

# Ventilator system

## Requirement to fulfil :

- **Modes:**

As per UK standard for rapid ventilator manufacturing , there must be atleast one mode of the following[best if both]

1. Must have mandatory ventilation (for the deeply sedated and paralysed). The user can set a tidal volume and the output is a pressure regulated flow to achieve this volume, for example, pressure regulated volume control (PRVC), SIMV-PC
2. **Optional** pressure support mode for those patients breathing to some extent themselves, for example, BIPAP. The user sets an inspiratory pressure and an expiratory pressure. The ventilator can sense when a patient starts to breathe in and apply the inspiratory pressure, then sense when the patient starts to breathe out and apply the expiratory pressure (this pressure is still positive but lower than the inspiratory pressure)

[Must be reliable. It must have 100% duty cycle for up to 14 days.

**Optionally** it can be used beyond 14 days, the expected durability must be specified.]

---

## **Respiratory Requirements:**

- **Inspiratory requirement:** [ the higher pressure setting that is applied to make the patient breathe in]
  1. plateau pressure should adapt to achieve volume and be limited to 35 cmH<sub>2</sub>O
  2. peak pressure should be no more than 2 cmH<sub>2</sub>O greater than plateau pressure
  3. ideally there should be a mechanical failsafe valve that opens at 40 cmH<sub>2</sub>O
- **Positive End Expiratory Pressure PEEP:**[ The lower pressure applied to the patients airway to allow them to breathe out, but not too much]
  1. range 5 to 25 cm H<sub>2</sub>O adjustable in 5 cmH<sub>2</sub>O increment
  2. patient breathing system must remain pressurised to at least the PEEP level setting at all times

Optional components : **Font** , **Mandatory : front** , **Misc. info: Font**

- **Inspiratory:** Expiratory ratio (I:E)
    1. 2.0 (i.e. expiration lasts twice as long as inspiration)
    2. **optionally** adjustable in the range 1.0 to 3.0
  
  - **Respiratory Rate.** [The number of breathing cycles every minute]:
    1. range 10 to 30 breaths per minute in increments of 2 (only in mandatory mode) can be set by the user
  - **Tidal Volume (Vt).** [The volume of gas flowing into the lungs during one inspiratory cycle]
    1. must have at least one setting of 400ml +/- 10 ml
    2. ideally 350ml and 450 ml options
    3. **Optionally** Range 250 to 600 ml in steps of 50ml
    4. even more optionally up to 800 ml
    5. **Optionally** the ability to input body weight and have volume calculated as, for example, 6ml/kg of ideal body weight.
- 

## **Gas & Electricity Supply:**

- **Incoming gas supply:**
  1. **all gas connectors and hoses** must use standard non-interchangeable connectors and be **colour coded according to current standards**
  2. must connect to **wall pipeline oxygen supply via Schrader valve connector (BS 5682, not the bicycle wheel version)**. If hose not permanently fixed to machine, then must connect with NIST (Non-Interchangeable Screw Thread – ISO 10802). Oxygen pipeline pressure **is 4 to 5 Bar**
  3. **Optionally** can incorporate a **backup oxygen cylinder** connected via either Schrader valve or Pin Index System
  4. must be able to be operated on any attached cylinders. Oxygen **cylinder pressure is either 1 to 137 bar if no regulator is fitted, or 4 bar** if the cylinder incorporates a pressure regulator. The ventilator must be able to work with either. The ventilator must include a pressure **regulator to decrease 137 bar cylinder pressure to 4 bar working**

pressure. Working pressure inside the ventilator may be up to 4 bar, but it must be impossible to expose the patient to any pressure above 40 cmH<sub>2</sub>O

5. **Optionally** can connect to wall pipeline medical air via Schrader valve (NB 'medical air' is 4 bar. Must not connect to 'surgical air 7 bar' supply)
  6. **Optionally** can connect to Anaesthetic Gas Scavenging System
  7. **Optionally** can operate using an oxygen concentrator device for input oxygen
- **Electricity supply:**
8. should connect to 240V mains
  9. battery backup . Must have 20 minutes backup battery in case of mains electricity failure
  10. **Optionally** hot swappable batteries so that it can be run on battery supply for an extended period, for example, 2 hours for within hospital transfer
  11. must avoid harmful RF or EM emissions that could interfere with other critical machinery

### Battery Backup

[Every current ventilator used inside hospitals has a battery backup, so users will expect it to be there and will behave as if it is, for example, unplug it from the wall in order to rearrange cables or while manoeuvring the patient. However, this needs very careful thought to balance the risks. Including this in the spec means instantly trying to source 30,000 large, heavy batteries. Specifying a DC voltage (ie 12VDC) may well be the most sensible for the machine working voltage. Need the advice of an electronic engineer with military/resource limited experience before specifying anything here. It needs to be got right first time.]

## Gas supply to patient:

1. user must be able to control **inspired oxygen proportion (FiO<sub>2</sub>)**. The percentage of oxygen in the gas being breathed in by the patient.  
**Room air is 21% oxygen**
2. at least **50% and 100% options**
3. very preferably ideally variable between **30 and 100% in 10% steps**
4. Patient breathing system connections: the ventilator must present **22mm outside diameter (OD) 'male' standard connectors for connection to user supplied 22mm 'female' connectors** on the breathing system

All elements in the gas pathway must meet biological safety and oxygen safety standards, especially to minimise risk of fire or contamination of the patient's airway.

---

## Infection control [imp]

All parts coming into contact with the **patient's breath** must be either **disposable or decontaminatable between** patients.

All **external surfaces must be cleanable** in the likely event that they get **respiratory secretions or blood splatter on them**. Cleaning would be by healthcare workers manually wiping using an approved surface wipe with disinfectant or cloths and approved surface cleaning liquid.

There will be a separately sourced **HMEF-bacterial-viral filter** between the **machine and patient** which may impact on resistance within the system, which may need to be accounted for with some designs. The pressure being delivered to the patient is the specified pressure. If the filter has a resistance of, say **2 cmH<sub>2</sub>O**, the **ventilator needs to output 37 cmH<sub>2</sub>O to achieve a set 35 cmH<sub>2</sub>O at the patient**. This will need further detailed consideration. Usually **HMEF filters have negligible resistance**, but the viral filtering filters may have much higher resistance that may be clinically relevant.

**Optionally** include facility for ultrasonic humidifier-warmer to be included.

## Alarms:

Must alarm at:

1. gas or electricity **supply failure**
2. **machine switched off while in mandatory** ventilation mode
3. inspiratory **airway pressure exceeded**
4. inspiratory and PEEP **pressure not achieved** (equivalent to disconnection alarm)
5. **tidal volume not achieved** or exceeded

## Monitoring

The following should be continuously displayed so the user can verify:

1. current settings of tidal volume, frequency, PEEP, FiO<sub>2</sub>, ventilation mode
  2. actual achieved rates of tidal volume, breathing rate, PEEP, plateau pressure, FiO<sub>2</sub>
  3. if it exists, in pressure support mode there must be real-time confirmation of each patient breath and an alarm if below acceptable range
  4. **optionally** CO<sub>2</sub> monitoring included
- 

### **Related to examining and training:**

must be intuitive to use for qualified medical personnel, but these may not be specialists in ventilator use:

- must not require more than 30 minutes training for a doctor with some experience of ventilator use
- must include instructions for use

- ideally instructions for use should be built into the labelling of the ventilator, for example, with 'connect this to wall' etc
  - must include clear labelling of all critical functions and controls using standard terms, pictograms and colours that will be readily recognised by UK healthcare staff..
- 

### **Material:**

Must be made from materials and parts readily available in the Pakistan supply chain (anticipating increasing global restrictions on freight movement)

---

### **Standards**

There are many standards that exist in this area. Below is a list of the most relevant ones. They are not formal regulatory requirements but many are harmonised against regulatory requirements. Consider them as helpful advisory standards for now. MHRA will lead an exercise to define which can be 'safely' relaxed for this emergency situation:

- BS EN 794-3:1998 +A2:2009: Particular requirements for emergency and transport ventilators
- ISO 10651-3:1997: Lung ventilators for medical use – emergency and transport
- BS ISO 80601-2-84:2018: Medical electrical equipment. Part 2 to 84. Particular requirements for basic safety and essential performance of emergency and transport ventilators – especially the parts on 'patient gas pathway' safety (very similar to IEC 60601)
- BS ISO 19223:2019: Lung ventilators and related equipment. Vocabulary and semantics

Link: [[https://www.gov.uk/government/publications/coronavirus-covid-19-ventilator-supply-specification/rapidly-manufactured-ventilator-system-specification?fbclid=IwAR1KfK48JVBCWpRYY-WNDqjM9-UpB\\_TEicXpvQXabn1Cto\\_kcgrNnhbnnPE#ventilation](https://www.gov.uk/government/publications/coronavirus-covid-19-ventilator-supply-specification/rapidly-manufactured-ventilator-system-specification?fbclid=IwAR1KfK48JVBCWpRYY-WNDqjM9-UpB_TEicXpvQXabn1Cto_kcgrNnhbnnPE#ventilation)]

Optional components : **Font** , Mandatory : front , Misc. info: **Font**