Design Requirements

Goals

- A minimum viable, safe design ventilator/automated BVM, to provide clinical benefits versus a scenario in which no ventilator is available.
- Open source for use worldwide and contributions from others worldwide
- Provide value beyond open sources efforts targeting :
  - Provide Safety that meets standards under emergency use authorization
  - Provide UI, controls, and history
  - Provide industrial quality design on top of open source efforts
  - Design for manufacture and scaling beyond what open source efforts can provide

Overall design philosophy

- Three steps
  a. Get the basics out at the right safety with maker-type hardware standards to meet critical timelines,
  b. time permitting add clinical value,
  c. and then add scaling value
- Adult ventilator (older adults at higher risk)
- Volume control (VCV) and SIMV with breathing assist (see appendix)
- The supplies and materials will be locally available or online to order easily
- The design(s) will be validated; validation will be documented and transparent;
- The design(s) will be modular allowing different modules to be mixed and matched depending on local availability
- Works on AC with 2 hours of battery backup

Assumptions:

1. FDA will provide authorization for the bare bones design if there is a massive shortage as we are already starting to see across some communities in the US with specified safety criteria
2. Traditional medical components and supplies used in ventilators will be in short supply

Adapted from MIT and Florida

Volume Controlled Intermittent Mechanical Ventilation

	Range	Accuracy	Settings
Tidal volume	150-800 ml	± 10%	Increments of 50 ml
Respiratory rate	5 – 35 bpm	100%	Fixed settings: 5 - 35 bpm, increments of 2. Continuous is nice to have (increments of 1)
I:E ratio; no inspiratory pause	1:1, 1-1.5, 1:2, 1:3	-	4 fixed setting
PEEP	5 – 24 cm H_2O; Default setting 5 cm H_2O	± 1 cm H_2O	Fixed for V1.0 with Ambubag. Nice to have PEEP pressure monitored Adjustable for Version 1.1: Prefer continuous variable in increments of 1 cm of H2O
Air and O_2 supplied at 50 ± 5 psig (345 kPa)			External to system, standard connector to AMBU BAG
FiO_2	0.21 or 1.0 0.21 – 1.0	± 0.05	Very Nice to have : Continues variable FIO2 setting with external blender
Anti-asphyxia valve	Opens at –3 ± 1 cm H_2O		We have to add this to our tubing or it is a feature in AMBU BAG

Pressure	Max Pressure at Opens at 40 cm H_2O ±5 cm H_2O, opened with Safety valve Plateau Pressure at 30 cm H_2O		
Assist Control (breath detection)	Sense pressure of -1 to -5 cm H20		Assist Control (breath detection)
Filtering			HEPA Filtering output Viral Filter Inline to patient
Humidification			External - can be connected to AMBU BAG

UI/UX

- Spec an interface (LCD and Buttons)
    - Respiratory Rate
    - Tidal Volume - IN and OUT
    - Tidal Volume Per Minute
    - PEEP - (nice to have)
    - Peak inspiratory pressure
    - Plateau pressures
    - Alarms (off and on, pause)
    - Ventilator History review (nice to have, with alarms)
- Has to work with double gloves - Nitrile and Latex
- Has to have an emergency stop
- Power Switch

Mechanical

- Portable

- Standalone operation - human in ear shot of alarms
- Robust mechanical, electrical and software systems (Simple, Corrosion resistant, Vibration resistant, Best crystal oscillator)
- Readily sourced and repairable parts (3D printing, laser cut, water cut)
- Minimal power req (Efficient motor controller)
- Mechnicals and EE separable

User interface

- Alarms for
  - Loss of power,
  - Loss of breathing circuit integrity,
  - High airway pressure and low battery life,
  - Low delivered tidal volume if lower than 30%
  - Apnea (no air movement) alarm
  - High pressure
  - Low pressure
- Display of settings and status
- Standard connection ports

Other

- Indicators within 5% of correct reading
- Be reliable. It must work continuously without failure (100% duty cycle) for blocks of 14days — 24 hours a day. If necessary, the machine may be replaced after each block of 14 days x 24 hours a day use.
- Device must last for 6 months use, with bag being replaced for each patient.
- Be built from O2 safe components to avoid the risk of fire and demonstrate avoidance of hot spots.
- Ability to sense when a patient is breathing, and support that breathing is highly desirable (dont want the ventilator to deliver a breath-in when the patient is breathing out).
- Support connections for hospital Oxygen supplies — whether driven by piped or cylinder infrastructure
- Be compatible with standard COTS catheter mount fittings (15mm Male 22mm Female)
- Fail SAFE, ideally generating a clear alarm on failure. Failure modes to be alarmed include (but are not limited to) pressure loss and O2 loss

- Have a potential to splice the ventilatory circuit in order to give medicines via the ET (endotracheal tube).
- Store data for 2 weeks with easy ability to review alarms and patient data (nice to have)

Appendix (From MIT)

Volume control mode is just that: a clinician defines the tidal volume. The machine will then try to deliver that volume with a uniform inspiratory flow rate, over a specified inspiratory time (see discussion on cycling). This is done regardless of how much pressure builds up in the lungs, referred to as peak inspiratory pressure, or PIP. Modern ventilators have safety features to limit max pressures, which can result in damage to the lungs (aka barotrauma). Ventilators have the capability to perform an "end-inspiratory hold", for a programmable duration over which the pressure in the circuit is recorded. This is called **plateau pressure (P_{plat})**. A volume-controlled breath cycle with inspiratory hold is illustrated in Figure 1.

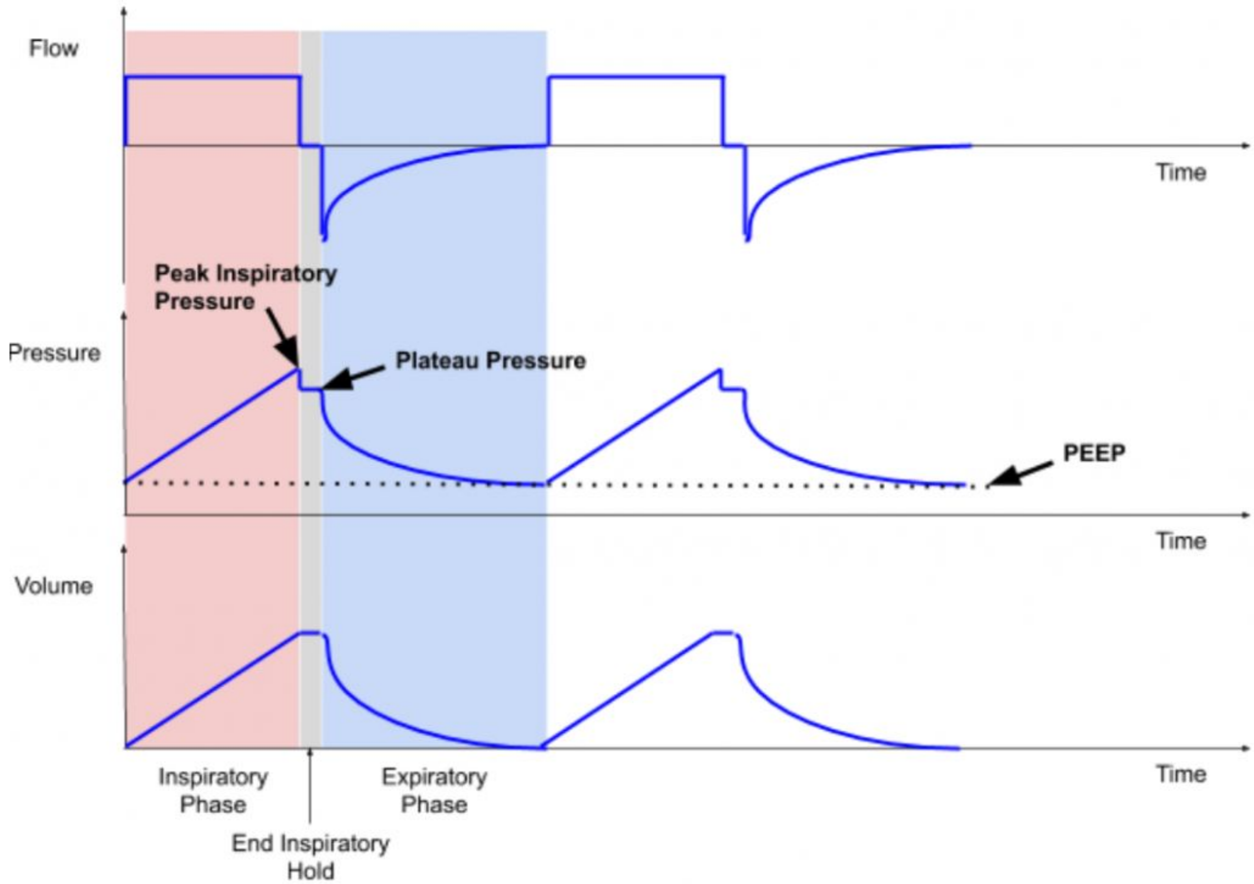

Figure 1: Flow, Pressure, and Volume profiles for volume-control ventilation over 2 breath cycles; PEEP is illustrated on the Pressure plot. Image courtesy AK.

Assist Control/: The system will sense airway pressure fluctuations, and supports patient-initiated breaths, and then recognizes and allows exhalation.

The first breath in this cycle is one initiated by the ventilator. The second breath is the patient triggered breath. There is a slight dip at the beginning of the breath, which is the patient creating a negative pressure.The ventilator senses this and delivers another breath. The user can set what the trigger is, in litres per minute of flow for example, to make it easier or harder for the patient to trigger the breath.The ventilator will then deliver that breath to the set volume or pressure depending on the parameters set by the user i.e. is it pressure controlled or volume controlled ventilation.So the ventilator assists the patient by controlling the amount of volume the patient receives.

SIMV: Just as in AC mode, if the patient does not trigger a breath, the patient will receive a set volume/pressure breath, as in the first breath here.However in SIMV when a triggered breath is initiated the patient determines the volume, which may be smaller than the non triggered breath.So if the patient wants a lower volume during their spontaneous efforts they will receive a lower volume.If the patient is taking good volumes during their spontaneous breaths, this may indicate that weaning might be possible.SMIVIf the spontaneous breaths are too small, then pressure support can be added to each breath to help the patient.