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(54) **INHALATION MONITORING SYSTEM AND METHOD**

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(57) **ABSTRACT**

An inhalation monitoring system includes an inhaler having a medicament delivery apparatus configured to deliver medicament to a user during an inhalation of the user; inhalation monitoring apparatus, configured to, during the inhalation, gather data for determining a measure of the user's lung function and/or lung health; and a processor configured to receive the data from the inhalation monitoring apparatus and, using the data, determine a measure of the user's lung function and/or lung health.

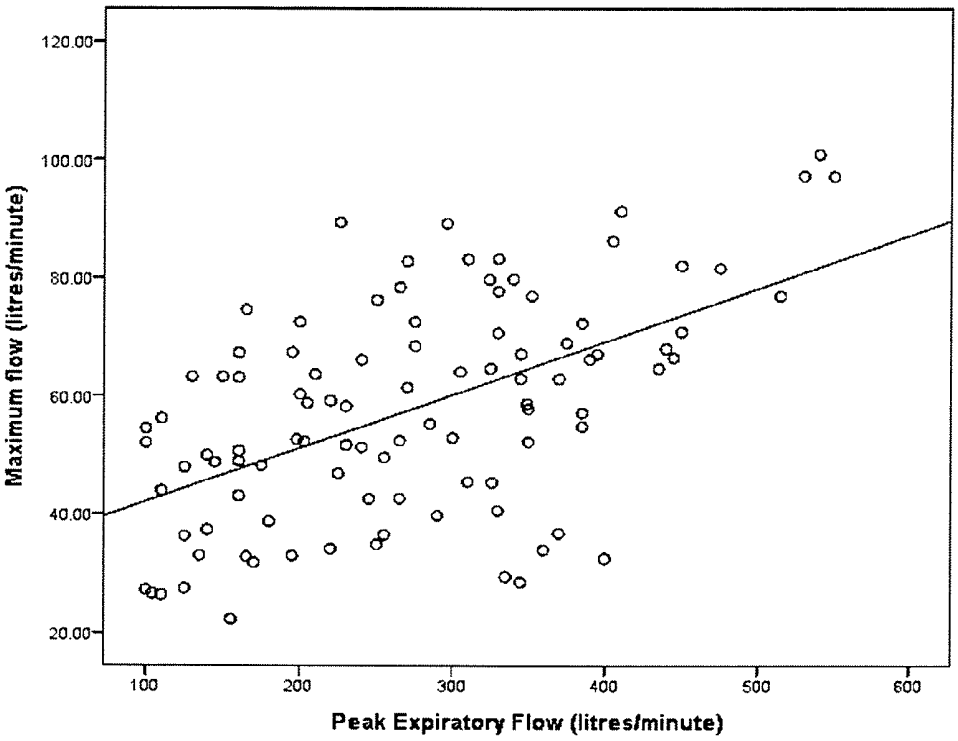
120.00
100.00
80.00
60.00
40.00
20.00
Maximum flow (litres/minute)
100
200
300
400
500
600
Peak Expiratory Flow (litres/minute)

FIG. 1A

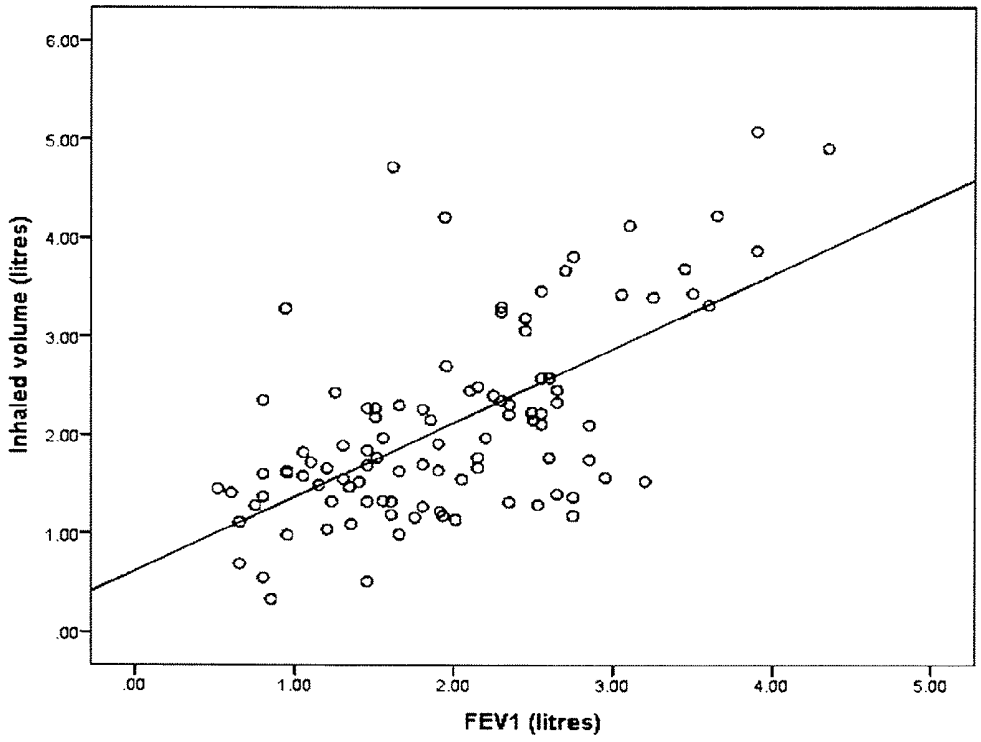
6.00
5.00
4.00
3.00
2.00
1.00
.00
Inhaled volume (litres)
.00
1.00
2.00
3.00
4.00
5.00
FEV1 (litres)

FIG. 1B

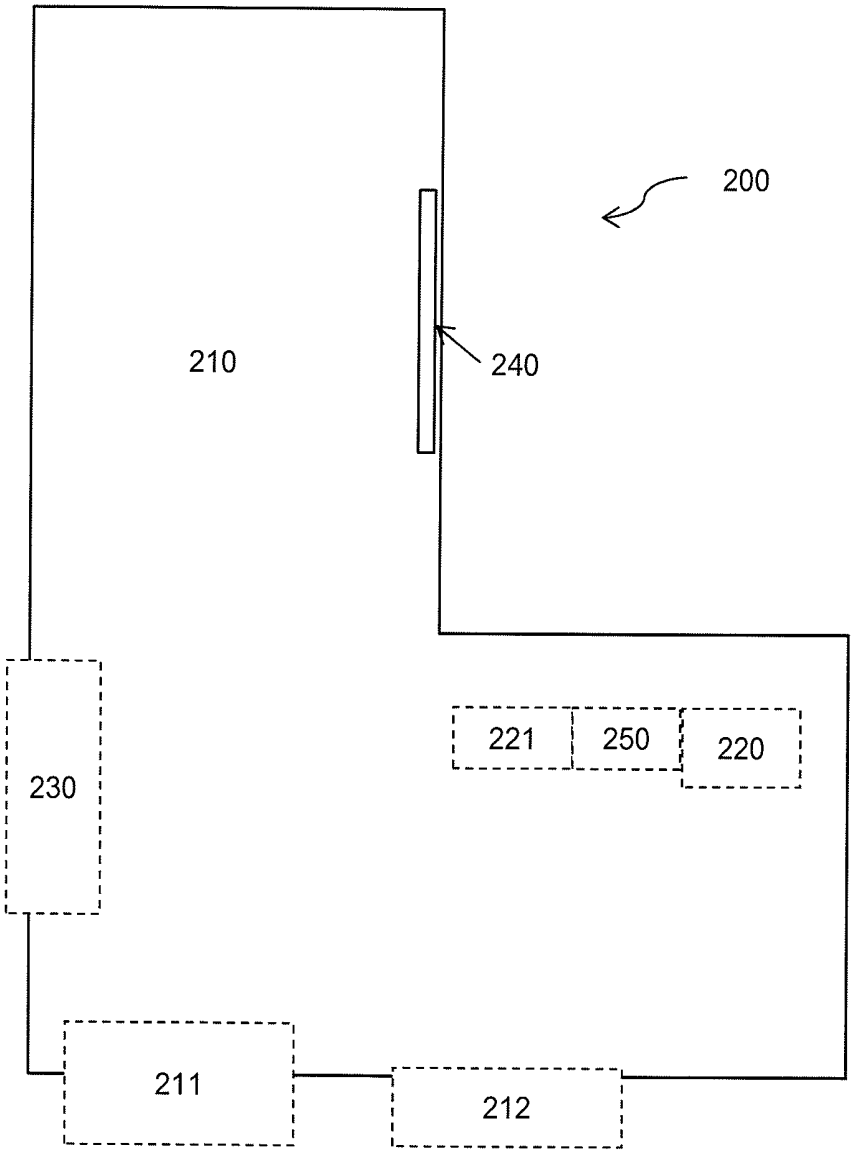

FIG. 2

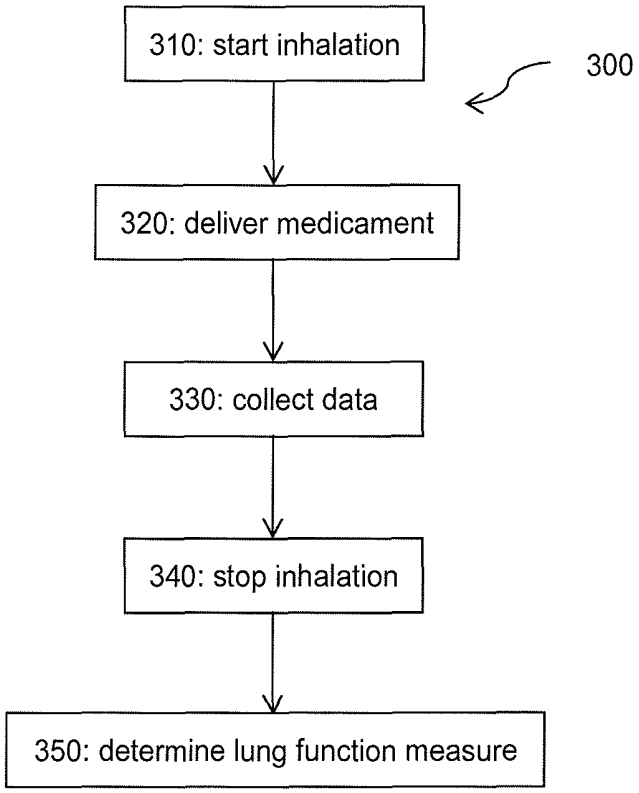
310: start inhalation
300
320: deliver medicament
330: collect data
340: stop inhalation
350: determine lung function measure

FIG. 3

INHALATION MONITORING SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This non-provisional patent application claims priority to U.S. Provisional Patent Application No. 62/087,567, filed Dec. 4, 2014, and U.S. Provisional Patent Application No. 62/087,571, filed Dec. 4, 2014, each of which is incorporated by reference herein in its entirety and for all purposes.

FIELD OF THE INVENTION

[0002] This invention is related to an inhaler, an inhalation monitoring system and a method for monitoring an inhaler.

BACKGROUND OF THE INVENTION

[0003] Inhalers or puffers are used for delivering medication into the body via the lungs. They can be used, for example, in the treatment of asthma and chronic obstructive pulmonary disease (COPD). Types of inhalers include metered dose inhalers (MDIs), Soft Mist Inhalers (SMIs), nebulisers and dry powder inhalers (DPIs).

[0004] A tidal inhaler is a class of inhaler in which the medication is consumed in multiple successive inhalations (referred to as tidal breaths) rather than a single inhalation. The patient uses their normal at rest breathing pattern without an exaggerated inhalation flow rate, also known as forced inhalation maneuver.

[0005] A spirometer is an apparatus for measuring the volume of air inspired and expired by a patient's lungs. Spirometers measure ventilation, the movement of air into and out of the lungs. From the traces, known as spirograms, output by spirometers, it is possible to identify abnormal (obstructive or restrictive) ventilation patterns. Existing spirometers use a variety of different measurement methods including pressure transducers, ultrasonic and water gauge.

[0006] Peak flow meters are used to measure peak expiratory flow (PEF), also called peak expiratory flow rate (PEFR). This is a person's maximum speed of expiration. PEF correlates with the airflow through the bronchi and thus the degree of obstruction in the airways. Peak flow readings are lower when the airways are constricted, for example due to an exacerbation of a lung condition. From changes in recorded values, patients and doctors may determine lung functionality, severity of symptoms, and treatment. Peak flow meters can also be used for diagnosis.

[0007] Spirometers and peak flow meters are generally used to monitor the lung function and/or lung health of individuals, in particular lung patients suffering from conditions such as asthma and COPD. Lung function is defined according to expiratory measures, such as PEF.

[0008] Another measure of lung function is forced expiratory volume in 1 second (FEV**1**). FEV**1** is the volume of air that can forcibly be blown out in one second, after full inspiration. In obstructive diseases (e.g. asthma, COPD, chronic bronchitis, emphysema) FEV_1 is diminished because of increased airway resistance to expiratory flow.

[0009] Patient lung function is generally monitored during appointments with medical practitioners, periodically or in response to a recurrence or worsening of symptoms. For reasons of practicality, monitoring is typically quite infrequent during periods of apparent good health. Reactive treatment is therefore not always administered as soon as it ideally would be, and preventative treatment can be used more than necessary.

[0010] Some patients find spirometers and peak flow meters tricky to use and may need training and supervision in their use. Due to this, and for reasons of cost, most patients do not possess personal spirometers or peak flow meters.

[0011] What is needed is an improved means of monitoring lung function and/or health for patients with obstructive lung conditions.

SUMMARY OF THE INVENTION

[0012] According to a first aspect, there is provided an inhalation monitoring system comprising: an inhaler comprising medicament delivery apparatus configured to deliver medicament to a user during an inhalation of the user; inhalation monitoring apparatus, configured to, during said inhalation, gather data for determining a measure of the user's lung function and/or lung health; and a processor configured to receive said data from said inhalation monitoring apparatus and, using the data, determine a measure of the user's lung function and/or lung health.

[0013] The inhaler could be a dry powder inhaler. The inhaler could be a pressurised metred dose inhaler (pMDI). The inhaler could be a wet nebuliser.

[0014] The inhaler could be a tidal inhaler.

[0015] Said processor could be configured to determine said measure of the user's lung function and/or lung health by determining, from the data, peak inspiratory flow (PIF). Said processor could be configured to determine said measure of the user's lung function and/or lung health by determining, from the data, total inhaled volume.

[0016] The inhalation monitoring system could further comprise a user interface. Such a user interface could be configured to provide an indication of said measure of the user's lung function and/or lung health to the user. Such a user interface could be configured to provide an indication of said measure of the user's lung function and/or lung health to a caregiver. Such a user interface could be configured to provide an indication of said measure of the user's lung function and/or lung health to a medical professional.

[0017] Said indication could comprise an absolute value. Said indication could comprise a relative value. Said indication could comprise a binary health indicator. Said indication could comprise a tertiary indicator of whether the measure is above, below, or within a safe zone.

[0018] Said indication could be dependent upon data relating to the user.

[0019] The inhalation monitoring system could further comprise a transmitter. Said transmitter could be wireless.

[0020] Said transmitter could be configured to send the data to a user device for processing. Said transmitter could be configured to send the data to a user device for storage.

[0021] Said transmitter could be configured to send the data to a user device for provision to the user. Said transmitter could be configured to send the data to a user device for provision to a caregiver. Said transmitter could be configured to send the data to a user device for provision to a medical professional.

[0022] Said transmitter could be configured to send the data to a server for processing. Said transmitter could be configured to send the data to a server for storage. Said transmitter could be configured to send the data to a server for provision to the user. Said transmitter could be configured to send the

data to a server for provision to a caregiver. Said transmitter could be configured to send the data to a server for provision to a medical professional.

[0023] Said transmitter could be configured to send the data to a data cloud for storage.

[0024] Said transmitter could be configured to send said measure to a user device for processing. Said transmitter could be configured to send said measure to a user device for storage. Said transmitter could be configured to send said measure to a user device for provision to the user. Said transmitter could be configured to send said measure to a user device for provision to a caregiver. Said transmitter could be configured to send said measure to a user device for provision to a medical professional.

[0025] Said transmitter could be configured to send said measure to a server for processing. Said transmitter could be configured to send said measure to a server for storage. Said transmitter could be configured to send said measure to a server for provision to the user. Said transmitter could be configured to send said measure to a server for provision to a caregiver. Said transmitter could be configured to send said measure to a server for provision to a medical professional.

[0026] Said transmitter could be configured to send said measure to a data cloud for storage.

[0027] U.S. Provisional Patent App. Nos. **62/011,808** and **62/135,798**, which are each incorporated by reference herein in their entirety, describe an interface device that supports communications between a medical device and an electronic device. Such an interface could be utilized in the inhalation monitoring system that is described herein.

[0028] Said processor could be comprised in said inhaler. Said inhalation monitoring apparatus could be comprised in said inhaler. Said inhalation monitoring apparatus could be configured to be connected to said inhaler such that it is in pneumatic communication with a flow channel thereof. Said user interface could be comprised in said inhaler. Said transmitter could be comprised in said inhaler.

[0029] Said inhalation monitoring apparatus could comprise a pressure sensor. said pressure sensor could be a microelectromechanical system (MEMS) pressure sensor. Said pressure sensor could be a barometric MEMS pressure sensor. Said pressure sensor could be a nanoelectromechanical system (NEMS) pressure sensor.

[0030] Said inhalation monitoring apparatus could be configured to gather the data by sampling a pressure differential or absolute pressure at a series of time points.

[0031] Said sampling could be periodic. Said sampling period could be approximately 50 ms. The sampling frequency could be 100 Hz, for example.

[0032] Said medicament delivery apparatus could be further configured to deliver medicament to the user during a further inhalation of the user subsequent to said inhalation. The further inhalation may be a new breath by the user using a tidal inhaler, or a continuation of the first inhalation by the user using a dry-powder inhaler, for example. Said inhalation monitoring apparatus could be further configured to, during said further inhalation, gather further data for determining a further measure of the user's lung function and/or lung health. Said processor could be further configured to receive said further data from the inhalation monitoring apparatus. Said processor could be further configured to, using the further data, determine a further measure of the user's lung function and/or lung health. Said processor could be further configured to make a comparison of the data with the further data. Said processor could be further configured to make a comparison of the measure of the user's lung function and/or lung health with said further measure of the user's lung function and/or lung health.

[0033] The processor could be further configured to determine efficacy of usage of said inhaler using said comparison.

[0034] The processor could be further configured to predict future changes to the user's lung function and/or lung health using said comparison.

[0035] Said future changes to the user's lung function and/or lung health could comprise exacerbations of an existing respiratory condition such as asthma or chronic obstructive pulmonary disease (COPD).

[0036] The inhalation monitoring system could be configured to provide an alert to the user in response to said processor predicting one of a predetermined set of future changes to the user's lung function and/or lung health. The inhalation monitoring system could be configured to provide an alert to a caregiver in response to said processor predicting one of a predetermined set of future changes to the user's lung function and/or lung health. The inhalation monitoring system could be configured to provide an alert to a medical professional in response to said processor predicting one of a predetermined set of future changes to the user's lung function and/or lung health.

[0037] Said prediction could use data collected from subjects other than the user.

[0038] Said processor could be configured to determine said measure of the user's lung function and/or lung health using a mathematical model such as a regression model.

[0039] Said mathematical model could be of the correlation between total inhaled volume and forced expiratory volume in 1 second (FEU. Said mathematical model could be of the correlation between peak inspiratory flow (PIF) and forced expiratory volume in 1 second (FEV_1). Said mathematical model could be of the correlation between total inhaled volume and peak expiratory flow (PEF). Said mathematical model could be of the correlation between peak inspiratory flow (PIF) and peak expiratory flow (PEF).

[0040] For a multiple inhalation tidal inhaler or nebulizer, said mathematical model could be of the correlation between forced expiratory volume in 1 second (FEV_1) and the rate of change of the expiratory flow.

[0041] For a single inhalation dry-powder inhaler, a measurement of the user's lung function and/or lung health may be based upon a single breath by a user. For a tidal inhaler or nebulizer, the measurement may be based upon multiple breaths by the user. It is envisioned that outlying data points generated by the multiple breaths may be rejected, leaving only the good data points available for data processing.

[0042] The mathematical model could take into account biometric data for the user.

[0043] Said biometric data could comprise gender. Said biometric data could comprise age. Said biometric data could comprise height. Said biometric data could comprise weight.

[0044] The inhalation monitoring system could further comprise a user interface device operable to switch on and/or off said medicament delivery apparatus such that, when the medicament delivery apparatus is switched off, said inhaler is usable as a spirometer.

[0045] Said user interface device could comprise a mouthpiece cover of the inhaler. Said mouthpiece cover could be coupled to the medicament delivery apparatus such that a dose of medicament is made available for inhalation through

a mouthpiece of the inhaler each time said cover is opened. The medicament delivery apparatus could be configured such that no further doses of medicament can be made available for inhalation through said mouthpiece until the cover has been completely closed and opened again.

[0046] The inhalation monitoring system could further comprise a placebo inhaler device. Said placebo inhaler device could comprise said inhalation monitoring apparatus. Said placebo inhaler device could be configured to be operably connected to said inhalation monitoring apparatus. Said placebo inhaler device could present substantially the same inhalation flow resistance to a user as said inhaler.

[0047] The inhalation monitoring system could comprise a battery configured to power the medicament delivery apparatus. The inhalation monitoring system could comprise a battery configured to power the inhalation monitoring apparatus. The inhalation monitoring system could comprise a battery configured to power the processor.

[0048] The inhalation monitoring system could further comprise memory configured to store the data. The inhalation monitoring system could further comprise memory configured to store said measure.

[0049] According to a second aspect there is provided a method comprising: using an inhaler, delivering medicament to a user during an inhalation of the user; during said inhalation, gathering data for determining a measure of the user's lung function and/or lung health; and using the data, making a determination of a measure of the user's lung function and/or lung health.

[0050] The inhaler could be a dry powder inhaler. The inhaler could be a pressurised metred dose inhaler (pMDI). The inhaler could be a wet nebuliser. The inhaler could be a tidal inhaler.

[0051] Said determination could be made by determining, from the data, peak inspiratory flow (PIF). Said determination could be made by determining, from the data, total inhaled volume.

[0052] The method could further comprise providing an indication of said measure of the user's lung function and/or lung health to the user by means of a user interface. The method could further comprise providing an indication of said measure of the user's lung function and/or lung health to a caregiver by means of a user interface. The method could further comprise providing an indication of said measure of the user's lung function and/or lung health to a medical professional by means of a user interface.

[0053] Said indication could comprise an absolute value. Said indication could comprise a relative value. Said indication could comprise a binary health indicator. Said indication could comprise a tertiary indicator of whether the measure is above, below, or within a safe zone.

[0054] Said indication could be dependent upon data relating to the user.

[0055] The method could further comprise, by means of a transmitter, sending the data to a user device for processing. The method could further comprise, by means of a transmitter, sending the data to a user device for storage. The method could further comprise, by means of a transmitter, sending the data to a user device for provision to the user. The method could further comprise, by means of a transmitter, sending the data to a user device for provision to a caregiver. The method could further comprise, by means of a transmitter, sending the data to a user device for provision to a medical professional.

[0056] The method could further comprise, by means of a transmitter, sending the data to a server for processing. The method could further comprise, by means of a transmitter, sending the data to a server for storage. The method could further comprise, by means of a transmitter, sending the data to a server for provision to the user. The method could further comprise, by means of a transmitter, sending the data to a server for provision to a caregiver. The method could further comprise, by means of a transmitter, sending the data to a server for provision to a medical professional.

[0057] The method could further comprise, by means of a transmitter, sending the data to a data cloud for storage.

[0058] The method could further comprise, by means of a transmitter, sending said measure to a user device for processing. The method could further comprise, by means of a transmitter, sending said measure to a user device for storage. The method could further comprise, by means of a transmitter, sending said measure to a user device for provision to the user. The method could further comprise, by means of a transmitter, sending said measure to a user device for provision to a caregiver. The method could further comprise, by means of a transmitter, sending said measure to a user device for provision to a medical professional.

[0059] The method could further comprise, by means of a transmitter, sending said measure to a server for processing. The method could further comprise, by means of a transmitter, sending said measure to a server for storage. The method could further comprise, by means of a transmitter, sending said measure to a server for provision to the user. The method could further comprise, by means of a transmitter, sending said measure to a server for provision to a caregiver. The method could further comprise, by means of a transmitter, sending said measure to a server for provision to a medical professional.

[0060] The method could further comprise, by means of a transmitter, sending said measure to a data cloud for storage.

[0061] Said transmitter could be a wireless transmitter.

[0062] As noted above, according to the second aspect of the invention, there is provided a method comprising: using an inhaler, delivering medicament to a user during an inhalation of the user; during said inhalation, gathering data for determining a measure of the user's lung function and/or lung health; and using the data, making a determination of a measure of the user's lung function and/or lung health.

[0063] Said gathering could be done by said inhaler. Said determination could be made by said inhaler.

[0064] Said gathering could be done by inhalation monitoring apparatus. Said method could further comprise connecting said inhalation monitoring apparatus to the inhaler such that the inhalation monitoring apparatus is in pneumatic communication with a flow channel of the inhaler.

[0065] Said user interface could be comprised in said inhaler. Said transmitter could be comprised in said inhaler.

[0066] Said gathering could be performed by means of a pressure sensor. Said pressure sensor could be a microelectromechanical system (MEMS) pressure sensor. Said pressure sensor could be a barometric MEMS pressure sensor. Said pressure sensor could be a nanoelectromechanical system (NEMS) pressure sensor.

[0067] Said data gathering could comprise sampling a pressure differential at a series of time points. Said data gathering could also comprise sampling an absolute pressure at a series of time points.

[0068] Said sampling could be periodic.

[0069] Said sampling period could be approximately 50 ms. The sampling frequency could be 100 Hz, for example.

[0070] The method could further comprise delivering medicament to the user during a further inhalation of the user subsequent to said inhalation. The method could further comprise during said further inhalation, gathering further data for determining a further measure of the user's lung function and/or lung health. The method could further comprise using the further data, making a determination of a further measure of the user's lung function and/or lung health. The method could further comprise making a comparison of the data with the further data. The method could further comprise making a comparison of the measure of the user's lung function and/or lung health with said further measure of the user's lung function and/or lung health.

[0071] The method could further comprise determining efficacy of usage of said inhaler using said comparison.

[0072] The method could further comprise predicting future changes to the user's lung function and/or lung health using said comparison.

[0073] Said future changes to the user's lung function and/or lung health could comprise exacerbations of an existing respiratory condition such as asthma, chronic obstructive pulmonary disease (COPD), respiratory syncytial virus (RSV), Cystic Fibrosis (CF), diopathic pulmonary fibrosis (IPF), or pulmonary embolism (PE).

[0074] The method could further comprise providing an alert to the user in response to said predicting. The method could further comprise providing an alert to a caregiver in response to said predicting. The method could further comprise providing an alert to a medical professional in response to said predicting.

[0075] Said prediction could use data collected from subjects other than the user.

[0076] Said determination of said measure of the user's lung function and/or lung health could use a mathematical model. Said mathematical model could be a regression model.

[0077] Said mathematical model could be of the correlation between total inhaled volume and forced expiratory volume in 1 second (FEU. Said mathematical model could be of the correlation between peak inspiratory flow (PIF) and forced expiratory volume in 1 second (FEV_1) Said mathematical model could be of the correlation between total inhaled volume and peak expiratory flow (PEF). Said mathematical model could be of the correlation between peak inspiratory flow (PIF) and peak expiratory flow (PEF).

[0078] The mathematical model could take into account biometric data for the user.

[0079] Said biometric data could comprise gender. Said biometric data could comprise age. Said biometric data could comprise height. Said biometric data could comprise weight.

[0080] The method could further comprise: switching off a medicament delivery function of the inhaler; and using the inhaler as a spirometer.

[0081] For a single inhalation dry-powder inhaler, for example, switching off said medicament delivery function could comprise opening a mouthpiece cover of the inhaler. Said cover could be configured such that a dose of medicament is made available for inhalation through a mouthpiece of the inhaler each time the cover is opened. The inhaler could be configured such that no further doses of medicament can be made available for inhalation through the mouthpiece until the cover has been completely closed and opened again.

[0082] The method could further comprise using a placebo inhaler device.

[0083] Said gathering could be performed by inhalation monitoring apparatus. Said placebo inhaler device could comprise said inhalation monitoring apparatus. Said placebo inhaler device could be configured to be operably connected to said inhalation monitoring apparatus.

[0084] Said placebo inhaler device could present substantially the same inhalation flow resistance to a user as said inhaler. For a multiple inhalation tidal inhaler or a wet nebulizer, which may have a lower inhalation flow resistance than a dry-powder inhaler, it may be advantageous to use a special non-drug cartridge having a defined inhalation flow resistance. The non-drug cartridge could electronically identify itself to the inhaler by the same means that is used to identify the drug within a cartridge, e.g., via an electrically erasable programmable read-only memory.

[0085] The method could further comprise storing the data and/or said measure in memory.

[0086] BRIEF DESCRIPTION OF THE DRAWING FIGURES

[0087] Aspects of the present invention will now be described by way of example with reference to the accompanying figures. In the figures:

[0088] FIG. **1***a* illustrates a correlation between PEF and the maximum flow measured during inhalation;

[0089] FIG. **1***b* illustrates a correlation between FEV**1** and total inhaled volume;

[0090] FIG. **2** schematically illustrates an example inhalation monitoring system; and

[0091] FIG. **3** is a flowchart of an example inhalation monitoring method.

DETAILED DESCRIPTION OF THE INVENTION

[0092] The following description is presented to enable any person skilled in the art to make and use the system, and is provided in the context of a particular application. Various modifications to the disclosed embodiments will be readily apparent to those skilled in the art.

[0093] The general principles defined herein may be applied to other embodiments and applications without departing from the spirit and scope of the present invention. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.

[0094] Many lung patients are prescribed inhalers so that they or a caregiver can administer medicament to them as a routine preventative measure, to ease an exacerbation, or both. Such patients and caregivers are trained in the use of these inhalers and become very familiar with them. It is therefore proposed to monitor patients' lung function using their inhalers. Monitoring lung health while administering medication reduces the time and effort required from patients, caregivers and medical professionals to manage lung conditions.

[0095] This has not been previously considered since, as explained above, lung function is generally assessed using expiratory measures and dry powder inhalers, for example, are not generally designed to permit exhalation. In some cases, for example some dry powder inhalers, exhalation into inhalers can impair their function (e.g. if moisture from an exhalation causes powdered medicament to form clumps, making even administration more difficult).

[0096] However, the applicant has established that there are correlations between some expiratory measures of lung function and some inspiratory measures. For example, see FIG. **1***a*, showing a correlation between PEF and the maximum flow measured during inhalation (peak inspiratory flow, PIF), and FIG. **1***b*, showing a correlation between FEV**1** and total inhaled volume. Regression lines and their equations are indicated on the plots, where:

x_1=gender (male=0; female=1)

x_2=age/years

x_3=height/cm

x_4=weight/kg

x_5=PEF/I.min^{-1}

x_6=FEV1/I.min^{-1}

y_1=inhaled volume/I

y_2=PIF/I

[0097] It is therefore proposed to process inhalation data gathered while administering medicament with an inhaler in order to determine lung function and/or health.

[0098] FIG. **2** schematically illustrates an example inhalation monitoring system **200**. An inhaler **210** comprises medicament delivery apparatus **211**. This could for example be as per the dry powder inhalers described in any of PCT patent application publication numbers WO 01/97889, WO 02/00281, WO 2005/034833 or WO 2011/054527, which are incorporated in their entirety herein. Inhalation monitoring systems could also comprise other types of inhalers/nebulisers, e.g. pressurised metred dose inhalers (pMDIs) or wet nebulisers. The inhalers could require forced inspiratory manoeuvres or only tidal breathing.

[0099] Inhalation monitoring apparatus **220** may also be comprised in the inhaler as shown, or may be comprised in a separate unit connected to it. The inhalation monitoring apparatus could for example comprise a miniature (e.g. microelectromechanical, MEMS, or nanoelectromechanical, NEMS) pressure sensor as described in any of U.S. patent application numbers 62/043,126 to Morrison, 62/043,120 to Morrison, and 62/043,114 to Morrison, which are incorporated in their entirety herein. Other suitable arrangements could be envisaged. For those making use of a pressure sensor, said sensor should be in pneumatic communication with an airflow channel of the inhaler through which the user inhales.

[0100] A processor **230** communicates with the inhalation monitoring apparatus in order to process data collected by the inhalation monitoring apparatus to determine a measure of the user's lung function and/or health. The processor could be comprised in the inhaler as shown, or if the inhalation monitoring apparatus is comprised in a separate accessory unit, the processor could also be comprised in said accessory unit. Alternatively, if the inhalation monitoring apparatus is equipped with a wired or wireless transmitter **221**, the processor could be in a separate device, for example a user device such as a smartphone, tablet, laptop or PC. If the inhalation monitoring apparatus is equipped with a transmitter capable of communicating with a network such as the internet, the processing could be done remotely, for example at a medical professional's PC or on a health service, inhaler manufacturer or cloud server. (Any of the abovementioned devices or servers could also be used for data storage.) Optionally, processor **230** could be made up of multiple processors in any of the abovementioned locations, for example some basic processing may be done on board the inhaler, while more detailed analysis is offloaded to a remote device or server.

[0101] The inhaler could optionally comprise a user interface **240** for providing information relating to use of the inhaler and/or determined lung function and/or lung health. This could, for example, be a screen, indicator light, indicator buzzer, speaker, traditional dose counter tape, vibrating alert etc. or any combination of these or similar. Alternatively, such information could be provided via one or more user interfaces of a user device of the patient or a caregiver or medical professional.

[0102] The system could also comprise a memory **250** for storing the collected data, calculation results and computer code instructions for execution by the processor. As with the processor, the memory could be located in the inhaler or an external device or server.

[0103] The electronic component of the inhaler could be powered by a battery **212** so that the inhaler can be portable.

[0104] The inhaler could further comprise switching means for putting the medicament delivery apparatus in or out of operation. When the medicament delivery apparatus is not functioning, the inhaler can be used as a spirometer. As one example, electronic switching means could be provided if the medicament delivery apparatus is under electronic (e.g. push-button) control. As another example, PCT patent application publication number WO 2005/034833, which is incorporated by reference herein in its entirety, describes a mechanism for a metered dose dry powder inhaler in which a metering cup measures out a dose of medicament from a hopper and is moved to a dosing position by action of a yoke linked to a mouthpiece cover. Thus, opening the mouthpiece cover primes the inhaler for use and once a dose has been inhaled, further dosing is not possible until the cover has been closed and opened again. Using such an inhaler with the inhalation monitoring apparatus proposed herein, a patient could take their dose of medicament and, before closing the mouthpiece cover, make one or more further inhalations through the mouthpiece for the purposes of further data collection. This allows greater volumes of data to be collected without risking the patient over-dosing. As yet another example, a spirometer cartridge could be connected to a replaceable cartridge tidal inhaler, and a patient could make one or more further inhalations through the spirometer cartridge for the purpose of further data collection.

[0105] Alternatively, the inhaler described above could be provided in a kit with a placebo or dummy inhaler which has a similar flow resistance to the real inhaler, but which either does not comprise medicament delivery apparatus, is empty or is loaded with a placebo substance such as lactose. The placebo inhaler could comprise similar inhalation monitoring apparatus to that described above, or could be connectable to such apparatus.

[0106] If inhaler **210** were a wet nebulizer, for example, then all of the electronic components could be located in a module that is removably connected to the inhalation port in order to protect the electronics from exposure to fluid. The module could be configured to be connected to different wet nebulizers of varying shape and size. The module could include a flow channel having a defined inhalation flow resistance that is higher than the inhalation flow resistance of the wet nebulizer alone (i.e., without the module).

[0107] FIG. **3** is a flowchart of an example inhalation monitoring method **300**. At **310**, inhalation (through an inhaler) commences. At **320**, medicament is delivered via the inhaler. At **330**, data concerning said inhalation is collected. At **340**, inhalation ends. At **350**, the data is processed to make a

determination of a measure of lung function and/or lung health. The order of steps **320** and **330** could be reversed or they could be carried out partially or fully in parallel. Step **350** could occur before, during or after **340** and before, after, or fully or partially in parallel with **320**.

[0108] The data could also be used for adherence monitoring by a medical practitioner, i.e., to ensure that the inhaler is being used properly by the user.

[0109] The processing could comprise use of a mathematical model such as the regression models illustrated in FIG. **1**.

[0110] Method **300** could be repeated each time the inhaler is used, which could for example be daily. Data gathered from multiple uses of the inhaler and/or determinations made from the data could be stored and compared to provide an indication of the progression of a condition over time. This information could be used to determine efficacy of the current treatment regime and inform any changes which may be required. The processor may also be capable of using the data and/or determinations to predict future changes in lung function and/or lung health. This prediction could be based only on data collected from the patient in question, or could incorporate data collected from other patients too. For example, data from users of many inhalers as described above could be collated and used to identify patterns in inhalation data changes preceding exacerbations of particular lung conditions. The processing logic could thus be self-learning. If a particular patient's data is then seen to match the beginning of such a pattern, they or their caregiver or medical practitioner could be alerted so that any required changes to a treatment regime (for example increased dosage, additional medications or therapies) can be made to help avoid an exacerbation.

[0111] The data collected by the inhalation monitoring apparatus could be, for example, a time series of pressure differential measurements or absolute pressure measurements. Measurements could be made periodically, for example every 10 ms, 50 ms or 100 ms over e.g. 2, 5 or 10 seconds. Data collection may be reset between uses of the inhalation monitoring apparatus.

[0112] The user interface could provide a numerical value, for example of measured PIF, calculated total inhaled volume, calculated PEF, calculated FEV1 or a fraction or percentage of one of these relative to an ideal value for the particular patient (said ideal value could be chosen based on biometric data such as age, gender, height, weight etc.). Alternatively it could provide a binary indicator as to whether or not the measured value is within a healthy range, or a tertiary indicator as to whether the measured value is below, above or within a healthy range. Boundaries of such a healthy range could again depend on biometric data stored for the particular patient. The user interface could alternatively or additionally be used to indicate number of doses taken or number of doses remaining in a disposable inhaler, refillable hopper or disposable cartridge. Another alternative or additional indication could be whether the inhaler has been used correctly, for example so that the patient or a caregiver or medical professional is alerted to missed doses, inhalations that are too short or weak for effective drug administration, or that medication has otherwise been taken incorrectly, and/or receives confirmation that medication has been taken correctly.

[0113] The applicant hereby discloses in isolation each individual feature described herein and any combination of two or more such features, to the extent that such features or combinations are capable of being carried out based on the present specification as a whole in the light of the common general knowledge of a person skilled in the art, irrespective of whether such features or combinations of features solve any problems disclosed herein, and without limitation to the scope of the claims. The applicant indicates that aspects of the present invention may consist of any such individual feature or combination of features. In view of the foregoing description it will be evident to a person skilled in the art that various modifications may be made within the scope of the invention.

What is claimed is:

1. An inhalation monitoring system comprising:
- an inhaler comprising a medicament delivery apparatus configured to deliver medicament to a user during an inhalation of the user;
- an inhalation monitoring apparatus, configured to, during said inhalation, gather data for determining a measure of the user's lung function and/or lung health; and
- a processor configured to receive said data from said inhalation monitoring apparatus and, using the data, determine a measure of the user's lung function and/or lung health.

2. The inhalation monitoring system of claim **1**, wherein the inhaler is a dry powder inhaler.

3. The inhalation monitoring system of claim **1**, further comprising a user interface configured to provide an indication of said measure of the user's lung function and/or lung health to the user and/or a caregiver and/or a medical professional.

4. The inhalation monitoring system of claim **1**, further comprising a transmitter.

5. The inhalation monitoring system of claim **4**, wherein said transmitter is configured to send the data and/or said measure to one or more of:
- a user device and/or server for: processing, and/or storage, and/or provision to the user and/or a caregiver and/or a medical professional; and
- a data cloud for storage.

6. The inhalation monitoring system of claim **1**, wherein said processor is comprised in said inhaler.

7. The inhalation monitoring system of claim **1**, wherein said inhalation monitoring apparatus is comprised in said inhaler.

8. The inhalation monitoring system of claim **1**, wherein said inhalation monitoring apparatus comprises a pressure sensor.

9. The inhalation monitoring system of claim **1**, further comprising a user interface device operable to switch on and/or off said medicament delivery apparatus such that, when the medicament delivery apparatus is switched off, said inhaler is usable as a spirometer.

10. The inhalation monitoring system of claim **9**, wherein said user interface device comprises a mouthpiece cover of the inhaler coupled to the medicament delivery apparatus such that a dose of medicament is made available for inhalation through a mouthpiece of the inhaler each time said cover is opened, the medicament delivery apparatus being configured such that no further doses of medicament can be made available for inhalation through said mouthpiece until the cover has been completely closed and opened again.

11. A method comprising:
- using an inhaler, delivering medicament to a user during an inhalation of the user;
- during said inhalation, gathering data for determining a measure of the user's lung function and/or lung health; and

using the data, making a determination of a measure of the user's lung function and/or lung health.

12. The method of claim **11**, wherein said determination is made by determining, from the data, peak inspiratory flow (PIF) and/or total inhaled volume.

13. The method of either of claim **11**, further comprising:

delivering medicament to the user during a further inhalation of the user subsequent to said inhalation;

during said further inhalation, gathering further data for determining a further measure of the user's lung function and/or lung health;

using the further data, making a determination of a further measure of the user's lung function and/or lung health; and

making a comparison of the data with the further data and/or of the measure of the user's lung function and/or lung health with said further measure of the user's lung function and/or lung health.

14. The method of claim **13**, further comprising determining efficacy of usage of said inhaler using said comparison.

15. The method of claim **13**, further comprising predicting future changes to the user's lung function and/or lung health using said comparison.

16. The method of claim **15**, wherein said future changes to the user's lung function and/or lung health comprise exacerbations of an existing respiratory condition such as asthma or chronic obstructive pulmonary disease (COPD).

17. The method of claim **15**, further comprising providing an alert to the user and/or a caregiver and/or a medical professional in response to said predicting.

18. The method of claim **11**, wherein said determination of said measure of the user's lung function and/or lung health uses a mathematical model.

19. The method of claim **18**, wherein said mathematical model is of the correlation between either total inhaled volume or peak inspiratory flow (PIF) and either forced expiratory volume in 1 second (FEV_1) or peak expiratory flow (PEF).

20. The method of claim **19**, wherein the mathematical model takes into account biometric data for the user.

* * * * *

专利名称(译)	吸入监测系统和方法		
公开(公告)号	US20160158469A1	公开(公告)日	2016-06-09
申请号	US14/802675	申请日	2015-07-17
[标]申请(专利权)人(译)	微剂量治疗技术公司		
申请(专利权)人(译)	微量THERAPEUTX INC. TEVA UK LIMITED		
当前申请(专利权)人(译)	微量THERAPEUTX INC. TEVA UK LIMITED		
[标]发明人	MILTON EDWARDS MARK CHRYSTYN HENRY MORRISON MARK STEVEN WEITZEL DOUGLAS E		
发明人	MILTON-EDWARDS, MARK CHRYSTYN, HENRY MORRISON, MARK STEVEN WEITZEL, DOUGLAS E.		
IPC分类号	A61M15/00 A61B5/00 A61B5/091 A61M16/00 A61B5/087		
CPC分类号	A61M15/0025 A61M16/0051 A61M16/0003 A61B5/0871 A61B5/091 A61M2205/3331 A61M2202/064 A61M2205/50 A61M2230/40 A61M2016/0027 A61M2205/18 A61B5/7275 A61B5/4839 A61K9/0075 A61M11/02 A61M15/00 A61M15/0001 A61M15/0026 A61M15/0051 A61M15/0081 A61M16/021 A61M2205/3553 A61M2205/3592 A61M2205/502 A61M2205/8206 A61M2209/06 G06Q50/22 G16H20/10 A61M2202/0007 G06F19/00		
优先权	62/087567 2014-12-04 US 62/087571 2014-12-04 US		
其他公开文献	US10058661		
外部链接	Espacenet USPTO		

摘要(译)

一种吸入监测系统，包括吸入器，所述吸入器具有药物输送装置，所述药物输送装置构造成在吸入使用者期间将药物输送给使用者。吸入监测装置，被配置为在吸入期间收集用于确定用户的肺功能和/或肺健康的量度的数据;处理器，被配置为从吸入监测装置接收数据，并使用该数据确定用户的肺功能和/或肺健康的量度。

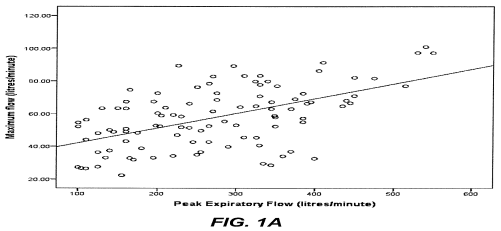

FIG. 1A

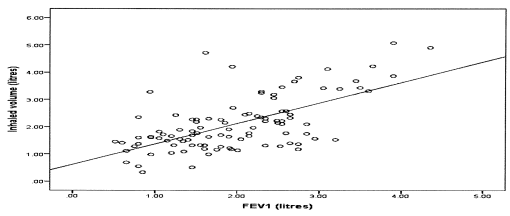

FIG. 1B