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IN REPLY REFER TO:

Attorney Docket No. 82828

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NON-CONTACT WAVEFORM MONITOR

TO WHOM IT MAY CONCERN:

BE IT KNOWN THAT (1) LYNN T. ANTONELLI, (2) JOHN F. LOMBA, employees of the United States Government, and (3) WILLIAM J. OHLEY, citizens of the United States of America and residents of (1) Cranston, County of Providence, State of Rhode Island, (2) Pawtucket, County of Providence, State of Rhode Island, and of (3) Wakefield, County of Washington, State of Rhode Island, have invented certain new and useful improvements entitled as set forth above of which the following is a specification:

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1 Attorney Docket No. 82828

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NON-CONTACT WAVEFORM MONITOR

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STATEMENT OF GOVERNMENT INTEREST

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The invention described herein may be manufactured and used by or for the Government of the United States of America for governmental purposes without the payment of any royalties thereon or therefore.

CROSS REFERENCE TO OTHER PATENT APPLICATIONS

Not applicable.

BACKGROUND OF THE INVENTION

(1) Field of the Invention

The present invention relates generally to a method and apparatus for measuring and monitoring physiological events in humans and animals, and more particularly to a non-contact method and apparatus for continuously measuring and monitoring physiological events in humans or animals using a laser Doppler vibrometer to create waveforms which are directly related to the physiological events.

(2) Description of the Prior Art

For decades, there has been a long felt but unsolved need to continuously and accurately measure physiological events such

1 as blood pressure without making contact with the patient. For
2 many patients, such as burn victims, neonates, and for patients
3 who need to be monitored without disturbing sleep or rest, the
4 ability to accurately monitor blood pressure waveforms without
5 contact has long been desired, but never accomplished.

6 Invasive monitoring systems, using intra-arterial catheters
7 containing miniature pressure transducers are implemented for
8 continuous monitoring of arterial pressure waveforms, as well as
9 determining blood pressure values throughout the cardiac cycle.
10 However, due to the requirement of inserting these sensors into
11 the arterial system, the patient may be placed in distress.

12 An extremely well known non-invasive, contact method of
13 measuring blood pressure uses a sphygmomanometer cuff wrapped
14 around the subject's arm above the elbow. As the cuff is being
15 inflated, a stethoscope is utilized to hear the sounds that
16 correspond to the systolic and diastolic end-points. These end-
17 points assist in determining the corresponding blood pressure
18 values. This method provides only systolic and diastolic
19 pressure values for a moment in time and does not provide time-
20 continuous pressure measurements.

21 Methods for continuously monitoring blood pressure that do
22 not require insertion of sensors into an artery, i.e., non-
23 invasive methods, have been developed within the last decade.
24 For instance, U.S. Patent No. 5,363,855, which is discussed
25 below, discloses a non-invasive means for continuously monitoring

1 blood pressure. However, contact must be made with the subject
2 and so a non-contact method for measuring blood pressure is not
3 disclosed. Other prior art teachings as listed below, disclose
4 various means for measuring blood flow velocity, blood oxygen
5 saturation, and the like, by non-contact means. However, such
6 techniques are complicated to set up and have not been able to
7 provide sufficient accuracy or definition of the timing of the
8 blood pressure waveform so as to be of any significant benefit in
9 analysis of the cardiac cycle beyond very roughly indicating
10 basic features such as the heart rate. For instance, such
11 techniques have never been utilized to accurately detect the
12 timing of the dicrotic notch within the arterial blood pressure
13 waveform, and may be incapable of doing so.

14 Continuous recording of an accurate blood pressure waveform
15 permits time series data analysis of the cardiac cycle. Analysis
16 of the arterial pressure waveform identifies important events in
17 the cardiac cycle, e.g., the timing of peak systole, the dicrotic
18 notch, the pre-ejection period (PEP), the left ventricular
19 ejection time (LVET), pulse rate, etc. Information about the
20 systolic time intervals is useful in assessing cardiac condition
21 and various disease states, including left ventricular failure,
22 myocardial infarction, coronary artery disease, and valve
23 disorders.

24 The time intervals of the various stages of the cardiac
25 cycle are also observed for changes under cardiac disease

1 conditions and pharmacological influence. For example,
2 continuous monitoring of pre-ejection period and left ventricular
3 ejection time ratios may be utilized to test the effects of
4 drugs, exercise, or other stimuli, whereby an increase or
5 decrease in the ratio may indicate an improvement or worsening of
6 systolic efficiency.

7 The three basic systolic time intervals are the pre-
8 ejection period (PEP), left ventricular ejection time (LVET) and
9 total electromechanical systole (QS2). Linear relationships
10 between heart rate (HR) and the duration of the systolic phases
11 of the left ventricle (LV) have been derived by observation.
12 These following equations have been utilized in the prior art to
13 predict the durations of the systolic time intervals for normal
14 patient observations based on the heart rate alone:

15
$$\text{PEP} = -0.0004 \cdot \text{HR} + 0.126 \quad (1)$$

16
$$\text{LVET} = -0.0016 \cdot \text{HR} + 0.394 \quad (2)$$

17
$$\text{QS2} = -0.020 \cdot \text{HR} + 0.522 \quad (3)$$

18

19 The dicrotic notch as observed on a blood pressure waveform
20 indicates the occurrence of the closure of the aortic valve and
21 marks the end of left ventricular ejection. This event
22 represents the end of the systolic phase and the start of
23 diastole and left ventricular relaxation. The location of the
24 dicrotic notch on a blood pressure waveform can be used for
25 evaluating the above listed linear regression equations that may

1 be utilized to predict the systolic time interval as a function
2 of heart rate. The regression equations are expected to deviate
3 for patients with cardiac dysfunction.

4 The following U.S. Patents describe various prior art
5 systems related to the above discussed problems but do not
6 satisfy the long felt but unsolved need for non-contact blood
7 pressure waveform monitoring.

8 U.S. Patent No. 5,778,878, issued July 14, 1998, to K.
9 Kellam, discloses a laser Doppler technique to determine the
10 velocity of blood cells in skin or other tissue capillaries. A
11 laser beam is focused on to a capillary by means of a lens,
12 mirror and beam splitter system. Measurement of the velocity of
13 the blood cells in a direction substantially perpendicular to the
14 surface of the tissue is effected by detecting directly back-
15 scattered radiation.

16 U.S. Patent No. 5,363,855, issued November 15, 1994, to
17 Drzewiecki et al., discloses a pressure waveform monitor that
18 noninvasively monitors the pressure waveform in an underlying
19 vessel such as an artery. The apparatus comprises at least one
20 continuous, relatively thin and narrow diaphragm mounted in a
21 housing to be placed on the tissue overlying the vessel of
22 interest. The diaphragm is longer than the diameter of the
23 vessel for purposely monitoring pressure in the tissue adjacent
24 to the vessel of interest. The device also comprises deformation
25 sensor means for measuring deformation of the diaphragm both over

1 the vessel and adjacent to the vessel, and signal processing
2 means for combining the waveform of the vessel as monitored by
3 the part of the diaphragm over the vessel with the waveforms of
4 adjacent tissue to accurately determine the actual pressure
5 waveform in the vessel.

6 U.S. Patent No. 5,361,769, issued November 8, 1994, to G.

7 Nilsson discloses a method and a system for reducing the
8 distance-dependent amplification factor when measuring fluid flow
9 movements with the aid of an image-producing laser-Doppler
10 technique, in particular when measuring blood perfusion through
11 tissue. A laser beam source directs a laser beam onto a
12 measurement object, which scatters and reflects the beam. The
13 reflected light is received by a detector that senses the
14 broadening in frequency caused by the Doppler effect. One or more
15 lenses are placed in the path of the beam and are intended to
16 maintain constant the number of coherence areas on the detecting
17 surface of the detector and independent of the distance between
18 detector and measurement object.

19 U.S. Patent No. 5,280,789, issued January 25, 1994, to R.
20 A. Potts, discloses an apparatus for vertically aligning a given
21 point on a pressure transducer unit with a desired point on a
22 patient comprising a light source, a housing adapted to contain
23 the light source, and at least one leveling tube having a
24 leveling axis that is substantially parallel to the light beam.
25 The leveling tube comprises a closed transparent envelope

1 containing a liquid and a bubble of gas, and lines formed on the
2 envelope, where the leveling axis is substantially horizontally
3 aligned when the bubble of gas is located between the two lines.

4 The apparatus includes an indicating mark formed on the housing
5 means where the beam of light is vertically aligned with the
6 given point on the transducer. A locking system selectively
7 locks the housing means to prevent movement thereof relative to
8 the transducer unit when the beam of light is both horizontally
9 aligned and vertically aligned with the given point on the
10 transducer unit. To vertically align the given point with the
11 desired point, one of the transducer units and the patient are
12 vertically displaced relative to the other until the light source
13 causes light to reflect off of the patient at the desired point.

14 U.S. Patent No. 4,166,695, issued September 4, 1979, to
15 Hill et al., discloses a means for measuring blood flow in
16 retinal blood vessels by directing laser radiation along an
17 optical path into the eye and onto a blood vessel. Laser
18 radiation reflected off moving blood corpuscles is directed back
19 along the optical path and into a detector. This reflected laser
20 radiation is mixed with a proportion of the original laser signal
21 to determine the Doppler shift produced by the moving blood
22 corpuscles and hence blood velocity.

23 U.S. Patent No. 5,995,856, issued November 30, 1999, to
24 Mannheim et al., discloses monitoring of physiological
25 parameters of a patient through the use of optical systems that

1 do not require direct physical contact with the patient. The
2 method and apparatus relate primarily to pulse oximetry for
3 monitoring pulse rate and arterial blood oxygen saturation.
4 However, the apparatus and method of this invention are
5 applicable to any form of optical detection of the physiological
6 parameters in which light of any wavelength, visible or
7 invisible, is directed from a remote instrument into a patient at
8 a first imaging site, and subsequently collected at a second site
9 spaced from the first site.

10 U.S. Patent No. 6,007,494, issued December 28, 1999, to
11 Zenner et al., discloses a device for determining data on
12 auditory capacity wherein the device preferably has non-contact
13 means for measuring vibrations of the middle-ear ossicles and/or
14 the tympanic membrane by means of electromagnetic waves. The
15 electromagnetic waves used for the measurement are input by means
16 of a microscope, in particular an optical microscope. This
17 microscope can be modular in design, and a module can be provided
18 for the input of a laser beam. The invention also concerns a
19 method of determining data on auditory capacity wherein the
20 method calls for the vibration of the middle ear and/or the
21 eardrum to be measured by means of electromagnetic waves and,
22 from the measurement signals thus obtained, the contributions to
23 the total signal by the middle ear and/or the eardrum determined
24 in at least one processing step.

1 The Journal of Biomedical Engineering, 4(2): 142-8, 1982,
2 by Brown et al. teaches that a rather complex light emitting
3 diode sensor (LED) has sufficient resolution to detect an
4 arterial pulse.

5 The above-discussed systems do not disclose a convenient
6 and completely non-contact means for accurately and continuously
7 monitoring blood pressure or creating blood pressure waveforms.
8 Consequently, those skilled in the art will appreciate the
9 present invention that addresses the above and other problems.

10

11

SUMMARY OF THE INVENTION

12 It is a general purpose and object of the present invention
13 to provide an improved non-contact blood pressure waveform
14 monitoring apparatus and method.

15 Another object is to provide a laser-based system that may
16 be utilized to continuously provide highly detailed information
17 about the timing characteristics of the blood pressure waveform.

18 Another object is to provide a system that does not require
19 elaborate adjustments of one or more lasers and laser detectors
20 so that the system may be quickly utilized.

21 These and other objects, features, and advantages of the
22 present invention will become apparent from the drawings, the
23 descriptions given herein, and the appended claims. However, it
24 will be understood that the above listed objects and/or
25 advantages of the invention are intended only as an aid in

1 understanding aspects of the invention, are not intended to limit
2 the invention in any way, and do not form a comprehensive list of
3 objects, features, and advantages.

4 Accordingly, a non-contact method and apparatus for
5 continuously measuring a blood pressure waveform is provided
6 which may comprise, for example, utilizing a laser based
7 measurement system mounted in a spaced relationship with respect
8 to a subject and directing a laser beam toward a section of the
9 subject's skin surface orienting the laser beam such that it is
10 substantially perpendicular to the skin surface at a location
11 wherein the skin surface is moveable in response to a blood
12 pressure pulse, and/or detecting one or more variables related to
13 movement of the skin surface, and/or producing a blood pressure
14 waveform representation by plotting the one or more variables
15 related to movement of the skin surface.

16 The non-contact method and apparatus may further comprise
17 use of detectors capable of detecting the one or more variables
18 related to movement of the skin surface in a direction
19 substantially parallel to the laser beam and/or producing the
20 blood pressure waveform representation by plotting skin surface
21 velocity with respect to time through the use of a signal
22 processor.

23 In one embodiment, the non-contact method and apparatus may
24 comprise utilizing interferometers and interferometer techniques
25 for detecting the one or more variables related to movement of

1 the skin surface. One advantage of the invention is that the
2 apparatus may comprise a single housing to support the means for
3 measuring the blood pressure waveform, i.e., the means to effect
4 steps such as directing of the laser beam to the skin surface and
5 the detecting of the reflected laser beam.

6 The non-contact method may further comprise analyzing the
7 blood pressure waveform representation to determine systolic time
8 interval parameters and/or analyzing the blood pressure waveform
9 parameters to determine heart rate and/or comparing systolic time
10 interval parameters estimated utilizing the heart rate with
11 systolic time interval parameters determined from the blood
12 pressure waveform.

13 If desired, the non-contact method may also be utilized to
14 measure other physiological events such as respiration to the
15 extent that a skin surface is moveable in response to such a
16 physiological event.

17

18 BRIEF DESCRIPTION OF THE DRAWINGS

19 A more complete understanding of the invention and many of
20 the attendant advantages thereto will be readily appreciated as
21 the same becomes better understood by reference to the following
22 detailed description when considered in conjunction with the
23 accompanying drawings, wherein like reference numerals refer to
24 like parts and wherein:

1 FIG. 1 is a schematic overview of the operation and setup of
2 a non-contact blood pressure waveform monitoring system in accord
3 with one embodiment of the present invention;

4 FIG. 2 is a graph of a blood pressure waveform obtained by
5 measuring skin velocity in accord with the present invention for
6 a single cardiac cycle; and

7 FIG. 3 is a graph of a blood pressure waveform obtained by
8 continuously measuring skin velocity for several cardiac cycles
9 in accord with the present invention.

10

11 DESCRIPTION OF THE PREFERRED EMBODIMENT

12 The present invention provides a non-contact method and
13 apparatus for continuously monitoring physiological events such
14 as the anatomical blood pressure waveform with sufficient
15 accuracy and precision to determine important timing related
16 parameters such as, for example, the left ventricular ejection
17 time (LVET) and pre-ejection period (PEP). For cardiac cyclic
18 timing diagnostic purposes, the timing of the blood pressure
19 waveforms should be measured with sufficient accuracy so that the
20 components of the waveform, e.g., the dicrotic notch, are
21 available for accurate analysis. However, it has been observed
22 by the inventors that cardiac cyclic analysis of the blood
23 pressure waveform does not require absolute values of blood
24 pressure. Thus, while the present technique does not necessarily
25 directly measure or provide absolute values of blood pressure,

1 cyclic analysis of the blood pressure waveform can be readily
2 performed utilizing the data produced by the present invention.
3 Calibration techniques may be utilized as discussed hereinafter
4 to provide absolute values in certain circumstances, if desired.

5 Referring now to the drawings and, more particularly, to
6 FIG. 1, there is shown a non-contact blood pressure waveform
7 monitoring system 10 in accord with a preferred embodiment of the
8 present invention. System 10 utilizes laser Doppler vibrometer
9 12 to detect the movement of skin on a patient, in this case the
10 skin surface 26 above the carotid artery.

11 Laser Doppler vibrometer 12 comprises laser source 14
12 capable of emitting a laser beam 32 that travels the distance 22
13 from laser source 14 to skin surface 26. The laser beam is
14 preferably directed perpendicularly or substantially
15 perpendicularly to skin surface 26. Blood flowing through the
16 carotid artery directly below the skin causes skin surface 26 to
17 pulsate in a rhythm corresponding to ventricular contractions of
18 the patient's heart. Skin surface 26 moves an amount Δx , as
19 indicated by numeral 24, from its initial position to a position
20 represented by plane 28. Δx represents the distance of movement
21 of the plane of skin surface 26 in a direction substantially
22 parallel to the laser beam produced by laser source 14. Laser
23 light is reflected by skin surface 26. The reflected laser beam
24 34 is focused by lens 16 and recovered by detector 18. The
25 reflected laser light beam 34 is modulated by the movement of

1 skin surface 26 by means of a Doppler shift in the optical
2 wavelength, as compared to the original laser beam 32 produced by
3 laser 14. Detector 18 determines the velocity of the pulsatile
4 skin motion as derived from the Doppler shift.

5 Detector 18 preferably comprises an interferometer for
6 comparison of the initially produced laser beam (or a reference
7 beam derived there from) with the reflected laser beam. In a
8 preferred embodiment, laser Doppler vibrometer 12 operates by
9 splitting the laser beam 32 with a beam splitter 36 into a
10 reference beam 32a and a sensing beam 32b. The reference beam
11 32a is frequency shifted by a modulator (not shown) in detector
12 18 so that the components of detector 18 can discriminate between
13 the reflected laser beam 34 with the Doppler modulation and the
14 reference beam 32a. Detector 18 measures the Doppler frequency
15 of the reflected beam 34 as modulated by the movement of skin
16 surface 26. The maximum and therefore optimum reflected signal
17 occurs when laser Doppler vibrometer 12 is oriented such that the
18 laser beam 32 produced by laser source 14 is substantially
19 perpendicular to skin surface 26.

20 Detector 18 generates a continuous stream of analog output
21 voltages corresponding to the pulsation velocity of skin surface
22 26. The analog voltage signals may be fed to computer 30 where
23 the analog voltage signals are digitized, recorded, and analyzed
24 as desired. Alternatively, the analog voltage may be fed to a

1 device, such as an oscilloscope for immediate display of the
2 blood pressure waveform.

3 Utilizing the pulsation velocity of skin surface 26 over
4 time, computer 30 can plot a highly accurate representative blood
5 pressure waveform 40 as indicated in FIG. 2. Such a waveform is
6 highly suitable for cardiac cyclic analysis. For instance,
7 dicrotic notch 42, which indicates the closing of the aortic
8 valve, is plainly visible as is the peak systole 44. Heart rate
9 is easily determined by timing the distance between the easily
10 distinguishable peaks of successive pulse waveforms as indicated
11 in FIG. 3, which shows multiple peak systole 44 over a period of
12 time. Once heart rate is determined, the PEP, LVET and QS2 can
13 be derived from formulae (1), (2) and (3) as indicated above.
14 Thus, while the present invention does not directly measure
15 arterial pressure, nonetheless it has been found by the inventors
16 that the blood pressure waveform so obtained is quite suitable
17 for timing analysis of the cardiac cycle to thereby evaluate
18 cardiac function with timing events such as the systolic peak 44
19 and dicrotic notch 42.

20 It will be noted that all of the components of the laser
21 Doppler vibrometer 12, including the laser source 14, the lens
22 16, and the detector 18, are preferably built into a single
23 housing and are therefore more easily and quickly set up than
24 prior art laser sensor instruments discussed herein. Moreover,
25 suitable laser Doppler vibrometers are commercially available so

1 that after review of the specification herein, one of skill in
2 the art will be able to practice the invention.

3 The arterial pressure waveform 40 obtained by laser Doppler
4 vibrometer 12 may be analyzed to obtain various waveform
5 characteristics. The timing of these waveforms may be combined
6 with an electrocardiogram signal to estimate systolic time
7 interval parameters. Alternatively, the systolic time interval
8 may be estimated using heart rate information from the recorded
9 waveform and applied to regression equations (1), (2), and (3).

10 While absolute blood pressures are not available directly
11 from the present invention, such readings may be obtained by
12 calibration techniques as described below. For example, a
13 patient to be monitored during sleep may have the maximum/minimum
14 blood pressures directly measured by existing contact means while
15 awake to thereby calibrate the blood pressure waveform that is
16 produced in accord with the present invention. Statistical
17 techniques relating to expansion distances directly measured may
18 be determined to estimate blood pressures in normal patients such
19 as based on the amplitude of the movement parameters. Thus, the
20 present invention might also be utilized to predict abnormalities
21 due to deviations from anticipated values of absolute blood
22 pressures determined statistically.

23 While similar but technically different in some ways, the
24 terms laser Doppler vibrometer, laser Doppler velocimeter, and
25 laser interferometer are used somewhat interchangeably herein and

1 may each be utilized in accord with the present invention. For
2 instance, the laser Doppler velocimeter is also sometimes
3 utilized to measure the velocity of objects in the direction
4 perpendicular to the laser beam and may therefore be utilized by
5 itself or in conjunction with a laser Doppler vibrometer to
6 measure the expansion of the artery by means of monitoring the
7 subsequent effect on the skin surface.

8 The present invention may also be utilized to provide
9 waveforms related to movement of any portion of the body that
10 moves and to record any physiological parameters using a laser
11 Doppler vibrometer containing a laser interferometer inherent to
12 its design.

13 In summary, the present invention utilizes a laser beam 32
14 produced by laser 14 to measure the movement of a particular skin
15 surface area, such as skin surface 26 adjacent to any artery,
16 such as the carotid artery. The invention detects the movement
17 and plots the velocity of skin movement versus time to create a
18 waveform of the physiological event corresponding to the skin
19 movement such as the arterial blood pressure.

20 Many additional changes in the details, materials, steps and
21 arrangement of parts, herein described and illustrated to explain
22 the nature of the invention, may be made by those skilled in the
23 art within the principle and scope of the invention. For
24 example, it may be desirable to utilize a fiber optic means for
25 directing and/or detecting the laser beams of interest. Due to

1 the motion of a patient's skin surface, which is not directly
2 related to the measurement of the biological signal of interest,
3 e.g., blood pressure waveform, an adaptive focus may be utilized
4 to maintain the interrogating laser beam on the desired
5 measurement area, such as the carotid artery.

6 It is therefore understood that within the scope of the
7 appended claims, the invention may be practiced otherwise than as
8 specifically described.

1 Attorney Docket No. 82828

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NON-CONTACT WAVEFORM MONITOR

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ABSTRACT OF THE DISCLOSURE

6 A non-contact method and apparatus for continuously
7 monitoring a physiological event in a human or animal, such as
8 blood pressure, which involves utilizing a laser-based
9 interferometer system to produce a waveform that is
10 representative of continuous blood pressure in a subject. The
11 invention may preferably utilize a laser Doppler vibrometer which
12 is oriented to produce a laser beam directed toward the subject
13 substantially perpendicular to a skin surface of the subject
14 wherein the skin surface is moveable in response to blood
15 pressure. The vibrometer is sensitive to motion of the skin
16 surface in a direction parallel to the laser beam and produces a
17 signal representative of this motion. By plotting the velocity
18 of the skin surface movement in the direction parallel to the
19 laser beam with respect to time, a waveform is produced that has
20 been found to be representative of the blood pressure waveform
21 and highly defined to thereby permit accurate timing analysis
22 thereof relating to cardiac cycles.

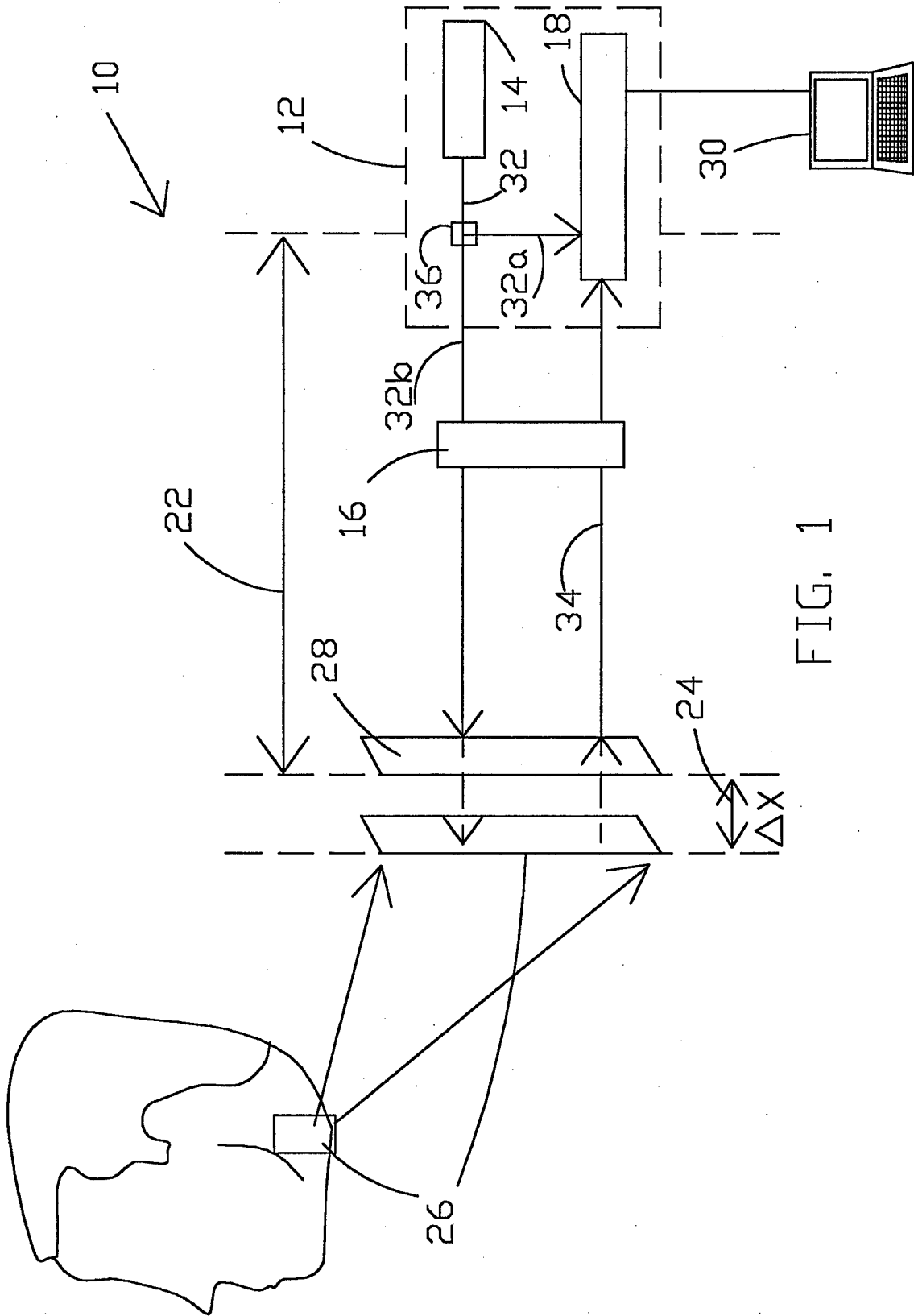
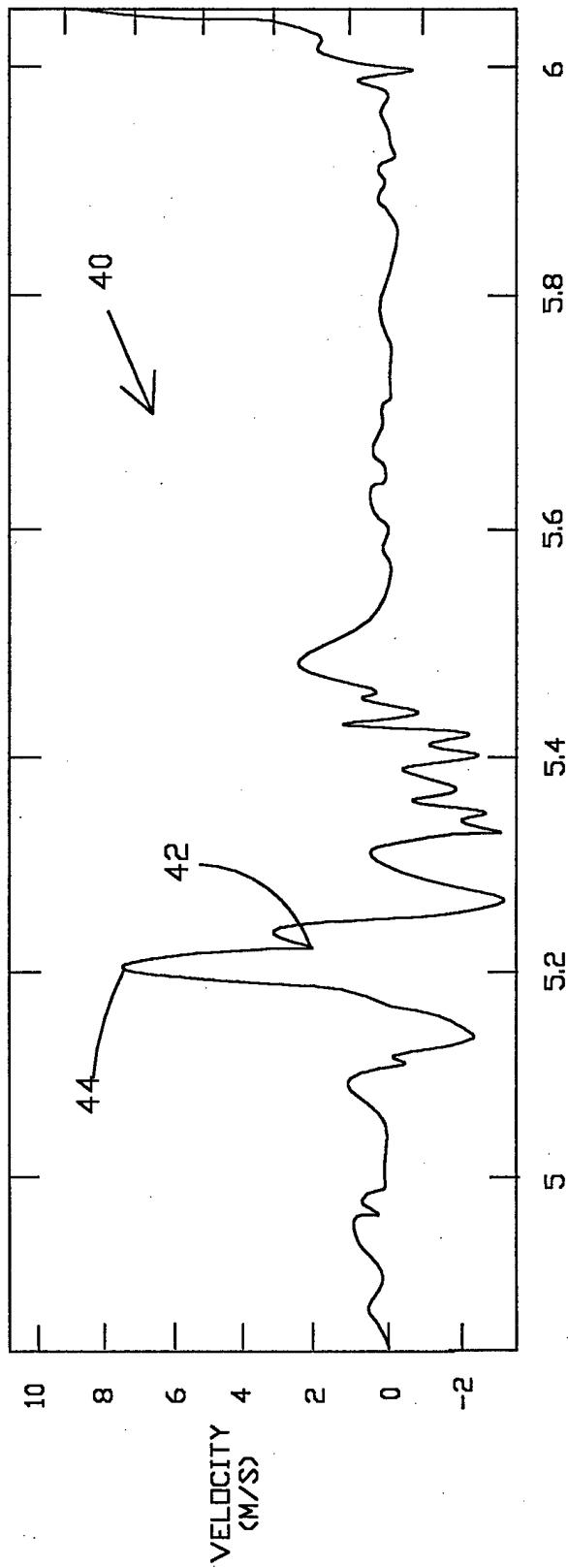


FIG. 1



TIME (S)

FIG. 2

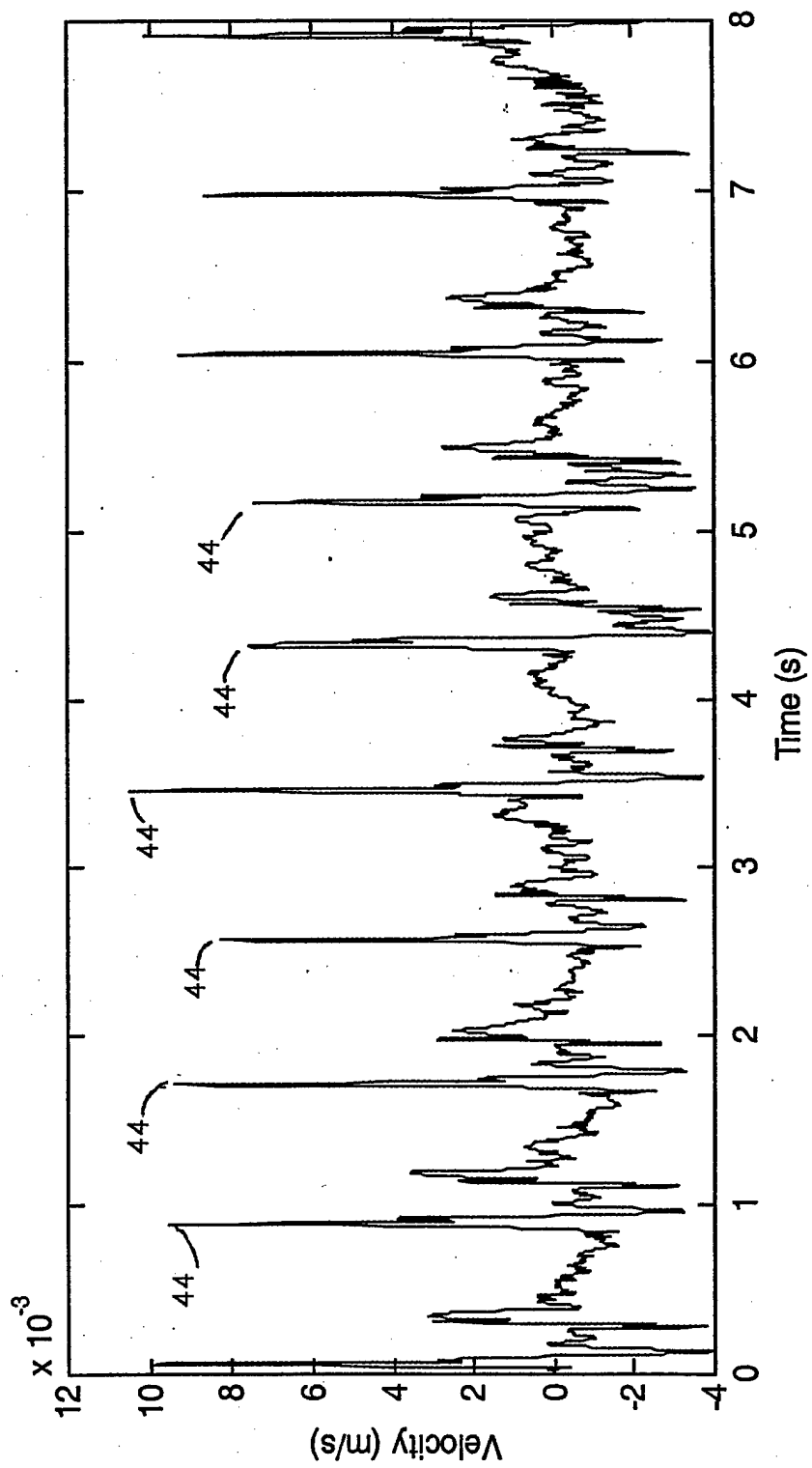


FIG. 3