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(54) Title: DIAGNOSIS OF ASTHMA

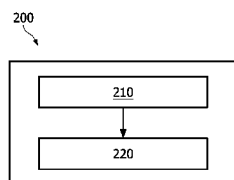


FIG. 2a

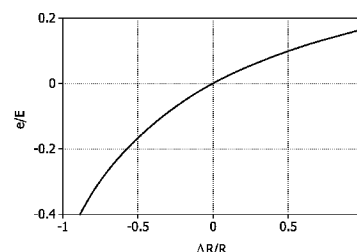


FIG. 2b

(57) **Abstract:** An apparatus (200) for diagnosing asthma is disclosed. The apparatus (200) comprises a data acquisition module (210) configured to acquire at least one physical deformation feature associated with at least one of nasal flaring, neck retraction and inter-coastal retraction of a subject under examination and an analysis module (220) configured to analyze the acquired at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination and diagnose the asthma based on the analyzed at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination. The disclosed apparatus (200) can be used for monitoring asthma at home, at hospital or in ambulatory patients.

Diagnosis of Asthma

Field of the invention

The subject matter relates to diagnosis of asthma.

Background of the invention

US7077810 discloses a method for predicting an onset of clinical episode, the method including sensing breathing of a subject, determining at least one breathing pattern of the subject responsively to the sensed breathing, comparing the breathing pattern with a baseline breathing pattern and predicting the onset of the clinical episode at least in part responsively to the comparison. Predicting the onset of the clinical episode may not be reliable and there could be variations in diagnosing asthma.

Summary of the invention

It is an object of the present subject matter to improve the diagnosis of asthma.

The object of the present subject matter is realized by providing an apparatus for diagnosing asthma, the apparatus comprising

a data acquisition module configured to acquire at least one physical deformation feature associated with at least one of nasal flaring, neck retraction and inter-coastal retraction of a subject under examination; and

an analysis module configured to analyze the acquired at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination and diagnose the asthma based on the analyzed at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

Generally, as breathing becomes more difficult, areas of the chest where retractions can be seen increases. It has been observed that

a) mild difficulty in breathing can cause retraction in the abdomen, just below the rib cage (sub costal) and at the bottom of the breastbone (sub sternal)

b) moderate difficulty in breathing can cause retraction in the same areas of the chest and abdomen as in mild difficulty in breathing and between the ribs (inter-coastal)

c) severe difficulty in breathing can cause retraction in the same areas of the chest and abdomen as mild and moderate difficulty in breathing and in the neck, just above the collarbone (supra clavicular) or just above the breastbone (supra sternal).

Generally, symptoms of asthma include i) nasal flaring wherein nostril size increases with breathing ii) neck retraction wherein neck area moves inward with breathing and iii) inter-coastal retraction wherein skin between or below the ribs move inward with breathing.

Nasal flaring, chest retraction and neck retraction signifies dysfunctional breathing pattern and is a characteristic of airway obstruction particularly asthma. The physical deformations caused on the nose, the inter-coastal spaces and the neck are the locations where distressed breathing generally gets manifested. Hence, monitoring and analyzing these physical deformations can enable an objective evaluation of the severity of the underlying obstructive respiratory disease. This can improve the diagnosis and management of asthma.

The disclosed apparatus can provide valuable input to arrive at the diagnosis of the possible asthmatic attack since the nasal flaring, the neck retraction and the inter-coastal retraction would occur during the episode of the asthma.

The diagnosis based on the physical deformations of the nose, the neck and the chest can be accurate and more reliable. The diagnosis is non-invasive and simple.

Further, the asthma can be diagnosed at incipient stage and can obviate the development and precipitation of the full blown attack.

In an embodiment of the apparatus, the data acquisition module comprises at least one strain gauge configured to acquire at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination during at least one respiratory cycle, the at least one physical deformation feature being acquired in the form of electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

The strain gauge can be attached to the nostrils or to the neck or to the inter-coastal region with the help of a suitable adhesive such as cyano-acrylate. The disclosed apparatus can facilitate the placement of the at least one strain gauge

a) below or atop the tip of the nostril for acquiring at least one physical deformation feature associated with the nasal flaring

b) in the area of the neck either bilaterally on right and left sides or unilaterally in between the lateral border of the sternocleidomastoid muscle and the upper border of the clavicle bone for acquiring at least one physical deformation feature associated with the neck retraction

5 c) in one or more of the nine inter-coastal spaces in front of the chest either unilaterally or bilaterally for acquiring at least one physical deformation feature associated with the inter-coastal retraction

The strain gauge can help in the measurement of physical deformations that evolve over time in the form of nasal flaring and suction of skin over the inter-coastal spaces and the neck region. As the nostrils or the neck region or the inter-coastal region deforms, the foil is also deformed, causing its electrical resistance to change. This resistance change can be measured using a Wheatstone bridge, which is related to the strain by a quantity known as gauge factor.

15 The idea disclosed is to measure the strain generated due to nasal flaring, chest and neck retraction and diagnose asthma based on the measurements.

In some embodiments, the at least one strain gauge is a mercury-in-rubber strain gauge. This kind of strain gauge consists of a small amount of liquid mercury enclosed in a small rubber tube, which is applied around the body part (nostrils, neck region and inter-coastal region). Physical deformation of the body part (nostrils, neck region and inter-coastal region) results in stretching of the tube, making it both longer and thinner, which increases electrical resistance. The advantages of using strain gauge are i) there are no moving parts ii) relatively simple in construction iii) small in size and iv) easy to dispose within the disclosed apparatus.

25 In a still further embodiment, the apparatus comprises a recording module configured to digitally record for a pre-determined time period the acquired at least one physical deformation feature in the form of electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination;

30 a feature extraction module configured to extract time domain feature and/or frequency domain feature from the digitally recorded at least one physical deformation feature in the form of electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination; and

a storing module configured to store the extracted time domain feature and/or frequency domain feature electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

This embodiment is well suited for home use. The parents can use the disclosed apparatus for recording and storing the extracted physical deformation features of their child associated with the neck retraction, the nasal flaring and the inter-coastal retraction. During the scheduled visit to the hospital, the doctor can analyze and interpret the stored recordings and diagnose the condition of the child for asthma.

Recording and storing the extracted features can

a) help the doctor to flawlessly formulate the clinical profile of the child (patient or subject) and prescribe suitable treatment

b) be useful for effective monitoring of the subjects already under treatment especially small children known to have asthma to have precise understanding of symptom evolution and remission

c) act as a history for tracking the trend of disease evolution

d) be clinically useful for especially young children, infants and elderly patients, patients with mental retardation or other behavioral disorders since these are the group of subjects (patients or children) who may not be able to conceive and convey their breathing problems accurately to the doctor.

Further, by the time the subject (patient or child) reaches the doctor the disease symptoms and signs would have subsided at least partially. This can give an incomplete clinical picture to the doctor. This can result in incorrect diagnosis. The stored extracted physical deformation features associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction can overcome the risk of making incorrect diagnosis. This embodiment finds its use amongst both the subjects (patients or child) and the doctor in home scenarios.

In a still further embodiment, the feature extraction module is configured to extract at least one of

a) the respiratory cycles associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction

b) the average of the electrical variations over a pre-determined number of respiratory cycles associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction

c) the frequency bands present in the respiratory cycles associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction

d) the minimum frequency band and the maximum frequency band present in the respiratory cycles associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction.

The symptoms of asthma can be better understood with the help of the extracted features. This can also help in carrying out a comparative analysis with other available baseline features and can further improve the diagnosis of asthma.

In a still further embodiment, the analysis module further comprises an input module configured to receive input, the input being at least one of gender, age, height, weight and ethnicity of the subject under examination; and

a pre-classified calibrated database having data associated with non-asthmatic subjects and asthmatic subjects, the data being at least one of

- i. gender
- ii. age
- iii. height
- iv. weight
- v. ethnicity
- vi. time domain and/or frequency domain features extracted using the acquired physical deformations in the form of electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction
- vii. condition of the subject: non-asthmatic, onset of asthma, mild asthma, acute asthma

The input module helps to collect data of the subject under examination. This input data can help in grouping the subjects and identifying symptoms related to asthma within the groups. Further, the collected data can help in carrying out a comparative study of the extracted physical deformation features with similar subjects. This can further improve the diagnosis and management of asthma.

Further, in developing countries, where economies do not permit every family to own the disclosed apparatus, families can own a shared apparatus which can be used on a need basis. In such cases, the input module can be of help to identify the subject under examination and the stored physical deformation features associated with at least one of the

nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

The pre-classified calibrated database can act as a baseline. It can help in analyzing and classifying the physical deformations of the subject under examination associated with at least one of the nasal flaring, the inter-coastal retraction and the neck retraction into different grades of asthma. The different grades of asthma can be onset of asthma, mild asthma and severe asthma.

The pre-classified calibrated database can be periodically updated. This can be done by testing the disclosed apparatus across sufficient number of subjects based on age, height, weight, gender and ethnicity. The physical deformations associated with at least one of the nasal flaring, the neck retraction, and the inter-coastal retraction can be acquired. The time domain and/or frequency domain features can be extracted, labeled as non-asthmatic/asthmatic subject and stored. The pre-classified calibrated database can further aid in improving the diagnosis of asthma.

In a still further embodiment, the analysis module comprises a logic module configured to compare the extracted time domain and/or frequency domain physical deformations associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination with the data available in the pre-classified calibrated database and diagnose the asthma condition of the subject under examination and store the diagnosis related information.

Known pattern matching algorithms can be used to compare the extracted physical deformation time domain and/or frequency domain features associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction with the extracted physical deformation time domain and/or frequency features available in the pre-classified calibrated database. The condition of the subject under examination can be obtained based on pattern matching results. It is also possible to obtain the grade of the asthma e.g. onset of asthma, mild asthma or severe asthma.

In some embodiments, a Support Vector Machine (SVM) can be used for classification. As an illustrative example, the SVM can view input data as two sets of vectors; one set corresponding to the actual features extracted using the strain gauges and the other set corresponding to the data available in the pre-classified calibrated database of asthmatic and non-asthmatic subjects. The SVM can construct a separating hyper plane in an n-dimensional space, the hyper plane being the one which maximizes the margin between the two data sets. To calculate the margin, two parallel hyper planes can be constructed, one on

each side of the separating hyper plane, which is “pushed up against” the two data sets. Intuitively, a good separation can be achieved by the hyper plane that has the largest distance to the neighboring data points of both classes, since in general the larger the margin the better the generalization error of the classifier.

5 In a still further embodiment, the apparatus comprises
a notification module, the notification module being at least one of a visual display unit, an audio unit or a colored light generation unit, the notification module configured to notify i) whether at least one of the nasal flaring, the neck retraction and the inter-coastal retraction is detected ii) the need for emergency consultation if the diagnosed
10 asthma is above a pre-determined threshold iii) that there is no need for emergency consultation if the diagnosed asthma is below a pre-determined threshold.

This embodiment has the following advantages

- i) it can avoid panic and discomfort of having severe asthmatic attack
- ii) minimize the need for emergency visits or hospitalizations
- 15 iii) can bring down the cost of treatment by avoiding unnecessary consultation
- iv) can prevent recurrent exacerbations of asthma.

The disclosed apparatus can notify the results in the form of visual display and indicate the severity of asthma to the subject under examination. Alternately, an alarm beep could guide both the adult patients and the anxious parents of the sick children to seek
20 medical consultation immediately in case of severe asthma.

The disclosed apparatus can also give information directly in the form of colored lights as to whether the nasal flaring, the neck retraction and the inter-coastal retraction are present. Further, the waveforms representing the physical deformations associated with at least one of the nasal flaring, the neck retraction and the inter-coastal
25 retraction can be displayed. This can form reliable input to the doctor to objectively evaluate the symptoms thereby easing the normal work flow of asthma diagnosis, assessment of asthma severity and response to treatment. This can further improve the diagnosis and management of asthma.

The subjective evaluation of nasal flaring, inter-coastal retraction and neck
30 retraction may not be reliable. There could be some variations in inter-observer (i.e. between different doctors) agreement on inter-coastal retractions and interpretation. To overcome these limitations, the nasal flaring, the neck retractions and the inter-coastal retractions are recorded and the extracted features are stored in digital form. The stored features can be

visualized by the doctor. This can further aid in improving the diagnosis of asthma by providing objective information about the symptoms.

In a still further embodiment, the apparatus further comprises an evaluation module configured to evaluate the progress of the therapy or remission based on i) the currently acquired at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination ii) the previously stored physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

The disclosed apparatus can be used to assess the evolution of asthma and the response to treatment as it provides objective measurements of asthma severity in the form of reduction/increase in the nasal flaring, the chest retraction and the inter-coastal retraction during the period of remission.

In some embodiments, the data from the strain gauges can be fed wirelessly or through wired connection to a wheeze monitoring device. The wheeze monitoring device can subsequently use this data as an additional input along with the wheezes to estimate the severity of asthma. This can further improve the diagnosis of asthma.

The object of the present subject matter is further realized by providing a method for diagnosing asthma, the method comprising:

acquiring at least one physical deformation feature associated with at least one of nasal flaring, neck retraction and inter-coastal retraction; and analyzing the acquired at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction and diagnosing asthma based on the analyzed at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction.

Brief description of the drawings

The above-mentioned aspects, features and advantages will be further described, by way of example only, with reference to the accompanying drawings, in which the same reference numerals indicate identical or similar parts, and in which:

Fig. 1a and Fig. 1b shows normal nostrils, flared nostrils and inter-coastal and neck retractions of an exemplary subject under examination;

Fig. 2a shows an exemplary schematic block diagram of an apparatus for diagnosing asthma according to an embodiment of the present subject matter;

Fig. 2b schematically shows an exemplary variation in resistance v/s output voltage in an exemplary Wheatstone bridge;

Fig. 3 shows an exemplary schematic block diagram of the analysis module according to an embodiment of the present subject matter;

5 Fig. 4a – Fig. 4c schematically shows exemplary waveforms;

Fig. 5 shows an exemplary schematic block diagram of an apparatus for diagnosing asthma according to a still further embodiment of the present subject matter;

Fig. 6 shows an exemplary schematic block diagram of the analysis module according to an embodiment of the present subject matter;

10 Fig. 7 shows an exemplary schematic block diagram of an apparatus for diagnosing asthma according to a still further embodiment of the present subject matter;

Fig. 8 shows an exemplary schematic block diagram of an apparatus for diagnosing asthma according to a still further embodiment of the present subject matter;

Fig. 9 schematically shows an exemplary wheeze monitoring device; and

15 Fig.10 schematically shows an exemplary flow chart illustrating the method of diagnosing asthma according to an embodiment of the present subject matter.

Detailed description of the embodiments

Referring now to Fig. 1a and Fig. 1b, the symptoms of asthma include i) nasal
20 flaring wherein nostril size increases with breathing ii) neck retraction wherein neck area moves inward with breathing and iii) inter-coastal retraction wherein skin between or below the ribs move inward with breathing.

Referring now to Fig. 2a, the apparatus for diagnosing asthma 200 comprises

- i) a data acquisition module 210
- 25 ii) an analysis module 220

The data acquisition module 210 can be configured to acquire at least one physical deformation feature of the subject under examination. The at least one physical deformation feature can be associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

30 The analysis module 220 can be configured to analyze the acquired at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination. Asthma can be diagnosed based on the analysis of least one physical deformation feature associated with at

least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

The data acquisition module 210 can have at least one strain gauge. The at least one strain gauge can be configured to acquire at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination during at least one respiratory cycle. The at least one physical deformation feature can be acquired in the form of electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

The at least one strain gauge can be attached to the nostrils or to the neck or to the inter-coastal region with the help of a suitable adhesive such as cyano-acrylate. The disclosed apparatus can facilitate the placement of the at least one strain gauge

a) below or atop the tip of the nostril for acquiring at least one physical deformation feature associated with the nasal flaring

b) in the area of the neck either bilaterally on right and left sides or unilaterally in between the lateral border of the sternocleidomastoid muscle and the upper border of the clavicle bone for acquiring at least one physical deformation feature associated with the neck retraction

c) in one or more of the nine inter-coastal spaces in front of the chest either unilaterally or bilaterally for acquiring at least one physical deformation feature associated with the inter-coastal retraction

The strain gauge can help in the measurement of physical deformations that evolve over time in the form of nasal flaring and suction of skin over the inter-coastal spaces and the neck region. As the nostrils or the neck region or the inter-coastal region deforms, the foil is also deformed, causing its electrical resistance to change. This resistance change can be measured using a Wheatstone bridge, which is related to the strain by a quantity known as gauge factor.

The idea disclosed is to measure the strain generated due to nasal flaring, chest and neck retraction and diagnose asthma based on the measurements.

Strain is a dimensionless unit, defined as a change in length per unit length. As an illustrative example, if a 1 meter long steel bar stretches to 1.000002 meter, the strain is defined as 2 micro strains. Strain gauges have a characteristic gauge factor, defined as the fractional change in resistance divided by the strain.

As an illustrative example, it could be that in the case of mild asthma, the nasal flaring causes 2 micro strain applied to a gauge with gauge factor of 2 and produces a fractional resistance change of

$$(2 \times 2) 10^{-6} = 4 \times 10^{-6} = 4 \mu\text{Ohms}$$

- 5 This change would reflect in appropriate voltage dissipation at the circuit level given by
 $V_0 = V_{ex} (X/4)$

Where

V_0 = Bridge output voltage

V_{ex} = excitation voltage applied to the bridge

- 10 X = relative change in resistance, BR/R

Fig. 2b shows the resistance v/s output voltage variations in a typical wheat stone bridge. This output voltage from the wheat stone bridge is recorded by the disclosed apparatus 200. The variations in the output voltages can be recorded for 3 minutes and the corresponding data can be stored as an array of numbers. These numbers can be analyzed to
 15 extract features such as minimum voltage change and maximum voltage change in a window of approximately 3 minutes. These features can be compared with a database using Support Vector Machine to classify as mild asthma or normal. Similarly for medium asthma the nasal flaring can for e.g. reflect 5 micro strains and for severe asthma the nasal flaring can reflect for e.g. 8 micro strains. Chest and inter-coastal retractions can also be analyzed using similar
 20 techniques.

- The at least one strain gauge can be a mercury-in-rubber strain gauge. This kind of strain gauge consists of a small amount of liquid mercury enclosed in a small rubber tube, which can be applied around the body part (nostrils, neck region and inter-coastal region). Physical deformation of the body part (nostrils, neck region and inter-coastal region)
 25 results in stretching of the tube, making it both longer and thinner, which increases electrical resistance.

The advantages of using strain gauge are:

- a) there are no moving parts
 b) relatively simple in construction
 30 c) small in size
 d) easy to dispose within the disclosed apparatus.

The strain gauge can acquire the physical deformations associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction in the form of

voltage/current variations. These variations are generally proportional to the amount of deformation that occurs during each respiratory cycle.

The strain gauges can be connected to data acquisition hardware which can record the voltage/current variations using analog components like resistors, capacitors and OP-AMPS. Analog to Digital Converters can be used to convert the analog signals of voltage/current waveforms into digital domain by properly sampling the signals. As an illustrative example, rate of respiration can be considered as input for choosing the right sampling frequency of Analog to Digital Converters. The rate of respiration in healthy subjects and diseased subjects generally vary from 12 to 25 respiratory cycles per minute.

Hence, the sampling frequency can be chosen as > 50 .

Referring now to Fig. 3, the analysis module 220 for diagnosing asthma further comprises

- a) a recording module 300
- b) a feature extraction module 310
- c) a storing module 320

The recording module 300 can be configured to digitally record for a pre-determined time period the acquired at least one physical deformation feature in the form of electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

The feature extraction module 310 can be further configured to extract time domain features and/or frequency domain features from the digitally recorded at least one physical deformation feature in the form of electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

The feature extraction module 310 can be configured to extract at least one of

- a) the respiratory cycles associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction
- b) the average of the electrical variations over a pre-determined number of respiratory cycles associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction
- c) the frequency bands present in the respiratory cycles associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction

d) the minimum frequency band and the maximum frequency band present in the respiratory cycles associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction.

The pattern of breathing, which includes the respiratory rate, rhythm and effort, can provide a useful practical tool for assessing the respiratory system. The presence of dis-coordinated breathing (lack of co ordination between thoracic and diaphragmatic muscles of respiration) is also a poor sign. In its extreme form, there is failure of synchronization and the chest moves inward during inspiration.

Increased respiratory effort and work of breathing may be evaluated by assessment of accessory muscle use, sub costal and inter-costal retractions, nasal flaring, and the rate and depth of respiratory effort. Children in moderate to severe respiratory distress will present in the initial states with marked accessory muscle activity as well as sub costal and inter-coastal retractions. Nasal flaring may indicate mild asthma, but use of sternocleidomastoid and other accessory muscles signifies increasing respiratory effort.

Asthma can be better diagnosed with the help of the extracted features. The extracted features can also help in carrying out a comparative analysis with other available baseline features and can further improve the diagnosis of asthma.

The storing module 320 can be configured to store the extracted time domain feature and/or frequency domain feature electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

The parents can use the disclosed apparatus 200 for recording and storing the extracted physical deformation features associated with the neck retraction, the nasal flaring and the inter-coastal retraction of their child. During the scheduled visit to the hospital, the doctor can analyze and interpret the stored recordings and diagnose the condition of the child for asthma.

Recording and storing the extracted features can

a) help the doctor to flawlessly formulate the clinical profile of the child (patient or subject) and prescribe suitable treatment

b) be useful for effective monitoring of the subjects already under treatment especially small children known to have asthma to have precise understanding of symptom evolution and remission

c) act as a history for tracking the trend of asthma evolution

d) be clinically useful for especially young children, infants and elderly patients, patients with mental retardation or other behavioral disorders since these are the group of subjects (patients or children) who may not be able to conceive and convey their breathing problems accurately to the doctor.

Generally, by the time the subject (patient or child) reaches the doctor the disease symptoms and signs would have subsided at least partially. This can give an incomplete clinical picture to the doctor and can result in incorrect diagnosis. The stored extracted physical deformation features associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction can overcome the risk of arriving at incorrect diagnosis.

The pattern of a normal respiratory cycle is shown in Fig. 4a. The respiratory cycle refers to the cyclical and rhythmic process of taking air into the lungs by a process called as inspiration and expelling out the air from the lungs by a process called as expiration with a pause in between inspiration and expiration. The process of respiration is mediated or controlled by the respiratory centre in the brain stem consisting of inspiratory and expiratory centers. Normal respiratory rate generally varies between 14 – 20 times per minute under various physiological conditions and is usually less than 25 times/minute.

Fig. 4b shows an exemplary electrical waveform generated by the strain gauge associated with the normal respiratory cycle in a healthy subject. As can be seen from the graph, the voltage generation by the strain gauges placed at the nostrils or the neck or the inter-coastal region is generally in the range of 400 – 500 mV in a healthy subject. The frequency band of the electrical waveform of the healthy subject is generally around 0.5Hz.

Fig. 4c shows an exemplary electrical waveform associated with the inter-coastal retraction of a severe asthmatic subject. The electrical waveform is suggestive of generation of progressively higher voltages and higher variations (zero crossings) in the time domain, leading to higher frequency bands in frequency domain. It is possible to divide the subjects into groups having mild asthma, moderate asthma and severe asthma based on the pattern of the variations in time domain, amplitude of the voltages and frequency bands. As an illustrative example, it is possible to deduce from Fig. 4c that the value of the potential difference generated through the strain gauge in a subject with mild asthma, moderate asthma and severe asthma is around 600, 800 and 1000 mV respectively. In the frequency domain the frequency bands of the electrical waveform for mild asthma, moderate asthma and severe asthma are around 3 Hz, 6 Hz and 10 Hz respectively.

Referring now to Fig 5, the apparatus 200 for diagnosing asthma further comprises

an input module 510 configured to receive input, the input being at least one of gender, age, height, weight and ethnicity of the subject under examination

a pre-classified calibrated database 520 having data associated with non-asthmatic subjects and asthmatic subjects, the data being at least one of

i) gender

ii) age

iii) height

iv) weight

v) ethnicity

vi) time domain and/or frequency domain features extracted using the acquired physical deformations acquired in the form of electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction

vii) condition of the subject: non-asthmatic, onset of asthma, mild asthma, acute asthma

The input module helps to collect data of the subject under examination. This input data can help in grouping the subjects and identifying symptoms related to asthma within the groups. Further, the collected data can help in carrying out a comparative study with the extracted physical deformation features with similar subjects. This can further improve the diagnosis of asthma. Further, in developing countries, where economies do not permit every family to own the disclosed apparatus, families can own a shared apparatus which can be used on a need basis. In such cases, the input module can be of help to identify the subject under examination and the stored physical deformation features associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

The pre-classified calibrated database can act as a baseline. It can help in classifying the physical deformations of the subject under examination associated with at least one of the nasal flaring, the inter-coastal retraction and the neck retraction into different grades of asthma. The different grades of asthma can be onset of asthma, mild asthma and severe asthma.

The pre-classified calibrated database can be periodically calibrated. This can be done by testing the disclosed apparatus across sufficient number of subjects based on age, height, weight, gender and ethnicity. The physical deformations associated with at least one

of the nasal flaring, the neck retraction, and the inter-coastal retraction can be acquired. The time domain features and/or frequency domain features can be extracted, labeled as non-asthmatic/asthmatic subject and stored in the database. The pre-classified calibrated database can be a useful tool for diagnosing asthma.

5 Referring now to Fig 6, the analysis module 220 further comprises
a logic module 610 configured to compare the extracted time domain and/or
frequency domain physical deformations associated with at least one of the nasal flaring, the
neck retraction and the inter-coastal retraction of the subject under examination with the data
available in the pre-classified calibrated database and diagnose the asthma condition of the
10 subject under examination and store the diagnosis related information.

Known pattern matching algorithms can be used to compare the extracted time
domain and/or frequency physical deformations associated with at least one of the nasal
flaring, the neck retraction and the inter-coastal retraction with the extracted physical
deformation time domain and/or frequency domain features available in the pre-classified
15 calibrated database. The condition of the subject under examination can be obtained based
on the classification results. It is also possible to obtain the grade of the asthma e.g. onset of
asthma, mild asthma or severe asthma.

In some embodiments, a Support Vector Machine (SVM) can be used for
classification. As an illustrative example, the SVM can view input data as two sets of
20 vectors; one set corresponding to the actual features extracted using the strain gauges and the
other set corresponding to the data available in the pre-classified calibrated database of
asthmatic and non-asthmatic subjects. The SVM can construct a separating hyper plane in an
n-dimensional space, the hyper plane being the one which maximizes the margin between the
two data sets. To calculate the margin, two parallel hyper planes can be constructed, one on
25 each side of the separating hyper plane, which is “pushed up against” the two data sets.
Intuitively, a good separation can be achieved by the hyper plane that has the largest distance
to the neighboring data points of both classes, since in general the larger the margin the better
the generalization error of the classifier.

Referring now to Fig. 7, the apparatus for diagnosing asthma 200 further
30 comprises

a notification module 710 configured to notify i) whether at least one of the
nasal flaring, the neck retraction and the inter-coastal retraction is detected ii) the need for
emergency consultation if the diagnosed asthma is above a pre-determined threshold iii) that
there is no need for emergency consultation if the diagnosed asthma is below a pre-

determined threshold. The notification module 710 can be at least one of a visual display unit, an audio unit or a color light generation unit.

This embodiment has the following advantages

- i) it can avoid panic and discomfort of having severe asthmatic attack
- 5 ii) minimize the need for emergency visits or hospitalizations
- iii) can bring down the cost of treatment by avoiding unnecessary consultation
- iv) can prevent recurrent exacerbations of asthma.

The disclosed apparatus can notify the results in the form of visual display and indicate the severity of asthma to the subject under examination. Alternately, an alarm beep
10 could guide both the adult patients and the anxious parents of the sick children to seek medical consultation immediately in case of severe asthma.

The subjective evaluation of nasal flaring, inter-coastal retraction and neck retraction may not be reliable. There could be some variations in inter-observer (i.e. between different doctors) agreement on inter-coastal retractions and interpretation. To overcome
15 these limitations, the nasal flaring, the neck retractions and the inter-coastal retractions are recorded and the extracted features are stored in digital form. The stored features can be visualized by the doctor. This can further aid in improving the diagnosis of asthma by providing objective information about the symptoms.

The disclosed apparatus can also give information directly as to whether the
20 nasal flaring, the neck retraction and the inter-coastal retraction are present in the form of colored lights. Further, the waveforms representing the physical deformations associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction can be displayed. This can form reliable input to the doctor to objectively evaluate the symptoms thereby easing the normal work flow of asthma diagnosis, assessment of asthma activity and
25 response to treatment. This can further improve the diagnosis of asthma.

Referring now to Fig. 8, the apparatus for diagnosing asthma 200 further comprises an evaluation module 810 configured to evaluate the progress of the therapy or remission based on i) the currently acquired at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal
30 retraction of the subject under examination ii) the previously stored physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination. The disclosed apparatus can be used to assess the evolution of asthma and the response to treatment as it provides objective

measurements of asthma severity in the form of reduction/increase in the nasal flaring, the chest retraction and the inter-coastal retraction during the period of remission.

The disclosed apparatus can be built as a standalone system or as an add-on to the existing devices for monitoring the asthma symptoms. Referring now to Fig. 9, the disclosed apparatus 200 for diagnosing asthma can be used as an add-on apparatus for a wheeze monitoring device. The data from the strain gauges can be fed wirelessly or through wired connection to the wheeze monitoring device. The wheeze monitoring device can subsequently use this data as an additional input along with the wheezes to estimate the severity of asthma. This can further improve the diagnosis of asthma.

Referring now to Fig. 10, the method for diagnosing asthma 1000 comprises a step 1010 of acquiring at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction and a step 1020 of analyzing the acquired at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction and diagnosing asthma based on the analyzed at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction.

The present subject matter discloses the use of strain gauges for measuring mechanical changes that evolve over time in diseases of airway obstruction in the form of nasal flaring and suction of skin over inter-coastal spaces and neck region. Further, these mechanical changes are calibrated to find the severity of the diseased condition.

In summary, an apparatus for diagnosing asthma is disclosed. The apparatus comprises a data acquisition module configured to acquire at least one physical deformation feature associated with at least one of nasal flaring, neck retraction and inter-coastal retraction of a subject under examination and an analysis module configured to analyze the acquired at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination and diagnose the asthma based on the analyzed at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

The disclosed apparatus can be used for monitoring asthma at home, at hospital or in ambulatory patients. The disclosed apparatus can also give indication of development of other airway obstruction related diseases such as Transient Tachypnea of the Newborn, Choanal Atresia, Persistent tachypnea in infants, Bronchiolitis, Croup, Acute

epiglottitis wherein chest and neck retractions and nasal flaring could be one of the clinical features.

While the subject matter has been illustrated in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive; the subject matter is not limited to the disclosed embodiments.

Other variations to the disclosed embodiments can be understood and effected by those skilled in the art of practicing the claimed subject matter, from a study of the drawings, the disclosure and the appended claims. Use of the verb “comprise” and its conjugates does not exclude the presence of elements other than those stated in a claim or in the description. Use

of the indefinite article “a” or “an” preceding an element or step does not exclude the presence of a plurality of such elements or steps. A single unit may fulfill the functions of several items recited in the claims. The mere fact that certain measures are recited in mutually different dependant claims does not indicate that a combination of these measures cannot be used to advantage. The figures and description are to be regarded as illustrative only and do not limit the subject matter. Any reference sign in the claims should not be construed as limiting the scope.

CLAIMS:

1. An apparatus (200) for diagnosing asthma, the apparatus comprising
a data acquisition module (210) configured to acquire at least one physical
deformation feature associated with at least one of nasal flaring, neck retraction and inter-
coastal retraction of a subject under examination; and
5 an analysis module (220) configured to analyze the acquired at least one
physical deformation feature associated with at least one of the nasal flaring, the neck
retraction and the inter-coastal retraction of the subject under examination and diagnose the
asthma based on the analyzed at least one physical deformation feature associated with at
least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject
10 under examination.
2. The apparatus (200) as claimed in claim 1, wherein the data acquisition
module (210) comprises
at least one strain gauge configured to acquire at least one physical
15 deformation feature associated with at least one of the nasal flaring, the neck retraction and
the inter-coastal retraction of the subject under examination during at least one respiratory
cycle, the at least one physical deformation feature being acquired in the form of electrical
variation associated with at least one of the nasal flaring, the neck retraction and the inter-
coastal retraction of the subject under examination.
20
3. The apparatus as claimed in claim 2, wherein the at least one strain gauge is a
mercury-in-rubber strain gauge.
4. The apparatus as claimed in claim 3, wherein the analysis module (220)
25 further comprises
a recording module (300) configured to digitally record for a pre-determined
time period the acquired at least one physical deformation feature in the form of electrical
variation associated with at least one of the nasal flaring, the neck retraction and the inter-
coastal retraction of the subject under examination;
30 a feature extraction module (310) configured to extract time domain feature
and/or frequency domain feature from the digitally recorded at least one physical deformation

feature in the form of electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination; and

a storing module (320) configured to store the extracted time domain feature and/or frequency domain feature electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

5. The apparatus as claimed in claim 4, wherein the feature extraction module (310) is configured to extract at least one of

a) the respiratory cycles associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction

b) the average of the electrical variations over a pre-determined number of respiratory cycles associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction

c) the frequency bands present in the respiratory cycles associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction

d) the minimum frequency band and the maximum frequency band present in the respiratory cycles associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction.

6. The apparatus as claimed in claim 4, wherein the analysis module (220) further comprises

an input module (510) configured to receive input, the input being at least one of gender, age, height, weight and ethnicity of the subject under examination; and

a pre-classified calibrated database (520) having data associated with non-asthmatic subjects and asthmatic subjects, the data being at least one of

a) gender

b) age

c) height

d) weight

e) ethnicity

f) time domain and/or frequency domain features extracted using the acquired physical deformations in the form of electrical variation associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction

g) condition of the subject: non-asthmatic, onset of asthma, mild asthma, acute asthma

7. The apparatus (200) as claimed in claim 6, wherein the analysis module (220) further comprises

a logic module (610) configured to compare the extracted time domain and/or frequency domain physical deformations associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination with the data available in the pre-classified calibrated database and diagnose the asthma condition of the subject under examination and store the diagnosis related information.

8. The apparatus (200) as claimed in claim 1, further comprising a notification module (710), the notification module (710) being at least one of a visual display unit, an audio unit or a colored light generation unit, the notification module configured to notify i) whether at least one of the nasal flaring, the neck retraction and the inter-coastal retraction is detected ii) the need for emergency consultation if the diagnosed asthma is above a pre-determined threshold iii) that there is no need for emergency consultation if the diagnosed asthma is below a pre-determined threshold.

9. The apparatus (200) as claimed in claim 1, further comprising an evaluation module (810) configured to evaluate the progress of the therapy or remission based on i) the currently acquired at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination ii) the previously stored physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction of the subject under examination.

10. A wheeze monitoring device (900) comprising the apparatus (200) as claimed in any one of the claims 1 – 9.

11. A method for diagnosing asthma (1000), the method comprising acquiring (1010) at least one physical deformation feature associated with at least one of nasal flaring, neck retraction and inter-coastal retraction; and

analyzing (1020) the acquired at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction and diagnosing asthma based on the analyzed at least one physical deformation feature associated with at least one of the nasal flaring, the neck retraction and the inter-coastal retraction.

5

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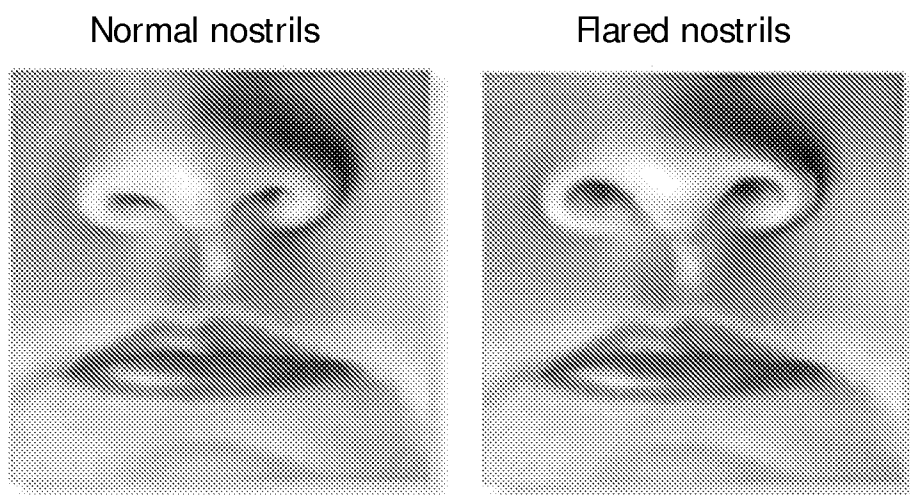


FIG. 1a

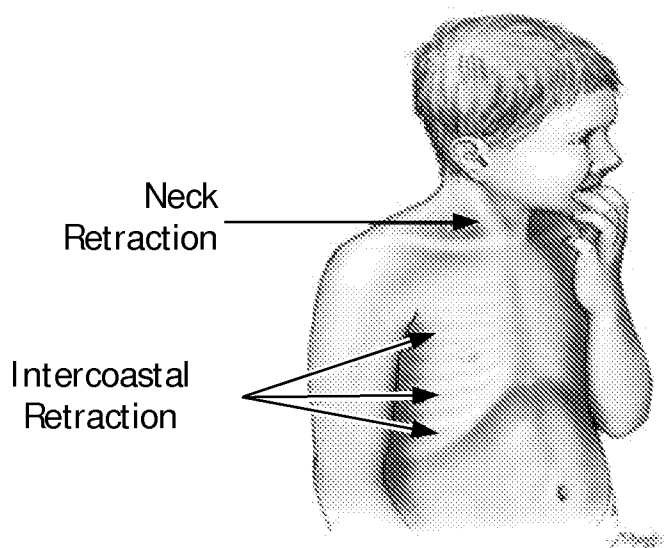


FIG. 1b

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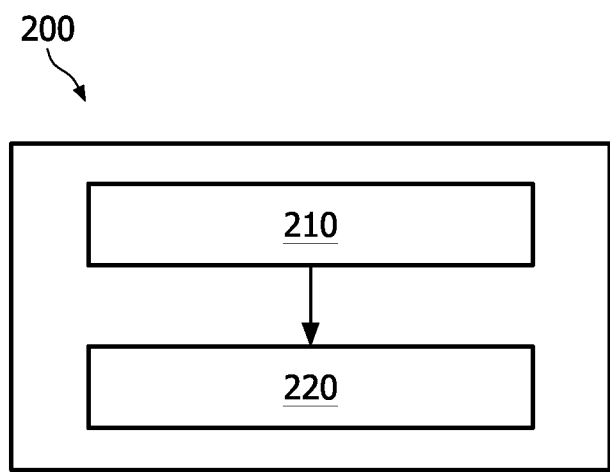


FIG. 2a

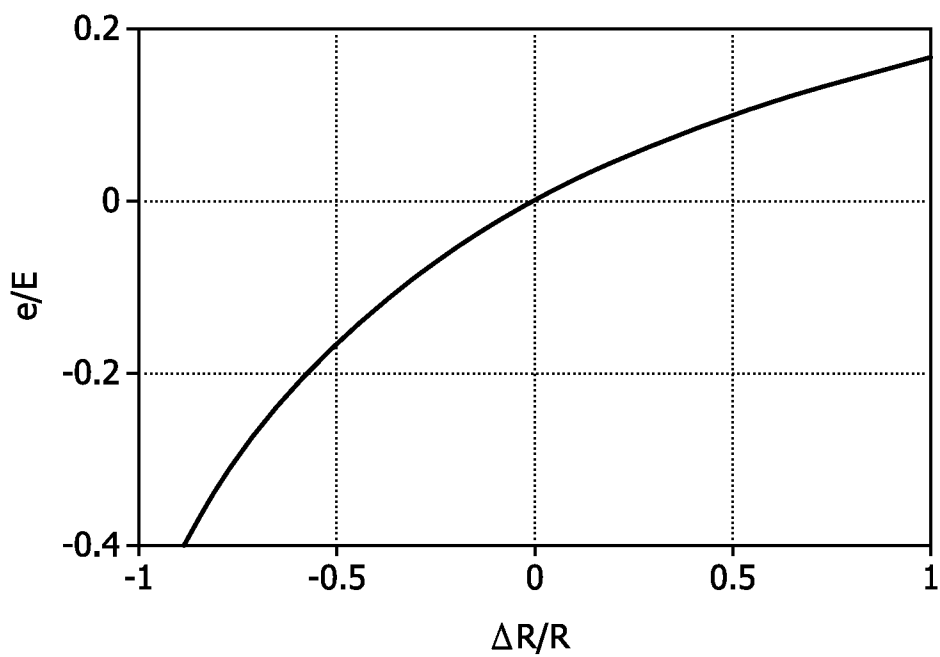


FIG. 2b

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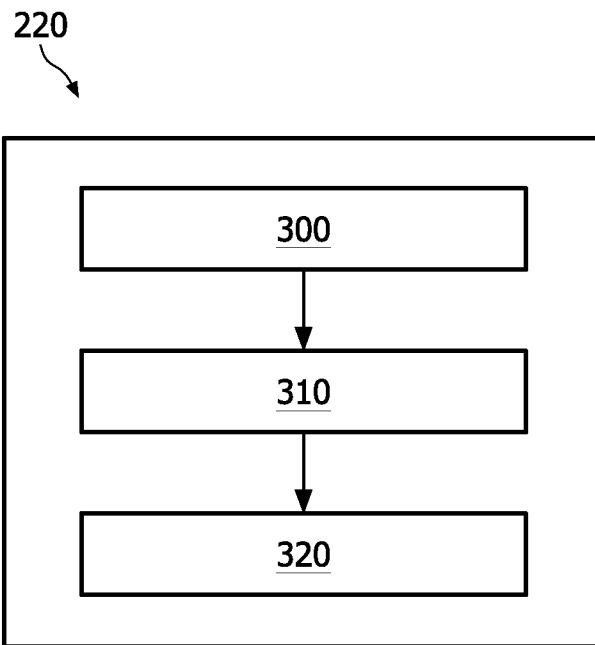


FIG. 3

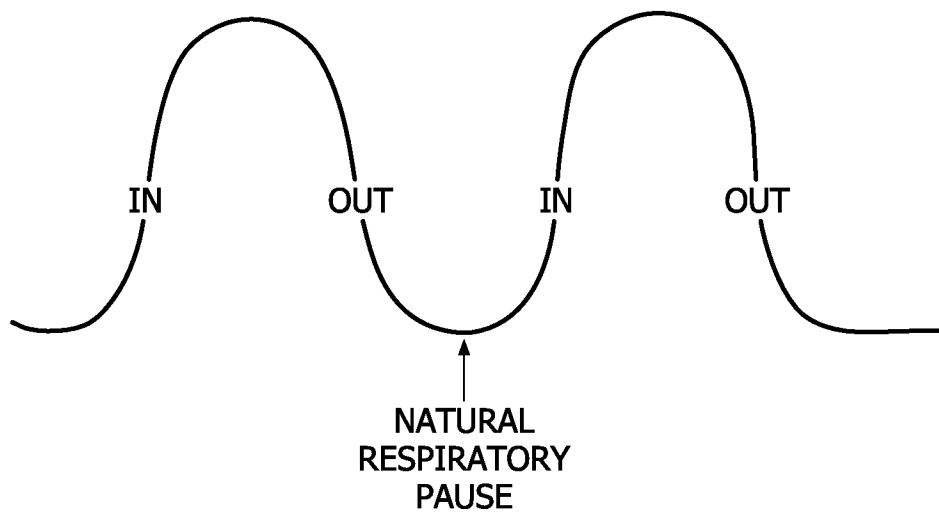


FIG. 4a

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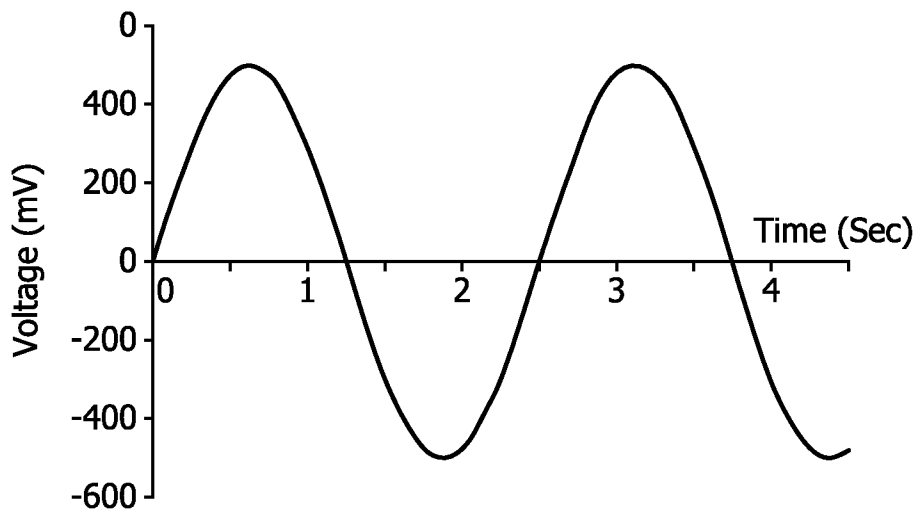


FIG. 4b

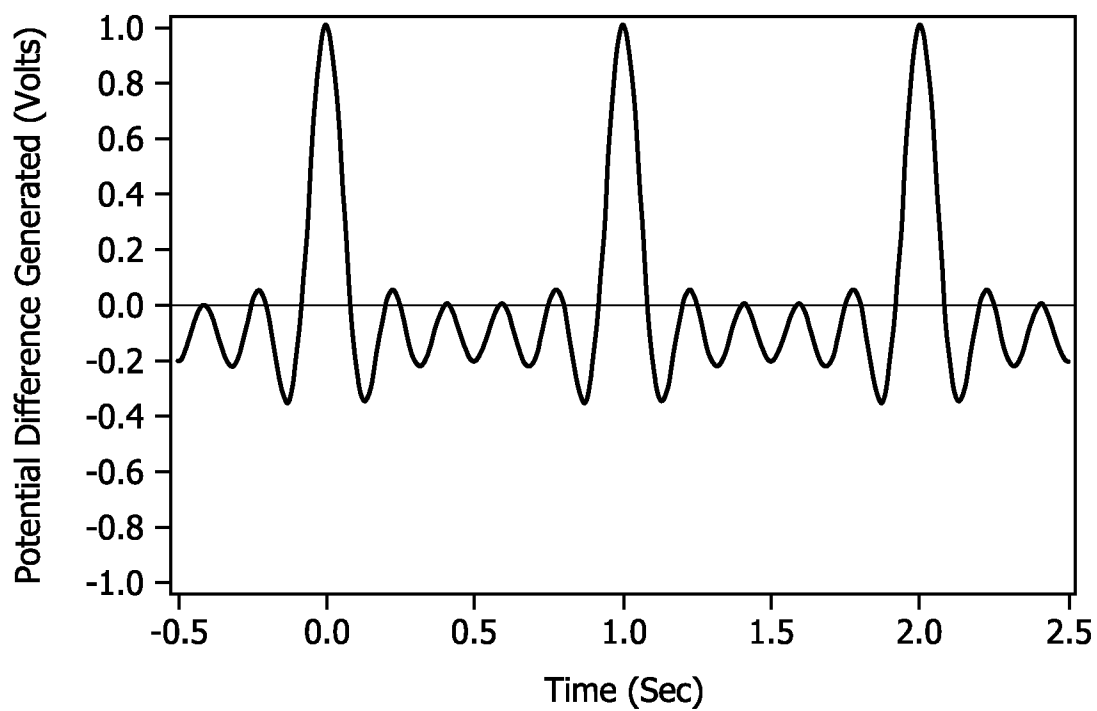


FIG. 4c

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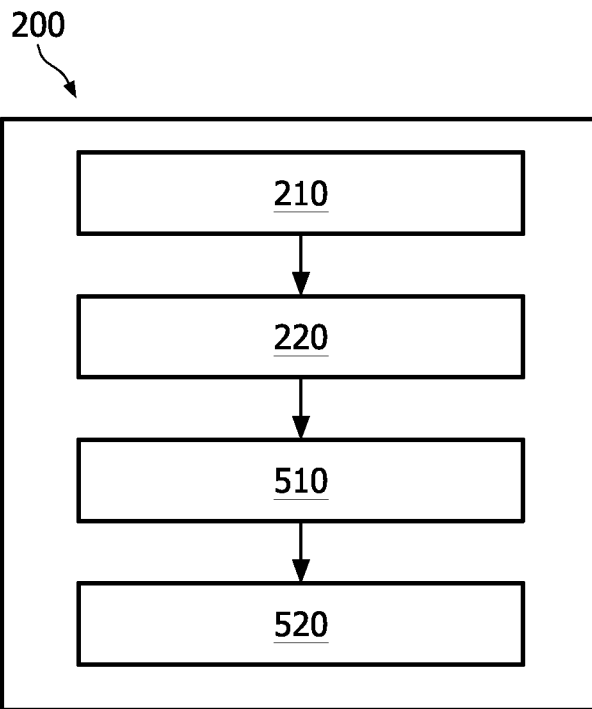


FIG. 5

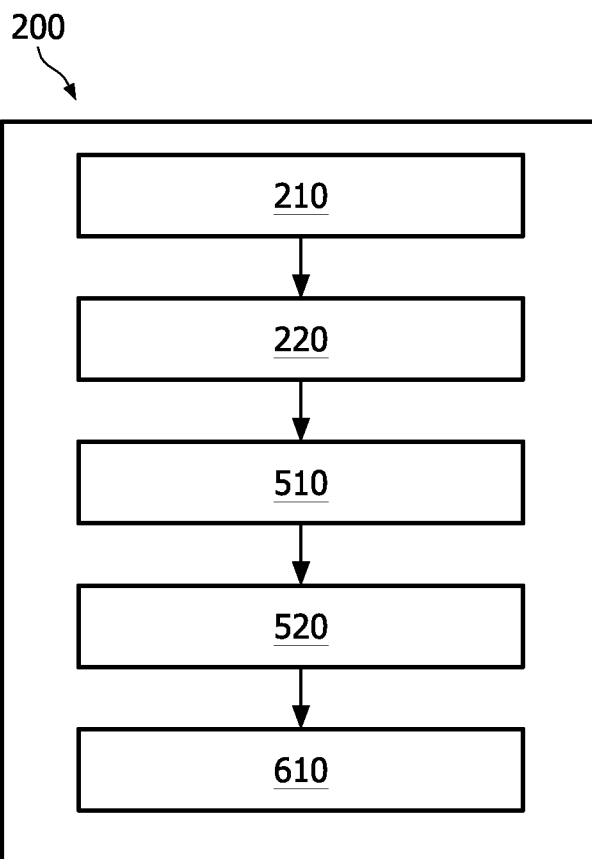


FIG. 6

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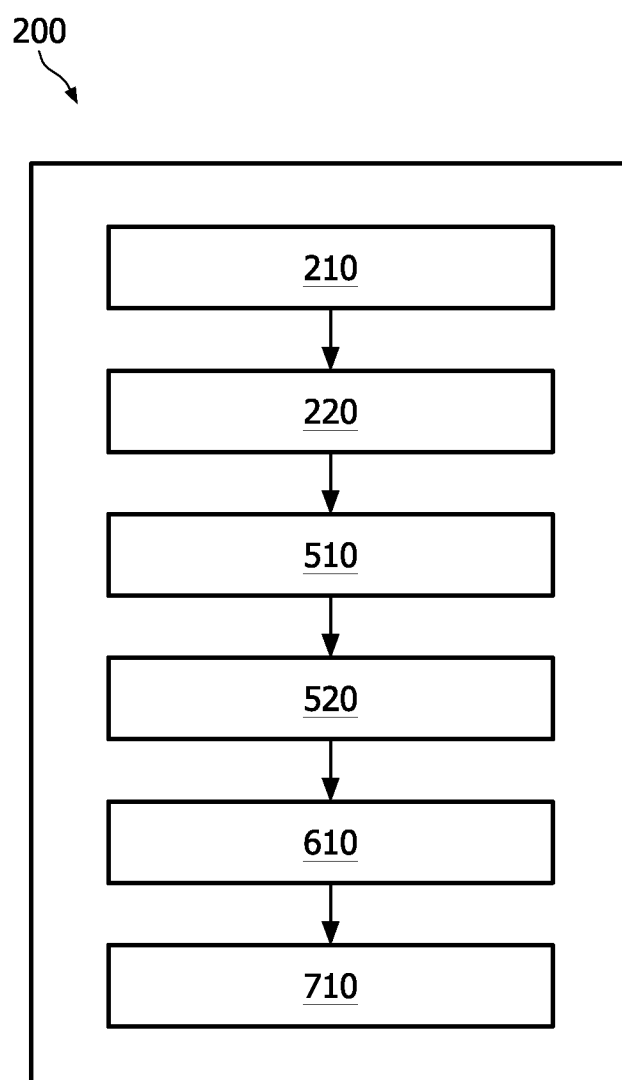


FIG. 7

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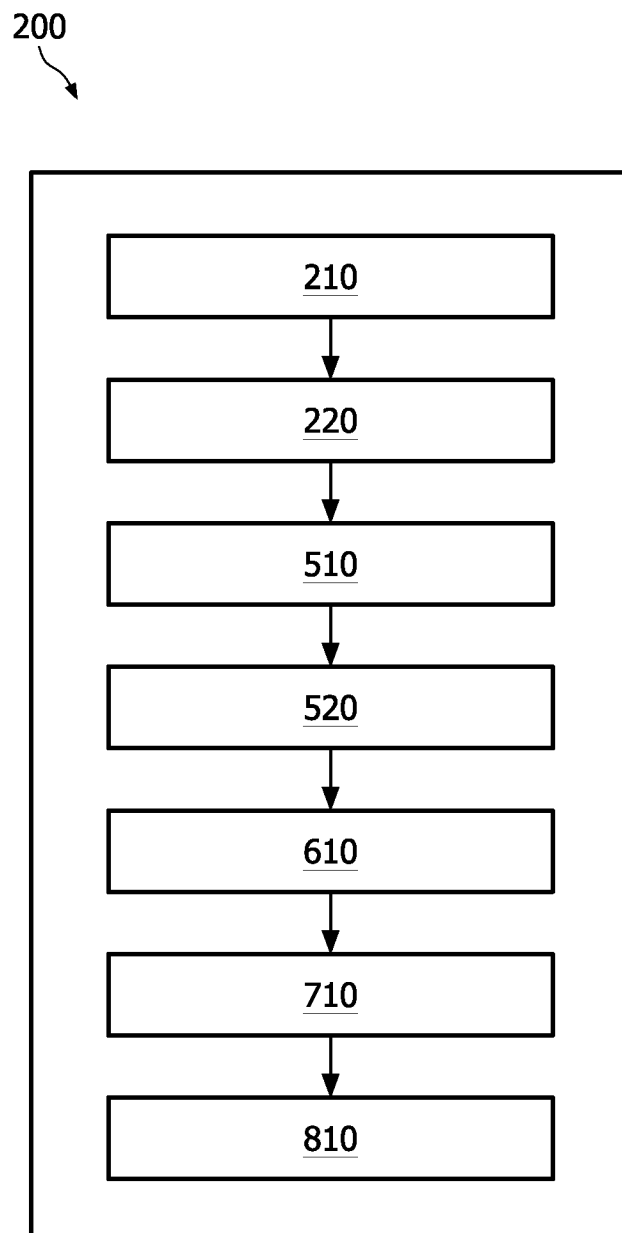


FIG. 8

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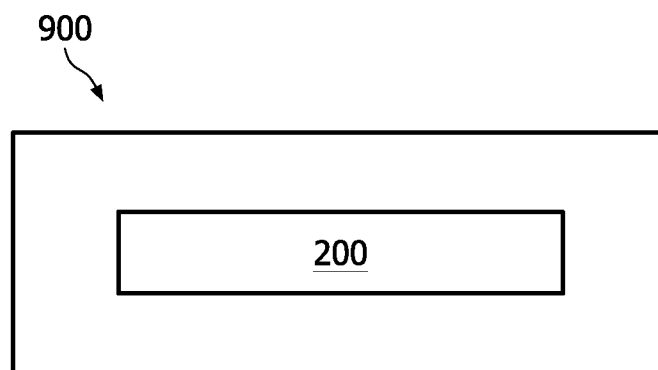


FIG. 9

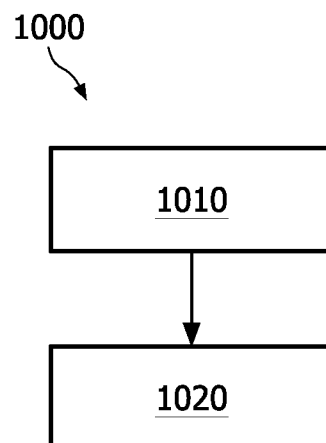


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2010/050933

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/103 A61B5/11 A61B5/113 A61B5/08
ADD.

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)

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)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/100843 A1 (HOFFMAN ANDREW [US]) 29 May 2003 (2003-05-29)	1, 2, 4, 5, 7-10
Y	paragraphs [0087] - [0113], [0122], [0127]; claims 1-26; figures 1-17 -----	3
X	US 2004/077934 A1 (MASSAD TAMIR [IL]) 22 April 2004 (2004-04-22)	1, 2, 4-10
Y	paragraphs [0312] - [0331], [333] - [0345], [357] - [0358], [0362] - [0363]; figures 1-10, 17 -----	3
Y	US 5 178 151 A (SACKNER MARVIN A [US]) 12 January 1993 (1993-01-12) column 10, lines 10-24 -----	3
	-/--	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

7 June 2010

Date of mailing of the international search report

15/06/2010

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Apostol, Simona

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2010/050933

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CHAM GW ET AL: "Clinical predictors of acute respiratory acidosis during exacerbation of asthma and chronic obstructive pulmonary disease" EUROPEAN JOURNAL EMERGENCE MEDICINE, CHAPMAN AND HALL, LONDON, GB, vol. 9, no. 3, 1 September 2002 (2002-09-01), pages 225-232, XP009134409 ISSN: 0969-9546 the whole document -----	1-10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2010/050933

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

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

1. ☒ Claims Nos.: 11
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 11

Claim 11 relate to a method for diagnosing asthma. The method seems to be oriented mainly to clinical applications in the field of medical diagnostic; as resulted from the description (p. 1, li. 9-p.2, li. 21) and from the claims 1-2. The method of claim 11 comprises the steps of acquiring (1010) (identifiable with the the examination phase (i) of a diagnostic method) and analysing (1020) at least one physical deformation feature of the body. The method steps are not detailed in the description, but a corresponding device is disclosed, comprising a data acquisition module (210) and an analysis module (220) configures to acquire and analyse said at least one physical deformation feature of the body. The analysis step appears to encompasses implicitly all the further steps of a diagnostic method: (ii) the comparison of these data with standard values (see cl. 7) (iii) the finding of any significant deviation, i.e. a symptom, during the comparison (see diagnose the asthma condition in cl. 7) (iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase (see the notification in cl. 8) Thus the method of claim 11 is considered to be a diagnostic method practised on the human or animal body according to the Rule 39.1(iv) PCT.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2010/050933

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2003100843	A1	29-05-2003	NONE	
US 2004077934	A1	22-04-2004	US 2010037753 A1	18-02-2010
US 5178151	A	12-01-1993	NONE	

专利名称(译)	哮喘的诊断		
公开(公告)号	EP2405812A1	公开(公告)日	2012-01-18
申请号	EP2010708642	申请日	2010-03-04
[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
申请(专利权)人(译)	皇家飞利浦电子N.V.		
当前申请(专利权)人(译)	皇家飞利浦N.V.		
[标]发明人	BUSSA NAGARAJU RAJAMANI KUMAR THIRUNELLAI JAIN ABHISHEK		
发明人	BUSSA, NAGARAJU RAJAMANI, KUMAR THIRUNELLAI JAIN, ABHISHEK		
IPC分类号	A61B5/103 A61B5/11 A61B5/113 A61B5/08 A61B5/00		
CPC分类号	A61B5/113 A61B5/6819 A61B5/6822 A61B5/6833 A61B2562/0261		
优先权	2009154707 2009-03-10 EP		
外部链接	Espacenet		

摘要(译)

公开了一种用于诊断哮喘的装置 (200)。该装置 (200) 包括数据采集模块 (210)，其被配置为获取与被检查对象的鼻翼扩张，颈缩回和沿海回缩中的至少一个相关联的至少一个物理变形特征和分析模块 (220)。配置成分析所获取的至少一个物理变形特征，该至少一个物理变形特征与检查中的受试者的鼻翼扩张，颈缩回和沿海内收缩中的至少一个相关联，并且基于所分析的至少一个物理变形特征来诊断哮喘。至少有一个鼻翼扩张，颈部收缩和受检对象的沿海收缩。所公开的装置 (200) 可用于监测家中，医院或门诊患者的哮喘。