The Shared Manifold Ventilator is a cost-effective ventilator that relies on three shared manifolds which can extend all around a shared ventilation ward.

There is an oxygen manifold, an air manifold, and an exhaust manifold. The hardware and sensors required for providing humidified breathing gas at any prescribed temperature and humidity through these manifolds is a shared expense over as many patients as are served by the manifolds.

The oxygen and air manifolds ideally are at a pressure appropriate for direct ventilation of a patient. Because there is no need to step down the pressure at each patient's bedside, the device can be simplified.

Furthermore because of the low pressures involved, no more than 4% above-normal atmospheric pressure, the solenoid valves for use on this device can be much less expensive than the normal solenoid valves used to control compressed air or natural gas. Appendix A describes the related invention of the peristaltic solenoid valve which is particularly applicable for this device.

Each patient is linked to each manifold via a solenoid valve. In line with each solenoid valve would be a one-way valve, and a virus capable filter. Ventilation of each patient is simple in that the breathing gas supply is controlled by two solenoid valves and the exhaust is controlled by a third solenoid valve.

Figure 1 of Appendix B shows a prior art manifold ventilator design in which each patient must have the same oxygen concentration and the same breathing cycle.

Figure 2 of Appendix B shows the Shared Manifold Ventilator in a basic confirmation, without software feedback controls to adjust blood oxygenation levels (as is feasible by adding additional hardware).

For most patients, the oxygen solenoid valve opens for a time that would be between 0.5 to 2 seconds, and then the air valve opens up until the end of the inhalation cycle. There can be a hold time before the beginning of the exhalation cycle.

The exhalation cycle will typically be between 1-3 seconds. The exhalation manifold can exhaust to an area outside of the hospital, through a ultraviolet radiation zone to kill the virus, or it can go through a filter to remove any aerosolized virus particles.

Figure 2 shows a way to maintain a constant pressure or near constant pressure in both the air manifold and the exhaust manifold. In this preferred method, a variable control valve links the air supply manifold to the exhaust manifold. The position of this valve is controlled to maintain an accurately defined air manifold pressure.

Downstream from this control valve, the air manifold can desirably exhaust into the exhaust manifold, which is at a slightly elevated pressure above atmospheric pressure, typically around 0.03% of standard atmospheric pressure above the actual environmental pressure, due to the exhaust blowing out below the surface of water. This is a well-known means for controlling pressure in a flowing gas stream. This method allows a single blower to pressurize both the air supply and exhaust manifolds.

Appendix A discloses the peristaltic solenoid valve. There is a previous patent application (US63005620) that has been filed on this device. Appendix A updates that application.

Appendix B is a detailed description of the Shared Manifold Ventilator. It describes various optional improvements to the invention which would enable control of pressure for each individual patient. It is also possible to use sensor inputs and feedback controls to modify the breathing cycle automatically to achieve medical targets such as blood oxygenation level.

Appendix A

Electromechanical Peristaltic Valves

I have created an open source project to design what I call the shared manifold ventilator. Although this device could be made with off-the-shelf industrial equipment it is obvious that the solenoid valves and the quick-connects could be a lot less expensive than the items which are available commercially to control the much higher air pressures used in industrial pneumatic systems.

A more appropriate solenoid valve would reduce the overall cost of the system substantially, and that would be particularly relevant in Africa and India. It would be feasible to make much less expensive components that would work fine in this application.

Abstract of the invention

The peristaltic solenoid valve uses an elastomeric tube through which gas will flow in the shared manifold ventilator application. This device is also suitable for liquid, such as in irrigation systems or in industrial processes including chip fabrication as well as chemical factories. Flow through the elastomer tube can be shut off by a plunger shaped to efficiently squeeze the elastomer tube shut. Said plunger is linked to a solenoid which is electrically actuated to control the flow. Since the fluid only contacts the elastomer tube, it will be much easier to design these peristaltic valves so as to minimize contamination from the valve body.

Another feature of this kind of valve that is unique is that it is also intrinsically a pressure relief valve.

Background of the invention

There is a prior art device known as a pinch valve in which fluid pressure is used to narrow a through-hole in the valve comprising an elastomeric sleeve. One example is: US7118086B1.

There are many examples of solenoid valves which operate in the conventional way of a valve in which a solid object gets in the way of the flow of a fluid until it is electro-mechanically retracted from the flow path to enable the opening of the valve. I have not found any examples however in which an elastomer tube is pinched by a solenoid in the manner suggested below.

Manual clamps are ubiquitous in hospitals, but I am not aware of any actuated pinching mechanism used in this way.

Description of the Invention

The innovation was originally designed for a low pressure solenoid valve to link a ventilated patient either to air, oxygen, or the exhaust manifold. Since the maximum pressure involved is less than ½ PSI, the existing types of solenoid valves are total overkill. In the low pressure application, the elastomeric tube would be a soft tube having a Shore A durometer probably between 40 to 60.

Higher pressures can be shut off with a peristaltic solenoid valve provided that stiffer elastomers are used for the elastomer tube, or fiber-reinforced elastomer hoses could also be used.

I envision a much less expensive low pressure solenoid valve. The device I envision is simpler than the pinch valve in that a linear actuator closes and opens the valve. This actuator can be a stepper motor driver or it can be a simple electromagnetic solenoid. It can be configured to be either normally open or normally closed.

Unlike pinch valves, the elastomer part of the valve would be an extruded tube which is much less expensive to produce than a molded rubber part.

In its simplest implementation, the peristaltic valve is a simple on/off valve which is normally closed. The device could also incorporate proportional flow control if the retracting mechanism for the plunger which closes off the flow is a stepper motor, or if the current going through the solenoid wires can be controlled so that the degree of retraction of the magnetic element against the spring could be controlled.

Proportional control of the valve is part of the invention but not part of the simplest implementation. The following example describes that simplest implementation, in which the solenoid valve is a simple on-off valve which is normally closed by the spring tension, and which can be opened by the magnetic attraction between the electromagnet and the ferromagnetic core which is connected to the solenoid plunger which pinches the elastomer tube through which fluid flows.

Example of the Invention

The plunger portion of the valve that closes off the flow is at least partially made of a magnetic material. There is a spring which keeps the valve closed regardless of the orientation, as long as no current flows. This spring pushes against a plunger which pinches off the elastomer tube except when current flows through the magnetic coil which partially surrounds the magnetic portion of the plunger. The plunger and the spring form the movable part of the solenoid valve. This mechanism means that the solenoid valve is only held closed up to a certain hydraulic pressure above which the spring is forced open. This makes such a valve into a pressure relief valve also.

When a current passes through a coil surrounding the magnetic part of the valve, the plunger is retracted and the valve opens. The current will flow as long as the valve is open and as soon as the current stops the spring will close the valve.

The magnetic part of the valve can either be a ferromagnetic metal, a polymer composite containing ferromagnetic particles, or a permanent magnet.

In the design of Figure 1, the solenoid valve is based on a plastic T-joint pipe fitting. The solenoid plunger is actuated through the T-joint pathway which is perpendicular to the flow path of fluid through the valve in an elastomer tube. The elastomer tube is linked to the manifold on one side, then goes through the valve body and is linked to the patient on the other side. There are three or 4 peristaltic solenoid valves for each ventilated patient in the envisioned hospital ward.

The elastomer tube can have an outside diameter of 1 inch. The T-joint has an inside diameter of 1.25 inch. The closing mechanism which is at the end of the solenoid actuated plunger is a spherical ball with an outside diameter of 1.125 inches. When the plunger is pushed forward, the elastomeric tube is closed by the plunger pushing the tube against the circular cross-section at the bottom of the valve.

There is a relationship between the elastomer tube diameter, the tube wall thickness, and the optimum diameter for the spherical ball which closes off the tube as well as the pipe shaped conduit through which the elastomer tube runs. Although I have not yet done these calculations it is obvious that the radius and exact shape of all of these components can be optimized.

The plunger and the spring are contained within a short segment of plastic pipe with inside diameter of 1.125 inch in this example. This pipe segment enters the perpendicular side of a 1.25 inch t-joint through which the elastomer tube goes. The pipe containing the plunger and spring is long enough so that the spring is compressed enough to close off the flow when pushed into the

pipe segment by a plastic cap that is screwed onto the end of this pipe segment. This allows for both easy fabrication and for replacement of the spring or the plunger assembly.

More Detailed Explanation of how the Valve Works in the Shared Manifold Ventilator.

The key concept is that air, oxygen or exhaust gas flows through the valves in an elastomeric tube which is pinched by a mechanical clamping device when the valve is closed. Alternatively, this spring could hold the valve open and the magnet could close the valve to make a normally open valve.

This means that the elastomer tube guarantees the cleanliness level of the fluid. This valve design also means there is no requirement for tightly fitting valve seats, as would be required in any conventional valve. This is very similar to the way that a peristaltic pump works. In fact, off-the-shelf peristaltic tubing can be used.

The shared manifold ventilator would have at least three different solenoid valves for each patient, one linked to an oxygen manifold, another linked to an air manifold, and the third linked to the exhaust manifold. All three solenoid valves could be identical.

The air and oxygen manifolds link through respective peristaltic valves to a common segment of pipe or tubing which then goes through a one-way valve or a virus capable filter before going to the equipment used for ventilating the patient. After the one-way valve and or virus capable filter, there is a junction to the patient interface device and also to the exhaust manifold through a third solenoid valve. This layout prevents back mixing of virally contaminated gas into the supply manifolds.

An ideal material for the elastomer tube would be a clean thermoplastic elastomer such as SEBS (Kraton G) based formulations, dynamically vulcanized EPDM/Polypropylene thermoplastic elastomers (Santoprene), or compounds based on blends of these two. These thermoplastic elastomers are inexpensive materials that are readily extruded or molded through conventional plastics extrusion or molding methods. These particular thermoplastic elastomers are routinely used in medical equipment. Santoprene has excellent fatigue resistance and is commonly used in peristaltic tubing for peristaltic pumps.

Such thermoplastic elastomers are much cleaner than thermoset elastomers in general and they also have very good fatigue properties.

The tube passing through the solenoid valve could be in any shape, it doesn't have to be circular in cross-section. It provides a conduit for the gas through the solenoid valve and should ideally have a shape that enables the plunger to shut off the flow efficiently while minimizing fatigue in the tube wall.

The tube through the solenoid valve could also be selected for particular chemical resistance applications or temperature resistance applications. There would be certain applications in a chemical factory for example where fluoroelastomer tubing would be particularly desirable. There would be applications in drug manufacturing where silicone tubing would be most desirable. There are many other examples where the ability to change the tubing through the valve gives a great deal of flexibility while using the same valve body. This multicomponent capability makes the valve highly adaptable.

The solenoid valve plunger simply pinches off the elastomer tube inside of the valve body. There is no direct contact between the valve components and the fluid which is contained inside the elastomer tube. The cleanliness of such a system would make these valves applicable in many places like chemical factories and computer chip manufacturing facilities, where extreme cleanliness of a washing solution is needed.

I visualize an optimized shape for the squeezing mechanism at the end of the plunger which actually touches the elastomer tube. The tip of the plunger would desirably have a spherical shape which pushes the elastomer tube against a mating surface which has a circular or spherical shape where it touches the tube during the time that the tube is squeezed shut. The plunger tip radius of curvature is larger than the elastomer tube’s outer radius. The mating surface into which the elastomer tube is pushed by the plunger ideally has a radius of curvature that is slightly greater than the radius of curvature of the plunger tip.

Appendix B: Detailed Description

Summary

The Shared Manifold Ventilator (SMV) is a ventilator design that achieves low cost per patient and uses commercially available parts for quick assembly. One of the ways the SMV reduces cost is by consolidating pressure regulation. There are three manifolds which can link to any patient in the shared ventilation ward. The pressure in those manifolds is carefully controlled. But the cost of this control per patient is dramatically less because one is controlling a manifold serving perhaps a hundred patients.

Each patient is linked to an oxygen manifold, an air manifold, and an exhaust manifold through normally closed solenoid valves. These manifolds are made of a large diameter pipe, ~2-3" such that the pressure on the manifold is nearly constant for all the patients linked to that manifold. By varying the time that the oxygen solenoid valve is open versus the air solenoid valve, the effective oxygen concentration for each patient can be controlled individually. The breathing cycle is also individually controllable.

It is possible to enable patient-triggered inhalation as is desirable for most COVID-19 patients.

The Concept

The Shared Manifold Ventilator will be an inexpensive ventilator that could serve 20 or more patients at once. It could be used in a typical hospital situation, but is designed for shared ventilation wards that are being set up for COVID-19 patients.

Our design is based on readily available industrial components, although Rethink Respironics has also made an invention to make one of the key components less costly, peristaltic solenoid valves (Appendix A) that control oxygen, air, and exhalation for each particular patient.

The key feature of the proposed Shared Manifold Ventilator is that there are three separate manifolds that link to each patient. Each patient can have their oxygen and air levels adjusted individually by electronic controls linked to solenoid valves between the patient and the manifolds. This is significantly different than the types of shared manifold ventilators which have been proposed by numerous people and companies, for example, the Combi-Ventilate which is supported by Enterprise Ireland.

In prior attempts to use a single ventilator to ventilate multiple patients, there is only one valve controlling the pressure in the entire shared inhalation manifold, so every patient must have the same breathing cycle and breathing gas mixture.

This is medically problematic as pointed out by a white paper from the American Association for Respiratory Care (Appendix C), which shows the flaws in the idea of shared ventilators with identical breathing cycles for several patients. The shared manifold ventilator gets around this by mixing air and oxygen for each individual patient, and also controlling the breathing cycle for each individual patient through the use of solenoid valves.

Figure 1 shows a prior art version of a manifold ventilator in which the flow of a breathing gas mixture is simultaneously varied to all the patients on the manifold. In this mode, all the patients would experience the same pressure cycle for inhalation and exhalation, and all the patients have to have the same oxygen concentration.

FIGURE 1

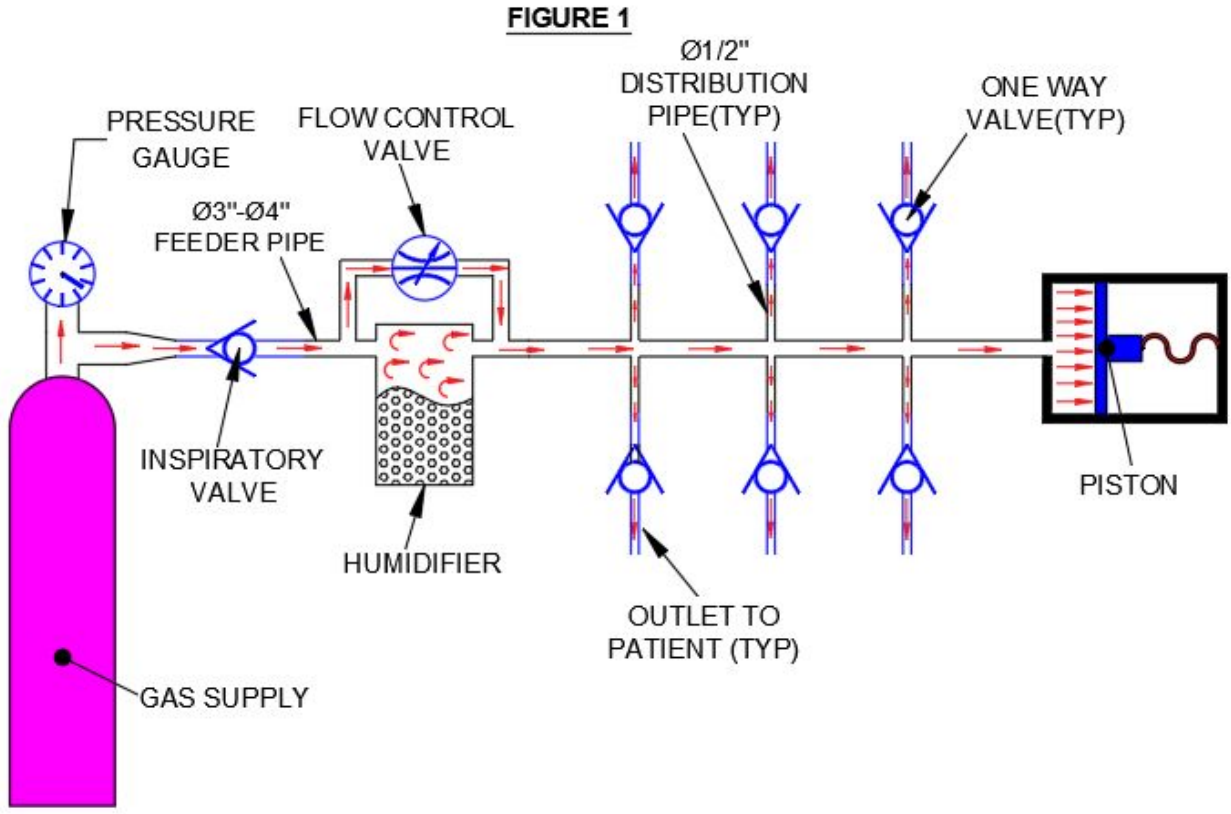

Figure 1 corresponds to the type of Shared Manifold Ventilator that has been tried by numerous hospitals since the COVID-19 outbreak. It suffers from a lack of individual control for each patient.

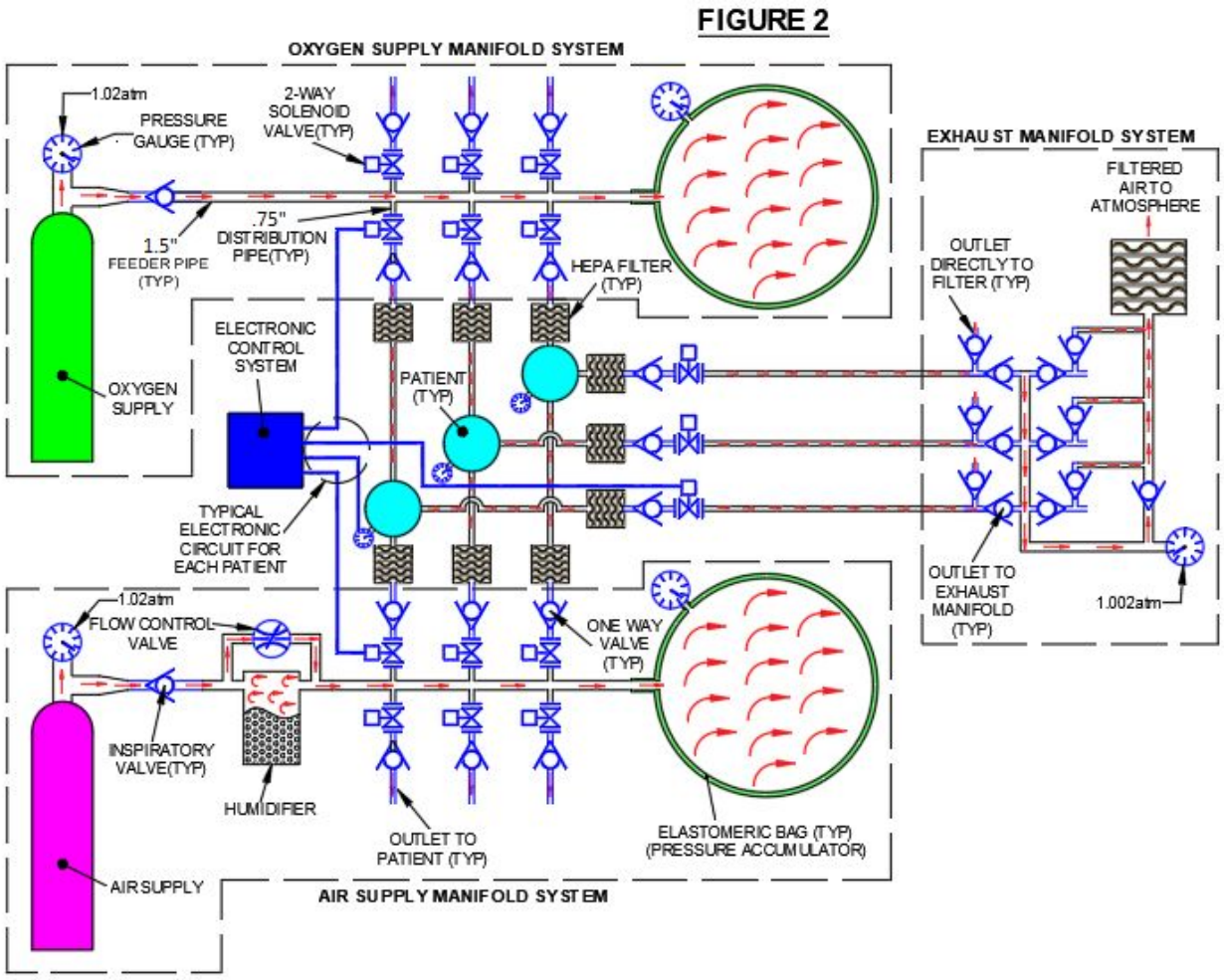

Figure 2 shows a 3-patient version of the Shared Manifold Ventilator which enables individualized control of the breathing mixture and the breathing cycle for each patient.

Figure 2 shows the solenoid valves which are in line with the one-way valves and the filters between the manifold and the patient. At each patient's bedside, there would be 3 solenoid valves and the necessary equipment to maintain isolation between each patient and the manifolds. There are two breathing supply manifolds in Figure 2, an oxygen manifold and an air manifold. Both of these manifolds are controlled at a realistic inhalation pressure, for example, 25 centimeters of water pressure. By holding the supply manifolds at an equal and modest pressure there is no danger to a patient of having their lungs stretched too much, which is a particular risk for COVID-19 infections.

Using a common inhalation pressure across the ward simplifies the design significantly without compromising the ability to individualize breathing cycles and oxygen concentration for each patient.

The air and oxygen manifolds should be at the same pressure so that oxygen and airflows are strictly determined by how long the solenoid valves are open. A respiratory therapist could also modify the rate of flow into a patient's lungs by adjusting a manual flow restriction valve at the bedside (not shown in Figure 2).

It is useful to have a pressure accumulator on the air and oxygen manifolds to maintain a near-constant pressure. These pressure accumulators can be elastomeric balloons similar to an exercise ball. This minimizes pressure fluctuations that would otherwise occur when individual patient solenoid valves open and close in order to control the inspiratory pressure to a value that is lower than the manifold pressure.

The oxygen and air manifolds would operate at approximately 25 cm of water head pressure at standard Earth gravity (water manometer height is used by respiratory therapists as the standard unit of air pressure; this is approximately equal to a pressure 2.5% above atmospheric pressure). The pressures used for ventilation are no more than the pressure it takes to start the inflation of a party balloon.

Figure 2 shows one mechanism for maintaining constant exhaust pressure, by simply exhausting the manifold through a pressure relief valve. While this mechanism is functional, it would result in a humid environment within the exhaust manifold that would enable bacterial growth.

Figure 3 shows an alternative, more desirable mechanism for maintaining pressure in an air or exhaust manifold.

FIGURE 3

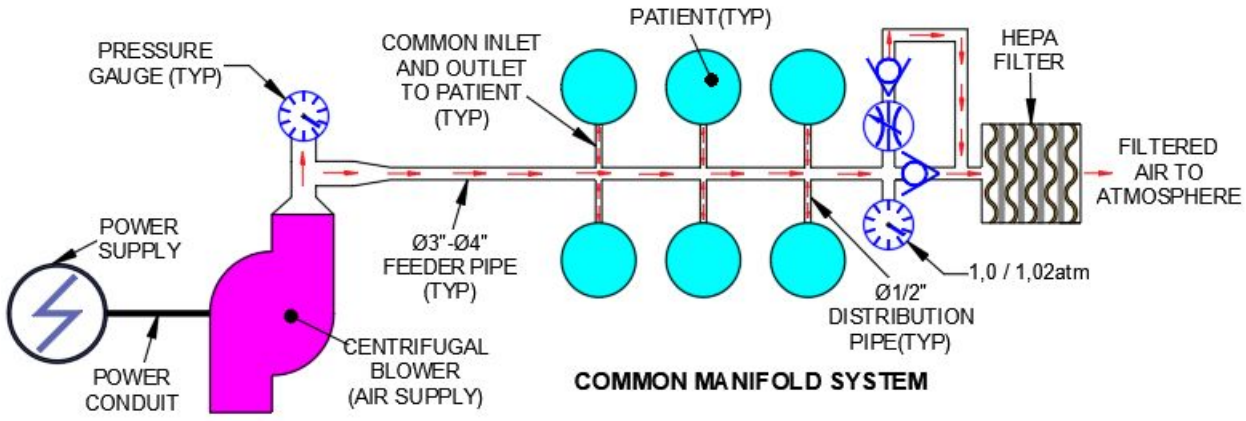

Figure 3 above shows a method to provide a consistent (but controllable) air pressure in a manifold via a constant flow through the manifold created by a simple blower, coupled with a controlled venting of air at the far end of the manifold through a flow restriction.

This flow restriction can be mechanical, or the exhaust stream may escape underwater so that hydrostatic pressure is the origin of the backpressure in the manifold. This is especially applicable for the exhaust manifold, somewhat less so for the air manifold, but it's still feasible for the air manifold as well. This corresponds to the very first prototype we are building now.

There are several options to release the exhalation gas. One conventional approach is to have small holes drilled in the mask or the supply line (to the mask or the endotracheal tube). Exhaust through such holes is how many masks handle exhalation. Viral particles cannot easily be captured using this method of exhalation.

Positive end-expiratory pressure (PEEP) is desirable to prevent lung collapse, and also makes it easier to apply a HEPA filter to the exhaust gas to prevent virus particle escape. Differential exhalation pressure in the exhaust manifold would typically be on the order of 2-4cm of water pressure (~0.002 to 0.004 atmospheres).

In acute respiratory distress, which occurs in the most severe cases of the COVID-19 infections, the alveoli thicken and fill with fluid, which interrupts transpiration of oxygen. This is why oxygen is so important, but for many COVID-19 patients, it is more desirable to have a patient-triggered inhalation cycle. This can be accommodated by adding a rest time at the end of the exhalation cycle where all the solenoid valves are closed. During this rest time, a pressure sensor would detect the patient’s inhalation attempt, which would trigger the opening of the oxygen valve at the beginning of the inhalation cycle. Some patients may also need help with exhalation, in some cases due to prior conditions such as COPD. COVID-19 may also affect lung elasticity.

This need for externally-powered exhalation could be addressed via prior art methods such as the pneumobelt or Rethink Respironics’ Conformal Vest Ventilator (US62943486).

The time that the oxygen supply valve is open to each patient controls the amount of oxygen delivered per breathing cycle. This valve open time will clearly depend on the patient's lung capacity as well as the patient’s need for oxygen.

Following the oxygen valve opening and closing, the air supply valve opens and closes. Inspiratory pressure below the manifold pressure could also be implemented by rapid opening and closing of valves coupled with a pressure sensor to feed back data to the control system. This feature is not illustrated in Figure 2. This would be further facilitated by an elastomer balloon pressure accumulator at each patient’s bedside.

The pressure accumulator balloons only need to withstand at most 0.04 atmospheres differential pressure. There would be advantages to using an elastomeric balloon made of an oxidation-resistant elastomer with low stress relaxation rate, such as EPDM. The inventor, Roger Faulkner is a polymer scientist and has expert input here.

Pure oxygen increases the possibility of combustion of polymers that will be used in the piping and the pressure accumulator tank. However, this is not a significant problem in the current design because the oxygen pressure will barely exceed atmospheric pressure, unlike the oxygen manifolds used in typical hospital rooms.

PVC pipe and various types of elastomer pressure accumulators can be used safely with atmospheric pressure oxygen. Using these materials for the manifolds would make them very inexpensive.

The shared manifolds can be laid out in different ways. It would be desirable for there to be built-in redundancy. If the respiratory ward is organized with supply manifolds all along the walls and crossing above the door so that it is one big manifold loop, there can be more than one source for air or oxygen. If there are valves in the main loop supply manifolds, it should be possible to section each manifold so that there can be two different pressure zones in the same ward, with valves separating these zones.

In an emergency, those valves would be opened and the entire ward would be supported by only one pressure source. That way if one of the sources failed, pressure could still be maintained by opening the valves to the next neighboring pressurized zone. Having two pressure zones on the respiratory ward would allow, for example, 1.02 atmospheres for some patients, and 1.03 atmospheres for others.

The largest part of the mass of this device is plastic pipe and fittings that are widely available standardized parts. Solenoid valves and quick-connects are also readily available. The pressure supply for air and the exhaust manifold would be based on a centrifugal blower such as those used in vacuum cleaners or leaf blowers.

Appendix C

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FOR IMMEDIATE RELEASE
March 26, 2020

Joint Statement on Multiple Patients Per Ventilator

SCCM, AARC, ASA, APSF, AACN, and CHEST Share Unified Message

(IRVING, TX – March 26, 2020) – The Society of Critical Care Medicine (SCCM), American Association for Respiratory Care (AARC), American Society of Anesthesiologists (ASA), Anesthesia Patient Safety Foundation (APSF), American Association of Critical-Care Nurses (AACN), and American College of Chest Physicians (CHEST) issue this consensus statement on the concept of placing multiple patients on a single mechanical ventilator.

The above-named organizations advise clinicians that sharing mechanical ventilators should not be attempted because it cannot be done safely with current equipment. The physiology of patients with COVID-19-onset acute respiratory distress syndrome (ARDS) is complex. Even in ideal circumstances, ventilating a single patient with ARDS and nonhomogenous lung disease is difficult and is associated with a 40%-60% mortality rate. Attempting to ventilate multiple patients with COVID-19, given the issues described here, could lead to poor outcomes and high mortality rates for all patients cohorted. In accordance with the exceedingly difficult, but not uncommon, triage decisions often made in medical crises, it is better to purpose the ventilator to the patient most likely to benefit than fail to prevent, or even cause, the demise of multiple patients.

Background: The interest in ventilating multiple patients on one ventilator has been piqued by those who would like to expand access to mechanical ventilators during the COVID-19 pandemic. The first modern descriptions of multiple patients per ventilator were advanced by Neyman et al in 2006[1] and Paladino et al in 2013.[2] However, in each instance, Branson, Rubinson, and others have cautioned against the use of this technique.[3-5] With current equipment designed for a single patient, we recommend that clinicians do not attempt to ventilate more than one patient with a single ventilator while any clinically proven, safe, and reliable therapy remains available (i.e., in a dire, temporary emergency).

Attempting to ventilate multiple patients would likely require arranging the patients in a spokelike fashion around the ventilator as a central hub. This positioning moves the patients away from the supplies of oxygen, air, and

vacuum at the head of the bed. It also places the patients in proximity to each other, allowing for transfer of organisms. Spacing the patients farther apart would likely result in hypercarbia.

Spontaneous breathing by a single patient sensed by the ventilator would set the respiratory frequency for all the other patients. The added circuit volume could preclude triggering. Patients may also share gas between circuits in the absence of one-way valves. Pendelluft between patients is possible, resulting in both cross-infection and over-distension. Setting alarms can monitor only the total response of the patients' respiratory systems as a whole. This would hide changes occurring in only one patient. The reasons for avoiding ventilating multiple patients with a single ventilator are numerous.

These reasons include:

- Volumes would go to the most compliant lung segments.
- Positive end-expiratory pressure, which is of critical importance in these patients, would be impossible to manage.
- Monitoring patients and measuring pulmonary mechanics would be challenging, if not impossible.
- Alarm monitoring and management would not be feasible.
- Individualized management for clinical improvement or deterioration would be impossible.
- In the case of a cardiac arrest, ventilation to all patients would need to be stopped to allow the change to bag ventilation without aerosolizing the virus and exposing healthcare workers. This circumstance also would alter breath delivery dynamics to the other patients.
- The added circuit volume defeats the operational self-test (the test fails). The clinician would be required to operate the ventilator without a successful test, adding to errors in the measurement.
- Additional external monitoring would be required. The ventilator monitors the average pressures and volumes.
- Even if all patients connected to a single ventilator have the same clinical features at initiation, they could deteriorate and recover at different rates, and distribution of gas to each patient would be unequal and unmonitored. The sickest patient would get the smallest tidal volume and the improving patient would get the largest tidal volume.
- The greatest risks occur with sudden deterioration of a single patient (e.g., pneumothorax, kinked endotracheal tube), with the balance of ventilation distributed to the other patients.
- Finally, there are ethical issues. If the ventilator can be lifesaving for a single individual, using it on more than one patient at a time risks life-threatening treatment failure for all of them.

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About the AARC

Founded in 1947, the American Association for Respiratory Care (AARC) is the leading national and international professional association for respiratory care. We encourage and promote professional excellence, advance the science and practice of respiratory care, and advocate for patients, their families, the public, the profession, and the respiratory therapist. Supporting more than 47,000 members worldwide, the AARC is a not-for-profit professional association headquartered in Irving, TX. Learn more about us at www.aarc.org.