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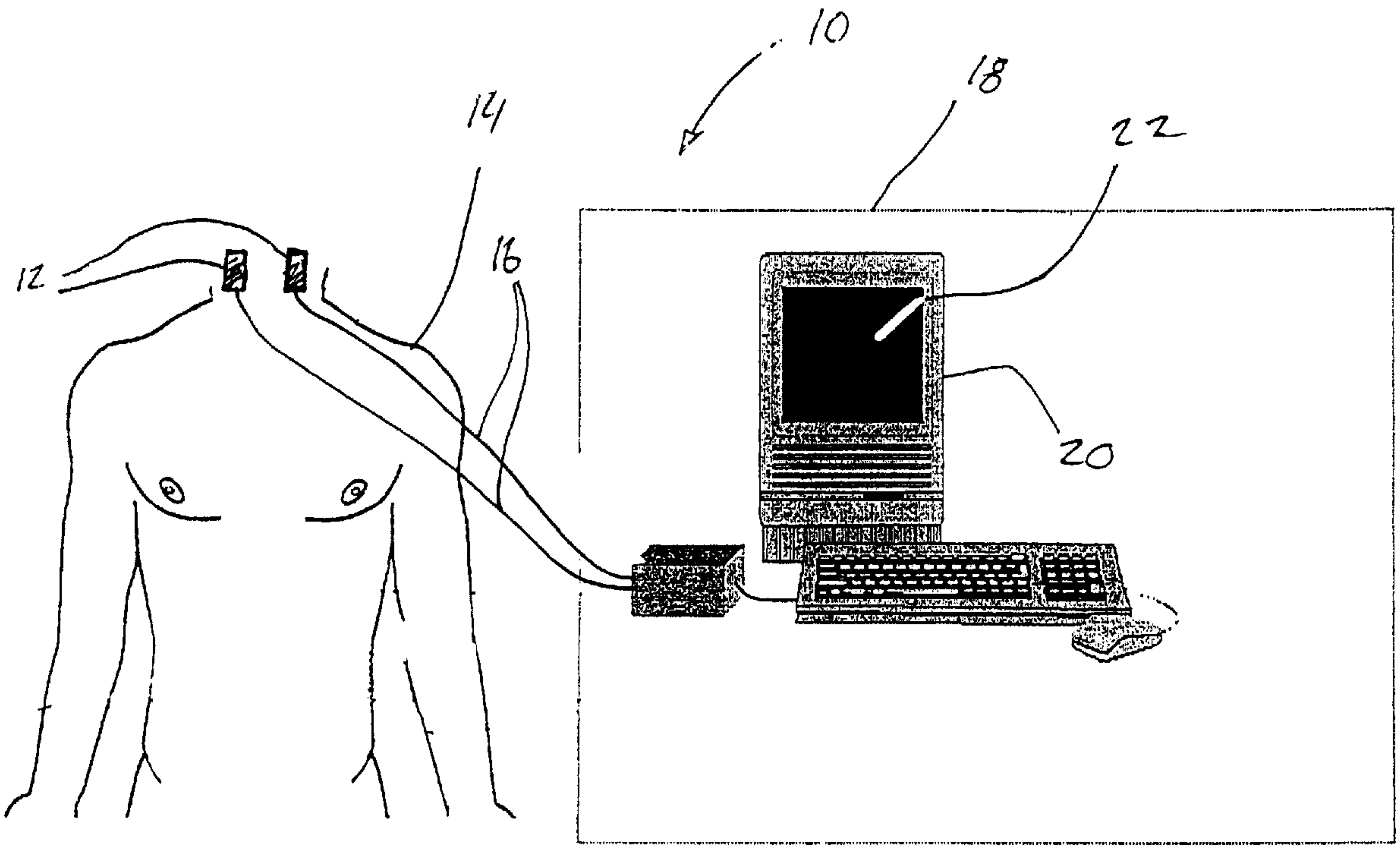
(54) Titre : MONITEUR D'AERATION NON INVASIF
(54) Title: NON-INVASIVE VENTILATION MONITOR



TITLE OF THE INVENTION

NON-INVASIVE VENTILATION MONITOR

BACKGROUND OF THE INVENTION

Tracheal sounds, typically heard at the suprasternal notch or at the lateral neck near the pharynx, have become of significant interest since the last decade. The tracheal sound signal is strong, covering a wider range of frequencies than lung sounds at the chest wall, has distinctly separable respiratory phases, and a close relation to airflow. Generally, the placement of a sensor over the trachea is relatively easy as there is less interference from body hair, garments, etc, as compared to chest-wall recording sites.

It is well known that the flow of air through the trachea during respiration causes vibrations in the tissue near the trachea, which propagate to the surface of the body and can be picked up by an acoustic sensor placed on the throat[2]. Since the vibrations are a direct result of the airflow, it is possible to estimate both timing and volumetric measures of inspiration and expiration.

The generation of tracheal sounds is primarily related to turbulent air flow in upper airways, including the pharynx, glottis, and subglottic regions. Flow turbulence and jet formation at the glottis cause pressure fluctuations within the airway lumen. Sound pressure waves within the airway gas and airway wall motion are likely contributing to the vibrations that reach the neck surface and are recorded as tracheal sounds. Because the distance from the various sound sources in the upper airways to a sensor on the neck surface is relatively short and without interposition of lung tissue, tracheal sounds are often interpreted as a more pure, less filtered breath sound. Tracheal sounds have been characterized as broad spectrum noise, covering a frequency range of less than 100 Hz to more than 1500 Hz, with a sharp drop in power above a cutoff frequency of approximately 800 Hz. While the spectral shape of tracheal sounds varies widely from person to person, it is quite reproducible within the same person. This likely reflects the strong influence of individual airway anatomy.

A close relation between airflow and tracheal sound intensity has long been recognized. Over the last decade or so, a number of studies have been performed to explore this relationship:

- Gavriely et al., *Spectral characteristics of normal breath sounds*, J Appl Physiol 1981; 50: 307-314, demonstrated a logarithmic relationship between airflow and tracheal sound intensity with flows from 0.5 – 3.0 l/s. They derived a general relationship between breath sound (BSA) amplitude and air flow (F) to be $F=BSA^{1.75}$, unless otherwise calibrated for an individual.
- Soufflet et al., *Interaction between tracheal sound and flow rate: A comparison of some different flow evaluations from lung sounds*, IEEE Trans Biomed Eng 1990; 37: 384-391, found that flow could be estimated using a number of different approaches. They computed eight estimates, 4 methods based on single parameters and 4 other methods based on hierarchical clustering analysis. The different estimators had variable success, with the best indicators producing accuracies of 15% for airflow estimates.
- In a study by Cheng-Li Que, Kolmaga, Durand, Keyyl, and Macklem, *Phonospirometry for non-invasive measurement of ventilation: methodology and preliminary results*, J Appl Physiol 2002; 93: 1515-1526, they found that inspiratory flows could be more accurately estimated than expiratory flows. This is because during prolonged expiration (flow rates below 0.3 l/s) there is insufficient turbulence in the trachea to generate sounds measurable above ambient noise, making it more difficult to estimate the end of the expiration phase. By basing

ventilation estimates on inspiratory flow alone, they were able to achieve accuracies within 15% of the measured volume signals. Furthermore, the accuracy did not appear to be significantly affected by head movement (left to right, up/down), other than during excessive neck extension. For postural changes, there was little change in the transfer function between sitting and standing. However, shifting to the supine position required a change in calibration in order to maintain accuracy. A means to automatically detect and compensate for postural changes was not explored.

- Recently, Harper et al., *Modeling and measurement of flow effects on tracheal sounds*, IEEE Trans on Biomed Eng 2003; 50: 1-10, derived a dynamic acoustic model of the respiratory tract that takes into consideration such factors as turbulent sound sources and varying glottal aperture. The group found that the tracheal sound power increased by approximately 30 dB between a flow rate of 0.5 to 2.0 l/s. They also found that expiratory sounds were generally louder than inspiratory ones, and that there was a minimum flow required in order to "turn on" measurable tracheal sounds as the flow increases through values near the critical Reynolds number. The minimum flow was found to be from 0.25 to 0.35 l/s.
- Lastly, in a study by Yee Leng Yap et al., *Acoustic airflow estimation from tracheal sound power* (Currently under review), they found that airflow could be estimated with an error of 5.8% ± 3% of the target airflow based on an exponential model relating the average power of tracheal sounds to airflow.

Pulmonary clinicians are interested in tracheal sounds as early indicators of upper airway flow obstruction and as a source for quantitative as well as qualitative assessments of ventilation. Measurements of tracheal sounds provide valuable and in some cases unique information about respiratory health. Apnea monitoring by simple acoustical detection of tracheal sounds is an obvious application and has been successfully applied in adults and in children. The potential applications for such continuous non-invasive estimation of ventilation parameters are plentiful (pre-post intubation monitoring, emergency and trauma care monitoring, conscious sedation monitoring, monitoring during exercise testing, etc.).

BRIEF DESCRIPTION OF THE DRAWINGS

In the appended drawings:

Figure 1 is a front view of a patient with two sensors attached to monitor respiratory sounds according to an illustrative embodiment of the present invention;

Figure 2 is a flow chart of a non-invasive ventilation monitor according to an illustrative embodiment of the present invention;

Figure 3 is a graph of a respiratory sound signal showing artefacts (glitches) and with glitches removed according to an illustrative embodiment of the present invention;

Figure 4 is a graph of a respiratory sound signal, flow signal and wavelet decomposition envelope according to an illustrative embodiment of the present invention;

Figure 5 is a graph of a respiratory sound signal divided into frequency bands according to an illustrative embodiment of the present invention;

Figure 6 is a graph of a respiratory sound signal, flow signal and squared envelope according to an illustrative embodiment of the present invention;

Figure 7 is a flow chart of speech processing method according to an illustrative embodiment of the present invention; and

Figure 8 is a graph of an example of a method based on a quadratic detection function of the speech processing method according to an illustrative embodiment of the present invention.

DETAILED DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENTS

Referring now to Figure 1, a non-invasive ventilation monitor, generally referred to using the reference numeral 10, will now be described. Identical biological sound sensors 12, for example as those described in US Patent No. 6,661,161, detect the biological sounds and vibrations emanating from the throat of a patient 14 and produces an output electrical signal. The signals are transferred via appropriate electrical leads 16 to a data acquisition system 18, which amplifies and filters the electrical signal prior to converting them into a digital format. Finally, the algorithms implemented in a computer 20 extract the physiological information from the data and display the results through a graphical user interface 22.

Acquisition System

The acquisition system comprises a Pentium based laptop computer running Windows 2000 and a two-channel custom designed biosignal amplifier. The bandwidth of the sound channel is from 100 to 1500 Hz and the bandwidth of the flow channel of 60 Hz. A sampling frequency for both channels was chosen and set at 3 kHz. The resolution of the A/D conversion of the data acquisition board was 12 bits. The graphical user interface was designed using the Labview® (National Instrument, Austin, TX, USA) programming language and digital signal processing algorithms were developed and tested in Matlab® (The MathWorks, Inc., Natick, MA, USA).

Algorithm

A flow chart indicating the key elements of the signal processing algorithm used to estimate the respiratory rate (RR) from the respiratory tracheal sound signal is provided in Figure 2. These elements are described herein below.

Sound signals and segmentation Step. The respiratory sound collection is performed at a sampling frequency of 3000 Hz. For analysis purposes, the sound signal is segmented into 20 second blocks with each block containing five seconds of signal from the previous block (overlap). The breathing frequency is estimated from 20 seconds of data collection, averaged and displayed every minute.

Pre-processing Step. This step is aimed at ensuring a respiratory sound signal which is as free of interference from internal and external sources of sounds as possible. The following actions are performed during the pre-processing step:

- A comb-filter is applied to remove the interference from 60 Hz and its harmonics;
- signals with extremely low signal to noise ratio or high artefacts that saturate the amplifiers are excluded;
- glitches (or motion artefacts) arising from rubbing clothes on the sensor, intermittent contact, etc., are removed (or attenuated);
- filtering based on the multi-resolution decomposition (MRD) of a wavelet transform.

Glitch Removal

Referring to Figure 3, illustratively, the presence of glitches is determined by sampling the respiratory tracheal data. Samples above and below three times (a value determined as sufficient to identify a large portion of glitches while avoiding capturing other non-glitch signals) the value of the standard deviation are categorized as glitches and removed and replaced by a constant value equal to the amplitude of the sample immediately preceding the removed sample. The mean and standard deviation are calculated for every one second of signal. The net effect is clipping the signal which means that glitches are not completely removed but rather attenuated. A previous attempt to use twice the standard deviation was not better because attenuated the signal significantly making the estimation process harder to accomplish specially in recordings with low signal to noise ratio. Figure 4 shows in the top panel the input signal with scattered glitches and bottom panel after removing some of the glitches.

Multi-Resolution Decomposition (MRD)

Referring to Figure 4, respiratory sounds (as well as heart sounds) are complicated multi-component non-stationary signals and lend themselves to the use of non-stationary analysis techniques for analyses. MRD allows splitting the respiratory signal into different spectral bands. This decomposition allows for extensive separation of sounds and allows the selection of the best frequency band for processing the respiratory sound signals with the least interference (see Figure 3).

The frequency range of the above-mentioned frequency bands is determined by the sampling frequency (Fs= 3000 Hz). The output is the filtered signal contained in the frequency bands from 187 Hz to 750 Hz (from 200 Hz to 800 Hz is known to contain the most important information of the tracheal signal). The MRD approach of the wavelet transform is applied to the respiratory sound signals based on a methodology previously published for the analysis of different cardiovascular bio-signals. See Sierra et al., *Multiresolution decomposition of the signal-averaged ECG using the Mallat approach for prediction of arrhythmic events after myocardial infarction*, J Electrocardiol 1996, 29:223-234, Sierra et al., *Risk stratification of patients after myocardial* *infarction based on wavelet decomposition of the signal-averaged electrocardiogram*, Annals of Noninvasive Electrocardiology 1997; 2: 47-58, Sierra et al., *Discrimination between monomorphic and polymorphic ventricular tachycardia using cycle length variability measured by wavelet transform analysis*, J Electrocardiol 1998; 31: 245-255 and Sierra et al., *Multiresolution decomposition of the signal-averaged ECG of postinfarction patients with and without bundle branch block*, Proceedings of the 18th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Amsterdam, Oct 31 - Nov 3, 1996, all incorporated herein by reference.

The MRD approach to wavelet transform allows noise to be removed from the input signals and the biological sounds to be separated into different frequency bands. As is known in the art, a variety of wavelet families exist one or more of which may be appropriate in a particular application. No established rules exist on how to evaluate the most suitable wavelet family for a specific application. Illustratively, the '*Coifflet*' wavelet family was used.

Illustratively, the original signal is decomposed into ten (10) frequency bands: 750 Hz – 1500 Hz, 375 Hz – 750 Hz, 187 Hz – 375 Hz, 93 Hz – 187 Hz, 46 Hz – 93 Hz, 23 Hz – 46 Hz, 12 Hz – 23 Hz, 6 Hz – 12 Hz, 3 Hz – 6 Hz and from DC to 3 Hz. As mentioned above, the range of these bands is determined by the sampling frequency (in the case at hand Fs=3000 Hz although a person of skill in the art would understand that a higher or lower sampling rate could be used). An illustrative example of the first five (5) frequency bands is shown in Figure 5. Referring to Figure 5, frequency bands two (2) and three (3) carry the most important information to estimate respiratory rate. Frequency bands four (4) and five (5) show clearly information related to a beating heart.

The estimation of RR is hindered by several factors such as the non-stationarity and non-linear nature of the respiratory sound signal, the interference of non-biological (60 Hz, environment noise, glitches, etc) and biological signals (heart beat, swallow, cough, speech and others) and recordings with low S/N ratio. Another problem arises when one of the respiratory phases is significantly stronger than the other and abnormal patterns, for example those which are the result of certain pulmonary diseases, although abnormal patterns are also present in some individuals without these diseases.

In order to overcome the difficulties found when using a single method to produce an estimation of RR with high accuracy, a multiple technique approach is used. As a result, the pre-processed signals are analysed using both envelope-related and speech-processing related methods as described in more detail herein below.

Envelope Related Methods for Estimating Respiratory Rate

The respiratory sound signal acquired on the tracheal site can be modelled as sinusoidal signals from 200 Hz to 800 Hz modulated by a slow oscillatory signal that represents inspiratory and expiratory envelopes. Illustratively, the envelope is obtained based on a Hilbert transform and decimation of the wavelet filtered sound signal (from 187 Hz to 750 Hz) in a proportion of fifty to one. The low frequency envelope is detected, followed by the determination of its oscillatory period. Based on this period (time lags between consecutive inspirations or expirations) the RR that would be accounted for after one minute has elapsed is estimated.

Estimation Respiratory Based on the Fast Fourier Transform (FFT).

The power spectrum is estimated from the detrended and windowed (Hanning) envelope signal based on a nonparametric fast Fourier transform (FFT). The magnitude squared of the FFT coefficients formed the power spectrum. Once the envelope is represented in the frequency domain, typically the component with the second highest peak has the information to correctly estimate the RR result.

Estimating Respiratory Rate Based on Envelope Counting

In order to estimate RR based on envelope counting, all possible peaks in the envelope signal of the respiratory sound signal are identified and then the RR computed as a function of the time between consecutive inspirations or expirations enclosed in the selected segment.

All possible peaks are detected by an analysis of samples that fulfil a criterion of local maximum plus a criterion of stability (amplitude higher than a number of samples before and after the peak, see Figure 6). Once all peaks have been determined, the mean of the difference of consecutive odd peaks included in the data segment is calculated. The inverse of this value multiplied by 60 equals the estimation of RR.

Estimating Respiratory Rate Based on the Autocorrelation Function

The autocorrelation function exploits the fact that a periodic signal, even if it is not a pure sine wave, will be similar from one period to the next. This is true even if the amplitude of the signal is changing in time, provided those changes do not occur too rapidly. Once the autocorrelation function is obtained, the first two peaks are analyzed to select the one with the RR information. Typically, the second peak is the correct choice (but this is not always so). Samples where one respiratory phase was more accentuated than the other and some other cases were better estimated by the first peak.

Estimating Respiratory Rate Based on Wavelet Transform

The appropriate frequency band to be selected for RR analysis changes according to the actual RR. Therefore guidance is required for the right band selection. This guidance is provided by the RR result of the FFT analysis, which allows choosing typically two, or exceptionally three, possible frequency bands. In these bands, the selection of peaks (based on maxima and minima analyses) and the estimation of RR (two or three) is performed similarly as explained in the method of envelope counting. Finally, the RR closest to the RR estimated by the FFT is taken as the RR estimated by the wavelet method.

Speech Processing Related Methods for Estimating Respiratory Rate

The speech processing approach was used to overcome some limitations of the methods that dealt directly with determining the envelope of the respiratory signal, particularly in low S/N ratio recordings. By combining methods based on the envelope and methods based on the respiratory signal, a better estimation of the RR can be arrived at.

Using the speech processing approach, relevant information of the signal under analysis is acquired through the processing of small segments of signals (20 ms duration in this case) where the statistical properties of the signal are assumed to remain stable (stationarity). The analysis is performed in the frequency domain and the main tool is a short-time FFT technique. The flowchart of Figure 7 illustrates the approach.

The speech processing approach faces some challenges due to the fact that there is no clear spectral differences between inspiration and expiration phases recorded at the tracheal site. To overcome these limitations, a pilot signal with a frequency of 1 kHz, out of the frequency range of interest (200 Hz to 800 Hz), and having an amplitude at least twice the minimum RMS of the respiratory signal is combined with the respiratory signal. During intervals of silence between inspiration and expiration (i.e. where there is an absence of any respiratory sounds) the pilot signal prevails. Likewise, during inspiration/expiration phases the respiratory signal prevails. As a result, detection of the pilot signal gives an indication of a silence interval.

An additional measure to help accentuate the difference between respiratory signal and silence is the removal (or attenuation) of biological sounds within the silence interval. This function identifies and attenuates biological sounds (mainly heart sounds) found in the silence interval and that were not considered glitches in the pre-processing stage. The processing is based on a non-linear energy operator used to detect these signals followed by processing to remove or attenuate the signals. Respiratory signals combined with the 1 kHz pilot signal provide the input. A FFT is applied to windows of 20 ms and parameters such as power (FFT magnitude squared), centroid (frequency multiplied by power divided by power) and a quadratic detection function (squared frequency multiplied by power) are estimated. All these parameters are used as RR estimators.

As an illustration, Figure 8 displays on the top panel a pre-processed respiratory sound signal. The middle panel shows a signal produced by the quadratic detection function with peaks indicating the position of zones of silence. The bottom panel represents the autocorrelation function of the signal in the middle panel. The second peak of the autocorrelation is used to estimate the RR.

Finally, a score system, comprising a logical analysis, is applied to determine the final RR based on the results of the individual estimators.

Scoring System

The final respiratory rate (FR) for a particular segment is determined as a function of the RR as determined by each of the individual estimators (as discussed hereinabove) as well as the final respiratory rate of the previous segment (FR Old). In an illustrative embodiment, the individual estimators are examined and if there is one value of RR which is predominant, FR is set to the predominant RR value. If no value of RR is predominant, but two or three values have equal representation, then the value which is closest to FR Old is selected. Finally, if more than three values have equal representation FR is set to the same value as FR Old.

Although the present invention has been described hereinabove by way of an illustrative embodiment thereof, this embodiment can be modified at will, within the scope of the present invention, without departing from the spirit and nature of the subject of the present invention.

WHAT IS CLAIMED IS:

1. A method for determining the respiratory rate of a patient, the method comprising the steps of:

recording respiratory sounds of the patient;

removing artefacts from said respiratory sounds;

decomposing said artefact free respiratory sounds into a plurality of frequency bands;

selecting an appropriate one of said frequency bands to estimate the respiratory rate;

estimating an inspiratory and expiratory envelope of said selected band respiratory sounds and deriving a first respiratory rate from a series of peaks of said envelope;

combining a pilot signal with said selected band respiratory sounds, determining a series of silent intervals in said selected band respiratory sounds using said pilot signal and deriving a second respiratory rate from said series of silent intervals; and

deriving the respiratory rate from said first respiratory rate with said second respiratory rate.

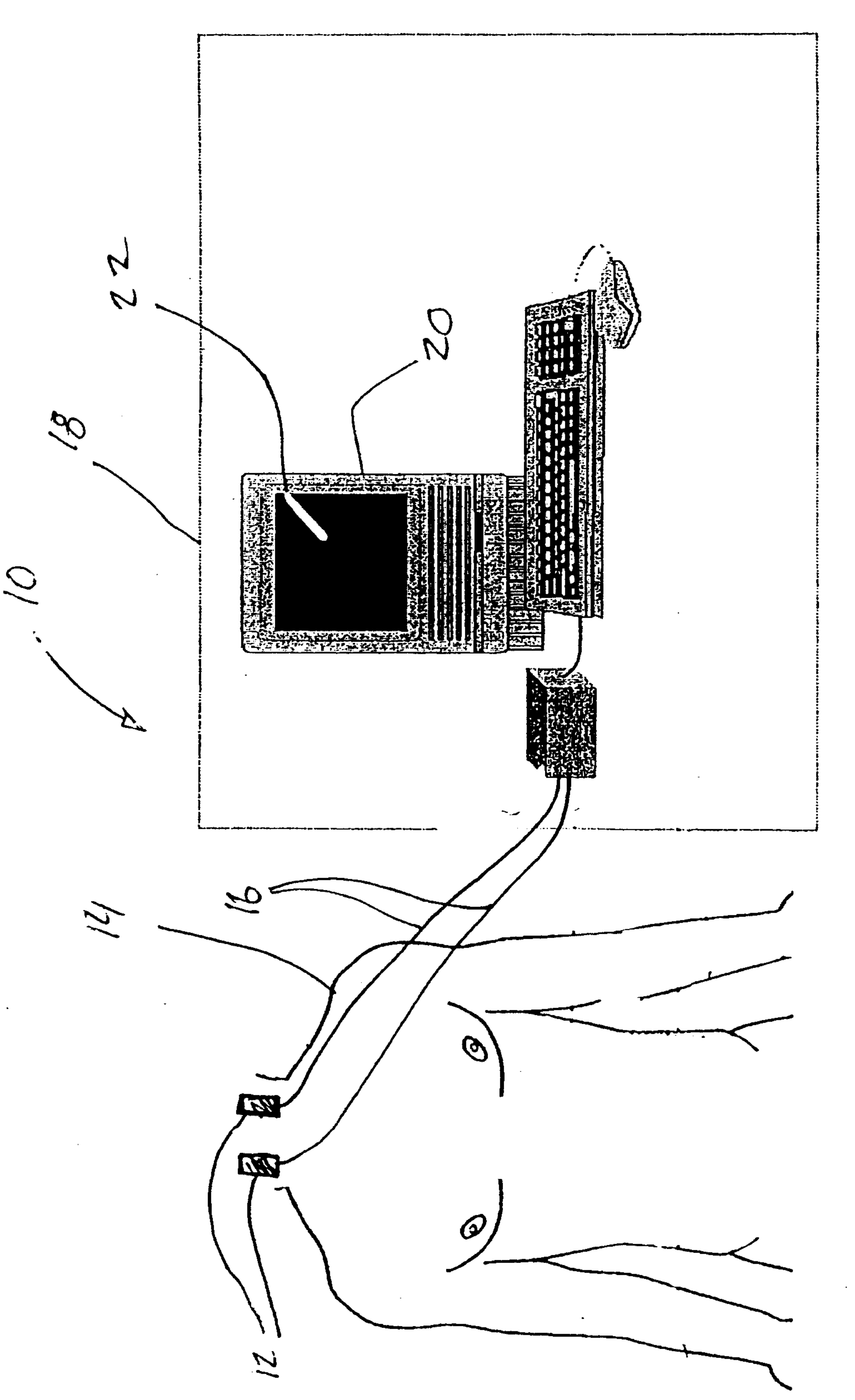
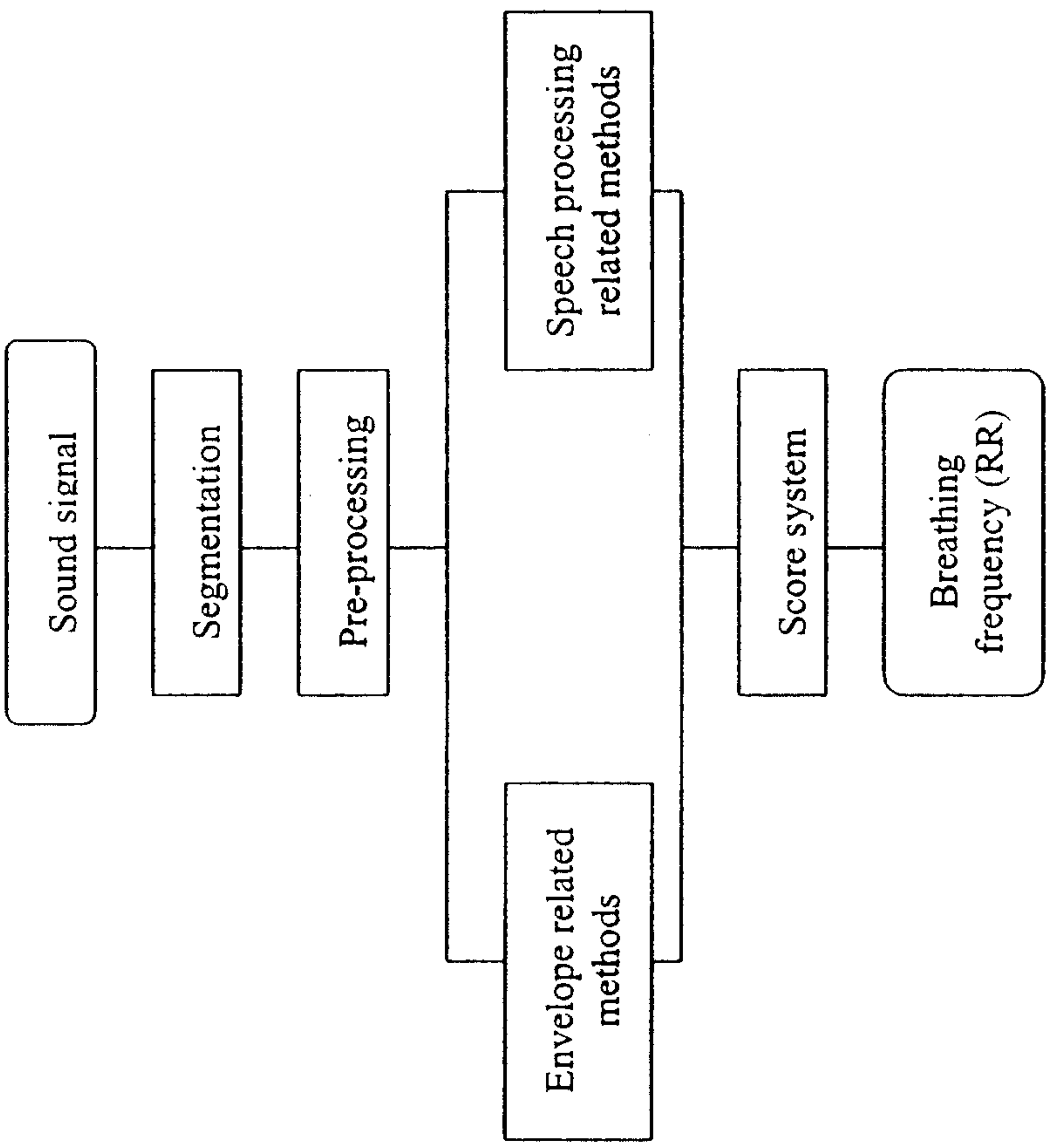


FIGURE 1



Sound signal
Segmentation
Pre-processing
Speech processing related methods
Envelope related methods
Score system
Breathing frequency (RR)

Figure 2

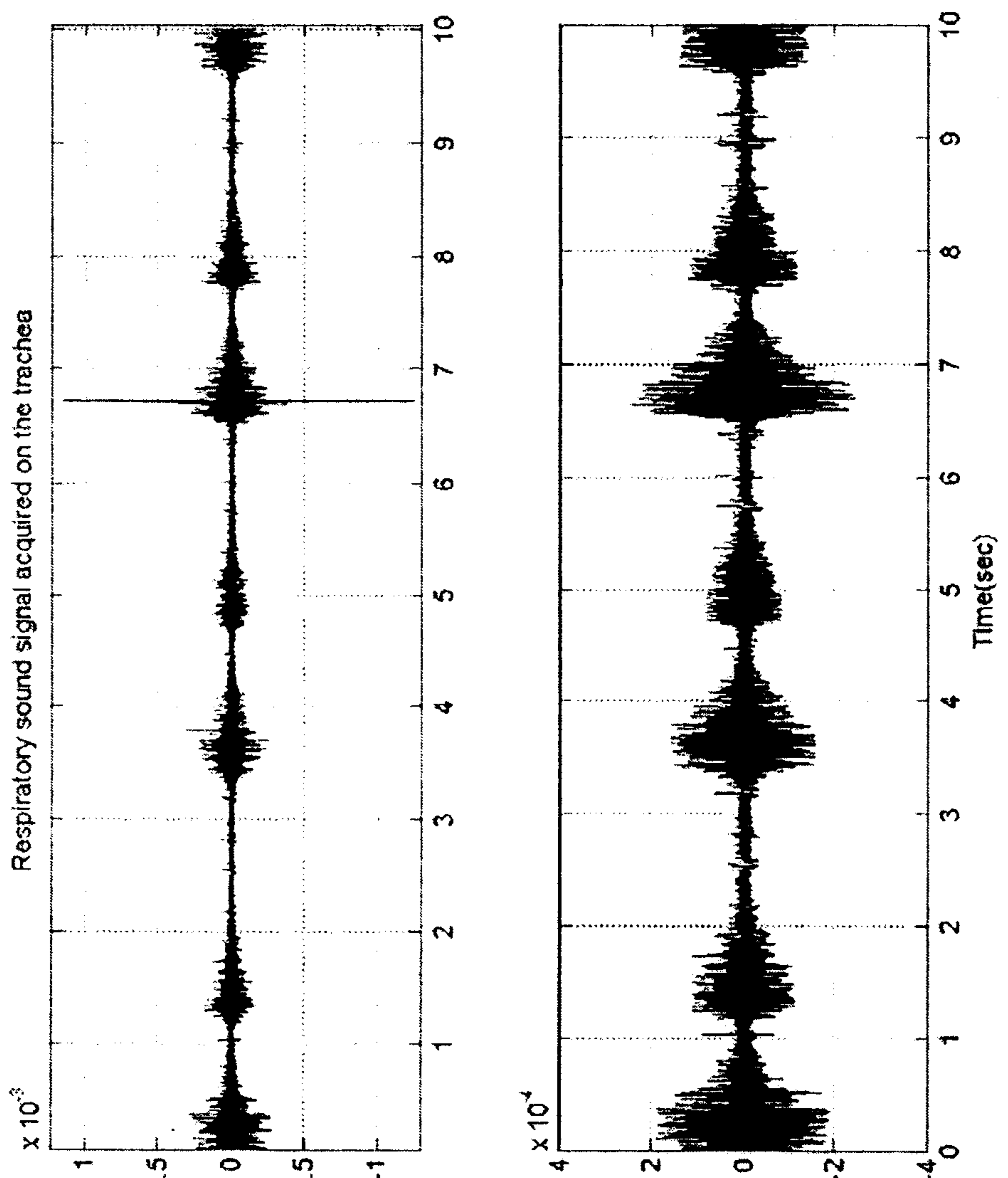

Respiratory sound signal acquired on the trachea
x 10^-3
Volts
1
0.5
0
-0.5
-1
x 10^-4
Volts
4
2
0
-2
-4
0
1
2
3
4
5
6
7
8
9
10
Time(sec)

Figure 3

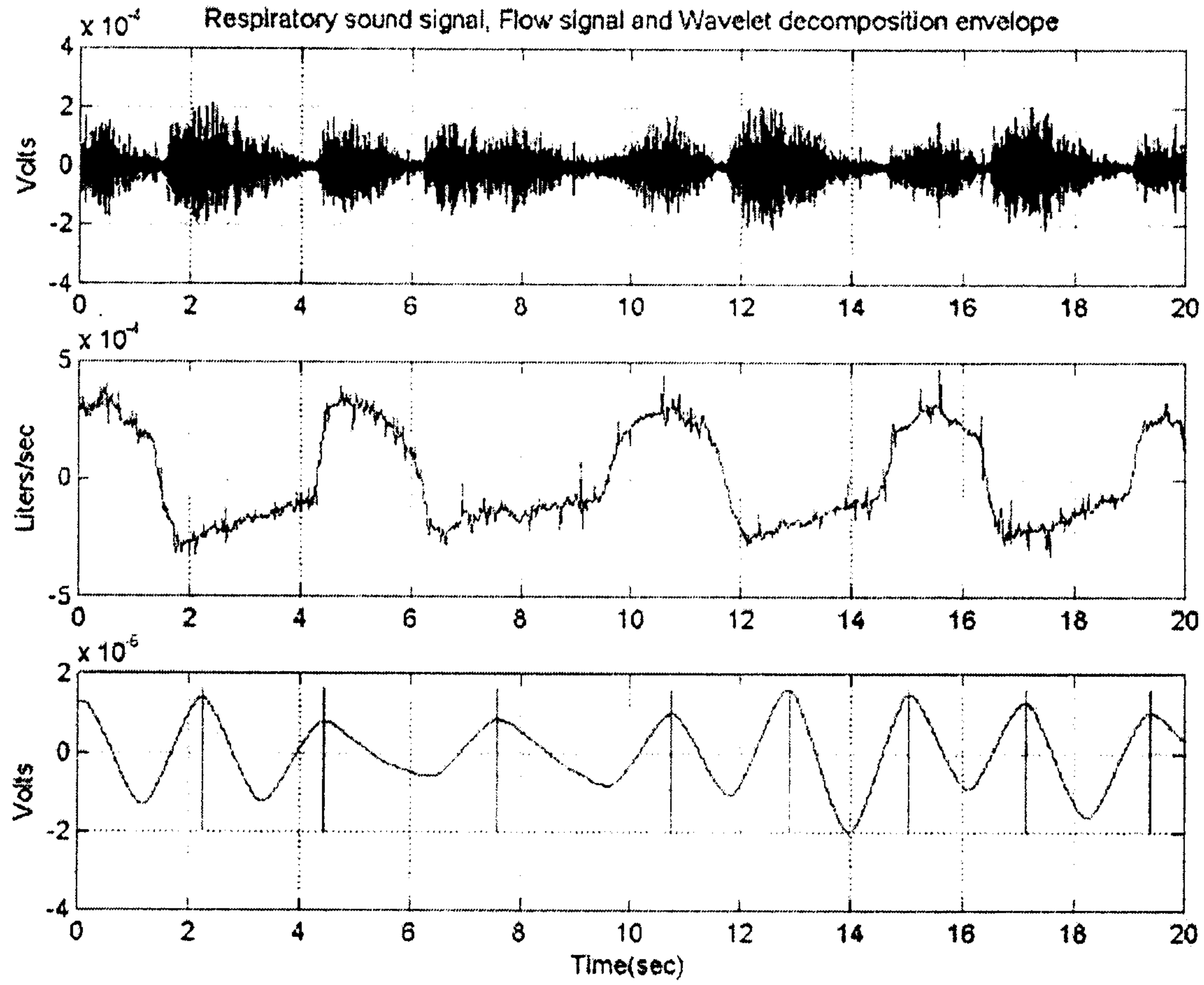

Respiratory sound signal, Flow signal and Wavelet decomposition envelope
x 10^-4
Volts
Liters/sec
x 10^-6
Time(sec)
0
2
4
6
8
10
12
14
16
18
20
-2
-4
5
0
-5

Figure 4

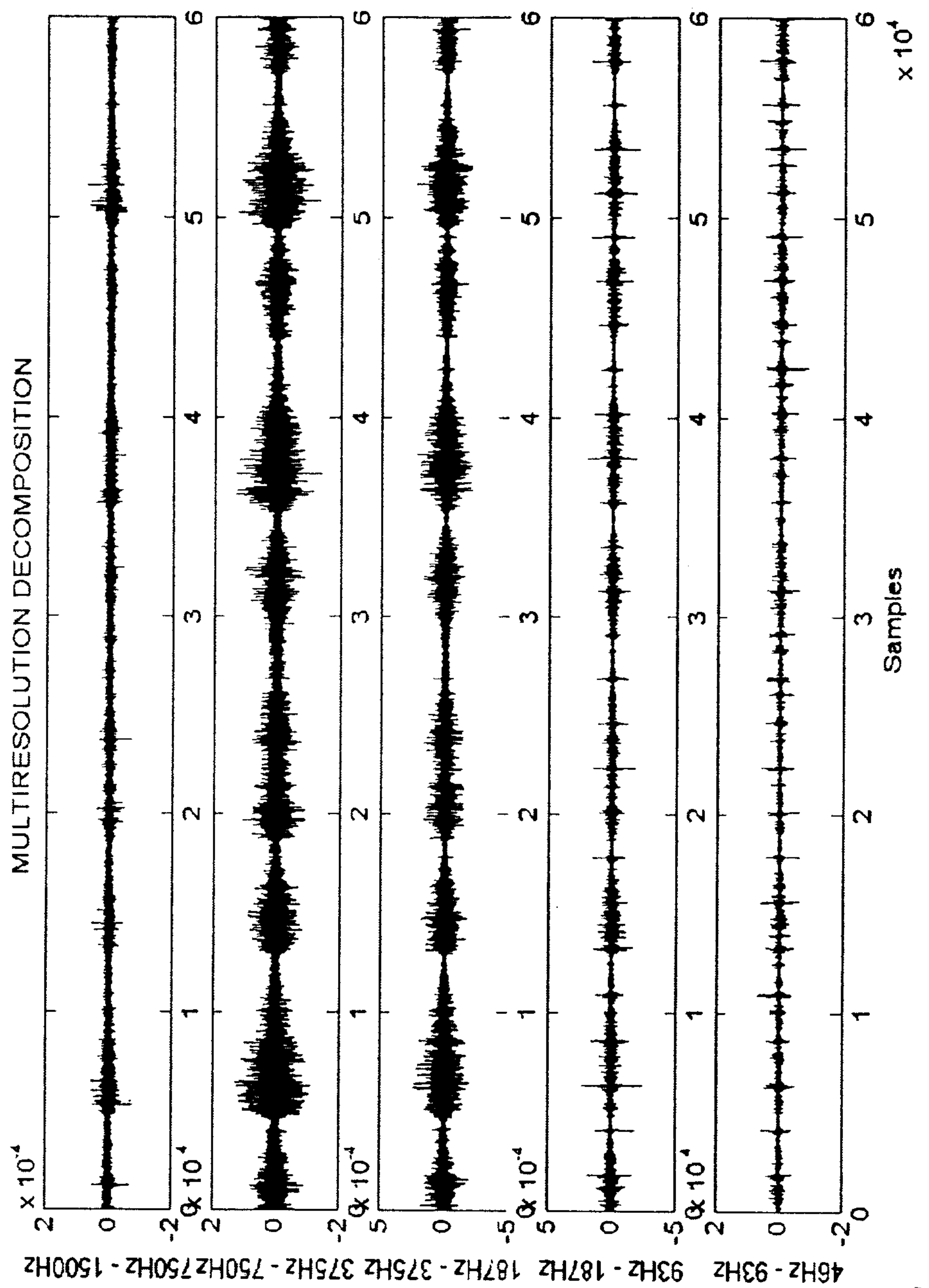

MULTIRESOLUTION DECOMPOSITION
750Hz - 1500Hz
375Hz - 750Hz
187Hz - 375Hz
93Hz - 187Hz
46Hz - 93Hz
Samples
x 10^4

Figure 5

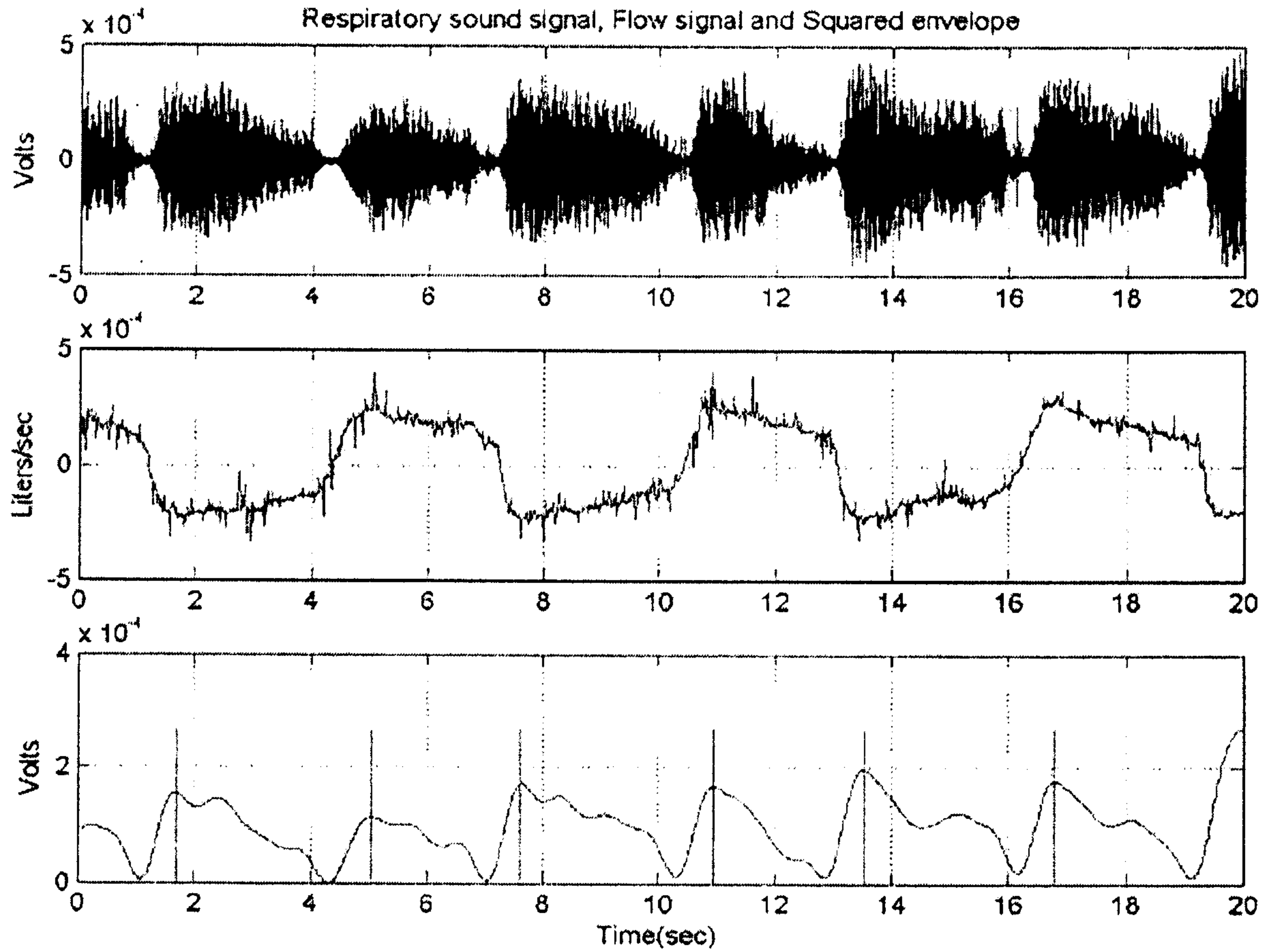

Respiratory sound signal, Flow signal and Squared envelope
x 10-4
Volts
Liters/sec
Volts
Time(sec)

Figure 6

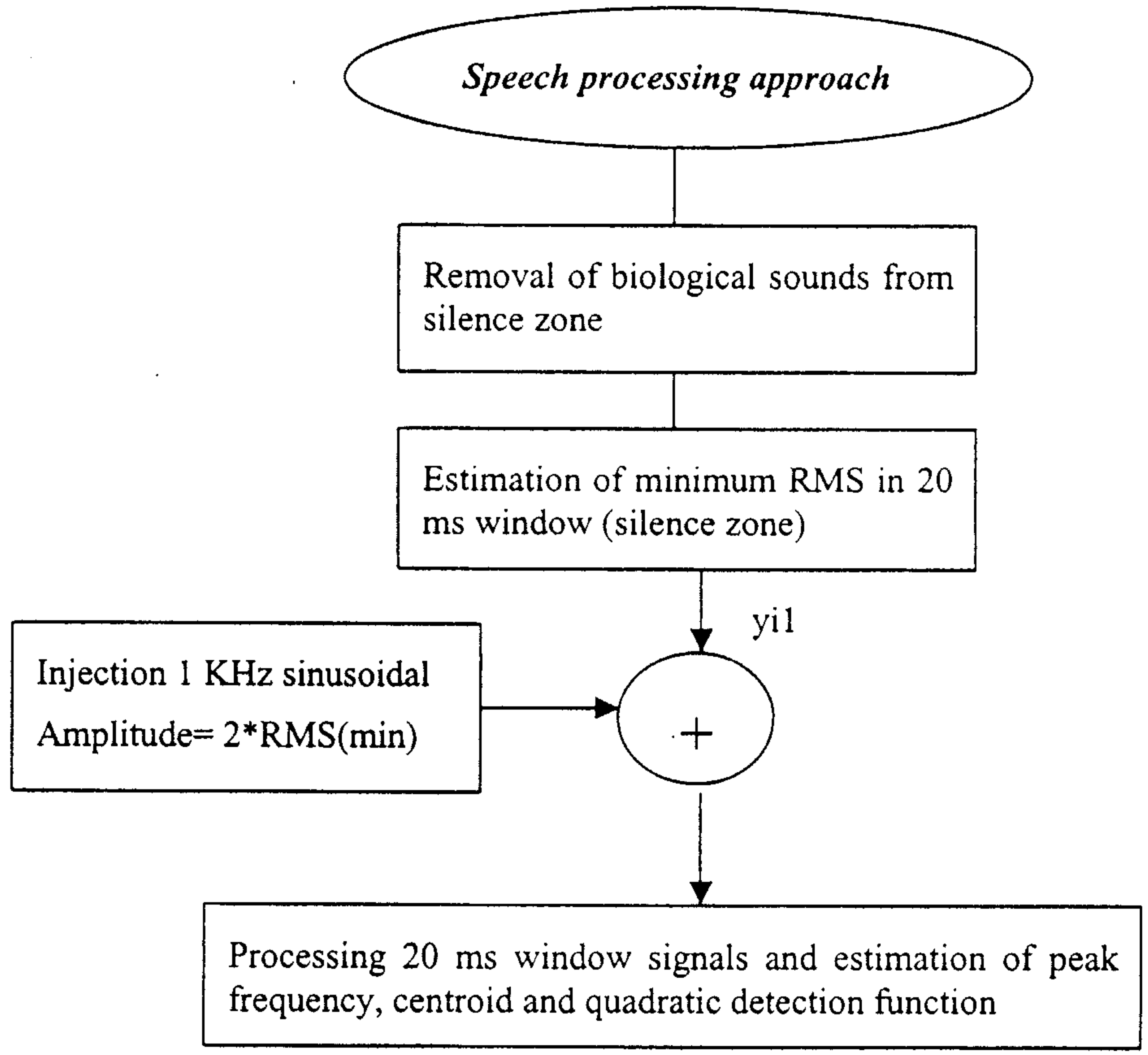

Speech processing approach
Removal of biological sounds from silence zone
Estimation of minimum RMS in 20 ms window (silence zone)
yi1
Injection 1 KHz sinusoidal
Amplitude= 2*RMS(min)
+
Processing 20 ms window signals and estimation of peak frequency, centroid and quadratic detection function

Figure 7

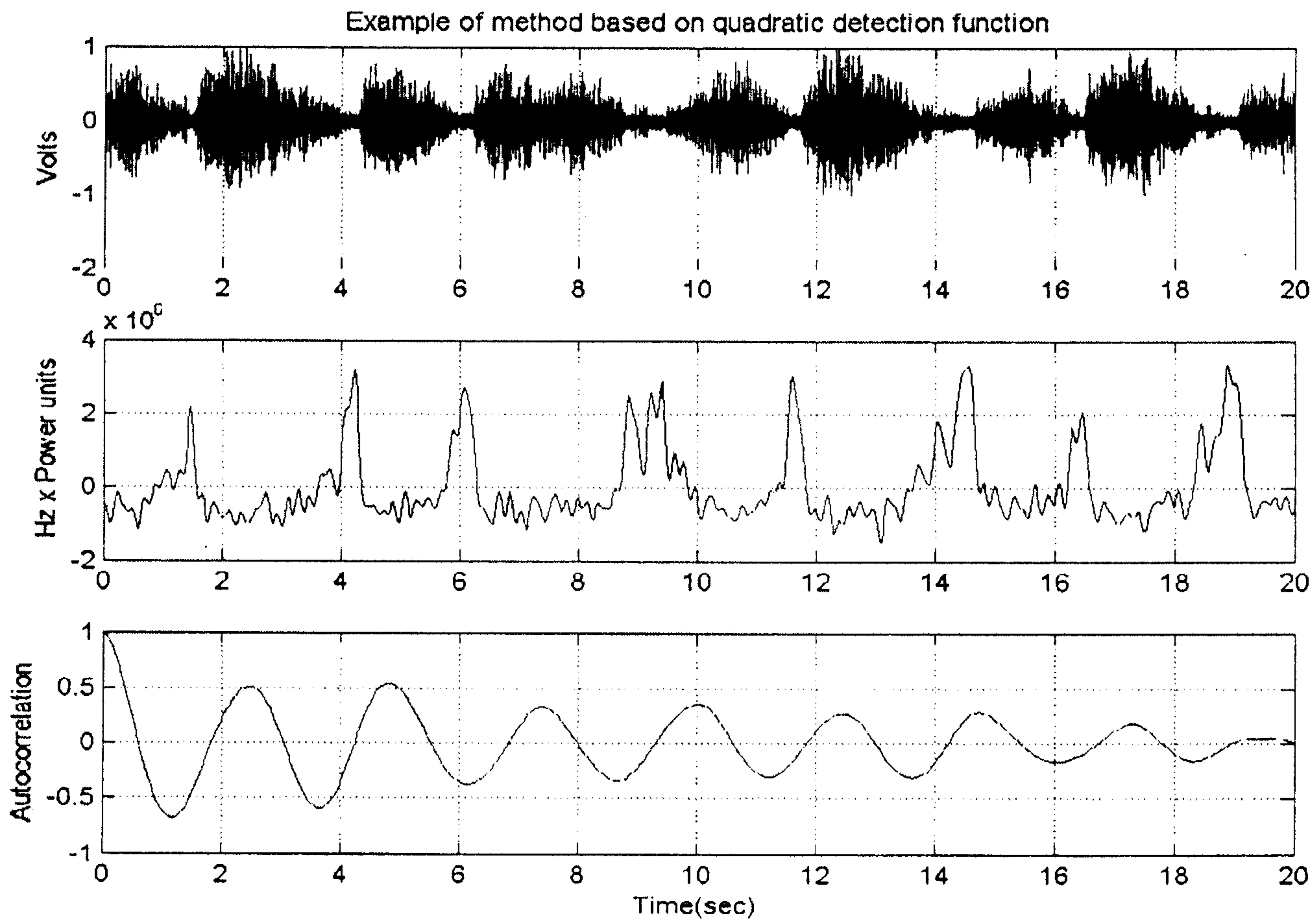
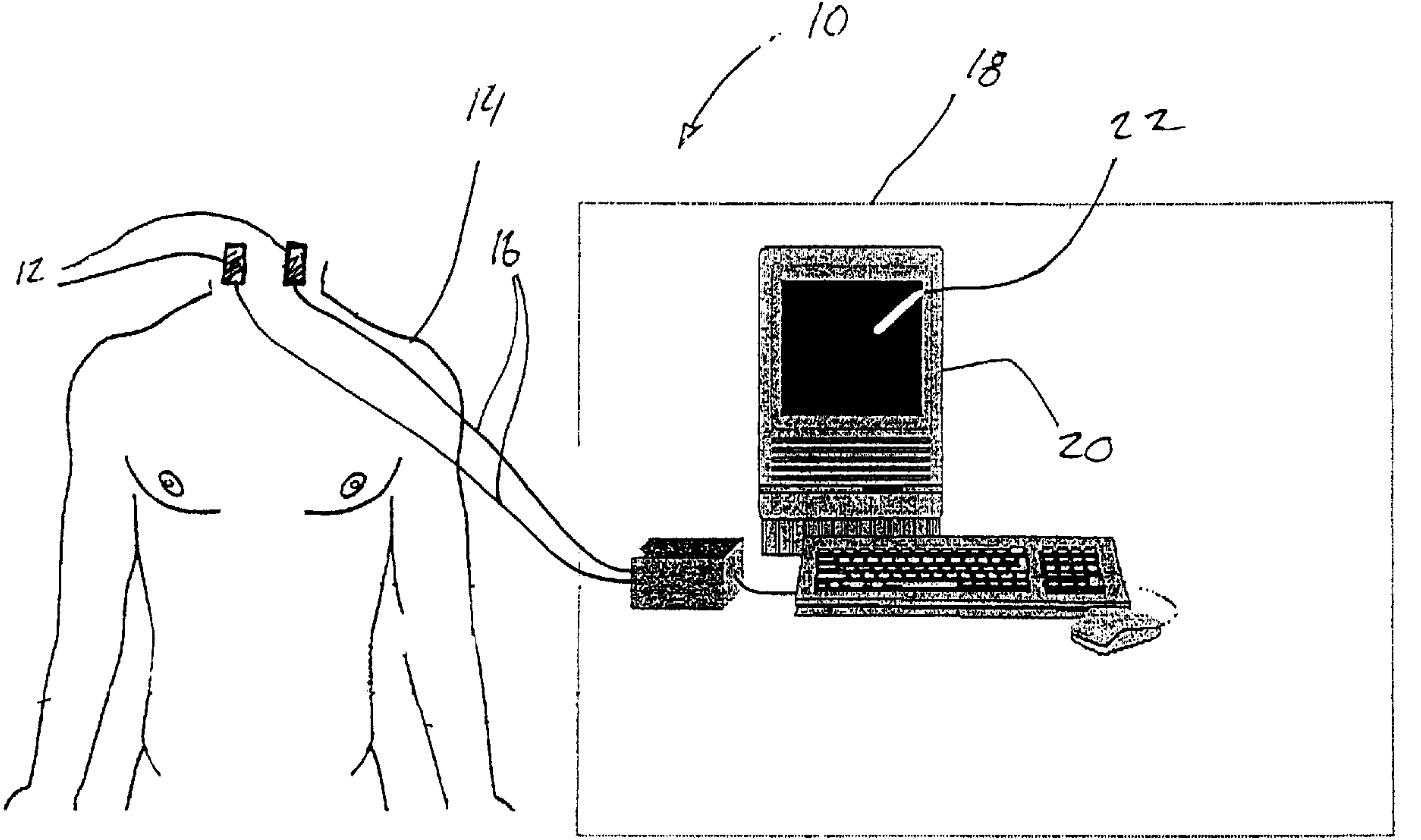

Example of method based on quadratic detection function
Volts
Hz x Power units
x 10^6
Autocorrelation
Time(sec)
0 2 4 6 8 10 12 14 16 18 20
1 0 -1 -2
4 2 0 -2
1 0.5 0 -0.5 -1

Figure 8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