

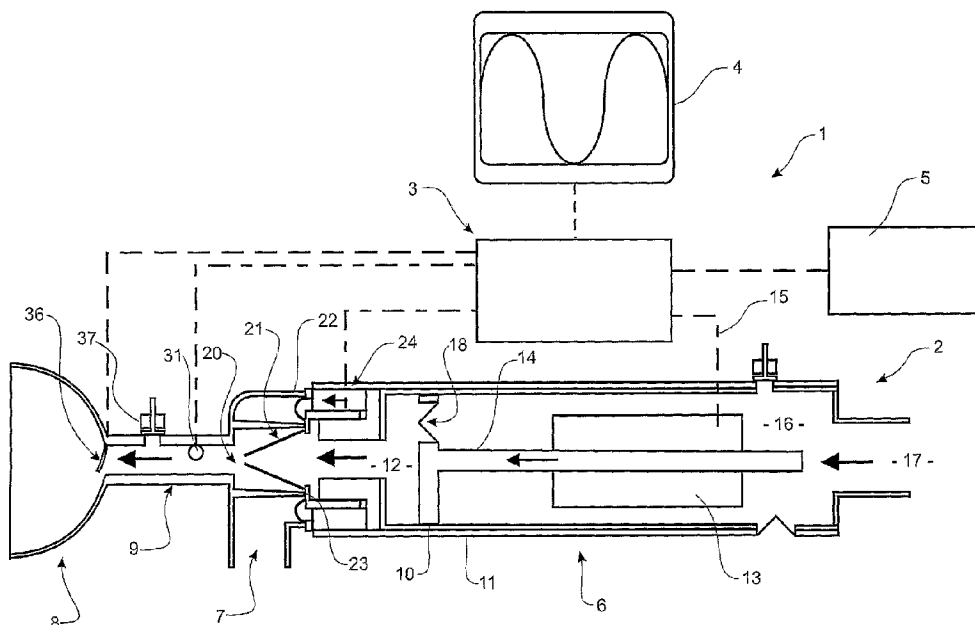


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(72) Inventeurs/Inventors:
KUYPERS, GILBERT JACOBUS, NZ;
MCCULLOCH, RICHARD ANTHONY, NZ
(73) Propriétaires/Owners:
KUYPERS, GILBERT JACOBUS, NZ;
MCCULLOCH, RICHARD ANTHONY, NZ
(74) Agent: SMART & BIGGAR LLP

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(57) Abrégé/Abstract:

The present invention relates to an electrically operable resuscitation device comprising a pump including a rigid cylinder including at least one gas inlet and at least one gas outlet, a piston to travel in said cylinder, and at least one valve, the or each valve configured to allow gas to be displaced into said cylinder through said at least one gas inlet during at least one of a first stroke direction and second stroke direction of said piston in said cylinder, and for allowing gas to be displaced through said at least one gas outlet during an opposite of said at least one of the first stroke direction and second stroke direction of said piston in said cylinder; a motor, selected from one of a stepper motor and feedback motor and stepper motor with feedback and linear motor, operatively connected to said piston to move said piston in said cylinder; a patient interface in ducted fluid connection with said pump to receive gas via said at least one gas outlet and to deliver said gas to said patient.

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(71) Applicants and

(72) Inventors: KUYPERS, Gilbert, Jacobus [NZ/NZ];
66 Whatipu Road, Waitakere, Auckland, 0604 (NZ).
MCCULLOCH, Richard, Anthony [NZ/NZ]; 33 Teal
Crescent, Beachhaven, Auckland, 0626 (NZ).(74) Agents: ADAMS, Matthew, D. et al.; A J Park, 6th Floor
Huddart Parker Building, PO Box 949, Wellington, 6015
(NZ).

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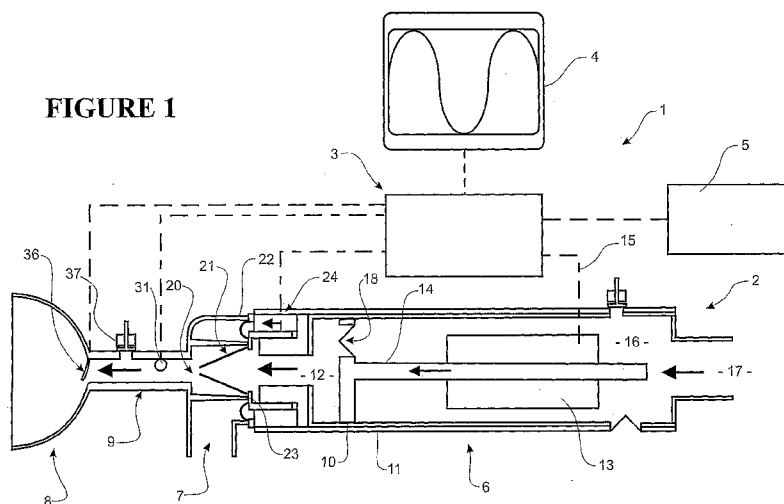
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FIGURE 1



(57) **Abstract:** The present invention relates to an electrically operable resuscitation device comprising a pump including a rigid cylinder including at least one gas inlet and at least one gas outlet, a piston to travel in said cylinder, and at least one valve, the or each valve configured to allow gas to be displaced into said cylinder through said at least one gas inlet during at least one of a first stroke direction and second stroke direction of said piston in said cylinder, and for allowing gas to be displaced through said at least one gas outlet during an opposite of said at least one of the first stroke direction and second stroke direction of said piston in said cylinder; a motor, selected from one of a stepper motor and feedback motor and stepper motor with feedback and linear motor, operatively connected to said piston to move said piston in said cylinder; a patient interface in ducted fluid connection with said pump to receive gas via said at least one gas outlet and to deliver said gas to said patient.

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IMPROVEMENTS TO RESUSCITATORS

FIELD

The present invention relates to improvements to resuscitators.

5

BACKGROUND

Resuscitators that can supply pressurised air or oxygen to a patient are well-known. Examples include bag or bellows type resuscitators and pump-like resuscitators and pressure-limited resuscitators. However, there are limitations in certain resuscitators.

10 For example, there is a risk of overinflating a patient's lungs by delivering a volume of air that is greater than desirable. There is also a risk the pressure of the air or oxygen delivered may be at undesirably high levels. Such undesirable characteristics of the air being delivered to the patient can have adverse affects on the patient. If a patient's airway passage is or becomes blocked and air is delivered by the known devices then undesirable
15 pressures may be reached. Further such increased pressure may cause sudden dislodgement of the blockage and may lead to serious consequences for the patient. Known devices do not readily lend themselves to predetermination of airway pressures and volumes to which the lungs of the patient are being subjected by the operator of the device. The operator may feel a resistance when they are applying a force to the device
20 to deliver air or oxygen. The operator may increase the force to overcome the blockage. However, when the blockage clears there is a risk of over-pressurising or overfilling the lungs, thereby causing barotrauma or volutrauma or both.

Eliminating human operation of a resuscitator for delivering air to a patient is advantageous. By eliminating the operator the risk of delivering too great a volume of air
25 into the patient and overinflating the patient's lungs, causing volutrauma, is reduced. By eliminating the operator the risk of delivering too great a pressure of air into the patient and therefore over pressurising the patient's lungs, causing barotrauma, is reduced. In

resuscitation it is desirable to start at the lowest risk procedure to the patient. The lowest risk procedure is volume resuscitation rather than pressure-limited resuscitation or manual-controlled resuscitation.

5 In known devices there is the risk that an operator may displace too great a volume of air into the patient and therefore overinflate the patient's lungs. There is also the risk of applying a pressure that is too great for the patient's lungs. For example, when the airway passage is blocked, prior art systems do not signal that the operator should stop and remove the blockage.

10 It would therefore be an advantage to provide improvements to resuscitators that addresses or goes at least somewhat towards addressing at least some of the abovementioned disadvantages and/or addresses at least some of the abovementioned advantages or that will at least provide the public or industry or both with a useful choice.

15 SUMMARY

The disclosure describes an electrically operable resuscitation device for resuscitating a non-breathing patient. The device includes a pump. The pump includes a rigid cylinder including at least one gas inlet and at least one gas outlet, a reciprocating piston movable to travel in the cylinder, in a first stroke direction and an opposed second stroke direction and at least one valve, the or each valve configured to allow a gas to be
20 displaced into the cylinder through the at least one gas inlet during at least one of a first stroke direction and/or a second stroke direction of the piston in the cylinder, and for allowing the gas to be displaced through the at least one gas outlet to a patient interface, during an opposite of the at least one of the first stroke direction and/or second stroke
25 direction of the piston in the cylinder. The electrically operable resuscitation device also includes an accurate velocity and position controllable motor, selected from one of a stepper motor, servo motor and linear motor, operatively connected to the piston to

move and position the piston in the cylinder, and a motor controller configured for controlling the motor to control the position and velocity of the piston in the cylinder to provide a pre-set tidal volume and pre-set respiratory rate of the gas for delivery from the cylinder to the patient interface via the at least one outlet at a pressure to inflate the lungs
5 of the patient but not exceeding a pre-set maximum pressure. The motor controller receives gas pressure data from a gas pressure sensor that measures patient interface gas pressure. The motor controller can reduce the velocity of the piston should said patient interface gas pressure exceed the pre-set maximum pressure. The patient interface is in ducted fluid connection with the pump to receive gas via said at least one gas outlet and
10 to deliver said gas to said patient.. One of the ducted fluid connection and the patient interface includes a pressure relief valve to allow pressure reduction of gas in the patient interface to occur.

The patient interface may be a face mask or an endotracheal tube or a naso-tube.

The motor controller may include a feedback system.

15 The motor may be a linear stepper motor and may be, in part, integrally formed with the piston.

The motor may be indirectly connected with the piston, via a linkage.

The piston may include a connection rod with which the motor is in operative connection.

20 The motor and cylinder may be connected together.

Intermediate of the patient interface and the at least one outlet of the cylinder and in the ducted fluid connection therewith may be an outlet gas flow controller.

The outlet gas flow controller may include a one way valve that allows gas to be displaced from the outlet of the cylinder towards the patient interface and that prevents
25 gas from flowing through the one way valve in the opposite direction.

The outlet gas flow controller may include an exhaust port via which gas can exhaust to relieve pressure at the patient interface.

The exhaust port may assume a closed condition when the piston is moving in a direction to displace gas towards the patient interface and may assume an open condition when the piston is moving in the opposite direction to allow gas due to exhalation of or by the patient to pass through the exhaust port.

- 5 The exhaust port may include at least one opening closable by a valve, the valve mounted on or to or in operative association with an actuator to actively control the movement of the valve relative to the opening.

10 The exhaust port may include at least one opening closable by a valve, the valve mounted for movement relative to the opening in a passive manner under the influence of pressure differential in the gas from the outlet gas flow controller and/or between the outlet gas flow controller and ambient gas pressure.

The exhaust port may be moved to a closed condition when gas is to be displaced into the patient and to an open condition to allow gas due to exhalation of or by the patient to pass through the exhaust port.

- 15 The exhaust port may include at least one opening closable by a valve, the valve mounted on or to or in operative association with an actuator to actively control the movement of the valve relative the opening.

20 The exhaust port may include at least one opening closable by a valve, the valve mounted for movement relative the opening in a passive manner under the influence of pressure differential in the gas from the outlet gas flow controller and/or between the outlet gas flow controller and ambient gas pressure.

When the exhaust port is in the open condition, the motor may stop or reduce the velocity of the piston.

- 25 The motor controller may be coupled to the motor to control at least the velocity and position of the motor.

The motor controller may be coupled to the motor to control at least the velocity and position of the motor. The motor controller may also be coupled to the actuator to move the actuator in a manner in synchronicity with control of the motor.

A source of electricity may be connected to the motor.

5 The source of electricity may be connected to the motor via the motor controller.

Via an interface, the motor controller may be instructed to operate the device.

The interface may allow for patient-related information to be entered into the motor controller, the information including at least one selected from a patient's age and weight.

10 The motor controller may receive data from other parts of the device, including at least tidal volume flow rate at the patient interface.

A sensor may be positioned at or proximate the patient interface in the flow path to and from the patient to sense at least one of the tidal volume flow rate, breath rate and exhale breath temperature.

15 The sensor may provide information to at least one of the motor controller and a recorder to record the information and a display device to display the information.

A display may be provided to display operating conditions of the device.

The operating conditions displayed may include inlet gas pressure, patient interface gas pressure, tidal volume at the patient interface, piston oscillation rate, piston stroke
20 length, battery power, duration of operation, each sensed by appropriate sensors of the device.

The operating conditions may be recorded and stored for subsequent use.

Fluid connection between the outlet of the cylinder and the patient interface may be defined in part by a flexible conduit.

25 Fluid connection between the outlet of the cylinder and the patient interface may be defined in part by a flexible conduit and the outlet gas flow controller may be located more proximate the patient interface than the cylinder.

The ducted fluid connection and/or the patient interface may include a pressure relief valve to allow pressure reduction of gas in the patient interface.

The pressure relief valve may become operative to relieve pressure when the pressure in the patient interface reaches a certain threshold.

5 The pump may include an inlet volute.

The inlet volute may include an opening to allow pressure relief of the inlet volute to occur.

The inlet volute may include a one way valve to allow pressure relief to occur into the inlet volute.

10 The inlet volute may include a pressure relief valve to allow pressure relief to occur out of the inlet volute.

The inlet of the cylinder may be in fluid connection with a supplementary gas supply to allow gas from the supplementary gas supply to pass into the cylinder for subsequent delivery to the patient, the gas is oxygen.

15 The cylinder may be split into two zones by the piston, a first zone being on one side of the piston and a second zone being on the other side of the piston and the gas inlet(s) may be provided to allow gas into the first zone and the gas outlet(s) may be provided to allow gas out of the second zone, wherein a one way pump valve may be provided to allow gas to transfer from the first zone to the second zone and that restricts
20 flow in the opposite direction.

The one way pump valve may be carried by the piston to operate on a passage through the piston.

The gas in the first zone, may become pressurised sufficiently to, upon the movement of the piston in its first stroke direction, allow some of the gas to displace
25 through the one way pump valve into the second zone.

The one way pump valve may be a passive one way valve that moves between an open and closed condition dependent on pressure differential across the one way pump valve.

5 A one way valve may be provided to allow gas to be drawn into the first zone upon the movement of the piston in its second stroke direction and that may restrict flow of gas in the opposite direction through the inlet one way valve upon the movement of the piston in the first stroke direction.

10 The inlet one way valve may be a passive one way valve that moves between an open and closed condition dependent on pressure differential across the inlet one way valve.

One or each of the one way valves mentioned may be valves under active control to be in the open and closed conditions in correspondence with the direction of movement of the piston.

15 The cylinder and piston stroke length may be of a size to allow a sufficient volume of gas to be displaced from the cylinder through the gas outlet(s) during the second direction of movement of the piston to deliver a desired volume and flow rate of gas for a single inhalation to a neonatal patient for resuscitation purposes.

20 The cylinder may be split into two zones by the piston, a first zone being on one side of the piston and a second zone being on the other side of the piston, and the pump may be a double acting pump. The pump may include a first one way valve to allow gas to enter into the first zone via a first gas inlet of the cylinder during movement of the piston in the second stroke direction, and restrict gas flow in the opposite direction through the first gas inlet during movement of the piston in the first stroke direction. The pump may include a second one way valve to allow gas to exit the first zone via a
25 first gas outlet of the cylinder during movement of the piston in its first stroke direction, and restrict gas flow in the opposite direction through the first gas outlet during movement of the piston in the second stroke direction. The pump may include a third

one way valve to allow gas to enter into the second zone via a second gas inlet of the cylinder during movement of the piston in its first stroke direction, and restrict gas flow in the opposite direction through the second gas inlet during movement of the piston in the second stroke direction. The pump may include a fourth one way valve to allow gas
5 to exit the second zone via a second gas outlet of the cylinder during movement of the piston in its second stroke direction, and restrict gas flow in the opposite direction through the second gas outlet during movement of the piston in the first stroke direction. The pump may include a manifold or ducting to duct gas from the first and second outlets to the patient interface.

10 Each of at least one of the first to fourth one way valves may be either actively controlling or passive in moving between their open and closed conditions.

The cylinder and piston stroke length may be of a size, and the motor may be able to move and be controlled, to allow a sufficient volume of gas to be displaced from the cylinder through the gas outlet(s) during multiple oscillations of the piston to deliver a
15 desired volume and flow rate of gas for a single inhalation to a patient for resuscitation purposes or ventilation purposes or both.

The pump may be a double acting pump and the motor may be of sufficient speed to, in multiple strokes of the piston, deliver a single tidal volume of gas for a single inhalation to a patient for resuscitation purposes.

20 The device may be portable.

At least one of the pump and patient interface and motor may be portable and unitary and able to be held in one hand by a user.

At least one of the motor controller and power supply and display may also be portable and unitary and able to be held in one hand by a user.

25 Communication to and from the motor controller may be wireless.

As used herein the term “and/or” means “and” or “or”, or both.

As used herein “(s)” following a noun means the plural and/or singular forms of the noun.

The term “comprising” as used in this specification means “consisting at least in part of”. When interpreting statements in this specification which include that term, the
5 features, prefaced by that term in each statement, all need to be present but other features can also be present. Related terms such as “comprise” and “comprised” are to be interpreted in the same manner.

It is intended that reference to a range of numbers disclosed herein (for example, 1 to 10) also incorporates reference to all rational numbers within that range (for example,
10 1, 1.1, 2, 3, 3.9, 4, 5, 6, 6.5, 7, 8, 9 and 10) and also any range of rational numbers within that range (for example, 2 to 8, 1.5 to 5.5 and 3.1 to 4.7).

BRIEF DESCRIPTION OF THE DRAWINGS

An embodiment of the present invention will now be described with reference to the accompanying drawings in which,

Figure 1 is a schematic view of a resuscitator and is shown to describe it being in
5 the inhalation phase,

Figure 2 is a schematic view of a resuscitator and is shown to describe it in the exhalation phase,

Figure 3 shows the resuscitator in a C-pap mode wherein a supplementary gas is supplied to the resuscitator,

10 Figure 4 is a schematic view of a variation of the resuscitator shown in Figures 1-3, also in a C-pap mode and wherein a flexible conduit extends between parts of the resuscitator to provide to some extent, independence of movement of the face mask relative some of the other components of the resuscitator,

Figure 5 is a schematic view of a variation of the resuscitator shown in an
15 exhalation phase with reference to Figures 1-4,

Figure 6 is a schematic view of the resuscitator of Figure 5 shown in operation, moving in an inhalation phase,

Figure 7 is a schematic view of the resuscitator of Figure 5 shown in an inhalation phase,

20 Figure 8 shows the resuscitator of Figure 5 in an inhalation mode and wherein an oxygen supply is provided to allow the operation of the resuscitator in a C-pap mode,

Figure 9 illustrates the resuscitator of Figure 5, wherein a flexible conduit is provided intermediate of certain parts of the resuscitator to provide, to a certain extent, independence of movement of the face mask relative to some of the other components
25 of the resuscitator,

Figure 10 is a sectional view of the face mask shown to include a flow and tidal volume sensor wherein the gas flow is shown in an inhalation direction, and

Figure 11 is a variation to that shown in Figure 10 wherein it is shown in an exhalation condition.

DETAILED DESCRIPTION

5 With reference to Figure 1, there is shown a resuscitator 1. The resuscitator 1 consists of a resuscitator body 2. It may also include associated hardware such as a controller 3, a display 4 and power supply 5 connected to each other and/or the resuscitator body 2.

 The resuscitator body 2 consists of a pump unit 6, a flow control unit 7 and a
10 patient interface 8.

Broadly speaking the pump unit 6 includes a pump that will deliver air to the flow control unit 7. The flow control unit 7 will control the flow of gas between the patient interface and the flow control unit 7 in conjunction with or without the pump unit 6 depending on the status of operation of the resuscitator 1.

5 In the most preferred form the pump unit 6 and flow control unit 7 are part of the same body as for example shown in Figure 1. A conduit 9 extending between the flow control unit 7 and the patient interface 8 facilitates the flow of gas between the interface and the flow control unit 7.

In the examples shown in the accompanying drawings, the interface is
10 preferably a face mask. However, alternatively, the interface may be an endotracheal tube or naso-tube that extends partly into the patient's airway.

The pump unit 6 consists of a piston 10 that locates in a cylinder 11 to displace gas through an outlet 12 of the cylinder and to the flow control unit 7. The piston and cylinder are a complementary shape and make sure that a sufficiently
15 tight seal exists between the piston and cylinder for the purposes of positively displacing gas through the outlet 12.

The cylinder 11 may be cylindrical in cross-section or may be any other shape in cross-section.

The piston is actuated via its connection rod 14, by a motor 13. In the most
20 preferred form the motor is an actuator preferably a linear motor. In an alternative form the actuator may be a servomotor, stepper motor or similar device. The connection rod 14 may be the reactor to operate in conjunction with the motor 13 for the purposes of displacing the piston 10 in the cylinder 11 in an oscillating manner. Alternatively the connection rod 14 may carry a reactor plate or surface in
25 conjunction with the motor 13. In the figures, the connection rod 14 is acted upon directly by the motor 13. The reactor plate may also be incorporated as part of the piston to be integral therewith. No connection rod may then be provided. Alternative mechanisms may be employed where such action is indirect via a linkage mechanism. Such linkage may include a rotor and crank and connection rod.

30 In the most preferred form the motor 13 is a linear motor or any other motor that has accurate and rapid positional control capabilities. The controller 3 via a

connection 15 with the motor 13 will operate the motor in a manner so that the desired flow rate, volume and pressures are being delivered through the outlet opening 12.

The flow control unit 7 consists of an inlet that may coincide with or define the outlet 12 of the pump unit. The flow control unit includes an outlet 20 and a passage extending between the inlet and outlet. The passage allows the transmission of gas being displaced from the pump unit 6 to the outlet 20. The outlet 20, preferably via a conduit 9, allows the delivery of this gas to the patient interface 8.

Intermediate of the inlet and outlet of the flow control unit is a one-way valve 21. The one-way valve allows for gas to travel from the inlet towards the outlet via the passage but prevents flow of gas from the outlet to the inlet.

The valve 21 may be mounted in a fixed manner to the housing 22 of the flow control unit 7 or alternatively and as shown in Figure 1, may be mounted to a movable mount 23 to move the valve mount.

In the preferred form the movable mount 23 forms part of a voice coil actuator 24 that can displace the movable mount 23 between two positions. The first position is as shown in Figure 1 and the second position is as shown in Figure 2. This creates a valve referred to herein as the exhalation or exhaust valve. In Figure 1 the moveable mount 23 is located in a position so that at least on the outlet 20 side of the valve 21, no other opening to the passage of the flow control unit 7 is created. All gas that is displaced by the pump unit 6 is captured for flow towards the patient interface 8.

In the second position of the mount as shown in Figure 2, an opening 27 is created between part of the housing 22 of the flow control unit 7 and the moveable mount 23. In this position gas can escape from that part of the passage of the flow control unit 7 intermediate of the valve 21 and the flow control unit outlet 20. In this position of the moveable mount 23, gas that may be exhaled from the patient can travel through the opening 27 for example towards the surrounding atmosphere through opening 29. The opening 27 may be an annular opening that is created between a substantially disk shaped mount portion and a circular shaped seat 30 of the housing 22 of the flow control unit 7.

As a consequence of a pressure differential between the patient side and pump side of the one-way valve 21, the one-way valve 21 will assume a closed position as shown in Figure 2 during the exhalation operating phase of the resuscitator. This negative pressure differential may be established by one or more of a combination of the patient breathing out, the retraction of the piston in its cylinder away from the outlet 12 and the movement of the voice coil actuator 24 in a direction establishing the opening 27. In the most preferred form it is the voice coil actuator 24 that primarily establishes the open and closed condition between the opening 27 and that part of the passage of the flow control unit 7 between the flow control unit outlet 20 and the one-way valve 21. However where a patient is breathing on their own and is able to create sufficient pressure, movement of the moveable mount 23 of the valve 21 to create the opening 27 may occur without assistance of the voice coil actuator. It will be appreciated that other actuators may be used. Actuators that move other components other than the valve 21 to create such an opening for exhaled gases to be discharged may be used.

In the exhalation operating phase of the resuscitator, the piston is withdrawn by the motor 13 preferably back to a predetermined start position. The piston retracts once it has travelled its full desired stroke during the inhalation operating phase and has delivered the required tidal volume or has timed out while holding the maximum airway pressure during the inhalation period. Control of the position or movement of the voice coil actuator 24 can occur by the controller 3 and is preferably synchronised with movement of the piston.

In a "PEEP" mode (positive end expiratory pressure) parameters can be preset by using the controller or the display panel PEEP so that pressure is controlled by the voice coil actuator. The voice coil actuator 24 will exert a closing force to the exhalation valve equal to the predetermined PEEP pressure. The PEEP pressure is measured by the airway pressure sensor 31. The controller 3 will activate the voice coil actuator 24 when the expiratory airway pressure has reached the predetermined level.

In operation of the resuscitator shown in Figures 1 and 2, the tidal volume delivered to the patient can be preset by the controller 3 or the display panel 4. The

tidal volume is controlled by the stroke length of the piston 10. Tidal volume is delivered to the patient on the compression stroke of the piston 10 and exhalation for the patient is facilitated during the retraction stroke of the piston 10.

Accordingly one inhale and exhale of the patient occurs during a movement of the piston 10 from one starting point to its opposite end travel and back to the starting point. For a given cylinder size, the longer the stroke of the piston, the greater the tidal volume.

The controller 3 instructs the motor 13 to move the piston 10 a predetermined distance at a predetermined velocity.

Feedback from the airway pressure sensor 31 and a flow and tidal volume sensor 36 can provide further control. These sensors may vary normal operation of the piston 10 and/or voice coil actuator 24 from conditions of operation predetermined by an operator and instructed to the device via the display panel 4 and/or controller 3. The stroke length and position of the piston 10 may in addition be monitored by a sensor (a piston position sensor) of or associated with the motor 13 and/or piston 10. The operation of the resuscitator will control the breath rate and inhalation/exhalation ratio. This can be preset by using the controller and/or display panel and may be controlled at least in part by a timer of the controller. Patient dependent parameters may also control operation. For example, input information into the controller 3 may include a patient's weight and age.

In a situation where the airway pressure sensor 31 senses that the maximum predetermined airway pressure has been reached, the controller 3 can instruct the motor 13 to slow or stop. This can result in a maintaining of the maximum predetermined airway pressure for the duration of the inhalation time period. In the event of an overpressure or system failure, a safety valve 37 may be actuated to open and relieve pressure on the patient airway. The safety valve 37 may be a passive valve that has predetermined operating conditions. Alternatively it may be a safety valve connected with the controller 3 and controlled by the controller for operation. Alternative to the safety valve 37, the airway pressure sensor 31 and/or flow and tidal volume sensor 36 may communicate with the controller 3 to direct

movement of the voice coil actuator in instances where undesirable conditions are being sensed to thereby relieve pressure and/or flow by exhausting gas through the opening 29.

This first form of resuscitator described as well as the form yet to be described
5 allows for data from the airway pressure sensor 31, the piston position sensor, the flow and tidal volume sensor 36 and from a timer to be used to record operating data and performance. A graphical display on the display panel 4 can also be generated. The graphical display can be used by the operator to monitor performance and determine if leakage, blockage or further adjustments are required
10 to the resuscitator. The graph and/or related data can be stored to assist in the setup of other life support systems and for clinical analysis. Such statistical information may offer significant benefits to future situations.

The electrical connection 15 will ensure that the controller 3 can appropriately control the linear motor to thereby control the position and movement of the
15 piston. The cylinder 11 has an inlet volute 16 that includes a primary inlet 17. It is through the primary inlet that ambient air may be drawing into the inlet volute as the piston displaces inside the cylinder towards the outlet 12. This direction of travel is shown in Figure 1. The piston 10 carries a one-way valve 18 that operates to be in a closed condition when the piston is travelling towards the outlet 12. This
20 will result in a drawing of ambient air into the inlet volute 16. When the piston 10 travels in the opposite direction being an exhalation direction of the resuscitator, the one-way valve 18 can open to allow for air in the inlet volute 16 to displace into the region between the piston 10 and the outlet 12 as for example shown in Figure 2. The primary inlet 17 may include a one-way valve to assist such displacement
25 through the opening created by the one-way valve through the piston by preventing air in the inlet volute 16 from displacing back out through the primary inlet 17. The gas that has displaced into the space between the piston 10 and the outlet opening 12 can then on the return stroke during the inhalation phase of operation be displaced at least in part through the outlet opening 12 and to the flow control unit
30 7.

The resuscitator may (for example shown in Figure 3) operate in a supplementary oxygen and C-pap mode. A supplementary oxygen reservoir 40 (that may or may not be connected to supplementary supply via the inlet 41) can be engaged to the primary inlet 17 of the pump unit 6. Rather than drawing ambient
5 air into the pump unit, the oxygen or other gas or gas mixture can be supplied to a patient via the resuscitator. This will allow the operator to control the delivery of an air/oxygen mixture by the use of for example an external blender. Supplementary gas such as oxygen may be delivered via the primary inlet 17 to the pump unit, under pressure. In the event of a failure or the gas supply exceeding the capabilities
10 of the resuscitator, then a safety valve 42 may open to exhaust gas from at least part of the pump unit 6. A pressure sensor may be located in an appropriate location for these purposes. If a failure occurs with the supplementary gas supply or the primary inlet 17 becomes blocked then a safety valve 43 may open to allow for ambient air to be drawn into the pump unit 6 allowing ongoing operation of the resuscitator
15 despite issues with the supply of supplementary gas.

In a C-pap mode operational conditions can be specified and preset by using the controller and/or display panel. Where the delivery rate and pressure to the supplementary gas reservoir 40 is set at an appropriate flow level, the ventilator can operate in the C-pap mode. The motor 13 will stop operation and the flow from
20 the supplementary oxygen reservoir 40 will pass through the one-way valve 18 through the one-way valve 21 to the patient interface 8. The airway pressure sensor 31 will determine the patient's airway pressure. When the predetermined C-pap pressure has been reached the voice coil actuator 24 will exert a closing force to the exhalation valve to the predetermined C-pap pressure.

25 With reference to Figure 4 there is shown a variation to the resuscitator described with reference to Figures 1-3 wherein a flexible conduit 56 is provided to extend between the pump unit 6 and the flow control unit 7. The flexible conduit 56 may be fitted between the pump unit and the flow control unit to allow for delivery for gas displaced by the piston 10 towards the patient interface 8. Having
30 the flow control unit 7 and airway pressure sensors and tidal volume sensors as well as the safety valve 37 close to the patient's airway, ensures a more accurate tidal

volume and pressure delivery. Also the controller can make adjustments for the compliance in the patient mask. Also possible but less advantageous is to provide a conduit 9 that is of a desired length to allow for more distal location between the patient interface 8 and the pump unit 6. However this has the disadvantage of dead space between the features of the flow control unit 7 and the patient interface 8.

The resuscitator of Figures 1-4, wherein the piston is single acting, lends itself particularly to resuscitation and ventilation of neonatal patients. A manageable sized pump unit can be provided wherein in one stroke of the piston a sufficient tidal volume of air can be delivered to a neonatal patient for inhalation. It is desirable for the unit to be relatively portable and therefore size can be a design constraint. However where size is not an issue, the pump unit 6 can be scaled up so that single compression stroke of the piston can deliver a sufficient tidal volume of gas to larger patients. However this will increase at least the size of the pump unit 6 making it less convenient for portability purposes.

An alternative configuration of resuscitator may be utilised where size can be smaller. This resuscitator is shown for example in Figure 5. The resuscitator 101 includes a patient interface 108, flow control unit 107 and related components that are preferably the same as those described with reference to the resuscitator of Figures 1-4.

This alternative form of resuscitator also includes a pump unit 106. The pump unit 106 varies to the pump unit 6 described with reference to Figures 1-4. There is provided a motor 113 such as a linear motor or servo motor controlled by a controller 103 that may be engaged with a display panel 104. The linear motor operates a piston 110 via a connection such as a connection rod 114 that operates in a cylinder 111. The pump unit 106 includes an inlet volute 116. The inlet volute via a primary inlet 117 can draw air or supplementary gas supply therethrough as a result of the action of the piston and into the inlet volute 116.

The cylinder includes two openings capable of being in communication with the inlet volute 116. A first opening 160 is provided on the extension side of the piston 110. A second opening 161 is provided on the retraction side of the piston 110. The opening 160 is closable by a one-way valve 162. The opening 161 is

closable by a one-way valve 163. The one-way valve 162 is able to assume an opening condition during the retraction stroke of the piston and is in a closed condition during the extension stroke of the piston. The one-way valve 163 is able to assume an open position during the extension stroke of the piston and is in a closed condition when the piston is retracting. On the extension side of the piston 110 is an outlet opening 164 of the cylinder 111. The outlet opening is closable by a one-way valve 165. The one-way valve 165 is in a closed condition during the retraction stroke of the piston and is able to assume an open condition during the extension stroke of the piston. The one-way valve 165 hence essentially works in an opposite mode to the one-way valve 162 to the cylinder. The outlet opening 164 is able to create a fluid connection of that part of the cylinder on the compression side of the piston with an outlet volute 166. The outlet volute 166 includes an outlet opening 112 through which gas displaced by the piston can pass to the flow control unit 7. The outlet volute 166 is separated from the inlet volute 116. The housing of the pump unit 106 may include both the inlet volute 116 and outlet volute 166 and partitions 167 and the cylinder 111 may separate the volutes. On the retraction side of the piston 110 the cylinder includes an opening 168 to the outlet volute 166. The opening 168 includes a one-way valve 169. The one-way valve is positioned so that during the retraction stroke of the piston, gas can displace on the retraction side of the cylinder through the one-way valve 169 into the outlet volute 166. The one-way valve 169 will assume a closed condition during the extension stroke of the piston 110.

In operation during the extension stroke of the piston as shown in Figure 6, the one way valve 163 opens allowing for air to be drawn into the retraction side of the cylinder. Air on the extension side of the piston during the extension stroke can be displaced through the one-way valve 165 to be delivered into the outlet volute. One-way valve 169 will be closed thereby only offering one outlet to the outlet volute 166 being the outlet 112. During the extension stroke of the piston the retraction side of the cylinder is charged with gas being drawn through the one-way valve 163. When the piston travels in its retraction stroke as shown in Figure 7, gas that has been drawn into the retraction side of the cylinder may then be displaced

through the one-way valve 169 into the outlet volute 166. The one-way valve 163 will close during the retraction stroke thereby creating only one outlet from the cylinder on its retraction side, namely the opening to discharge the gas into the outlet volute 166. During the retraction stroke the one-way valve 165 is closed
5 thereby offering only one outlet for gas being delivered into the outlet volute, namely being the outlet opening 112. During the retraction stroke the extension side of the cylinder is charged with gas from the inlet volute 116 via the one-way valve 162 that is in that condition opened. As can be seen the pump unit 106 hence operates in a double acting manner. Both during the extension and retraction stroke
10 of the piston gas is displaced towards the opening 112 for delivery towards the patient. With the use of a linear motor or servo motor having high frequency capabilities and accurate and immediate start and stop timing, a high frequency operating piston can deliver gas to the patient in effectively a continuous manner during both the retraction and extension strokes. Each tidal volume delivered to the
15 patient may involve a high number of strokes of the piston. This allows for a compact and preferably portable unit to be provided. Upon exhalation of the patient the flow control unit 107 may be operated to open the exhaust valve to allow for exhalation to occur may coincide with the linear motor stopping operation. Alternatively the linear motor may continue oscillating the piston but
20 where a waste valve may be opened to discharge displaced air from the piston from reaching the flow control valve. Alternatively such wasting may occur via the exhaust valve of the flow control.

With reference to Figure 8 the resuscitator described with reference to Figures 5-7 is also capable of operating in a supplementary gas and/or C-pap mode. This is
25 shown for example in Figure 8. Furthermore an extension conduit 156 may be utilised as shown in Figure 9.

The number of oscillations that the piston may run through can be predetermined. The oscillations determine the tidal volume that is delivered to the patient. An operator may interact with the control unit and/or display to set
30 parameters of operation of the resuscitator. Like the resuscitator described with reference to Figures 1-4 stroke length and position of the piston as well as airway

pressures and tidal volume flow and volume sensing may occur and be recorded and displayed.

The airway pressure may be monitored by a pressure sensor. When the pressure sensor senses that the maximum predetermined airway pressure has been reached the controller then instructs the linear motor to stop or slow to maintain the maximum predetermined airway pressure for the duration of the inhalation period. Alternatively the controller may instruct the linear motor to stop to reduce pressure. In the event of any over pressure or system failure a safety valve like that described with reference to Figures 1-4 may open.

The voice coil actuator may be preloaded so that the exhaust port tends to an open biased condition allowing external air to enter the patient airway.

The resuscitator of Figures 5-9 may also operate in a PEEP mode as previously described. In the C-pap mode of operation all one-way valves to the cylinder are opened. This allows for direct transfer of gas from the inlet volute 116 to the outlet volute 166 and to the patient. Pressure sensors and relief valves may be included for failsafe purposes.

With reference to the resuscitators in Figures 1-9, parts of the resuscitator may be disposable. In particular those parts of the resuscitator that have been exposed to exhaled breath or air from a patient may be disposable. They may be manufactured and assembled in a way to facilitate their disposable use. For example the patient interface 8, the flow control unit 7 and one way valve 21 and/or the voice coil actuator 24, movable mouth 23 and housing 22 may all be disengageable from the pump unit 6 and be disposed after use. Circuits to allow for a quick connection of the controller 3 to a replacement assembly of such parts may be provided through simple plug/socket arrangement(s). A single plug/socket may be provided. This may automatically become coupled upon the engagement of the disposable components with the pump unit 6.

With reference to Figures 10 and 11 there is shown more detail in respect of the tidal volume and flow sensor. In Figure 10 there is shown the patient interface 208 wherein the flow and tidal volume sensor 236 is shown during the inhalation phase of operation. It is connected to the controller 203 via a connection 283.

With reference to Figure 11, the sensor 236 is shown in the exhalation phase. The sensor 236 is of a kind that displaces dependent on air flow past it. Such may not be ideal for accurate sensing due to inertial mass of the sensor.

An alternative form of a sensor is one that has no inertial mass delay characteristics. An alternative form of sensor that may be used may be a gas flow meter that measure flow thermally. An example of such a flow meter is one manufactured by Sensirion.com such as their digital gas flow sensor ASF1400/ASF/1430. It may be one that is made in accordance to that described in US6813944. Such a flow sensor has a high response rate, given that it has unlike the sensor of Figure 10, it has no mass to be displaced by the flow. A fast response can be beneficial. Such sensors may commonly be referred to as a hot wire flow sensor or thermal mass flow meters. The sensor or an alternative sensor may also measure the temperature of the exhaled breath. With an appropriate sensor where the response rate is very quick (a matter of, for example one tenths of a second) it is possible during the exhale of a patient to measure the patient's core temperature. This information may also be collected and/or displayed or otherwise used by the resuscitator.

The invention may offer the advantages of being portable, hand held (including being able to be held by one hand in order to hold the patient interface in the appropriate condition) and self contained by virtue of including its own power source (such as a 12 v power supply).

The device may have programmable profiles fixed and/or customised to suit patients, clinicians and operators requirements.

A heart rate monitoring facility may also be incorporated with the device, wherein heart rate can be accounted for in the control of the device and be displayed by the device.

The display can assist the operator in evaluating resuscitation of the patient. The performance, operating parameters and status of the features of the device are able to be recorded. This can assist in statistical analysis and to gather information for set-up of other devices.

The patient as herein defined may a mammal such a person or animal.

EMBODIMENTS IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. An electrically operable resuscitation device for resuscitating a non-breathing patient, comprising:

5 a) a pump including:

a rigid cylinder including at least one gas inlet and at least one gas outlet; and

a reciprocating piston movable to travel in said cylinder, in a first stroke direction and an opposed second stroke direction; and

10 at least one valve, the or each valve configured to allow a gas to be displaced into said cylinder through said at least one gas inlet during at least one of a first stroke direction and/or a second stroke direction of said piston in said cylinder, and for allowing the gas to be displaced through said at least one gas outlet to a patient interface, during an opposite of said at least one of the first stroke direction and/or second stroke direction of said piston in said cylinder;

15

b) an accurate velocity and position controllable motor, selected from one of a stepper motor, servo motor and linear motor, operatively connected to said piston to move and position said piston in said cylinder;

20 c) a motor controller configured for controlling the motor to control the position and velocity of the piston in the cylinder, to provide a pre-set tidal volume and pre-set respiratory rate of the gas for delivery from the cylinder to the patient interface via the at least one outlet at a pressure to inflate the lungs of the patient but not exceeding a pre-set maximum pressure, wherein the motor controller receives gas pressure data from a gas pressure sensor that measures patient interface gas pressure, wherein the motor controller can reduce the velocity of the piston should said patient interface gas pressure exceed the pre-set maximum pressure; and

25

- d) the patient interface is in ducted fluid connection with the pump to receive gas via said at least one gas outlet and to deliver said gas to said patient wherein one of the ducted fluid connection and the patient interface includes a pressure relief valve to allow pressure reduction of gas in said patient interface to occur.
- 5 2. The device as claimed in claim 1 wherein said patient interface is a face mask or an endotracheal tube or a naso-tube.
3. The device as claimed in claim 1 or 2 wherein the motor controller comprises a feedback system.
4. The device as claimed in claim 1 or 2 wherein said motor is a linear stepper motor and is
10 in part integrally formed with said piston.
5. The device as claimed in any one of claims 1 to 4 wherein the motor is indirectly connected with said piston, via a linkage.
6. The device as claimed in any one of claims 1 to 5 wherein said piston includes a connection rod with which said motor is in operative connection.
- 15 7. The device as claimed in any one of claims 1 to 6 wherein the motor and cylinder are connected together.
8. The device as claimed in any one of claims 1 to 7 wherein intermediate of the patient interface and the at least one outlet of the cylinder and in said ducted fluid connection therewith is an outlet gas flow controller.
- 20 9. The device as claimed in claim 8 wherein the outlet gas flow controller includes a one way valve that allows gas to be displaced from the outlet of the cylinder towards the patient interface and that prevents gas from flowing through the one way valve in the opposite direction.
10. The device as claimed in claim 8 or 9 wherein the outlet gas flow controller includes an
25 exhaust port via which gas can exhaust to relieve pressure at the patient interface.

11. The device as claimed in claim **10** wherein said exhaust port assumes a closed condition when the piston is moving in a direction to displace gas towards the patient interface and assumes an open condition when the piston is moving in the opposite direction to allow gas due to exhalation of or by the patient to pass through the exhaust port.
- 5 12. The device as claimed in claim **11** wherein said exhaust port includes at least one opening closable by a valve, said valve mounted on or to or in operative association with an actuator to actively control the movement of the valve relative to the opening.
- 10 13. The device as claimed in claim **11** wherein said exhaust port includes at least one opening closable by a valve, said valve mounted for movement relative to the opening in a passive manner under the influence of pressure differential in the gas from the outlet gas flow controller and/or between the outlet gas flow controller and ambient gas pressure.
14. The device as claimed in claim **13** wherein said exhaust port is moved to a closed condition when gas is to be displaced into said patient and to an open condition to allow gas due to exhalation of or by the patient to pass through the exhaust port.
- 15 15. The device as claimed in claim **14** wherein said exhaust port includes at least one opening closable by a valve, said valve mounted on or to or in operative association with an actuator to actively control the movement of the valve relative the opening.
- 20 16. The device as claimed in claim **14** wherein said exhaust port includes at least one opening closable by a valve, said valve mounted for movement relative the opening in a passive manner under the influence of pressure differential in the gas from the outlet gas flow controller and/or between the outlet gas flow controller and ambient gas pressure.
17. The device as claimed in any one of claims **14** to **16** wherein when the exhaust port is in the open condition, said motor stops or reduces the velocity of the piston.
- 25 18. The device as claimed in claim **1** wherein the motor controller is coupled to said motor to control at least the velocity and position of the motor.

19. The device as claimed in claim **12** or **15** wherein the motor controller is coupled to said motor to control at least the velocity and position of the motor and wherein said motor controller is coupled to said actuator to move said actuator in a manner in synchronicity with control of said motor.
- 5 20. The device as claimed in claim **18** or **19** wherein a source of electricity is connected to said motor.
21. The device as claimed in claim **20** wherein said source of electricity is connected to said motor via said motor controller.
22. The device as claimed in claim **20** or **21** wherein via an interface, the motor controller
10 can be instructed to operate the device.
23. The device as claimed in claim **22** wherein the interface allows for patient-related information to be entered into the motor controller, the information including at least one selected from a patient's age and weight.
24. The device as claimed in any one of claims **18** to **23** wherein the motor controller
15 receives data from other parts of the device, including at least tidal volume flow rate at the patient interface.
25. The device as claimed in any one of claims **1** to **24** wherein a sensor is positioned at or proximate the patient interface in the flow path to and from the patient to sense at least one of the tidal volume flow rate, breath rate and exhale breath temperature.
- 20 26. The device as claimed in claim **25** wherein said sensor provides information to at least one of the motor controller and a recorder to record the information and a display device to display the information.
27. The device as claimed in any one of claims **1** to **26** wherein a display is provided to display operating conditions of said device.
- 25 28. The device as claimed in claim **27** wherein the operating conditions displayed include inlet gas pressure, patient interface gas pressure, tidal volume at the patient interface,

piston oscillation rate, piston stroke length, battery power, duration of operation, each sensed by appropriate sensors of the device.

29. The device as claimed in claim **28** wherein the operating conditions are recorded and stored for subsequent use.
- 5 **30.** The device as claimed in any one of claims **1** to **29** wherein fluid connection between said outlet of said cylinder and the patient interface is defined in part by a flexible conduit.
- 10 **31.** The device as claimed in claim **30** wherein fluid connection between said outlet of said cylinder and the patient interface is defined in part by a flexible conduit and said outlet gas flow controller is located more proximate said patient interface than said cylinder.
- 15 **32.** The device as claimed in any one of claims **1** to **31** wherein the pressure relief valve becomes operative to relieve pressure when the pressure in said patient interface reaches a certain threshold.
- 15 **33.** The device as claimed in any one of claims **1** to **32** wherein said pump includes an inlet volute.
- 15 **34.** The device as claimed in claim **33** wherein the inlet volute includes an opening to allow pressure relief of said inlet volute to occur.
- 15 **35.** The device as claimed in claim **33** or **34** wherein said inlet volute includes a one way valve to allow pressure relief to occur into the inlet volute.
- 20 **36.** The device as claimed in any one of claims **33** to **35** wherein the said inlet volute includes a pressure relief valve to allow pressure relief to occur out of said inlet volute.
- 25 **37.** The device as claimed in any one of claims **1** to **36** wherein said inlet of said cylinder is in fluid connection with a supplementary gas supply to allow gas from said supplementary gas supply to pass into said cylinder for subsequent delivery to the patient, the gas is oxygen.

38. The device as claimed in any one of claims **1** to **37** wherein said cylinder is split into two zones by said piston, a first zone being on one side of said piston and a second zone being on the other side of said piston and wherein said gas inlet(s) are provided to allow gas into the first zone and said gas outlet(s) are provided to allow gas out of said second zone, wherein a one way pump valve is provided to allow gas to transfer from said first zone to said second zone and that restricts flow in the opposite direction.
39. The device as claimed in claim **38** wherein the one way pump valve is carried by the piston to operate on a passage through the piston.
40. The device as claimed in claim **38** or **39** wherein said gas in said first zone, is or becomes pressurised sufficiently to, upon the movement of the piston in its first stroke direction, allow some of the gas to displace through the one way pump valve into the second zone.
41. The device as claimed in any one of claims **38** to **40** wherein the one way pump valve is a passive one way valve that moves between an open and closed condition dependent on pressure differential across the one way pump valve.
42. The device as claimed in any one of claims **38** to **41** wherein an inlet one way valve may be provided to allow gas to be drawn into the first zone upon the movement of the piston in its second stroke direction and that restricts flow of gas in the opposite direction through said inlet one way valve upon the movement of the piston in the first stroke direction.
43. The device as claimed in claim **42** wherein the inlet one way valve is a passive one way valve that moves between an open and closed condition dependent on pressure differential across the inlet one way valve.
44. The device as claimed in any one of claims **38** to **40** wherein one or each of the one way valves mentioned are valves under active control to be in the open and closed conditions in correspondence with the direction of movement of the piston.
45. The device as claimed in any one of claims **38** to **40** wherein the cylinder and piston stroke length are of a size to allow a sufficient volume of gas to be displaced from said

cylinder through said gas outlet(s) during said second direction of movement of the piston to deliver a desired volume and flow rate of gas for a single inhalation to a neonatal patient for resuscitation purposes.

5 46. The device as claimed in any one of claims **1** to **39** wherein said cylinder is split into two zones by said piston, a first zone being on one side of said piston and a second zone being on the other side of said piston, and wherein the pump is a double acting pump that includes:

a) a first one way valve to:

10 i) allow gas to enter into the first zone via a first gas inlet of said cylinder during movement of the piston in said second stroke direction; and

 ii) restrict gas flow in the opposite direction through said first gas inlet during movement of the piston in the first stroke direction;

b) a second one way valve to:

15 i) allow gas to exit the first zone via a first gas outlet of said cylinder during movement of the piston in its first stroke direction; and

 ii) restrict gas flow in the opposite direction through said first gas outlet during movement of the piston in the second stroke direction;

c) a third one way valve to:

20 i) allow gas to enter into the second zone via a second gas inlet of said cylinder during movement of the piston in its first stroke direction; and

 ii) restrict gas flow in the opposite direction through said second gas inlet during movement of the piston in the second stroke direction;

d) a fourth one way valve to:

- i) allow gas to exit the second zone via a second gas outlet of said cylinder during movement of the piston in its second stroke direction; and
 - ii) restrict gas flow in the opposite direction through said second gas outlet during movement of the piston in the first stroke direction;
- 5 e) a manifold or ducting to duct gas from said first and second outlets to said patient interface.
47. The device as claimed in claim **46** wherein each of at least one of the first to fourth one way valves are either actively controlling or passive in moving between their open and closed conditions.
- 10 48. The device as claimed in claim **46** or **47** wherein the cylinder and piston stroke length are of a size, and the motor is able to move and be controlled, to allow a sufficient volume of gas to be displaced from said cylinder through said gas outlet(s) during multiple oscillations of the piston to deliver a desired volume and flow rate of gas for a single inhalation to a patient for resuscitation purposes or ventilation purposes or both.
- 15 49. The device as claimed in claim **1** wherein the pump is a double acting pump and the motor is of sufficient speed to, in multiple strokes of the piston, deliver a single tidal volume of gas for a single inhalation to a patient for resuscitation purposes.
50. The device as claimed in any one of claims **1** to **49** wherein the device is portable.
51. The device as claimed in any one of claims **1** to **50** wherein at least one of the pump and patient interface and motor are portable and unitary and able to be held in one hand by a user.
- 20 52. The device as claimed in claim **51** wherein at least one of the motor controller and power supply and display are also portable and unitary and able to be held in one hand by a user.
- 25 53. The device as claimed in any one of claims **1** to **52** wherein communication to and from the motor controller may be wireless.

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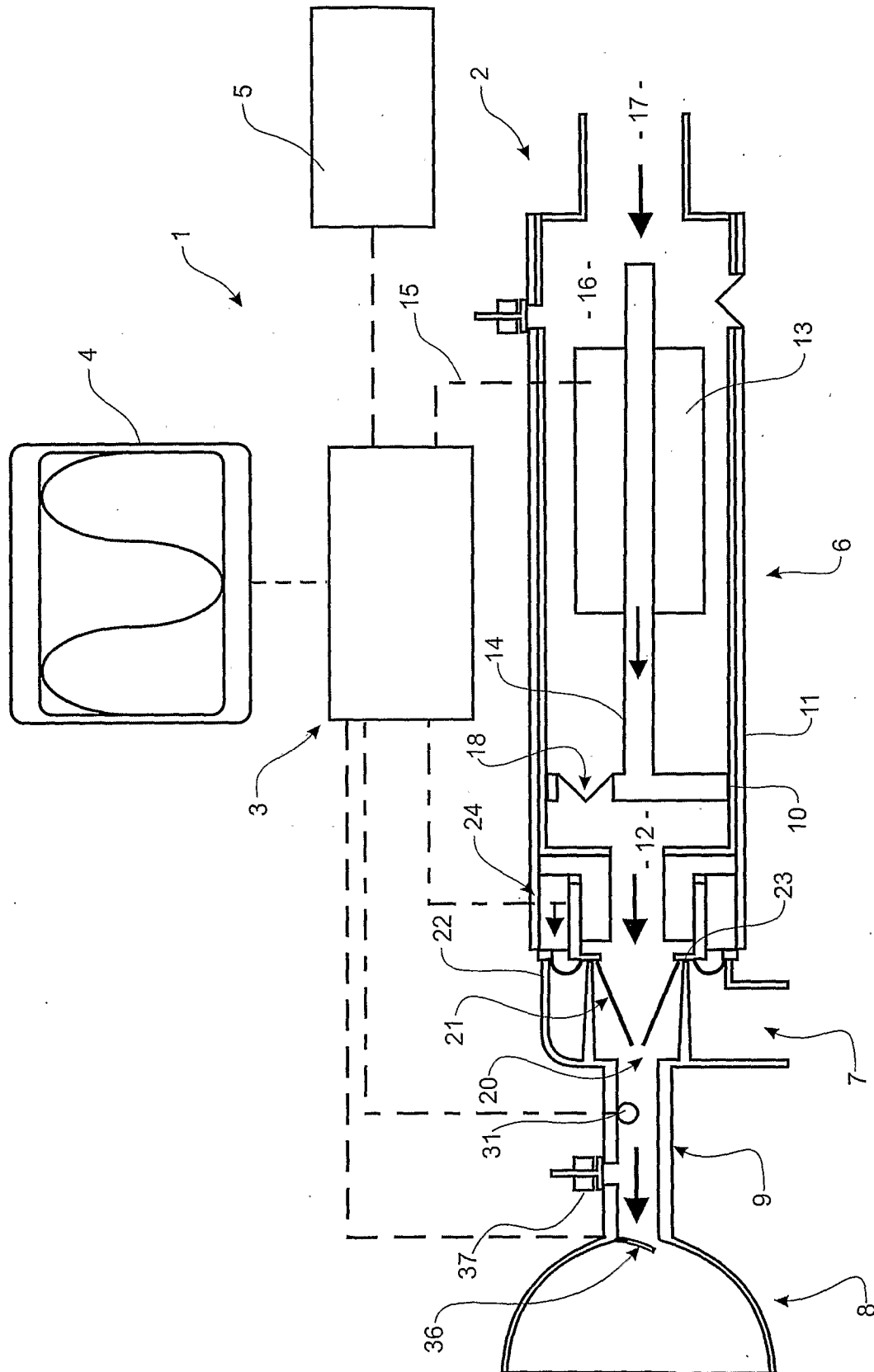


FIGURE 1

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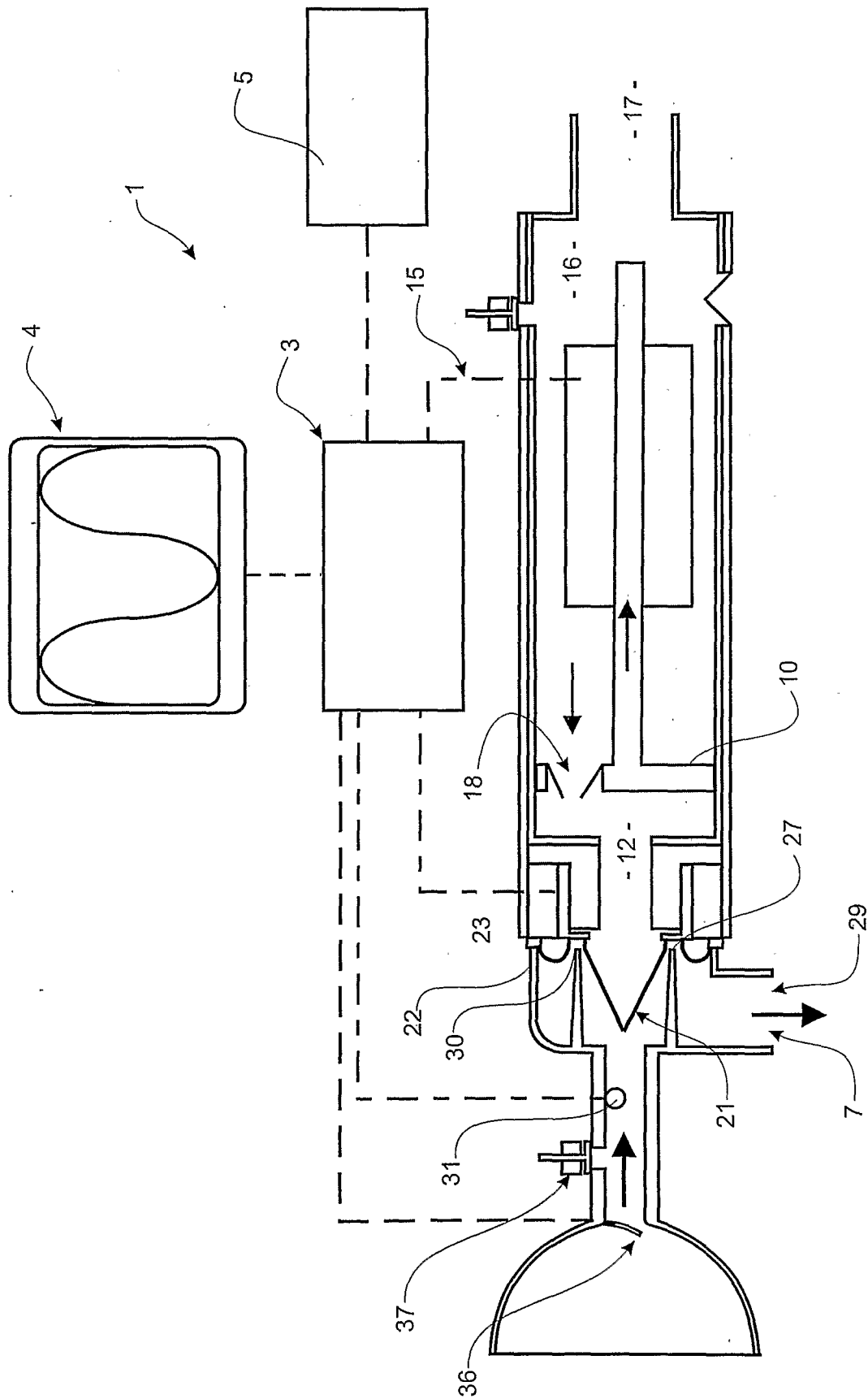


FIGURE 2

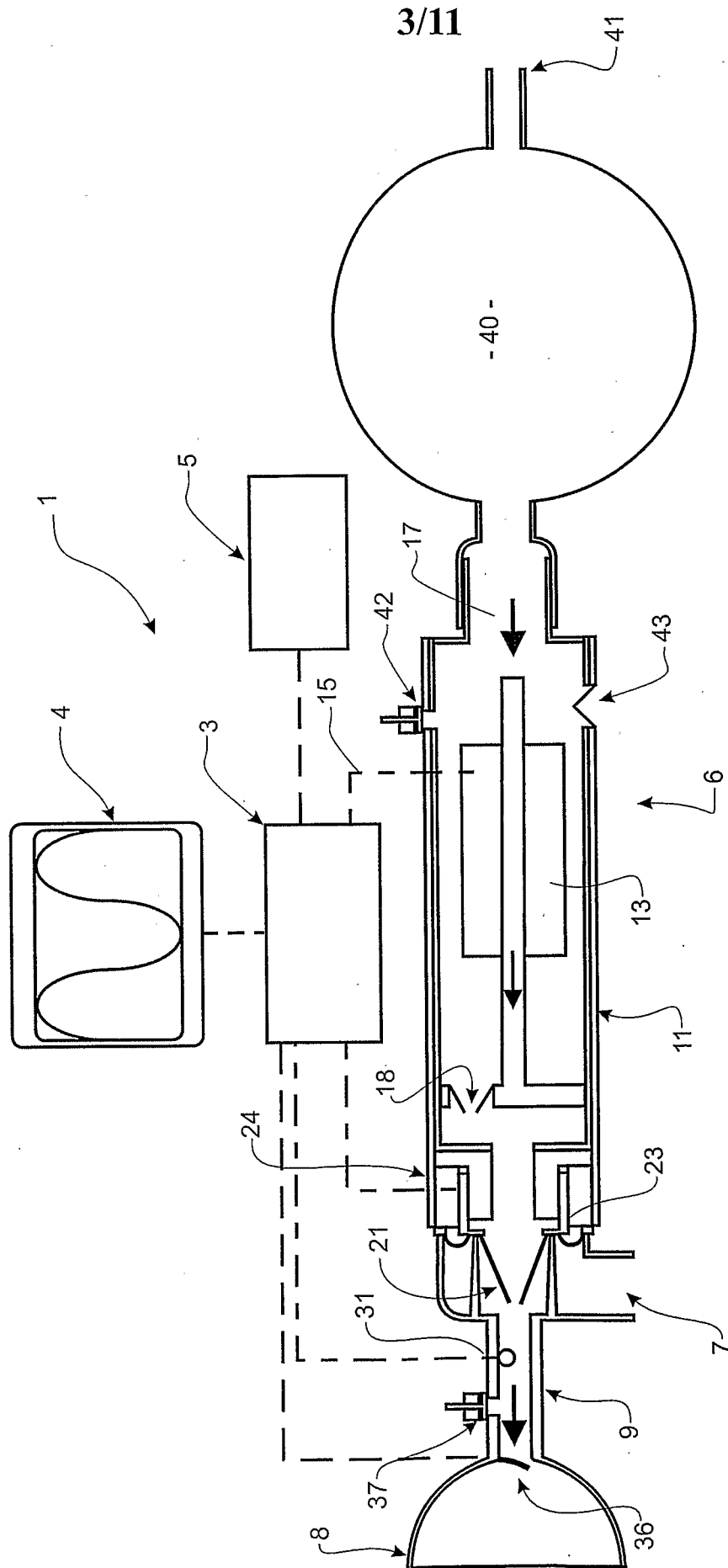


FIGURE 3

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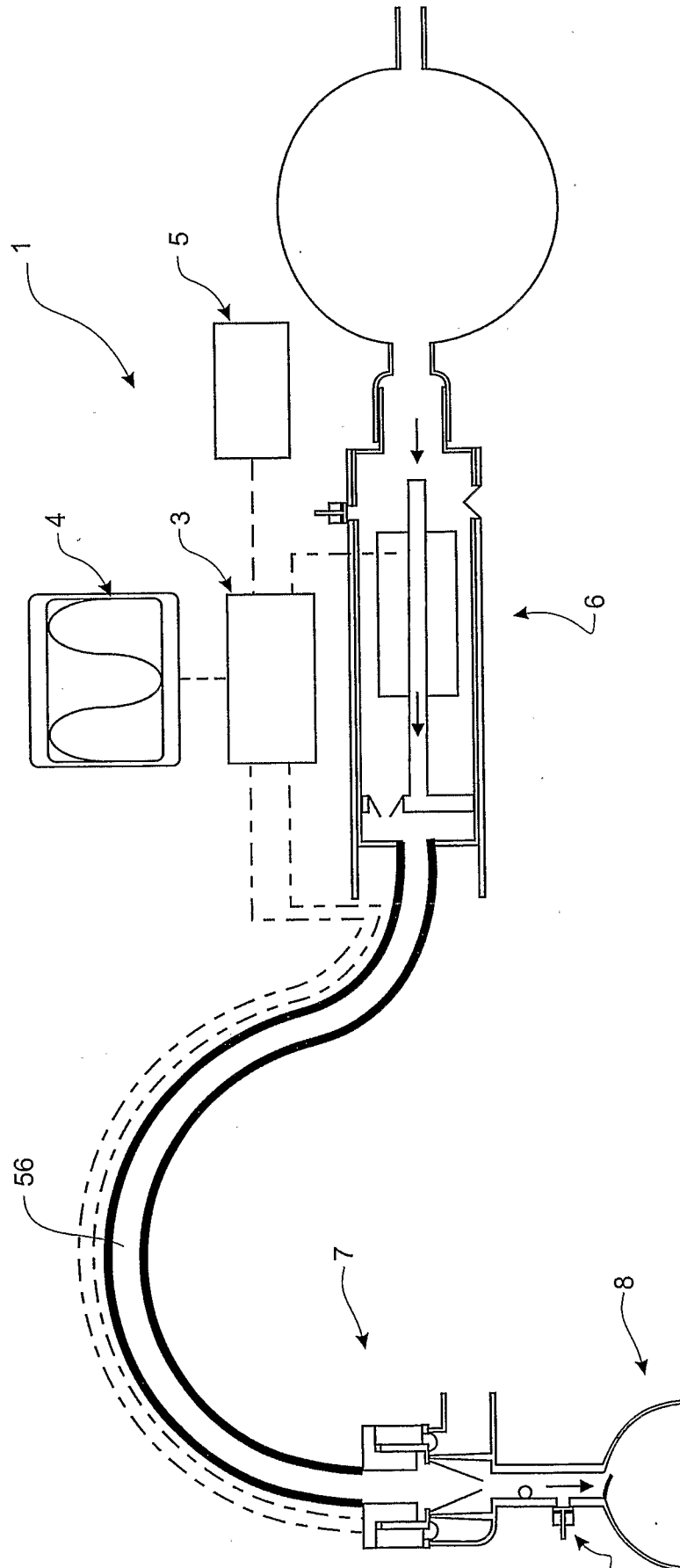


FIGURE 4

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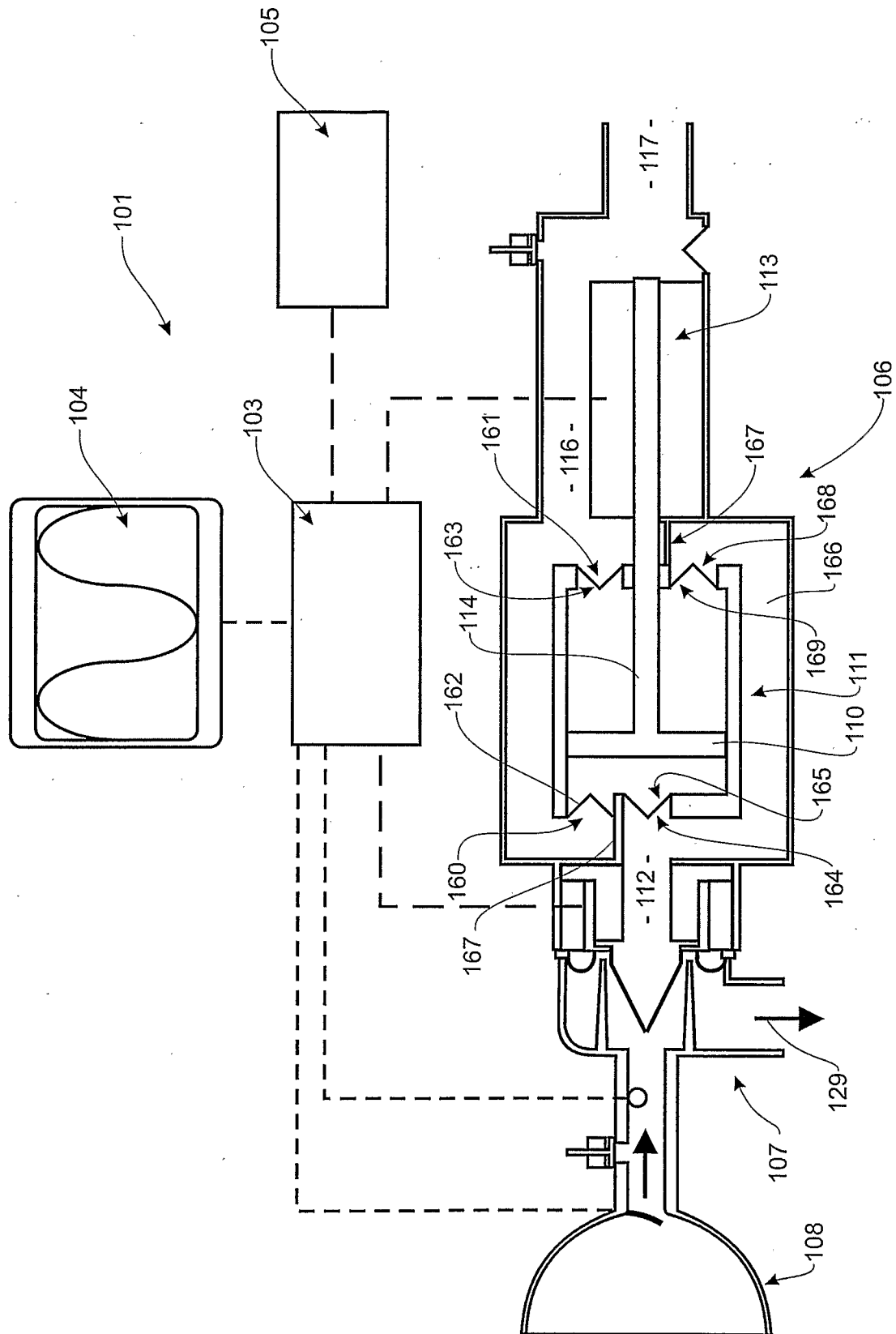


FIGURE 5

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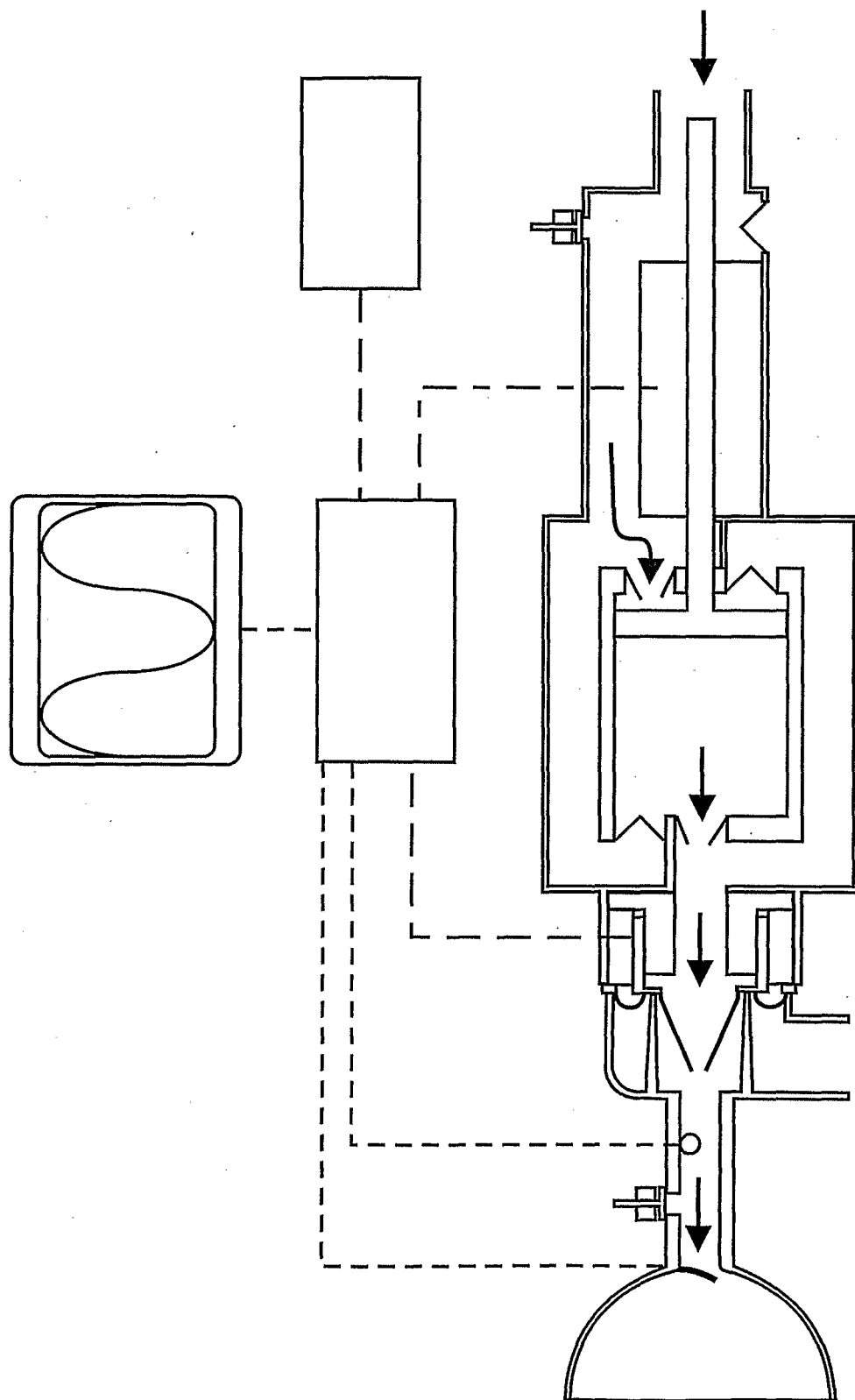
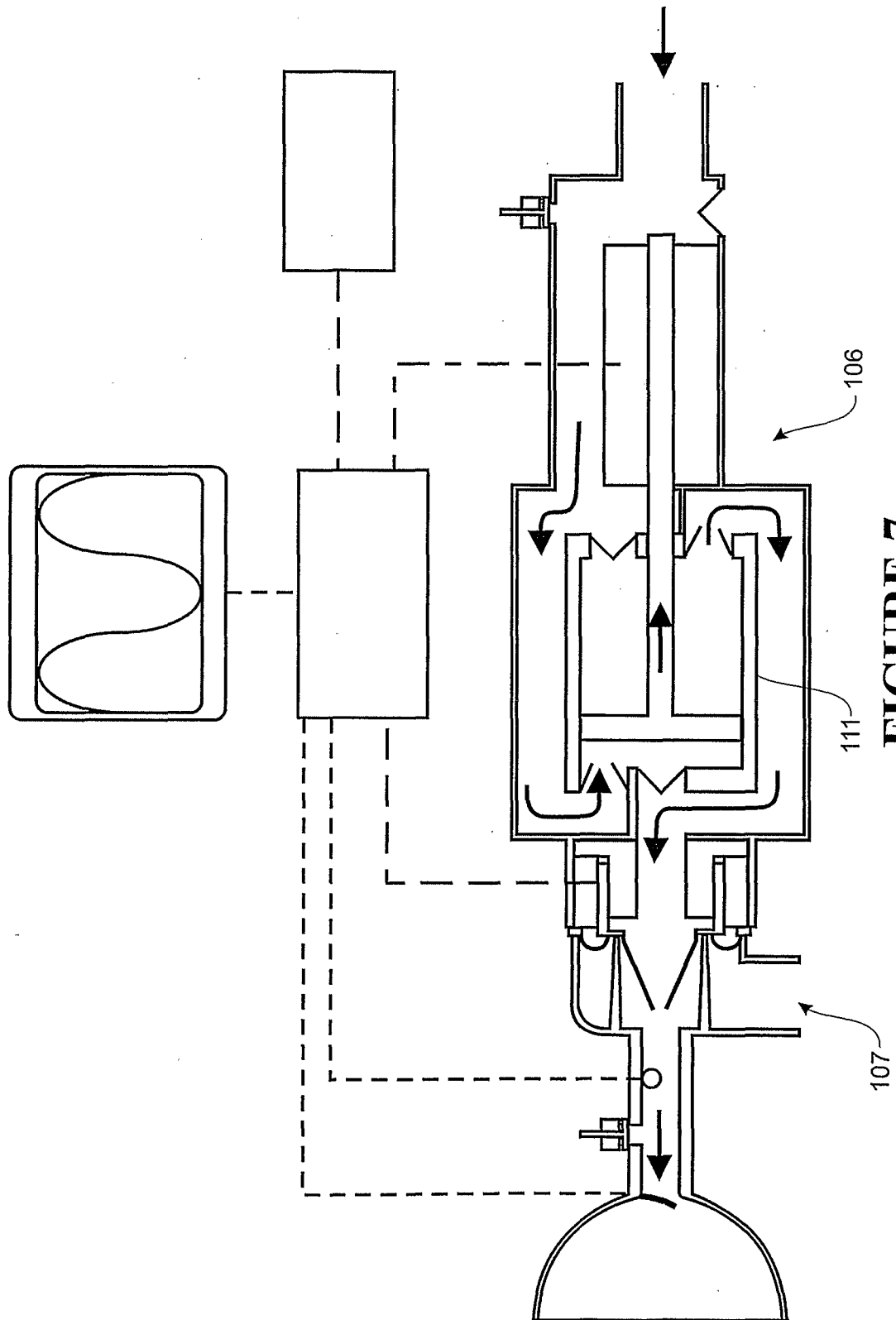


FIGURE 6

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**FIGURE 7**

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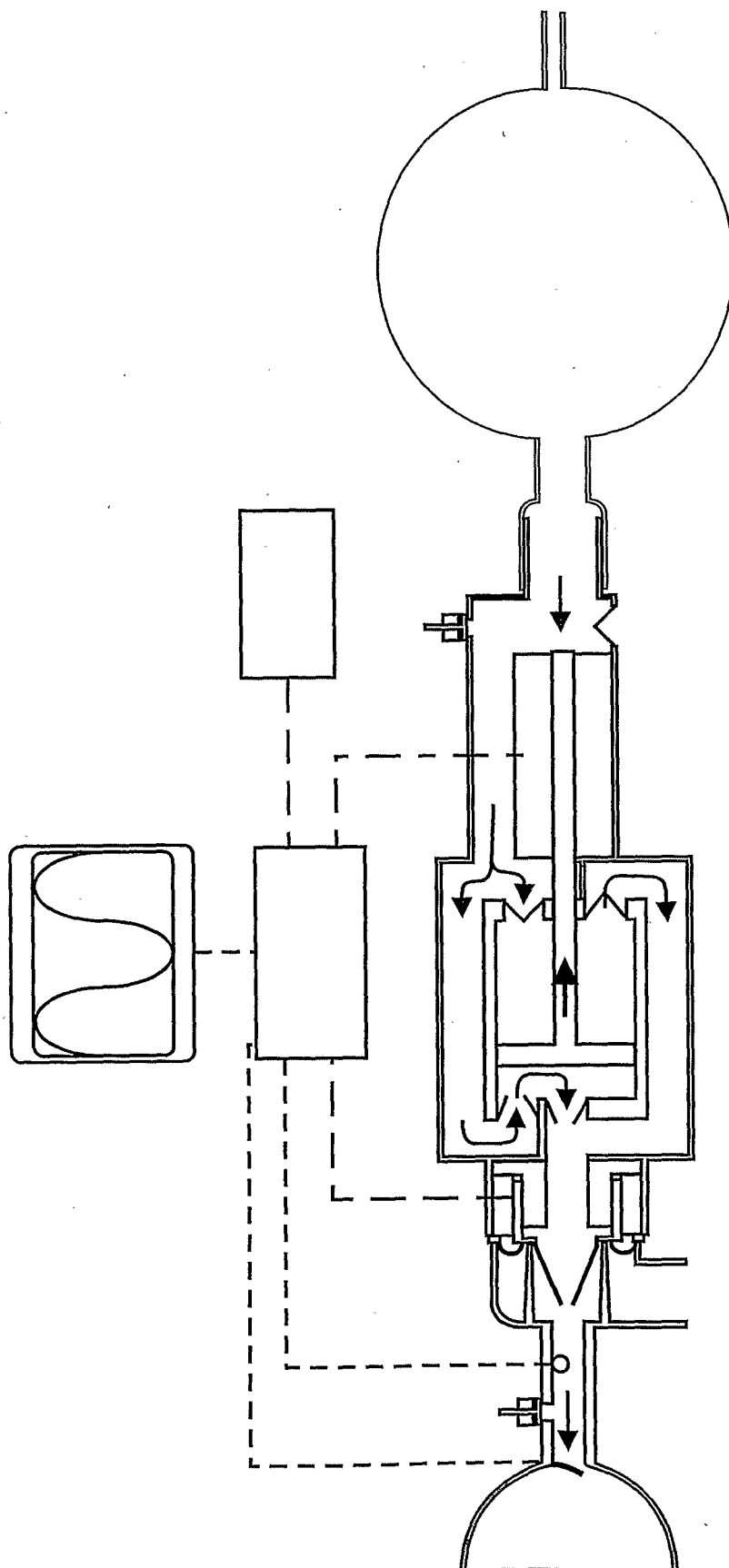
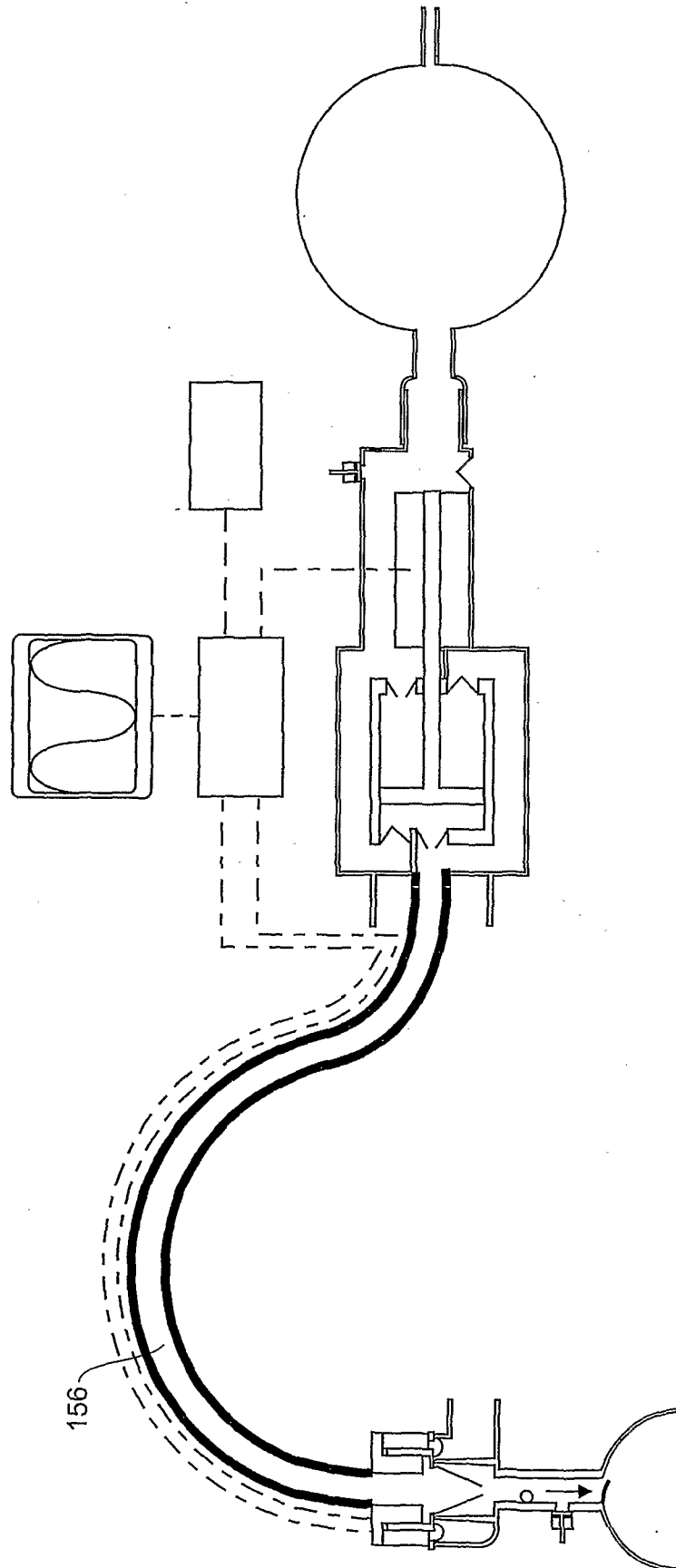


FIGURE 8

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**FIGURE 9**

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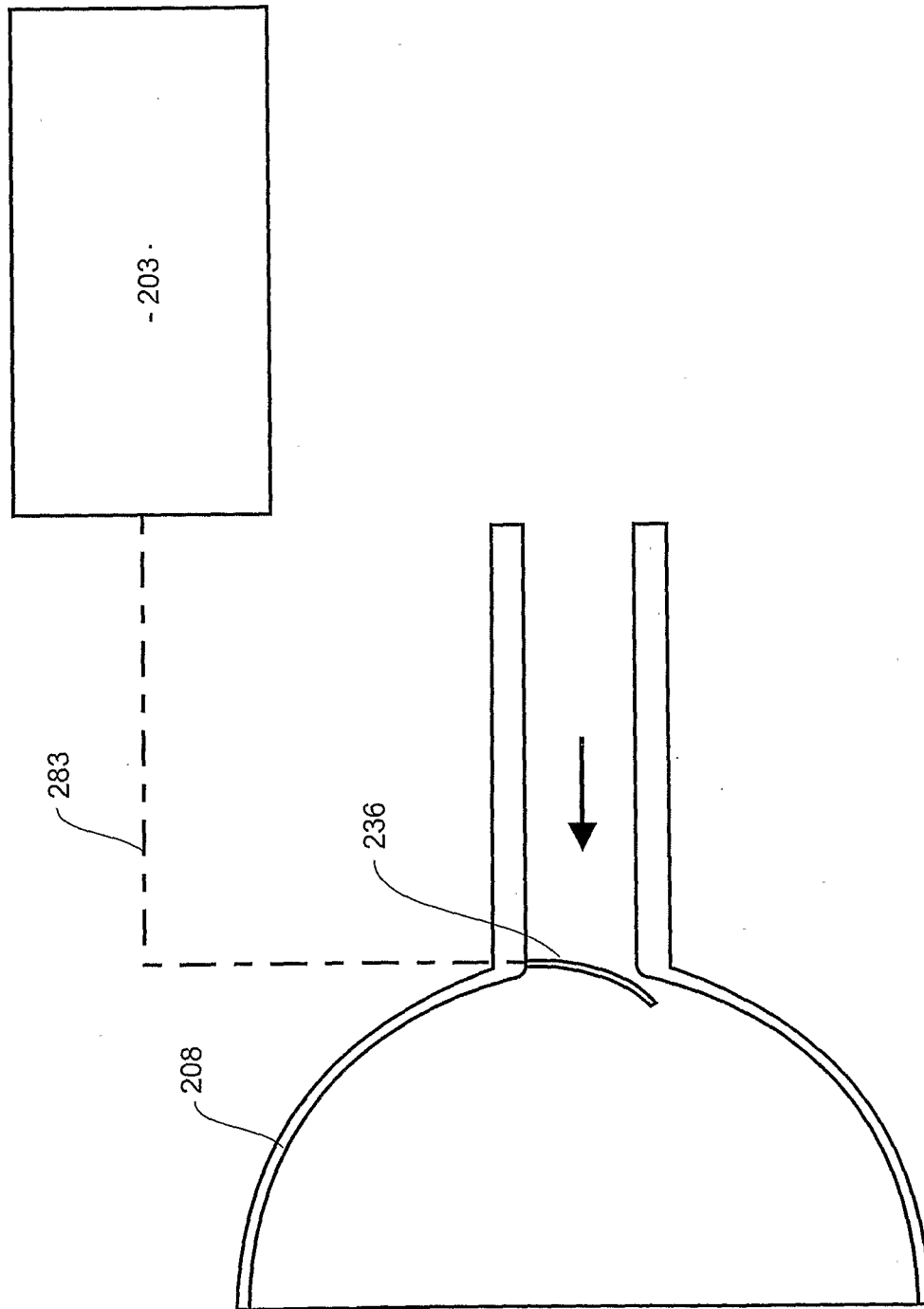


FIGURE 10

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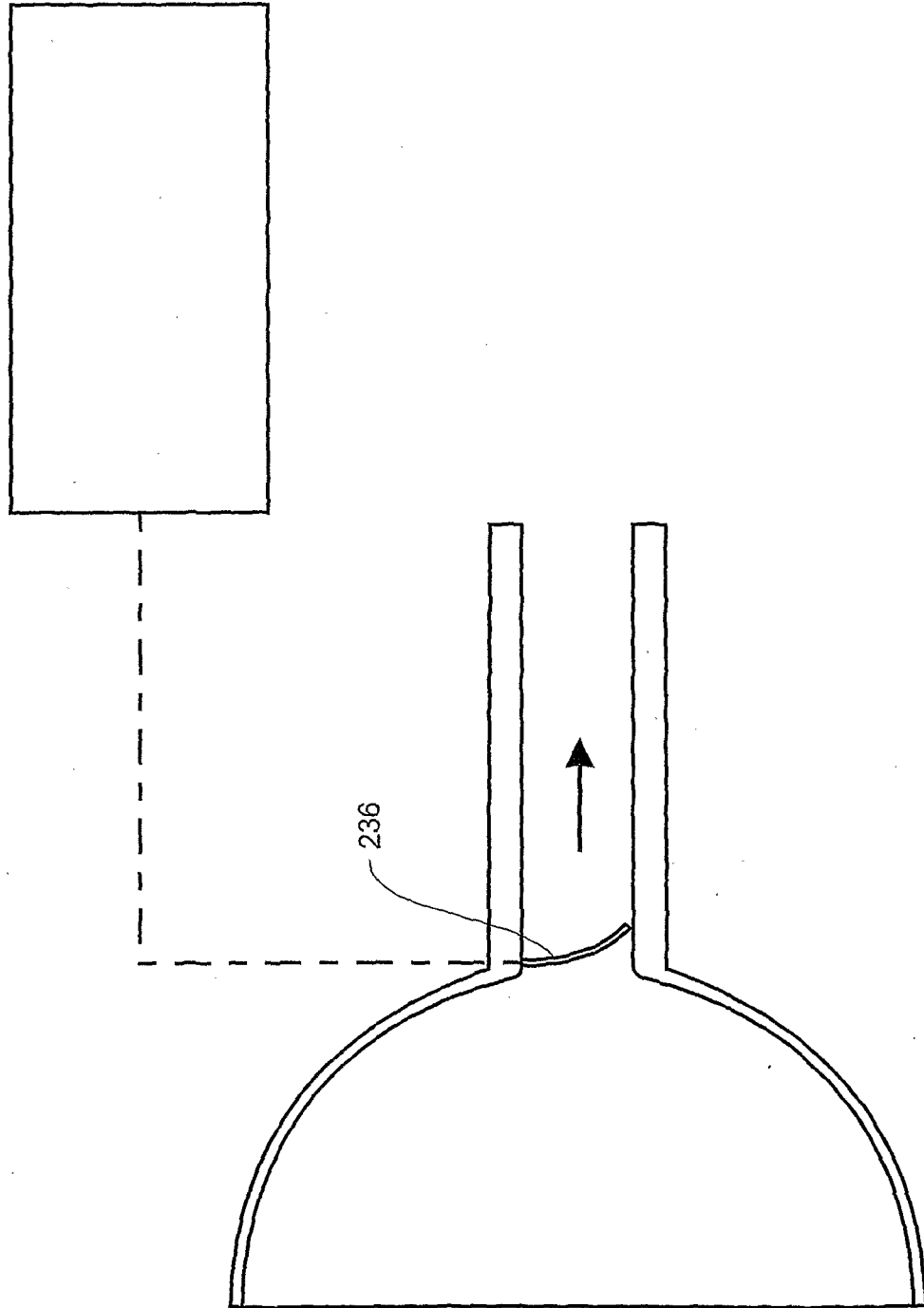


FIGURE 11

