Apparatus and Method for Breath Sounds Monitoring

Breath analysis apparatus comprising: a spirometer, including a breath tube, which generates breath flow information and a breath sounds sensor situated in the breath tube, which generates breath sounds information.
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APPARATUS AND METHOD FOR BREATH SOUNDS MONITORING

FIELD OF THE INVENTION

The present invention relates to the field of monitoring of asthma and more particularly to apparatus and methods for measurement and classification of breath sounds, especially utilizing breath sounds measured at an airway opening.

BACKGROUND OF THE INVENTION

Experts from the American Lung Association have stated that "Asthma is one of the most common chronic diseases of childhood. An estimated 4.8 million children under 18 years old have asthma (in the United States) and many others have "hidden" or undiagnosed asthma. Asthma is a disease of all age groups, but the steepest recent increases in asthma cases have been among the young. Even though asthma cannot be cured, it can almost always be controlled. … Until rapid breathing, wheezing and coughing become obvious, the condition of many children with asthma will go undetected. These children with asthma usually suffer some degree of airway obstruction and unless it is brought under control, the children may suffer respiratory illness more frequently than necessary."

A connection between wheezes and asthma is known. Generally, the onset of wheezes is determined by a physician listening to the chest of a patient during forced or regular breathing. The time of onset during forced breathing or the duration of wheezing during quiet breathing is related to the extent of flow limitations in the airways. However, traditional diagnostic techniques are both subjective and non-quantitative, due in part to the lack of objective determination of the onset of a wheeze and due in part to the lack of quantitative time correlation of the wheeze and the breathing.

Spirometric devices, which measure the velocity of air in a tube and thus can calculate the volume of air being expelled or which measure the volume directly are well known. These devices include volume measuring devices such as the spirometer (bell, wedge, rolling seal, etc.), flow measuring devices such as the pneumotachometer, turbine, vanes, etc., and chest expansion devices such as induction spirometry, magnetometers and impedance measuring devices. While volume measuring devices are accurate, they are large, sensitive and cumbersome. Flow meters are more compact, but have a limited dynamic range. Chest expansion devices need individual patient calibration.

SUMMARY OF THE INVENTION

One aspect of some preferred embodiments of the present invention is related to the correlation of spirometry information and wheeze detection. In some preferred embodiments
of the invention, the time of onset of wheezes and/or their duration is correlated with the relative time in the breathing cycle during regular and/or forced breathing. In some preferred embodiment of the invention, the time of onset of wheezes is correlated with spirometric data to provide information indicative of the extent of flow limitation in airways of the patient.

A second aspect of some preferred embodiments of the invention is related to a novel acoustic flow meter, which optionally includes a sensor for the measurement of breath sounds. In a preferred embodiment thereof, flow is measured by introducing turbulence in the flow to generate eddy currents in the flow. Unlike sound waves, which travel with the speed of sound, eddies which are generated in the flow travel with the speed of the air itself. Thus, by measuring pressure changes at the wall of the tube, caused by the movement of the eddies, the velocity of the eddies can be determined. Using a determined relationship, time varying flow volume can be determined, based on the velocity of the eddies.

In a preferred embodiment of the invention, the flow meter is formed with ring protuberances having sharp edges which promote generation of eddies in the flow.

A third aspect of some preferred embodiments of the present invention relates to the placement of a breath sounds detector in the flow tube of a spirometer. Preferred embodiments of this device are especially suitable for use in the first aspect of the invention.

A fourth aspect of some preferred embodiments of the invention relates to detection of wheeze, cackle, secretion sounds and the spectral pattern of normal breath sounds at an airway opening.

In one preferred embodiment of the invention, the breath sounds are sensed by a sensor in a flow tube, as for example a spirometer flow tube. In this embodiment of the invention, the detection may be correlated with measured air flow. In other preferred embodiments of the invention, the breath sounds detector is placed in an endotracheal tube inserted into the airway via either the mouth, nose or in a tube used for a tracheotomy. Preferably, the breath sounds detector is placed in a portion of the tube which is outside the body. Preferably, the breath sounds sensor is connected to circuitry which determines the presence of wheezes, cackles secretion sounds and/or determines the spectral pattern of the basic breath sounds of the subject.

There is thus provided, in accordance with a preferred embodiment of the invention, breath analysis apparatus comprising:

a spirometer, including a breath tube, which generates breath flow information and
a breath sounds sensor situated in the breath tube, which generates breath sounds information.

In a preferred embodiment of the invention, the spirometer comprises:

an obstruction in the flow tube which causes the generation of pressure disturbances in air flow in the tube, said disturbances traveling down the tube with the air flow;

wherein said spirometer generates flow volume information based on a measurement of said disturbances.

Preferably, the spirometer comprises a velocimeter which determines the velocity of the disturbances.

Preferably, the breath tube includes a second obstruction situated on the other side of the velocimeter from the obstruction, and the velocimeter determines the direction of the flow.

Preferably, the velocimeter comprises a pair of pressure monitors spaced in the direction of flow of the air. Preferably, the velocimeter determines the phase difference of the pressure spectrum at at least one frequency at the pair of pressure monitors. Preferably, the apparatus includes circuitry which determines the volume of air flow in the tube based on said determination of velocity. Preferably, the circuitry comprises a look-up table which relates the total flow in the tube to the measured velocity.

In a preferred embodiment of the invention, the obstruction generates sounds whose amplitude is characteristic of the flow volume and the apparatus includes an audio sensor which measures the amplitude of the sounds.

In accordance with a preferred embodiment of the invention the apparatus includes an obstruction in the flow tube which generates audio sounds whose amplitude is characteristic of the flow volume and an audio sensor which measures the amplitude of the sounds.

Preferably the apparatus includes a look-up table which determines the flow volume from the measured sound amplitude.

In a preferred embodiment of the invention, the apparatus includes correlation circuitry which receives the breath sounds information and the breath flow information and correlates the breath sounds information with the breath flow information. Preferably, the apparatus includes circuitry which receives the breath sounds information and determines the presence of wheezes.

There is further provided, in accordance with a preferred embodiment of the invention, a breath analysis apparatus comprising:

a spirometer, including a breath tube, which supplies breath flow information;
a breath sounds sensor which generates breath sound information;

wheeze determination circuitry which receives the breath sound information and
detects the presence of wheezes in the breath sounds; and

correlation circuitry which correlates the detected wheezes with the breath flow
information.

Preferably, the breath flow information includes information on the total flow and
wherein the correlation circuitry correlates the total flow with the onset of wheezes.

In a preferred embodiment of the invention the flow information includes information
on the phase of the flow and the correlation circuitry correlates the phase of the flow with the
onset of wheezes.

Preferably, the apparatus includes a display which displays information correlating
information derived from the breath flow information and information derived from the breath
sounds information. Preferably, the display displays wheeze rate information. Alternatively or
additionally the display displays the time of onset of wheezes within a breath cycle.

Alternatively or additionally the display displays a critical wheeze onset parameter determined
by the flow rate at which wheezes occur.

Preferably, the apparatus includes a memory for recording test results wherein the
display displays an indication of test results which differ significantly from previous results.

Preferably, the display is mounted on the breath tube for visual display of the
information to a subject being tested.

Preferably, the display is mounted on a base which allows for turning the display for
viewing by a tester.

There is further provided, in accordance with a preferred embodiment of the invention,
breath flow measurement apparatus, comprising:

a flow tube;

an obstruction in the flow tube which causes the generation of pressure disturbances in
air flow in the tube, said disturbances traveling along the tube with the air flow; and

a velocimeter which determines the velocity of the disturbances.

Preferably, the velocimeter comprises a pair of pressure monitors spaced in the
direction of flow of the air. Preferably, the velocimeter determines the phase difference of the
pressure spectrum at at least one frequency at the pair of pressure monitors.

In a preferred embodiment of the invention, the apparatus includes circuitry which
determines the volume of air flow in the tube based on said determination of velocity.
Preferably, the circuitry comprises a look-up table which relates the total flow in the tube to the measured velocity.

In a preferred embodiment of the invention, wherein the obstruction generates sounds whose amplitude is characteristic of the flow volume, the apparatus includes an audio sensor which measures the amplitude of the sounds.

There is further provided, in accordance with a preferred embodiment of the invention, breath flow measurement apparatus, comprising:

- a breath flow tube;
- an obstruction in the flow tube which generates audio sounds whose amplitude is characteristic of the flow volume; and
- an audio sensor which measures the amplitude of the sounds.

Preferably, the apparatus includes a look-up table which determines the flow volume from the measured amplitude of the sounds.

There is further provided, in accordance with a preferred embodiment of the invention, an endotracheal tube, comprising:

- an endotracheal tube having a lumen;
- a microphone which detects breath sounds within the lumen or within a lumen which is an extension thereof and generates a sound signal in response thereto; and
- circuitry which analyzes the sound signal to determine the presence of one or more breath sounds.

Preferably, the circuitry analyzes the sound signal to determine the presence of wheezes. Additionally or alternatively, the circuitry analyzes the sound signal to determine the presence of cackles. Additionally or alternatively the circuitry analyzes the sound to determine the presence of secretion sounds. Additionally or alternatively the circuitry generates the spectral pattern of basic breath sounds from the sound signal.

There is further provided, in accordance with a preferred embodiment of the invention a method of determining the presence of adventitious breath sounds in a subject, comprising:

- providing a tube having a lumen, said lumen being connected to a main airway of the subject;
- measuring breath sounds in the lumen; and
- determining the presence of a particular adventitious sound based on the measured breath sounds.
In a preferred embodiment of the invention the adventitious sound is a wheeze. Alternatively or additionally the adventitious sound is a cackle. Alternatively or additionally the adventitious sound is a secretion sound.

Preferably, providing a tube comprises inserting a tube into the trachea. Alternatively, providing a tube comprises placing a tube in the mouth.

There is further provided, in accordance with a preferred embodiment of the invention, a method of breath analysis comprising:

determining breath flow of a subject;

determining presence of wheezes in the breath of the subject; and

correlating the presence of wheezes with the breath flow.

Preferably, determining breath flow comprises determining the total breath flow.

Preferably, correlating the presence of wheezes comprises determining the flow correlating the onset of wheezes with the magnitude of the breath flow. Alternatively or additionally, determining breath flow comprises determining the breath flow as a function of time. Preferably, correlating the presence of wheezes comprises determining the percentage of the breathing time cycle during which wheezes occur. Alternatively or additionally correlating the presence of wheezes comprises determining the time within the breathing cycle during which wheezes occur. Alternatively or additionally correlating the presence of wheezes comprises determining the presence of inspiratory wheezes.

In accordance with a preferred embodiment of the invention, the method includes comparing the results of the correlation with previous correlation results.

There is further provided, in accordance with a preferred embodiment of the invention a method for the measurement of the flow of air in a flow tube comprising:

providing a flow of air in the flow tube;

generating a disturbance in the air flow which travels with the air flow;

determining the velocity of the disturbance; and

determining the total flow in the tube from the determined velocity of the disturbance.

Preferably, the velocity of the disturbance comprises measuring a characteristic of the disturbance at two points along the length of the tube. Preferably the characteristic is a pressure associated with the disturbance. Preferably, the disturbance is an eddy.

In a preferred embodiment of the invention generating a disturbance comprises partially obstructing the flow.
In a preferred embodiment of the invention the method includes providing a breath sounds sensor in the flow tube; and generating a breath sounds signal from breath sounds sensed by the sensor. Preferably, the method includes determining the presence of wheezes based on the breath sounds signal.

5 BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more clearly understood from the following description of non-limiting preferred embodiments thereof, in which:

Fig. 1 shows a flow meter in accordance with a preferred embodiment of the invention;
Fig. 2 is a flow chart illustrating the steps of an exemplary wheeze detection method in accordance with a preferred embodiment of the present invention;
Figs. 3A and 3B are graphs illustrating an exemplary amplitude spectra calculated by different steps of the wheeze detection method of Fig. 2 in accordance with a preferred embodiment of the present invention;
Fig. 4 shows a preferred embodiment of the invention as it is used to analyze the breath of a subject;
Fig. 5A shows a tracheal tube according to a preferred embodiment of the invention, in use; and
Fig. 5B shows a portion of the tracheal tube of Fig. 5A in greater detail.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

One aspect of the present invention is the provision of a novel flow-meter. A second aspect of the invention is the provision of a breath sounds detector in the flow tube of a flow meter. Fig. 1 shows a combined flow-meter/breath sounds detector 10, in accordance with a preferred embodiment of the invention which combines these two aspects. Meter/detector 10 comprises a tube 12 into which are fitted two rings 14 and 16. Rings 14 and 16 are so shaped that if air flows into tube 12 from a left opening 18 therein, the flow is separated, by ring 14 into a jet flow portion in the center of the tube and flow which includes a series of eddies in the region of the tube indicated by reference number 20, downstream from ring 14. A similar situation occurs when air enters tube 12 via a right opening 22.

The eddies, which comprise regions of varying pressure, travel together with the main flow of the tube at the center thereof at the velocity of the fluid in the tube rather than at the velocity of sound. Tube 12 is fitted on the wall thereof, between rings 14 and 16, with two thin tubes 24 and 26 which lead to two pressure transducers 28 and 30 respectively. In a preferred embodiment of the invention the transducers are piezo-resistive ultra-low pressure sensor
model 395-263 available from RS Big Head, Ltd. of the UK, with a full scale of ±5 inches of water full scale and a 1 msec response time. In a preferred embodiment of the invention an additional pressure sensor (not shown) is situated outboard of each of rings 14 and 16. These additional sensors are used to cancel the non-eddy pressures from the outputs of sensors 28 and 30 to improve the sensitivity of the eddy pressure measurement.

As the eddies pass tubes 24 and 26 they cause a variation in pressure in the tubes which variation is measured by transducers 28 and 30. One method for converting the measured pressure variations into an eddy velocity is to derive a Fourier transform of the two signals and to find the complex "transfer function" between the two signals. The arc-tangent of the ratio between the imaginary and real parts of the transfer function is the phase difference of the pressure fluctuations (as a function of frequency) at the two tubes.

If it is assumed that the form of the pressure wave is not a function of the distance along the tube and that the only effect on the eddy currents as they travel down the tube is that their amplitude decays, then the phase is linearly dependent on the frequency and on the transit time. The transit time can thus be estimated from: \( T = \phi/\omega = \phi/2\pi f \). In principle, the transit time can be found from a single frequency measurement. However, accuracy is greatly enhanced when the transit time is based on an average of determinations of transit time at different frequencies. It has been determined, empirically, that utilizing a number of determinations made over the frequency range of 200-600 Hz gives good results. However, an optimum range depend on the diameter of tube 12, the distance between tubes 24 and 26 and other physical factors. In any particular situation, the frequency range can be determined from a "coherency" determination, namely a determination of the range of frequencies over which the coherence of the transfer function is greater than 0.7. Within this frequency range the transit time remains fairly constant (i.e., the phase varies linearly with the frequency). The above frequency range appears to be optimum for a tube 12 having a diameter of 21 mm, utilizing rings 14 and 16 having an inner diameter of 13 mm and an axial extent 42 mm with tubes 24 and 26 having a diameter of 2.2 mm placed symmetrically with respect to the rings and spaced a distance of 30 mm apart. For other dimensions, the frequency range can be determined empirically.

In general, the velocity of flow in a tube is not uniform and the flow is faster at the center of the tube than nearer the walls. The exact ratio between the speed of the eddies and the average flow rate is a non-linear function, best determined by experiment. Thus, in a preferred embodiment of the invention, meter/detector 10 includes a microcomputer 100 which receives
the time varying pressure information from transducers 28 and 30 and computes the eddy velocity, preferably utilizing the method described above. Microcomputer 100 also preferably includes a memory in which the relationship between flow rate and eddy current velocity is stored. Based on this stored relationship, the flow as a function of time is determined and stored. In general, this relationship need not be determined for each device, but is relatively constant for flow tubes of a given design.

In a preferred embodiment of the invention, meter/detector 10 incorporates a breath sounds detector 32 is situated in flow tube 12. The function of sounds detector 32 is to detect breath sounds of the subject using monitor/detector 10. Sounds detector 32 can be a small microphone or other sound transducer such as for example a miniature capacitive microphone preferably one having a flat response from 75 Hz to 4000 Hz such as that manufactured by Bosung Electronics of the UK and sold as model number CMS-2750). Preferably, detector 32 is placed flush with the inner wall of the tube near the end of the tube that is closer to the subject to provide minimum perturbation to the flow. The particular microphone indicated above has a 6 mm diameter and is 2.7 mm thick, however other microphones and other sensor types may be employed. In a preferred embodiment of the invention, the microphone and associated circuitry are used to determine the presence of wheezes in the subject's breathing. Preferably, microcomputer 100 is used to perform the determination of wheezes, preferably, in the manner described below. It has been found that while the generation of eddies does cause substantial noise to be generated, the spectral properties of the noise are such that they do not affect the method for wheeze detection described below adversely. The wheezing breath sounds can be further protected from the eddy noise by placing an acoustic screen just past the microphone, in the direction of the rings. Such a screen may comprise several layers of porous material. In addition to isolating sensor 32 from the noise generated by the rings, the acoustic filter also acts as a barrier against moisture and dust and against moisture and dust carried germs.

Thus, in a preferred embodiment of the invention, a separate mouthpiece is provided. This mouthpiece preferably includes end 18, sensor 32 and the acoustic filter. Preferably, this mouthpiece is used only once, while the more expensive components in the rest of the flow tube shown in Fig. 1 are reused.

Additionally or alternatively, the noise generated by the rings may be used to determine the air flow. Sensor 32 (or an additional sensor) is utilized to measure the noise generated at the rings. The amplitude of this sound is related in a non-linear fashion, with the
flow velocity and thus with the flow volume. Sensor 32 (in the absence of an acoustic shield) or the additional sensor could be utilized as a stand alone measure of velocity or to check the accuracy of the measurement of the velocity of the eddy currents. Such a measurement does not give an indication of direction of flow, and thus, optimally some method of measurement of direction of flow should be provided. This may include the pressure sensor method of the present invention or any other method of measuring the direction of flow. Furthermore, while the rings of the present invention provide an audio noise source whose amplitude may be correlated with the flow volume, other obstructions may be noisier and better suited for this aspect of the invention.

Fig. 2 is a flow chart illustrating the steps of an exemplary wheeze detection method in accordance with a preferred embodiment of the present invention. In a preferred embodiment of the invention, the methodology used in PCT application PCT/IL97/00318, filed 30 September 1997, the disclosure of which is incorporated herein by reference, is used. However, since in the simplest form of this aspect of the present invention, the detection of wheezes is the only breath analysis function to be carried out, the associated circuitry may be greatly simplified. Much of the following presentation, which is included herein for completeness, is adapted from the PCT application, which can be consulted for further details.

Adventitious breath sounds are usually divided into continuous and discontinuous sounds depending on their duration. Continuous sounds are further subdivided into wheezes, which are higher pitched music-like sounds indicating the presence of airway narrowing and rhonchi, which are low-pitched, grinding sounds.

The first step in the detection of wheezes is a screening in the frequency domain in which peaks of power above an underlying spectrum of basic sounds are sought. If any are detected, they are evaluated to determine whether these peaks correspond to true wheezes, for example as to their sharpness and prominence over the underlying spectrum. A sub-set of wheezes is called "squeaks." Squeaks and regular wheezes are similar except that squeaks last between about 80 and 150 milliseconds while wheezes last longer than 150 milliseconds and they have other distinctions as well. Wheezes can be separated into "low", "high" and "ultra high" frequency types.

Preferably, tentatively identifying the breath sound as a wheeze comprises detecting narrow peaks within the spectrum of the breath sound and determining if the narrow peaks are located within a narrow frequency range over a number of consecutive time periods. Preferably
confirming comprises determining if the narrow peaks of the tentatively identified wheeze have less than three harmonics each.

Preferably said consecutive time periods span at least 150 ms. Preferably, the narrow frequency range is not greater than 64 Hz among any two consecutive time periods.

In accordance with a preferred embodiment of the invention a breath sound is confirmed as a squeak type wheeze when said consecutive time periods span between 80 and 150 ms.

Preferably, a breath sound is classified as a low frequency wheeze when the frequency of the narrow peak is less than 400 Hz. Preferably, a breath sound is classified as a high frequency wheeze when the frequency of the narrow peak is between 400 Hz and 1600 Hz. Preferably, a breath sound is classified as an ultra-high frequency wheeze if the frequency of the narrow peak is above 1600 Hz.

In a preferred embodiment of the invention, the breath sounds are compared to at least one wheeze template which comprises a narrow peak in the frequency domain of breath sound data, whose width at half height spreads less than a predetermined frequency width and which has fewer than three harmonics. Preferably, the narrow peak occurs within at least three time segments comprising a predetermined time period, the frequency of the narrow peaks varying less than 1.5 Hz per msec within the at least three said occurrences.

Reference is now made to Fig. 2 which illustrates a wheeze detection method in accordance with a preferred embodiment of the present invention.

Wheezes may be multiple ("polyphonic") or single ("mono-wheeze"), have a constant frequency or a varying frequency and may be localized or widely distributed over the chest or heard at the mouth. The time-domain characteristics of a single wheeze are usually similar to a pure sinusoidal wave. It may, however, contain a small number of harmonics. The frequency domain (amplitude spectrum) pattern of wheezes is therefore characterized by a single or a few sharp and narrow peaks.

The wheeze detection method preferably receives as input a sound segment (N data points) digitized from the amplified and preferably conditioned signal of detector 32 as described in the above referenced PCT application (step 352) This preconditioning preferably includes amplification and band pass filtration at preferably 75-4000 Hz. In a preferred embodiment of the invention a sampling rate of 11025 Hz is used and an 8-12 (but more preferably a 12) bit A/D is used. The higher bit accuracy is desirable if automatic gain control is not used. While an integrated sensor/detector of the present invention is preferred, in some preferred embodiments of the invention, a tracheal or a chest breath sounds sensor may be used to acquire the breath
sounds. The system preferably calculates the total acoustic energy within the segment (step 354) and preferably evaluates the segment's acoustic energy (step 356). If the segment's total acoustic energy is less than or equal to the most recent value of the background's acoustic energy, the segment is identified as "below level" and the system returns control to step 350 for sampling the next segment. This "low-level" designation may be due to breath hold, "silent lung" (a condition with extreme bronchoconstriction where no breath sounds or even wheezes are heard), or due to equipment failure. If the segment's total acoustic energy is larger than the background, the system calculates the amplitude spectrum of the segment and preferably subtracts the background noise amplitude spectrum (determined, for example when the patient holds his breath) from it (step 358).

The system then preferably searches for peaks of power in the spectrum. Preferably it does so by calculating the pattern of the amplitude spectrum of the underlying basic breath sound by preferably curve fitting, or by low pass filtration of the spectrum, for example by a Hamming or a 10% FIR filter, or by smoothing (step 360) of the spectrum, preferably the logarithmic spectrum, or by using a spectrum averaged over a number of breath cycles, and subtracts it from the segment's amplitude spectrum (step 362), generating an array of difference values between the spectrum and the underlying basic breath sounds pattern. The system preferably proceeds to search for narrow spectral peaks by preferably calculating the variance of the array of differences (the residuals) (step 364). Significant spectral peaks are always positive, so that, based on statistical considerations, when no peaks are present, the residuals are randomly distributed around zero and there will generally be no values that are greater than 4 variances of the mean value of the residuals within a segment or greater than 5 variances within an ensemble of segments.

The system then preferably equates all the amplitudes within the segment whose values are less than k×(variance) to k×(variance) (step 366) and subtracts k×(variance) from all the amplitude values within the segment (step 368). An exemplary value that can be used for this procedure is k=5. Thus, the only peaks remaining in the segment have positive values whereas the values in between them become zero. The system then searches the spectrum for peaks by comparing the spectrum data to a threshold which has the value of m×(variance), for example, m=0.5. Other threshold values including zero or near zero values can also be used under certain circumstances. The system identifies a spectrum amplitude value in excess of m×(variance) as a peak (step 370).
Note that other methods of peak detection may be applied to detect spectral peaks characteristic of wheezes, in accordance with other preferred embodiments of the invention.

It is further noted that, as an alternative to comparing the spectrum's data to a threshold in step 370, the system can calculate the 4th moment of the difference (residual) array which is the outcome of step 362. If the 4th moment of the difference (residual) array is significantly greater than 3, for example if the 4th moment is 6, the system searches for peaks.

If a peak is detected by any method, its sharpness is evaluated using the absolute value of the first or second derivative of the difference (residual) array as an evaluation criterion (step 372). If the absolute value of the first or second derivative of the difference (residual) array at the frequency of the peak is larger than a predetermined threshold value, the system registers the peak's frequency \( f_{wz} \) and its spectral amplitude \( A_{wz} \) (step 374) and blanks the peak region by equating to zero a range within the residual array that is centered at \( f_{wz} \) and spans \( \pm \Delta f \) around \( f_{wz} \) (step 376), for example, \( \Delta f = 32 \) Hz.

\( \Delta f \) is determined by \( N \) which is the number of data points in the segment and by the sampling rate of the analog to digital converter. If the absolute value of the first or second derivative of the residuals is not larger than a predetermined threshold value, the system blanks the peak region (step 376). The system then continues to search for additional (secondary) peaks within the spectrum by repeating the peak searching steps 364-376 until no more significant peaks are found.

Reference is now made to Figs. 3A and 3B which illustrate a graphic representation of an amplitude spectra calculated by different steps of the wheeze detection method. In Figs. 3A and 3B the vertical axis represents the amplitude and the horizontal axis represents the frequency. Fig. 3A illustrates two superimposed curves. The first curve, labeled 423, represents the amplitude spectrum curve of the breath sound segment calculated by step 358 of Fig. 2. The second curve, labeled 427, represents the amplitude spectrum of the basic breath sounds (BS) pattern calculated by step 360 of Fig. 2. The three largest peaks of curve 423 are labeled 425. Fig. 3B illustrates the output of step 368 of the wheeze detection method of Fig. 2 after the first pass through steps 364 - 376. The largest spectral peak which was detected is labeled 429. It is noted that the range around and including the first detected peak 429 is blanked on subsequent passes so that the secondary peaks may be detected.

Returning to Fig. 2, if no more peaks are found in the segment, the system transfers control to step 378. Step 378 is based upon experimental observations of the duration of actual wheezes and of their trends within a breath. The method evaluates each peak to assure that it is
part of a group of peaks that appear at approximately the same frequency in preceding or subsequentsegment's amplitude spectra. A peak is accepted as a wheeze only if it appears consecutively in preferably three or more segments that span at least 150 ms but no more than 2500 ms (2.5 seconds). Thus, the system checks if there was any peak in the current segment's spectrum (step 378) using the information recorded by step 374. If there is no peak in the current segment's spectrum, the system transfers control to step 350 for obtaining the next segment. If any peaks were detected in the current segment's spectrum, the method checks the record of the previous n segments for the presence of significant peaks at \( f_{wz} \pm \delta f \) (step 380), where \( \delta f \) may be set as a fraction of the Nyquist frequency (half the sampling rate) or as a constant, for example, \( \delta f = 64 \) Hz which give 64 Hz per 50 ms or 1.28 Hz per ms. Values of 0.5 to 2 Hz per ms are preferably used for the wheeze frequency rate of change in time. An exemplary value of n is \( n=2 \) where the total number of segments checked, including the current segment, is 3. Thus, for an exemplary segment duration of 50 ms, the total duration checked by the system for the presence of significant peaks is preferably 150 ms.

Note that shorter wheezes, often called squeaks, may be detected by this method, but since they are shorter than regular wheezes (they have a length of between 80 and 150 msec), n is preferably equal to one. Squeaks also differ from wheezes in the peaks associated with squeaks may appear in a time period comprising only 2-3 segments of 50 msec. Squeaks are clinically relevant in artificially ventilated patients and represent air “sneaking” out (or in) in an almost collapsed airway or around the cuff of the endotracheal tube at the end of inspiration if the cuff is not sufficiently inflated.

If corresponding peaks appear in previous segments, the peak is registered as potential wheeze (step 382). If no matching peaks are found in the previous segments the registration is temporary (step 384), pending the findings in the next segments.

The final part of the method's preferred wheeze verification procedure is the separation of true wheezes from other signals that generate sharp prominent peaks in the amplitude spectrum. The latter include speech (vocalization), snoring, and rhonchi. All three signals are periodic but non-sinusoidal in the time domain, displaying repetitive, relatively complex, sound structures. These signals are represented in the frequency domain by a series of sharp peaks that are uniformly spaced in the amplitude spectrum. These peaks are distinguished from the peaks of true wheezes by the number of harmonics which is the number of peaks that are spaced exactly \( \Delta f \) Hz apart. While speech, snores and rhonchi always have more than three such peaks, wheezes usually have one peak with an occasional additional harmonic that is substantially
attenuated. The separation of non-wheeze "peaked" signals into the subgroups of rhonchi, snores, and speech is disclosed in detail hereinafter. Thus, after the system registered a potential wheeze (step 382), the system checks whether there are more than two harmonics in the segment (step 386). If there are more than two (or optionally, three) harmonics in the segment, the segment is not designated as belonging to a potential wheeze and the system returns control to step 350 for obtaining the next segment. If there are no more than two harmonics in the segment, the segment is designated as belonging to a wheeze and the system registers the peaks that correspond in at least n+1 segments as wheezes (step 390), where \((n+1)\times(\text{segment duration})>150\) ms, and transfers control to step 350 for obtaining the next segment.

Once the evaluation and verification of a segment is completed, the system moves on to analyze the next sound segment. It is noted that, in accordance with a preferred embodiment of the present invention, the analysis of a segment is completed before the end of the acquisition of the data of the next consecutive segment, so that quasi real-time monitoring is accomplished. This feature, in particular, enables the continuous on-line monitoring of the results of the breath analysis performed by the preferred embodiments of the present invention.

In a preferred embodiment of the invention a second microphone 33 is provided outside the tube. Microphone 33 measures ambient sounds and determines if the sounds are strong enough such that the wheeze measurement may be contaminated. In a preferred embodiment of the invention, the output of microphone 33 is analyzed for the presence of ambient noise with a "wheeze-like" form. When such noise is present the user is preferably notified that the test cannot be performed or that the results are possibly inaccurate.

Preferably, in addition to the determination of the presence of wheezes, and the flow characteristics as a function of time, a method according to a preferred embodiment of the invention calculates spirometric indices from the flow data, including the total amount of air inhaled and exhaled. Preferably, in both a quiet breathing mode and a forced expiratory mode, the flow rate and pattern of breathing is measured and the presence of wheezes, their duration and their time of onset within the breathing cycle is detected and recorded. The method preferably detects the presence and duration of inspiratory, expiratory and/or forced expiratory wheezes. The subject's performance is registered and compared to previous levels of the performance parameters. Among parameters which are useful in the practice of the invention are the wheeze rate defined as the percentage of the active breathing time during which wheezes occur, the wheeze timing within the breathing cycle, timing and duration of wheezes during inspiration, expiration and a critical wheeze flow onset parameter which is the flow at which
wheezes occur, for a particular lung volume. Values that represent a significant difference from the subject's previous results are highlighted and preferably activate an alert. Values which are abnormal, such as any wheezing not during forced expiration or at less than maximum flow capability of the subject during expiration are also highlighted and also preferably activate an alert.

Fig. 4 shows a preferred embodiment of the invention which utilizes the above principles and apparatus. A subject is shown blowing into tube 12. A switch 102 is provided to turn on the microprocessor and a display 104, such as an LCD display. Microprocessor 100 which receives information from the microprocessor and displays information for the subject or (if the screen is turned away from the subject) to an examining physician or the subject's guardian. The display may provide alphanumerical values of flow and/or the presence of wheezes and/or characterizing parameters such as those described above and/or a comparison with previous results. Alternatively or additionally, the information may be presented qualitatively rather than quantitatively; the value of the displayed parameter, etc., being indicated by colored lights, such as red, yellow and green.

Additionally or alternatively, meter/detector 10 may transmit either the "raw" flow and sound information or parameters as generated by microprocessor 100 to a computer, storage device or remote location where the information is evaluated or stored for later evaluation and analysis by medical personnel or for additional evaluation of data. A remote center may provide instructions on adjustment of medications and/or generate a periodic report for review by the subject and/or attending medical personnel.

The present application describes a number of features and aspects which are novel. While in a preferred embodiment of the invention, substantially all of these features are present, many of the features of the invention are usable without the other features. For example, meter/detector 10 combines a flow meter with a microphone in the flow tube. The microphone is used to pick up breath sounds during flow measurement and, in the preferred embodiment of the invention, to determine the presence of wheezes. However, some aspects of the invention do not require that the microphone be used to determine the presence of wheezes, but may use the microphone for other purposes. Furthermore, while the determination of wheezes is preferably performed by the method outlined above, according to some aspects of the invention, the presence of wheezes may be determined by other methods. Furthermore, while the flow meter of the present invention is preferred, in some aspects of the present invention, any flow meter type
may be used. Thus, a broad aspect of the invention is characterized by a flow meter having a flow tube and a microphone within the flow tube for reception of airway opening breath sounds.

Additionally, while preferred embodiments of the invention utilize a flow meter having a flow tube and a microphone within the flow tube for reception of breath sounds, some aspects of the invention are concerned with providing quantitative wheeze information correlated with flow information. These aspects of the invention do not necessarily require that the microphone be in the flow tube and a tracheal or body breath sound reception device may be used. Furthermore, these aspects of the invention do not necessarily require the use of the wheeze determination method described above, but may use other wheeze detection algorithms. Finally, these aspects of the invention do not necessarily require that the preferred flow meter of the invention be used and any flow meter as known in the art may be used.

In some aspects of the invention other characteristics of the breath sounds may also be measured such as crackles, secretion sounds and the spectral pattern of the basic breath sounds. Crackles, and in particular the presence of both inspiratory and expiratory cackles may is characteristic of secretion sounds. Shift in the spectral pattern (toward higher frequencies) indicates the presence of a narrowing of the central airway, a condition which precedes wheezes.

In some preferred embodiments of the invention, breath sounds are detected at an airway using a microphone in an endotracheal tube and the presence of one or more of the above conditions is determined from these sounds. In the broadest embodiment of this aspect of the invention a device includes no more than a microphone or other sound sensor in a tube connected with an airway and circuitry for the analysis of breath sounds.

Fig. 5A shows an endotracheal tube 50 inserted into the airway of a patient via the mouth. Tube 50 includes a section 52 shown in more detail in Fig. 5B. As shown in Fig. 5B, section 52 incorporates a microphone 54, preferably in its wall and electronic circuitry 56. In general, circuitry 56 includes at least an amplifier which amplifies the sound signal generated by microphone 52. It should be understood that electronics 56 may simply be used to buffer the signal prior to its transfer to a more powerful computer. Alternatively, 56 may comprise an on-board computer to detect the various types of breath sounds.

In a further preferred embodiment of the invention a tube may be inserted into one of the lungs or into a bronchi such that it selectively carries sound from that position to the sound sensor. Under these conditions, localized sound detection may be carried out.
In one aspect of the invention, the apparatus of Fig. 1 or Fig. 5 is used in biofeedback therapy to provide information to the subject so that the subject can learn to control the effects of asthma or other problematic breathing situations.

The present invention has been described in the context of preferred embodiments thereof. It should be understood that these embodiments contain combinations of features which, while preferred, may not all be required for carrying out of the invention, which is defined by the claims.
CLAIMS

1. Breath analysis apparatus comprising:
   a spirometer, including a breath tube, which generates breath flow information and
   a breath sounds sensor situated in the breath tube, which generates breath sounds
   information.

2. Apparatus according to claim 1 wherein the spirometer comprises:
   an obstruction in the flow tube which causes the generation of pressure disturbances in
   air flow in the tube, said disturbances traveling down the tube with the air flow;
   wherein said spirometer generates flow volume information based on a measurement of
   said disturbances.

3. Apparatus according to claim 2 wherein the spirometer comprises:
   a velocimeter which determines the velocity of the disturbances.

4. Apparatus according to claim 3 wherein the flow tube includes a second obstruction
   situated on the other side of the velocimeter from the obstruction, wherein the velocity sensor
   determines the direction of the flow.

5. Apparatus according to claim 3 or claim 4 wherein the velocimeter comprises a pair of
   pressure monitors spaced in the direction of flow of the air.

6. Apparatus according to claim 4 or claim 5 wherein the velocimeter determines the
   phase difference of the pressure spectrum at at least one frequency at the pair of pressure
   monitors.

7. Apparatus according to any of claims 3-6 and including circuitry which determines the
   volume of air flow in the tube based on said determination of velocity.

8. Apparatus according to claim 7 wherein the circuitry comprises a look-up table which
   relates the total flow in the tube to the measured velocity.
9. Apparatus according to any of claims 2-8 wherein the obstruction generates sounds whose amplitude is characteristic of the flow volume and including:
   an audio sensor which measures the amplitude of the sounds.

5 10. Apparatus according to claim 1 and including:
   an obstruction in the flow tube which generates audio sounds whose amplitude is characteristic of the flow volume; and
   an audio sensor which measures the amplitude of the sounds.

10 11. Apparatus according to claim 9 or claim 10 and including:
   a look-up table which determines the flow volume based on the measured sound amplitude.

12. Apparatus according to any of claims 7-11 and including correlation circuitry which receives the breath sounds information and the breath flow information and correlates the breath sounds information with the breath flow information.

13. Apparatus according to claim 12 and including circuitry which receives the breath sounds information and determines the presence of wheezes.

14. Breath analysis apparatus comprising:
   a spirometer, including a breath tube, which supplies breath flow information;
   a breath sounds sensor which generates breath sound information;
   wheeze determination circuitry which receives the breath sound information and detects the presence of wheezes in the breath sounds; and
   correlation circuitry which correlates the detected wheezes with the breath flow information.

15. Apparatus according to any of claims 12-14 wherein the breath flow information includes information on the total flow and wherein the correlation circuitry correlates the total flow with the onset of wheezes.
16. Apparatus according to any of claims 12-15 wherein the flow information includes information on the phase of the flow and wherein the correlation circuitry correlates the phase of the flow with the onset of wheezes.

17. Apparatus according to any of the preceding claims and including a display which displays information correlating information derived from the breath flow information and information derived from the breath sounds information.

18. Apparatus according to claim 17 wherein the display displays wheeze rate information.

19. Apparatus according to claim 17 or claim 18 wherein the display displays the time or phase of onset of wheezes within a breath cycle.

20. Apparatus according to any of claims 17-19 wherein the display displays a critical wheeze onset parameter determined by the flow rate at which wheezes occur.

21. Apparatus according to any of claims 17-20 and including a memory for recording test results wherein the display displays an indication of test results which differ significantly from previous results.

22. Apparatus according to any of claims 17-21 wherein the display is mounted on the breath tube for visual display of the information to a subject being tested.

23. Apparatus according to any of claims 17-22 wherein the display is mounted on a base which allows for turning the display for viewing by a tester.

24. Breath flow measurement apparatus, comprising:
   a flow tube;
   an obstruction in the flow tube which causes the generation of pressure disturbances in air flow in the tube, said disturbances traveling along the tube with the air flow; and
   a velocimeter which determines the velocity of the disturbances.
25. Apparatus according to claim 24 wherein the velocimeter comprises a pair of pressure monitors spaced in the direction of flow of the air.

26. Apparatus according to claim 25 wherein the velocimeter determines the phase difference of the pressure spectrum at at least one frequency at the pair of pressure monitors.

27. Apparatus according to any of claims 24-26 and including circuitry which determines the volume of air flow in the tube based on said determination of velocity.

28. Apparatus according to claim 27 wherein the circuitry comprises a look-up table which relates the total flow in the tube to the measured velocity.

29. Apparatus according to any of claims 24-28 wherein the obstruction generates sounds whose amplitude is characteristic of the flow volume and including:

an audio sensor which measures the amplitude of the sounds.

30. Breath flow measurement apparatus, comprising:

a breath flow tube;

an obstruction in the flow tube which generates audio sounds whose amplitude is characteristic of the flow volume; and

an audio sensor which measures the amplitude of the sounds.

31. Apparatus according to claim 29 or claim 30 and including:

a look-up table which determines the flow volume based on the measured noise.

32. An endotracheal tube, comprising:

an endotracheal tube having a lumen;

a microphone which detects breath sounds within the lumen or within a lumen which is an extension thereof and generates a sound signal in response thereto; and

circuitry which analyzes the sound signal to determine the presence of one or more breath sounds.
33. A tube according to claim 32 wherein the circuitry analyzes the sound signal to determine the presence of wheezes.

34. A tube according to claim 32 or claim 33 wherein the circuitry analyzes the sound signal to determine the presence of cackles.

35. A tube according to any of claims 32-34 wherein the circuitry analyzes the sound to determine the presence of secretion sounds.

36. A tube according to any of claims 32-35 wherein the circuitry generates the spectral pattern of basic breath sounds from the sound signal.

37. A method of determining the presence of adventitious breath sounds in a subject, comprising:

    providing a tube having a lumen, said lumen being connected to a main airway of the subject;
    measuring breath sounds in the lumen; and
    determining the presence of a particular adventitious sound based on the measured breath sounds.

38. A method according to claim 37 wherein the adventitious sound is a wheeze.

39. A method according to claim 37 or 38 wherein the adventitious sound is a cackle.

40. A method according to any of claims 37-39 wherein the adventitious sound is a secretion sound.

41. A method according to any of claims 37-40 wherein providing a tube comprises inserting a tube into the trachea.

42. A method according to any of claims 37-40 wherein providing a tube comprises placing a tube in the mouth.
43. A method of breath analysis comprising:
   determining breath flow of a subject;
   determining presence of wheezes in the breath of the subject; and
   correlating the presence of wheezes with the breath flow.

44. A method according to claim 43 wherein determining breath flow comprises
determining the total breath flow.

45. A method according to claim 43 or claim 44 wherein correlating the presence of
wheezes comprises determining the breath flow and correlating the onset of wheezes with the
magnitude of the breath flow.

46. A method according to any of claims 43-45 wherein determining breath flow
comprises determining the breath flow as a function of time.

47. A method according to claim 46 wherein correlating the presence of wheezes
comprises determining the percentage of the breathing time cycle during which wheezes occur.

48. A method according to claim 46 or claim 47 wherein correlating the presence of
wheezes comprises determining the time within the breathing cycle during which wheezes
occur.

49. A method according to any of claims 46-48 wherein correlating the presence of
wheezes comprises determining the presence of inspiratory wheezes.

50. A method according to any of claims 43-49 and including comparing the results of the
correlation with previous correlation results.

51. A method for the measurement of the flow of air in a flow tube comprising:
   providing a flow of air in the flow tube;
   generating a disturbance in the air flow which travels with the air flow;
   determining the velocity of the disturbance; and
   determining the total flow in the tube from the determined velocity of the disturbance.
52. A method according to claim 51 wherein determining the velocity of the disturbance comprises measuring a characteristic of the disturbance at two points along the length of the tube.

53. A method according to claim 52 wherein the characteristic is a pressure associated with the disturbance.

54. A method according to claim 51 or claim 52 wherein the disturbance is an eddy.

55. A method according to any of claims 51-54 wherein generating a disturbance comprises partially obstructing the flow.

56. A method according to any of claims 51-55 and including:
   providing a breath sounds sensor in the flow tube; and
   generating a breath sounds signal from breath sounds sensed by the sensor.

57. A method according to claim 56 and comprising:
   determining the presence of wheezes based on the breath sounds signal.
Fig. 3A

Fig. 3B
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/087 A61B7/00

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

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>see page 129, right-hand column, line 27 - page 130, left-hand column, line 8; table 1</td>
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Further documents are listed in the continuation of box C.

Date of the actual completion of the international search: 9 November 1998

Date of mailing of the international search report: 16/11/1998

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016

Authorized officer

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