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(54) **SLEEP APNEA BI-LEVEL POSITIVE AIRWAY PRESSURE MACHINE WITH ADVANCED DIAGNOSTICS AND SELF-CLEANING CAPABILITIES**

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(57)

ABSTRACT

A new Continuous/Bi-Level Positive Airway Pressure device (C/BiPAP) is operable which includes both a device with a bi-directional mode of operation in a housing and a user mask to deliver air and oxygen flows and direct exhaled air to a control device. A control system receives inputs for oxygen, carbon monoxide, heart rate and air flow, both inhaled and exhale pressure and varies the input of air and oxygen and adjust the negative pressure in response to those readings. The novel features of the device including self-cleaning of the mask when it is placed in the within the housing, the inclusion of a lithium battery for back-up and for use outdoors, and wireless capabilities in the control device. The self cleaning regime includes a water storage compartment, a water heater, and a tube running to the self-cleaning compartment.

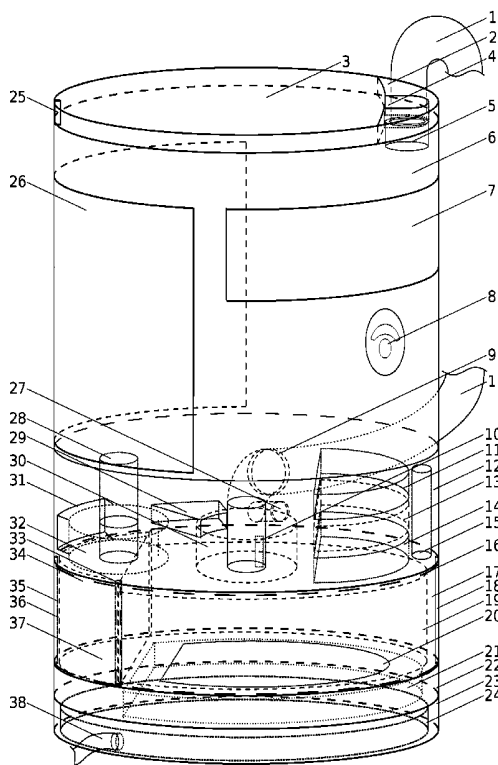


FIG. 1

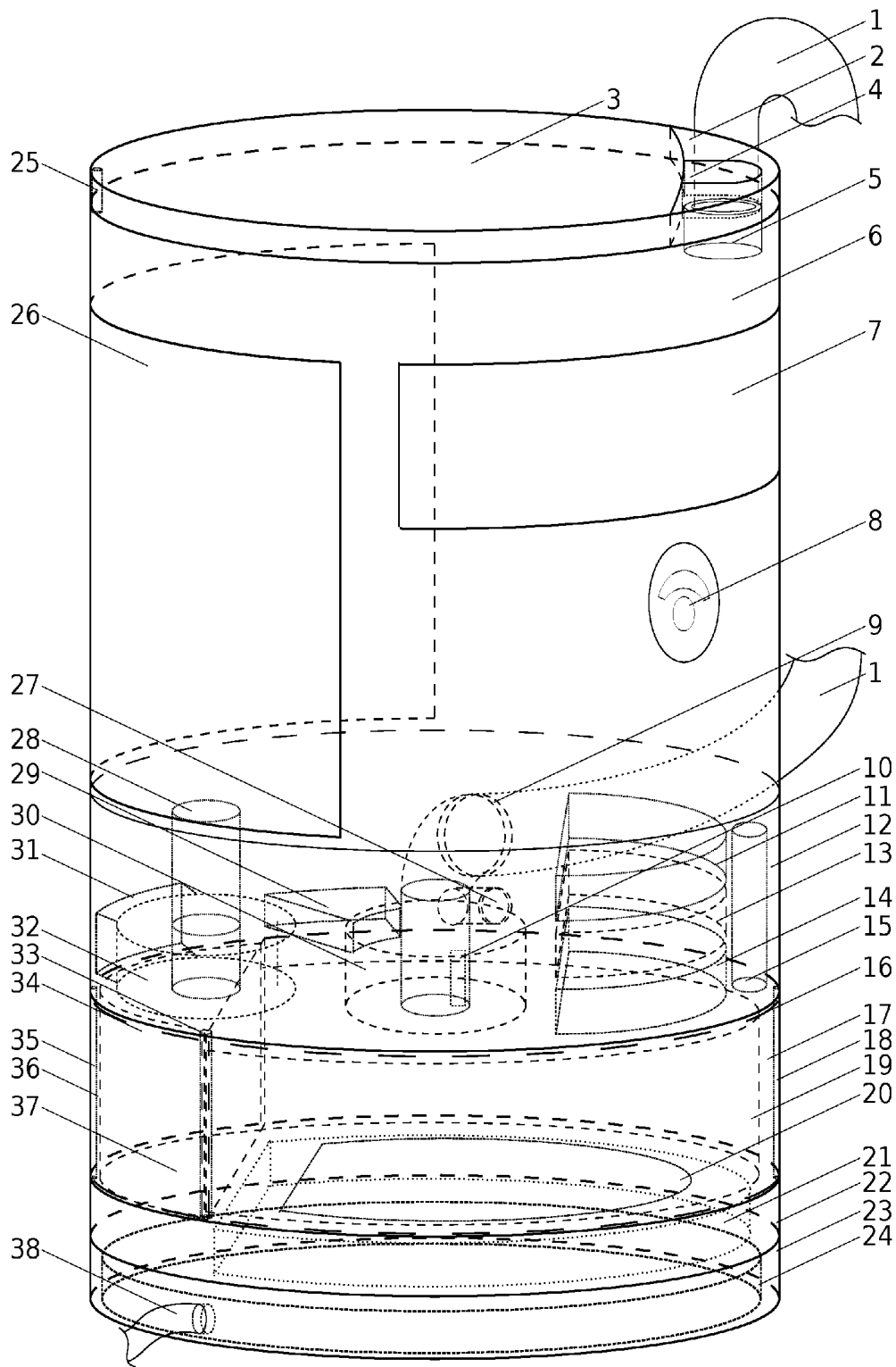


FIG. 2

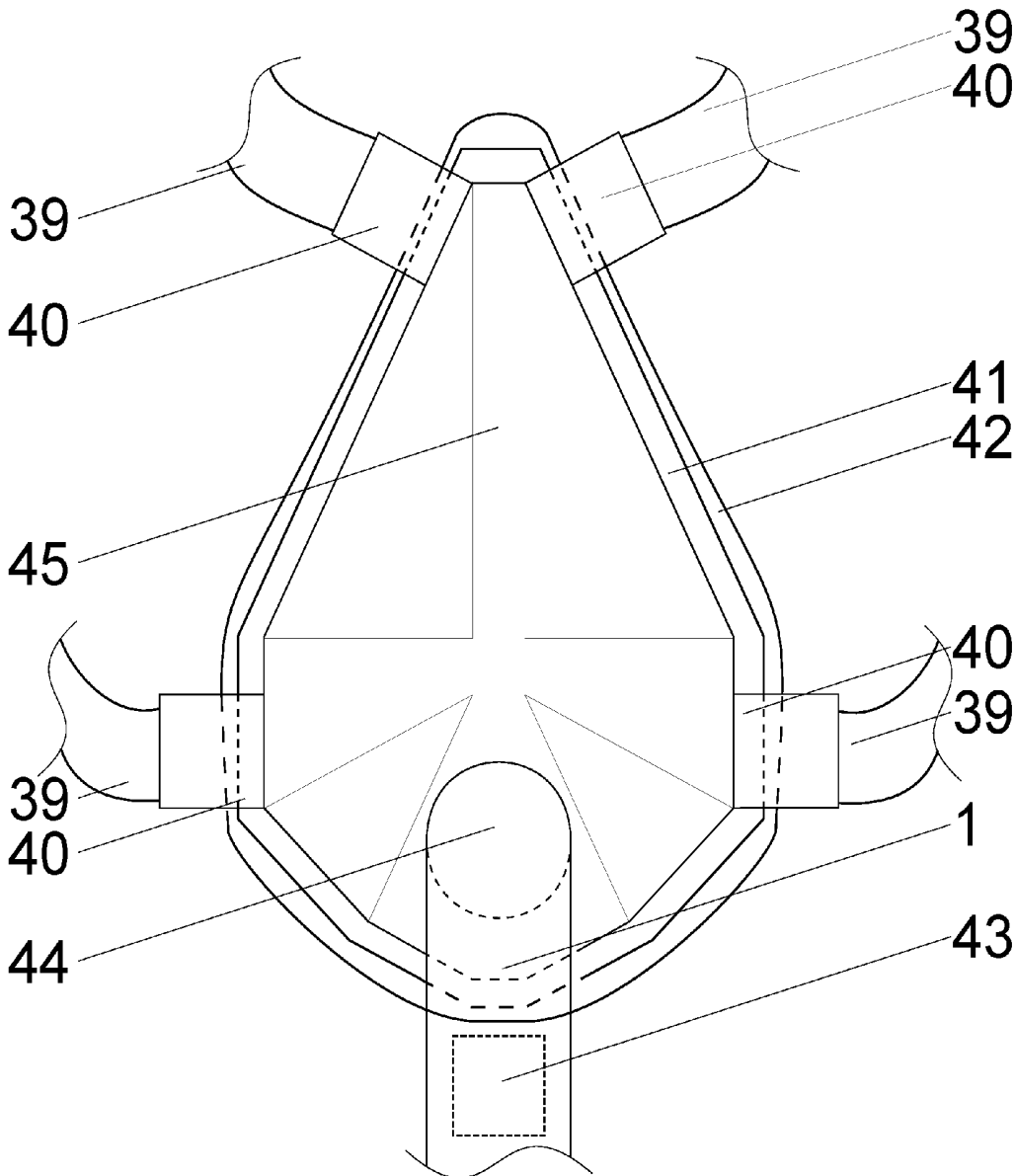


FIG. 3

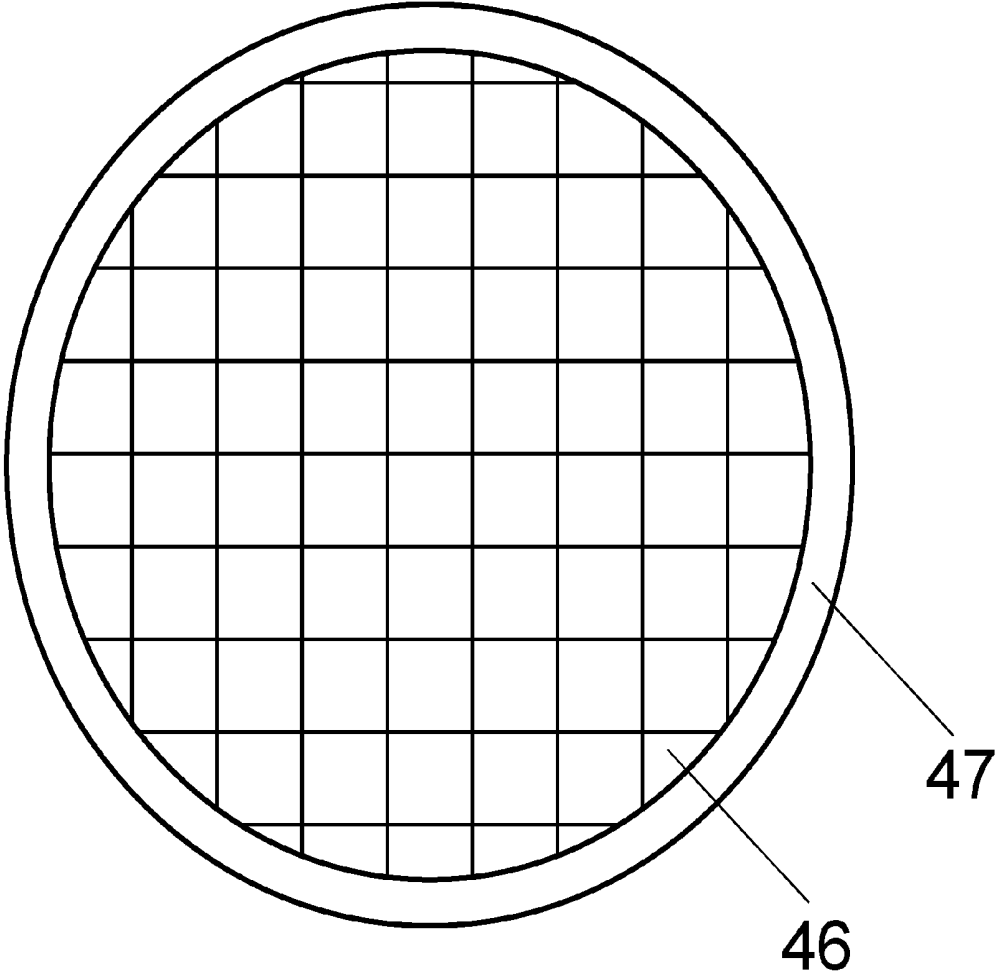


FIG. 4

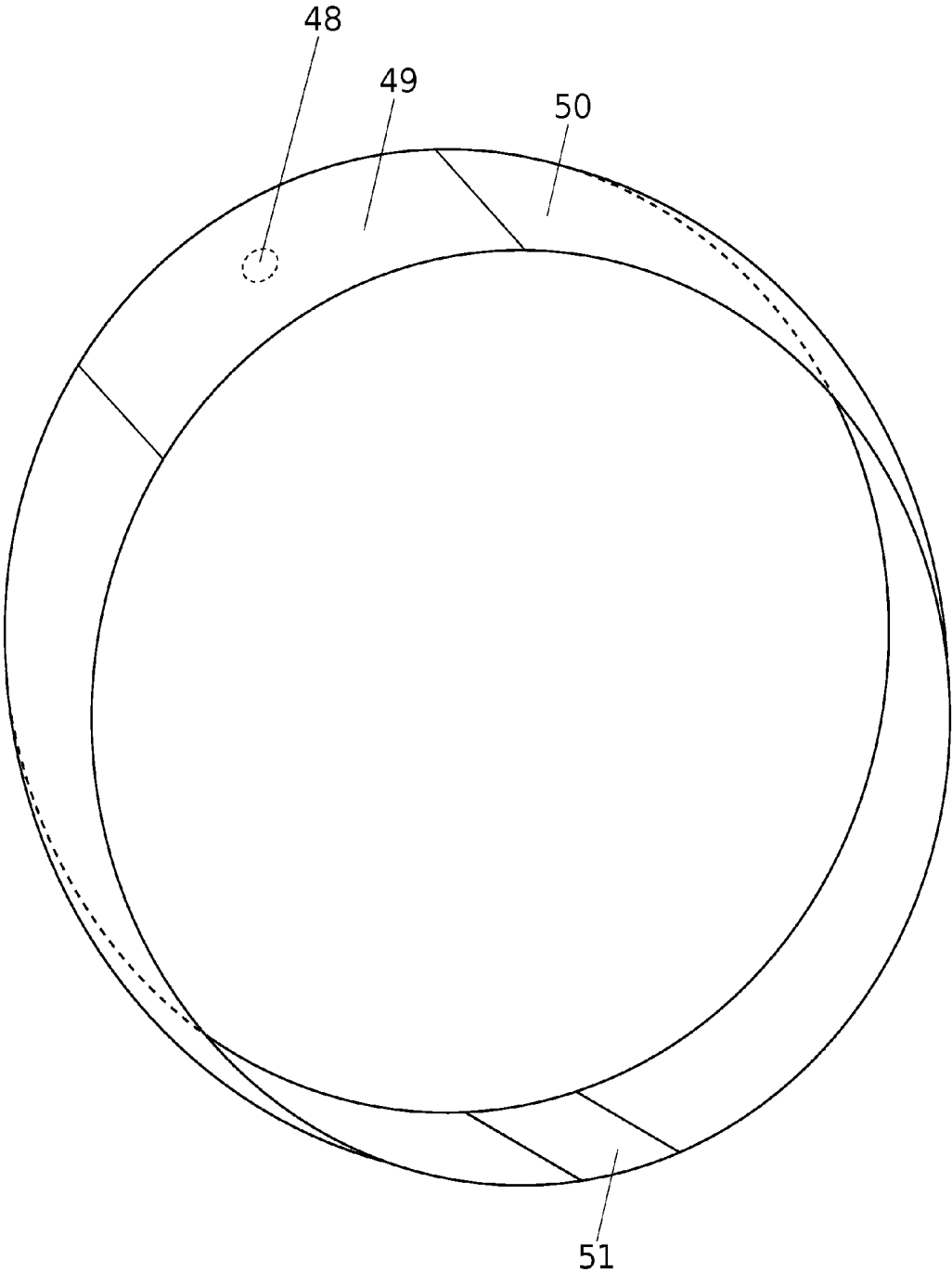


FIG. 5

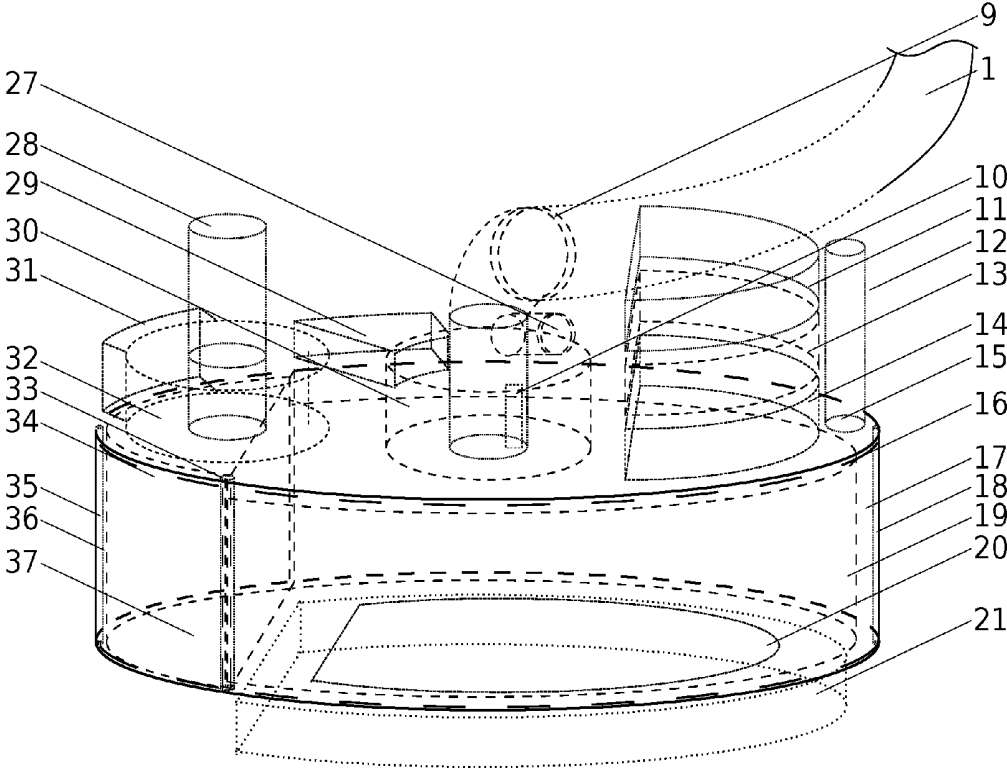


FIG. 6

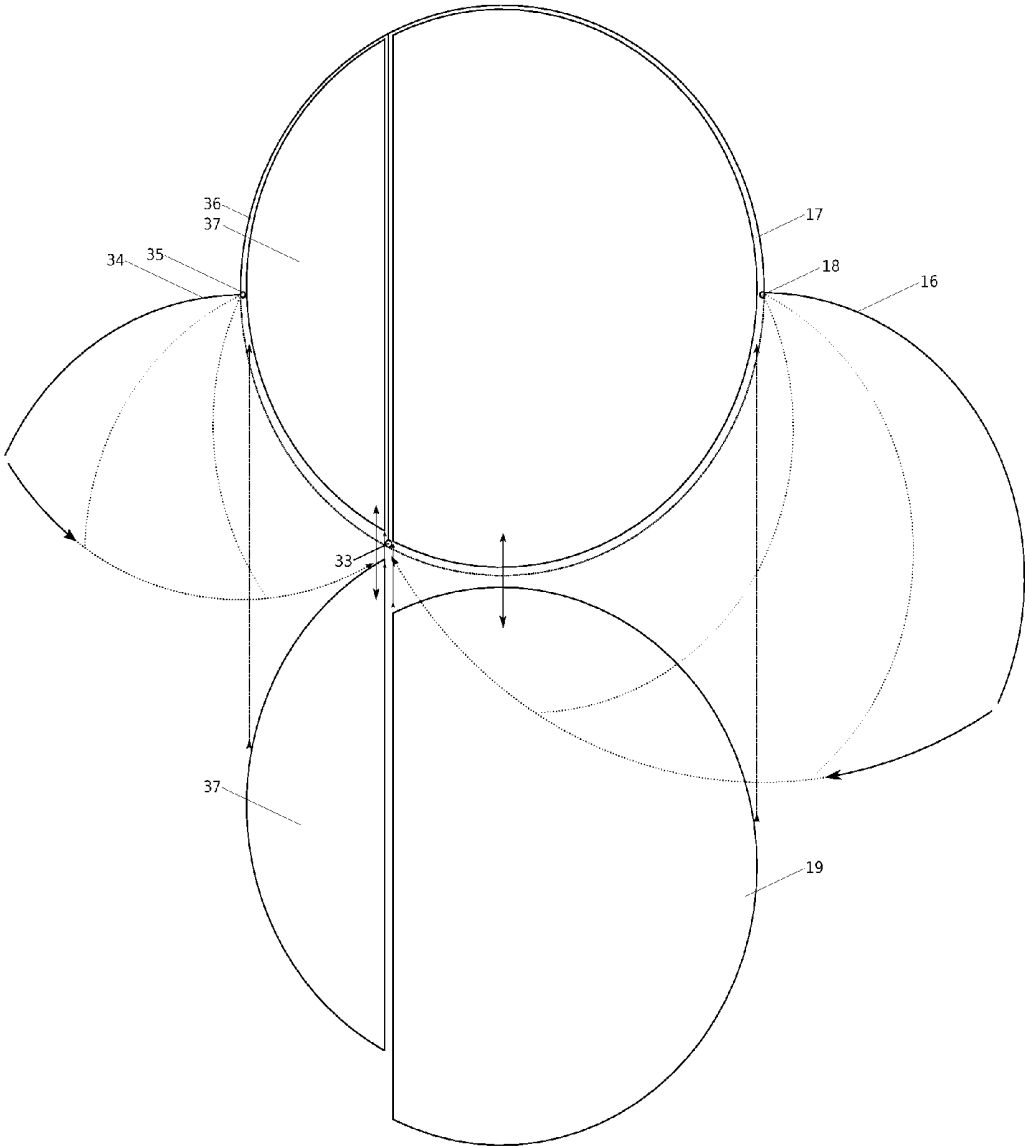


FIG. 7

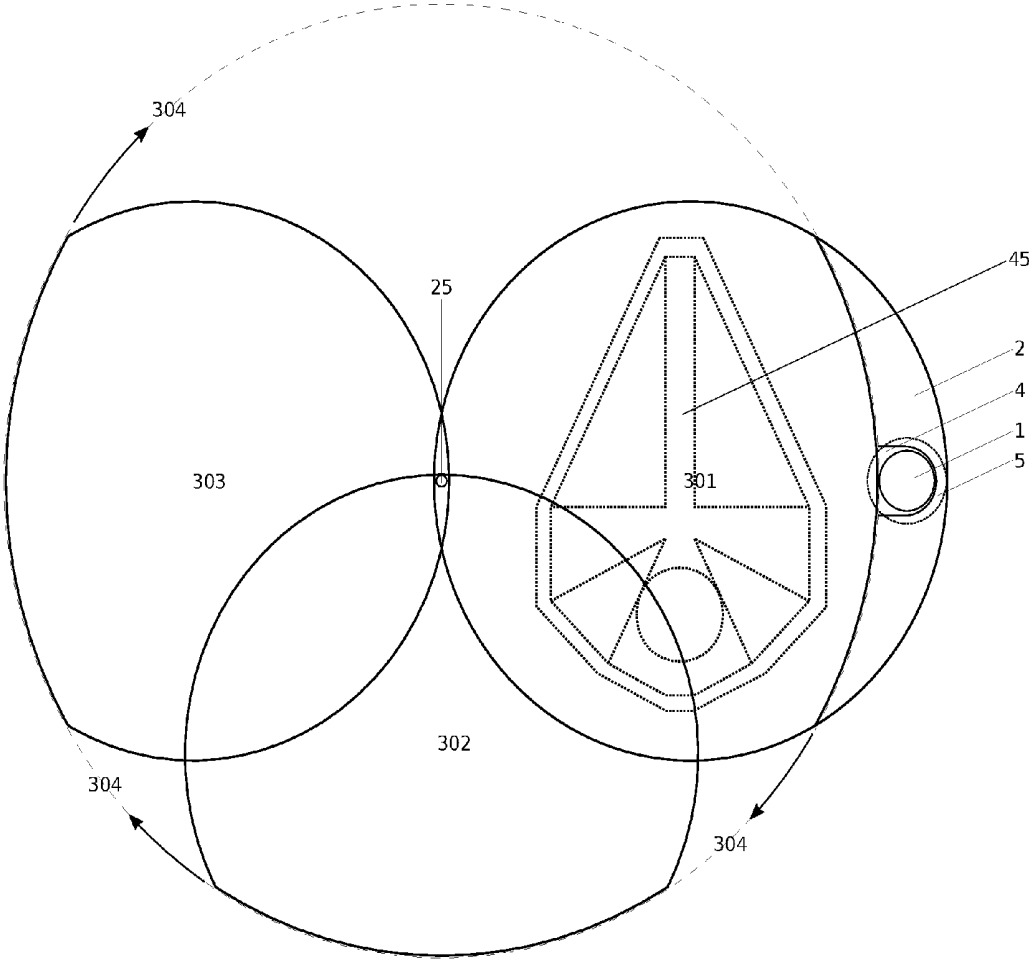


FIG. 8

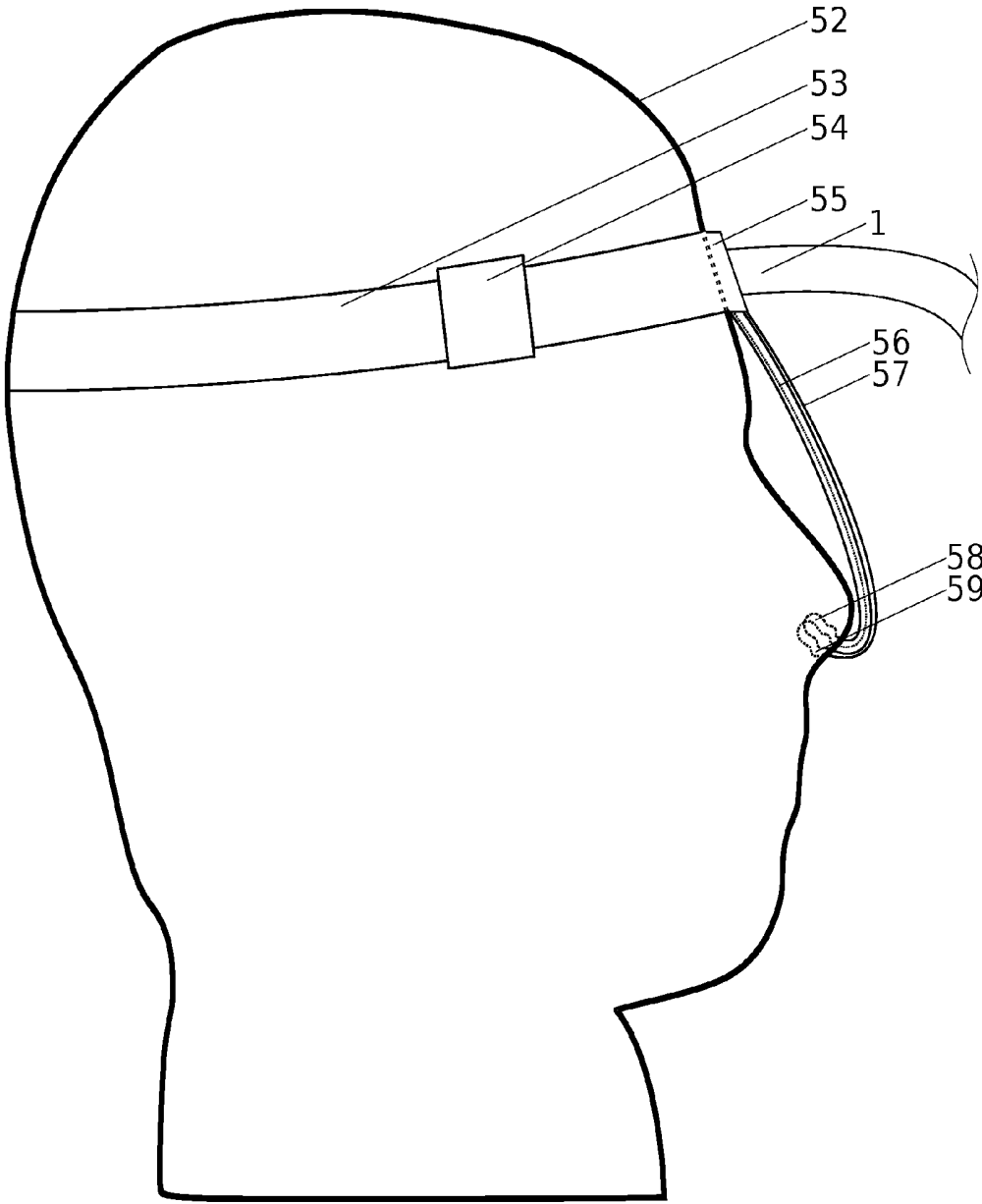
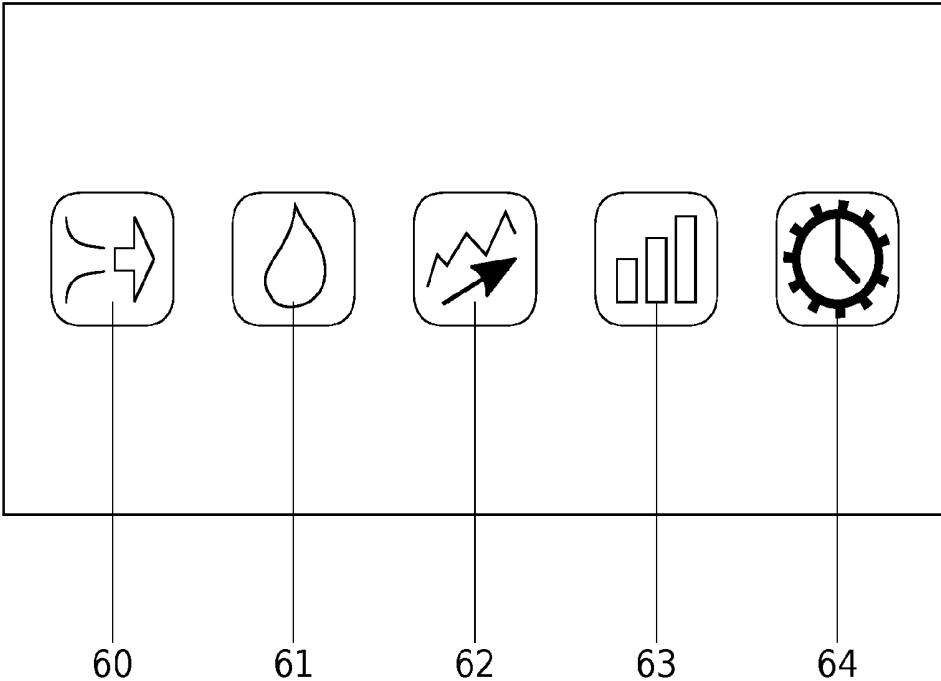


FIG. 9



SLEEP APNEA BI-LEVEL POSITIVE AIRWAY PRESSURE MACHINE WITH ADVANCED DIAGNOSTICS AND SELF-CLEANING CAPABILITIES

[0001] This patent claims the benefit of Provisional Patent 62/088,657, filed on 2014 Dec. 7

BACKGROUND

Prior Art

U.S. Patents

[0002]

Patent number	Kind Code	Issue Date	Patentee
U.S. Pat. No. 3,221,733	A	Dec. 7, 1965	Noel F. Beasley
U.S. Pat. No. 4,197,843	A	Apr. 15, 1980	Forest M. Bird
U.S. Pat. No. 5,065,756	A	Nov. 19, 1991	David M. Rapoport
U.S. Pat. No. 5,239,995	A	Aug. 31, 1993	Mark C. Estes, Janice M. Gatano
U.S. Pat. No. 5,320,093	A	Jun. 14, 1994	Dan Raemer
U.S. Pat. No. 5,423,313	A	Jun. 13, 1995	Sven-Gunnar Olsson
U.S. Pat. No. 5,743,253	A	Apr. 28, 1998	Sven-Gunnar Olsson
U.S. Pat. No. 6,105,575	A	Aug. 22, 2000	Mark C. Estes, Douglas M. Mechlenburg, John H. Fiore
U.S. Pat. No. 6,349,724	B1	Feb. 26, 2002	David Burton
U.S. Pat. No. 6,367,474	B1	Apr. 9, 2002	Michael Berthon Jones
U.S. Pat. No. 6,512,938	B2	Jan. 28, 2003	Nelson R. Claire
U.S. Pat. No. 6,532,960	B1	Mar. 18, 2003	Gregory Yurko
U.S. Pat. No. 6,561,187	B2	May 5 2013	Mathew F. Schmidt, John S. Baun, Catherine A. Nordman
U.S. Pat. No. 6,679,257	B1	Jun. 20, 2004	Christopher John Robertson
U.S. Pat. No. 7,556,038	B2	Jul. 7, 2009	Ted Kirby, Leonardo A. Balboa, Erik K. Witt
U.S. Pat. No. 8,136,525	B2	Mar. 20, 2012	Steven John Lubke
U.S. Pat. No. 9,138,169	B2	Sept. 22, 2015	John S. Beard

Publication number	Kind Code	Publication Date	Applicant
20050016536	A1	Jan. 27, 2005	David Rapoport, Robert Norman
20050166922	A1	Aug. 4, 2005	Michael Knepper
20070283958	A1	Dec. 13, 2007	Ray Naghavi

Field of the Invention

[0003] This invention relates to a new Bi-Level Positive Airway Pressure device (BiPAP) that delivers breathing gas such as air, oxygen or a mixture thereof at relatively higher and lower pressures to minimize sleep disorders from partial or complete upper airway obstruction

BACKGROUND

[0004] BiPAP (Bi-Level Positive Air Pressure) devices or Bi-level PAP are breathing devices that uses bi-level positive airway pressure to treat patients with central and obstructive apnea.

[0005] Bi-level positive airway pressure means that the machine delivers air under higher pressure as the sleeper inhales, and switches to a lower pressure during exhalation to make it easier to breathe out. Some of the benefits of a BiPAP machine include: 1) patients have good respiratory rates with BPAP machines, 2) the therapy is effective in terms of clinical status and improvement in blood gas levels;

3) the technology for BiPAP, named expiratory pressure relief (C-Flex), monitors the patient's airflow during his expiration and reduces the pressure in response to the patient's needs. Toward the end of the expiration, the pressure is increased again to prevent airway collapse.

[0006] The core of a Bi-Flex Pressure Relief system is an adaptive flex pressure relief system called Bi-Flex to sense your breathing patterns and then provide pressure relief at key points during inhalation and exhalation to provide a more natural breathing experience. The air pump is within the housing with simple processor controls and readouts connected to a mask that fits over the nose and mouth, with the air hose running into the mouth.

[0007] The current state of commercial products is that BiPAP machines are a breathing apparatus that optimizes the positive pressure to the airway of a patient. The apparatus is configured to detect flow limitations in the patient airway from an analysis of inspiratory flow waveforms. The airway pressure settings is raised, lowered or maintained depending on whether a flow limitation has been detected.

[0008] The standard BiPAP product does not include readings of oxygen sensor levels, CO2 levels, and blood pressure. These are important readings especially since some users of BiPAP machines also oxygen. BiPAP machines also do not commonly include a supply of oxygen, nor do they have a blood pressure monitor. While the standard BiPAP machine has a sensor to determine when the user is breathing in and breathing out, it doesn't provide additional diagnostics, including monitoring when the patient is in distress, measuring resting energy levels, and measuring respiration levels

[0009] There are separate pieces of equipment to these tasks, oxygen masks, see U.S. Pat. No. 9,138,169 B2, infrared sensors are used in pulse oximeter which is placed on the finger, see patent U.S. Pat. No. 5,995,859A and wrist based blood pressure monitors, but no product currently on the market or currently with a patent or patent application includes all these features in one unit with a processor cable of reading the data and reacting to the data.

[0010] Other potential useful features that current products don't have include self-cleaning of the mask, the lack of which is a major drawback for users as it is either

inconvenient for users to clean, or bacteria can form in the mask, a lack of battery backup, both for use in the home if power goes out, or if the user goes camping and in the woods, a bidirectional pump that brings out the exhaled air to measure CO₂, O₂ and using the data to determine a person resting energy levels to detect user distress. Current equipment also does have data logging capabilities or the ability to transfer data wirelessly to an outside monitoring site.

[0011] The deficiencies as listed above in current equipment include:

- [0012]** 1. readings of O₂ levels and O₂ supply and adjustment as needed;
- [0013]** 2. measurement of exhaled flow and O₂ and CO₂ levels;
- [0014]** 3. blood pressure readings;
- [0015]** 4. self-cleaning capabilities;
- [0016]** 5. battery backup;
- [0017]** 6. measurement of respiratory levels;
- [0018]** 7. measurement of resting energy levels
- [0019]** 8. a processor capable of reading CO₂, O₂ and exhaled air flow;
- [0020]** 9. a processor capable of taking CO₂, O₂, and in and out airflow measurements and dictating changes in operation as required, setting of alerts when required, data logging readings and information at appropriate intervals and wireless transferring of that data to an outside source.

[0021] Some of the current deficiencies have been covered by patents by others. Reading and adjusting oxygen levels have been addressed by patent U.S. Pat. No. 6,512,938 and U.S. Pat. No. 6,501,187 application US 20070283958. Measuring respiratory levels, which is an additional and useful feature is addressed in U.S. Pat. No. 6,532,960. Measuring resting energy is addressed in U.S. Pat. No. 6,532,960. Measuring the exhaled air for O₂ and CO₂ levels is addressed in U.S. Pat. No. 7,556,038.

[0022] No patent, patent application or current product on the market address the need for battery back-up or self-cleaning. These are the two unique features being added to the BiPapp machine in the proposed device in this application. Nor do patents, patent applications or current products have a process designed to taking CO₂, O₂, and in and out airflow measurements and dictating changes in operation as required, setting of alerts when required, data logging readings and information at appropriate intervals and wireless transferring of that data to an outside source.

DESCRIPTION OF PRIOR ART

[0023] U.S. Pat. No. 3,221,733 is an before sleep apnea correcting devices that deals with using alternating periods of air pressure, either compressed air or oxygen, with periods of no pressure, a principle used by all sleep apnea devices.

[0024] U.S. Pat. No. 4,197,843 is another device using a bellow system to control air into a mask or similar device with periods of no pressure to allow the user to exhale.

[0025] U.S. Pat. No. 5,065,756 is the first device related to continuous pressure to a nose mask, with vents in the mask to allow the pressure to drop while the user exhales. The mask does not cover the mouth. Key points of the invention are establishing a threshold control value, and the vent holes in the mask to allow user to more efficiently exhale.

[0026] 5239995 covers the use of high and low pressure to a sleep apnea device the corresponds to the users respiratory patterns.

[0027] U.S. Pat. No. 5,320,093 deals with a method of measuring CO₂ gas in a patient after surgery coming out of anesthesia and adjust the CO₂ level as needed.

[0028] U.S. Pat. No. 5,423,313 deals with having two lines with two different air streams to a respirator, such as a stream of O₂ and compressed air, each stream being regulated. The gas supply also pulses as the air flow would be in a sleep apnea device. This patent calls for two separate respirators. The patent deals with tracheal tubes as the delivery device rather than a mask, but the use of two air streams still applies.

[0029] U.S. Pat. No. 5,743,253 is by the same inventors as U.S. Pat. No. 5,423,313 and covers the measuring of the pressures of the air steams being delivered.

[0030] U.S. Pat. No. 6,105,575 involves applying separate and independent gains to flow rates of pressurized gas delivered to a patient during inspiratory and expiratory phases of a respiratory cycle

[0031] U.S. Pat. No. 6,349,724 This patent involves a device that monitors the breathing of sleep apnea patient and then regulates high and low pressure to correspond to the breathing pattern of the patient.

[0032] U.S. Pat. No. 6,367,474. This patent improves over prior art of U.S. Pat. No. 6,349,724 by measuring the breathing of the patient and providing air flow at a higher rate when an apnea event occurs, then lower air flow when apnea is not occurring rather than provide air on a continuing basis.

[0033] U.S. Pat. No. 6,512,938 deals with monitoring O₂ levels in patients and then adjusting the O₂ levels based on those results.

[0034] U.S. Pat. No. 6,532,960 is a further improvement on sleep apnea design where the device monitors the user's respiration and then responds with different levels of pressure

[0035] U.S. Pat. No. 6,532,960 measures a sleep apnea patient resting energy to determine if the pressure should be adjusted.

[0036] U.S. Pat. No. 6,561,187 discusses various methods to control oxygen flow through a monitoring process.

[0037] U.S. Pat. No. 6,679,257 proposes a mouth piece rather than a nose piece delivery system for the air pressure to a sleep apnea patient.

[0038] U.S. Pat. No. 7,556,038 includes monitoring respiration of a user and determining a user breathing frequency including an inspiration portion and an expiration portion of the breathing

[0039] U.S. Pat. No. 8,136,525 is for a mask device that is more comfortable delivering a breathable gas to the patient includes a mouth cushion, a pair of nasal prongs, an elbow, and a headgear assembly.

[0040] U.S. Pat. No. 9,138,169 is for a mask that includes using both the nose and the mouth for equipment designed for use for sleep apnea sufferers.

[0041] Application US20050016536 an application for a device that monitors patient respiration and then adjust the air flow accordingly.

[0042] Application US20050166922 deals with adjusting the pressure for before and after the user falls asleep

[0043] Application US20070283958 deals with monitoring users air pressure and oxygen levels to adjusting both air pressure and oxygen levels to the user.

SUMMARY OF THE INVENTION

[0044] This device incorporates many of the features of currently on the market, plus incorporating some of the additional features of items that have appeared in patent applications, but adds four new features to field, a self-cleaning chamber; a lithium battery component; data logging capabilities; and Wi-Fi (wireless) capabilities to send data to an outside data collection point. This device in this application is referred to as C/BiPaP for Continues Bi-level Positive Airway Pressure device, as it assists the user during both the inhaling and exhaling breathing cycle. The features of the invention includes:

- [0045] 1. A breathing circuit, one end of which includes a patient interface device such as a nasal face mask.
- [0046] 2. A first integrated control unit using ASCII infrared technology configured to read and adjust:
 - [0047] a. flow rates to and from the patient;
 - [0048] b. oxygen levels;
 - [0049] c. carbon dioxide levels (read only);
 - [0050] d. heart rate (read only).
- [0051] 3. A second integrated control unit able to monitor and report waveforms of air flow to and from the patient.
- [0052] 4. A wrist mounted blood pressure monitor that can send blood pressure and heart rate readings to the microprocessor.
- [0053] 5. A microprocessor configured to:
 - [0054] a. accept input for limits of acceptable flow rates, O₂ levels, CO₂ levels and blood pressure;
 - [0055] b. calculate respiratory patterns base on flow rates, oxygen levels and heart rate;
 - [0056] c. detect flow limitations in the patient airway from an analysis of inspiratory flow waveforms;
 - [0057] d. Determine resting energy of user from inputs;
 - [0058] e. Initiate alerts when readings for all O₂, CO₂, blood pressure, air flow, respiratory functions or resting energy levels fall below set limits.
 - [0059] f. Data log data from each sensor, as well as calculations for respiratory patterns, and resting energy levels.
 - [0060] g. Communicate wirelessly to a computer either on or off-site.
- [0061] 6. A mask that with air and oxygen ports that allows the exhaled air through a third port to be sent through CO₂ and O₂ sensors that use infrared technology located in the mask with the data sent to the integrated control unit.
- [0062] 7. A bi-directional circulating pump that both pushes airflow to the user and pulls exhaled air from the user.
- [0063] 8. A self-cleaning feature that with a procedure that includes activation with a button or toggle. The self-cleaning feature includes a heater to and a water reservoir to heat up and steam the hose and mask.
- [0064] 9. A cone shape housing with the top acting as a storage compartment for the mask. This will keep the mask clean from dust particles and other particulates when not used. The top storage compartment is also the area in which the mask is cleaned.

[0065] 10. A lithium battery both for battery back-up and so the device can be used in outdoor activities when required.

[0066] Additional embodiments can include a variety of additional features including:

- [0067] 1. an oxygen sensor to determine at least one of a pulse of the patient and the oxygen saturation level of the patient;
- [0068] 2. An oxygen port located on the mask rather than adding oxygen to the air flow in the C/BiPAP device
- [0069] 2. an oxygen concentrator communicatively linked to the oxygen sensor;
- [0070] 4. a carbon dioxide meter to determine at least a metabolic rate of the patient;
- [0071] 5. an emergency condition system with audible alerts and alerts transferred wirelessly to a receiving station. The alerts can be activated by:
 - [0072] a. a leak detector that determine if air is leaking from the C/BiPAP device;
 - [0073] b. an electric current detector to detect power conditions to the C/BiPAP device;
 - [0074] c. a pressure detector.
- [0075] 6. response capabilities to emergency alerts including:
 - [0076] a. a backup power supply to power the C/BiPAP device;
 - [0077] b. an emergency valve that opens to provide ambient air to the patient;
- [0078] 7. a humidifier circuit including
 - [0079] a. a heater/cooler;
 - [0080] b. a dehumidifier;
 - [0081] c. a filter;
 - [0082] d. a communication interface;
 - [0083] e. a monitor and interface
 - [0084] f. a medication chamber.
- [0085] 8. The addition to the main device of
 - [0086] a. a pulse meter;
 - [0087] b. a blood pressure reading device
 - [0088] c. a heart rate monitor.
- [0089] 9. a communication device that transmits information between the patient and a medical professional or monitoring system.

DETAILED SUMMARY OF THE INVENTION

[0090] Standard features of the invention which are included in the housing include

- [0091] 1) Co₂ sensor an ASCII sensor infrared monitoring sensor that will analyze Bi-level positive airway pressure machine and read data from a display panel.
- [0092] 2) UV Flux 25% Oxygen Sensor will measure ambient O₂ levels in 0-25% in the patient. This sensor will benefit the user by measuring the oxygen pressure and temperature compensation. Both are vital for patients who need to use oxygen along with their Bi-level Positive airway pressure machine.
- [0093] 3) The shape of the housing will be a cone shape on top which will acts as a storage compartment for the mask. This will keep the mask clean from dust particles and other particulates when not used.
- [0094] 4) This device will have a feature to self-clean. Self-cleaning procedure will consist of a button toward the top can be pushed for self-cleaning mode. The

device will have a heater to and a water reservoir to heat up and steam the hose and mask.

[0095] 5) The top of the housing can be opened for storage and cleaning of the mask and hose.

[0096] 6) The continuous Bi-level Positive Airway Machine will be shaped like a cylinder—see drawings.

[0097] 7) The Continuous Bi-level Positive Airway Pressure device will have a built in battery that will back the unit up when there is a power outage. The battery life will be 4-6 hours until power is repaired.

[0098] 8) The processor will include the control of a CO2 data logger, infrared O2 sensor, and blood pressure monitor, and it can incorporate a variety of sensors including NDIR, electro-chemical and MOS. The air flow from the ports on either side of the mask will have airflow activated by pumps within the module if needed

[0099] 9) The process will include alerts when CO2 levels, blood pressure or O2 levels fall out a prescribed range that is entered in to unit

[0100] 10) The C/BiPAP device will be compatible for both with apple IOS and android IOS systems for sleep mapping and data use.

[0101] 11) The C/BiPAP device will have a display with an Interactive touch screen display,

The Mask of the C/BiPAP features:

[0102] 1) A foam piece(s) or other comfort material for the user to apply underneath the mask for comfort.

[0103] 2) The mask will have additional strapping and size to accommodate the ports that send airflow back to the sensors for reading.

[0104] 3) At prescribed times air flow from the end user is returned where CO2 and O2 levels are read and shown on the monitor.

[0105] 4) If CO2 and/or O2 levels, or blood pressure fall out of a prescribed range an alarm will go off.

[0106] 5) When the end user arises the mask is set back into the top of the housing and the self-cleaning function is activated

The Blood Pressure Wrist Monitor

[0107] 1) The processor of the C/BiPAP device will be able to take readings from a variety of blood pressure monitors and sound an alert when required.

[0108] 2) pressure monitor to the end user's arm

[0109] 3) The pump in the arm band keeps regular positive pressure to the user.

[0110] 4) At prescribed times air flow from the end user is returned where CO2 and O2 levels are read and shown on the monitor.

[0111] 5) If CO2 and/or O2 levels, or blood pressure fall out of a prescribed range an alarm will go off.

[0112] 6) When the end user arises the mask is set back into the top of the housing and the self-cleaning function is activated

The Self Adjusting Breathing Cycle Software

[0113] The Self Adjusting Breathing Cycle Software works with data from the wrist pulse reader, O2 readings, CO2 readings, air pressure in and air pressure out to synchronize breathing during all cycles of operation. The Continuous Bi-level Positive Airway Pressure device (C/BiPAP)

will provide a more complete diagnostic system to monitor key levels of CO2, O2, and blood pressure in order to sound alerts when problems occur.

Operation of the Display

[0114] Icons on the first menu

On/Off Icon

[0115] Icons on second menu

[0116] 1. Air Flow Icon

[0117] 2. Humidity

[0118] 3. Monitoring Levels

[0119] 4. Data Logger

[0120] 5. Use Last settings Icon

[0121] Icons on Screen after Air Flow Icon Pushed on Second Menu

Air Flow to Patient—when pushed display shows;

[0122] a. a range, with last setting, average setting, and an arrow for target setting. Arrow moves with finger touch on touch screen.

[0123] b. Enter button

Air Flow from Patient—when pushed display shows:

[0124] c. a range, with last setting, average setting, and an arrow for target setting. Arrow moves with finger touch on touch screen.

[0125] d. Enter button

Timing—when pushed display shows:

[0126] e. Seconds gauge labeled Air To Patient with arrow that moves with finger movement on the touch screen, and enter button. Gauge shows last setting.

[0127] f. Seconds gauge labeled Air From Patient with arrow that moves with finger movement on the touch screen, and enter button. Gauge shows last setting.

Adjustment—when pushed display shows:

[0128] g. Seconds gauge with 1-5 labeled—Air flow to Patient on top, on bottom pressure adjustment increments till synchronized. Gauge has an arrow that moves with finger movement on the touch screen, and enter button. Gauge shows last setting.

[0129] h. Seconds gauge with 1-5 labeled—Air flow from Patient on top, on bottom pressure adjustment increments till synchronized. Gauge has an arrow that moves with finger movement on the touch screen, and enter button. Gauge shows last setting.

Ramping—when pushed display shows:

[0130] i. First Phase Icon—When pushed shows minutes gauge with moves with finger movement on the touch screen, and enter button. Gauge shows last setting. When enter button pushed the Timing display with (e) and (f) shows and is operated in the same way.

[0131] i. Second Phase Icon—When pushed shows minutes gauge with moves with finger movement on the touch screen, and enter button. Gauge shows last setting. When enter button pushed the Timing display with (e) and (f) shows and is operated in the same way.

Alarm—when pushed display shows:

[0132] j. Minutes Gauge labeled air flow to Patient on top of display and with time without synchronization before alarm on the bottom with an arrow that moves with finger movement on the touch screen, and enter button. Gauge shows last setting

When the Humidity Icon is pushed on the second menu the display shows:

[0133] k. Gauge labeled Moisture Gauge with percentages with arrow that moves with finger movement on the touch screen, and an enter button. Gauge shows last setting.

When the enter button on k is present the display shows:

[0134] l. % gauge labeled deviation prior to alarm with arrow that moves with finger movement on the touch screen, and enter button. Gauge shows last setting.

When the enter button on l is pressed the display shows:

[0135] m. Minutes gauge with label Minutes Off Target Prior to Alarm

When the Monitoring Icon on the second menu is pressed the display shows the following icons are displayed

[0136] 1. CO2
[0137] 2. O2
[0138] 3. Heart Rate

When CO2 Icon is Pressed Display Shows

[0139] n. PPM Gauge Labeled CO2 levels with arrow that moves with finger movement on the touch screen, and enter button. Gauge shows last setting.

[0140] o. PPM Gauge labeled Deviation PPM before Potential Alarm

[0141] p. Minutes gauge labeled Minutes of Deviation Prior to Alarm with arrow that moves with finger movement on the touch screen, and enter button. Gauge shows last setting.

When O2 Icon is Pressed Display Shows:

[0142] q. PPM Gauge Labeled CO2 levels with arrow that moves with finger movement on the touch screen, and enter button. Gauge shows last setting.

[0143] r. Percentage Gauge labeled % Increase Per Minute to Adjust O2 levels

[0144] s. PPM Gauge labeled Deviation PPM before Potential Alarm

[0145] t. Minutes gauge labeled Minutes of Deviation Prior to Alarm with arrow that moves with finger movement on the touch screen, and enter button. Gauge shows last setting.

When Heart Rate Icon is Pressed Display Shows

[0146] u. Notice that Wrist Heart Rate Monitor Must first be in Place

[0147] v. Digital Display with Heart Rate Showing

[0148] w. Blood Pressure Gauge Labeled Deviation to Blood Pressure Prior to Alarm, with arrow that moves with finger movement on the touch screen, and enter button. Gauge shows last setting

[0149] x. Minutes Gauge Labeled Minutes of Deviation Prior to Alarm. with arrow that moves with finger movement on the touch screen, and enter button. Gauge shows last setting

When the Data Logger Icon on second menu is pressed the following icons are displayed

[0150] 1. Sleep Pattern
[0151] 2. Sleep Time
[0152] 3. Leak time
[0153] 4. Therapy time (time device is regulating air flow to user)
[0154] 5. patients apnea/hypopnea index

[0155] 6. leak rate of mask
[0156] 7. blower hours from ventilator air
[0157] 8. patient set alarms

When Icons 1 through 7 are pressed the display shows three icons:

[0158] 1. One Day
[0159] 2. One Week
[0160] 3. One Month

When any of the three icons are pressed a chart comes up detailing data requested

When the Icon Used Last Settings on Second menu is pressed the device operates identically to the last time the machine was run.

DRAWINGS

[0161] Figures

[0162] FIG. 1: is an inside and outside look of housing for the device.

[0163] FIG. 2 is the mask that provides positive pressure to the end user and also sends air back to the housing for O2 and CO2 monitoring.

[0164] FIG. 3 is a picture of the filter that is between the air input tube and the mask.

[0165] FIG. 4 is armband with display for reading patient's pulse

[0166] FIG. 5 is a view of the mask cleaning mechanism, with the water reservoir and heater and steam chamber.

[0167] FIG. 6 is a view of the door that opens to remove the water reservoirs and door that opens to remove the waste water reservoir opening so the reservoirs can be removed.

[0168] FIG. 7 shows how the mask cleaning chamber opens to accept the mask

[0169] FIG. 8 details how the mask fits over the users face when in use.

[0170] FIG. 9 is a view of the display with the second menu

PART NUMBER DESCRIPTIONS

[0171] 1. Air hose.
[0172] 2. Air hose holder on the mask cleaning chamber cover.
[0173] 3. Mask cleaning chamber cover.
[0174] 4. Opening in mask cleaning chamber cover.
[0175] 5. Air hose connection during self-cleaning.
[0176] 6. Mask cleaning chamber.
[0177] 7. Touch screen digital display.
[0178] 8. Start button push once on/off push twice for the mask self-cleaning function.
[0179] 9. Air filter hose connection (which goes to the mask 45).
[0180] 10. Temperature sensor.
[0181] 11. Memory/data logger module.
[0182] 12. Chamber that holds data logger, processor, pumps, and battery.
[0183] 13. Processor module and alarm.
[0184] 14. Battery module.
[0185] 15. WiFi/Bluetooth antenna
[0186] 16. Door for removing water reservoir module from water reservoir chamber.
[0187] 17. Chamber of housing for removable water reservoir.
[0188] 18. Hinge for opening door for removing water reservoir module

- [0189] 19. Removable water reservoir.
- [0190] 20. Metal heat conveyance module for warming water
- [0191] 21. Ceramic heating unit.
- [0192] 22. Ceramic heating unit chamber.
- [0193] 23. Retractable power cord storage chamber.
- [0194] 24. Power cord retraction/winding mechanism.
- [0195] 25. Hinge for mask cleaning chamber lid.
- [0196] 26. Solar cell.
- [0197] 27. Intake valve for oxygen supply.
- [0198] 28. Waste water hose with drain.
- [0199] 29. Two way air intake valve with a pressure release
- [0200] 30. Bi-directional pump for air and water to send air to the mask.
- [0201] 31. Two-way air valve with a pressure release
- [0202] 32. One-directional pump to clean air and water from the mask cleaning chamber.
- [0203] 33. Magnetic door closure bar
- [0204] 34. Waste water reservoir chamber
- [0205] 35. Door to remove waste water reservoir for waste water receptacle.
- [0206] 36. Hinge for the door to remove the waste water reservoir
- [0207] 37. Removable waste water reservoir.
- [0208] 38. Retractable power cord.
- [0209] 39. Mask strap
- [0210] 40. Connection piece from mask to strap.
- [0211] 41. Platform for mask comfort material.
- [0212] 42. Comfort material for mask.
- [0213] 43. CO₂ and O₂ monitoring device with wireless capability.
- [0214] 44. Mask air hose connector/filter
- [0215] 45. Mask.
- [0216] 46. Air filter material.
- [0217] 47. Air filter liner.
- [0218] 48. Pulse reader.
- [0219] 49. Digital display on pulse monitoring wrist-band.
- [0220] 50. Pulse monitoring armband.
- [0221] 51. Armband clasp system.
- [0222] 52. Human (user) head.
- [0223] 53. Mask headband.
- [0224] 54. Mask headband clasp.
- [0225] 55. Mask connection to air hose.
- [0226] 56. Right flexible hose to right nasal bud.
- [0227] 57. Left flexible hose to left nasal bud.
- [0228] 58. Right nasal bud.
- [0229] 59. Left nasal bud.
- [0230] 60. Air flow icon
- [0231] 61. Humidity icon.
- [0232] 62. Monitoring levels icon
- [0233] 63. Data logger icon
- [0234] 64. Use last settings icon
- [0235] 301. Closed position mask cleaning chamber lid
- [0236] 302. Half open position mask cleaning chamber lid.
- [0237] 303. Full open position mask cleaning chamber lid
- [0238] 304. Path of travel mask cleaning chamber lid

DETAILED DESCRIPTION OF DRAWINGS

[0239] FIG. 1 is an inside and outside look of housing for the device. The housing holds on the top a mask cleaning

chamber cover **3** which is opened by the use of a hinge **25**. The air hose **1** is included in the cleaning process by inserting the air hose **1**, which in normal operation goes to the mask, into the air hose holder on the mask cleaning chamber cover air hose holder **2**. The air hose holder is positioned in opening in mask cleaning chamber cover **4**. The cleaning process is initiated by pushing the start button **8** twice for the mask cleaning operation. Note: The start button **8** pushed once turns the device on. If the device is on, pushing the self-leaning device start button **8** once will start the self-cleaning process. If the device is off, the start button **8** must be pushed twice, once to start the device, and once to start the self-cleaning process. The cleaning process is initiated by starting up the ceramic heater unit **21**, is positioned in a ceramic heating element chamber **22**, which allows the ceramic heating element to rest against the bottom of the removable water reservoir, which has a bottom portion made of metal impregnated plastic **20**. Vents (not shown in the drawing) in the top of the removable water reservoir **19**, floor of and top of the chamber that holds data logger, processor, pumps, and battery **12** allow the warm air and steam to rise into the mask cleaning chamber. Once the mask cleaning procedure is complete the one-directional (vacuum) pump **32** is activated to clear the water and air in mask cleaning compartment **6** through the waste water hose with drain **28**. If excess pressure from the pump is accumulated in the evacuation process it is released through the air valve with a pressure release **31**. Waste water drawn out by the one-directional pump **32** goes into the removable waste water reservoir **37**.

[0240] When the Continuous Bi-Level Positive Airway Pressure (C/BiPAP) device is started to help the user sleep with sufficient air flow, the air hose **1** is disconnected from the air hose holder on the mask cleaning chamber cover **2** and directed to the mask air hose connector/filter **44**. Not shown in the drawings is that there is an opening with a gasket in the wall of the mask cleaning compartment **6** and an opening with a gasket from the ceiling of chamber that holds data logger, processor, pumps, and battery **12** to the mask cleaning compartment **6** so that the hose can travel from the bi-directional pump **30** through the air hose filter connection **9** to the mask **45**.

[0241] Once the mask is ready the bi-directional pump for air and water **30** is activated with the display **7** to send air to the mask **45**. The bi-directional air pump brings water vapor from the removable water reservoir **19** and taking in air from the chamber that holds data logger, processor, pumps, and battery **12**, which also pulls air through the vents in the floor of the mask cleaning compartment **6** through the two way air intake valve with a pressure release valve **29**. The bi-directional pump **30** sends air to the mask **45** for a time preset on the touch screen display **7** for breathing and then for a time preset on the digital display **7**, pulls air back from the user (vacuum operation) while the user exhales. If the air pressure is too high it is released through the two way air intake valve with a pressure release **29**. In cases where the user requires oxygen, oxygen is delivered to the air filter hose connection to the mask **9** through intake valve for oxygen supply **27**. Not shown in the figure is the oxygen line which leaves through a port with a sealing gasket to the outside oxygen supply.

[0242] During the exhaling process of the user CO₂ and O₂ levels are monitored by the CO₂ and O₂ monitoring device with wireless capability **43** which send information

wirelessly to the processor module 13. The processor module 13 has the capability of adjusting air and oxygen supply levels and times sequences for user inhaling and exhaling cycles based on CO₂, O₂, and pulse reading levels (from the digital display 49 on the pulse monitoring armband 50 which send pulse readings to the processor wirelessly.) The processor module 13 receives the data from the CO₂ and O₂ monitoring device 43 and the digital display 49 of pulse reading armband 50 through a WiFi/Bluetooth antenna 15. The data received by the processor is stored in the memory/data logger module 11 which can be accessed wirelessly through the WiFi/Bluetooth antenna 15 by outside computers or computer type devices including pads and smart-phones.

[0243] The removable water reservoir 19 is removed by opening the door for removing the water reservoir module from water reservoir chamber 16, using the hinge for opening door for removing the water reservoir module 17.

[0244] Other items of note on FIG. 1 include a solar powered battery 14, a solar cell 26 for charging the battery (not electrical connections between solar cell and battery are not shown), the retractable power cord 38, the compartment for the retractable power cord, 23 and power cord retraction/winding mechanism 24.

[0245] FIG. 2 shows the mask 45 (in an upside down view, with the top on the bottom, and the bottom on top) that provides positive pressure to the end user through the air hose 1 which connects to mask air hose connector/filter 44 and also sends air back to the device when the bi-directional air/water pump 28 is pulling exhaled air away from the user. During the exhale process CO₂ and O₂ monitoring occurs through the CO₂ and O₂ monitoring device with wireless capability 43. The mask 45 fits over the patients mouth and nose and has an opening for the hose 1 that bring in air to develop a positive air pressure for the housing. The mask 45 has a platform comfort material platform 41 which holds comfort material for the mask 42. The mask 45 is held around the head with a mask strap 39 and connection pieces from mask to strap 40.

[0246] FIG. 3 shows the filter in the mask air hose connection/filter 44. The filter has air filter liner 47, the liner could also be called a housing and filter material 46.

[0247] FIG. 4 show the pulse reading arm ban 50, with its pulse reader 48, digital display 49 and arm band clasp system 51.

[0248] FIG. 5 shows the water reservoir and waste water reservoirs and the chamber that holds the data logger, processor pumps and battery. The air hose filter connection 9 to the mask 45 comes off of the bi-direction air water pump 30. The pump has intakes for oxygen 27 (oxygen lines from oxygen source not shown). The bi-directional air water pump 30 is connected to a two way air intake valve with a pressure release that brings air into the bi-directional air water pump 30, and also releases air to the during the exhale cycle. Humidity and temperature are adjusted up by activating the ceramic heating unit 21 to release additional water vapor through the ceiling of the chamber of housing for removable water reservoir 17 and the floor chamber that holds the data logger, processor pumps and battery 12.

[0249] The chamber holds in water proof compartment (which is not specifically show in the drawing) holds the temperature sensor 10, the memory data logger module 11, the processor 13 and the battery 14 and the WiFi/Bluetooth antenna.

[0250] The removable water reservoir 19 plays a key role as using the ceramic heating unit 21 to heat water to steam to go into the mask cleaning chamber, and it also provides adjustments for humidity and temperature. The heat is transferred to the removable water reservoir 19 through a metal heat conveyance module 20 that sits on the top of the ceramic heating unit 21 just below the removable water reservoir.

[0251] The waste water reservoir 39 in the waste water reservoir chamber 35 is filled through the waste water hose with drain 29 through activation of one-directional pump to clean air and water from the mask cleaning chamber 34.

[0252] FIG. 6 shows how the door for the removable waste water reservoir 37 is removed for the waste water chamber 36 and how the removable water reservoir 19 is removed for the chamber for the removable water reservoir chamber 17. For the removable waste water reservoir 37 the waste water reservoir door is opened 34 and the reservoir slides out the opening. For the removable water reservoir 19, the water reservoir door 16 is opened and the reservoir slides out the opening.

[0253] FIG. 7 shows how the mask cleaning chamber opens to accept the mask. Movement is centered on the hinge for the cleaning chamber lid 25. Position 301 shows the mask 45 inside the lid, ready for cleaning. Position 302 shows the lid half open, and position 303 shows the mask in a full open position. The line 304 shows the path the mask cleaning chamber cover 3 leaning chamber covers while being opened or closed.

[0254] FIG. 8 shows the mask 45 on a user's head detailing how the mask 45 fits on the head but also how air is delivered to the user. Parts of the mask in FIG. 2, including #s 39 through 44 are not shown on this Figure. Air flow goes to the user through a right flexible hose 56 to the right nasal bud 58, and a left flexible hose 57 to the left nasal bud 58.

[0255] FIG. 9 show a view of the display 7 with the second menu icons as a sample of what the display will look like. Shown on the display are the Air Flow icon 60. The Humidity icon, 61, the monitoring level icon, 62, the data logger icon, and the use last settings icon, 64.

I claim:

1. A Continuous Bi-Level Positive Airway Pressure (C/BiPAP) device for treating a patient suffering from sleep apnea, comprising:

- a. A breathing circuit, one end of which includes a patient interface device such as a nasal face mask.
- b. A first integrated control unit using ASCII infrared technology configured to read and adjust:
 - i. flow rates to and from the patient;
 - ii. oxygen levels;
 - iii. carbon dioxide levels (read only);
 - iv. heart rate (read only).
- c. A second integrated control unit able to monitor and report waveforms of air flow to and from the patient.
- d. A wrist mounted blood pressure monitor that can send blood pressure and heart rate readings to the microprocessor.
- e. A microprocessor configured to:
 - i. accept input for limits of acceptable flow rates, O₂ levels, CO₂ levels and blood pressure;
 - ii. calculate respiratory patterns base on flow rates, oxygen levels and heart rate;
 - iii. detect flow limitations in the patient airway from an analysis of inspiratory flow waveforms;

- iv. Determine resting energy of user from inputs;
 - v. Initiate alerts when readings for all O₂, CO₂, blood pressure, air flow, respiratory functions or resting energy levels fall below set limits.
 - vi. Data log information from each sensor, as well as calculations for respiratory patterns, and resting energy levels.
 - vii. Communicate wirelessly to a computer either on or off-site.
- f. A mask that with air and oxygen ports that allows the exhaled air through a third port to be feed to the integrated control unit for analyzing CO₂ and O₂ levels with infrared technology;
- g. A bi-directional circulating pump that both pushes airflow to the user and pulls exhaled air from the user;
- h. A self-cleaning feature that with a procedure that includes activation with a button or toggle;
- i. The self-cleaning feature includes a heater to and a water reservoir to heat up and steam the hose and mask;
- j. A cone shape housing with the top acting as a storage compartment for the mask. This will keep the mask clean from dust particles and other particulates when not used. The top storage compartment is also the area in which the mask is cleaned;
- k. A lithium battery both for battery back-up and so the device can be used in outdoor activities when required.
2. The C/BiPAP device of claim 1, further comprising an oxygen sensor to determine and the oxygen saturation level of the patient.
3. The C/BiPAP device of claim 2, further comprising an oxygen concentrator communicatively linked to the oxygen sensor.

4. The C/BiPAP device of claim 2, further comprising a carbon dioxide meter to determine at least a metabolic rate of the patient.

5. The C/BiPAP device of claim 1, further comprising an emergency condition system with audible alerts and alerts transferred wirelessly to a receiving station. The alerts can be activated by:

- a. a leak detector that determine if air is leaking from the C/BiPAP device;
- b. an electric current detector to detect power conditions to the C/BiPAP device;
- c. a pressure detector.

6. The C/BiPAP device of claim 1 further consisting of response capabilities to emergency alerts including:

- a. a backup power supply to power the C/BiPAP device;
- b. an emergency valve that opens to provide ambient air to the patient.

7. The C/BiPAP device of claim 1, further comprising at least one of a humidifier, heater/cooler, dehumidifier, filter, communication interface, a monitor and interface and medication chamber.

8. The C/BiPAP device of claim 1 further comprising at least one of a pulse meter, blood pressure device, weight monitor, and heart rate monitor.

9. The C/BiPAP device of claim 1, further comprising a communication device.

10. The C/BiPAP device of claim 9, wherein the communication device transmits information between the patient and a medical professional or monitoring system.

* * * * *

专利名称(译)	睡眠呼吸暂停双水平气道正压通气机，具有先进的诊断和自我清洁功能		
公开(公告)号	US20180028770A1	公开(公告)日	2018-02-01
申请号	US15/225797	申请日	2016-08-01
[标]发明人	PARRISH TIMOTHY JOSHUA		
发明人	PARRISH, TIMOTHY JOSHUA		
IPC分类号	A61M16/00 A61B5/021 A61B5/024 A61B5/00 A61M16/16 A61B5/08 A61B5/145 A61M16/10 A61B5/083 A61M16/20 A61M16/06 A61M16/08		
CPC分类号	A61M16/0057 A61M2205/35 A61B5/021 A61B5/02438 A61B5/6824 A61B5/746 A61M16/0051 A61M16/085 A61B5/082 A61B5/14542 A61M16/101 A61B5/0836 A61M16/20 A61M16/16 A61M16/1075 A61M16/105 A61B5/0002 A61B5/4806 A61M2205/3334 A61M2016/1025 A61M2230/432 A61M2230/06 A61M2205/50 A61M2209/10 A61M2205/8206 A61M2230/205 A61M2205/15 A61M16/06 A61B5/08 A61B5/4818 A61B5/4836 A61M16/0683 A61M16/1055 A61M2205/3569 A61M2205/3592 A61M2205/502 A61M2230/30		
其他公开文献	US10080521		
外部链接	Espacenet USPTO		

摘要(译)

新的连续/双水平气道正压通气装置 (C / BiPAP) 是可操作的，其包括在壳体中具有双向操作模式的装置和用于输送空气和氧气流并将呼出空气引导至a的用户面罩。控制装置。控制系统接收氧气，一氧化碳，心率和气流的输入，包括吸入和呼出压力，并改变空气和氧气的输入，并根据这些读数调节负压。该装置的新颖特征包括当掩模放置在壳体内时自动清洁掩模，包括用于备用和户外使用的锂电池，以及控制装置中的无线功能。自清洁系统包括储水室，热水器和延伸到自清洁室的管。

