### THE PHILIPPINE - AMERICAN



## **OUR RESPONSE TO COVID-19**

## AGHAM AT KAALAMAN PARA SA BAYAN!

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WEBSITE www.paase.org ON PAASE STRATEGIC ACTION GROUP 2: TRIAGE AND TREATMENT

Addressed to: National Inter-Agency Task Force for the Management of Emerging & Infectious Diseases (IATF), Department of Health

THE NEED FOR A LOW COST VENTILATOR NOW

PAASE BULLETIN # 14

The rapid implementation of a low cost ventilator manufacturing, validating, and approval program:

- 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.
- 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.
- There are many low cost ventilator designs that have been proposed and are freely available online. There is some concern, however, that the some of these designs is not up to the requirements for critically ill COVID patients, especially those in the Philippines. An important consideration always is prevention of aerosolization and hygenic operation that mitigates further spreading of the virus pathogen.
- 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.

#### **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

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WEBSITE www.paase.org 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.

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\* Members of a committee formed to address the topic of ventilator needs. We are a group of scientists, engineers, medical doctors, and entrepreneurs that seeks to guide those interested in understanding the needs and challenges of developing ventilators for the current COVID-19 and SASRS-CoV-2 pandemic. They can be reached at their respective e-mails and also at <u>www.paase.org</u>

Full White Paper:

The Need for a Low Cost Ventilator