

Mandatory Technical Specifications for Ventilators

Background

The Public Health Agency of Canada (PHAC) has a requirement for up five hundred and fifty (550) Ventilators for the COVID19 pandemic. The Ventilators will be used throughout Canada as a means of providing ventilator support in a hospital emergency department or critical care settings.

Ventilators

1. The ventilator must be suitable to use with Neonatal, Pediatric and Adult aged populations.

2. The ventilator must provide mandatory and spontaneous breath types.

3. The ventilator must provide the following standard ventilation modes:

- a. Controlled ventilation - Pressure Control (PC) and Volume Control (VC)
- b. Supported ventilation - Pressure Support (PS) / CPAP)
- c. Combined ventilation - SIMV(VC) + PS and SIMV(PC) + PS and Airway Pressure Release Ventilation (APRV) / biphasic or equivalent

4. The ventilator must have back-up ventilation (volume and pressure) triggered by the low minute volume alarm in ventilation modes with spontaneous breathing.

5. The ventilator must have the following parameters and features:

- a. Inspiratory Tidal Volume: 5 - 2000 ml
- b. Inspiratory Pressure Level: 0 - 80cmH₂O
- c. Frequency (f): 1 -150 breaths per minute
- d. Pressure Support above PEEP: 0 - 60 cmH₂O
- e. Positive End Expiratory Pressure (PEEP): 0 - 35cmH₂O
- f. Oxygen Concentration: 21 - 100%
- g. Peak Inspiratory Flow Range: 0 - 150 litres per minute or greater
- h. Inspiratory Time (T_{insp}): 0.1 - 5 seconds
- i. Flow pattern: square and deceleration ramp
Inspiratory Rise Time (seconds): 0 - 0.4s

- <. Flow and pressure trigger sensitivity
- L. Suction support (pre oxygenation time: 2 minutes)
- m. Alarm silence (2 minutes) and reset

6. The ventilator must have the following alarm settings and features:

- a. Airway Pressure (upper/lower limits)
- b. Expired Minute Volume (upper/lower limit)
- c. Respiratory Frequency
- d. Oxygen Concentration
- e. Apnea
- f. Safety Valve Open
- g. Gas Supply
- h. Battery
- i. Ventilator Inoperative
- j. Event and Alarm Log
- k. Alarm Volume: 45dBA - 85dBA

7. The ventilator must be able to display coloured parameters and have touch screen capabilities with the following monitored data:

- a. Ventilation mode and breath type
- b. Delivered FIO₂
- c. Airway Pressures (including peak, mean, plateau and end expiratory pressure)
- d. Respiratory Rate
- e. Tidal Volume
- f. Minute Volume
- g. I:E Ratio
- h. Graphic display of pressure, flow and volume waveforms and loops

8. The ventilator must provide 99.9% effective filtration via inlet filter to protect all internal parts from viruses, bacteria, dust and other particulate contaminants.

9. The ventilator must provide either internally or as an attachment a heated N100 expiratory valve assembly for infection control purposes.

10. The ventilator must come equipped with a humidifier, temperature probe and supporting cable(s) as well as DISS Air and O2 gas hoses and fittings, moveable stand with wheels, patient tubing stand and arm and configure each ventilator to PHAC's requirements with a supply of disposable equipment including 16 humidifiers ready to be mounting and integrated onto the ventilator with appropriate patient circuits able to accept sterile water and temperature probes.

11. The ventilator must have an internal built-in air compressor or allow for the additional feature that enables the ventilator to operate without a separate Air/O2 gas source.

12. The ventilator must have a standard electrical power supply of 100 - 120 V AC \pm 10%, 50 - 60 Hz and power cords must be CSA approved.

13. The ventilator must have all associated documentation to support the operation of each unit (Operator manuals in both official languages, quick reference sheets, etc.) as well as the list of all consumables needed to operate the ventilator in the following patient modes Adult/Paediatric/Neonatal. (Patient circuits, filters, SST user test tubing and lungs, etc.)

14. The ventilator must have the following gas supply features:

- a. Inlet gas pressure: 29 - 94 PSI / 200 - 650 kPa
- b. Pneumatic oxygen and medical air DISS connections
- c. Oxygen and medical air high pressure hoses CSA approved
- d. Flow is automatically compensated with the loss of one of the gas pressures

15. The ventilator must come with two (2) complete sets of all appropriate test equipment and calibration tools. (Ventilator tester, calibration software, interface cables, test lungs, test jigs, measuring devices, fittings, plugs, etc.)

16. Upon award of contract for the procurement of approved ventilator units, the manufacturer must provide manufacturer level training for two (2) PHAC staff at manufacturer's facility with required service manuals, hotel accommodations and course tuition costs.

17. The ventilator must be a registered medical device with Health Canada.

18. Units must come with two (2) year additional warranties that include annual O2 cell replacements and batteries.

19. Each unit must come with an air-worthy, hard-shelled, plastic or equivalent protective shipping container for deployments.

20. Each ventilator must be accompanied by all consumables and components required to operate with 1 neonatal patient; 1 paediatric patient and 3 adults patients (total of 5 consumable packages per ventilator).