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(54) Title: SYSTEMS AND METHODS FOR CALIBRATION OF HEART SOUNDS

(57) Abstract: An auscultation system includes a transducer for generating an acoustic signal at a transducing location of the subject, and a sensor for receiving an attenuated acoustic signal at a sensing location of the subject. The attenuated signal received at the sensing location is digitized, and may be analyzed in the frequency and/or time domain. The comparison of the digitized attenuated signal against the initial transduced signal allows for the computation of the degree of acoustic attenuation between the transducing and sensing locations. Acoustic attenuation may be utilized to generate an intensity ratio. The ejection fraction of the heart subject may then be computed by correlation to the intensity ratio. Pulse echo methods are also disclosed. The echo transducer is oriented on the subject and generates a series of signal pulses. The return echo on the pulse is then received and a brightness encoded image is produced. The return echo provides location data on the internal structures of the subject including location, motion and speed.

SYSTEMS AND METHODS FOR CALIBRATION OF HEART SOUNDS

BACKGROUND OF THE INVENTION

[0001] This invention relates generally to medical electronic devices for analysis of auscultatory cardiac sounds. More particularly, this invention relates to a method for improving the analysis of heart sounds by compensating for acoustic attenuation of the human body, useful for example in measuring ejection fraction through auscultation.

[0002] The heart has four chambers -- two upper chambers (called atria) and two lower chambers (ventricles). The heart has valves that temporarily close to permit blood flow in only one direction. The valves are located between the atria and ventricles, and between the ventricles and the major vessels from the heart. In healthy adults, there are two normal heart sounds: a first heart sound (S_1) and second heart sound (S_2). The first heart sound is produced by the closure of the Atrioventricular (AV) valves and the second heart sound is produced by semilunar valves closure. Because the heart is also divided into a "right side" and a "left side," sometimes these sounds may be somewhat divided; most commonly noted is a “split S2,” caused when the right and left ventricles relax, and valves close at very slightly different times. Split S2 is normal, but occasionally the nature of the split can indicate an abnormality such as enlargement of one of the ventricles.

[0003] Moreover, in addition to these normal sounds a variety of other sounds may be present, including heart murmurs and adventitious sounds, or clicks. Murmurs are blowing, whooshing, or rasping sounds produced by turbulent blood flow through the heart valves or near the heart. Murmurs can happen when a valve does not close tightly, such as with mitral regurgitation which is the backflow of blood through the mitral valve, or when the blood is flowing through a narrowed opening or a stiff valve, such as with aortic stenosis. A murmur does not necessarily indicate a disease or disorder, and not all heart disorders cause murmurs.

[0004] Murmurs may be physiological (benign) or pathological (abnormal). Different murmurs are audible in different parts of the cardiac cycle, depending on the cause and grade of the murmur. Significant murmurs can be caused by: chronic or

acute mitral regurgitation, aortic regurgitation, aortic stenosis, tricuspid stenosis, tricuspid regurgitation, pulmonary stenosis and pulmonary regurgitation.

[0005] The first heart tone, or S_1, is caused by the sudden block of reverse blood flow due to closure of the mitral and tricuspid atrioventricular valves at the beginning of ventricular contraction, or systole.

[0006] The second heart tone, or S_2, marks the beginning of diastole, the heart's relaxation phase, when the ventricles fill with blood. The second heart sound is caused by the sudden block of reversing blood flow due to closure of the aortic valve and pulmonary valve. In children and teenagers, S2 may be more pronounced. Right ventricular ejection time is slightly longer than left ventricular ejection time.

[0007] A normal third heart sound or S_3 may be heard at the apex. This sound usually occurs approximately 0.15 seconds after the second heart sound. The third heart sound is a low pitched soft blowing sound. It may be caused by congestive heart failure, fluid overload, cardiomyopathy, or ventricular septal defect. The third heart sound usually occurs whenever there is a rapid heart rate, such as over 100 beats per minute (bpm). The third heart sound is caused by vibration of the ventricular walls, resulting from the first rapid filling. However, it may also be found in young persons, pregnant women or people with anemia with no underlying pathology.

[0008] The fourth heart sound S_4 occurs during the second phase of ventricular filling: when the atriums contract just before S1. As with S3, the fourth heart sound is thought to be caused by the vibration of valves, supporting structures, and the ventricular walls. An abnormal S4 is heard in people with conditions that increase resistance to ventricular filling, such as a weak left ventricle.

[0009] Auscultatory sounds have long been the primary inputs to aid in the noninvasive detection of various physiological conditions. For instance the stethoscope is the primary tool used by a clinician to monitor heart sounds to detect and diagnose the condition of a subject's heart. Auscultation itself is extremely limited by a number of factors. It is extremely subjective and largely depends on the clinician's expertise in listening to the heart sounds and is compounded by the fact that certain components of the heart sounds are beyond the gamut of the human ear.

[0010] In heart failure (HF) patients, the relative acoustic levels of the S_1 and S_2 heart sounds as heard by the stethoscope vary widely from that of a healthy person.

In such HF patients the S_2 level is often greatly decreased, however, this problem is often not obvious due to the fact that the fat content and body variability change the acoustic levels, or due to the fact that the heart sounds are so faint the variation is difficult to discern. On the other hand pulmonary hypertension typically increases the P_2 component of S_2 level, but this also may be missed for the same reasons. What is desired is a way to calibrate, e.g., to normalize, the actual S_1 and S_2 levels at the locus or source inside the body of the HF patient when using a normal stethoscope chestpiece.

[0011] The first sound should be dependent on the effectiveness of the left heart. By collecting data, links may be established between the intensity of the first heart sound (S1) and the relative efficiency of the left heart. Specifically, 'Ejection Fraction' (EF), may be chosen as the measure of the effectiveness of the left heart. Ejection Fraction (EF) is the fraction of blood pumped out of a ventricle with each heart beat. The term ejection fraction applies to both the right and left ventricles; one can speak equally of the left ventricular ejection fraction (LVEF) and the right ventricular ejection fraction (RVEF). Without a qualifier, the term ejection fraction refers specifically to that of the left ventricle.

[0012] By definition, the volume of blood within a ventricle immediately before a contraction is known as the end-diastolic volume. Similarly, the volume of blood left in a ventricle at the end of contraction is end-systolic volume. The difference between end-diastolic and end-systolic volumes is the stroke volume, the volume of blood ejected with each beat. Ejection fraction (EF) is the fraction of the end-diastolic volume that is ejected with each beat; that is, it is stroke volume (SV) divided by end-diastolic volume (EDV). In a healthy 70-kg (154-lb) man, the SV is approximately 70 ml and the left ventricular EDV is 120 ml, giving an ejection fraction of 70/120, or 58%. Right ventricular volumes being roughly equal to those of the left ventricle, the ejection fraction of the right ventricle is normally equal to that of the left ventricle within narrow limits.

[0013] Damage to the muscle of the heart (myocardium), such as that sustained during myocardial infarction or in cardiomyopathy, impairs the heart's ability to eject blood and therefore reduces ejection fraction. This reduction in the ejection fraction can manifest itself clinically as heart failure. The ejection fraction is one of the most

important predictors of prognosis; those with significantly reduced ejection fractions typically have a poorer prognoses.

[0014] Ejection fraction is currently commonly measured by echocardiography, in which the volumes of the heart's chambers are measured during the cardiac cycle. Ejection fraction can then be obtained by dividing stroke volume by end-diastolic volume as described above. Other methods of measuring ejection fraction include cardiac MRI, fast scan cardiac computed axial tomography (CT) imaging, ventriculography, Gated SPECT, and the MUGA scan. A MUGA scan involves the injection of a radioisotope into the blood and detecting its flow through the left ventricle. The historical gold standard for the measurement of ejection fraction is ventriculography. However, many of these methods are either expensive, uncomfortable, or require injection with radioactive material. Due to the cost benefits, ease of use, and minimally invasiveness of heart sound measurements, a preferred system of utilizing acoustic measurements to determine Ejection Fraction is desired.

[0015] Due to differences in the amount of soft tissue between different subjects, some way of calibrating data is required as to compare all subjects.

[0016] It is therefore apparent that an urgent need exists for an improved auscultatory device capable of calibrating the relative acoustic levels of heart sounds by compensating for the acoustic attenuation caused by the internal body structures and fluid boundaries of the patient; thereby, for example, enabling measuring of ejection fraction in a patient utilizing calibrated acoustic levels of heart sounds.

SUMMARY OF THE INVENTION

[0017] To achieve the foregoing and in accordance with the present invention, a method and system of analyzing heart sounds is provided. Such an auscultation system is useful for a clinician to efficiently and accurately auscultate patients.

[0018] In one embodiment, the auscultation system includes a transducer for generating an acoustic signal at a transducing location of the patient, and a sensor for receiving an attenuated acoustic signal at a sensing location of the patient. The attenuated signal received at the sensing location is digitized, and may be analyzed in the frequency and/or time domain. The comparison of the digitized attenuated signal against the initial transduced signal allows for the computation of the degree of acoustic attenuation between the transducing and sensing locations.

[0019] The auscultation system, e.g., an electronic stethoscope, aids the clinician's diagnosis of the heart sounds by using the measured attenuation to calibrate the heart sounds received at the sensing location by a chest-piece of the auscultation system.

[0020] In some embodiments, the transducer is combined with an ECG sensor. In other embodiments, the transducer and the sensor are incorporated in a chestpiece for the auscultation system.

[0021] The method for measuring acoustic attenuation in a patient includes generating an acoustic signal on the patient and receiving an attenuated acoustic signal resulting from the original signal and computing an acoustic attenuation. The signal generation and sensing may be at separate locations or at a single location. In the event of a single location for both sensing and signal generation then a single transducer may be utilized to both generate acoustic signals and sense the resulting attenuation and heart signals.

[0022] When separate locations are utilized for signal generation and sensing the locations may be close together. The locations are located on a thoracic region of the patient. Additionally in some embodiments the sensing location may be a standard electrocardiogram position.

[0023] A noise canceller may be utilized in order to eliminate background noise during acoustic sensing. Then the heart sounds of the patient may be sensed and normalized based on the computed acoustic attenuation.

[0024] Also disclosed is a method for calibrating heart sounds of a subject, useful in association with an auscultation device having a transducer, a sensor and a heart sound processor. The transducer is oriented on the patient, as is the sensor. Sensing and transducing locations may be separate locations in close proximity.

[0025] An audio signal is generated by the transducer. The sensor receives the resulting attenuation signal and the heart signal. The heart signal may be filtered from the attenuation signal, and an acoustic attenuation may be computed. The heart sound may be calibrated from the computed acoustic attenuation.

[0026] Pulse echo methods are also disclosed, which is useful in association with an auscultation device having an echo transducer and a heart sound processor. The echo transducer is oriented on the patient and generates a series of signal pulses. The return echo on the pulse is then received and a brightness encoded image is produced. The return echo provides location data on the internal structures of the patient.

[0027] Heart sound signal of the patient are also received and filtered from the echo pulse. The heart sound is calibrated by acoustic properties of the tissues represented in the brightness encoded image.

[0028] Motion of the internal structures of the patient may be detected by comparing the subsequent brightness encoded images generated by subsequent pulses. Structure speed may also be determined by referencing the distance traveled by a time differential, wherein the time differential is computed by comparing times of generation of the different acoustic pulses. Additionally, analysis of Doppler shift between the generated acoustic pulse and the received echo may be utilized to determine speed of the moving internal structure.

[0029] Operating suggestions may be generated and displayed to the user by analyzing brightness encoded image for statistical confidence.

[0030] Additionally, a method for measuring the ejection fraction of a patient, useful in association with an auscultation device having a transducer, a sensor and a heart sound processor, is disclosed. The transducer and sensor are oriented on the

patient. The transducer generates an acoustic signal, and the sensor receives the attenuated signal. The heart sounds are also received by the sensor and are filtered from the attenuation signal. The heart sound signals are then conditioned.

[0031] Acoustic attenuation may then be computed and utilized to generate an intensity ratio. The ejection fraction of the heart patient may then be computed by correlation to the computed intensity ratio.

[0032] Note that the various features of the present invention described above may be practiced alone or in combination. These and other features of the present invention will be described in more detail below in the detailed description of the invention and in conjunction with the following figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] These and other features of the present invention will be described in more detail below in the detailed description of the invention and in conjunction with the following figures.

[0034] In order that the present invention may be more clearly ascertained, one or more embodiments will now be described, by way of example, with reference to the accompanying drawings, in which:

[0035] FIG. 1A illustrates an exemplary pair of transducing and sensing positions for measuring acoustic attenuation of a thoracic region in accordance with the present invention;

[0036] FIG. 1B illustrates an exemplary single location echo method for measuring acoustic attenuation of a thoracic region in accordance with the present invention;

[0037] FIG. 2 shows exemplary frontal ECG sensing positions located on the thoracic region;

[0038] FIG. 3A shows a front view illustrating one embodiment of a chest-patch which combines an ECG sensor with an acoustic transducer for the auscultation device of the present invention;

[0039] FIG. 3B shows a side view illustrating one embodiment of a chest-patch which combines an ECG sensor with an acoustic transducer for the auscultation device of the present invention;

[0040] FIG. 4A shows a front view illustrating another embodiment of a rectangular chest-patch which combines an ECG sensor with an acoustic transducer for the auscultation device of the present invention;

[0041] FIG. 4B shows a side view illustrating another embodiment of a rectangular chest-patch which combines an ECG sensor with an acoustic transducer for the auscultation device of the present invention;

[0042] FIG. 5 shows a side view illustrating one exemplary chest-piece which combine an acoustic transducer with an acoustic sensor for the auscultation device of the present invention;

[0043] FIG. 6 shows a side view illustrating a second exemplary chest-piece which combine an acoustic transducer with an acoustic sensor for the auscultation device of the present invention;

[0044] FIG. 7 shows a bottom view illustrating a third exemplary chest-piece which combines an acoustic transducer with an acoustic sensor in separate acoustic cavities for the auscultation device of the present invention;

[0045] FIG. 8A is a bottom view illustrating yet another chest-pad which includes a triplet of Acoustic Sensors in accordance with an embodiment of the present invention;

[0046] FIG. 8B is a bottom view illustrating yet another chest-pad which includes a quintuplet of Acoustic Sensors in accordance with an embodiment of the present invention;

[0047] FIG. 8C is a bottom view illustrating yet another chest-pad which includes a sextet of Acoustic Sensors in accordance with an embodiment of the present invention;

[0048] FIG. 9 shows an exemplary diagram of pressure, timing, blood volume and signals associated in a typical cardiac cycle;

[0049] FIG. 10A shows a functional block diagram of one embodiment of the auscultatory device in accordance with an embodiment of the present invention;

[0050] FIG. 10B shows a functional block diagram of another embodiment of the auscultatory device in accordance with an embodiment of the present invention;

[0051] FIG. 10C shows a functional block diagram of yet another embodiment of the auscultatory device in accordance with an embodiment of the present invention;

[0052] FIG. 10D shows a functional block diagram of yet another embodiment of the auscultatory device in accordance with an embodiment of the present invention;

[0053] FIG. 11 shows an illustration of a functional block diagram for the analyzer in accordance with an embodiment of the present invention;

[0054] FIG. 12 provides a detailed block diagram illustrating heart sound signal conditioner in accordance with an embodiment of the present invention;

[0055] FIG. 13 shows an exemplary process for self calibration of heart signals utilizing an embodiment of the auscultatory device;

[0056] FIG. 14 shows an exemplary process for signal conditioning of heart signals utilizing an embodiment of the auscultatory device;

[0057] FIG. 15 shows an exemplary process for generating the attenuation matrix utilizing an embodiment of the auscultatory device;

[0058] FIG. 16 shows an exemplary process for pulsed echo utilizing an embodiment of the auscultatory device;

[0059] FIG. 17 shows an exemplary process for motion detection in pulsed echo utilizing an embodiment of the auscultatory device;

[0060] FIG. 18 shows an exemplary process for structure speed detection in pulsed echo utilizing an embodiment of the auscultatory device;

[0061] FIG.19 shows an exemplary process for using the auscultatory device to determine ejection fraction in accordance with an embodiment of the present invention;

[0062] FIG. 20 shows an exemplary process for signal processing for ejection fraction determination in accordance with an embodiment of the present invention;

[0063] FIG. 21A shows an exemplary illustration of ECG and sound wave measurements for usage by ejection fraction analysis;

[0064] FIG. 21B shows an exemplary illustration of sound wave measurements for usage by ejection fraction analysis;

[0065] FIG. 22 shows an exemplary illustration of isolated ECG and sound wave measurement for usage by ejection fraction analysis;

[0066] FIG. 23A shows an exemplary illustration of ECG and sound wave measurements when attenuation signal is applied for usage by ejection fraction analysis;

[0067] FIG. 23B shows an exemplary illustration of sound wave measurements when attenuation signal is applied for usage by ejection fraction analysis;

[0068] FIG. 24 shows an exemplary illustration of filtered measured transduction signals for ejection fraction analysis;

[0069] FIG. 25A shows an exemplary illustration of pre-filtered measured heart signals for ejection fraction analysis;

[0070] FIG. 25B shows an exemplary illustration of post-filtered measured heart signals for ejection fraction analysis; and

[0071] FIG. 26 shows an exemplary illustration of measured heart signals before and after de-noising for ejection fraction analysis.

DETAILED DESCRIPTION OF THE INVENTION

[0072] The present invention will now be described in detail with reference to several embodiments thereof as illustrated in the accompanying drawings. In the following description, numerous specific details are set forth in order to provide a thorough understanding of the present invention. It will be apparent, however, to one skilled in the art, that the present invention may be practiced without some or all of these specific details. In other instances, well known process steps and/or structures have not been described in detail in order to not unnecessarily obscure the present invention. The features and advantages of the present invention may be better understood with reference to the drawings and discussions that follow.

[0073] Systems and methods for heart auscultation are provided. The present invention utilizes active sound signals in order to generate attenuation of sound signals through patient. In some embodiments, a transducer provides an active acoustic signal. The signal may be continuous wave or pulse in nature. At least one sensor perceives the signal that has propagated through the patient's soft tissue. The sensor may, in some embodiments, be coupled to an electronic stethoscope or similar device. Such devices may include additional signal processing as is desired. The received signal may be analyzed for attenuation caused by structures in the patient. These measurements may be utilized to calibrate the perceived heart sounds.

[0074] Alternatively, in some embodiments, the generated signal may be a pulse in nature which reflects within the body causing an echo. The sensor may perceive the echo to generate a brightness representation of reflectivity due to impedance inhomogeneities in the body. Motion, location and speed of valve closure may additionally be determined.

[0075] Additionally, Ejection Fraction (EF) may be computed by correlation to a calibrated first (S1) heart sound and heart sound ratios. Electrocardiogram measurements and catheter readings may be utilized to confirm Ejection Fraction values.

[0076] The present invention will be disclosed as a series of electro-mechanical auscultation devices enabled to generate and perceive the required signals. Additional

methods for the use of such devices for calibration, pulsed echo and ejection fraction will also be discussed.

[0077] Particular subheadings are included to provide guidance and organization to the disclosure. These sub headings are not intended to suggest or impose limitations upon the disclosed invention.

Auscultation Devices

[0078] To facilitate discussion, FIG. 1A shows an exemplary pair of transducing and sensing positions for measuring acoustic attenuation of the thoracic region **110** using an auscultation device, e.g., an Electronic Stethoscope **120**, of the present invention. Such an auscultation device includes an Acoustic Transducer **150** coupled to transducing position **141**, and an acoustic sensor or stethoscope **120**, coupled to sensing location **131**. Additional pairs of transducing and sensing positions may be used to generate an acoustic attenuation map of thoracic region **110**.

[0079] A suitable acoustic signal of known amplitude and frequency, e.g. a sine wave, may be provided by the Acoustic Transducer **150** at Transducing Location **141**. Since one primary object of the invention is to measure and compensate for the acoustic attenuation of S1, S2, S3, S4 heart sounds and heart murmurs as these heart sounds travel from the heart to the acoustic sensor of Stethoscope **120**, the acoustic signal may include a frequency range of about 50 Hz to 300 Hz. Depending on the implementation, this acoustic signal may include a series of stepped frequencies, a swept range of frequencies and/or multi-frequency signals.

[0080] In alternate embodiments, the acoustic signal from the transducer may have an acoustic frequency of 1 MHz and higher. Such embodiments enable the transducer signal to be filtered from the heart sounds by the Stethoscope **120**. Additionally, such frequency range may provide directional information through Doppler analysis that would not be ascertainable at lower frequency transducer signal.

[0081] Additionally, in some embodiments the transducer signal may be pulsed as to minimize interference with the Stethoscope **120** microphone. Such a pulsed

transducer signal, or echo pulse, may be relatively short, e.g. on the order of microseconds up to tens of microseconds.

[0082] The attenuated signal received at Sensing Location **131** is digitized, and may be analyzed in the frequency and/or time domain. For example, comparison of the digitized attenuated signal against the initial transduced signal allows for the computation of the degree of attenuation between Location **141** and Location **131**. The computed degree of attenuation may be a single constant of volume attenuation or a multi-value measurement of attenuation of volume at one or more frequencies. This measurement of attenuation may also include time variant measurements as a function of frequency. Other standard signal processing techniques known to one skilled in the arts may also be used to compute attenuation.

[0083] By taking measurements from suitable pairs of transducing and sensing locations distributed over the area of interest, a matrix of the attenuation may be compiled. Subsequently, this attenuation matrix may be used to calibrate heart sounds to compensate for acoustic attenuation caused by the intervening tissues and fluids between the heart and the sensor, thereby increasing the accuracy of the diagnosis of the various heart sounds and murmurs.

[0084] Figure 1B shows an exemplary diagram of transducer placement for pulse echo devices. In such embodiments the transducer and sensor may be located within the Echo Auscultation Devise **160**. Thus, in these embodiments, the Sensing Location **131** and Transducing Position **141** may be adjacent to one another, or may be the same Common Location **170**.

[0085] The Echo Auscultation Devise **160** provides the acoustic signal and subsequently senses the return echo, at the same Common Location **170** on the patient. Thus comfort and simplicity of the system is improved since there is only one pad needed.

[0086] As noted above, a suitable acoustic signal of known amplitude and frequency, e.g. a sine wave, may be provided by the acoustic transducer portion of the Echo Auscultation Device **160** at the Common Location **170**. Again, the acoustic signal may include a frequency range of about 50 Hz to 300 Hz or may have an acoustic frequency of 1 MHz and higher. Depending on the implementation, this

acoustic signal may include a series of stepped frequencies, a swept range of frequencies and/or multi-frequency signals.

[0087] Additionally, in some embodiments the transducer signal may be pulsed as to minimize interference from acoustic signal generation and acoustic measurements. Such a pulsed transducer signal, or echo pulse, may be relatively short, e.g. on the order of tens of microseconds.

[0088] The pulse echo is received at the Common Location **170**, where it is digitized, and may be analyzed in the frequency and/or time domain. Other standard signal processing techniques known to one skilled in the arts may also be used to compute analysis. Echo patterns may be compiled within an attenuation matrix, which may be used to calibrate heart sounds to compensate for acoustic attenuation caused by the intervening tissues and fluids between the heart and the sensor, thereby increasing the accuracy of the diagnosis of the various heart sounds and murmurs.

[0089] Figure 2 shows a selection of suitable auscultation sensing locations. These locations include aortic, pulmonary, mitral, tricuspid and apex locations. Other exemplary sensing locations include typical ECG sensing locations **231, 232, 233, 234, 235, 236** corresponding to anterior thoracic ECG positions V1, V2, V3, V4, V5 and V6 may also be used as shown in FIG. 2. Additional thoracic ECG sensing locations such as posterior ECG positions V7, V8 and V9 (not shown) may also be used. Other auscultation locations known to one skilled in the cardiac diagnostic arts may also be used.

[0090] In some embodiments, the method for measuring heart sounds is performed to identify motion within the chest cavity. When the sensory location is fixed on the patient's torso, the received acoustic signals are processed for structures and fluids along the acoustic path.

[0091] A "brightness line" image may be generated from the received acoustic signals as to provide a representation for the structures along the acoustic path. By maintaining a fixed acoustic path, and repeatedly sensing the structures, motion may be identified and tracked. A heart valve is in motion with respect to the patient's chest wall, thus the distance of the valve to the chest wall may be deduced. Such a deduction may accurately be used to enable the calibration of the heart sound of that

particular patient to his chest size or attenuation characteristics (the amount of subcutaneous fat, for example).

[0092] FIGS. 3A and 3B are front and side views illustrating one embodiment **300** of the present invention which combines an ECG sensor **320** and an acoustic transducer **330** housed in a bell-shaped body **310**. In this embodiment, ECG sensor **320** is a conductive ring allowing ECG electrical signal transmission from the base of body **310**. The bell-shaped body **310** focuses the acoustic signal generated by acoustic transducer **330**, e.g., a miniature speaker, located at the top of body **310**. ECG sensor **320** may include a sealing membrane to ensure both electrical conduction and mechanical air seal for superior acoustic transmission. Sealing may also be accomplished by an ECG gel in combination with or in place of a sealing membrane. Bell-shaped body **310** may be filled with air or fluid to facilitate acoustic transmission.

[0093] The Acoustic Transducer **330** may, in some embodiments, may be a traditional membrane and magnet speaker. Alternatively, Acoustic Transducer **330** may be a piezo transducer. Of course additional transducers may be utilized as is known by those skilled in the art.

[0094] A piezo Acoustic Transducer **330** may be capable of producing an acoustic signal, as well as sensing acoustic waves. Thus the Acoustic Transducer **330**, in some embodiments where piezo or similar designs are utilized, may both supply the acoustic signal as well as provide sensory reception. Such a transducer may be utilized in the Pulse Echo Unit **170** of Figure 1B. In these embodiments the Acoustic Transducer **330** provides a pulse of acoustic signal. During pulse generation the Acoustic Transducer **330** is unable to provide sensory, thus the length of pulse may be limited to a practical duration. In some embodiments, pulse duration of 10-30 microseconds is sufficient. The average cardiac cycle is on the magnitude of a full second, thus the pulse is a relatively short time for the Acoustic Transducer **330** to be unable to sense acoustic signals. Moreover, by interleaving the pulse and heart sounds over the cardiac signal, data loss may be mitigated.

[0095] In some alternate embodiments, the Acoustic Transducer **330** may be designed to only generate acoustic signals. Such an embodiment may be utilized in the separated Acoustic Transducer **150** and Stethoscope **120** design as illustrated in

Figure 1A. In these embodiments the Acoustic Transducer **330** may provide pulse acoustic signals, constant acoustic signals or a combination thereof.

[0096] Figures 4A and 4B are front and side views illustrating one embodiment **400** of the present invention which combines an ECG sensor **420** and an acoustic transducer in a flat housing **410** which may be square-shaped as shown, or may be another suitable shape such as rectangular, polygonal, or oval. Acoustic transducer may be a piezoelectric element coupled to the base of housing **410,** or may include additional acoustic generator designs, such as traditional speakers.

[0097] Again, the embodiment seen generally at **400** may include both acoustic generation and sensory, or may be limited to generation only, dependent on whether an echo type design, or a separated transducer and sensor design is required, as seen in Figure 1B and 1A respectively.

[0098] ECG sensor **420** may include a sealing membrane to ensure both electrical conduction and mechanical air seal for superior acoustic transmission. Sealing may also be accomplished by an ECG gel in combination with or in place of a sealing membrane.

[0099] FIG. 5 is a side view illustrating one embodiment of a chest-piece **500** which combines an acoustic transducer **530** with an acoustic sensor **540** in a bell shaped housing **510,** the chest-piece **500** useful with the auscultation device of the present invention. Such a devise may be utilized in an echo type method as illustrated in Figure 1B. Acoustic transducer **530** and an acoustic sensor **540** may be piezos, however traditional microphone and speaker arrangements may also be utilized.

[00100] The acoustic sensor **540** may be sensitive to sound frequencies between 10 Hz to 500 Hz as well as frequencies generated by the acoustic transducer **530.** Thus the acoustic sensor **540** may provide auscultation as well as attenuation measurement for calibration. Alternatively, in some embodiments, the acoustic transducer **530** generates sound waves in the MHz range, and it may be more desirable for the acoustic sensor **540** may be comprised of multiple sensors to cover the range of physiological and generated sound waves. Thus one benefit of a separate acoustic sensor **540** may be a more sensitive sensory capability across a greater frequency range.

[00101] An additional benefit of separate acoustic transducer **530** and acoustic sensor **540** is the elimination of the sensory blindness that occurs during generation when a single transducer is utilized. As such, a chest-piece as illustrated generally at **500** may provide continuous, as well as pulse acoustic attenuation.

[00102] ECG sensor **520** may include a sealing membrane to ensure both electrical conduction and mechanical air seal for superior acoustic transmission. Sealing may also be accomplished by an ECG gel in combination with or in place of a sealing membrane.

[00103] FIG. 6 is a side view of another exemplary chest-piece **600** which includes an acoustic transducer **630** located in an outer annulus **650** combined with an acoustic sensor **640** located on an inner sensing bell **610**, the chest-piece **600** useful with the auscultation device of the present invention.

[00104] The chest piece depicted generally at **600** provides the same functionalities as the one shown at Figure 5; however, by separating the acoustic transducer **630** from the acoustic sensor **640** within separate bells there may be a reduction in interference from the acoustic transducer **630** signal and the acoustics received by the acoustic sensor **640**. Again the acoustic sensor **640** may be a sensory array, enabled to sense across a wide range of sound frequencies.

[00105] ECG sensor **620** may include a sealing membrane to ensure both electrical conduction and mechanical air seal for superior acoustic transmission. Sealing may also be accomplished by an ECG gel in combination with or in place of a sealing membrane.

[00106] FIG. 7 is a bottom view illustrating yet another chest-piece **700** which includes an acoustic sensor **740** located in a sensing cavity **710** combined with an acoustic transducer **730** located in an attached auxiliary cavity **750**. Cavities **710, 750** function as independent acoustic chambers to minimize cross-interference between transducer **730** and sensor **740**. Optional sealing membrane **720a, 720b** may be added to improve the acoustic properties of cavities **710, 750**, respectively.

[00107] Although not illustrated, the Chest-Piece **700** may include an ECG sensor, which may include a sealing membrane to ensure both electrical conduction and mechanical air seal for superior acoustic transmission. Sealing may also be accomplished by an ECG gel in combination with or in place of a sealing membrane.

[00108] FIG. 8A is a bottom view illustrating yet another chest-pad **810** which includes a triplet of Acoustic Sensors labeled **811a, 811b** and **811c** respectively. Acoustic Sensors **811a, 811b** and **811c** may be interconnected by a Webbing **812.**

[00109] Webbing **812** may, in some embodiments, be a cloth mesh or plastic. Alternatively, Webbing **812** may be rigid in nature and include metal or plastics. In some embodiments, Webbing **812** may be connector rods of any suitable material. Webbing **812** functions to maintain the relative positions of the Acoustic Sensors **811a, 811b** and **811c** to one another.

[00110] Acoustic Sensors **811a, 811b** and **811c** may be arranged in an isosceles triangular fashion. Alternate orientations may additionally be utilized as is desired. In some embodiments, Acoustic Sensors **811a, 811b** and **811c** may be bell shaped sensor pads, with a microphone or piezo sensor in the vertex of the bell. Additionally, Acoustic Sensors **811a, 811b** and **811c** may include ECG functionality.

[00111] Acoustic Sensors **811a, 811b** and **811c** may, in some embodiments, additionally provide an active signal through a transducer. In other embodiments, a separate transducer may be utilized to generate the active acoustic signals.

[00112] Moreover, perceived signals by the Acoustic Sensors **811a, 811b** and **811c** may enable depth and location triangulation for internal structures when utilizing echo signals.

[00113] In some embodiments, the Chest Pad **810** may be designed in variant sizing for separate body sizes and types. In some embodiments, the Webbing **812** may be elastic as to increase wearer comfort and enable a singular device to be utilized by a wide gamut of individuals.

[00114] FIG. 8B is a bottom view illustrating yet another chest-pad **820** which includes a quintuplet of Acoustic Sensors labeled **821a, 821b, 821c, 821d** and **823** respectively. Acoustic Sensors **821a, 821b, 821c, 821d** and **823** may be interconnected by a Webbing **822.** In the present design Acoustic Sensors **821a, 821b, 821c** and **821d** are oriented in a square geometry around a central Acoustic Sensor **823.** Alternate orientations may additionally be utilized as is desired. The central Acoustic Sensor **823** may, in some embodiments, provide a transducer. Additional Acoustic Sensors **821a, 821b, 821c, 821d** and **823** may, in some embodiments, additionally provide an active signal through a transducer. In other

embodiments, a separate transducer may be utilized to generate the active acoustic signals.

[00115] As previously discussed, Webbing **822** may, in some embodiments, be a cloth mesh or plastic. Alternatively, Webbing **822** may be rigid in nature and include metal or plastics. In some embodiments, Webbing **822** may be connector rods of any suitable material. Webbing **822** functions to maintain the relative positions of the Acoustic Sensors **821a, 821b, 821c, 821d** and **823** to one another.

[00116] In some embodiments, Acoustic Sensors **821a, 821b, 821c, 821d** and **823** may be bell shaped sensor pads, with a microphone or piezo sensor in the vertex of the bell. Additionally, Acoustic Sensors **821a, 821b, 821c, 821d** and **823** may include ECG functionality.

[00117] Moreover, perceived signals by the Acoustic Sensors **821a, 821b, 821c, 821d** and **823** may enable depth and location triangulation for internal structures when utilizing echo signals.

[00118] As previously discussed, in some embodiments, the Chest Pad **820** may be designed in variant sizing for separate body sizes and types. In some embodiments, the Webbing **822** may be elastic as to increase wearer comfort and enable a singular device to be utilized by a wide gamut of individuals.

[00119] FIG. 8C is a bottom view illustrating yet another chest-pad **830** which includes a sextet of Acoustic Sensors labeled **831, 832, 833, 834, 835** and **836** respectively. Acoustic Sensors **831, 832, 833, 834, 835** and **836** may be interconnected by a Webbing **839**. In the present design Acoustic Sensors **831, 832, 833, 834, 835** and **836** are oriented at the anterior thoracic ECG positions V1, V2, V3, V4, V5 and V6 respectively, as shown in FIG. 2. The Webbing **839** ensures proper placement of the Acoustic Sensors **831, 832, 833, 834, 835** and **836** across the patients torso, and enables the application of a single pad for multiple readouts.

[00120] As previously discussed, Webbing **839** may, in some embodiments, be a cloth mesh or plastic. Alternatively, Webbing **839** may be rigid in nature and include metal or plastics. In some embodiments, Webbing **839** may be connector rods of any suitable material. Webbing **839** functions to maintain the relative positions of the Acoustic Sensors **831, 832, 833, 834, 835** and **836** to one another.

[00121] In some embodiments, Acoustic Sensors **831, 832, 833, 834, 835** and **836** may be bell shaped sensor pads, with a microphone or piezo sensor in the vertex of the bell. Additionally, Acoustic Sensors **831, 832, 833, 834, 835** and **836** may include ECG functionality.

[00122] Moreover, Acoustic Sensors **831, 832, 833, 834, 835** and **836** may, in some embodiments, additionally provide an active signal through a transducer. In other embodiments, a separate transducer may be utilized to generate the active acoustic signals.

[00123] Moreover, perceived signals by the Acoustic Sensors **831, 832, 833, 834, 835** and **836** may enable depth and location triangulation for internal structures when utilizing echo signals.

[00124] As previously discussed, in some embodiments, the Chest Pad **830** may be designed in variant sizing for separate body sizes and types. In some embodiments, the Webbing **839** may be elastic as to increase wearer comfort and enable a singular device to be utilized by a wide gamut of individuals.

[00125] Figure 9 shows an exemplary diagram of pressure, timing, blood volume and signals associated in a typical cardiac cycle, shown generally at **900**.

[00126] The cardiac cycle diagram shown depicts changes in aortic pressure (AP) **911**, left ventricular pressure (LVP) **912**, left atrial pressure (LAP) **913**, left ventricular volume (LV Vol) **920**, acoustic echo Pulse **940** and heart sounds **950** during a single cycle of cardiac contraction and relaxation. These changes are related in time to the electrocardiogram.

[00127] Typically aortic pressure is measured by inserting a pressure catheter into the aorta from a peripheral artery, and the left ventricular pressure is obtained by placing a pressure catheter inside the left ventricle and measuring changes in intraventricular pressure as the heart beats. Left arterial pressure is not usually measured directly, except in investigational procedures. Ventricular volume changes can be assessed in real time using echocardiography or radionuclide imaging, or by using a special volume conductance catheter placed within the ventricle.

[00128] A single cycle of cardiac activity can be divided into two basic stages. The first stage is diastole, which represents ventricular filling and a brief period just

prior to filling at which time the ventricles are relaxing. The second stage is systole, which represents the time of contraction and ejection of blood from the ventricles.

[00129] The Pulse **940** shown is intended to be exemplary in nature. The Pulse **940** may be 10 to 100 microseconds in length. In some embodiments, longer pulses may be utilized. The diagram illustrates a longer Pulse **940** for viewing ease. In yet other embodiments, continuous acoustic signals may be supplied by the acoustic transducer. Additionally, the Pulse **940** may be varied in time across the cardiac cycle as to interleave the Pulse **940** and heart sounds.

[00130] Figures 10A through 10D provide exemplary functional diagrams of the auscultatory device. Additional embodiments are possible, and it is intended that the spirit of these additional embodiments is included in the exemplary embodiments.

[00131] Figure 10A shows a functional block diagram of one embodiment of the auscultatory device shown generally at **1000A**. The Acoustic Transducer **1010** may be any of the sensory devices illustrated in Figures 3A to 7, as well as any sensory design as is known by those skilled in the art. The Acoustic Transducer **1010** may couple to a Pre-amplifier **1020**. An Acoustic Sensor **1015** may be any acoustic sensor designed to be responsive to heart sounds, such as a Stethoscope **120**. The Acoustic Sensor **1015** may likewise couple to the Pre-amplifier **1020**. In some embodiments, the Acoustic Sensor **1015** and Acoustic Transducer **1010** may be housed within the same unit. Additionally, in some embodiments, a single sensor may incorporate both the Acoustic Sensor **1015** and Acoustic Transducer **1010**.

[00132] The Pre-amplifier **1020** may amplify the source signal to line signal levels. Additional equalizing and tone control may be performed by the Pre-amplifier **1020** as well. In some embodiments, where the echo signal received from the Acoustic Transducer **1010** far outweighs the heart signals from the Acoustic Sensor **1015**, additional protective circuitry may be utilized in order to preserve the heart sound signals.

[00133] The Pre-amplifier **1020** couples to a Filter **1030**, which is enabled to separate the signals relating to heart sounds from those received from the echo of the generated acoustic signals. As previously discussed, heart sounds are typically low in frequency, e.g. typically 10 to 500 Hz. The generated acoustic signals may be in the MHz range. As such, high pass and low pass filters may easily distinguish between

sounds originating from the heart, and those echoing from the generated signals from the acoustic transducer.

[00134] The Filter **1030** may be coupled to a Doppler Engine **1040** and an Analyzer **1050**. The Doppler Engine **1040** may, in some embodiments, receive the echo signals separated by the Filter **1030**, while the heart sounds are sent directly to the Analyzer **1050**. The Doppler Engine **1040** may be enabled to deduce the speed at which the valve leaflet is moving with respect to the sound wave by detecting Doppler shifting. Alternatively, another way to deduce the speed is to measure the distance traversed by the moving leaflet, and knowing the time interval between the two measurements and computing leaflet speed. In such embodiments the Doppler Engine **1040** may be unnecessary. The former involves more sophisticated electronics; the latter is simpler in implementation but may be less precise. Additional methods of determining valve leaflet speed may be utilized as is known by those skilled in the art.

[00135] The Doppler Engine **1040** also allows for blood flow to be detected and further helps to characterize any heart sound component caused by regurgitant jet. Additionally, Doppler processing increases the accuracy and robustness of determining the spatial (which valve) and temporal (systole or diastole) origin of a murmur.

[00136] The Analyzer **1050** may provide display and analysis of the received signals. Such analysis includes, but is not limited to S1/S2 sound ratios and heart sound calibration utilizing the ratio of S1 and the attenuated sound (Sc), the intensity ratio (S1/Sc).

[00137] Figure 10B shows a functional block diagram of another embodiment of the auscultatory device shown generally at **1000B**. The Acoustic Transducer **1010** may be any of the sensory devices illustrated in Figures 3A to 7, as well as any sensory design as is known by those skilled in the art. The Acoustic Transducer **1010** may couple to a Transducer Pre-amplifier **1070**. An Acoustic Sensor **1015** may be any acoustic sensor designed to be responsive to heart sounds, such as a Stethoscope **120**. The Acoustic Sensor **1015** may be couple to the Microphone Pre-amplifier **1090**. In some embodiments, the Acoustic Sensor **1015** and Acoustic Transducer **1010** may be housed within the same unit.

[00138] The Transducer Pre-amplifier **1070** may amplify the perceived pulse echo signal to a line signal levels. Additional equalizing and tone control may be performed by the Transducer Pre-amplifier **1070** as well. Likewise, the Microphone Pre-amplifier **1090** may amplify the perceived heart sound signal to a line signal levels. Additional equalizing and tone control may be performed by the Microphone Pre-amplifier **1090** as well. The utilization of two channels dedicated to heart sounds and pulse echo signals separately eliminates the requirement for filters.

[00139] The Transducer Pre-amplifier **1070** may be coupled to a Doppler Engine **1040**. As previously stated, the Doppler Engine **1040** may be enabled to deduce the speed at which the valve leaflet is moving with respect to the sound wave by detecting Doppler shifting. Alternatively, as previously discussed, alternative methods for determining valve leaflet speed may be utilized.

[00140] The Doppler Engine **1040** also allows for blood flow to be detected and further helps to characterize any heart sound component caused by regurgitant jet. Additionally, Doppler processing increases the accuracy and robustness of determining the spatial (which valve) and temporal (systole or diastole) origin of a murmur.

[00141] The Microphone Pre-amplifier **1090** and the Doppler Engine **1040** couple to the Analyzer **1050** which may provide display and analysis of the received signals. Such analysis includes, but is not limited to S1/S2 sound ratios and heart sound calibration utilizing the ratio of S1 and the attenuated sound (Sc), the intensity ratio (S1/Sc).

[00142] Figure 10C shows a functional block diagram of yet another embodiment of the auscultatory device shown generally at **1000C**. The Acoustic Transducer **1010** may be any acoustic generation device, such as speaker or piezo, as is known by those skilled in the art. An Acoustic Sensor **1015** may be any acoustic sensor designed to be responsive to heart sounds and the acoustic signal generated by the Transducer **1010**, such as a Stethoscope **120**. The Acoustic Sensor **1015** may be couple to the Microphone Pre-amplifier **1090**. In some embodiments, the Acoustic Sensor **1015** and Acoustic Transducer **1010** may be housed within the same unit.

[00143] The Microphone Pre-amplifier **1090** may amplify the perceived heart sound signal and tansduced signal to a line signal levels. Additional equalizing and

tone control may be performed by the Microphone Pre-amplifier **1090** as well. A Filter **1030** may separate the perceived heart sound signal from the transduced signal. Alternatively, in some embodiments, time interleaving may be utilized in order to temporally separate heart signals from transduced signals.

[00144] The Transducer **1010** and the Filter **1030** couples to the Analyzer **1050** which may provide display and analysis of the received signals. Such analysis includes, but is not limited to S1/S2 sound ratios and heart sound calibration utilizing the ratio of S1 and the attenuated sound (Sc), the intensity ratio (S1/Sc).

[00145] Figure 10D shows a functional block diagram of yet another embodiment of the auscultatory device shown generally at **1000D**. The Acoustic Transducer **1010** may be any of the sensory devices illustrated in Figures 3A to 7, as well as any sensory design as is known by those skilled in the art. In this and similar embodiments the Transducer **1010** may both generate a pulse echo as well as provides sensory ability. The Acoustic Transducer **1010** may couple to a Transducer Pre-amplifier **1070**. Transducer **1010** may be designed to be responsive to heart sounds as well as the generated pulse echo.

[00146] The Transducer Pre-amplifier **1070** may amplify the perceived pulse echo signal and heart sound signal to a line signal levels. Additional equalizing and tone control may be performed by the Transducer Pre-amplifier **1070** as well. A Filter **1030** may separate the perceived heart sound signal from the tansduced signal. Alternatively, in some embodiments, time interleaving may be utilized in order to temporally separate heart signals from transduced signals.

[00147] The Filter **1030** may be coupled to a Doppler Engine **1040**. As previously stated, the Doppler Engine **1040** may be enabled to deduce the speed at which the valve leaflet is moving with respect to the sound wave by detecting Doppler shifting. Alternatively, as previously discussed, alternative methods for determining valve leaflet speed may be utilized.

[00148] The Doppler Engine **1040** also allows for blood flow to be detected and further helps to characterize any heart sound component caused by regurgitant jet. Additionally, Doppler processing increases the accuracy and robustness of determining the spatial (which valve) and temporal (systole or diastole) origin of a murmur.

[00149] The Doppler Engine **1040** couples to the Analyzer **1050** which may provide display and analysis of the received signals. Such analysis includes, but is not limited to S1/S2 sound ratios and heart sound calibration utilizing the ratio of S1 and the attenuated sound (Sc), the intensity ratio (S1/Sc), speed and motion analysis and localization of sound sources.

[00150] FIG. 11 shows an illustration of a functional block diagram for the Analyzer **1050** in accordance with an embodiment of the present invention. Analyzer **1050** includes a Signal Conditioner **1152**, Signal Processor **1153**, Memory **1154**, User Interface **1155**, Video Display **1156** and Acoustic Input/Output Device **1157**.

[00151] Input Signals **1151** are received from the Doppler Engine **1040**, Filter **1030** and Microphone Pre-Amplifier **1090**. Such raw Input Signals **1151** are processed through a Signal Conditioner **1152**. Conditioned signals may then be analyzed by the Signal Processor **1153**. Signal Processor **1153** may couple to Memory **1154**, User Interface **1155**, Video Display **1156** and Acoustic Input/Output Device **1157**.

[00152] Memory **1154** can be fixed or removal memory, and combinations thereof. Examples of suitable technologies for memory **1154** include solid-state memory such as flash memory, or a hard disk drive.

[00153] User interface **1155** can be a keypad, a keyboard, a thumbwheel, a joystick, and combinations thereof. Video display **1156** can be an LCD screen, or can be an LED display or a miniature plasma screen. It is also possible to combine video display **1156** with user interface **1155** by use of technologies such as a touch screen. Contrast and brightness control capability can also be added to display **1156**.

[00154] Acoustic input/output (I/O) device **1157** includes a microphone, and speakers, earphones or headphones, any of which can be internal or external with respect to Analyzer **1050**. It is also possible to use wireless acoustic I/O devices such as a Bluetooth-based headset. Volume control may also be provided.

[00155] Logical couplings of these components may be otherwise organized as is advantageous. Additionally, alternate or additional components may be included in the Analyzer **1050**.

[00156] FIG. 12 provides a detailed block diagram illustrating heart sound Signal Conditioner **1152** which includes an Input Buffer **1210**, one or more Band Pass

Filter(s) **1220**, a Variable Gain Amplifier **1230**, a Gain Controller **1240** and an Output Buffer **1250**. Output buffer **1250** is coupled to Signal Processor **1153** which in turn is coupled to Gain Controller **1240**.

[00157] In some embodiments, Filter **1220** is a 4th order Butterworth pass band of 5 Hz to 2 kHz which limits the analysis of the heart sound signal to frequencies less than 2 kHz, thereby ensuring that all frequencies of the heart sounds are faithfully captured and at the same time eliminating noise sources that typically exist beyond the pass band of Filter **1220**. Of course additional Filters **1220** may be utilized as is desired.

[00158] Variable Gain Amplifier **1230** of Signal Conditioner **1152** serves to vary the signal gain based on a user-selectable input parameter, and also serves to ensure enhanced signal quality and improved signal to noise ratio. The conditioned heart sound signal after filtering and amplification is then provided to Signal Processor **1153** via Output Buffer **1250**.

[00159] Additional signal conditioning components may be incorporated into the Signal Conditioner **1152** as is desired. For example, in some embodiments, a component for eliminating low amplitude noise signals may be utilized.

Self Calibration

[00160] Figures 13 to 15 provide methods and processes for the calibration of heart sound measurements by use of an active transduction signal. Such a signal may be measured to produce attenuation values and subsequent heart sound calibrations. Heart sound calibration has diagnostic use, and provides an ability to perform cross-patient heart sound analyses.

[00161] Figure 13 shows an exemplary process for self calibration of heart signals utilizing an embodiment of the auscultatory device, shown generally at **1300**. Such a process may be performed automatically by the auscultatory device, without need of user input. Such a process may equalize heart sounds from a range of patients. Additionally, calibrated heart signals may be utilized in a range of subsequent diagnostic processes, such as Ejection Fraction determination.

[00162] In some embodiments, there are two ways to calibrate S1, each with its own advantages and disadvantages. The first includes calibrating S1 with S2. The advantage of this method is that each patient will calibrate him/herself, since the body equally attenuates both sounds and there is no additional need to work out different attenuations for different people. A simple comparison of a patient's S1 intensity to their S2 intensity may be utilized to produce meaningful diagnostic ratios. The disadvantage of this method is that S2 itself may be affected by a heart condition and may be unsuitable.

[00163] Secondly, calibration of the S1 may be performed by utilizing the attenuation values recorded. In some embodiments, multiple tones may be utilized, at various frequencies in the first heart sound spectrum. The advantage of this method is that the attenuation of the tones should be representative on each subject of sound attenuation in their body. There is no bias regarding their cardiac health, as is the case with calibration by S2. In some embodiments, the transmission tones are just simple tones,; however more complex attenuation signals may be utilized.

[00164] The process begins at step **1301** where the transducer is placed upon the patient at the Transducing Location **141**. Any transducer disclosed in Figures 3 to 8c may be utilized. In some embodiments, such transducers produce a constant active signal during calibration. A sensor, may be placed at the Sensing Location **131** at step **1302**. The sensor may receive signals that pass through the patient's body. These received signals are measured at step **1303**. As addressed earlier, the transduced signals may be within physiological frequency ranges. Additional frequencies, steeped frequencies and variable frequencies may also be utilized. A single sensor may be utilized to measure both generated attenuation signal as well as patient heart sounds. Alternatively, additional sensors may be utilized to measure heart sounds and attenuation signals. Sensor(s) responsive range is calibrated to be sensitive to attenuation signal range and physiological sound ranges.

[00165] At step **1304**, a determination is made as to whether heart sounds and attenuation signals are on the same channel. Such is the case when attenuation signal and heart sounds are perceived by a common sensor. If these signals share a single channel, the signals may be filtered at step **1305**. Filtering may be performed by band pass filtering, in the instances where attenuation signal is of a separate frequency range than heart sounds. Alternatively, filtering may include a very narrow band pass

filter for the attenuation frequency when the attenuation signal is within a physiological range. The signal is then conditioned at step **1306**.

[00166] If, at step **1304**, the attenuation signal and the heart sounds are on separate channels, then the signal is conditioned at step **1306**. Separate channels for the heart signals and attenuation signals is achieved when separate frequency ranges are utilized for the attenuation signal as compared to the heart sound frequency, and separate sensors are utilized for the measuring of the respective signals. The sensors may, in some embodiments, be responsive to the particular frequency range they are measuring thereby providing an intrinsic filtering.

[00167] After signal conditioning, the process proceeds to step **1307**, where an attenuation matrix is generated. To generate the matrix, the signal amplitude for each transducer/sensor location is compiled.

[00168] Then at step **1308**, the measured heart sounds may be calibrated by using the attenuation matrix. The S1 may be calibrated by the use of any combination of the values in the attenuation matrix.

[00169] Figure 14 shows an exemplary process for signal conditioning of heart signals utilizing an embodiment of the auscultatory device, shown generally at **1306**. Signal conditioning may occur at the Signal Conditioner **1152**.

[00170] The process begins from step **1305** from figure 13. The process then proceeds to step **1401** where the input signal is buffered. Buffering occurs at the Input Buffer **1201**. Then, at step **1402**, the signal may undergo additional filtering. The filtering operations may involve simple filters, for example a straightforward analog Butterworth nth order bandpass/lowpass/highpass filter. It is conceivable that wavelet operations, which by their nature divide up the signal into various frequency bands, can also be used to carry out measurements on the heart sound signal. Additional filtering techniques may be employed as is known by those skilled in the art. Filtering may occur at the Band Pass Filter(s) **1202**.

[00171] The process then proceeds to step **1403** where gain may be automatically controlled. A Variable Gain Amplifier **1203** in conjunction with the Gain Controller **1204** may effectuate automatic gain control.

[00172] The process then proceeds to step **1404** where the output is buffered. The Output Buffer **1205** may perform this operation. Additional signal conditioning steps

may be performed as is known by those skilled in the art. The process then ends by proceeding to step **1307**.

[00173] Figure 15 shows an exemplary process for generating the attenuation matrix utilizing an embodiment of the auscultatory device, shown generally at **1307**. The use of an attenuation matrix is but one suitable method of representing attenuation signal data for use with calibration. As such, the present method is intended to be exemplary in nature. No limitations upon the present invention are suggested by the disclosure of attenuation matrix generation. Moreover, additional representations, such as a single attenuation value, an attenuation value list or three dimensional attenuation value matrices may be utilized.

[00174] The process begins from step **1306**. Then at step **1501** an inquiry is made whether an additional sensing location is desired. If at step **1306** an additional sensing location is desired, then the process proceeds to step **1502**, where the known initial transduction signal is compared to the perceived attenuation signal. The initial transduction signal may, in some embodiments, include a constant sinusoidal sound signal. Alternative sound waveforms, frequencies and durations may be utilized as is desired. The difference between the known initial transduction signal and the perceived attenuation signal provides information about internal structures along the sound wave path.

[00175] Then at step **1503**, an inquiry is made as to whether the transduction signal was a single frequency signal. If so, then at step **1504** a single attenuation value may be generated. The single attenuation value may then be added to an attenuation matrix in step **1506**.

[00176] Else, if at step **1503**, the initial transduction signal was not of a single frequency, then the process proceeds to step **1505** where multiple attenuation values are generated. The multiple attenuation values may then be added to an attenuation matrix in step **1506**.

[00177] Then in step **1507**, a time variant value may be added to the matrix. The time variant value is the time differential between signal transduction and perceived attenuation signal measurement.

[00178] The process then proceeds back to step **1501**, where an inquiry is made whether an additional sensing location is desired. In this way the process will be

repeated for each sensing location desired. Attenuation values for each sensing location may be compiled into the attenuation matrix. Once all sensing locations have been measured the process ends.

[00179] In this way heart sounds may be calibrated for by utilizing an active transduction signal that passes through the patient's chest cavity. Additional methods for heart sound calibration may additionally be utilized, including both invasive and non-invasive procedures.

Pulsed Echo

[00180] Figures 16 to 18 further illustrate methods for pulsed echo cartographic analysis. Pulsed echo refers to the usage of pulsed acoustics to provide a reflective "image" of internal structures. In some embodiments, the echo pulse may be of higher frequencies as to provide adequate resolutions. The ability to sense structure motion, location and speed of motion makes the pulsed echo of particular use in identifying pathologies such as a faulty valve.

[00181] Figure 16 shows an exemplary process for pulsed echo utilizing an embodiment of the auscultatory device, shown generally at **1600**. The process begins at step **1601** where the pulsed echo transducer is placed in the transducer position on the patient's torso. Then, at step **1602**, an echo pulse is induced. The echo pulse, in some embodiments, may be a few microseconds up to few tens of microseconds in duration. Operating in MHz range provides adequate resolution. Echo pulses may be repeated as necessary.

[00182] At step **1603** the return echo is measured. Then, at step **1604**, an inquiry is made whether to utilize time interleaving. -If time interleaving is desired then the process proceeds to step **1605** where echo pulses and cardiac signals are interleaved as to minimize the potential loss of signal data. Time interleaving separates heart signals from echo pulse temporally, thereby removing the need for additional filtering. Time interleaving may additionally be useful when the echo pulse saturates the received signals. Then at step **1607** a bright line image is generated. The bright line image is a representation of the structures encountered by the pulse echo.

[00183] Else if at step 1604 time interleaving is not desired the process then proceeds to step **1606**, where the heart signals are filtered from the echo signals. Since, in some embodiments, the echo pulse is of much higher frequency than heart sounds, a simple high pass filtering may be utilized to separate heart signals from the echo pulse. Then at step **1607** a bright line image is generated. The bright line image is a representation of the structures encountered by the pulse echo.

[00184] Then at step **1608** structure motion is identified. An inquiry is made if moving structure speed is to be determined at step **1609**. In some embodiments, speed of moving structures may be automatically generated. In other embodiments, speed determination may be performed on a case by case basis. In such embodiments the user physician may select a mode for speed capture on the auscultatory device. If speed of the moving structure is desired the process proceeds to step **1610** where the structure speed is identified. Typical structures which speed may be measured includes heart valve leaflet closure rates, blood flow, heart wall constriction or any additional moving structure. After structure speed is determined the process ends. Else, if at step **1609** structure speed is not a required measurement, the process ends.

[00185] Figure 17 shows an exemplary process for motion detection in pulsed echo utilizing an embodiment of the auscultatory device, shown generally at **1608**. A brightness line image generated from the received acoustic signals provides a representation for the structures along the acoustic path. By maintaining a fixed acoustic path, and repeatedly sensing the structures, motion may be identified and tracked. A heart valve is in motion with respect to the patient's chest wall, thus the distance of the valve to the chest wall may be deduced. Such a deduction may accurately be used to enable the calibration of the heart sound of that particular patient to his chest size or attenuation characteristics (the amount of subcutaneous fat, for example).

[00186] Motion analysis helps to orient the heart sound to the particular valve as indicated by the motion trace and can achieve better isolation of particular disease signature of the heart sound associated with that particular valve.

[00187] The process begins from step **1607**. At step **1701** a first brightness encoded image is generated. This first image is generated with the sensor fixed to the patient's chest. Thus the image provided is stationary in relation to patient's chest

wall. Then at step **1702** another brightness encoded image is generated. Likewise, this additional image is generated with the sensor fixed to the patient's chest. Thus the image provided is stationary in relation to patient's chest wall. The two images are compared for moving structures at step **1703**. Since both images "look" at the same space related to the patient's chest wall, discrepancies between the two brightness encoded images is a result of movement of the a structure. Additionally, pulse echo timing and orientation may additionally provide structure location information. Thus, the moving structures location may be likewise identified.

[00188] At step **1704** an inquiry is made whether the moving structure is adequately identified. A statistical analysis of confidence levels, as measured by a threshold, may be utilized to determine this. For example, if the auscultatory device is calibrated such that a greater than 75% identification of moving structures is required, and the brightness encoded images identify a moving structure 50% of the time the auscultatory device may determine that the structure is not adequately identified. In such a circumstance, the process then proceeds to step 1705 where an inquiry is made whether moving structure identification has timed out. If the process has not timed out, then the process may return to step 1702 where an additional brightness encoded image is generated in an attempt to clarify the identification. The process then continues the cycle of comparison, confidence inquiry, etc.

[00189] Else, if at step **1705** the process for determining the moving structure has timed out then the process proceeds to step **1707**, where an error message is generated. Such an error message may provide either an information request or suggestion. For example, if the sensor is not pointing in a stable fashion due to hand motion etc, it may indicate repositioning or provide feedback to the user and likewise indicate when the sensor is pointing accurately at the moving structure. The process then ends by proceeding to step **1609**.

[00190] Otherwise, if at step **1704** the moving structure is adequately identified then the process may output the moving structure's location at step **1706**. The process then ends by proceeding to step **1609**.

[00191] Figure 18 shows an exemplary process for structure speed detection in pulsed echo utilizing an embodiment of the auscultatory device, shown generally at **1610**. The illustrated method includes utilizing a motion trace, Doppler shift

detection and alternate methods. In some embodiments, there may be limitations on hardware available, such as Doppler processors. In these embodiments the available hardware may dictate speed determination decisions.

[00192] The process begins from step **1609**. Then at **1801** an inquiry is made whether to perform a Doppler shift analysis. If a Doppler shift analysis is desired then the process proceeds to step **1802** where the shift analysis is performed. As the pulse reflects from a moving structure the return echo will have shifted frequency as related to the speed of the moving structure. A Doppler Engine **1040** may measure the amount of frequency shift in order to determine structure speed. The process then progresses to step **1803** where an inquiry is made whether to determine structure speed by motion tracking.

[00193] Else, if at step **1801** a Doppler shift analysis is not performed, then the process progresses to step **1803** where an inquiry is made whether to determine structure speed by motion tracking. Motion tracking for speed determination is simpler than Doppler analysis and requires less hardware, however it tends to be less precise. In some embodiments, motion tracking may be performed in conjunction with Doppler analysis for speed confirmation. If motion tracking for speed determination is desired then the distance the structure has moved is determined at step **1804**. The location information generated during motion detection may be utilized to compute distance traveled. Distance may then be referenced by time taken to travel said distance to generate structure velocity, at step **1805**. Then the process proceeds to step **1806** where an inquiry is made whether to determine structure speed by alternate methods.

[00194] Otherwise, if at step **1803** motion tracking for speed determination is not desired then the process proceeds to step **1806** where an inquiry is made whether to determine structure speed by alternate methods. Alternate methods may include invasive optical readings, radioactive tagging or any alternate method as is known by those skilled in the art for speed detection. If the alternate method is desired then it may be performed at step **1807**. The speed value is then output at step **1808**.

[00195] Else, if at step **1806** determining structure speed by alternate methods is not desired then the process continues directly to step **1808** where speed values are output. Speed value output may include average speed values, maximum and

minimum structure speed, and any additional statistical information on structure speed as is desired. The process then ends.

[00196] Pulsed echo techniques have particular implications for diagnosis of conditions such as heart murmurs and characterization of any heart sound component caused by regurgitant jet. In heart murmurs sound location in relation to specific heart valves, valve leaflet closure speed, and blood flow speeds are of particular importance for proper characterization and diagnosis of the ailment. Pulsed echo's ability to locate moving structures, such as heart valves, and determine structure speed is ideal for aiding these heart murmur diagnosis.

[00197] Additionally, pulsed echo methods may provide tissue characterization by determination of the distance of the valve to the chest wall. Said distance information may be utilized to calibrate the heart sound of that particular patient to his chest size or attenuation characteristics (the amount of subcutaneous fat, for example). Thus pulsed echo, in conjunction with attenuation information may be utilized to further provide detailed and accurate calibrations of perceived heart sounds.

Ejection Fraction Analysis

[00198] Figures 19 to 26 provide exemplary methodologies and examples of the utilization of the auscultatory device to determine Ejection Fraction values for heart patients. Ejection Fraction (EF) is the fraction of blood pumped out of a ventricle with each heart beat. The term ejection fraction applies to both the right and left ventricles; one can speak equally of the left ventricular ejection fraction (LVEF) and the right ventricular ejection fraction (RVEF). Without a qualifier, the term ejection fraction refers specifically to that of the left ventricle.

[00199] By definition, the volume of blood within a ventricle immediately before a contraction is known as the end-diastolic volume. Similarly, the volume of blood left in a ventricle at the end of contraction is end-systolic volume. The difference between end-diastolic and end-systolic volumes is the stroke volume, the volume of blood ejected with each beat. Ejection fraction (EF) is the fraction of the end-diastolic volume that is ejected with each beat; that is, it is stroke volume (SV) divided by end-diastolic volume (EDV). In a healthy 70-kg (154-lb) man, the SV is approximately 70

ml and the left ventricular EDV is 120 ml, giving an ejection fraction of 70/120, or 58%. Right ventricular volumes being roughly equal to those of the left ventricle, the ejection fraction of the right ventricle is normally equal to that of the left ventricle within narrow limits.

[00200] Damage to the muscle of the heart (myocardium), such as that sustained during myocardial infarction or in cardiomyopathy, impairs the heart's ability to eject blood and therefore reduces ejection fraction. This reduction in the ejection fraction can manifest itself clinically as heart failure. The ejection fraction is one of the most important predictors of prognosis; those with significantly reduced ejection fractions typically have a poorer prognoses.

[00201] Figure 19 shows an exemplary process for using the auscultatory device to determine Ejection Fraction (EF), shown generally at step **1900**. Such a process may be utilized by physicians to aid in bedside diagnostics. Additional processes may be performed utilizing the auscultatory device. The present process is intended to provide an exemplary use of the auscultatory device in a novel diagnostic technique enabled by the auscultatory device.

[00202] The process begins at step **1901** where an acoustic attenuation signal is generated from the acoustic transducer. Such an acoustic signal may be a pulse signal or a continuous acoustic signal. Additionally the acoustic signal may be at physiological frequencies or at elevated frequencies to increase resolution and eliminate interference.

[00203] The process then proceeds to step **1902** where the chest cavity of the patient is measured for sound waves. In this step a single acoustic sensor may be used to sense heart sounds and attenuation signals. In such embodiments the acoustic sensor must be able to be responsive across a wide frequency range. In some embodiments, more than one sensor may be utilized, each designed to sense acoustic signals within select frequency ranges. Moreover, at least one of the sensors, in some embodiments, may be the transducer that generates the attenuation signal. In these embodiments, the echo of the generated acoustic signal is sensed.

[00204] The process then proceeds to step **1904** where an inquiry is made if the acoustic signals are received on a single channel. If the acoustic signals are on a single channel, which is the case where a single acoustic sensor is used to sense heart

sounds and attenuation signals, then the process proceeds to step **1903** where the acoustic signals are filtered by frequency. High frequency attenuation signals are thus separated from the low frequency heart sounds. The process then proceeds to step **1905**, where signal processing is performed.

[00205] If at step **1904** separate channels are utilized for heart sound signals and attenuation signals then the process may proceed directly to the signal processing of step **1905**.

[00206] The process then proceeds to step **1906** where intensity ratios are generated. The intensity ratio is the acoustic intensity of S1 divided by the attenuation measures Sc.

[00207] Lastly, the process proceeds to step **1907** where ejection fraction may be determined. By using by the intensity ratio (S1/Sc), and the ratio between the 2 main heart sounds (S1/S2), the current ejection fraction may be estimated. The process then ends.

[00208] Figure 20 shows an exemplary process for signal processing for Ejection Fraction (EF) determination, shown generally at step **1905**. The process begins from step **1904** or step **1903**. Then at step **2001** signals may be filtered. The process then proceeds to step **2002** where signals are de-noised. Then at step **2003** suitable cycles may be selected for analysis. In some embodiments, each patient has recordings from 3 different sites for extended durations, as well as an ECG recording. A 20 second sound recording may result in a number of heart sound cycles per site depending on the patient's heart rate. On some patients almost all of the cycles may be usable except for occasional spikes present in data. On others, there will be 2 or 3 useful cycles because of noise. In some embodiments, one method for cycle selection is to choose the median of the data. For example, all S1 and S2 amplitudes for a patient at the Pulmonic location are found. The median S1 amplitude as the representative S1 and the median S2 as the representative S2 (Note that these may not occur during the same cycle) may be selected, and then the median Signal to Noise Ratio (SNR) of all the cycles may be generated and used as the general indicator of the SNR of the entire recording. Alternate cycle selection may be utilized such as discarding all cycles below a given SNR level, use the mean of the amplitudes instead of the median, selection of the 'best' cycle in an entire recording (such as highest SNR) and use only

the S1 and S2 from that cycle, selecting a cycle depending on a specific part of the breathing cycle, or any other appropriate cycle selection method. The process then ends by proceeding to step **1906**.

[00209] Figure 21A shows an exemplary illustration of ECG and sound wave measurements for usage by Ejection Fraction analysis, shown generally at **2100A**. The first plot **2101** is the ECG capture, and the subsequent plot is from a microphone at the Pulmonic location **2102**. Figure 21B shows an exemplary illustration of sound wave measurements for usage by Ejection Fraction analysis, shown generally at **2100B**. These plots are from microphones at the Apex and Aortic locations, **2103** and **2104** respectively. Each plotting is graphed along a linear timescale. S1 is seen clearly in each plot shortly after the QRS peak in the ECG, and S2 appears shortly after the T wave.

[00210] Using the exemplary data all QRS points in the ECG data are found, which marks the beginning of each heart cycle. Since two adjacent QRS points demarcate one cycle, in the first third of that cycle, looking for the maximum and minimum signal amplitude delineates the S1 signal. The difference of maximum and minimum signal amplitude is S1 amplitude. In the next third of the cycle look once again for the maximum and minimum, the difference of which is the S2 amplitude.

[00211] Figure 22 shows an exemplary illustration of isolated ECG and sound wave measurement for usage by Ejection Fraction analysis, shown generally at **2200**. Two Xs mark the two subsequent QRSs in the subject's ECG **2201**, and there is a Line **2202** between them.

[00212] In the heart sound graph **2203**, during the first third of that interval, the minimum and maximum is found **2206** and **2204** respectively. During the next third of that cycle, the minimum and maximum is found **2207** and **2205** respectively. The difference between the minima and the maxima are the amplitudes of the S1 and S2 respectively.

[00213] Figure 23A shows an exemplary illustration of ECG and sound wave measurements when attenuation signal is used for Ejection Fraction analysis, shown generally at **2300A**. The first plot **2301** is the ECG capture, and the subsequent plot is from the microphone at the Pulmonic **2302**. Figure 23B shows an exemplary illustration of sound wave measurements when attenuation signal is used for Ejection

Fraction analysis, shown generally at **2300B**. The plots are from the microphones at the Apex and Aortic locations **2303** and **2304** respectively. Each plotting is graphed along a linear timescale.

[00214] Figure 24 shows an exemplary illustration of filtered measured transduction signals for Ejection Fraction analysis, shown generally at **2400**. The data collected during the operation of the transducer is passed through a very narrow band pass filter for each tone, and the Amplitude **2401** of the output from the filter is taken as the amplitude of the tone at that location. In some embodiments, the amplitude of the tone has been defined as 4 times the Standard Deviation **2402** after the narrowband filter. Even at the narrow frequency range, the amplitude of the data fluctuates with breathing cycles and additive/subtractive effects of noise and other data within that band.

[00215] In some embodiments, the filter is a bandpass filter with appropriate cutoffs.

[00216] Figure 25A shows an exemplary illustration of pre-filtered measured heart signals for Ejection Fraction analysis, shown generally at **2510**. **2511** and **2512** represent the total intensity of the first and second heart sound respectively. Figure 25B shows an exemplary illustration of post-filtered measured heart signals for Ejection Fraction analysis, shown generally at **2520**. **2521** and **2522** represent the total intensity of the first and second heart sound respectively after the filtering operation.

[00217] Certain combinations of these intensities correlate well with particular pathologies. One such relationship is the ratio of the first heart sound after the filtering operation **2521** divided by the unfiltered first heart sound **2511** vs. Ejection Fraction when the filtering operation has been a band pass operation centered around a particular frequency band. Another such relationship has been the ratio of the unfiltered first heart sound **2511** divided by the unfiltered second heart sound **2512** vs. Ejection Fraction.

[00218] It is quite conceivable that there are other relationships between the mentioned intensities **2511, 2512, 2521, 2522** and other cardiac measures. Some of these ratios may also correlate well with the presence of certain cardiac pathologies. For example, after a particular filtering operation, the value of a particular ratio such

as the filtering operation **2521** divided by the unfiltered first heart sound **2511** may indicate the presence of a particular cardiac disease such as Aortic Stenosis or Mitral Regurgitation.

[00219] Some of these relationships may involve looking at multiple ratios after multiple filtering operations, and a particular pathology might have a distinct frequency signature, whereby looking at a number of ratios over a number of filtering operations might indicate the subject's pathology.

[00220] The filtering operations may involve simple filters, for example a straightforward analog nth order bandpass/lowpass/highpass filter. It is conceivable that wavelet operations, which by their nature divide up the signal into various frequency bands, can also be used to carry out measurements on the heart sound signal.

[00221] Figure 26 shows an exemplary illustration of measured heart signals before and after de-noising for Ejection Fraction analysis, shown generally at **2600**. Issues of noisy recording may affect the intensity of the heart sound parameters being analyzed. This issue may, in some embodiments, be dealt with on two separate levels. First of all, by developing a measure for the noise level within the signal a threshold may be developed to decide whether a particular heart cycle is clean enough to include in measurements. Secondly, data may be cleansed via de-noising.

[00222] Signal to Noise Ratio (SNR) may be determined and utilized in the de-noising process. Measuring the noise level, at least in the context of heart sound study, is to measure the power of the signal in a 'good' region compared to the power of the signal in a 'noise' region.

[00223] In some embodiments, the entire signal is filtered with a bandpass filter in the frequency range of the first and second heart sounds.

[00224] Wavelet de-noising works quite effectively in removing Gaussian type noise. The de-noising is done on a cycle by cycle basis (as opposed to de-noising the entire capture in one go). This does not have a huge impact, except that the noise cutoff thresholds are chosen on a cycle by cycle basis as opposed to one noise threshold for the entire cycle. The graph illustrated at **2610** is an example of recorded heart sounds before de-noising. The graph illustrated at **2620** is an example of the same recorded heart sounds after de-noising.

[00225] One novel aspect of the present invention is that all of the capabilities described may be performed in the background – i.e. the image processing extraction of the valve from the motion trace, distance measurements, signal processing for speed determination, Doppler frequency shift, and blood flow estimation. The physicians, or other users, require no new skills to effectuate the system.

[00226] Additionally, display of information may be defined based upon statistical confidence levels to minimize misdiagnosis and provide user recommendations. For example, if the valve responsible for a murmur is not reliably detected, say, over 50% of the cardiac cycle, the sensor/transducer may not be pointing in a stable fashion due to hand motion etc, it may indicate repositioning or provide feedback to the user and likewise indicate when the sensor/transducer is pointing accurately at a valve or provide feedback to maximize the motion trace indicating a look direction that sees maximum travel of the leaflet.

[00227] Modifications of the present invention are also possible. For example, it is possible to incorporate noise cancellation capability to the embodiments described above, thereby substantially removing ambient environmental noises from the heart sounds received by the acoustic sensors, e.g., sensors of chest-pieces **500**, **600**, **700**.

[00228] In sum, the present invention provides many advantages over the existing auscultatory devices, including ease of use, improved accuracy, portability, and cost effectiveness. The present invention also allows for the concurrent gathering of acoustic and electrical heart information from the patient by combining an acoustic sensing with an ECG sensing.

[00229] While a number of preferred embodiments have been illustrated as applying to the measurement and calibration for heart sounds, the present invention is intended for the measurement of any suitable sounds, including but not limited to lung sounds, fetal sounds, and applications on sound processing on inorganic medium.

[00230] While this invention has been described in terms of several preferred embodiments, there are alterations, modifications, permutations, and substitute equivalents, which fall within the scope of this invention. Although sub-section titles have been provided to aid in the description of the invention, these titles are merely illustrative and are not intended to limit the scope of the present invention.

[00231] It should also be noted that there are many alternative ways of implementing the methods and apparatuses of the present invention. It is therefore intended that the following appended claims be interpreted as including all such alterations, modifications, permutations, and substitute equivalents as fall within the true spirit and scope of the present invention.

CLAIMS

What is claimed is:

1. A method for measuring acoustic attenuation in a subject, the method comprising:

generating a first acoustic signal at a first location of the subject;

receiving an attenuated acoustic signal resulting from the first acoustic signal, wherein the attenuated acoustic signal is received at a second location of the subject; and

computing an acoustic attenuation between the first location and the second location based on differences between the first acoustic signal and the attenuated acoustic signal.

2. The method of claim 1 wherein the first location is closely located to the second location.

3. The method of claim 1 wherein the first location and the second location are located on a thoracic region of the subject.

4. The method of claim 1 wherein the second location is a standard ECG position.

5. The method of claim 1 further comprising:

sensing at least one heart sound at the second location of the subject; and

normalizing the at least one heart sound based on the computed acoustic attenuation.

6. An auscultation system useful in association with a subject, the system comprising:

a transducer configured to generate a first acoustic signal at a first location of the subject;

a sensor configured to receive an attenuated acoustic signal resulting from the first acoustic signal, wherein the attenuated acoustic signal is received at a second location of the subject; and

a signal processor configured to compute an acoustic attenuation between the first location and the second location based on differences between the first acoustic signal and the attenuated acoustic signal.

7. The system of claim 6 wherein the first location is closely located to the second location.

8. The system of claim 6 wherein the first location is located at the same location as the second location.

9. The system of claim 8 wherein the transducer includes the sensor.

10. The system of claim 6 wherein the first location and the second location are located on a thoracic region of the subject.

11. The system of claim 6 wherein the second location is a standard ECG position.

12. The system of claim 6 wherein the sensor is further configured to sense at least one heart sound at the second location of the subject, and wherein the signal processor is further configured to normalize the at least one heart sound based on the computed acoustic attenuation.

13. The system of claim 6 further comprising a noise canceller.

14. A method for calibrating heart sounds of a subject, useful in association with an auscultation device having a transducer, a sensor and a heart sound processor, the method comprising:

orienting the transducer on a first location of the subject;

orienting the sensor on a second location of the subject;

generating an audio signal at the first location of the subject by utilizing the transducer;

receiving an attenuated audio signal resulting from the generated audio signal, and wherein the attenuated audio signal is received at the second location of the subject by the sensor;

receiving a heart sound signal at the second location of the subject by utilizing the sensor;

computing an acoustic attenuation between the first location and the second location based on differences between the generated audio signal and the received attenuated audio signal; and

calibrating the heart sound signal by utilizing the computed acoustic attenuation.

15. The method of claim 14 further comprising:

filtering the attenuated audio signal from the heart sound signal; and

conditioning the heart sound signal.

16. The method of claim 14 wherein the first position and the second position are located in a substantially close proximity.

17. A method for pulse echo auscultatory diagnosis of a subject, useful in association with an auscultation device having an echo transducer and a heart sound processor, the method comprising:

orienting the echo transducer on the subject;

generating a first audio signal pulse from the echo transducer;

receiving a first return echo of the audio signal pulse, wherein the first return echo is received by the echo transducer;

generating a first brightness encoded image from the first received return echo, wherein the first brightness encoded image represents internal structures of the subject, and wherein the first received return echo provides location data on the internal structures of the subject;

receiving a heart sound signal of the subject; and

calibrating the heart sound signal by utilizing the first brightness encoded image, wherein calibrating the heart sound signal includes relating acoustic properties of tissues to the represented internal structures of the subject.

18. The method of claim 17 further comprising:

filtering the first audio signal pulse from the heart sound signal; and

conditioning the heart sound signal.

19. The method of claim 17 further comprising:

generating a second audio signal pulse from the echo transducer, wherein the first and second audio signal are interleaved in relation to subject's cardiac cycle;

receiving a second return echo of the audio signal pulse, wherein the second return echo is received by the echo transducer;

generating a second brightness encoded image from the second received return echo, wherein the second brightness encoded image represents internal structures of

the subject, and wherein the second received return echo provides location data on the internal structures of the subject; and

detecting motion of the internal structures of the subject by comparing the first brightness encoded image and the second brightness encoded image for discrepancies.

20. The method of claim 17 further comprising:

detecting distance of the moving internal structure of the subject by comparing the first brightness encoded image and the second brightness encoded image; and

computing speed of the moving internal structure by referencing the distance traveled by a time differential, wherein the time differential is computed by comparing times of generation of the first acoustic pulse and the second acoustic pulse.

21. The method of claim 19 further comprising determining speed of the moving internal structure by detecting Doppler shift between the first generated acoustic pulse and the first received echo.

22. The method of claim 17 further comprising generating operating suggestions, wherein the operating suggestions are generated by statistical analysis of brightness encoded image.

23. A method for measuring ejection fraction of a subject, useful in association with an auscultation device having a transducer, a sensor and a heart sound processor, the method comprising:

orienting the transducer on a first location of the subject;

orienting the sensor on a second location of the subject;

generating an audio signal at the first location of the subject by utilizing the transducer;

receiving an attenuated audio signal resulting from the generated audio signal, wherein the attenuated audio signal is received at the second location of the subject by the sensor;

receiving a heart sound signal at the second location of the subject by the sensor;

computing an acoustic attenuation between the first location and the second location based on differences between the generated audio signal and the received attenuated audio signal;

computing an intensity ratio by dividing an amplitude of the conditioned heart sound signal by the acoustic attenuation; and

computing ejection fraction of the heart subject by correlation to the computed intensity ratio.

24. The method of claim 23 further comprising:

filtering the attenuated audio signal from the heart sound signal; and

conditioning the heart sound signal.

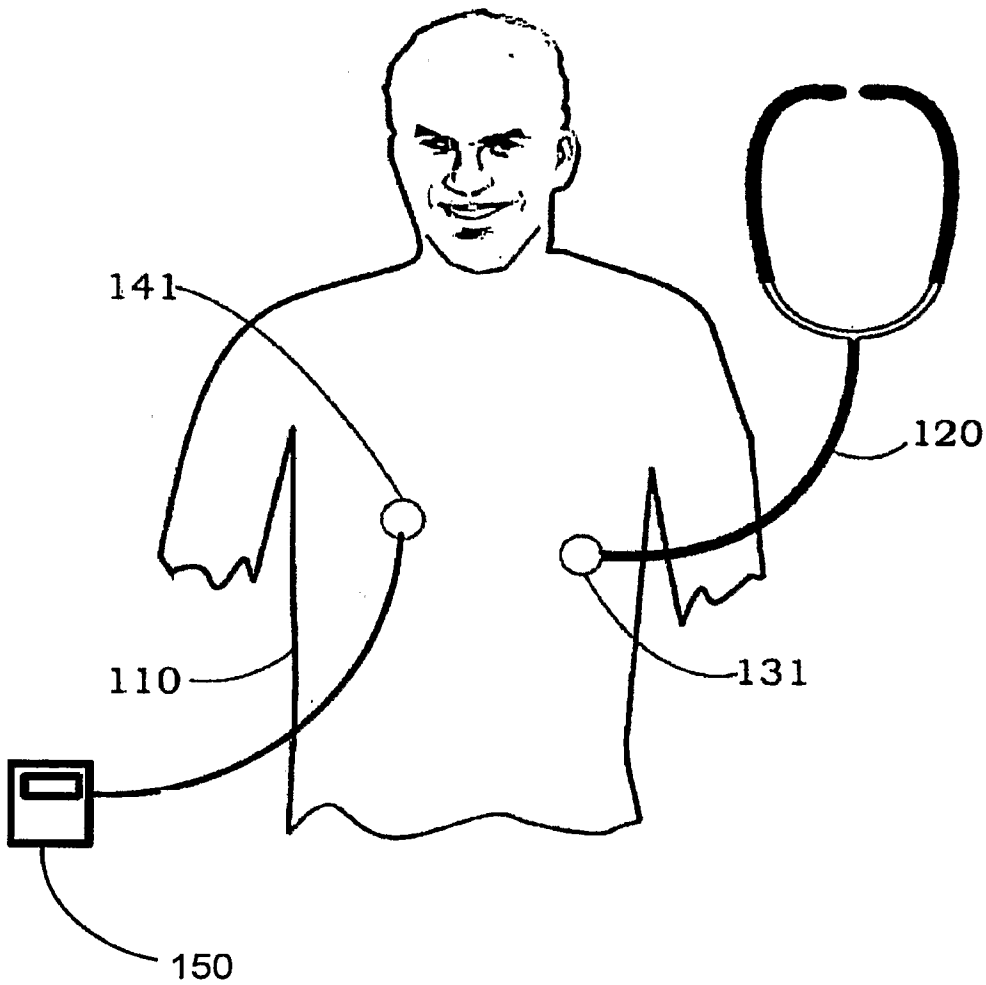

FIG. 1A

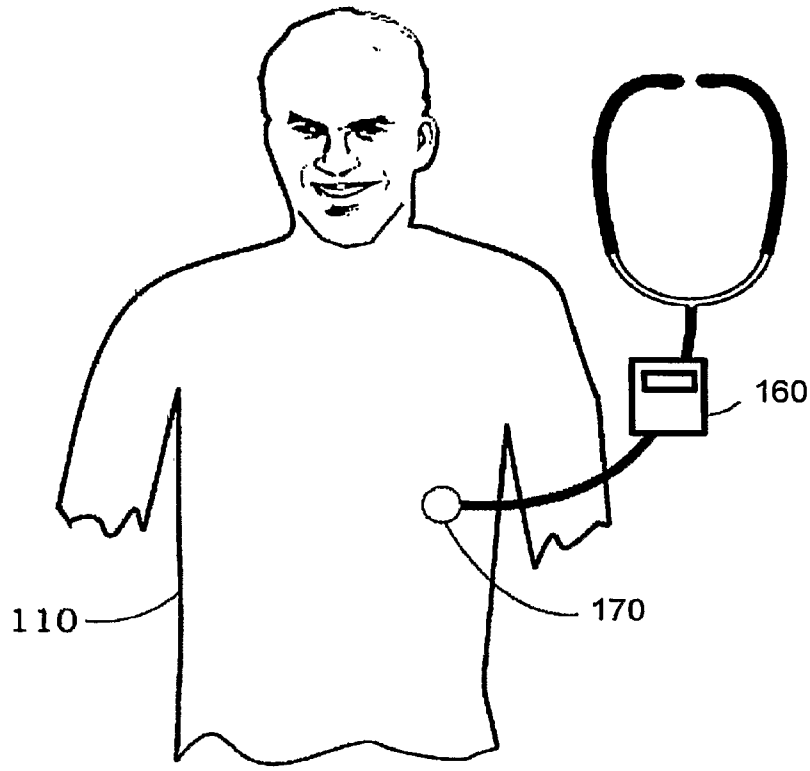

FIG. 1B

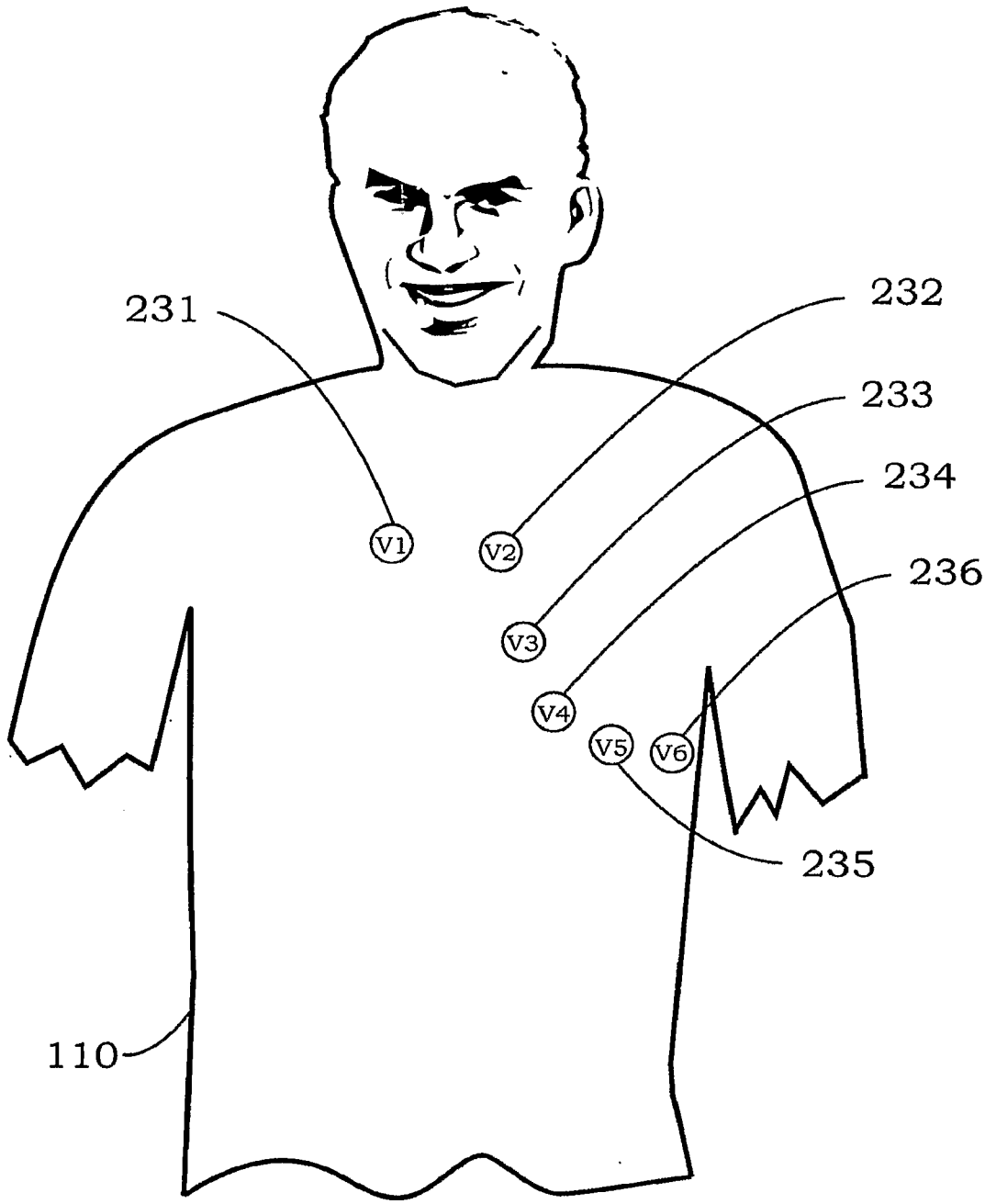

FIG. 2

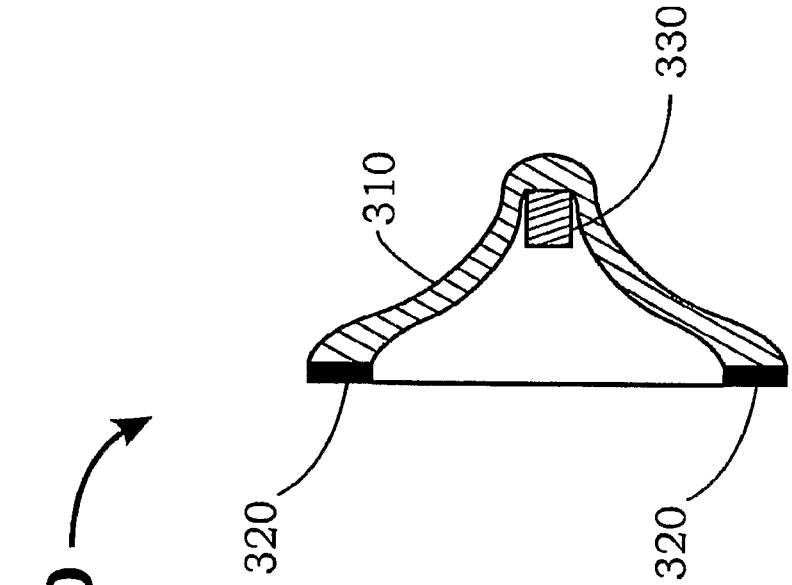

FIG. 3B

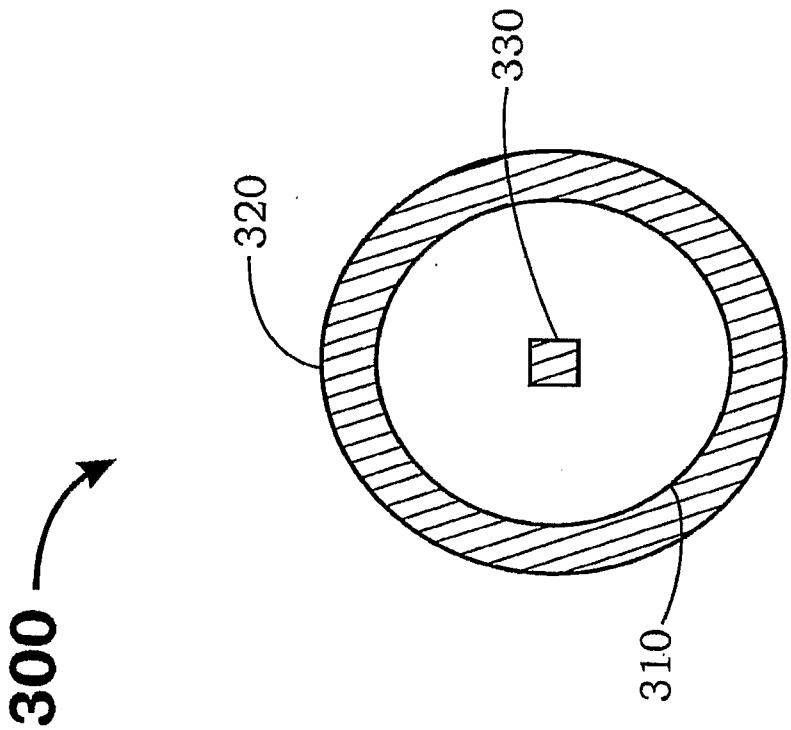

FIG. 3A

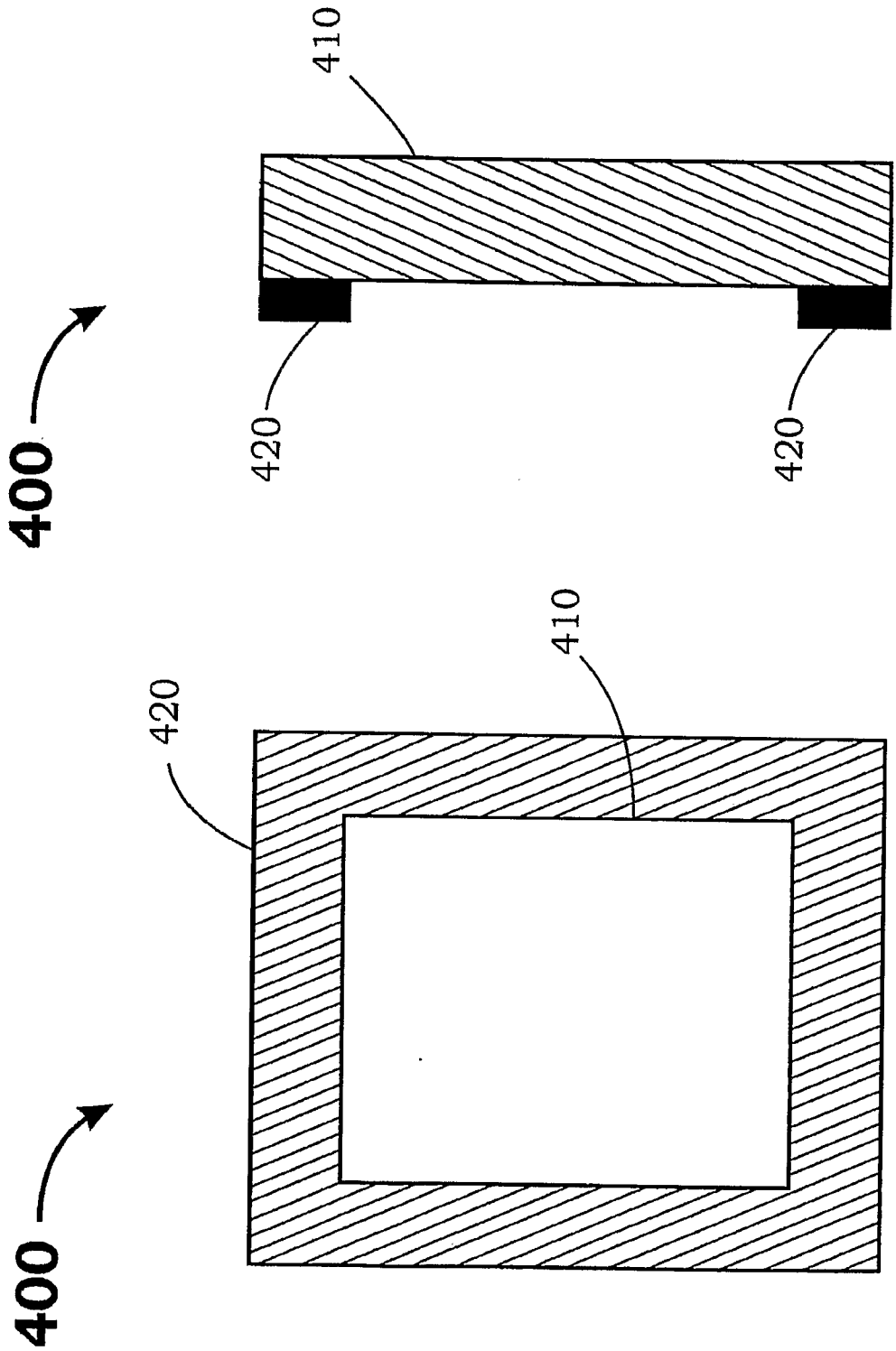

FIG. 4B

FIG. 4A

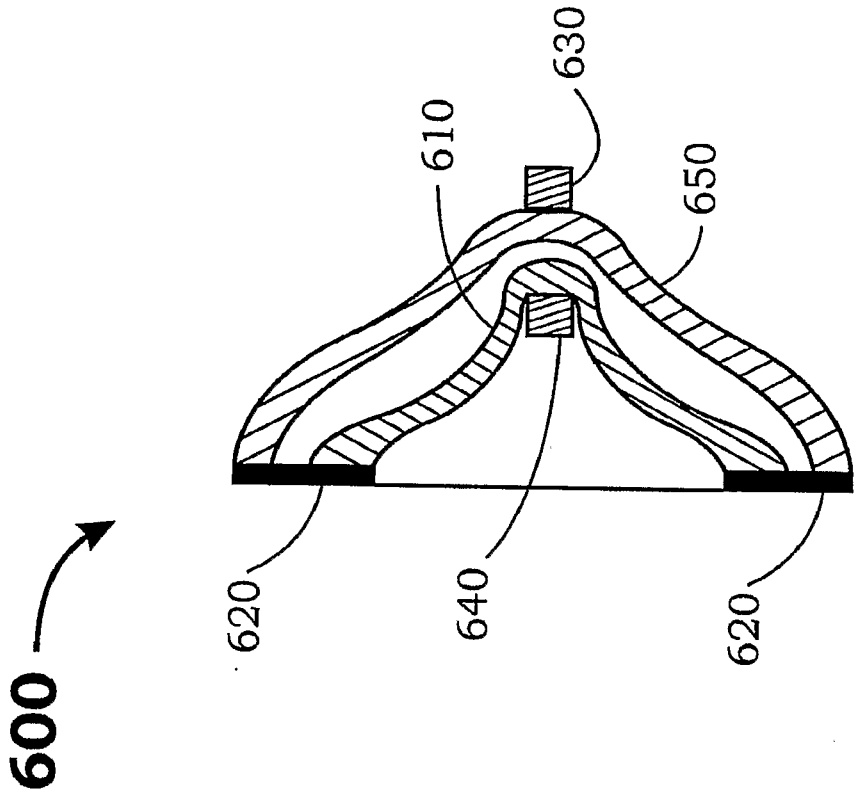

FIG. 6

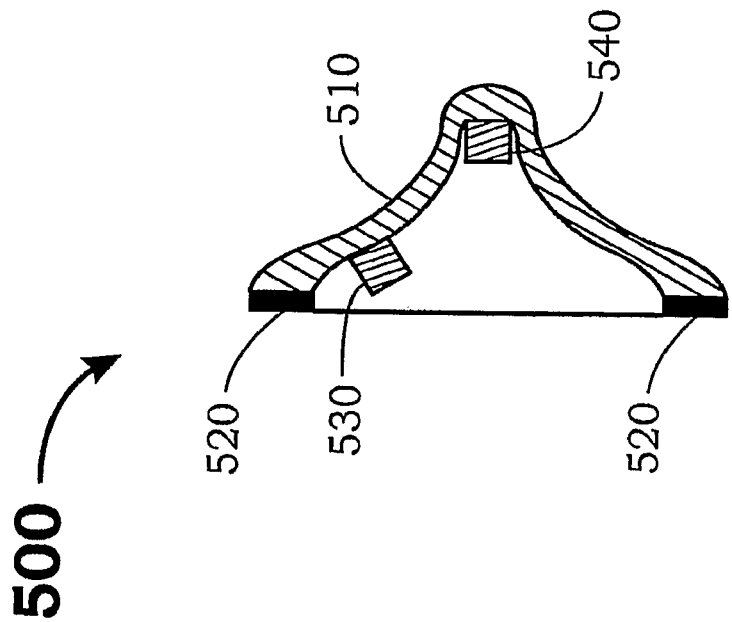

FIG. 5

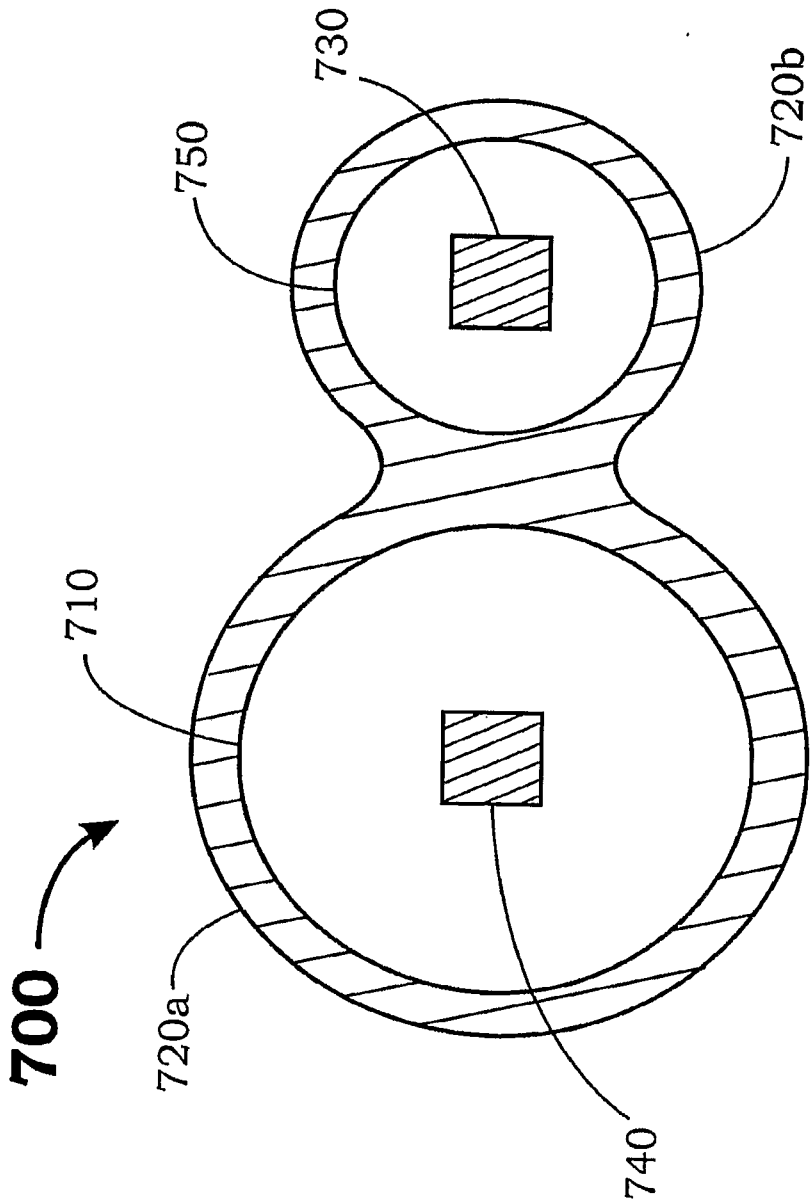

FIG. 7

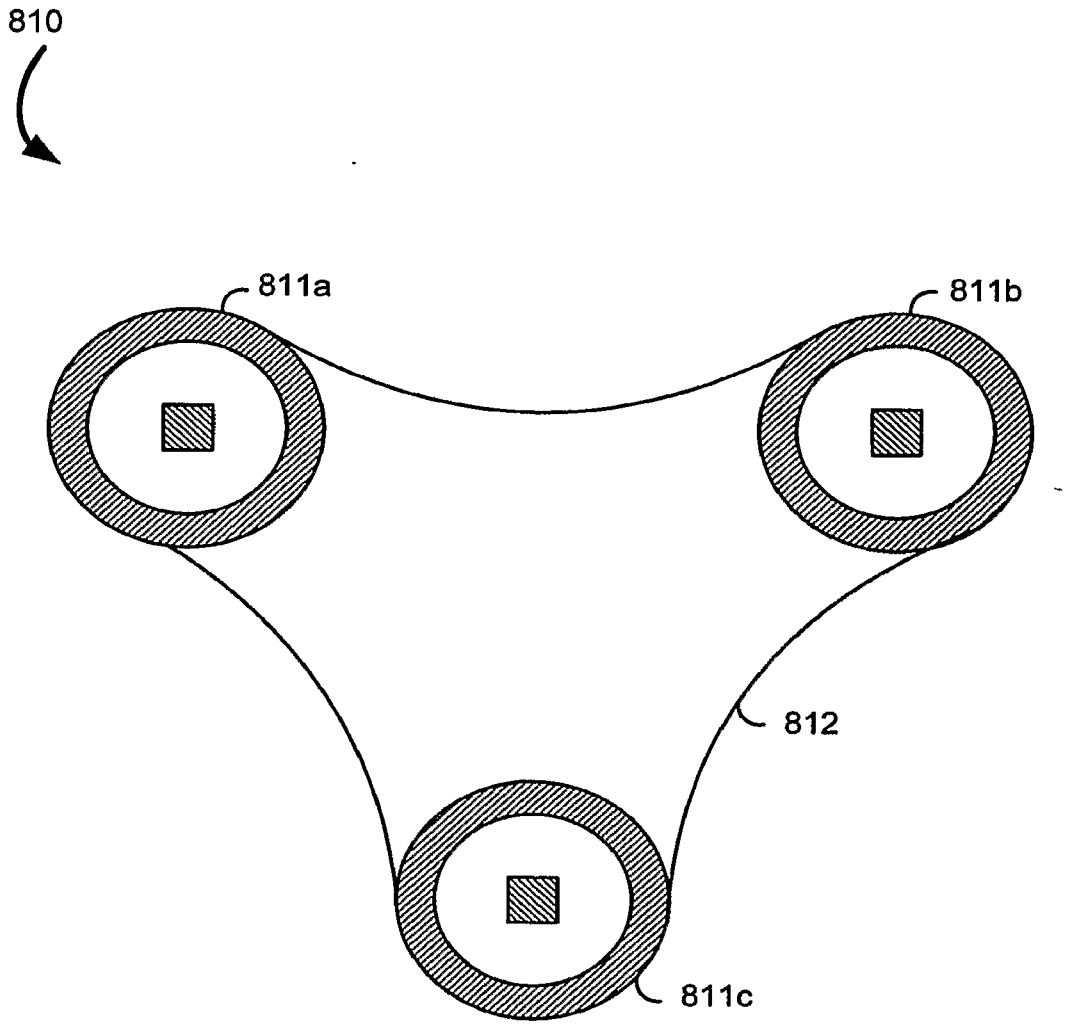

FIG. 8A

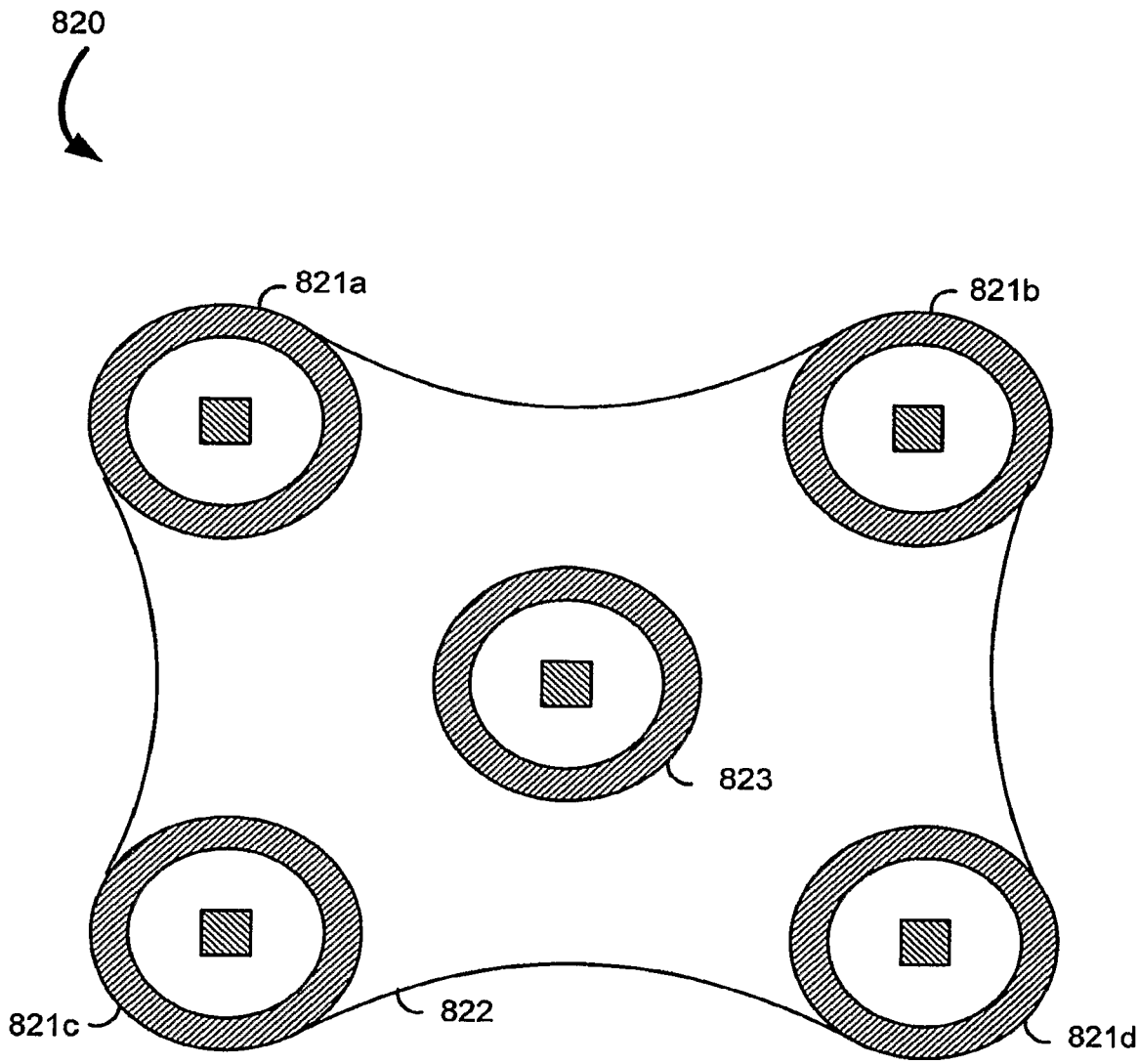

FIG. 8B

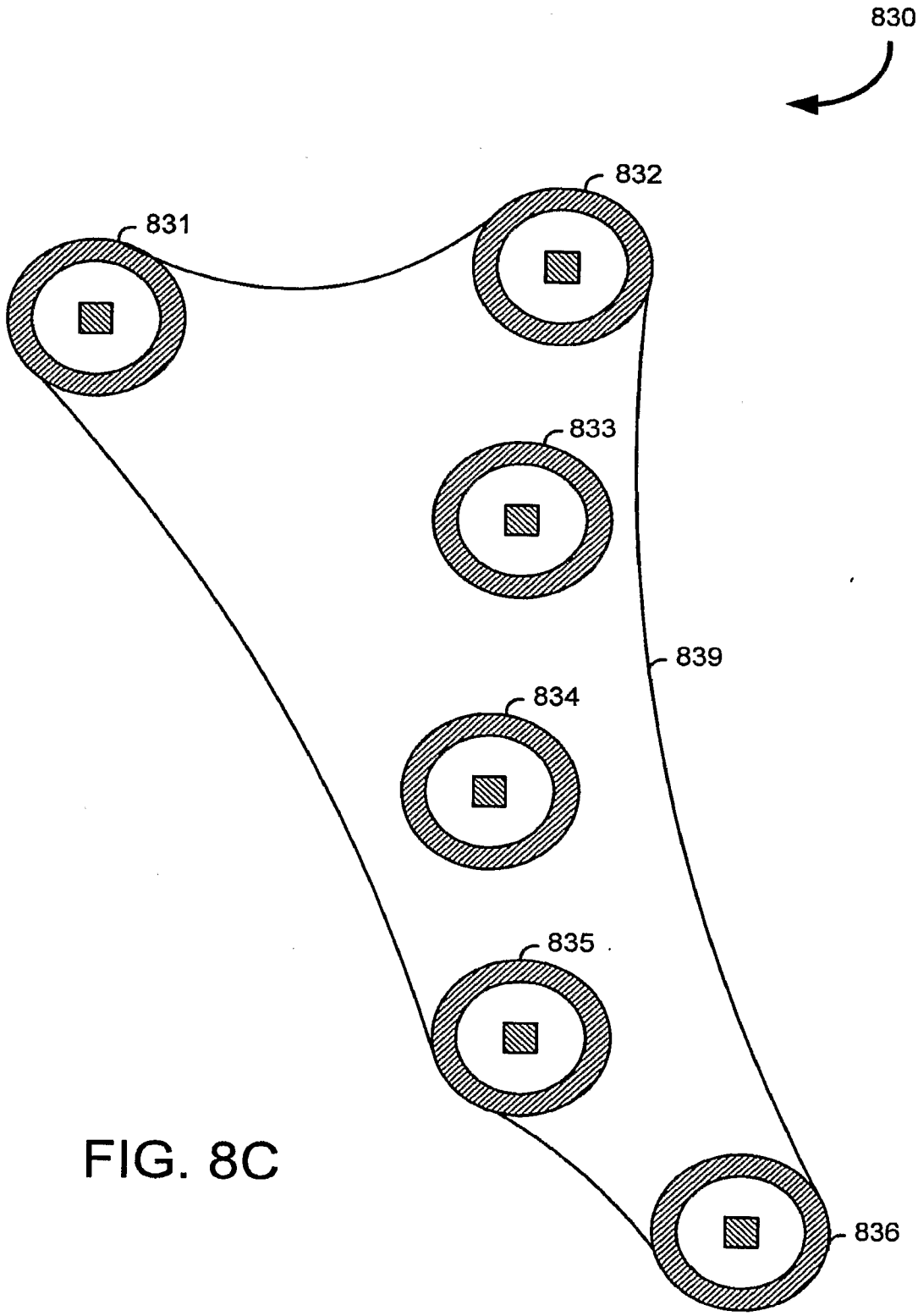

FIG. 8C

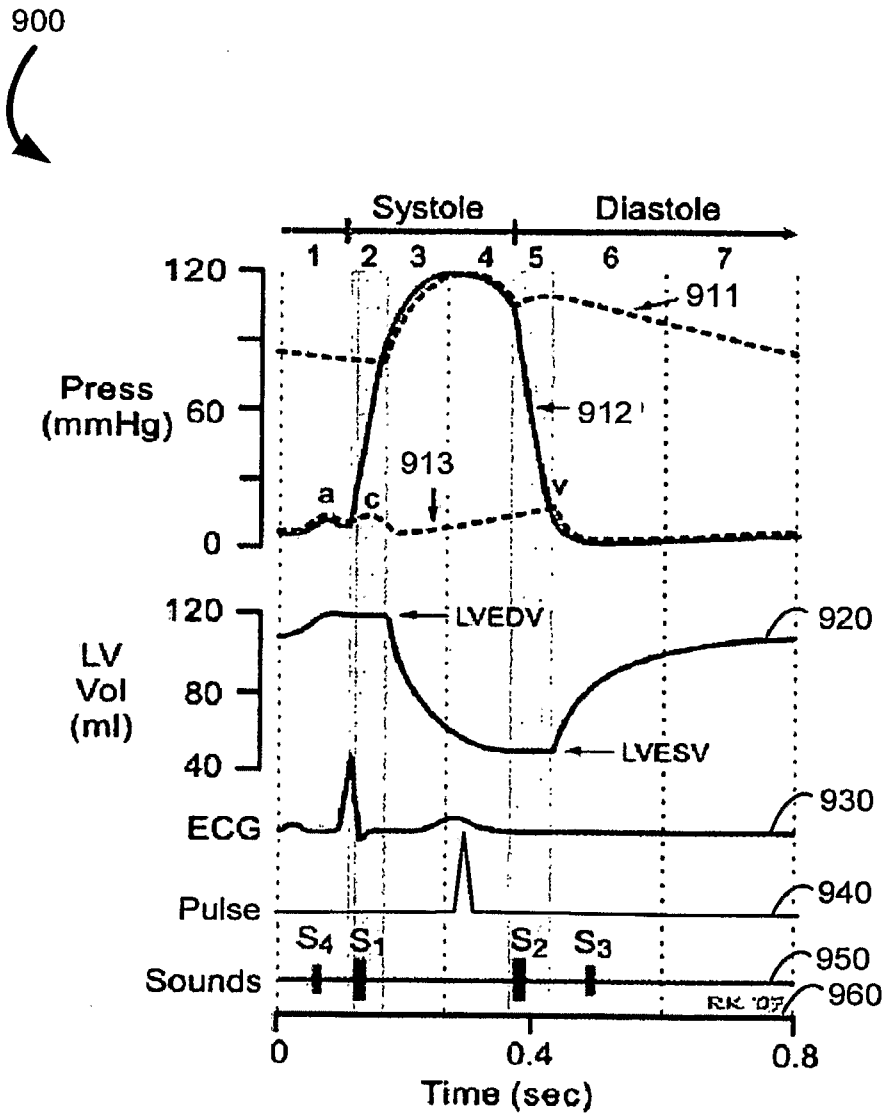
900
Systole
Diastole
1
2
3
4
5
6
7
120
60
0
Press
(mmHg)
911
912
913
a
c
v
120
80
40
LV
Vol
(ml)
LVEDV
LVESV
920
ECG
930
Pulse
940
S4
S1
S2
S3
Sounds
950
960
0
0.4
0.8
Time (sec)

FIG. 9

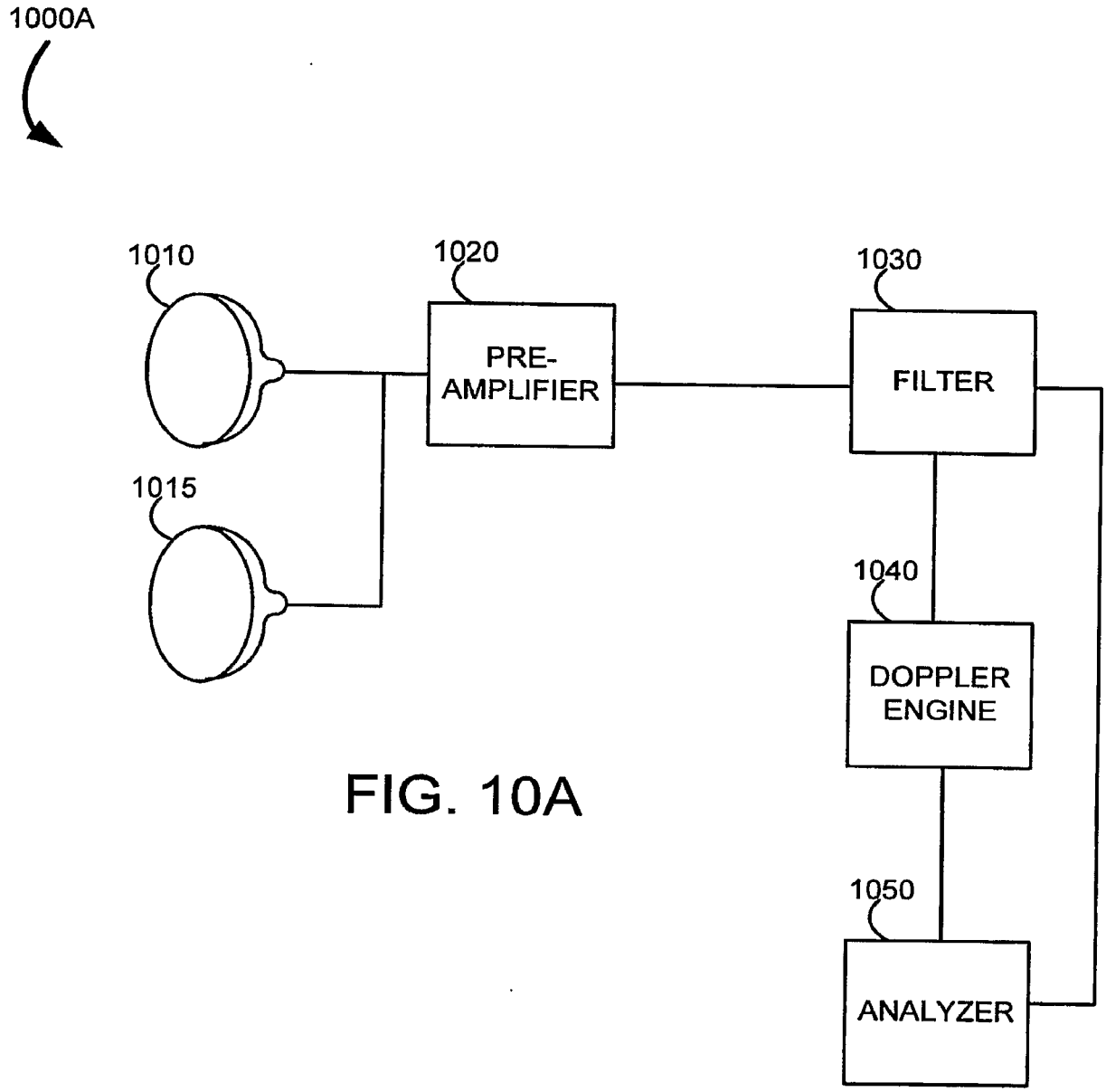
1000A
1010
1020
1030
PRE-
AMPLIFIER
FILTER
1015
1040
DOPPLER
ENGINE
1050
ANALYZER

FIG. 10A

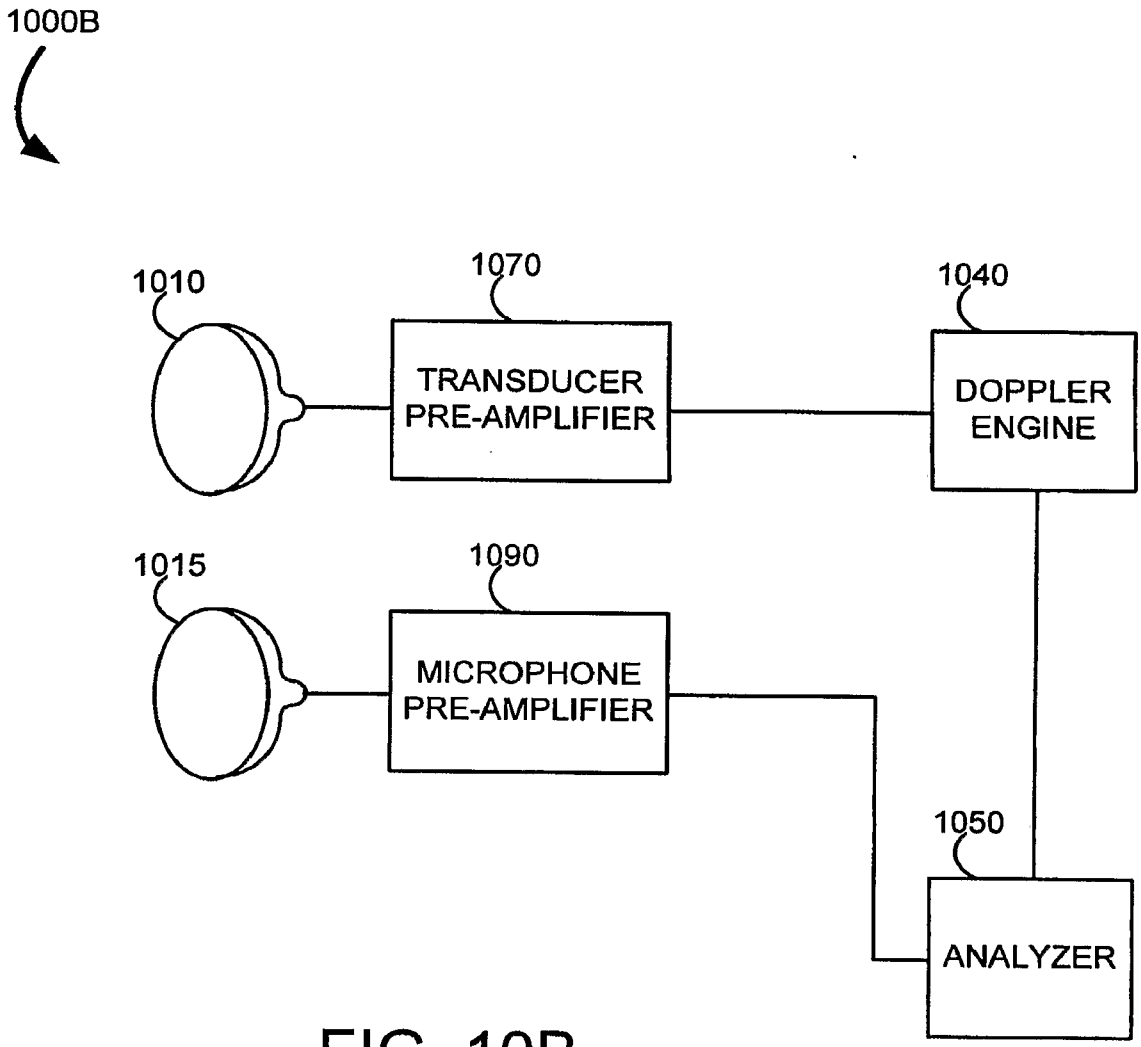
1000B
1010
1070
1040
TRANSDUCER PRE-AMPLIFIER
DOPPLER ENGINE
1015
1090
MICROPHONE PRE-AMPLIFIER
1050
ANALYZER

FIG. 10B

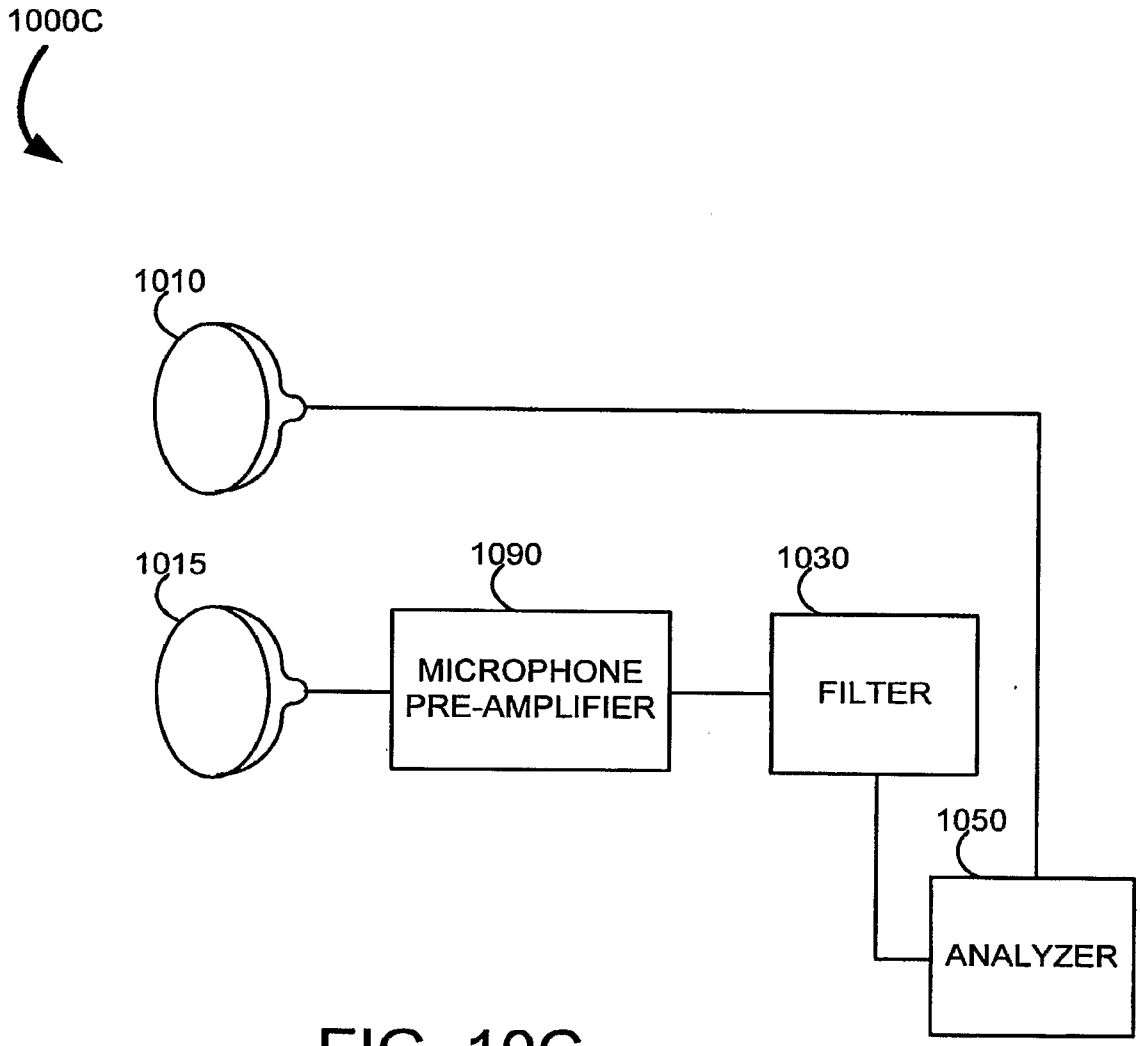
1000C
1010
1015
1090
MICROPHONE
PRE-AMPLIFIER
1030
FILTER
1050
ANALYZER

FIG. 10C

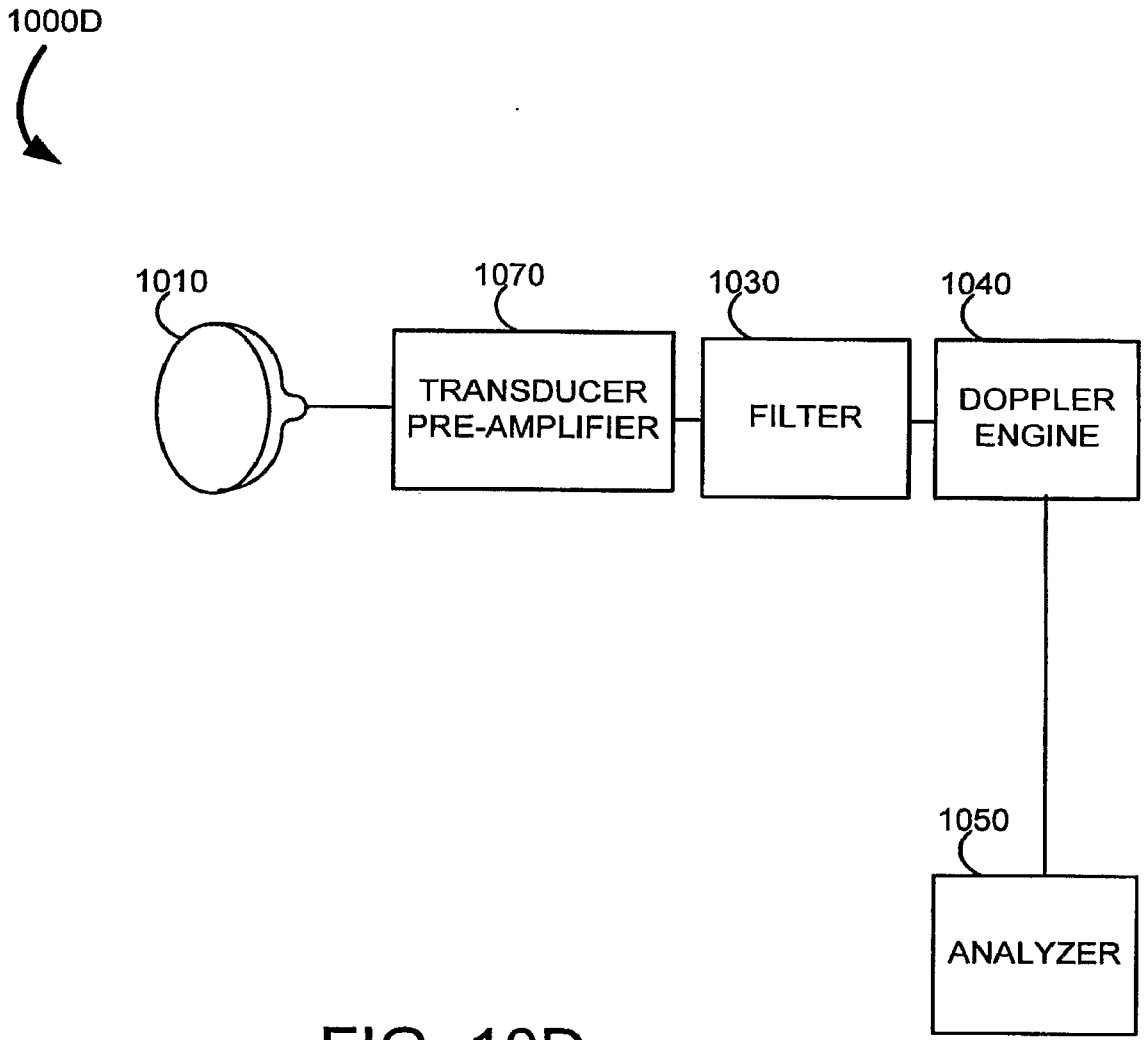
1000D
1010
1070
1030
1040
TRANSDUCER PRE-AMPLIFIER
FILTER
DOPPLER ENGINE
1050
ANALYZER

FIG. 10D

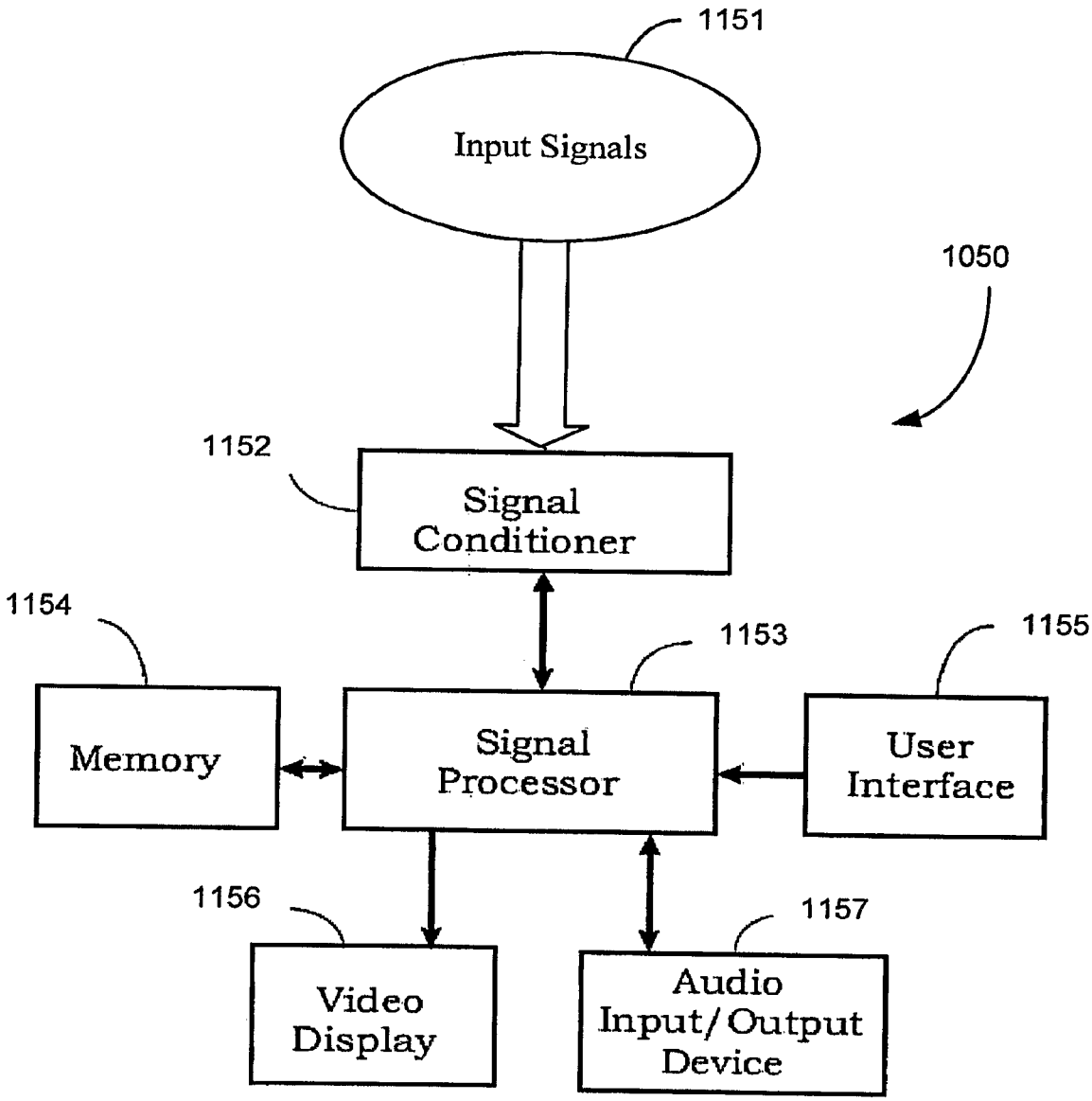
1151
Input Signals
1050
1152
Signal Conditioner
1154
1153
1155
Memory
Signal Processor
User Interface
1156
1157
Video Display
Audio Input/Output Device

FIG. 11

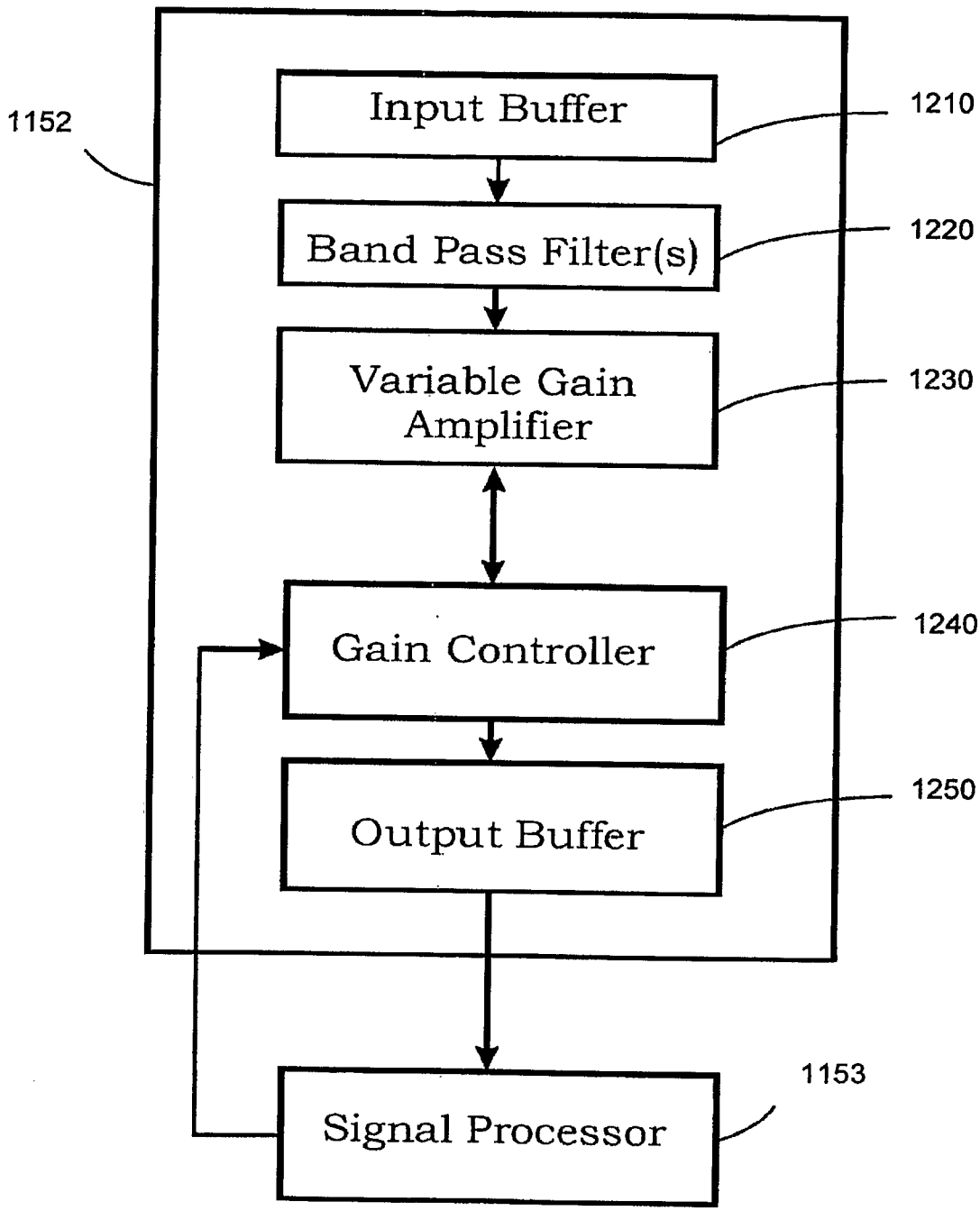
1152
Input Buffer
1210
Band Pass Filter(s)
1220
Variable Gain Amplifier
1230
Gain Controller
1240
Output Buffer
1250
Signal Processor
1153

FIG. 12

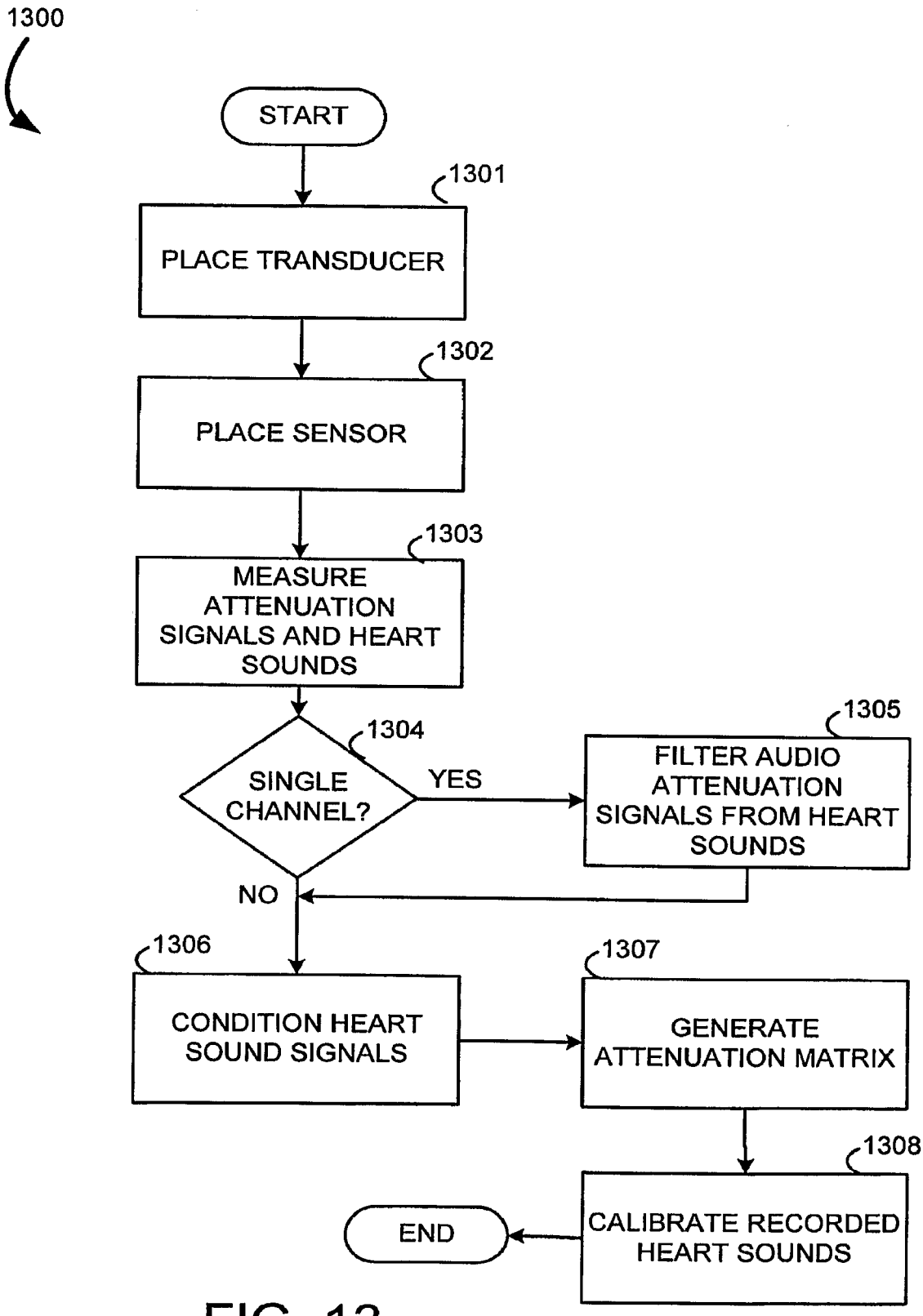
1300
START
1301
PLACE TRANSDUCER
1302
PLACE SENSOR
1303
MEASURE ATTENUATION SIGNALS AND HEART SOUNDS
1304
SINGLE CHANNEL?
YES
1305
FILTER AUDIO ATTENUATION SIGNALS FROM HEART SOUNDS
NO
1306
CONDITION HEART SOUND SIGNALS
1307
GENERATE ATTENUATION MATRIX
1308
CALIBRATE RECORDED HEART SOUNDS
END

FIG. 13

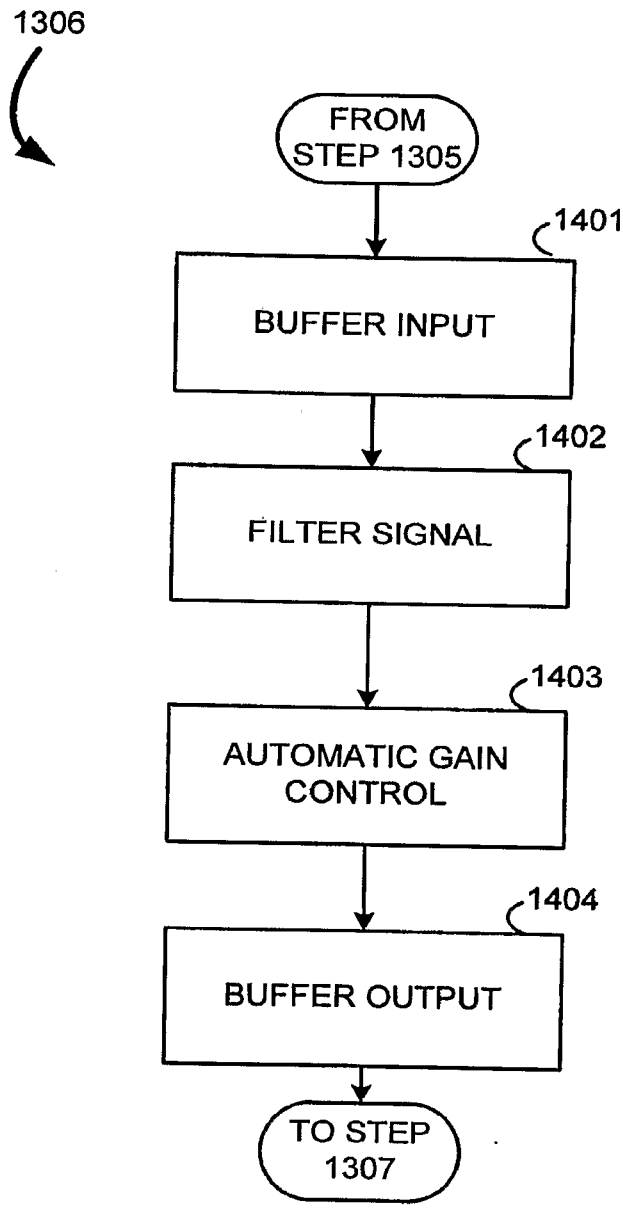
1306
FROM STEP 1305
1401
BUFFER INPUT
1402
FILTER SIGNAL
1403
AUTOMATIC GAIN CONTROL
1404
BUFFER OUTPUT
TO STEP 1307

FIG. 14

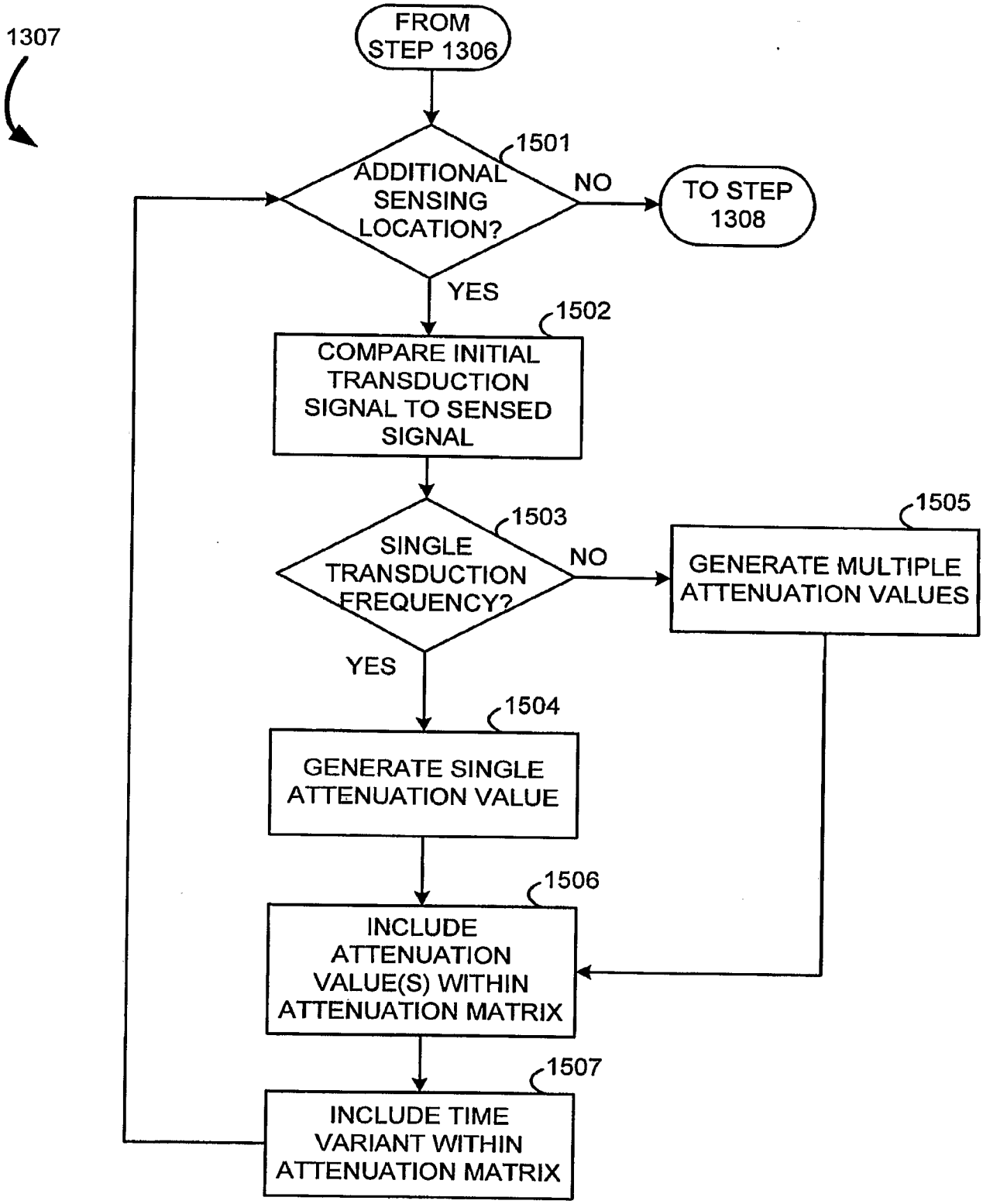
1307
FROM STEP 1306
1501
ADDITIONAL SENSING LOCATION?
NO
TO STEP 1308
YES
1502
COMPARE INITIAL TRANSDUCTION SIGNAL TO SENSED SIGNAL
1503
SINGLE TRANSDUCTION FREQUENCY?
NO
1505
GENERATE MULTIPLE ATTENUATION VALUES
YES
1504
GENERATE SINGLE ATTENUATION VALUE
1506
INCLUDE ATTENUATION VALUE(S) WITHIN ATTENUATION MATRIX
1507
INCLUDE TIME VARIANT WITHIN ATTENUATION MATRIX

FIG. 15

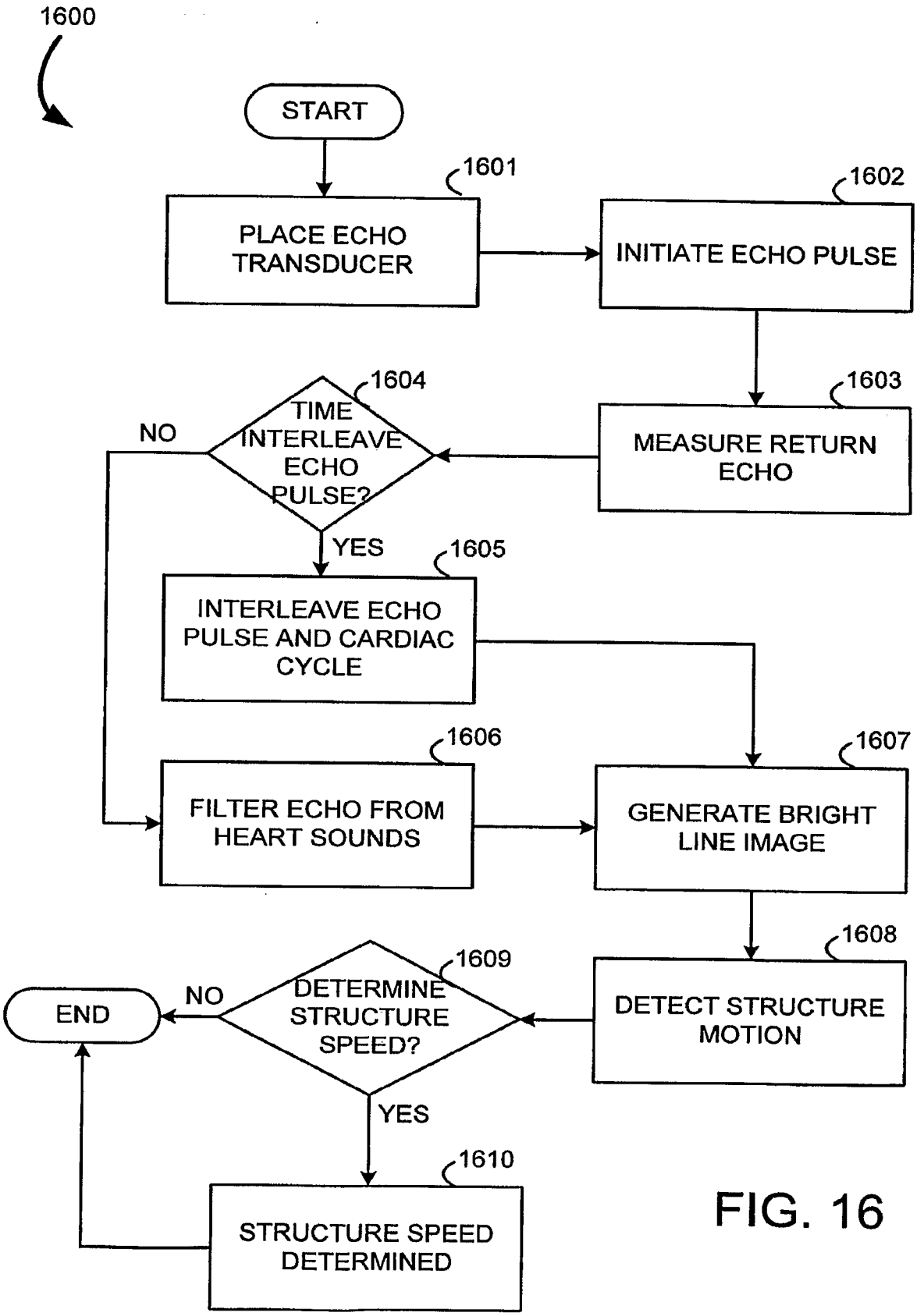
1600
START
1601
PLACE ECHO TRANSDUCER
1602
INITIATE ECHO PULSE
1603
MEASURE RETURN ECHO
1604
TIME INTERLEAVE ECHO PULSE?
NO
YES
1605
INTERLEAVE ECHO PULSE AND CARDIAC CYCLE
1606
FILTER ECHO FROM HEART SOUNDS
1607
GENERATE BRIGHT LINE IMAGE
1608
DETECT STRUCTURE MOTION
1609
DETERMINE STRUCTURE SPEED?
NO
END
YES
1610
STRUCTURE SPEED DETERMINED

FIG. 16

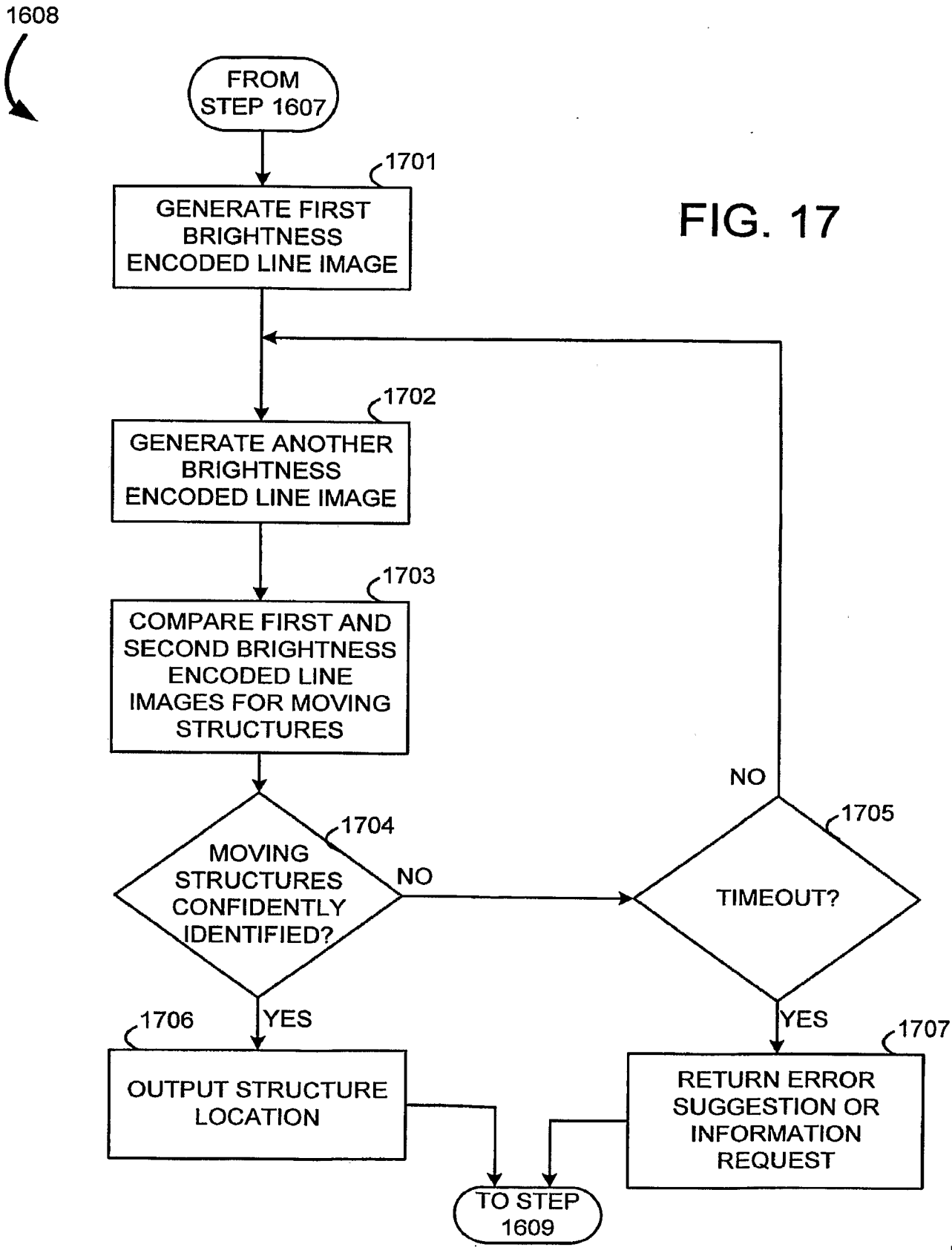
1608
FROM STEP 1607
1701
GENERATE FIRST BRIGHTNESS ENCODED LINE IMAGE
1702
GENERATE ANOTHER BRIGHTNESS ENCODED LINE IMAGE
1703
COMPARE FIRST AND SECOND BRIGHTNESS ENCODED LINE IMAGES FOR MOVING STRUCTURES
1704
MOVING STRUCTURES CONFIDENTLY IDENTIFIED?
NO
YES
1705
TIMEOUT?
NO
YES
1706
OUTPUT STRUCTURE LOCATION
1707
RETURN ERROR SUGGESTION OR INFORMATION REQUEST
TO STEP 1609

FIG. 17

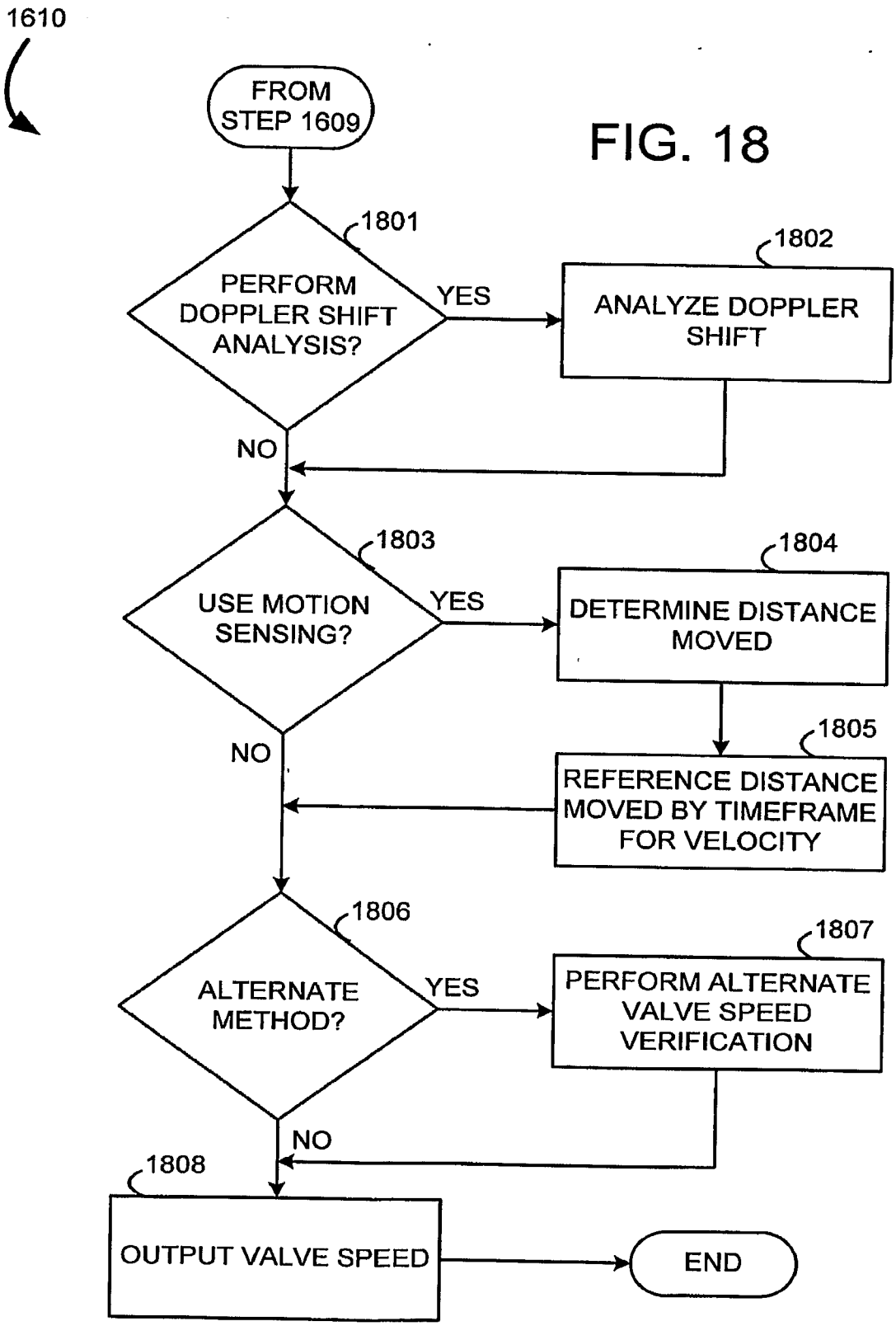
1610
FROM STEP 1609
1801
PERFORM DOPPLER SHIFT ANALYSIS?
YES
1802
ANALYZE DOPPLER SHIFT
NO
1803
USE MOTION SENSING?
YES
1804
DETERMINE DISTANCE MOVED
NO
1805
REFERENCE DISTANCE MOVED BY TIMEFRAME FOR VELOCITY
1806
ALTERNATE METHOD?
YES
1807
PERFORM ALTERNATE VALVE SPEED VERIFICATION
NO
1808
OUTPUT VALVE SPEED
END

FIG. 18

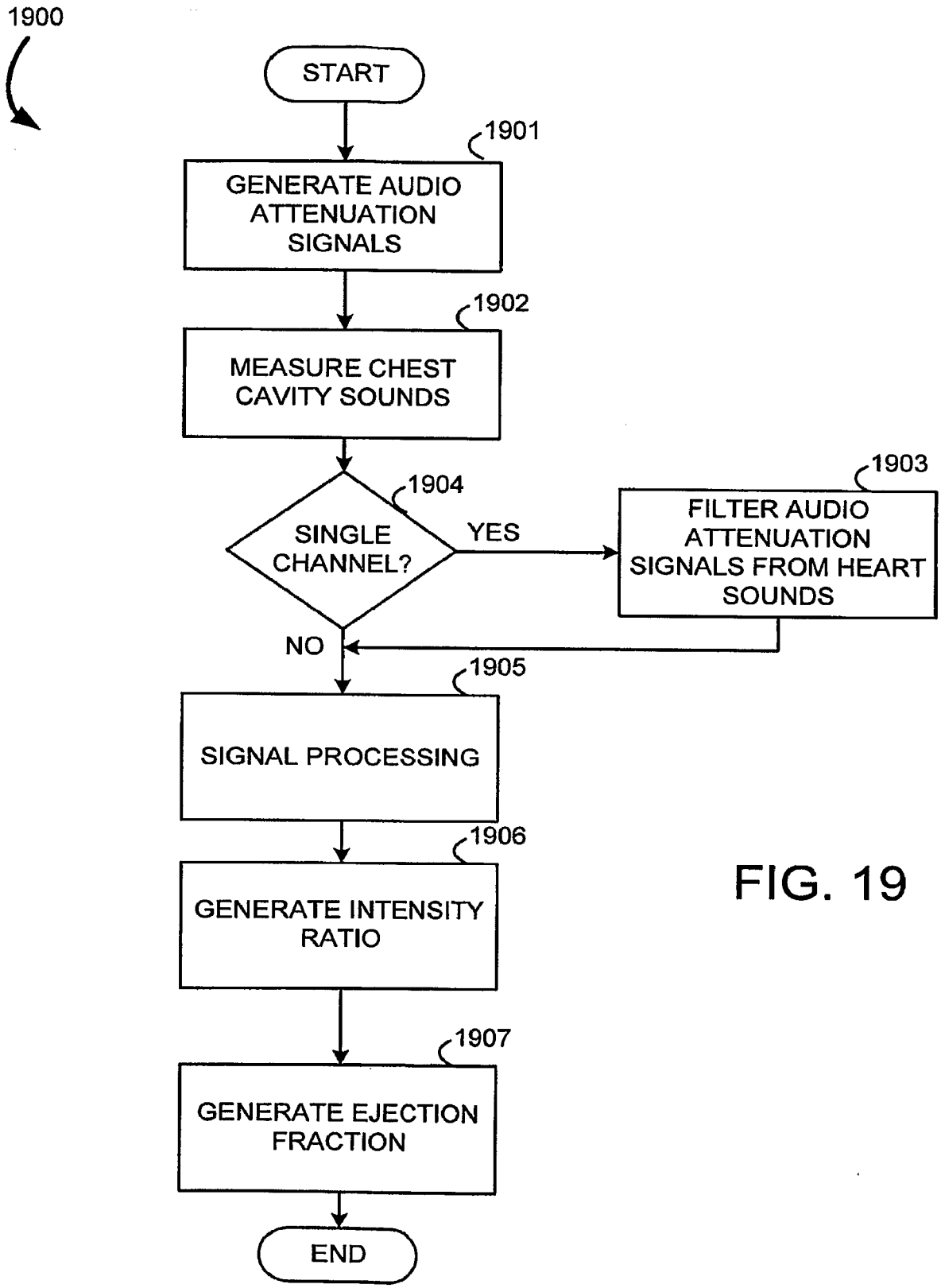
1900
START
1901
GENERATE AUDIO ATTENUATION SIGNALS
1902
MEASURE CHEST CAVITY SOUNDS
1904
SINGLE CHANNEL?
YES
1903
FILTER AUDIO ATTENUATION SIGNALS FROM HEART SOUNDS
NO
1905
SIGNAL PROCESSING
1906
GENERATE INTENSITY RATIO
1907
GENERATE EJECTION FRACTION
END

FIG. 19

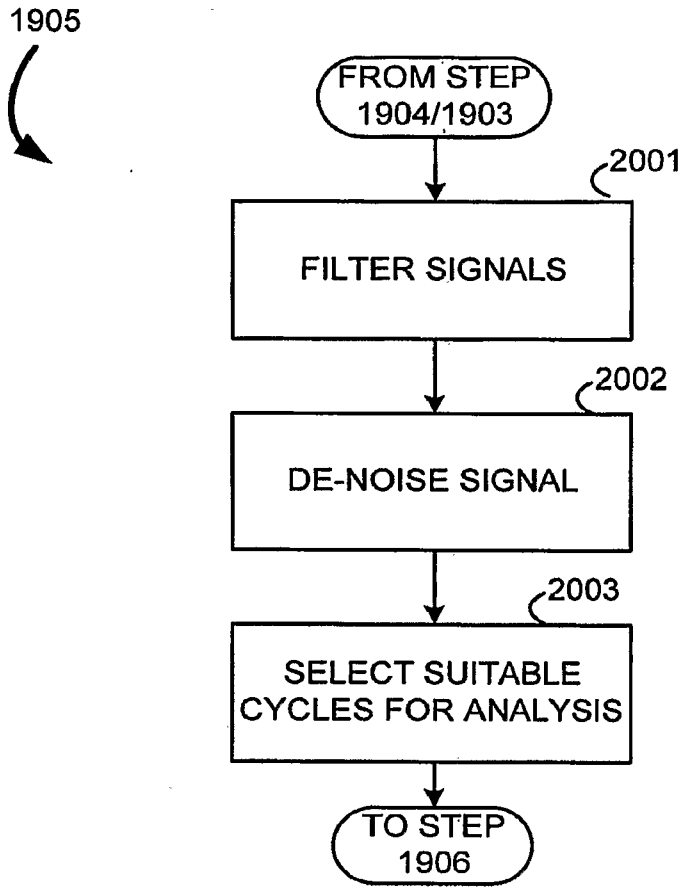
1905
FROM STEP 1904/1903
2001
FILTER SIGNALS
2002
DE-NOISE SIGNAL
2003
SELECT SUITABLE CYCLES FOR ANALYSIS
TO STEP 1906

FIG. 20

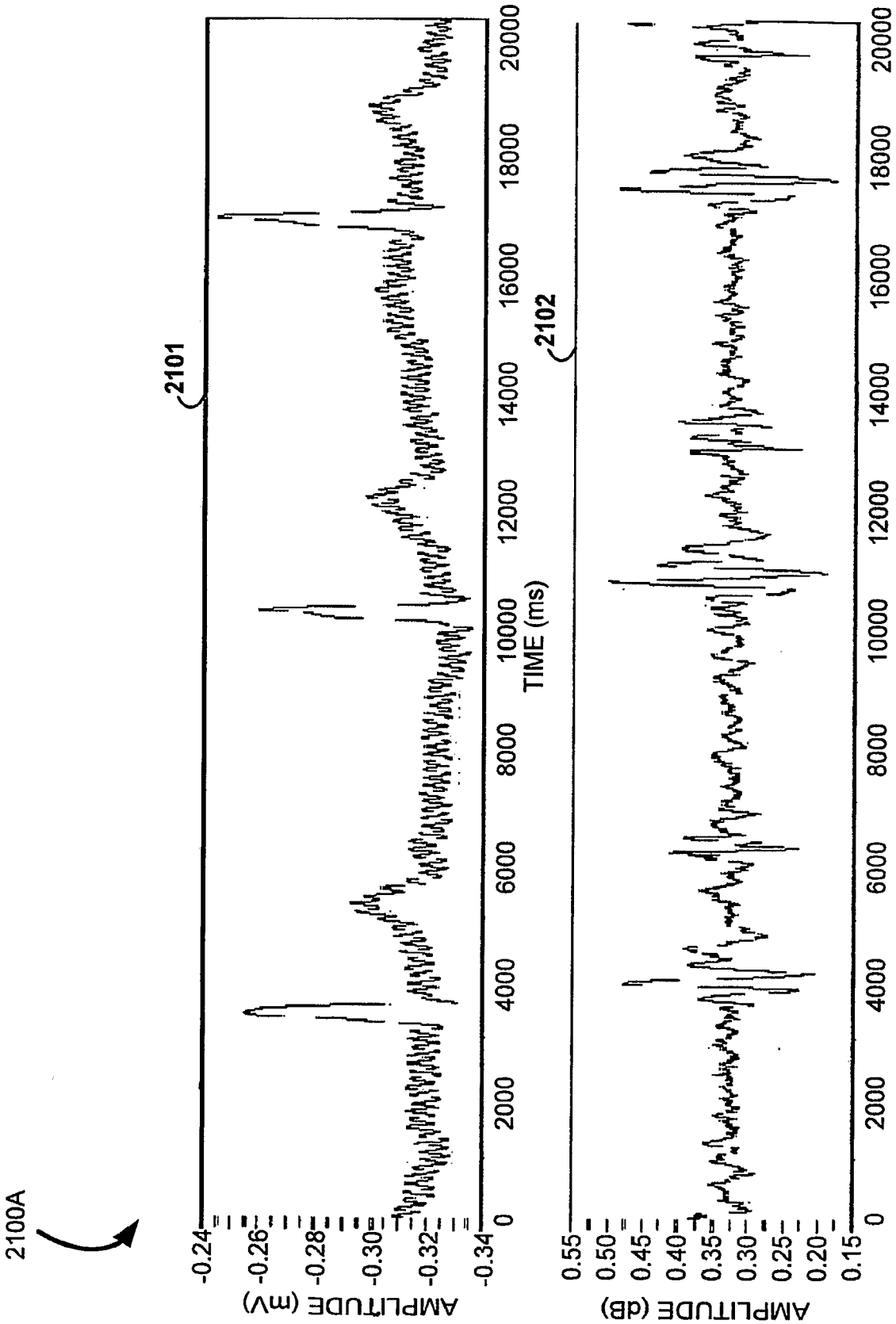
2100A
2101
2102
AMPLITUDE (mV)
-0.24
-0.26
-0.28
-0.30
-0.32
-0.34
0
2000
4000
6000
8000
10000
12000
14000
16000
18000
20000
TIME (ms)
AMPLITUDE (dB)
0.55
0.50
0.45
0.40
0.35
0.30
0.25
0.20
0.15
0
2000
4000
6000
8000
10000
12000
14000
16000
18000
20000
TIME (ms)

FIG. 21A

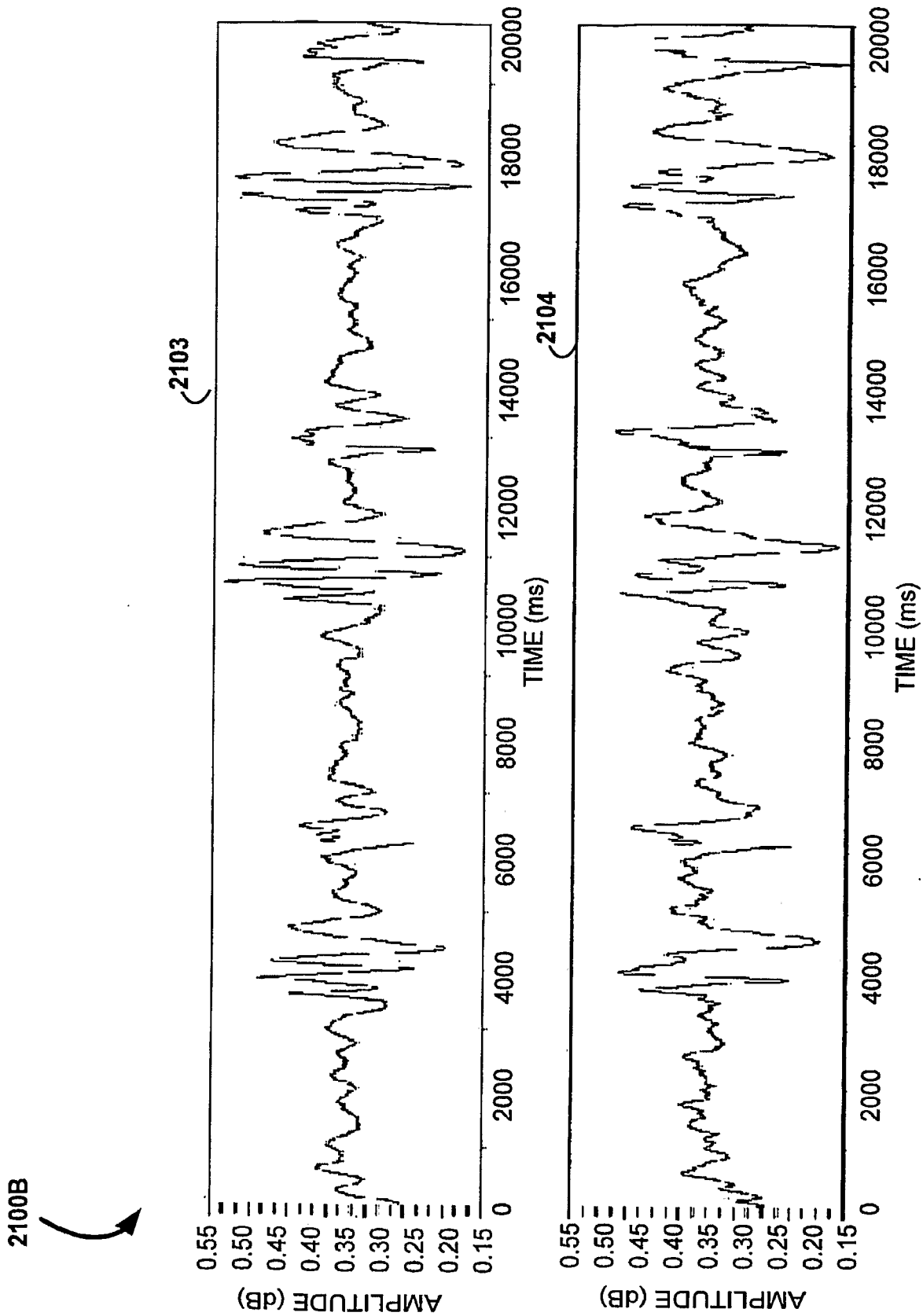
2100B
2103
2104
AMPLITUDE (dB)
0.55
0.50
0.45
0.40
0.35
0.30
0.25
0.20
0.15
0
2000
4000
6000
8000
10000
12000
14000
16000
18000
20000
TIME (ms)

FIG. 21B

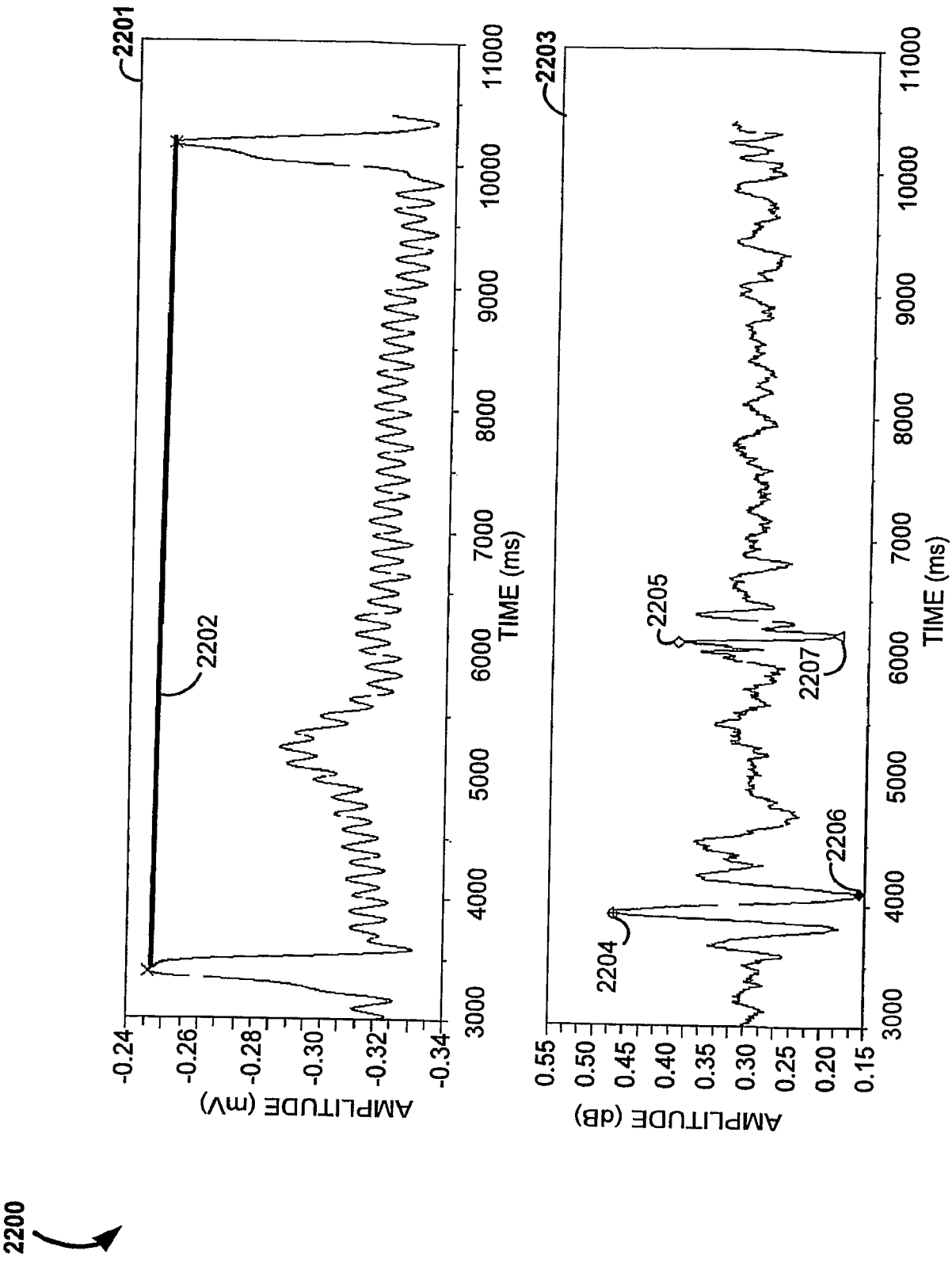
2200
2201
2202
AMPLITUDE (mV)
-0.24
-0.26
-0.28
-0.30
-0.32
-0.34
3000
4000
5000
6000
7000
8000
9000
10000
11000
TIME (ms)
2203
2204
2205
2206
2207
AMPLITUDE (dB)
0.55
0.50
0.45
0.40
0.35
0.30
0.25
0.20
0.15
3000
4000
5000
6000
7000
8000
9000
10000
11000
TIME (ms)

FIG. 22

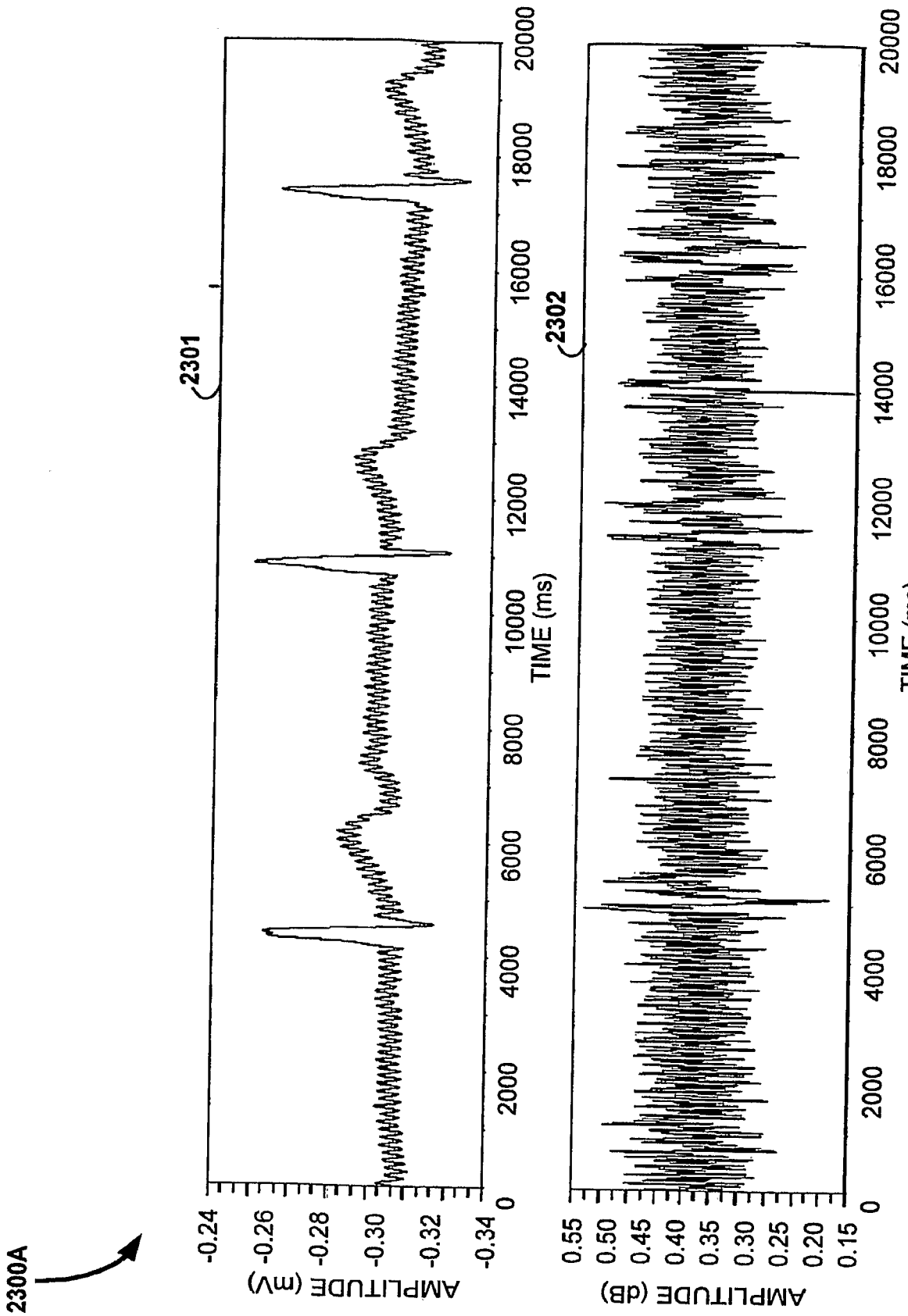
2300A
2301
2302
AMPLITUDE (mV)
-0.24
-0.26
-0.28
-0.30
-0.32
-0.34
0
2000
4000
6000
8000
10000
12000
14000
16000
18000
20000
TIME (ms)
AMPLITUDE (dB)
0.55
0.50
0.45
0.40
0.35
0.30
0.25
0.20
0.15
TIME (ms)

FIG. 23A

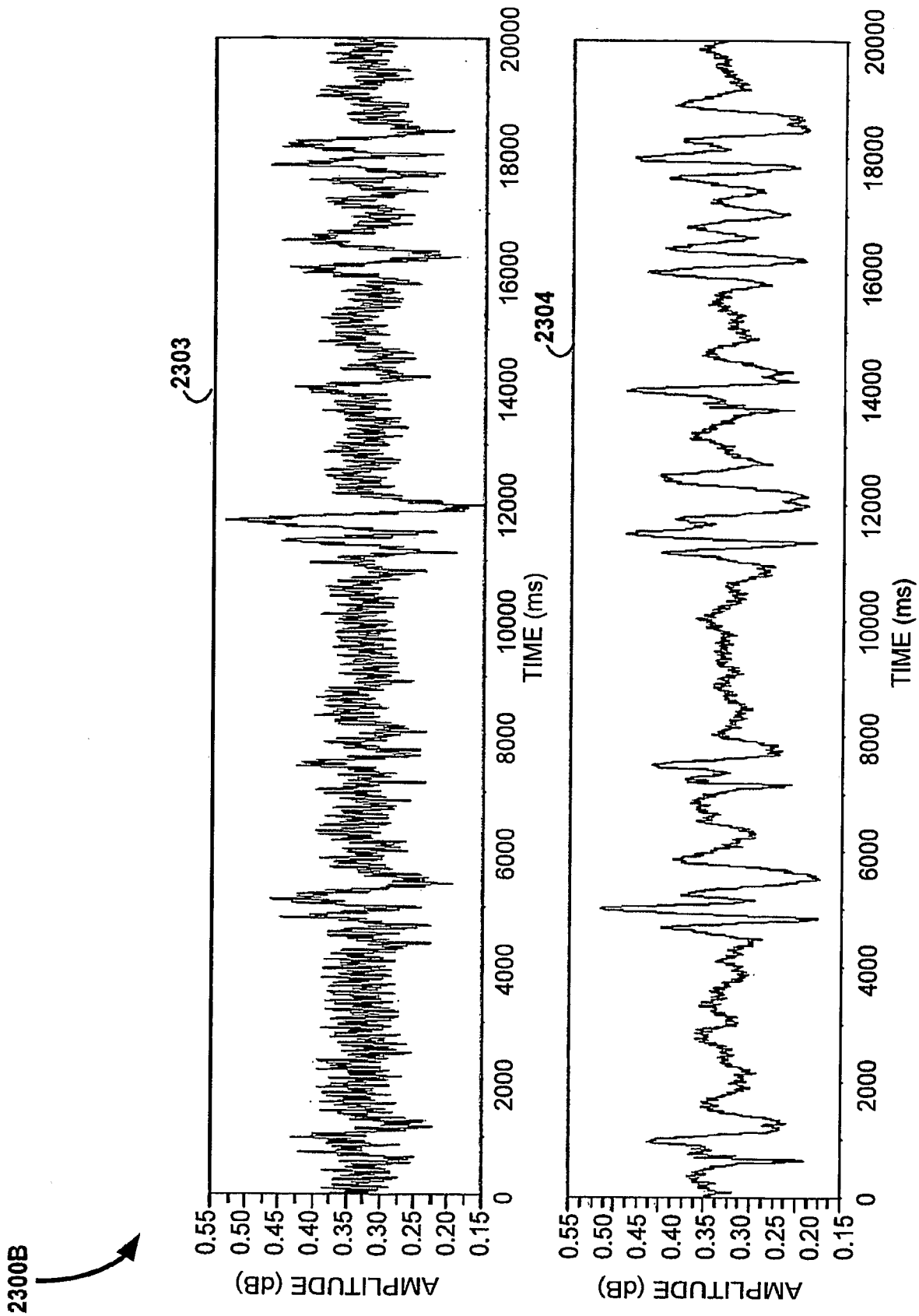
2300B
2303
2304
AMPLITUDE (dB)
TIME (ms)
0.55
0.50
0.45
0.40
0.35
0.30
0.25
0.20
0.15
0
2000
4000
6000
8000
10000
12000
14000
16000
18000
20000

FIG. 23B

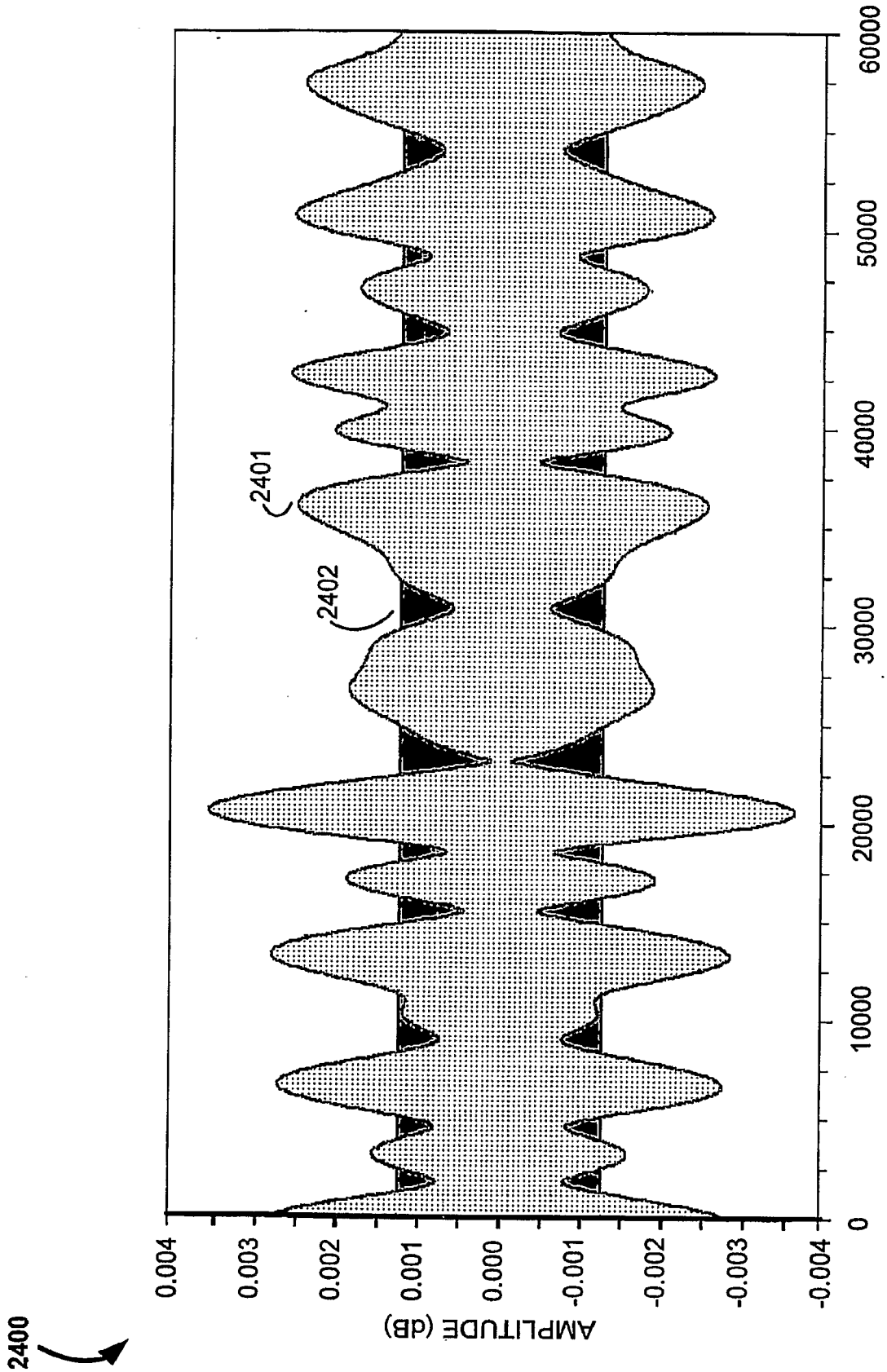
2400
AMPLITUDE (dB)
0.004
0.003
0.002
0.001
0.000
-0.001
-0.002
-0.003
-0.004
0
10000
20000
30000
40000
50000
60000
TIME (ms)
2401
2402

FIG. 24

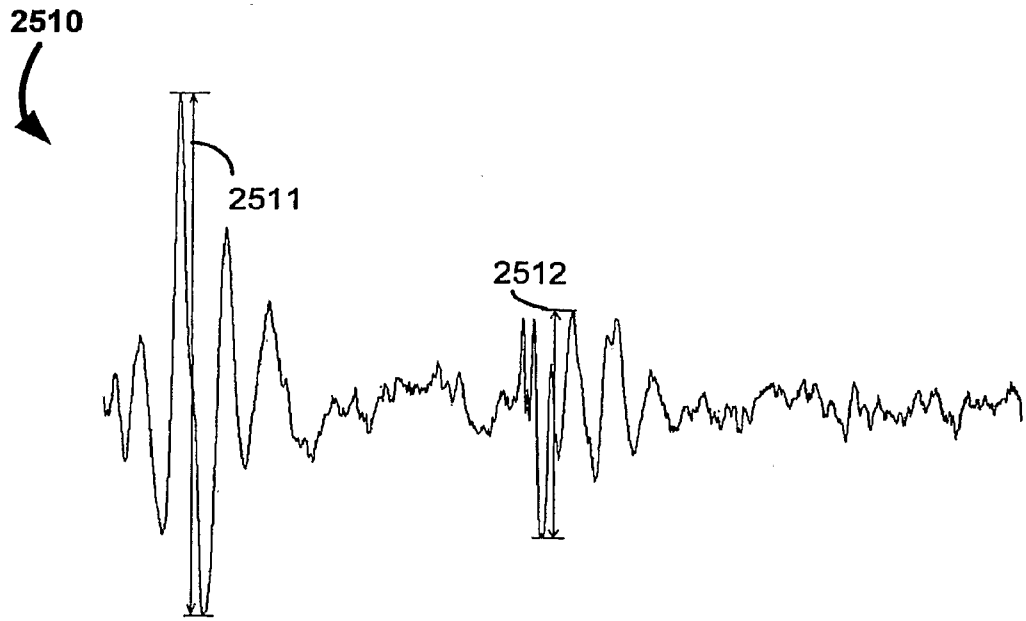

FIG. 25A

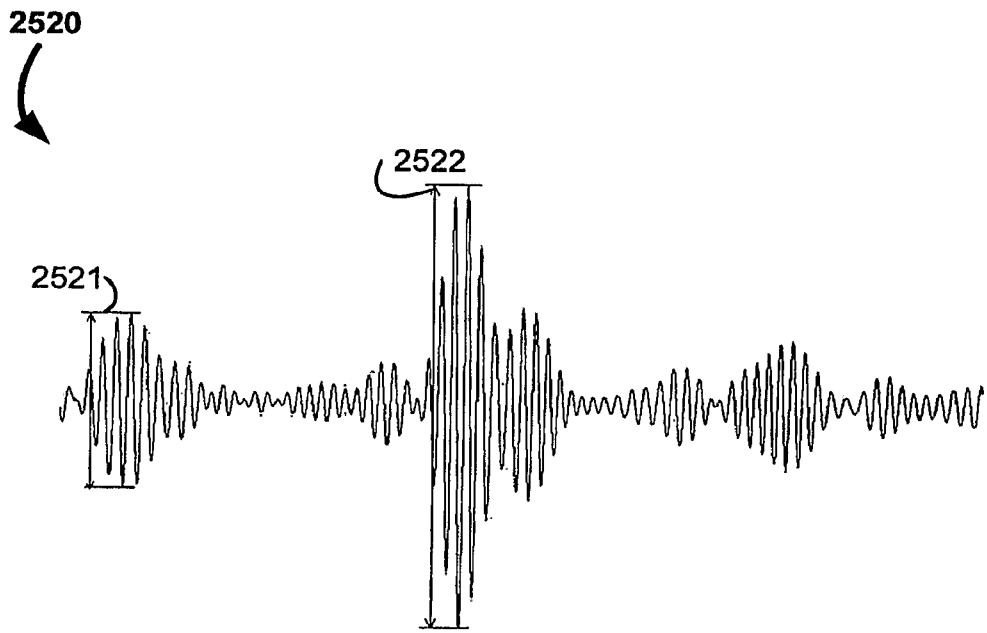

FIG. 25B

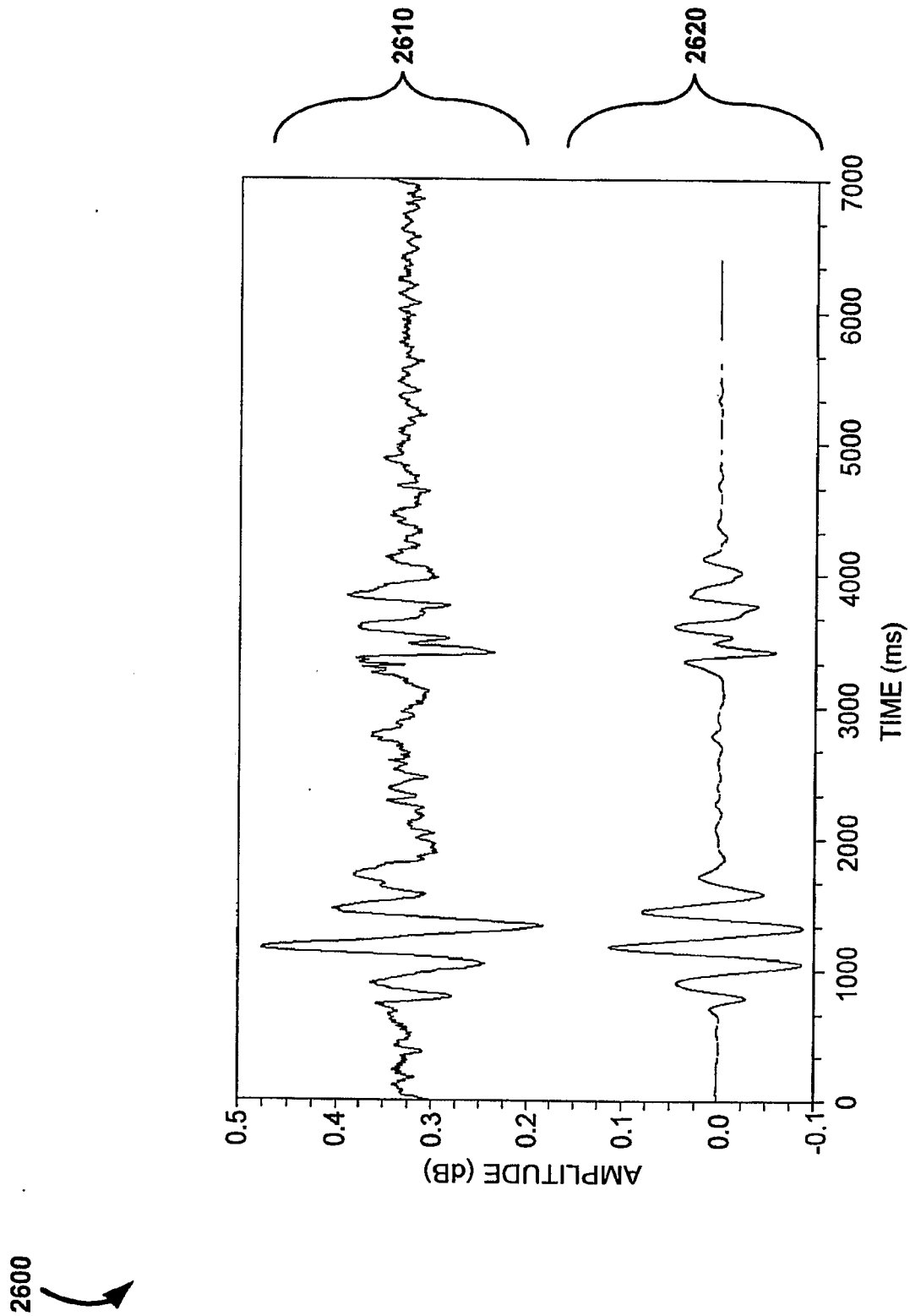
2600
2610
2620
AMPLITUDE (dB)
0.5
0.4
0.3
0.2
0.1
0.0
-0.1
0
1000
2000
3000
4000
5000
6000
7000
TIME (ms)

FIG. 26