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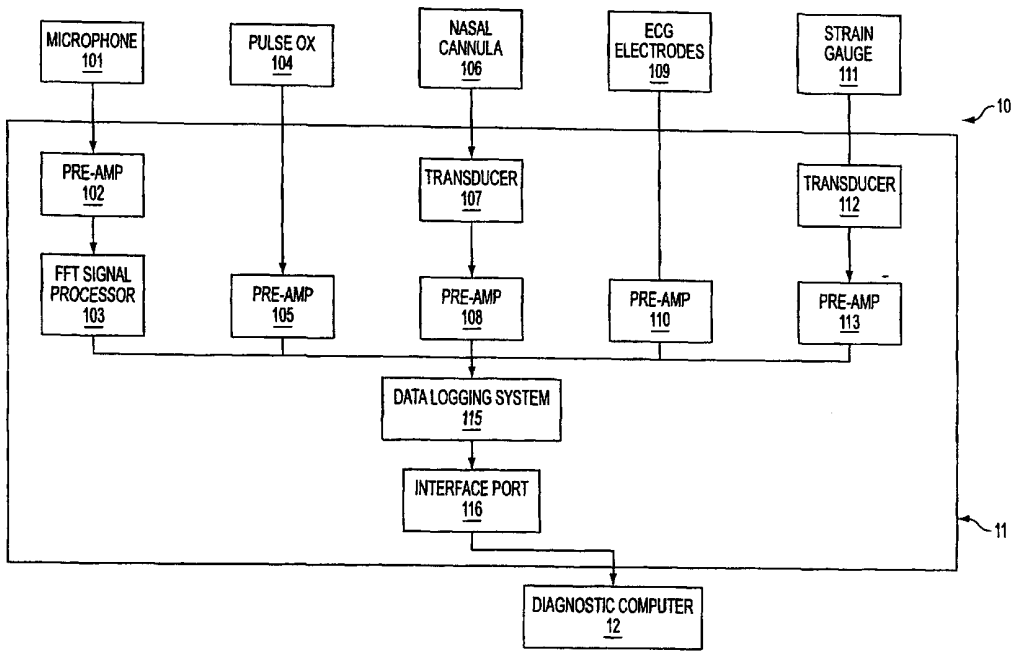
(54) Title: SYSTEM AND METHOD FOR THE DIAGNOSIS OF RESPIRATORY DISORDERS



(57) Abstract: A method and system (10) for monitoring and diagnosing respiratory disorders, such as Sleep Disorders Breathing and Obstructive Lung Diseases. A method and system (10) according to the invention involves detecting and analyzing a patient's respiratory-related sounds to thereby diagnose the occurrence of respiratory disorder events. The sounds are obtained through use of a microphone (101). More particularly, it has been discovered that relatively high frequency respiratory sounds above 1250 Hz, more particularly above about 3kHz, are associated increased airway resistance and indicative of respiratory disorder events.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SYSTEM AND METHOD FOR THE DIAGNOSIS OF RESPIRATORY DISORDERS

TECHNICAL FIELD

The invention relates to a method and apparatus for monitoring and diagnosing respiratory disorders, and more particularly to a method and apparatus for monitoring and diagnosing respiratory disorders by detecting and/or analyzing a patient's high frequency respiratory related sounds.

BACKGROUND ART

Sleep Disordered Breathing ("SDB") is a term which includes all forms of breathing disturbances during sleep including the Pickwickian Syndrome, also called the Obesity Hypoventilation Syndrome, Obstructive Sleep Apnea ("OSA"), Obstructive Sleep Hypopnea, Obstructive Sleep Apnea and Hypopnea, and the Upper Airway Resistance Syndrome. SDB can occur in adults and children. Sleep-related respiratory disorders, such as SDB, are a significant cause of excessive daytime sleepiness, chronic fatigue, automobile accidents, hypertension, pulmonary hypertension, and even death. In SDB, a disease that has been estimated to occur in approximately 4% of adults, the upper airway narrows or closes during sleep thereby increasing upper airway resistance and making it more difficult or impossible to breath. Episodes of SDB are frequently but not always terminated by arousal. Some of the physiological responses to SDB can include nocturnal awakening resulting in daytime sleepiness and fatigue, impaired neurocognitive function including difficulty concentrating, as well as activation of the sympathetic nervous system and increased risk of heart failure.

SDB is frequently diagnosed by laboratory based polysomnography ("PSG"). PSG involves the measurement of sleep and respiratory variables including electroencephalogy ("EEG"), electromyography ("EMG"), electoocculogram ("EOG"), electrocardiogram ("ECG"), nasal and oral airflow, oxyhemoglobin saturation, and respiratory effort with one or more types of monitors including those that detect chest and abdominal movements,

intercostal EMGs and esophageal pressure. The data gathered leads to a calculation of the number of apneas per hour of sleep, the number of hypopneas per hour of sleep, the number of upper airway resistance events (elevated upper airway resistance leads to arousal) per hour of sleep, the number of arousals per hour of sleep, the number of arousals per hour of sleep related to apneas, hypopneas, and/or upper airway resistance events, as well as parameters describing sleep such as total sleep time, sleep efficiency, etc. The Respiratory Disturbance Index ("RDI"), a term used by some to describe the average number of apneas and optionally hyponeas per hour, can also be determined. PSG has the inconvenience of requiring the patient to sleep in a clinic for a whole night. It is also a labor intensive and expensive procedure, requiring continuous technician attendance.

Definitive diagnosis of the Upper Airway Resistance Syndrome currently requires measurement of esophageal pressure to document increasing respiratory effort that occurs when the airway narrows, but increased effort maintains airflow at a near normal or only modestly reduced level. Measurement of esophageal pressure requires a patient to swallow a tube and sleep with it in place. This is uncomfortable and many patients are unwilling to swallow the tube making it difficult to diagnose this condition. Thus, there is a need for an easier, accurate method of detecting the Upper Airway Resistance Syndrome.

As an alternative to the above, U.S. Pat. No. 4,982,738 to Griebel discloses a diagnostic apnea monitor system that monitors and records snoring and respiration sounds made by a patient, as well as the patient's heart rate while the patient is sleeping. Signals indicative of snoring sounds and the time intervals therebetween are produced from the recorded respiration. The system generates a first respiration disturbance index representing the number of intervals per hour between episodes of snoring. An average heart rate is also generated in response to the patient's recorded second respiration disturbance index representing the number of episodes per hour in which the patient's heart

rate remained at 90% to 109% of its average rate is calculated. A physician can then evaluate the first and second disturbance indices to determine whether Obstructive Sleep Apnea is indicated.

Further, U.S. Pat. No. 5,797,852 to Karakasoglu *et al.* discloses a sleep apnea detecting apparatus and method. It is comprised of a first microphone positioned in the vicinity of a patient's nose and mouth to pick up audible sounds created by breathing of the patient. A second microphone is provided which is positioned near the patient for picking up ambient noise in the vicinity of the patient to provide a baseline. The signals from the two microphones are then processed to provide a waveform that is closely correlated to the airflow of the patient. The waveform is then evaluated to determine the presence and magnitude of patient airflow. If patient airflow is determined to be decreased or absent, as reflected by the evaluated waveform, an apnea event is indicated.

It has also been recognized that cardio and respiratory functions, such as nasal air flow, chest wall effort, oxygen saturation, heart rate and heart activity, can provide markers of sleep-related respiratory disorders. For instance, see U.S. Pat. No. 5,769,084 to Katz *et al.* and U.S. Pat. No. 6,091,973 to Colla *et al.*

However, there is still a need for a relatively easily implemented procedure that provides an efficient method and system for monitoring and diagnosing sleep-related respiratory disorders.

SUMMARY OF THE INVENTION

The invention relates to a method and system for monitoring and diagnosing respiratory disorders, such as Sleep Disordered Breathing. A method and system according to the invention involves detecting a patient's respiratory-related sounds and analyzing a patient's respiratory related sounds for the presence of high frequency respiratory-related sounds to thereby diagnose the occurrence of a respiratory disorder event. More particularly, it has been discovered that relatively high frequency respiratory sounds above 1250 Hz, and more particularly above about 3 kHz, are associated with disordered breathing, such as when upper airway resistance is high and the

upper airway is narrowed.

Generally, a method according to the invention includes the steps of detecting a patient's respiratory-related sounds and analyzing the patient's respiratory-related sounds for the presence of high frequency respiratory-related sounds to non-invasively monitor and diagnose disordered breathing such as increases in upper airway resistance and sleep-related respiratory disorders. The method may further include the steps of measuring and analyzing other cardio-respiratory parameters such as heart rate, heart activity, airflow, oxygen saturation, and chest wall effort. The analyzed cardio-respiratory parameters can then be used in the diagnosis of upper airway resistance and sleep-related respiratory disorders.

A system according to the invention may include at least one respiratory-related sound detection module and a respiratory disorder diagnosis module. The respiratory sounds can be detected using microphones or other devices which can detect high frequency sounds, either attached or unattached to the patient. A system of the invention can be embodied in a hand-held, home-use instrument as well as in a instrument designed more particularly for use in a sleep laboratory or medical care facility, or in any proprietary or nonproprietary system for spectral analysis. The system may further include at least one cardio-respiratory parameter measurement and analysis module.

In yet another aspect of the invention, a method or system of the invention can be used to predict the location, the geometry, and the approximate and/or relative size of the airway, anatomical location, or anatomical structure generating the detected respiratory sounds.

Further, a method and system according to the invention can be used to monitor and diagnose other breathing disorders including obstructive lung diseases such as asthma, COPD, and emphysema.

These and other features and advantages of the present invention will become apparent from the following disclosure of the invention with reference to the description and Figures herein.

DISCLOSURE OF THE INVENTION

It has been discovered that the frequency distribution and/or characteristics of the respiratory-related sounds of a sleeping patient provide diagnostic information on the degree of narrowing of the nose, nasopharynx, and pharynx. Narrowing of the nose, nasopharynx, and pharynx occurs in Obstructive Sleep Apnea, Upper Airway Resistance Syndrome, and other sleep-related respiratory disorders. Alternatively, the present invention can be used to monitor and diagnose any breathing disorder which involves the narrowing of any aspect of the respiratory pathway. For instance, a method and system of the invention can be used to monitor and diagnose obstructive lung disorders such as asthma, COPD, and emphysema.

More particularly, it has been discovered that relatively high frequency sounds are made when a patient inhales through a narrowed airway, as occurs when a patient's upper airway or lungs are narrowed or constricted. Just as a horn sounds a higher note when the player forces air through a small orifice, a patient makes a high pitched sound when they try and inhale through a narrow upper airway. By analyzing the respiratory sounds, narrowing of a patient's airway can be detected and monitored.

Without intending to be limited by theory, it is believed that the increased pressure gradient across a narrowed airway is associated with increased velocity of airflow. This high airflow velocity in turn induces high frequency sounds. On the other hand, normal snoring through a larger airway results predominantly in lower frequency sounds. For instance, it was found that low resistance normal snoring was associated with respiratory sounds predominantly below about 1250 Hz. Increasing resistance was associated with increasing amplitude of respiratory sounds above 1250 Hz, and preferably above about 3 kHz.

Since patients with sleep-related respiratory disorders have a spectrum of abnormal respiration including total apnea and breaths with increased airway resistance, these patients produce high frequency sounds during some of their

abnormal breaths. Further, patients with other conditions may also exhibit increased upper airway resistance and high frequency sounds as an index of ventilatory distress.

In accordance with the invention, the spectral characteristics of the sounds made by patients may be detected to provide diagnostic information relating to the degree of upper airway resistance present. Since increased upper airway resistance occurs in SDB, such sleep-related respiratory disorders may be diagnosed by detecting and analyzing the respiratory-related sounds made by patients during sleep for the presence of high frequency respiratory-related sounds.

In yet another aspect of the invention, a method and system according to the can be used to predict the location, geometry, and approximate and/or relative size of the airway, anatomical location, or anatomical structure generating the detected respiratory-related sounds. For instance, the frequency distribution and/or characteristics of the detected respiratory-related sounds can indicate the extent of apnea and/or narrowing of the upper airway and can be correlated with the dimensions of the narrowest point within the upper airway. The frequency range of the high frequency sounds may be used to determine the location of any obstruction within the patient's airway to thereby aid in potential therapy.

In one embodiment, the invention relates to a method for monitoring and diagnosing sleep-related respiratory disorders. Generally, a method according to the invention includes the steps of detecting a patient's respiratory-related sounds during sleep; and analyzing the patient's respiratory-related sounds for the presence of high frequency respiratory-related sounds to thereby diagnosing the occurrence of sleep-related respiratory disorder events. As described in more detail below, the presence of relatively high frequency sounds, *i.e.*, those above 1250 Hz and preferably above about 3 kHz, in the frequency distribution and/or characteristics of a patient's respiratory-related sounds is indicative of respiratory disorders, and thus can serve as a diagnostic indicator of the

occurrence of respiratory disorders.

In another embodiment, a method according to the invention can further include the steps of measuring and analyzing at least one additional cardio-respiratory parameter. The analyzed cardio-respiratory parameter can then be used in the diagnosis of the occurrence of a respiratory disorder event in the patient. For example, the analyzed cardio-respiratory parameter can be used to detect the particular phase of breathing in which the high frequency sound occurs, to thereby verify the occurrence of respiratory disorder events during periods when high frequency respiratory sounds are detected. The cardio-respiratory parameter measured can be any physiological parameter that is reflective of sleep-related respiratory disorders known in the art. For instance, such cardio-respiratory parameters can include, but are not limited to, heart rate, heart activity, timing of heart rate and heart activity, airflow, oxygen saturation, chest wall effort, and abdominal movement.

Another aspect of the invention relates to a system for monitoring and diagnosing sleep-related respiratory disorders by detecting a patient's respiratory-related sounds; and analyzing the patient's respiratory-related sounds for the presence of high frequencies. Generally, a system of the invention includes at least one respiratory sound detection module for detecting the respiratory-related sounds of a patient during sleep; and a diagnostic module for analyzing the detected respiratory-related sounds for the presence of high frequency respiratory-related sounds to thereby diagnose the occurrence of sleep-related respiratory disorder events in the patient.

A system of the invention may also include at least one module to monitor and analyze at least one additional cardio-respiratory parameter reflective of the occurrence of sleep-related breathing disorder events, such as, but not limited to heart rate, heart activity, oxygen saturation, chest wall resistance, and/or airflow. The analyzed cardio-respiratory parameters can then be used by the diagnostic module in the diagnosis of the occurrence of respiratory disorder events. The cardio-respiratory parameters can be measured

using any method known in the art for measuring such parameters, including, but not limited to the use of a nasal cannula, a pulse oximetor, an ECG, and/or a chest strain gauge.

The method and system of the invention may be used for monitoring and/or diagnosing sleep-related respiratory disorders or obstructive lung diseases. For instance, the method and system may be used to screen patients at low to intermediate risk for sleep-related breathing disorders; to perform sleep studies in a medical care facility, to monitor the efficacy of treatment by measuring airway sounds during patient treatment; to monitor patients in acute care settings for abnormal respiration as a sign of cardiopulmonary distress; to monitor patients outside the hospital, such as infants, for abnormal respiration as a sign of cardiopulmonary distress; or any other monitoring system for disordered respiration in humans or animals. Further, a system of the invention can be portable or stationary, depending on its intended use.

A method or system according to the invention may also be configured to log patient data regarding the spectral characteristics of respiratory-related sounds, as well as any additional measured cardio-respiratory parameters, for later diagnostic analysis. Alternatively, a method or system of the invention can be configured to provide for real-time diagnosis of respiratory disorder events. As would be apparent to one of skill in the art, a real-time diagnostic method or system could also incorporate data logging if desired.

Patient respiratory-related sounds can be detected using any method known in the art. For instance, a microphone can be placed in proximity to the patients nose and/or mouth to detect respiratory sounds. Alternatively, a microphone can be placed in a nasal cannula. Optionally, more than one microphone can be used to detect respiratory sounds from both the nose and mouth individually, or as a background noise monitor. The microphone can also optionally be interfaced with an audio recorder for data logging.

The microphone(s) can be either attached, or unattached to the patient. For instance, the microphone can be incorporated into a nasal cannula as

described in U.S. Pat. No. 5,671,733 to Raviv *et al.*, the disclosure of which is hereby incorporated by reference in a manner consistent with this disclosure. Alternatively, the microphone(s) may be placed and/or suspended, *e.g.*, from the ceiling, in proximity to the nose and/or mouth of the patient.

The detected respiratory-related sounds can be analyzed for the presence of high frequency respiratory-related sounds using any frequency domain conversion processes known in the art, such as fast fourier transform ("FFT") processes. One skilled in the art would appreciated that various transformers may be employed besides the Fourier Transform ("FT") depending on factors such as the type of signal being analyzed, the available processing capability, etc. For example, but not limited thereto, the invention may employ Short-Time FT ("STFT"), Discrete Cosine Transforms ("DCT"), or wavelet transforms ("WT"). Alternatively, high pass filters can be used to isolate and detect the presence of high frequency respiratory-related sounds.

In one embodiment of the invention, the patient's respiratory-related sounds can be analyzed for any the presence of any frequency above a certain frequency level, *e.g.*, above 1250 Hz, preferably above 3 kHz. Alternatively, the frequency distribution of the patient's respiratory-related sounds can be analyzed for the presence of respiratory-related sounds in particular frequency ranges, *e.g.*, between about 4 and 6 kHz and between about 9 and 12 kHz. Such frequency distribution analysis can serve to more particularly identify and diagnose the respiratory disorder event.

More particularly, Figure 1 illustrates a system 10 according to the invention. In the embodiment of Figure 1, a microphone 101 is connected to a box 11 containing a preamplifier 102 and a digital signal processor 103 that converts sound input into a frequency vs. amplitude measurement. The box 11 serves as a container for the system, and may be designed, for example, to be hand-held for home or portable use. The frequency vs. amplitude measurements are then stored in a data logger 115, optionally along with other cardio-respiratory parameter measurements as needed (e.g. oxygen saturation, nasal

flow, ECG, and other measurements) which provide additional diagnostic information beyond the analysis of sound.

The optional cardio respiratory parameters can be measured using any methodologies and instrumentation known in the art. For instance, a pulse oximetor 104 can be connected to box 11 and preamplifier 105 for measuring oxygen saturation. Further, a nasal cannula 106 can be connected to box 11, transducer 107, and preamplifier 108 for measuring nasal airflow. ECG (electrocardiogram) electrodes 109 can also be connected to box 11 and preamplifier 110 to provide measurement information regarding heart activity and heart rate. Additionally, a chest-encircling strain gauge 111 can be connected to box 11, pressure transducer 112, and preamplifier 113 to measure chest wall resistance. The data logger 115 may be connected with an on-line analysis system if needed. In the embodiment shown, the data logger 115 interfaces through port 116 with computer 12 to download data for analysis and for programming the data collection box.

Figure 2 illustrates another embodiment of the invention that is configured as a real-time diagnostic system 20. In the embodiment of Figure 2, a microphone 101 is connected to a box 11 containing a preamplifier 102 and a digital signal processor 103 that converts sound input into a frequency vs. amplitude measurement. The frequency vs. amplitude measurement is analyzed by a built-in diagnostic system 114 in real time in combination with other easily obtained measurements (e.g. oxygen saturation, nasal flow, ECG, and other measurements). If the real-time diagnostic system 114 detects the occurrence of a sleep-related respiratory disorder event, an alarm system 117 is activated and patient data is passed to data logger 115 for future download to computer 12 through interface port 116 for analysis. Interface port 116 also allows for programming of the diagnostic system 114.

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 is a block diagram of one embodiment of the portable sleep related breathing disorder diagnostic system of the invention.

Figure 2 is a block diagram of one embodiment of the portable sleep related breathing disorder alarm system of the invention.

Figure 3 shows a representative tracing of the association between airway flow, esophageal pressure (an estimate of effort), and the spectral characteristics of the sound during six inspirations. The bottom tracing shows esophageal pressure ("PES") measured with a catheter and the second from bottom tracing shows airway flow measured with nasal prongs attached to a pressure transducer. The spectral characteristics were measured during six inspirations labeled A-F and are displayed as intensity (loudness) on the Y-axis and frequency in kHz on the X-axis.

Figure 4 shows another representative tracing of the association between airway flow, esophageal pressure (an estimate of effort), and the spectral characteristics of the sound during three inspirations. The bottom right tracing shows PES measured with a catheter and the top right tracing shows airway flow. The spectral characteristics were measured during three inspirations labeled A-C as in Fig. 3.

Figure 5 shows a third representative tracing of the association between airway flow, esophageal pressure (an estimate of effort), and the spectral characteristics of the sound during three inspirations. The bottom right tracing shows PES measured with a catheter and the top right tracing shows airway flow. The spectral characteristics were measured during three inspirations labeled A-C as in Fig. 3.

MODE FOR CARRYING OUT THE INVENTION

In connection with the invention, 12 patients underwent a sleep study with an esophageal catheter. Respiratory-related sounds produced by patient breathing during sleep were recorded with a microphone suspended 3 ft above the bed. FFT spectral analysis of taped sound was correlated with resistance determined by nasal flow divided by peak negative esophageal pressure. Three patients exhibited "staircase" increases in upper airway resistance allowing within patient comparison. It was found that low resistance snoring was associated with sound predominantly below 1250 Hz, while increased resistance was associated with respiratory sounds above about 1250 Hz and more particularly above about 3 kHz. For instance, increasing resistance was associated with increasing amplitude of sound at both 4-6 kHz and/or 9-12 kHz. Thus, it was found that evaluation of the spectral characteristics of respiratory sounds allows for outpatient screening for sleep-related breathing disorder events.

The study was performed in the diagnostic sleep study rooms at the University of Virginia. The University of Virginia has four such diagnostic rooms for sleep studies. Each is soundproofed from the other rooms. The sleep studies were standard studies, and data was collected with Sandman software (Toronto, Canada). All patients had esophageal pressure measured with a catheter made from P100 tubing and a 10 cm latex balloon at the distal end.

One room at the University of Virginia's sleep disorders laboratory was modified by hanging from the ceiling an Audio-Technica model AT853Rx condenser cardioid (unidirectional) microphone 1.2 m directly above the patients chest. The microphone was aimed directly down and the windscreen was installed. The microphone's output was amplified by a Sampson Mixpad 4 and then recorded on a Sony VCR. The Sandman data collection system controlled the VCR and provided relative synchronization between the VCR and Sandman software.

To ensure accurate synchronization, a portable PC was programmed to

emit a series of calibrating pulses at 1 min intervals. These pulses varied by number, duration, and frequency (9 and 10 kHz) such that the pulse sequence did not repeat for 6 hours. These pulses were wired into an extra AD channel (25 Hz) of the Sandman system and also into a small speaker in the patient room where they were detected by the microphone system. These timing pulses were easily discernible from airway sound on the recording by their narrow bandwidth. These pulses were observed on the Sandman system as square waves. Interestingly, only one patient of the 12 patients with sleep apnea could hear these 9 and 10 kHz sounds, suggesting that sleep apnea is associated with high frequency hearing loss.

Figures 3-5 demonstrate, in three separate patients, the association between airway (nasal) flow, esophageal pressure (an estimate of effort), and the spectral characteristics of the sound made during several inspirations.

Fig. 3 shows 40 sec of a sleep study in a patient with obstructive sleep apnea. Flow remained similar during all the breaths shown, therefore, increases in resistance correlate with the degree of negative deflection in esophageal pressure ("PES"). During inspirations A and B, the effort was low as demonstrated by small negative PES deflections. The sound predominantly was observed at less than 0.5 kHz (other than an artifactual fan sound at 8.3 kHz). The inspirations at C and D required additional effort as demonstrated by more negative PES. New sounds were observed at 4-5 kHz, 8 kHz, and 10-11 kHz. The inspirations at E and F required the most effort. These inspirations were associated with increased amplitude of the sounds at 2 kHz, 4-5 kHz, 8 kHz, and 10-11 kHz.

Fig. 4 shows three successive breaths of a sleep study in a second patient with obstructive sleep apnea. Each successive inspiration was associated with increasing effort (more negative PES). Inspiration A, with low effort, was associated with sound predominantly less than 3 kHz (there was no artifactual fan sound). Inspirations B was associated with increased sound at 8-9 kHz. Inspiration C, with the highest effort, was associated with increased sound, both

below 3 kHz and at 8-11 kHz.

Fig. 5 shows three successive breaths of a sleep study in a third patient with obstructive sleep apnea. In this patient, each successive inspiration was associated with less effort (less negative PES) and increasing flow, indicating decreasing airway resistance with each breath. Inspiration A, with high resistance, was associated with sound at 0-3 kHz, 4-5 kHz, and 8-11 kHz. Inspirations B was associated with less sound at 8-11 kHz. Inspiration C, with the least resistance, was associated with substantially less sound at 8-11 kHz and less sound at 4-5 kHz.

INDUSTRIAL APPLICABILITY

The invention is applicable to the monitoring and diagnosis of respiratory disorders, such as Sleep Disordered Breathing and Obstructive Lung Diseases. The invention allows for simple, non-invasive monitoring and diagnosis of respiratory disorders through the detection and analysis of high frequency respiratory-related sounds.

The embodiments described herein-above are merely illustrative and are not intended to limit the scope of the invention. It is understood that various changes, alterations, rearrangements and modification can be made by those skilled in the art without departing from the spirit and scope of the present invention.

CLAIMS

1. A method for monitoring and diagnosing respiratory disorder events in a patient comprising the steps of:

detecting a patient's respiratory-related sounds during sleep; and

analyzing the detected respiratory-related sounds for the presence of frequencies above 1250 Hz to thereby diagnose the occurrence of respiratory disorder events.

2. The method of claim 1 wherein the detected respiratory-related sounds are analyzed for the presence of frequencies above about 3 kHz to thereby diagnose the occurrence of respiratory disorder events.

3. The method of claim 1 wherein the detected respiratory-related sounds are analyzed for the presence of frequencies between about 9 kHz and about 12 kHz to thereby diagnose the occurrence of respiratory disorder events.

4. The method of claim 1 wherein the respiratory-related sounds are detected using at least one microphone.

5. The method of claim 4 wherein the at least one microphone is located near the patient, attached to the patient, or incorporated into a nasal cannula worn by the patient.

6. The method of claim 1 further comprising the step of logging data relating to the detected respiratory-related sounds.

7. The method of claim 1 further comprising the step of estimating the geometry and size of the patient's airway or the anatomical structure generating the detected respiratory sounds based on the detected respiratory-related sounds.

8. The method of claim 1 further comprising the step of estimating the location of the anatomical structure generating the detected respiratory-related sounds based on the detected respiratory-related sounds.

9. The method of claim 1 further comprising the steps of:

measuring at least one cardio-respiratory parameter reflective of the occurrence of respiratory disorder events; and

analyzing the at least one cardio-respiratory parameter in conjunction with the detected respiratory-related sounds to thereby diagnose of the occurrence of respiratory disorder events.

10. The method of claim 9 further comprising the step of logging data relating to the at least one cardio respiratory parameter.

11. A system for monitoring and diagnosing respiratory disorder events in a patient comprising:

at least one respiratory sound detection module for detecting a patient's respiratory-related sounds during sleep; and

a sleep-related respiratory disorder event diagnosis module for analyzing the detected respiratory-related sounds for the presence of frequencies above 1250 Hz to thereby diagnose the occurrence of respiratory disorder events.

12. The system of claim 11 wherein the diagnosis module analyzes the detected respiratory-related sounds for the presence of frequencies above about 3 kHz to thereby diagnose the occurrence of respiratory disorder events.

13. The system of claim 11 wherein the diagnosis module analyzes the detected respiratory-related sounds for the presence of frequencies between about 9 kHz and about 12 kHz to thereby diagnose the occurrence of respiratory disorder events.

14. The system of claim 11 wherein the at least one respiratory sound detection module comprises at least one microphone.

15. The system of claim 11 wherein the at least one respiratory sound detection module comprises a nasal cannula including at least one microphone.

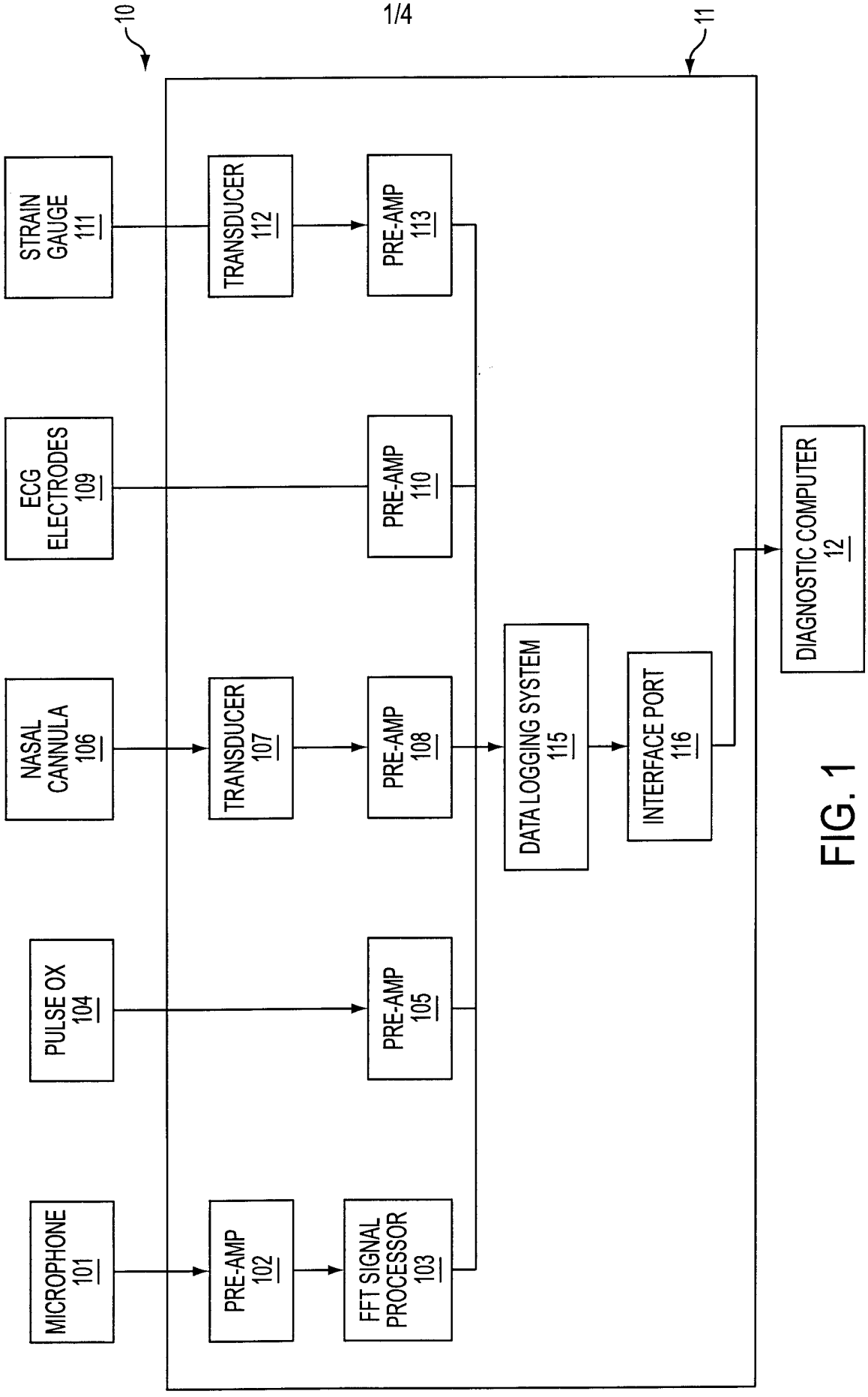
16. The system of claim 11 further comprising a data logging module for logging data relating to the detected respiratory-related sounds.

17. The system of claim 11 further comprising a geometric estimation module for estimating the geometry and size of the patient's airway or anatomical structure generating the detected respiratory-related sounds based on the detected respiratory-related sounds.

18. The system of claim 11 further comprising a location estimation module for estimating the location of the anatomical structure generating the detected respiratory-related sounds based on the detected respiratory-related sounds.

19. The system of claim 11 further comprising at least one cardio-respiratory parameter measurement module for measuring at least one cardio-respiratory parameter reflective of the occurrence of respiratory disorder events; wherein the at least one cardio-respiratory parameter is analyzed by the diagnosis module in conjunction with the detected respiratory-related sounds to thereby diagnose of the occurrence of respiratory disorder events.

20. The system of claim 19 further comprising the a cardio-respiratory parameter data logging module for logging data relating to the at least one cardio respiratory parameter.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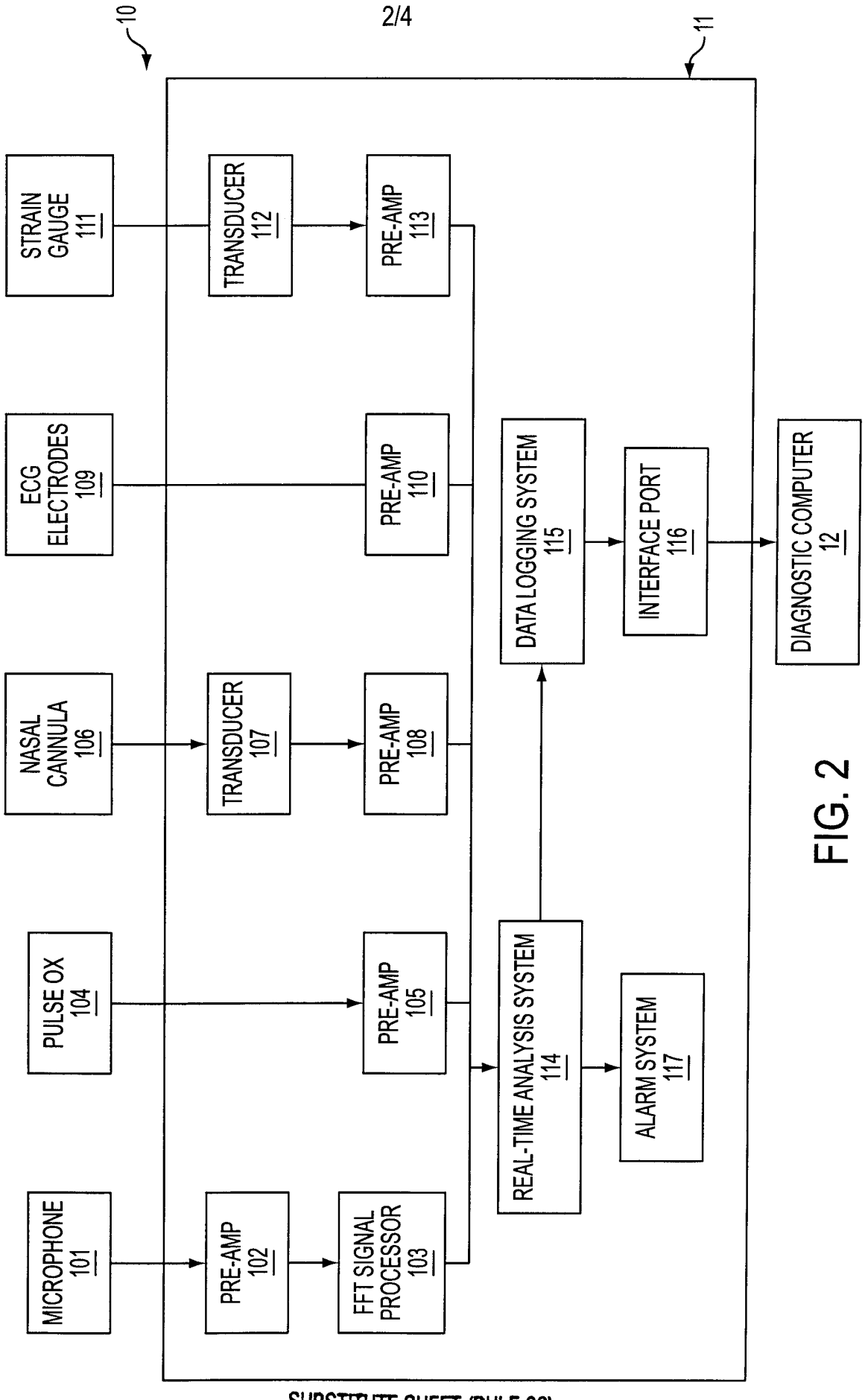
TRANSDUCER 112
PRE-AMP 113
ECG ELECTRODES 109
PRE-AMP 110
NASAL CANNULA 106
TRANSDUCER 107
PRE-AMP 108
DATA LOGGING SYSTEM 115
INTERFACE PORT 116
DIAGNOSTIC COMPUTER 12
PULSE OX 104
PRE-AMP 105
MICROPHONE 101
PRE-AMP 102
FFT SIGNAL PROCESSOR 103

FIG. 1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PRE-AMP 102
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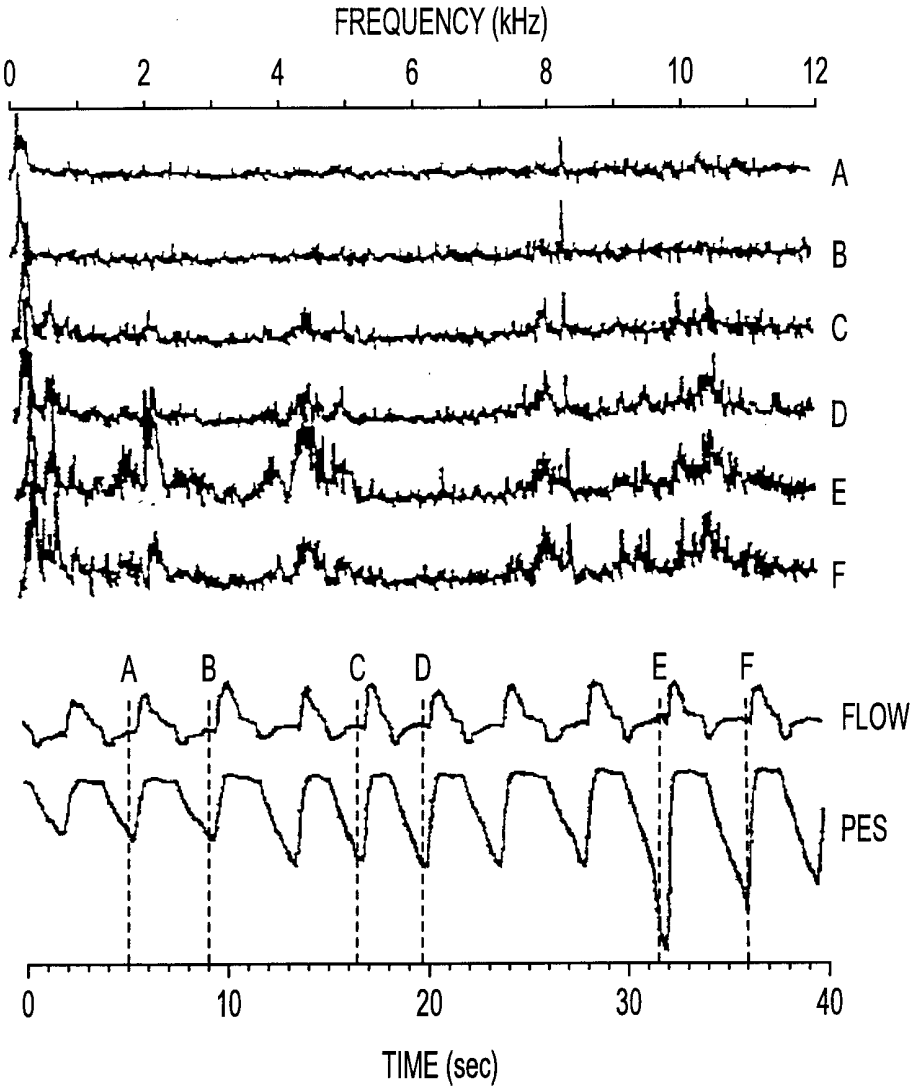
REAL-TIME ANALYSIS SYSTEM 114
DATA LOGGING SYSTEM 115
INTERFACE PORT 116
ALARM SYSTEM 117
DIAGNOSTIC COMPUTER 12

FIG. 2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10
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40
TIME (sec)

FIG. 3

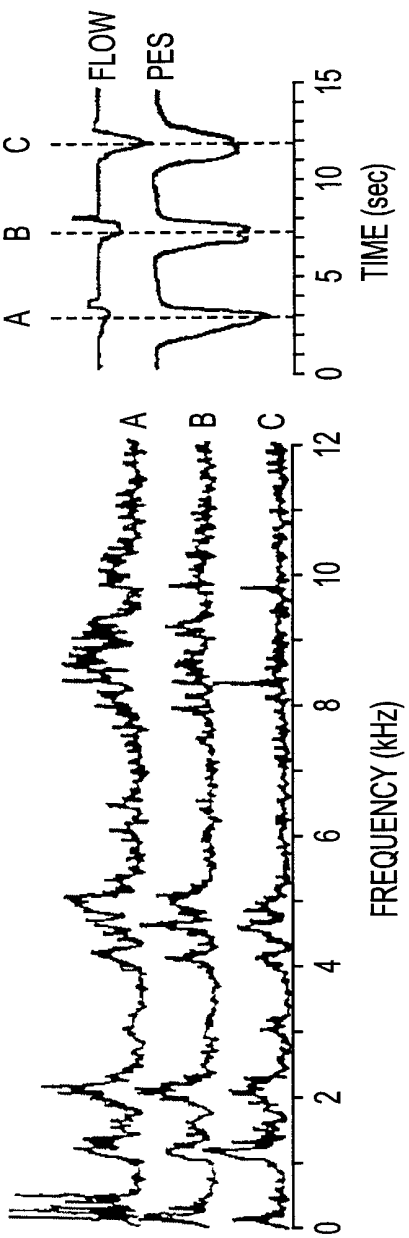
A
B
C
FLOW
PES
0
5
10
15
TIME (sec)
A
B
C
0
2
4
6
8
10
12
FREQUENCY (kHz)

FIG. 4

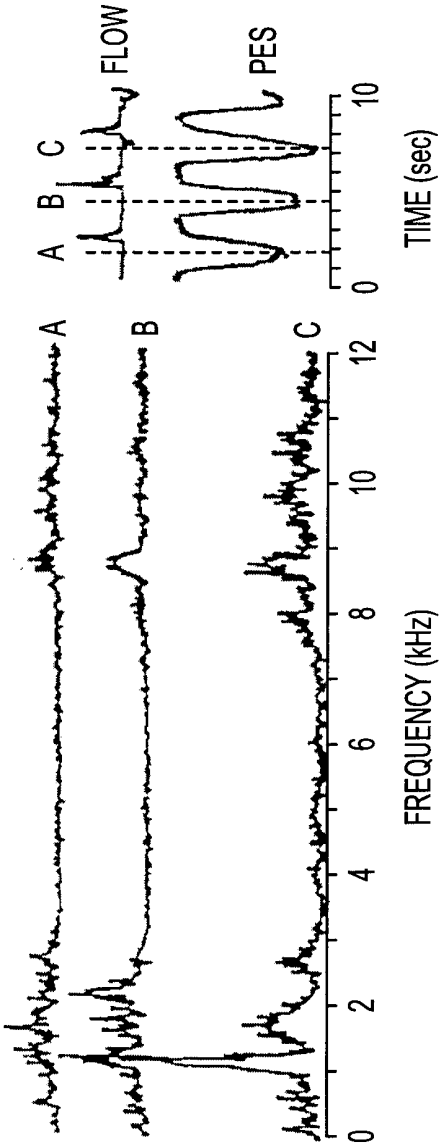
A
B
C
FLOW
PES
0
10
TIME (sec)
A
B
C
0
2
4
6
8
10
12
FREQUENCY (kHz)

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/24275

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 5/08
US CL : 600/529; 128/220.24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/529, 531-538; 128/220.24

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,505,199 A (KIM) 09 April 1996, see entire document.	1-20
A	US 5,203,343 A (AXE et al.) 20 April 1993, see entire document.	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
04 NOVEMBER 2000

Date of mailing of the international search report
27 NOV 2000

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