Technical Requirements
- AAU Pandemic Ventilator

Revision History			
Rev	**ECO**	**Changes**	**Author**
1	N/A	Initial release	SR
2	N/A	Updated requirements for Revision 2.0	SR

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1 Scope

1.1 Identification

The present document contains the Product Specification for the medical device identified as:

- AAU Pandemic Ventilator

1.2 System overview

The AAU Pandemic Ventilator is a simple designed ventilator capable of volume control at different levels of inspired oxygen, PEEP, and inspiratory settings with modular options for delivering the inspiration.

Consists of a mechanically simple expiratory unit, where a spring-loaded valve adjusts PEEP. Inspiratory unit is adjustable (Freq, Vt, I:E, Pause time, Inspiratory rise time) and comes in different configurations. The ventilator is shown in the figure below:

Figure 1: AAU Pandemic Ventilator overview. 1: Air and O_2 supply, 2: Power cord, 3: Screen and controls, 4: Inspiratory outlet, 5: Expiratory inlet, 6: PEEP adjustment.

1. Air and O_2 supply
2. Power cable
3. User interface
4. Inspiratory outlet (delivers fresh gas to patient at inspiration)
5. Expiratory inlet (expiratory gas returning from the patient)
6. Adjustment of PEEP and expiratory gas outlet.

All parts are industry standard units with proven durability and control from a PCL. System is controlled via a simple interface consisting of a few analog buttons, a touch screen and a mechanically operated PEEP valve.

2 References

Ref 1. VENT-30-001-DOC Risk Analysis (Top-Down)
Ref 2. VENT-20-002-DOC Guideline Evaluation Report
Ref 3. VENT-60-001-DOC Verification Specification & Report

3 Requirement Structure

3.1 Specification of requirements

The specification section (chapter 4 and subsequent chapters) defines the technical requirements for the AAU Pandemic Ventilator.

It consists of a set of tables that are organized in the following format:

TR-ID	Source	Standard	Specification	Verification	Rev
1	2	3	5	6	7

1. TR-ID: A unique identifier for the product specification requirement, which will be used to identify the specific requirement.

2. Source: Contains references to where the requirement originates from:

RA.#z-##: Risk item **#z-##** from the Risk Analysis [Ref 1].
UK.G.XXX: The source is the UK guidelines [Ref 2].

3. Standard: Contains a reference to the applicable standard related to the requirement.

4. Specification: References to where the technical specification is given. Comments may be provided with the specification. In that case they are marked in cursive and in a smaller font that clearly separates them from the requirement. In the case of a discrepancy between a requirement and a comment, the requirement always supersede the comment.

5. Verification: Contains references to the verification specification and test case ID where the requirement is verified:
   TID-XXX: Test case XXX from the Verification Specification and Report [Ref 3]

   If the requirement has not been tested, the planned verification method is specified. Please refer to Verification Specification and Report [Ref 3] for a specification of the verification methods.

6. Rev: Refers to which revision the requirement was last revised in. This is helpful when the document is going to be reviewed in later revisions where only a few requirements are changed.

3.2 Requirement identification

Each requirement is identified with a unique ID that has the format TR**.xx-##** where “xx” refers to the part or interface, “##” is a running number.

4 Ventilation

TR-ID	Source	Standard	Specification	Verification	Rev
TR-01-001	UK.G.V.1.1		The AAU Pandemic Ventilator must implement a mandatory mode in the form of volume controlled ventilation (VCV).	TID-001	001
TR-01-002	UK.G.V.1.1		Volume Control – the user sets a tidal volume and respiratory rate. The tidal volume must be delivered during the inspiratory period.	TID-001	001
TR-01-003	UK.G.V.3.1		Plateau pressure shall be adjusted to achieve volume and be limited to 35 cmH2O by default.	TID-002	001
~~TR-01-004~~	~~UK.G.V.3.1~~				~~001~~
TR-01-005	UK.G.V.3.1		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.	TID-002	001
TR-01-006	UK.G.V.3.3		There must be a mechanical failsafe valve that opens at 80 cmH2O.	Testing	001
TR-01-007	UK.G.V.4		There must be Positive End Expiratory Pressure (PEEP).	TID-003	001
TR-01-008	UK.G.V.4		Patient breathing system must remain pressurised to at least the PEEP level setting at all times.	TID-003	001

TR-01-009	UK.G.V.5 UK.G.V.5.1 UK.G.V.5.2		Inspiratory:Expiratory ratio (I:E) shall be adjustable in the range 1:1 – 1:3 , also including the standard clinical value of 1:2.	TID-004	001
TR-01-010	UK.G.V.6.1		Respiratory rate shall be adjustable by the user in the range 10 – 30 breaths per minute in increments of 2.	TID-005	001
TR-01-011	UK.G.V.7 UK.G.V.7.1 UK.G.V.7.2 UK.G.V.7.3		Tidal Volume (Vt) must be adjustable by the user in the range of 250 – 600 ml in steps of 50ml.	TID-006	002

5 Construction

TR-ID	Source	Standard	Specification	Verification	Rev
~~TR-02-001~~					~~001~~
TR-02-002	UK.G.GE.1.2		Must be designed for an oxygen pipeline pressure is approximately 3 – 6 bar.	Analysis	002
TR-02-003	GE.2.5 RA.21-01		The ventilator must be built with CE marked electrical parts for industrial use.	Analysis	001
TR-02-004	RA.21-01		The ventilator must be enclosed in a metal box that acts as a faraday cage.	Inspection	001

TR-02-005	RA.31-01		All mechanical parts must have a guaranteed life cycle past 14 days operation	Analysis	001
TR-02-006	UK.G. M.3		The ventilator should provide a possibility for being floor standing	Inspection	001
TR-02-007	UK.G. M.8		The ventilator must have a size that it can be carried. The ventilator will have handles that permits it to be moved.	Testing	001

6 Electrical supply

TR-ID	Source	Standard	Specification	Verification	Rev
TR-03-001	GE.2.1		The ventilator must connect to 240V mains.	Testing	001
TR-03-002	GE.2.2 RA.10-01		There must be a battery backup that last at least 20 min.	Testing	001

7 Gas supply

TR-ID	Source	Standard	Specification	Verification	Rev
TR-04-001	G.E.3.1		User must be able to control inspired oxygen fraction (FiO2).	TID-007	001
TR-04-002	GE.3.2		Oxygen must be provided in a user adjusted the range 21% - 100% in steps of 10%.	TID-007	001

TR-ID	Source	Standard	Specification	Verification	Rev
TR-04-003	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	Inspection	001
TR-04-004	GE.4		All parts in contact with the patient must be single use disposable items.	Inspection	001
TR-04-005	RA.11-01		All pressure reduction and proportional valves must be O2 and fire safe	Analysis	001
~~TR-04-006~~	~~RA.11-02~~		~~Pressure reduction valves must be attached in the inspiratory inlet.~~	~~Inspection~~	~~001~~
TR-04-007	RA.11-03		An over pressure listener must be coded in the software, so if inspiratory circuit pressure reaches 40cmH2O, the inspiratory valve closes and expiratory valve opens	TID-002	001
TR-04-008	RA.11-04		An individually tested and certified mechanical safety release valves must be inserted in the respiratory circuit	Testing	001
TR-04-009	RA.11-05		All components must be secured inside the metal cabinet	Inspection	001
TR-04-010	RA.20-02		The expiratory exit port must be on the opposite side of the inspiratory inlet side.	Inspection	001

TR-ID	Source	Standard	Specification	Verification	Rev
TR-04-011	RA.20-03		Before the expiratory gas enters the ventilator it must pass through a water trap that will catch most of the water, saliva etc from the patient.	Inspection	001
TR-04-012	RA.20-04		Before the inspiratory gas exits the ventilator, it must pass through a disposable antibacterial filter.	Inspection	001
TR-04-013	RA.41-04		There must be a software controlled pressure release valve is activated at a threshold level to safeguard against dangerous pressures.	TID-002	001

8 Infection control

TR-ID	Source	Standard	Specification	Verification	Rev
TR-05-001	UK.G.IF.1		All parts coming into contact with the patient's breath must be either disposable or able to be decontaminated between patients.	Inspection	001
TR-05-002	UK.G.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.	Analysis	001
~~TR-05-003~~	~~UK.G.IF.3~~				
~~TR-05-004~~	~~UK.G.IF.4~~				

9 Control, monitoring and alarms

TR-ID	Source	Standard	Specification	Verification	Rev
TR-06-001	UK.G.MA.1.1 RA.11-07		There must be an alarm at gas failure.	Testing	001
TR-06-002	UK.G.MA.1.1 RA.10-01		There must be an alarm at electrical supply failure.	Testing	001
TR-06-003	UK.G.MA.1.2		There must be an alarm if the ventilator is switched off while in mandatory ventilation mode.	Testing	001
TR-06-004	UK.G.MA.1.3 RA.41-04		There must be an alarm if inspiratory airway pressure exceeded.	Testing	001
TR-06-005	UK.G.MA.1.4		There must be an alarm if inspiratory and PEEP pressure not achieved.	Testing	001
TR-06-006	UK.G.MA.1.5		There must be an alarm if tidal volume not achieved or exceeded.	Testing	001
TR-06-007	UK.G.MA.2.1		Current settings of tidal volume, frequency, PEEP, FiO2, ventilation mode must be displayed.	Testing	001
TR-06-008	UK.G.MA.2.2		Actual achieved rates of tidal volume, breathing rate, PEEP, plateau pressure must be displayed.	Testing	001

TR-06-009	RA.10-01		There must be an alarm if battery is discharged	Testing	001
TR-06-010	RA.10-02		Alarm screen must appear to verify shut down	Testing	001
TR-06-011	RA.20-05 RA.20-06		Alarm must appear if there is a mismatch between the set and delivered tidal volume and respiratory rate.	Testing	001
TR-06-012	RA.20-07		Alarm must appear if the peak and plateau airway pressure is so high that there is a risk of lung injury due to too high pressure.	Testing	001
TR-06-013	RA.41-01		A confirmation prompt must appear when the user stops the ventilator. This confirmation prompt must inform the user of the potential consequences of stopping the ventilator. The ventilator must first stop when the user confirms the action on this prompt.	Testing	001
TR-06-014	RA.41-02		A status icon must indicate which setting is selected and modifiable. Dark grey: not selected, light green: selected.	Testing	001
TR-06-015	RA.41-02		It must only be possible to modify one setting on the ventilator at any time.	Testing	001
TR-06-016	RA.41-02		Change of settings must only take effect after a short period.	Testing	001

TR-06-017	RA.41-03		It must always be possible to access FiO2, Vt, RR and I:E directly by clicking F1 analog button, regardless of which screen is being accessed/reviewed in the rest of the HMI	Testing	001
TR-06-018	RA.41-04 RA.41-04		The threshold of the software controlled pressure release valve must be able to be set by the user according to the state of the current patient.	Testing	001
TR-06-019			A pre-use check must be performed and an alarm must appear if leakage or malfunction is detected	Testing	002
TR-06-020			Alarm must appear if the PEEP pressure is >19cmH2O indicating obstructions in the airway circuit.	Testing	002
TR-06-021			Alarm must appear if the wall pressure exceeds 10cmH2O.	Testing	002
TR-06-022			There must be a pre-use check option	Testing	002
TR-06-023			The ventilator must be able to shut down	Testing	002

10 Labelling

TR-ID	Source	Standard	Specification	Verification	Rev
TR-07-001	RA.20-01		Instructions for Use must include a warning that the patient should be further sedated.	Inspection	001
TR-07-002	RA.30-01		Instructions for Use must specify that items in direct contact with the patient are single use.	Inspection	001
TR-07-003	RA.40-01		The AAU Pandemic Ventilator must have a label: “for adult patients only”	Inspection	001

TR-07-004	RA.40-01		Instruction for Use must contain a warning: “for adult patients only”	Inspection	001
TR-07-005	RA.20-02		Instruction for Use must contain cleaning instructions	Inspection	001
TR-07-006	UK.G.GE.1.1 RA.11-06		Instruction for Use must contain information to technical staff to inform them that 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.	Inspection	001
TR-07-007			Instructions for use must specify pre-use check	Inspection	001
TR-07-008	UK.G. M.6.3		Labels must be placed on the ventilator that provide instructions in its use.	Inspection	001
TR-07-009	UK.G. M.7		All information on the design of the ventilator, its manufacture, supply chain, development and production processes must be publicly available.	Inspection	001
TR-07-010			Instructions for use must specify that the AAU Pandemic Ventilator is only for invasive ventilation	Inspection	001