Emergency Mechanical Ventilator

DRAFT Operations Manual

THIS DOCUMENT IS AN ***EARLY DRAFT*** AND NOT FOR REFERENCE IN A MEDICAL SETTING.

This DRAFT document assumes a ventilator design which meets the “Indicative Specification for a Rapidly Manufactured Ventilation System”, as published by the British Chamber of Commerce at <https://www.britishchambers.org.uk/media/get/Specification%20For%20RMVS%20Challenge.pdf>.

Prior to publication for use in the field, this document will be revised to conform to the final emergency ventilator design, appearance and specifications. Such revisions will include images of the actual ventilator, a table of contents, contact information, etc. All editing comments (shown in the same blue as this text) will be removed from any final revisions. Final revisions of this document will be subjected to review for technical accuracy by (1) an engineer familiar with the final product requirements, design, components and method of construction, and (2) a medical professional certified in the use of mechanical ventilators for respiratory care.

# Intended Use

This mechanical ventilator is intended only for emergency situations where a commercial, medical-grade mechanical ventilator is unavailable. Only trained medical personnel are to use this ventilator for patient care. Serious harm or death to the patient *or care providers* may result from improper use or from failing to abide by the **Requirements, Restrictions and Precautions**, below.

# Non-Standard Testing and Certification

This ventilator was designed in a crash program to devise an inexpensive and locally buildable ventilator to respond to the COVID-19 pandemic. Neither the design nor the final product have been through normal quality control or certification processes.

This Emergency Mechanical Ventilator’s individual components, as specified in the *\_\_\_\_\_\_\_ Emergency Mechanical Ventilator Parts List, Construction and Assembly Instruction Set, Revision \_\_\_\_\_\_\_*, have been through the following testing and certification processes:

Motor: Manufactured by \_\_\_\_\_\_\_\_\_\_\_\_\_ with ISO \_\_\_\_ certification [assumption], having a duty cycle of \_\_\_\_% \_\_\_\_\_ continuous.

Bag Valve (air bladder): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Pneumatic Valves: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Electronic Components: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Similar Emergency Mechanical Ventilator units as a whole have been built from the *\_\_\_\_\_\_\_ Emergency Mechanical Ventilator Parts List, Construction and Assembly Instruction Set, Revision \_\_\_\_\_\_\_* and then subjected to the following informal testing processes:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: The ventilator may lack redundancy and other safety features found on commercially manufactured medical-grade mechanical ventilators.

# Requirements, Restrictions and Precautions

**Supervision:** medical staff must remain close enough to the ventilator at all times so that any audible alarm can be heard and responded to. Such medical staff must have the training and ability to detach the ventilator from the patient and replace it with a spare unit or manual bag valve should the unit fail for any reason.

**Basic Safety:** Keep the unit away from excessive humidity levels, flammable gases and hazardous chemicals. Exercise the same precautions as with any electric device.

**Pathogen Risk:** pathogens carried as aerosols in the patients exhalations may be exhausted from the unit during operation. Medical staff must use N95 masks to protect themselves. An optional HEPA filter can provide additional protection against pathogens.

**Duty Cycle:**  100% for 14 days continuous

The ventilator must not be run for longer than 14 days (336 hours) cumulative in total – whether continuous or discontinuous.

The ventilator must be decommissioned (and optionally refurbished) after the equivalent of 14 days of cumulative operation (336 hours).

A simple digital watch with a stopwatch/timer feature can be used to track cumulative run time (run times should be noted in a paper log book to accompany the ventilator).

**Power requirements:** (see Specifications)

**Operating Environment:** the Emergency Mechanical Ventilator is designed for indoor use, where the unit can be placed horizontally on its base and where extremes of humidity, temperature, vibration and dust can be avoided.

# Controls and Operation

It is assumed that the operator is a trained medical professional with experience in the use of mechanical ventilators. It is beyond the scope of this manual to cover respiratory care, intubation, patient positioning and monitoring requirements, etc.

[A note should be included here to describe

* the mode(s) of mechanical ventilation offered by this unit, .i.e. Volume Cycled, SIMV, Pressure Control Ventilation, Pressure Support Ventilation, etc.
* whether breaths are strictly timed or triggered by the patient
* whether pressure is fixed or adjustable

– as defined in the Merck Manual at <https://www.merckmanuals.com/professional/critical-care-medicine/respiratory-failure-and-mechanical-ventilation/overview-of-mechanical-ventilation>.]

The Emergency Mechanical Ventilator offers a few basic controls and features, as shown in the image below:

**Volume Knob:** adjust the volume of air or oxygen delivered to the patient with each inhalation cycle. Volume should be set according to standard practice for ventilation of a patient. Volume settings are typically 350 ml per breath or 450 ml per breath, depending on the patient. [ does ventilator have the ability to show actual volume via gauges/sensors?] [does unit need to be calibrated to ensure accurate volume settings?] [should this control offer fixed positions for specific pressures?]

Note: the patient inhalation supply pipework will remain pressurised at all times to maintain PEEP pressure at 150mm H20 [Assumed per RMVS specifications. Need to know if this requires a switch to turn on/off].

**Breaths Per Minute (BPM) Knob:** adjustable rate of between 12 and 20 cycles/breaths per minute. Rate set according to the specific patient’s needs; may require periodic manual adjustment.

**Inspiratory/Expiratory (I/E) Ratio Knob:** adjust the relative duration of the inhalation cycle and the exhalation cycle. Ratio set according to the specific patient’s needs; may require periodic manual adjustment.

**(Optional) Digital Display:** Shows the current settings for Volume, Breaths Per Minute and I/E.

**(Optional) Pressure Relief Valve:** Ensure air pressure to the patient (high pressure) never exceeds 350 mm H2O.

**Inspiratory Connection Port:** connection point for flexible tubing leading to the patient.

**Oxygen Port:** connection point for oxygen tank to supply oxygen to the patient.

**(Optional) Oxygen Mix Valve:** Adjust the concentration of oxygen to air in the gas mixture supplied to the patient. Assumes O2 supplied at \_\_\_\_\_ pressure. [assumption that a mix valve is a valid option] NOTE: No alarm is provided to alert if the oxygen supply diminishes [assumption]

**Expiratory Connection Port:** connection point for flexible tubing leading from the patient.

**Expiratory Exhaust Port:** exhausts exhalation from the patient to the environment, optionally through a HEPA filter attachment.

**(Optional) HEPA filter for expiratory output port:**  Minimizes the spread of viruses or other pathogens from the patient (via aerosols) to the immediate environment – for the welfare of nearby medical staff or anyone else nearby who is not already suffering from the same respiratory infection(s) as the patient. NOTE: N95 face masks (or equivalent) must be worn by all medical staff in proximity to the patient or the ventilator even if the ventilator is equipped with a HEPA filter.

The HEPA filter (and the ventilator itself) must be replaced after a cumulative run-time of 14 days (336 hours). In a field hospital setting with dusty conditions, the HEPA filter may need to be replaced prior to the decommissioning of the ventilator. Note that ventilator run time must be logged in a log book which accompanies the ventilator.

**(Optional) Pressure Loss Alarm:**  Audible alarm sounds when unit is powered on and pressure falls below \_\_\_\_ mm H2O on the inhalation line for any reason.

# Cleaning, Sanitation and Maintenance

Do not clean a ventilator actively being used by a patient.

Unplug the ventilator before attempting to clean it.

The ventilator exterior can be cleaned with a paper towel lightly dampened with isopropyl alcohol. Do not get the ventilator wet.

The ventilator’s motor(s) should not be cleaned or lubricated. Rather, the motor(s) should be refurbished after the ventilator reaches the end of its duty cycle of 14 days (336 hours of cumulative operation).

The ventilator’s inflatable bag and flex lines which make up the inhalation line should be replaced if the ventilator needs to be connected to a different patient.

The ventilator’s inflatable bag and flex lines which make up the inhalation line *could possibly* be disconnected from the ventilator and sanitized, provided these components are capable of withstanding the temperatures needed for sanitation. Refer to product documentation for the inflatable bag and ventilation valves and flex lines [need to validate].

Ventilator run time must be logged in a log book which accompanies the ventilator, to ensure the ventilator does not exceed its duty cycle of 14 days (336) hours of cumulative run-time (whether continuous or intermittent).

# Specifications

Power requirements:

Volts A/C: \_\_\_\_ [assuming A/C]

Watts: \_\_\_\_\_

Duty Cycle: 100% continuous for 14 days (336 hours)

Volume accuracy: +/- 10 ml per breath @ 350 ml/breath or 450 ml/breath

Breath Frequency Accuracy: within 1 breath per minute.

Audible alarm volume (dB): \_\_\_\_\_

These specifications are subject to change. Duty cycle may be lengthened as more testing data accumulates.

# Obtaining Assistance

Contact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for support.

Register this product online at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to receive any notifications or gain access to additional documentation including:

* safety recalls (due to design or components)
* new options
* possible duty cycle extensions
* refurbishing procedures
* revisions to or translations of this operations manual or specifications
* spare parts availability
* refinements to the design
* parts lists, build and assembly instructions