Version 3-E-Vent

Contents

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

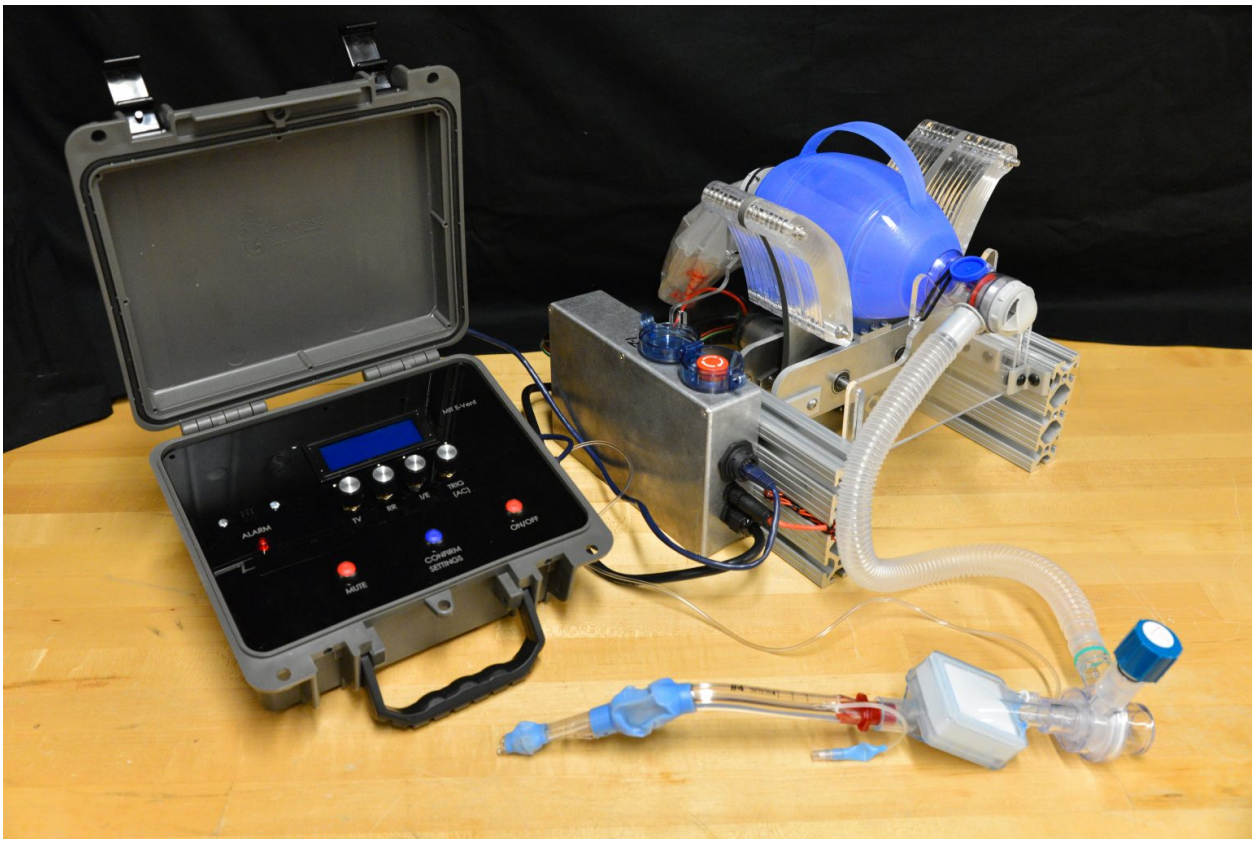

Figure 1: MIT E-Vent Version 3 showing control box and full setup

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

MIT E-Vent Version 3 showing control box and full setup 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. We have just posted essential safety information on removing dead space.

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

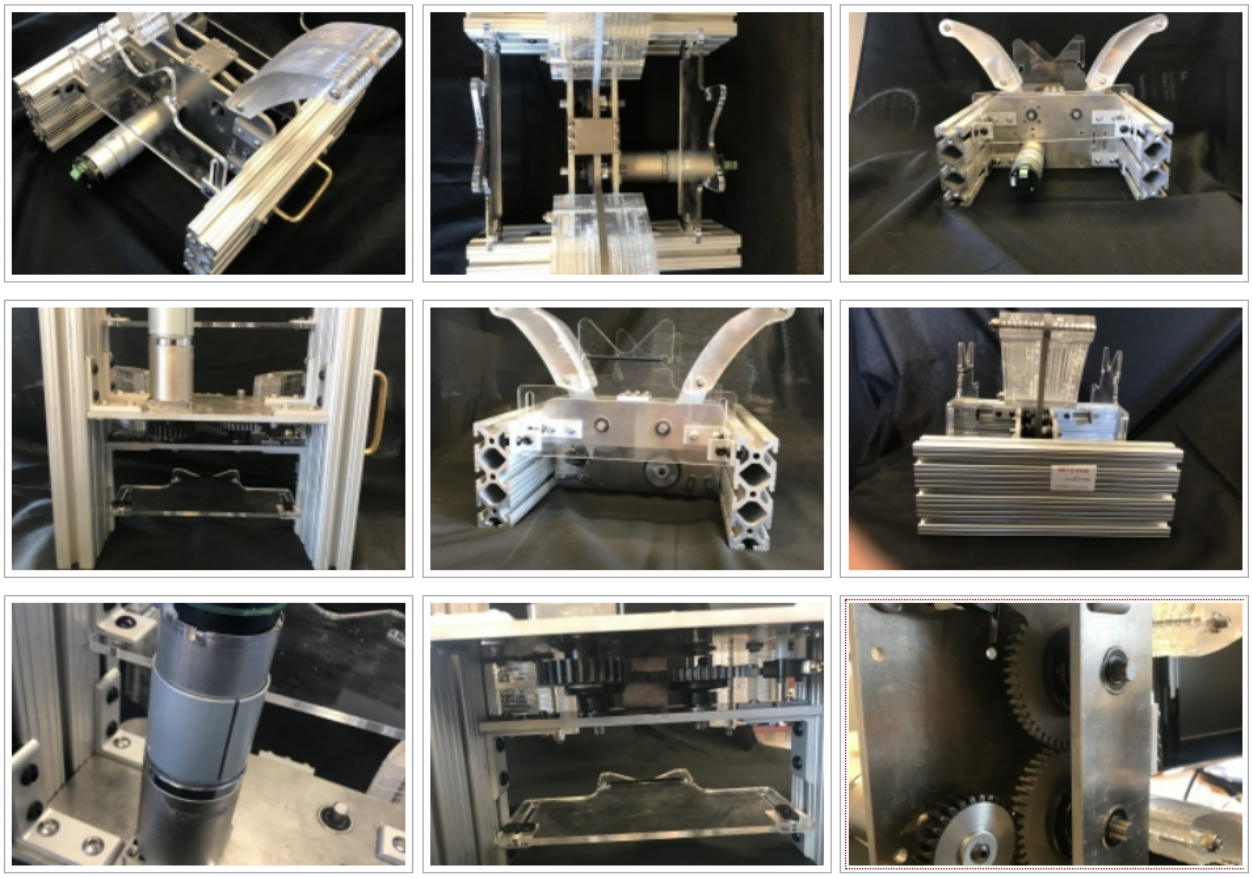


Figure 2: Collage of all hardware views

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

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.

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

- 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 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.

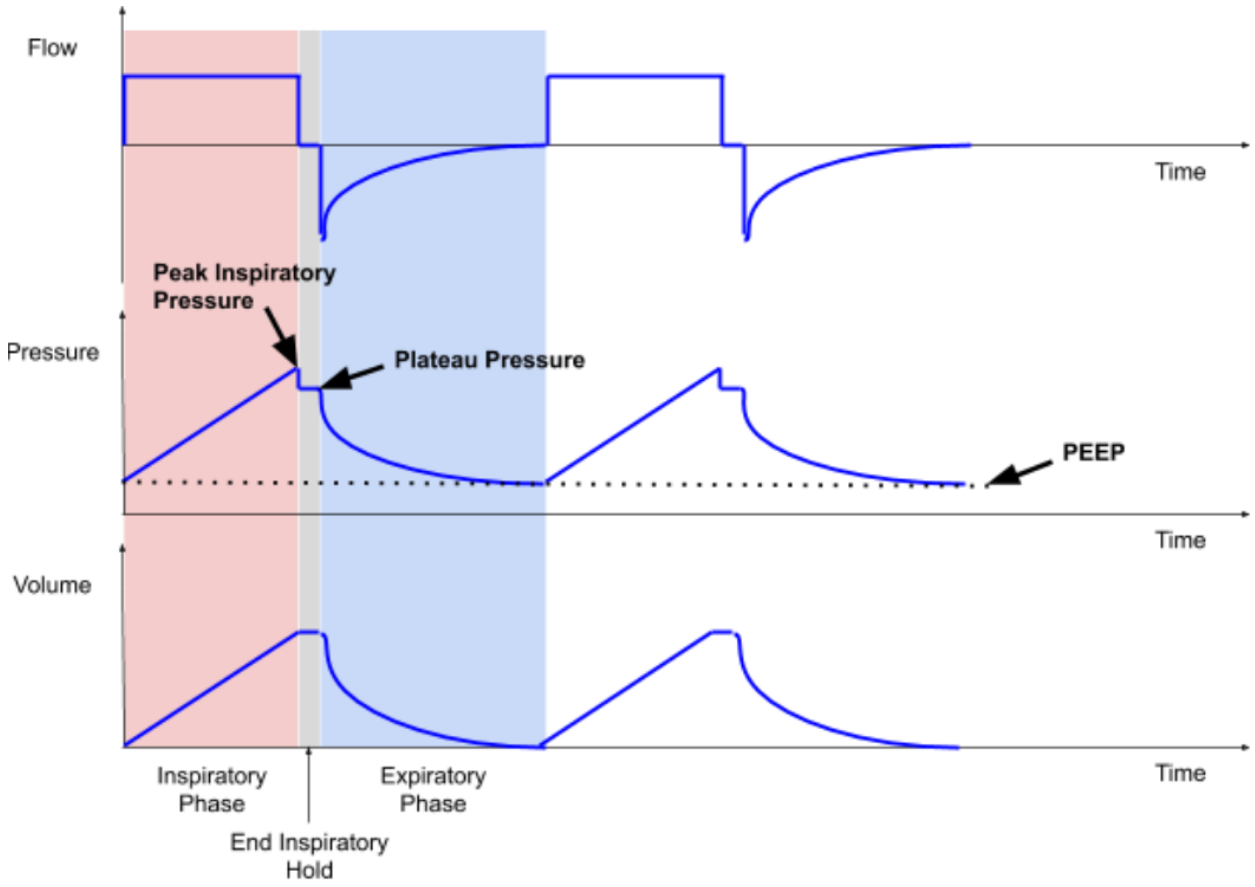


Figure 3: Flow, Pressure, and Volume profiles for volume-control ventilation over 2 breath cycles; PEEP is illustrated on the Pressure plot. Image courtesy AK.

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.

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,

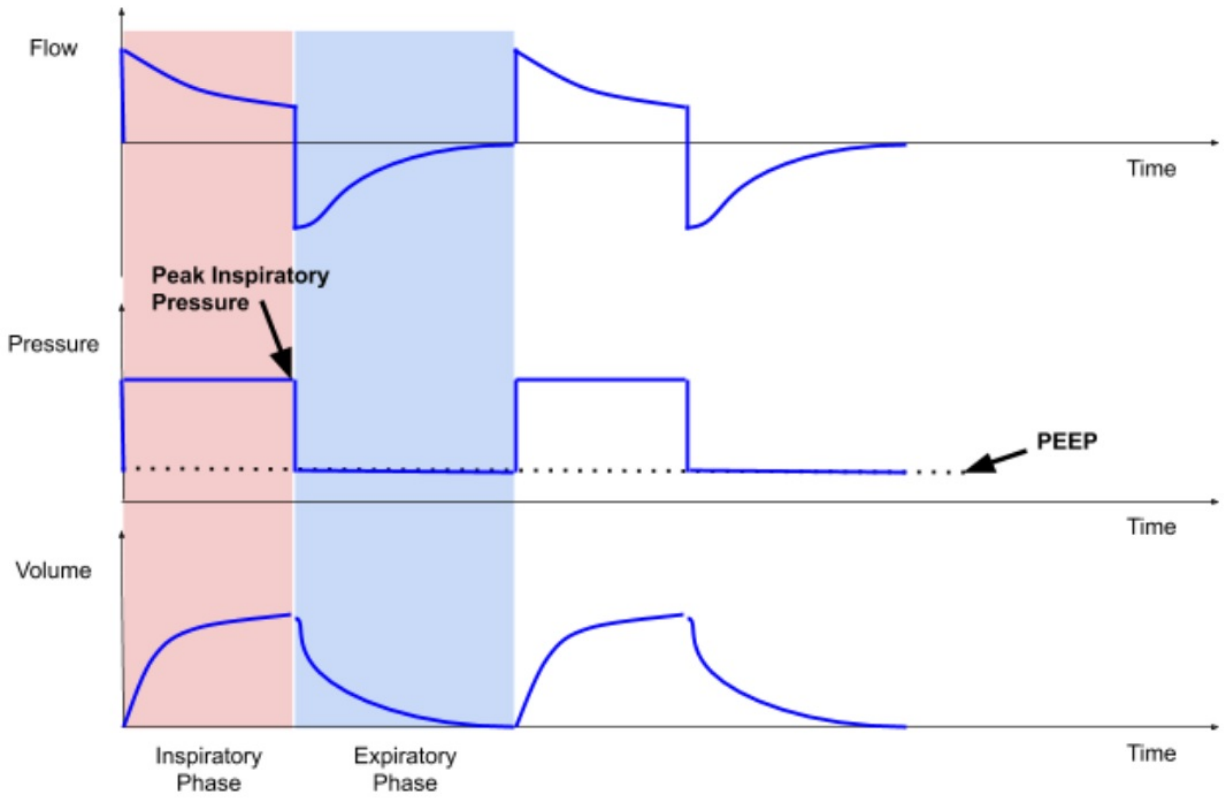


Figure 4: Flow, Pressure, and Volume profiles for pressure-control ventilation over 2 breath cycles; PEEP is illustrated again on the Pressure plot. Image courtesy AK.

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', 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,

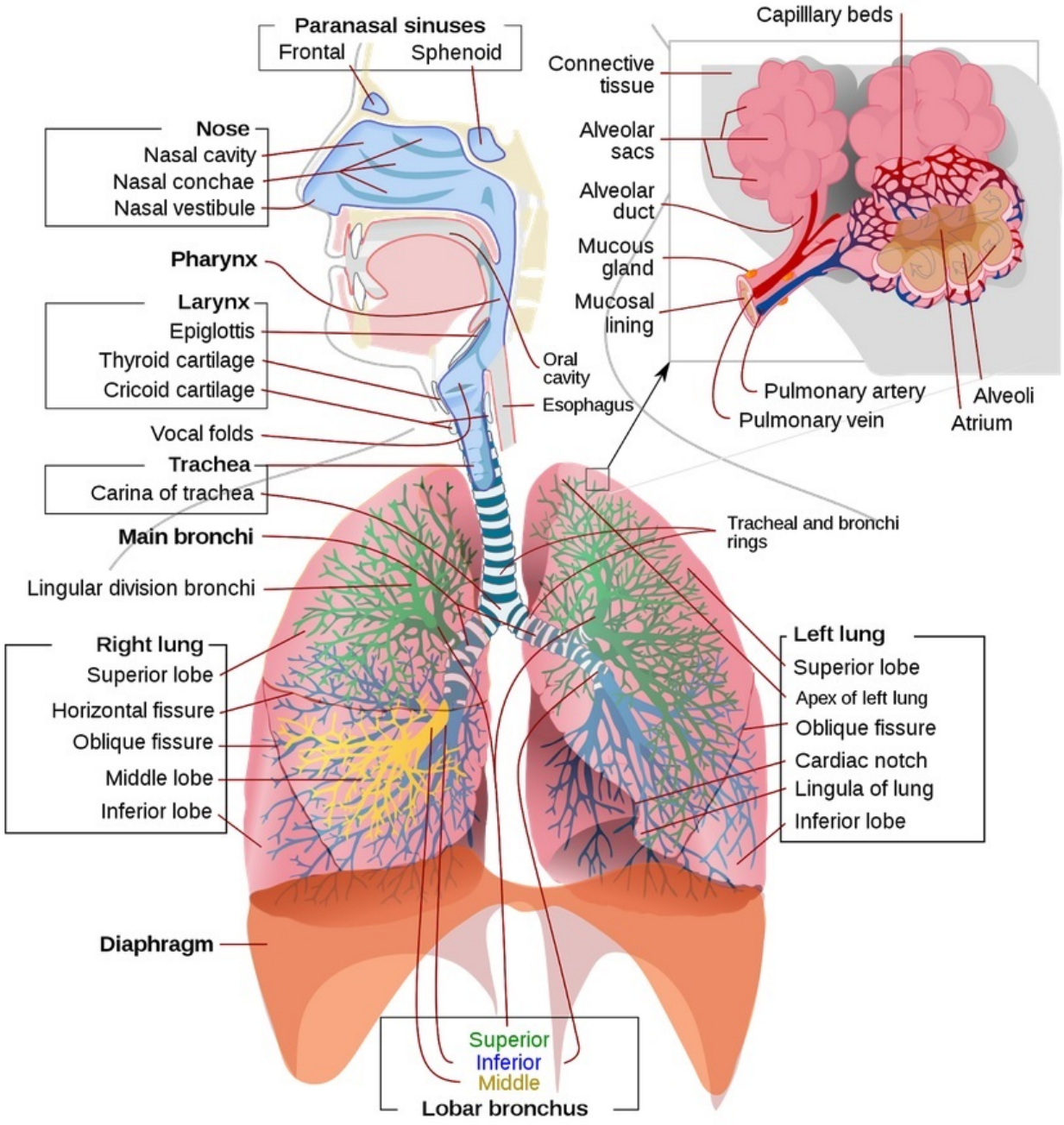


Figure 5: Upper and lower human airway anatomy (Image courtesy Wikimedia Commons)

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

5 Mechanical

Updated 15 April 2020

This section documents the mechanical design of the MIT E-Vent.

Note: Any mechanical design must meet the specifications outlined in the Key Ventilation Specifications section.

We are in process of continually testing and refining our prototypes to increase robustness. The basic concept consists of two arms that gently close in sync to compress the bag. This must be coupled with a closed loop control system. Major mechanical design requirements include:

- Be nice to your bag and its hoses – Up to 7 day X 24 hour X 60 minute X 30 bpm X 2 stroke = 604,800 cycles will be needed for 7 day usage. Any design must secure the bag and gently grasp and squeeze it from both sides to reduce the risk of material fatigue. The grippers must be smooth and shaped to maximise air expelled without damaging the bag. The bag must be supported with flexibility to allow motion during operation.
- Fail-Safe operation – If the machine fails, a clinician must be able to immediately shut down, open the device manually, remove the bag and convert to manual bagging.
- Keep It Simple – Empower and support others to fabricate. We are focusing on the lowest specification system and open-souring our design information for adaptation to local supply chains.
- Multiple drive motor and sensing possibilities! Enable multiple configurations to meet local supply chain capabilities. The overall dimensions and operation are now set and any skilled mechanical designer will be able to execute this design and adjust it to suit locally available materials and fabrication technologies. We have ready access to waterjet and laser cutters and 80/20 components, however we are now focusing on designs that can be CNC milled, stamped, molded, welded and bolted as per your supply chain and capability.

Version 3.1 herein is our most recent prototype design. Older prototypes are available in Past Designs.

Version 3.1 – Testing / Pre-Production

- Big gear (bottom of arms): 16 pitch, 48 tooth, 3 in. pitch dia., 14.5° pressure angle, 0.25 in thick.
- Pinion dear (driving): 16 pitch, 30 tooth, 1.875 in. pitch dia., 14.5° pressure angle. 0.5 in thick – this is to accommodate axial misalignment with the arms' gears.

- Gear ratio: 1.6 (arm/pinion)
- Based on the estimated torque (τ) of 10 N-m per arm, given in Power Calculation, divided by the gear ratio, we arrive at 12.5 N-m applied to the pinion of diameter (d) 0.0476 m (1.875 in) with pressure angle (ϕ) of 14.5° the net radial load (F) on the pinion is given by: F = $2\tau/(\cos(\phi)\text{d})$ = 2*12.5/(cos(14.5)0.0476) = 550 N.
- Also, for a handy diagram see Engineer's Edge.
- This radial load is applied to the pinion approximately 2 cm from the face of the gearbox which results in a bending force on the on the gearbox shaft that must be withstood by the gearbox bearings. Consult your motor manufacturer.
- We have created a Gear Torque and Speed Estimator Spreadsheet, available in src folder.
- Material choice is extremely important – we prototyped, based on the materials readily available in the shop. Arm gear and driving pinion life must be checked for wear and fatigue, as a function of your material selection and width of parts. (Note: this is an oscillating load with force on the in stroke, while the return stroke is nearly unloaded.)
- Aluminium is not recommended. We recommend steel gears, but not stainless as this will gall/spall. Hardening the steel gears and adding lubrication will increase life.
- We have created a Gear Stress Estimator Spreadsheet, available in src folder.

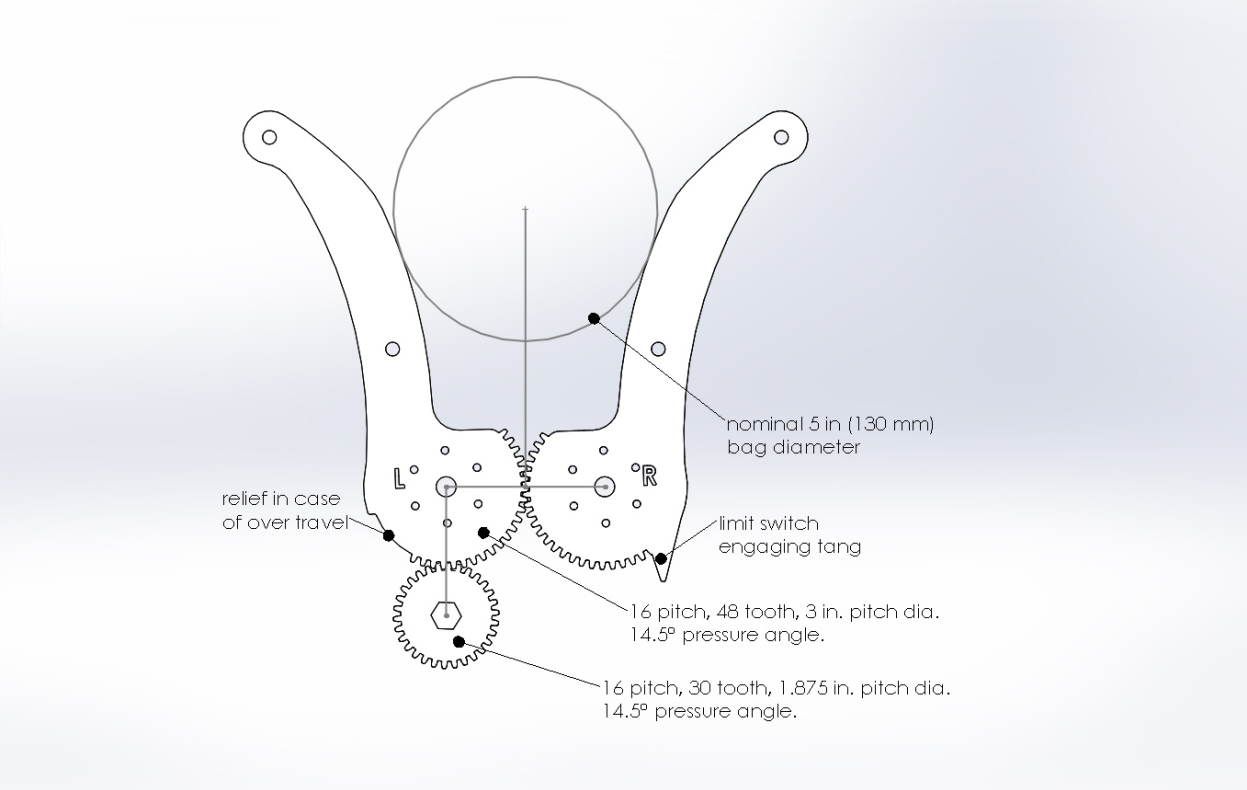


Figure 6

5.1 Power Calculation

Updated 13 April 2020

This page provides an estimate of the maximum power required by a motor used to compress an Ambu bag using a double gripper design, actuated from the bottom. Different designs, with other actuation methods, will change motor specifications, but the power should stay approximately the same.

Caution: Many designs circulating on the internet significantly underestimate the pressures needed to inflate a subject's lungs. There is a reason why the diaphragm is a large muscle. However, adding more power without great care is equally dangerous. In addition, COVID-19 compromised patients may require more aggressive motion profiles, i.e. short, quick breaths and longer exhalation times. In specific, clinicians are reporting I:E ratios of 1:4 in COVID-19 patients. (Our estimates use 1:4.)

5.1.1 Theoretical Power Requirement

Independent of the mechanical design of the gripper, the required power output can be computed from the worst-case values of the following variables:

Maximum pressure at airway: $P_{airway,max} = 40$ cm H_2O (pop off cracking pressure) Maximum respiration rate: $RR_{max} = 40$ bpm Minimum inhale/exhale ratio of 1:4: $IE_{ratio,min} = 4$ Maximum volume output: $V_{max} = 800$ cm^3

That is, in the worst case the device needs to squeeze of air at a pressure of 40 cm H_2O , in a 0.3 second t_{inhale} = 60 sec / RRmax / (1 + $IE_{ratio,min}$)).

The volumetric flow rate needed in the worst-case (peak) scenario is (eq. (1)), then:

$$Q_{airway} = V_{max}/t_{inhale} = 0.0027 m^3/s \tag{1}$$

The power output (in the form of pressurized volume flow in the airway) is:

$$Power_{airway} = P_{airway,max} \tag{2}$$

$$Q_{airway} = 10.46W \tag{3}$$

However, some of the power used for squeezing the bag is lost (bag deformation, friction, etc.) and let's estimate that 50% is converted to pressurized volume flow. Taking this efficiency into account, the power required at the gripper is:

$$Power_{gripper} = 2Power_{airway} = 20.92W \tag{4}$$

The actual power needed from the motor will be higher, how much higher depends on the mechanical and electrical designs. Assuming half the power output of the motor is lost to mechanical and electrical inefficiencies (gears, thermal dissipiation, etc.), the power output required from the motor is given by:

$$Power_{motor} = 2Power_{gripper} = 41.84W \tag{5}$$

5.2 Power requirement for 2-finger design

This is an alternative approach to calculating power.

The following is an illustration of a 2-finger gripper design:

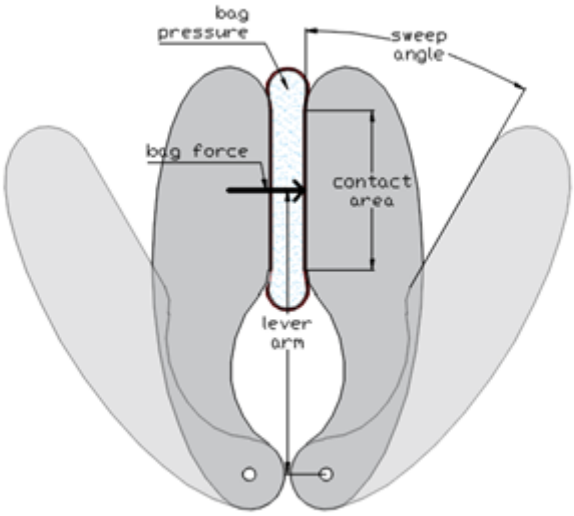


Figure 7

A more direct approach can be used for this design provided the following quantities can be measured:

- Finger-bag contact area
- Finger lever arm length
- Sweep angle

For one particular prototype, we have:

- Finger-bag max contact area: Abag = 90 mm x 115mm
- Finger lever arm length: lfinger = 12 cm
- Sweep angle: $\alpha_{sweep} = 30°$
- The maximum force of the bag on one finger (when fully squeezed) is, using the same 50% pressure transmission efficiency as before:

$$F_{finger} = 2A_{bag}P_{airway,max} = 81.199N \tag{6}$$

The maximum torque needed on each finger is then:

$$\tau_{finger} = F_{finger} l_{finger} = 9.74 N.m \tag{7}$$

Now we can compute the power required for the two-finger gripper using the sweep angular rate (in 0.3 second):

$$P_{gripper} = 2 \times \tau_{finger} w_{finger} = 34.01 W \tag{8}$$

The total power for the motor (assuming a single motor) when additionally applying the same 50% motor and gearbox efficiency, we get:

$$P_{motor} = 2 \times P_{gripper} = 68.03 W \approx 70 W. \tag{9}$$

5.2.1 Benchtop Validation

During testing of a 2-finger gripper design, E-Vent Unit 3.1, equipped with an Andy Mark motor am-3656 (188:1 gearbox) we observed under normal operations a peak current of about 5 A at 12V or 60 W.

5.2.2 Recommendation Minimums

The minimum motor power is approximately 70 W. Therefore, a power supply at 12 V should be specified with a minimum of a 5.8 (~6 A) supply.

Caution: The torque required of the motor will be a function of whether the arms are driven directly or with a driving pinion. It is essential to consult your motor curves and apply a safety factor.

5.3 Motor Selection

Updated 15 April 2020

This page describes our best information to date regarding selecting motors.

5.3.1 Motor & Encoder

- The mechanical system should be driven with a motor under closed loop control. For feedback measurement, we are using a DC gear motor with integrated quadrature feedback.
- Prototype component: Andy Mark AM 3656 188:1 gearmotor with encoder. This was scavenged from a FIRST Robotics kit and we are using it in test applications. This is provided as an example, builders must use their supply chain to identify correct motors for their application.

- Motor Options: Brushed DC motor with gearbox and position feedback. Any sufficiently high-torque, back-driveable motor with angle sensing, integrated or separated, should work.

Note: The motor and mechanism, together, must be back drivable in order to move the mechanism by hand, remove the bag and immediately convert to manual bagging. It is not ideal to back drive gear motors, but this is primarily for use in a fault condition.

5.3.2 Stepper Motors? – hard

Stepper motors are best suited for precision motion control where the motion profile can be well defined, the load is constant and disturbances are limited. Industrial motion control and 3D printers are good examples.

Patients present a very different scenario where the load on the motor changes dynamically over short and long terms. With each breath the motor faces increasing resistance as the balloon (the patient) is inflated. Over time the patient's airway resistance and lung compliance can also change. There is no straightforward way to close a PID loop around a stepper; fundamentally it is designed to run open loop. More complicated control strategies can be employed.

Caution – If a stepper motor is used, position must be taken from an angle sensor so that missed steps do not cause position drift and failures to reach desired tidal volume are not detected and responded to.

5.3.3 Operating Parameters

Understanding the best way to care for COVID-19 patients is changing daily.

These are our best, current working specifications. Be sure to apply your own safety factors, recommended 2x.

In advance, we apologise profusely to our international colleagues for using English units and gears. It's hard to undo this decision at this point.

- Assumed nominal operating parameters: Referencing the most recent clinical documentation of max 40 breath-per-minute (bpm), up to a 1:4 I:E ratio and a pop off set to 40 H2O, our Unit 003 Design consists of:
- rom Power Calculation we estimated 10 N-m of torque required by each finger. Doubling this yields 20 N-m for the gripper. As described in Mechanical our Version 3 has a 1.6 (48/30 teeth) gear ratio yielding a desired motor torque of 12.5 N-m, which we round up to 15 N-m.
- Arm: Approximately 30° back and forth
- Two week operation minimum: approximately 1 million cycles, 100% duty.

- Quadrature encoder integrated (ours provides 7 pulses / rev of motor shaft). This is integrated with the base of the motor so that it does not respond to any backlash in the system.
- The radial force on the gearbox shaft is estimated at 530 N, as described in Mechanical. This is applied by the pinion approximately 1 cm from the face of the gearbox; thus bending on the output shaft must also be considered.
- We have created a Gear Torque and Speed Estimator Spreadsheet, available in Downloads. ***Caution: In deployed use, the motor must be able to operate continuously for several days, 100% duty cycle. This may require larger motors than expected or increased motor cooling to prevent overheating.***

5.3.4 Windshield wiper motors? – maybe

We have investigated windshield wiper motors and they are NOT back-drivable, due to the worm drive, they lack integrated position sensing, nor can they necessarily take the shaft loads resulting from gear separation forces. People with access to automotive tier suppliers may be able to access better information.

Windshield wiper motors vary greatly in their specifications, so we cannot make general recommendations. If they are to be used, a mechanical arm release should be incorporated so that a bag can be instantly removed to facilitate instant conversion to manual bagging. The larger issue is the lack of position sensing – without this volume control is not feasible nor is safe ventilation even possible. Mechanical cams have been suggested, but they do not enable sufficient control of respiratory parameters to have any useful therapeutic effect. Encoders and potentiometers (POTs) can be used, but they should only be implemented by someone with experience in feedback control. They are a potential solution.

Shown below is a Toyota replacement wiper motor. From inspection we can see that it employs a tapered spline, with limited area for more traditional connections. While there are limit switches (three contactors) there is no accurate position feedback. From inspection of other models, bolt patterns, dimensions and connections vary widely. We hesitate to make any specific recommendations.

5.4 Plumbing

Updated 1 May 2020

This page describes critical design requirements of the patient breathing circuit. This details a key dead space issue, which if not addressed, will result in a patient breathing in expelled CO2 and deoxygenation fast with immediate adverse result. For a detailed primer on Breathing Circuits read Mapleson's Breathing Systems.

Normally, self-inflating manual resuscitators are directly connected to the patient's endotracheal tube adapter. Manual resuscitators have a "patient valve" that directs oxygen/air gas mixture into the patient and shunts the exhaled gas out to the environment. Integrated into the end bag valve mask (BVM) are a number of critical features:

Figure 8: Toyota wiper motor 1536x1152

- Oxygen connection and reservoir
- Pop-off valve for safety (location not important)
- One-way valve that guides air to the patient
- Exhalation valve (this stays closed while there is any pressure on the bag)
- PEEP valve that is installed post the exhalation valve and maintains backpressure
- Sensing port for manometer connection (we use this for our pressure sensor connection)
  Caution: Manual resuscitator bags are in no way FDA approved for use as long-term ventilation solutions.

Some considerations regarding how the patient should be connected to a manual resuscitator-based ventilator include:

- The ventilator must be placed as close to the patient as possible.
- Bag should be secured to ventilator to prevent an awake patient from pulling on it or otherwise disengaging the bag from the mechanism. This is a fault condition that should be detected by pressure sensing.
- Care must be taken to prevent rebreathing of CO2 due to long hoses. A fundamental challenge is the location of the one way and expiratory valves, which are typically directly integrated into the bag.

When a manual resuscitator is placed into an MIT E-Vent, or similar design, the system cannot be placed right up against the patient's head. In addition, patients need to be turned intermittently for routine care and patients can thrash and move in their beds. Even when patients are paralyzed, the paralytic may wear off at times and we must consider how to keep the patient safe from inadvertent breathing circuit disconnection or extubation. Therefore, a safe method to extend the "reach" and flexibility of the manual resuscitator to a patient lying on a hospital bed is needed. If a simple tube is used to do so, it creates a critical safety concern of "dead space."

Note: In a 1 m long tube of nominal 2 cm diameter, there is an unacceptable 314 mL dead space that the patient will breath in and out and not be oxygenated.

Dead space simply means volume in the respiratory circuit that does not participate in gas exchange in the lungs. Our natural anatomy has dead space as well. Considering gas exchange occurs at the alveoli in our lungs, every anatomical structure above it can be considered "dead space": nasal/oral passages, pharynx, larynx, trachea, and primary / secondary / tertiary bronchi. Extending the tubing through which bidirectional flow of inhaled/exhaled gas mixture occurs only increases dead space.

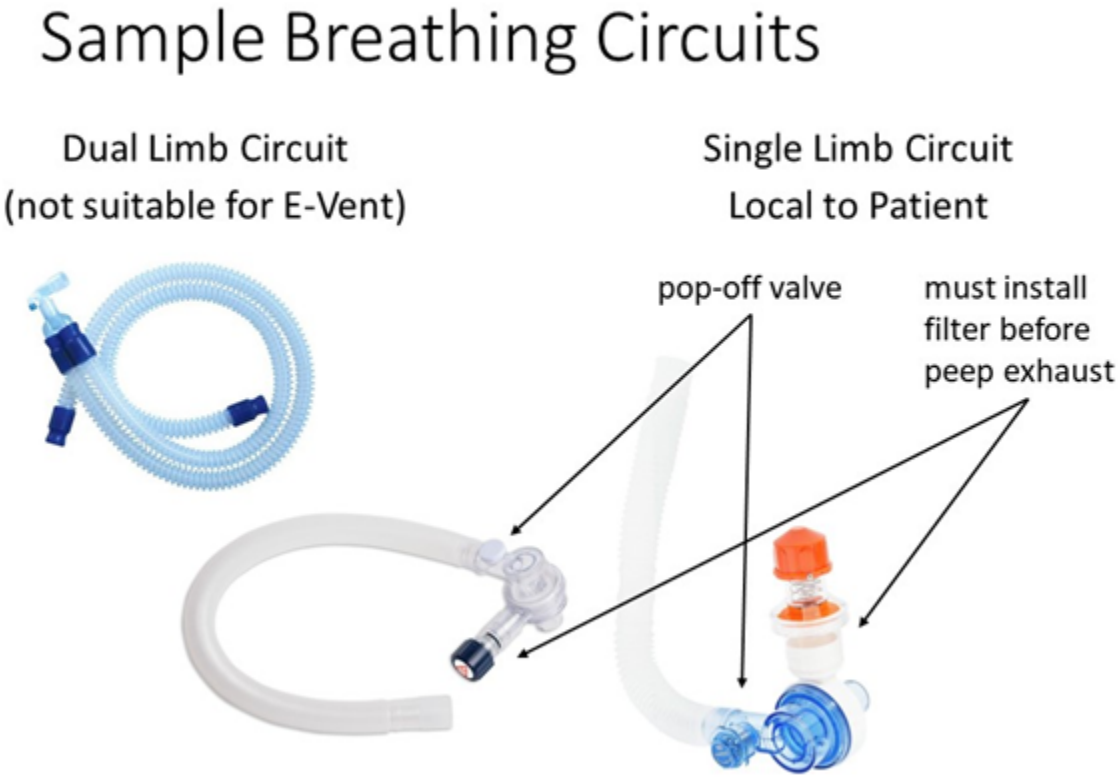
A way to move the patient valve of the manual resuscitator closer to the patient is critical in solving this issue. Standard ventilator circuits have two limbs, one for inspiration and one for expiration, so that gases can be recaptured by the ventilator. Single limb ventilator circuits with a patient valve located distally already exist on the market, but are not necessarily optimized for use with a manual resuscitator.

Note: Solving this problem requires creativity – to the best of our knowledge, no manual resuscitator manufacturer makes an approved solution and no manu-

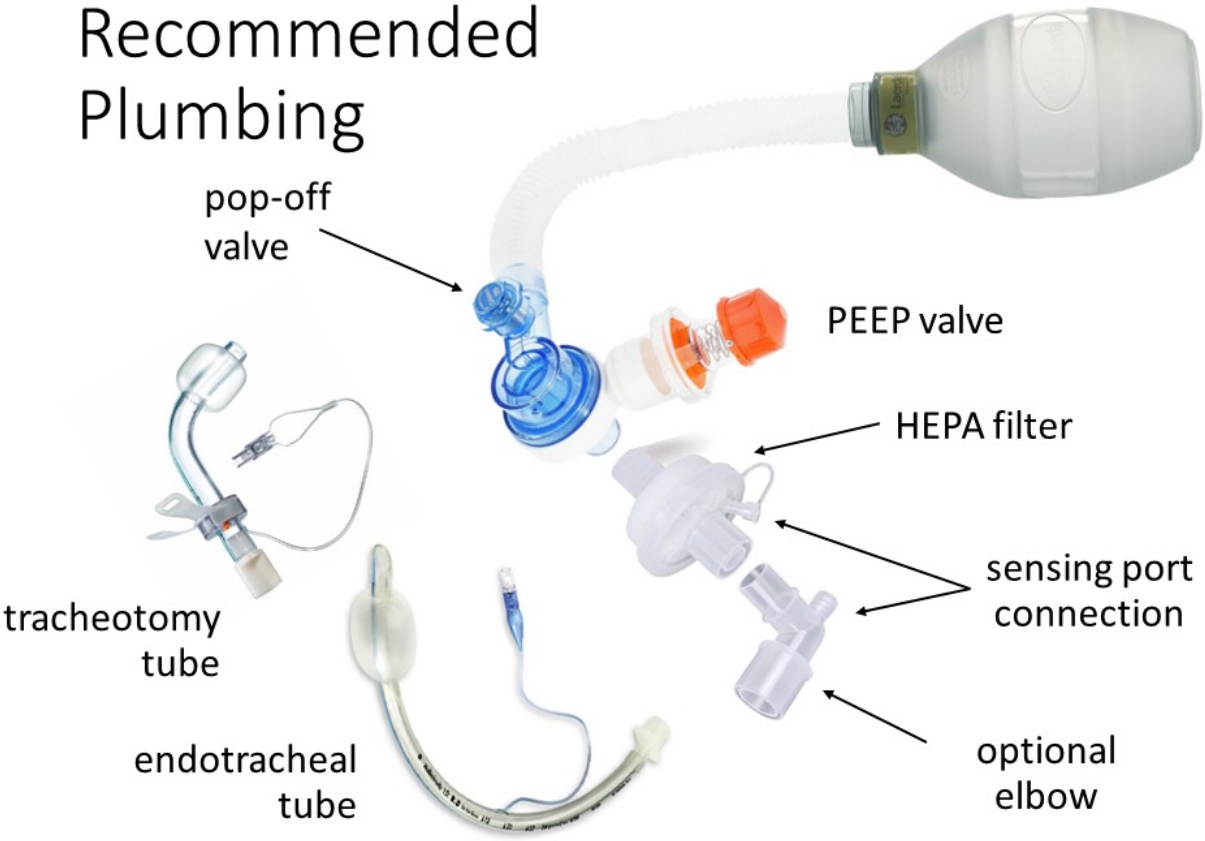

Manual Resuscitator Bag Features
sensing port
(required for monitoring)
pop-off valve (required safety)
PEEP valve
pressure gauge
connects to sensing port
oxygen
connection

Figure 9

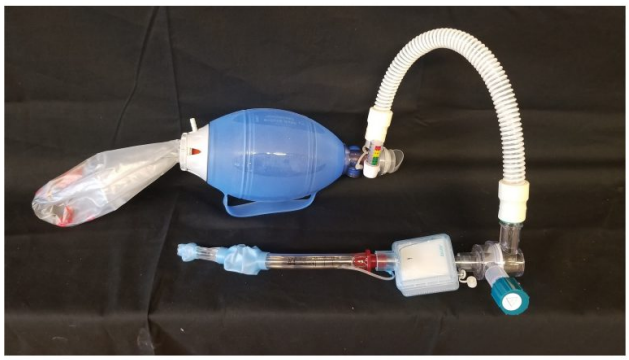
facturer makes all the parts that will assemble together correctly.

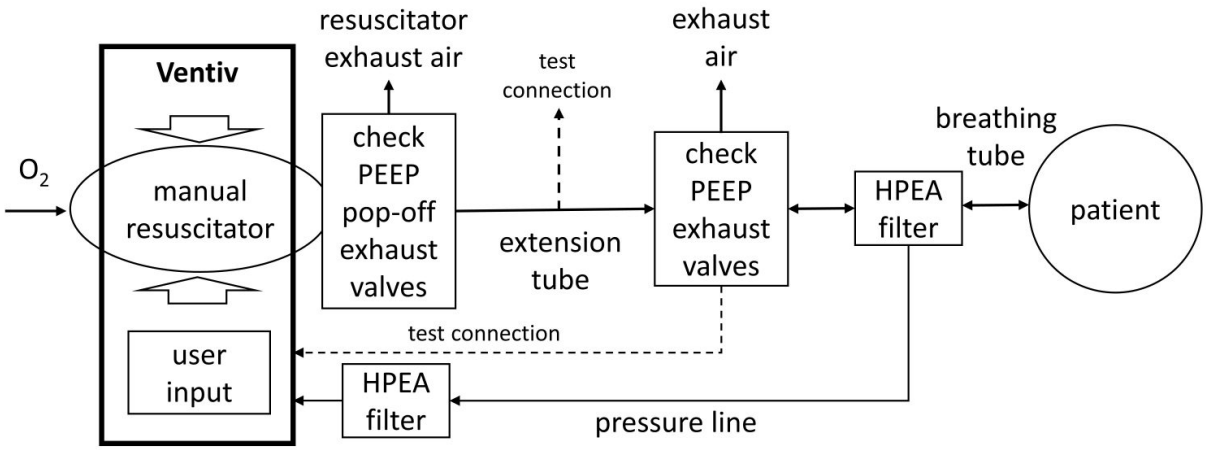


Recommended Plumbing



Full breathing circuit





This circuit shows our best assembled circuit with Ambu Oval Silicone resuscitator, manual analog pressure gauge, extension tube, additional patient valving, PEEP valve (green), HELP filter and endotracheal tube. Note, the patient valve on the bag serves partially on exhale, but is not involved in inhale and all air passes through the HEPA filter.

Note: Leaving a analog pressure gauge connected to the bag's unused sensing port (not on the end of the breathing circuit) provides a visual backup to quickly inspect system operation.

5.4.1 Industry Notes

In reviewing products available on the market, we have some notes:

No bag makers supply extension hoses with the appropriate fittings. Bags designed for reuse, i.e. autoclavable, are the only bags that can potentially survive under repeated use. We do not have any information about lifespan. Some Ambu bags do not have detachable heads, but they do incorporate pop-off and easily attached PEEP valves in their designs. They can only be used if extended with a separate head and extension tube. Ambu Mark 5 and Silicon Oval heads are detachable and may be available as parts. They have easily combined manometers and PEEP valves. Laerdal bags do have detachable heads, however in the adult sizes these heads do NOT come with pop-off valves; these are available in the Pediatric model. The

pediatric model head will probably fit the adult bag. When a long tube is used, without a dual limb circuit and one way valving to address the dead space issue, this may affect the volume delivered to the patient; it may be necessary to increase the inspired volume. Addition of the HEPA filter will cause a pressure drop and may affect PEEP settings. Tightness of all connections is important. Caution: In the worst-case scenario, placing the head as close as possible to the patient will reduce the dead space, but it is not an optimal or safe solution, especially for patients with reduced inspiratory volume.

5.4.2 Sample Circuits

Two versions of single limb circuits are shown below. The first uses readily available components and two printed adaptors to make them fit together, with the HEPA filter placed between the exhalation port and the PEEP. The second uses a single limb breathing circuit, with most of the necessary features integrated, and a HEPA filter added inline between the porcine and the breathing circuit. This is a better position as it filters air heading both in and out of the patient, including any air that escapes from the pop-off valve. It may also help to moisten air inbound to the patient.

Note: The best location, if you have only one filter, for it is between the endotracheal tube and the breathing circuit.

5.4.3 Dead Air – Additional Potential Solution

Our friends at the US Air project, an Oregon based group of fabricators currently scaling up, have dissembled Ambu bags and developed an adaptor, that demonstrates the feasibility of DIY circuits with a little feasibility.

Ambu has readily available complete patient valve assemblies, though limited information is available on their website. For example:

- Mk IV Ped (w/ pop-off and Mport) #299 000 508
- Silicon Oval (w pop-off and Mport) #470 000 503

The ideal solution is to order these valves, with a hasty solution being "harvesting" valves from disposable SPUR II units. Note: Valve is not replaceable from the bag once removed. This method places the pressure port in the correct position to monitor patient airway pressure.

Connecting these valves can be accomplished with na adaptor. All Ambu valve assemblies have a conical taper from injection molding that allows for a reliable adapter connector to be quickly fabricated. This adaptor can be 3D printed (fast, but sub-optimal), CNC milled with a sub 1 min cycle (in 6061) or injection molded (ProtoMold quote of $1.63 in 5000 volumes, in HDPE). A hose can now be used to connect this valve to an intact manual resuscitator. The extra valve assembly on the intact manual resuscitator should be inactive for practical purposes.

Caution: Care must be taken to ensure that connections are secure. Medical grade adhesive should be used.

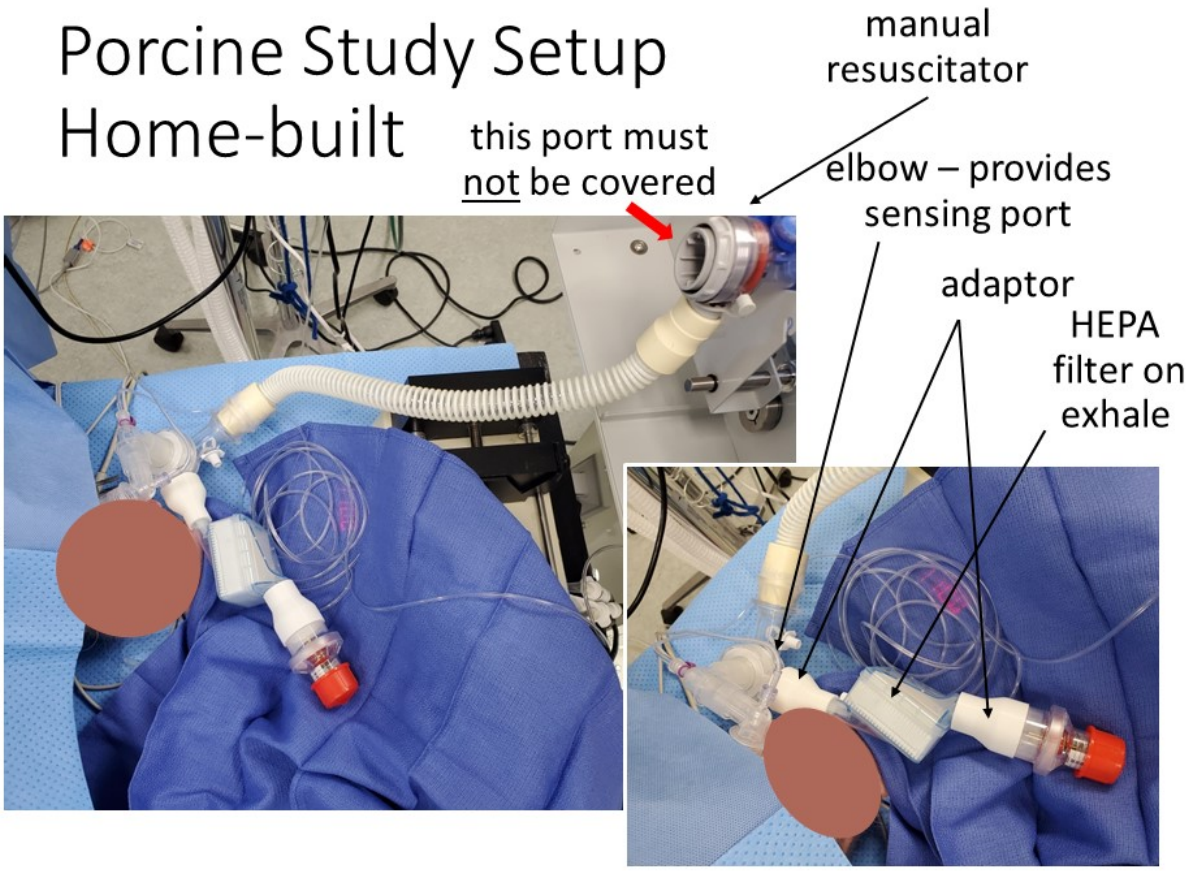

Porcine Study Setup
Home-built
this port must
not be covered
manual
resuscitator
elbow – provides
sensing port
adaptor
HEPA
filter on
exhale

Figure 10

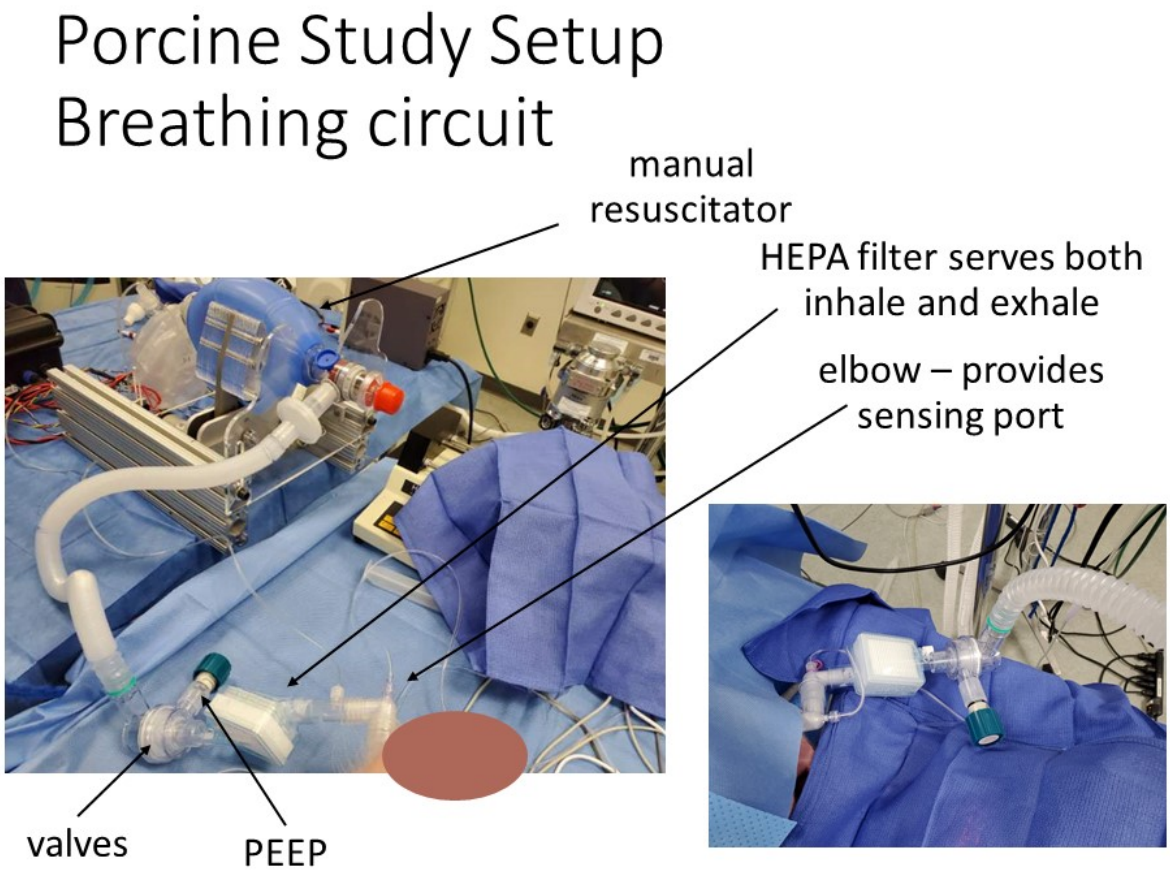

Porcine Study Setup
Breathing circuit
manual
resuscitator
HEPA filter serves both
inhale and exhale
elbow – provides
sensing port
valves
PEEP

Figure 11

Dead Air - Potential Solution

Adapt factory valve assembly to standard ISO 22mm/15mm Tube Fitting

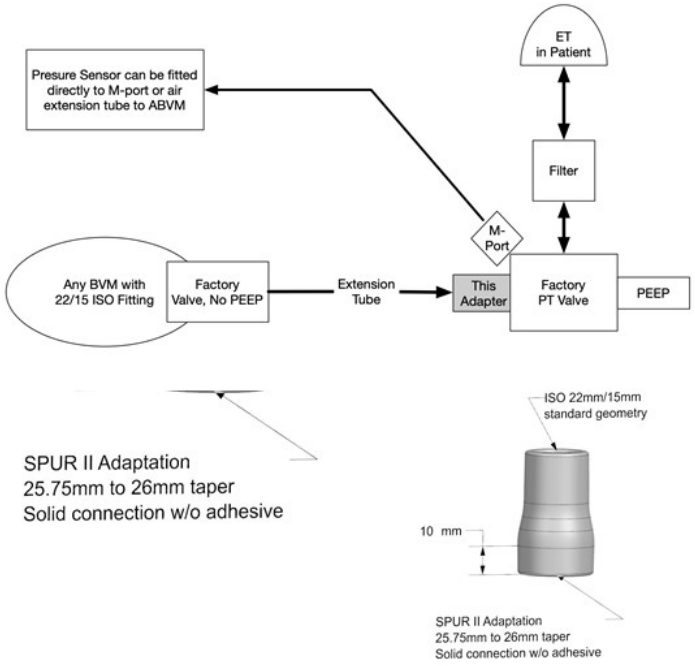


Figure 12

5.4.4 Bag Sizing

13 April 2020

This page details various bag sizes and why the bag supports in any design should be adjustable. The key is to find points on each bag that provide support and lateral constraint, but do allow the bag to flex as it is compressed. The bag should be centered laterally and vertically between the grippers. The table below gives dimensions at the contact points and the center of the bag. We place the bag with the bottom towards the motor and head, with patient valving, overhanging. Remember, this valving must be extended as described in the Plumbing section.

For practical purposes, spacing the bag mounts 21 cm apart should fit most bags, but the mounts must have vertical adjustability.

bag	distance	bottom ø	top ø	center ø
Ambu Spur II & Adult Silicon	21	61	29	129
Care Fusion	21	54.5	50	134
Laerdal The Bag	21	na	40	139
Portex	20.5	61.5	37	131

Figure 13

Below are pictures of each bag type that we measured, shown in Version 2: **Note: In Version 3 we added hooks and an elastic to prevent unintended bag removal.**

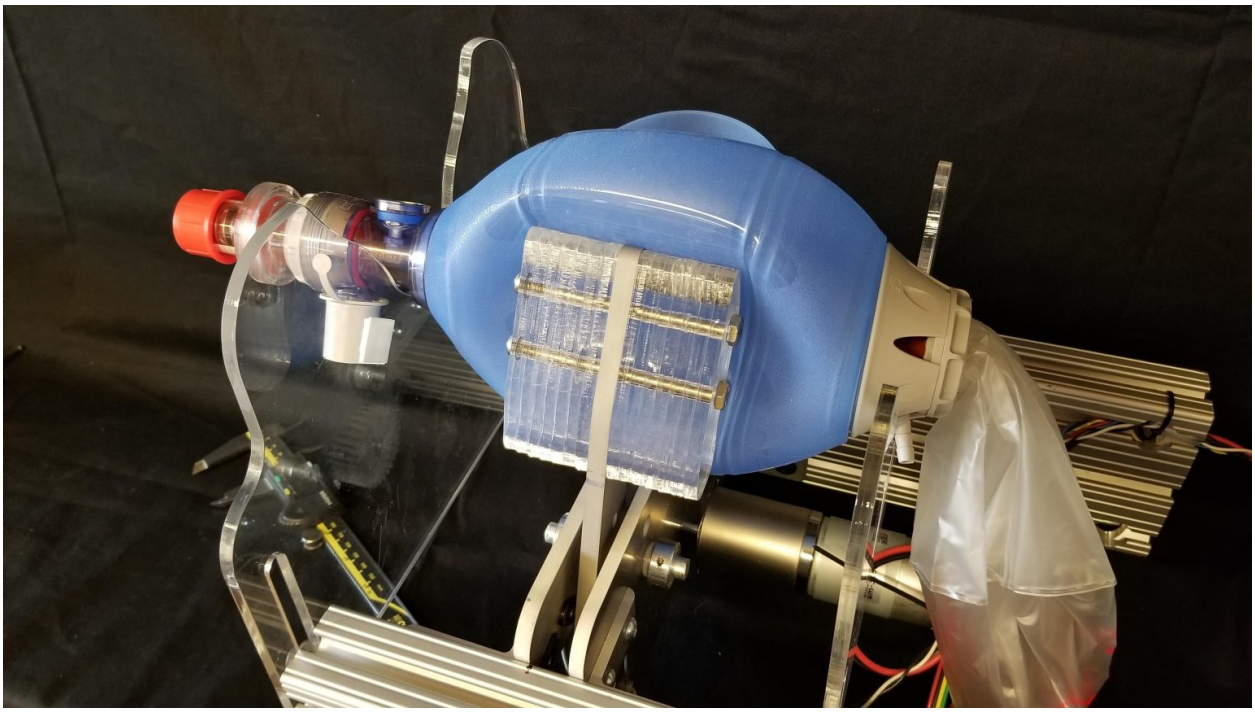


Figure 14: Ambu brand bag, note use of barb fitting to secure rear of bag

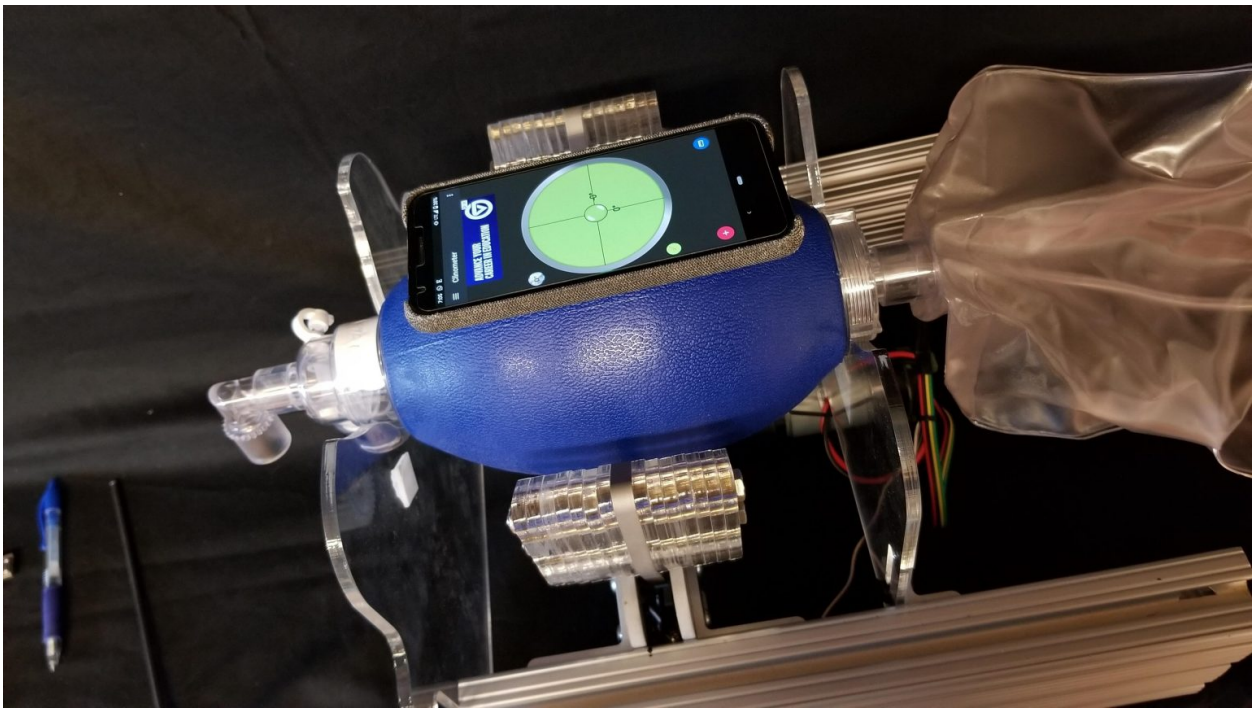


Figure 15: Using a phone level to position a Care Fusion bag

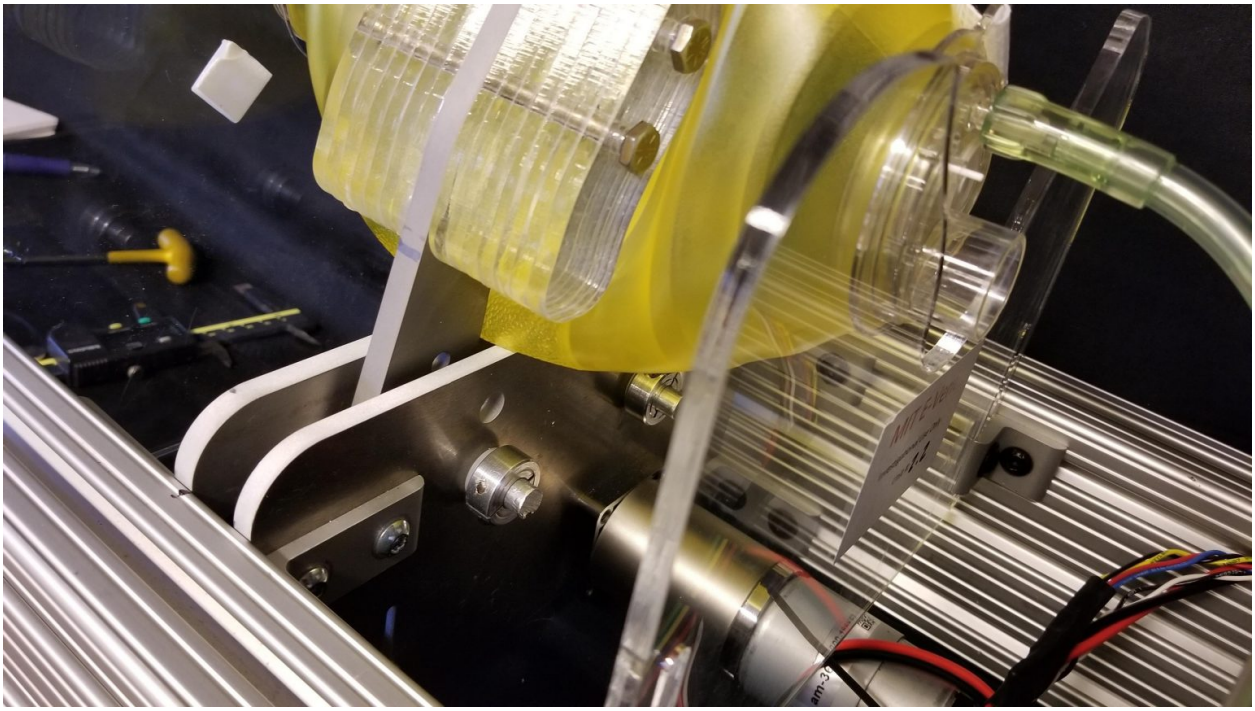
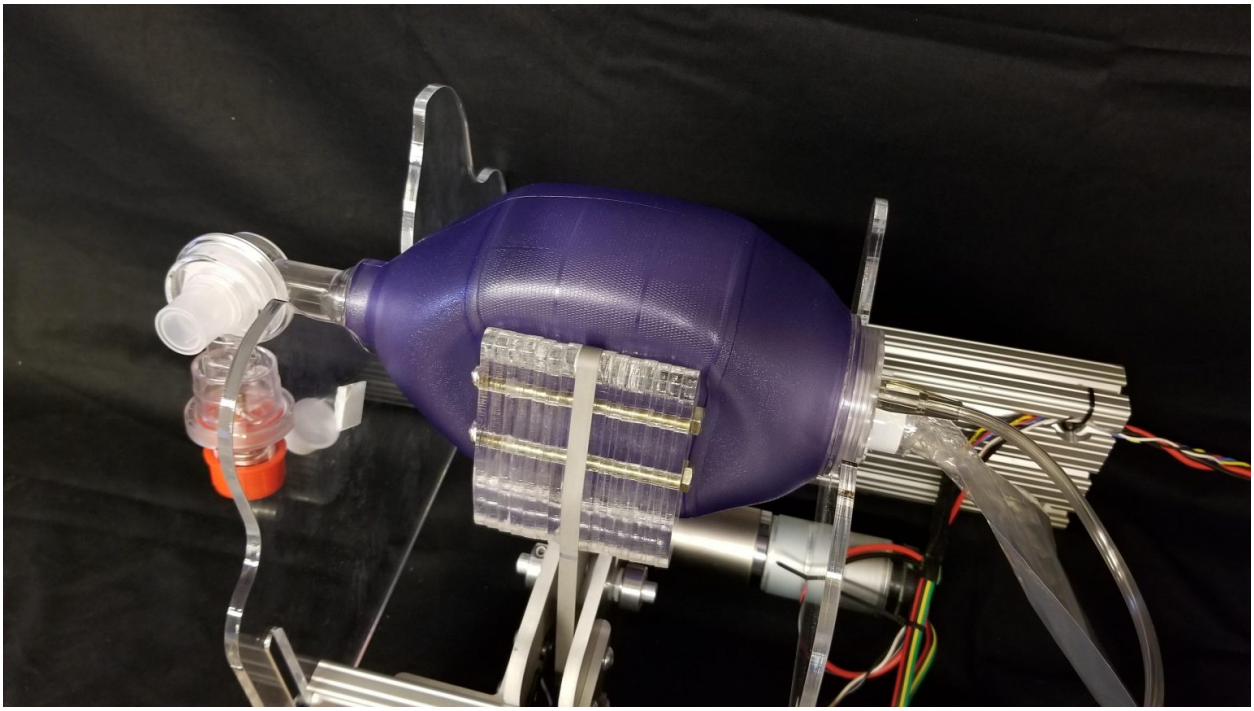


Figure 16: The Laerdal bag is large. Care must be taken to not pinch the bag when compressed and, as seen here, the bag lifts up and out in current configuration. This is not a good fit and longer arms are needed.



Controls and Electrical

Updated 25 March 2020

This section provides a description of the system architecture, the control strategy and the underlying logic. All ventilation requires a clinician in the loop to titrate parameters, in response to direct observation of patient physiology. The earliest successful ventilators had limited parameters and we aim to replicate this, with specificity to COVID-19.

Ambu bags are readily available and provide a convenient means to connect to an intubated patient and deliver ventilation. However:

Ambu bags have limited safeties beyond a pop-off valve for pressure release and a PEEP that is set manually. Any ventilator design must incorporate pressure sensing and actively monitor both peak and plateau pressures. Peak pressure exceeding 40 cm H2O (or a pressure set just below the pop-off pressure of the selected bag) must trigger an alarm.

All decisions are being made on the basis of safety and minimizing complexity, which sometimes means omitting features. Please reference our other documents for more information on these tradeoffs.

This is a living design and will continue to be updated as we receive more information and learn from our ongoing testing.

5.5 Modes

In the interest of simplicity and ease of use our prototype system has only two modes of operation:

5.5.1 Mode 1 – Volume Control (VC)

Clinician selected breaths are delivered at a constant rate automatically, with pressure monitoring only for safety. VC is only suitable for sedated and paralyzed patients. Tidal Volume, BPM and I:E are set as per clinical guidance.

5.5.2 Mode 2 – Assist Control (AC)

When the patient tries to breathe in, the pressure sensor will see a pressure drop, and the machine will begin squeezing the bag in order to assist in the breath. (Because the compression is triggered by the patient's breath, the machine will be operating in sync with the patient's natural breathing.) In AC mode the desired BMP is set slower than the patient's expected breath rate. This sets a timer that is reset each time a patient takes a self-initiated breath. If the timer runs out the system initiates a breath.

Activation of the assist control must trigger an alarm to indicate that a patient is not self breathing.

Caution: Assist control has not yet been tested in a porcine model due to the additional complexity and failure modes.

- Controllable Parameters
- Breaths per minute (BPM)
- Tidal volume (TV)

- Inspiration to Expiration ratio (I:E)
- Trigger pressure (only active in AC mode)