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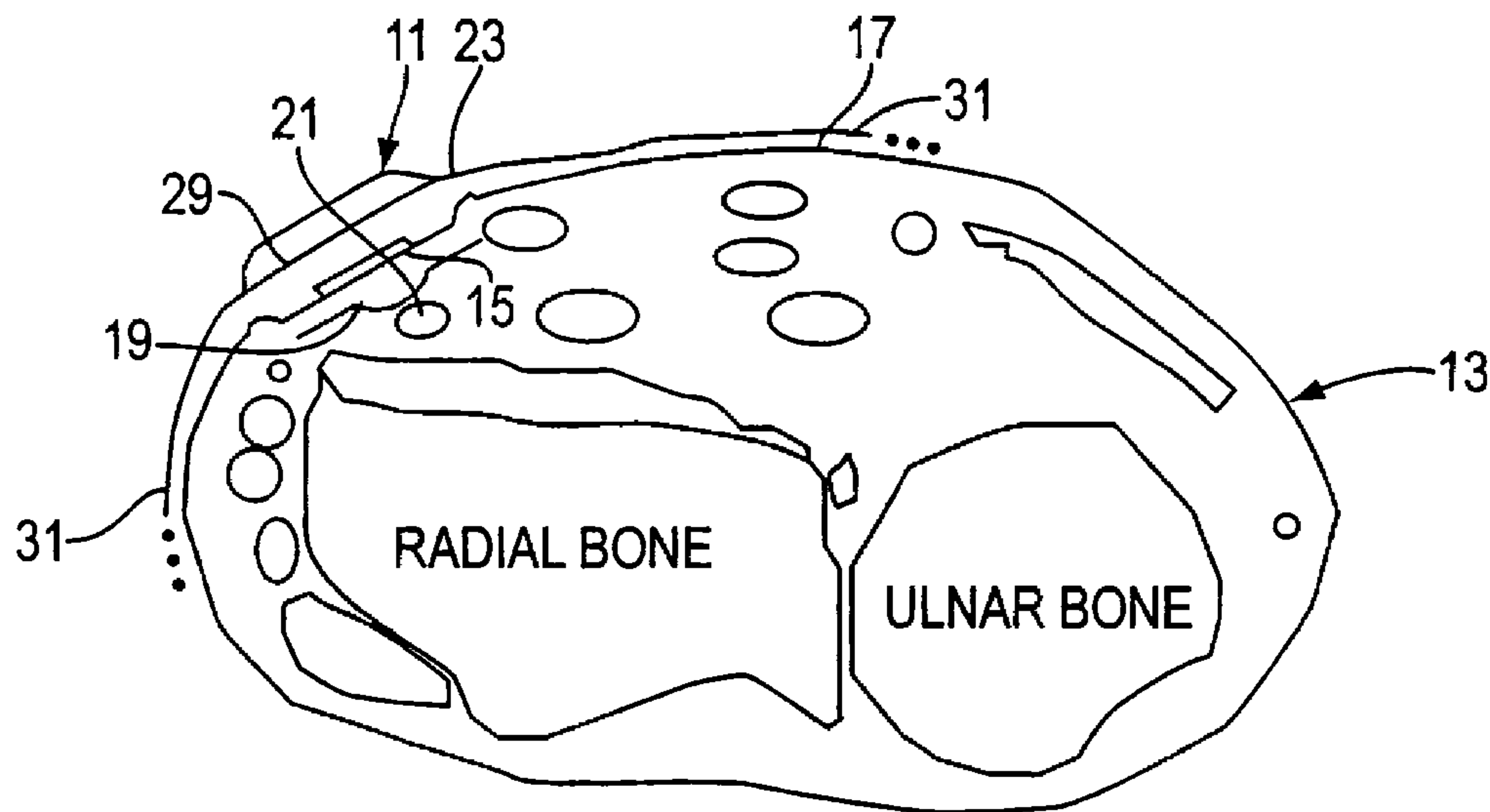
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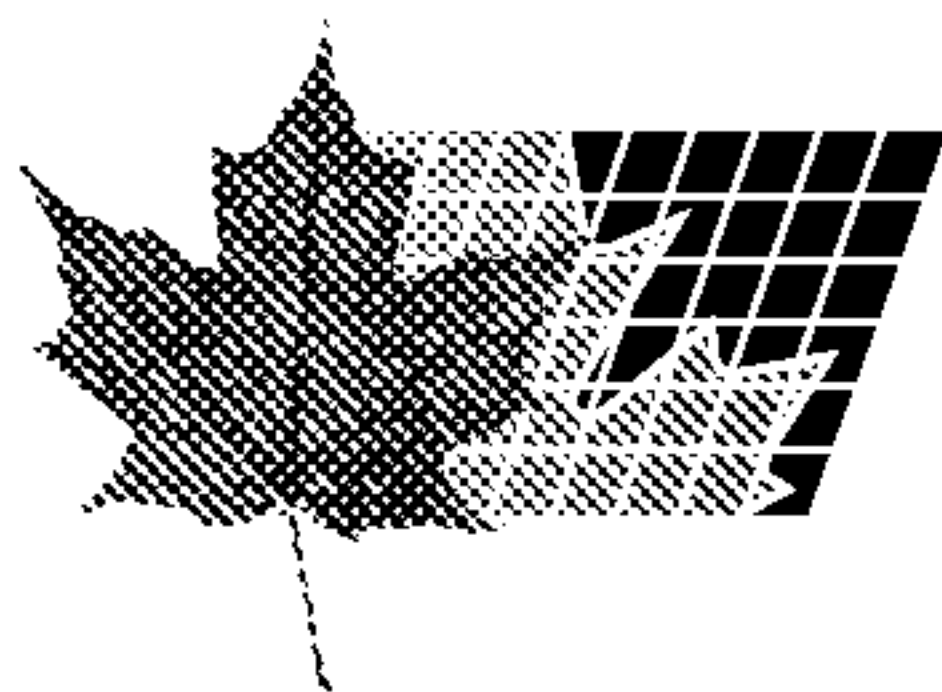
(54) **DISPOSITIF PERMETTANT UNE SURVEILLANCE NON
INVASIVE DE LA PRESSION ARTERIELLE D'UN PATIENT
ET PROCEDE CORRESPONDANT**

(54) **APPARATUS AND METHOD FOR NON-INVASIVELY
MONITORING A PATIENT'S BLOOD PRESSURE**



(57) L'invention a trait à un dispositif permettant une surveillance de la pression artérielle d'un patient et ce, de façon non invasive. Dans ce dispositif, une membrane souple emprisonnant une enceinte remplie de liquide est comprimée contre les tissus sus-jacents à une artère, avec une force suffisante pour aplanir cette artère. Un premier système de commande optimise l'ampleur de l'aplanissement artériel, survenant à une pression transmurale d'une valeur sensiblement nulle, par modulation du volume du liquide contenu dans l'enceinte et grâce à une observation de l'effet résultant sur la pression régnant dans l'enceinte. Dans la mesure

(57) An apparatus is disclosed for monitoring a patient's non-invasive blood pressure, in which a flexible diaphragm (15) that encloses a liquid-filled chamber (23) is compressed against tissue overlying an artery, with sufficient force to applanate the artery. A first control system will optimize the amount of artery applanation, which occurs at a transmural pressure of about zero, by modulating the volume of liquid within the chamber (23) and noting the resulting effect on the pressure within the chamber (23). Since different pressure effects are realized according to the amount of artery applanation, an appropriate control signal can be produced, and



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où il existe plusieurs effets de poussée selon l'ampleur de l'aplanissement artériel, un signal adapté de commande peut être généré, permettant d'obtenir la pression moyenne optimale de la membrane. De plus, un second système de commande à servocommande agit sur la position de la membrane en régulant le volume de liquide présent dans l'enceinte afin de compenser les écarts de pression dues au pouls artériel, ce qui a pour effet de minimiser des variations du diamètre de l'artère, la pression régnant dans l'enceinte remplie de liquide se conformant, par le fait, très étroitement aux oscillations de la forme d'onde réelle du pouls artériel.

provides the optimum mean diaphragm pressure. In addition, a second control system servo controls the diaphragm (15) position by controlling the amount of liquid within the chamber (23). This minimizes variations in the artery diameter, whereby the pressure within the liquid-filled chamber (23) closely follows the actual arterial pulse waveform.

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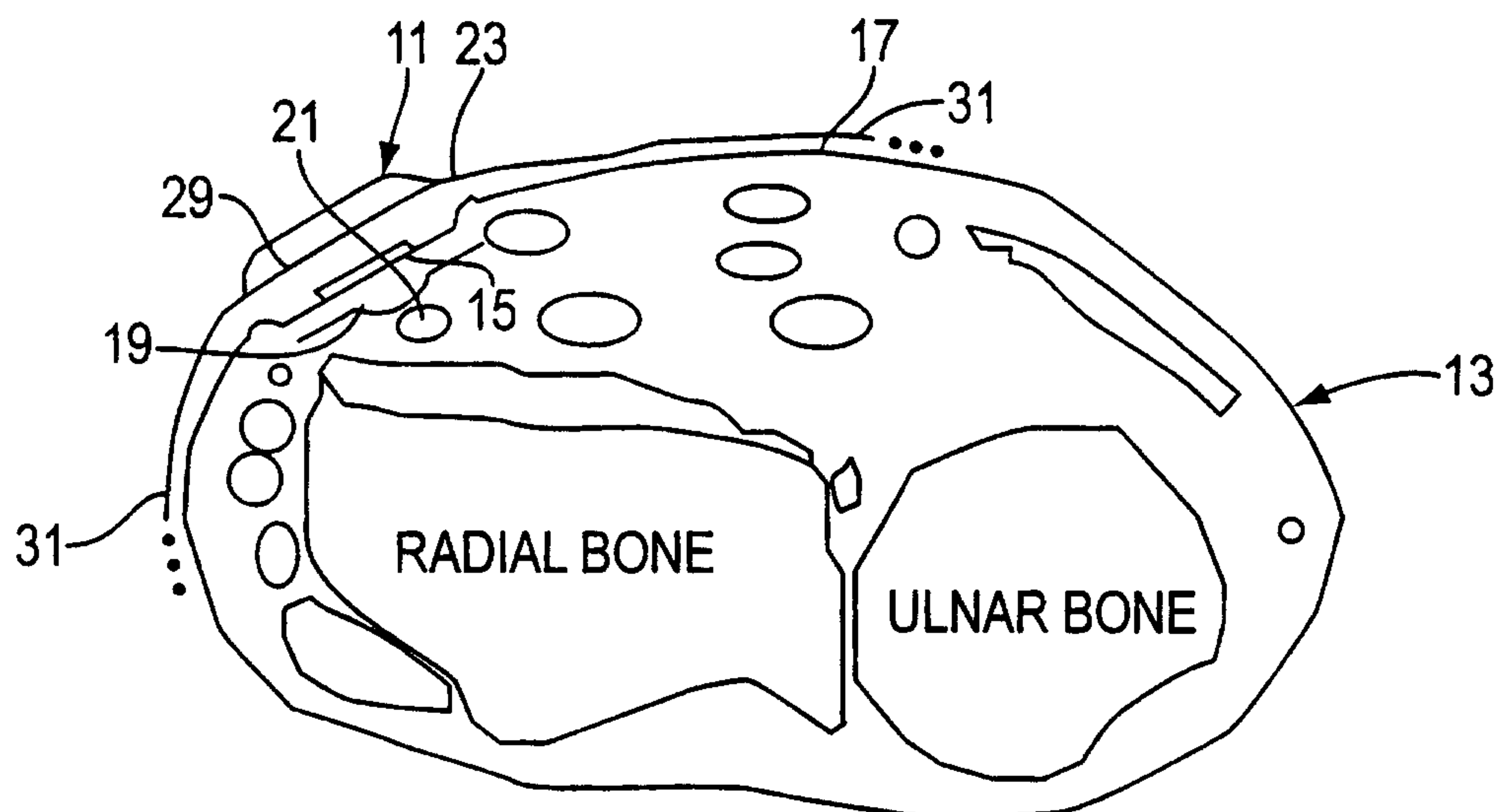
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(57) Abstract

An apparatus is disclosed for monitoring a patient's non-invasive blood pressure, in which a flexible diaphragm (15) that encloses a liquid-filled chamber (23) is compressed against tissue overlying an artery, with sufficient force to appanate the artery. A first control system will optimize the amount of artery appanation, which occurs at a transmural pressure of about zero, by modulating the volume of liquid within the chamber (23) and noting the resulting effect on the pressure within the chamber (23). Since different pressure effects are realized according to the amount of artery appanation, an appropriate control signal can be produced, and provides the optimum mean diaphragm pressure. In addition, a second control system servo controls the diaphragm (15) position by controlling the amount of liquid within the chamber (23). This minimizes variations in the artery diameter, whereby the pressure within the liquid-filled chamber (23) closely follows the actual arterial pulse waveform.

APPARATUS AND METHOD FOR NON-INVASIVELY
MONITORING A PATIENT'S BLOOD PRESSURE

BACKGROUND OF THE INVENTION

5 This invention relates generally to apparatus and
methods for monitoring a patient's blood pressure and, more
particularly, to such apparatus and methods that monitor
blood pressure non-invasively by at least partially
occluding a blood vessel by applying a flexible diaphragm
10 against the vessel.

Two well known techniques have been used to non-
invasively monitor a patient's blood pressure waveform,
namely, auscultation and oscillometry. Both techniques use
a standard inflatable arm cuff that occludes the patient's
15 brachial artery. The auscultatory technique determines the
patient's systolic and diastolic pressures by monitoring
certain Korotkoff sounds that occur as the cuff is slowly
deflated, whereas the oscillometric technique determines
these pressures, as well as the patient's mean pressure, by
20 measuring actual pressure changes that occur in the cuff as
the cuff is deflated. However, both techniques determine
pressure values only intermittently, because of the need to
alternately inflate and deflate the cuff, and they cannot
replicate the patient's blood pressure waveform. Thus, true
25 continuous, beat-to-beat blood pressure monitoring cannot be
achieved using these techniques.

Occlusive cuff instruments of the kind described
briefly above generally have been effective in sensing long-
term trends in a patient's blood pressure. However, such
30 instruments generally have been ineffective in sensing
short-term blood pressure variations, which are of critical
importance in many medical applications, including surgery.

One technique that has been used to provide
information about short-term blood pressure variations is
35 called arterial tonometry. One device for implementing this

technique includes a rigid array of miniature pressure transducers that is applied against the tissue overlying a peripheral artery, e.g., the radial artery. The transducers each directly sense the mechanical forces in the underlying patient tissue, and each is sized to cover only a fraction of the underlying artery. The array is compressed against the tissue, to applanate the underlying artery and thereby cause beat-to-beat pressure variations within the artery to be coupled through the tissue to the transducers.

10 There are several drawbacks to the rigid arterial tonometer described briefly above. First, its discrete transducers are relatively expensive and, because they are exposed, they are easily damaged. In addition, the array of discrete transducers generally is not anatomically
15 compatible with the continuous contours of the patient's tissue overlying the artery being sensed. This has led to inaccuracies in the resulting transducer signals. Another drawback is that such rigid arterial tonometers have failed to correct for signal artifacts that arise when the
20 patient's arm is moved. This is particular problem when the patient is exercising.

 Another device that implements the arterial tonometer technique includes a housing having a closed, liquid-filled chamber with one wall of the chamber defined
25 by a flexible diaphragm. The device is applied to a patient with the flexible diaphragm compressed against the tissue overlying a peripheral artery, e.g., the radial artery, and several electrodes located in separate compartments of the chamber sense volume changes in the compartments that result
30 from the beat-to-beat pressure variations in the underlying artery. Although generally effective in replicating the arterial pressure waveform, this device is considered to have an unduly low gain, making it unduly susceptible to noise. Further, the device must be calibrated periodically,

during which time its continuous monitoring of the patient's blood pressure waveform necessarily is interrupted.

It should, therefore, be appreciated that there is a continuing need for an apparatus, and related method, for non-invasively and continuously monitoring a patient's blood pressure, with reduced susceptibility to noise and without the need to intermittently interrupt the device's normal operation for calibration. The present invention fulfills this need.

10 SUMMARY OF THE INVENTION

The present invention resides in an improved apparatus, and related method, for non-invasively and continuously monitoring a patient's blood pressure, with reduced susceptibility to noise and without the need to intermittently interrupt the pressure monitoring for calibration. The apparatus includes a body having an open cavity, a flexible diaphragm extending across the open cavity to define a closed chamber, and a fluid volume controller that supplies a fluid to and from the closed chamber. In use, the diaphragm is held against the tissue overlying a patient's blood vessel, such that pressure variations within the vessel could cause the diaphragm to flex. To counteract this flexing, however, the fluid volume controller controllably supplies fluid to and from the closed chamber such that the diaphragm remains substantially fixed in a prescribed mean position despite these pressure variances within the vessel. Finally, a pressure sensor senses the pressure of the fluid within the closed chamber, to produce a corresponding pressure signal indicative of the patient's blood pressure.

In a separate and independent feature of the invention, the flexible diaphragm's prescribed mean position is regulated to provide an optimal partial appplanation of

the patient's underlying blood vessel. At this optimal
applanation, the vessel's transmural pressure is
substantially zero. This enables the masking effect of the
tissue overlying the vessel to be effectively eliminated and
5 it enables a substantially increased gain and noise immunity
to be provided. The optimum vessel applanation is achieved
by configuring the fluid volume controller to modulate the
fluid volume within the closed chamber while monitoring the
resulting effect on the pressure signal, to produce a
10 control signal that then is used to regulate the fluid
volume such that the diaphragm is maintained at the optimal
position.

More particularly, the fluid volume controller
includes a sensor that produces a diaphragm position signal
15 indicative of the flexible diaphragm's actual position
relative to the body, means for producing an error signal
indicative of any difference between that actual position
and the diaphragm's prescribed mean position, and a summer,
responsive to the diaphragm position signal and the error
20 signal, that produces the control signal. A fluid supply
supplies the fluid to and from the closed chamber based on
this control signal. The means for producing an error
signal includes an oscillator that produces a modulation
signal coupled to the summer, for incorporation into the
25 control signal. This modulation signal causes the volume
controller to supply the fluid to and from the closed
chamber in a manner that modulates the actual position of
the flexible diaphragm about a mean position. A correlator
correlates the modulation signal with the pressure signal,
30 to sense any deviation of the diaphragm's actual mean
position from its prescribed mean position and to produce
the error signal.

In a more detailed feature of the invention, the
modulation signal includes a succession of alternating
35 positive and negative lobes of substantially uniform

amplitude, e.g., a sine wave, and it has a frequency substantially greater than the patient's expected heartbeat frequency. In addition, the correlator is configured to compare the amplitude and shape of the pressure signal during positive lobes of the modulation signal with the amplitude and shape of the pressure signal during negative lobes of the modulation signal, which is indicative of any deviation of the flexible diaphragm's actual mean position from its prescribed mean position. The correlator is configured to compare the amplitude of the pressure signal during a first stage of the patient's heartbeat (e.g., systole) with the amplitude of the pressure signal during a second stage of the heartbeat (e.g., diastole), to sense any deviation of the diaphragm's actual mean position from its prescribed mean position.

Other features and advantages of the present invention should become apparent from the following description of the preferred embodiments, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic cross-sectional view of a tonometer assembly in accordance with the invention, in its prescribed position secured to a patient's wrist, with a flexible diaphragm and liquid-filled chamber disposed adjacent to the patient's radial artery.

FIG. 2 is a block diagram of a first embodiment of a blood pressure monitoring apparatus in accordance with the invention, incorporating the tonometer assembly of FIG. 1.

FIG. 3 is a graph depicting the typical relationship between the transmural pressure of a patient's

radial artery and the artery's diameter. Superimposed on the graph are several waveforms representing the patient's actual blood pressure over several heartbeats, along with waveforms representing the resulting changes in the artery's diameter for conditions of under applanation, optimal applanation, and over applanation.

FIGS. 4A-4C are graphs of typical pressure signal waveforms over one heartbeat that are provided by the blood pressure monitoring apparatus of FIG. 2, for conditions of under applanation, over applanation, and optimal applanation, respectively. The waveforms incorporate pressure oscillations that result from application of a 25-Hz modulation of the volume in the liquid-filled chamber.

FIG. 5 is a block diagram of a second embodiment of a blood pressure monitoring apparatus in accordance with the invention, incorporating the tonometer assembly of FIG. 1.

FIGS. 6A-6C are graphs of typical pressure signal waveforms over one heartbeat that are provided by the blood pressure monitoring apparatus of FIG. 5, for conditions of under applanation, over applanation, and optimal applanation, respectively. The waveforms incorporate pressure oscillations that result from application of a 25-Hz modulation of the volume in the liquid-filled chamber.

FIG. 7 is a schematic diagram of a model of the patient's wrist, with the tonometer assembly of FIG. 1 disposed adjacent to it. The diagram schematic representations of the wrist's radial bone, radial artery, skin, and underlying tissue.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference now to the drawings, and particularly to FIGS. 1 and 2, there is shown a blood pressure monitoring apparatus having a tonometer assembly 11 configured for attachment to a patient's wrist 13, with a flexible diaphragm 15 of the assembly compressively engaging the skin 17 and other tissue 19 overlying the patient's radial artery 21. Blood pressure variations within the artery are coupled through the tissue to the diaphragm, and through a liquid-filled chamber 23 located behind the diaphragm, to a pressure sensor 25, to produce a pressure signal output on line 27 that represents the artery's pressure waveform.

More particularly, the tonometer assembly 11 includes a plastic base 29 having the shape of an inverted, shallow cup, and a wrist strap 31 that holds the base in its prescribed position on the patient's wrist 13. The flexible diaphragm 15 extends across the opening of the cup-shaped base, to define the chamber 23 that carries a suitable working liquid, e.g., water. When the tonometer assembly is properly secured to the patient's wrist, it compressively engages the skin 17 and adjacent tissue 19 and applanates the radial artery 21. The amount of appplanation affects the degree of coupling of the pressure variations within the artery to the liquid-filled chamber 23 and, in turn, to the pressure sensor 25. The pressure sensor is coupled to the liquid-filled chamber via a low-compliance conduit 33.

FIG. 3 is a graph depicting the sigmoidal relationship between the radial artery's transmural pressure and effective diameter. Transmural pressure is the pressure across the artery wall, i.e., the difference between the pressure inside the artery and the pressure outside the artery. A high transmural pressure indicates that the artery 21 is applanated by a small amount and thus has a

relatively large diameter, whereas a low transmural pressure indicates that the artery is applanated by a large amount and thus has a relatively small diameter.

It will be noted in FIG. 3 that a normal arterial pressure variation of about 50 mm (i.e., 50 millimeters of mercury), due to a normal heartbeat, will cause the artery's transmural pressure to vary by 50 mm, as well. This assumes, of course, that the pressure outside the artery 21 remains unchanged.

When the artery 21 is applanated by only a small amount, i.e., when the mean transmural pressure is highly positive, this 50 mm pressure excursion will cause only a relatively small change in the artery's diameter. This relationship is shown by the vertically oriented waveform at the right of FIG. 3 and the horizontally oriented waveform at the top of FIG. 3. Similarly, when the artery is applanated by a large amount, i.e., when the mean transmural pressure is highly negative, this 50 mm pressure excursion likewise will cause only a relatively small change in the artery's diameter. This relationship is shown by the vertically oriented waveform at the left of FIG. 3 and the horizontally oriented waveform at the bottom of FIG. 3.

However, if the artery 21 is applanated by an amount that corresponds to a mean transmural pressure near zero, this 50 mm pressure excursion will cause a relatively large change in the artery's diameter. This relationship, which is shown by the waveforms at the middle bottom and middle left of FIG. 3, represents a maximum coupling between the arterial pressure and the tonometer assembly 11. It is desirable, therefore, to regulate the mean arterial applanation to match this optimum value.

To this end, the apparatus further includes a volume controller 35 having a liquid source 37 that supplies

liquid to and from the chamber 23 of the tonometer assembly 11, via a conduit 39. The volume controller implements a control scheme that regulates the volume of liquid within the chamber so as to provide optimal applanation of the patient's radial artery 21. Under this control scheme, the volume controller actively modulates the position of the tonometer assembly's flexible diaphragm 15, so as to modulate, or dither, the diameter of the patient's artery 21, and it analyzes the resulting effect on the pressure signal produced by the pressure sensor 25. Different effects on the pressure signal are provided by different amounts of artery applanation.

The volume controller 35 effects this modulation of the diaphragm's position by applying a 25-Hz sinusoidal signal to the liquid source 37. This sinusoidal signal is produced by an oscillator 41 and coupled via line 43 to a summer 45 and, in turn, via line 47 to the liquid source. A 25-Hz frequency is selected, because it is generally higher than the highest frequency components of interest in the artery's blood pressure waveform.

It will be appreciated that, if the artery 21 is under applanated, then the ac amplitude of the 25-Hz pressure oscillation will be larger during systole than during diastole. This is because an incremental change in the diameter of the artery (i.e., an incremental vertical movement along the sigmoid curve of FIG. 3) will induce a greater pressure change (i.e., horizontal movement along the curve of FIG. 3) when the pressure is highest, i.e., at systole, than when the pressure is lowest, i.e., at diastole. This phenomenon is depicted in FIG. 4A, which depicts the pressure signal on line 27 aligned with the pressure waveform representing one heartbeat, including both a systolic stage and a diastolic stage. It will be noted that the pressure signal's ac amplitude is substantially

greater during the systolic stage than during the diastolic stage.

Conversely, if the artery 21 is over applanated, then the ac amplitude of the 25-Hz pressure oscillation will be larger during diastole than during systole. This is because an incremental change in the diameter of the artery (i.e., an incremental vertical movement along the curve of FIG. 3) will induce a greater pressure change (i.e., horizontal movement along the curve of FIG. 3) when the pressure is lowest, i.e., at diastole, than when the pressure is highest, i.e., at systole. This phenomenon is depicted in FIG. 4B, which depicts the pressure signal on line 27 aligned with the pressure waveform representing one heartbeat. It will be noted that the pressure signal's ac amplitude is substantially greater during the diastolic stage than during the systolic stage.

However, if the artery 21 is optimally applanated, then the ac amplitudes of the 25-Hz pressure oscillation during the systolic and end-diastolic stages will be substantially the same. In addition, the overall amplitude of the pressure oscillation is at a minimum when the artery is optimally applanated. This is because the sigmoid curve of FIG. 3 is steepest at the point of optimal applanation. These phenomena are depicted in FIG. 4C.

The control system for implementing the control scheme described above is depicted in FIG. 2. In addition to the volume controller 35, the tonometer assembly 11, and the pressure sensor 25 identified above, the control system further includes a 25-Hz bandpass filter 49 that filters the pressure signal received on line 27 from the pressure sensor. The filtered signal, which incorporates only the 25-Hz component of the pressure signal, is supplied on line 51 to the volume controller. An analyzer 53 that is part of the volume controller receives the filtered signal and

compares its ac amplitude during systole with its ac amplitude during diastole, to determine whether the artery 21 is under applanated, over applanated, or optimally applanated. The analyzer produces a corresponding error
5 signal that is supplied on line 55 to the summer 45, which sums the error signal with the 25-Hz modulation signal, to produce a control signal that controls the liquid source 37.

Operation of the control system automatically regulates the amount of liquid in the liquid-filled chamber
10 23 of the tonometer assembly 11 such that the assembly optimally applanates the patient's radial artery 21. For example, if the analyzer 53 of the volume controller 35 determines that the ac amplitude of the filtered pressure signal is greater during systole than it is during diastole,
15 then a positive error signal is produced, which is coupled through the summer 45 to the liquid source 37, to supply additional liquid to the tonometer chamber and thereby increase the applanation of the artery. The opposite would occur if the analyzer determines that filtered pressure
20 signal's ac amplitude is greater during diastole than it is during systole.

To provide a visible display of the patient's arterial pressure waveform, the apparatus further includes a 25-Hz band stop filter 57 and a display 59. The filter
25 receives the pressure signal on line 27 from the pressure sensor 25, and it samples this signal at a rate of 50 samples per second. This sampling is phased with the 25-Hz modulation signal output on line 43 by the oscillator 41 such that it always occurs at the modulation signal's zero
30 crossings. The sampled pressure signal then is coupled on line 61 to the display, for real-time display.

In an independent feature of the invention, enhanced coupling of the pressure variance within the patient's radial artery 21 due to heartbeats is provided by

actively maintaining the artery fixed at its optimal
applanation level throughout each heartbeat pulse. This is
accomplished by a second control system, which servo
controls, in real time, the amount of liquid in the chamber
5 23 of the tonometer assembly 11 so as to counteract the
effect of the arterial pressure variations. Moreover, this
servo control is effected in combination with the control
system that regulates the tonometer assembly to provide the
optimal mean artery applanation, as described above. A
10 block diagram of a blood pressure monitoring apparatus that
implements both such control systems is provided in FIG. 5.
Major portions of this apparatus are identical to the
apparatus of FIG. 2 and are identified by the same reference
numerals.

15 With reference to FIG. 5, an optical position
sensor 63 (e.g., incorporating a light-emitting diode and a
photodiode) is carried on the base 29 of the tonometer
assembly 11, to provide a signal that indicates the position
of the flexible diaphragm 15 relative to the base. The
20 diaphragm position can be assumed to be related directly to
the position of the patient's skin and, thus, to the
diameter of the patient's radial artery 21. The position
signal is coupled via line 65 from the position sensor
directly to the summer 45 of the volume controller 35, for
25 incorporation into the control signal supplied on line 47 to
the liquid source 37.

Thus, for example, as the pressure within the
artery 21 rises during systole, the position sensor 63
senses an increase in the artery's diameter and the position
30 signal therefore exhibits a corresponding increase. This
increase is coupled to the liquid source 37, which responds
by supplying sufficient additional liquid through the
conduit 39 to the chamber 23 of the tonometer assembly 11 to
counteract the increased pressure. The result is that the
35 artery diameter remains substantially fixed throughout the

arterial pulse. A loop bandwidth of about 100 Hz is preferred, which is significantly higher than the 25-Hz modulation signal and the important harmonics of the arterial pulse.

5 As the liquid source 37 of the volume controller 35 regulates the volume of liquid within the chamber 23 of the tonometer assembly 11 so as to maintain the diameter of the patient's radial artery 21 substantially fixed, the pressure within the chamber necessarily will vary.
10 Moreover, because of the relatively low compliance of the liquid contained within the chamber, the pressure variance within the chamber will closely match the pressure waveform of the artery.

FIGS. 6A-6C depict the pressure signal output on
15 line 27 by the pressure sensor 25 for the time period of one complete arterial pulse, for conditions of under applanation, over applanation, and optimal applanation, respectively. It will be noted that the signals closely follow the actual arterial pressure waveform, which also is
20 shown in the three drawings. It will be noted that a pressure oscillation due to the 25-Hz modulation signal is present in each of the depicted pressure signals.

In the under applanation condition (FIG. 6A), the 25-Hz component of the pressure signal is skewed with its
25 positive lobes significantly smaller than its negative lobes. Conversely, in the over applanation condition (FIG. 6B), the 25-Hz component of the pressure signal is skewed with its negative lobes significantly smaller than its positive lobes. In the optimal applanation condition (FIG.
30 6C), the 25-Hz component has positive and negative lobes of substantially the same amplitude. In addition, the total ac amplitude of the 25-Hz component of the pressure signal is smaller than it is when either under applanated or over applanated. This, of course, naturally follows from the

shape of the sigmoid curve of FIG. 3; the incremental pressure will vary the least in response to an incremental artery diameter change at the point where the curve is steepest, i.e., where the artery's transmural pressure is zero.

The blood pressure monitoring apparatus of FIG. 5 implements a different technique from that of the apparatus of FIG. 2 to maintain the artery 21 at its optimum amount of applanation. In the FIG. 5 apparatus, the analyzer 53 of the volume controller 35 examines the relative amplitudes of the positive and negative lobes of the 25-Hz component of the pressure signal, which is provided to the analyzer on line from the 25-Hz bandpass filter 49. If the negative lobes are determined to be larger than the positive lobes, then it is deduced that the artery is under applanated and an appropriate error signal is coupled to the summer 45 and, in turn, the liquid source 37. Conversely, an error signal having the opposite sense is produce if the positive lobes are determined to be larger than the negative lobes, in which case it is deduced that the artery is over applanated.

As mentioned above, the pressure signal produced by the pressure sensor 25 closely follows the actual arterial pressure waveform. This benefit is due primarily to the servo control of the flexible diaphragm 15 of the tonometer assembly 11 such that the diameter of the artery 21 remains substantially fixed throughout each arterial pulse, as well as to the low compliance of the liquid within the chamber 23. The schematic diagram of FIG. 7 will help to provide an understanding of this phenomenon.

The schematic diagram of FIG. 7 includes a spring model of the patient's wrist 13, including its radial artery 21, radial bone 67, and skin 17, as well as the tissue 19 located above and adjacent to the radial artery. Also included in the schematic diagram is a spring model of the

tonometer assembly 11, including its wrist strap 31. The radial bone advantageously serves as a fairly rigid backing for the radial artery, but the artery wall and the tissue above and adjacent to the radial artery are modeled as a plurality of resilient springs. The coupling between the wrist strap and the base 29 of the tonometer assembly also is modeled as a spring.

It will be appreciated that if the flexible diaphragm 15 is servo controlled so as to minimize any variation in the diameter of the artery 21, then the attenuating effects of the various springs that represent the wall of the artery, the skin 17, and adjacent wrist tissue 19 is effectively eliminated. The only remaining element having an attenuating effect is the spring 69 that models the coupling between the base 29 of the tonometer assembly 11 and the wrist strap 31. This provides a dramatically improved coupling of the arterial waveform to the pressure sensor 25, whereby a substantially improved pressure signal can be produced.

It should be appreciated from the foregoing description that the present invention provides an improved apparatus for monitoring a patient's blood pressure, non-invasively, in which a flexible diaphragm is compressed against tissue overlying an artery with sufficient force to applanate the artery by an amount that optimally couples pressure waveforms within the artery. In addition, the amount of liquid contained within a chamber located behind the diaphragm is servo controlled, to compensate for pressure variations due to arterial pulses. This minimizes variations in the artery diameter, whereby the pressure within the liquid-filled chamber is made to closely follow the actual arterial pulse waveform.

Although the invention has been described in detail with reference only to the preferred embodiments,

those skilled in the art will appreciate that various modifications can be made without departing from the invention. Accordingly, the invention is defined only by the following claims.

WE CLAIM:

1. Apparatus for non-invasively monitoring the pressure within a patient's blood vessel, comprising:

a base having an open cavity;

5 a flexible diaphragm extending across the open cavity of the base to define a closed, fluid-filled chamber;

a device configured to urge the diaphragm into compressive engagement with tissue overlying a patient's blood vessel, to appanate the vessel and ensure that
10 pressure variances within the blood vessel are coupled through the tissue to the diaphragm;

a fluid volume controller that controllably supplies a fluid to and from the closed chamber, such that the mean position of the portion of the flexible diaphragm
15 overlying the patient's blood vessel remains substantially fixed despite pressure variances within the blood vessel; and

a pressure sensor that senses the pressure of the fluid within the closed chamber and produces a corresponding
20 pressure signal indicative of the pressure within the patient's blood vessel.

2. Apparatus as defined in claim 1, wherein the mean position for the flexible diaphragm partially appanates the blood vessel and provides a mean transmural vessel pressure of substantially zero.

3. Apparatus as defined in claim 1, wherein the fluid volume controller is configured to modulate the position of the flexible diaphragm and to monitor the resulting effect on the pressure signal, to produce a
5 control signal that is used to regulate the position of the flexible diaphragm to a prescribed mean position.

4. Apparatus as defined in claim 3, wherein:
the fluid volume controller is configured to modulate the position of the flexible diaphragm at a substantially uniform ac amplitude; and

5 the fluid volume controller includes a device that compares the ac amplitude of the pressure signal during systole with the ac amplitude of the pressure signal during diastole and that produces the control signal in accordance with the comparison.

5. Apparatus as defined in claim 3, wherein:
the fluid volume controller is configured to modulate the position of the flexible diaphragm substantially sinusoidally; and

5 the fluid volume controller includes a device that compares the ac amplitude of the pressure signal during positive portions of the diaphragm modulation with the ac amplitude of the pressure signal during negative portions of the diaphragm modulation and that produces the control
10 signal in accordance with the comparison.

6. Apparatus as defined in claim 1, wherein the fluid volume controller includes:

a fluid supply that supplies the fluid to and from the closed chamber based on a control signal;

5 a diaphragm position sensor that produces a diaphragm position signal indicative of the flexible diaphragm's actual position relative to the base;

means for producing an error signal indicative of any difference between the diaphragm's actual position and
10 a prescribed mean position; and

a summer, responsive to the diaphragm position signal and the error signal, that produces the control signal.

7. Apparatus as defined in claim 6, wherein the means for producing an error signal includes:

an oscillator that produces a modulation signal that is coupled to the summer, for incorporation into the control signal, to cause the fluid supply to supply the fluid to and from the closed chamber in a manner that modulates the actual position of the flexible diaphragm about a mean position; and

a correlator that correlates the modulation signal with the pressure signal, to sense any deviation of the flexible diaphragm's actual mean position from the flexible diaphragm's prescribed mean position and to produce the error signal.

8. Apparatus as defined in claim 7, wherein:

the modulation signal includes a succession of alternating positive and negative lobes; and

the correlator is configured to compare the amplitude and shape of the pressure signal during positive lobes of the modulation signal with the amplitude and shape of the pressure signal during negative lobes of the modulation signal, to sense any deviation of the flexible diaphragm's actual mean position from the flexible diaphragm's prescribed mean position and to produce the error signal.

9. Apparatus as defined in claim 7, wherein:

the modulation signal has a substantially uniform ac amplitude; and

the correlator is configured to compare the ac amplitude of the pressure signal during a first stage of the patient's heartbeat with the ac amplitude of the pressure signal during a second stage of the patient's heartbeat, to sense any deviation of the flexible diaphragm's actual mean position from the flexible diaphragm's prescribed mean position and to produce the error signal.

10. Apparatus as defined in claim 7, wherein:

the patient's blood vessel is an artery; and

the modulation signal is a sine wave having a frequency substantially greater than the patient's expected
5 heartbeat frequency.

11. Apparatus as defined in claim 1, wherein:
the fluid is a liquid; and
the patient's blood vessel is a peripheral artery.

12. Apparatus as defined in claim 11, wherein:
the peripheral artery is a radial artery; and
the diaphragm is sized to extend only over the
portion of the patient's wrist that overlies the radial
5 artery.

13. Apparatus for non-invasively monitoring the pressure within a patient's blood vessel, comprising:
a base having an open cavity;
a flexible diaphragm extending across the open
5 cavity of the base to define a closed, fluid-filled chamber;
a device configured to urge the diaphragm into compressive engagement with tissue overlying a patient's blood vessel, to applanate the vessel and ensure that pressure variances within the blood vessel are coupled
10 through the tissue to the diaphragm;
a fluid volume controller that supplies a fluid to and from the closed chamber in accordance with a modulation signal, such that the flexible diaphragm oscillates about an actual mean position;
15 a pressure sensor that senses the pressure of the fluid within the closed chamber and produces a corresponding pressure signal;
a correlator that correlates the pressure signal with the modulation signal, to sense any deviation of the
20 flexible diaphragm's actual mean position from a prescribed mean position and to produce a corresponding error signal that is coupled to the fluid volume controller, to cause the volume controller to supply fluid to or from the closed

chamber to move the flexible diaphragm toward the prescribed
25 mean position; and

a filter that filters the pressure signal to
produce a filtered pressure signal indicative of the
pressure within the patient's blood vessel.

14. Apparatus as defined in claim 13, wherein:
the apparatus further includes a diaphragm
position sensor that produces a diaphragm position signal
indicative of the flexible diaphragm's actual position
5 relative to the base; and

the fluid volume controller is configured to
supply the fluid to and from the closed chamber in
accordance with the diaphragm position signal, such that the
mean position of the portion of the flexible diaphragm
10 overlying the patient's blood vessel remains substantially
fixed despite pressure variances within the blood vessel.

15. Apparatus as defined in claim 13, wherein:
the modulation signal includes a succession of
alternating positive and negative lobes; and
the correlator is configured to compare the
5 amplitude and shape of the pressure signal during positive
lobes of the modulation signal with the amplitude and shape
of the pressure signal during negative lobes of the
modulation signal, to sense any deviation of the flexible
diaphragm's actual mean position from the flexible
10 diaphragm's prescribed mean position and to produce the
error signal.

16. Apparatus as defined in claim 13, wherein:
the modulation signal has a substantially uniform
ac amplitude; and

the correlator is configured to compare the
5 amplitude of the pressure signal during a first stage of the
patient's heartbeat with the amplitude of the pressure
signal during a second stage of the patient's heartbeat, to

sense any deviation of the flexible diaphragm's actual mean position from the flexible diaphragm's prescribed mean position and to produce the error signal.

17. Apparatus as defined in claim 13, wherein:
the patient's blood vessel is an artery; and
the modulation signal is a sine wave having a frequency substantially greater than the patient's expected heartbeat frequency.

18. Apparatus as defined in claim 13, wherein:
the fluid is a liquid; and
the patient's blood vessel is a peripheral artery.

19. Apparatus as defined in claim 18, wherein:
the peripheral artery is a radial artery; and
the diaphragm is sized to extend only over the portion of the patient's wrist that overlies the radial artery.

20. Apparatus for non-invasively monitoring the pressure within a patient's blood vessel, comprising:
a base having an open cavity;
a flexible diaphragm extending across the open cavity of the base to define a fluid-filled chamber;
a device configured to urge the diaphragm into compressive engagement with tissue overlying a patient's blood vessel, to appanate the vessel and ensure that pressure variances within the blood vessel are coupled through the tissue to the diaphragm;
a first control system that supplies fluid to and from the fluid-filled chamber such that the portion of the flexible diaphragm overlying the patient's blood vessel has a prescribed mean position that optimally appanates the blood vessel;
a second control system that supplies fluid to and from the fluid-filled chamber so as to servo control the

position of the flexible diaphragm and maintain the diaphragm in its prescribed mean position despite pressure
20 variances within the blood vessel; and

a pressure sensor that senses the pressure of the fluid within the fluid-filled chamber and produces a corresponding pressure signal indicative of the pressure within the patient's blood vessel.

21. Apparatus for non-invasively monitoring the pressure within a patient's blood vessel, comprising:

a base having an open cavity;

5 a flexible diaphragm extending across the open cavity of the base to define a closed, fluid-filled chamber;

a device that urges the diaphragm into compressive engagement with tissue overlying a patient's blood vessel, to applanate the vessel and ensure that pressure variances within the blood vessel are coupled through the tissue to
10 the diaphragm;

a fluid volume controller that regulates the mean amount of fluid in the closed chamber, such that the compressive engagement of the diaphragm with the tissue overlying the patient's blood vessel optimally applanates
15 the vessel; and

a sensor that senses the pressure of the fluid within the closed chamber and produces a corresponding pressure signal indicative of the pressure within the patient's blood vessel.

22. Apparatus as defined in claim 21, wherein:
the fluid volume controller includes

5 a fluid source that supplies fluid to and from the closed chamber in accordance with a modulation signal, such that the flexible diaphragm oscillates about an actual mean position, wherein this oscillation induces a corresponding oscillation in the pressure signal produced by the sensor, and

10 a correlator that correlates the pressure signal with the modulation signal, to sense any

deviation of the flexible diaphragm's actual mean position from a prescribed mean position and to produce a corresponding error signal that is coupled to the fluid source, to cause the fluid source to supply fluid to or from the closed chamber to move the flexible diaphragm toward the prescribed mean position; and

a filter that filters the pressure signal to produce a filtered pressure signal indicative of the pressure within the patient's blood vessel.

23. Apparatus as defined in claim 22, wherein:

the apparatus further includes a diaphragm position sensor that produces a diaphragm position signal indicative of the flexible diaphragm's actual position relative to the base; and

the fluid source is configured to supply the fluid to and from the closed chamber in accordance with the diaphragm position signal, such that the mean position of the portion of the flexible diaphragm overlying the patient's blood vessel remains substantially fixed despite pressure variances within the blood vessel.

24. Apparatus as defined in claim 22, wherein:

the modulation signal includes a succession of alternating positive and negative lobes; and

the correlator is configured to compare the amplitude and shape of the pressure signal during positive lobes of the modulation signal with the amplitude and shape of the pressure signal during negative lobes of the modulation signal, to sense any deviation of the flexible diaphragm's actual mean position from the flexible diaphragm's prescribed mean position and to produce the error signal.

25. Apparatus as defined in claim 22, wherein:

the modulation signal has a substantially uniform ac amplitude; and

25

the correlator is configured to compare the
5 amplitude of the pressure signal during a first stage of the
patient's heartbeat with the amplitude of the pressure
signal during a second stage of the patient's heartbeat, to
sense any deviation of the flexible diaphragm's actual mean
position from the flexible diaphragm's prescribed mean
10 position and to produce the error signal.

26. Apparatus as defined in claim 22, wherein:
the patient's blood vessel is an artery; and
the modulation signal is a sine wave having a
frequency substantially greater than the patient's expected
5 heartbeat frequency.

27. Apparatus as defined in claim 22, wherein:
the fluid is a liquid; and
the patient's blood vessel is a peripheral artery.

28. Apparatus as defined in claim 27, wherein:
the peripheral artery is a radial artery; and
the diaphragm is sized to extend only over the
portion of the patient's wrist that overlies the radial
5 artery.

29. Apparatus as defined in claim 21, wherein the
fluid volume controller is configured to maintain the
patient's blood vessel optimally applanated continuously,
without the need for separate, periodic calibration.

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FIG. 1

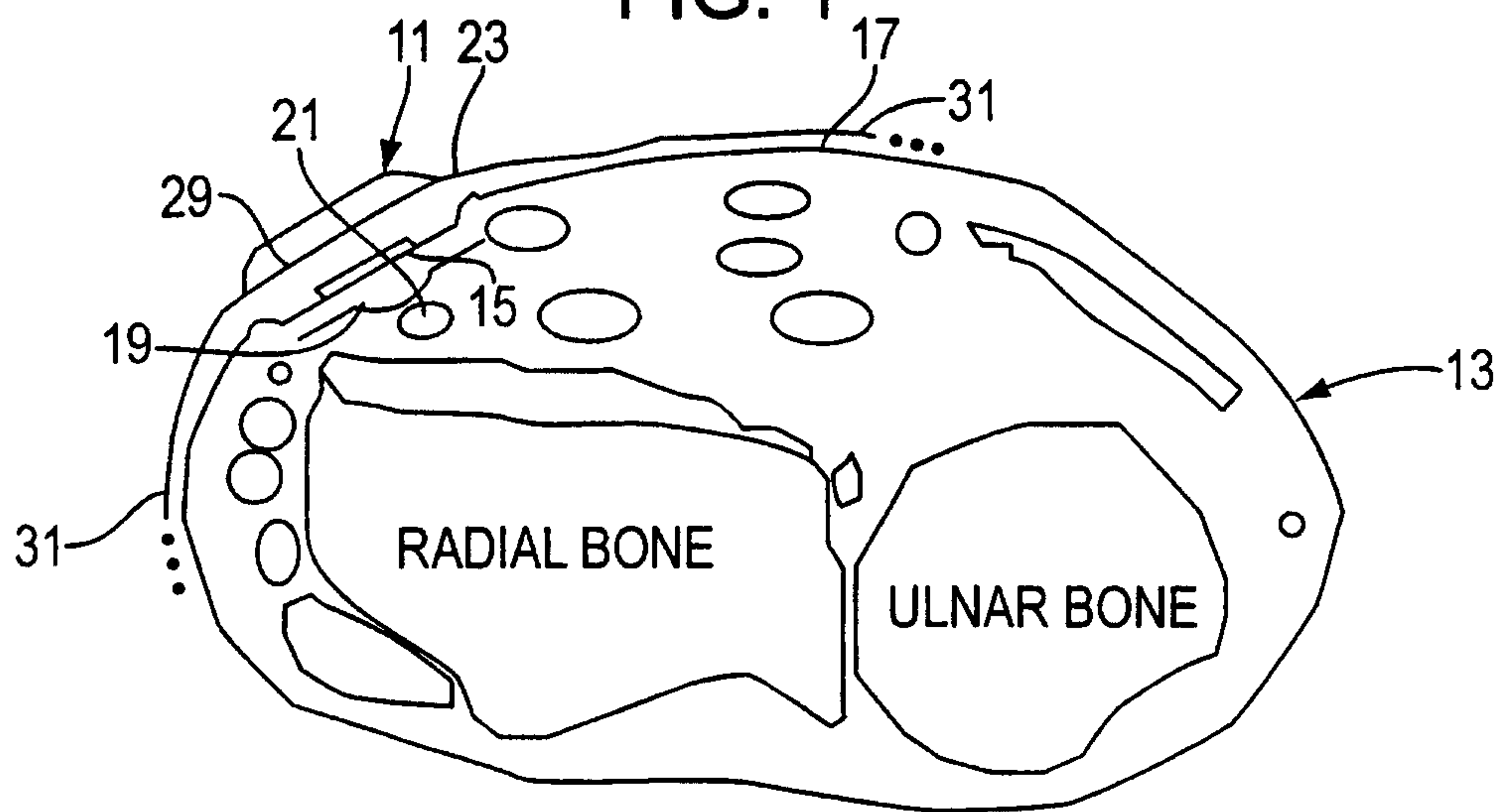


FIG. 3

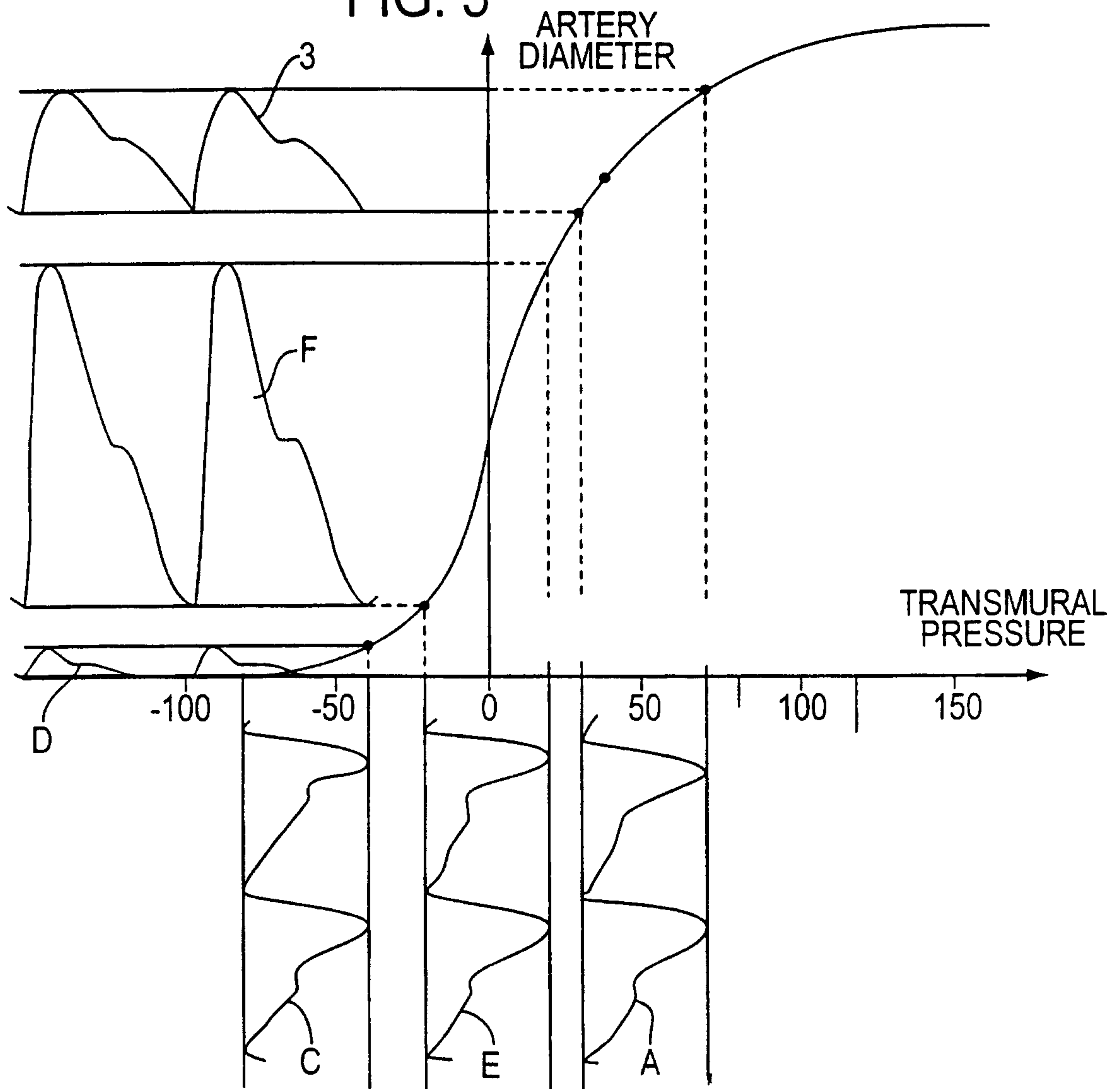


FIG. 2

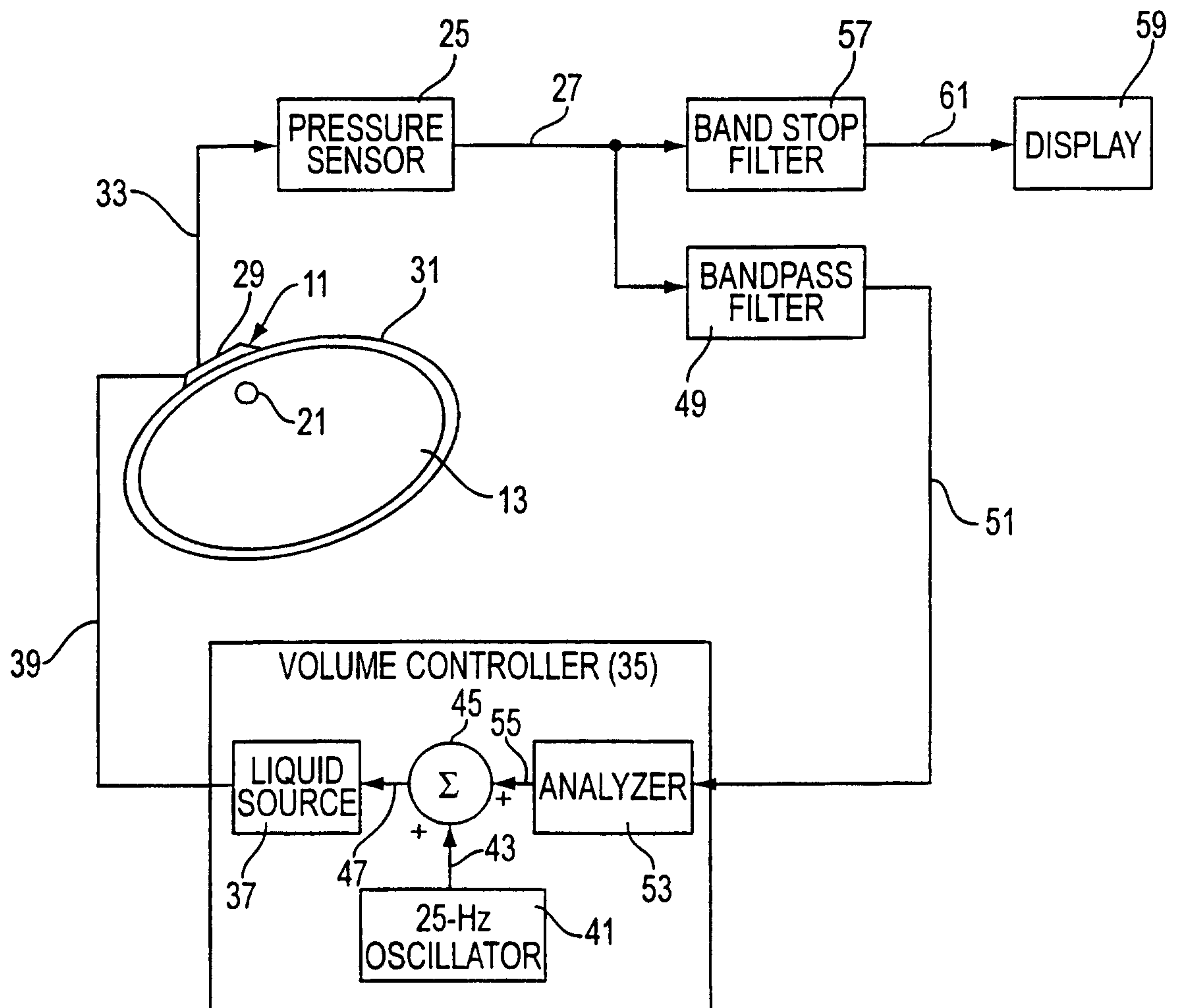


FIG. 4A

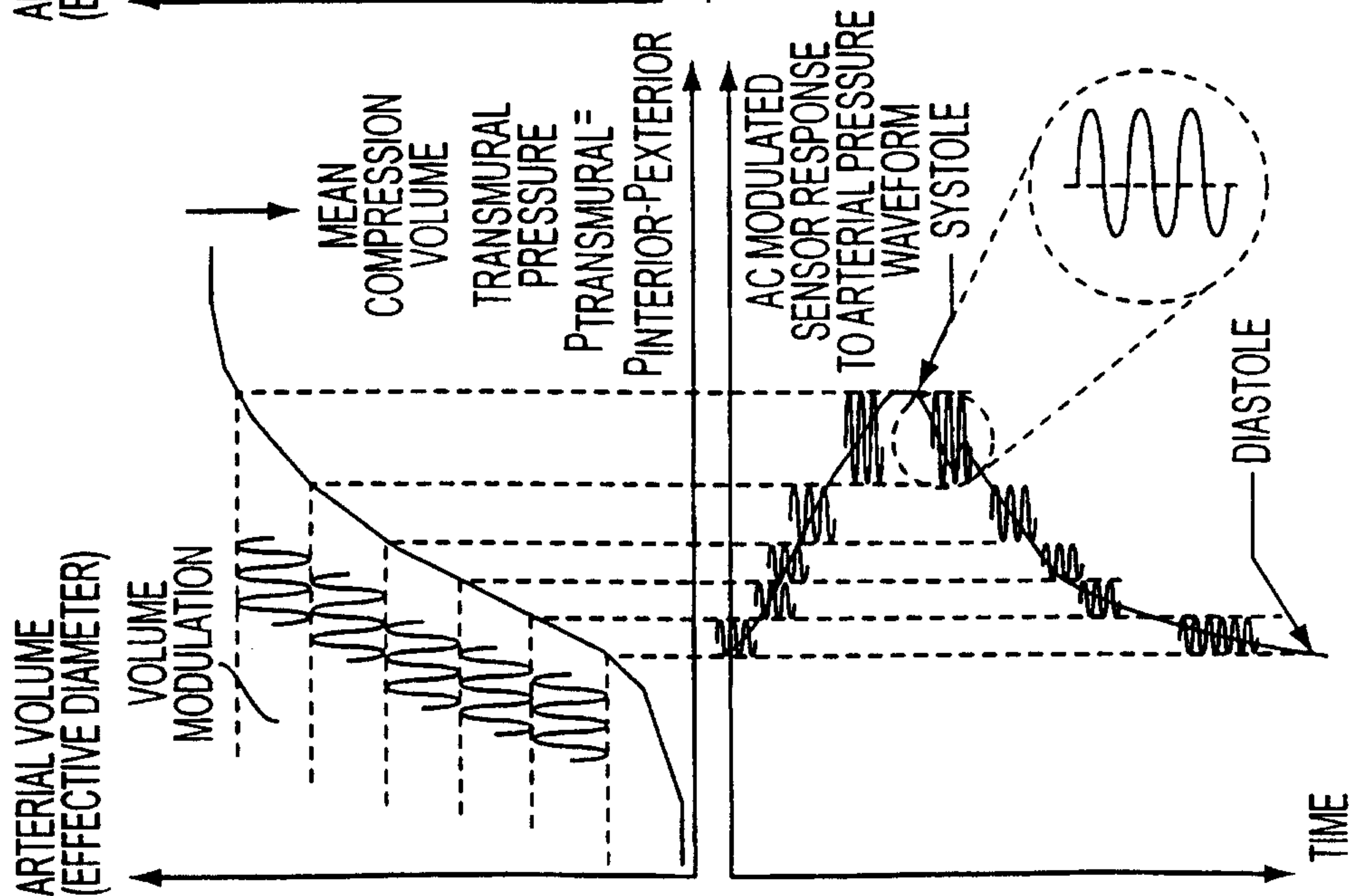


FIG. 4B

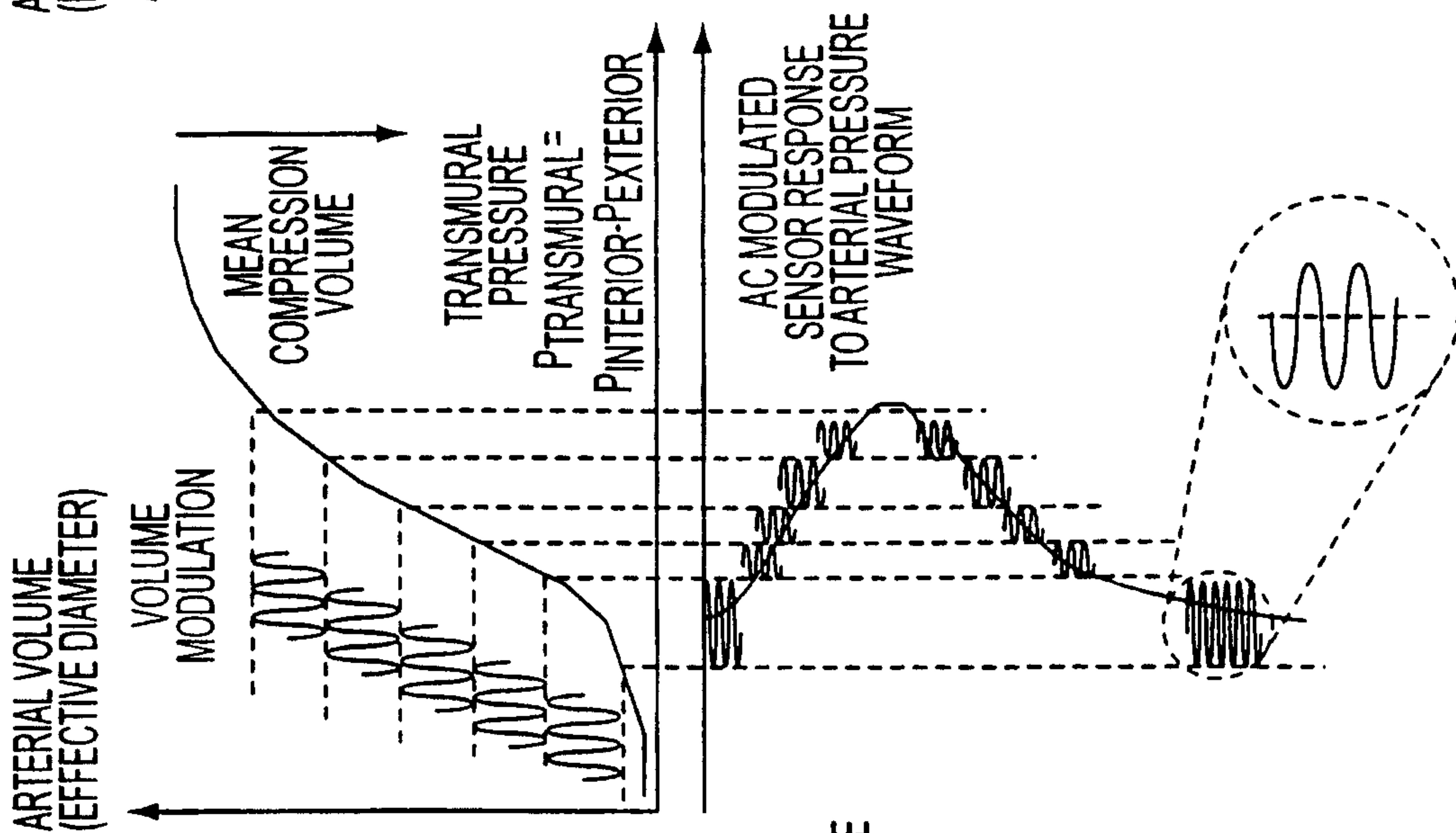
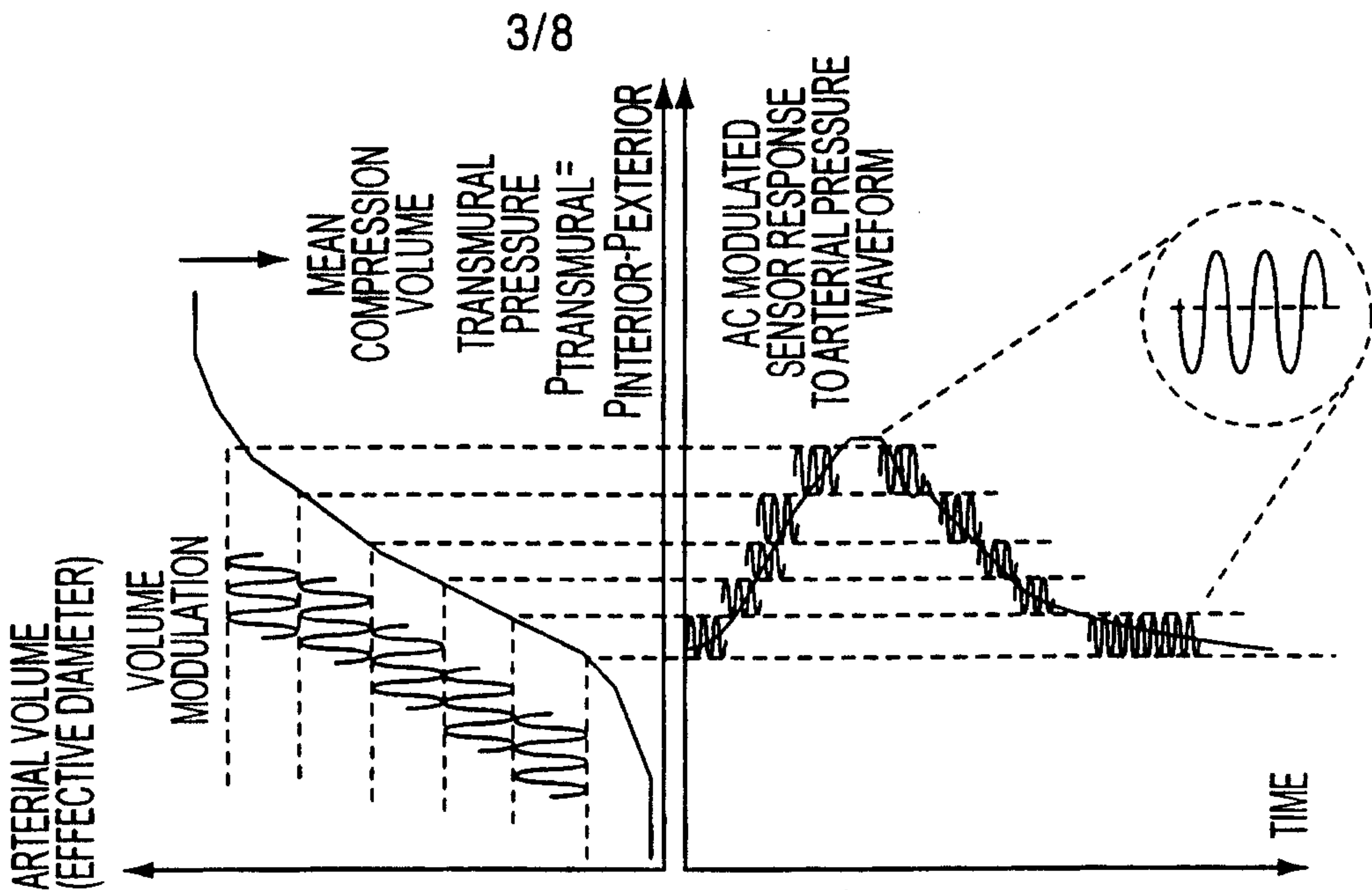


FIG. 4C



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FIG. 5A

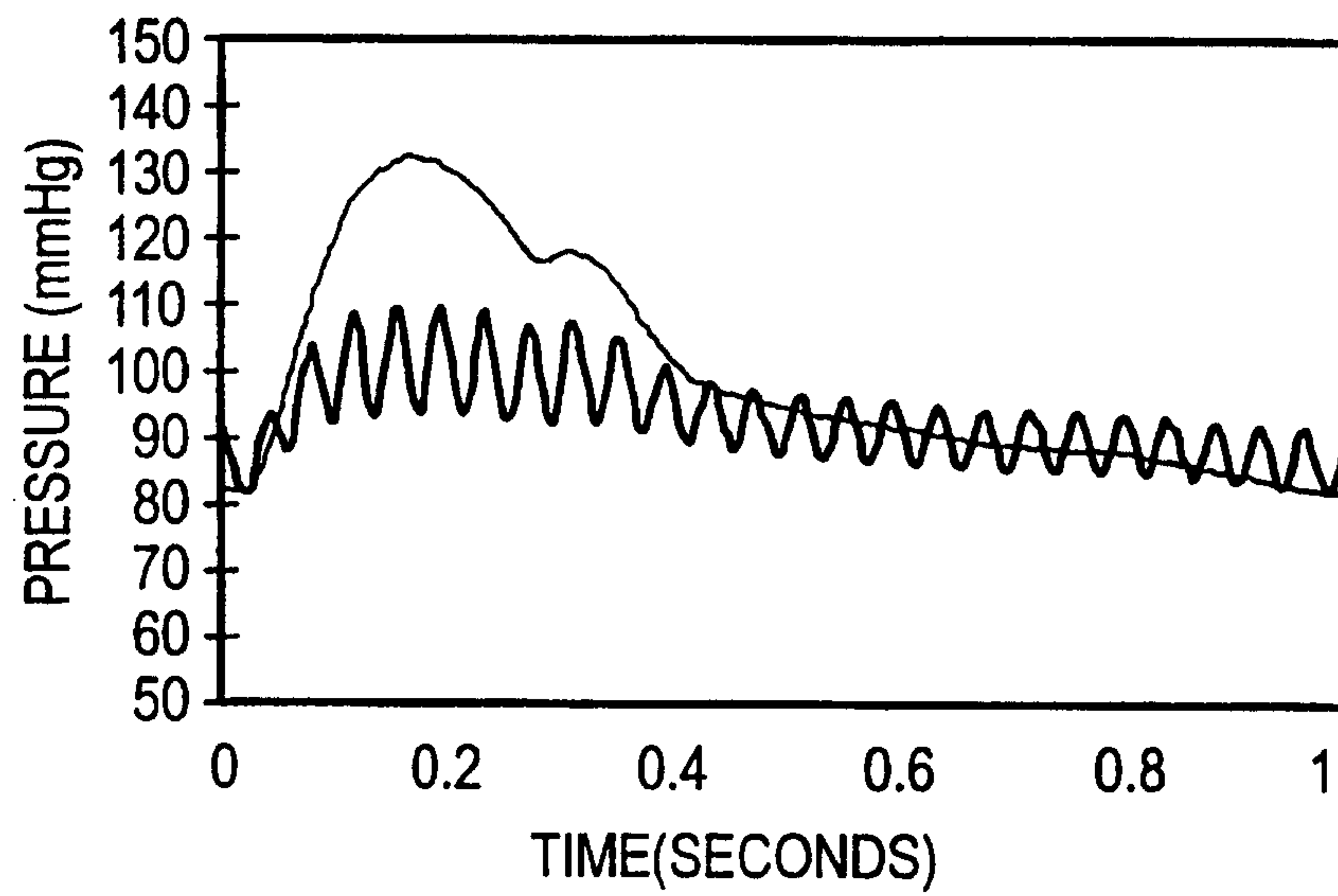


FIG. 5B

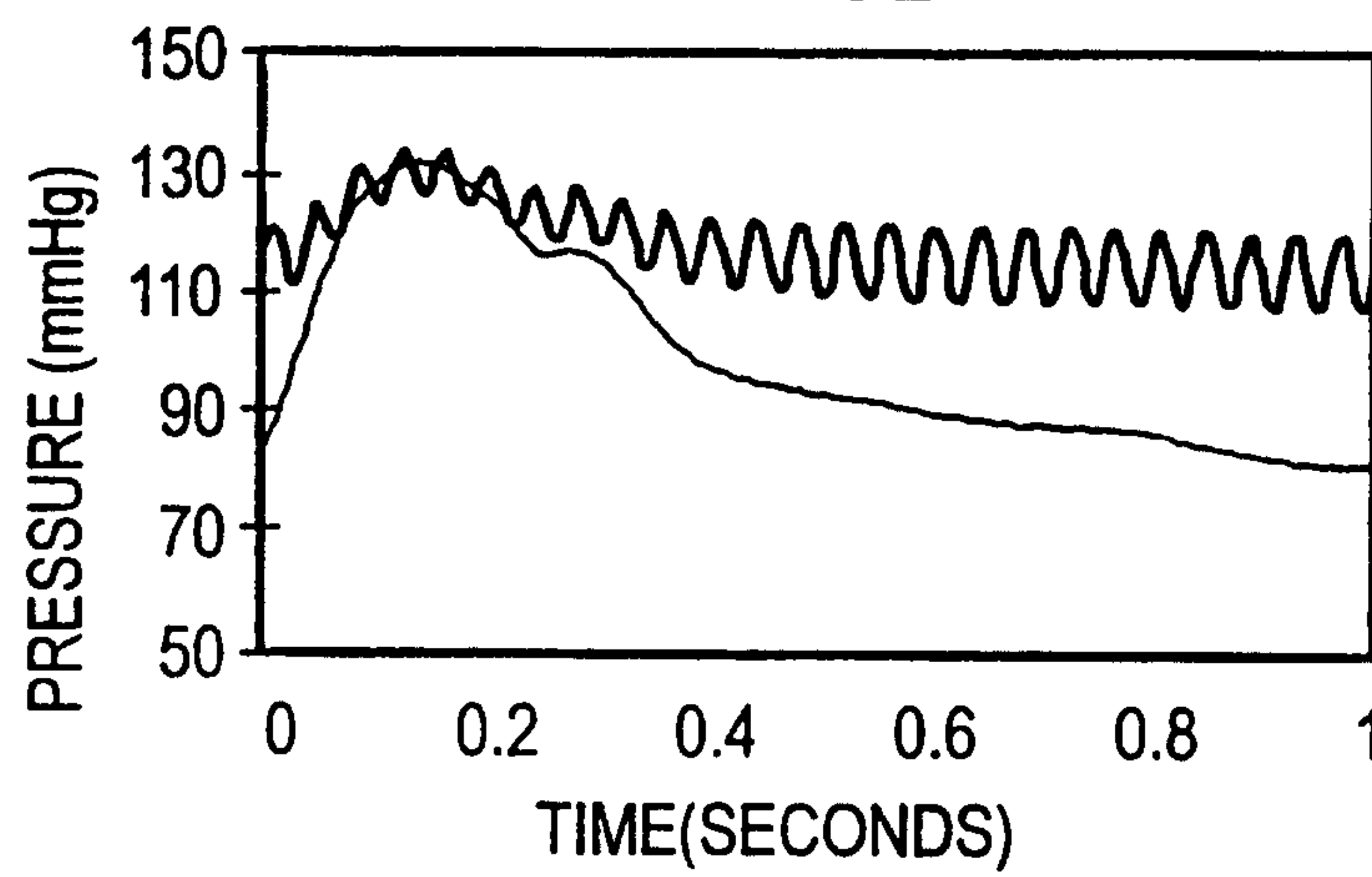


FIG. 5C

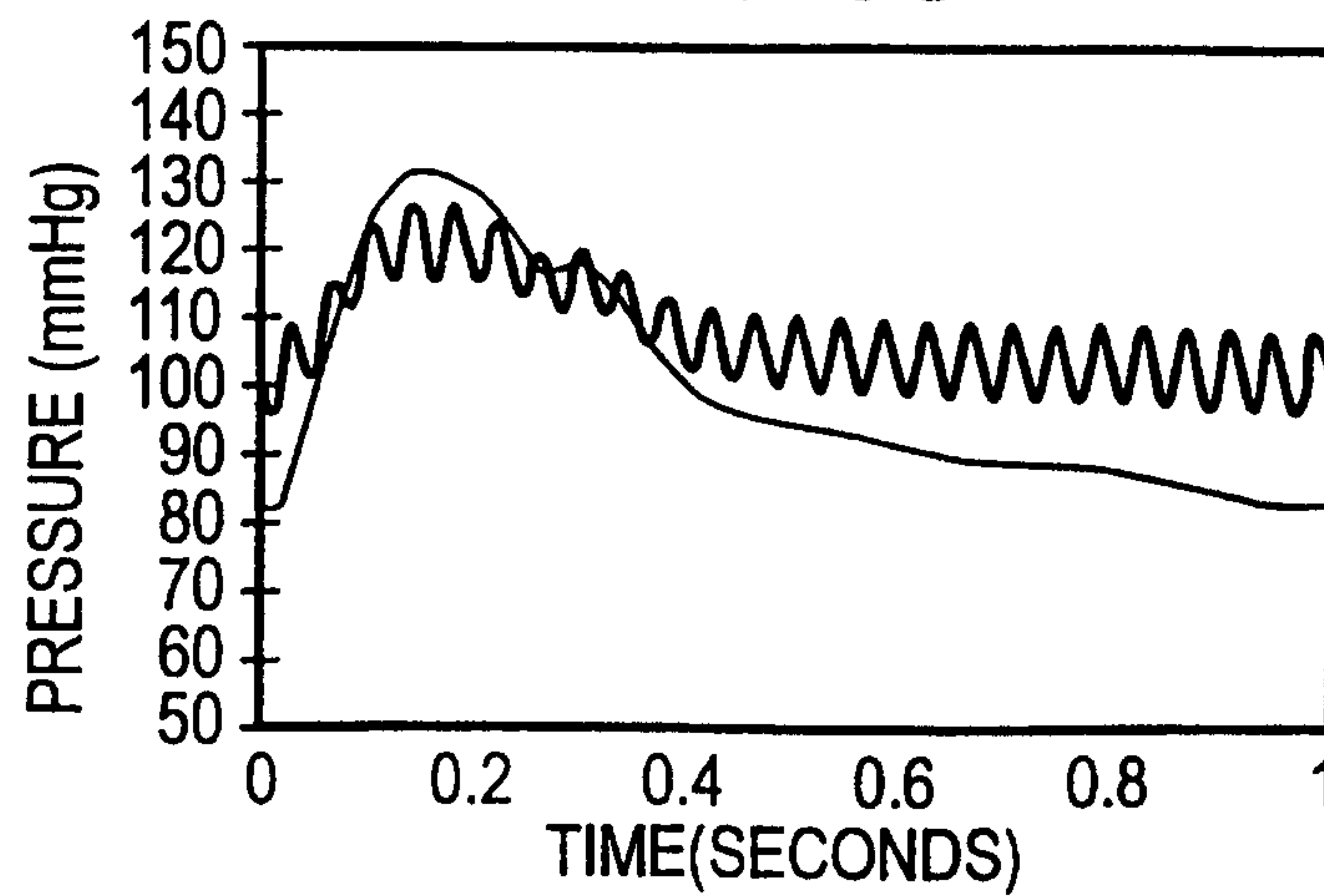


FIG. 6

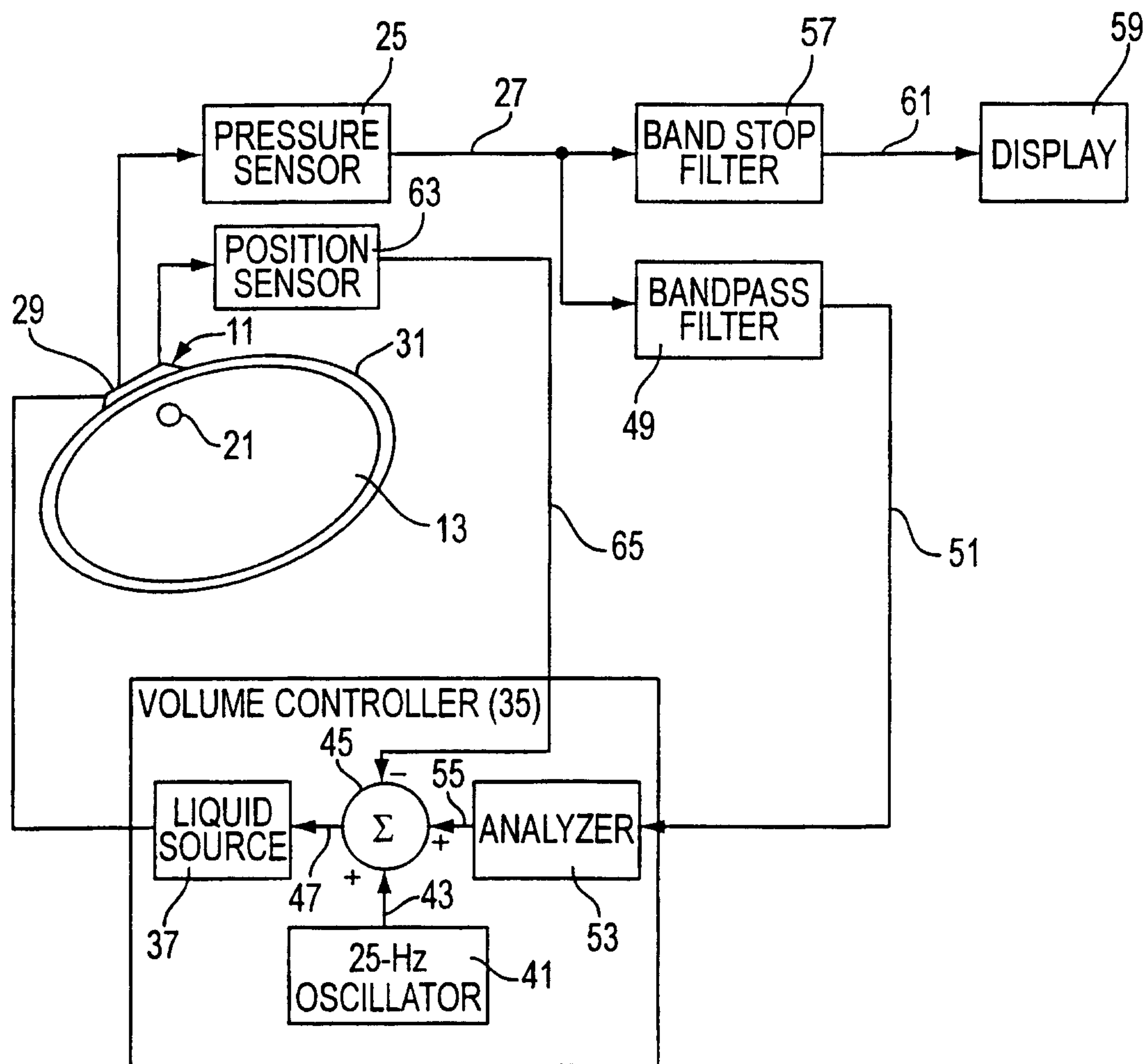
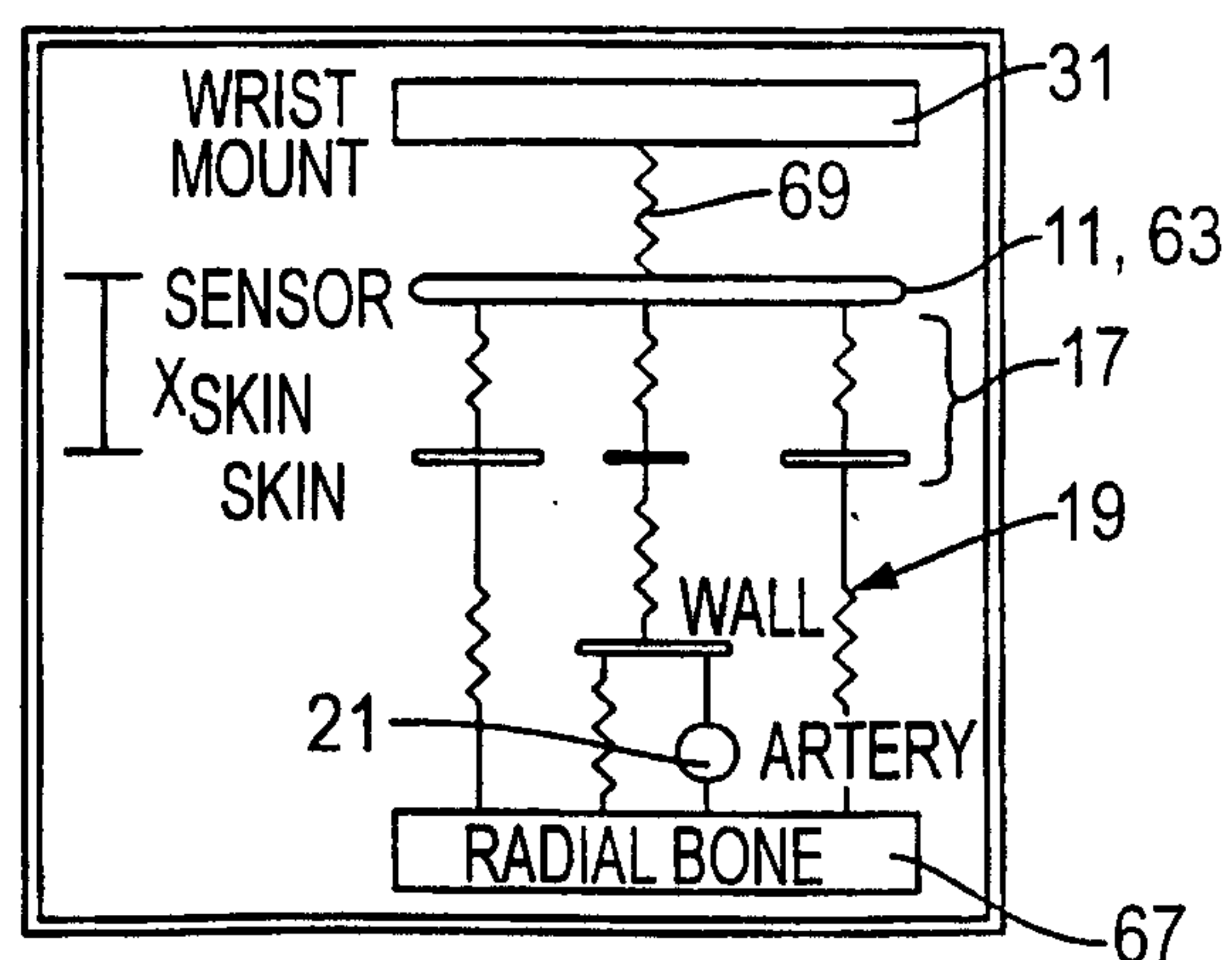


FIG. 8



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FIG. 7A

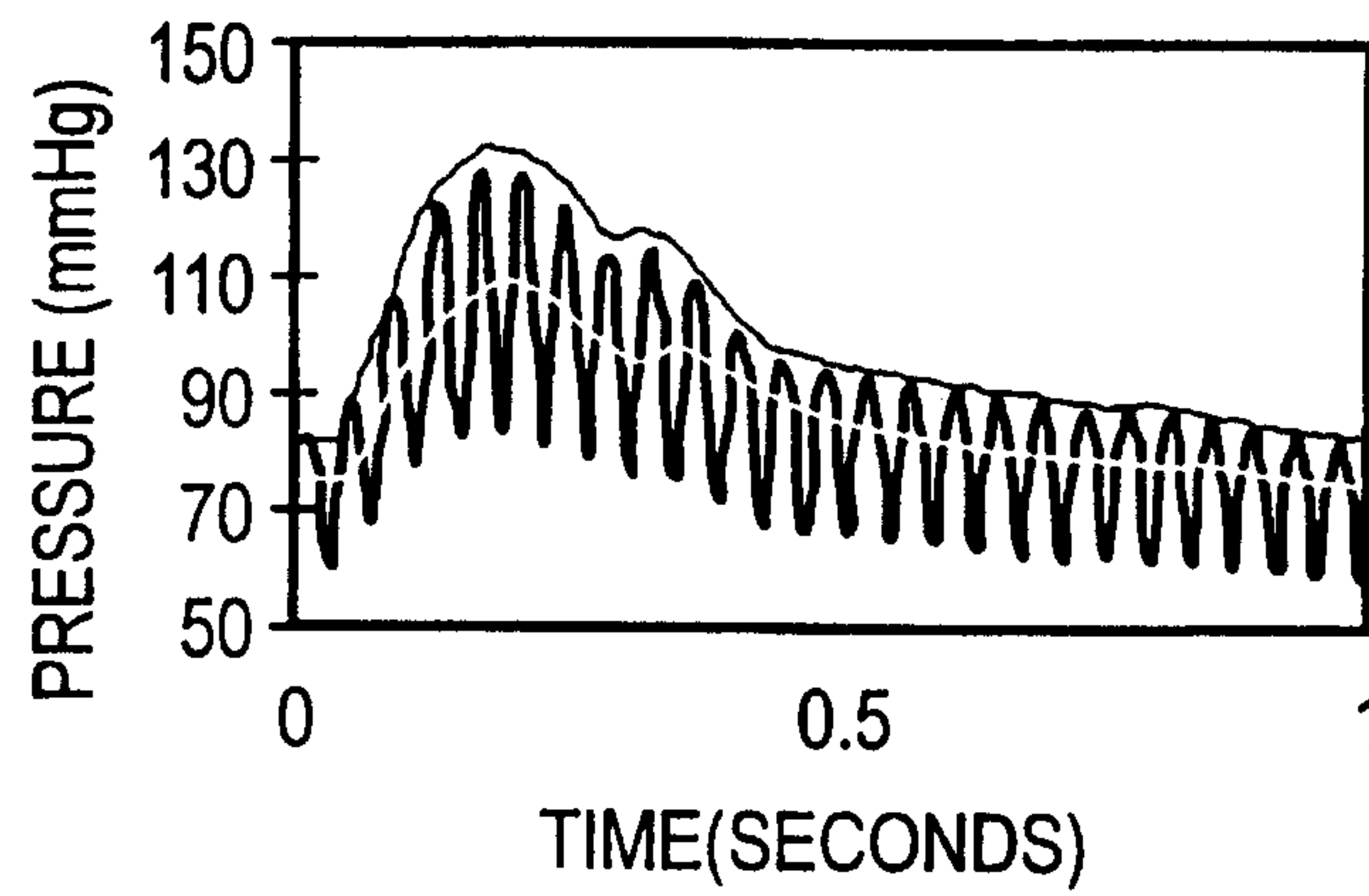


FIG. 7B

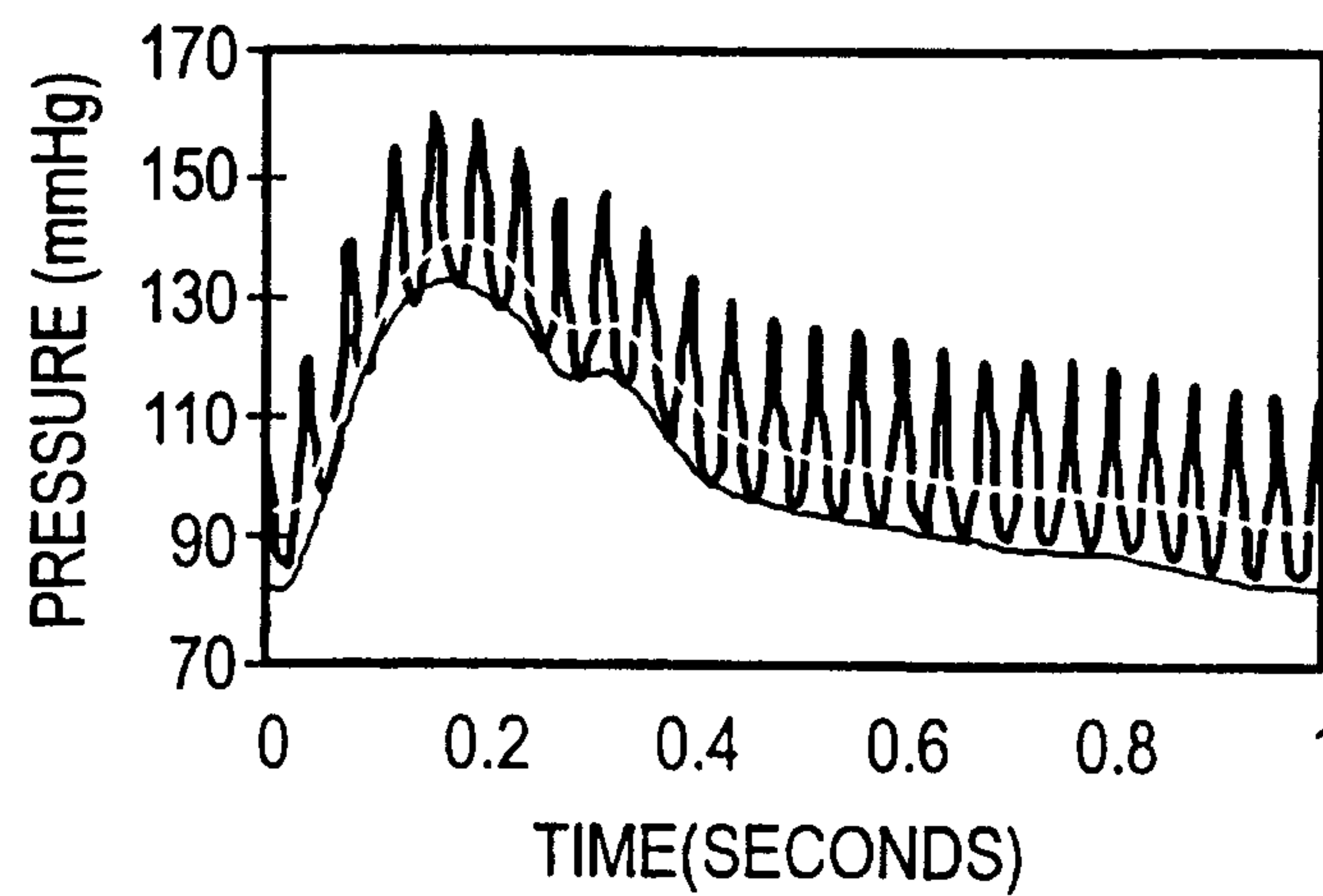


FIG. 7C

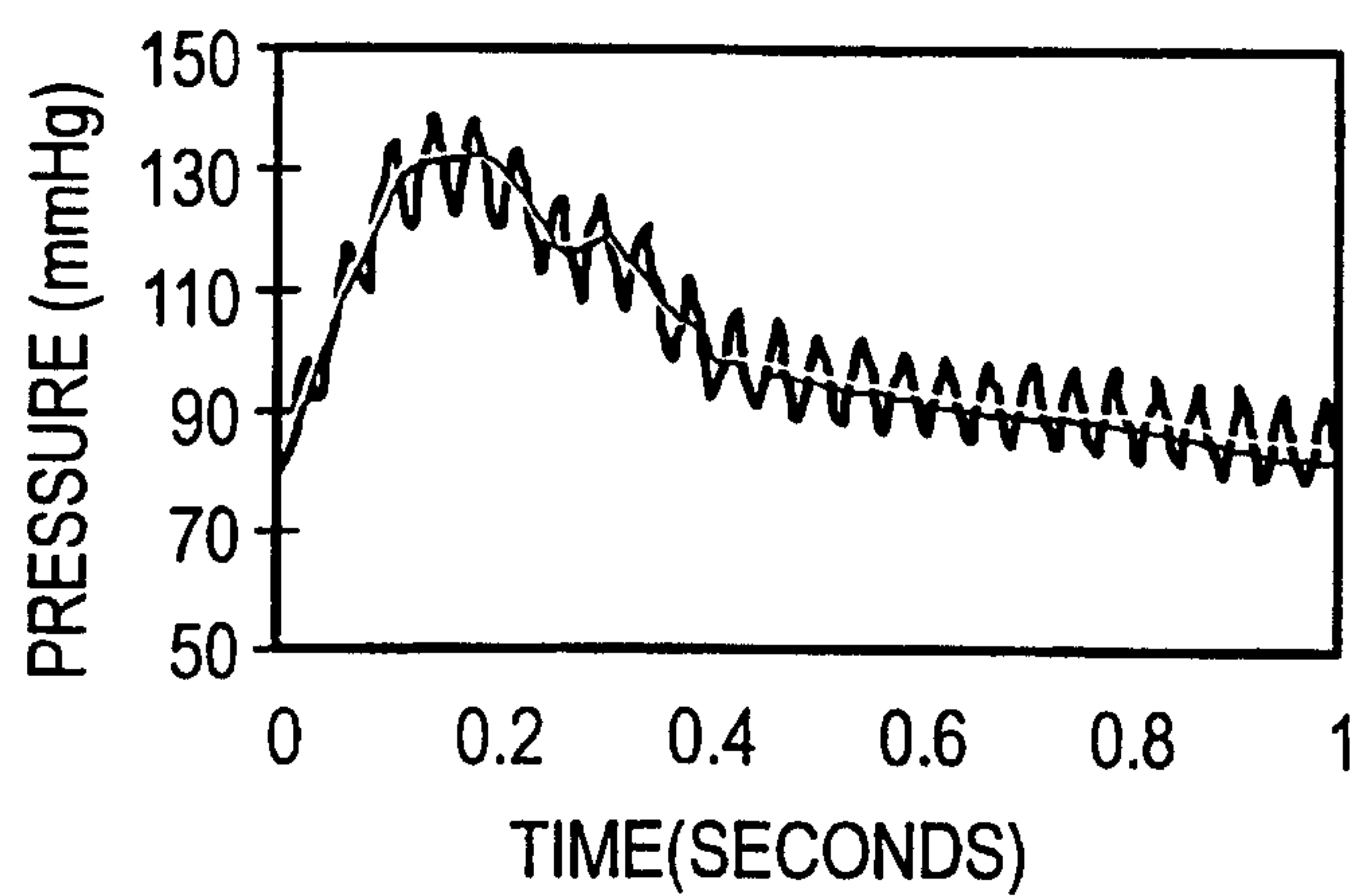
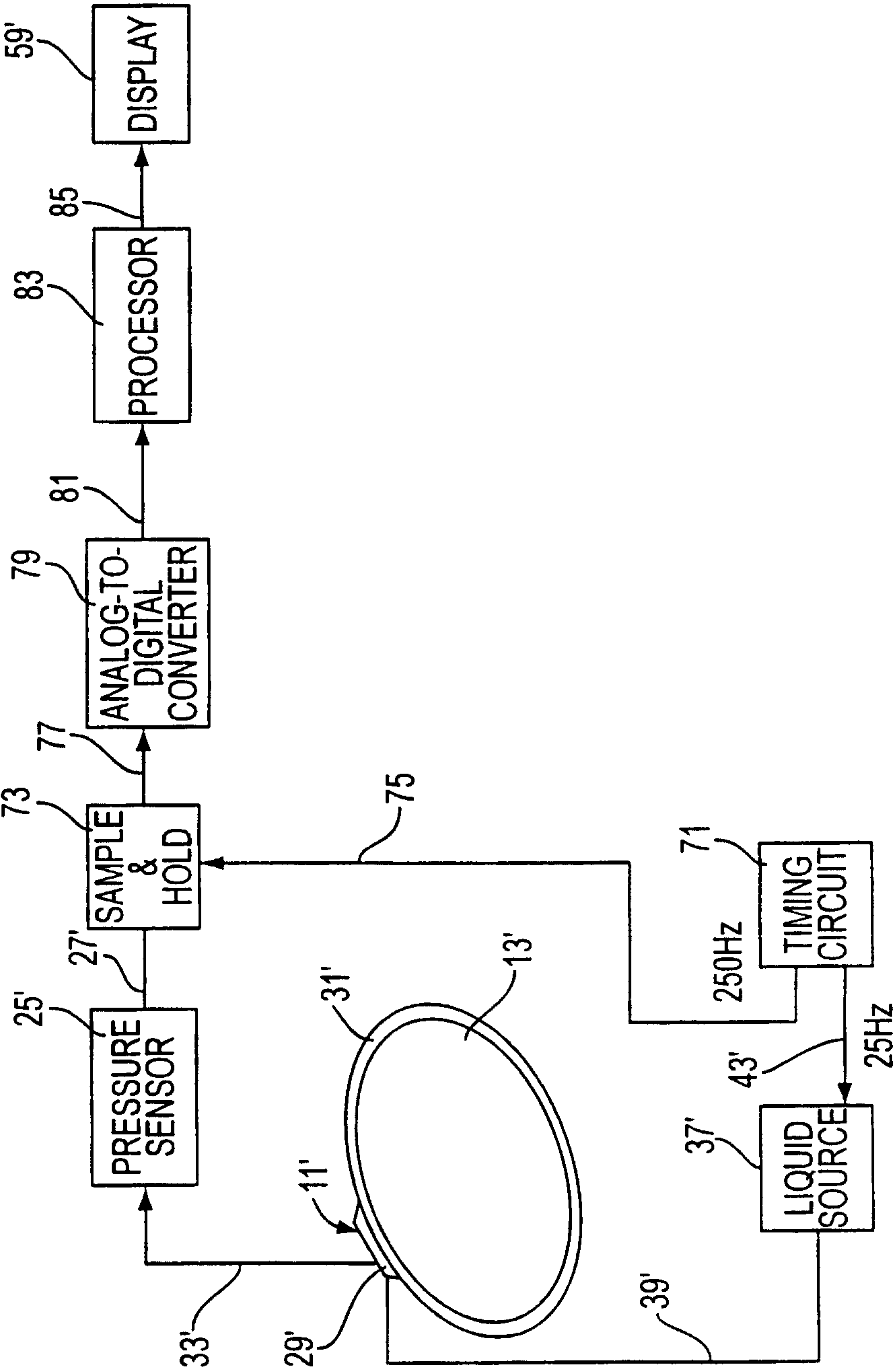


FIG. 9



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FIG. 10A

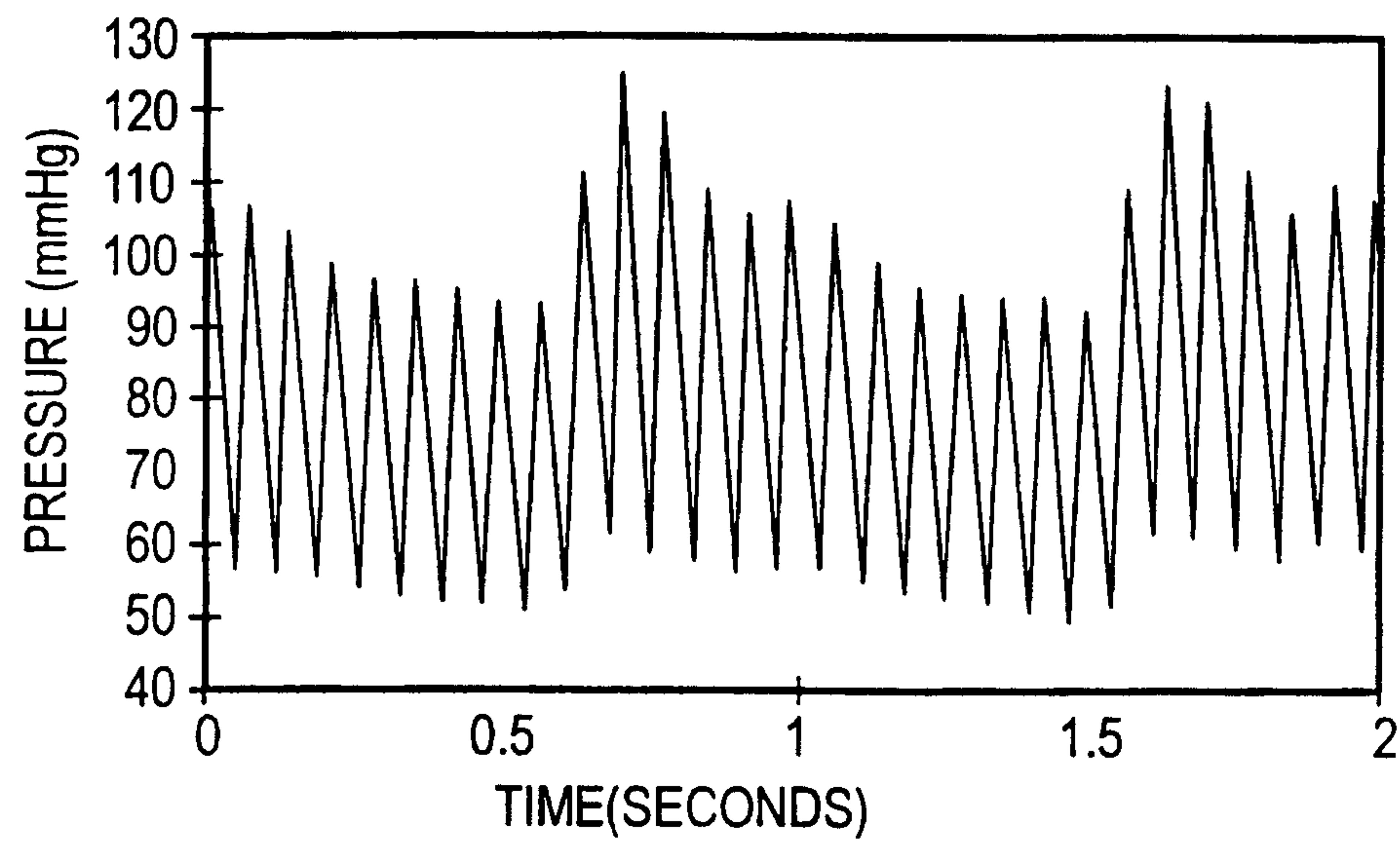


FIG. 10B

