

## VENTILATION PERFORMANCE

1. Pressure controlled
  1. Inspiratory pressure up to 40cmH<sub>2</sub>O
  2. Expiratory pressure up to 20cm H<sub>2</sub>O
  3. Respiratory rate from 5-40 breaths a minute
  4. Measurement of tidal volume at the Y piece
2. FiO<sub>2</sub> from 20% to 100% in discreet steps of 10%
3. Triggering—timed or patient-effort triggered
4. Connect to standard masks and tubes
5. Connect to standard oxygen connectors
6. Accuracy (<10% for volumes and pressure, to 1 breath a minute for rate)
7. Can work on internal battery for >180 min
8. Oxygen concentration NOT mandatory, recommended

## PATIENT SAFETY

### ALARMS OR LIMITS

1. Minute Ventilation (low/High) alarm
2. Peak pressure, Low expiratory pressure and/or disconnection alarm
3. Low expiratory pressure
4. Oxygen concentration
5. Non-rebreathing valves

### DEVICE SAFETY

1. Electrical safety requirements
2. Fire safety (i.e., pure O<sub>2</sub> flowing)

### INFECTION CONTROL

1. HEPA filtered inlet and outlet
2. Easy-to-clean surfaces

## DESIGN REQUIREMENTS

### USER INTERACTION

1. Simple to use—must not require specialized training
2. Modular, with known failure potential for each component
3. Easy to maintain (related to modularity)
4. Settings legible from 1m
5. Clear flow directions

### MATERIAL AND MANUFACTURABILITY

1. Widely available material (e.g. 3D printable filaments, plastic/metal sheets)
2. Can be built locally using either simple tools or rapid prototyping (i.e. 3D printing, CNC, etc.)
3. Only eligible material allowed (see list to exclude)

### OPERATIONAL REQUIREMENTS

1. Both 110V and 220V

### TESTING, CALIBRATION, AND MAINTENANCE REQUIREMENTS

1. Tests to calibrate and validate volume and pressure settings
2. Tests to verify limits and alarms
3. Illustrated and clear diagram for taking apart, replacing, and rebuilding the device safely

## REFERENCES

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