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(54) **HEADSET FOR MEASURING  
PHYSIOLOGICAL PARAMETERS**

**Publication Classification**

(75) Inventors: **Kevin S. Honeyager**, San Antonio, TX  
(US); **Keith A. Bartels**, San Antonio,  
TX (US); **Larry D. Canady JR.**,  
Bergheim, TX (US)

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Correspondence Address:  
**OLIFF & BERRIDGE, PLC**  
**P.O. BOX 19928**  
**ALEXANDRIA, VA 22320 (US)**

(57) **ABSTRACT**

(73) Assignee: **Southwest Research Institute**, San  
Antonio, TX

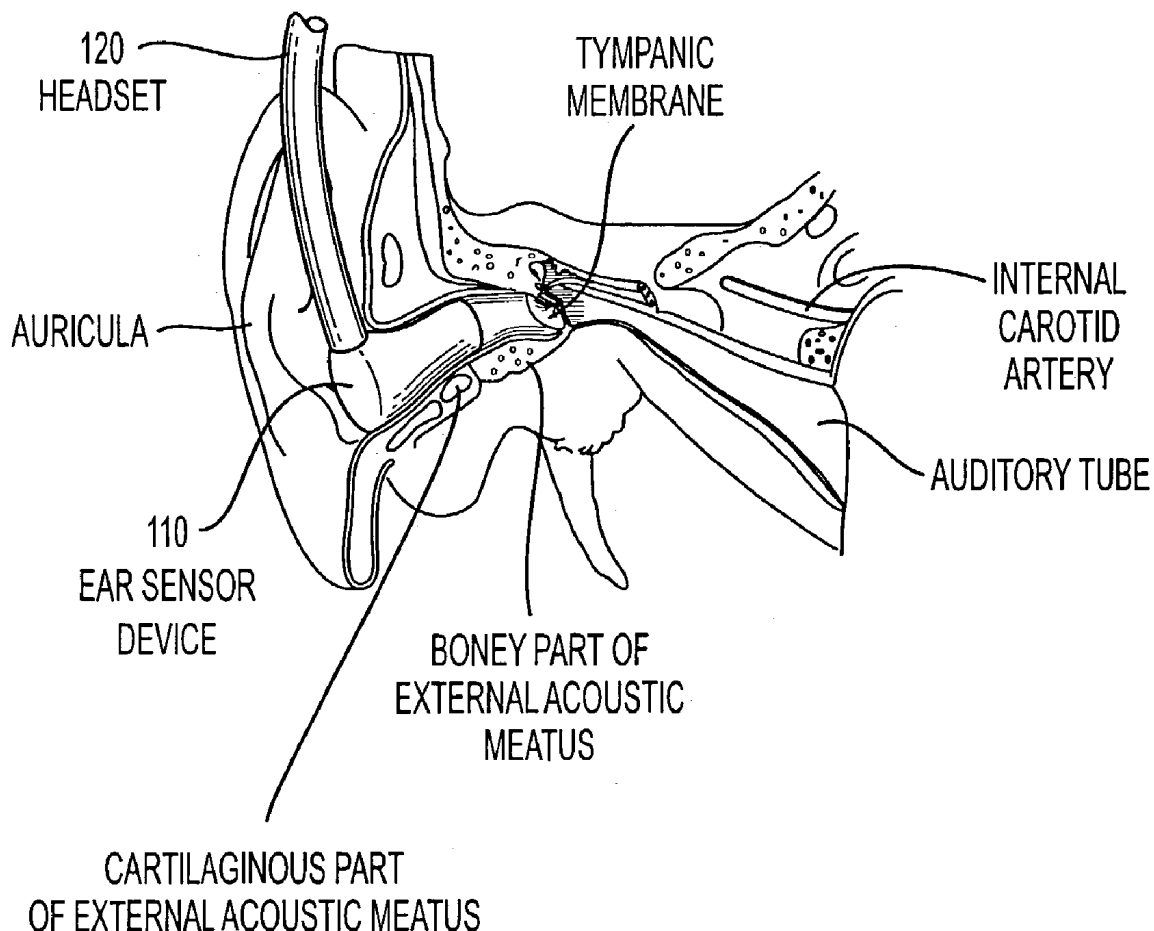
Methods and systems for determining physiological parameters from body sounds obtained from a person's ear. In various exemplary embodiment, the system includes an earplug housing; a sensing element disposed within a portion of the earplug housing; an acoustic shield coupled to the earplug housing, the acoustic shield reducing or eliminating extracorporeal sounds; and a preamplification circuit electrically coupled to the sensing element. In various exemplary embodiments, the system is operable to determine motion and/or vibration of the external acoustic meatus or the tympanic membrane of the ear due to internally generated body sounds.

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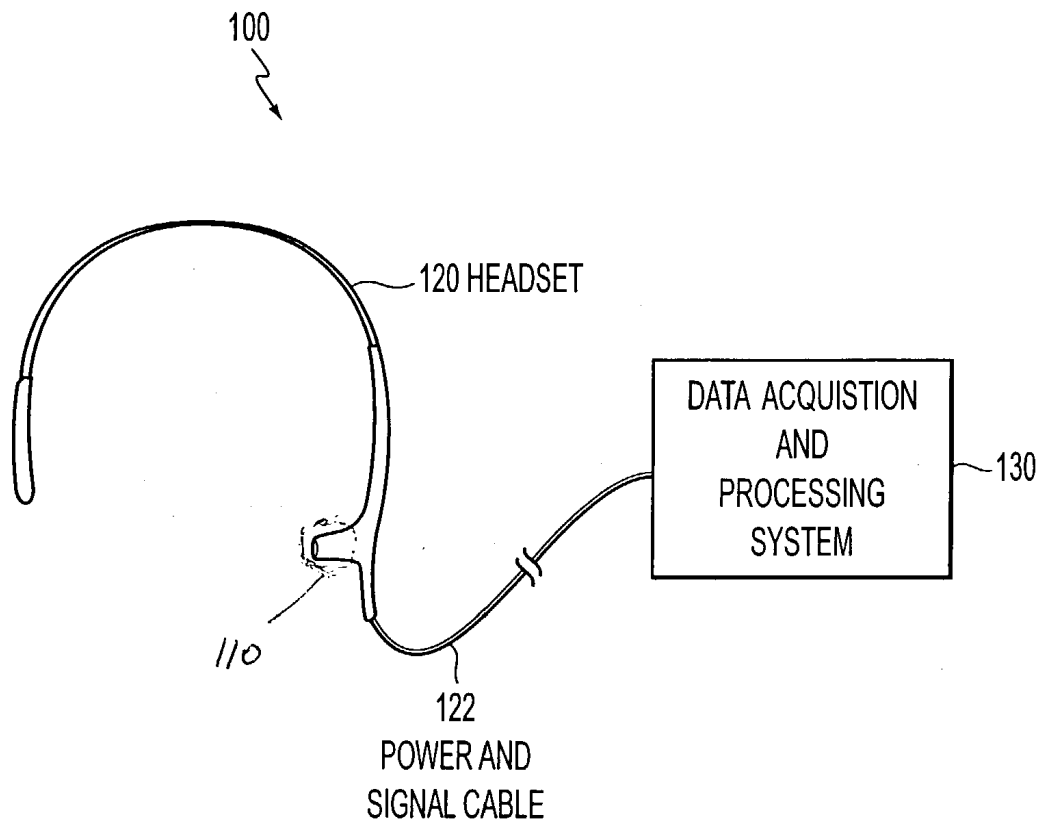


FIG. 1A

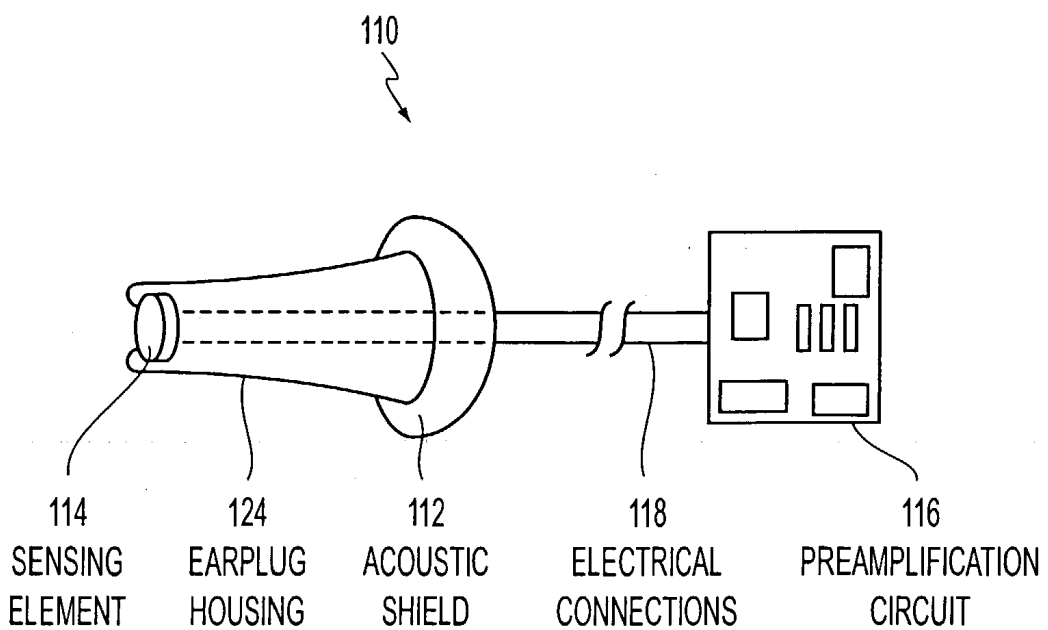
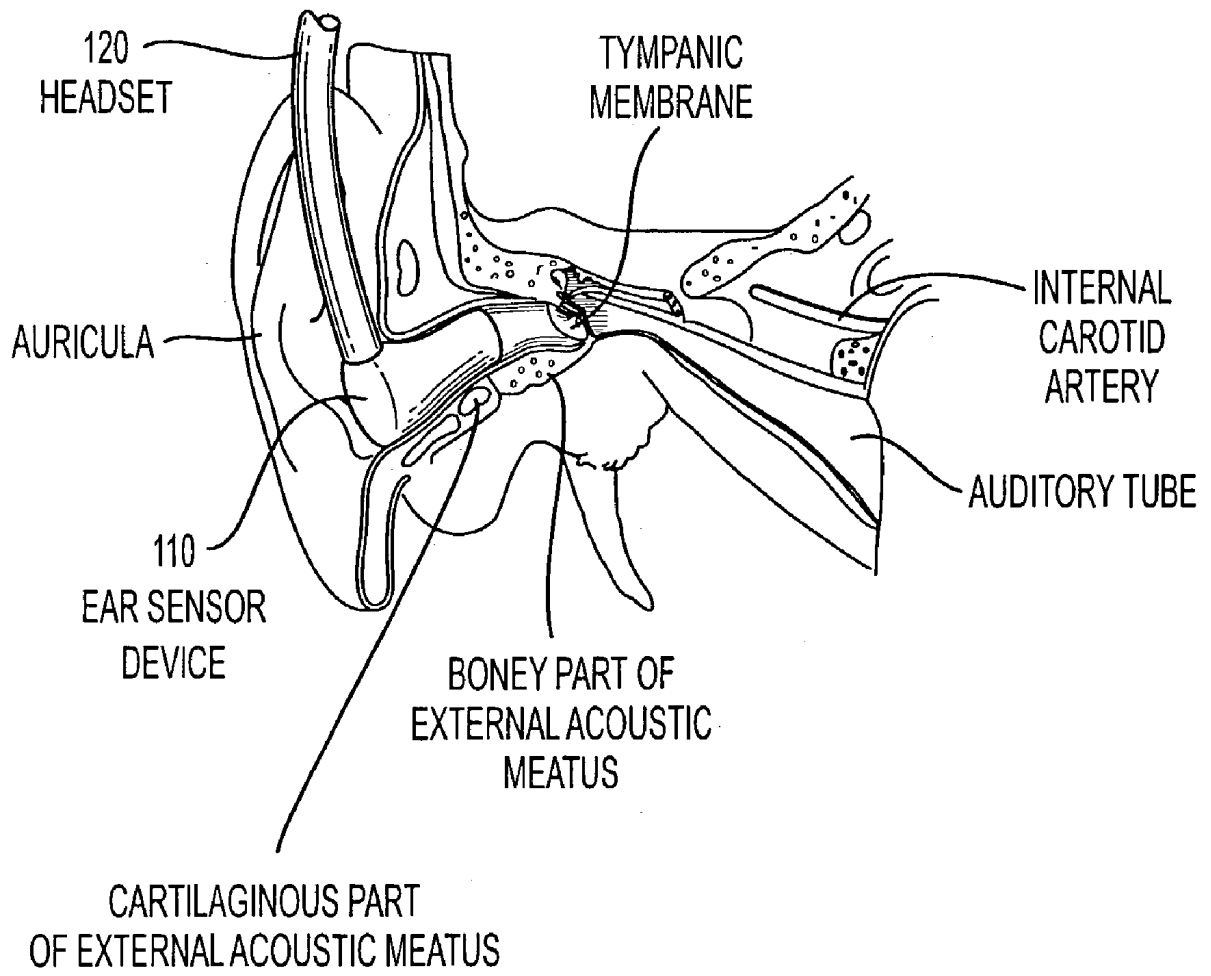


FIG. 1B



**FIG. 2**

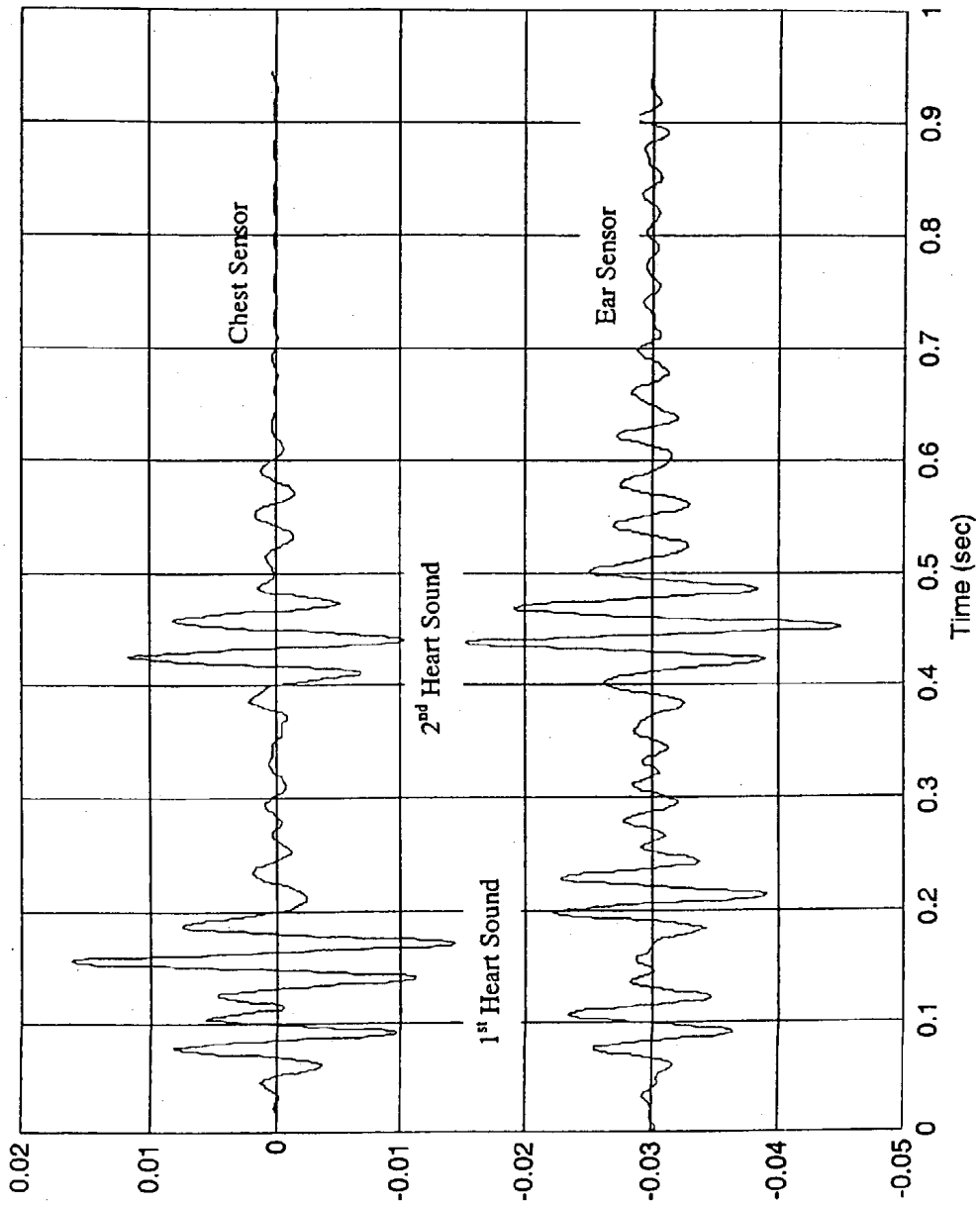


FIG. 3

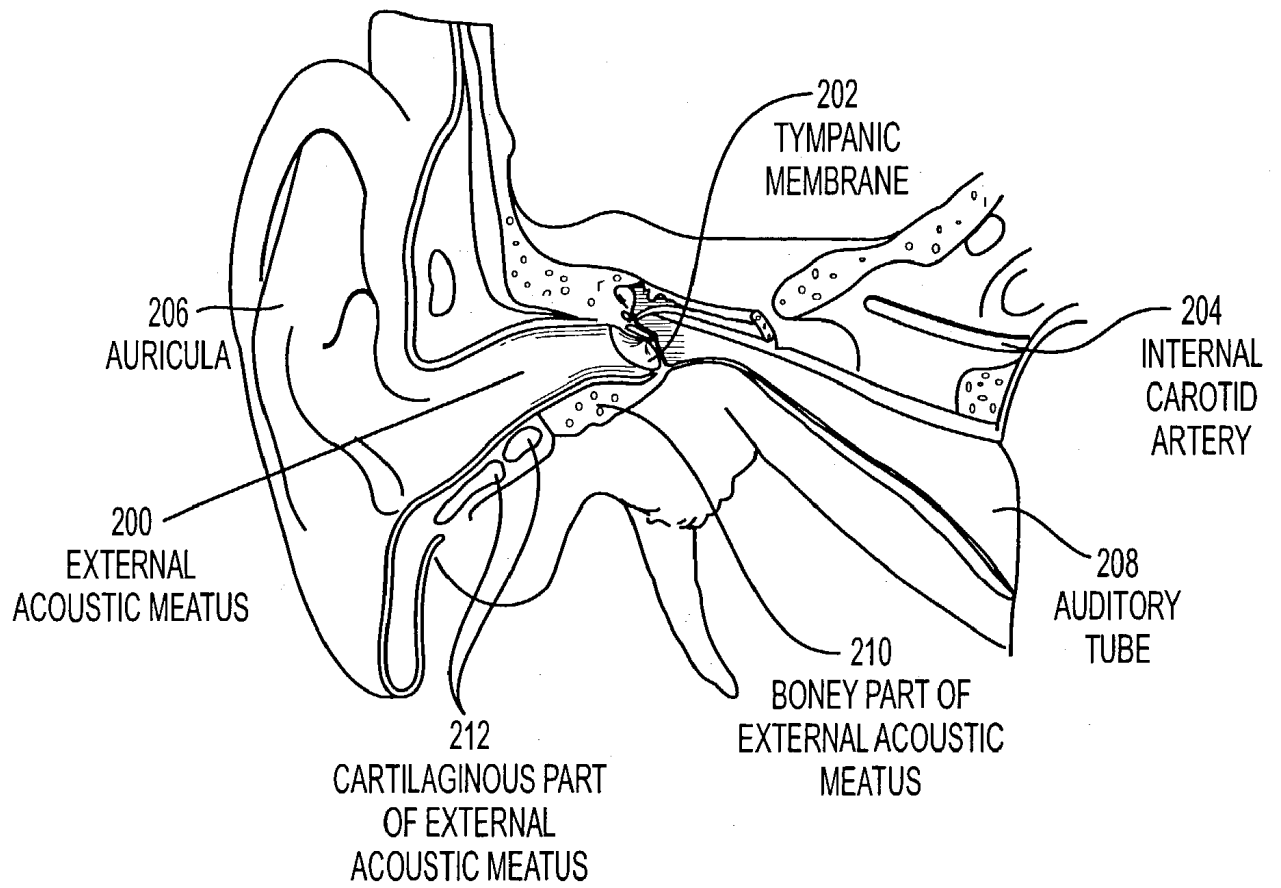


FIG. 4

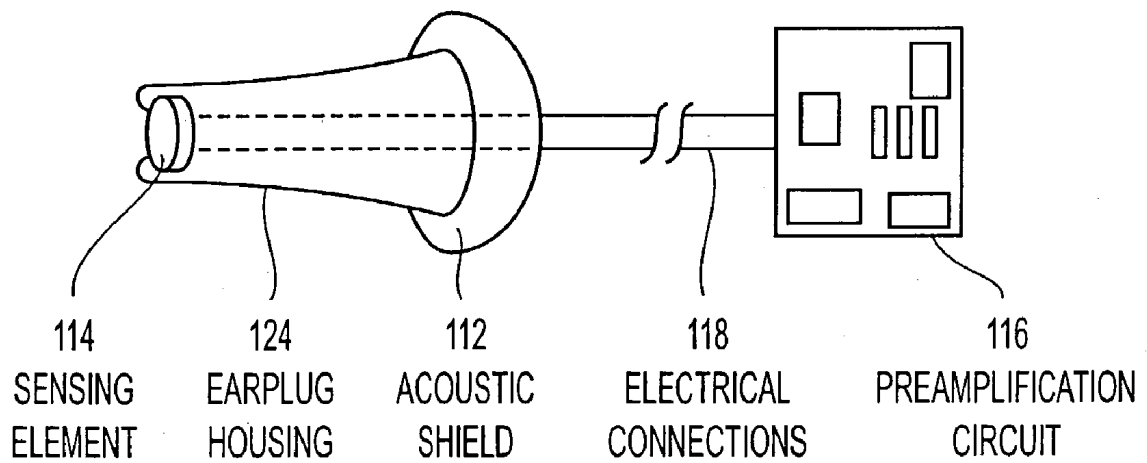


FIG. 5

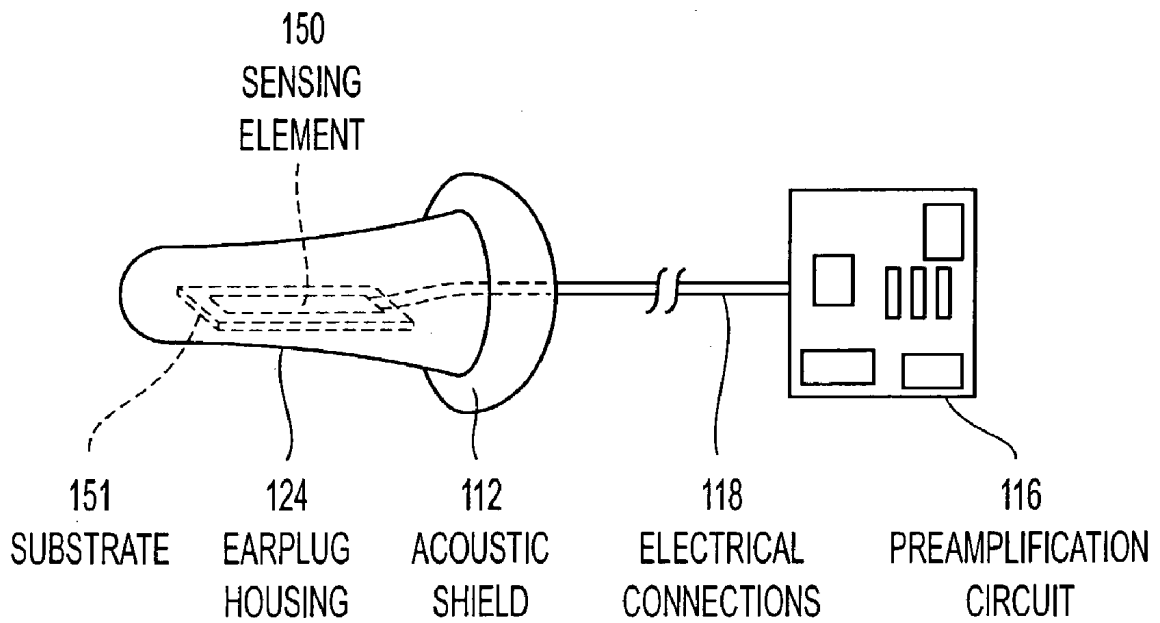


FIG. 6

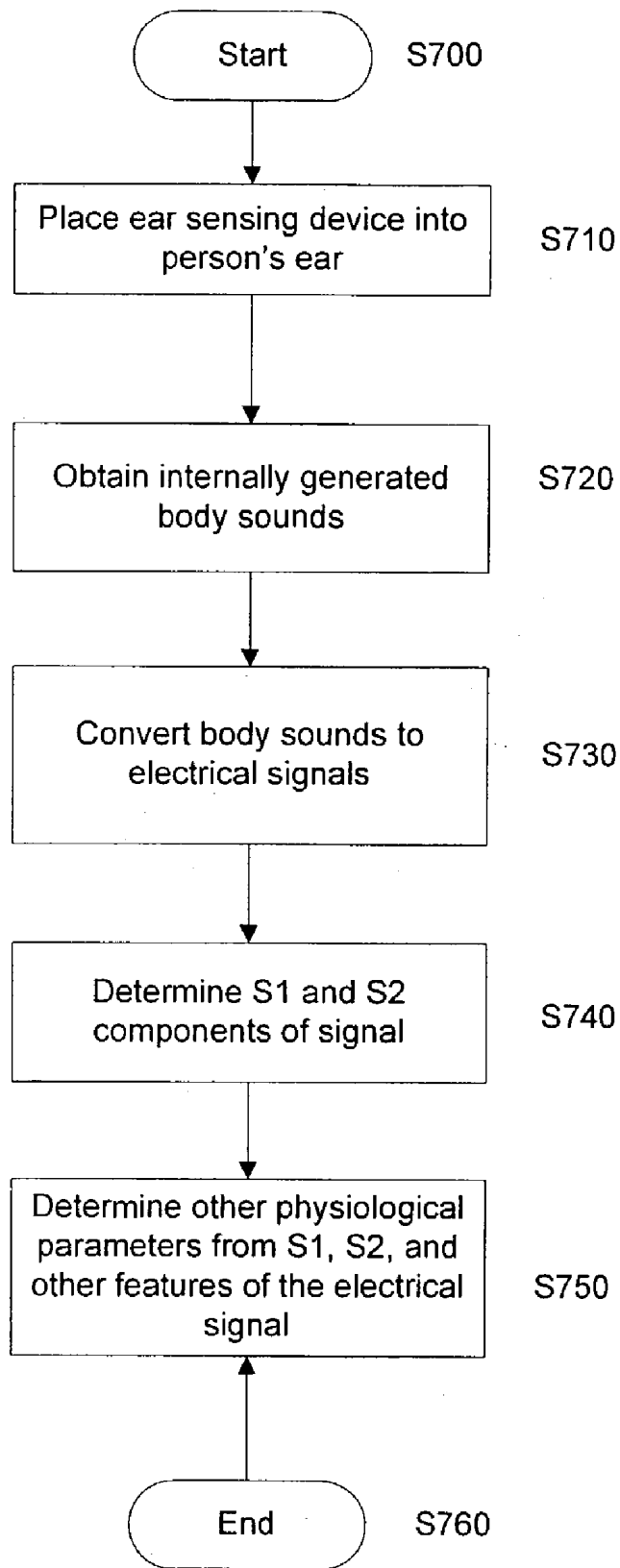


FIG. 7

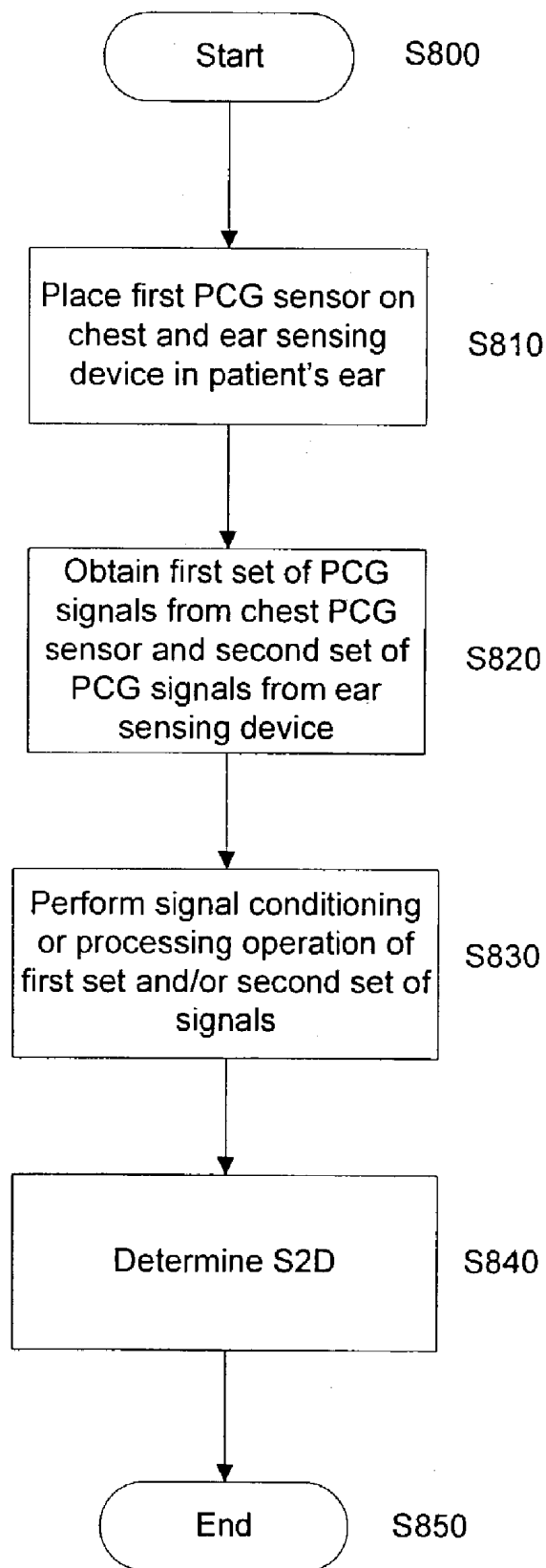


FIG. 8

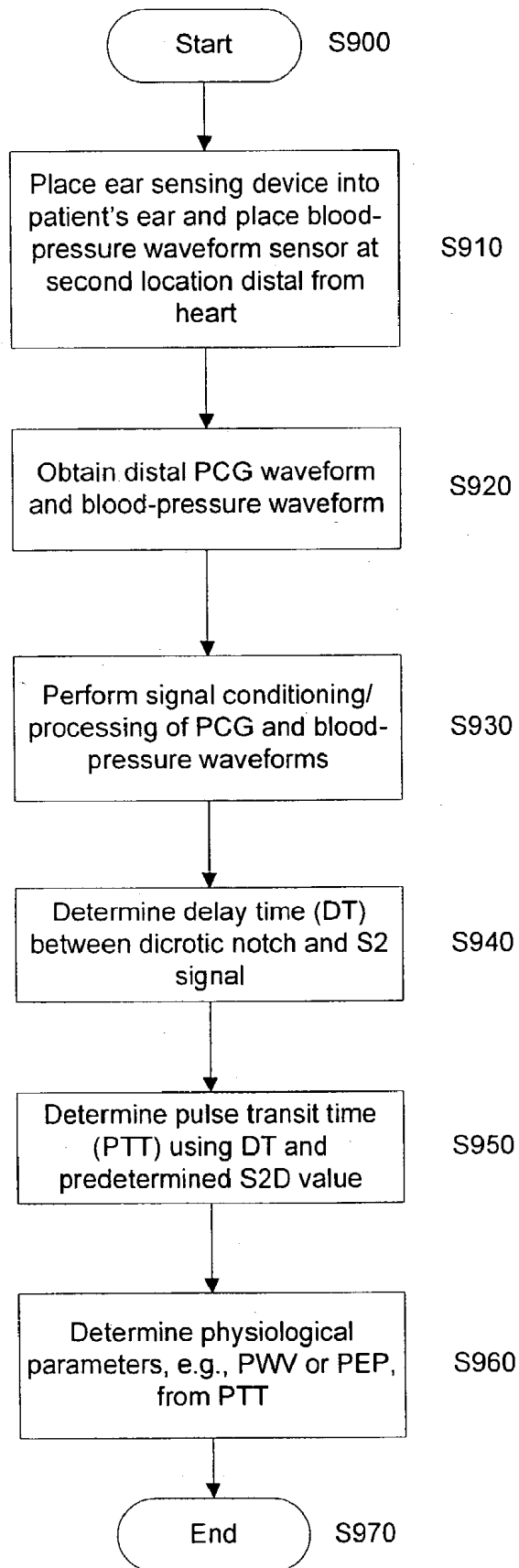


FIG. 9

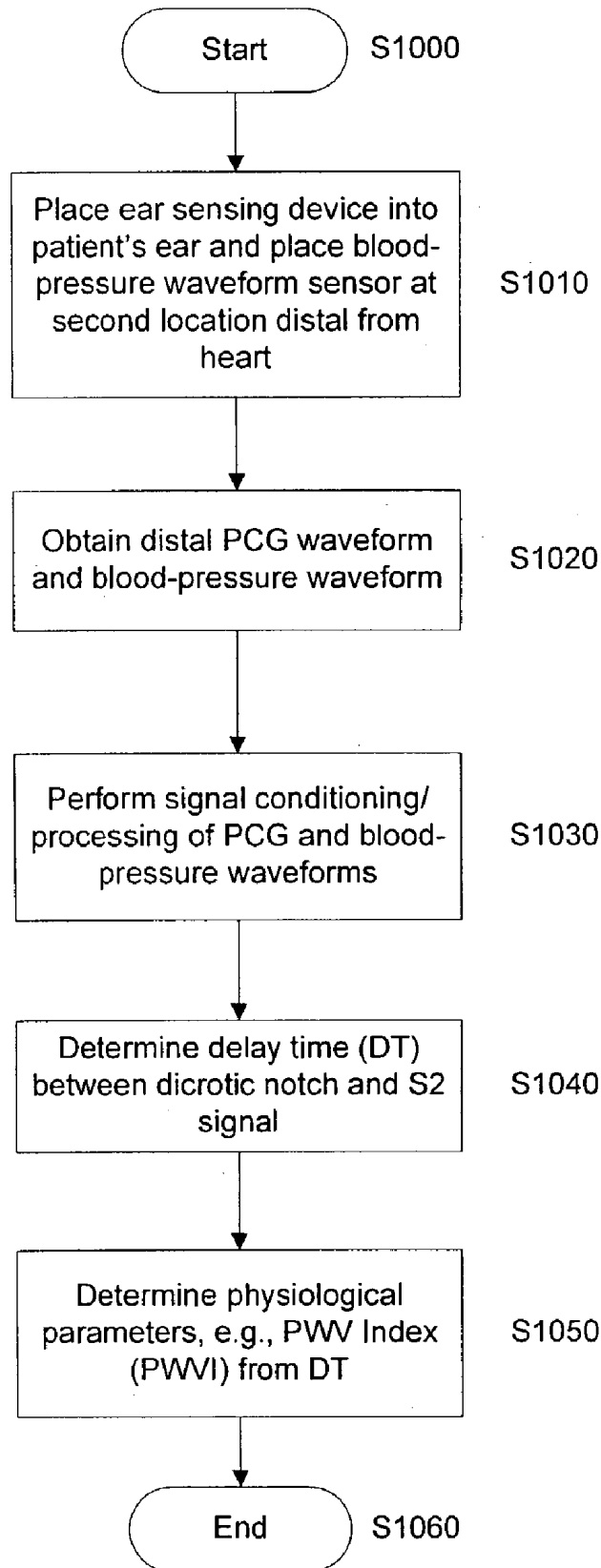


FIG. 10

## HEADSET FOR MEASURING PHYSIOLOGICAL PARAMETERS

### BACKGROUND OF THE INVENTION

#### [0001] 1. Field of Invention

[0002] This invention relates to systems and methods for detecting and/or measuring a person's physiological parameters by detecting the person's internally generated body sounds, such as heart sounds, at a location within a person's ear, and processing the measured body sounds to obtain physiological parameters of interest.

#### [0003] 2. Description of Related Art

[0004] Sound signals recorded from the heart are called phonocardiogram (PCG) signals. A healthy heart generates two distinct sounds that are coincident with the closure of the heart valves. These two sounds are called the first heart sound (S1) and the second heart sound (S2). In particular, S2 is coincident with the closure of the aortic valve. The closure of the aortic valve also creates a distinct feature on the arterial blood pressure waveform called the dicrotic notch. The pulse transit time (PTT) is defined as the time required for an arterial blood pressure pulse to travel from the heart to a distal location to the heart. The PTT can be measured by determining the delay between the closure of the aortic valve and the arrival of the dicrotic notch at a distal measurement point. This measurement is possible since, by placing a phonocardiogram (PCG) sensor on the chest near the aortic valve, it can be assumed that the delay between the closure of the valve and the measurement of the S2 sound on the chest is negligible. The arterial blood pressure pulse wave velocity (PWV) is computed by dividing the arterial path length between the heart and the measurement point by the PTT. Because the PWV is dependent on the stiffness of the arterial walls, it can be a useful parameter in determining the health of the cardiovascular system (e.g. arteriosclerosis).

[0005] Conventional methods and devices measure PWV using a PCG sensor in a standard location on the chest and a blood pressure waveform measurement at a location distal to the heart. When PTT/PWV is to be measured using a PCG sensor at a location distal to the heart, the true PTT/PWV cannot be calculated unless one accounts for the propagation delay, hereinafter referred to as S2D, where S2D is the measured delay between the aortic valve closure and the arrival of the second heart sound (S2) at the distal location. The accuracy of the PTT/PWV measurement is directly proportional to the accuracy with which S2D is known.

[0006] In addition to PWV, heart sound information can be used to determine heart rate from the timing of successive S1 or S2 components. Respiration rate can be determined from monitoring the splitting of S2 into its component aortic and pulmonary valve closure due to breathing. It is well known that inspiration causes an increase in the time delay between the aortic and pulmonary valve closure events. Respiration rate can also be determined from breath sounds obtained from a phonocardiogram sensor.

### SUMMARY OF THE INVENTION

[0007] This invention provides systems and methods for detecting a person's internally generated body sounds at a location within a person's external acoustic meatus, or ear canal.

[0008] This invention separately provides systems and methods for determining a person's physiological conditions and/or parameters based on internally generated body sounds detected within a person's ear canal.

[0009] This invention separately provides systems and methods for determining a person's heart sounds, based on internally generated body sounds detected within a person's ear canal.

[0010] This invention separately provides systems and methods for measuring and/or detecting one or more of a person's heart rate, respiration rate, pulse wave velocity (PWV), blood pressure or blood pressure trend, and other cardiac-related parameters, based in whole or in part on internally generated body sounds detected within a person's ear canal.

[0011] In various exemplary embodiments of the systems and methods according to this invention, heart sounds are obtained by placing a transducer within an ear of a person to detect internally generated body sounds, producing a signal representative of the vibration and/or motion occurring within the ear, and processing said signal to extract heart sound and other physiological information.

[0012] In various exemplary embodiments of the systems and methods according to this invention, signals are obtained by determining the vibrations and/or motion of the tympanic membrane caused by internally generated body sounds.

[0013] In various exemplary embodiments of the systems and methods according to this invention, signals are obtained by determining the vibrations and/or motion of the cartilaginous and bony portion of the ear's external acoustic meatus caused by internally generated body sounds.

[0014] In various exemplary embodiments of the systems and methods according to this invention, the ear sensor device includes an ear plug housing, a vibration or motion sensor disposed through at least a portion of the ear plug housing, and one or more electrical signal connectors that connect the sensor to a data acquisition and processing system.

[0015] In various exemplary embodiments of the systems and methods according to this invention, an enhanced distal phonocardiogram (PCG) recording is performed using a signal conditioning or processing operation of the ear sensor signals triggered by the dicrotic notch of a separately obtained blood-pressure waveform.

[0016] In various exemplary embodiments of the systems and methods according to this invention, the S2 obtained from a sensor other than the ear sensor is used as a trigger signal.

[0017] In various exemplary embodiments of the systems and methods according to this invention, an enhanced distal PCG recording using a signal conditioning or processing operation is performed using an ensemble averaging operation of the ear sensor waveform triggered by the dicrotic notch of the separately obtained blood-pressure waveform.

[0018] In various exemplary embodiments of the systems and methods according to this invention, DT, the delay time between a dicrotic notch signal and an S2 signal, is deter-

mined by using a recording of the blood pressure waveform and a recording of the ear sensor signal, both acquired from a location distal to the heart.

[0019] In various exemplary embodiments of the systems and methods according to this invention, a corrected PTT is determined by adding S2D to DT.

[0020] In various exemplary embodiments of the systems and methods according to this invention, PWV is determined using the corrected PTT and artery length.

[0021] In various exemplary embodiments of the systems and methods according to this invention, an index of PWV (PWVI) is determined using DT.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0022] Various exemplary embodiments of this invention will be described in detail, with reference to the following figures, wherein:

[0023] FIGS. 1A and 1B represent a schematic illustration of one exemplary embodiment of a system used to detect internally generated body sounds, such as for example, the first and second heart sounds (S1 and S2);

[0024] FIG. 2 is a drawing of one exemplary embodiment of the system used to detect internally generated body sounds, positioned in its measuring location;

[0025] FIG. 3 is a graph plotting data acquired simultaneously from the ear sensor device illustrated in FIG. 1 and a reference chest microphone commonly used for obtaining phonocardiograms;

[0026] FIG. 4 is a drawing of the referenced external and internal structures of the ear;

[0027] FIG. 5 is a schematic illustration of one exemplary embodiment of a system used to detect internally generated body sounds, such as for example, the first and second heart sounds S1 and S2, wherein the vibration and/or motion of the tympanic membrane is detected;

[0028] FIG. 6 is a schematic illustration of another exemplary embodiment of a system used to detect internally generated body sounds, such as for example, the first and second heart sounds S1 and S2, wherein the vibration and/or motion of the external acoustic meatus is detected;

[0029] FIG. 7 is a flowchart outlining an exemplary embodiment of a method for obtaining internally generated body sounds from a person, such as the first and second heart sounds (S1 and S2);

[0030] FIG. 8 is a flowchart outlining one exemplary embodiment of a method for determining S2D, the delay between the aortic valve closure and the arrival of a second heart sound (S2) within an ear of a person;

[0031] FIG. 9 is a flowchart outlining one exemplary embodiment of a method for determining and/or measuring physiological parameters of a person, including cardiovascular parameters, such as, for example, PTT, PWV and PEP, using a determined S2D value; and

[0032] FIG. 10 is a flowchart outlining another exemplary embodiment of a method for determining and/or measuring

physiological parameters of a person, including cardiovascular parameters, such as, for example, PWVI, without using a determined S2D value.

#### DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[0033] As described herein, this invention provides systems and methods for acquiring body sound information from a person's ear, which can then be converted to useful physiological parameters of interest, such as heart rate, heart valve closure timing, pulse wave velocity, blood pressure, and the like.

[0034] FIGS. 1A and 1B show one exemplary embodiment of a system 100 according to this invention in which internally generated body sounds are detected or measured using an ear sensor device 110 inserted into the ear of a person. As shown in FIGS. 1A-1B, the ear sensor or ear sensing device 110 includes an ear plug housing 124, a sensor element 114 disposed within a portion of the ear plug housing 124, an acoustic shield 112 and a preamplification circuit 116 electrically coupled to sensor element 114 via electrical connections 118. The purpose of the acoustic shield 112 is to shield the sensor element 114 from ambient noise generated outside the person's body. The preamplification circuit 116 is used to convert the motion or vibration signal acquired by the sensor element 114 into an output, such as a voltage and/or a current, to be read by a data acquisition and processing system 130.

[0035] FIG. 2 shows one exemplary embodiment of a system 100 when properly worn in the ear.

[0036] In one exemplary embodiment, the ear plug housing 124 is made of a foam like material, such as compressible foam. Alternatively, the ear plug housing 124 is made of a biocompatible rigid or semi-rigid polymer.

[0037] As shown in FIG. 1A, in one exemplary embodiment, the ear sensor device 110 is integrated into a headset 120, which can be positioned on a person's head. The headset 120 may be any style of headset device known in the art. Generally, the headset device is electrically coupled to a data acquisition and processing system 130. The data acquisition and processing system may include any data acquisition and processing system known in the art.

[0038] In an exemplary embodiment, motion of vibrations detected by the sensing element 114 are converted to electrical signals by the preamplification circuit 116, and are then transmitted to the data acquisition and processing system via the power and signal cable 122.

[0039] The data acquisition and processing system 130 may be located external to the headset 120, or may be located within the headset 120 for purposes of converting the analog signals to the digital domain and performing such signal processing as necessary to obtain the desired physiological parameters.

[0040] It will be appreciated by those skilled in the art that the system 100 shown in FIG. 1A represents one exemplary embodiment of the types of devices that may be used with this invention.

[0041] The headset 120 is used for placement of the sensing device within the ear. The headset may contain a single sensor for one ear, or sensors for both ears. The design

is such that sufficient tension is provided against the ear to securely retain the sensor element **114** and acoustic shield **112** within the ear's external acoustic meatus **200** (shown in **FIG. 4**). A secondary function of the headset **120** may be to acoustically isolate external ambient sounds from the ear sensor device **110**. For this purpose the headset **120** may be constructed in such a fashion as to fully enclose the ear's auricula **206** (shown in **FIG. 4**) using a padded material surrounding the auricula **206** to minimize external ambient noise.

[0042] In an alternative exemplary embodiment of the system, the ear sensor device **110** could be manually placed in the ear, and a protective headset could be positioned over the sensor(s), with a cable connecting the sensors to the headset.

[0043] In an exemplary embodiment, the preamplification circuit **116** is located in the ear plug housing **124** with the sensor element **114** and the ear sensor device **110** is then used without headset **120**. In this embodiment the ear sensor device **110** is designed as a standalone system wherein the signal output from preamplification circuit **116** is delivered through a cable to an external device with a power supply and data acquisition and processing capability. The sensor is held in place by the friction of the ear plug housing **124** and acoustic shield **112** against the external acoustic meatus **200** (shown in **FIG. 4**).

[0044] In another exemplary embodiment, the preamplification circuit **116** is located in the headset **120**.

[0045] **FIG. 5** shows a sensor element **114** that consists of a vibration or motion sensor able to detect the modulations of the tympanic membrane **202** (shown in **FIG. 4**). If the ear canal is acoustically sealed between the sensing element and the outer ear, the effect of extracorporeal sounds on tympanic membrane motion will be reduced or eliminated. The resulting motion of the tympanic membrane will therefore be due to sounds generated from within the body.

[0046] An alternative embodiment of ear sensor device **110** is shown in **FIG. 6**. This embodiment shows a sensor element **150** used to detect motion and vibrations of the external acoustic meatus **200** of the ear (shown in **FIG. 4**). Internally generated body sounds are transmitted through various body tissues, including the bony and cartilaginous structures of the body. These structures include the bony and cartilaginous parts of the ear's external acoustic meatus (**210** and **212** in **FIG. 4**). Sensor element **150** is designed to maximize the signal obtained from the motion and vibration of the external acoustic meatus **200**.

[0047] **FIG. 6** shows one possible exemplary embodiment of a sensor used to measure the vibrations of the external acoustic meatus. A strain gage or polyvinylidene fluoride (PVDF) sensor element **150** or the like is attached to a substrate **151**, which is shaped to fit within a substantial portion of the earplug housing **124**. The sensor element, substrate and associated wire connections are encapsulated in a semi-rigid biocompatible compressible material such as a polyurethane elastomer. Vibrations emanating from the external acoustic meatus **200** will cause the substrate **151** and attached sensor element **150** to flex, thereby producing a signal. The encapsulated sensor is attached to the headset **120** so that the wire connections are internal to the headset **120** and can be connected to a preamplification circuit **116**.

[0048] In another exemplary embodiment of the invention, an ear sensor device **110** is used in each ear to obtain two channels of the previously described motion or vibration signals. The signals from each ear can be used together for purposes of assessing signal quality and performing motion artifact rejection. For instance, heart sounds that generate vibrations of the external acoustic meatus **200** will be delivered in the same general timeframe at each ear. Detection of a distinct feature such as the first or second heart sound (**S1** or **S2**) could be required by a signal processing algorithm to occur nearly simultaneously in both ears. If a signal is detected in one ear but not the other, the signal could then be rejected as a motion artifact unrelated to heart sounds. The same principle can be applied to any feature of interest in the signal that is expected to be common to both channels.

[0049] Likewise, the ear sensor device **110** in one ear may be positioned improperly so that the signal of interest is undetectable or of poor quality. The ear sensor device **110** in the opposite ear can be used to provide the physiological parameters of interest providing that it has sufficient signal quality.

[0050] **FIG. 3** shows a plot of heart sound data, for example **S1** and **S2** signal data, acquired simultaneously from an ear sensor device **110** and a reference chest microphone commonly used for obtaining phonocardiograms. As shown in **FIG. 1**, the ear sensor device **110** is clearly able to detect the first and second heart sounds, **S1** and **S2**. The waveform shapes of the **S1** and **S2** heart sounds are not identical because of the difference in construction between the ear sensor device **110** and the chest sensor, and the additional travel time required by sound to travel up to the ear. However, it will be appreciated that the desired information is present and able to be acquired at the ear using the methods and systems according to this invention.

[0051] The chest PCG data shown in **FIG. 3** were acquired using a commercially available PCG sensor that uses condenser microphone technology. Similar results are obtained using other technologies such as piezoelectric materials and accelerometers. The waveform data shown were enhanced by a digital bandpass filter that passed frequencies between 25 and 55 Hz.

[0052] This invention further provides systems and methods that improve the signal-to-noise ratio (SNR) of the acquired or measured heart sounds by improving signal processing. In various exemplary embodiments, improving signal conditioning or processing, and thus improving signal-to-noise ratio (SNR) of the acquired or measured heart sounds, is performed by averaging two or more consecutive heart cycles, also called ensemble averaging.

[0053] To perform the ensemble averaging, the individual heart cycles must first be identified. This can be done by detecting a unique feature that occurs during each heart cycle. In one exemplary embodiment, the R-wave of a separately obtained ECG signal is used as the delimiter of heart cycles. This is called R-wave triggering of the ensemble averaging.

[0054] In another exemplary embodiment, the **S2** signal from of a separate chest PCG sensor can be used to delimit the ear sensor waveform for ensemble averaging. Using the **S2** trigger is advantageous over the R-wave trigger in that a

higher signal-to-noise ratio (SNR) for the averaged ear sensor S2 signal is obtained. This is because there is a beat-to-beat variability of the time between the R-wave and the S2 signal. This variability can cause a "jitter" of the S2 signal when using the R-wave trigger and hence some signal amplitude can be averaged away.

[0055] The R-wave trigger is advantageous in that it is easily performed. The R-wave of an ECG is a very easily identifiable signal.

[0056] The advantage of the S2-triggered ensemble averaging could also be obtained by using the dicrotic notch of a separately obtained blood pressure waveform as the trigger. The dicrotic notch and S2 signal both result from the closure of the aortic valve and hence have the same timing.

[0057] It will be noted that in various exemplary embodiments of the systems and methods according to this invention, ensemble averaging is not required to be performed to detect the S2 signal at a person's ear. One such example is if the signal-to-noise ratio (SNR) of the ear's S2 signal is high due to relatively low noise from sources (other than the heart valves) within the body and from the external environment. That is, ensemble averaging may not be required if external ambient noise and/or body vibration is low or negligible and the signal components of interest can be detected on a beat-to-beat basis.

[0058] As described above, the PTT is measured with current technology as the time between the S2 signal measured on the chest and the dicrotic notch of an arterial blood pressure waveform. In various exemplary embodiments of the systems and methods according to this invention, the PTT is measured as the time between the distally measured S2 signal, i.e., ear measured S2 signal, and the dicrotic notch plus S2D, where S2D is the measured delay between the aortic valve closure as measured at the chest and the arrival of the S2 signal at the ear location.

[0059] In one exemplary embodiment, the S2D value could be determined as an average value for the entire population. In another exemplary embodiment, a predetermined S2D value for the particular individual may be used. In yet another exemplary embodiment, the S2D value could be experimentally determined based on a person's demographics, such as height, weight, or age.

[0060] The predetermined S2D value could be obtained for an individual by using a first PCG sensor, for example a chest PCG sensor, during a calibration step. The S2D would be measured as the time delay between the S2 measured by the ear sensor device and the S2 measured by the chest PCG. An individually calibrated value for S2D adds an additional initial step to using the device, but would give a more accurate measurement than if a population-based standardized value was used. For some applications, however, the standardized S2D value would give sufficiently accurate results.

[0061] In various exemplary embodiments of the systems and methods according to this invention, a person's physiological parameters, such as, for example PWVI, can be obtained by using the delay time (DT) between dicrotic notch and S2 signals without using the S2D signal. That is, an index of PWV, e.g., PWVI, can be determined without having to determine the S2D signal. The PWVI monitored over time would still show increases or decreases in PWV.

[0062] FIG. 7 is a flowchart outlining another exemplary embodiment of a method for determining physiological parameters by using body sounds obtained from the ear.

[0063] As shown in FIG. 7, the method starts at step S700 and continues to step S710 where an ear sensor device is placed into a person's ear canal. Next, at step 720, a first set of body sounds is obtained using the ear sensor device.

[0064] Then, at step S730, the body sounds acquired by the ear sensor device are converted into electrical signals using the preamplification circuit. The operation continues to step S740, where an S1 and S2 value are determined along with other stable features in the waveform. Next, at step S750, various physiological parameters of a person are determined from the ear signal values determined in step S740 using techniques well known in the art. These physiological parameters may include one or more of: a person's heart rate; a person's respiration rate; a person's valve closure timing; an indication of murmur detection; breath sounds; a person's PWV; and a person's blood pressure or blood pressure trend.

[0065] FIG. 8 is a flowchart outlining one exemplary embodiment of a method for determining S2D. The various steps of the method shown in FIG. 8 are generally performed only occasionally for each individual.

[0066] As shown in FIG. 8, the method starts at step S800 and continues to step S810 where a first PCG sensor is placed on a person's chest and a second ear sensor device is placed in the person's ear canal. Next, at step S820, data are acquired simultaneously from both sensors, for example, a first set of heart sound signals are obtained or acquired using the first PCG sensor and a second set of heart sound signals are obtained or acquired using the ear sensor device.

[0067] Then, at step S830, a signal processing or conditioning operation is performed using the first and second sets of heart sound signals acquired. In an exemplary embodiment of the systems and methods according to this invention, an ensemble averaging operation is performed using the first and second sets of signals acquired. In another exemplary embodiment of the systems and methods according to this invention, signal processing or conditioning S830 may be performed using a bandpass filter. In yet another exemplary embodiment of the systems and methods according to this invention, signal processing is performed for determining a stable detection point in the ear sensor device signal.

[0068] Next, at step S840, using the results obtained from the signal processing or conditioning operation, such as for example from an ensemble averaging operation, the S2D is determined. The method then continues to step S850, where the method stops.

[0069] FIG. 9 is a flowchart outlining one exemplary embodiment of a method for determining physiological parameters, including for example, PWV, PEP and the like, by using distally measured heart sounds. In one exemplary embodiment, the timing of the closure of the aortic valve in combination with simultaneously obtained ECG and blood pressure waveforms can be used to compute the heart's pre-ejection period (PEP). PEP is also known as the isovolumetric contraction period and is the time during which ventricular pressure is increasing while the aortic valve is still closed. When the pressure within the ventricle surpasses

the aortic pressure the aortic valve opens and the PEP ends. PEP, especially when used in ratio to the ventricular ejection time, is another important parameter indicating cardiovascular health.

[0070] As shown in FIG. 9, the method starts at step S900 and continues to step S910 where the ear sensor device is placed into a person's ear canal, and a blood-pressure waveform sensor is placed at a second distal location to the heart. Next, at step 920, a first set of waveforms is obtained from the ear sensor device. A second set of waveforms is simultaneously obtained from the blood-pressure waveform sensor.

[0071] Then, at step S930, a signal conditioning/processing operation, such as for example, an ensemble averaging operation, may optionally be performed using the first and second sets of waveforms obtained in step S920. The operation continues to step S940, where a time delay (DT) between the dirotic notch of the blood pressure signal and the S2 component of the ear signal is determined.

[0072] At step S950, a blood pressure pulse transit time (PTT) value is determined by adding a previously determined or known value of S2D, representing a time delay between a person's aortic valve closure time and an arrival time of the S2 signal at the ear, to the time delay DT between a dirotic notch component and the S2 component of the ear signal.

[0073] Next, at step S960, various cardiovascular parameters of a person are determined using the determined blood pressure pulse transit time calculated in step S950 and at least one physical parameter representative of an arterial distance between the aortic valve and the measurement location of the blood-pressure waveform sensor. The method then continues to step S970 where the method stops.

[0074] In one exemplary embodiment, the method shown in FIG. 9 is used to determine arterial blood pressure pulse wave velocity (PWV) by dividing the arterial path length between the heart and the distal blood pressure measurement point by the PTT. Because the pulse wave velocity is dependent on the stiffness of the arterial walls, PWV can be a useful parameter in determining the health of the cardiovascular system (e.g. arteriosclerosis).

[0075] In one exemplary embodiment of the method according to this invention, step S930, performing a signal conditioning/processing operation, for example, an ensemble averaging operation, includes determining a person's individual heart cycles. In one exemplary embodiment, determining a person's individual heart cycles includes determining a delimiter in the person's individual heart cycles. A delimiter of heart cycles may be obtained from a separately obtained ECG R-wave. Alternatively, determining a delimiter of heart cycles may be performed by determining an S2 signal, representative of a second heart sound associated with closure of the aortic heart valve, from the first set of heart sound vibration signals acquired by the ear sensor device.

[0076] In various exemplary embodiments of the systems and methods according to this invention, performing a signal conditioning/processing operation, for example, an ensemble averaging operation, may include using the dirotic notch of a separately obtained arterial blood pressure waveform as a trigger.

[0077] Furthermore, it will be appreciated by those skilled in the art that the blood pressure waveform sensor may include a blood pressure cuff, an arterial tonometer, or other sensor sensitive to the blood pressure waveform.

[0078] FIG. 10 is a flowchart outlining another exemplary embodiment of a method for determining physiological parameters, including for example, PWVI and the like, by using distally measured heart sounds.

[0079] As shown in FIG. 10, the method starts at step S1000 and continues to step S1010 where an ear sensor device is placed into a person's ear canal, and a blood-pressure waveform sensor is placed at a second distal location to the heart. Next, at step S1020, a first set of waveforms is obtained from the signal acquired by the ear sensor device. A second set of waveforms is simultaneously obtained from the blood-pressure waveform sensor.

[0080] Then, at step S1030, a signal conditioning/processing operation, such as for example, an ensemble averaging operation, may optionally be performed using the first and second sets of waveforms obtained in step S1020. The operation continues to step S1040, where a time delay (DT) between the blood pressure signal's dirotic notch component and the S2 component of the ear signal is determined.

[0081] Next, at step S1050, various parameters, including cardiovascular parameters, of a person are determined using the determined delay time DT calculated in step S1040. In one exemplary embodiment, the method shown in FIG. 10 is used to determine arterial blood pressure pulse wave velocity index (PWVI). Because the pulse wave velocity is dependent on the stiffness of the arterial walls, PWVI can be a useful parameter in determining the health of the cardiovascular system (e.g. arteriosclerosis). The method then continues to step S1060 where the method stops.

[0082] In one exemplary embodiment of the method according to this invention, step S1030, performing a signal conditioning/processing operation, for example, an ensemble averaging operation, includes determining a person's individual heart cycles. In one exemplary embodiment, determining a person's individual heart cycles includes determining a delimiter in the person's individual heart cycles. Determining a delimiter of heart cycles may be performed by determining an R-wave using the first set of electrocardiogram signals. Alternatively, determining a delimiter of heart cycles may be performed by determining an S2 signal, representative of a second heart sound associated with closure of the heart valves, from the first set of ear sensor signals.

[0083] In various exemplary embodiments of the systems and methods according to this invention, performing a signal conditioning/processing operation, for example, an ensemble averaging operation, may include using the dirotic notch component of the pressure waveform as a trigger.

[0084] While this invention has been described in conjunction with the specific embodiments outlined above, it is evident that many alternatives, modifications and be apparent to those skilled in the art. Accordingly, the preferred f the invention as set forth above are intended to be illustrative, not us changes may be made without departing from the spirit and scope of the fined in the following claims.

What is claimed is:

1. A system for determining the motion and/or vibration of the external acoustic meatus of the ear, the system comprising:

an earplug housing;

a sensing element disposed within a portion of the earplug housing;

an acoustic shield coupled to the earplug housing, the acoustic shield reducing or eliminating extracorporeal sounds; and

a preamplification circuit electrically coupled to the sensing element.

2. The system according to claim 1 further comprising a data acquisition and/or processing system electrically coupled to the preamplification circuit.

3. The system according to claim 2, wherein the system is operable to determine motion and/or vibration of the external acoustic meatus of the ear due to internally generated body sounds.

4. The system according to claim 3, wherein the data acquisition and/or processing system uses the determined motion and/or vibration to determine one or more of the person's heart rate, respiration rate, heart sounds, blood pressure or blood pressure trends, PWV or PWVI, and indicators of heart murmurs.

5. The system according to claim 1 further comprising a power supply system electrically coupled to the data acquisition and/or processing system.

6. The system according to claim 1, wherein the acoustic shield is disposed between the earplug housing and external environment.

7. The system according to claim 1, wherein the earplug housing is made of compressible foam, a biocompatible rigid or semirigid polymer, or the like.

8. The system according to claim 1, wherein the sensing element is a strain gage, a PVDF film, an accelerometer, a piezoceramic substrate, or the like.

9. The system according to claim 1, wherein the earplug housing, the sensing element, the preamplification circuit and the acoustic shield are located within the ear.

10. A headset device for positioning and/or retaining at least one of the system according to claim 1 in the external acoustic meatus of at least one ear.

11. The headset device according to claim 10, wherein the preamplification circuitry is disposed within the headset.

12. The headset device according to claim 10, wherein the data acquisition and/or signal processing system is either integral to the headset or external to the headset.

13. The headset according to claim 12, wherein the data acquisition and/or signal processing system is used to determine one or more of the person's heart rate, respiration rate, S1 timing, S2 timing, blood pressure or blood pressure trends, PWV or PWVI, and indicators of heart murmurs.

14. A system for determining the motion or vibration of the tympanic membrane of the ear, the system comprising:

an earplug housing;

a sensing element disposed within a portion of the earplug housing;

an acoustic shield coupled to the earplug housing, the acoustic shield reducing or eliminating extracorporeal sounds;

a preamplification circuit electrically coupled to the sensing element.

15. The system according to claim 14 further comprising a data acquisition and/or processing system electrically coupled to the preamplification circuit.

16. The system according to claim 15, wherein the system is operable to determine motion or vibration of the external acoustic meatus of the ear due to internally generated body sounds.

17. The system according to claim 16, wherein the data acquisition and/or processing system uses the determined motion and/or vibration to determine one or more of the person's heart rate, respiration rate, S1 timing, S2 timing, blood pressure or blood pressure trends, PWV or PWVI, and indicators of heart murmurs.

18. The system according to claim 14 further comprising a power supply system electrically coupled to the data acquisition and/or processing system.

19. The system according to claim 14, wherein the acoustic shield is disposed between the earplug housing and external environment.

20. The system according to claim 14, wherein the earplug housing is made of compressible foam, a biocompatible rigid or semirigid polymer, or the like.

21. The system according to claim 14, wherein the sensing element is a strain gage, a PVDF film, an accelerometer, a piezoceramic substrate, or the like.

22. The system according to claim 14, wherein the earplug housing, the sensing element, the preamplification circuit and the acoustic shield are located within the ear.

23. A headset device for positioning and retaining at least one of the system according to claim 14 in the tympanic membrane of at least one ear.

24. The headset device according to claim 23, wherein the preamplification circuitry is disposed within the headset.

25. The headset device according to claim 23, wherein the data acquisition and signal processing system is either integral to the headset device or external to the headset device.

26. The headset device according to claim 25, wherein the data acquisition and/or signal processing system is used to determine one or more of the person's heart rate, respiration rate, S1 timing, S2 timing, blood pressure or blood pressure trends, PWV or PWVI, and indicators of heart murmurs.

27. The headset device of claim 10 having a system according to claim 1 in each ear, wherein signals associated with motion and/or vibration of the external acoustic meatus from each ear can be used to assess signal quality, perform motion artifact rejection, and the like.

28. The headset device of claim 23 having a system according to claim 14 in each ear, wherein signals associated with motion and/or vibration of the external acoustic meatus from each ear can be used to assess signal quality, perform motion artifact rejection, and the like.

29. A method for determining cardiovascular parameters of a person, the method comprising:

placing a sensing device within a person's ear;

placing a blood-pressure waveform sensor at a location distal to the heart;

obtaining a first set of waveforms from the sensing device;

obtaining a second set of waveforms from the blood-pressure waveform sensor;

performing a signal processing or conditioning operation using the first and second sets of waveforms;

determining a time delay between the dicrotic notch component of the conditioned blood-pressure waveform signal and the S2 component of the conditioned ear sensor signal;

determining a blood pressure pulse transit time value by adding S2D, representing a time delay between a person's heart valve closure time and an arrival time of the S2 signal at the first distal location, to the time delay between the dicrotic notch signal and the S2 signal; and

determining cardiovascular parameters of a person using the determined blood pressure pulse transit time and at

least one physical parameter representative of a arterial distance between a location of aortic valve of the heart and a location of the blood-pressure waveform sensor.

**30.** The method according to claim 29, wherein the sensing device is a motion or vibration sensing device.

**31.** The method according to claim 29, wherein cardiovascular parameters include blood pressure-wave velocity, heart rate, a person's heart isovolumetric contraction period or the like.

**32.** The method according to claim 29, wherein performing a signal processing or conditioning operation comprises one or more of performing an ensemble averaging operation, performing a processing using a bandpass filter, and performing a processing to determine a stable detection point on the S2 signal from the ear.

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| [标]申请(专利权)人(译) | 西南研究会   |         |            |
| 申请(专利权)人(译)    | 西南科学研究院   |         |            |
| 当前申请(专利权)人(译)  | COLIN医疗科技股份有限公司   |         |            |
| [标]发明人         | HONEYAGER KEVIN S<br>BARTELS KEITH A<br>CANADY LARRY D JR   |         |            |
| 发明人            | HONEYAGER, KEVIN S.<br>BARTELS, KEITH A.<br>CANADY, LARRY D. JR.                                  |         |            |
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摘要(译)

用于从人的耳朵获得的身体声音确定生理参数的方法和系统。在各种示例性实施例中，该系统包括耳塞外壳；传感元件设置在耳塞外壳的一部分内；声屏蔽连接到耳塞外壳，声屏蔽减少或消除体外声音；以及电耦合到传感元件的前置放大电路。在各种示例性实施例中，该系统可操作以由于内部产生的身体声音而确定外耳道或耳朵的鼓膜的运动和/或振动。

