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Modeling and Control of Systems for Critical Care Ventilation

Mike Borrello, stablesystems@ieee.org, Trex Enterprises, San Diego, CA

This paper, and the good will and engineering it may one day inspire, is dedicated in loving memory to my beloved daughter, Marina May Ivy Borrello

1.0 Introduction

In medical practice, critical care ventilation provides a vital life support function for patients that have difficulty or are unable to breath for themselves. For the machines that provide this function, control engineering plays a key role in providing safe and accurate delivery of gas to the patient. While critical care ventilation is widely treated in the literature, most books and papers are written by clinical specialists and few if not any fully and specifically address the role of control engineering in ventilation from the engineer's perspective. This tutorial attempts to help fill this gap by presenting an overview of the modeling and control techniques practiced by engineers in critical care ventilation.

2.0 Background

The efficient intake and distribution of oxygen to all the cells of the body is essential to maintain life. While the heart and blood vessels provide the means for distribution, the lung serves as the critical interface between the atmosphere and organism, where the exchange of oxygen and carbon dioxide occurs. The lung consists of a complex system of tubular branches that connect the upper airways (trachea and bronchi) to a system of progressively smaller branches (bronchioles). Bronchioles eventually terminate in microscopic sac-like structures called alveoli. Surrounding the thin walls of each alveolus are the capillary junctions where veins transition to arterioles. This junction is the site for gas exchange. The alveoli, which number about 600 million in the human lung, have an amazing collective surface area of about 100 m^2, permitting gas diffusion at rates capable of supporting metabolism even during the most severe physical exercise.

When disease or injury prevails over the healthy lung, respiratory mechanics may become burdened, and the muscles that drive breathing may have to work harder to maintain the required rate of gas exchange. With prolonged effort, respiratory muscles become fatigued and eventually fail to function. In this event medical intervention is required to either partially or entirely support breathing. A machine, known as a *ventilator*, facilitates this vital function of life support through the precision control of gas flow, pressure, volume and gas composition.

Early methods used the technique of *negative pressure ventilation* where the patient's entire body, below the head, was encapsulated in a rigid compartment. Popularized as the *iron lung*, pressure within the compartment was cyclically reduced below atmosphere causing the lung to expand, and gas to enter the airway. This life saving device supported breathing for the ill but made it difficult to manage the patient, take x-rays or perform surgery while the patient was under care. Iron lungs, first introduced in 1927, were eventually replaced with machines that, to this day, use *positive pressure ventilation* where gas, under pressure, is introduced via the patient's airway. Early positive pressure ventilators were controlled entirely using mechanical bellows and valves to cycle gas into the lung. Simple proportional or proportional integral controllers were implemented using pneumatic components. Electronic controls, using operational amplifiers, eventually replaced pneumatic controls but with the advent of microprocessors, analog controls were soon replaced by software based digital controls. Software based controls actuate valves through interface electronics and measure flow and pressure using sensors. The high MIPS-volume per/unit cost capability of today's processors, together with modern control technologies, welcomes entirely new considerations for solving control problems in ventilation.

Figure 1 illustrates an example of today's positive pressure ventilator. The patient is connected to the ventilator by means of the *patient circuit*, made from semi rigid plastic tubing.

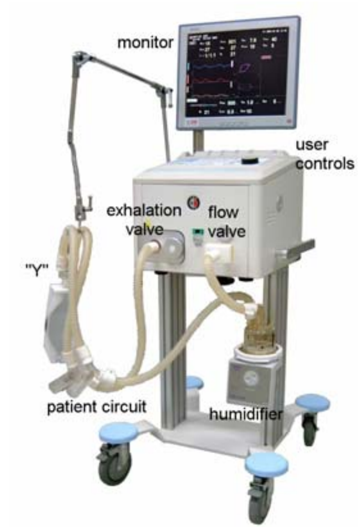

Figure 1 Typical ICU Ventilator

One leg of the circuit connects to a flow supply valve, and the other to an exhalation valve, each located inside the ventilator. The other ends of each circuit leg join at a "Y" fitting that terminates at a sealed connection with the patient's airway. This connection may be through an *endotracheal tube* (ETT), which connects to the trachea through the mouth, or a *tracheostomy tube* that connects through an external incision. The flow supply and exhalation valves are alternately cycled at a regular breath rate to deliver and subsequently vent gas from the patient's lungs.

Ventilators sold and used in the USA are regulated by the FDA and categorized as class II medical devices which require special design controls, special labeling requirements, mandatory performance standards and post market surveillance. Regulations cover both the manufacture and design process which includes control systems design and development.

There are presently four or five leading ventilator manufacturers that compete in a worldwide market of about 2.5 billion dollars. With the rising expense of healthcare, cost reduction has become a prority in ventilator design although manufacturers still strive for performance advantages and new features to maintain an edge on the market. Clinical experts in the field of respiratory care frequently publish studies that evaluate, analyze and compare performance between ventilators. The success or failure of this performance ultimately depends on the controls design.

The basic control functions required in a ventilator system include flow, mix, volume and pressure controls. More advanced applications of control may consider SaO_2 control (blood oxygen saturation), impedance targeted controls, and knowledge based systems that either aid or replace higher level decisions made by clinical personnel. Before these control systems are discussed, modeling of the lung and ventilator system components will first be introduced.

3.0 Modeling the Lung and Ventilator System

With the specific goal of designing controls, the simple and practical approach models lung-ventilator mechanics using lumped parameters directly based on physical properties of the system. This approach captures sufficient detail and provides good prediction of response to feedback control. Linear electrical circuits are a good choice for a system analogy where voltages represent pressures, currents are flows, electrical resistance is flow resistance, and capacitance is compliance [11]. Pressures are assumed to be relative to atmospheric pressure and for either side of the analogy, Kirchoff's voltage laws apply. The system elements described above are used to model simple behavior of the lung and airway as well as gas flow characteristics in the ventilator and connecting circuit. The linear circuit analogy lends itself well to analysis, but for high fidelity simulations, linear dynamic components are extended using static nonlinear relations to synthesize linear parameter varying (LPV) models.

3.1 Basic Elements

Before describing lumped parameter models, the basic individual elements that comprise these system models will first be addressed.

3.1.1 Flow Resistance

Analogous to electrical resistance and current that occurs from an applied voltage potential, pressure potentials across a restriction result in the flow of gas. Higher resistance impedes flow or conversely results in larger pressure differences for any fixed flow. Physical properties of the gas as well as the size, shape and roughness of the flow channel all affect the size of flow resistance. In lung-ventilator dynamics, linear resistance is an exception except perhaps in distal bronchi where channel diameters and flow velocity become extremely small.

Based on the assumptions of isentropic flow and a relatively low difference between upstream and downstream pressures, Andersen [2] approximates the weight flow of gas across a restriction of cross sectional area A_{12} as equation 1.

$$W_{12} = \left(\frac{1 - \frac{3}{2\gamma} \frac{\Delta P}{P_1}}{1 - \frac{1}{\gamma} \frac{\Delta P}{P_1}} \right)^{\frac{1}{2}} A_{12} \sqrt{2 g \rho_2 \Delta P} \quad (1)$$

Here γ is the specific heat ratio which is 1.4 for diatomic gases such as oxygen and nitrogen as well as their mixtures. P_1 is the upstream pressure, and the pressure difference is $\Delta P = P_1 - P_2$. P_2 is the pressure downstream of the restriction. The first term in (1) is derived from the series expansion of the flow factor, N_{12}, and ρ_2 represents specific weight (rather than density) of the gas downstream of the restriction. g is the gravitational acceleration constant. Expression (1) is particularly suitable for modeling the static flow-pressure relationship through restrictions where A_{12} as well as ΔP are considered as input variables. It therefore serves as a nonlinear model for fixed restrictions such as tubing and fittings as well as valves where the restriction, A_{12}, is an input variable. For modeling patient-ventilator systems, volumetric flow is used more often than mass or weight flow. By selective unit conversions in (1), a further simplified expression for volumetric flow is derived as equation 2.

$$Q = A \sqrt{\frac{g}{5} |\Delta P|} \left(\mathrm{sgn}(\Delta P) \right) \quad (2)$$

Introducing the *sgn(·)* function in (2) accommodates bidirectional flow. For this approximation, the first term in (1) is assumed near unity, introducing less than 1% error for delta pressures less than 60 cm H_2O at sea level. For (2), Q is the flow in liters per second, ΔP is either the gauge or absolute pressure difference in cm H_2O, g is the gravitational acceleration = 9.8 m/s^2, and A is the effective flow area in cm^2. A in this equation is the effective flow area and not necessarily the geometric area or the physical throat of the valve. The effective area accounts for any *vena contracta* as well as losses which occur from the fact the flow process is not truly isentropic. These affects can introduce a significant difference between the actual flow and flow predicted by (1). Effective area is often replaced by the product C_d and the true geometric area. Here C_d is the discharge coefficient which is a function of the restriction geometry. For a variable restriction, as in the case of a valve, C_d may also change as a function of A. Regardless, (1) or (2) is suitable for predicting general flow through restrictions for most ventilator feedback control system applications.

Equation 2 is non-Lipschitz at zero delta pressure which makes it problematic for simulation. Stiff solvers will often fail and the best solution is to relax equation (2) by adding a linear term. This seemingly ad-hoc approach actually has a physical basis since small flows are better characterized by equations that consider frictional effects and model laminar flow through capillary restrictions [2]. Equation 3 describes flow in this regime for a smooth circular tube.

$$W = \rho \frac{D^2}{32\mu} A \frac{\Delta P}{L} \quad (3)$$

For capillary flow the boundary layer nearly vanishes and pressure loss is dominated by frictional effects from the gas dynamic viscosity, μ, and the capillary surface area. For (3) , ρ is the specific weight of the gas (not density). D, A and L are the diameter, area and length of the capillary respectively.

From (3) capillary flow is expressed in terms of volumetric flow, Q, in liters per sec and an input column pressure, ΔP, in cm H_2O as equation 4.

$$Q = \frac{\pi D^4 \rho g}{12.8 \mu L} \Delta P \quad (4)$$

For (4), D and L are in cm, ρ is the gas density in g/cm^3, and μ is the viscosity in $N\text{-}s/m^2$. g is the gravitational acceleration constant, 9.8 m/sec^2.

3.1.2 Compliance

The state equation for an ideal gas is expressed by (5).

$$PV = mRT \quad (5)$$

Assuming V defines the volume of a fixed rigid container, the change in mass with respect to change in pressure within the container is described by equation 6.

$$\frac{\partial m}{\partial P} = \frac{V_{container}}{RT} \quad (6)$$

Since

$$\partial m = \rho_{amb} \cdot \partial V \quad (7)$$

$$\frac{\partial V}{\partial P} = \frac{V_{container}}{\rho_{amb} \cdot RT} = \frac{V_{container}}{P_{ambient}} = \mathrm{C} \quad (8)$$

C in (8) is called *compliance*. For a fixed container volume and fixed barometric pressure, compliance is a constant. The reciprocal of compliance is known as *elastance*.

Neither the lung nor patient circuit compliance is truly linear, but for analysis and design, linearity is assumed. For simulation, LPV models are synthesized where the parameter of compliance becomes a function of volume.

3.1.3 Inertance

While resistance and compliance properties capture the chief behavior of lung circuit systems, some researchers include *inertance* elements in their models. While the moving mass of the chest walls are modeled with inertia, inertance properties represent non compressive, bulk inertial effects of the gas in motion. In open loop systems, where ringing is observed, considerations on modeling with inertance may be justified however for the most part, lung-circuit systems without feedback do not tend to ring. Inertance properties may have more influence in systems with long tubing. The inertance per unit length of tubing is described by equation 9.

$$L_a \equiv \frac{m}{A^2} = \frac{P\ell}{RTA} = \frac{\rho \ell}{A} \quad (9)$$

3.2 Pressure and flow sources

Analogous to a voltage or current source, the output impedance of a pressure or flow source must also be considered in a system as it determines how the source will respond to a pneumatic load. Feedback controls applied to either source are used to lower source output impedance and reduce sensitivity to loading. For ventilator controls, pressure or flow sources are realized using valves, blowers, compressors or turbines. Strictly speaking each of these elements is a flow controlling device which are converted to a pressure source using feedback. As a source of flow, it may be possible to apply these devices open loop, but for more precision, feedback is usually required. Valves, blowers and turbines are characterized by affective bandwidth, determined by pneumatic properties as well as actuator dynamics. Either component can limit bandwidth.

3.3 Linear Lung-Circuit Models

3.3.1 The RC model of the Unassisted Lung

The simplest model of respiratory admittance, based on an analogy of an electrical linear RC circuit is shown in figure 2.

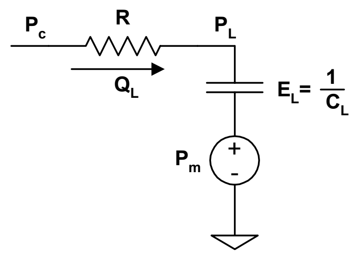

Figure 2 Linear 'RC' Model of the Unsupported Lung

In the linear RC model, P_c is the pressure at the airway inlet also referred to as circuit pressure. Q_L is the flow into the lung, R is the airway resistance, P_L is the pressure in the lung, E_L is the lung elastance, and P_m models respiratory effort in terms of pressure exerted by muscles. The admittance model from figure 2 as a function of the LaPlace operator *s* is equation 10.

$$Q_L = \frac{s}{Rs + E_L}\left(P_c - P_m\right) \qquad (10)$$

P_m is a periodic, negative valued function so a positive Q_L is flow entering the lung. For P_c zero (atmospheric pressure), the unsupported lung admittance is equation 11.

$$\frac{Q_L}{P_m} = \frac{-s}{Rs + E_L} \qquad (11)$$

For an unsupported, healthy lung, the admittance in (11) provides sufficient flow and volume for some sustained exertion by P_m. Figure 3 illustrates simulated waveforms for P_m and Q_L in a normal healthy adult.

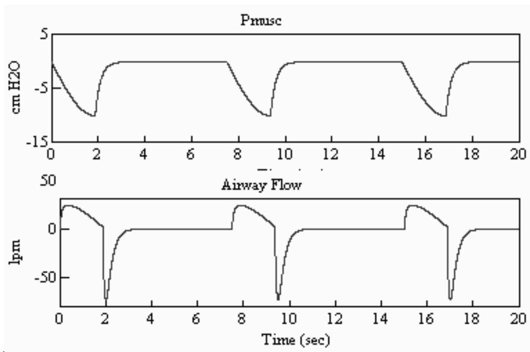

Figure 3 Unsupported (Spontaneous) Breath Waveforms

Disease or injury that can stiffen the lung and/or restricts airflow increases E_L and R respectively. Either impairment in lung mechanics decrease admittance so P_m must increase to compensate for insufficient flow and volume. If this persists for too long, fatigue and failure of the respiratory muscles ensue. In this event the patient may require external support from a ventilator to relieve the additional work imposed on P_m.

3.3.2 Introducing Support ;The RRCC Model

With support from the ventilator, dynamics of the patient circuit need to be considered in the model. The linear 'RRCC' model is shown in figure 4.

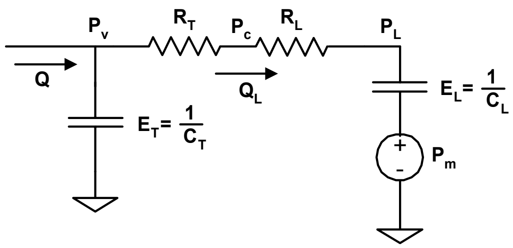

Figure 4 Linear 'RRCC' Model of Patient Circuit and Lung

For this model, Q may represent flow either entering or exiting the patient circuit on the ventilator side. P_v is the pressure at the ventilator outlet port, R_T and E_T are patient circuit tubing resistance and elastance respectively. As a model for designing pressure based ventilation (see 4.4) , the circuit pressure, P_c, is considered the output, Q is the input, and P_m is a disturbance. For analysis and simulation, the linear transfer function of this model is equation 12.

$$P_c = \frac{\frac{1}{C_T}\left(\frac{R_L}{R_L+R_T}\right)\left(s+\frac{E_L}{R_L}\right)}{s\left(s+\frac{E_L+E_T}{R_L+R_T}\right)}Q + \frac{\left(\frac{R_T}{R_L+R_T}\right)\left(s+\frac{E_T}{R_T}\right)}{s+\frac{E_L+E_T}{R_L+R_T}}P_m \quad (12)$$

For adult patient circuit, $R_T << R_L$, so R_T is neglected. In this case (12) simplifies to the 'RCC' model for circuit pressure described by equation 13.

$$P_c = \frac{\frac{1}{C_T}\left(s+\frac{E_L}{R_L}\right)}{s\left(s+\frac{E_L+E_T}{R_L}\right)}Q + \frac{\frac{E_T}{R_L}}{s+\frac{E_L+E_T}{R_L}}P_m \quad (13)$$

For volume ventilation or impedance based ventilation, where effective admittance is analyzed, Q_L is considered as the output, Q as the input and P_m as a disturbance. In this case the RRCC model results in the linear transfer function of equation 14.

$$Q_L = \frac{\frac{E_T}{R_L+R_T}}{s+\frac{E_L+E_T}{R_L+R_T}}Q - \frac{\frac{1}{R_L+R_T}s}{s+\frac{E_L+E_T}{R_L+R_T}}P_m \quad (14)$$

And for adult circuits, (14) simplifies to the RCC model for lung flow described by equation 15.

$$Q_L = \frac{\frac{E_T}{R_L}}{s+\frac{E_L+E_T}{R_L}}Q - \frac{\frac{1}{R_L}s}{s+\frac{E_L+E_T}{R_L}}P_m \quad (15)$$

For any of the transfer function models in (12) through (15) and for a passive (sedated) patient, where Pm is zero, the second term on the right is zero. Considering (15) for a passive patient with constant input flow $Q(t) = Q_v$, the steady state flow delivered to the lung is equation 16.

$$Q_L = \frac{E_T}{E_L+E_T}Qv = \frac{C_L}{C_L+C_T}Qv \quad (16)$$

Clearly volume, the integration of flow, is lost to compression of gas in the patient circuit. More on this will be discussed in paragraph 4.3 on volume ventilation.

3.3.3 Dynamic range of the linear models

Patient size can range from neonatal to adult and the state of health can substantially vary for a single patient or for different diseases. Considering all combinations, patient dynamics can range more than four orders of magnitude in terms of the lung time constant, R_L/E_L, illustrated by the log-log plot of figure 5. In this plot diagonal lines represent iso-temporal dynamics as a function of airway resistance and lung compliance. The large variation in dynamics underlines the difficulty ventilator controls present where the expectation is to provide a predictable and consistent response regardless of the patient load or ventilator settings.

3.3.4 Synthesizing LPV Lung-Circuit Models

For simulation, high fidelity may be needed to investigate proposed control designs. The linear models presented in the last section may be extended to consider selected nonlinear

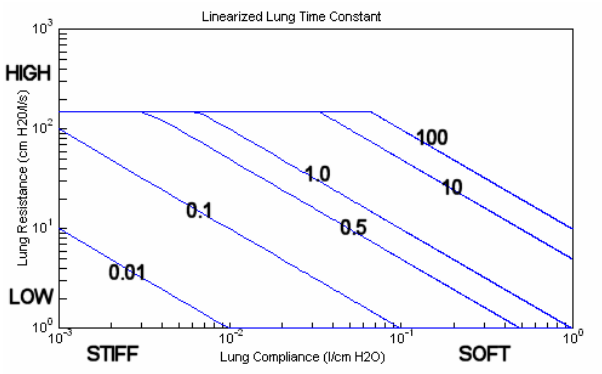

Figure 5 Dynamic Range of the RCC Lung Model

behavior by expressing these models as a nonlinear state space system from which simulation equations are easily written. Figure 6 illustrates an example of component nonlinearity by the static nonlinear pressure-flow behavior of ET tubes ranging from 2.5 mm to 9.0 mm in diameter using the inverse of equation 2.

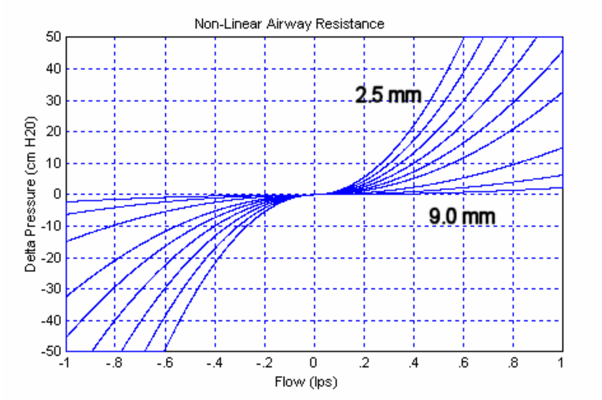

Figure 6 Nonlinear Resistance of ETT Tubes

For another example an LPV system is synthesized. The set of nonlinear differential equations in (17), (18) and (19), based on the linear RCC model of (13), models the system for exhalation flow controls by substituting the flow equation in (2) for the linear resistance. For this system the states x_1 and x_2 are the circuit and lung pressures, respectively and A is the input valve flow control area.

$$\dot{x}_1 = -\frac{E_T}{R_L}\sqrt{|x_1 - x_2|}\,\mathrm{sgn}(x_1 - x_2) + E_T\sqrt{\frac{g}{5}}\sqrt{x_1}\,\mathrm{sgn}(x_1)A \quad (17)$$

$$\dot{x}_2 = \frac{E_L}{R_L}\sqrt{|x_1 - x_2|}\,\mathrm{sgn}(x_1 - x_2) \quad (18)$$

$$Pc = x_1 \quad (19)$$

3.3.5 Modeling leaks

Although some effort is made to seal all connections between the ventilator and patient, leaks are unavoidable. The effects that leaks have on the control system depend on where the leak is located and the type of control applied. Leaks in the patient circuit usually occur from loose fittings, swivel joints, etc. In the specialized application of noninvasive ventilation (NIV), leak size on the patient circuit side may be very significant. Leaks on the patient side can occur from an under-inflated ETT cuff, open wounds or chest tubes in the lung. Based on the RCC model, leaks influence distinctly different dynamics depending on whether they occur on the patient side or patient circuit side of the lumped airway resistance, R, in the model. A leak is modeled as a resistive element between any pressurized compartment and the atmosphere resulting in a loss of gas. For the RCC model R_1 represents the cumulative leak resistance on the circuit side of the airway resistance and R_2 represent the cumulative leak resistance on the patient side. Considering these combined leaks, the transfer function from inlet flow to circuit pressure is expressed by the transfer function in equation 20.

$$\frac{P_c}{Q} = \frac{E_T\left(s + E_L\left(\frac{R_2 + R}{RR_2}\right)\right)}{s^2 + \left(E_T\left(\frac{RR_2 + R_1R_2}{RR_1R_2}\right) + E_L\left(\frac{R_1R_2 + RR_1}{RR_1R_2}\right)\right)s + E_TE_L\left(\frac{R + R_1 + R_2}{RR_1R_2}\right)} \quad (20)$$

(20) was used to analyze what effects leaks have on the stability of PAV in [7].

3.4 Flow Actuating Devices

The movement of flow to and from the patient may be actuated using a number of different devices. For flow delivery, valves blowers or pumps are usually used, and for flow exhaust, valves are the primary method. Valves and blowers will be discussed, but pumps or piston devices, which are tending to be used less often, are not addressed.

3.4.1 Valve based flow delivery systems

To deliver a controlled flow at a specified concentration of oxygen, most ventilators designed for the hospital ICU use proportional flow valves since plumbed air and oxygen are readily available. Modeling of flow delivery valves is approached by separating the model into two parts, one that considers the valve actuator moving mass dynamics, represented by G(s) in figure 7, and another part that models static flow based on (1) or (2).

Dynamics of the manifold that connects the valve and pressure supply may also require consideration. Flow-pressure dynamics of manifolds can have significant effect on the rise time of exiting flow, Q_v , even if actuator dynamics are relatively fast. Flow delivery valves may be designed to work with either sonic (choked) or subsonic flows which depend on the set upstream pressure of the valve, $P_{manifold}$ and variable valve flow area, A. One advantage of operating sonic is that downstream pressure disturbances at P_c cannot easily propagate upstream. Since $P_{manifold}$ is usually regulated at a constant pressure, and is relatively high with respect to P_c, the flow source impedance for flow delivery valves is considered low even in the subsonic regime. Another thing to consider in the flow model, especially for unbalanced valve designs are the influence of net pneumatic based forces on the valve actuator. These forces may or may not need to be taken into account depending on the stiffness of the actuator dynamics in G(s).

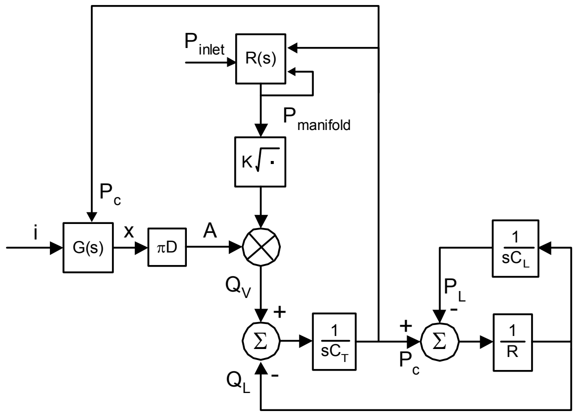

Figure 7 Block Model of Valve Based Flow Delivery

Most valve based flow delivery systems rely on a source of constant pressure provided by pneumatic regulators as part of the ventilator pneumatics assembly. The transfer function R(s) in figure 7 includes the model for a pressure regulator and manifold R-C dynamics that connect the regulator to the valve input. Pressure regulators are typically mechanical mechanisms that can introduce flow dependent dynamics leading to control issues. Droop in outlet pressure at high flow, slow recovery after liftoff, oscillations, and flow limiting are a few of issues imposed by regulators that can degrade control performance. Although the source of inlet air and oxygen between different hospitals can vary, they are often limited between some known minimum and maximum pressures. By selecting a low set point for $P_{manifold}$, the ventilator can better accommodate a wide range of service connections and thus minimize impact on flow delivery. Operating the flow delivery at a fixed set point significantly reduces the complexity of the controls which may otherwise need to take upstream pressure measurements into account. Since the flow valve inlet pressure determines flow control sensitivity at all points of operation, its value has direct implications of response and stability for fixed gain controllers. On the other hand, eliminating input regulation can significantly reduce costs. Selection of either approach certainly warrants a tradeoff analysis that must consider all component alternatives in the flow delivery system, their cost and performance requirements.

3.4.2 Turbomachine based flow delivery systems

For ventilator use outside the ICU, pressurized gas sources may not be readily available or cost effective. The cost of maintaining compressed air for ICU applications has also prompted industry to design ventilators that do not require compressed air connections but rather work with ambient air. Turbomachines, such as blowers and compressors, are the obvious approach but their application requires additional consideration in control systems as well as other design aspects that are not issues in valve based systems.

Modeling flow – pressure relations in a turbomachine is typically more complicated than determining flow in a valve based system. Flow is not only a function of the delta pressure across the machine but also dependent on the speed. Figure 8 illustrates the typical state diagram for a centrifugal blower where the curves N_1 – N_5 represent constant, increased speeds.

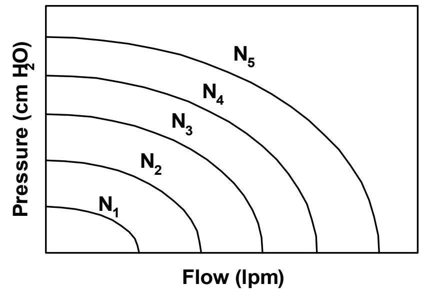

Figure 8 Typical Characteristics of Centrifugal Blower

An in-depth treatment of turbomachines is beyond the scope of this paper but the reader is referred to [14] and [15] for more detailed information on the subject. Some of the more salient issues regarding controls with turbomachines will be briefly presented here. The typical turbomachine has higher output impedance relative to systems based on valves with compressed air sources, thus they are more sensitive to loading. However stiffness in flow delivery may be increased using feedback controls.

While some turbomachine based ventilators operate at constant rotor speeds and use valves to control flow, others have chosen to eliminate the valve and directly control flow by varying rotor speed. Performance using this latter approach usually cannot be satisfied using commercial off the shelf blowers thus requiring custom motor and blower designs that provide very fast response times. For this approach full quadrant amplifiers are needed to provide bidirectional torque that can rapidly accelerate the rotor in either direction. At operating speeds that can exceed 50,000 rpm, laser balanced, low inertia rotors may be required to keep peak current, acoustic noise, vibration and heating within acceptable limits.

3.4.3 Exhalation Valve Modeling

While flow delivery is used to control downstream pressure in the patient circuit during inspiration, the exhalation valve is used to control upstream pressure in the circuit during exhalation. This fundamental difference introduces a higher degree of nonlinear behavior in the control of exhalation and makes exhalation controls the most difficult. For most breath types, when inspiration ends, the pressure is elevated above set Positive End Expiratory Pressure (PEEP), and the exhalation valve must be controlled to vent flow so that the pressure accurately reaches PEEP. The controls must do so without overshoot since the circuit-lung system may not have enough reserve gas to regain pressure once a critical volume is vented.

The design of exhalation valves is approached in one of two ways, characterized by the mechanism that couples the valve actuator and valve seat, the relative size between the

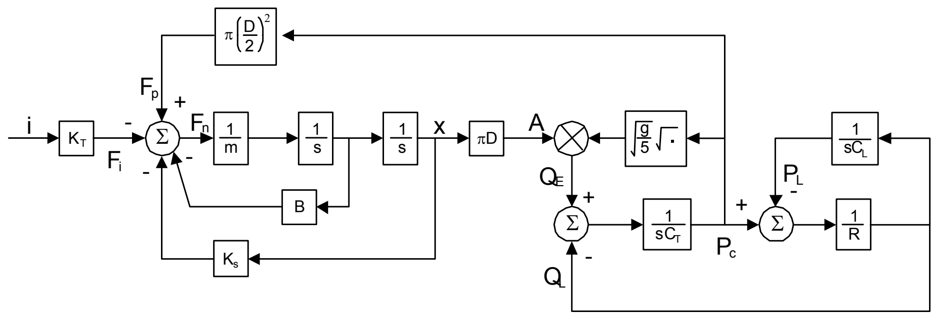

Figure 9 Block Model of Exhalation Valve Flow

actuating force and pressure force, and the actuation stiffness. The first approach attempts to match the pressure force applied on the seat by circuit pressure with an equal actuating force. This method of 'force balancing' is done using an electromechanical (voice coil or motor) actuator or pneumatic mechanism such as a proportional flow valve and Venturi. By applying a known force over a known seat area, upstream pressure is automatically regulated at steady state, constant or zero flow. The second approach disregards force and strictly controls flow area proportional to valve voltage or current.

While the force balance approach provides automatic relief in the case of an over pressurized patient circuit, this type of valve is more difficult to control during the rapid transition from terminal inspiratory pressures to PEEP. For either approach, figure 9 helps illustrate the differences between force balance and area controlled exhalation valves.

For force balance controls K_s, the total actuator stiffness, is zero or very small. The control force, F_i, is adjusted to balance the pressure force, F_p, determined by the circuit pressure and seat area. It's clear from figure 9 this applied force must be the product of the desired pressure and area of the seat plus the actuator restoring force at steady state.

For area control, K_s is large so that intrinsic restoring forces are large compared to F_p thus allowing stiff control of the flow area with respect to input current, i. For area control, F_p is considered a disturbance. More will be discussed in section 4.5 regarding exhalation controls. For now further characteristics of the exhalation valve will be examined.

In terms of the flow behavior with respect to changes in pressure and area either type of valve design described above is governed by the nonlinear equations for flow and pressure in (1) or (2). To illustrate the radical difference between flow delivery and exhalation valves, the equations in (2) are used to generate characteristic curves shown in figures 10 and 11.

For this illustration, typical valve seat diameters of 0.1 and 0.7 inches were used for a flow delivery and exhalation valve respectively. A flow range of 0 to 120 lpm was considered with constant circuit pressures ranging between 0 and 140 cm H_2O. Note that while circuit pressure represents downstream pressure in the flow delivery valve, where upstream pressure was a constant 15 psig, for the exhalation valve circuit pressure represents upstream pressure, while downstream pressure is ambient (zero gauge). These plots clearly show the more nonlinear behavior observed in exhalation controls by characteristic curves that are much more unevenly spaced and more broadly separated than the curves that characterize the flow delivery valve.

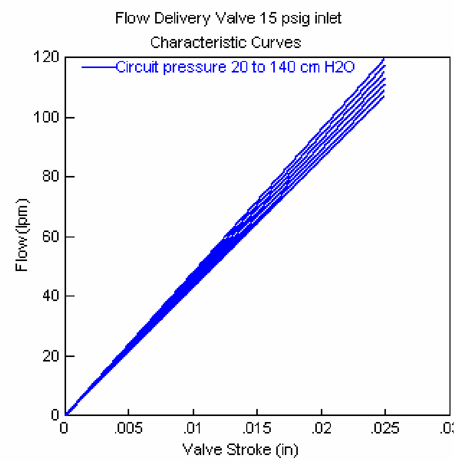

Figure 10 Typical Static Flow Response For Flow Delivery Valves

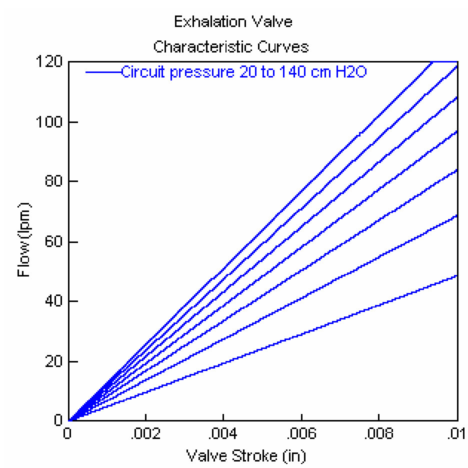

Figure 11 Typical Static Flow Response For Exhalation Valves

In terms of control gains for pressure controls, the model in (2) is inverted and the upstream pressure response is plotted in figure 2 over the stroke of the valve and at various iso-flow curves. These characteristic curves represent a state diagram for flow, pressure and valve displacement and graphically illustrate the range in static $\Delta P/\Delta x$ gain imposed by an

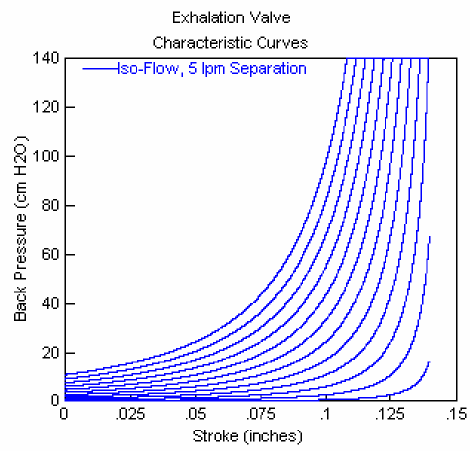

Figure 12 Characteristic Curves For Typical Exhalation Valve

exhalation valve in closed loop. Zero on the horizontal axis represents full open position and 0.15 inches is fully closed. It's clear the gains become enormous when the valve closes which largely explains why tail end flow oscillations are so common in exhalation pressure feedback controls. The equally extreme low gains at the other end of the curves explain why the valves may become non responsive for large breaths where the valve must initially fully open and then quickly throttle back.

4.0 Ventilator Control Systems

Ventilator control systems may be grouped into two major categories: (1) the basic building blocks that establish the control of flow, mix, volume and pressure, and (2) higher level controls that use these building blocks to meet more complex ventilation goals. High level controls are further categorized into two groups: one that uses patient monitored variables, and the other that does not. Patient monitored variables includes measurements or estimates of lung mechanics, blood gas, etc. Examples of the higher level controls that don't use patient monitored variables include Volume Assured Pressure Support (VAPS) and flow regulated CPAP (FRCPAP). Examples of higher level controls that use either direct or indirect monitoring of patient variables include Proportional Assist Ventilation (PAV) and Volume Targeted Pressure Control (VTPC). The higher level ventilation controls that use direct monitoring of patient variables are often referred to as 'Closed Loop Ventilation' by clinicians since these systems replace some of the decision processes normally executed by doctors or clinicians.

For either of the two categories mentioned above, control engineering is faced with significant challenges by the large range of parameter variations, nonlinearity and the complexity of human physiology.

4.1 Flow control

Flow control is the foundation for other basic ventilator controls, often applied as an inner feedback loop. Flow control provides the basis for accurate mix control, volume delivery and pressure control. Separate flow control loops for air and oxygen stabilize and deliver accurate mass flows into a mixing manifold to obtain a desired oxygen concentration for the total delivered flow. For volume control, accurate total flow tracking is required for square, ramp or sinusoidal flow trajectories such that the accumulated flow meets a set tidal volume. Inner loop flow controls can reduce sensitivity to disturbance for PBV controls (see 4.4). Some lower cost ventilators do manage without flow feedback controls by careful calibration of the flow delivery valve and pre-mixing air and oxygen with a mechanical device called a *blender*. The disadvantages these systems encounter in loss of performance as a tradeoff to cost is obvious from the benefits closed loop controls are known to offer.

Flow controllers for critical care ventilation are typically simpler to design than pressure controls since flow response is less sensitive to circuit and patient dynamics. Feedforward-integral, PI and PID controls are typically used. Since the range of delivered flow spans from zero to the saturation limits of the valve or blower, the controller must be designed to consider these limits to avoid windup in the control.

Perhaps the greatest challenge in flow control is at extremely low flow delivery. Extreme settings in mix (near 21% or 100% O_2) and/or flow delivery for neonatal patients can tax the resolution limits of the flow control valve and/or flow sensors. Flow delivery valves exhibit rapidly reduced gain at flows less than 1 lpm and often show hysteresis, non-monotonic and unrepeatable behavior. The current or voltage at which the valve begins to flow is called *liftoff*.

Liftoff and large changes in slope near zero flow are due to mechanical limitations of the valve, and are not directly characteristic of the flow equation described in (1). The smaller sensitivity of the valve at lower flow results in relatively slower closed loop dynamics if fixed gain controls, based on nominal flow are used. In this situation flow control at low flow may not be able to track the desired trajectory. This can result in inaccurate mix and volume errors and slower rise time in PBV controls. One way to solve gain inconsistency is to schedule control gains according to the input command. Still, repeatability of an individual valve as well as variability among a manufacturing population can complicate this approach.

4.2 Mix Control

Mix control, or control of fractional inspired oxygen (FiO_2), is required to provide a desired oxygen concentration in the delivered gas. Early ventilator designs relied on mechanical blenders to provide premixed gas to a single flow control valve. Blenders are still used today. With availability of high quality flow sensors and processing capabilities, more accurate mixing becomes possible by using separate flow valves for air and oxygen. Since air already contains about 21% oxygen, the equations that ratiometrically divide the total flow control command between the oxygen and air valve are expressed by equations (21) and (22) where Q_T is the total desired flow and M is the required fractional oxygen (from 0.0 to 1.0). From these equations it is clear that, for extreme mix settings, the valve that supplies the minor flow at low total flow requirements may fall below the resolution limits that

$$Q_{O2} = \frac{(M - 0.21)}{0.79} Q_T \quad (21)$$

$$Q_{Air} = \frac{(1.0 - M)}{0.79} Q_T \quad (22)$$

either flow delivery or measurement can provide. For example: if minimum flow for a volume control breath is 3 lpm, and a 22% concentration is desired, the required flow from the oxygen valve is 0.038 lpm. The best flow sensors claim no better than 0.1 lpm resolution, but designers tend to push these limits.

Accurate delivered mix depends on accurate flow delivery but if accurate and reliable oxygen sensors are obtained, improved mix accuracy may be possible by feeding back measured concentration for mix correction. Galvanic based oxygen sensors drift and cannot meet these requirements, but the more recent zirconium oxide based technology with a 5 years + lifetime and accuracy may soon find practical applications in closed loop FiO_2 controls.

4.3 Volume based ventilation controls

The simplest method of breath delivery is volume ventilation where a specified volume of gas is delivered to the patient. This is accomplished by commanding a specific trajectory in flow over a specified time. Although the concept is simple, accurate volume delivery may be a challenge since some of the volume that exits the ventilator is compressed in the patient circuit. This volume should be accounted for if the goal is accurate volume delivery to the lung. This issue is most pronounced in small patients such as neonates, where the patient circuit volume is comparable to or exceeds lung volume. Most ventilators ignore loss of volume in the patient circuit and expect the clinician to compensate by setting a slightly larger volume. At steady state, the actual volume delivered to the lungs is determined by the compliance ratio between the circuit and lung. But in practical application, the set inspiratory time may be on the order of the lung-airway time constant and airway resistance can dynamically influence lung volume.

According to the RCC model, equation 15 relates flow issued by the ventilator, Q, to flow that enters the patient airway, Q_L, and for volume delivery to a passive patient, P_m is zero. Assuming a constant flow, Q_p, for t = 0 to T_i, the input is (23).

$$Q(s) = \frac{Q_p}{s}\left(1 - e^{-sTi}\right) \quad (23)$$

Substituting (23) into (15) and solving for Q_p in the time domain, and furthermore substituting t = T_i , provides a generalized equation for determining the necessary size of Q_p for square flow waveform volume delivery with patient circuit compliance compensation as (24).

$$Q_p = \left(\frac{C_L + C_T}{C_L}\right)\left(\frac{V_T}{T_i}\right)\left(\frac{T_i}{T_i - \tau_{RCC}}\right) \quad (24)$$

where the inspiratory time, *Ti*, is determined by (25),

$$T_i = \frac{V_T}{Q_{pset}} \quad (25)$$

V_T and Q_{pset} are the set tidal volume and peak flow respectively, and (26) is the lung-circuit time constant.

$$\tau_{RCC} = \frac{R C_L C_T}{C_L + C_T} \quad (26)$$

In the case where Ti is significantly larger than the circuit-lung time constant, (24) reduces to (27)

$$Q_p = \left(\frac{C_L + C_T}{C_L}\right) Q_{pset} \quad (27)$$

While (27) is an approximation, (24), (25) and (26) provide an exact calculation based on the RCC model for the required flow to compensate for patient circuit compliance. Given that the ventilator is limited in how much flow is sourced, Q_{max}, These equations determine an upper bound on what dynamics are compensated as a function of V_T, Q_{pset} and the compliance ratio by equation (28).

$$\tau_{RCC} < \frac{V_T}{Q_{pset}}\left(1 - \frac{Q_{pset}}{Q_{\max}}\left(1 + \frac{C_T}{C_L}\right)\right) \quad (28)$$

Since this analysis is based on the RCC model, and dynamics are actually nonlinear, it can only serve to illustrate the need to take full dynamics into account rather than just the steady state correction shown by (27). Furthermore it suggests that system ID methods may be a useful approach towards more accurate volume delivery.

Other than the simple square flow waveform command, other waveform types include descending ramp and sinusoidal although sinusoidal is not used very often. A similar analysis using these other waveforms leads to similar results in terms of the required components for compensation.

Besides compensating for volume loss from compression in the patient circuit, volume must also be corrected for humidity and barometric pressure. Since gases supplied to the ventilator are dry, a humidification system is required to provide moisture in the delivered gas. This prevents damage to the sensitive tissues in the airway and lung. A humidifier is typically connected between the ventilator outlet port and patient circuit (see figure 1). The humidifier adds water vapor and heats the gas to near body temperature. The set tidal volume is typically specified in BTPS (Body Temperature Pressure Saturated) units so the state equation for an ideal gas and Dalton's laws for partial pressure are applied.

4.4 Pressure based ventilation (PBV)

An even more challenging problem in basic ventilation controls is pressure based ventilation (PBV). For PBV controls, variation in plant parameters have a more significant effect on control response than flow or volume controls. For typical PBV controls that assist breathing effort, the goal is to rapidly step and settle to an elevated pressure in the patient circuit. The initial pressure difference between the circuit and lung causes flow to enter the airway. As the lung eventually fills, pressure in the circuit and lung equalize and flow ceases. For PBV, patient demand as well as set target pressure can influence the volume of gas delivered to the lung.

Transient response in PBV must be capable of rising and settling within a 1 cm H_2O accuracy in the short period of the inspiratory and expiratory phases of the breath. When considering patient size can range from neonatal to adult, these periods may be as short as a couple hundred milliseconds in inspiration and as long as several seconds in exhalation. For lungs compromised by disease, repetitive overshoot in inspiration may be disturbing to the patient or worse cause excessive shear stress on tissues that may lead to *barotrauma*. Repetitive and excessive overshoot in exhalation may lead to *atelectasis* (further discussed in 4.4.2). Further demand on basic PBV controls requires adjustable rise time on the inspiratory transient or for higher level control applications, the ability to track an arbitrary input trajectory. For basic PBV, accurate rise time is controlled using a specified trajectory as the input command. Although a simple ramp can work, the choice of an exponential input trajectory essentially serves as a prefiltered input step command to the closed loop system which helps to avoid overshoot.

Clearly the RCC model is a type 1 system. A proportional controller is ideal for airway resistance, $R \to \infty$ or $R \to 0$. At either extreme, the plant is essentially a single integrator and the closed loop system under proportional control of the error behaves like a single pole. Delay in the pressure sense lines, dynamics of the flow valve and sensor noise become the only limitations on how much gain, and correspondingly bandwidth, is obtained using proportional gain.

For R between either of the extremes discussed above, feedback with non-integrating, stabilizing compensators indeed result in a zero steady state error for a step change in input, but some combinations of airway resistance and compliance can cause significant undershoot for non-integrating controllers. For these cases, the time to reach target may substantially exceed the breath phase interval. This may lead to considerable pressure error at the end of the breath. A non integrating compensator avoids this problem if it contains a pole that matches the lung time constant, but this requires adaptive compensation since the time constant may vary throughout the course of treatment. No fixed gain controller exists that can adequately compromise between the range of dynamics illustrated by figure 5. Therefore, for fixed structure controllers with fixed gain, integration is required.

The preferred site for pressure measurement and control is the Y connector. Pressure transducers are typically located in the ventilator and either small bore tubing with a separate Y connection or the exhalation leg of the patient circuit itself is used to sense pressure. The speed of sound limits the ultimate rate at which pressure changes can propagate through the patient circuit and sense lines. This limitation introduces a pure time delay in pressure sensing. This delay is about 1 millisecond per foot of tubing. In addition, any distributed RC properties of the tubing can contribute additional phase lag. Patient circuits can range from 6 to 8 ft. in length and sense lines are equally long.

Traditional control of PBV uses PI compensation. This is mainly due to a legacy of inadequate processor bandwidth, but as processor speed has improved, progress towards more advanced control methods has been impeded by the manufacturer. This hesitation stems both from the cost to change and the cost to validate safety and efficacy under the scrutiny of regulatory agencies.

Figure 13 illustrates a typical system that applies to basic PBV controls including Continuous Positive Airway Pressure ventilation (CPAP), Pressure Control Ventilation (PCV) and Pressure Support Ventilation (PSV). The only difference between these three breath types is the choice of the reference pressure and how the breath is cycled.

In any case, patient demand at P_m reduces pressure in the circuit, P_c, through lung and circuit impedance, and this reduction is sensed by the pressure transducer in the circuit. The error between the reference pressure and measured pressure then drive more flow through the controller and valve G(s) to increase circuit pressure. The controller is suspended , shutting of the flow delivery at the start of and during exhalation, and re-initialized at the start of each new breath. Limits and windup controls are essential for rapid and accurate response.

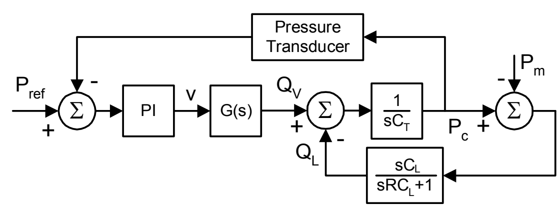

Figure 13 Fixed Gain Control of PBV

To visualize the stability of the RCC model using a fixed gain PI compensator, a median test case is chosen from figure 5 that represents a middle point for dynamics: R = 15 cm H_2O/l/s and C_L = 0.03 l/cm H_2O. For this test case, a PI compensator was designed to provide an optimal transient response: best tracking performance following an exponential trajectory with ~ 100 msec rise time. From this design, The R and C_L parameters were varied for a $C_T \sim 0.0018$ l/cm H_2O; a typical adult patient circuit compliance. Phase margin was then calculated for all of these parameter combinations and plotted in a 3 dimensional graph, shown by figure 14.

The results of this analysis show more than adequate phase margin at the original design parameters, high sensitivity in margin drop-off as airway resistance decreases however less sensitive decrease in margin as compliance decreases. At either of these cases of decreased phase margin, the small amount of lag introduced by pressure sensing or valve dynamics may lead to instability.

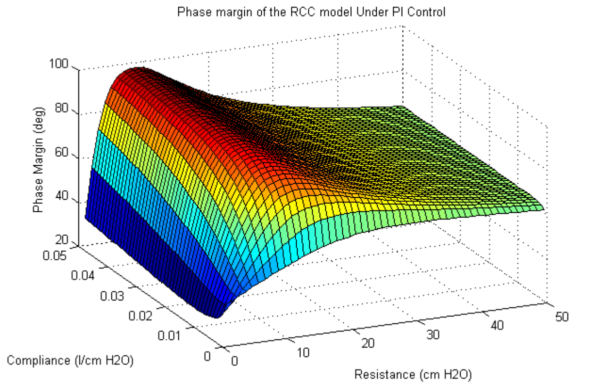

Figure 14 Phase Margin for PI Control of the RCC Model

Fixed gain PI control results in remarkably different transient response depending on the variability of lung/circuit loads. At extreme dynamic loads stiff unrestrictive lungs result in overshoot if gain is too small, and soft restrictive lungs induce oscillation if gain is too large. PI control provides a zero steady state error, for all C_L, C_T and R however the compensator zero = K_i/K_p introduces overshoot along with the plant zero at $1/RC_L$. For $R \to 0$, the system is 2nd order, and K_i and K_p independently set the bandwidth and damping respectively. For larger R , the closed loop system approaches 3rd order dynamics, and transient behavior becomes harder to predict. The problem with PI control is if the gain is fixed for adequate response near small R, then systems with larger R will respond with ringing. The typical solution is to compromise at some gain selections that tradeoff speed at R near zero with reduced ringing at larger R. Either a compromise must be made in selecting the control structure, parameters or some means of adaptation must be employed.

4.4.1 An Adaptive Control Solution to PBV

The variability of plant parameters as disease progresses, between patients or even within a single breath was shown to be manageable using a simple adaptive method. An indirect inverse model adaptive controller using least squares parameter identification was successfully applied to PBV in an experimental PB840 ventilator [5]. Although parameter estimates in this approach may not necessarily converge to the true parameters, the tracking error for all patient loads is significantly reduced relative to fixed gain controllers. Figure 15 shows an example of LSE on the PB840 prototype. The result is uniform transient response for all patient and circuit loads. This is true for ventilation of a passive (sedated) patient as well as an actively breathing patient.

With the indirect approach to adaptive control, the covariance of the estimation error may tend to grow excessively large at very low breath rate since persistent excitation is not satisfied. Simulation shows that the growth of covariance is limited by allowing parameter estimation only during the exhalation phase of the breath. Another problem with practical application of this method is initial startup. Normally a few seconds are required for the parameter estimates to settle, and the pressure response may tend to be sluggish, impulsive or even unstable until the estimator settles. One solution is to apply a known stable fixed gain controller for the first few

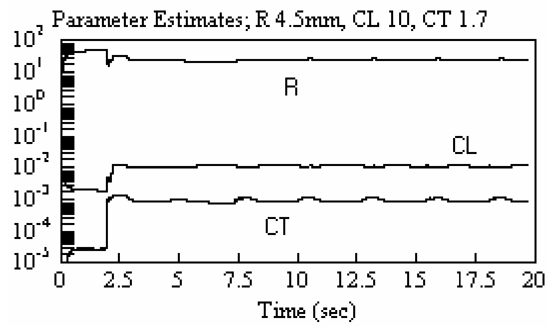

Figure 15 LSE Parameter Estimates Based on RCC Model

seconds then switch to adaptive control at the start of the next breath following stable estimates. Figure 16 illustrates the basic concept of the adaptive control architecture. The compensator, C(s) has the structure of the inverse RCC model less the integrator shown by (29).

$$C(s) = \frac{\omega(s+k_3)}{k_1(s+k_2)} \quad (29)$$

By assuming certainty equivalence, the poles and zeros of C(s)*G(s) cancel leaving a single integrator in the closed loop. The result is an equivalent first order closed loop dynamics.

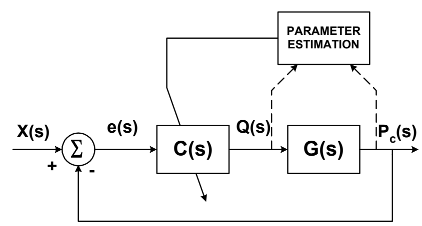

Figure 16 Adaptive Control of PBV

Parameter estimates for the adaptive control are determined using a discrete time parametric model based on the RCC model in (13) and by measuring circuit pressure and ventilator inlet flow. (30) through (36) define the estimator.

$$w(s) = \Theta^T \Phi(s) \quad (30)$$

$$\Theta^T = \begin{bmatrix} \theta_1 & \theta_2 & \theta_3 \end{bmatrix} \quad (31)$$

$$\theta_1 = RC_L C_T \quad (32)$$

$$\theta_2 = C_L + C_T \quad (33)$$

$$\theta_3 = RC_L \quad (34)$$

$$\Phi^T(s) =$$

$$\begin{bmatrix} \frac{s^2}{(s+\lambda)^2} P_C(s) & \frac{s}{(s+\lambda)^2} P_C(s) & \frac{s}{(s+\lambda)^2} Q_V(s) \end{bmatrix} \quad (35)$$

$$w(s) = \frac{1}{(s+\lambda)^2} Q_V(s) \quad (36)$$

4.5 Exhalation Pressure (PEEP) Controls

In ventilation, accurate control of pressure during patient exhalation is just as crucial as controlling pressure or volume during inspiration. Many types of lung disease tend to deplete *surfactant*, a material naturally produced within the alveoli that lubricates and keeps the walls of the alveoli from ‘sticking’ together. A collapse of the lung in this state is known as atelectasis. By applying a positive pressure in the lung during exhalation (PEEP), the alveoli are kept expanded and the risk of atelectasis is reduced. Regulating pressure at the PEEP level is desired as well as providing rapid transient response from the end inspiratory pressure to PEEP without overshoot and disturbing settling transients. A rapid fall in pressure immediately reduces the expiratory work of breathing and allows the patient to exhale under the natural elastic recoil of the lung. Retarding the fall in pressure may stimulate the patient to force exhalation, which in the long term can fatigue respiratory muscles. Delayed exhalation can also cause gas trapping which can lead to higher end tidal CO_2. Overshoot of PEEP must be avoided since the collapse of alveoli can occur for even a brief reduction in pressure. Rapid transient response with no overshoot together with a greater nonlinear flow to pressure relation in the exhalation valve make exhalation controls the most challenging and difficult problem in ventilation controls.

4.6 Triggering, Disconnect and Occlusion

Other issues in ventilation not directly related to feedback controls, but usually the responsibility of control engineering, include breath triggering and detection of patient circuit occlusion and disconnects. For breaths that assist breathing some means are required to sense patient demand to synchronize actions between the patient and ventilator. This requires sensing to trigger the ventilator into an appropriate breath phase. To minimize the effort to initiate trigger, sensitive measurements from either pressure or flow are required. These measurements are usually compared against a set threshold and often require special algorithms to reject noise and artifacts that can cause false trigger. Flow triggering is intrinsically more sensitive than pressure triggering since two flow sensors, one at the ventilator flow outlet, and one at the exhalation valve are differenced to estimate patient flow demand at the wye. For flow trigger, exogenous pressure disturbance from the circuit is cancelled as ‘common mode’ noise. Breath cycling is categorized as mandatory, where the ventilator decides when to begin and end inspiration, or triggered, where trigger determines the start of the breath. Termination of the breath (start of exhalation) is normally determined by specific flow criteria, volume or time. Triggering can apply to either volume or pressure based breaths. False triggering can lead to *autotrigger*, uncontrolled limit cycles that result in small rapid repetitive breath cycling. Besides the algorithm itself, which provides high discrimination between patient effort and noise, sensitivity to autotrigger is also minimized with stiff, accurate control of PEEP during exhalation.

Besides leaks, faults that can occur in the patient circuit include occlusions or disconnects. Occlusions restrict or entirely block the passage of gas between the ventilator and patient. Occlusions occur from excessive condensation in the patient circuit or any external force that causes the flow area to collapse such as the circuit being trapped between the bed and bedpost. Disconnects occur from loose fittings anywhere in the circuit as well as extubation, where the ET tube or canula becomes disconnected from the patient. Both occlusions and disconnects may be life threatening. The ventilator should have some means to detect either condition, and alert medical personnel through the ventilator alarm systems. Control engineering is often responsible for the algorithms that detect occlusion or disconnect. Like triggering, the algorithms require some means to discriminate between true faults and noise or anomalies. If the systems are not sensitive enough they may miss detecting a fault. If they are too sensitive excessive false alarms distract clinical personnel and eventually become ignored. At either extreme the system becomes ineffective and poses a hazard to the patient.

4.7 Higher Level Controls

At the highest level of ventilation controls, the doctor or clinician must assess the patient’s state of health and decide what type of ventilation should be applied and what specific settings should be used on the ventilator. Breath rate, tidal volume, peak flow, PEEP and inspiratory pressure are just a few examples of the settings that may be considered. These settings in turn determine the trajectory that commands the flow, pressure or volume controls. With a ‘clinician in the loop’, frequent adjustments of these settings are required as the patient’s health either improves or deteriorates. The term “closed loop ventilation”, as used by clinicians, refers to automating this decision process and either reducing participation by or entirely removing the clinician from the loop. Closed loop ventilation requires direct measurement of one or more patient variables. Brunner [10] describes some of the methods that have been explored in closing the loop on ventilator settings. Although some methods have shown promise, for obvious concern, clinicians are not yet willing to relinquish control to automation. One of the approaches to closed loop control cited in [10] targets a desired end tidal CO_2 using capnometer measurements. Based on the difference between a desired and measured end tidal CO_2, breath rate is adjusted. The desired end tidal CO_2 presumes achieving this level results in an optimal delivered minute volume and corresponding optimal gas exchange.

Another approach to closed loop ventilation that was widely explored is targeting a desired level on the imposed work of breathing. Imposed work is quantified in terms of thermodynamic work calculated by the contour integration of the pressure volume loop at the patient airway which is equivalent to the time integration of the pressure flow product as shown by (37).

$$W(t) = K \oint_{VT} P_{WYE}\ V\,dV = K \int_0^t P_{WYE}(t) Q_L(t)\,dt \quad (37)$$

Neither too much nor too little imposed work is beneficial to the patient, and so the supposition is that some level of unloading is optimal. Analysis of PAV may be approached from this perspective however its basis is closer to normalizing respiratory impedance. Since an automatic method for determining work of breathing is difficult to apply in the clinical setting, researchers have considered indirect methods that approximate imposed work. One of these methods, $P_{0.1}$, is a minimally invasive, automatic maneuver executed at the start of a breath. In this maneuver, the patient circuit is occluded for the first 100 msec and pressure drop is measured over that period. Researchers have shown that the maximum slope in pressure over the interval of occlusion correlates with the patient's level of effort. By assessing effort, an adequate level of support is prescribed.

Since a functional respiratory system involves many coupled interconnections between the circulatory, muscular and nervous systems, any control interface with the lung can, without a doubt, be considered a complex multi-input multi-output (MIMO) system. Furthermore clinical goals in ventilation seek multiple objectives including adequate perfusion and reduced patient effort constrained by limits that safeguard the patient. Any closed loop approach to ventilation must consider many factors to emulate the safety and effectiveness presently offered by a clinician in the loop. Although patient assessment can likely be broken down into a well defined system of measurements and rules, there are certainly other factors that may not be easily assessed by a machine. Obviously clinical expertise is critical to formulate an automated approach. Systems engineering can only be expected to glue this expertise together for safe and efficient systems.

Some of the more well known methods of higher level controls are further discussed in the next few paragraphs.

4.7.1 Volume Assured Pressure Support VAPS

PBV may not provide satisfactory delivery of minute volume if the clinician were to set the inspiratory pressure too low. Modifications to the basic pressure control or pressure support breaths were developed to address this problem. VAPS or Volume Assured Ventilation, first suggested by Amato et al [1] uses a pressure support or pressure control breath to initiate inspiratory support however the constraint of minimum delivered volume and minimum flow is defined as termination criteria so that the breath is not allowed to terminate until the minimum volume is achieved. Depending on the settings, a VAPS breath can appear as a volume breath at one extreme and a pressure control breath at the other. In between either of these extremes, the pressure waveform will first appear similar to a pressure based breath and transition to what appears more like a volume breath where pressure rises over time. Figure 17 illustrates typical VAPS waveforms.

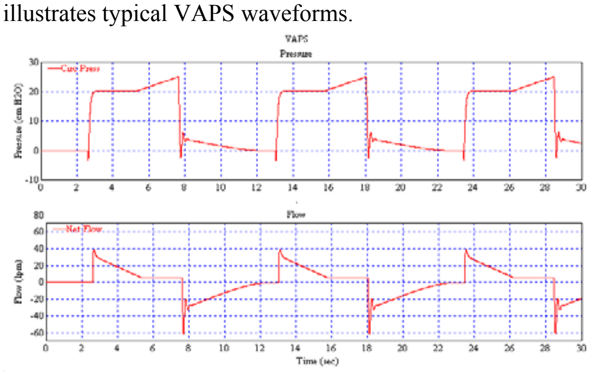

Figure 17 VAPS Breath Waveforms

4.7.2 FRCPAP

As mentioned before one goal in ventilation is to reduce the imposed work of breathing. Respiratory loading is expressed by (37). By choosing the appropriate scale factor, K = 0.098, in (37) , work is calculated in Joules for P_{WYE} in cm H_2O and Q_L in liters/sec. The output impedance of the ventilator/patient circuit system, Z_o, is defined as the complex ratio between pressure and flow at the airway (38).

$$Z_o(t) \equiv \frac{P_{WYE}(t)}{Q_L(t)} \qquad (38)$$

By substituting (38) into (37), the work imposed on the patient is expressed in terms of output impedance and airway flow as (39). Note that since work is a vector and has particular direction, the sgn function is included.

$$W(t) = \int_0^t Z_o(t) Q_L^2(t) \operatorname{sgn}(Q_L) dt \qquad (39)$$

Since Q_L is determined by the patient, work imposed on the patient is minimized by minimizing the output impedance of the ventilator-patient circuit system. Hence a control system that minimizes impedance of the patient circuit will lead to minimized work. FRCPAP, or Flow Regulated CPAP, addressed in an earlier paper [3], is based on this concept.

FRCPAP provides tighter regulation of inspiratory pressure for a CPAP breath, results in a significant decrease in inspiratory work of breathing and serves as a sensitive trigger base for other flow triggered, pressure based breaths such as pressure support and PAV. Figures 18 and 19 compare standard CPAP under PI control with FRCPAP for identical patient demands.

The difficult however interesting issue in FRCPAP controls is the problem of dual conflicting control objectives. Here the flow inlet valve, which is used to satisfy patient flow demand, operates concurrently with the exhalation valve, which is used to modulate desired circuit pressure.

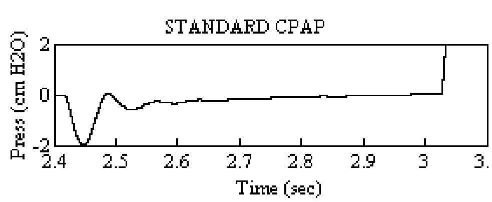

Figure 18 Standard CPAP Response To Patient demand

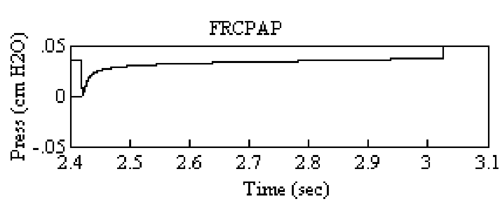

Figure 19 FRCPAP Response To Patient Demand

4.7.3 HFOV

HFOV or High Frequency Oscillation Ventilation is considered to be a specialized, rescue mode of ventilation presently approved only for infants and pediatrics in the US. In HFOV small mandatory breaths between 3 and 15 Hz in frequency are cycled to the patient's airway. The basic theory behind HFOV is that higher frequencies promote mixing or diffusion of oxygen and CO_2. without stressing the lung as conventional methods do. HFOV is usually mechanized using a reciprocating piston, bellows or diaphragm connected to the patient circuit. Special patient circuits with stiffer wall compliance and smaller volume are used to minimize pressure loss at the patient's airway. Feedback controls are employed to provide stiff reciprocating motion of the oscillating device against the backpressure of the circuit and control of mean airway pressure (MAP) superimposed on the oscillation which is the greatest challenge in HFO. One approach to MAP control uses adjustable, high cutoff filters however the phase lag these filters introduce presents problems where detection of patient demand is required.

4.7.4 Adapting Inspiratory Pressure According to a Targeted Volume; PRVC & VTPC

One problem with VAPS is that transition to the volume phase of the breath can cause the pressure to rise to unsafe levels in order to achieve a desired minute volume. It is also not clear how to determine the minimum flow setting. One solution to this problem is to use a pressure control or pressure support breath and, on a breath to breath basis, adjust the inspiratory pressure target to achieve a set volume. This approach was named Pressure Regulated Volume Control (PRVC) or Volume Targeted Pressure Control (VTPC) depending on the manufacturer. A control loop, applied outside of the pressure control or pressure support control loop compares the target volume with the measured delivered volume of the last breath or averaged previous breaths and uses the error to adjust the inspiratory pressure (fixed during the subsequent breath). A simple integrator clocked at the start of every breath together with error deadband easily achieves this goal. In VTPC or PRVC it's desired to get to a target pressure that meets the target volume within a few breaths but not so quickly that the inspiratory pressure limit cycles about the deadband. This method of breath delivery, like basic control (volume) breaths, is subject to volume losses in the circuit which should be compensated.

4.7.5 Proportional Assist Ventilation (PAV)

PAV or Proportional Assist Ventilation is one of the more complex methods of closed loop ventilation where support pressure is shaped to match a specified fraction of P_m. This is accomplished using an internal model of the lung admittance in the controller with positive feedback of lung flow. The clinical goal of PAV is to promote *Synchrony* between the patient and ventilator. *Asynchrony* is a common problem with conventional breath types often leading to patient sedation, a backward step towards recovery. Current clinical results seem to indicate PAV is achieving the goal. PAV controls are more thoroughly discussed in [8].

4.7.6 SpO_2 Controls

As discussed in 4.2, mix controls determine the delivered FiO_2. The health of the patient's lung and circulatory system further determine how oxygen perfuses into the bloodstream. Instruments can now estimate oxygen saturation (SaO_2) in the blood as measured SpO_2 from the noninvasive pulse oximeter. Current medical practice closes the loop on SpO_2 through the clinician, in other words, the clinician reads the saturation and determines the FiO_2 setting on the ventilator. Other than established procedure and the lack of regulatory approvals, there are no current technical reasons why the loop cannot be closed automatically to target and regulate a desired SpO_2. Of course such a change in approach deserves considerable caution and investigation. Clinical experiments were done to support automatic control, and so far have demonstrated feasibility [13], [16]. The main concern reliability of measurements. The payback in incorporating automatic SpO_2 control could be huge in terms of reducing the frequency of clinical monitoring as well as immediate response to patient needs. This is especially important in infants and pediatrics where SpO_2 tends to change rapidly and unexpectedly. The incidence of retinopathy in prematurity (ROP), which leads to infant blindness from exposure to excess oxygen may also be reduced by automatic controls. Modeling the saturation of oxygen in terms of applied FiO_2 is expressed by the transfer function of (40)

$$\frac{\Delta S_a O_2(s)}{\Delta F_I O_2(s)} = \frac{G_s G_p e^{-T_d s}}{1+\tau_p s} \quad (40)$$

T_d System transport lag in (sec)

G_p Sensitivity of P_aO_2 to F_IO_2 (torr/% O_2)

τ_p is the time constant (sec)

G_s is the linearized sensitivity of the O_2 dissociation curve

This model is useful in simulating control systems for SpO_2 or in synthesizing model based controls.

5.0 Lung Mechanics, System Identification

Another function served by critical care ventilation is monitoring patient lung mechanics. Clearly a diagnostic tool for assessing health and tracking the progress of treatment, besides monitoring, patient mechanics is also useful for control applications. Since there is no easy way to directly measure mechanics, indirect methods, that estimate lung mechanics based on pressure and flow measurements and model assumptions are most often employed. The models discussed in section 3.3 of this paper may be used as a basis for system identification for either application. Since clinicians almost always assume the lung as a linear system of lumped resistance and compliance, estimation methods can lead to problems since the mechanics are actually distributed, nonlinear and time varying. Least squares methods that assume the basic lumped parameter models can provide an 'averaged' airway resistance and compliance, but these estimates may not match parameters obtained using clinical 'static' maneuvers that estimate resistance and compliance at fixed flows and volumes respectively.

Motivated by some of the more advanced methods of ventilation such as PAV, a subject of recent interest is accurate determination of lung flow. Lung flow differs from flow issued at the ventilator as modeled in (15). The direct measurement of lung flow requires placing a flow sensor at the airway which is prone to fouling by patient secretions. To avoid this problem, lung flow may be estimated using a discrete time adaptive filter which processes the net difference in flow from inlet and exhalation flow sensors, safely distanced from the patient's airway. The estimator is illustrated in figure 20. Patient and circuit parameters are determined using least squares methods with the RCC model as a basis. α and β are calculated by (41) and (42), and T is the filter sample period.

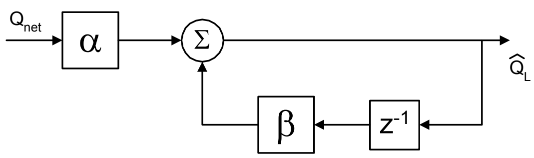

Figure 20 Adaptive Filter - Lung Flow Estimate

$$\alpha = \frac{TC_L}{RC_LC_T + (C_L + C_T)T} \quad (41)$$

$$\beta = \frac{RC_LC_T}{RC_LC_T + (C_L + C_T)T} \quad (42)$$

This technique provides an accurate estimate of lung flow provided the patient is not actively breathing which unfortunately prohibits its use for PAV. For an active patient, the estimator requires measurement of P_{mus}. Direct measurement of P_{mus} is difficult. P_{mus} does have structure, and if correctly characterized, may serve as an internal model for a modified estimator that considers unknown exogenous disturbances with known structure. This problem remains a challenge and open area of research for control engineering.

Final Note

It seems that with every new ventilator project control engineering is always faced with having to redevelop a new controls solution although the basic problems have not really changed. So why can't engineering just pull a solution out of the bag? One reason is that the hardware (valves, sensors and processors) change from project to project, and for the reasons cited in this paper, controls must change to accommodate differences in dynamics. But the main reason is that more universal control solutions have not yet been determined. The adaptive controller for PBV described herein is certainly a step in the right direction, providing evidence of substantial improvements over the PI solutions presently embraced by the industry. It is hoped that this paper will help inspire and encourage both industry and academia to explore these new possibilities.

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