Ventilator for COVID-19 use in Australia

Version 1.0

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This specification describes the minimal acceptable performance and desired features for a ventilator to be used in Australian hospitals during the current SARS-CoV2 outbreak. It has been compiled based on advice from anaesthesia and intensive care medicine professionals and advice from the Therapeutic Goods Administration.

The ventilator is intended for use with adult patients. It will not be suitable in all cases, such as adults who are extremely small or large, or have particularly complex responses to the infection. In these cases, it is assumed that other, more sophisticated ICU invasive ventilators will be used.

This specification does not apply retrospectively to any existing, approved ventilators.

It must be borne in mind that intensive care medicine is a whole system of care and ventilators cannot be safely used on any patient without trained staff and other equipment and medicines.

Required Features

Mandatory ventilation

- the operator can set a tidal volume and respiratory rate. The output will be selected by the operator to be either pressure-controlled ventilation (PCV) or volume-controlled ventilation (VCV)

Positive end expiratory pressure (PEEP)

- range from 5 to 25 cm H2O adjustable in increments of 2 cm H2O or smaller
- patient breathing system must remain pressurised to at least the PEEP level setting at all times

Respiratory rate

- range from 5 to 30 breaths per minute adjustable in increments of 2 or smaller

Tidal volume (Vt)

- range from at least 200 mL to 800 mL, adjustable in increments of 50 mL or smaller.
- inspiratory flow rate up to 100 litres per minute
- inspiratory time adjustable from 0.5 seconds to 2 seconds

Airway pressure safety

- peak inspiratory pressure should adapt to achieve the set tidal volume and have an operator-adjustable limit up to 50 cm H2O
- a mechanical failsafe valve must open at 80 cm H2O

Inspired oxygen proportion (FiO_2)

- range up to 100%, adjustable in increments of 5% or smaller
- the ventilator must present 22 mm outside diameter (OD) 'male' standard connectors for connection to operator-supplied 22 mm 'female' connectors on the breathing system
- All elements in the gas pathway must meet biological safety and oxygen safety standards for 100% oxygen, especially to minimise risk of fire or contamination of the patient's airway

Oxygen supply to ventilator

- all gas connectors and hoses must use standard non-interchangeable connectors and be colour coded according to AS 2902-2005 or equivalent standards
- must connect to wall pipeline oxygen supply via Sleeve Index System (SIS) defined in AS 2896-2011 or equivalent. Assume oxygen pipeline pressure is in the range 400 kPa (4 bar) to 500 kPa
- must be able to be operated on any attached oxygen cylinder connected via SIS and fitted with a 400 kPa output regulator

Air supply to ventilator

- it is preferable not to require pressurised air, as it will not be available in all care areas in pandemic conditions, however if pressurised air is required for ventilator operation:
- all gas connectors and hoses must use standard non-interchangeable connectors and be colour coded according to applicable standards
- must connect to the wall pipeline air supply via SIS
- Assume wall pipeline pressure is in the range 400 kPa (4 bar) to 500 kPa

Displays

- current settings of tidal volume, frequency, inspiratory time, PEEP, FiO2, ventilation mode
- mechanical displays on control devices such as knobs and sliders are acceptable

Alarms

Must generate an audible alarm at:

- gas or electricity supply failure
- machine switched off while connected to a patient
- inspiratory and PEEP pressure not achieved
- expiratory tidal volume not achieved by 10%
- inspiratory tidal volume exceeded by 10%

Electricity supply

- 240V AC mains
- 20 minutes backup battery in case of mains electricity failure
- should avoid RF or EM emissions that could interfere with other critical machinery

Miscellaneous

- must achieve 100% operating duty cycle for at least 14 days
- must include instructions for use and trouble shooting
- clear labelling of all critical functions and controls using standard terms, pictograms and colours that will be readily recognised by Australian healthcare staff
- must have transparent design, supply chain, manufacture and testing processes and field service arrangements that are of sufficient quality to enable health department officials and Therapeutic Goods Administration (TGA) officials to deem them appropriate for usage in exceptional circumstances
- must be able to be moved easily within hospital premises
- must be amenable to standard disinfection and cleaning procedures
- must be made from materials and parts, including disposables, that are readily available in the Australian supply chain (anticipating increasing global restrictions on freight movement):

1. Materials of Construction (raw materials)

a) The chosen material must be reasonably pure and simple in nature (minimise the use of additives where possible)
b) For components requiring flexibility avoid the use of materials requiring plasticisers. Good candidates are those materials that belong to the polyolefin family, examples include polyethylene and polypropylene
c) For structural components, materials such as polycarbonate or acrylonitrile butadiene styrene (ABS) should be used without additives, although reinforcement with glass fibre would be acceptable
d) Polyvinyl chloride (PVC) must be avoided in the patient gas pathway
e) PVC should be avoided elsewhere

2.Manufacturing Process (risk from contaminants)

a) Mould release agents used within extrusion or injection moulding techniques may be required in setting up the machine, they should not be needed once a process is in full scale production
b) Approximately, the first 20 or so items in an injection moulding production run should be discarded to minimise risk from contamination with mould release agents
c) Extrusion and moulding techniques are comparatively simple and well controlled; therefore, ventilators will not be required to be manufactured within cleanroom specifications
d) Manufacture in a reasonably clean room and protection of components and products from contamination should suffice
e) If a-d above are followed, chemical or particulate testing of the air coming out of the breathing circuit should not be necessary

3. Hazard Mitigation

a) Particulate matter: solid particles suspended in a gas. Particulate matter emissions are not of significant concern if the manufacturing process is adequately controlled as per the above criteria
b) Volatile organic compound (VOC): organic compound whose boiling point is in the range of 50^0C to 260^0C. Risk of exposure to VOCs can be minimised through the appropriate choice of materials as set out in section 1 (materials of construction)
c) Leachable substances (in condensate): chemicals removed from the medical device by the action of water, other liquids or other gases related to the use of the medical device. Ensure an HME filter is used between the ventilator and breathing system.

Other relevant standards

- See Appendix A, Relevant Standards and Documents
- Device verification and validation testing must be carried out by the manufacturer. Testing should be aligned to the requirements in the UK MHRA guidelines in Appendix B (Testing protocol for final validation of safety and performance of RVMS) at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876167/RMVS001_v3.1.pdf
- Rapidly manufactured ventilators are likely to include software. Included software falls under the definition of a medical device and must meet requirements that will ensure product performance and safety. See Appendix C (software development requirements) from the MHRA guideline at the link above.

Desirable Features

Spontaneous ventilation

- the operator sets an inspiratory pressure and PEEP. The ventilator will sense when a patient starts to breathe in and apply the operator-specified inspiratory pressure, then sense when the patient starts to breathe out and apply the operator-specified expiratory pressure.
- If the patient stops breathing in pressure support mode, it must failsafe automatically to mandatory ventilation.

Synchronized mandatory ventilation

- same as mandatory ventilation but mandatory breaths are synchronized to patient effort through flow sensing or pressure sensing, also known as synchronized intermittent mandatory ventilation volume control (SIMV-VC) or pressure control (SIMV-PC)
- additional inspiratory pressure support for those patients breathing to some extent themselves.

Tidal volume

- capacity to set inspiratory rise-time as a fraction of the inspiratory time, through waveform control or ratio control.
- inspiratory flow rate up to 150 litres per minute

Exhalation filters

- use modular expiratory components that can be removed for disinfection, and that can vent to long life viral filters

Gas supply

- can operate using an oxygen concentrator device for input oxygen

Extended battery use

- hot swappable batteries to run on battery supply for an extended period, for example, 2 hours for within-hospital transfer

Alarms

- inspiratory airway pressure exceeded
- respiratory rate exceeds a set limit

Displays

- actual achieved measurements of tidal volume, breathing rate, PEEP, peak and plateau pressure, FiO2, inspiratory to expiratory time ratio (I:E)
- displayed waveforms of key parameters including but not limited to flow, pressure and volume versus time
- if it exists, in pressure support mode there must be real-time confirmation of each patient breath and an alarm if below acceptable range

Appendix A: Relevant Standards and Documents

1. Rapidly Manufactured Ventilator System Specification by MHRA - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876167/RMVS001_v3.1.pdf
2. ISO 10651-3:1997 Lung Ventilators for Medical Use - Emergency and Transport
3. ISO 80601-2-84:2018 Medical electrical equipment. Part 2-84. 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)
4. ISO 80601-2-12:2020 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
5. ISO 19223:2019 Lung ventilators and related equipment. Vocabulary and semantics
6. AS 2896-2011 Medical gas systems - Installation and testing of non-flammable medical gas pipeline systems.
7. AS 2902-2005 Medical gas systems - Low pressure flexible hose assemblies
8. IEC 60601-1-11:2015 Medical electrical equipment - General requirements for basic safety and essential performance
9. IEC 62353:2014 Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment