

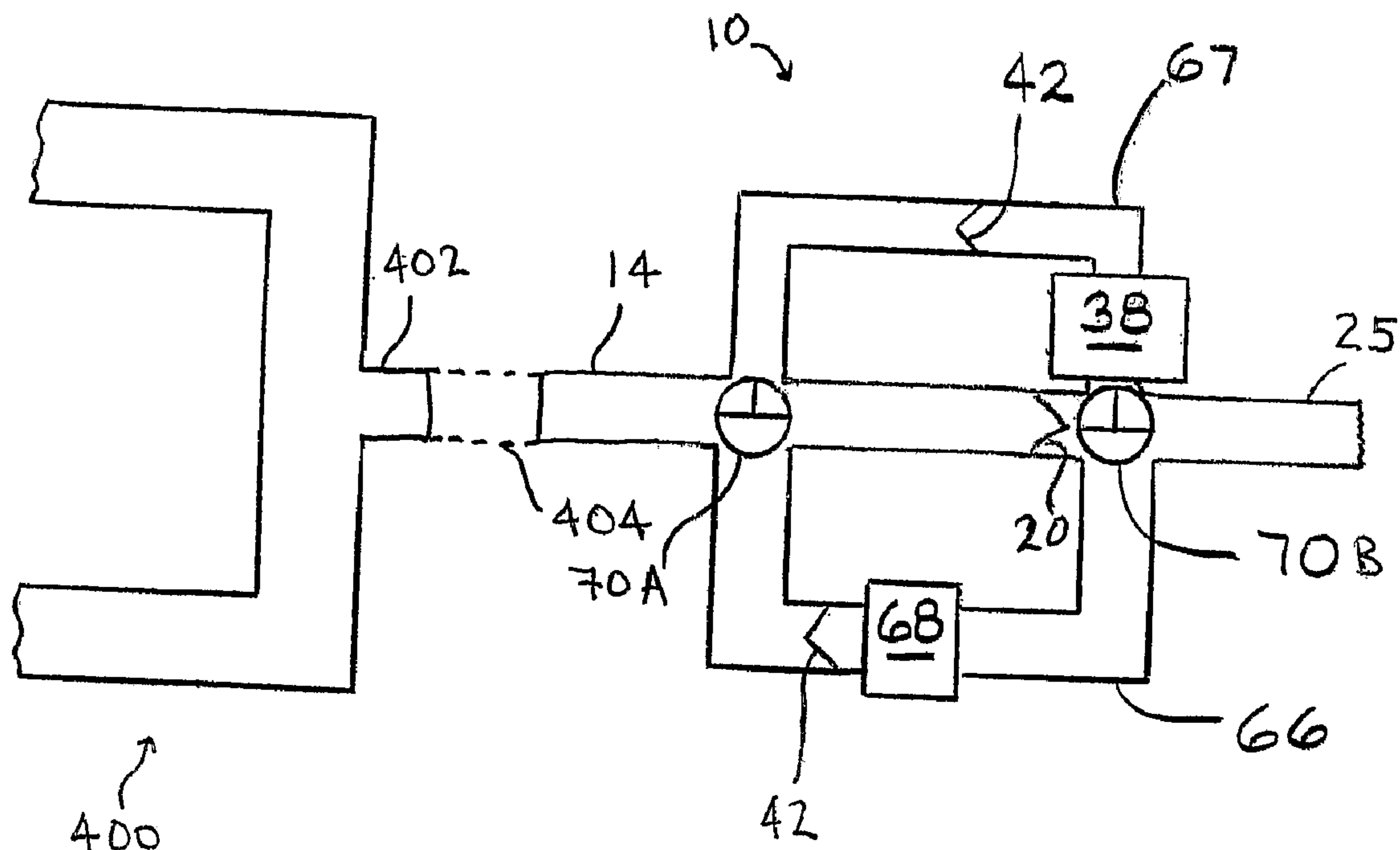


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(54) Title: DEVICE AND METHOD OF REDUCING BIAS FLOW IN OSCILLATORY VENTILATORS



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A device and method of ventilating a patient reduces the bias flow relative to existing oscillatory ventilators. The device has a gas flow circuit comprising an oscillating line (14), a patient line (25) and an exhalation or a return line (67). A gas supply line (18) and an outlet valve (52) are in pneumatic communication with the gas flow circuit. One or more carbon dioxide scrubbers (38, 68) and one or more check valves (20, 42) are provided in the circuit. A method of ventilating using such a device is also disclosed.



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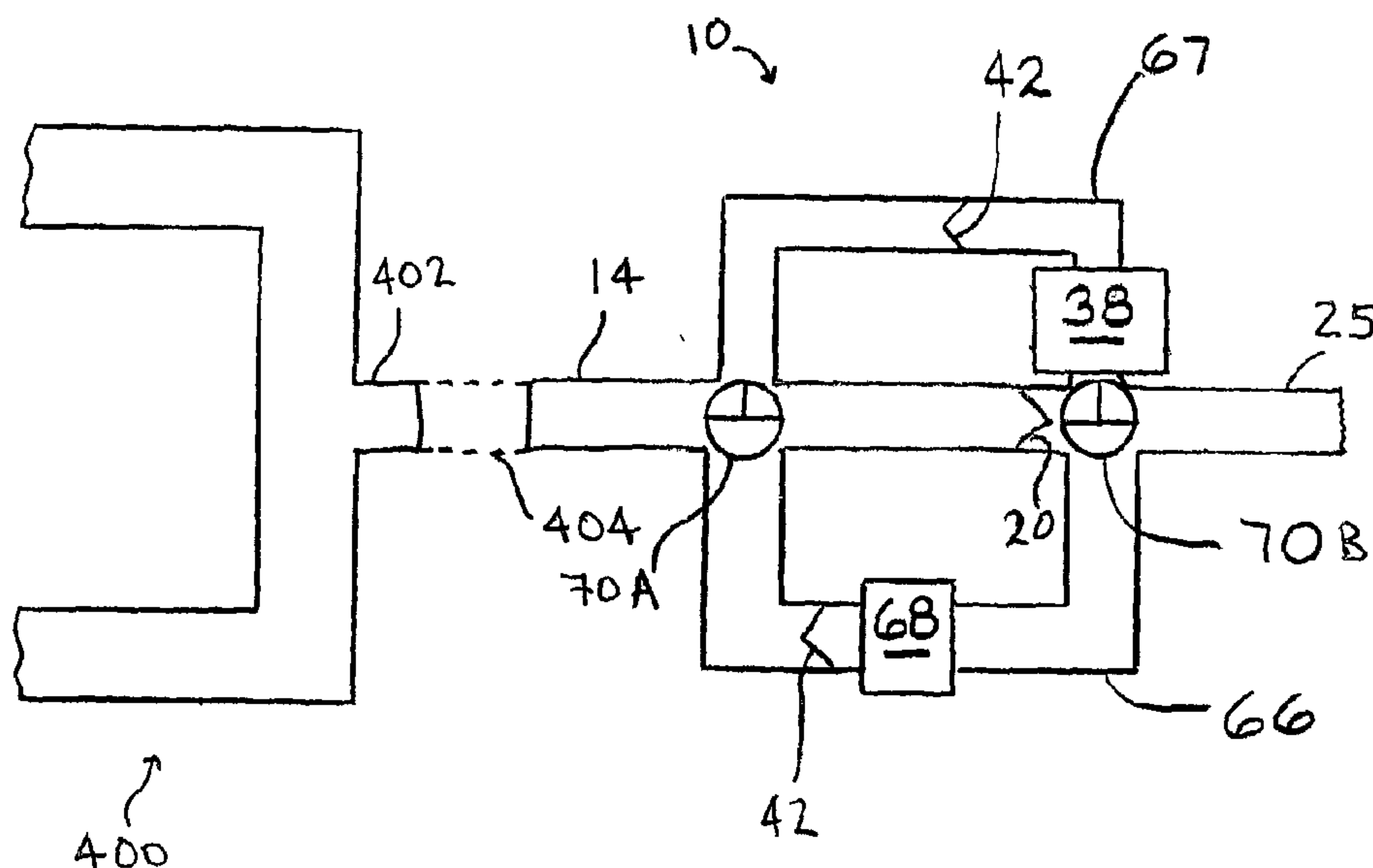
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(54) Title: DEVICE AND METHOD OF REDUCING BIAS FLOW IN OSCILLATORY VENTILATORS



(57) Abstract: A device and method of ventilating a patient reduces the bias flow relative to existing oscillatory ventilators. The device has a gas flow circuit comprising an oscillating line (14), a patient line (25) and an exhalation or a return line (67). A gas supply line (18) and an outlet valve (52) are in pneumatic communication with the gas flow circuit. One or more carbon dioxide scrubbers (38, 68) and one or more check valves (20, 42) are provided in the circuit. A method of ventilating using such a device is also disclosed.

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DEVICE AND METHOD OF REDUCING BIAS FLOW IN OSCILLATORY VENTILATORS

5 This application claims priority to U.S. provisional patent application 60/353,461 filed on February 1, 2002 and is also a continuation in part of U.S. patent application no. 09/631,464 filed on August 3, 2000 which in turn claims priority to U.S. provisional application no. 60/146,863, filed on August 3, 1999, the disclosures of which are incorporated herein by reference.

10 FILED OF THE INVENTION

 The present invention relates generally to ventilators for supporting breathing in animals. More particularly, the present invention provides a device and method of ventilating.

DISCUSSION OF RELATED ARTS

15 There are many situations in which normal breathing by an animal patient is impaired and must be assisted by external means. Oscillatory ventilators are used to facilitate breathing in such situations. Among the types of ventilators available are high frequency oscillating ventilators. U.S. Patent 4,719,910 describes a high frequency oscillating ventilator. A flow of gas is conducted from a gas source to a
20 high frequency oscillator. The high frequency oscillator comprises a housing including a magnet and having a diaphragmatically sealed piston mounted therein, an inlet connecting the space within the housing on the first side of the diaphragm to the gas conducting means, and a coil mounted to the first side of the diaphragm. Circuitry is provided which is operable to reverse the polarity of the flow of the
25 current in the coil, thereby causing the diaphragm to move back and forth within the housing. A tube connecting the space on the second side of the diaphragm to the gas source and the patient's airway is provided.

 In the prior art, inspiratory gas is moved into and out of the patient via a U-shaped tube and movement of the diaphragm. For purposes of describing the prior
30 art, the U-shaped tube can be described as having a first limb with a distal end, a second limb with a distal end, and a tube between the limbs. Connected to the tube between the limbs is another tube (the "patient line") that delivers gas from the U-

shaped tube to the patient and also delivers gas from the patient to the U-shaped tube. The patient line may be connected to the patient via an endotracheal tube. The distal end of the first limb is placed in sealing relation to the diaphragm so that gas inside the U-shaped tube is caused to oscillate as the diaphragm moves back and forth. Gas suitable for inspiration ("inspiratory gas") is supplied at a location on the U-shaped tube between the diaphragm and the patient line.

Inspiratory gas passes through the first limb of the U-shaped tube, and exhaled gas exits to the atmosphere through the second limb of the U-shaped tube and out of the distal end of the second limb. To prevent expired gases from being drawn back into the first limb during the expiratory phase of breathing, more inspiratory gas than needed by the patient is provided in order to move the expired gas into the second limb. The inspiratory gas provided in excess of the needs of the patient is referred to herein as "bias flow".

To move expired gas into the second limb of the U-shaped tube, an inspiratory gas flow rate of approximately 20 liters per minute is used when ventilating infants, and as much as 60 to 80 liters per minute when ventilating older children and adults. Such large volumes of inspiratory gas would quickly exhaust the available supply of most transport and ambulance vehicles. Furthermore, such prior art devices necessitate large and costly volumes of therapeutic gases that might be mingled with the inspiratory gas (e.g., volatile anesthetics, nitric oxide, vaporized perfluorocarbons, helium/oxygen mixtures etc.). Finally, such prior art devices are inefficient when one considers the amount of inspiratory gas required by the patient and the relatively large amount of inspiratory gas supplied to the ventilator.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a device and a method of ventilating. The object is achieved by a ventilating device having an oscillator, such as an oscillatory diaphragm, and gas flow circuit comprising an oscillating line having a first end in sealing or pneumatic relationship with the oscillator. A gas supply line is connected to the oscillating line, and a patient line is connected to a

second end of the oscillating line. An outlet line is in pneumatic communication with the patient line, and an end of the outlet line distal from the patient line is connected to an outlet valve. The outlet valve releases gas from the outlet line during inhalation, and prevents the release of gas from the outlet line during exhalation. In one embodiment of the invention, the device has an oscillating line with a gas supply line connected thereto, a patient line connected to the second end of the oscillating line, an outlet line in pneumatic communication with the patient line, an outlet valve connected to the outlet line, one or more CO₂ scrubbers and one or more check valves to ensure unidirectional flow of gas through the one or more scrubbers. This device of this embodiment can be attached to an oscillating ventilator.

In another embodiment, the device of the present invention is adapted for connecting to the U-type ventilator attachments of the prior art. In one embodiment of the invention, the device has a gas flow circuit comprising an oscillating line having a first end and a second end. The first end is adapted for connecting to an oscillating ventilator either directly or through another device such as a conventional U-type tube, a patient line connected to the second end of the oscillating line, a return line connected to the oscillating line, one or more CO₂ scrubbers and one or more check valves to ensure unidirectional flow of gas. Optionally, the device may have an outlet valve and a gas supply line or when used in conjunction with a conventional U-type tube, may use the outlet valve and the gas supply line of the conventional U-type tube.

In a method according to the present invention, a ventilation device, such as the one described above, is provided. A patient in pneumatic communication with the patient line is provided and gas is supplied to the oscillating line. The oscillator is moved toward the oscillating line and the outlet valve is opened. Then, the oscillator is moved away from the oscillating line and the outlet valve is closed.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature and objects of the invention, reference should be made to the following description taken in conjunction with the accompanying drawings, in which:

5 Figure 1 is a schematic sectional view of a device according to the present invention illustrating the major components of the device and utilizing a CO₂ scrubber;

 Figures 2a and 2b are schematic sectional representations of the closed and open positions respectively of an outlet valve according to the present invention;

10 Figures 3a and 3c are each a schematic sectional representation of an embodiment of the present invention;

 Figure 3b is a schematic sectional representation of another embodiment of the present invention;

15 Figures 4a and 4b are schematic sectional views of other embodiments of the present invention having a CO₂ scrubber;

 Figure 5 is a schematic sectional representation of another embodiment of the present invention.

 Figure 6 is a schematic sectional view of another embodiment of the invention without a CO₂ scrubber;

20 Figures 7a and 7b are schematic sectional representations of the closed and open positions respectively of another outlet valve according to the present invention; and

 Figure 8 is a flow chart showing steps of a method according to the present invention.

Figures 9a, 9b, 9c and 9c are schematic sectional views of an embodiment of the invention that can be connected to a U-type oscillator tube (9a, 9b and 9c) or to an oscillating ventilator (9d).

DETAILED DESCRIPTION OF THE INVENTION

5 As used herein the term "gas" means a pure gas or a mixture of gases. Thus, the term "gas" may refer to a mixture of O₂ and N₂, and may include therapeutic gases.

10 A device 10 according to the present invention can be connected to an oscillating machine having an oscillator 11, such as a diaphragm, like those described in U.S. Patent No. 4,719,910 and No. 5,307,794. As illustrated in Figure 1, an inspiratory gas source 5 is connected to a device 10 according to the present invention through supply line 8. The flow of inspiratory gas into the device 10 can be regulated by a flow regulator 9 connected to supply line 8. Preferably, the flow of inspiratory gas from supply line 8 and into connecting line 18 is essentially at a
15 constant rate. Connecting line 18 is connected to the oscillating line 14.

20 In the embodiment shown in Figure 1, an inbound check valve 20 is in the oscillating line 14. The portion of the oscillating line 14 that is downstream of the inbound check valve 20 is referred to herein as the inbound line 15. The check valve 20 permits the flow of gas in the direction of arrow 21 and prevents the flow of gas in the opposite direction. When the pressure on the upstream side of the inbound check valve 20 is higher than the pressure on the downstream side of the inbound check valve 20, the inbound check valve 20 opens allowing gas to flow in the direction of arrow 21. When the pressure on the upstream side of the inbound check valve 20 is lower than on the downstream side, the inbound check valve 20 shuts,
25 effectively stopping the flow of gas through inbound line 15.

Further downstream of inbound check valve 20, for example along inbound line 15 may be placed an O₂ sensor 24 and a CO₂ sensor 22 to monitor the quality of the gas therein. Additional modifiers and monitors like humidifiers, nebulizers and the like can also be installed. Inbound line 15 connects to patient line 25, which is in

turn connected to an endotracheal tube (not shown in Figure 1) for delivery of gas to the patient's airways, and ultimately to the patient's lungs.

Inbound line 15 is also connected to exhalation line 30. In exhalation line 30 may be placed a pressure monitoring device, such as a manometer, through port 28. 5 Exhalation line 30 includes a scrubber line 36 and connects to recirculation line 34. Recirculation line 34 connects to the oscillating line 14. At the junction of recirculation line 34 and scrubber line 36 is a two-position valve 32 which directs the flow of gas either toward the recirculation line 34 or toward the scrubber line 36. The two position valve 32 is normally positioned to direct the flow of gas to the 10 scrubber line 36. Preferably, the two-position valve 32 is normally adjusted so that no gas flows through recirculation line 34.

Included in the exhalation line 30 is a scrubber canister 38, an outbound line 40, and a discharge line 16. A second scrubber 68 may also be included and used when the scrubber canister 38 is not being used, for example, while scrubber canister 15 38 is being replaced or recharged, for example, by purging CO₂ using a separate flow of gas (not shown). The scrubber valves 70A and 70B preferably operate together so that either scrubber canister 38 or the second scrubber 68 is in operation. In a preferred embodiment, the scrubber valves 70A and 70B are not two separate valves, but instead a slide type valve, commonly used in the medical community, 20 having an outer cylindrical shell and a movable inner cylinder, each with holes therethrough that allow either the scrubber canister 38 or the second scrubber 68 to be in service.

The outbound line 40 is fitted with an outbound check valve 42, which permits the flow of gas in the direction of arrow 43 and prevents the flow of gas in 25 the opposite direction. Downstream of the outbound check valve 42 is discharge line 16 having within it a shut-off valve 44. The shut-off valve 44 is normally set to the open position. The shut-off valve 44 in its open position, permits the flow of gas, but in its closed position blocks the flow of gas. Discharge line 16 connects to oscillating line 14.

Oscillating line 14 connects at one end to the patient line 25, and is placed in sealing relationship at the other end with the oscillator 11. Preferably, the oscillator 11 is a diaphragm of a high frequency oscillating machine. Connected to the oscillating line 14 is an outlet line 50, which is in turn connected to outlet valve 52.

5 The outlet valve 52 may open and shut in response to a control pressure provided via control line 54. The closed and open positions of outlet valve 52 are shown in Figures 2a and 2b respectively. The external control pressure may be provided to control line 54 by the oscillating machine that controls the oscillator 11. In one embodiment of the present invention, the control pressure provided by line 54 is
10 substantially stable and the oscillating pressure in line 14 caused by movement of the diaphragm 11 causes the outlet valve 52 to open and close. Alternatively, operation of the outlet valve 52 may be by other means, such as a solenoid.

High frequency oscillation of the oscillator 11 facilitates movement of gas into and out of the patient's airways. Thus, during the inspiration phase, when the
15 oscillator 11 is moving toward the oscillating line 14, a pressurizing cycle occurs, and during the expiration phase, when the oscillator 11 is moving away from the oscillating line 14, a depressurizing cycle occurs. During the pressurizing cycle, the pressure on the upstream side of the inbound check valve 20 increases, forcing it to open thereby allowing gas to flow in the direction of arrow 21, and consequently
20 into the patient's lungs via patient line 25. At the same time, due to the oscillator 11 moving toward the device 10, the pressure on the downstream side of outbound check valve 42 becomes higher than the pressure on its upstream side, which forces the outbound check valve 42 to close, thereby preventing the flow of gas from discharge line 16 into the scrubber canister 38.

25 During the expiration phase (or depressurizing part of the cycle), the oscillator 11 moves away from the oscillating line 14 and the pressure differential across the inbound check valve 20 causes the inbound check valve 20 to close. The exhaled gas is pushed by the patient's lungs into exhalation line 30, and into the CO₂ scrubber canister 38. At the same time, the pressure differential across the outbound
30 check valve 42 causes the outbound check valve 42 to open. Thus, CO₂ scrubbed

gas is returned to oscillating line 14 through the normally open shut-off valve 44.

The gas returning to the oscillating line 14 via the discharge line 16 mixes with the gas in the oscillating line 14. The gas in oscillating line 14 is moved toward the outlet valve 52 when the inbound check valve 20 is closed by the movement of the

oscillator 11. Figures 2a and 2b illustrate the open and closed positions of the pneumatic version of the outlet valve 52. When the control pressure supplied by control line 54 exceeds the pressure in the oscillating line 14 (Figure 2a), the outlet valve 52 is in the closed position and gas from oscillating line 14 is prevented from escaping from the device 10. When the control pressure supplied by control line 54 is less than the pressure in the oscillating line 14 (Figure 2b), the outlet valve 52 is in the open position and gas from oscillating line 14 is allowed to escape from the device 10. In the embodiments shown in Figures 1 through 5, preferably the outlet valve 52 is closed for at least part of the expiration phase (i.e. when the pressure in oscillating line 14 is decreasing due to movement of the oscillator 11 away from the device 10), and the outlet valve 52 is open for at least part of the inspiration phase (i.e. when the pressure in oscillating line 14 is increasing due to movement of the oscillator 11 toward the device 10).

The CO₂ scrubber canister 38 in the device 10 of the present invention may be used in other locations. For example, as shown in Figures 3a, 3b and 3c, the scrubber canister 38 may be placed at the end of patient line 25 distal from the inbound line 15. As shown in Figures 3a and 3c, suitable check valves 20, 42 and return line 67 can be incorporated to assure unidirectional flow through the scrubber canister 38. A bypass line 66 could be provided to accommodate replacement of the scrubber canister 38. In a preferred embodiment of the present invention, the second scrubber canister 68 is provided in the bypass line 66. The second scrubber canister 68 may be incorporated into any embodiment described herein which has a scrubber canister 38. The device depicted in Figures 3a, 3b and 3c could be used with prior art ventilator circuits.

The scrubber canister 38 contains a material that removes unwanted gas, such as CO₂. For example, the scrubber canister 38 may contain sodium hydroxide,

calcium hydroxide, or barium hydroxide. Sodium hydroxide and calcium hydroxide mixed with silica is available as Soda LimeTM. Another commercially available CO₂ scrubber is BaralymeTM which comprises barium hydroxide and calcium hydroxide. Once the CO₂ scrubber canister 38 is depleted of its scrubbing capacity, it can be replaced. To replace the scrubber canister 38, the two-position valve 32 is set to direct the gas from the exhalation line 30 to the recirculation line 34, while the shut-off valve 44 is set to the closed position. Upon replacement of the scrubber canister 38, the two-position valve 32 and the shut-off valve 44 are reset to their normal positions.

Figures 4a and 4b show two additional embodiments of the present invention. As illustrated in Figure 4a, the scrubber canister 38 may be placed in the oscillating line 14 upstream of the CO₂ and O₂ sensors 22, 24, or as shown in Figure 4b, downstream of the sensors 22, 24. In the embodiments shown in Figures 4a and 4b, check valves are not required to direct the flow of inspiratory gas toward the patient line 25 or to direct the flow of expired gas toward the scrubber canister 38. Normally, gas moves in both directions through the scrubber canister 38. To replace the scrubber canister 38, two block valves 62, 64 can be temporarily adjusted so that gas flows through the bypass line 66.

Figure 5 shows another embodiment of the present invention in which the scrubber is located in the oscillating line 14, and gas flows through the scrubber canister 38 toward the patient line 25. Flow from the patient line 25 moves through the exhalation line 30 to oscillating line 14. A check valve 42 is in bypass line 66 to assure that flow moves through exhalation line 30 in one direction only. An additional check valve 20 may be included in oscillating line 14 to assure flow through the scrubber canister 38 in one direction only.

In another embodiment of the present invention, illustrated in Figure 6, instead of scrubbing CO₂ from the exhaled gas, the exhaled gas is simply allowed to leave a device 100. The device 100 is connected to an inspiratory gas source 5 through connecting line 18. The inspiratory gas enters an oscillating line 14 and moves toward the patient line 25 in the direction of arrow 21 via the inbound check

valve 20. CO₂ and O₂ sensors 22, 24 and pressure monitoring port 28 can be placed near the patient line 25. The exhaled gas is conducted by the exhalation line 30 to another type of outlet valve 52. The outlet valve 52 shown in Figures 6, 7a and 7b operates based on the pressure differential between oscillating line 14 and the exhalation line 30. During the pressurizing cycle, outlet valve 52 is caused to close the end 132 of exhalation line 30 by the rising pressure in oscillating line 14. However, during the depressurizing phase, the pressure in the outlet line 50 causes the outlet valve 52 to open the end 132 and allow gas to escape to the atmosphere. Preferably, for at least part of the pressurization cycle, outlet valve 52 is closed and there is no communication between the exhalation line 30 and the atmosphere, and for at least part of the depressurization cycle, outlet valve 52 is open and there is communication between line 30 and the atmosphere.

Figures 7a and 7b show a preferred embodiment of the outlet valve 52 shown in Figure 6. The outlet valve 52 in Figures 7a and 7b has a first flexible membrane 300 disposed in the oscillating line 14 and a second flexible membrane 303 situated to selectively close the end 132 of the outlet line 50. The flexible membranes 300, 303 are connected by a pressure communication line 306. The pressure communication line 306 may be filled with a gas or a fluid. When the pressure in the pressure communication line 306 is above the pressure in outlet line 50, the end 132 of the outlet line 50 is closed by the second flexible membrane 303. When the pressure in the outlet line 50 is above the pressure in the pressure communication line 306, gas is allowed to escape from the end 132 of the outlet line 50. It will be recognized that due to the first flexible membrane 300, the pressure in oscillating line 14 will change the pressure in the pressure communication line 306.

In a preferred embodiment, a control pressure line 309 is connected to the pressure communication line 306. When the control pressure line 309 is provided, the pressure in the pressure communication line 306 may be changed, and thereby, the pressure in the outlet line 50 required to open the end 132 of the outlet line 50 may be changed.

In another embodiment of the invention shown in Figures 9a, 9b and 9c, device 10 may be connected to an U-type oscillator tube (termed herein as a connecting tube) of the prior art. The U-type tubes typically have a gas supply line and an outlet valve or means. In this embodiment, the device has a gas flow circuit comprising an oscillating line, a patient line and a return line. The first end of the oscillating line 14 is adapted for communication with a connector 402 of the U-type oscillator tube 400 as indicated by dotted lines 404. The second end of the oscillating line 14 is connected to patient line 25. A return line 67 is provided for return of exhaled air. The return line at both ends is connected to the oscillating line. On the oscillating line between the ends of the return line is located check valve 20 to move the gas toward patient line 25. A CO₂ scrubber 38 is located in the return line (Figure 9a) or in the oscillating line (Figure 9b). In a preferred embodiment (Figure 9a), another check valve 42 is provided in the return line. The device may also have a gas supply line and an outlet valve. For use of this device directly with an oscillating ventilator 410 as indicated by dotted lines 404 (Figure 9d), a gas supply line 8 having a flow regulator 9 is connected to any location in the gas flow circuit through connecting line 18. An outlet valve 52 may also be placed at any location in the gas flow circuit. One example of a location for the supply line 18 and outlet valve 52 is shown in Figure 9d. The scrubber canister 38 may be placed at any location in the oscillating line or return line, but is preferably placed in the return line. Optionally, as shown in Figure 9c, a second CO₂ scrubber canister 68 may be provided in another return line 66. Scrubber valves 70A and 70B operate as described above such that either scrubber canister 38 or scrubber canister 68 is in use. Oxygen and CO₂ sensors, and pressure monitoring devices can also be placed in the gas flow circuit as shown in Figures 1, 4a, 4b or 6.

To illustrate the concept of the present invention, mathematical relationships were developed for the device 10 shown in Figure 1. Tables 1-10 below list data corresponding to these mathematical relationships. In the tables:

VO₂ is the volume rate of oxygen consumed by the patient;

VI is the volume rate of inspiratory gas supplied to the device 10;

FiO_2 is the mole fraction of oxygen in the inspiratory gas;

FmO_2 is the mole fraction of oxygen in the mixed gas crossing inbound check valve 20;

5 $FiO_2 = 1 - FiN_2$, where FiN_2 is the mole fraction of nitrogen in the inspiratory gas;

$FmO_2 = 1 - FmN_2$, where FmN_2 is the mole fraction of nitrogen in the mixed gas exiting the outlet valve 52;

$VI = K + VO_2$, where K = outflow volume from outlet valve;

$VI \times FiN_2 = K \times FmN_2$;

10 $VI (1 - FiO_2) = K (1 - FmO_2)$;

$(VI \div K) (1 - FiO_2) = 1 - FmO_2$;

$FmO_2 = 1 - (VI \div K) (1 - FiO_2)$.

TABLE 1

VO_2 ml/kg/ min	VI ml/kg/ min	FiO_2	FmO_2	$FmO_2 \div$ FiO_2	K ml/kg/ min	$Vi \div VO_2$
5.0	6.0	0.21	-3.74	-17.81	1.0	1.2
5.0	10.0	0.21	-0.58	-2.76	5.0	2.0
5.0	20.0	0.21	-0.05	-0.25	15.0	4.0
5.0	30.0	0.21	0.05	0.25	25.0	6.0
5.0	40.0	0.21	0.10	0.46	35.0	8.0
5.0	50.0	0.21	0.12	0.58	45.0	10.0
5.0	60.0	0.21	0.14	0.66	55.0	12.0
5.0	70.0	0.21	0.15	0.71	65.0	14.0
5.0	80.0	0.21	0.16	0.75	75.0	16.0
5.0	90.0	0.21	0.16	0.78	85.0	18.0
5.0	100.0	0.21	0.17	0.80	95.0	20.0

5.0	200.0	0.21	0.19	0.90	195.0	40.0*
5.0	500.0	0.21	0.20	0.96	495.0	100.0
5.0	1000.0	0.21	0.21	0.98	995.0	200.0

TABLE 2

VO ₂ ml/kg/ min	VI ml/kg/ min	FiO ₂	FmO ₂	FmO ₂ ÷ FiO ₂	K ml/kg/ min	Vi ÷ VO ₂
5.0	6.0	0.30	-3.20	-10.67	1.0	1.2
5.0	10.0	0.30	-0.40	-1.33	5.0	2.0
5.0	20.0	0.30	0.07	0.22	15.0	4.0
5.0	30.0	0.30	0.16	0.53	25.0	6.0
5.0	40.0	0.30	0.20	0.67	35.0	8.0
5.0	50.0	0.30	0.22	0.74	45.0	10.0
5.0	60.0	0.30	0.24	0.79	55.0	12.0
5.0	70.0	0.30	0.25	0.82	65.0	14.0
5.0	80.0	0.30	0.25	0.84	75.0	16.0
5.0	90.0	0.30	0.26	0.86	85.0	18.0
5.0	100.0	0.30	0.26	0.88	95.0	20.0
5.0	200.0	0.30	0.28	0.94	195.0	40.0*
5.0	500.0	0.30	0.29	0.98	495.0	100.0
5.0	1000.0	0.30	0.30	0.99	995.0	200.0

TABLE 3

VO ₂ ml/kg/ min	VI ml/kg/ min	FiO ₂	FmO ₂	FmO ₂ ÷ FiO ₂	K ml/kg/ min	Vi ÷ VO ₂
5.0	6.0	0.40	-2.60	-6.50	1.0	1.2
5.0	10.0	0.40	-0.20	-0.50	5.0	2.0
5.0	20.0	0.40	0.20	0.50	15.0	4.0

5.0	30.0	0.40	0.28	0.70	25.0	6.0
5.0	40.0	0.40	0.31	0.79	35.0	8.0
5.0	50.0	0.40	0.33	0.83	45.0	10.0
5.0	60.0	0.40	0.35	0.86	55.0	12.0
5.0	70.0	0.40	0.35	0.88	65.0	14.0
5.0	80.0	0.40	0.36	0.90	75.0	16.0*
5.0	90.0	0.40	0.36	0.91	85.0	18.0
5.0	100.0	0.40	0.37	0.92	95.0	20.0
5.0	200.0	0.40	0.38	0.96	195.0	40.0
5.0	500.0	0.40	0.39	0.98	495.0	100.0
5.0	1000.0	0.40	0.40	0.99	995.0	200.0

TABLE 4

VO ₂ ml/kg/ min	VI ml/kg/ min	FiO ₂	FmO ₂	FmO ₂ ÷ FiO ₂	K ml/kg/ min	Vi ÷ VO ₂
5.0	6.0	0.50	-2.00	-4.00	1.0	1.2
5.0	10.0	0.50	0.00	0.00	5.0	2.0
5.0	20.0	0.50	0.33	0.67	15.0	4.0
5.0	30.0	0.50	0.40	0.80	25.0	6.0
5.0	40.0	0.50	0.43	0.86	35.0	8.0
5.0	50.0	0.50	0.44	0.89	45.0	10.0
5.0	60.0	0.50	0.45	0.91	55.0	12.0*
5.0	70.0	0.50	0.46	0.92	65.0	14.0
5.0	80.0	0.50	0.47	0.93	75.0	16.0
5.0	90.0	0.50	0.47	0.94	85.0	18.0
5.0	100.0	0.50	0.47	0.95	95.0	20.0
5.0	200.0	0.50	0.49	0.97	195.0	40.0
5.0	500.0	0.50	0.49	0.99	495.0	100.0
5.0	1000.0	0.50	0.50	0.99	995.0	200.0

TABLE 5

VO ₂ ml/kg/ min	VI ml/kg/ min	FiO ₂	FmO ₂	FmO ₂ ÷ FiO ₂	K ml/kg/ min	Vi÷VO ₂
5.0	6.0	0.60	-1.40	-2.33	1.0	1.2
5.0	10.0	0.60	0.20	0.33	5.0	2.0
5.0	20.0	0.60	0.47	0.78	15.0	4.0
5.0	30.0	0.60	0.52	0.87	25.0	6.0
5.0	40.0	0.60	0.54	0.90	35.0	8.0*
5.0	50.0	0.60	0.56	0.93	45.0	10.0
5.0	60.0	0.60	0.56	0.94	55.0	12.0
5.0	70.0	0.60	0.57	0.95	65.0	14.0
5.0	80.0	0.60	0.57	0.96	75.0	16.0
5.0	90.0	0.60	0.58	0.96	85.0	18.0
5.0	100.0	0.60	0.58	0.96	95.0	20.0
5.0	200.0	0.60	0.59	0.98	195.0	40.0
5.0	500.0	0.60	0.60	0.99	495.0	100.0
5.0	1000.0	0.60	0.60	1.00	995.0	200.0

TABLE 6

VO ₂ ml/kg/ min	VI ml/kg/ min	FiO ₂	FmO ₂	FmO ₂ ÷ FiO ₂	K ml/kg/ min	Vi÷VO ₂
5.0	6.0	0.70	-0.80	-1.14	1.0	1.2
5.0	10.0	0.70	0.40	0.57	5.0	2.0
5.0	20.0	0.70	0.60	0.86	15.0	4.0
5.0	30.0	0.70	0.64	0.91	25.0	6.0*
5.0	40.0	0.70	0.67	0.94	35.0	8.0
5.0	50.0	0.70	0.67	0.95	45.0	10.0
5.0	60.0	0.70	0.68	0.96	55.0	12.0

5.0	70.0	0.70	0.68	0.97	65.0	14.0
5.0	80.0	0.70	0.68	0.97	75.0	16.0
5.0	90.0	0.70	0.68	0.97	85.0	18.0
5.0	100.0	0.70	0.68	0.98	95.0	20.0
5.0	200.0	0.70	0.69	0.99	195.0	40.0
5.0	500.0	0.70	0.70	1.00	495.0	100.0
5.0	1000.0	0.70	0.70	1.00	995.0	200.0

TABLE 7

VO ₂ ml/kg/ min	VI ml/kg/ min	FiO ₂	FmO ₂	FmO ₂ ÷ FiO ₂	K ml/kg/ min	Vi ÷ VO ₂
5.0	6.0	0.80	-0.20	-0.25	1.0	1.2
5.0	10.0	0.80	0.60	0.75	5.0	2.0
5.0	20.0	0.80	0.73	0.92	15.0	4.0*
5.0	30.0	0.80	0.76	0.95	25.0	6.0
5.0	40.0	0.80	0.77	0.96	35.0	8.0
5.0	50.0	0.80	0.78	0.97	45.0	10.0
5.0	60.0	0.80	0.78	0.98	55.0	12.0
5.0	70.0	0.80	0.78	0.98	65.0	14.0
5.0	80.0	0.80	0.79	0.98	75.0	16.0
5.0	90.0	0.80	0.79	0.99	85.0	18.0
5.0	100.0	0.80	0.79	0.99	95.0	20.0
5.0	200.0	0.80	0.79	0.99	195.0	40.0
5.0	500.0	0.80	0.80	1.00	495.0	100.0
5.0	1000.0	0.80	0.80	1.00	995.0	200.0

TABLE 8

VO ₂ ml/kg/	VI ml/kg/	FiO ₂	FmO ₂	FmO ₂ ÷ FiO ₂	K ml/kg/	Vi ÷ VO ₂
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min	min				min	
5.0	6.0	0.90	0.40	0.44	1.0	1.2
5.0	10.0	0.90	0.80	0.89	5.0	2.0
5.0	20.0	0.90	0.87	0.96	15.0	4.0*
5.0	30.0	0.90	0.88	0.98	25.0	6.0
5.0	40.0	0.90	0.89	0.98	35.0	8.0
5.0	50.0	0.90	0.89	0.99	45.0	10.0
5.0	60.0	0.90	0.89	0.99	55.0	12.0
5.0	70.0	0.90	0.89	0.99	65.0	14.0
5.0	80.0	0.90	0.89	0.99	75.0	16.0
5.0	90.0	0.90	0.89	0.99	85.0	18.0
5.0	100.0	0.90	0.89	0.99	95.0	20.0
5.0	200.0	0.90	0.90	1.00	195.0	40.0
5.0	500.0	0.90	0.90	1.00	495.0	100.0
5.0	1000.0	0.90	0.90	1.00	995.0	200.0

TABLE 9

VO ₂ ml/kg/ min	VI ml/kg/ min	FiO ₂	FmO ₂	FmO ₂ ÷ FiO ₂	K ml/kg/ min	Vi ÷ VO ₂
5.0	6.0	1.00	1.00	1.00	1.0	1.2*
5.0	10.0	1.00	1.00	1.00	5.0	2.0
5.0	20.0	1.00	1.00	1.00	15.0	4.0
5.0	30.0	1.00	1.00	1.00	25.0	6.0
5.0	40.0	1.00	1.00	1.00	35.0	8.0
5.0	50.0	1.00	1.00	1.00	45.0	10.0
5.0	60.0	1.00	1.00	1.00	55.0	12.0
5.0	70.0	1.00	1.00	1.00	65.0	14.0
5.0	80.0	1.00	1.00	1.00	75.0	16.0
5.0	90.0	1.00	1.00	1.00	85.0	18.0

5.0	100.0	1.00	1.00	1.00	95.0	20.0
5.0	200.0	1.00	1.00	1.00	195.0	40.0
5.0	500.0	1.00	1.00	1.00	495.0	100.0
5.0	1000.0	0.00	1.00	1.00	995.0	200.0

TABLE 10

VO ₂ ml/kg/ min	VI ml/kg/ min	FiO ₂	FmO ₂	FmO ₂ ÷ FiO ₂	K ml/kg/ min	VI÷VO ₂	Tolerance
5.0	200.0	0.21	0.19	0.90	195.0	40.0	10%
5.0	200.0	0.30	0.28	0.94	195.0	40.0	10%
5.0	80.0	0.40	0.36	0.90	75.0	16.0	10%
5.0	60.0	0.50	0.45	0.91	55.0	12.0	10%
5.0	40.0	0.60	0.54	0.90	35.0	8.0	10%
5.0	30.0	0.70	0.64	0.91	25.0	6.0	10%
5.0	20.0	0.80	0.73	0.92	15.0	4.0	10%
5.0	20.0	0.90	0.87	0.96	15.0	4.0	10%
5.0	6.0	1.00	1.00	1.00	1.0	0.83	10%

Tables 1-9 illustrate the FmO₂ achieved at various inspiratory gas flow rates (VI) assuming an oxygen consumption rate of 5 ml/kg/min. An asterisk in the column labeled VI/VO₂ indicates the minimum flow rate of inspiratory gas needed to achieve an FmO₂ that is within 10% of the corresponding FiO₂. The inspiratory gas corresponding to Table 1 was air (21% oxygen). As seen in Table 1, an inspiratory gas flow rate of 50 ml/kg/min results in the fraction of O₂ in the mixed gas (mixture of inspiratory gas and scrubbed exhaled gas) to be about 0.12. Thus, the ratio of FmO₂ to FiO₂ is about 0.58. To achieve the fraction of oxygen in the mixed gas (FmO₂) to be within 10% of the FiO₂, a flow rate of inspiratory gas of 200 ml/min is needed.

Tables 2-9 illustrate the flow rate of inspiratory gas required for FiO_2 values of 0.3 (30% oxygen) to 1.0 (pure oxygen). With a higher percentage of oxygen in the inspiratory gas, a lower flow of inspiratory gas is needed to achieve the same ratio of FmO_2 to FiO_2 . For example to achieve an FmO_2 value that is within 10% of FiO_2 , for gas containing 21% oxygen (air) an inspiratory gas flow rate of 200 ml/min is required, whereas for inspiratory gas containing 80% oxygen, a 10 times lower inspiratory gas flow rate (20 ml/kg/min) is required (Table 7). Table 10 presents a composite of inspiratory gas flow rates for various concentrations of oxygen in the inspiratory gas to achieve an FmO_2 value that is within 10% of the FiO_2 (10% tolerance level). As seen in Table 10, to deliver a desired concentration of oxygen to the patient line 25, one could adjust the inspiratory gas flow keeping the FiO_2 constant, or one could adjust the FiO_2 keeping the inspiratory gas flow rate constant.

The data presented in these tables illustrates that by using the device of the present invention, inspiratory gas flow rates can be reduced to 6 to 200 ml/kg/min. This compares to an inspiratory gas flow rate of approximately 1000 to 2000 ml/kg/min required with currently available high frequency oscillatory ventilators.

Figure 8 shows steps of a method according to the present invention. In the method, a ventilating device, such as the device 10 described above, is provided (step 200). In addition, a patient connected to the patient line is provided (step 203) and gas is supplied with the gas supply line to the oscillating line (step 206). The oscillator is moved toward the oscillating line and the outlet valve is opened (step 209). Then, the oscillator is moved away from the oscillating line and the outlet valve is closed (step 212). Preferably, the gas is supplied to the oscillating line at approximately a constant flow rate.

Devices and methods according to the present invention are more efficient than currently available high frequency oscillating ventilators primarily because the present invention substantially reduces the need for bias flow. This reduction in bias flow enables smaller ventilation systems. It is now clear the device and method of the present invention reduces the volume of bias flow required for safe ventilation.

By using the present device, it is believed the volume of inspiratory gas delivered to the ventilator can be reduced from 20,000 to 80,000 ml/min to as little as 20 to 800 ml/min.

5 Another advantage of the present invention may be to counter the loss of mean lung volume associated with prolonged oscillatory ventilation, which is believed to be a problem with this form of mechanical ventilation. It is currently believed by some that this problem might be intensified by reductions in inspiratory gas flow. One approach to this problem that may counter a tendency to lose mean lung volume and thus preserve lung expansion involves redirection of some or all of the inspiratory gas flow to a small channel adapted to the endotracheal tube to allow
10 delivery of some or all of the bias flow directly to the trachea. While potentially hazardous at high (conventional) inspiratory gas flow rates, it is believed that this would be safe at the lower inspiratory gas flow rates envisioned for this invention. Moreover, it is recognized that there might be some advantage to redirecting some or all of the inspiratory gas flow to the distal trachea (closer to the lungs) even when
15 practicing oscillation using conventional high flow rates of inspiratory gas. Redirection of some or all of the inspiratory gas to the trachea would trap inspiratory gas in the lung during the inspiratory phase of the cycle, and release it to the device
10 at lower pressure during the expiratory phase. This should aid in the expansion of an atelectatic or de-recruited lung.
20

Although embodiments of the invention have been described herein, the invention is not limited to such embodiments. The claims which follow are directed to the invention, and are intended to further describe the invention, but are not intended to limit the scope of the invention.

What is claimed is:

1. A device for attachment to an oscillating ventilator comprising a gas flow circuit comprising:

5 an oscillating line having a first end and a second end, wherein the first end is adapted for communication with an oscillator through a connecting tube;

a patient line connected to the second end of the oscillating line;

a return line, wherein both ends of the return line are connected to the oscillating line;

10 a check valve in the oscillating line located between the two ends of the return line; and

a CO₂ scrubber located in the oscillating line or return line.

2. The device of claim 1, wherein the CO₂ scrubber is located in the return line.

15 3. The device of claim 1, wherein the CO₂ scrubber is located in the oscillating line.

4. The device of claim 1 wherein the return line has a check valve.

20 5. The device of claim 1, wherein the CO₂ scrubber comprises a compound selected from the group consisting of sodium hydroxide, calcium hydroxide, barium hydroxide and combinations thereof.

25 6. The device of claim 1, wherein the gas flow circuit further comprises oxygen and CO₂ sensors.

7. The device of claim 1, further comprising a pressure gauge connected to the gas flow circuit.

30 8. The device of claim 1, further comprising a gas supply line connected to the oscillating line or the patient line.

9. The device of claim 1 further comprising an outlet valve.

10. A device for attachment to an oscillating ventilator comprising:

5

a) a gas flow circuit comprising:

an oscillating line having a first end and a second end, wherein the first end is adapted for pneumatic communication with an oscillator;

a patient line connected to the second end of the oscillating line;

10 a return line, wherein both ends of the return line are connected to the oscillating line;

a check valve in the oscillating line located between the two ends of the return line;

a CO₂ scrubber located in the oscillating line or return line.

15 b) a gas supply line in pneumatic communication with the gas flow circuit; and

c) an outlet valve in pneumatic communication with the gas flow circuit

11. The device of claim 10, wherein the CO₂ scrubber is located in the return line.

20

12. The device of claim 10, wherein the CO₂ scrubber is located in the oscillating line.

13. The device of claim 10 further comprising a bypass line, wherein both ends of the bypass line are connected to the oscillating line.

25

14. The device of claim 13, wherein the bypass line has a CO₂ scrubber.

15. The device of claim 10 wherein the gas supply line is connected to the oscillating line.

30

16. The device of claim 10, wherein the outlet valve is connected to the oscillating line.

5 17. The device of claim 10 wherein the CO₂ scrubber comprises a compound selected from the group consisting of sodium hydroxide, calcium hydroxide, barium hydroxide and combinations thereof.

10 18. The device of claim 10, wherein the gas flow circuit further comprises oxygen and CO₂ sensors.

19. The device of claim 10 further comprising a pressure gauge connected to the gas flow circuit.

15 20. A device for attaching to an oscillating ventilator comprising:
a) a gas flow circuit comprising:
an oscillating line having a first end and a second end, the first end is adapted for connecting to the oscillating ventilator and having a check valve;
a patient line connected to the second end of the oscillating line; and
an exhalation line having one end connected to the patient line and the other
20 end connected to the oscillating line and having a CO₂ scrubber;
b) a gas supply line in pneumatic communication with the gas flow circuit; and
c) an outlet valve in pneumatic communication with the gas flow circuit.

25 21. The gas flow circuit of claim 20 further comprising a check valve in the exhalation line.

30 22. The device of claim 20, wherein the outlet valve is connected to the oscillating line.

23. The device of claim 20 further comprising a recirculation line between the exhalation line and the oscillating line.

24. The device of claim 20, further comprising a bypass line connected to the exhalation line.

5 25. The device of claim 24 wherein the bypass line has a CO₂ scrubber.

26. A method of ventilating, comprising the steps of:

providing a ventilating device having an oscillator, a gas flow circuit comprising an oscillating line including a first end and a second end, wherein the
10 first end is in pneumatic relationship with the oscillator and the second end is connected to a patient line, an exhalation line having a CO₂ scrubber and connected to the patient line at one end and to the oscillating line at the other end, and further having a gas supply line and an outlet valve connected to the gas flow circuit, and a CO₂ scrubber;

15 providing a patient connected to the patient line;

supplying gas with the gas supply line to the gas flow circuit; and

causing the movement of the oscillator toward and away from the oscillating line.

20 27. The method of claim 26, wherein the gas supplied is a mixture of oxygen and nitrogen.

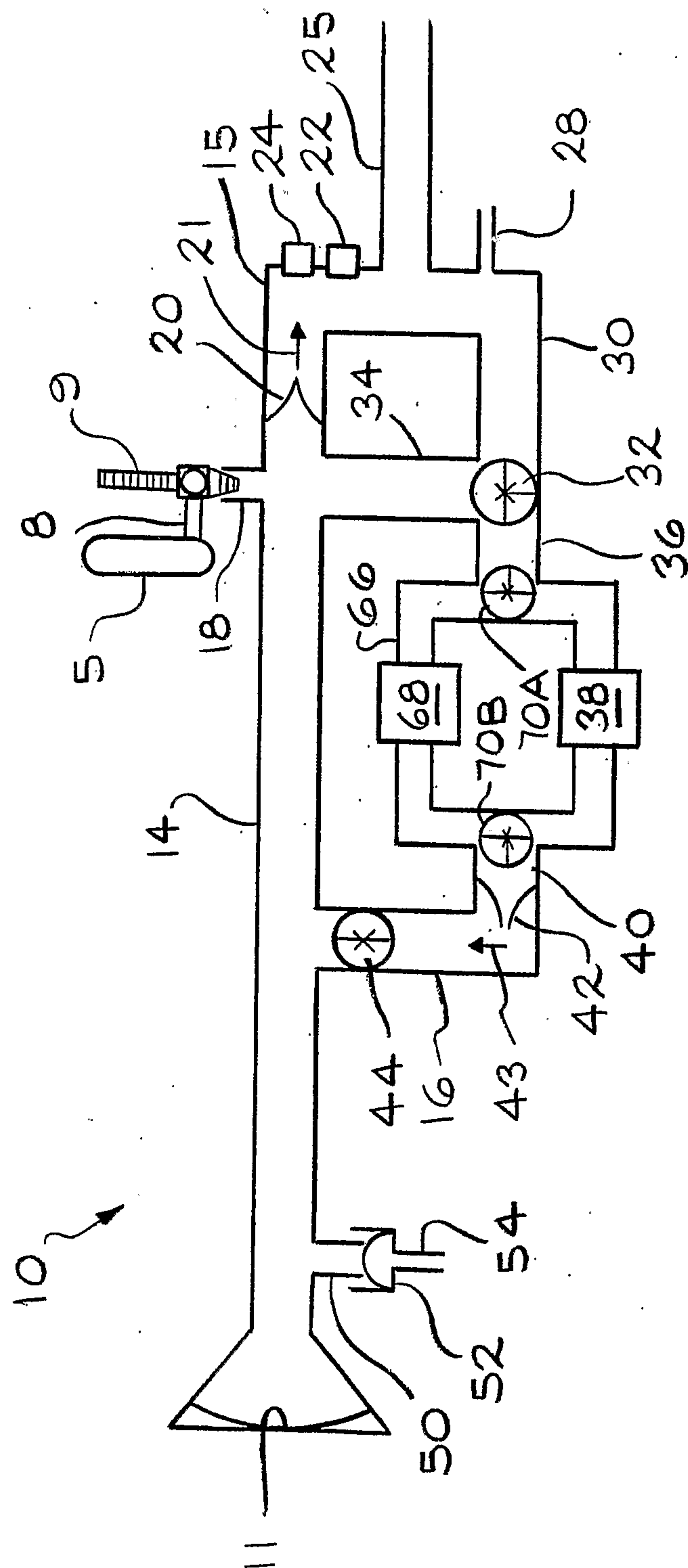


FIG. 1

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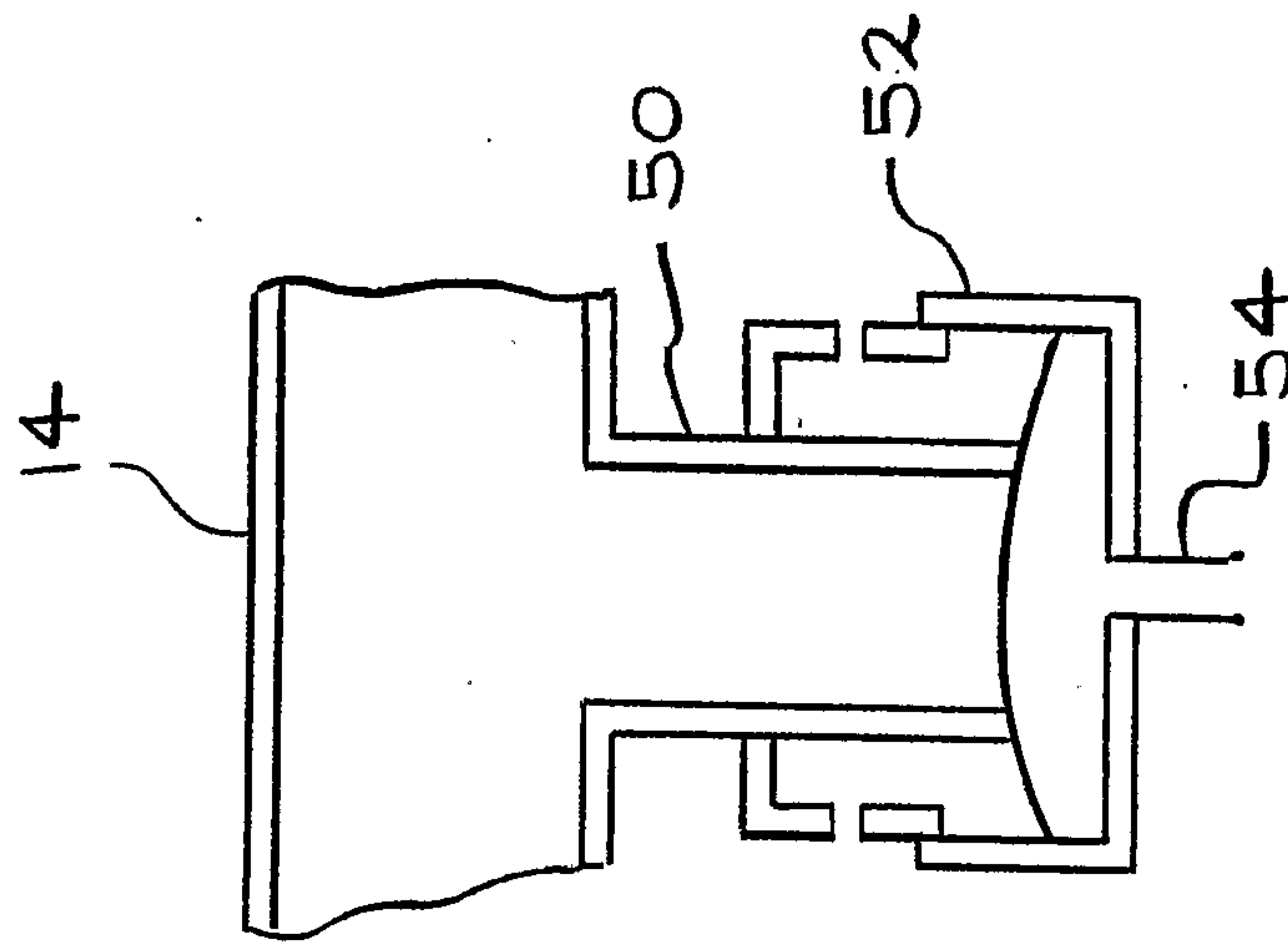


FIG. 2a

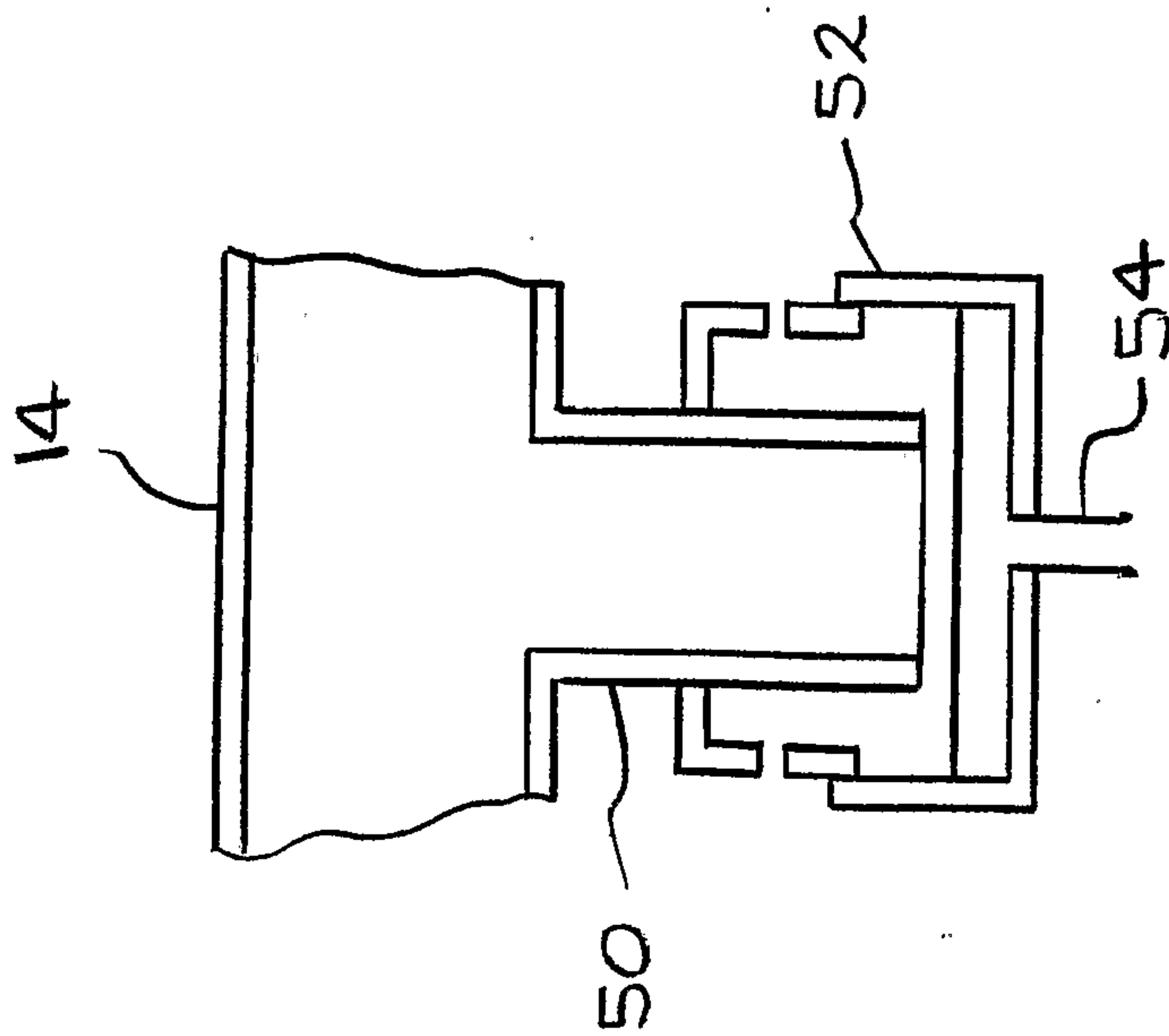


FIG. 2b

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FIG. 3a

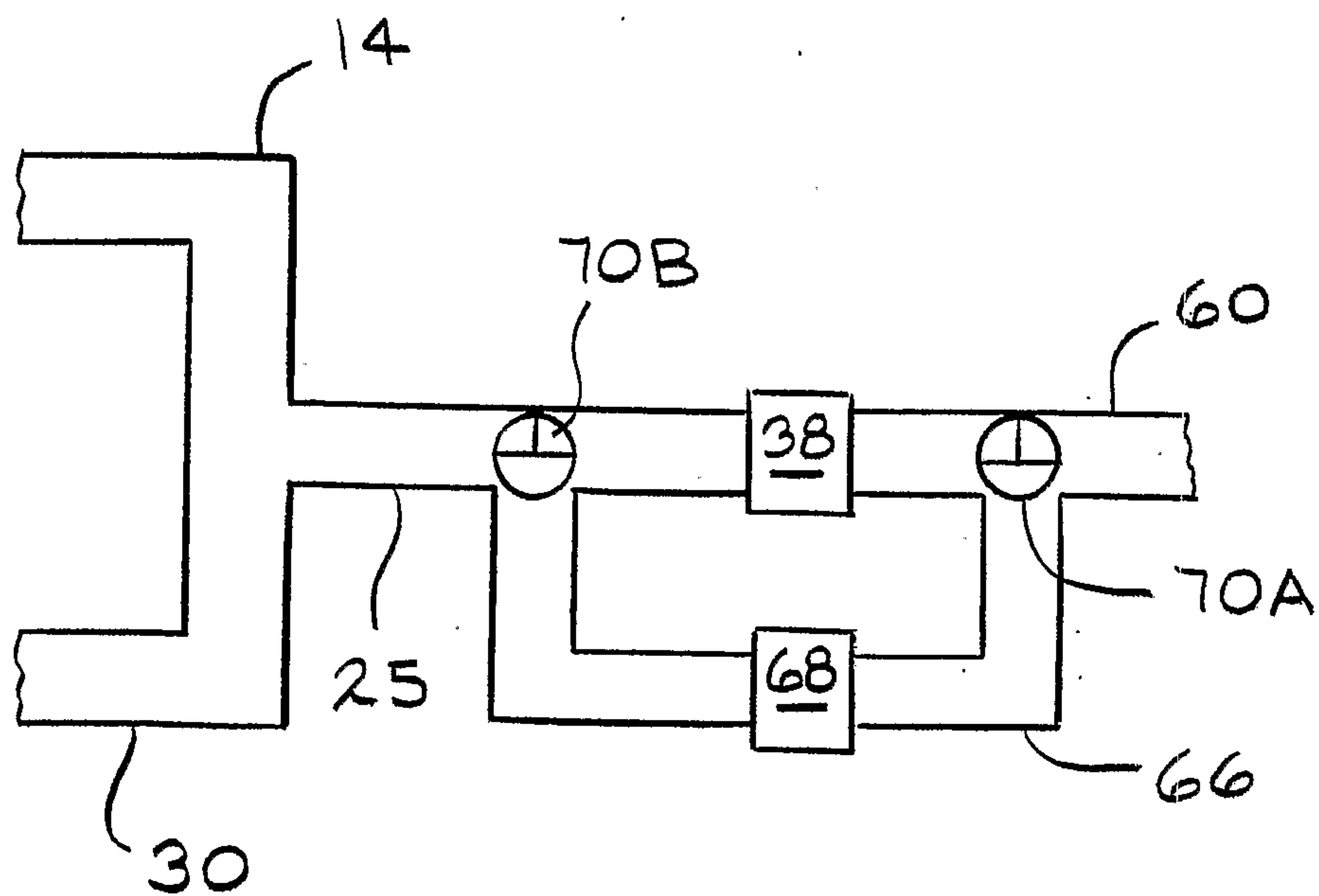
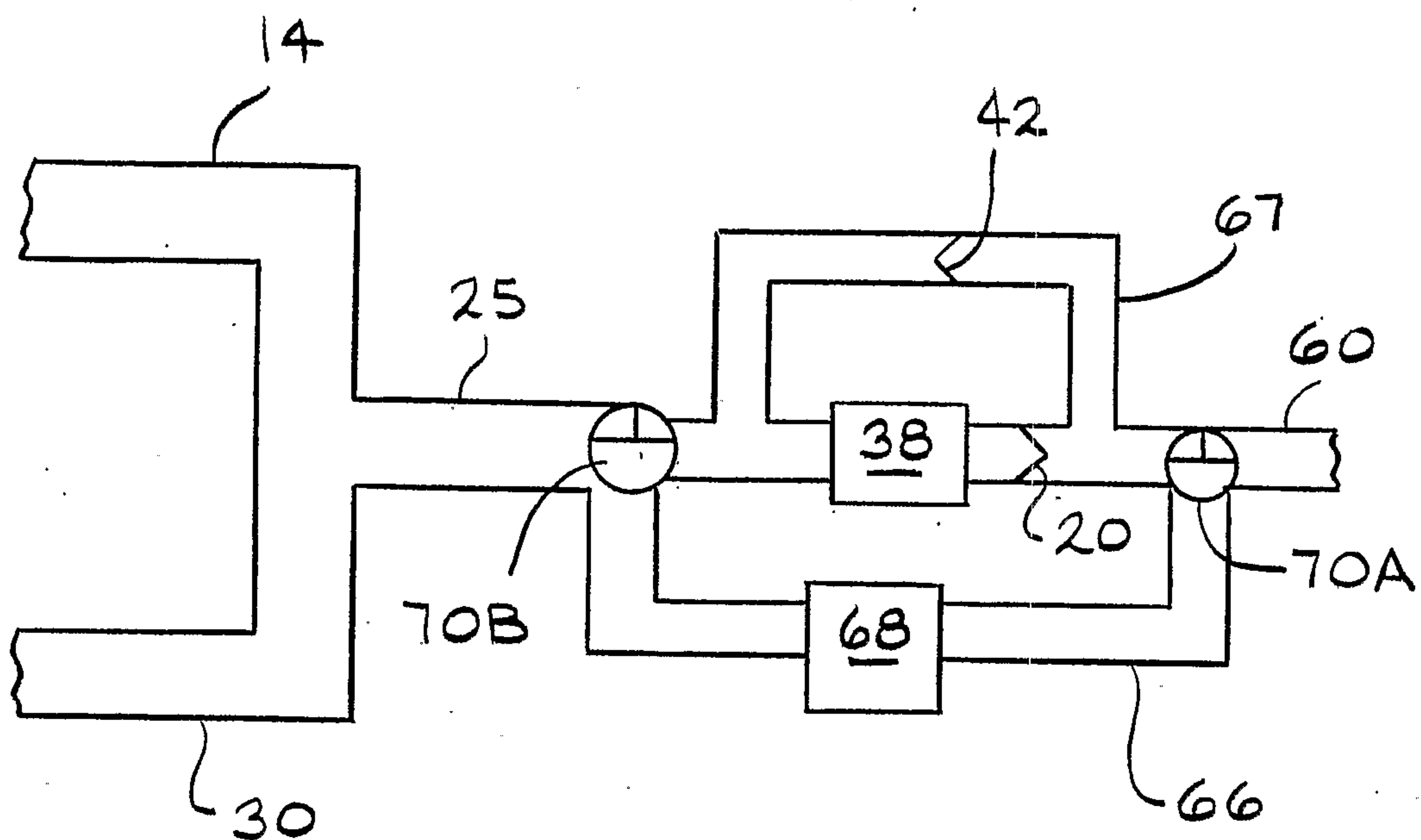
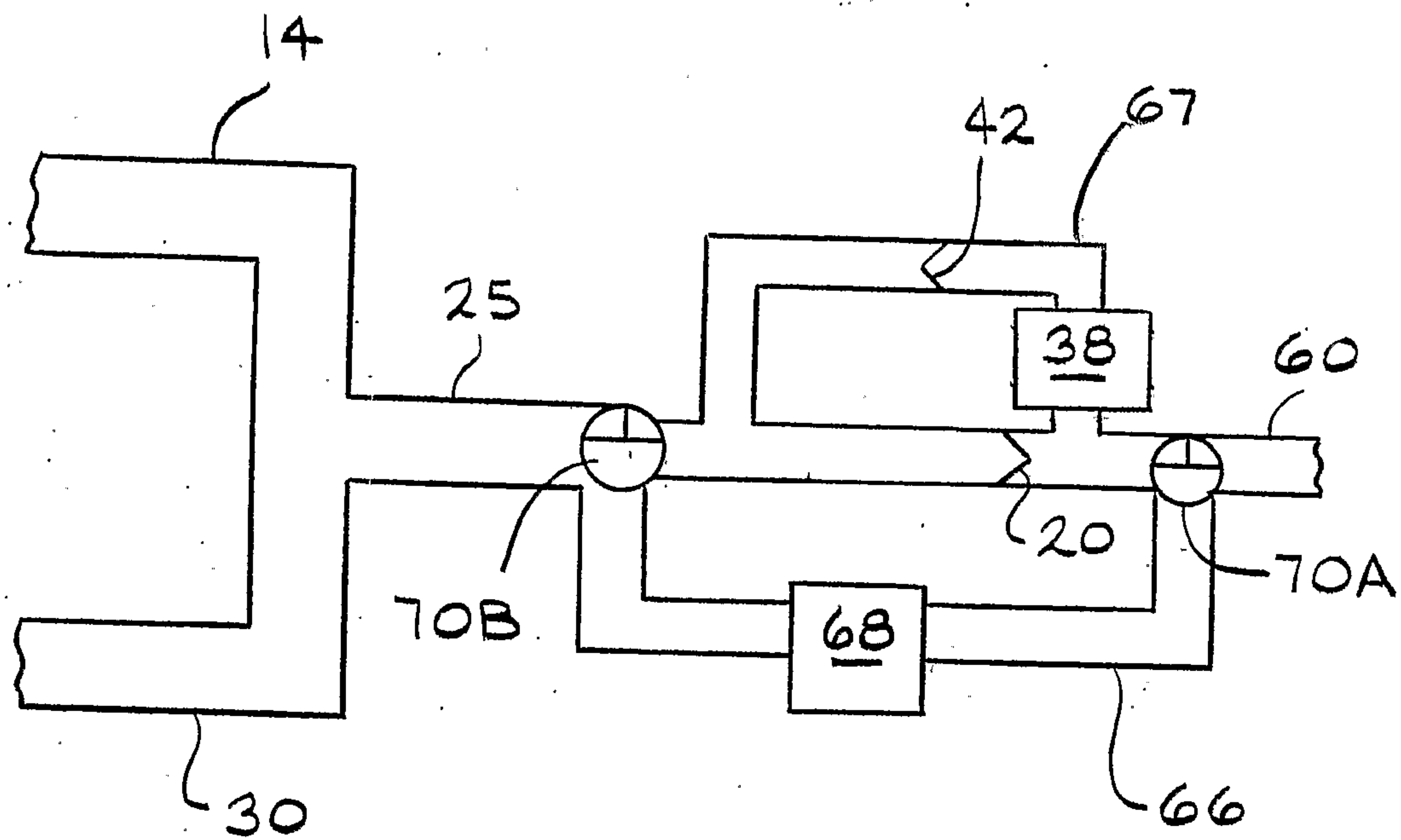


FIG. 3b

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FIG. 3c



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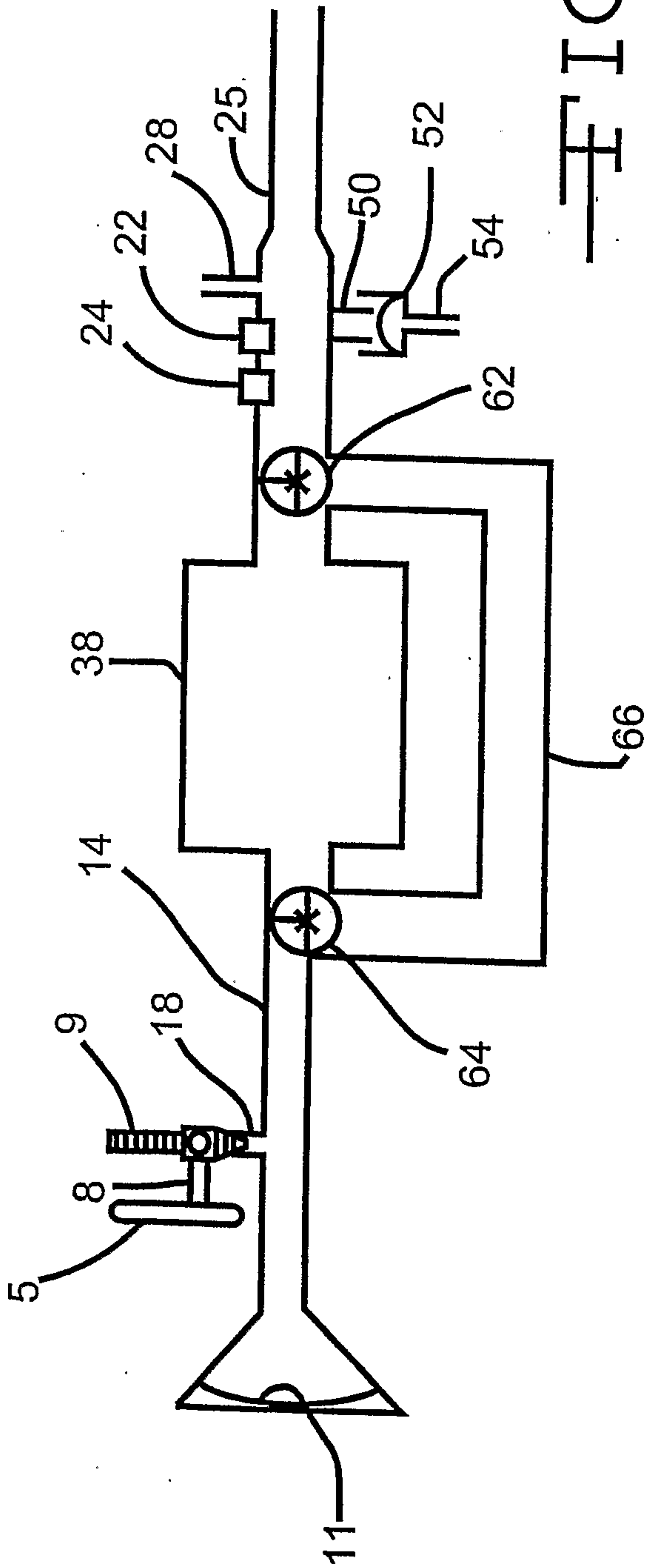


FIG. 4a

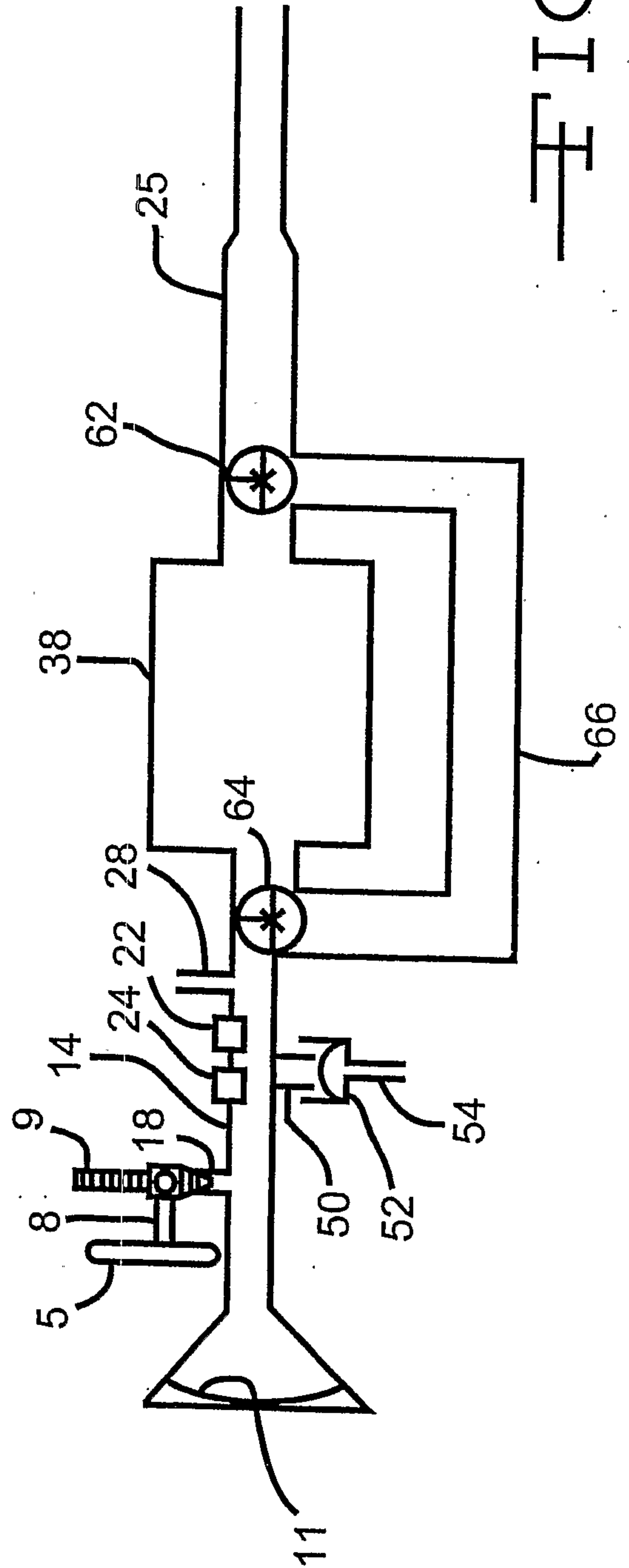


FIG. 4b

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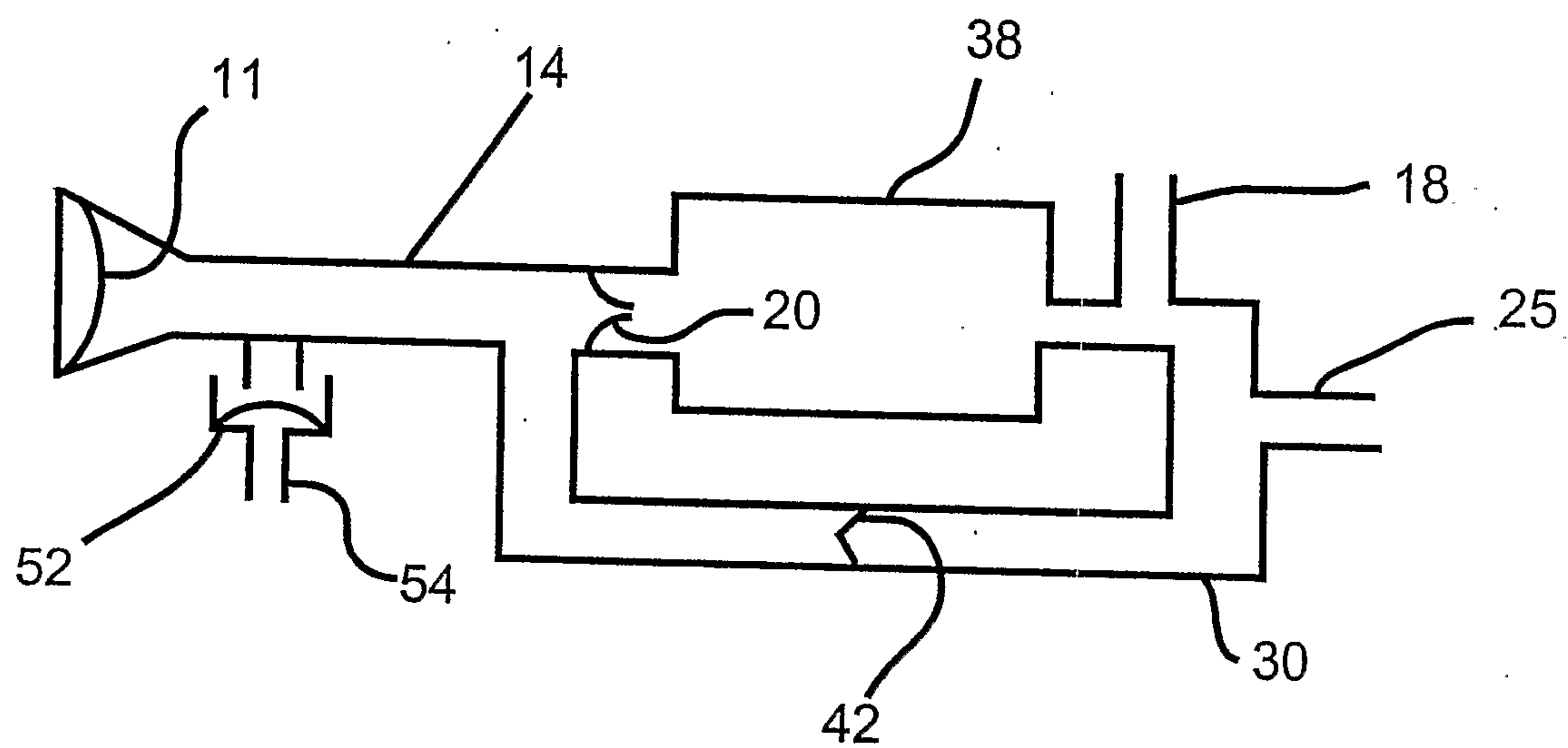


FIG. 5

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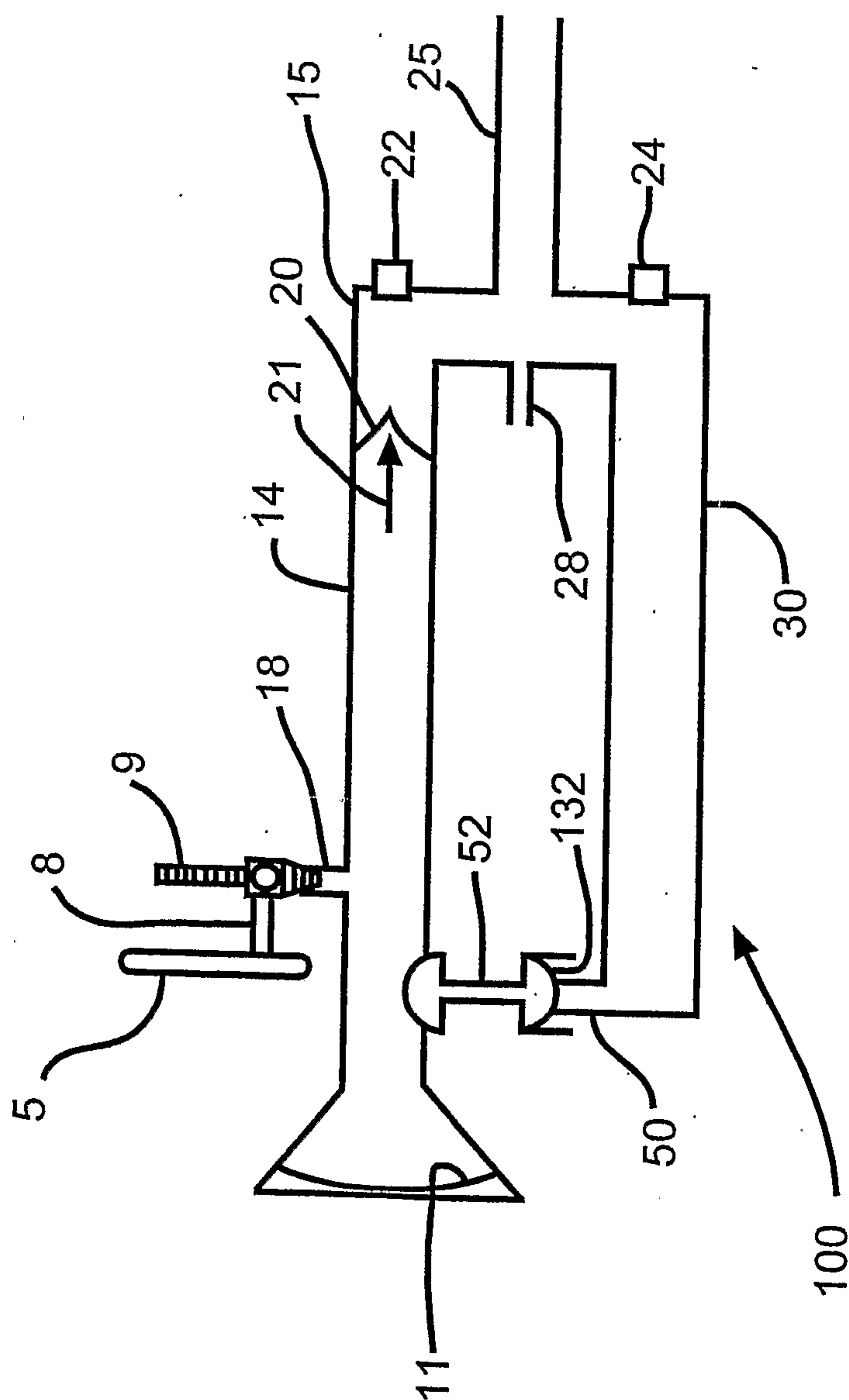


FIG. 6

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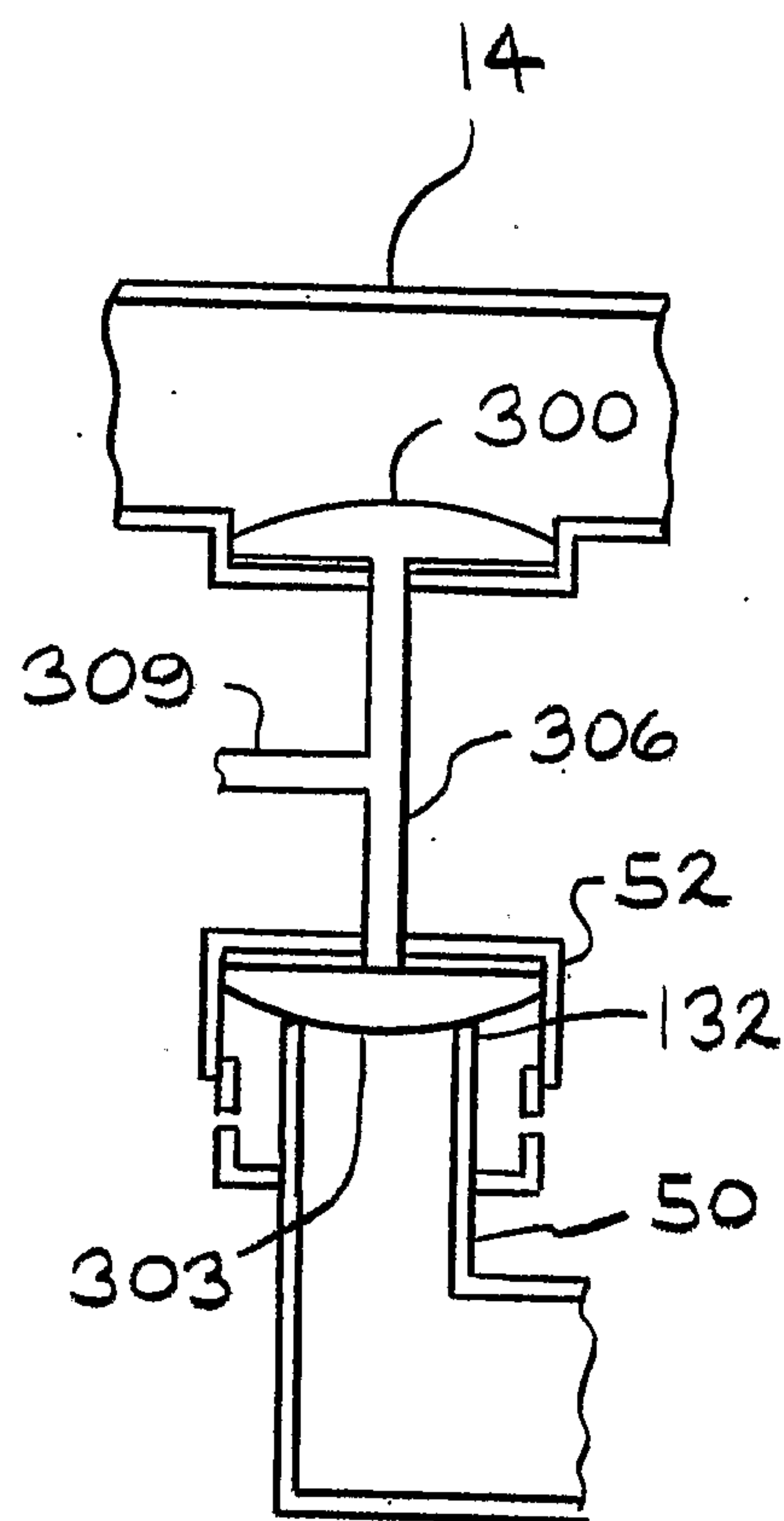


FIG. 7a

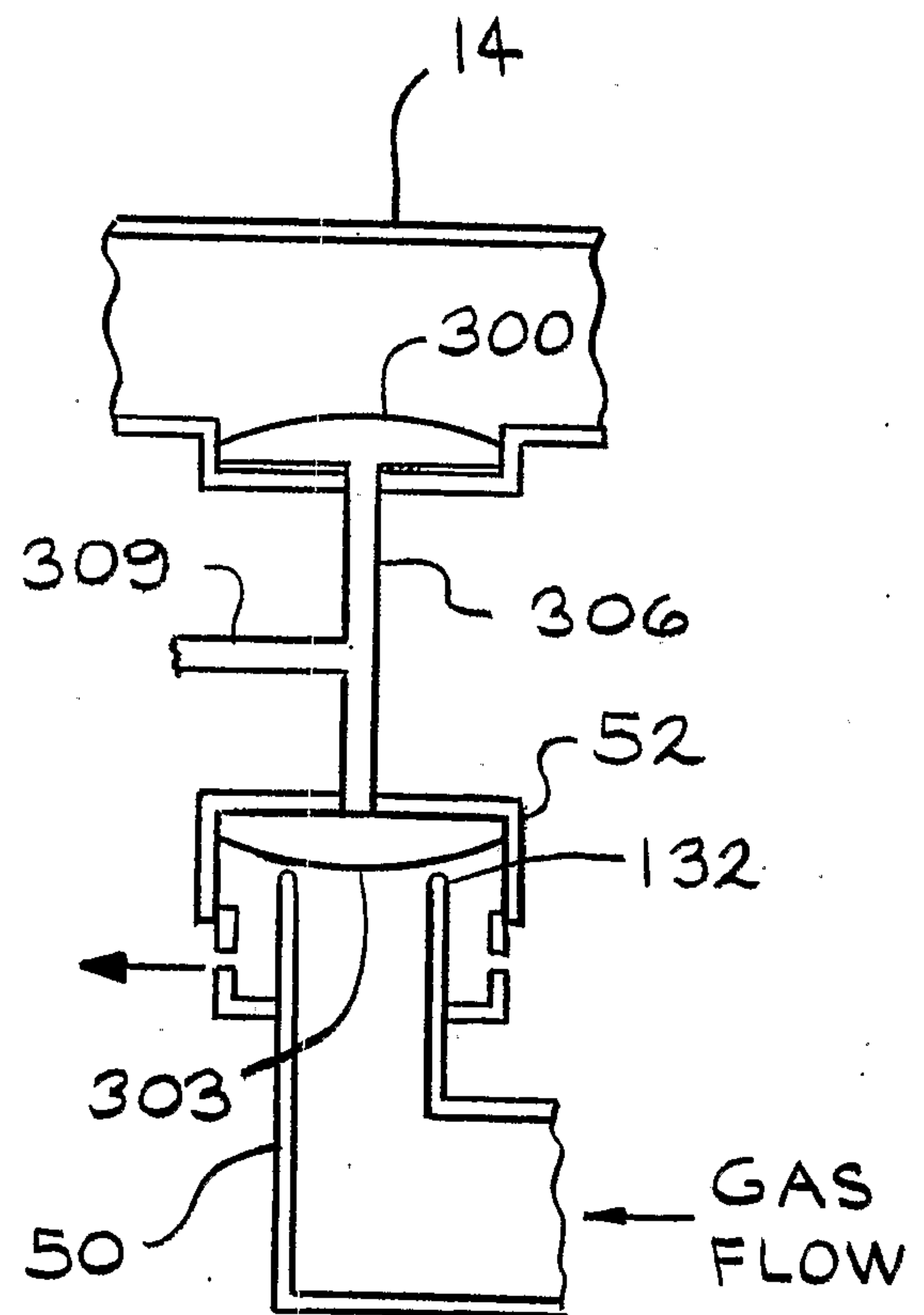
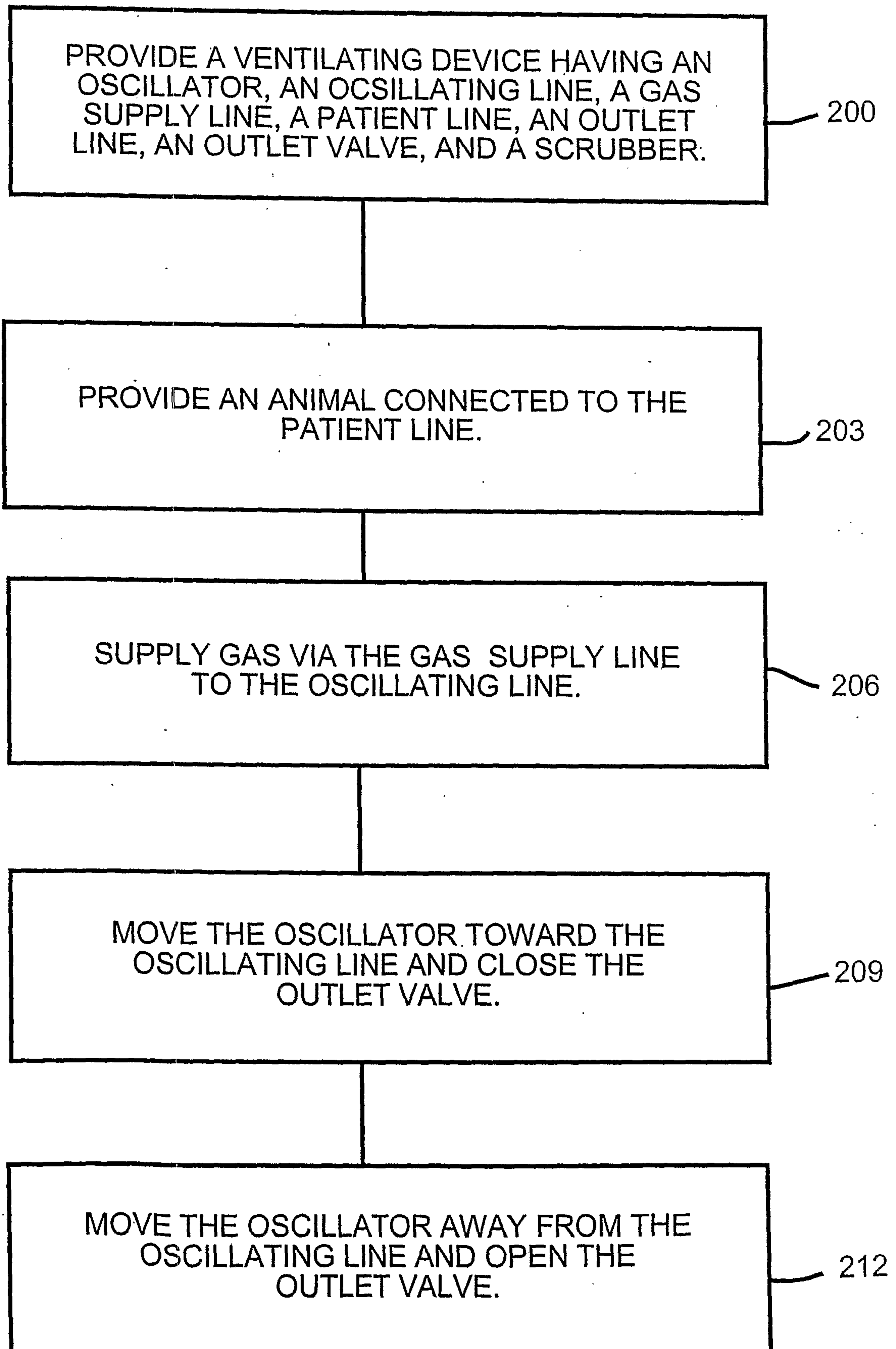


FIG. 7b

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—FIG. 8

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FIG. 9a

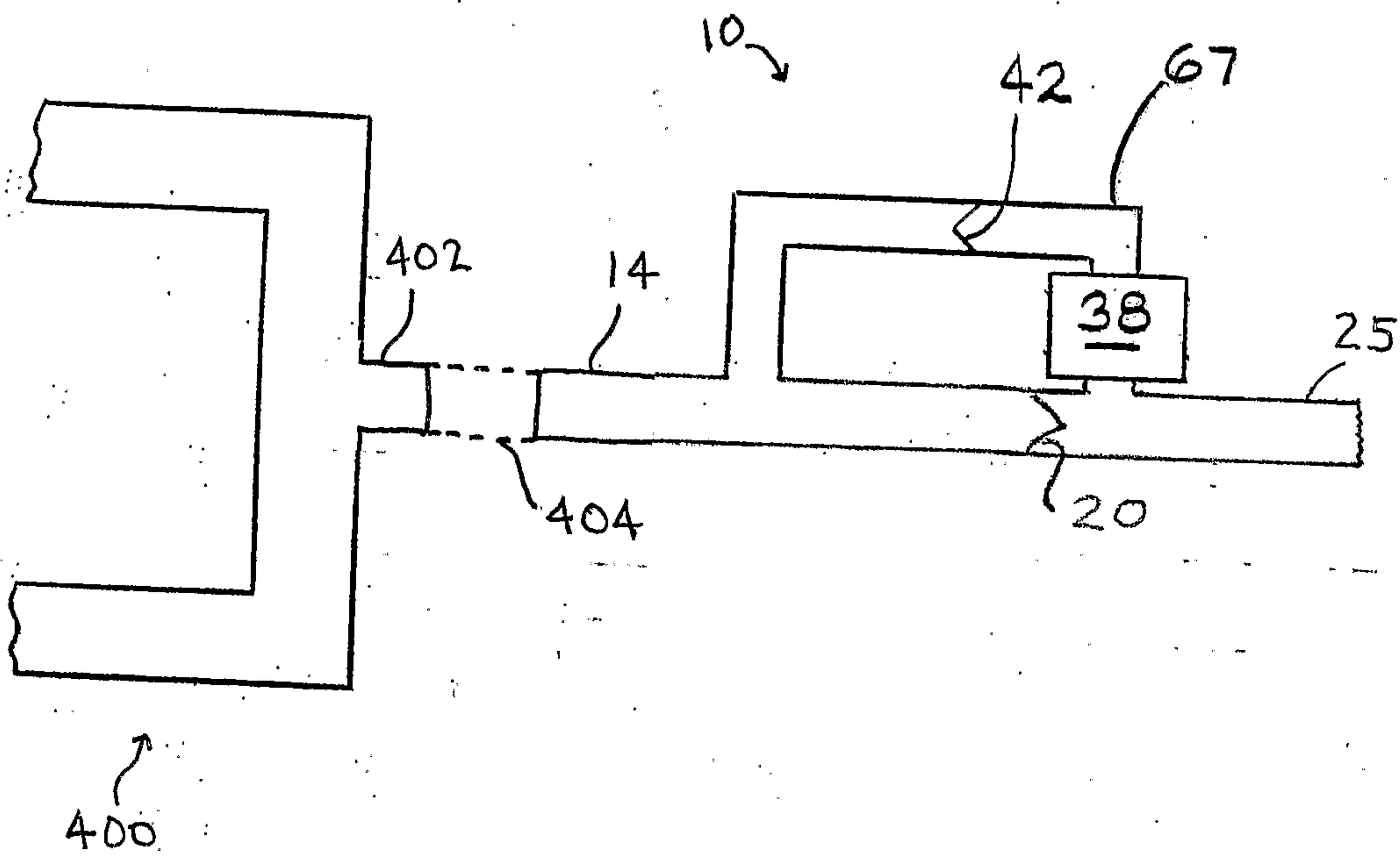
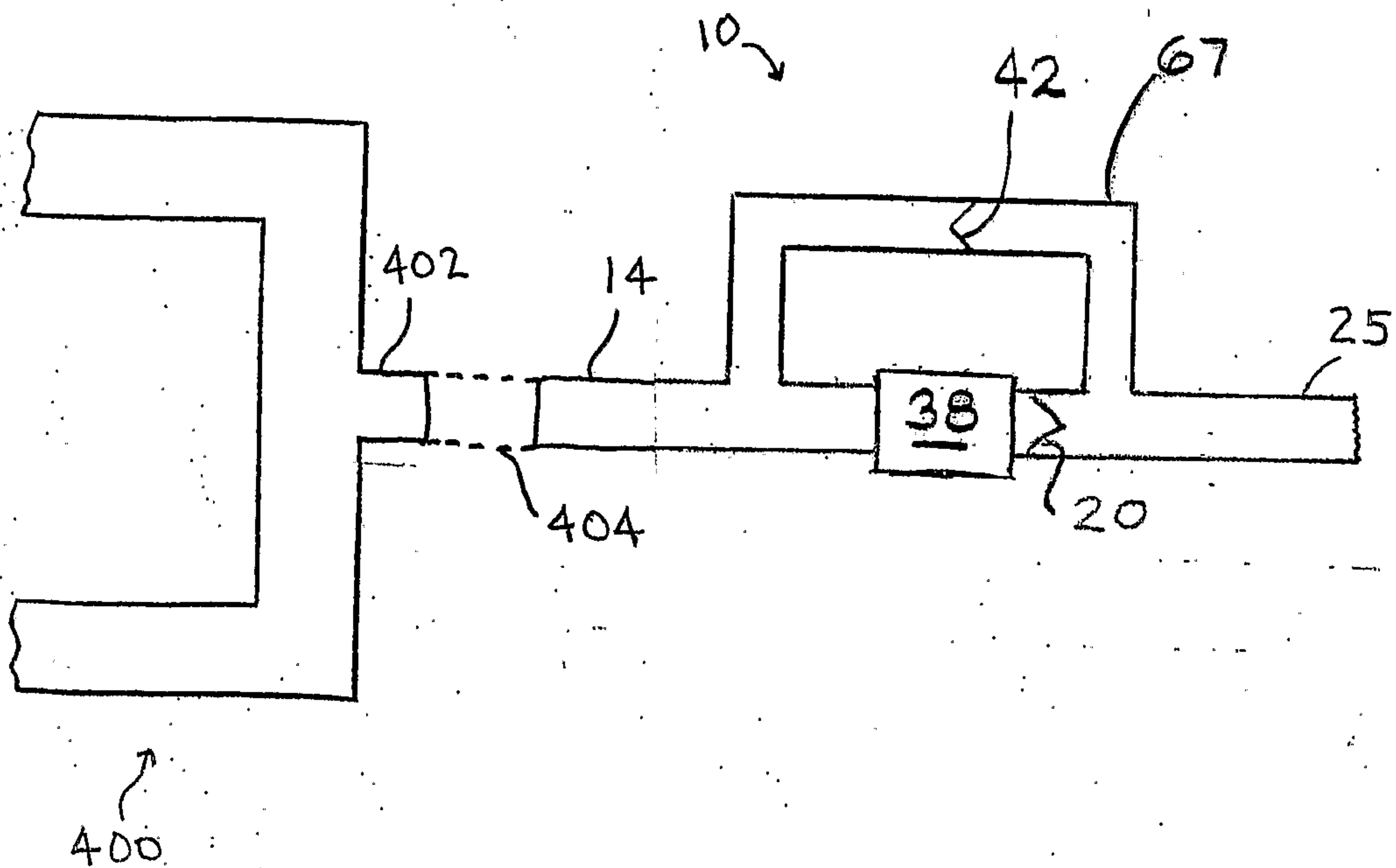


FIG. 9b



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FIG. 9c

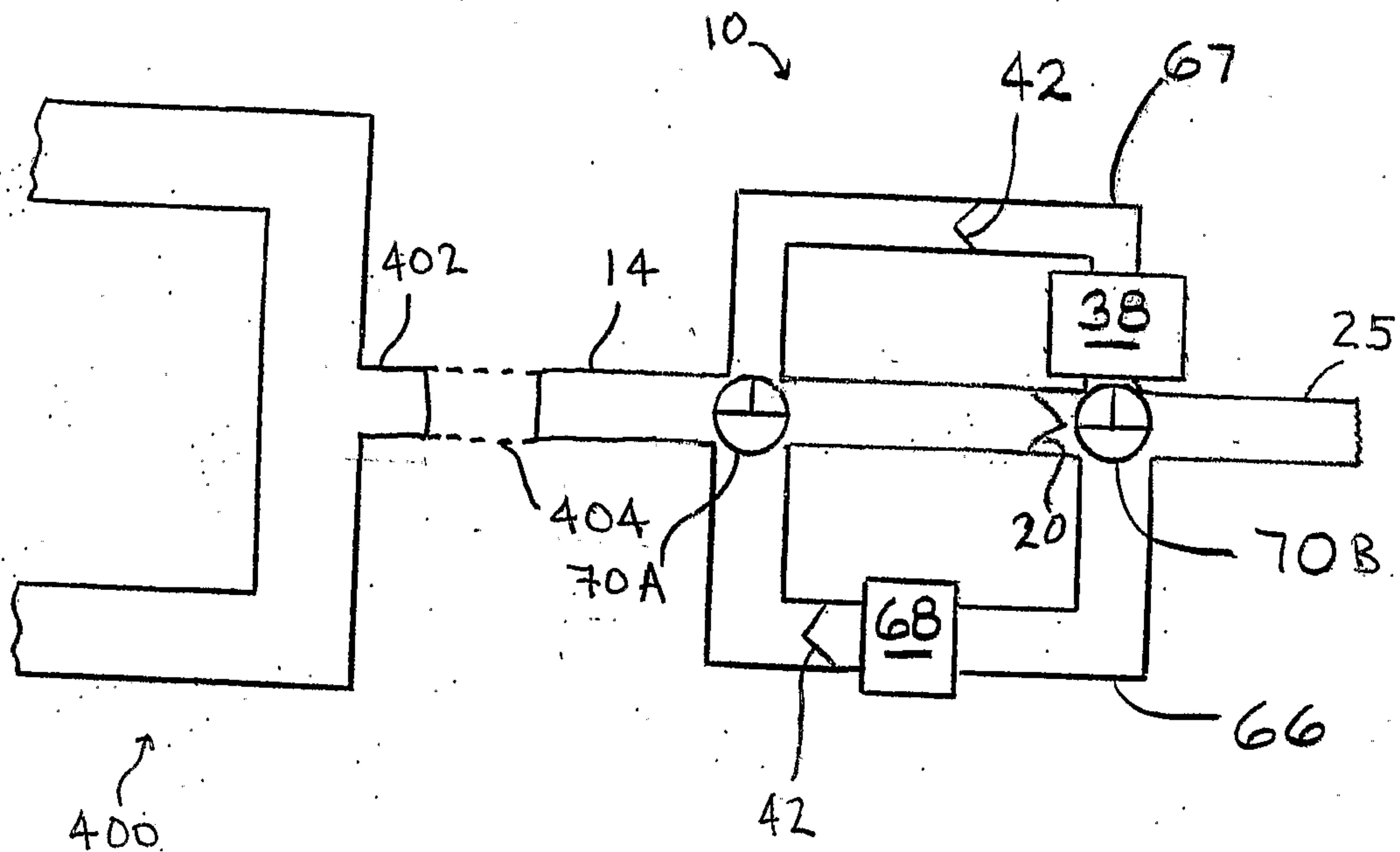


FIG. 9d

