DESIGN DOCUMENT

VERSION 5.0.1

12/04/2020

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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.

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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 cmH2O, but possibly up to 60 cmH2O 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 cmH2O – normal working range is 30 cmH2O

• Plateau pressure not to exceed 35 cmH2O by default, with option to increase to 70 cmH2O

• Peak pressure should not exceed plateau pressure by more than 2 cmH2O

• Exhalation pressure (PEEP) of 5-20 cmH2O

• 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.

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DESIGN SCHEMATIC

**Figure 1:** Overall Design Schematic

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OPERATING PRINCIPLES

GAS MIXING

• During Exhalation phase, oxygen valve (A) and air valve (B) open to reach a target pressure in the reservoir Pres =Ptarget

• 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.

• FIO2 is determined according to proportion of the time that Valve A is open (TA) relative to Valve B (TB),

FIO2 = (1 + 0.21 TBTA) /(1 + TBTA) × 100 % (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:

Qin = aC∆PnC (2) where

∆P = Pres − Psys (3)

and the values of aC and nC can be calculated by calibration.

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

Vin = ∑Qin dt (4)

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

Pmouth = Psys − αQin2 /Kf2 (5) where Kf2 is the flow factor for the filter [m3/hr/bar0.5] and α = 0.005 is a conversion factor for units of l/min and cmH2O

• When Vin = VT (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

Qex = aDPsysnD (6)

and the values of aD and nD can be calculated by calibration.

• Pressure in mouth is given by

Pmouth = Psys + αQex2 /Kf2 (7)

• When Pmouth = PEEP, exhalation valve (D) closes to maintain lung pressure and keep alveoli open.

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END OF CYCLE

• Inhaled and Exhaled tidal volume, Exhaled minute volume, Peak pressure and PEEP are calculated for last cycle

• Ptarget for next cycle is calculated based on achieved Inhaled Tidal Volume relative to VT or how much before the end of the inhalation VT was reached

**Figure 2**: (a) Overview of valve timing. (b) Schematic of air movement during each phase of the timing cycle.

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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 FIO2 and peak pressure.

**Figure 4:** Flow chart for software implementation

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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

FIO2 Fraction of inspired oxygen.

Tidal Volume (ml), VT Volume of air entering lungs during the inhalation period

Respiratory Rate (1/min) Number of breaths per minute

PEEP (cmH2O) 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 (cmH2O)

Maximum pressure in the lung. A safety factor that can be varied from the default value of 35 cmH2O up to 70 cmH2O 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, Tloop Software controlling timing parameter, e.g. 0.02 ms

Buffer length (s) Time to store data for and display on screen

Tsample (s) = 1/Acquisition Rate Time that each sample represents, e.g. 0.005 ms

Mbuffer = Buffer Length x Acquisition Rate Total number of samples in buffer

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

Tbreath (s) 60/respiratory rate Period of full breath cycle, e.g. 4 s

iloop - Iteration number of the software loop

Ncycle Tbreath/Tloop Number of software loops per breathing cycle

icycle remainder(iloop, Ncycle) Iteration number within a given breathing cycle

Nin I:E Ratio x Ncycle Number of software loops for inhalation period Mcycle Tbreath x Acquisition

rate Number of samples per cycle

**Table 4**: Boolean Conditions. Evaluated every software loop.

a icycle<Nin Are we in the inhalation phase?

b Psys<Pmax Is the pressure below the maximum limited pressure

c Volume<VT Is the current volume less than desired tidal volume

d Valve D(icycle -1) What was the previous state of the exhalation valve (D)

e Pmouth > PEEP + εPEEP+ Is the current mouth pressure above the threshold

f Pmouth< PEEP – εPEEP- Is the current mouth pressure below the threshold

g Pres<Ptarget Is the reservoir pressure below the target pressure?

h icycle<Nox Are we in the oxygen filling phase?

j icycle<Nair+Nox Are we in the air filling phase?

k icycle=Nin Flag used to identify TVTi (see control)

l Volume just =VT Flag used to identify Vi (see control)

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

Valve A ¬a ∧ g ∧ h

Valve B ¬a ∧ g ∧ ¬h ∧ j

Valve C a ∧ b ∧ c

Valve D (¬a ∧ (d ∨ (¬e ∧ f))) ∨ b

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

Peak pressure Maximum pressure reached for Pmouth

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

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**Figure 5:** Flow chart of software implementation

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

Upper PEEP buffer εPEEP+ Pressure above PEEP to open exhalation pathway if pressure is

increasing, e.g. 1 cmH2O Lower PEEP buffer εPEEP- Pressure below PEEP to close exhalation pathway if pressure is

increasing

Ptarget Target value of Pres, tuned to achieve VT

kres Gain term for the Ptarget control

ε Error term for the Ptarget control

λ Relaxation factor for oxygen control

Nox Number of software loops for oxygen

Nair Number of software loops for air

Rlung Lung resistance – calculated for PEEP control (see Figure 8)

Clung Lung compliance – will be calculated for Pres initial guess.

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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 Ptarget 2. To deliver the required gas concentration, while accurately achieving Ptarget, by choosing the

appropriate Nox and Nair 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 PTARGET 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

• ε = VTVi , if VT was not reached on the previous cycle, and only Vi was inhaled (store when k is true)

• ε = TVTiTin , if VT was reached on the previous cycle in time TVTi relative to inhalation time Tin (store when l is true)

Ptarget i+1 = Ptarget i + kres(ε − 1) (8)

SELECTING NOX AND NAIR First the total time to reach Ptarget i+1 is estimated, assuming a constant flow rate through valves A and B when open

Nres i+1 = (Ptarget i+1Pres i )Nres i (9)

The initial guess for TB/TA is given by Equation (1)(i.e. at start or when FIO2 changes)

(NBNA)ideal = (1 − FIO2)

(FIO2 − 0.21) × 100 %

(10)

We then iterate upon this based on the measured FIO2i

(NBNA)i+1

= (NBNA)i

+ λ(FIO2 − FIO2i)

FIO2 *(*11*)*

with λ as a scaling factor.

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Finally,

NAi+1 = 1 + N(res NNi+1

BA)i+1 NBi+1 = (NNABi+1

)NAi+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 CO2 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).

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**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 (Plung – see Figure 1) is higher than in the system (Psys), 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 Psys=PEEP is achieved (Figure 7c). However, if the resistance of the lung is known in advance, Plung can be predicted in real-time, allowing the valve to only shut once: at the point where Plung=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 (cmH2O/(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 εPEEP. In this case, on the subsequent cycle, the valve is triggered when the estimated lung pressure reaches PEEP+ εPEEP, which successfully accounts for the delay on the subsequent breath.

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**Figure 8:** Pressure and flow traces from an experiment with an artificial lung, Rlung~ 20 cmH2O/(l/s), Clung~35 ml/cmH2O. (a) blue line shows system pressure and grey line shows estimated lung pressure Plung, (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

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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 Cv~0.05 (orifice ~ 1 mm)

o High enough to allow Pres to reach target during exhalation phase o Low enough to allow sufficient resolution on gas mixing control o If choice is limited, lower Cv is preferable to higher Cv o NC to protect from high pressure in event of power failure

• Valve C needs to be rated at Cv~0.2 (orifice ~ 2.5 mm)

o High enough to allow peak flow requirements o Low enough such that pressure drop across it regulates flow into lung and allows accurate

flow measurement o If choice is limited, lower Cv is preferable to higher Cv o NC to protect from high pressure in event of power failure

• Valve D needs Cv~0.4 (orifice ~ 6mm)

o High enough to not limit exhalation o If choice is limited, higher Cv is preferable to lower Cv o Optimally, NO to allow breathing in event of power failure (current prototype does not include

NO, due to delay in sourcing). o 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

• Pres range must be up to 1020 cmH2O, accuracy ideally better than 10 cmH2O

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.

• Psys range must be up to 100 cmH2O, accuracy must be better than 2 cmH2O

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 1⁄4” G threads, which are widely available and provide a robust connection.

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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

o For driving solenoids o Current requirement dependent on solenoids, 3A is likely to be sufficient

• Linear Power Supply

o To provide a clean input for pressure sensors o 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).

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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.

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**Figure 10**: External view of the Mk III prototype

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**Figure 11:** Internal view of the Mk III prototype

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PNEUMATIC CONNECTIONS

**Figure 12:** Pneumatic connections for prototype Mk III

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**Table 8:** Pneumatic connections

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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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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, Cv~0.2, NC (valve C) SCG256B404VMS.24/DC Asco 1/2\* Link 2/2 DC solenoid, Cv~0.4, NC (valve D) – see VZWD-L-M22C-M-G14-60-V-1P4-4 Festo 1 Link 2/2 DC solenoid, Cv~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

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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 Cv~0.2 valve would be suitable valve E in parallel with valve D if it is beneficial as described in Valves section.

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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 Qin = 1.2487 ∆P0.5991, Qex = 1.9748∆P0.5958.

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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

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DRAWING FOR **1⁄4**” G TO 2MM ADAPTORS

Drawing by Satpal Sangha

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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 cmH2O by default, can increase up to 70 cmH2O if positive decision provided by user. 6 Ventilation

Labelling

5a Par. 5

I:E ratio should be 1:2 by default setting. FiO2: 90-100%, Tidal volume: 400 ml, PEEP: 15 cmH2O, 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, FiO2,

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

FiO2. 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 cmH2O PEEP, respiratory rate 20 breaths/min. Pressurise d 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 cmH2O. 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.

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**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

If patient becomes disconnected, a disconnect alarm will sound within 3 Acceptable

seconds of disconnection. Performance

Note: we need to establish the best way to detect this.