JAMVENT

EVALUATION OF PERFORMANCE ACCORDING TO MHRA TESTING STANDARDS

VERSION 1.1.1

19/04/2020

VERSION CONTROL

Version	Date Issued	Description
1.0.1	16/04/2020	Original version.
1.1.1	12/04/2020	Evidence of spontaneous mode added.

CONTENTS

Version Control i
Overview 1
Methods 1
Testing Requirements 1
Mock Lungs 2
Our Test Rig 2
Suction tests 3
Spontaneous Mode 4
Calibration 4
Pressure Sensors 4
Flow Sensors 4
Resistances 4
Compliances 5
Data Acquisition and Analysis 5
Results 6
Sample Traces 6
Summary Figures and Tables 7
Tidal Volume 7
Resistance 9
Compliance 11
Additional Performance Tests 13
Suction tests 14
Discussion 16
Conclusion 16

OVERVIEW

The purpose of this document is to provide initial evidence to demonstrate that the JamVent prototype system, built according to the specifications in the accompanying Design Document (v5-0-1), is capable of performing the standards specified in the guidelines set out by the MHRA (v4.0). Where specific details of analysis methods are not reported in the guidelines, we have specified and applied an appropriate analysis approach.

In addition to the general performance tests, we demonstrate that JamVent can successfully maintain PEEP during suction and can operate in spontaneous mode. The system therefore has the capability of performing all of the major tasks required by ICU ventilators for supporting COVID-19 patients.

We are continually testing JamVent and will provide additional performance information via updates provided at:

https://www.imperial-consultants.co.uk/areasofexpertise/emergency-ventilator/

METHODS

Testing Requirements

MHRA divide the main ventilator tests into three categories

1. Tidal Volume
2. Resistance
3. Compliance

We have added a further three categories to test the performance

4. High Volume
5. High Respiratory Rate
6. FiO_2 resolution

Not all tests consider all cases of these parameters, but this provides a guideline for selecting combinations.

Table 1: Input parameters. Note default values for lung parameters are representative of a challenging ARDS patient. Resistance-Compliance combinations with strikethroughs are replaced by the values in the right hand column do to a lack of sufficiently low resistance test units.

	Parameter	MHRA Test Values	Additional values considered
User Inputs	FiO_2 (%)	55, 95	35,45,65,75,85
	Tidal Volume, V_T (ml)	300, 500	800
	Respiratory Rate (breaths/min)	12, 20	30
	PEEP (cmH_2O)	5, 10, 15	
	I:E ratio	1:2	
Model lung	Resistance ($cmH_2O/(l/s)$) | Compliance (ml/cmH_2O)	~~5|10~~, ~~5|20~~, ~~5|50~~, 20|20, 50|10	9|10, 9|20, 12.5|50

Full combinations required by the MHRA on pages 17-19 are provided in the results section, as well as results for our additional performance tests.

Note that where we used higher resistance values in Table 1 than the MHRA specifications, this was in anticipation of clinical challenges beyond the MHRA specifications, as higher resistances are more challenging to ventilate.

Output parameters given in Table 2 are defined in the MHRA guidelines on Page 24 for FiO_2, P_{airway} and V_T exhaled on Page 6, Point 4b for PEEP. Further definition of how the outputs should be analysed is not provided

in the MHRA guidelines. We have therefore used a straightforward statistical analysis to produce a single value for each output parameter. This involved calculation the error signal, as described in the table. For each parameter, we calculated the 95th percentile of the absolute value of the error signal.

Table 2: Output parameters and error calculations. Note that MHRA guidelines allow an extra 4% on P_{airway}* and an extra 4ml on Tidal Volume**, which we have not considered in the interest of clarity.

Parameter	Readout	Target	Error Signal
FIO_2 (%)	Min/Max	Must be within ±5% of target	$e_{FIO_2} = FIO_2\|_{target} - FIO_2\|_{target}$
P_{airway} (cmH_2O)	Min/Max	Difference between reported and measured value must be less than ± 2 cmH_20*.	$e_{P_{airway}} = P_{airway}\|_{test} - P_{airway}\|_{system}$
V_T exhaled (ml)	Min/Max	Measured values must be ±15%**	$e_{V_T} = V_T\|_{measured} - V_T\|_{target}$
PEEP (cmH_2O)	Min	Value measured in the lung must not be below target	$e_{V_T} = PEEP\|_{measured} - PEEP\|_{target}$

Mock Lungs

Our main testing mock lung (Figure 1) comprised a 2L anaesthetic reservoir bag (Intersurgical, 2820000) with various resistance elements added in upstream (described in the calibration section). This bag has a baseline compliance at 20 cmH_2O of ~20 ml/cmH_2O. To reduce this to ~10 ml/cmH_2O, we constricted the bag to a circumference of 300 mm along a 20 mm wide band around the centre of the bag, using Velcro hook and loop tape.

In order to achieve a compliance of 50 ml/cmH_2O, we built a second mock lung (Figure 1), comprising a 3L hydration bladder constrained between two 6mm acrylic sheets, hinged at one end with springs at the other. The resistance in this system was 12.5 (cmH_2O/(l/s)) and we were not able to get it lower for the present data set.

Our Test Rig

Figure 1 shows a schematic of the test rig we built for this analysis. This aligns with MHRA guidelines as closely as possible, given current difficulties in acquiring parts, with the exceptions:

i. We only have access to a single O_2 sensor, placed as indicated in Figure 1. Our system therefore used the same O_2 signal as the test rig. This was amplified with a signal conditioner (TXDIN 1620 from Omega Engineering).
ii. We added an additional flow sensor in the inhalation pathway to provide an additional baseline for that measurement.

Table 3: Components in the test rig.

	Oxygen Sensor	Flow Sensor	Calibration flow sensor	Pressure Sensors
Manufacturer	TeleDyne	Honeywell	Sensirion	Omega
Product code	C43690-R22MED	AWM720P1	SFM3000-200C	PXM319-0.35G10V
Range	0-100%	0 to 200 SLPM	-200 to 200 SLPM	0 to 357 cmH_2O
Accuracy	±1%	Repeatability and hysteresis < 0.35% of the measured value	1.5%	Static accuracy (linearity, hysteresis and repeatability) 0.7 cmH_2O
Response	<6 s	6 ms	0.5	1 ms

Test rig acquisition was carried out with a National Instruments USB 6008 multifunction data acquisition card at 1000 Hz, and was down-sampled by averaging to the required 200Hz. Data for JamVent were also acquired at 1000Hz, and down-sampled to 100 Hz.

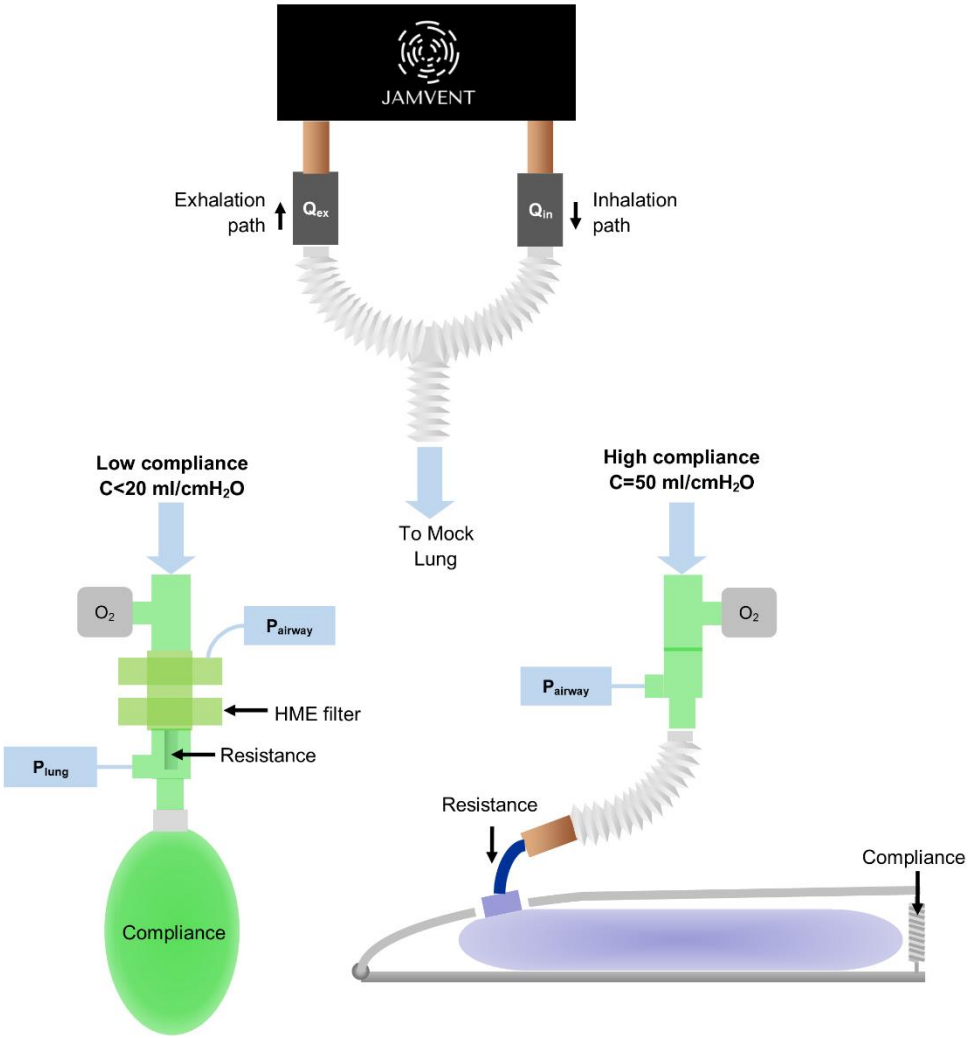

Figure 1: Schematic of the testing setup. JamVent was connected to one of two test lung setups for high (right side) or low (left side) lung compliances.

SUCTION TESTS

In the recent update to the MHRA documentation, emphasis on the importance of the closed suctioning test has increased. This test mimics sucking out excess secretions from the lung and is required up to hourly in COVID-19 and other ITU patients. It is critical that during this process, the lung pressure remains elevated so as to maintain recruitment of the alveoli.

With available equipment, we mimicked the key requirement of this test, which is to maintain PEEP while withdrawing air from the lung at a rate of 30 l/min with a vacuum pump. The guidelines aim to maintain a minimum 5 cmH_2O.

In order to do this, we programmed an additional mode of operation into JamVent that can be activated by the user from the front screen. Additional details of the operation will be provided in Design Document version 5.1. In brief, the inhalation valve is open, and the exhalation valve only opens if the pressure exceeds some specified value, e.g. PEEP + 5 cmH_2O. Valves A and B are programmed to open when the pressure reaches PEEP and to close when the pressure equals PEEP plus a selected amount, e.g. 2 cmH_2O. As the suctioning occurs, additional flow can easily pass from the system to the suctioning setup, in order to maintain lung

volume and hence lung pressure. Once the suctioning has completed, normal ventilation mode can be resumed.

The test specifies tidal volume of 300 ml, PEEP of 10 cmH_2O and a respiratory rate of 10 breaths/min. A lung compliance of 10 ml/cmH_2O is specified, but resistance is not, so for the present demonstration we chose R=9 cmH_2O/(l/s).

Spontaneous Mode

A spontaneous mode is important for weaning patients off ventilation and the absence of this mode has been a criticism of other emergency ventilator designs by leaders in Intensive Care. In essence, this mode requires the ability to sense an inhalation by the patient and to provide a supporting breath of specified tidal volume over a selected period. After exhalation the pressure is maintained at PEEP until another breath is sensed. If no breath occurs within 20 seconds, the system automatically switches into PRVC mode.

We have added an additional mode to JamVent, which can be selected on the user interface when the clinician decides that a patient might be suitable for supported ventilation. To sense attempted breaths, we monitor the system pressure after exhalation. An attempted intake of breath will increase the volume of the lungs, and thereby briefly lower the measured pressure. In our demonstration, we used the high-compliance mock lung and mimicked an intake by manually releasing some of the pressure from the springs. When the pressure drops below a sensing threshold (we used 1 cmH_2O in this demonstration, but this can be selected by the user) the breath is triggered. If no breath is attempted within 20 seconds, the system returns to PRVC mode.

In our demonstration, we started in PRVC mode, moved into spontaneous mode, simulated 5 breaths and then left the system to return to PRVC mode automatically.

Calibration

Pressure Sensors

These were calibrated with 9-point calibration against a Dwyer instruments pressure calibrator (475-3-FM, accuracy 0.5%). Prior to acquisition, the system was opened to atmosphere to establish a zero-pressure baseline.

Flow Sensors

Although the Honeywell sensors have high repeatability and low hysteresis, their flow rate-voltage behaviour is non-linear. We therefore used a pre-calibrated digital Sensirion flow sensor for calibration. We measured the voltage v from the Honeywell flow sensor at 14 flow rates Q in the range 0-50 slpm and fit a model of the form $Q=av^n$ to calibrate readings.

Resistances

In laminar flow, pressure drop scales linearly with flow, and resistance is constant. In turbulent flow, the pressure drop scales with the square of the flow rate, which can be viewed as resistance increasing linearly with flow rate. Resistances for ventilator testing are evaluated at flow rates of 60 l/min, where laminar (linear) and turbulent (parabolic) resistances in cmH_2O/(l/s) are equal. We measured the pressure drop across resistive components at 30 l/min, and doubled them to calculate the resistance at 60 l/min, which is equivalent to the rated value.

First, we measured the flow-pressure behaviour downstream of the JamVent system pressure sensor, with pressure drop being caused by flow within the manifold and the 22mm adaptor. From this, we calculated a flow coefficient K_v=1.0 ($m^3/hr/bar^{0.5}$) from which we correct the airway pressure according to $P_{airway}=P_{sys}-(\alpha Q/K_v)^2$, where α=0.0707 and is a conversion factor for K_v into l/min/$cmH_2O^{0.5}$.

For our lowest resistance (R5 in the standards) we added two HME filters (Intersurgical, 1941001) and measured the pressure P_{airway} at 30 l/min, and calculated a resistance of 9 cmH_2O/(l/s). This is greater than the required 5 cmH_2O/(l/s), but would represent a more clinically challenging situation. Similarly, for the high-compliance mock lung setup (Figure 1), the connectors had a resistance of 12.5 cmH_2O/(l/s). For a resistance

of ~20 $cmH_2O/(l/s)$, we added a tube with a length of 50mm and ¼ inch inner diameter. For a resistance of ~50 $cmH_2O/(l/s)$, we used a 145mm length of tubing with a 5mm inner diameter.

Compliances

To measure compliance, we pre-pressurised the system to 20 cmH_2O then rapidly injected volumes of 20, 40 or 60 ml using a 60 ml syringe and recoded the spike in pressure. Compliance was calculated as $C=\Delta V/\Delta P$. Average values of 9.8, 19.1, 49.5 are equated to the MHRA testing guidelines of 10, 20 and 50 ml/cmH_2O.

Data Acquisition and Analysis

For each set of conditions, we allowed the system to reach steady state, then acquired 45 seconds of data. Temporal responses will be evaluated in future releases. For each experimental case, 7 cycles were extracted for analysis.

All data analysis was carried out in MATLAB. The beginning and end of each cycle were identified using peak finding algorithms applied to the derivative of the valve timing signals, which were acquired in both systems. For each system (JamVent and the testing rig), tidal volume was calculated by integrating the flow rate during the exhalation periods. PEEP was calculated as the average over the last 100 data points acquired for each cycle. The oxygen signal was filtered with a median filter of 20 data points (0.1s) to minimise electrical noise. For the airway pressure, data from JamVent were up-sampled from 100Hz to 200Hz by the application of a spline fit to enable direct subtraction for the testing rig measurement. A median filter of 20 data points (0.1s) was applied to the difference between the two signals to reduce noise.

RESULTS

SAMPLE TRACES

For each set of experimental conditions, traces were generated of the critical parameters (Figure 2).

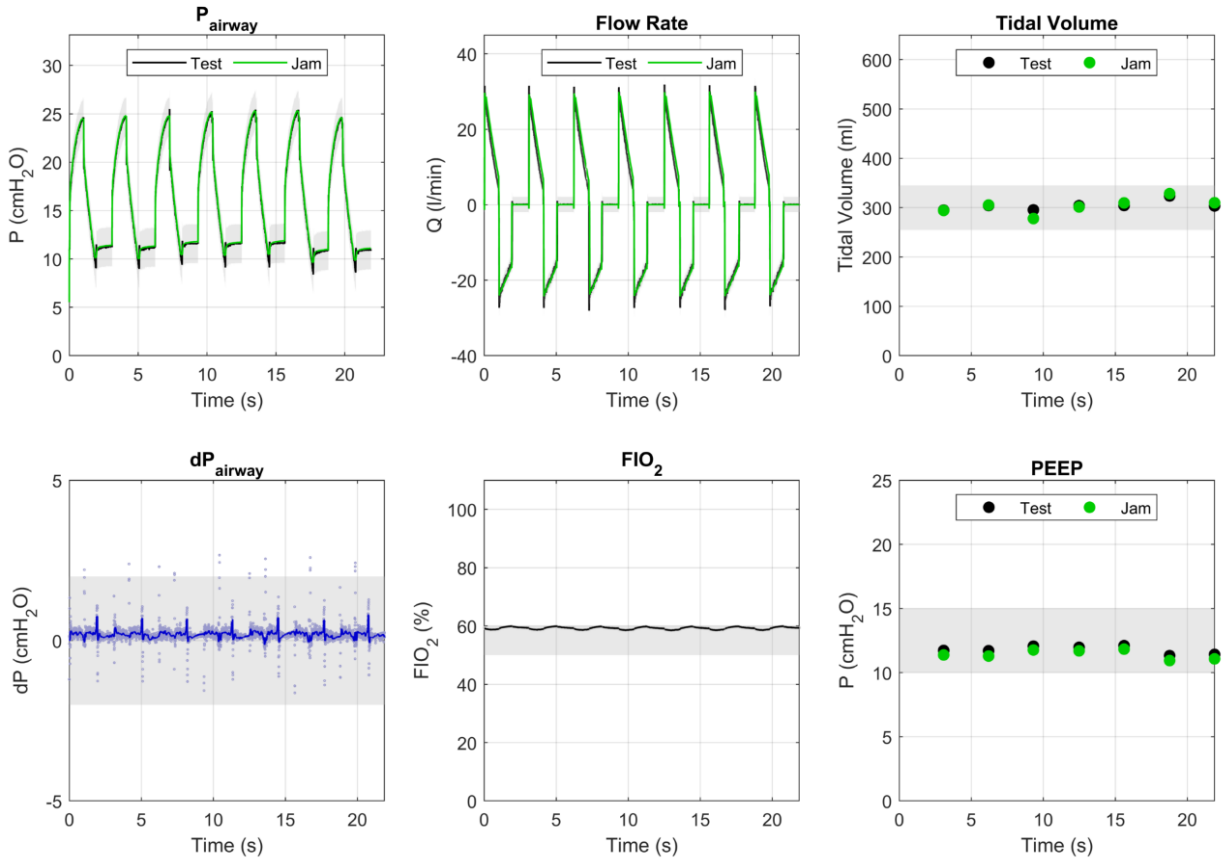

Figure 2: Sample trace for representative case from Tidal Volume experiments (MHRA test number 17). Resistance 20, Compliance Resistance 20 $cmH_2O/(l/s)$ Compliance 20 ml/cmH_2O, Tidal volue 300 ml, respiratory rate 20 breaths/minute, PEEP 10 cmH_2O, FIO_2 50-60%. Green lines show data acquired using Jament, black lines indicate data from the test rig, blue line shows difference between measured airway pressures after filtering, with dots showing raw data points. Grey shaded regions indicate acceptable performance.

Both the flow rate and the airway pressures in Figure 2 are closely matched between JamVent and the test rig. Over all of the tidal volume, resistance and compliance tests, the error signal (95th percentile of the absolute difference) was 3.2 ± 0.7 l/min (mean ± 2 standard deviations) for flow and 0.34 ± 0.34 cmH_2O for airway pressure. Both of these ranges are within the uncertainty of the test rig components, which demonstrates the accuracy of the system and the approach used to measure flow rate with JamVent. The tidal volumes and FIO_2 are all within the required resolution. The PEEP values are slightly above the minimum level, as required by the MHRA. An acceptable band of 5 cmH_2O has been added for visualisation only and is not specified.

Equivalent traces for all cases can be downloaded as an appendix.

Summary Figures and Tables

The following summary figures and tables confirm that with few isolated exceptions, the tests were successful. The few cases that were not successful are scattered within the testing requirements (see Tables), rather than being at the limits (e.g. highest PEEP or highest resistance), indicating again that these do not represent limitations of the system. Furthermore, in the rare cases where the test conditions are not met it is by around 1 percent, except in the additional performance tests where tidal volume is exceeded by less than three percent.

Tidal Volume

These tests are carried out at 300 ml tidal volume and include resistance-compliance combinations of 12.5|50, 20|20 and 50|10.

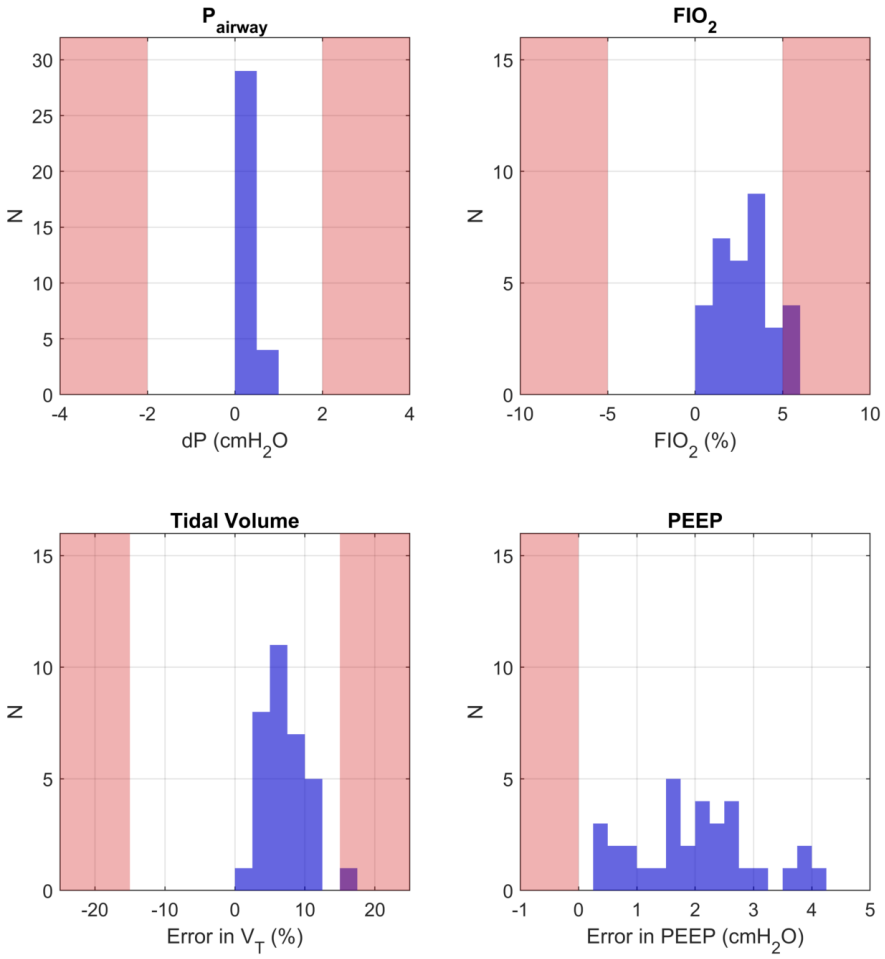

Figure 3: Summary histograms for tidal volume test conditions. Red shaded regions indicate data points outside performance specifications.

Table 4: Each of the test conditions in the tidal volume data set and their performance. Grey bars indicate missing tests. Green indicates conditions met, pink indicates condition failed.

MHRA Test No.	Compliance	Resistance	VT	Rate	FiO_2 (%)	PEEP	O_2 error (%) Threshold ±5%	P_{airway} error (cmH2O) Threshold ±2 cmH2O	V_T error (%) Threshold ±15%	PEEP error (cmH2O) Threshold >0 cmH2O
1	50	12.5	300	20	55	5	0.2	0.2	10.7	0.8
2					95					
3				12	55		0.7	0.2	8.3	0.8
4					95		2.6	0.2	12.2	0.5
5				20	55	10	0.7	0.3	11.5	1.7
6					95		1.7	0.4	2.2	0.3
7				12	55		3.3	0.2	10.9	1.1
8					95		2.5	0.2	9.3	0.6
9				20	55	15	0.8	0.3	9.6	1.4
10					95					
11				12	55		1.3	0.2	5.9	0.4
12					95		1.3	0.2	6.3	0.4
13	20	20		20	55	5	3.8	0.4	2.7	1.5
14					95		3	0.2	4.9	1.5
15				12	55		4.6	0.3	5.7	1.7
16					95		1.2	0.2	9.1	1.7
17				20	55	10	4.8	0.3	7.9	2.1
18					95		5.4	0.3	5.2	2
19				12	55		3.4	0.3	5.3	2
20					95		2.4	0.2	6.7	2.1
21				20	55	15	4.4	0.4	10.5	2.4
22					95					
23				12	55		3.7	0.3	4.4	2.6
24					95		1.7	0.3	4.2	2.6
25	10	50		20	55	5	5.3	0.5	2.6	1.9
26					95		2.7	0.4	1.7	1.9
27				12	55		1.9	0.2	3.3	2.3
28					95		2.9	0.2	7.7	2.3
29				20	55	10	3.2	0.6	6.9	2.7
30					95		3.5	0.8	4.6	2.7
31				12	55		1.9	0.2	6.4	3.2
32					95		3.4	0.4	6.5	2.8
33				20	55	15	5.5	0.2	15.1	3.9
34					95		3.1	0.4	7.1	3.7
35				12	55		5.3	0.5	6.2	3.9
36					95		2.5	0.3	4.7	4

RESISTANCE

These tests are carried out at 500 ml tidal volume and include resistance-compliance combinations of 12.5|50, 50|10, 20|20.

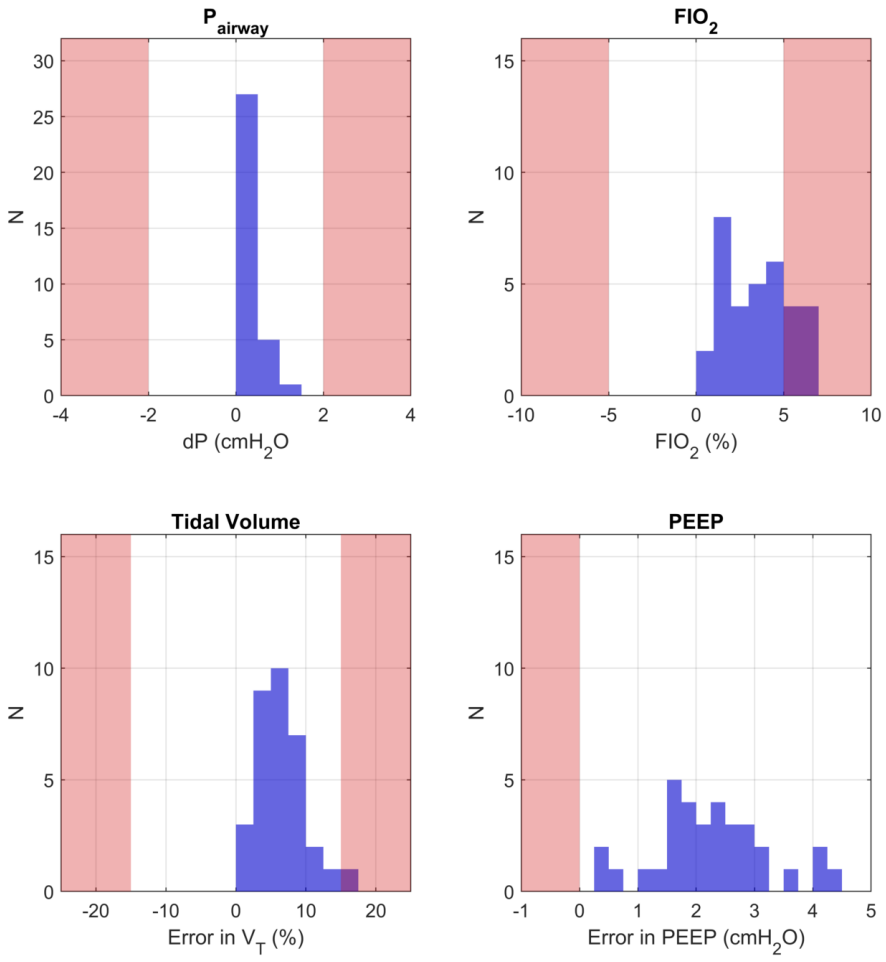

Figure 4: Summary histograms for resistance test conditions. Red shaded regions indicate data points outside performance specifications.

Table 5: Each of the test conditions in the tidal volume data set and their performance. Grey bars indicate missing tests. Green indicates conditions met, pink indicates condition failed.

MHRA Test No.	Compliance	Resistance	VT	Rate	FiO_2 (%)	PEEP	O_2 error (%) Threshold ±5%	P_{airway} error (cmH2O) Threshold ±2 cmH2O	V_T error (%) Threshold ±15%	PEEP error (cmH2O) Threshold >0 cmH2O
1	50	12.5	500	20	55	5				
2					95		0.9	0.3	6.4	2.4
3				12	55		0.5	0.2	6.4	1.3
4					95		2.9	0.2	15.3	0.6
5				20	55	10	1.6	0.5	13.4	0.3
6					95		1.8	0.4	5.9	0.3
7				12	55		1.5	0.2	9	1.7
8					95		3.1	0.3	8.9	1
9				20	55	15	1.6	0.4	12	1.5
10					95					
11				12	55		1	0.2	6.7	1.8
12					95		1.3	0.2	6.3	0.4
13	20	20		20	55	5	2.1	0.3	6.1	1.5
14					95		1.5	0.3	1.7	1.7
15				12	55		4.5	0.2	8.5	1.8
16					95		5.4	0.2	8.2	1.6
17				20	55	10	4.5	0.3	8.3	2
18					95		2.6	0.4	4.6	2.4
19				12	55		3.7	0.2	1.5	1.8
20					95		1.8	0.3	7.4	1.9
21				20	55	15	3.9	0.3	10.5	2.9
22					95		2.1	0.4	4.4	2.8
23				12	55		5.1	0.2	4.7	2.6
24					95		1.3	0.3	4.9	2.7
25	10	50		20	55	5	4.2	1.2	3.7	2
26					95		4.9	0.4	8.4	2.2
27				12	55		6	0.2	6.4	2.3
28					95		3	0.4	5.2	2.4
29				20	55	10	5.1	0.4	6.8	2.8
30					95		4.6	0.7	3.7	2.7
31				12	55		6.2	0.6	3	3.2
32					95		3.7	0.3	3.6	3.2
33				20	55	15	6.3	0.4	9.9	4
34					95		5.1	0.8	6.7	3.6
35				12	55		6.1	0.5	2.4	4
36					95		4.5	0.4	4.3	4.3

COMPLIANCE

These tests are carried out at 500 ml tidal volume, and include resistance-compliance combinations of 12.5|50, 9|20 and 9|10.

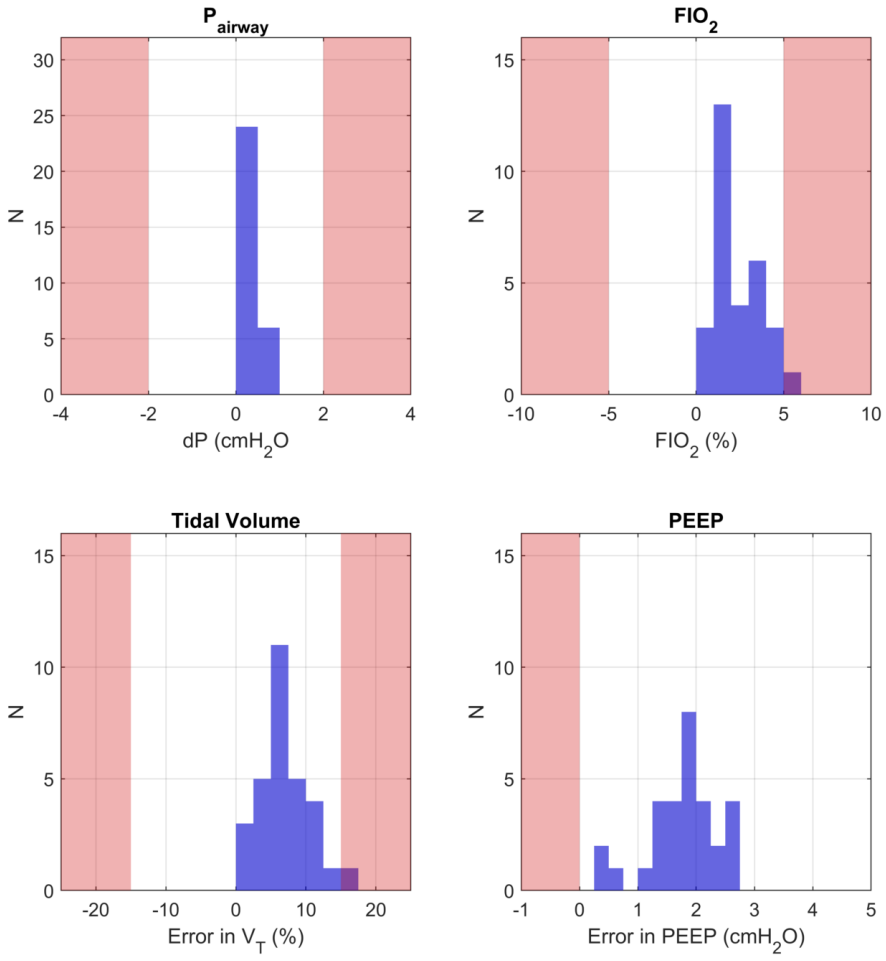

Figure 5: Summary histograms for compliance test conditions. Red shaded regions indicate data points outside performance specifications.

Table 6: Each of the test conditions in the tidal volume data set and their performance. Grey bars indicate missing tests. Green indicates conditions met, pink indicates condition failed.

MHRA Test No.	Compliance	Resistance	VT	Rate	FiO_2 (%)	PEEP	O_2 error (%) Threshold ±5%	P_{airway} error (cmH2O) Threshold ±2 cmH2O	V_T error (%) Threshold ±15%	PEEP error (cmH2O) Threshold >0 cmH2O
1	50	12.5	500	20	55	5				
2					95		0.9	0.3	6.4	2.4
3				12	55		0.5	0.2	6.4	1.3
4					95		2.9	0.2	15.3	0.6
5				20	55	10	1.6	0.5	13.4	0.3
6					95		1.8	0.4	5.9	0.3
7				12	55		1.5	0.2	9	1.7
8					95		3.1	0.3	8.9	1
9				20	55	15	1.6	0.4	12	1.5
10					95					
11				12	55		1	0.2	6.7	1.8
12					95					
13	20	5		20	55	5				
14					95		1.8	0.3	5.2	1.7
15				12	55					
16					95		2.5	0.2	3.5	1.8
17				20	55	10	0.7	0.4	10.4	1.9
18					95		2.1	0.3	2.5	1.8
19				12	55					
20					95		1.2	0.2	3	2.1
21				20	55	15	1	0.5	10.7	2.6
22					95		3.6	0.4	6.5	2.6
23				12	55		4.9	0.3	8.6	2.7
24					95		2.5	0.2	2.2	2.6
25	10			20	55	5	1.8	0.6	9.1	1.4
26					95		3	0.7	5.2	1.3
27				12	55		1.7	0.2	2.2	2
28					95		3.9	0.3	2.9	2.1
29				20	55	10	1.9	0.4	6.2	1.3
30					95		3.1	0.5	3	1.6
31				12	55		1.3	0.2	6.7	1.8
32					95		4.8	0.2	1.6	1.8
33				20	55	15	3	0.4	12.4	1.8
34					95		4.3	0.6	7.8	1.9
35				12	55		1.3	0.2	5.1	2.3
36					95		5.4	0.2	6.2	2.1

Additional Performance Tests

We carried out additional tests to investigate the system performance at the extremes of the MHRA specifications. The high volume tests used a tidal volume of 800 ml, which was consistently achieved along with other parameters. The high respiratory rate tests at 30 breaths/minute likewise reach standards, with a slight tendency to provide a too high tidal volume, which could be optimised for in the control algorithm. To test the resolution to FIO_2 values, we demonstrated the ability to achieve values spaced 10% apart within the required accuracy specifications.

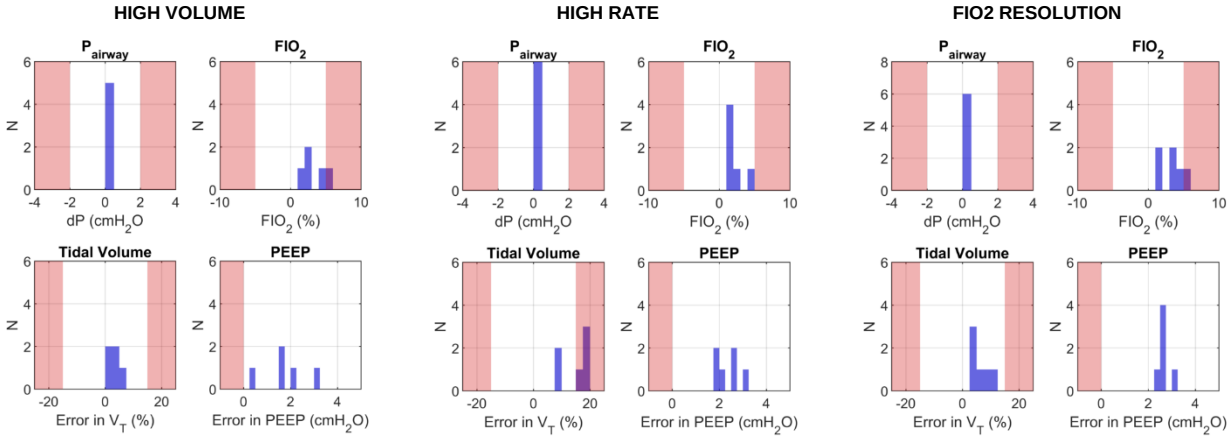

Figure 6: Summary histograms for additional performance conditions. Red shaded regions indicate data points outside performance specifications.

Table 7: Each of the test conditions in additional performance data set and their performance. Grey bars indicate missing tests. Green indicates conditions met, pink indicates condition failed.

	Our Test No.	Compliance	Resistance	VT	Rate	FiO_2 (%)	PEEP	O_2 error (%) Threshold ±5%	P_{airway} error (cmH2O) Threshold ±2 cmH2O	V_T error (%) Threshold ±15%	PEEP error (cmH2O) Threshold >0 cmH2O
High Rate	1	20	20	300	30	55	5	4.0	0.4	17.9	3.0
	2					95		1.9	0.4	7.6	2.0
	3					55	10	1.8	0.4	17.6	1.8
	4					95		2.6	0.4	9.7	1.8
	5					55	15	1.8	0.3	18.8	2.5
	6					95		1.7	0.4	16.4	2.6
High Volume	7			800	12	55	5	4.0	0.3	3.9	1.6
	8					95		2.1	0.2	2.0	1.6
	9					55	12	5.1	0.3	5.0	0.3
	10					95	10	2.3	0.2	1.4	2.1
	11					55	15	4.6	0.2	4.9	3.0
	12					95		1.8	0.3	3.5	3.0
FiO2 Resolution	13			400	12	35	15	4.0	0.2	6.5	3.0
	14					45		1.8	0.2	4.1	2.6
	15					55		3.1	0.2	3.7	2.5
	16					65		5.2	0.3	11.0	2.6
	17				20	75		1.8	0.3	7.7	2.6
	18					85		3.7	0.3	3.8	2.3
	19					95		3.5	0.2	4.5	2.6

SUCTION TESTS

JamVent is capable of maintaining lung pressure during suction of 30 l/min from within the lung, as demonstrated in Figure 7. Due to the response time of the pump we used, the suction period in Figure 7 are ~6 seconds, and the system has no problem maintaining pressure even though this is twice the time required by the MHRA guidelines.

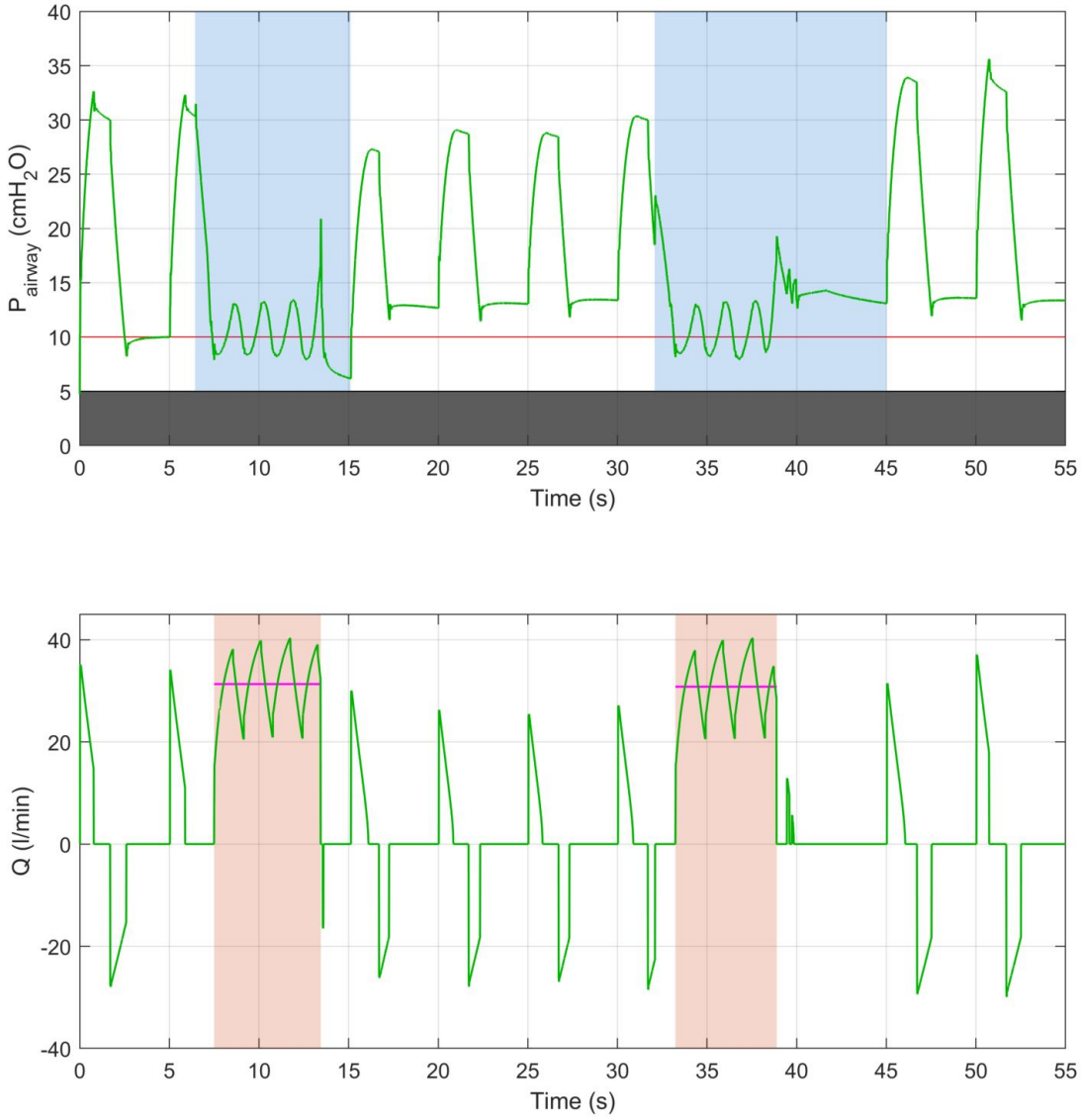

Figure 7: Demonstration of response to suction tests at 30 l/min. Top panel: airway pressure is shown in green. Red line is PEEP and black shaded region shows 5 cmH2O below which airway pressure must not reach. Blue shaded areas show regions where suction mode was activated in the software. Bottom panel: flow rate shown in green. with average flow during suctioning indicated in magenta. Shaded red regions indicate periods when suctioning was occurring.

The control algorithm for restarting the breath will be optimised, but the current performance demonstrates that the JamVent hardware is more than capable of maintaining pressure during suctioning.

Spontaneous Mode

Figure 8 demonstrates that JamVent is capable of operating in spontaneous breathing mode. The first 3 breaths indicated here are in PRVC mode, and spontaneous mode was selected on the GUI at 10 seconds. The first breath is sensed a few seconds later, and the system delivers a tidal volume that is very close to the desired value. The subsequent four breaths are intermittently spaced to demonstrate the sensing capability. After the fifth breath, the system was left alone, and 20 seconds passed from the end of the last breath. At this point, PRVC mode automatically resumed, and with the exception of a single breath of borderline tidal volume, normal breathing was resumed straight away.

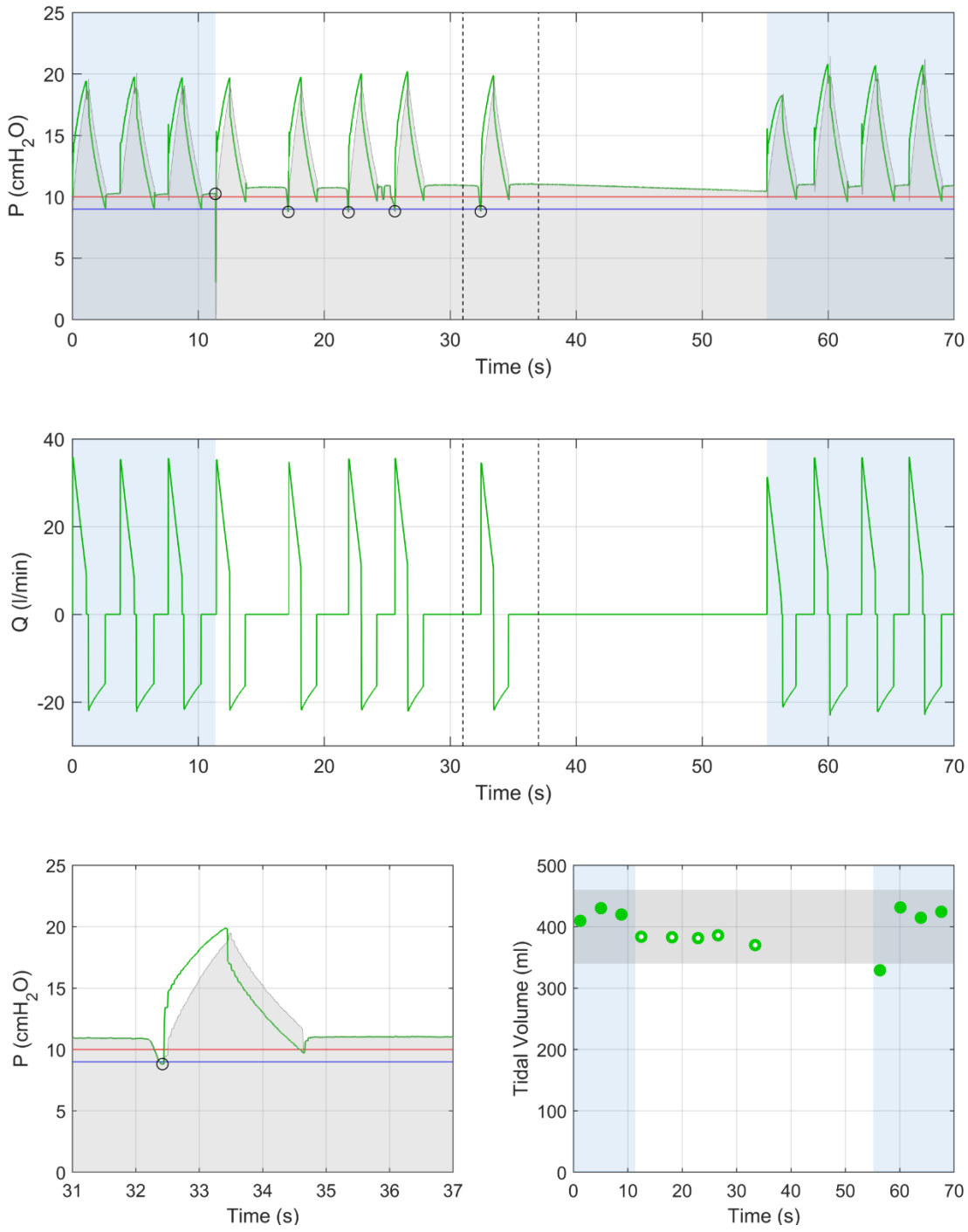

Figure 8: Demonstration of spontaneous mode. Blue regions indicate PRVC mode active. Top panel: airway pressure is shown in green and lung pressure estimated by the system is shown in grey. Red line is PEEP and blue line below is the set pressure threshold for breath sensing, which occurred at the times indicated by the black circles.. Dashed vertical lines indicate sample breath shown in lower left panel. Middle panel: flow rate traces during demonstration. Bottom left panel: close up of region highlighted by dashed lines. Bottom right panel: expired tidal volume during the demonstration. Hollow markers indicate patient-triggered breaths.

DISCUSSION

In the present testing of JamVent, the system reached the MHRA specifications in the vast majority of cases. Small tweaks to the control algorithm, which are ongoing, will ensure that this is achieved in 100% of cases. The performance of the system even at the limits of the MHRA specifications demonstrates the capability of the technology to perform as required.

The ability of the system to maintain PEEP during suctioning, highlighted as critical in the updated MHRA documentation, is demonstrated in Figure 7. The ability to operate in spontaneous breathing mode is invaluable for weaning patients off ventilation.

Limitations include the need for an additional O_2 sensor within the JamVent system (rather than sharing with the test rig) and lower lung resistance to match the values specified by MHRA. We will also optimise the control algorithms to improve the precision and accuracy of the system.

Not specified by the MHRA, but of interest regarding system performance are the temporal responses to parameter changes, and the robustness to perturbations, such as coughing. These will be provided in future iterations of this document.

CONCLUSION

We tested our Prototype JamVent system against the MHRA specifications and demonstrated that it can perform as required and in some cases beyond the requirements. It is capable of PRVC and spontaneous modes, and is therefore perfectly suited for treating COVID-19 patients.