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CA 2281835 C 2009/07/07

(11)(21) 2 281 835

(12) BREVET CANADIEN
CANADIAN PATENT

(13) C

(86) Date de dépôt PCT/PCT Filing Date: 1998/02/24
(87) Date publication PCT/PCT Publication Date: 1998/09/24
(45) Date de délivrance/Issue Date: 2009/07/07
(85) Entrée phase nationale/National Entry: 1999/08/18
(86) N° demande PCT/PCT Application No.: US 1998/003748
(87) N° publication PCT/PCT Publication No.: 1998/041268
(30) Priorité/Priority: 1997/03/14 (US08/818,173)

(51) Cl.Int./Int.Cl. *A61M 16/00* (2006.01)

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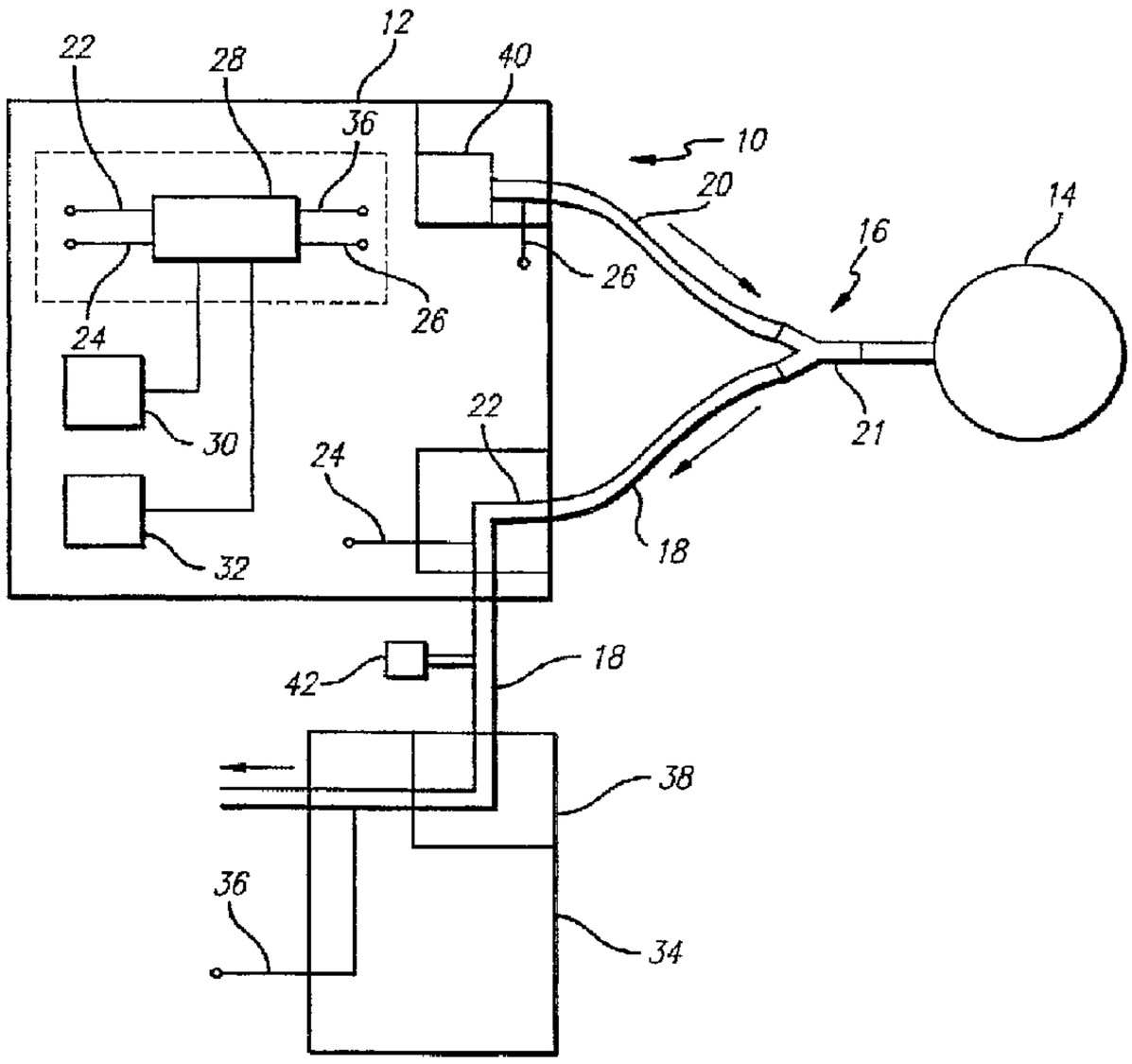
(54) Titre : SYSTEME ET PROCEDE PERMETTANT DE DECELER LE DEBRANCHEMENT ET L'OCCLUSION D'UN RESPIRATEUR COTE MALADE

(54) Title: SYSTEM AND METHOD FOR DISCONNECTION AND OCCLUSION DETECTION IN A PATIENT VENTILATOR



(57) Abrégé/Abstract:
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WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61M 16/00

A1

(11) International Publication Number: WO 98/41268

(43) International Publication Date: 24 September 1998 (24.09.98)

(21) International Application Number: PCT/US98/03748

(22) International Filing Date: 24 February 1998 (24.02.98)

(30) Priority Data:
08/818,173 14 March 1997 (14.03.97) US

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(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

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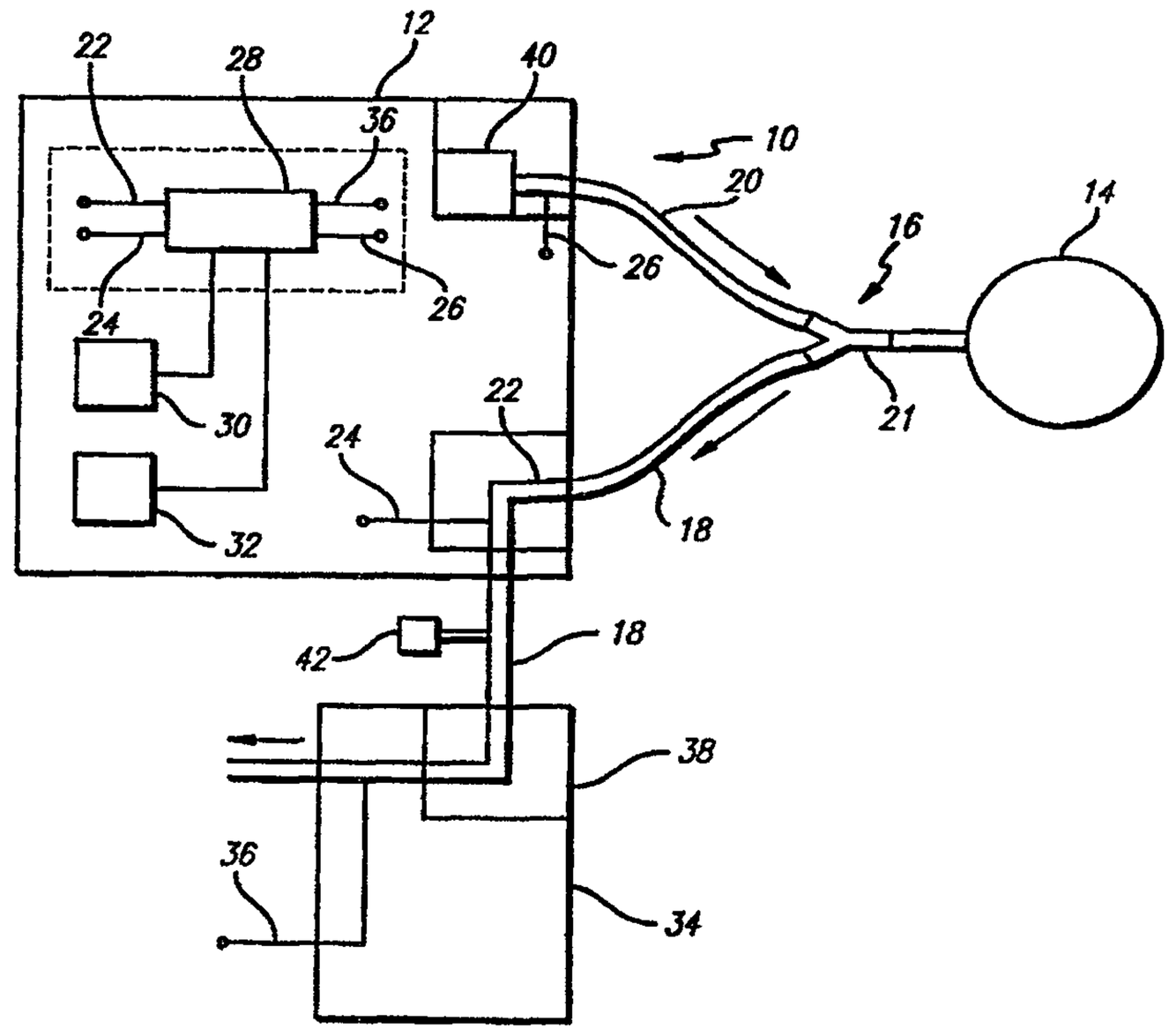
The system (10) and method for detecting disconnection and occlusion of a tubing system (16) of a patient ventilator (12) detects disconnection of the tubing system (16), opens the exhalation valve, delivers an idle flow of breathing gas to the tubing system (16), disables breath triggering, and generates an alarm. A reconnection of the tubing system (16) can also be detected, to initiate resumption of pressure supported inspiration. For occlusion detection, the pressure drop in the tubing system is determined by pressure sensors (26, 36) in the inspiratory and expiratory airways (20, 18) of the tubing system (16). The two pressure drop values are compared, and once occlusion is detected, an alarm is generated, and the ventilator (12) responds to protect the patient (14) from over distension. Abatement of the occlusion can also be monitored in a pressure based occlusion status cycling mode, and the ventilator (12) can revert back to normal ventilation when either circuit occlusion or exhaust port occlusion are not detected.



SYSTEM AND METHOD FOR DISCONNECTION AND OCCLUSION DETECTION IN A PATIENT VENTILATOR

This invention relates generally to breathing ventilators, and more particularly relates to a pneumatically driven, electronically controlled ventilator system for providing breathing gas to a patient, and a method and system for detection of disconnection and occlusion in an airway of the ventilator system.

A patient receiving breath pressure support from a ventilator system typically receives breathing gas through a patient circuit of the ventilator. The patient circuit generally consists of two flexible conduits connected to a fitting called a patient wye. The free ends of the conduits are attached to the ventilator so that one conduit receives breathing gas from the ventilator's pneumatic system, and the other conduit returns gas exhaled by the patient to the ventilator. The volume of the exhaled gas may then be measured in a spirometer before it finally exits through an exhalation valve. The wye fitting is typically connected to the patient's breathing attachment or enclosure, which conducts breathing gas into the lungs, and exhaled gas from the lungs to the exhalation branch of the patient circuit. The pneumatic system at the inspiratory end of the patient circuit is typically closed before a breath, and the exhalation valve at the exhalation end of the patient circuit is typically preceded by a one-way valve, to prevent gas from flowing retrograde in the exhalation branch of the patient circuit.

Occurrences of low pressures in the exhalation limb of the patient's breathing gas circuit during the exhalation phase of the pressure supported breath can be a cause of concern for the patient unless they are carefully controlled. Pressures in the patient lung that fall below PEEP (Positive End Expiratory Pressure, a baseline pressure value) can impair a patient's lung function, and it can be important to maintain PEEP in a patient's

lung to prevent collapse of the lung.

Disconnections of a patient breathing circuit can occur at the inspiratory limb, the expiratory limb, the patient circuit wye, or between the endotracheal tube and the patient wye. Patient breathing circuit disconnections result in the patient receiving either no breathing gas or very little gas from the ventilator, and can interfere severely with maintenance of PEEP. During ventilation, it is also desirable to be able to assess the state of the tubing system so that conditions such as kinked tubes and high resistance filters that can occlude the flow of breathing gas and interfere with maintenance of PEEP are detected, to prevent injury to the patient attached to the ventilator, and so that increases in the work of breathing are minimized. It is also important to detect an occlusion condition in which the exhalation valve is stuck closed. Therefore, it is important to be able to detect disconnections and occlusions and to alert the respiratory therapist to these conditions. The present invention meets these needs.

In accordance with the present invention there is provided an electronically controlled, pneumatically driven ventilator system, comprising means to detect disconnection or occlusion of patient tubing of the system, said system comprising:

means delivering a flow of breathing gas to a patient during an inspiratory phase of a breath cycle;

means determining an onset of an exhalation phase of said breath cycle;

means establishing a plurality of control intervals during said exhalation phase;

means monitoring exhalation flow and pressure in the patient tubing during a plurality of said control intervals to determine by one or more sets of criteria whether a condition indicating disconnection of the patient tubing has occurred;

means monitoring inhalation and exhalation pressure in the patient tubing during a plurality of said control intervals to determine whether a condition indicating occlusion of the patient

tubing has occurred; and

means generating a disconnection signal when said condition indicating disconnection of the patient tubing has occurred and if said condition indicating occlusion of the patient tubing has not occurred.

In a different aspect, the present invention also provides an electronically controlled, pneumatically driven ventilator system, comprising means to detect occlusion of patient tubing of the system, the system comprising:

means delivering a flow of breathing gas to a patient during an inspiratory phase of a breath cycle;

means determining an onset of an exhalation phase of said breath cycle;

means establishing a plurality of control intervals during said exhalation phase

means monitoring exhalation pressure in the patient tubing during a plurality of said control intervals to determine whether a condition indicating occlusion of the patient tubing has occurred; and

means generating an occlusion signal when said condition indicating occlusion of the patient tubing has occurred.

These and other aspects and advantages of the invention are defined in the dependent claims and are apparent from the following detailed description and the accompanying drawings, which illustrate by way of example the features of the invention.

Fig. 1 is a schematic diagram of the system for detecting disconnection and occlusion of a patient tubing system for a patient ventilator, according to the invention; and

Fig. 2 is a flow chart illustrating the occlusion status cycling mode of the system of the invention.

Pressures in the tubing system of a patient ventilator can fall below a baseline pressure value during disconnections and

occlusions of the tubing system, risking impairment of a patient's lung function, and possible collapse of the lung. Patient breathing circuit disconnections result in the patient receiving either no breathing gas or very little gas from the ventilator, and can interfere severely with maintenance of PEEP. Occlusions in the tubing system can also dangerously increase the work of breathing. It is therefore important to be able to detect disconnections and occlusions and to respond to these conditions.

As is illustrated in the drawings, which illustrate, by way of example, the invention, in a first embodiment, the invention provides for a method and system for detection of disconnection and occlusion of a patient tubing system of a pneumatically driven, electronically controlled ventilator system. Parameters used to detect patient tubing system disconnections include pressure and exhalation flow levels measured by the pressure and flow sensors located in the exhalation module during the first 200 msec of exhalation, the volume returned during the exhalation phase, the volume delivered during the previous inspiratory phase, and in pressure based ventilation, the desired flow level if the time limit is reached.

The system 10 for detecting disconnection and occlusion of the patient tubing system of a pneumatically driven, electronically controlled ventilator system 12 is illustrated schematically in Fig. 1. The patient 14 is connected by the tubing system 16 to receive breathing gas. The tubing system includes an exhalation line 18 and an inhalation line 20 connected to the patient by a patient wye 21. A pressure sensor 22 and a flow sensor 24 are connected to the exhalation line to monitor pressure and flow, respectively, of the breathing gas in the exhalation line, and a pressure sensor 26 is also connected to the inhalation line to monitor the pressure in the inhalation line. All inputs from the sensors are received by a microprocessor 28 which governs all of the microcomputer based functions of the ventilator system, and which controls activation of a disconnection alarm 30, and an occlusion alarm 32. The exhalation

line is connected to an exhalation compartment 34, which also includes a pressure sensor 36 for monitoring pressure of breathing gas in the exhalation compartment. The ventilator system includes a pressure control valve 40 controlling pressure of breathing gas delivered to the patient, and a safety valve 42, typically connected to the exhalation line, for relieving excessive pressure of the breathing gas in the tubing system.

In a first set of criteria, a condition indicating disconnection of the patient tubing system has occurred can be declared if, during a control interval, the pressure in the tubing system as sensed by a pressure sensor in the exhalation line of the tubing system falls outside a desired, predetermined range, and exhalation flow is less than a desired, predetermined threshold, for a contiguous period of consecutive control intervals within a predetermined initial period of time following onset of an exhalation phase. In a preferred embodiment of the first set of criteria, the control interval is 5 msec., and all of the following three conditions must be met at some time during the first 200 msec. of an exhalation phase, for a contiguous period of 100 consecutive milliseconds:

$$\begin{aligned} &\text{If} && \text{Pat\_press}(n) && \geq -0.5 && \text{cmH}_2\text{O} \\ &\text{AND} && \text{Pat\_press}(n) && \leq 0.5 && \text{cmH}_2\text{O} \\ &\text{AND} && \text{Dry\_exh\_flow}(n) && \leq 0.5 && \text{lpm} \end{aligned}$$

where Pat_press(n) is the pressure in the tubing system as sensed by a pressure sensor in the exhalation line of the tubing system during a control interval, and Dry_exh_flow(n) is the exhalation flow as measured by the exhalation flow sensor, compensated for the breathing gas mix and for humidity in the gas to represent dry conditions. Typically, an estimated amount of water vapor flow is removed from the initial flow measurement from the exhalation flow sensor Exh_flow. Then, the remaining dry flow is compensated for the expected gas mix (N_2, O_2).

However, even if all of the above conditions of the first set of criteria are met, the declaration of the patient

tubing system disconnection is preferably deferred until a period of time has elapsed, in which it can be determined whether occlusion of the tubing system has occurred. In a presently preferred embodiment, this delay period is about 300 msec following the onset of exhalation, independent of the breath phase. Detection of a tubing occlusion is allowed to be declared first, since it is possible for a tubing occlusion to falsely generate all the patient tubing system disconnection conditions of the first criteria.

Patient tubing system disconnections will usually be detected based on the flow seen by the exhalation flow sensor and the Pat_press level, during the first 200 msec of any exhalation. In the vast majority of cases, the Pat_press level will be at or near zero cmH_2O of pressure, and since no communication exists between the ventilator's inspiration and exhalation ports, no flow will be detected by the exhalation flow sensor.

In a second set of criteria, a condition indicating disconnection of the patient tubing system has occurred can be declared if the pressure in the tubing system as sensed during a control interval by a pressure sensor in the exhalation line of the tubing system falls outside a desired, predetermined range, and exhalation flow is less than a disconnection flow limit threshold based upon a flow target and a predetermined disconnection sensitivity, for a contiguous period of consecutive control intervals within a predetermined initial period of time following onset of an exhalation phase. In a preferred embodiment of the second set of criteria, the control interval is 5 msec., and all of the following three conditions must be met for a contiguous period of 10000 consecutive milliseconds, during the exhalation phase:

$$\begin{aligned} \text{If} \quad & \text{Pat\_press}(n) \geq -0.5\ cmH_2O \\ \text{AND} \quad & \text{Pat\_press}(n) \leq 0.5\ cmH_2O \\ \text{AND} \quad & \text{Dry\_exh\_flow}(n) \leq \text{disconnect\_flow\_limit} \end{aligned}$$

where flow_target is the value of the ventilator's predetermined

desired steady state flow delivery during the exhalation phase; disconnect_flow_limit is defined as flow_target * (1-disconnect_sensitivity/100), and if disconnect_flow_limit is less than 0.5 lpm, then disconnect_flow_limit is 0.5 lpm.

Disconnect_sensitivity is a setting, expressed in percent, that represents the percent of volume delivered in the previous inspiration, that was not returned (i.e, was lost) during the exhalation phase of the same breath. In a presently preferred embodiment, the range for disconnect_sensitivity is as follows:

$$20\% \leq \text{disconnect\_sensitivity} \leq 95\%$$

In the case of a disconnection at the patient circuit inspiratory limb it is possible for the patient to generate flows in excess of 0.5 lpm and pressures outside the ± 0.5 cmH_2O range of the first set of criteria, but it is unlikely that these events will coincide with the first 200 msec of exhalation for long periods of time. This is the reason why the second set of criteria was developed.

When patient tubing system disconnections occur in a particular exhalation phase, they will usually be detected during a next exhalation, or if the disconnection does not cause autocycling of the ventilator, the disconnection can be detected during the current exhalation by the second set of criteria.

In a third set of criteria, a condition indicating disconnection of the patient tubing system has occurred can be declared if a desired flow target is greater than or equal to a maximum flow input to the flow controller, and the duration of a current inspiration is greater than or equal to a maximum allowed spontaneous inspiration time. This third set of criteria can be defined as follows:

If Desired_flow >= Flow_cmd_limit

AND Insp_time >= Time_limit

where Insp_time is the duration of the current inspiration, Time_limit is the maximum allowed spontaneous inspiration time, and Flow_cmd_limit is the maximum flow input to the flow controller. For Pressure Based Ventilation (PBV), Flow_cmd_limit is dependent upon the patient type, and is typically 200 lpm for adult patients, and 80 lpm for pediatric patients.

The third set of criteria applies during the inspiration phase of a breath only, and only for spontaneous breaths, such as for Continuous Positive Airway Pressure (CPAP) or Pressure support, for example.

The third set of disconnection detection criteria reflects the fact that if a true disconnection occurs, during Pressure Based Ventilation (PBV), the desired flow will be driven to the maximum command limit if enough time is allowed. This type of response is guaranteed, even for the lowest pressure support level, if a total disconnection occurs at the beginning of the breath or during the previous exhalation, at any of the limbs or the endotracheal tube side of the wye. Thus this criteria fits very well for reconnection verification purposes, which will be discussed further below.

In a fourth set of criteria, a condition indicating disconnection of the patient tubing system has occurred can be declared if the exhalation volume is less than the integral of the net flow from the beginning of inspiration to the beginning of exhalation with respect to time, multiplied by a proportional factor and a disconnection sensitivity factor, for three consecutive breaths. The fourth criterion can be defined as follows:

Exh_vol < Insp_vol * proportional_factor * (1-disconnect_sensitivity/100)

for three (3) consecutive breaths

where:

$$Inspvol = - \int_{BeginInsp}^{BeginExhal} NetFlow * \delta t / 60$$

(Eq. 1)

Exh_vol = Σ(Net_flow * δt/60) if Q_exh_finished = 0; and proportional_factor is defined by the pseudo code below:

If EIP - SOIP ≤ 0.1

Then proportional_factor = 0

Else proportional_factor = (EIP - EEPU0)/(EIP - SOIP)

where EIP = End of inspiration pressure; $EEPU_0$ = End of exhalation pressure unfiltered at the time Q_exh_finished is set to 1; and SOIP (start of inspiration pressure) = value of P_wye_unfiltered at the beginning of the current breath's inspiration.

P_wye_unfiltered is calculated using the equation:

$$P\_wye\_estimate_n = MAX\ (P\_wye\_insp\_based\_estimate_n, P\_wye\_exh\_based\_estimate_n);$$

where

$$P\_wye\_insp\_based\_estimate_n = Pat\_press\_insp\_filtered_n - Ri * (Air\_flow_n + O2\_flow_n).$$

The term $P\_wye\_exh\_based\_estimate_n$ is defined by the pseudo code below:

If Exh_flow < 150

Then $P\_wye\_exh\_based\_estimate_n = Pat\_press\_filtered_n - Re*Exh\_flow_n$

Else $P\_wye\_exh\_based\_estimate_n = Pat\_press\_filtered_n - Re*150$

where:

$Ri = Ri\_slope * (Air\_flow_n + O2\_flow_n) + Ri\_intercept$

$Re = Re\_slope * Exh\_flow_n + Re\_intercept$

Ri_slope = Slope for the inspiratory limb resistance equation

Ri_intercept = intercept for the inspiratory limb resistance equation

Re_slope = Slope for the expiratory limb resistance equation.

Re_intercept = intercept for the expiratory limb resistance equation.

Q_exh_finished is set to 0 (zero) at the beginning of exhalation and becomes 1 (one) the first time Net_flow_change_counter is greater than 20 AND at least 200 msec of exhalation have elapsed or if the exhalation phase ends, whichever occurs first. Once Q_exh_finished is set to 1, it remains in this state until the beginning of the next exhalation phase. Net_flow_change_counter is initialized to zero at the beginning of exhalation and incremented as indicated by the pseudo code below:

If $Abs(Net\_flow\_filtered_n - Net\_flow\_filtered_{n-1}) < 0.01 * flow\_target$

AND $Net\_flow \leq 0.2 + 0.08 * flow\_target$

Then $Net\_flow\_change\_counter = Net\_flow\_change\_counter + 1$

Else $Net\_flow\_change\_counter = 0;$

where:

flow_target = Value of the ventilator's predetermined desired steady state flow delivery during the exhalation phase. For pressure triggering mode the value for flow_target is 1 lpm (Purge_flow). For flow triggering mode the value is Base_flow.

n = control interval initialized to zero at the beginning

of exhalation

$Net\_flow\_filtered_n$ = Filtered Net_flow value. An alpha filter ($\alpha = 0.9$) is used to filter Net_flow.

$Net\_flow\_filtered_{-1}$ = Net_flow of last inspiration interval.

Insp_vol is initialized to 0 (zero) at the beginning of inspiration. Exh_vol is initialized to zero at the beginning of exhalation. The inequality in the criteria is tested only once, and always during the interval where Q_exh_finished is set to 1.

The fourth set of criteria enables the ventilator to also detect disconnections at the patient side of the endotracheal tube, since the volume returned will be much less than the volume delivered during a previous inspiration. A detection threshold setting, used by the therapist, is incorporated in the fourth set of criteria to avoid false disconnection detections generated by leaks in the patient lungs or the tubing circuit. Three consecutive breaths are needed for the fourth set of criteria for declaration of disconnection to avoid false declarations when the patient "out-draws" the ventilator during volume ventilation.

Once any one set of criteria for declaring disconnection of the patient tubing system are met, the ventilator will open the exhalation valve, deliver an idle flow, such as typically a 5 lpm idle flow with 100% oxygen in the breathing gas mix, if possible, disable breath triggering, and generate an alarm indicating disconnection of the patient tubing.

Abatement of the condition of disconnection of the tubing system, or reconnection, will be detected when any one of the following conditions occurs:

1) If 80% of the idle flow is detected by the exhalation flow sensor as Q_{exh} (the exhalation flow compensated to dry flow) for 500 consecutive milliseconds; or
2) When both P_{insp} and P_{exh} read less than -1.5 cmH_2O for more than 100 consecutive milliseconds;

3) When both P_{insp} and P_{exh} read more than 1.0 cmH_2O for more than 100 consecutive milliseconds; or

4) If P_{insp} reads more than 10 cmH_2O for more than 100 msec, consecutively.

Upon detection of a reconnection, the ventilator will initiate delivery of a pressure supported inspiration (PSI), and will return to normal ventilation, typically using the settings in effect prior to the patient tubing system disconnection, once the inspiration phase of the PSI is over. Typically, the ventilator system will check for disconnection of the tubing system from the beginning of the PSI until the end of the exhalation following the PSI using all but the fourth set of criteria, and then using all criteria thereafter.

In another currently preferred embodiment, the invention also provides for a method and system for dynamically monitoring the pressure drop of the tubing system (i.e. including the patient airway tubing, bacteria filters, and humidifier system), with the exhalation phase having a plurality of control intervals, and each of the control intervals having a predetermined duration, for increases in pressure drop due to occlusions in the tubing system. Those skilled in the art will recognize that the predetermined duration of the control intervals may be fixed, and will also recognize that it may be advantageous to vary the control intervals according to sampling criteria established during operation of the ventilator, based upon performance of the ventilator while ventilating the patient. During ventilation, the pressure drop for a severe occlusion is computed based on the tubing type obtained, the delivered flows and the exhaled flows. The actual pressure drop is determined by comparing the pressure drop values from the inspiratory and expiratory pressure sensors, and an alarm indicating severe occlusion will be generated if the actual pressure drop exceeds a predetermined severe threshold level. The ventilator monitors the occlusion in a pressure based occlusion status cycling mode. This mode serves to protect the patient from over distension and to

determine if the severe occlusion abates. The ventilator reverts back to normal ventilation when either tubing circuit occlusion or exhaust port occlusion are not detected.

The tubing pressure drop mathematical model (dP_{model}) can be expressed by a quadratic equation with flow as the independent variable, as follows:

$$dP_{model} = A * Q^2 + B * Q + C \qquad \text{(Eq. 2)}$$

where A, B, C are constants and Q is the flow through the tubing. The constant C is zero since dP is zero when Q is zero. Therefore Eq. 2 becomes

$$dP_{model} = A * Q^2 + B * Q \qquad \text{(Eq. 3)}$$

The remaining coefficients, A and B, can be obtained using a straight line fit of dP_{model} / Q:

$$dP_{model} / Q = A * Q + B \qquad \text{(Eq. 4)}$$

where A and B are constants to the straight line fit.

The quadratic pressure drop model (Eq. 3) is valid only for static measurements in flows. For dynamic flow rates, some errors are encountered in this model; but the model still serves as a good approximation of the pressure drop as a function of flow.

The actual or measured tubing circuit pressure drop, dP, is the difference between the inspiratory pressure sensor reading, P_{insp}, and the expiratory reading, P_{exh}:

$$dP = P_{insp} - P_{exh} \qquad \text{(Eq. 5)}$$

For occlusion detection purposes Eq. 5 is modified to account for the pressure and flow sensor accuracies (i.e. offset & gain drift). The determination of dP is thus typically adjusted for such factors as offset and gain drift, based upon the

following equation:

$$dP_{meas} = (P_{insp} - P_{exh}) - (0.7 + Abs(P_{insp}) * 0.062) \quad \text{(Eq. 6)}$$

The pressure drop threshold for a severe occlusion is dependent upon the tubing classification as either adult or pediatric. Thus the pressure drop threshold for a severe occlusion, dP_{severe}, is defined for an adult patient by:

$$dP_{severe} = 0.005 * Q^2 + 0.1491 * Q + 0.0142 \quad \text{(Eq. 7)}$$

and for a pediatric patient by:

$$dP_{severe} = 0.0082 * Q^2 + 0.1431 * Q + 0.0136 \quad \text{(Eq. 8)}$$

where Q is the flow in lpm causing the pressure drop to rise to a severe level. Since the location of the pressure drop increase is unknown, the maximum flow between Q_{insp} and Q_{exh} is used:

$$Q = \max[Q_{insp}, Q_{exh}] \quad \text{(Eq. 9)}$$

The threshold dP_{severe} is typically limited to a minimum value of 5 cmH_2O to prevent false triggering of the alarm due to the usage of a Cascade Humidifier or due to the presence of water in the tubing circuit, and typically is limited to a maximum of 100 cmH_2O, since 100 cmH_2O is typically the maximum set wye pressure.

The actual or measured tubing circuit pressure drop, and the pressure drop threshold for a severe occlusion, dP_{severe}, for either an adult patient or a pediatric patient, is determined in every 5 ms cycle and are compared. If the measured pressure drop exceeds the pressure drop threshold for a severe occlusion for the prescribed durations discussed below, a severe occlusion alarm is

annunciated and ventilation switches to an occlusion status cycling mode, discussed further below. In one currently preferred embodiment, three independent time counters are used to monitor violations of a severe occlusion threshold depending on the magnitude of dP_{meas}. A violation occurs when dP_{meas} exceeds the threshold dP_{severe}. The three time counters are associated to dP_{meas} values that fall in the pressure ranges of >20, >10, and >5 cmH_2O respectively. Each counter is individually incremented if a violation occurs and if dP_{meas} is greater than the corresponding pressure range. If the condition for each counter is not met, then the counter is reset. Once the counters exceed 10, 20, and 40 cycles (i.e., for 50, 100, or 200 consecutive milliseconds) respectively, a severe occlusion alarm is annunciated.

The following pseudo code implements the above algorithm:

```
if (dP_meas > dP_severe)
{
    if (dP_meas > 20)
        t_20_cm = t_20_cm + 1 ;
    else
        t_20_cm = 0 ;

    if (dP_meas > 10)
        t_10_cm = t_10_cm + 1 ;
    else
        t_10_cm = 0 ;

    if (dP_meas > 5)
        t_5_cm = t_5_cm + 1 ;
    else
        t_5_cm = 0 ;
}
else
{
    t_5_cm = 0 ;
    t_10_cm = 0 ;
```

t_{20_cm} = 0 ;
}

if (t_{5_cm} > 40 OR t_{10_cm} > 20 OR t_{20_cm} > 10)
severe_occlusion_detected = 1 ;

Occlusion of the exhalation exhaust port can also be detected from increases in the pressure drop of the exhalation compartment. The exhalation compartment includes those portions of the conduit downstream of the exhalation pressure transducer, including the heater manifold, flow sensor, exhalation valve, and any tubing attached to the exhalation outlet port. The amount of increase in pressure drop for the exhalation compartment is the same for a severe occlusion defined for adult patients. This increase is typically given by

$$P_{increase} = 0.005 * Q^2 + 0.1491 * Q + 0.0142 \quad \text{(Eq. 10)}$$

where $Q = Q_{exh}$

The exhaust port pressure threshold, $P_{exhaust\_port\_thresh}$, is calculated as the pseudo code below indicates.

If $P_{increase} < 1$

Then $P_{exhaust\_port\_thresh} = 7.35 + PEEP + P_{exh} * 0.03$ (Eq. 11)

Else $P_{exhaust\_port\_thresh} = P_{increase} + PEEP + P_{exh} * 0.03 + 6.35$ (Eq 12)

where $P_{exhaust\_port\_thresh}$ has an upper bound of 100 cmH_2O.

The exhalation pressure sensor measurement, P_{exh}, is compared to $P_{exhaust\_port\_thresh}$. If $P_{exh} > P_{exhaust\_port\_thresh}$, for 100 consecutive milliseconds, and 200 msec have elapsed in the

exhalation phase, a severe occlusion alarm is annunciated and ventilation switches to the occlusion status cycling mode. It is commonly difficult to detect this type of occlusion during inspiration, and this mode of occlusion detection is disabled during exhalation pauses.

The maximum flow delivered from the ventilator is dependent upon patient type. The maximum flow limits (Flow_cmd_limit) for adult and pediatric patients are typically 200 and 80 lpm, respectively.

In a presently preferred embodiment, concurrently with the declaration of severe occlusion or the detection of exhalation exhaust port occlusion, the invention provides for a pressure-based occlusion status cycling mode. Occlusion status cycling serves two objectives: 1) protecting the patient from over distension while attempting to ensure that the patient receives some ventilation, and 2) monitoring the inspiratory and expiratory phases to determine if the severe occlusion abates. As occlusion status cycling ensues, the severe occlusion may relax to either a partial or a normal state. If an occlusion does abate, it must qualify as less than a severe before the ventilator system will revert to settings in effect prior to the patient tubing system occlusion. During occlusion status cycling, a purge flow is not to be established.

Referring to Fig. 2, the flow chart depicts the sequence of events that must be performed for the implementation of occlusion status cycling. Five phases of occlusion status cycling have been defined for the purpose of flow charting.

Phase 1: An exhalation phase in which the ventilator closes the pressure solenoid valves, controls the expiratory valve to zero PEEP, discontinues flow triggering, sets PEEP equal to zero, sets the breathing gas oxygen percentage to 100, and opens the safety valve. This shut-down state persists until $P_{insp} \leq 5$ cmH_2O or until 15 seconds have elapsed, whichever occurs first. This phase is typically entered if an occlusion is detected while ventilating with normal settings.

Phase 2: An inspiration phase, in which at the

beginning the ventilator closes the safety valve. After the 500 msec have elapsed, to allow for safety valve closure, the ventilator system delivers a Pressure Controlled Ventilation (PCV) based breath with an inspiratory pressure target of 15 cmH_2O, a flow acceleration percent of 100, an inspiratory time of (2500 - 500) msec., and using P_{insp} as the feedback signal for control.

Phase 3: An exhalation phase, in which the ventilator closes the pressure solenoid valves and controls the exhalation valve to zero PEEP. Exhalation will last until ($P_{insp} \leq 5$ cmH_2O AND at least 2.5 sec have passed) OR a total of 5 seconds have elapsed since the beginning of the exhalation.

Phase 4: An exhalation phase, in which the ventilator closes the pressure solenoid valves, controls the exhalation valve to zero PEEP and opens the safety valve. Exhalation will last until ($P_{insp} \leq 5$ cmH_2O AND at least 2.5 sec have passed) OR a total of 5 secs. have elapsed since the beginning of the exhalation

Phase 5: An inspiration phase with current mandatory settings, the only exception being PEEP which remains at zero. P_{exh} is used as the feedback signal for control purposes if the breathing algorithm is pressure based.

CLAIMS

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A use of a pneumatically driven, electronically controlled ventilator system configured to deliver a flow of breathing gas to a patient, comprising means to detect disconnection or occlusion of patient tubing of the system:

to determine an onset of an exhalation phase of a breath cycle;

to establish a plurality of control intervals during said exhalation phase;

to monitor exhalation flow and pressure in the patient tubing during a plurality of said control intervals to determine by one or more sets of criteria whether a condition indicating disconnection of the patient tubing has occurred;

to monitor inhalation and exhalation pressure in the patient tubing during a plurality of said control intervals to determine whether a condition indicating occlusion of the patient tubing has occurred; and

when said condition indicating disconnection of the patient tubing has occurred, to generate a disconnection signal if said condition indicating occlusion of the patient tubing has not occurred.

2. An electronically controlled, pneumatically driven ventilator system, comprising means to detect disconnection or occlusion of patient tubing of the system, said system comprising:

means delivering a flow of breathing gas to a patient during an inspiratory phase of a

breath cycle;

means determining an onset of an exhalation phase of said breath cycle;

means establishing a plurality of control intervals during said exhalation phase;

means monitoring exhalation flow and pressure in the patient tubing during a plurality of said control intervals to determine whether a condition indicating disconnection of the patient tubing has occurred;

means monitoring inhalation pressure and means monitoring exhalation pressure in the patient tubing during a plurality of said control intervals to determine whether a condition indicating occlusion of the patient tubing has occurred; and

means generating a disconnection signal when said condition indicating disconnection of the patient tubing has occurred and if said condition indicating occlusion of the patient tubing has not occurred.

3. The system of Claim 2, wherein said tubing includes an exhalation line, and said means for monitoring exhalation flow and pressure in the patient tubing comprises a pressure sensor and a flow sensor in said exhalation line, and a first set of criteria for declaring that disconnection of the patient tubing has occurred comprises, during a control interval, the pressure in the exhalation line being less than or greater than a predetermined pressure range, and exhalation flow being less than a predetermined flow threshold, for a contiguous period of consecutive control intervals within a predetermined initial period of time following onset of an exhalation phase.

4. The system of Claim 2, wherein said tubing includes an exhalation line, and said means for monitoring exhalation flow and pressure in the patient tubing comprises a pressure sensor and a flow sensor in said exhalation line, and a second set of criteria for declaring that disconnection of the patient tubing has occurred comprises, during a control interval, the pressure in the exhalation line being less than or greater than a predetermined pressure range, and exhalation flow being less than a disconnection flow limit threshold based upon a flow target and a predetermined disconnection

sensitivity, for a contiguous period of consecutive control intervals within a predetermined initial period of time following onset of an exhalation phase

5. The system of Claim 2, wherein said tubing includes an exhalation line, and said means monitoring exhalation flow and pressure in the patient tubing comprises a flow sensor in said exhalation line, the system further comprising means to detect inspiration flow, and a third set of criteria for declaring that disconnection of the patient tubing has occurred comprises a desired inspiration flow target being greater than or equal to a maximum inspiration flow threshold, and the duration of a current inspiration being greater than or equal to a maximum allowed spontaneous inspiration time.

6. The system of Claim 2, wherein said tubing includes an inhalation and an exhalation line, and said means monitoring exhalation flow and pressure in the patient tubing comprises a flow sensor in said exhalation line for measuring exhalation flow, the system further comprising:

a flow sensor in said inhalation line monitoring flow therein;

means determining from the sensed exhalation flow an exhalation volume from the beginning of exhalation to the beginning of inspiration; and

means determining an inhalation volume from the integral of the net inhalation flow from the beginning of inspiration to the beginning of exhalation with respect to time; wherein

a fourth set of criteria for declaring that disconnection of the patient tubing has occurred comprising the exhalation volume being less than the inhalation volume, multiplied by a proportional factor and a disconnection sensitivity factor, for three consecutive breaths.

7. The system of claim 2, wherein said control intervals have a predetermined duration.

8. The system of Claim 2, wherein said tubing includes an exhalation line and an inhalation line, and wherein said means monitoring inhalation and exhalation pressure in the patient tubing comprises a pressure sensor in said exhalation line, a pressure sensor in said inhalation line, a comparator for determining a pressure drop across said inhalation and exhalation lines, the system further comprising means generating an occlusion signal if said pressure drop exceeds a predetermined threshold.

9. The system of Claim 8, further including means for adjusting said pressure drop for a pressure offset and a gain drift.

10. The system of Claim 8, wherein said ventilator system includes a plurality of counters, each having a different limit value and each counter having associated therewith a different pressure drop threshold value, said means generating an occlusion signal further comprising means incrementing each of said plurality of counters when the pressure drop is greater than the corresponding threshold of said counters, respectively, and generating an occlusion signal if the respective limit value of any of said plurality of counters is exceeded.

11. The system of Claim 2, wherein said tubing includes an exhalation line and an exhalation compartment in said exhalation line, and wherein said means monitoring exhalation pressure in the patient tubing comprises a pressure sensor for measuring pressure in said exhalation compartment, the system further comprising means generating an occlusion signal if said pressure in said exhalation compartment exceeds a predetermined exhaust port threshold pressure for a predetermined number of consecutive control intervals within a predetermined period of time during an exhalation phase.

12. The system of any of Claims 8 to 11, further comprising an exhalation valve in said exhalation line, and on generation of said occlusion signal, means opening the exhalation valve, means for delivering an idle flow of breathing gas, and means for monitoring flow and pressure to determine whether a condition indicating abatement of occlusion of the patient tubing has occurred.

13. The system of any of Claims 8 to 11, further comprising a pressure control valve,

a safety valve, and means for flow triggering breath support, and further comprising shut-down phase means which, on generation of said occlusion signal, closes the pressure control valve, controls the exhalation valve to maintain patient end expiratory pressure at approximately zero, discontinues flow triggering, sets the breathing gas mix to contain 100 percent oxygen, and opens the safety valve.

14. The system of Claim 13, further comprising means for initiating a resumption of flow of breathing gas to the patient tubing during an inspiratory phase of a breath cycle if a condition indicating abatement of occlusion of the patient tubing has occurred.

15. The system of Claim 13, and further comprising occlusion status cycling means sensing inspiratory pressure in said inhalation line, maintaining said shut-down phase until inspiratory pressure is less than or equal to 5 cmH_2O or until 15 seconds have elapsed, whichever occurs first; initiating an inspiration phase, in which at the beginning the ventilator closes the safety valve, waiting a predetermined interval of time to allow for the safety valve to close, delivering a Pressure Controlled Ventilation based breath with an inspiratory pressure target of approximately 15 cmH_20; initiating a first exhalation phase, in which the ventilator closes the pressure control valve and controls the exhalation valve to maintain a patient end expiratory pressure of approximately zero, until the inspiratory pressure is less than or equal to 5 cmH_20 and at least 2.5 sec have passed, or a total of 5 seconds have elapsed since the beginning of the first exhalation phase; initiating a second exhalation phase, in which the ventilator closes the pressure control valve, controls the exhalation valve to maintain a patient end expiratory pressure of approximately zero and opens the safety valve until the inspiratory pressure is less than or equal to 5 cmH_2O and at least 2.5 sec have passed, or a total of 5 seconds have elapsed since the beginning of the first exhalation phase; and initiating an inspiration phase with mandatory breath settings while maintaining patient end expiratory pressure of approximately zero

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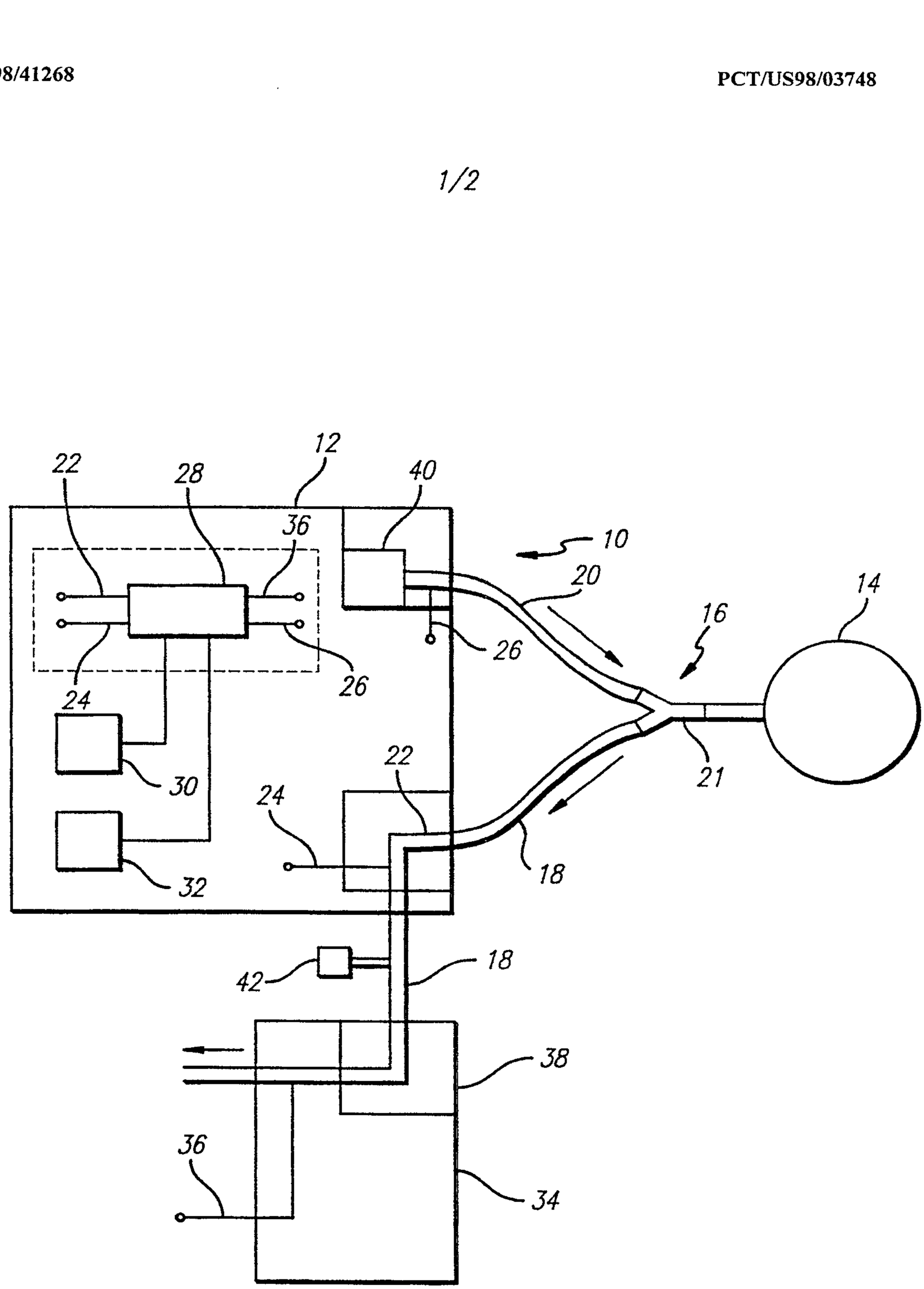
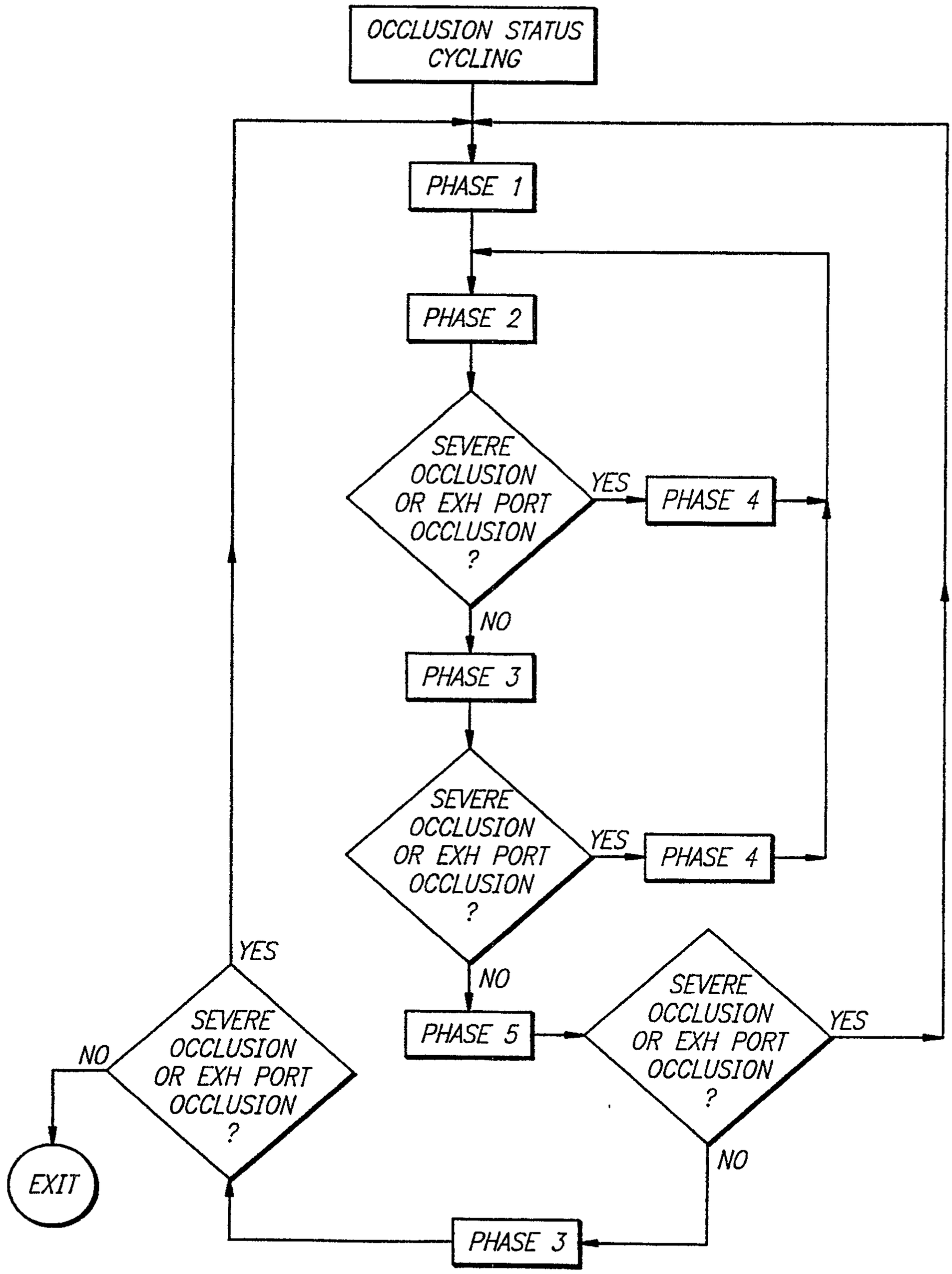


FIG. 1

FIG. 2


OCCLUSION STATUS CYCLING
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PHASE 2
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YES
PHASE 4
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PHASE 3
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PHASE 4
NO
PHASE 5
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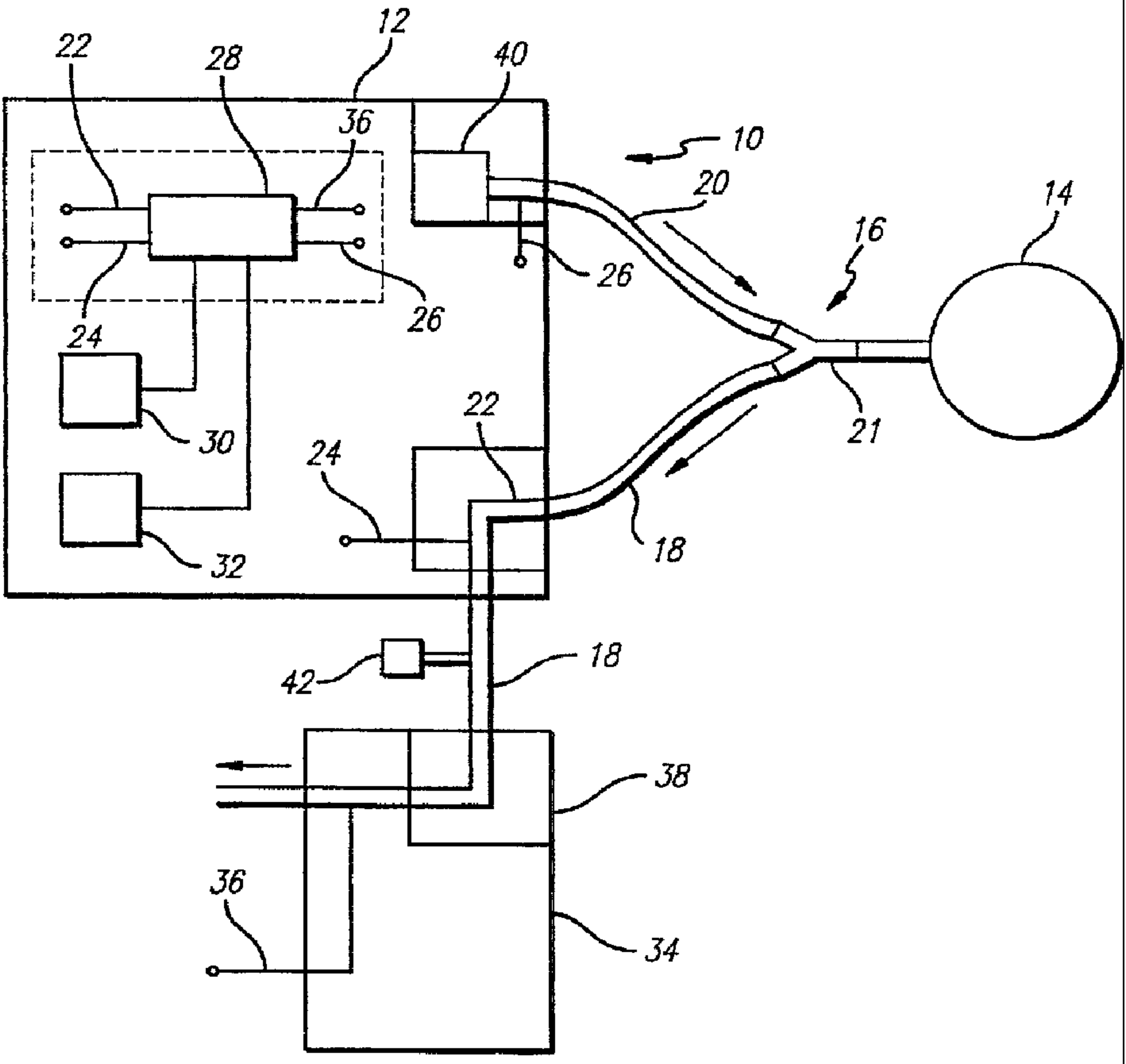
YES
PHASE 3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