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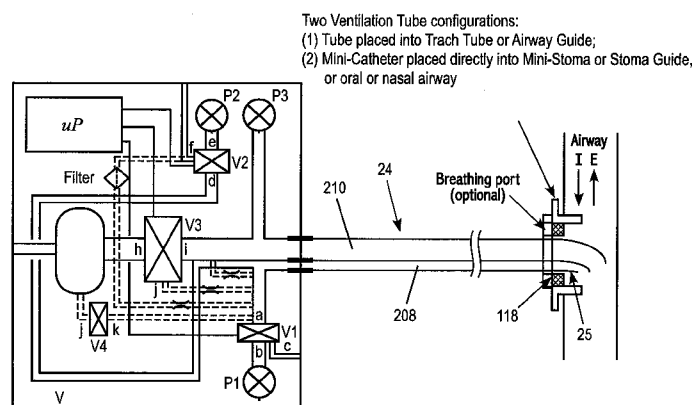


FIG. 6

(57) Abstract: Improved methods and devices are described for sensing the respiration pattern of a patient and controlling ventila-
tor functions, particularly for use in an open ventilation system. A ventilation and breath sensing apparatus may include a ventila-
tion gas delivery circuit and a ventilation tube coupled to the ventilation gas delivery circuit. A plurality of pressure sensing ele-
ments may be separated by a distance and may produce independent signals. The signals may be used to detect pressure differen-
tials between the plurality of pressure sensing elements. Sensing ports may be located in an airway, and connected to transducers
that are valved to optimize sensitivity and overpressure protection. Airway pressure and flow can both be obtained and used to op-
timize ventilator synchronization and therapy.

METHODS AND DEVICES FOR SENSING RESPIRATION AND CONTROLLING VENTILATOR FUNCTIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Patent Application No. 61/071,252, entitled "Methods and Devices for Sensing Respiration and Controlling Ventilator Functions", filed April 18, 2008, the content of which is incorporated by reference in its entirety.

This application incorporates by reference in their entireties: U.S. Patent Application No. 10/870,849, entitled "Methods, Systems and Devices for Improving Ventilation in a Lung Area", filed June 17, 2004; U.S. Patent Application No. 12/153,423, entitled "Methods and Devices for Sensing Respiration and Providing Ventilation Therapy", filed May 19, 2008; U.S. Patent Application No. 10/771,803, entitled "Method and Arrangement for Respiratory Support for a Patient Airway Prosthesis and Catheter", filed February 4, 2004; U.S. Patent Application No. 11/523,518, entitled "Systems, Methods and Apparatus for Respiratory Support of a Patient", filed September 20, 2006; and U.S. Patent Application No. 11/523,519, entitled "Systems, Methods and Apparatus for Respiratory Support of a Patient", filed September 20, 2006.

FIELD OF THE INVENTION

The present invention relates to ventilation therapy for persons requiring respiratory support from a ventilator. Conditions can include respiratory impairment and breathing disorders, such as chronic obstructive pulmonary disease (COPD), pulmonary fibrosis, acute respiratory distress syndrome (ARDS), neuromuscular impairment, and sleep apnea, or anesthesia, emergency and the

like. The present invention relates more specifically to measuring a patient's respiratory pattern using breath sensing approaches, and using that measured information from breath sensors to synchronize ventilator output to a breathing pattern of a patient.

BACKGROUND OF THE INVENTION

There are two general types of control systems for conventional ventilators. A first type delivers gas to a patient based on a frequency selected by the clinician that is independent of patient activity. This control system is used when the patient is non-alert, sedated, unresponsive or paralyzed. In this type of system, the ventilator is breathing for the patient. A second type of control system delivers gas to the patient in response to an inspiratory effort created by the patient. This type of ventilation helps the patient breathe. There are also ventilators and modes of ventilation that combine these two types of control systems. The present invention relates to ventilation systems and modes that respond to an inspiratory effort by the patient.

Control systems that respond to patient breathing efforts require breath sensors to detect inspiration. Conventional systems use pressure or flow sensors to detect the start of an inspiratory effort by the patient. The sensor is located somewhere in-line with the ventilation gas delivery circuit, either inside the ventilator, or in the tubing between the ventilator and the patient, or at the patient end of the tubing. In-line breath sensors are also used to measure the entire respiratory curve in addition to just the start of inspiration; however, because the gas being delivered by the ventilator also moves past the sensor, the sensor during that time no longer measures the patient's respiration but rather the ventilator activity. In a closed ventilation system, the patient lung pressure and the gas delivery circuit pressure, while not necessarily identical, are typically very close. In an

open ventilation system in which the patient is also spontaneously breathing, the patient lung pressure and the gas delivery circuit pressure can be very different. In this case, a breath sensor in-line with the ventilation gas delivery circuit can be ineffective in measuring the entire respiratory pattern.

In ventilation systems in which the patient is expected to be breathing or partially breathing spontaneously, synchronization between the ventilator and the patient is important for comfort and efficacy. However, poor synchrony is still reported in some cases because of the demanding and exacting task of measuring all the different possible spontaneous breathing signals and the vast range of variations that exist.

Some attempts have been made to use sensors that are in parallel with the ventilation gas delivery system and are more directly coupled to the patient's actual respiration. The intent of these systems is to improve breath detection, to improve responsiveness of the ventilator, to improve the synchrony of the ventilator to the patient, or to reduce work of breathing required for a patient to trigger the ventilator.

For example, chest impedance sensors can be used to measure the entire respiratory curve of a patient and to use that signal to control the ventilator and synchronize the ventilator to the patient's breathing. However, this approach is technically challenging because the signal is prone to drift, noise and artifacts caused by patient motion and abdominal movement. In another technology, the neural respiratory drive measured with an esophageal catheter is used to measure the respiration of a patient. However, this technique requires an additional invasive device and sensor, and does not monitor exhalation activity since that is a neurally passive function.

Thermal intra-airway breath sensing is promising because it directly measures airflow in the trachea and, if implemented correctly, can determine the complete breathing pattern of the patient and can generate a breathing signal that is not disrupted by the ventilator gas flow.

Pressure-based breath sensing in the airway measures pressure at the distal end of an endotracheal tube, and using that pressure measurement to control a ventilator function for the purpose of reducing the patient's breath effort required for the patient to trigger a mechanical breath from the ventilator. Reduction in effort is a result of a quicker response time of the pressure signal because of the proximity of the signal to the patient's lung. While an improvement over conventional triggering techniques in conventional ventilation, this technique still has disadvantages and in fact has not yet been converted into commercial practice. For example, a sensor must have the necessary sensitivity and accuracy to detect light breathing pressures, while also withstanding high pressures so that it does not fail during a high pressure condition, such as a cough. This is especially of concern in medium and higher pressure ventilation delivery systems. Further, additional information related to the respiration pattern is desirable to increase the efficacy of the therapy. Also, existing systems have a logistically cumbersome interface with the external control system. In summary, existing systems have the one or more of the following disadvantages that require improvement: (1) they do not measure the complete breath cycle, (2) they are in-line with the channel used for ventilation gas delivery, (3) they have a limited range of accuracy and sensitivity, and (4) they are logistically cumbersome to interface with the ventilator.

SUMMARY OF THE INVENTION

The current invention is an improvement over existing breath sensing techniques. The invention may include pressure-based breath sensing methods and systems that may be in parallel with the ventilation circuit. The methods and systems may measure intra-tracheal breathing pressures or nasal or oral breathing pressures, and may be in series or in-line with airflow in a patient airway.

Various techniques for intra-airway pressure-based breath sensing are described in the present invention. In an exemplary embodiment, a system includes a multichannel, multi-transducer breath sensing arrangement is described. The system is capable of measuring pressure throughout a wide range, while maintaining the necessary resolution at low pressures, by intelligently switching between channels. In an exemplary embodiment, a system includes means to measure or derive intra-tracheal flow or nasal or oral air flow. In an exemplary embodiment, a system includes positioning of a transducer close to the patient on the patient interface. In an exemplary embodiment, other types of pressure or flow sensing technologies are described.

Improved methods and devices are described for sensing the respiration pattern of a patient and controlling ventilator functions, particularly for use in an open ventilation system. A ventilation and breath sensing apparatus may include a ventilation gas delivery circuit and a ventilation tube coupled to the ventilation gas delivery circuit. A plurality of pressure sensing elements may be separated by a distance and may produce independent signals. The signals may be used to detect pressure differentials between the plurality of pressure sensing elements.

In certain embodiments, a ventilation and breath sensing method and apparatus may use two intra-airway sensing systems, a thermal sensor for measuring tracheal, nasal or oral airflow and a pressure sensor for measuring tracheal pressure, and wherein the tracheal airflow signal is used to derive breathing flow rate and breathing volume. The pressure and flow signals may be used to determine compliance, resistance and an approximation for work of breathing. In exemplary embodiments, a ventilation and breath sensing method and apparatus may use two pressure sensing lumens terminating in the airway, the ports of which are separated by a distance to create a pressure differential between the two signals, thereby obtaining both tracheal pressure and tracheal airflow. A ventilation and breath sensing method and apparatus may use an intra-airway sensor and a flush lumen and flush port in the delivery tube to maintain a contamination-free sensor. A ventilation and breath sensing method and apparatus may use an intra-airway sensor and a flush lumen connected to the main ventilation gas delivery lumen to maintain a contamination-free sensor. A ventilation and breath sensing method and apparatus may use a pressure sensor mounted in the stomal flange or connector of the ventilation catheter, pneumatically communicating with the airway through the stoma via an extension tube extending transcutaneously into the airway. A ventilation and breath sensing method and apparatus may use a two section system, an external section including a pressure sensor, and an inserted section with a breath sensing lumen, the pressure sensor pneumatically communicating with the sensing lumen when the two sections are connected, and a flush lumen included in the external section connecting to the sensing lumen when the two sections are connected. The sensing lumen may be flushed via an interconnecting channel with the ventilator gas delivery lumen. A ventilation and breath sensing method and apparatus may be used in which a ventilation catheter is placed into a outer sleeve, such as a tracheostomy tube or stomal guide, with a heat moisture exchanger, bacterial filter, breathing port, intra-airway spontaneous breath sensors, and an inspiratory valve positioned in the annular space between the catheter and outer sleeve, and

optionally a expiratory relief valve. A ventilation and breath sensing method and apparatus with a tracheal airflow conduit may be positioned in the airway for measuring tracheal airflow with sensors positioned in the airflow conduit to measure tracheal breathing pressure and conduit airflow, wherein the conduit airflow is used to derive tracheal breathing flow rate. A ventilation and breath sensing method and apparatus may be used in which a spontaneous breathing lumen separate from the ventilator gas delivery lumen extends into the airway and includes multiple pressure taps connecting to the lumen, to measure a pressure drop across the pressure taps, and the pressure drop correlated to tracheal airflow, and the pressure tap closest to the patient used to measure patient ventilation pressure. A ventilation and breath sensing method and apparatus may use a pressure sensor mounted in the stomal flange of the ventilation catheter or outer tube around the ventilation catheter, pneumatically communicating with a lumen in the catheter which extends to the airway, with the catheter placed in a sleeve such as a tracheostomy tube. A ventilation and breath sensing method and apparatus may use a pressure sensor mounted in the flange or connector of a ventilation catheter, with a sensing extension tube connected to the pressure sensor, where the catheter is placed inside an outer sleeve such as a tracheostomy tube. The outer sleeve may be a stomal sleeve, guide or stent. The pressure transducer may be positioned near a neck flange. The pressure transducer signal may be transmitted wirelessly. A ventilation and breath sensing method and apparatus may be used in which an array of three pressure sensors may be used to measure spontaneous breathing, airway lung pressure and ventilation gas delivery pressure, where at least one pressure sensor senses pressure in a transtracheal sensing lumen, and at least one pressure sensor sense pressure in the ventilation gas delivery circuit. One pressure sensor in the ventilation gas delivery circuit may be disabled during ventilator gas delivery. A ventilation and breath sensing method and apparatus may include a gas delivery circuit with a sensing lumen, and an outer sleeve such as a tracheostomy tube with a sensing lumen, and with pneumatic coupling between the gas

delivery circuit and outer sleeve such that the gas delivery circuit sensing lumen taps into the outer sleeve sensing lumen. A ventilation and breath sensing method and apparatus may include a two piece ventilation interface in which a ventilation catheter is placed in a thin wall small diameter profile outer sleeve, such as a thin walled small diameter profile tracheostomy tube which includes a tight to shaft cuff when deflated and a stomal spacer, for the purpose of reducing resistance to upper airway breathing. A ventilation and breath sensing method and apparatus may include two sections in which an inserted disposable ventilation catheter section receives an external reusable gas delivery section, in which a sensor is positioned near the connector of the external section and connects to a sensing lumen of the inserted section. A ventilation and breath sensing method and apparatus may include three sections, a pressure transducer, a gas delivery circuit, and a ventilation tube, in which a reusable pressure transducer is attached to the flange of the gas delivery circuit or ventilation catheter, and when attached plugs into a receiving port that communicates with a sensing lumen extending into the airway. A ventilation and breath sensing method and apparatus may include a ventilation delivery cannula with an array of sensing lumens in the wall of the delivery cannula extrusion, and with a plurality of ports connecting the sensing lumens with the space outside the cannula, in order to provide multiple sites of pressure sensing in the airway. A ventilation and breath sensing method and apparatus may use two pressure sensing elements or ports with a physical screen between the elements to dampen the signal response time and amplitude of relative to the direction of flow. A ventilation and breath sensing method and apparatus may use two sensing elements on the inferior and superior aspects of the delivery cannula to create a physical barrier to bias the response time of each element that correlates to the direction of flow. A ventilation and breath sensing method and apparatus may use a fiber optic sensor positioned on a portion of the catheter residing in the airway. A ventilation and breath sensing method and apparatus may use a fiber optic sensor positioned on a reusable portion of the ventilation catheter,

communicating with a catheter lumen extending into the airway. A ventilation and breath sensing method and apparatus may use a liquid filled sensing lumen to transmit the pressure signal from the airway to the transducer. A ventilation and breath sensing method and apparatus may use a strain gauge or array of strain gauges, measuring direction and amplitude of strain of the gauge, to determine flow direction, speed and amplitude. The sensing lumen may be placed on the posterior aspect of the ventilation catheter, on the anterior aspect of the ventilation catheter, on the superior aspect of the ventilation catheter, on the inferior aspect of the ventilation catheter, on the lateral aspect of the ventilation catheter, on the multiple locations or aspects of the ventilation catheter, or on the posterior aspect of the ventilation catheter. The sensing lumen may terminate beyond the tip of the ventilation tube or at a location recessed from the tip of the ventilation tube. The flow and pressure data may be used to determine airway resistance, lung compliance and an estimate of work of breathing. A ventilation tube may be placed into the airway and may include a sensing lumen, a flush port, fenestrations, and an inflatable cuff. The ventilation tube may include an inflatable and deflatable cuff, and at least two sensing lumens with one lumen terminating distal to the cuff and one lumen terminating proximal to the cuff, wherein the pressures of the two sensing lumens are compared to provide an indication of the degree of obstruction being caused by the cuff.

Additional features, advantages, and embodiments of the invention are set forth or apparent from consideration of the following detailed description, drawings and claims. Moreover, it is to be understood that both the foregoing summary of the invention and the following detailed description are exemplary and intended to provide further explanation without limiting the scope of the invention as claimed.

BRIEF DESCRIPTION OF THE INVENTION

The accompanying drawings, which are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification, illustrate preferred embodiments of the invention and together with the detailed description serve to explain the principles of the invention. In the drawings:

Figure 1 shows prior art breath sensing in series with breathing circuit for ventilator control.

Figure 1A shows graphical representation of the respiration signal masked by the ventilator gas delivery pressure.

Figure 2 shows breath sensing for ventilator control using chest impedance.

Figure 2A shows a graphical representation of the ventilation gas delivery pressure and the respiration sensor signal.

Figure 3 shows an intra-airway breath sensing for ventilator control.

Figure 3A shows graphical representation of the ventilation gas delivery pressure and the respiration sensor signal.

Figure 4A shows graphically conventional breath sensing.

Figure 4B shows graphically breath sensing described in this invention.

Figure 4C shows graphically chest impedance breath sensing.

Figure 5 shows a ventilation and breath sensing system in which a ventilation catheter is placed into a outer sleeve, such as a tracheostomy tube or stomal guide, with a heat moisture

exchanger, bacterial filter, breathing port, spontaneous breath sensors, and an inspiratory valve positioned in the annular space between the catheter and outer sleeve.

Figure 5A shows the ventilation catheter of the system in Figure 5.

Figure 5B shows the outer sleeve of the system of Figure 5.

Figure 5C shows the cross section through line D-D in Figure 5.

Figure 5D shows the cross section through line E-E in Figure 5.

Figure 6 shows a breath sensing and ventilation system in which an array of three pressure sensors are used to measure spontaneous breathing, intratracheal pressures, and ventilation gas delivery pressures.

Figure 7 shows a detailed view of the valving to operate the sensors of the system of Figure 6.

Figure 8 shows valve timing control of the system described in Figure 6.

Figure 9 shows resultant pressure tracings of the sensors used in the system of Figure 6.

Figure 10 shows a ventilation and breath sensing system comprising a ventilation catheter and outer sleeve such as a tracheostomy tube, with a sensing lumen in the outer sleeve, and with pneumatic coupling between the ventilation catheter and outer sleeve such that the ventilation catheter sensing lumen taps into the outer sleeve sensing lumen.

Figure 11 shows a breath sensing and two piece ventilation interface in which a ventilation catheter is placed in a thin wall small diameter profile outer sleeve, such as a thin walled small

diameter profile tracheostomy tube which includes a tight to shaft cuff when deflated and a stomal spacer, for the purpose of reducing resistance to upper airway breathing.

Figure 12 shows two section breath sensing and ventilation delivery system in which an inserted disposable ventilation catheter section receives an external reusable gas delivery section, in which a sensor is positioned near the connector of the external section and connects to a sensing lumen of the inserted section.

Figure 13 shows a breath sensing and ventilation delivery cannula with an array of sensing lumens in the wall of the delivery cannula extrusion, and with a plurality of ports connecting the sensing lumens with the space outside the cannula, in order to provide multiple sites of pressure sensing in the airway.

Figure 13A shows a detailed view of a cross section through area H of Figure 13.

Figure 13B shows a cross sectional view through line G-G of Figure 13.

Figure 13C shows a cross sectional view that is an alternative cross section to that of Figure 13b.

Figure 14 shows breath sensing using two sensing elements with a physical screen between the elements to bias the response time of each element due to the direction of flow.

Figure 14A shows graphically the signal tracings of the sensors shown in Figure 14, during inspiration.

Figure 14B shows graphically the signal tracings of the sensors shown in Figure 14, during exhalation.

Figure 15 shows breath sensing using two sensing elements on the inferior and superior aspects of the delivery cannula to create a physical barrier to bias the response time of each element that correlates to the direction of flow.

Figure 15A shows graphically the signal tracings of the sensors shown in Figure 15 during inspiration.

Figure 15B shows graphically the signal tracings of the sensors shown in Figure 15 during exhalation.

Figure 16 shows breath sensing using two sensing systems, a thermal sensor for measuring tracheal airflow and a pressure sensor for measuring tracheal pressure.

Figure 16A shows resultant flow and pressure signals for system of Figure 16, showing determination of compliance, resistance and an approximation for work of breathing.

Figure 17 shows breath sensing using two pressure sensing lumens terminating in the airway, the ports of which are separated by a distance to create a pressure differential between the two signals, thereby obtaining both tracheal pressure and tracheal airflow.

Figure 17A shows an alternative to Figure 17 in which two pressure sensing ports are placed on opposite surfaces on the ventilation tube.

Figure 18 shows resultant pressure signals from system of Figure 17.

Figure 19 shows an alternate shape of the delivery cannula from that of Figure 17 in which the two pressure sensing lumen ports are positioned on a straight section of cannula and positioned parallel to the patient's breath airflow path. .

Figure 19A shows an alternative to Figure 19 in which two pressure sensing ports are placed on a straight section of ventilation tube on opposite surfaces of the ventilation tube, orthogonal to the direction of breathing airflow.

Figure 20 shows breath sensing using an intra-airway sensor and a flush lumen and flush port in the delivery tube to maintain a contamination-free sensor.

Figure 20A describes in more detail the flush lumen and flush port of Figure 20.

Figure 21 shows breath sensing using an intra-airway sensor and a flush lumen connected to the main ventilation gas delivery lumen to maintain a contamination-free sensor.

Figure 22A show an alternate configuration of a flush port from that described in Figure 20 with the flush port located on the anterior or inferior surface of the cannula.

Figure 22B shows an alternate configuration of a flush port from that described in Figure 20 in which the flush media is directed retrograde at the sensor.

Figure 23A shows a graphical description of a constant steady state flushing pressure profile.

Figure 23B shows a graphical description of an intermittent flushing pressure profile in which flushing occurs as needed or intermittently.

Figure 23C shows a graphical description of a cyclical flushing pressure profile, optionally in synchrony with the patient's respiration pattern.

Figure 24 shows a ventilation and breath sensing system with a tracheal airflow conduit positioned in the airway for measuring tracheal airflow.

Figure 24A shows a ventilation and breath sensing system with two pressure sensors or pressure sensing ports in the flow conduit and separated by a flow conduit screen.

Figure 25 shows a ventilation and breath sensing system in which a spontaneous breathing lumen extends into the airway and including multiple pressure taps connecting to the lumen, to measure a pressure drop that can be correlated to tracheal airflow.

Figure 25A shows a schematic cross section of the system of Figure 25.

Figure 25B shows a resultant pressure sensing signals and derivation of ΔP for determination of tracheal airflow from the system described in Figure 25.

Figure 26 shows a ventilation interface and sensing system with a ventilation tube and flow conduit on the ventilation tube to obtain flow rate readings.

Figure 26A shows a graphical representation of the sensor signal of the sensor shown in Figure 26, indicating how the signal is correlated to flow rate.

Figure 27 shows breath sensing using a pressure sensor mounted in the stomal flange of the ventilation catheter, pneumatically communicating with the airway through the stoma via an extension tube extending transcutaneously into the airway.

Figure 27A shows a schematic cross section of Figure 27.

Figure 27B shows a detail of Figure 27A.

Figure 28 shows a ventilation gas delivery and breath sensing using a two section system, an external section including a pressure sensor mounted in proximal connector of the ventilation catheter, and an inserted section with a breath sensing lumen, the pressure sensor pneumatically

communicating with the sensing lumen when the two sections are connected, and a flush lumen included in the external section connecting to the sensing lumen when the two sections are connected.

Figure 28A shows a cross section schematic of system in Figure 28.

Figure 28B shows a cross section of alternate configuration of Figure 28, where the sensing lumen is flushed via an interconnecting channel with the ventilator gas delivery lumen.

Figure 29 shows a ventilation and breath sensing using a pressure sensor mounted in the stomal flange of the ventilation catheter, pneumatically communicating with a lumen in the catheter which extends to the airway, with the catheter placed in a sleeve such as a tracheostomy tube.

Figure 30 shows a ventilation and breath sensing system using a pressure sensor mounted in the flange or connector of a ventilation catheter, with a sensing extension tube connected to the pressure sensor, where the catheter is placed inside an outer sleeve such as a tracheostomy tube.

Figure 30A shows a detailed cross sectional view of system of Figure 30.

Figure 31 shows the system of Figure 30 where the outer sleeve is a stomal sleeve, guide or stent.

Figure 32 shows a two or three piece ventilation interface and sensing system in which a reusable pressure transducer is attached to the flange of the ventilation catheter or gas delivery tube, and when attached plugs into a receiving port that communicates with a sensing lumen extending into the airway.

Figure 33 shows breath sensing using a fiber optic sensor positioned on a portion of the catheter residing in the airway.

Figure 33A shows an alternative to Figure 33 in which the sensor tip is recessed from the tip of the catheter and is on the outside of the catheter.

Figure 33B shows an alternative to Figure 33 in which the sensor tip is recessed from the tip of the catheter and is on the inside of the catheter.

Figure 34 shows breath sensing using a fiber optic sensor positioned on a reusable portion of the ventilation catheter, communicating with a catheter lumen extending into the airway.

Figure 35 shows breath sensing using a liquid filled sensing lumen to transmit the pressure signal from the airway to the transducer.

Figure 35A shows an alternative to Figure 35 in which the tip of the sensing lumen is recessed from the tip of the catheter.

Figure 36 shows breath sensing using a strain gauge or array of strain gauges, measuring direction and amplitude of strain of the gauge, to determine flow direction, speed and amplitude.

Figure 36A shows a cross section through the catheter of Figure 36 at line K-K.

Figure 36B shows an alternate location of the sensors of Figure 36, with the sensors on the anterior or inferior side of the catheter.

Figure 36C shows an alternate location of the sensors of Figure 36 in which the sensors are located on a lateral side of the catheter.

Figure 36D shows an alternate location of the sensors of Figure 36 in which the sensors are positioned circumferentially around the surface of the catheter.

Figure 36E shows a cross section of Figure 36d at line L-L.

Figure 36F shows an alternate location of the sensors of Figure 36 in which the sensors are positioned inside a sensing lumen which is integral to the ventilation cannula or catheter.

Figure 37 shows graphical tracing of the strain gauge signal of the system of Figure 36.

Figure 37A shows the resting state of the strain gauge during no flow corresponding to breath phases of signal of Figure 37.

Figure 37B shows the deflected state of the strain gauge during inspiration corresponding to breath phases of signal of Figure 37.

Figure 37C shows the deflected state of the strain gauge during exhalation corresponding to breath phases of signal of Figure 37.

Figure 37D shows the deflected state of the strain gauge during inspiration, corresponding to breath phases of signal of Figure 37.

Figure 38A shows an alternate location of strain gauges of the system described in Figure 36 in which the gauge is located at a connector positioned outside of an airway.

Figure 38B shows an alternate location of strain gauges of the system described in Figure 36 in which the gauge is located in a ventilation circuit or cannula outside of an airway.

Figure 38C shows an alternate location of strain gauges of the system described in Figure 36 in which the gauge is located inside the ventilator.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 (prior art) describes a conventional ventilator system in which the breath sensor is in line with the ventilation gas being delivered in the breathing circuit. The Ventilator V delivers gas to the patient Pt through the ventilation gas delivery circuit, dual limb 21 and ventilation tube 25. A pressure tap 23 in series or in line with the ventilator gas flow senses a negative pressure created by a patient inspiratory effort. Alternatively, a flow sensor can be used in series with the ventilation circuit to detect when the patient inspires. The signal from the breath sensor is delivered to a ventilator control unit 20 in the ventilator V. As seen in Figure 1a these in-series sensor systems measure the start of a patient inspiratory effort 63, but after the ventilator V is triggered to deliver a mechanical breath to the patient Pt, the sensor signal predominantly indicates the ventilator activity in the form of a ventilator gas delivery pressure tracing 52, and not the patient activity.

Figure 2 describes a ventilator breath sensing triggering system in which the breath sensor is a chest impedance sensor system, as described in U.S. Publication No. 2005/0034721. In this case, the sensor is placed in parallel with the ventilation circuit. A chest impedance band 62 is connected to the ventilator V control unit 20 by chest impedance wires 60. The patient spontaneous respiration curve 58 is not masked by the pressure waveform of the patient Pt, as shown in Figure 2a. Although an improvement over prior art, the impedance sensor can have a tendency to register motion of the person which is not related to breathing and hence can include artifacts.

Figure 3 describes an overall configuration of an embodiment of the present invention, including a ventilator V, a ventilation gas delivery circuit, single limb 24, ventilation tube 25 and sensor or pressure sensing port S1 positioned to measure intra-airway tracheal air flow or breathing

pressures or nasal or oral air flow, positioned inside or near the airway. While the following exemplary embodiments are described for intra-airway tracheal air flow, similar concepts may apply to nasal and oral air flow. The breath sensor or sensing port S1 may be an intra-tracheal sensor, conduit or port located in the tracheal airway TA in the path of the patient's airflow, and in parallel with the ventilation circuit 24. The sensor, conduit or sensing port is typically but not always part of or attached to the ventilation tube 25. The signal may be delivered to the ventilator control unit 20 by means of wires or sensing conduits, or alternate transmission means such as fiber optic or wireless. The ventilator V may have one or more processors 10 for receiving and analyzing signals from the sensors. The processor 10 may process receive and process signals from the sensors and compute relevant parameters as described below. The processor 10 may then output the signals and/or the results of computations. The processor 10, ventilator V, and/or ventilator control unit 20 may then output the signals, the results of the analyzing and/or control ventilation based upon the analysis. As seen in Figure 3a, this may be an improvement over conventional in-series breath sensing systems in that the actual breathing signal 58 is not masked by the ventilation gas delivery 52, and the sensor measures both the patient's true breathing activity 58 as well as the effect that the ventilation gas delivery has on the patient's lung pressure and airway breath flow. This is especially important in open ventilation systems. Also, as will be explained in later sections, the present invention describes improvements related to signal drift, artifacts, and disturbance caused by patient movement and changing temperature conditions. It should be noted that while in the following descriptions, the sensing system is described typically in conjunction with a transtracheal ventilation catheter, however this is exemplary only and other interfaces are included in the invention, such as but not limited to: a trans-nasal catheter, a trans-oral catheter, transtracheal tube catheters, percutaneous catheters, oral cannula, nasal cannula, non-invasive mask oral and/or nasal interfaces, open nasal and open oral cannula interfaces. For simplicity, the following describes are typically

described with a transtracheal catheter; however, the invention is also applied to the other interfaces stated above.

Figures 4a-4c graphically describes the difference between using intra-airway sensors which directly measure tracheal pressure and respiration, versus conventional in-line ventilator sensing systems. Figure 4a describes a conventional system in which the pressure sensor measures a patient inspiratory effort 63 but then measures the ventilator gas flow 52. As one example of the disadvantages of this conventional system, the resultant inspiratory time determined by the ventilator is the inspiratory time set by the user on the ventilator, and not the true patient's spontaneous inspiratory time determined by a spontaneous breathing sensor, and for example as a result the patient's exhalation tracheal flow/pressure curve 66 begins later than the patient's true start of exhalation. Figure 4b describes mechanical augmented ventilation in which tracheal pressure is measured at all times, hence during the period of ventilation gas delivery, the waveform accurately shows the combined effect in the lung or airway of spontaneous breathing and artificial ventilation. Figure 4c shows a system with chest impedance sensors which show an artificial trigger of the ventilator gas delivery 52 due to an artifact in the chest impedance tracing 77 occurring before the true start of inspiration.

Figures 5-13 describe an embodiment of the invention in which intra-airway pressure may be measured using a combination of channels or conduits in the gas delivery circuit and/or the patient interface assembly, including for example in the gas delivery channel, in dedicated sensing conduits with sensing lumens or tubes, and in the annular space around the patient interface. The multiple channel sensing may provide the range, accuracy, resolution and reliability sought by the invention, as will be explained subsequently. The sensing system can be used with a transtracheal catheter

interface, or other patient interfaces as described above, such as a nasal or oral catheter or cannula interface.

Figures 5-5d describe an embodiment of the present invention in which a ventilation and breath sensing system may include a ventilator V, a gas delivery circuit 24, and a ventilation tube 25 or ventilation catheter placed into an outer sleeve, such as a tracheostomy tube 28 or a stomal sleeve (not shown). A ventilation catheter flange 115 may be provided and may be coupled to a tracheostomy tube ventilation circuit connector 111. Figure 5a describes the ventilation tube 25; Figure 5b shows the tracheostomy tube 28; and Figures 5c and 5d show the cross-section through lines D-D and E-E in Figure 5, respectively. In addition to the patient inspiring spontaneously through the upper airway 200, optionally the patient can also inspire from ambient air through the annular space between the ventilation catheter and outer sleeve through an inspiratory flow valve 122 with a breathing flow port 116. This permits minimal work required to inspire ambient air, since air can be inhaled through the valve and also through the mouth and nose, while directing exhaled air through the upper airway to further facilitate speech. Optionally, a heat moisture exchanger 118 and a bacterial filter 120 can be provided in the annular space. Further, breath sensors can optionally be placed in the annular space, for example a thermal sensor T1 for detecting inspiratory and expiratory flow and/or a pressure sensor or sensing port P1 for measuring tracheal pressure. Optionally, an expiratory pressure relief valve can be provided so that if the patient airway pressure exceeds a safe limit, gas can be exhaled or vented through the relief valve (not shown). Optionally, a PEEP valve is provided (not shown) between the ventilation tube and tracheostomy tube, to maintain a level of pressure in the lung.

Figures 6 - 9 describe an embodiment of the present invention with a ventilation breath sensing and control system using three pressure transducers to optimize the sensing of spontaneous

breathing airway pressures and controlling and monitoring ventilator functions. Figure 6 describes the overall layout and describes the purpose of the pressure transducers P1, P2 and P3. Transducer P1 has a range for example of -100 to +100 cmH₂O with 0.1 cmH₂O resolution. P1 is used for (1) airway alarm handling such as for high peak pressure and high inadvertent PEEP, (2) determination of respiratory rate, T(inspiration), T(expiration), end of expiration, end of inspiration, and start of expiration, and (3) airway pressure signal to be delivered to the GUI display screen for real time display of the airway pressure. P1 is open to the airway pressure sensing lumen continuously when the ventilator is powered on. It is decoupled from the sensing lumen when the ventilator power is off, through the closure of valve V1, in order to protect the valve from inadvertent misuse and overpressure conditions. Transducer P2 has a range for example of -20 to +20 cmH₂O with a 0.025 cmH₂O resolution. P2 is used expressly for the determination of the start of inspiration. The high resolution and accuracy near zero of the transducer maximizes the sensitivity of the system to detect the start of inspiration, which can be used for optimizing the response time of the system and synchronization of the ventilator output with the patients inspiratory phase. P2 is opened to the sensing lumen after the ventilator is powered on and after P1 determines the system is operating correctly without any inadvertent high pressure conditions. For example, P2 is opened to the sensing lumen after P1 determines that the breathing circuit and catheter are connected to the patient based on a normal breathing airway pressure signal detected by P1. During operation, P2 is cycled open and closed to the sensing lumen through valve V2. P2 is closed after the detection of inspiration, during the ventilator augmentation phase, in order to protect it from over-pressure damage that may occur from the ventilator pressure pulse. It is reopened to the sensing lumen upon completion of the ventilator augmentation phase. Optionally, P2 can be connected to the ventilation gas delivery channel rather than the sensing lumen, in order for P2 to provide a redundancy to P1. Or, optionally, an additional high resolution transducer similar to P2 can be

attached to the ventilation gas delivery lumen for a redundancy to P1. Transducer P3 has a range for example of 0-30 psi. P3 is used for (1) monitoring of the ventilator augmentation waveform. (2) low gas delivery pressure, such as delivery circuit disconnect, or ventilator malfunction, low source gas pressure, and (3) high gas delivery pressure, such as delivery circuit obstruction, ventilator malfunction. P3 can also be used as a redundancy or cross check to P1 for measuring and monitoring airway pressure alarm handling functions, such as high PEEP and high peak airway pressure events and alarms, such as inadvertent PEEP and coughs or airway obstructions. P3 is open to the gas delivery circuit at all times. While Figure 6 describes a transtracheal interface, the invention applies to other interfaces as described previously, such as oral and nasal catheter or cannula interfaces.

Figure 7 describes in more detail the valve control to control ventilator output and pressure transducer operation. Graph P1 in Figure 8, with the timing diagrams, describes the airway pressure signal being generated by transducer P1. Signal V3 depicts the state of valve V3; when open the ventilator V is delivering pressurized augmentation gas to the gas delivery circuit. Signal V2 depicts the state of valve V2; when open P2 is in communication with the sensing lumen, or alternatively the gas delivery channel. Signal V1 depicts the state of the valve V1; when open, P1 is in communication with the airway pressure sensing lumen. Signal V4 depicts the state of valve V4 which controls a flow of purge gas through the sensing lumen to keep the sensing lumen patent, preventing moisture or secretions from blocking the P1 from detecting the airway pressure signal; when open, V4 allows the flow of purge gas through the sensing lumen, and can be opened continuously when the ventilator is powered on, or cyclically at a strategic cycle. The sequence of operation of the valves is as follows. Time t1 depicts the time of powering on of the ventilator, and the opening of valve V1 to the sensing lumen. Time t2 depicts the time of the gas delivery circuit being attached to the patient which is confirmed by a pressure signal starting to be detected by P1.

Time t3 depicts the time that the breathing circuit and patient interface is attached correctly to the patient and the system is ready for normal operation.

Figure 9 describes in more detail the resultant pressure signals obtained by the pressure transducers, during one exemplary breath cycle. The top graph depicts actual tracheal or airway pressure, with an inspiratory phase I and an expiratory phase E. The second graph depicts the signal from sensor P1, indicating an increase in airway pressure compared to baseline B, corresponding in time with the augmentation pulse from the ventilator. The third graph depicts the signal from sensor P2, which measures the sensing lumen pressure, or alternatively the gas delivery circuit pressure. The valve V2 closes P2 to the sensing lumen when the ventilator augmentation output is on, depicted by the absence of a signal during the augmentation pulse. The fourth graph depicts the signal from sensor P3 which measures the ventilator output augmentation pressure in the gas delivery channel. The time t10 depicts the actual start of inspiration based on actual change in tracheal airway pressure. Time t11 depicts the detection of the start of inspiration based on sensor P2, which can be for example a 5-30msec response time delay from the actual start of inspiration, based on the time constant of the monitoring system. Time t12 depicts the time of closing off P2 from communicating with the sensing lumen by the closure of valve V2, which can be for example a 10-40 msec delay after the detection of the start of inspiration, based on the electromechanical response time of the system. Time t12 is typically 10-50 msec before the start of the augmentation delivery. Time t13 depicts the time that the ventilator augmentation gas flow begins, by opening valve V3, which is typically 50-150 msec after the actual start of inspiration, however can also include a deliberate delay so that the gas flow begins at a desired time within inspiration, such as when the patient's breathing effort reaches or is close to the maximum effort. Time t14 depicts the time after completion of ventilator augmentation gas flow at which time the P2 is reopened to be in communication with the sensing lumen. The delay between the end of augmentation gas delivery,

and P2 obtaining the sensing lumen signal is typically 10-20 msec after the valve V3 turns off ventilator augmentation gas delivery.

Figure 10 describes an optional embodiment in which the ventilation tube 25 is placed inside an outer sleeve, such as a tracheostomy tube 28. A breathing pressure sensing conduit with a pressure sensing lumen 208 may be integrated into the tracheostomy tube 28. The tracheostomy tube connector 110 on the ventilation catheter 25 may include a sensing lumen connector 226 which engages with the tracheostomy tube sensing lumen 228 when the ventilation tube 25 is connected to the tracheostomy tube 28. The sensing lumen 208 may extend back to the machine end of the delivery circuit 24. A ventilator gas flow lumen 210 may pass through the ventilation gas delivery circuit 24. An optional low profile cuff 260 may be included. The tracheostomy tube 28 may include one or more outer cannula fenestrations 100.

Figure 11 describes an optional embodiment in which the ventilation tube 25 is placed into a thin wall small diameter tracheostomy tube 28'. The smaller profile of the tracheostomy tube 28' may minimize resistance to spontaneous breathing in the tracheal airway. Because of the smaller diameter, the tracheostomy tube 28' may include a stoma spacer 30, or optionally a tracheostomy tube outer cannula 28. The stoma spacer 30 can be reduced in size or can be replaced with different sizes in order to fit the stoma of the patient. A sensing lumen may be placed in the wall of the ventilation tube 25, or in the wall of the stoma spacer 30, or tracheostomy tube outer cannula 28', or optionally a sensing lumen can be a separate tube in the annular space around the outside of the ventilation tube 25. The tracheostomy tube 28' may include one or more outer cannula fenestrations 100. In Figures 10 and 11, the tip of the ventilation catheter is shown at different locations within the outer tube or tracheostomy tube, such as near the mid-point, or near the tip, or alternatively in

the proximal half of the tracheostomy tube or alternatively beyond the distal tip of the tracheostomy tube.

Figure 12 describes an optional embodiment with an external gas delivery circuit 24, which is external to the patient and connects to the ventilator V, and an internal ventilation tube section 25, which is placed so that the distal end is placed into the patient's airway. A sensing lumen 208 in the ventilation tube 25 may connect to a sensing lumen in the gas delivery circuit 24 when the two sections are connected through the pressure sensing lumen connectors 226 and 228. Optionally, a pressure transducer can be included in the connector 110 and can connect directly to the sensing lumen connection 228. This configuration may allow reuse of the external section and frequent cleaning and/or disposal of the internal section. Also, this configuration may allow for different models of the gas delivery section 25 to be used without removing the inserted section, for example, a long section gas delivery circuit can be attached when the patient is connected to a stationary ventilator, or during sleep, so that the circuit can reach the ventilator, and a short section gas delivery circuit can be attached when the person is wearing or toting the ventilator during mobile use of the system. Or when the patient pauses therapy, he or she can disconnect the gas delivery circuit without having to remove the inserted section, as might be important during certain activities.

Figure 13 describes another main embodiment of the present invention in which the ventilation tube 25 includes a plurality of sensing lumens (not shown) in the construction of the ventilation tube 25. The multiple lumens may provide a plurality of sensing ports 209 on an inserted section of the ventilation tube 25, such that there are multiple opportunities to acquire a tracheal pressure signal. If one sensing port 209 clogs or rests against the tracheal wall tissue, or the inner wall of the tracheostomy tube or outer cannula or outer sleeve that surrounds the ventilation tube, there are still other sensing ports 209 available for sensing. For example, if a single port is used, and

the port rests against the wall of the outer tube, such as a tracheostomy tube, outer cannula or stoma sleeve, then the port could be masked and have poor responsiveness to the airway pressure. The plurality of lumens can extend from the machine end of the gas delivery tube 24 to the distal end of the ventilation tube (as shown), or can extend for part of the distance (not shown). For example, the lumens can be terminated before reaching the distal tip of the ventilation tube, for example 1mm to 20 mm from the tip. And for example, the lumens can be joined into a single lumen or few lumens in the gas delivery section so that fewer lumens extend between the ventilator and the ventilation tube.

Figure 13a describes a detailed sectional view of the machine end of the delivery circuit at area H in Figure 13 and describes the sensing lumen connector 266 of the sensing lumens 208 to the ventilator pressure sensing system, and the gas delivery connector 264 to the ventilator gas delivery system. Openings 262 may connect the sensing lumens 209 to the sensing lumen connector 266. Figure 13b describes a sectional view of Figure 13 at line G-G, describing the opening of a sensing lumen 208 to a sensing port 209. In this figure, ridges are described on the inner diameter of the ventilation tube; these provide space for the sensing lumens 208, but also serve to provide kink resistance of the ventilation tube. Figure 13c describes an alternate configuration of sensing lumens 208 at the cross section at line G-G.

Figures 14-26 describe an embodiment of the invention in which intra-airway air flow measurements are made that correspond to the patient's spontaneous respiration pattern. Direct measurement of airflow in the airway is a significantly useful technique in tracking the spontaneous breathing of the patient. Direct air flow measurements, for example, can be used to not only determine the inspiratory and expiratory phases, but also can determine strength of respiration or breathing effort. Air flow measurements can also be used to derive or estimate breathing volumes,

to diagnose disease conditions such as breathing disorders, asthma or expiratory flow limitations, and to help distinguish between breaths and non-breath events. Pressure sensing elements may be separated by a distance and produce independent signals. Pressure differentials between pressure sensing elements determined from the independent signals may be used as input to determine pressure measurements. The pressure measurements may then be used to determine tracheal airflow. Tracheal airflow measurements may then be used to control ventilation.

Figure 14 describes an embodiment of the invention in which a ventilation tube 25 includes a physical screen or barrier 214 separating two sensing elements S1 and S2. The screen 214 provides a dampening or phase shift between the signals from the two sensors S1 and S2. As air flows in one direction, for example, inspiration, the signal strength of S1 is relatively strong and undampened, and the strength of S2 is relatively weak and dampened due to the dampening effect that the screen 214 has on airflow. Temporal and amplitude differences in the signal can be used to determine the direction of airflow. As shown in Figure 14a, the S2 signal lags the S1 signal, and t_1 is less than t_2 , hence the system knows the respiration phase is inspiration 200. As shown in Figure 14b, the S1 signal lags the S2 signal, and t_2 is less than t_1 hence the system knows the respiration phase is exhalation 202. The sensing elements S1 and S2 can be pressure sensors or pressure sensing ports or may work on other principles such as temperature, sound, ultrasound, optical, or other. Alternatively to Figure 14, Figure 15 describes a ventilation tube in which the sensors or pressure sensing ports are separated by the ventilation tube 25 itself, achieving a similar result comparing the graphs shown in Figures 15a and 15b, with 14a and 14b.

In another embodiment of the invention, Figure 16 describes a ventilation tube 25 that includes both a temperature sensing element T1 and a pressure sensor element or pressure sensing port P1 to obtain both a temperature-derived airway airflow signal and an airway pressure signal as

shown in Figure 16a. Optionally, a second temperature sensing element T2 can be used with T1 in a sensing array or Wheatstone bridge arrangement to compensate for drift and artifacts and to normalize the signal. The pressure signal can be used to determine breath phase as well as airway pressure (i.e., negative pressure may correspond to inspiration and positive pressure may correspond to exhalation), and the breath phase determination can be used to calibrate the temperature-flow signal to the correct phase of breathing, so inspiratory airway airflow can be distinguished reliably from expiratory airway airflow, regardless of the temperature conditions. The information obtained by this sensing configuration can be used to derive or estimate breathing volumes and breath effort, as well as determining the breath phases. Alternatively, the configuration can be used to determine lung compliance, airway resistance and an estimate of work of breathing, using pressure and flow, by establishing a correlation between airway pressure and pleural pressure, and a correlation between the flow signal and total flow. A flow signal, Q , multiplied by a correction factor or used in a differential equation governing the relationship between tracheal flow and other prevailing conditions, may provide a real time continuous estimate of total airway air flow rate, referred to as Q' . Compliance can be determined by the integral of Q' divided by pressure measured by P1. Airway resistance can be determined by dividing the product of pressure of P1 and time by the integral of Q' . WOB can be estimated by multiplying the product of the integral of Q' and pressure of P1 by a correction factor correlating P1 with pleural pressure. While in Figure 16 the sensor is described as being inside an airway, the invention includes other placements of the sensors, for example, the pressure sensing port can be placed inside an airway, such as the tracheal, oral or nasal airway, while the thermal sensor can be placed in the proximity of the entrance to the airway, such as the tracheotomy or tracheostomy, oral or nasal airway. The thermal sensor proximity to the airway entrance can be slightly inside the opening to the airway, or directly at the entrance to the airway, or outside the entrance to the airway in the path of inspired and exhaled airflow.

Figure 17 describes an embodiment of the invention in which a ventilation tube includes two sensing lumens, 208 and 208', which terminate along the inserted section of the ventilation tube 25 at different locations separated by a distance, at sensing ports Pp and Pd. The ventilation tube 25 can be inserted directly into the airway, or can be inserted into the lumen of an outer tube as described previously. A slightly different pressure signal may be applied to the two ports, labeled Pp and Pd in Figure 18, during inspiratory flow and during expiratory flow. Therefore, a pressure differential, for example ΔP during inspiration, can be measured. The measured ΔP can be used in a flow rate equation to compute flow rate, while making the appropriate assumptions regarding the effective radius of the cross-sectional area of the trachea, the viscosity or density of the air in the trachea, and conditions from other effects such as drag. With this sensing configuration, both the tracheal pressure and tracheal airflow can be measured, monitored and used for display and ventilator control purposes. The flow information, and combination of flow and pressure information can be used as previously described. Figure 17a describes an alternative configuration to Figure 17 wherein the pressure ports are located on opposite aspects of the ventilation tube, an inferior surface for Pd and a superior surface for Pp.

Figure 19 describes an alternate configuration in which the ventilation tube 25 is angulated, for example, approximating a right angle, and where the pressure sensing lumen pressure ports Pp and Pd are located on the distal straight section of the tube. This configuration creates spacing between the pressure ports that is parallel with the lumen of the trachea, aligning the pressure ports with the tracheal axis. Figure 19a describes an alternative embodiment to the configuration in Figure 19 in which the pressure ports Pp and Pd are on the proximal straight section of the ventilation tube, on the inferior and superior aspects.

Figure 20 describes another main embodiment of the present invention in which the sensor S1 is flushed with flow exiting a flush port 220. Figure 20a describes detail J of Figure 20, illustrating a dedicated flush lumen 224, the flush port 220, and the sensor S1 of the ventilation tube 25. Figure 21 describes an alternative embodiment to Figure 20a wherein the flush lumen 224 branches off of the main gas delivery lumen 210. Figure 22a describes an alternative embodiment in which the sensor S1 and the flush port 220 are located on the inferior/anterior side of the ventilation tube 25 as opposed to the superior/posterior side as previously illustrated. In addition, the sensor and flush port can be located on the lateral side, on the superior side, or on the inferior side of the ventilation tube (not shown). Figure 22b describes an alternate configuration in which the flush port 220 flushes in the reverse direction back at the sensor S1. Figures 23a-c describe alternate pressure or flow delivery profiles of the flushing media being delivered, for example continuous shown in Figure 23a, intermittent shown in Figure 23c or as needed when the sensor signal appears degraded shown in Figure 23b. The flushing media can also be delivered in a pulsatile waveform, or in any combination of the above. The flush media can be a respiratory gas such as oxygen, a therapeutic gas such as helium, humidified air, or a liquid such as saline or a medicant.

In Figures 24 and 26 another embodiment of the invention is described in which sensing elements or sensing ports are placed in a sensor flow conduit 206 in the tracheal airway TA. Inspiratory and expiratory flow may pass through the conduit 206. The conduit 206 may be positioned on the ventilation catheter such that the proximal and distal openings of the conduit 206 are in line with the axis of the tracheal airflow. The sensor signal can be correlated to airflow rate, based on for example known correlation factors and look up tables. For example, the sensors can be thermal sensors, and the slope of the sensor signal divided by the cross sectional area of the conduit may give a value in units of $[(\text{volts} * [\text{cross sectional area}]^2) / \text{time}]$, which can be correlated to liters per minute based on a correlation factor of volts to distance. The resultant value

is the flow rate $Q(c)$ through the conduit. $Q(c)$ can then be correlated to the flow rate in the trachea by a correlation factor correlating the conduit size with the tracheal lumen size. This sensor is useful in deriving the patient's spontaneous inspiratory and expiratory flow rates and breathing volumes as well as pressure.

Alternatively, two pressure sensors or pressure sensing ports can be included in the flow conduit, P1 and P2, and optionally as illustrated in Figure 24a can be separated by a flow conduit screen 232 and positioned a distance apart to measure dynamic pressure drop across that distance and using Poiseuille's Law. The pressure drop can be converted to flow rate, which can be integrated to obtain breathing volumes. Inspiratory flow 200 and expiratory flow (not shown) flows through the conduit and pressure is registered by the pressure taps P1 and P2. Tracheal pressure is also determined. Optionally a flush lumen and flush port (not shown) can be routed into the conduit 206 through a gas delivery tube and/or the ventilation tube 25 in order to maintain a patent flow conduit and screen, or optionally, flushing fluid can be delivered into the flow conduit through the pressure sensing lumens 208 leading to the pressure ports P1 and P2. Alternatively, the sensing flow conduit can be recessed on the outside wall of the ventilation tube, or flush with the outer profile of the ventilation tube, so that the outer surface of the tube does not protrude. Or alternatively, the sensing lumen can be within the ventilation tube, on the inside wall, or the sensing conduit can be the ventilation tube itself, with a proximal and distal entrance and exit port positioned in the airway. Or, alternatively, if the ventilation tube is used inside of an outer tube, as described previously, the sensing conduit can be part of the outer tube similar to the options described when associated with the ventilation catheter, or the conduit can be in the annular space between the outer tube and ventilation tube. As illustrated in Figure 26a, the slope of the flow signal generated by the two sensors in the sensing conduit, can be divided by the trachea cross sectional

area, and multiplied by a correction factor X to determine the total flow rate of the patient, from which effort, volume, and other breathing parameters can be derived.

Figure 25 describes another embodiment of the invention in which a ventilation system includes a ventilator V, a gas delivery circuit 24 with a ventilator gas flow lumen 210, and a ventilation tube 25 placed in the patient's airway TA. A flow sensing lumen 208 is provided from the ventilator V to the patient's airway TA. The sensing lumen 208 can be open to atmosphere ATM at the proximal or machine end of the system so that when the patient breathes, a small portion of the inspiratory and expiratory flow moves through the sensing lumen 208. Pressure taps 219 and 221 are provided to measure pressure at different points of the sensing lumen 208 and registered on pressure sensors P1 and P2, respectively. In this manner tracheal pressure can be measured using pressure tap 219, which is proximal to the patient's airway, and a breathing flow rate can be derived by measuring the flow rate through the sensing lumen 208 calculating flow rate from the pressure drop across the pressure signals P2 and P1 shown graphically in Figure 25b. The sensing lumen flow rate can be used to determine the relative strength or amplitude of tracheal airflow. Figure 25a describes a cross sectional schematic of the system in Figure 25. A ventilator gas delivery pump may be a compressor or accumulator. Optionally a flush media can be delivered to the sensing lumen flush lumen 224 to keep it free from obstructions as previously described.

Figures 27-32 describe an embodiment of the present invention in which a breath sensing transducer element is integrated into the patient interface, for example the ventilation tube 25 or the distal end of the ventilation gas delivery circuit 24 close to the patient, or the outer tube if used, such as a tracheostomy tube, a tracheostomy tube outer cannula, or a stoma sleeve or spacer.

Figure 27 describes an embodiment of the invention in which a ventilation catheter 25 includes a micro pressure transducer 222 mounted on or near the stomal flange or catheter flange

115. The system may include a pressure sensing extension tube 218 extending from the flange 115 transtracheally into the airway of the patient and with a sensing port 216 on or near a distal end of the extension tube 218. This configuration may allow for a more sensitive and responsive measurement of tracheal breathing pressures compared to a conventional ventilator pressure-based breath sensor because of the transducer's proximity to the patient's airway. Also, during mechanical breaths delivered by the ventilator, the pressure measured by the transducer may be closer to lung or airway pressure rather than ventilator output pressure, again due to the proximity of the transducer to the patient. A wire may transmit the signal from the transducer back to the ventilator.

Optionally, the signal can be transmitted wirelessly by a transmitter positioned somewhere near the flange or incorporated in the flange. For example, the transmitter can be placed in a neck band that is used to secure the flange and tube in place. This arrangement provides a minimum response time signal of tracheal pressure because the transducer is placed as proximal as possible to the airway without actually being placed in the airway. Placement of the transducer close to but not inside the airway may avoid at least some reliability and maintenance problems compared to configurations where the transducer is placed in the airway. Figure 27a describes a cross section of an optional feature in which a flush lumen 224 is included in the gas delivery circuit 24. A flow rate of fluid is delivered from the ventilator through the flush lumen 224 to the extension tube sensing lumen 208 to keep the sensing lumen 208 free from obstructions or restrictions. The fluid can be a gas or a liquid as previously described. Figure 27b describes a cross section of Figure 27a showing in more detail the pressure transducer 222 sensing surface communicating with the sensing lumen 208, and the flush lumen connected 224 connected to the sensing lumen 208. While a pressure transducer is used in this example, other types of breath sensors can be used in the same arrangement, such as thermal sensors, for example, thermistors, strain gauge sensors, piezoelectric sensors, optical sensors, gas composition sensors or ultrasonic sensors.

Figure 28 describes an embodiment of the invention in which a removably coupled two piece system is used, including an external reusable gas delivery section 24 and an internal disposable ventilation catheter section 25. The ventilation gas delivery channels 210 are interconnected with a pneumatic connector 230, shown in Figure 28a. In addition to the advantages served by a removably coupled two piece system as described in Figure 12, a two piece system may provide a cost advantage by including a relatively expensive transducer on the reusable external portion and not the disposable internal portion. As shown in the cross sectional schematic view in Figure 28a, the reusable section may contain a micro pressure transducer 222 in the connector 110 or flange. When connected to the internal section connector 111, the pressure transducer pneumatic connector 226 may connect to a receptacle 228 to pneumatically communicate with a sensing lumen 208 in the inserted section. A flush lumen 224 can be provided in the external section, connected to a flush source in or near the ventilator V. The flush lumen 224 may connect with the sensing lumen 208 with a flush lumen connector 227 when the external and internal sections are joined. Figure 28b describes an alternate configuration in which the sensing lumen 208 may be flushed with a flush lumen 224 branching off of the main gas delivery lumen 210, at one or multiple locations. While a pressure transducer is illustrated in this embodiment, the sensor can be of other sensing types as previously explained. The ventilation tube can be placed directly through a stoma into the airway of the patient, or in to an outer tube, as previously explained.

Figure 29 describes an embodiment of the invention with a ventilation tube 25 inserted into an outer sleeve such as a tracheostomy tube 28. The ventilation tube 25 may include a micro pressure transducer integrated with the tube connector 110, and communicates with the ventilator V with a wire 92, or wirelessly as previously described. The transducer communicates through a connecting port 216 with a sensing lumen 208 of the ventilation tube 25. The ventilation tube sensing lumen 208 terminates at or near the tip of the ventilation tube 25, and may be recessed

inside the tracheostomy tube 28, or may extend beyond the tracheostomy tube 28. The ventilation tube 25 can extend beyond the tracheostomy tube 28 as shown, or be recessed inside the tracheostomy tube 28, such as near the midpoint of the tracheostomy tube 28, or near the proximal end of the tracheostomy tube 28. Optionally, the sensing lumen 208 can terminate at the transducer, or can extend to the machine end of the system to be attached to a flushing source.

Figure 30 describes an embodiment in which the sensing lumen 208 is part of a sensing tube 218 that extends for a short distance from the flange/connector 110. Figure 30a describes a cross section of an optional embodiment of Figure 30 in which a flush port 224 extends to the ventilator so that the sensing lumen 208 can be flushed to remain patent. The distal tip of the ventilation tube of Figures 30 and 30a can extend beyond the tracheostomy tube, can be flush with the tip of the tracheostomy tube, can be recessed inside the tracheostomy tube, or can be at the proximal end of the tracheostomy tube as previously described.

Figure 31 describes an embodiment in which the ventilation tube 25 is inserted into a stomal sleeve or guide or stent 29 and includes a sensing tube 218 with a sensing lumen 208. In the various examples, optionally, the transducer 222 can be integrated into or attached to the tracheostomy tube, stomal sleeve or guide or stent, with a sensing lumen extending from the transducer into the airway. The sensing lumen can be a separate tube, can be inside of or outside of, or can be part of the tracheostomy tube, stomal sleeve or guide or stent. The ventilation tube can electrically attach to the transducer and optionally pneumatically connect with the sensing lumen to provide a flow for flushing to maintain its patency as previously described.

Figure 32 describes an optional configuration in which a reusable pressure transducer 222 can be connected to the connector 110 of the gas delivery circuit 24 and connected to the sensing lumen connector 228 on the ventilation tube connector/flange 115. Thus, the pressure transducer

assembly can be reusable while the remaining sections can be disposable. Optionally (not shown), the gas delivery circuit 24 and ventilation tube 25 can be a one piece assembly rather than two assemblies, and the pressure transducer assembly can attach to the one piece circuit and ventilation tube assembly. While the sensor illustrated in these examples is a pressure sensor, other sensors can be used as previously described.

Multiple options for configuring the micro pressure transducer 222, the gas delivery circuit 24 connection to the ventilation tube 25, and/or tracheostomy tube 28 can be employed. For example, the transducer 222 can be part of the gas delivery circuit, the ventilation tube 25, or the tracheostomy tube 28. Alternatively, the transducer 222 can be permanently attached, or removably attached. The gas delivery circuit 24 can be removably attached to the ventilation tube 25 or the tracheostomy tube 28. The sensing lumen 208 can be part of the ventilation tube 25 and/or tracheostomy tube 28, and can be a lumen in the construction of the tube(s) terminating at the tip of the tube, or terminating at a distance from the tip of the tube. Alternatively, the sensing lumen 208 can be a separate tube on the inside or outside of the ventilation tube 25 or tracheostomy tube 28. As previously mentioned the tracheostomy tube 28 can be a stoma sleeve or stent. The flush lumen can be a dedicated lumen from the gas delivery circuit 24 or can branch off of the gas delivery lumen at any location. The transducer can be integrated into a flange or a connector, or placed near the flange or connector for example in or on a neck collar. The transducer signal can be transmitted from the transducer to the ventilator control system with wires or wirelessly as well, for example by placing a transmitter in the neck band of the patient, or in a module that can be placed inside the persons shirt for example.

Figures 33 to 38 describe an embodiment of the invention in which other types of breath sensing transducers and sensing elements are used. The types of transducers and elements are used in arrangements that improve reliability, response time and accuracy.

Figure 33 describes another embodiment of the present invention in which a fiber optic pressure sensor 240 may be placed on the ventilation tube 25, and the signal may be transmitted to the ventilator V through wires or fiber optic fibers 242. Figure 33a describes an optional configuration in which the fiber optic sensor 240 is located on the outside surface of the ventilation tube 25, and optionally is recessed from the tip of the ventilation tube. Figure 33b describes an alternative configuration in which the fiber optic sensor 240 is located on the inside of the ventilation tube 25 recessed from the tip.

Figure 34 describes an optional embodiment in which the ventilation tube includes a fluid filled sensing lumen 244, and a micro pressure transducer 222 in or near the connector 110 or flange 115 of the gas delivery circuit 24. The micro pressure transducer 222 may sense pressure in the sensing lumen 244 and transmits the signal to the ventilator V.

Figure 35 describes an optional embodiment in which the fluid filled sensing lumen 244 extends for a longer distance toward the ventilator V, or the entire distance to the ventilator V. Figure 35a describes an optional embodiment in which the sensing lumen 244 terminates at a point recessed from the tip of the ventilation tube 25.

Figures 36-38 describe another embodiment of the present invention in which strain gauge sensors 270 are used to sense tracheal airflow and tracheal pressure. The resistance or voltage signal of the strain gauge element may be measured to determine the deflection level of the element. The elements are preferably placed in a recessed area of the ventilation tube 25 so that the elements are

protected from resting against the tracheal wall. Figure 36a describes the strain gauge element being protected by a shield 136 by being recessed. Either two elements can be used, and placed in a circuit configuration such as a wheatstone bridge to compensate for drift and artifacts, or a single element can be used. Figures 36b-f describe alternate ventilation tube positions for placing the strain gauge elements 270, including on the inferior/anterior aspect of the ventilation tube 25 (as shown in Fig. 36b), on the sides of the ventilation tube 25 (as shown in Fig. 36c), multiple locations around the tube 25 (as shown in Fig. 36d and Fig. 36e), and inside the ventilation tube 25 in a sensing lumen 208 (as shown in Fig. 36f).

Figure 37 describes the resultant signal from the strain gauge 270. Figs. 37a, 37b, 37c and 37d show corresponding deflection of the strain gauge 270 for different portions of the breathing curve represented by t1, t2, t3 and t4, respectively.

Figures 38a-c illustrate different locations for the strain gauge 270 throughout the ventilation gas delivery system, in which case the strain gauge 270 may be used to measure spontaneous breathing effort by the patient but also the ventilation gas delivery flow or pressure. In Figure 38a, the strain gauge 270 is located in a tracheostomy tube connector 110. In Figure 38b, the strain gauge 270 is located in the ventilation gas delivery circuit. In Figure 38c, the strain gauge 270 is located in the ventilator V.

The embodiments described above are exemplary and certain features can be combined in all reasonable combinations. The sensors or sensing ports can be disposed on the ventilation catheter or ventilation tube or on an outer sleeve, and can be placed on the anterior, posterior, inferior, superior or lateral sides, or combinations thereof. The ventilation catheter or tube can be inserted directly into a stoma, or into a tracheal sleeve, such as a tracheostomy tube, stoma guide or stent. The ventilation catheter or tube and the sleeve, if used, can be comprised of a variety of shapes and

curves, and can include protective features to protect the sensors and centering features to center the catheter or tube in the airway. In the case that the ventilation catheter or tube is placed directly in through the stoma, shapes and protective features may be employed to prevent the sensing element from contacting the tracheal wall and signal disruption. In the case that the ventilation catheter or tube is placed into a sleeve such as a tracheostomy tube, the sensors can be inside the tracheostomy tube for protection. Typically the tracheostomy tube is fenestrated so that there is adequate airflow past the sensors during inspiration and exhalation.

In addition, while the embodiments have been described as transtracheal or with a transtracheal ventilation tube or interface, they can also be endotracheal, oral, nasal, or face or nose mask interfaces. For example, the patient interface can be a trans-nasal or trans-oral catheter entering the airway from the nose or mouth. Or, the patient interface can be a open oral or open nasal cannula or catheter, in which the distal end of the cannula or catheter can be adapted to be positioned slightly inside the oral or nasal cavity, or at the entrance to the oral or nasal airway, or outside of the oral or nasal airway directed at the entrance to the airway. Or, the patient interface can be an oral and/or nasal mask. In the case of the more invasive interfaces or catheters, the tip of the catheter can be located in any of the lung airways. In the case of the less invasive interfaces, the tip of the catheter can penetrate the airway barely. In the case of non-invasive interfaces, the tip of the tube, cannula, or mask can be outside of the airway.

The ventilation tube or tracheostomy tube may include an inflatable and deflatable cuff, and the sensors or sensing lumens can be provided on the distal and proximal side of the cuff (not shown) to sense pressures or flows on both sides of the cuff, to provide an indication of the resistance being caused by the cuff. For example if the cuff is not completely deflated, the data from the two sensors or sensing ports may register a higher than expected pressure drop, indicating to the

user that the cuff is not fully deflated for upper airway breathing, or the tube is too big for that particular patient or situation. Optionally the two sensors can be used to monitor cuff inflation if and when closed ventilation is being applied to the patient.

The pressure sensing elements described are typically diaphragm or bellows type elements. The pressure sensing elements, however, can be polymers, or other piezoelectric, optical, ultrasonic elements.

The ventilation therapy described herein can be augmented ventilation in which the patient is receiving a portion of their tidal volume from the ventilator, can be open ventilation in which the patient is spontaneously breathing through their upper airway, or can be closed or partially closed ventilation in which the patient's effort triggers the ventilator. The delivery circuit can be a single limb breathing circuit or dual limb breathing circuit. The invention can be applied to respiratory insufficiencies such as COPD, forms of neuromuscular weakness and paralysis, or airway disorders such as sleep apnea therapy. The therapy can be applied to adults, pediatrics and neonates.

The information made available by the breath sensors described herein can be used to synchronize ventilator functions to the patient's breath cycle, but can also be used to automatically adjust ventilator output and can be used for diagnostic purposes and trending analysis. The ventilator functions being controlled by the sensor information can be (1) delivery timing of gas from the ventilator, for example at a certain point of the inspiratory phase, a certain point of the expiratory phase, etc.; (2) amplitude, speed or waveform shape of ventilator output; or (3) frequency of ventilator output; or (4) composition of ventilator output, or combinations of the above.

Typical dimensions of the embodiments, assuming a transtracheal catheter interface are listed below. Dimensions for other interfaces, such as oral or nasal catheters or cannula may include the requisite dimensional adjustments.

1. Ventilation tube or catheter: 2mm OD to 12mm OD, preferably 3-5mm, 0.5-6mm ID, preferably 1-3mm ID. Insertion length 10mm to 150mm, preferably 30-100mm. Curved such that there is a distal straight section aligned with the lumen of the trachea. Durometer 40-80 Shore D.

2. Single limb ventilation circuit: 4mm OD to 12mm OD, preferably 5-8mm OD, and 24-48 inches in length.

3. Outer Sleeve (tracheostomy tube): 4-10mm ID, preferably 5-8mm ID, with 1-2mm wall thickness.

4. Outer Sleeve (thin wall minimal profile tracheostomy tube): 4-8mm ID, preferably 5.5-6.5mm ID with .75-1.25mm wall thickness. 40mm-120mm length, preferably 60-90mm.

5. Outer Sleeve (stoma guide): 4-10mm ID, preferably 5-8mm ID, with 1-2mm wall thickness. 20-50mm length, preferably 25-35mm length.

6. Gas delivery lumen: 0.5-6mm ID, preferably 1-3mm ID.

7. Sensing lumen: 0.25-3mm ID, preferably .5-1.75mm and most preferably 0.75-1.5mm.

8. Micro Pressure transducer: 1mm – 8mm length and width dimensions, 1-5mm thickness.

9. Fiber optic pressure transducer: 0.5-3mm cross sectional dimension at the sensing element, preferably 1-2mm.
10. Flow conduit: 0.5-2.0mm ID, preferably 1-1.5mm ID.
11. Flush port: 0.25-2mm width or length or diameter.
12. Flush lumen: 0.2mm -1.0mm, preferably 0.25-0.5mm.

List of Reference Symbols:

Atm: atmosphere	92: Breath sensor wiring
B: Baseline	100: Outer cannula fenestration(s)
E: Expiratory	110: Ventilation Catheter to tracheostomy tube connector
I: Inspiratory	111: tracheostomy tube ventilation circuit connector
L: Lung(s)	115: Ventilation catheter flange
P1, P2, P3: pressure transducer 1, 2 and 3	116: Ventilation catheter – outer cannula breathing flow port
Pp: proximal pressure sensor port	118: Ventilation catheter – outer cannula heat moisture exchange
Pd: distal pressure sensor port	120: Ventilation catheter – outer cannula filter
Pt: Patient	122: Inspiratory valve
Pf: Flush pressure level	136: Sensor protective shield
Q: Tracheal airflow trace	200: Inspiratory flow
Q': Estimate of total airway air flow rate	202: Expiratory flow
S1, S2, S3: sensing elements	206: Sensor flow conduit
TA: Tracheal airway	208: Sensing lumen
T, t1, t2, t3: time	208': Sensing lumen
T1: thermal sensing element one	209: Sensing ports
T2: thermal sensing element two	210: Ventilator gas flow lumen
V: Ventilator	214: Sensor physical barrier
V1, V2, V3, V4: valves 1, 2, 3 and 4	216: Pressure sensor sensing port
WOB: Work of breathing	218: Pressure sensing extension tube
WOB': Work of breathing	219: Sensing lumen pressure tap, proximal
X: Constant	220: Sensor flush port
10: Processor	221: Sensing lumen pressure tap, machine end
20: Ventilator control unit	222: Micro transducer
21: Ventilation gas delivery circuit, dual limb	224: Flush lumen
23: Pressure tap	226: Pressure sensing lumen connector, male
24: Ventilation gas delivery circuit, single limb	227: Flush lumen connector
25: Ventilation tube	228: Pressure sensing lumen connector, female
28: tracheostomy tube outer cannula	230: Gas delivery lumen connector
28': Thin wall small diameter tracheostomy tube	232: Flow conduit screen
29: Stoma Sleeve	240: Fiber optic pressure transducer
30: Stoma spacer	242: Fiber optic signal conduction fibers/wires
52: Ventilator gas delivery pressure tracing	244: Fluid filled sensing lumen
58: Patient spontaneous respiration curve	260: Low profile cuff
60: Chest impedance wires	262: Opening
62: Chest impedance band	264: Gas delivery connector
63: Patient inspiratory effort	266: Sensing lumen connector
66: Patient exhalation tracheal flow/pressure curve	270: Strain gauge sensor
77: Chest impedance tracing	

Although the foregoing description is directed to the preferred embodiments of the invention, it is noted that other variations and modifications will be apparent to those skilled in the art, and may be made without departing from the spirit or scope of the invention. Moreover, features described in connection with one embodiment of the invention may be used in conjunction with other embodiments, even if not explicitly stated above.

WHAT IS CLAIMED IS:

1. A ventilation and breath sensing apparatus comprising:
a ventilation gas delivery circuit;
a ventilation tube coupled to the ventilation gas delivery circuit;
a plurality of pressure sensing elements;
wherein the plurality of pressure sensing elements are separated by a distance and produce independent signals to detect pressure differentials between the plurality of pressure sensing elements.
2. The ventilation and breath sensing apparatus of claim 1, wherein the plurality of pressure sensing elements are pressure sensing conduits.
3. The ventilation and breath sensing apparatus of claim 1, wherein the plurality of pressure sensing elements are pressure sensing transducers.
4. The ventilation and breath sensing apparatus of claim 1, wherein the plurality of pressure sensing elements are a combination of pressure sensing conduits and pressure sensing transducers.
5. The ventilation and breath sensing apparatus of claim 1, wherein at least one of the plurality of pressure sensing elements is associated with the ventilation tube.
6. The ventilation and breath sensing apparatus of claim 1, wherein at least one of the plurality of pressure sensing elements is associated with the ventilation gas delivery circuit.
7. The ventilation and breath sensing apparatus of claim 1, wherein at least one of the plurality of pressure sensing elements is associated with a ventilator.

8. The ventilation and breath sensing apparatus of claim 1, wherein at least one of the plurality of pressure sensing elements is a pressure sensing conduit, and the pressure sensing conduit has at least one port.

9. The ventilation and breath sensing apparatus of claim 1, wherein at least one of the plurality of pressure sensing elements is a transtracheal sensing conduit, and wherein at least one of the plurality of pressure sensing elements is coupled to the ventilation gas delivery circuit.

10. The ventilation and breath sensing apparatus of claim 1, wherein two or more of the plurality of pressure sensing elements are at a distal end of the ventilation tube for positioning in a tracheal, nasal or oral airway.

11. The ventilation and breath sensing apparatus of claim 1, wherein the ventilation tube is removably coupled to the ventilation gas delivery circuit.

12. The ventilation and breath sensing apparatus of claim 1, wherein the ventilation gas delivery circuit includes a first pressure sensing element and the ventilation tube includes a second pressure sensing element, and wherein in a coupled arrangement, the first pressure sensing element and the second pressure sensing element are in fluid communication.

13. The ventilation and breath sensing apparatus of claim 1, further comprising a tracheal, nasal or oral airflow conduit coupled to a distal end of the ventilation tube that is for positioning within a tracheal, nasal or oral airway, wherein the plurality of pressure sensing elements are disposed within the tracheal, nasal or oral airflow conduit.

14. The ventilation and breath sensing apparatus of claim 1, further comprising a spontaneous breathing conduit separate from the ventilator gas delivery circuit for extending into a tracheal, nasal or oral airway, wherein the spontaneous breathing conduit comprises a plurality of pressure taps for measuring pressure drop across the plurality of pressure taps.

15. The ventilation and breath sensing apparatus of claim 1, further comprising an outer sleeve, wherein the ventilation tube is disposed in the outer sleeve.

16. The ventilation and breath sensing apparatus of claim 1, wherein the ventilation tube includes a patient interface.

17. The ventilation and breath sensing apparatus of claim 16, wherein at least one of the plurality of breath sensing elements is located in the patient interface.

18. The ventilation and breath sensing apparatus of claim 1, further comprising a physical barrier between at least two of the plurality of pressure sensing elements.

19. The ventilation and breath sensing apparatus of claim 18, wherein the physical barrier creates a pressure drop or biases the response time of each of the at least two of the plurality of pressure sensing elements depending on direction of airflow.

20. The ventilation and breath sensing apparatus of claim 1, further comprising at least one thermal sensor disposed near or in an entrance of an airway, wherein the at least one thermal sensor is used to determine spontaneous breathing airflow, and at least one of the plurality of pressure sensing elements is used to determine breathing pressure, and wherein a combination of the spontaneous breathing airflow and the breathing pressure is used to optimize ventilator synchronization and titration of therapy.

21. A ventilation and breath sensing method comprising:
measuring pressure from a first pressure sensing element;
measuring pressure from a second pressure sensing element, wherein the second pressure sensing element is separated by a distance from the first pressure sensing element, and the first pressure sensing element produces a first signal independent from a second signal from the second pressure sensing element;
determining a pressure differential between the first signal and the second signal;

determining tracheal, nasal or oral pressure using the first signal and the second signal;
determining tracheal, nasal or oral airflow using the tracheal, nasal or oral pressure;
initiating ventilation from a ventilator based upon the determined tracheal, nasal or oral
airflow.

22. The ventilation and breath sensing method of claim 21, wherein the plurality of pressure sensing elements are pressure sensing conduits.

23. The ventilation and breath sensing method of claim 21, wherein the plurality of pressure sensing elements are located within a tracheal, nasal or oral airway.

24. The ventilation and breath sensing method of claim 21, wherein the plurality of pressure sensing elements are located within an interface between the ventilation tube and the ventilation gas delivery circuit.

25. The ventilation and breath sensing method of claim 21, further comprising determining spontaneous breathing airflow from at least one thermal sensor disposed near or in an entrance of an airway, and wherein a combination of the spontaneous breathing airflow and the tracheal, nasal or oral pressure is used to optimize ventilator synchronization and titration of therapy.

26. A ventilation and breath sensing apparatus comprising:
a ventilation gas delivery circuit;
a ventilation tube coupled to the ventilation gas delivery circuit;
wherein the ventilation tube comprises a plurality of breath sensing elements;
wherein the plurality of breath sensing elements include at least one pressure sensing port to measure airway breathing pressure, and at least one thermal sensor to measure airway breathing airflow.

27. The ventilation and breath sensing apparatus of claim 26, further comprising at least two thermal sensors coupled in an array.

28. A ventilation and breath sensing apparatus comprising:

a ventilation interface tube with a gas delivery conduit, at least one breath sensing channel not connected to and parallel to the gas delivery channel, and a first sensor and a second sensor in the at least one breath sensing conduit;

wherein the first sensor produces a first signal;

wherein the second sensor produces a second signal;

wherein the second sensor is at a distance from the first sensor and producing a signal independent from the first signal;

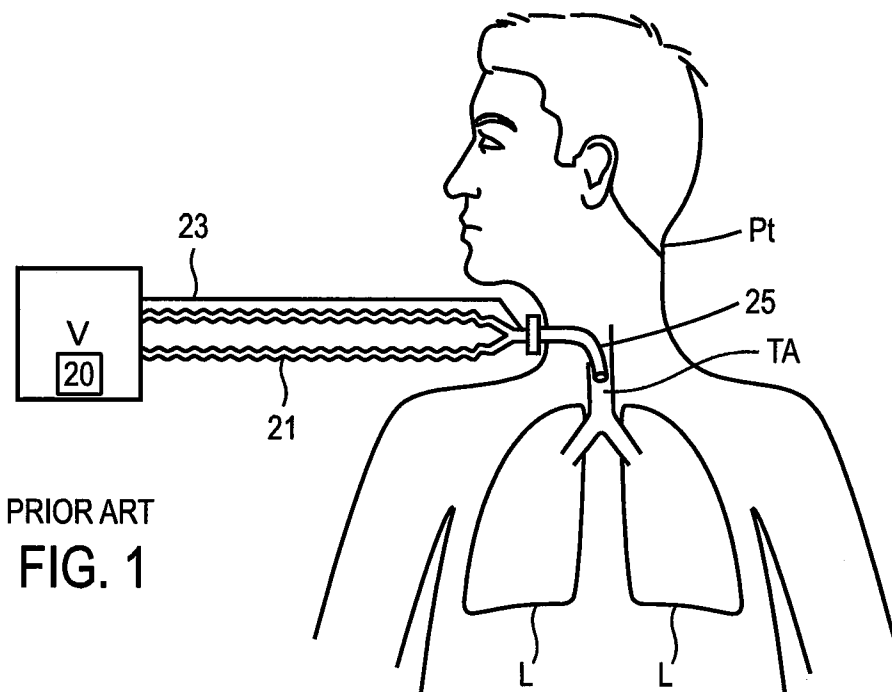
a processor for calculating (1) a pressure differential between the first signal and the second signal, (2) a tracheal, nasal or oral pressure, and (3) a tracheal, nasal or oral air flow; and

wherein the processor initiates ventilation based upon the tracheal, nasal or oral air flow.

29. The ventilation and breath sensing apparatus of claim 28, wherein at least one of the first sensor and the second sensor are pressure sensors.

30. The ventilation and breath sensing apparatus of claim 28, further comprising at least one thermal sensor disposed near or in an entrance of an airway, wherein the at least one thermal sensor is used to determine spontaneous breathing airflow, and wherein a combination of the spontaneous breathing airflow and the tracheal, nasal or oral pressure is used to optimize ventilator synchronization and titration of therapy.

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PRIOR ART
FIG. 1

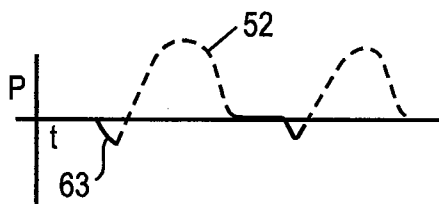
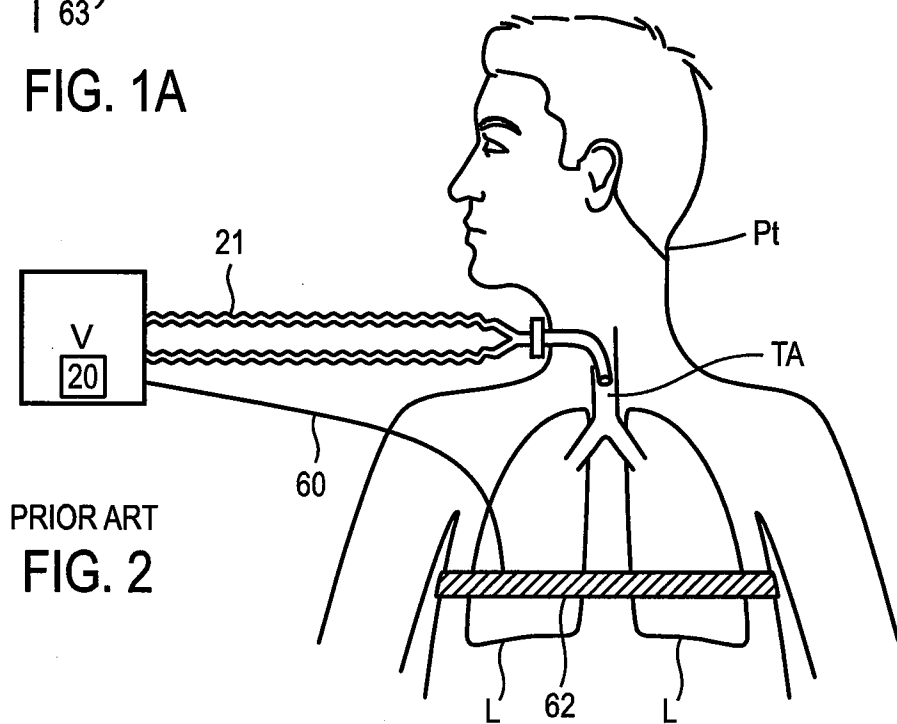


FIG. 1A



PRIOR ART
FIG. 2

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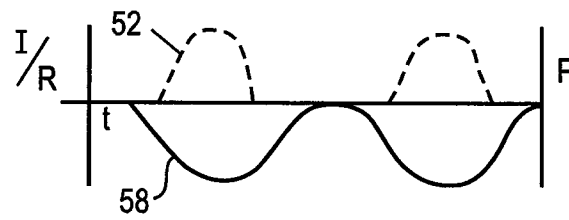


FIG. 2A

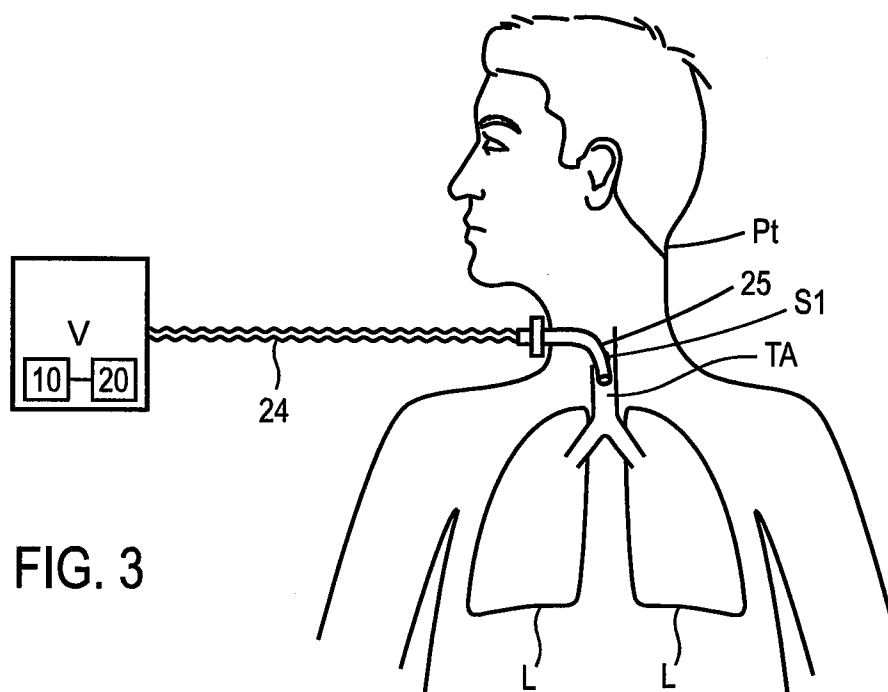


FIG. 3

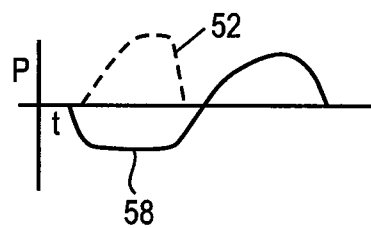


FIG. 3A

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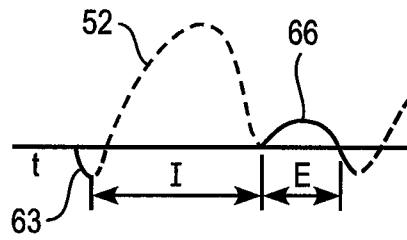


FIG. 4A

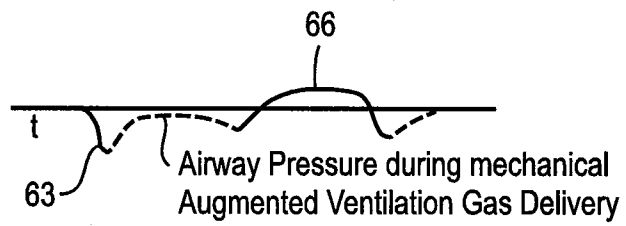


FIG. 4B

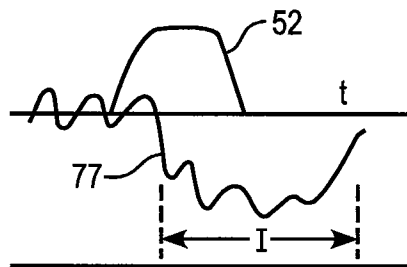
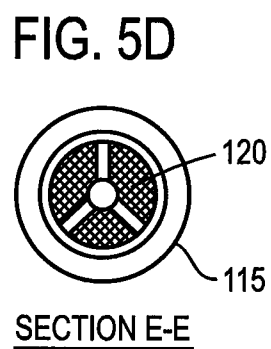
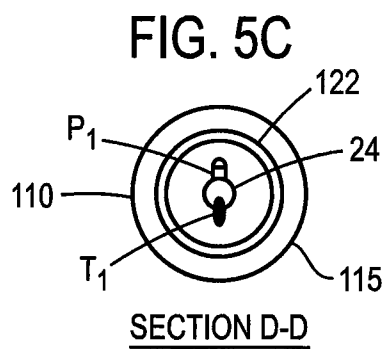
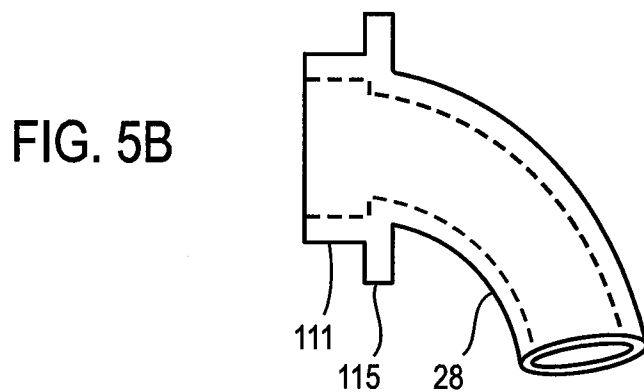
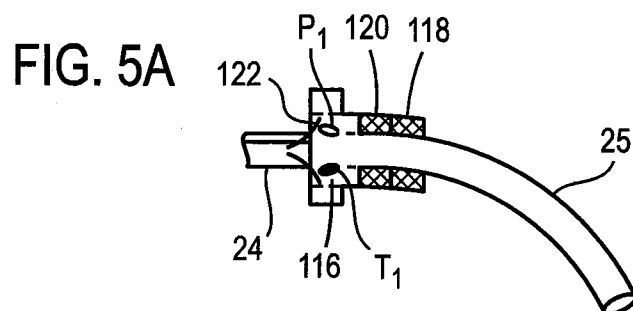
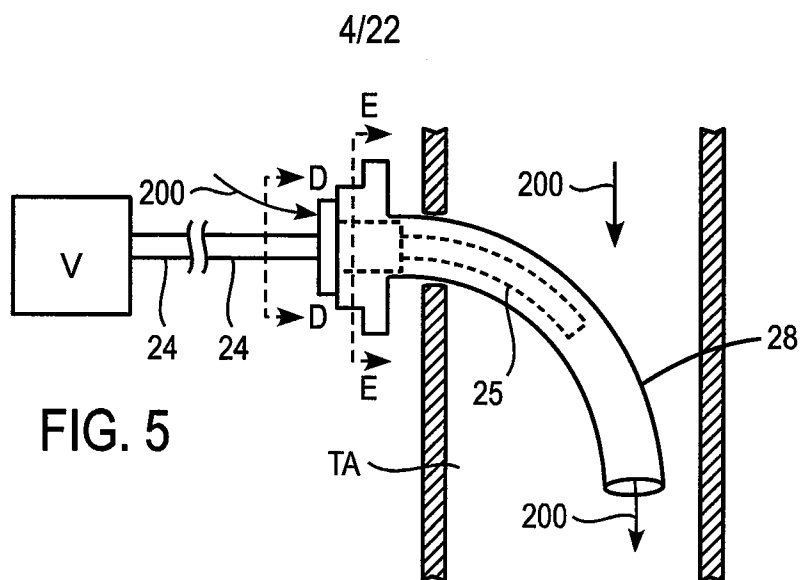


FIG. 4C



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Two Ventilation Tube configurations:
(1) Tube placed into Trach Tube or Airway Guide;
(2) Mini-Catheter placed directly into Mini-Stoma or Stoma Guide,
or oral or nasal airway

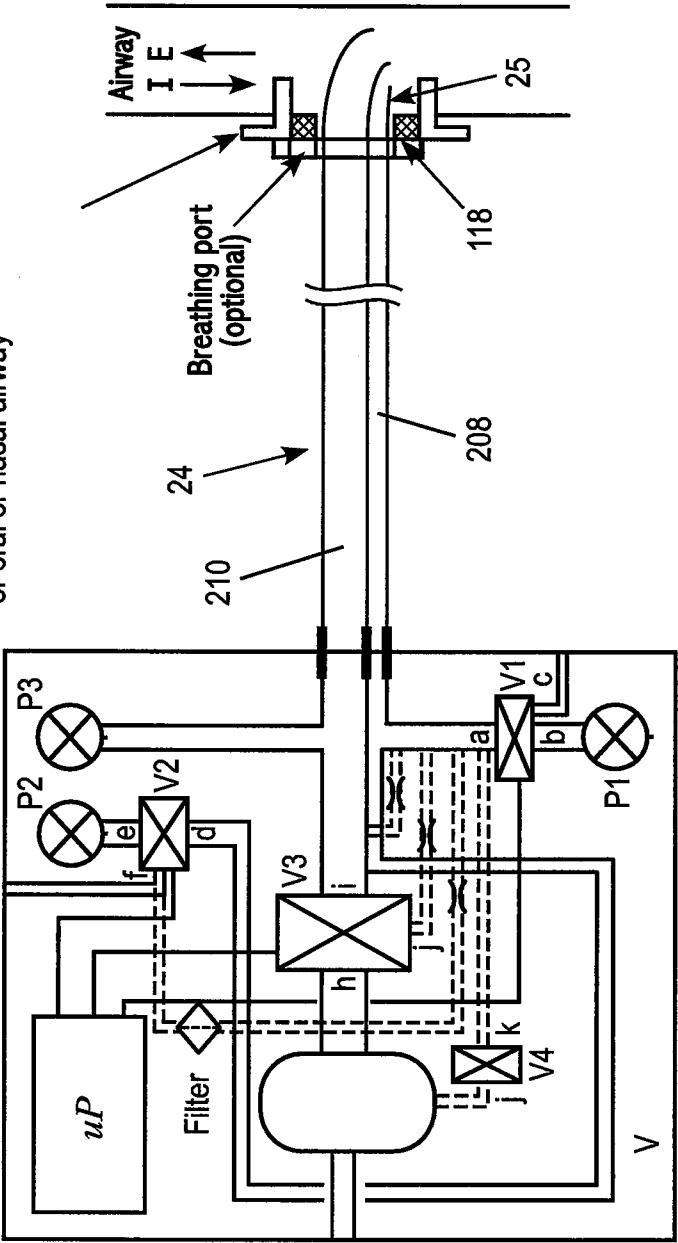


FIG. 6

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FIG. 7

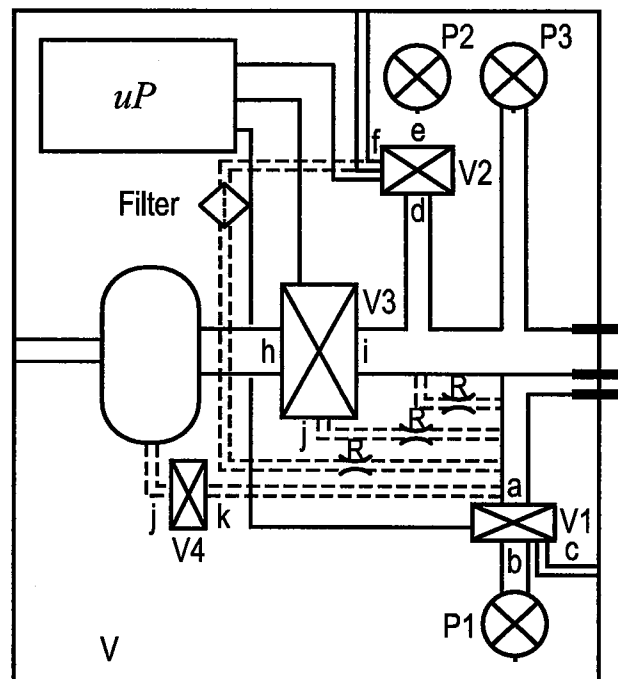
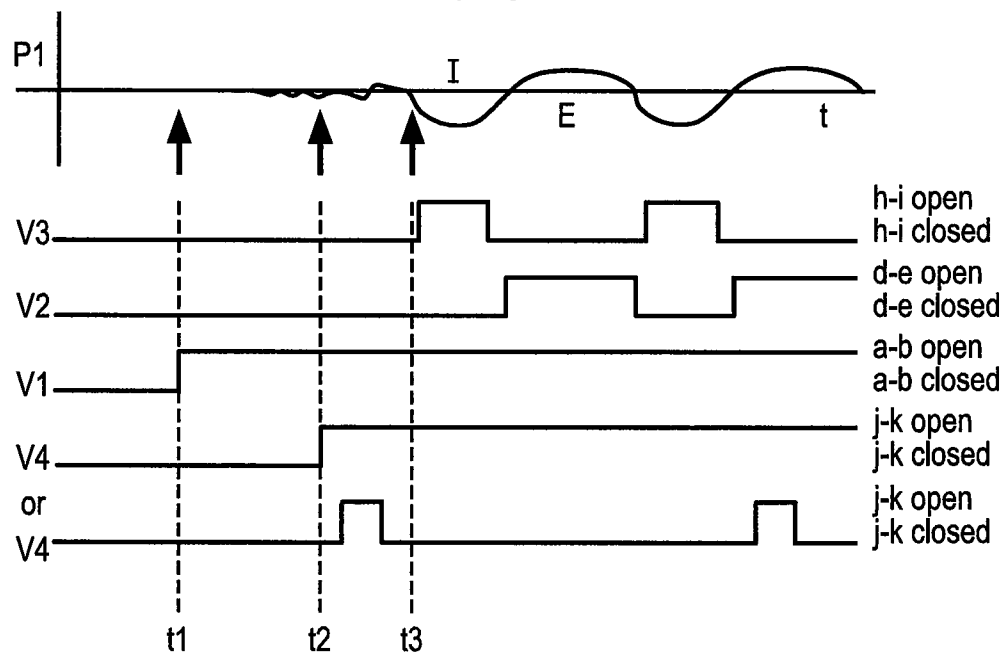
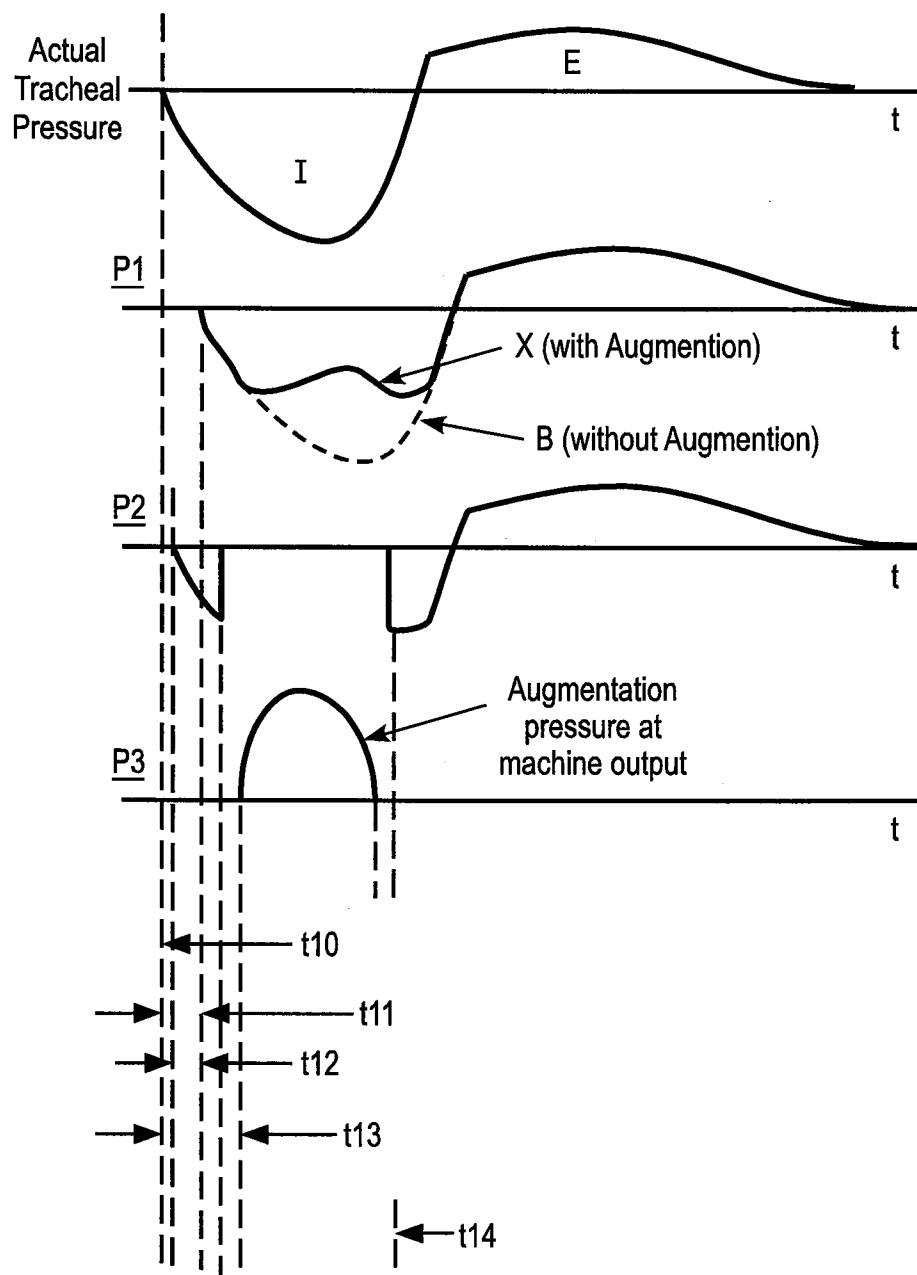


FIG. 8

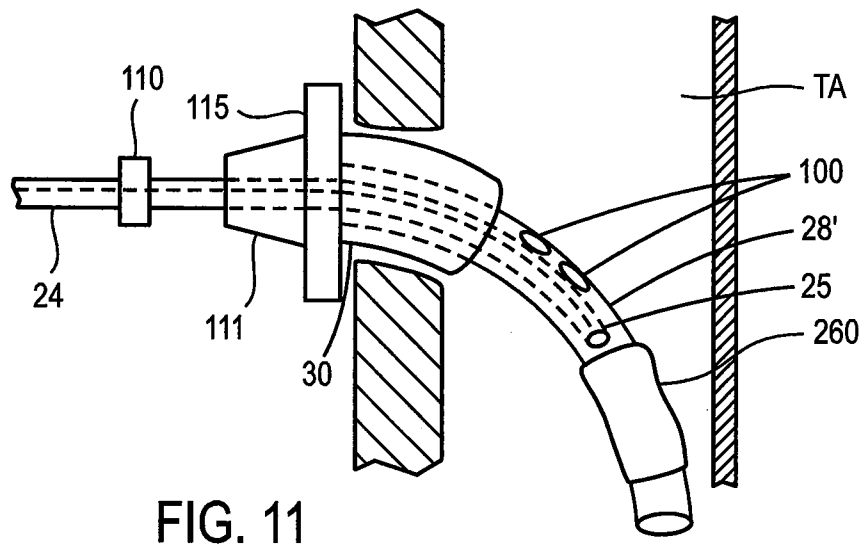
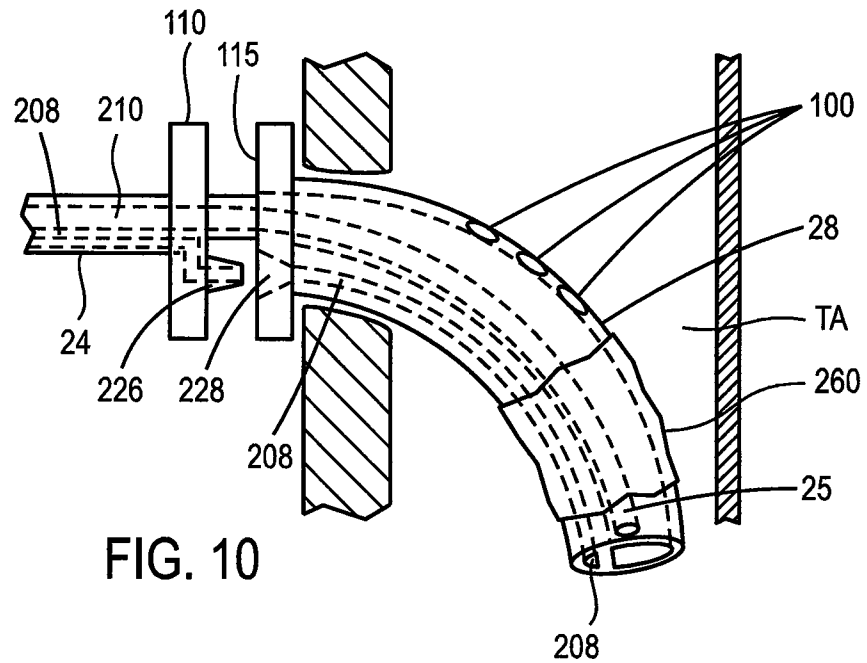


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FIG. 9



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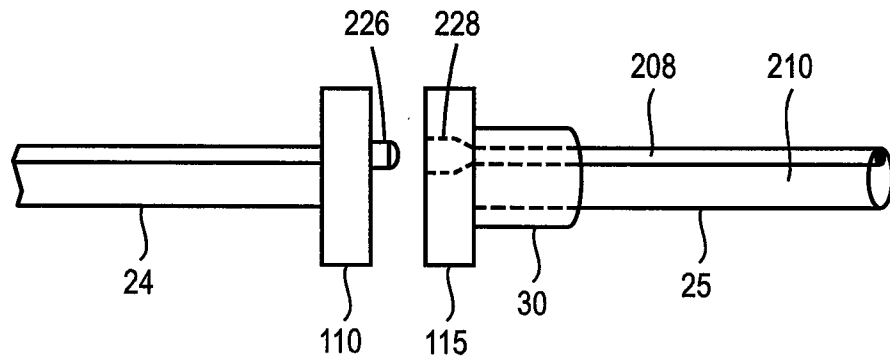


FIG. 12

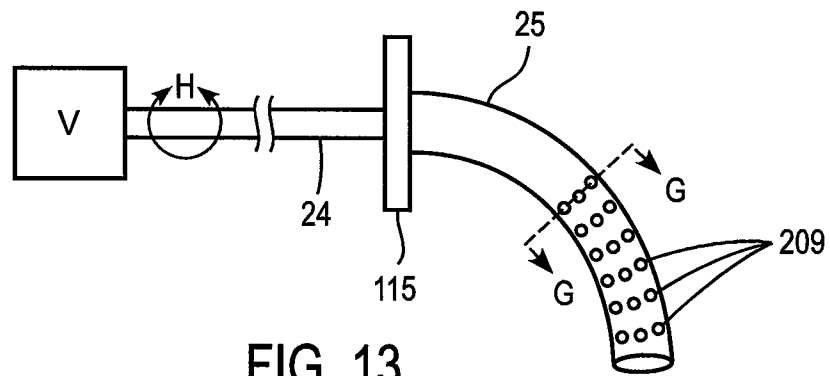


FIG. 13

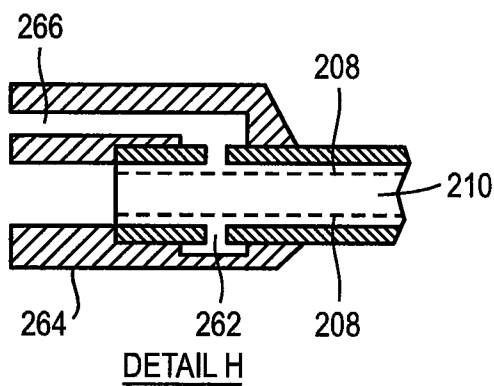


FIG. 13A

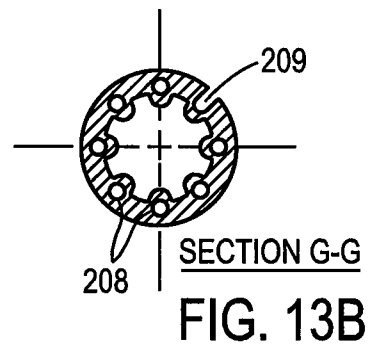


FIG. 13B

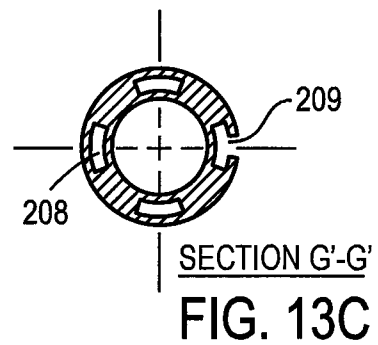


FIG. 13C

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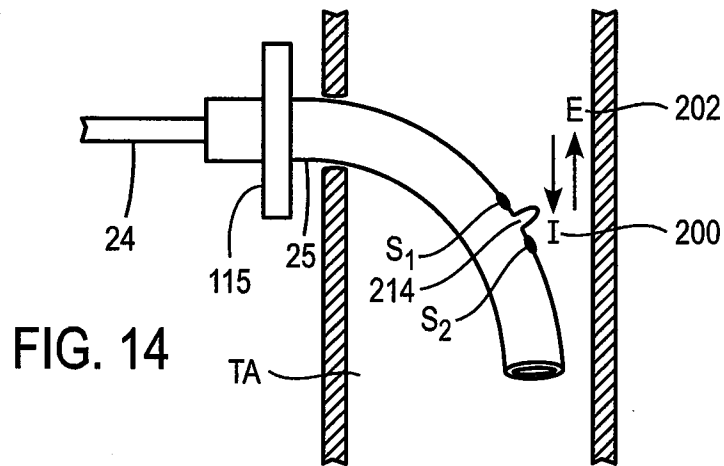


FIG. 14

FIG. 14A

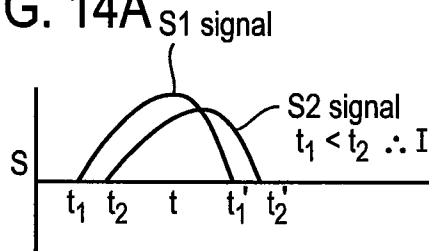


FIG. 14B

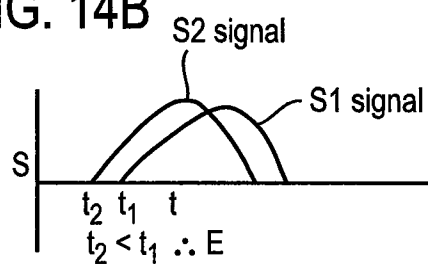


FIG. 15

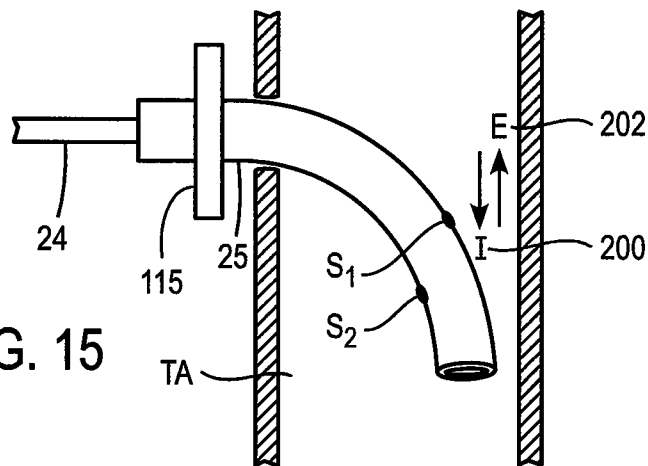


FIG. 15A

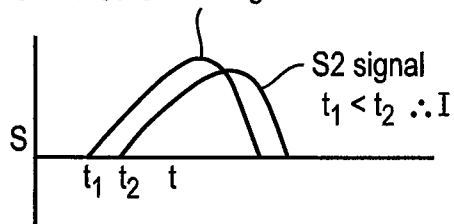
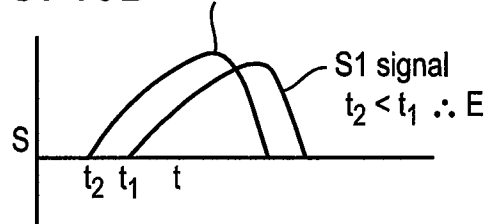


FIG. 15B



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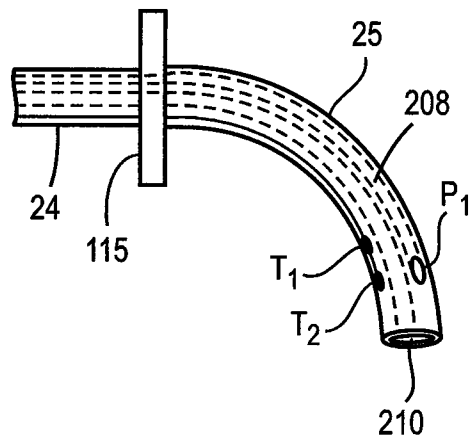


FIG. 16

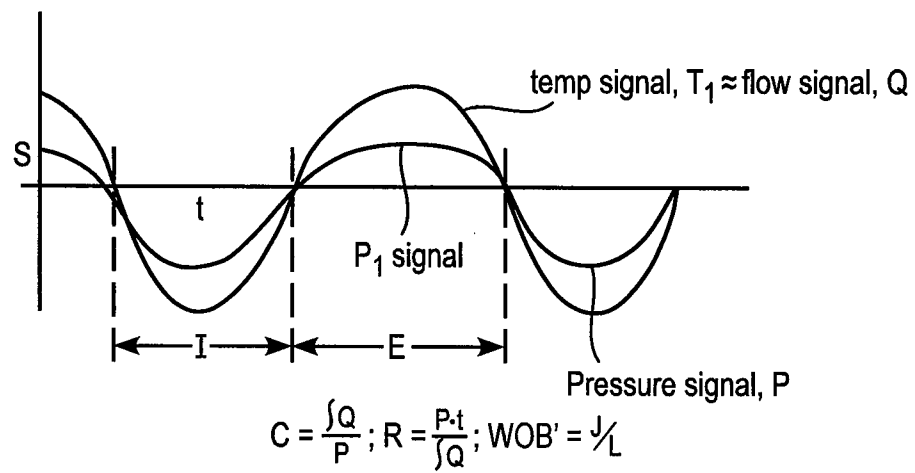


FIG. 16A

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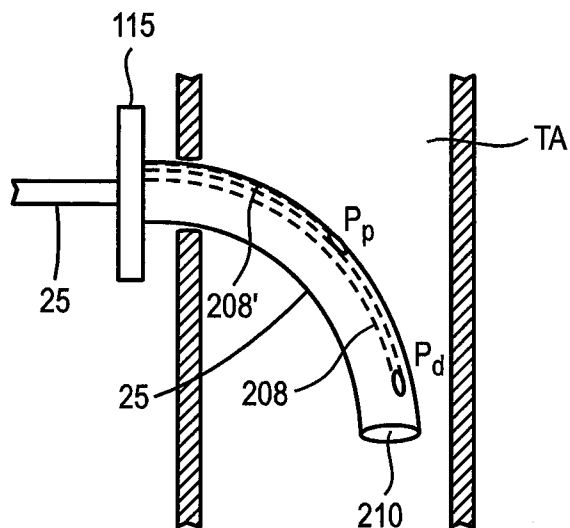


FIG. 17

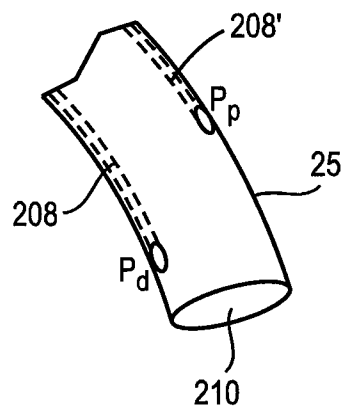


FIG. 17A

FIG. 18

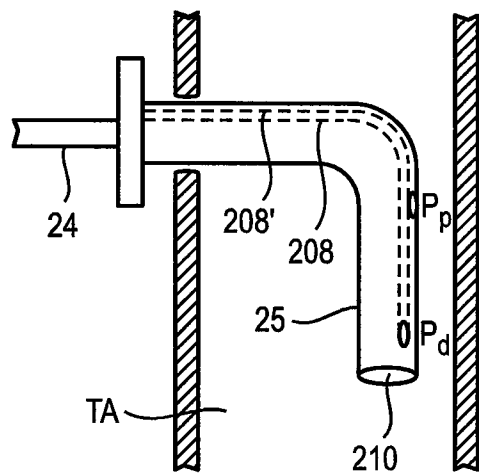
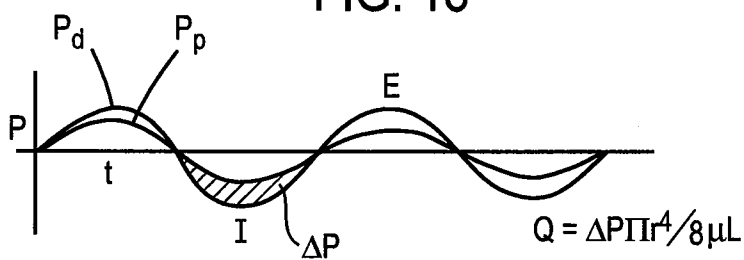


FIG. 19

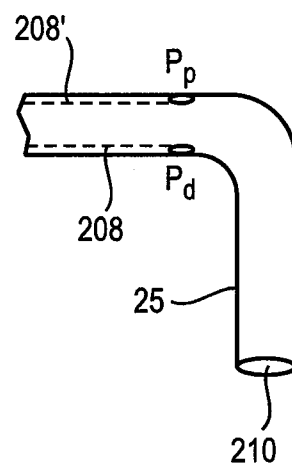


FIG. 19A

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FIG. 20

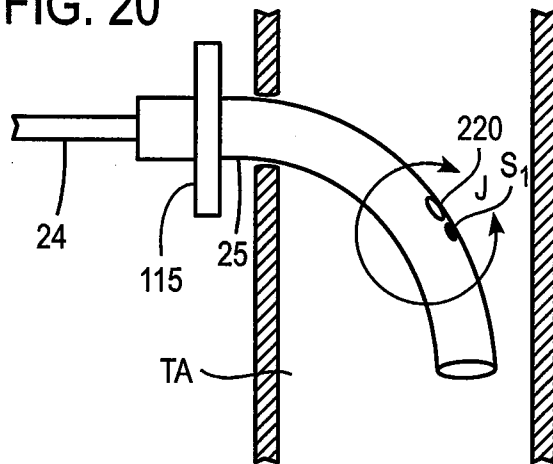


FIG. 20A

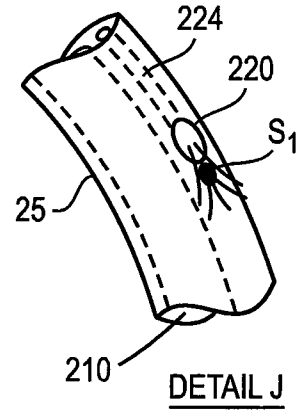


FIG. 21

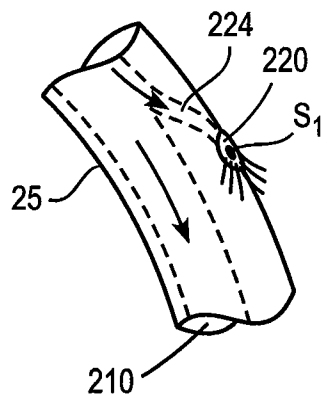


FIG. 22A

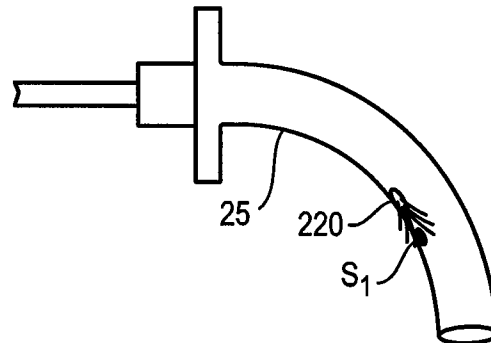
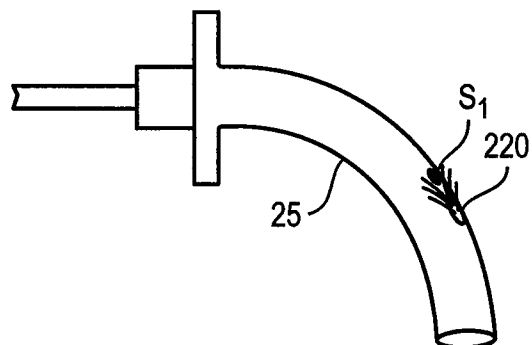


FIG. 22B



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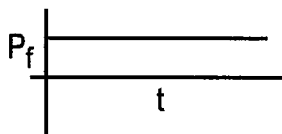


FIG. 23A

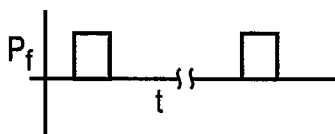


FIG. 23B

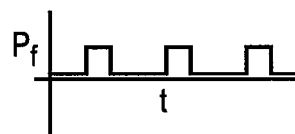


FIG. 23C

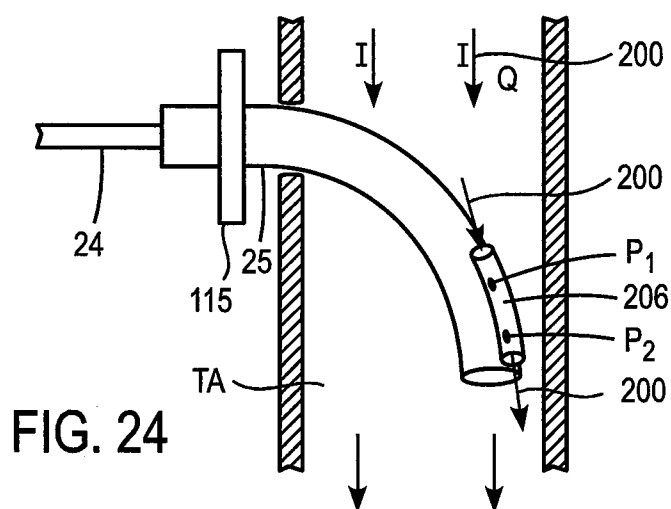


FIG. 24

$$Q = \Delta P \pi r^4 / 8 \mu L$$

$$P_1 - P_2 = \Delta P$$

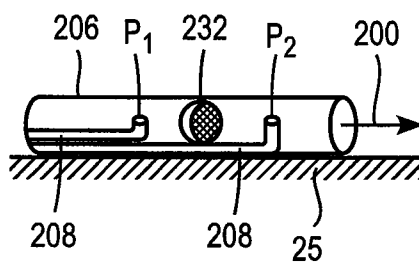


FIG. 24A

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FIG. 26

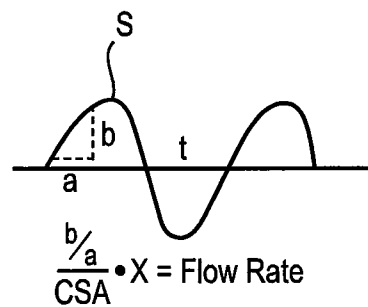
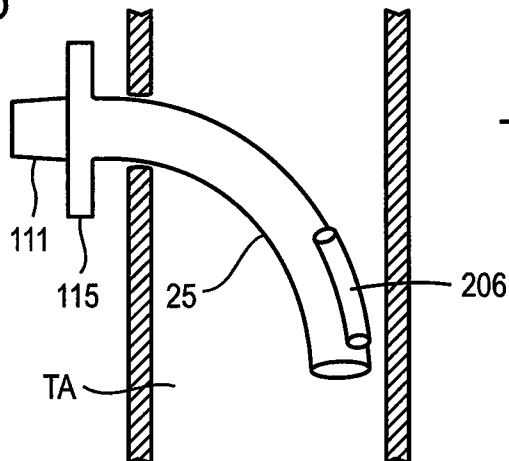


FIG. 26a

FIG. 27

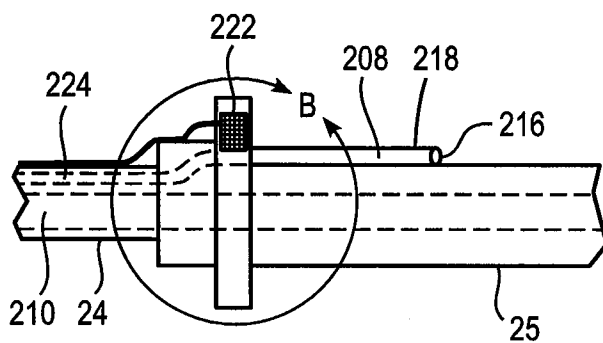
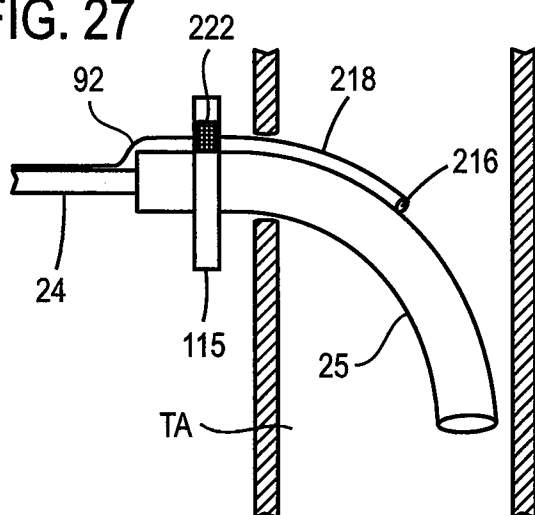


FIG. 27A

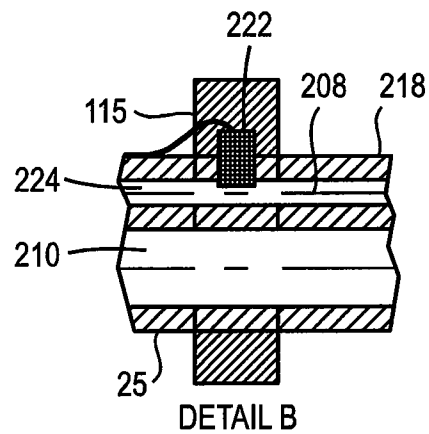


FIG. 27B

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FIG. 28

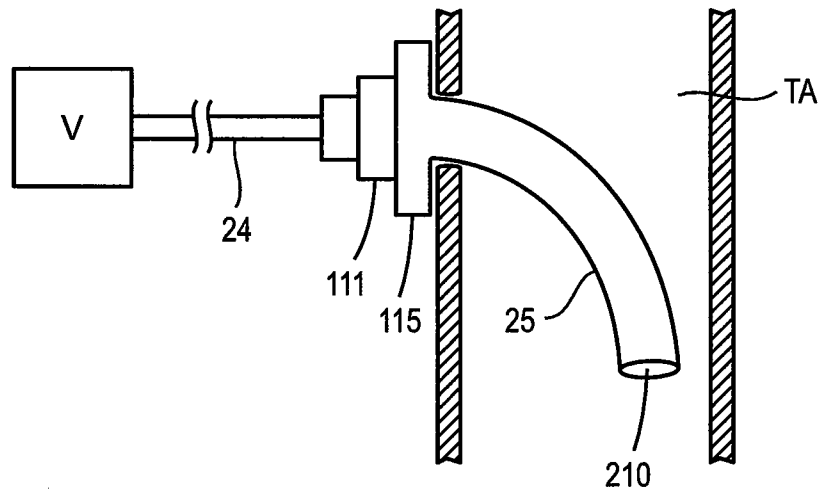


FIG. 28A

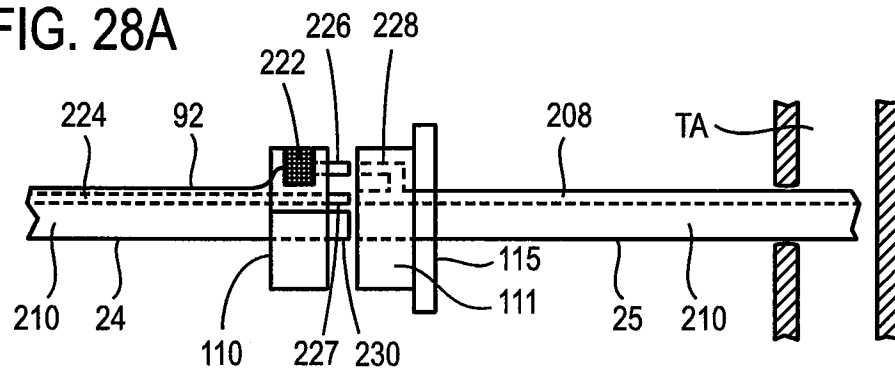
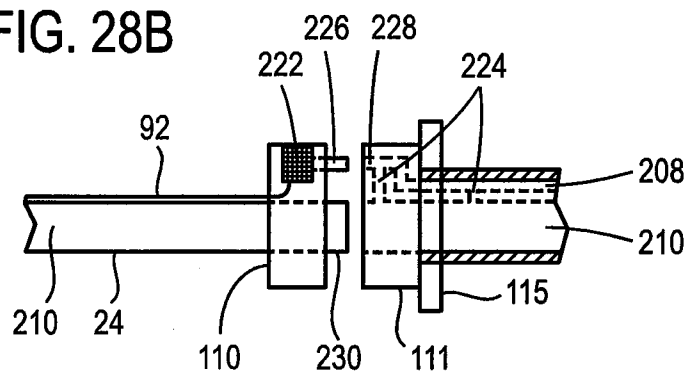


FIG. 28B



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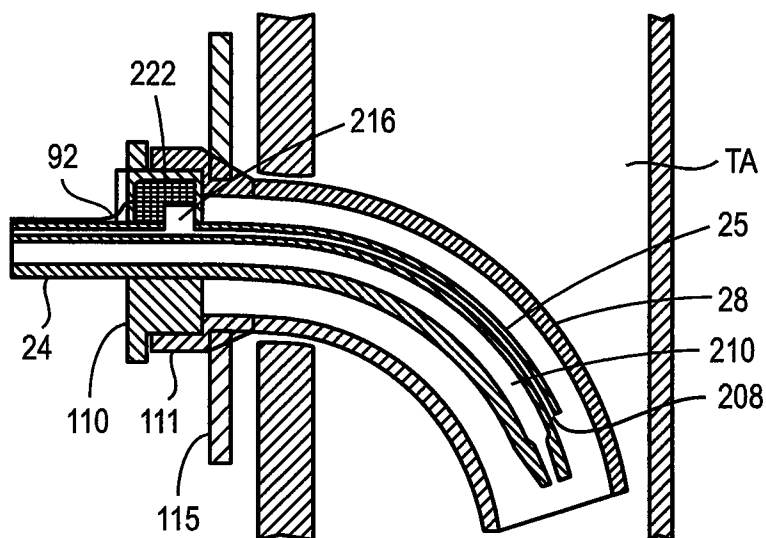


FIG. 29

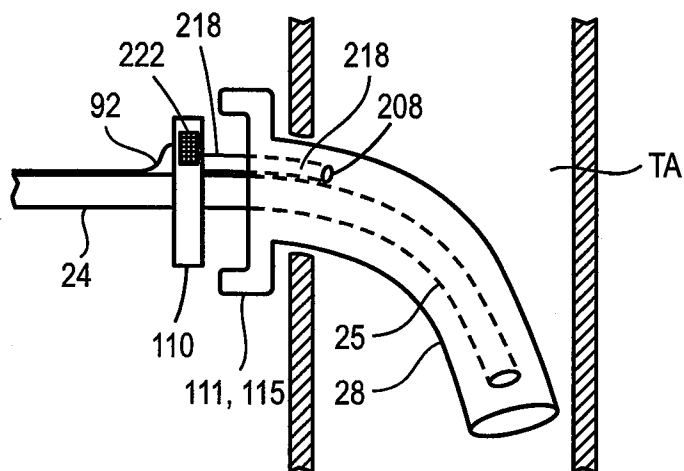


FIG. 30

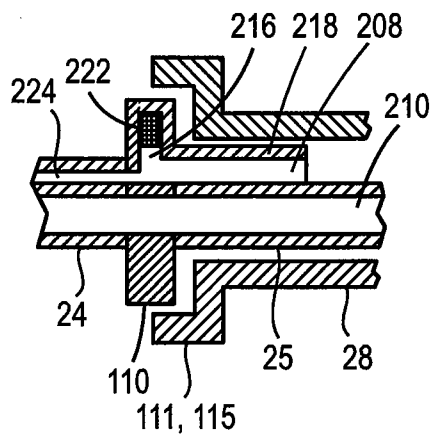


FIG. 30A

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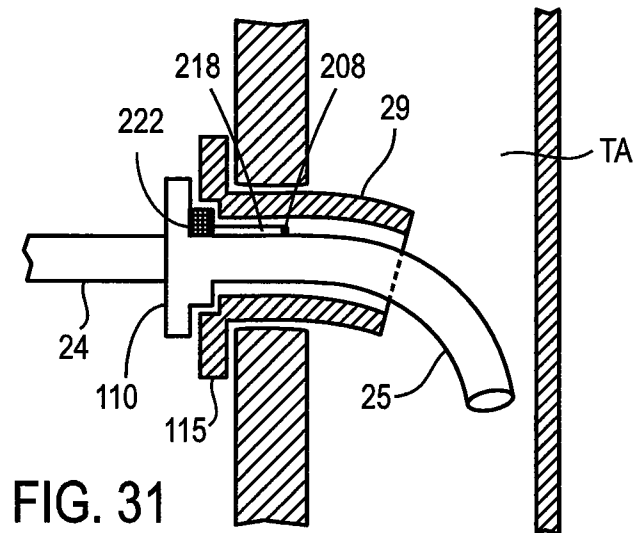


FIG. 31

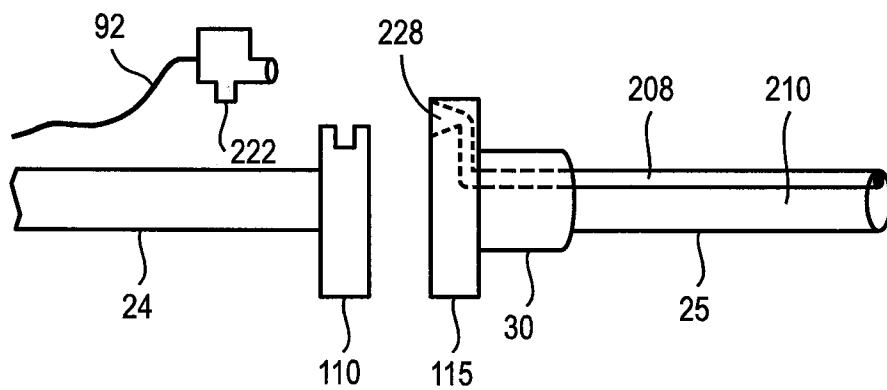


FIG. 32

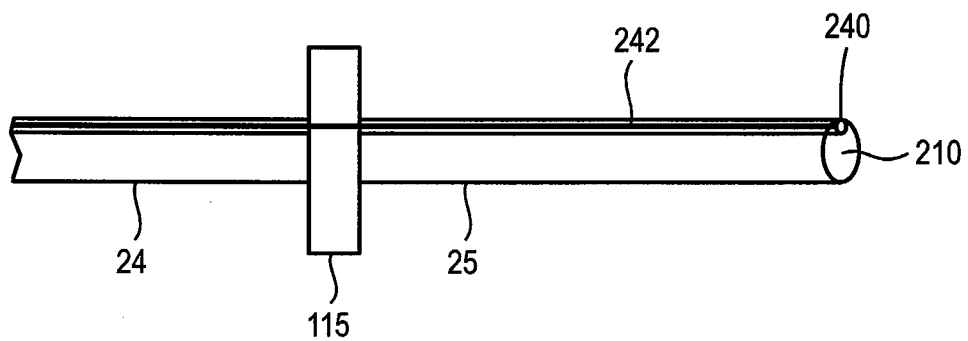


FIG. 33

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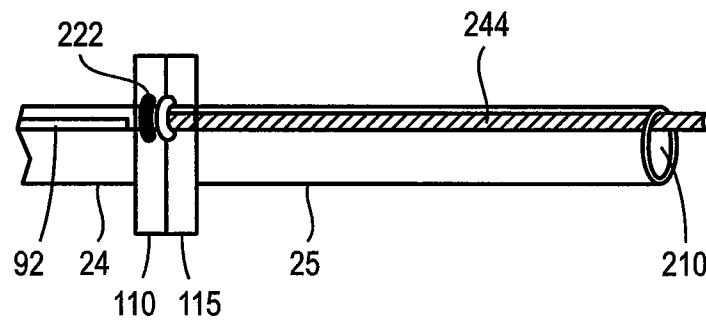
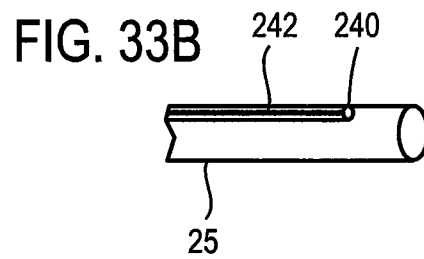
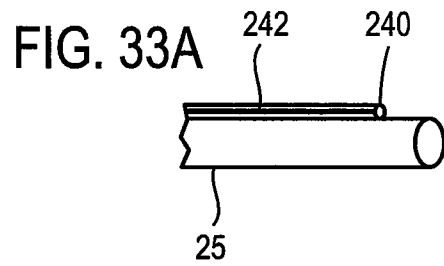


FIG. 34

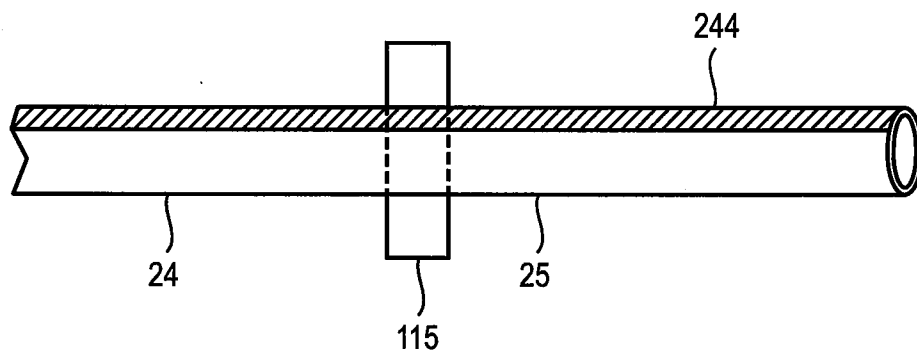


FIG. 35

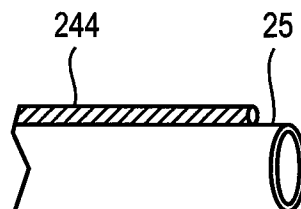


FIG. 35A

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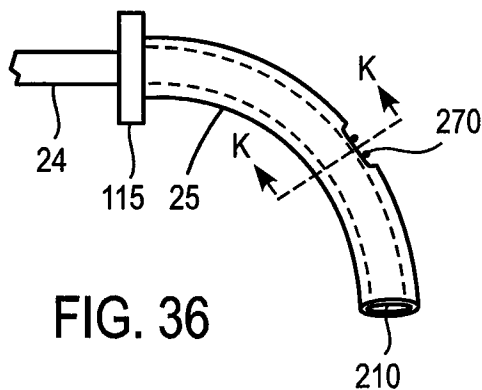


FIG. 36

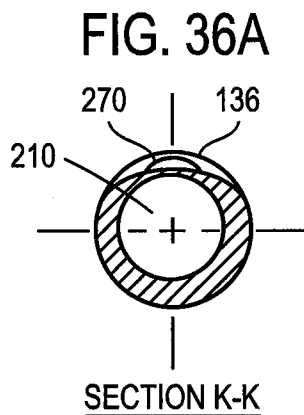


FIG. 36A

FIG. 36B

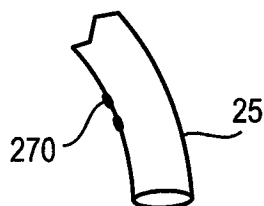


FIG. 36C

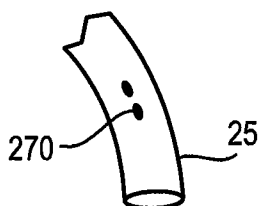


FIG. 36D

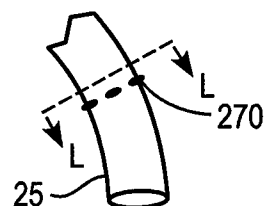
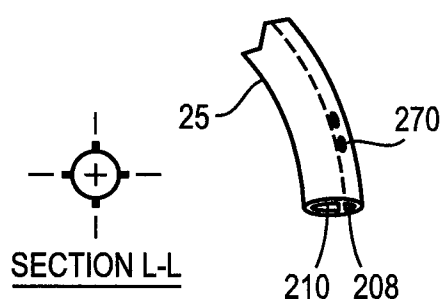


FIG. 36F



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FIG. 36E

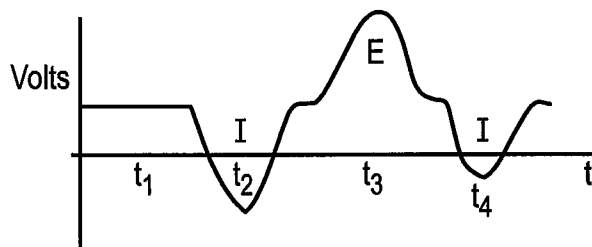


FIG. 37



FIG. 37A

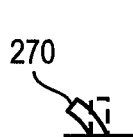


FIG. 37B

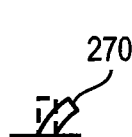


FIG. 37C

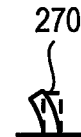


FIG. 37D

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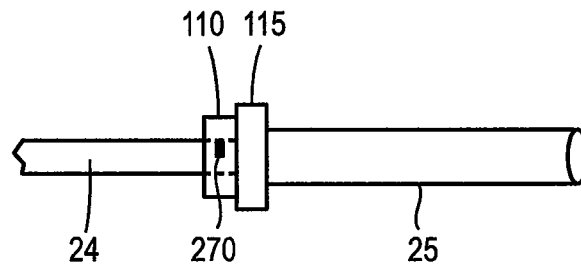


FIG. 38A

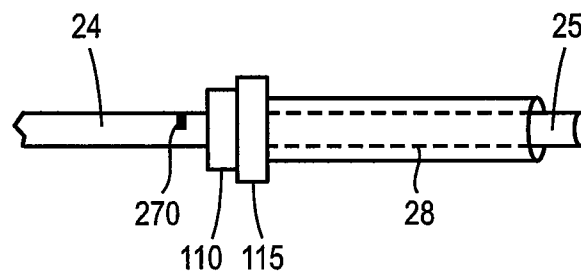


FIG. 38B

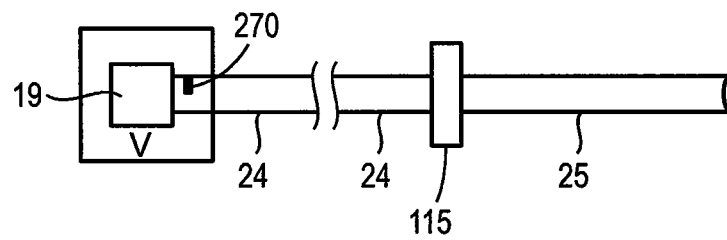


FIG. 38C