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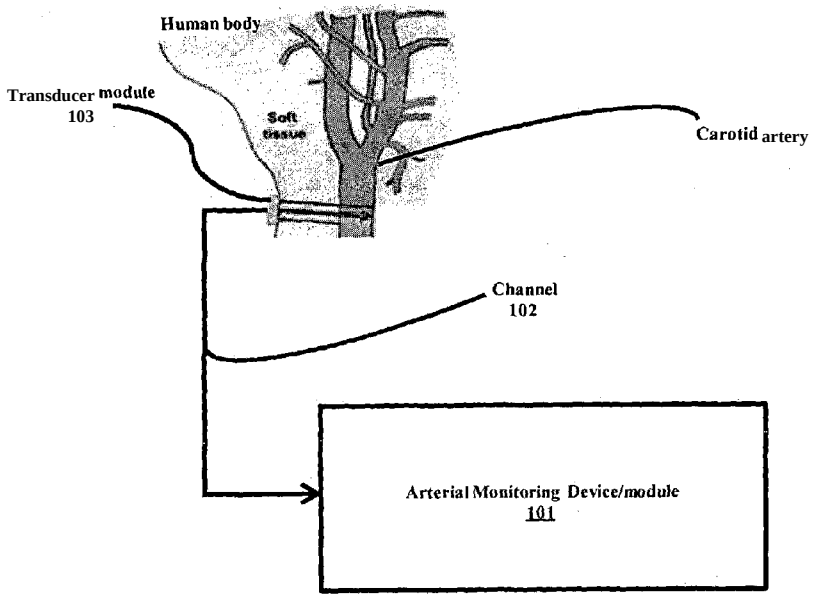
(54) Title: AUTOMATED EVALUATION OF ARTERIAL STIFFNESS FOR A NON-INVASIVE SCREENING



(57) Abstract: This invention relates to medical monitoring and analysis, and more particularly to automated evaluation of arterial stiffness for non-invasive cardiovascular screening. The system tracks and measures motion of carotid artery in the human body using ultrasound based mechanism. Once position of the carotid artery is detected, a wall motion correlation check mechanism is used to measure motion of the artery wall echoes from one frame to another and to ensure that the artery wall motion only is continuously tracked and measured for cardiovascular screening. Further, using values of certain parameters measured during the ultrasound tracking, arterial compliance is measured. Further, from the arterial compliance parameter, arterial stiffness and other associated heart diseases are identified.

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AUTOMATED EVALUATION OF ARTERIAL STIFFNESS FOR A NON-INVASIVE SCREENING

FIELD OF INVENTION

[001] This invention relates to medical monitoring and analysis, and more particularly to automated evaluation of arterial stiffness for non-invasive cardiovascular screening.

BACKGROUND OF INVENTION

[002] Cardio vascular screening is the process of evaluating people for evaluating different forms of heart disease and stroke.. The type and intensity of testing may vary from people to people based various parameters such as age, health conditions and so on.

[003] During cardio vascular screening, the system used for performing the cardio vascular screening monitors and measures certain health parameters that may be further analyzed to identify if the user is suffering from any type of heart disease or not.

[004] One major factor/health parameter that can be analyzed to identify occurrence of any type of heart disease is arterial stiffness. Arterial stiffness occurs when elastic fibers on the wall of the artery frays due to mechanical stress. Increased arterial stiffness may increase risk of cardiovascular events. Occurrence of arterial stiffness may be identified by measuring arterial compliance.

[005] Arterial compliance refers to the action in which an artery yields to pressure without disruption and hence, is a measure of elasticity of large arteries present in the human body. Arterial compliance decreases with increase in age and systolic blood pressured (SBP).

[006] Existing systems for cardiovascular screening measure arterial compliance using an ultrasound imager. The ultrasound imager obtains an ultrasound image of the artery. By properly positioning an ultrasound probe, a sequence of images of the artery can be

recorded. Further, the recorded images are analyzed to track arterial wall motions and to measure arterial distension (AD) and end-diastolic diameter (Dd).

[007] One disadvantage of the existing systems is that the user may have to provide inputs manually to the system. As a result, a real time measurement is not possible or else the user may not be able to indulge in other works, while the cardiovascular measurement is taking place. Another disadvantage of the existing systems is that once the ultrasound images of the artery are obtained, then a trained medical practitioner such as a sonologist is required to identify artery walls and to analyze the images to detect occurrence of any type of heart disease. The sonologist may have to be paid for his/her service, making the existing systems too costly for public to use. Further, in the existing systems, the user may have to use a separate dedicated system to measure ECG (Electro Cardio Graph) waveforms to identify cardiac cycles. This may further increase operational complexity of the overall system.

OBJECT OF INVENTION

[008] The principal object of this invention is automated evaluation of arterial stiffness for non-invasive cardiovascular screening.

[009] Another object of the invention is providing a mechanism for detecting arterial walls using covariance and sliding window based estimation.

[0010] A further object of the invention is to provide a mechanism for tracking wall motions of the artery to ensure that the arterial monitoring device is continuously receiving echo signals only from the artery.

[001 1] Another object of the invention is to provide a device to assist the operator in positioning the transducer at the correct location and keeping the position stable for quick estimation of arterial stiffness.

[0012] Another object is to provide a mechanism to automatically position the transducer over the carotid artery.

STATEMENT OF INVENTION

[0013] Accordingly the invention provides a system for automated evaluation of arterial stiffness for non-invasive cardiovascular screening. The system measures an arterial compliance value of the user which in turn may indicate arterial stiffness level of the user. The system initially measures a distension value, an end-diastolic value and an arterial compliance value using the arterial monitoring module. Further, the arterial monitoring device calculates the arterial compliance value based on the measured distension value, end-diastolic value and the arterial compliance values.

[0014] There is also provided a method of automatically evaluating arterial stiffness value in a user for non-invasive cardiovascular screening. In order to evaluate the arterial stiffness value in the user, an arterial compliance value of the user is calculated, which may further indicate arterial stiffness level of the user. In order to calculate the arterial compliance value, initially parameters such as a distension value, an end-diastolic value and a carotid pulse pressure value are measured. Further, based on the measured distension value, end-diastolic value and the carotid pulse pressure values, the arterial compliance value is calculated.

[0015] These and other aspects of the embodiments herein will be better appreciated and understood when considered in conjunction with the following description and the accompanying drawings. It should be understood, however, that the following descriptions, while indicating preferred embodiments and numerous specific details thereof, are given by way of illustration and not of limitation. Many changes and modifications may be made

within the scope of the embodiments herein without departing from the spirit thereof, and the embodiments herein include all such modifications.

BRIEF DESCRIPTION OF FIGURES

[0016] This invention is illustrated in the accompanying drawings, through out which like reference letters indicate corresponding parts in the various figures. The embodiments herein will be better understood from the following description with reference to the drawings, in which:

[0017] FIGS. 1A and 1B depict a general block diagram of an arterial monitoring device connected to a user for performing arterial stiffness evaluation and example structure of the arterial monitoring device, as disclosed in the embodiments herein;

[0018] FIG. 2 depicts a block diagram which shows various components of the arterial monitoring device, as disclosed in the embodiments herein;

[0019] FIG. 3 depicts block diagram which shows various components of the I/O processing module, as disclosed in the embodiments herein;

[0020] FIG. 4 depicts block diagram which shows various components of the analysis- and measurement module, as disclosed in the embodiments herein;

[0021] FIG. 5 depicts a flow diagram which shows various steps involved in the process of measuring arterial compliance using arterial monitoring device, as disclosed in the embodiments herein; and

[0022] FIGS. 6A, 6B, 6C and 6D illustrate various example implementations of the arterial monitoring device and a measured arterial diameter waveform respectively, as disclosed in the embodiments herein.

DETAILED DESCRIPTION OF INVENTION

[0023] The embodiments herein and the various features and advantageous details thereof are explained more fully with reference to the non-limiting embodiments that are illustrated in the accompanying drawings and detailed in the following description. Descriptions of well-known components and processing techniques are omitted so as to not unnecessarily obscure the embodiments herein. The examples used herein are intended merely to facilitate an understanding of ways in which the embodiments herein may be practiced and to further enable those of skill in the art to practice the embodiments herein. Accordingly, the examples should not be construed as limiting the scope of the embodiments herein.

[0024] The embodiments herein disclose a method and system for automated evaluation of arterial stiffness for non-invasive cardiovascular screening by continuously tracking and measuring carotid arterial wall motion.

[0025] Referring now to the drawings, and more particularly to FIGS. 1 through 6, where similar reference characters denote corresponding features consistently throughout the figures, there are shown preferred embodiments.

[0026] FIGS. 1A and IB depict a general block diagram of an arterial monitoring device connected to a user for performing arterial stiffness evaluation and example structure of the arterial monitoring device respectively, as disclosed in the embodiments herein. The Fig.lA comprises shows the arterial monitoring device/module 101 connected to a transducer module 103 via a channel 102. The transducer module 103 is properly positioned so as to track walls of carotid artery to perform cardiovascular screening. In an embodiment the transducer module 103 may be able to track and monitor any artery to perform cardiovascular screening. In a preferred embodiment, the carotid artery is tracked and monitored for

performing cardiovascular screening due to common practice in medical field for better results.

[0027] The transducer module 103 receives voltage pulse signals from the arterial monitoring device 101 and converts the received voltage pulse signals to corresponding ultrasound pulse signals. Further, the ultrasound pulses travel to body of the user and get reflected from walls of the artery. The reflected ultrasound signals (echo pulses) may comprise echo signals reflected from a near wall of artery and from a far wall of the artery. Further, the echo pulses are received by the transducer module 103, which in turn converts the echo pulses to corresponding voltage pulses.

[0028] The voltage pulses are then transmitted to the arterial monitoring device 101 through the channel. In a preferred embodiment, the channel 102 may be a wired channel that is capable of carrying high amplitude, high frequency voltage pulses. The frequency of the voltage signals used may be 5MHz or more. In another embodiment, the channel 102 may be a wireless channel that is capable of carrying high amplitude, high frequency voltage pulses.

[0029] The arterial monitoring device 101 receives and amplifies the voltage pulses transmitted by the transducer nodule 103. Further, the amplified voltage pulses are digitized and are processed to compute arterial stiffness. In an embodiment, in addition to echo pulses from the artery walls, the echo pulses may also comprise echo pulses from other body parts. The arterial monitoring device 101 may distinguish echo signals from artery walls from echo signals from other body parts by analyzing the characteristic movement of the echo signals towards and away from each other.

[0030] In a preferred embodiment, the arterial monitoring device 101 uses a wall motion correlation check based mechanism to track wall motion of the artery, once position of the artery walls are identified. By monitoring and measuring wall motion of the artery, the arterial monitoring device 101 measures diameter (end-diastolic diameter) and distension of

the artery. Further, using a pressure monitoring and measurement module, the arterial monitoring device 101 measures carotid pulse pressure value. Further, by combining the measured variables, the arterial monitoring device 101 computes arterial stiffness.

[0031] In a preferred embodiment, suitable means may be provided for positioning of the transducer module 103 to track and measure artery wall movements. In various embodiments, the system may use fully automated, semi-automatic and/or manual means for positioning of the transducer module 103 to track and measure artery wall movements.

[0032] For example, the transducer module 103 may be mounted on a holder. The holder may also comprise a pressure sensor using which the arterial monitoring device 101 measures pressure applied by the transducer module 103 on the artery of the user. Further, the measured pressure value may be used by the arterial monitoring device 101 to standardize and to control the amount of pressure that is applied to alleviate interfering effect of jugular vein pulsation. The pressure sensor used may be a strain gage sensor, a piezoelectric sensor or any such suitable sensor that is capable of measuring the pressure value applied by the transducer module 103 on the user who is being monitored.

[0033] In an embodiment, the arterial monitoring device 101 may function as an arterial compliance device. When functioning as an arterial compliance device, the arterial monitoring device 101 obtains upstream and downstream blood flow waveforms at two locations on the artery. The waveforms may be further used to measure local Pulse Wave Velocity (PWV). The system may also be employed in measuring local pulse pressure. In an embodiment, dedicated sensors may be used for obtaining the blood flow waveforms. The sensor may be a magnetic sensor, an optical sensor or any such suitable sensor.

[0034] In various embodiments, the arterial monitoring device 101 may be a dedicated device or may be any suitable device such as a laptop, a mobile phone, a personal digital assistant (PDA) and so on which is provided with arterial monitoring functionality. An

example design is depicted in Fig. IB. Further, the arterial monitoring device 101 may be able to store tracked and measured information over a particular time span (a session) for future reference in an associated memory. The user may access previous information and compare with other session information to check health progress over time.

[0035] In another embodiment, the arterial monitoring device 101 may provide control mechanism for the user/ an operator to control various functionalities of the arterial monitoring device 101. For example, separate control options may be provided for the user to start/stop the transducer excitation and to start/stop the data sensing and recording using the arterial monitoring device 101. Further, the control mechanism may be in a suitable form such as a mechanical switch, a touch sensitive pad and so on.

[0036] FIG. 2 depicts a block diagram which shows various components of the arterial monitoring device, as disclosed in the embodiments herein. The arterial monitoring device 101 comprises an Input/Output (I/O) processing module 201, a controller module 202 and an analysis and measurement module 203.

[0037] The I/O processing module 201 is responsible for tracking carotid artery and measuring wall motions. The I/O processing module 201 excites the transducer module 103 by generating and transmitting the high amplitude, high frequency voltage pulses to the transducer module 103. Further, the I/O processing module 201 receives echo signals transmitted by the transducer module 103 and digitizes the signal for further processing. Further, the I/O processing module 201 transmits the digitized data to the analysis and measurement module 203 for further processing.

[0038] The analysis and measurement module 203 receives digitized signals as input from the I/O processing module 201. The input signal is initially analyzed by the analysis and measurement module 203 to detect artery walls. Once the artery walls are detected, the analysis and measurement module 203 uses a wall motion tracking mechanism to track

motion of the artery wall from one frame of data to next. In an embodiment, a frame of data may refer to data fetched over a set period of time by the transducer module 103. Further, by processing the received frames of data, the analysis and measurement module 203 measures diameter (end-diastolic diameter) and distension of the artery. The analysis and measurement module 203 further receives carotid pulse value from an associated pulse measurement device such as a sphygmomanometer. Further, by combining the measured variables, the analysis and measurement module 203 computes arterial stiffness.

[0039] The control module 202 may be used to control and cpordinate operations of the I/O processing module 201 and the analysis and measurement module 203. In a preferred embodiment, the control module 202 may generate and transmit control signals that are capable of controlling operations such as transducer excitation, synchronized data acquisition;, wall identification, wall motion tracking, end-diastolic diameter measurement, distension measurement and so on to facilitate imageless evaluation and measurement of arterial compliance.

[0040] FIG. 3 depicts block diagram which shows various components of the I/O processing module, as disclosed in the embodiments herein. The I/O processing module 201 comprises a transmitter module 301, a receiver module 302 and the transducer module 103.

[0041] The transmitter module 301 further comprises a pulse generation module 301.a and a pulse driver module 301 .b. The pulse generation module 301 .a may be used to generate pulses that can be used to excite the transducer module 103. The pulse generation module 301.a may provide means for controlling parameters such as frequency, amplitude and so on of the pulse being generated. In a preferred embodiment, the voltage pulse generated by the pulse generator module 301.a possesses high amplitude and high frequency.

[0042] Further, the voltage pulse is fed to the pulse driver module 301.b. The pulse driver module 301.b may be used to control/regulate amount of voltage pulse that is to be fed

to other parts of the system i.e. to the transducer module 103. The transducer 103 is capable of converting one form of energy to another form of energy and may be placed over the user body with an intension of detecting and tracking arterial wall motion. Upon receiving the voltage pulse from the transmitter module 301, the transducer module 103 converts the received voltage pulses to corresponding ultrasound pulses. In a preferred embodiment, the transducer module 103 may be optimized to generate narrow band ultrasound beam with very small half angle beam spread so as to ensure that measurement of arterial dimensions are performed always along dimensions of the artery. Further, the narrow half angle beam width may ensure that the transducer module 103 sensitive only to specular scatters located along the mid-axis line of the transducer, thereby ensuring that the echo peaks detected arise from specular, normal reflection at the arterial walls. This may further ensure that the measurements performed by the analysis and measurement module 203 always gives wall to wall distance measured along diameter of the artery.

[0043] Further the transducer module 103 receives echo signals from far and near walls of the artery. The transducer module 103 further converts the received ultrasound echo signals to voltage pulses and transmits the pulses to receiver module 302 in the I/O processing module 201.

[0044] The receiver module further comprises a protection circuitry 302.a, an analog signal processing module 302.b and a digitizer module **302.C.** The protection circuit 302.a may protect the receiver module circuit from excessive voltage. For example, the protection circuit receives voltage pulses transmitted by the transducer module 103 and may check if the received voltage pulses are capable of harming the receiver circuitry or not. If the received voltage pulses are found to be harmful to the receiver circuitry, the protection circuit 302.a may perform any specified action to protect the circuit.

[0045] Further, the protection circuit 302.a transmits the voltage pulses to the analog signal processing module 302.b. The analog signal processing module 302.b processes and converts the received voltage pulses to a set of continuous values. The analog values are then transmitted to the digitizer module **302.C,** where the digitizer 302.c converts the continuous signals are converted to discrete set of values. Further, output of the digitizer module 302.c i.e. the discrete set of values is fed to the analysis and measurement module 203.

[0046] FIG. 4 depicts block diagram which shows various components of the analysis and measurement module, as disclosed in the embodiments herein. The analysis and measurement module 203 further comprises a digital signal pre-processing module 401, an artery wall detection module 402, a wall motion tracking module 403, a distension measurement module 404, a pressure estimation module 405, an arterial compliance evaluation module 406, an end-diastolic diameter measurement module 407 and a waveform display module 408.

[0047] The digital signal pre-processing module 401 receives the digitized data frames from the I/O processing module 201 and pre-processes the data frames. During pre-processing of the digitized data, the pre-processing module 401 may remove noise present in the data using suitable method such as a sliding window covariance method. The noise is removed to clearly visualize echo peaks in the received data i.e. frames of signals. Further, a suitable motion estimation method such as sliding window based motion estimation is applied on the signals. The motion estimation method eliminates static echoes and outputs a motion profile signal having high amplitudes at positions corresponding to moving echoes.

[0048] The motion profile signal from output of the pre-processing module 401 is then fed to input of the artery wall detection module 402. The artery wall detection module 402 recalculates motion of each of the identified moving echoes with respect to each other. Further, the artery wall detection module 402 analyzes the recalculated data and identifies

artery wall locations as those corresponding to two successively located moving echoes which move out of phase to each other. Further, the artery wall detection module 402 verifies the identified wall locations by comparing their detected locations with expected range of values based on established clinical data on the depth and diameter of the artery.

[0049] Further, the identified artery wall location is passed to the wall motion tracking module 403. In a preferred embodiment, a correlation based tracking method is used by the wall motion tracking module 403 to track motion of the artery wall echoes from one frame to another. In this method, estimated frame to frame shifts are cumulatively combined to obtain the wall motion waveform. In a preferred embodiment, in order to ensure that the wall motion tracking module 403 always tracks the arterial walls, the two individual wall motion waveforms are continuously verified for significantly high negative correlation. If the wall motion tracking module 403 finds that the correlation coefficient of the two wall motion waveforms are positive, then the wall motion tracking module 403 re-initiates the wall identification process.

[0050] Further, the wall motion waveform is fetched by the distension measurement module 404. The distension measurement module 404 analyzes the received wall motion waveform and calculates difference between the far wall motion and near wall motion waveform. This distance gives the arterial distension waveform (AD) over the time period corresponding to the data frame being analyzed.

[0051] Further, the wall motion waveform is fetched and analyzed by the end-diastolic diameter measurement module 407. The end-diastolic diameter measurement module 407 analyses multiple cycles of distension using a method based on expected signal morphology to identify the valleys and the time corresponding to the diastole. The original echo signal acquired at these time-instants corresponding to the end-diastole is then separated out from the data-frame buffer and is analyzed. The end-diastolic diameter measurement

module 407passes the data frames through a set of filters and nonlinear gain functions so as to detect envelope of the waveform. The end-diastolic diameter measurement module 407 then starts from the lumen of the artery, and works outwards and identifies the walls as the region corresponding to the first sudden rise in the slope of the envelope. Further, the end-diastolic diameter measurement module 407 measures the lumen diameter/end-diastolic diameter (Dd).

[0052] Further, the pressure estimation module 405 measures carotid pressure using an associated pressure measurement device. In an embodiment, the carotid pressure value may be automatically measured by the pressure measurement device. In another embodiment, the pressure estimation module 405 may estimate carotid pressure value from manually input branchial pressure values.

[0053] Further, the end-diastolic diameter value, distension value and the estimated pressure values are fed to the arterial compliance evaluation module 406. The arterial compliance evaluation module 406 measures the arterial compliance and arterial stiffness values using the received end-diastolic diameter, distension and the estimated pressure values. In an embodiment, the arterial compliance evaluation module 406 may measure parameters such as distensibility, elastic modulus, stiffness index and so on that indicate arterial stiffness using suitable equations. For example, equations given below may be used for measuring the parameters that indicate arterial stiffness.

$$\text{Distensibility} = \frac{AD}{Dd * AP} \quad \text{— (1)}$$

$$\text{Elastic modulus (E)} = \frac{Dd * AP}{AD} \quad \text{— (2)}$$

$$\text{Stiffness index } (\beta) = \frac{\ln(\frac{Ps}{Pd})}{(\frac{\Delta D}{Dd})} \quad \text{---- (3)}$$

[0054] Further, the measured parameters may be analyzed by the arterial compliance evaluation module 406 to detect occurrence of arterial compliance in the user.

[0055] The pre-processed signal from output of the digital signal pre-processor module 401, artery wall position detected by the artery wall detection module 402, distension waveform from the distension measurement module 404, end diastolic diameter in the wall motion waveform, output of the arterial compliance waveform module 406 and so on may be displayed to the users using the waveform display module 408.

[0056] FIG. 5 depicts a flow diagram which shows various steps involved in the process of measuring arterial compliance using arterial monitoring device, as disclosed in the embodiments herein. Once properly positioned or is attached to the user, the transducer module 103 receives voltage pulse signals from the arterial monitoring device 101/ and converts the received voltage pulse signals to corresponding ultrasound pulse signals. Further, the ultrasound pulses travel to body of the user and get reflected from walls of the artery. The reflected ultrasound signals (echo pulses) may comprise echo signals reflected from a near wall of artery and from a far wall of the artery. Further, the echo pulses are received by the transducer module 103, which in turn converts the echo pulses to corresponding voltage pulses.

[0057] The voltage pulses are then split into frames of data, preprocessed and digitized. Motion profile signal, output of the pre-processing module 401 is then fed to the artery wall detection module 402 to detect (501) location of the artery walls. The motion profile signal from output of the pre-processing module 401 is then fed to input of the artery wall detection module 402. The artery wall detection module 402 recalculates motion of each of the identified moving echoes with respect to each other. Further, the artery wall detection module 402 analyzes the recalculated data and identifies artery wall locations as those corresponding to two successively located moving echoes which move out of phase to each

other. Further, the artery wall detection module 402 verifies the identified wall locations by comparing their detected locations with expected range of values based on established clinical data on the depth and diameter of the artery.

[0058] Further, motion of the artery wall echoes from one frame to another is tracked (502) using a suitable mechanism. In a preferred embodiment, a correlation based tracking method is used by the wall motion tracking module 403 to track motion of the artery wall echoes from one frame to another. In this method, estimated frame to frame shifts are cumulatively combined to obtain the wall motion waveform. In a preferred embodiment, in order to ensure that the wall motion tracking module 403 always tracks the arterial walls, the motion tracking module 403 continuously verifies two individual wall motion waveforms for significantly high negative correlation. The wall motion tracking module 403 re-initiates the wall identification process upon detecting that the correlation coefficient of the two wall motion waveforms are positive.

[0059] Further, distension value (AD) is measured (503) using the distension measurement module 404. Distension value may be defined as the difference between near wall motion and far wall motion when the artery is in stretched position. The distension measurement module 404 fetches and analyzes wall motion waveform and calculates difference between the far wall motion and near wall motion waveform. This distance gives the arterial distension waveform (AD) over the time period corresponding to the data frame being analyzed.

[0060] Further, the end-diastolic diameter value (D_d) is measured (504) using the end diastolic diameter measurement module 407. The end-diastolic diameter value may refer to diameter across a ventricle at the end of a diastole, where diastole is the time at which the heart is in expanded state and blood gets filled to the heart. The end-diastolic diameter measurement module 407 analyses multiple cycles of distension .using a method based on

expected signal morphology to identify the valleys and the time corresponding to the diastole. The original echo signal acquired at these time-instants corresponding to the end-diastole is then separated out from the data-frame buffer and is analyzed. The end-diastolic diameter measurement module 407 passes the data frames through a set of filters and nonlinear gain functions so as to detect envelope of the waveform. The end-diastolic diameter measurement module 407 then starts from the lumen of the artery, and works outwards and identifies the walls as the region corresponding to the first sudden rise in the slope of the envelope. Further, the end-diastolic diameter measurement module 407 measures the lumen diameter/end-diastolic diameter (Da).

[0061] Further, carotid pressure value (ΔP) is measured (505) using the pressure estimation module 405 using an associated pressure measurement device. In an embodiment, the carotid pressure value may be automatically measured by the pressure measurement device. In another embodiment, the pressure estimation module 405 may estimate carotid pressure value from manually input branchial pressure values.

[0062] Further, arterial compliance value is evaluated (506) using the arterial compliance evaluation module 406. In order to evaluate the arterial compliance value, parameters such as the end-diastolic diameter value, distension value and the estimated pressure value are fed to the arterial compliance evaluation module 406. The arterial compliance evaluation module 406 measures the arterial compliance and arterial stiffness values using the received end-diastolic diameter, distension and the estimated pressure values. In an embodiment, the arterial compliance evaluation module 406 may measure parameters such as distensibility, elastic modulus, stiffness index and so on that indicate arterial stiffness using suitable equations. Further, the measured parameters may be analyzed by the arterial compliance evaluation module 406 to detect occurrence of arterial compliance in the user.

[0063] The various actions in method 500 may be performed in the order presented, in a different order or simultaneously. Further, in some embodiments, some actions listed in FIG. 5 may be omitted.

[0064] FIGS. 6A, 6B, 6C and 6D illustrate various example implementations of the arterial monitoring device and an arterial diameter waveform, as disclosed in the embodiments herein. In an example, the transducer module 103 may be mounted at the tip of a flexible goose-neck stand 601 as shown in Fig. 6A. The base of the goose neck may be attached to a clamp 602, preferably of adjustable type which may be fixed to the cot, chair or even a support placed below the neck of the user while in supine position. The goose-neck allows the user or an operator to angulate the transducer module 103 to any direction, and once the walls are detected, the operator/user may leave the transducer module 103 in that particular position. The goose-neck stand allows the transducer to remain in position steadily.

[0065] In another example, the transducer module 103 may be mounted at the tip of a sparingly neck holder 603 as shown in Fig. 6B. A length adjustment facility is provided to adjust length of the neck holder probe for convenience of the user.

[0066] In another example, an automated positioning arm may be used which preferable is a 3-axis positioner system (a robotic arm) 605 as depicted in Fig. 6C. An operator or the user guides the arm to position the transducer module 103 on the neck of the user roughly near the carotid artery. A feedback control system connected to the arm as well as the arterial monitoring device 101 then control the motion of the arm 605, as well as the angulation of the transducer module 103 until a correct transducer position is achieved, as indicated by the wall-identification and tracking modules.

[0067] In another example, a Flexible mounting arrangement with automatic transducer angulation is used, which possesses an automatic control mechanism to adjust the angulation of the transducer module 103 mounted at the tip of the goose-neck. The control

system may communicate with the arterial monitoring device 101 and use control signal outputs from a wall identification module to adjust the angulation of the transducer until distinct wall echoes are visualized in the echo signal.

[0068] In another example, a shoulder clamp arrangement may be used for transducer positioning. The transducer module 103 may be mounted on edge of a C-shaped clamp, mounted against a vertical arm fixed on the arm-rest / back support of a chair. As the patient/user sitting on the chair lies back in a relaxed manner, the C-clamp may be used to lock the transducer in position. A ball-and-socket mount at the tip of the clamp gives flexibility that allows easy angulation of the transducer module 103.

[0069] The arterial diameter waveform as in Fig. 6D maps change in diameter (Y axis) of carotid artery with respect to time (X axis). The waveform may be further analyzed to measure values of specific parameters such as arterial distension (AD), end-diastolic diameter (D_d) and so on. The arterial distension (AD) and end-diastolic diameter (D_d) values may be further used to detect and measure arterial stiffness.

[0070] The embodiments disclosed herein can be implemented through at least one software program running on at least one hardware device and performing network management functions to control the network elements. The network elements shown in Fig. 2 include blocks which can be at least one of a hardware device, or a combination of hardware device and software module.

[0071] The embodiment disclosed herein describes a method and system for automated evaluation of arterial stiffness for non-invasive cardiovascular screening. Therefore, it is understood that the scope of the protection is extended to such a program and in addition to a computer readable means having a message therein, such computer readable storage means contain program code means for implementation of one or more steps of the method, when the program runs on a server or mobile device or any suitable programmable

device. The method is implemented in a preferred embodiment through or together with a software program written in e.g. Very high speed integrated circuit Hardware Description Language (VHDL) another programming language, or implemented by one or more VHDL or several software modules being executed on at least one hardware device. The hardware device can be any kind of portable device that can be programmed. The device may also include means which could be e.g. hardware means like e.g. an ASIC, or a combination of hardware and software means, e.g. an ASIC and an FPGA, or at least one microprocessor and at least one memory with software modules located therein. The method embodiments described herein could be implemented partly in hardware and partly in software. Alternatively, the invention may be implemented on different hardware devices, e.g. using a plurality of CPUs.

[0072] The foregoing description of the specific embodiments will so fully reveal the general nature of the embodiments herein that others can, by applying current knowledge, readily modify and/or adapt for various applications such specific embodiments without departing from the generic concept, and, therefore, such adaptations and modifications should and are intended to be comprehended within the meaning and range of equivalents of the disclosed embodiments. It is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation. Therefore, while the embodiments herein have been described in terms of preferred embodiments, those skilled in the art will recognize that the embodiments herein can be practiced with modification within the spirit and scope of the embodiments as described herein.

CLAIMS

We Claim;

1. A method for automated evaluation of arterial stiffness in a user, said method comprises:

measuring a distension value;
measuring an end-diastolic value;
measuring a carotid pulse pressure value; and
calculating an arterial compliance value, based on said distension value, said end-diastolic value and said carotid pulse pressure value.

2. The method as in claim 1, wherein said measuring of the distension value further comprises:

directing an ultrasound signal towards artery of said user;
receiving an echo signal corresponding to said directed ultrasound signal; and
analyzing said received echo signal.

3. The method as in claim 2, wherein said analyzing the received echo signal further comprises:

identifying walls of said artery from said received echo signal;
tracking motion of said walls from said received echo signal;
forming a distension waveform corresponding to said identified wall motion from said received echo signal; and
measuring distance between a far wall and a near wall of said artery in said waveform.

4. The method as in claim 1, wherein said measuring of the end-diastolic diameter further comprises:

directing an ultrasound signal towards artery of said user;
receiving an echo signal corresponding to said directed ultrasound signal; and
analyzing said received echo signal.

5. The method as in claim 4, wherein said analyzing of the received echo signal further comprises:

forming a waveform corresponding to said received echo signal;
identifying at least one of a valley and a time period corresponding to a diastole from said waveform;
identifying an envelope of said waveform; and
measuring an inner distance between two walls of said artery from said identified envelope.

6. The method as in claim 5, wherein said valley and said time period is identified by analyzing at least one of a distension cycle.

7. The method as in claim 6, wherein said analyzing of the distension cycle is using an expected signal morphology technique.

8. The method as in claim 1, wherein at least one of said distension value, end-diastolic diameter value, carotid pulse pressure value and arterial compliance value are displayed to said user.

9. A system for automated evaluation of arterial stiffness in a user, said system provided with atleast one means configured for:

measuring a distension value using an arterial monitoring module;
measuring an end-diastolic value using said arterial monitoring module;
measuring a carotid pulse pressure value using said arterial monitoring module; and
calculating an arterial compliance value based on said distension value, said end-diastolic value and said carotid pulse pressure value using said arterial monitoring module.

10. The system as in claim 9 is further configured for measuring said distension value by:

directing an ultrasound signal towards artery of said user using a transducer module;
receiving an echo signal corresponding to said directed ultrasound signal using said transducer module; and
analyzing said received echo signal using said arterial monitoring module.

11. The system as in claim 10 is further configured for performing said analysis of the received echo signal by:

identifying walls of said artery from said received echo signal;
tracking motion of said walls from said received echo signal;
forming a distension waveform corresponding to said identified wall motion from said received echo signal; and

12. The system as in claim 9 is further configured for measuring said end-diastolic diameter by:

directing an ultrasound signal towards artery of said user using a transducer module;
receiving an echo signal corresponding to said directed ultrasound signal using said transducer module; and
analyzing said received echo signal using said arterial monitoring module.

13. The system as in claim 12 is further configured for performing said analysis of the received echo signal by:

forming a waveform corresponding to said received echo signal using said arterial monitoring module;
identifying at least one of a valley and a time period corresponding to a diastole from said waveform using said arterial monitoring module;
identifying an envelope of said waveform using said arterial monitoring module; and
measuring an inner distance between two walls of said artery from said identified envelope using said arterial monitoring module.

14. The system as in claim 13 is further configured for identifying said valley and said time period by analyzing at least one of a distension cycle using said arterial monitoring module.

15. The system as in claim 14 is further configured for analyzing said distension cycle using an expected signal morphology technique.

16. The system as in claim 9 is further configured for displaying atleast one of said distension value, end-diastolic diameter value, carotid pulse pressure value and arterial compliance value to said user.

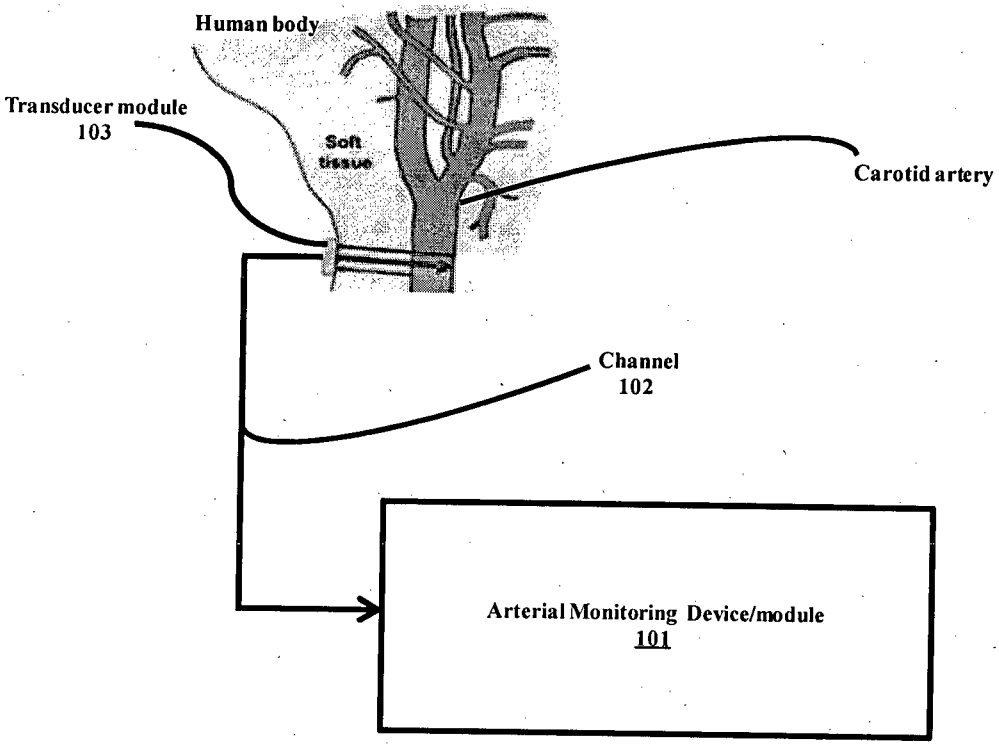
Human body
Transducer module
103
Soft
tissue
Carotid artery
Channel
102
Arterial Monitoring Device/module
101

Fig. 1A

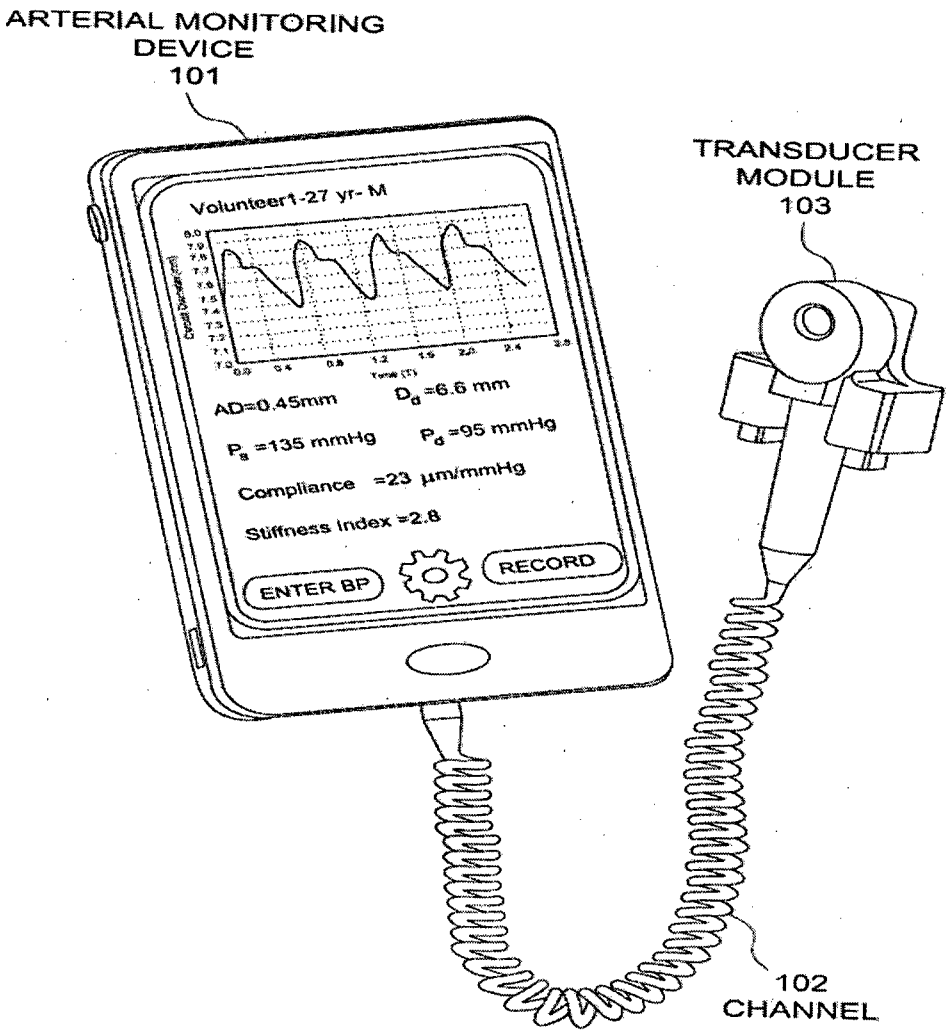
ARTERIAL MONITORING DEVICE
101
TRANSDUCER MODULE
103
Volunteer1-27 yr- M
AD=0.45mm
D_d =6.6 mm
P_s =135 mmHg
P_d =95 mmHg
Compliance =23 µm/mmHg
Stiffness Index =2.8
ENTER BP
RECORD
102
CHANNEL

Fig. 1B

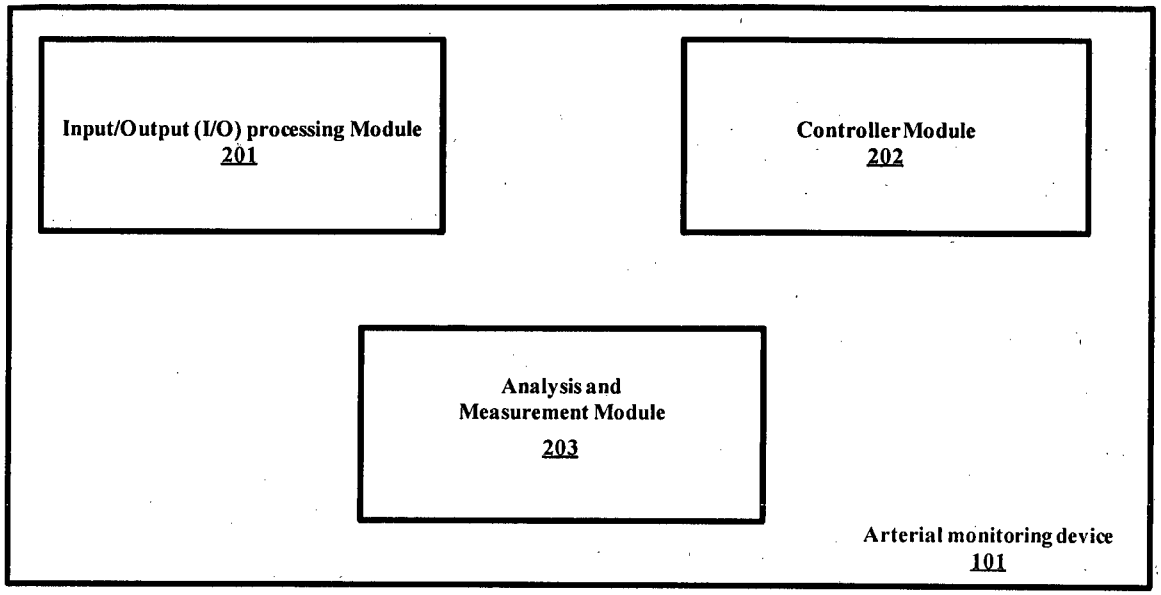
Input/Output (I/O) processing Module
201
Controller Module
202
Analysis and
Measurement Module
203
Arterial monitoring device
101

Fig. 2

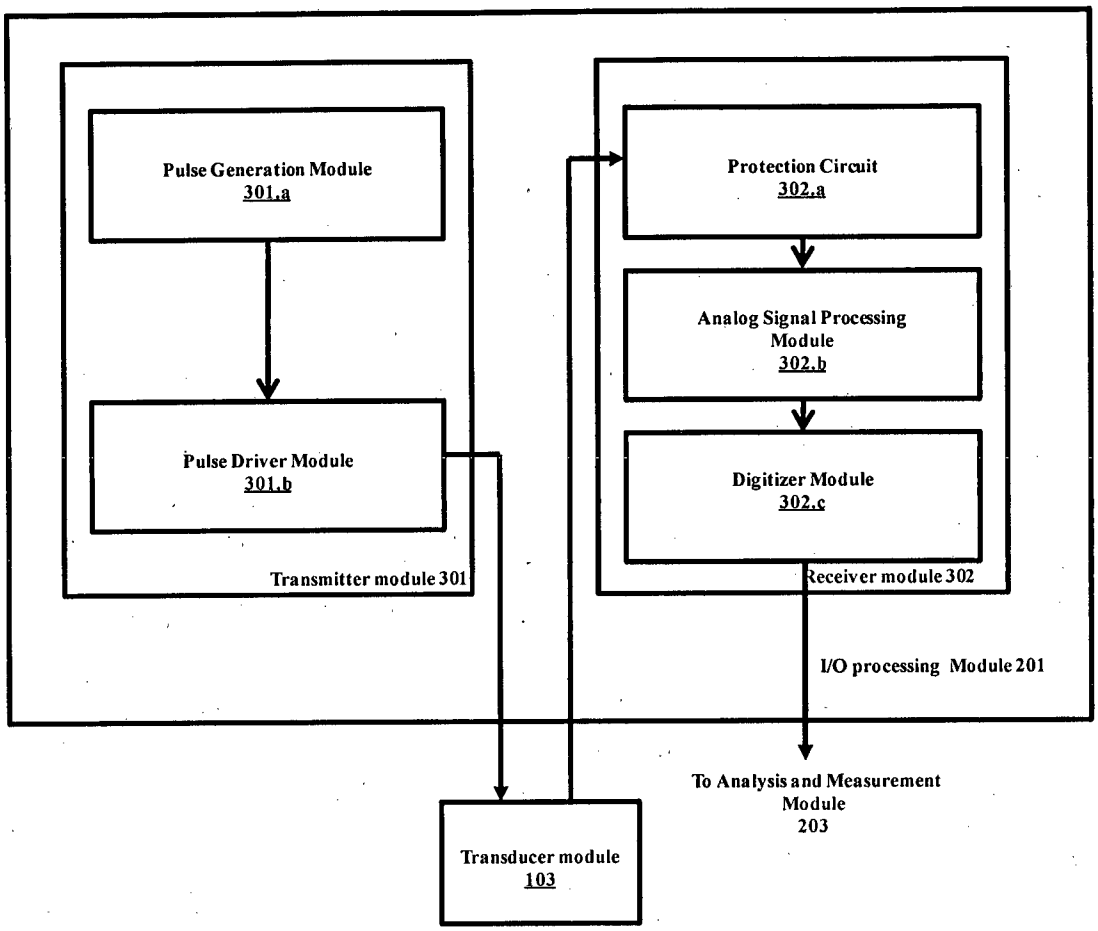
Pulse Generation Module
301.a
Pulse Driver Module
301.b
Transmitter module 301
Protection Circuit
302.a
Analog Signal Processing Module
302.b
Digitizer Module
302.c
Receiver module 302
I/O processing Module 201
To Analysis and Measurement Module
203
Transducer module
103

Fig. 3

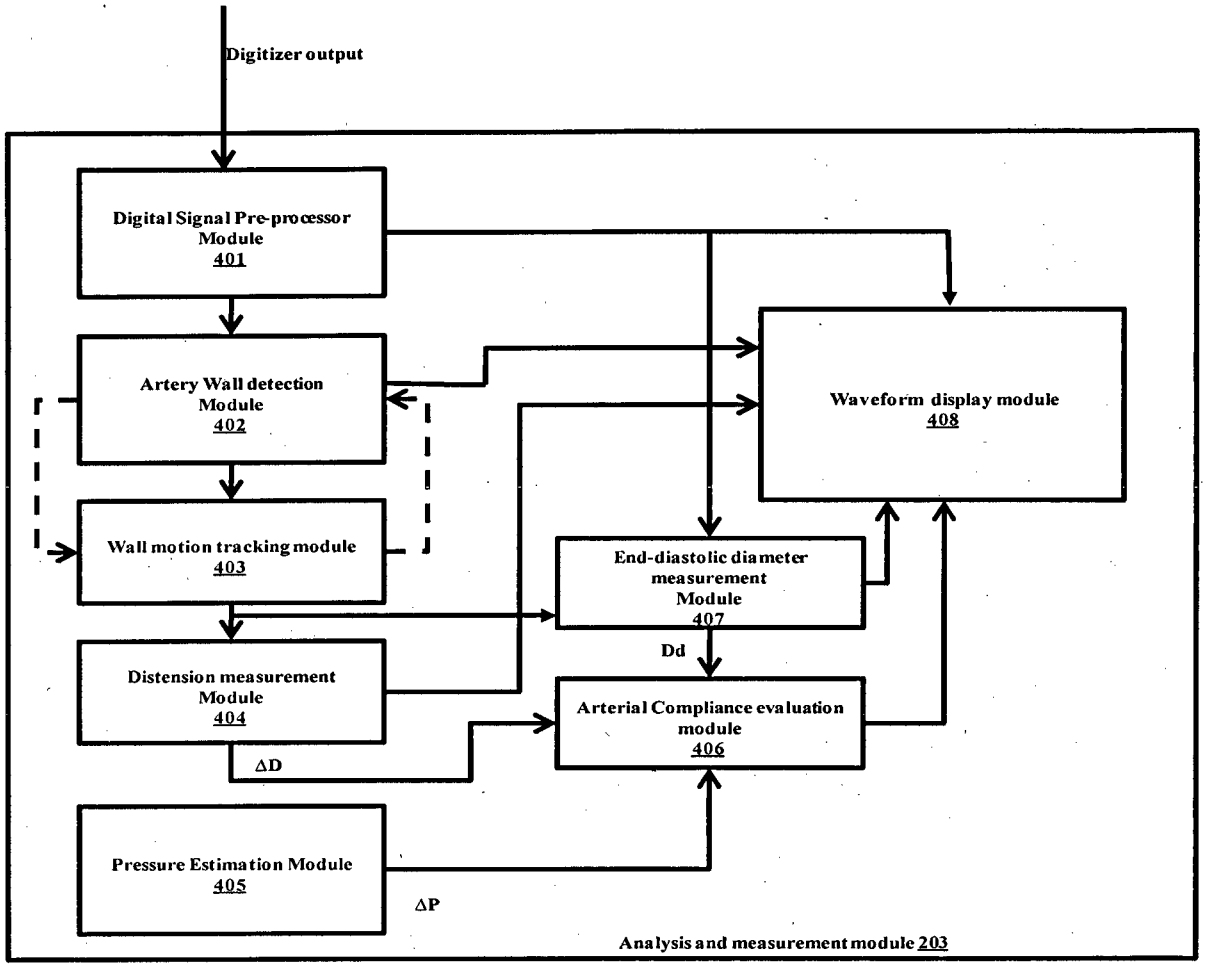
Digitizer output
Digital Signal Pre-processor Module 401
Artery Wall detection Module 402
Wall motion tracking module 403
Distension measurement Module 404
Pressure Estimation Module 405
Waveform display module 408
End-diastolic diameter measurement Module 407
Dd
Arterial Compliance evaluation module 406
ΔD
ΔP
Analysis and measurement module 203

FIG.4

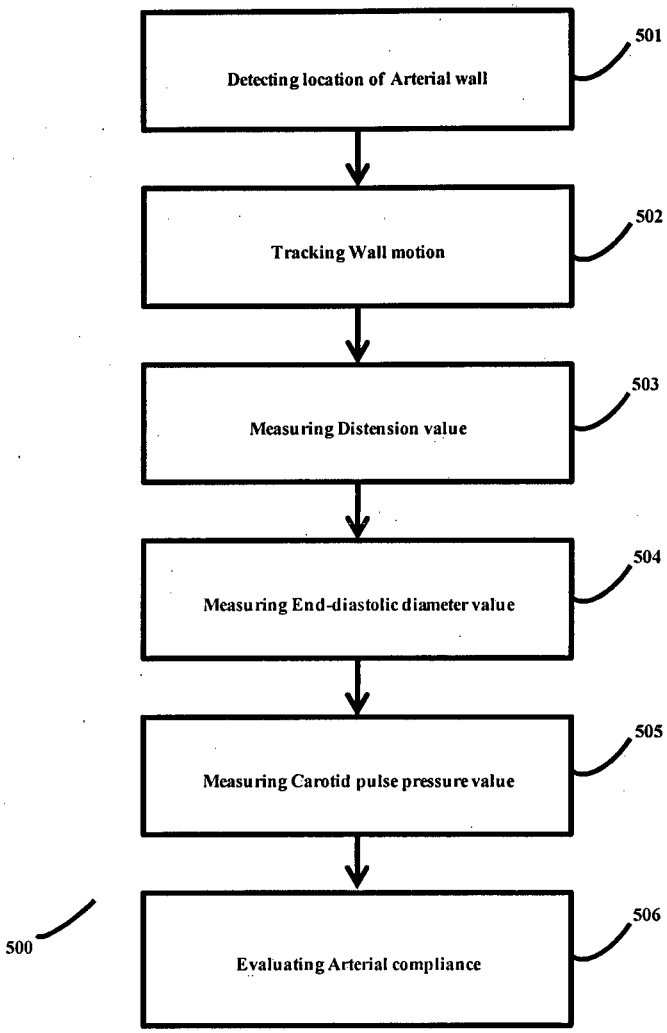
Detecting location of Arterial wall
501
Tracking Wall motion
502
Measuring Distension value
503
Measuring End-diastolic diameter value
504
Measuring Carotid pulse pressure value
505
Evaluating Arterial compliance
506
500

Fig. 5

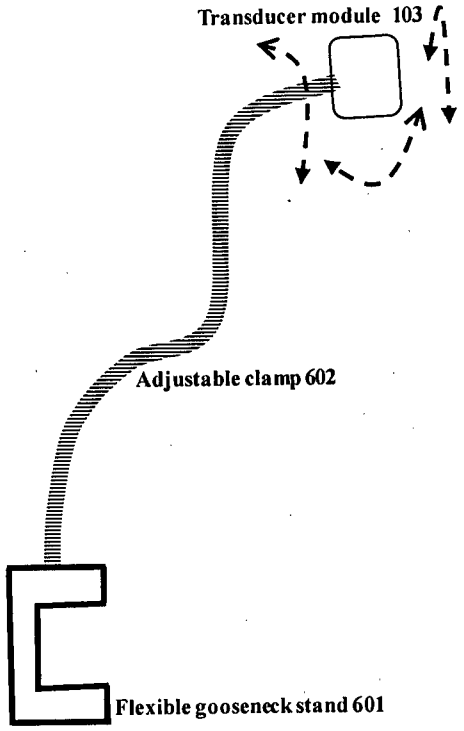
Transducer module 103
Adjustable clamp 602
Flexible gooseneck stand 601

Fig. 6A

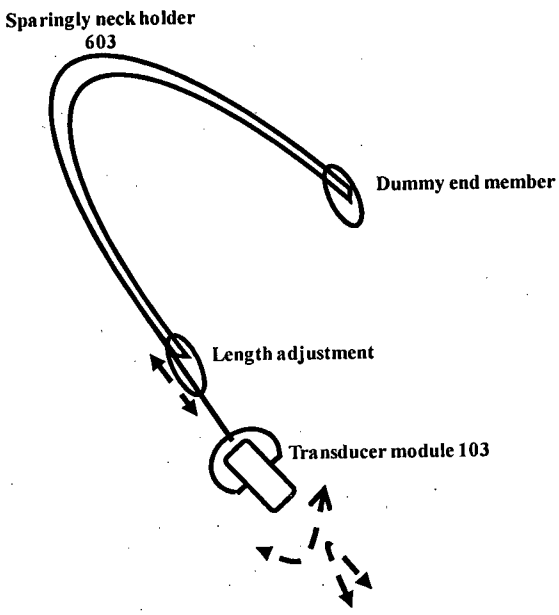
Sparingly neck holder
603
Dummy end member
Length adjustment
Transducer module 103

Fig. 6B

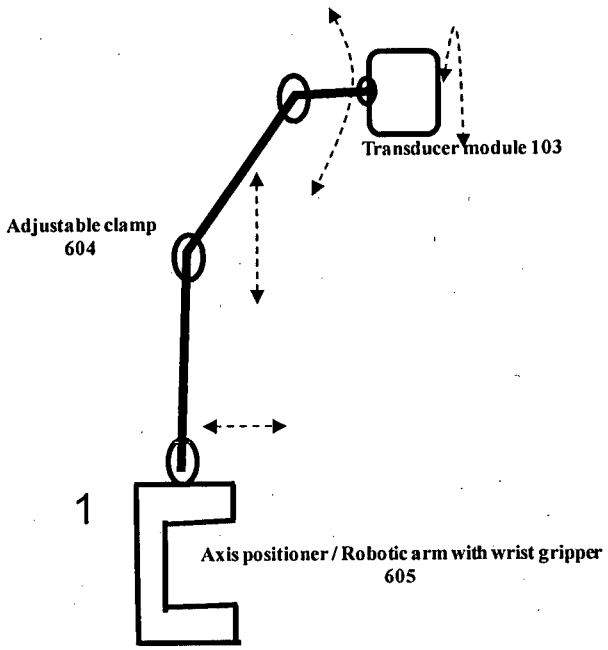
Transducer module 103
Adjustable clamp
604
1
Axis positioner / Robotic arm with wrist gripper
605

Fig. 6C

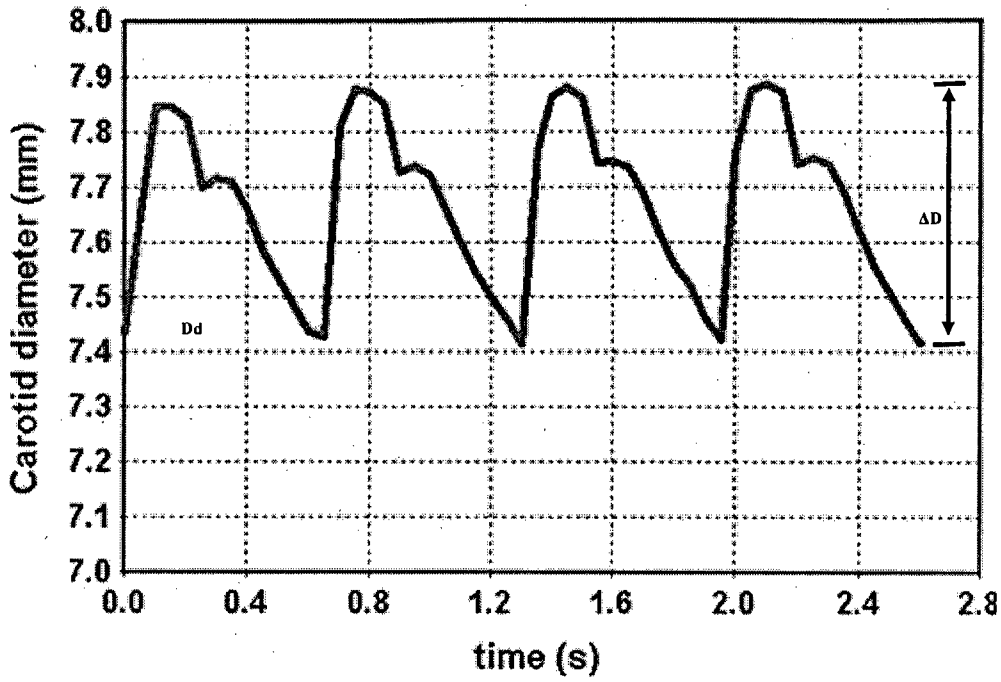
8.0
7.9
7.8
7.7
7.6
7.5
7.4
7.3
7.2
7.1
7.0
Carotid diameter (mm)
Dd
ΔD
0.0
0.4
0.8
1.2
1.6
2.0
2.4
2.8
time (s)

Fig. 6D