



**ISTITUTO  
ITALIANO DI  
TECNOLOGIA**

# FI5 Ventilator Overview

<b>Date:</b>	<b>09 05 2020</b>
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<b>Description:</b>	This document describes the FI5 solution from Scuderia Ferrari and IIT
<b>Revision:</b>	<b>5</b>

Rev.	Author	Description	Date
0	Marco Maggiali	First emission	13/04/2020
1	Corrado Onorato	Added section 3	28/04/2020
2	Ugo Pattacini	Added section 4.2, 4.5 and 4.6	04/05/2020
4	Marco Crepaldi	Added electronics parts, rearranged all sections	07/05/2020
5	Marco Maggiali	links and figures review	09/05/2020

## Table of Contents

1.	Introduction and Goals.....	4
2.	Reference clinical requirements.....	5
2.1	UK Requirements for Emergency Ventilators .....	5
2.1.1	Modes of Ventilation .....	6
2.1.2	Gas and Electricity .....	7
2.1.3	Infection Control .....	8
2.1.4	Monitor and Alarms .....	8
2.1.5	Biological and safety.....	9
2.1.6	Miscellaneous .....	9
2.2	Acceptable Performance .....	10
3.	Principle of Operation and System Overview.....	11
3.1	Pneumatic scheme.....	11
3.2	Electrical scheme .....	12
3.2.1	CTR1 System .....	14
3.2.2	CTR1P Sub-System – Pressure Sensors and Flow-Meters Interfacing.....	14
3.2.3	CTR1S Sub-System – Motherboard Shield .....	15
3.3	H-M interface scheme .....	17
3.4	Ventilator Mechanical Layout .....	17
3.4.1	Layout of Internal Components .....	18
3.4.2	Layout of the External Case and H-M interface .....	21
3.5	Open source data.....	23
4.	Simulations .....	25
4.1	Overview.....	25
4.2	Modeling of the Human Lungs .....	25
4.3	Modeling of the Manifold .....	26
4.3.1	Summary of main results .....	27
4.4	Permeability targets .....	28
4.4.1	PR1 & V1: “AP-spec” valve permeability target.....	28
4.4.2	PR1 & V1: “CP-spec” valve permeability target.....	29
4.4.3	“CP-spec” flow-rate test.....	30

4.4.4	V2 valve permeability target.....	31
4.4.5	Flow line pressure drop and permeability scan.....	32
4.4.6	Effect on Pressure Dynamics: Helmet vs Mask.....	33
4.4.7	System volumes (stage 1 and stage 2).....	34
4.5	Development of the Ventilator Controller .....	36
4.5.1	Controller's Modes .....	37
4.5.2	Controllers' Components .....	37
4.5.3	Assisted Ventilation .....	39
4.6	Development of the Finite-State Machine .....	41
4.7	CO2 rebreathing.....	44
4.7.1	CO2 Rebreathing Helmet.....	46
4.8	FMEA .....	48
5.	References.....	52

## 1. INTRODUCTION AND GOALS

**DISCLAIMER:** These Technical Specifications are the result of scientific research activities carried out by IIT in the context of the project FI5 (“Rapidly manufactured ventilator system”). They are provided “AS IS”, without any warranty, and only to facilitate the design of a replicable prototype of a ventilator that is not legally classified as medical device under the laws and regulations of the country where it was developed nor is CE marked. Any prototype shall in any case undergo mandatory procedures set forth by the laws and regulations in force in the country of prospective use prior to any use (compassionate use included) and/or commercialization.

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 <sup>[1]</sup>. 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 <sup>[2]</sup> and the U.S Food and Drug Administration (FDA) <sup>[3]</sup> 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 <sup>[4]</sup>. 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. <sup>[5]</sup>. 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 <sup>[3]</sup>). A team of 13 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 <sup>[2]</sup> 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 (Vt) 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.

- a. must connect with NIST (Non-Interchangeable Screw Thread to ISO 18082:2014/AMD 1:2017).

Electricity Supply.

- a. Must be PAT tested to the adapted IEC 60601, IEC 62353 standards
- b. If electricity is required for functioning, RMVS must have a battery backup of at least 20 minutes in case of mains electricity failure.
- c. Must avoid harmful RF or EM emissions that could interfere with other critical care equipment.

*Gas supply to patient. (provided by STAGE1)*

- a. 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.
- b. 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

All parts coming into contact with the patient's breath must be either disposable or designed to be reusable.

All working components of the device must be contained within an impermeable casing.

All external surfaces must be cleanable in the likely event that they get respiratory secretions or blood splatter on them. Cleaning would be by healthcare workers manually wiping using an approved surface wipe with disinfectant or cloths and approved surface cleaning liquid.

There will be a separately sourced HMEF-bacterial-viral filter between the machine and patient which may impact on resistance within the system, which may need to be accounted for with some designs. The pressure being delivered to the patient is the specified pressure. If the filter has a resistance of, say 2 cmH<sub>2</sub>O at 30 lpm, the ventilator needs to output 37 cmH<sub>2</sub>O to achieve a set 35 cmH<sub>2</sub>O at the patient. This will need further detailed consideration. Viral filtering filters may have much higher resistance that may be clinically relevant.

#### 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:**

- a. Gas or electricity supply failure.
- b. Machine switched off while in mandatory ventilation mode.
- c. Inspiratory airway pressure exceeded.
- d. Inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm).
- e. Tidal volume not achieved or exceeded.

**Monitoring displayed continuously so the user can verify.**

- f. Must show the current settings of tidal volume, frequency, PEEP, FiO<sub>2</sub>, ventilation mode.
- g. Must show the actual current airway pressure
- h. Should show the achieved tidal volume, breathing rate, PEEP, and FiO<sub>2</sub>.
- i. If pressure support mode is provided there must be real time confirmation of each patient breath and an alarm if below acceptable range.
- j. Could provide CO<sub>2</sub> monitoring.

#### 2.1.5 BIOLOGICAL AND SAFETY

The authoritative standard covering this area is ISO 18562-1:2017 “Biocompatibility evaluation of breathing gas pathways in healthcare applications. Evaluation and testing within a risk management process”.

#### 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

- a. Under steady-state conditions, the indicated airway pressure shall be accurate to within  $\pm(2 + (4\% \text{ of the actual reading})) \text{ cmH}_2\text{O}$ .
- b. The accuracy of measurement of expired volumes greater than 50 ml shall be within  $\pm(4,0 + (15\% \text{ of the actual volume expired through the patient-connection port})) \text{ ml}$ .
- c. Oxygen concentrations will be  $\pm 5\%$  of the set value.
- d. Disconnect alarm will sound within 3 seconds of disconnection.

### 3. PRINCIPLE OF OPERATION AND SYSTEM OVERVIEW

#### 3.1 PNEUMATIC SCHEME

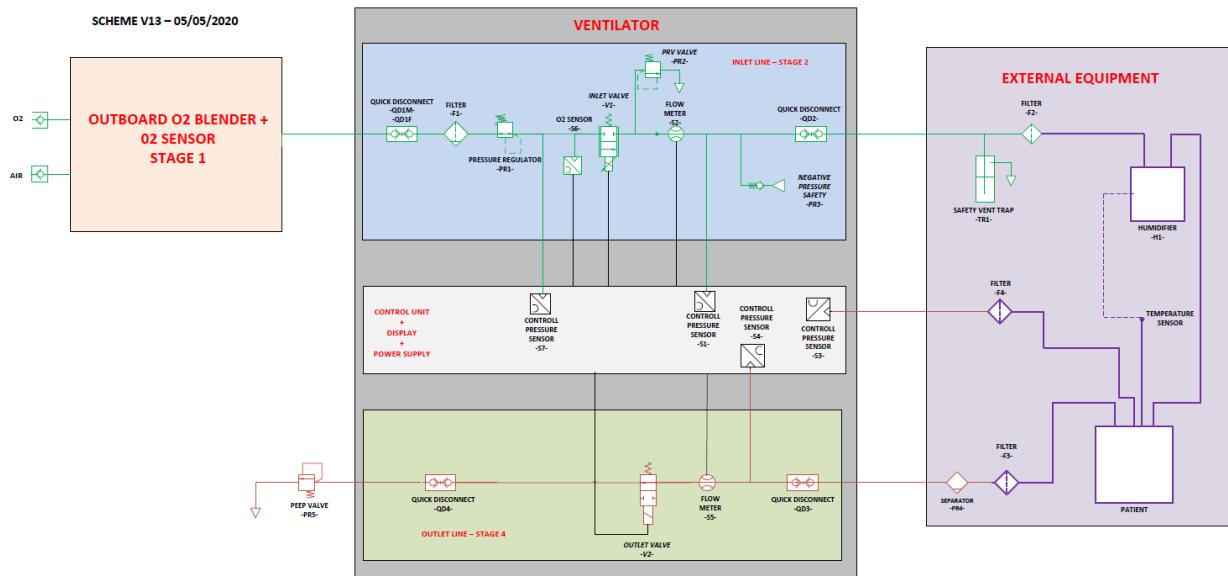


Figure 1 – FI5 Pneumatic Scheme

Figure 1 shows the FI5 pneumatic scheme. The 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 (in principle, 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

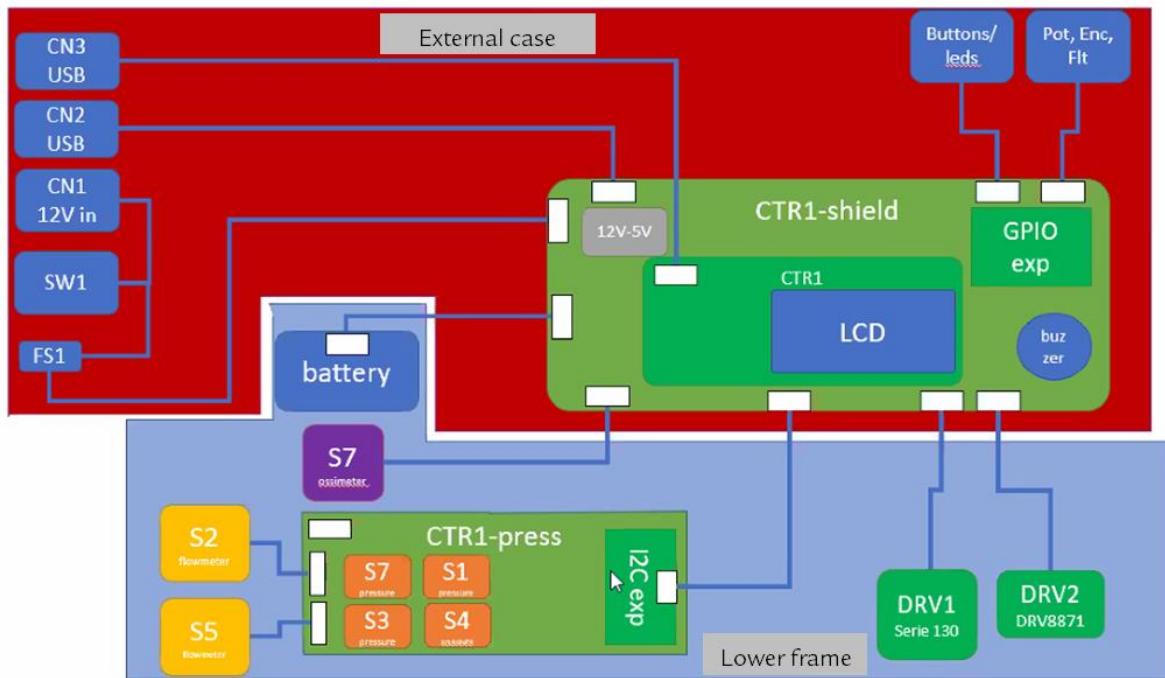
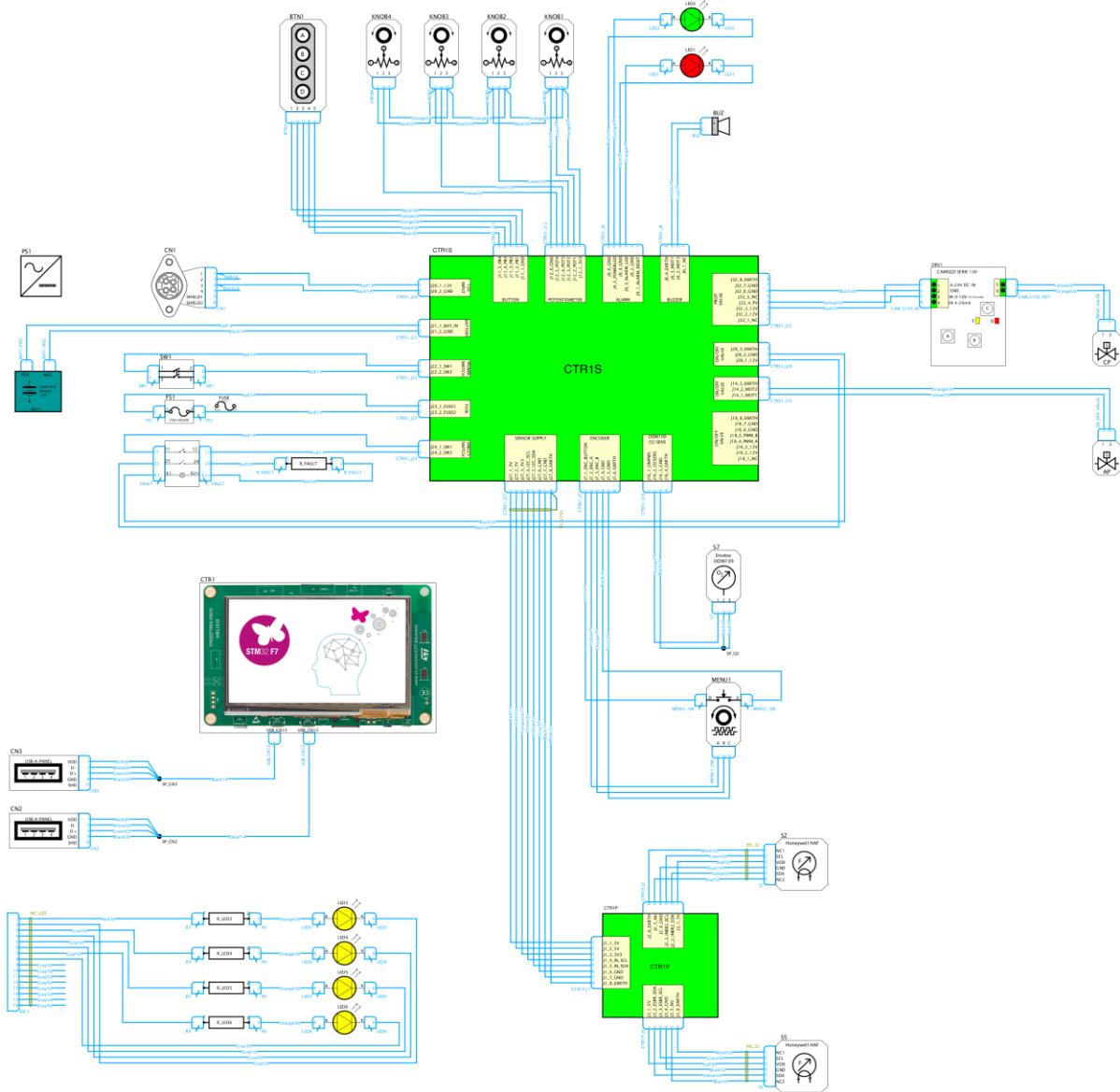


Figure 2 – FI5 Electrical Block Scheme

Figure 2 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 Figure 3.



*Figure 3 – FI5 Detailed Electrical Schematic*

The electronic system comprises three separate modules, an STM32F746 Discovery Board (CTR1), its respective shield board CTR1S and a separate control board sub-system, namely CTR1P for pressure sensors and flow-meter interfacing. The choice of the electronic components and the design of the two control sub-systems is dictated by the necessary requirements of i) availability in the ultra-short term (warehouse, or availability through gross distributors of electronic components), and ii) ease and effectiveness of the design. During the COVID-19 pandemics, one of the major objectives for the implementation of the FI5 ventilator was the use of components in stock to minimize design time. The same reasoning applies for the battery that is directly interfaced to the CTR1-shield. The use of a

commercial reference design board for this project is justified by the rapid prototyping nature of the ventilator and the shortest design time as possible. The logic behind the use of these commercial modules is that interfacing can be achieved by simply using piggyback boards or other commercial modules that in turn can be easily installed in shields. The electronic design, therefore, has been based on the re-use of existing shields and the rapid design of full custom ones, capable of integrating them.

### 3.2.1 CTR1 SYSTEM

The STM32F746 discovery board is manufactured by ST-Microelectronics, that provides both bill-of-materials, schematic and layout for reference designs as open source data, <https://www.st.com/en/evaluation-tools/32f746gdiscovery.html>. The STM32 discovery board modules is a reference design for the evaluation of the STM32F746 microcontroller that includes an embedded 4.3" RGB 480×272 color LCD-TFT with capacitive touch screen, to implement data visualization based on human device interfaces. The STM32F746 microcontroller provides a maximum CPU frequency of 216MHz, it provides an internal L1 cache and a specific hardware accelerator for the external LCD capacitive touch screen. The use of such an evaluation kit represents an effective design choice from a functional point of view thanks to the presence of the display, enough computation power to handle complex tasks, ease of interfacing with respect to external modules and provides all the software libraries required to handle completely the hardware modules. Moreover, it is supported also for high-level software automatic generation such as Matlab and the consequent integration with such simulation environment. Another advantage of the use of a discovery board for these purposes is undoubtedly, in general, the rapid prototyping constraint for which these solutions are designed and that can be effectively applied to our ventilator design context.

### 3.2.2 CTR1P SUB-SYSTEM – PRESSURE SENSORS AND FLOW-METERS INTERFACING

The CTRL1P sub-system is in charge of interfacing all flow meters and pressure sensors of the ventilator. All these sensors that are interfaced through an I2C bus cannot be interfaced with the main motherboard system (CTR1) due to unavailability of I2C ports. Therefore, the CTR1P Sub-System integrates an I2C multiplexer to concentrate all the I2C interfaces to a single end-point. The multiplexer can be latched to poll a single I2C sensor using a minimum number of bits for selection during a single bust transaction. Figure 4, shows an image of the implemented printed circuit board, with detail on connectors S2 and S5 for flow meters interfacing, the four commercial pressure sensors S1, S4, S3 and S7, and the I2C multiplexer (please refer to the schematic and the bill of material for further details on the component). All sensors are interfaced using an I2C which potentially enables detection of communication interruption in case of confined faults within the module.

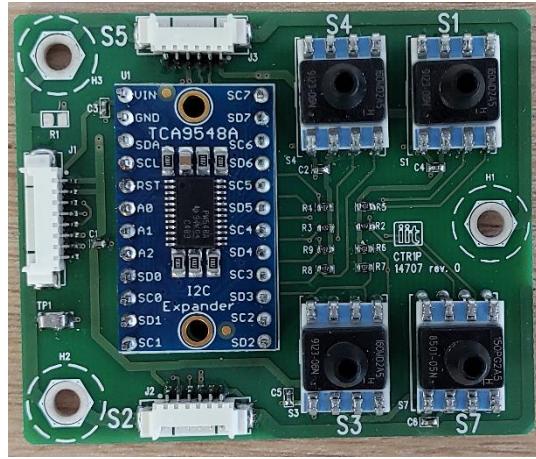


Figure 4 FI5 CTR1P sub-system

### 3.2.3 CTR1S SUB-SYSTEM – MOTHERBOARD SHIELD

The motherboard shield connects the CTR1 discovery board, the CTR1P and all the other I/O interfaces to the ventilators, including buzzers (both internal and external), potentiometers, connectors for the external oximeter, a secondary USB connector, voltage regulators, and a GPIO expander. Importantly, it includes also two PWM drivers for both proportional and on-off valves. Combined with the CTR1 module, it accepts an external 12V input from a battery, an external 12V power supply, and provides an emergency switch input. The board is designed to match the spacing and the pin specifications of the CTR1 module so that they can be sandwiched to save space inside the enclosure. The GPIO expander provides I2C connectivity to the CTR1, therefore providing bus handshake and potential detection of idle states in case of malfunction. The shield board provides 5V, 12V and 3.3V power supplies for all the ventilator modules. Figure 5 shows a prototype of the implemented CTR1S when connected to the CTR1 module.

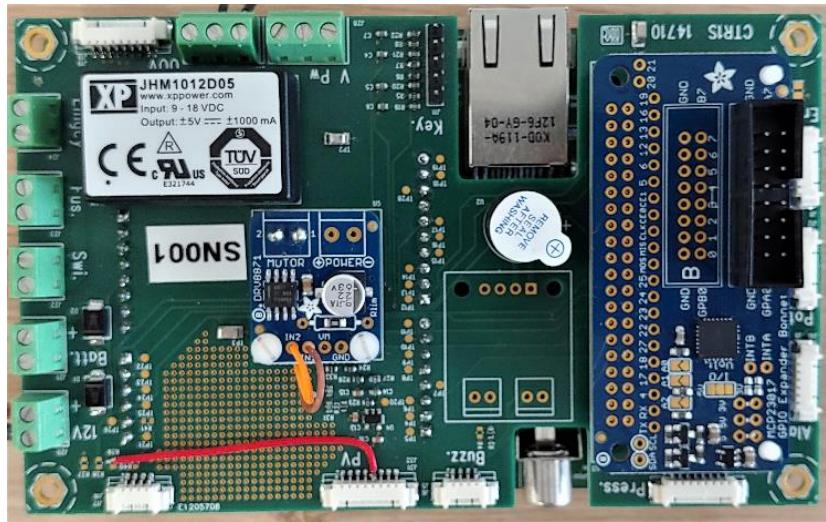


Figure 5 Implemented FI5 CTR1S sub-system when connected to the CTR1 main module

### 3.3 H-M INTERFACE SCHEME

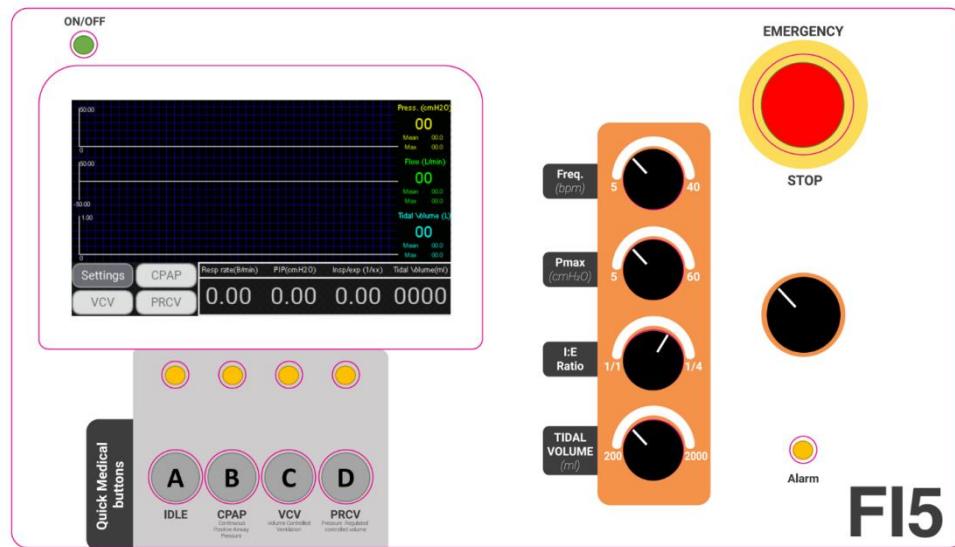


Figure 6 Representation of the FI5 control panel with LCD display

Figure 6 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.

The control panel has been maintained simple and easy to use. It is possible to select the ventilation mode by pressing on A, B, C or D buttons and depending on the operation mode that has been set, the corresponding parameters, i.e., Respiration Frequency, Maximum Pressure (PEEP), Inspiration/Expiration Ratio and Tidal Volume can be set. The system provides an emergency stop button, an ON/OFF button, an alarm led to show malfunction and the LCD display provided by the CTR1 module.

The display shows the current ventilation mode, the four parameters set on the right of the display (i.e., Respiration Frequency, Maximum Pressure (PEEP), Inspiration/Expiration Ratio and Tidal Volume), the current measured pressure, flow and tidal volume, with respective traces in time domain.

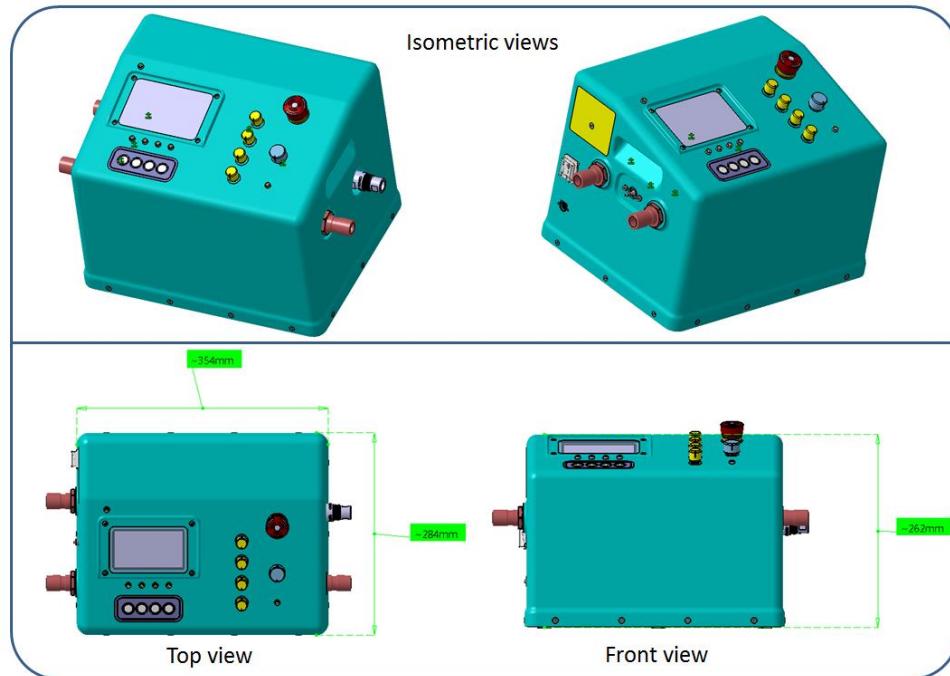
### 3.4 VENTILATOR MECHANICAL LAYOUT

The FI5 ventilator 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.

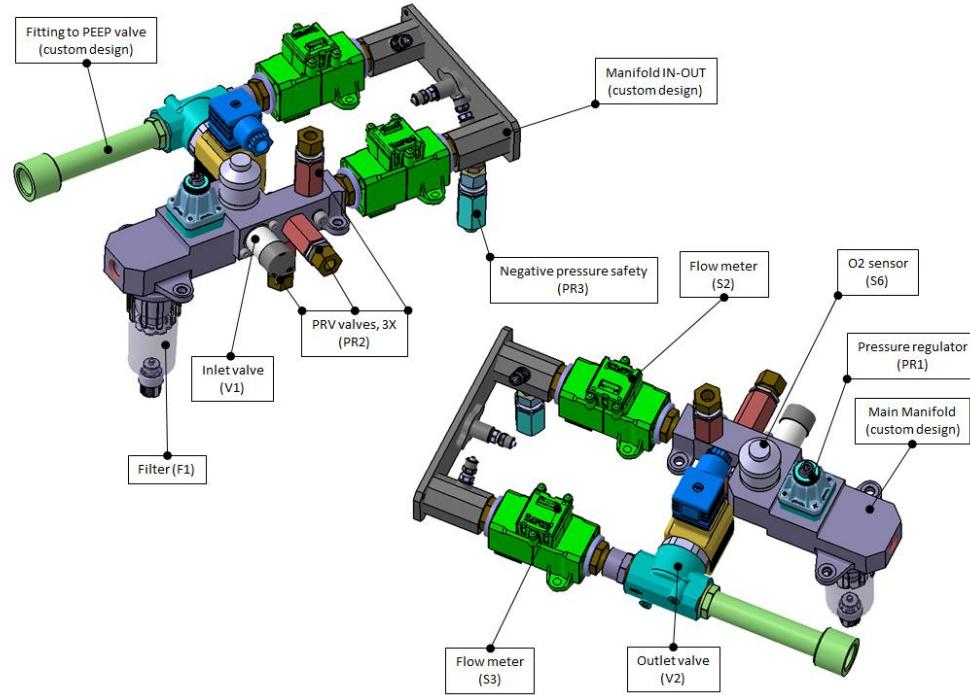
Figure 7 below shows main dimensions of the external case (354mm X 284mm X 262mm).



*Figure 7 Isometric, top and front view of the mechanical enclosure of the FI5*

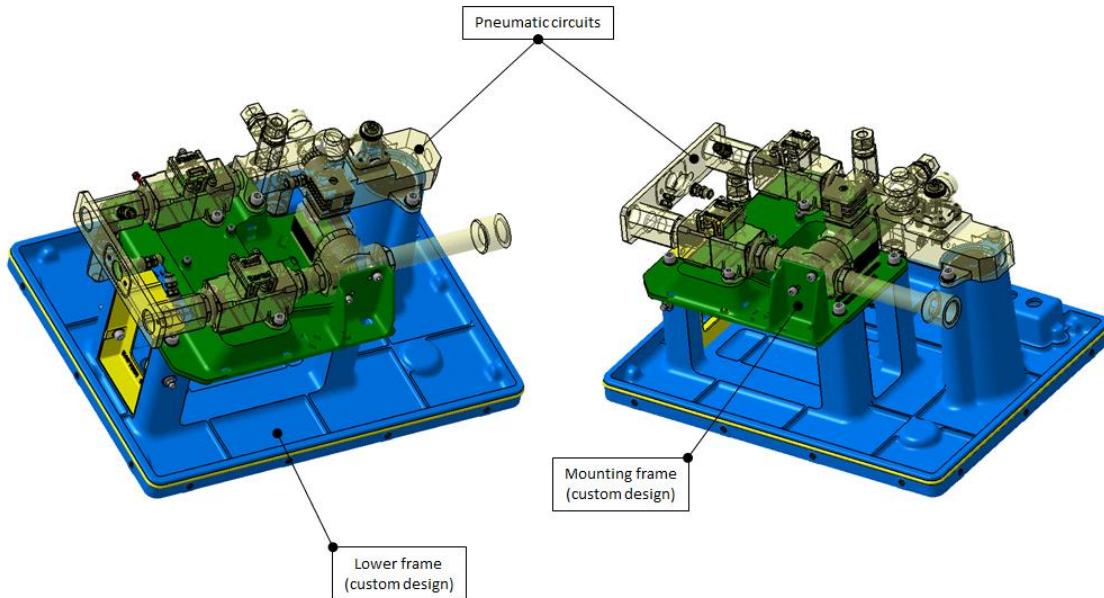
#### 3.4.1 LAYOUT OF INTERNAL COMPONENTS

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 8 shows the internal pneumatic layout.



*Figure 8 Internal 3D view of the FI5 pneumatic system with detail on valves and sensors.*

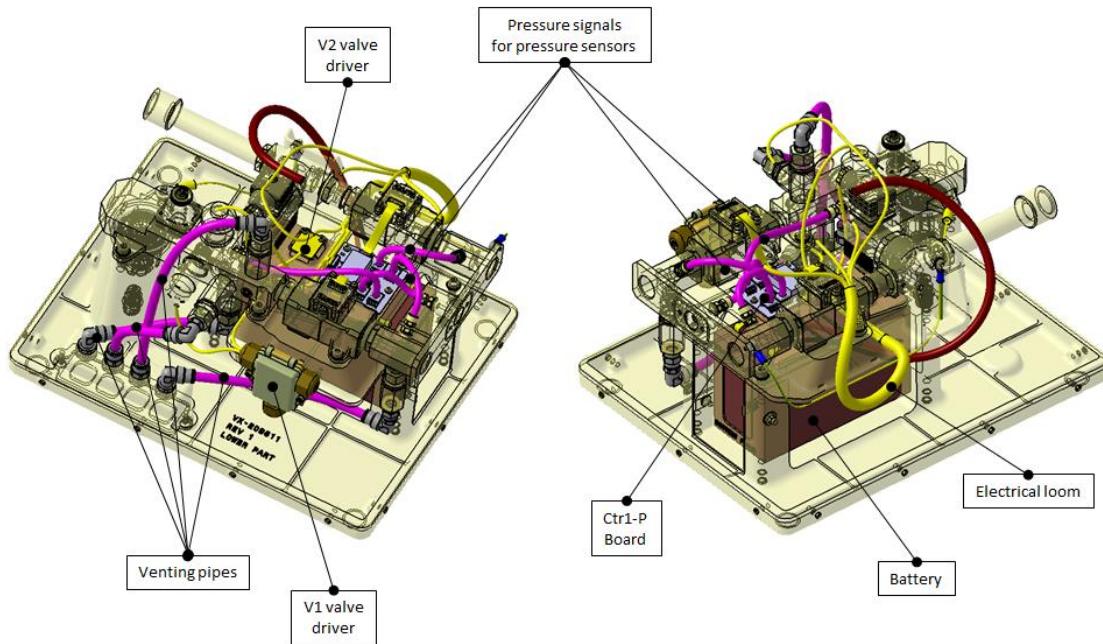
The pneumatic layout is fully mounted and supported on a couple of plastic frames (custom design) as shown in Figure 9.



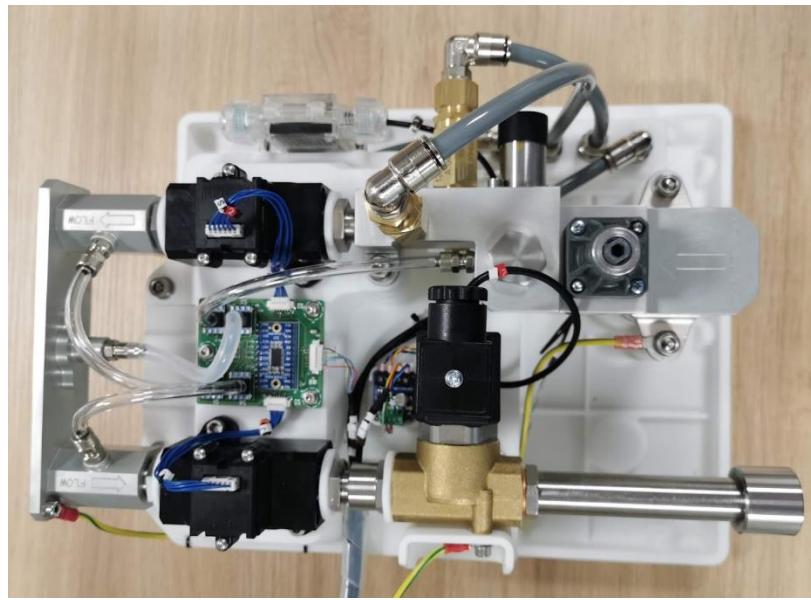
*Figure 9 Pneumatic layout mounted on a custom plastic frame.*

As described in the electrical scheme, part of the electrical cables, the CTR1P board, the two valves drivers and the pressure sensors are directly mounted to the lower frame in order to facilitate the ventilator mounting/dismounting.

Also the pressure relief valves and the negative pressure relief valves are connected to a filter by means of venting pipes (see Figure 10 below and Figure 11 below showing the CAD assy and the first prototype).



*Figure 10 CAD assy of the complete FI5 internal assembly.*



*Figure 11 Prototype of the complete FI5 internal assembly.*

### 3.4.2 LAYOUT OF THE 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).

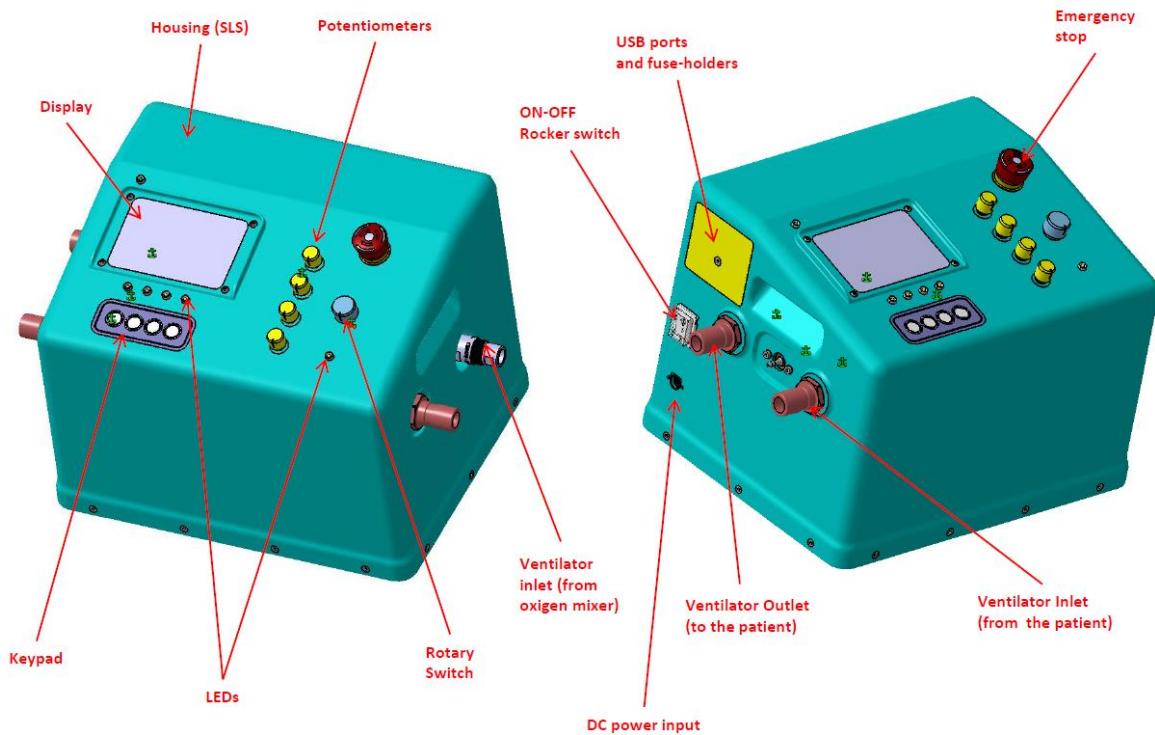


Figure 12 CAD model of the complete FI5 enclosure including 3D models of the I/O interface and LCD display

Figure 12 shows the CAD models while the following image shows the appearance of the first prototype assembled and tested at iCub Tech Facility in Genova – San Quirico.

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 Figure 13. The electronic components and modules are concentrated on the upper part of the enclosure so that to enable an easy mounting/unmounting of the enclosure in case of intervention.



Figure 13 – FI5 full prototype (left) and (right) with open enclosure and detail on the positioning of the electronics

### 3.5 OPEN SOURCE DATA

All the relevant information related to the ventilator 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 Firmware for the control board.

In addition to that a detailed Bill Of Material (BOM) 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:** describes of the part/assembly
- **Version:** 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:** implements a filter to 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, shows the order code by which the correct component can be purchased by the designated supplier.

Table 1 shows a snippet of the bill of material.

Number	Name	Version	Quantity	Status	ID	Category	Manufacturer	Manufacturer Part Number
VX-209641	MAIN ASSY - PROJECT VENTILATOR FI5	0	1	WIP		Assembly		
VX-209503	ASSY - VENTILATOR FI5	0	1	WIP		Assembly		
VX-209513	ASSY - LIST OF EXTERNAL PNEUMATIC COMPONENTS	0	1	WIP		Assembly		
VX-209473	QD BEHRINGER HP120A 02 NIST ISO 18082 - 1/4 M	0	1	WIP	QD1_F	Quick Disconnect	Behringer	
VX-209562	FITTING FOR QD 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	Custom - see drawing	
VX-209608	WASHER 21.3X28X1.5 (1/2") ISO 7089 COPPER - COMMERCIAL	0	3	REL		Washer	Standard component	
VX-209706	FITTING CAMOZZI 1511 6/4 - M6	0	1	REL		Fitting	Camozzi	1511 6/4 - M6
VX-209724	O-RING FKM 70SH D-10.8X21.78	0	1	REL		O-Ring	Standard component	
VX-209755	O-RING FKM 70SH D-23.4X2.95	0	3	REL		O-Ring	Standard component	
VX-209756	O-RING FKM 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 M6X1 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 M5X18 ISO4762 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	

Table 1 – A snippet of BOM available online as open source data

## 4. SIMULATIONS

### 4.1 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.

### 4.2 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 14 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 Figure 15). 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.

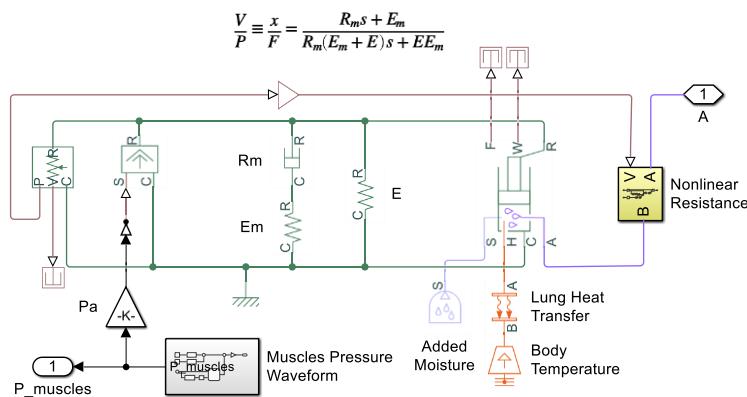


Figure 14. Model of the human lungs in Simscape.

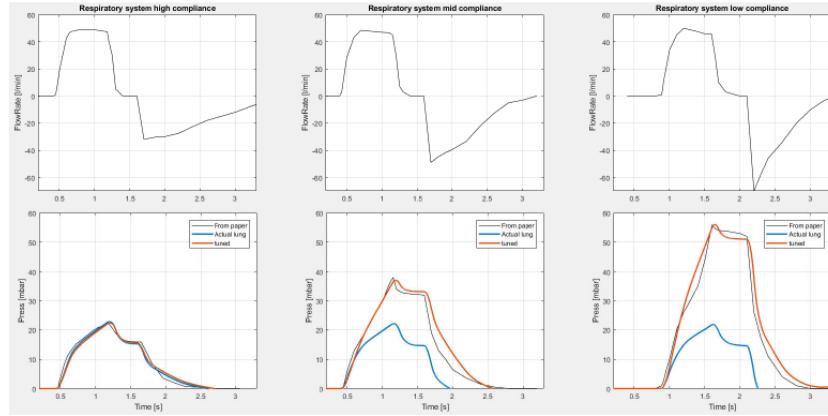


Figure 15. Responses of the human lungs characterized by three different compliance values.

### 4.3 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).

The 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. Figure 16 shows an overview of the Simulink model.

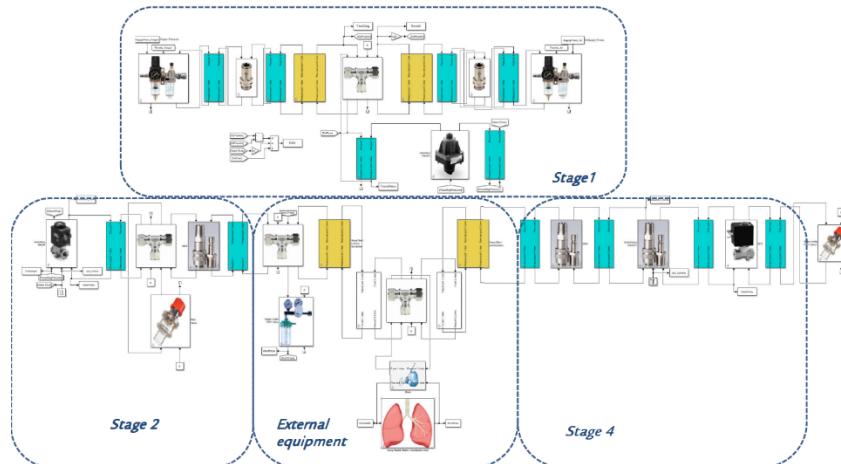


Figure 16 – Overview of the FI5 simulink model

#### 4.3.1 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-D21JW1S01 valve 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).
- CO2 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 CO2 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 eventuality that a 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.

## 4.4 PERMEABILITY TARGETS

### 4.4.1 PR1 & V1: “AP-SPEC” VALVE PERMEABILITY TARGET



The 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 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 in Figure 17. Valve’s working point is at 50% of FS (current) but flowrate strongly saturates from 78% onward due to the 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).

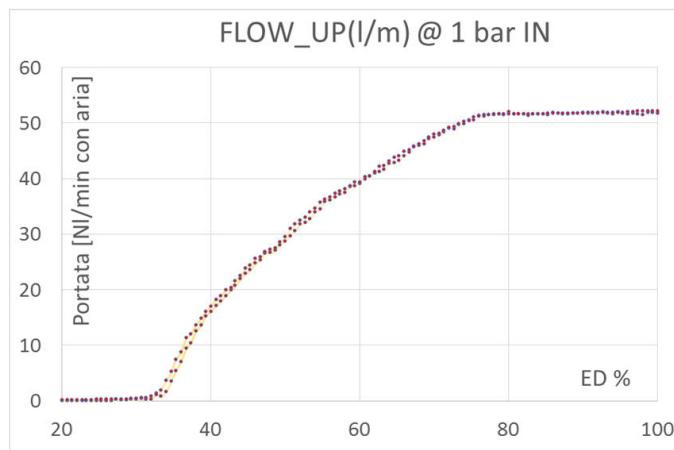


Figure 17 – Pressure regulator set at 1000mbar

Basing on previous considerations made with regulator set @ 1000 mbar, for this condition a further reduction of flow-rate is expected. Therefore no further analysis was investigated on this point.

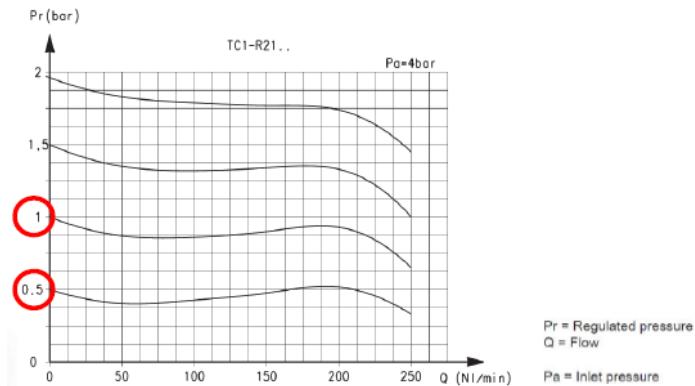


Figure 18 – Pressure-flow curves for the AP-spec

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



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

“CP-spec” valve, due to the presence of a 4.4 mm nozzle is more permeable than the “AP-spec” and fits the requirement to reduce as much as possible the operating pressure of PR1, achieving the target flow-rates. CP-spec valve flushing test has been performed in Camozzi on 10/04/2020 (see Figure 19) 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.

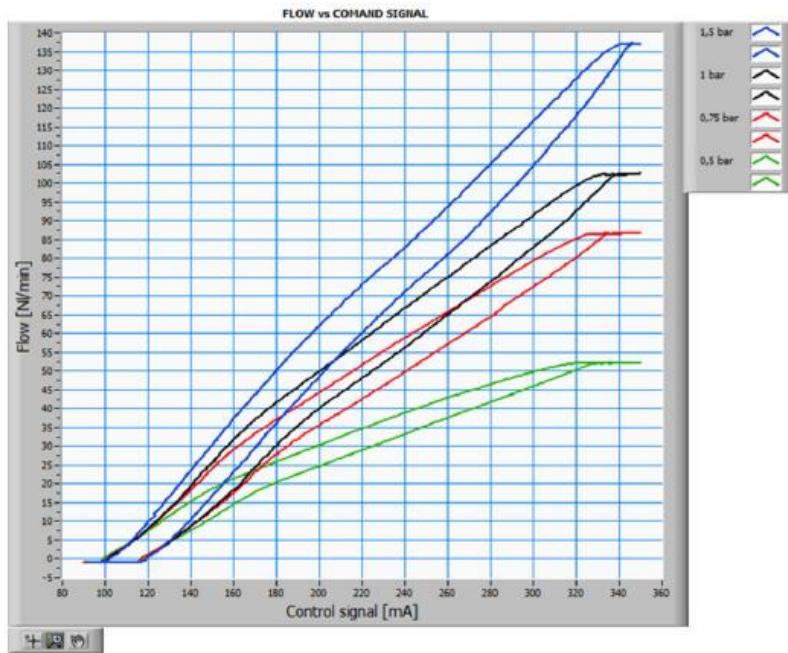


Figure 19 – Flow versus control signal current for the CP-spec valve

- 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.

#### 4.4.3 “CP-SPEC” FLOW-RATE TEST

Figure 20 shows two simulation results using “CP-spec” valve at 750 mbar inlet pressure and considering an “high compliance” lung characteristics.

The top graph refers to a 12 cyc/min breathing frequency and in this case the required flowrate peak will be around 21 lpm. The 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 60/65 lpm.

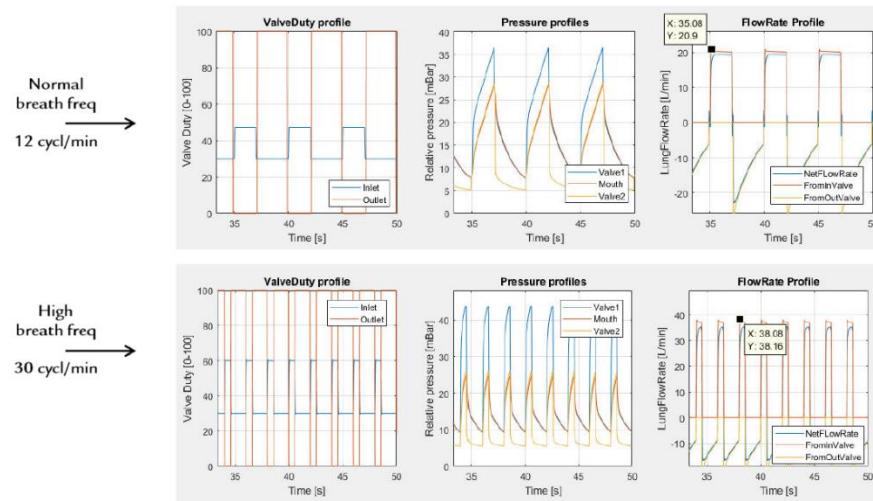


Figure 20 – CP-spec valve simulation considering high compliance lung characteristics

#### 4.4.4 V2 VALVE PERMEABILITY TARGET

Figure 21 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  $K_v = 1.7 \text{ NL/min}$ . Based on these considerations the CFB-D22G-W1 valve has been adopted for the simulations. For working-prototype has been then used a CFB-D21JW1S01 with a bigger orifice (8mm) and higher  $K_v = 1 \text{ m}^3/\text{h}$ , functionality of Normally Open valve.

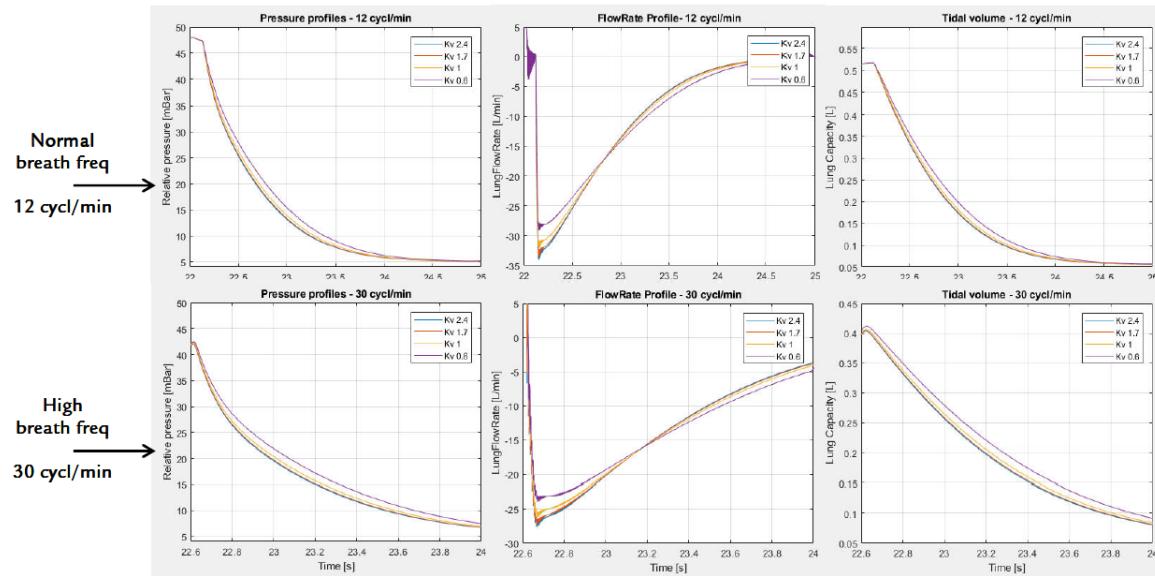


Figure 21 – V2 valve permeability test

#### 4.4.5 FLOW LINE PRESSURE DROP AND PERMEABILITY SCAN

Table 2 shows the main sources of pressure drop in the system: the 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 these 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

Table 2 – Main sources of pressure drop in the FI5 system

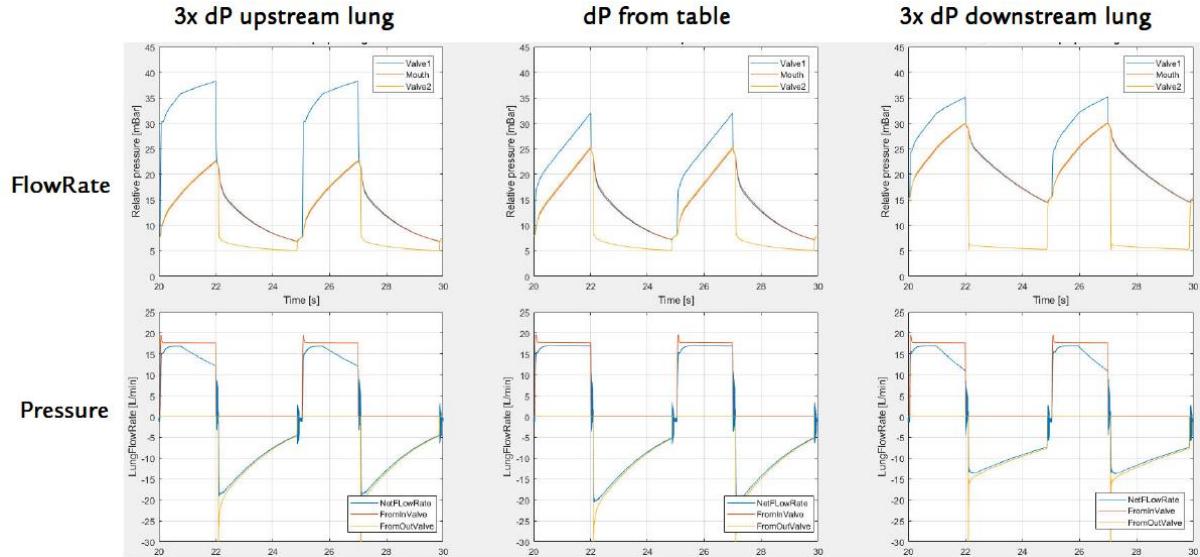


Figure 22 – Effect of pressure drops in the system

#### 4.4.6 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 Figure 23 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.

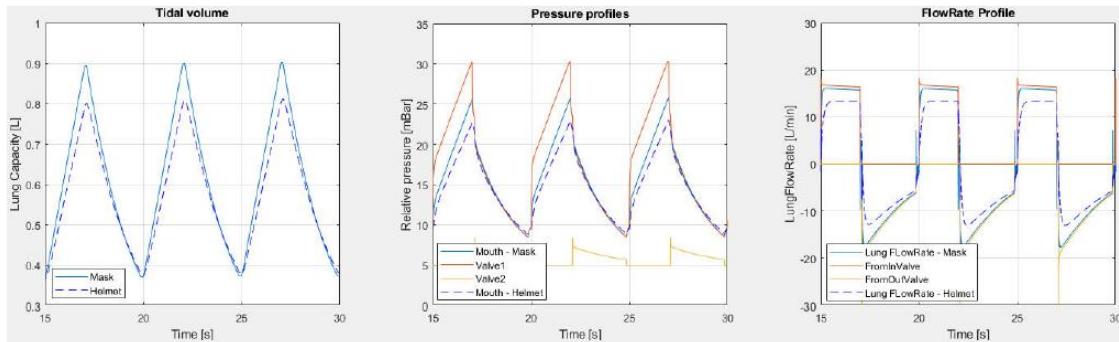


Figure 23 – Helmet vs Mask effect simulation

By increasing V1 (see Figure 24) 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.

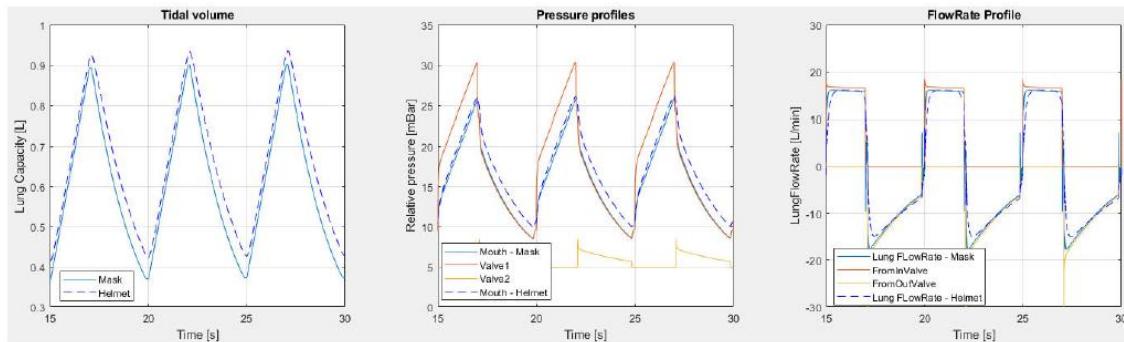


Figure 24 – Recovery of the original tidal volume by increasing control current of V1

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

Figure 25 shows the influence of “stage1 volume” on  $\text{FiO}_2$ , 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.

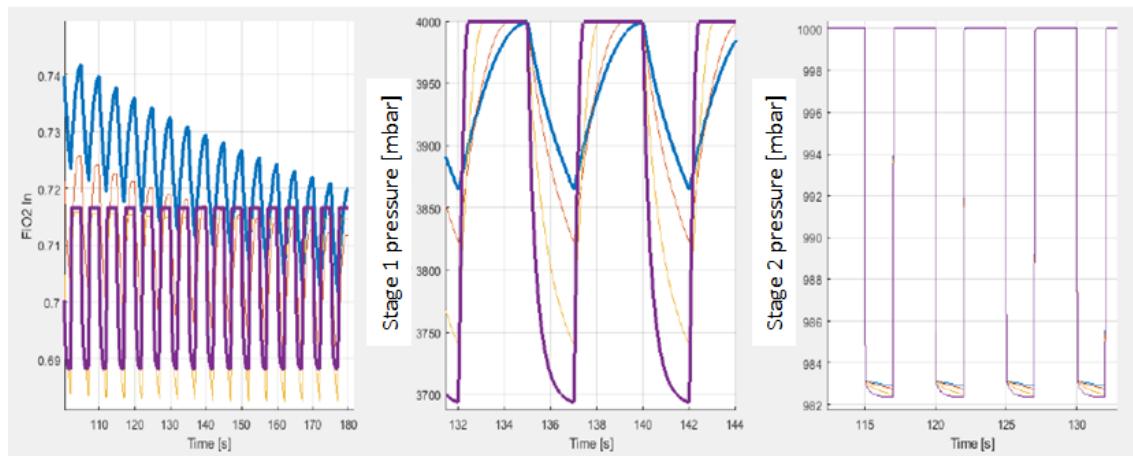


Figure 25 – Influence of stage1 volume on  $\text{FiO}_2$ , stage1 pressure and stage2 pressure.

The influence of the “stage 2 volume” is instead shown in Figure 26: 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).

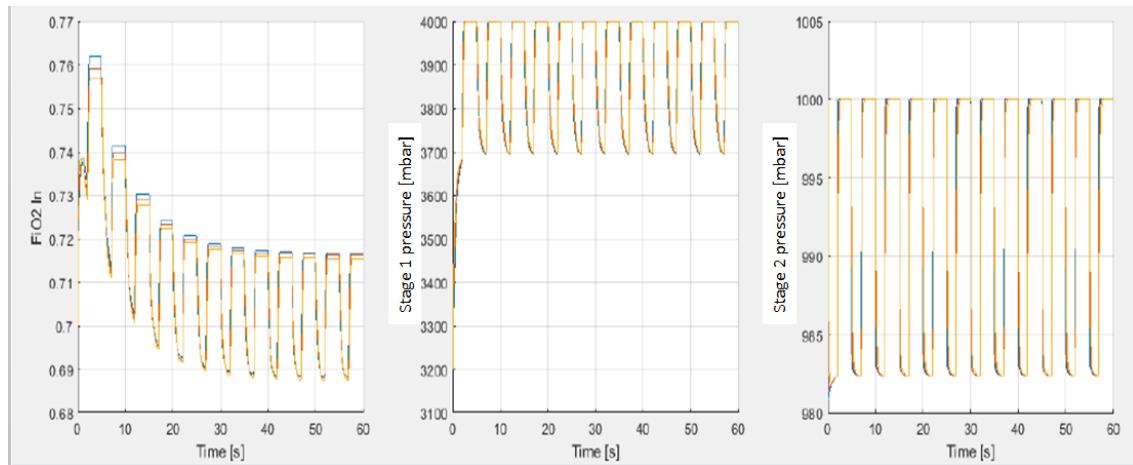
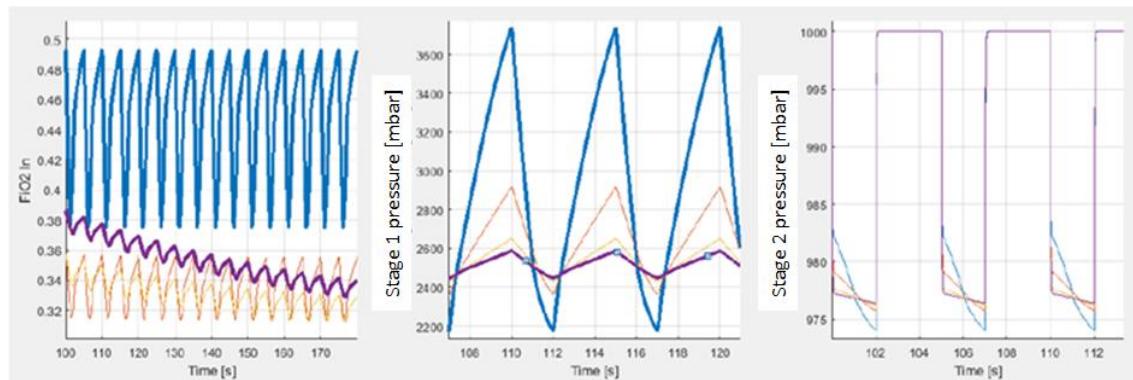
Figure 26 – Influence of stage2 on  $\text{FiO}_2$ 

Figure 27 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 – Influence of state1 volume on  $\text{FiO}_2$ 

The effect of the “stage2-volume” is negligible (see Figure 28), while the “stage1-volume” has quite a big effect and at least 3L are recommended to stabilize pressures and  $\text{FiO}_2$ .

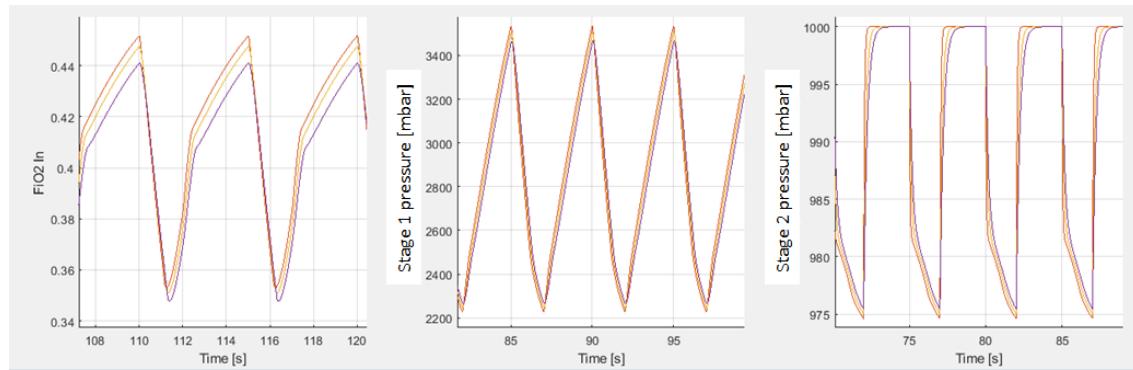


Figure 28 – Influence of stage 2 volume on  $F_{IO2}$

#### 4.5 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 29) to reproduce most of the physical behaviors of the manifold analyzed in Section 4.3. and thus help the design stage.

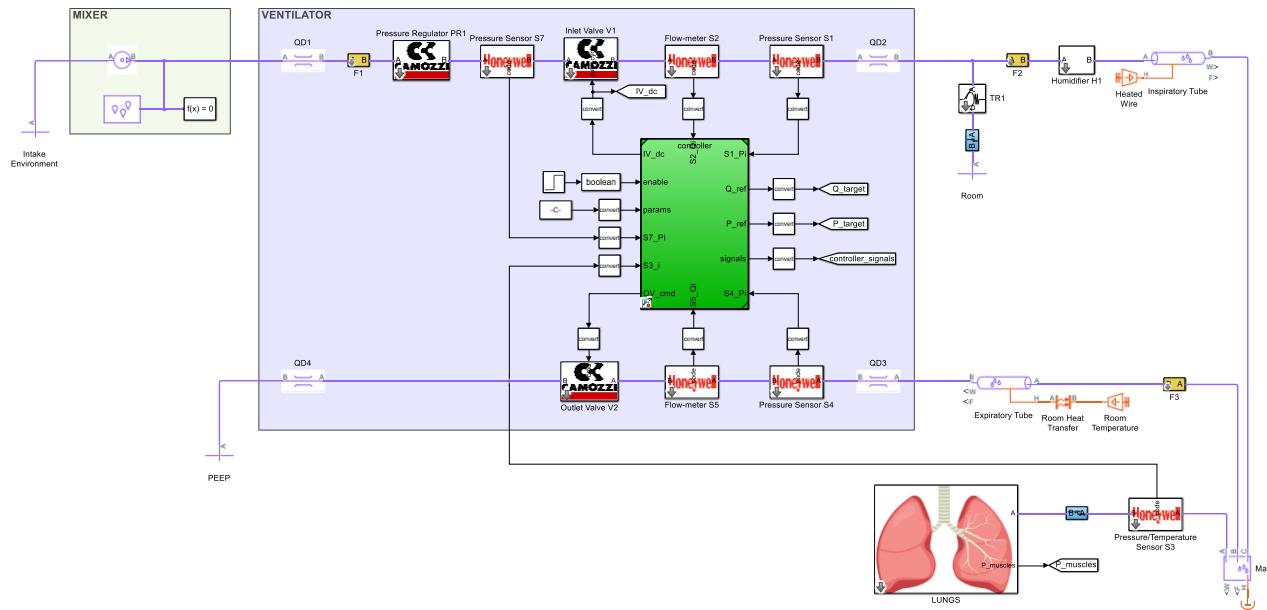


Figure 29. The complete model of the Ventilator in Simscape with the controller component shown as a green block.

#### 4.5.1 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: 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 by controlling the IV and OV valves. Other than BPM and IE parameters, the operator can also specify the Peak Inspiratory Pressure (PIP).

#### 4.5.2 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 30:

- **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.

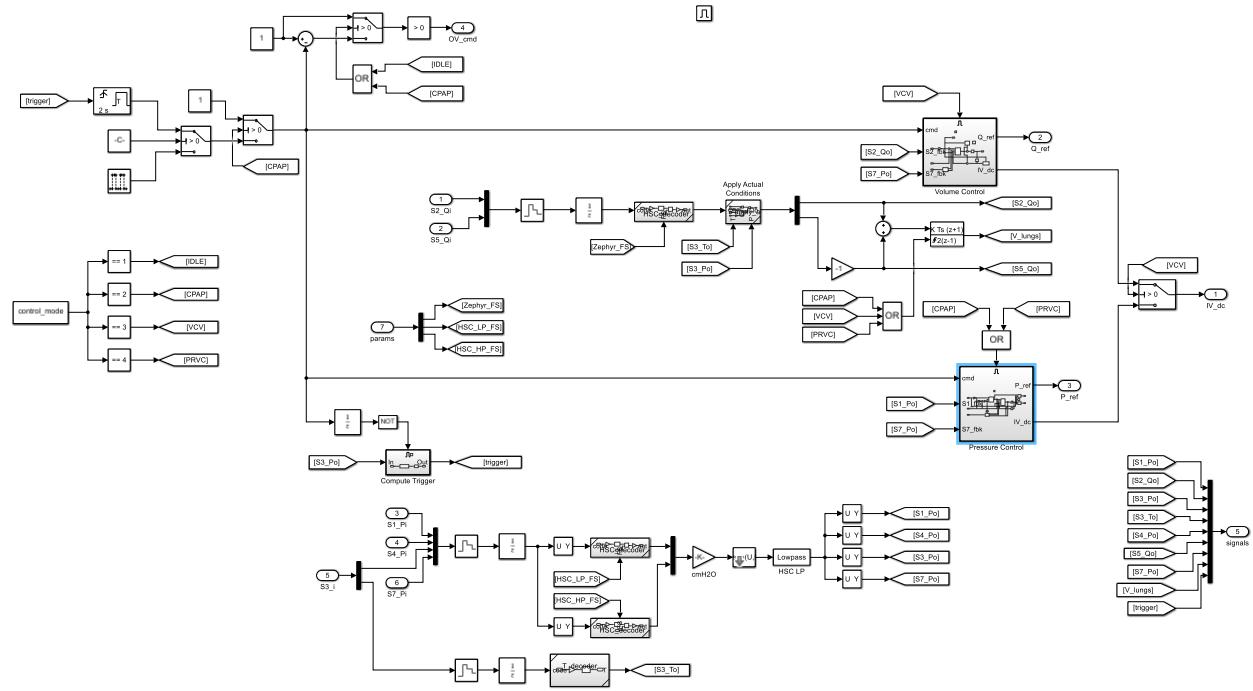


Figure 30. The internal blocks of the controller comprising sensors filtering, VCV and PRVC controllers, and triggering of the assisted ventilation.

The PI controller responsible for regulating the pressure in PRVC mode, whose diagram is reported in Figure 31, is further characterized by the presence of a **Input-Shaping** module, which shapes the input pressure steps into suitable waveforms (see Figure 30 for more details) by applying smoothing through a minimum-jerk filter.

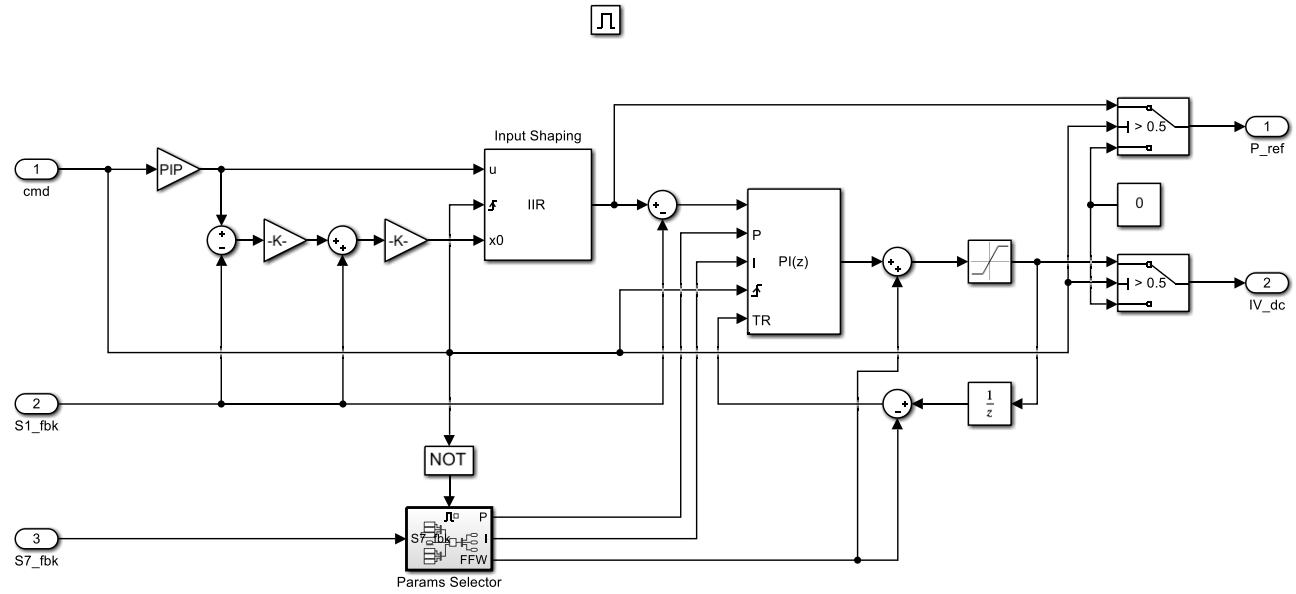
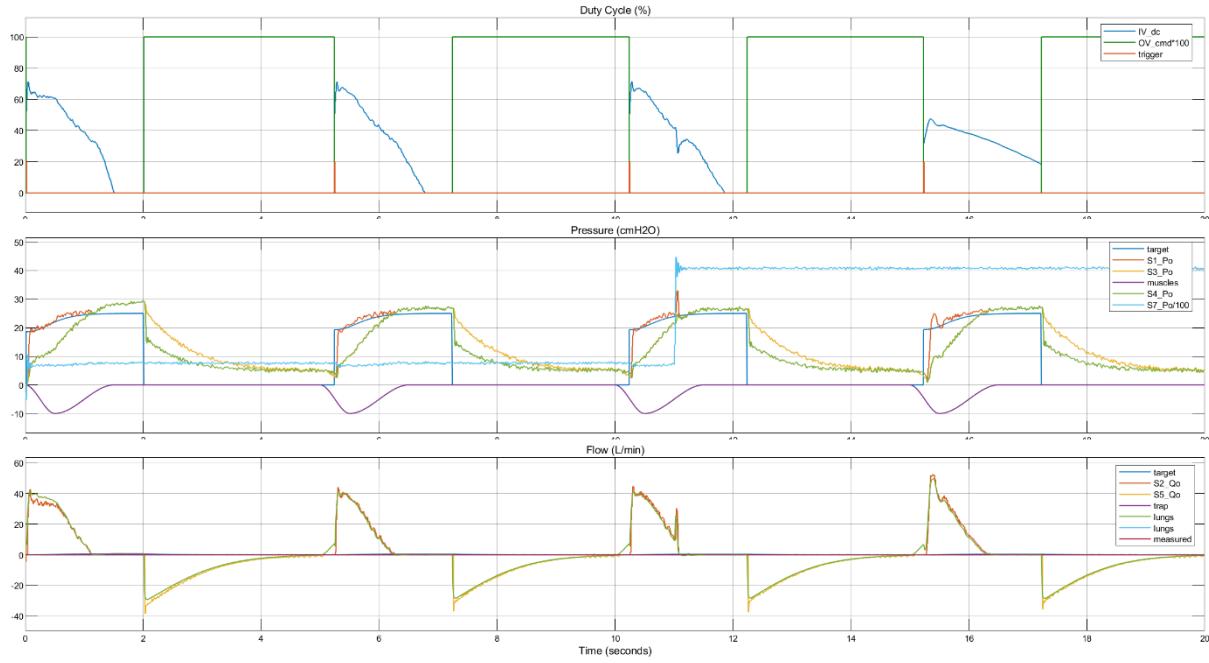


Figure 31. The PID controller with gain scheduling and input shaping devoted to the Pressure-Regulated-Volume-Control (PRVC) mode.

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 32.

#### 4.5.3 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 shows an example simulation during assisted ventilation.



*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. At  $t = 11$  s, a failure occurs to PRI 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.*

## 4.6 DEVELOPMENT OF THE FINITE-STATE MACHINE

We applied the same development approach used for the controller as described in Section 4.5 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.

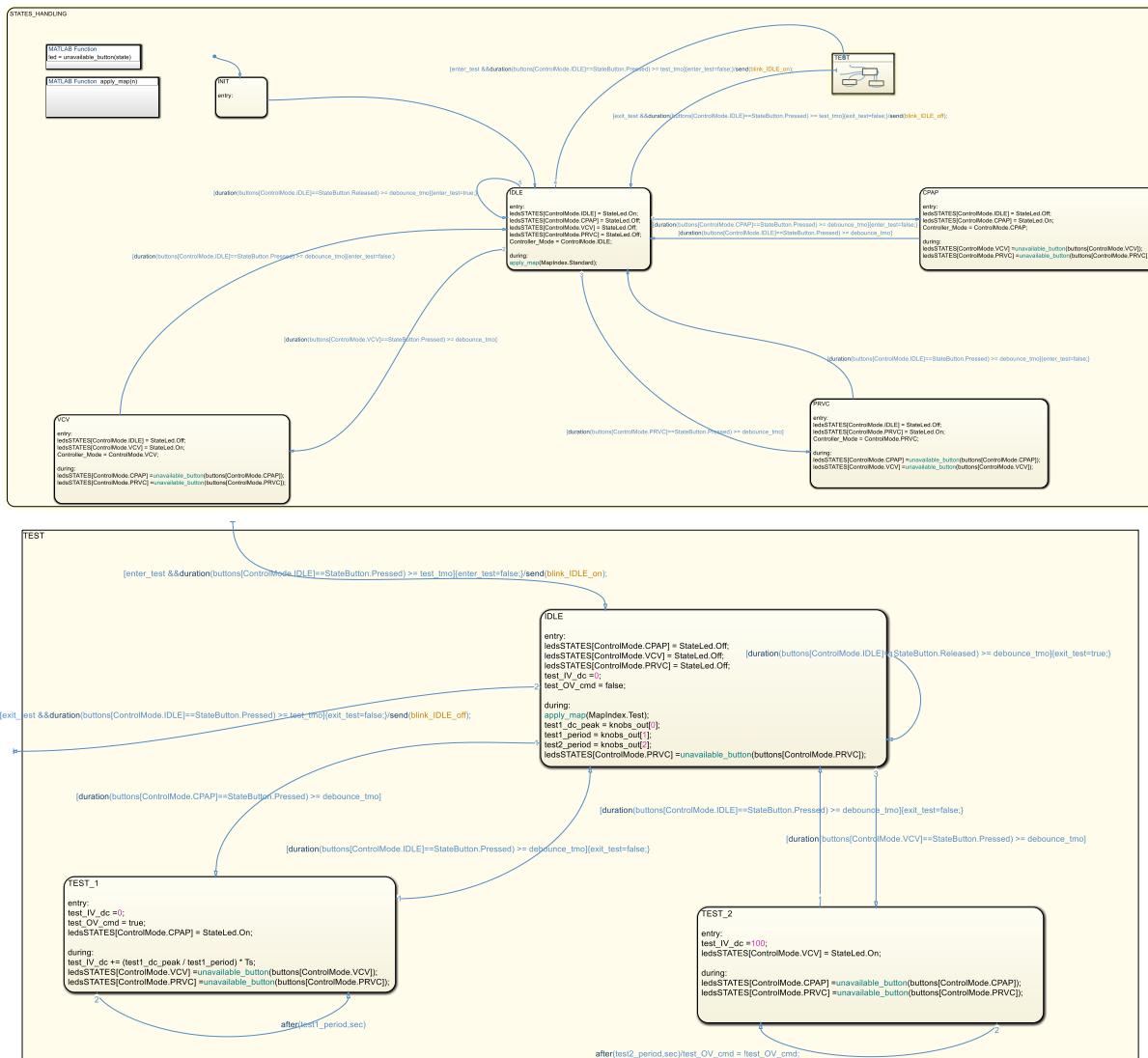


Figure 33. A subset view of the FSM states handling the HMI.

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

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

1. The HMI-FSM (see Figure 33) 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 34).

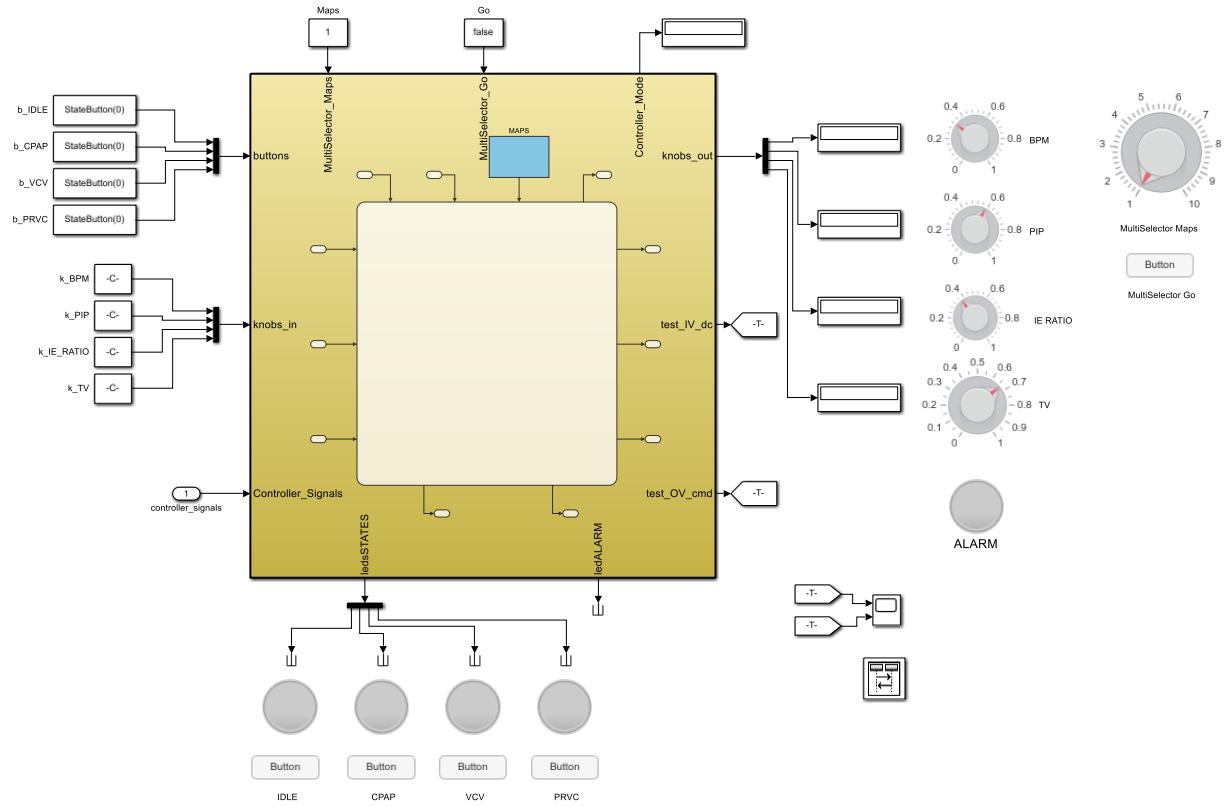


Figure 34. The high-level diagram of the FSM along with the dashboard inputs/outputs.

## 4.7 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)

Table 3 – Concentrations of CO<sub>2</sub> in air.

In normal conditions the CO<sub>2</sub> rebreathing could be a serious issue (see Table 3). 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 Figure 35).

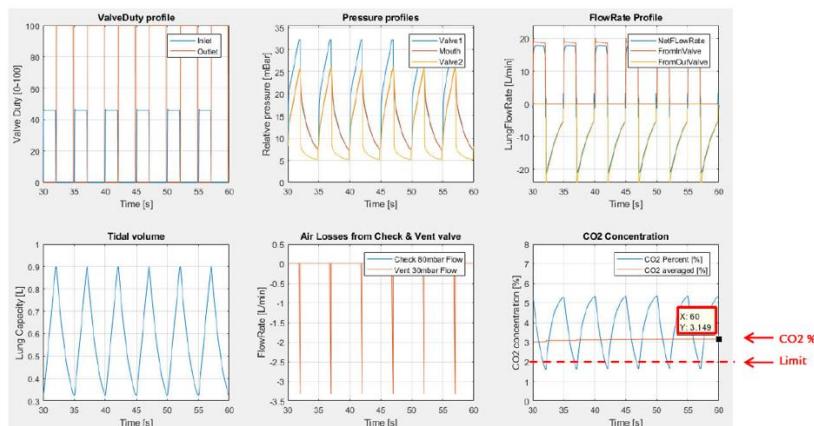


Figure 35 CO<sub>2</sub> concentration simulation with detail on stabilization in 30s

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 (see Figure 36). As further downside it changes significantly the mouth pressure profile in both peak value and shape.

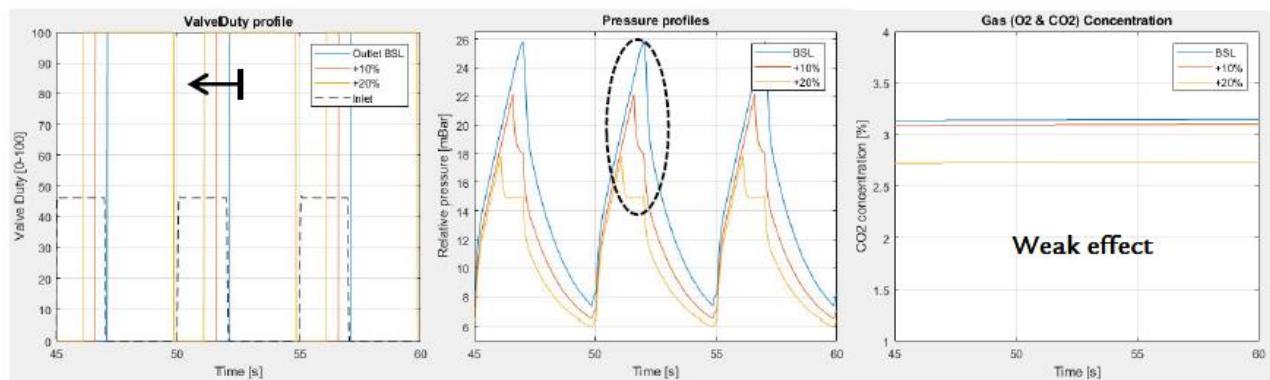


Figure 36 Effect of valves overlap (inhalation) in the CO<sub>2</sub> concentration.

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), as depicted in Figure 37. The effect on the pressure curve is reduced in both peak value and general shape.

Effect of valves overlap (exhalation) in the CO<sub>2</sub> concentration.

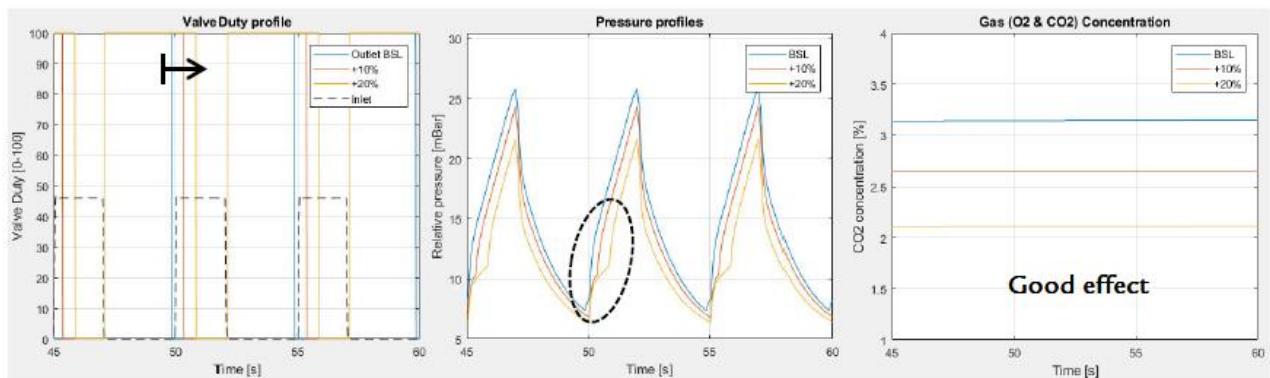


Figure 37 Effect of valves overlap (exhalation) in the CO<sub>2</sub> concentration.

Minimum flow through V1 valve during the exhalation phase (flow-by) seems the most efficient way to reduce CO<sub>2</sub> % (see Figure 38). The effect on pressure curve shape is small and with few lpm is easy to bring CO<sub>2</sub> % below a 2% threshold.

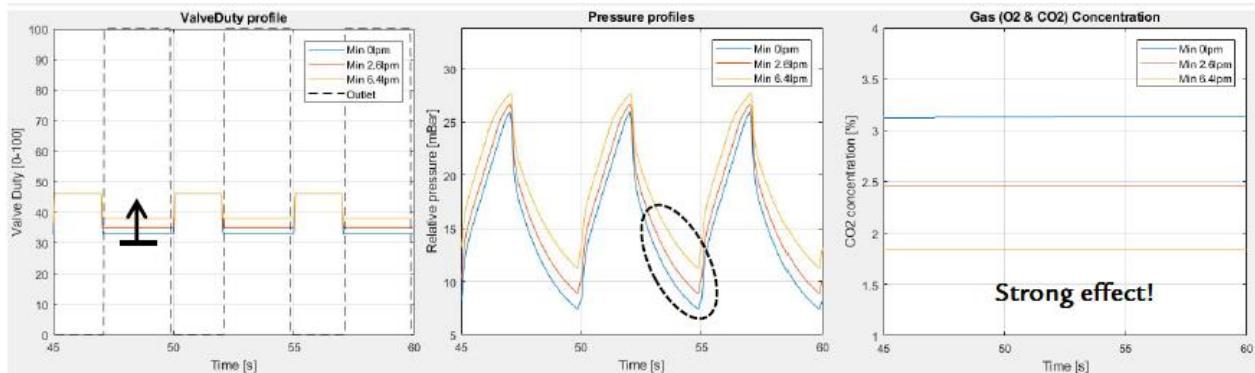


Figure 38 Minimum flow through V1 during exhalation that has a strong effect on CO<sub>2</sub> concentration.

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

A quantity of 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 Figure 39).

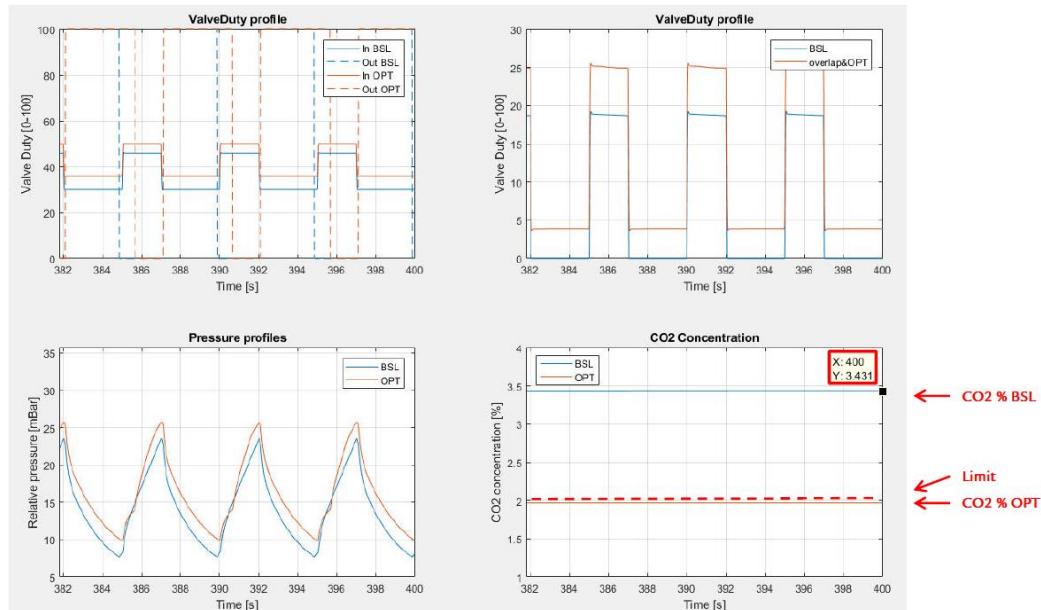


Figure 39 CO<sub>2</sub> rebreathing simulation.

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 require 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).

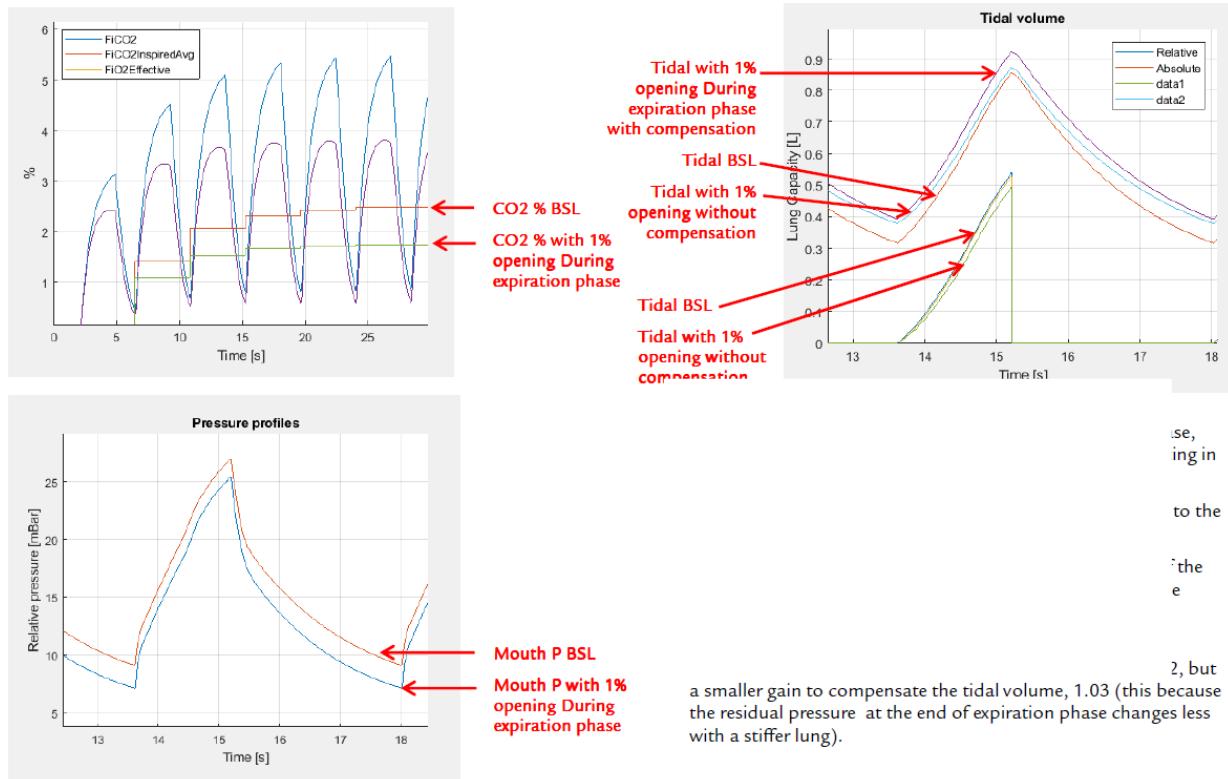


Figure 40 Simulation assuming a stiff lung for CO<sub>2</sub> concentration and consequent amount of flow-by.

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 Figure 41).

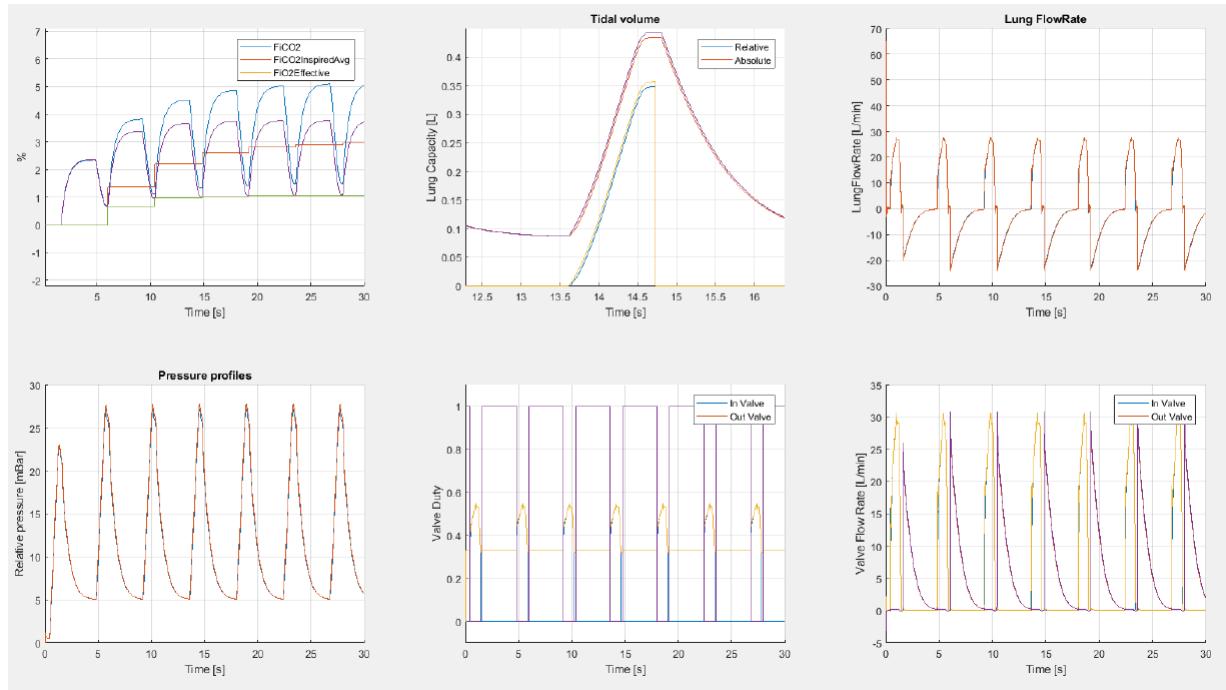


Figure 41 Absence of target correction in case of flow-by for flow control.

## 4.8 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 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 Figure 42).

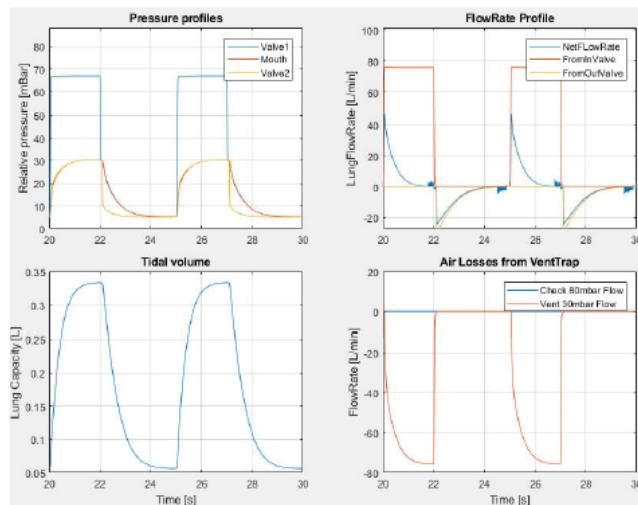


Figure 42 SIM1: Effect of the safety vent trap in the stabilization of the mouth pressure to 31mbar and not exceeding the 80mbar limit.

- 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 Figure 43 and Figure 44.

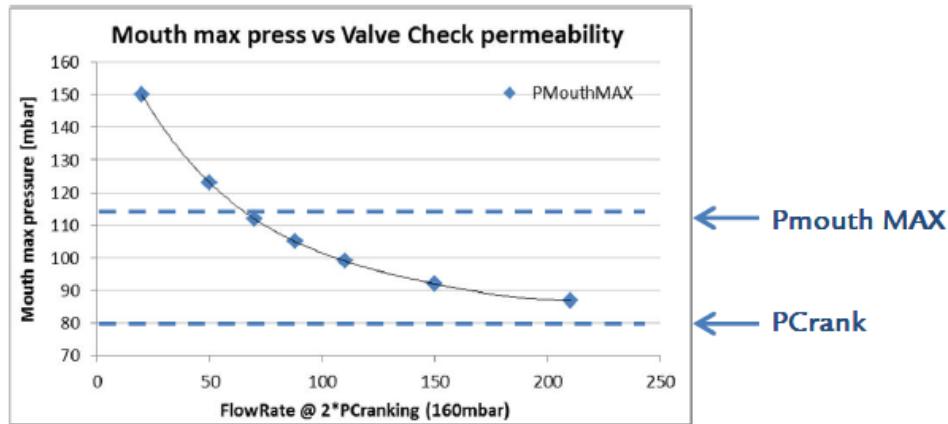


Figure 43 Mouth maximum pressure versus valve check permeability.

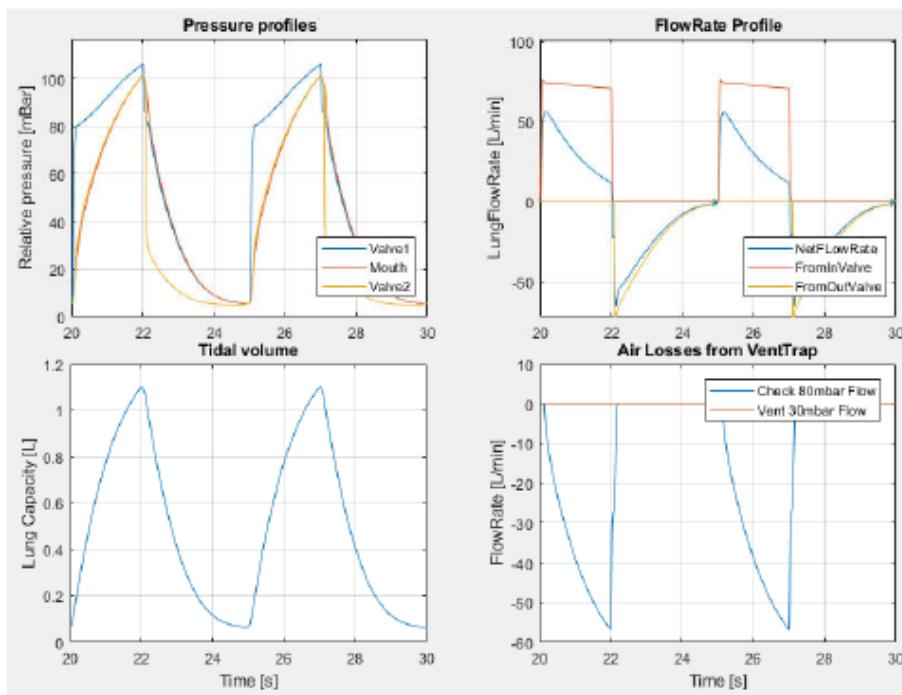


Figure 44 SIM2: safety vent trap not fitted.

- 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 (see Figure 45 and Figure 46).

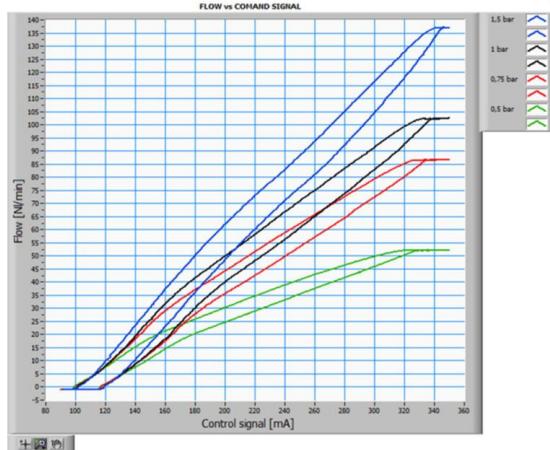


Figure 45 Flow versus current control signal.

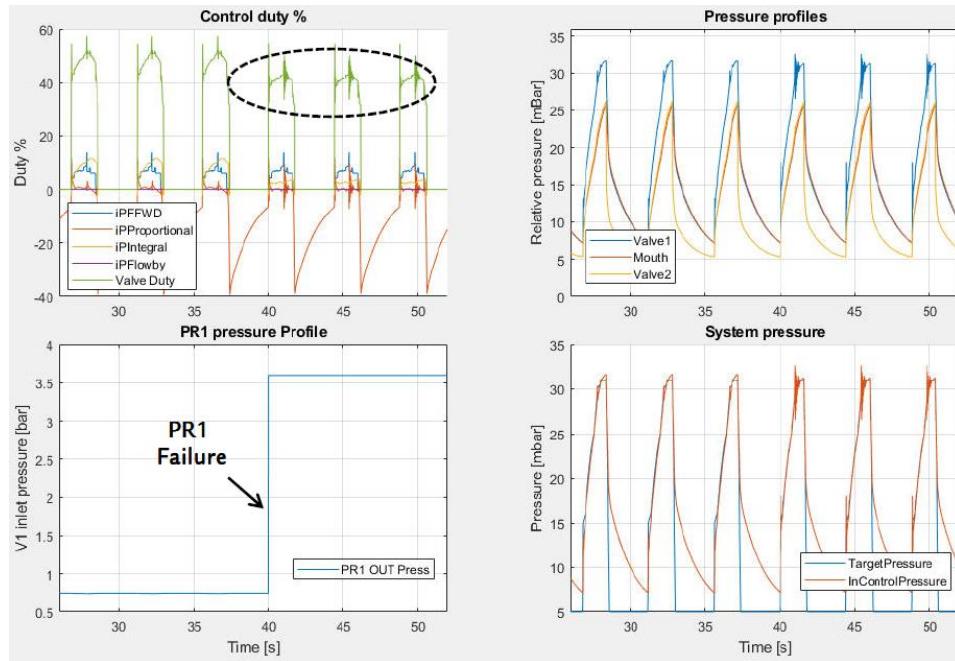


Figure 46 SIM3: Pressure regulator failure at  $t = 40s$ .

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