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Respiratory care system with electronic indicator

Abstract

A respiratory care system includes a user interface. A flow indicator is moveable in response to inhalation and/or exhalation, or both, by a user through the user interface. An electronic indicator is operable in response to an electronic signal transmitted in response to the movement of the flow indicator. Methods of use and assembly are also provided.

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Background/Summary

(1) This application is a continuation of U.S. application Ser. No. 15/467,450, filed Mar. 23, 2017 and entitled “Respiratory Care System With Electronic Indicator,” now U.S. Pat. No. 10,894,142, which application claims the benefit of U.S. Provisional Application 62/337,626, filed May 17, 2016 and entitled “Respiratory Care System With Electronic Indicator,” U.S. Provisional Application No. 62/312,830, filed Mar. 24, 2016 and entitled “Medicament Delivery System With Electronic Indicator,” and U.S. Provisional Application 62/465,479, filed Mar. 1, 2017 and entitled “Smart Metered Dose Inhaler Applicator,” the entire disclosures of which are hereby incorporated herein by reference.

TECHNICAL FIELD

(1) The present invention relates generally to a respiratory care system, and in particular, to a medicament delivery device, an accessory device to a medicament delivery device, or respiratory exercise device, each configured with an electronic indicator, which may provide visual, auditory or tactile feedback to a user or caregiver of inhalation, exhalation, and/or completion of a respiratory cycle, as well as end of life information for the system or device.

BACKGROUND

(2) Individuals suffering from asthma, COPD or other respiratory ailments may require medication delivered in aerosol form for inhalation into the lungs for treating or preventing the respiratory ailment. In some cases, medication is administered in aerosol form from a nebulizer, catheter, dry powder inhaler (DPI), or metered dose inhaler (MDI). Patients suffering from respiratory ailments may also benefit from using respiratory exercise devices, such as oscillating expiratory pressure devices.

(3) MDIs require the user to time their inhalation corresponding to actuation of the MDI, which may be difficult for some users, specifically children. Poor coordination may lead to medication being deposited in the mouth or throat rather than the lungs. To improve drug delivery from MDIs, an accessory device, such as a valved holding chamber (VHC), may be used to suspend the medication dispensed from the MDI in the chamber until the user inhales. While a VHC aids in proper drug delivery from MDIs, the VHC may be enhanced by further indicating to the user that, for example, inhalation is successful. Such feedback may provide the user, whether a patient or caregiver, confidence that the patient is properly using the MDI and VHC and, thus, receiving the required medication. Electronic MDIs that provide feedback to a user or caregiver regarding the proper use of the MDI are known in the art. These MDIs are typically quite expensive.

(4) While various devices may provide features that indicate to the user that inhalation and/or exhalation is being achieved, often the indicator is positioned within a chamber or other component housing, and may be difficult to observe due to humidity or moisture buildup during treatment. In addition, many devices are not able to provide an indication that a successful treatment was completed. For example, while information about flow is important, such indicators often do not provide information about whether all of the medication was properly delivered.

(5) In addition, many of the known devices have chambers that may degrade over time due to material/coating degradation and the like, which may lead to users continuing treatment with VHCs beyond a recommended time period.

SUMMARY

(6) A medication delivery system includes a user interface, A flow indicator is moveable in response to inhalation and/or exhalation, or both, by a user through the user interface. An electronic indicator is operable in response to an electronic signal transmitted in response to the movement of the flow indicator. Methods of use and assembly are also provided. In some embodiments, the flow indicator may also be an inhalation valve, exhalation valve or actuator. By using a VHC with electronic indicator capability as described herein, a user or caregiver is able to use a less expensive mechanical MDI without electronic indicia capability. Other types of accessory devices with feedback indicia may also be used as training tools to teach and promote proper usage techniques

with medicament delivery devices.
(7) In one embodiment, a medication delivery system includes a holding chamber having an input end, an output end having a user interface having an outlet and an interior volume of space defined between the input and output ends, and a flow indicator. The flow indicator is moveable in response to inhalation and/or exhalation by a user through the user interface. In some embodiments, the flow indicator is a mechanical flow indicator. An electronic indicator is operable in response to an electronic signal transmitted in response to the movement of the flow indicator. Methods of use and assembly are also provided.
(8) The various aspects and embodiments provide significant advantages relative to the prior known devices. For example, in one embodiment, the holding chamber may be used with an MDI, or other medicament delivery devices, such as a dry powder inhaler or nebulizer, and/or respiratory exercise devices, such as a PEP device or OPEP device, with an indicator providing electronic feedback, for example and without limitation by way of visual feedback via LED, as to when sufficient inhalation is achieved and/or when all of the drug has been inhaled and treatment is complete. The flow indicator may be incorporated for mechanical feedback, with movement between first and second positions indicating that inhalation is sufficient. The electronic components may be integrated in the assembly of the device, or embodied in a modular component that may be fitted or connected to existing valved holding chambers or other medicament delivery systems and/or respiratory exercise systems.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) The Figures show different embodiments of the medication delivery system, block/flow diagrams and methods for use and assembly thereof.
(2) FIG. **1** is a cross-sectional view of a first embodiment of a valved holding chamber with an inhalation valve in a closed position and a flow indicator in a neutral position.
(3) FIG. **2** is a cross-sectional view of the valved holding chamber s shown in FIG. **1** with the inhalation valve in an open position, the flow indicator in an operable position and the electronic indicator indicating proper inhalation.
(4) FIG. **3** is a cross-sectional view of the valved holding chamber shown in FIG. **1** with an electronic indicator indicating an end of life for the valved holding chamber.
(5) FIG. **4** is a cross-sectional view of a second embodiment of a valved holding chamber with an inhalation valve in a closed position and a flow indicator in a neutral position.
(6) FIG. **5** is a cross-sectional view of the valved holding chamber shown in FIG. **3** with the inhalation valve in an open position and the flow indicator in an operable position and the electronic indicator indicating proper inhalation.
(7) FIG. **6** is a cross-sectional view of the valved holding chamber shown in FIG. **1** with an electronic indicator indicating an end of life for the valved holding chamber.
(8) FIG. **7** is a schematic flow chart diagram showing the operation of the electronic indicator.
(9) FIG. **8** is a perspective view of an embodiment of a nebulizer having a flow indicator and an electronic indicator.
(10) FIG. **9** is a perspective view of an embodiment of a positive expiratory pressure device having a flow indicator and an electronic indicator.
(11) FIG. **10** is a perspective view of an embodiment of a dry powder inhaler having a flow indicator and an electronic indicator.
(12) FIG. **11** is a partial, perspective view of a valved holding chamber with a flow indicator and an electronic indicator.
(13) FIGS. **12**A and B are side and top views of the valved holding chamber shown in FIG. **11**.

(14) FIG. **13** is a perspective view of releasable end assembly for a valve holding chamber having a flow indicator and an electronic indicator.
(15) FIG. **14** is a partial cross-sectional view of the end assembly shown in FIG. **13**.
(16) FIG. **15** is a front perspective view of the end assembly shown in FIG. **13**.
(17) FIG. **16** is an enlarged, partial view of the end assembly with the flow indicator removed.
(18) FIG. **17** is perspective view of the end assembly shown in FIG. **13** with a patient interface secured thereto.
(19) FIGS. **18** and **19** are front and rear perspective views of the valved holding chamber shown in FIG. **1**.
(20) FIG. **20** is a cut-away view of an end assembly with an electronic flow indicator.
(21) FIG. **21** is an enlarged view of the end assembly shown in FIG. **20**.
(22) FIG. **22** is an exploded view of an end assembly having a valve.
(23) FIG. **23** is a cross-sectional view of a medicament delivery device incorporating the end assembly of FIG. **22**.
(24) FIG. **24** is an exploded view of a mask assembly having a valve.
(25) FIG. **25** is a perspective view of the mask assembly of FIG. **24**.
(26) FIG. **26** is an exploded view of a mouthpiece having a valve.
(27) FIG. **27** is a perspective view of the mouthpiece of FIG. **26**.
(28) FIG. **28** is a perspective view of a nebulizer having a diaphragm.
(29) FIG. **29** is a cross-sectional view of the nebulizer shown in FIG. **28**.
(30) FIGS. **30**A and B are opposite views of a combined inhalation/exhalation valve.
(31) FIG. **31** is a cross-sectional view of a medicament delivery device incorporating the valve shown in FIGS. **30**A and B.
(32) FIG. **32** is an enlarged, partial view of the device shown in FIG. **31**.
(33) FIG. **33** is a side view of a nebulizer.
(34) FIG. **34** is a top view of a diaphragm.
(35) FIG. **35** is a bottom view of a dial.
(36) FIG. **36** is a side view of a holding chamber assembly.
(37) FIG. **37** is a cross-sectional view of the holding chamber assembly shown in FIG. **36** taken along line **37**-**37**.
(38) FIG. **38** is a back view of an inhalation valve for a valved holding chamber.
(39) FIG. **39** is a perspective view of a retainer incorporated into a valved holding chamber.
(40) FIG. **40** is a perspective view of a mask.
(41) FIGS. **41**A-C are front, side and rear views of valve incorporated into the mask shown in FIG. **40**.
(42) FIG. **42** is a perspective view of a mouthpiece.
(43) FIGS. **43**A-C are front, side and rear views of a valve incorporated into the mouthpiece shown in FIG. **42**.
(44) FIG. **44** is a side view of a nebulizer.
(45) FIGS. **45**A-C are front, side and rear views of a nebulizer actuator incorporated into the nebulizer of FIG. **44**.
(46) FIG. **46** is a perspective view of a holding chamber.
(47) FIG. **47** is a perspective view of a connector for the holding chamber of FIG. **46**.
(48) FIGS. **48**A-C are front, side and rear views of a combined inhalation/exhalation valve incorporated into the holding chamber of FIG. **46**.
(49) FIG. **49** is a schematic diagram of a manometer.
(50) FIG. **50** is a schematic side view of an optic sensor interfacing with a mechanical flow indicator.
(51) FIG. **51** is a perspective view of a flow indicator.
(52) FIG. **52** is an exploded perspective view of one embodiment of a valved holding chamber

assembly.
(53) FIG. **53** is an exploded perspective view of another embodiment of a valved holding chamber assembly.
(54) FIG. **54** is a schematic view of a microprocessor for an electronic indicator.
(55) FIG. **55** is a side view of a metered dose inhaler being applied to another embodiment of a valved holding chamber.
(56) FIG. **56** is an enlarged exploded view of the valved holding chamber and end piece shown in FIG. **55**.
(57) FIG. **57** is a schematic cross section of a metered dose inhaler actuation assist device.
(58) FIGS. **58**A and B are partial cross-sectional views of medication delivery adapter for use in a ventilator system.
(59) FIG. **59** is a perspective view of a compressor for use with a medication delivery system.
(60) FIG. **60** is an exploded view of tubing and an indicator.
(61) FIG. **61** is a schematic cross-sectional view of a peak flow meter.
(62) FIG. **62** is a cross-sectional view of one embodiment of a valved holding chamber.
(63) FIG. **63** is a perspective view of the inhalation valve used in the valved holding chamber of FIG. **62**.
(64) FIG. **64** is a schematic flow chart illustrating the operation of a metered dose inhaler actuation assist device and valved holding chamber.
(65) FIG. **65** is a cross-sectional view of another embodiment of a valved holding chamber.
(66) FIGS. **66**A-C are enlarged, partial cross-sectional views of the mechanical flow indicator and an array of electronic indicators.
(67) FIG. **67** is a flow chart illustrating the sequence of flow detection and corresponding indication thereof.
(68) FIG. **68** is a side view of metered dose inhaler adapter being applied to a valved holding chamber.
(69) FIG. **69** is a schematic showing a system with communication between the MDI applicator and remote server and/or local computing device.
(70) FIG. **70** is a schematic showing the computer and network used in the system of FIG. **69**.
(71) FIG. **71** is a rear view of the MDI positioned in the MDI applicator of FIGS. **1** and **2** with the lever in a raised position.
(72) FIG. **72** is a front view of the embodiment of the MDI shown in FIG. **5** with the MDI positioned in an actuated position in a MDI applicator.
(73) FIG. **73** is a perspective view of another embodiment of a MDI positioned in an MDI applicator.

DETAILED DESCRIPTION OF THE DRAWINGS

(74) It should be understood that the term “plurality,” as used herein, means two or more. The term “coupled” means connected to or engaged with, whether directly or indirectly, for example with an intervening member, and does not require the engagement to be fixed or permanent, although it may be fixed or permanent. It should be understood that the use of numerical terms “first,” “second,” “third,” etc., as used herein does not refer to any particular sequence or order of components; for example “first” and “second” ring-like housing components may refer to any sequence of such members, and is not limited to the first and second ring-like housing components of a particular configuration unless otherwise specified. As used herein, “respiratory care system” includes any one or more of a medicament delivery device, an accessory device to a medicament delivery device, and respiratory exercise device.
(75) Referring to the drawings, the various medicament delivery systems include a valved holding chamber **2** having an input end **12**, an output end **14** having a user interface **16** with an outlet **18** and an interior volume **20** of space defined between the input and output ends. A flow indicator **22** is moveable in response to inhalation and/or exhalation by a user through the outlet. An electronic

indicator **220** is operable in response to an electronic signal transmitted in response to the movement of the flow indicator **22**. A housing **23** surrounds the flow indicator and defines a viewing window or port. The viewing port may be made translucent or transparent, such that the user may observe the movement of the flow indicator. Alternatively, the viewing window where the mechanical flow indicator **22** is located may be made opaque or obscured with a non-see through coating or color, such that the user is only able to observe the electronic indicator **220**. In this latter embodiment, the user or caregiver would only see one indicator. Various respiratory care systems may include without limitation a valved holding chamber **2**, a dry powder inhaler **4**, a positive expiratory pressure device **6** or a nebulizer **8**.

(76) In one embodiment, shown in FIGS. **1**-**6**, **10**-**19**, and **50**-**53**, a mechanical flow indicator **22** functions as an electrical switch as it moves between first and second positions during inhalation, for example as a flow path (P) is created along an inhalation path defined between the input and output ends **12**, **14** of the holding chamber **2**. An MDI includes a medicament canister **13** and an actuator boot **15**, having a mouthpiece that is fitted within said input end **12**, for example with a friction fit. In this embodiment, the mechanical flow indicator **22** may be positioned outside of the inhalation path (P), but is responsive to flow along the flow path, for example by way of a negative pressure being created. It should be understood that the flow indicator may also be configured to move during exhalation. Various aspects of the flow indicator are shown for example and without limitation in U.S. Pat. No. 8,550,067 for a “Visual Indicator for An Aerosol Medication Delivery Apparatus and System,” the entire disclosure of which is hereby incorporated herein by reference.

(77) As shown in FIGS. **1**-**4**, **52** and **53**, the valved holding chamber **2** includes a front piece, or patient interface **16**, having an adapter **24** or baffle section, otherwise referred to as a retainer, releasably secured to the end of the valved holding chamber, for example with tabs. A mouthpiece section **26** is coupled to the baffle section, for example with tabs **28** engaging openings **30**. As shown in FIGS. **22**, **38**-**39**, **52** and **53**, the adapter or baffle section includes an annular attachment collar **32** with slots **34**, a transition piece **36** and a cylindrical exit port **38**. The adapter is attached to the chamber by snap inserting tabs **40** on the chamber housing into the slots **34** and then twisting the chamber housing or adapter so that the tabs are locked into place within the slots. The baffle section **24** may alternatively be integrally formed as an end portion of the holding chamber.

(78) An inhalation valve **241** is seated on a front surface **42** of a baffle, which defines a valve seat. The inhalation valve is formed as an annular valve in one embodiment. The annular valve **241** has a central opening with an inner peripheral sealing edge **44** that seals against the valve seat **42**. An outer peripheral edge **46** of the annular valve defines an exhalation valve that seats against a valve seat **48** defined by the mouthpiece. The inhalation valve may alternatively be formed as a duckbill valve, center post valve, slit petal valve and/or flap valve. The valve may be made of a soft plastic, such as silicone or a thermoplastic elastomer.

(79) The flow indicator **22** may be integrally attached to the inhalation valve, or separately formed as shown in FIG. **51**. In either embodiment, the flow indicator is hingedly connected to the valve or a base **50**, for example with living hinge formed at the junction thereof, or with a hinge pin. The base **50** may be secured to the valved holding chamber or the user interface. The resiliency of the flow indictor biases the indicator to an at rest position. The flow indicator provides a visual indicator to the user or caregiver that the user is inhaling. The flow indicator may be rectangular in shape, although other shapes, such as a square or an ellipse, may also be suitable. For example, the visual flow indicator may have a rounded top edge as shown in FIGS. **23** and **51**.

(80) Referring to the embodiment of FIGS. **65** and **66**A-C, the mechanical flow indicator **22** is positioned in a housing **23** located at the input end of holding chamber **2**. The flow indicator may be incorporated into a backpiece **230**, secured to the input end of the chamber. In this embodiment, the mechanical flow indicator **22** is configured to provide a range of electrical responses, rather than a simple normally open or closed switch. In on embodiment, the flow indicator **22** is configured with, or incorporates, a flexible resistor. As the flow indicator **22** is deformed (e.g.,

bent) greater amounts, as shown in FIGS. **66**A-C, the resistance is varied, e.g., increased (or decreased). The resistor is incorporated into a circuit coupled to an electronic indicator, shown in this embodiment as an array of lights **1040**, e.g., LED's, as further explained below. In this embodiment, the flow indicator is positioned outside the flow path P, but ambient air is entrained through an opening in the housing **23**, whether formed as a part of the back piece **230** or as part of the holding chamber **2**. The air flow past the indicator **22** causes the flow indicator bend a greater or lesser amount depending on the flow rate or volume. As a starting point, when the system is at rest, and the flow indicator is at rest, as shown in FIG. **66**A, the resistance of the resistor in the circuit will cause a single light to illuminate, providing indicia that the system is ready, or there is no flow. As the patient inhales, the magnitude of the flow will rise to a predetermined desired flow rate, which causes the flow indicator **22** to bend, with the resistance being varied to signal the circuit to illuminate additional lights.

(81) For example, a range of acceptable flow rates/volumes may be registered by the flow indicator bending between upper and lower limits, with the corresponding resistance change causing the circuit to illuminate between 2 and 3 additional lights for example. If the flow is too great, the flow indicator may bend beyond the acceptable range, causing an additional light (for example a different color, intensity or blinking) to illuminate and providing feedback that the flow rate is too great. This electronic indicator thereby provides feedback to the user and/or caregiver about the proper usage of the device. The array of lights may provide various indicia, such as change in colors (green to yellow to red) associated with acceptable, borderline and unacceptable flows. The circuit, which may include a microprocessor, or may communicate with a remote computer or processor as further explained below in connection with FIGS. **69** and **70**, may also record the length or duration of the inhalation sequence, or the length or duration of the inhalation in the predetermined, acceptable flow range.

(82) Referring to the embodiment of FIGS. **55** and **56**, and similarly to FIG. **65**, the mechanical flow indicator **22** and electronic flow indicator **220** are housed at the input end of the valved holding chamber. In this embodiment, a back piece **820** is configured with a housing **23**, which houses the flow indicator. Again, ambient air is drawn through openings in the housing, causing the flow indicator to deflect/deform/bend. The flow indicator may close a switch, or incorporate a resistor that changes resistance, so as to provide input to a circuit and a signal to the electronic indicator **220** that flow, for example by way of inhalation, is occurring. The flow indicator may be configured to deflect in either direction. The flow indicator and electronic indicator may also be incorporated into a whistle, for example a slot provided in the back piece. By locating the indicator at the input end of the chamber, the system is provided with a secondary flow path into the chamber, but avoids the possibility of leakage at the output end/user interface. In addition, the electronic indicator may be more visible to the user, due to the increased line of sight.

(83) In one embodiment, shown in FIG. **68**, a metered dose inhaler (MDI) includes actuator boot **15**, medicament canister **13** and adapter **802**. The adapter **802** has an input end **804** shaped to receive a mouthpiece portion **806** of the boot, and an output end **808** shaped to be received in an opening of the input end of the valved holding chamber, for example as formed in the back piece **230**. As the canister **13** is discharged, aerosolized medicament is discharged through the mouthpiece **806** and adapter **802** and into the valved holding chamber **2**. The adapter **802** may include a housing **23** and a flow indicator **22**. The adapter may be configured with an upstanding flange, or standard/upright **810**, which extends radially beyond an outer circumferential surface of the holding chamber such that an electronic indicator **812**, such as a light, disposed on the upright is visible to the user of the holding chamber. It should be understood that the adapter may be used without a holding chamber, with the output end **808** configured and serving as a mouthpiece that may be inserted into the mouth of a user. The flow indicator **22**, circuitry and electronic indictor **812** function as described herein elsewhere with respect to other embodiments. Because the electronic components are incorporated into the back piece in this embodiment, the back piece may

be removed for cleaning, for example high temperature cleaning like dishwashing and/or autoclaving, which avoids the need to insulate the components from heat and/or water, e.g., water proofing. This in turn allows for the components to be manufactured with less expense.

(84) Now Referring to FIG. **57**, one embodiment of a MDI positioned in a MDI applicator **902** is shown. The MDI applicator **902** may include a lever **904** and a housing **906**. The constructions of various embodiments of an applicator are disclosed in U.S. Pub. No. 2014/0318534A1, filed Mar. 14, 2014, published Oct. 30, 2014, and entitled "Metered Dose Inhaler Applicator," the entire disclosure of which is hereby incorporated herein by reference. The components may be made of various material, including for example plastics used in the injection molding industry, for example polypropylene, ABS and acetal. The lever **904**, which is moveably coupled to the housing **906**, for example by way of a pivoting about a pivot axis/axle or hinge, assists the user, whether a patient or caregiver, in actuating a MDI. The housing is coupled to the MDI, for example with a stretchable seal **908**. A flow indicator **22** is positioned in the housing **906**, with an electronic indicator **220** disposed in the housing and visible to the user. The electronic circuitry is further disposed in the housing. Air flow may be entrained through various openings **911**, **913** in the housing, for example in the top of the housing above the canister, or along the side of the housing as shown in FIG. **57**, causing the flow indicator **22** to move, with an associated signal being sent to the electronic indicator.

(85) Referring to FIGS. **71-73**, the MDI boot **15** may be positioned into the applicator **902**. The lever **904** is then rotated or pivoted relative to the housing about a pivot axis to an at-rest position, with a post **934** of the lever **904** positioned against an end of the canister **13** of the MDI. A force may be applied to the lever **904** of the MDI applicator **902**, which lever **904** pivots about the pivot axis relative to the housing and MDI. The pivotal movement of the lever **904** and the post **934** transfers the force applied to the lever **904** to a downward force against the canister **13** of the MDI. When the downward force against the canister **13** of the MDI causes a stem of the MDI to compress enough to open an internal valve of the MDI, medicine within the canister passes through the stem and out of a nozzle of the MDI in an aerosolized form for inhalation by a patient. The pivot axis is oriented substantially orthogonal to the mouthpiece, or an axis defined by the flow path exiting therefrom. When sufficient force is applied to the canister **13** of the MDI via the lever **904**, the MDI dispenses an aerosolized medicine, for example through a mouthpiece, or into a valved holding chamber **2**, which may thereafter be inhaled by a patient.

(86) Specifically, as the lever **904** is depressed, the canister **13** of the MDI is forced into the actuator boot **15**, which has a well receiving the valve stem in one embodiment. Once the canister has travelled far enough into the boot **15**, the valve stem is depressed by the well until the valve is opened, thereby releasing the dose of aerosolized medicine. The MDI may be configured with a dose counter **930**, for example a mechanical or electronic dose counter, which records the number of actuations of the canister.

(87) Referring to the embodiment shown in FIGS. **82**, the lever is pivotally coupled to the housing about an axis, which is oriented parallel to the flow path axis, or forms an acute angle relative thereto. This alternate lever position provides improved comfort to at least some users.

(88) The movement of the lever **904** relative to the housing **906**, canister **13** or boot **15**, provides input to an electronic actuation indicator/tracker that signals and/or records that an actuation of the canister has occurred. For example, in the embodiments shown in FIGS. **71** and **72**, a conductive portion, e.g., strip **935**, is disposed on a surface of the lever and leads to a microcontroller **940**, which may be housed in a case **942**. The lever further includes a conductive portion, e.g., strip **936**, that leads to a battery **944**, which may also be housed in the case **942**. A conductive portion, e.g., strip **932**, is disposed on the housing **906**, or alternatively on the canister or boot. It should be understood that the lever and housing may include other electrically conductive properties, or be integrally formed from a conductive material, isolated at attachment points by an insulator, or include various conductive portions, whether applied as a separate member or integrally formed.

The case **942** may be disposed in and coupled to the lever **904**. It should be understood that the strips **935**, **936** and case **942**, with battery **944** and controller **940**, may be disposed on or coupled to the housing **906**, boot **15** or canister **13**, with strip **932** disposed on the lever. The strips **932**, **935**, **936** act as a (normally open) switch when the lever is a raised and/or at-rest position as shown in FIGS. **71** and **72**. As the lever is pivoted to an actuation position, the strip **932** is brought into contact with and electrically connects strips **935**, **936**, with the strips **932**, **935**, **936** functioning as a closed switch. The completion of the circuit **936**, **932**, **935** signals the microcontroller to record an actuation of the MDI and acquire a time stamp associated with the actuation and store the data on the onboard memory, or communicate the data to a remote server or local computing device as further explained below. The switch is closed (or opened) when the lever has been displaced a predetermined minimum distance. The switch may alternatively be configured as a limit switch, wherein the switch is activated only when the lever has travelled a certain distance, or pivoted through a certain angle. The switch may be toggled by contacting the housing, MDI canister and/or actuator.

(89) The applicator may also be configured with an electronic indicator, such as an LED disposed on one of the lever or housing, which provides indicia that an actuation has occurred. The activation of the circuit by the closing of the switch may activate the electronic circuit utilizing low power circuitry enclosed within a portion of the lever or housing, for example the controller. The conductive properties may be specific to a small region of the lever and housing, e.g., a thin strip or other geometry, or the entire end of the housing may be conductive. Alternatively, the system uses capacitive sensing to determine when the lever has reached an actuation position. Feedback from the electronic indicator indicates that a sufficient actuation is achieved.

(90) In other embodiments, the switch may be a normally closed switch, which activates the circuit when the switch is opened, for example when the lever is pivoted. Actuation may also be detected by a pressure sensor, a capacitive sensor, an inductive sensor, or other proximity sensor or switch. Upon reaching a predetermined second position, the electrically conductive properties of the lever and/or housing act as a switch, whether open or closed, to activate the electronic feedback utilizing low power circuitry enclosed with the housing **942**, located on the lever, housing or MDI. The switch on the mating surface may be configured as two small conductive point contacts or conductive pads, emerging from an encapsulated, potted, conformal coated or sealed printed circuit board (PCB). If the switch is created using capacitive sensing, the sensor within the encapsulation is a small pad and a ground pad matching the size of the PCB at a minimum to increase sensitivity of the sensor. The ground pad may be incorporated within the encapsulation or may be formed by a conductive path from the conductive region of the indicator along one of the applicator or MDI components. The human body may come in contact with the conductive path while holding the applicator and act as a ground.

(91) The electronic components may be integrated in the assembly of the device or embodied in a modular component or housing **942** that can be fit to any MDI or applicator. In either scenario, the electronic components are encapsulated, potted, conformal coated or sealed in the housing **942**. It should be understood that in the various embodiments, the circuitry is not visible to the user or caregiver.

(92) Referring to the alternative embodiment of FIG. **73**, the housing **906** is configured with an IR detector **962** and emitter **960**. Then the canister is in the at-rest position, infrared radiation is emitted from the emitter **960** along a radiation path, reflected off of the canister **13** along a radiation path, and detected by the detector **62**. When the MDI is actuated, the canister moves downwardly in response to the force from the lever **904** until the canister is no longer in the radiation path. In other words, in the actuated position, the canister **13** is no longer in a position to reflect the infrared radiation path, and the change of signal from the detector **962** is used to infer actuation.

(93) In another embodiment, the emitter **960** and detector **962** may be positioned 180 degrees apart

from one another, with the canister **13** breaking the radiation beam there between. In this embodiment, when the lever and canister are in the at-rest position, no radiation emitted from the emitter **960** is detected by the detector **962**. During actuation, the canister moves out the path, such that the detector **962** detects the radiation beam from the emitter **960**, and thereby senses and sends a signal associated with an actuation of the MDI. Light curtain and reflection/proximity sensing embodiments and configurations may also be suitable.

(94) Referring to an alternative embodiment, a force sensor is provided on the lever. The force sensor may serve the function of the post **934**, or be incorporated into the post. Actuation of the MDI occurs at a fairly consistent force. Accordingly, the force sensor may be correlated with the actuation force, and send a signal when the lever is pivoted to apply such a force. For example, once a certain threshold value is recorded or detected by the sensor, an actuation is recorded/registered. The microcontroller, battery and case may be incorporated into the lever as disclosed above. Alternatively, the force sensor may be applied to the housing **906** or MDI, and electronically communicate with the electronic components associated therewith.

(95) It should be understood that the different modules and embodiments may record and register actuations, individually and cumulatively, including the time and date of the actuation, and/or the location when the device is configured and/or associated with a GPS module, which may be embedded in, or housed with, the microcontroller. The accumulated data may be analyzed to provide feedback on when and how the device is used, and/or compliance with particular delivery protocols prescribed by the caregiver.

(96) In order to provide faster and more accurate processing of the sensor data generated within the MDI applicator, data may be wirelessly communicated to a smart phone, local computing device and/or remote computing device to interpret and act on the raw sensor data.

(97) Referring to FIG. **64**, the MDI applicator **902**, for example as disclosed in FIGS. **71**-**73**, may be used with a holding chamber (e.g., FIGS. **1**-**5**), which is configured with a flow indicator. The MDI applicator **902** may be configured with a module as disclosed above that records and registers actuations, individually and cumulatively, including the time and date of the actuation, and/or the location when the device is configured and/or associated with a GPS module, which may be embedded in, or housed with, a microcontroller disposed on or in the housing. The accumulated data may be analyzed to provide feedback on when and how the device is used, and/or compliance with particular delivery protocols prescribed by the caregiver.

(98) In order to provide faster and more accurate processing of the sensor data generated within the MDI applicator, or the other devices (e.g., holding chamber, peak flow meters, dry powder inhalers, nebulizers, etc.) disclosed herein, data may be wirelessly communicated to a smart phone, local computing device and/or remote computing device to interpret and act on the raw sensor data.

(99) Referring to FIGS. **64**, **69** and **70**, the MDI applicator **902**, or other device (e.g., holding chamber, peak flow meters, dry powder inhalers, nebulizers, etc.), includes circuitry for transmitting raw sensor data in real time to a local device, such as a smart phone. The smart phone may display graphics or instructions to the user and implement processing software to interpret and act on the raw data. The smart phone may include software that filters and processes the raw sensor data and outputs the relevant status information contained in the raw sensor data to a display on the smart phone. The smart phone or other local computing device may alternatively use its local resources to contact a remote database or server to retrieve processing instructions or to forward the raw sensor data for remote processing and interpretation, and to receive the processed and interpreted sensor data back from the remote server for display to the user or a caregiver that is with the user of the smart MDI applicator.

(100) In addition to simply presenting data, statistics or instructions on a display of the smart phone or other local computer in proximity of the MDI applicator or other device (e.g., holding chamber, peak flow meters, dry powder inhalers, nebulizers, etc.), proactive operations relating to the MDI applicator may be actively managed and controlled. For example, if the smart phone or other local

computer in proximity to the MDI applicator, or other device (e.g., holding chamber, peak flow meters, dry powder inhalers, nebulizers, etc.), determines that the sensor data indicates that a dose has been administered, the smart phone or other local computing device may communicate that information to the user or caregiver.

(101) In yet other implementations, real-time data gathered in the smart MDI applicator or other device (e.g., holding chamber, peak flow meters, dry powder inhalers, nebulizers, etc.) and relayed via to the smart phone to the remote server may trigger the remote server to track down and notify a physician or supervising caregiver regarding a problem with the particular session or a pattern that has developed over time based on past sessions for the particular user. Based on data from the one or more sensors in the smart MDI applicator or other device (e.g., holding chamber, peak flow meters, dry powder inhalers, nebulizers, etc.), the remote server may generate alerts to send via text, email or other electronic communication medium to the user's physician or other caregiver. The data may be uploaded to a mobile application via wireless communications (e.g., Bluetooth) whenever the mobile device (e.g., phone, tablet, laptop, etc.) is in range for synchronizing the data. The data my then be analyzed on the application and presented to the user in a manner that is beneficial for the user/patient's engagement and adherence/compliance. The data may also be forwarded to a cloud service via WiFi or mobile network so that the data may be reviewed by other caregivers, healthcare providers and/or payers (e.g., insurance companies).

(102) By combining the applicator **902** and valved holding chamber configured with an electronic indicator **220**, a more accurate calculation of the end of treatment may be provided to the user or care giver. For example as shown in FIGS. **7** and **64**, the applicator **902**, or microcontroller **940**, registers an actuation of the MDI and communicates that information, or sends a signal, to a processor, for example by wireless communication. In other embodiments the applicator and valved holding chamber may communicate by direct communication links, for example hard wiring when the applicator is inserted into the valved holding chamber. In operation, the mechanical flow indicator **22** provides input, or sends a signal, that inhalation has commenced by closing a switch, or actuating another sensor, as disclosed above. That information is communicated to a microcontroller (MCU) or microprocessor. An internal clock records the time, while the processor identifies whether the MDI actuation has taken place by way of communication of the signal from the applicator **902**. If the actuation has not transpired, the internal clock loops, and/or computes the time from actuation, such that data is gathered as to the length of the inhalation through the valved holding chamber, which causes the flow indicator associated therewith to move or deform and send a signal, as well as the length of the inhalation after the MDI is actuated. Once an MDI actuation has occurred, as recorded by the applicator **902** and controller **940**, a volume calculation is performed, using the data as to the inhalation flow before and after actuation, with electronic feedback provided. In this way, feedback is provided that treatment is finished, or that sufficient volume has been inhaled subsequent to the actuation of the MDI. The data may also be collected and communicated as noted to the healthcare provider.

(103) The electronic circuitry in the MDI applicator or other device (e.g., holding chamber, peak flow meters, dry powder inhalers, nebulizers, etc.) may include some or all of the capabilities of a computer **500** in communication with a network **526** and/or directly with other computers. As illustrated in FIGS. **69** and **70**, the computer **500** may include a processor **502**, a storage device **516**, a display or other output device **510**, an input device **512**, and a network interface device **520**, all connected via a bus **508**. The computer may communicate with the network. The processor **502** represents a central processing unit of any type of architecture, such as a CISC (Complex Instruction Set Computing), RISC (Reduced Instruction Set Computing), VLIW (Very Long Instruction Word), or a hybrid architecture, although any appropriate processor may be used. The processor **502** executes instructions and includes that portion of the computer **500** that controls the operation of the entire computer. Although not depicted in FIG. **70**, the processor **502** typically includes a control unit that organizes data and program storage in memory and transfers data and

other information between the various parts of the computer **500**. The processor **502** receives input data from the input device **512** and the network **526** reads and stores instructions (for example processor executable code) **524** and data in the main memory **504**, such as random access memory (RAM), static memory **506**, such as read only memory (ROM), and the storage device **516**. The processor **502** may present data to a user via the output device **510**.

(104) Although the computer **500** is shown to contain only a single processor **502** and a single bus **508**, the disclosed embodiment applies equally to computers that may have multiple processors and to computers that may have multiple busses with some or all performing different functions in different ways.

(105) The storage device **516** represents one or more mechanisms for storing data. For example, the storage device **516** may include a computer readable medium **522** such as read-only memory (ROM), RAM, non-volatile storage media, optical storage media, flash memory devices, and/or other machine-readable media. In other embodiments, any appropriate type of storage device may be used. Although only one storage device **516** is shown, multiple storage devices and multiple types of storage devices may be present. Further, although the computer **500** is drawn to contain the storage device **516**, it may be distributed across other computers, for example on a server.

(106) The storage device **516** may include a controller (not shown) and a computer readable medium **522** having instructions **524** capable of being executed on the processor **502** to carry out the functions described above with reference to processing sensor data, displaying the sensor data or instructions based on the sensor data, controlling aspects of the smart MDI applicator or other device (e.g., holding chamber, peak flow meters, dry powder inhalers, nebulizers, etc.) to alter its operation, or contacting third parties or other remotely located resources to provide update information to, or retrieve data from those remotely located resources. In another embodiment, some or all of the functions are carried out via hardware in lieu of a processor-based system. In one embodiment, the controller is a web browser, but in other embodiments the controller may be a database system, a file system, an electronic mail system, a media manager, an image manager, or may include any other functions capable of accessing data items. The storage device **516** may also contain additional software and data (not shown), which is not necessary to understand the invention.

(107) The output device **510** is that part of the computer **500** that displays output to the user. The output device **510** may be a liquid crystal display (LCD) well-known in the art of computer hardware. In other embodiments, the output device **510** may be replaced with a gas or plasma-based flat-panel display or a traditional cathode-ray tube (CRT) display. In still other embodiments, any appropriate display device may be used. Although only one output device **510** is shown, in other embodiments any number of output devices of different types, or of the same type, may be present. In an embodiment, the output device **510** displays a user interface. The input device **512** may be a keyboard, mouse or other pointing device, trackball, touchpad, touch screen, keypad, microphone, voice recognition device, or any other appropriate mechanism for the user to input data to the computer **500** and manipulate the user interface previously discussed. Although only one input device **512** is shown, in another embodiment any number and type of input devices may be present.

(108) The network interface device **520** provides connectivity from the computer **500** to the network **526** through any suitable communications protocol. The network interface device **520** sends and receives data items from the network **526** via a wireless or wired transceiver **514**. The transceiver **514** may be a cellular frequency, radio frequency (RF), infrared (IR) or any of a number of known wireless or wired transmission systems capable of communicating with a network **526** or other smart devices **102** having some or all of the features of the example computer of FIG. **2**. The bus **508** may represent one or more busses, e.g., USB, PCI, ISA (Industry Standard Architecture), X-Bus, EISA (Extended Industry Standard Architecture), or any other appropriate bus and/or bridge (also called a bus controller).

(109) The computer **500** may be implemented using any suitable hardware and/or software, such as a personal computer or other electronic computing device. The computer **500** may be a portable computer, laptop, tablet or notebook computers, smart phones, PDAs, pocket computers, appliances, telephones, and mainframe computers are examples of other possible configurations of the computer **500**. The network **526** may be any suitable network and may support any appropriate protocol suitable for communication to the computer **500**. In an embodiment, the network **526** may support wireless communications. In another embodiment, the network **526** may support hard-wired communications, such as a telephone line or cable. In another embodiment, the network **526** may support the Ethernet IEEE (Institute of Electrical and Electronics Engineers) 802.3×specification. In another embodiment, the network **526** may be the Internet and may support IP (Internet Protocol). In another embodiment, the network **526** may be a LAN or a WAN. In another embodiment, the network **526** may be a hotspot service provider network. In another embodiment, the network **526** may be an intranet. In another embodiment, the network **526** may be a GPRS (General Packet Radio Service) network. In another embodiment, the network **526** may be any appropriate cellular data network or cell-based radio network technology. In another embodiment, the network **526** may be an IEEE 802.11 wireless network. In still another embodiment, the network **526** may be any suitable network or combination of networks. Although one network **526** is shown, in other embodiments any number of networks (of the same or different types) may be present.

(110) It should be understood that the various techniques described herein may be implemented in connection with hardware or software or, where appropriate, with a combination of both. Thus, the methods and apparatus of the presently disclosed subject matter, or certain aspects or portions thereof, may take the form of program code (i.e., instructions) embodied in tangible media, such as floppy diskettes, CD-ROMs, hard drives, or any other machine-readable storage medium wherein, when the program code is loaded into and executed by a machine, such as a computer, the machine becomes an apparatus for practicing the presently disclosed subject matter. In the case of program code execution on programmable computers, the computing device generally includes a processor, a storage medium readable by the processor (including volatile and non-volatile memory and/or storage elements), at least one input device, and at least one output device. One or more programs may implement or use the processes described in connection with the presently disclosed subject matter, e.g., through the use of an API, reusable controls, or the like. Such programs may be implemented in a high level procedural or object-oriented programming language to communicate with a computer system. However, the program(s) can be implemented in assembly or machine language, if desired. In any case, the language may be a compiled or interpreted language and it may be combined with hardware implementations. Although exemplary embodiments may refer to using aspects of the presently disclosed subject matter in the context of one or more stand-alone computer systems, the subject matter is not so limited, but rather may be implemented in connection with any computing environment, such as a network or distributed computing environment. Still further, aspects of the presently disclosed subject matter may be implemented in or across a plurality of processing chips or devices, and storage may similarly be spread across a plurality of devices. Such devices might include personal computers, network servers, and handheld devices, for example.

(111) Referring to FIGS. **58**A and B, adapters **1000**, **1002** for use in a ventilator circuit are shown, with the adapters inserted into a flow path between the ventilator and a user interface. The construction of the adapters is disclosed in U.S. Pub. No. 2014/0360498, filed Mar. 14, 2014, published Dec. 11, 2014, and entitled “Ventilator Circuit, Adapter for Use in Ventilator Circuit and Methods for The Use Thereof,” the entire disclosure of which is hereby incorporated herein by reference. The adapters **1000**, **1002** include medication delivery ports **1004**, **1006**, which are suited and configured to receive medicament delivery devices, including for example and without limitation inhalers **1008** and nebulizers **1010**. The adapters **1000**, **1002** are configured with a

mechanical flow indicator **22** disposed in the flow path. The adapter may be configured with an electronic indicator **220**, such as a light, disposed on an exterior surface of the adapter such that the indicator is visible to the user or care giver. The flow indicator **22**, circuitry and electronic indictor **220** function as described herein with respect to other embodiments.

(112) In a ventilator circuit, drug delivery is preferably performed at the onset of an inhalation cycle, which may be difficult for a care giver to ascertain by just listening to the ventilator machine. The indicator **220** provides more certainty, and helps prevent drug delivery from being performed during exhalation. In operation, the drug delivery devices **1008**, **1010** are actuated when the mechanical indicator **22**, which may be visible to the user, moves and/or when the electronic indicator **220** provides indicia, e.g., by illuminating. The indicator **22** may be made of silicone, and may operate as a switch (normally open or closed), or be configured with a flexible resistor in a circuit, as described herein elsewhere. As shown, the indicators **22** are positioned on the upper side of the adapter, or extend downwardly therefrom, when such adapters are in their normal use positions to prevent drug pooling or accumulation against the indicator **22**.

(113) Referring to FIGS. **59** and **60**, a compressor **1020**, or tubing **1022** connecting the compressor or other air supply, may be configured with a mechanical flow indicator, which moves or is deformed in response to a fluid flow (P), whether gas or liquid. The flow indicator **22** is coupled to a circuit, which provides a signal to an electronic indicator **220** when actuated. The electronic indicator provides indicia to the user that flow is occurring. As shown in FIG. **59**, the flow indicator **22** is embedded in a flow path in the compressor **1020**, while an electronic indicator **220** is provided on or in the compressor, and is visible to the user if embodied as a visual indicator.

(114) As shown in FIG. **60**, the flow indicator may be positioned in a connector, or adapter, having an insert portion received in an end portion **1026** of the tubing **1022** and a receiving end connector portion **1028**, which is shaped and configured to connect to the same devices as the end portion **1026** of the tubing. The flow indicator may alternatively be directly positioned in the tubing **1022** and operably connected to an electronic indicator, whether by direct circuitry or wirelessly.

(115) Referring to FIG. **61**, a peak flow meter **1050** is configured with a mechanical flow indicator **22**, for example a flow indicator configured with a flexible resistor. The amount of flow deflects the indicator and deforms or bends the resistor varying amounts. The amount of deflection or deformation may be correlated with a varying display by an electronic indicator, for example an array of LED's **1040**, with a greater number of LED's being illuminated as the flow increases. The indicator **1040** may also be configured with different color lights providing indicia about different flow levels. Usage data may also be collected and tracked, and connected to a computer or smartphone app, as described above with respect to the MDI applicator, such that the data may be shared with the patient, care giver or other healthcare providers.

(116) In one embodiment, shown in FIGS. **24**, **25** and **40**-**41**A, the patient interface includes a mask **52** secured to an adapter **62**, which in turn may be secured to the end of the valved holding chamber or the baffle section. The mask includes an exhalation valve **54**, which functions as a flow indicator. Other patient interfaces may include for example and without limitation, various mouthpieces, masks, endotracheal tubes, etc. The valve may have a central post **56**, which engages an opening on the mask and secures the valve to the mask. A protective dome or shroud **58** may be disposed around the valve. The exhalation valve **54** is inserted into an exit port formed in a nasal reception area of a mask and is attached thereto. Examples of various mask and exhalation valve embodiments are disclosed in U.S. Pat. Nos. 5,988,160 and 5,645,049, the entire disclosures of which are hereby incorporated herein by reference. A cylindrical input port **60** of the mask is placed over the exit port of the adapter and attached thereto by a friction fit, or by way of an interface of a rib **64** formed on the input port engaging a channel or corresponding rib on the mask **52**.

(117) Referring to FIGS. **26**, **27** and **42**-**43**C, a mouthpiece **70**, incorporated for example into a dry powder inhaler (FIG. **10**), a nebulizer (FIG. **8**), or a oscillating positive expiratory pressure device (FIG. **9**), includes an exhalation valve **72** secured over an opening **74** in the mouthpiece, which

defines a valve seat **76**. The valve is configured with two flaps **78**, such as a butterfly valve in one embodiment, with a central post or protuberance **82** extending through an opening **80** in the valve and securing it to the exterior of the mouthpiece. A shield (not shown) may be disposed over the valve to protect it from tampering.

(118) Referring to FIGS. **28**, **29**, **33-35** and **44-45**C, a nebulizer **90** includes a chamber **92**, a diaphragm **96** and a dial **98** disposed on top of an actuator **94**. The actuator **94** and dial **98** move axially along axis **107** during inhalation. A bottom **104** of the dial **98** engages an inner periphery of the diaphragm **96**, and a bottom **102** of the actuator has a surface that engages a nozzle cover **100**, as the actuator is moved axially downwardly during inhalation.

(119) Referring to FIGS. **30**A-**32** and **46-48**C, another embodiment of a valved holding chamber **110**, which may be used for example and without limitation in a ventilator circuit, is shown. The valved holding chamber has a connector component **112**, which defines a ventilator port. The connector has first and second passageways **114**, **116** separated by a wall **118**. An integrally formed inhalation/exhalation valve **120** has a pair of flaps **122**, **124** extending from opposite directions from a base portion **126**. The connector has a valve seat **128** for the inhalation valve **122**, while the chamber has a valve seat **130** for the exhalation valve **124**. Various aspects of the valved holding chamber and connector are disclosed in U.S. Pat. No. 8,875,706, the entire disclosure of which is hereby incorporated herein by reference.

(120) It should be understood that various components of the above-described medicament delivery devices are flow indicators, and in particular mechanical flow indicators, which move dynamically in response to a flow. The various components, regardless of whether they are visible, provide indicia of a flow, whether inhalation or exhalation. The various components may or may not be visible to the user and/or caregiver. The movement of the flow indicators provides input to an electronic flow indicator that sufficient inhalation has occurred. For example, the number of movements of the flow indicator **22**, whether upon inhalation or exhalation (or both), during a breathing cycle (defined as the number of breaths (N) taken while the medicament is being administered), or the cumulative duration (T) of the change of position of the flow indicator during the breathing cycle, provides input to the circuitry that is correlated with sufficient inhalation. Specifically, a predetermined number or duration (whether singular or cumulative) of contacts, or sufficient proximity to contact, between the flow indicator **22** and a seat, or contact point, provides input to and actuates the electronic indicator, for example by displaying a green light or other indicia. If the number of movements of the flow indicator, or the duration (singular or cumulative) thereof, is not achieved, or if sufficient contact(s) or proximity of contact(s) is not achieved, then the electronic circuit will not activate the electronic indicator, or alternatively, the electronic indicator may be activated to show inadequate medicament administration, for example by displaying a yellow or red light, an auditory signal, vibration (e.g., tactile) or other indicia.

(121) For example, in one embodiment, as shown in FIGS. **1-6**, **11-21** and **51-53**, the visual flow indicator **22** defines a mechanical flow indicator having a conductive strip **130**, or including other electrically conductive properties, which act as a (normally open) switch closing a circuit when it seals against a seat **132**. The activation of the circuit by the closing of the switch thereby activates the electronic feedback utilizing low power circuitry enclosed within a portion of the user interface, such as a mouthpiece or mask adapter. The conductive properties may be specific to a small region of the flow indicator, e.g., a thin strip or other geometry, or the entire face of the flow indicator may be conductive. Alternatively, the system uses capacitive sensing to determine when the flow indicator has reached a second position corresponding to a predetermined flow. Feedback from the electronic indicator **220** indicates that a sufficient inhalation flow rate is achieved and/or that proper treatment has been completed based on a number of breaths and/or the volume calculated based on the minimum flow required to seal the mechanical flow indicator and/or the length to time in which the seal (switch) is maintained. The minimum flow required to seal the mechanical flow indicator may be between 3-5 L/min.

(122) In other embodiments, the switch may be a normally closed switch, which activates the circuit when the switch is opened, for example when an inhalation or exhalation valve (flow indicator) is operated. Again, the number of movements of the flow indicator (e.g., inhalation or exhalation valve or actuator), or duration of the opening of the switch, may provide input to the circuit (FIG. **54**) that sufficient medication delivery has been achieved, with the circuit then activating the electronic indicator. For example, and referring to the embodiments shown in FIGS. **22**, **23**, **38**A-C, **39**, **46**-**48**C, **62** and **63** the mechanical flow indicator is defined by the inhalation valve **241**, **122**, **1060** which may function as the input or switch for the electronic feedback. Again, the inhalation valve may be configured with a region **150**, **152** or material having conductive properties, for example around the inner or outer periphery **33** of the annular valve, or along a free end **154** of the inhalation flap **122**, that mate with a mating surface, e.g., valve seat **42**, **128**, forming a part of an electronic circuit, for example in the baffle, also having a conductive material or region. In this embodiment, when the valve **241**, **122** is in the closed position, flow is not sufficient and no electronic feedback is present. Once the valve (normally closed switch) moves to an open position, for example during inhalation, and is no longer in contact with a baffle, or valve seat, on which it is contact when closed, electronic feedback is activated. In the latter case, movement detection may be performed by a pressure sensor, a capacitive sensor, an inductive sensor, or other proximity sensor or switch. Upon reaching a predetermined second position, the electrically conductive properties of the indicator act as a switch, whether open or closed, to activate the electronic feedback utilizing low power circuitry enclosed with a housing **160**, located on the chamber housing, mouthpiece, mask adapter or other component. The switch on the sealing surface **42**, **128** where the flow indicator mates upon its second position may be configured as two small conductive point contacts or conductive pads, emerging from an encapsulated, potted, conformal coated or sealed printed circuit board (PCB) or microcontroller **261**.

(123) If the switch is created using capacitive sensing, the sensor within the encapsulation is a small pad with a sensing area no larger than 25 mm.sup.2 and a ground pad matching the size of the PCB at a minimum to increase sensitivity of the sensor. The ground pad may be incorporated within the encapsulation or may be formed by a conductive path from the conductive region of the indicator along the body of the chamber. The human body may come in contact with the conductive path while holding the chamber and act as a ground.

(124) As shown in FIGS. **62** and **64**, the mechanical flow indicator is configured as a duckbill valve **1060**, which has a pair of flaps **1064** that open to form a central opening **1062** in response to a flow through the valve. The valve provides one-way flow control. The valve flaps **1064** may have conductive strips **1066** that are in contact with the valve is in a normally closed position, such that an opening of the valve cause the circuit to identify a flow and send a signal to an electronic indicator **220** and/or record an opening in a database. The valve flaps **1064** may alternatively be provided with a flexible resistor **1068**, which deflects with the valve flaps, in a circuit that signals the electronic indicator **220** to provide indicia that flow has occurred, for example by illuminating. The sensor may alternatively be configured as a capacitive sensor.

(125) The electronic components in the various embodiments may be integrated in the assembly of the device, or embodied in a modular component or housing **160** that can be fit to any valved holding chamber (or other respiratory device). In either scenario, the electronic components are encapsulated, potted, conformal coated or sealed in an area preferably between 25×25×5 mm (L×W×H) and 45×45×20 mm (L×W×H). It should be understood that the electronic indicator and flow indicator may be incorporated into a removable patient interface, e.g., mask, mouthpiece, adapter, etc., that may be used by the same patient/user with more than one respiratory care system. It should be understood that in the various embodiments, the circuitry is not visible to the user or caregiver.

(126) Other embodiments of the mechanical flow indicator include the exhalation valve **54**, **72**, **124** on the mask, mouthpiece or connector, which act as the switch (normally open or closed) described

above. In each of these embodiments, the valve (or other moving member) has conductive properties in a region **180** (outer periphery of valve **54**), **182** (periphery of valve **72**), **184** (free edge of flap **124**) in contact with a sealing surface **181**, **76**, whether in a normally open or closed configuration, also having a conductive material or region. While contact is maintained, the switch is on or off (dependent on what feedback is desired) and the switch changes state when flow is enabled to overcome the valve (or other moving member). Alternatively, a proximity sensor or switch may be incorporated into a chamber that accepts an MDI canister to provide indication that the canister is sufficiently inserted in the device. As shown in FIG. **50**, an optic sensor **190** may be provided to signal **192** when the flow indicator **22** has moved to a second position, with sensor **190** providing input to the circuit. Referring to FIGS. **31**, **32** and **46-48**C, either of the multipurpose inhalation/exhalation valves **122**, **124** on the chamber may be configured with a conductive material or region **152**, **184** that closes a switch during inhalation and/or exhalation. The chamber may be utilized in combination with mechanical ventilation, a manual resuscitation bag or a standard aerosol resuscitation mask.

(127) Alternatively, as shown in FIGS. **28**, **29** and **33-35**, the bottom **104** of the dial and an inner periphery **106** of the diaphragm on a nebulizer may be configured with a conductive material or region, which complete a switch when coming into contact, for example during inhalation as the actuator moves axially downwardly. Alternatively, as shown in FIGS. **44-45**C, a bottom surface of the actuator has a conductive material or region that comes into contact with a conductive material or region on the muzzle cover **100** as the actuator moves axially, thereby closing or opening a switch as described above.

(128) In other embodiments, shown in FIG. **49**, a piston **200** on a manometer may be configured with a magnetic or conductive material or region, with a variable output relative to pressure provides an input to an electronic indicator. The various steps performed by the system are shown in the block/flow diagram of FIG. **7**. The sensor or switch input, which may also be related to a mechanical feedback, relays information to a microcontroller unit **261**. The microcontroller **261**, also shown in FIGS. **3**, **12**A and B, **13 20** and **22**, controls the electronic feedback output, and transmits a signal to the electronic indicator (e.g., LED) **220**, and may provide output as disclosed herein. A light pipe may diffuse the light from the LED. A battery **521** provides power to the circuit.

(129) The entirety of the system may be washed by the user without special attention to the electronics, which may also be configured to withstand the heat of a dishwasher. Alternatively, the electronics may be removed prior to washing or exposure to heat. In one embodiment, the battery chemistry is a lithium coin cell, specifically poly-carbon monofluoride lithium that is specifically designed to operate at temperatures up to 125C, has an annual deterioration rate as low as 0.5% and has a relatively flat discharge voltage curve. Incorporating sufficient thermal insulation properties in the encapsulation material may allow for the entirety of the device to withstand autoclaving processes.

(130) In an alternative embodiment, shown in FIGS. **36-37**, linear induction may be utilized to generate power for the circuit and thereby eliminate the need for a battery. The linear electrical generator is composed of one or more neodymium magnet(s) **210** that move reciprocally back and forth along a longitudinal axis **51** (or parallel thereto) or direction within a center space defined by a copper coil **212** wrapped around the axis **51** when a chamber **602** is shaken. This shaking motion is necessary prior to actuating an MDI **13**, **15** and does not imply an additional step in the drug delivery process. The shaking induces a current in the coil **212**, which is stored in a supercapacitor **214** to power the circuitry connected to an electronic indicator **220**.

(131) When taking the device out of the package the first time, an internal timer on the device will activate. For example, a light sensor (or other sensor) will activate an internal clock to begin tracking elapsed time. Alternatively, the timer may be activated upon the first use. The device will function as described herein for the duration of a predetermined recommended life of the device as

determined by the timer, at which point the electronic indicator will either stop functioning or produce a warning signal different from the previously seen signal that indicates prior inhalation and/or treatment completion. This warning signal (e.g., red LED) will indicate to the user that it is time to dispose of the chamber. Nonetheless, the mechanical flow indicator will continue to function after the expiration of the predetermined recommended life, e.g., 1 year, so as to not diminish the safe use of the device.

(132) The user interface, including for example the mouthpiece or mask adapter, holding chamber and retainer may be made of transparent anti-static material (ABS). A back-piece **230**, which interfaces with a MDI **13**, **15**, may be made of an ultra-soft thermoplastic elastomer. The inhalation valve may be made of silicone. The mechanical flow indicator may be made of silicone with magnetic or conductive properties, including a conductive region made of a conductive silicone, metal foil or a conductive coating/ink. The conductive materials may be silver oxide, carbon black, aluminum, or other known conductive materials. The electronics, such as the microcontroller **261**, may be potted conformal coated, sealed, or encapsulated in silicone, epoxy, urethane, hot melt or other materials resistant to high temperatures.

(133) In one embodiment, the electronic indicator **220** is a visual indicator (e.g., LED or LCD display), which provides the electronic feedback. Other electronic indicators may be used, for example an audible signal or feedback, such as a buzzer, a sequence of LED's or other visual cues showing a percentage of treatment completion (e.g., LED bar graph), a segmented numerical display of the treatment percentage completed, an LED or OLED screen showing the progress or numerical representation of the flow or volume remaining, or possible connection to and communication with a smart phone application via bluetooth low energy (BLE) to show data from inhalation or to incorporate flow data into a game.

(134) In operation, as illustrated in FIG. **67**, when the MDI or other drug delivery device is actuated, a medicament will fill the chamber, for example when an inhalation valve is closed. The mechanical flow indicator, whether separately configured or defined by the inhalation valve, or actuator, is in a neutral position since no inhalation is taking place. Accordingly, the electronic indicator, e.g. LED, is off as no feedback is being provided. As the user begins to inhale, the inhalation valve will open, creating a negative pressure and causing the mechanical flow indicator to move forward from a first position to a second position until the flow indicator creates a seal with a seat at a predetermined, sufficient inhalation flow. When the flow indicator creates a seal with the seat, or is sufficiently proximate thereto, a circuit is closed and the electronic feedback is activated, for example by an LED, which provides feedback to indicate proper inhalation. For example, a green LED will provide positive feedback. The LED will stay illuminated while the seal is maintained, and turns off when the seal is broken, e.g., at the end of inhalation or upon improper inhalation. The circuit and electronic indicator may also be configured to be activated when a predetermined number of movements of the flow indicator, or a cumulative duration of such movements, has been achieved. Alternatively, or in addition to indicating proper individual inhalations, the LED may illuminate and stay on for an extended period of time when treatment is complete to relay that the user has completed a successful treatment, for example requiring multiple breathing cycles.

(135) The same process occurs with the exhalation valves or nebulizer actuators configured as the flow indicator, but with the opening of the exhalation valve or actuator closing or opening a circuit so as to provide feedback via the electronic indicator.

(136) At the end of predetermined life for the chamber or other components (e.g., 1 year), as tracked for example by the internal timer or clock, the LED will be deactivated, or the LED will provide a warning signal (e.g., turn red), indicating that the device should be replaced. In the former embodiment, with the lack of positive LED feedback during inhalation, the user will be made aware that the device should be replaced.

(137) Although the present invention has been described with reference to preferred embodiments,

those skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention. As such, it is intended that the foregoing detailed description be regarded as illustrative rather than limiting and that it is the appended claims, including all equivalents thereof, which are intended to define the scope of the invention.

Claims

1. A user interface for a respiratory care system comprising: an inlet adapted to be connected to a respiratory device; an outlet adapted to interface with a user, wherein an inhalation flow path is defined between the inlet and the outlet; a flow indicator positioned outside the inhalation flow path, wherein the flow indicator is moveable from a first, at rest, closed position to a second, actuated, open position at least in response to inhalation by a user through the outlet; an optic sensor directed at and configured to sense when the flow indicator has moved from the first position to the second position, wherein the optic sensor is configured to provide an input signal when the flow indicator has moved from the first position to the second position; a controller configured to receive the input signal from the optic sensor and to transmit a feedback signal; and a feedback device operable to provide feedback about the inhalation flow in response to the feedback signal transmitted from the controller.
2. The user interface of claim 1 wherein the flow indicator is visible to the user.
3. The user interface of claim 1 wherein the outlet comprises at least one of a mask and/or mouthpiece.
4. The user interface of claim 1 wherein the feedback device comprises an electronic indicator.
5. The user interface of claim 4 wherein the electronic indicator comprises at least one of a visual indicator, audible indicator and/or a vibratory indicator.
6. A respiratory care system comprising: a respiratory device; and a user interface comprising: an inlet connected to a respiratory device; an outlet adapted to interface with a user, wherein an inhalation flow path is defined between the inlet and the outlet; a flow indicator positioned outside the inhalation flow path, wherein the flow indicator is moveable from a first, at rest, closed position to a second, actuated, open position at least in response to inhalation by a user through the outlet; an optic sensor directed at and configured to sense when the flow indicator has moved from the first position to the second position, wherein the optic sensor is configured to provide an input signal when the flow indicator has moved from the first position to the second position; a controller configured to receive the input signal from the optic sensor and to transmit a feedback signal; and a feedback device operable to provide feedback about the inhalation flow in response to the feedback signal transmitted from the controller.
7. The respiratory care system of claim 6 wherein the flow indicator is visible to the user.
8. The user interface of claim 6 wherein the outlet comprises at least one of a mask and/or mouthpiece.
9. The user interface of claim 6 wherein the feedback device comprises an electronic indicator.
10. The user interface of claim 9 wherein the electronic indicator comprises at least one of a visual indicator, audible indicator and/or a vibratory indicator.
11. The user interface of claim 6 wherein the respiratory device comprises one of a valved holding chamber, an oscillating positive expiratory pressure device, a nebulizer or a dry powder inhaler.
12. A method of treating a respiratory system of a user comprising: inhaling and/or exhaling through an outlet of a user interface; creating an inhalation flow along an inhalation flow path through the user interface between an inlet and the outlet when inhaling through the outlet, wherein a respiratory device is connected to the inlet; moving a flow indicator positioned outside the inhalation flow path from a first, at rest, closed position to a second, actuated, open position at least in response to the inhaling; sensing when the flow indicator is moved from the first position to the second position with an optic sensor; providing an input signal with the optic sensor when the flow

indicator has moved from the first position to the second position; receiving the input signal with a controller; transmitting a feedback signal with the controller; and providing feedback to the user about the inhalation flow with a feedback device in response to the feedback signal transmitted from the controller.

13. The method of claim 12 wherein the flow indicator is visible to the user.

14. The method of claim 12 wherein the outlet comprises at least one of a mask and/or mouthpiece.

15. The method of claim 12 wherein the feedback device comprises an electronic indicator.

16. The method of claim 15 wherein the electronic indicator comprises at least one of a visual indicator, audible indicator and/or a vibratory indicator.

17. The user interface method of claim 12 wherein the respiratory device comprises one of a valved holding chamber, an oscillating positive expiratory pressure device, a nebulizer or a dry powder inhaler.