

Monitoring Respiratory Mechanics During Mechanical Ventilation: Where Do the Signals Come From?

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Graphical patient data have become essential to the understanding and management of ventilator-dependent patients. These electronically generated data often reveal clues to subtle complications that, if corrected, could lead to improved patient-ventilator harmony. The apparent precision of the waveforms and the 3- or 4-place display of numeric data imply high accuracy. Laboratory devices and equipment, with their required certification, generally exhibit accuracies of approximately 2% for flow and significantly less than 1% for pressure. But the cost constraints placed on hospital-grade medical equipment dictate the use of commercial sensors-transducers, which means that pressure measurements will range between 3% and 5% of reading, and flow measurements will range between 6% and 10% (± 3 standard deviations of the mean). Other direct and indirect influences, such as temperature, humidity, absolute pressure, system pressure, type of gas, contamination, and myriad additional effects further interfere with the transformation of the variable of interest into an electrically equivalent signal. The abundance of viewable information pertinent to the management of the ventilated patient can be traced to the availability of the many types of transducers combined with microprocessor electronics. The process of capturing a variable of interest (sensing and signal transduction), converting it to a digitized electronic signal (analog-to-digital-conversion), operating on that signal (such as for control of the breathing algorithm and checking for violation of alarm thresholds), and finally converting it back to an analog signal that appears on a monitor generally receives scant appreciation. The process, however, lies at the core of data management in modern ICU ventilators. *Key words: signal processing, transducers, sensors, signal analysis, mechanical ventilator, waveforms.* [Respir Care 2005;50(1):28–52. © 2005 Daedalus Enterprises]

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Introduction

Since the early 1980s, waveforms and automated respiratory mechanics maneuvers have become available on many intensive-care ventilators, sometimes as an upgrade option, and in recent years as a standard feature. These advances trace directly to the transition from analog electronics to microprocessor electronics.

The rapid and embracing advances in microprocessor electronics and sophisticated control algorithms have led to the digital control of many electronic devices. Alternating-current power is not required; there are many types of batteries and they can power most any type of device.

Microprocessor electronics, running under software control, enable intensive-care ventilators to orchestrate an ever-widening array of automatically-managed functions, only 2 of which are waveform displays of respiratory mechanics. Other functions include extended self-checking during routine and scheduled maintenance, bedside self-checking, power-on-self-checking, extensive component-and-power-checking during operation, and alarm-threshold checking for technical and patient-related alarm conditions. *Signals* lie behind the management of all of these functions. Signals of interest may be intrinsic to a system or designed and built in. In most cases a signal represents the behavior of a variable of interest. Quite often a variable is introduced into a system as a way to monitor its function. The variable-to-signal transformation consists of 2 events: signal sensing and signal transduction.

To understand this article, a common vocabulary will be required. Using an on-line, scientific dictionary as the source,¹ I define the following terms:

Analog. “Analog” can refer to a continuous signal that is the representation of a variable; for example, the grandfather clock in my hallway represents time in analog format.

Data. “Data” can refer to the results of measurements, but the results, in themselves, have no meaning until they undergo a further processing step; for example, the numbers in a matrix could show the ages of the patients who in the past year received ventilatory support in your intensive-care unit.

Digital. “Digital” refers to the noncontinuous representation of an information signal; for example, Morse code, with its dots and dashes, was an early example of digital signal transmission.

Information. “Information,” in the general sense, refers to the transmission of a message or something communicated from a sender to a receiver. Accuracy is not implied. In our “information age” we hear of “turning data into information.”

Parameter. This term has several meanings. “Parameter” can mean a value on which something else depends; for example, a meteorological understanding of the weather depends on wind and cloud cover, along with other parameters.

Sensor. “Sensor” is generally that element or component that detects the input signal; for example, a metal diaphragm, to which is bonded a strain gauge, deflects in the presence of pressure. The strain gauge-diaphragm component is the pressure-sensing element.

Signal. “Signal” refers to a physical phenomenon that carries information (eg, a radio signal, which can be analog or digital, carries information).

Transducer. “Transducer” refers to a device that converts one type of energy into another; for example, an electric pressure transducer converts pressure into an electrical signal.

Variable. “Variable” usually refers to something that can vary (eg, wind velocity is an important variable for monitoring a storm).

I could end my discussion at this point, simply directing the reader to Figure 1, which illustrates a ventilator that monitors a number of system variables (1 through n), whose signals are processed and manipulated by the ventilator and eventually displayed as waveforms, graphs, and numeric data. Such an approach, however, would drastically diminish the topic and limit the information necessary to grasp a basic appreciation of signal acquisition, transformation, digitization, and processing that lead to the display of information on a modern intensive-care ventilator.

Excluding patient-related waveforms and breathing mechanics, other aspects of ventilator operation in which signals play an important role are:

- Patient safety
- Patient status (eg, blood oxygen saturation or end-tidal carbon dioxide)
- Management of a breathing algorithm (eg, estimation of the time constant for adaptive support ventilation, estimation of resistance and elastance for proportional assist ventilation, and estimation of compliance for volume-targeted pressure-controlled ventilation and volume-targeted pressure-support ventilation, to predict the target pressure)
- Provide “specialty” data in unique situations, such as optimizing positive end-expiratory pressure (PEEP) during impedance tomography
- Machine status and machine safety

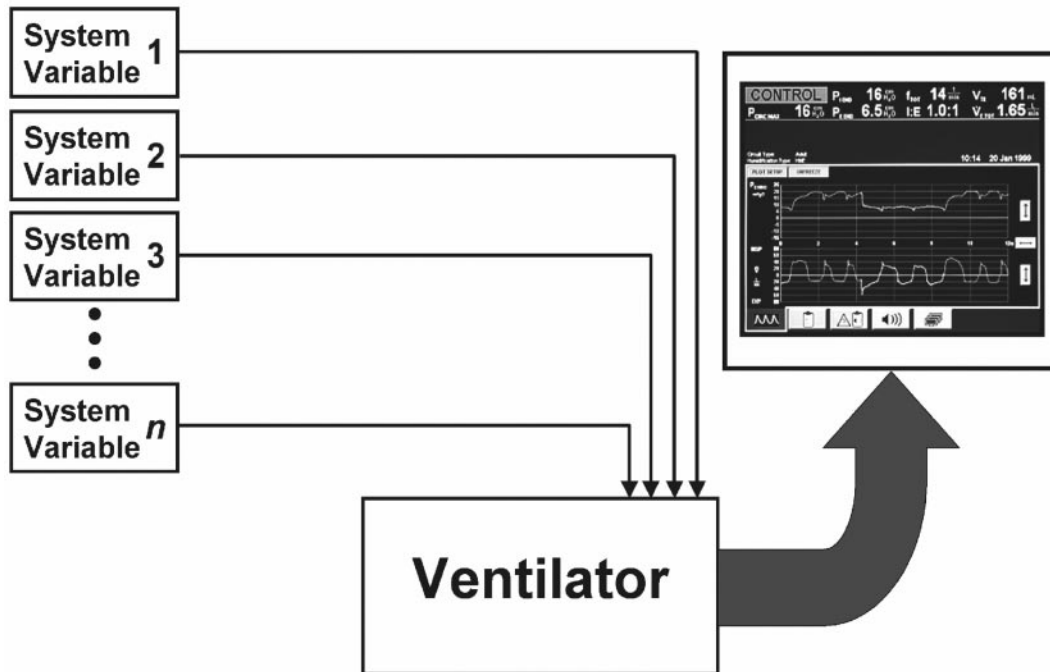


Fig. 1. Simplistic view of data management in an intensive-care ventilator. Variables 1 through n are monitored and processed by the ventilator, then sent to the display monitor, where the information appears as numerical values, waveforms, trends, and loops. The data can be stored, retrieved, and manipulated (eg, compared to other data).

What Are Signals and Why Are They Important?

Before we can discuss signals and where they come from, it will be instructive to step back and examine why signals are important. The control system of a modern intensive-care ventilator, its safe operation, and its clinical management require considerable information, which includes signals essential to the ventilator as a system, as well as those viewed by the operator and used to manage the patient's respiratory state. Valve position, for example, is a necessary, internal signal required for the precise metering of gas flow. Measurement of the pressure at the patient Y-piece (P_Y) is required for the control of all pressure-based breath types (eg, pressure-control, volume-targeted pressure-control, pressure support, volume-targeted pressure-support), and P_Y is an essential input to the alarm system and, thus, patient safety. When the pressure at the Y-piece equals or exceeds the current setting for the high-pressure limit, the ventilator ceases inspiration and cycles into the expiratory phase, thereby limiting the patient's exposure to potentially injurious high pressure. The P_Y signal, representing the variable $P_Y = f(t)$ (in which f stands for *function* and t stands for *time*), is one of the primary, patient-related waveforms. And P_Y captured when end-inspiratory flow equals zero (which in this situation represents alveolar pressure) is essential for the estimation of respiratory-system compliance.

Signals and the information they communicate are of prime importance to the intelligent management of an intensive-care ventilator. The issue faced by manufacturers and clinicians is the required quality of the information, which is inextricably linked to the issue of *measurement* versus *estimation*. I will assert that the accuracy of ventilator-derived data falls more on the side of *estimation* than of precise *measurement*. A micrometer yields a precise measurement; a ruler yields an estimation. The readings from today's inexpensive, mass-produced pressure transducers are accurate to approximately a few percent of the reading, whereas laboratory-quality pressure transducers are accurate to better than one percent of the reading. High accuracy comes at a high price; good estimation comes at a reasonable price.

That the accuracy of ventilator-generated signals is less than that of their laboratory equivalent need not concern us in the larger picture. The human body exhibits a rather wide functional envelope. For example, in a large sample of subjects² ages 6–80 years old and weighing a few kg to > 90 kg, a number of respiratory variables were monitored. For any variable the standard deviation as a percent of any local mean value of the independent variable was large, ranging from 5% to 30%. Therefore, the accuracy of pressure, flow, and volume values can be ± 5 –10% without cause for alarm, although accuracy should always be a focus of attention.³

Over the past few decades a quiet revolution has unfolded in the arena of transducer design, signal transduction, and microprocessor electronics. Virtually every variable can be monitored and transduced into an electrical signal and, via microprocessor electronics, conveyed digitally to every subsystem of a device. Even the requirement for electrical power need not concern us; batteries abound for every purpose.

Compare our current state with that of decades ago. Signal capture and transduction was almost entirely mechanical. Pressure was sensed and transduced by a small, bellows-like assembly to which a gear mechanism was attached. Pressure caused the bellows to expand, which moved the clock-like gear assembly, which moved a needle. In the 19th century and first half of the 20th century, needles were used to scratch waveforms onto smoked drums. Later, pens drew inked lines onto moving paper. Today, variables of interest are captured by sensors, transduced into electrical signals, converted into digital signals, and sent to various subsystems for control and management of the ventilator and lastly converted back to analog format for visualization on the display screen. Many devices allow printing of the waveform data at the touch of a button. However, the *sophistication* with which today's data (eg, waveforms, loops, graphs, and numeric characters) are managed and displayed should not be confused with *precision* and *accuracy*. Plus-or-minus 10% accuracy, however exquisitely displayed, is still $\pm 10\%$.

Another issue is the complexity and cost of quantifying a variable. Pressure, for example, is readily monitored. A relatively inexpensive (less than \$30 in large quantities) but quite accurate (better than $\pm 5\%$ of reading with autozeroing) pressure transducer suffices for biological purposes. However, the quantification of respiratory-system compliance presents a particularly complex set of challenges. First, 2 separately acquired signals are required: volume (flow \times time) and pressure. Second, both the non-linearity of the pressure-volume relationship and the viscoelasticity of the lung-thorax system thwart a precise measurement. Even with laboratory-quality transducers and under the best of conditions, the quantification of respiratory-system compliance, in my view, should be taken as an *estimate* rather than as a *measurement*.

The Generation of a Signal

If we conclude that airway pressure, lung flow, lung volume, respiratory-system compliance, and lung resistance (all of which are expected to exhibit time dependence) constitute an adequate data set for ventilatory management of a patient, we would expect our ventilator to provide that information in an easy-to-understand format. Of course, we could include more variables (eg, blood

oxygen saturation, end-tidal carbon dioxide, or the ratio of respiratory frequency to tidal volume).

The next issue is how we sense, capture, and represent these variables. Today, almost without exception, we answer, electrically and digitally. However, none of our variables of interest intrinsically exhibits an electrical component. Engineers impart that quality to the variable through the means of a sensor-transducer function. The sensor, in a way of thinking, intercepts some inherent attribute of the signal's energy and, through the application of the transduction function, transforms that energy into an electrical equivalent. This entire process cannot be 100% efficient. The higher the desired precision, the more costly the process. Notwithstanding cost, each step involved in sensing and transducing introduces some error.

Each variable of interest and its associated signal will encompass a bounded range. For example, at their extremes, pressure at the patient Y-piece might vary between -50 cm H₂O and 100 cm H₂O and for flow, between -250 L/min to 200 L/min. This information is important because no individual sensor can accommodate an infinite range of the variable. Consider a pressure sensor for which signal strength is expressed by the deformation of a metal or solid-state membrane. With a marked mismatch between the design range of the sensor and the actual range of the signal, either sensitivity at extremely low signal strength will be inadequate (design range much greater than the actual signal range), or at high signal strength the sensor will fail structurally (design range of the sensor much less than the actual signal strength). Regardless of the underlying methodology of a given sensor, a significant mismatch between the signal's actual range and the sensor's design range will cause unacceptable errors at low signal strength or at high signal strength, where structural failure may occur.

Over the expected range of a signal of interest, an ideal sensor should exhibit a constant error, expressed as a specified percent of reading. Some variables are readily sensed, eg, pressure. And with attention to signal management, this ideal can be well approached. By autozeroing a pressure sensor-transducer (see Figure 3 and later discussion) the measurement error can be expressed as a constant percent of the reading. For other variables of interest and the means by which the signal is sensed, flow being a good example, a uniform reading error, under all appropriate applications, may not be achievable. Although multiple reasons apply, at least two are significant: inability to detect zero-to-near-zero signal strength and low signal-to-noise as the signal strength approaches zero. Consider a flow sensor claiming a range of zero to 350 L/min and an accuracy of $\pm 2.5\%$ of reading or ± 0.04 L/min, whichever is greater. Therefore, this hypothetical flow sensor exhibits an accuracy of $\pm 2.5\%$ of reading between 1.6 and 350 L/min, but below 1.6 L/min the absolute error remains constant at 0.04 L/min. Thus if our flow sensor indicated

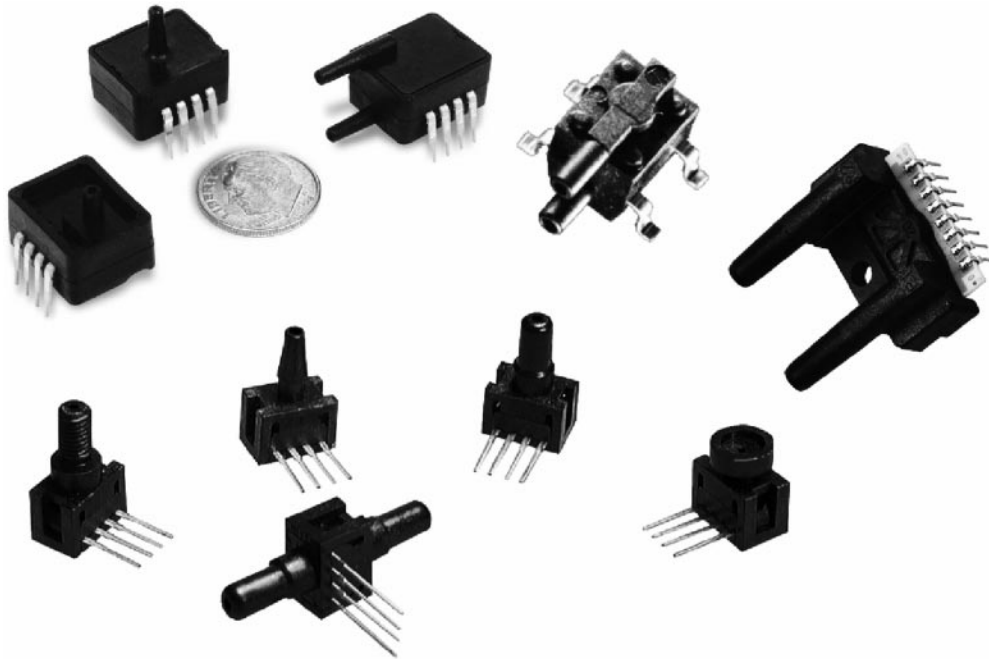


Fig. 2. Inexpensive, solid-state pressure transducers designed to be mounted on printed circuit boards (dime for scale; diameter = 0.7 in, 18 mm). These devices are available as differential, absolute, and “delta P” (ie, change in pressure; these are the units with 2 ports for measuring the pressure gradient generated by a flow sensor). (From Reference 4, with permission.)



Fig. 3. Laboratory-grade pressure transducer. Note the calibration sticker on the cylinder. When combined with a 3-way solenoid valve (a), periodic activation of the valve (autozeroing) eliminates the drift error.

1.0 L/min, the accuracy would be $\pm 4\%$, and at 0.5 L/min, $\pm 8\%$.

This issue affects virtually all sensors and transducers. Filtering might help as might the selection a sensor with a smaller signal range. The exact reasons for the near-zero phenomenon could stem from the physical attributes of the sensor, thermal noise, vibration, electromagnetic interference, or the physical properties of the signal at near zero. Good signal sensing/transduction depends on maximizing the signal-to-noise ratio.

Not to be slighted is the frequency response of the sensor/transducer unit. One type of sensor might yield outstanding accuracy at steady state but show marked attenuation at typical signal frequencies in the range of interest. My bathroom scale with its torsion-balance mechanism should not be expected to show the same accuracy when measuring a vibratory force. Good fidelity of signal capture and transduction depends on matching the frequency of the variable of interest with the frequency capabilities of the measurement system.

Pressure

Of all the patient-related variables, the estimation of pressure is, perhaps, the most accurate and least costly. Figure 2 shows a representative sampling of some commercial, solid-state pressure transducers, which cost approximately \$30/unit, when purchased in large quantities.⁴ These devices come packaged in numerous form factors; they are available from many manufacturers and are readily



Fig. 4. Laboratory-grade, screen pneumotachometers with their signal-processing units and a display monitor. These units are available in various sizes to accommodate various sizes of animal or human subject. Similar configurations of these pressure-gradient devices are incorporated into many intensive-care ventilators. Note the 2 sizes of transducer shown, the larger one intended for adult patients and the smaller one for pediatric patients. (From Reference 5, with permission.)

attached to printed circuit boards. Accuracy is specified as a zero-signal, offset pressure plus a percent of full scale reading (eg, $\pm[A \text{ cm H}_2\text{O} + B \text{ percentage of full scale reading}]$). Design engineers aim to minimize the A and B errors. This error issue is discussed further below. For the moment we need only understand that, with attention to detail, the accuracy of these commercial pressure transducers will lie in the range of $\pm(4 + 4\% \text{ of observed reading}) \text{ cm H}_2\text{O}$.

Earlier I stated that the quantification of the variables monitored by commercial devices such as ventilators (and automobiles for that matter) falls in the range of 4–10% of reading plus an offset error, and for that reason the numeric values really represent *estimates* rather than precise *measurements*. Figure 3 shows a pressure measurement system that is accurate to substantially less than 1% of reading. However, that accuracy comes at a price. Such transducers are expensive (several hundred dollars) and continued operation at that level of accuracy requires periodic, certified recalibration. Those reasons relegate that type of transducer to the laboratory, where accuracy is essential.

Flow

Of the suite of patient-related variables important to ventilation, flow represents one of the most difficult to quantify. In the context of a ventilator system, flow can be defined as the transfer of gas through a plane perpendicular to the flow path of the gas. In general, the physics of this situation dictate that in some way the sensing device

must interfere with the flow of the gas. Of the many types of flow-sensing techniques, five have found general favor in the field of mechanical ventilation: (1) pressure gradient (of which representative examples are the Fleisch pneumotachometer, screen pneumotachometer, variable orifice, and “venturi”), (2) vane displacement, (3) thermal cooling, (4) vortex shedding, (5) ultrasonic.

Compared with pressure sensing, flow sensing may incur additional constraints. Pressure sensing rarely interferes with the performance of the patient-ventilator system. A pressure sensor-transducer functions as a dead-end device, an appendage to the system. The sensor-transducer directly intercepts the signal of the variable; in the arena of patient management, pressure is pressure. Flow on the other hand is ill defined. Flow sensors do not directly sense gas flow, rather they sense some attribute of flow, for example the pressure gradient as the gas moves through a restrictive barrier or the thermal transfer characteristic as the gas flows over and cools a heated wire or the vortices generated as gas flows around a shedder bar placed in the gas stream. As gas moves through the flow sensor and depending on the physical configuration of the sensor, the flow may have to be retarded or manipulated in some specific way for the sensor to generate a quantifiable signal. And further, the flow (an its integral, volume) estimated by the sensor is rarely the flow (volume) of the interest. As clinicians, we are interested in lung volume at body temperature and pressure, saturated (BTPS), which requires yet more corrections. Add a non-physiologic gas like helium and our flow sensor may suddenly exhibit

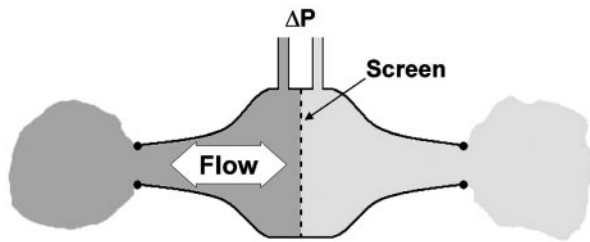


Fig. 5. Diagram of a screen pneumotachometer of the type shown in Figures 4 and 13. Whatever the methodology responsible for the flow-generated pressure gradient (ΔP = change in pressure), the minimum differential pressure must match the capability of the companion pressure transducer. The higher the quality and stability of the pressure transducer, the lower can be the imposed pressure-based work to move gas through the restrictive element. At some high flow the pressure gradient will exceed what is necessary for an adequate signal, and the pressure-based work will be excessive. At the other end of spectrum, the reverse is true: at some low flow the pressure-based work is minimal and the pressure signal is overwhelmed by the system noise. By offering various sizes of flow sensors, manufacturers aim to match the performance of the transducer with the needs of the measurement.

degraded accuracy or even become unserviceable. This phenomenon stems from the recognition that our flow sensor detects a surrogate of flow rather than flow itself. If the error due to the addition of a foreign gas becomes significant, a way must be found to correct for the error.

The patient and ventilator link to form a ventilatory system, and the safe management of the ventilatory function requires the monitoring of 3 gas flows: the mixed breathing gas leaving the ventilator, the gas entering the patient, and the gas leaving the patient. This requirement can be satisfied by incorporating the flow-sensing function entirely within the ventilator or by splitting the flow-sensing function by monitoring within the ventilator as well as external to the ventilator.

Each approach has advantages and disadvantages. By integrating the flow-estimation function into the pneumatic system, flow-sensing becomes a permanent component of flow delivery. When located internally, both the sensing and the transduction functions are protected from the harsh environment in the Y-piece. Internal flow-sensing is rarely or never recalibrated and is costly (\$100–\$200 per sensor). The ventilator's software validates the operational status of the flow-estimation function during a special self-test procedure or it is checked by a qualified service person at specified intervals. The intrinsic accuracy of this type of flow-measurement function may lie between 2% and 5% of reading, but after other corrections for certain factors (eg, barometric pressure, gas temperature, humidity, and percent oxygen), the accuracy will probably be between 5% and 10% of reading. A further allowance must be made for the interval between performance checks, perhaps another 1–2% of reading. And recognize that as yet

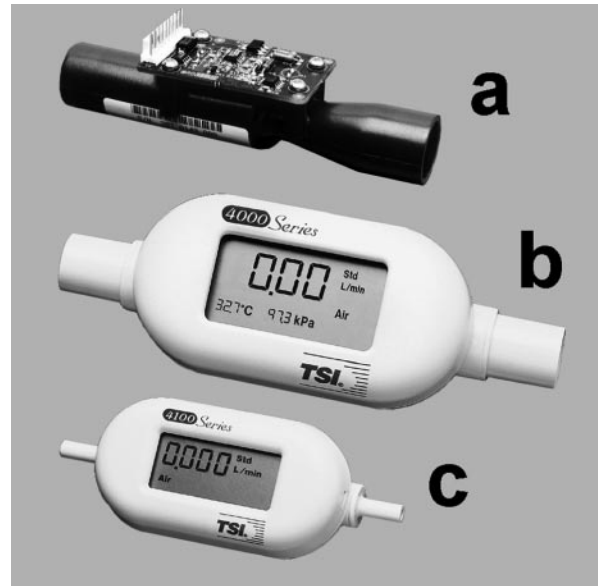


Fig. 6. Three hot-film anemometers. Device (a) is intended to be incorporated into equipment as the principle flow-measuring sensor. Over its specified flow range, the delivered accuracy would be listed as $\pm 1.75\%$ of reading or 0.05 L/min, whichever is greater. After allowances for barometric pressure, gas pressure, humidity, temperature, aging, and time before preventive maintenance, the accuracy would degrade to approximately $\pm 5\%$ of reading. That accuracy, however, applies only to the gas delivered by the pneumatic system. Estimation of flow at the patient Y-piece would degrade the accuracy further, to perhaps 7–10% of reading, depending of the sophistication of the prediction algorithm. Devices (b) and (c) are designed for laboratory measurements of high and low flows, respectively. Their listed accuracies are the greater of $\pm 2\%$ of reading or some minimal flow appropriate to each device. (From Reference 6, with permission.)

we have not attempted to convert the gas to its actual pressure, temperature, and humidity to body-temperature-and-pressure-saturated conditions within the lung. When flow and its integral, volume, are calculated at the site of gas delivery, international standards³ require the concurrent calculation of expired flow and volume. This requirement adds additional expense.

Gas flow into and out of the patient can be measured by placing a flow sensor at the patient Y-piece, but that design does not obviate monitoring the flow of mixed gas delivered by the ventilator's pneumatic system. An external flow sensor operates in a harsh environment, which usually dictates the use of a disposable flow device that costs \$25–\$75. Because the flow transduction and calculation functions are integrated into the ventilator, the external sensor/transducer must be linked to the ventilator via a connection. The accuracy of the flow and volume estimates depends on the intrinsic accuracy of the flow sensor and the degree to which the flow equations include all of the factors that affect any given flow sensor.

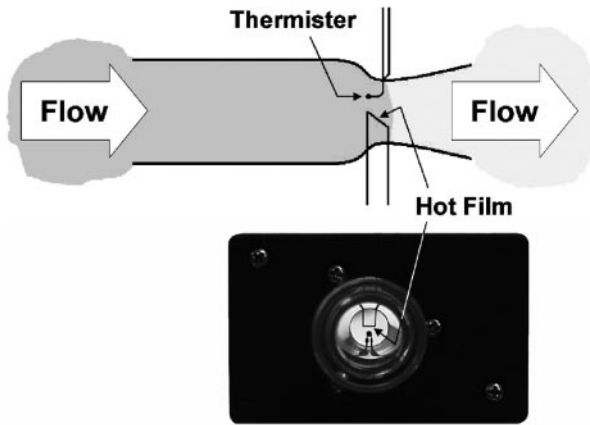


Fig. 7. Diagram (above) and picture (below) of a hot-film anemometer of the type shown in Figure 6a. The diagram shows the hot-film element and the thermistor that monitors gas temperature. Below is a view down the throat of the sensor body, showing both the thermistor and the hot film. With this configuration (the hot film perpendicular to the gas flow), the sensor monitors only unidirectional flow. Other configurations are capable of monitoring bidirectional flow.

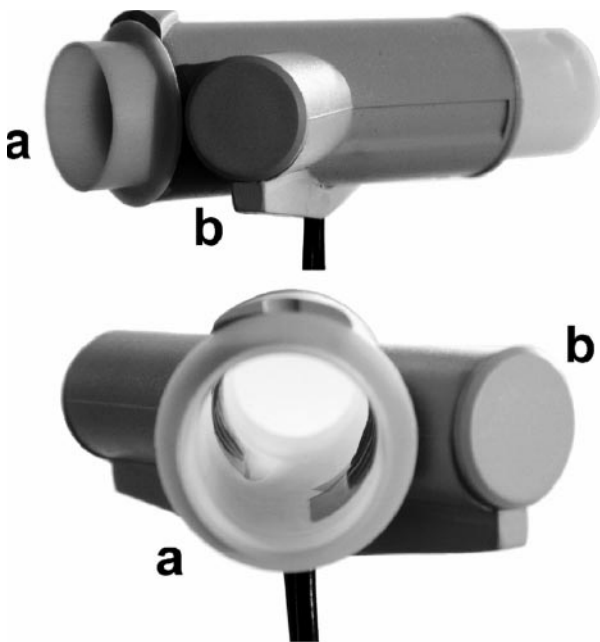


Fig. 8. The ndd Medizintechnik “time-of-flight” flow sensor (also see Figures 9 and 10). On opposite sides of the flow tube (a) are positioned matched sensor pairs, consisting of an ultrasonic transducer and a microphone unit (b). Note the unobstructed flow path through the gas channel (a), which in this device is approximately 2.0 cm in diameter. One of the advantages of this design is that it does not depend on the generation of a pressure gradient. Flow accuracy is listed at $\pm 3\%$ of reading. (From Reference 7, with permission.)

Internal Flow Sensing. Figures 4–10 show examples of the permanent type of internal flow sensor and models of those flow sensors specifically used for research. In the

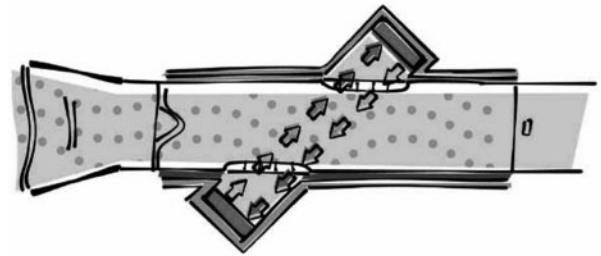


Fig. 9. Cross-sectional diagram of the ndd Medizintechnik flow sensor (as in Fig. 8). Each end of the send-receive channel has an ultrasonic transducer and a microphone. The time difference between the send and receive intervals is a function of flow velocity. Because each end of the send-receive channel contains both send and receive elements, the opposing signals may be sent separately or concurrently. (Courtesy of ndd Medizintechnik AG, Zurich, Switzerland.)

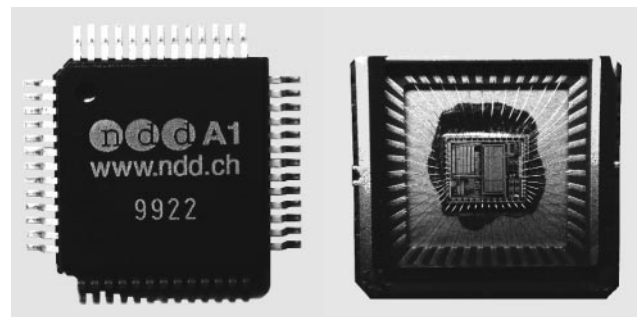


Fig. 10. Two views of the ndd Medizintechnik custom chip, which contains the specialized algorithms appropriate to each flow sensor. Left: Finished chip. Right: Cover removed to show microelectronic circuitry. This approach to the transduction function finds greater appeal as microprocessor electronics become more cost-effective. (Courtesy of ndd Medizintechnik, Zurich, Switzerland.)

research setting the accuracy will be higher than when the equivalent sensor is used in a ventilator because in the research setting the sensor and its signal conditioning equipment are calibrated either before each experiment or on a rigid schedule. When integrated into a ventilator’s pneumatic system, periodic recalibration is impractical, which requires an error allowance for aging, warm-up, contamination, and other factors.

Figure 4 shows representative, laboratory-grade flow sensors of the screen-pneumotachometer design, with signal conditioners.⁵ The conditioned flow signals are displayed on a monitor and, if required, recorded for later retrieval and analysis. Figure 5 illustrates the principle by which the flow signal is sensed and transduced. Flow enters the screen pneumotachometer, where it encounters a precision-manufactured mesh screen oriented perpendicular to the gas flow path. The mesh behaves as an array of orifices, which generates a pressure loss as the gas passes through the screen. Two pressure ports, one before the screen and the other after the screen, provide the link to the

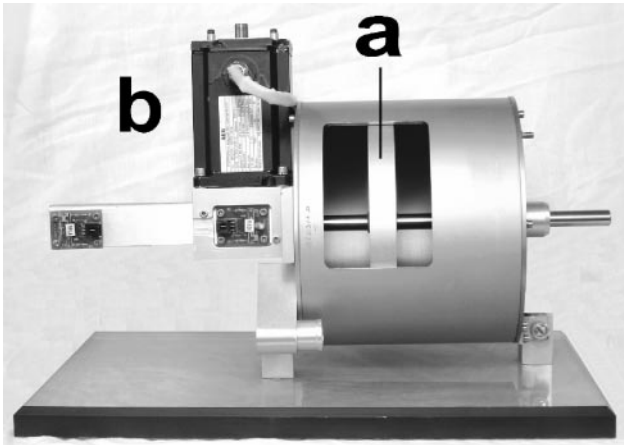


Fig. 11. Cutaway view into a piston-cylinder pump. In this design the piston (a) rides on 2 linear bearings centered in each end-plate. The piston clears the walls of the cylinder by $50\ \mu\text{m}$. The motor (b) drives the piston through a rack-and-pinion gear arrangement. Like all such devices, the diameter of the cylinder and the fidelity of the motor-gear drive place a lower limit on the smallest tidal volume and the resolution of flow.

appropriate differential pressure transducer. If the flow sensor were used in a research setting, it would be connected to a highly-accurate, low-delta-P, differential pressure transducer of the type found in the signal processing packages shown in Figure 4 (and in principle, similar to the differential pressure transducer shown in Figure 3). When integrated into a ventilator's pneumatic system, however, the associated delta-P, differential pressure transducer would be one of the types shown in Figure 2 but with a slightly higher-pressure range.

Thus, the pressure-gradient-type flow sensor interposes in the gas flow path an interference element that reduces the pressure as the gas traverses the interference element. The resulting pressure gradient is a function of the flow velocity. As with all sensors, the highest accuracy is realized by carefully matching the range of the sensor with the expected range of the variable of interest.

Another type of flow sensor, used in ventilators and in the laboratory, is the *hot-film anemometer* (Fig. 6).⁶ Gas enters the device and encounters a thin (fraction of a millimeter), heated platinum wire. As gas passes over the hot wire, heat is transferred to the gas, which cools the hot wire and thereby changes its resistance. An electronic circuit senses the change in resistance and restores the element to its designed operating temperature. Thus, the amount of electric current supplied to the platinum wire is a function of the gas flow. Because of the physical principle of thermal transfer from the heated element to the gas, this device effectively measures *mass flow* rather than *volume flow*. Appropriate equations account for variables such as the type of gas (eg, air or oxygen) and the baro-

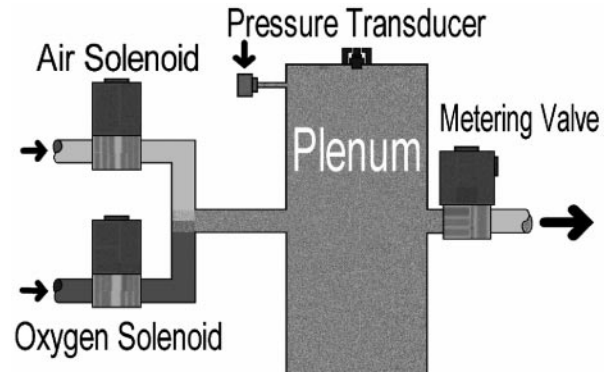


Fig. 12. Diagram of a plenum-based pneumatic system that needs no flow sensor. This design (and its several offshoots) solve the issue of gas mixing and flow delivery without the need for a flow sensor. During exhalation, each solenoid is separately commanded *On* for a precise time, based on the starting pressure in the plenum chamber. At the end of the pressurization cycles, the plenum will have reached its targeted pressure at the specified oxygen percentage. As the metering valve opens, the plenum pressure falls. Thus the 3 elements (metering valve, plenum, and pressure transducer) constitute a control loop that, under microprocessor control, performs the flow-metering/sensing function. This specific design functions like a piston-cylinder system (see Fig. 11) in that it cannot deliver a bias flow, and the plenum must recharge during exhalation. By linking 2 plenum chambers together, separated by a solenoid valve, the first plenum can feed the second, which avoids the 2 constraints just described. A further design modification combines a flow sensor with each solenoid and a flow sensor with the metering valve. Thus, in this modified design the dual-solenoid, flow-sensor elements constitute a software-based oxygen-mixing function, and the pressure transducer in the plenum no longer forms an essential part of the flow-metering function.

metric pressure, and a transfer function converts mass flow to volume flow.

Figure 7 shows a custom, commercial hot-film flow sensor and a diagram of its principle of operation. The gas passes through a choked throat where the heated element resides, and the gas exits via an angled nozzle designed to minimize turbulence. Near the heated element is a thermistor that monitors the gas temperature as it exits the throat. As suggested by the geometry of the throat design, this particular sensor is sensitive to the direction of flow. With other designs, bidirectional flow sensitivity is possible. The printed circuit board mounted on the flow sensor (see Fig. 6a), carries the electronic circuitry to power and condition the hot film and generate the raw output signal. As indicated by the 2 sizes of flow-sensor unit (see Fig. 6b and 6c), the geometry of the flow sensor matches the expected range of gas flow. As with most flow sensors, the geometry of the sensor element must be designed for best efficiency. A low flow range requires a smaller-diameter barrel and orifice, to maintain optimum thermal transfer.

The "time-of-flight," ultrasonic flow sensor, made by ndd Medizintechnik, shown in Figure 8, is an interesting

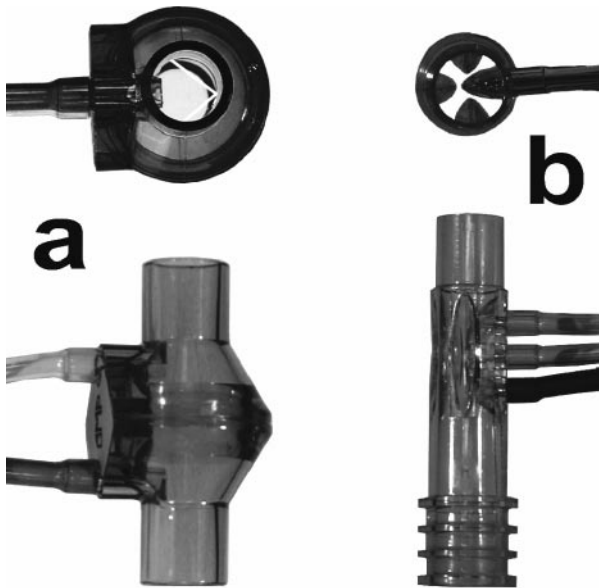


Fig. 13. Two disposable flow sensors based on flow-pressure gradient methodologies. Design (a) relies on a variable orifice to generate the flow-pressure function. Design (b) relies on Bernoulli flow to generate the pressure gradient. In the frontal view of the variable-orifice device (a) I have enhanced the outline of the slot that forms the movable flap. Flow-based pressure deforms the flap in the direction of flow. That process defines the pressure-flow relationship for each flap configuration. The frontal view of the Bernoulli device (b) shows the arrangement of the 4 airfoils that constrain the air stream over the primary foil, located on the right-hand side of the inner diameter (see relationship by comparing with the side view, below).

design because its principle of operation requires no geometric obstructions in the flow path and no adjustment of the transduction function to accommodate adult-to-pediatric ranges of gas flow, at least in the range of human physiology.⁷ Two matched send-and-receive sensor units (see Fig. 8b), positioned 40 degrees to the flow axis, reside on opposite sides of the flow tube (Fig. 9). Each sensor emits a brief ultrasonic pulse train across the flow path to its opposing receiver (Fig. 9). In the absence of gas flow, the send-receive intervals across the flow tube are equal. In the presence of flow, the signal emitted against the flow arrives at its receiver later than the signal emitted into the direction of flow. The time difference between the 2 signals is a function of the flow. Because of the bilaterally symmetrical geometry of the flow tube, the device can measure flow in either direction.

With today's technology and depending on the physical principle underlying a specific sensor, the sensor's base signal (eg, pressure or flow) is transduced into an electrical equivalent, using a transfer function. This seemingly simple approach springs from the application of microelectronics to the transduction and calculation function, which

permits the output signal of the transfer function to be corrected for all relevant secondary factors, such as barometric pressure, temperature, humidity, and type of gas. As electronic circuitry has become more miniaturized, many manufacturers have incorporated the transduction electronics directly with the sensor. Figure 10 shows the custom integrated circuit that accompanies the ultrasonic flow sensor (see Fig. 8). With such factory-supplied, electronic circuits, recalibration of the flow sensor is eliminated. However, as with all similar nonrecalibratable systems, sensor performance must be periodically verified to ensure the specified accuracy (also see Fig. 6a).

The sensors and technologies described above represent a class of devices that specifically estimate flow. However, flow can be well estimated by other means (Figs. 11 and 12). The precision, motor-driven, piston-cylinder shown in Figure 11 simultaneously delivers volume and estimates flow. From knowledge of piston velocity, flow is calculated by the equation:

$$\dot{V}_{\text{vent}} = dV/dt - C \times dP/dt \quad (1)$$

in which \dot{V}_{vent} is the flow leaving the ventilator, dV/dt (the change in volume divided by the change in time) is the instantaneous volume change as the piston is driven forward or backward, C is the cylinder compliance of the instantaneous stroke volume, and dP/dt is the instantaneous rate of change of the cylinder pressure. Like the pressure-gradient and hot-film flow transducers, the geometry of the piston and the fidelity of the motor determine the accuracy of flow and volume estimates.

The scheme illustrated in Figure 12 shows a plenum supplied with a filling means, a pressure transducer and an outflow metering means. Knowing the starting conditions (plenum, compliance, and instantaneous pressure), we can compute the flow out of the chamber during a controlled depressurization (by the precision metering valve) using the equation:

$$\dot{V}_{\text{vent}} = C \times dP/dt \quad (2)$$

in which C = plenum compliance and dP/dt = instantaneous rate of pressure-change in the plenum. This design, like the piston cylinder design, must recharge during exhalation to prepare for the next inspiration. Other more sophisticated designs allow the plenum to be continuously recharged, which enables the system to generate bias flow.

External Flow Sensing. External flow sensing, except for the purposes of research, appears to favor the use of precision-molded-plastic, disposable devices of which 2 types are illustrated in Figure 13. In most cases the sensing function is based on the pressure-gradient concept. The sensor shown in

MONITORING RESPIRATORY MECHANICS DURING MECHANICAL VENTILATION

Table 1. Variables Sensed and Transduced in 2 Common Types of Ventilator

Variable	Required by International Standards*	How Monitored If Ventilator Has Flow Sensor at Y-piece	How Monitored If Ventilator Only Senses and Transduces Flow Inside the Ventilator	Comments
Pressure at pneumatic system outlet	No	Sensed and transduced at specified site	Sensed and transduced at specified site†	Transducer also used to estimate P_Y †
Pressure at Y-piece	Yes*	Sensor at Y-piece, transducer in ventilator	Predicted from model†	Model data obtained during self-test†
Pressure at carina	No	Estimated from P_Y	Estimated from P_Y	Size and type of artificial airway must be specified
Pressure in lung	No	Estimated from P_Y	Estimated from P_Y	Total resistance between Y-piece and alveoli must be known, estimate at end inspiration when flow into lung = 0
Pressure in expiratory compartment	No	Depends on manufacturer	Sensed and transduced at specified site†	Transducer also used to estimate P_Y †
Flow from pneumatic system	No	Sensed and transduced at specified site	Sensed and transduced at specified site‡	Transducer also used to estimate Y-piece flow‡
Flow into lung	No	Sensor at Y-piece, transducer in ventilator	Predicted from internal flow transducers‡	Model data obtained during self-test‡
Flow from lung	No	Sensor at Y-piece, transducer in ventilator	Predicted from internal flow transducers‡	Model data obtained during self-test‡
Flow from expiratory compartment	No	Not sensed, same as flow from lung	Sensed and transduced at specified site‡	Transducer also used to estimate Y-piece flow‡
Inspiratory volume	No	Integration of Y-piece flow	Integration of predicted Y-piece flow	
Expiratory volume	Yes*	Integration of Y-piece flow	Integration of predicted Y-piece flow	
Inspiratory minute volume	No	Integration of Y-piece flow and time	Integration of predicted Y-piece flow and time	
Expiratory minute volume	Yes*	Integration of Y-piece flow and time	Integration of predicted Y-piece flow and time	
Percent oxygen from pneumatic system	No	Sensed and transduced at specified site	Sensed and transduced at specified site	
Percent oxygen into patient	Yes*	Assumed equivalent to transducer in ventilator	Assumed equivalent to transducer in ventilator	

P_Y = pressure at Y-piece

*International standards of the International Electrotechnical Commission³

†Linkage for the pressure variable

‡Linkage for the flow variable

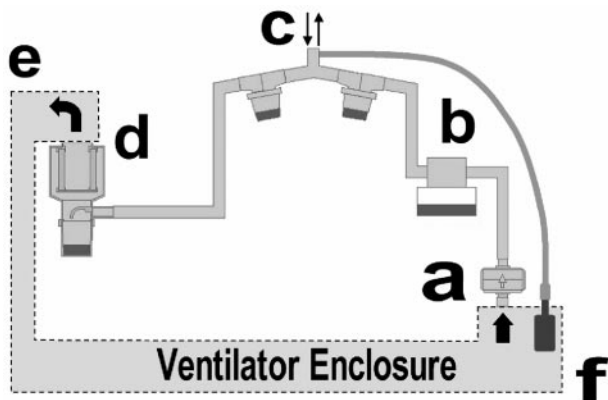


Fig. 14. Diagram of a ventilator with patient breathing circuit (a-b-c-d), expiratory compartment (e), and pressure-sensing at the patient Y-piece (c). This configuration generally dictates the use of a disposable, pressure-gradient-type flow sensor similar to those in Fig. 13. In turn, this requires that the manufacturer incorporates in the enclosure both a dedicated 2-port, low-pressure, differential pressure transducer (not shown) and a single-port, high-pressure pressure transducer (f) of the type shown in Figure 2.

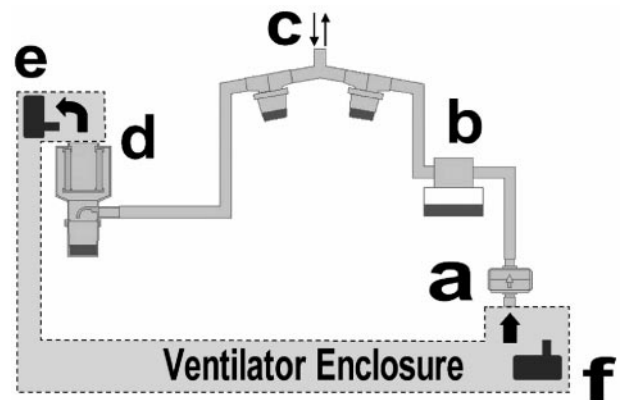


Fig. 15. Diagram of a ventilator with patient breathing circuit and 2 dedicated pressure transducers located in the ventilator enclosure and from which pressure at the patient Y-piece (c) is predicted. One of the pressure transducers (f) monitors the pressure at the outlet of the pneumatic system (a), and the other transducer (e) monitors pressure in the expiratory compartment. The prediction model requires knowledge of the gas flow through the inspiratory (a-b-c) and expiratory (c-d) limbs of the breathing circuit and their respective flow-based resistances. Typical pressure transducers are of the single-port configuration shown in Figure 2.

Figure 13a typifies the variable-orifice design. Situated in the center of the housing and perpendicular to the flow path resides a thin plastic sheet with a centrally-located, movable vane in the form of the end of a man’s tie (see Fig. 13a, upper picture). The flap functions as a resistive vane, moving out of the plane of the main sheet and in the direction of the flow. Each increment in flow increases the displacement of the flap, effectively increasing the area of the orifice. The device in Figure 13b is typical of the fixed-orifice design. Four airfoils, situated 90° apart, form a modified venturi (see Fig. 13b, upper picture), which generates a pressure gradient across the airfoils as gas flows through the orifice.

As with all pressure-gradient devices, a differential transducer located in the ventilator (or in a separate enclosure if the flow monitor is a stand-alone device) receives the pressure signal via flexible tubing.

Because the pressure-flow relationship is unique for each flow sensor and each manufacturer selects a specific pressure transducer and signal-conditioning circuitry to generate the electrical output signal, different flow sensors cannot be connected to different ventilators (or stand-alone monitors). Such “swapping” would lead to significant errors, unless the manufacturer specifically designed the product to accept other specified flow sensors.

Summary of Signal-Generation

Most of the variables of importance to the ventilatory management of patients have been known and understood for many years. The standards are pressure, which drives flow, which when integrated with time generates volume. These variables then permit the estimation of 2 additional

lumped variables, lung resistance and lung-thorax compliance. Technology has stepped in and generated the capability to design and manufacture the primary sensors-transducers that permit the efficient capture and transduction of these signals. Sensor-transducer manufacturers produce an ever-wider array of compact, acceptably cost-effective, and accurate devices. One cannot claim that the lack of appropriate sensors-transducers limits the sophistication and capability of today’s acute care ventilators.

I find interesting the recognition that, although the flow-time and pressure-time waveforms convey the most information about the instantaneous state of patient-ventilator interaction, the strategic goal of mechanical ventilation focuses on the management of lung pressure and lung volume. From this view, the absolute accuracy of the flow-time waveform is less important than its time-dependent relationship with the pressure-time waveform. On the other hand, of paramount importance is the accuracy of lung volume and the corresponding lung pressure. This requirement expands the burden on the estimation of flow. Because lung volume equals the time integral of lung flow (converted to body-temperature-and-pressure-saturated conditions), that flow estimation should be accurate not only under static conditions but under dynamic conditions as well. The true accuracy of flow transduction, and ultimately the flow-time integral, volume, depends on understanding and accounting for all of the factors that relate to the sensing and transduction functions and their frequency dependence.

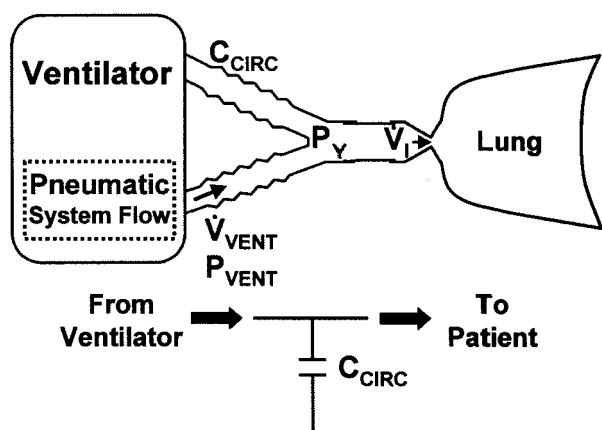


Fig. 16. Diagram of a ventilator-circuit-lung system. The pneumatic system meters flow (\dot{V}_{vent}), which is intended to inflate the lung. Forgetting for the moment the resistance of the artificial airway and the patient's own lung resistance, the pressure at the Y-piece (P_Y) will increase as the lung inflates ($P_Y = V_{lung}[t]/C_{lung}$). Because the compliance of the breathing circuit (C_{circ}) is in parallel with the lung, P_Y also represents the pressure in the breathing circuit. If we assume that \dot{V}_{vent} is constant and C_{lung} and C_{circ} are constants, then $V_{circ}[t] = C_{circ} \times P_Y[t]$. At the end of inspiration, $V_{lung} = C_{lung} \times P_Y$, and $V_{circ} = C_{circ} \times P_Y$. Knowing the volume delivered by the pneumatic system ($V_{vent} = \dot{V}_{vent} \times T_i$) (in which T_i is the inspiratory time), we calculate that $V_{lung} = V_{vent} - V_{circ}$. We presume that by calculating C_{circ} in the laboratory and capturing end-inspiratory pressure, we can apply the above equation to estimate V_{lung} . The lower part of the figure shows the electronic-diagram analog that describes this assumption; a capacitor represents the compliance of the breathing circuit. The simplicity of the circuit diagram allows us to formulate the following expression for $\dot{V}_Y[t]$ as a function of \dot{V}_{vent} ; specifically, $\dot{V}_{vent}[t] - C_{circ} \times dP_Y[t]/dt$. Studies by my colleagues at Puritan Bennett and at Boston University's School of Bioengineering (unpublished data) demonstrate that C_{circ} is not a constant, as has been assumed, but is instead a function of the rate of inflation of the breathing circuit.

The Site Specificity of a Variable

When we monitor a variable, physiologic or otherwise, its site specificity must be recognized. Consider "respiratory pressure." Until we address the issue of which pressure is meant (alveolar, carinal, Y-piece, or pneumatic system of the ventilator), the site at which the pressure must be sensed remains undefined. On the other hand, if respiratory rate is our variable of interest, specificity refers only to an identified patient. Any of several approaches would suffice to yield the patient's respiratory rate.

There are 3 methods to generate a representative signal for a site-specific variable: (1) sense and transduce at the site of interest, (2) sense at the site of interest and transduce at another location, or (3) sense and transduce remotely, then use a model to predict the desired signal. To illustrate this process, let's assume that the variable of interest is carinal pressure. I could (1) attach a small solid-state pressure transducer to the tip of the endotracheal

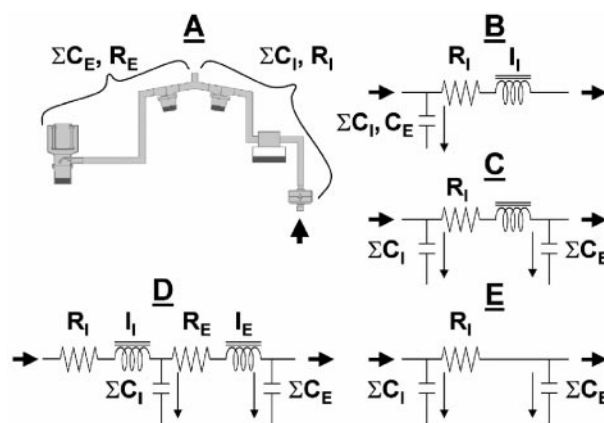


Fig. 17. Diagram of the patient breathing circuit (A) and 4 analog electrical models (B, C, D, and E) that might characterize the circuit. R_I = inspiratory resistance. C_I = inspiratory compliance. R_E = expiratory resistance. C_E = expiratory compliance. I_i = inspiratory inductance. I_e = expiratory inductance. The arrows show the direction of gas flow. Studies indicate that inclusion of an inductance term does not improve the results, so the inductance elements were eliminated from Models B and C. Note that except for the added inductance element in Model B, Model B is identical to the model in Figure 16. Models C and E are identical except for the inclusion of the inductance element in Model C. Models C and E assume that delivered flow traverses only through the inspiratory limb, whereas Model D assumes that delivered flow traverses both the inspiratory and expiratory limbs of the breathing circuit. Except for distortions concurrent with the initiation of flow and the termination of flow, the data generated by Model E most closely match the true data recorded at the patient Y-piece (see Fig. 18).

tube, which would allow both sensing and transduction at the desired site, (2) sense the carinal pressure through a catheter, either via a separate catheter or via a bore in the wall of the endotracheal tube, and transduce the pressure signal at some remote location, or (3) sense a surrogate pressure on the ventilator side of the endotracheal tube and predict the carinal pressure using a model that relates carinal pressure and the pressure at the remote location. For example, knowing the pressure at the Y-piece ($P_Y[t]$), the flow through the endotracheal tube ($\dot{V}[t]$), and the tube's resistance ($R_{ET}[\dot{V}_Y]$), I can write:

$$P_{carina}[t] = P_Y[t] - \dot{V}_Y[t] \times R_{ET}[\dot{V}_Y] \quad (3)$$

For this method to succeed, R_{ET} must be a predictable function of Y-piece flow. Many of today's ventilators use this method (model) to compute a continuous estimate of carinal pressure. Because the intent of the present discussion is to explain signal-generation and display of waveforms in today's intensive-care ventilators, this discussion does not provide the information necessary to fully understand the details of modeling, statistical analysis, and related technical topics.

The point of the above discussion identifies that it is not always essential to sense a variable of interest at the site of

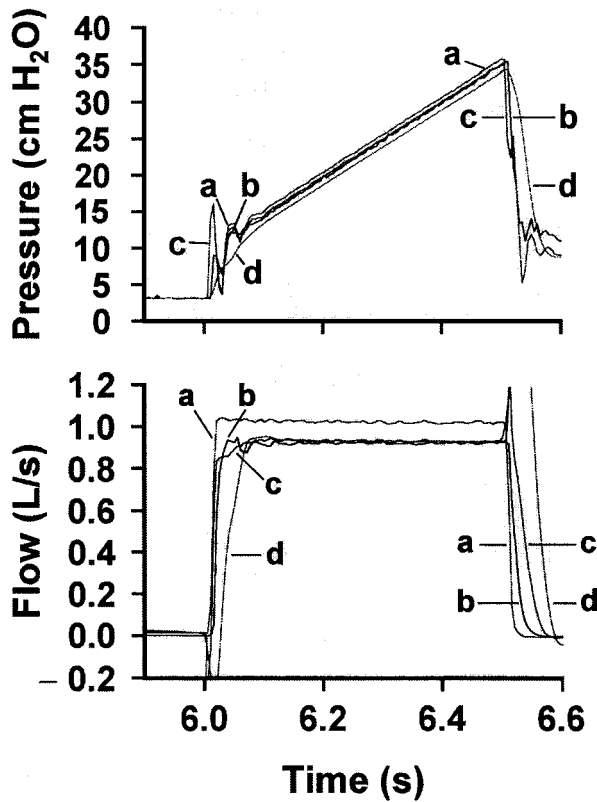


Fig. 18. Overlaid waveforms of pressure and flow, monitored (a and b) and predicted (c and d) at the outlet of the pneumatic system and at the patient Y-piece, as a ventilator inflates a model lung with a constant gas flow of approximately 1 L/s. Waveforms (a) and (b) were recorded with pressure and flow sensors at the outlet of the pneumatic system and at the patient Y-piece, respectively. Waveforms (c) and (d) were predicted using 2 of the models shown in Figure 17. Except for deviations concurrent with the initiation and termination of flow, the pressure and flow waveforms labeled c (which derive from Model E in Figure 17) exhibit good agreement with the “true” waveforms (b) (unpublished data from Puritan Bennett Inc).

interest. The site of interest might be inaccessible, sensing at the site of interest might entail considerable risk to the patient or be prohibitively costly, or the signal might be just as well predicted by the model approach.

Table 1 summarizes many of the common variables captured and displayed by today’s ventilators, identifies the location of the respective sensors and their transducers, and indicates how remote variables are estimated. Note that if a ventilator does not sense pressure and flow at the Y-piece, these will probably be predicted based on a model that takes as its inputs pressure and flow signals monitored inside the ventilator.

Sensing at the Site of Interest. Figure 14 depicts a ventilator and breathing circuit that has the pressure-sensing port at the Y-piece (c) and a small-bore tube connecting the sensing port to the pressure transducer inside the

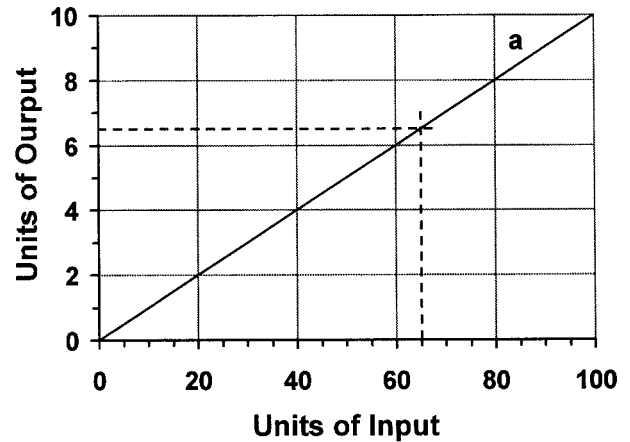


Fig. 19. Diagram of a linear transfer function. For each input value (X axis), the transfer function (Line a) generates a corresponding output value (Y axis). Let’s assume that the input variable is pressure and the output variable is volts. The graph indicates that an input of 65 cm H₂O generates an output of 6.5 v. In this example the X-axis variable could be generated by the sensing element of a pressure transducer of the type shown in Figures 2 and 3, and the voltage range generally would be 0–10, 0–5, or even 0–1 volts. In the case of flow sensors of the types illustrated in Figures 4, 5, and 13, which generate a differential pressure with increasing flow, the differential signal is then applied to a dual-port, low-pressure transducer of the type shown in Figure 2. Thus, the transformation from the variable of interest to an output voltage involves 2 transfer functions: flow to differential pressure and differential pressure to voltage. Note that the transfer function is not necessarily linear.

ventilator (f). This configuration typifies ventilators that use disposable flow sensors to estimate lung flow. (Many home-care ventilators also use this configuration but generally without the flow sensor.) With this configuration come specific considerations. For example, the Y-piece may become contaminated with condensate, nebulized medications, or sputum. To minimize corruption of the pressure signal generated by the flow sensor, the ventilator periodically purges the sensing tubes and the manufacturer recommends a vertical orientation for the pressure-sensing ports.

Sensing at a Remote Site and Applying the Principles of Modeling. Ventilator manufacturers that elect not to sense pressure directly at the Y-piece (c) adopt a different strategy (Fig. 15). During inspiration, with a closed expiratory valve, the pressure sensed in the expiratory compartment (e) is equivalent to the pressure sensed directly at the Y-piece. Conversely, during exhalation with a closed pneumatic system, the pressure-sensing port in the pneumatic system (f) captures P_Y. This 2-transducer configuration performs equally well, even during continuous flow through the breathing circuit, regardless of the phase of the breathing cycle. With known values for the resistance of the inspiratory and the expiratory limbs of the breathing

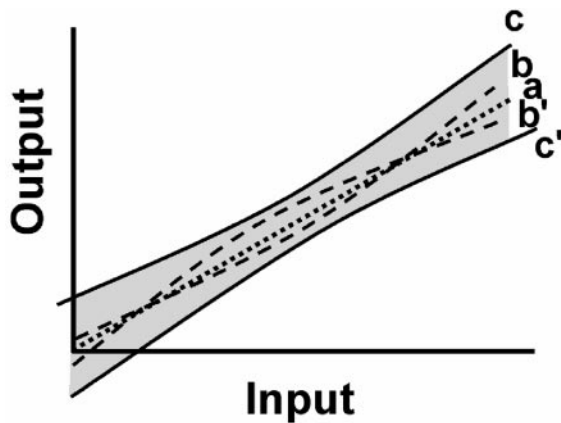


Fig. 20. Diagram of the method by which a linear transfer function is defined for the universe of a specific transducer. In many cases a manufacturer will standardize on a specific transducer, like one of those shown in Figure 2. Suppose we tested one of our transducers and found that Line b represents the best fit for all input-output pairs of data points. Further, we might discover that although the locus of those data points could be fitted nicely with a straight line, a curvilinear fit (Line b) would be statistically superior. Next we select at random several more transducers (perhaps 20 or more), and for each transducer repeat our testing protocol. Some of the transducers might exhibit a best-fit line such as Line b', with a slight downward curvature. But in each case the departure from linearity would be small and barely significant. At the conclusion of our testing we might observe that all of our point pairs lie tightly grouped about the best-fit line (Line a) between the boundaries defined by Line c and Line c'. If (1) Lines c and c' represent the ± 3 -standard deviation boundaries around Line a, (2) those boundaries lie within $\pm 3\%$ of reading, (3) all other errors (eg, aging, humidity, and ambient pressure) add no more than 1% additional error, and (4) temperature only offset line a but did not change its slope, then we could claim that our transducer has an accuracy of $\pm 4\%$ of reading. If we had no method of eliminating the offset error, the accuracy of our transducer would be given by $\pm(\text{offset error} + 4\% \text{ of reading}) \text{ cm H}_2\text{O}$.

circuit, P_Y predicted from the inspiratory pressure transducer is given by:

$$P_Y^i = P_i - \dot{V}_I \times R_I \quad (4)$$

and from the expiratory side

$$P_Y^e = P_e + \dot{V}_E \times R_E \quad (5)$$

in which i and e identify inspiratory and expiratory locations, respectively; I and E identify inspiratory and expiratory elements, respectively; and R represents the resistances of the inspiratory and expiratory flow conduits, which are also functions of their respective flows. Because no 2 pressure transducers have identical transfer functions, the best estimate of P_Y will be given by:

$$(P_Y^i + P_Y^e)/2 \quad (6)$$

In the above prediction algorithms, the ventilator derives all of the necessary data during its normal operation; only the resistance functions for the inspiratory and expiratory limbs of the breathing circuit remain unspecified. Micro-processor-executed, self-test routines allow the ventilator to derive the functions for R_I and R_E . By following the manufacturer's recommendations for performing the self-test routines, R_I and R_E are readily updated.

Although slightly more complicated, the procedure for estimating lung flow follows a similar strategy. Figure 16 depicts a ventilator connected to a patient. Our variable of interest is \dot{V}_I , which we know is some function of \dot{V}_{vent} . Figure 16 also shows the breathing circuit compliance (C_{circ}), as a simple capacitor. A first approximation for $\dot{V}_I[t]$ yields:

$$\dot{V}_I[t] = \dot{V}_{\text{vent}} - C_{\text{circ}} \times (dP_Y[t]/dt) \quad (7)$$

A comparison of \dot{V}_I predicted by this model and \dot{V}_I measured at the Y-piece shows poor agreement. Therefore, we must look to a more complete model.

Figure 17 shows other possible models. We compared the data from those models and concluded that Model E gave the most accurate results. The time-based pressure and flow waveforms in Figure 18 represent early results from those models. Except for the transient behavior at the beginning and at the end of flow, Model E yields a close approximation of the actual flow and pressure signals recorded at the Y-piece. The early and late discrepancies can be traced to the action of the filter (signal filtering is discussed below). As mentioned earlier, the constants, descriptive of the ventilator breathing circuit, may be estimated during a self-test routine conducted at specified intervals.

The Transfer Function

In this section I will focus on the general principles that underlie the generation of the transformation of the sensed variable to its electrically equivalent analog output signal. A simple example may prove useful. In the toolbox in my car I have a measuring instrument called a digital tire pressure gauge. It costs a little over \$20 and replaces my older analog (dial type) pressure gauge. Like so many similar devices, it requires a battery (warranted for more than 5 years). Inside the instrument are a solid-state pressure transducer and a microelectronic circuit that converts the pressure variable to an electrical equivalent, which is then digitized and fed to a 3-character display. The specifications claim a reading accuracy of $\pm 1\%$. Let's analyze

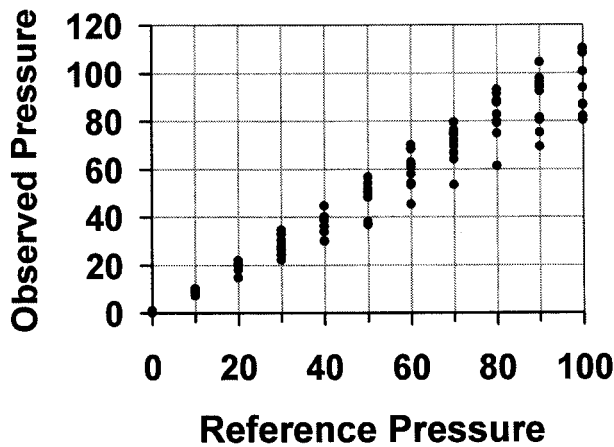


Fig. 21. Scattergram example of a hypothetical pressure transducer of the type shown in Figure 2. Data sets were constructed for 10 transducers. Each transducer was bench-tested at 10-cm H₂O intervals over the range of zero to 100 cm H₂O, using a precision pressure reference. Note that, for the purpose of illustration, the scatter of data sets at each 10-cm H₂O interval is exaggerated. Although pressure transducers are manufactured to exacting specifications, there will be very small differences between individual transducers. Only by testing randomly selected units of the same configuration can we determine if a single transfer function will adequately describe the universe of a specific transducer. Even though the best-fit transfer function for an individual transducer would be expected to deviate slightly from a straight line, experience indicates that the data from all transducers tested at each reference pressure will exhibit a tight grouping around a mean value. After statistically testing the entire set of data, we expect that a linear, best-fit line will define the transfer function for all pressure transducers of a given specific design, with a 3-standard-deviation error of not greater than $\pm 4-5\%$ of reading. Autozeroing (see Fig. 27) will eliminate any offset error. If the calibration exercise described above were applied to an individual, precision pressure transducer of the type shown in Figure 3, we would expect to observe that the best-fit, linear transfer function would define a 3-standard-deviation error substantially less than $\pm 1.0\%$ of reading.

the transduction/transform function that underlies the device:

- The identification of the variable of interest; in our example, pressure.
- The selection of a methodology or element to sense our variable; in the above example, a solid-state device whose sensing element deflects when exposed to pressure.
- The selection of the sensing element, along with an electronic circuit that yields a voltage proportional to the deflection of the sensing element, whose deflection is a function of the pressure.

Digitization and display of the signal require additional steps, to be discussed later.

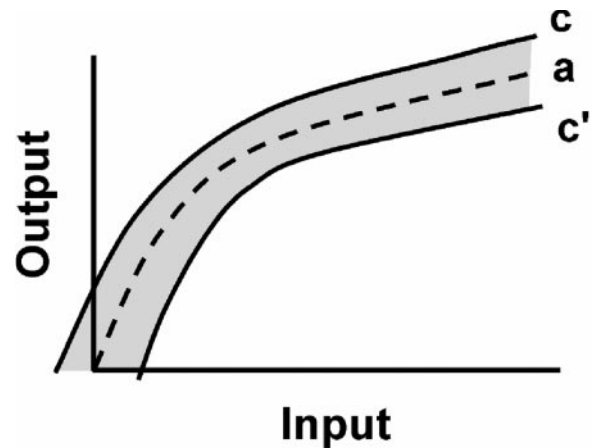


Fig. 22. Diagram of the generation of a nonlinear transfer function. Few sensors generate a linear transfer function, but microelectronics have eliminated this formerly cumbersome issue. Whether the need is to determine the transfer function for one specific sensor or for a specific type of sensor, the procedure is the same. First, all parameters that affect the sensing function must be identified (eg, ambient pressure, pressure at the sensor, temperature of the variable of interest, type and viscosity of gas, thermal transfer coefficient, humidity, and frequency response of the sensing means). If all of the confounding parameters can be identified and quantified, then the corrections can be made at the level of the transfer function, or downstream at the level of the software. Depending on the intended use of the equipment, all corrections could be made in one seamless operation. If the transfer function for our variable of interest is to satisfy all transducers of a specific type, we proceed much as we did in the example in Figure 20. To calibrate a specific transducer, we would perform multiple calibration tests, overlapping the range we expect our transducer to experience. Next we find the best-fit line through the locus of our data points, applying various types of nonlinear equations and testing each result to verify goodness of fit. If the transfer function cannot be corrected with an autozeroing maneuver, then our error must include an offset allowance. Often the offset error will be identified as a resolution error, which means that at a reading of zero or near zero some specified error would dominate. That type of error allowance is also seen in the accuracy claim for a sensor exhibiting extremely low error, as in the case of a laboratory standard. Such an accuracy claim will be for \pm a certain percentage of the reading or a certain number of units, whichever is greater. Flow sensors of the type shown in Figures 4, 6, and 8 generally exhibit sensitivity to several confounding parameters. By correcting for those effects the manufacturers are able to claim accuracies equal to or better than $\pm 2\%$ of reading, plus a threshold error that places a lower limit on the lowest meaningful reading.

The Linear Transfer Function. Figure 19 illustrates a linear transfer function. On the X axis appears the input variable and on the Y axis the electrical equivalent. For a 65-unit input the transfer function yields an output signal of 6.5 units. This example might represent a pressure signal equal to 65 cm H₂O and its voltage representation of 6.5 v. The transfer function, therefore, yields 0.1 volt for each 1 cm H₂O of pressure.

Construction of an actual transfer function is considerably more complex than the above discussion implies. In

addition to the issue of linearity, signal-to-noise, repeatability, and frequency response are of paramount importance to signal quality. However, in the present discussion I will ignore all secondary factors, concentrating instead on just the basic construction of the transfer function.

Figure 20 more clearly illustrates the steps to define a transfer function applicable to a given type of transducer design. First, the transducer of interest (eg, pressure transducer of the type shown in Fig. 2) is placed in a test stand configured for the purpose. Second, and of greatest importance, the input variable feeds not only into the transducer of interest but also into a primary measurement system of known accuracy (a device that meets a national standard or a laboratory standard, with an accuracy at least 10 times the expected accuracy of the transducer of interest). Other factors are also concurrently monitored and recorded, including type of gas, temperature, humidity, and barometric pressure. If the input variable ranged between zero and 100, as in our example, we might examine 20 transducers, each with a different date of manufacture, recording between 9 and 11 readings every 10 input units. Note that the current example aims to describe the process for quantifying the transfer function applicable to a “universe” of a particular type of transducer purchased by a manufacturer in quantities of thousands and intended to be installed in a specific device. Contrast this example to the situation in which a single, very accurate (much less than 1% error), and more costly transducer receives its annual calibration certification by a metrology laboratory (see Figs. 3, 4, 6 and 8). Also note that if those expensive transducers were designed into the ventilator’s pneumatic system, each transducer would receive its own unique calibration, necessarily with a greater error allowance than that of a recalibratable laboratory device.

Referencing Figures 20 and 21, we can review the steps leading up to validation exercise. Early in the process that led to the development of our transducer, information would have been assessed to verify that the product met its design goals (as discussed in connection with Fig. 21). Our task in this exercise is that of verifying that the performance of our transducer meets our specific expectations. Although each transducer of the type illustrated in Figure 2 would be expected to exhibit a smooth, near-linear, input-output relationship, as indicated by Lines b and b’ in Figure 20, the scattergram of all data points from all transducers should lie diagonally and tightly grouped across the graph, bounded by Lines c and c’, which would suggest a linear relationship between input and output. If our statistical analysis verified that a ± 3 -standard-deviation confidence band (c and c’) about the best-fit line (a) measured not greater than $\pm 3\%$ of reading, and our transducers did represent the universe of all such devices, we could confidently claim that the true value of any measured value would lie within $\pm 3\%$ of any observed reading. Finally, after complete test-

Bit Length	Mathematical Expression	Number Words	First Word	Last Word
1	2^1	2	0	1
2	2^2	4	00	11
4	2^4	16	0000	1111
6	2^6	64	000000	111111
8	2^8	256	00000000	11111111
10	2^{10}	1,024	0000000000	1111111111
12	2^{12}	4,096	000000000000	111111111111
14	2^{14}	16,384	00000000000000	11111111111111
16	2^{16}	65,536	0000000000000000	1111111111111111

Fig. 23. Summary of the relationship between bits and words. In bit language all words have the same number of characters, and all the characters are either “0” or “1”. The bit length of a word equals its bit number. Thus, a word whose bit number is 16 will always contain 16 characters, formed from all 0s, all 1s, or any combination thereof. If the bit length is 16, the number of unique words possible is given by $2^{16} = 65,536$. An analog-to-digital converter transforms an analog input signal into its digital “word” equivalent. Typically, the analog signal begins with the variable of interest, which is either directly sensed and transformed at the transducing stage into an analog voltage or which is initially transformed into an analog equivalent that feeds into a secondary stage of transduction, at which point a voltage equivalent emerges. The final transduction stage scales the variable of interest into a standard voltage range of 0–10, 0–5, or 0–1 volts (direct current). At that point both the variable of interest and its voltage equivalent may or may not be continuous functions of time. At precise intervals (eg, every 1, 5, 10, or 20 ms) (the *sampling frequency*) software reads the output voltage of the transducer and sends it to the analog-to-digital converter designed to accept the standard voltage range. Out of the A/D converter emerges the word equivalent of the original variable of interest.

ing with consideration of all influencing factors, we would be able to specify the accuracy of our transducer of interest as \pm (zero crossing error + h percentage of reading), in which h represents the ± 3 -standard-deviation band (c and c’) bounding the best-fit line (a). For transducers used in ventilators, the error band should not be less than ± 3 standard deviations. Exhaustive studies of pressure transducers of the type used in ventilators demonstrate that the zero crossing error is eliminated by periodic autozeroing (by software-controlled valving, which transiently exposes both sides of the differential transducer to the atmosphere). The slope error changes very little with age and altitude, which allows h to absorb aging and any other errors. Figure 21 shows an example of the process of generating a linear transfer function (of the type discussed above with reference to Fig. 20).

When accuracy is of utmost importance (eg, internal flow transducers and research flow and pressure transducers), each transducer is individually calibrated. At suggested intervals, the operator initiates a manufacturer-designed, self-test routine that determines if the transducer(s) is within its window of operational accuracy. At scheduled

preventive-maintenance intervals (approximately every 10,000 hours, as specified by the manufacturer) the internal transducer(s) is checked by a certified test instrument. For research-grade transducers, a metrology department performs the calibration and certification. Various other strategies have been designed to code unique transducer calibrations (eg, using embedded microcircuits or an optical reader). When one of these transducers is connected to the ventilator, it reads the encoded calibration curve and stores the data in memory.

The Nonlinear Transfer Function. With the development of microelectronics, there is no longer a need for linearity between the input and output signals. Monotonicity is the only requirement (Fig. 22), and many different transducers exhibit that type of response. By examining the input-output scattergram, we assess the curvilinear relationship. The data are fitted by various equations that express nonlinearity until we discover the statistical best fit. We then encode the equation in memory, effectively linearizing the output with respect to the input.

In the era of microelectronics nonlinearity is not the problem it once was. The requirements for accuracy are repeatability and resolution, both at the sensing stage and at the transduction stage. Optimal sensing arises when the relationship between the input variable and the output variable is described by a slope of 1.0. With such a relationship, the resolution of the input and the output are equal. An examination of the curve shown in Figure 22 illustrates this issue. At the early part of this curve, a unit of input generates a much greater resolution in the output, but far out on the input scale a unit of input generates a much reduced output resolution. This issue of reduced resolution at the far end of the input scale can be solved by supplying the transducer with a voltage from an extremely well controlled power supply and feeding the transducer output to a large-capacity ADC. Suppose the range of the input is 0 to 100 units and the transducer is fed with a 0 to 10 volt supply. The overall gain of the transducer is 0.10 volt/unit input. Near the early part of the input range, the local gain might be 0.15 volt/unit input. However, at the far end of the input range, the gain might be as low as 0.05 volt/unit input. Only where the slope of the input-output function = 1 does the transducer generate a gain of 0.10 volt/unit input. If high accuracy over the full input range is desired, we could solve this apparent conundrum by supplying the transducer with a highly stable voltage resolvable to tens of microvolts instead of a few millivolts. If effect we have excess resolution in the low part of the input range but sufficient resolution at the far end of the input range. Many of today's sensor-transducers operate in this manner. We would quantify the accuracy of such a transducer much in the same way as described in the last section. The ± 3 -standard-deviation confidence interval must always con-

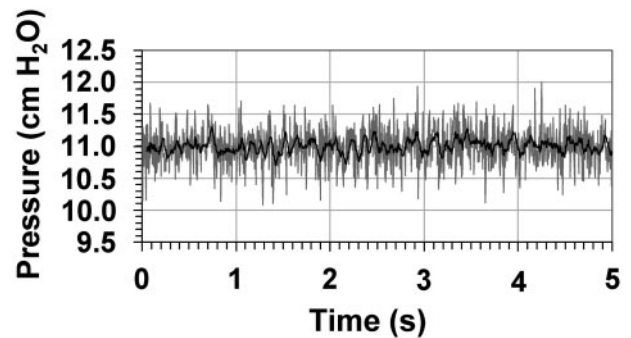


Fig. 24. Five-second simulation of noisy data whose steady-state value was 11 cm H₂O. Samples were monitored every 5 ms (ie, at 200 Hz) and subjected to a random error function that generated maximum errors of approximately ± 0.9 cm H₂O around the 11 cm H₂O line (gray waveform). That simulated, noisy signal was then subjected to a 10-sample, moving average filter, which yielded the black line. The filter reduced the noise to a maximum of approximately ± 0.3 cm H₂O about the 11-cm H₂O line.

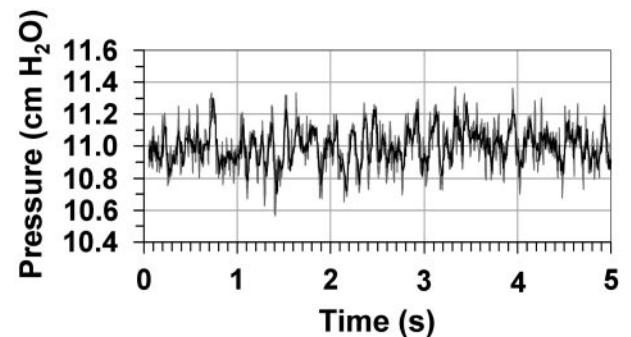


Fig. 25. Comparison of 2 types of filters: a 10-sample, moving average (gray waveform, as in Fig. 24) and an exponential smoothing filter ($\alpha = 0.7$, black waveform). Note that both filters, which are widely used to reduce signal noise, yield similar smoothing.

tain 99.7% of all values at the specified accuracy and resolution.

Signal Processing

At this point our transducer has sensed our variable of interest and transformed it into a proportional voltage. If we simply wanted to observe the raw output signal, we could connect it to some type of display and read the result. Oscilloscopes and televisions did this years ago. If our system were based on an analog design, signals of interest would be fed into various types of analog filters and then sent to a display monitor. With the availability of microprocessor electronics, new opportunities have materialized. We can store the data, transform it, operate on it, retrieve it, and display it. These capabilities and possibilities derive from the process of digitization.

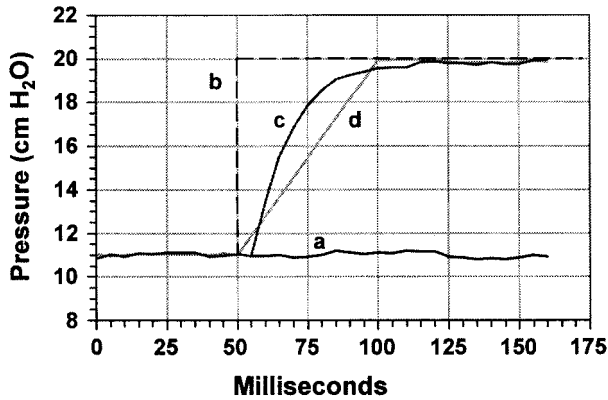


Fig. 26. Comparison of the lag resulting from the application of filtering to the true signal after a step change in the true signal. Waveform (a) is the original, filtered signal shown in Figures 24 and 25. At the 50-ms mark (b) the true signal increased from 11 cm H₂O to 20 cm H₂O. The output of the 10-sample, moving-average filter (Waveform d) rose linearly to 20 cm H₂O after 50 ms, as expected. The output of the exponential smoothing filter (Waveform c) showed no effect until the first sample after the step change, but rose more quickly over the next 7 samples, at which point it tapered into the steady-state value.

Before discussing digital signal filtering, our signals of interest must be converted to digital format. This step requires that we determine how much information each signal needs to convey. Let's consider as an example the digitization of the output of a pressure transducer. First we need to specify the pressure range that the transducer will monitor. A range of -50 cm H₂O to 150 cm H₂O (ie, total range of 200 cm H₂O) suffices to allow both negative inspiratory pressure maneuvers and cracking of the safety valve. If our pressure transducer specifies an output range 0–10 volts (direct current), the scaling becomes 10 volts/200 cm H₂O or a scale factor of 0.05 volts/cm H₂O. The output voltage of the pressure transducer is now fed into an analog-to-digital (A/D) converter, which performs the conversion from voltage to its digital equivalent.

Next we determine the required resolution for our variable of interest. A resolution of 0.1 cm H₂O appears sufficient, since resolution beyond 0.1 cm H₂O would have no physiologic value. Thus the A/D conversion must discriminate between 2,000 levels of pressure, which means that the voltage signal generated by the transducer must be resolvable down to the millivolt range. This requirement lies well within the capability of microelectronics.

The A/D converter transforms the output voltage of a transducer by generating a digital "word" equivalent of the voltage. But, instead of using letters to create the words, the A/D converter generates a string of bits, which are either 1s or 0s. The more discrete the levels of information the A/D converter must render (2,000 for our transducer example), the longer the bit string for each digital word. A/D converters come in various sizes; that is, they gener-

ate more or fewer words, as defined by a mathematical formula. Each word for a given size A/D conversion has the same bit length.

The bit size of the A/D conversion is important, because the cost of the A/D conversion rises as bit size rises. In our example the A/D converter needs to discriminate between at least 2,000 levels of pressure. To explain that function, I will discuss the rules by which an A/D converter operates. First, I will explain bits. In current technology, bits come in only 2 types: 0 and 1. Suppose I ask you a question that has only 2 possible answers: yes or no. I could give you 2 signs; one with a large "0" printed on it and the other with a large "1." Rather than responding "yes" or "no" to my question, you could substitute 0 for yes and 1 for no. In digital language we could say that to satisfy the possible number of answers (two) we need a 1-bit system, or as it is expressed mathematically, 2^1 bits.

Now suppose that my question could be answered with one of 4 answers: "yes," "probably," "maybe," or "no." I could assign yes = 00, probably = 01, maybe = 10 and no = 11. That would be a 2-bit system ($2^2 = 4$), which discriminates among 4 separate levels of information. What we note is that the levels of discrimination are given by 2^n , in which "n" stands for the number of bits. Again, in digital language we refer to the type of A/D converter as either a 2-bit A/D converter, a 4-bit A/D converter ($2^4 = 2 \times 2 \times 2 \times 2 = 16$ discrete levels of information), or an n -bit A/D converter. Borrowing from language, we say that an n -bit A/D converter allows 2^n "words" (the term "counts" is also used). Figure 23 summarizes the relationships inherent in bit language.

Returning to our example of a pressure transducer, we note that to provide 2,000 discrete levels of information (ie, 2,000 words) we must select at least an 11-bit A/D converter. But that choice would leave no room for overrun and autozeroing. That recognition forces the selection of a 12-bit A/D converter, which yields 4,096 words, which is enough to meet our needs and then some.

Filtering

Filtering is one of the key operations applied to all signals. Beginning with sensing of the variable of interest through the process of signal transduction via the application of the transfer function, noise seeps into the signal—both during the generation of the raw signal and as it is transduced. Filtering, a rigorous and complex discipline in its own right, is the process by which the signal is enhanced at the expense of noise. I will briefly discuss 2 types of filtering: analog and digital. Analog filtering can be applied regardless of whether digitization is planned. Digital filtering occurs after A/D conversion.

```

1. End_exh_press shall be set to Pat_press at the beginning of each exhalation and updated every cycle.
2. If (Q_exh_finished = 1) or (Net_flow ≤ 0.5 L/min), then

    End_exh_press(n) = P_Y_estimate(n),
    Else
3. End_exh_press(n) = End_exh_press(n-1).
4. Q_exh_finished = 0 at the beginning of exhalation and = 1 when flow exiting the patient's lungs ceases;
5. Net_flow = defined term; see section xx;
6. P_Y_estimate(n) = max (P_Y_insp_based_estimate(n), P_Y_exh_based_estimate(n));
7. P_Y_insp_based_estimate(n) = Pat_press_insp_filtered(n) - Ri × (Air_flow(n) + O2_flow(n));
8. P_Y_exh_based_estimate(n) = Pat_press_exh_filtered(n) + Re × (Exh_flow(n) + delta_p × C_exh_manifold × 60 / T);
9. delta_p = Pat_press_exh_filtered(n) - Pat_press_exh_filtered(n-1); where
10. Ri = inspiratory limb resistance, see section xx;
11. Re = expiratory limb resistance, see section xx;
12. max ( ) = maximum function;
13. Pat_press_filtered(n) = P_Y_estimate(n) = Pat_press as determined by the algorithm;
14. Pat_press_insp_filtered = defined term;
15. Pat_press_exh_filtered = defined term;
16. C_exh_manifold = defined term;
17. T = 0.005 s (5 ms)
    
```

Fig. 27. An algorithm (see text) that selects the value of end-expiratory pressure from several possibilities.

Analog Filtering. There are 2 types of analog filtering: passive and active. Imagine a vocalist singing with the aid of a microphone-amplifier-speaker system. Noise can enter the system beginning at the microphone and in the amplifier. Passive filters, which are essentially energy-absorbing elements, smooth the signal and reduce the noise, while preserving the analog nature of the signal. Active filtering means that at specific points in the signal-processing, energy is added to correct for the loss that occurs with passive filtering. Usually, one or more transistors are used to add energy.

I use an automobile suspension system as an analogy to explain analog filtering. A car's 4 wheels are not rigidly attached to the body of the car. Rather, support arms attached to the car and to the wheel assembly position each wheel in a 3-dimensional relationship with respect to the car's body, but the car "sits" on springs placed between each wheel assembly and the body, much like a spring assembly attached the seat of an old horse-drawn carriage to the carriage frame. Although this spring mechanism smoothes the ride as the car passes over bumps, the passenger may notice that under certain circumstances the car exhibits substantial and uncomfortable bounce (oscillation). We control that bounce by adding shock absorbers (in engineering terms, "dashpots") in parallel with each spring. Automobile engineers match spring and shock absorber characteristics to achieve the desired ride quality.

This spring-and-shock-absorber combination can be actively controlled. A "special" rheological fluid (the viscosity of which is alterable) replaces the ordinary hydraulic oil in the shock absorber, and a "special" magnetic orifice through which the fluid flows during a bounce replaces the standard orifice. By varying the field strength of the magnetic orifice, we control the viscosity of the oil flowing through the orifice and thereby control the stiffness of the ride.

Digital Filtering. Once the signal representing our transduced variable is available in electronic form, it can be digitized and filtered, transformed, stored, retrieved, and otherwise operated on in myriad ways. Figures 24 and 25 illustrate simple, straightforward filtering.

In Figure 24, the gray waveform represents a simulated pressure signal sampled at 200 Hz (ie, sampled every 5 ms) during a 5-second recording interval. Without filtering, there is a scatter of values, perhaps 0.9 cm H₂O above and below a central value of about 11 cm H₂O. After applying a simple moving average filter, with a sample size of 10, the maximum deviations above and below 11 cm H₂O appear limited to approximately 0.3 cm H₂O. Virtually the same reduction of the above-and-below deviation appears to result from the application of an exponential smoothing algorithm having an alpha factor of 0.7 (gray waveform in Fig. 25).

Signal clarity would suffer without filtering, but noise reduction comes at a price. Filters induce lag in the output signal when the actual value of the variable undergoes real change. Figure 26 depicts this issue. Using the same modeling as that in Figure 25, I introduced a step change (Line b in Fig. 26) to 20 cm H₂O at the 50-ms mark. Note that the 10-sample moving average (Waveform d) required 50 ms to reach the new value of 20 cm H₂O, as expected (5 ms per sample × 10 samples = 50 ms). The exponential smoothing algorithm (Waveform c) demonstrates a distinctly different strategy. First, note that this filter always lags the step change by one sample. But at the fifth sample (25 ms) after the step change, the filtered signal equals 78% of the step change; and after 50 ms, when the moving average reaches the new steady-state value, the exponentially smoothed signal lies just a few percent shy of the steady-state value.

The examples just discussed typify 2 methods to minimize noise affecting a continuous signal. But in the world of digital filtering, software processing can take myriad and complex forms. Figure 27 shows such an algorithm, the purpose of which is to select among several possibilities the value that will be displayed as end-expiratory pressure. That value updates at the beginning of each new inspiration. The algorithm is interpreted as follows (refer to the line numbers in Figure 27):

1. Software shall determine the value for the variable **End_exh_press** (end-expiratory pressure), which is displayed at the beginning of each new inspiration. **Pat_press** is a generalized term for the best estimate for the current value of pressure at the Y-piece (see 9 below).
2. The statement **Q_exh_finished = 1 or Net_flow ≤ 0.5 L/min** indicates that expiration has ceased or very nearly ceased. If either of those conditions is true, the software declares that the best estimate of end-expiratory pressure is the corresponding value of P_Y. The subscripted letter “n” represents a given sample period. In a digital system the software samples data at a specified frequency (eg, 50, 100, 200, or 1,000 Hz, which is equivalent to sampling every 20 ms, 10 ms, 5 ms, or 1 ms, respectively). The subscripted “n-1” refers to one sample-period back.
3. If neither of the above 2 conditions is true at the beginning of a new inspiration, the software selects as the best estimate of P_Y the value monitored during the previous sample period, when the criteria for a new inspiration were not yet met.
4. This step defines a “flag” status. At the beginning of expiration, the software sets the value of the flag to 0, and as long as the value remains 0, the patient is considered to be exhaling. When specific criteria in-

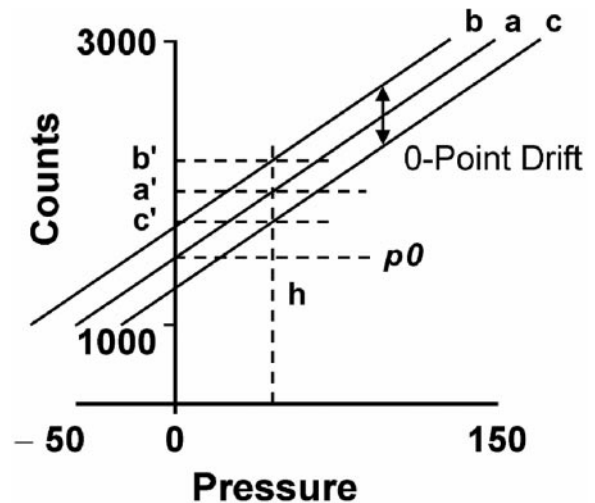


Fig. 28. Example of the autozeroing process. The transfer function of a solid-state pressure transducer of the type shown in Figure 2 can be characterized as linear with an offset, with an error given by the expression $\pm(A + B \text{ percentage of reading})$ cm H₂O, in which A is the offset error (in cm H₂O) and B is the error about any observed value. Autozeroing is conveniently accomplished after analog-to-digital conversion when the transfer function reads counts (see text) on the Y axis and cm H₂O on the X axis. The best-fit line is Line a; with no offset, it intersects zero cm H₂O on the counts axis at the point labeled p_0 . Studies show that, of all of the factors that affect measurement error, only the temperature of the transducer itself is significant. And because the slope of the transfer function does not change with temperature, autozeroing can be used to remove that error. If Line h represents the true pressure, its intersection with line a yields the true-count equivalent of that pressure. However, if the best-fit line drifts up (Line b) or down (Line c) with temperature, the counts equivalent of that drift will overestimate the true equivalent by $(b' - a')$ counts or underestimate the equivalent by $(a' - c')$ counts, respectively. After autozeroing, we know that h will intersect Line b at $(p_0 + b' - a')$ and Line c at $(p_0 - c' + a')$, respectively. Given that temperature does not affect the slope (gain) of the transfer function (slope Line a = slope Line b = slope Line c), the pressure equivalent at any count reading is readily calculated with the equation: equivalent pressure = $([\text{count reading} - \text{autozero count reading}] \times \text{slope} [1 \text{ cm H}_2\text{O}/10 \text{ counts}])$.

dicative of the cessation of expiratory flow become true, the software sets the flag value to 1. In this state, every value of P_Y qualifies as a value for end-expiratory pressure.

5. **Net_flow** is a defined term; it is the flow attributed to the patient, which is corrupted during flow-triggering when the bias flow coexists with the patient's flow.
6. Ventilators that have 2 differential pressure transducers measure pressure at the site where breathing gas is delivered and at the site where the expiratory valve resides. Either pressure may, in conjunction with other ancillary data, yield an estimate of P_Y (“P_Y” in the algorithm). The statement in line 6 of the algorithm tells the software to compute estimates of P_Y from

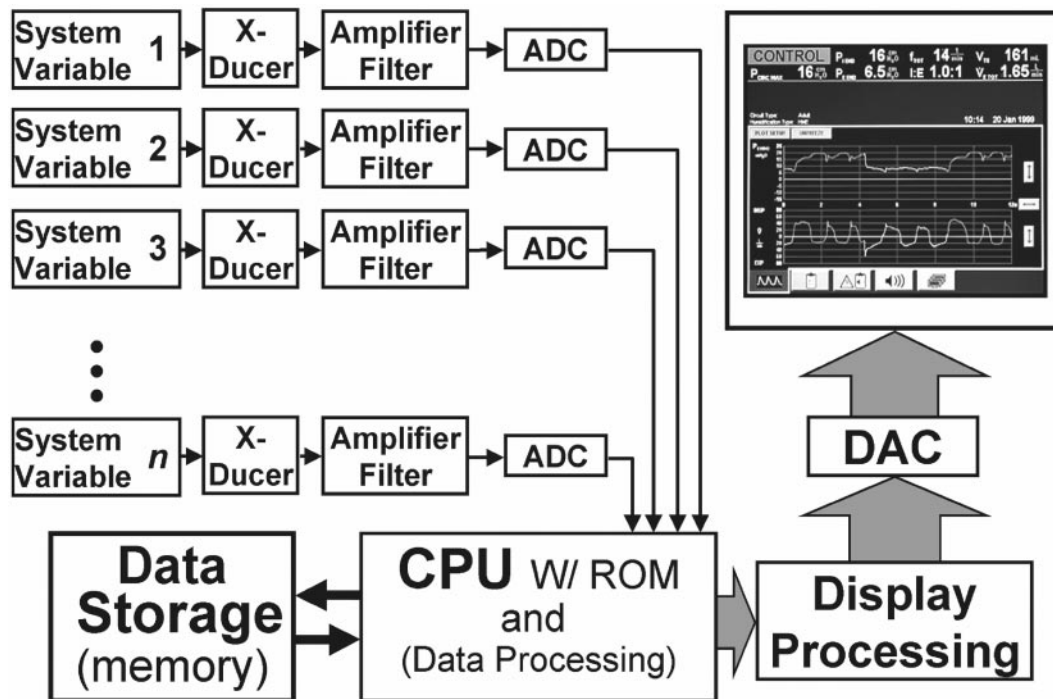


Fig. 29. Complex view of data management in an intensive-care ventilator. Variables 1 through n are monitored by specific sensor-transducers, appropriately amplified, converted into digital-equivalent signals, processed by specific software algorithms, stored for later retrieval, or sent on to the display subsystem where the digital signals are reconverted into their analog equivalents and displayed on a monitor. Even this description is much too simplistic. Some variables of interest are quantified based on data from indirect sensor-transducers and system models. By convention, specific variables are tracked and displayed as functions of time (eg, pressure, flow, volume, minute ventilation, end-tidal carbon dioxide). Specific combinations of variables, each of which are time-dependent (eg, pressure-and-volume, and flow-and-volume), are processed and displayed as loops and displayed breath-by-breath. Still, the clinician may initiate software-controlled, perturbation maneuvers that yield the values of other variables (eg, lung resistance, respiratory-system compliance, and airway occlusion pressure) The key steps in this process of data management are the transduction of a variable into its electrical equivalent and, then, digitization of that electrical signal. Once a variable (eg, pressure at a specific moment) is transduced and digitized it becomes like a picture, which can be copied, filed, shared, compared, and manipulated in myriad other ways.

both pressure transducers and, for a given sample period, to assign the highest estimate as the value of P_Y .

7. This statement identifies the formula by which the software estimates P_Y , using data from the inspiratory pressure transducer and the flow-based pressure loss across the inspiratory limb of the breathing circuit. In simple terms, P_Y for the n th interval equals the inspiratory pressure minus the product of the inspiratory flow and the flow-based resistance of the inspiratory limb, all values taken at successive n th intervals. Notice that the appropriate inspiratory pressure is a filtered value (as specified by another algorithm).
8. As in line 7 of the algorithm, P_Y can be estimated using data from the expiratory side of the breathing circuit. The equations differ, however. Because the expiratory compartment sits downstream of the patient Y-piece, the pressure monitored by the expiratory pressure transducer will be reduced by the flow-based loss across the expiratory limb of the circuit. But note the additional term that accounts for the pressure fluctuations occurring within and that are unique

to the compliant volume attributable to the expiratory compartment.

9. The last term in the equation shown in line 8 contains the elements $\Delta p \times C_{\text{exh manifold}} \times 60/T$. In a mathematics textbook, where time is considered continuous, this equation would take the form $C \times dp/dt$, which is compliance multiplied by the instantaneous rate of change of pressure with respect to time. However, in discrete mathematics, and even though p and t are continuous, their values are sampled once every interval T . The element dp becomes (expiratory pressure at interval $[n]$) minus (expiratory pressure at interval $[n - 1]$), and dt becomes T , which equals 5 ms. Again note that all pressure terms represent filtered values.
10. The resistance of the inspiratory limb of the breathing circuit is a defined term, which means that the calculation of R_i follows a set of rules.
11. The explanation in line 10 also applies to R_e .
12. The maximum (or minimum) function widely appears in discrete calculations in which a variable may as-

sume multiple possible values but only the greater (or minimum) of which will be selected.

13. Line 13 simply states that the variable “patient pressure” is equal to the estimate of P_Y , which in turn is equal to one out of other possible filtered estimates, as indicated in line 6.
14. As in Lines 5, 10, and 11, the variable **Pat_press_insp_filtered** is a defined term. In some section of a software document this term will be explained, as will be the rules for its estimation.
15. The explanation of Line 14 also applies to the expiratory term, **Pat_press_exh_filtered**, in Line 15.
16. The compliance of the expiratory manifold (**C_exh_manifold**) is a defined term and is estimated according to a set of rules found in a specific document.
17. This line indicates the sample frequency and sample time in our example (200 Hz and 5 ms [0.005 s], respectively).

The above illustration conveys some of the flexibility possible with digital filtering. Whereas analog filtering operates on the signal of interest continuously over time, digital filtering operates discretely over time, as defined by the sample interval or the sampling frequency. There are also other advantages to digital filtering, particularly with regard to conditional alternatives. Suppose you were in the market for a new house. You have identified an interesting neighborhood and you begin driving through the area looking for houses that might suit your needs. As you view the houses one by one, you think “not that one,” “maybe that one,” or “yes, that one I want to view the inside.” You write down the address and continue your search. If you could operationally identify your acceptance criteria, you could search an electronic database and save only those addresses of houses that you will view the inside of. Digital filtering operates the same way. Conditional statements are inserted into the algorithm, such as, “If this, do that; but if this, do something else; and if both things are observed, stop then restart.” Digital camcorders and numerous other electronic devices use these conditional algorithms.

Maintaining Signal Accuracy

Proper patient care requires accurate information. During the era of analog-based electromedical equipment, before microprocessor electronics, service technicians and biomedical engineers performed periodic maintenance and calibration on specific medical equipment. The calibration process consisted of supplying a standardized physiologic signal to a specific transducer, then adjusting a potentiometer linked to its analog circuitry until the ventilator’s transducer indicated the same value as the reference transducer.

The accuracy of the calibration could be no better than the combined accuracies of the 2 transducers: the ventilator device and the reference device.

Today, with microprocessor electronics, reference calibration has been replaced by software-controlled self-testing, which relies on internal cross-referencing and auto-zeroing. In certain situations (eg, when erroneous readings are suspected and during preventive maintenance), calibration is conducted against a certified reference standard.

Cross-Referencing. This type of accuracy assessment can take 2 forms. If a manufacturer incorporates into a ventilator’s design a reference element, such as a calibrated orifice that produces a known flow at a specified pressure, and if a manufacturer verifies that the error in signal transduction results primarily from an upward or downward shift of the calibration curve (and not from the shape of the calibration curve), a comparison of the ventilator’s signal and the reference signal enables software to correct the ventilator’s signal.

Consider a ventilator with 3 flow transducers (air and oxygen transducers on the inspiratory side and a single flow transducer on the expiratory side). During a self-test routine, the software commands the airflow valve to deliver a series of flows, say, every 10 L/min up to maximum flow. The software then captures and stores the values generated by the expiratory flow transducer. Next the software executes the same routine with the oxygen flow transducer. The software then compares the 2 sets of values from the expiratory transducer and cross-correlates them with the command values. The test algorithm checks for consistency rather than accuracy because the ventilator has no reference standard. The expiratory flow transducer serves as the “referee.” If the expiratory flow transducer verifies a matching set of values from the air and oxygen valves, but they are offset either above or below the expected values, the software concludes that the expiratory flow transducer is out of calibration. If the air valve alone generates a set of values within expectations, but the oxygen valve does not, the oxygen valve is suspect. And if the reverse is true, the air valve is suspect. Regardless of which flow transducers are out of calibration, the software reports the problem as a flow inconsistency and messages the operator to call for service. The service person then introduces a calibrated, certified flow transducer into the system, which allows identification and replacement of the offending flow transducer.

Autozeroing. Some types of transducers that exhibit a well-characterized zero signal lend themselves to autozeroing. Pressure transducers that respond to both positive and negative pressures are good examples. Their voltage-pressure transfer function, although not truly linear, is treated as if it were linear. Thus, a differential pressure

transducer with a range of -50 cm H₂O to 150 cm H₂O is characterized by a constant-slope (gain) transfer function (see Fig. 20). Altitude, humidity, age, and other factors imperceptibly affect the slope of the transfer function. Changing temperature, however, can substantially shift the zero-signal reference point. The accuracy specification for these devices takes the following form: $\pm(A + B$ percentage of reading) cm H₂O, in which A = the zero-signal error (or offset error) and B = error due to the magnitude of the signal. The value of A over a representative range of temperatures between room and after stable warm-up might lie between 2 and 4 cm H₂O.

Figure 28 depicts the autozero issue. The no-drift, linear transfer function (Line a) passes linearly left to right, from -50 cm H₂O to 150 cm H₂O. To simplify our calculations let's assign to -50 cm H₂O a count number (the count model fits our example better than the word model: see earlier discussion about A/D converters) of $1,000$ (out of $4,096$ counts for a 12-bit A/D converter) and to 150 cm H₂O a count number of $3,000$ (to satisfy our requirement of 0.1 cm H₂O resolution over our 200 -cm H₂O range = $2,000$ levels of pressure). The slope of our transfer function is expressed as $2,000$ counts/ 200 cm H₂O or 10 counts/cm H₂O. If our transfer function reads -50 cm H₂O at $1,000$ counts and 150 cm H₂O at $3,000$ counts, zero cm H₂O generates a reading of $1,500$ counts.

Experience gives us the confidence to claim that only changes in the immediately nearby temperature will cause predictable errors in the accuracy of the transduction of our pressure signal. Line a represents the reference transfer function—no errors. Line b simulates the situation when the transduced signal drifts upward and Line c simulates downward drift. Upward drift means that transfer function indicates a positive change in pressure when actually there is no change. Downward drift means the transduced pressure reads less than the actual pressure. By autozeroing we discover the actual state of the transducer and how to correct for the error.

During the autozero maneuver, both sides of the transducer are exposed to atmospheric pressure, which allows the sensing element to establish its rest (or zero) position. By definition, the differential reference pressure now equals zero. Let's examine 2 examples: first an upward drift of 30 cm H₂O and second, a downward drift of 30 cm H₂O. In Figure 27, in the absence of drift, I have labeled as " p_0 " the point at which the reference line a crosses the zero-pressure line. The coordinates are $1,500$ counts and 0 cm H₂O. But during autozeroing, the coordinates of Line b and the zero reference line are $1,800$ counts and 0 cm H₂O. And upon autozeroing in the downward-drift example, the coordinates are $1,200$ counts and 0 cm H₂O. Over the anticipated range of temperature changes, the slope of the calibration curve remains constant, so any upward or down-

ward pressure drift can be corrected by subtracting or adding, respectively, 30 cm H₂O to any monitored pressure.

The actual transduction of pressure is much simpler than one might assume from the above example. First, the gain factor in our example (1 cm H₂O per 10 counts) does not change. Second, during the autozero, the software captures the counts at zero pressure (zero reference counts). Any new pressure is computed as (counts at interval $[n]$ minus reference counts) times the gain factor.

As part of the development process of a new ventilator, the engineers characterize the temperature warm-up profile under a variety of operational and environmental conditions. This information leads to the specification of an autozero schedule that will minimize the early pressure errors during device warm-up. After steady-state operation, a periodic autozero (eg, every 10 min) would probably suffice to maintain minimum pressure errors.

Displaying the Variables of Interest

Our discussion began with an examination of variables and signals. The next steps focused on different means by which a variable's signal could be sensed and transduced to yield an electrical signal. That issue embodies considerable complexity, not the least of which is the selection of each of the transducers, as required by the design of the host product. Effectively, our product specifications establish the system's operational accuracy and its allowed errors. I discussed signal transduction at the site of interest and transduction at a remote site. The latter method is viable only if we can model the relationship between the variable's value at the desired site and at the remote site. This methodology finds wide application in our high-technology world. In conjunction with the step of signal capture and transduction, I noted that signal processing becomes essential. Rarely is a raw signal directly displayed without some type of filtering. Signal processing embraces a broad discipline applicable to all forms of information management.

Once our signals of interest emerge from this complex signal-processing stage, the software can manage the remaining stages in various ways, such as direct display, trending, combining the signal with other variables to yield multiparameter variables (eg, rapid-shallow-breathing index), and data storage for later retrieval and comparison with other data (eg, with overlay visualization). Data transmission within a system and from one system to another (eg, from a ventilator to an intensive-care monitor) occurs in digital format. However, when ready for display on a monitor, the digital data are converted back to analog form via a digital-to-analog converter.

Summary

At the beginning of my discussion I suggested that the schematic shown in Figure 1 might convey an adequate outline for the purpose of tracing the path of a variable from sensing to display. That schematic might have sufficed had I not been convinced that it presented too shallow a view. The outline implicit in Figure 29 represents a compromise between a thorough technical description and the too-simple approach that I rejected.

The multiplicity of graphics and numeric data that can be displayed by today's acute care ventilators stems from three factors: a) the proliferation of cost-effective sensor-transducer devices, b) microelectronics hardware, including software, and c) inexpensive display screens. For virtually every variable there exists a small, compact, relatively inexpensive sensor-transducer capable of capturing its signal with an error of not more than 3% to 6% of reading. These same variables, if monitored in the research laboratory, would be sensed-transduced by devices more expensive than their commercial "equivalents" by a factor 3 to 10 or higher. In serious research one seeks the highest accuracy, whereas in patient care one accepts good estimates.

Ventilatory support begins with pressure, which drives flow, which after integration with time yields volume. These primary variables, along with their transduced signals, generate additional variables, resistance and compliance. Ideally, we would want to know the patient's regional lung volume, regional lung pressure, regional airway resistance, and regional lung-thorax compliance. But lung-thorax heterogeneity precludes such specificity. Without highly complex and very expensive equipment we are left with lumped and approximate values for all of these variables. And even with perfect knowledge we may, at this time, not have a full understanding of how to apply such information.

Discussion

Hess: These are things that as clinicians we hardly ever think about, and it occurs to me that earlier in my career we thought about these things a lot more—maybe before microprocessors, and when ventilators were not as sophisticated as they are today.

I really like the point that you made about the difference between a measurement and an estimation. I'll give you an example that comes up frequently. I get several calls a year from fellows or residents or respiratory ther-

apists who ask, "Do you think there's something wrong with the ventilator, because the inspired volume is 400 mL and the exhaled volume is 415 mL on every breath. Where is that extra 15 mL coming from?" I think it gets to the issue of measurement versus estimation. As clinicians, we take those numbers very literally, and if it says 400, we believe it's 400.0000. But it's really an estimation, as you pointed out, rather than a measurement. I think it's very important to understand that principle.

As an anecdote, once we had a severely asthmatic patient who was me-

chanically ventilated with a Puritan Bennett 7200 ventilator, with whom we switched the gas mix to heliox. When we did that, the ventilator chattered a lot and then it shut down. It was our failure to understand that the flow sensors were hot-wire flow sensors, and they were affected by the thermal conductivity of helium, which is very high. The helium cooled the sensor so the ventilator thought there was too much flow and that something was wrong.

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REFERENCES

1. TheFreeDictionary. Huntingdon Valley, Pennsylvania: Farlex. Available at <http://www.encyclopedia.thefreedictionary.com>. Accessed October 25, 2004.
2. Jammes T, Auran Y, Couvernet J, Delpieree S, Grimaud C. The ventilatory pattern of conscious man according to age and morphology. *Bull Eur Physiopathol Respir* 1979;15:527-540.
3. International Electrotechnical Commission. Geneva, Switzerland. IEC 60601-2-12: Particular requirements for the safety of lung ventilators for medical use. Critical care ventilators, 2003. Available at <http://www.iec.ch/index.html>. Accessed October 25, 2004.
4. Honeywell Inc. Minneapolis, Minnesota. Available at <http://honeywell.com>. Accessed October 25, 2004.
5. Hans Rudolph Inc. Kansas City, Missouri. Available at <http://www.rudolphkc.com>. Accessed October 25, 2004.
6. TSI Inc. Shoreview, Minnesota. Available at <http://www.tsi.com>. Accessed October 25, 2004.
7. ndd Medizintechnik AG. Zurich, Switzerland. Available at <http://www.ndd.ch>. Accessed October 25, 2004.

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Durbin: One of the issues that keeps bothering me, which is along the same

lines as what Dean mentioned, is the zero or reference condition. There are certainly physiologic transducer systems in which the zero reference changes a lot. This occurs with blood pressure measurement, using an arterial line, for instance. In the old days we had to calibrate every time we made a measurement. We didn't trust the transducer system to remain stable for more than 15 minutes. We were more sensitive to the issue of zero reference and calibration. Now, it's not infrequent to walk in and see the transducer-reading "on the floor" or "on the ceiling," or some place it shouldn't be, and the vasopressor drip is wide open with a patient who's really not in shock. You didn't specifically mention the zero reference of these systems. Many references are internal now, and calibrations are usually done digitally, so no one ever has to think about that part of the measurement system. I think it is still critically important to recognize where the zero—or where we are *calling* the zero—is when we make our measurements. Any comments about this issue?

Sanborn: Pressure transduction is very well managed by this process, because the one point that's known is zero pressure, and to solve that problem there is a 3-way solenoid between the transducer and the signal, and, every so many minutes or hours, that solenoid switches, under the control of software, allowing both sides of the pressure transducer to see the atmospheric pressure, which represents zero differential pressure. The assumption is that the slope of the pressure-voltage relationship doesn't change much, and that can be verified in a laboratory. The pressure-voltage slope of these inexpensive (\$30) pressure-transducers is very well managed. The pressure transducer's handbook shows how the slope error varies with temperature, pressure, age, and whatnot, and you sum up all of those errors and add them into the total slope error. If you concluded that the total error was $\pm 3\%$ of the reading, you'd probably

be right over the next 20 years. But it's the zero error that will change, because as the device warms up, the transducer undergoes a thermal change that ever-so-slightly alters its shape. The manufacturer sets it to perform an autozero, say, every minute after the unit is turned on, until after 15 or 20 minutes the autozeroing shifts to once every 10 minutes, and then later it shifts to once every hour, and from then on, for as long as the device is operating, it will autozero every hour, every 2 hours, or whatever. The pressure transducer issue has been pretty well resolved. It's very difficult to do that for a flow sensor. Many flow sensors have intrinsic noise at zero flow, and it's difficult to get a good zero reading.

Durbin: I want to ask about the pressure sensors for the cardiovascular pressure waveforms, not for the ventilator. That still requires a manual, mechanical zeroing that can't be built in because it has to be referenced to where the patient actually is, and the value is of a different scale. These 2 things (zero and scale) combine to describe the arterial pressure. With venous pressures, because they are much smaller, the appropriate zero is even more critical. It would be nice if transducers systems could automatically re-zero and calibrate themselves, but I'm not sure how you would do that when the device is connected to the patient.

Sanborn: Right. That's it. You're stuck. There's no clever place to get a known reference point.

On second thought, let's look at your issue. There are 2 zero references. The first has to do with the transducer zero and the second has to do with ensuring that the sensor element of the transducer and center of the heart are in the same horizontal plane. The error in the transducer zero reference can be handled by an autozero device that links a single-patient, 3-way, controllable valve with the pressure transducer assembly. I would see the 3-way valve unit as a throwaway, plastic as-

sembly that snaps onto the controllable unit that positions the 3-way valve, either automatically or on command by the clinician.

I see the second error managed by an automatically-positioned laser beam that illuminates a spot on the patient. When the laser spot lines up with the center of the patient's heart, you know that the transducer assembly, the 3-way autozero valve, and the patient's heart all lie in the same horizontal plane. Every so often or on command the controller opens the pressure transducer to the atmosphere and simultaneously seals the blood filled catheter from the patient, then reverses the cycle. Clinical personnel would be responsible for ensuring that the autozero device and the pressure transducer lay in the same horizontal plane as the patient's heart. Software would handle the number crunching. Would it work? I don't see why not. Cost? I can only guess—maybe \$3,000 to \$5,000.

Thompson: I work in pediatrics, and we frequently change to a pneumotachometer size that is suitable for pediatric patients. Other than dead space, is there a good reason to change to a different-size pneumotachometer? An adult pneumotachometer may have a flow range of zero-to-300 L/min, and the one I may use is zero-to-30 L/min. What do I gain by using the zero-to-30 L/min, as opposed to the zero-to-300 L/min, since they both start at zero? Other than dead space, what are the other issues of concern?

Sanborn: The problem is that as you get close to zero flow, your signal and any inherent noise in the transducer blend together. That is, the signal-to-noise ratio gets poor. As you get very close to zero, you may not find a signal at all, so you always want to have the range of the transducer encompass the range you really need. Any extra range burdens you with the full-scale error that overloads your signal. This problem arises because of the way the

transducers are specified; full-scale error burdens your short-range reading; it would be like trying to measure a fine wire with a micrometer designed to measure a diameter of 2 feet. You wouldn't have enough resolution in the thread pitch to measure a fine wire.

The same thing occurs when you attempt to measure pressures < 1 cm H₂O with a pressure transducer designed to measure hundreds of cm H₂O. What you're doing in your flow example is swamping the signal with excess noise. What you need to do is reduce the range of your flow sensor. Even with filtering you may not be able to extract the true signal. So always, as a rule, you want to choose a transducer whose range most completely overlaps the actual variable range you are going to be monitoring. And a linear transducer may be the worst of all, because the input-output relationship is actually proportional and a near-zero signal generates a near-zero output signal. At zero there is no signal; you have all noise.

Hot-film anemometers have the advantage, because the input-output relationship is quasi-exponential: the lower the flow, the more sensitive the flow sensor becomes. The penalty is that you have lower resolution up in the high-flow range, but you don't need high resolution up at high flows. So a linear device can be a problem when the input signal is very close to zero.

Thompson: We also have trouble with the downstream geometry at the inlet of the pneumotachometer. Anything we do to manipulate post-pneumotachometer affects the pneumotachometer measurement. Is that turbulence?

Sanborn: Turbulence is the devil of flow measurements. A flow transducer usually makes measurements based on an assumption of laminar flow; but when you introduce accessory fittings or the like in the flow path near the flow sensor, flow may change from laminar to turbulent, or eddies could

develop, all of which could affect the transducer accuracy. If you are looking for high accuracy, you need to know what your transducer is capable of, and either not do what you're doing or do it in a different way. That's the only thing I can think of.

Thompson: I gathered from what you presented that if I try to subtract the lost compression volume of the circuit tubing, the measurement would be inaccurate.

Sanborn: Yes. Well, that approach is better than not making any correction at all. The trouble is that the effective compliance during a breath is a transient—a ferocious transient. And if you study compliance as a function of the frequency of gas delivery—that is, you deliver a sine flow wave (we usually like to study these things with a sine wave) and you generate a very slow sine wave, with a long time between cycles, then it may be that the static compliance you measure on a bench is very close to the compliance you measure with your very slow sine wave. But if you deliver the gas with a higher cycle frequency you'll find that the compliance value you measure varies from the static number by 20% or more.

Thompson: The pneumotachometers we use, according to the manufacturer's specifications, have an accuracy of $\pm 15\%$. Some of the ventilators currently on the market, which subtract the volume, claim to have accuracies of $\pm 5\text{--}7\%$. Clinically, it seems that with microprocessors it would be more accurate to subtract the lost volume than to actually measure it at the airway, with all the variables.

Sanborn: Yes, but most manufacturers employ a model of the ventilator breathing circuit—all volume elements, including tubes, fittings, chambers, and vials—between the outlet of the pneumatic system and the expiratory valve. They've devel-

oped the model either mathematically or empirically, as disclosed years ago in a Siemens patent that disclosed the use of a computer connected to the patient Y-piece, where data were collected for the purpose of determining the relationship between gas delivered by the pneumatic system and gas exiting the Y-piece. From the data, they tried to analyze empirically how they would have to correct the pressure and flow at the ventilator to estimate the pressure and flow at the Y-piece.

We at Puritan Bennett started at the other end and looked at models that would tell us how the Y-piece flow was as a function of flow from the ventilator, given various types of breathing circuits and whatever else. To predict flow at different locations, for example at the Y-piece and at the expiratory port, knowing machine flow, is a tricky maneuver. My experience tells me that it's very adventuresome to say that Y-piece flow can be predicted to $\pm 5\%$, just knowing ventilator flow and the static compliance of the ventilator breathing circuit. Maybe under ideal conditions and with a well-modeled ventilator breathing circuit, one can predict Y-piece flow to $\pm 5\%$, but my guess is that everyday estimates would exceed that error value. It's more than that; perhaps $\pm 10\%$ at best.

Thompson: That's still better than $\pm 15\%$.

Sanborn: In certain cases the model will be extraordinarily accurate. But with very rapid pressurization and depressurization of the ventilator breathing circuit, particularly if you are ventilating an infant with a very brief inspiratory time, the pressure rises and—poof!—it's up like an impulse function. Since the circuit behaves like a viscoelastic substance during the impulse-like rise of pressure, the bench-calculated, static compliance is not all equal to the actual working compliance. So a model is the only way you can get a good flow prediction.