VENTILATION PERFORMANCE

1. Pressure controlled
   1. Inspiratory pressure up to 40cmH2O
   2. Expiratory pressure up to 20cm H2O
   3. Respiratory rate from 5-40 breaths a minute
   4. Measurement of tidal volume at the Y piece
2. FiO2 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 O2 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