**This document was prepared following** [**user need requirements**](https://drive.google.com/file/d/1WitcPoqPPmHopEo9YMWe8MoB9p_oZJxK/view?usp=sharing)**, collected from Ethiopian medical doctors and clinicians,** [**MIT E-Vent Design Toolbox**](https://e-vent.mit.edu/) **AND rapidly manufactured ventilator system** [**document specification**](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879382/RMVS001_v4.pdf) **issued by MHRA, UK government. We are proposing a** [**design and development plan**](https://drive.google.com/file/d/1XvoGB-r7dA24zw7E4kKBlHemAfWygtyN/view?usp=sharing) **following ISO 13485 design controls and ISO 14971 risk management standard.**

**Introduction**

This is a specification of the minimal clinically accepted ventilator to be used by intensive care medical doctors or junior nurses/practitioners that are trained to monitor alarms and do necessary suctioning during this pandemic. Functional and low cost mechanical ventilators are intended to serve as a valuable tool in developing countries in Africa. This device will expand access to breathing assistance by providing basic ventilator functionality in the arsenal of emergency situations where there are no options available.

This document sets out the clinical requirements based on the consensus of what is ‘minimally acceptable’ performance in the opinion of UK medical device regulators (MHRA), MIT EVent Design Toolbox and input from Ethiopia’s medical doctors and clinicians involved in the initial care of patients requiring urgent ventilation. A ventilator with lower specifications than this is likely to provide no clinical benefit and might lead to increased harm, which would be unacceptable for clinicians.

Please note, intensive care medicine is a whole system of care and ventilators cannot be safely used on any patient without trained staff and other equipment and medicines.

It is proposed these “bridge” ventilators would be for short-term stabilization for a few hours to provide minimal ventilator support.

**Project Methodology**

Our design and development plan was developed following ISO 13485, design controls, and ISO 14971 risk management for medical devices. We have established and maintained a plan that describes design and development activities, and defined responsibility for implementation. Please note, the plan will be reviewed, updated, and approved as design and development evolves. Please refer below for a brief description of the product development stages and deliverables to be completed by May 8th, 2020.

**Statement of Need**

Unfortunately, at this point in time, we have no therapeutic methods to stop people from getting COVID-19 pneumonia. There are clinical trials for all sorts of medications and there is hope that we may discover that various combinations of viral and antiviral medications are effective against COVID-19. The best care that patients with COVID-19 pneumonia get is supportive treatment in intensive care. *“The standard approach to treat COVID-19 pneumonia is to ventilate patients and maintain high oxygen levels until their lungs are able to function in a normal way again as they recover.”* Last year, 77,000 new ventilators were enough to meet the market demand of the entire planet. In April, New York City alone forecasts a need for 30,000 additional machines1,2; Some ventilator manufacturers have already boosted their production by 30-50% but, by themselves, can’t deliver the 500 or 1000% growth in production required. *There is a need for ventilators.*

There was a need for ventilators in the developing world before COVID 19.3 Thus, COVID-19 spreading to the developing world sounds ominous. COVID-19 has been slow to arrive in Africa, or at least has been slow to be detected there. But the wave is coming.(Wood 2020). There is an urgent need for low cost ventilators for Africa.

As Ethiopia’s Covid-19 cases increase, WHO is advising African countries to mobilize additional ventilators. Ventilators are not typically manufactured locally, therefore the government has been assessing avenues to overcome this challenge of scarcity of medical equipment, especially ventilators. There is undoubtedly a huge gap between the foreseen demand of mechanical ventilators and the current available supply in the country. [For a population of 109.8 Million, there are 450 functional ventilators and 197 non-functional ventilators that require maintenance.](https://www.africanews.com/2020/04/04/africa-s-ventilator-dystopia-ethiopia-trains-doctors-on-covid-19-lifesavers//) Without an adequate supply, doctors are faced with life-or-death decisions on who needs mechanical ventilators the most, to continue breathing.

The DIY Ventilator Project was initiated in efforts to rapidly design, develop, and mass produce low-cost “bridge” ventilators locally in response to the need outlined above.

[According to the Ministry of Health and Embassy of the Federal Democratic Republic of Ethiopia](https://www.ethioembassy.org.uk/coronavirus-an-urgent-appeal-for-ethiopia-amharic/), London UK, the country needs 1500 mechanical ventilators, with the following breakdown:

* 1000 mechanical ventilators with all accessories for adults
* 500 mechanical ventilators with all accessories for children

**Device Description**

The Ethiopia mechanical “bridge” ventilator will address the shortage of ventilators by providing a “recipe” to rapidly manufacture a low-cost mechanical ventilator that meets minimum clinical and performance specifications outlined by MHRA without compromising safety and efficiency. Ethiopia mechanical “bridge” ventilator will be compatible with existing manual resuscitator bags, and clinicians can control key ventilatory parameters.

Intended USE (general purpose and function):

The device is intended to provide respiratory support to help less critically ill patients with impending respiratory failure breathe by:

* + Delivering oxygen
  + Maintaining oxygen saturation and concentration
  + Maintaining positive end ventilation pressure (as required)

Until the patient is out of respiratory failure.

Device with a back-up battery that replicates the functionality of a:

* “Bridge Ventilator”
* A manual resuscitator “Ambu” bag
* A portable device

Based on our user need requirements, Ethiopia mechanical “Bridge” ventilators will be designed to be compatible with accessories such as standard splitters. The splitter compatibility will be crucial, due to future plans of developing respiratory accessories, such as [splitter](https://drive.google.com/open?id=1grHS_Hvk6ieL0i-mhWVSgwfzK9hLmkfg) designed by Vesper. This will allow a single ventilator fitted with the Vent Splitter can be used for two patients for ventilatory support during the COVID-19 pandemic when individual ventilators are not available.

This medical device is typically operated manually to provide ventilation to emergency patients, with less critical respiratory conditions. This is not intended to replace a standard ventilator. The “bridge” ventilators, or automatic resuscitators are intended to help less critically ill patients breathe. If patients become sicker, with lung function more compromised by the disease, they still need to be placed on standard ventilators. The device will be configured to be used by intensive care medical doctors or junior nurses/practitioners that are trained to monitor alarms and do necessary suctioning. The device will have tested usability aided with instructions for use to allow clinical workers with non-technical knowledge to train and quickly adapt to its use.

The original design for a basic ventilator came from a classroom project at the Massachusetts Institute of Technology a decade ago. Since the coronavirus outbreak, M.I.T. professors and students have worked to upgrade the design in collaboration with outside groups. The M.I.T open source design will serve as the core technology of this DIY-ventilator, with improved functionality, reliability, and quality control. A predicate device, Spiro Wave recently gained FDA Emergency Use Authorization has been a selected primary predicate device. Minor or moderate changes will be made to this design in efforts to tailor it to Ethiopia’s needs.

**Key specifications**

**Points of consideration Specific To Ethiopia:**

* ***Reliability:***
  + As manufacturers who have received the emergency use authorization from the FDA are not required to comply with quality system regulations, such as depth of testing, validation, and performance is not verified. Long-term investment in temporary solutions via modified devices can likely cause patient injury*.*
  + Device specifications based according to the corresponding open source design and website.
    - Hours of ventilation
    - Are sensing, Alert, and Safety capabilities standardized?
    - **Sensitivity trigger:** the ventilator needs to sense the patient’s efforts to breath in and out. If a ventilator is lacking this feature, the patient has to be fully sedated and paralyzed when this machine is applied to avoid significant dys-sinchrony which will intern cause lung injury. Lack of this feature also prevents the ability to wean patients on this device.
    - **Cylinder gauge:** the device needs to recognize whether oxygen is flowing to the ambulance-bag to know when cylinder runs out of oxygen
      * Needs a good ambu-bag which has a working PEEP valve
      * The ability to hold a higher peep and at the same time give a set Tidal volume while measuring the total pressure(Inspiratory Pressure).
        + This is good for professionals to know and monitor continuously.
* ***Infection Control:***
  + Can Ethiopia support proper decontamination / reprocessing between use? Reusable AMBU bags, valves, and masks are typically used up to 20 times before they are disposed of. The parts must be disassembled, cleaned, sterilized, reassembled and tested prior to use on each patient.
    - **Important** because basic needs like access to clean water in Addis Ababa hospitals are still insufficient. Addis Ababa based Women's philanthropic group (EWOK/NEGAT) recently donated water tanks to local hospitals in an effort to facilitate proper hand washing practices in the midst of COVID-19.
    - Are filters embedded into the open source device we’re considering?
      * Filters are required to ensure ventilation does not impact the patient environment. Improper maintenance and disposal can expose healthcare professionals and others to the viral agent.
* ***Infrastructure Support***
  + Ventilators require continuous energy to sustain life.
    - How can Ethiopia’s electric infrastructure of healthcare facilities accommodate this crucial need?
    - How are we addressing power outages?
      * Battery operated?
      * Rechargable?

**Clinical**

1. Patients must be under management of a trained clinician for mandatory ventilation.

The minimum controllable parameters in order to ventilate are as follows:

* At least 1, optionally 2 modes of ventilation listed below must be included.
* Mandatory mode must be either: **Pressure Regulated Volume Control (PRVC)**, **pressure-controlled ventilation (PCV),** or **volume-controlled ventilation (VCV)**

a. **PRVC/Pressure Controlled** - a set pressure is delivered for the period of inspiration and the volume achieved is measured and displayed. Ideally PRVC, an adaptive mode where the tidal volume is set and the lowest possible pressure is delivered to achieve this volume. Pressure Control Ventilation where the user has to provide the adaptive control to achieve tidal volume is only acceptable if the tidal volume delivered is clearly displayed and the user can set patient specific upper and lower tidal volume alarms to alert to the need to adjust the pressure.

b. **Volume Control** – the user 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, see *Inspiratory airway pressure* section.

c. Optional pressure support mode for those patients breathing to some extent themselves, e.g. BIPAP or SIMV-PC. The user sets an inspiratory pressure and an expiratory pressure. The ventilator can sense when a patient starts to breathe in and apply the inspiratory pressure, then sense when the patient starts to breathe out and apply the expiratory pressure (this pressure is still positive but lower than the inspiratory pressure).

2. If the patient stops breathing in a spontaneous mode it must failsafe automatically onto mandatory ventilation.

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

a. **Plateau pressure** should be adjusted to achieve volume and be limited to 35 cmH2O by default. It is acceptable if an option to increase this to 70 cmH2O in exceptional circumstances is provided

b. **Peak pressure** should be no more than 2 cmH2O greater than plateau pressure.

c. If volume control ventilation is used, the user must be able to set the **inspiratory airway pressure** limit in the range at least 15 – 40 cmH2O in at least increments of 5 cmH2O.

d. There must be a mechanical failsafe valve that opens at 80 cmH2O.

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

a. Airway pressure must be monitored: Range 5-20 cmH2O adjustable in 5 cmH2O increments required. Many patients need 10–15 cmH2O.

b. Assist Detection pressure or Trigger Sensitivity: When a patient tries to inspire, they can cause a dip on the order of 1 to 5 cmH2O, with respect to PEEP pressure (not necessarily equal to atmospheric pressure).

c. Patient breathing system must remain pressurized to at least the PEEP

level setting at all times.

5. **Inspiratory: Expiratory ratio (I:E).** The proportion of each breathing cycle that is spent breathing in compared to breathing out.

a. 1:2.0 (i.e. expiration lasts twice as long as inspiration).

b. Optionally adjustable in the range 1:1 – 1:3.

6. **Respiratory Rate.** The number of breathing cycles every minute.

a. Range 10 – 30 breaths per minute in increments of 2 (only in mandatory

mode) can be set by the user.

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

a. Must have at least one setting of 400ml +/- 10 ml.

b. Ideally 350 ml and 450 ml options.

c. Optionally Range 250 – 600 ml in steps of 50 ml.

d. Even more optionally up to 800 ml.

e. Optionally the ability to input body weight and have volume calculated as e.g. 6 ml/kg of ideal body weight.

8. Failure conditions must permit conversion to **manual clinician override**, i.e. if automatic ventilation fails, the conversion to immediate ventilation must be immediate.

9. Ventilation of r**oom air is better than no ventilation at all**. Blending of oxygen and air gas mixture to adjust FiO2 is an option 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.

10. COVID-19 can get 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 infections. In-line HEPA filters can usually be purchased alongside manual resuscitator bags.

11. Heat and moisture exchanger should be used in line with the breathing circuit. Failure conditions must result in an alarm. 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.

12. Any ventilator design must incorporate pressure sensing and actively monitor both peak and plateau pressures.

13. Peak pressure exceeding 40 cmH2O (or a pressure set just below the pop-off pressure of the selected bag) must trigger an alarm.

**Minimum Performance Parameters for Ethiopia “Bridge” Ventilator:**

**Gas and electricity**

**1. Incoming Gas Supply**

a. If oxygen outlets are not expected, it can optionally operate using an oxygen concentrator device for input oxygen, these will typically be limited to 10 lpm.

**2. Gas supply to Patient**

a. Users must be able to control inspired oxygen proportion (FiO2). The percentage of oxygen in the gas being breathed in by the patient. Room air is 21% oxygen.

b. Gauge devices such as flow meters are used with continuous increment and decrement levels to regulate FiO2 going into the patient.

c. At least 50% (or 60%) and 100% FiO2 options

d. Ideally variable between 30 – 100 % in 10% steps.

e. Patient breathing system connections: the ventilator must present 22mm outside diameter (OD) ‘male’ standard connectors to ISO 5356-1:2015 on both outlet and inlet ports for connection to user supplied 22mm ‘female’ connectors on the breathing system. These must be rigid and robust (not plastic) and separated by a minimum of 10 cm between centres to accommodate filter HMEs.

All elements in the gas pathway must meet biological safety and low-pressure oxygen safety standards, especially to minimize risk of fire or contamination of the patient’s airway.

**3. Electricity Supply**

a. Should connect to 220-240V main supply. This will avoid electrical components designed for 60 HZ System with additional backup generator supply.

b. Should be PAT tested to the adapted IEC 60601, IEC 62353 standards. There are normally required standards to verify emissions and immunity to electromagnetic disturbances.

c. Battery backup – Must have a minimum of 20 minutes back up battery in case of mains electricity failure.

d. Optionally hot swappable batteries so that it can be run on battery supply for an extended period, e.g. 2 hours for within hospital transfer. This is a good option to consider in design as power failure is expected in Ethiopia.

e. Must avoid harmful RF or EM emissions that could interfere with other critical machinery.

f. 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.

g. Although all major hospitals in Ethiopia have back-up generators, the potential of power outage is high during a pandemic. The generators at all medical facilities and the makeshift Hospital at Millennium hall will be overloaded due to high usage, additional steps like uninterruptible power source (UPS) should be considered.

**Infection Control**

1. All parts coming into contact with the patient’s breath must be either disposable or able to be decontaminated between patients.

2. All external surfaces must be cleanable in the likely event that they get respiratory secretions or blood splatter on them. Cleaning would be by healthcare workers manually wiping using an approved surface wipe with disinfectant or cloths and approved surface cleaning liquid.

3. There will be a separately sourced HMEF-bacterial-viral filter between the machine and patient which may impact on resistance within the system, which may need to be accounted for with some designs. The pressure being delivered to the patient is the specified pressure. If the filter has a resistance of, say 2 cmH2O at 30 lpm, the ventilator needs to output 37 cmH2O to achieve a set 35 cmH2O at the patient. This will need further detailed consideration. Viral filtering filters may have much higher resistance that may be clinically relevant.

4. Optionally include a facility for hot water humidifiers to be included in the breathing system.

**Monitoring and Alarms**

1. Must alarm at minimum:

a. Gas or electricity supply failure. Devices cannot deliver air at a pressure higher than 40 cm H20 to mitigate risk of barotrauma (lung damage).

b. Low Battery level (when operating on battery mode): When there are 10 minutes or less of battery capacity remaining.

b. Machine switched off while in mandatory ventilation mode.

c. Inspiratory airway pressure exceeded: **tier 1** - Last breath ≥ set limit, **tier 2** - last 3 breaths ≥ set limit, **tier 3** - last 4 or more breaths ≥ set limit.

d. Inspiratory and PEEP pressure of atleast 5-15 cm H20 not achieved (equivalent to disconnection alarm): **tier 1** - Last 2 breath **tier 2** - Last 4 breaths **tier 3** - Last 10 or more breaths’ Peak inspiratory pressure ≤ set limit. *Applicable in certain operation modes*

e. Tidal volume of at minimum 250 ml not achieved or exceeded. The alarm indicates the measured exhaled mandatory tidal volume is less than or equal to and more than or equal to the Set Mandatory amount respectively.

2. Monitoring – the following should be continuously displayed so the user can verify.

a. Current settings of tidal volume, frequency, PEEP, FiO2, ventilation mode.

b. Actual achieved rates of tidal volume, breathing rate, PEEP, plateau pressure, FiO2.

c. If it exists, in pressure support mode there must be real time confirmation of each patient's breath and an alarm if below acceptable range.

d. Optionally CO2 monitoring included.

**Miscellaneous**

1. Ethiopia “Bridge” Ventilators must pass reliability testing outlined in verification and validation. It must have a 100% duty cycle for up to 14 days.

2. Optionally, it can be used beyond 14 days. The expected durability must be specified.

3. Can be floor standing or portable.

4. Ideally small and light enough to mount on a patient bed and orientation independent functioning.

5. Should be as robust as possible. For example, it may be dropped from 6-8 inches bed height to floor.

6. It must be intuitive to use for qualified medical personnel, but these may not be specialists in ventilator use.

a. Must not require more than 30 minutes training for a doctor with some experience of ventilator use.

b. Must include Instructions for Use.

c. Ideally instructions for use should be built into the labelling of the ventilator, e.g. with ‘connect this to wall’ etc.

d. Must include clear labelling of all critical functions and controls using standard terms, pictograms and colors that will be readily recognized by Ethiopian healthcare staff.

7. Must have transparent design, supply chain, manufacture, quality assurance and testing processes that are of sufficient quality following ISO 13485 and ISO14971 to enable Ethiopia FDA officials to deem appropriate for usage in exceptional circumstances.

8. Must not be excessively cumbersome so that it would impede hospital operations or prevent easy movement within hospital premises.

9. Must be made from materials and parts readily available in Ethiopia supply chain (anticipating increasing global restrictions on freight movement).

10. Relevant Standards – Advisory and applicable to ventilators.

a. BS EN 794-3:1998 +A2:2009 Particular requirements for emergency and transport ventilators

b. ISO 10651-3:1997 Lung Ventilators for Medical Use - Emergency and Transport

c. BS ISO 80601-2-84:2018 Medical electrical equipment. Part 2-84. Particular requirements for basic safety and essential performance of emergency and transport ventilators – especially the parts on ‘patient gas pathway’ safety (very similar to IEC 60601)

d. ISO 80601-2-12:2020 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

e. BS ISO 19223:2019 Lung ventilators and related equipment. Vocabulary and semantics

**Verification and Validation Testing**

1. It is accepted that full demonstration of compliance to [**ISO 80601-2-12:2020**](https://drive.google.com/open?id=17LxYLbfzzse89G70xYauKqdOjAa3BnZ5) is unrealistic in the time frame required for development. Nevertheless, compliance with the essential safety standards must be demonstrated for patient safety.

2. It is not anticipated that the device will gain 510(k) clearance from the U.S FDA or CE market given the time constraint due to pandemic. Therefore, we are proposing approval from Ethiopia FDA following the “Exceptional use of non-CE marked medical devices” route.

Manufacturer/Applicant is required to present the following:

a. Identify predicate devices (similar devices currently in use)

b. Clinical investigations currently using device

c. Details of aspects of device that differentiate it from other devices already on the market

d. Information on risk analysis, identification of hazards, estimation of risks and how such risks have been addressed, together with information to support a positive risk benefit analysis

3. Applicants will derive a Usability testing plan leveraging [Formative Usability Test released by UK Gov](https://drive.google.com/file/d/1ClyIX4NcIDQ8isVjATpTJsIAS02Tm5z2/view?usp=sharing) at both **prototype** and **final production** stages will be required. This should be done as a short Formative Usability Test to ISO 62366 in a realistic environment .The user will be wearing complex protective clothing which includes: Eye goggles (in addition to spectacles if worn), Face shield, Plastic apron, Surgical gown, Two layers of gloves, usually nitrile non- handed small, medium, large variants, Gloves are donned in layers and sticky taped onto sleeves of gown in between layers

4. The user must be able to instantly see the settings selected and be able to easily operate all controls while dressed in protective gear. They may be required to remain so clothed and operate the ventilator for a number of hours without breaks.

**Glossary**

BIPAP – Bilevel Positive Airway Pressure: a non-invasive ventilation mode that provides different levels of pressure when the patient inhales and exhales.

EM – ElectroMagnetic Emissions: Many medical devices are sensitive to EM interference. Care should be taken to ensure that this is kept to a minimum.

FiO2 – Fraction of inspired oxygen: concentration of oxygen in the gas mixture that the patient inhales

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. Can also filter bacteria and viruses, this will be used on all patients. WARNING can affect delivered pressure.

PEEP – Positive End-Expiratory Pressure: The lower pressure applied to the patient’s airway to allow them to breathe out, but not too much.

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, to avoid trauma.

RF – Radio Frequency: Many medical devices are sensitive to RF interference. Care should be taken to ensure that this is kept to a minimum.

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

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