JAMVENT

EVALUATION OF PERFORMANCE

VERSION 2

04/06/2020

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1 OVERVIEW

In our first Evaluation of Performance document (Version 1, 19/04/2020), we demonstrated that JAMVENT built as described in Design Document Version 5, could perform the requirements set out for the MHRA RMVS specification.

The purpose of this document is to update our initial evidence to demonstrate that JAMVENT, built according to the specifications in Design Document Version 6, is capable of performing the standards specified in the guidelines set out in ISO 80601-2-12:2020, 'Particular requirements for basic safety and essential performance of critical care ventilators'. 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 performance tests, we have included data from Evaluation of Performance Document Version 1, showing 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/

See JAMVENT.com for further details.

2 VALIDATION TESTING

We carried out four main sets of testing for validation of the system. These included tests for accuracy using a secondary test rig, tests for control response, effect of changing supply pressure, and response time of FiO_2 changes using the system on its own. We also provide evidence of functioning in spontaneous and suction modes.

2.1 ACCURACY TESTING

2.1.1 ACCURACY TESTING METHODS

In order to ascertain the accuracy of JAMVENT, a testing setup was constructed following ISO 80601-2-12:2020 Figure 201.102, with the exception of an oxygen sensor. The components of the test rig are detailed in Table 1 below; the corresponding test setup for JAMVENT is shown in Figure 1.

Table 1 Components of the test rig for accuracy testing, following ISO 80601-2-12:2020.

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

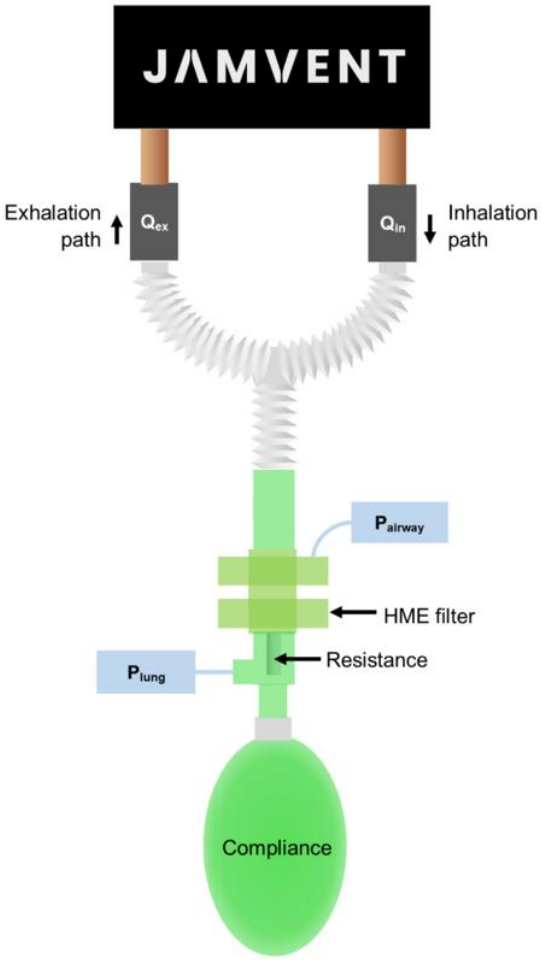

Figure 1 Overview of the JAMVENT test system for accuracy testing.

Combinations of mock-lung lung parameters and ventilation settings were carried out as described in Table 2. All combinations of RR, FiO_2, and PEEP were investigated.

Table 2 Test parameters for accuracy testing. All combinations of RR, FiO2 and PEEP were carried out.

Test Category	Compliance (ml/cmH_2O)	Resistance (cmH_2O/(l/s))	V_T (ml)	RR (bpm)	FiO_2 (%)	PEEP (cmH_2O)
Tidal Volume	24	30	300	12, 20	55, 95	5, 10, 15
	12	50		12, 20	55, 95	5, 10, 15
Resistance	24	30	500	12, 20	55, 95	5, 10, 15
	12	50		12, 20	55, 95	5, 10, 15
Compliance	24	6		12, 20	55, 95	5, 10, 15
	12			12, 20	55, 95	5, 10, 15

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. For each set of conditions, we allowed the system to reach steady state, then acquired 45 seconds of data. For each experimental case, 5 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 50ms of P_{airway} for each breath. 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 from the testing rig measurement. A median filter of 10 data points (0.05s) was applied to the difference between the two signals to reduce noise.

Comparison between the test rig and JAMVENT was carried out using Bland-Altman analysis (Figure 2). The x-axis shows the average of the measurement from the two systems and the y-axis shows the difference. The blue horizontal line shows the average difference and the shaded blue region shows the mean ±1.96 standard deviations.

2.1.2 ACCURACY TESTING RESULTS

As shown in Table 3, the mean difference between JAMVENT and the test rig for inhaled and exhaled tidal volume, PEEP, and airway pressure is low. It is recommended that the accuracy of tidal volume (both inhaled and exhaled) is ±15%. JAMVENT performs significantly better than this accuracy threshold. Similarly, with respect to airway pressure, JAMVENT has accuracy much better than ±2cmH_2O. JAMVENT exhibited high precision with respect to PEEP.

Table 3 The average difference and 1.96 standard deviation between the test rig and JAMVENT determined for inhaled and exhaled tidal volume, PEEP, and airway pressure.

	$V_{T,in}$ (ml)		$V_{T,ex}$ (ml)		PEEP (cmH_2O)	P_{airway} (cmH_2O)
User Input	300	500	300	500	5, 10, 15	0-50
Mean	-2	2	-5	1	0.5	0.4
1.96 SD	15	19	18	24	0.4	0.8

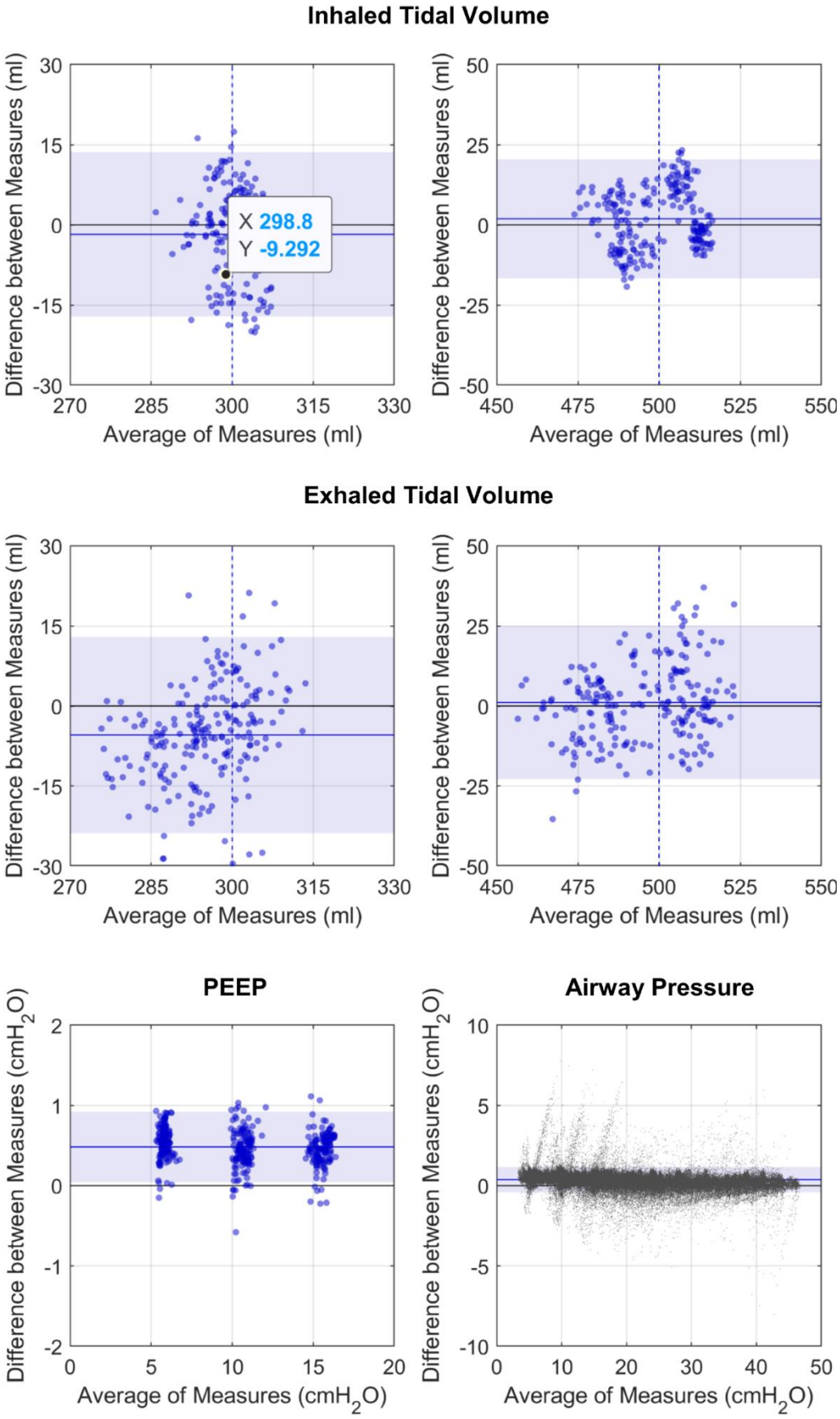

Figure 2 Comparison between JAMVENT and test rig for inhaled and exhaled tidal volume, PEEP, and airway pressure.

2.2 CONTROL TESTING

2.2.1 CONTROL TESTING METHODS

A second set of validation testing was conducted with JAMVENT to analyse the response time of the system with respect to ISO guidelines.

- 7 unique combinations of test parameters, including compliance, resistance, V_T, RR, FiO_2, and PEEP (Table 4)
- Response times of FiO_2, V_T, and PEEP were analysed.
- Inspiration time was 1s for all cases. For each test, system reached steady state in the default condition (Table 4), then User Inputs were changed manually to the target values. Data was recorded for 45s.
- All tests were repeated in triplicate.

Table 4 Test parameters from ISO guidelines.

ISO Test No.	Compliance	Resistance	V_T (ml)	RR (bpm)	FiO_2 (%)	PEEP (cmH_2O)
Default	-	-	400	16	60	5
1	50	5	500	20	30	5
2		20		12	90	10
3	20	6		20		5
4		20		20	30	10
5			300	20		5
6		50		12	90	10
7	10			20	30	10

2.2.2 CONTROL TESTING RESULTS

Figure 3 shows the triplicate testing results for the first row of Table 4. The intended accuracy range for the output parameter is shaded in grey (FiO_2: ±5%; V_T: ±15ml; PEEP: +2cmH_2O). The default settings are indicated by the black line. Both V_T and PEEP stabilised quickly (<10s) to their respective target values. Values of FiO_2 reached the new set point within 30-40s; FiO_2. Excellent consistency was observed between the replicate tests for all output parameters. Additional figures for the remaining 6 lines of Table 4 are provided in Appendix D. Regardless of the system configuration, V_T and PEEP were achieved accurately within a few breaths and accurate FiO_2 was achieved, but at a rate depending on tidal volume and respiration rate.

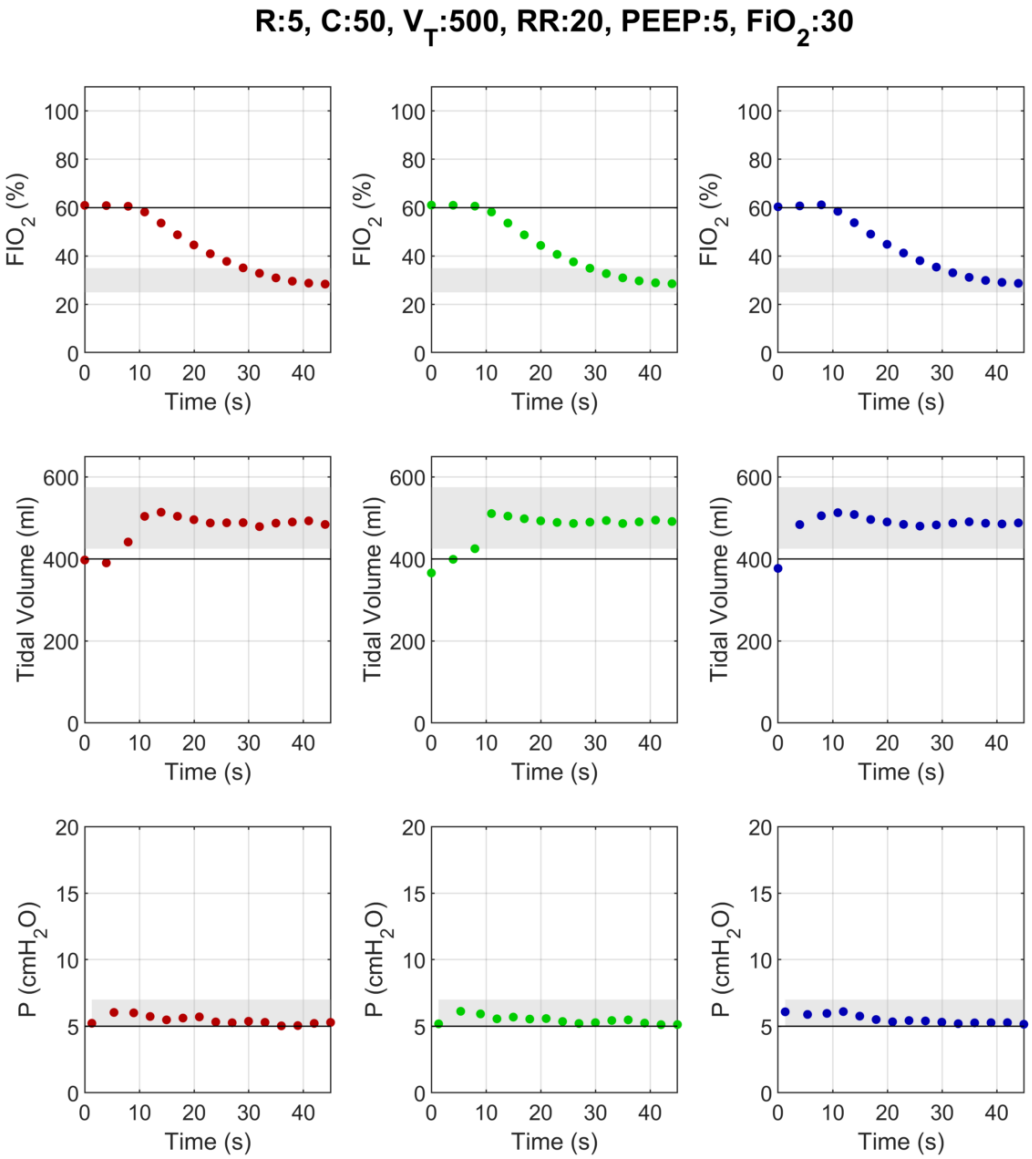

Figure 3 Response time of FiO_2, V_T, and PEEP of the JAMVENT system for ISO Test No. 1. The individual replicate test results are provided for all output parameters.

The results at steady state for all 7 tests are presented in Figure 4 and Table 5. The histograms in Figure 4 indicate that an acceptable distribution of error was observed within the data set, which was within the intended accuracy range of each parameter (FiO_2: ±5%; V_T: ±15ml; PEEP: +2cmH_2O). The median error, as well as the corresponding 2.5% and 97.5% percentiles, for each output parameter are provided in Table 5.

Table 5 Median error, 2.5% and 97.5% percentiles for each output parameter.

	Proportional error in VT (%)	Error in PEEP (cmH_2O)	Error in FiO2 (%)
Median	-2.9	0.5	-0.3
2.5% percentile	-9.4	-0.1	-8.8
97.5% percentile	0.9	1.4	6.9

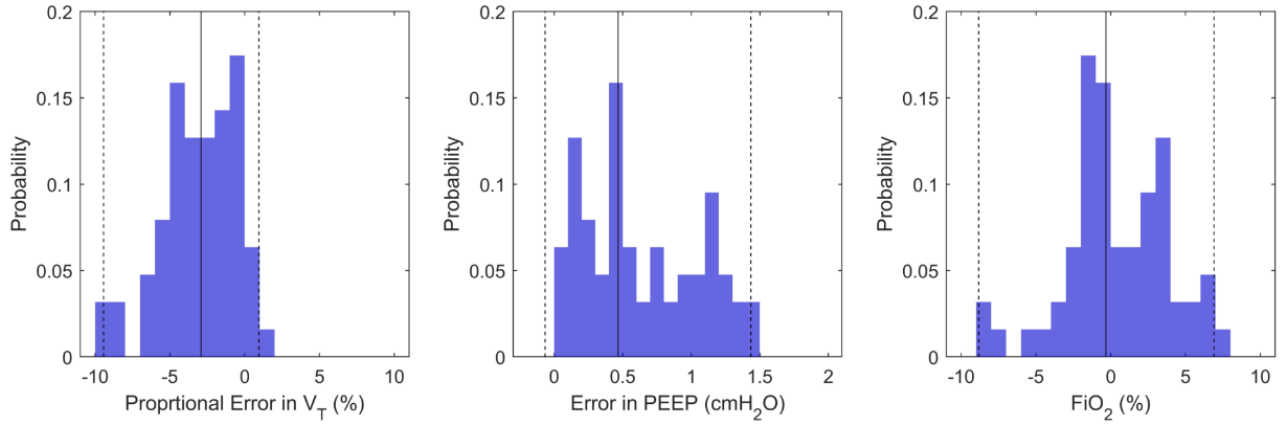

Figure 4 Histogram depicting probability distribution of error for FiO_2, V_T, and PEEP.

These small errors indicate repeatable and accurate delivery of the user defined parameters.

2.3 SUPPLY PRESSURE TESTING

2.3.1 SUPPLY PRESSURE TESTING METHODS

To evaluate how JAMVENT performs with different supply pressures, the system response time from default to target values for different gas supply pressures was evaluated. The following parameters were implemented:

- Gas supply pressures of 2, 4, and 6 bar gauge
- Constant target values of V_T, RR, FiO_2, and PEEP (Table 6)
- Response time of FiO_2, V_T, and PEEP were analysed
- Inspiration time was 1 second for all cases
- For each test, system reached steady state in default condition, then User Inputs were changed manually to the target values. Data was recorded for 40s.

Table 6 Test parameters for gas supply test.

Test Condition	Compliance	Resistance	V_T (ml)	RR (bpm)	FiO_2 (%)	PEEP (cmH_2O)
Default	-	-	400	16	60	5
P_{sup} = 2 bar	20	20	500	20	90	10
P_{sup} = 4 bar						
P_{sup} = 6 bar						

2.3.2 SUPPLY PRESSURE TESTING RESULTS

The results of the gas supply test are presented in Figure 5. The output parameters behaved consistently regardless of supply pressure. Target values of PEEP and tidal volume (within its accuracy range) were reached in approximately 2-3 breaths or less for all evaluated parameters. FiO_2 reached its set point within approximately 20s. This confirms that the system is robust to differences in supply pressure.

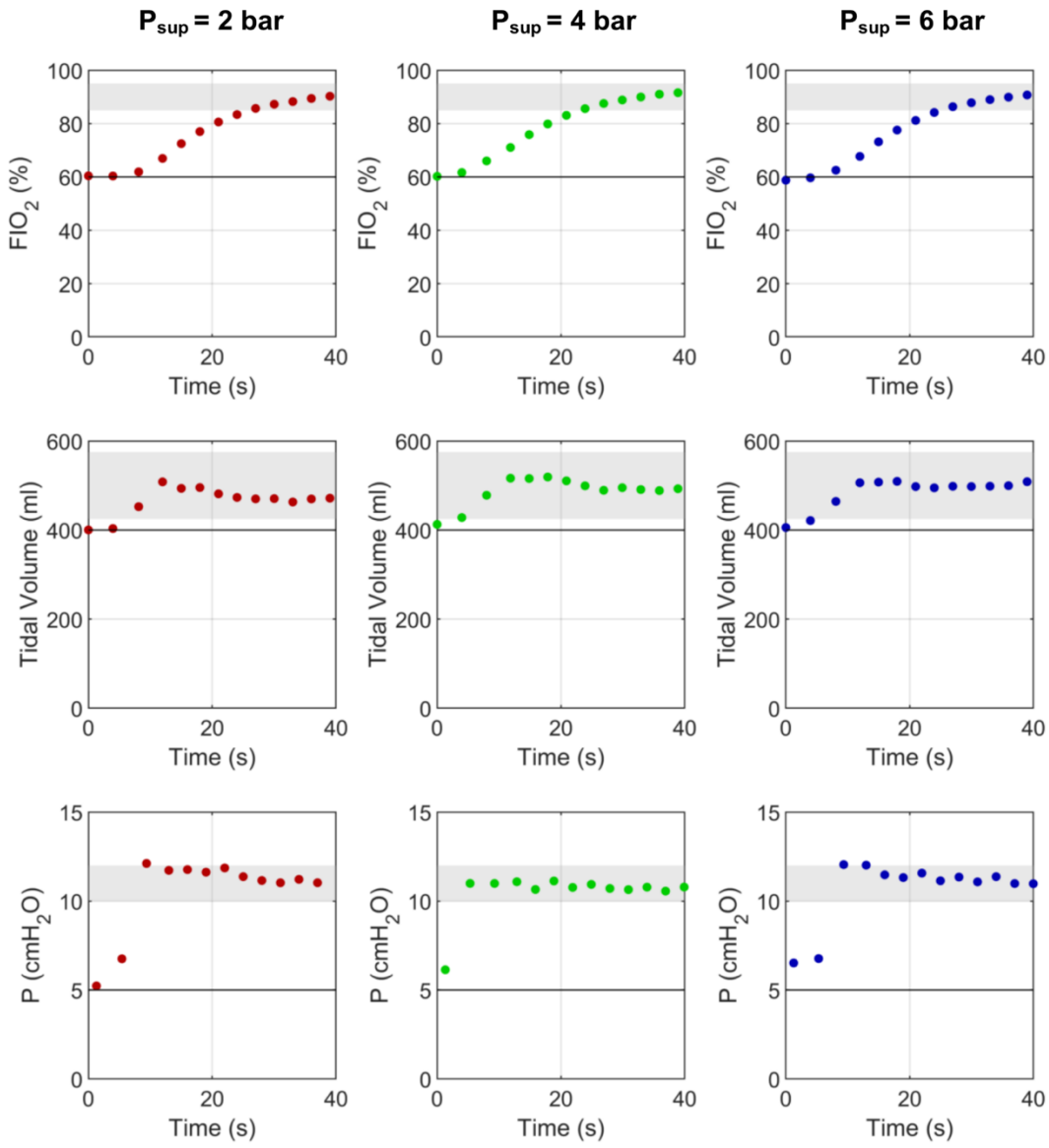

Figure 5 Response time of FiO_2, V_T, and PEEP of the JAMVENT system for different gas supply pressures.

2.4 OXYGEN RESPONSE TIME TESTING

2.4.1 OXYGEN RESPONSE TIME METHODS

FiO_2 response time from default to target values was evaluated using two different minute volumes (MV): the product of respiration rate and tidal volume. The following parameters were utilised:

- Low MV (3.6 l) and high MV (10 l)
- Response time of FiO_2, V_T, and PEEP were analysed
- Inspiration time was 1s for all cases. For each test, system reached steady state in default condition, then User Inputs were changed manually to the target values. Data was recorded for 120s
- Tests repeated in triplicate.

Table 7 Test parameters for oxygen response test.

Test Condition	Compliance	Resistance	V_T (ml)	RR (bpm)	FiO_2 (%)	PEEP (cmH_2O)
Low MV	20	20	300	12	100	10
High MV			500	20		

2.4.2 OXYGEN RESPONSE TIME RESULTS

The results of the minute volume tests are shown for low and high MVs in Figures 6 and 7, respectively. For a low MV, target values for all output parameters were reached in less than 100s. This delay is due to the dead volume in the reservoir. It should be noted that an abnormal discontinuity was observed in the FiO_2 values for the low MV. This was a result of an issue identified with the oxygen sensor. For a high MV, target values were reached in less than 45s. All values remained within their intended accuracy range once reached. Excellent consistency was observed between the replicate tests for all output parameters.

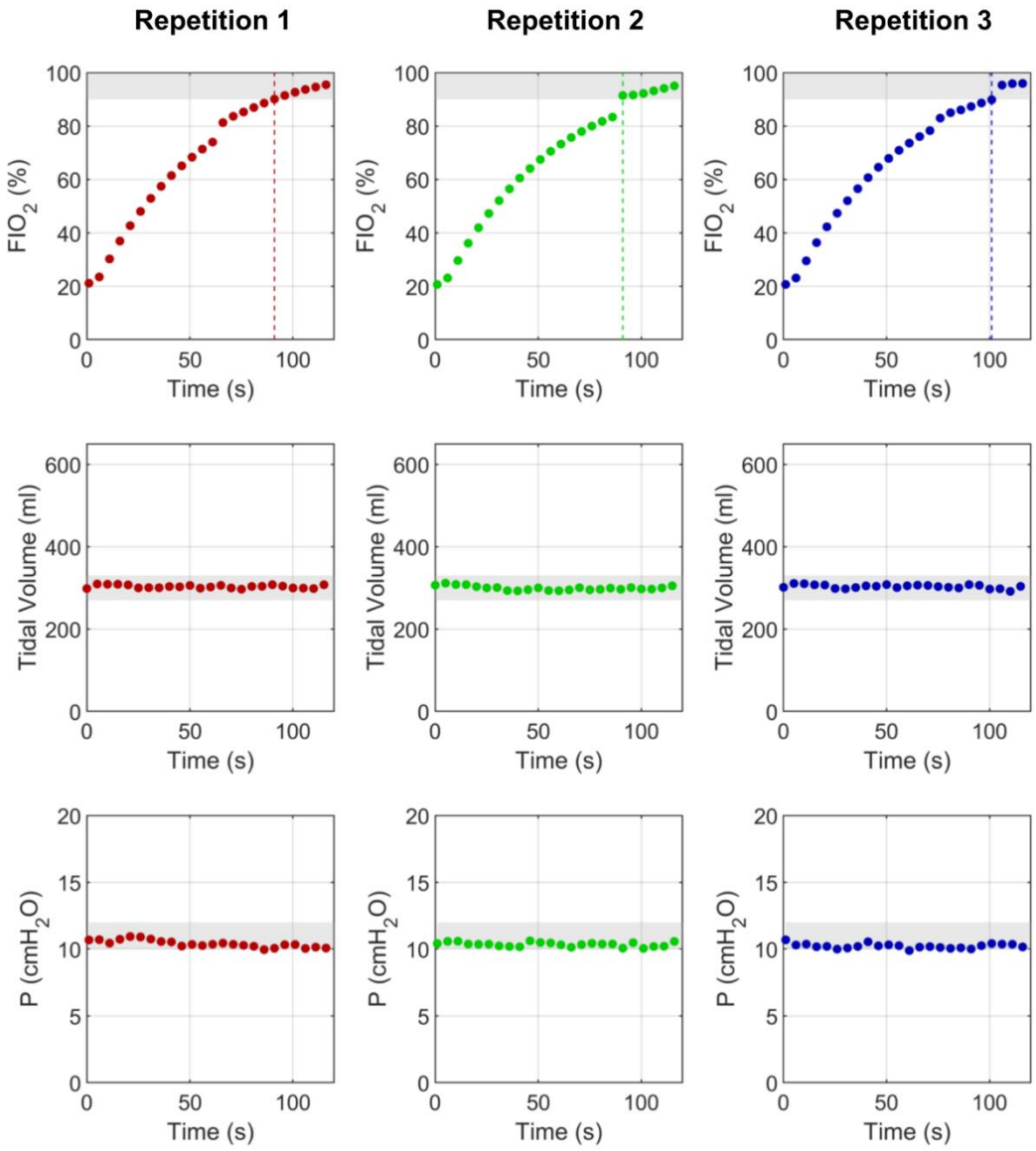

Figure 6 Response time of FiO_2, V_T, and PEEP of the JAMVENT system for low MV.

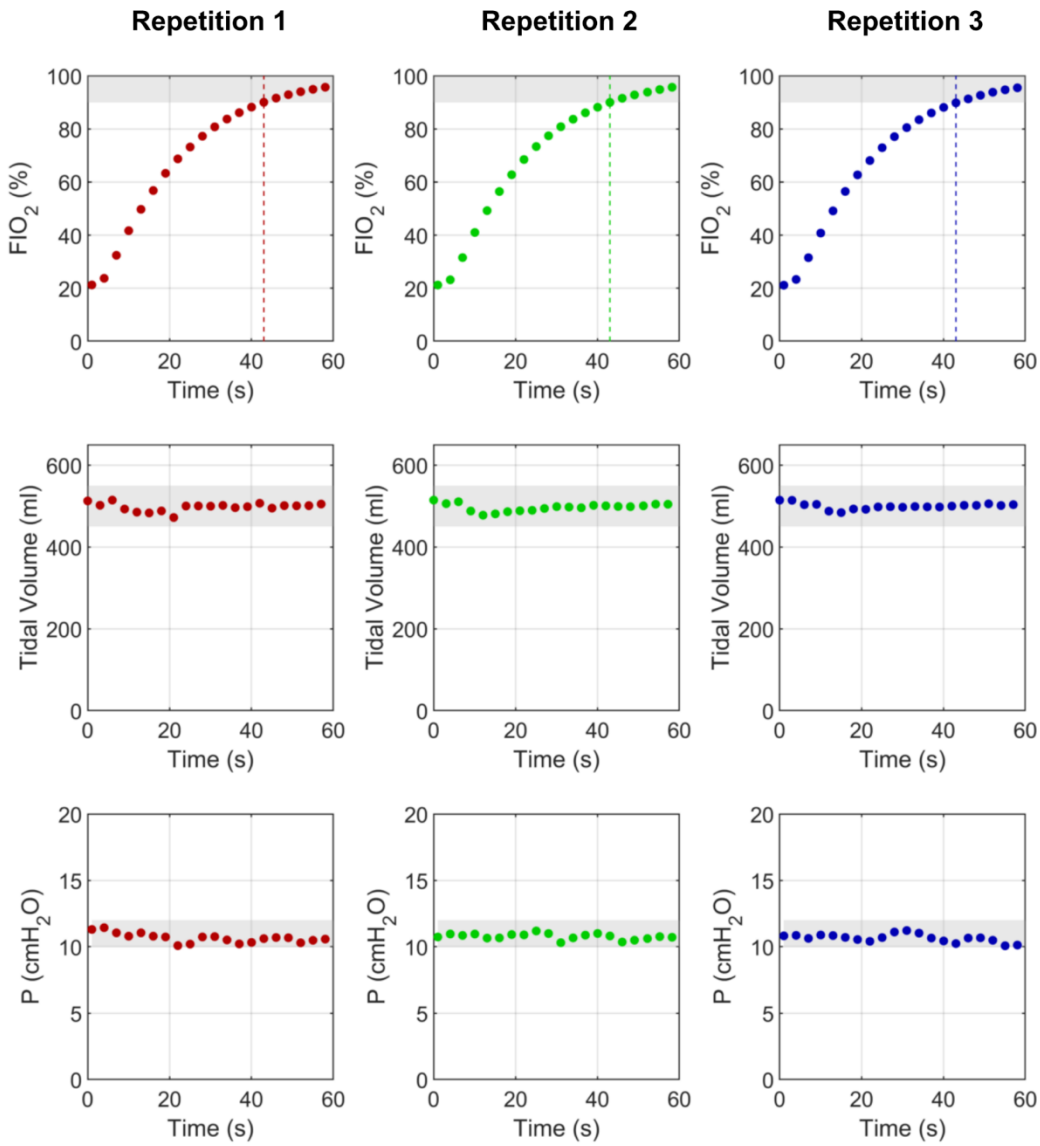

Figure 7 Response time of FiO_2, V_T, and PEEP of the JAMVENT system for high MV.

2.5 SUCTION TESTING

2.5.1 SUCTION TESTING METHODS

To test the Suction mode of JAMVENT, air was withdrawn from a test lung at a rate of 30l/min with a vacuum pump. The key requirement of the test is to maintain minimum PEEP of 5cmH_2O during suctioning. A tidal volume of 300ml, PEEP of 10cmH_2O, and a respiratory rate of 10 breaths/min were implemented. A lung compliance and resistance of 10 ml/cmH_2O and 9 cmH_2O/l/s were utilised, respectively.

Note that this data is duplicated from our previously released Evaluation of Performance document. With the new control algorithm described in §3.3, pressure never goes below PEEP.

2.5.2 SUCTION TESTING RESULTS

JAMVENT is capable of maintaining lung pressure during suction of 30 l/min from within the lung, as demonstrated in Figures 8 and 9. Due to the response time of the vacuum pump, the suction period in Figures 8 and 9 is ~6 seconds, and the system maintains pressure for the entire duration. The current performance demonstrates that the JAMVENT hardware is capable of maintaining pressure during suctioning.

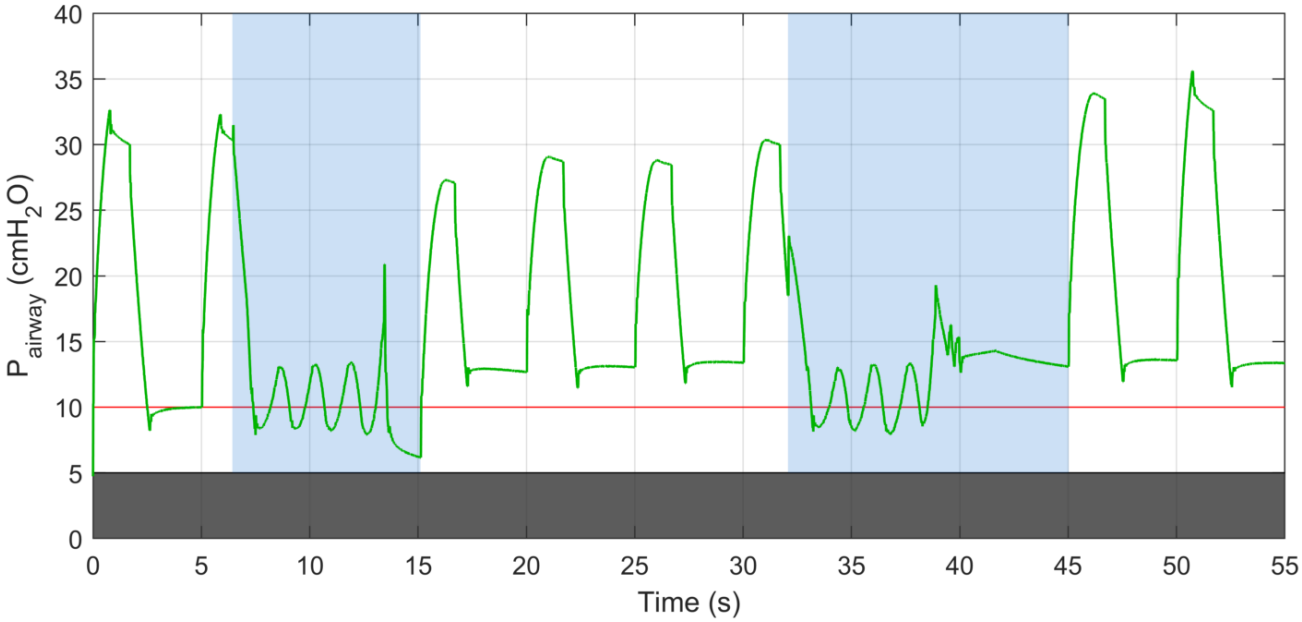

Figure 8 Demonstration of response to suction tests at 30 l/min. Airway pressure is shown in green. Red line is PEEP and black shaded region shows 5 cmH2O below which airway pressure must not reach. Blue shaded areas show regions where suction mode was activated in the software.

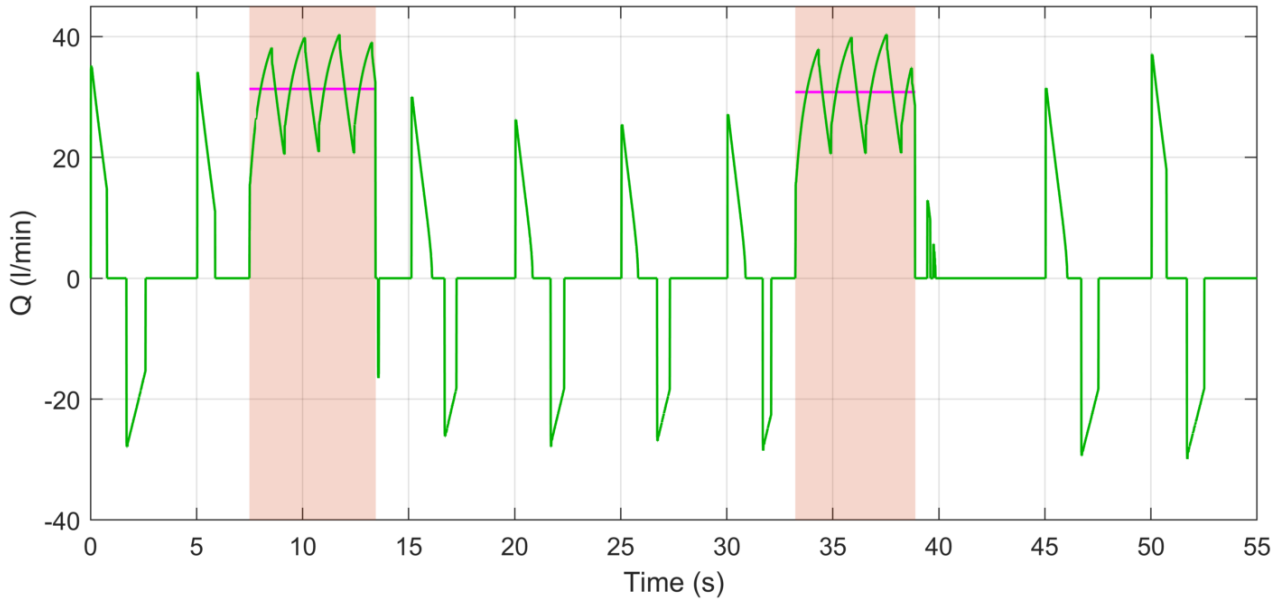

Figure 9 Demonstration of response to suction tests at 30 l/min. Flow rate shown in green with average flow during suctioning indicated in magenta. Shaded red regions indicate periods when suctioning was occurring.

2.6 SPONTANEOUS MODE TESTING

2.6.1 SPONTANEOUS MODE TESTING METHODS

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.

To test Spontaneous mode, JAMVENT was started in PRVC mode, moved into spontaneous mode, simulated 5 breaths and then left the system to return to PRVC mode automatically.

2.6.2 SPONTANEOUS MODE TESTING RESULTS

Figure 10 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.

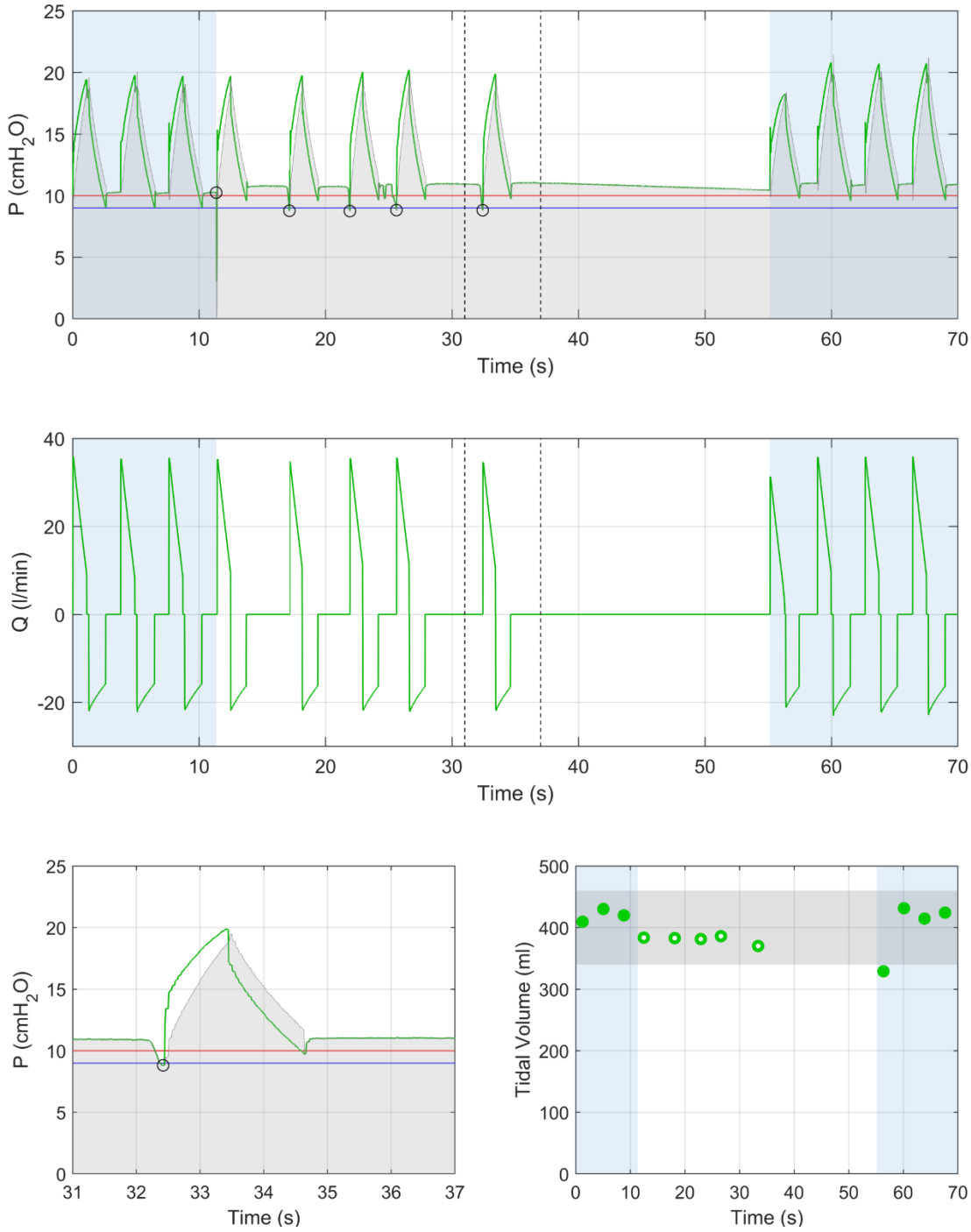

Figure 10 Demonstration of spontaneous mode. Blue regions indicate PRVC mode active. Top panel: airway pressure is shown in green and lung pressure estimated by the system is shown in grey. Red line is PEEP and blue line below is the set pressure threshold for breath sensing, which occurred at the times 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.

APPENDIX A: ADDITIONAL CONTROL TESTING RESULTS

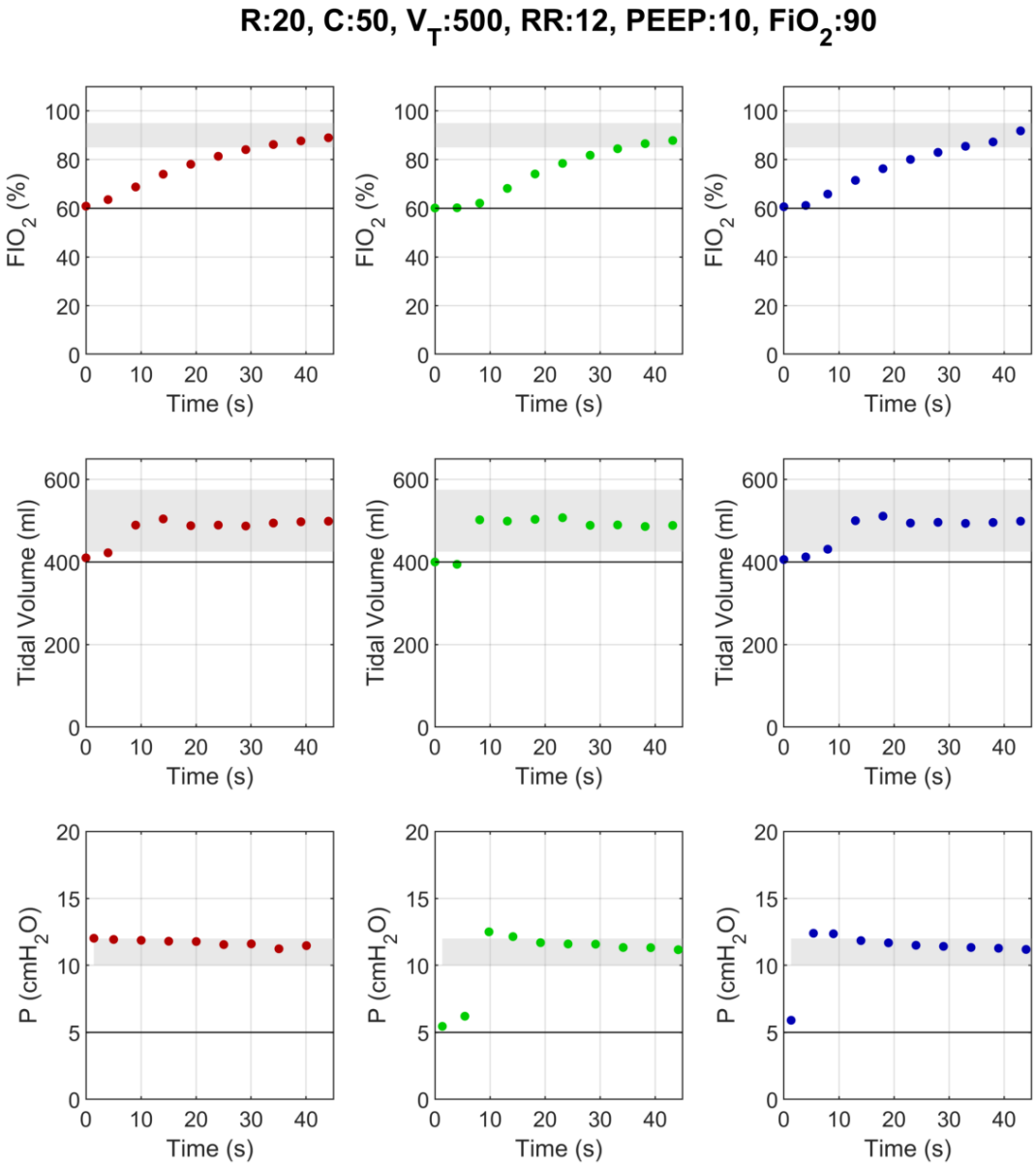

Figure A1 Response time of FiO_2, V_T, and PEEP of the JAMVENT system for ISO Test No. 2. The individual replicate test results are provided for all output parameters.

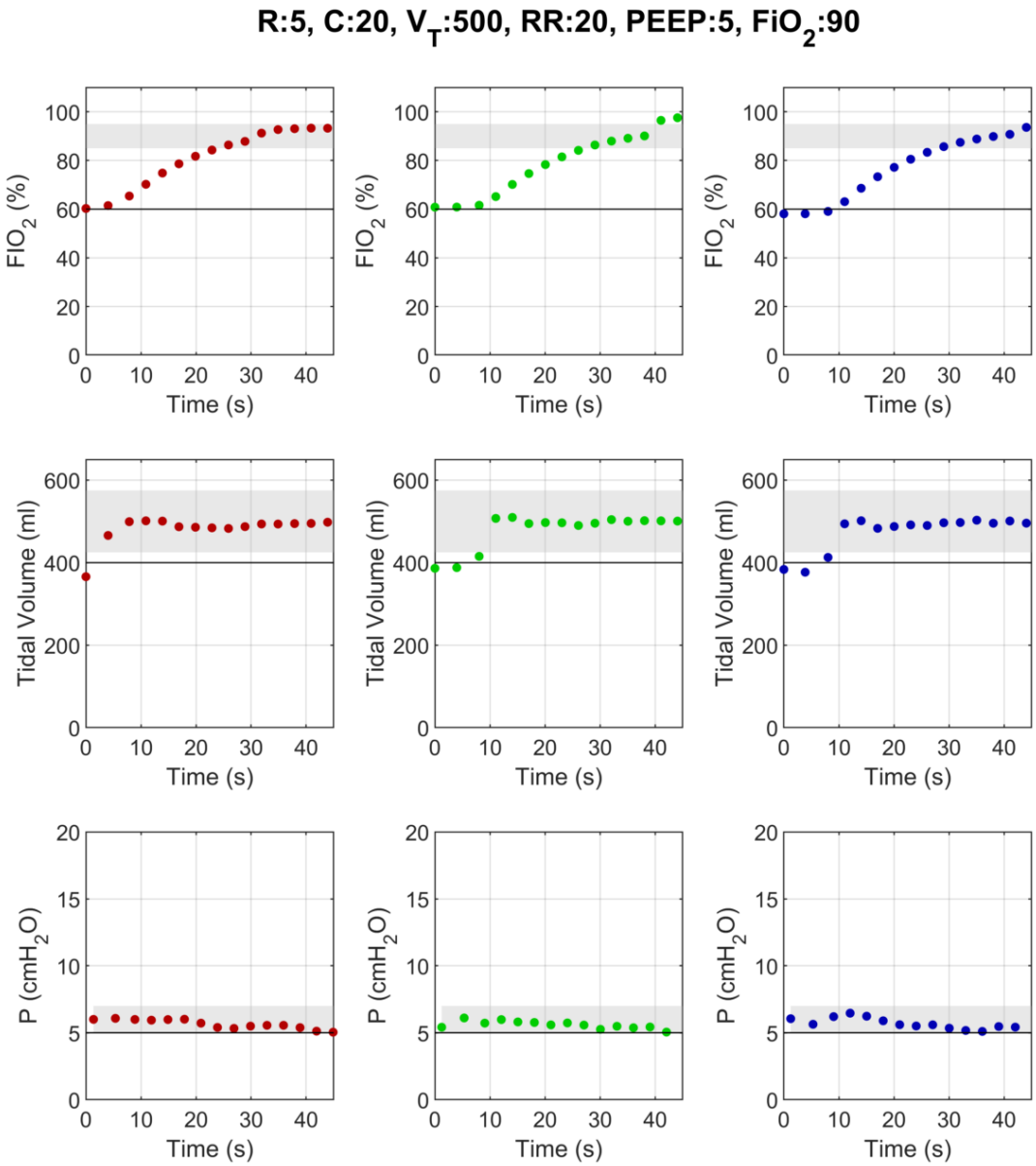

Figure A2 Response time of FiO_2, V_T, and PEEP of the JAMVENT system for ISO Test No. 3. The individual replicate test results are provided for all output parameters.

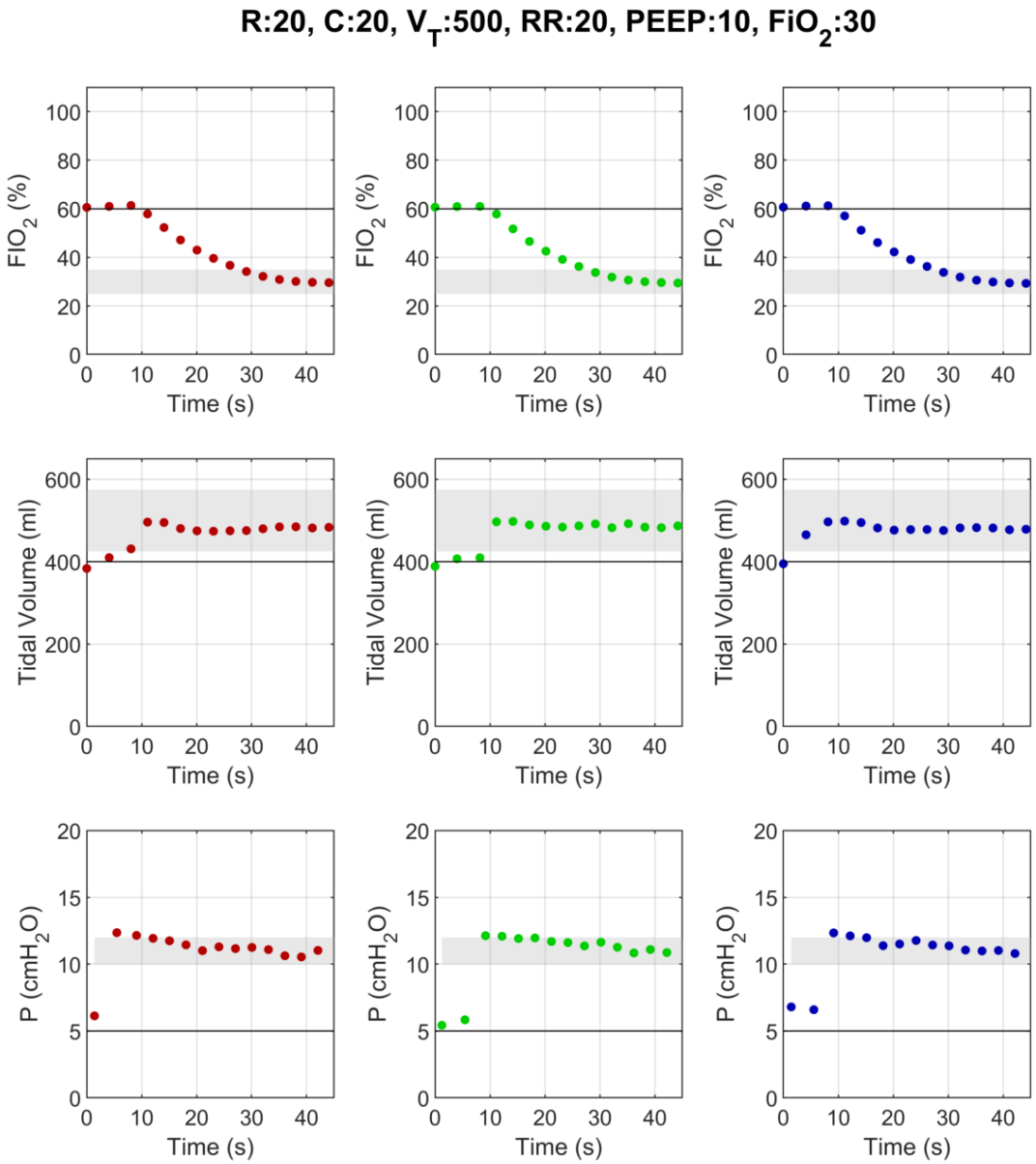

Figure A3 Response time of FiO_2, V_T, and PEEP of the JAMVENT system for ISO Test No. 4. The individual replicate test results are provided for all output parameters.

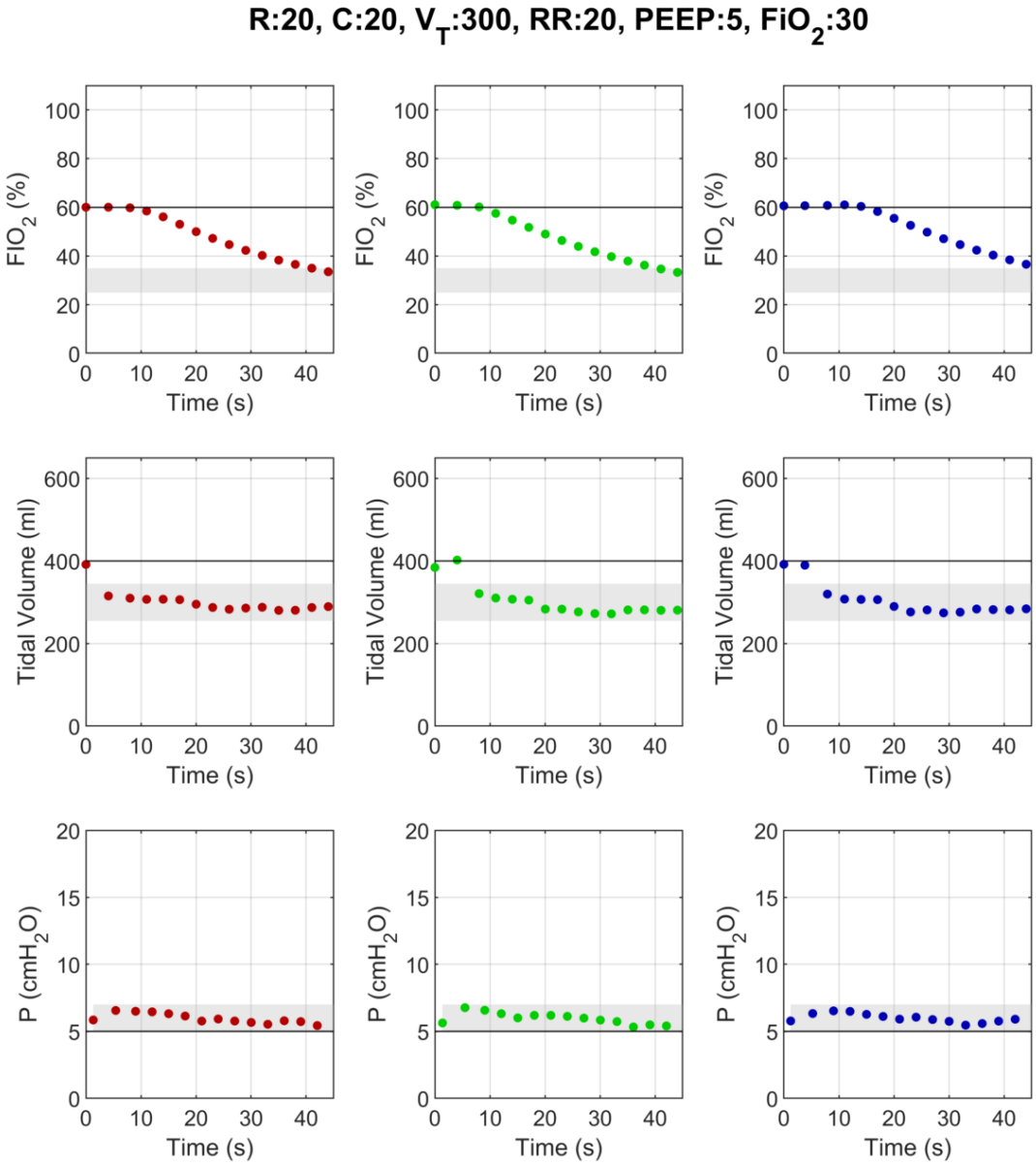

Figure A4 Response time of FiO_2, V_T, and PEEP of the JAMVENT system for ISO Test No. 5. The individual replicate test results are provided for all output parameters.

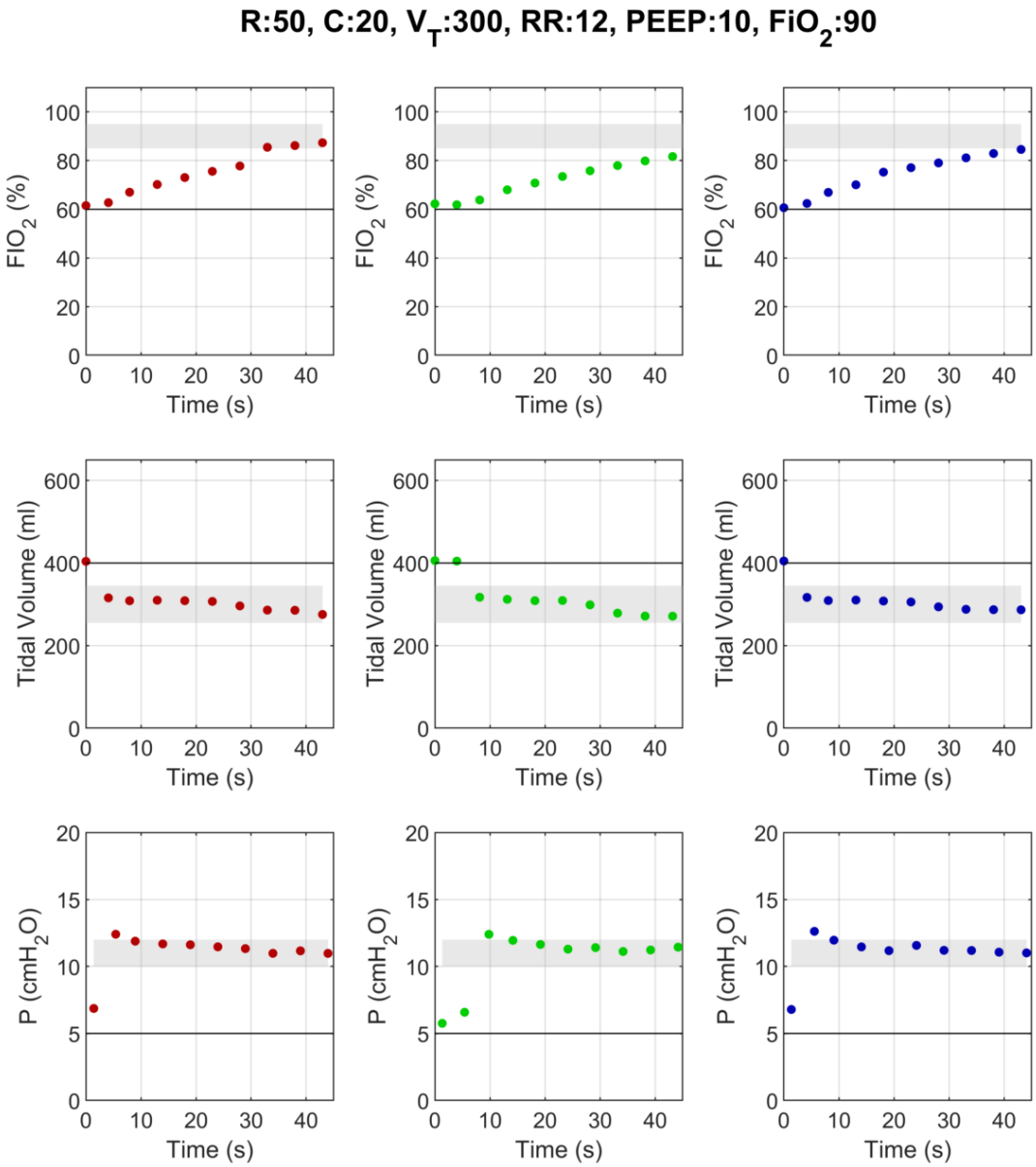

Figure A5 Response time of FiO_2, V_T, and PEEP of the JAMVENT system for ISO Test No. 6. The individual replicate test results are provided for all output parameters.

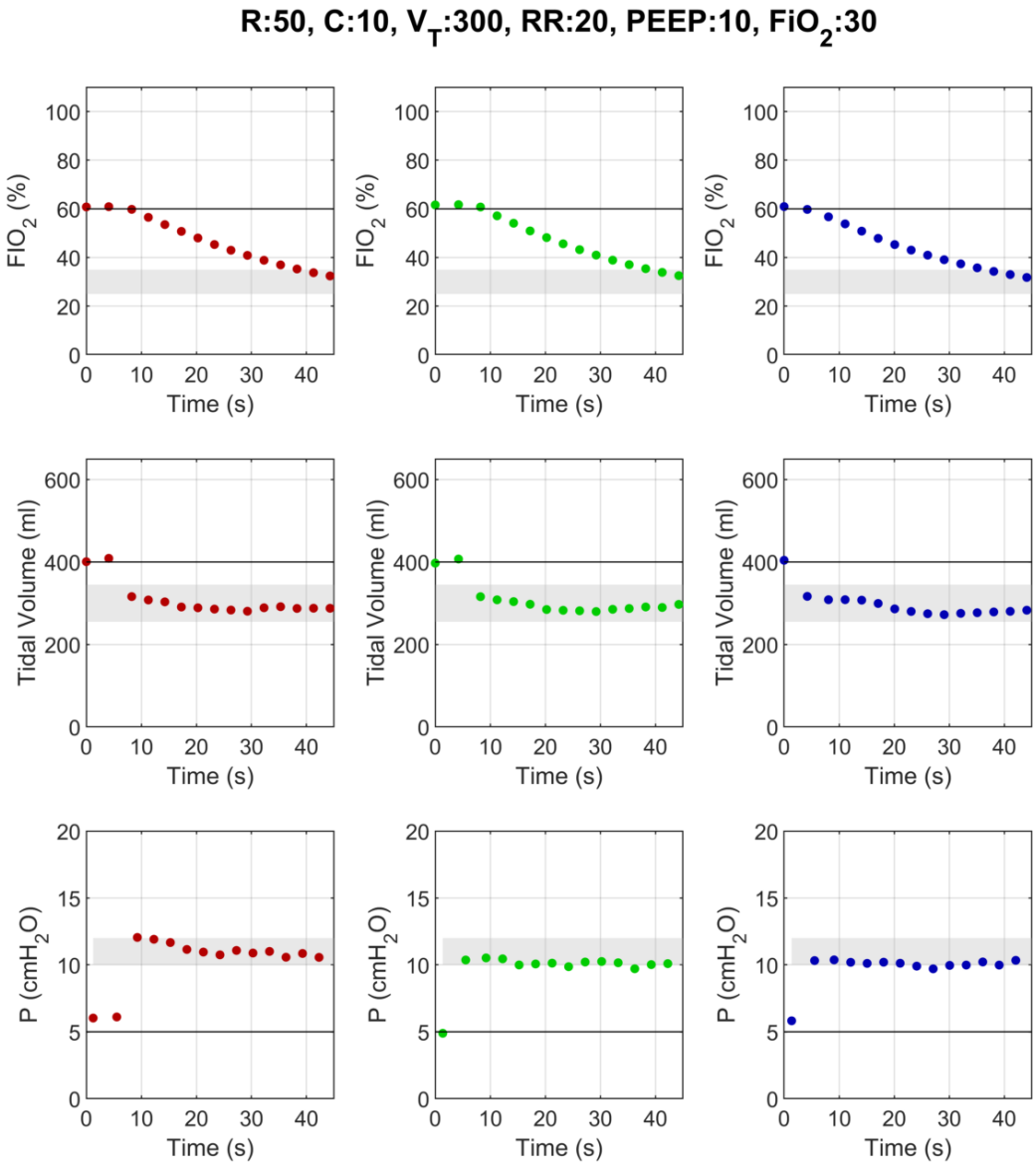

Figure A6 Response time of FiO_2, V_T, and PEEP of the JAMVENT system for ISO Test No. 7. The individual replicate test results are provided for all output parameters.