



US 20150126879A1

(19) **United States**(12) **Patent Application Publication**
HOSKULDSSON et al.(10) **Pub. No.: US 2015/0126879 A1**(43) **Pub. Date: May 7, 2015**(54) **METHOD, APPARATUS, AND SYSTEM FOR
MEASURING RESPIRATORY EFFORT**(52) **U.S. CL.**CPC *A61B 5/1135* (2013.01); *A61B 5/7278*
(2013.01); *A61B 5/0205* (2013.01); *A61B*
5/0809 (2013.01)(71) Applicant: **NOX MEDICAL**, Reykjavik (IS)(72) Inventors: **Sveinbjorn HOSKULDSSON**,
Reykjavik (IS); **Haraldur Tomas**
HALLGRIMSSON, Hafnarfjodur (IS);
Gudjon Teitur SIGURDARSON,
Reykjavik (IS)

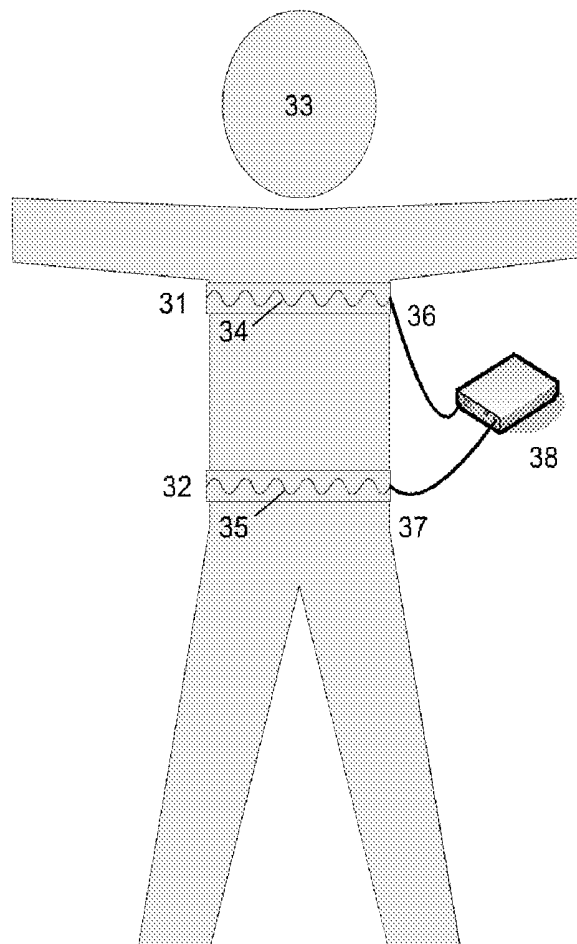
(57)

ABSTRACT

A method, apparatus, and system for measuring respiratory effort of a subject are provided. A thorax effort signal and an abdomen effort signal are obtained. The thorax effort signal and the abdomen effort signal are each divided into a volume-contributing component of the respiratory effort and a paradox component. The paradox component represents a non-volume-contributing component of the respiratory effort. The abdomen paradox component is negatively proportional to the thoracic paradox component. The thorax effort signal or the abdomen effort signal or both are weighted by a weight factor to obtain a volume-proportional signal. The volume-proportional signal is proportional to the actual respiratory volume of the respiratory effort. A calibration factor for calibrating the thorax effort signal and the abdomen effort signal is obtained by optimizing the weight factor by minimizing thoracic paradox component and the abdomen paradox component.

(21) Appl. No.: **14/535,093**(22) Filed: **Nov. 6, 2014**(30) **Foreign Application Priority Data**

Nov. 6, 2013 (IS) 050066

Publication Classification(51) **Int. Cl.***A61B 5/113* (2006.01)
A61B 5/0205 (2006.01)
A61B 5/00 (2006.01)

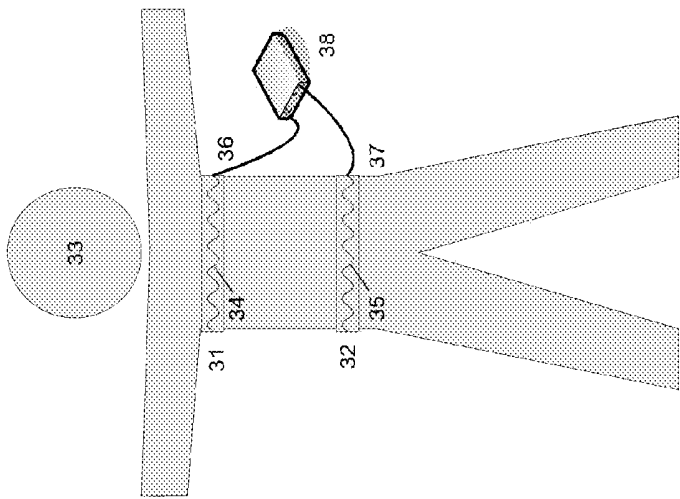


Figure 1a

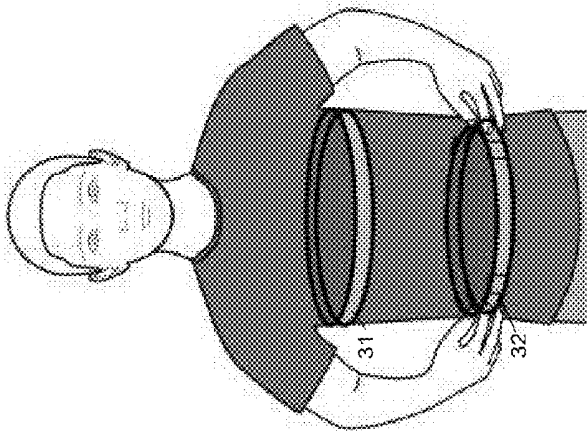


Figure 1b

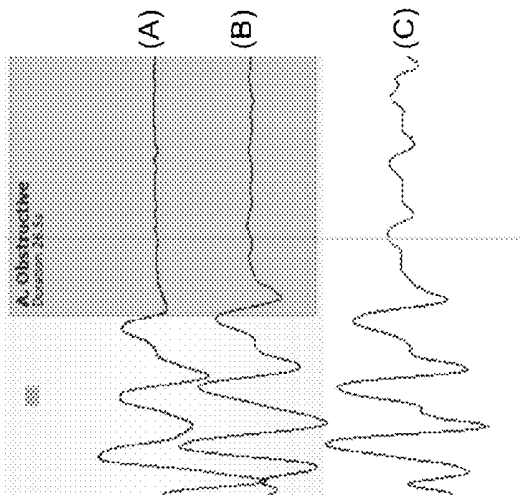


Figure 2

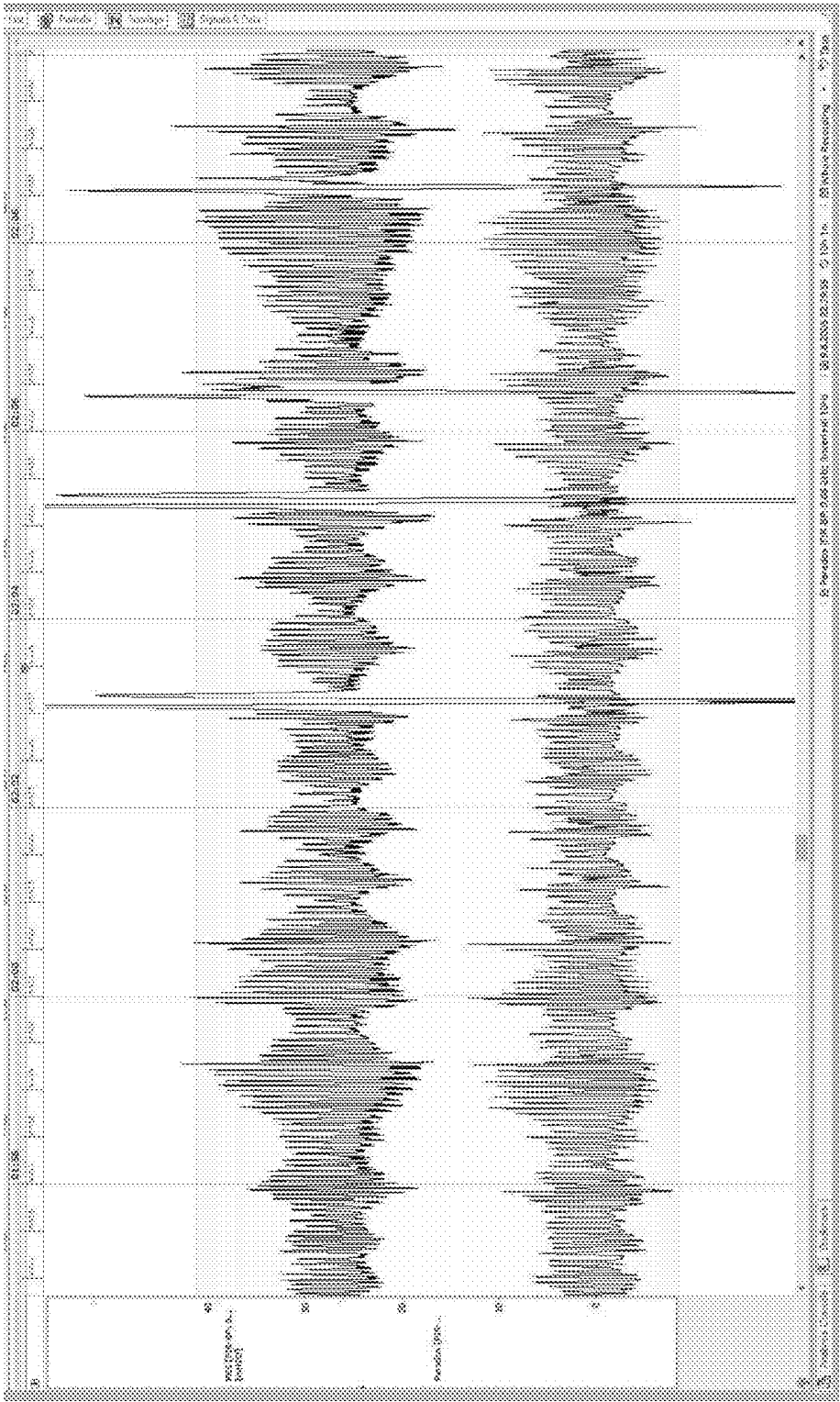


Figure 3

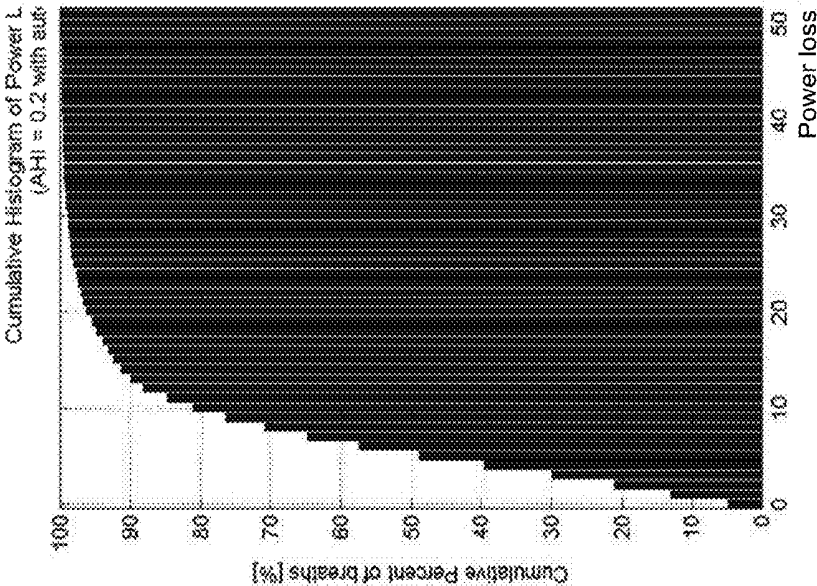


Figure 4a

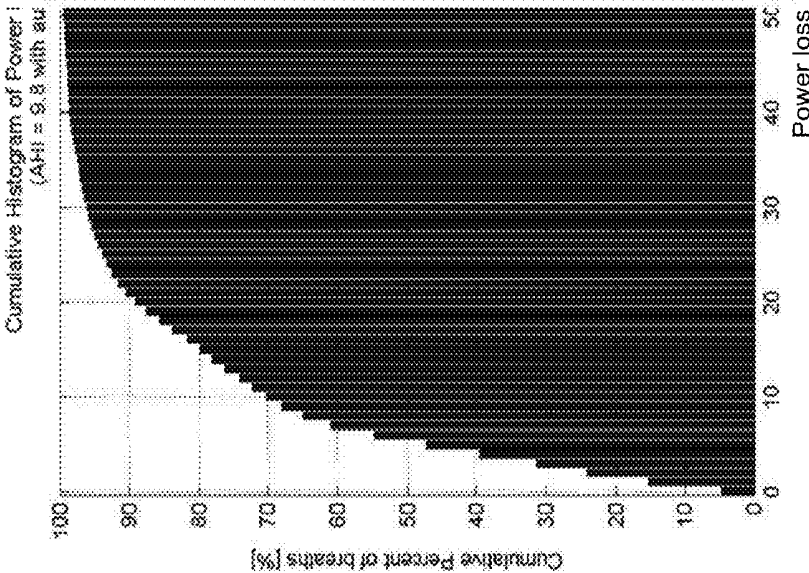


Figure 4b

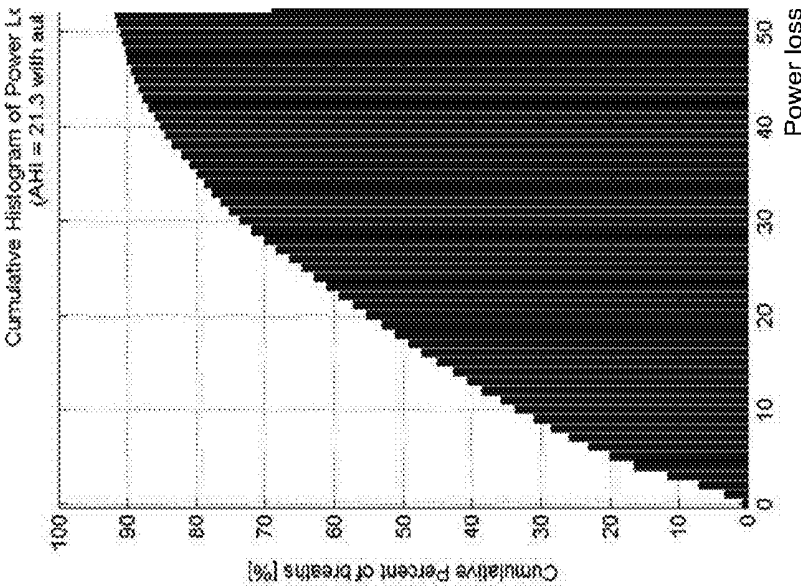


Figure 4c

METHOD, APPARATUS, AND SYSTEM FOR MEASURING RESPIRATORY EFFORT

FIELD OF THE DISCLOSURE

[0001] The present disclosure relates to a method, apparatus, and system for measuring respiratory effort of a subject, and to a method, apparatus, and system for calculating a calibration factor for calibrating signals representative of the respiratory effort of a subject.

BACKGROUND

[0002] Non-invasive methods are useful and popular to measure breathing movements and respiratory effort. Respiratory Inductive Plethysmography (RIP) is one such method, which includes the use of respiratory bands to measure respiratory effort related areal changes. RIP technology includes a measurement of an inductance of a conductive belt or belts that encircle a respiratory region of a subject.

[0003] The signal amplitude received from the respiratory effort belts depends on both the shape of the subject and the placement of the belts. To create a respiration volume signal by summing the signal of the respiratory effort belts, one must use correct weighting constants for the measured belt signals to transform each signal correctly into a volume signal before summing them together. Further, to perform a quantitative calibration, the signals of the respiratory effort belts must be measured simultaneously with a quantitative reference measure. Known methods therefore require quantitative equipment for respiratory volume measure, such as a spirometer, body-box or similar ways to measure respiratory volume accurately during the calibration.

[0004] Due to the complexity added with using reference respiratory volume equipment and the fact that the weighting constants are subject to change over time with belt and body movements, it would simplify the measurement of respiratory efforts considerably if there were a method available that would evaluate weighting constants without the need of special quantitative equipment for reference measures.

[0005] Statistical measures of RIP during normal breathing to evaluate weighting constants may be used for respiratory analysis and sleep diagnostics. However, the calculation of a calibration factor will change if the belts move or the subject changes position. To maintain accuracy, recalibration is needed after such movements and changes, which requires a few minutes of normal, non-obstructive breathing. This can be difficult with a sleeping subject, especially with subject's suffering from sleep disordered breathing.

[0006] A method for calculating and calibrating the respiratory signals in a more continuous fashion without the need for quantitative equipment would be advantageous.

SUMMARY

[0007] The present disclosure concerns a method, apparatus, and system for measuring respiratory effort of a subject. According to one example, the method includes obtaining a thorax effort signal (T). The thorax effort signal (T) being an indicator of a thoracic component of the respiratory effort. An abdomen effort signal (A) is obtained, the abdomen effort signal (A) being an indicator of an abdominal component of the respiratory effort. The thorax effort signal (T) is separated into a volume-contributing thoracic component (V_{ST}) and a thoracic paradox component (P_T). The thoracic paradox component (P_T) represents a non-volume-contributing thoracic

component of the respiratory effort, and the volume-contributing thoracic component (V_{ST}) representing a volume-contributing component of the respiratory effort. The abdomen effort signal (A) is separated into a volume-contributing abdominal component (V_{SA}) and an abdomen paradox component (P_A). The abdomen paradox component (P_A) represents a non-volume-contributing abdominal component of the respiratory effort, and the volume-contributing abdominal component (V_{SA}) represents a volume-contributing component of the respiratory effort. The non-volume-contributing abdominal component (P_A) is negatively proportional to the non-volume-contributing thoracic component (P_T). The thorax effort signal (T) is weighted by a weight factor k_T and the abdomen effort signal (A) is weighted by a weight factor k_A to obtain a volume-proportional signal (V_{SW}). The volume-proportional signal (V_{SW}) being proportional to the actual respiratory volume of the respiratory effort. The weight factors k_T and k_A are optimized by minimizing the non-volume-contributing thoracic component (P_T) and the non-volume-contributing abdominal component (P_A) in the resulting volume-proportional signal (V_{SW}). In another embodiment, a calibration factor for calibrating the thorax effort signal (T) and the abdomen effort signal (A) may be obtained based on the optimized weight factors k_T and k_A . According to another embodiment, a power loss parameter that is useful to predict respiration efficiency may also be determined based on the optimized weight factors k_A and k_T by comparing the amplitude of V_{SW} to the sum of the amplitudes of the weighted thorax effort signal T and the weighted abdomen effort signal A.

[0008] Also described herein is a hardware storage device having stored thereon computer executable instructions which, when executed by one or more processors, implement a method of measuring respiratory effort of a subject. According to one example, the method includes separating a received thorax effort signal (T) into a volume-contributing thoracic component (V_{ST}) and a thoracic paradox component (P_T). The thorax effort signal (T) is an indicator of a thoracic component of the respiratory effort, and the thoracic paradox component (P_T) represents a non-volume-contributing thoracic component of the respiratory effort. The volume-contributing thoracic component (V_{ST}) represents a volume-contributing component of the respiratory effort. An abdomen effort signal (A) is separated into a volume-contributing abdominal component (V_{SA}) and an abdomen paradox component (P_A). The abdomen effort signal (A) is an indicator of an abdominal component of the respiratory effort. The abdomen paradox component (P_A) represents a non-volume-contributing abdominal component of the respiratory effort, and the volume-contributing abdominal component (V_{SA}) represents a volume-contributing component of the respiratory effort. The non-volume-contributing abdominal component (P_A) is negatively proportional to the non-volume-contributing thoracic component (P_T). The thorax effort signal (T) is weighted by a weight factor k_T and the abdomen effort signal (A) is weighted by a weight factor k_A to obtain a volume-proportional signal (V_{SW}). The volume-proportional signal (V_{SW}) being proportional to the actual respiratory volume of the respiratory effort. The weight factors k_T and k_A are optimized by minimizing the non-volume-contributing thoracic component (P_T) and the non-volume-contributing abdominal component (P_A) in the resulting volume-proportional signal (V_{SW}). In another embodiment, a calibration factor for calibrating the thorax effort signal (T) and the abdomen effort

signal (A) may be obtained based on the optimized weight factors k_T and k_A . According to another embodiment, a power loss parameter that is useful to predict respiration efficiency may also be determined based on the optimized weight factors k_A and k_T by comparing the amplitude of V_{Sw} to the sum of the amplitudes of the weighted thorax effort signal T and the weighted abdomen effort signal A.

[0009] In another embodiment, a respiratory effort measuring system is described. The system includes a first sensor device configured to obtain a thorax effort signal (T), the thorax effort signal (T) being an indicator of a thoracic component of the respiratory effort, a second sensor device configured to obtain an abdomen effort signal (A), the abdomen effort signal (A) being an indicator of an abdominal component of the respiratory effort, and a processor configured to receive the thorax effort signal (T) and the abdomen effort signal (A). The processor separates the thorax effort signal (T) into a volume-contributing thoracic component (V_{ST}) and a thoracic paradox component (P_T), the thoracic paradox component (P_T) representing a non-volume-contributing thoracic component of the respiratory effort, and the volume-contributing thoracic component (V_{ST}) representing a volume-contributing component of the respiratory effort. The processor separates the abdomen effort signal (A) into a volume-contributing abdominal component (V_{SA}) and an abdomen paradox component (P_A), the abdomen paradox component (P_A) representing a non-volume-contributing abdominal component of the respiratory effort, and the volume-contributing abdominal component (V_{SA}) representing a volume-contributing component of the respiratory effort, wherein the non-volume-contributing abdominal component (P_A) is negatively proportional to the non-volume-contributing thoracic component (P_T). The thorax effort signal (T) is weighted by a weight factor k_T and the abdomen effort signal (A) is weighted by a weight factor k_A to obtain a volume-proportional signal (V_{Sw}). The volume-proportional signal (V_{Sw}) being proportional to the actual respiratory volume of the respiratory effort. The weight factor k_T and k_A are optimized by minimizing the non-volume-contributing thoracic component (P_T) and the non-volume-contributing abdominal component (P_A) in the resulting volume-proportional signal (V_{Sw}). In another embodiment, a calibration factor for calibrating the thorax effort signal (T) and the abdomen effort signal (A) may be obtained based on the optimized weight factors k_T and k_A . According to another embodiment, a power loss parameter that is useful to predict respiration efficiency may also be determined based on the optimized weight factors k_A and k_T by comparing the amplitude of V_{Sw} to the sum of the amplitudes of the weighted thorax effort signal T and the weighted abdomen effort signal A.

[0010] In another embodiment, a method of measuring respiratory effort of a subject is provided. The method includes obtaining a first effort signal, the first effort signal being an indicator of a first component of the respiratory effort. A second effort signal is obtained, the second effort signal being an indicator of a second component of the respiratory effort. The first effort signal is separated into a first volume-contributing component and a first paradox component, the first paradox component representing a non-volume-contributing of the first effort signal component of the respiratory effort, and the first volume-contributing component representing a first volume-contributing component of the respiratory effort. The second effort signal is separated into a second volume-contributing component and a second paradox component,

the second paradox component representing a non-volume-contributing of the second effort signal component of the respiratory effort, and the second volume-contributing component representing a second volume-contributing component of the respiratory effort. The first non-volume-contributing component is negatively proportional to the second non-volume-contributing component. The first effort signal is weighted by a first weight factor k_1 and the second effort signal is weighted by a second weight factor k_2 to obtain a volume-proportional signal, the volume-proportional signal being proportional to the actual respiratory volume of the respiratory effort. The weight factors k_1 and k_2 are optimized by minimizing the first non-volume-contributing component and the second non-volume-contributing component in the resulting volume-proportional signal (V_{sg}). In another embodiment, a calibration factor for calibrating the first and the second effort signals may be obtained based on the optimized weight factors k_1 and k_2 . Or, a power loss may be determined based on the optimized first or second weight factor (k_1 and k_2). According to another embodiment, a power loss parameter that is useful to predict respiration efficiency may also be determined based on the optimized weight factors k_1 and k_2 by comparing the amplitude of V_{sg} to the sum of the amplitudes of the weighted first effort signal and the weighted second effort signal.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIGS. 1a and 1b illustrate an example of respiratory inductance plethysmograph (RIP) belts, 1a shows an example of the wave-shaped conductors in the belts, 1b shows the cross-sectional area of each belt, which is proportional to the measured inductance.

[0012] FIG. 2 illustrates a reference flow signal (top), a flow signal from calibrated RIP sum (middle), and flow signal derived from uncalibrated RIP signals (bottom).

[0013] FIG. 3 shows a comparison between measured esophageal pressure (top) and a non-volume contributing effort signal (bottom) derived from RIP signals.

[0014] FIGS. 4a, 4b, and 4c, respectively, show a cumulative and relative histograms for power loss in 3 subjects with different levels of upper airway obstruction, from left, (a) subject 1: AHI 0.2, (b) subject 2: AHI 9.8, and (c) subject 3: AHI 21.3.

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

[0015] Non-invasive methods to measure breathing movements and respiratory effort may include the use of respiratory effort bands or belts placed around the respiratory region of a subject. The sensor belt may be capable of measuring either changes in the band stretching or the area of the body encircled by the belt when placed around a subject's body. A first belt may be placed around the thorax and second belt may be placed around the abdomen to capture respiratory movements caused by both the diaphragm and the intercostal muscles. When sensors measuring only the stretching of the belts are used, the resulting signal is a qualitative measure of the respiratory movement. This type of measurement is used for example for measurement of sleep disordered breathing and may distinguish between reduced respiration caused by obstruction in the upper airway (obstructive apnea), where there can be considerable respiratory movement measured, or

if it is caused by reduced effort (central apnea), where reduction in flow and reduction in the belt movement occur at the same time.

[0016] Unlike the stretch sensitive respiratory effort belts, areal sensitive respiratory effort belts provide detailed information on the actual form, shape and amplitude of the respiration taking place. If the areal changes of both the thorax and abdomen are known, by using a certain calibration technology, the continuous respiratory volume can be measured from those signals and therefore the respiratory flow can be derived.

[0017] Respiratory Inductive Plethysmography (RIP) is a method to measure respiratory related areal changes. As shown in FIG. 1, in RIP, belts **31**, **32** may contain a conductor **34**, **35** that when put on a subject **33**, form a conductive loop that creates an inductance that is directly proportional to the absolute cross sectional area of the body part that is encircled by the loop. When such a belt is placed around the abdomen or thorax, the cross sectional area is modulated with the respiratory movements and therefore also the inductance of the belt. Conductors **34**, **35** may be connected to signal processor **38** by leads **36**, **37**. Processor **38** may include a memory storage. By measuring the belt inductance, a value is obtained that is modulated directly proportional with the respiratory movements. RIP technology includes therefore an inductance measurement of conductive belts that encircle the thorax and abdomen of a subject.

[0018] In another embodiment, conductors may be connected to a transmission unit that transmits respiratory signals, for example raw unprocessed respiratory signals, or semi-processed signals, from conductors to processing unit. Respiratory signals or respiratory signal data may be transmitted to the processor by hardwire, wireless, or by other means of signal transmission.

[0019] Resonance circuitry may be used for measuring the inductance and inductance change of the belt. In a resonance circuit, an inductance L and capacitance C can be connected together in parallel. With a fully charged capacitor C connected to the inductance L, the signal measured over the circuitry would swing in a damped harmonic oscillation with the following frequency:

$$f = \frac{1}{2\pi\sqrt{LC}}, \quad (1)$$

until the energy of the capacitor is fully lost in the circuit's electrical resistance. By adding to the circuit an inverting amplifier, the oscillation can however be maintained at a frequency close to the resonance frequency. With a known capacitance C, the inductance L can be calculated by measuring the frequency f and thereby an estimation of the cross-sectional area can be derived.

[0020] The signal amplitude received from the respiratory effort belts depends on both the shape of the subject and the placement of the belts. The thorax respiration signal may be approximately the same for the whole thorax region but the areal change may be differently proportional to the thorax respiration signal, depending on where on the thorax the belt is placed and how the subject is shaped.

[0021] The same may be true for the abdomen region. The abdomen respiration signal may be driven by the diaphragm alone and therefore may be the same all over the abdomen

region, but depending on where the belt is located and the shape of the abdomen, the areal change may be differently proportional to the abdomen respiration signal.

[0022] To create a respiration volume signal by summing the thorax respiration and abdomen respiration, one must therefore use the correct weights for the measured belt signals to transform each signal correctly into a volume signal before summing them together.

[0023] If the thorax RIP signal is T and the abdomen RIP signal is A the total volume signal can be represented as:

$$V_R = k_T(k_T \times T + (1 - k_T) \times A) \quad (2),$$

where k_T is the weight of the thorax signal towards the abdomen signal and the k_V is the gain required to change the weighted belt sum to the actual V_R measured in liters or other volume unit.

[0024] To perform a quantitative calibration, the signals T and A must be measured simultaneously with a quantitative reference measure of V_R . Based on the result, the constants, k_V and k_T can be derived using methods such as least square fitting. This method does therefore require quantitative equipment for respiratory volume measure, such as a spirometer, body-box or similar ways to measure V_R accurately during the calibration.

[0025] Even if the quantitative measure of V_R is of interest, e.g. for pulmonary function tests, it is sufficient for many applications to derive a signal that is only proportional to the actual volume. This is the case in sleep monitoring, where the purpose with the measure is to detect abnormal breathing patterns, generally by determining if the amplitude of one breath deviates from a reference breath. In this case it is sufficient to evaluate the proportion between the thorax and abdomen signals before summing, that is, for a volume proportional sum V_{S1} ,

$$V_{S1} = (k_T \times T + (1 - k_T) \times A) \quad (3),$$

[0026] As one of skill in the art would understand, due to the linearity of the system, as the absolute gain of the signal is not relevant, the weight factor for T can be changed to any value as long as the weight factor for A is changed proportionally. A simplified presentation of the above equation can therefore be used for the sake of argument, where $k_T = 1$ and $k_A = (1 - k_T)/k_T$ resulting in the equation:

$$V_S = (T + k_A \times A) \quad (4.1).$$

[0027] Due to the complexity added with using reference respiratory volume equipment and the fact that the k_A is a subject to change over time with belt and body movements, it would simplify the measure considerably if there would be a method available that would evaluate k_A without the need of a special equipment for reference measures.

[0028] A method may use statistical measures of RIP during normal breathing to evaluate k_A , using an algorithm referred to as Qualitative Diagnostic Calibration (QDC).

[0029] The QDC algorithm allows a qualitative calibration of the RIP signals during normal breathing to estimate the k_A without the use of a reference volume signal. The method is based on the findings that during normal breathing (non-obstructive), the variance in the amplitude of the thorax and abdomen RIP signals, when correctly calibrated should be the same, given that the tidal volume of the breaths are approximately the same. By measuring a number of breaths (e.g. for a 5 minute period), selecting the breaths that are close to being normal distributed around the average tidal volume and calculating the standard deviation of the selected breaths for the

thorax signal (Sd(T)) and abdomen signals (Sd(A)), the gain factor can be evaluated as follows:

$$k_A = -\frac{Sd(T)}{Sd(A)}. \quad (5)$$

[0030] This method may be useful for respiratory analysis and sleep diagnostics. The drawback is however that the k_A will change if the belts move or the subject changes position. To maintain accuracy, recalibration is needed after such movements and changes, and that requires a few minutes of normal, non-obstructive breathing. This can be difficult with a sleeping subject, especially with subject's suffering from sleep disordered breathing. Preferably, a calibration factor for the respiratory signals would be obtainable in a more continuous fashion.

[0031] The underlying model and parameters of a preferable method are herein described. For a calibrated system the following applies:

$$\text{From equation (3.1) } V_S = (T + k_A A) \quad (3.2),$$

As explained above, due to the linearity of the system, other weight factors for k_T , and k_A have the same effect, such as choosing to set the weight factor k_A to be equal to one ($k_A=1$), arriving at equation (3.3) below, and k_T may be determined as the weight factor, which may be defined as the ration of weights for T towards A.

$$V_{S2} = (k_T T + A) \quad (3.3),$$

Furthermore, both Thorax and Abdomen could have weights other than 1 resulting in

$$V_{S2} = (k_T T + k_A A) \quad (3.4),$$

For ease in understanding the model, in the description below, the weight factor k_T is, however, chosen to be equal to one ($k_T=1$). Based on equation (3.2), the following may be further defined:

$$T = k_{VT} \times V_S + P \quad (6),$$

$$k_A A = (1 - k_{VT}) \times V_S - P \quad (7).$$

[0032] In the above formulas k_{VT} is the contribution of the thorax movement, in the range from 0 to 1 to the volume sum V_S , whereas the remaining contribution of $(1 - k_{VT})$ must come from the abdomen movement. The product of $k_{VT} \times V_S$ is therefore the flow-contributing component of T while $(1 - k_{VT}) \times V_S$ is the flow-contributing component of A. The residual movement of the thorax, T may be termed herein as a paradox component P and is the exact opposite of a paradox movement in $k_A A$. Therefore by summing the two, the P and -P cancel the effect of each other, as this movement is not contributing any respiratory volume.

[0033] In the extreme case of almost non-obstructive breathing, the P close to zero and the shape of both T and $k_A A$ is close to be identical to V_S ,

$$T = k_{VT} \times V_S \text{ and } k_A A = (1 - k_{VT}) \times V_S.$$

During the other extreme case of fully obstructive breathing, V_S drops to zero, $T=P$ while $k_A A=-P$.

[0034] The model may therefore successfully describe respiratory movements of thorax and abdomen for differing levels of obstruction, given that the coefficients, k_A and k_{VT} are known. Further, a calibration factor for calibrating the thorax effort signal T and the abdomen effort signal A may be

obtained based on the optimized weight factor k_A . The weight factor coefficients k_A and k_{VT} may then be stored, and the calibrated thorax effort signal T and the abdomen effort signal A and the volume sum V_S may be stored and displayed on a display device.

[0035] From equations (5) and (6) an equation for the parameter P can be derived:

$$P = T - k_{VT} V_S \quad (8).$$

As can be seen in equation (7) above, the paradox signal cannot be determined from the T, $k_A A$ and V_S only but is also a function of the actual volume contribution from each belt k_{VT} .

[0036] In accordance with the model of this embodiment, there are different ways to suitably determine the coefficients k_A and k_{VT} , some examples of which are described herein.

[0037] Amplitude and Power Loss Due to Summing of Channels

[0038] As V_S is the sum of the volume-contributing components of the thorax and abdomen signals, the paradox components present in T and $k_A A$ disappear in the sum. As part of the signal is lost, the amplitude of the summed signal V_S is therefore less than the sum of the amplitudes of T and $k_A A$, and the same is true for the power of the summed signal V_S as compared to the sum of the powers of T and $k_A A$. (In this context, 'power' refers to mathematical power function, not electrical power.) Thus, based on equation (3), $V_S = (T + k_A A)$, it follows that for the amplitude, the following applies:

$$|V_S| \leq |T| + |k_A A| \quad (9),$$

and therefore its power is as follows:

$$P < V_S > \leq P < T > + P < k_A A >. \quad (10).$$

[0039] This power loss is minimal during normal breathing, increases with increased partial obstruction until it is absolute during complete obstruction. For any given timeframe, the amplitude and power loss are at maximum when the sum is correctly calibrated. Accordingly, a useful k_A value can be obtained which is a value that maximizes the power loss and/or amplitude loss, compared with the sum of the power or amplitudes respectively, of T and A over a period of time. This is done in certain useful embodiments of the disclosure and readily achieved with iterative calculations.

[0040] Paradox Present in Higher Frequencies

[0041] Obstructive changes in the airway during a single breath are by nature quicker events than the respiration itself and do therefore contain higher frequency components compared with the flow signal. The power of P is therefore more in the higher frequencies compared with V_S and the relative power of the fundamental frequency is therefore higher in V_S than in both T and $k_A A$.

[0042] Accordingly, in some embodiments a useful k_A value is obtained, by finding a k_A value such that the proportional power of lower frequencies in the respiratory signal is maximized as compared with higher frequencies in the respiratory signal, over a period of time. It is apparent that "lower" and "higher" frequencies in this context are determined based on normal breathing frequencies. Thus lower frequencies could be, in one embodiment, frequencies lower than double the average frequency being measured (which is generally the fundamental frequency of the breathing signal, readily determined, e.g. by FT transforming of the signal). Or in other embodiments frequencies lower than 1 Hz, 0.5 Hz or lower, such as lower than 0.2 Hz (12 breathes per minute) or lower than 0.1 Hz. Higher frequencies would accordingly be

those frequencies that are higher than the cutoff between lower and higher frequencies, or in some embodiments those frequencies that are higher than the fundamental frequency of the breathing signal.

[0043] Based on the above, the present disclosure further provides for, in some embodiments, ways to use the magnitude of the loss of amplitude or power, the magnitude of loss of the higher frequency components or a combination of these to determine a k_A value that is considered optimal over a certain period of time.

[0044] Maximum Fundamental Frequency Optimization (MFF)

[0045] In another embodiment, a MFF method seeks by trial and error over a certain period, the k_A that results in the $V_S = (T + k_A A)$ that maximizes the power of the fundamental frequency of the signal relative to the overall signal power. The logic is that as P contains higher frequency components than V_S , maximizing the relative power of the fundamental frequency is the same as minimizing the effects of P in the sum.

[0046] The MFF method is applied in useful embodiments. The fundamental frequency is generally the undisturbed breathing rhythm, the period referred to can be relatively short, such as but not limited to breath by breath (one breathing cycle), or a predetermined period such as 1 min or a few minutes. Different time-frequency analysis methods can be used separately or together for maximizing of the method efficiency, including but not limited to, Wavelet transform, Fourier transformation, statistical modeling, etc.

[0047] Minimum Signal Amplitude Optimization (MSA)

[0048] A MSA method seeks by trial and error for a given period the k_A that results in the $V_S = (T + k_A A)$ that minimizes the resulting signal compared with the amplitude of T and $k_A A$,

$$S_{Imin} = \min \left\{ \frac{\text{RMS}(V_S)}{\text{RMS}(T) + \text{RMS}(k_A A)} \right\}. \quad (11)$$

S_I can be understood as relative difference between the V_S amplitude versus the sum of the amplitudes of T and $k_A A$. The logic is that P contributes to the amplitude of the measured signal but not to the amplitude of the respiration. By minimizing the amplitude of the resulting signal S_P , one is minimizing the influence of P and the respiration part of the signal is therefore maximized. The period in the MSA method can in some embodiments be the period of a single breath (suitably determined as described above), or a few breaths, or longer, such as in the range from about 10 sec. to about 10 minutes, such as e.g. about 0.5 minute, or about 1 min period, about 5 minutes or about 10 min period. In other embodiments longer periods are used, such as 0.5 hour, 1 hour, or a period of a few hours (e.g. 2, 3, 4 or 5 hours), where a suitable period can be selected depending on the application.

[0049] Minimum Obstruction Amplitude (MOA) Optimization

[0050] The MOA method is useful for periods of time in embodiments where there are quick changes in the signal amplitudes between breaths and periods of obstruction. The obstructive periods provide the opportunity to perform conventional isovolume calibration, by selecting the k_A that minimizes in the best way the V_S during obstruction. This can be done for a period of the signal (e.g. 0.5 minute, or 1 min or a few minutes such as in the range 1-5 minutes), by dividing the

period into a number of n shorter time frames of few seconds each (such as e.g. in the range of 3-10 seconds, or in the range of 3-5 seconds; should fit within an apnea). For a given timeframe i, the $S_{Imin< i >}$ is found and the relative $k_{A< i >}$ is stored. The value of k_A for the whole period (longer period) is then selected by a weighted average over the period by giving the timeframes that resulted in the lowest S_{Imin} values the maximum weight. More weight can be given to the timeframes that performed in the best way by using a non-linear weight transformation.

[0051] In some embodiments, combinations of two or more of the above methods are applied to obtain a suitable optimal k_A value.

[0052] In other embodiments one or more method as described above is applied to derive an intermediate k_A value for a shorter time span, such as e.g. in the range of 5-60 seconds, such as 5-30 seconds, or in the range 5-20 seconds, or in the range 10-30 seconds, and weighing the performance for each timespan and choosing a k_A for the longer timespan (e.g. in the range 1-15 minutes, or in the range 1-10 minutes, such as 5-10 minutes, or longer time spans such as in the range 10-60 minutes, or in some embodiments even longer periods, such as in the range 1-10 hours, e.g. in the range 1-5 hours or in the range 5-10 hours), based on selecting the method providing the most determinant result.

[0053] For evaluating and deriving a suitable determinant value of the weighing ratio, various methods can be applied. In one embodiment the performance of the intermediate periods and intermediate values is evaluated by weighing the performance for each intermediate time span (e.g. averaging or otherwise statistically comparing), then the different methods can be compared by comparing which method(s) gives a most consistent value with minimal fluctuations while maintaining the minimal paradoxical components.

[0054] Weighting in the Neighboring Periods

[0055] The method reliability is in some embodiments enhanced further by selecting a set of periods and basing the selection of k_{A_j} on an average, weighted sum or other performance criteria from the periods in the set. In this way, an accurate k_{A_j} value can be selected for periods that have low signal and frequency magnitude losses, based on a more reliable estimation of a neighboring period.

[0056] This is in some embodiments done, e.g., by splitting each minute (or other chosen time span) into overlapping intermediate periods (e.g. 5 seconds, or intermediate periods of other chosen time length, such as but not limited to 3 seconds, 8, or 10 seconds), the k_{A_j} value used for the whole time span can be the weighted sum of the k_A values for each intermediate period where the weight of the periods that have the maximum amplitude/power loss and/or frequency loss is higher than for periods that show lower losses. This can then be applied for longer periods, taking a set of time spans (e.g., minute time spans) and for example calculating a weighted trend-curve for the changes of k_A minute by minute, giving the minutes with the strongest losses the maximum weight and those with low losses the minimum weight.

[0057] Selecting an Optimization Method

[0058] To adapt optimally to the information available at each period in the signal, the method should preferably use the k_A that fits best for each condition. The measure of how well a method performs can be based on the quantity of the amplitude, signal or frequency loss, where the method providing the highest loss is generally considered the optimal one.

[0059] A good criteria for selecting the k_A also preferably results in less switching between methods and optimally that switching from one method to the other occurs when the two methods predict nearly the same value of k_A . This way a continuous trend is achieved where sudden shifts in the resulting signal are avoided, caused by switching methods.

[0060] To further optimize the selection criteria, a good result can be achieved by processing a series of periods instead of one by one and then choosing the methods for each period that maximizes the continuity of the k_A between periods, minimizes the number of switches between methods or a combination of both.

[0061] Signals Derived from the Calibrated Effort

[0062] A number of interesting and useful signals can be derived with the embodiments of this disclosure, from the calibrated thorax and abdomen signals.

[0063] The Paradox P and the Thorax Volume Contribution k_{VT}

[0064] As demonstrated in equation (7), even after optimally calibrating the sum, the level of the paradox signal P has more than one solution depending on the k_{VT} .

[0065] To evaluate the P, a method must be created to seek for the correct k_{VT} . The physiological characteristics of P is that the paradox is driven by the pressure difference in the Thorax and in the surrounding atmosphere, caused by the inhalation of air over a partial obstruction in the upper airway. For a given pressure difference, the paradox status generally has a balance to the lowest energy level capable of creating that status. This characteristic can be used to determine a useful and correct value P by choosing the k_{VT} that results in the lowest power function/amplitude of P. Accordingly, in a further embodiment, this disclosure provides a method for determining a useful value of the paradox component P.

[0066] The paradox signal P is of special interest as it is directly derived from the thorax internal pressure and is a strong indication of the respiratory effort taking place for each breath. This parameter is a candidate for being used as a substitute for a very invasive method currently being used in sleep medicine. This method is direct measure of the esophageal pressure that is currently performed by threading a catheter through the nose and into the esophageal to monitor the respiratory pressure below the upper airway obstruction.

[0067] The other signal is the thorax contribution that is also of interest as the physiology suggests that the ratio of thorax contribution vs. abdomen contribution changes with the level of sleep, the respiratory muscular activity being different during REM sleep compared with the S1, S2 and S3. Sudden changes in the contribution ratio are therefore strongly related with REM onset and offset.

[0068] The Power Loss Ratio

[0069] As described in equations (8) and (9) the total amplitude and thus the power of the sum V_S is less than the sum of the amplitude and power of the T and $k_A A$ due to the loss of the paradox signal P.

[0070] The value S_{min} defined in (10) describes the efficiency of the respiration, that is, what portion of the respiratory movement did result in respiratory flow and what portion did not. This index is of great interest as it predicts in a continuous manner the quality of the breathing, being 100% during no obstruction to become 0% for total obstruction or the other way around, the power loss being 0% for no obstruction and 100% for full obstruction.

[0071] As this index is the same as is used to seek the calibration value $k_A A$, it can also be calculated directly from

the belt signals by applying the model defined in (10), seeking the k_A that results in the minimum S_{min} and use that value as a power loss index. FIGS. 5a, 5b, and 5c show cumulative and relative histograms of power loss in three subjects with different breathing. As can be seen the histograms are quite different, illustrating difference between subjects with healthy breathing and subjects with disordered breathing. Using 20% power loss as a threshold, only 5% of the breaths of Subject 1 are above that threshold, 20% of the breaths of Subject 2 and half of the breaths of Subject 3. The power loss index is therefore a candidate to be used as a quantitative measure of the level of partial obstruction.

[0072] Volume Calibration and Stabilization

[0073] As can be seen from equations (2) and (3), V_R is an absolute volume signal measured in liters, while V_S is a signal that is directly proportional to V_R but is not the absolute volume signal. If the sensitivity of T changes in (3) due to belt movement or other changes in physiology, the gain between V_S and V_R changes during the night. This causes the problem for signal like the V_S and P that even if their initial values where known in a volume unit like liters, they would change or drift through the night. This can be prevented to some degree by fixing the belts as tightly to the subject as possible. However, if there were a biomedical parameter that would allow the belts to be regulated to show a constant ratio towards V_R the results would allow the signals to be used with confidence to compare amplitudes at different times over the night.

[0074] The present disclosure provides a further method that makes use of the physiological characteristics that the human body regulates the intake of oxygen to match the need of the cells at all time, not building up or dropping oxygen levels during normal breathing. The indication of increased metabolism is higher minute ventilation (minute ventilation referring to the total volume inspired or expired per minute) and heart rate and during aerobic breathing the ratio between minute ventilation and heart rate is close to linear. The method monitors the relative minute ventilation from the V_S signal and compares it to a measured heart rate. The characteristic linearity between the minute ventilation and heart rate is captured during periods where the k_A is not changing significantly but where there is a variation in the minute ventilation and heart rate. The captured value is then used to correct the V_S when there is a change in the k_A values. This way the V_R/V_S ratio can be kept nearly constant throughout the recording, allowing volume calibration to take place at one or more points during the recording and delivering reliable measure for all periods.

[0075] Certain terms are used throughout the description and claims to refer to particular methods, features, or components. As those having ordinary skill in the art will appreciate, different persons may refer to the same methods, features, or components by different names. This disclosure does not intend to distinguish between methods, features, or components that differ in name but not function. The figures are not necessarily to scale. Certain features and components herein may be shown in exaggerated scale or in somewhat schematic form and some details of conventional elements may not be shown or described in interest of clarity and conciseness.

[0076] Although various example embodiments have been described in detail herein, those skilled in the art will readily appreciate in view of the present disclosure that many modifications are possible in the example embodiments without materially departing from the concepts of present disclosure.

Accordingly, any such modifications are intended to be included in the scope of this disclosure. Likewise, while the disclosure herein contains many specifics, these specifics should not be construed as limiting the scope of the disclosure or of any of the appended claims, but merely as providing information pertinent to one or more specific embodiments that may fall within the scope of the disclosure and the appended claims. Any described features from the various embodiments disclosed may be employed in combination. In addition, other embodiments of the present disclosure may also be devised which lie within the scopes of the disclosure and the appended claims. Each addition, deletion, and modification to the embodiments that falls within the meaning and scope of the claims is to be embraced by the claims.

[0077] Certain embodiments and features may have been described using a set of numerical upper limits and a set of numerical lower limits. It should be appreciated that ranges including the combination of any two values, e.g., the combination of any lower value with any upper value, the combination of any two lower values, and/or the combination of any two upper values are contemplated unless otherwise indicated. Certain lower limits, upper limits and ranges may appear in one or more claims below. Any numerical value is “about” or “approximately” the indicated value, and takes into account experimental error and variations that would be expected by a person having ordinary skill in the art.

What is claimed:

1. A method of measuring respiratory effort of a subject, the method comprising:

obtaining a thorax effort signal (T), the thorax effort signal (T) being an indicator of a thoracic component of the respiratory effort;

obtaining an abdomen effort signal (A), the abdomen effort signal (A) being an indicator of an abdominal component of the respiratory effort;

separating the thorax effort signal (T) into a volume-contributing thoracic component (V_{ST}) and a thoracic paradox component (P_T), the thoracic paradox component (P_T) representing a non-volume-contributing thoracic component of the respiratory effort, and the volume-contributing thoracic component (V_{ST}) representing a volume-contributing component of the respiratory effort;

separating the abdomen effort signal (A) into a volume-contributing abdominal component (V_{SA}) and an abdomen paradox component (P_A), the abdomen paradox component (P_A) representing a non-volume-contributing abdominal component of the respiratory effort, and the volume-contributing abdominal component (V_{SA}) representing a volume-contributing component of the respiratory effort, wherein the non-volume-contributing abdominal component (P_A) is negatively proportional to the non-volume-contributing thoracic component (P_T);

weighting the thorax effort signal (T) by a first weight factor (k_T) and weighting the abdomen effort signal (A) by a second weight factor (k_A) to obtain a volume-proportional signal (V_{SW}), the volume-proportional signal (V_{SW}) being proportional to the actual respiratory volume of the respiratory effort; and

optimizing the weight factors (k_T and k_A) by minimizing the non-volume-contributing thoracic component (P_T) and the non-volume-contributing abdominal component (P_A) in the resulting volume-proportional signal (V_{SW}).

2. The method according to claim 1, further comprising obtaining a calibration factor for calibrating the thorax effort signal (T) and the abdomen effort signal (A) based on the optimized first and second weight factors (k_T and k_A).

3. The method according to claim 1, further comprising determining the power loss based on the optimized first and second weight factors (k_A and k_T).

4. The method according to claim 3, wherein determining the power loss includes maximizing the power loss of a resulting signal compared with a sum of the power of the thorax effort signal (T) weighted by the optimized first weight factor (k_T) and the abdomen effort signal (A) weighted by the optimized second weight factor (k_A) over a period of time.

5. The method according to claim 1, wherein a volume-proportional signal (V_{S2}) is obtained by weighting the thorax effort signal (T) by the first weight factor (k_T).

6. The method according to claim 1, wherein the volume-proportional signal (V_S) is obtained by weighting the abdomen effort signal (A) by the second weight factor (k_A).

7. The method according to claim 6, wherein the second weight factor (k_A) is a weight ratio for the abdomen effort signal (A) towards the thorax effort signal (T) such that the resulting volume-proportional signal (V_S) equals $T+(k_A \times A)$.

8. The method according to claim 1, further comprising calculating the respiratory flow proportional signal (F_S) by calculating the first derivative of the thorax effort signal (T) with respect to time (T') and the first derivative of the abdomen effort signal (A) with respect to time (A') to minimize the non-volume-contributing thoracic component (P_T) and the non-volume-contributing abdominal component (P_A).

9. The method according to claim 1, wherein the first and second weight factors (k_T and k_A) are optimized by comparing a maximized proportion power of lower frequencies of the thorax effort signal (T) and the abdomen effort signal (A) with a proportional power of higher frequencies of the thorax effort signal (T) and the abdomen effort signal (A) over a period of time.

10. The method according to claim 1, further comprising maximizing an amplitude loss of a resulting signal compared with a sum of the amplitude of the thorax effort signal (T) and the abdomen effort signal (A) over a period of time.

11. The method according to claim 1, further comprising obtaining a calibration factor for calibrating the thorax effort signal (T) and the abdomen effort signal (A) over a plurality of time spans including a first timespan within a second time span, the first time span being shorter than the second time span, and

selecting a calibration ratio for the second time span based on the most determinant calibration factor of the obtained calibration factors of the plurality of time spans.

12. The method according to claim 1, further comprising selecting a value for the first and second weight factors (k_T and k_A) by determining intermediate values for weighing ratios for a set of a plurality of consecutive intermediate time spans and calculating the value for the first and second weight factors (k_A and k_T) by weighing values within the set of time spans so as to maximize the continuity of weighed values over the set.

13. The method according to claim 1, further comprising deriving a paradox signal, a derivative of the paradox signal, or an integration of the paradox signal of the thorax effort signal (T) or the abdomen effort signal (A) by deriving an intermediate value of the first and second weight factors (k_T

and k_A) by determining a value for the first and second weight factors (k_T and k_A) that results in the minimization of the amplitude or power of the paradox signal of the thorax effort signal (T) or the abdomen effort signal (A).

14. The method according to claim 1, further comprising evaluating flow resistance from the obtained paradox signal of the thorax effort signal (T) or the abdomen effort signal (A) and the first derivative of the volume-proportion signal (V_S) with respect to time.

15. A method of measuring respiratory effort of a subject, comprising evaluating respiration energy by integrating the multiplication product of the thorax paradox signal derived according to claim 8, with the first derivative of the volume-proportion signal (V_S) with respect to time.

16. A method of measuring respiratory effort of a subject, comprising determining the first and second weight factors (k_T and k_A) according to the methods of claim 1,

using the first and second weight factors (k_T and k_A) to create a weighted sum of signals based on the thorax effort signal (T) and the abdomen effort signal (A), calculating the ratio between the amplitude or power or any transformation function of the amplitude or power towards the sum of the amplitudes, power, or the other transformation function of each of the signals derived from the thorax effort signal (T) and the abdomen effort signal (A).

17. The method according to claim 16, wherein the thorax effort signal (T) is obtained by providing a first sensor device configured to measure the thoracic component of the respiratory effort of the subject, and

the abdomen effort signal (A) is obtained by providing a second sensor device configured to measure the abdominal component of the respiratory effort of the subject.

18. The method according to claim 1, further comprising determining a respiratory volume calibration based on a measured heart rate of the subject.

19. A hardware storage device having stored thereon computer executable instructions which, when executed by one or more processors, implement a method of measuring respiratory effort of a subject comprising:

separating a received thorax effort signal (T) into a volume-contributing thoracic component (V_{ST}) and a thoracic paradox component (P_T), the thorax effort signal (T) being an indicator of a thoracic component of the respiratory effort, the thoracic paradox component (P_T) representing a non-volume-contributing thoracic component of the respiratory effort, and the volume-contributing thoracic component (V_{ST}) representing a volume-contributing component of the respiratory effort;

separating an abdomen effort signal (A) into a volume-contributing abdominal component (V_{SA}) and an abdominal paradox component (P_A), the abdomen effort signal (A) being an indicator of an abdominal component of the respiratory effort, the abdominal paradox component (P_A) representing a non-volume-contributing abdominal component of the respiratory effort, and the volume-

contributing abdominal component (V_{SA}) representing a volume-contributing component of the respiratory effort, wherein the non-volume-contributing abdominal component (P_A) is negatively proportional to the non-volume-contributing thoracic component (P_T);

weighting the thorax effort signal (T) by a first weight factor (k_T) and weighting the abdomen effort signal (A) by a second weight factor (k_A) to obtain a volume-proportional signal (V_{Sw}), the volume-proportional signal (V_{Sw}) being proportional to the actual respiratory volume of the respiratory effort; and

optimizing the first and second weight factors (k_T and k_A) by minimizing the non-volume-contributing thoracic component (P_T) and the non-volume-contributing abdominal component (P_A) in the resulting volume-proportional signal (V_{Sw}).

20. A respiratory effort measuring system comprising:

a first sensor device configured to obtain a thorax effort signal (T), the thorax effort signal (T) being an indicator of a thoracic component of the respiratory effort;

a second sensor device configured to obtain an abdomen effort signal (A), the abdomen effort signal (A) being an indicator of an abdominal component of the respiratory effort; and

a processor configured to receive the thorax effort signal (T) and the abdomen effort signal (A); wherein the processor

separates the thorax effort signal (T) into a volume-contributing thoracic component (V_{ST}) and a thoracic paradox component (P_T), the thoracic paradox component (P_T) representing a non-volume-contributing thoracic component of the respiratory effort, and the volume-contributing thoracic component (V_{ST}) representing a volume-contributing component of the respiratory effort,

separates the abdomen effort signal (A) into a volume-contributing abdominal component (V_{SA}) and an abdominal paradox component (P_A), the abdomen paradox component (P_A) representing a non-volume-contributing abdominal component of the respiratory effort, and the volume-contributing abdominal component (V_{SA}) representing a volume-contributing component of the respiratory effort, wherein the non-volume-contributing abdominal component (P_A) is negatively proportional to the non-volume-contributing thoracic component (P_T),

weights the thorax effort signal (T) by a first weight factor (k_T) and weights the abdomen effort signal (A) by a second weight factor (k_A) to obtain a volume-proportional signal (V_{Sw}), the volume-proportional signal (V_{Sw}) being proportional to the actual respiratory volume of the respiratory effort; and

optimizes the first and second weight factors (k_T and k_A) by minimizing the non-volume-contributing thoracic component (P_T) and the non-volume-contributing abdominal component (P_A) in the resulting volume-proportional signal (V_{Sw}).

* * * * *

专利名称(译)	用于测量呼吸努力的方法，设备和系统		
公开(公告)号	US20150126879A1	公开(公告)日	2015-05-07
申请号	US14/535093	申请日	2014-11-06
[标]申请(专利权)人(译)	NOX医疗		
申请(专利权)人(译)	NOX医疗		
当前申请(专利权)人(译)	NOX医疗		
[标]发明人	HOSKULDSSON SVEINBJORN HALLGRIMSSON HARALDUR TOMAS SIGURDARSON GUDJON TEITUR		
发明人	HOSKULDSSON, SVEINBJORN HALLGRIMSSON, HARALDUR TOMAS SIGURDARSON, GUDJON TEITUR		
IPC分类号	A61B5/113 A61B5/0205 A61B5/00		
CPC分类号	A61B5/1135 A61B5/7278 A61B5/0205 A61B5/024 A61B5/087 A61B5/091 A61B5/0809 A61B5/0806 A61B5/0535 A61B2560/0223		
优先权	050066 2013-11-06 IS		
其他公开文献	US10588550		
外部链接	Espacenet USPTO		

摘要(译)

提供了一种用于测量受试者的呼吸努力的方法，设备和系统。获得胸部努力信号和腹部努力信号。胸部努力信号和腹部努力信号每个被分成呼吸努力的体积贡献分量和悖论分量。悖论成分代表呼吸努力的非体积贡献成分。腹部悖论成分与胸悖论成分呈负相关。胸部力量信号或腹部力量信号或两者通过加权因子加权以获得体积比例信号。体积比例信号与呼吸努力的实际呼吸量成比例。通过最小化胸部悖论分量和腹部悖论分量来优化权重因子，获得用于校准胸部力量信号和腹部力量信号的校准因子。

