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(72) Inventor(s):
Martin McVicar
Robert Moffett
Mark Whyte
Antonio Patacho

(73) Proprietor(s):
Combilift
(Incorporated in Ireland)
Gallinagh, Monaghan Town, Co. Monaghan, Ireland

(74) Agent and/or Address for Service:
FR Kelly
4 Mount Charles, BELFAST, Northern Ireland,
BT7 1NZ, United Kingdom

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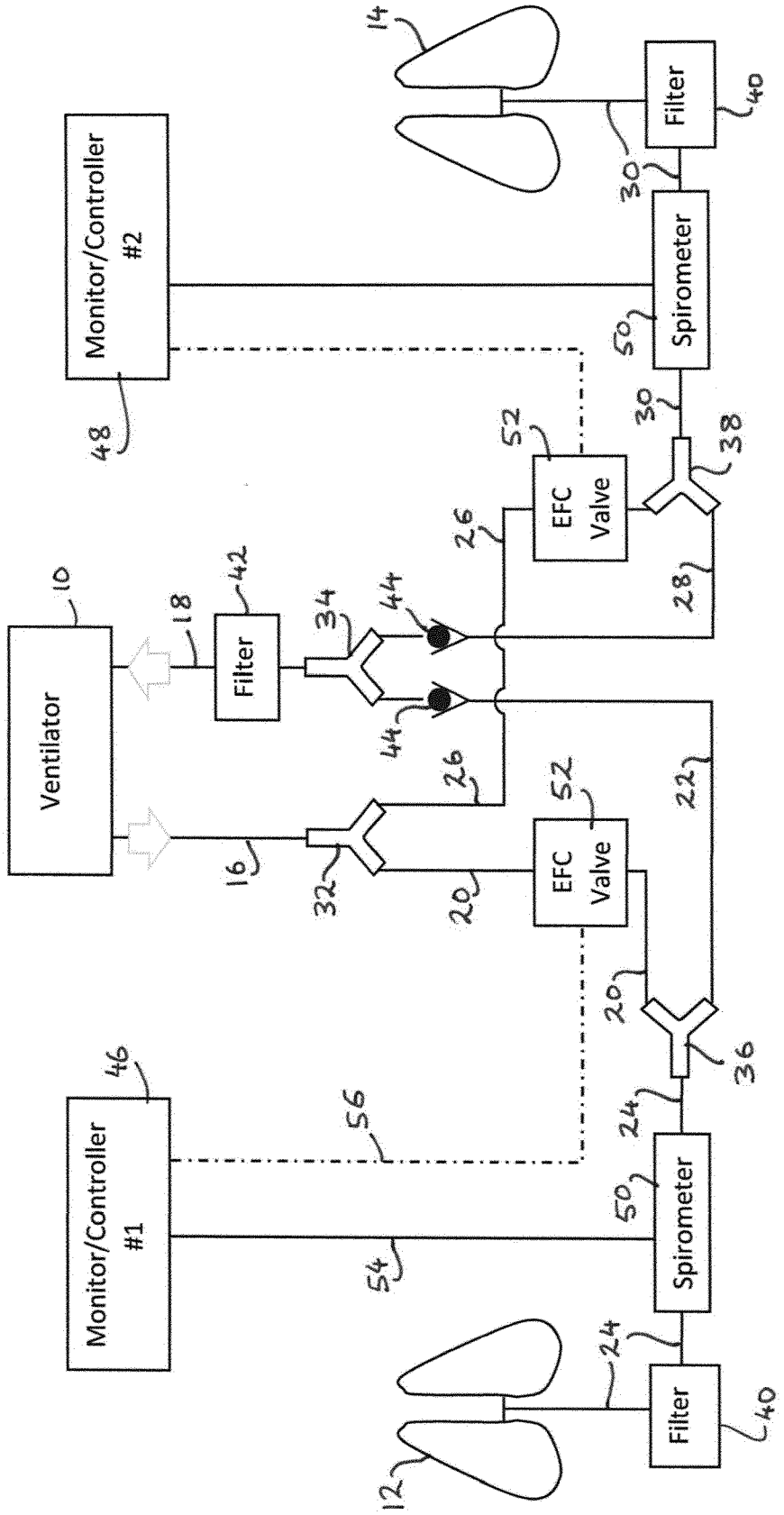

Monitor/Controller #2
Monitor/Controller #1
Ventilator
Filter
Filter
Filter
Filter
Spirometer
Spirometer
EFC Valve
EFC Valve
10
12
14
16
18
20
22
24
26
28
30
32
34
36
38
40
42
44
46
48
50
52
54
56

FIG. 1

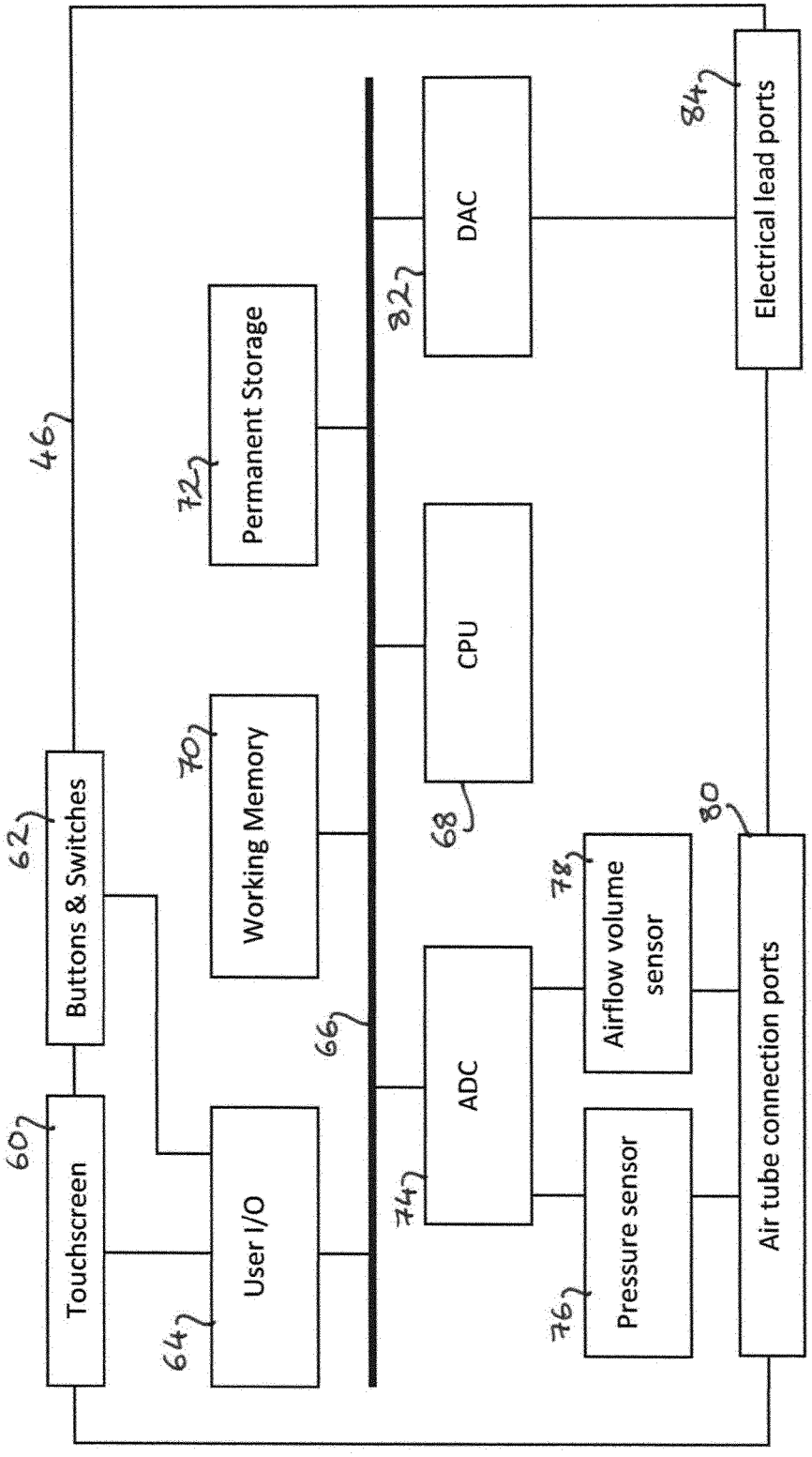

46
Touchscreen
60
Buttons & Switches
62
User I/O
64
Working Memory
70
Permanent Storage
72
CPU
68
DAC
82
ADC
74
66
Airflow volume sensor
78
Pressure sensor
76
Air tube connection ports
80
Electrical lead ports
84

FIG. 2

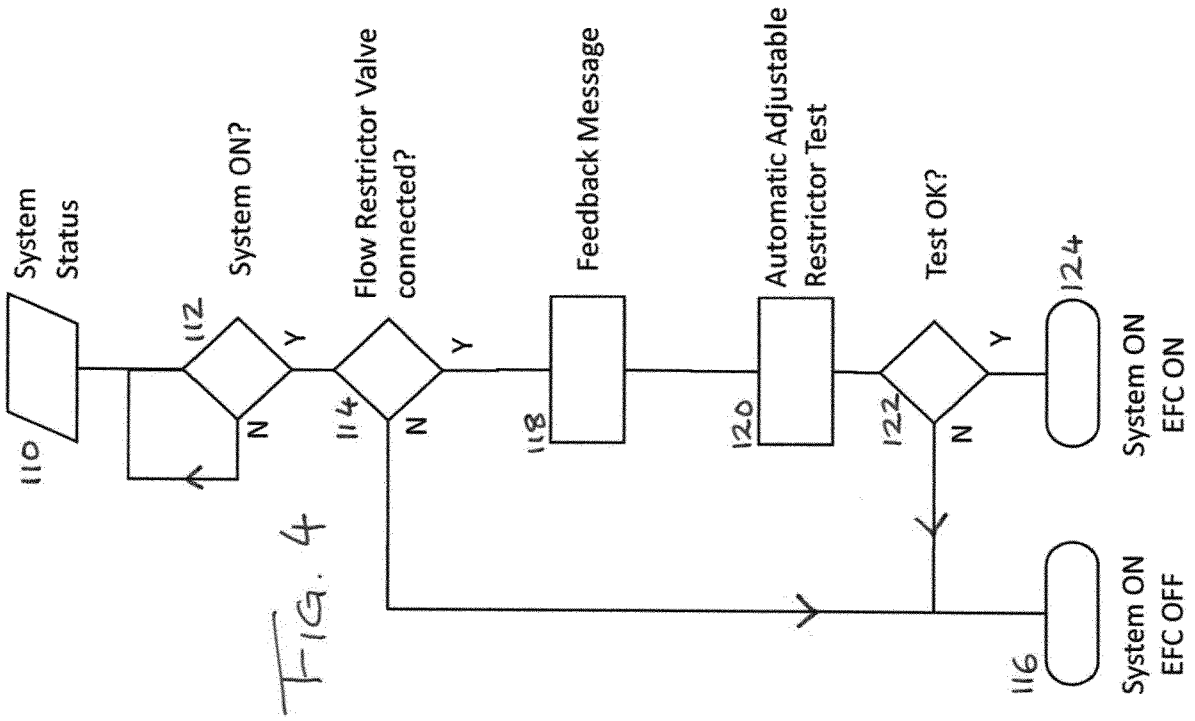

System Status
110
System ON?
112
Y
N
Flow Restrictor Valve connected?
114
Y
N
Feedback Message
118
Automatic Adjustable Restrictor Test
120
Test OK?
122
Y
N
124
System ON EFC ON
116
System ON EFC OFF

FIG. 4

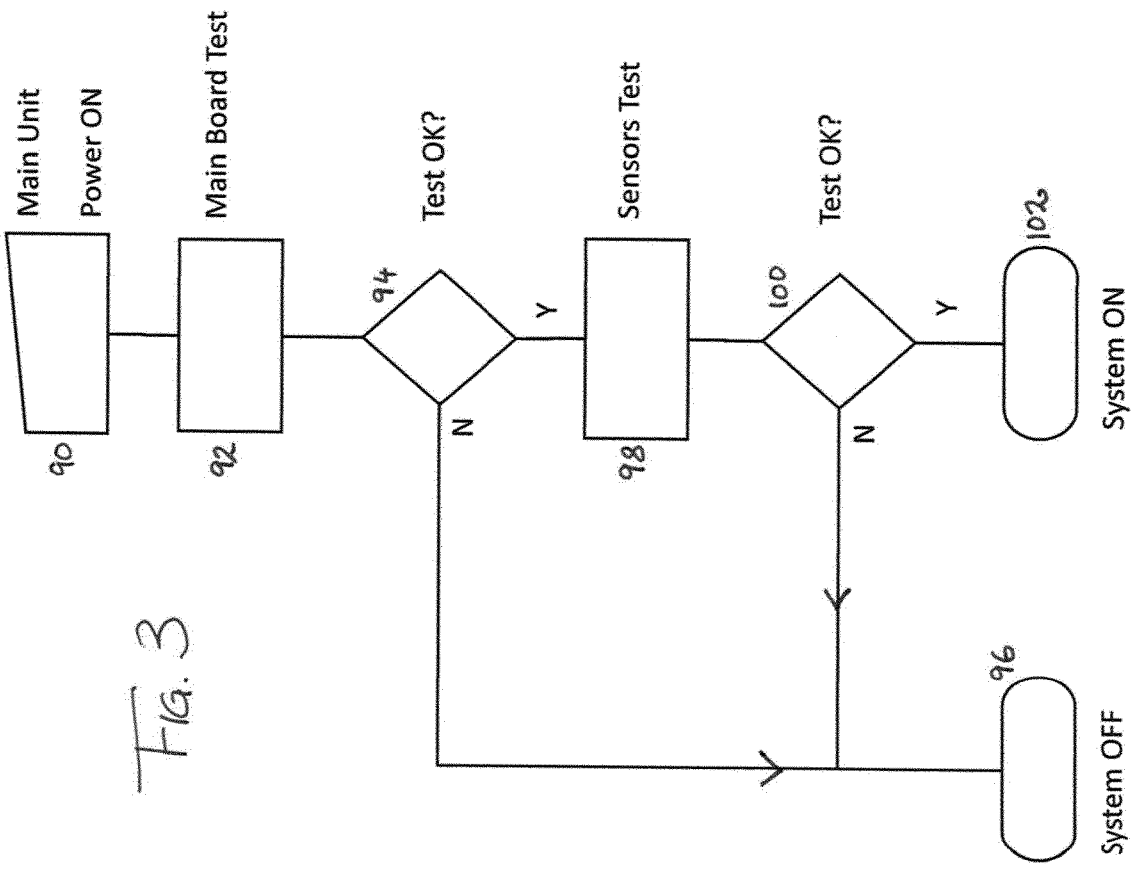

Main Unit Power ON
90
Main Board Test
92
Test OK?
94
Y
N
Sensors Test
98
Test OK?
100
Y
N
102
System ON
96
System OFF

FIG. 3

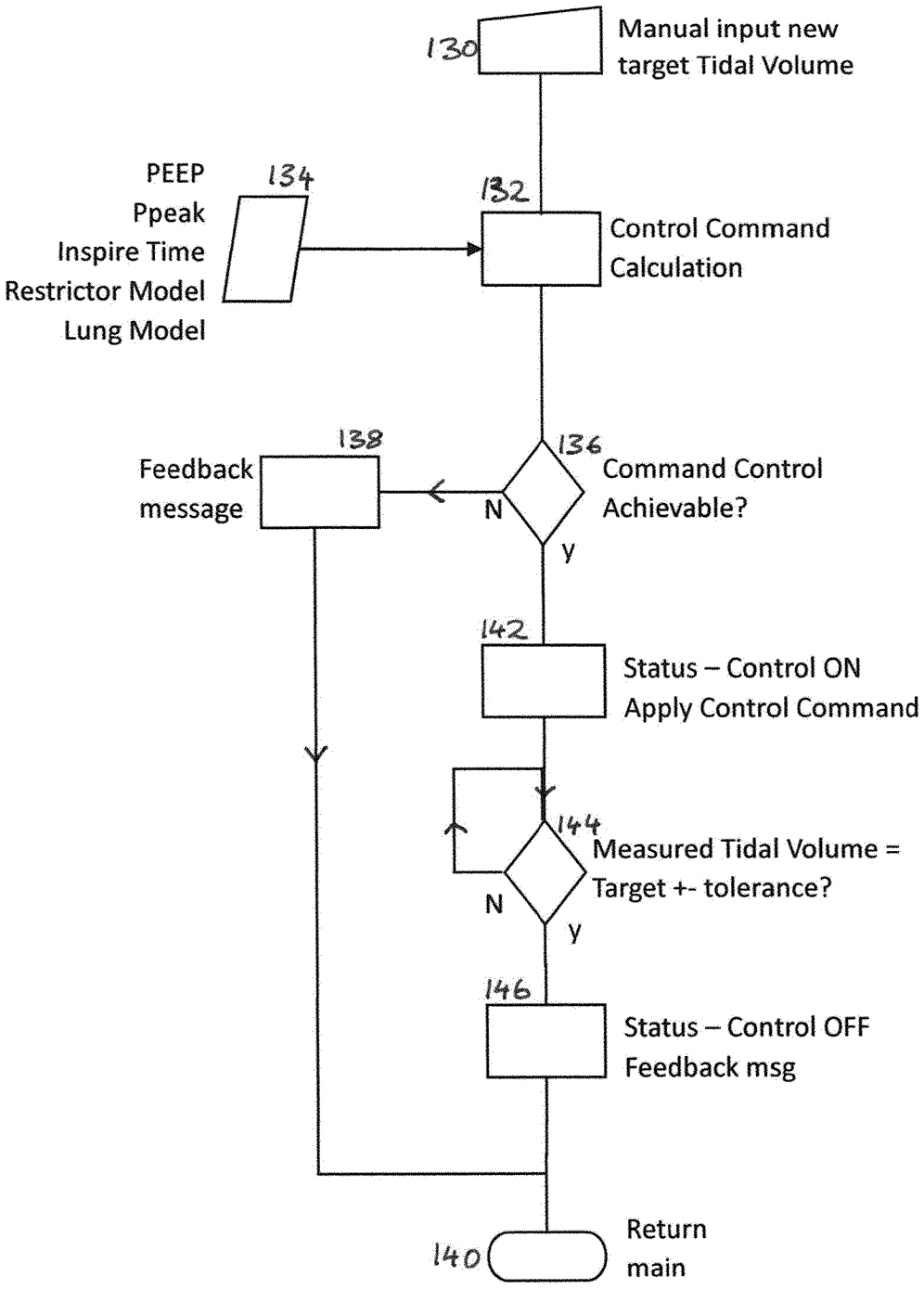

130
Manual input new target Tidal Volume
PEEP
Ppeak
Inspire Time
Restrictor Model
Lung Model
134
132
Control Command Calculation
138
Feedback message
136
Command Control Achievable?
N
y
142
Status – Control ON
Apply Control Command
144
Measured Tidal Volume = Target +- tolerance?
N
y
146
Status – Control OFF
Feedback msg
140
Return main

FIG. 5

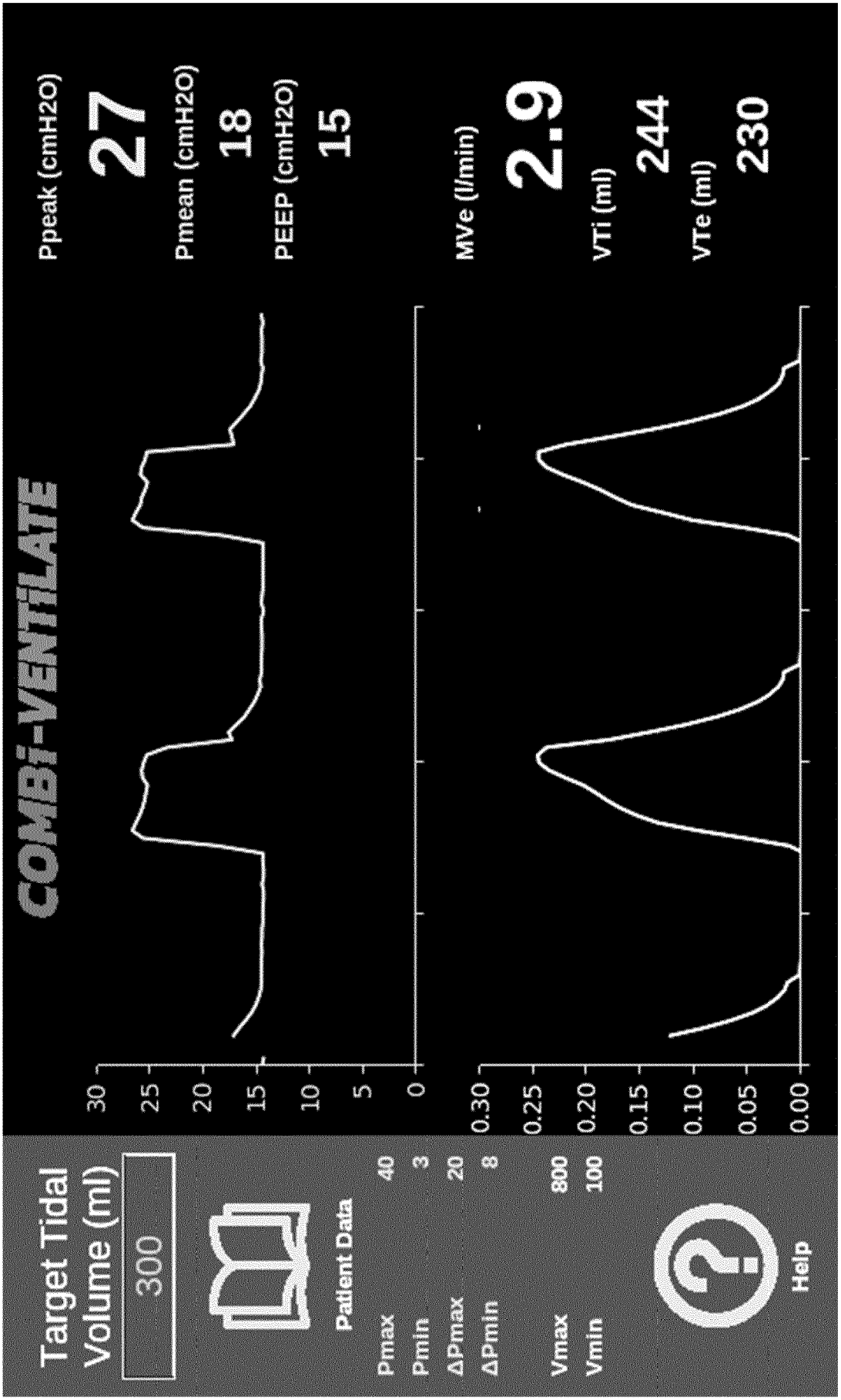

COMBI-VENTILATE
Target Tidal Volume (ml)
300
Patient Data
Pmax 40
Pmin 3
ΔPmax 20
ΔPmin 8
Vmax 800
Vmin 100
Help
Ppeak (cmH2O)
27
Pmean (cmH2O)
18
PEEP (cmH2O)
15
MVe (l/min)
2.9
VTi (ml)
244
VTe (ml)
230
30
25
20
15
10
5
0
0.30
0.25
0.20
0.15
0.10
0.05
0.00

Fig. 6

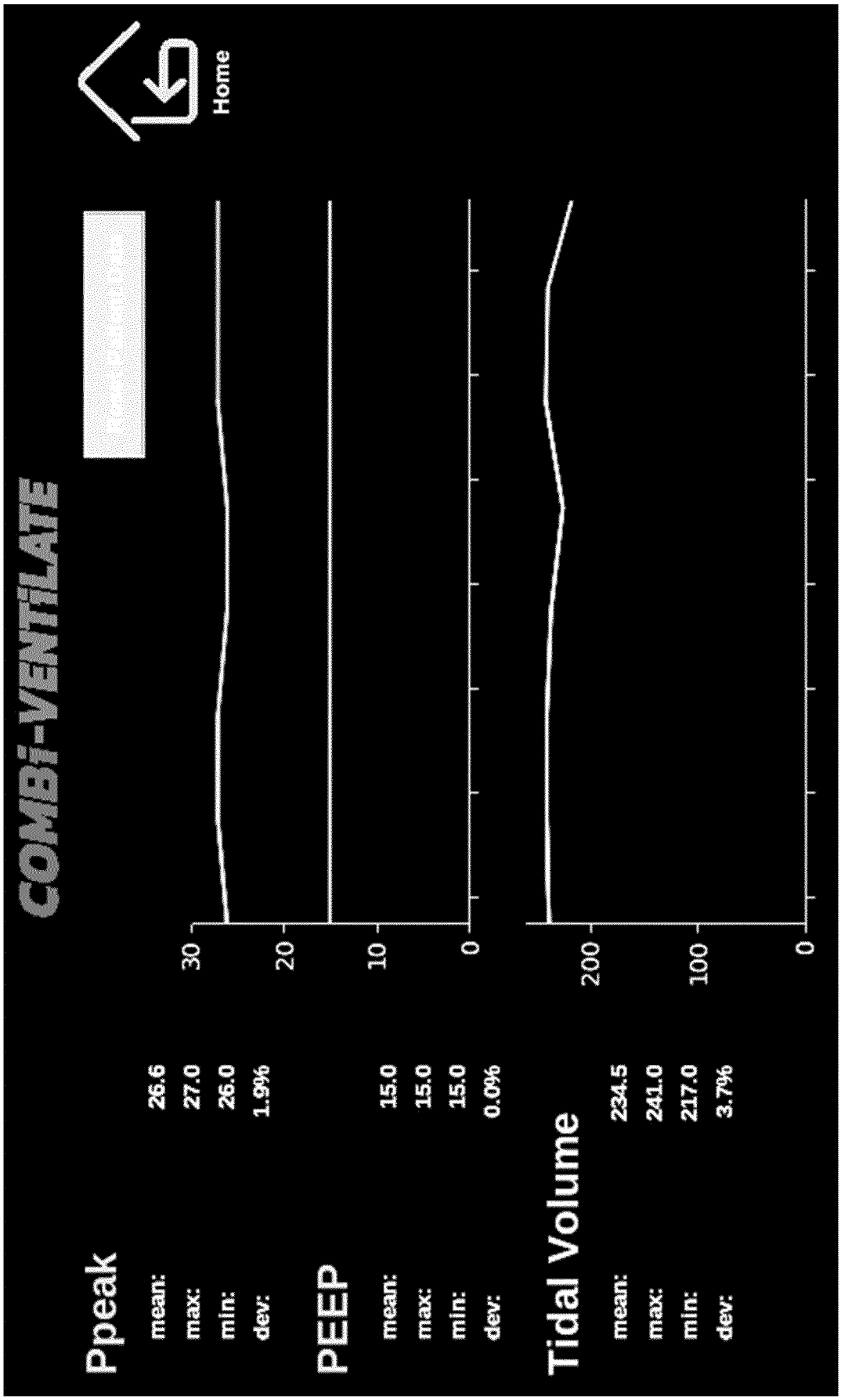

COMBI-VENTILATE
Home
Ppeak
mean: 26.6
max: 27.0
min: 26.0
dev: 1.9%
30
20
PEEP
mean: 15.0
max: 15.0
min: 15.0
dev: 0.0%
10
0
Tidal Volume
mean: 234.5
max: 241.0
min: 217.0
dev: 3.7%
200
100
0

Fig. 7

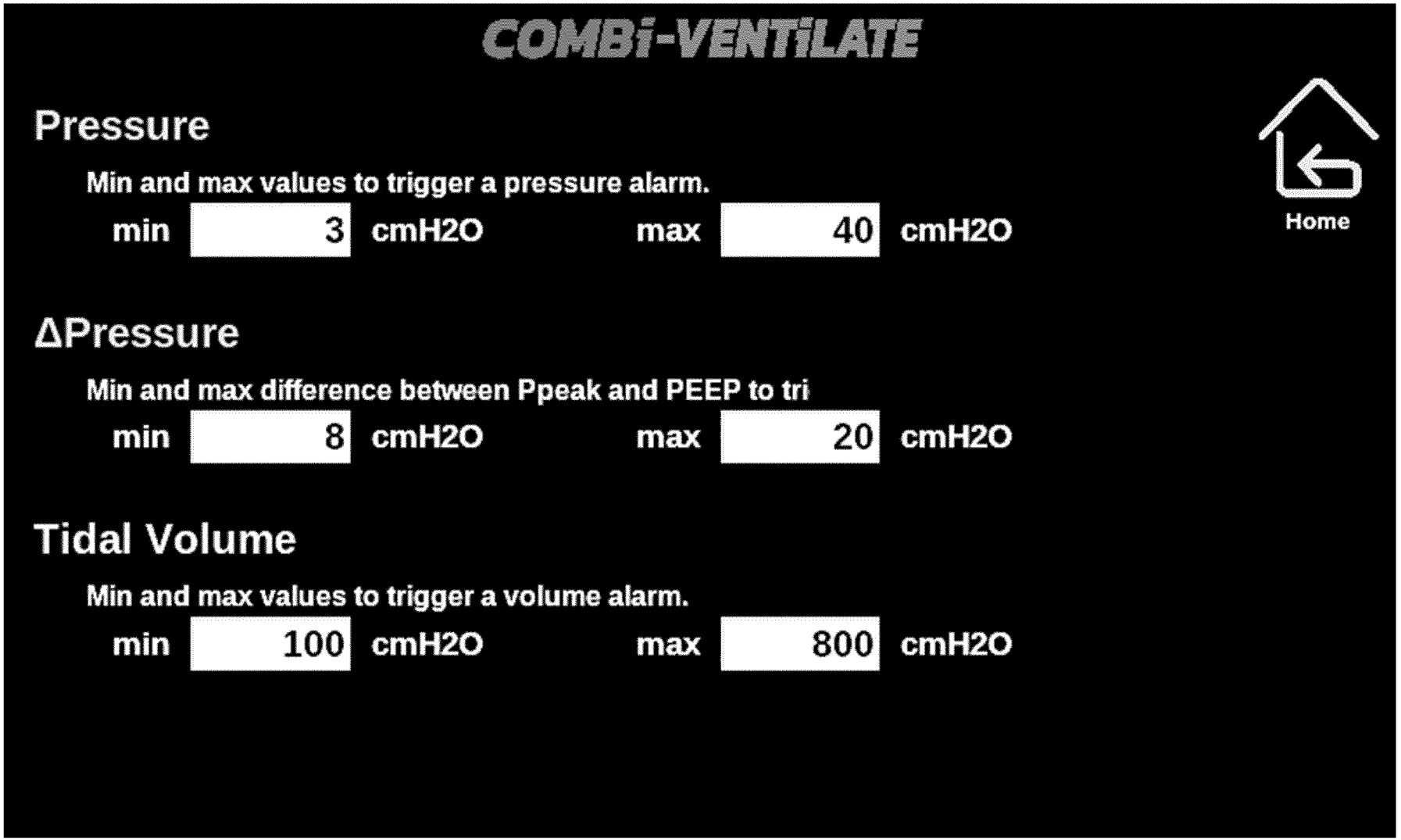

COMBi-VENTiLATE
Pressure
Min and max values to trigger a pressure alarm.
min
3
cmH2O
max
40
cmH2O
Home
ΔPressure
Min and max difference between Ppeak and PEEP to tri
min
8
cmH2O
max
20
cmH2O
Tidal Volume
Min and max values to trigger a volume alarm.
min
100
cmH2O
max
800
cmH2O

Fig. 8

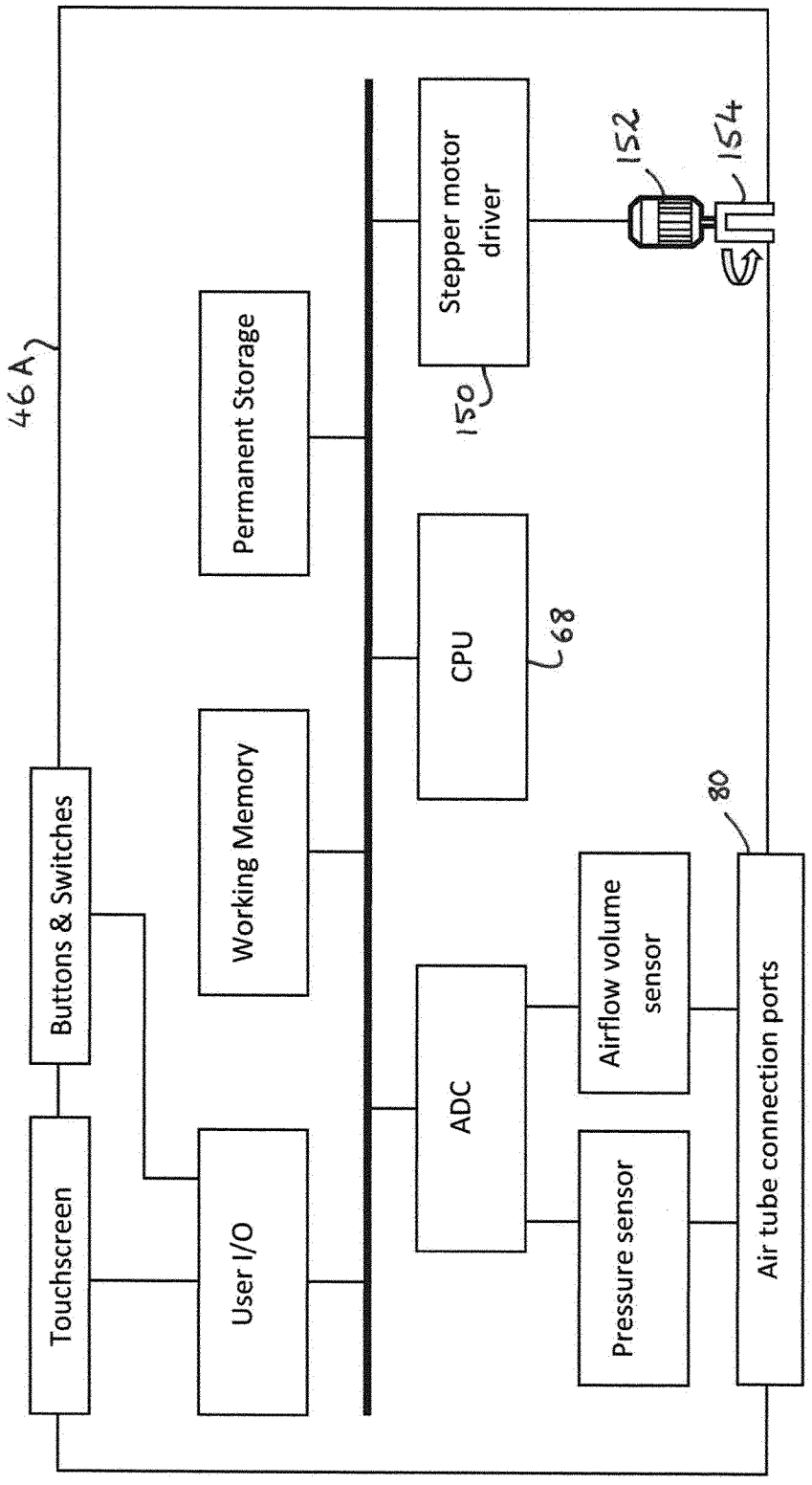

46A
Touchscreen
Buttons & Switches
User I/O
Working Memory
Permanent Storage
ADC
CPU
68
Stepper motor driver
150
152
154
Airflow volume sensor
Pressure sensor
80
Air tube connection ports

FIG. 9

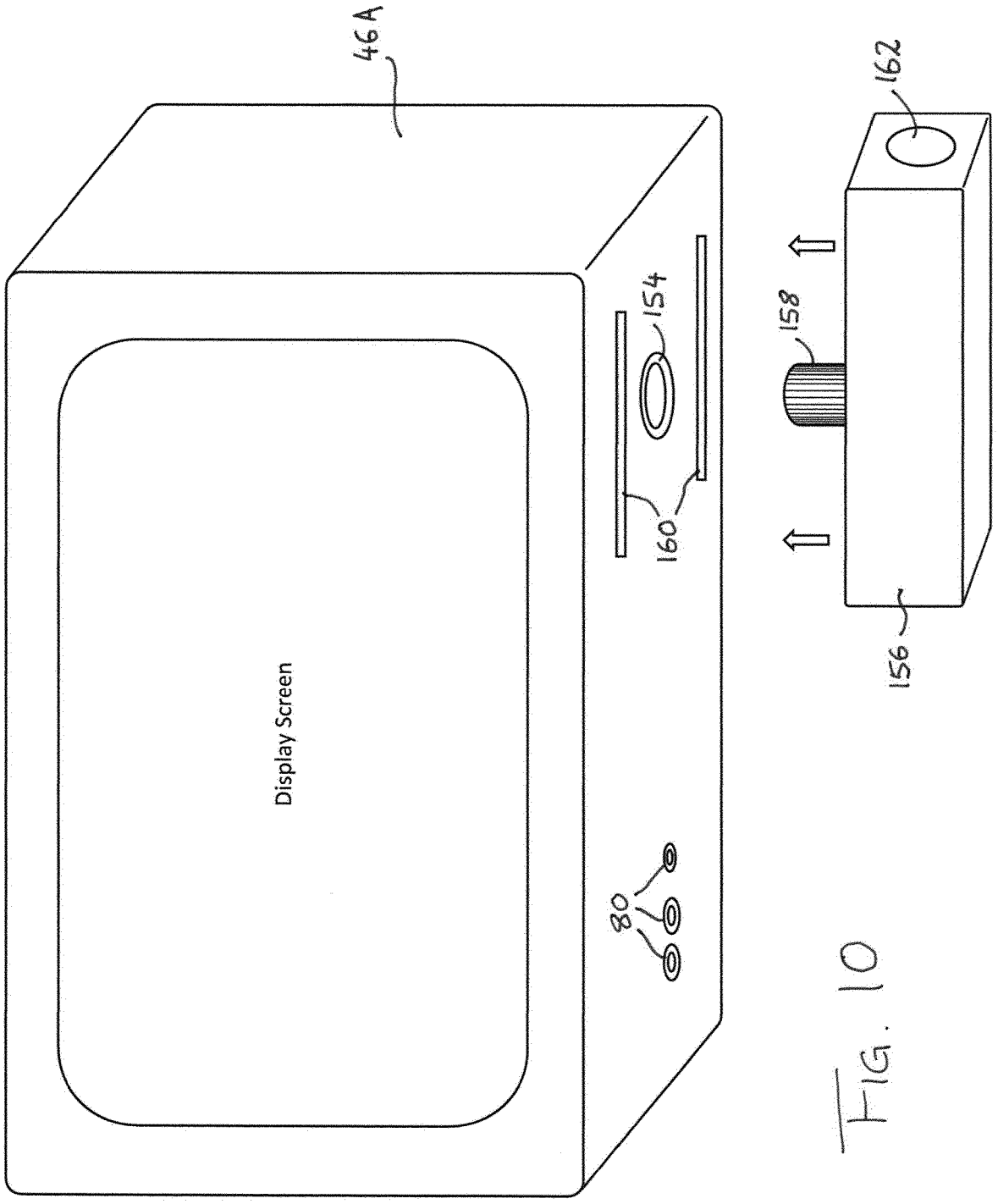


FIG. 10

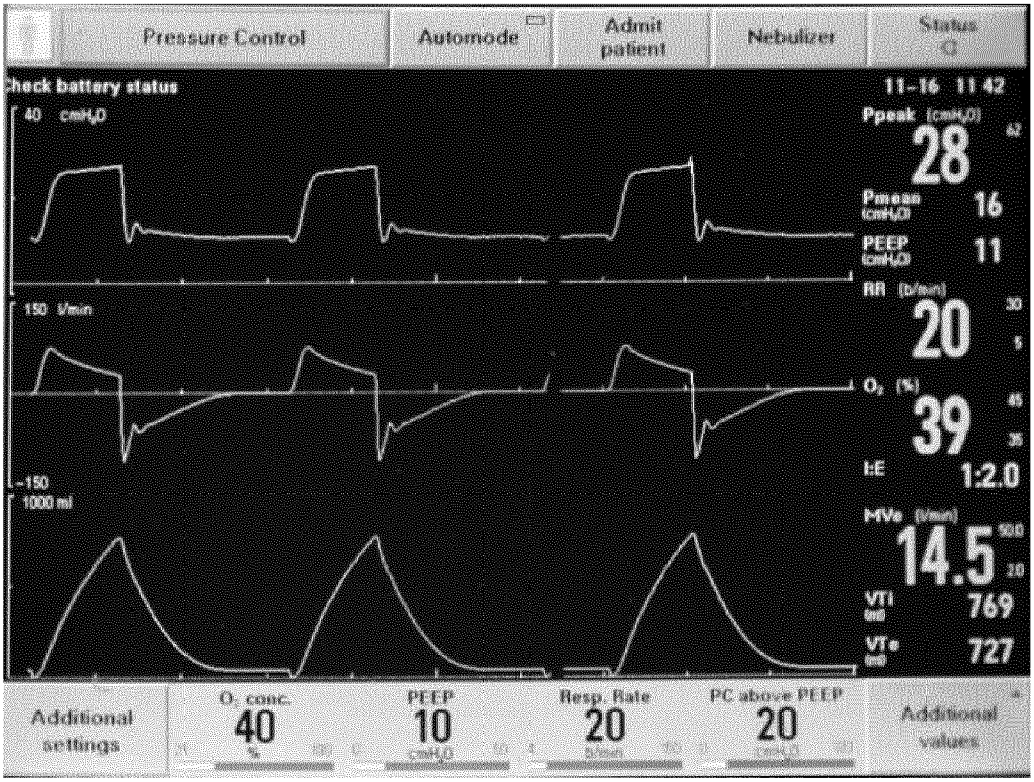
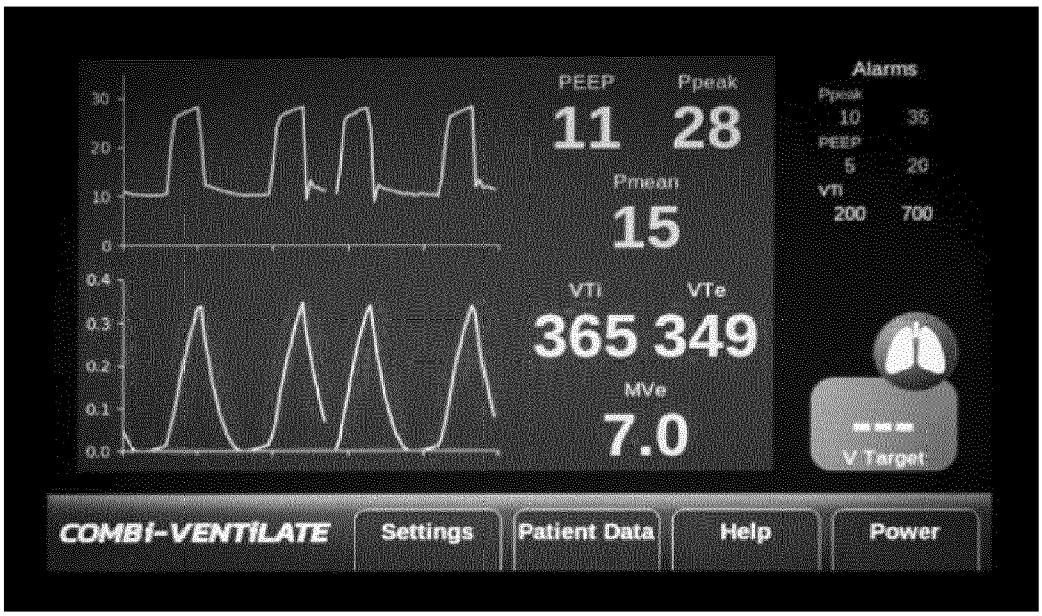

Pressure Control
Automode
Admit patient
Nebulizer
Status
Check battery status
11-16 11 42
40 cmH2O
150 l/min
-150
1000 ml
Ppeak (cmH2O)
28
Pmean (cmH2O)
16
PEEP (cmH2O)
11
RR (b/min)
20
O2 (%)
39
I:E
1:2.0
MVe (l/min)
14.5
VTi (ml)
769
VTe (ml)
727
Additional settings
O2 conc.
40
%
PEEP
10
cmH2O
Resp. Rate
20
b/min
PC above PEEP
20
cmH2O
Additional values

Fig. 11


30
20
10
0
0.4
0.3
0.2
0.1
0.0
PEEP
Ppeak
11
28
Pmean
15
VTi
VTe
365
349
MVe
7.0
Alarms
Ppeak
10
35
PEEP
5
20
VTi
200
700

V.Target
COMBI-VENTILATE
Settings
Patient Data
Help
Power

Fig. 12

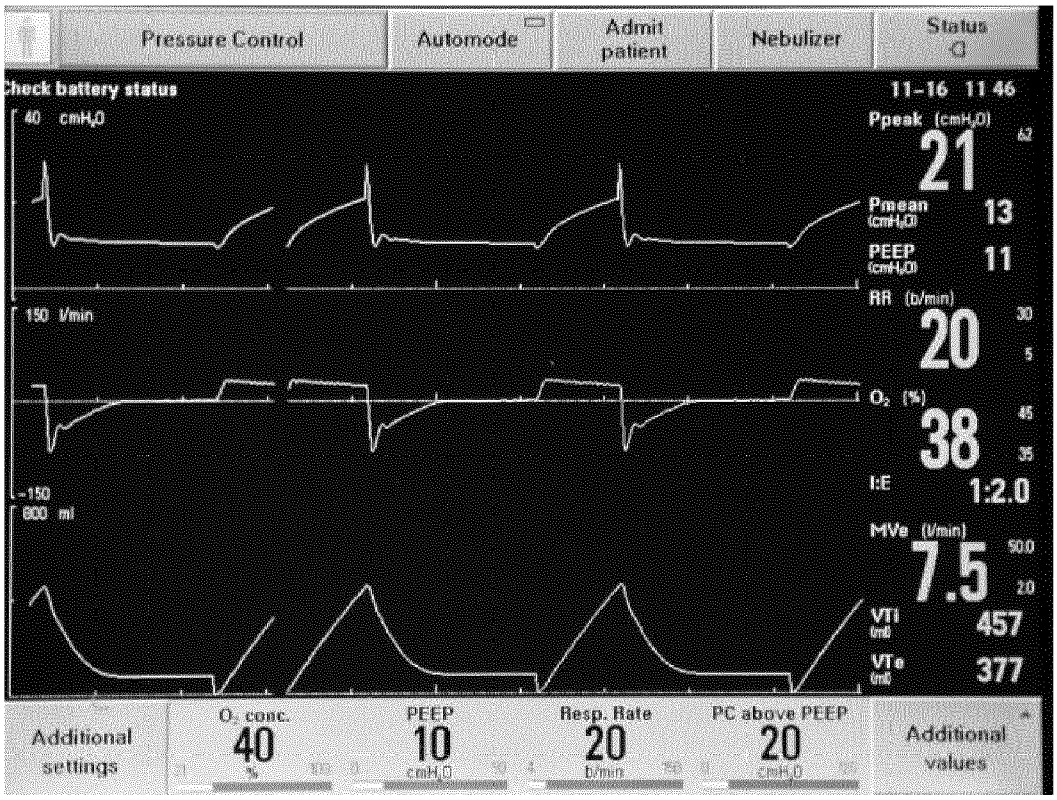

Pressure Control
Automode
Admit patient
Nebulizer
Status
Check battery status
11-16 11 46
40 cmH2O
Ppeak (cmH2O)
21
Pmean (cmH2O)
13
PEEP (cmH2O)
11
RR (b/min)
20
150 l/min
O2 (%)
38
-150
800 ml
I:E
1:2.0
MVe (l/min)
7.5
VTI (ml)
457
VTe (ml)
377
Additional settings
O2 conc.
40
PEEP
10
Resp. Rate
20
PC above PEEP
20
Additional values

Fig. 13

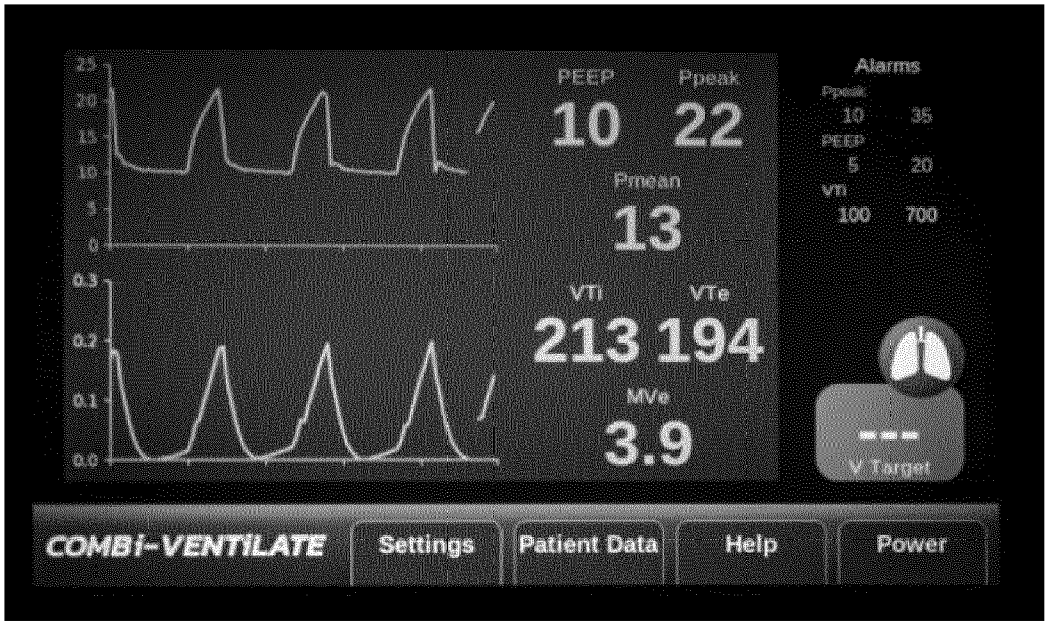

PEEP
Ppeak
10
22
Pmean
13
VTi
VTe
213
194
MVe
3.9
Alarms
Ppeak
10
35
PEEP
5
20
VTi
100
700
V. Target
COMBI-VENTILATE
Settings
Patient Data
Help
Power

Fig. 14

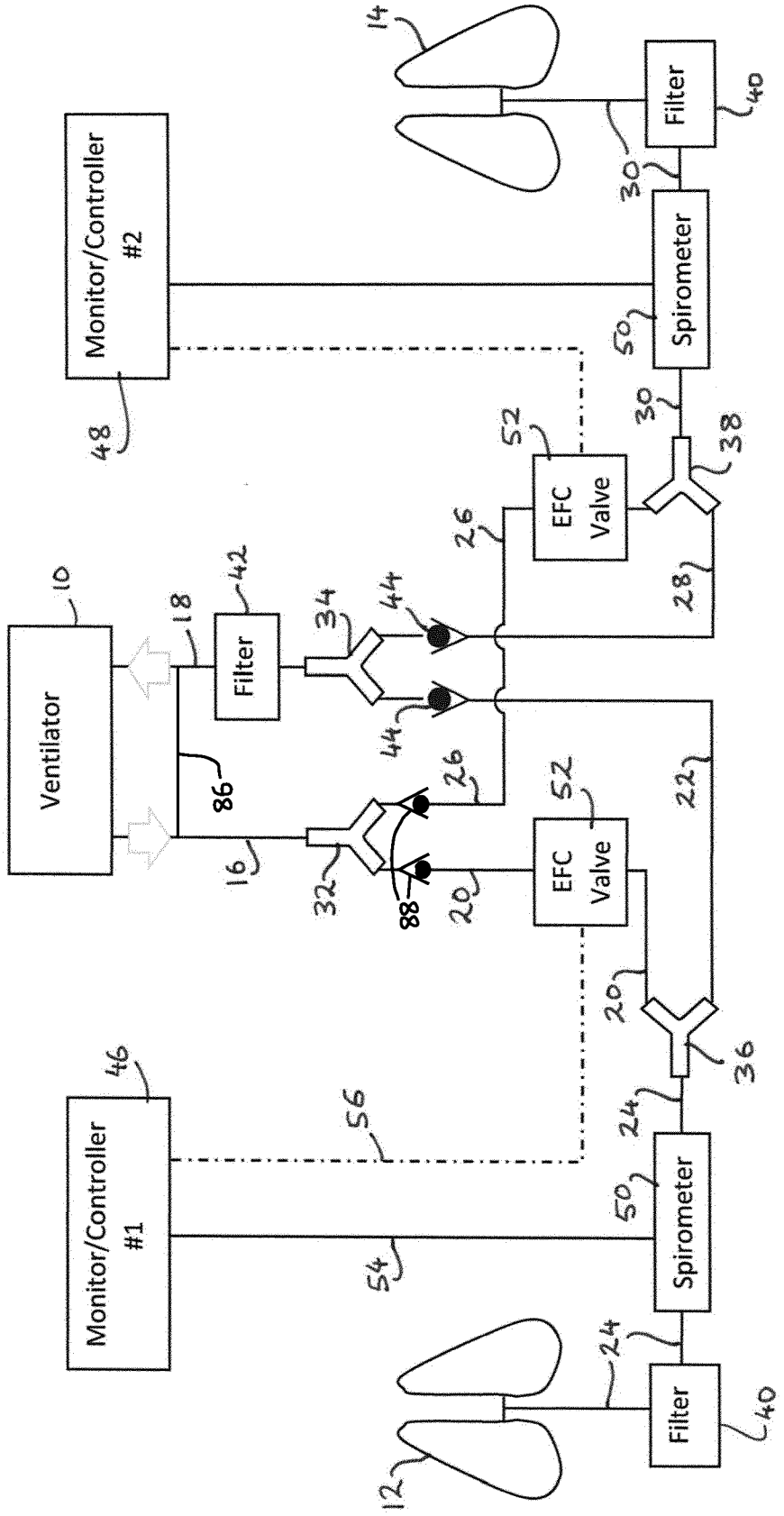

Ventilator
10
18
Filter
42
34
44
44
26
86
16
32
88
20
EFC Valve
52
26
EFC Valve
52
22
20
36
24
Spirometer
50
54
Monitor/Controller #1
46
56
24
Filter
40
12
14
Filter
40
30
Spirometer
50
30
38
28
Monitor/Controller #2
48

Fig. 15

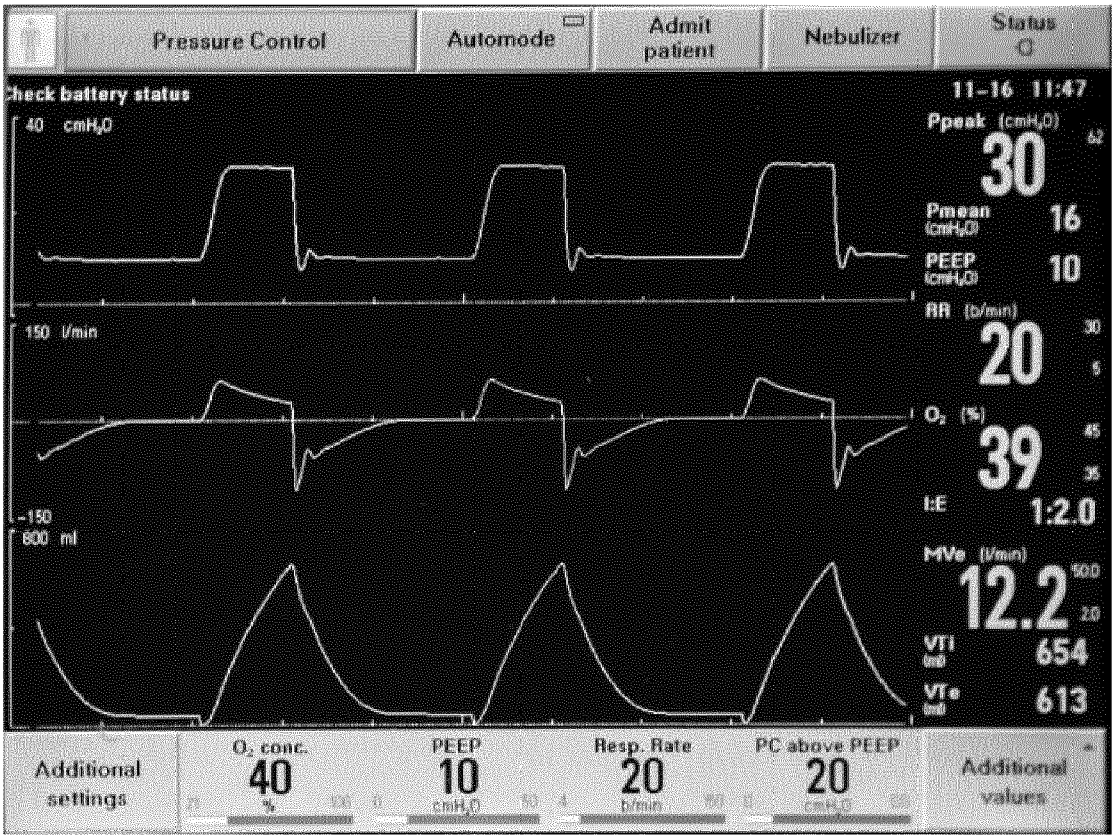

Pressure Control
Automode
Admit patient
Nebulizer
Status
Check battery status
11-16 11:47
40 cmH2O
Ppeak (cmH2O)
30
Pmean (cmH2O)
16
PEEP (cmH2O)
10
RR (b/min)
20
150 l/min
O2 (%)
39
I:E
1:2.0
-150
800 ml
MVe (l/min)
12.2
VTi (ml)
654
VTe (ml)
613
Additional settings
O2 conc.
40
%
PEEP
10
cmH2O
Resp. Rate
20
b/min
PC above PEEP
20
cmH2O
Additional values

Fig. 16

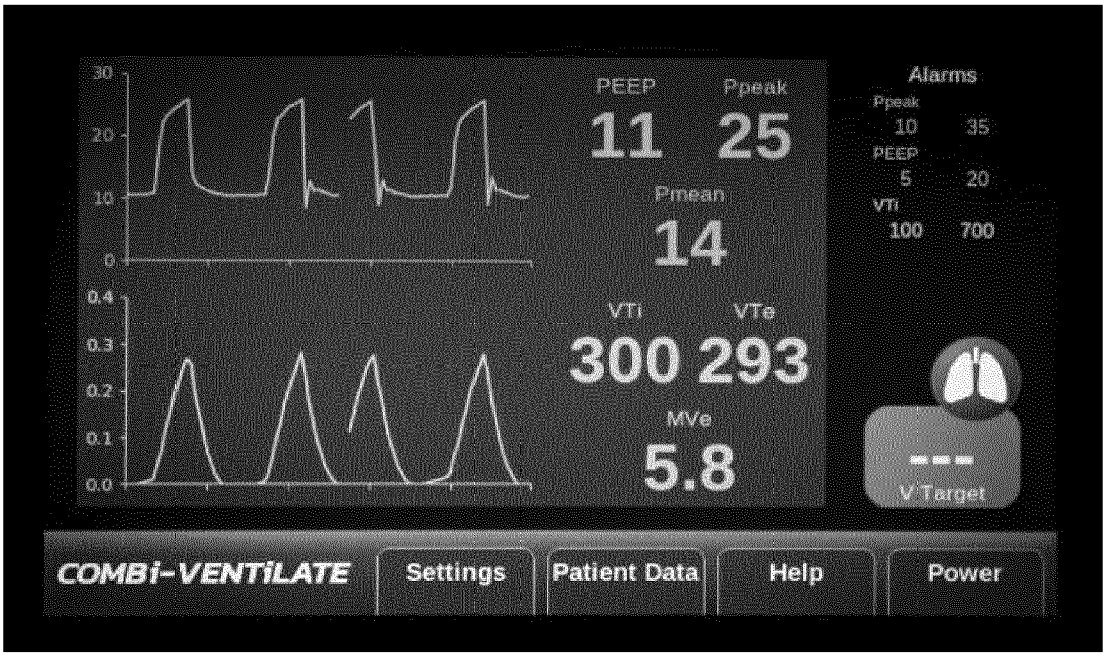

30
20
10
0
0.4
0.3
0.2
0.1
0.0
PEEP
Ppeak
11
25
Pmean
14
VTi
VTe
300
293
MVe
5.8
Alarms
Ppeak
10
35
PEEP
5
20
VTi
100
700
V Target
COMBi-VENTiLATE
Settings
Patient Data
Help
Power

Fig. 17

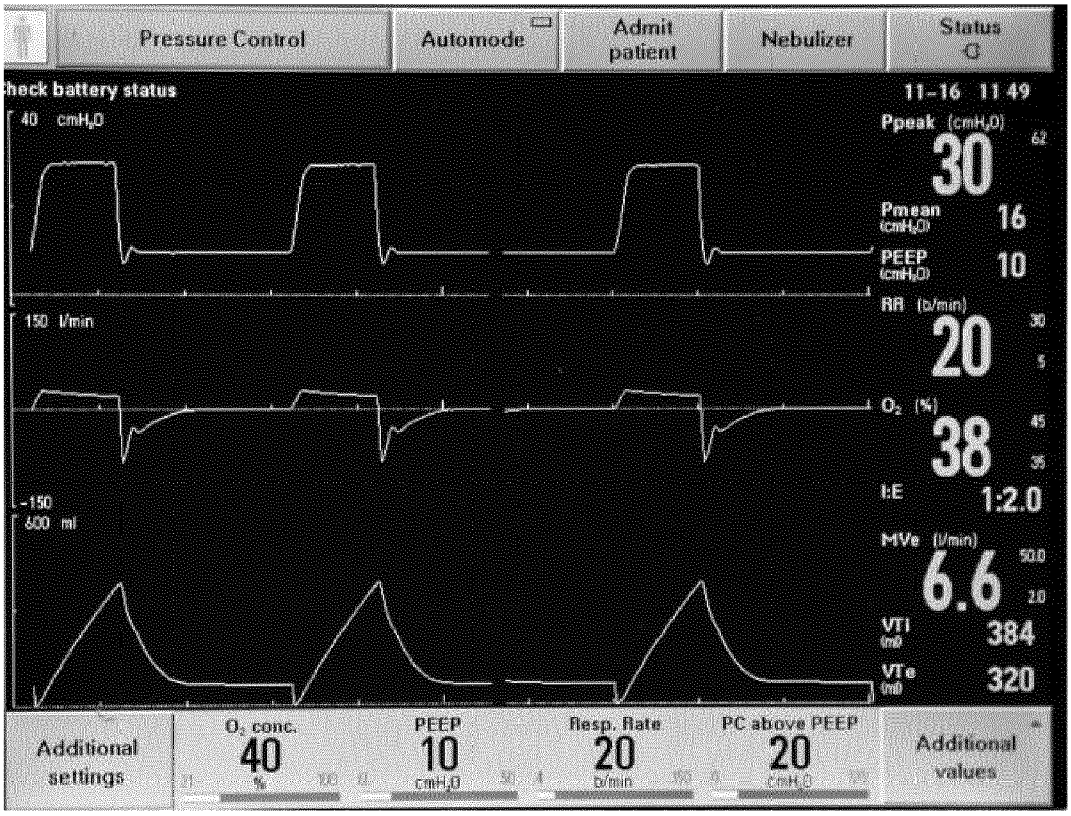

Pressure Control
Automode
Admit patient
Nebulizer
Status
Check battery status
11-16 11 49
40 cmH2O
Ppeak (cmH2O)
30
Pmean (cmH2O)
16
PEEP (cmH2O)
10
RR (b/min)
20
150 l/min
O2 (%)
38
I:E
1:2.0
-150
600 ml
MVe (l/min)
6.6
VTi (ml)
384
VTe (ml)
320
Additional settings
O2 conc.
40
PEEP
10
Resp. Rate
20
PC above PEEP
20
Additional values

Fig. 18

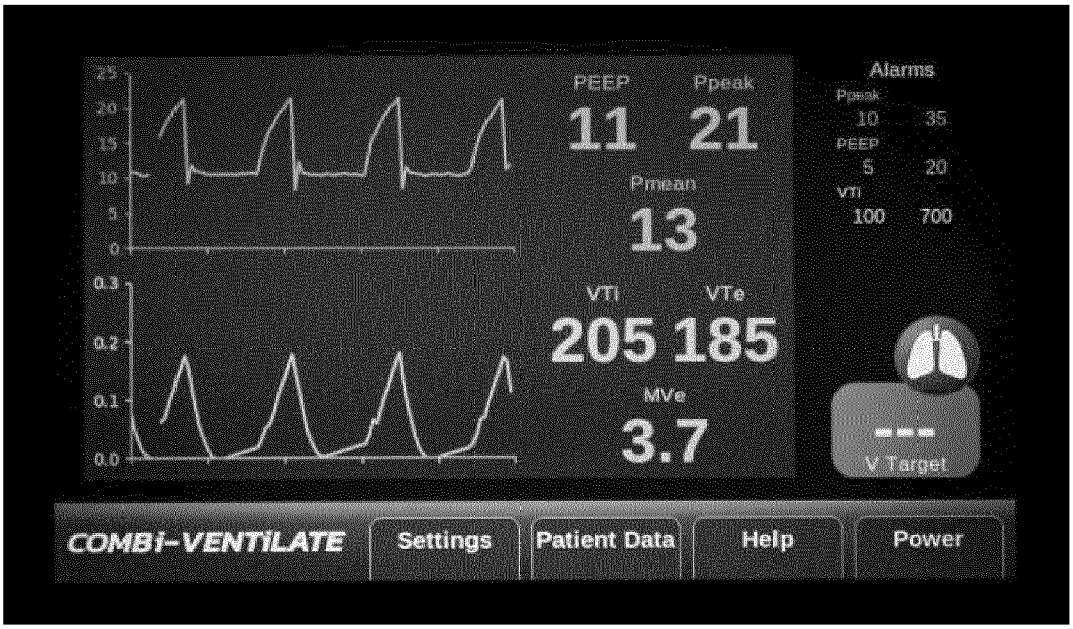

PEEP
Ppeak
11
21
Pmean
13
VTi
VTe
205
185
MVe
3.7
Alarms
Ppeak
10
35
PEEP
5
20
VTi
100
700
V Target
COMBI-VENTILATE
Settings
Patient Data
Help
Power

Fig. 19

Systems for use in the ventilation of patients

Technical Field

This invention relates to systems for use in the ventilation of patients.

Background Art

Artificial or mechanical ventilation of patients is generally carried out using a single ventilator which provides the inspiration and expiration function to a single patient. In emergency situations or where there is a shortage of equipment, such as in the novel coronavirus (COVID-19) emergency which is ongoing at the time of filing, it has been proposed to share a ventilator between two or more patients.

Sharing of ventilators, i.e. plugging two breathing circuits into the same ventilator inspire/expire line pair, is not always satisfactory because different patients may have different lung function and ventilation needs.

It is an object of this invention to provide improvements in the sharing of ventilators.

Disclosure of the Invention

There is provided a system for use in the ventilation of a patient, the system comprising:

an airflow volume sensing means adapted to provide a measurement of the volume of air passing through an air line forming part of a patient breathing circuit when said airflow volume sensing means is in communication said air line;

a pressure sensing means adapted to provide a measurement of the pressure within an air line forming part of said patient breathing circuit when said airflow volume sensing means is in communication with said air line;

a flow control valve which is controllable with a control signal to alter the airflow through an inspiration air line of said patient breathing circuit on which it is mounted;

a user interface enabling a user to input a target volumetric parameter for ventilation of a patient connected to said breathing circuit; and

processing means having inputs connected to said airflow volume sensing means, pressure sensing means and user interface and an output connected to said flow control valve, the processing means being programmed with instructions which are effective to:

receive a measurement from the airflow volume sensing means indicative of the volume of air passing through an air line of the patient breathing circuit;

receive a measurement from the pressure sensing means indicative of the pressure within an air line of the patient breathing circuit;

receive a target volumetric parameter from said user interface;

calculate a control signal which is effective to control the flow control valve to alter the airflow through the inspiration air line of the patient breathing circuit to achieve the target volumetric parameter in the ventilation of the patient to within a predetermined tolerance; and

output said control signal to said flow control valve.

The airflow volume sensing means may be directly mounted on the air line of the breathing circuit with which it is in communication or it may be mounted remotely and in communication via an air conduit leading from the air line to the sensor. Similarly, the pressure sensing means may be directly mounted or remotely mounted.

The airflow volume sensing means and the pressure sensing means may be in communication with the same air line of the breathing circuit or with different air lines of the same breathing circuit.

The system may comprise said breathing circuit. Alternatively the system may be separately supplied from and connected to a breathing circuit.

Preferably, the breathing circuit comprises said inspiration air line having a proximal end adapted for connection to an inspiration air line of a ventilator, an expiration air line having a proximal end adapted for connection to an expiration air line of a ventilator, and the inspiration and expiration air lines having distal ends that are connected to a common inspire/expire air line to which the patient is connected.

Preferably, the inspiration air line of the ventilator and the expiration air line of the ventilator, to which the breathing circuit air lines are connected, support a plurality of breathing circuits.

Preferably, the inspiration air line of the ventilator and the expiration air line of the ventilator are connected by an open connection line.

Preferably, the airflow volume sensing means is in communication with the common inspire/expire air line.

Preferably, the pressure sensing means is in communication with the common inspire/expire air line.

Preferably, the target volumetric parameter is a target tidal volume.

Preferably, the flow control valve is mounted to a controller body and mechanically coupled to a motor in the controller body.

This arrangement significantly simplifies configuring the system for use, since the mechanical coupling allows the flow control valve to be plugged into or otherwise mechanically coupled onto the controller body to engage with a motor in the controller body. This makes the flow control valve unit mechanically simpler, avoids the need to incorporate a motor with the control valve unit, and avoids the need for electrical connections to carry flow control valve control signals from the controller body to the flow control valve unit. It also makes the system neater and less liable to be disturbed and uncoupled.

Preferably, the calculation of a control signal comprises comparing a measured volume of air delivered to the patient with the target volumetric parameter to determine a required change in delivered air volume; and determining a control signal that will be effective to alter the airflow sufficiently to achieve the target volumetric parameter within a predetermined tolerance.

The predetermined tolerance may be input via the user interface, or it may be a stored value. It may be determined as a proportion of the absolute value of the volumetric parameter or as a fixed value.

Optionally, the calculation of a control signal may be a signal to cause an incremental change to the valve state which causes the airflow to more closely approach the target volumetric parameter, and the processor operates a feedback loop using the measured volume of air to

continue changing the valve state incrementally until the target volumetric parameter is achieved within a predetermined tolerance.

Preferably, the airflow volume sensing means continues to provide measurements to the processor after the adjustment of the flow control valve has terminated, and if a change is detected in the measured airflow volume which exceeds a threshold, a further control signal is calculated and output to the valve to restore the airflow towards the target volumetric parameter.

Preferably, the system is configured to deactivate the flow control valve a predetermined time after the target volumetric parameter is achieved.

In this way the electronic valve is not always powered on and will only operate again when the user adjusts the tidal volume. The electronic valve may thus be used only to achieve the target tidal volume.

There is also provided a method of operating a processor of a system for use in the ventilation of a patient comprising the steps, carried out by the processor, of:

receiving a measurement from an airflow volume sensing means indicative of the volume of air passing through an air line of a patient breathing circuit;

receiving a measurement from a pressure sensing means indicative of the pressure within an air line of the patient breathing circuit;

receiving a target volumetric parameter from a user interface;

calculating a control signal which is effective to control a flow control valve to alter the airflow through an inspiration air line of the patient breathing circuit to achieve the target volumetric parameter in the ventilation of the patient to within a predetermined tolerance; and

outputting said control signal to said flow control valve.

There is further provided a computer program product comprising instructions which when carried out by a processor of a system for use in the ventilation of a patient are effective to cause said processor to carry out the method as recited above.

There is further provided breathing circuit comprising a system as recited above, an inspiration air line, an expiration air line, and a common air line from which a patient is ventilated, wherein the flow control valve of the system is mounted on the inspiration air line, the airflow volume sensing means is in communication with one of said air lines, and the pressure sensing means is in communication with one of said air lines.

There is also provided a ventilation system for a plurality of patients comprising a common ventilator connected to a ventilator inspire line and a ventilator expire line, and a plurality of breathing circuits according to the preceding paragraph, each of said breathing circuits having its inspiration air line connected to the ventilator inspire line, and each of said breathing circuits having its expiration air line connected to the ventilator expire line.

The ventilation system preferably further comprises a connection line providing an open connection between the ventilator inspire line and the ventilator expire line.

In another independent aspect there is provided a system for ventilating a plurality of patients, comprising:

a shared ventilator having an inspire port to which a shared ventilator inspire line is connected, and an expire port to which a shared ventilator expire line is connected;

a first patient breathing circuit having a first patient circuit inspiration line connected to the shared ventilator inspire line and a first patient circuit expiration line connected to the shared ventilator expire line;

a second patient breathing circuit having a second patient circuit inspiration line connected to the shared ventilator inspire line and a second patient circuit expiration line connected to the shared ventilator expire line;

wherein at least one of the patient breathing circuits comprises a flow control valve which is controllable with a control signal to alter the airflow through the breathing circuit of which it forms part; and

a connection line providing an open connection between the shared ventilator inspire line and the shared ventilator expire line.

As described further below, the provision of an open connection causes the shared breathing circuits to be seen by the ventilator as a normally operating breathing circuit, and to avoid an alarm or abnormal condition from being detected due to restrictions being imposed by the or each flow control valve.

Preferably, the shared ventilator is configured to alternately open and close the inspire and expire ports.

Because the inspire ports are alternately opened and closed the open connection line does not permit airflow to bypass the breathing circuits directly from the inspire port to the expire port, because these ports are not open simultaneously. Instead the inspire port opens during the inspire phase and closes during the expire phase, while the expire port opens only during the expire phase and closes during the inspire phase.

Preferably, the first patient breathing circuit and/or the second patient breathing circuit is a breathing circuit as recited above, incorporating a system according to the first recited aspect of the invention.

Brief Description of the Drawings

The invention will now be further illustrated by the following description of embodiments thereof, given by way of example only with reference to the accompanying drawings, in which:

Fig. 1 is a system diagram showing the components of a pair of patient breathing circuits connected to a common ventilator;

Fig. 2 is a block diagram of a controller for use in ventilating a patient in the system of Fig. 1;

Fig. 3 is a flowchart of a power on self-test operated by the controller of Fig. 2;

Fig. 4 is a flowchart of a system status check routine operated by the controller of Fig. 2;

Fig. 5 is a flowchart of a program module used by the controller of Fig. 2 to adjust the tidal volume delivered to the patient;

Fig. 6 is a screenshot of a display screen of the controller of Fig. 2 in normal operation mode;

Fig. 7 is a screenshot of a display screen of the controller of Fig. 2 in a patient data display mode;

Fig. 8 is a screenshot of a display screen of the controller of Fig. 2 in alarm setting mode;

Fig. 9 is block diagram of a further embodiment of monitor/controller;

Fig. 10 is a perspective view from in front and below of a controller housing;

Fig. 11 is a screenshot of a display output from a ventilator with two breathing circuits attached;

Fig. 12 is a screenshot of a display output from a patient monitor/controller of one of the breathing circuits attached to the ventilator providing the display output of Fig. 11;

Fig. 13 is a screenshot similar to Fig. 11 showing the effect arising from restricting the airflow through the patient breathing circuits;

Fig. 14 is a screenshot similar to Fig. 12 showing the effect arising from restricting the airflow through the patient breathing circuits;

Fig. 15 is a system diagram showing the components of a pair of patient breathing circuits connected to a common ventilator, in a modification to the system of Fig. 1; and

Figs. 16-19 are screenshots similar to those of Figs. 11-14, respectively, where the patient breathing circuits are modified to include an equalising tube connected across the inspire and expire ports of the ventilator.

Detailed Description of Preferred Embodiments

In Fig 1 there is shown a shared ventilation system in which a single ventilator 10, which is a conventional ventilator, is shared between two patients 12, 14. The ventilator 10 has an inspire

line 16 and an expire line 18. A first breathing circuit 20, 22, 24 and a second breathing circuit 26, 28, 30 are connected to the ventilator.

It can be seen that the first breathing circuit has an inspiration air line 20 and an expiration air line 22, both connected to a common air line 24 from which the first patient 12 is ventilated. Similarly, the second breathing circuit has an inspiration air line 26 and an expiration air line 28, both connected to a common air line 30 from which the second patient 14 is ventilated. The inspiration air lines 20, 26 of the first and second breathing circuits are connected to the ventilator inspire line 16 by a first Y-connector 32, and the expiration air lines 22, 28 of the first and second breathing circuits are connected to the ventilator expire line 18 by a second Y-connector 34. Third and fourth Y-connectors 36, 38 are used in the first and second breathing circuits, respectively, to couple the inspiration 20,26 and expiration 22, 28 air lines of each breathing circuit to the breathing circuit's common air line 24, 30.

Each breathing circuit has a filter 40 on the common air line, which is preferably a heat and moisture exchange (HME) filter combined with bacterial and viral filtering ability such as a HEPA filter. A further similar filter 42 is provided on the expire line of the ventilator. A pair of non-return valves 44 are provided at the end of each breathing circuit's expiration air line 22, 28 to prevent cross-mixing of expired air between the breathing circuits. Non-return valves may also be provided at the start of each breathing circuit's inspiration air line 20, 26 (as seen in e.g. the embodiment of Fig. 15).

The ventilator 10 is a conventional ventilator and therefore is designed to be used with a single patient. In normal use it can be configured to the ventilation needs of that one patient, with a tailored air pressure and tidal volume. However, when shared between two patients with different medical needs, it cannot adequately ventilate both patients with their optimal air supply due to differences in lung function, breathing rates, and so on.

The ventilator is preferably used in pressure mode rather than volume mode, i.e. it is configured to maintain a constant pressure to the inspire line, which allows each breathing circuit to consume a different volume of air from a common pressurised source.

In Fig. 1 therefore there can be seen two patient monitor/controllers 46, 48, one for each patient. As each is identical, only the first of these will be described. The patient monitor/controller 46 (referred to herein as a controller 46 for brevity) is connected to a

spirometer 50 and to an electronic flow control (EFC) valve 52. The EFC valve plugs directly into the breathing circuit using standard air tube connectors.

The spirometer 50 is a pitot spirometer such as the Intersurgical Patient Spirometry Set sold by Intersurgical Ltd of Wokingham, UK. Such a spirometer has a pair of pitot tubes which are connected by first and second air tubes and a side stream gas tube connected by a third air tube (the three tubes being collectively indicated by the pneumatic connection 54 in Fig. 1). The controller 46 has an integrated air volume flow sensor which operates by detecting the pressure in the pitot tubes to measure the instantaneous and time-integrated air flows. From these measurements, the tidal volume and other measurements may be determined. The controller 46 is also provided with an integrated pressure sensor for determining the instantaneous pressure in the spirometer 50 and thereby the peak and PEEP pressures.

The EFC valve may be controlled by a solenoid or a motorized actuator (e.g. step motor). It may be controlled digitally or using analog signals carried on an electrical connection 56. In the embodiment illustrated, the connection 56 is two-way and carries feedback on the actuator position back to the controller 46 using current, position sensor or encoder signals.

Referring additionally to Fig. 2, a block diagram of the components of the controller 46 is shown. The controller 46 operates as a monitor and has a touchscreen display 60 and input buttons and switches 62 to allow a user, typically a trained nurse or doctor, to control the unit and provide inputs, such as desired ventilation parameters. Such inputs, and the output of display graphics, sounds, etc. are handled by a User I/O interface 64, which is connected via a communications bus 66 to a CPU 68. It will be appreciated that the CPU may be a general-purpose CPU, or a programmable microcontroller, or a dedicated electronic circuit which performs the functions described below.

In common with typical computing devices, there is a power supply (not shown), a working memory 70 for storing program instructions, inputs and outputs, and working parameters used by a program, and also a permanent storage 72 which stores boot system instructions, programs, log data, and the like.

An analog-to-digital converter (ADC) 74 is used to interface between a pressure sensor 76 and airflow volume sensor 78 on the one hand, and the CPU 68 on the other hand. This assumes that the sensors 76, 78 provide analog outputs, but the skilled person will appreciate that digital

sensors may equally be used with their signals being passed by appropriate microcontrollers to the CPU. The sensors in this embodiment are integrated with the controller, but they may equally be remote from the controller with signal ports receiving electrical signals encoding raw or processed values of the pressure and airflow volume. In the illustrated embodiment, the pressure sensor 76 and airflow volume sensor 78 are pneumatically connected to the spirometer (Fig. 1) via the air lines 54 (Fig. 1) that plug into a set of compatible air tube connection ports 80 using suitable male/female connectors.

A digital-to-analog converter (DAC) 82 receives command control signals from the CPU 68 via the bus 66 and communicates these as analog control signals to the EFC valve 52 (Fig. 1) via the electrical connection 56 (Fig. 1) that plugs into electrical lead ports 84 via suitable electrical connectors. Again, it will be appreciated that the choice of analog or digital control signals is dependent on the type of EFC valve used, and the control signals required by the EFC valve to control the airflow through the valve.

The CPU is programmed to receive measurements of pressure and airflow volume and to determine from these measurements if the airflow should be restricted or increased in order to match a desired volumetric parameter, typically expressed as a tidal volume. The volumetric parameter is input via the user I/O 64 and is compared to the current measured airflow volume to determine how to control the valve in order to achieve the desired tidal volume. The translation of the required change in airflow volume into a valve control signal will depend on the physical parameters of the system and the physical components, and may take into account the pressure characteristics observed, such as the peak and PEEP pressures exhibited. Control signals may specify an absolute valve position, or an incremental change which is feedback-controlled to continue, be increased or decreased, until the delivered air volume is determined to be within the desired range. Typically, the target volumetric parameter will be interpreted as a range with tolerances (which may be relative or absolute) in order to avoid overshooting and fluctuation and to minimise the number of adjustment steps.

The program running on the CPU will now be described with reference to the flowcharts of Figs. 3-5. It will be appreciated that these flowcharts describe only the operation of the program elements required to initiate and control the airflow via the valve; the CPU will also be programmed to implement conventional functions of a monitor used in ventilation.

In Fig. 3 there is shown a flowchart for a power on self-test (POST). This is a system safety feature that occurs every time the controller is switched on. When the main unit is powered on, step 90, a main board test is run, step 92, and the result of this test, step 94 determines if the system is powered off immediately after a fail, step 96 or if the process continues. If the main board test passes, a sensors test is performed, step 98, and a determination is made, step 100 whether the sensors test is passed. If not, the system powers off, step 96, while if the test is passed the system powers on successfully, step 102.

Fig. 4 shows the next test that runs after the system successfully powers up. The system status is determined in step 110, and if the system status is ON (i.e. the POST has completed and has passed as in Fig. 3), step 112, a check is made whether a flow restrictor valve (referred to herein also as an electronic flow control or EFC valve) is detected, step 114. If no valve is detected as being connected to the electrical connection port, then the system status is set as System ON, EFC OFF, step 116.

If an EFC valve is detected, a feedback message is generated, step 118 which may be used for instance to cause an icon or message to be displayed on the monitor. Next a valve test is carried out, step 120, which may involve actuating the valve from fully open to fully closed and determining from signals received back from the valve that it is operating correctly, such as by checking that the position reported for the valve actuator matches the expected position form the command signals sent during the test. If it is determined, step 122, that the test has failed, then the same status is set in step 116, i.e. System ON, EFC OFF. If the test passes, then the status is set, step 124, to System ON, EFC ON.

Fig. 5 is a flowchart of a program module that is activated only when the status is System ON, EFC ON, and when a user desires to change the ventilation parameters for a patient. In step 130, a user manually inputs a target tidal volume, this being the most commonly used volumetric parameter for ventilation in the medical profession, and this being the input step that initiates the program module shown in this flowchart.

In step 132, the CPU calculates the control command that would have to be implemented either to directly achieve this target tidal volume (i.e. by a single adjustment of the valve to a new position) or to incrementally move towards the target tidal volume. The CPU has access to variables 134 stored in memory or permanent storage such as the measured pressure values PEEP and P_{peak}, measured inspire time, the restrictor valve model and characteristics, a lung

model, and (not shown) currently measured tidal volume. It will be appreciated that other variables and parameters may be taken into account in any given algorithm.

A check is made, step 136, whether the command control is achievable, i.e. that the required valve position can be physically achieved, or e.g. whether if the valve was fully open the tidal volume would still be insufficient. If unachievable, a feedback message is generated in step 138 and returned for display or communication to the user, following which the module ends in step 140 and normal operation of the unit resumes.

If the command control appears to be achievable, the status changes to Control ON, and the control command is applied by outputting a control signal to the valve, step 142. This control continues to be applied while checking whether the measured tidal volume has arrived within the range specified by the target tidal volume plus or minus the predefined tolerance, step 144. The command may be generated to incrementally increase or decrease the valve position, pause, observe the new tidal volume, and then repeat until the desired volume is observed. The feedback control may also be varied such as by watching for overshoot and then reversing the valve movement until the tidal volume stabilises within the desired range. Also, the feedback loop may operate under a timeout operation, whereby if the required tidal volume is not observed within a reasonable timeout period, an error is reported in a feedback message.

When the tidal volume has reached the required range, and typically after a short timeout of e.g. 30 seconds to ensure that it is stable, the status is changed in step 146 to Control OFF, and a feedback message is generated to report that the control has ended, following which the module ends in step 140. During the period that the status is Control ON, the unit will preferably display a notification onscreen to this effect as a warning and to ensure that unqualified personnel do not unwittingly alter the tidal volume parameter.

It will be appreciated that this system allows the user to quickly and intuitively change the patient's ventilation by entering a single value (desired tidal volume) into the main screen of the unit.

Representative screen displays are shown in Figs. 6-8. It will be appreciated that these are in no way limiting.

Fig. 6 shows the main display screen in normal operation. In the centre of the screen upper and lower traces show the time-varying measured pressure and volume values. On the right of the screen, derived pressure values are shown alongside the pressure trace (such as the peak and mean measured pressures P_{peak} and P_{mean} and the positive end-expiratory pressure or PEEP), while derived volumetric values are shown alongside the volume trace (such as the minute ventilation MV_e, tidal volume VTi and VTe). On the left of the screen, the target tidal volume is shown, this being an interactive screen area where the user can enter a new value. A book icon allows access to patient data stored in the device's storage, and below this, alarm values are shown, i.e. maximum and minimum values for pressure, delta pressure (this being the difference between P_{peak} and PEEP) and tidal volume, these representing outer limits which if breached cause an alarm to sound.

Fig. 7 is the patient data screen, accessed from the screen of Fig. 6 using the book icon. This shows historical mean, maximum, minimum and standard deviation values for the primary parameters of interest, as well as a graphical representation of the evolution of these values over time. It also provides a user button, shown in light colour over the graphical representations, which allows the user data to be reset e.g. when a new patient is connected to the monitor.

Fig. 8 is a user input screen which allows the user to set the alarm values, i.e. the upper and lower limits for the pressure, delta pressure and tidal volume shown on the left-hand side of Fig. 6.

Fig. 9 is a further embodiment of the monitor/controller, indicated as 46A. It is identical to the monitor/controller of Fig. 2, other than in the details described below. Accordingly, those elements that have already been described in Fig. 2 are not described again for Fig. 9.

Whereas the controller of Fig. 2 outputs electrical control signals to a remote valve having its own actuator, the embodiment of Fig. 9 is designed to have a valve housing mounted directly onto the housing of the monitor/controller and uses a mechanical connection between a stepper motor which is built into the controller housing and a valve actuator which is part of the valve.

The CPU sends the control command signals to a stepper motor driver 150 which outputs electrical signals to the stepper motor 152. The stepper motor has a rotatable socket 154 connected to its shaft and the socket is exposed to the outside of the housing.

As seen in Fig. 10, the controller 46A housing has on its underside the air tube connection ports 80, the exposed socket 154, and mounting brackets 160 to engage with and retain the body of a valve housing 156. Projecting from the valve housing is a knurled shaft 158 that is rotatable to open or restrict an internal passageway within the valve leading from an inlet port 162 at one end and an outlet port (not shown) at the opposite end. These ports are provided with standard push-on connectors to receive standard ventilation tubing.

In use, the valve 156 is connected into the inspiration line of a breathing circuit, then the valve housing is pushed upwards so that the knurled shaft 158 is friction fitted into the socket 154 and the brackets engage and retain the valve housing. A simple contact sensor (not shown) within the socket can be used to detect the presence of the shaft and this sends a signal which is used in the process of Fig. 4 to confirm that the EFC valve is fitted.

The valve unit 156 may thus be a sterilisable component with no electronic parts, allowing it to be cleaned and reused with standard sterilisation techniques (e.g. autoclaving).

Both the embodiment of Fig. 2 and that of Fig. 9 provide similar benefits in the ventilation of multiple patients from a shared ventilator. The medical staff can tailor the ventilation to a single patient by setting a single value (tidal volume) and the flow control valve setting will tailor the airflow to obtain that tidal volume. If the air supply to one patient is occluded or some alarm condition arises, this has no effect on the air supply to the patient on the other breathing circuit.

Referring to Fig. 11, the ventilator provides a readout derived from pressure and airflow meters that are integrated into the ventilator. The pressure readings are taken as a pressure differential internally in the ventilator across the inspire and expire ports to which the inspire line 16 and expire line 18 (Fig. 1) are connected in use. The airflow readings are taken using an airflow meter integrated within the ventilator on the inspire and/or expire lines.

The top trace in Fig. 11 shows the instantaneous pressure as a continual trace with derived values to the right of this trace indicated as pressure values in cm H_2O, such as Ppeak, Pmean and PEEP (which are respectively seen to be 28, 16 and 11 cm H_2O). The middle trace shows the

inspiratory flow measured in l/min, with values on the right of this trace showing the respiratory rate (RR = 20 breaths/min), oxygen fraction (39%) and inspire:expire ratio (1:2.0). The bottom trace shows the tidal volume in milliliters with derived volumetric values shown alongside the volume trace (minute ventilation MV_e of 14.5, and inhaled/exhaled tidal volumes VTi = 769ml and VTe = 720 ml).

As indicated in the top bar of the display the ventilator is operating in "Pressure Control" mode. This means that the ventilator is configured to maintain a constant pressure to the inspire line, which allows each breathing circuit to consume a different volume of air from a common pressurised source. The pressure (top trace) can be seen to follow an approximately square wave pattern, with a relatively sharp rise at the beginning of the inspire phase, reaching a higher pressure that is maintained through the inspire phase and then a relatively sharp drop as the expire phase starts, dropping to a lower pressure that is maintained until the end of the expire phase and the start of the next cycle. Looking at the inspiratory flow (middle trace) it can be seen that the periodicity of the square wave cycle is mirrored by the flow of air, though the air flow rate follows a different shape with a rapid increase, and a slight taper off as the lungs fill during the inspire phase, and then a sudden reversal (to negative values) and a tail off of the expired air flow as the lungs empty. The tidal volume (bottom trace) describes a series of saw tooth peaks.

The display on the screen of the patient monitor/controller (Fig. 12) is similar, in the sense that the pressure profile (top trace) mirrors the pressure at the ventilator, and the tidal volume (bottom trace) mirrors the tidal volume at the ventilator. Fig. 12 shows the operation of one of the patient controllers when the flow control valves are open in both patient circuits (i.e. the circuit to which the display of Fig. 12 is attached and the other patient circuit.

It has been found that when both flow control valves (i.e. in both connected patient circuits) are restricted, then the pressure profile changes, as shown in the ventilator display of Fig. 13. The pressure profile no longer follows a square wave pattern, but instead the pressure is seen to build slowly during the inspire phase. When we restrict the valves, we slowdown the build up pressure after the valve. This mean that the pressure after the valve might not reach the pressure that the ventilator is putting in the inspire port. It also means that the peak pressure delivered to the patient will be less than that set in the ventilator.

If the ventilator senses a slow build up of pressure then this may be interpreted as e.g. a disconnected line or leak in the system and an alarm may be triggered. Depending on the ventilator design, the airflow may be adjusted in such an alarm condition (or the airflow may be adjusted without any alarm being provided, leading to unexpected operation). Referring additionally to Fig. 14 it can be seen that the pressure profile builds slowly due to the restriction and no longer follows or approximates a square wave. If the pressure builds so slowly that it never has time to reach the peak pressure that has been set in the ventilator, then this also can trigger the alarm, as the ventilator is set to operate at a peak pressure set by the operator and expects to measure this peak pressure across the ports.

Fig. 15 shows a modification to the Fig. 1 system, in which an open line 86 has been added to connect the inspire line to the expire line. In addition, a pair of non-return valves 88 have been added to the individual patient circuit inspire lines 20, 26.

The open connection 86 has no adverse effect when both patient circuits are unrestricted, as can be seen from Figs. 16 and 17, which are qualitatively the same as Figs. 11 and 12. However, when the flow valves in both patient circuits are restricted, as seen in Figs. 18 and 19, the effect at the ventilator is marked (comparing in particular Fig. 18 where this line has been added with Fig. 13 where there is no connecting line). The ventilator pressure is now once again seen as a square wave and the ventilator considers that the operation is normal. The alarm condition no longer exists and the airflow operates as normal.

The open connection does not allow airflow to bypass the breathing circuits directly from the inspire port to the expire port, because these ports are not open simultaneously in a conventional ventilator. Instead the inspire port opens during the inspire phase and closes during the expire phase, while the expire port opens only during the expire phase and closes during the inspire phase.

Claims

1. A system for use in the ventilation of a patient, the system comprising:

airflow volume sensing means for provide a measurement of the volume of air passing through an air line forming part of a patient breathing circuit when said airflow volume sensing means is in communication said air line;

pressure sensing means for providing a measurement of the pressure within an air line forming part of said patient breathing circuit when said pressure sensing means is in communication with said air line;

a flow control valve which is controllable with a control signal to alter the airflow through an inspiration air line of said patient breathing circuit on which it is mounted;

a user interface enabling a user to input a target volumetric parameter for ventilation of a patient connected to said breathing circuit; and

processing means having inputs connected to said airflow volume sensing means, pressure sensing means and user interface and an output connected to said flow control valve, the processing means being programmed with instructions which are effective to:

receive a measurement from the airflow volume sensing means indicative of the volume of air passing through an air line of the patient breathing circuit;

receive a measurement from the pressure sensing means indicative of the pressure within an air line of the patient breathing circuit;

receive a target volumetric parameter from said user interface;

calculate a control signal which is effective to control the flow control valve to alter the airflow through the inspiration air line of the patient breathing circuit to achieve the target volumetric parameter in the ventilation of the patient to within a predetermined tolerance; and

output said control signal to said flow control valve;

wherein the calculation of a control signal is such as to provide an incremental change to the valve state which causes the airflow to more closely approach the target volumetric parameter, and wherein the processor operates a feedback loop using the

measured volume of air to continue changing the valve state incrementally until the target volumetric parameter is achieved within a predetermined tolerance.

2. The system of claim 1, wherein the airflow volume sensing means and the pressure sensing means are in communication with the same air line of the breathing circuit.

3. The system of any preceding claim, further comprising said breathing circuit.

4. The system of any preceding claim, wherein the breathing circuit comprises said inspiration air line having a proximal end adapted for connection to an inspiration air line of a ventilator, an expiration air line having a proximal end adapted for connection to an expiration air line of a ventilator, and the inspiration and expiration air lines having distal ends that are connected to a common inspire/expire air line to which the patient is connected.

5. The system of claim 4, wherein the inspiration air line of the ventilator and the expiration air line of the ventilator, to which the breathing circuit air lines are connected, support a plurality of breathing circuits.

6. The system of claim 5, wherein the inspiration air line of the ventilator and the expiration air line of the ventilator are connected by an open connection line.

7. The system of any of claims 4-6, wherein the airflow volume sensing means is in communication with the common inspire/expire air line.

8. The system of any of claims 4-7, wherein the pressure sensing means is in communication with the common inspire/expire air line.

9. The system of any preceding claim, wherein the target volumetric parameter is a target tidal volume.

10. The system of any preceding claim, wherein the flow control valve is mounted to a controller body and mechanically coupled to a motor in the controller body.

11. The system of any preceding claim, wherein the calculation of a control signal comprises comparing a measured volume of air delivered to the patient with the target volumetric

parameter to determine a required change in delivered air volume; and determining a control signal that will be effective to alter the airflow sufficiently to achieve the target volumetric parameter within a predetermined tolerance.

12. The system of any preceding claim, wherein the airflow volume sensing means continues to provide measurements to the processor after the adjustment of the flow control valve has terminated, and if a change is detected in the measured airflow volume which exceeds a threshold, a further control signal is calculated and output to the valve to restore the airflow towards the target volumetric parameter.

13. The system of any preceding claim, wherein the system is configured to deactivate the flow control valve a predetermined time after the target volumetric parameter is achieved.