Verification Specification & Report - AAU Pandemic Ventilator

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

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1 Purpose/Scope

This document describes the verification process and results of the implemented technical requirements described in 'VENT-10-002-DOC Technical Requirements'. It specifies the verification methods, the test set-ups, and then the series of tests performed referencing these back to the technical requirements, and providing a summary table of the results of these tests.

2 References

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

3 Test operators

Initial	Name	Qualification
SR	Stephen Rees	Professor and expert in ventilators.
JH	John Hansen	Associated professor and expert in electrical systems.

4 Verification Methods

The following verification methods will used to verify the technical requirements of the AAU Pandemic Ventilator :

Activity	Definition
Testing	Verification testing is performed on the AAU Pandemic Ventilator in the laboratory at Aalborg University. Results can be evaluated by stating the verdict "Pass/Fail".
Analysis	Rationale for conformance to the requirement by performing an analysis of literature studies or other data. Results can be evaluated by stating the verdict "Accepted/Not Accepted".
Assessment	A design assessment is performed when a review by relevant experts of designs outputs is required for the verification of a requirement. Results can be evaluated by stating the verdict "Accepted/Not Accepted".
Inspection	Is performed when an objective evaluation of the design is required to verify the implementation of a technical requirement. Examples, are the use of a specific connector, presence of labelling, the colors and material used in the design. This evaluation of design output can be applied to both design documentation (e.g. drawings, data sheets, circuit diagrams etc.) and/or to actual implementation (i.e. the Device Under Test). Results can be evaluated by stating the verdict “Pass/Fail”.

5 Test Setups

5.1 Test setup: ventilator test setup

Figure 1 illustrates the test set up for all of the tests performed here to evaluate the functionality of the AAU Pandemic Ventilator . These are test numbers TID-001 to TID-007 as described in section 6.

The test set up includes a commercially available, programmable, artificial lung, known as TestChest (Organis, Switzerland). As the AAU Pandemic Ventilator provides mandatory modes alone, this lung is used to simulate situation of patient apnoea, i.e. situations without spontaneous breathing and is set to two pre-defined cases: a normal lung, and a severely diseased lung with acute respiratory distress syndrome (ARDS). The primary difference between these cases is that the ARDS lung is of lower volume and less is compliant. As such the ARDS lung will have higher pressures that the normal lung for application of the same tidal volume.

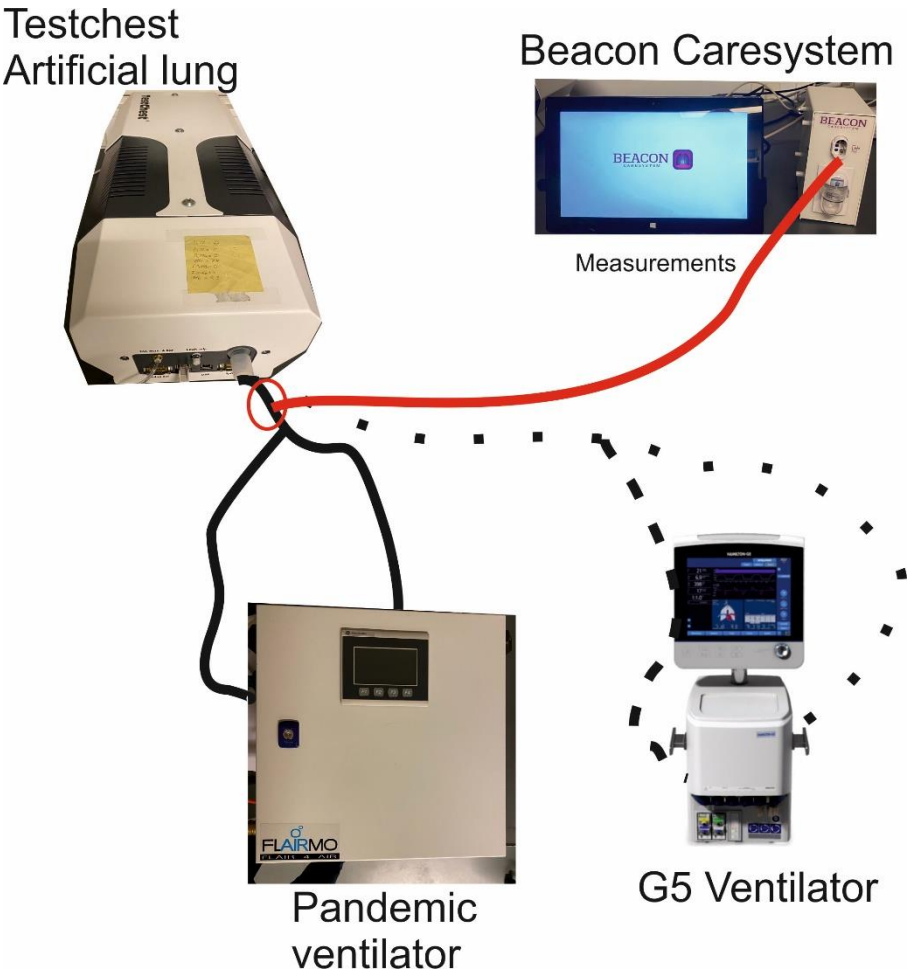

Figure 1: The test set up for ventilator functionality requirements evaluation. Black lines indicate gas delivery and red lines measurement sampling. Solid black lines illustrate connection from the AAU Pandemic Ventilator to the artificial lung and dashed from the commercial G5 ventilator. Only one of these two ventilators are connected to the lung at any one time.

For the majority of tests described here the AAU Pandemic Ventilator is used to mechanically ventilate the artificial lung, for selected tests the G5 ventilator is used to ventilate the artificial lung.

For all tests, measurements taken are performed by the Beacon Caresystem (Mermaid Care A/S), a CE and FDA approved device. The Beacon Caresystem is connected to the input port of the artificial lung such that all respiratory flow passes through the Beacon Caresystem's respiratory tube on its way to and from the artificial lung. In the context of these tests, the Beacon Caresystem measures, continuous flow and pressure and continuous oxygen fraction, determines the onset of inspiration and expiration and therefore calculates respiratory rate. In addition, the Beacon Caresystem provides a measure of tidal volume from mathematical integration of inspiratory flow. In this way the Beacon Caresystem provides independent verification of the volumes, flows, pressures, oxygen levels and respiratory rate of the AAU Pandemic Ventilator and, on occasion, the G5 ventilator where comparison of the AAU Pandemic Ventilator and G5 ventilator is helpful.

6 Verification specification and results

6.1 TID-001: Test: Ability to provide mandatory ventilation – volume control ventilation

To illustrate that the AAU Pandemic Ventilator delivers a volume controlled (VCV) mode, Figure 2 illustrate pressure and flow characteristics from a series of breaths. To do it is shown that the ventilator can be set at Vt = 400 ml, RR = 15 breaths/min, I:E ratio 1: 2 and inspiratory oxygen concentration FIO2 = 21 %, with the lung simulator set to simulate a diseased lung. For comparison similar pictures are shown from a commercially available mechanical ventilator, for this mode, with identical setting ventilating the same artificial lung.

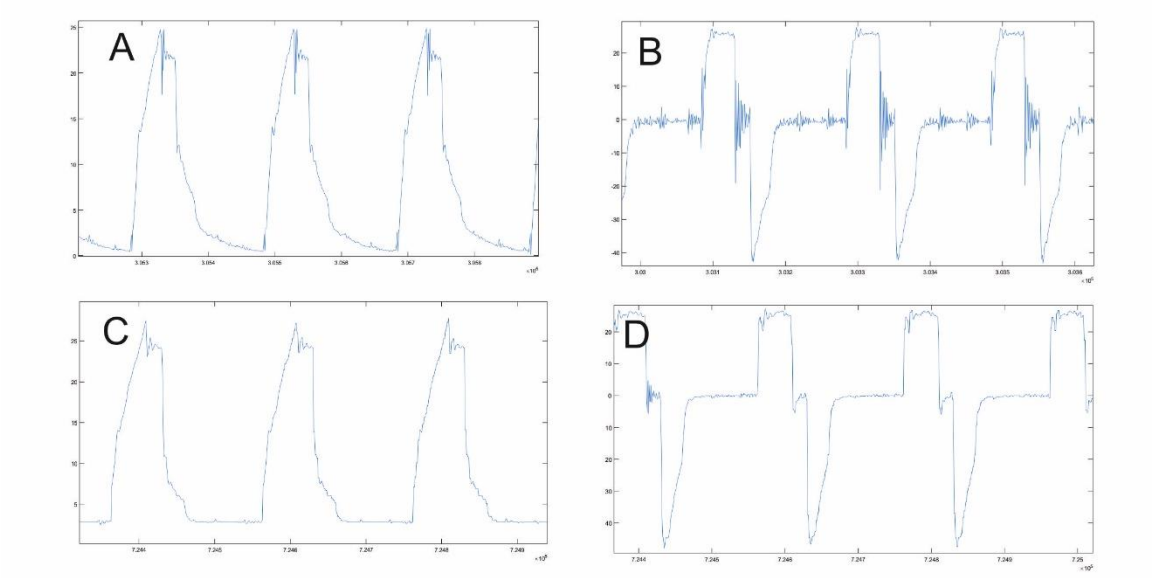

Figure 2: Standard volume control ventilation profiles of pressure (A, C) and flow (B, D). Profiles are illustrated for the AAU Pandemic Ventilator (A, B) and for a CE marked commercial ventilator (G5, Hamilton Medical) (C, D).

The pressure profile clearly illustrates the peak and pause pressure on inspiration, typical of VCV, and the flow profile the typical square wave flow delivery seen in VCV. Please note that evaluation of the correct delivery of each of the ventilator settings is documented later in this description, with the above evaluation limited to describing the correct delivery of VCV in terms of typical flow and pressure waveforms.

6.2 TID-002: Test: - Plateau pressure should be adjusted to achieve volume and be limited to 35 cmH2O by default.

To illustrate that the AAU Pandemic Ventilator prevents excessive pressure, Figure 3 illustrates pressure characteristics from a series of breaths at different settings of Vt from 400 ml to 600 ml, RR = 15 breaths/min, I:E ratio 1: 2 and inspiratory oxygen concentration FIO2 = 21 %, with the lung simulator set to simulate a diseased lung. In a diseased lung with low compliance, it is expected that high tidal volumes will result in the delivery of high pressures, which require pressure limiting so as not to be harmful.

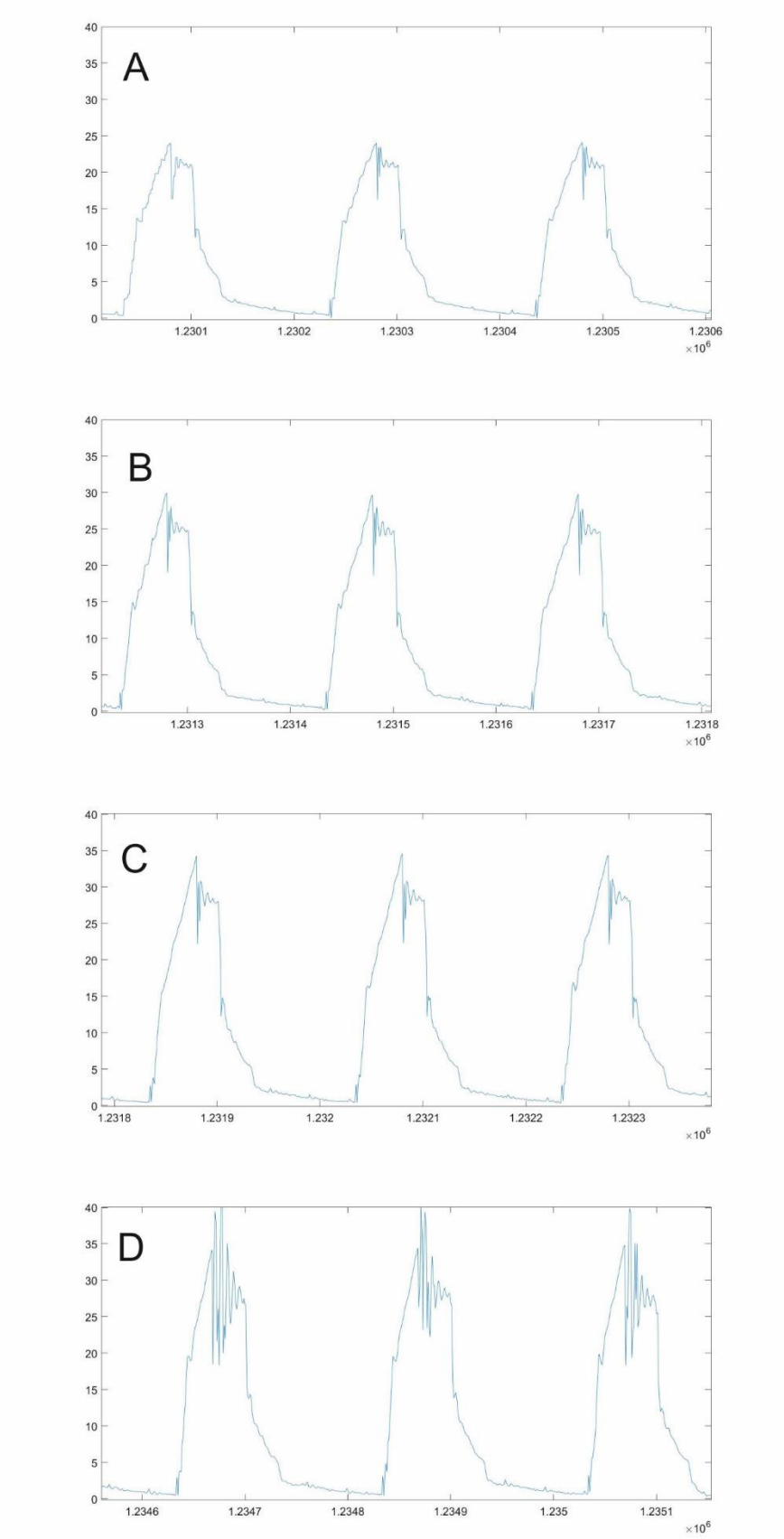

Figure 3: Pressure profiles on the delivery of different tidal volumes of 450 ml (A), 500 ml (B), 550 ml (C), and 600 ml (D).

Figure 3 illustrates that with delivery of Vt levels from 450 to 550 ml (A-C), Peak pressure remains below the 35 cmH20 threshold without need for emergency valve opening. Peak pressures are about 25 cmH2O for a Vt = 450 ml, 30 cmH2O for Vt = 500 ml, and 35 cmH2O for a Vt of 550 ml. For a Vt of 600 ml the 35 cmH2O threshold is exceeded and inspiratory valves are closed and expiratory opened. When this occurs pressure falls rapidly, and below 35 cmH2O allowing inspiratory valves to open once again during the inspiration. An oscillating pressure therefore occurs with repeated opening and closing of the valves during the inspiration as seen in the pressure traces of inset D. The small pressure increase above the 35 cmH2O seen in inset D is due to the signal sampling rate of 10 ms, allowing a small increment in peak pressure prior to closing the inspiratory valves. This increment is negligible with regards to safety to the patient.

The maximum level of this airway pressure limit can be adjusted on a screen by the user in the range at least 15 – 40 cmH2O in increments of 5 cmH2O to a maximum of 70 cmH20, as illustrated in the instructions to use. Increase in this setting has been tested in a similar way as above.

6.3 TID-003: Test: - PEEP range 5 to 25 cm H2O adjustable in 5 cmH2O increment

To illustrate that the AAU Pandemic Ventilator provides a controllable value of positive end expiratory pressure (PEEP) which is adjustable in steps of 5 cmH20 and which provides appropriate levels of PEEP. Figure 4 illustrates photographs of the manually adjusted PEEP setting, along with pressure characteristics from a series of breaths at different settings of PEEP. For other values of ventilator settings this test uses standard settings of Vt = 400 ml, RR = 15 breaths/min, I:E ratio 1: 2 and inspiratory oxygen concentration FIO2 = 21 %, with the lung simulator set to simulate a normal lung.

Figure 4 illustrates that the manual setting of PEEP in the range 5-20 cmH2O modifies the pressures profiles so as to increase baseline pressure, i.e. the positive end expiratory pressure. This results in a vertical upward shift in the pressure signal with increasing PEEP from inset A to D. The figure also illustrates that the level of PEEP is equivalent to that shown on the manual setting dial, within the limit of the readability of the dial. As the measured value of PEEP from pressure tracings is shown on the screen the user is able to modify the manual setting until the correct PEEP level is achieved.

The data presented in Figure 4 are snapshots of a test lasting approximately 30 minutes. During these 30 minutes, the pressure remaining in the breathing system, i.e. the PEEP level, was a minimum of the PEEP level at all times.

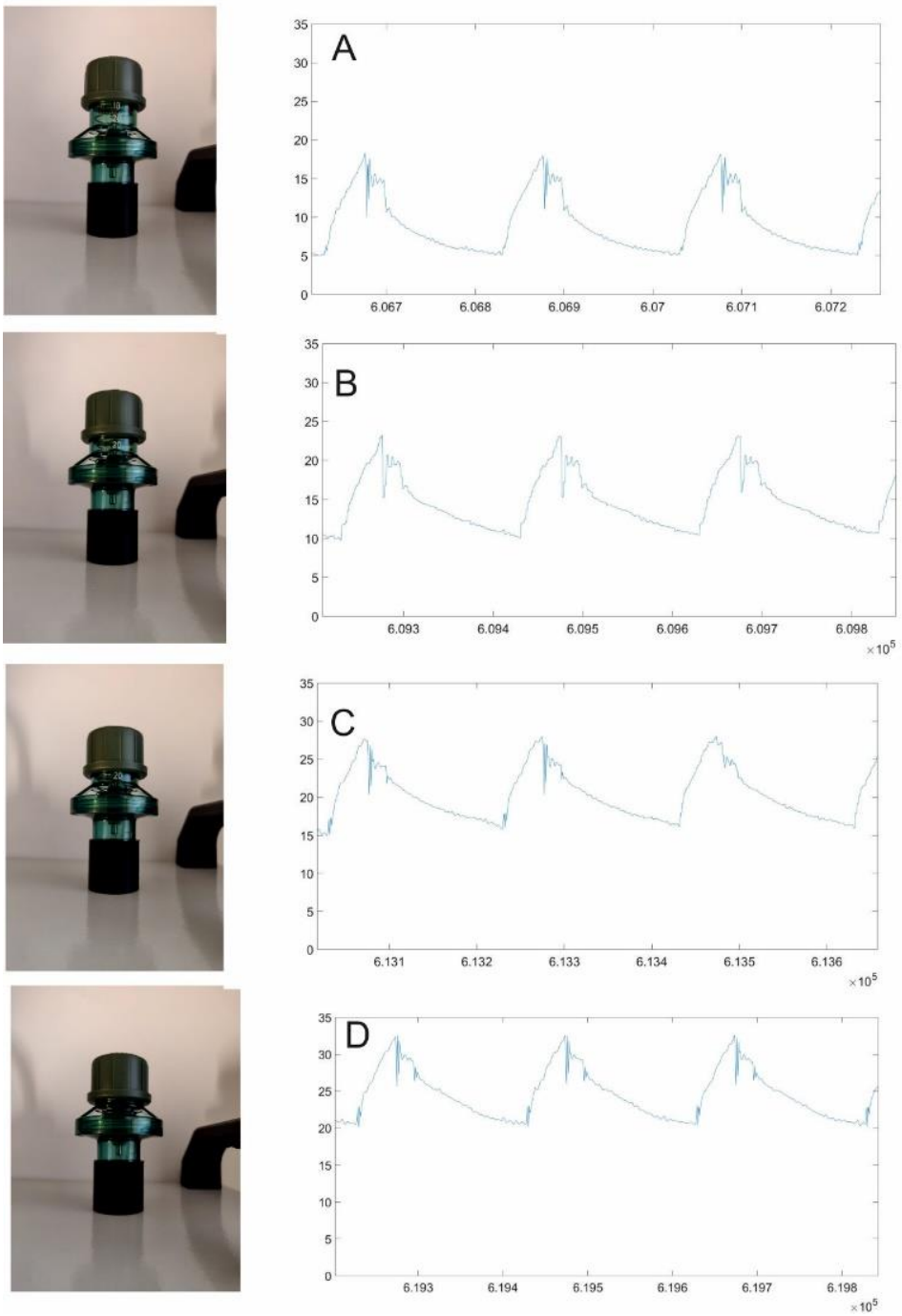

Figure 4: Pictures of the manually set PEEP level (left hand side) and the resulting pressure profiles when PEEP is set to 5 cmH20 (A), 10 cmH20 (B), 15 cmH2O (C), and 20 cmH2O (D).

6.4 TID-004: Test: - Inspiratory: Expiratory (I:E) ratio of 1:2, and adjustable in the range 1:1 to 1:3.

To illustrate that the AAU Pandemic Ventilator provides a controllable value of Inspiratory: Expiratory ratio, and that this can be adjusted across the range 1:1 to 1:3, including 1:2, Figure 5 illustrates flow measurements from a series of breaths at different settings of I:E. For other values of ventilator settings this test uses standard settings of Vt = 400 ml, RR = 15 breaths/min and inspiratory oxygen concentration FIO2 = 21 %, with the lung simulator set to simulate a normal lung, as described in section 5.1.

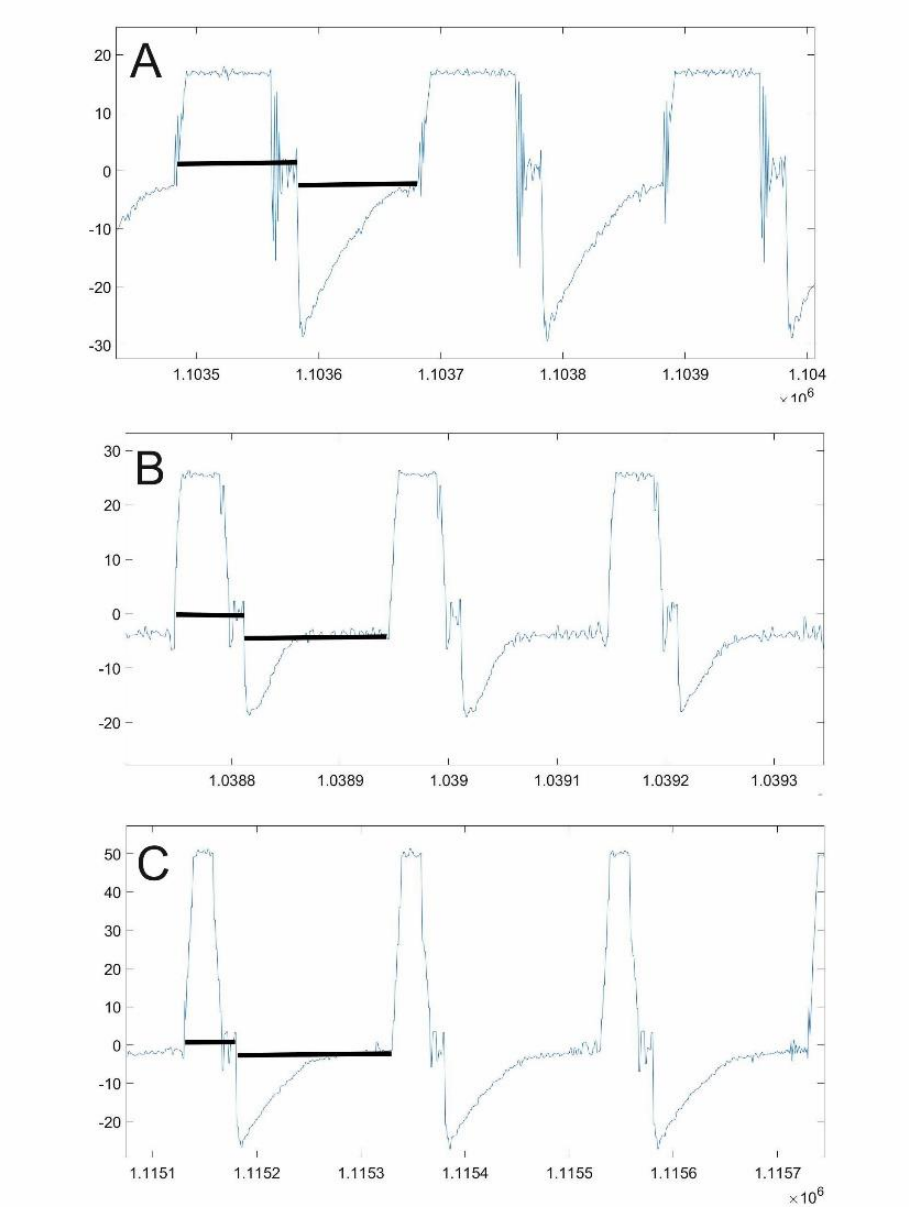

Figure 5: Flow profiles when I:E ratio is set at 1:1 (A), 1:2 (B) and 1:3 (C). Black lines are drawn in to highlight the inspiratory and expiratory durations.

Figure 5 illustrates that setting I.E ratio at the levels 1:1, 1:2 and 1:3 results in flow profiles indicating the correct inspiratory to expiratory durations for each of these settings.

6.5 TID-005: Test: - Respiratory rate in the range 10 to 30 breaths per minute in increments of 2 (only in mandatory mode) can be set by the user.

To illustrate that the AAU Pandemic Ventilator provides a controllable value of respiratory rate (RR), and that this can be adjusted across the range 10 to 30 breaths, Figure 6: Measurement of respiratory rate (RR) when set RR is varied across the required range. illustrates RR measurements from a series of breaths at different settings of RR. For other values of ventilator settings this test uses standard settings of Vt = 400 ml, I:E ratio of 1:2 and inspiratory oxygen concentration FIO2 = 21 %, with the lung simulator set to simulate a normal lung.

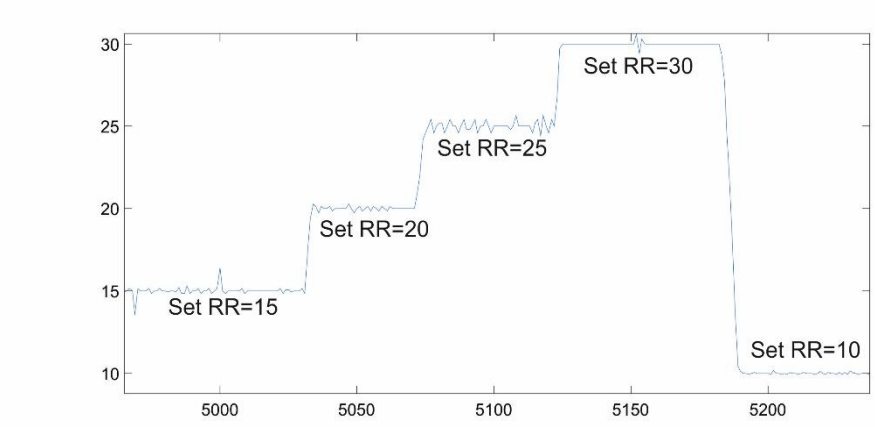

Figure 6: Measurement of respiratory rate (RR) when set RR is varied across the required range.

Figure 6 illustrates that setting RR at the levels across the range 10-30 breaths/min results in measured values approximately equivalent to set values. It should be noted that RR can be set at intervals of 1 breath/min on the ventilator, with steps of 5 breaths/minute only used in the figure for illustrative purposes.

6.6 TID-006: Test: - Tidal volume (Vt) must have at least one setting of 400ml +/- 10 ml, ideally 350ml and 450 ml options, optionally Range 250 to 600 ml in steps of 50ml

To illustrate that the AAU Pandemic Ventilator provides a controllable value of tidal volume (Vt), and that this can be adjusted across the range 250-600, regardless of the disease state of the lung Table 1 illustrates the set and measured tidal volume when the lung simulator is set to both normal lung or diseased lung conditions, the latter simulating acute respiratory distress syndrome. For comparison, Table 2 illustrates the same analysis for a CE marked commercial ventilator (G5 – Hamilton) generated from a test performed as part of this analysis.

Table 1: Set and measured tidal volumes in the AAU Pandemic Ventilator .

Set VT (ml)	Measured Vt, normal lung (ml)/ (% difference from set)	Measured Vt, sim ARDS (ml)
250	255/2.0	260/4.0
300	306/2.0	294/2.0
400	362/9.5	356/11.0
450	414/8.0	402/10.7
500	473/5.4	453/9.4
550	523/4.9	481/12.5
600	625/4.1	596/0.6

Table 2: Set and measured tidal volumes in the G5 ventilator.

Set VT (ml)	Measured Vt, normal lung (ml)/ (% difference from set)	Measured Vt, sim ARDS (ml)
400	366/8.5	403/0.7
450	413/8.2	448/0.4
500	456/8.8	481/3.8
550	495/10.0	524/4.7
600	540/10.0	545/9.1

Both the AAU Pandemic Ventilator and the CE approved commercial ventilator show a similar range of differences with a maximum difference between ventilator settings and measurements of about 10-12%. For both the AAU Pandemic Ventilator and the CE marked ventilator used here, measured tidal volume is displayed on the screen, allowing the user to modify the setting if not satisfied that the setting is achieving the desired tidal volume level.

6.7 TID-007: Test: - Gas supply to the patient – Oxygen delivery user must be able to control inspired oxygen proportion (FiO2), at least 50% and 100% options very preferably ideally variable between 30 and 100% in 10% steps.

To illustrate that the AAU Pandemic Ventilator provides a controllable value of inspired oxygen, and that this can be adjusted across the range 21 to 100 % Table 3 illustrates a table including set and measured

values of FiO2 with all other ventilator settings maintained at Vt = 400 ml, RR = 15 breaths/min and I:E = 1:2.

Table 3: Set and measured FiO2 values from the AAU Pandemic Ventilator .

Set FiO2 (%)	Measured FiO2 (%)/
21 (air)	21
30	34
40	47
50	55
60	64
70	72
80	80
90	88
100	95

Table 3 illustrates that setting FiO2 at the levels across the range 21-100 % results in measured values approximating set values. Measured values are always above set, eliminating a potential risk of low oxygen delivery, and within the 10% FiO2 step in the technical specification for this setting.

7 Test result

Test. ID	Verification Method	Verdict	Date and initials
TID-001	Testing	Pass	SR, 2020-04-02
TID-002	Testing	Pass	SR, 2020-04-02
TID-003	Testing	Pass	SR, 2020-04-02
TID-004	Testing	Pass	SR, 2020-04-02
TID-005	Testing	Pass	SR, 2020-04-02
TID-006	Testing	Pass	SR, 2020-04-02
TID-007	Testing	Pass	SR, 2020-04-02