Philippine American Academy for Science and Engineering (PAASE)

The Need for a Low-Cost Ventilator

The Case. The ongoing COVID-19 pandemic has resulted in an unprecedented demand for mechanical ventilators. It is estimated that ~5% of all patients with COVID-19 will be critically ill and will need ventilators to support their respiration while recovering from severe lung disease. It is a critical step in mitigating the number of deaths as the capacity for clinical access will be limited based on the number of units available. Thus, it is unsurprising that many different designs and prototypes of ventilators are increasingly being pushed to address this need. An understanding of ventilators as they relate to clinical needs of critically ill patients with severe lung disease due to COVID-19 is essential. Faulty design and operation and lack of reliability can have unintended consequences. Moreover, the contagious nature of COVID-19 requires more scrutiny against spreading the pathogen during operation. FDA approval while needed will eventually be fast tracked in order to meet this demand including right-to-try clauses. *But what are the essential factors in a ventilator operation?* The critically ill patient to put it simply is unable to breath on their own. Mechanical ventilators support the patient's respiration by providing positive pressure to the lungs. During inspiration, the positive pressure from the ventilator provides tidal volume for a set amount of time. During expiration, the positive pressure is removed and the patient is allowed to exhale passively. This sequence of events occurs at a set number of breaths per minute. The peak pressure during inspiration is called the peak inspiratory pressure (PIP), while the remaining pressure during expiration is called positive end expiratory pressure (PEEP). The fraction of inspired oxygen delivered by the ventilator ranges from room air at 0.21 up to 1.00.

In the ICU. Mechanical ventilation can be delivered non-invasively using masks or helmet, or invasively using endotracheal tubes (intubation). In the United States, non-invasive ventilation is not recommended for patients with COVID-19 because of high risk of *aerosolization* and rapidity of respiratory deterioration in these patients. Therefore, nearly all critically ill patients with COVID-19 will eventually require invasive ventilation. A recent case series of these patients suggest that they receive mechanical ventilation for a median of 10 days (interquartile range: 7-12 days). These patients are recommended to receive tidal volumes of 4-6 mL/kg of ideal body weight for improved outcomes. For a 70 kg man, the mechanical ventilator should be able to deliver tidal volumes of ~280-420 mL at a rate of 10-30 breaths per minute. In patients with COVID-19, median PIP of ~25 cmH2O (interquartile range: 20-29 cmH2O) at median PEEP of ~12 cmH2O (interquartile range: 9-13 cmH2O) were used to deliver this tidal volume on the first day of mechanical ventilation. The median fraction of inspired oxygen on the first day of mechanical ventilation was 0.90 (interquartile range: 0.70-1.00*). Operation of the device beyond these parameters may actually cause fatal lung damage to the patient.* In summary, any proposed design and prototype for mechanical ventilators to be used in patients with COVID-19 need to consistently deliver the right tidal volumes and pressures for prolonged periods of time and beyond emergency service. The ventilator should be clinically relevant for intensive care, controllable, and reliable. Intensivists and pulmonologists need to have their important input. *The problem is that these ventilators are expensive and in limited supply*.

The Options. There are many low cost ventilator designs that have been proposed and are freely available online such as the Oxford University, OxVent (Fig. 1), Mechanical Ventilator Milano (Fig. 2) and MIT Mechanical Ventilator (Fig. 3) designs, as well as the UMBC CAST (Fig. 4) design (available upon request) to name a few. The Philippines has the Ginhawa (Fig. 4) ventilator or ReliefVent supported by the Department of Science and Technology (DOST). It has been in development for 12 years but has not been fully tested on animals or humans. It is claimed to be ready for manufacturing but appears to require components that make it more expensive than other designs, which are generally < US $ 300. On the other hand, the OstreaVent (Fig. 6), which has been tested and validated, is originally designed for neonates and would require modifications to increase capacity for adults. The OstreaVent also falls in the low cost category. It is assumed that the design of OstreaVent is more similar to the MIT, OxVent, and Milano designs. The MIT design uses a bag valve that in current practice can be manually operated during patient transport and is attached to a mask. It automates compression and release of the bag/balloon. There is some concern, however, that the MIT design is not up to the requirements for critically ill COVID patients, especially those in the Philippines because of the longer wait for emergency care (mostly patients delaying until they are critically ill). Intubation procedures are certain. Nevertheless, there are many groups in the Philippines which are adopting to

these lower cost designs without a strong clinical perspective. Perhaps some other designs that have been put forward including the G-Tech (Fig. 11)and the Ventilaid Group (Fig. 12) have more promise in simplicity and manufacturability. In particular, the latter is an open source design that is very amenable for 3D Printing. An important consideration always is prevention of aerosolization and hygenic operation that mitigates further spreading of the virus pathogen. *Other related existing commercial devices have been considered.* This is the case of continuous positive airway pressure (CPAP) machines used for sleep apnea treatment or EMS emergency respiratory units, which are not suitable replacements for ventilators and long-term operation. It has been recommended that perhaps bi-level positive airway pressure (BiPAP) machines can be modified for ventilators. *Non-intubation methods with the use of masks simply exposes more risk for spreading the disease.*

The Stakeholders in Manufacturing. As many parties put their stake in helping the country design and manufacture ventilators for this unprecedented emergency, it is crucial that the clinical priority and patient safety be the main driver in the design and operation of the units and not necessarily cost and rapid manufacturing. Specifically for the COVID-19 response or future pandemic diseases, these units should mitigate aerosolization and leakage to prevent risk to frontline health workers. For manufacturability, low cost is important but high reliability in operation is needed. The supply chain for parts will be crucial and should be matched with best practices in manufacturing. 3D Printing of newly designed parts (it takes time for making tools and molds) or even replacement parts can play an important role. *Testing of each unit for reliability before shipment is important.* Lastly, there are other supply needs for a clinical setting that can also be in limited supply, e.g. oxygen tanks or concentrators, valves, disposables, replacement HEPA filters, etc. that needs to be planned along with the unit in any location.

Recommendation: Here are things to consider in producing ventilators for this unprecedented need. They can be classified as short-term and long-term solutions.

1. Consider commercially available units that has been long used in clinical settings for modification and simplification in manufacturing. Partner or license with the manufacturer. One possibility is to establish a program for repairing or upgrading machines including multiple hookups of patients on a single machine.
2. Consider modifying other respirators and breathing aids of the same operation principle that are currently used for a different purpose. Modify their design and operation to be closer to that of a long-term mechanical ventilator. This will require testing the modification and FDA approval.
3. For upcoming designs that have already been prototyped and undergone limited testing, consider getting now the valuable input from clinicians and plan for limited testing and operation even prior to getting FDA approval.
4. For entirely new designs being put forth with even simpler components and lower cost for high throughput manufacturing, be familiar with the demands in a clinical setting first and work the way up towards a minimum viable product (MVP). Then plan for FDA approval.
5. It is also important now to line up the supply chain for parts or assemblies that is needed for manufacturing these devices. For rapid prototyping and production, planning for available parts will now be crucial and will necessitate collaborating with distributors and local OEM suppliers and manufacturers.

All these options need to be considered and fast!

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APPENDIX

Ventilator Accessories

Endotracheal Tube. As mentioned above, ventilators provide a positive pressure to aid in the breathing of the COVID patient. However, the ventilator has to be connected to the patient either through a mask (noninvasive) or through an endotracheal tube (ET), Figure 7. The recommended mode of care for COVID patients is the ET as it has the advantage of not producing virus-containing aerosols that can be inhaled by the doctors and nurses by the bedside. In addition, most doctors in the ICU prefer intubation as they have a better handle in caring for critical patients. At present, there appears to be no immediate need for more ETs in the Philippines, as the common practice is to clean and re-use. While this is good news, it may be prudent to check the current availability of ETs and if there is a need to acquire more as the number of patients increase. The same is true for the holders that keep the ET in place on the face of the patient.

Tracheal Intubation Fiberscope. When a doctor intubates a patient, the natural tendency is to get as close to the patient as possible. This puts the doctor in danger of contagion from the patient. The recommended solution is a fiber optic camera (Figure 8) that can aid in the process of intubating the patient. These cameras at the end of a fiber optic are common not only in medicine but, for example, in looking for a leak in a plumbing system. Thus, they are not very expensive and can be easily improvised from easily sourced components. The recommendation is for engineering groups in the Philippines to build these devices for the doctors in the frontlines.

Compressed Air and Oxygen Tanks and Oxygen Concentrators. Will there be enough sources of oxygen should the number of patients needing ventilation increases? Is oxygen concentration doable in the Philippine hospital setting should there be a shortage of oxygen sources?

Disposables. Masks, HEPA filters, tubing hose, disposable circuit hoses, mouthpieces, etc.

Clinical Testing

Here are suggestions to facilitate clinical testing.

1. Have a master protocol with buy-in from regulatory agencies such as the FDA.

2. Assign a central internal review board or IRB in the Philippines. The central IRB will approve the master protocol and any proposed amendments.

3. Have a set of minimum standards from device safety point of view, ventilator parameters that can be delivered and measured, etc. that every prototype has to adhere to.

4. Once the prototype has achieved the minimum standards, only an amendment to the master protocol needs to be submitted to the central IRB. The amendment has to document that the minimum standards have been achieved. IRBs don't usually have engineers. For purposes of these recommendations, I suggest having an engineer in the IRB to quickly review the documentation.

5. Create a cadre of physicians and research personnel who are certified and willing and able to do the clinical testing using the IRB-approved clinical protocol. These folks should already be trained even before the first prototype is available. Once a prototype is approved, it can be rolled out quickly for testing. Testing can be done simultaneously or immediately after one has been tested because the protocol is the same.

The needs are immediate and the process can be circumvented if there is enough buy-in and will from the stakeholders.

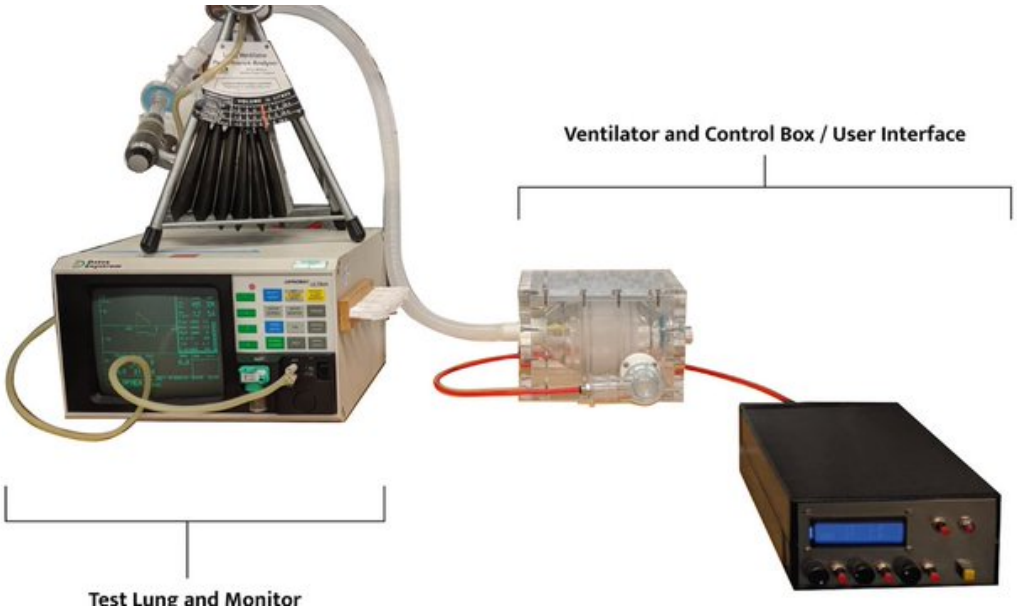


Figure 1. OxVent by Oxford and King's College in the UK

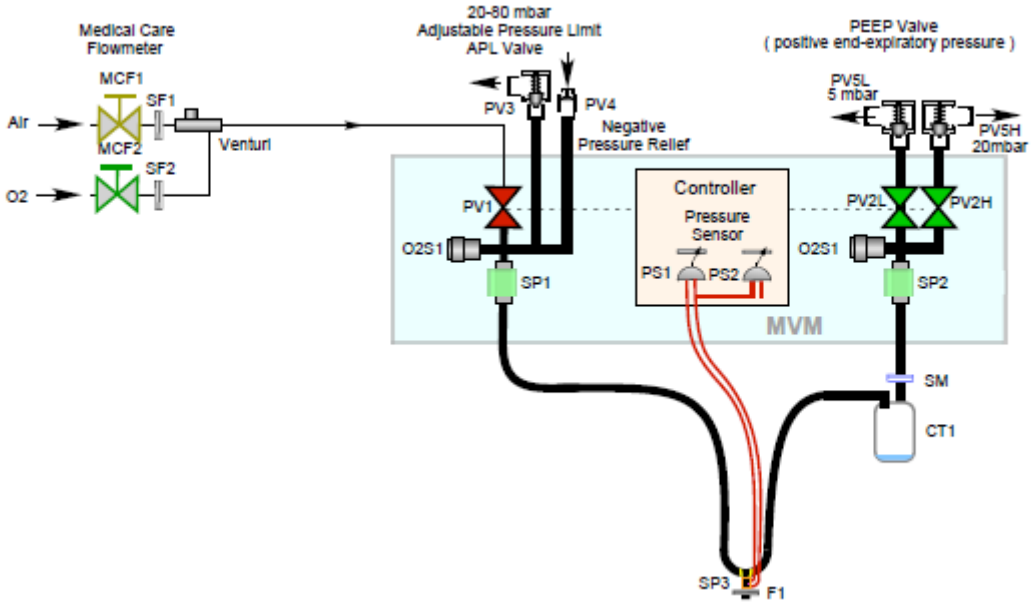


Figure 2. Mechanical Ventilator Milano

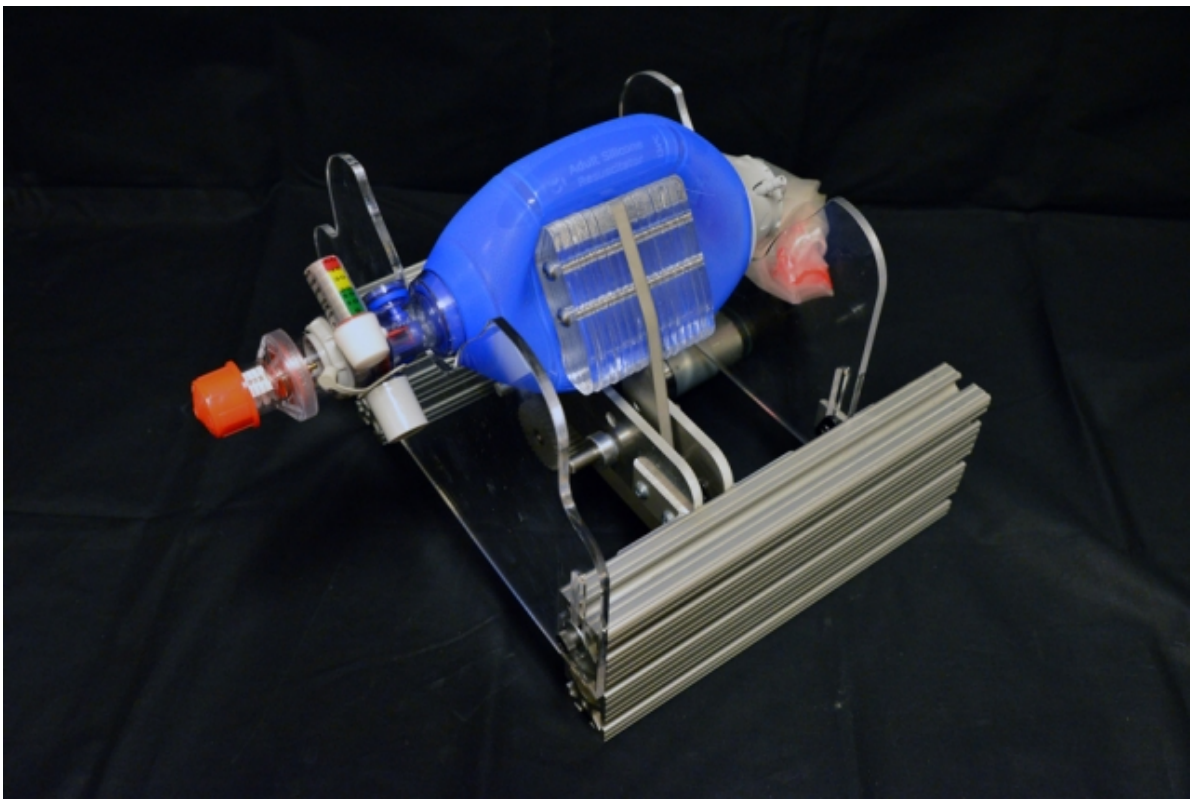
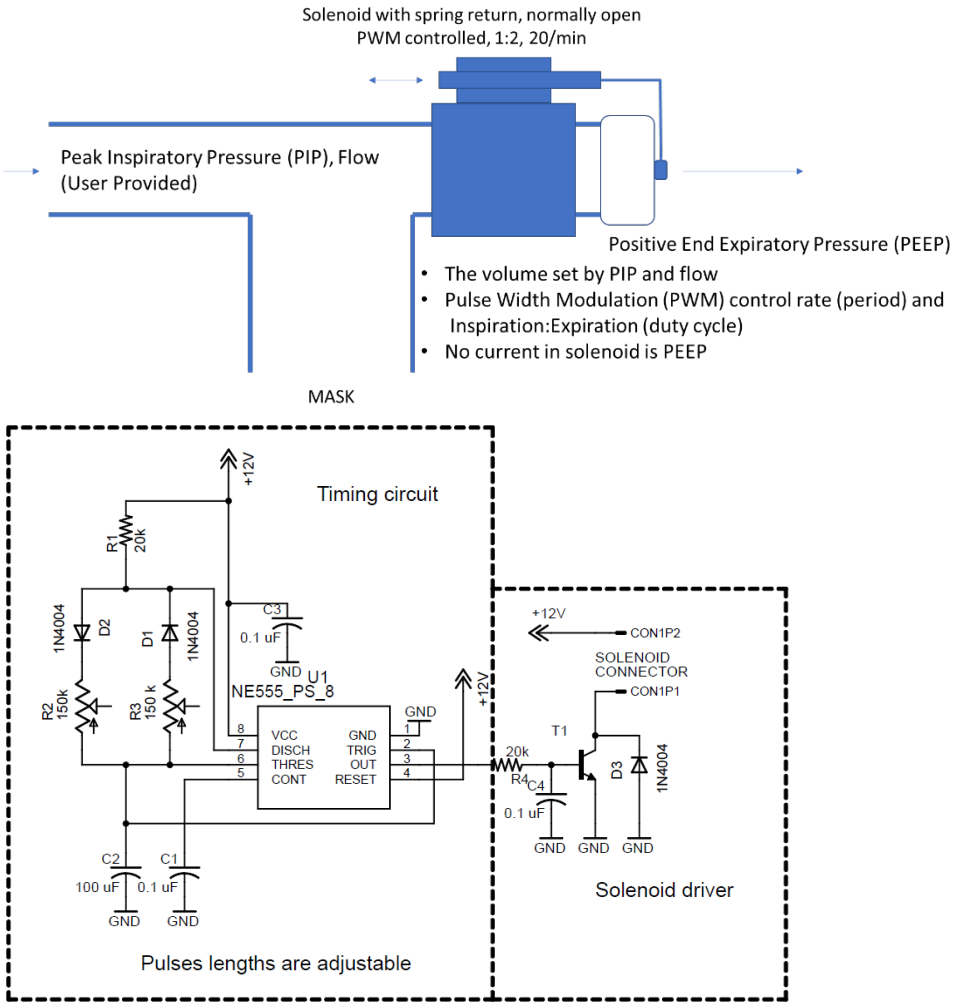


Figure 3. MIT Ventilator



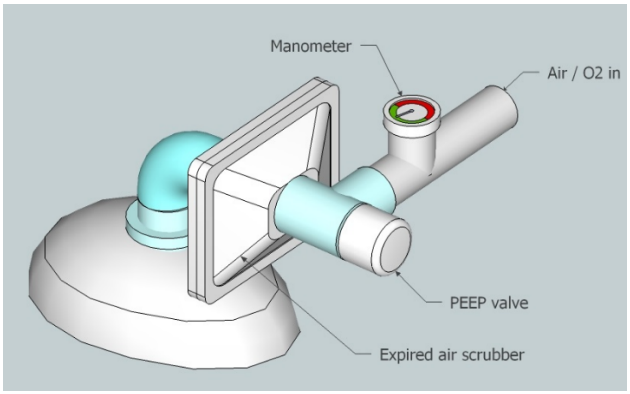


Figure 4. University of Maryland Baltimore County, Center for Advanced Sensor Technology

Figure 5. Ginhawa (ReliefVent)

Figure 6. OstreaVent for neonates

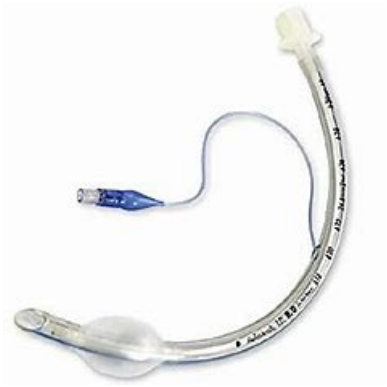


Figure 7. Endotracheal Tube

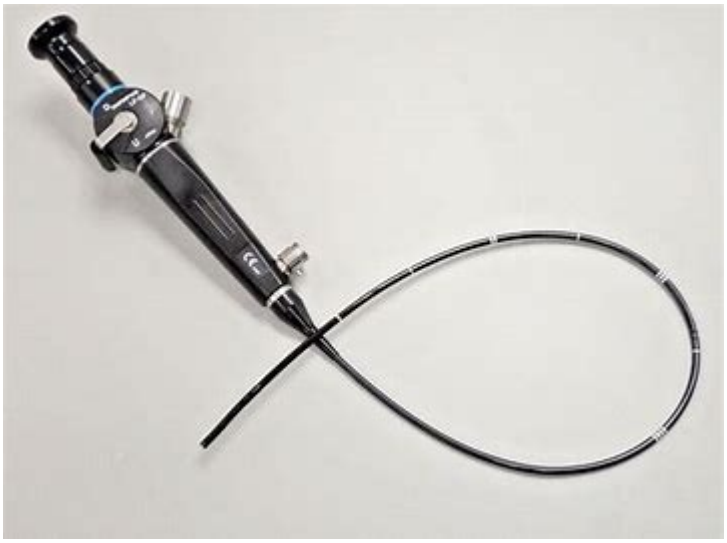


Figure 8. Tracheal Intubation Fiberscope

Figure 9. Oxygen or Compressed Air Tanks

Figure 10. Oxygen Concentrator for Hospital Use

Figure 11. GTech Ventilator with a simplified design

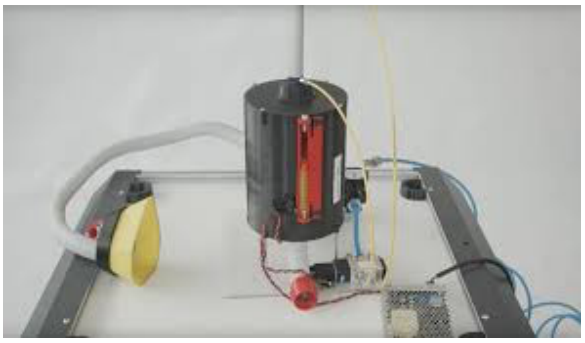


Figure 12. Ventilaid a 3D Printable Ventilator