is incorporated by reference herein in their entirety.

BACKGROUND

[0002] Peripheral arterial disease (PAD) is a serious problem, affects at least 12 million people in the US. PAD is found most commonly in people over age 50 with a history of smoking, diabetes, high blood pressure or heart disease. PAD occurs when arteries in the legs become narrowed or blocked (occluded) by plaque build-up, reducing blood flow to the limbs. PAD can lead to interventions including amputation if left untreated.

[0003] With technological advances in vascular interventions and tools (wires and catheters and devices), advances in ultrasound detail, and the exponential rise in critical limb ischemia (CLI) the treatment of amputation prevention is being spotlighted across the country. The current practice to track if a patient has critical limb ischemia is perform (blood pressures) ankle-brachial indices (diagnostic technique 100 of FIG. 1 and diagnostic technique 200 of FIG. 2) and toe-brachial indices (diagnostic technique 300 of FIG. 3).

[0004] In a typical ABI approach (FIG. 1), the ABI value is determined by taking the higher pressure of the two arteries at the ankle, divided by the brachial arterial systolic pressure. In

[0005] 0.79-0.89—Mild Arterial Disease

[0006] 0.50-0.78—Moderate Arterial Disease

[0007] 0.49 or less—Severe Arterial Disease-Critical limb ischemia

[0008] In a typical TBI approach (FIG. 2), the TBI value is determined by taking the pressure of the great toe, divided by the brachial arterial systolic pressure. Ranges are then consulted to determine a diagnosis, for example:

[0009] Normal-0.70 or greater

[0010] Abnormal-0.70 or less

[0011] These methods are widely known for not producing reliable diagnoses, especially in the case of diabetes where the measurements are very often erroneous.

Description

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0012] To easily identify the discussion of any particular element or act, the most significant digit or digits in a reference number refer to the figure number in which that element is first introduced.

[0013] FIG. 1 illustrates a conventional diagnostic technique 100 for ankle brachial index (ABI) measurement.

[0014] FIG. 2 illustrates a diagnostic technique 200 in accordance with one embodiment.

[0015] FIG. 3 illustrates a diagnostic technique 300 for toe brachial index (TBI).

[0016] FIG. 4 illustrates an example of the pedal arch 400.

[0017] FIG. 5 illustrates blood vessels in the human foot 500 in accordance with one embodiment.

[0018] FIG. 6 illustrates blood flow acceleration measurement system 600 in accordance with one embodiment.

[0019] FIG. 7 illustrates a diagnostic system 700 a planar acceleration measurement and diagnostic system in accordance with one embodiment.

[0020] FIG. 8 is an example block diagram of a diagnostic system 800 that may incorporate embodiments of the present invention.

[0021] FIG. 9 illustrates a Table 900 in accordance with one embodiment.

DETAILED DESCRIPTION

[0022] The pedal arch 400 in the foot (FIG. 4) provides an alternative diagnostic area for PAD, and an alternative approach to conventional ABI and TBI approaches that measure blood pressures. Disclosed herein are devices and procedures to utilize correlation between blood flow acceleration time in the pedal/plantar arteries and pathologies involving occluded blood vessels. Such techniques may be employed, for example, to demonstrate if enough blood flow is getting to the foot to heal a wound to prevent amputation.

[0023] Vascular specialists currently do not utilize reliable tools to accurately measure the amount of blood flow the foot. When a patient is in the operating room, there is no clear way for a physician to conclusively determine that enough blood flow is restored to the foot.

[0024] Referring to FIG. 5, the blood vessels in the human foot 500 include a posterior tibial artery 502, an anterior tibial artery 504, a peroneal artery 506, a lateral tarsal artery 508, a *dorsalis pedis* artery 510, an arcuate artery 512, a deep plantar artery 514, a lateral plantar artery 516, and a medial plantar artery 518.

[0025] FIG. 6 illustrates blood flow acceleration measurement system 600 in accordance with one embodiment. The sensors 604 measures a time interval between a diastolic pressure (t1) and a systolic pressure (t2), or vice versa. An acceleration time for blood in the measured blood vessel may be computed from the difference of t2-t1 (or vice versa).

[0026] For an un-occluded blood vessel 608, the interval t2-t1 will typically be less than 100 milliseconds. For an occluded blood vessel 606 including an occlusion 602, the interval t2-t1 will typically exceed 225 milliseconds. See Table 900 in FIG. 9.

[0027] The sensors 604 may be utilized to measure the plantar acceleration time in the operating room, so that vascular specialists have reliable data to see real time physiologic feedback in the amount of blood flow the distal end point, the foot.

[0028] Slow acceleration time predicts low arterial blood supply areas for wound healing. Options for one or more sensors 604 to measure the acceleration time include continuous wave doppler and infra-red sensors. Photoplethysmography (PPG) is a simple and low-cost optical technique for the sensors 604 that can be used to detect blood volume changes in the microvascular bed of tissue. It may be deployed non-invasively to make measurements at the skin surface. Duplex ultrasound imaging is another sensor technology that may be utilized.

[0029] In the diagnostic system 700 embodiment of FIG. 7, the sensors 604 is disposed in a foot pad that adheres to the bottom of the foot (pedal arch deployment 704), specifically the pedal arch. The sensor is coupled with or

includes an RF transmitter **706** (Bluetooth, WiFi, or other) connection to an RF receiver **714** of a display system **708** that displays real time waveforms and measures acceleration time pre, during, and post-surgical procedure. The display system **708** may communicate with a diagnostic system **710** that includes a diagnostic classifier such as exemplified by Table **900** in FIG. **9**.

[0030] The sensors **604** may include an array of transducers (as illustrated) strategically positioned to measure acceleration in a network of blood vessels. A collection of readings may be made at each point in time from the sensor array, and collectively analyzed to identify pathologies in blood flow. The array of sensors may be positioned to align with key blood vessels for example, the illustrated blood vessels in the human foot **500** of FIG. **5**.

[0031] In some embodiments, the sensors **604** may be arranged to align with the arteries of the deep palmar arch. This arch is a series of arteries formed at the junction of the ulnar and radial arteries in the palm of the hand. This semicircular artery branches into the fingers, where its divisions are known as palmar digital branches.

[0032] In another embodiment, the sensors **604** may be disposed in a pad placed on the technician's hand or as part of a glove (hand deployment **702**) and engaged with the pedal arch by pressing the hand on the pedal arch, or engaged with the deep palmar arch by holding the patient's hand.

[0033] In yet another embodiment, the sensors **604** may be located in a non-weightbearing planar surface **712** upon which the patient can rest a foot or a hand.

[0034] FIG. **8** is an example block diagram of a diagnostic system **800**, such as display system **708** or diagnostic system **710**, that may incorporate embodiments of the present invention. FIG. **8** is merely illustrative of a machine system to carry out aspects of the technical processes described herein, and does not limit the scope of the claims. One of ordinary skill in the art would recognize other variations, modifications, and alternatives. In one embodiment, the diagnostic system **800** typically includes a monitor or graphical user interface **802**, a data processing system **820**, a communication network interface **812**, input device(s) **808**, output device(s) **806**, and the like.

[0035] As depicted in FIG. **8**, the data processing system **820** may include one or more processor(s) **804** that communicate with a number of peripheral devices via a bus subsystem **818**. These peripheral devices may include input device(s) **808**, output device(s) **806**, communication network interface **812**, and a storage subsystem, such as a volatile memory **810** and a nonvolatile memory **814**.

[0036] The volatile memory **810** and/or the nonvolatile memory **814** may store computer-executable instructions and thus forming logic **822** that when applied to and executed by the processor(s) **804** implement embodiments of the processes disclosed herein, such as measurement of blood flow acceleration in the pedal arch, and classifying an associated pathology.

[0037] The input device(s) **808** include devices and mechanisms for inputting information to the data processing system **820**. These may include a keyboard, a keypad, a touch screen incorporated into the monitor or graphical user interface **802**, audio input devices such as voice recognition systems, microphones, and other types of input devices. In various embodiments, the input device(s) **808** may be embodied as a computer mouse, a trackball, a track pad, a

joystick, wireless remote, drawing tablet, voice command system, eye tracking system, and the like. The input device(s) **808** typically allow a user to select objects, icons, control areas, text and the like that appear on the monitor or graphical user interface **802** via a command such as a click of a button or the like.

[0038] The output device(s) **806** include devices and mechanisms for outputting information from the data processing system **820**. These may include speakers, printers, infrared LEDs, and so on as well understood in the art.

[0039] The communication network interface **812** provides an interface to communication networks (e.g., communication network **816**) and devices external to the data processing system **820**. The communication network interface **812** may serve as an interface for receiving data from and transmitting data to other systems. Embodiments of the communication network interface **812** may include an Ethernet interface, a modem (telephone, satellite, cable, ISDN), (asynchronous) digital subscriber line (DSL), FireWire, USB, a wireless communication interface such as Bluetooth or Wi-Fi, a near field communication wireless interface, a cellular interface, and the like.

[0040] The communication network interface **812** may be coupled to the communication network **816** via an antenna, a cable, or the like. In some embodiments, the communication network interface **812** may be physically integrated on a circuit board of the data processing system **820**, or in some cases may be implemented in software or firmware, such as "soft modems", or the like.

[0041] The diagnostic system **800** may include logic that enables communications over a network using protocols such as HTTP, TCP/IP, RTP/RTSP, IPX, UDP and the like.

[0042] The volatile memory **810** and the nonvolatile memory **814** are examples of tangible media configured to store computer readable data and instructions to implement various embodiments of the processes described herein. Other types of tangible media include removable memory (e.g., pluggable USB memory devices, mobile device SIM cards), optical storage media such as CD-ROMS, DVDs, semiconductor memories such as flash memories, non-transitory read-only-memories (ROMS), battery-backed volatile memories, networked storage devices, and the like. The volatile memory **810** and the nonvolatile memory **814** may be configured to store the basic programming and data constructs that provide the functionality of the disclosed processes and other embodiments thereof that fall within the scope of the present invention.

[0043] Logic **822** that implements embodiments of the present invention may be stored in the volatile memory **810** and/or the nonvolatile memory **814**. Said software may be read from the volatile memory **810** and/or nonvolatile memory **814** and executed by the processor(s) **804**. The volatile memory **810** and the nonvolatile memory **814** may also provide a repository for storing data used by the software.

[0044] The volatile memory **810** and the nonvolatile memory **814** may include a number of memories including a main random-access memory (RAM) for storage of instructions and data during program execution and a read only memory (ROM) in which read-only non-transitory instructions are stored. The volatile memory **810** and the nonvolatile memory **814** may include a file storage subsystem providing persistent (non-volatile) storage for program

and data files. The volatile memory **810** and the nonvolatile memory **814** may include removable storage systems, such as removable flash memory.

[0045] The bus subsystem **818** provides a mechanism for enabling the various components and subsystems of data processing system **820** communicate with each other as intended. Although the communication network interface **812** is depicted schematically as a single bus, some embodiments of the bus subsystem **818** may utilize multiple distinct busses.

[0046] It will be readily apparent to one of ordinary skill in the art that the diagnostic system **800** may be a mobile device such as a smartphone, a desktop computer, a laptop computer, a rack-mounted computer system, a computer server, or a tablet computer device. As commonly known in the art, the diagnostic system **800** may be implemented as a collection of multiple networked computing devices. Further, the diagnostic system **800** will typically include operating system logic (not illustrated) the types and nature of which are well known in the art.

[0047] “Circuitry” in this context refers to electrical circuitry having at least one discrete electrical circuit, electrical circuitry having at least one integrated circuit, electrical circuitry having at least one application specific integrated circuit, circuitry forming a general purpose computing device configured by a computer program (e.g., a general purpose computer configured by a computer program which at least partially carries out processes or devices described herein, or a microprocessor configured by a computer program which at least partially carries out processes or devices described herein), circuitry forming a memory device (e.g., forms of random access memory), or circuitry forming a communications device (e.g., a modem, communications switch, or optical-electrical equipment).

[0048] “Firmware” in this context refers to software logic embodied as processor-executable instructions stored in read-only memories or media.

[0049] “Hardware” in this context refers to logic embodied as analog or digital circuitry.

[0050] “Logic” in this context refers to machine memory circuits, non-transitory machine readable media, and/or circuitry which by way of its material and/or material-energy configuration comprises control and/or procedural signals, and/or settings and values (such as resistance, impedance, capacitance, inductance, current/voltage ratings, etc.), that may be applied to influence the operation of a device. Magnetic media, electronic circuits, electrical and optical memory (both volatile and nonvolatile), and firmware are examples of logic. Logic specifically excludes pure signals or software per se (however does not exclude machine memories comprising software and thereby forming configurations of matter).

[0051] “Programmable device” in this context refers to an integrated circuit designed to be configured and/or reconfigured after manufacturing. The term “programmable processor” is another name for a programmable device herein. Programmable devices may include programmable processors, such as field programmable gate arrays (FPGAs), configurable hardware logic (CHL), and/or any other type programmable devices. Configuration of the programmable device is generally specified using a computer code or data such as a hardware description language (HDL), such as for example Verilog, VHDL, or the like. A programmable device may include an array of programmable logic blocks

and a hierarchy of reconfigurable interconnects that allow the programmable logic blocks to be coupled to each other according to the descriptions in the HDL code. Each of the programmable logic blocks may be configured to perform complex combinational functions, or merely simple logic gates, such as AND, and XOR logic blocks. In most FPGAs, logic blocks also include memory elements, which may be simple latches, flip-flops, hereinafter also referred to as “flops,” or more complex blocks of memory. Depending on the length of the interconnections between different logic blocks, signals may arrive at input terminals of the logic blocks at different times.

[0052] “Software” in this context refers to logic implemented as processor-executable instructions in a machine memory (e.g. read/write volatile or nonvolatile memory or media).

[0053] Herein, references to “one embodiment” or “an embodiment” do not necessarily refer to the same embodiment, although they may. Unless the context clearly requires otherwise, throughout the description and the claims, the words “comprise,” “comprising,” and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of “including, but not limited to.” Words using the singular or plural number also include the plural or singular number respectively, unless expressly limited to a single one or multiple ones. Additionally, the words “herein,” “above,” “below” and words of similar import, when used in this application, refer to this application as a whole and not to any particular portions of this application. When the claims use the word “or” in reference to a list of two or more items, that word covers all of the following interpretations of the word: any of the items in the list, all of the items in the list and any combination of the items in the list, unless expressly limited to one or the other. Any terms not expressly defined herein have their conventional meaning as commonly understood by those having skill in the relevant art(s).

[0054] Various logic functional operations described herein may be implemented in logic that is referred to using a noun or noun phrase reflecting said operation or function. For example, an association operation may be carried out by an “associator” or “correlator”. Likewise, switching may be carried out by a “switch”, selection by a “selector”, and so on.

[0055] Those skilled in the art will recognize that it is common within the art to describe devices or processes in the fashion set forth herein, and thereafter use standard engineering practices to integrate such described devices or processes into larger systems. At least a portion of the devices or processes described herein can be integrated into a network processing system via a reasonable amount of experimentation. Various embodiments are described herein and presented by way of example and not limitation.

[0056] Those having skill in the art will appreciate that there are various logic implementations by which processes and/or systems described herein can be effected (e.g., hardware, software, or firmware), and that the preferred vehicle will vary with the context in which the processes are deployed. If an implementer determines that speed and accuracy are paramount, the implementer may opt for a hardware or firmware implementation; alternatively, if flexibility is paramount, the implementer may opt for a solely software implementation; or, yet again alternatively, the implementer may opt for some combination of hardware,

software, or firmware. Hence, there are numerous possible implementations by which the processes described herein may be effected, none of which is inherently superior to the other in that any vehicle to be utilized is a choice dependent upon the context in which the implementation will be deployed and the specific concerns (e.g., speed, flexibility, or predictability) of the implementer, any of which may vary. Those skilled in the art will recognize that optical aspects of implementations may involve optically-oriented hardware, software, and or firmware.

[0057] Those skilled in the art will appreciate that logic may be distributed throughout one or more devices, and/or may be comprised of combinations memory, media, processing circuits and controllers, other circuits, and so on. Therefore, in the interest of clarity and correctness logic may not always be distinctly illustrated in drawings of devices and systems, although it is inherently present therein. The techniques and procedures described herein may be implemented via logic distributed in one or more computing devices. The particular distribution and choice of logic will vary according to implementation.

1. A method comprising:

contacting one or more Doppler ultrasound blood flow sensors with a pedal arch;

aligning the one or more Doppler ultrasound blood flow sensors with one or more respective blood vessels of the pedal arch such that each Doppler ultrasound blood flow sensor is aligned with a respective blood vessel of the pedal arch selected from a group consisting of a posterior tibial artery, an anterior tibial artery, a peroneal artery, a lateral tarsal artery, a *dorsalis* pedis artery, an arcuate artery, a deep plantar artery, a lateral plantar artery, and a medial plantar artery;

processing Doppler signals received from the one or more Doppler ultrasound blood flow sensors to determine a blood flow acceleration time respectively associated with each Doppler ultrasound blood flow sensor; and for each blood vessel, processing the respective blood flow acceleration time to assess occlusion, such that:

on condition the blood flow acceleration time is less than 100 milliseconds, identifying the blood vessel as being un-occluded; and

on condition the blood flow acceleration time is greater than 225 milliseconds, identifying the blood vessel as being occluded;

such that the determination of potential occlusion or un-occlusion is made based on the blood flow acceleration time in the absence of other measures;

identifying at least one blood vessel as being occluded by an occlusion; and

performing an intravascular intervention to treat the occlusion.

2. The method according to claim 1 wherein the sensor mount includes a pad, wherein the pad is placed on a technician's hand and engaged with the pedal arch during measurement.

3. The method according to claim 1 wherein the sensor mount includes a glove, wherein the glove is worn on a technician's hand and engaged with the pedal arch during measurement.

4. The method according to claim 1 wherein the sensor mount comprises a non-weightbearing planar surface, and wherein a foot of the patient is rested on the non-weightbearing planar surface during measurement.

5. The method according to claim 1 further comprising, for each blood vessel, processing the respective blood flow acceleration time to assess claudication, such that:

on condition the blood flow acceleration time is greater than 120 milliseconds and less than or equal to 180 milliseconds, identifying the blood vessel as being associated with mild claudication; and

on condition the blood flow acceleration time is greater than 180 milliseconds and less than or equal to 224 milliseconds, identifying the blood vessel as being associated with severe claudication.

* * * * *