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(54) **Title**: PORTABLE DEVICE FOR MONITORING AND REPORTING OF MEDICAL INFORMATION FOR THE EVIDENCE -BASED MANAGEMENT OF PATIENTS WITH CHRONIC RESPIRATORY DISEASE

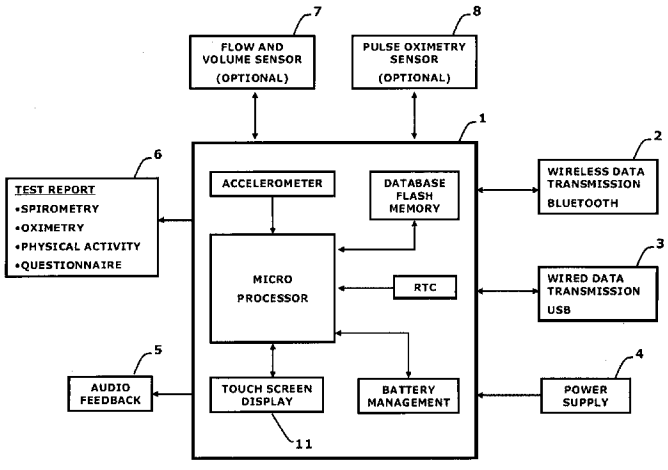

FIG. 1

(57) **Abstract**: The present invention relates to an integrated tele-health system/device for the monitoring and reporting of medical information for the evidence-based management of patients with chronic ' respiratory disease. The device comprises substantially a central unit which measures and collects information related to the state of health of the patient, and it is provided with means for wireless or cable transmission of the collected data using a microprocessor based system with a touch screen display, USB communication port and Bluetooth. According to the invention, the device further comprises: a removable sensor for the measurement of respiratory air flow and volume, a removable pulse oximetry sensor and a motion sensor. Stored data can be then delivered through landline, broadband, wireless and cell-phone technology to be received by a web server and can then be accessed by medical staff. Being completely portable, the device according to the invention is provided with a battery of known type, which can be substituted by the user or it can be rechargeable.

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PORTABLE DEVICE FOR MONITORING AND REPORTING OF MEDICAL INFORMATION FOR THE EVIDENCE-BASED MANAGEMENT OF PATIENTS WITH CHRONIC RESPIRATORY DISEASE.

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The present invention relates to an integrated tele-health system/device for the monitoring and reporting of medical information for the evidence-based management of patients with chronic respiratory disease.

The device comprises substantially a central unit which measures and collects information related to the state of health of the patient, and it is provided with means for wireless or cable transmission of the collected data using a microprocessor based system with a touch screen display, USB communication port and Bluetooth. According to the invention, the device further comprises: a removable sensor for the measurement of respiratory air flow and volume, a removable pulse oximetry sensor and a motion sensor. Stored data can be then delivered through landline, broadband, wireless and cell-phone technology to be received by a web server and can then be accessed by medical staff.

Being completely portable, the device according to the invention is provided with a battery of known type, which can be substituted by the user or it can be rechargeable.

INTRODUCTION

At the base of the new requirements for better and more intelligent treatments must be a series of evidence-based management tools to help to create a

more rational and intelligent way to deal with health based on evidence.

Scientific, economic, cultural and social progress have combined to help us obtain significant advantages in health management. The average life expectancy of the population has increased over the last ten years. The conditions which society must come to terms with are those chronic degenerative diseases, which although they cannot be cured, can be kept under control with suitable pharmaceutical and behavioural therapies.

The respiratory pathologies are at the current state of play one of the most significant health problems for the number of patients afflicted - even younger people - as well as for the high rate of mortality and the prevalence, and the significantly disabilitating effects on the patients and for the very high direct and indirect costs associated.

According to the American Thoracic Society (ATS) and the European Respiratory Society (ERS) "chronic obstructive pulmonary disease (COPD) affects about 210 million people globally and causes some 3 million deaths annually. The disease is a major drain on healthcare budgets with 50% of costs accounted for by hospital admissions, much of which could be avoided through development of more responsive models of care that allow earlier recognition and treatment of exacerbations".

An exacerbation can be defined as a sustained worsening of the patient's symptoms from that beyond normal day-to-day variation. Exacerbations can result in a more rapid decline of lung function, increased

peripheral muscle weakness, decreased quality of life, increased health care costs, and increased mortality. It has been demonstrated that early therapy speeds exacerbation recovery, and reduces health care utilization. Patients should be instructed to respond early in the course of an exacerbation by activating their predetermined action plan.

In a self-management program, well-designed clinical trials that provide valid, reproducible and interpretable results should also instruct the patient to treat and prevent the onset of respiratory exacerbations.

Real-time patient remote monitoring and screening for homecare purposes can be delivered through landline, broadband, wireless and cell-phone technology. These tele-health applications may forever change, while dramatically improving the way healthcare will reach the ever increasing number of COPD patients worldwide.

Chronic respiratory diseases can lead to chronic respiratory failure: inadequate gas exchange by the respiratory system, with the result that arterial oxygen and/or carbon dioxide levels cannot be maintained within their normal ranges. When chronic respiratory failure occurs, there is an increase in the impact of the disease on the patient's daily life and well-being.

Lifestyle, which includes physical inactivity in daily life, plays a very important role in terms of both disability and mortality. It is now well recognized that regular physical activity may prevent

or delay the onset or progress of different chronic diseases. It is known, for instance, that in patients with chronic obstructive pulmonary disease (COPD), lower levels of physical activity in daily life are related to higher risk of hospital readmission and also to shorter survival.

One of the main consequences of chronic respiratory disease is a daily activity performance drop, which must be measured in this patient population. Therefore, the assessment of the amount and intensity of physical activity in daily life is of major importance given the close relationship between activity levels and health.

A better understanding of the present invention will be obtained with reference to the following description and with reference to the attached plates of drawings, which illustrate merely by way of non-limiting example a preferred embodiment thereof:

Figure 1 is a block diagram of the device according to the present invention;

Figure 2 shows a preferred embodiment of the device with flow and volume sensor connected;

Figure 3 is a different view corresponding to fig. 2;

Figure 4 shows the invention with sensors disconnected; and

Figure 5 is a diagram of SpO2% vs time during 6MWT.

DESCRIPTION OF THE INVENTION

In view of the above, it appears clear that the state of health of a patient affected by respiratory

disease like COPD requires a daily "overview" of several vital signs (or vital parameters) in order to spot in advance any potential worsening of the condition which, if not brought under control, generally leads to exacerbations and eventually to a spell in hospital.

The present invention is specifically aimed to provide a device and/or system for carry out said "overview" directly by the patient him/herself.

Often these patients are able to monitor several vital signs at home, for instance pulse oximetry, which with respect to the patients baseline resting value can be subject to a fall off under exercise or during sleep, when the spontaneous ventilation reduces for physiological reasons.

Pulse oximetry is the most simple, non-invasive method for evaluating the level of oxygen in the blood. This measurement provides a parameter called oxygen saturation (%SpO_2), closely related to SaO_2 measured by blood sampling, a much more complicated and invasive method. There isn't life without oxygen: this is why pulse oximetry is considered a vital sign.

In the past few years through technological progress, which has enabled the production of pocket-size pulse oximeters and spirometers at reduced costs, many doctors have included the measurement of %SpO_2 and expiratory peak flow (PEF) as vital signs equally as important as the standard ones (such as body temperature, heart rate, blood pressure), used when performing a general medical check-up of a patient to identify the type of disorder present.

PERFORMANCE EVALUATION

A fundamental objective in the management of respiratory disease is to increase a patient's performance in routine daily activities. Performance assessment is possible by either patient reporting or by direct observation by noting the rate, speed or efficiency of a particular activity. However this impractical process is difficult to standardize and extremely time consuming.

According to the present invention, it is provided a device comprising motion detectors and activity monitors that allow for a plausible daily activity evaluation in any setting.

The precise quantification of physical activity is of particular importance in measuring the outcomes of interventions in frail, sedentary populations such as COPD and the elderly, because even small improvements in physical functioning such as walking and balance may translate into significantly improved quality of life.

Objective assessment of daily activity performance in non laboratory-settings is becoming a reality thanks to activity monitors in the form of a simple pedometer which counts the number of steps taken by a patient to more elaborate devices capable of measuring movement on three axis.

An accelerometer is a technologically very advanced device, which allow the quantity and intensity of movements to be determined and measured. The instrument is able to measure both the total amount and the intensity of spontaneous activities performed throughout the day in the subject's own environment.

capacity". Walking is now considered as the most important and common type of physical activity performed in daily life and is the activity targeted for improvement in most pulmonary rehabilitation programs. Walking more in daily life is an important indicator of improvement after respiratory rehabilitation protocols, and this walking can indeed be accurately assessed by motion sensors. Some tests can be self-paced such as the 6-minute walk test (6MWT), and require no advanced training or special equipment. The 6MWT is a very simple, safe and reproducible fitness test, and it is widely used in the evaluation of respiratory diseases. The test requires no complex instrumentation, can be made easily even by patients with a severe level of disability and, last but not least, represents more closely than any other test "normal life activity" and so is therefore an excellent indicator of the quality of life of the patient.

Guidelines for the application of the 6MWT in a clinical setting were developed by the American Thoracic Society (ATS) in 2002. The standard procedure requires that at the start of the test and then at every one minute interval during the test, a pulse oximeter is used to record (a) the saturation (SpO2%) and (b) the heart rate (BPM) of the patient. In addition, at the end of the test, the total distance covered should be recorded.

People who suffer of moderately severe respiratory impairment can perform a 6MWT which has proven to be extremely useful to measure patient response to

therapeutic interventions for pulmonary and cardiac disease.

It is common practice that, in the event that the SpO2 level falls below 82% during the 6MWT, the test should be halted and then repeated with the patient given supplemental oxygen (O2).

In this case, the test in generally repeated following a rest interval of at least 15 minutes, with increasing oxygen flow of 2, 4 and then 6 litres per minute until the patient is able to complete the test maintaining an SpO2% level of at least 90% during the whole test.

According to the present invention, the mechanisms of exercise intolerance can now be studied in further depth through the acquisition of physiologic measurements such as the distance walked and the reduction of the oxygen level in the blood during the exercise.

Walking is a simple yet ideal form of daily exercise to evaluate the overall response of the pulmonary and cardiovascular systems, systemic circulation, peripheral circulation, blood, neuromuscular units, and muscle metabolism.

Exercise testing in the routine clinical assessment of the functional status of a patient is now considered a fundamental component because health-related quality of life, survival rates and hospitalization rates are all affected by the degree of exercise tolerance impairment in COPD patients.

CALCULATION OF THE CS INDEX OR O2_GAP FOR LONG TERM OXYGEN PRESCRIPTION

One of the objective of the invention is the use of the 6MWT to determine the prescription of long term oxygen. An equation which can be integrated into an electronic device, in order to calculate the oxygen requirement of the patient through a 6MWT carried out without any additional oxygen supply to the patient.

The equation was derived according to the following method. Ninety six patients with respiratory disease were required to carry out the 6MWT in ambient air and without any supplementary oxygen. The parameters of this 6MWT were recorded every minute ie the distance walked, the SpO2% from the start to the end of the test, as well as the Heart Rate, the recovery time, the degree of breathlessness and fatigue, as per the international guidelines.

Then using this data, the following parameters were derived or calculated as illustrated below.

(a) AUCgap, which represents the difference between the area under the curve where SpO2% = 100% vs. time and the area below the curve showing the SpO2% vs. time of the patient during the test. The time limits for the evaluation of the area are represented by the duration of walk phase (see FIG. 4).

(b) MT, which represents the test duration expressed in minutes (from a minimum of 0 to a maximum of 6).

(c) Base SpO2gap, which represents the difference between SpO2% = 100% and the SpO2% baseline at rest before the start of the walk phase.

(d) RT which represents the recovery time in seconds of the patient at the end of the test, for the SpO2 value to return to the base value recorded before the

test, even if the test is stopped before the full 6 minutes.

(e) PPD which represents the percent predicted distance, which is the percentage of the distance covered by the patient during the test compared to the distance covered by a normal subject. The distance (in metres) covered by a normal subject is calculated from the equation by Enright and Sherill, where:

For males : (7.57 x height in cm) - (5.02 x age in years) - (1.76 x weight in kg) - 309

For females: (2.11 x height in cm) - (5.78 x age in years) - (2.29 x weight in kg) - 667

In the case that a patient has a base SpO2% at rest below 82% prior to the start of the test, then the patient cannot make the test without a supplement of 6 L/min of oxygen.

The equation for the calculation of the CS Index or O2_Gap, is expressed as follows:

$$\begin{cases} \textit{If } MT \geq 1, \textit{ then:} \\ \qquad O2\ (L/min) = \dfrac{\left\{ \dfrac{[(AUCgap/MT) + (BaseSpO2gap/7)]^2 + \sqrt{RT}}{\sqrt{PPD}} - 9.31 \right\}}{8.94} \\ \\ \textit{If } MT = 0, \textit{ then:} \\ \qquad O2\ (L/min) = 6 \end{cases}$$

This equation enables us to calculate the O2_Gap, that we have defined also CS Index, which represents the quantity of oxygen expressed in L/min which must be given to a patient in order that the patient can complete the 6MWT without desaturating below the level

of 90% SpO2, and also without desaturating below the level of 82% SpO2 for the patients who require 6 L/min of oxygen in order to complete the test.

The application of the CS Index equation in the calculation of the "oxygen gap" in the 6MWT carried out without the supply of supplemental oxygen, to calculate the oxygen requirement when the test is carried out with supplemental O2.

The capacity of the 6MWT to determine the quantity of oxygen required for the test to be carried out has been evaluated using a group of patients which included:

(a) A sub group of patients able to make the test without supplemental O2 (0L, n=27),

(b) A sub group requiring supplemental oxygen at a flow rate of 2L/min (2L, n=24)

(c) A sub group requiring supplemental oxygen at a flow rate of 4L/min (4L, n=24)

(d) A sub group requiring supplemental oxygen at a flow rate of 6L/min (6L, n=21).

The application of the equation to calculate the CS Index to the analysis of the results of the 6MWT in patients within the same subgroup enables distinctions to be made between these patients.

The advantages of using the CS Index equation in clinical practice and in pulmonary/respiratory laboratories. The equation is of considerable benefit in the management of respiratory patients within pulmonary and respiratory laboratories, in the pulmonology, cardiology and rehabilitation fields as the equation, as illustrated above, enables the GAP_O2

(ie the O2 requirement to complete the test) to be determined by a single standard walking test without any supplemental oxygen. In this way, the successive tests with supplemental oxygen supplies of 2L/min up to 6L/min are no longer required, it is sufficient to analyse the parameters measured in the 6MWT using the new equation.

This brings both a greatly reduced level of effort and stress for the patient as well as a saving for the respiratory lab in terms of physical resources as well as trained personnel due to the reduced time required, the new total time could be even 1/8 - 1/10 of the time required to determine the amount of oxygen necessary.

In particular, the function obtained predicts the oxygen requirement as shown in the successive 6MWT carried out with an O2 flow from 0 to 6 L/min, showing in a statistically significant way the quantity of oxygen required to make the test without desaturating below 90% SpO2 or below 82% for the patients needing 6L/min O2.

In conclusion, the equation calculates the size of the oxygen gap in the walking test with a high degree of sensibility, specificity and diagnostic accuracy with sensibility = 91.35%, specificity = 92.59% and diagnostic accuracy = 91.88%, in the calculation and prediction of the O2 requirement to complete the exercise.

QUALITY-OF-LIFE MEASUREMENTS

Quality of life can be defined as "the gap between that which is desired in life and that which is

achieved". The areas affected by health status which reflect the effect of respiratory disease on the ability to perform and enjoy daily activities are the main focus of health-related quality of life (HRQL)

Increasing documentation of the favourable effect of rehabilitation therapy for COPD patients is proof that no other therapy has the same rate of improvement in exercise endurance, dyspnea, functional capacity and overall quality of life.

According to the most recent guidelines published by the main international scientific lung societies, the assessment of patient-centered outcomes, such as symptoms, performance in daily activities, exercise capacity and health-related quality of life (HRQL), should be an integral component of pulmonary disease management. As well as the value of oxygen saturation, the management suggested by the new guide lines requires the evaluation of the improvement of the performance and of the exercise capacity, intended to mean the patient's ability to engage in activities of daily living, the measurement of the respiratory function by spirometry as well as the compilation of a specific questionnaire on the quality of life and on the symptoms.

In practice for the patient, and in particular for the older patients, it is very complex if not impossible to manage several different medical devices able to measure all of the parameters proposed by the new guide lines. In addition, it is very difficult for the patient to transfer all of the measured parameters to the medical centre.

The innovative new device/system according to the present invention, is developed to measure and to transmit all of the required diagnostic parameters for the "home care" monitoring of a patient with chronic respiratory disease. However, it has become clear that regardless of the type of respiratory disease, patients experience a substantial morbidity from secondary impairments, such as peripheral muscle, cardiac, nutritional, and psychosocial dysfunction.

This device carries out the functions required by the healthcare givers, who need to provide a better level of care based on new high technology at low cost with complete integration. The clinical application consists of non invasive and high technology testing, with low cost and easy to use instruments and sensors. The device is simple to use which is a new development for home care, where the technology has not always been simple, especially for older patients.

So the traditional concept of a visit to the doctor is extended to a virtual visit, as every patient can make use of these services even staying at home. And thus a new intelligent and completely digital ambient is created, combining diagnostic instrumentation with information technology as well as communications.

A COMPARISON OF THE PHYSICAL ACTIVITY CARRIED OUT BY A PATIENT

According to the latest scientific publications in the field of pneumology, the distance walked is of fundamental importance in the evaluation of the state of health of a patient with chronic respiratory

disease. In addition, when two tests by the same patient are compared, then if the trend of the desaturation (in other words the reduction of the $\%SpO_2$) during the test is different, then the evaluation only of the distance walked is not sufficient.

Let us therefore define an innovative index/parameter: Desaturation Area/Movement.

This parameter represents the area under the curve, including the baseline value at rest of the $\%SpO_2$ value and the graph of the $\%SpO_2$ during exercise, for instance during walking, shown in relation to the total movement recorded in all three directions by the accelerometer activity during the test. This area under the curve can also be shown in relation to the movement represented by the number of steps taken, also calculated by the accelerometer.

Considering that the device according to the present invention is able to measure simultaneously the $\%SpO_2$ (pulse oximetry) as well as the physical activity (accelerometry), the device is also able to calculate said index (Desaturation Area/Movement) and to show it on the display at the end of a measurement session.

This represents a peculiar feature of the invention and has a very significant implication in the evidence-based evaluation of the cardio-respiratory system during physical exercise, and thus in the evidence-informed manner. Indeed until now, as well as the difficulty of having to use two different devices, for instance a pedometer and a pulse oximeter, to

measure the SpO_2 values and the distance walked, this index was simply not available.

The current situation gives great difficulties both to the patient seeking efficient self-management, as well as to the medical staff. Using the present invention these problems can be completely overcome.

In other words, if we consider a car which is in perfect mechanical condition, it is logical to think that this car is able to cover a greater distance with a litre of fuel compared to a car which is not in perfect mechanical condition. In the same way, a patient during physical activity will have a lesser or a greater level of fall of the $\%SpO_2$ (desaturation) according to his or her state of health. The relationship between Desaturation Area and Movement indicates the level of desaturation in relation to the movement or the distance covered and can therefore be considered an index of the performance of the patient.

The Desaturation Area/Movement enables the comparison of two measurement sessions in order to measure the variation in the state of health of the patient through their own performance and exercise capacity.

DESCRIPTION OF THE SENSORS

The heart of the system is the central unit which is based on microprocessor technology. The invention is also provided with input/output means by which the user interfaces with the unit. These I/O means are preferably constituted by a touch-screen display.

In a preferred embodiment, when the device is

switched on, it requires the insertion of some general and some respiratory-specific health-related quality of life questions. This questionnaire is first configured for the patient by the health team, who can switch on or off the various optional questions according to the specific patients requirements. Individual components of quality of life, for instance working or resting activity etc., include symptoms, functional status, mood. Questionnaires can measure these components individually or with a composite score. When the information session is completed then the patient can select the type of diagnostic test to be carried out.

One of the main advantages offered by this invention is that the central unit comprises an electrical and mechanical connection assembling system for connecting to a removable sensor for the measurement of respiratory air flow and volume. In order to allow a simpler access to the other functions the system offers, this sensor can be completely removed from the central unit when spirometry testing is not required. When the flow measurement head has been connected to the central unit through the associated conjugated connector with conjugate contact elements, spirometry tests can be carried out to determine the most important spirometry parameters such as the PEF, FEV1, FEF25%-75%. At the end of the test, the unit displays the results and compares them to the reference values which have been set by the doctor during the device setup. Thus the patient can view various messages about his/her state of health. When the test is finished the respiratory measurement head

(the complete sensor) can be removed from the central unit.

The central unit can be placed within a belt worn close to the body on the waist, wrist or ankle of the patient, and then a finger probe is worn connected to the central unit for the pulse oximetry, to measure both the $\%SpO_2$ and the Pulse Rate (BPM). The test can be carried out at rest, or during physical exercise or even overnight during sleep.

According to a peculiar feature of the invention, at the same time as the pulse oximetry is measured and recorded, the trixial accelerometer which is integrated into the central unit, carries out the function of activity monitor as well as motion detector.

If the patient walks then the number of paces can be detected and recorded as well as the physical activity in each of the three directions. If instead the patient sleeps then the position of the body can be recorded during sleep face up, face down, right side or left side, etc., as well as the movements during the complete test period.

At the end of the test, any periods of arterial desaturation, will be analyzed and compared to the results of the physical activity measured by the accelerometer. Indeed, it is well known that in many cases patients with chronic respiratory conditions will have a rapid fall off in arterial oxygen saturation following exercise, even very modest exercise.

Specifically the calculation of the index Desaturation Area/Movement or the steps taken, will give very important information for each test, or on

the improvement or deterioration in the respiratory condition by comparing the current test with a previous test made: this also enables effective self management by the patient who has objective data with which to compare his or her exercise tolerance and to remain within the limits suggested by the doctor.

A further and very significant advantage of the invention is the possibility to transmit the test data to a web server so that the test data can then be seen by the doctor and thus the doctor can vary the therapy as required very quickly indeed. In some cases, these patients are treated with oxygen at home in order to compensate any desaturation.

In addition, desaturation during sleep, and above all the rapid desaturation caused by sleep apnea, can be linked to a body position and the analysis of the sleeping position is possible thanks to the accelerometer within the device. Also, even minimum periods during sleeping hours when the patient stands up or walks can be identified as waking hours and thus excluded from the sleep analysis.

FURTHER ADVANTAGES OF THE INVENTION

The subject of this invention is a new device with a specific and innovative way of use both for the patient who uses it and also for the manufacturer.

The patient has the advantage of being able to use and to purchase, if required, a single product - i.e. the central unit - which carries out four functions: questionnaire, spirometer, pulse oximeter and activity monitor or motion detector. Furthermore, as an alternative, he/she can also reduce the number of

sensors depending on his/her specific diagnostic or therapeutic requirements. Then later on if the requirements change, additional sensors can be purchased without the needing of substitute the central unit.

Having a single central unit which is able to manage and to integrate with every sensor within the system guarantees a major simplicity of use as well as an economic advantage, and the device fully respects the recommendations of the international guide lines for the management of chronic respiratory disease.

The manufacturer has the advantage of manufacturing a single product which can include one or more sensors, according to the needs of the customer. This will reduce the production costs and also optimize the level of stock required to be held, given that only one instead of three different devices needs to be manufactured.

In more detail, the respiratory measurement head through the associated conjugate connector with conjugate contact elements, which then connects to the central unit, represents a very innovative technology and simplifies the use for the patient.

For instance, during the walking test to measure the pulse oximetry and the movement, it is very convenient to reduce the size of the device to be carried by removing the respiratory measurement head and thus facilitate walking. The same advantage is also available when measuring overnight pulse oximetry, when the patient is connected to the device worn on the belt.

All of these aspects improve the use of the device and enable multiple devices to be incorporated into a single system able to carry out a multitude of fundamental diagnostic tests, vital for the home management of chronic respiratory disease.

So to summarize, the integration into a single device of three different sensors for spirometry, pulse oximetry and for motion analysis and of the derived index which compares the desaturation with the movement, completely and totally follows the recommendations of the latest guide lines of the major Scientific Societies for the home management of patients with chronic respiratory disease.

So the very significant strength of this new invention is the real application of these guide lines using a single and simple to use device.

LIST OF REFERENCE USED IN DRAWINGS:

(1) central unit
(2) Bluetooth module
(3) USB port for data transmission
(4) external power supply
(5) speaker for audio feedback
(6) test report output
(7) flow and volume sensor
(8) pulse oximetry finger sensor
(9) oximetry sensor male connector
(10) oximetry sensor female connector
(11) touch screen display
(12) flow and volume sensor female conjugated connector
(13) central unit male conjugated connector.

CLAIMS

1. Device for monitoring and reporting of medical information for the evidence-based management of patients with chronic respiratory disease, characterized in that it is portable and it substantially comprises a central unit (1) which measures and collects information related to the state of health of the patient, wherein it further comprises, in combination: a removable sensor for the measurement of respiratory air flow and volume with special connecting means, a removable pulse oximetry sensor and motion sensor/detector means.

2. Device according to claim 1, characterized in that it is provided with means for wireless or cable transmission of the collected/stored data using a microprocessor based system comprised in said central unit (1); said data related to the patient being delivered through landline, broadband, wireless and cell-phone technology to be received by a web server and can then be accessed by medical staff.

3. Device according to claim 1, characterized in that it is provided with an input/output touch screen display, USB communication port and/or Bluetooth and/or wireless communication means.

4. Device according to claim 1, characterized in that said motion sensor/detector means comprise motion detectors and activity monitors for evaluation of a plausible daily activity of the patient in any setting.

5. Device according to preceding claim, characterized in that said motion sensor/detector means comprise a triaxial accelerometer for "activity

monitor", that is suitable to discriminate between low, moderate and high overall activity levels as well as to categorise individuals as sedentary, moderately active or active and it is also able to detect a variety of body positions and physical activities; the output of the accelerometer being measured in the three dimensions - X = anteroposterior, Y = vertical, Z = mediolateral vectors - and being then integrated by the central unit (1) to represent movement as velocity over time using the square root of the sum of squares of each individual vector.

6. Device according to claim 1, characterized in that the collecting/storing data relating to the patient comprise the acquisition of physiologic measurements such as the distance walked and the reduction of the oxygen level in the blood during the exercise.

7. Device according to claim 1, characterized in that it is provided with means for measuring simultaneously the $\%SpO_2$ (pulse oximetry) as well as the physical activity (accelerometry), wherein the central unit (1) is able to calculate a Desaturation Area/Movement index and to store and show it on a display at the end of a measurement session; said index representing the area under the $\%SpO_2$ curve, including the baseline value at rest of the $\%SpO_2$ value and the graph of the $\%SpO_2$ during exercise, for instance during walking, shown in relation to the total movement recorded in all three directions by the accelerometer activity during the test.

8. Device according to claim 1, characterized in that the central unit (1) comprises a special electrical and mechanical connection assembling system for connecting to a removable spirometry sensor for the measurement of respiratory air flow and volume; thereby obtaining that when spirometry testing is not required the device is absolutely and completely operational for providing its other functions to the user.

9. Device according to preceding claim, characterized in that when the spirometry sensor, or flow measurement head, has been connected to the central unit (1) through the special electrical and mechanical connection assembling system comprising an associated conjugated connector with conjugate contact elements, spirometry tests can be carried out to determine the most important spirometry parameters like the PEF, FEV1, FEF25%-75%, thereby obtaining that at the end of the test, the central unit (1) displays the results and compares them to the reference values which have been set by the doctor during the device setup, further providing to the patient suitable various messages about his/her state of health; when the test is finished the respiratory measurement head being removed from the central unit (1).

10. Device according to claim 1, characterized in that the central unit (1) can be placed within a belt worn close to the body on the waist, wrist or ankle of the patient, and then a finger probe which is removably connected to the central unit (1) is worn for the pulse oximetry test, for measuring both the $\%SpO_2$ and the Pulse Rate (BPM), thereby obtaining that the test can

be carried out at rest, or during physical exercise or even overnight during sleep; wherein at the same time as the pulse oximetry is measured and recorded, a trixial accelerometer which is integrated into the central unit (1), carries out the function of activity monitor as well as motion detector.

11. Device according to claim 1, characterized in that said central unit (1) comprises data processing and storing means and acceleration detecting and storing means, so that when the patient walks then the number of paces can be detected and recorded as well as the physical activity in each of the three directions, while when the patient sleeps then the position of the body can be recorded during sleep: face up, face down, right side or left side etc., as well as the movements during the complete test period.

12. Device according to preceding claim, characterized in that said data processing means are suitable for linking any desaturation during sleep, and above all any rapid desaturation caused by sleep apnea, to a body position; furthermore, even minimum periods during sleeping hours when the patient stands up or walks being identified as waking hours and thus excluded from the sleep analysis.

13. Device according to claim 1, characterized in that it comprises means for transmission of the collected data of a patient to a web server so that said data can then be seen by a doctor and thus the doctor can vary the therapy as required very quickly indeed; in some cases, these patients being treated with oxygen at home in order to compensate any

desaturation.

14. Device according to claim 1, characterized in that it is provided with means for measuring simultaneously the %SpO_2 (pulse oximetry) as well as the physical activity (accelerometry), wherein the central unit (1) is able to calculate a CS index or O2_Gap and to store and show it on a display at the end of a measurement session; said CS index representing the quantity of oxygen expressed in L/min which must be given to a patient in order that the patient can complete the 6MWT without desaturating below the level of 90% SpO2, and also without desaturating below the level of 82% SpO2 for the patients who require 6 L/min of oxygen in order to complete the test.

15. Device according to previous claim, characterized in that said CS index or O2_gap is calculated by using the following equation:

$$\begin{cases} \textit{If } MT \geq 1, \textit{ then:} \\ \qquad \text{O2 (L/min)} = \dfrac{\left[\dfrac{[(AUCgap/MT) + (BaseSpO2gap/7)]^2 + \sqrt{RT}}{\sqrt{PPD}} - 9.31\right]}{8.94} \\ \\ \textit{If } MT = 0, \textit{ then:} \\ \qquad \text{O2 (L/min)} = 6 \end{cases}$$

where:

AUCgap represents the difference between the area under the curve where SpO2% = 100% vs. time and the area below the curve showing the SpO2% vs. time of the patient during the test;

MT represents the test duration expressed in minutes (from a minimum of 0 to a maximum of 6);

Base SpO2gap represents the difference between SpO2% = 100% and the SpO2% baseline at rest before the start of the walk phase;

RT represents the recovery time in seconds of the patient at the end of the test, for the SpO2 value to return to the base value recorded before the test, even if the test is stopped before the full 6 minutes;

PPD represents the percent predicted distance, which is the percentage of the distance covered by the patient during the test compared to the distance covered by a normal subject.

16. Use of the equation according to previous claim for the analysis of the six minute walk test (6MWT) in the following clinical applications:

- Calculation of the requirement of oxygen during exercise using the 6MWT for the prescription of long term oxygen therapy (LTOT); and/or
- Calculation of the oxygen requirement using the 6MWT in the field of rehabilitation therapy; and/or
- Calculation of the severity of a lung disease such as COPD, pulmonary fibrosis and other respiratory conditions, and for treatments of pulmonary conditions using the 6MWT for the calculation of the disease prognosis in a patient and for the evaluation of the results of a course of therapy in a patient.

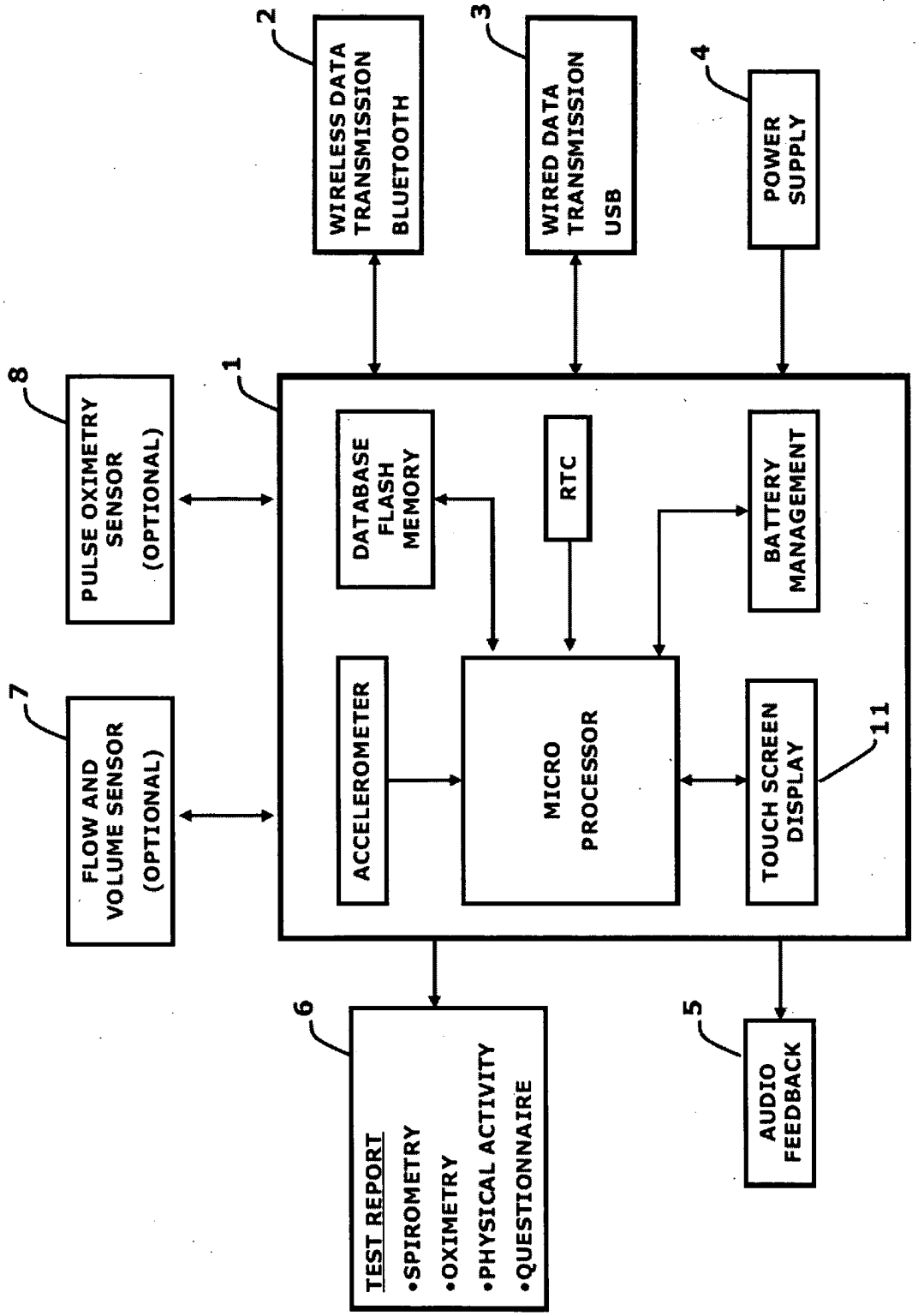
2
WIRELESS DATA TRANSMISSION BLUETOOTH
3
WIRED DATA TRANSMISSION USB
4
POWER SUPPLY
8
PULSE OXIMETRY SENSOR (OPTIONAL)
1
DATABASE FLASH MEMORY
RTC
BATTERY MANAGEMENT
7
FLOW AND VOLUME SENSOR (OPTIONAL)
ACCELEROMETER
MICRO PROCESSOR
TOUCH SCREEN DISPLAY
11
6
TEST REPORT
•SPIROMETRY
•OXIMETRY
•PHYSICAL ACTIVITY
•QUESTIONNAIRE
5
AUDIO FEEDBACK

FIG. 1

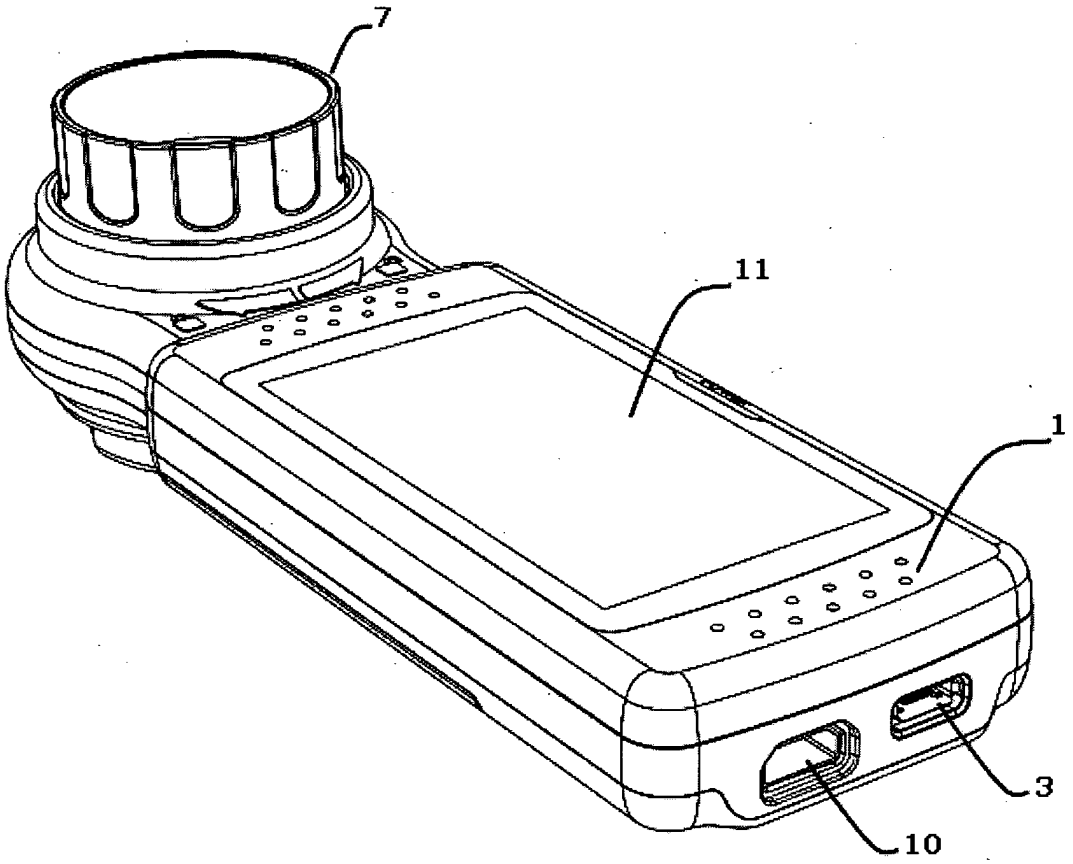

FIG. 2

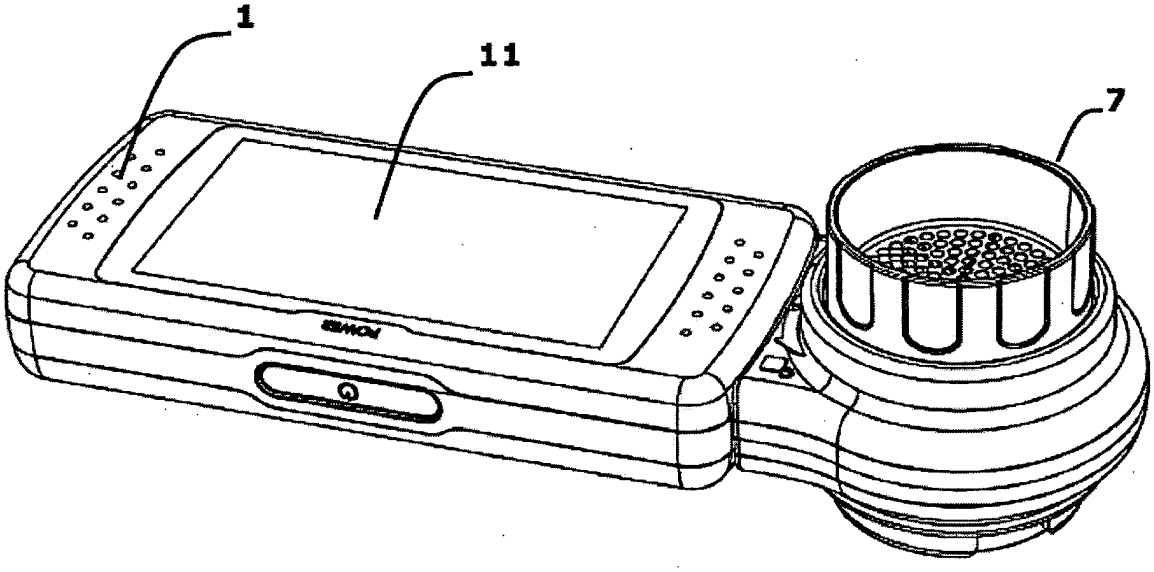

FIG. 3

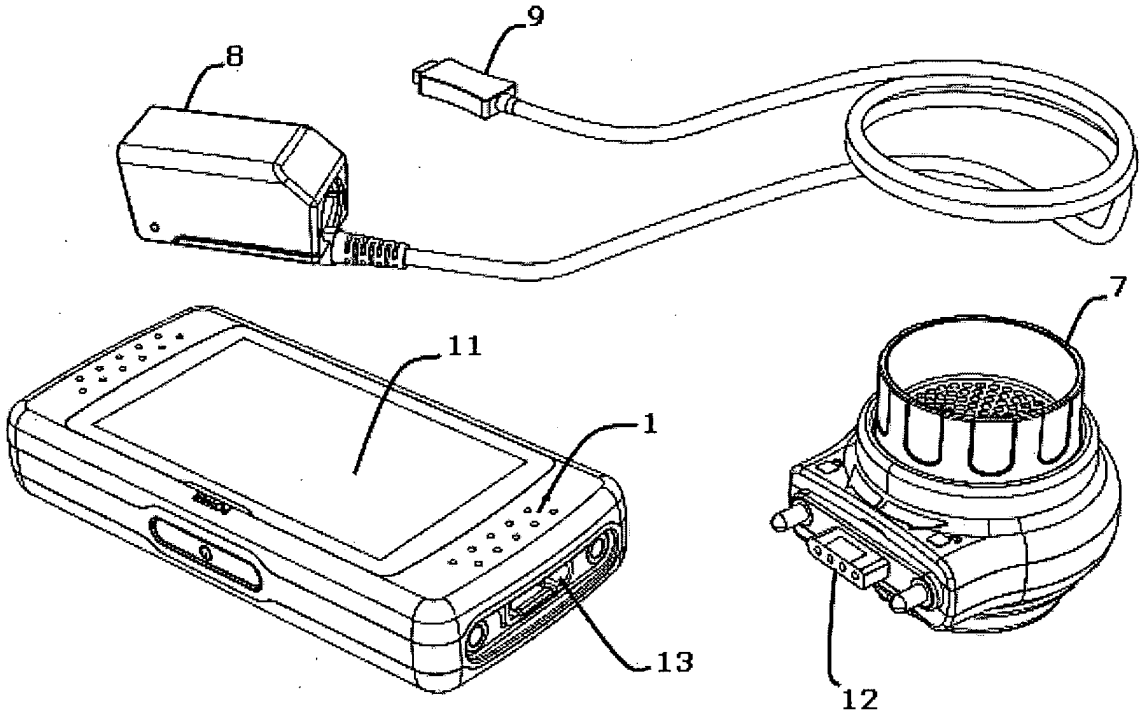
9
8
11
1
13
7
12

FIG. 4

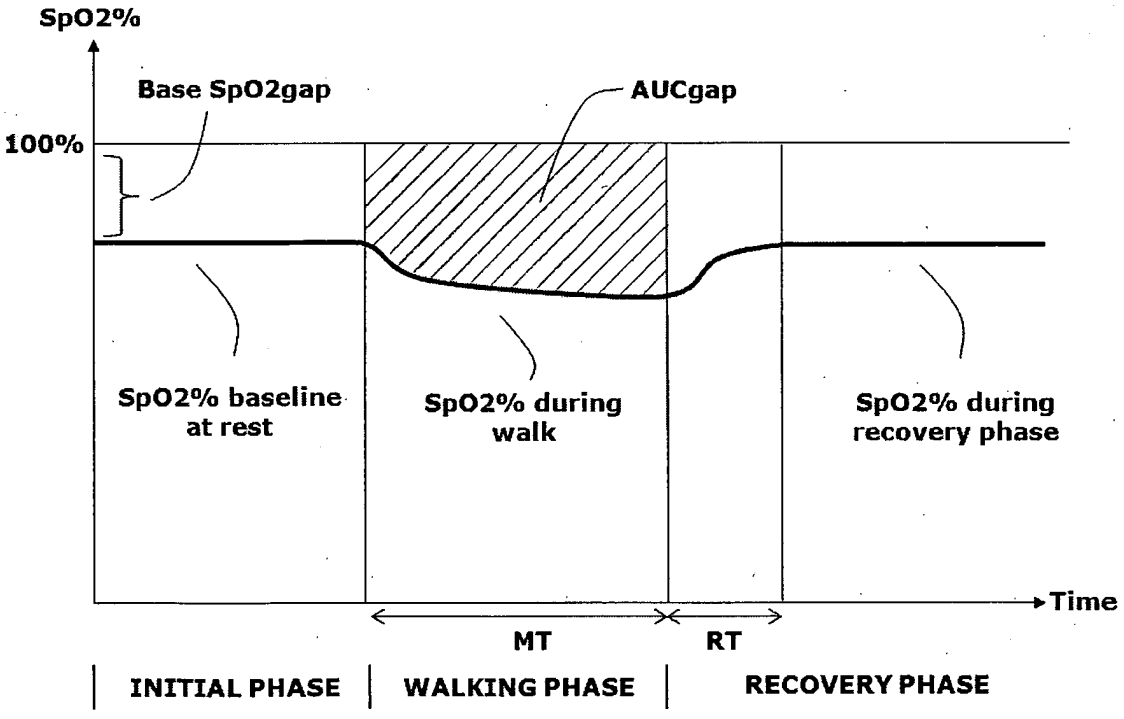
SpO2%
Base SpO2gap
AUCgap
100%
SpO2% baseline at rest
SpO2% during walk
SpO2% during recovery phase
Time
MT
RT
INITIAL PHASE
WALKING PHASE
RECOVERY PHASE

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2010/000361

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/0205 A61B5/08 A61B5/11 A61B5/145
G01N33/483
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 G01N

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 2006/173257 A1 (NAGAI YOSHIROH [JP] ET AL) 3 August 2006 (2006-08-03) paragraphs [0047] - [0062], [0127] - [0136], [173] - [0203]; claims 1-16; figures 1-3,11-29	1-7, 10-15
X	US 6 790 178 B1 (MAULT JAMES R [US] ET AL) 14 September 2004 (2004-09-14) column 4, line 15 - column 7, line 26; figures 1-7,20 column 10, line 30 - column 13, line 55 column 18, line 30 - column 19, line 60 column 24, line 35 - column 25, line 4; claim 1	1-5, 8-10,13

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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	Date of mailing of the international search report
10 May 2011	20/05/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Apostol, Simona

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IT2010/000361

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. [X] Claims Nos.: 16
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.

Continuation of Box II.1

Claims Nos.: 16

Claim 16 claims the use of an equation for the analysis of a walking test in clinical application for calculation of a parameter. The step of use of an equation for calculating a parameter is a purely mental act, and therefore the subject-matter of claim 16 falls under the provision of Article 17(2)(a)(i) PCT (see also Rule 39 and PCT Guidelines IV-16.17 and III-9.07).

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2010/000361

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 712 762 B1 (LICHTER PATRICK A [US] ET AL) 30 March 2004 (2004-03-30) column 6, line 44 - column 10, line 67; figures 1-7,10,15 column 12, line 43 - column 13, line 67 column 16, lines 33-48	1
X	WO 2007/071180 A1 (CHOU CHANG-AN [CN]) 28 June 2007 (2007-06-28) abstract; claims 1-3, 5, 9,13; figures 1-6, 12-13 page 12, line 1 - page 13, line 17	1
X	US 2010/083968 A1 (WONDKA ANTHONY D [US] ET AL) 8 April 2010 (2010-04-08) abstract; claims 1-45; figures 1-11 paragraphs [0051] - [0052], [0 59] - [0064], [0 70] - [0071] paragraphs [0090] - [0110]	1,6,7, 14,15
A	US 2006/217603 A1 (NAGAI YOSHIROH [JP] ET AL) 28 September 2006 (2006-09-28) abstract; claims 4,7, 9, 14; figures 1-4, 13-18	7
A	HATEM ALAMERI ET AL: "Submaximal exercise in patients with severe obstructive sleep apnea", SLEEP AND BREATHING ; INTERNATIONAL JOURNAL OF THE SCIENCE AND PRACTICE OF SLEEP MEDICINE, SPRINGER, BERLIN, DE, vol. 14, no. 2, 25 September 2009 (2009-09-25), pages 145-151, XP019833400, ISSN: 1522-1709 abstract; tables 2-3 section Material and methods	14,15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IT2010/000361

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006173257 A1	03-08-2006	JP 2006204742 A	10-08-2006
US 6790178 B1	14-09-2004	EP 1217942 A1	03-07-2002
		WO 0128416 A1	26-04-2001
US 6712762 B1	30-03-2004	NONE	
WO 2007071180 A1	28-06-2007	CN 1985752 A	27-06-2007
US 2010083968 A1	08-04-2010	WO 2010039989 A1	08-04-2010
US 2006217603 A1	28-09-2006	JP 2006263054 A	05-10-2006

专利名称(译)	便携式设备，用于监测和报告基于证据的慢性呼吸道疾病患者管理的医疗信息		
公开(公告)号	EP2603132A1	公开(公告)日	2013-06-19
申请号	EP2010763871	申请日	2010-08-09
申请(专利权)人(译)	MIR SRL医疗国际研究		
当前申请(专利权)人(译)	MIR SRL医疗国际研究		
[标]发明人	BOSCHETTI SACCO PAOLO SALTINI CESARE CALZETTA LUIGINO		
发明人	BOSCHETTI SACCO, PAOLO SALTINI, CESARE CALZETTA, LUIGINO		
IPC分类号	A61B5/00 A61B5/0205 A61B5/08 A61B5/11 A61B5/145 G01N33/483 A61B5/087 A61B5/1455 G06F19/00		
CPC分类号	A61B5/4884 A61B5/087 A61B5/1118 A61B5/14551 A61B2560/0431 G06F19/00 G06F19/3418 G16H40/63		
其他公开文献	EP2603132B1		
外部链接	Espacenet		

摘要(译)

本发明涉及一种用于监测和报告用于慢性“呼吸道疾病患者的基于证据的管理的医疗信息的集成远程保健系统/设备”。该设备基本上包括测量和收集与患者的健康状态有关的信息的中央单元，并且设备具有用于使用具有触摸屏显示器，USB通信的基于微处理器的系统无线或有线传输所收集的数据的装置。端口和蓝牙。根据本发明，该装置还包括：用于测量呼吸空气流量和体积的可拆卸传感器，可拆卸脉搏血氧饱和度传感器和运动传感器。然后，存储的数据可以通过固定电话，宽带，无线和蜂窝电话技术传送，由网络服务器接收，然后由医务人员访问。作为完全便携式，根据本发明的装置设置有已知类型的电池，其可以由用户代替或者可以是可再充电的。