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(54) COMPUTER CONTROLLED DOSAGE SYSTEM

COMPUTERGESTEUERTES DOSIERUNGSSYSTEM

SYSTÈME DE DOSAGE COMMANDÉ PAR ORDINATEUR

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Description

Technical Field

[0001] The present disclosure relates to a dosage device. More particularly, the present disclosure relates to a computer controlled dosage system for administering pharmaceutical compounds. The dosage device may be an inhaler.

Background

[0002] In recent years attention has been turned to inhalers. Inhalers are normally used by a patient in a manner that has been prescribed by a doctor. While this provides satisfactory results in everyday life, it would be desirable to tailor inhaled dosage as you go along. A higher dosage may be desirable under certain conditions. A lower dosage may be desirable under other conditions. It is a problem how to adjust the dosage to inhale according to the patient's present condition or changes. It is a problem how to adjust the inhaled dosage according to the patient's environment.

[0003] An inhaler is a device that delivers a fixed dosage of medicine. It is a problem to adjust the dosage when necessary. For example, when to adjust the dosage is not known to an average patient. What conditions justifies an adjustment of the dosage and what is the amount of the adjustment is not known to a patient. How much the dosage should be adjusted, up or down, is not known to an average patient. While a patient may take more inhalations or less inhalations the adjustment of the dosage is not known to the patient. It is a problem to adjust the dosage so that not too much medication is used, but also so that not too little medication is used. Too much medication (overmedicating) is not good in the long run and too little medication (undermedicating) will not be sufficient to reach therapeutic effect for the patient.

[0004] A technical restriction is the existing inhalers on the marked and the desire to provide a system that is compatible with such inhalers. Furthermore, the systems in place and national law and restriction concerning medical dosage systems put a limitation on what can be done. To improve evidence-based care, it is desirable, also by a National Board of Health and Welfare to address problems such as: close follow-up and regular symptom monitoring; regular measurements of lung function; increased education of health care staff and patients; and individualized treatment plans for all patients. It is a problem how to automate this so that more patients can have their individual treatment plans according to recommendations and, in addition, how it can be provided so that they have it with them wherever they may need it. The recommended regular measurement of lung function is time consuming and expensive as it has to be performed several times before and after medication at a clinic by a trained nurse, and afterwards the result has to be interpreted by a physician.

[0005] The present invention is directed to overcoming one or more of the problems as set forth above. The article "Internet-based self-management plus education compared with usual care in asthma: a randomized trial" by Van der Meer et al. published in Annals of internal medicine, 21 July 2009, pages 110-120 discloses a system for Internet-based self-management of asthma.

[0006] WO 2005/087091 discloses a method of displaying a peak flow measurement result as a needle on a red-amber-green scale. The article "Development and pilot testing of a mobile health solution for asthma self-management: Asthma action plan smartphone application pilot study" by Licskai et al. published in the Canadian Respiratory Journal, vol. 20, no. 4, 1 July 2013 discloses a smartphone application for managing asthma.

Summary

[0007] It is an object of the present invention to provide a computer controlled dosage system. This object can be achieved by the features as defined by the independent claim. Further enhancements are characterized by the dependent claims.

[0008] According to one embodiment, a computer controlled dosage system, for dosage adjustment for a mobile, hand held, inhaler for delivering a dosage of a medicine, is provided. The system comprises at least one measuring device for measuring at least one parameter; and a handheld mobile computer separate from the inhaler, the computer being configured to communicate with the at least one measuring device and with a remote memory for sending and receiving information to and from patient medical records of the remote memory for storage in a memory of the computer, and the computer being configured to receive a manual input for storage in the memory of the computer. The computer is configured to create a data set for setting a plurality of levels of different dosages of medicine based on the medicine used by the inhaler, the information from the patient's medical records of the remote memory, and the manual input; and the computer is further configured to store the data set in the memory of the computer. The computer is further configured to generate an indication indicating a dosage adjustment for the inhaler, based on the at least one parameter and on one of the plurality of levels of dosage of the data set, the indication indicating one of the plurality of levels of dosage of the data set as the dosage adjustment for the inhaler.

[0009] According to one embodiment, the computer may further be configured to receive an automatic input and the configuration for generating the indication further is based on the automatic input. The automatic input may be one or more of the following group: pollen levels, air pollution, weather conditions, biological parameter, pollen index, lung volume, air flow to or from lung, blood sample, blood sugar level, body weight, body surface area, environmental condition, humidity, air pressure, height above sea level, GPS position, recent or future

user activity, nutrition intake, or user data.

[0010] According to one embodiment, the measuring device may be one or more of the following group: a spirometer, an accelerometer, a pulse oximeter, an impulse oscillometer (IOS), a blood sample device, a flow meter for lungs, a peak flow meter, a device sampling marker of inflammation, and/or a device sampling marker of inflammation from exhaled air.

[0011] According to one embodiment, the indication may be a text and/or graphic message on a screen of the computer. The indication may be a dosage adjustment by one of the following adjustments or by a combination of one or more of the following adjustments: adjusting the amount of medicine delivered at each inhalation; adjusting the frequency of inhalations; adjusting the number of inhalations; and adjusting by adding a further medicine.

[0012] According to one embodiment, the computer is a mobile phone and the configuration of the computer is an application on the mobile phone or an application in an internet cloud.

[0013] According to one embodiment, the system further comprises a reminding system to communicate when a dosage should be taken, preferably the communication is made via a phone, a mobile phone, a smartphone, sms, or an e-mail.

[0014] According to one embodiment, the system is configured to collect information and/or parameters from a user's electronic diary, wherein the information from a user's electronic diary comprises past, present, and future information regarding one or more of the following group: gym visits, exercises, and location.

[0015] According to one embodiment, the at least one measuring device is configured to measure markers of inflammation from the airway of a user, preferably a fraction of exhaled Nitric Oxide (FeNO), and the system is configured to use this as the parameter to adjust the dosage of the inhaler.

[0016] According to one embodiment, the computer is further configured for providing reports or logged information regarding the user's condition based on the at least one measured parameter for adjusting the dosage.

[0017] According to one embodiment, the inhaler is configured to provide a dosage of insulin for the treatment of diabetes.

[0018] According to one embodiment, the inhaler is a powder dose metered inhaler, an aerosol form inhaler, a nebulised form inhaler, or any kind of dosage delivery apparatus.

[0019] According to one embodiment, the computer is further configured to limit the dosage for the purpose of not adjusting the dosage to a dangerous dosage or to a non-affective dosage, avoiding under- or overmedication.

According to one embodiment, a dosage regime for a dosage system as disclosed herein wherein a dosage of medicine is adjusted to one of the plurality of levels of dosage of the data set.

[0020] According to one embodiment, a computer controlled inhaler system, for dosage adjustment, may comprise an inhaler for delivering a dose (dosage) of medicine; at least one measuring device for measuring at least one parameter; and a computer in communication with the at least one measuring device; wherein the computer indicates a dosage adjustment for the inhaler based on the at least one parameter.

[0021] At least one of the above embodiments provides one or more solutions to the problems and disadvantages with the background art. Other technical advantages of the present disclosure will be readily apparent to one skilled in the art from the following description and claims. Various embodiments of the present application obtain only a subset of the advantages set forth. No one advantage is critical to the embodiments.

Brief Description of the Drawings

[0022] The accompanying drawings illustrate presently preferred exemplary embodiments of the disclosure, and together with the general description given above and the detailed description of the preferred embodiments given below, serve to explain, by way of example, the principles of the disclosure.

[0023] FIG. 1 is a diagrammatic illustration of some exemplary embodiments of the present disclosure.

Detailed Description

[0024] FIG. 1 illustrated a computer controlled dosage system, for example a computer controlled inhaler system. This system is suitable for dosage adjustment for a mobile, hand held, inhaler (10) for delivering a dosage of a medicine. The inhaler (10) may be a purely mechanical inhaler, without any electronic components. The system comprises at least one measuring device (20) for measuring at least one parameter (24). This may for example be a spirometer allowing measurement of lung function and providing such a measurement as a parameter (24) to the system.

[0025] The system comprises a handheld mobile computer (30). This may for example be a mobile smart phone. The computer (30) is separate from the inhaler (10). The dosage deliverer (10), inhaler (10), does not comprise a computer. This allows the system to work with any inhaler (10). The computer (30) is configured to communicate with the at least one measuring device (20). The computer (30) is further configured to communicate with a remote memory (40) for sending and receiving information (42) to and from patient medical records of the remote memory (40). This allows for a two way communication between the remote memory (40) and the computer (30). The remote memory (40) is not part of the computer (30) or the inhaler (10) and is, for example, a large central data base comprising patient data. This information (42) may be stored in a memory (36) of the computer (30). The computer (30) is also con-

figured to receive a manual input (50), and this input (50) may be stored in the memory (36) of the computer (30).

[0026] The computer (30) is configured to create a data set (32) for setting a plurality of levels of different dosages (321, 322, 323) of medicine. This data set (32) may be a treatment plan according to national requirements or legislation. The configuration of this data set (32) is based on the medicine used by the inhaler (10), the information (42) from the patient's medical records of the remote memory (40), and the manual input (50). This allows the computer to create a data set that comprises a plurality of different levels, e.g. green (321), yellow (322), and red (323), of different dosages of the medicine tailored to a user, but also according to the patient's medical records, the medicine and answers to questions asked by the computer (manual input), and technically fulfilling national requirements or legislation. Thus, the configuration for creating the data set (32) can be a pre-set condition, such as a national standard or regulation. The plurality of levels of different dosages of medicine can be any number, for example, 2, 3, 4, 5, 6, 7, 8, 9, or more. The computer (30) may further be configured to store the data set (32) in the memory (36) of the computer (30).

[0027] The computer (30) is further configured to generate an indication (34). This indication (34) is indicating a dosage adjustment for the dosage system, the inhaler (10), based on the at least one parameter (24) and on one of the plurality of levels of dosage (321, 322, 323) of the data set. The indication (34) is indicating one of the pluralities of levels of dosage (321, 322, 323) of the data set (32) as the dosage adjustment for the inhaler (10).

[0028] In one embodiment, which may apply to the entire disclosure, the computer (30) may have a processor. The configuring the computer may be done by configuring the processor of the computer (30).

[0029] A technical effect of the computer controlled dosage system, as claimed in claim 1, is given by how the different components (20, 30) are arranged and how they are connected, and the way the computer (30) has been configured. This allows the system to technically provide the data set (32) and technically define the different levels of dosage (321, 322, 323). It is this technical configuration of the system that achieves the data set to be generated, not merely defined, and useful for dosage adjustment. Important is that the system is configured to adapt the data set (32) to the national legislation or other predetermined rules, making it technically possible to use the system in real life and integrate the system in the national health care system. Furthermore, the arrangement of the different components (20, 30) of the system, how they are connected, can communicate, and how they are configured, allows the system to provide an indication of the dosage. This indication may be a level of dosage from the data set. This indication may, as an example and in a simple form, be a text message, and allows the dosage system, e.g. an inhaler, to give an adjusted dosage, not too much or too little (overmedicating or undermedicating).

[0030] According to one embodiment, the computer (30) may further be configured to receive an automatic input (60) and the configuration for generating the indication (34) may further be based on the automatic input (60). Such an automatic input (60) may be one or more of the following group: pollen levels, air pollution, weather conditions, biological parameter, pollen index, lung volume, air flow to or from lung, blood sample, blood sugar level, body weight, body surface area, environmental condition, humidity, air pressure, height above sea level, GPS position, recent or future user activity, nutrition intake, or user data. The computer may be configured such that the automatic input may be pulled in via the internet or any other accessible remote data.

[0031] According to one embodiment, the indication (34) may be a text and/or graphic message on a screen (38) of the computer (30). The computer (32) may indicate, e.g. on a screen or by sound, the adjustment to the dosage and the user may make the adjustment. The indication (34) may be a dosage adjustment by one of the following adjustments or by a combination of one or more of the following adjustments: adjusting the amount of medicine delivered at each inhalation; adjusting the frequency of inhalations; adjusting the number of inhalations; and adjusting by adding a further medicine. For example, a dosage adjustment could be moving from a first level of two inhalations every morning and evening to a second level of three inhalations every morning, midday, and evening. For example, a dosage adjustment can be effected by subsequent actuation of the dosage system, the inhaler. The system may be configured to provide the user of the inhaler with information how to adjust the dosage of the inhaler. For example, the system may inform the user that two inhalations should be taken rather than only one inhalation each time. For example the system may inform the user that six inhalations should be taken within 24 hours, rather than only four inhalations. This would allow a user to take the correct dosage, thus allowing the dosage of the medication to be taken in the most effective way for the user.

[0032] According to one embodiment, the measuring device (20) may be one or more of the following group: a spirometer, an accelerometer, a pulse oximeter, an impulse oscillometer (IOS), a blood sample device, a flow meter for lungs, a peak flow meter, a device sampling marker of inflammation, and/or a device sampling marker of inflammation from exhaled air.

[0033] According to one embodiment, the computer (30) is a mobile phone and the configuration of the computer (30) is an application on the mobile phone or an application in an internet cloud. The computer may be a part of a smart phone, tablet, or similar. The configuration of the computer may be the configuration of a processor within the computer. The configuration may be done by an application and by providing any necessary hardware.

[0034] According to one embodiment, the system may further comprise a reminding system to communicate when a dosage should be taken; preferably the commu-

nication is made via a phone, a mobile phone, a smartphone, sms, or an e-mail. This may ensure that a dosage is actually taken, or at least noted.

[0035] According to one embodiment, the system is configured to collect information and/or parameters from a user's electronic diary, wherein the information from a user's electronic diary comprises past, present, and future information regarding one or more of the following group: gym visits, exercises, and location. For example, if a user has been to the gym, entering that into a dairy, or manually directly into the system, the system may be configured to take account of that information when generating the indication for dosage adjustment.

[0036] According to one embodiment, the at least one measuring device (20) may be configured to measure markers of inflammation from the airway of a user, preferably a fraction of exhaled Nitric Oxide (FeNO). Additionally, the system may be configured to use this as the parameter to adjust the dosage indication for the inhaler.

[0037] According to one embodiment, the computer may further be configured for providing reports or logged information regarding the user's condition based on the at least one measured parameter (24). This report may be displayed on the computer itself (on the screen (38)), and/or may be sent to the remote memory (40) for access by others, e.g. medical staff. This may allow for the system to be supervised according to national legislation. As a result, information may be sent back to the system, allowing a modification/improvement of the dosage system, e.g. by generating a modified data set (32) allowing for improved dosage adjustment.

[0038] According to one embodiment, the dosage delivery system, the inhaler (10), may be configured to provide a dosage of insulin for the treatment of diabetes. As such, the system may be suitable for any kind of medicine. According to one embodiment, the inhaler (10) may be a powder dose metered inhaler, an aerosol form inhaler, a nebulised form inhaler, or any kind of dosage delivery apparatus.

[0039] According to one embodiment, the computer (30) may be further configured to limit the dosage for the purpose of not adjusting the dosage to a dangerous dosage or to a non-affective dosage, avoiding under- or over-medication. This may depend on the medicine used and the medicine used may be input to the system as a manual input, thus the computer may be configured to receive a manual input of what medicine is used.

[0040] According to one embodiment, a dosage regime is disclosed for a dosage system as described herein with reference to any one embodiment or combination thereof, wherein a dosage of medicine is adjusted to one of the plurality of levels of dosage (321, 322, 323) of the data set (32). The system generates the data set (32) that comprises a plurality of levels of different dosages (321, 322, 323). The dosage regime comprises the system indicating what level of dosage should be taken by a user. As disclosed and explained herein, the system generates a dosage regime for the user and the medicine in question. In this way the dosage of the medicine may be given to a user resulting in the most effective dosage given, and avoiding giving a dangerous dosage or a non-affective dosage.

[0041] According to embodiments, the system may be configured to limit the dosage for the purpose of not adjusting the dosage to a dangerous dosage or to a non-affective dosage. This may be done to comply with health regulations and/or any attempted misuse of the inhaler (10).

[0042] According to at least one embodiment, the indication (34) may be no adjustment at all, thus maintaining the present dosage. This would indicate that the dosage used is the appropriate and effective dosage.

[0043] In one embodiment, the at least one measuring device (20) is configured to measure markers of inflammation from the airway of a user, preferably a fraction of exhaled Nitric Oxide (FeNO), and the system is configured to use this as the parameter to adjust the dosage of the inhaler.

[0044] At least one of the embodiments provides a computer controlled inhaler system with the objective to administer pharmaceutical compounds. It can contain medicine in powder form (powder dose metered inhaler), aerosol form, or nebulised form. The dose can be adjusted, allowing the dose of inhaled medicine to be increased or reduced, tailored, to that specific user's requirements. The dose adjustment function allows for optimisation of treatment by increasing or reducing the dose without delay when required. This also reduces the total amount of medicine administered. The system may comprise the administering device (powder dose metered inhaler, aerosol form or nebulised form) and may be used for all medical conditions where inhaled medicine is appropriate.

[0045] A dosage may be the amount of medicine given, the administration of medicine in doses, and/or the number or frequency of doses. Dosage may be the administration of a drug or agent in prescribed amounts and at prescribed intervals. Dosage may be the optimum therapeutic dose and optimum interval between doses. The dose may be electronically controlled via software that adjusts the administered dose depending on the at least one parameter. It may take a range of other factors into account when calculating the dose.

[0046] According to at least one embodiment, a computer controlled dosage system could also be used with conventional inhalers informing the user how many inhalations to take any day. An example of use is for users with asthma or chronic obstructive pulmonary disease (COPD), diseases that are characterised by variability where the dose may need rapid adjustment upwards or downwards. Another compound that may be administered via inhalation is insulin for the treatment of diabetes. For example, a dosage for diabetes may be adjusted each time taken.

[0047] Embodiments of the system software may have other uses such as for example: communicate with the

patient's treating doctor or nurse to inform him/her of any exacerbation in the patient's condition; collect information from the internet or relevant institutions regarding environmental conditions such as weather, humidity, smog/fine particle levels, pollen levels and take these into account when calculating the dose. This information can be related to the user's geographical location as identified by gps or smartphone location as there may be local variations regarding proximity to heavy traffic or going to the countryside where pollen levels may be higher.

[0048] According to at least one embodiment, a user may make manual adjustments either by entering information by hand or letting the device collect information from the user's electronic diary about gym visits and/or exercise where the dosage may need adjustment.

[0049] According to at least one embodiment, the system may collect information from other devices measuring markers of disease. These devices can be anything from taking simple home blood tests to devices that measure markers of inflammation from the airway such as for example the fraction of exhaled Nitric Oxide (FeNO). The latter is useful for patients with allergic asthma. The collected information, parameters, may be used to adjust the dosage.

[0050] According to at least one embodiment, the system may provide reports or logged information for the benefit of treating medical staff or the user him or herself regarding the user's condition as well as compliance to medication.

[0051] According to at least one embodiment, the system may link with the user's medical records giving treating medical staff information about the user's condition and making dosage adjustments improving treatment.

[0052] Turning to some more specific embodiments, the computer controlled system overcomes one or more problems mentioned above by supporting self-management of the disease, improving communication between user and healthcare as well as making health care more efficient while also increasing the quality of clinical decisions. The system may be an easy-to-use self-management application with portable spirometry to enable healthcare to better follow guidelines without increasing number of visits while also reducing number of unplanned visits given that dosage can be adapted to variable factors over time (lung function, health condition, weather, pollen count etc.) and given that users' motivation to follow the dosage will increase. The user may take control over the disease and experience an increase in quality of life.

[0053] At least one embodiment may benefit asthma/COPD patients and care providers as well as specialized lung clinics. The may provide more timely and accurate diagnosis; more efficient organization of the clinical work; more focus on structured patient evaluation; increased capacity and competence of health care professionals, particular general practitioners; and improved user education and self-management programs.

[0054] At least one embodiment of the system may provide a user the possibility of self-monitoring and to achieve disease control. The user will get dosage recommendations based on variable factors without spending much time with the application. The dosage system, for example for asthma and COPD, may be arranged in relatively clear guidelines by international consensus. Specifically there are steps wherein the gathered information on symptoms, lung function, etc. may be transferred into information on dosage (e.g. frequency) of medication. The system will let a user or health care worker know clearly which dosage step they should be following and thereby improve individualized care. Tailored dosage leads to reduced risk of side effects. The system may also educate users in self-management and for example remind asthma patients to take the allergy medication when the pollen count of their specific allergy goes up. Potentially, the end result will be an empowered and motivated user achieving increased quality of life. The improved communication possibility benefits both healthcare and users. Healthcare can decide what information they want to collect from the system and how frequently. The most fundamental biological end marker that may be collected regularly is one or two lung function parameters. Seeing longitudinal changes of lung function may improve the quality of decisions made and in addition has valuable diagnostic and prognostic information. The user will be able to easily access an updated individual dosage plan if needed without visiting the primary care facility saving time and money for all involved.

[0055] According to one specific exemplary embodiment, the system may comprise a small lung function measurement device (a spirometer). The cost of this is comparable to very simple peak flow meters for home use. The spirometer can be used with a smartphone that will be configured by an application. The data collected by the system may be visible in the patient's medical records of the remote memory. The remote memory may be direct, or indirectly, via an internet based portal to the national health care. By doing this, information such as, for example, asthma or COPD, known allergies, medications, weight, and height will be entered into the app which can then establish a treatment plan according to national and international guidelines for every patient. The user will be able to measure their lung function themselves and will receive questions. This information collected by the system, together with information on for example pollen counts, air pollution and influenza epidemics, will generate an indication of the dosage. The system may send data to the health care provider so that for example lung function over time can be displayed in the medical record at the next visit at the health care provider. The possibility of contacting the health care system can also be used to automate procedures like booking appointments, requesting new prescriptions or similar.

[0056] According to one exemplary embodiment, the system may comprise a smart phone, a computer, configured to receive manual data input (for example, age,

sex, anthropometrics, comorbidities, informed consent, answer burden symptoms and intake of dosage, schedule reminders for intake of dosage, dosage adherence, set alerts according to information gathered in automatic data input); automatic data input (for example: pollen levels, air pollution, weather conditions, GPS location, data from additional devices); data from additional devices (for example, connected via Bluetooth, spirometer, accelerometer, registrations of sleep and physical activity); and hands-on guidance through national service portal to a remote memory (for example, inquiry to physician, prescription, dosage adjustment, schedule clinical visits, transfer individual information of e.g. symptoms and lung function). The computer may display graphs and statistics, and visual a dosage plan.

[0057] According to one embodiment, the computer is configured to comprise three modules: Manual Data Input, Automatic Data Input and Hands-on guidance, as described above. The module Manual data input may include personal data and personalized settings for each user. In addition, the system may ask users, at regular intervals (from daily to monthly basis) to register symptoms through validated questionnaires. In Automatic data input user-generated data may be gathered from the portable spirometer together with relevant background information from external web services. Web services may provide air quality information of pollen levels, weather conditions and particle concentrations based on GPS-location or other selected location. In Manual data input, optional alerts are set in relation to poor air quality. In case of severe conditions, the system may recommend an alert to be send to a clinic through secure access of Hands-on guidance.

[0058] According to one embodiment, hands-on guidance may provide a user with information and self-management support through any national portal to any national health care system. Such service may allow for a two-way communication between user and health care professionals. Examples on how hands-on guidance may be used: automatic transfer of user's dosage plan from the primary source (medical record) to the system. This may be a treatment plan following national plans and regulations, provided by a national board of health and welfare; follow a user's medical adherence (e.g. based on manual data input); the possibility to set clinical alerts in case of impairment (symptoms, lung function, environmental factors or increased need of medication alerts signs of exacerbations); the possibility of contacting health care provider through inquiries; and transfer gathered information of biological end markers from the system for clinical evaluation.

[0059] According to one embodiment, the system may be configured for measurement of lung function in a more detailed way, and for giving the user immediate visual feedback and dosage adjustment recommendations. It may also be configured to provide a possibility of transferring information to a user's health care provider. The system may help to automate a dosage plan so that more users can have their individual dosage plans according to recommendations and, in addition, as it is provided electronically in their mobile phone, will carry it with them wherever they may need it.

[0060] According to at least one embodiment, the success of a user's self-management is depended on dedicated health-care providers or a key individual who work closely with the treating physician. In other words, users should not be left alone, and self-management is not a goal itself that replace proactive involvement from health care professionals. The claimed system may enable evaluation of user's symptoms, lung function, intake daily medication automatic data input of user dosage plan, air quality based on particle concentrations, pollen and weather conditions. The concept also enables users to send inquiry to the clinic, schedule appointments and transfer gathered information to a clinic for hands-on guidance. Furthermore, the system may provide choice of medication and dosage adjustments. The system may reduce a burden of disease for individuals and society, reduction of emergency visits.

[0061] According to at least one embodiment, the system overcomes one or more of the problems mentioned above by supporting self-management of a disease, improving communication between patient and healthcare as well as making health care more efficient while also increasing the quality of clinical decisions. An easy-to-use self-management application with portable spirometry will enable healthcare to better follow guidelines without increasing number of visits while also reducing number of unplanned visits given that a user's dosage plan can be adapted to variable factors over time (lung function, health condition, weather, pollen count etc.) and given that a user's motivation to follow treatment will increase.

[0062] It will be apparent to those skilled in the art that various modifications and variations can be made to the system and dosage regime. Especially that one or more of the embodiments disclosed above can be combined with each other to achieve the overall goals with the system. Other embodiments will be apparent to those skilled in the art from consideration of the specification and practice of the disclosed system and dosage regime. It is intended that the specification and examples be considered as exemplary only, with a scope being indicated by the following claims.

Claims

1. A computer controlled dosage system, for dosage adjustment for a mobile, hand held, inhaler (10) for delivering a dosage of a medicine, comprising:

   at least one measuring device (20) for measuring at least one parameter (24); and
   a handheld mobile computer (30) separate from the inhaler (10), the computer (30) being config-

ured to communicate with the at least one measuring device (20) to receive the at least one parameter (24) and to communicate with a remote memory (40) for sending and receiving information (42) to and from patient medical records of the remote memory (40) for storage in a memory (36) of the computer (30), and the computer (30) being configured to receive a manual input (50) for storage in the memory (36) of the computer (30);

characterised in that the computer (30) is configured to create a data set (32) setting a plurality of levels of different dosages (321, 322, 323) of medicine, by configuring a treatment plan, where the treatment plan is a treatment plan according to national requirements or legislation, based on the medicine used by the inhaler (10), the information (42) from the patient's medical records of the remote memory (40), and the manual input (50);

wherein the computer (30) is further configured to store the data set (32) in the memory (36) of the computer (30);

wherein the computer (30) is further configured to generate an indication (34) indicating a dosage adjustment for the inhaler (10), based on the at least one parameter (24) and on one of the plurality of levels of dosage (321, 322, 323) of the data set, the indication (34) indicating one of the plurality of levels of dosage (321, 322, 323) of the data set (32) as the dosage adjustment for the inhaler (10).

2. The system according to claim 1, wherein the computer (30) is further configured to receive an automatic input (60) and the configuration for generating the indication (34) further is based on the automatic input (60).

3. The system according to claim 1 or 2, wherein the indication (34) is a text and/or graphic message on a screen (38) of the computer (30).

4. The system according to any one of the preceding claims, wherein the measuring device (20) is one or more of the following group: a spirometer, an accelerometer, a pulse oximeter, an impulse oscillometer (IOS), a blood sample device, a flow meter for lungs, a peak flow meter, a device sampling marker of inflammation, and/or a device sampling marker of inflammation from exhaled air.

5. The system according to any one of the preceding claims, wherein the indication (34) is a dosage adjustment by one of the following adjustments or by a combination of one or more of the following adjustments:

adjusting the amount of medicine delivered at each inhalation;
adjusting the frequency of inhalations;
adjusting the number of inhalations; and
adjusting by adding a further medicine.

6. The system according to any one of the preceding claims, wherein the computer (30) is a mobile phone and the configuration of the computer (30) is an application on the mobile phone or an application in an internet cloud.

7. The system according to claim 2, wherein the automatic input (60) is one or more of the following group: pollen levels, air pollution, weather conditions, biological parameter, pollen index, lung volume, air flow to or from lung, blood sample, blood sugar level, body weight, body surface area, environmental condition, humidity, air pressure, height above sea level, GPS position, recent or future user activity, nutrition intake, or user data.

8. The system according to any one of the preceding claims, wherein the system further comprises a reminding system to communicate when a dosage should be taken; preferably the communication is made via a phone, a mobile phone, a smartphone, sms, or an e-mail.

9. The system according to any one of the preceding claims, wherein the system is configured to collect information and/or parameters from a user's electronic diary, wherein the information from a user's electronic diary comprises past, present, and future information regarding one or more of the following group: gym visits, exercises, and location.

10. The system according to any one of the preceding claims, wherein the at least one measuring device (20) is configured to measure markers of inflammation from the airway of a user, preferably a fraction of exhaled Nitric Oxide (FeNO), and the system is configured to use this as the parameter to adjust the dosage of the inhaler.

11. The system according to any one of the preceding claims, wherein the computer is further configured for providing reports or logged information regarding the user's condition based on the at least one measured parameter.

12. The system according to any one of the preceding claims, wherein the inhaler (10) is configured to provide a dosage of insulin for the treatment of diabetes.

13. The system according to any one of the preceding claims, wherein the inhaler (10) is a powder dose metered inhaler, an aerosol form inhaler, a nebulised

form inhaler, or any kind of dosage delivery apparatus.

14. The system according to any one of the preceding claims, wherein the computer (30) is further configured to limit the dosage for the purpose of not adjusting the dosage to a dangerous dosage or to a non-affective dosage, avoiding under- or overmedication.

Patentansprüche

1. Ein computergesteuertes Dosierungssystem zur Dosierungsanpassung für einen mobilen, tragbaren Inhalator (10) zur Abgabe einer Dosierung eines Arzneimittels, beinhaltend:

mindestens eine Messvorrichtung (20) zum Messen mindestens eines Parameters (24); und einen tragbaren mobilen Computer (30), der von dem Inhalator (10) getrennt ist, wobei der Computer (30) konfiguriert ist, um mit der mindestens einen Messvorrichtung (20) zum Empfangen von des mindestens eines Parameters (24) zu kommunizieren, und mit einem entfernten Speicher (40) zum Senden und Empfangen von Informationen (42) an und von Krankenakten eines Patienten in dem entfernten Speicher (40) zur Speicherung in einem Speicher (36) des Computers (30) zu kommunizieren, und wobei der Computer (30) konfiguriert ist, um eine manuelle Eingabe (50) zur Speicherung in dem Speicher (36) des Computers (30) zu empfangen;
dadurch gekennzeichnet, dass der Computer (30) konfiguriert ist, um einen Datensatz (32) zu erzeugen, der eine Vielzahl von Höhen unterschiedlicher Arzneimitteldosierungen (321, 322, 323) festsetzt, durch Konfigurieren eines Behandlungsplans, wobei der Behandlungsplan ein Behandlungsplan gemäß den nationalen Anforderungen oder Gesetzen ist, auf der Basis des von dem Inhalator (10) verwendeten Arzneimittels, der Informationen (42) aus den Krankenakten des Patienten in dem entfernten Speicher (40) und der manuellen Eingabe (50);
wobei der Computer (30) ferner konfiguriert ist, um den Datensatz (32) in dem Speicher (36) des Computers (30) zu speichern;
wobei der Computer (30) ferner konfiguriert ist, um auf der Basis des mindestens eines Parameters (24) und einer der Vielzahl von Höhen der Dosierung (321, 322, 323) des Datensatzes eine Angabe (34), die eine Dosierungsanpassung für den Inhalator (10) angibt, zu generieren, wobei die Angabe (34) eine der Vielzahl von Höhen der Dosierung (321, 322, 323) des Datensatzes (32) als die Dosierungsanpassung für den Inhalator (10) angibt.

2. System gemäß Anspruch 1, wobei der Computer (30) ferner konfiguriert ist, um eine automatische Eingabe (60) zu empfangen, und die Konfiguration zum Generieren der Angabe (34) ferner auf der automatischen Eingabe (60) basiert.

3. System gemäß Anspruch 1 oder 2, wobei die Angabe (34) eine Textnachricht und/oder eine grafische Nachricht auf einem Bildschirm (38) des Computers (30) ist.

4. System gemäß einem der vorhergehenden Ansprüche, wobei die Messvorrichtung (20) eine oder mehrere der folgenden Gruppe ist: ein Spirometer, ein Beschleunigungsmesser, ein Pulsoximeter, ein Impulsoszillometer (IOS), eine Blutprobenvorrichtung, ein Durchflussmesser für Lungen, ein Peak-Flow-Meter, eine Vorrichtung, die Entzündungsmarkerproben nimmt, und/oder eine Vorrichtung, die Entzündungsmarkerproben aus der exhalierten Luft nimmt.

5. System gemäß einem der vorhergehenden Ansprüche, wobei die Angabe (34) eine Dosierungsanpassung durch eine der folgenden Anpassungen oder durch eine Kombination von einer oder mehreren der folgenden Anpassungen ist:

Anpassen der mit jeder Inhalation abgegebenen Menge an Arzneimittel;
Anpassen der Häufigkeit der Inhalationen;
Anpassen der Anzahl der Inhalationen; und
Anpassen durch Hinzufügen eines weiteren Arzneimittels.

6. System gemäß einem der vorhergehenden Ansprüche, wobei der Computer (30) ein Mobiltelefon ist und die Konfiguration des Computers (30) eine Anwendung auf dem Mobiltelefon oder eine Anwendung in einer Internet-Cloud ist.

7. System gemäß Anspruch 2, wobei die automatische Eingabe (60) eine oder mehrere der folgenden Gruppe ist: Pollenniveaus, Luftverschmutzung, Wetterbedingungen, biologischer Parameter, Pollenindex, Lungenvolumen, Luftströmung in die oder aus der Lunge, Blutprobe, Blutzuckerniveau, Körpergewicht, Körperoberfläche, Umgebungsbedingung, Luftfeuchtigkeit, Luftdruck, Höhe über Meeresspiegel, GPS-Position, kurzfristig zurückliegende oder zukünftige Benutzeraktivität, Nahrungsmittelaufnahme oder Benutzerdaten.

8. System gemäß einem der vorhergehenden Ansprüche, wobei das System ferner ein Erinnerungssys-

tem zum Kommunizieren, wenn eine Dosierung genommen werden sollte, beinhaltet; wobei die Kommunikation vorzugsweise über ein Telefon, ein Mobiltelefon, ein Smartphone, eine SMS oder eine E-Mail erfolgt.

9. System gemäß einem der vorhergehenden Ansprüche, wobei der Parameter manuell von dem Benutzer dem System hinzugefügt wird, und/oder wobei das System konfiguriert ist, um Informationen und/oder Parameter aus einem elektronischen Kalender des Benutzers zu sammeln, wobei die Informationen aus einem elektronischen Kalender des Benutzers Informationen aus Vergangenheit, Gegenwart und Zukunft bezüglich eines oder mehrerer der folgenden Gruppe beinhalten: Besuche im Fitnesscenter, körperliche Betätigungen und Ort.

10. System gemäß einem der vorhergehenden Ansprüche, wobei die mindestens eine Messvorrichtung (20) konfiguriert ist, um Entzündungsmarker aus dem Luftweg eines Benutzers, vorzugsweise eine Fraktion des exhalierten Stickstoffmonoxids (FeNO), zu messen, und das System konfiguriert ist, um dies als den Parameter zum Anpassen der Dosierung des Inhalators zu verwenden.

11. System gemäß einem der vorhergehenden Ansprüche, wobei der Computer ferner konfiguriert ist, um Berichte oder aufgezeichnete Informationen bezüglich des Zustands des Benutzers auf der Basis des mindestens einen gemessenen Parameters bereitzustellen.

12. System gemäß einem der vorhergehenden Ansprüche, wobei der Inhalator (10) konfiguriert ist, um eine Dosierung von Insulin zur Behandlung von Diabetes bereitzustellen.

13. System gemäß einem der vorhergehenden Ansprüche, wobei der Inhalator (10) ein Pulverdosierinhalator, ein Inhalator für aerosolförmige Arzneimittel, ein Inhalator für zerstäubte Arzneimittel oder eine beliebige Art von Dosierungsabgabegerät ist.

14. System gemäß einem der vorhergehenden Ansprüche, wobei der Computer (30) ferner konfiguriert ist, um die Dosierung zu dem Zweck zu beschränken, die Dosierung nicht auf eine gefährliche Dosierung oder eine nicht effektive Dosierung anzupassen, wodurch Unter- oder Übermedikation verhindert wird.

Revendications

1. Un système de dosage commandé par ordinateur, pour un ajustement de dose pour un inhalateur mobile portable (10) destiné à administrer une dose d'un médicament, comprenant :

au moins un dispositif de mesurage (20) destiné à mesurer au moins un paramètre (24) ; et
un ordinateur portable mobile (30) distinct de l'inhalateur (10), l'ordinateur (30) étant configuré afin de communiquer avec l'au moins un dispositif de mesurage (20) pour recevoir le au moins un paramètre (24) et de communiquer avec une mémoire distante (40) pour envoyer et recevoir des informations (42) vers des et en provenance de dossiers médicaux de patient de la mémoire distante (40) pour les stocker dans une mémoire (36) de l'ordinateur (30), et l'ordinateur (30) étant configuré afin de recevoir une entrée manuelle (50) pour la stocker dans la mémoire (36) de l'ordinateur (30) ;
caractérisé en ce que l'ordinateur (30) est configuré afin de créer un ensemble de données (32) établissant une pluralité de niveaux de différentes doses (321, 322, 323) de médicament, en configurant un plan de traitement, où le plan de traitement est un plan de traitement conforme aux exigences ou à la législation nationale, basé sur le médicament utilisé par l'inhalateur (10), les informations (42) en provenance des dossiers médicaux du patient de la mémoire distante (40), et l'entrée manuelle (50) ;
où l'ordinateur (30) est en sus configuré afin de stocker l'ensemble de données (32) dans la mémoire (36) de l'ordinateur (30) ;
où l'ordinateur (30) est en sus configuré afin de générer une indication (34) indiquant un ajustement de dose pour l'inhalateur (10), basée sur l'au moins un paramètre (24) et sur un niveau de la pluralité de niveaux de dose (321, 322, 323) de l'ensemble de données, l'indication (34) indiquant un niveau de la pluralité de niveaux de dose (321, 322, 323) de l'ensemble de données (32) comme l'ajustement de dose pour l'inhalateur (10).

2. Le système selon la revendication 1, où l'ordinateur (30) est en sus configuré afin de recevoir une entrée automatique (60) et la configuration pour générer l'indication (34) est en sus basée sur l'entrée automatique (60).

3. Le système selon la revendication 1 ou la revendication 2, où l'indication (34) est un message texte et/ou graphique sur un écran (38) de l'ordinateur (30).

4. Le système selon l'une quelconque des revendications précédentes, où le dispositif de mesurage (20) est un ou plusieurs dispositifs du groupe suivant : un spiromètre, un accéléromètre, un oxymètre de pouls, un oscillomètre d'impulsion (IOS), un dispo-

sitif pour échantillon de sang, un débitmètre pour poumons, un débitmètre de pointe, un dispositif prélevant des échantillons de marqueur d'inflammation, et/ou un dispositif prélevant des échantillons de marqueur d'inflammation de l'air expiré.

5. Le système selon l'une quelconque des revendications précédentes, où l'indication (34) est un ajustement de dose par un des ajustements suivants ou par une combinaison d'un ou de plusieurs des ajustements suivants :

ajustement de la quantité de médicament administrée à chaque inhalation ;
ajustement de la fréquence d'inhalations ;
ajustement du nombre d'inhalations ; et
ajustement par ajout d'un autre médicament.

6. Le système selon l'une quelconque des revendications précédentes, où l'ordinateur (30) est un téléphone mobile et la configuration de l'ordinateur (30) est une application sur le téléphone mobile ou une application dans un nuage (*cloud*) internet.

7. Le système selon la revendication 2, où l'entrée automatique (60) est une ou plusieurs entrées du groupe suivant : niveaux de pollen, pollution de l'air, conditions météorologiques, paramètre biologique, indice de pollen, volume pulmonaire, débit d'air vers ou en provenance du poumon, échantillon de sang, taux de sucre dans le sang, poids corporel, surface corporelle, condition environnementale, humidité, pression d'air, hauteur au-dessus du niveau de la mer, position GPS, activité utilisateur récente ou future, apport nutritionnel, ou données utilisateur.

8. Le système selon l'une quelconque des revendications précédentes, où le système comprend en sus un système de rappel afin de communiquer lorsqu'une dose devrait être prise ; la communication se fait préférablement par le biais d'un téléphone, d'un téléphone mobile, d'un smartphone, de sms, ou d'un e-mail.

9. Le système selon l'une quelconque des revendications précédentes, où le paramètre est ajouté manuellement par l'utilisateur au système, et/ou le système est configuré afin de collecter des informations et/ou des paramètres en provenance du journal électronique d'un utilisateur, où les informations en provenance du journal électronique d'un utilisateur comprennent des informations passées, présentes, et futures concernant un ou plusieurs éléments du groupe suivant : visites à la salle de sport, exercices, et emplacement.

10. Le système selon l'une quelconque des revendications précédentes, où l'au moins un dispositif de mesurage (20) est configuré afin de mesurer des marqueurs d'inflammation en provenance des voies respiratoires d'un utilisateur, préférablement une fraction d'oxyde nitrique (FeNO) expiré, et le système est configuré afin d'utiliser cela comme paramètre afin d'ajuster la dose de l'inhalateur.

11. Le système selon l'une quelconque des revendications précédentes, où l'ordinateur est en sus configuré pour fournir des rapports ou des informations enregistrées concernant l'état de l'utilisateur basés sur l'au moins un paramètre mesuré.

12. Le système selon l'une quelconque des revendications précédentes, où l'inhalateur (10) est configuré afin de fournir une dose d'insuline pour le traitement du diabète.

13. Le système selon l'une quelconque des revendications précédentes, où l'inhalateur (10) est un inhalateur doseur pour poudre, un inhalateur pour médicament sous forme d'aérosol, un inhalateur pour médicament sous forme nébulisée, ou tout type d'appareil d'administration de dose.

14. Le système selon l'une quelconque des revendications précédentes, où l'ordinateur (30) est en sus configuré afin de limiter la dose dans le but de ne pas ajuster la dose à une dose dangereuse ou à une dose inefficace, évitant une sous- ou surmédication.

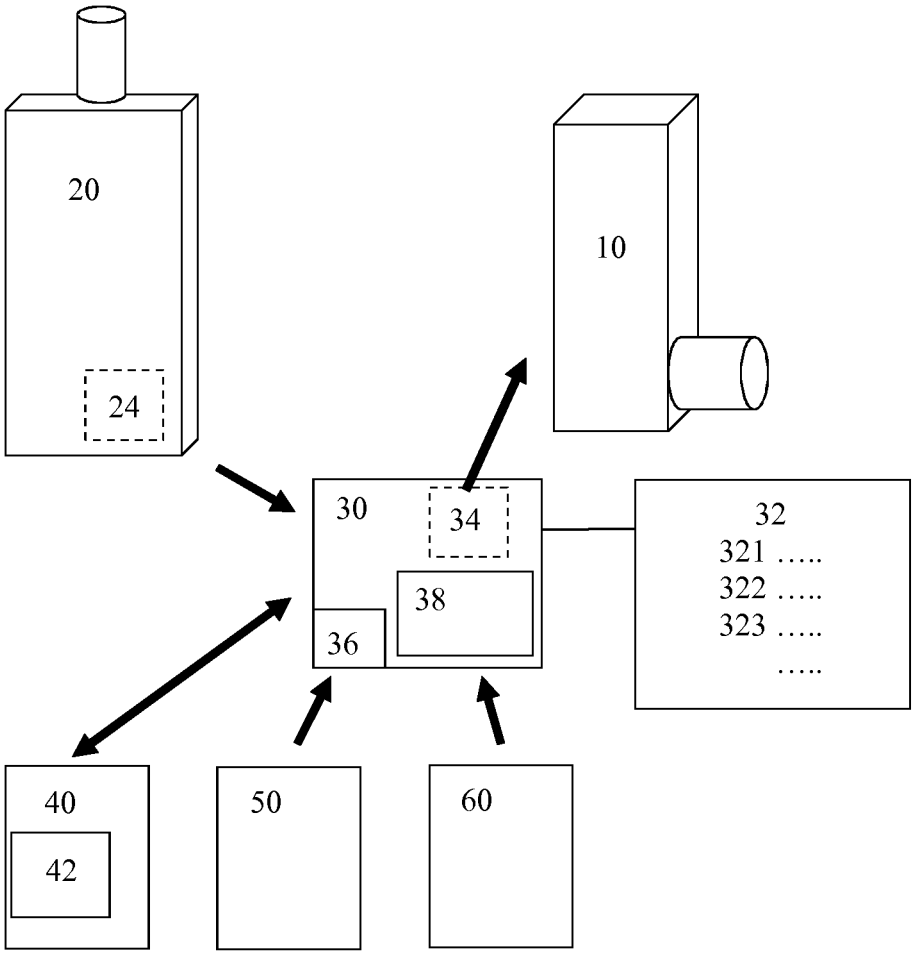

FIG 1

REFERENCES CITED IN THE DESCRIPTION

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- WO 2005087091 A **[0006]**

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- **VAN DER MEER et al.** Internet-based self-management plus education compared with usual care in asthma: a randomized trial. *Annals of internal medicine,* 21 July 2009, 110-120 **[0005]**
- **LICSKAI et al.** Development and pilot testing of a mobile health solution for asthma self-management: Asthma action plan smartphone application pilot study. *the Canadian Respiratory Journal,* 01 July 2013, vol. 20 (4 **[0006]**

专利名称(译)	计算机控制加药系统		
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[标]申请(专利权)人(译)	MEDITUNER		
申请(专利权)人(译)	MEDITUNER AB		
当前申请(专利权)人(译)	MEDITUNER AB		
[标]发明人	LJUNGBERG HENRIK		
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代理机构(译)	MURGITROYD & COMPANY		
其他公开文献	EP3195160A1		
外部链接	Espacenet		

摘要(译)

公开了一种计算机控制的剂量系统，其提供了用于调节用于递送药物剂量的移动的手持式吸入器的剂量的方法。 该系统包括至少一个用于测量至少一个参数的测量装置； 以及与所述吸入器分离的手持式移动计算机，所述计算机被配置为与所述至少一个测量设备以及与远程存储器通信，所述远程存储器用于向所述远程存储器的患者病历发送信息以及从所述远程存储器的患者病历接收信息，以存储在所述存储器中。 计算机，并且该计算机被配置为接收手动输入以存储在计算机的存储器中。该计算机被配置为基于吸入器所使用的药物，来自远程存储器的患者病历的信息以及手动输入来创建用于设置多种不同剂量药物水平的数据集； 所述计算机还被配置为将所述数据集存储在所述计算机的存储器中。 所述计算机还被配置为基于所述至少一个参数和所述数据集的多个剂量水平之一来生成指示用于所述吸入器的剂量调整的指示，所述指示指示所述多个剂量水平之一。 数据集作为吸入器的剂量调整。 还公开了由计算机控制的剂量系统产生的剂量方案。

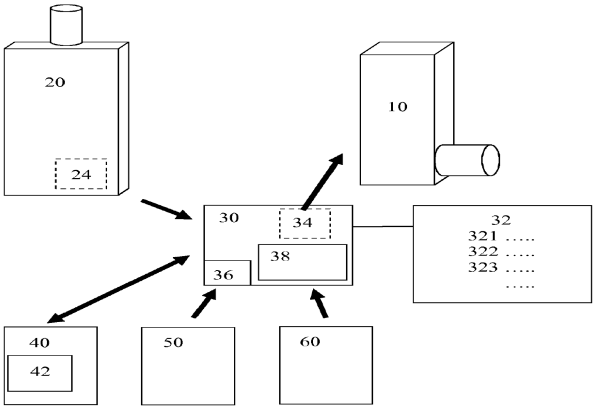

FIG 1