Guideline Evaluation Report (UK Guidelines) - AAU Pandemic Ventilator

Revision History			
Rev	**ECO**	**Changes**	**Author**
1	N/A	Initial release	SR

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1 Purpose/Scope

The purpose of the present document is to evaluate the:

- Guidance: Rapidly manufactured ventilator system specification, Published 20 March 2020 (https://www.gov.uk/government/publications/coronavirus-covid-19-ventilator-supply-specification/rapidly-manufactured-ventilator-system-specification

In order to translated this guideline into the Technical Requirements [Ref 1] for the AAU Pandemic Ventilator .

2 References

Ref 1. VENT-10-002-DOC Technical Requirements

3 Ventilation

ID	Guideline	Evaluation	Req.
V.1	At least 1, optionally 2 modes of ventilation:	Evaluated in V1.1 and V1.2	N/A
V1.1	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	The AAU Pandemic Ventilator has mandatory ventilation, in the form of a volume controlled ventilation (VCV). **Analysis:** For Volume Control Ventilation – the user sets a tidal volume and respiratory rate. The tidal volume is delivered during the inspiratory period. It is usual that the pressure delivered during inspiration is limited, as required in V.3. VCV ventilation is associated with typical patterns of pressure and flow during the inspiratory period, and a pause period at the end of inspiration where all valves are closed for a short period prior to expiration. These patterns will be required for correct delivery of this mode.	TR-01-001 TR-01-002
V.1.2	Optional pressure support mode for those patients breathing to some extent themselves, e.g. BIPAP or SIMV-PC. 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).	Pressure support mode is not implemented in the AAU Pandemic Ventilator	N/A
V.2	If the patient stops breathing in a spontaneous mode it must failsafe automatically onto mandatory ventilation.	Not applicable – pressure support mode is not implemented by the AAU Pandemic Ventilator	N/A
V.3	Inspiratory airway pressure, the higher pressure setting that is applied to make the patient breathe in:	Evaluated in V.3.1, V.3.2, V.3.3	N/A
V.3.1	plateau pressure should be adjusted to achieve volume and be limited to 35 cmH2O by default.	Implemented by the AAU Pandemic Ventilator . Analysis: If volume control ventilation is used, the user must be able to set inspiratory airway pressure limit in the range at least 15 – 40 cmH2O in at least increments of 5 cmH2O.	TR-01-003 TR-01-005

ID	Guideline	Evaluation	Req.
V.3.2	peak pressure should be no more than 2 cmH2O greater than plateau pressure.	Not implemented in the AAU Pandemic Ventilator . Analysis: Rationale for not implementing the guideline: Nonsensical demand in UK guidelines as respiratory physiology of the patient dictates this difference, and expected range of this difference in patients on controlled mechanical ventilation will be outside 2 cm H2O using standard (and required) ventilator settings. E.g. normal value of ARDS patients (target patient population) at square wave flow of 60 L/min has been reported to be Raw=8 to 12 cmH2O/L/s which would give a Ppeak-Pplat difference of: Ppeak-Pplat = Raw/flow = (8 cmH2O/L/s*60 s/min)/60 L/min = 8 cm H2O i.e. 6 cm H2O more than the requirement in the UK guideline Source: Henderson et al. Am J Respir Crit Care Med Vol 196, Iss 7, pp 822–833, Oct 1, 2017	N/A
V.3.3	Ideally there should be a mechanical failsafe valve that opens at 40 cmH2O.	The AAU Pandemic Ventilator has a mechanical failsafe valve. Analysis: There must be a mechanical failsafe valve that opens at 80 cmH2O, or lower.	TR-01-006
V.4	Positive End Expiratory Pressure PEEP (usually called EPAP during pressure support mode). The lower pressure applied to the patients airway to allow them to breathe out, but not too much:	Implemented in the AAU Pandemic Ventilator . Analysis: Patient breathing system must remain pressurised to at least the PEEP level setting at all times.	TR-01-007 TR-01-008
V.4.1	Range 5 to 25 cm H2O adjustable in 5 cmH2O increment	Implemented in the AAU Pandemic Ventilator . Analysis: Range 5-20 cm H2O adjustable in 5 cmH2O increments.	TR-01-007 TR-01-007
V.4.2	Patient breathing system must remain pressurised to at least the PEEP level setting at all times.	Implemented in the AAU Pandemic Ventilator .	TR-01-008
V.5	Inspiratory:Expiratory ratio (I:E) (note, confusingly, it is actually E/I time). The proportion of each breathing cycle that is spent breathing in compared to breathing out:	Implemented in the AAU Pandemic Ventilator . Analysis: Inspiratory:Expiratory ratio (I:E). The proportion of each breathing cycle that is spent breathing in compared to breathing out. The usual range of interest is 1:1, to 1:3, with a standard value of 1:2	TR-01-009

ID	Guideline	Evaluation	Req.
V.5.1	2.0 (i.e. expiration lasts twice as long as inspiration)	Adjustment of the I:E ratio is implemented in the AAU Pandemic Ventilator . Note that a value of 2.0 is equivalent to a ratio of 1:2 and usually expressed as such	TR-01-009
V.5.2	optionally adjustable in the range 1.0 to 3.0	Implemented in the AAU Pandemic Ventilator . Note that a value of 1.0 is equivalent to a ratio of 1:1 and usually expressed as such. As value of 3.0 is equivalent to a ratio of 1:3 and usually expressed as such	TR-01-009
V.6	Respiratory Rate. The number of breathing cycles every minute.	Evaluated in V.6.1	N/A
V.6.1	Range 10 – 30 breaths per minute in increments of 2 (only in mandatory mode) can be set by the user.	Implemented in the AAU Pandemic Ventilator	TR-01-010
V.7	Tidal Volume (Vt) setting, if provided. The volume of gas flowing into the lungs during one inspiratory cycle	A range of 250 – 600 in steps of 50ml is implemented by the AAU Pandemic Ventilator	TR-01-011
V.7.1	Must have at least one setting of 400ml +/- 10 ml.	Is included in the implemented range.	TR-01-011
V.7.2	Ideally 350ml and 450 ml options.	Is included in the implemented range.	TR-01-011
V.7.3	Optionally Range 250 – 600 ml in steps of 50ml.	Is included in the implemented range.	TR-01-011
V.7.4	Even more optionally up to 800 ml.	Not implemented in the AAU Pandemic Ventilator	N/A
V.7.5	Optionally the ability to input body weight and have volume calculated as e.g. 6ml/kg of ideal body weight.	Not implemented in the AAU Pandemic Ventilator	N/A

4 Gas and electricity

ID	Guideline	Evaluation	Req
GE.1	Incoming Gas Supply.		
GE.1.1	all gas connectors and hoses must use standard non-interchangeable connectors and be colour coded according to current standards	Implemented in the AAU Pandemic Ventilator Analysis: All gas connectors and hoses must comply with BS EN ISO 5359:2014+A1:2017, ISO 5359:2014/AMD 1:2017 and BS 2050: 1978 Electrical Conductivity.	TR-07-006

ID	Guideline	Evaluation	Req
GE.1.2	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	Not implemented in the AAU Pandemic Ventilator Analysis: In Denmark each hospital has their own standard for valve connectors. Consequently, it will be the responsibility of each hospital to supply the correct valve connectors for the AAU Pandemic Ventilator . Hose is permanently fixed to the machine Oxygen pipeline pressure is approximately 3.7 – 4.5 bar. The AAU Pandemic Ventilator will handle 3.7 – 10 bar.	N/A N/A TR-02-002
GE.1.3	optionally can incorporate a backup oxygen cylinder connected via either Schrader valve or Pin Index System	Not implemented in the AAU Pandemic Ventilator	N/A
GE.1.4	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 cmH2O	Not applicanle – GE.1.3	N/A
GE.1.5	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)	See evaluation of GE.1.2	N/A
GE.1.6	optionally can connect to Anaesthetic Gas Scavenging System	Not implemented in the AAU Pandemic Ventilator .	N/A
GE.1.7	optionally can operate using an oxygen concentrator device for input oxygen	Not implemented in the AAU Pandemic Ventilator .	N/A
GE.2	Electricity Supply.	Is evaluated in GE.2.X	N/A
GE.2.1	Should connect to 240V mains.	Implemented in the AAU Pandemic Ventilator .	TR-03-001
GE.2.2	Battery backup – see Unknown issues section. Must have 20 minutes back up battery in case of mains electricity failure.	Is implemented in the AAU Pandemic Ventilator .	TR-03-002

ID	Guideline	Evaluation	Req
GE.2.4	Optionally hot swappable batteries so that it can be run on battery supply for an extended period, e.g. 2 hours for within hospital transfer.	Not implemented in the AAU Pandemic Ventilator .	N/A
GE.2.5	Must avoid harmful RF or EM emissions that could interfere with other critical machinery.	All components used will be CE marked for industrial use in critical process control system where failure to function due to RF and EM interference would be critical.	TR-02-003
GE.3	Gas supply to patient.		
GE.3.1	User must be able to control inspired oxygen proportion (FiO2). The percentage of oxygen in the gas being breathed in by the patient. Room air is 21% oxygen.	Implemented	TR-04-001
GE.3.2	At least 50% and 100% options	Implemented. Analysis: Oxygen can be provided in the range 21% - 100% in steps of 10%.	TR-04-002
GE.3.3	very preferably ideally variable between 30 and 100% in 10% steps	See GE.3.2	TR-04-002
GE.3.4	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	Implemented	TR-04-003
GE.4	All elements in the gas pathway must meet biological safety and low-pressure oxygen safety standards, especially to minimise risk of fire or contamination of the patient's airway.	All parts in contact with the patient must be single use disposable items as standard in the use of commercially available CE marked mechanical ventilators. All pressure reduction and proportional valves must be O2 will be fire safe	TR-04-004 TR-04-005

5 Infection control

ID	Guideline	Evaluation	Req
IF.1	All parts coming into contact with the patient's breath must be either disposable or able to be decontaminated between patients.	Inspiratory and expiratory limbs must be isolated to prevent contamination from the expiratory limb to the next patient. External ventilator tubes, not part of the ventilator, are otherwise the only sources of contamination. It is standard clinical practice for these to be single use, in any CE marked commercial ventilator.	TR-04-010 TR-05-001

ID	Guideline	Evaluation	Req
IF.2	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.	It is necessary for the cabinet enclosing the ventilator, and any control screens and buttons to be wiped, and a description provided in the instructions manual to that effect	TR-05-002 TR-07-005
IF.3	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 cmH2O at 30 lpm, the ventilator needs to output 37 cmH2O to achieve a set 35 cmH2O at the patient. This will need further detailed consideration. Viral filtering filters may have much higher resistance that may be clinically relevant.	Analysis: not applicable in VCV The mode supported by this ventilator, volume controlled ventilation (VCV), delivers a fixed volume. As such an increased resistance in the inspiratory line will result in a higher pressure delivered to overcome this resistance. It is therefore a usual feature of VCV that inspiratory pressure is automatically adjusted to overcome either resistance or compliance.	N/A
IF.4	Optionally include facility for hot water humidifier to be included in breathing system.	Not implemented in AAU Pandemic Ventilator . Analysis: Humidification and warming of respiratory gasses it typically either performed by a stand alone device, or sometimes in conjunction with control from a commercial ventilator. In this case the AAU Pandemic Ventilator provides no such control functionality, and this optional requirement is not therefore implemented	N/A

6 Monitoring and alarms

ID	Guideline	Evaluation	Req
MA.1	Must alarm at:		
MA.1.1	Gas or electricity supply failure.	Is implemented in the AAU Pandemic Ventilator .	TR-06-001 TR-06-002
MA.1.2	Machine switched off while in mandatory ventilation mode.	Is implemented in the AAU Pandemic Ventilator .	TR-06-003
MA.1.3	Inspiratory airway pressure exceeded.	Is implemented in the AAU Pandemic Ventilator .	TR-06-004
MA.1.4	Inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm).	Is implemented in the AAU Pandemic Ventilator .	TR-06-005
MA.1.5	Tidal volume not achieved or exceeded.	Is implemented in the AAU Pandemic Ventilator .	TR-06-006

6.1 Monitoring

ID	Guideline	Evaluation	Req
MA.2.	Monitoring – the following should be continuously displayed so the user can verify.	Evaluated in MA.2.1, MA.2.2, MA.2.3, MA.2.4.	N/A

ID	Guideline	Evaluation	Req
MA.2.1	Current settings of tidal volume, frequency, PEEP, FiO2, ventilation mode.	Is implemented in the AAU Pandemic Ventilator .	TR-06-007
MA.2.2	Actual achieved rates of tidal volume, breathing rate, PEEP, plateau pressure, FiO2.	Except for FiO2 this is implemented in the AAU Pandemic Ventilator .	TR-06-008
MA.2.3	If it exists, in pressure support mode there must be real time confirmation of each patient breath and an alarm if below acceptable range.	N/A - Pressure support is not implemented in the AAU Pandemic Ventilator .	N/A
MA.2.4	Optionally CO2 monitoring included.	Not implemented in the AAU Pandemic Ventilator .	N/A

7 Miscellaneous

ID	Guideline	Evaluation	Req
M.1	Must be reliable. It must have 100% duty cycle for up to 14 days.	This has not been tested, because in the current critical situation where CE approved ventilators are not available, 14 days is not a reasonable time to delay use of the technology and would potentially place many lives at risk. Parts used should, however, be CE approved and as such tested. This will be tested at AAU and there will be a system for reports to be submitted from the users of the AAU Pandemic Ventilator .	TR-02-005
M.2	Optionally it can be used beyond 14 days, the expected durability must be specified.	See M.1, not yet available.	TR-02-005
M.3	Can be floor standing.	Implemented in the AAU Pandemic Ventilator .	TR-02-006
M.4	Ideally small and light enough to mount on patient bed and orientation independent functioning.	Not implemented in the AAU Pandemic Ventilator . Analysis: Ventilators are usually not mounted on the patient bed at Danish hospitals	N/A
M.5	Should be as robust as possible. For example, it may be dropped from bed height to floor.	Not implemented. Analysis: Ventilator is not patient bed mounted and is placed on the floor. Consequently, it is unlikely to be dropped to the floor.	N/A
M.6	It must be intuitive to use for qualified medical personnel, but these may not be specialists in ventilator use.	Usability validation is postponed pending the verification of the AAU Pandemic Ventilator .	N/A
M.6.1	Must not require more than 30 minutes training for a doctor with some experience of ventilator use.	Usability validation is postponed pending the verification of the AAU Pandemic Ventilator .	N/A

ID	Guideline	Evaluation	Req
M.6.2	Must include Instructions for Use.	Instructions for use will be provided: Analysis: An IFU has been created: VENT-10-003-DOC Instruction For Use	N/A
M.6.3	Ideally instructions for use should be built into the labelling of the ventilator, e.g. with 'connect this to wall' etc.	Labels will be included on the ventilator.	TR-07-003 TR-07-008
M.6.4	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.	Labels will be included on the ventilator. Analysis: UK healthcare staff is changed to DK healthcare staff.	TR-07-008
M.7	Must have transparent design, supply chain, manufacture, quality assurance and testing processes that are of sufficient quality to enable MHRA officials to deem appropriate for usage in exceptional circumstances.	Design, supply chain and manufacturer and processes will be open source and provided on a publicly available webpage/repository.	TR-07-009
M.8	Must not be excessively cumbersome so that it would impede hospital operations or prevent easy movement within hospital premises.	The ventilator has a size that it can be carried. The ventilator has handles that permits it to be moved.	TR-02-007
M.9	Must be made from materials and parts readily available in the UK supply chain (anticipating increasing global restrictions on freight movement).	Changed UK to DK Analysis: There has been a focus on available parts within DK throughout the development process.	N/A

8 Standards

ID	Guideline	Evaluation	Req
M.10	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.	Standards has been considered throughout the development process as helpful advisory standards. However, an evaluation of compliance to standards has not been performed for the AAU Pandemic Ventilator .	N/A
M.10.1	BS EN 794-3:1998 +A2:2009 Particular requirements for emergency and transport ventilators	Evaluation in M.10	N/A
M.10.2	ISO 10651-3:1997 Lung Ventilators for Medical Use - Emergency and Transport	Evaluation in M.10	N/A

M.10.3	BS 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)	Evaluation in M.10 Analysis: Changed to ISO 80601-2-12:2020 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	N/A
M.10.4	BS ISO 19223:2019: Lung ventilators and related equipment. Vocabulary and semantics	Evaluation in M.10	N/A

9 Battery backup

ID	Guideline	Evaluation	Req
B.1	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.	A battery backup is implemented in the AAU Pandemic Ventilator .	TR-03-002