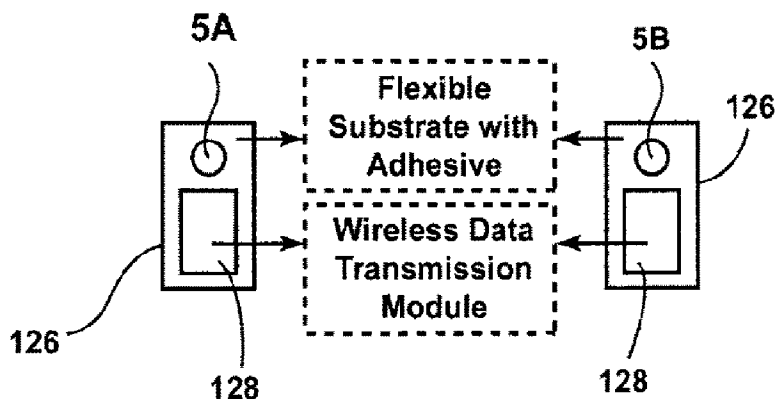




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(57) Abrégé/Abstract:

A multi-channel stethographic device includes a plurality of individual stethoscopes that may be embedded in a foam pad or surface mounted on a thin flexible substrate. Additional stethoscopes for the heart and thorax may also be utilized. The system may include a signal conditioning circuit, wireless DAQ module, and software (algorithms). The algorithms are configured to identify and diagnose various disease conditions such as pneumonia, chronic obstructive pulmonary disease (COPD), asthma, congestive heart failure (CHF), and vocal cord dysfunction (VCD).

ABSTRACT OF THE DISCLOSURE

A multi-channel stethographic device includes a plurality of individual stethoscopes that may be embedded in a foam pad or surface mounted on a thin flexible substrate. Additional stethoscopes for the heart and thorax may also be utilized. The system may include a signal conditioning circuit, wireless DAQ module, and software (algorithms). The algorithms are configured to identify and diagnose various disease conditions such as pneumonia, chronic obstructive pulmonary disease (COPD), asthma, congestive heart failure (CHF), and vocal cord dysfunction (VCD).

STETHOGRAPHIC DEVICE

RELATED APPLICATION

[0001] The instant application claims the benefit of priority to United States Provisional Patent Application serial number 62/650,781, filed March 30, 2018, and entitled "STETHOGRAPHIC DEVICE".

BACKGROUND OF THE INVENTION

[0002] Stethoscopes are used to obtain the acoustic information from the chest of a patient to facilitate diagnosis of various conditions.

[0003] Several categories of heart and lung sounds may be detected and classified utilizing a stethoscope. Clinicians may listen to lung sounds using a stethoscope. However, this process may be subject to a variety of limitations. In an effort to overcome limitations of stethoscopes, research has been conducted to develop robust computerized system to record heart and lung sounds for various cardiovascular diseases (CD) analysis.

[0004] Computerized systems for recording either lung sounds or heart sounds are known. For example, a robust multichannel lung sound recording device has been developed as described in E. Messner, M. Hagnmüller, P. Swatek, F. M. Smolle-Jüttner, and F. Pernkopf, "Respiratory airflow estimation from lung sounds based on regression", IEEE in Acoustics, Speech and Signal Processing Conf. Proceedings, pp. 1123-1127, 2017.

The recording devices include a commercially available pre-amplifier device with an integrated ADAT interface that is commonly used for computer audio systems, stand-alone hard disk recorders, and/or analog or digital workstations.

[0005] A multi-channel computerized heart sound recording apparatus has also been developed (S. G. Wong, "Design, Characterization and Application of a Multiple Input Stethoscope Apparatus", Master thesis, California polytechnic state university, San Luis Obispo, 2014.) This recording apparatus uses a commercially available signal conditioning device which is a fixed-gain microphone amplifier.

[0006] However, known devices and processes may suffer from various drawbacks.

SUMMARY OF THE INVENTION

[0007] One aspect of the present invention is a multi-channel stethograph system including a signal conditioning circuit providing both variable gain and Wi-Fi communication. The multi-channel stethograph system provides more advanced diagnostic and monitoring capability with respect to heart and lung sounds with high precision. The multi-channel stethograph system of the present invention overcomes various limitations of prior systems.

[0008] In one aspect, there is provided a multi-channel wireless stethograph system which comprises a plurality of electronic stethoscopes each having a signal in a separate channel corresponding to sounds detected thereby; a signal condition circuit for receiving the signals from the plurality of electronic stethoscopes and for filtering and amplifying the signals; a data acquisition circuit for receiving filtered and amplified signals from the signal condition circuit and for digitizing the filtered and amplified signals; a wireless transmitter for receiving digital signals from the data acquisition circuit and for wirelessly transmitting digital signals; a wireless receiver for receiving transmitted digital signals from the wireless transmitter and for outputting the digital signals; a processor for processing and analyzing the digital signals received from the wireless transmitter; a display for displaying processed signals received from the processor. Furthermore, the signal condition circuit comprises: a second order high pass filter stage for filtering the signals from the plurality of electronic stethoscopes; an isolator amplifier stage for isolating DC voltage and amplifying and transmitting AC voltage of filtered signals received from the second order high pass filter stage; a second order active low pass filter stage for filtering signals received from the isolator amplifier stage; a third order active high pass filter stage for filtering signals received from the second order active low pass filter stage; a non-inverting amplifier stage for amplifying the signals received from the third order active high pass filter stage; and a first order passive low pass filter stage for filtering signals received from the non-inverting amplifier stage.

[0009] In some embodiments of the multi-channel wireless stethograph system, there is provided as foam pad for securing at least a subset of the plurality of electronic stethoscopes in a predefined pattern such that when the foam pad may be placed on a

patient's torso wherein each of the subset of the plurality of electronic stethoscopes is simultaneously positioned against the patient.

[0010] In another aspect, there is provided a signal conditioning circuit for a multi-channel wireless stethographic system, the signal conditioning circuit which comprises a second order high pass filter stage for filtering the signals from the plurality of electronic stethoscopes; an isolator amplifier stage for isolating DC voltage and amplifying and transmitting AC voltage of filtered signals received from the second order high pass filter stage; a second order active low pass filter stage for filtering signals received from the isolator amplifier stage; a third order active high pass filter stage for filtering signals received from the second order active low pass filter stage; a non-inverting amplifier stage for amplifying the signals received from the third order active high pass filter stage; and a first order passive low pass filter stage for filtering signals received from the non-inverting amplifier stage.

[0011] In some embodiments of the signal conditioning circuit, the stages together provide a signal-to-noise ratio of at least about 15.27 dB.

[0012] In some embodiments of the signal conditioning circuit, the stages together function as a band pass filter having a frequency range of about 50 Hz to about 1600 Hz.

[0013] In some embodiments of the signal conditioning circuit, the stages together provide a gain of at least about 24.

[0014] In some embodiments of the signal conditioning circuit, the second order high pass filter stage has a cut-off frequency of about 2.3 Hz; the second order active low pass filter stage has a cut-off frequency of about 1600 Hz; the third order active high pass filter stage has a cut-off frequency of about 50 Hz; and the first order passive low pass filter stage has a cut-off frequency of about 1600 Hz.

[0015] In yet another aspect, there is provided a method of diagnosing heart and lung diseases of a patient, the method comprising:
utilizing a plurality of stethoscopes to generate a plurality of audio data sets corresponding to each stethoscope, wherein the audio data sets comprise:

- a) at least one data set generated by a heart stethoscope positioned on the patient to generate a heart audio data set;

- b) at least one trachea data set generated by a trachea stethoscope positioned on the patient to generate a trachea audio data set; and
- c) a plurality of lung data sets generated by a plurality of lung stethoscopes positioned on the patient;

utilizing a signal conditioning circuit for receiving signals from the plurality of stethoscopes and for filtering and amplifying the signals to provide the audio data sets;

utilizing a computing device to extract features comprising respiratory rates, inspiration and expiration from the trachea data set;

utilizing a computing device to extract features comprising heartbeat rate and abnormal heartbeat patterns from the heart data set;

utilizing a computing device to extract features comprising wheeze, rhonchi, squawk, coarse crackle and fine crackle and corresponding frequencies from the lung data sets; and

causing a computing device to utilize predefined disease criteria and the extracted features to determine a result, wherein the result comprises at least one of COPD, asthma, VCD, pneumonia, or CHF,

wherein the signal conditioning circuit comprises:

- a second order high pass filter stage for filtering the signals from the plurality of electronic stethoscopes;

- an isolator amplifier stage for isolating DC voltage and amplifying and transmitting AC voltage of filtered signals received from the second order high pass filter stage;

- a second order active low pass filter stage for filtering signals received from the isolator amplifier stage;

- a third order active high pass filter stage for filtering signals received from the second order active low pass filter stage;

- a non-inverting amplifier stage for amplifying the signals received from the third order active high pass filter stage; and

- a first order passive low pass filter stage for filtering signals received from the non-inverting amplifier stage.

[0016] In some embodiments of the method, the predefined disease criteria for COPD comprises at least one of wheeze, rhonchi, inspiration-expiration ratio, high inspiration lag and lead time, high expiration time delay, or abnormal respiratory rates.

[0017] In some embodiments of the method, the predefined disease criteria for asthma comprises at least one of wheeze, rhonchi, low inspiration-expiration ratio, high expiration time delay, or abnormal respiration rates; and wherein asthma is diagnosed if inspiration lag and lead time are not present in the data sets.

[0018] In some embodiments of the method, the predefined disease criteria for VCD comprises at least one of a) wheeze, or b) highly symmetrical wheeze at both lungs, wherein a symmetry coefficient is utilized to determine if the wheeze meets predefined VCD symmetry criteria.

[0019] In some embodiments of the method, the predefined disease criteria for pneumonia comprises at least one of a) coarse crackles, b) rhonchi, c) squawk, or d) abnormal respiratory rate, wherein coarse crackles are determined to be present if discontinuous adventitious lung sounds with low frequency are detected in one or more of the data sets; and wherein squawks are determined to be present if short duration wheeze having quick sinusoidal waveform is detected in one or more of the data sets.

[0020] In some embodiments of the method, the predefined disease criteria for CHF comprises at least one of a) coarse crackle, b) irregular heartbeat, or c) abnormal respiration rates, wherein the irregular heartbeat includes a rapid heartbeat rate and an abnormal heartbeat pattern.

[0021] In some aspects of the method, the predefined COPD criteria comprises a) an inspiration-expiration ratio below about 0.7, b) an inspiration lag and lead time greater than about 3 ms, c) an expiration time delay greater than about 3 ms, and d) respiratory rates that are less than about 12 breaths per minute or greater than about 25 breaths per minute.

[0022] In some embodiments of the method, the predefined VCD symmetry criteria comprises a symmetry coefficient equal to or greater than about 0.5.

[0023] In some embodiments of the method, the method includes utilizing a predefined pneumonia criteria comprising respiratory rates less than about 12 breaths per minute or greater than about 25 breaths per minute; utilizing a coarse crackles criteria comprising discontinuous adventitious lung sounds having a frequency equal to or less than about 333 Hz; and utilizing a squawk criteria comprising wheeze of equal to or less than about 100 ms.

[0024] In some embodiments of the method, the method includes determining that coarse crackle is detected utilizing predefined criteria comprising discontinuous adventitious lung sounds having a frequency equal to or less than about 333 Hz are present; determining that an abnormal respiration rate is detected utilizing predefined criteria comprising a) respiration rates less than about 12 breaths per minute, or b) respiration rates above about 25 breaths per minute; and determining that a rapid heartbeat is detected utilizing predefined criteria comprising a heartbeat rate equal to or above about 100 beats per minute is detected.

[0025] In some embodiments of the method, the method comprises determining that fine crackles are detected utilizing predefined criteria comprising crackles having a frequency equal to or greater than about 333 Hz; and determining that an abnormal respiration rate is detected utilizing predefined criteria comprising respiration rates less than about 12 breaths per minute or respiration rates above about 25 breaths per minute are detected.

[0026] These and other features, advantages, and objects of the present invention will be further understood and appreciated by those skilled in the art by reference to the following specification, claims, and appended drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] FIG. 1 is a partially fragmentary perspective view of a stethograph system according to one aspect of the present invention;

[0028] FIG. 2 is a schematic drawing of the components of the stethograph system of FIG. 1;

[0029] FIG. 3 is a schematic drawing of software data flow of the stethograph system of FIG. 1;

[0030] FIG. 4 is a schematic drawing showing a multi-channel wireless stethograph system according to another aspect of the present invention;

[0031] FIG. 5 is a partially fragmentary perspective view of a stethoscope according to one aspect of the present invention;

[0032] FIG. 6 is a schematic top plan view of a foam pad according to one aspect of the present invention;

[0033] FIG. 7 is a schematic side elevational view of the foam pad of FIG. 6;

- [0034]** FIG. 8 is a schematic top plan view of a foam pad according to another aspect of the present invention;
- [0035]** FIG. 9 is a schematic side elevational view of the foam pad of FIG. 8;
- [0036]** FIG. 10 is a partially schematic flowchart showing production of a foam pad with stethoscopes according to one aspect of the present invention;
- [0037]** FIG. 11 is a circuit diagram showing a signal conditioning circuit according to one aspect of the present invention;
- [0038]** FIG. 12 is a schematic of a power circuit of FIG. 11;
- [0039]** FIG. 13 is a schematic of a second power circuit;
- [0040]** FIG. 14 comprises graphs showing the result of a single channel input signal of 244 mV and amplified output signal of 6.08 V with gain of 24.9;
- [0041]** FIG. 15 is an isometric view showing components of a wireless DAQ;
- [0042]** FIG. 16 is a graphical user interface (GUI) showing real time sound waveforms;
- [0043]** FIG. 17 is a GUI showing audio.WAV files and waveforms that may be utilized to analyze the heart and lung conditions by visual examination;
- [0044]** FIG. 18 is a screenshot (GUI) showing waveforms plotted in Version 1.0 by STG 16 software;
- [0045]** FIG. 19 is a screenshot (GUI) showing waveforms plotted in Version 2.0 by a custom built MATLAB program; and
- [0046]** FIG. 20 is a perspective view of a chair and component organizer that may be utilized to support the components of the multi-channel stethograph system in use;
- [0047]** FIG. 21 is a rear perspective view of the chair and organizer of FIG. 20;
- [0048]** FIG. 22 is a screen shot (GUI) of waveforms generated during testing, wherein the waveforms are generated by a MATLAB program according to one aspect of the present invention;
- [0049]** FIG. 23 is a graph (GUI) showing the time expanded waveform of a heart sound generated during testing of a device according to the present invention;
- [0050]** FIG. 24 is a graph (GUI) showing the signal-to-noise ratio of a heart signal measured by a MATLAB program according to one aspect of the present invention;
- [0051]** FIG. 25 is an electrical circuit diagram in block form of a wireless multi-channel stethograph system according to one aspect of the present invention;

[0052] FIG. 26 is a front and back view of a wearable version of a wireless multi-channel stethograph system according to one aspect of the present invention;

[0053] FIG. 27 is a back view of the multi-channel stethograph system of FIG. 26; and

[0054] FIG. 28 is a schematic view of flexible microphone patches of the system of FIGS. 26 and 27 for the heart and trachea.

DETAILED DESCRIPTION

[0055] FIG. 1 shows a 16-channel stethograph system 1 according to one aspect of the present invention. Each of the 16 channels corresponds to data collected by sixteen stethoscopes. Stethograph system 1 is capable of acquiring acoustic sounds from a patient's lung, trachea and heart, and simultaneously converting the sounds to an electrical signal. As discussed below, system 1 also includes noise filtering capabilities.

[0056] With reference to FIGS. 1 and 2, the stethograph system 1 includes a sensor assembly 2 comprising a memory foam padding 3 with fourteen stethoscopes 4, two additional stethoscopes 5A and 5B for heart and thorax, a signal conditioning box 6, a screw terminal panel 7, a DAQ 8, and a standard PC 10 configured to execute software developed by Stethographics Inc. of Boston, Massachusetts.

[0057] As discussed in more detail below in connection with FIG. 5, the stethoscopes 4, 5A, 5B may be fabricated by placing microphone-based transducers 38 in a polymer casing 40 with a diaphragm 44. As shown in FIGS. 6 and 8, fourteen stethoscopes 4 may be positioned in the memory foam padding 3 to thereby position stethoscopes 4 at predefined chest cavity locations (over the posterior chest and lateral bases). This placement/positioning enables accurate sensing/acquisition of lung sounds. A first external stethoscope 5A may be placed on an area of a patient near the patient's heart to sense heart sounds. A second external stethoscope 5B may be on the side of a patient's wind pipe to monitor tracheal sounds. Signal conditioning box 6 may be used to reduce noise and to amplify electrical signals acquired from the stethoscopes 4, 5A, 5B. The data acquisition (DAQ) system 8 may be used to acquire the amplified analog signals from the signal conditioning box 6 through screw terminal panel 7. The analog signals are then converted to digital signals. The digital signals may be recorded and analyzed using a computer 10 running software to detect/identify any disorders in the lungs and heart.

In a preferred embodiment, the digital signals have a signal to noise ratio (SNR) of at least about 7.3 dB. This software is available from Stethographics Inc. of Boston Massachusetts.

[0058] Data flow of the software is shown schematically in FIG. 2. Digital data from DAQ 8 is transferred to computer 10 via a USB cable. In use, the software program launches a LabVIEW VI program which configures the DAQ 8 and records a data sample (e.g. 20 seconds) for each channel/stethoscope. The LabVIEW VI program also converts the channel buffers to .WAV file format by using a 'C' DLL program. Then, the program opens the .WAV files directly and reads in the .WAV files, to plot and analyze the sound data.

[0059] A second multi-channel stethograph system 20 according to another aspect of the present invention is shown schematically in FIG. 4. The multi-channel stethograph system 20 includes a high-density memory foam pad 23 embedded with fourteen stethoscopes 24, a 16-channel signal conditioning system 26, DAQ 28 with Wi-Fi chassis, and a Wi-Fi enabled computer 30 (e.g. a PC or tablet) with LabVIEW® program. External stethoscopes 25A, 25B may be utilized for the heart and thorax. Stethoscopes 4, 5A, 5B, 24, 25A, 25B may have substantially identical construction.

[0060] With reference to FIG. 5, a stethoscope 24 for stethoscope systems 1 and/or 20 may be fabricated by placing microphone based transducers 38 in a through-hole 41 of a disk-shaped casing 40. Casing 40 may be formed by machining a polymer (e.g. Delrin®) material. The casings/disks 40 have a height of 0.5 inches and a radius of 0.875 inch. A wire 42 from transducer 38 is disposed in a groove 43 formed in disk 40. Transducer 38 is covered by a 3M Littmann diaphragm 44. Fourteen stethoscopes 24 are positioned in a high-density memory foam pad 23 (FIG. 4). The high-density memory foam pad 23 provides good contact with a patient's chest wall. Foam pad 23 also provides comfort to the patient and conforms to the patient's body contour when lying/leaning on the pad 23. Still further, pad 23 also provides acoustic isolation from stethoscope-to-stethoscope.

[0061] In use, the stethoscopes are placed directly on the heart and trachea areas to acquire sounds simultaneously from the lung, heart and trachea. The lungs, heart and trachea sounds are very small in amplitude and produce very small electrical signals from the stethoscopes (<100 mV). This may create difficulties with respect to direct analysis of the sound characteristics. The sounds (electrical signals) acquired from the sixteen

stethoscopes 24, 25A, 25B are processed (noise reduction and amplification) through a 16-channel signal conditioning PCB 26. A National Instruments (NI) data acquisition system (DAQ) 28 may be used to acquire and convert the conditioned signal from the PCB 26 to a digital signal. An NI wireless module of DAQ 28 is used to wirelessly transmit the digital data to a Wi-Fi enabled computer 30 (e.g. a PC or tablet). A custom LabVIEW program 32 records/stores the digital data from the DAQ 28. A MATLAB program 34 converts the recorded data from the stethoscopes 24, 25A, 25B into 16 audio files (for audio playback) and plots the audio waveforms in time domain for visual examination.

[0062] Examples of waveforms displayed on a screen of computer 30 via graphical user interfaces (GUIs) are discussed below in connection with FIGS. 16-19. Visual examination of the audio waveforms can be used to identify abnormal patterns in breathing (inspiration and expiration). This provides information on any wheezes, crackles and rhonchi sounds which helps in analyzing the condition of the heart and the lungs. The audio waveforms are displayed in a time expanded mode and provide objective evidence to assist physicians with respect to clinical diagnosis and monitoring of lung and heart disorders, particularly chronic obstructive pulmonary disease (COPD), asthma, pneumonia, and congestive heart failure.

[0063] Foam pads 3, 23 (FIGS. 6-9) may comprise high density memory foam having 5.3 lbs/Cubic ft density with indentation force deflection (IFD) of 9-10 lbs/50 sq. inches. High-density memory foam provides better compression rates and longer life compared to medium and low-density memory foams. Top and bottom memory foam pads 3A and 3B respectively of foam pad 3 (FIGS. 6, 7) are 15 inches in length and 9 inches in width, and have 0.5 inches and 1 inch thickness, respectively. The top and bottom memory foam pads 23A and 23B of pad 23 (FIGS. 8, 9) are 17 inch in length and 11 inches in width with a thickness of 1 inch each.

[0064] With reference to FIG. 10, at steps 10A and 10B, 40 mm holes 46 were formed (e.g. punched out) in the top memory foam pad layers 3A, 23A to embed the stethoscopes. At step 10C, the punched-out pieces from the foam pad were sliced horizontally in half (0.5 inch thick). These cut pieces 48 are then attached to the bottom of the stethoscopes 24 to hold the stethoscopes 24 in place without being pushed into the foam pad 3, 23 when placed behind the patient's chest. To attach the cut pieces 48 to the stethoscopes, a dummy memory foam pad with punched-out holes was made. The

stethoscopes 24 were inserted into the dummy foam pad holes and the punched-out memory foam pieces were attached to the stethoscopes 24 using a spray adhesive as shown at step 10E. The dummy foam pad protects the sides and top part of the casings/discs 40 from being exposed to the spray adhesive. The stethoscopes 24 were glued to the punched-out foam pieces 48 to form assemblies 50 as shown at step 10F.

[0065] Then, the assemblies 50 comprising stethoscopes 24 glued to the foam pieces 48 were embedded into the top memory foam pad layer (3A or 23A). In order to relieve stress on the stethoscope wires, superficial cuts were made in the memory foam pad, and the top and bottom layers 3A, 3B and 23A, 23B are adhered together utilizing spray adhesive.

[0066] The electrical signals generated by the stethoscopes 24, 25A, 25B in response to noise comprise small voltages (<100 mV) that are prone to external noise such as body noises, ambient/background noises, etc. These signals therefore cannot be used directly for further analysis. To address this issue, a signal conditioning circuit 52 (FIG. 11) may be used to reduce the noise level in the electrical signal and amplify it for further analysis such as analog-to-digital (A/D) conversion or to plot the waveforms.

[0067] Signal conditioning circuit 52 was designed with a gain of 24 with an operating frequency range from about 50 Hz to about 1600 Hz. Various components such as capacitors, resistors, and IC chips were used for building filters and amplifiers, and IL300-DEPO were used as isolators. In addition to this, two power supply circuit designs: power circuit_1 (FIG. 12) and power circuit_2 (FIG. 13) were used for generating specific voltages to power the signal conditioning circuit for Section 1 and Section 2, respectively.

[0068] The signal conditioning circuit is divided in to 6 stages with each stage performing a particular function. Stage 1 is a second order high pass filter powered by power circuit_1 and it includes a passive high pass filter with cut-off frequency of 2.3 Hz (for blocking the DC) (Eq. (1)) and a non-inverting amplifier (to amplify the input ac signal from stethoscope) with a gain of 6 calculated using Eq. (2):

$$\text{Frequency} = \frac{1}{2\pi \cdot R1 \cdot C1} = 2.3 \text{ Hz} \quad (1)$$

$$\text{Gain} = 1 + \frac{R17}{R18} = 6 \quad (2)$$

[0069] Stage 2 functions as an isolator amplifier (powered by power circuit_1 and power circuit_2) and isolates the DC voltage from power circuit_1. It allows only the AC signal from stage 1 and amplifies this signal with a gain of 1.14, calculated based on the Eq. (3):

$$\text{Gain} = \frac{K2 \cdot R5}{K1 \cdot R20} = 1.14 \quad (3)$$

[0070] Stage 3 is a second order active low pass filter with a cut-off frequency of 1600 Hz, calculated using Eq. (4). The signal frequencies (from stage 2) that are greater than 1600 Hz are considered to be interference sounds and are filtered in order to reduce the noise. Stage 3 is powered by power circuit_2.

$$\text{Frequency} = \frac{1}{2\pi^2 \sqrt{C11 \cdot C12 \cdot R8 \cdot R9}} = 1600 \text{ Hz} \quad (4)$$

[0071] Stage 4 is a third order active high pass filter with a cut-off frequency at 50 Hz, calculated using Eq. (5), and powered by power circuit_2. The signal frequencies from stage 3 that are lower than 50 Hz are considered as noises and are filtered.

$$\text{Frequency} = \frac{1}{2\pi^3 \sqrt{C7 \cdot C8 \cdot C9 \cdot R4 \cdot R7 \cdot R14}} = 50 \text{ Hz} \quad (5)$$

[0072] Stage 5 is a non-inverting amplifier and amplifies the signal from stage 4 with a gain of 3.5 and is powered by power circuit_2.

$$\text{Gain} = 1 + \frac{R13}{R12} = 3.5 \quad (6)$$

[0073] The stage 6 is a first order passive low pass filter with cut-off frequency at 1600 Hz, calculated using Eq. (7), and is powered by power circuit_2.

$$\text{Frequency} = \frac{1}{2\pi \cdot R15 \cdot C15} = 1600 \text{ Hz} \quad (7)$$

[0074] In summary, stage 1, stage 3, stage 4 and stage 6 together function as a band pass filter with frequency range from 50 Hz to 1600 Hz.

[0075] During testing of circuit 52, a 200 mV AC signal was supplied to the input of 50 Hz frequency and an output signal of 4.9 V AC at 50 Hz was observed on a digital oscilloscope with a gain of 24.5.

[0076] FIG. 12 is a schematic of power circuit_1, which includes various components such as a transformer driver (MAX845ESA), a DC/DC Converter (TGM-250) along with a diode circuit for generating +2.5 V, a negative low dropout micro power regulator (LT1175CST) for generating -5 V and a low dropout micro power regulator (LM1117MPX) for generating +5 V. Power circuit_1 provides output voltages of +5 V, -5 V and +2.5 V for the input voltage 9 V DC. Section 1 in FIG. 12 shares the ground with Section 1 in FIG. 11. Similarly, Section 2 in FIG. 12 shares the ground with Section 2 in FIG. 11.

[0077] FIG. 13 is a schematic of power circuit_2 which includes various components such as a low-dropout linear regulator (LM1117MPX) for generating +5 V, a micro power inverting DC/DC converter (LT1617ES5) for generating -5 V and -4.1 V. Power circuit_2 provides output voltages of +5 V, -5 V and -4.1 V for the input voltage 9 V DC. Power Circuit_2 shares the ground with Section 2 of signal conditioning circuit in FIG. 11.

[0078] After implementing the signal conditioning circuit for single channel on a breadboard (not shown), a STEP file of the 16-channel signal conditioning circuit was generated and a PCB was fabricated. The fabricated 16-channel signal conditioning PCB was mounted with a 44-pin D-sub female connector and a 37-pin D-sub female connector to connect the foam pad 23 and DAQ 28, respectively. The 16-channel signal conditioning circuit may be powered by an AC to DC adapter that converts 100-240V AC to 9 V DC. With reference to FIG. 14, a 244 mV AC ("Channel A Input") is supplied as the input signal at 50 Hz frequency, and an output signal ("Channel A Output") of 6.08 V AC at 50 Hz was observed on a digital oscilloscope with a gain of 24.9.

[0079] With reference to FIG. 15, an NI-9205 C series voltage input module DAQ system 58 was used to acquire the analog signal from the signal conditioning circuit 52, and the analog signal is converted to a digital signal using an in-built A/D converter. An NI DAQ-9191 Wi-Fi module 60, with chassis, was used to transmit the digital signals from DAQ 58 to Wi-Fi enabled devices (FIG. 15). These DAQ and Wi-Fi chassis modules were chosen because the DAQ 58 can fit in the chassis 60 as one unit, providing a compact and portable system.

[0080] Bluetooth 4.0 and Wi-Fi 802.11 (a, b, g, n) are widely used communication protocols for wireless data transmission. Table 1 (below) summarizes the characteristics of Wi-Fi and Bluetooth. Even though Bluetooth offers better battery life with lower power consumption when compared to Wi-Fi, the data throughput, bit rate and access range is lower for Bluetooth. Wi-Fi wireless transmission was chosen for the systems 1, 20 because the minimum raw bit rate required is 2.93 Mbps (Appendix B) which cannot, at present, be achieved by Bluetooth communication.

Name	Bluetooth Classic	Bluetooth 4.0 Low Energy (BLE)	ZigBee	WiFi
IEEE Standard	802.15.1	802.15.1	802.15.4	802.11 (a, b, g, n)
Frequency (GHz)	2.4	2.4	0.868, 0.915, 2.4	2.4 and 5
Maximum raw bit rate (Mbps)	1-3	1	0.250	11 (b), 54 (g), 600 (n)
Typical data throughput (Mbps)	0.7-2.1	0.27	0.2	7 (b), 25 (g), 150 (n)
Maximum (Outdoor) Range (Meters)	10 (class 2), 100 (class 1)	50	10-100	100-250
Relative Power Consumption	Medium	Very low	Very low	High
Example Battery Life	Days	Months to years	Months to years	Hours
Network Size	7	Undefined	64,000+	255

[0081] A custom built LabVIEW program 32 (FIG. 4) was developed in the Wi-Fi enabled device (PC or tablet) to acquire the digital signals from the Wi-Fi module, which were converted and conditioned from lung, heart and trachea sounds sensed by the stethoscopes. In the LabVIEW program, 'DAQ Assistant' function was used to select the data channels (1-16) and the sample rate, which was 8 kHz for one channel and 128 kHz for 16 channels. The 'Waveform Graph' function was used to display the real time waveform signals on the display screen of computer 10, 30. The 'Time Target' function was used to set the sound recording time of the wireless multi-channel stethograph system for 20 seconds. 'Write to Measurement File' option was used to save the recorded data in a '.lvm' format database. The real time sound waveform sensed by the 16 stethoscopes may be shown simultaneously on the custom built graphical user interface (GUI) 62 (FIG. 16) and the data may be saved in '.lvm' file format.

[0082] A MATLAB program 34 (FIG. 4) was developed to convert the recorded data from LabVIEW program into 16 audio files of '.WAV' format (for audio playback) as shown

in FIG. 17 and to plot the waveforms for analyzing the heart and the lung conditions by visual examination. The 'textread' command may be used to load the data recorded by LabVIEW and loop logic was used to select the channels. In addition to this, 'audiowrite' command may be used to convert the recorded data to '.WAV' audio format and the 'audioread' command may be used to plot the waveforms from the audio file.

[0083] FIGS. 18 and 19 show time unexpanded mode waveforms plotted in stethograph system version 1.0 (by using STG 16 software) and version 2.0 (by using custom built MATLAB program), respectively. The waveforms plotted in the two versions are visually identical. The sounds generated by the heart and trachea are more prominent in amplitudes than the sounds generated by lungs. Thus, the waveforms on channel 8 (heart sound) and channel 16 (tracheal sound) have much higher amplitude than other channels.

[0084] To make the version 1.0 software compatible with version 2.0 hardware, the I/O function of the LabVIEW VI program in version 1.0 was replaced with the new I/O function specifying the pin numbers of the channels of the wireless DAQ.

[0085] With further reference to FIGS. 20 and 21, a chair 64 having a back 65 may be utilized during patient testing. An organizer 66 made from flexible fabric or other suitable material may be positioned on the chair back 65. The organizer 66 includes pockets A, B, and C as shown in FIG. 21. Pocket A may be utilized to store the stethoscopes, pocket B may be used to store the signal conditioning PCB, and pocket C may be utilized to store the DAQ with Wi-Fi unit. Referring again to FIG. 20, the foam pad 23 with stethoscopes 24 may be positioned on a front side 68 of chair back 65 for patient testing. A patient sitting in chair 64 leans back against the foam pad 23 and stethoscopes 24, thereby permitting the stethoscopes 24 to generate data as discussed above. It will be understood that the additional stethoscopes 25A and 25B may also be connected to the patient's heart (front side of chest) and thorax while the patient is sitting in the chair 64.

[0086] With further reference to FIGS. 22-24, testing of a multi-channel stethograph system 20 according to the present invention resulted in the waveforms shown in FIG. 22. More specifically, FIG. 22 is a screen shot (GUI) of a computer 30 showing the output of a MATLAB program according to one aspect of the present invention. FIG. 23 is a screen shot (GUI) showing a time expanded waveform of a heart

sound generated during testing of a multi-channel stethograph system according to the present invention. FIG. 24 is a graph (GUI) showing the signal-to-noise ratio of a heart signal measured by a MATLAB program according to one aspect of the present invention.

[0087] The waveforms in time domain were analyzed and converted to spectrograms as well as frequency domain using digital signal processing techniques such as continuous wavelet transform (CWT) and fast Fourier transform (FFT)/discrete Fourier transform (DFT) by MATLAB® Script, respectively. The time domain plots, frequency domain plots, and spectrograms provide information about the inspiration, expiration and heart rhythms from the recorded lung, heart and trachea sounds. Any abnormal patterns such as crackles, squawks, wheeze, rhonchi, and rale can be identified and analyzed from the plotted waveforms in time domain, frequency domain and spectrogram with the help of custom designed algorithms developed using box filter, signal envelope, digital filter, 2-D correlation coefficient and cross-correlation. These custom developed algorithms are employed to identify and diagnose the disease conditions such as Pneumonia, Chronic obstructive pulmonary disease (COPD), Asthma, Congestive heart failure (CHF), Vocal cord dysfunction (VCD).

[0088] Methods such as statistical analysis, digital signal processing (such as CWT, FFT, DFT, short-time Fourier transform (STFT)) or neural networks (such as shallow neural networks, deep convolution neural networks) can be used for classification and identification. The methods can be developed on platforms such as MATLAB® Script, C, C++, Python, C#, Perl programming languages.

[0089] The components such as signal conditioning circuit and wireless DAQ module can be fabricated in to a single compact and miniaturized PCB module, and placed within the foam pad as shown in Fig. 1.

[0090] As shown in Fig. 25, the miniaturization can be done using a bias circuit 100, a first order low pass filter 102, a 16-channel ADC integrated circuit 104 paired with a microprocessor 106 with Wi-Fi capabilities or interfaced with an off-the-shelf Wi-Fi module 108. Isolation can be accomplished with a medical-rated DC power supply 110 providing power to a +5V analog boost regulator 112 and a +2.5V-3.3V digital regulator 114 with an optional battery 116. A quality ADC with low voltage range, built-in buffers, and digital oversampling can greatly simplify the design so that even active components might be eliminated from the design.

[0091] This multi-channel stethograph system can be implemented as a wearable device that can be attached either directly to the skin or integrated into a jacket/cloth for continuous monitoring of lung and heart conditions. As shown in FIGS. 26 and 27, this can be achieved by developing the system on a flexible substrate 120. Substrate 120 may comprise a suitable polyester film such as polyethylene terephthalate (PET), polyethylenenaphthalate (PEN); polyimide films such as Kapton, Upilex; paper/coated papers; polyurethane plastics/ thermoplastic elastomers such as thermoplastic polyurethane; silicon based organic polymers such as polydimethylsiloxane (PDMS), Ecoflex. The array of microphones 4 and electrical components 124, including signal conditioning components 26 and DAQ components 28, can be surface mounted on flexible substrate 120. The interconnects for the circuit can be deposited using additive print manufacturing processes such as screen, inkjet, flexography, aerosol jet or gravure. The materials used for printing may include non-transparent, transparent, flexible and stretchable inks that could be conductors, semi-conductors and dielectrics.

[0092] Surface mounted microphones 5A and 5B may be attached to flexible substrate patches 126. Circuits 128 may have wireless capabilities, and may be placed close to the heart and trachea of a patient using adhesives to thereby acquire heart and trachea sounds. The system can be powered using either conventional batteries or printed and flexible batteries. The data collected from the flexible and hybrid multi-channel stethograph system can be wirelessly streamed and stored in cloud networks or health care servers for maintaining and accessing patient records remotely.

[0093] The multi-channel stethograph system of the present invention records and plots heart and lung sounds non-invasively using 16 stethoscopes. As discussed above, the stethoscopes may be fabricated by placing microphones in a CNC machined polymer material covered material that is covered using a diaphragm. Fourteen of the stethoscopes are positioned in a memory foam pad 23, and two may be placed directly on the heart and trachea. This enables the system to acquire sound simultaneously from the lung, heart, and trachea. The sounds acquired from the 16 stethoscopes are processed through a custom designed 16-channel signal conditioning PCB. A data acquisition system (DAQ) and WiFi chassis may be used to acquire and wirelessly transmit the data from the 16-channel PCB to a WiFi-enabled device such as a PC or tablet. The system includes a custom LabVIEW program developed on the WiFi-enabled device to

record the data from the DAQ. In addition, a MATLAB program was developed to convert the recorded data from the stethoscopes into 16 audio files for audio playback, and to plot the waveforms in time domain.

[0094] The system has an amplification gain of at least about 24, and a signal to noise ratio of at least about 15.27 dB (measured for the heart signal). The recorded audio files and plotted waveforms of the lung, heart and trachea sounds demonstrated that the multi-channel stethograph system 20 may be utilized for visual examination to determine if abnormal patterns in inspiration and expiration are present. The stethographic device/system provides information to a physician to facilitate diagnosing and analyzing the condition of a patient's heart and lungs.

[0095] Information as herein shown and described in detail is fully capable of attaining the above-described object of the present disclosure, the presently preferred embodiment of the present disclosure, and is, thus, representative of the subject matter which is broadly contemplated by the present disclosure. The scope of the present disclosure fully encompasses other embodiments which may become apparent to those skilled in the art, and is to be limited, accordingly, by nothing other than the appended claims, wherein any reference to an element being made in the singular is not intended to mean "one and only one" unless explicitly so stated, but rather "one or more." Moreover, no requirement exists for a system or method to address each and every problem sought to be resolved by the present disclosure, for such to be encompassed by the present claims. Furthermore, no element, component, or method step in the present disclosure is intended to be dedicated to the public regardless of whether the element, component, or method step is explicitly recited in the claims. However, that various changes and modifications in form, material, work-piece, and fabrication material detail may be made, without departing from the spirit and scope of the present disclosure, as set forth in the appended claims, as may be apparent to those of ordinary skill in the art, are also encompassed by the disclosure.

CLAIMS

The invention claimed is:

1. A multi-channel wireless stethograph system comprising:
 - a plurality of electronic stethoscopes each having a signal in a separate channel corresponding to sounds detected thereby;
 - a signal condition circuit for receiving the signal from each of the plurality of electronic stethoscopes and for filtering and amplifying the signals;
 - a data acquisition circuit for receiving filtered and amplified signals from the signal condition circuit and for digitizing the filtered and amplified signals;
 - a wireless transmitter for receiving digital signals from the data acquisition circuit and for wirelessly transmitting digital signals;
 - a wireless receiver for receiving transmitted digital signals from the wireless transmitter and for outputting the digital signals;
 - a processor for processing and analyzing the digital signals received from the wireless transmitter; and
 - a display for displaying processed signals received from the processor,wherein the signal condition circuit comprises:
 - a second order high pass filter stage for filtering the signals from the plurality of electronic stethoscopes;
 - an isolator amplifier stage for isolating DC voltage and amplifying and transmitting AC voltage of filtered signals received from the second order high pass filter stage;
 - a second order active low pass filter stage for filtering signals received from the isolator amplifier stage;
 - a third order active high pass filter stage for filtering signals received from the second order active low pass filter stage;
 - a non-inverting amplifier stage for amplifying the signals received from the third order active high pass filter stage; and
 - a first order passive low pass filter stage for filtering signals received from the non-inverting amplifier stage.

2. The multi-channel wireless stethograph system of claim 1, including:
 - a foam pad for securing at least a subset of the plurality of electronic stethoscopes in a predefined pattern such that when the foam pad may be placed on a patient's torso wherein each of the subset of the plurality of electronic stethoscopes is simultaneously positioned against the patient.

3. A signal conditioning circuit for a multi-channel wireless stethographic system, the signal conditioning circuit comprising:
 - a second order high pass filter stage for filtering signals received from a plurality of electronic stethoscopes;
 - an isolator amplifier stage for isolating DC voltage and amplifying and transmitting AC voltage of filtered signals received from the second order high pass filter stage;
 - a second order active low pass filter stage for filtering signals received from the isolator amplifier stage;
 - a third order active high pass filter stage for filtering signals received from the second order active low pass filter stage;
 - a non-inverting amplifier stage for amplifying the signals received from the third order active high pass filter stage; and
 - a first order passive low pass filter stage for filtering signals received from the non-inverting amplifier stage.

4. The signal conditioning circuit of claim 3, wherein:
 - the second order high pass filter stage, the isolator amplifier stage, the second order active low pass filter stage, the third order active high pass filter stage, the non-inverting amplifier stage, and the first order passive low pass filter stage together provide a signal-to-noise ratio of at least 15.27 dB.

5. The signal conditioning circuit of claim 3, wherein:
 - the second order high pass filter stage, the isolator amplifier stage, the second order active low pass filter stage, the third order active high pass filter stage, the non-inverting amplifier stage, and the first order passive low pass filter stage together function as a band pass filter having a frequency range of 50 Hz to 1600 Hz.

6. The signal conditioning circuit of claim 3, wherein:
the second order high pass filter stage, the isolator amplifier stage, the second order active low pass filter stage, the third order active high pass filter stage, the non-inverting amplifier stage, and the first order passive low pass filter stage together provide a gain of at least 24.

7. The signal conditioning circuit of claim 3, wherein:
the second order high pass filter stage has a cut-off frequency of 2.3 Hz;
the second order active low pass filter stage has a cut-off frequency of 1600 Hz;
the third order active high pass filter stage has a cut-off frequency of 50 Hz; and
the first order passive low pass filter stage has a cut-off frequency of 1600 Hz.

8. A method of diagnosing heart and lung diseases of a patient, the method comprising:
utilizing a plurality of stethoscopes to generate a plurality of audio data sets corresponding to each stethoscope, wherein the audio data sets comprise:
 - a) at least one data set generated by a heart stethoscope positioned on the patient to generate a heart audio data set;
 - b) at least one trachea data set generated by a trachea stethoscope positioned on the patient to generate a trachea audio data set; and
 - c) a plurality of lung data sets generated by a plurality of lung stethoscopes positioned on the patient;utilizing a signal conditioning circuit for receiving signals from the plurality of stethoscopes and for filtering and amplifying the signals to provide the audio data sets;
utilizing a computing device to extract features comprising respiratory rates, inspiration and expiration from the trachea data set;
utilizing a computing device to extract features comprising heartbeat rate and abnormal heartbeat patterns from the heart data set;

utilizing a computing device to extract features comprising wheeze, rhonchi, squawk, coarse crackle and fine crackle and corresponding frequencies from the lung data sets; and

causing a computing device to utilize predefined disease criteria and the extracted features to determine a result, wherein the result comprises at least one of COPD, asthma, VCD, pneumonia, or CHF,

wherein the signal conditioning circuit comprises:

a second order high pass filter stage for filtering the signals from the plurality of electronic stethoscopes;

an isolator amplifier stage for isolating DC voltage and amplifying and transmitting AC voltage of filtered signals received from the second order high pass filter stage;

a second order active low pass filter stage for filtering signals received from the isolator amplifier stage;

a third order active high pass filter stage for filtering signals received from the second order active low pass filter stage;

a non-inverting amplifier stage for amplifying the signals received from the third order active high pass filter stage; and

a first order passive low pass filter stage for filtering signals received from the non-inverting amplifier stage.

9. The method of claim 8, wherein:

the predefined disease criteria for COPD comprises at least one of wheeze, rhonchi, inspiration-expiration ratio, high inspiration lag and lead time, high expiration time delay, or abnormal respiratory rates.

10. The method of claim 9, wherein:

the predefined disease criteria for asthma comprises at least one of wheeze, rhonchi, low inspiration-expiration ratio, high expiration time delay, or abnormal respiration rates; and

wherein asthma is diagnosed if inspiration lag and lead time are not present in the data sets.

11. The method of claim 10, wherein:
the predefined disease criteria for VCD comprises at least one of a) wheeze, or b) highly symmetrical wheeze at both lungs, wherein a symmetry coefficient is utilized to determine if the wheeze meets predefined VCD symmetry criteria.
12. The method of claim 11, wherein:
the predefined disease criteria for pneumonia comprises at least one of a) coarse crackles, b) rhonchi, c) squawk, or d) abnormal respiratory rate, wherein coarse crackles are determined to be present if discontinuous adventitious lung sounds with low frequency are detected in one or more of the data sets; and
wherein squawks are determined to be present if short duration wheeze having quick sinusoidal waveform is detected in one or more of the data sets.
13. The method of claim 12, wherein:
the predefined disease criteria for CHF comprises at least one of a) coarse crackle, b) irregular heartbeat, or c) abnormal respiration rates, wherein the irregular heartbeat includes a rapid heartbeat rate and an abnormal heartbeat pattern.
14. The method of claim 9, wherein:
the predefined COPD criteria comprises a) an inspiration-expiration ratio below 0.7, b) an inspiration lag and lead time greater than 3 ms, c) an expiration time delay greater than 3 ms, and d) respiratory rates that are less than 12 breaths per minute or greater than 25 breaths per minute.
15. The method of claim 10, wherein:
the predefined asthma criteria comprises a) an inspiration-expiration ratio below 0.7, b) an expiration time delay greater than 3 ms, and c) respiratory rates less than 12 breaths per minute or greater than 25 breaths per minute.
16. The method of claim 11, wherein:
the predefined VCD symmetry criteria comprises a symmetry coefficient equal to or greater than 0.5.

17. The method of claim 12, including:
 - utilizing a predefined pneumonia criteria comprising respiratory rates less than 12 breaths per minute or greater than 25 breaths per minute;
 - utilizing a coarse crackles criteria comprising discontinuous adventitious lung sounds having a frequency equal to or less than 333 Hz; and
 - utilizing a squawk criteria comprising wheeze of equal to or less than 100 ms.

18. The method of claim 13, including:
 - determining that coarse crackle is detected utilizing predefined criteria comprising discontinuous adventitious lung sounds having a frequency equal to or less than 333 Hz are present;
 - determining that an abnormal respiration rate is detected utilizing predefined criteria comprising a) respiration rates less than 12 breaths per minute, or b) respiration rates above 25 breaths per minute; and
 - determining that a rapid heartbeat is detected utilizing predefined criteria comprising a heartbeat rate equal to or above 100 beats per minute is detected.

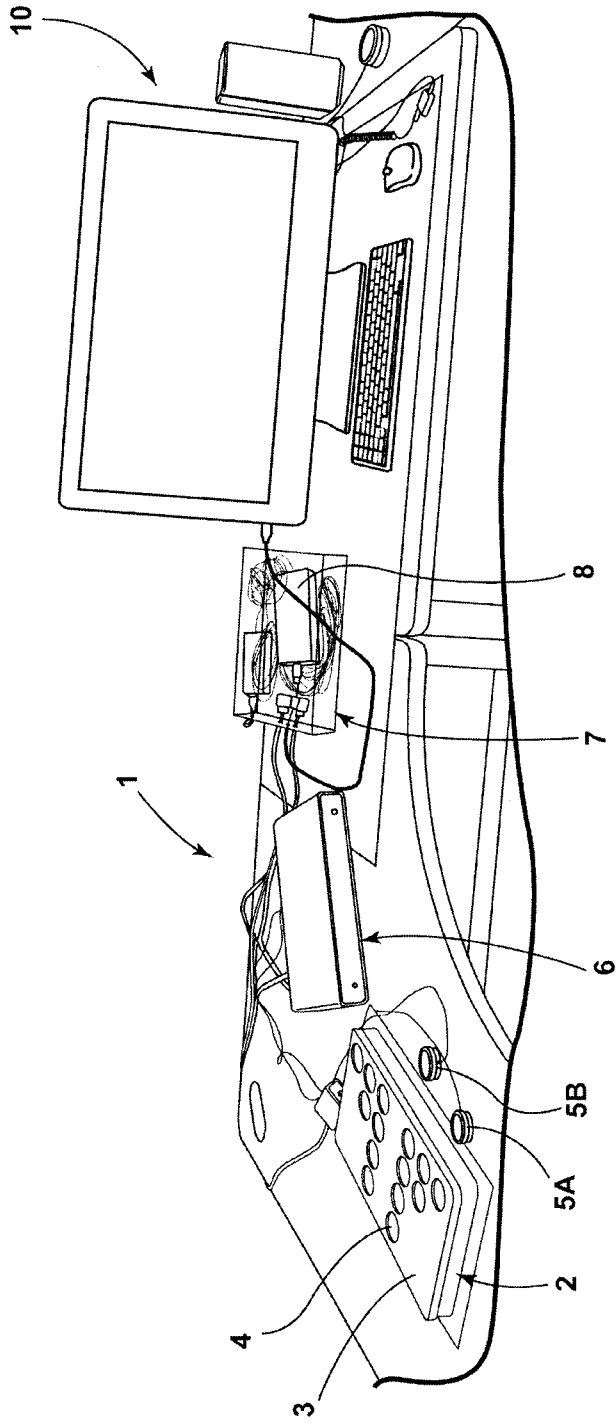


FIG. 1

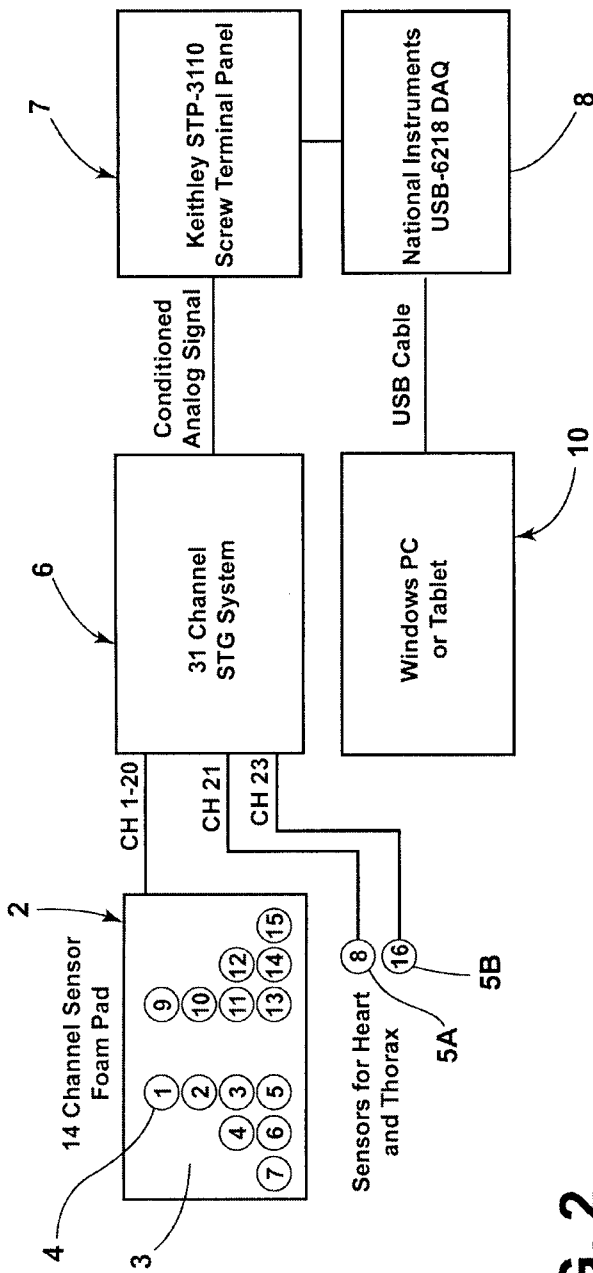


FIG. 2

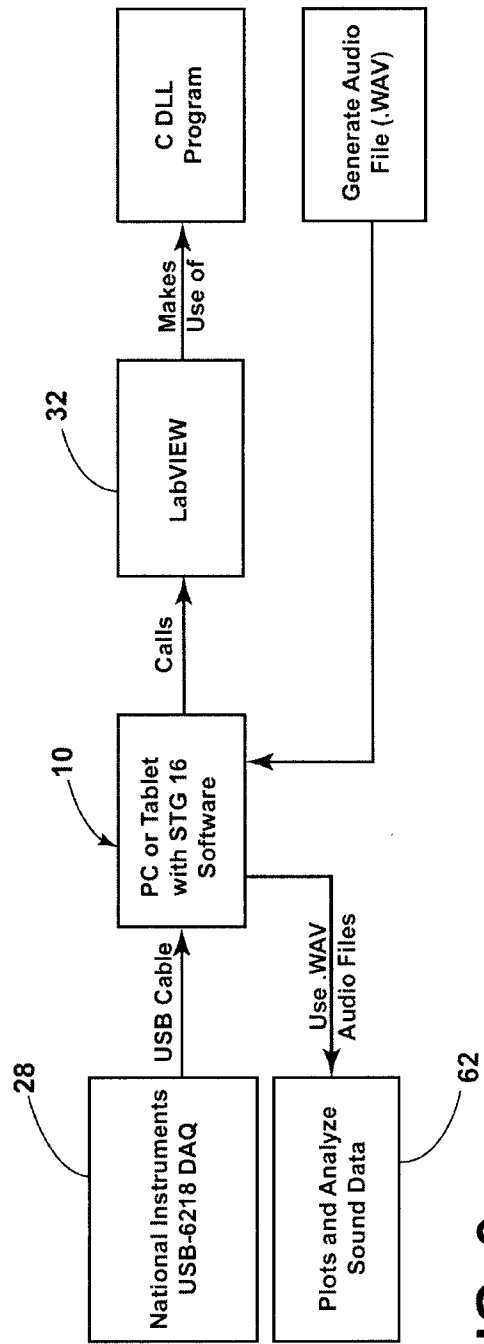


FIG. 3

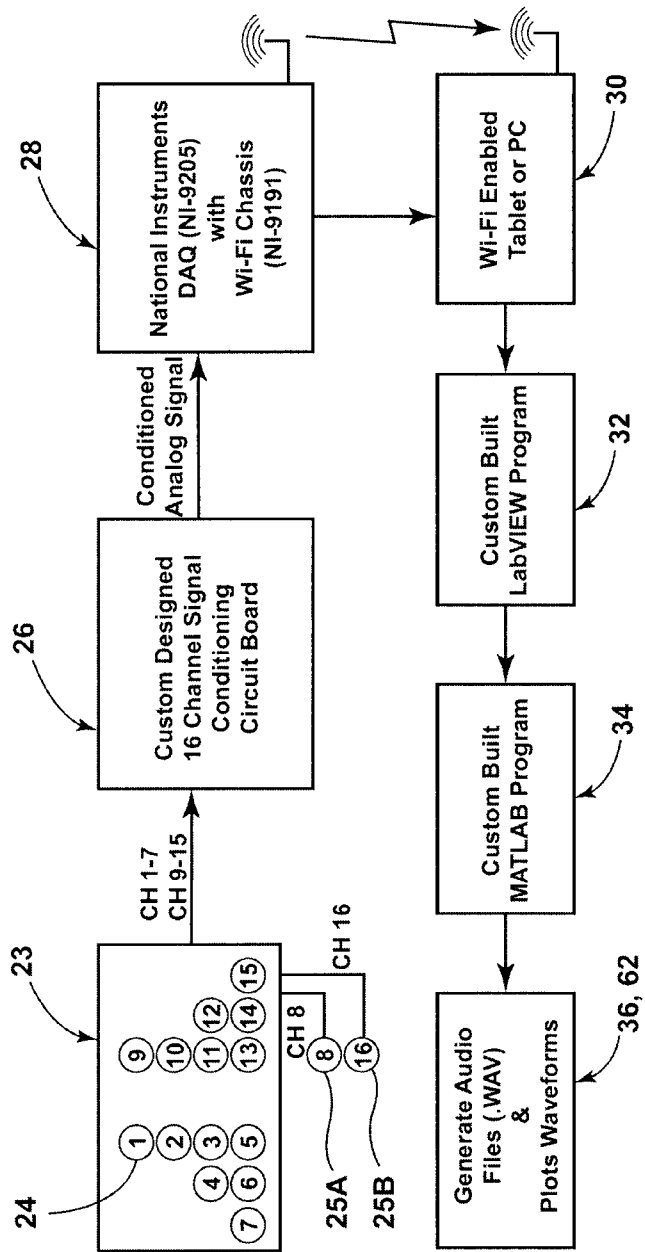


FIG. 4

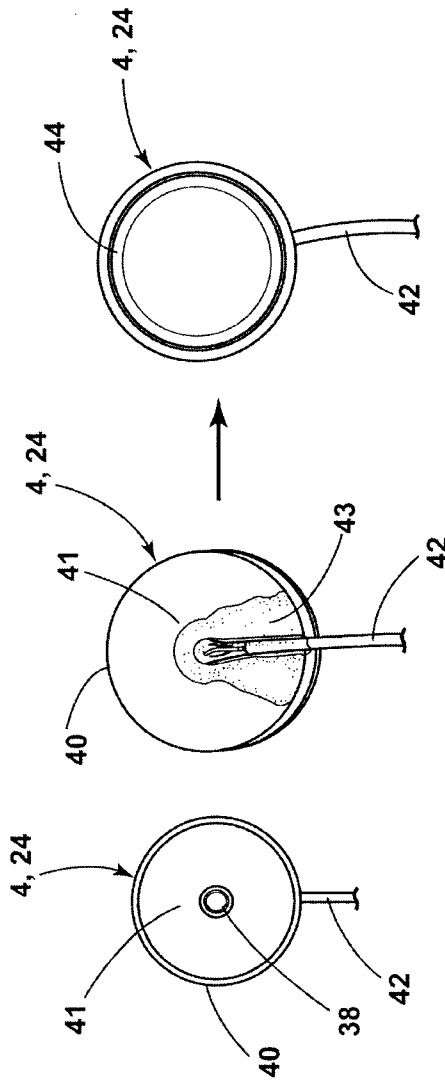
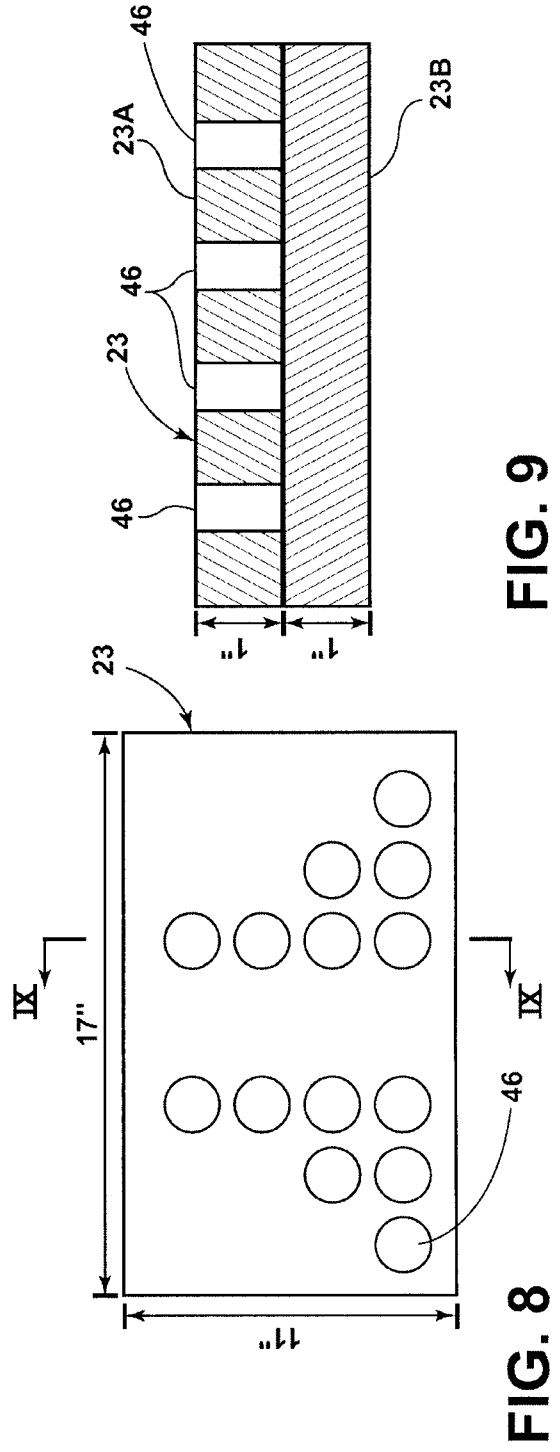
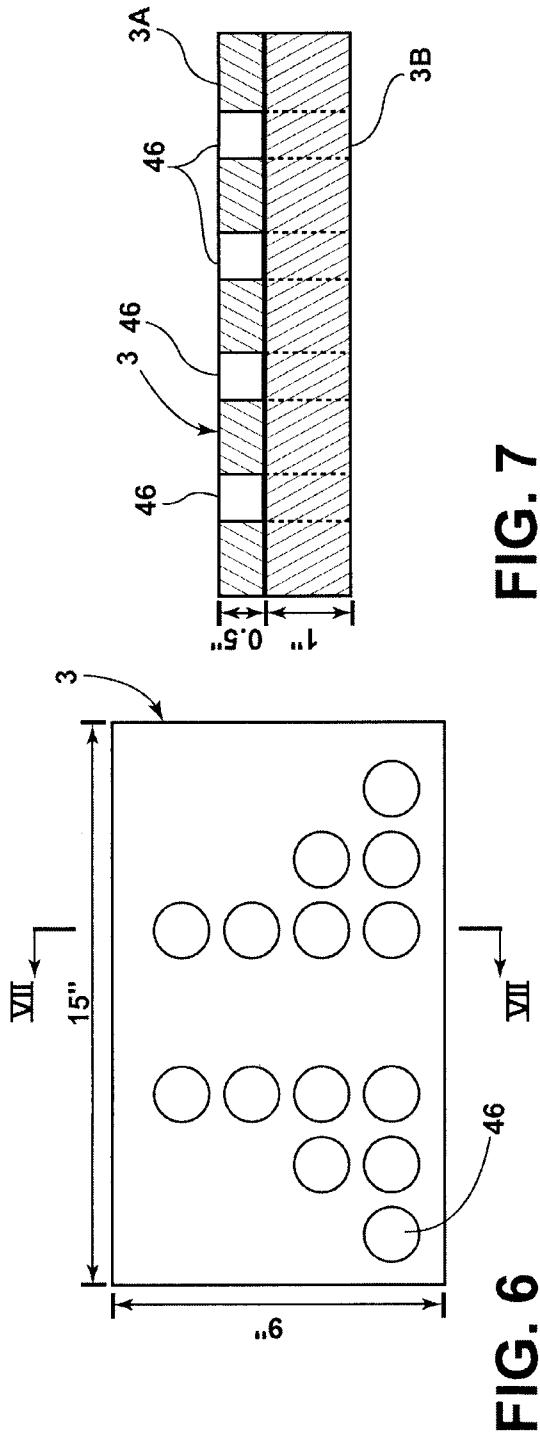


FIG. 5



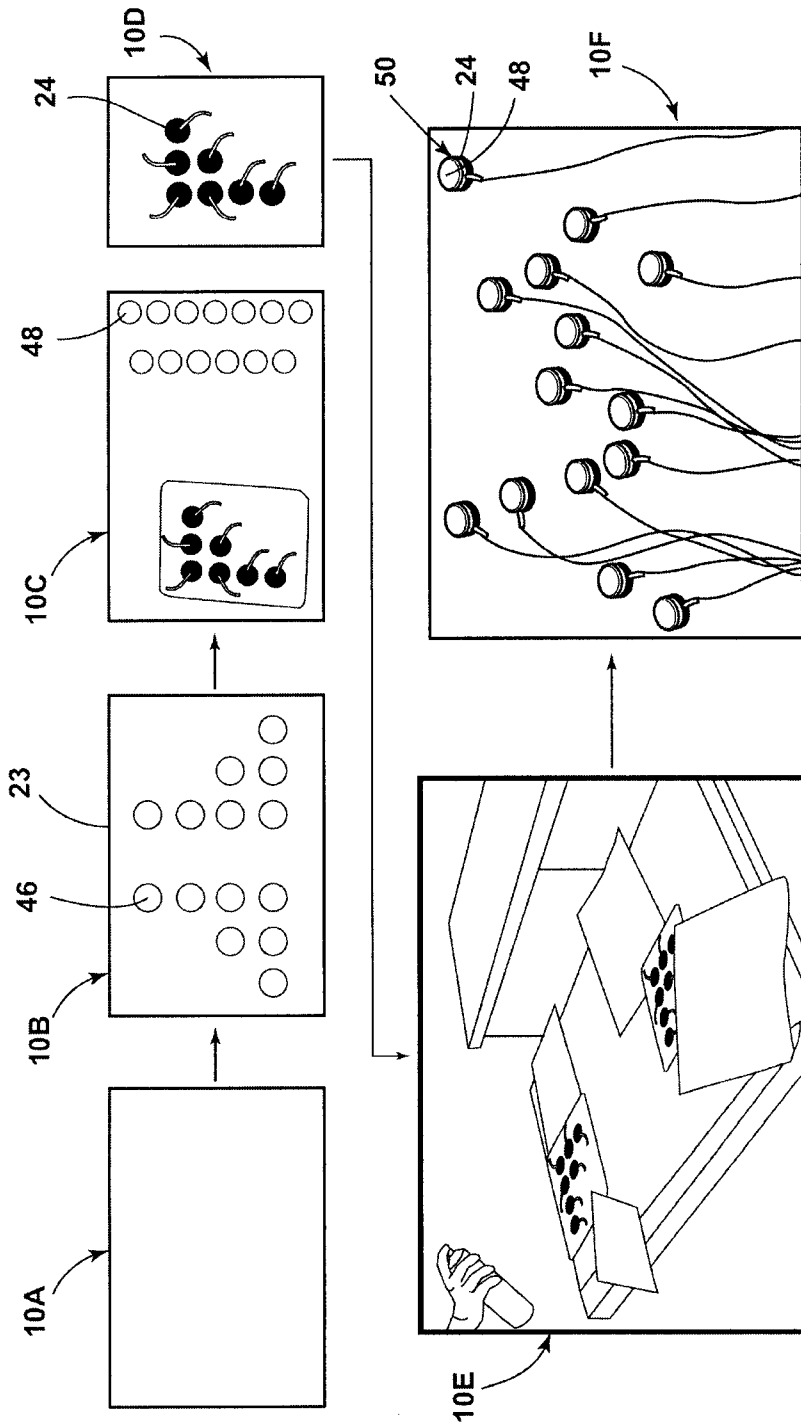


FIG. 10

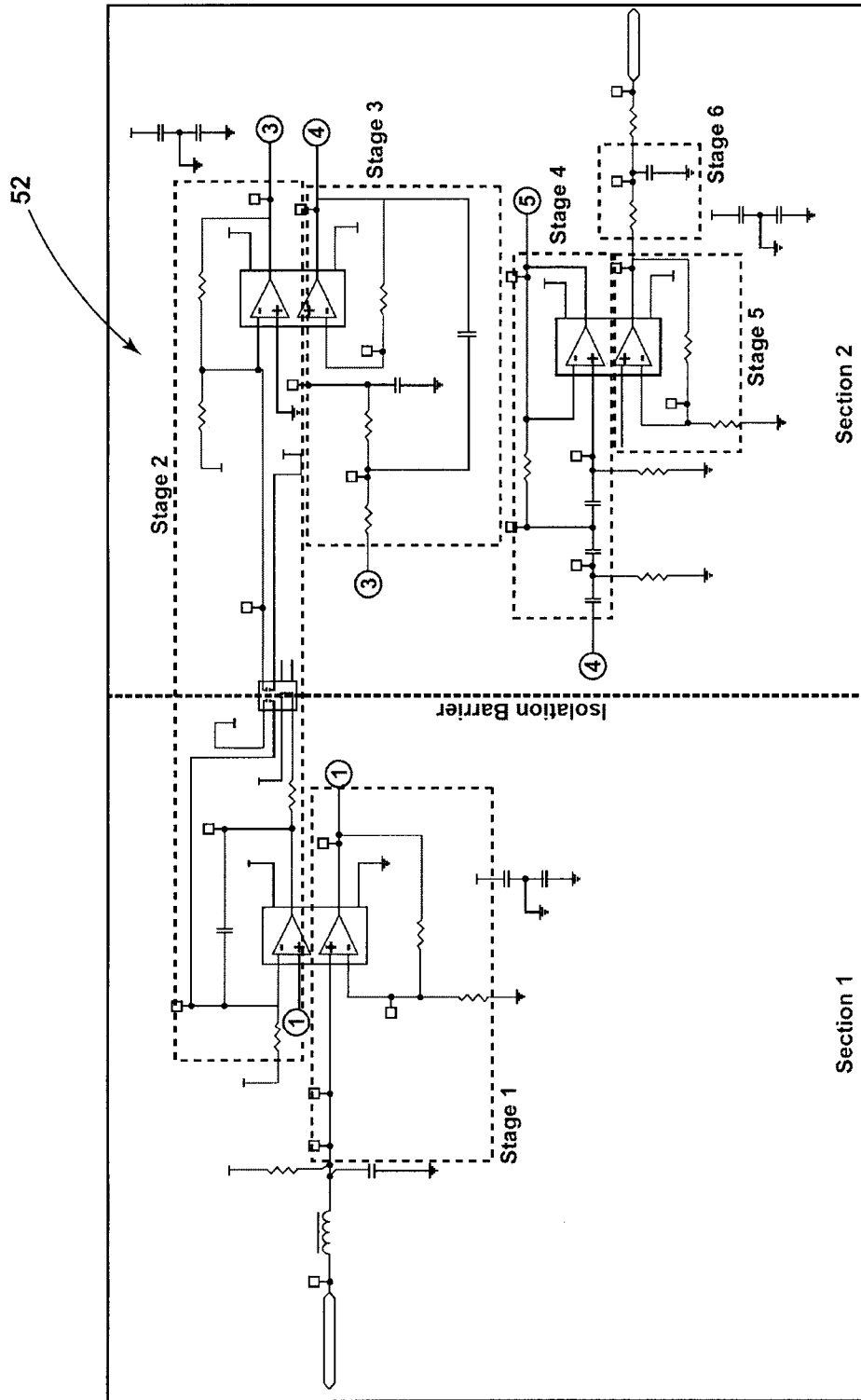


FIG. 11

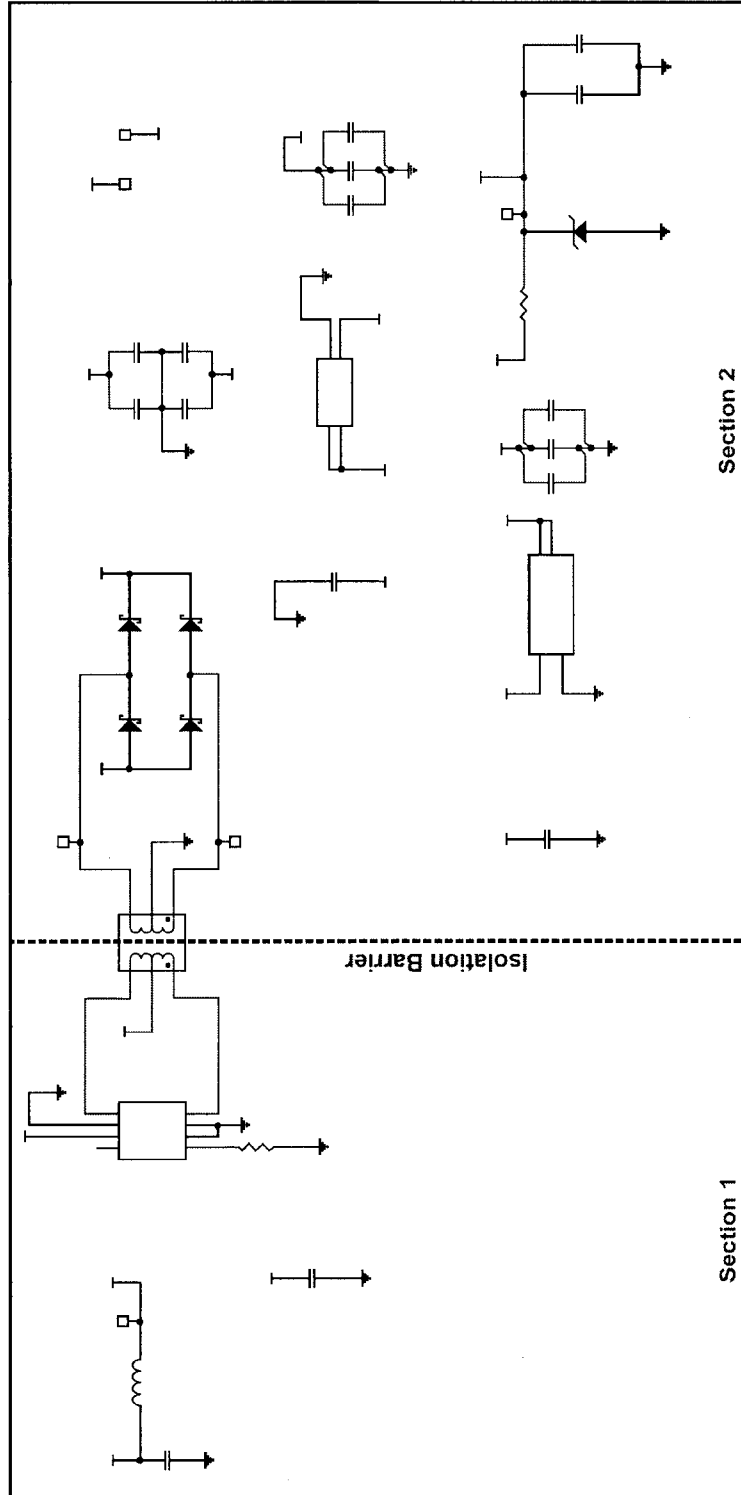


FIG. 12

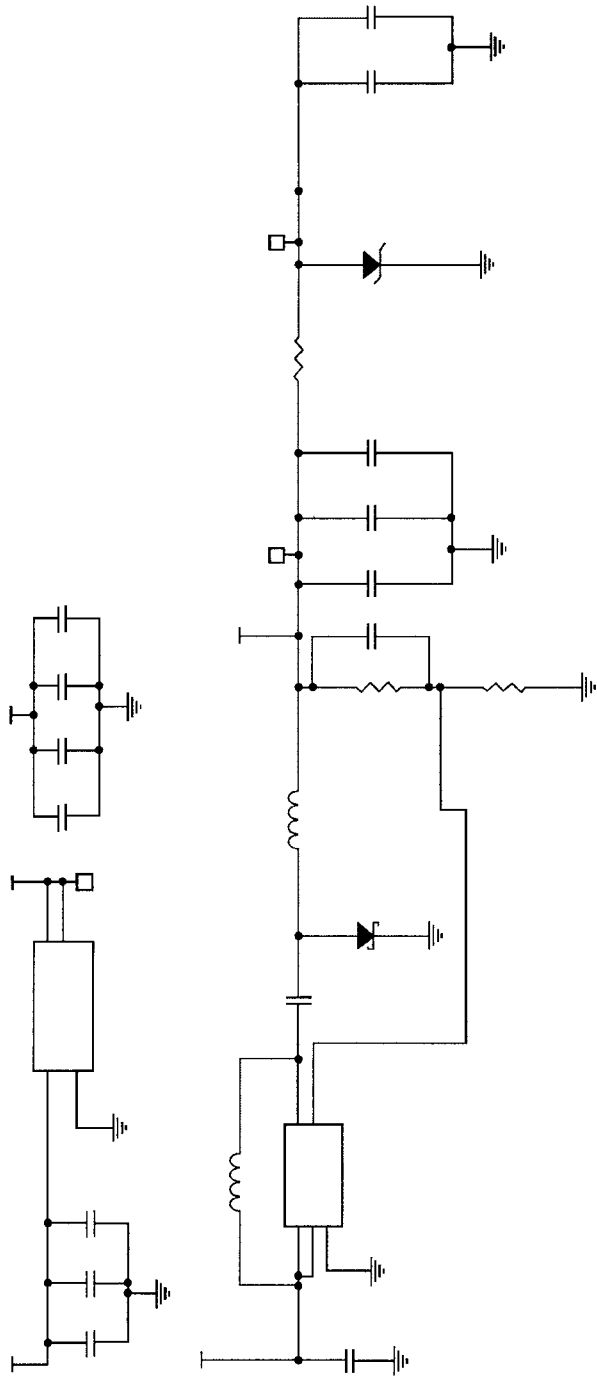


FIG. 13

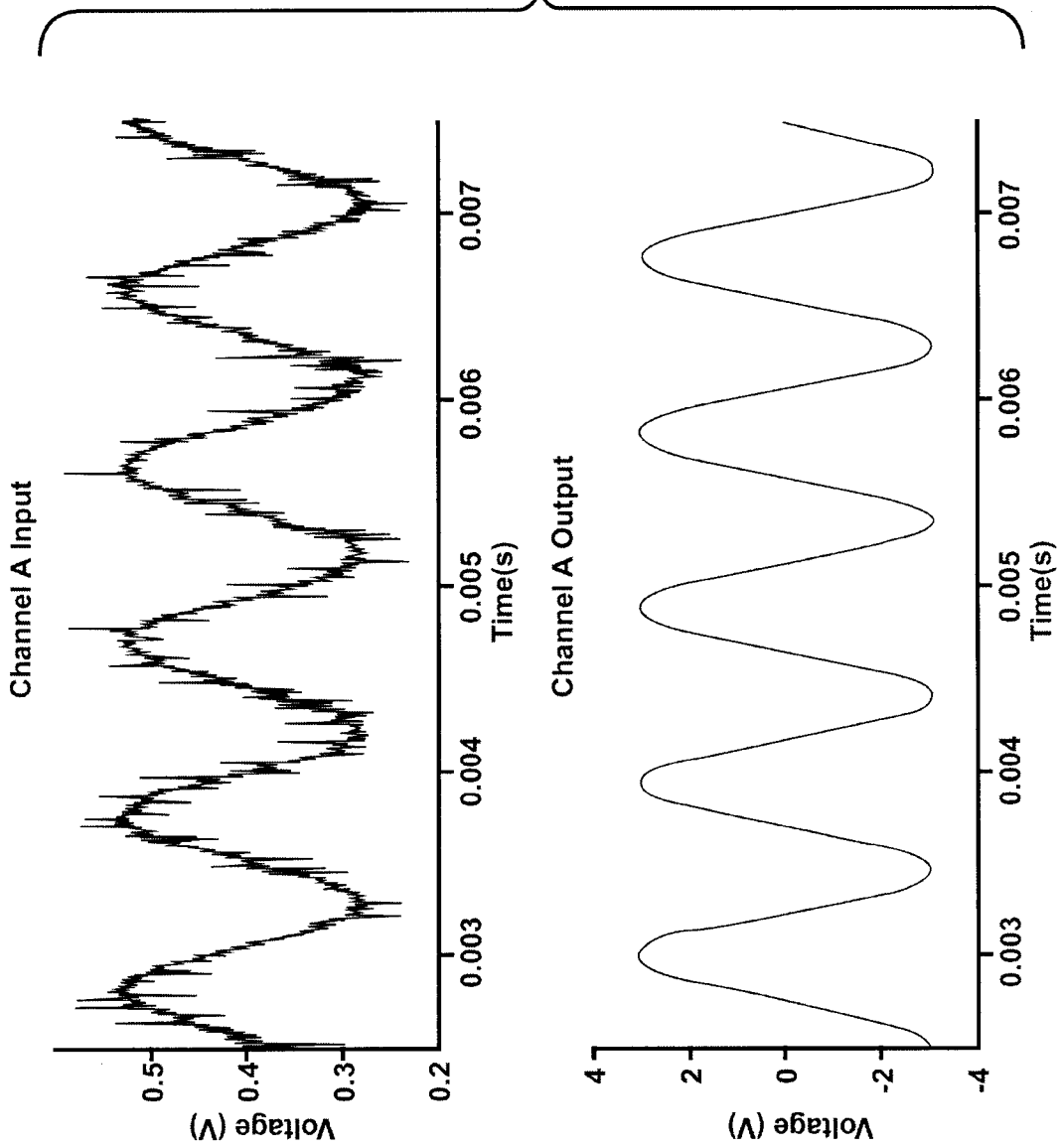


FIG. 14

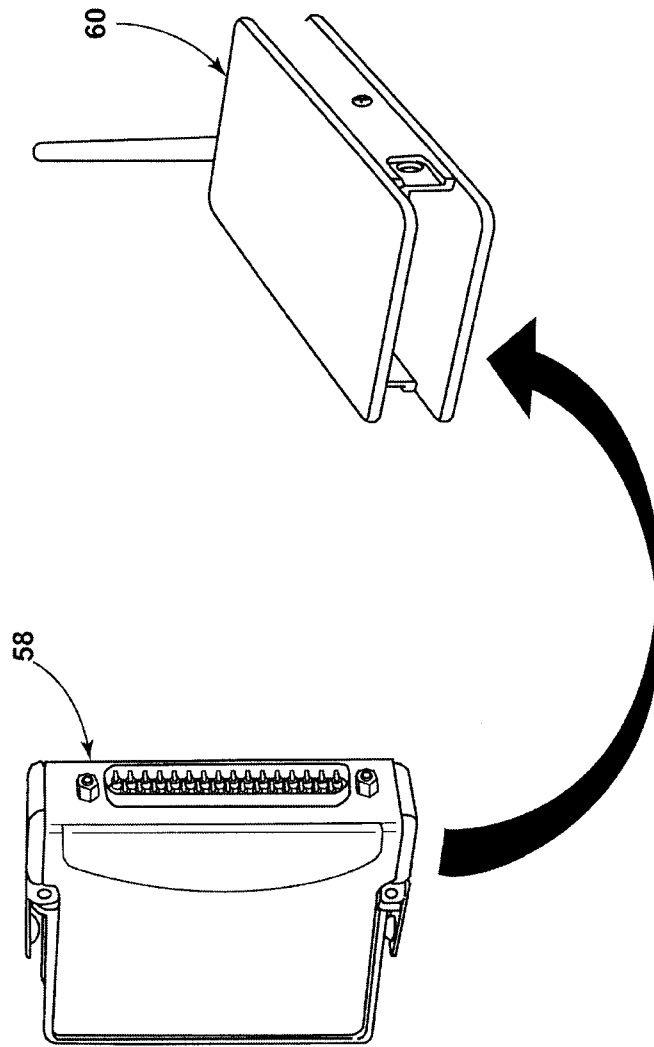


FIG. 15

62

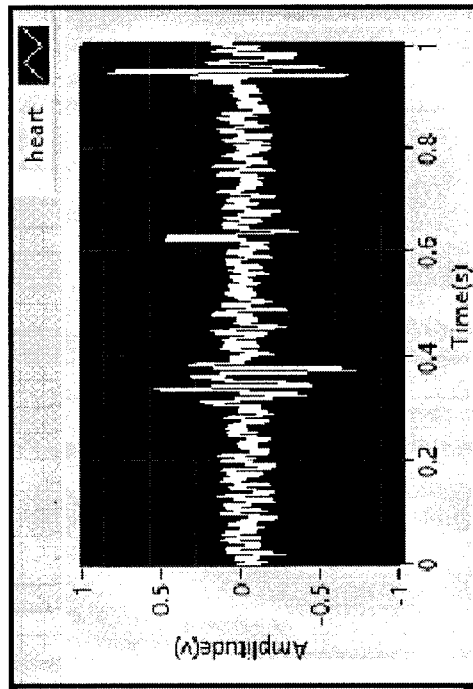
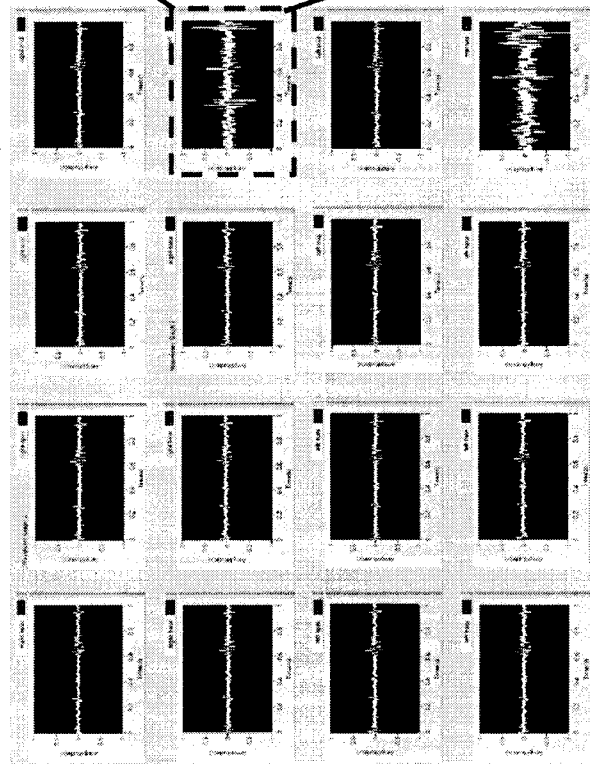
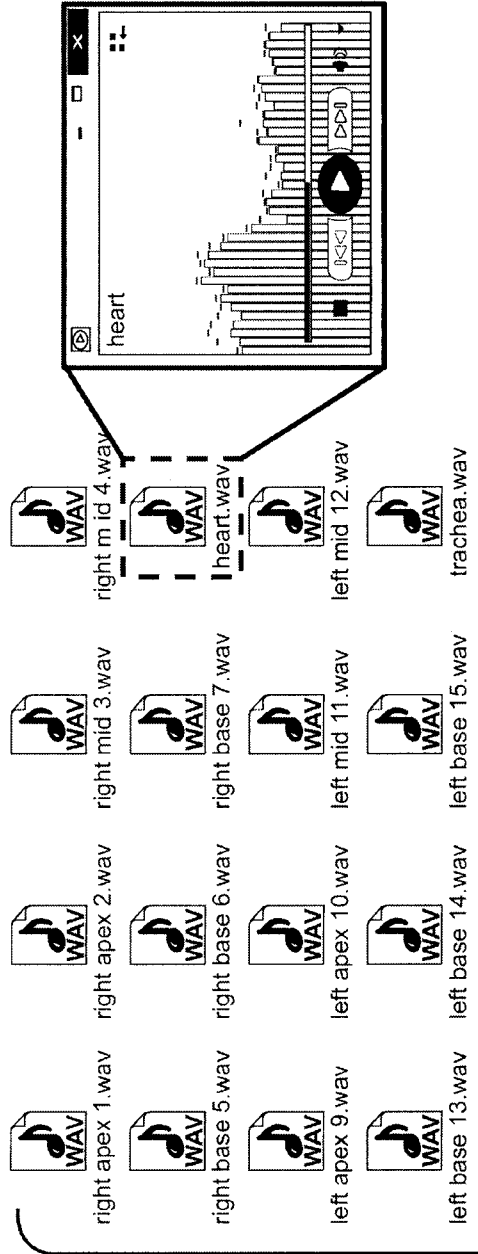


FIG. 16



Waveform Plot Developed by WMU

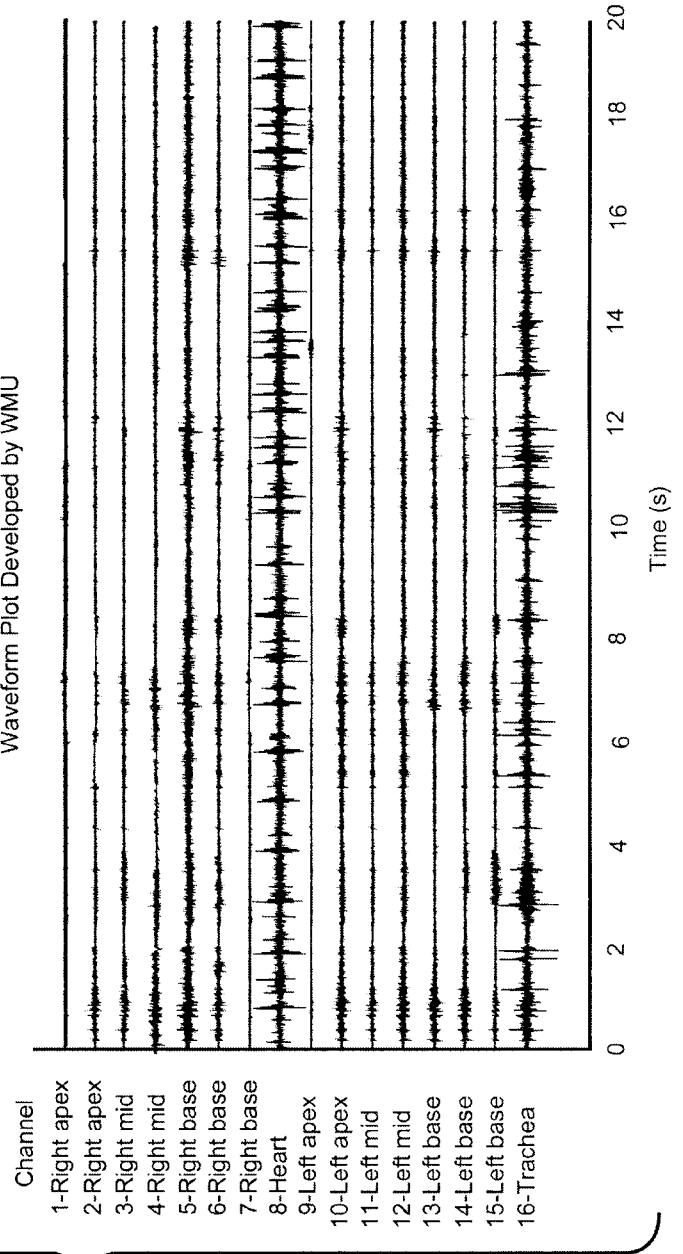


FIG. 17

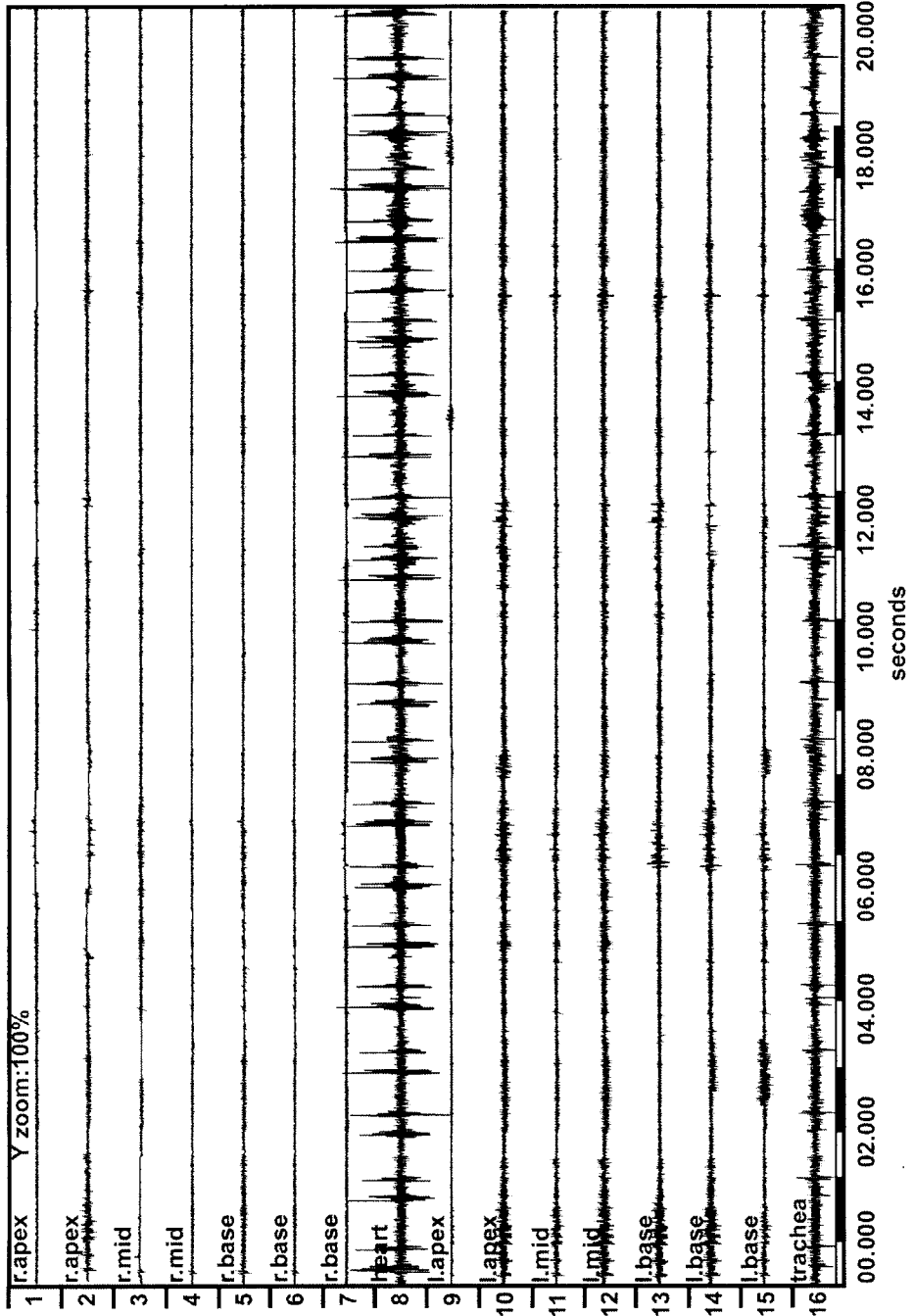


FIG. 18

Waveform Plot Developed by WMU

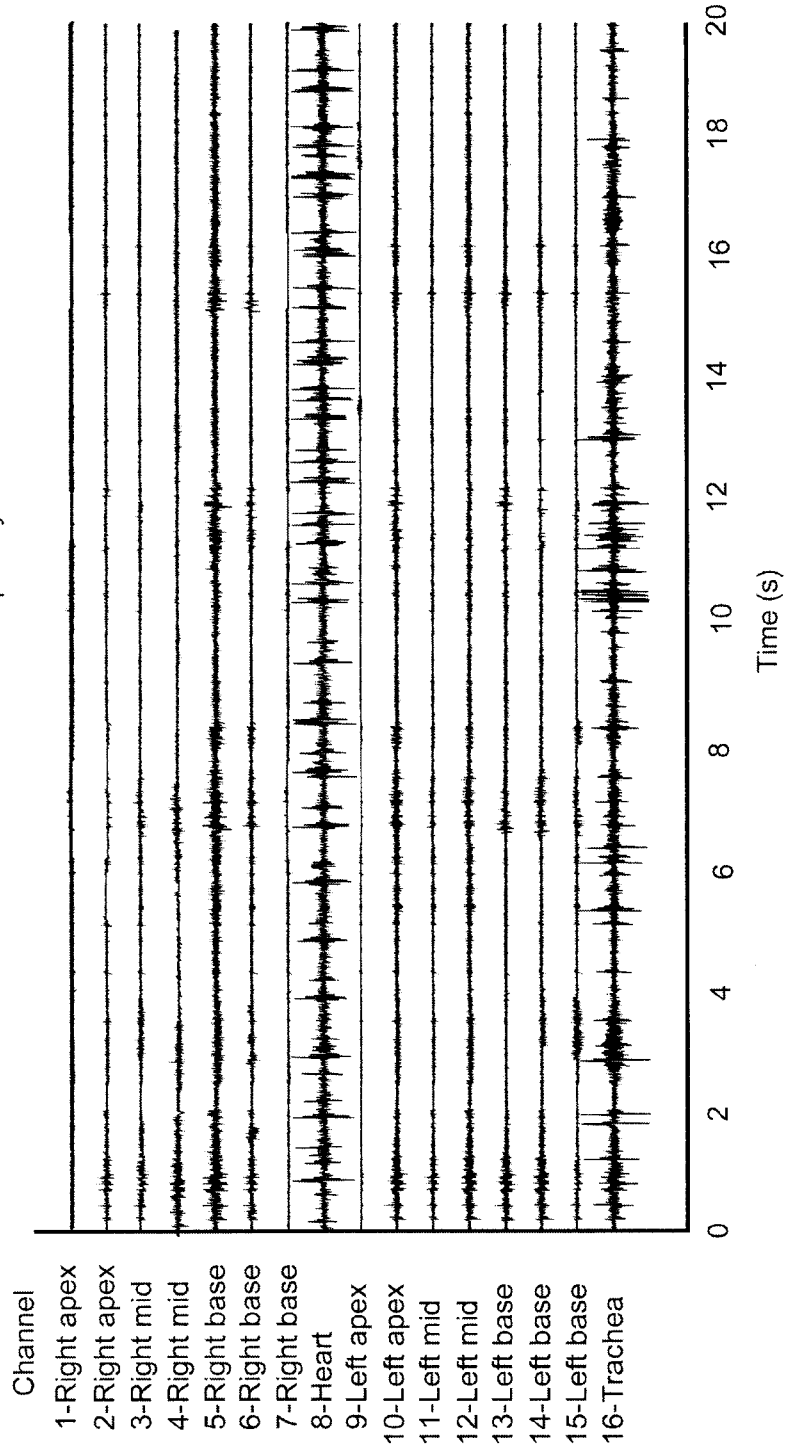


FIG. 19

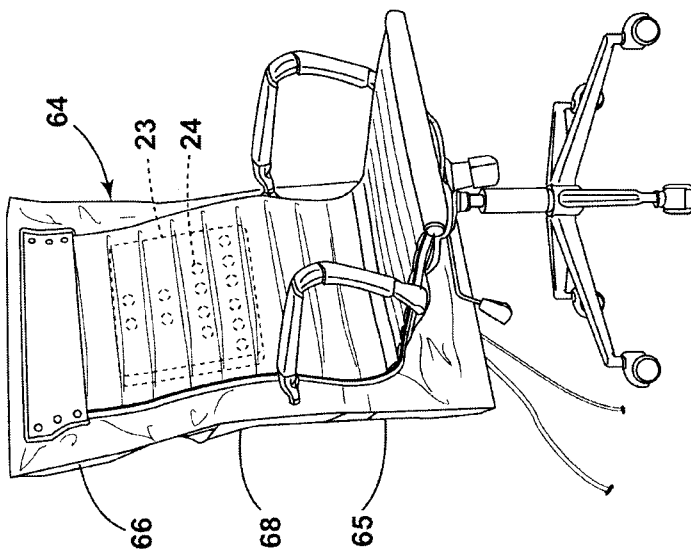


FIG. 20

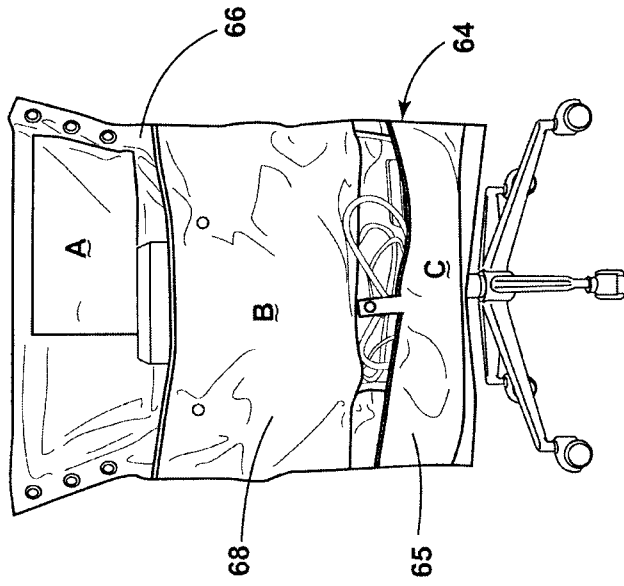


FIG. 21

Waveform Plot Developed by WMU

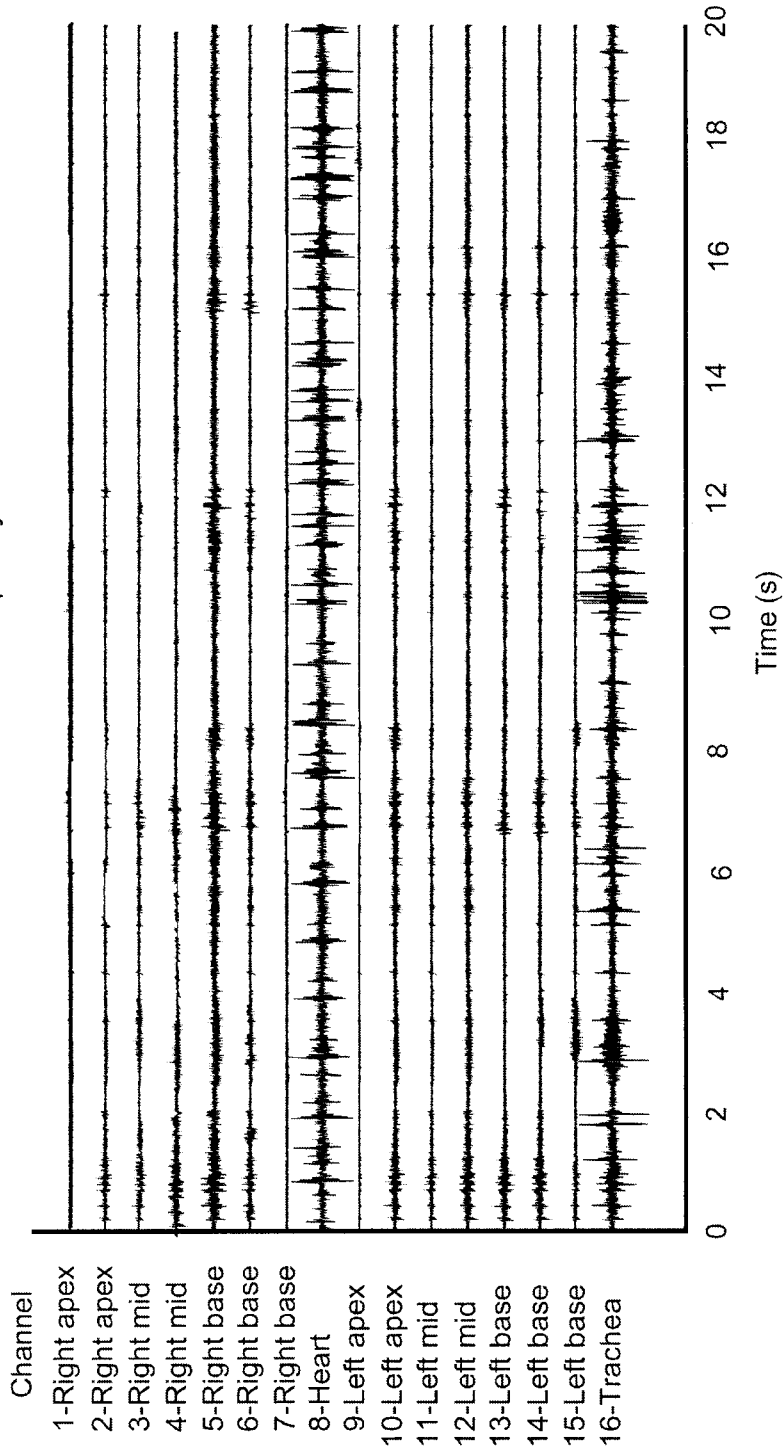


FIG. 22

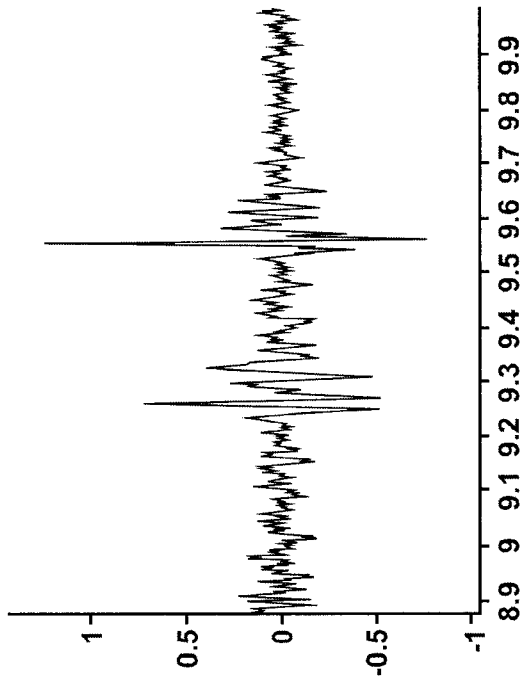


FIG. 23

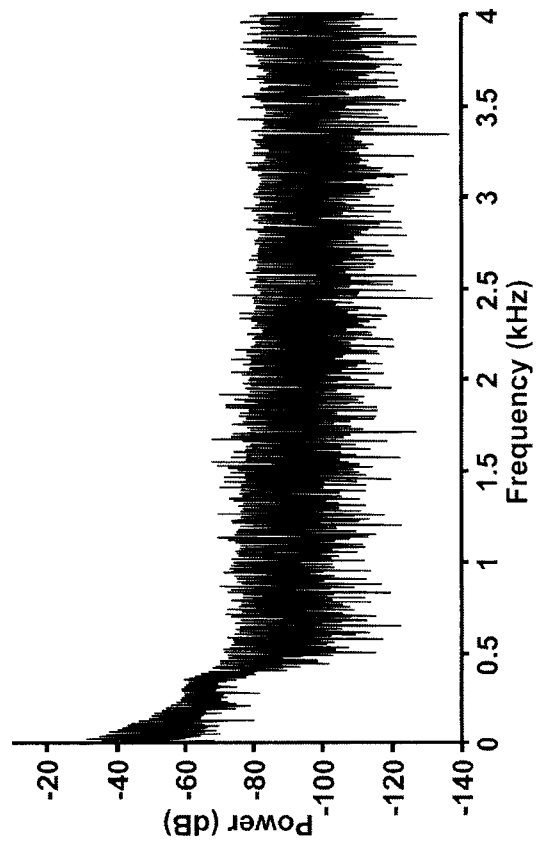


FIG. 24

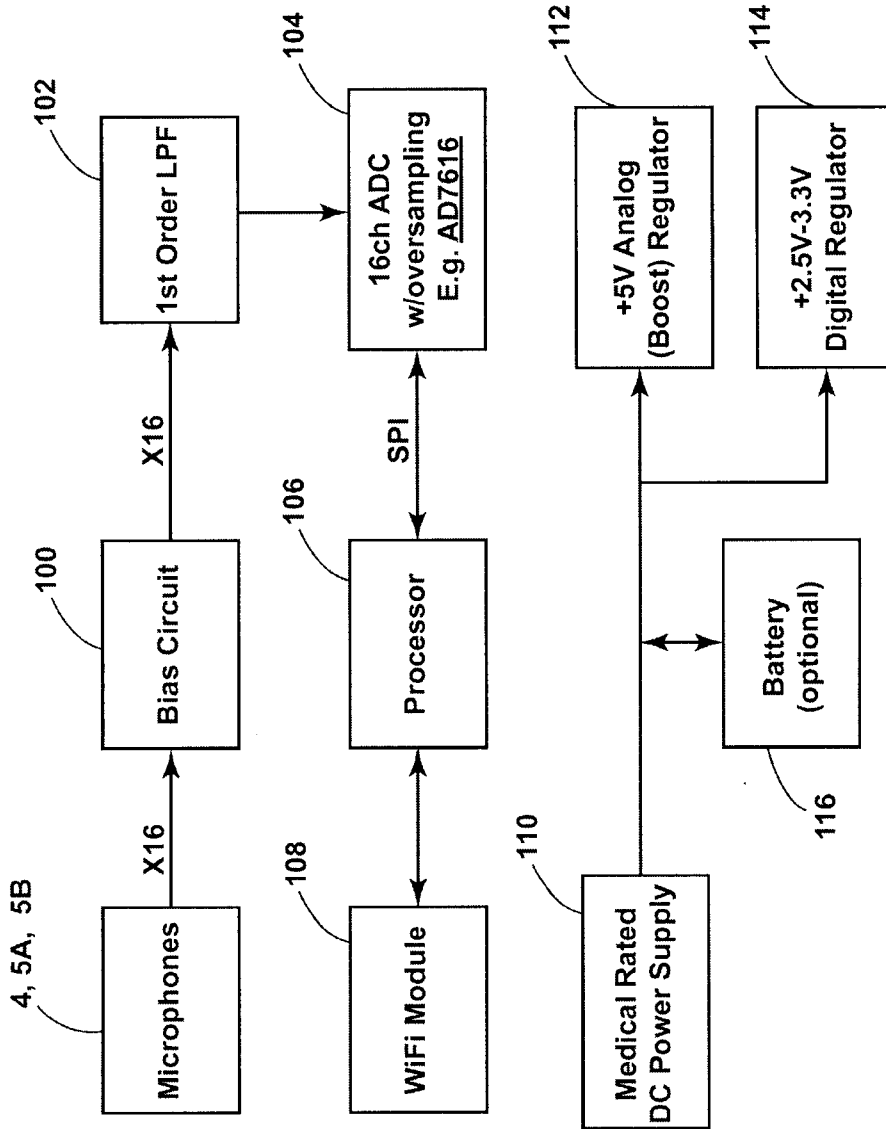


FIG. 25

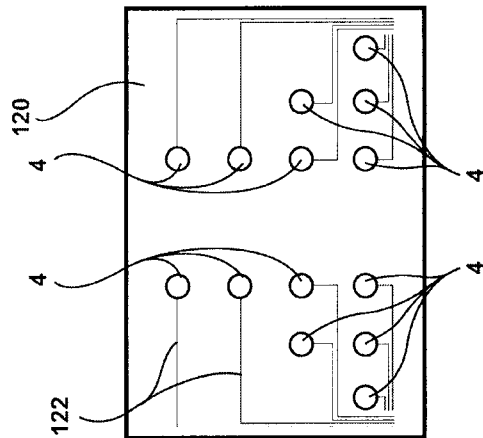


FIG. 26

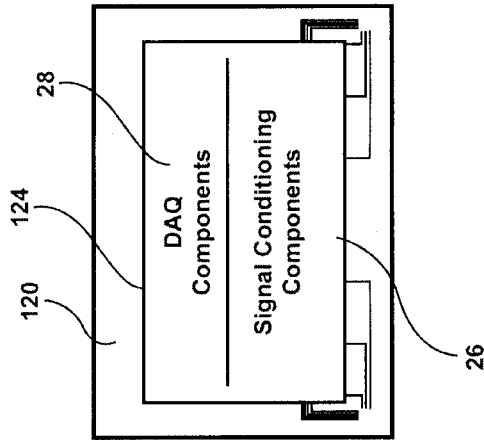


FIG. 27

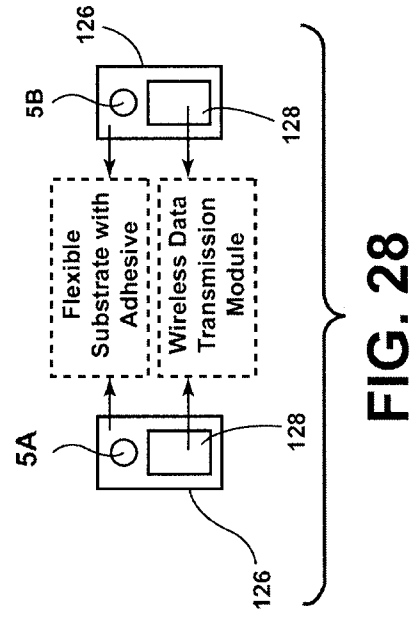


FIG. 28

