Title: DIAGNOSTIC SYSTEM FOR DISORDERED BREATHING

Abstract: A method and apparatus for monitoring and storing breathing disorder events utilizing an artificial neural network system for the measurement, detection, quantification, and diagnosis of breathing disorder events using a flow or pressure curve divided into two or more intervals using a predefined time factor or intervals indicative of patient breathing cycle phases in the neural network system.
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
Diagnostic system for disordered breathing

Field of the invention

The present invention relates to a medical monitoring device and in particular it relates to the measurement of breathing and physiological status, recording of related input parameters, storage of said parameters, and processing of said parameters using an artificial neural network system for diagnostic classification and quantification of breathing disorder events, and in particular for the detection, diagnosis and quantification of breathing disorders during sleep or awake.

Background of the invention

Breathing abnormalities during sleep appear to be extremely common and may be found during the wake condition. The exact prevalence of hypoventilation and ventilatory failure exclusively occurring during the sleeping period or aggravated during sleep is unknown but likely to be, to a considerable extent, related to comorbid respiratory and neurological disorders. Other breathing abnormalities during sleep appear to be extremely common. For instance, sleep apnea and related conditions have been reported in up to 8-24% of the adult population, the exact prevalence pending factors such as gender, age, body weight as well as the exact cut-off level for event severity applied for the particular population. A proportionally small number (<20%) of these subjects appear to exhibit daytime symptoms including sleepiness functional distress and cognitive dysfunction. Complications of sleep apnea appear to be largely unrelated to frequency and occurrence of such daytime symptoms. It is therefore a general object in diagnostic (and screening procedures) to provide a correct diagnosis and a reasonably accurate estimate of the intensity and severity of the sleep and breathing disorder in terms of number of events per hour of sleep.

Sleep disordered breathing encompasses a wide range of breathing disorders such as hypoventilation and ventilatory failure during sleep, periodic breathing during sleep and awake and different forms of sleep apnea that occur exclusively during sleep. Ventilatory failure includes all forms of insufficient ventilation with respect to metabolic need whether occurring during wake or periods of sleep. Hypoventilation and periodic breathing, in its most frequently occurring form referred to as Cheyne-Stokes ventilation, may occur periodically or constantly.
during wake or sleep. Conditions associated with hypoventilation, in particular nocturnal hypoventilation include e.g. central nervous system disorders such as stroke, muscular dystrophies, certain congenital conditions, advanced chronic obstructive pulmonary disease (COPD), etc. Cheyne-Stokes ventilation or various forms of central apnea are commonly associated with cardiac and circulatory disorders, in particular cardiac failure.

Sleep apnea can be categorized into two different forms that occur selectively or in combination. In central sleep apnea, a primarily central nervous system coordination disorder, all respiratory movement is interrupted leading to a sleep apnea event. Obstructive sleep apnea, in contrast, is associated with upper airway collapse, presumably caused by loss of or inadequate upper airway muscle tone. This condition is particularly likely to occur in subjects with narrow upper airways due to excess soft tissue or anatomical abnormalities. Obstructive sleep apnea is the most common type of sleep apnea event. Apnea events are considered pathological, for instance, if they exceed 10 seconds in duration and if they occur more frequently than 10 times per hour of sleep.

Ventilatory failure is a potentially life threatening condition. The general comorbidity in patients with failing ventilation is considerable. The condition is highly disabling in terms of reduced physical capacity, cognitive dysfunction in severe cases and poor quality of life. Patients with ventilatory failure therefore experience significant daytime symptoms but in addition, the majority of these cases experience a general worsening of their condition during state changes such as sleep. The phenomenon of disordered breathing during sleep, whether occurring as a consequence of ventilatory failure or as a component of sleep apnea in accordance with the description above causes sleep fragmentation. Daytime complications include sleepiness and cognitive dysfunction. Severe sleep disordered breathing occurring in other comorbid conditions like obesity, neuromuscular disease, post polio myelitis states, scoliosis or heart failure may be associated with considerable failure of ventilation and compromised blood gas balance. Sleep apnea has been associated with cardiovascular complications including coronary heart disease, myocardial infarction, stroke, arterial hypertension, thrombosis, and cardiac arrhythmia. It is therefore of both immediate and long-term interest to identify and quantify the extent of sleep disordered breathing in an individual.
Patients suffering from different forms of breathing disorders can be subject to several types of treatments depending on the illness or disorder present. Such treatments include surgical procedures, intraoral devices, pharmacologic therapy, and non-invasive mechanical ventilation techniques. All techniques may partially or completely resolve the sleep and breathing problem in a manner that to a large extent is individually determined. Consequently, diagnostic techniques are not only used for identification and quantification of the disorder but also frequently applied to monitor outcome of treatment of the sleep and breathing disorder. It is an object of the present invention to provide a technique that fulfills both these areas of usage.

Sleep disordered breathing leads to a number of physiological consequences exemplified by, not limited to, altered ventilatory gas exchange (e.g. hypoxemia, hypercapnia), sleep fragmentation (e.g. arousals from sleep, sleep stage shifts, altered amounts of consolidated sleep) and cardiovascular changes (e.g. blood pressure changes, heart rate changes, regional blood flow changes). In general, these consequences may be measured and quantified as solitary phenomena but they are generally not considered in their physiological context. For instance, a given breathing event occurring during sleep may qualify as an event in a pure diagnostic sense but it may result in none, a single, several or all the above mentioned physiological consequences. It follows that a given event may bear specific diagnostic information pending its association with the evoked physiological consequence. Events associated with arousal may be particularly important for quantification of sleep fragmentation and therefore for the presence of daytime hypersomnolence and cognitive dysfunction. Alternatively, an event associated with a blood pressure change may be particularly important in the assessment and occurrence of a high blood pressure during the wake daytime period. It follows that analytical attempts in sleep disordered breathing ideally should include multiple signal acquisition and analysis.

Devices generated to date for the purpose of quantifying breathing disorders during sleep are generally cumbersome, complex and expansive. For instance, the gold standard - polysomnography - is based on a large number of signals recorded in parallel. Alternatively, devices have been based on a limited number of signals (e.g. oximetry) and therefore tend to have an inherent element of inexactness. There are also several devices that rely on four to six channels. Such devices may be used in the home environment and are generally cheaper to use. Most of them, however, are hampered by limited exactness as compared
with the gold diagnostic standard, polysomnography. Yet another limitation of these devices is that several of them do not provide a sufficient distinguishing function to separate different forms of sleep disordered breathing or even other forms of movement disorders that are known to occur during the sleeping period. Also, they do not have the function of providing detailed information on time spent sleep/awake during the recording period.

Before determination of course of action and treatment of above mentioned problems, the patient needs to be monitored for some time in order to fully characterize the type and severity of the disorder. During such a monitoring stage different approaches can be used wherein one such approach can be a polysomnographic sleep study in a sleep laboratory or in the home. Alternatively the patient may be monitored by means of a simplified limited channel device, a so-called sleep screening device, for one or several nights. Simplified techniques may be as sensitive but less specific due to that actual sleep is not monitored or quantified. These drawbacks are however frequently balanced by their simplicity, improved tolerability and lower cost.

One such device is mentioned in US patent 6,368,287 wherein an ambulatory device capable of monitoring breathing status of a patient and obtained data is recorded in a storage device. A crude diagnosis is also supplied in that a recommended course of action is presented in a non-volatile marker system which tells the user if he needs to consult a physician or seek a sleep laboratory service for further analysis. This is a very crude diagnosis and later re-analysis is needed by trained medical personnel. Only one measurement parameter is used in this invention.

In US patent 5,233,983 another device is described that measures a plurality of input channels but this system does not have the capability of diagnosing the type of apnea event, neither is it ambulatory.

Summary of the invention

It is an object of the present invention to provide a system that remedies the above mentioned limitations and provides an improved diagnostic device technology for use to diagnose and monitor treatment intervention in patients with ventilatory disorders during sleep and to quantify the intensity of such disorders.
The invention utilizes a sensor system that measures one or several input parameters selectively related to the breathing pattern of a subject or in combination with other physiological variables, exemplified but not limited to airflow limitation and dynamics of airflow restriction, alteration and dynamics of upper airway pressure, dynamic characteristics of thoracic and abdominal muscle movements and activity, dynamics of oxygen desaturation and transcutaneous carbon dioxide changes, heart rate changes, snoring sounds, alteration of muscle tone or activity derived by actigraphy or electromyography or the like, electroencephalographic signals, blood pressure changes and so on, and using these data in an artificial neural network processing system for generation of diagnostic information. The identical principle may be applied for therapeutic monitoring whereby single or multiple different parameters related breathing using an air support system such as a continuous positive airway pressure (CPAP) or ventilator system are monitored alone or in combination with one or more of the above mentioned variables. Such air support system derived signals may be for instance CPAP pressure and its dynamics during CPAP use, the ratio between, or dynamics of, EPAP and IPAP pressure (EPAP = Expiratory Positive Airway Pressure, IPAP = Inspiratory Positive Airway Pressure) during bi-level positive pressure ventilation or volume related variables during volume controlled ventilator treatment.

An example of an artificial neural network that can be used in this analysis is described in detail in for instance WO 02/28281, incorporated hereby by reference. However, it should be understood that the present invention is not limited to this artificial neural network scheme but it should be appreciated that other algorithms may be used.

In the present invention the artificial neural network consists of one or a plurality of artificial neural network algorithms. These can be the same or different algorithms. Each artificial neural network or networks acts on one or several measured input parameters that reflect the physiological state of the patient, for instance one or more of the following signals; gas flow, gas pressure, electromyography (EMG) signals, electroencephalogram (EEG) signals, electrocardiogram (ECG) signals, blood pressure, heart rate, eye movements for instance from electrooculograms (EOG), and sound events indicative of a breathing disorder, such as snoring or similar.
The artificial neural network may also in the context of information acquisition during treatment with a breathing support system operate on sampled data from sensor signals relating to the physiological status of a patient and it may specifically operate on flow/pressure data which has been divided into intervals either related to a predefined time factor or intervals indicative of different phases of the breathing duty cycle.

This is done by providing a device with a plurality of input channels and a processing unit operating on measurement data taken from these input channels and performing an artificial neural network analysis in order to provide quantification, temporal allocation and a diagnosis of hypoventilation events that have occurred and determining the type of event or events that has occurred during for instance a sleep screening process. The device is placed in a small convenient ambulatory casing and can be used both at home and in the clinical environment.

The device, when used alone or in conjunction with a therapeutic intervention can also give recommendations on possible settings for use in a breathing assisting apparatus, for instance in a continuous positive airway pressure system, a so called CPAP system, used for the treatment of sleep apnea disorders.

Several artificial neural networks can act on the same input parameter but be used for determining different control signal parameters.

In another preferred embodiment, a breathing disorder monitoring method, comprising the steps:

obtaining one or several sensor signals from input channels;

processing the measured sensor signal or signals using an artificial neural network solution; and

storing the measured sensor signal or signals and results from the processing step, wherein the processing comprises an artificial neural network system for detection, quantification, and diagnosis of breathing disorder events; the number of said events and the type of each registered breathing disorder event, said artificial neural network system working on said measured sensor signal or signals related to a flow or pressure curve being divided into two or more intervals using a predefined time factor or intervals indicative of patient breathing cycle.
The method further comprises the step of producing a clinical report based on the stored measured sensor signal or signals (5, 6, 7, 8, 9) and obtained results.

In the method, the result is used to give recommendations on appropriate control settings for a breathing assisting apparatus.

*Brief description of the drawings*

10 Fig. 1 is a schematic depiction of a ventilatory screening system according to the present invention.

Fig. 2 is a schematic block diagram of a ventilatory screening device according to the present invention.

15 Fig. 3 is a schematic block diagram of a method according to the present invention.

*Detailed description of the invention*

In Fig. 1 a schematic depiction of a typical setup with a patient 1 is shown. On, or in the close vicinity of the patient, sensor means 5, 6, 7, 8, and 9 are located for measuring different types of physiological parameters for determination of the status of the patient 1. In Fig. 1 only a subset of possible sensors 5, 6, 7, 8, and 9 are shown in order give an example of sensor signals that can be used and the depicted locations are only given as examples and are in no way limiting to the invention. The sensors 5, 6, 7, 8, and 9 are connected to the screening device 4 with some connection means 5a, 6a, 7a, 8a, and 9a. The connection means 5a, 6a, 7a, 8a, and 9a may for instance be electrical, wireless, pneumatic or optical.

The screening device 4 acquires data from one or several sensor signals 5, 6, 7, 8, and 9 and there is an interest to obtain information about many physiological aspects of the patient in order to understand the current status of the patient. Some of the interesting parameters can be found in table 1 together with a short description of usage:
<table>
<thead>
<tr>
<th><strong>Signal</strong></th>
<th><strong>Purpose</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal cannula flow sensor</td>
<td>Used for pattern recognition.</td>
</tr>
<tr>
<td>Thoracic effort belt sensor</td>
<td>Used for measurement of thoracic effort of breathing.</td>
</tr>
<tr>
<td>Abdominal effort belt sensor</td>
<td>Used for measurement of abdominal effort of breathing.</td>
</tr>
<tr>
<td>SpO₂</td>
<td>Used for measurement of oxygen saturation level.</td>
</tr>
<tr>
<td>Pulse sensor</td>
<td>Used for measurement of heart rate.</td>
</tr>
<tr>
<td>Sound sensor</td>
<td>Used to detect sound events, e.g. snoring.</td>
</tr>
<tr>
<td>PLM (Periodic Limb Movement) sensor</td>
<td>Used for detection of limb muscle movement (electrodes or piezo electric sensor).</td>
</tr>
<tr>
<td>SPI (Sleep Position Indicator) sensor</td>
<td>Used for identification of body position during recording.</td>
</tr>
<tr>
<td>ECG (Electrocardiogram) by cutaneous electrodes</td>
<td>Used for detection of heart rate, cardiac arrhythmia as well as thoracic breathing movements by impedance.</td>
</tr>
<tr>
<td>EEG (electroencephalogram)</td>
<td>Used for detecting the brain activity of the patient.</td>
</tr>
<tr>
<td>AUX (one or several)</td>
<td>An auxiliary channel or channels for interfacing external sensors or equipment.</td>
</tr>
<tr>
<td>Event button</td>
<td>Used for patient or monitor indication of specific events including for instance lights-on, lights-out, state changes, periods out of bed or specific events such as episodes of effort, pain, appearance of symptoms and the like</td>
</tr>
<tr>
<td>EMG (electromyography)</td>
<td>Used for recording of electric muscle potential.</td>
</tr>
<tr>
<td>EOG (electrooculargram)</td>
<td>Used for detection of eye movement.</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Used for monitoring the patient blood pressure.</td>
</tr>
</tbody>
</table>
The AUX channel or channels can be used for interfacing sensors with standard types of interfaces like for instance, 0-1 V, 0-5 V, 0-10 V, ±1, V±5 V, ±10 V, 4-20 mA and so on. The AUX channel can be configured either through software or hardware to input any signals within the range of ±1000 V or 0-1 A depending on sensor to be inputted.

The different input channels can be individually configured in order to be used for interfacing different types and brands of sensors apart from those normally supplied with the device 4.

The screening device 4 comprises a casing 21 in which several components are located, for instance there is a sensor signal conditioning means 25 for conditioning of the sensor signal and delivering the sensor signal in an appropriate form to a processing unit 22. The processing unit 22 processes the signals according to chosen processing demands, stores data, and stores results in a non-volatile memory 23 or battery backed volatile memory 23 for later analysis and/or inspection. Results and data may also be displayed with a display means 24 which can be for instance an LCD unit, a CRT screen, or a chart recorder. Preferably the display means 24 is an LCD unit incorporated in the screening device 4.

Power means (not shown) is provided either as an external power source or as an internal power source, like for instance a battery.

Input means (not shown) may also be provided for manually inputting control parameters or similar parameters necessary for the operation or for facilitating the operation of the device. For instance, an event button is supplied on the user interface of the device in order to allow the user, or some other person supervising a screening process, to mark an event that is considered external in some sense, like for instance a visit to the toilet by the patient, lights-on, lights-out, state changes, periods out of bed or specific events such as episodes of effort, pain, appearance of symptoms and the like during screening. The user interface is also provided with an on/off switch and several LED indicators indicating if the device is on or off, if any errors has occurred, if the device is active, and several indicators for indicating the status of the screening device.

The screening device 4 is prepared for interfacing add-on modules (not shown) for future expansion of the functionality of the screening device 4. For instance
an ETCO\textsubscript{2} module can be implemented. These modules may be located internally or externally of the device 4.

In the screening device 4 there can also be a connection means for an external non-volatile memory device 29, like for instance a memory device using a USB connection, an external hard drive, a floppy disk, a CD-ROM writer, a DVD writer, a Memorystick, a Compact Flash memory, a Secure Digital memory, an xD-Picture memory card, or a Smart Media memory card. These are only given as examples, and are not limiting for the invention. Thus, other external memory devices not expressly mentioned in this description, may be used according to the present invention.

The screening device 4 can also have several output connections 27 and 28 for connecting other external devices like for instance a chart recorder or for establishing communication with a personal computer (PC), server, workstation, or other computational device for download of measured data or results from the data processing for later inspection and analysis.

The communication means 27 or 28 can be of a serial type, like for instance according to the standards RS232, RS485, USB, Ethernet, or Firewire, or of a parallel type like for instance according to the standards Centronics, ISA, PCI, or GPIB/HPIB, or any wireless system of the standards in the IEEE 802.11 series, HiperLAN, Bluetooth, IR, GSM, GPRS, or UMTS, or any other appropriate fixed or wireless communication system. It can also be of any proprietary non-standardized formats. The communication means may also be connected to a standard PSTN connection (Public Switched Telephone Network) through an external or built in communication modem (commonly referred to in everyday language as a telephony modem).

The processing unit 22 inputs the data, either directly or indirectly from a pre-processing hardware unit (not shown) and stores the data in a storage unit 23. The processing unit 22 also performs an analysis on the data, obtained either directly or indirectly through a software pre-processing unit (not shown), using an artificial neural network system in the processing unit 22. The artificial neural network system processes the signals and determines if a hypoventilation event has occurred and then gives a diagnosis of the type of hypoventilation event. The processing unit 22 stores these results and periodically takes data from the sensors 5, 6, 7, 8, and 9. The artificial neural network system can also give
recommendations on appropriate reference settings for a CPAP system to be used in treatment of ventilatory problems or disorders.

In the present invention several artificial neural networks may be used in order to determine hypoventilation events and periods. The system acquires pressure/flow curves using the sensors 5, 6, 7, 8, and 9 and divides the acquired curves into segments according to either predefined time factor settings (such as fixed time lengths, e.g. a number of seconds) or preferably into segments indicative of breathing cycle phase. These breathing cycle phases are determined by large changes in the flow/pressure curve. The different breathing cycle phases may be divided for example into four segments, illustrated in the following exemplifying phases:

1. the inspiratory phase when the patient is inhaling breathing gas (IPAP level, Inspiratory Positive Airway Pressure);
2. the transfer phase between the inspiratory phase and the expiratory phase;
3. the expiratory phase when the patient exhales the breathing gas (EPAP level, Expiratory Positive Airway Pressure); and
4. the transfer phase from the expiratory phase to the inspiratory phase.

Each breathing phase can provide information about different types of breathing disorders, since these disorders will affect the breathing phases differently. This may be used in an analysis of the breathing phases, by analyzing the different breathing phases separately and thus provide indications of different breathing disturbances and subsequently used in different analysis schemes in order to determine the patient status and for determining appropriate responses and ventilator control parameters according to determined status.

The artificial neural network system can be one single network acting on one input parameter or it can act on a plurality of input parameters to determine one control parameter or diagnosis signal. It can also consist of a plurality of artificial neural networks each with a single or a plurality of input parameters, each of the neural networks processing the data in order to deduce independent diagnosis results or control parameters for later use in, for example, a CPAP system.
Depending on the chosen scheme and input parameters, different pre-processing procedures will be utilized in order to feed the artificial neural network with appropriate data and in an appropriate data format.

The artificial neural network will for a given measured data sequence determine the most likely hypoventilation event from the database, described in WO 02/28281, incorporated hereby by reference, for the specific patient by comparing the input parameters with the templates in the database. This is done on a subset of data from the sensor or sensors input stream/streams. As an example, the determined event can be a flow limitation. The neural network now determines the next event by working on a subset offset by a small distance wherein part of the former subset is also present. For examples sake, again the determined event might be a flow limitation. If the calculations for a certain number of times determine that a flow limitation is present for the patient, the processing system triggers a response appropriate for a flow limitation. This can be done for many types of hypoventilation events, for example, but not limited to, flow limitations, flow apnea both for central apnea and obstructive apnea or a combination of these two apnea types, and other hypoventilation events. In this way, the patient breathing pattern is analyzed in real-time during a screening process and the number of hypoventilation events is determined. The different types of hypoventilation are classified and all data is stored in the memory of the screening device 4. Since the processing unit 22 has access to the database of previous measurements on a large population of patients, it is possible for the system to give recommendations on appropriate action and settings for breathing assisting apparatuses, like for instance a CPAP system.

In a preferred embodiment of the present invention a method for monitoring breathing disorder is developed and is schematically illustrated in Fig. 3. The method comprise the steps of obtaining 301 one or several sensor signals from input channels 5, 6, 7, 8, and 9, processing 302 the measured sensor signals 5, 6, 7, 8, and 9 using an artificial neural network solution comprising one or several artificial neural network systems working on signals related to a flow or pressure curve divided into two or more intervals using a predefined time factor or intervals indicative of patient 1 breathing cycles, and finally storing 303 the measured sensor signal or signals 5, 6, 7, 8, and 9 and results from the processing step 302. The result from the processing step includes the detection, quantification, and diagnosis of breathing disorder events; the number of events and type of each registered breathing disorder event.
The screening device 4 can be used for monitoring and diagnosing different types of hypoventilation problems and the results from the processing scheme can later be used in hypoventilation treating devices and methods. These kinds of methods and devices are often used for treating disordered breathing during sleep in the home but they can also be used in a clinical environment for such treatment. The methods and devices can also be used for treatment of many other different kinds of hypoventilation events both at home and in the clinical environment.

The above mentioned and described embodiments are only given as examples and should not be limiting to the present invention. Other solutions, uses, objectives, and functions within the scope of the invention as outlined in the below described claims should be apparent for the person skilled in the art.
Reference signs

1  Patient
2  Mask
5  3  Tubing
   4  Screening device
   5  Sensor
   5a Connection means
   6  Sensor
10 6a Connection means
   7  Sensor
   7a Connection means
   8  Sensor
   8a Connection means
15 9  Sensor
   9a Connection means
21  Casing
22  Processing unit
23  Storage unit
20 24 Display means
25  Signal conditioning means
26  Connection means
27  Communication means
28  Communication means
25 29 Connection means for external non-volatile memory device
Claims

1. A breathing disorder monitoring apparatus (4), comprising:
   one or several sensor input channels (5, 6, 7, 8, 9);
   processing means (22) utilizing an artificial neural network
   solution for processing measured sensor signal or signals (5, 6, 7,
   8, 9); and
   storage means (23) for storing measured sensor signal or signals
   (5, 6, 7, 8, 9) and results from said processing means,
   \textbf{characterized in}
   that said processing means (22) comprises an artificial neural
   network system for detection, quantification, and diagnosis of
   breathing disorder events; the number of said events and the type of
   each registered breathing disorder event, said artificial neural
   network system working on said measured sensor signal or signals
   related to a flow or pressure curve being divided into two or more
   intervals indicative of patient (1) breathing cycle phases.

2. An apparatus (4) according to claim 1, \textbf{characterized in} that said
   apparatus (4) produces a clinical report based on said stored
   measured sensor signal or signals (5, 6, 7, 8, 9) and obtained
   results.

3. An apparatus (4) according to claim 1, \textbf{characterized in} that said
   result is used to give recommendations on appropriate control
   settings for a breathing assisting apparatus.

4. An apparatus (4) according to claim 1, \textbf{characterized in} that the
   apparatus comprises display means (24) for displaying measured
   sensor signal or signals (5, 6, 7, 8, 9) and results from the
   processing means (22).

5. An apparatus (4) according to claim 3, \textbf{characterized in} that said
   breathing assisting apparatus is a continuous positive airway
   pressure system (CPAP).
6. An apparatus (4) according to claim 3, characterized in that said breathing assisting apparatus is an automatic adaptive continuous positive airway pressure system (AAPCAP).

7. An apparatus (4) according to claim 1-4, characterized in that said storage means (23) is a non-volatile storing means of one or several of a battery backup RAM memory, chart recorder, printer, hard drive, floppy disk, CD-ROM writer, DVD writer, MEMORY stick, Compact Flash memory, Secure Digital memory, xD-Picture memory card, and a Smart Media memory card.

8. An apparatus (4) according to claim 1, characterized in that the apparatus (4) has communication means (27, 28) for communication with a personal computer, workstation, server, or any other computational device.

9. An apparatus (4) according to claim 1, characterized in that said communication means (27, 28) can be one or several of RS232, RS485, USB, communication modem, Firewire, Centronics, ISA, PCI, GPIB, and Ethernet, or any wireless system of the standards in the IEEE 802.11 series, HiperLAN, Bluetooth, IR, GSM, GPRS, and UMTS.

10. An apparatus (4) according to claim 1, characterized in that said sensor signals (5, 6, 7, 8, 9) can be one or several of nasal flow cannula sensor signals, effort belt thorax and/or abdomen sensor signals, SpO2 sensor signals, pulse sensor signals, sound sensor signals, periodic limb movement (PLM) sensor signals, sleep position indicator (SPI) sensor signals, electrocardiogram (ECG/EKG) sensor signals, electroencephalogram (EEG) sensor signals, and electromyography (EMG) sensor signals.

11. An apparatus (4) according to claim 1, characterized in that the apparatus (4) has at least one auxiliary input channel for interfacing sensors of standardized types like, one of, 0-1 V, 0-5 V, 0-10 V, ±1 V, ±5 V, ±10 V, or 4-20 mA.
12. An apparatus (4) according to claim 11, characterized in that said auxiliary channel can be configured to any voltage or current input limits within the ranges of ±1000 V or 0-1 A, respectively.

13. An apparatus (4) according to claim 1, characterized in that the apparatus (4) has at least one interface for add-on modules to be used for other detection equipment or sensors, where the modules can be located internally or externally of the apparatus (4).

14. An apparatus (4) according to claim 1, characterized in that the apparatus (4) include means for sound identification and extraction for the detection of sound events, like for instance snoring.

15. A breathing disorder monitoring method, comprising the steps:
   obtaining one or several sensor signals from input channels (5, 6, 7, 8, 9);
   processing said measured sensor signal or signals (5, 6, 7, 8, 9) using an artificial neural network solution; and
   storing said measured sensor signal or signals (5, 6, 7, 8, 9) and results from said processing step, characterized in that said processing comprises an artificial neural network system for detection, quantification, and diagnosis of breathing disorder events; the number of said events and the type of each registered breathing disorder event, said artificial neural network system working on said measured sensor signal or signals related to a flow or pressure curve being divided into two or more intervals indicative of patient (1) breathing cycle phases.

16. The method according to claim 15 characterized in that the method further comprise the step of producing a clinical report based on said stored measured sensor signal or signals (5, 6, 7, 8, 9) and obtained results.

17. The method according to claim 15, characterized in that said result is used to give recommendations on appropriate control settings for a breathing assisting apparatus.
INTERNATIONAL SEARCH REPORT

Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. □ Claims Nos: 15–17 because they relate to subject matter not required to be searched by this Authority, namely:
   
   see additional sheet

2. □ Claims Nos:
   
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. □ Claims Nos:
   
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. □ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. □ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. □ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos:

4. □ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos:

Remark on Protest

□ The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee.

□ The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.

□ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)
Claims 15-17 relate to methods of treatment of the human or animal body by surgery or by therapy/diagnostic methods practised on a human or animal body/ Rule 39.1.(iv).
Nevertheless, a search has been executed for claims 15-17 based on the alleged effects of the compound/compositions/product/device.
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

**IPC7:** A61B 5/087, A61M 16/00

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

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbol(s))

**IPC7:** A61B, A61M, A61N, G06F

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

SE, DK, FI, NO classes as above

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

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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

* Special categories of cited documents

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"I" document member of the same patent family

Date of the actual completion of the international search 8 August 2005

Date of mailing of the international search report 12 -08- 2005

Name and mailing address of the ISA/Swedish Patent Office Box 5055, S-102 42 STOCKHOLM

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**Information on patent family members**

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