Version 3-E-Vent

Contents

List of Figures

1 Version 3 MIT Emergency Ventilator (E-Vent) Project

1.0.1 References:

All the information compiled here is from the MIT Emergency Ventilator (E-Vent) Project

To download our repo: **DOWNLOAD**

This is the url of our repo : https://github.com/CombatCovid/mit-emergency-ventilator

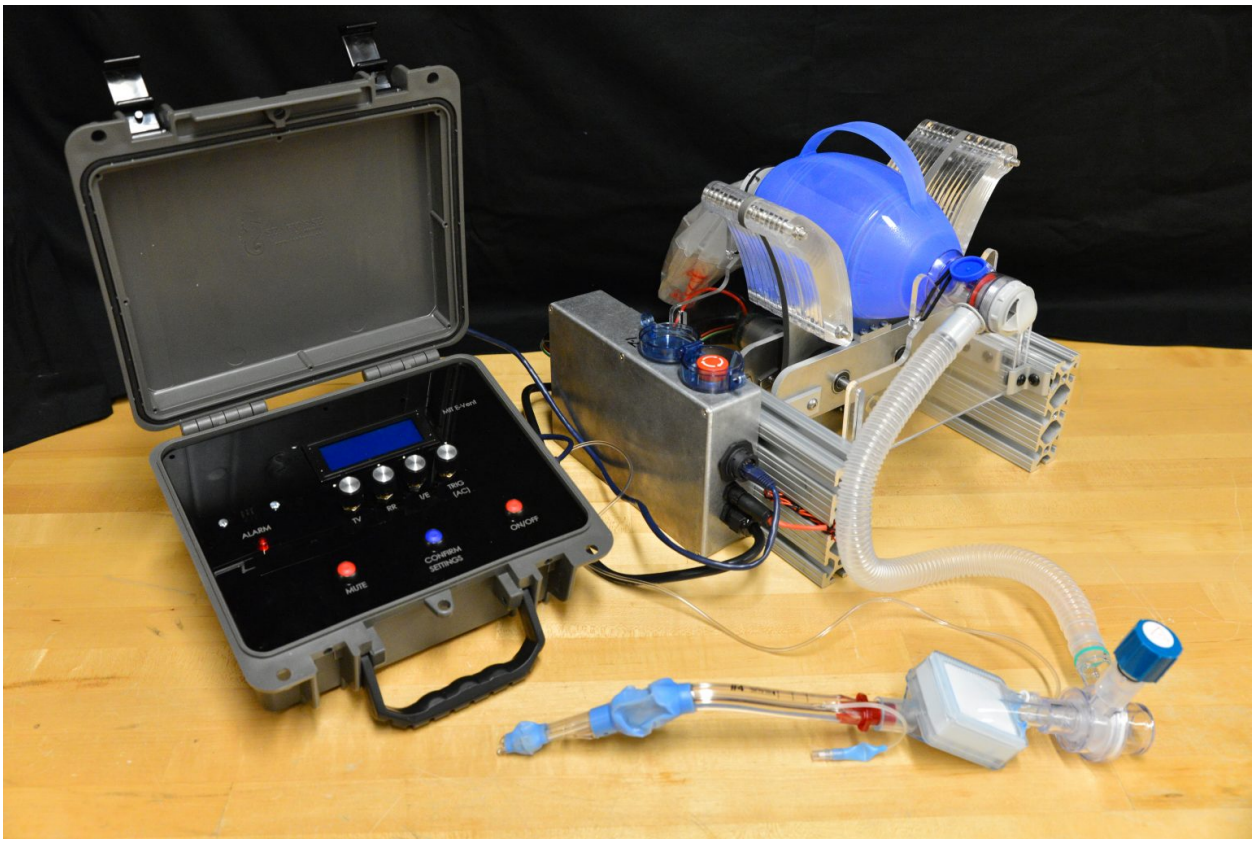

Figure 1: MIT E-Vent Version 3 showing control box and full setup

See it working here : VentPumping-compressed.mp4

1.1 Goal

The goal of this site is to provide the best information we can, focused around safety, on automating a manual resuscitator, as a potential means for longer-term ventilation. This is a completely off-label use, but we recognize the global interest when a hospital has used up all ventilators and the only option is manual bagging a patient. We hope that such systems may serve as bridge devices and help with the triage of available respirators and clinicians trained in respiratory therapy. This may allow less severe patients to be cared for by less specialized clinicians, while resources are focused on those most in need. However, at no time

should a patient be unattended without someone skilled available to directly monitor their vital signs. Effectively, we are reprising the early days of safe ventilation where direct clinical observation of patient condition served as the key feedback.

Begin by reading the Key Ventilation Specifications, then the detailed clinical information. This is critical to understand the logic underlying the mechanical, electrical, controls and testing information.

1.2 Background & Need

We are one of several teams who recognized the challenges faced by Italian physicians, and are working to find a solution to the anticipated global lack of ventilators. In the US alone, the COVID-19 pandemic may cause ventilator shortages on the order of 300,000-700,000 units (CDC Pandemic Response Plans). These could be present on a national scale within weeks, and are already being felt in certain areas. An increase in conventional ventilator production is very likely to fall short and with significant associated cost (paywall warning).

Almost every bed in a hospital has a manual resuscitator nearby, available in the event of a rapid response or code where healthcare workers maintain oxygenation by squeezing the bag. Automating this appears to be the simplest strategy that satisfies the need for low-cost mechanical ventilation, with the ability to be rapidly manufactured in large quantities. However, doing this safely is not trivial.

Use of a bag-valve mask (BVM) in emergency situations is not a new concept. A portable ventilator utilizing a manual resuscitator was introduced in 2010 by a student team in the MIT class 2.75 Medical Device Design (original paper here and news story here), but did not move past the prototype stage. Around the same time, a team from Stanford developed a lower-cost ventilator for emergency stockpiles and the developing world.

It looks similar to a modern ICU ventilator (Onebreath), but "production for US hospitals would start in about 11 months", making it "a second wave solution" (MIT Tech Review Article). Last year, the concept was re-visited by two student teams, one from Rice university , and another Boston-based team who won MIT Sloan's Healthcare prize (MIT News: Umbilizer). Other teams currently working on this challenge can be found linked on our Resources page.

1.3 MIT Emergency Ventilator (E-Vent) Project

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1.4 Background & Need

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1.5 Key Research Question

We have launched an emergency research project with a team of MIT Engineers and American clinicians to address the question:

Is it possible to safely ventilate a COVID-19 patient by automatically actuating a manual resuscitator?

Our process in approaching this question is to first identify the minimum requirements for a low-cost ventilator, based on the collective wisdom of many clinicians; design against these requirements; conduct immediate testing; report the results; iterate and facilitate discussion.

Manual ventilation is a short-term solution in a critical care environment, without any apparent clinical evidence regarding the safety of long-term use (days-weeks). There are multiple scenarios in which respiratory support could be needed: patients can be awake or

asleep, sedated or sedated and paralyzed, breathing spontaneously, weaning off of a vent, etc. Furthermore, changing clinical presentations with ARDS require shifting minute ventilation (tidal volume X respiratory rate) to "lung-protective" strategies, which place patients at risk for things like auto-PEEP. Some of these situations are simpler than others, with the simplest being ventilating a sedated, paralyzed patient. In such a situation, at a minimum a safe emergency ventilator could be used to free-up a conventional ventilator.

Any solution should be utilized only in a healthcare setting with direct monitoring by a clinical professional. While it cannot replace an FDA-approved ICU ventilator, in terms of functionality, flexibility, and clinical efficacy, the MIT E-Vent is anticipated to have utility in helping free up existing supply or in life-or-death situations when there is no other option.

Further, any low-cost ventilator system must take great care regarding providing clinicians with the ability to closely control and monitor tidal volume, inspiratory pressure, bpm, and I/E ratio, and be able to provide additional support in the form of PEEP, PIP monitoring, filtration, and adaptation to individual patient parameters. We recognize, and would like to highlight for anyone seeking to manufacture a low-cost emergency ventilator, that failing to properly consider these factors can result in serious long-term injury or death.

2 How to use the BOM for Version 3 of E-Vent

1. The new design in a nutshell is shown here:
2. Source files for mechanical design:

- CAD files: with help from Neal Drapeau
- Mechanical BOM: Spreadsheet

3. Access the code from GitHub, in the e-vent repo
4. Two design tools that will allow you to explore different gear configurations and select appropriate motors:

    - Gear Stress Estimator Spreadsheet

      This is designed to calculate the maximum bending stress experienced by gear teeth. This should be compared to stress – fatigue curves for a given candidate material.

    - Gear Torque and Speed Estimator Spreadsheet

      Purpose: This outputs the torque and speed required by the driven arm and the pinion. The radial load from the pinion on the gearbox shaft is also calculated. The speed and torque results should help you select and appropriate motor, based on comparing these to a given motor's curves.

5. Source files for circuit diagram:

- KiCad project: Source files , and Gerber files
- Electrical BOM: Spreadsheet

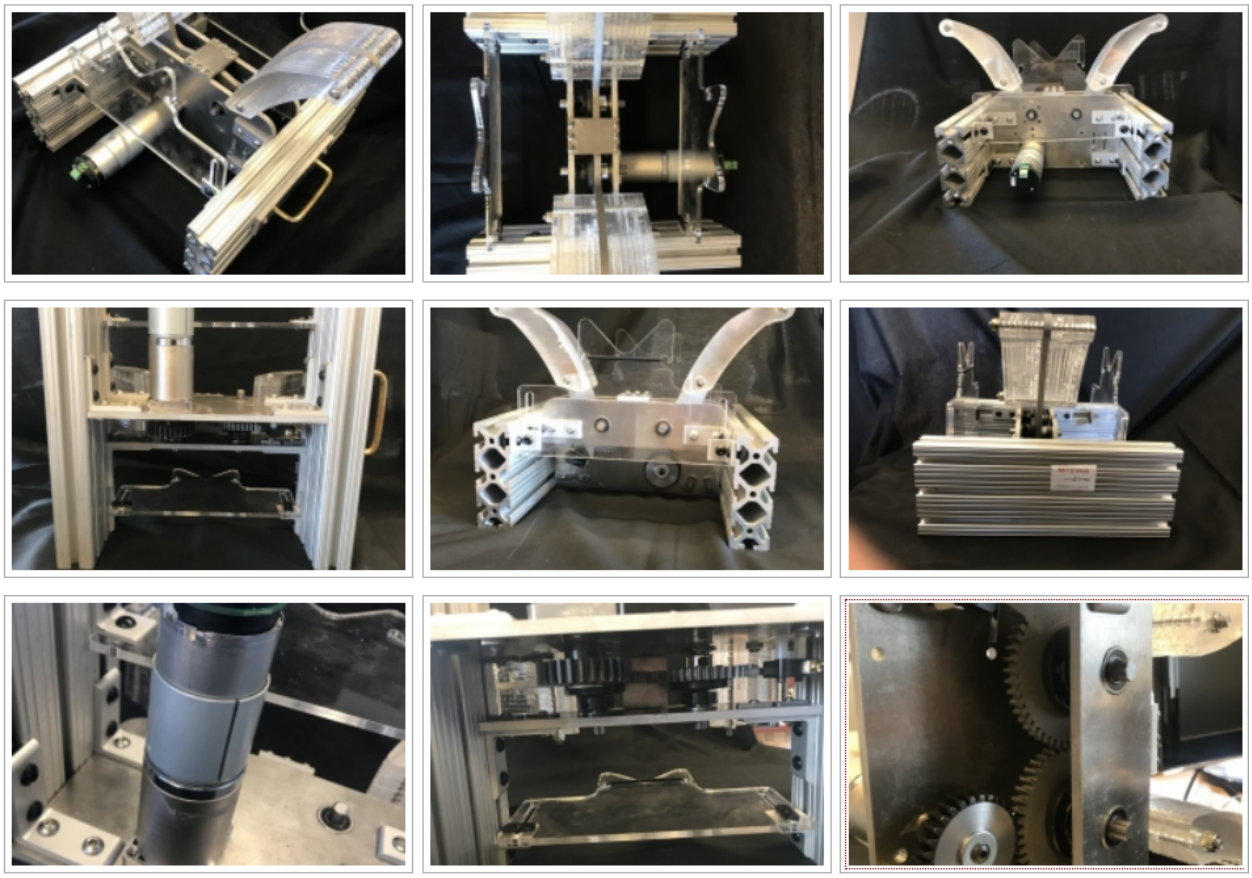

Figure 2: Collage of all hardware views

6. Past Designs

- More details are available in Past Designs.

3 Key Ventilation Specifications

This page summarizes the minimum set of controllable parameters and recommended ranges, in order to ventilate a patient,summarized from Clinical.

Caution!!!:

Patients must be under the management of a trained clinician.

- Respiratory Rate (RR) (breaths per minute): between 6 – 40. Note that the low RRs of 6 – 9 are only applicable to Assist Control.
- Tidal Volume (TV) (air volume pushed into lung): between 200 – 800 mL based on patient weight.
- I/E Ratio (inspiratory/expiration time ratio): recommended to start around 1:2; best if adjustable between range of 1:1 – 1:4[1].
- Assist Control is based on a Trigger Sensitivity: When a patient tries to inspire, they can cause a dip on the order of 2 to 7 cm H2O, with respect to PEEP pressure (not necessarily equal to atmospheric pressure).
- Airway pressure must be monitored continually. Maximum pressure should be limited to 40 cm H2O at any time
- Plateau pressure should be limited to max 30 cm H2O.
- The use of a passive mechanical blow-off valve fixed at 40 cm H2O is strongly recommended. This is integrated into most manual resuscitators.
- Clinician require readings of plateau pressure and PEEP (refer to Clinical tab).
- PEEP of 5–15 cm H2O required; many patients need 10–15 cmH2O.
- Failure conditions must result in an alarm and permit conversion to manual clinician override, i.e. if automatic ventilation fails, the conversion to immediate ventilation must be immediate.
- This is a minimum requirement set for emergency use. Equipment designed for more regular use, even if for emerging markets, will require additional features to be used on a regular basis.
- Ventilation on room air is better than no ventilation at all. Blending of oxygen and air gas mixture to adjust FiO2 is not important in an emergency scenario.
- It is certainly nice to have that ability and can easily be implemented with an oxygen/air gas blender that some hospitals already have.
- COVID-19 can become aerosolized (airborne), so HEPA filtration on the patient's exhalation is required or between the ventilator unit and the patient (at the end of the

[1]Range determined based on several COVID-19 patients' ventilator settings reported from Boston area ICUs.

endotracheal tube) to protect clinical staff from certain infection. This can serve to provide heat and moisture exchange between exhaled and inspired air. In-line HEPA filters can usually be purchased alongside manual resuscitator bags.

4 Clinical studies

This section guides the engineering design with a focus on safety.

Caution: This section MUST be read and understood fully first. No engineering team should consider designing a ventilator without a clinician experienced in mechanical ventilation and respiratory management involved.

The MIT E-Vent is intended for emergency use only when all available conventional invasive respiratory support has been exhausted. It should only be used in a clinical environment under careful monitoring by trained medical professionals.

This has been developed by a team of physicians certified in Anesthesia and Critical Care, working with mechanical, electrical, and software engineers. There were two critical tasks which we started with:

1. Identify potential use scenarios
2. Define the minimum safe clinical functional requirements (specs)

To minimize time to bedside without compromising patient safety, the clinical functional requirements were distributed to a broad team of clinical advisors.

In parallel, a peer-review process was used to identify what was felt to be the best design concept (in spirit, loosely based on a prior student project which was not clinically validated). Once a review of the clinical functional requirements was completed, it was distributed to the design and controls teams.

We hope that this website can act as a reference point to help others and encourage discussion. Also, it is intended as a resource for makers or manufacturers to access and utilize the latest design. As it stands, several important tasks remain:

1. FDA review and feedback, work towards approval
2. Long-term (days) porcine trials
3. Implement design for manufacturing
4. Logistics for manufacture, distribution, and quality controls

4.1 Anticipated Clinical Scenarios

Specific to the present COVID-19 pandemic, we anticipate the following scenarios in which an emergency mechanical ventilator could be safely used to provide respiratory support:

- A deteriorating COVID-19 patient, who is short of breath & hypoxic; hypoxemic respiratory insufficiency means they are not breathing well enough to adequately oxygenate their blood. Clinicians at this point can initiate respiratory support. An MIT E-Vent could provide basic respiratory support in this situation

- Worsening clinical status recognized when a patient develops Acute Respiratory Distress Syndrome (ARDS). An MIT E-Vent could be a bridging solution until a traditional ICU ventilator becomes available
- The patient will be intubated or have a tracheostomy (limited / no applicability to mask)
- Those patients are otherwise going to be sedated and paralyzed (invasive ventilation requires sedation, and paralysis will prevent patient-ventilator dyssynchrony if assist-control is not available)
- Ventilated patients required to leave the ICU for imaging or procedures can be supported with the MIT E-Vent, unless determined that the patient requires support outside its range.
- A multidisciplinary team consisting of a physician, critical care nurse, and respiratory therapist should be available to monitor ventilated patients at all times. Additionally, a clinical lab capable of timely reporting of blood gases and other common ICU laboratory markers should be available to enable the clinical team to make appropriate decisions and adjustments.

4.2 Acute Respiratory Distress Syndrome

Those patients with ARDS would preferentially receive mechanical ventilation by standard ICU ventilators. A manual resuscitator is meant as a backup should institutions run out of traditional ventilators, and for patients with milder forms of lung disease that require less sophisticated modes and features.

Changes in lung mechanics (compliance) can be a result of acute and chronic lung conditions. In general, lung compliance is affected by a multitude of factors; in ARDS, fluid is present in the alveoli and/or interstitial space (between the alveoli and a capillary blood vessel) and results in changes in the diffusion of gases between the alveoli and blood vessel. Other conditions include:

- Any pathologies that cause fluid accumulation in the lung ('wet lung') through infectious, inflammatory, mechanical, or hydrostatic factors (pulmonary edema, TRALI, pneumonia, pneumonitis, diffuse alveolar hemorrhage, heart failure, cardiogenic shock, mitral valve regurgitation)
- Any pathology that causes fibrosis (scarring and thus stiffening – 'stiff lung') of the lung structure, otherwise known as the "parenchyma" (ARDS related, interstitial lung disease, sarcoidosis, idiopathic pulmonary fibrosis, radiation or chemotherapy-related, post pneumonia or hemothorax related trapped lung or lung fibrosis)

The safe limit for ventilation therapy has not yet been determined. In the life-and-death situation we are currently facing, this will give patients a chance until an ICU or OR ventilator becomes available. We are actively engaging with animal testing laboratories to determine what, if any, these limitations may be. Further, we plan to perform multi-day trials in pigs to evaluate the safety of longer-term MIT E-Vent use.

4.3 Clinical Mechanical Ventilation 101

If we boil down how a modern ICU ventilator works, there are three important parameters.

- Tidal volume (air delivered to the patient)
- Inspiratory phase start ("triggering")
- Expiratory phase start ("cycling")

Each of these values is first determined by the machine and healthcare operator. Adjustments are made in real-time to optimize the patient's clinical status, as measured by checking lab draws and monitoring vital signs. The patient acts as a "built-in" sensor!

4.4 Tidal Volume: Volume-Control vs. Pressure-Control

- Tidal volume, one can set a specific volume in milliliters or set an inspiratory pressure on the mechanical ventilator; tidal volume is often discussed and thought about as a value based on cc/kg of ideal body weight (see Equation 1).

- In Acute Respiratory Distress Syndrome (ARDS), patients' tidal volumes are kept between 4 to 8 cc/kg. Here is a convenient chart (PDF) provided by ARDSNet with values for ideal or predicted body weight and different tidal volumes corresponding to the patient's height.

Equation 1. Gender-specific formulas to calculate ideal body weight (courtesy: ARDSNet):

- Male Ideal Body Weight (kg) = 50 +[0.91 (height in cm – 152.4)]
- Female Ideal Body Weight (kg) = 45.5 +[0.91 (height in cm – 152.4)]

Volume control mode is just that: a clinician defines the tidal volume, see Fig. 3. The machine will then try to deliver that volume with a uniform inspiratory flow rate, over a specified inspiratory time (see discussion on cycling). This is done regardless of how much pressure builds up in the lungs, referred to as peak inspiratory pressure (PIP). Modern ventilators have safety features to limit max pressures, which can result in damage to the lungs (a.k.a. barotrauma). Ventilators have the capability to perform an "end-inspiratory hold", for a programmable duration over which the pressure in the circuit is recorded. This is called plateau pressure (P_{plat}). A volume-controlled breath cycle with inspiratory hold is illustrated in Fig. 3.

Pressure control mode utilizes pressure supplied by the ventilator, and the patient's lung compliance and inspiratory time determine the volume of gas delivered (tidal volume), see Fig. 4.

As we are actively learning more about patients with COVID-19, what we do know is that there is an ARDS-like clinical picture. Therefore we know that in COVID-19 patients, the lung compliance changes with the disease course, and thus tidal volume will change with long-term use of pressure control ventilation.

This presents another branch point for granular clinical details: **compliance** can be further broken down into that of the upper and lower airways, see Fig. 5.

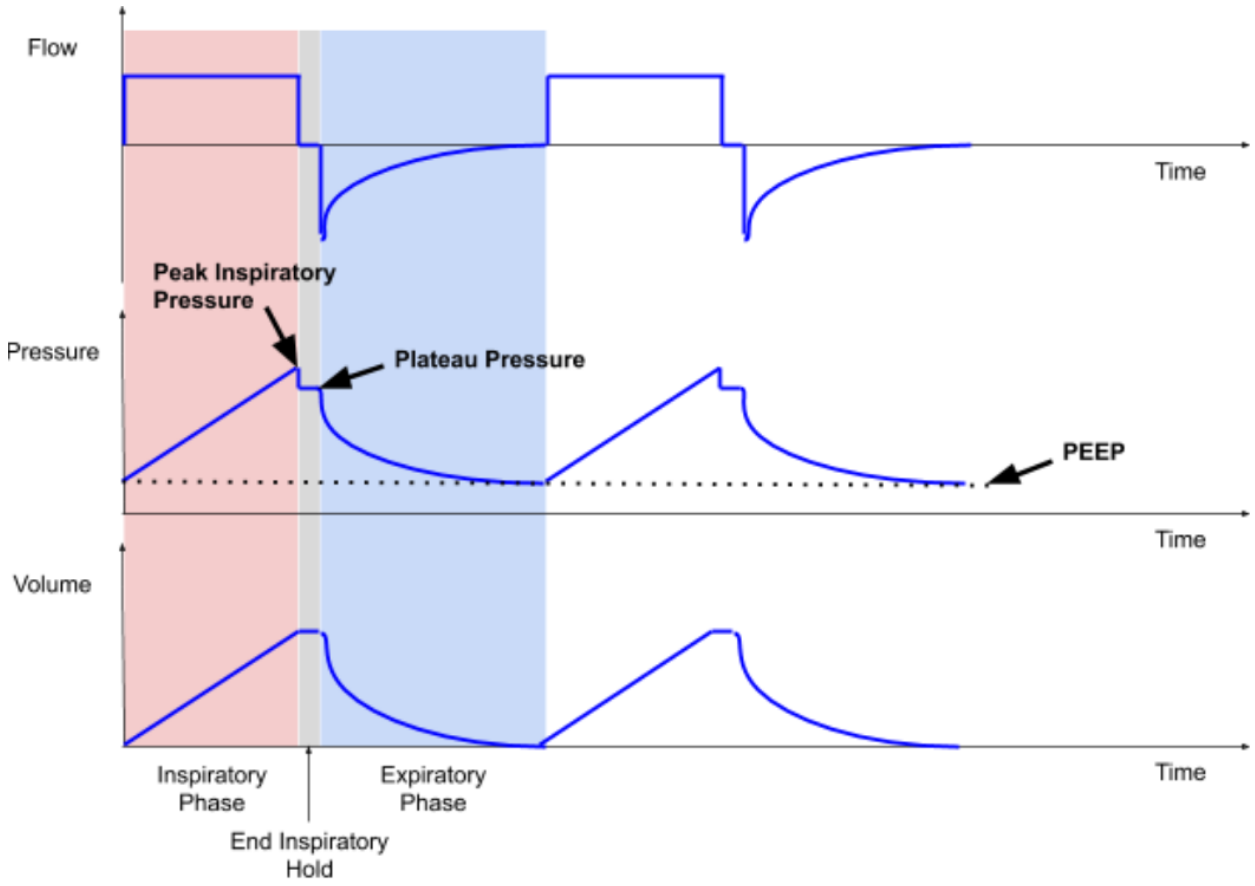

Figure 3: Flow, Pressure, and Volume profiles for volume-control ventilation over 2 breath cycles; PEEP is illustrated on the Pressure plot. Image courtesy AK.

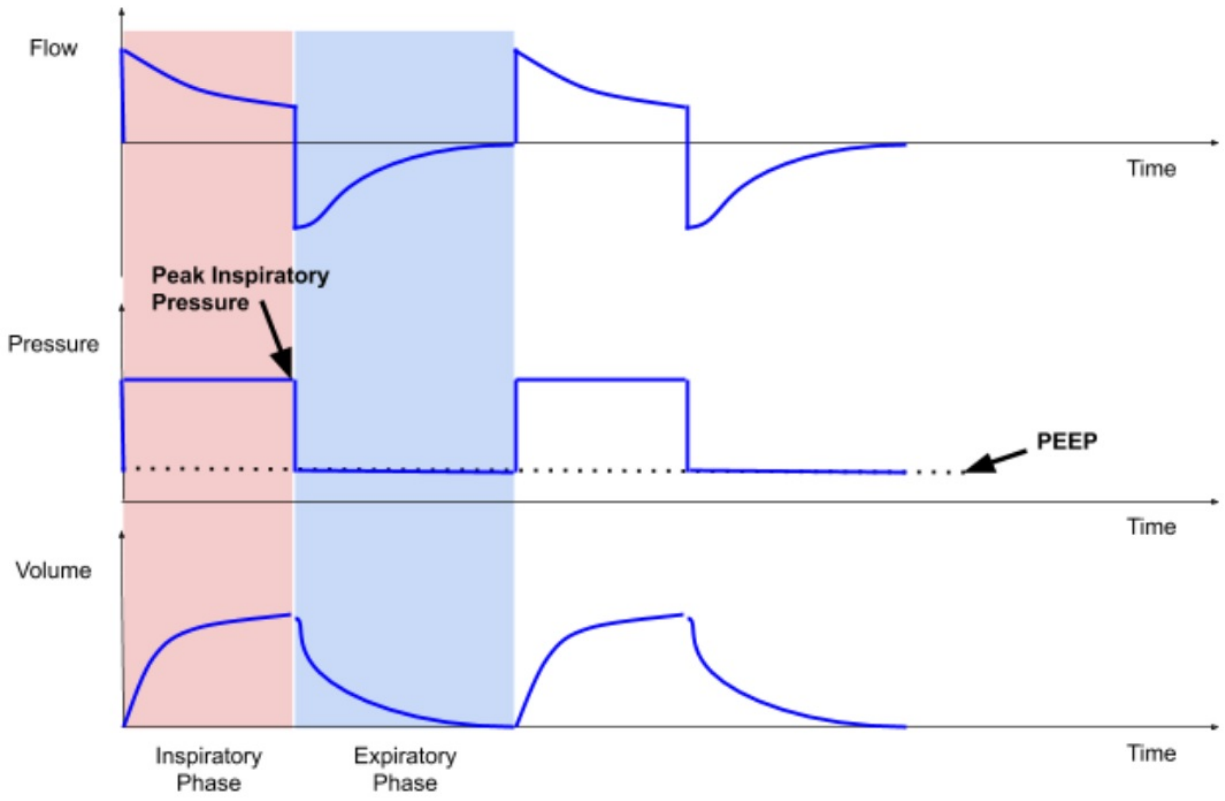

Figure 4: Flow, Pressure, and Volume profiles for pressure-control ventilation over 2 breath cycles; PEEP is illustrated again on the Pressure plot. Image courtesy AK.

The upper airway consists of some structures bypassed by something like an endotracheal tube, namely the mouth, nose, oropharynx, and trachea. The lower airway consists of the bronchi (left and right mainstem, which further branches into secondary and tertiary bronchi, bronchioles, and alveoli). Compliance is also affected by the type of lung disease, grouped into restrictive or obstructive types, each further divided into extrinsic and intrinsic types. COVID-19 patients who develop ARDS have an intrinsic, restrictive disease which requires additional baseline pressure to help "prop" open alveoli to maintain gas exchange. This is achieved by positive end-expiratory pressure (PEEP).

Inspiratory phase start: time / pressure / flow triggering

Inspiratory phase can either be set to start at a regular interval by locking in a constant respiratory rate (e.g. time triggering) or have the ventilator sense the patient's native inspiratory effort (with a pressure or flow sensor on the circuit), and time the start of the inspiratory phase according to the patient's effort. This is analogous to oxygen pulse devices used by acrobatic plane pilots. Modern ICU ventilators can be set to trigger based on thresholds of flow (e.g. 1–4 L/min) or pressure (e.g. -1 to -5 cm H20) to initiate breaths. These are either inherent to a specific built-in ventilation mode (SIMV, PS, CPAP, etc; outside the present scope), or set by the clinical operator (respiratory therapist, nurse, CRNA, physician, etc).

Here, it should be noted that there is a difference between ICU ventilators and OR ventilators: ICU ventilators tend to be more advanced and are designed to care for patients who may require support for days, or weeks. OR ventilators are simpler and generally used on healthier patients for shorter periods of time (minutes to hours).

Expiratory phase start: time / volume / flow / pressure cycling

The start of the expiratory phase can be determined by different variables: time, volume, flow, and pressure. Inspiratory phase duration can be programmed and expiration starts immediately after the time for inspiration is complete; this is called "time cycling." In volume control, inspiration stops after the target inspiratory volume has been delivered; this is called "volume cycling." When inspiratory flow can be sensed, mechanical ventilator breath can switch from inspiration to expiration when the inspiratory flow reaches 10–25% of peak inspiratory flow; this is called "flow cycling." Lastly, inspiration can be cycled into exhalation when a threshold pressure is reached. For instance, if a patient coughs and becomes asynchronous with the ventilator, the airway pressure increases dramatically. This can be dangerous to the patient as ventilation is not effective when the patient is "fighting the vent." In this state, the ventilator switches inspiration to the exhalation phase and usually concurrently triggers the high-pressure alarm. This is called "pressure cycling."

Additionally, in considering a single breath "cycle", the ratio of time spent breathing in (inspiratory) vs. exhaling (expiratory) is important to consider as more time is required to fully exhale and prevent over-inflation (i.e. breath stacking or auto-PEEP). Inspiratory phase duration can be adjusted by altering the inspiratory to expiratory (I:E) ratio on the ventilator when a specific respiratory rate (bpm) is being used.

Positive end-expiratory pressure (PEEP) is applied in order to maintain an 'open lung',

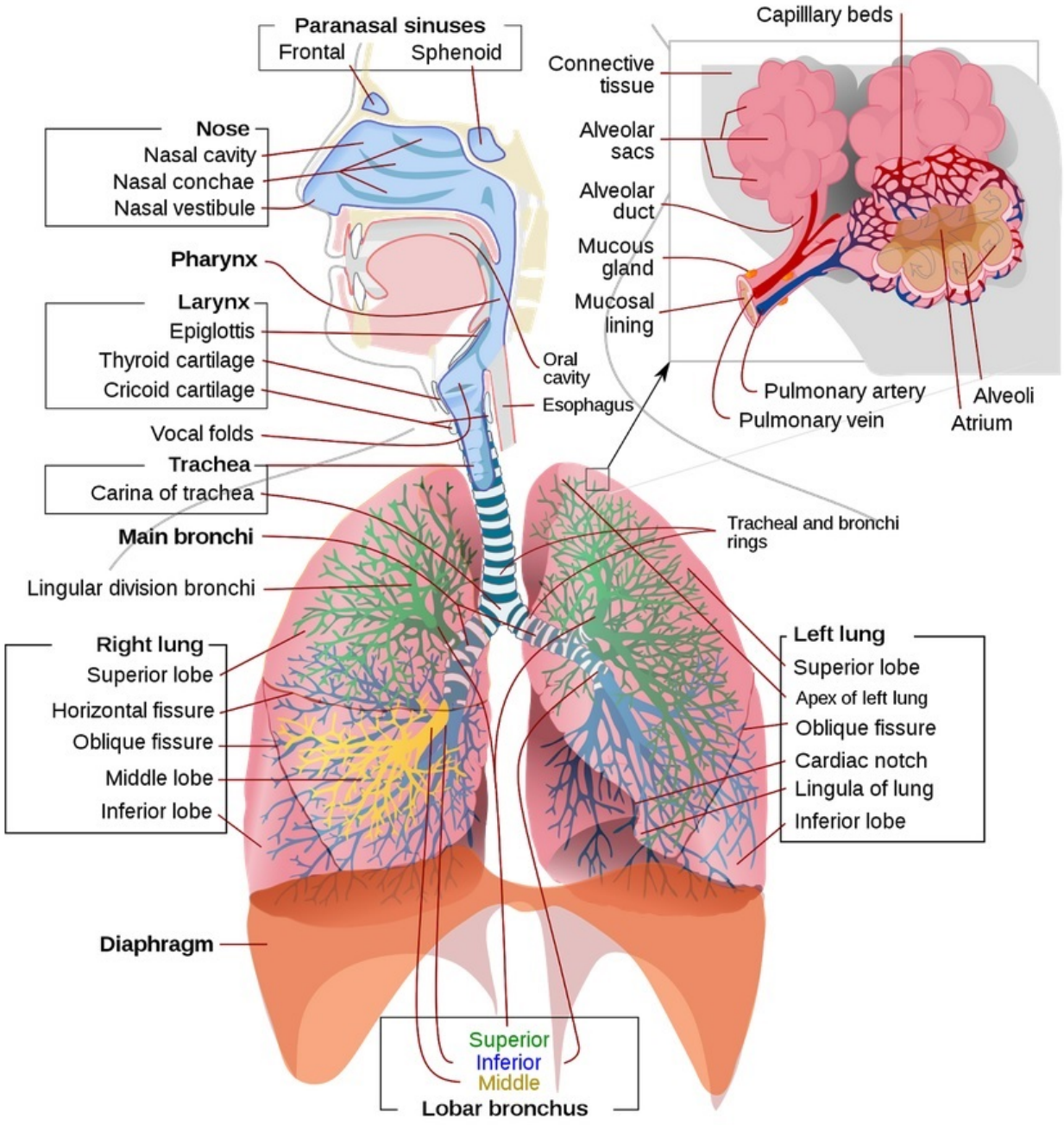

Figure 5: Upper and lower human airway anatomy (Image courtesy Wikimedia Commons)

prevent alveolar collapse and thus improve gas exchange and minimize atelectrauma (repeated opening and collapse of alveoli "atelectasis" can also cause damage; the result of which is referred to as atelectrauma). In addition, due to the inhomogeneity of the lung tissues, positive pressure ventilation may lead to regional overdistention of alveoli (volutrauma and barotrauma), which can impair gas exchange and possibly further injure the diseased lung. The regional differences in lung compliance are dynamic and significantly change throughout a patient's hospital course.

Depending on whether the patient or the machine determines each of the above parameters, different ventilatory modes are created. Some examples include volume control, pressure control, assist control, pressure support, SIMV, and spontaneous modes. Full-feature ICU ventilators have other ventilatory modes available that better serve longer-term mechanical ventilation strategies.

4.4.1 Minimum Parameter Set

An automated mechanical ventilator should initially operate in volume control mode, with an initial rate, adjusting minute ventilation as the patient's homeostasis is optimized with vital signs and lab draws. We envision two versions:

1. Volume Control: closed-loop delivery of a given tidal volume; closed-loop implies airway pressure sensing use for safety.
2. Assist Control: the system will sense airway pressure fluctuations, and supports patient-initiated breaths, and then recognizes and allows exhalation.

In the simplest implementation, the system will be tuned using direct clinical observation and laboratory studies. This can serve as a transient device (e.g. for transport or bridge to more advanced ventilator) or as a definitive ventilator once demand outpaces available resources.

The minimum required hospital-supplied components are below, and harnesses existing infrastructure to increase scale-ability:

1. Manual resuscitator "Ambu" bag: different configurations; it is recommended that a pop off (pressure release) valve and PEEP valve (listed in alphabetical order, with no preference given for any model) are included in any circuit. Suggested models include:
    - Ambu SPUR II Disposable Resuscitator (need to purchase PEEP valve adapter separately)
    - CareFusion AirLife Adult Disposable Self Inflating Resuscitation Device (need to buy PEEP valve adapter separately)
    - Teleflex Lifesaver Disposable Manual Resuscitator (Catalog #5374; pop-off valve and PEEP included)
    - VBM Germany PVC Resuscitator Set (40 cm H2O pop off valve and PEEP valve included)
2. PEEP valve can be purchased separately if needed:
    - Ambu PEEP Valves
    - CareFusion AirLife Adjustable PEEP Valves
3. Endotracheal (ET) and/or Tracheostomy tubes:

    - Follows ISO standards and have standardized connectors
4. Proper breathing circuit with proper valve mechanism at the patient end to minimize dead space and rebreathing of CO2
5. Short flexible connector to connect end of breathing circuit to ET/trach
    - AirLife Omni-Flex Patient Connector
6. Oxygen / Air mixer if available (to adjust FiO2)
7. HEPA filter to remove virus particles from expired gases (optional; likely not required if patient is in isolation).
    - Thermovent HEPA Low Deadspace Heat and Moisture Exchange Filter