



**ISTITUTO  
ITALIANO DI  
TECNOLOGIA**

# FI5 Ventilator

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## Technical Specifications

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## 1. OVERVIEW

**WARNINGS:** The following technical solution has been developed *to help during the SARS-CoV-2 epidemic shortage of ventilators for use and accessibility open-source.*

The design is not certified nor covered by any warranty: the resulting ventilator units shall be used only in case of emergency under the responsibility of the medical personnel.

Within the medical infrastructure, there are critical technologies that are generally available, but simply do not exist in a high enough density to handle the excessive volume of patients associated with SARS-CoV-2 pandemic. Ventilators are an example of technologies that are currently in critical short supply. Mechanical ventilators are essential for treating both influenza and COVID-19 patients in severe acute respiratory failure. Past studies have shown that intensive care units (ICUs) will not have enough resources to treat all patients requiring ventilator support during a massive pandemic [1]. The current medical system relies exclusively on specialized, proprietary, mass-manufactured ventilators from a small selection of suppliers. This supply model clearly fails when there is a sudden surge in demand for a relatively low-volume specialty product such as ventilators in a pandemic as analyzed here. The majority of medical equipment is heavily patented by a few specialty medical firms that sell small volumes because during ‘normal’ times, a medium-sized hospital only needs a handful.

In order to address the emergency situation caused by the outbreak, Principle of Operation the Medicine and Healthcare products Regulatory Agency (MHRA) in UK [2] and the U.S Food and Drug Administration (FDA) [3] provides guidelines with simplified procedure for rapidly manufacture Ventilators. Many groups all over the world (academic institutions, industries but also makers) started working on ventilator devices with different approaches. The majority of the open source projects were inspired by the E-Vent project from MIT [4]. The device is an accessory that automatize the AMBU bag, by means of motor and electronics that press and release it. These projects are very simple and easy to manufacture, but they rely on the AMBU bag, that has a life spam of about 10 hours.

A completely different approach is the one proposed by Galbiati et al. [5]. The Mechanical Ventilator Milano (MVM) is a novel mechanical ventilator designed for rapid mass production has been presented and an International group of scientists are currently working on the design of a prototype.

The design of the FI5-Ventilator took inspiration by the MVM, with the idea of working on a more modular system and with the goal of being able to use it with Noninvasive mask (NIV), either total face or helmet. Using a ventilator with helmets reduces the waste of oxygen and increase the effectiveness of the treatment. These requirements pose constraints in the design and requires specific control strategies. The modular design approach was chosen to avoid issues in case of shortage of specific components (a change in the BOM of a device needs to go through a certification procedure, but in emergency situation, they may reduce the amount of paperwork like in [3]). A team of 5 people from Ferrari Gestione Sportiva leaded by Corrado Onorato joined the IIT team working together on the design of the Ventilator (simulation and control, pneumatics, mechanics, electronics, firmware, wiring and normative). Moreover, a team of engineers from Camozzi provides a great support in the selection of the core components

(valves and pressure regulator) thanks to their great expertise in the field carrying on specific tests on subsystems to provide data for the simulation

## 2. REFERENCE CLINICAL REQUIREMENTS

The FI5 ventilator's design is based on the requirements set by the document "RMVS001" issued by MHRA (Medicine and Healthcare products Regulatory Agency) in UK on 18/03/20 and subsequently amended. The information shown in the sections below are extracted from the MHRA document and reported here for making easier the understanding of the objectives set for the FI5 ventilator's project.

### 2.1 UK REQUIREMENTS FOR EMERGENCY VENTILATORS

This is a specification of the minimally clinically acceptable ventilator to be used in UK hospitals during the current COVID-19 pandemic caused by SARS-CoV-2 virus as reported in [2] for a Rapid manufactured Ventilator System (**RMVS**). It sets out the clinical requirements based on the consensus of what is 'minimally acceptable' performance in the opinion of the anesthesia and intensive care medicine professionals and medical device regulators given the emergency situation. It is for devices, which are most likely to confer therapeutic benefit on a patient requiring invasive ventilation because of respiratory failure caused by SARS-CoV-2, used in the initial care of patients requiring urgent ventilation.

Here after a list of the Requirements that applies to the FI5 ventilator: for the sake of clarity all the requirements shown below are achieved by the ventilator.

#### 2.1.1 MODES OF VENTILATION

- *Must have CMV.*
  - a) The CMV mode must be either
    - i. (ideally) Pressure Regulated Volume Control,
    - ii. or pressure controlled ventilation (PCV) or
    - iii. minimally a volume controlled ventilation (VCV).
  - b) PRVC/Pressure Controlled - a set pressure is delivered for the period of inspiration and the volume achieved is measured and displayed. Ideally PRVC, an adaptive mode where the tidal volume is set and the lowest possible pressure is delivered to achieve this volume. PCV where the user has to provide the adaptive control to achieve tidal volume is only acceptable if the tidal volume delivered is clearly displayed and the user can set patient specific upper and lower tidal volume alarms to alert to the need to adjust the pressure.
  - c) Volume Control Ventilation— the user sets a tidal volume and respiratory rate. The tidal volume is delivered during the inspiratory period. Acceptable only if additional pressure limiting controls are available, see Inspiratory Pressure section.
- *Inspiratory airway pressure*, the higher pressure setting that is applied to make the patient breathe in:
  - a. Plateau pressure should be adjusted to achieve volume and must be limited to 35 cmH<sub>2</sub>O by default.

- b. Peak pressure should be no more than 2 cmH<sub>2</sub>O greater than plateau pressure.
- c. If volume control ventilation is used, the user must be able to set inspiratory airway pressure limit in the range at least 15 – 40 cmH<sub>2</sub>O in at least increments of 5 cmH<sub>2</sub>O.
- d. There must be a mechanical failsafe valve that opens at 80 cmH<sub>2</sub>O.
  
- *Positive End Expiratory Pressure (PEEP).* The pressure maintained in the breathing system during expiration.
  - e. RMVS must provide a range 5-20 cm H<sub>2</sub>O adjustable in 5 cmH<sub>2</sub>O increments.
  - f. The patient breathing system must remain pressurized to at least the PEEP level setting at all times.
  
- *Inspiratory:Expiratory ratio (I:E).* The proportion of each breathing cycle that is spent breathing in compared to breathing out.
  - g. RMVS must provide 1:2.0 (i.e. expiration lasts twice as long as inspiration) as the default setting.
  - h. RMVS could provide adjustable I:E in the range 1:1 – 1:3.
  
- *Respiratory Rate.* The number of breathing cycles every minute.
  - i. RMVS must provide a range 10 – 30 breaths per minute in increments of 2 (only in mandatory mode) that can be set by the user.
  
- Tidal Volume (V<sub>t</sub>) setting, if provided. The volume of gas flowing into the lungs during one inspiratory cycle
  - j. Must have at least one setting of 400ml +/- 10 ml.
  - k. Should have 350ml and 450 ml options.
  - l. Could have a range 250 – 600 ml in steps of 50ml.
  - m. Could have a range up to 800 ml.

## 2.1.2 GAS AND ELECTRICITY

- *Incoming Gas Supply.*
  - must connect with NIST (Non-Interchangeable Screw Thread to ISO 18082:2014/AMD 1:2017)
  
- *Electricity Supply.*
  - Must be PAT tested to the adapted IEC 60601, IEC 62353 standards
  - If electricity is required for functioning, RMVS must have a battery backup of at least 20 minutes in case of mains electricity failure.
  - Must avoid harmful RF or EM emissions that could interfere with other critical care equipment.
  
- *Gas supply to patient. (provided by STAGE1)*

- User must be able to control inspired oxygen proportion (FiO<sub>2</sub>). The percentage of oxygen in the gas being breathed in by the patient. Room air is 21% oxygen.
- Must provide a (50% or 60%) and 100% options
- All elements in the gas pathway must meet biological safety and low-pressure oxygen safety standards, especially to minimize risk of fire or contamination of the patient's airway.

### 2.1.3 INFECTION CONTROL

### 2.1.4 MONITOR AND ALARMS

IEC60601-1-8:2006 is the one relevant standard for alarms for RMVS. Alarms, alarm limits, and priorities are complex areas to optimize for human usability. The key is to get enough alarms but not too many and for alarms to be clearly ranked so that more urgent patient safety problems are highlighted more. Early attention to this area is important and should be built in from the start.

- Must alarm at:
  - Gas or electricity supply failure.
  - Machine switched off while in mandatory ventilation mode.
  - Inspiratory airway pressure exceeded.
  - Inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm).
  - Tidal volume not achieved or exceeded.
- Monitoring displayed continuously so the user can verify.
  - Must show the current settings of tidal volume, frequency, PEEP, FiO<sub>2</sub>, ventilation mode.
  - Must show the actual current airway pressure
  - Should show the achieved tidal volume, breathing rate, PEEP, and FiO<sub>2</sub>.
  - If pressure support mode is provided there must be real time confirmation of each patient breath and an alarm if below acceptable range.
  - Could provide CO<sub>2</sub> monitoring.

### 2.1.5 BIOLOGICAL AND SAFETY

### 2.1.6 MISCELLANEOUS

- Must be reliable. RMVS must be capable of continuous operation (100% duty cycle) for 14 days.
- It must be intuitive to use for qualified medical personnel, but these may not be specialists in ventilator use.
  - i. Must not require more than 30 minutes training for a doctor with some experience of ventilator use.
  - ii. Must include Instructions for Use.
  - iii. Must include clear labelling of all critical functions and controls using standard terms, pictograms and colours that will be readily recognised by UK healthcare staff.

## 2.2 ACCEPTABLE PERFORMANCE

- Under steady-state conditions, the indicated airway pressure shall be accurate to within  $\pm(2 +(4 \text{ \%})$  of the actual reading) cmH<sub>2</sub>O.
- The accuracy of measurement of expired volumes greater than 50 ml shall be within  $\pm(4,0 +(15 \text{ \%})$  of the actual volume expired through the patient-connection port) ml.
- Oxygen concentrations will be  $\pm 5 \text{ \%}$  of the set value.
- Disconnect alarm will sound within 3 seconds of disconnection

### 3. PRINCIPLE OF OPERATION AND VENTILATOR'S LAYOUT

#### 3.1 PNEUMATIC SCHEME

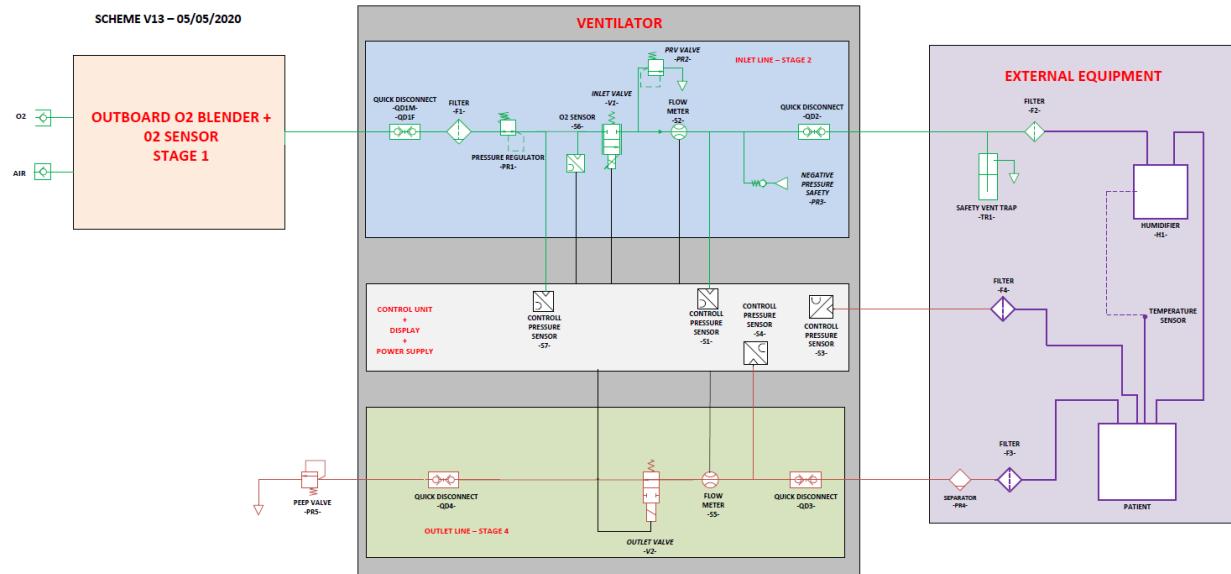


Figure 1

The FI5 ventilator comprises three pneumatic stages and the electronic control module.

The system connects directly to a line of pressurized medical oxygen or medical air (STAGE1), and relies on regulation of the flow to deliver medical air, medical oxygen, or a mixture of air and oxygen to the patient at a flow in the range suitable for treatment (30 to 120l/min).

The ventilator is composed by an inlet line with a pressure regulator and a proportional valve (STAGE2) and an outlet stage with an on/off valve (STAGE4). The ventilator is connected throughout standard quick connectors with the external tubing and equipment to the patient mask (the ventilator is intended to be used with a non-invasive ventilation mask [NIV]). In STAGE2 there is a safety valve (for not exceeding the maximum pressure the lung may accept) and a non-return valve (in case the patient breaths in opposition to the ventilator). Sensors in STAGE2 and STAGE4 provide feedback for implementing safety mechanisms and different types of control strategies (Continuous Mandatory Ventilation CMV, Volume controlled ventilation VCV, Pressure Controlled Ventilation PCV, Pressure Regulated Volume controlled PRVC, CPAP, BiPAP, etc.). For the sake of clarity the information provided in this document are related to the design of a new ventilator (shown in the “ventilator” box in the image above): components described as “stage 1” (outboard pressure regulator – mixer with O2 sensor), “external equipment” and “peep valve” are not considered being part of this project but represent the minimum requirements that should be available in the medical infrastructures for operating properly the ventilator.

### 3.2 ELECTRICAL SCHEME

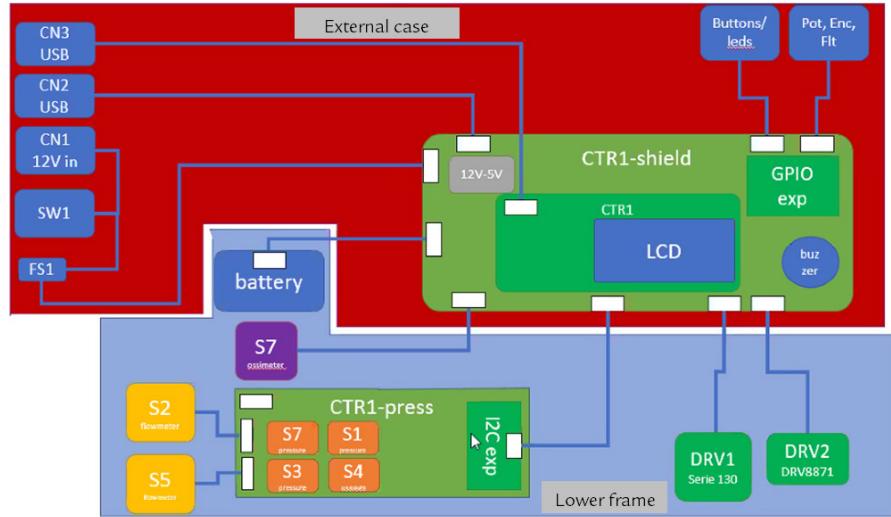


Figure 2

The figure above shows the basic electrical scheme of the ventilator and highlights the hardware architecture. It is important to note that the nomenclature of the sensors is coherent with the pneumatic scheme described above and the number of electrical connections between the lower mounting frame and the external case is kept to the minimum to facilitate the ventilator's mounting and dismounting procedure. A detailed Electrical Scheme is depicted in the figure below:

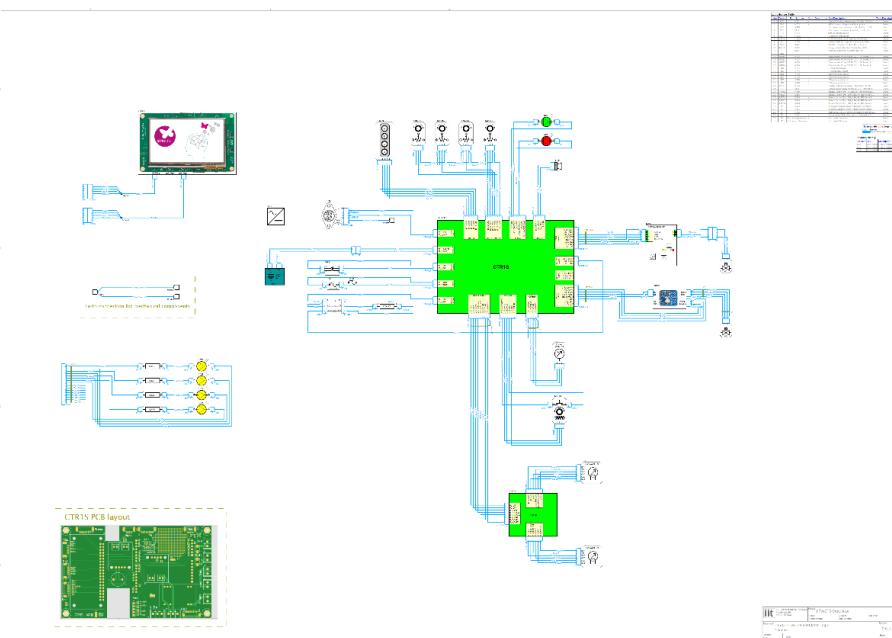


Figure 3

### 3.3 H-M INTERFACE SCHEME

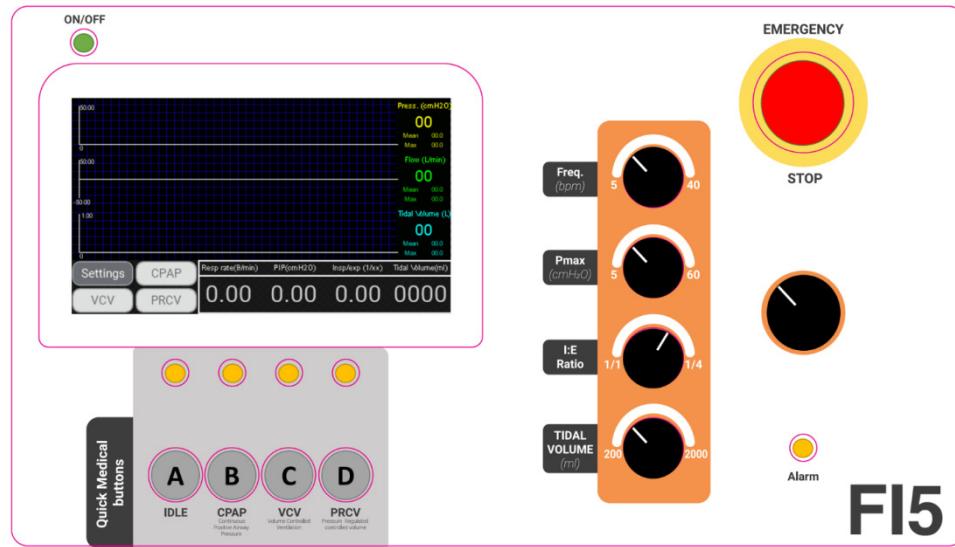


Figure 4

The figure above shows how the human-machine interface was set up aiming to make the usage of the ventilator such as not to require more than 30 minutes training for a doctor with some experience of ventilator use.

### 3.4 VENTILATOR'S LAYOUT

The FI5 ventilator's design has been developed in order to match the following requirements:

- Compliant with requirements set by MHRA (RMVS001 issued on 18/03/20 and subsequently amended), see section 2 for reference.
- Reliable and failsafe
- Low cost
- Compact, light, easy to handle and portable.
- Mainly made by off-the-shelf components globally available
- Limited oxygen consumption
- Easy to manufacture and assemble
- Easy to use
- Customizable based on specific clinical needs

Figure 2 below shows main dimensions of the external case (354mm X 284mm X 262mm).

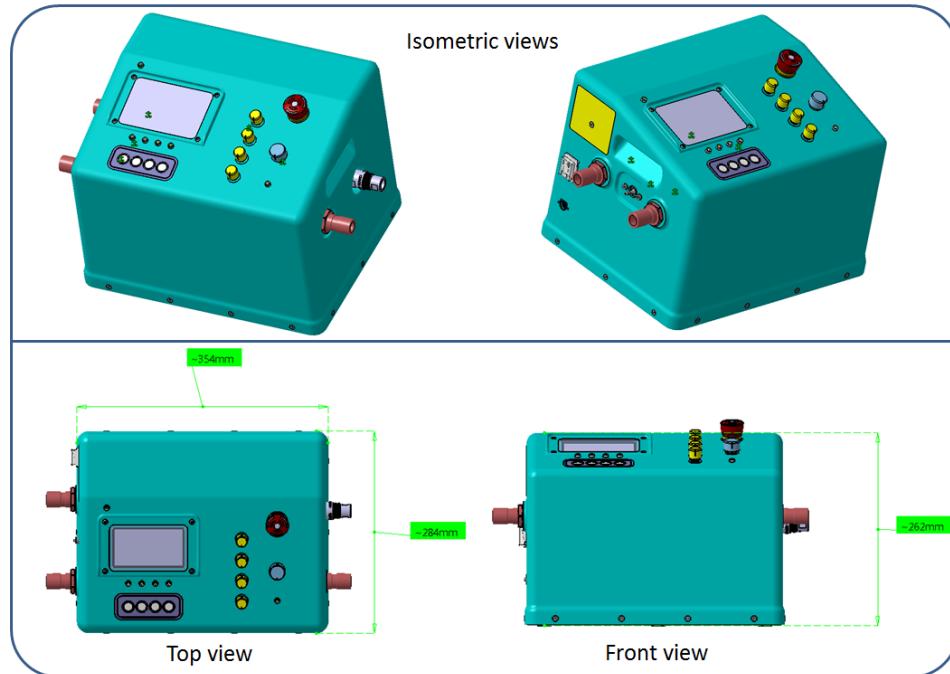


Figure 5

### 3.4.1 LAYOUT OF INTERNAL COMPONENTS

The design of the internals has been carried out by limiting the number of custom components and making use of globally available off-the-shelf parts: the figure below shows the functional layout of all the pneumatic components with reference to the nomenclature shown in the pneumatic scheme.

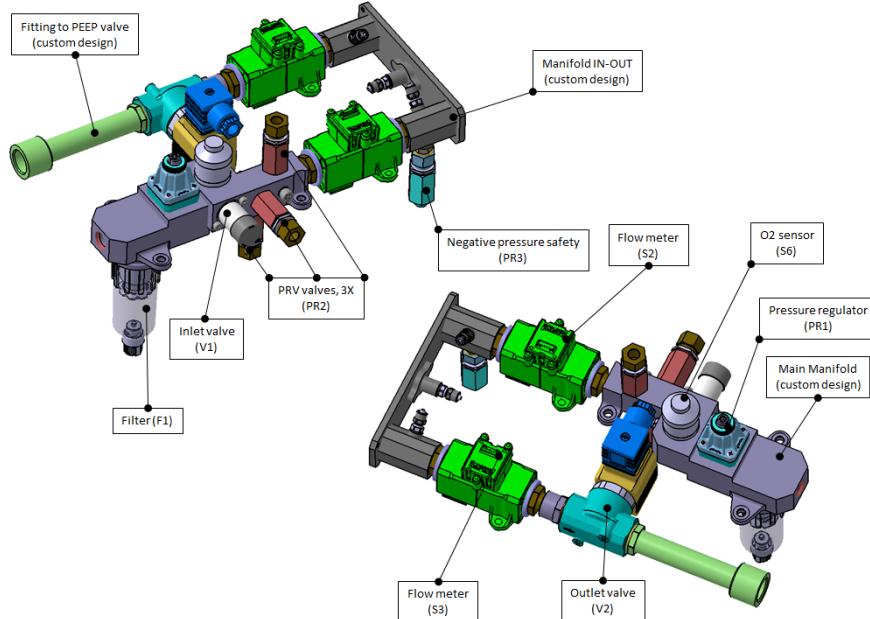


Figure 6

The pneumatic lay-out is fully mounted and supported on a couple of plastic frames (custom design)

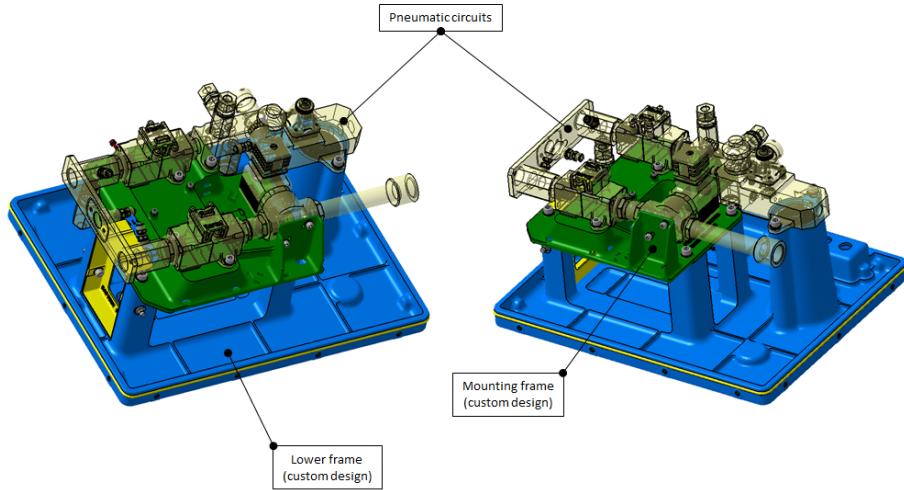


Figure 7

As described in the electrical scheme, part of the electrical cables, the Ctr1-P board, the two valves' drivers and the pressure sensors are directly mounted to the lower frame in order to facilitate the ventilator's mounting/dismounting.

Also the pressure relief valves and the negative pressure relief valves are connected to a filter by mean of venting pipes (see images below showing the CAD assy and the first prototype).

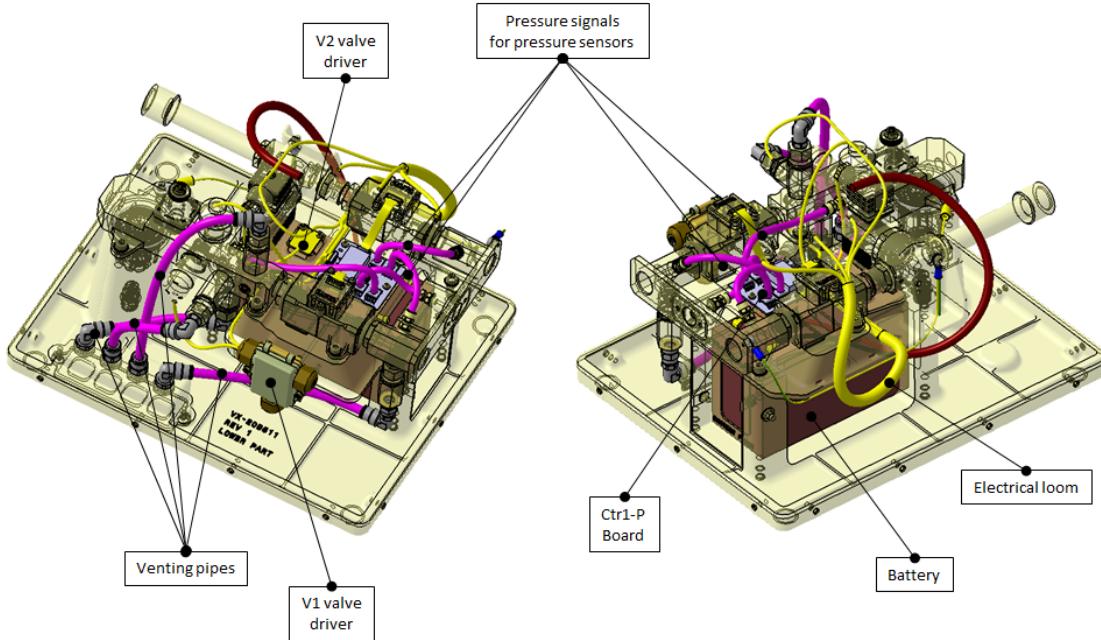
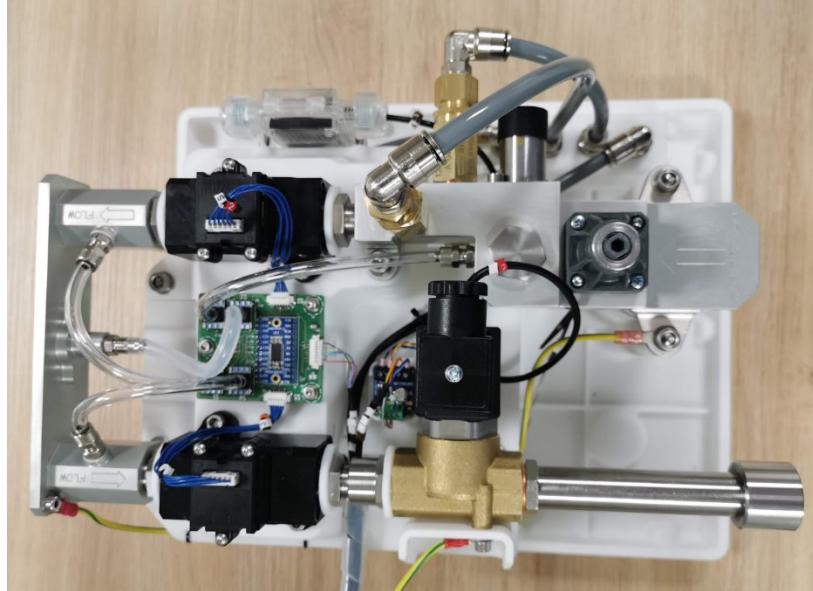


Figure 8



*Figure 9*

### 3.4.2 LAYOUT OF EXTERNAL CASE AND H-M INTERFACE.

As briefly stated in section 3.3 above, the H-M interface has been developed in order to be as simpler as possible. In detail there are only the following options for a doctor to interact with the ventilator:

- Keypad to set the ventilation mode (idle, CPAP, VCV and PRCV modes are available, see section 5.4.1 for more details)
- Potentiometers to set the proper target value for the most important parameters such as frequency, maximum pressure, I:E ratio and tidal volume.
- A rotary switch by which it is possible to change the general setting of the device and to set the parameters of each control mode.
- A display through which it is possible to monitor the most important operating parameters of the ventilator.
- An emergency stop

In addition to that LEDs have been implemented to give a visual feedback about the active modes.

Two USB ports to upgrade the software and fuse-holders are also available on the left side on the ventilator's case and protected by a cover to avoid any possible misuse. The ventilator's internals are in communication with the external environment by mean of four ports (feeding line from the oxygen mixer, inspiratory outlet line from the ventilator to the patient, expiratory inlet line from the patient to the ventilator and expiratory outlet line to the PEEP valve).

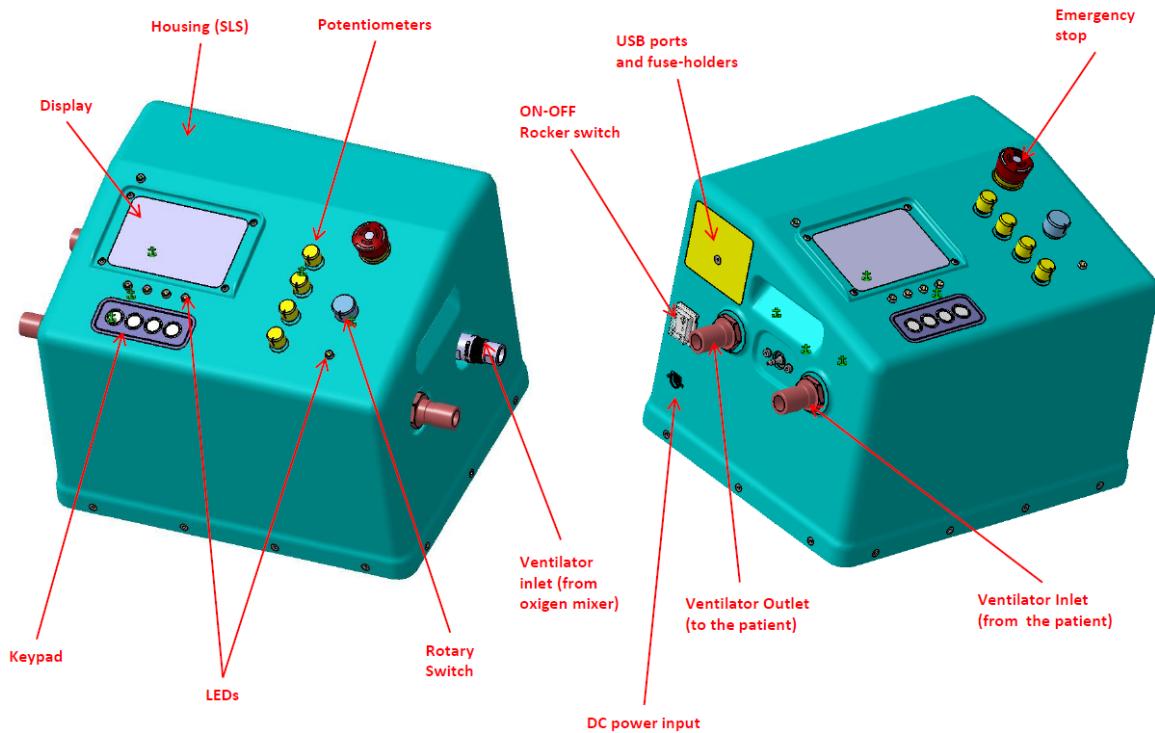


Figure 10

The previous image shows the CAD models while the following image shows the appearance of the first prototype assembled and tested at iCub Tech Facility in Genoa.



Figure 11

It is important to note that the loom has been designed in order to facilitate the procedures for mounting and dismounting the ventilator as briefly anticipated in section 3.2 above and shown in the image below.

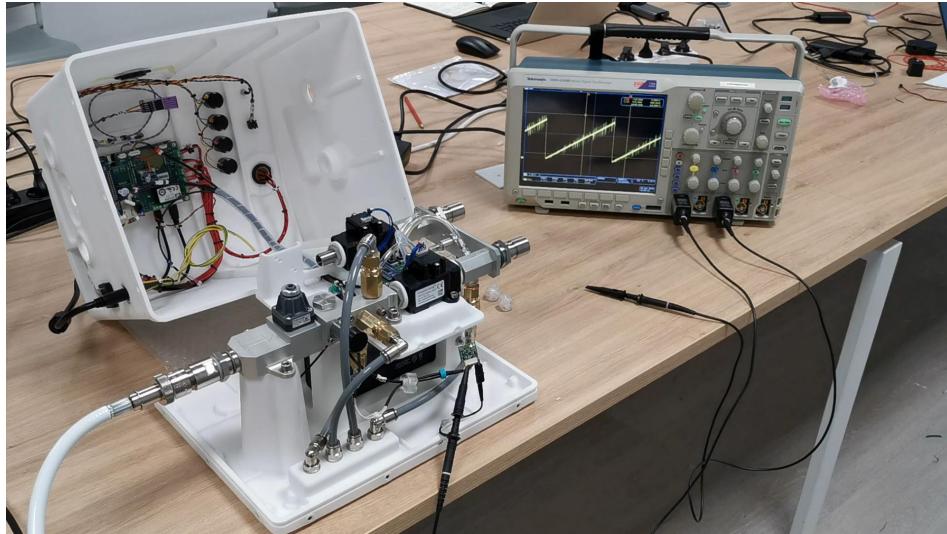


Figure 12

### 3.5 OPEN SOURCE DATA

All the relevant information related to the ventilator's design, manufacture and supply chain are available as "open source data" at the following link:

<https://github.com/icub-tech-iit/ventilator-fi5>

In detail the following data can be downloaded:

- Detailed .stp files of all the ventilator's components
- Detailed .pdf files of all the ventilator's components including drawings for all the custom-design components with all the relevant information for manufacturing.
- Detailed .pdf assembly drawings showing the correct mounting sequences and highlighting all the additional procedures where required.
- Detailed .pdf file of the ventilator's electrical scheme.
- Detailed .pdf file of the ventilator's wiring.
- Source files of the electronic boards
- Gerber files of the electronic boards

In addition to that a detailed bill of material is available with the following information:

- Number: indicates the part number associated to each single component or assembly drawing. The bill of material is organized in a way such that each component is classified below the relevant assembly drawing in order to have full coherence with the .pdf files.

- Name: description of the part/assembly
- Version: this field highlights the revision number for each part/assembly. It is useful to track changes between different project's releases.
- Quantity: indicates the number of physical components required for mounting one ventilator. If the quantity is “zero” it means that the number is associated to an assembly drawing.
- ID: indicates the equivalent name for a component shown in the pneumatic or electrical scheme described in sections 3.1 and 3.2.
- Category: can be used to filter a specific family of components.
- Manufacturer: indicates the name of the designated supplier for commercial components that rely on specific suppliers, just “standard component” for commercial components that don’t rely on a specific supplier and “custom component” if the component requires manufacturing based on a custom design.
- Manufacturer part number: for commercial components that rely on specific suppliers indicates the order code by which the correct component can be purchased by the designated supplier.

The following image show how the bill of material looks like.

Number	Name	Version	Quantity	Status	ID	Category	Manufacturer	Manufacturer Part Number
VX-209641	MAIN ASSY - PROJECT VENTILATOR FI5	0	WIP			Assembly		
VX-209503	ASSY - VENTILATOR FI5	0	1	WIP		Assembly		
VX-209513	ASSY - LIST OF EXTERNAL PNEUMATIC COMPONENTS	0	1	WIP	QD1_F	Quick Disconnect	Behringer	
VX-209473	QD BEHRINGER HP120N O2 NIST ISO 18082 - 1/4 M	0	1	WIP		Fitting	Custom - see drawing	
VX-209562	FITTING FOR QD O2 G1/4 - M14X1.5	1	1	WIP		Fitting	Custom - see drawing	
VX-209573	FITTING G1/2 MALE - CONIC 22M	1	3	WIP	QD2-QD3-QD4	Fitting	Standard component	
VX-209608	WASHER 21.3X28X1.5 (1/2") ISO 7089 COPPER - COMMERCIAL	0	3	REL		Washer		
VX-209706	FITTING CAMOZZI 1511 6/4 - M6	0	1	REL		Fitting	Camozi	1511 6/4 - M6
VX-209724	O-RING KKM 70SH D=10.8X2.178	0	1	REL		O-Ring	Standard component	
VX-209755	O-RING KKM 70SH D=23.4X7X2.95	0	3	REL		O-Ring	Standard component	
VX-209756	O-RING KKM 70SH D=19X2	0	1	REL		O-Ring	Standard component	
VX-209534	ASSY - LIST OF COVER EXTERNAL FIXINGS	0	1	WIP		Assembly		
VX-209710	WASHER 4.3X8X0.5 INOX UNI 6592 B - COMMERCIAL	0	2	REL		Washer	Standard component	
VX-209721	LOW HEAD SOCKET CAP SCREW M4X10 ISO 4762 10.9 - COMMERCIAL	0	14	REL		Fixing	Standard component	
VX-209722	LOW HEAD SOCKET CAP SCREW M4X8 ISO 4762 10.9 - COMMERCIAL	0	2	REL		Fixing	Standard component	
VX-209543	ASSY - PNEUMATIC & ELECTRONIC CIRCUITS ON LOWER CASE	0	1	WIP		Assembly		
VX-209537	ASSY - FIXING FOR PNEUMATIC CIRCUIT	0	1	WIP		Assembly		
VX-209707	SCREW HEX SOCKET M6X20 ISO 4762 12.9 - COMMERCIAL	0	4	REL		Fixing	Standard component	
VX-209708	WASHER 6.4X11X1 INOX UNI 6592 B - COMMERCIAL	0	6	REL		Washer	Standard component	
VX-209709	SCREW HEX SOCKET M4X10 ISO 4762 12.9 - COMMERCIAL	0	2	REL		Fixing	Standard component	
VX-209710	WASHER 4.3X8X0.5 INOX UNI 6592 B - COMMERCIAL	0	2	REL		Washer	Standard component	
VX-209711	LOCKNUT MK61 SIMMONDS - COMMERCIAL	0	2	REL		Fixing	Standard component	
VX-209538	ASSY - ELECTRONIC FIXING TO EXTERNAL CASE LOWER PART	0	1	WIP		Assembly		
VX-209515	BATTERY FIXING FRAME	1	1	WIP		Structure	Custom - see drawing	
VX-209690	SCREW HEX SOCKET M6X18 ISO 4762 12.9 - COMMERCIAL	0	4	REL		Fixing	Standard component	
VX-209691	WASHER 5.3X10X0.8 INOX UNI 6592 B - COMMERCIAL	0	12	REL		Washer	Standard component	

## 4. FI5 VENTILATOR SPECIFICATIONS (V1.0)

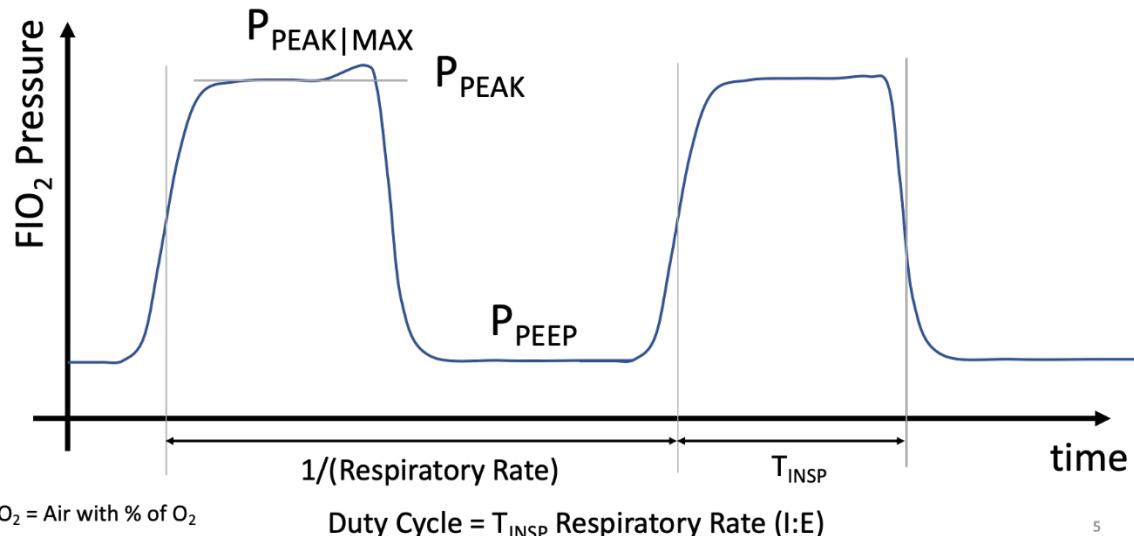
### 4.1 SYSTEM MEASUREMENTS PERFORMANCE

- P1. Pressure measurement shall be accurate within  $\pm [2 + (4 \% \text{ of the actual reading})] \text{ cmH}_2\text{O}$ ;
- P2. Volume measurement for volumes greater than 50ml shall be within  $\pm [4,0 + (15 \% \text{ of the actual volume expired through the patient-connection port})] \text{ ml}$ ;
- P3. Oxygen concentration shall be set with accuracy  $\pm 5 \%$ ;
- P4. Time base accuracy shall be  $\pm 100 \text{ ms}$ ;
- P5. Supply voltage  $V_{DD}$  measurement accuracy  $\pm 5 \%$ ;
- P6. Battery voltage  $V_{BATT}$  level accuracy  $\pm 10 \%$ ;
- P7.  $\text{FiO}_2$  temperature measurement accuracy  $\pm 0.5^\circ\text{C}$ ;

### 4.2 VENTILATION AND RATE

- C1. Pressure Controlled Ventilation (PCV). PCV is defined based on inspiratory pressure set  $P_{PEAK}$ ,  $P_{PEEP}$  set and Tidal Volume set ( $TV_{SET}$ ) with corresponding lower and upper threshold  $TV_{MAX}$  and  $TV_{MIN}$ ;

**Pressure Control** = the ventilator maintains a set airway pressure for a given inspiratory time. The clinician would set the inspiratory pressure level ( $P_{PEAK}$ ),  $P_{PEEP}$ , I:E ratio (Duty Cycle), Respiratory Rate, and  $\text{FiO}_2$ . In this mode, the peak airway pressure is constant (inspiratory pressure  $P_{PEAK}$  and  $P_{PEEP}$ ) while the tidal volume can be variable depending on patient characteristics (compliance, airway/tubing resistance) and driving pressures.



C2. <MODE>

C3. <MODE>

#### 4.3 SET POINTS

- S1. Range 10 – 30 breaths per minute in increments of 1 that can be set by the user;
- S2. Adjustable I:E in the range 1:1 – 1:3;
- S3. Tidal Volume within a range 250 – 600 ml in steps of 50ml;
- S4.  $P_{PEAK} \leq 35 \text{ cmH}_2\text{O}$ ;
- S5.  $P_{PEAK| MAX} \leq 2 \text{ cmH}_2\text{O} + P_{PEAK}$ ;
- S7.  $P_{PEEP} \in [5, 20] \text{ cm H}_2\text{O}$  adjustable in  $\Delta P_{PEEP} = 5 \text{ cm H}_2\text{O}$  increments;
- S8.  $P_{PEAK}$  must be adjustable to achieve  $TV_{SET}$ ;
- S9. Temperature must not exceed  $T_{MAX} = 38^\circ\text{C}$ ;

#### 4.4 FAILSAFE VALVES

- F1. Mechanical failsafe valve that opens at  $P = 80 \text{ cmH}_2\text{O}$ ;

#### 4.5 ALARMS AND FAILURE INDICATIONS

- A1. All alarms of the device shall be issued within 3 seconds from the alarm event in any condition;
- A2. O2 disconnection;
- A3. Exceeding  $P_{PEAK| MAX}$ ;
- A4. Exceeding  $P_{PEEP}$  pressure by P1 accuracy;
- A5. Rate not consistent with P4 accuracy;
- A7. AC power system ripple, i.e., supply voltage not respecting  $12V \pm 10\%$ ;
- A8. AC power supply failure, i.e., supply voltage  $< 12V \pm 10\%$  for a complete respiratory cycle;
- A9. Battery recharge failure;
- A10. TV exceeding thresholds defined in C1 (both upper and lower thresholds);
- A11. Machine off indication;
- A12. Temperature exceeding  $T_{MAX}$ ;

#### 4.6 DISPLAY AND MONITORING

- M1. Battery not fully charged;
- M2. Current settings of tidal volume  $TV_{SET}$ ,  $TV_{MAX}$ ,  $TV_{MIN}$ ,  $P_{PEAK}$ , Respiratory Rate, I:E,
- M3. Current graph of Tidal Volume, Pressure and Volume Flow;
- M4. Mechanical Ventilation Activated/Deactivated;

#### 4.7 LABELING

- L1. Must include labeling of all critical functions and control;

L2. Must include a label saying it will NOT be usable for routine care unless it has been CE marked through the Medical Device Regulations, e.g., «Only for SARS-CoV-19»;

#### 4.8 BATTERY AND SUPPLY

- B1. AC powered;
- B2. Backup battery for at least 20 min;

#### 4.9 ELECTROMAGNETIC INTERFERENCE

I1. The system must avoid harmful interference w.r.t. other medical devices, according to IEC 60601-1-2:2014;

#### 4.10 BIOLOGICAL SAFETY

BS1. All elements in the gas pathway must meet biological safety and low-pressure oxygen safety standards, especially to minimize risk of fire or contamination of the patient's airway;

#### 4.11 INFECTION CONTROL

- IC1. Must be able to be decontaminated between patients;
- IC2. Must provide a Heat and Moisture Exchange Filter to the patient end;

## 5. SIMULATIONS

### 5.1 OVERVIEW

We have developed a complete model of the ventilator manifold along with the human lungs and equipment comprising the pipes, the humidifier, and the mask. The main objectives were: (1) to perform a suitable sizing of the pneumatic circuit; (2) to study the permeability of the inlet and outlet valves; (3) to analyze the impact on pressure dynamics resulting from the use of a respiratory mask and an helmet with a particular care to CO<sub>2</sub> rebreathing; (4) to carry out preliminary FMEA analyses; (5) to design and implement the controller and the state machine components.

### 5.2 MODELING OF THE HUMAN LUNGS

To model the behavior of human lungs, we adopted the approach well described in Mešić et al.<sup>[6]</sup>, where the usual linear single-compartment model is extended to comprise also the dynamic compliance and the nonlinear airways resistance of the respiratory system. Figure 13 reports on the mechanical equivalent of such a model as implemented in Simscape.

Relevantly, we further characterized the model by accounting for three different values of lungs compliance (soft, medium, stiff) as suggested in Lucangelo et al.<sup>[7]</sup>. We manually tuned the parameters of the original model in [6] in order to match the flowrate profiles given in [7] at the same fixed tidal volume (see 14). The objective was to always refer in any working condition to one of the three characteristic curves with the aim to define a reasonable worst case. On one hand, high-compliant lungs will be used for sizing the inlet valve as they clearly request higher flowrate for a given mouth pressure; on the other hand, low-compliant lungs are dealt with when designing the outlet valve since they release higher flow peaks when the valve starts opening.

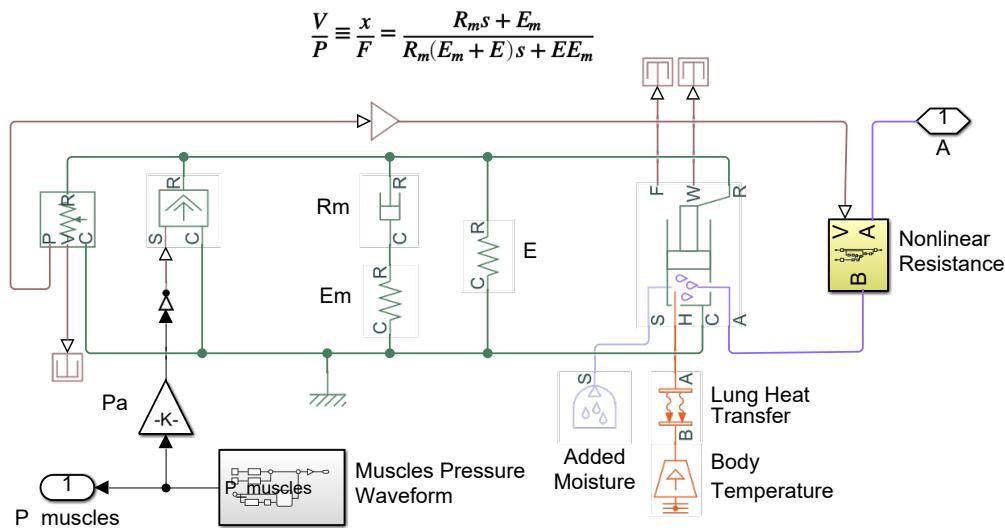


Figure 13. Model of the human lungs in Simscape.

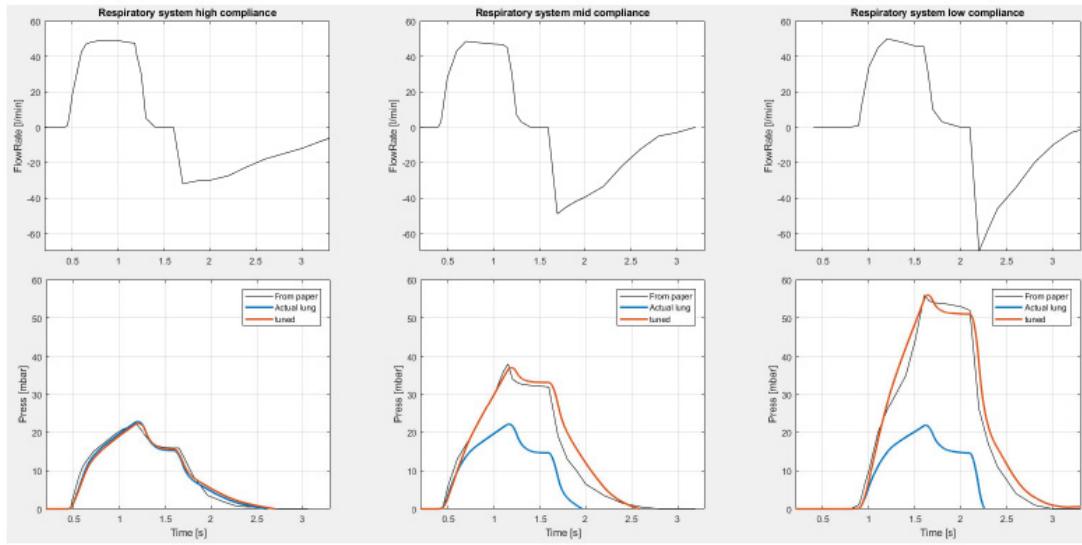


Figure 14. Responses of the human lungs characterized by three different compliance values.

### 5.3 MODELING OF THE MANIFOLD

A Simulink model has been created and is now available open-source. It includes the following features:

- Three mathematical models of human lungs (stiff, avgm soft) as described above
- Air/Oxygen mixing device (to reach O<sub>2</sub> target %) and pressure regulator to allow inlet valve to operate in controlled pressure
- Main flow line with controlled valves, pressure relief valves, quick disconnect, pipes (capacitive and resistive).

Main outcome from the model is the validation of the hardware layout in terms of components' selection and operating pressure levels across the entire system. The following image shows an overview of the Simulink model:

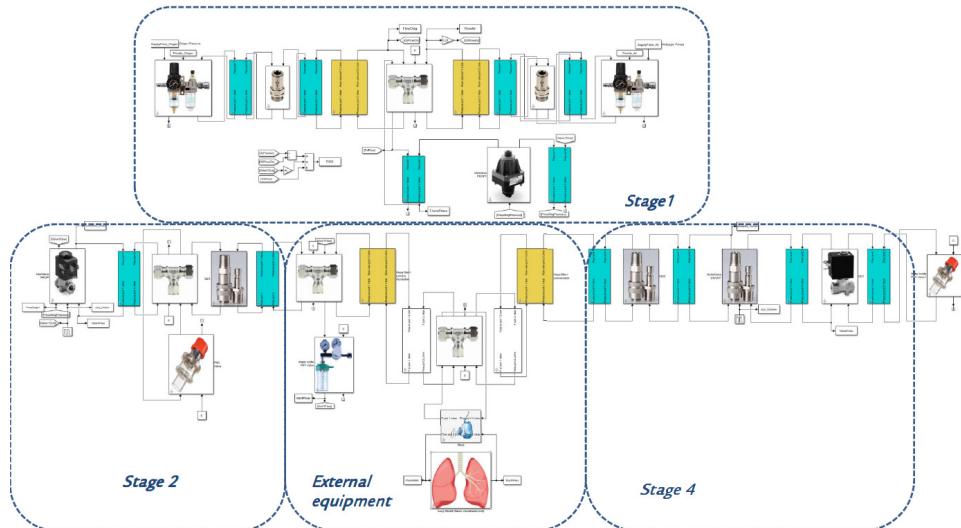


Figure 15

### 5.3.1 SUMMARY OF MAIN RESULTS

- Inlet valve (V1)
  - Camozzi “AP-spec” valve is below target having too low maximum flowrate at its most permeable setting (low preload spring) and at its maximum operating pressure (1 bar)
  - Camozzi “CP-spec” valve operating at 750mbar of inlet pressure matches all the requirements having a full open flowrate >80lpm while we estimate 60-65lpm as maximum requirement. This is the V1 valve’s spec adopted for the ventilator
- Outlet valve (V2): CFB-D22G-W1valve has been adopted for the ventilator: this valve is assumed to evacuate the required lungs’ air flow without affecting exhalation dynamics.
- Permeability scan to assess robustness of the system has not highlighted any criticality
- Helmet vs mask: the increased volume (around +8L) leads to a 100cc of tidal volume loss. By increasing V1 command current of about 4-5% it is possible to entirely recover lungs’ tidal volume matching mask-like pressure dynamics.
- Inlet mixing volume is not needed if the mixer is inherently pressure compensated (as most of the ones on the market and currently available in the hospitals).
- CO<sub>2</sub> rebreathing is not an issue using mask with <250ml of volume. For bigger mask and helmet, valve’s duty must be increased significantly to reduce CO<sub>2</sub> concentration below 2% limit. Flow-by is the most effective strategy for this purpose.
- FMEA results
  - If the safety vent trap valve is fitted there are no issues in evacuating the exceeding air flowrate. Maximum calculated mouth pressure will be safely equal to the vent cranking pressure.
  - Considering the evenience that safety vent trap valve is not available, mechanical pressure relief valves have need dimensioned in a way such their permeability is enough to not increase consistently the patient’s mouth pressure.  
Assuming 100 mbar as hard limit for max mouth pressure, the pressure relief valves’ permeability target is ok for 110 lpm at 160mbar.

## 5.4 PERMEABILITY TARGETS

### 5.4.1 PR1 & V1: "AP-SPEC" VALVE PERMEABILITY TARGET



Target is to reduce as much as possible the operating pressure of PR1 (pressure regulator) for improving the safety of the system in case of V1 (inlet valve) failure. Camozzi's biggest "AP-spec" valve (size 22, nozzle 2.4mm) is not able to deliver the target flowrate even at 1.5 bar of inlet pressure. Reducing the preload of the spring inside the valve it is possible to increase the valve's permeability achieving the values shown in the following plots. The valve must satisfy the air flow rate target with high compliance lung characteristic (25-30 mbar mouth pressure) at 50% of its FS (current) to compensate components' scatter and to achieve strong dynamics in pressure control.

- PR1 (pressure regulator) set @ 1000mbar

The minimum spring's preload leads to the results shown below. Valve's working point is at 50% of FS (current) but flowrate strongly saturates from 78% onward due to the small orifice (2.4mm) at the valve exit. This valve is quite tight and does not provide an adequate margin in high pressure dynamics and for reducing CO2% when using helmets (see dedicated section).

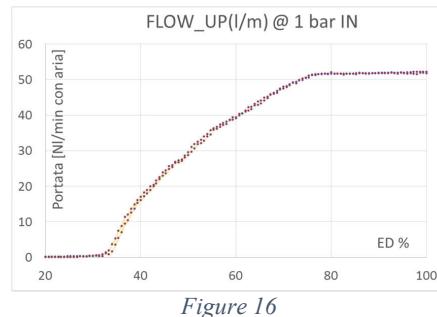


Figure 16

- PR1 (pressure regulator) set @ 500mbar

Curve from Camozzi (figure below) shows too low flowrate in all the operating conditions.

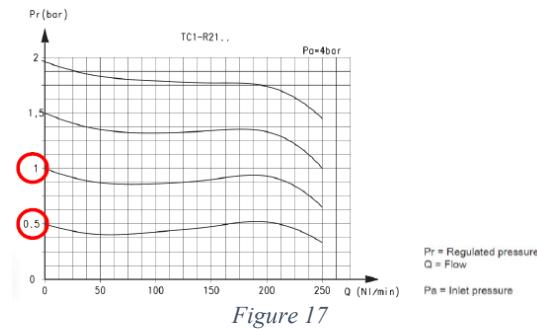


Figure 17

Based on the above considerations we believe that the "AP-spec" valve is not adequate for being used in the ventilator.

#### 5.4.2 PR1 & V1: “CP-SPEC” VALVE PERMEABILITY TARGET



“CP-spec” valve, due to the presence of a 4.4 mm nozzle is inherently more permeable than the “AP-spec”. CP-spec valve flushing test has been performed in Camozzi on 10/04/2020 (see image below) and test results have been used to feed the model.

750 mbar as PR1 pressure threshold is the ideal case due to the reduced maximum flow delivered at 100% FS current and normal working condition at 46% of FS (current). 1 bar would provide a too high flowrate in fully open condition while 500 mbar of pressure would be tight for delivering the max flowrate.

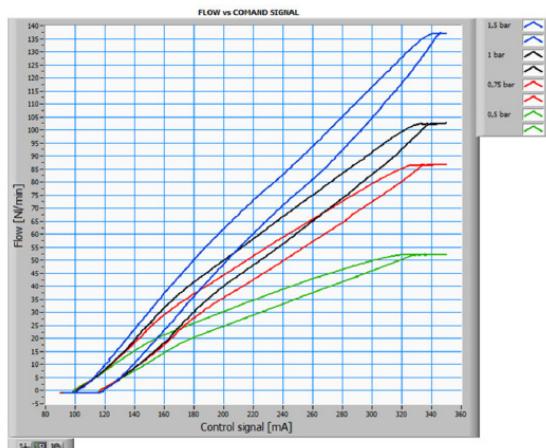


Figure 18

- PR1 (pressure regulator) set @ 1000mbar

Minimum %FS current to satisfy the target pressure is 45%. Too high flow rate level if running @100%FS current (>100 lpm): such a high flow could be challenging to be evacuated by the pressure relief valve.

- PR1 (pressure regulator) set @ 750mbar

Minimum %FS current to satisfy the target pressure is 46%, pretty similar to the 1000mbar case study due to the fact that the two curves are very similar for low FS. Flow rate @100%FS current is about 88lpm and it's manageable with the pressure relief valve. This is the pressure level recommended for the pressure regulator.

- PR1 (pressure regulator) set @ 500mbar

Minimum %FS current to satisfy the target pressure is 51%. Flow rate @100%FS is slightly higher than 50lpm and could be a limiting factor when trying to follow the desired dynamics on pressure target.

### 5.4.3 “CP-SPEC” FLOW-RATE TEST

Below two simulation results using “CP-spec” valve at 750 mbar inlet pressure and considering an “high compliance” lung characteristics.

Top graph refers to a 12 cyc/min breathing frequency and in this case the required flowrate peak will be around 21lpm. Bottom graph refers instead to higher frequency (30 cycles/min) and here the flowrate request increases significantly up to 38 lpm.

Considering a 30-40% margin for valve’s flowrate and considering that an excess of flowrate will be needed in order to shape the pressure curve as desired (more like a step) this confirms that the maximum valve’s flowrate must be above the region of 60/65lpm.

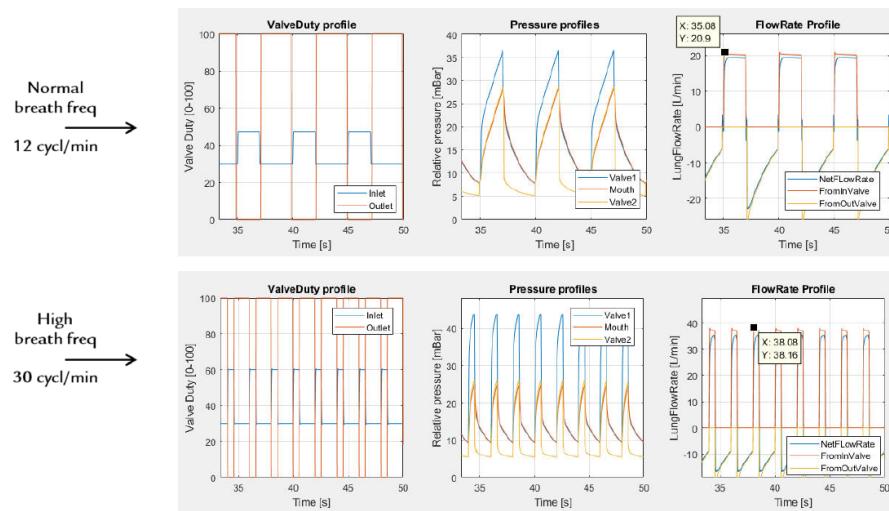


Figure 19

### 5.4.4 V2 VALVE PERMEABILITY TARGET

The following image shows a scan of outlet valve permeability using Camozzi physical components and considering the worst case of stiffest lung characteristic.

Simulations have been performed with two breathing frequencies and in both the scenarios the system is saturated using a permeability of  $Kv=1.7$ . Based on these considerations the CFB-D22G-W1valve has been adopted for the prototype.

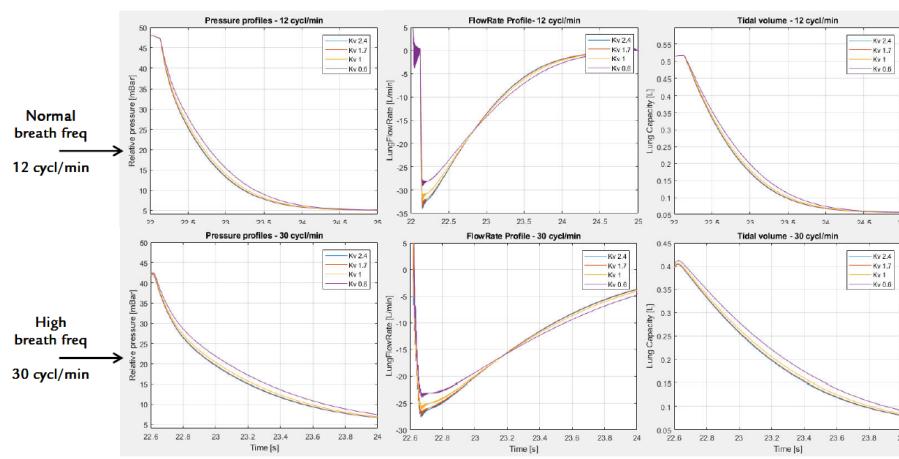


Figure 20

### 5.4.5 FLOW LINE PRESSURE DROP AND PERMEABILITY SCAN

The next table shows the main sources of pressure drop in the system: main ones come from filters and flowmeters. For all the devices not in-line (like safety vent trap and pressure relief valves) the values shown in this sections represent a target of permeability to satisfy the safety requirements explained in the FMEA section. The in-line permeability scan has been performed in order to assess the robustness of the results.

- Increasing 3x the pressure drop upstream of the lung does not affect much the mouth pressure and the control is expected to compensate this effect completely. Water should be added in the safety vent trap (if present) to prevent air flow.
- Increasing 3x the pressure drop downstream of the lung increases mouth pressure's curves. The effect is the same of having a less permeable peep valve.

Name	INLine / Deriv	Note	Flow [Lpm]	dP [mbar]
Pipe	inline	22mm Din, 1.5mt long, corrugated	20	0.04
QD	inline	Conical conection	20	0.1
Flowmeter	inline	Honeywell datasheet	20	2.44
Filter	inline	"used" HEPA	20	5
Humidifier	inline		20	0.2
PEEP	inline	averaged from customers	20	1.76
Check valve	deriv	cranking press 80mbar	106	80
Vent valve	deriv	30-50 mbar of water press	10	5

Figure 21

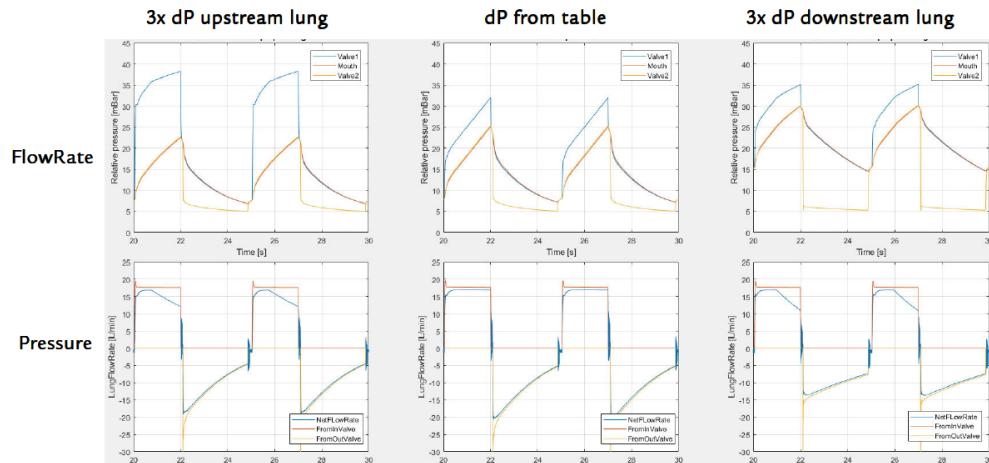


Figure 22

#### 5.4.6 EFFECT ON PRESSURE DYNAMICS: HELMET VS MASK

Representative volumes of 0.5L for the mask and 8L for the helmet have been considered for this calculation; please note that no air leakages have been modeled in helmet case (although probably there are some). Dotted line in following graphs represent case with helmet.

With almost +8L volume before the patient, pressure dynamics @ mouth change significantly. About 100cc of tidal volume is lost due to the reduction of either 3 mbar (mouth pressure) and 4l/min of lungs inflation flowrate.

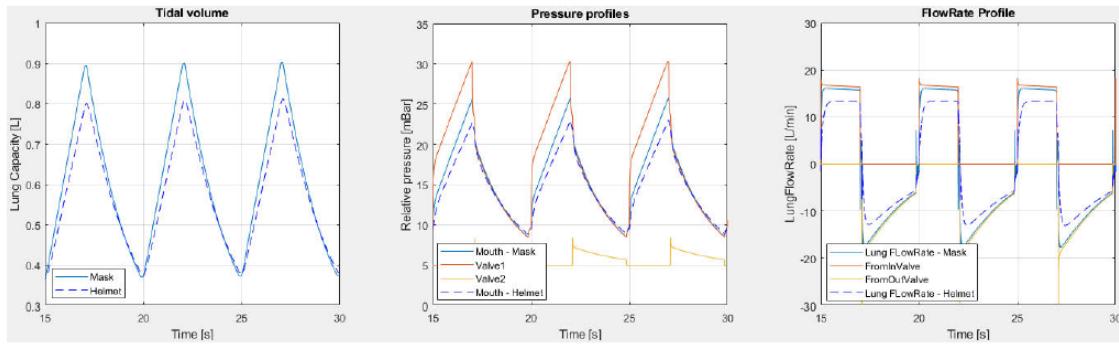


Figure 23

By increasing V1 command current of 4-5% it is possible to entirely recover the original lung's tidal volume matching a mask-like pressure dynamics. Expiration phase is instead driven by lungs dynamics and cannot be replicated using helmet.

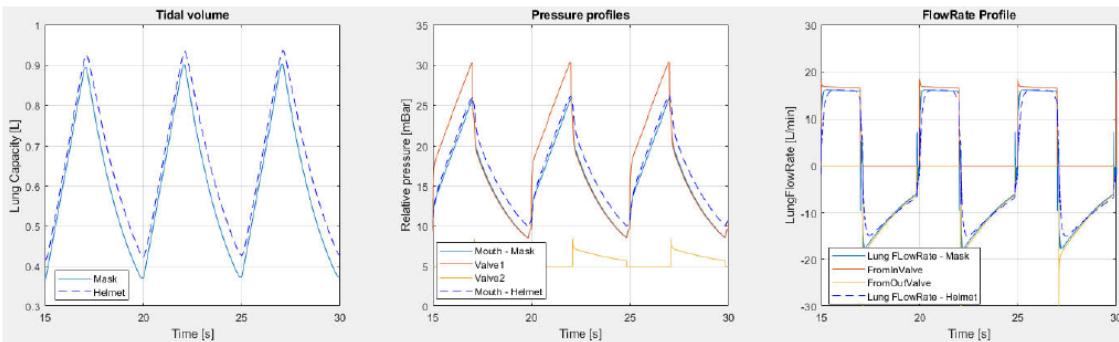


Figure 24

#### 5.4.7 SYSTEM VOLUMES (STAGE 1 AND STAGE 2)

The following graph shows the influence of “stage1 volume” on FiO<sub>2</sub>, stage1-pressure and stage2-pressure. Feeding pressure of 4bar for both medical air and O<sub>2</sub> supply has been considered and a sensitivity with a scan of 0.1L – 1L – 3L – 5L has been carried out.

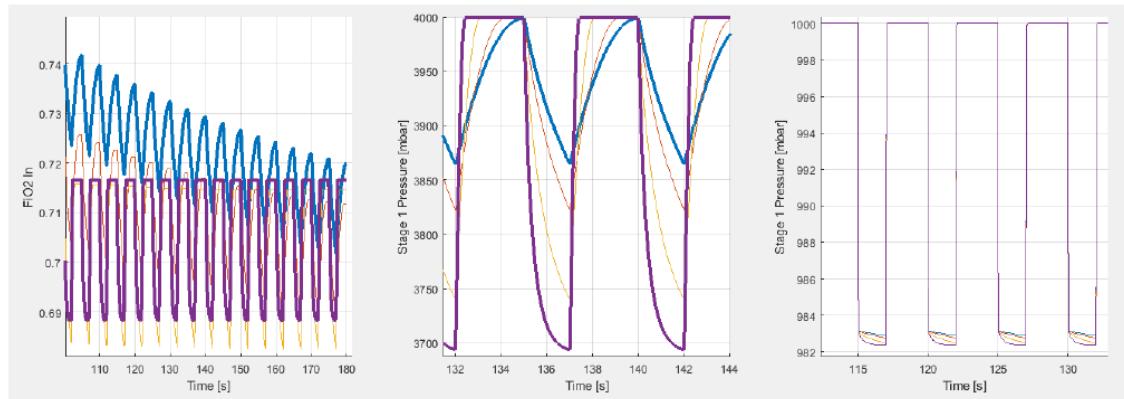


Figure 25

The influence of the “stage 2 volume” is instead shown in the next graph: as expected it is negligible and close to the ideal behavior of the pressure regulator.

Increasing the “stage 1 volume” stabilizes pressure, but even in the worst case the dynamics are quite slow and should be managed by the pressure regulator.

The  $\text{FiO}_2$  is stable (within a 3% band)

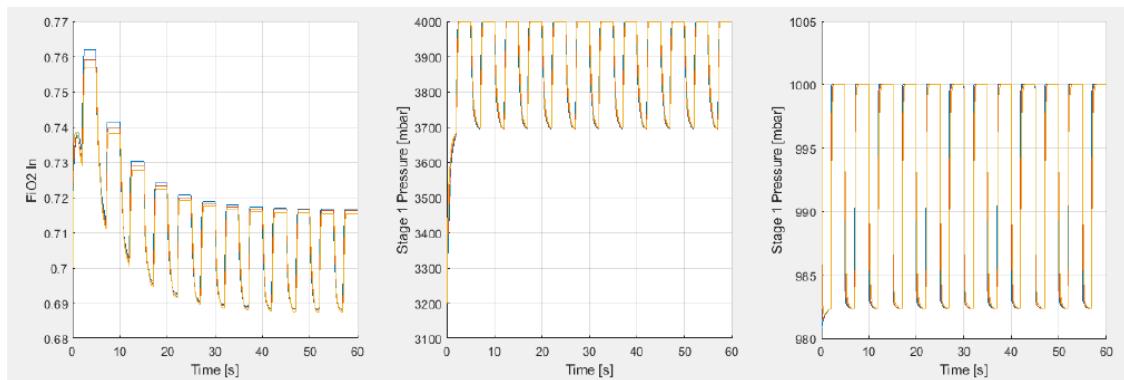


Figure 26

The following graph shows the influence of “stage1 volume” on  $\text{FiO}_2$ , stage 1-pressure and stage2-pressure. Feeding pressures of 2.5bar for O<sub>2</sub> supply and 4bar for medical air supply have been considered: a sensitivity with a scan of 0.1L – 1L – 3L – 5L has been carried out.

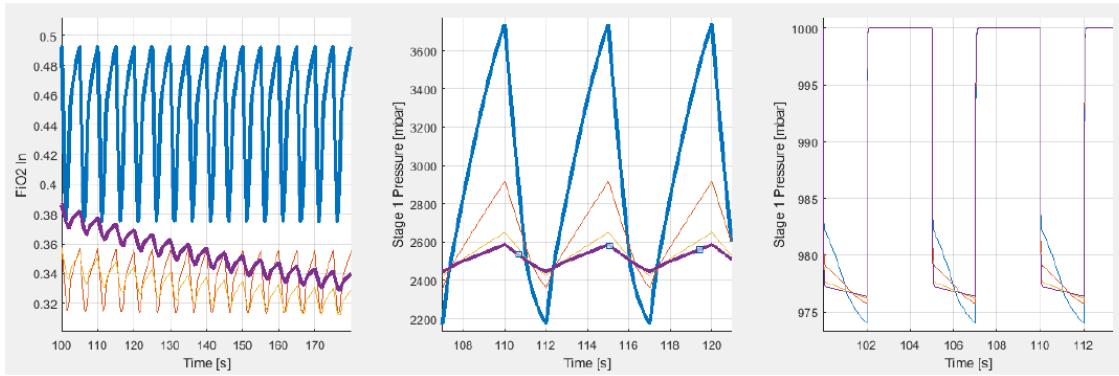


Figure 27

The effect of the “stage2-volume” is negligible (see graph below), while the “stage1-volume” has quite a big effect and at least 3L are recommended to stabilize pressures and  $\text{FiO}_2$ .

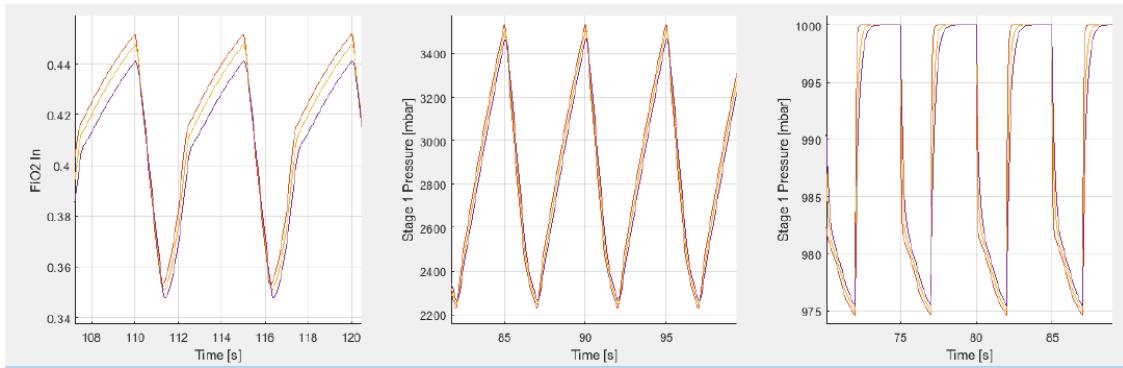


Figure 28

## 5.5 DEVELOPMENT OF THE VENTILATOR CONTROLLER

The controller component has been designed and implemented in Simulink to leverage on the ability of such a framework to generate the code directly from the model to be deployed on the physical device.

Moreover, the controller block has been also complemented with a dedicated circuitry in Simscape (see Figure 3) to reproduce the most of the physical behaviors of the manifold analyzed in Section 4.3 and thus help the design stage.

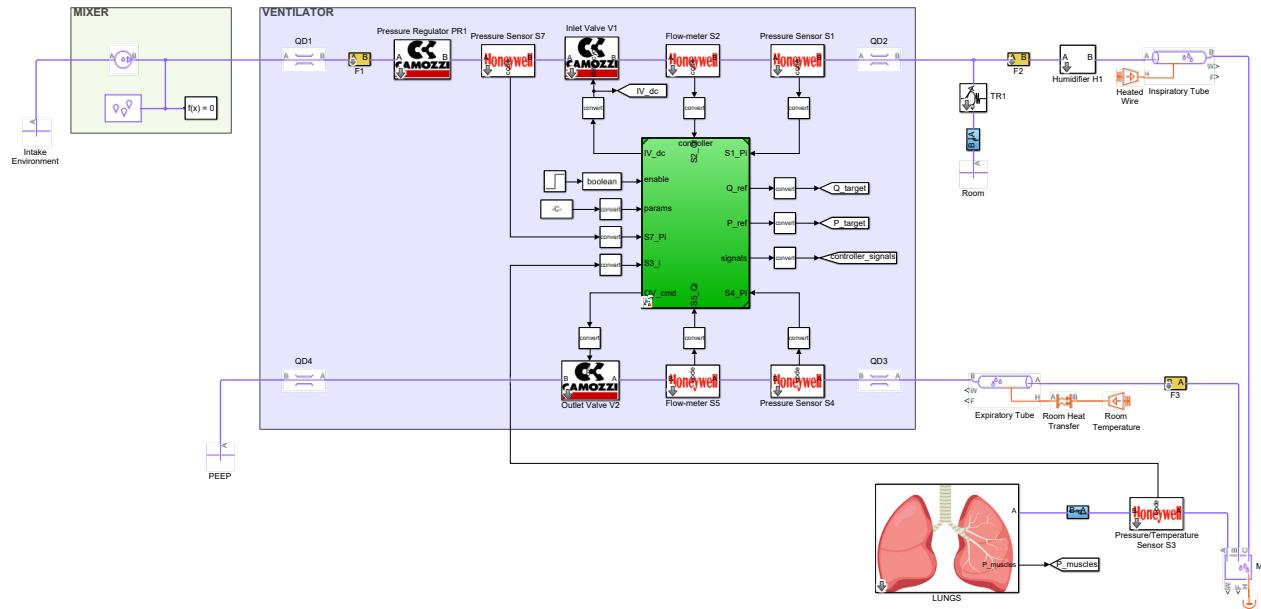


Figure 29. The complete model of the Ventilator in Simscape with the controller component shown as a green block.

### 5.5.1 CONTROLLER'S MODES

The controller can operate in the following four modalities:

1. **IDLE**. The controller is not operational in that the inlet valve (IV) and the outlet valve (OV) are always kept closed and wide open, respectively. Filtering of the sensors feedback is active though.
2. **CPAP** (Continuous Positive Airway Pressure). The controller regulates IV in order to achieve a constant inlet pressure, whereas OV is kept wide open.
3. **VCV** (Volume-Control-Ventilation). The controller regulates the flowrate delivered to the patient by controlling IV and OV valves. The operator can set up the following relevant parameters are: the Tidal Volume (TD), the Respiratory Rate (BPM), and the Inspiration-to-Expiration Ratio (IE).
4. **PRVC** (Pressure-Regulated-Volume-Control). The controller delivers a specific pressure profile to the patient controlling the IV and OV valves. Other than BPM and IE parameters, the operator can also specify the Peak Inspiratory Pressure (PIP).

### 5.5.2 CONTROLLERS' COMPONENTS

The discrete controller runs at a sample frequency of 100 Hz and is composed of the following main blocks, as depicted in Figure 4:

- **Filtering of sensors feedback.** Pressure readouts are filtered by means of an IIR 3<sup>rd</sup> order Low-Pass filter with a specified cutoff frequency to denoise input signals.
- **PI controllers.** VCV and PRVC modes are implemented by resorting to a standard parallel PI controller with anti-windup.
- **Feed-Forward terms.** PI controllers can take advantage of the predictive actions provided by feed-forward terms. In VCV mode, the feed-forward term is auto-adaptive, whereas in PRVC mode, the feed-forward term is directly specified by the operator. The predictive action aims to compensate for the required nonnull duty-cycle (dc) commands to be delivered to the valves (visible as elbows in the flowrate/dc static diagrams) to start yielding flows.

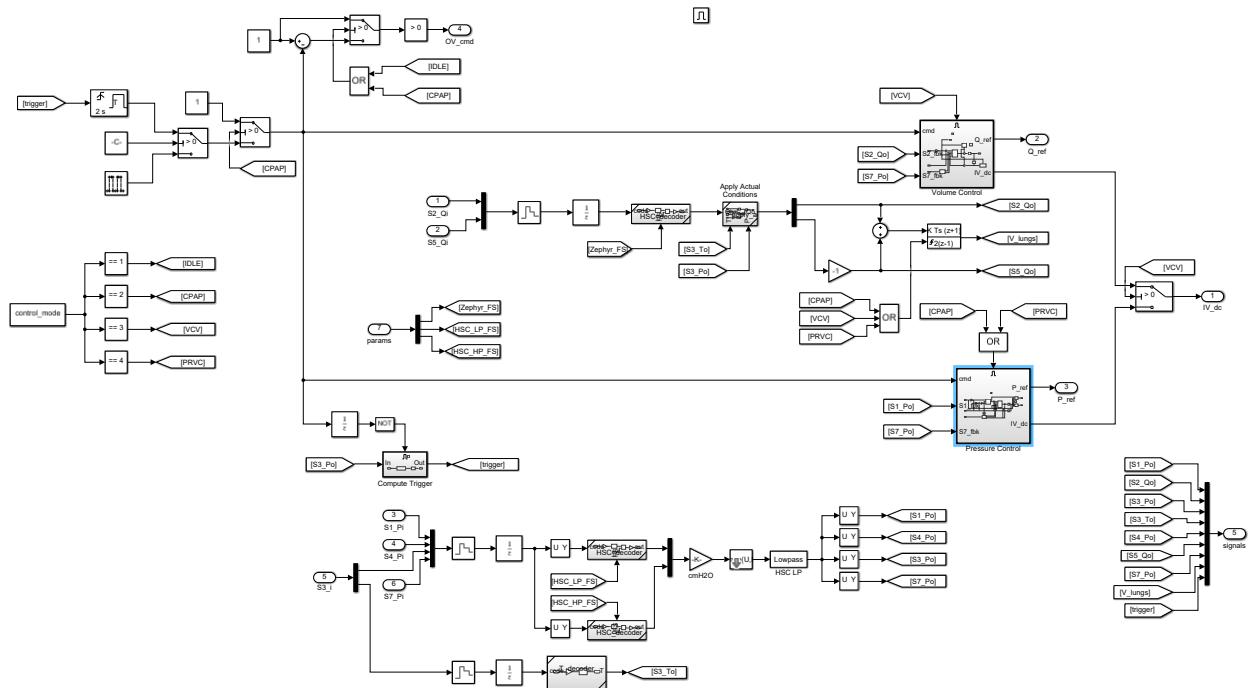


Figure 30. The internal blocks of the controller comprising sensors filtering, VCV and PRVC controllers, and triggering of the assisted ventilation.

The PI controller responsible for regulating the pressure in PRVC mode, whose diagram is reported in Figure 5, is further characterized by the presence of a **Input-Shaping** module, which shapes the input pressure steps into suitable waveforms (see Figure 6 for more details) by applying smoothing through a minimum-jerk filter.

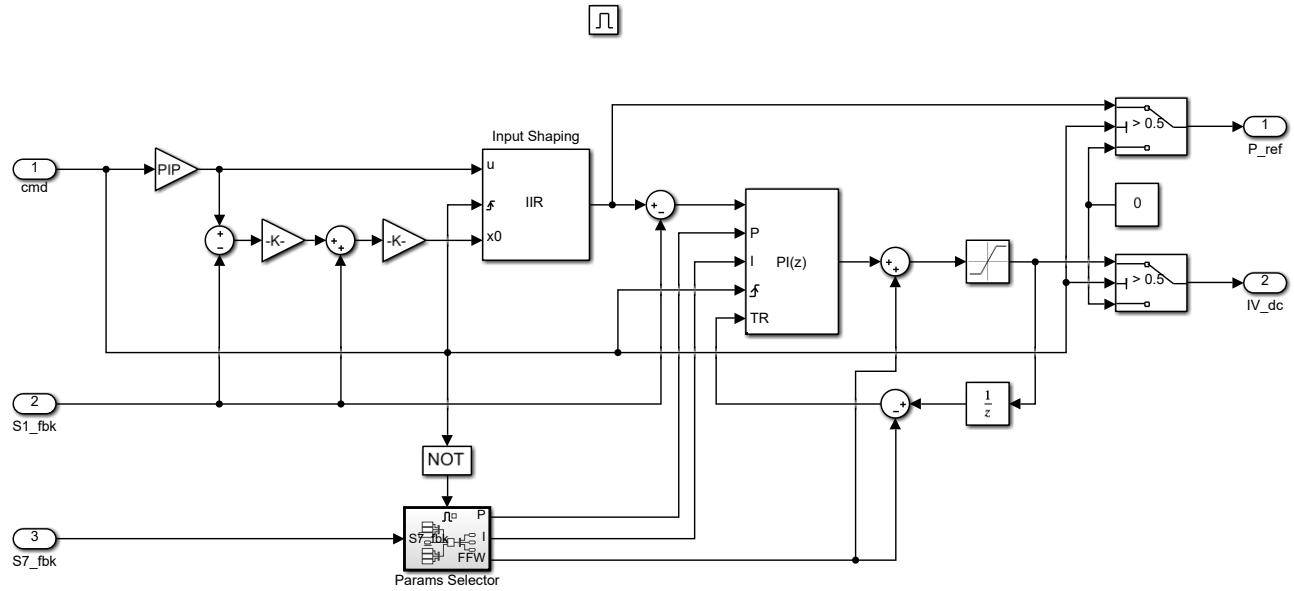
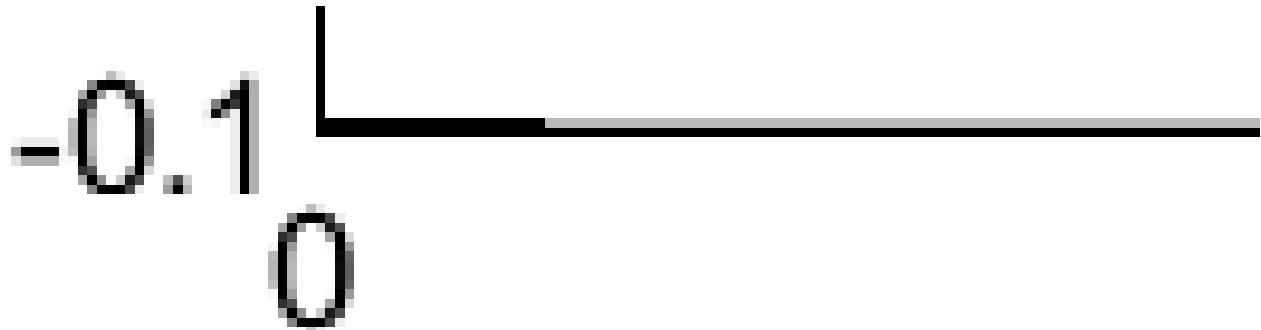


Figure 31. The PID controller with gain scheduling and input shaping devoted to the Pressure-Regulated-Volume-Control (PRVC) mode.

Both VCV and PRVC controllers are finally equipped with a **Gain-Scheduling** capability that help deal with fault conditions when a failure occurs at the PR1 pressure regulator letting the high-pressure ( $> 2$  bar) reach the inlet valve IV. This failure can be profitably detected by means of S7 readout and a counteraction can be undertaken by changing the P and I gains of the controllers (scheduling) to still guarantee acceptable control performance. An example of such a failure is reported in Figure 6.

### 5.5.3 ASSISTED VENTILATION

The controller can deliver forced ventilation at a given rate, but can also provide assisted ventilation, whereby the triggering of the inspiratory phase gets synchronized with the patient requests. This synchronization is achieved by measuring the pressure at the mask through the S3 sensor: triggers occur when the pressure goes below a configurable threshold.



*Figure 32. Example of control outputs in PRVC mode. From top to down: (1) control signals driving the IV and OV valves; (2) pressure feedback as read and filtered from the sensors; (3) flowrate feedback; (4) tidal volume estimates as computed by integrating the inlet and outlet flows. At  $t = 11$  s, a failure occurs to PR1 causing high-pressure to reach the valve IV; the controller is still able to regulate the pressure correctly, although a subsequent gain-scheduling ensures that the performance remains in the acceptable range.*

## 5.6 DEVELOPMENT OF THE FINITE-STATE MACHINE

We applied the same development approach used for the controller as described in Section 4.4 also to the implementation of the Finite-State Machine (FSM) that is responsible for managing the Human-Machine Interface (HMI) and the Alarms Handling. To this end, we employed the MATLAB toolbox Stateflow<sup>1</sup> that allows for an easy design of state machines within the Simulink environment and the subsequent code generation to address the deployment stage onto the target device.

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<sup>1</sup> <https://mathworks.com/products/stateflow.html>.

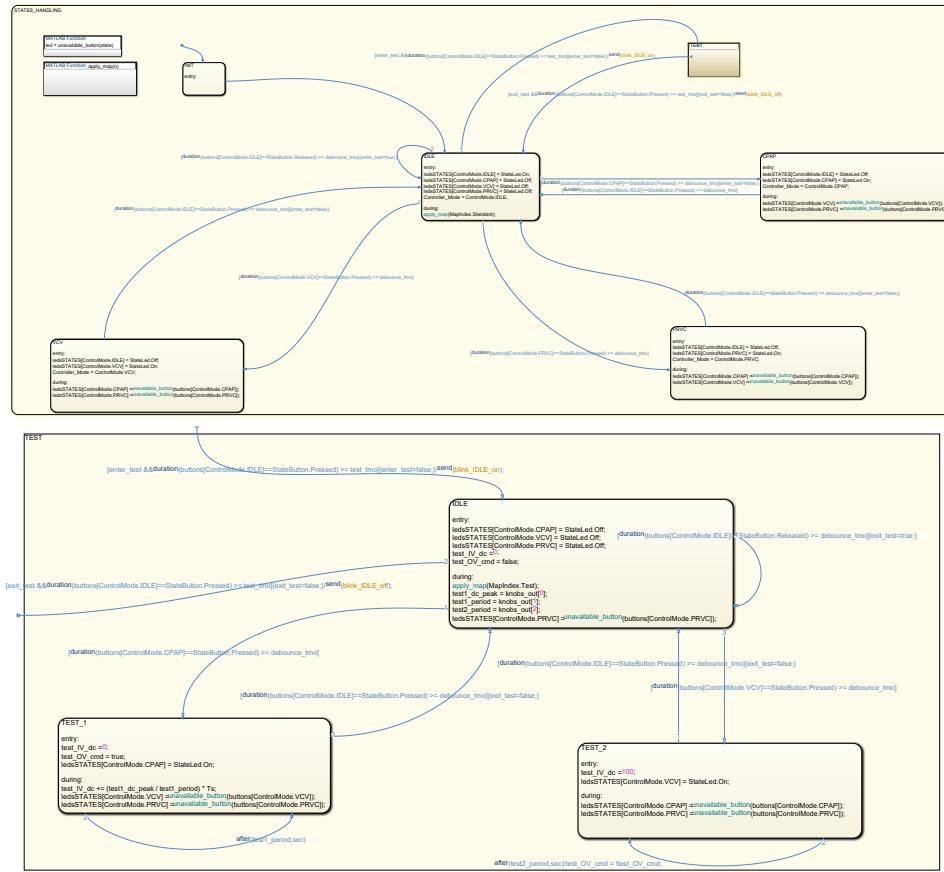


Figure 33. A subset view of the FSM states handling the HMI.

In detail, the FSM consists of the two main parallel sub-FSMs outlined below:

1. The HMI-FSM (Figure 7) oversees the handling of the user inputs provided through the buttons, the knobs, and the multi-selector encoder with the goal to:
  - a. select the controller mode by means of the buttons among the 4 available functionalities IDLE, CPAP, VCV, and PRVC.
  - b. switch on/off the LED as well as manage the blinking mode.
  - c. when in IDLE, latch the parameters values as specified by the knobs' positions.
  - d. manage the available maps that can be applied through the multi-selector encoder to the current knobs configuration to allow for a fine-tuning of the low-level controller's parameters.
  - e. switch between the standard (STD) and the test (TEST) working modes of the ventilator.
  - f. when in TEST mode, generate suitable signals to drive the inlet and outlet valves.
2. The ALARM-FSM controls the handling of the alarms by reading the sensors feedback as well as the controller's outputs. In case a fault condition is detected, this component is responsible for:
  - a. undertaking the required actions to put the device in safe mode.
  - b. signaling the failure by the activating the buzzer and the alarm LED.

Importantly, we carried out extensive verifications of the functionalities of the FSM in simulation thanks to the available rich set of Simulink widgets that allowed us to conceive a complete mockup of the device dashboard equipped with buttons, LED, knobs for testing the user interaction through the HMI (see Figure 8).

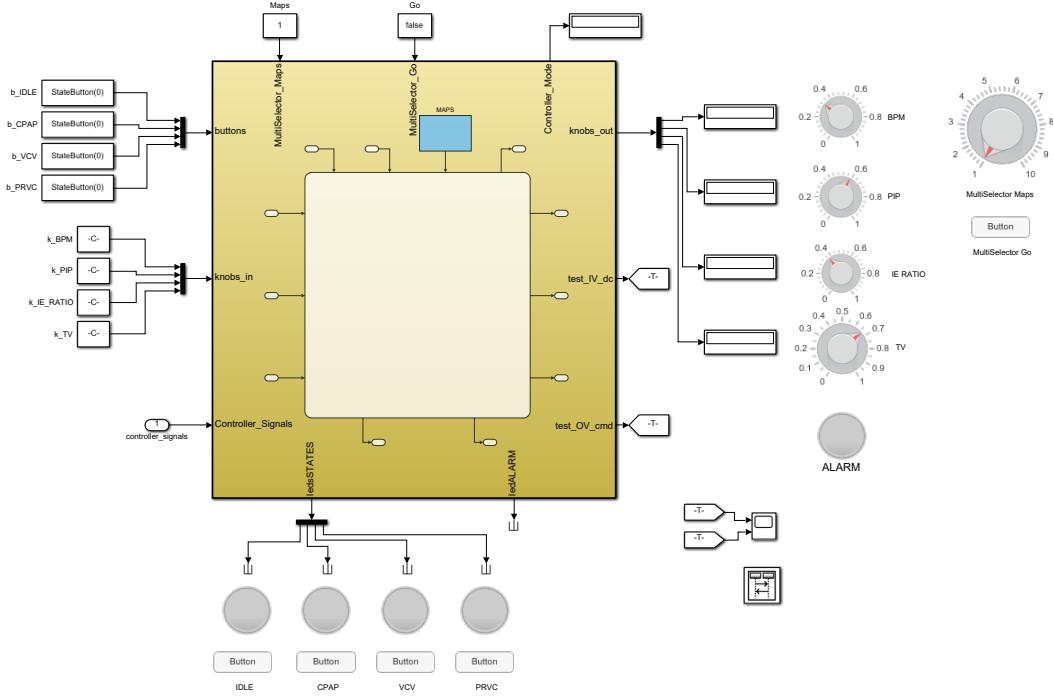


Figure 34. The high-level diagram of the FSM along with the dashboard inputs/outputs.

## 5.7 CO<sub>2</sub> REBREATHING

CO <sub>2</sub> concentration in air	Symptoms and effects of inhaling CO <sub>2</sub>
1-1.5%	No health impacts are expected
3%	Slight Headache, Nausea
4-5%	Headache, Slight Drowsiness, Dizziness, Respiratory Rate Increases
5-10%	Bad Headache, Breathing Difficulty, Impaired Judgement, Vision Impairment, Drowsiness, Stomach Pain
10-100%	Pounding Headache, Confusion, Shortness of Breath, Blurred Vision, Loss of Coordination, Uncontrolled Loss of Consciousness, Vertigo, Chest Pain, Memory Loss, Death (if not removed from CO <sub>2</sub> exposure)

Figure 35

In normal conditions the CO<sub>2</sub> rebreathing could be a serious issue (see table above)

From medical feedback, max CO<sub>2</sub> concentration must not exceed 2%. With mask smaller than 250ml CO<sub>2</sub> stabilizes at lower value so there's no need of any dedicated strategy to reduce CO<sub>2</sub> concentration. Over this volume the mask can accumulate critical value of CO<sub>2</sub>, for example having 500 ml as worst case scenario, the CO<sub>2</sub> concentration tends to stabilize in half a minute at 3.1% (see graphs below).

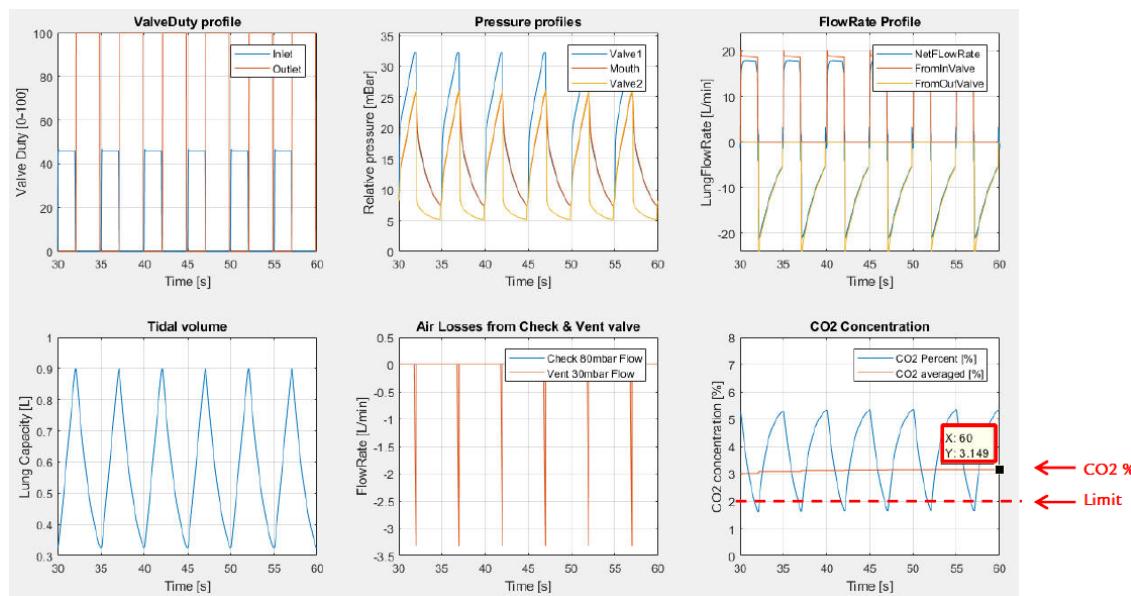


Figure 36

Different options have been simulated in order to study the best solution to lower CO<sub>2</sub>:

1. Valves overlap on inhalation phase
2. Valves overlap on exhalation phase
3. Valve1 minimum flow
4. Valves overlap on inhalation phase

Increasing valves' overlap in the inhalation phase is not efficient in reducing CO<sub>2</sub> concentration because it replaces already low % CO<sub>2</sub> air with air at zero concentration. As further downside it changes significantly the mouth pressure profile in both peak value and shape.

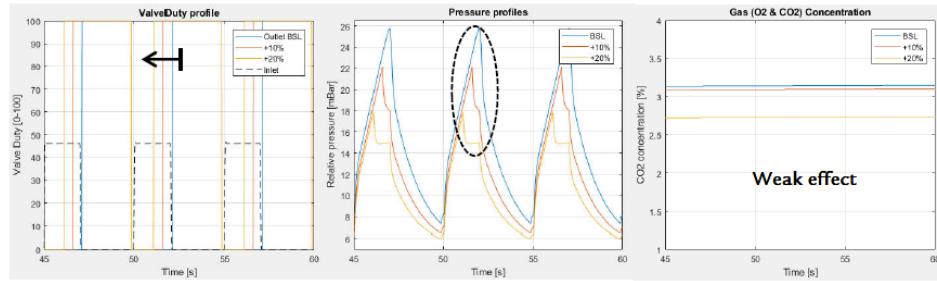


Figure 37

Acting on overlap in exhalation phase is much more efficient due to the action on much higher concentration CO<sub>2</sub> air (~ +4% of the inlet). The effect on the pressure curve is reduced in both peak value and general shape.

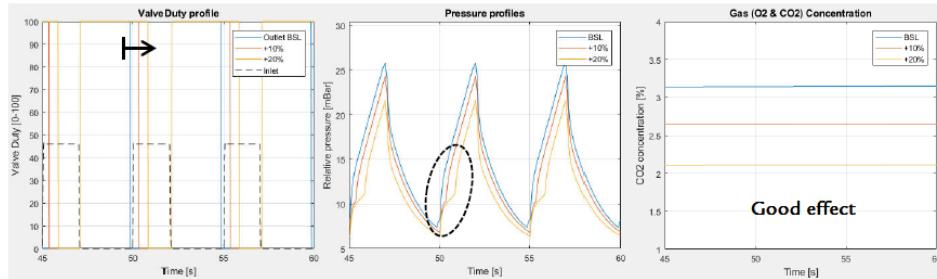


Figure 38

Minimum flow through V1 valve during the exhalation phase (flow-by) seems the most efficient way to reduce CO<sub>2</sub> %. The effect on pressure curve shape is small and with few lpm is easy to bring CO<sub>2</sub> % below 2% threshold.

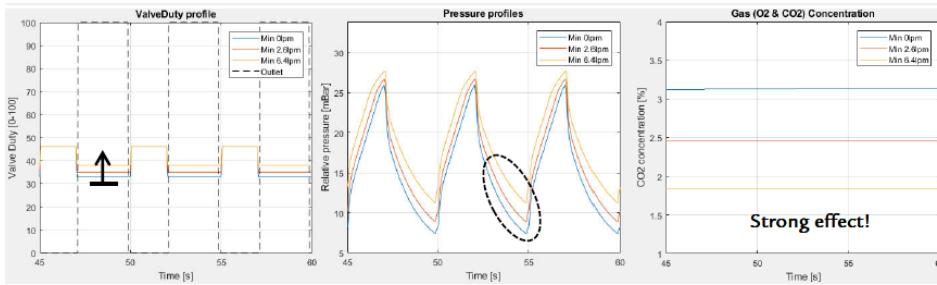


Figure 39

### 5.7.1 CO<sub>2</sub> REBREATHING HELMET

8L has been considered as worst case for the helmet volume: without any dedicated strategy, CO<sub>2</sub> will stabilize in 5 minutes at 3.4% (vs 3.1% of mask), slightly over the mask value but still well over the medical limit (see graphs below)

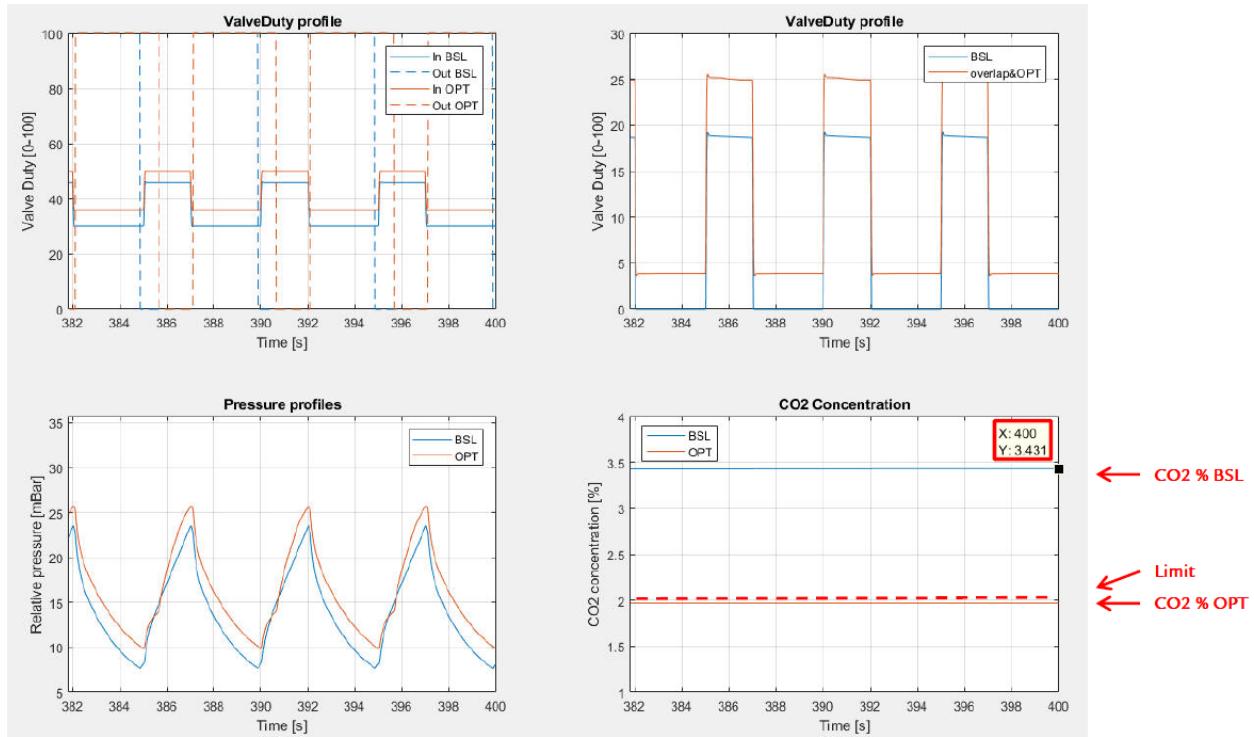


Figure 40

Applying a small valve overlap and a constant flow through the inlet valve is possible to lower the CO<sub>2</sub> % below this limit without affecting the pressure shape.

As previously seen, the most efficient way to reduce the Co<sub>2</sub> concentration is to keep the inlet valve slightly open during the expiration phase.

Due to the fact that the inlet valve is kept open during expiration phase, the pressure achieved in the expiration phase is higher and it results in a reduction of the actual tidal volume.

To compensate this effect it is sufficient to apply a gain to the pressure target (relative w.r.t. the Peep pressure).

In case of soft or average lungs a 1% (more than the zero of the valve) duty is enough to reduce the CO<sub>2</sub> concentration, while applying a 1.1 gain on the target relative pressure we can compensate the tidal volume.

Stiff lungs requires a higher amount of flow-by to reduce Co<sub>2</sub>, but a smaller gain to compensate the tidal volume, 1.03 (this because the residual pressure at the end of expiration phase changes less with a stiffer lung).

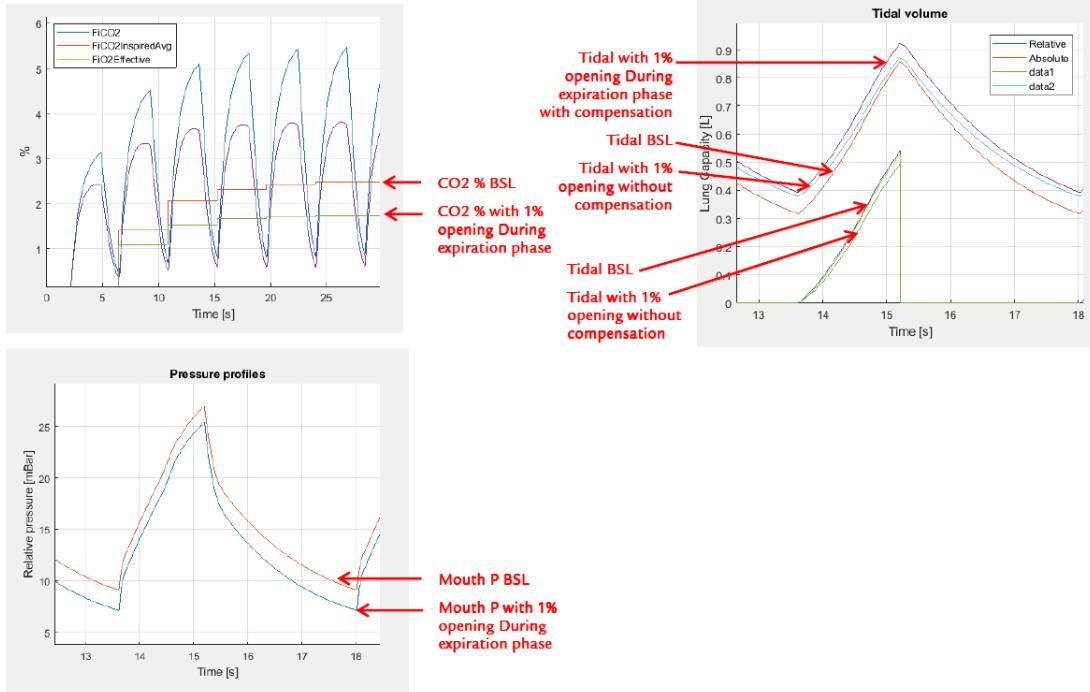


Figure 41

The flow control on the other hand, does not need any target correction in order to keep the tidal volume constant in case of flow-by (see below).

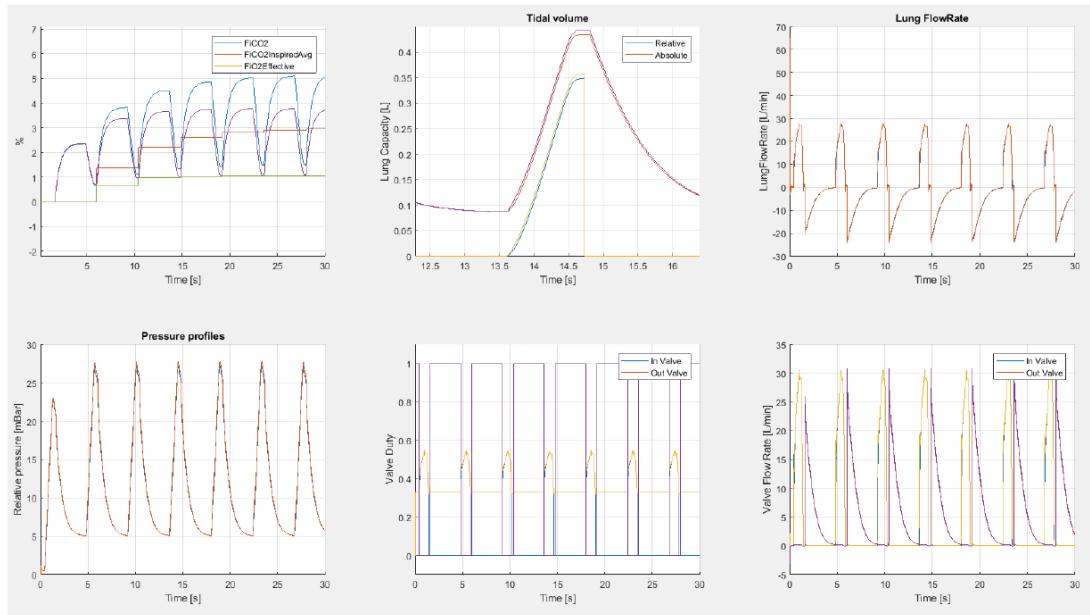


Figure 42

## 5.8 FMEA

Four mechanical devices define the flow/pressure level on patient's mouth.

- PR1 (pressure regulator) set in these simulations to 750 mbar.
- V1(inlet proportional valve)
- PR2 (pressure relief valve) set to a cranking pressure of 80mbar in compliance with MHRA requirements
- TR1 (safety vent valve valve) set from 30 to 50mbar and optional in these simulations being an external device.

A failure of each single component inside the ventilator assembly has been considered with the safety vent trap valve fitted and not fitted. Worst cases have been simulated in order to verify and asses the minimum level of permeability of the valves to be safe.

- Vent valve fitted and operative
  - If V1 doesn't work properly due to control issues or to a valve failure, the safety vent trap will evacuate all flowrate without triggering the pressure relief valve (SIM1)
  - If PR1 fails, V1 control will correct the valve duty to account for change in boundary condition (SIM3)
  - If PR2 fails but all the other device are working properly, the behaviour of the system will not be affected(no need of sim)
- Vent valve NOT fitted or broken.
  - If V1 doesn't work properly , the pressure relief valve must evacuate all the flowrate (SIM2)
  - If PR1 fails, V1 control will correct the valve duty to account for change in boundary condition (SIM3)
  - If PR2 fails but all the other device are working properly, the behaviour of the system will not be affected\_(no need of sim)

All the simulations have been carried out taking into account the stiffest lung characteristics (worst case) and V1 (inlet valve) running with 750mbar of inlet pressure thanks to the pressure regulator; this case produce an air flow rate through the valve V1 of 88 lpm. Assuming that the pressure drop associated to the safety vent trap is equivalent to a 0.3meters pipe with a diameter of 10mm (pessimistic) we got a loss of 0.1 mbar each 20lpm.

- SIM1 (V1 failure, safety vent trap fitted)

The safety vent trap thanks to its high permeability will evacuate all the excess of air without triggering the mechanical pressure relief valve. The pressure drop associated to the flow-meter (almost 20mbar) helps for increasing the operating pressure on the pressure relief valve without achieving 80mbar of cranking pressure.

In this condition the mouth pressure tends to 31mbar (see next image).

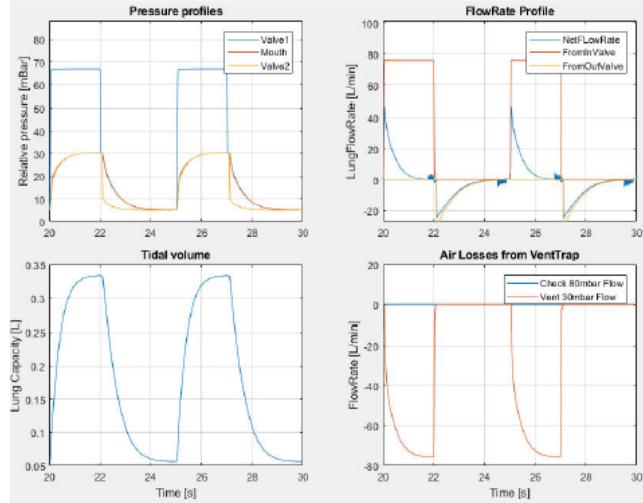


Figure 43

- SIM2 (V1 failure, safety vent trap NOT fitted)

The only protection in this case is represented by the mechanical relief valve set at 80mbar. The permeability target for this valve has been defined considering 110-120 mbar of maximum allowable mouth pressure. The valve must evacuate around 65 lpm of air at 160mbar pressure (+80 wrt cranking), see next couple of images.

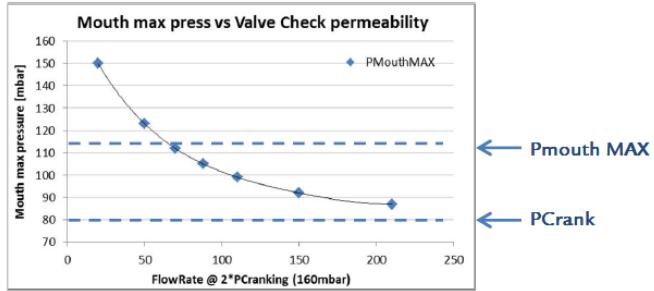


Figure 44

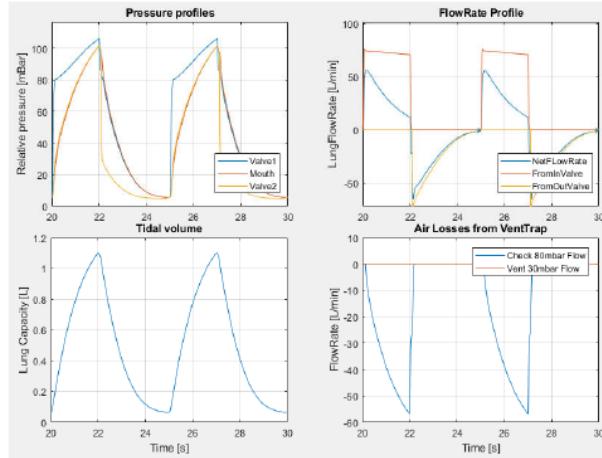


Figure 45

- SIM3 (PR1 issue, pressure control)

Pressure regulator's failure has been simulated at time 40sec, providing worst case supply pressure close to 4 bar rather than 0.75 bar (working point)..

No big issue on delivered pressure due to both the authority of the implemented control and due to the low sensitivity of the pressure-compensated valve V1 to the inlet pressure in low flowrate operating point.

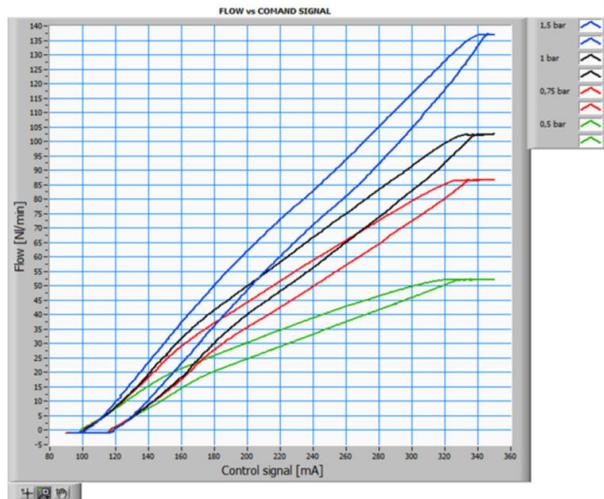


Figure 46

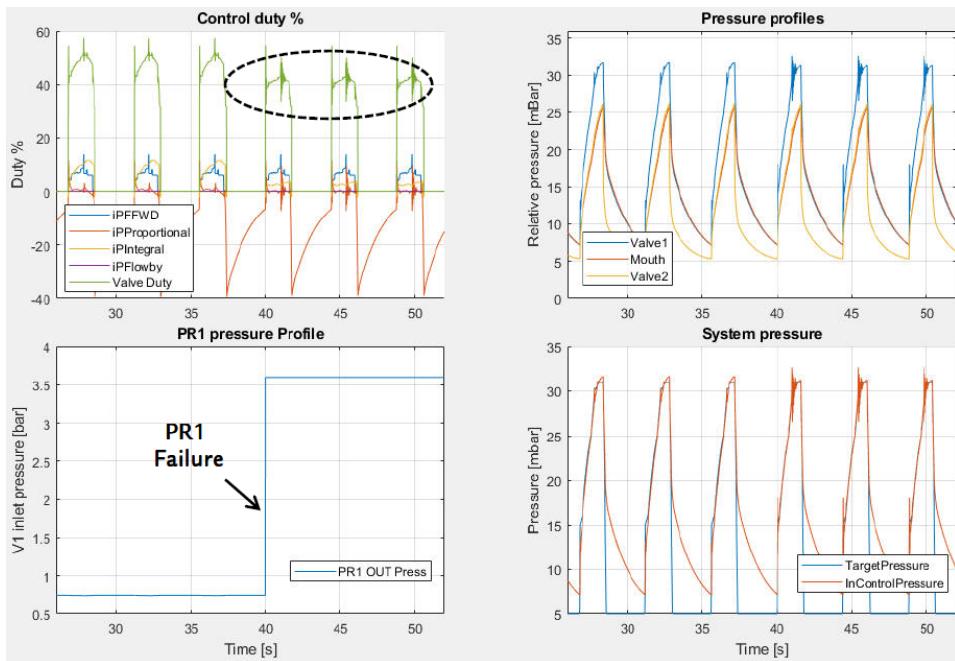


Figure 47

## 6. REFERENCES

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