# ETHIOPIA COVID-19 CHALLENGE:
# MECHANICAL VENTILATOR

## WHAT IS THE CHALLENGE?

The Ethiopian Society of Mechanical Engineers (ESME) and Ethiopian Society of Electrical Engineers (ESEE) are pleased to announce a Grand Challenge call to Ethiopian mechanical/electrical/biomedical/system/software engineers, innovators, product designers, and device builders to design and provide a prototype for a mechanical ventilator that can be manufactured in Ethiopia considering the unique resources constraints in the country.

The first submission of this Challenge will consist of design concepts, CAD drawings, and rough prototype. The final submission will consist of a functional prototype that can be manufactured inside the country. Design specifications and background information on mechanical ventilation are provided below.

- **Launch Date:** April 30, 2020
- **Initial Submission:** June 08, 2020 (**Extended**)
- **Final Submission (Invite Only Round):** June 22, 2020
- **Top 3 Winning Designs Announced:** June 25, 2020

**Prizes**
1st Place Winner – 20,000 Birr
2nd Place Winner – 12,500 Birr
3rd Place Winner – 10,000 Birr

**Judging Criteria**
1. Meets system requirements as defined in the attached document
2. Manufacturing complexity is appropriate for conditions in Ethiopia
3. Likelihood of success
4. Innovations in design and approach

**Materials for Submission**

1. Project Abstract - list of team members, description of the design and how it works, project timeline, and any information the teams deem appropriate for defining the proposed design
2. Detailed 2D and 3D CAD drawings.
3. Fully annotated circuit diagrams (.pdf)
4. Bill of materials (.pdf)
5. Clear and concise assembly instructions (.pdf)
6. Clear user's manual (.pdf) (Final Submission only)
7. Test methods and test results (.pdf) (Final Submissions only)

Both the initial and final submissions are to be made by email to: ESME_ESEE@GMAIL.COM.

**Judging Panel:** Dr. Korbaga Woldekidan, Professor Ermias Koricho, Dr. Achalu Tirfe, Eng. Thomas Gabre, Eng. Berhanu Kebede, Eng. Hailu Seifu, Eng. Seifu Churnet, Eng. Yeneneh Dawit, Eng. Abdissa Lema, and Eng. Samrawit Kassaya

# Design Specifications for Mechanical Ventilator for Ethiopian Conditions

Joint ESME and ESEE Call for Innovative Designs Appropriate for Fabrication, Operation, and Maintenance in Ethiopia

## 1. Introduction

This document is designed to provide a brief description and specifications of a simplified mechanical ventilator design that will help COVID-19 patients in Ethiopia. According to the American Thoracic Society, a mechanical ventilator is defined as a device that takes over the work of breathing when a person is not able to breathe enough on their own. There are many reasons why a patient may need a ventilator, but low oxygen levels or severe shortness of breath (one of the typical symptoms of COVID-19) from an infection such as pneumonia are the most common reasons. There are various types of mechanical ventilator designs ranging from a hand-operated simple ventilator (Ex. Ambu bag) to very complicated and advanced ones. Readers are encouraged to refer to the resources provided in the Appendix section for different types of design options. An illustrative example of a simplified mechanical ventilator is shown in **Figure 1** through **Figure 3**. Note that, depending on what is available in the health facility, some of the components could be removed. For example, if there is a gas for compressed oxygen and air, there will not be a need for a compressor and the duty of the mechanical ventilator would be only to modulate the flow of oxygen/air to the patient in a proper proportion. It should also be noted that the whole objective of this example is to give readers some perspectives about the ventilator's working mechanism and everyone is encouraged to be as innovative as possible within the boundaries set in the specification sections of this document.

**Figure 1** shows the sequences of operation during inspiration. During inspiration:

- The air will be pressurized by the compressor.
- The pressurized air will pass through the check valves, and the humidifier, and goes into the lungs.
- The air pressure and flow rate will be measured continuously.
- If the pressure or flow rate exceeds the set point, the pressure-flow control valve will open and release the air.
- Expiration control valve will remain closed.
- The mechanical relief valve will be opened if pressure exceeds the high pressure limit.

During expiration, **Figure 2**, the ventilator performs two operations: Charging and Expiration. During charging, filtered fresh air and oxygen(optional) will be sucked to the compressor through the check valve. In the expiration side:

- The expiration valve will open.
- The pressurized lungs push the air out passively.
- The check valve will prevent the air from going upstream.

**Figure 3** illustrates one way of providing the required pressure and volume control using a microchip. Readers are encouraged to investigate what kind of control mechanisms are easily available before deciding the control architecture.

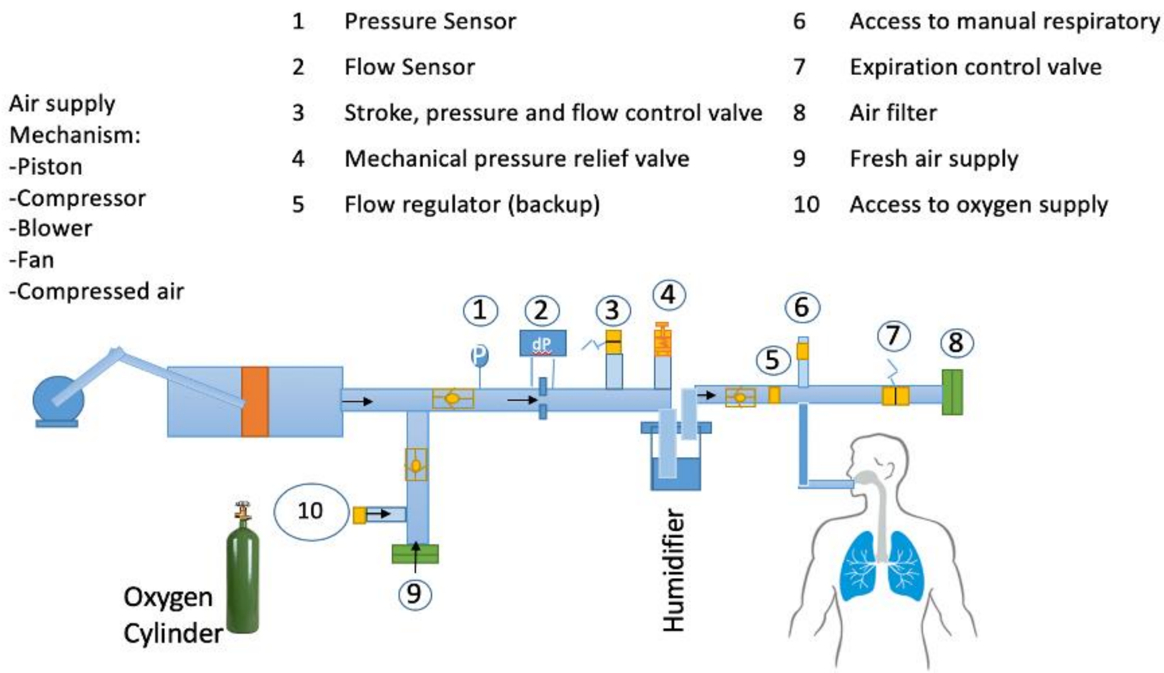


**Figure 1.** Ventilator operation during inspiration (active system).

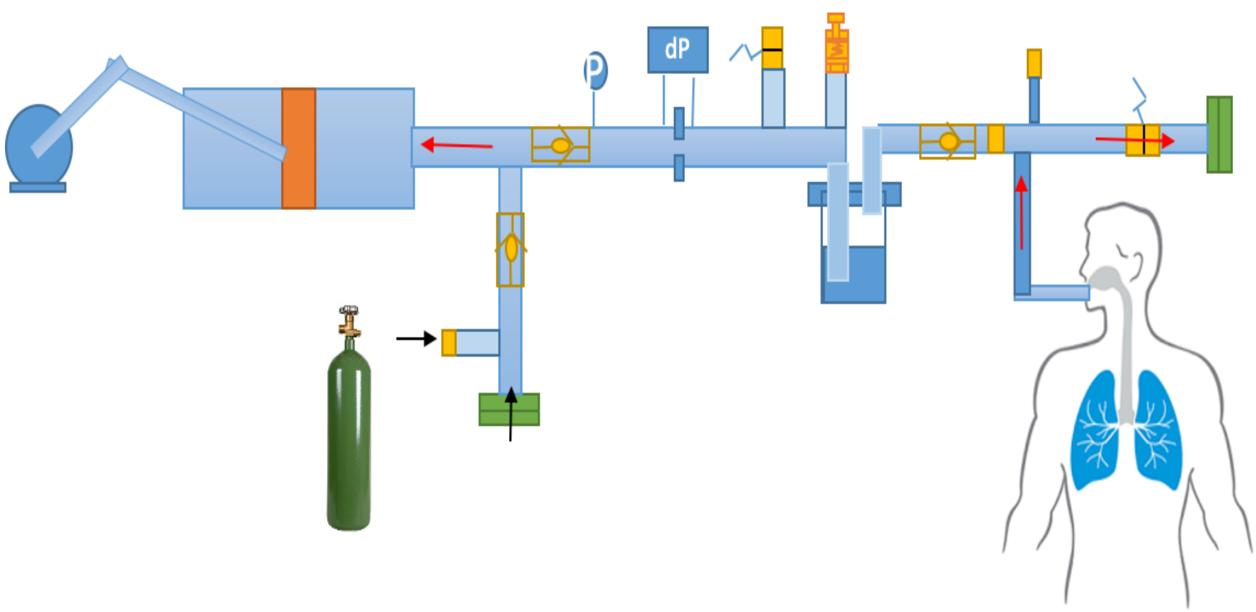


**Figure 2.** Ventilator operation during expiration (passive system).

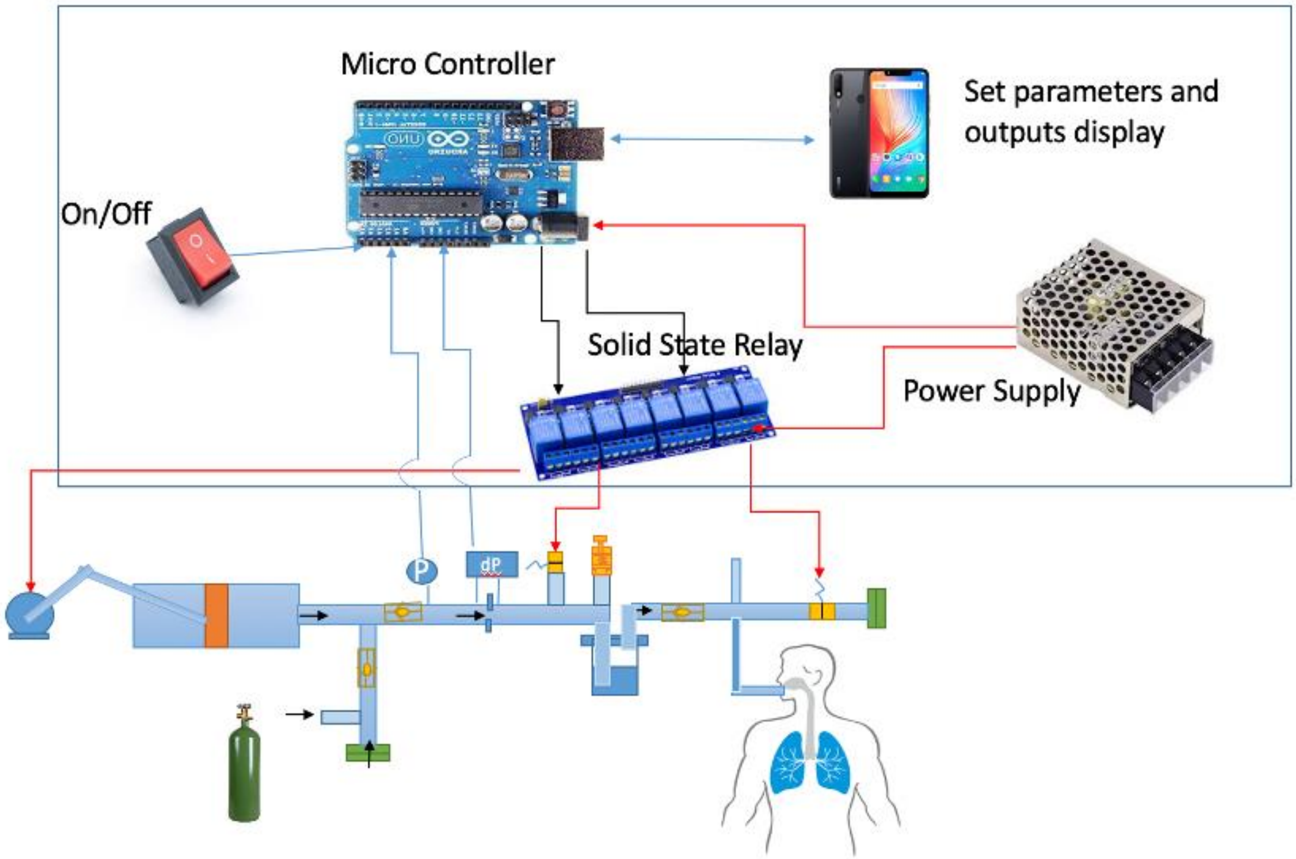


**Figure 3.** Ventilator control setup.

## 2. Design Specifications

This section summarizes the clinical as well as mechanical/electrical specifications for the mechanical ventilator. These specifications were gathered mainly from the following sources:

a. **Guidelines for rapidly manufactured ventilator system criteria** (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876167/RMVS001_v3.1.pdf)
b. **coVent-19 Challenge** (https://www.coventchallenge.com/#challenge)
c. **Design and Prototyping of a Low-cost Portable Mechanical ventilator** (https://web.mit.edu/2.75/projects/DMD_2010_Al_Husseini.pdf), and
d. **Application Package Requirements** https://opportunitydesk.org/2020/03/23/code-life-ventilator-challenge-2020/

## 2.1. Ventilation

2.1.1. Must have at least 1, and optionally 2 modes of ventilation

2.1.1.1. Must have Continuous Mandatory Ventilation (CMV).

2.1.1.2. The CMV mode must be either:

I. Pressure Regulated Volume Control (PRVC) (ideal);

II. Pressure Controlled Ventilation (PCV); or

III. Volume Controlled Ventilation (VCV) (minimum requirement)

2.1.1.3. Should have a spontaneous breathing pressure support mode for patients breathing, to some extent, on their own, e.g. BIPAP or SIMV-PC.

2.1.2. If a pressure support mode is provided, the ventilator must failsafe automatically onto mandatory ventilation, if the patient stops breathing in this mode.

2.1.3. Inspiratory airway pressure, the higher pressure setting that is applied to make the patient breathe in:

2.1.3.1. Plateau pressure should be adjusted to achieve volume and must be limited to 35 $cmH_2O$ by default. An option to increase this to 70 $cmH_2O$ for exceptional circumstances is acceptable.

2.1.3.2. Peak pressure should be no more than 2 $cmH_2O$ greater than plateau pressure.

2.1.3.3. If volume control ventilation is used, the clinician must be able to set the inspiratory airway pressure limit in the range at least 15 – 40 $cmH_2O$ in at least increments of 5 $cmH_2O$.

2.1.3.4. There must be a mechanical failsafe valve that opens at 80 $cmH_2O$.

2.1.4. Positive End Expiratory Pressure (PEEP) (The pressure maintained in the breathing system during expiration):

I. The SMV must provide a range 5-20 cm $H_2O$ adjustable in 5 $cmH_2O$ increments.

II. The patient breathing system must remain pressurized to at least the PEEP level setting at all times.

2.1.5. Inspiratory:Expiratory (I:E) ratio, the proportion of each breathing cycle that is spent breathing in compared to breathing out:

2.1.5.1. SMV must provide 1:2.0 I:E ratio as the default setting (i.e. expiration lasts twice as long as inspiration).

2.1.5.2. SMV could provide adjustable I:E in the range of 1:1 – 1:3.

2.1.6. Respiratory Rate (The number of breathing cycles per minute): SMV must provide a range of 10 – 30 breaths per minute in increments of 2 (only in mandatory mode) that can be set by the clinician.

2.1.7. Tidal Volume (Vt) setting, if provided (The volume of gas flowing into the lungs during one inspiratory cycle):

2.1.7.1. Should have a range of 250 – 800 ml in increments of 50ml.

2.1.8. Should be able to provide a flow rate of > 60 l per minute

## 2.2. Mechanical

2.2.1. Portable

2.2.2. Standalone operation

2.2.3. Robust mechanical, electrical and software systems
2.2.4. Readily or locally sourced and repairable parts
2.2.5. Battery-powered
2.2.6. Option for manual operation in case of power outage and battery unavailability
2.2.7. Shall be easily modified to be used for 2 to 4 patients simultaneously.

**2.3. User-Interface**

2.3.1. Separate alarms should be provided for each of the following potential malfunctions
Must alarm at:
I. gas or electricity supply failure
II. machine switched off while in mandatory ventilation mode
III. inspiratory airway pressure exceeded
IV. inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm)
V. tidal volume not achieved or exceeded

2.3.2. Display of settings and status should include:
2.3.2.1. current settings of tidal volume, frequency, PEEP, FiO2, ventilation mode
2.3.2.2. actual achieved rates of tidal volume, breathing rate, PEEP, plateau pressure, FiO2(optional)
2.3.2.3. if provided, under pressure support mode, there must be real-time confirmation of each patient breath and an alarm when it is below acceptable range
2.3.2.4. optionally $CO_2$ monitoring

2.4. Gas supply to patients. The ventilator should have the following gas options
2.4.1. Should be able to provide air without gas line (oxygen 21 %)
2.4.2. Should have an option to connect it with an oxygen supply
2.4.3. Should have a way to modulate the oxygen proportion (FiO2)

2.5. Infection Control
2.5.1. All components coming in contact with the patient's breath must be disposable OR sterilizable (e.g., autoclavable)
2.5.2. 0.22um or smaller filter on patient inspiration and expiration pathway
2.5.3. All external surfaces must not degrade with application of standard agents for disinfection (e.g. bleach solution)
2.5.4. May include facility for hot water humidifier to be included in breathing system
2.5.5. To prevent contamination of the patient gas pathway, and internal components, the device should be designed to use separately sourced HMEF-bacterial-viral filters between the machine and patient.

2.6. Economic consideration
2.6.1. Low-cost (i.e., under 30,000 Birr)
2.6.2. The product should be relatively easy to manufacture locally considering the available tools, processes, and parts.

## 3. Documents to be Submitted

The following items should be included in the **final** COVID-19 mechanical ventilator submittal package with concise names and abbreviations:

- Detailed 2D and 3D CAD drawings.
- Fully annotated circuit diagrams (.pdf)
- Bill of materials (.pdf)
- Clear and concise assembly instructions (.pdf)
- Clear user's manual (.pdf)
- Test methods and test results (.pdf)

## Glossary

**ARDS** (Acute Respiratory Distress Syndrome): Life-threatening form of respiratory failure where the lungs become severely inflamed due to an infection or injury and cannot provide the body's vital organs with enough oxygen.

**SIMV-PC** (Synchronized Intermittent Mandatory Ventilation – Pressure Controlled): Mode of ventilation where the patient is allowed to take spontaneous breaths. The machine will assist the patient's breathing when a spontaneous breath is taken. If the patient does not make a pre-set number of breaths a minute (i.e. 10) the machine provides mechanical ventilation to provide the set number.

**CMV** – Continuous Mandatory Ventilation

**SMV** - Simplified Mechanical Ventilator

**PCV** (Pressure Controlled Ventilation): PCV is where the clinician has to provide the adaptive control to achieve the required tidal volume. This is acceptable only if the tidal volume delivered is clearly displayed, and the clinician can set patient specific upper and lower tidal volume alarms to alert to the need to adjust the pressure.

**VCV** (Volume Controlled Ventilation): In this mode of ventilation, the clinician sets a tidal volume and respiratory rate. The tidal volume is delivered during the inspiratory period. Acceptable only if additional pressure limiting controls are available.

**PRVC** (Pressure Regulated Volume Controlled): A mode of ventilation where a set tidal volume is delivered to the patient while maintaining the lowest pressure possible in the airway in order to avoid trauma. At each breath, the tidal volume will be checked against a setpoint and the pressure will be modulated between the lower and upper limits to maintain the setpoint.

**BIPAP** (Bilevel Positive Airway Pressure): Non-invasive ventilation mode that provides different levels of pressure when the patient inhales and exhales.

**PEEP** (Positive End-Expiratory Pressure): The lower pressure applied to the patient's airway to allow them to breathe out, but not too much

**HMEF** (Heat and Moisture Exchange Filter): Device fitted to the patient end of the breathing system, contains a hydrophobic medium that absorbs heat and moisture from the patients exhaled breath and uses absorbed moisture to humidify inhaled gases. It also filters bacteria and viruses, and will be used on all patients. WARNING can affect delivered pressure.

**Fi02** (Fraction of inspired oxygen): Concentration of oxygen in the gas mixture that the patient inhales.

**Appendix**

**Reading Materials:**

https://github.com/PubInv/covid19-vent-list (list of open source ventilator projects)

https://www.hackster.io/news/an-open-source-ventilator-powered-by-raspberry-pi-and-arduino-goes-into-testing-in-colombia-6c3f04b1ca94

https://docs.google.com/document/d/1sdrKYQ0mDOu4bJum6Fx6piRutIJovo7UqFKYHHxUD5A/edit#heading=h.zfqx8qqil1g1

https://docs.google.com/document/d/1SBT8auegsJCKCVMBHFLWaVo8rKbs0zsJc3dDVAqeADE/edit#heading=h.sx9qnelsso49(Hardware Specifications)

https://docs.google.com/document/d/1-eV7ClGCTgaqPug7u9ovE_s-U6J5s8Hzc3XAalkEgVE/edit#heading=h.sx9qnelsso49 (Software and control)

**YouTube Videos:**

https://www.youtube.com/watch?v=_6fWpdXvOYk
https://www.youtube.com/watch?v=xohUDG607s0&feature=youtu.be
https://www.youtube.com/watch?v=QA3MKDsYGP4
https://www.youtube.com/watch?v=NiMcbdYNMMI
https://www.youtube.com/watch?v=oLQ5bXakWq8
https://www.youtube.com/watch?v=JJXzlCK4vnY