Analysis of pressure and flow characteristics of "Project Inspiration" Rapidly Manufactured Ventilator

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Abstract—This document evaluates the experimental performance of the Project Inspiration ventilator with the RMVS guidelines provided by the MHRA [1] and elaborates on the previous experimental evaluation by H. Vallery [2]. The effect of the input parameters such as Positive End Expiratory Pressure (PEEP), set pressure, breathing rate, FiO2, and the influence of the humidifier are investigated. Solutions such as orifice plates and compliance in the tubing are explored to alter the pressure and flow characteristics of the ventilator.
Testing revealed that the Peak Inspiratory Pressure (PIP) was higher than allowed by the MHRA specifications. The orifice plate solution proved to be effective at reducing the PIP with minimal alteration to the machine. Therefore an orifice plate with 9x1.5 mm orifices was implemented in the machine. An umbrella valve was used to reduce the resistance of airflow into the bellow, reducing motor load.

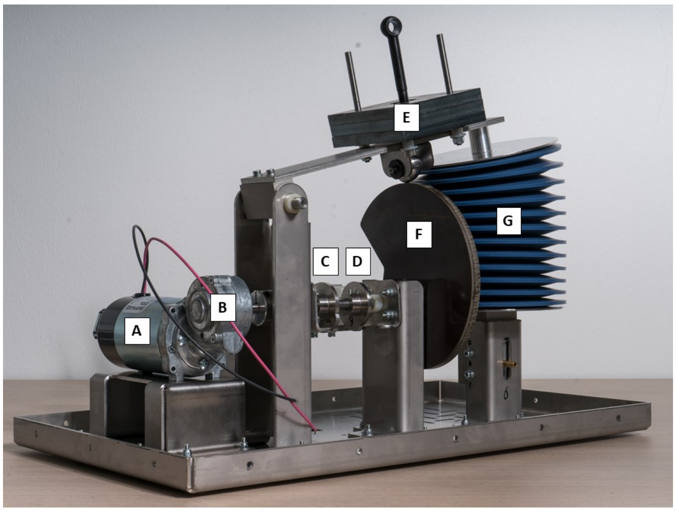

Fig. 1. Project Inspiration ventilator prototype. A: DC motor, B: gearbox, C: air valve expiration, D: air valve inspiration, E: weights, F: main cam, G: bellow

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I. Introduction

Project Inspiration is an initiative of the Delft University of Technology led by G. Smit. The goal is to develop a low cost Rapidly Manufactured Ventilator System conform to the regulations by the MHRA [1]. The machine is based on the East-Radcliffe ventilator, provided by the Boerhaven museum in Leiden. More background information about the project can be found on the website[1]. This development led to the prototype shown in Figure 1.

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[1] https://www.projectinspiration.nl/

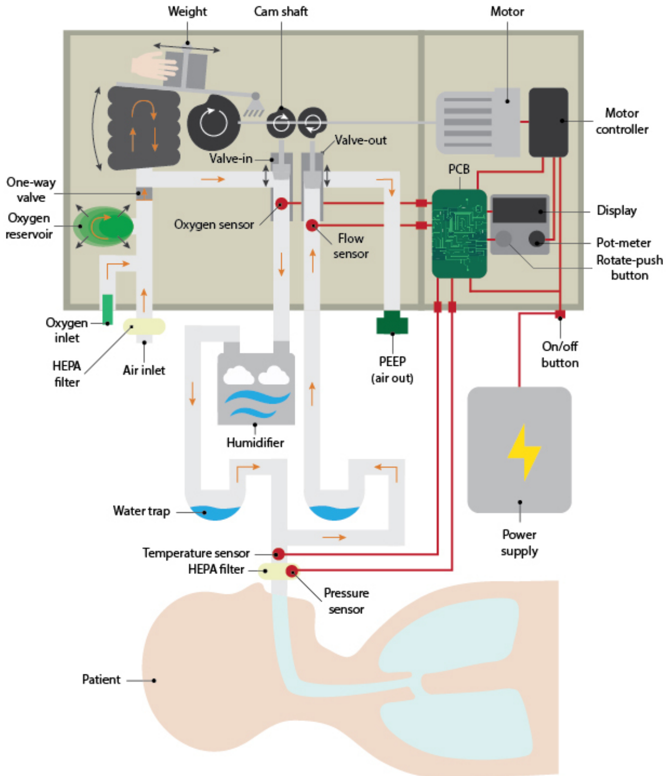


Fig. 2. Systematic overview of the ventilator.

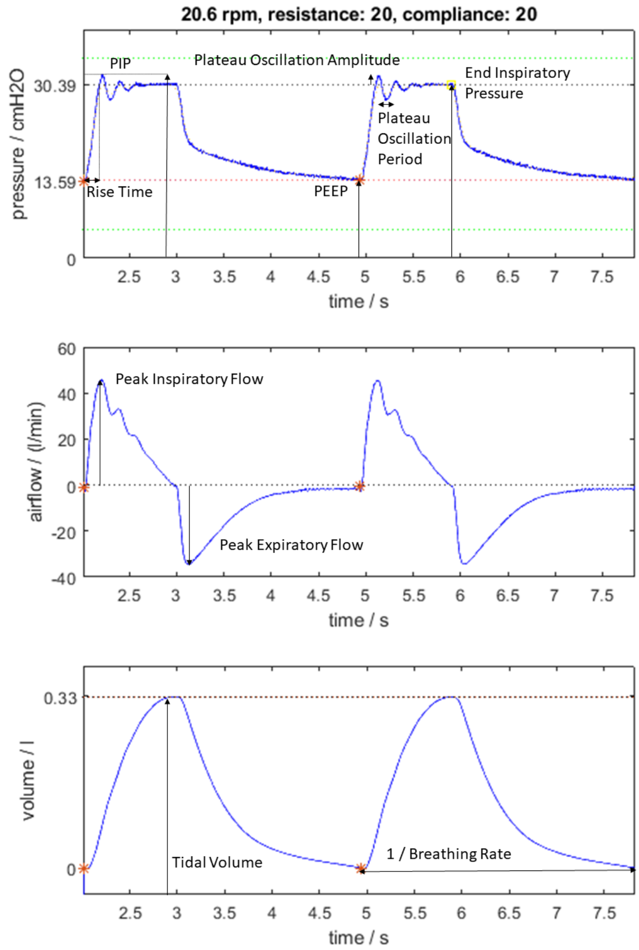


Fig. 3. Example data from Reference configuration measurement set, with indication of important vocabulary following the guidance of ISO 19223:2019 Annex C.

A systematic overview of the working principle of the ventilator is provided in Figure 2. Breathing rate is adjusted with a potentiometer, PEEP is set with a PEEP valve, FiO2 is changed by altering the supplied flow, and the inspiratory pressure is generated by the weights which exert a force on the bellow (top left of the figure). Moving weights closer to the bellow increases the pressure. The weight may cause oscillations in the pressure that can exceed the maximum pressure overshoot of 2 cmH2O as specified by the MHRA. [1]. This is caused by the inertia of the weight, which compresses the air in the bellow and functioning as an air spring. First, these oscillations are quantified by testing all conditions of the MHRA protocol. Then the influence of multiple modifications is evaluated, such as using orifice plates, increasing compliance or increasing volume in the humidifier.

The essential terms regarding pressure and volume curves are shown in Figure 3, following the guidelines of ISO 19223:2019 Annex C. Added to these terms are the plateau oscillation amplitude and plateau oscillation period. These represent the amplitude and period of the pressure fluctuation during inspiration.

The following list of experiments is documented in this report:

- Reference configuration: machine as shown in the systematic overview of Figure 2, tested with conditions as specified in Appendix B of the MHRA specifications [1] with and without oxygen.
- Oxygen rise time: test rise time according to 201.12.1.104 of NEN-EN-ISO 80601-2-12:2011.
- Influence of humidifier volume: MHRA protocol without oxygen with the humidifier on the lowest water level.
- Calibration of weight scale: varying number of weight and location on the arm to determine how pressure is affected by location and magnitude of weight.
- Influence of orifice plates: vary different numbers and diameters of orifices to reduce Peak Inspiratory Pressure (PIP) while maintaining a sufficient Tidal Volume. These tests are conducted with a smaller set of conditions to evaluate the performance.
- Orifice plate with umbrella valve: this orifice plate is based on Orifice plate three from II, but contains an umbrella valve with extra openings to ensure that the flow of air into the bellow can occur with less resistance, as this relieves effort of the motor, increasing endurance.
- Influence of compliance in VBS: a series of experiments to evaluate the influence of compliance in the

Ventilator Breathing System (VBS)[2]. This condition was tested with the same protocol as the orifice plate experiments.
- Influence of compliance in pump: a series of experiments to evaluate the influence of compliance in the pumping stage of the ventilator. The pumping stage consists of the region between the inlet of the bellow and the inspiration valve.
- Validation of orifice plate with umbrella valve and Hudson PEEP valve: this configuration aims to validate that the machine complies to the MHRA specifications when the orifice plate with umbrella valve and Hudson PEEP valve is used.

II. Experiment setup

First, all components are listed, and the protocol for recording data is described in short for each experiment. The full protocol can be found in the Excel sheets in the data folder[3].

A. Components

Project Inspiration ventilator number 11 was used for all experiments in this report. The ventilator was connected to a Michigan Instruments configurable test lung provided by PulmoTech for all experiments up to and including the calibration of the weight scale. In the following tests, a Fluke Biomedical ACCU Lung (s/n 2387318-1001) was used. This lung does not have any analog sensors and does not allow the user to read the lung pressure. The used PEEP valve was an Intersurgical S-C-K01-2226000[4] and was measured to be the most consistent among the available valves in the previous Evaluation Report. This PEEP valve does not maintain the PEEP value but does have a repeatable drop. The electronics included a pressure sensor (Differential Pressure Sensor: NXP MPXV7007DP) and a flow sensor (SFM3000-200C, Sensirion). The humidifier, as designed by D. Lemus, was used to test the influence of volume in the VBS. The humidifier is still in development. Orifice plates were manufactured from PMMA plates and can be placed in the bottom plate of the bellow, as shown in Figure 8. A variant of the orifice plates was produced that contains an umbrella valve, as shown in Figure 22(b). In both the compliance tests a 2L Intersurgical Reservoir bag (2820000)[5] was used to introduce additional compliance to the tubing. In the pump compliance tests, a 5 cmH2O PEEP valve (unbranded) was used as a makeshift one-way valve. Oxygen was tapped from a UN1072 oxygen tank provided by Linde Gas Benelux, containing 50L of oxygen at 200 bar. A Dräger regulator (s/n 10679342) was combined with an analog airflow meter similar to RS-918-6730 to set the oxygen flow, as shown in figure 4(a).

B. Data acquisition

Data was acquired using custom electronics and sent via serial communication (USB) to a Windows laptop to be recorded. The sampling rate was 500 Hz. The electronics included a pressure sensor (Differential Pressure Sensor: NXP MPXV7007DP) and a flow sensor (SFM3000-200C, Sensirion). The pressure was measured at the machine side of the bacterial filter against atmospheric pressure. The flow sensor is mounted next to the pressure sensor, measuring the flow in both directions. When measurements are taken with a patient, the flow sensor must always be at the machine side to avoid contamination.

The configuration of the data acquisition is the same for the Fluke Biomedical ACCU Lung, but no values can be read by hand as the lung does not have analog sensors. The patient connection port is slightly shorter as the airway resistance is integrated within the test lung. Both setups are shown in Figure 5.

C. Data processing

The following features were extracted from sensor signals for each cycle:

- Tidal volume was calculated via integration of flow over time, making use of the timestamps of the recorded data.
- Plateau pressure for each cycle was extracted from the pressure curves taking the average pressure of the last 50 ms of inhalation as specified by NEN-EN-ISO 80601 201.12.1.102.
- Positive End Expiratory Pressure (PEEP) for each cycle was calculated by taking the average pressure of the last 50 ms of exhalation as specified by NEN-EN-ISO 80601 201.12.1.102.
- Peak Inspiratory Pressure (PIP) was calculated by storing the maximum pressure value of the measurement. This value is used to calculate the overshoot by subtracting the plateau pressure from the PIP.

The median was stored for volume, plateau pressure, and PEEP. The minimum pressure determines the start of a breath cycle in the low pass filtered pressure. The breathing rate is determined as 60 divided by the median breath duration of all breaths during the measurement.

III. Experiment Protocol

A. Reference configuration

The reference configuration is the machine as shown in the systematic overview of Figure 2. Experiments are conducted as specified in the MHRA specifications version 4 [1]. The Michigan test lung was used configured as in Figure 5(a). The tests were also done without oxygen and with the additional conditions rate = 30 RPM and

[2] VBS refers to all the tubing between the patient and the outlet of the ventilator.

[3] This report is intended to be shipped together with all measurement data, which is contained in the data folder. In the subfolders, all performed experiments are saved as .csv files. MATLAB code to read all measurements is provided.

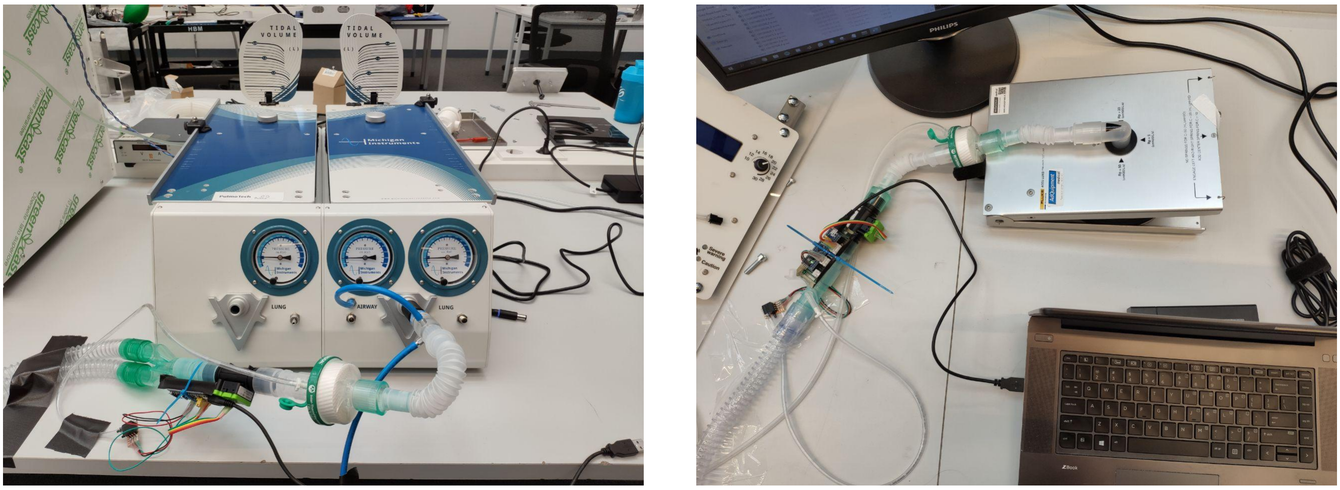
[4] https://www.smhealthcare.com.my/product.php?section=4&category=57&sub-category=140&product-id=4186

[5] https://www.intersurgical.com/products/anaesthesia/reservoir-bags-single-use

(a) Oxygen tank with regulator and airflow meter.

(b) Machine 11 with oxygen sensors connected to the air inlet (bottom left) and machine-patient pathway (middle).

Fig. 4. Setup of oxygen tank and oxygen sensors for all experiments that require use of oxygenated air.



(a) Michigan test lung with data acquisition

(b) Fluke Biomedical ACCU Lung with data acquisition

Fig. 5. Both test lungs with data acquisition. Order of components from machine to patient: flow sensor, HEPA filter with pressure sensor at machine side, lung resistance, test lung.

Plateau Pressure = 25 cmH2O. These conditions serve as an indication of how the machine performs at higher rates and intermediate lower pressure. It was concluded that the oxygen level does not affect the pressure and flow curves in any major way. As oxygen is a valuable resource, it was decided not to use oxygen in the other experiments and comparing the performance at the atmospheric oxygen level. The set without oxygen is also used to evaluate how accurately the angle of the arm can be used to determine the tidal volume.

Varied settings with oxygen:

- Test Lung Compliance and Resistance: 10 & 50, 20 & 20, 50 ml/cmH2O & 5 cmH2O/l/s
- Rate: 12, 20 RPM
- PEEP: 5, 10, 15 cmH2O
- Plateau Pressure: 15, 30 cmH2O
- FiO2: 55, 95 %
- Inspiratory:Expiratory ratio: 1:2 (cannot be changed)

Varied settings without oxygen:

- Test Lung Compliance and Resistance: 10 & 50, 20 & 20, 50 ml/cmH2O & 5 cmH2O/l/s
- Rate: 12, 20, 30 RPM
- PEEP: 5, 10, 15 cmH2O
- Plateau Pressure: 15, 25, 30 cmH2O
- FiO2: 21 % (ambient)
- Inspiratory:Expiratory ratio: 1:2 (cannot be changed)

Manually recorded:

- Angle of the arm, degrees
- Minimum observed airway pressure as read from the analog sensor of the Michigan Instruments test lung, cmH2O.
- Maximum observed airway pressure as read from the analog sensor of the Michigan Instruments test lung,

cmH2O. (misread on measurements without oxygen)
- Maximum observed lung pressure as read from the analog sensor of the Michigan Instruments test lung, cmH2O. This corresponds to the pressure inside of the lung, so after the airway resistance.
- Maximum lung volume as read from the analog scale on the Michigan Instruments test lung, L.
- Minimum lung volume as read from the analog scale on the Michigan Instruments test lung, L.
- O2 concentration in machine-patient connection port, %.
- O2 concentration in the air inlet, %. If the oxygen is set too high, the air inlet will let oxygen out instead to prevent over-pressurizing the patient.
- O2 flow from the gas tank, L/min
- Date and time of each measurement

B. Oxygen rise time

Test rise time according to 201.12.1.104 of NEN-EN-ISO 80601-2-12:2011. During this experiment the settings for worst case oxygen rise time were not known. As the table in the norm does not specify which settings exactly must be used, two representative measurements of normal use cases were chosen. The time was recorded manually with a cell phone as soon as the oxygen valve was opened, and stopped when the oxygen sensor to the patient reaches 90%. These results serve as an indication of the expected rise times, not the worst case. Michigan test lung was used configured as in 5(a).

Chosen settings:

- Test Lung Compliance and Resistance: 20 ml/cmH2O & 20 cmH2O/l/s
- Rate: 20 & 30 RPM
- PEEP: 15 & 5 cmH2O
- Plateau Pressure: 15 & 30 cmH2O
- FiO2: start 21 % (ambient), end 90 %
- Inspiratory:Expiratory ratio: 1:2 (cannot be changed)

Manually recorded:

- Angle of the arm, degrees
- Minimum observed airway pressure as read from the analog sensor of the Michigan Instruments test lung, cmH2O.
- Maximum observed airway pressure as read from the analog sensor of the Michigan Instruments test lung, cmH2O.
- Maximum observed lung pressure as read from the analog sensor of the Michigan Instruments test lung, cmH2O. This corresponds to the pressure inside of the lung, so after the airway resistance.
- Maximum lung volume as read from analog scale on the Michigan Instruments test lung, L.
- Minimum lung volume as read from analog scale on the Michigan Instruments test lung, L.
- O2 concentration in machine-patient connection port at both the start and end of the experiment, %.
- O2 concentration in air inlet at both the start and end of the experiment, %.

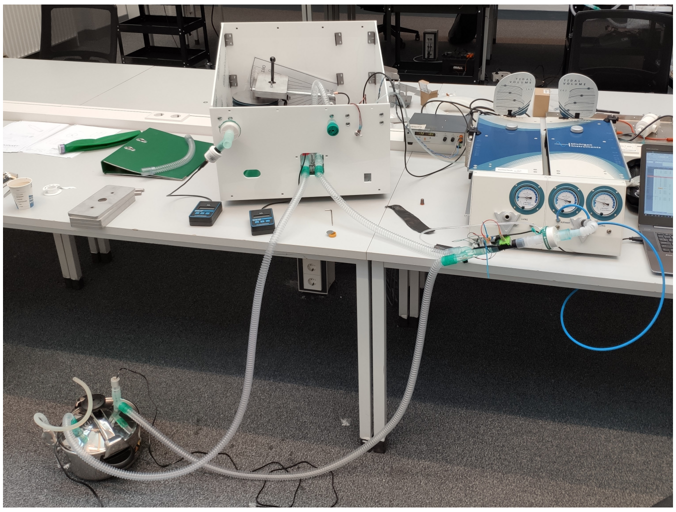


Fig. 6. Setup with humidifier connected in the VBS.

- O2 flow from gas tank, L/min
- Date and time of each measurement

C. Influence of humidifier volume

The influence of the extra volume in the humidifier was evaluated by using the humidifier while turned off, and repeating a part of the MHRA protocol. For measurements regarding the performance of the humidifier, refer to the Gitlab page[6] by Daniel Lemus [3]. Michigan test lung was used configured as in Figure 5(a). The water level in the humidifier is changed to evaluate the effect of extra volume in the system. Without humidifier the VBS volume is the smallest, with a low water level the largest. The setup is shown in subsection III-C.

Varied settings:

- Test Lung Compliance and Resistance: 10 ml/cmH2O & 50 cmH2O/l/s
- Rate: 12, 20, 30 RPM
- PEEP: 5, 10, 15 cmH2O
- Plateau Pressure: 15, 30 cmH2O
- FiO2: Ambient
- Inspiratory:Expiratory ratio: 1:2 (cannot be changed)
- Humidifier: low water level, high water level, not present

Manually recorded:

- Angle of the arm, degrees
- Minimum observed airway pressure as read from the analog sensor of the Michigan Instruments test lung, cmH2O.
- Maximum observed airway pressure as read from the analog sensor of the Michigan Instruments test lung, cmH2O.
- Maximum observed lung pressure as read from the analog sensor of the Michigan Instruments test lung, cmH2O. This corresponds to the pressure inside of the lung, so after the airway resistance.

[6]https://gitlab.tudelft.nl/dslemusp/inspiration_humidifer

- Maximum lung volume as read from the analog scale on the Michigan Instruments test lung, L.
- Minimum lung volume as read from the analog scale on the Michigan Instruments test lung, L.
- Date and time of each measurement
- Length of measurement, seconds

D. Calibration of the weight scale

Tests were conducted to determine the correct values for the weight scale on the arm, with different combinations of the number of weights and their location on the arm. A low rate was chosen to ensure that the plateau pressure has time to settle. This data can then be used to find the plateau pressure and evaluate the plateau pressure's sensitivity to the location and mass of the weights. Michigan test lung was used configured as in 5(a).

Varied settings:

- Test Lung Compliance and Resistance: 10 ml/cmH2O & 50 cmH2O/l/s
- Rate: 12 RPM
- PEEP: 5 cmH2O
- Plateau Pressure: Determined from measurement
- FiO2: Ambient
- Inspiratory:Expiratory ratio: 1:2 (cannot be changed)
- Location of weight as measured from hinge to the center of the weight assembly perpendicular to the arm: 54, 100, 125, 150, 175, 197 mm
- Number of weights: 2, 3, 4, 5, 6

Manually recorded:

- Angle of the arm, degrees
- Minimum observed airway pressure as read from the analog sensor of the Michigan Instruments test lung, cmH2O.
- Maximum observed stationary airway pressure at the end of inhalation as read from the analog sensor of the Michigan Instruments test lung, cmH2O.
- Maximum observed lung pressure as read from the analog sensor of the Michigan Instruments test lung, cmH2O. This corresponds to the pressure inside of the lung, so after the airway resistance.
- Maximum lung volume as read from the analog scale on the Michigan Instruments test lung, L.
- Minimum lung volume as read from the analog scale on the Michigan Instruments test lung, L.
- Date and time of each measurement

The number of weights and corresponding mass are given in Table I. The slider and pins to hold the weight are 220 grams. The used machine has 3 weights with a small diameter hole in the middle whith a mass of 1515 grams, and three weights with a mass of 1500 grams, with a larger diameter hole that fits over the pin. During the experiment nuts were used instead of the pins, making the assembly 40 grams lighter. To fit on the slider, first the weights with small holes have to be used, and then the weights with larger holes. The weights are listed in Table I.

TABLE I
Number of weights and the corresponding mass of the entire sliding assembly.

Number of weights	Mass
2	3180 grams
3	4735 grams
4	6235 grams
5	7735 grams
6	9235 grams

TABLE II
List of used orifices

Orifice no.	# of Holes	Hole diam.	Hole area	Thickness
-	-	mm	mm^2	mm
0	1	30	314.2	2
1	9	3.5	86.6	2
2	9	2.5	44.2	2
3	9	1.5	15.9	1, 2
4	17	1.5	30.0	2
5	31	1.5	54.8	2
6	106	1	83.3	2
7	300	1	235.6	2
8	5	1.5	8.8	1, 2
9	5	1	3.9	2
10	7	1	5.5	2
11	10	1	7.9	1, 2
12	16	1	12.6	2
13	20	1	15.7	2
14	15	1	11.8	1

E. Influence of orifice plates

From this experiment onward, the Fluke Biomedical lung was used, see Figure 5(b). During early testing, it was observed that orifices could help reduce the oscillations in the pressure curve. Therefore, this more elaborate experiment was conducted. The orifices can be integrated into the bottom plate of the bellow. However, to speed up experimentation, the orifice plates were manufactured as 50x50mm PMMA plates that can be placed on the bottom of the bellow as shown in Figure 8. The hole configurations can be read in Table II. The thickness specifies at what thickness the orifice plate was produced and tested. Only of the most promising orifice the 1mm thick version was produced. The machine's original design uses the configuration of holes labelled Orifice 1, corresponding to 9 holes of 3.5mm. The bottom plate of the bellow was modified with an open hole to allow placement of the orifice plates over it. Without any orifice, this hole has a diameter of 30mm, corresponding to Orifice 0. The orifice plates are shown aligned by hole diameter and number of holes in Figure 7. The main focus of this series of experiments is to improve the worst conditions of the reference configuration. A smaller protocol which only includes the tests at the extreme values of the MHRA protocol was used. This greatly accelerates testing, meaning that a lot of different orifice plates can be tested quickly.

Varied settings:

- Test Lung Compliance and Resistance: 10 & 50, 50 ml/cmH2O & 5 cmH2O/l/s
- Rate: 12, 20 RPM

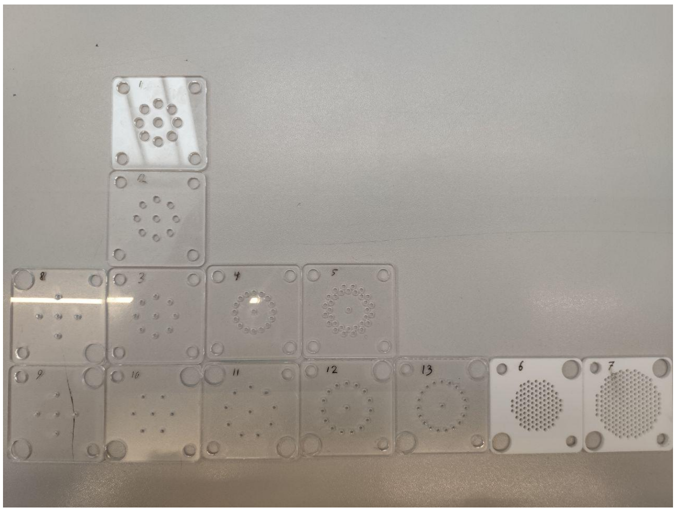


Fig. 7. 2mm thick orifice plates, ordered based on hole diameter and number of holes.

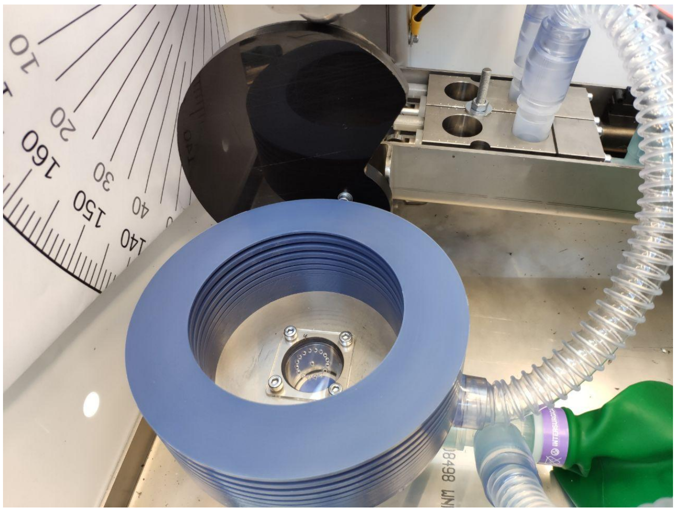


Fig. 8. Orifice installed in the bottom plate of the bellow.

- PEEP: 5, 15 cmH2O
- Plateau Pressure: 15, 30 cmH2O
- FiO2: Ambient
- Inspiratory:Expiratory ratio: 1:2 (cannot be changed)
- Orifice plate: All conditions are tested on all listed orifice plates in Table II

Manually recorded:

- Date and time of each measurement

F. Orifice plate with umbrella valve

For this section, only a single orifice plate was tested based on Orifice plate 3 (9x1.5mm), as this was found to provide the optimal trade-off for both minimal PIP and maximal tidal volume. The used umbrella valve is the same as for the check valve inside of the bellow construction, so a 24 mm umbrella valve[7]. The plate is shown in 9(a). It is attached in the machine similar to the regular orifice plates, as shown in Figure 8.

This configuration is tested in the same manner as the regular orifice plates. It can be compared to the orifice results without an umbrella valve to ensure that the performance is not negatively affected.

Varied settings:

- Test Lung Compliance and Resistance: 10 & 50, 50 ml/cmH2O & 5 cmH2O/l/s
- Rate: 12, 20 RPM
- PEEP: 5, 15 cmH2O
- Plateau Pressure: 15, 30 cmH2O
- FiO2: Ambient
- Inspiratory:Expiratory ratio: 1:2 (cannot be changed)
- Orifice plate: number 3 with umbrella valve

Manually recorded:

- Date and time of each measurement

G. Influence of compliance in VBS

As an alternative to manage the Peak Inspiratory Pressure, a small series of experiments was done by testing the influence of compliance. Experiments were done with and without a 2L Intersurgical Reservoir bag to add more compliance to the system. This component is by no means rated for this application and is not meant for reuse. Therefore these experiments provide just basic insight into the effects of compliance. The setup is shown in Figure 10, the reservoir bag can be replaced with a cap to remove the additional compliance.

Varied settings:

- Test Lung Compliance and Resistance: 10 & 50, 50 ml/cmH2O & 5 cmH2O/l/s
- Rate: 12, 20 RPM
- PEEP: 5, 15 cmH2O
- Plateau Pressure: 15, 30 cmH2O
- FiO2: Ambient
- Inspiratory:Expiratory ratio: 1:2 (cannot be changed)
- Orifice plate: Orifice plate 1 (2mm thick)
- Influence of compliance in VBS: Reservoir bag or sealed, see Figure 10

Manually recorded:

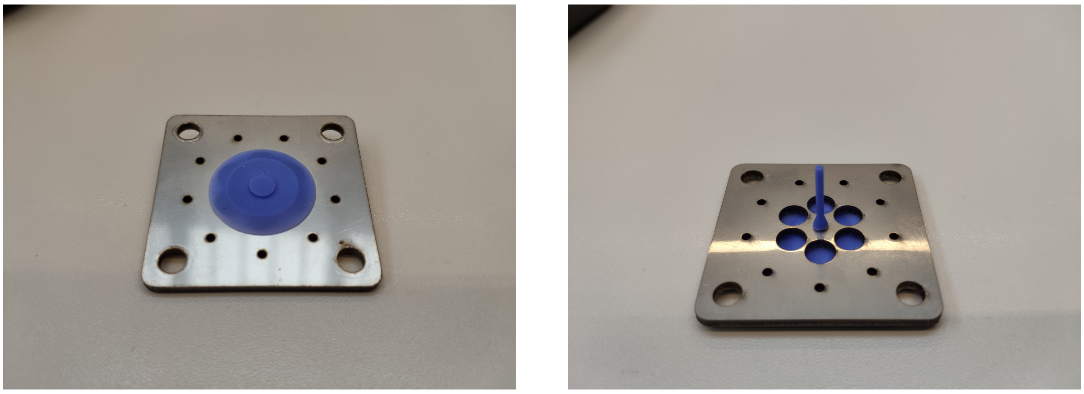
- Date and time of each measurement

H. Influence of compliance in pump

Pump refers to the first stage of the machine, located between the air inlet and the inspiration valve, including the bellow. Making this stage of the machine more compliant can reduce peaks in the pressure. A check valve is required to ensure that the bellow does not use air from the compliant parts. At the time, no proper check valve was available. A 5 cmH2O PEEP valve was connected as shown in Figure 11 instead. This valve ensures that the air does not flow back, but reduces the plateau pressure by 5 cmH2O.

Varied settings:

[7] https://www.better-silicone.com/Silicone-Umbrella-Valve-pd367135.html



(a) Top view (b) Bottom view

Fig. 9. Orifice plate with umbrella valve.

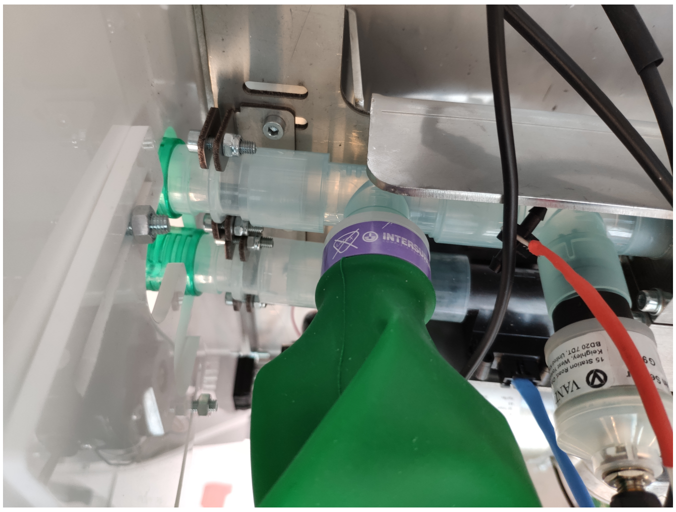


Fig. 10. Setup for VBS compliance testing. The reservoir bag can be placed on the available slot at the air outlet of the machine.

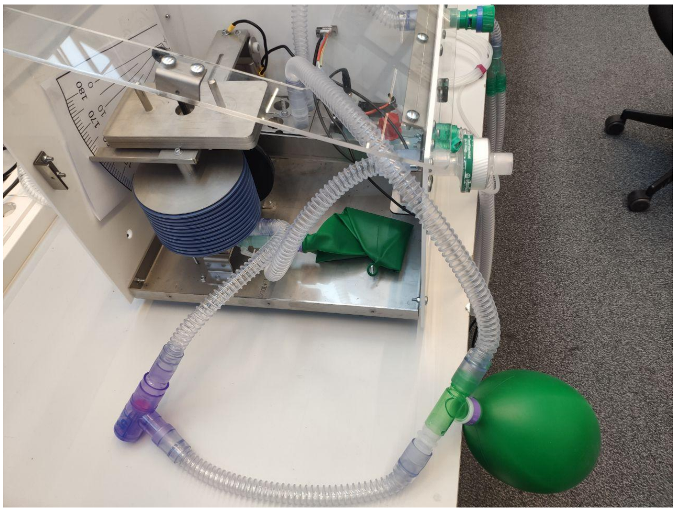


Fig. 11. Setup for pump compliance testing, with PEEP valve as check valve (purple) and a reservoir bag (green) as compliance.

- Test Lung Compliance and Resistance: 10 & 50, 20 & 20, 50 ml/cmH2O & 5 cmH2O/l/s
- Rate: 12, 20 RPM
- PEEP: 5, 10, 15 cmH2O
- Plateau Pressure: 15, 30 cmH2O
- FiO2: 21, 55, 95 %
- Inspiratory:Expiratory ratio: 1:2 (cannot be changed)

Manually recorded:

- Date and time of each measurement

I. Validation of orifice plate with umbrella valve and Hudson PEEP valve

Compared to the Reference configuration experiments, two major changes were made: the orifice plate with umbrella valve as discussed in subsection III-F was used, and the PEEP valve was replaced with the blue Hudson PEEP valve[8]. This PEEP valve is better at maintaining pressure over long periods of time. A 3D printed adapter was used to connect it to the machine as shown in Figure 12. The rest of the setup is the same as the umbrella valve tests.

Varied settings:

- Test Lung Compliance and Resistance: 10 & 50, 20 & 20, 50 ml/cmH2O & 5 cmH2O/l/s
- Rate: 12, 20 RPM
- PEEP: 5, 10, 15 cmH2O
- Plateau Pressure: 15, 30 cmH2O
- FiO2: Ambient
- Inspiratory:Expiratory ratio: 1:2 (cannot be changed)

Manually recorded:

- Date and time of each measurement

IV. Results

A. Reference configuration

Table III shows whether the conditions in the MHRA protocol are met. The results are sorted by compliance, rate and plateau pressure. For each of these conditions,

[8]https://cdn.ironpla.net/i/2418/807/2418807_11703_0_0006.jpg

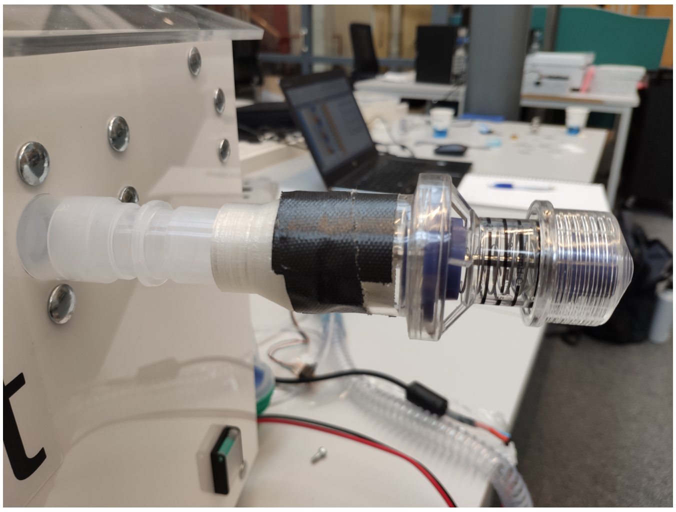


Fig. 12. Setup: Hudson PEEP valve used in final Machine, including 3D printed adapter.

the PEEP was varied between 5, 10 and 15 cmH2O, and the FiO2 at 21, 55, and 95%. The 21% FiO2 condition was used to test the repeatability of the experiments. These are summed together to make the results more readable. Notice that the sum of passing and violated conditions can exceed the total number of conditions in each row, as a single test can violate both conditions. The plateau pressure never exceeded 35 cmH2O, so this failure mode was omitted. PEEP low corresponds to measurements where the PEEP value drops below 5 cmH2O. PIP high corresponds to measurements where $PIP - PlateauPressure \leq 2$ as specified in condition 3.b in the MHRA specifications.

The influence of oxygen concentration is compared in Figure 13.

Table IV lists a summary of the additional tests conducted which are not listed in the MHRA protocol.

The angle of the arm can be used to read the tidal volume in an analog manner. The MHRA requirements specify that the readout error must be $\pm 4 + 15\%$ of actual reading. The measured tidal volume is plotted against the change in angle in Figure 14, together with the fitted line (green) and tolerable boundaries (red).

B. Oxygen rise time

The worst-case oxygen rise time recorded was 2:37 minutes, as summarized in Table V.

C. Influence of humidifier volume

The results are sorted in ascending order of dead volume in Figure 15. During this set, the humidifier had significant leakage, which may affect the measured volume flow and pressure drop after the inlet valve is opened. The numeric values are recorded in Table VI.

D. Calibration of the weight scale

Sensitivity of position and weight of carriage is plotted in 16(a) and 16(b) respectively. A linear line is fitted for all data points. In the previous measurement report, it was concluded that the relation between plateau pressure, weight, and position is expected to be linear. The data of 16(a) converges at roughly 15 mm from the rotation point, at a plateau pressure of 12.5 cmH2O. The data of 16(b) converges at a weight of 250g, at a plateau pressure of roughly 12.6 cmH2O.

E. Influence of orifice plates

Figure 17 shows exemplary data of orifice plate 3. It can be observed that the plateau pressure is not reached completely, due to the fact that the orifice limits the flow. This results in a lower tidal volume as well. The condition shown in Figure 17(b) is affected by this the most.

Figure 18 and Figure 19 show the influence of the number of orifices in the plate for both 1 mm and 1.5 mm. Each line corresponds to one of the 16 test conditions. The red dotted line indicates the 2 cmH2O limit as provided in the MHRA specifications. Figure 20 shows the influence of the diameter for a constant number of orifices. It is observed that reducing the diameter of the holes significantly reduces the pressure overshoot, while minimally affecting the tidal volume for most conditions.

Thickness of the plate was observed to have no effect on both the tidal volume and maximum pressure overshoot, as shown in Figure 21.

F. Orifice plate with umbrella valve

The umbrella valve has minor influence on most measurements, and does not . For all measurements the plateau pressure is unaffected. Measurements that do not reach the plateau pressure such as 22(b) show a slight reduction in maximum pressure; moving down from 23.51 cmH2O to 21.06 cmH2O.

G. Influence of compliance in VBS

Sample VBS compliance data is provided in 23(a) and 23(b). It is observed that the compliance has a smoothing effect on the pressure curve, while the volume remains virtually unaltered.

H. Influence of compliance in pump

In Figure 24(a), the extra compliance almost completely removes all oscillation and increases the initial airflow, resulting in shorter rise time. In 24(b) a low resistance condition is plotted. It is important to notice that the plateau pressure is lower than the set plateau pressure. This is caused by the PEEP valve with a pressure threshold of 5 cmH2O, which was used as a check valve. Therefore the expected plateau pressure is the set plateau pressure minus the threshold, resulting in 25 cmH2O. In 24(b) this seems accurate, but in 24(a) this is not the case. Instead the plateau pressure is 27.14 cmH2O. The PEEP valve's flow-dependent behavior may cause this, but no certain conclusion can be made from the measurements.

TABLE III
Reference configuration: list of conditions required to pass the MHRA requirements. Each row varies the PEEP and FiO2, resulting in 9 conditions in each row.

Condition				Result			
Compliance	Resistance	Rate	Plateau Press.	Total	Passed	PEEP Low	PIP high
l/cmH2O	cmH2O/l/s	RPM	cmH2O	-	-	-	-
10	50	12	15	9	6	3	
10	50	12	30	9	0	2	9
10	50	20	15	9	8	1	
10	50	20	30	9	0		9
20	20	12	15	9	7	2	
20	20	12	30	9	7	2	1
20	20	20	15	9	9		
20	20	20	30	9	8	1	
50	5	12	15	9	9		
50	5	12	30	9	9		
50	5	20	15	9	9		
50	5	20	30	9	9		

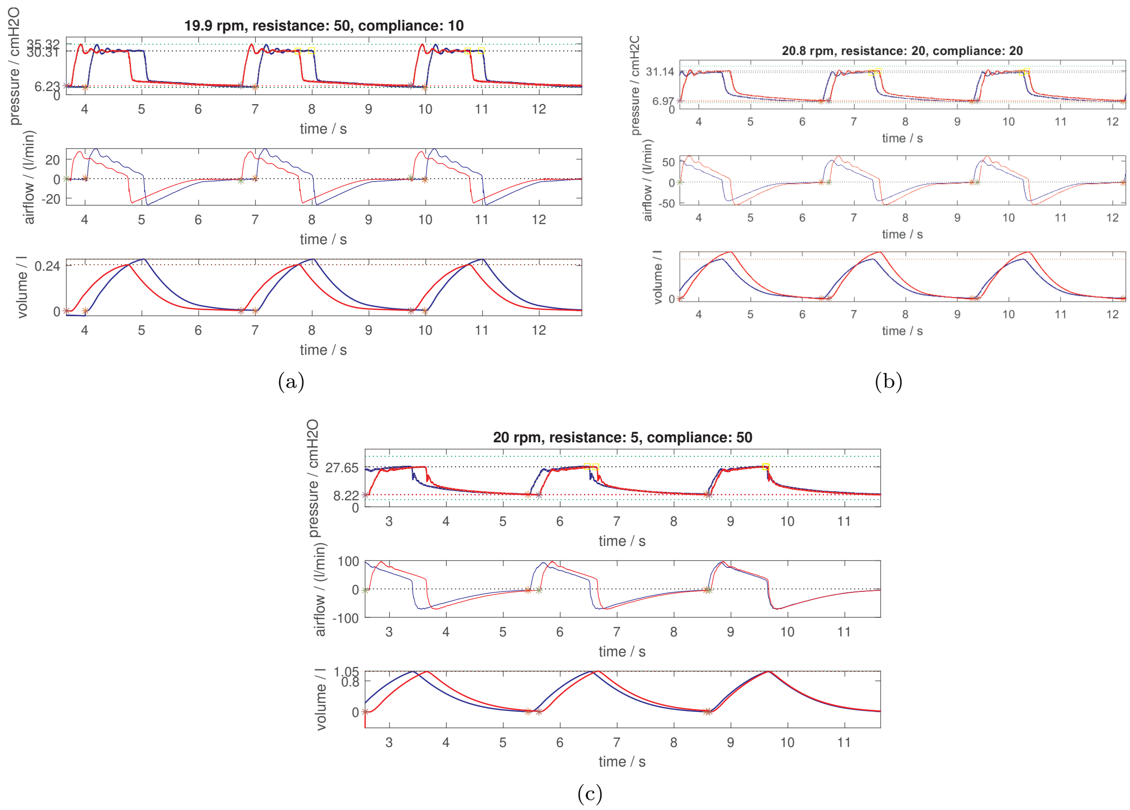


Fig. 13. Reference configuration: FiO2, blue: 55% FiO2, red: 95% FiO2. All figures at 20 RPM, PEEP = 5 cmH2O, plateau pressure = 30 cmH2O.
(a) resistance = 50 cmH2O/l/s, compliance = 10 ml/cmH2O; (b) resistance = 20 cmH2O/l/s, compliance = 20 ml/cmH2O; (c) resistance = 5 cmH2O/l/s, compliance = 50 ml/cmH2O

I. Validation of orifice plate with umbrella valve and Hudson PEEP valve

Due to the noise of the PEEP valve, the feature recognition does not find the correct peaks reliably. This has lead to the development of improved onboard processing for the ventilator, ensuring that the machine reads the correct pressures regardless of the PEEP valve. Despite the noise, we can see that the PEEP is not far from the set value of 5 cmH2O in the sample data of Figure 25. A total of 36 conditions were tested, which are summarized in Table VII. Only a single condition was not passed as the PEEP has decayed slightly further than 2 cmH2O from the set value. This condition is shown in Figure IV-I.

V. Discussion

A. Reference configuration

The PEEP drops substantially in all measurements. The used PEEP valve was known not to maintain PEEP properly as it continuously lets air escape even below the set PEEP. For certification testing, a different one should be used. In previous research, it was concluded that

TABLE IV
Reference configuration: additional testing on conditions that are not required by the MHRA protocol. PEEP is varied in each row, resulting in 3 conditions per row.

Condition				Result			
Compliance	Resistance	Rate	Plateau Press.	Total	Passed	PEEP Low	PIP high
l/cmH2O	cmH2O/l/s	RPM	cmH2O	-	-	-	-
10	50	12	25	3	1	2	2
10	50	20	25	3	0		3
10	50	30	15	3	0		3
10	50	30	25	3	0		3
10	50	30	30	3	0		3
20	20	12	25	3	2	1	
20	20	20	25	3	3		
20	20	30	15	3	3		
20	20	30	25	3	3		
20	20	30	30	3	0		3
50	5	12	25	3	3		
50	5	20	25	3	3		
50	5	30	15	3	3		
50	5	30	25	3	3		
50	5	30	30	3	2		1

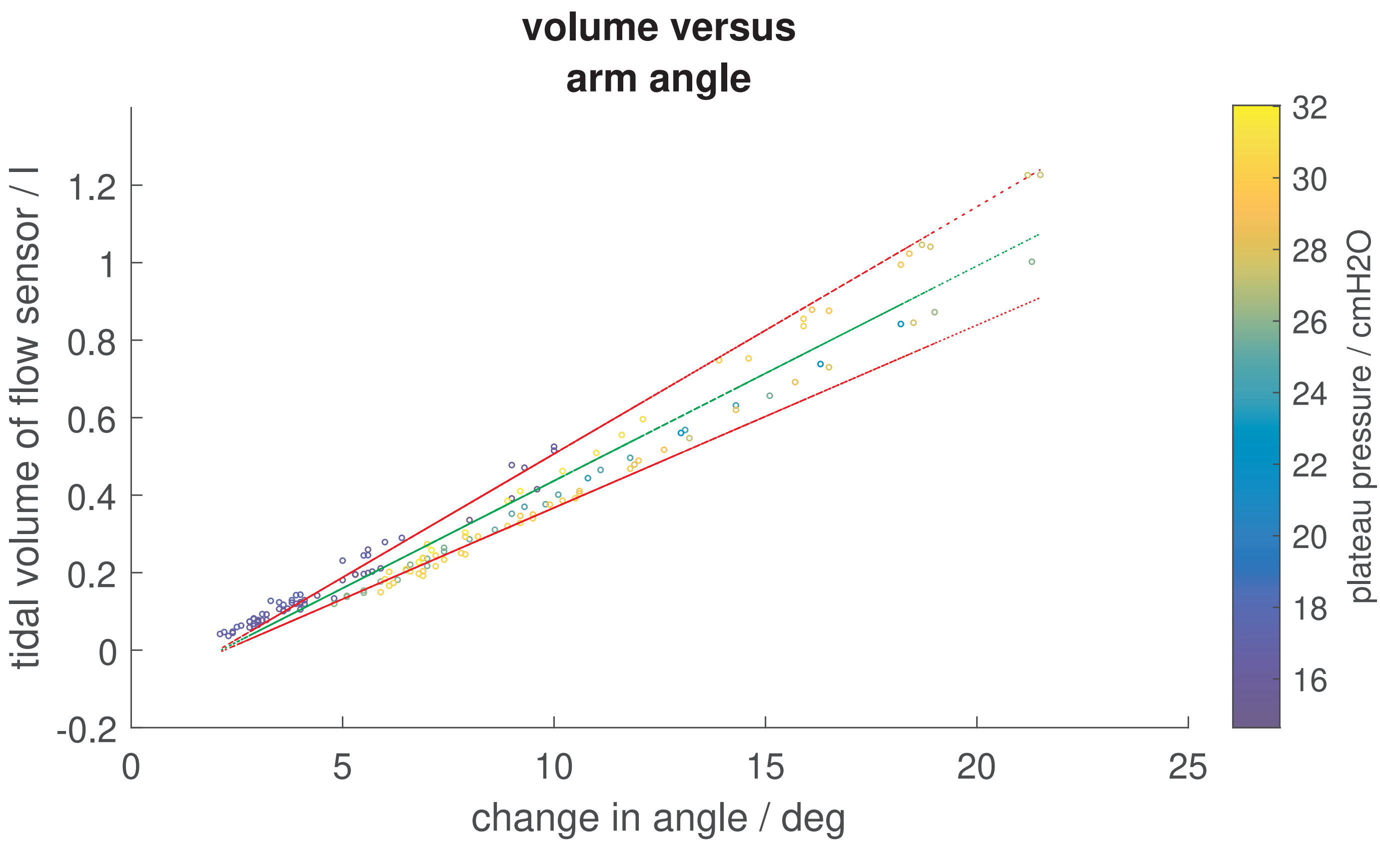
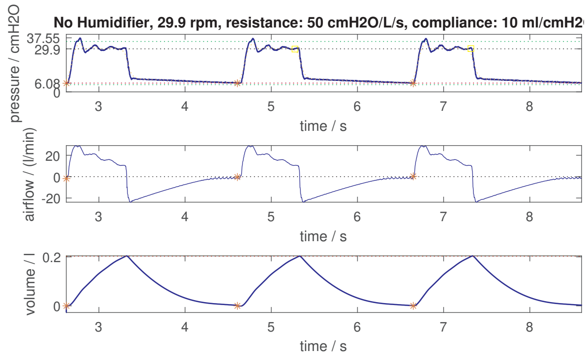


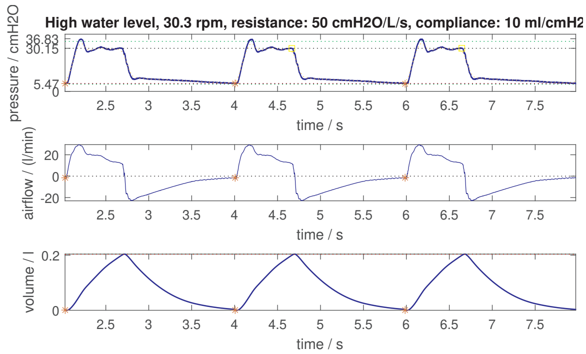
Fig. 14. Reference configuration: Angle of the arm of the ventilator compared to the measured tidal volume. Green is a linear fit, red shows the maximum tolerable deviation from the read value on the angle scale as specified by the MHRA requirements.

TABLE V
Oxygen rise time results

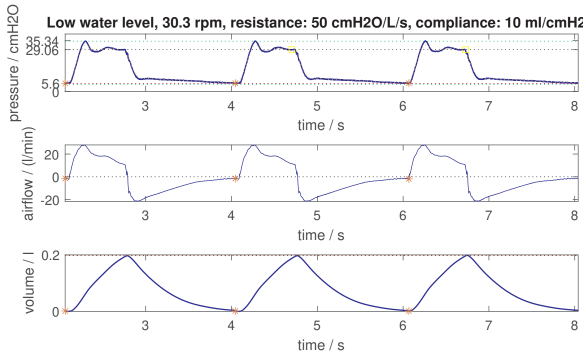
Test Lung Compliance	Test Lung Resistance	FiO2	Plateau Pressure	Rate	PEEP	O2 Rise time
ml/cmH2O ± 10%	cmH2O/l/s ± 10%	%	cmH2O	RPM	cmH2O	minutes
20	20	21 to 90	15	20	15	02:37
20	20	21 to 90	30	20	5	01:32



(a) No humidifier



(b) Humidifier with high water level

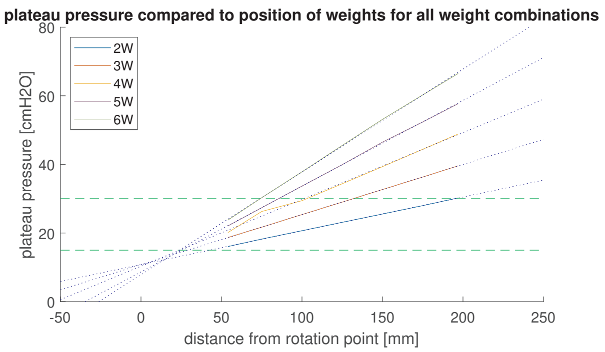


(c) Humidifier with low water level

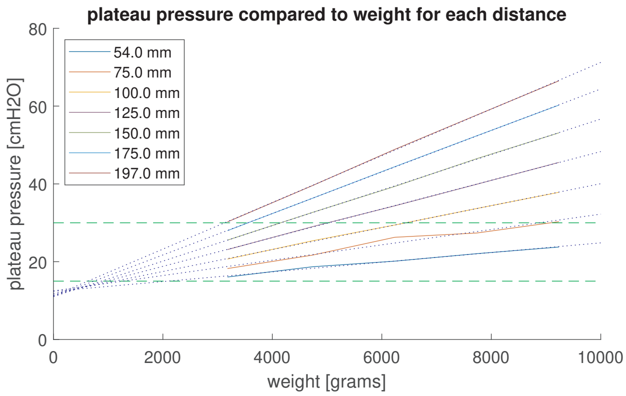
Fig. 15. Influence of humidifier volume: influence of additional dead volume in humidifier in ascending order. All figures at 30 RPM, PEEP = 5 cmH2O, plateau pressure = 30 cmH2O.

TABLE VI
Humidifier: summarized results of Figure 15

Value	Unit	No Humidifier	High Water Level	Low Water Level
PIP	cmH2O	37.5507	36.8327	35.3422
Plateau Pressure	cmH2O	29.9024	30.1489	29.0641
PEEP	cmH2O	6.0821	5.4733	5.6013
Tidal Volume	L	0.2036	0.2036	0.1976
Plateau Oscillation Frequency	Hz	5.3	4.1	3.8
Plateau Oscillation Amplitude	cmH2O	7.6483	6.6837	6.2781

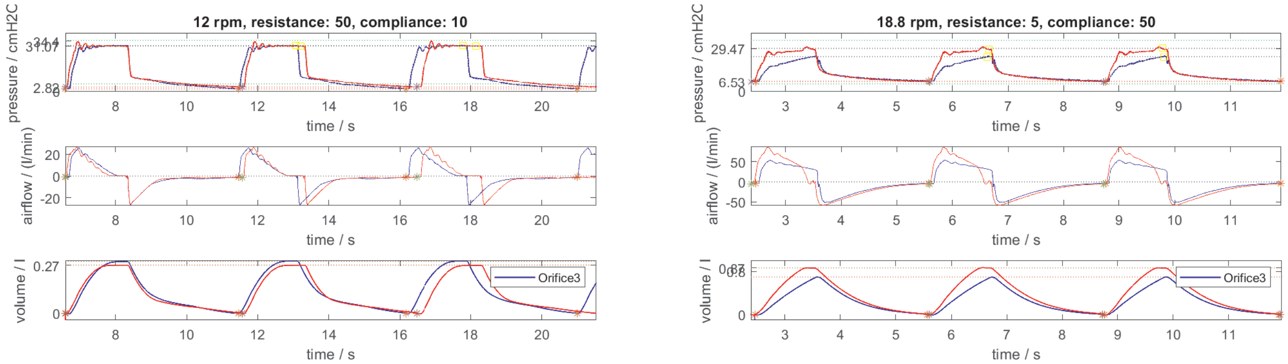


(a) Plateau pressure as influenced by distance from rotation point, drawn for each available number of weights.



(b) Plateau pressure as influenced by the weight of the carriage assembly, drawn for each measured position.

Fig. 16. Calibration of the weight scale: sensitivity to position and weight of carriage.



(a) resistance = 50 cmH2O/l/s, compliance = 10 ml/cmH2O (b) resistance = 5 cmH2O/l/s, compliance = 50 ml/cmH2O

Fig. 17. Influence of orifice plates: orifice plate 3 (blue) compared to orifice plate 1 (red), which is the configuration of the current machine. PEEP = 5 cmH2O, plateau pressure = 30 cmH2O, Rate = 20 RPM

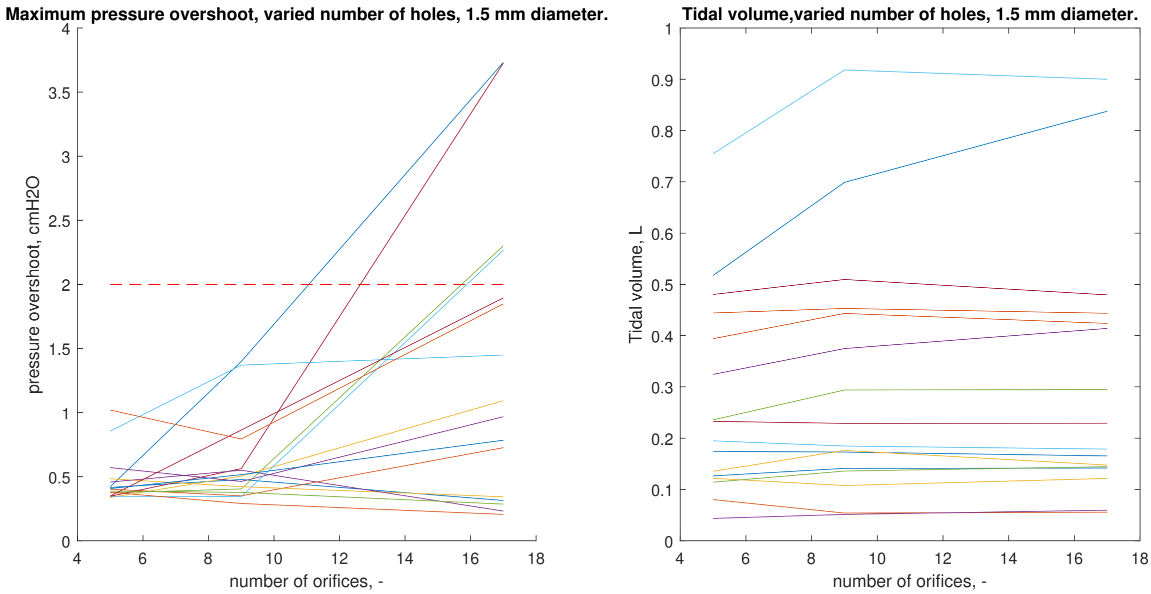


Fig. 18. Influence of orifice plates: sensitivity of maximum pressure overshoot and tidal volume for varied number of orifices, for a diameter of 1.5 mm, and thickness of 2 mm.

TABLE VII
Validation of orifice plate with umbrella valve and Hudson PEEP valve: list of conditions required to pass MHRA specifications. PEEP is varied within each row, resulting in 3 conditions per row.

Condition				Result			
Compliance	Resistance	Rate	Plateau Pressure	Total	Passed	PEEP Low	PIP high
l/cmH2O	cmH2O/l/s	RPM	cmH2O	-	-	-	-
10	50	12	15	3	3		
10	50	12	30	3	2	1	
10	50	20	15	3	3		
10	50	20	30	3	3		
20	20	12	15	3	3		
20	20	12	30	3	3		
20	20	20	15	2	2		
20	20	20	30	3	3		
50	5	12	15	3	3		
50	5	12	30	3	3		
50	5	20	15	3	3		
50	5	20	30	3	3		

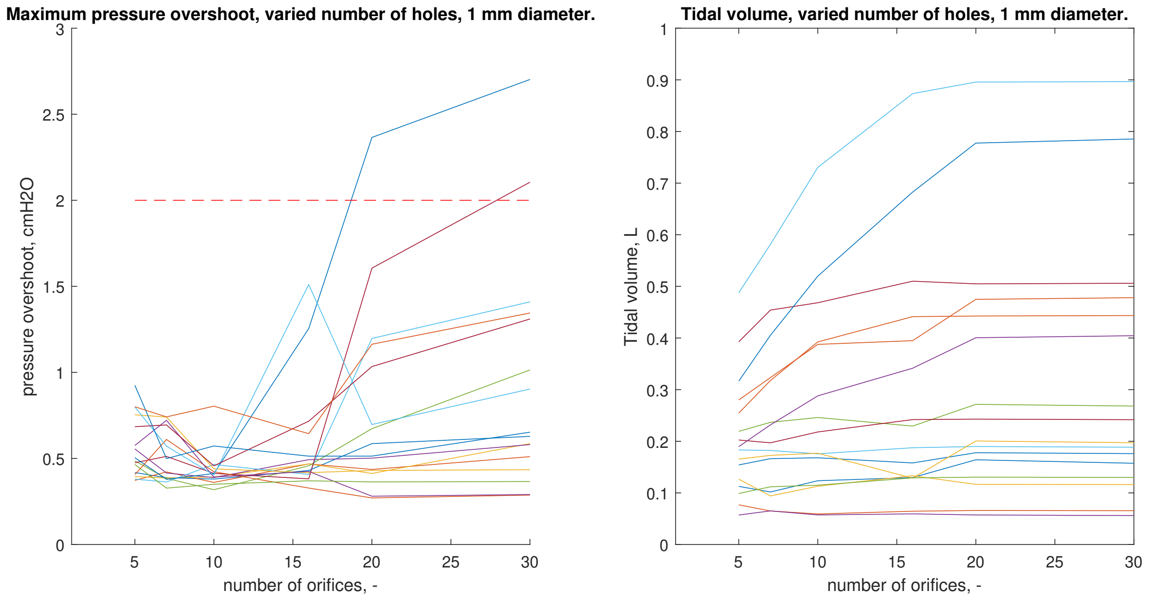


Fig. 19. Influence of orifice plates: sensitivity of maximum pressure overshoot and tidal volume for varied number of orifices, for a diameter of 1 mm, and thickness of 2 mm.

the Hudson PEEP valve[9] was better at maintaining the correct PEEP value, but gives the same PEEP value less consistently over different tests and emits a strong noise that can complicate feature recognition of the signal.

The Peak Inspiratory Pressure (PIP) is too high for most conditions on high pressure and high resistance. The MHRA specifications permit the PIP to be 2 cmH2O larger than the plateau pressure. This overshoot is roughly 5 cmH2O for most conditions that violate this requirement. The flow is still positive during these oscillations, so the pressure in the lung must be lower than the airway pressure. This means that the Alveolar pressure is likely not fluctuating, reducing the risk of damage. However, this must be validated in in-vivo experiments.

To minimize all risks and achieve conformity to the MHRA specifications, methods should be considered to remove the overshoot altogether. Currently considered solutions are orifice plates, VBS compliance, and Pump compliance.

Oxygen has a minimal impact on the machine as seen in Figure 13. The difference in tidal volume corresponds to the difference in driving pressure caused by inconsistent PEEP. This difference of volume can be calculated with Equation 1, where c is the compliance of the lung, p_{plat} is the plateau pressure, and p_{peep} is the peep pressure.

$$\Delta V = c \cdot (p_{\text{plat}} - p_{\text{peep}}), \tag{1}$$

The following list summarizes all MHRA requirements [1], and whether they are met:

- Plateau pressure should adapt to achieve volume and be limited to 35 cmH2O: This was achieved. plateau pressure is limited to 30 cmH2O unless additional weight is added.
- Peak pressure should be no more than 2 cmH2O greater than plateau pressure: This was not achieved for half of the measurements done at a plateau pressure of 30 cmH2O, mainly at high lung resistances.
- PEEP range 5 to 25 cmH2O adjustable in 5 cmH2O increment: PEEP valve is adjustable, but current valve is limited to 10 cmH2O, and does not maintain the PEEP properly. Therefore the valve has to be changed to a better performing one such as the Hudson PEEP valve..
- Patient breathing system must remain pressurized to at least the PEEP level setting at all times: PEEP can drop below considerably during expiration, criteria not met. A different PEEP valve should be used to meet this requirement..
- Inspiratory:Expiratory ratio (I:E) 2.0 (i.e. expiration lasts twice as long as inspiration): This was achieved, as it is mechanically fixed. Note that the optional requirement of different ratios cannot be achieved without hardware changes and/or motor speed variation within one cycle, which is currently not possible.
- Respiratory Rate. The number of breathing cycles every minute: Range 10 to 40 breaths per minute in increments of 2 (only in mandatory mode) can be set by the user: This was achieved, and adjustment is continuous, not only in discrete increments.
- Tidal Volume (Vt). The volume of gas flowing into the lungs during one inspiratory cycle must have at least one setting of 400 ml +/- 10 ml: This tidal volume was achieved. To set the volume, the machine requires setting pressure..

[9] https://cdn.ironpla.net/i/2418/807/2418807_11703_0_0006.jpg

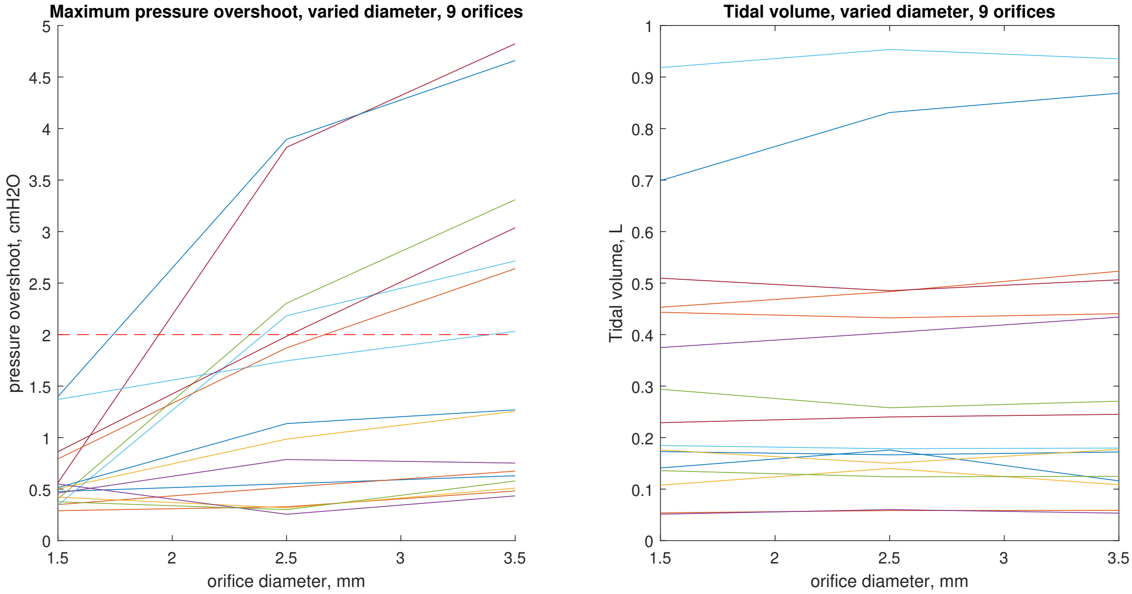
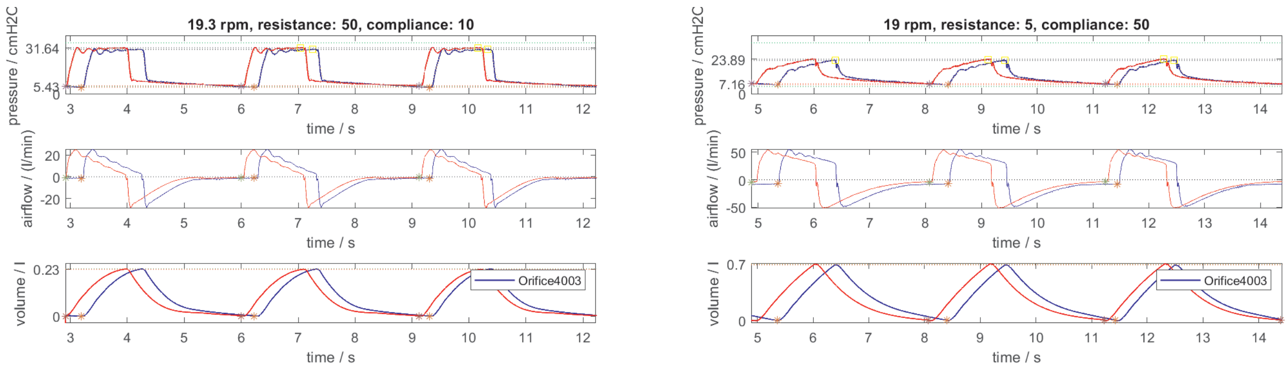


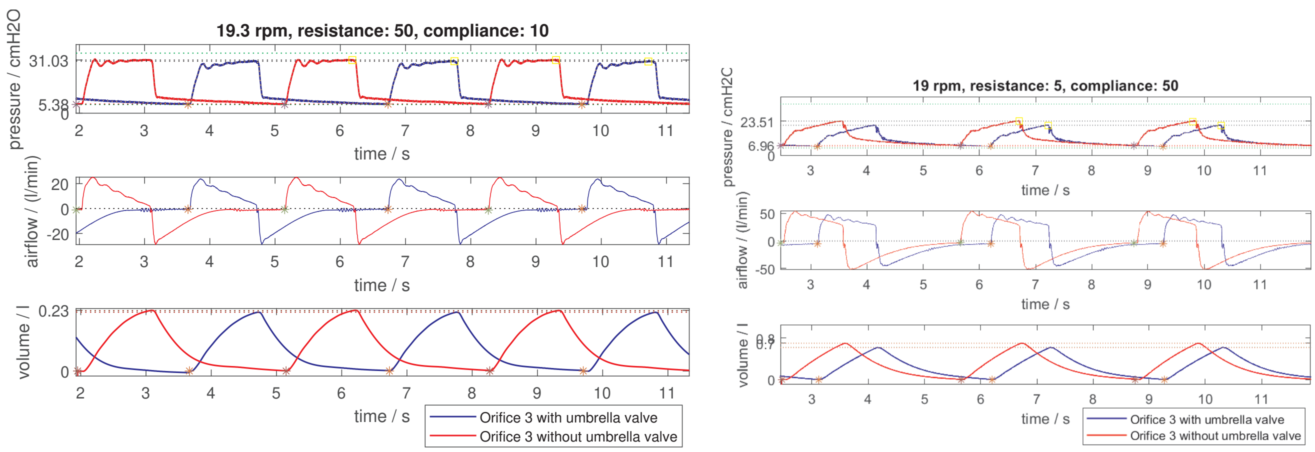
Fig. 20. Influence of orifice plates: sensitivity of maximum pressure overshoot and tidal volume for varied diameter, for number of 9 orifices, and thickness of 2 mm.



(a) resistance = 50 cmH2O/l/s, compliance = 10 ml/cmH2O

(b) resistance = 5 cmH2O/l/s, compliance = 50 ml/cmH2O

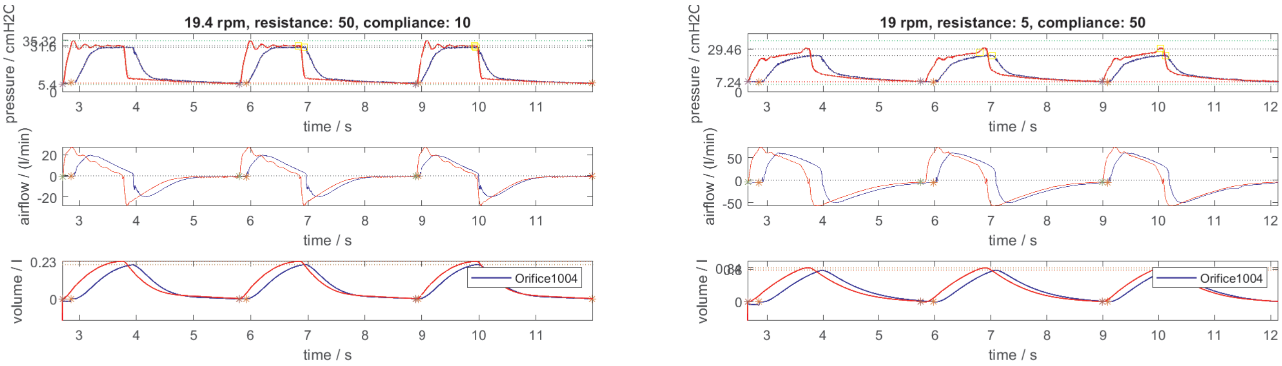
Fig. 21. Influence of orifice plates: orifice plate 3 of 2 mm thick PMMA (blue) compared to orifice plate 3 with a thickness of 1 mm (red) PEEP = 5 cmH2O, plateau pressure = 30 cmH2O, Rate = 20 RPM



(a) resistance = 50 cmH2O/l/s, compliance = 10 ml/cmH2O

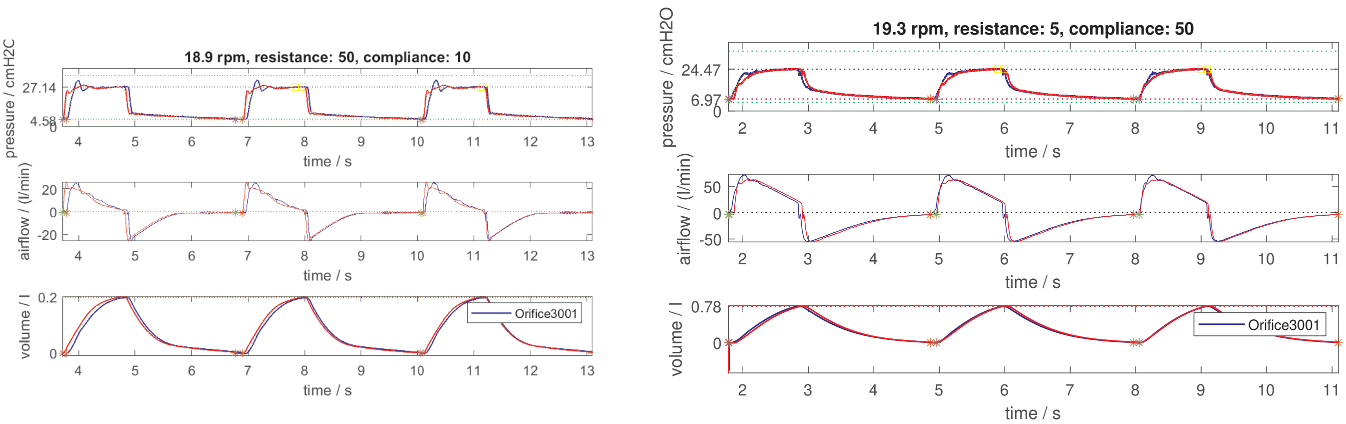
(b) resistance = 5 cmH2O/l/s, compliance = 50 ml/cmH2O

Fig. 22. Umbrella Orifice: orifice plate 3 with umbrella valve (blue) compared to orifice plate 3 without umbrella valve (red) PEEP = 5 cmH2O, plateau pressure = 30 cmH2O, Rate = 20 RPM



(a) resistance = 50 cmH2O/l/s, compliance = 10 ml/cmH2O (b) resistance = 5 cmH2O/l/s, compliance = 50 ml/cmH2O

Fig. 23. Influence of compliance in VBS: orifice plate 4 with additional compliance (blue) and without (red). PEEP = 5 cmH2O, plateau pressure = 30 cmH2O, Rate = 20 RPM



(a) resistance = 50 cmH2O/l/s, compliance = 10 ml/cmH2O (b) resistance = 5 cmH2O/l/s, compliance = 50 ml/cmH2O

Fig. 24. Influence of compliance in pump: orifice plate 1 with additional compliance (red) and without (blue). PEEP = 5 cmH2O, plateau pressure = 30 cmH2O, Rate = 20 RPM

- Tidal Volume ideally has 350 ml and 450 ml options: This was achieved as well, and adjustment is continuous by means of varying number or location of weights, not only in discrete increments.
- Tidal Volume optionally has range 250 to 600 ml in steps of 50 ml : The machine did easily achieve lower volumes such as 250 ml . 600 ml were achieved as well, but only for low-to-medium breathing rates. Variation is continuous, not discrete..

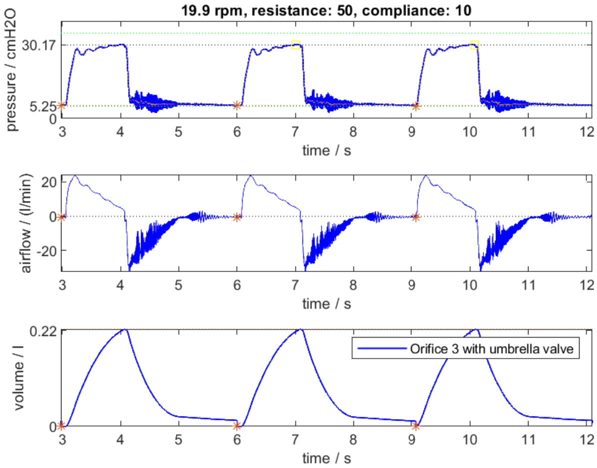
In the additional conditions of Table IV it can be observed that increasing the rate increases the PIP as well. At a rate of 30 RPM the overshoot is too large for all test conditions at a resistance of 50 cmH2O/l/s, and even at 5 cmH2O/l/s one of the conditions is not sufficient. The analog reading of the arm is not accurate enough to completely meet the MHRA specifications, as seen in Figure 14. Therefore an electronic measurement is also included in the machine. At the time of recording the data, this sensor was not yet operational. The analog reading can still provide a valuable estimation of the approximate tidal volume, but not within the accuracy bounds specified by the MHRA specifications.

B. Oxygen rise time

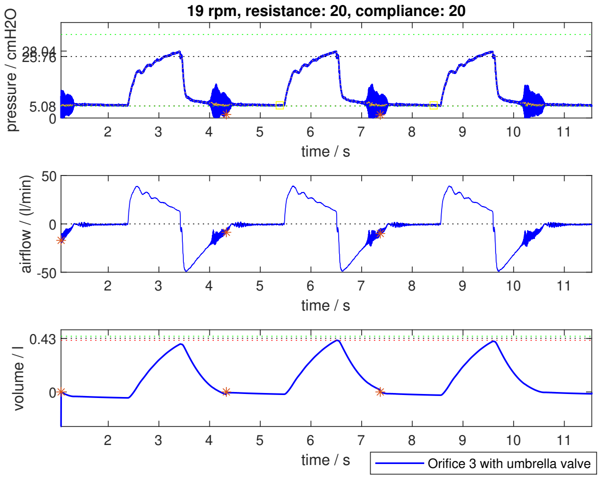
The currently worst recorded rise time was achieved by choosing a setting where a minimal volume is pumped. This means that each cycle only a small portion of the bellow is emptied. The oxygen level of the air fed to the patient only gradually increases if pure oxygen is fed to the machine if we assume the bellow to function as a continuous mixer. The rise time can be reduced by completely emptying the bellow and then feeding oxygen, or by temporarily using a larger tidal volume to cycle the air in a shorter time.

C. Influence of humidifier volume

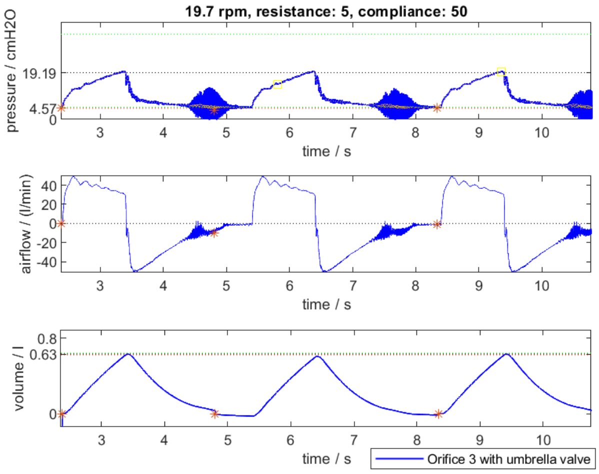
The extra volume introduced to the VBS by the humidifier has a minor effect on the height of the Peak Inspiratory Pressure (PIP), reducing it from 37.55 cmH2O (No humidifier) to 35.34 cmH2O (Low water level). Furthermore, the presence of more volume in the VBS reduces the plateau oscillation frequency considerably. This has no direct effect on the performance of the machine. If the breathing rate is high, combined with a low plateau



(a) resistance = 50 cmH2O/l/s, compliance = 10 ml/cmH2O



(b) resistance = 20 cmH2O/l/s, compliance = 20 ml/cmH2O



(c) resistance = 5 cmH2O/l/s, compliance = 50 ml/cmH2O

Fig. 25. Validation of orifice plate with umbrella valve and Hudson PEEP valve: PEEP = 5 cmH2O, plateau pressure = 30 cmH2O, Rate = 20 RPM

oscillation frequency, the oscillation may not be dampened when the plateau pressure is evaluated. This may result in inconsistent readings from the pressure sensors. At the low water level measurement, it can be observed that the plateau pressure is determined during the lower peak of the oscillation. Though most of the oscillation has dampened at this point, it still results in a plateau pressure measurement that is roughly 1 cmH2O smaller than that of both other measurements.

It is important to consider that all measurements were done at high lung resistance, which inherently carries the most oscillations. As observed in Figure 13, the oscillations are less influential at 20 and 5 cmH2O/L/s.

Generally, the volume of the VBS should not be made too large as this can increase the settling time of supplied oxygen, as well as increasing compliance of the system due to the compressibility of air. This additional compliance increases oxygen consumption as all volume that was admitted by the compliance will not enter the lungs of the patient but instead will be expelled through the PEEP valve. This volume is measured by the flow sensor, which will overestimate the tidal volume.

D. Calibration of the weight scale

It is observed that the plateau pressure can range between 16.1 and 30.3 cmH2O with the minimum number of weights, and between 24.1 and 66.5 cmH2O with maximum weight. MHRA specifications requirement 3.a is met by providing 2 weights as the default option, which limits plateau pressure to 30.3 cmH2O. The operator can add extra weights as desired if this setting is not considered sufficient. With the extra weights, it still is not possible to increase plateau pressure above 70 cmH2O.

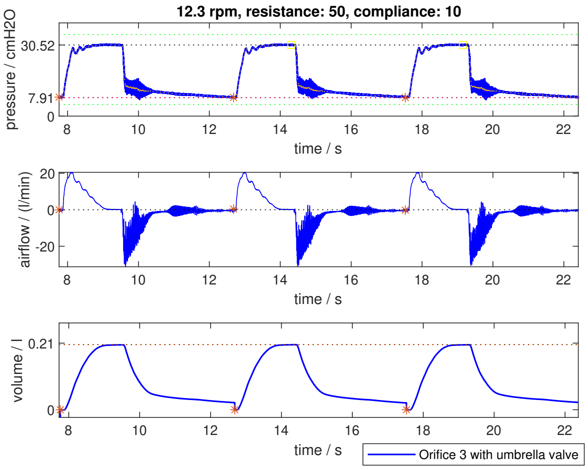


Fig. 26. Validation of orifice plate with umbrella valve and Hudson PEEP valve: failed condition, PEEP deviates more than 2 cmH2O, resistance = 5 cmH2O/l/s, compliance = 50 ml/cmH2O, PEEP = 10 cmH2O, plateau pressure = 30 cmH2O, Rate = 12 RPM

E. Influence of orifice plates

It is observed that both the diameter and number of orifices tend to lead to the same tidal volume eventually. This is because the flow is not limited by the flow through the orifices but instead by the maximum tidal volume that can be generated considering the clinical plateau pressure, which is determined by the driving pressure and the lung compliance. Currently, the orifice plate is installed on the bottom plate of the bellow. This is the easiest place to install the plate, but also increases the load on the motor during the air intake. The orifice plate could instead be placed in the tubing towards the first cam to reduce the load on the motor. This achieves the same effect regarding pressure to the patient but does not put extra strain on the motor, increasing the machine's lifespan. Another way to achieve this is to allow air to flow into the bellow easier than out, as explored in the next section.

F. Orifice plate with umbrella valve

The reduction of pressure and tidal volume in Figure 22(a) can be attributed to a slight difference in rate as the pressure rises at an equal rate for both of the measurements. The difference in rate causes the breath to be ended earlier, resulting in a lower peak inspiratory pressure and tidal volume. The goal of the umbrella valve was to reduce strain on the motor. The arm assembly can be pulled up considerably easier when the umbrella valve orifice plate was used, but this hypothesis was not quantified.

G. Influence of compliance in VBS

Adding compliance to the VBS reduces the peaks in the pressure. Since the VBS is directly connected to the PEEP valve as soon as the outlet valve is open, all extra volume used to deform the compliant part is lost through the PEEP valve. This results in increased air consumption and, therefore, oxygen consumption as well. Furthermore, this extra volume cannot be distinguished from the tidal volume, causing higher volume measurements. In the test setup, the flow sensor is placed at the patient port, meaning that only the flow to the patient is measured. The air intake is significantly larger than the tidal volume that is provided to the patient. The reservoir bag used in the experiments can only serve as a short term solution as the balloon can stretch over prolonged use at high pressures. Therefore a different compliant component must be selected, which is more durable.

H. Influence of compliance in pump

In contrast to compliance in the VBS, Pump compliance (so compliance in the section from the bellow to the inlet valve to the patient connection) does not increase the air consumption, so it does not introduce volume measurement inaccuracies. A one-way valve must be introduced to prevent the bellow from compressing the compliant component. This always carries a small pressure drop. It can be observed that the plateau pressure is considerably lower. This is because the PEEP valve used as one way valve reduces the pressure difference between the VBS and bellow by 5 cmH2O. However, as observed in Figure 24(a) and 24(b), this pressure drop is not constant as the plateau pressure is not the same for both conditions. The used PEEP valve has damping built-in, which may be the origin of this inconsistency.
The pressure characteristics look promising since the PIP is only slightly larger than the plateau pressure for all conditions. Less tidal volume is lost compared to the orifice plate solutions.

I. Validation of orifice plate with umbrella valve and Hudson PEEP valve

This configuration outperforms the initial system considerably, as only a single test was not passed. It should be noted that the orifice plate does limit the maximum tidal volume that can be provided to the patient. Therefore the other solutions addressed in this report can be considered if this is deemed problematic. The noise of the Hudson PEEP valve can yield pressures greater than the pressure that was reached during inspiration. The noise is emitted at roughly 144 Hz and is clearly audible. This noise does not reach the lungs of the patient as discussed by T. A. Wilson: "It should also be noted that for frequencies higher than 50 Hz, most of the signal introduced by oscillations imposed at the mouth is reflected by the rapid area increase at the distal end of the tube." [4]. Therefore this noise is not dangerous for the lungs of the patient.

The following list summarizes the MHRA requirements and how they are met.

- Plateau pressure should adapt to achieve volume and be limited to 35 cmH2O: This was achieved. plateau pressure is limited to 30 cmH2O unless additional weight is added.

- Peak pressure should be no more than 2 cmH2O greater than plateau pressure: Achieved for all conditions.
- PEEP range 5 to 25 cmH2O adjustable in 5 cmH2O increment: PEEP valve is adjustable.
- Patient breathing system must remain pressurized to at least the PEEP level setting at all times: PEEP can drop below set level slightly, the PEEP valve can be set roughly 1 cmH2O higher than the desired value to make sure the pressure never drops too far.
- Inspiratory:Expiratory ratio (I:E) 2.0 (i.e. expiration lasts twice as long as inspiration): This was achieved, as it is mechanically fixed. Note that the optional requirement of different ratios cannot be achieved without hardware changes and/or motor speed variation within one cycle, which is currently not possible.
- Respiratory Rate. The number of breathing cycles every minute: Range 10 to 40 breaths per minute in increments of 2 (only in mandatory mode) can be set by the user: This was achieved, and adjustment is continuous, not only in discrete increments.
- Tidal Volume (Vt). The volume of gas flowing into the lungs during one inspiratory cycle must have at least one setting of 400 ml +/- 10 ml: This tidal volume was achieved. To set the volume, the machine requires setting pressure. This volume can easily be achieved despite orifice flow restriction.
- Tidal Volume ideally has 350 ml and 450 ml options: This was achieved as well, and adjustment is continuous by means of varying number or location of weights, not only in discrete increments.
- Tidal Volume optionally has range 250 to 600 ml in steps of 50 ml : The machine did easily achieve lower volumes such as 250 ml . 600 ml were achieved as well, but only for low-to-medium breathing rates. Variation is continuous, not discrete.

VI. Conclusion

In the reference configuration experiments, it was concluded that the PIP could overshoot the plateau pressure by up to 6 cmH2O. Adding an orifice plate is the easiest modification to implement. Orifice plate 3, with 9x1.5 mm orifices, gives a good trade-off between lost tidal volume and reduction of pressure overshoot. With this orifice plate, the largest overshoot in all tested conditions is less than 1.5 cmH2O. The orifice plate restricts the airflow, which can increase the time it takes to reach clinical plateau pressure. This effect scales with intended tidal volume, meaning that breaths larger than 500 ml may require lower rates, which is indicated in Figure 18.

The orifice plate with the umbrella valve reduces the load on the motor and does meet the MHRA specifications criteria for pressure overshoot, but does not improve the tidal volume.

The Hudson PEEP valve replaces the Intersurgical PEEP valve, which ensures that pressure is maintained more consistently. Combining the Hudson PEEP valve and the orifice plate with umbrella valve results in performance that is almost entirely in compliance with the MHRA requirements, with only a single failed condition due to low PEEP.

If reduction of tidal volume for large breaths is found to be unacceptable, the pump compliance method can be investigated further. This method does introduce a new single-point failure to the system as all functionality is lost if the compliant part leaks. Furthermore, it requires an additional check valve which may decrease the end inspiratory pressure.

Known Issues

- PEEP valve generates pressure noise and oscillations that can disturb feature recognition. Improved processing is in development by Project Inspiration.
- Set pressure cannot be reduced all the way to 15 cmH2O. The lowest pressure is approximately 16 cmH2O for most lung settings. This is within tolerable bounds set by the MHRA specifications. The results from Figure 16(b) can be used to adjust the weight assembly if there is a need to achieve a lower minimum set pressure.
- The maximum achieve-able tidal volume is reduced by roughly 17% with the orifice plate solution. This mainly affects tidal volumes larger than 500 ml. As tidal volumes larger than 450 ml are optional according to the MHRA specifications, this is not considered problematic.

Recommendations for further research

- Investigate the compliance solutions with a better check valve. As opposed to the orifice plate solutions, these do not negatively affect the tidal volume, meaning the solution is more suited to ventilate patients who can benefit from a larger volume per minute.
- For use in any European market the machine requires a full CE declaration and approval of at least one notified body. The CE requires more research and is a lot more strict than the MHRA RMVS specifications.
- An I:E ratio of 2 is enough to satisfy the MHRA specifications, but methods to allow other ratios are considered. This can be achieved by changing the motor velocity during exhalation to lengthen or shorten the expiration phase. The current machine does not yet have this functionality.

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has manufactured the PCBs of the Project Inspiration Ventilator.

References

[1] Medicines and Healthcare products Regulatory Agency (MHRA), "Specification for ventilators to be used in uk hospitals during the coronavirus (covid-19) outbreak," https://www.gov.uk/government/publications/specification-for-ventilators-to-be-used-in-uk-hospitals-during-the-coronavirus-covid-19-outbreak, March 2020, consulted on 9-7-2020.

[2] H. Vallery, "Experimental evaluation of the "project inspiration" rapidly manufactured ventilator," TU Delft, Tech. Rep., 2020, https://github.com/CombatCovid/TU-Delft-PI-Emergency-Ventilator/tree/master/src/research.

[3] Daniel Lemus, "Project inspiration humidifier gitlab," https://gitlab.tudelft.nl/dslemusp/inspiration_humidifer, June 2020, consulted on 9-7-2020.

[4] T. A. Wilson, Respiratory Mechanics. Springer, 2016, page 48.

[5] M. Leeuwis and H. Vallery, "Evaluation of the "project inspiration" rapidly manufactured ventilator for mexico," TU Delft, Tech. Rep., 2020, https://github.com/CombatCovid/TU-Delft-PI-Emergency-Ventilator/tree/master/src/research.