# JAMVENT

DESIGN DOCUMENT

VERSION 5.0.1

12/04/2020

PREAMBLE

This document is intended to provide the details required for building and operating JamVent. We can confirm that the system functioned properly when we built it to these specifications. We have noted components that could likely be replaced with equivalent but not identical components without significantly affecting system performance. Please note that appropriate expertise is required, and email us with any questions and recommendations. There will be regular updates to provide further details as they become ready. Anyone wishing to use this design document for any purposes must read carefully the section headed "Licence and Disclaimers" that follows.

Thank you to all those involved in the project.
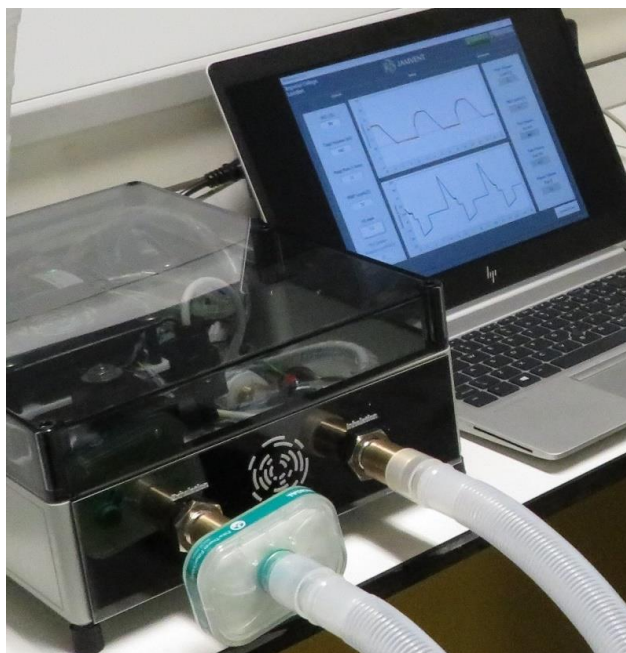
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VERSION CONTROL

Version	Date Issued	Description
5.0.0	11/04/2020	Original version.
5.0.1	12/04/2020	Licence and disclaimers added.

CONTENTS

MISSION STATEMENT

There is a severe shortage of ventilators in the UK and across the world due to the spread of the coronavirus. Major manufacturers have been asked to increase production of medical ventilators to address the issue, but the output is unlikely to be sufficient. The shortfall could be made up by providing designs for a relatively-easy-to-manufacture alternative that could perform the basic requirements. There will also be significant pressure on the medical and specialist component supply lines.

COVID-19 is associated with severe pneumonia. Hence,

- To keep alveoli open during exhalation, a positive pressure is applied during the exhalation phase (positive end exhalation pressure, PEEP).
- The lung compliance can be significantly decreased, hence higher pressures than normal are required to deliver the same volume.
- Face mask systems lead to aerosolization, hence full intubation is preferred.

The pandemic leads to supply limitations, hence the design should

- Not use *specialist* or medical supply chain components, so as to enable mass production and low cost.
- Enable mixing of oxygen with air, as oxygen supplies in hospitals could be limited and total throughput will be limited.

Finally, safety features of the system require

- Pressure-relief valve to ensure pressure in the lung never exceeds a critical value that would cause barotrauma (typically 45 cmH_2O, but possibly up to 60 cmH_2O is required for stiffer lungs).
- Measurement of the flow into and out of the lungs. Inhaled volume is set by clinician, exhaled volume is used for monitoring.

Key specifications determined by the MHRA are described in RMVS001 v3.1

- Inhalation pressures of up to 40 cmH_2O – normal working range is 30 cmH_2O
- Plateau pressure not to exceed 35 cmH_2O by default, with option to increase to 70 cmH_2O
- Peak pressure should not exceed plateau pressure by more than 2 cmH_2O
- Exhalation pressure (PEEP) of 5-20 cmH_2O
- Tidal volumes of 250-600 ml – precision ±10 ml, could be up to 800ml
- Oxygen concentrations of 30-100%
- Respiratory rates of 10-30 breaths per minute
- Inhalation to exhalation ratios of 1:1 to 1:3
- Oxygen concentration resolution of 5%
- Gas supply lines in hospitals are 4 bar.
- Oxygen compatible and biologically safe components

OUR APPROACH

Our main aims in this design were to use generic components that are not specialist, or part of the medical supply chain (such as Ambu bags). We also do not use any drive gas, so the system is 100% efficient in terms of gas use.

Our design uses 2 pressure sensors and 4 pneumatic switches (2/2 on-off solenoid valves). This document provides outlines of the design concept, including sample connectors for pneumatic and electrical connections. Individual elements could potentially be replaced with similar parts from other manufacturers, if those function within certain performance ranges.

DESIGN SCHEMATIC

1. Oxygen mixing valve
2. Air mixing valve
3. 2L pressure reservoir
4. Reservoir pressure sensor
5. Pressure relief safety valve
6. Inhalation valve
7. Oxygen sensor
8. System pressure sensor
9. Pressure relief safety valve
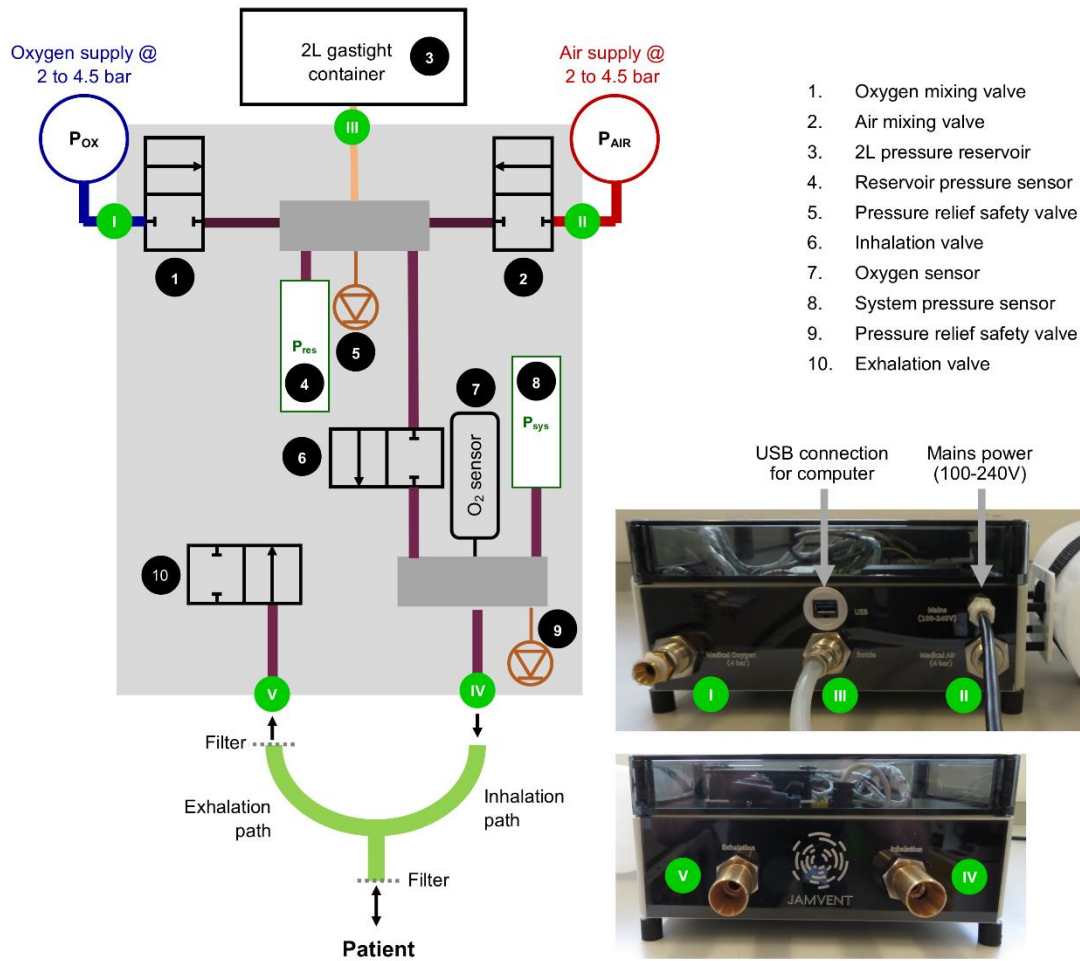10. Exhalation valve

Figure 1: Overall Design Schematic

OPERATING PRINCIPLES

GAS MIXING

- During Exhalation phase, oxygen valve (A) and air valve (B) open to reach a target pressure in the reservoir $P_{res} = P_{target}$
- Once target is reached, valves A and B shut
- We find that a 2 litre container provides ideal pressure-flow behaviour. With smaller volumes, pressure decays more rapidly, resulting in a higher peak pressure for a given tidal volume.
- FIO_2 is determined according to proportion of the time that Valve A is open (T_A) relative to Valve B (T_B),

$$FIO_2 = \left(1 + 0.21\frac{T_B}{T_A}\right) / \left(1 + \frac{T_B}{T_A}\right) \times 100\% \tag{1}$$

INHALATION PHASE

- At the beginning of inhalation phase, inhalation valve (C) opens, and the reservoir releases air towards the lungs
- Flow rate into the lungs is calculated as:

$$Q_{in} = a_C \Delta P^{n_C} \tag{2}$$

where

$$\Delta P = P_{res} - P_{sys} \tag{3}$$

and the values of a_C and n_C can be calculated by calibration.

- Volume into lung can be determined by integrating flow rate, with dt as the sample time

$$V_{in} = \sum Q_{in}\, dt \tag{4}$$

- Pressure applied to the mouth should be corrected due to pressure drop across the filter

$$P_{mouth} = P_{sys} - \alpha Q_{in}^2 / K_f^2 \tag{5}$$

where K_f^2 is the flow factor for the filter $[m^3/hr/bar^{0.5}]$ and $\alpha = 0.005$ is a conversion factor for units of l/min and cmH_2O

- When $V_{in} = V_T$ (tidal volume), inhalation valve (C) closes

EXHALATION PHASE

- At the beginning of the exhalation phase, exhalation valve (D) opens and air leaves via the exhalation path
- Expiratory flow rate can be estimated according to

$$Q_{ex} = a_D P_{sys}^{n_D} \tag{6}$$

and the values of a_D and n_D can be calculated by calibration.

- Pressure in mouth is given by

$$P_{mouth} = P_{sys} + \alpha Q_{ex}^2 / K_f^2 \tag{7}$$

- When $P_{mouth} = PEEP$, exhalation valve (D) closes to maintain lung pressure and keep alveoli open.

END OF CYCLE

- Inhaled and Exhaled tidal volume, Exhaled minute volume, Peak pressure and PEEP are calculated for last cycle
- P_{target} for next cycle is calculated based on achieved Inhaled Tidal Volume relative to V_T or how much before the end of the inhalation V_T was reached
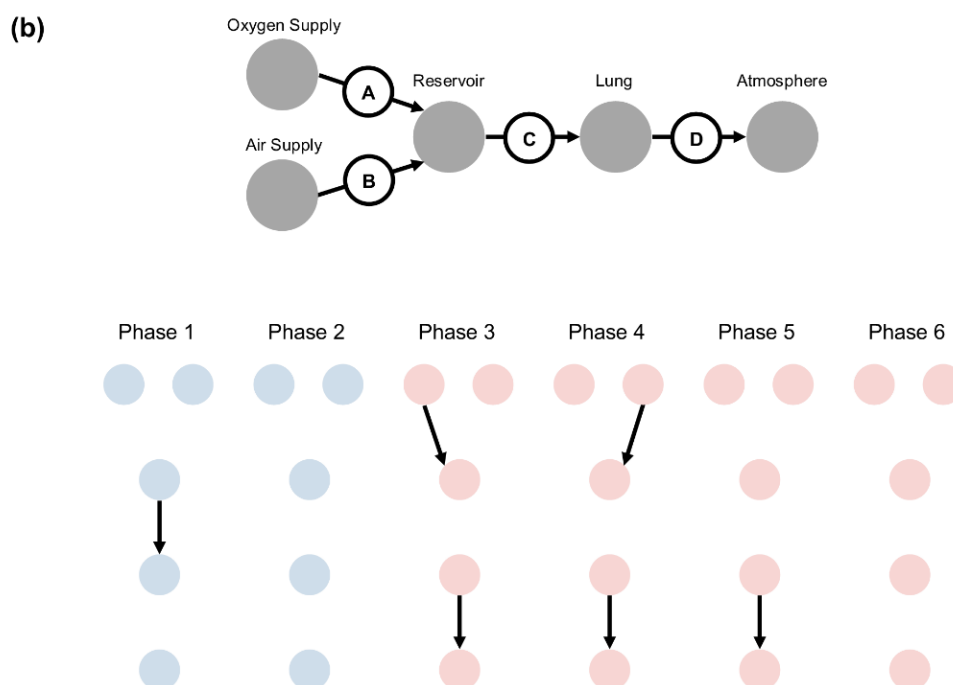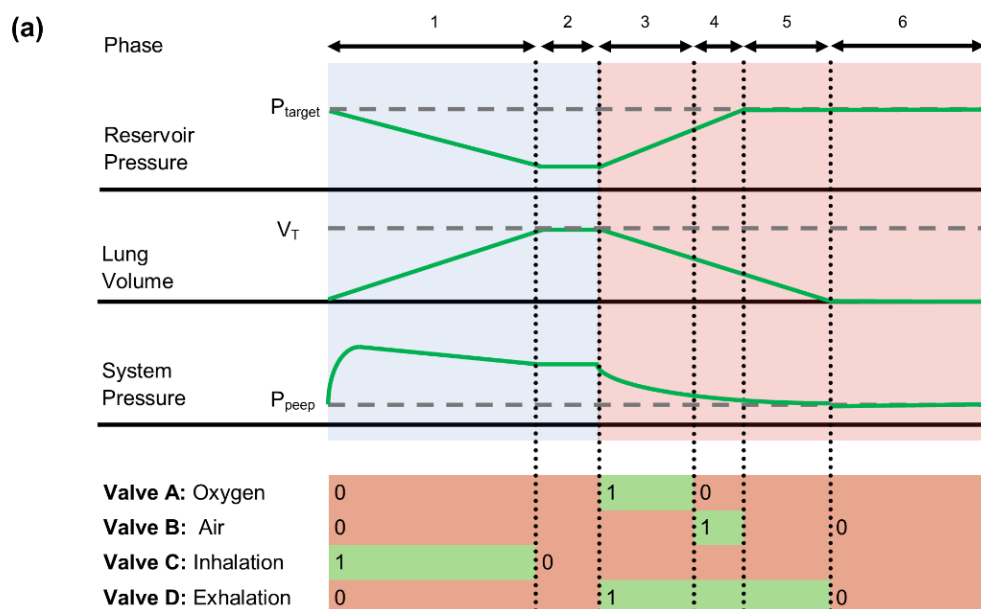
Figure 2: (a) Overview of valve timing. (b) Schematic of air movement during each phase of the timing cycle.

SOFTWARE DESIGN

GUI

The graphical user interface is designed to be familiar to clinicians with experience of ICU ventilators, minimising additional time to gain familiarity.

Figure 3: Flow chart for software implementation

OVERVIEW

An overall flow chart for the software implementation is shown in Figure 4. The tasks are separated into i) measurement (acquiring and processing pressure volume and flow), ii) calculations of valve state and valve control, iii) Control algorithms to optimise FIO_2 and peak pressure.
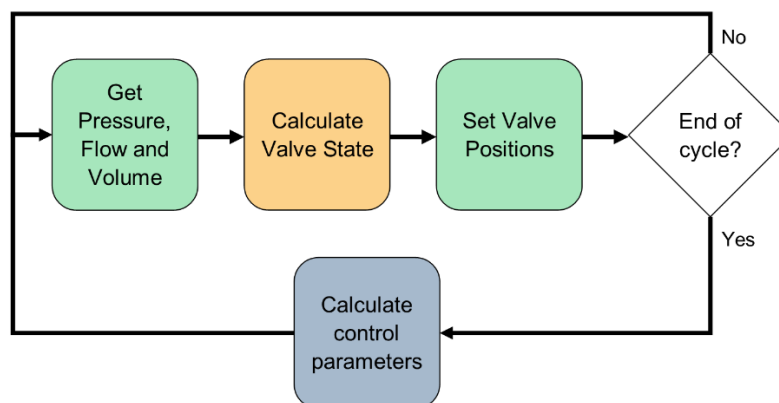

Figure 4: Flow chart for software implementation

CALCULATING FLOW AND VOLUME

To calculate the flow rate during inhalation and exhalation, Equations (2) and (6) can be applied respectively. However, these flow calculations need to be gated off when the valves are shut (as a pressure difference remains after the valve shuts, but no flow occurs).

The initial prototype calculated used software gating, i.e. the flow rate calculated on a given next loop would be gated according to the Valve logic of the previous loop. However, this resulted in a variable lag and hence poor predictions of flow rate close to where valve switching occurred. Currently, the software lag is corrected for by reading an analogue signal of the digital output lines into the code, and using that as the indicator of when the valve is shut to gate the flow rate. The delay in valve triggering must still be accounted for empirically.

VALVE TIMINGS

Table 1 provides definitions of the parameters selected by the end user. Table 2 provides software control parameters. In general, the software runs a timed-loop and calculates valve timings dependent on the time relative to a given breath. Timing parameters are therefore calculated in terms of loop iterations, with the parameters described in Table 3. The logic for valve switching is dependent on around 10 Boolean conditions, that are dependent on relative time within a breath and monitored system parameters (volume during inhalation and pressure during exhalation).

There are two basic timescales in the system, the length of the sample and the length of the timed-acquisition and control loop. We use M to indicate a number of samples and N to indicate a number of software loops.

Table 1: End User Inputs. Can be changed by user

FIO_2	Fraction of inspired oxygen.
Tidal Volume (ml), V_T	Volume of air entering lungs during the inhalation period
Respiratory Rate (1/min)	Number of breaths per minute
PEEP (cmH$_2$O)	Peak expiratory end pressure, the minimum pressure in the lungs during the exhalation period
I:E ratio	Proportion of breath that is inhalation relative to exhalation. Expressed in the code as a fraction, e.g. 1:3 = 0.25.
Maximum pressure (cmH$_2$O)	Maximum pressure in the lung. A safety factor that can be varied from the default value of 35 cmH$_2$O up to 70 cmH$_2$O in extreme circumstances of lung resistance.

Table 2: System Constants. Do not change when software is running.

Acquisition Rate (samples/sec)	Sampling rate (after down-sampling to reduce noise if required)
Software loop period, T_{loop}	Software controlling timing parameter, e.g. 0.02 ms
Buffer length (s)	Time to store data for and display on screen
T_{sample} (s) = 1/Acquisition Rate	Time that each sample represents, e.g. 0.005 ms
M_{buffer} = Buffer Length x Acquisition Rate	Total number of samples in buffer

Table 3: Iteration parameters. N is used for software loops, M is used for samples. Modified by User Inputs.

T_{breath} (s)	60/respiratory rate	Period of full breath cycle, e.g. 4 s
i_{loop}	-	Iteration number of the software loop
N_{cycle}	T_{breath}/T_{loop}	Number of software loops per breathing cycle
i_{cycle}	remainder(i_{loop}, N_{cycle})	Iteration number within a given breathing cycle
N_{in}	I:E Ratio x N_{cycle}	Number of software loops for inhalation period
M_{cycle}	T_{breath} x Acquisition rate	Number of samples per cycle

Table 4: Boolean Conditions. Evaluated every software loop.

a	$i_{cycle}<N_{in}$	Are we in the inhalation phase?
b	$P_{sys}<P_{max}$	Is the pressure below the maximum limited pressure
c	Volume$<V_T$	Is the current volume less than desired tidal volume
d	Valve D(i_{cycle} -1)	What was the previous state of the exhalation valve (D)
e	$P_{mouth} > PEEP + \varepsilon_{PEEP+}$	Is the current mouth pressure above the threshold
f	$P_{mouth}< PEEP - \varepsilon_{PEEP-}$	Is the current mouth pressure below the threshold
g	$P_{res}<P_{target}$	Is the reservoir pressure below the target pressure?
h	$i_{cycle}<N_{ox}$	Are we in the oxygen filling phase?
j	$i_{cycle}<N_{air}+N_{ox}$	Are we in the air filling phase?
k	$i_{cycle}=N_{in}$	Flag used to identify $T_{V_T}^i$ (see control)
l	Volume just $=V_T$	Flag used to identify V^i (see control)

Table 5: Valve Logic. Truth tables for this calculation are provided in the appendix. Evaluated every software loop.

Valve A	$\neg a \wedge g \wedge h$
Valve B	$\neg a \wedge g \wedge \neg h \wedge j$
Valve C	$a \wedge b \wedge c$
Valve D	$(\neg a \wedge (d \vee (\neg e \wedge f))) \vee b$

Table 6: User Output calculated and displayed for the previous cycle.

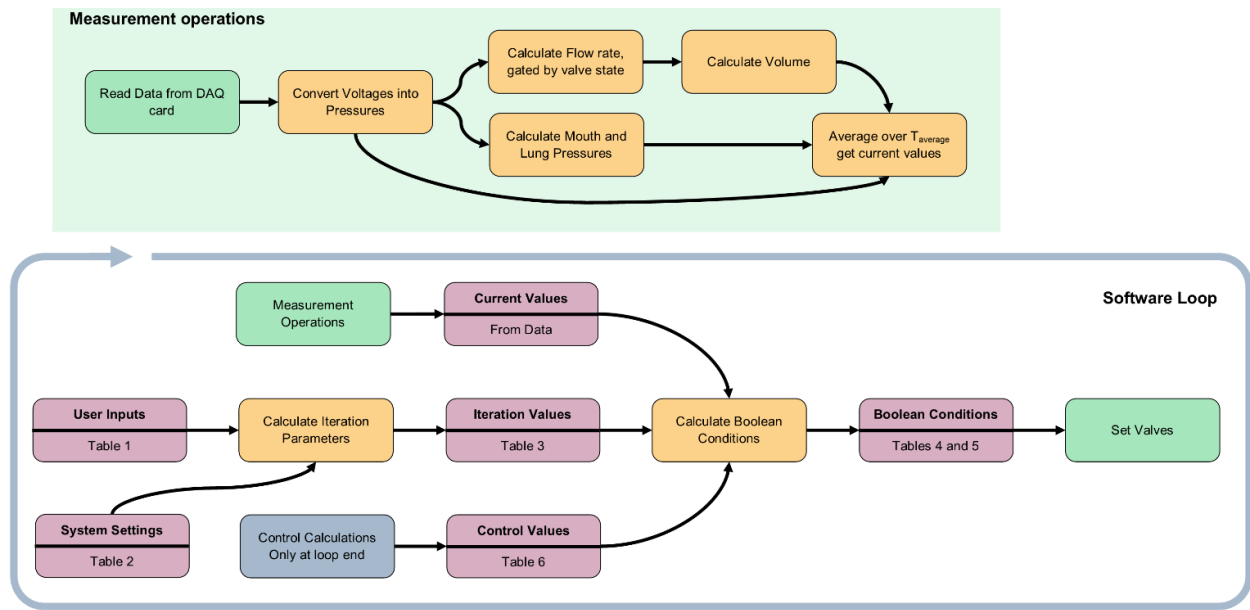| Peak pressure	Maximum pressure reached for P_{mouth}
PEEP	Minimum value of pressure
Tidal Volume Inhaled	Calculated volume inhaled
Tidal Volume Exhaled	Calculated volume exhaled
Minute Volume Exhaled	Projected volume exhaled over a whole minute

Figure 5: Flow chart of software implementation

Table 7: Control Parameters. Calculated at the end of each cycle.

Upper PEEP buffer ε_{PEEP+}	Pressure above PEEP to open exhalation pathway if pressure is increasing, e.g. 1 cmH$_2$O
Lower PEEP buffer ε_{PEEP-}	Pressure below PEEP to close exhalation pathway if pressure is increasing
P_{target}	Target value of P_{res}, tuned to achieve V_T
k_{res}	Gain term for the P_{target} control
ϵ	Error term for the P_{target} control
λ	Relaxation factor for oxygen control
N_{ox}	Number of software loops for oxygen
N_{air}	Number of software loops for air
R_{lung}	Lung resistance – calculated for PEEP control (see Figure 8)
C_{lung}	Lung compliance – will be calculated for P_{res} initial guess.

Control Algorithms

The system requires three simple control algorithms. The aims of these algorithms are:

1. To achieve tidal volume with the minimum required pressure, by choosing the appropriate P_{target}
2. To deliver the required gas concentration, while accurately achieving P_{target}, by choosing the appropriate N_{ox} and N_{air}
3. To achieve the target PEEP as efficiently as possible

For points 1 and 2, we make an initial guess when the value is changed, then use a proportional control to optimise. More extensive testing may show us that integral and derivative components or a non-linear proportional term are beneficial.

We anticipate adding some additional cases to Tables 6 and 7 to account for extra variables involved in the final form of the control algorithm.

Selecting P_{TARGET}

Currently, the system is operating with a proportional control. We are working on an approach to make an initial guess based on the system dynamics, but this requires refinement and will be described in future updates.

The input, ϵ, to the proportional control is dependent on whether the desired tidal volume was reached on the previous cycle,

The subsequently, use a proportional control with an input ϵ, where

- $\epsilon = \frac{V_T}{V^i}$, if V_T was not reached on the previous cycle, and only V^i was inhaled (store when k is true)

- $\epsilon = \frac{T_{V_T}^i}{T_{in}}$, if V_T was reached on the previous cycle in time $T_{V_T}^i$ relative to inhalation time T_{in} (store when l is true)

$$P_{target}^{i+1} = P_{target}^i + k_{res}(\epsilon - 1)$$

(8)

Selecting N_{OX} and N_{AIR}

First the total time to reach P_{target}^{i+1} is estimated, assuming a constant flow rate through valves A and B when open

$$N_{res}^{i+1} = \left(\frac{P_{target}^{i+1}}{P_{res}^i}\right) N_{res}^i$$

(9)

The initial guess for T_B/T_A is given by Equation (1)(i.e. at start or when FIO_2 changes)

$$\left(\frac{N_B}{N_A}\right)_{ideal} = \frac{(1 - FIO_2)}{(FIO_2 - 0.21)} \times 100 \text{ %}$$

(10)

We then iterate upon this based on the measured FIO_2^i

$$\left(\frac{N_B}{N_A}\right)^{i+1} = \left(\frac{N_B}{N_A}\right)^i + \frac{\lambda(FIO_2 - FIO_2^i)}{FIO_2}$$

(11)

with λ as a scaling factor.

Finally,

$$N_A^{i+1} = \frac{N_{res}^{i+1}}{1 + \left(\frac{N_B}{N_A}\right)^{i+1}}$$

$$N_B^{i+1} = \left(\frac{N_B}{N_A}\right)^{i+1} N_A^{i+1}$$

(12)

PEEP CONTROL

Conventional expiratory systems control PEEP by regulating air flow with a valve that provides varying resistance to flow. The simplest ventilators use a passive spring-loaded diaphragm system, with the resistance tuned by the clinician, to achieve the desired PEEP. Conventional ICU ventilators use actively controlled proportional valves that can vary their resistance in real-time, improving the performance significantly, but requiring complex and expensive expiratory valve subsystems. We have developed a solution that can achieve equivalent performance to existing ventilator designs, using only a single on-off valve.

The primary aims of ventilation (oxygenation and CO_2 clearance) require a balance between PEEP and minute volume (the total volume of gas breathed over a minute). A limiting factor for increasing minute volume is the time needed to exhale the tidal volume (the amount of gas in one breath). If a breath is not fully exhaled before the next breath starts (referred to as breath stacking), this can lead to hyperinflation and patient harm.
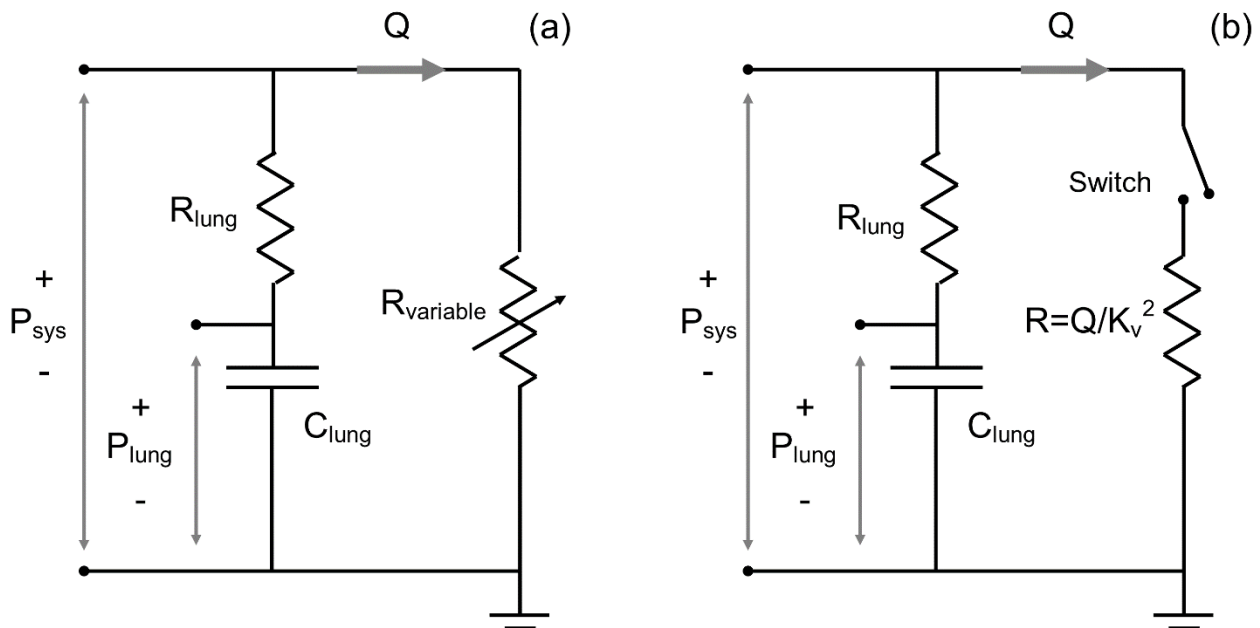

Figure 6: Lumped parameter models of (a) Conventional expiratory valve systems, using a variable resistance (b) Switching valve systems, using an on-off switch. Valve resistance increases with flow rate due to turbulence and can be calculated using flow factor K

For conventional systems (Figure 6a) with passive valves, a higher PEEP requires a higher resistance, and therefore increases the exhalation time (Figure 7a). Actively controlled proportional valves can mitigate this using complex control systems (Figure 7b). Switching systems (Figure 6b) are simple to implement but result in oscillating system pressures (Figure 7c). Our solution predicts lung resistance from a single breath, and thus enables short exhalation times under all clinically relevant conditions, with simple hardware and a straightforward control approach (Figure 7d).
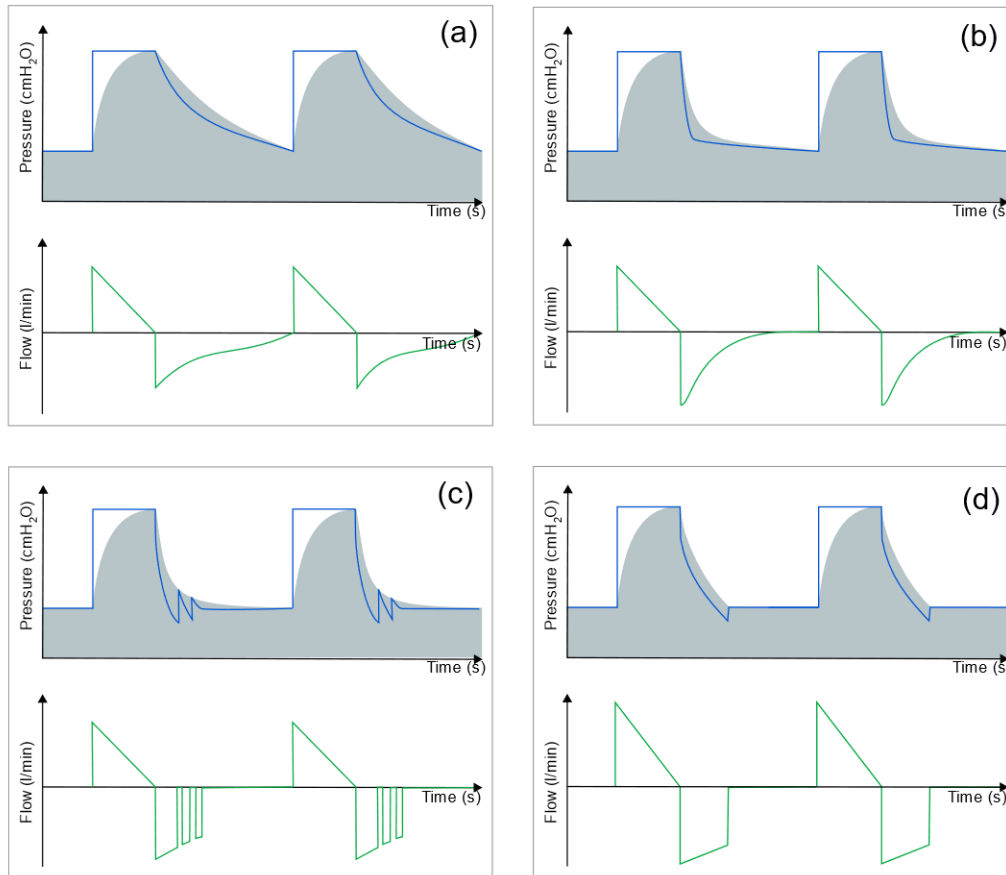
Figure 7: Representative pressure and flow curves for ventilation. Blue indicates system pressure, Psys, shaded grey regions indicate approximate pressure in the alveoli (downstream of the lung resistance). (a) Passive PEEP valve, with manually controlled resistance, (b) Actively controlled proportional valve, (c) Switching valve with basic control, (d) Switching valve with new solution.

In the basic switching system (Figure 7c), the controller closes the on-off valve when the system pressure reaches a setpoint at PEEP-ΔPEEP, with ΔPEEP defined as a system control parameter. Before the valve closes, the pressure in the lung (P_{lung} – see Figure 1) is higher than in the system (P_{sys}), due to the pressure drop across the lung resistance. Once the valve is closed, flow is stopped and the system pressure rapidly increases to match the lung pressure. When the system pressure exceeds PEEP+ΔPEEP, the valve opens again. This process is repeated until a stable P_{sys}=PEEP is achieved (Figure 7c). However, if the resistance of the lung is known in advance, P_{lung} can be predicted in real-time, allowing the valve to only shut once: at the point where P_{lung}=PEEP (Figure 7d).

Our solution enables us to estimate lung resistance based on the change in pressure and flow that occur when the valve position changes (Figure 8). Lung resistance can be characterised according to R=ΔP/ΔQ.

Figure 8 uses a model lung. R is initially set to 0 (cmH$_2$O/(l/s)), hence assuming zero airway resistance, and the predicted lung pressure (grey) and system pressure (blue) are equal. When the valve first closes (~1.6 seconds) the change in pressure, ΔP, and flow, ΔQ, are captured (Figures 3 b and d). R is then calculated and applied at the start of the next breath (~4s). In the second cycle, the true lung pressure can be observed, and the switching only occurs once, as when the valve closes, the system and lung are already in equilibrium.

As a switch still occurs, the lung resistance can be continually monitored to account for dynamic changes.

In cases of high lung resistance or high lung compliance, pressure equalisation between the lung and system, as well as response time of the software or hardware can result in an undershoot, resulting in a PEEP that is too low by ε_{PEEP}. In this case, on the subsequent cycle, the valve is triggered when the estimated lung pressure reaches PEEP+ ε_{PEEP}, which successfully accounts for the delay on the subsequent breath.
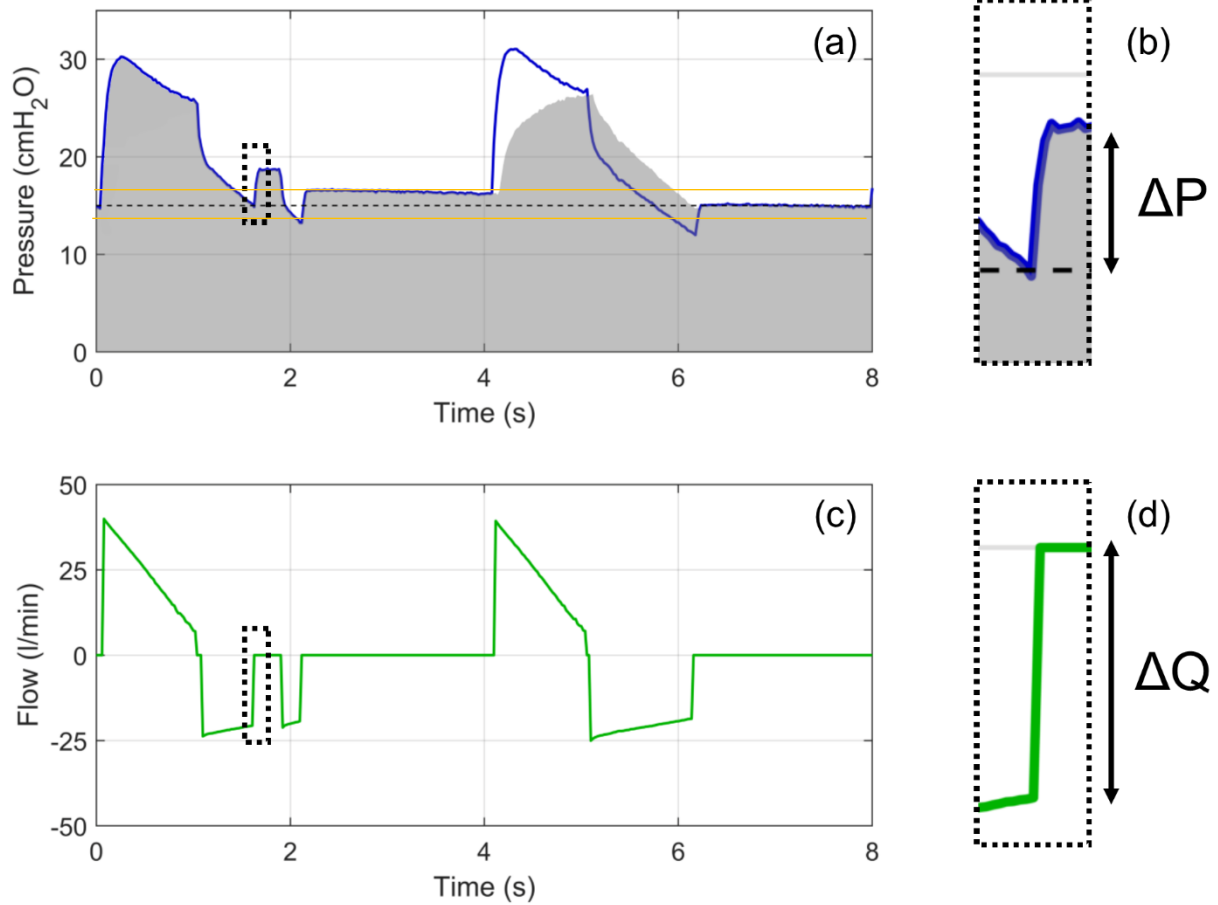
Figure 8: Pressure and flow traces from an experiment with an artificial lung, $R_{lung} \sim 20$ cmH$_2$O/(l/s), Clung~35 ml/cmH$_2$O. (a) blue line shows system pressure and grey line shows estimated lung pressure P_{lung}, (b) shows signal in dashed region and the corresponding pressure jump ΔP that occurs after the switch. (c) and (d) show the corresponding flow traces and the change in pressure ΔQ

HARDWARE SPECIFICATIONS

GENERAL REQUIREMENTS

The system is designed to be buildable with readily available solenoid valves, pressure sensors and pneumatic components, plus an oxygen sensor and safety features. In the following, we provide general performance details determined from our prototyping process. We then provide guidelines for constructing our Mk III prototype.

VALVES

All valves must be 'oxygen clean', but this criterion is only critical on valves A and C (as D operates at low pressures). The flow coefficient of the valves is a critical part of the system performance. Note that if the flow coefficient is too high, the additional resistance can be added with ease using small diameter tubing.

Approximate values are provided below. Modelling is ongoing to characterise optimal ranges.

- Valves A and B to be rated at C_v~0.05 (orifice ~ 1 mm)
    - High enough to allow P_{res} to reach target during exhalation phase
    - Low enough to allow sufficient resolution on gas mixing control
    - If choice is limited, lower C_v is preferable to higher C_v
    - NC to protect from high pressure in event of power failure
- Valve C needs to be rated at C_v~0.2 (orifice ~ 2.5 mm)
    - High enough to allow peak flow requirements
    - Low enough such that pressure drop across it regulates flow into lung and allows accurate flow measurement
    - If choice is limited, lower C_v is preferable to higher C_v
    - NC to protect from high pressure in event of power failure
- Valve D needs C_v~0.4 (orifice ~ 6mm)
    - High enough to not limit exhalation
    - If choice is limited, higher C_v is preferable to lower C_v
    - Optimally, NO to allow breathing in event of power failure (current prototype does not include NO, due to delay in sourcing).
    - Could be replaced by solenoid pinch valves with comparable flow characteristics that compresses disposable tubing to avoid the need for cleaning

We are also considering a possible valve E, in parallel with valve D, but with a lower flow coefficient. This would allow for three finite levels of resistance in the exhalation pathway, which may be useful for extreme cases (outside the MHRA specifications), as well as additional functionality for potential future use of the system in support mode. However, this would require multiple flow calibrations, or more likely a flow sensor, so we are not directly pursuing this at present.

PRESSURE SENSORS

- P_{res} range must be up to 1020 cmH$_2$O, accuracy ideally better than 10 cmH$_2$O
    - Due to the pressure drop across valves A and B, no more than 1 bar pressure will occur in this part of the system. Using a smaller range optimises for accuracy, which is important as this sensor plays a role in calculation of the inhalation flow rate.
- P_{sys} range must be up to 100 cmH$_2$O, accuracy must be better than 2 cmH$_2$O
    - Using higher range would sacrifice accuracy on calculation of both inhalation and exhalation flow rates. Minimal drift is advantageous.

In the prototype, we have used voltage output (pre-amplified) sensors, which minimises reliance on additional circuitry. We have also used sensors with male ¼" G threads, which are widely available and provide a robust connection.

OXYGEN SENSOR
- Our current pressure sensor has the key characteristic of having a response time of less than 15 seconds. It also has a male 3/8" G threaded connector which is convenient for interfacing. A custom amplifier circuit with a gain of 100 was built for this.

ANALOGUE TO DIGITAL CONVERSION
- We are using a National Instruments USB 6001, which is the bottom end of the NI multifunction DAQ range. It has a 14-bit ADC and multiple digital output ports for controlling the valves.

LOGIC CONTROLLER
- This block provides an interface between the DAQ card and the solenoids, such that the 5V digital lines can switch on the higher current 24V supply to switch the solenoids
- Each output provides 24V when the associated input is at digital high
- Solenoids require full voltage to switch, but not to hold, hence the reference line outputs 0V only when switching
- At all other times it outputs a square wave with period significantly less than solenoids switching time (e.g. 2ms). The duty cycle of the square wave determines holding voltage.

POWER SUPPLIES
Our system uses two 24V power supplies in order to separate the valve supply from the pressure readings, and thereby reduce noise.

- Switch mode power supply
  - For driving solenoids
  - Current requirement dependent on solenoids, 3A is likely to be sufficient
- Linear Power Supply
  - To provide a clean input for pressure sensors
  - Low current, low noise (e.g. <30 mV pk to pk ripple),

UPS
Although not visualised here, we run the mains power through a standard uninterruptible power supply (UPS), giving protection for power loss for more than 30 minutes.

COMPUTER
The system is run by a PC or laptop, running LabVIEW or an executable file generated using LabVIEW.

TOTAL POWER USE
Although the current prototype runs from the mains, the power usage is <50W (excluding the computer).

PROTOTYPE SPECIFICATIONS

The following specifications describe our current prototype. We will continue to refine the enclosure design to optimise for easy fabrication using a larger enclosure. The base, label covers, risers for the DAQ and amplifier, and the bottle holder have been laser cut from 3 mm acrylic. Drawings can be shared if requested.
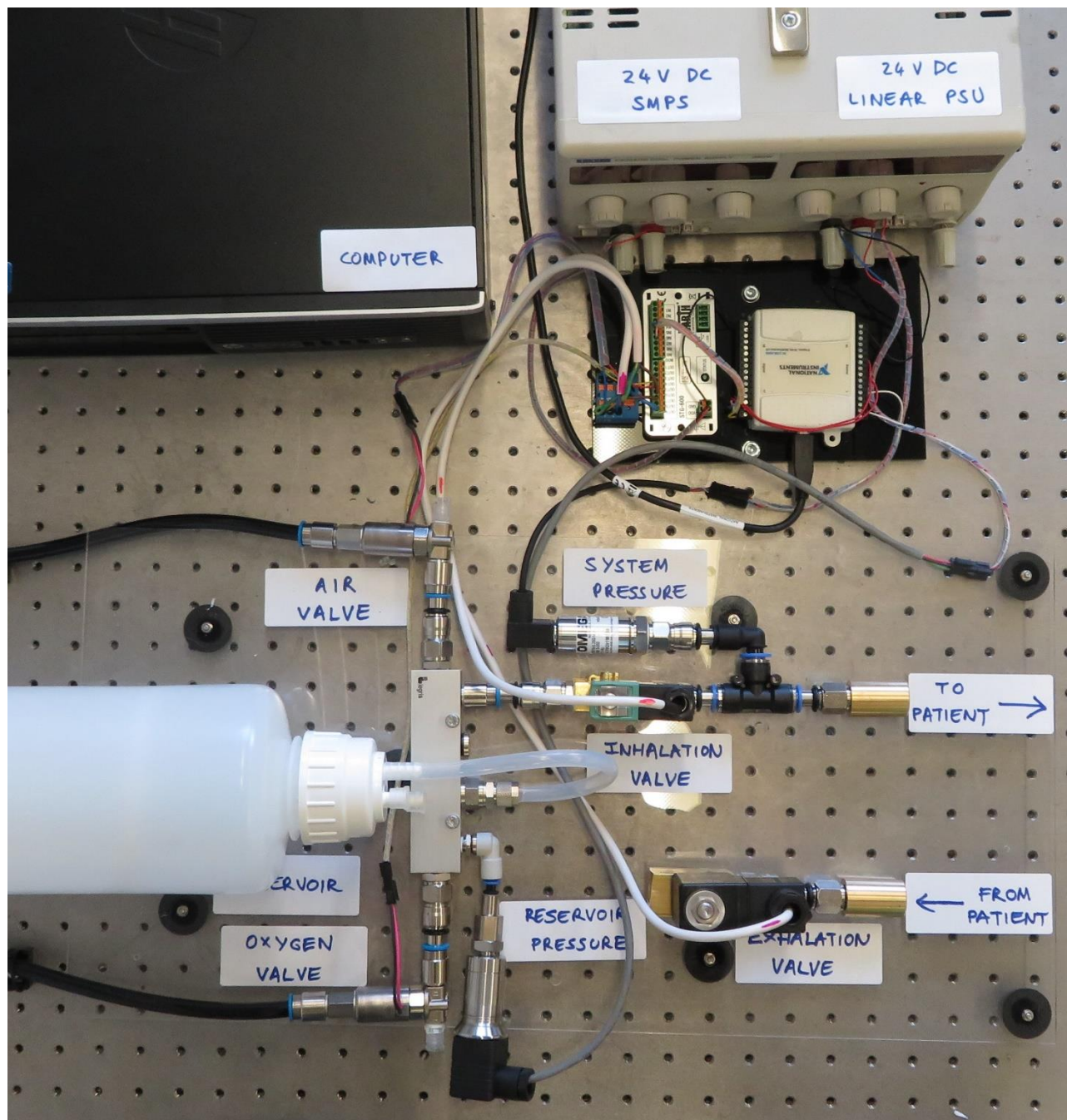
SAMPLE IMAGES

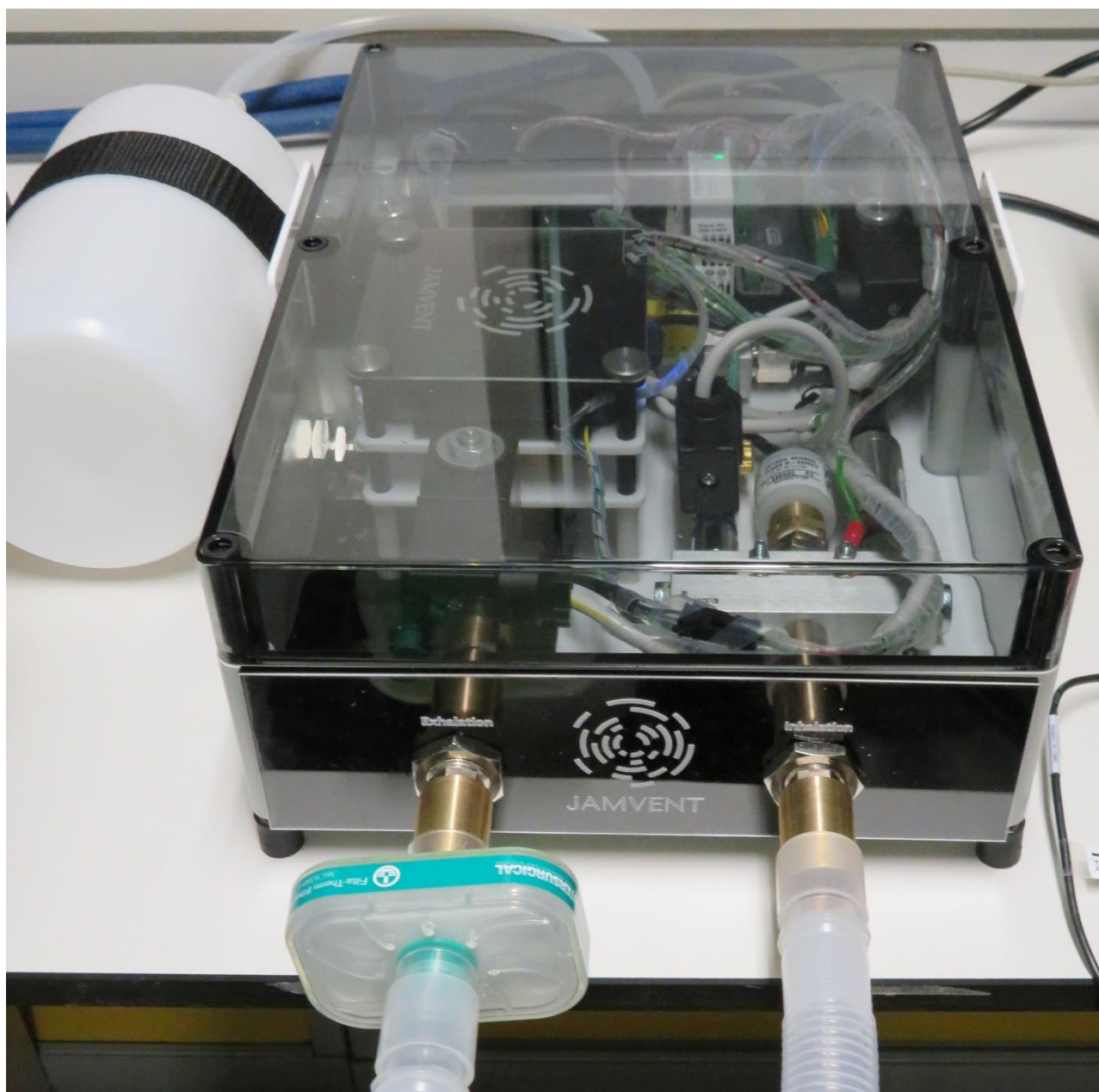**Figure 9:** the Mk II prototype with labels indicating key components.

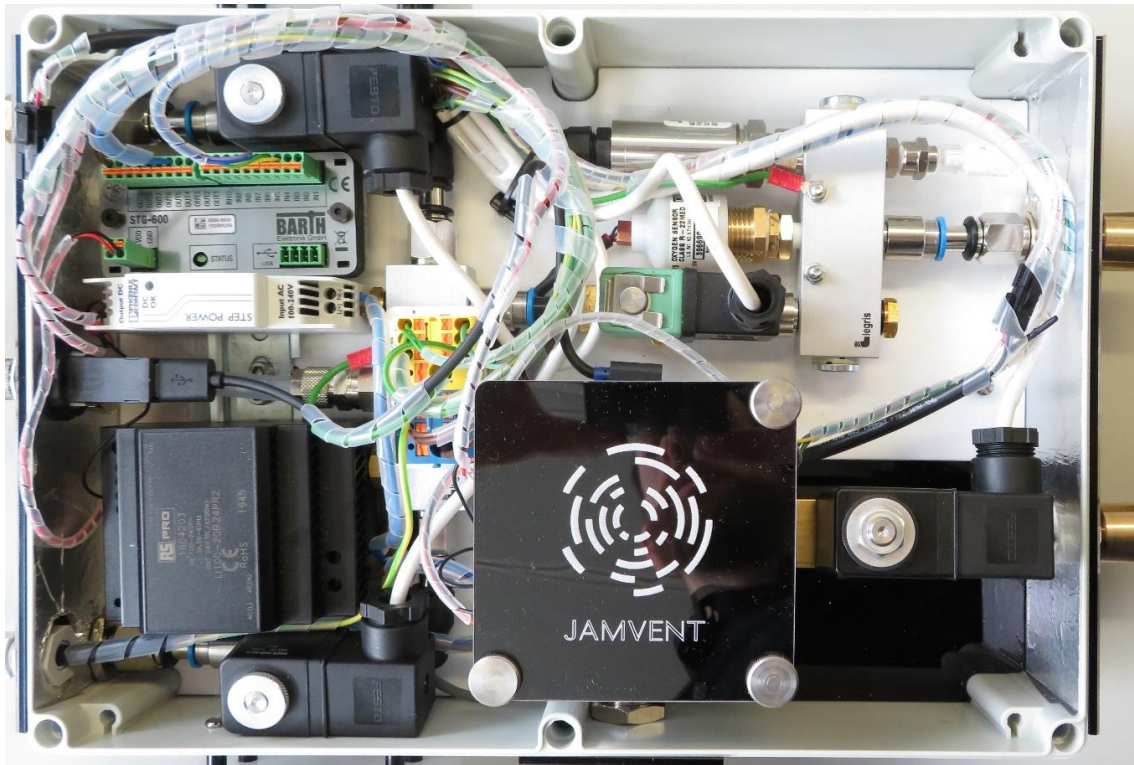**Figure 10**: External view of the Mk III prototype
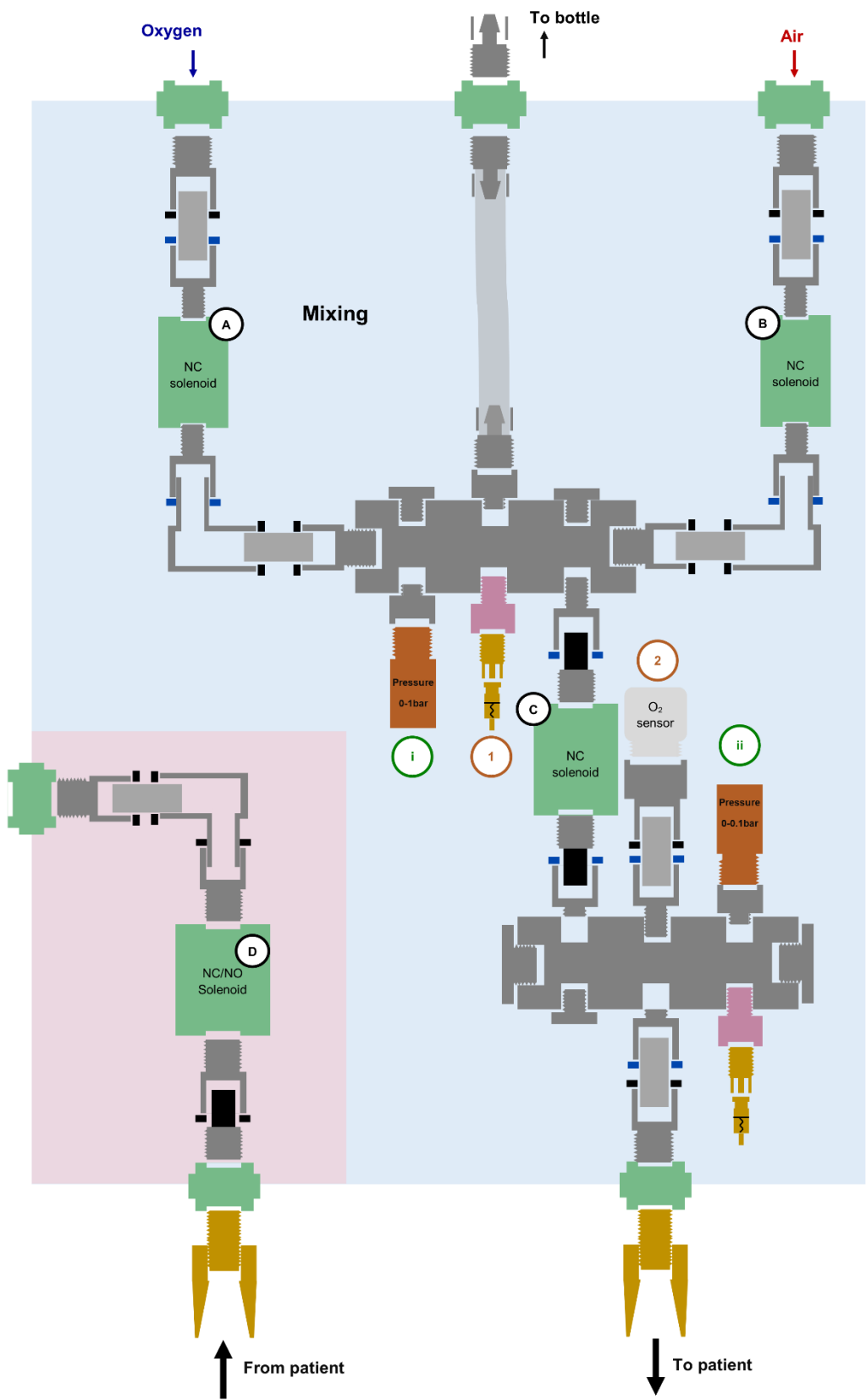
Figure 11: Internal view of the Mk III prototype
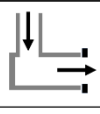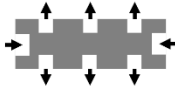
Figure 12: Pneumatic connections for prototype Mk III

Table 8: Pneumatic connections

Part	Left Connector	Right Connector	Number	Part	Left Connector	Right Connector	Number
	F 1/4" G Bulkead	F 1/4" G	5		M 1/8" G	F 1/8" NPT	2
	M 1/4" G	10 mm push-in	8		F 3/8" G	10 mm push-in	1
	M 1/8" G	10 mm push-in	8		F 1/4" G	22 mm	2
	M 1/4" G	Barb (for 10 mm push-in)	3		10 mm plug-in	10 mm plug-in	7
	End	M 1/8" G	3		M 1/4" G	10 mm plug-in	3
	End	M 1/4" G	2		10 mm plug-in	10 mm push-in	3
	M 1/4" G	M 1/4" G	2		F 1/4" G	F 1/8" G	2
	M 1/8" G	F 1/4" G	3		M 1/8" NPT	Male luer lock	2

ELECTRICAL CONNECTIONS

Figure 13 shows a schematic of the electric connections in the system. The bypass wires between digital lines P0.2 and P0.3 and analogue inputs AI2 and AI3 is a simple way to help with synchronisation of the flow rate calculation with the valve switching.

Figure 13: Electrical Connections Schematic

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JAMVENT

BILL OF MATERIALS FOR PROTOTYPE

Company Name:	Imperial College London
Name of product:	JamVent
Version number of product:	5.0
Date:	09/04/2020
Version number of BOM:	4

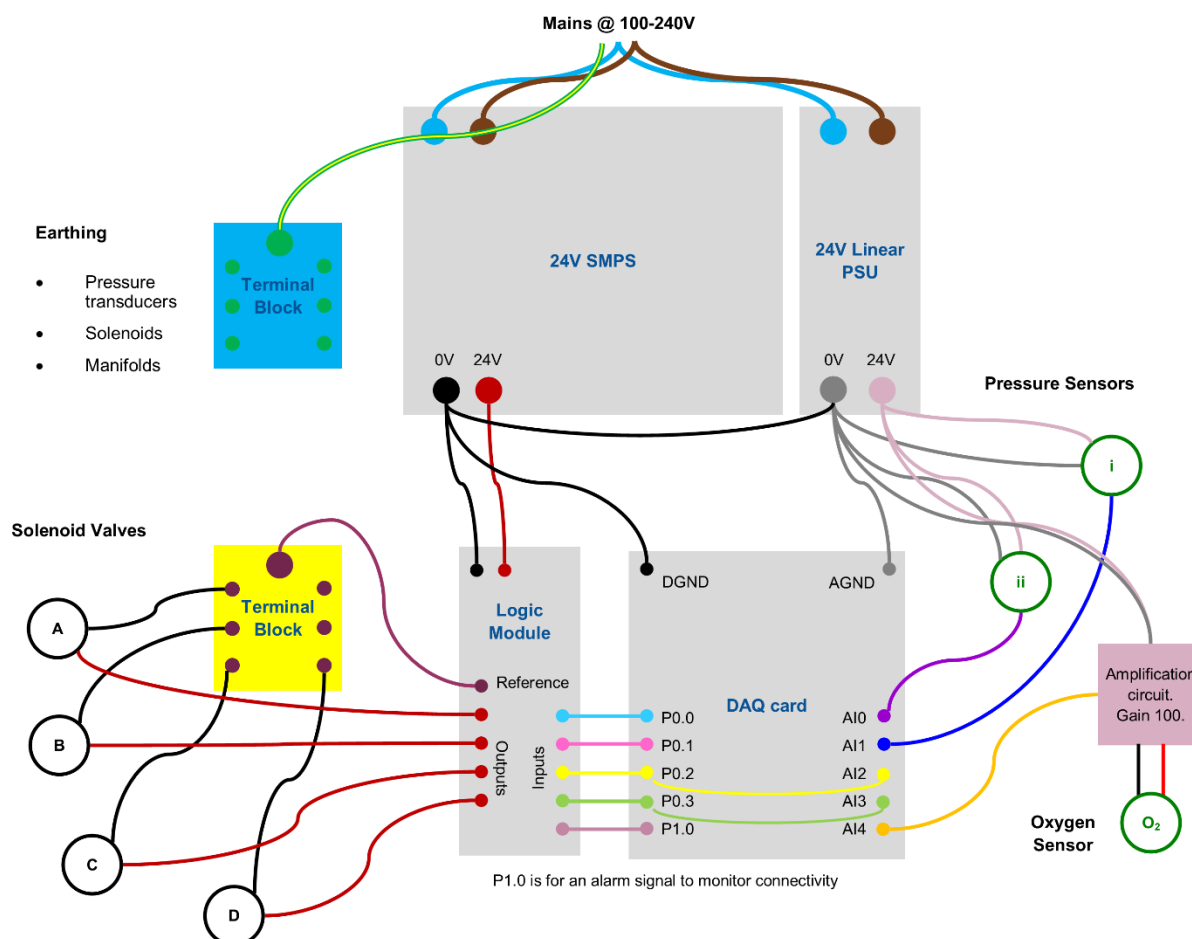| Category	Description	Part #	Vendor	Quantity	Link
Key Components	2/2 DC solenoid, C_v~0.2, NC (valve C)	SCG256B404VMS.24/DC	Asco	1/2*	Link
	2/2 DC solenoid, C_v~0.4, NC (valve D) – see	VZWD-L-M22C-M-G14-60-V-1P4-4	Festo	1	Link
	2/2 DC solenoid, C_v~0.04, NC (valve A/B)	VZWD-L-M22C-M-G18-10-V-1P4-50	Festo	2	Link
	100 kPa range pressure sensor	PXM319-001G10V	Omega	1	Link
	10 kPa range pressure sensor	PXM319-0.14G10V	Omega	1	Link
	Oxygen Sensor	C43690-R22MED	TeleDyne	1	Link
Pneumatic connectors	F 4 Bar Oxygen Nist Female to 1/8" BSP Male	3601118BS	MEC Medical	1	Link
	F 4 Bar Air Nist Female to 1/8" BSP Male	3601518BS	MEC Medical	1	Link
	Flashback arrestor	0764470RS	GCE	1	Link
	F 1/4"G bulkhead	0920 00 13	Legris	5	Link
	M 1/4"G adapter to 10 mm push	176-1761	RS	8	Link
	M 1/4"G adapter to 10 mm barbed push	176-0940	RS	3	Link
	M 1/8" G to 10mm	QS-G1/8-10-I	Festo	7	Link
	F 1/4"G to M 1/8"G	367-5708	RS	3	Link
	10mm plug to 10 mm plug	3120 10 00 85	Legris	6	Link
	elbow, 10mm push to 10mm plug	3182 10 00	Legris	3	Link
	Manifold 2 x G 1/4, 6 x G 1/8	3313 10 13 03	Legris	2	Link
	1/4" G stopper	0919 00 13	Legris	2	Link
	1/8" G stopper	0919 00 10	Legris	3	Link
	M 1/4" to M 1/4" G	0901 00 13	Legris	2	Link
	M 1/4" G to 10mm plug	3131 10 13	Legris	4	Link
	F 3/8" G to push in 10 mm	176-1771	RS	1	Link
	M 1/8" NPT to Luer Lock	WZ-45505-86	Cole-Parmer	2	Link
	M 1/8 R To F 1/8" NPT	0167 10 11	Legris	2	Link
	Thread to 22mm ISO vent connector			2	N/A
Pneumatic valves	F Luer to M luer, opening pressure 16.56 PSI	541542PB-0200S000	Smart Products	1	Link
	F Luer to M luer, opening pressure 2.09 PSI	541542PB-2000S000	Smart Products	1	Link
Pneumatic reservoir	2 L vacuum bottle - plastic	2126-2000	Thermo Scientific	1	Link
	Lid for vacuum bottle with 1/4" tubing	2162-0531	Thermo Scientific	1	Link
Electronics	24 V dc SMPS (>3 A output)	190-4203	RS	1	Link
	24 V dc LPS (low noise, >500 mA)	708-0444	Phoenix contact	1	Link
	Cable Gland	53111220+53119120	Lapp	1	Link
	Terminal Block (Blue)	PTFIX 6/6X2,5 BU	Phoenix contact	1	Link
	Terminal Block (Yellow)	PTFIX 6/6X2,5 YE	Phoenix contact	1	Link
	USB Connector, panel mount	111-6759	Harting	1	Link
	USB Connector, dust cover	125-7929	RS PRO	1	Link

	Amplifier (for Oxygen sensor)	AD620	Analog Devices	1	Link
	Uninterruptible Power Supply	TS1000B	OPTI	1	Link
	M4 spacers, 16 mm	TNSPG-M4-8-16-I/S	Richco	4	Link
	M4 spacers, 25 mm	SS 8 8L	Richco	4	Link
	M4 spacers, 30 mm	TNSPG-M4-8-32-I/I	Richco	4	Link
	Alarm	457-027	RS PRO	1	Link
	Enclosure	11101201	Spelsberg	1	Link
Control	>4 AI (single-ended), >4 DO	USB-6001	National Instruments	1	Link
	STG600, Logic controller / relay	0850-0600	Barth	1	Link
	Logic controller mounting bracket	122-1520	Barth	1	Link
Misc	Male USB A to Male USB A	121-6564	RS	1	Link
	Black 3mm A4 Acrylic			1	
	Clear 1mm A4 Acrylic			1	
	White 3mm A4 Acrylic			1	
	White 3mm A3 Acrylic			1	
	M6 feet, 15mm diameter, 15mm Stud	126-4934	RS	6	Link
	M4 nuts			<10	
	M4 , 10 mm			<30	
	A few(<5 each) resistors and capacitors				
	Small piece of breadboard (~10x10 rows)			1	
	4 core wire			2 metre	
	3 core wire				
	single core wires (7 colours preferred)			0	

* the optional second C_v~0.2 valve would be suitable valve E in parallel with valve D if it is beneficial as described in Valves section.

APPENDIX

Sample Calibrations
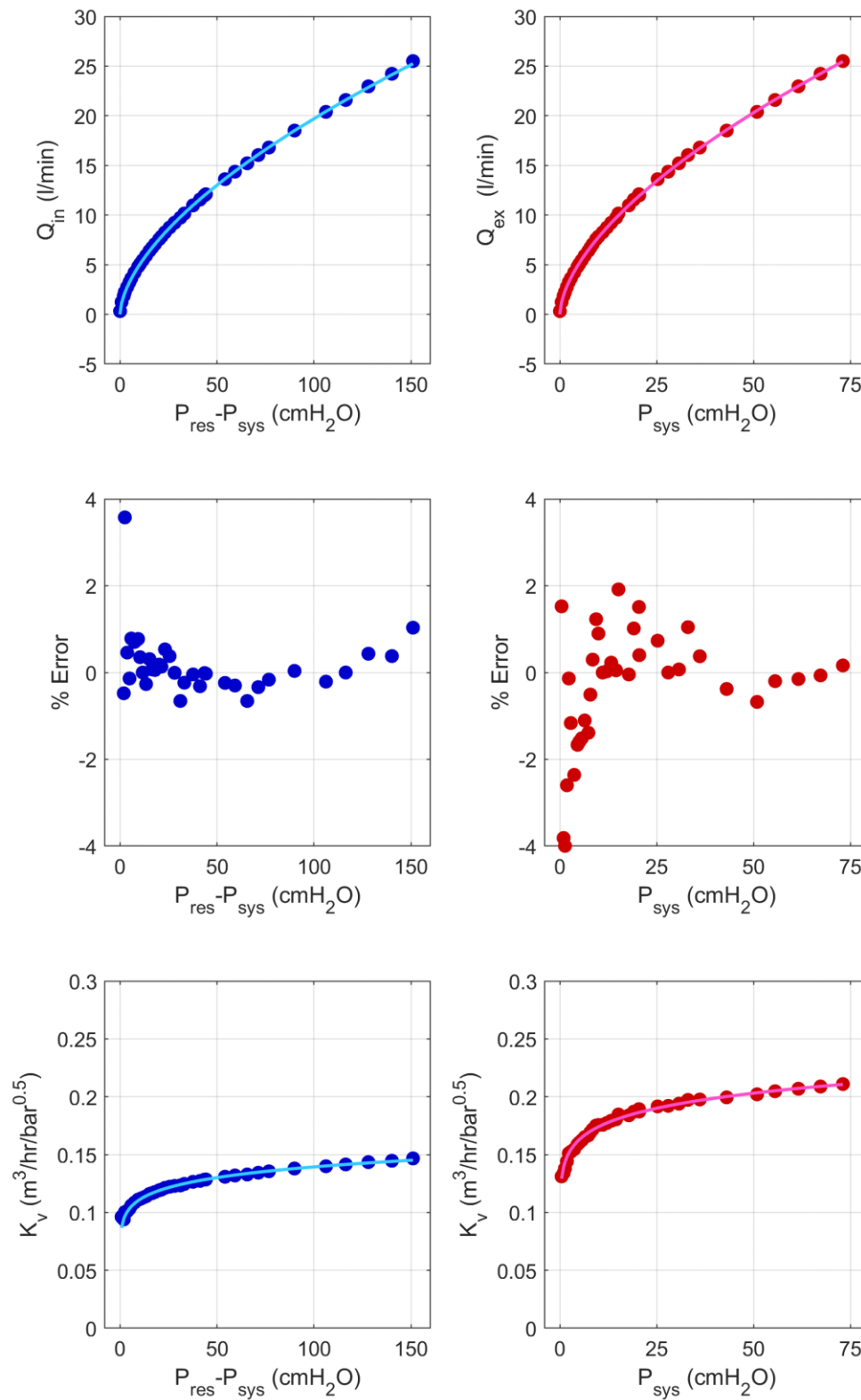
Figure A1: Sample calibrations. Blue is inhalation side, red is exhalation side. Flow rate was measured with Honeywell AWM720P1 flow sensor, itself calibrated with variable area flow meters. Nonlinear regression yielded $Q_{in} = 1.2487 \, \Delta P^{0.5991}$, $Q_{ex} = 1.9748 \Delta P^{0.5958}$.

COMPACT TRUTH TABLES

VALVES A AND B

Table A1: Truth table for valves A and B.

a	g	h	j	Valve A	Valve B
1	All combinations			0	0
0	0	All combinations		0	0
0	1	0	0	0	0
0	1	0	1	0	1
0	1	1	0	1	0
0	1	1	1	1	0

VALVE C

Table A2: Truth table for valve C.

a	b	c	Valve C
0	All combinations		0
1	0	0	0
1	0	1	0
1	1	0	0
1	1	1	1

VALVE D

Table A3: Truth table for valve D.

a	b	d	e	f	Valve D
1	0	All combinations			0
0	0	0	0	0	0
0	0	0	1	0	0
0	0	1	0	0	1
0	0	1	1	0	N/A
0	0	0	0	1	1
0	0	0	1	1	0
0	0	1	0	1	1
0	0	1	1	1	N/A
0/1	1	All combinations			1

Imperial College London

Drawing for ¼" G to 2mm adaptors

Thread to suit 1/4" BSP running nipple

SECTION A-A
SCALE 2 : 1

	NAME	SIGNATURE	DATE		
DRAWN	S S Sangha		30/03/2020		
CHK'D					
APPV'D					
MFG					
Q.A					

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH:
TOLERANCES:
 LINEAR:
 ANGULAR:

FINISH:

DEBURR AND BREAK SHARP EDGES

DO NOT SCALE DRAWING

REVISION

TITLE:

Ventilator_head3

MATERIAL:
Brass

DWG NO.

A4

WEIGHT:

SCALE:1:1

SHEET 1 OF 1
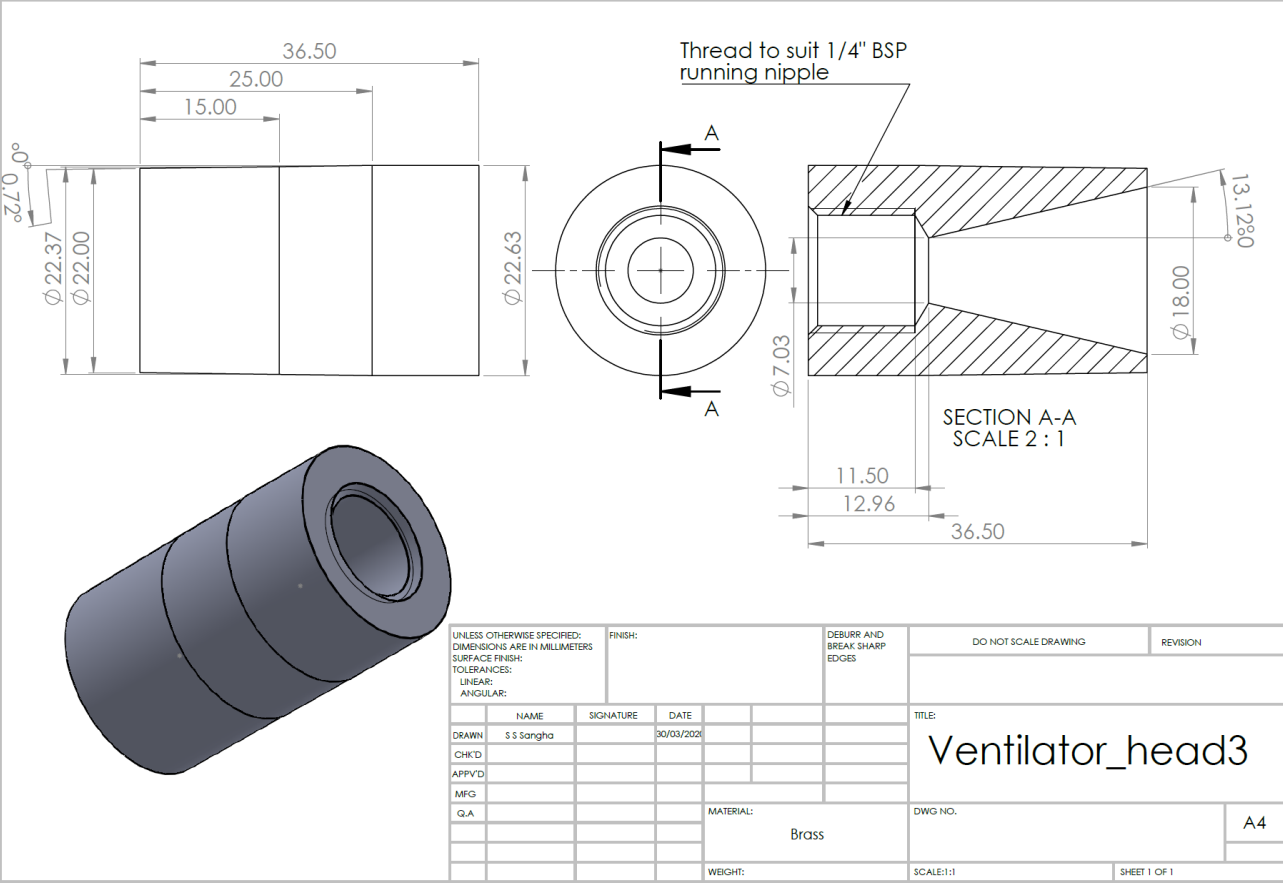
Drawing by Satpal Sangha

TABLES OF REQUIREMENTS

The following tables describe key regulations set out in the MHRA documentation, please refer to RMVS001 v3.1 for the complete documentation Version 3.1 (note page numbers may vary following further amendments).

Table A4: Features to be present in the user interface.

pg.	Section	Part	Comment
5	Ventilation		Airway pressure must be limited to 35 cmH$_2$O by default, can increase up to 70 cmH$_2$O if positive decision provided by user.
6	Ventilation Labelling	5a Par. 5	I:E ratio should be 1:2 by default setting. FiO$_2$: 90-100%, Tidal volume: 400 ml, PEEP: 15 cmH$_2$O, Respiratory rate: 20 breaths/min.
6	Ventilation	6a	Respiratory rate should be limited to 10 - 30 breaths per minute.
6	Ventilation	7d	Maximum Tidal Volume is 800 ml.
8	Monitoring and Alarms	2a	Must show current settings of tidal volume, respiratory rate, PEEP, FiO$_2$, ventilation mode.
8	Monitoring and Alarms	2b	Must show the actual current airway pressure.
8	Monitoring and Alarms	2c	Should show the achieved expiratory tidal volume, respiratory rate, PEEP and FiO$_2$.
5	Ventilation	1c	User set alarms for upper and lower limits on tidal volume. We suggest default ± 100 ml
We suggest			Also showing inspiratory tidal volume and expiratory minute volume.
We suggest			Button to correct airway pressure for a filter using filter flow factor
We suggest			Start/stop switch, with required positive decision by user.

Table A5: Labels that must be visible on the enclosure.

pg.	Section	Part	Comment
10	Misc.	6d	Clear label of all critical functions and controls. Use standard terms, pictograms and colours.
3 & 5	Testing	2&3	Must have sign saying "Device not CE marked. Usage of this device must cease after the end of the COVID-19 epidemic has passed."
14	Labelling	Par. 1	Must have a label with the words: "Follow Instructions for Use", accompanied by the following ISO 7010 compatible permanent labels: M002, M004, M009, M013 and M016.
15	Labelling	Par. 2	System inlets and outlets must be clearly marked with direction arrows on the top of the box.
15	Labelling	Par. 4	A clearly visible permanent label with the words "Manual Back Up Ventilation Must Be Available" in a minimum of 50 point text.
15	Labelling	Par. 5	Clear mark or label to indicate the default settings of 90-100% oxygen, 400 ml tidal volume, 15 cmH$_2$O PEEP, respiratory rate 20 breaths/min.
	Pressurised gas input		Inlets for pressurised gases must be marked with the gas name or chemical symbol and the rated gas pressure.

Table A6: Accuracy of measurements.

24	Acceptable Performance	b.p. 1	Under steady-state conditions (once periodic breathing cycles have been achieved), the indicated airway pressure must be accurate to ±4% of the reading, with an additional buffer of ±2 cmH$_2$O.
24	Acceptable Performance	b.p. 2	Measurement of expired volumes must be ±15%.
24	Acceptable Performance	b.p. 3	Oxygen concentration must be within ±5% of the set value.

Table A7: System performance tests required for MHRA approval.

pg.	Section	Part	Comment
9 & 11	Miscellaneous	1 & 2	Must be capable of continuous operation for 14 days. Expected device duration must be specified.
6	Ventilation	4b	Airway pressure must remain pressurised to at least the PEEP. Note: our design deliberately uses the PEEP control algorithm to maintain intrapulmonary pressure above PEEP, and in doing so increases performance.
7 & 8	Gas & Electricity	4	All elements in gas pathway must be biologically safe (ISO 18562-1:2017) and meet low-pressure oxygen safety standards.
7	Appendix A	Par. 3	*Preferably* all components in direct contact with the patient's breath will be disposable. Alternatively the process for sterilising reusable components should be detailed in the instructions for use. If disposable, patient's expired gas route should be labelled with words "Do not re-use". Or must be decontaminated between patients. Note: in our system, we will use non-disposable parts and therefore must describe decontamination procedure.
7	Gas & Electricity	3d	Gas inlets must be at least 10 cm apart (between centres).
7	Gas & Electricity	3d	Outlets to patient must be 22 mm male connectors and must not be plastic.
7	Gas & Electricity	2	Must connect to mains via a UK 3 pin plug.
7	Gas & Electricity	2b	Must be PAT tested to the adapted IEC 6061, IEC 62353 standards.
7	Gas & Electricity	2c	Must have 20 minutes of backup battery in case of a power failure.
7	Infection control	1	All parts coming into contact with patient's breath must be either disposable or reusable.
10	Testing	4	Must be usable when wearing a gloves, eye goggles, plastic apron etc.
15	Pressurised gas		Limit reverse flow from system into gas supply to 100 ml/min in normal condition or single fault condition. Note: our design inherently complies.
15	Pressurised gas	8	Each high pressure input port shall be provided with a filter having a pore size less than or equal to 100 µm.
24	Pressure Relief	-	"**Pressure relief Test**". See page 24.
24	Closed Suctioning		"**Closed Suctioning Test**". See page 24.
24	EMC Testing		"**EMC Testing (TBC)**", Must comply with IEC 60601-1-2:2014
	Sound Levels		Must be documented.

Table A8: Specifications for the enclosure.

pg.	Section	Part	Comment
9	Biological Safety	2E	Should (not must) only use organic compounds with boiling point >260°C.
14	General	1	Enclosure must be at least IP22 protected.
14	General	1	Must experience no harmful effects when the enclosure is tilted at an angle up to 15° from its normal position and exposed to dripping water for a duration of 10 minutes and a water flow equivalent to 3mm rainfall per minute.
14	General	2	Box must be cleanable using a cleaning wipe.
14	General	7.5	No connection to exhaust port required for our design.

Table A9: Details of the alarms that must be included in the system.

pg.	Section	Part	Comment
8	Monitoring and Alarms	1a	Gas or electricity failure.
8	Monitoring and Alarms	1b	Machine switched off while in mandatory ventilation mode.
8	Monitoring and Alarms	1c	Inspiratory airway pressure exceeded.
8	Monitoring and Alarms	1d	PEEP not achieved.
8	Monitoring and Alarms	1e	Tidal volume not achieved or exceeded.
N/A	N/A		Negative pressure – if this occurs, open exhalation valve.
8	Monitoring and Alarms	Intro	Multiple alarm levels and sounds. See IEC60601-1-8:2006.
22	Acceptable Performance		If patient becomes disconnected, a disconnect alarm will sound within 3 seconds of disconnection. Note: we need to establish the best way to detect this.