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(54) **DIAGNOSIS AND TREATMENT OF RESPIRATORY DISORDERS**

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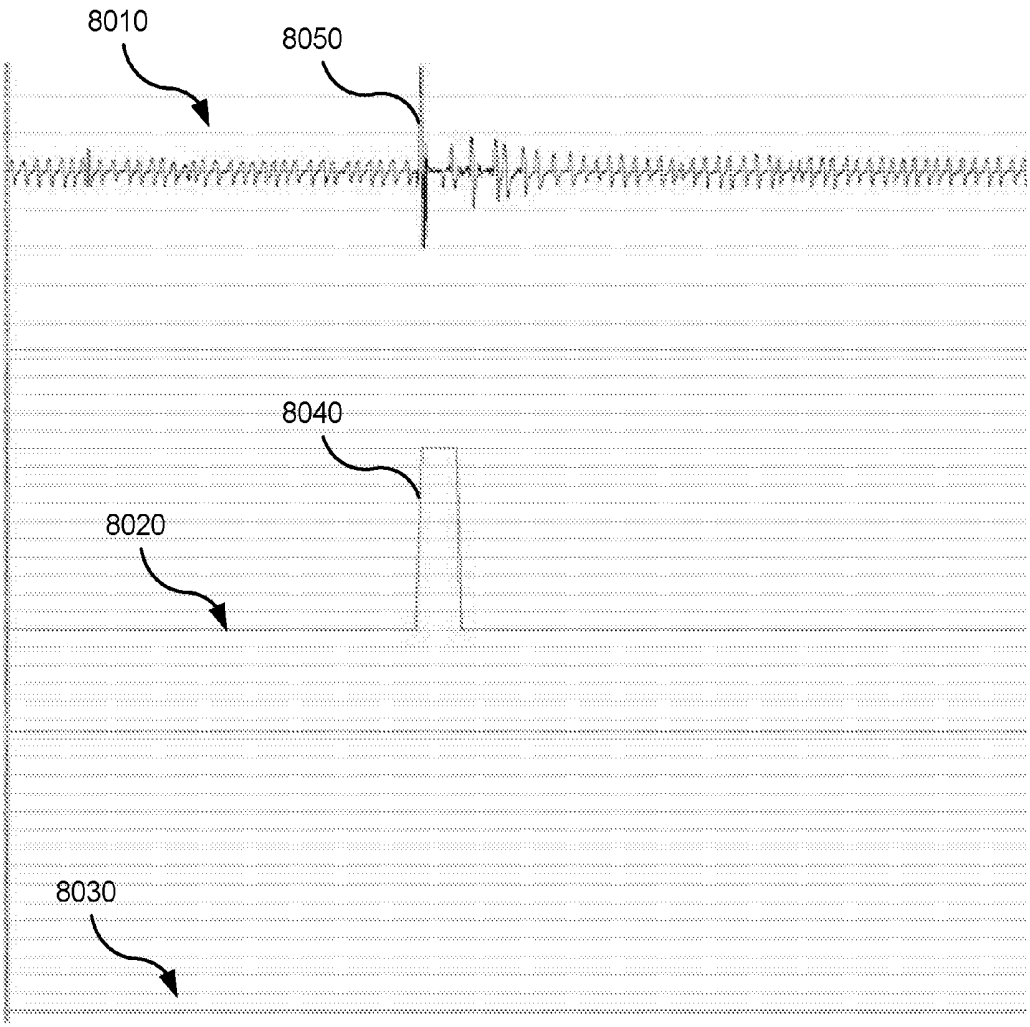
(57) **ABSTRACT**

A method of a device detects a respiratory effort-related arousal in a respiratory airflow signal of a patient. The method may include computing a measure of consistency of inspiratory flow limitation over a plurality of recent breaths from the signal. The method may further include computing a measure of step change in ventilation indicating a sudden big breath. The method may further include computing a measure indicating a degree of confidence of occurrence of a respiratory effort-related arousal from the measure of consistency of inspiratory flow limitation and the measure of the step change in ventilation.



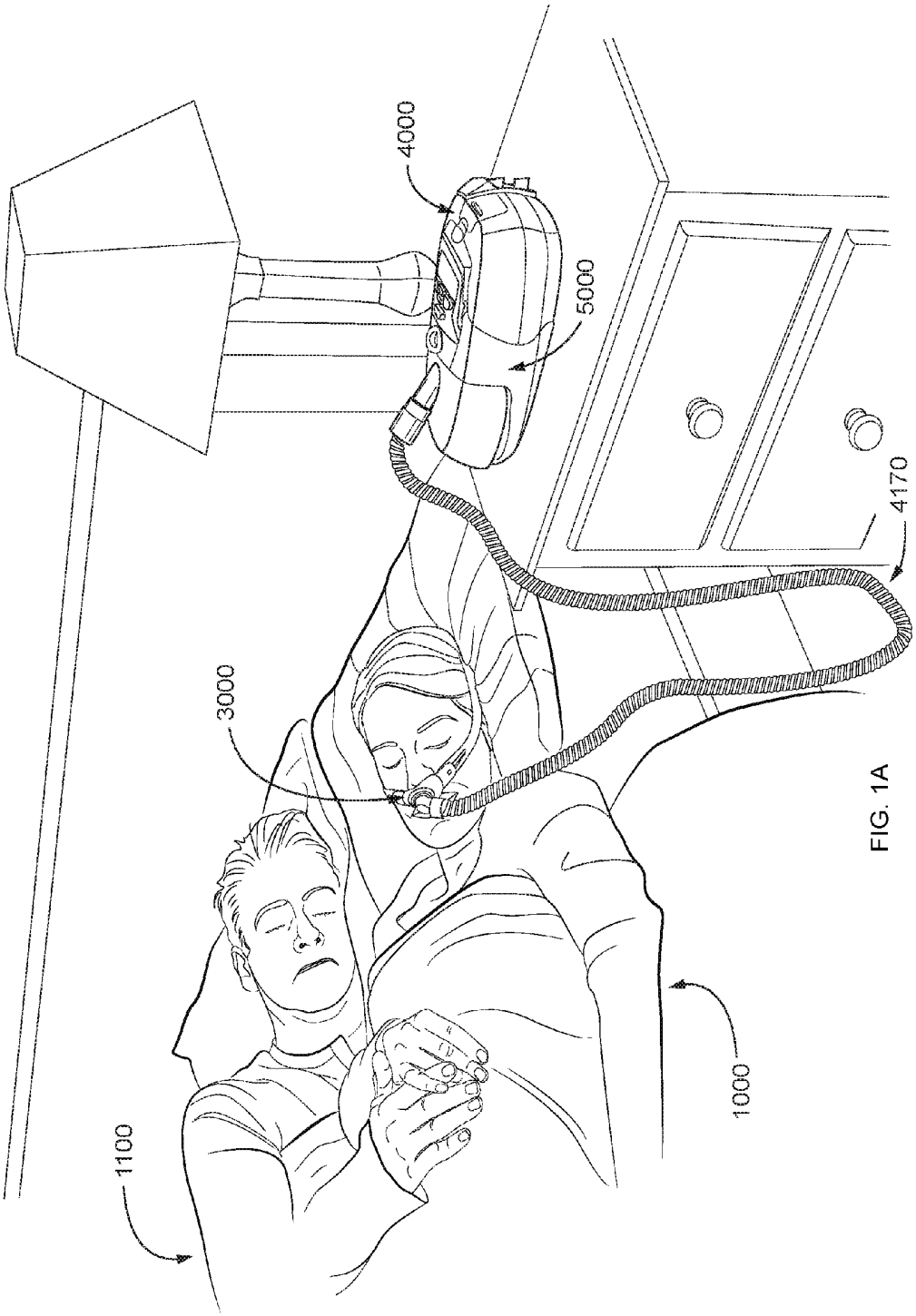


FIG. 1A

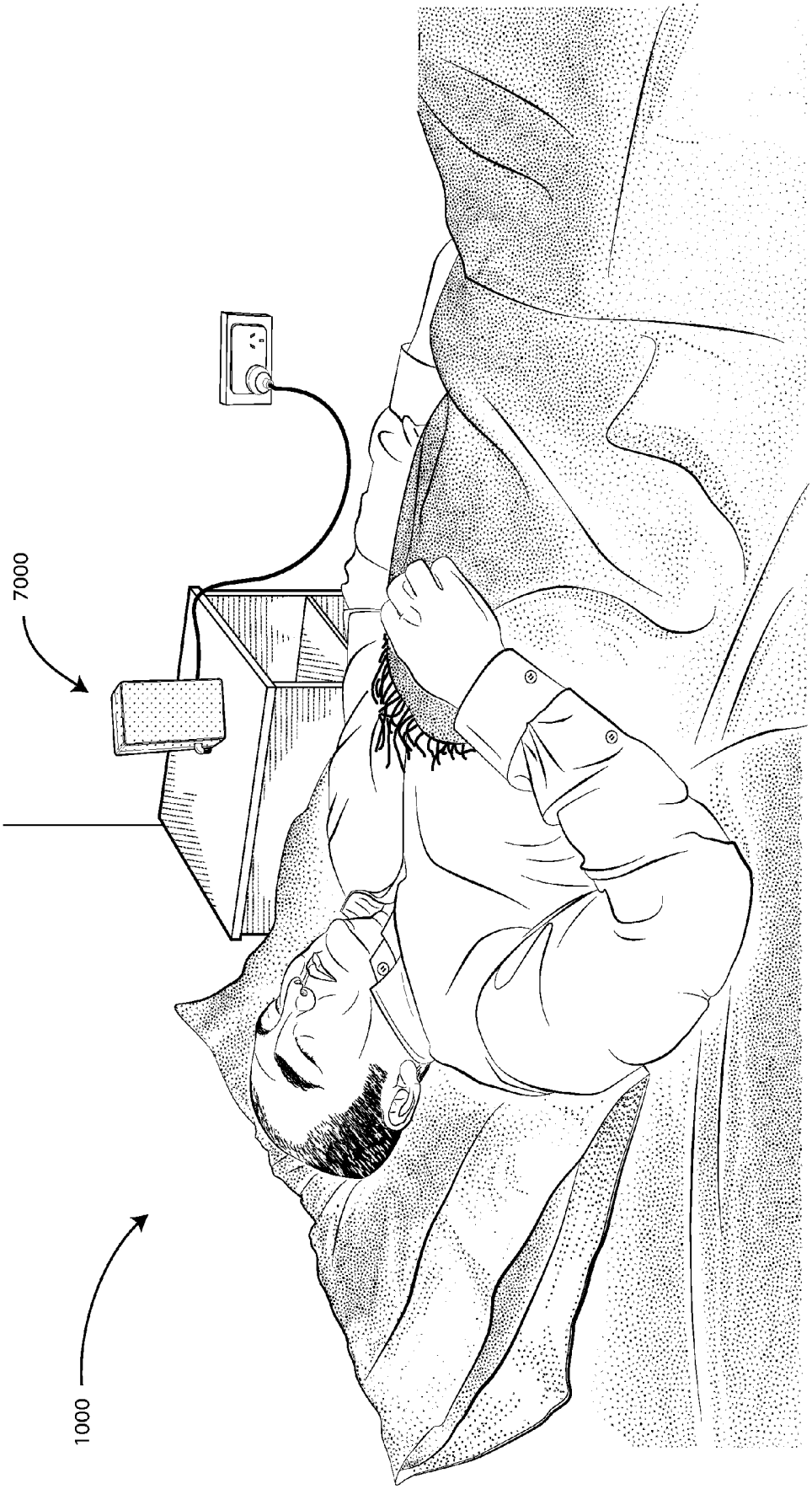


FIG. 1B

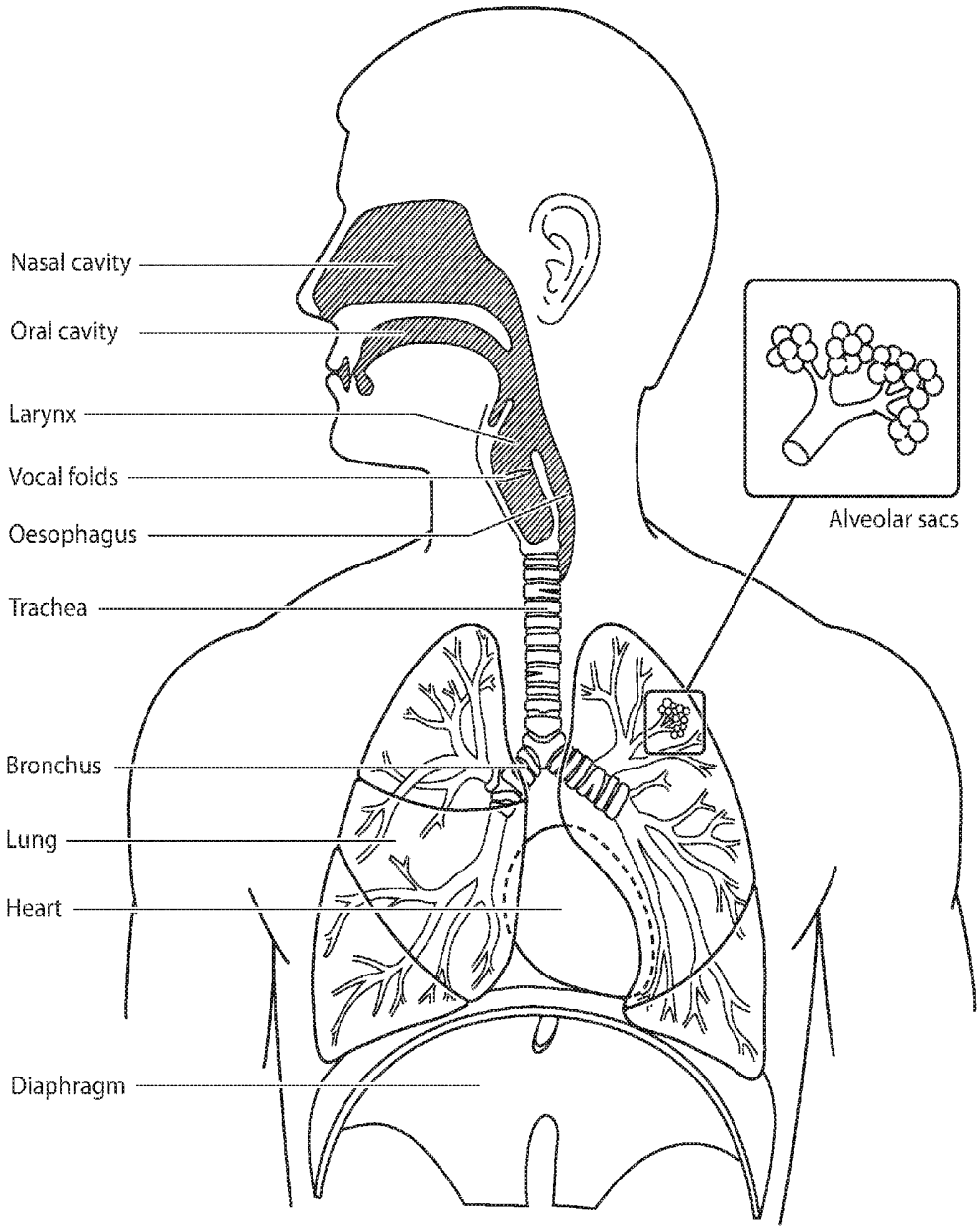

Nasal cavity
Oral cavity
Larynx
Vocal folds
Oesophagus
Trachea
Bronchus
Lung
Heart
Diaphragm
Alveolar sacs

FIG. 2A

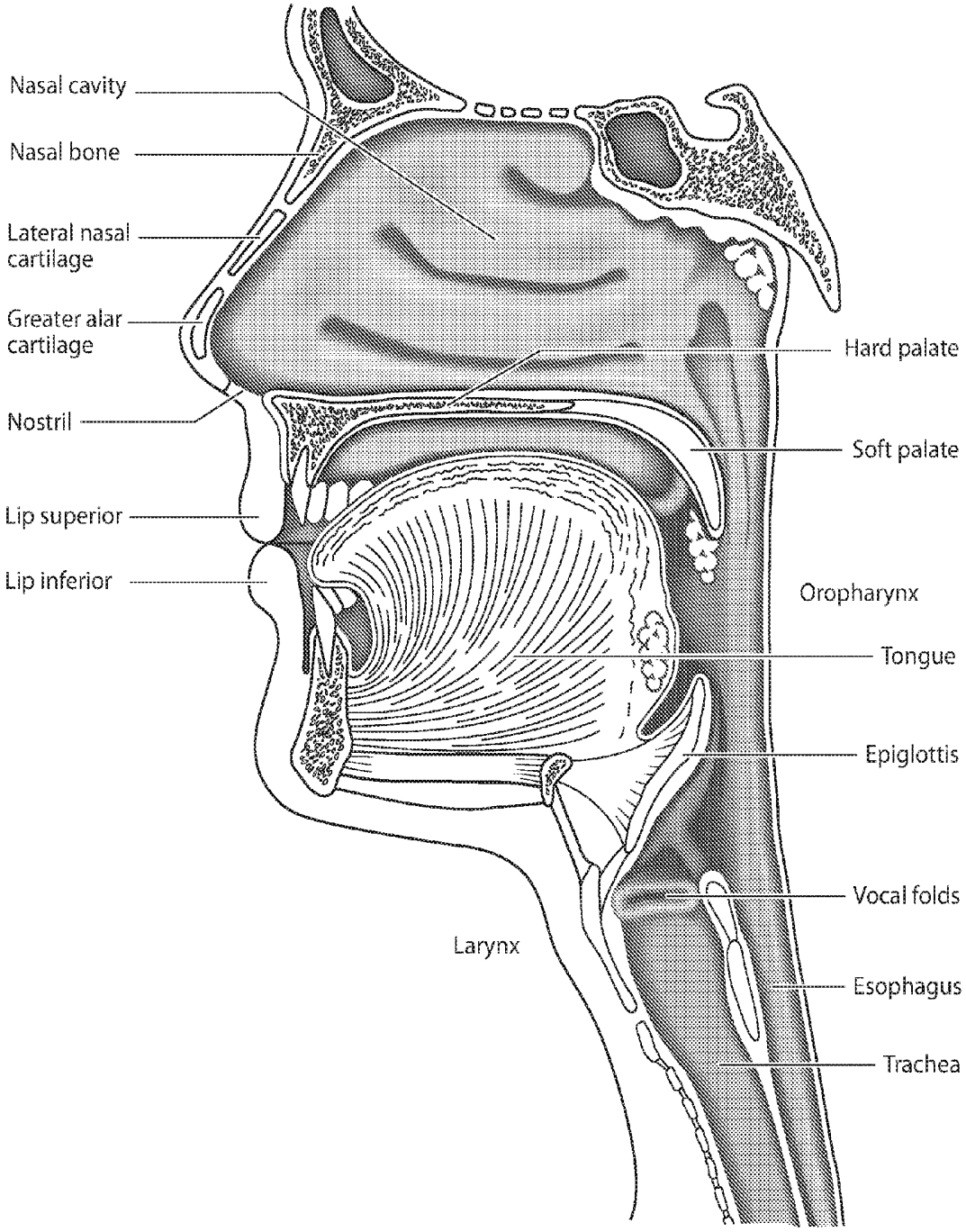

Nasal cavity
Nasal bone
Lateral nasal cartilage
Greater alar cartilage
Nostril
Lip superior
Lip inferior
Hard palate
Soft palate
Oropharynx
Tongue
Epiglottis
Vocal folds
Larynx
Esophagus
Trachea

FIG. 2B

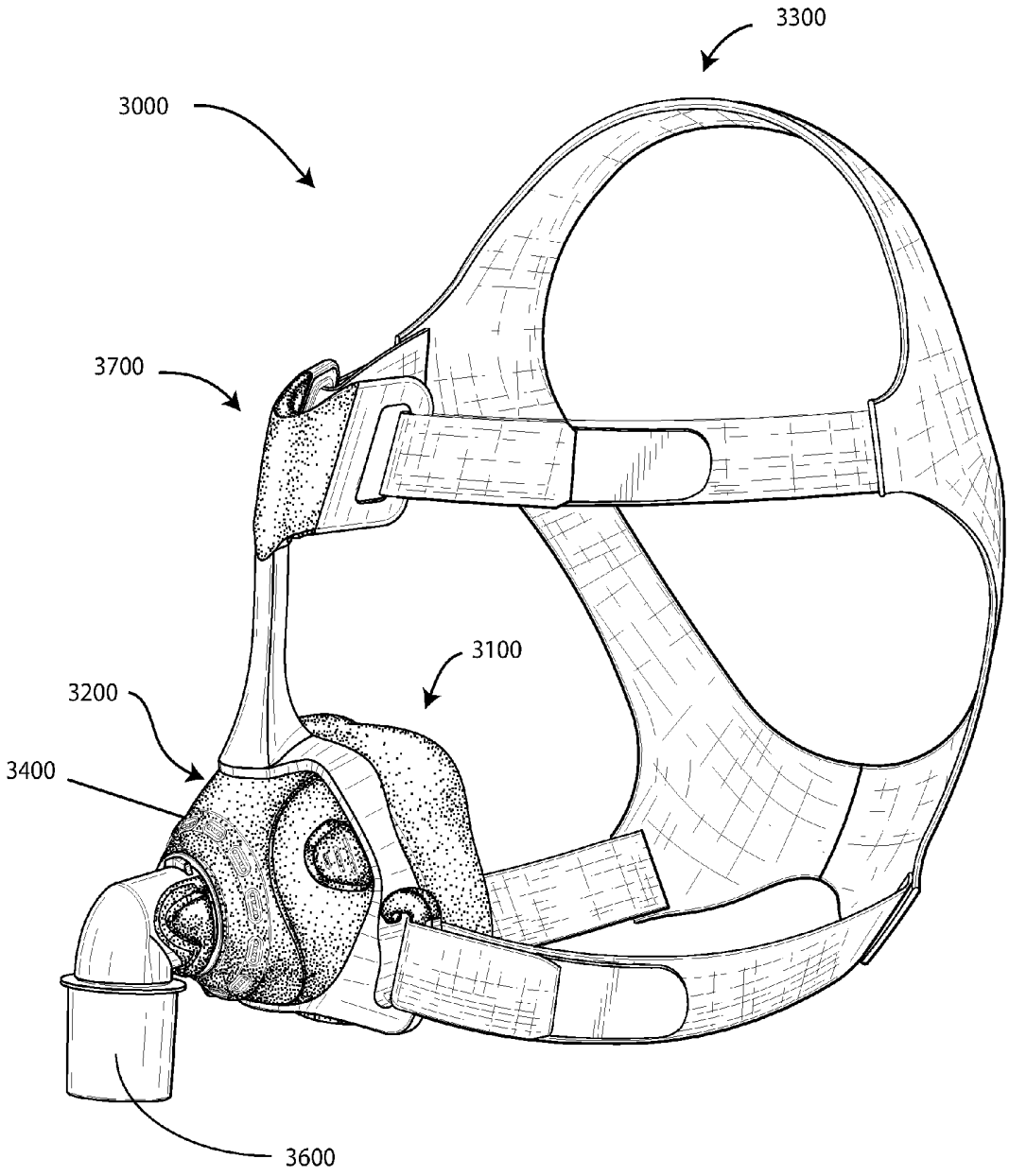


FIG. 3

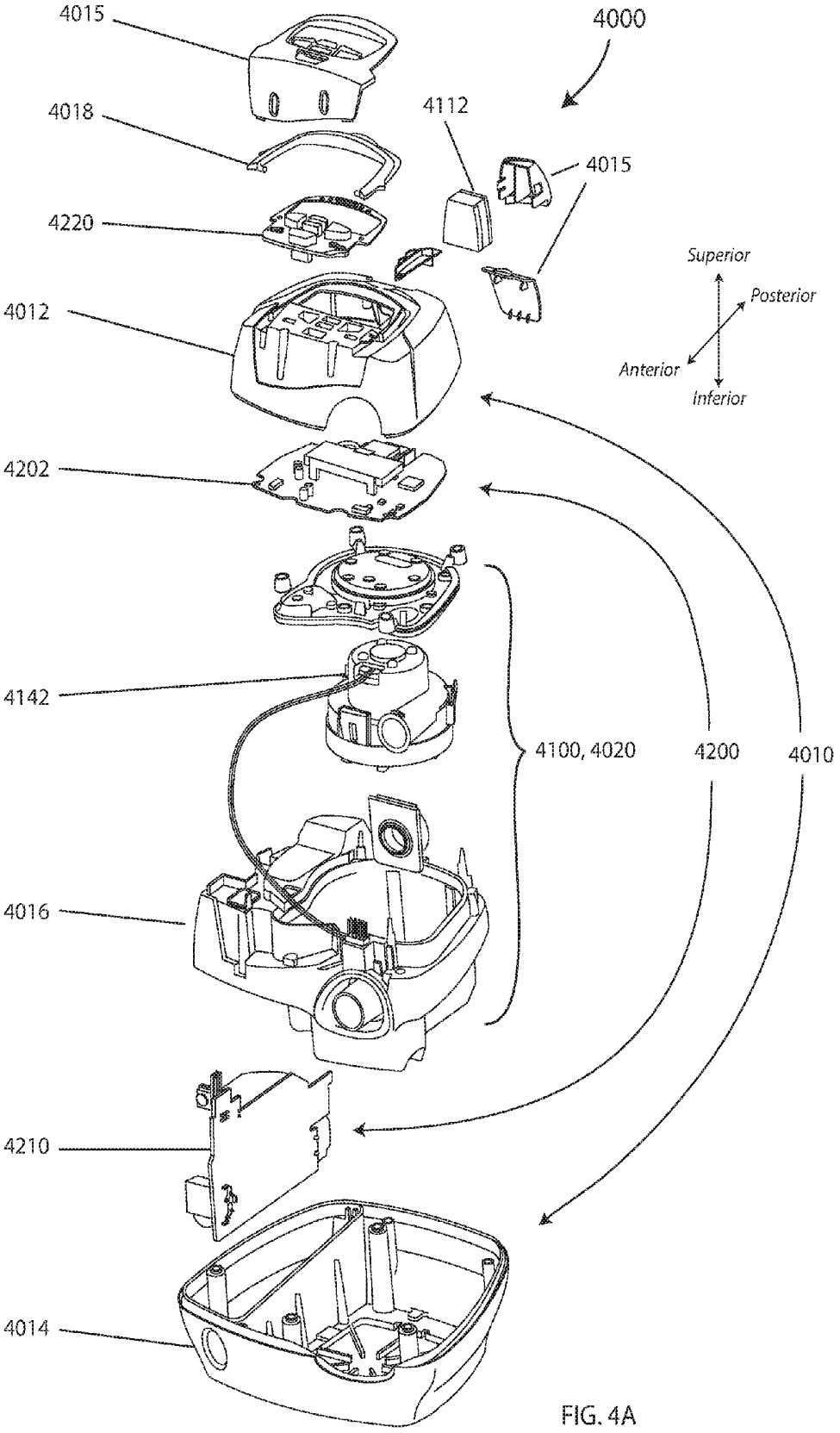

4015
4000
4018
4112
4015
4220
Superior
Posterior
Anterior
Inferior
4012
4202
4142
4100, 4020
4200
4010
4016
4210
4014

FIG. 4A

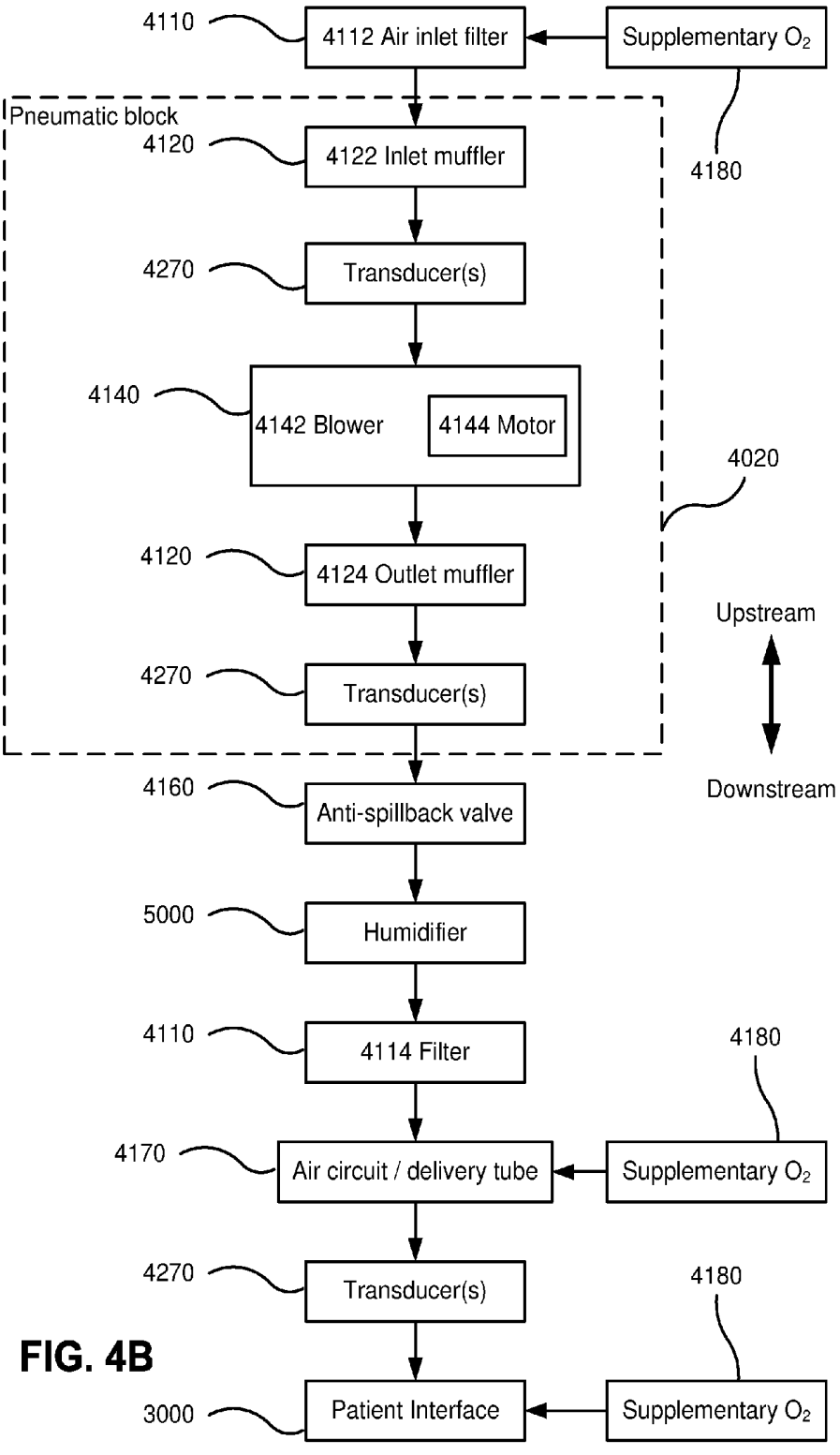

4110
4112 Air inlet filter
Supplementary O_2
Pneumatic block
4120
4122 Inlet muffler
4180
4270
Transducer(s)
4140
4142 Blower
4144 Motor
4020
4120
4124 Outlet muffler
Upstream
4270
Transducer(s)
Downstream
4160
Anti-spillback valve
5000
Humidifier
4110
4114 Filter
4180
4170
Air circuit / delivery tube
Supplementary O_2
4270
Transducer(s)
4180
3000
Patient Interface
Supplementary O_2

FIG. 4B

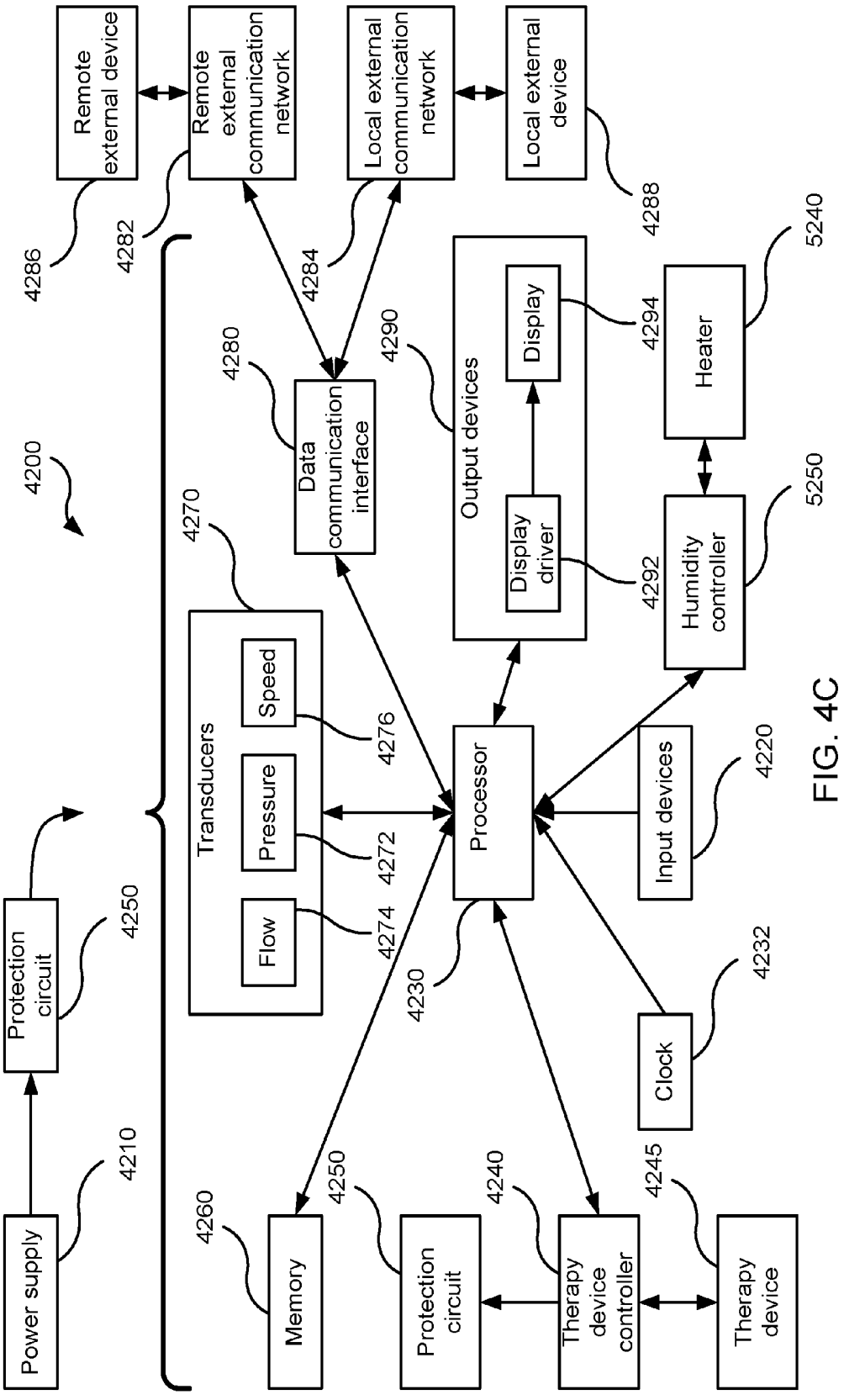

Remote external device
Remote external communication network
Local external communication network
Local external device
4286
4282
4284
4288
4280
4290
4294
5240
Data communication interface
Output devices
Display
Heater
4200
4270
Display driver
4292
Humidity controller
5250
Transducers
Speed
4276
Pressure
4272
Flow
4274
Processor
Input devices
4220
Protection circuit
4250
4230
4232
Clock
Power supply
4210
4260
4250
4240
4245
Memory
Protection circuit
Therapy device controller
Therapy device

FIG. 4C

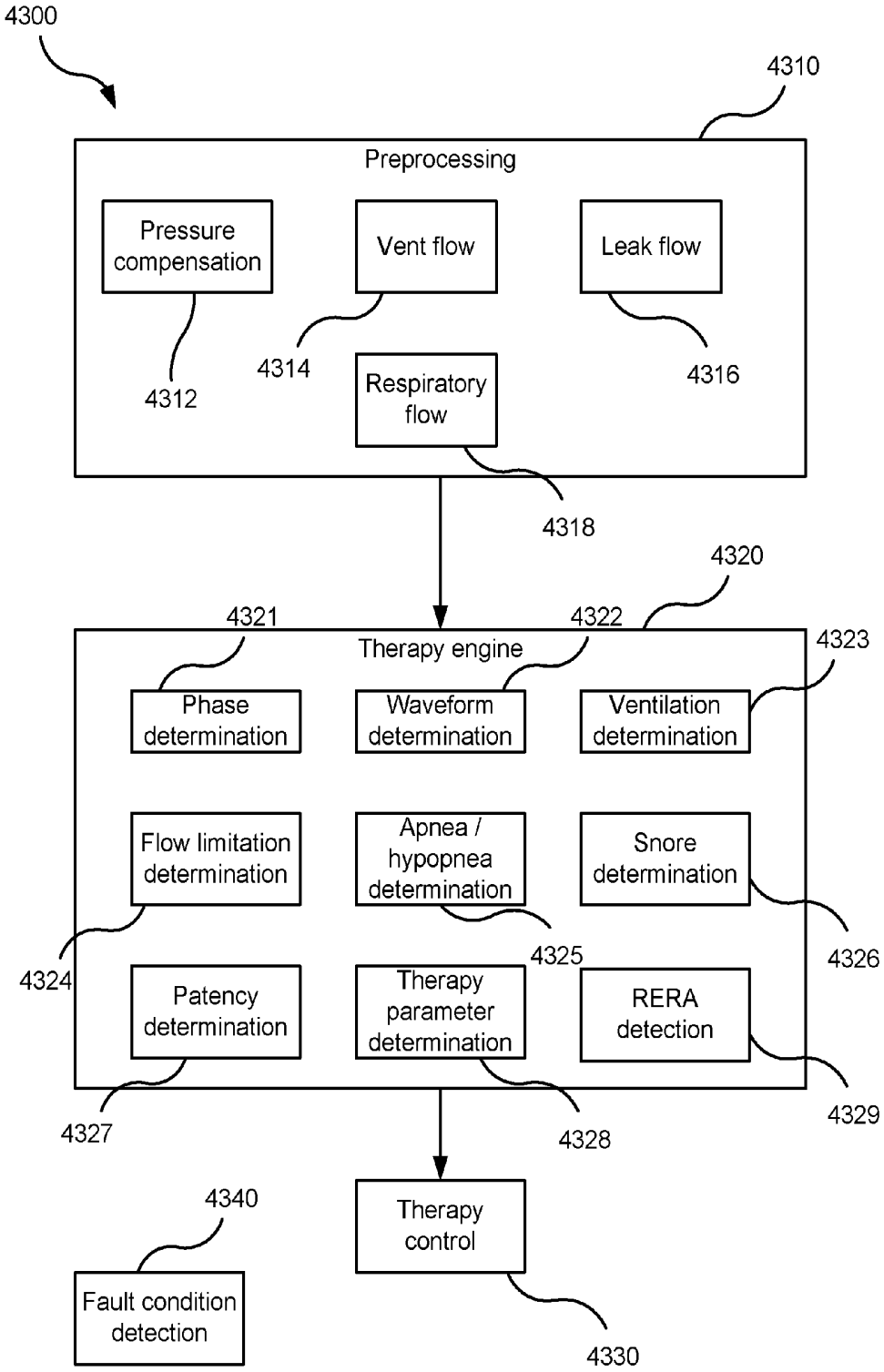

4300
4310
Preprocessing
Pressure compensation
Vent flow
Leak flow
4312
4314
Respiratory flow
4316
4318
4320
4321
4322
Therapy engine
4323
Phase determination
Waveform determination
Ventilation determination
Flow limitation determination
Apnea / hypopnea determination
Snore determination
4324
4325
4326
Patency determination
Therapy parameter determination
RERA detection
4327
4328
4329
4340
Therapy control
Fault condition detection
4330

FIG. 4D

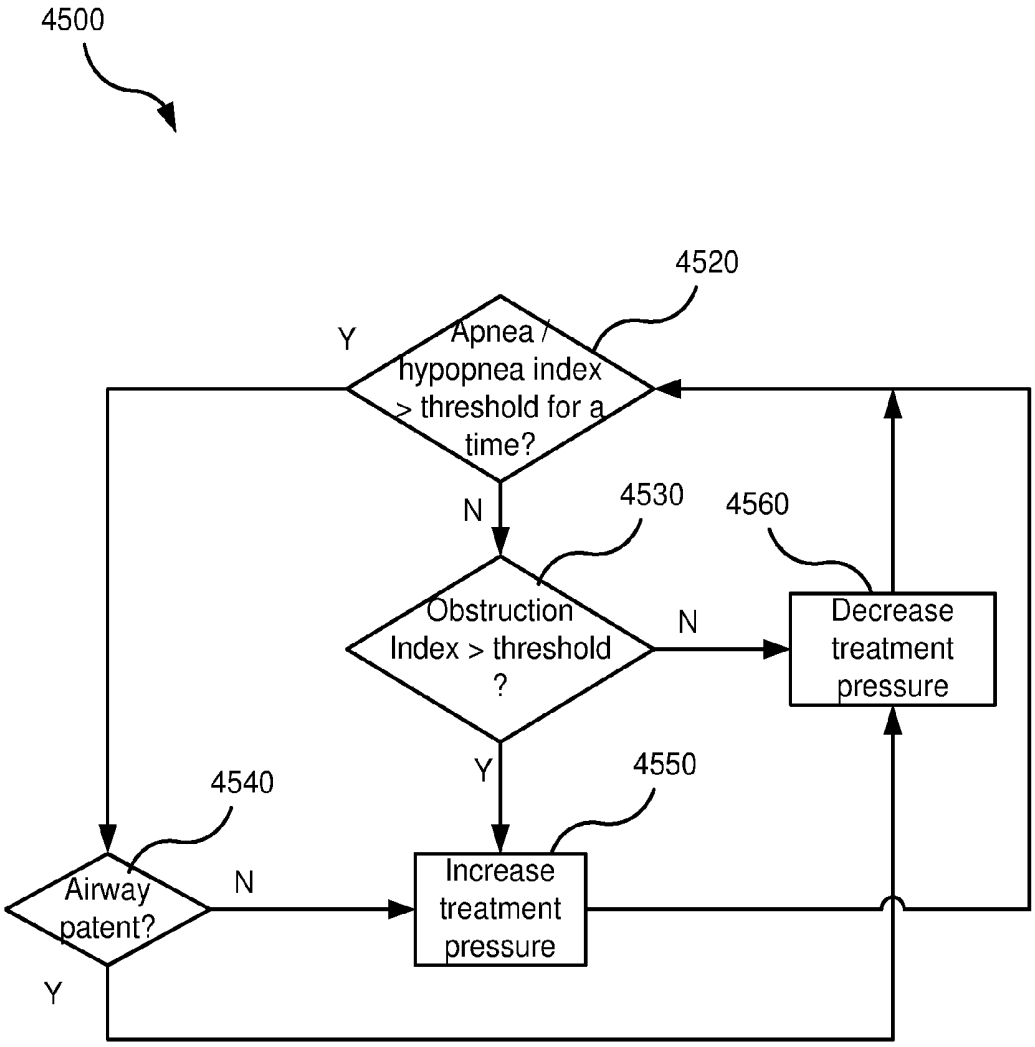

4500
4520
Apnea / hypopnea index > threshold for a time?
Y
N
4530
Obstruction Index > threshold ?
N
4560
Decrease treatment pressure
Y
4550
4540
Airway patent?
N
Increase treatment pressure
Y

FIG. 4E

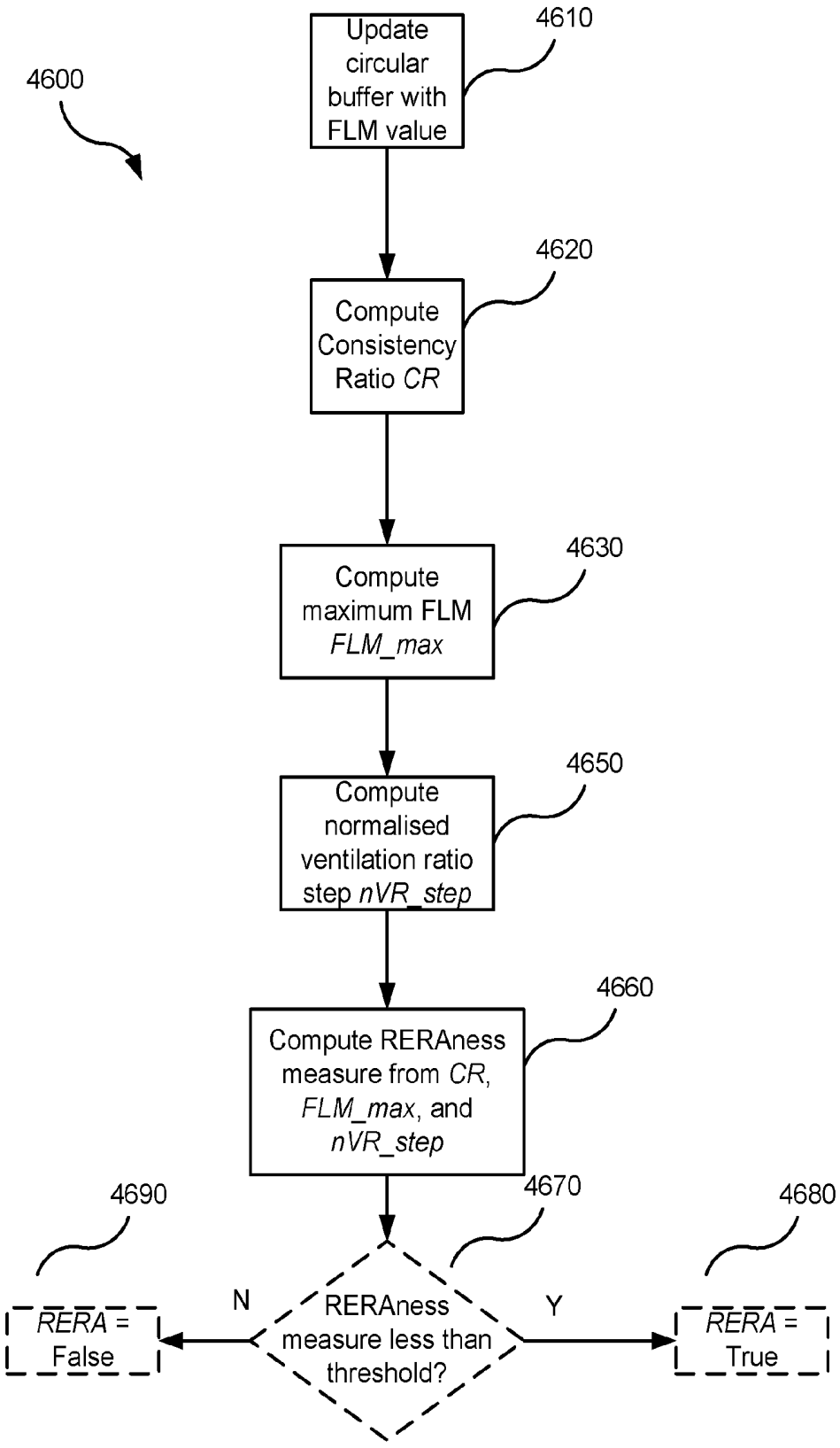

4600
Update circular buffer with FLM value
4610
Compute Consistency Ratio CR
4620
Compute maximum FLM FLM_max
4630
Compute normalised ventilation ratio step nVR_step
4650
Compute RERAness measure from CR, FLM_max, and nVR_step
4660
RERAness measure less than threshold?
4670
N
Y
RERA = False
4690
RERA = True
4680

FIG. 4F

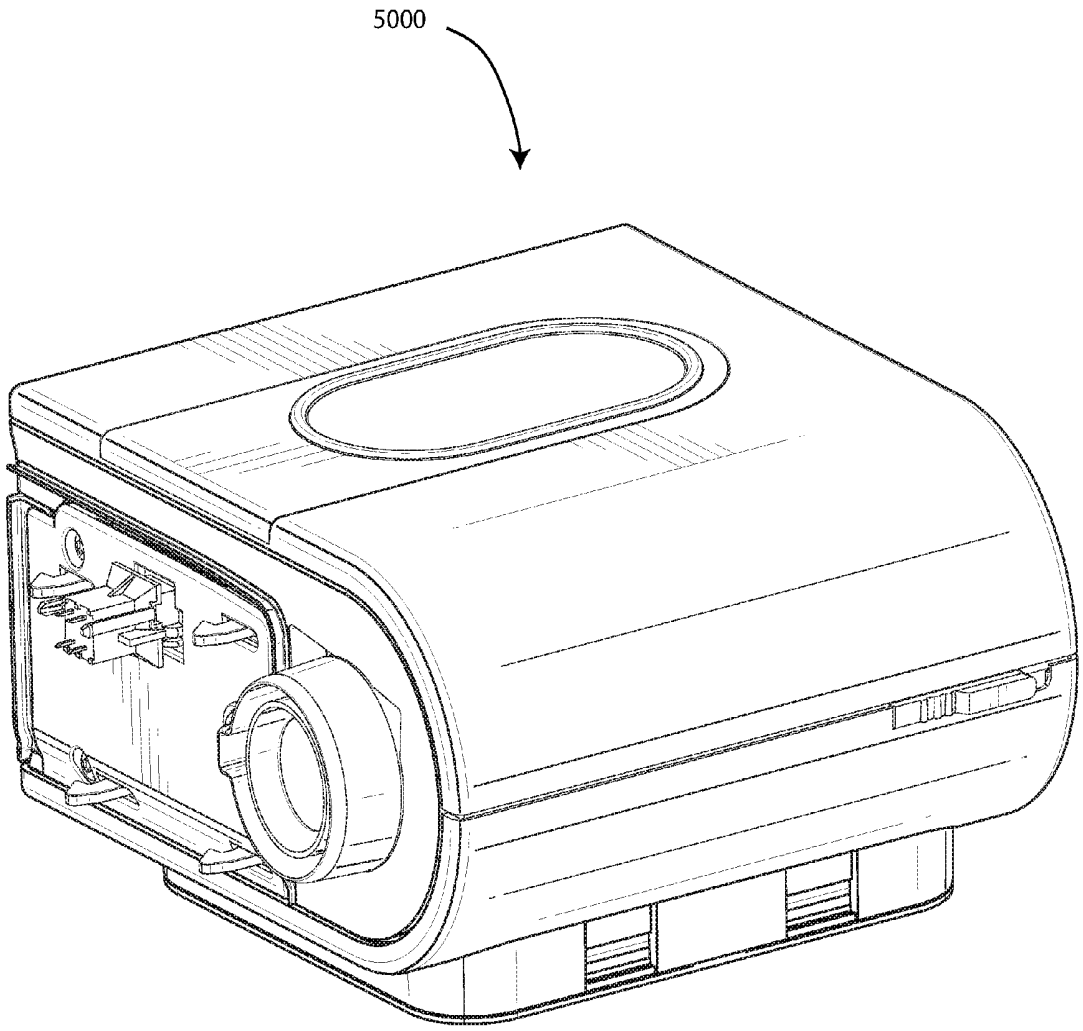


FIG. 5

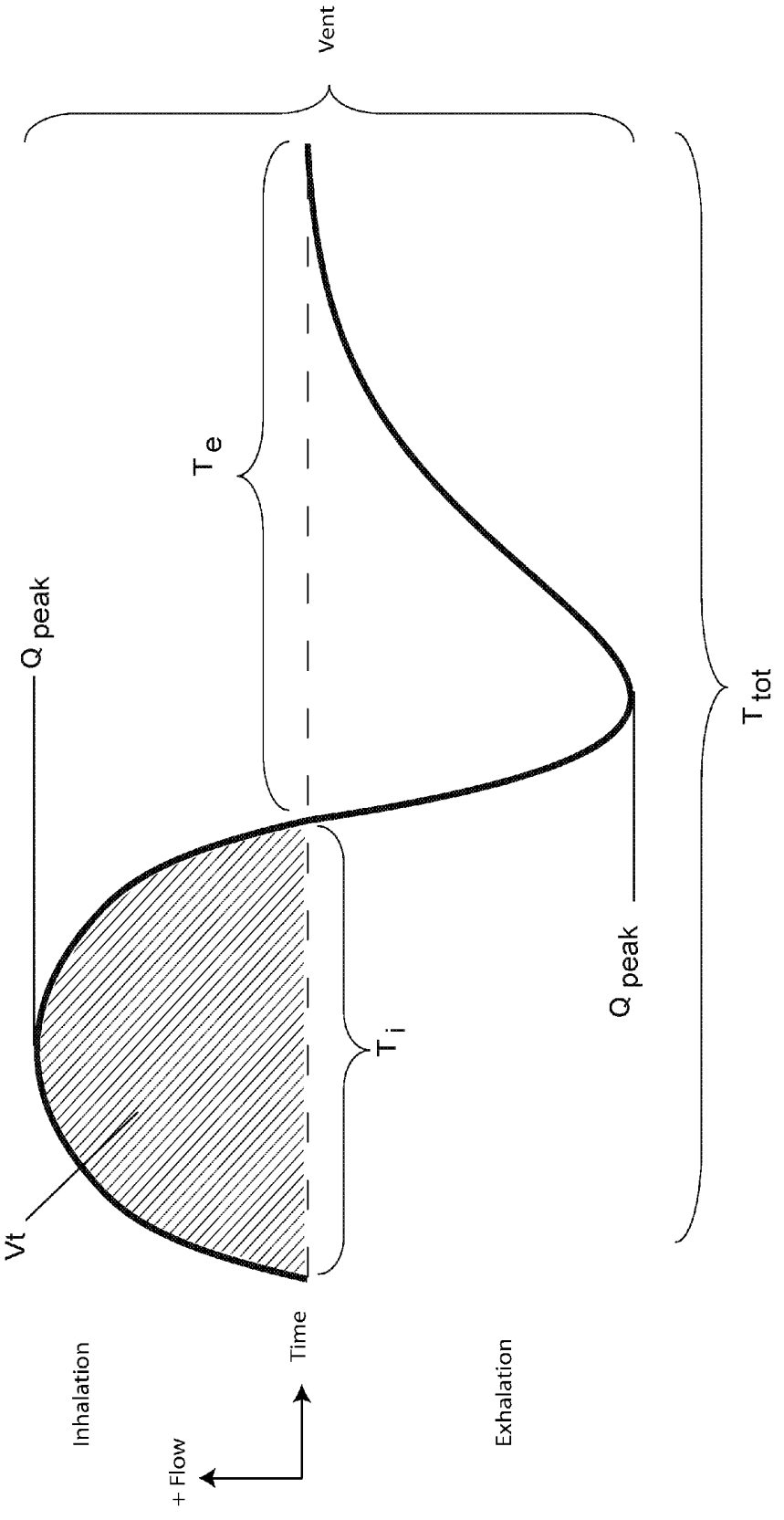

Vent
T e
Q peak
T tot
Q peak
T i
Vt
Inhalation
Time
+ Flow
Exhalation

FIG. 6A

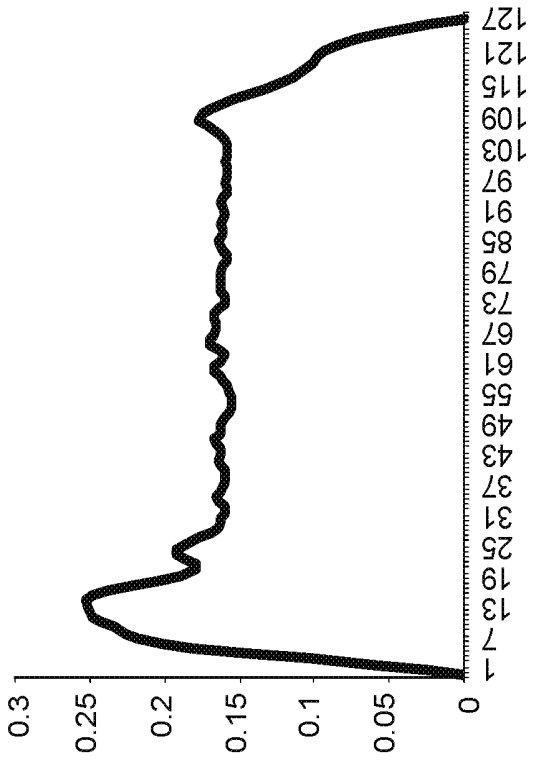

0.3
0.25
0.2
0.15
0.1
0.05
0
1
7
13
19
25
31
37
43
49
55
61
67
73
79
85
91
97
103
109
115
121
127

FIG. 6B

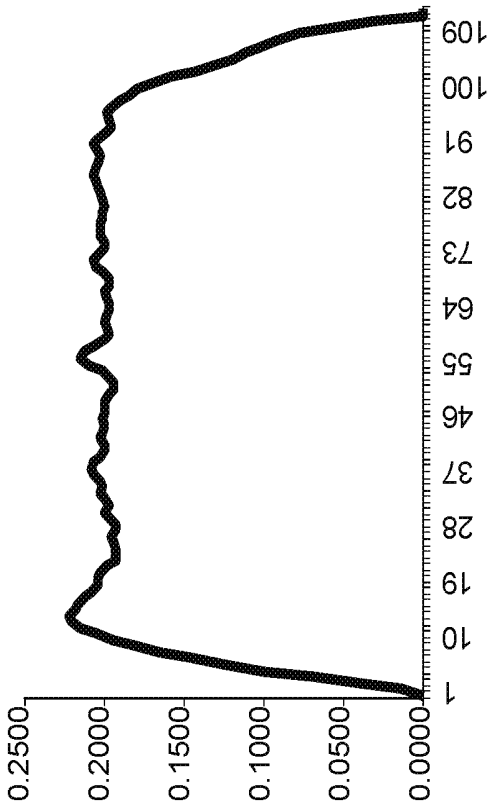

0.2500
0.2000
0.1500
0.1000
0.0500
0.0000
1
10
19
28
37
46
55
64
73
82
91
100
109
Mesa

FIG. 6C

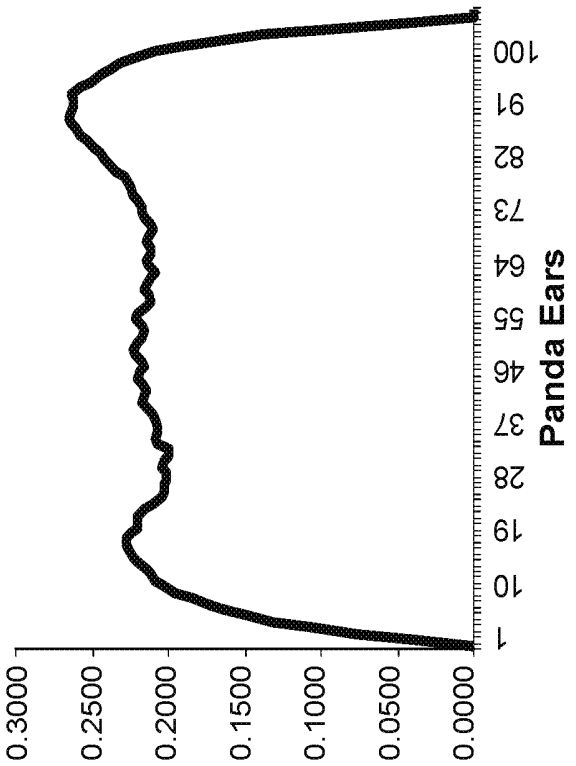

0.3000
0.2500
0.2000
0.1500
0.1000
0.0500
0.0000
1
10
19
28
37
46
55
64
73
82
91
100
Panda Ears

FIG. 6D

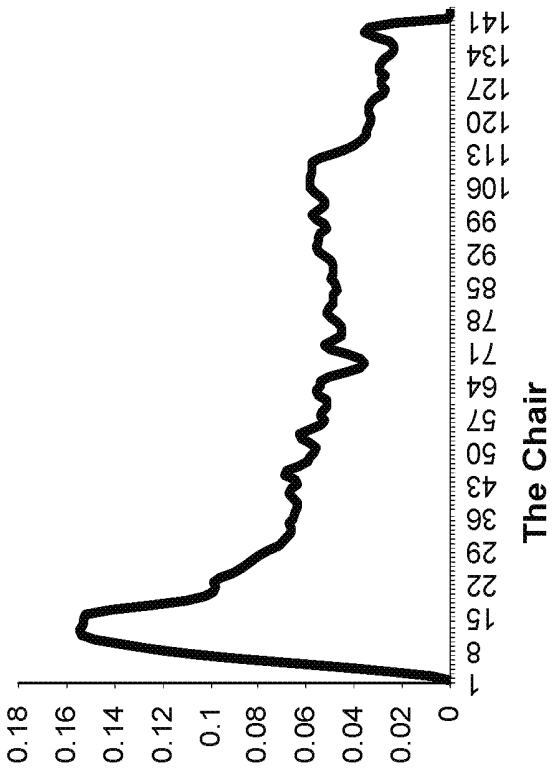

0.18
0.16
0.14
0.12
0.1
0.08
0.06
0.04
0.02
0
1
8
15
22
29
36
43
50
57
64
71
78
85
92
99
106
113
120
127
134
141
The Chair

FIG. 6E

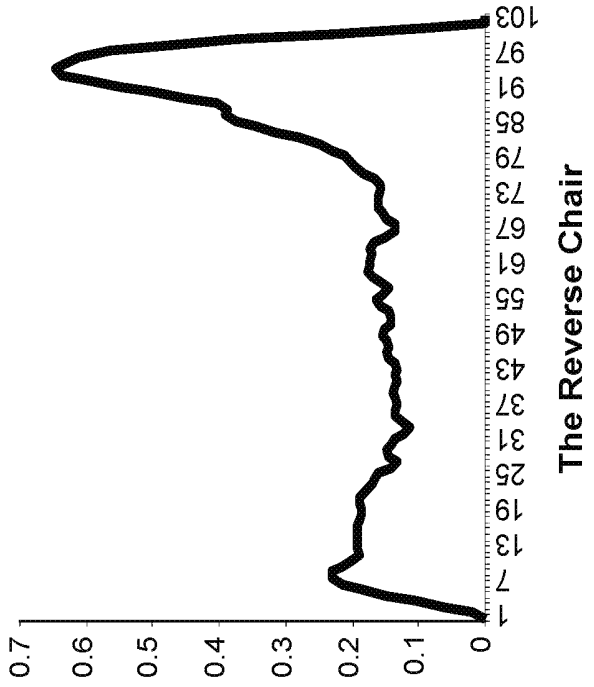

The Reverse Chair
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
1
7
13
19
25
31
37
43
49
55
61
67
73
79
85
91
97
103

FIG. 6F

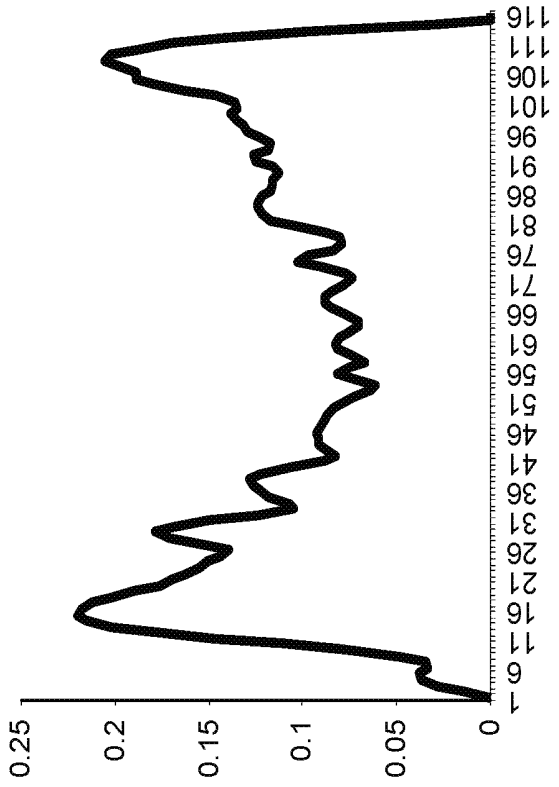

0.25
0.2
0.15
0.1
0.05
0
1
6
11
16
21
26
31
36
41
46
51
56
61
66
71
76
81
86
91
96
101
106
111
116
The "M"

FIG. 6G

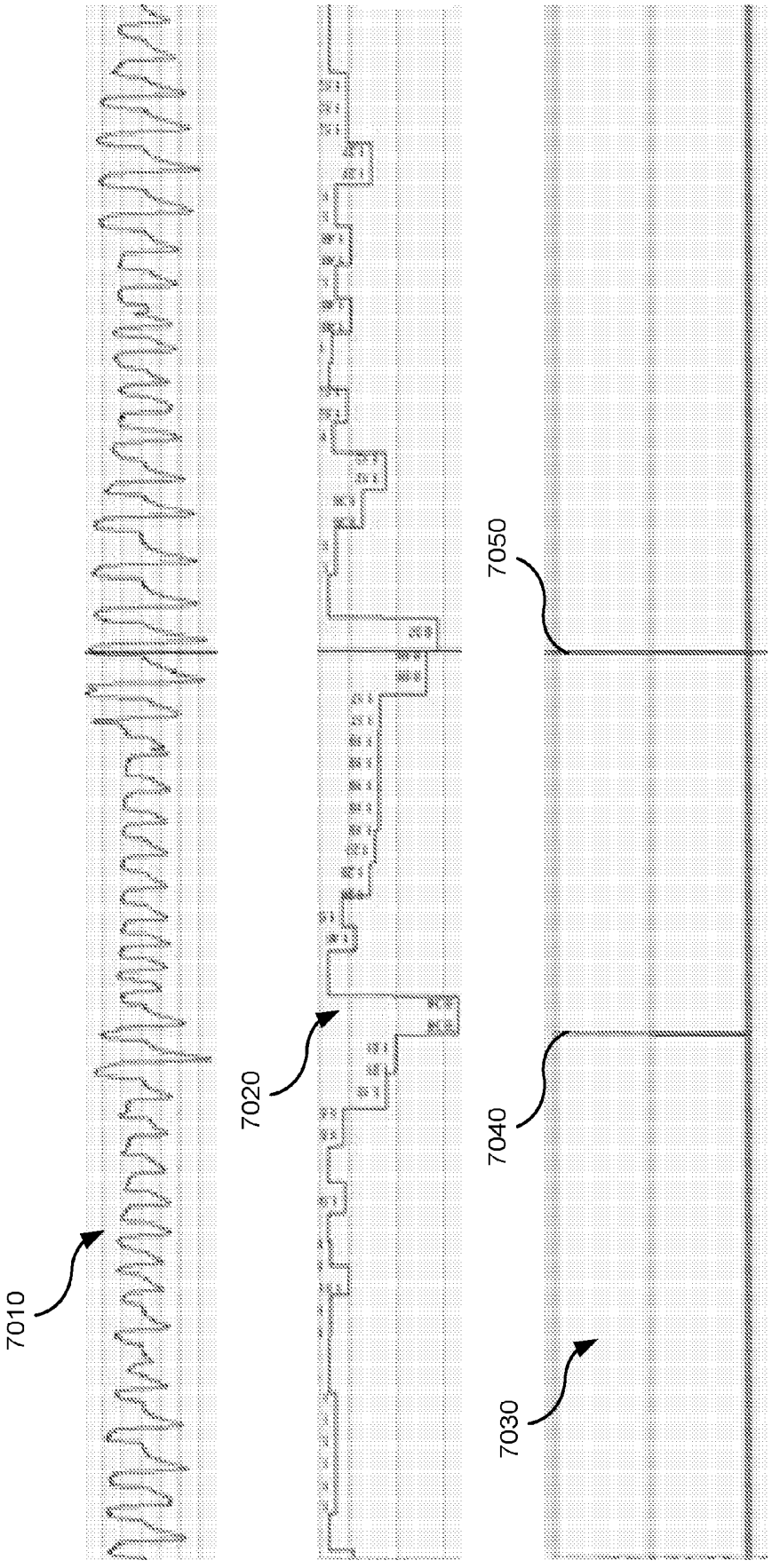


FIG. 7

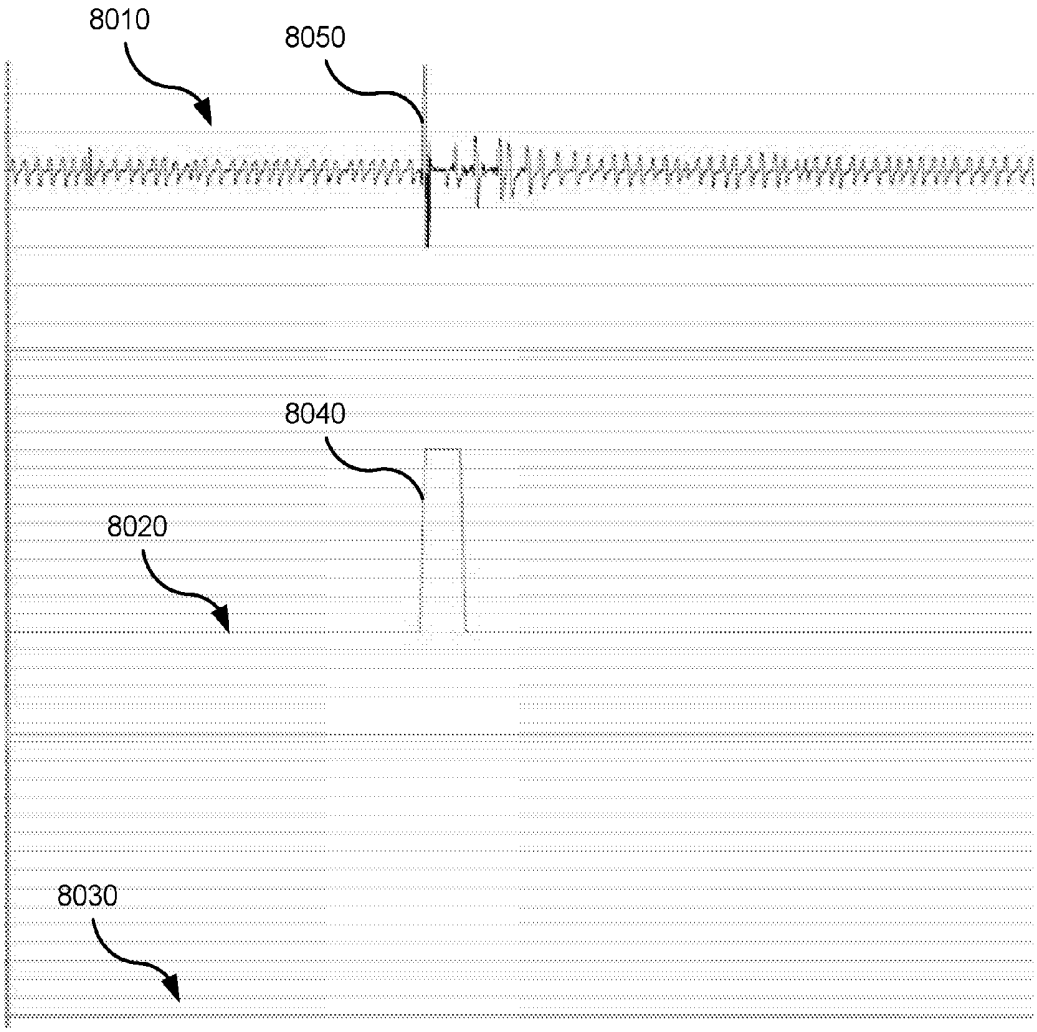


FIG. 8

DIAGNOSIS AND TREATMENT OF RESPIRATORY DISORDERS

1 CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of Australian provisional application no. 2014900439, filed 13 Feb. 2014, the entire disclosure of which is incorporated herein by reference.

2 STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not Applicable

3 THE NAMES OF PARTIES TO A JOINT RESEARCH DEVELOPMENT

[0003] Not Applicable

4 SEQUENCE LISTING

[0004] Not Applicable

5 BACKGROUND OF THE INVENTION

[0005] 5.1 Field of the Invention

[0006] The present technology relates to one or more of the detection, diagnosis, treatment, prevention and amelioration of respiratory-related disorders. In particular, the present technology relates to medical devices or apparatus, and their use for the above purposes.

[0007] 5.2 Description of the Related Art

5.2.1 Human Respiratory System and its Disorders

[0008] The respiratory system of the body facilitates gas exchange. The nose and mouth form the entrance to the airways of a patient.

[0009] The airways include a series of branching tubes, which become narrower, shorter and more numerous as they penetrate deeper into the lung. The prime function of the lung is gas exchange, allowing oxygen to move from the air into the venous blood and carbon dioxide to move out. The trachea divides into right and left main bronchi, which further divide eventually into terminal bronchioles. The bronchi make up the conducting airways, and do not take part in gas exchange. Further divisions of the airways lead to the respiratory bronchioles, and eventually to the alveoli. The alveolated region of the lung is where the gas exchange takes place, and is referred to as the respiratory zone. See West, Respiratory Physiology—the essentials.

[0010] A range of respiratory disorders exist.

[0011] Obstructive Sleep Apnea (OSA), a form of Sleep Disordered Breathing (SDB), is characterized by occlusion or obstruction of the upper air passage during sleep. It results from a combination of an abnormally small upper airway and the normal loss of muscle tone in the region of the tongue, soft palate and posterior oropharyngeal wall during sleep. The condition causes the affected patient to stop breathing for periods typically of 30 to 120 seconds duration, sometimes 200 to 300 times per night. It often causes excessive daytime somnolence, and it may cause cardiovascular disease and brain damage. The syndrome is a common disorder, particularly in middle aged overweight males, although a person affected may have no awareness of the problem. See U.S. Pat. No. 4,944,310 (Sullivan).

[0012] Cheyne-Stokes Respiration (CSR) is a disorder of a patient's respiratory controller in which there are rhythmic alternating periods of waxing and waning ventilation, causing repetitive de-oxygenation and re-oxygenation of the arterial blood. It is possible that CSR is harmful because of the repetitive hypoxia. In some patients CSR is associated with repetitive arousal from sleep, which causes severe sleep disruption, increased sympathetic activity, and increased afterload. See U.S. Pat. No. 6,532,959 (Berthon-Jones).

[0013] Obesity Hyperventilation Syndrome (OHS) is defined as the combination of severe obesity and awake chronic hypercapnia, in the absence of other known causes for hypoventilation. Symptoms include dyspnea, morning headache and excessive daytime sleepiness.

[0014] Chronic Obstructive Pulmonary Disease (COPD) encompasses any of a group of lower airway diseases that have certain characteristics in common. These include increased resistance to air movement, extended expiratory phase of respiration, and loss of the normal elasticity of the lung. Examples of COPD are emphysema and chronic bronchitis. COPD is caused by chronic tobacco smoking (primary risk factor), occupational exposures, air pollution and genetic factors. Symptoms include: dyspnea on exertion, chronic cough and sputum production.

[0015] Neuromuscular Disease (NMD) is a broad term that encompasses many diseases and ailments that impair the functioning of the muscles either directly via intrinsic muscle pathology, or indirectly via nerve pathology. Some NMD patients are characterised by progressive muscular impairment leading to loss of ambulation, being wheelchair-bound, swallowing difficulties, respiratory muscle weakness and, eventually, death from respiratory failure. Neuromuscular disorders can be divided into rapidly progressive and slowly progressive: (i) Rapidly progressive disorders: Characterised by muscle impairment that worsens over months and results in death within a few years (e.g. Amyotrophic lateral sclerosis (ALS) and Duchenne muscular dystrophy (DMD) in teenagers); (ii) Variable or slowly progressive disorders: Characterised by muscle impairment that worsens over years and only mildly reduces life expectancy (e.g. Limb girdle, Facioscapulohumeral and Myotonic muscular dystrophy). Symptoms of respiratory failure in NMD include: increasing generalised weakness, dysphagia, dyspnea on exertion and at rest, fatigue, sleepiness, morning headache, and difficulties with concentration and mood changes.

[0016] Chest wall disorders are a group of thoracic deformities that result in inefficient coupling between the respiratory muscles and the thoracic cage. The disorders are usually characterised by a restrictive defect and share the potential of long term hypercapnic respiratory failure. Scoliosis and/or kyphoscoliosis may cause severe respiratory failure. Symptoms of respiratory failure include: dyspnea on exertion, peripheral oedema, orthopnea, repeated chest infections, morning headaches, fatigue, poor sleep quality and loss of appetite.

[0017] Otherwise healthy individuals may take advantage of systems and devices to prevent respiratory disorders from arising.

5.2.2 Therapy

[0018] Nasal Continuous Positive Airway Pressure (CPAP) therapy has been used to treat Obstructive Sleep Apnea (OSA). The hypothesis is that continuous positive

airway pressure acts as a pneumatic splint and may prevent upper airway occlusion by pushing the soft palate and tongue forward and away from the posterior oropharyngeal wall.

[0019] Non-invasive ventilation (NIV) provides ventilator support to a patient through the upper airways to assist the patient in taking a full breath and/or maintain adequate oxygen levels in the body by doing some or all of the work of breathing. The ventilator support is provided via a patient interface. NIV has been used to treat CSR, OHS, COPD, MD and Chest Wall disorders.

[0020] Invasive ventilation (IV) provides ventilatory support to patients that are no longer able to effectively breathe themselves and is provided using a tracheostomy tube.

[0021] Ventilators may control the timing and pressure of breaths pumped into the patient and monitor the breaths taken by the patient. The methods of control and monitoring patients typically include volume-cycled and pressure-cycled methods. The volume-cycled methods may include among others, Pressure-Regulated Volume Control (PRVC), Volume Ventilation (VV), and Volume Controlled Continuous Mandatory Ventilation (VC-CMV) techniques. The pressure-cycled methods may involve, among others, Assist Control (AC), Synchronized Intermittent Mandatory Ventilation (SIMV), Controlled Mechanical Ventilation (CMV), Pressure Support Ventilation (PSV), Continuous Positive Airway Pressure (CPAP), or Positive End Expiratory Pressure (PEEP) techniques.

5.2.3 Systems

[0022] One known device used for treating sleep disordered breathing is the S9 Sleep Therapy System, manufactured by ResMed. Ventilators such as the ResMed Stellar™ Series of Adult and Paediatric Ventilators may provide support for invasive and non-invasive non-dependent ventilation for a range of patients for treating a number of conditions such as but not limited to NMD, OHS and COPD.

[0023] The ResMed Elisée™ 150 ventilator and ResMed VS III™ ventilator may provide support for invasive and non-invasive dependent ventilation suitable for adult or paediatric patients for treating a number of conditions. These ventilators provide volumetric and barometric ventilation modes with a single or double limb circuit.

[0024] A system may comprise a PAP Device/ventilator, an air circuit, a humidifier, a patient interface, and data management.

5.2.4 Patient Interface

[0025] A patient interface may be used to interface respiratory equipment to its user, for example by providing a flow of breathable gas. The flow of breathable gas may be provided via a mask to the nose and/or mouth, a tube to the mouth or a tracheostomy tube to the trachea of the user. Depending upon the therapy to be applied, the patient interface may form a seal, e.g. with a face region of the patient, to facilitate the delivery of gas at a pressure at sufficient variance with ambient pressure to effect therapy, e.g. a positive pressure of about 10 cmH2O. For other forms of therapy, such as the delivery of oxygen, the patient interface may not include a seal sufficient to facilitate delivery to the airways of a supply of gas at a positive pressure of about 10 cmH2O.

5.2.5 Respiratory Apparatus (PAP Device/Ventilator)

[0026] Examples of respiratory apparatuses include ResMed's S9 AutoSet™ PAP device and ResMed's Stellar™ 150 ventilator. PAP devices or ventilators typically comprise a flow generator, such as a motor-driven blower or a compressed gas reservoir, and are configured to supply a flow of air or other breathable gases to the airway of a patient. In some cases, the flow of air or other breathable gases may be supplied to the airway of the patient at positive pressure. The outlet of the PAP device or the ventilator is connected via an air circuit to a patient interface such as those described above.

[0027] Ventilators or PAP devices typically include a flow generator, an inlet filter, a patient interface, an air circuit connecting the flow generator to the patient interface, various sensors and a microprocessor-based controller. The patient interface may include a mask or a tracheostomy tube as described above. The flow generator may include a servo-controlled motor, volute and an impeller that forms a blower. In some cases a brake for the motor may be implemented to more rapidly reduce the speed of the blower so as to overcome the inertia of the motor and impeller. The braking can permit the blower to more rapidly achieve a lower pressure condition in time for synchronization with expiration despite the inertia. In some cases the flow generator may also include a valve capable of discharging generated air to atmosphere as a means for altering the pressure delivered to the patient as an alternative to motor speed control. The sensors measure, amongst other things, motor speed, mass flow rate and outlet pressure, such as with a pressure transducer or the like. The apparatus may optionally include a humidifier and/or heater elements in the path of the air delivery circuit. The controller may include data storage capacity with or without integrated data retrieval and display functions.

5.2.6 Monitoring Systems

[0028] Polysomnography (PSG) is a conventional system for diagnosis and prognosis of cardio-pulmonary disorders. PSG typically involves the placement of 15 to 20 contact sensors on a person in order to record various bodily signals such as electroencephalography (EEG), electrocardiography (ECG), electrooculograpy (EOG), etc. However, while they may be suitable for their usual application in a clinical setting, such systems are complicated and potentially expensive, and/or may be uncomfortable or impractical for a patient at home trying to sleep.

5.2.7 Respiratory Effort-Related Arousals (RERAs)

[0029] In 1999 the AASM Task Force defined RERAs as

[0030] A sequence of breaths characterized by increasing respiratory effort leading to an arousal from sleep, but which does not meet criteria for an apnea or hypopnea. These events must fulfil both of the following criteria:

[0031] 1. Pattern of progressively more negative esophageal pressure, terminated by a sudden change in pressure to a less negative level and an arousal;

[0032] 2. The event lasts 10 seconds or longer.

[0033] In 2000, the study "Non-Invasive Detection of Respiratory Effort-Related Arousals (RERAs) by a Nasal Cannula/Pressure Transducer System" done at NYU School of Medicine and published in Sleep, vol. 23, No. 6, pp.

763-771, demonstrated that a Nasal Cannula/Pressure Transducer System was adequate and reliable in the detection of RERAs.

[0034] A RERA detector may be based on a real flow signal derived from a PAP device. For example, a flow limitation measure may be determined based on a flow signal. A measure of arousal may then be derived as a function of the flow limitation measure and a measure of sudden increase in ventilation. One such method is described in PCT Patent Publication no. WO 2008/138040, assigned to ResMed Ltd., the disclosure of which is hereby incorporated herein by reference.

6 BRIEF SUMMARY OF THE TECHNOLOGY

[0035] The present technology is directed towards providing medical devices used in the diagnosis, amelioration, treatment, or prevention of respiratory disorders having one or more of improved comfort, cost, efficacy, ease of use and manufacturability.

[0036] A first aspect of the present technology relates to devices used in the diagnosis, amelioration, treatment or prevention of a respiratory disorder.

[0037] Another aspect of the present technology relates to methods used in the diagnosis, amelioration, treatment or prevention of a respiratory disorder.

[0038] One form of the present technology comprises methods that detect respiratory effort-related arousals based on a combination of consistent inspiratory flow limitation and "big breath" detection.

[0039] Some versions of the present technology may involve a method, such as in one or more processors, for detecting a respiratory effort-related arousal in a respiratory airflow signal of a patient. The method may include receiving in a processor a computed measure of consistency of inspiratory flow limitation over a plurality of recent breaths from the signal. The method may include receiving in a processor a computed measure of step change in ventilation indicating a sudden big breath. The method may include computing in a processor a measure indicating a degree of confidence of occurrence of a respiratory effort-related arousal from the measure of consistency of inspiratory flow limitation and the measure of the step change in ventilation.

[0040] In some versions, the method may include, in a processor, calculating the measure of consistency of inspiratory flow limitation over a plurality of recent breaths from the signal. The method may also include, in a processor, calculating the measure of step change in ventilation indicating a sudden big breath. The method may also include computing a maximum measure of inspiratory flow limitation over said plurality of recent breaths, wherein the measure indicating a degree of confidence may be a function of the maximum measure of inspiratory flow limitation. In some cases, the computing the measure indicating the degree of confidence may involve computing a distance between a three-dimensional point whose components are the measure of consistency of inspiratory flow limitation, the measure of a step change in ventilation, and the maximum measure of inspiratory flow limitation and a corner point of a three-dimensional cube. Optionally, the measure of consistency of inspiratory flow limitation may be computed as a fraction of recent flow limitation measures that exceed a predetermined threshold. In some cases, the measure of step change in ventilation may be computed as a difference between a current value of a ventilation ratio and a previous value of the ventilation ratio. The measure of step change in ventilation may be the difference mapped to a range [**0**, **1**]. In some cases, the ventilation ratio may be computed as a mean inspiratory flow rate divided by a measure of current ventilation. The mean inspiratory flow rate may be computed as an average of inspiratory and expiratory tidal volumes divided by an inspiratory time for a current breath.

[0041] Optionally, the method may also include comparing the degree of confidence of occurrence of a respiratory effort-related arousal with a predetermined threshold to provide an indication of whether the patient is currently experiencing a respiratory effort-related arousal. The method may also include calculating a respiratory disturbance index from a number of indications of respiratory effort-related arousals in a predetermined interval. The method may also include determining a change to a parameter of a respiratory therapy for the patient based on the measure indicating the degree of confidence.

[0042] Some versions of the present technology may include a computer-readable memory storage medium having program instructions encoded thereon configured to cause a processor to perform a method of detecting a respiratory effort-related arousal in a respiratory airflow signal of a patient. The method may include computing a measure of consistency of inspiratory flow limitation over a plurality of recent breaths from the signal. The method may include computing a measure of step change in ventilation indicating a sudden big breath. The method may include computing a measure indicating a degree of confidence of occurrence of a respiratory effort-related arousal from the measure of consistency of inspiratory flow limitation and the measure of the step change in ventilation.

[0043] Some versions of the present technology may include a device for detecting a respiratory effort-related arousal in a respiratory airflow signal of a patient. The device may include a sensor configured to provide a signal representative of patient respiratory airflow. The method may include a processor configured to detect a respiratory effort-related arousal. The processor may be configured to compute a measure of consistency of inspiratory flow limitation over a plurality of recent breaths from the signal. The processor may be configured to compute a measure of step change in ventilation indicating a sudden big breath. The processor may be configured to compute a measure indicating a degree of confidence of occurrence of a respiratory effort-related arousal from the measure of consistency of inspiratory flow limitation and the measure of the step change in ventilation.

[0044] According to one aspect of the present technology, there is provided a method of detecting respiratory effort-related arousals in a respiratory airflow signal of a patient, comprising the steps of: computing a measure of consistency of inspiratory flow limitation over a plurality of recent breaths from the signal; computing a measure of step change in ventilation indicating a sudden big breath; and computing a measure indicating a degree of confidence of occurrence of a respiratory effort-related arousal from the measure of consistency of inspiratory flow limitation and the measure of the step change in ventilation.

[0045] According to another aspect of the present technology, a device for detecting respiratory effort-related arousals in a respiratory airflow signal of a patient comprises a sensor configured to provide a signal representative of patient respiratory airflow, and a processor configured to

detect a respiratory effort-related arousal. The processor is configured to: compute a measure of consistency of inspiratory flow limitation over a plurality of recent breaths from the signal; compute a measure of step change in ventilation indicating a sudden big breath; and compute a measure indicating a degree of confidence of the occurrence of a respiratory effort-related arousal from the measure of consistency of inspiratory flow limitation and the measure of the step change in ventilation.

[0046] According to a further aspect of the present technology, a computer-readable storage medium has encoded thereon code so as to configure a processor to carry out a method of detecting respiratory effort-related arousals in a respiratory airflow signal of a patient, the method including: computing a measure of consistency of inspiratory flow limitation over a plurality of recent breaths from the signal; computing a measure of step change in ventilation indicating a sudden big breath; and computing a measure indicating a degree of confidence of occurrence of a respiratory effort-related arousal from the measure of consistency of inspiratory flow limitation and the measure of the step change in ventilation.

[0047] Of course, portions of the aspects may form sub-aspects of the present technology. Also, various ones of the sub-aspects and/or aspects may be combined in various manners and also constitute additional aspects or sub-aspects of the present technology.

[0048] Other features of the technology will be apparent from consideration of the information contained in the following detailed description, abstract, drawings and claims.

7 BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0049] The present technology is illustrated by way of example, and not by way of limitation, in the figures of the accompanying drawings, in which like reference numerals refer to similar elements including:

7.1 Treatment Systems

[0050] FIG. **1**A shows a system in accordance with the present technology. A patient **1000** wearing a patient interface **3000**, receives a supply of air at positive pressure from a PAP device **4000**. Air from the PAP device is humidified in a humidifier **5000**, and passes along an air circuit **4170** to the patient **1000**. A bed partner **1100** is also shown.

[0051] FIG. **1**B shows a contactless sensor unit **7000** monitoring a sleeping patient **1000**. The contactless sensor unit **7000** may be a Doppler radar movement sensor that provides a signal representing respiratory movement of the patient **1000**, which signal may be used as a proxy for patient respiratory flow.

7.2 Respiratory System

[0052] FIG. **2**A shows an overview of a human respiratory system including the nasal and oral cavities, the larynx, vocal folds, oesophagus, trachea, bronchus, lung, alveolar sacs, heart and diaphragm.

[0053] FIG. **2**B shows a view of a human upper airway including the nasal cavity, nasal bone, lateral nasal cartilage, greater alar cartilage, nostril, lip superior, lip inferior, larynx, hard palate, soft palate, oropharynx, tongue, epiglottis, vocal folds, oesophagus and trachea.

7.3 Patient Interface

[0054] FIG. **3** shows a patient interface in accordance with one form of the present technology.

7.4 PAP Device

[0055] FIG. **4**A shows a PAP device in accordance with one form of the present technology.

[0056] FIG. **4**B shows a schematic diagram of the pneumatic circuit of a PAP device in accordance with one form of the present technology. The directions of upstream and downstream are indicated.

[0057] FIG. **4**C shows a schematic diagram of the electrical components of a PAP device in accordance with one aspect of the present technology.

[0058] FIG. **4**D shows a schematic diagram of the algorithms implemented in a PAP device in accordance with an aspect of the present technology. In this figure, arrows with solid lines indicate an actual flow of information, for example via an electronic signal.

[0059] FIG. **4**E is a flow chart illustrating a method carried out by the therapy engine of FIG. **4**D in accordance with one aspect of the present technology.

[0060] FIG. **4**F is a flow chart illustrating a method that may be implemented for the RERA detection algorithm of FIG. **4**D in one form of the present technology.

7.5 Humidifier

[0061] FIG. **5** shows a humidifier in accordance with one aspect of the present technology.

7.6 Breathing Waveforms

[0062] FIG. **6**A shows a model typical breath waveform of a person while sleeping. The horizontal axis is time, and the vertical axis is respiratory flow. While the parameter values may vary, a typical breath may have the following approximate values: tidal volume, Vt, 0.5 L, inhalation time, Ti, 1.6 s, peak inspiratory flow, Qpeak, 0.4 L/s, exhalation time, Te, 2.4 s, peak expiratory flow, Qpeak, −0.5 L/s. The total duration of the breath, Ttot, is about 4 s. The person typically breathes at a rate of about 15 breaths per minute (BPM), with Ventilation, Vent, about 7.5 L/minute. A typical duty cycle, the ratio of Ti to Ttot is about 40%.

[0063] FIG. **6**B shows a scaled inspiratory portion of a breath where the patient is experiencing an example of flattened inspiratory flow limitation.

[0064] FIG. **6**C shows a scaled inspiratory portion of a breath where the patient is experiencing an example of "mesa" flattened inspiratory flow limitation.

[0065] FIG. **6**D shows a scaled inspiratory portion of a breath where the patient is experiencing an example of "panda ears" inspiratory flow limitation.

[0066] FIG. **6**E shows a scaled inspiratory portion of a breath where the patient is experiencing an example of "chair" inspiratory flow limitation.

[0067] FIG. **6**F shows a scaled inspiratory portion of a breath where the patient is experiencing an example of "reverse chair" inspiratory flow limitation.

[0068] FIG. **6**G shows a scaled inspiratory portion of a breath where the patient is experiencing an example of "M-shaped" inspiratory flow limitation.

[0069] FIG. **7** contains three graphs illustrating the output of the RERA detection algorithm illustrated in FIG. **4**F on an example flow signal.

[0070] FIG. **8** contains three graphs illustrating the output of the RERA detection algorithm illustrated in FIG. **4**F and a previous RERA detection algorithm on an example flow signal.

8 DETAILED DESCRIPTION OF EXAMPLES OF THE TECHNOLOGY

[0071] Before the present technology is described in further detail, it is to be understood that the technology is not limited to the particular examples described herein, which may vary. It is also to be understood that the terminology used in this disclosure is for the purpose of describing only the particular examples discussed herein, and is not intended to be limiting.

8.1 Therapy

[0072] In one form, the present technology comprises a method for treating a respiratory disorder comprising the step of applying positive pressure to the entrance of the airways of a patient **1000**.

[0073] In certain embodiments of the present technology, a supply of air at positive pressure is provided to the nasal passages of the patient via one or both nares.

8.2 Treatment Systems

[0074] In one form, the present technology comprises apparatus for treating a respiratory disorder. The apparatus may comprise a PAP device **4000** for supplying pressurised respiratory gas, such as air, to the patient **1000** via an air delivery tube leading to a patient interface **3000**.

8.3 Patient Interface

[0075] A non-invasive patient interface **3000** in accordance with one aspect of the present technology comprises the following functional aspects: a seal-forming structure **3100**, a plenum chamber **3200**, a positioning and stabilising structure **3300**, a vent **3400**, a connection port **3600** for connection to air circuit **4170**, and a forehead support **3700**. In some forms a functional aspect may be provided by one or more physical components. In some forms, one physical component may provide one or more functional aspects. In use the seal-forming structure **3100** is arranged to surround an entrance to the airways of the patient so as to facilitate the supply of air at positive pressure to the airways.

8.4 PAP Device

[0076] A PAP device **4000** in accordance with one aspect of the present technology comprises mechanical and pneumatic components **4100** and electrical components **4200** and is programmed to execute one or more algorithms **4300**. The PAP device **4000** preferably has an external housing **4010**, preferably formed in two parts, an upper portion **4012** of the external housing **4010**, and a lower portion **4014** of the external housing **4010**. In alternative forms, the external housing **4010** may include one or more panel(s) **4015**. Preferably the PAP device **4000** comprises a chassis **4016** that supports one or more internal components of the PAP device **4000**. In one form a pneumatic block **4020** is supported by, or formed as part of the chassis **4016**. The PAP device **4000** may include a handle **4018**.

[0077] The pneumatic path of the PAP device **4000** preferably comprises an inlet air filter **4112**, an inlet muffler **4122**, a controllable pressure device **4140** capable of supplying air at positive pressure (preferably a blower **4142**), and an outlet muffler **4124**. One or more sensors or transducers **4270** are included in the pneumatic path.

[0078] The preferred pneumatic block **4020** comprises a portion of the pneumatic path that is located within the external housing **4010**.

[0079] The PAP device **4000** preferably has an electrical power supply **4210**, one or more input devices **4220**, a processor **4230**, a therapy device controller **4240**, a therapy device **4245**, one or more protection circuits **4250**, memory **4260**, transducers **4270**, data communication interface **4280** and one or more output devices **4290**. Electrical components **4200** may be mounted on a single Printed Circuit Board Assembly (PCBA) **4202**. In an alternative form, the PAP device **4000** may include more than one PCBA **4202**.

8.4.1 PAP Device Mechanical & Pneumatic Components **4100**

8.4.1.1 Air Filter(s) **4110**

[0080] A PAP device in accordance with one form of the present technology may include an air filter **4110**, or a plurality of air filters **4110**.

[0081] In one form, an inlet air filter **4112** is located at the beginning of the pneumatic path upstream of a pressure device **4140**.

[0082] In one form, an outlet air filter **4114**, for example an antibacterial filter, is located between an outlet of the pneumatic block **4020** and a patient interface **3000**.

8.4.1.2 Muffler(s) **4120**

[0083] In one form of the present technology, an inlet muffler **4122** is located in the pneumatic path upstream of a pressure device **4140**.

[0084] In one form of the present technology, an outlet muffler **4124** is located in the pneumatic path between the pressure device **4140** and a patient interface **3000**.

8.4.1.3 Pressure Device **4140**

[0085] In a preferred form of the present technology, a pressure device **4140** for producing a flow of air at positive pressure is a controllable blower **4142**. For example the blower may include a brushless DC motor **4144** with one or more impellers housed in a volute. The blower may be preferably capable of delivering a supply of air, for example about 120 litres/minute, at a positive pressure in a range from about 4 cmH_2O to about 20 cmH_2O, or in other forms up to about 30 cmH_2O.

[0086] The pressure device **4140** is under the control of the therapy device controller **4240**.

8.4.1.4 Transducer(s) **4270**

[0087] In one form of the present technology, one or more transducers **4270** are located upstream of the pressure device **4140**. The one or more transducers **4270** are constructed and arranged to measure properties of the air at that point in the pneumatic path.

[0088] In one form of the present technology, one or more transducers **4270** are located downstream of the pressure device **4140**, and upstream of the air circuit **4170**. The one or more transducers **4270** are constructed and arranged to measure properties of the air at that point in the pneumatic path.

[0089] In one form of the present technology, one or more transducers **4270** are located proximate to the patient interface **3000**.

8.4.1.5 Anti-Spill Back Valve **4160**

[0090] In one form of the present technology, an anti-spill back valve is located between the humidifier **5000** and the pneumatic block **4020**. The anti-spill back valve is constructed and arranged to reduce the risk that water will flow upstream from the humidifier **5000**, for example to the motor **4144**.

8.4.1.6 Air Circuit **4170**

[0091] An air circuit **4170** in accordance with an aspect of the present technology is constructed and arranged to allow a flow of air or breathable gasses between the pneumatic block **4020** and the patient interface **3000**.

8.4.1.7 Supplemental Oxygen **4180**

[0092] In one form of the present technology, supplemental oxygen **4180** is delivered to a point in the pneumatic path.

[0093] In one form of the present technology, supplemental oxygen **4180** is delivered upstream of the pneumatic block **4020**.

[0094] In one form of the present technology, supplemental oxygen **4180** is delivered to the air circuit **4170**.

[0095] In one form of the present technology, supplemental oxygen **4180** is delivered to the patient interface **3000**.

8.4.2 PAP Device Electrical Components **4200**

8.4.2.1 Power Supply **4210**

[0096] In one form of the present technology power supply **4210** is internal of the external housing **4010** of the PAP device **4000**. In another form of the present technology, power supply **4210** is external of the external housing **4010** of the PAP device **4000**.

[0097] In one form of the present technology power supply **4210** provides electrical power to the PAP device **4000** only. In another form of the present technology, power supply **4210** provides electrical power to both PAP device **4000** and humidifier **5000**.

8.4.2.2 Input Devices **4220**

[0098] In one form of the present technology, a PAP device **4000** includes one or more input devices **4220** in the form of buttons, switches or dials to allow a person to interact with the device. The buttons, switches or dials may be physical devices, or software devices accessible via a touch screen. The buttons, switches or dials may, in one form, be physically connected to the external housing **4010**, or may, in another form, be in wireless communication with a receiver that is in electrical connection to the processor **4230**.

[0099] In one form the input device **4220** may be constructed and arranged to allow a person to select a value and/or a menu option.

8.4.2.3 Processor **4230**

[0100] In one form of the present technology, the processor **4230** is a processor suitable to control a PAP device **4000** such as an x86 INTEL processor.

[0101] A processor **4230** suitable to control a PAP device **4000** in accordance with another form of the present technology includes a processor based on ARM Cortex-M processor from ARM Holdings. For example, an STM32 series microcontroller from ST MICROELECTRONICS may be used.

[0102] Another processor **4230** suitable to control a PAP device **4000** in accordance with a further alternative form of the present technology includes a member selected from the family ARMS-based 32-bit RISC CPUs. For example, an STR9 series microcontroller from ST MICROELECTRONICS may be used.

[0103] In certain alternative forms of the present technology, a 16-bit RISC CPU may be used as the processor **4230** for the PAP device **4000**. For example a processor from the MSP430 family of microcontrollers, manufactured by TEXAS INSTRUMENTS, may be used.

[0104] The processor **4230** is configured to receive input signal(s) from one or more transducers **4270**, and one or more input devices **4220**.

[0105] The processor **4230** is configured to provide output signal(s) to one or more of an output device **4290**, a therapy device controller **4240**, a data communication interface **4280** and humidity controller **5250**.

[0106] In some forms of the present technology, the processor **4230**, or multiple such processors, is configured to implement the one or more methodologies described herein such as the one or more algorithms **4300** expressed as computer programs stored in a non-transitory computer readable storage medium, such as memory **4260**. In some cases, as previously discussed, such processor(s) may be integrated with a PAP device **4000**. However, in some forms of the present technology the processor(s) may be implemented discretely from the flow generation components of the PAP device **4000**, such as for purpose of performing any of the methodologies described herein without directly controlling delivery of a respiratory treatment. For example, such a processor may perform any of the methodologies described herein for purposes of determining control settings for a ventilator or other respiratory related events by analysis of stored data such as from any of the sensors described herein.

[0107] The processor **4230** of the PAP device **4000** is programmed to execute one or more algorithms **4300**, preferably including a pre-processing module **4310**, a therapy engine module **4320**, a therapy control module **4330**, and a fault condition module **4340**.

8.4.2.4 Clock **4232**

[0108] Preferably PAP device **4000** includes a clock **4232** that is connected to processor **4230**.

8.4.2.5 Therapy Device Controller **4240**

[0109] In one form of the present technology, therapy device controller **4240** is a therapy control module **4330** that forms part of the algorithms **4300** executed by the processor **4230**.

[0110] In one form of the present technology, therapy device controller **4240** is a dedicated motor control integrated circuit. For example, in one form a MC33035 brushless DC motor controller, manufactured by ONSEMI is used.

8.4.2.6 Protection Circuits **4250**

[0111] Preferably a PAP device **4000** in accordance with the present technology comprises one or more protection circuits **4250**.

[0112] One form of protection circuit **4250** in accordance with the present technology is an electrical protection circuit.

[0113] One form of protection circuit **4250** in accordance with the present technology is a temperature or pressure safety circuit.

8.4.2.7 Memory **4260**

[0114] In accordance with one form of the present technology the PAP device **4000** includes memory **4260**, preferably non-volatile memory. In some forms, memory **4260** may include battery powered static RAM. In some forms, memory **4260** may include volatile RAM.

[0115] Preferably memory **4260** is located on PCBA **4202**. Memory **4260** may be in the form of EEPROM, or NAND flash.

[0116] Additionally or alternatively, PAP device **4000** includes a removable form of memory **4260**, for example a memory card made in accordance with the Secure Digital (SD) standard.

[0117] In one form of the present technology, the memory **4260** acts as a non-transitory computer readable storage medium on which is stored computer program instructions expressing the one or more methodologies described herein, such as the one or more algorithms **4300**. The processor **4230** is configured to execute such instructions stored on the non-transitory computer readable storage medium.

8.4.2.8 Transducers **4270**

[0118] Transducers may be internal of the PAP device **4000**, or external of the PAP device **4000**. External transducers may be located for example on or form part of the air circuit **4170**, e.g. at the patient interface **3000**. External transducers may be in the form of non-contact sensors such as a Doppler radar movement sensor that transmit or transfer data to the PAP device **4000**.

8.4.2.8.1 Flow Transducer **4274**

[0119] A flow transducer **4274** in accordance with the present technology may be based on a differential pressure transducer, for example, an SDP600 Series differential pressure transducer from SENSIRION. The differential pressure transducer is in fluid communication with the pneumatic circuit, with one of each of the pressure transducers connected to respective first and second points in a flow restricting element.

[0120] In one example, a signal representing total flow Qt from the flow transducer **4274** is received by the processor **4230**.

8.4.2.8.2 Pressure Transducer **4272**

[0121] A pressure transducer **4272** in accordance with the present technology is located in fluid communication with the pneumatic path. An example of a suitable pressure transducer **4272** is a sensor from the HONEYWELL ASDX series. An alternative suitable pressure transducer is a sensor from the NPA Series from GENERAL ELECTRIC.

[0122] In use, a signal from the pressure transducer **4272** is received by the processor **4230**. In one form, the signal from the pressure transducer **4272** is filtered prior to being received by the processor **4230**.

8.4.2.8.3 Motor Speed Signal **4276**

[0123] In one form of the present technology a motor speed signal **4276** is generated. A motor speed signal **4276** is preferably provided by therapy device controller **4240**. Motor speed may, for example, be generated by a speed sensor, such as a Hall effect sensor.

8.4.2.9 Data Communication Interface **4280**

[0124] In one preferred form of the present technology, a data communication interface **4280** is provided, and is connected to processor **4230**. Data communication interface **4280** is preferably connectable to remote external communication network **4282**. Data communication interface **4280** is preferably connectable to local external communication network **4284**. Preferably remote external communication network **4282** is connectable to remote external device **4286**. Preferably local external communication network **4284** is connectable to local external device **4288**.

[0125] In one form, data communication interface **4280** is part of processor **4230**. In another form, data communication interface **4280** is an integrated circuit that is separate from processor **4230**.

[0126] In one form, remote external communication network **4282** is the Internet. The data communication interface **4280** may use wired communication (e.g. via Ethernet, or optical fibre) or a wireless protocol to connect to the Internet.

[0127] In one form, local external communication network **4284** utilises one or more communication standards, such as Bluetooth, or a consumer infrared protocol.

[0128] In one form, remote external device **4286** is one or more computers, for example a cluster of networked computers. In one form, remote external device **4286** may be virtual computers, rather than physical computers. In either case, such remote external device **4286** may be accessible to an appropriately authorised person such as a clinician.

[0129] Preferably local external device **4288** is a personal computer, mobile phone, tablet or remote control.

8.4.2.10 Output Device **4290** Including Optional Display, Alarms

[0130] An output device **4290** in accordance with the present technology may take the form of one or more of a visual, audio and haptic unit. A visual display may be a Liquid Crystal Display (LCD) or Light Emitting Diode (LED) display.

8.4.2.10.1 Display Driver **4292**

[0131] A display driver **4292** receives as an input the characters, symbols, or images intended for display on the display **4294**, and converts them to commands that cause the display **4294** to display those characters, symbols, or images.

8.4.2.10.2 Display **4294**

[0132] A display **4294** is configured to visually display characters, symbols, or images in response to commands received from the display driver **4292**. For example, the display **4294** may be an eight-segment display, in which case the display driver **4292** converts each character or symbol, such as the figure "0", to eight logical signals indicating whether the eight respective segments are to be activated to display a particular character or symbol.

8.4.3 PAP Device Algorithms **4300**

8.4.3.1 Pre-Processing Module **4310**

[0133] A pre-processing module **4310** in accordance with the present technology receives as an input, raw data from a transducer, for example a flow or pressure transducer, and preferably performs one or more process steps to calculate one or more output values that will be used as an input to another module, for example a therapy engine module **4320**.

[0134] In one form of the present technology, the output values include the interface or mask pressure Pm, the respiratory flow Qr, and the leak flow Ql.

[0135] In various forms of the present technology, the pre-processing module **4310** comprises one or more of the following algorithms: pressure compensation **4312**, vent flow **4314**, leak flow **4316**, and respiratory flow **4318**.

8.4.3.1.1 Pressure Compensation **4312**

[0136] In one form of the present technology, a pressure compensation algorithm **4312** receives as an input a signal indicative of the pressure in the pneumatic path proximal to an outlet of the pneumatic block **4020**. The pressure compensation algorithm **4312** estimates the pressure drop in the air circuit **4170** and provides as an output an estimated pressure, Pm, in the patient interface **3000**.

8.4.3.1.2 Vent Flow **4314**

[0137] In one form of the present technology, a vent flow estimation algorithm **4314** receives as an input an estimated pressure, Pm, in the patient interface **3000** and estimates a vent flow of air, Qv, from a vent **3400** in a patient interface **3000**.

8.4.3.1.3 Leak Flow **4316**

[0138] In one form of the present technology, a leak flow algorithm **4316** receives as an input a total flow, Qt, and a vent flow Qv, and provides as an output a leak flow Ql by calculating an average of Qt−Qv over a period sufficiently long to include several breathing cycles, e.g. about 10 seconds.

[0139] In one form, the leak flow algorithm **4316** receives as an input a total flow, Qt, a vent flow Qv, and an estimated pressure, Pm, in the patient interface **3000**, and provides as an output a leak flow Ql by calculating a leak conductance, and determining a leak flow Ql to be a function of leak conductance and pressure, Pm. Preferably leak conductance is calculated as the quotient of low pass filtered non-vent flow Qt−Qv, and low pass filtered square root of pressure Pm, where the low pass filter time constant has a value sufficiently long to include several breathing cycles, e.g. about 10 seconds.

8.4.3.1.4 Respiratory Flow **4318**

[0140] In one form of the present technology, a respiratory flow algorithm **4318** receives as an input a total flow, Qt, a vent flow, Qv, and a leak flow, Ql, and estimates a respiratory flow of air, Qr, to the patient, by subtracting the vent flow Qv and the leak flow Ql from the total flow Qt.

8.4.3.2 Therapy Engine Module **4320**

[0141] In one form of the present technology, a therapy engine module **4320** receives as inputs one or more of a pressure, Pm, in a patient interface **3000**, and a respiratory flow of air to a patient, Qr, and provides as an output one or more therapy parameters.

8.4.3.2.1 Phase Determination **4321**

[0142] In one form of the present technology, a phase determination algorithm **4321** receives as an input a signal indicative of respiratory flow, Qr, and provides as an output a phase of a breathing cycle of a patient **1000**.

[0143] In one form, the phase output is a discrete variable with values of either inhalation or exhalation. The phase output is determined to have a discrete value of inhalation when a respiratory flow Qr has a positive value that exceeds a positive threshold. In one form, a phase is determined to have a discrete value of exhalation when a respiratory flow Qr has a negative value that is more negative than a negative threshold.

[0144] In one form, the phase output is a discrete variable with values of one of inhalation, mid-inspiratory pause, and exhalation.

[0145] In one form, the phase output is a continuous variable, for example varying from 0 to 1, or 0 to 2π, or 0° to 360°.

8.4.3.2.2 Waveform Determination **4322**

[0146] In one form of the present technology, a control module **4330** controls a therapy device **4245** to provide an approximately constant positive airway pressure throughout a respiratory cycle of a patient.

[0147] In another form of the present technology, a control module **4330** controls a therapy device **4245** to provide positive airway pressure according to a predetermined waveform of pressure vs phase. In one form, the waveform is maintained at an approximately constant level for all values of phase. In one form, the waveform is a square wave, having a higher value for some values of phase, and a lower level for other values of phase.

[0148] In one form of the present technology a waveform determination algorithm **4322** receives as an input a value indicative of current patient ventilation, Vent, and provides as an output a waveform of pressure vs. phase.

8.4.3.2.3 Ventilation Determination **4323**

[0149] In one form of the present technology, a ventilation determination algorithm **4323** receives an input a respiratory flow Qr, and determines a measure indicative of current patient ventilation, Vent.

[0150] In one form, the ventilation determination algorithm **4323** determines the measure of current patient ventilation, Vent, as half the low-pass filtered absolute value of respiratory flow, Qr. In one implementation, the low-pass filter has a time constant of three minutes.

[0151] In one form, the ventilation determination algorithm **4323** also computes a ventilation ratio VR that is a measure of a "big breath". Values of VR greater than 1 may be taken as indicating breaths that are large compared to the medium term ventilation. In one implementation, the ventilation determination algorithm **4323** computes the ventilation ratio VR as the mean inspiratory flow rate divided by the current ventilation, Vent. The mean inspiratory flow rate may be computed as the mean tidal volume (the average of inspiratory and expiratory tidal volumes for the current breath) divided by the inspiratory time Ti.

8.4.3.2.4 Determination of Inspiratory Flow Limitation **4324**

[0152] In one form of the present technology, a processor executes one or more algorithms **4324** for the determination of a measure of inspiratory flow limitation in the current breath. Examples of inspiratory flow limitation are illustrated in FIGS. **6**B to **6**G.

[0153] In one form, the inspiratory flow limitation determination algorithm **4324** receives as an input the respiratory flow signal Qr and provides as an output a measure of the extent to which the inspiratory portion of the current breath exhibits inspiratory flow limitation. This measure is referred to as the flow limitation measure (FLM).

[0154] In one implementation, the inspiratory portion of each breath is identified by a zero-crossing detector. A number of evenly spaced points (for example, sixty-five), representing points in time, are interpolated by an interpolator along the inspiratory flow-time curve for each breath. The curve described by the points is then scaled by a scaler to have unity length (duration/period) and unity area to remove the effects of changing respiratory rate and depth. The scaled breaths are then compared in a comparator with a pre-stored template representing a normal unobstructed breath, similar to the inspiratory portion of the breath shown in FIG. **6**A. Breaths deviating by more than a specified threshold (typically 1 scaled unit) at any time during the inspiration from this template, such as those due to coughs, sighs, swallows and hiccups, as determined by a test element, are rejected. For non-rejected data, a moving average of the first such scaled point is calculated by processor **4230** for the preceding several inspiratory events. This is repeated over the same inspiratory events for the second such point, and so on. Thus, for example, sixty-five scaled data points are generated by processor **4230**, and represent a moving average of the preceding several inspiratory events, e.g. three events. The moving average of continuously updated values of the (e.g. sixty-five) points are hereinafter called the "scaled flow", designated as Qs(t). Alternatively, a single inspiratory event can be utilised rather than a moving average.

[0155] From the scaled flow Qs, two shape factors relating to the determination of partial obstruction are calculated.

[0156] Shape factor 1 is the ratio of the mean of the middle (e.g. thirty-two) scaled flow points to the mean overall (e.g. sixty-five) scaled flow points. Where this ratio is in excess of unity, the breath will be taken to be normal. Where the ratio is unity or less, the breath will be taken to be obstructed. A ratio of about 1.17 is taken as a threshold between partially obstructed and unobstructed breathing, and equates to a degree of obstruction that would permit maintenance of adequate oxygenation in a typical user.

[0157] Shape factor 2 is calculated as the RMS deviation from unit scaled flow, taken over the middle (e.g. thirty two) points. An RMS deviation of about 0.2 units is taken to be normal. An RMS deviation of zero is taken to be a totally flow-limited breath. The closer the RMS deviation is to zero, the more the breath will be taken to be flow limited.

[0158] The flow limitation measure FLM is a combination of shape factor 1 and shape factor 2, mapped to the range [0, 1], such that the closer the value of FLM is to 1, the more flow-limited is the inspiratory portion of the breath.

[0159] In variations of the above implementation, the number of sampled points, breaths and middle points may differ from those described above. Furthermore, the threshold values can other than those described above.

[0160] In another implementation, the inspiratory flow limitation determination algorithm **4324** receives as input the respiratory flow signal Qr, the ventilation Vent, and the ventilation ratio VR, and computes the flow limitation measure FLM. In one such implementation, the computation of the flow limitation measure FLM is carried out as described in PCT Patent Publication no. WO 2008/138040, assigned to ResMed Ltd., the disclosure of which is hereby incorporated herein by reference. This implementation produces a value of FLM in the range [0, 1], such that the closer the value of FLM is to 1, the more flow-limited is the inspiratory portion of the breath.

8.4.3.2.5 Determination of Apneas and Hypopneas **4325**

[0161] In one form of the present technology, a processor **4230** executes one or more algorithms **4325** for the determination of the presence of apneas and/or hypopneas.

[0162] Preferably the one or more algorithms **4325** receive as an input a respiratory flow signal Qr and provide as an output a flag that indicates that an apnea or a hypopnea has been detected.

[0163] In one form, an apnea will be said to have been detected when a function of respiratory flow Qr falls below a flow threshold for a predetermined period of time. The function may determine a peak flow, a relatively short-term mean flow, or a flow intermediate of relatively short-term mean and peak flow, for example an RMS flow. The flow threshold may be a relatively long-term measure of flow.

[0164] In one form, a hypopnea will be said to have been detected when a function of respiratory flow Qr falls below a second flow threshold for a predetermined period of time. The function may determine a peak flow, a relatively short-term mean flow, or a flow intermediate of relatively short-term mean and peak flow, for example an RMS flow. The second flow threshold may be a relatively long-term measure of flow. The second flow threshold is greater than the flow threshold used to detect apneas.

8.4.3.2.6 Determination of Snore **4326**

[0165] In one form of the present technology, a processor **4230** executes one or more snore algorithms **4326** for the detection of snore.

[0166] In one form the snore algorithm **4326** receives as an input a respiratory flow signal Qr and provides as an output a metric of the extent to which snoring is present.

[0167] Preferably the algorithm **4326** comprises the step of determining the intensity of the flow signal in the range of 30-300 Hz. Further preferably, algorithm **4326** comprises a step of filtering the respiratory flow signal Qr to reduce background noise, e.g. the sound of airflow in the system from the blower.

8.4.3.2.7 Determination of Airway Patency **4327**

[0168] In one form of the present technology, a processor **4230** executes one or more algorithms **4327** for the determination of airway patency.

[0169] In one form, airway patency algorithm **4327** receives as an input a respiratory flow signal Qr, and determines the power of the signal in the frequency range of about 0.75 Hz and about 3 Hz. The presence of a peak in this frequency range is taken to indicate an open airway. The absence of a peak is taken to be an indication of a closed airway.

[0170] In one form, the frequency range within which the peak is sought is the frequency of a small forced oscillation in the treatment pressure Pt. In one implementation, the forced oscillation is of frequency 2 Hz with amplitude about 1 cmH_2O.

[0171] In one form, airway patency algorithm **4327** receives as an input a respiratory flow signal Qr, and determines the presence or absence of a cardiogenic signal. The absence of a cardiogenic signal is taken to be an indication of a closed airway.

8.4.3.2.8 Determination of Therapy Parameters **4328**

[0172] In one form of the present technology, processor **4230** executes one or more algorithms **4328** for the determination of therapy parameters.

[0173] In one form, the algorithm **4328** receives as an input one of more of the following:

[0174] i. A measure of inspiratory flow limitation;

[0175] ii. A measure of the presence of apnea and/or hypopnea;

[0176] iii. A measure of the presence of snore; and

[0177] iv. A measure of the patency of the airway;

[0178] and generates a treatment pressure Pt as a function of the current time t.

[0179] FIG. **4**E is a flow chart illustrating a method **4500** carried out by the processor **4230** as one implementation of the algorithm **4328**. The method **4500** starts at step **4520**, at which the processor **4230** compares the measure of the presence of apnea/hypopnea with a first threshold, and determines whether the measure of the presence of apnea/hypopnea has exceeded the first threshold for a predetermined period of time, indicating an apnea/hypopnea is occurring. If so, the method **4500** proceeds to step **4540**; otherwise, the method **4500** proceeds to step **4530**. At step **4540**, the processor **4230** compares the measure of airway patency with a second threshold. If the measure of airway patency exceeds the second threshold, indicating the airway is patent, the detected apnea/hypopnea is deemed central, and the method **4500** proceeds to step **4560**; otherwise, the apnea/hypopnea is deemed obstructive, and the method **4500** proceeds to step **4550**.

[0180] At step **4530**, the processor **4230** compares the measure of flow limitation with a third threshold. If the measure of flow limitation exceeds the third threshold, indicating inspiratory flow is limited, the method **4500** proceeds to step **4550**; otherwise, the method **4500** proceeds to step **4560**.

[0181] At step **4550**, the processor **4230** increases the treatment pressure Pt by a predetermined pressure increment ΔP, provided the increased treatment pressure Pt would not exceed an upper limit Pmax. In one implementation, the predetermined pressure increment ΔP and upper limit Pmax are 1 cmH_2O and 20 cmH_2O respectively. The method **4500** then returns to step **4520**.

[0182] At step **4560**, the processor **4230** decreases the treatment pressure Pt by a decrement, provided the decreased treatment pressure Pt would not fall below a lower limit Pmin. The method **4500** then returns to step **4520**. In one implementation, the decrement is proportional to the value of Pt−Pmin, so that the decrease in Pt to the lower limit Pmin in the absence of any detected events is exponential. In one implementation, the constant of proportionality is set such that the time constant τ of the exponential decrease of Pt is between 10 and 20 minutes, and the lower limit Pmin is 4 cmH_2O. Alternatively, the decrement in Pt could be predetermined, so the decrease in Pt to the lower limit Pmin in the absence of any detected events is linear.

8.4.3.2.9 Detection of RERAs **4329**

[0183] In one form of the present technology, one or more processors may implement one or more of the methodologies, or aspects thereof, described herein for detection of a RERA. For example, a processor **4230** executes one or more RERA detection algorithms **4329** for detection of respiratory effort related arousals (RERAs) implementing the methodologies described herein. The one or more processors may, for example, be implemented in a PAP device that can provide a respiratory treatment, in a computing device that analyses previously-recorded flow data input to the computer, or in a monitor/detection device having one or more sensor(s) to measure and analyse signals indicative of patient respiration, such as a non-contact sensor, and which may or may not provide a respiratory or other treatment.

[0184] In one form, the RERA detection algorithm **4329** receives as an input the current flow limitation measure FLM (from the flow limitation determination algorithm **4324**) and the current ventilation ratio VR (from the ventilation determination algorithm **4323**) and provides as an output an indication of the occurrence of a RERA. Thus, a RERA may be detected based on one or more measures derived from sensor signals, such as a flow sensor or respiration sensor. For example, the RERA indication may be determined based of a measure of sleep disordered breathing events and/or a measure of ventilation.

[0185] In one implementation, the RERA indication is a continuously-valued measure (referred to as a "RERAness" measure) indicating the degree of confidence of occurrence of a RERA. In another implementation, the RERAness measure is compared with a predetermined threshold to provide a Boolean-valued indication of occurrence of a RERA.

[0186] In one implementation, the RERA detection algorithm **4329** is based on the following methodology: if there has been flow limitation recently (e.g., the flow limitation measure FLM is greater than a threshold, (e.g., 0)) followed by a step change in ventilation (indicating a sudden "big breath"), then a RERA is indicated.

[0187] Known methods of detecting RERAs according to this methodology can result in false positives because the ventilation step change and flow limitation measure FLM are multiplied to provide the RERAness measure. In cases where the ventilation step change is large and the flow limitation measure FLM is inappropriately elevated (if only by a small amount), such methods would indicate a RERA when there actually was only a normal arousal rather than an arousal related to respiratory effort.

[0188] To reduce the number of false positives compared to known methods, a RERA detection algorithm **4329** according to one form of the present technology evaluates recent consistency of elevated flow limitation, as well as a step change in ventilation indicating a sudden big breath. This reduces the number of false positives significantly compared to previously known methods, as further described below with reference to FIG. **8**.

[0189] FIG. **4**F is a flow chart illustrating a method **4600** of detecting RERAs that may be implemented by the RERA detection algorithm **4329** according to one form of the present technology. The method **4600** starts at step **4610**, which updates a data structure or buffer, such as a circular buffer, with the current value FLM of the flow limitation measure. The data structure contains a small number of the most recent values of the flow limitation measure FLM, which may be on a per breath basis. In one implementation, the data structure contains the three most recent values of the flow limitation measure FLM, such as from the three most recent breaths. In the circular buffer case, step **4610** overwrites the oldest flow limitation measure FLM in the circular buffer with the current flow limitation measure FLM.

[0190] Step **4620** follows, which computes a measure of consistency of inspiratory flow limitation over recent breaths (e.g., the recent flow limitation measures represented in the circular buffer). In one implementation, the measure of consistency is the Consistency Ratio CR, computed as the fraction of flow limitation measures in the circular buffer that exceed a predetermined threshold. In one implementation, the threshold is 0.1. In step **4630** the maximum flow limitation measure in the circular buffer, FLM_max is determined.

[0191] Next, in step **4650**, a measure of a step change in ventilation indicating a sudden "big breath" is computed. In one implementation, the measure is the normalised ventilation ratio step nVR_step, computed as the difference VR_step between the current value VR of the ventilation ratio and the previous value of the ventilation ratio, mapped to the range [0, 1]. In one implementation, this mapping is carried out according to the following function:

$$nVR\_step = \begin{cases} 0, & VR\_step < 0.1 \\ \dfrac{\sqrt{VR\_step}}{\sqrt{2}}, & 0.1 \le VR\_step \le 2 \\ 1, & VR\_step > 2 \end{cases}$$

[0192] In step **4660**, the RERAness measure is computed by calculating a distance between the three-dimensional point (CR, FLM_max, nVR_step) and the corner point of a three-dimensional cube. In one implementation, the corner point is the three-dimensional point (1, 1, 1). In one implementation, the distance is a Euclidean distance. A smaller value of the RERAness measure indicates a greater degree of confidence of occurrence of a RERA.

[0193] In an optional step **4670**, the RERAness measure is compared with a predetermined threshold to provide a variable (e.g, a Boolean-valued variable (RERA)) indicating an occurrence of a RERA. In one implementation, this threshold has the value 0.75. If the RERAness measure is less than the predetermined threshold ("Y" at step **4670**), step **4680** sets RERA to True. Otherwise ("N" at step **4670**), step **4690** sets RERA to False.

[0194] FIG. **7** contains three graphs illustrating the output of the RERA detection algorithm **4329** on an example flow signal. The top graph **7010** shows an example respiratory flow signal Qr with a duration of approximately three minutes. The middle graph **7020** shows a continuously-valued RERAness measure obtained from the respiratory flow signal Qr in the top graph **7010** using the above-described RERA detection algorithm **4329**. The bottom graph **7030** contains the Boolean-valued indication RERA (represented as a binary variable) obtained by comparing the continuously-valued RERAness measure in the middle graph **7020** with a threshold of 0.75. The value of RERA is generally False (0) but rises to True (1) at two points **7040**, **7050** when the continuously-valued RERAness measure in the middle graph **7020** falls below 0.75.

[0195] In one form of the present technology, the number of positive detections (e.g., with Boolean indications RERA) provided by the RERA detection algorithm **4329** during an interval, together with the number of apneas and/or number of hypopneas detected by the apnea/hypopnea determination algorithm **4325** during the interval may be applied to calculate an RDI (Respiratory Disturbance Index) as a function of an interval measure such as interval duration (e.g., divided by interval duration). In one form the RDI is computed by the following equation:

RDI=(#_of_RERAs+#_of_Apneas+#_of_Hypopneas)/interval_duration

Where:

[0196] #_of_RERA is a count of RERAs, such as with the RERA variable in a time interval;

[0197] #_of_Apneas is a count of apneas detected in the time interval;

[0198] #_of_Hypopneas is a count of hypopneas detected in the time interval; and

[0199] interval_duration is the length of the time interval (e.g., in hours).

[0200] Alternatively, the RERA indication could be reported by a PAP device **4000** as an indication of the effectiveness of the therapy. Such reporting may be made to external devices through the data communication interface **4280**, or to a user via the output devices **4290**.

[0201] In yet another form, the RERAness measure computed by the RERA detection algorithm **4329** could be implemented as input into the therapy parameter determination algorithm **4328**. For example, the RERAness measure may be averaged over a certain time frame, such as per hour,

and the result may be applied in an "outer loop controller" to set a threshold (or gain) for the flow limitation measure to affect the target treatment pressure. An example of an outer loop controller is described in PCT Publication no. WO 2005/051470 (PCT/AU2004/001652) assigned to ResMed Ltd., the disclosure of which is hereby incorporated herein by reference. For example, a patient who arouses from sleep as determined by the RERAness measure may be treated more aggressively (e.g., a higher pressure change) in response to subsequently detected sleep disordered breathing events when compared to the response (e.g. a lower pressure change) to detected sleep disordered breathing events that coincide with an absence of arousal indicated by the RERAness measure.

[0202] As mentioned above, the RERA detection algorithm **4329** according to one form of the present technology evaluates recent consistency of elevated flow limitation, as well as a step change in ventilation indicating a sudden big breath. This may reduce the number of false positives significantly compared to previously known methods. FIG. **8** contains three graphs illustrating the output of the RERA detection algorithm **4329** and a previous RERA detection algorithm on an example flow signal. The top graph **8010** shows an example respiratory flow signal Qr with a duration of approximately nine minutes and no RERAs. The middle graph **8020** shows a Boolean-valued indication of RERAs obtained from the respiratory flow signal Qr in the top graph **8010** using a previous RERA detection algorithm. The bottom graph **8030** shows a Boolean-valued indication of RERAs obtained from the respiratory flow signal Qr in the top graph **8010** using the RERA detection algorithm **4329**. The middle graph **8020** shows one indication of a RERA at the point **8040**. This is caused by the large breath **8050** which provides a one-off elevation in the flow limitation measure. However, the bottom graph **8030** does not show any indication of a RERA at the same point **8040**, because there is no consistency of elevated flow limitation at that point.

8.4.3.3 Control Module **4330**

[0203] A control module **4330** receives the one or more therapy parameters computed by the therapy parameter determination module **4328**, and controls a therapy device **4245** in accordance with the one or more therapy parameters.

[0204] In one form of the present technology, the control module **4330** receives as an input a treatment pressure Pt, and controls a therapy device **4245** to deliver that pressure.

[0205] In one form of the present technology, the control module **4330** receives as an input an EPAP pressure and an IPAP pressure, and controls a therapy device **4245** to deliver those respective pressures.

8.4.3.4 Detection of Fault Conditions **4340**

[0206] In one form of the present technology, a processor executes one or more methods for the detection of fault conditions. Preferably the fault conditions detected by the one or more methods includes at least one of the following:

[0207] Power failure (no power, or insufficient power)

[0208] Transducer fault detection

[0209] Failure to detect the presence of a component

[0210] Operating parameters outside recommended ranges (e.g. pressure, flow, temperature, PaO_2)

[0211] Failure of a test alarm to generate a detectable alarm signal.

[0212] Upon detection of the fault condition, the corresponding algorithm signals the presence of the fault by one or more of the following:

[0213] Initiation of an audible, visual &/or kinetic (e.g. vibrating) alarm

[0214] Sending a message to an external device

[0215] Logging of the incident

8.4.3.5 Therapy Device **4245**

[0216] In a preferred form of the present technology, the therapy device **4245** is under the control of the control module **4330** to deliver therapy to a patient **1000**.

[0217] Preferably the therapy device **4245** is a pressure device **4140**.

8.5 Glossary

[0218] For the purposes of the present technology disclosure, in certain forms of the present technology, one or more of the following definitions may apply. In other forms of the present technology, alternative definitions may apply.

8.5.1 General

[0219] Air: In certain forms of the present technology, air supplied to a patient may be atmospheric air, and in other forms of the present technology atmospheric air may be supplemented with oxygen.

[0220] Continuous Positive Airway Pressure (CPAP): CPAP treatment will be taken to mean the application of a supply of air or breathable gas to the entrance to the airways at a pressure that is continuously positive with respect to atmosphere, and approximately constant through a respiratory cycle of a patient. In some forms, the pressure at the entrance to the airways will vary by a few centimetres of water within a single respiratory cycle, for example being higher during inhalation and lower during exhalation. In some forms, the pressure at the entrance to the airways will be slightly higher during exhalation, and slightly lower during inhalation.

[0221] Automatic Positive Airway Pressure (APAP): CPAP treatment using a pressure that is continually adjustable between minimum and maximum limits, depending on the presence or absence of indications of SDB events.

[0222] Positive Airway Pressure (PAP) device: A device for providing a supply of air at positive pressure to the airways.

8.5.2 Aspects of PAP Devices

[0223] Air circuit: A conduit or tube constructed and arranged in use to deliver a supply of air or breathable gas between a PAP device and a patient interface. In particular, the air circuit may be in fluid connection with the outlet of the pneumatic block and the patient interface. The air circuit may be referred to as air delivery tube. In some cases there may be separate limbs of the circuit for inhalation and exhalation. In other cases a single limb is used.

[0224] Blower or flow generator: A device that delivers a flow of air at a pressure above ambient pressure.

[0225] Controller: A device or portion of a device that adjusts an output based on an input. For example one form of controller has a variable that is under control—the control variable—that constitutes the input to the device. The output

of the device is a function of the current value of the control variable, and a set point for the variable.

[0226] Transducers: A device for converting one form of energy or signal into another. A transducer may be a sensor or detector for converting mechanical energy (such as movement) into an electrical signal. Examples of transducers include pressure sensors, flow sensors, carbon dioxide (CO_2) sensors, oxygen (O_2) sensors, effort sensors, movement sensors, noise sensors, a plethysmograph, and cameras.

8.5.3 Aspects of the Respiratory Cycle

[0227] Apnea: Preferably, apnea will be said to have occurred when flow falls below a predetermined threshold for a duration, e.g. 10 seconds. An obstructive apnea will be said to have occurred when, despite patient effort, some obstruction of the airway does not allow air to flow. A central apnea will be said to have occurred when an apnea is detected that is due to a reduction in breathing effort, or the absence of breathing effort.

[0228] Breathing rate: The rate of spontaneous respiration of a patient, usually measured in breaths per minute.

[0229] Duty cycle: The ratio of inhalation time, Ti, to total breath time, Ttot.

[0230] Effort (breathing): Preferably breathing effort will be said to be the work done by a spontaneously breathing person attempting to breathe.

[0231] Expiratory portion of a breathing cycle: The period from the start of expiratory flow to the start of inspiratory flow.

[0232] Flow limitation: Preferably, flow limitation (or partial obstruction) will be taken to be the state of affairs in a patient's respiration where an increase in effort by the patient does not give rise to a corresponding increase in flow. Where flow limitation occurs during an inspiratory portion of the breathing cycle it may be described as inspiratory flow limitation. Where flow limitation occurs during an expiratory portion of the breathing cycle it may be described as expiratory flow limitation.

[0233] Types of inspiratory flow limited waveforms:

[0234] (i) Flattened: Having a rise followed by a relatively flat portion, followed by a fall.

[0235] (ii) M-shaped: Having two local peaks, one at the leading edge, and one at the trailing edge, and a relatively flat portion between the two peaks.

[0236] (iii) Chair-shaped: Having a single local peak, the peak being at the leading edge, followed by a relatively flat portion.

[0237] (iv) Reverse-chair shaped: Having a relatively flat portion followed by single local peak, the peak being at the trailing edge.

[0238] Hypopnea: Preferably, a hypopnea will be taken to be a reduction in flow, but not a cessation of flow. In one form, a hypopnea may be said to have occurred when there is a reduction in flow below a threshold for a duration. In one form in adults, the following either of the following may be regarded as being hypopneas:

[0239] (i) a 30% reduction in patient breathing for at least 10 seconds plus an associated 4% desaturation; or

[0240] (ii) a reduction in patient breathing (but less than 50%) for at least 10 seconds, with an associated desaturation of at least 3% or an arousal.

[0241] Inspiratory portion of a breathing cycle: Preferably the period from the start of inspiratory flow to the start of expiratory flow will be taken to be the inspiratory portion of a breathing cycle.

[0242] Patency (airway): The degree of the airway being open, or the extent to which the airway is open. A patent airway is open. Airway patency may be quantified, for example with a value of one (1) being patent, and a value of zero (0), being closed.

[0243] Positive End-Expiratory Pressure (PEEP): The pressure above atmosphere in the lungs that exists at the end of expiration.

[0244] Peak flow (Qpeak): The maximum value of flow during the inspiratory portion of the respiratory flow waveform.

[0245] Respiratory (air)flow, (air)flow, patient (air)flow (Qr): These synonymous terms may be understood to refer to an estimate of the "true respiratory (air)flow", which is the instantaneous respiratory flow being experienced by the patient, usually expressed in litres per minute.

[0246] Tidal volume (Vt): The volume of air inhaled or exhaled during normal breathing, when extra effort is not applied.

[0247] (inhalation) Time (Ti): The duration of the inspiratory portion of the respiratory flow waveform.

[0248] (exhalation) Time (Te): The duration of the expiratory portion of the respiratory flow waveform.

[0249] (total) Time (Ttot): The total duration between the start of the inspiratory portion of one respiratory flow waveform and the start of the inspiratory portion of the following respiratory flow waveform.

[0250] Typical recent ventilation: The value of ventilation around which recent values over some predetermined timescale tend to cluster, that is, a measure of the central tendency of the recent values of ventilation.

[0251] Upper airway obstruction (UAO): includes both partial and total upper airway obstruction. This may be associated with a state of flow limitation, in which the level of flow increases only slightly or may even decrease as the pressure difference across the upper airway increases (Starling resistor behaviour).

[0252] Ventilation (Vent): A measure of the amount (e.g., total) of gas being exchanged by the patient's respiratory system, including inspiratory and/or expiratory flow, per unit time. When expressed as a volume per minute, this quantity is often referred to as "minute ventilation". Minute ventilation is sometimes given simply as a volume, understood to be the volume per minute.

8.5.4 PAP Device Parameters

[0253] Flow rate: The instantaneous volume (or mass) of air delivered per unit time. While flow rate and ventilation have the same dimensions of volume or mass per unit time, flow rate is measured over a much shorter period of time. Flow may be nominally positive for the inspiratory portion of a breathing cycle of a patient, and hence negative for the expiratory portion of the breathing cycle of a patient. In some cases, a reference to flow rate will be a reference to a scalar quantity, namely a quantity having magnitude only. In other cases, a reference to flow rate will be a reference to a vector quantity, namely a quantity having both magnitude and direction. Flow will be given the symbol Q. Total flow, Qt, is the flow of air leaving the PAP device. Vent flow, Qv, is the flow of air leaving a vent to allow washout of exhaled

gases. Leak flow, Ql, is the flow rate of unintentional leak from a patient interface system. Respiratory flow, Qr, is the flow of air that is received into the patient's respiratory system.

[0254] Leak: Preferably, the word leak will be taken to be a flow of air to the ambient. Leak may be intentional, for example to allow for the washout of exhaled CO_2. Leak may be unintentional, for example, as the result of an incomplete seal between a mask and a patient's face.

[0255] Pressure: Force per unit area. Pressure may be measured in a range of units, including cmH_2O, g-f/cm^2, hectopascal. $1cmH_2O$ is equal to 1 g-f/cm^2 and is approximately 0.98 hectopascal. In this specification, unless otherwise stated, pressure is given in units of cmH_2O. The pressure in the patient interface, or mask pressure, is given the symbol Pm. A target value for the mask pressure, referred to as the treatment pressure, is given the symbol Pt.

8.6 Other Remarks

[0256] A portion of the disclosure of this patent document contains material which is subject to copyright protection. The copyright owner has no objection to the facsimile reproduction by anyone of the patent document or the patent disclosure, as it appears in the Patent and Trademark Office patent file or records, but otherwise reserves all copyright rights whatsoever.

[0257] Unless the context clearly dictates otherwise and where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit, between the upper and lower limit of that range, and any other stated or intervening value in that stated range is encompassed within the technology. The upper and lower limits of these intervening ranges, which may be independently included in the intervening ranges, are also encompassed within the technology, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the technology.

[0258] Furthermore, where a value or values are stated herein as being implemented as part of the technology, it is understood that such values may be approximated, unless otherwise stated, and such values may be utilized to any suitable significant digit to the extent that a practical technical implementation may permit or require it.

[0259] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this technology belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present technology, a limited number of the exemplary methods and materials are described herein.

[0260] When a particular material is identified as being preferably used to construct a component, obvious alternative materials with similar properties may be used as a substitute. Furthermore, unless specified to the contrary, any and all components herein described are understood to be capable of being manufactured and, as such, may be manufactured together or separately.

[0261] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include their plural equivalents, unless the context clearly dictates otherwise.

[0262] All publications mentioned herein are incorporated by reference to disclose and describe the methods and/or materials which are the subject of those publications. The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present technology is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates, which may need to be independently confirmed.

[0263] Moreover, in interpreting the disclosure, all terms should be interpreted in the broadest reasonable manner consistent with the context. In particular, the terms "comprises" and "comprising" should be interpreted as referring to elements, components, or steps in a non-exclusive manner, indicating that the referenced elements, components, or steps may be present, or utilized, or combined with other elements, components, or steps that are not expressly referenced.

[0264] The subject headings used in the detailed description are included only for the ease of reference of the reader and should not be used to limit the subject matter found throughout the disclosure or the claims. The subject headings should not be used in construing the scope of the claims or the claim limitations.

[0265] Although the technology herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the technology. In some instances, the terminology and symbols may imply specific details that are not required to practice the technology. For example, although the terms "first" and "second" may be used, unless otherwise specified, they are not intended to indicate any order but may be utilised to distinguish between distinct elements. Furthermore, although process steps in the methodologies may be described or illustrated in an order, such an ordering is not required. Those skilled in the art will recognize that such ordering may be modified and/or aspects thereof may be conducted concurrently or even synchronously.

[0266] It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the technology.

8.7 Reference Signs List

[0267]

patient	1000
patient interface	3000
structure	3100
plenum chamber	3200
structure	3300
vent	3400
connection port	3600
forehead support	3700
PAP device	4000
external housing	4010
upper portion	4012
portion	4014
panel	4015
chassis	4016
handle	4018
pneumatic block	4020

-continued

pneumatic component	4100
air filter	4110
inlet air filter	4112
outlet air filter	4114
muffler	4120
inlet muffler	4122
outlet muffler	4124
pressure device	4140
blower	4142
motor	4144
back valve	4160
air circuit	4170
supplemental oxygen	4180
PAP device electrical components	4200
PCBA	4202
electrical power supply	4210
input device	4220
processor	4230
clock	4232
therapy device controller	4240
therapy device	4245
protection circuit	4250
memory	4260
transducer	4270
pressure transducer	4272
flow transducer	4274
motor speed signal	4276
data communication interface	4280
remote external communication network	4282
local external communication network	4284
remote external device	4286
local external device	4288
output device	4290
display driver	4292
display	4294
algorithms	4300
pre-processing module	4310
pressure compensation algorithm	4312
vent flow determination algorithm	4314
leak flow algorithm	4316
respiratory flow determination algorithm	4318
therapy engine module	4320
phase determination algorithm	4321
waveform determination algorithm	4322
ventilation determination algorithm	4323
inspiratory flow limitation determination algorithm	4324
apnea/hypopnea determination algorithm	4325
snore determination algorithm	4326
patency determination algorithm	4327
therapy parameter determination algorithm	4328
RERA detection algorithm	4329
therapy control module	4330
fault condition detection module	4340
method	4500
step	4520
step	4530
step	4540
step	4550
step	4560
method	4600
step	4610
step	4620
step	4630
step	4650
step	4660
optional step	4670
step	4680
step	4690
humidifier	5000
humidity controller	5250
contactless sensor unit	7000
top graph	7010
middle graph	7020
bottom graph	7030
point	7040

-continued

point	7050
top graph	8010
middle graph	8020
bottom graph	8030
RERA indication	8040
large breath	8050

1. A method in a processor for detecting a respiratory effort-related arousal in a respiratory airflow signal of a patient, the method comprising:

receiving in a processor a computed measure of consistency of inspiratory flow limitation over a plurality of recent breaths from the signal;

receiving in the processor a computed measure of step change in ventilation indicating a sudden big breath; and

computing in the processor a measure indicating a degree of confidence of occurrence of a respiratory effort-related arousal from the measure of consistency of inspiratory flow limitation and the measure of the step change in ventilation.

2. The method according to claim **1**, further comprising, in the processor, calculating the measure of consistency of inspiratory flow limitation over a plurality of recent breaths from the signal.

3. The method according to any one of claims **1-2** further comprising, in the processor, calculating the measure of step change in ventilation indicating a sudden big breath.

4. A method according to any one of claims **1-3**, further comprising computing a maximum measure of inspiratory flow limitation over said plurality of recent breaths, wherein the measure indicating a degree of confidence is a function of the maximum measure of inspiratory flow limitation.

5. A method according to any one of claims **2-4**, wherein computing the measure indicating the degree of confidence comprises computing a distance between a three-dimensional point whose components are the measure of consistency of inspiratory flow limitation, the measure of a step change in ventilation, and the maximum measure of inspiratory flow limitation and a corner point of a three-dimensional cube.

6. A method according to any of claims **1-5**, wherein the measure of consistency of inspiratory flow limitation is computed as a fraction of recent flow limitation measures that exceed a predetermined threshold.

7. A method according to any of claims **1-6**, wherein the measure of step change in ventilation is computed as a difference between a current value of a ventilation ratio and a previous value of the ventilation ratio.

8. A method according to claim **7**, wherein the measure of step change in ventilation is the difference mapped to a range [0, 1].

9. A method according to any of claim **7** and claim **8**, wherein the ventilation ratio is computed as a mean inspiratory flow rate divided by a measure of current ventilation.

10. A method according to claim **9**, wherein the mean inspiratory flow rate is computed as an average of inspiratory and expiratory tidal volumes divided by an inspiratory time for a current breath.

11. A method according to any of claims **1-10**, further comprising comparing the degree of confidence of occurrence of a respiratory effort-related arousal with a predeter-

mined threshold to provide an indication of whether the patient is currently experiencing a respiratory effort-related arousal.

12. A method according to claim **11**, further comprising calculating a respiratory disturbance index from a number of indications of respiratory effort-related arousals in a predetermined interval.

13. A method according to any of claims **1-12**, further comprising determining a change to a parameter of a respiratory therapy for the patient based on the measure indicating the degree of confidence.

14. A computer-readable memory storage medium having program instructions encoded thereon configured to cause a processor to perform a method of detecting a respiratory effort-related arousal in a respiratory airflow signal of a patient, the method comprising:

computing a measure of consistency of inspiratory flow limitation over a plurality of recent breaths from the signal;

computing a measure of step change in ventilation indicating a sudden big breath; and

computing a measure indicating a degree of confidence of occurrence of a respiratory effort-related arousal from the measure of consistency of inspiratory flow limitation and the measure of the step change in ventilation.

13. A device for detecting a respiratory effort-related arousal in a respiratory airflow signal of a patient, the device comprising a sensor configured to provide a signal representative of patient respiratory airflow,

a processor configured to detect a respiratory effort-related arousal, wherein the processor is configured to:

compute a measure of consistency of inspiratory flow limitation over a plurality of recent breaths from the signal;

compute a measure of step change in ventilation indicating a sudden big breath; and

compute a measure indicating a degree of confidence of occurrence of a respiratory effort-related arousal from the measure of consistency of inspiratory flow limitation and the measure of the step change in ventilation.

* * * * *

专利名称(译)	呼吸系统疾病的诊断和治疗		
公开(公告)号	US20170164871A1	公开(公告)日	2017-06-15
申请号	US15/117099	申请日	2015-02-13
[标]申请(专利权)人(译)	雷斯梅德有限公司		
申请(专利权)人(译)	瑞思迈有限公司		
当前申请(专利权)人(译)	瑞思迈有限公司		
[标]发明人	RAMANAN DINESH		
发明人	RAMANAN, DINESH		
IPC分类号	A61B5/08 A61B5/00		
CPC分类号	A61B5/08 A61B5/0816 A61M2230/42 A61M2230/40 A61B5/4818 A61B5/087 A61M16/0051 A61M16/0066 A61M16/024 A61M16/1055 A61M16/107		
优先权	2014900439 2014-02-13 AU		
其他公开文献	US10575758		
外部链接	Espacenet USPTO		

摘要(译)

一种装置的方法检测患者的呼吸气流信号中的呼吸努力相关的唤醒。该方法可以包括计算来自信号的多个近期呼吸的吸气流量限制的一致性度量。该方法还可以包括计算通气中的步进变化的度量，指示突然的大呼吸。该方法可以进一步包括根据吸气流量限制的一致性度量和通气中的阶跃变化的度量来计算指示呼吸努力相关唤醒发生的置信度的度量。