**USER NEED REQUIREMENTS**

Intended USE (general purpose and function):

* Provide Respiratory Support to help patients (with respiratory failure or impending respiratory failure) breathe by:
  + Delivering oxygen
  + Maintaining oxygen saturation and concentration
  + Maintaining positive end ventilation pressure (as required)

Until patient is out of respiratory failure.

Indications for Use (target population, medical conditions etc):

* Target Population: All Age Groups
  + COVID19 patients tend to be older >60 and need more respiratory/ventilation support
    - Predominantly men, Greater than 50 years of age
    - older patients mostly have other comorbid illnesses that makes them vulnerable for the disease b/c they don’t have the immune system to fight the disease and suffer the most.
  + Typical Underlying Health Conditions seen in patients who require ventilation:
    - patients with underlying illness like lung disease, heart conditions
    - Concomitant chronic or acute illness which could be pulmonary or extra pulmo pulmonary
    - Obesity
    - Heart disease and liver disease Acute Respiratory Distress Syndrome patients secondary to SARI (primarily) Hemorrhagic encephalitis (Cases reported)
    - Head injuries, major chest trauma

Framework for Medical Device Product Design:

* The machine should have specific buttons and adjustable parameters including respiratory frequency, volume as well as pressure at least.
  + Ability to have positive airway pressure
  + Ability to alter Oxygen concentration and volume (based on the patients’ weight and age) variables.
* The basic design of mechanical ventilators is similar for all age groups. Mechanical ventilators
* should be usable for most age categories regardless of underlying conditions listed in indication for use.
* **ELECTRICITY** 
  + There is frequent power fluctuation and instability, 4-5 times a week. Only referral hospitals and some other general hospitals have generators where it’s highly unlikely to get an outage of a ventilator.
  + Ventilators should have their own reservoir battery so in case there is no electricity or a problem with the backup generator. Ventilators can work for a specified time with back-up battery until the issues are resolved.
* Ventilators must be compatible with oxygen tank/cylinder and standard endo-tracheal (ET) tubes, outlet source, capnograph, pulse oximeter.
  + conduits that connect the ventilator and patient (ET tubes, Conduits)
  + A capnograph (this is an instrument hooked up on the conduits that detects the level of CO2 in the exhaled air). It ascertains that the tube is in the right location.

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General Requirements

* Cheap, mass producible, easy to use manuals and reliable
* Easily accessible and sustainable
* Quantity (increase production) and maintenance of mechanical ventilators
* It should be cost effective, portable, and reusable
* Due to shortage of ventilators, machine will be used 24/7 for one patient at a time.
* Disinfection of machine is key as it will be used on different patients, one at a time.
* Ventilators should be configured by trained healthcare professionals and function without user intervention.
* To be used by trained professionals and any junior nurse or practitioner can be trained to monitor alarms and do necessary suctioning.
* Should be user-friendly to allow workers with non-technical knowledge to train and quickly adapt to its use.