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METHOD AND APPARATUS FOR CONTROLLING SLEEP DISORDER BREATHING

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(57) Claim

1. A method of controlling sleep disorder breathing in a person, the method comprising the steps of:

connecting an interface (39) from a source of compressed air (43) to a person's breathing passages;

supplying compressed air from the source of compressed air through the interface to the person's breathing passages;

measuring flow related variables and pressure variables of the compressed air in the interface;

detecting from the measured flow related variables and the measured pressure variables indications of sleep disorder breathing;

responsive to the detection of indications of sleep disorder breathing, adjusting pressure of the compressed air while continuing to monitor the measured flow related variables and the measured pressure variables for sleep disorder breathing; and

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responsive to passage of a period without detection of indications of sleep disorder breathing, adjusting pressure of the compressed air.

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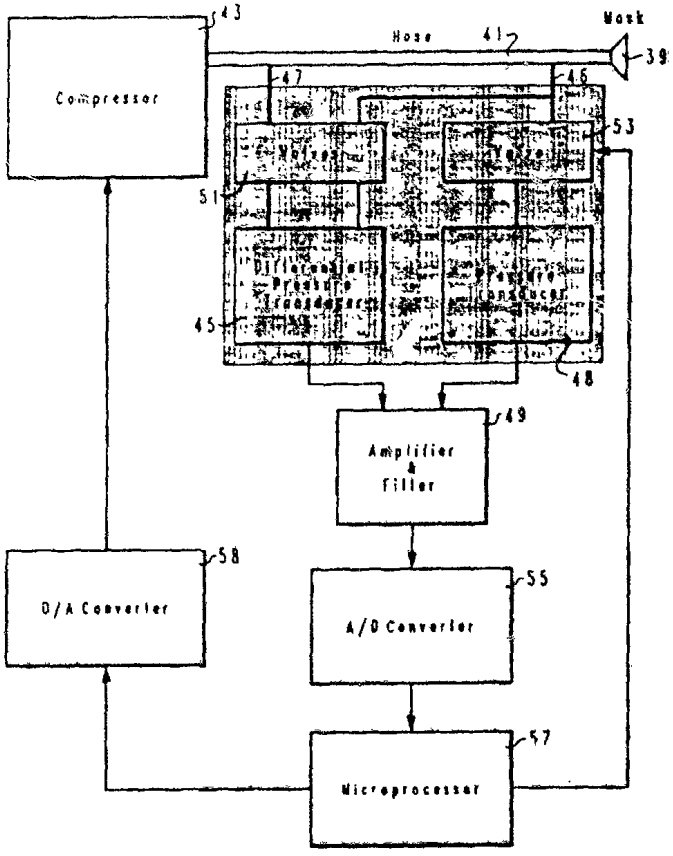
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(54) Title: METHOD AND APPARATUS FOR CONTROLLING SLEEP DISORDER BREATHING

(57) Abstract

A method and device for controlling sleep disorder breathing utilizes variable multiple level pressures. A pressure source (43) supplies compressed breathable gas at a relatively low pressure to the user's airway. Pressure transducers (45, 48) monitor pressures and convert them into electrical signals. The electrical signals are filtered and processed (49, 55) to extract specific features such as duration and energy levels. If these features exceed selected threshold values for duration and energy level over a minimum period of time, then the microprocessor (57) declares the presence of sleep disorder breathing. If a selected number of these events occur within a selected time period, then the microprocessor adjusts the pressure delivered by the pressure source. If sleep disorder breathing is not detected within a certain time period, then the microprocessor lowers the pressure level gradually. The device and method disclosed in this patent is capable of detecting apnea, hypopnea, and pharyngeal wall vibration. Further, it is able to distinguish between obstructive, central and mixed apnea and hypopnea.



Description

Method and Apparatus for Controlling Sleep Disorder Breathing

Technical Field

This invention relates in general to a method and apparatus for controlling sleep disorder breathing, particularly one utilizing positive air pressure supplied to a person's breathing passages.

Background Art

The majority of patients diagnosed with sleep disorders in the United States suffer from excessive daytime sleepiness. The leading cause of this symptom is sleep apnea.

Sleep disorder breathing, such as hypopnea, apnea, or other partial pharyngeal closure, is often combined with pharyngeal wall vibration, which may or may not be audible. Sleep apnea is a potentially lethal condition characterized by multiple obstructive, central or mixed apneas occurring during sleep. A characteristic symptom of sleep apnea includes repetitive episodes of pharyngeal wall vibration, often referred to as snoring when audible. The vibration noted with this syndrome is one in which inspiratory vibrations gradually increase when pharyngeal closure or obstruction of the upper airway develops. A loud, choking inspiratory gasp then occurs as a person's respiratory efforts succeed in overcoming the occlusion. The person frequently wakes. In the morning, the aroused person is usually aware of neither the breathing difficulty nor of the numerous accompanying body movements that at times violently disturb his sleep.

A diagnostic study is necessary for an adequate description of the person's sleep breathing pattern.

Apneic episodes during sleep are defined as cessations of air flow at nose and mouth lasting 10 seconds or longer and can be readily documented by polysomnographic recordings. Variations in night-to-night frequency of apneic pauses exist in many patients, with increased frequency appearing to follow upper respiratory infections or use of sedating drugs or alcohol.

In obstructive sleep apnea (OSA), breathing passageways are blocked. In central sleep apnea (CSA), the brain has ceased signaling the body to breathe. Obstructive hypopnea is a milder form of obstructive apnea, usually referring to episodes of partial obstruction of the upper airway passages. Central hypopnea is a milder form of central apnea. Excessive pharyngeal wall vibration, without hypopnea or apnea occurrences, can also be a serious problem. Obstructive and central apnea, obstructive and central hypopnea, and pharyngeal wall vibration will be referred to herein as sleep disorder breathing. In the case of central apnea, the passageways are still open. The lungs of the person form a reservoir for air flow even though the person is not breathing.

Treatments available for sleep apnea vary from weight loss to surgical intervention to prosthetic devices. Although weight loss is the most desirable approach, few patients are able to comply with their diets, and very few can afford to continue the exposure to the symptoms of sleep apnea for six months to a year while losing sufficient weight to reduce or cure the condition. Surgical approaches are only effective in about 50% of the cases, are invasive, expensive and may produce undesirable side effects.

The most successful treatment device has been the nasal continuous positive airway ventilator ("CPAP"). CPAP initially used an adapted vacuum sweeper motor to supply air under pressure to a hose. The hose fed a nasal mask attached it to the patient's face. The advantages of the nasal CPAP system are that it produces immediate relief, is non-invasive and can be used while achieving weight loss and thus avoids the need for surgery. The primary problem with nasal CPAP has been compliance. While nearly all of patients are fitted with nasal CPAP as an initial treatment modality, many cease using the system after about six months.

Investigation of the causes for poor compliance among patients has identified three primary factors all relating to patient comfort. The first factor is the lack of perfect fit and discomfort of wearing the nasal mask. The positive pressure of the ventilator flow is often mentioned as the second factor. Some patients experience a uncomfortable and annoying sensation from the forced air stream in their nose and mount. Third, dry mouth and throat are often cited as the source of dissatisfaction with the sleep apnea ventilators.

Disclosure of the Invention

The method and apparatus of the invention provide for the detection and control of sleep disorder breathing in a person. Control of sleep disorder breathing with reduced discomfort due to flow of forced air, is accomplished by selection of pressure for the air flow. Increased pressure is selected upon detection of sleep disorder breathing. Absent occurrence of sleep disorder breathing, the forced air flow is reduced in pressure.

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In one aspect, the present invention provides a method of controlling sleep disorder breathing in a person, the method comprising the steps of:

connecting an interface (39) from a source of compressed air (43) to a person's breathing passages;

supplying compressed air from the source of compressed air through the interface to the person's breathing passages;

measuring flow related variables and pressure variables of the compressed air in the interface;

detecting from the measured flow related variables and the measured pressure variables indications of sleep disorder breathing;

responsive to the detection of indications of sleep disorder breathing, adjusting pressure of the compressed air while continuing to monitor the measured flow related variables and the measured pressure variables for sleep disorder breathing; and

responsive to passage of a period without detection of indications of sleep disorder breathing, adjusting pressure of the compressed air.

In another aspect, the present invention provides a method for sleep disorder breathing therapy of a person, comprising the steps of:

connecting a face mask (39) from an air compressor (43) to a person's breathing passages;

supplying air from the air compressor through an interface (46, 47) to the face mask;

periodically measuring pressure difference along the interface and pressure in the face mask;

detecting from the measured pressure difference and the face mask pressure indications of sleep disorder breathing;

responsive to the detection of indications of sleep disorder breathing, adjusting pressure from the compressor while continuing to monitor pressure and pressure difference for continued indication of sleep disorder breathing; and

responsive to passage of a period without detection of indications of sleep disorder breathing, adjusting pressure of the compressed air.

In yet another aspect, the present invention provides apparatus for controlling sleep disorder breathing comprising:

a source of compressed breathable gas (43);
an interface (41) connected at a first end to the source of compressed breathable gas and adapted at a second end (39) to fit over a person's breathing passages;
means for measuring differential pressure (45, 47, 51) from the first end to the second end of the interface;
means for measuring pressure (46, 48, 53) in the second end of the interface;
means for detecting indications in the measurements of sleep disorder breathing (49, 55, 57) from the measurement of pressure and differential pressure;
means responsive to detection of indications of sleep disorder breathing (57, 58) for adjusting pressure of breathable gas from the source of breathable gas; and
means responsive to passage of a period of time without detection of indication of sleep disorder breathing (57) for adjusting pressure from the source of breathable gas.

In a further aspect, the present invention provides a method of diagnosis of sleep disorder breathing, comprising the steps of:

forcing air through a pressure line (41) to a person's breathing passages;
periodically sampling a pressure rate variable related to pressure of air in the pressure line;
accumulating samples of the pressure rate variable;
generating a mean pressure rate for intervals of samples of the pressure rate variable;
generating a variance measure for the intervals of samples of the pressure rate variable;
comparing the variance measure with a threshold to detect pharyngeal wall vibration;
maintaining a running average of mean pressure rates;
comparing a generated mean pressure rate against the running average to detect hypopnea or apnea in the patient; and
signalling the results of the comparing steps where sleep disorder breathing is detected.

The pressure rate variable may be the rate of change of measured pressure differential in the interface or mask and hose.

For sleep, a patient is fitted with a nasal mask adapted to deliver air from a source of compressed air to

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the patient's nasal passages. A hose connects the compressed air source and nasal mask. Detection of sleep disorder breathing involves monitoring of face mask pressure and pressure difference (ΔP) between two spaced points along the hose. Specific conditions, including occurrence of apnea, hypopnea and pharyngeal wall vibration are identified. Also detectable are nasal mask problems such as dislodgement of the mask or leakage from the mask. Inhalation and exhalation by the patient are also detected. Diagnosis of apnea, hypopnea, pharyngeal wall vibration and complete or partial closure of the breathing path is based on measurements of breathing by the patient.

Pressure selection is microprocessor controlled and is responsive to detection of specific conditions. Pressure may be adjusted to multiple levels during and following occurrences of sleep disorder breathing. Increased pressure for inhalation, exhalation, or both may be used to suppress sleep disorder breathing, with the pressure level adjusted to achieve suppression of the condition. Mask dislodgement results in reduction of pressure to a minimum level.

Description of the Drawings

Figure 1 is a block diagram illustrating the method and apparatus of this invention;

Figure 2 is a pair of graphs, one illustrating the difference in pressure that exists between the mask and the compressor output and the other illustrating the mask pressure during an occurrence of obstructive sleep apnea;

Figure 3 is a pair of graphs, one illustrating the difference in pressure that exists between the mask and the compressor output and the other illustrating the mask pressure during an occurrence of central sleep apnea;

Figure 4 is a pair of graphs, one illustrating the difference in pressure that exists between the mask and the compressor output and the other illustrating the mask pressure during an occurrence of obstructive sleep hypopnea;

Figure 5 is a pair of graphs, one illustrating the difference in pressure that exists between the mask and the compressor output and the other illustrating the mask pressure during an occurrence of central sleep hypopnea;

Figure 6 is a pair of graphs, one illustrating the difference in pressure that exists between the mask and the compressor output and the other illustrating command pressure to the compressor for periods of normal breathing as well as episodes of pharyngeal wall vibration and obstructive hypopnea;

Figure 7 is a pair of graphs, one illustrating the difference in pressure that exists between the mask and the compressor output and the other illustrating command pressure to the compressor for normal breathing as well as episodes of pharyngeal wall vibration , obstructive hypopnea, and obstructive apnea;

Figure 8 is a pair of graphs, one illustrating the difference in pressure that exists between the mask and the compressor output and the other illustrating command pressure to the compressor for normal breathing as well as episodes of central hypopnea, and central apnea; and

Figures 9-29 are logical flow charts of a computer process executed on a microprocessor detecting episodes of control and obstructive hypopnea and adjusting mask pressure for the control thereof.

Detailed Description of the Invention

Referring to **Figure 1**, the apparatus will include any type of mask or nostril adapter **39**. Mask **39** may be a commercially available product that has two nozzles,

each of which fits within a nostril (not shown) of a user. Mask **39** connects to a flexible hose **41** that leads to a low pressure air source such as compressor **43**. Mask **39** and hose **41** make up an interface for supplying air under pressure to the user. Compressor **43** draws in ambient air and compresses it to a pressure which can be selected as described below. Increasing the pressure will increase the flow rate of the air through the hose **41** if mask **39** is open to atmosphere.

The differential pressure transducer **45** senses the dynamic pressure difference between the output of the compressor **43** and the mask **39**. Differential pressure transducer **45** has one sensing tube **46** connected to the interior of mask **39**. Another sensing tube **47** connects to the output of compressor **43**. Mask sensing tube **46** is downstream from output pressure sensing tube **47**. The pressure difference between sensing tubes **46** and **47** corresponds to the quantity of air flow through the hose **41**. Normal breathing causes the difference in pressure sensed by the pressure transducer **45** to fluctuate.

Pressure transducer **48** measures only the dynamic pressure in the mask **39**. Pressure transducer **48** is connected to sensing tube **46**. Mask pressure transducer **48** and differential pressure transducer **45** apply analog signals to amplifier/ filter circuitry **49**. The amplifier/filter circuitry **49** amplify the signal and may optionally filter out signals clearly not associated with sleep disorder breathing. Electrically actuated valves **51**, **53** connected into sensing tubes **47**, **46**, respectively, are normally closed. These valves are used for periodic calibration of pressure transducers **45** and **48**. When actuated, each valve **51**, **53** opens the sensing tubes **46**, **47** to the atmosphere. The amplifier **49** applies the sensed pressure waveforms to an analog to digital converter **55**, which in turn is applied to a

microprocessor **57**. Microprocessor **57** will control the output pressure of the pressure source **43** of the pressure transducers **45** and **48** respectively. Microprocessor **57** performs the calibration, also on a timed basis.

The microprocessor **57** is programmed to sample the incoming signals from converter **55** at a rate of 4000 times per second and process the sampled signals at the rate of 10 times per second. For every 400 pressure difference values collected, a mean pressure difference value and a pressure difference standard deviation value are calculated and stored. The mean pressure difference value calculation is, in effect, a low pass filter, whereas the standard deviation calculation is, in effect, a high pass filter. The mean pressure difference values are used to calculate a mean pressure difference base line, which is arbitrarily defined as the signal level dividing inspiration and expiration.

If the mean value is larger than the pressure difference base line value by a threshold for more than 15 seconds, the algorithm responds with a "mask off" signal. Experience has shown that if the mask **39** is removed, the pressure difference becomes very large and will exceed an pressure difference base line value established before the mask was dislodged.

The microprocessor **57** algorithm uses the pressure difference standard deviation values to calculate the energy of disturbances in the pressure difference signal greater than an arbitrarily defined threshold. The threshold level is determined according to the following formula:

standard deviation threshold = (command pressure - A)* B + C

where A, B and C are fixed empirical values that set the threshold above the level of disturbances caused by ordinary turbulence in the hose **41**. Alternately, the

standard deviation threshold values could be adaptive and changed based on past standard deviation values calculated for the person utilizing the mask **39**. If the standard deviation value is equal to zero for 10 seconds then the system responds with a "power off" signal.

Detection of pharyngeal wall vibration is based on the energy and duration of the pressure waveforms associated with the sleep disorder breathing. The energy is calculated as the sum of pressure difference standard deviation values in excess of the standard deviation threshold divided by the pharyngeal wall vibration duration. The algorithm responds with a " pharyngeal wall vibration" signal when the energy of the standard deviation values is greater than an energy threshold, and when the duration of pharyngeal wall vibration exceeds a duration threshold. The command pressure is raised after a selected number of pharyngeal wall vibration signals, such as three, where the time between successive sleep disorder breathing signals does not exceed a selected duration, such as 20 seconds. The amount by which pressure from compressor **43** is raised is adjustable. The command pressure is reduced after any selected period, such as five minutes, in which no sleep disorder breathings occur. The amount by which pressure is reduced is adjustable.

The command pressure from microprocessor **57** is output as a digital signal, which passes through digital to analog converter **58** where it is converted to an analog signal for varying the speed, and thus the output pressure, of compressor **43**. The microprocessor **57** can vary the output of compressor **43** with each inspiration and expiration cycle, increasing pressure during inspiration and decreasing pressure to a lower base level during expiration. Either level may be adjusted independently if sleep disorder breathing is detected.

Also, the output of compressor **43** is modulated by a small amplitude 5 Hz signal, which is used to detect the difference between central and obstructive apnea and central and obstructive hypopnea.

Figures 2-5 illustrate graphical traces of episodes of obstructive sleep apnea (OSA), central sleep apnea (CSA), obstructive sleep hypopnea (OSH) and central sleep hypopnea (CSH), obtained from a normal subject simulating the conditions. Referring to **Figure 2**, the curve **59** represents the delta P measurement measured by pressure transducer **45**. Curve **61** represents the mask pressure sensed by transducer **48**. The magnitudes of the pressures of curves **59** and **61**, as illustrated by the graph of **Figure 2**, are shown against the same time coordinate for convenience. Period **63** indicates normal breathing. During period **63**, the delta P measurement **59** increases and decreases normally. The mask pressure **61** also increases and decreases normally, about 180 degrees out of phase with the delta P measurement **59**, during normal breathing. Delta P **59** will be relatively high during inspiration, while the mask pressure **61** will be reduced.

Period **65** corresponds to the occurrence of OSA. During OSA, the upper airway is blocked completely. Consequently, little flow will occur and the pressure difference measurement will be insignificant. The mask pressure **61** will fluctuate as indicated by the numeral **67** proportional to the five hertz modulation applied to compressor **43** (**Fig. 1**).

Curve **59** is graph of a delta P measurement, or the changes in difference in pressure between sensing tubes **46**, **47** over time. Under normal circumstances, delta P curve **59** is always positive with a greater pressure at compressor output sensing tube **47** than at interface sensing tube **46**. The difference in pressure increases when the person inhales and decreases when the person

exhales. The curve **61** represents the mask pressure during normal breathing.

In **Figure 3**, numeral **69** indicates an occurrence of CSA. In CSA, the brain has signaled the body to stop breathing. Because the upper airway is open, the lungs function as a reservoir. Consequently, the pressure difference measurement of the 5 hertz modulation during CSA is larger than that observed during OSA. Conversely, the mask pressure measurement of the 5 hertz modulation during CSA is less than that observed during OSA.

Delta P curve **59** has a normal breathing section **63** just as in **Figure 2**. However, section **69** indicates that breathing has stopped. The delta P curve **59** becomes almost constant. This indicates that there is no dynamic pressure changing due to a person's breathing, and thus the difference between the pressure sensing tubes **46** and **47** will be almost constant, except for the pressure variations due to 5 Hz modulation.

If that condition occurs, there will be essentially no cycles above a noise threshold level to compute areas upon and compare to the average area of the past 50 breath cycles. The microprocessor **57** in this instance will initiate a delay, preferably ten seconds. If at the end of the delay breathing has not resumed, the microprocessor **57** increases pressure in attempt to alleviate the condition in the same manner as described previously. Also, the microprocessor **57** will attempt to determine whether the condition of lack of breathing is due to central sleep apnea (CSA) or obstructive sleep apnea (OSA). In obstructive apnea, breathing passageways are blocked. In central apnea, the brain has ceased signaling the body to breathe. In the case of central apnea, the passageways are still open.

The curves shown in **Figures 2** and **3**, illustrate the difference in both the patient mask pressure and the

delta P pressure signals for OSA and CSA. Specifically, the 5 Hz modulation frequency present in the mask pressure is accentuated and delta P diminished when OSA occurs. This is due to the fact that during OSA the airway is obstructed reducing the overall airway volume and increasing its resistance. Conversely, during CSA changes in delta P and mask pressure due to the 5 Hz modulation pressure resemble normal breathing. Detection of CSA is accomplished by noting that flow through hose **41** has stopped.

Referring to **Figure 4**, a milder form of OSA called obstructive sleep hypopnea, or OSH, is illustrated. OSH is a partial obstruction of the upper airway, which allows some air to pass. In the episode **71** of OSH, there is some pressure difference in hose **41** varying at a low frequency due to breathing. However, the amplitude of the pressure difference **59** is much less in OSH **71** than in normal breathing **63**. Mask pressure **67** reflects the 5 hertz modulation.

In **Figure 4**, section **63** represents normal breathing, while section **71** represents partially obstructed breathing or obstructive hypopnea. The amplitude of delta P curve **59** in region **71** is much less than before. The reason is that due to the partial obstruction, there will be less flow of air into and out of the person. The difference in pressure between sensing tubes **46, 47** is considerably less in section **71** than in section **63**.

When hypopnea is detected Microprocessor **57** will ordinarily signal compressor **43** to increase the output upper pressure first in an attempt to alleviate that condition. If the hypopnea is not eliminated then the upper pressure will be increased further until the maximum allowed pressure is reached. Furthermore, the output pressure will be reduced if the condition ceases to exist after a selected time period. Hypopnea can

occur and be detected with the delta P measurements even though no other sleep disorder breathing signals are occurring.

Figure 5 depicts Central Sleep Hypopnea (CSH), which is a milder form of CSA. CSH is characterized by shallow breathing, although there is no blockage of the upper airway. Pressure differences occurring in hose **41** are reduced substantially relative to those occurring during normal breathing in **63**. Mask pressure fluctuates, but because the upper airway is open, the 5 hertz modulation of pressure will be the same as the case of breathing with no obstruction **63**.

Tables 1-2 provides command pressure components and indicates the combinations of events indicating a condition to be treated.

The processes described with reference to the flow charts of **Figures 9-29** include various diagnostic determinations. The basic determinations are set out in **Table 1**. The letters relate into graphic depictions of the conditions shown in **Figures 6-8**.

Table 1

A	-	No pharyngeal wall vibration and power on
B	-	Pharyngeal wall vibration occurring
C	-	Central or obstructed sleep hypopnea
D	-	Central or obstructed sleep apnea
E	-	Normal breath volume
F	-	Complete pharyngeal closure
G	-	Partial pharyngeal closure
H	-	Upper airway open
I	-	Mask off
J	-	Mask leak
O	-	Power on
P	-	Power off

Complete diagnosis for purposes of treatment or response requires combining of several basic indications as set out in **Table 2**.

Table 2

CONDITIONS	DIAGNOSIS
A+E+H	Normal breathing
B+E+H	Pharyngeal wall vibration (PV) only
A+C+H	Central hypopnea
A+C+G	Obstructive hypopnea
A+D+H	Central apnea
A+D+F	Obstructive apnea

Figure 6 illustrates various abnormal breathing conditions and the modification of command pressure to treat the conditions as they occur. The upper curve **601** is a pressure difference measurement showing breathing over a period of time including sessions of normal breathing, indicated by conclusions A, E and H, pharyngeal wall vibration (B+E+H) and obstructive hypopnea (A+C+G). During the first period of normal breathing, the command pressure to the compressor **43** (**Fig. 1**) is at a minimum level indicated by curve **603** and is not varied with inspiration and expiration cycles. Pharyngeal wall vibration, indicated by "PV", is shown occurring during the inspiration and expiration cycles of breathing. This higher frequency wave form is detected through standard deviation calculations. After detection of pharyngeal wall vibration, command pressure **603** begins to follow inspiration and expiration cycles of the patient, with inspiration command pressure being substantially boosted over expiration command pressure. The command pressure **603** is raised after detection pharyngeal wall vibration signals **93**, where the time between pharyngeal wall vibration signals does not exceed 20 seconds. The command pressure includes an inspiration level, set at a first increment of pressure component

level P3 (Press 3), and an expiration level which here returns to base pressure. Expiration command pressure can be boosted over minimum levels under certain circumstances, however. After normal breathing returns or is restored, overall command pressure **603** is reduced, first by cutting inspiration cycle pressure, followed by elimination of the inspiration cycle boost and concluded with gradual reduction in base pressure to minimum levels.

Referring to **Figure 7**, occurrences of OSH and OSA are illustrated. After the onset of OSH, command pressure **703** is increased for inspiration levels by adjustment of a pressure component level P2 (or Press 2). However, the difference between the inspiration level and base pressure is not allowed to exceed a maximum differential.

During OSA, the base level of command pressure **703** is ramped up in steps as long as it does not exceed a maximum permitted base pressure level. Obviously, inspiration is not occurring during apnea, so no variation in command pressure due to inspiration and expiration occur. **Figure 7** also shows episodes of normal breathing, and pharyngeal wall vibration and obstructive hypopnea.

Figure 8 shows episodes of central hypopnea and apnea in pressure waveform **801**. In the case of central hypopnea, the base pressure level of command pressure **803** remains constant. If breathing remains shallow for ten seconds, an inspiration cycle appears and its level gradually increases until normal breathing reappears. During the occurrence of central apnea, the command pressure **803** remains constant.

Figure 9 is a logical flow chart illustrating a main program for microprocessor **57**. The main program is used to control flow of the process among a plurality of

subroutines relating to the acquisition of data from mask **39** and hose **41**, the processing of that data, the use of the processed data for diagnostic purposes and the control of air pressure applied to the mask. The main program is entered at step **1000** with a call to initialize various variables, arrays and flags used by the subsequent data acquisition, data processing, diagnostic and pressure adjustment subroutines. Then step **1002** is executed to call a Getdata subroutine in which data is retrieved from an analog to digital converter **55** and organized for use by the data processing and diagnostic subroutines. Step **1004** is a call to the data processing subroutine. Step **1006** is then executed to call the diagnostic subroutine. Finally a test is done to determine if power to the compressor for the mask is still on at step **1008**. If power is on, step **1010** is executed to call a pressure adjustment subroutine. Processing is then returned to step **1002**. If compressor power was off at step **1008**, the NO branch is followed to discontinue execution of the program.

Figure 10 is a logical flow chart illustrating a subroutine for initialization of assorted variables and flags used by subsequent subroutines described herein. The subroutine is entered at step **1100** with initialization of an analog to digital converter sampling rate and the setting of the number of channels and sample size used. In the preferred embodiment, analog to digital converter **55** samples the pressure difference along hose **39** and the mask pressure 4000 times a second. There are two channels, corresponding to the pressure difference and mask pressure signals respectively. The data is stored to two arrays each sized for 400 such sample points corresponding to a sampling interval. Step **1102** is executed to initialize indices for a pressure difference array and mask pressure array to which the

values from the channel arrays will be transferred. In step **1104** an index is initialized to an array used for storing measurements of the area between the delta P curve and the base line. The size of this array is 50. In step **1106** a number of sample and calculated variable values are initialized. The specific variables used will be introduced in the discussion of the appropriate subroutines. Similarly at step **1108** initial values for a number of flags are set. Again specific flags will be described at the time of the discussion of the appropriate subroutine. After step **1108** processing is returned to the main program.

Figure 11 is a logical flow chart illustrating acquisition of data by microprocessor **57** from A/D converter **55**. Step **1200** is an input/output step corresponding to the transfer of data to buffer arrays from the analog to digital converter for an interval of 400 samples. Step **1202** controls looping through step **1200** until a full interval has been loaded into the buffer arrays. Once a full interval of samples has been transferred to a buffer array, step **1204** is executed to initialize an index. Until a full interval of samples has been accumulated the process loops from step **1202** back to step **1200**. Next, step **1206** is executed to transfer data from one buffer array into a pressure difference array. This array is sometimes also referred to as a delta P array. In step **1208** mask pressure readings are loaded into a pressure reading array from the transfer buffers. Step **1210** provides for incrementation of the index in use. Step **1212** controls looping of the transfer process back through step **1206**. Once the index exceeds in size a buffer array the YES branch is followed to the return the processing to the main program of **Figure 9**.

Figure 12 is a logical flow chart illustrating a data processing subroutine. The data process subroutine consists essentially of a series of calls to five calculation functions. These functions include a subroutine for calculation of a mean value and a standard deviation value for the samples in the pressure difference array (step **1300**). Step **1302** is a call to a function for the calculation of a baseline and the area of the mean value of the pressure difference array. Step **1304** is a call to a subroutine for calculation of a hypopnea threshold using the previously calculated mean. Step **1306** is a call to a calculation of the area and duration of the standard deviation of the delta P signal. Step **1308** is a call to a subroutine for calculation of the energy and phase of the pressure difference and mask pressure at a frequency of 5 hertz. The subroutine is then exited back to the main program.

Figure 13 is a logical flow chart illustrating the subroutine used for the calculation of the mean and standard deviation of a set of samples from a pressure difference array. The process is entered with step **1400** with determination of the average value of the entries in the pressure difference array. In step **1404**, the standard deviation is calculated using the mean and mean square values previously determined. Next, step **1406** is executed to store the mean value into a storage array of pressure difference mean values having a size of 400. This group of values is used for calculating an initial baseline. Incrementation of an appropriate index for this array is also done at this time. The subroutine is then exited back to the parent subroutine.

Figure 14 illustrates a logical flow chart of a subroutine used for calculation of the mean pressure difference baseline and area. Area is a proxy for the energy content of the delta P signal. The process is

entered at step **1500** where it is determined if a baseline has already been obtained. If YES, the YES branch is followed to step **1502** where the last calculated baseline is stored as the old baseline. Next, step **1504** is executed to generate a current baseline as a function of the old baseline and the current mean. Next, step **1506** is executed to determine if the current pressure difference mean exceeds the new baseline. If not, a new area of expiration is set equal to the old area plus the new baseline less the current pressure difference mean (step **1508**). Next, step **1510** is executed to set the expiration flag to negative and processing is returned to the parent subroutine.

If at step **1506** it is determined that the current pressure difference mean exceeds the new baseline, the YES branch is followed to step **1512** to determine if the inspiration flag is positive. If YES, step **1514** is executed to calculate a new inspiration area equalling the old area plus the mean less the current baseline. Processing is then returned to the parent subroutine. If however the inspiration flag is negative, the NO branch is followed from step **1512** to step **1516**. There the area of respiration is set equal to the area of inspiration and expiration. In step **1518** the area of inspiration is reset to equal the pressure difference mean less the baseline. The inspiration flag is set to positive and the expiration area is set to zero. This is done preparatory to the next respiratory cycle.

If at step **1500** it is determined that a current baseline has not yet been obtained, the NO branch is taken to step **1520**. At step **1520** it is determined if a completed interval has been acquired. If NO, processing is returned to the main program for acquisition of another interval of sample points. If the array of 100 mean values is completed in step **1520**, the YES branch is

taken to step **1522** where the current baseline is set to equal zero and an appropriate flag is set to mark a baseline as available. In step **1524** the array of mean values are summed. In step **1526** this sum is divided by the array size to generate a baseline. Processing is then returned to the parent subroutine.

Figure 15 is a logical flow chart of a subroutine for the calculation of a hypopnea threshold for use in the diagnostic subroutines. The process is entered at step **1600** where it is determined if a minimum required number of measurements for the area between delta P and the base line (referred to as "Area" for brevity) from step **1518** have previously been obtained. If YES, step **1602** is executed to add the latest Area measurement to a First-In, First-Out (FIFO) array of such measurements and to drop the oldest Area measurement from the array. Next, step **1604** is executed to sum and average a set of the measurements. The subset includes the middle 30 by magnitude of the 50 measurements in the FIFO buffer. In step **1606** an hypopnea threshold is established to be equal to 30% of the average of the subset. After step **1606**, processing is returned to the parent subroutine. Returning to step **1600**, if a minimum number of Area calculations have not been performed, the NO branch is taken to step **1608** where the current measurement is simply added to the array of Area measurements. At step **1610** it is determined if the Area measurement array was filled by the last added entry. Step **1612** is executed to set a flag indicating that the mean pressure difference array is filled. Processing then continues with execution of **1604** as set forth above. Along the NO branch from step **1610** processing is returned to the main program.

Figure 16 is a logical flow chart of a subroutine used for the calculation of the area of the standard

deviation of delta P which exceeds a threshold. The results are used for detection of pharyngeal wall vibration. The process is entered with execution of step **1700**. There a variable called standard deviation threshold is set equal to a function of the current command pressure and old standard deviation values. The calculation of command pressure is described below. Next, in step **1702**, it is determined if the current standard deviation exceeds the standard deviation threshold just calculated. If YES, step **1704** is executed to set a flag so indicating and step **1706** is executed to generate a measure of the area of the standard deviation. The measure is equated to an area found by summing the values by which the standard deviations exceed the threshold. If at step **1702** a negative determination has been made, step **1708** is executed to determine if the standard deviation over threshold flag has previously been set. If YES, step **1710** is executed to reset the flag. Step **1712** is then executed to store the area of standard deviation over threshold and duration. If at step **1708** the flag has not been set processing is simply returned to the parent subroutine. After completion of step **1706** or **1712** processing is returned to the parent subroutine.

Figure 17 illustrates a logical flow chart for the subroutine for use in calculation of energy of the 5 Hz signal and phase difference between the pressure and pressure difference signals. The process is entered at step **1800** to determine if one second has elapsed since the last such calculation. If not, the calculation is not done and processing is returned immediately to the parent subroutine. If one second has passed since the last energy and phase measurement, the energy and phase difference calculations are done at step **1802** before return to the parent subroutine.

Figure 18 is a logical flow chart of a diagnostic subroutine. The diagnostic subroutine includes a plurality of calls used for the detection of various types of obstructed breathing and for detection of leak from or loss of the face mask. Step **1900** reflects a call to a subroutine used for the detection of pharyngeal wall vibration. Step **1902** is a call to a subroutine for the detection of apnea. Step **1904** is a call to a subroutine for the detection of hypopnea. Step **1906** is a call to a subroutine for the detection of a mask off condition or a mask leak condition. Step **1908** is a call to a subroutine for the detection of pharyngeal closure. Step **1910** is a call to a subroutine for the detection of whether compressor power is off.

Figure 19 illustrates a logical flow chart for the subroutine used for detection of pharyngeal wall vibration. Step **2000** is used to determine if the area and duration of the standard deviation of delta P as calculated in step **1700** exceeds a threshold. If not, step **2002** is executed to set a flag indicating no pharyngeal wall vibration is occurring. If YES, a flag is set indicating such vibration at step **2004**. After either step **2002** or **2004** processing is returned to the parent subroutine.

Figure 20 illustrates a logical flow chart for the subroutine used for detection of apnea. The subroutine is entered at step **2100** with a comparison of the absolute value of the ΔP mean less the current base line with the apnea threshold. If the former is less than the latter, step **2102** is executed to determine if the condition detected at step **2100** has persisted for more than 10 seconds. If the condition has persisted for more than 10 seconds an apnea flag is set to ON at step **2104** and processing is returned to the parent subroutine. If either step **2100** or **2102** is not true, step **2106** is

executed to set the apnea flag to OFF and processing is returned to the parent subroutine.

Figure 21 illustrates a logical flow chart for a subroutine used for the detection of hypopnea. The process is entered at step **2200** where it is determined if the Mean is less than the hypopnea threshold. If YES, step **2202** is executed to determine if the condition has persisted for more than 15 seconds. If the condition has persisted more than 15 seconds, the YES branch is followed to step **2204** to set the hypopnea flag to ON. If either the step **2200** or **2202** conditions are not met, the hypopnea flag is set to OFF by execution of step **2206**. After step **2206**, the process is returned to the parent subroutine.

Figure 22 is a logical flow chart for a subroutine used for detection of a mask off condition or a mask leaking condition. The process is entered with execution of step **2300** where it is determined if the mean pressure difference between sensing tubes **46** and **47** exceeds a mask off threshold. If YES, step **2302** is executed to determine if the condition has lasted more than 5 seconds. If the condition has lasted more than 5 seconds, a mask off flag is set to high at step **2304** and processing is returned to the parent subroutine. If the condition has not lasted over 5 seconds at step **2302**, the NO branch is followed to step **2305** where the mask off flag is set to low before returning processing to the parent subroutine. The NO branch from step **2300** directs processing to step **2306** where it is determined if the baseline exceeds the mask leak threshold. If YES, a mask leak flag is set to high at step **2308**. If NO a mask leak flag is set low by execution of step **2310**. After either step **2308** and **2310**, step **2305** is executed.

Figure 23 illustrates the logical flow chart for a process subroutine used for the detection of closure of

the breathing path. The process is entered with execution of step **2400** where the energy of the pressure difference array is compared to the threshold level for closure. If the energy of the pressure difference array less than the threshold level, the YES branch is followed to step **2402** where it is determined if the energy of entries in the mask pressure array are greater than a threshold. If YES step **2404** is executed to determine if the phase difference is greater than a phase difference threshold. If YES, step **2406** is executed to determine if the conditions of step **2400**, **2402** and **2404** have exceeded 5 seconds. If YES, step **2408** is executed to set the closure flag to high. If the conditions have not yet lasted 5 seconds the NO branch is followed to step **2410** to set the closure flag as low. After completion of step **2408** and **2410** processing is returned to the parent subroutine.

If any of the conditions tested at steps **2400**, **2402** or **2404** fail, step **2412** is executed. At step **2412** it is determined if the energy of the pressure difference array is less than the threshold level for partial closure. If it does, step **2414** is executed to determine if the energy of entries in the mask pressure array is greater than a threshold. If YES, step **2416** is executed to determine if the phase difference exceeds a partial closure phase difference threshold. If YES, step **2418** is executed to determine if the conditions of **2412**, **2414** and **2416** have persisted beyond 5 seconds. If YES, step **2420** is executed to set a partial closure flag to high. If any of the conditions of **2412** through step **2418** fail, step **2422** is executed to set the partial closure flag low. After either step **2420** or **2422**, the processing is returned to the parent subroutine.

Figure 24 illustrates a logical flow chart for a subroutine used for the detection of a power off

condition of the compressor used to pressurize face mask **39**. Entered at step **2500**, it is determined if the standard deviation of delta P and the baseline fall below their respective power off threshold levels. If YES, step **2502** is executed to determine if the conditions have lasted more than 5 seconds. If YES, step **2504** is executed to set the power flag to off. Processing is then returned to the parent subroutine. If the result of the tests of step **2500** or **2502** are negative, step **2506** is executed to set the power flag to ON. Processing is then returned to the parent subroutine.

Figure 25 is a logical flow chart of a subroutine called for adjustment of command pressure. Command pressure is the output requested of compressor **43**. The command pressure adjustment subroutine comprises four calls to subroutines. Steps **2600**, **2602** and **2604** are calls to subroutines for adjustment of components contributing to the command pressure. Call **2606** provides for combinations of the components to provide command pressure.

Figure 26 is a logical flow chart of a process for a subroutine for adjustment of a base pressure level, Press 1. Entered at step **2700** it is determined if the compressor is on and if processing is in the first sample interval. If YES, step **2702** is executed to set a flag indicating the first sample interval is completed. Step **2704** is then executed to set Press 1 and preliminary adjustment components Press 2P and Press 3P to their respective minimum permitted values. Processing is then returned to the parent subroutine. If the result at step **2700** is negative, step **2706** is executed to determine if a mask leak or mask off flag has been set high. If YES, step **2704** is executed as set forth above. If NO, step **2708** is executed to determine if the apnea and complete closure flags are both set high. If YES, step **2710** is

executed to determine if more than 10 seconds have passed since the last boost in base pressure and to determine if base pressure is less than the maximum allowed. If both conditions are satisfied, step **2712** is executed to boost base pressure and reset the appropriate timer. Processing is then returned to the parent subroutine. If at step **2710** either condition failed then no further action is taken and processing is returned to the parent subroutine.

If at step **2708** a negative result is obtained, step **2714** is executed to determine if more than 300 seconds have passed since the last change in base pressure. If NO, processing is returned immediately to the parent subroutine. If YES, step **2716** is executed to determine if base pressure is greater than the minimum. If base pressure is equal to minimum, the NO branch is followed to return processing to the parent subroutine. If at step **2716** base pressure exceeded minimum, step **2718** is executed to cut base pressure and to reset the timer used at step **2714**. Processing is then returned to the parent subroutine.

Figure 27 illustrates a logical flow chart for a subroutine used for the adjustment of preliminary pressure component Press 2P. At step **2800** it is determined if the hypopnea; or partial closure flags are set. If neither flag is set, processing is advanced to step **2802** where it is determined if more than 10 seconds have passed since the last change in Press 2P. If YES step **2804** is executed to determine if Press 2P exceeds its minimum allowed value. If either of the conditions of **2802** or **2804** are not met, processing is immediately advanced to step **2816**. Following the YES branch from step **2804**, step **2806** is executed to reduce Press 2P and reset of the appropriate timer. Processing then advances to step **2816**.

Returning to step **2800** and following the YES branch, step **2807** is executed to reset timers running on Press 1 and Press 2P. The timers track time elapsed since the last change in value of Press 1 and Press 2P. Step **2808** is then executed to determine if the time elapsed since the last boost of Press 2P exceeds 5 seconds. If YES, step **2810** is executed to boost Press 2P by a unit and the boost timer is reset to zero. Next, step **2812** is executed to determine if Press 2P exceeds its maximum allowed level. If YES, step **2813** is executed to boost base pressure Press 1 by one unit and to reduce Press 2P to its maximum permitted level. Next, step **2814** is then executed to determine if Press 1 now exceeds maximum permitted command pressure level. If NO, processing advances to step **2816**. If YES, step **2815** is executed to reset Press 1 to the maximum permitted value for command pressure. Following the NO branch from step **2812**, or after execution of step **2814**, the processing is advanced to step **2816**. Step **2816** is also executed along the NO branch from step **2808**.

At step **2816**, the sum of Press 1 and Press 2P are compared to the maximum permitted value for command pressure. Where the sum exceeds the maximum permitted value, the YES branch is taken to step **2818** to set command pressure component Press 2 to the maximum permitted value of command pressure less Press 1. At step **2820**, it is determined if the inspiration flag is set. If YES, step **2822** is executed to set Press 2 to Press 2P. If NO, step **2824** is executed to set Press 2 to zero because expiration is occurring. Processing is returned to the appropriate parent subroutine after any of steps **2818**, **2822** and **2824**.

Figure 29 illustrates a logical flow chart for a subroutine used for the adjustment of preliminary pressure component Press 3P. At step **2900** it is

determined if the pharyngeal wall vibration flag is set. If the pharyngeal wall vibration flag is not set, processing is advanced to step **2902** where it is determined if more than 10 seconds have passed since the last change in Press 3P. If YES, step **2904** is executed to determine if Press 3P exceeds its minimum allowed value. If either of the conditions tested in steps **2902** or **2904** are not met, the NO branches are taken to step **2916**. Following the YES branch from step **2904**, step **2906** is executed to reduce Press 3P and reset of the appropriate timer. Processing then advances to step **2916**.

Following the YES branch from step **2900**, step **2907** is executed to reset timers running on Press 1, Press 2P and Press 3P. The timers track time elapsed since the last changes in value of Press 1, Press 2P and Press 3P. Step **2908** is then executed to determine if the time elapsed since the last boost of upper base pressure exceeds 5 seconds. If YES, step **2910** is executed to boost Press 3P by a unit and to reset the boost timer for Press 3P. Next, step **2912** is executed to determine if the new Press 3P exceeds its maximum allowed level. If YES, step **2913** is executed to boost base pressure Press 1 and to reduce Press 3P to its maximum permitted level. Next, step **2914** is executed to determine if Press 1 now exceeds the maximum permitted level for command pressure. If NO, processing advances to step **2916**. If YES, step **2915** is interposed and executed to reset Press 1 to the maximum permitted value for command pressure. Following the NO branch from step **2908**, step **2912** or from step **2914** advances processing to step **2916**.

At step **2916**, the sum of Press 1 and Press 3P are compared to the maximum permitted value for command pressure. Where the sum exceeds the maximum permitted value, the YES branch is taken to step **2918** to set Press

3 to the maximum permitted command pressure level less Press 1. Along the NO branch from step **2916** step **2920** determines if the inspiration flag is set. If YES, step **2922** is executed to set Press 3 to Press 3P. If NO, step **2924** is executed to set Press 3 to zero because expiration is occurring.

Following steps **2918**, **2922**, or **2924**, processing advances to step **2926** where it is determined if Press 3 exceeds a minimum level. If Press 3 is greater than the minimum limit, pressure level Press 2 is reset to 0 and the subprocess exited. If Press 3 does not exceed the minimum level, the pressure components are left unchanged and the subprocess exited.

Figure 29 is a logical flow chart illustrating adjustment of command pressure. The process is entered in step **3000** where command pressure is set equal to the sum of components Press 1, Press 2P and Press 3P. In step **3002** the phase of an oscillating pressure value is reversed, i.e. the negative of the old value is used. Next, step **3004** is executed to set output pressure to command pressure plus oscillating pressure. In step **3006** output pressure value is output to the digital to analog converter. Processing is then returned to the appropriate parent subroutine.

The invention provides air or a mixture of breathable gases at low pressure to a sleeper when sleep disorder breathing is not occurring. This is more comfortable to the user than the higher pressures used to control sleep disorder breathing. If the system fails to stop the sleep disorder breathing an alarm can be sounded to alert other people or the person to avoid a potentially dangerous situation. The system automatically adapts to the level of air pressure required by the user during the night.

While the invention has been shown in only one of its forms, it should be apparent to those skilled in the art that it is not so limited but is susceptible to various changes without departing from the scope of the invention.

Claims

1. A method of controlling sleep disorder breathing in a person, the method comprising the steps of:

connecting an interface (39) from a source of compressed air (43) to a person's breathing passages;

supplying compressed air from the source of compressed air through the interface to the person's breathing passages;

measuring flow related variables and pressure variables of the compressed air in the interface;

detecting from the measured flow related variables and the measured pressure variables indications of sleep disorder breathing;

responsive to the detection of indications of sleep disorder breathing, adjusting pressure of the compressed air while continuing to monitor the measured flow related variables and the measured pressure variables for sleep disorder breathing; and

responsive to passage of a period without detection of indications of sleep disorder breathing, adjusting pressure of the compressed air.

2. A method as set forth in Claim 1, wherein the step of detecting indications of sleep disorder breathing includes:

computing a running mean of a series of measured flow related variables;

setting a hypopnea threshold based on a fraction of the running mean for the measured flow related variables; and

comparing a value determined over an interval of samples for the measured flow related variable

against the hypopnea threshold for indication of sleep disorder breathing.

3. A method as set forth in Claim 1, wherein the step of detecting indications of sleep disorder breathing includes:

computing a standard deviation value for the measured flow related variables over an interval;

periodically determining if the computed standard deviation value exceeds a standard deviation threshold; and

comparing the computed standard deviation value with the standard deviation threshold over a certain time interval to establish occurrence of pharyngeal wall vibration.

4. A method as set forth in Claim 1, wherein the step of detecting indications of sleep disorder breathing includes:

computing a mean over an interval of measured flow related variables; and

comparing the mean from the computing step to an apnea threshold.

5. A method as set forth in Claim 1, wherein the measured flow rate variables include a measurement of pressure difference along the interface and the step of detecting indications of sleep disorder breathing includes:

accumulating a plurality of mean pressure difference measurements;

accumulating a plurality of pressure measurements;

calculating energy values for the accumulated measurements of pressure differences and pressure;

determining a phase difference between the pressure measurements and the pressure difference measurements; and

comparing the energy values and the phase difference to thresholds to determine full or partial closure of a patient's breathing passages.

6. A method as set forth in Claim 1, wherein the step of detecting indication of sleep disorder breathing further includes:

determining if the measured flow related variable exceeds a threshold for an interface off condition;

responsive to an affirmative determination of the interface off condition, signaling the interface off condition;

absent determination of an interface off condition, determining if a pressure difference mean baseline exceeds a threshold for an interface leak condition; and

responsive to an affirmative determination of an interface leak condition, signaling the interface leak condition.

7. The method as set forth in Claim 1, wherein the step of detecting sleep disorder breathing further includes:

comparing a baseline calculation and a standard deviation calculation for a plurality of samples of measured pressure related variables against a plurality of a thresholds for failure of supply of compressed air.

8. A method for sleep disorder breathing therapy of a person, comprising the steps of:

connecting a face mask (39) from an air compressor (43) to a person's breathing passages;

supplying air from the air compressor through an interface (46, 47) to the face mask;

periodically measuring pressure difference along the interface and pressure in the face mask;

detecting from the measured pressure difference and the face mask pressure indications of sleep disorder breathing;

responsive to the detection of indications of sleep disorder breathing, adjusting pressure from the compressor while continuing to monitor pressure and pressure difference for continued indication of sleep disorder breathing; and

responsive to passage of a period without detection of indications of sleep disorder breathing, adjusting pressure of the compressed air.

9. A method as set forth in Claim 8, wherein the step of detecting indications of sleep disorder breathing includes:

taking mean pressure difference measurements at each of a plurality of sample points during an interval; and

calculating a mean for the sample points of each interval and a standard deviation for the sample of points of the interval.

10. A method as set forth in Claim 9 wherein the step for detecting indications of sleep disorder breathing further includes:

generating an initial base line from an accumulation of mean values for a sequence of intervals of sample points;

thereafter adjusting the baseline for each subsequent pressure difference mean calculated; and

generating an area of respiration value from the area difference between the base line and each pressure difference mean calculated.

11. A method as set forth in Claim 10, wherein the step of detecting indications of sleep disorder breathing further includes:

maintaining a first-in, first-out list of areas of respiration measurements for a plurality of respiration measurements;

calculating a hypopnea threshold from the measurements in the first-in, first-out list;

comparing each area of respiration measurement against the hypopnea threshold and indicating hypopnea if the area fails to meet the threshold either as a single value or multiple values over a period of time.

12. A method as set forth in Claim 10, wherein the step of detecting indications of sleep disorder breathing further includes:

providing an apnea threshold;

comparing the absolute value of the difference between the mean pressure difference for a latest interval and the baseline against the apnea threshold; and

if the absolute value is less than the apnea threshold over a period of time, signaling that apnea is occurring.

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13. A method as set forth in Claim 10, wherein the step of supplying air from the air compressor through the interface to a face mask further includes:

setting an initial command pressure to control pressure from the air compressor at a minimum setting.

14. A method as set forth in Claim 13, wherein the step of adjusting pressure from the compressor while continuing to monitor pressure and pressure difference for continued indication of sleep disorder breathing further includes:

adjusting command pressure in response to signaling by the step of detecting, indications of sleep disorder breathing.

15. A method as set forth in Claim 14, wherein the step of detecting indications of sleep disorder breathing further include:

setting a pharyngeal wall vibration threshold;

comparing variation of the standard deviation for a most current interval beyond a standard deviation threshold against the pharyngeal wall vibration threshold; and

responsive to the variation in standard deviation exceeding the threshold over a period of time and signaling the occurrence of pharyngeal wall vibration.

16. A method as set forth in Claim 8, wherein the step adjusting pressure further includes:

responsive to determination that indications of sleep disorder breathing are present, periodically boosting the pressure for as long

as the indications remain and pressure is less than a maximum permitted level; and

absent determination that indications of sleep disorder breathing are present, periodically reducing the pressure as long as pressure remains above a minimum permitted level.

17. Apparatus for controlling sleep disorder breathing comprising:

a source of compressed breathable gas (43);

an interface (41) connected at a first end to the source of compressed breathable gas and adapted at a second end (39) to fit over a person's breathing passages;

means for measuring differential pressure (45, 47, 51) from the first end to the second end of the interface;

means for measuring pressure (46, 48, 53) in the second end of the interface;

means for detecting indications in the measurements of sleep disorder breathing (49, 55, 57) from the measurement of pressure and differential pressure;

means responsive to detection of indications of sleep disorder breathing (57, 58) for adjusting pressure of breathable gas from the source of breathable gas; and

means responsive to passage of a period of time without detection of indication of sleep disorder breathing (57) for adjusting pressure from the source of breathable gas.

18. Apparatus as set forth in Claim 17, wherein the means for detecting indications of sleep disorder breathing include:

means for calculating a mean over a set of sample points taken during an interval and for calculating a standard deviation for the set of sample points; and

means for accumulating mean values for a plurality of intervals.

19. Apparatus as set forth in Claim 18, wherein the means for detecting indications of sleep disorder breathing furtner include:

means for generating an initial base line from the accumulation of mean values for a sequence of intervals of sample points;

means for adjusting the initial baseline for each subsequent pressure difference mean calculated; and

means for generating an area of respiration value from the area difference between the base line and each pressure difference mean calculated.

20. Apparatus as set forth in Claim 19, wherein the means for detecting indications of sleep disorder breathing further include:

maintaining a first-in, first-out list of areas of respiration measurements for a plurality of respiration measurements;

calculating a hypopnea threshold from the measurements in the first-in, first-out list;

means for comparing each area of respiration measurement against the hypopnea threshold and for indicating hypopnea if the area fails to meet the threshold either as a single value or multiple values over a period of time.

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21. Apparatus as set forth in Claim 19, wherein the means for detecting indications of sleep disorder breathing further include:

an apnea threshold;

means for comparing the absolute value of the difference between the mean pressure difference for a latest interval and the baseline against the apnea threshold; and

means responsive to the absolute value being less than the apnea threshold over a period of time for signaling that apnea is occurring.

22. Apparatus as set forth in Claim 19, wherein the means for supplying breathable gas to the interface further include:

means for setting an initial command pressure to control pressure from the compressed breathable gas source at a minimum setting.

23. Apparatus as set forth in Claim 22, wherein the means for adjusting pressure from the compressed breathable gas source while continuing to monitor pressure and pressure difference for continued indication of sleep disorder breathing further include:

means for adjusting command pressure in response to signaling by the means for detecting of sleep disorder breathing.

24. Apparatus as set forth in Claim 23, wherein the means for detecting indications of sleep disorder breathing further include:

means for setting a minimum standard deviation threshold as a function of the command pressure;

means for computing the area and duration of the standard deviation curve above the minimum standard deviation threshold;

means for comparing the area and duration against their corresponding thresholds; and

means responsive to the area and duration exceeding their respective thresholds for signaling occurrence of pharyngeal wall vibration.

25. Apparatus as set forth in Claim 17, wherein the means for adjusting pressure further include:

means responsive to determination that an indication of sleep disorder breathing is present for periodically boosting pressure from the source of compressed breathable gas for as long as the indication remains and pressure is less than a maximum permitted level; and

means responsive to passage of a period without determination that indications of sleep disorder breathing are present for periodically reducing pressure as long as pressure remains above a minimum permitted level.

26. A method of controlling sleep disorder breathing in a person substantially as hereinbefore described with reference to the accompanying drawings.

27. A method for sleep disorder breathing therapy of a person substantially as hereinbefore described with reference to the accompanying drawings.

28. Apparatus for controlling sleep disorder breathing substantially as hereinbefore described with reference to the accompanying drawings.

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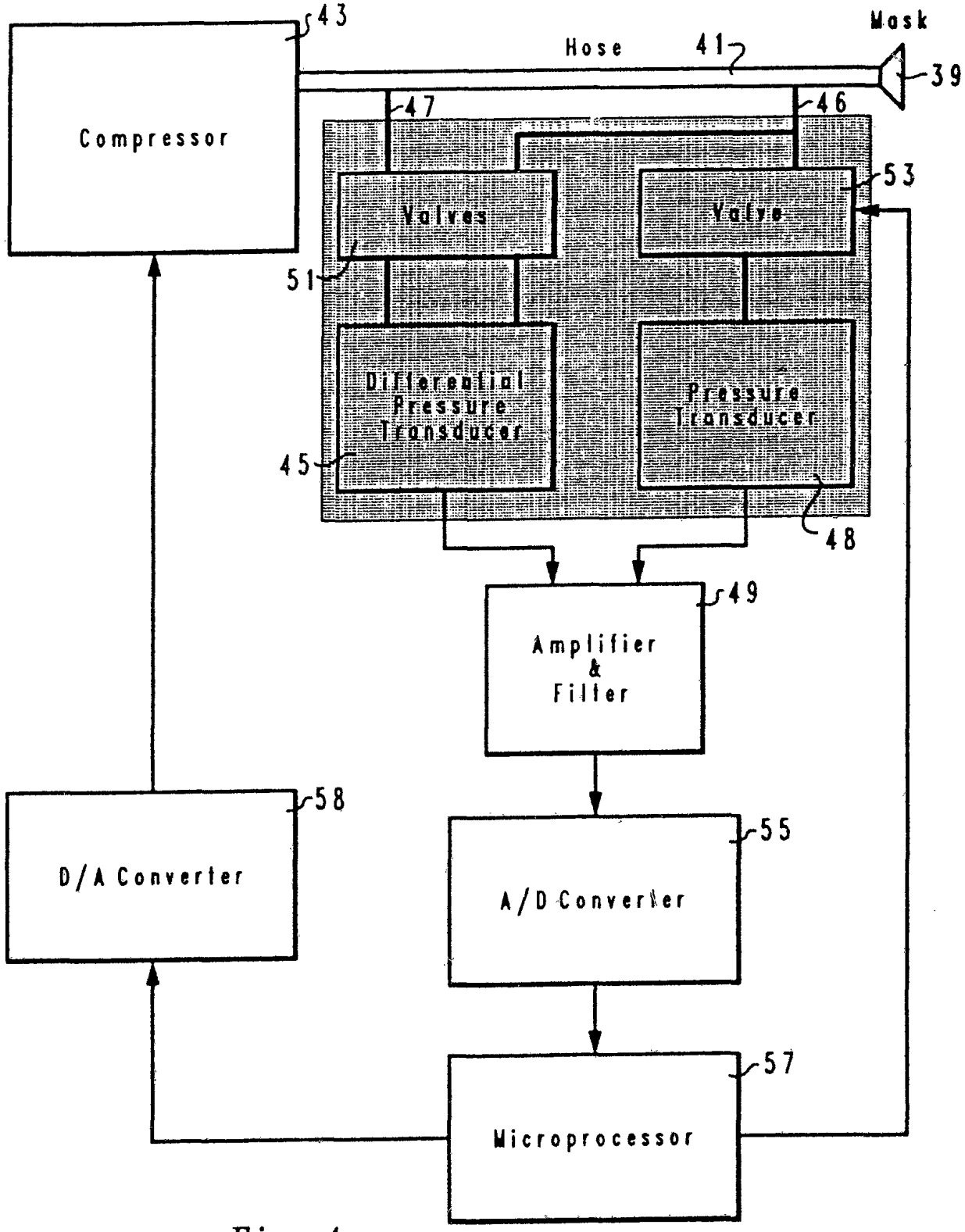

43
Mask
Hose
41
39
Compressor
47
46
53
Valves
Valve
51
Differential Pressure Transducer
Pressure Transducer
45
48
49
Amplifier & Filter
58
55
D/A Converter
A/D Converter
57
Microprocessor

Fig. 1

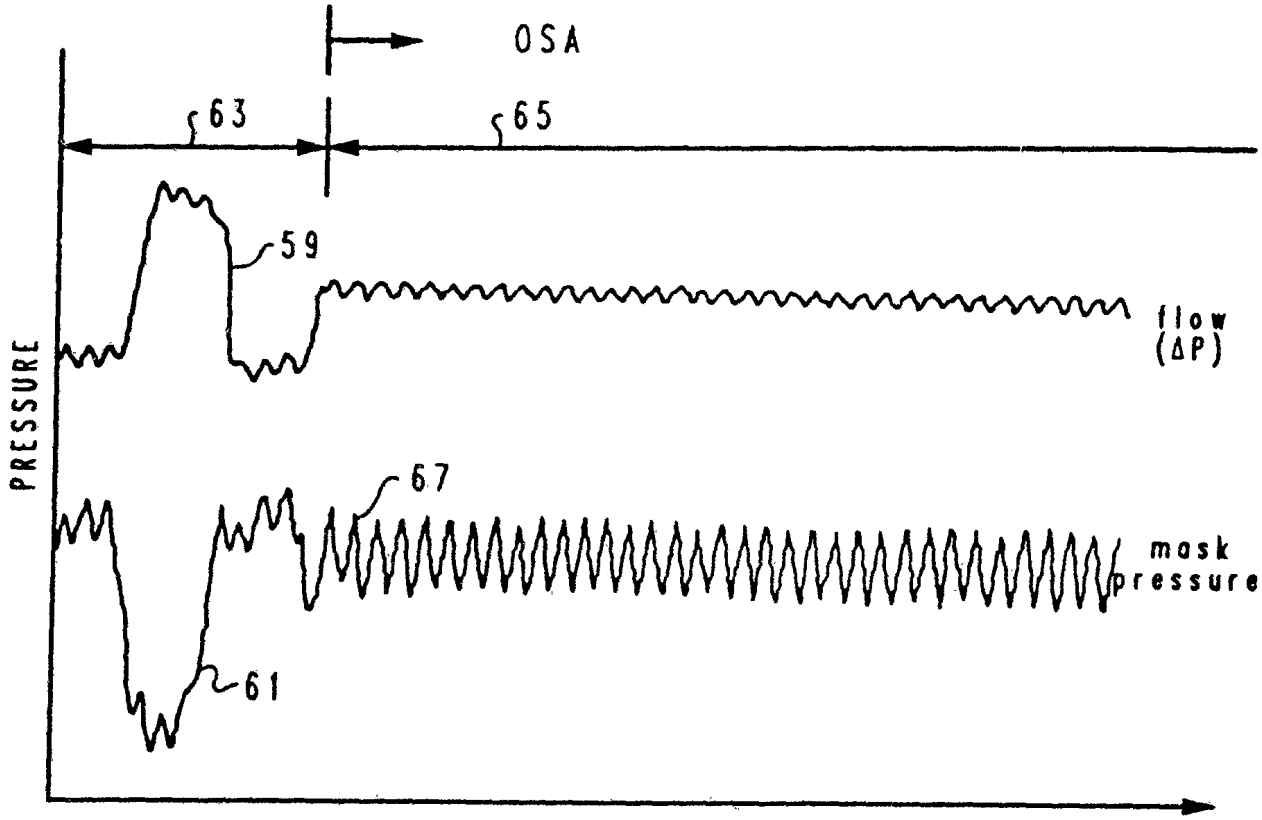

OSA
63
65
59
flow
(ΔP)
PRESSURE
67
mask
pressure
61
TIME

Fig. 2

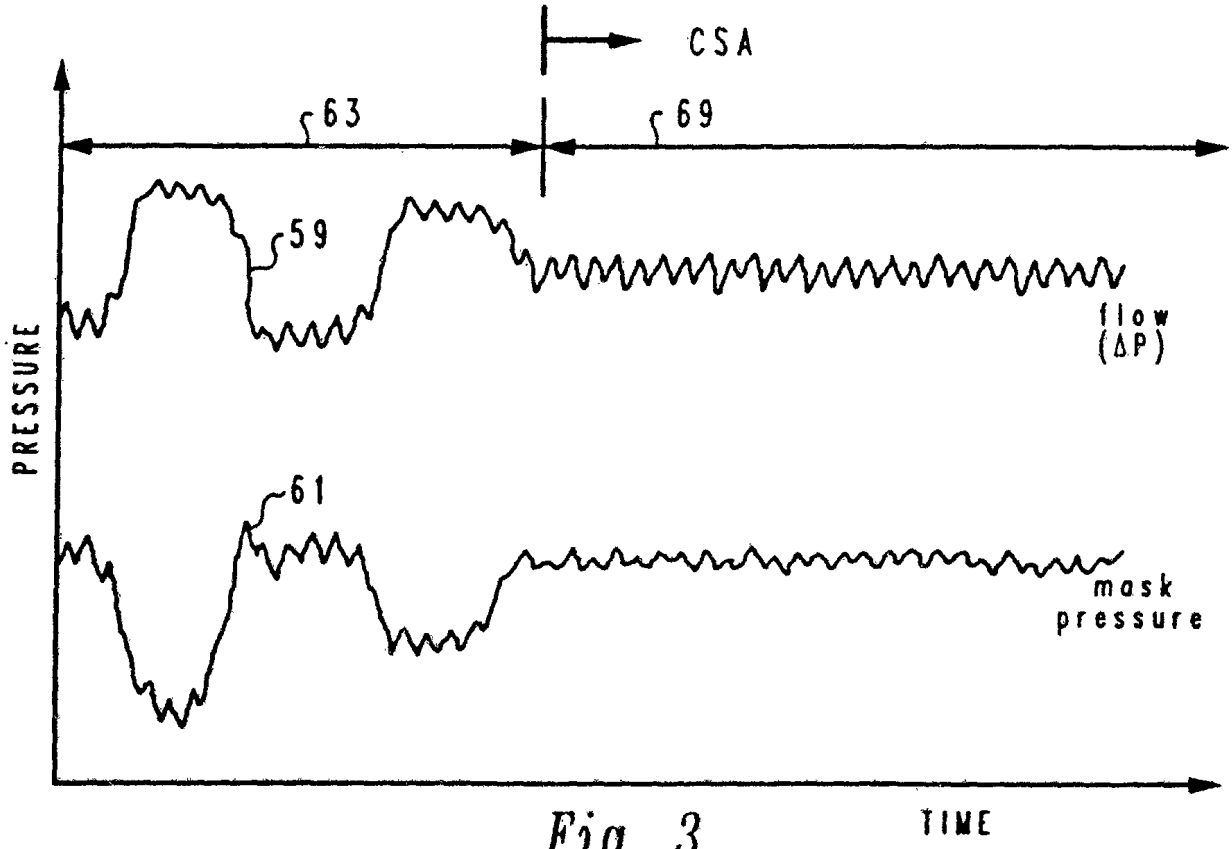

CSA
63
69
59
flow
(ΔP)
PRESSURE
61
mask
pressure
TIME

Fig. 3

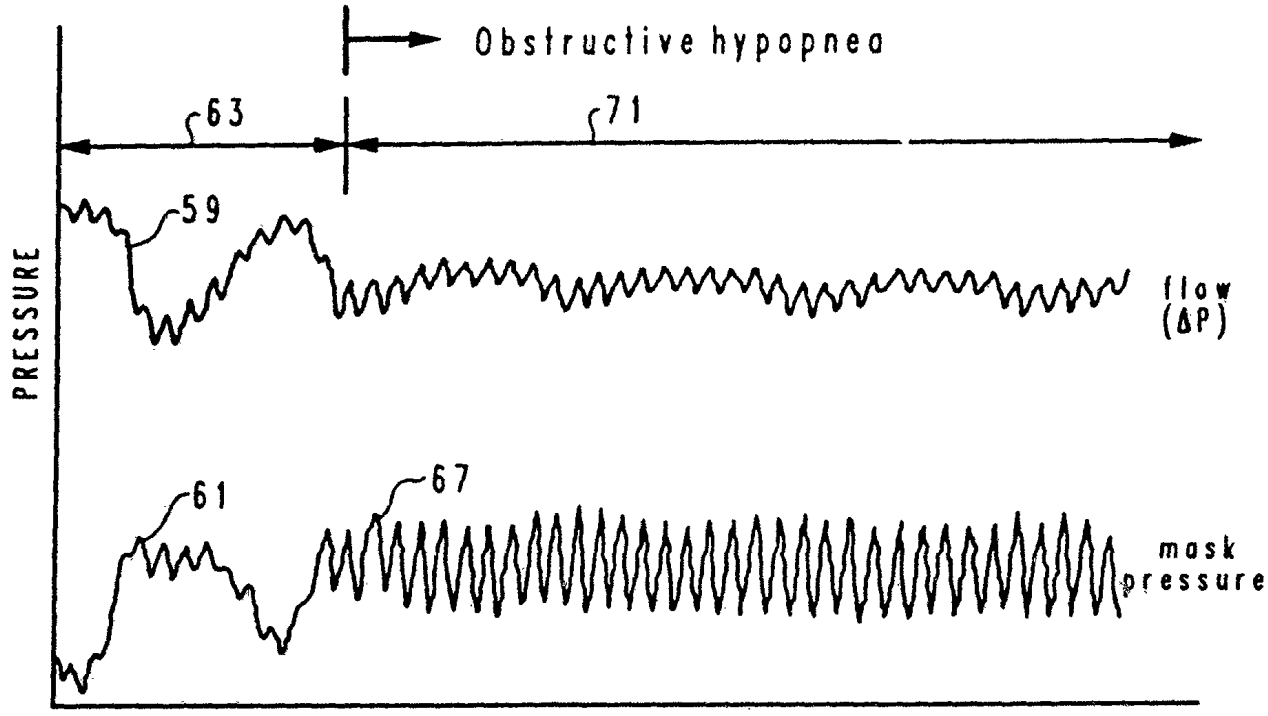

Obstructive hypopnea
63
71
59
PRESSURE
flow (ΔP)
61
67
mask pressure
TIME

Fig. 4

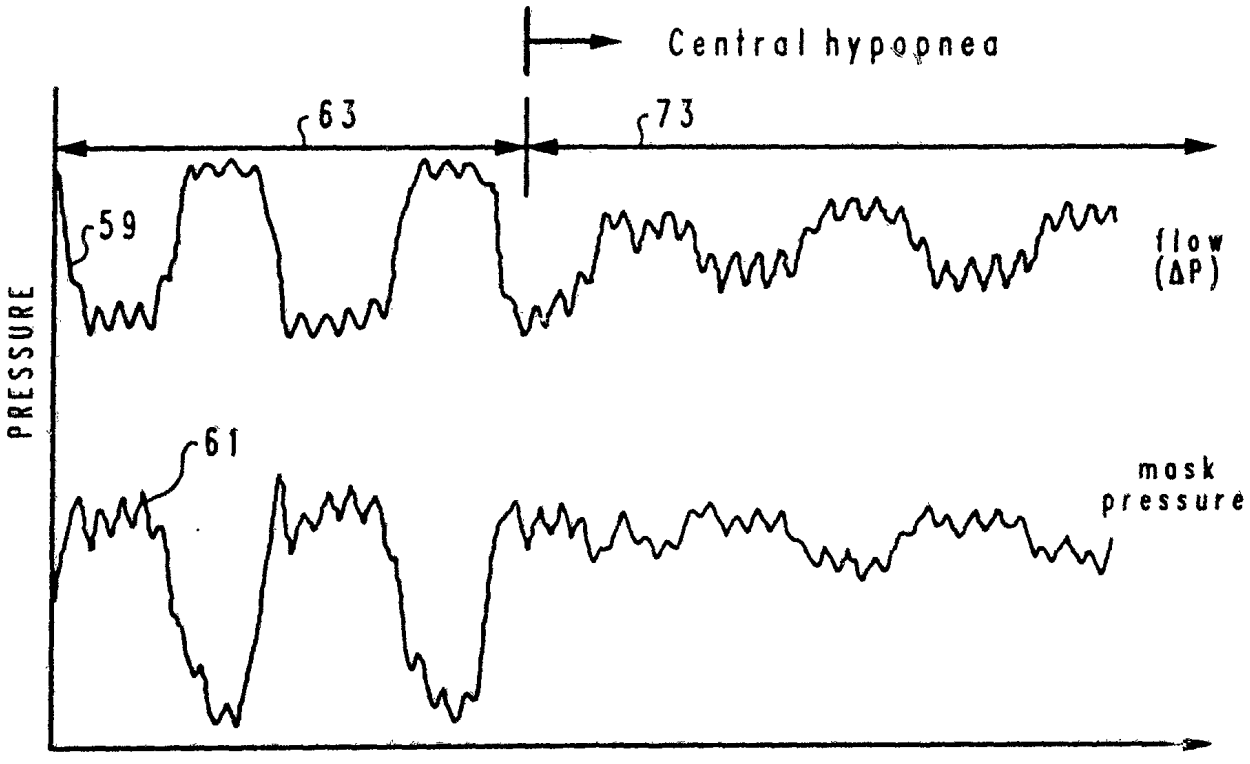

Central hypopnea
63
73
59
PRESSURE
flow (ΔP)
61
mask pressure
TIME

Fig. 5

Fig. 6

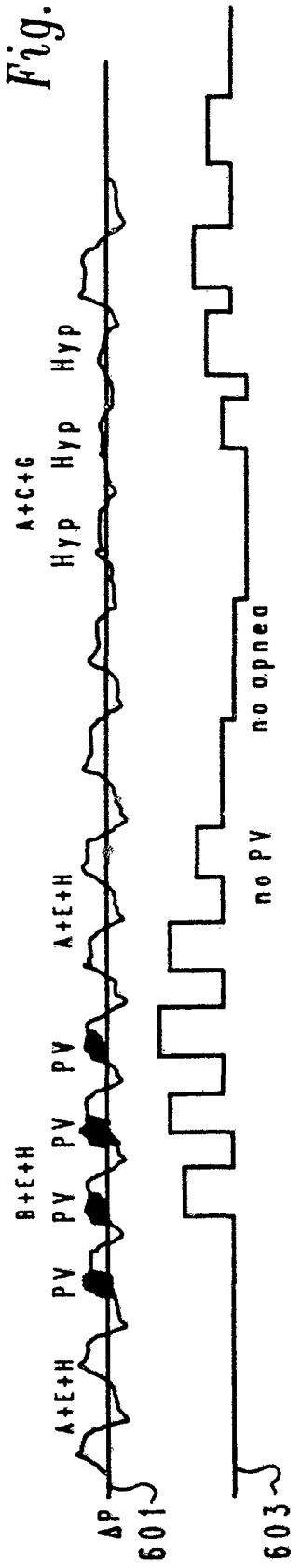


Fig. 7

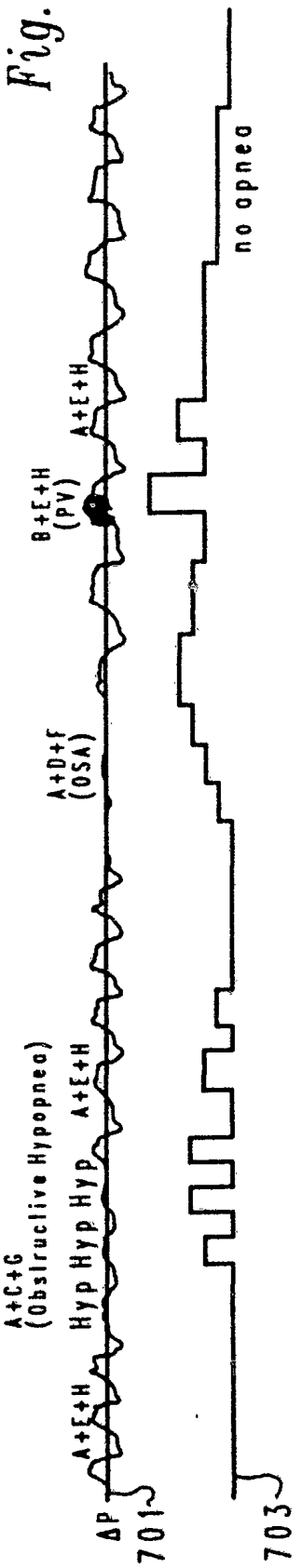
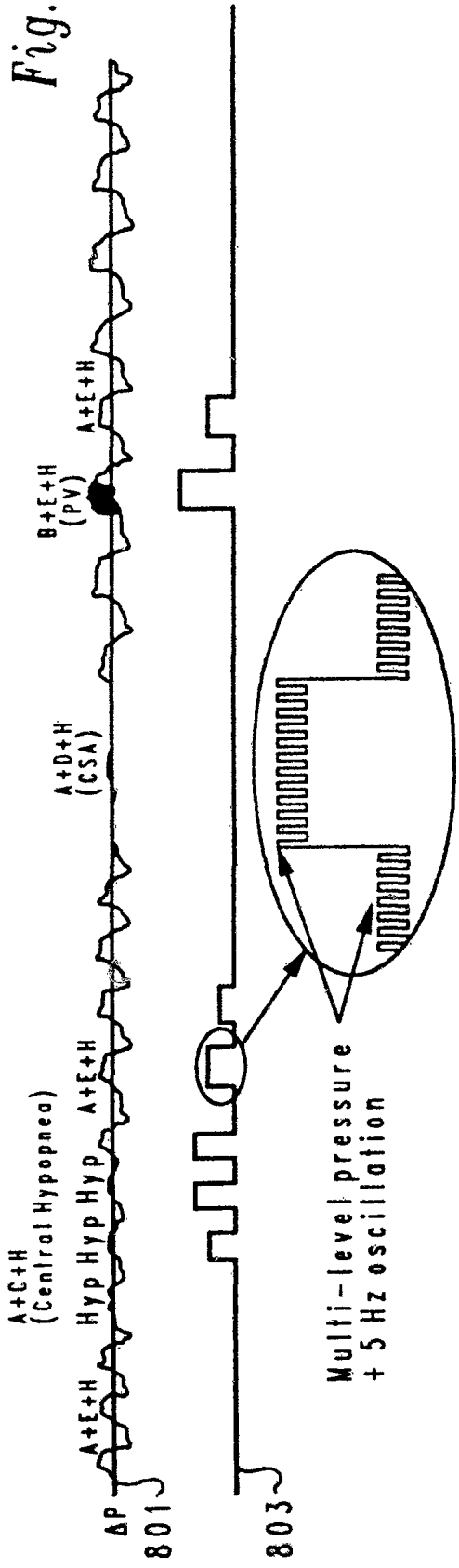


Fig. 8



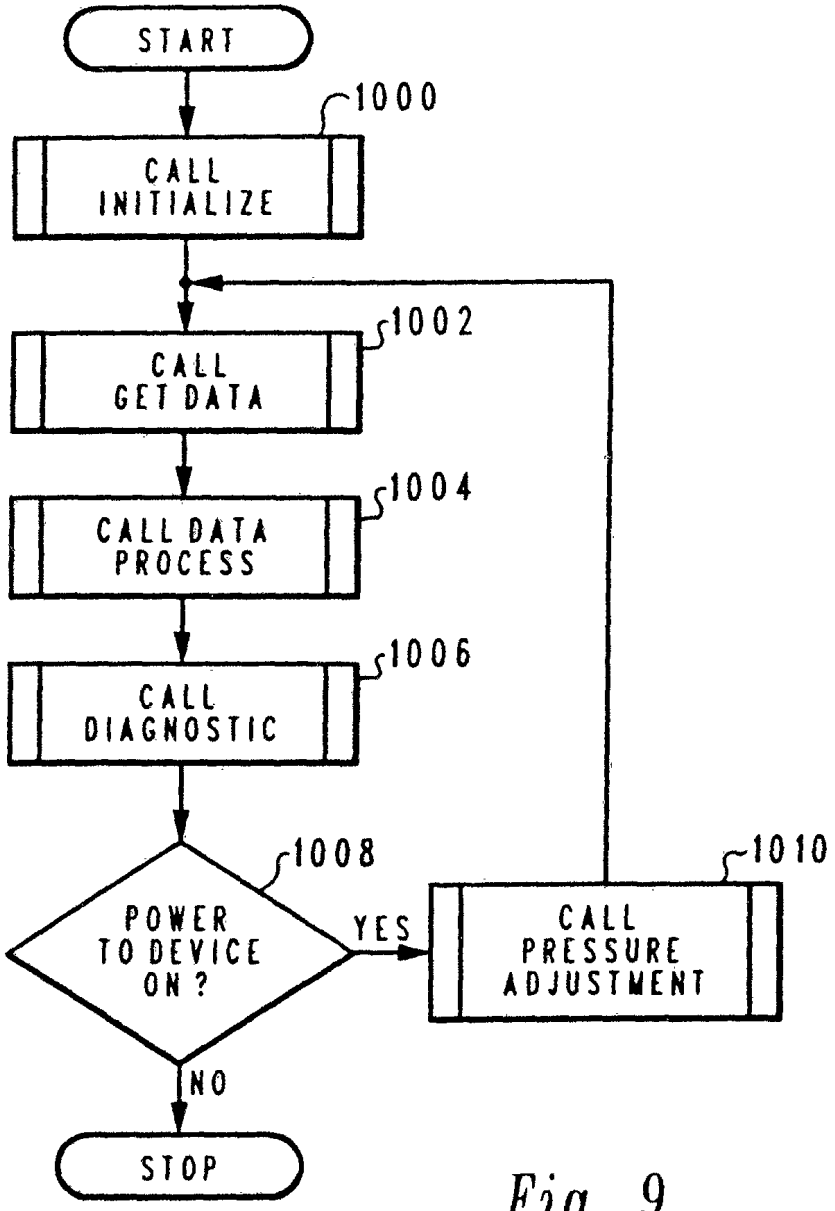

START
1000
CALL INITIALIZE
1002
CALL GET DATA
1004
CALL DATA PROCESS
1006
CALL DIAGNOSTIC
1008
POWER TO DEVICE ON ?
YES
1010
CALL PRESSURE ADJUSTMENT
NO
STOP

Fig. 9

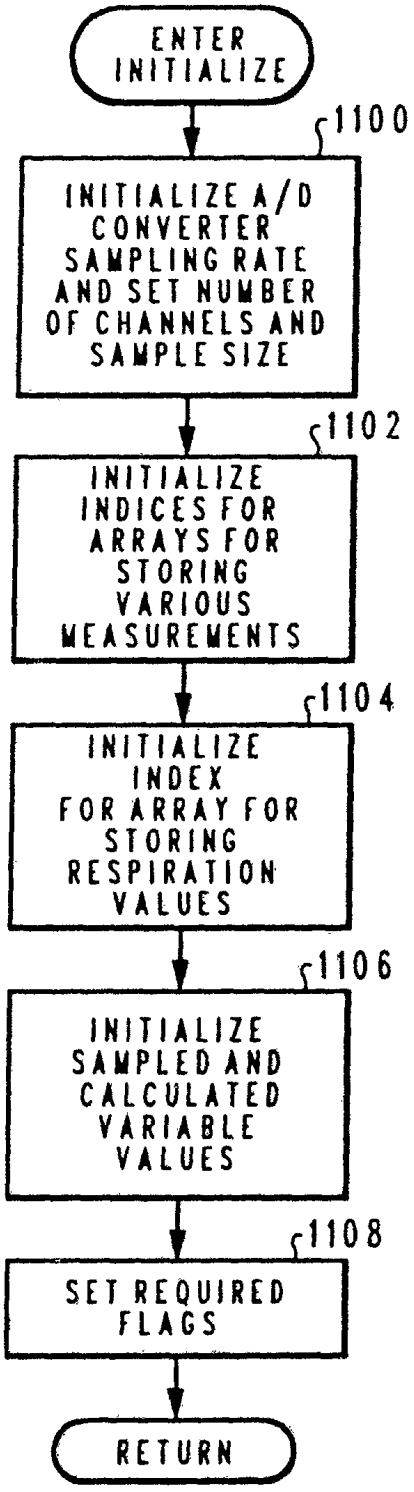

ENTER INITIALIZE
1100
INITIALIZE A/D CONVERTER SAMPLING RATE AND SET NUMBER OF CHANNELS AND SAMPLE SIZE
1102
INITIALIZE INDICES FOR ARRAYS FOR STORING VARIOUS MEASUREMENTS
1104
INITIALIZE INDEX FOR ARRAY FOR STORING RESPIRATION VALUES
1106
INITIALIZE SAMPLED AND CALCULATED VARIABLE VALUES
1108
SET REQUIRED FLAGS
RETURN

Fig. 10

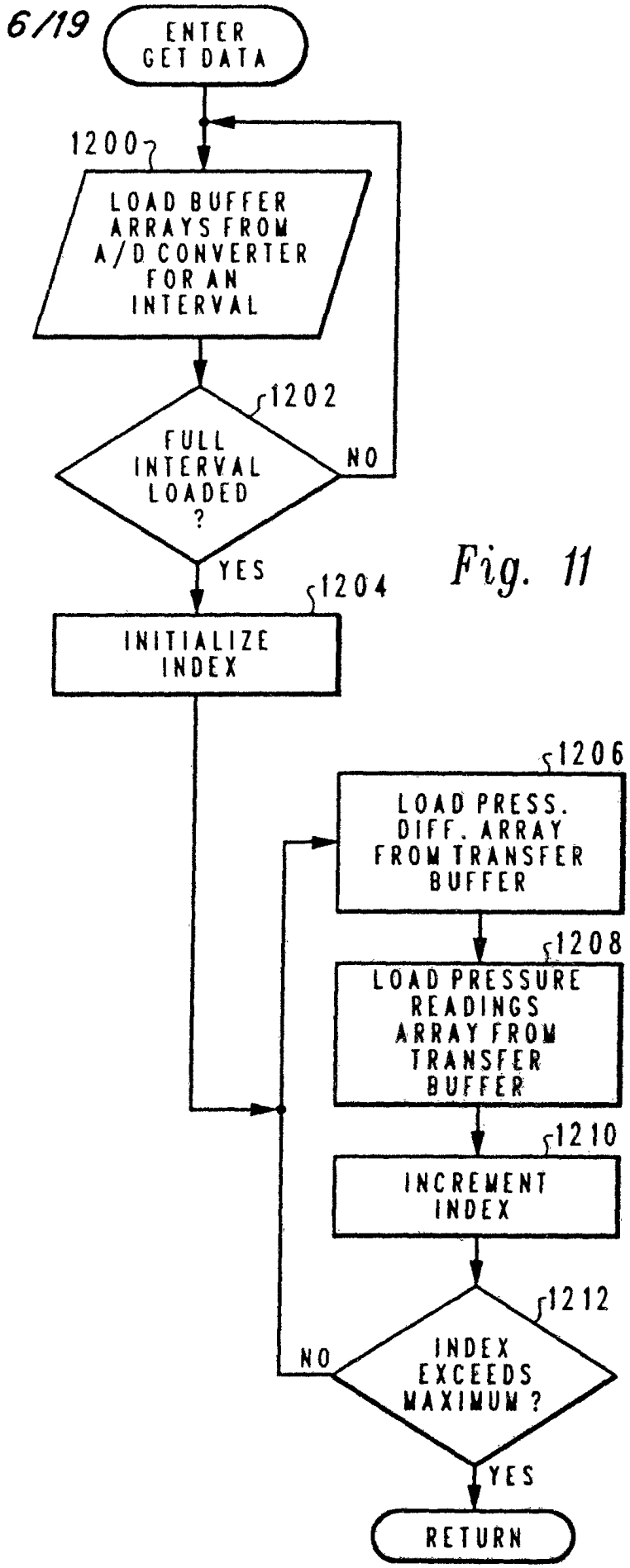
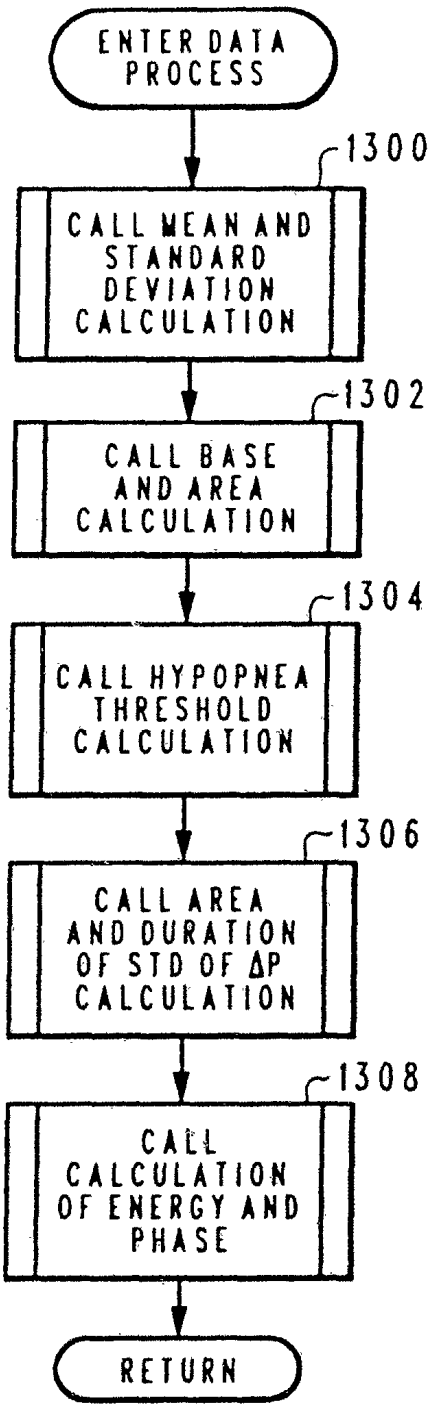

ENTER GET DATA
1200
LOAD BUFFER ARRAYS FROM A/D CONVERTER FOR AN INTERVAL
1202
FULL INTERVAL LOADED ?
NO
YES
1204
INITIALIZE INDEX
1206
LOAD PRESS. DIFF. ARRAY FROM TRANSFER BUFFER
1208
LOAD PRESSURE READINGS ARRAY FROM TRANSFER BUFFER
1210
INCREMENT INDEX
1212
INDEX EXCEEDS MAXIMUM ?
NO
YES
RETURN

Fig. 11

Fig. 12


ENTER DATA PROCESS
1300
CALL MEAN AND STANDARD DEVIATION CALCULATION
1302
CALL BASE AND AREA CALCULATION
1304
CALL HYPOPNEA THRESHOLD CALCULATION
1306
CALL AREA AND DURATION OF STD OF ΔP CALCULATION
1308
CALL CALCULATION OF ENERGY AND PHASE
RETURN

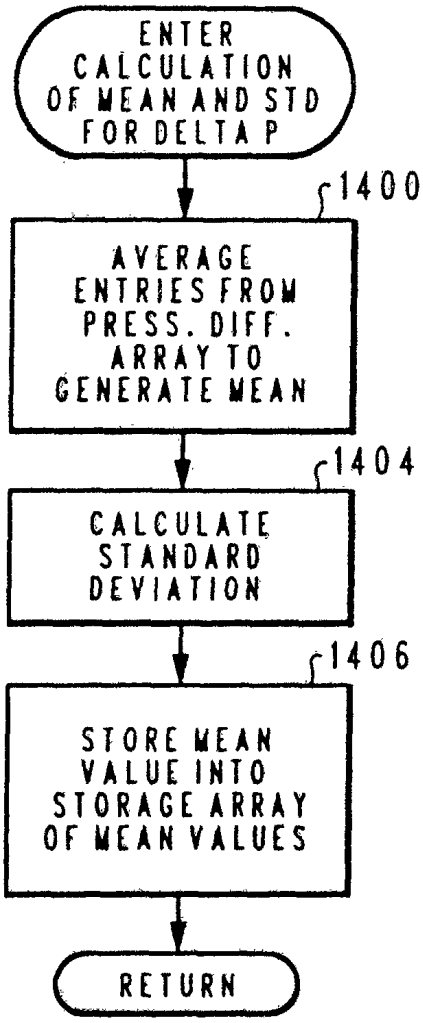

ENTER CALCULATION OF MEAN AND STD FOR DELTA P
1400
AVERAGE ENTRIES FROM PRESS. DIFF. ARRAY TO GENERATE MEAN
1404
CALCULATE STANDARD DEVIATION
1406
STORE MEAN VALUE INTO STORAGE ARRAY OF MEAN VALUES
RETURN

Fig. 13

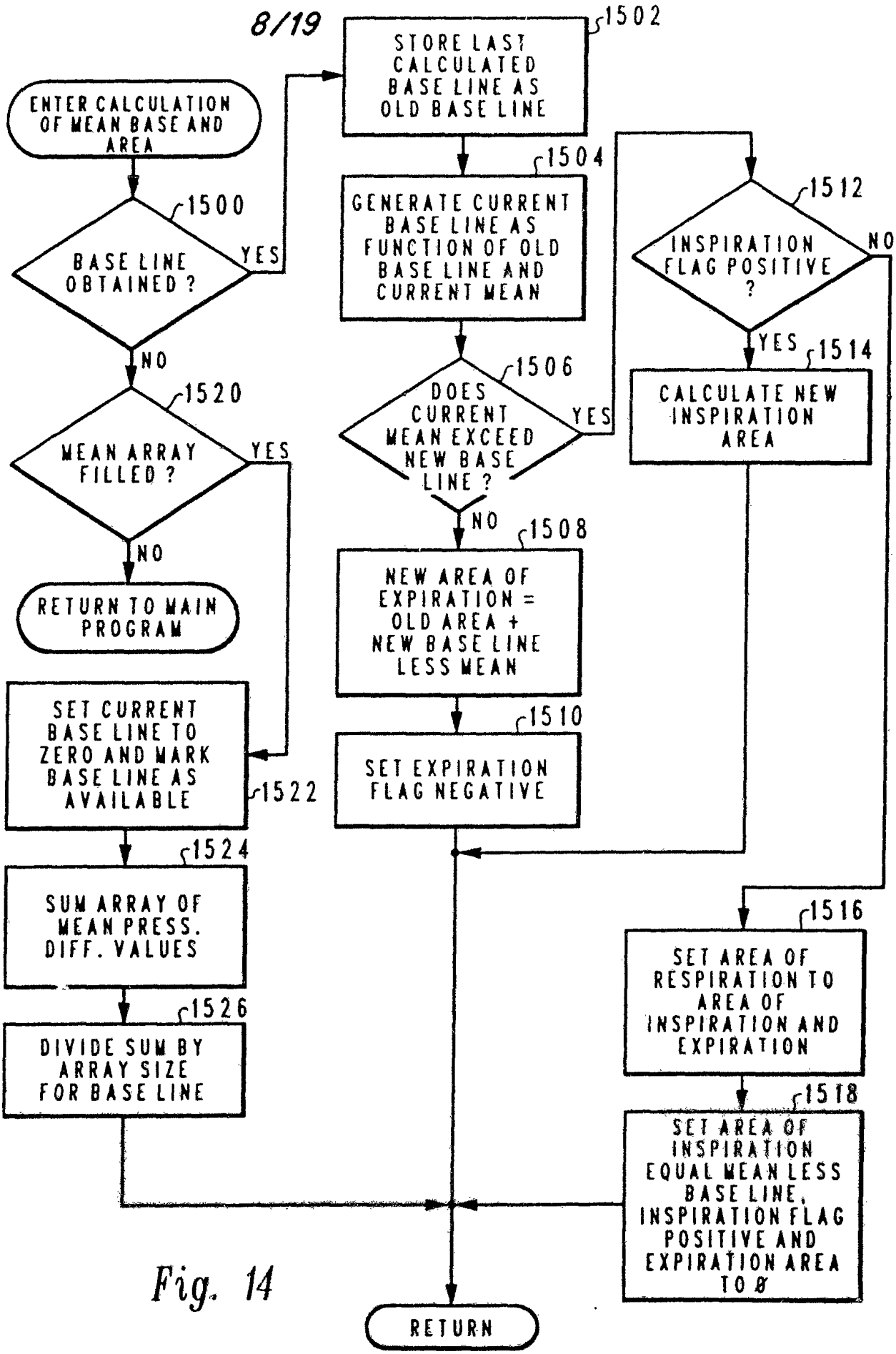

ENTER CALCULATION OF MEAN BASE AND AREA
1500
BASE LINE OBTAINED ?
YES
NO
1520
MEAN ARRAY FILLED ?
YES
NO
RETURN TO MAIN PROGRAM
SET CURRENT BASE LINE TO ZERO AND MARK BASE LINE AS AVAILABLE
1522
1524
SUM ARRAY OF MEAN PRESS. DIFF. VALUES
1526
DIVIDE SUM BY ARRAY SIZE FOR BASE LINE
1502
STORE LAST CALCULATED BASE LINE AS OLD BASE LINE
1504
GENERATE CURRENT BASE LINE AS FUNCTION OF OLD BASE LINE AND CURRENT MEAN
1506
DOES CURRENT MEAN EXCEED NEW BASE LINE ?
YES
NO
1508
NEW AREA OF EXPIRATION = OLD AREA + NEW BASE LINE LESS MEAN
1510
SET EXPIRATION FLAG NEGATIVE
1512
INSPIRATION FLAG POSITIVE ?
NO
YES
1514
CALCULATE NEW INSPIRATION AREA
1516
SET AREA OF RESPIRATION TO AREA OF INSPIRATION AND EXPIRATION
1518
SET AREA OF INSPIRATION EQUAL MEAN LESS BASE LINE, INSPIRATION FLAG POSITIVE AND EXPIRATION AREA TO 0
RETURN

Fig. 14

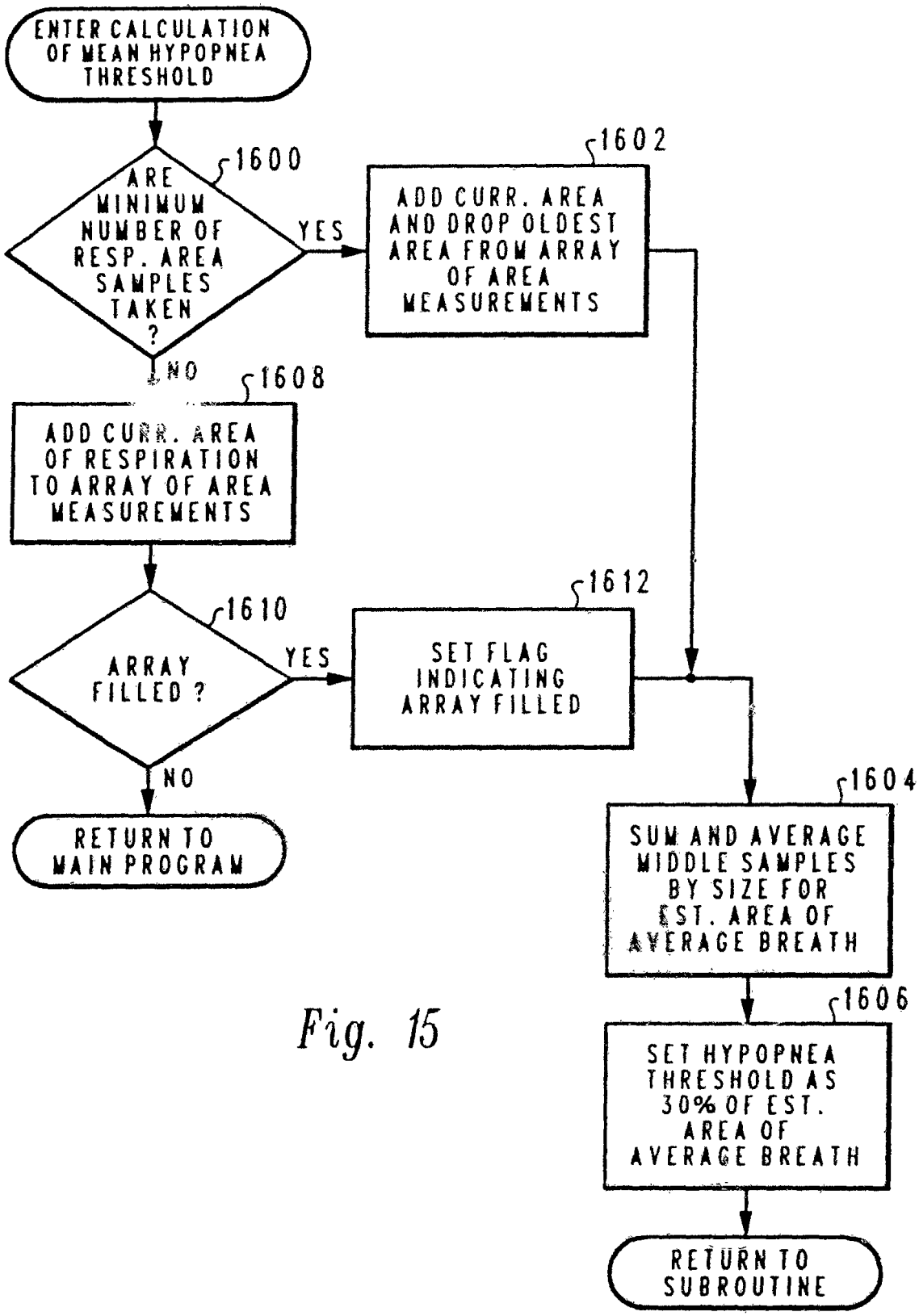

ENTER CALCULATION OF MEAN HYPOPNEA THRESHOLD
1600
ARE MINIMUM NUMBER OF RESP. AREA SAMPLES TAKEN ?
YES
NO
1602
ADD CURR. AREA AND DROP OLDEST AREA FROM ARRAY OF AREA MEASUREMENTS
1608
ADD CURR. AREA OF RESPIRATION TO ARRAY OF AREA MEASUREMENTS
1610
ARRAY FILLED ?
YES
NO
1612
SET FLAG INDICATING ARRAY FILLED
RETURN TO MAIN PROGRAM
1604
SUM AND AVERAGE MIDDLE SAMPLES BY SIZE FOR EST. AREA OF AVERAGE BREATH
1606
SET HYPOPNEA THRESHOLD AS 30% OF EST. AREA OF AVERAGE BREATH
RETURN TO SUBROUTINE

Fig. 15

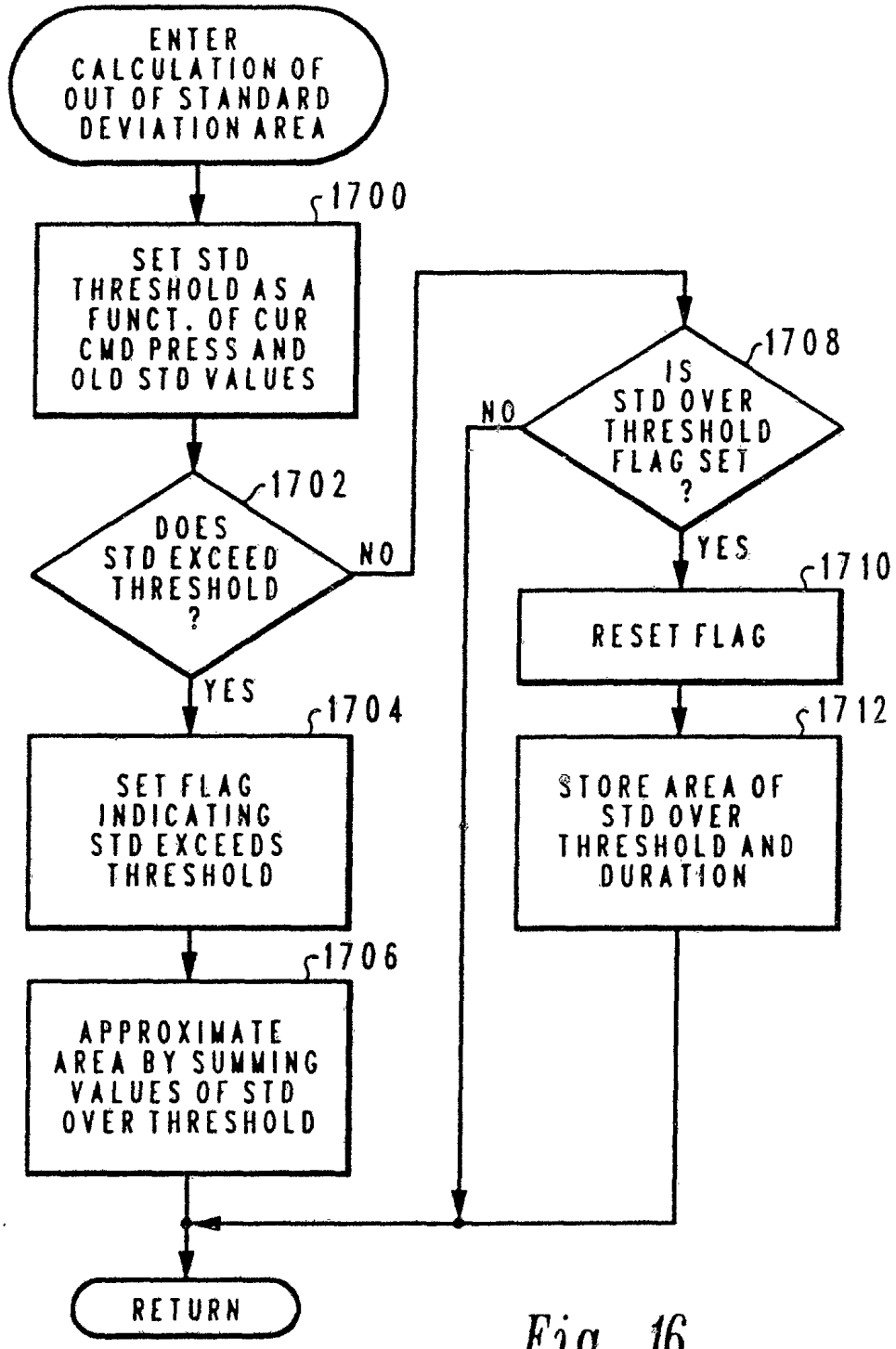
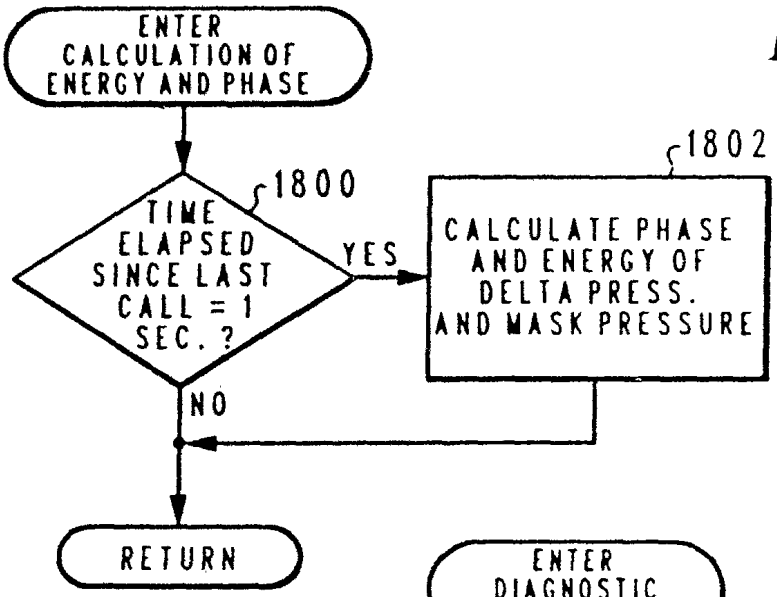

ENTER CALCULATION OF OUT OF STANDARD DEVIATION AREA
1700
SET STD THRESHOLD AS A FUNCT. OF CUR CMD PRESS AND OLD STD VALUES
1702
DOES STD EXCEED THRESHOLD ?
NO
YES
1704
SET FLAG INDICATING STD EXCEEDS THRESHOLD
1706
APPROXIMATE AREA BY SUMMING VALUES OF STD OVER THRESHOLD
RETURN
1708
IS STD OVER THRESHOLD FLAG SET ?
NO
YES
1710
RESET FLAG
1712
STORE AREA OF STD OVER THRESHOLD AND DURATION

Fig. 16

Fig. 17


ENTER CALCULATION OF ENERGY AND PHASE
1800
TIME ELAPSED SINCE LAST CALL = 1 SEC. ?
YES
1802
CALCULATE PHASE AND ENERGY OF DELTA PRESS. AND MASK PRESSURE
NO
RETURN

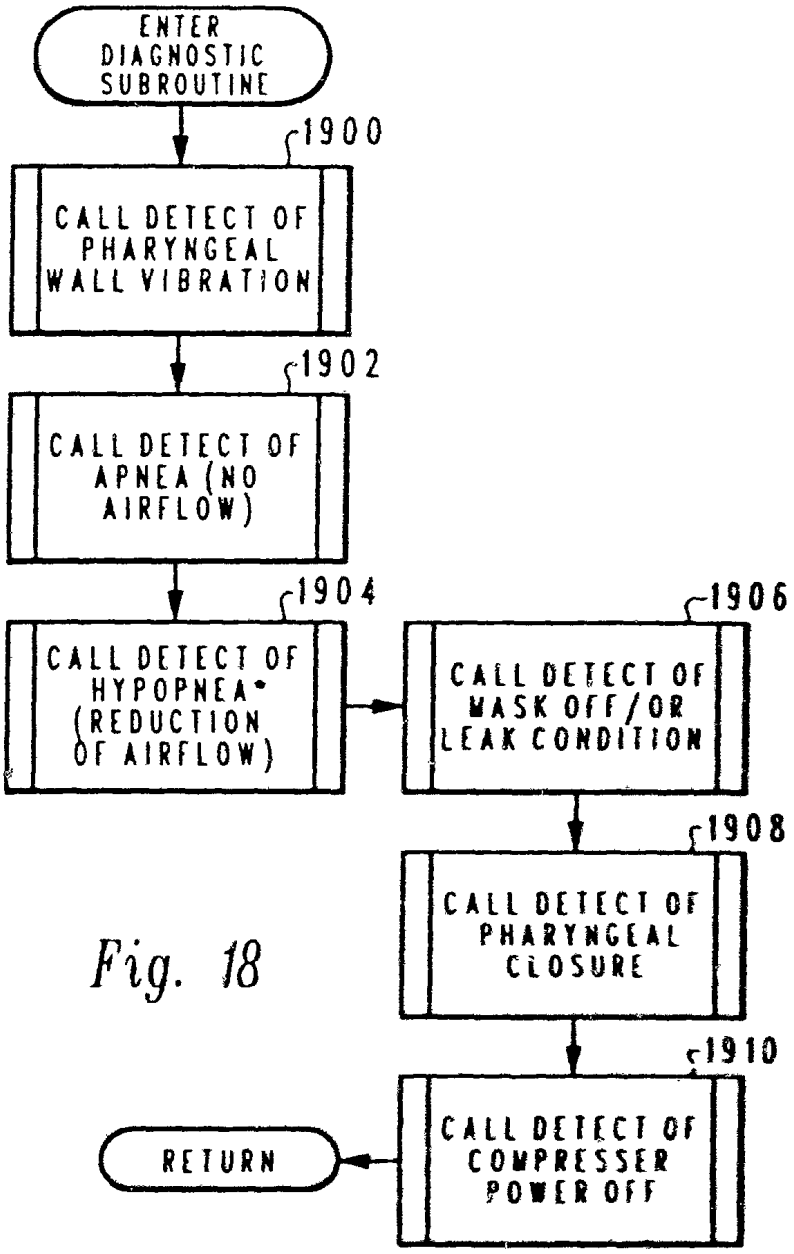

ENTER DIAGNOSTIC SUBROUTINE
1900
CALL DETECT OF PHARYNGEAL WALL VIBRATION
1902
CALL DETECT OF APNEA (NO AIRFLOW)
1904
CALL DETECT OF HYPOPNEA (REDUCTION OF AIRFLOW)
1906
CALL DETECT OF MASK OFF/OR LEAK CONDITION
1908
CALL DETECT OF PHARYNGEAL CLOSURE
1910
CALL DETECT OF COMPRESSER POWER OFF
RETURN

Fig. 18

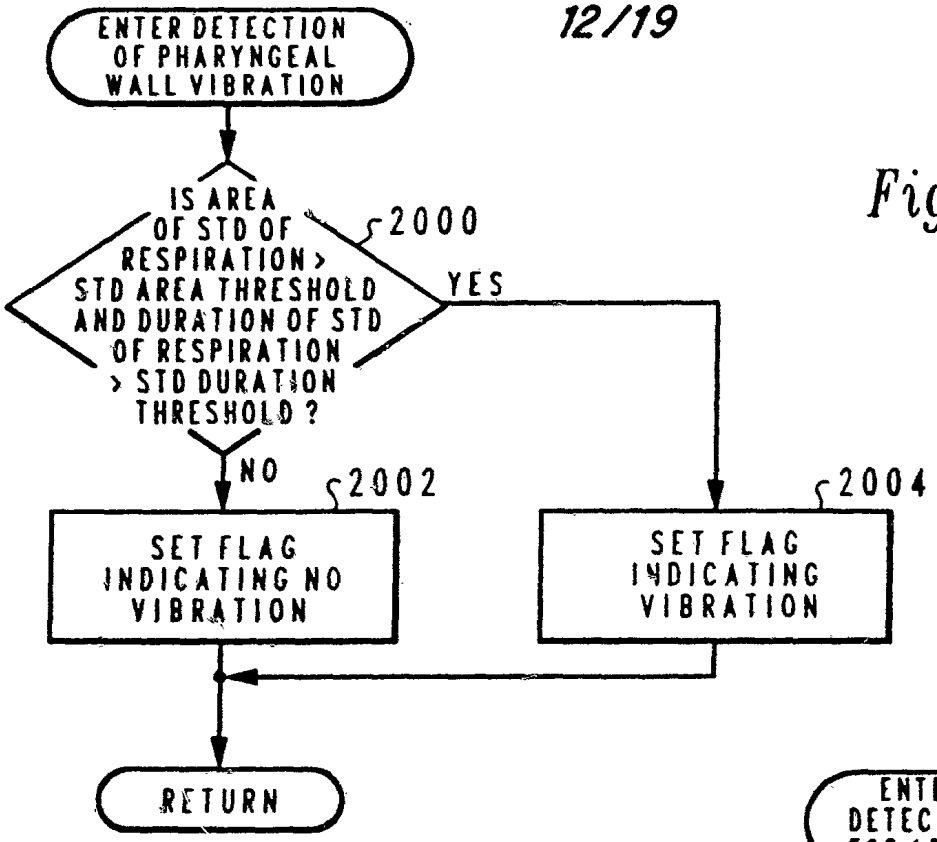

ENTER DETECTION OF PHARYNGEAL WALL VIBRATION
IS AREA OF STD OF RESPIRATION > STD AREA THRESHOLD AND DURATION OF STD OF RESPIRATION > STD DURATION THRESHOLD ?
2000
YES
NO
2002
2004
SET FLAG INDICATING NO VIBRATION
SET FLAG INDICATING VIBRATION
RETURN

Fig. 19

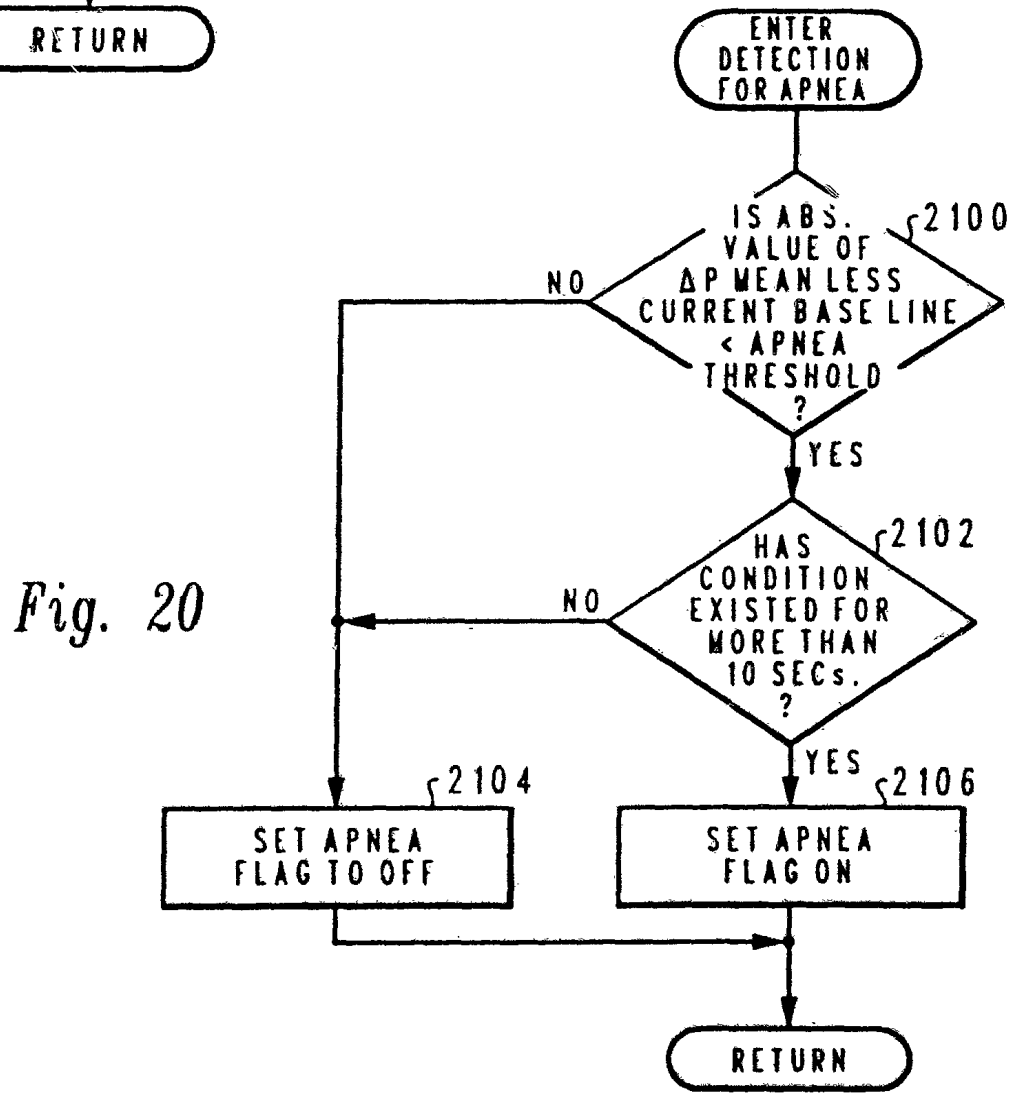

ENTER DETECTION FOR APNEA
IS ABS. VALUE OF ΔP MEAN LESS CURRENT BASE LINE < APNEA THRESHOLD ?
2100
NO
YES
HAS CONDITION EXISTED FOR MORE THAN 10 SECs. ?
2102
NO
YES
2104
2106
SET APNEA FLAG TO OFF
SET APNEA FLAG ON
RETURN

Fig. 20

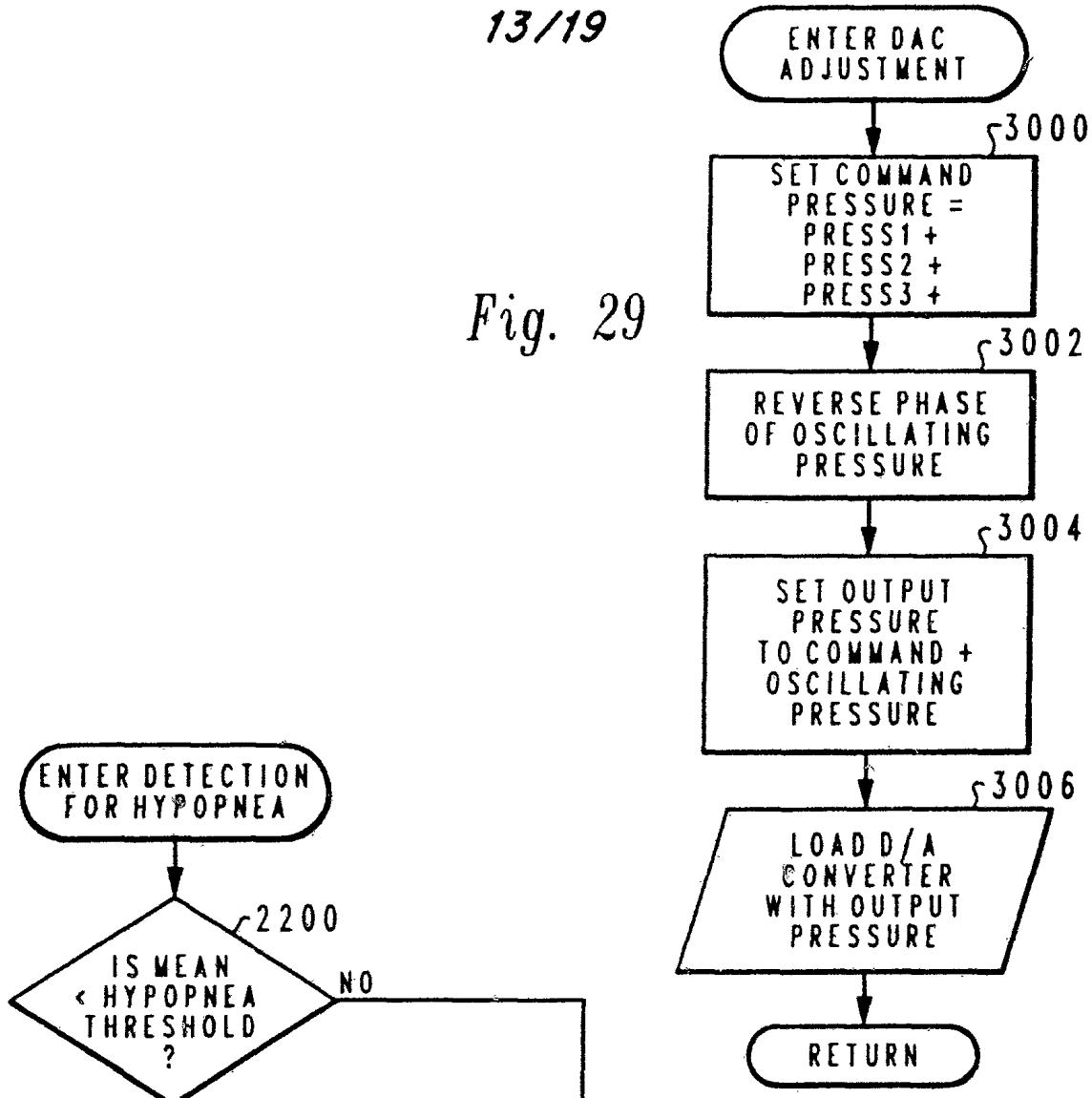

ENTER DAC ADJUSTMENT
3000
SET COMMAND PRESSURE = PRESS1 + PRESS2 + PRESS3 +
3002
REVERSE PHASE OF OSCILLATING PRESSURE
3004
SET OUTPUT PRESSURE TO COMMAND + OSCILLATING PRESSURE
3006
LOAD D/A CONVERTER WITH OUTPUT PRESSURE
RETURN

Fig. 29

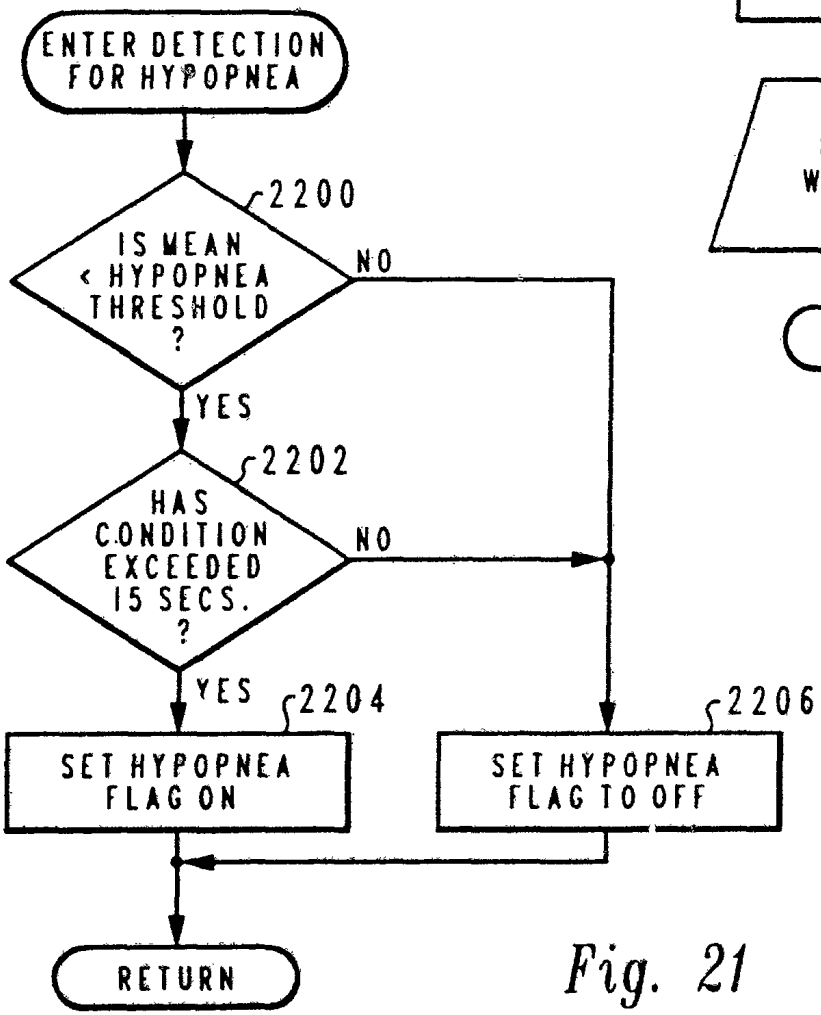

ENTER DETECTION FOR HYPOPNEA
2200
IS MEAN < HYPOPNEA THRESHOLD ?
NO
YES
2202
HAS CONDITION EXCEEDED 15 SECS. ?
NO
YES
2204
SET HYPOPNEA FLAG ON
2206
SET HYPOPNEA FLAG TO OFF
RETURN

Fig. 21

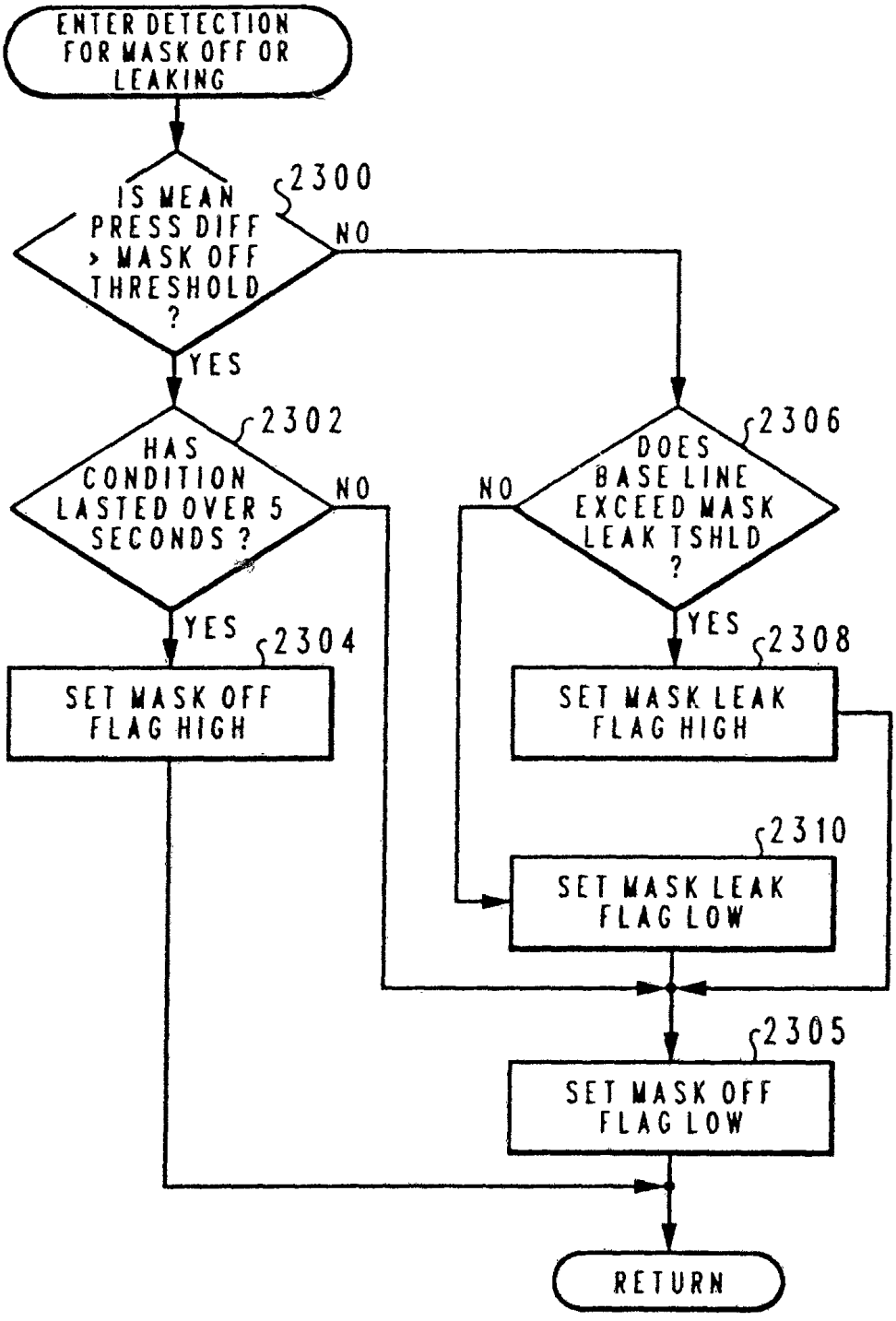

ENTER DETECTION FOR MASK OFF OR LEAKING
IS MEAN PRESS DIFF > MASK OFF THRESHOLD ?
2300
NO
YES
HAS CONDITION LASTED OVER 5 SECONDS ?
2302
NO
YES
SET MASK OFF FLAG HIGH
2304
DOES BASE LINE EXCEED MASK LEAK TSHLD ?
2306
NO
YES
SET MASK LEAK FLAG HIGH
2308
SET MASK LEAK FLAG LOW
2310
SET MASK OFF FLAG LOW
2305
RETURN

Fig. 22

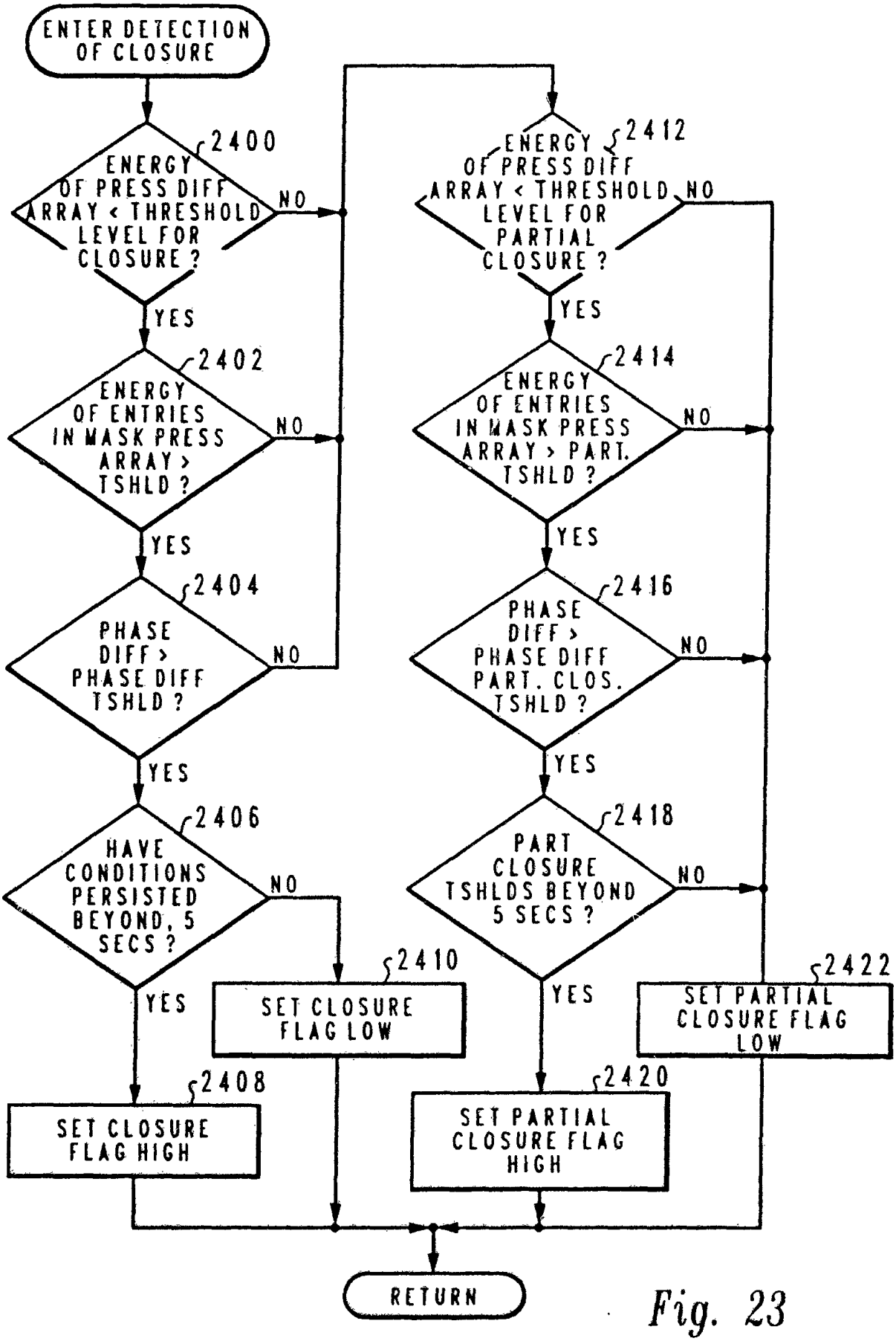

ENTER DETECTION OF CLOSURE
2400
ENERGY OF PRESS DIFF ARRAY < THRESHOLD LEVEL FOR CLOSURE ?
NO
YES
2402
ENERGY OF ENTRIES IN MASK PRESS ARRAY > TSHLD ?
NO
YES
2404
PHASE DIFF > PHASE DIFF TSHLD ?
NO
YES
2406
HAVE CONDITIONS PERSISTED BEYOND, 5 SECS ?
NO
YES
2408
SET CLOSURE FLAG HIGH
2410
SET CLOSURE FLAG LOW
2412
ENERGY OF PRESS DIFF ARRAY < THRESHOLD LEVEL FOR PARTIAL CLOSURE ?
NO
YES
2414
ENERGY OF ENTRIES IN MASK PRESS ARRAY > PART. TSHLD ?
NO
YES
2416
PHASE DIFF > PHASE DIFF PART. CLOS. TSHLD ?
NO
YES
2418
PART CLOSURE TSHLDS BEYOND 5 SECS ?
NO
YES
2420
SET PARTIAL CLOSURE FLAG HIGH
2422
SET PARTIAL CLOSURE FLAG LOW
RETURN

Fig. 23

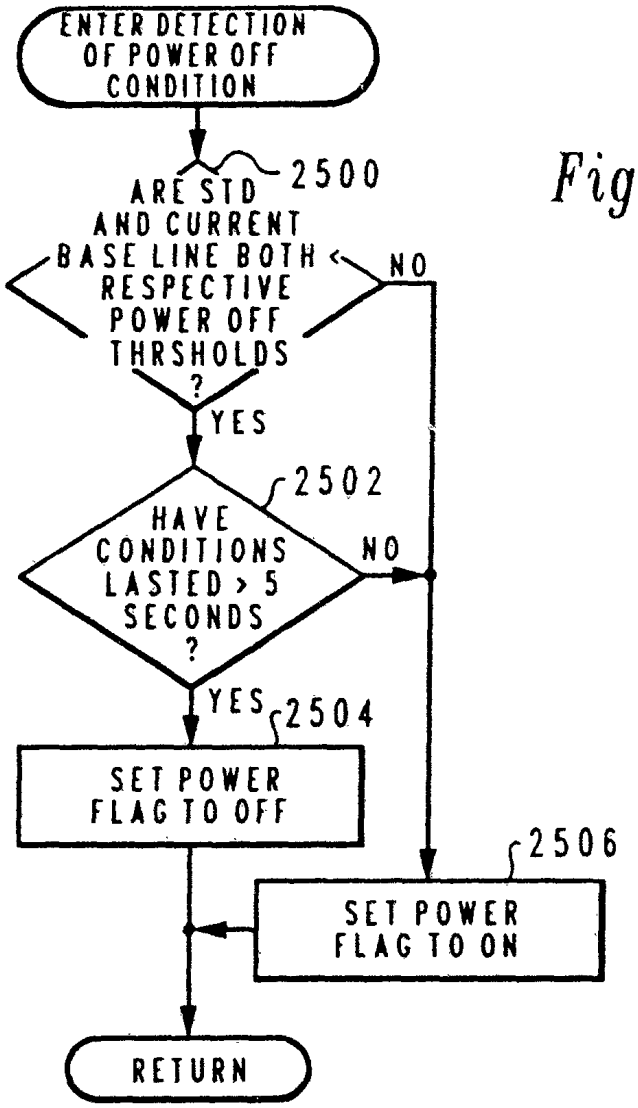

ENTER DETECTION OF POWER OFF CONDITION
2500
ARE STD AND CURRENT BASE LINE BOTH RESPECTIVE POWER OFF THRSHOLDS ?
NO
YES
2502
HAVE CONDITIONS LASTED > 5 SECONDS ?
NO
YES
2504
SET POWER FLAG TO OFF
2506
SET POWER FLAG TO ON
RETURN

Fig. 24

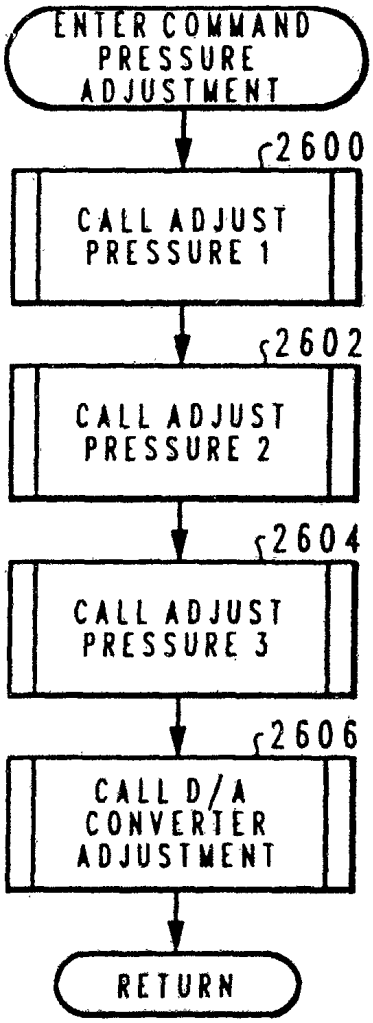

ENTER COMMAND PRESSURE ADJUSTMENT
2600
CALL ADJUST PRESSURE 1
2602
CALL ADJUST PRESSURE 2
2604
CALL ADJUST PRESSURE 3
2606
CALL D/A CONVERTER ADJUSTMENT
RETURN

Fig. 25

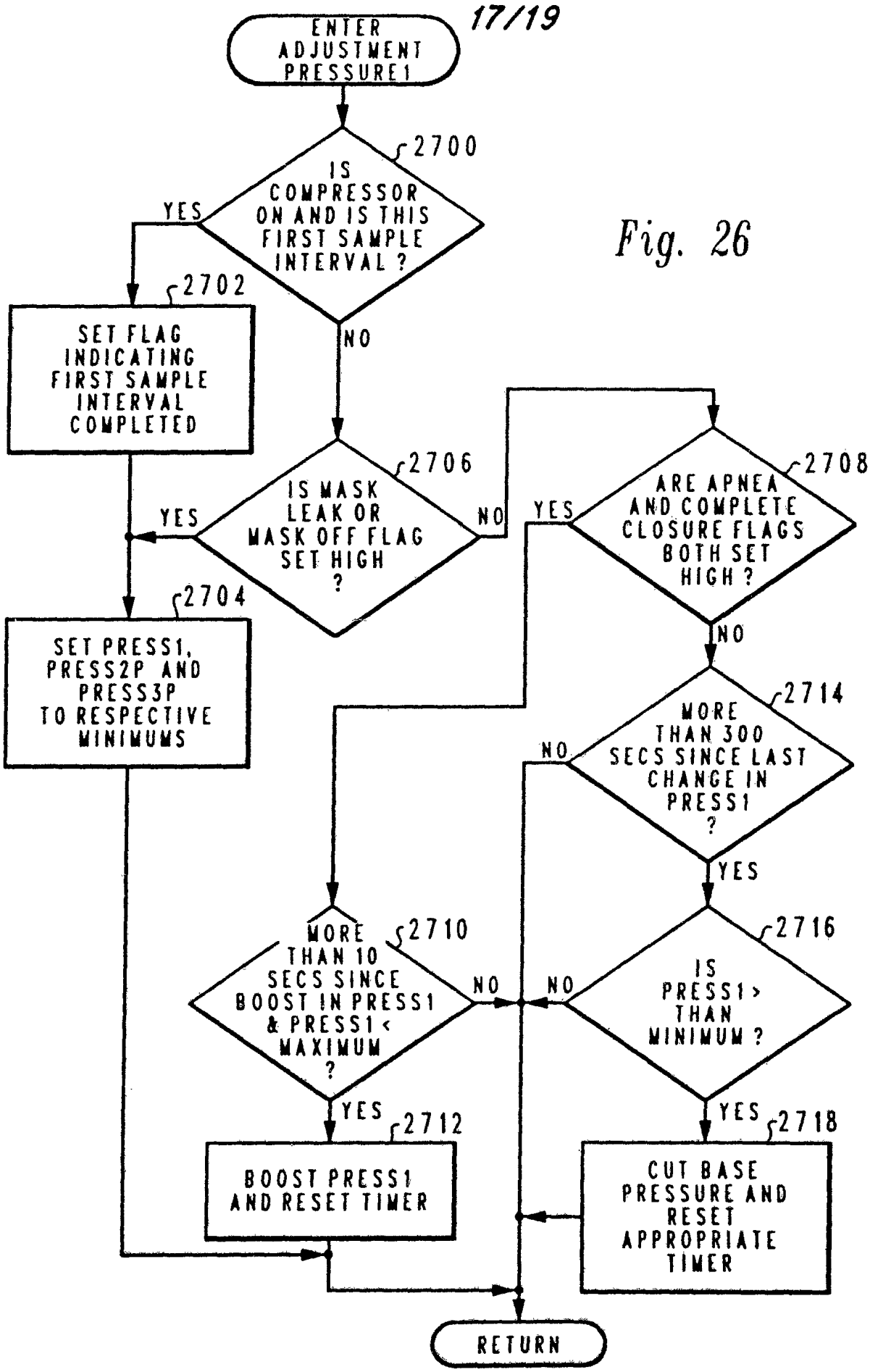

ENTER ADJUSTMENT PRESSURE1
2700
IS COMPRESSOR ON AND IS THIS FIRST SAMPLE INTERVAL ?
YES
NO
2702
SET FLAG INDICATING FIRST SAMPLE INTERVAL COMPLETED
2706
IS MASK LEAK OR MASK OFF FLAG SET HIGH ?
YES
NO
2708
ARE APNEA AND COMPLETE CLOSURE FLAGS BOTH SET HIGH ?
YES
NO
2704
SET PRESS1, PRESS2P AND PRESS3P TO RESPECTIVE MINIMUMS
2714
MORE THAN 300 SECS SINCE LAST CHANGE IN PRESS1 ?
NO
YES
2710
MORE THAN 10 SECS SINCE BOOST IN PRESS1 & PRESS1 < MAXIMUM ?
NO
YES
2716
IS PRESS1 > THAN MINIMUM ?
NO
YES
2712
BOOST PRESS1 AND RESET TIMER
2718
CUT BASE PRESSURE AND RESET APPROPRIATE TIMER
RETURN

Fig. 26

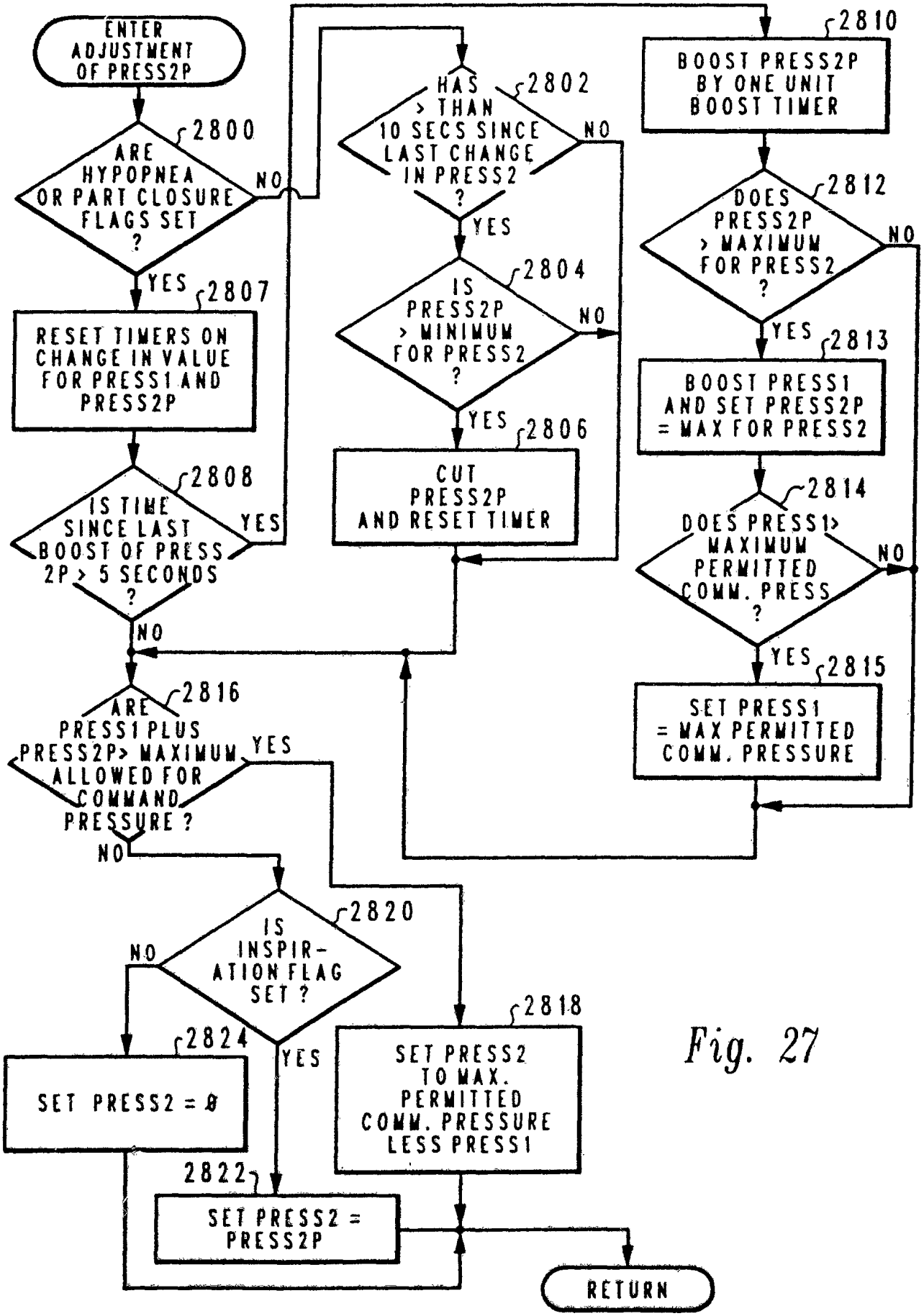

ENTER ADJUSTMENT OF PRESS2P
2800
ARE HYPOPNEA OR PART CLOSURE FLAGS SET ?
NO
YES
2807
RESET TIMERS ON CHANGE IN VALUE FOR PRESS1 AND PRESS2P
2808
IS TIME SINCE LAST BOOST OF PRESS 2P > 5 SECONDS ?
YES
NO
2802
HAS > THAN 10 SECS SINCE LAST CHANGE IN PRESS2 ?
NO
YES
2804
IS PRESS2P > MINIMUM FOR PRESS2 ?
NO
YES
2806
CUT PRESS2P AND RESET TIMER
2810
BOOST PRESS2P BY ONE UNIT BOOST TIMER
2812
DOES PRESS2P > MAXIMUM FOR PRESS2 ?
NO
YES
2813
BOOST PRESS1 AND SET PRESS2P = MAX FOR PRESS2
2814
DOES PRESS1> MAXIMUM PERMITTED COMM. PRESS ?
NO
YES
2815
SET PRESS1 = MAX PERMITTED COMM. PRESSURE
2816
ARE PRESS1 PLUS PRESS2P> MAXIMUM ALLOWED FOR COMMAND PRESSURE ?
YES
NO
2820
IS INSPIR- ATION FLAG SET ?
NO
YES
2824
SET PRESS2 = 0
2818
SET PRESS2 TO MAX. PERMITTED COMM. PRESSURE LESS PRESS1
2822
SET PRESS2 = PRESS2P
RETURN

Fig. 27

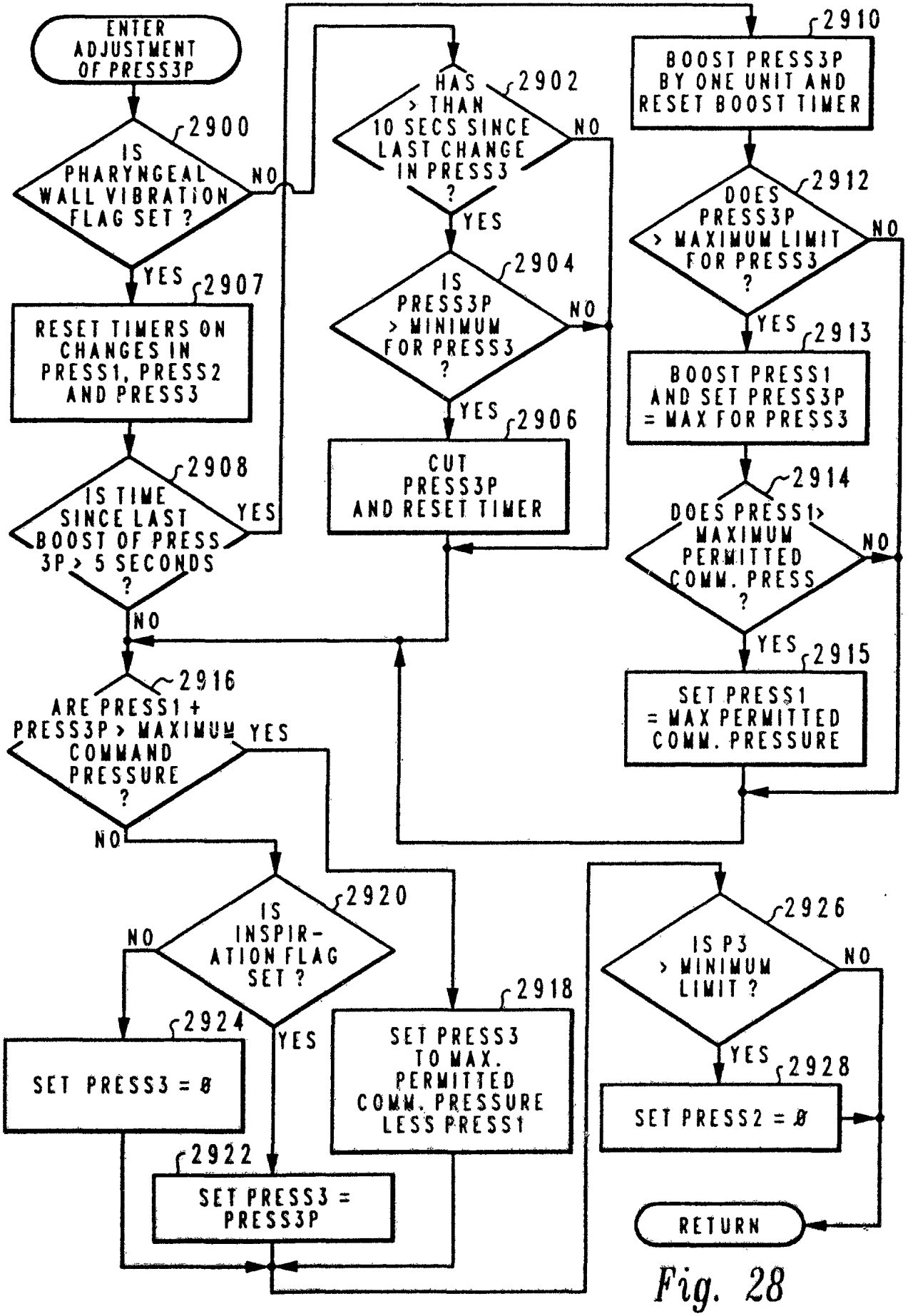

ENTER ADJUSTMENT OF PRESS3P
2900
IS PHARYNGEAL WALL VIBRATION FLAG SET ?
NO
YES
2907
RESET TIMERS ON CHANGES IN PRESS1, PRESS2 AND PRESS3
2908
IS TIME SINCE LAST BOOST OF PRESS 3P > 5 SECONDS ?
YES
NO
2902
HAS > THAN 10 SECS SINCE LAST CHANGE IN PRESS3 ?
NO
YES
2904
IS PRESS3P > MINIMUM FOR PRESS3 ?
NO
YES
2906
CUT PRESS3P AND RESET TIMER
2910
BOOST PRESS3P BY ONE UNIT AND RESET BOOST TIMER
2912
DOES PRESS3P > MAXIMUM LIMIT FOR PRESS3 ?
NO
YES
2913
BOOST PRESS1 AND SET PRESS3P = MAX FOR PRESS3
2914
DOES PRESS1> MAXIMUM PERMITTED COMM. PRESS ?
NO
YES
2915
SET PRESS1 = MAX PERMITTED COMM. PRESSURE
2916
ARE PRESS1 + PRESS3P > MAXIMUM COMMAND PRESSURE ?
YES
NO
2920
IS INSPIR-ATION FLAG SET ?
NO
YES
2924
SET PRESS3 = 0
2922
SET PRESS3 = PRESS3P
2918
SET PRESS3 TO MAX. PERMITTED COMM. PRESSURE LESS PRESS1
2926
IS P3 > MINIMUM LIMIT ?
NO
YES
2928
SET PRESS2 = 0
RETURN

Fig. 28

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/03901

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) :A61M 16/00; A62B 7/00; F16K 31/02
US CL :128/204.18, 204.21, 204.23
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. : 128/ 202.22, 202.27, 204.18, 204.21-204.23

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

NONE

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

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---, P Y	US, A, 5,259,373, (GRUENKE ET AL.), 09 November 1993. See entire document.	1, 3, 8, 13, 14, 16, 17, 25 --- 2, 4-7, 9, 10, 12, 15, 18, 19, 21- 24, 26, 27
Y	US, A, 4,972,842, (KORTEN ET AL.), 27 November 1990. See entire document.	2, 4, 5, 9, 10, 12, 15, 18, 19, 21-24, 26, 27
Y	US, A, 4,766,894, (LEGRAND ET AL.), 30 August 1988. See entire document.	6, 7

☐ 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 part 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
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Date of the actual completion of the international search 12 MAY 1994	Date of mailing of the international search report JUN 24 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer FOR KIMBERLY ASHER Telephone No. (703) 308-0332

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B. FIELDS SEARCHED
Electronic data bases consulted (Name of data base and where practicable terms used):

APS, SEARCH TERMS: VENTILAT?, (ALARM# OR SIGNAL#### OR MONITOR### OR BUZZ###), (LEAK#### OR DIS(1W)CONNECT## OR CONNECT?), MASK CATHETER#, CANNULA#, ENDOTRACHEAL, TUBE#, PRESSURE#, MASK(5A)CONNECT?,MEAN, APNEIC, APNEUSTIC, APNEA, PRESSURE, MEAN(3A)PRESSURE#, AVERAGE#