Mechanical Ventilator Milano (MVM): A Novel Mechanical Ventilator Designed for Mass Production in Response to the COVID-19 Pandemic

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Presented here is the design of the Mechanical Ventilator Milano (MVM), a novel mechanical ventilator designed for rapid mass production in response to the COVID-19 pandemic to address the urgent shortage of ventilators in many countries, and the growing difficulty in procuring these devices through normal supply chains across borders. This ventilator is an electro-mechanical equivalent of the old, reliable Manley Ventilator, able to operate in both independent and patient-assisted modes. The design is optimized to permit large-sale production in a short amount of time and at a limited cost, relying on off-the-shelf components, readily available worldwide. Operation of the MVM requires only a source of compressed oxygen (or compressed medical air) and electrical power. The MVM control and monitoring unit can be connected and networked via WiFi so that no additional electrical connections are necessary other than the connection to the electrical power. Initial tests of a prototype device with a silicon test bag lung are also presented. Further tests and developments are underway. At this stage the MVM is not yet a certified medical device but certification work is in progress.

1. INTRODUCTION

The large number of people affected by SARS-CoV-2 has created an urgent demand for ventilators on a global basis, a demand that exceeds the capacity of the existing supply chains, especially in some regions where cross-border supply has been disrupted. This need has motivated the development of the mechanical ventilator (Mechanical Ventilator Milano, MVM) - a reliable, fail-safe, and easy to operate mechanical ventilator that can be produced quickly, at large scale, based on readily-available parts. It was inspired by the Manley ventilator [1], which was proposed in 1961, based on *"the possibility of using the pressure of the gases from the anaesthetic machine as the motive power for a simple apparatus to ventilate the lungs of the patients in the operating theatre"* [2]. The MVM is designed with the same principle of simplicity in mind. The MVM does not include a system to measure the tidal volume provided to the patient directly with each breathing cycle, but rather, uses a system to measure the peak and average expiratory flow rate. The MVM is compliant with the guidelines for "Rapidly Manufactured Ventilator System (RMVS)" [3], recently released by the UK Medicine & Healthcare products Regulatory Agency.

The current version of this paper includes revisions that have been made to date from our testing and from recommendations from the medical experts with whom we are working. This version of the paper contains as much of that detail as possible to make available our progress to date. However, there may be further changes as we proceed with our testing process and as we look for

the availability of specific parts that may vary from country to country. We are also proceeding with the required tests for certification of this ventilator, working with regulators in Italy and several other countries

The MVM uses a pressure controlled ventilation (PCV) mechanism, and can be operated in both independent and patient-assisted control modes.

The system connects directly to a line of pressurized medical oxygen or medical air, 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 pressure in the range 20–80 mbar/cm H_2O. Pressure regulation of the end-expiratory cycle is achieved by discharging the expiratory flow through a valve which sets the desired minimum positive end-expiratory pressure (PEEP) at 5 mbar/cm H_2O. Another adjustable pressure limiting valve is connected to the delivery line and ensures that the maximum pressure delivered does not exceed the pre-set value.

Important features of the MVM are:

Small Number of Components: the MVM consists of a medical care flowmeter [4] for direct regulation of the maximum flow rate, an oxygen-therapy humidifier [4], three electrically-controlled, VDC-actuated proportional valves (two in parallel), a pressure sensor, four manual valves, medical tubing, and the control system directly connected to the proportional valves and to the control sensor; backup power for the control system is provided by a VDC battery;

Ease of Procurement: the parts required for the construction of the MVM have been selected based on those that are available in many nations globally. The parts selected are also characterized by their ease of use in large-scale manufacturing and assembly;

Simplicity of Construction: assembly of the parts into a complete MVM is achievable based on a small set of clear instructions. The process for loading the software into the controller is simple. The controller software is open source and available for customization by end users;

Cost Containment: the total cost of the components is in the hundred € 's.

Convenience of Deployment: the device requires only connection to a line of pressurized oxygen and standard AC electrical power (either 220 V or 110 V); this makes it suitable for home care, use in ambulances, and readily deployable in medical clinics with centralized oxygen and air supply systems, such as COVID-19 hospitals or COVID-19-care areas in general hospitals;

Customizability: the MVM can operate in different ventilation modes (independent and patient-assisted) as described in Section 3. Also, the operating parameters can be tuned by the operator with a simple user interface;

Scalability: the MVM control system is based on a WiFi micro-controller that allows both for local control of the system and for monitoring and tuning of the parameters of multiple units from a single work station.

Reliability: the components in the MVM are commercial and readily available. We note that the reliability of MVM has to be carefully studied based on the specifications of the components. The system is designed to be easy to repair, just by replacing any non-functioning parts.

Limited oxygen consumption: the consumption of oxygen with this device will not exceed 6 LPM

2. DESIGN AND COMPONENTS

The conceptual design and P&ID of the MVM are shown in Fig.1. The main components are described following the order of the oxygen flow:

Connection to oxygen and air supply: at the left-hand side, the MVM is connected to a pressurized oxygen/air line.

Medical care flowmeter MCF1: The air flow is controlled a medical care flowmeter MCF1, which restricts the flow to a maximum value.

Medical care flowmeter MCF2: The oxygen flow is controlled by medical care flowmeter MCF2.

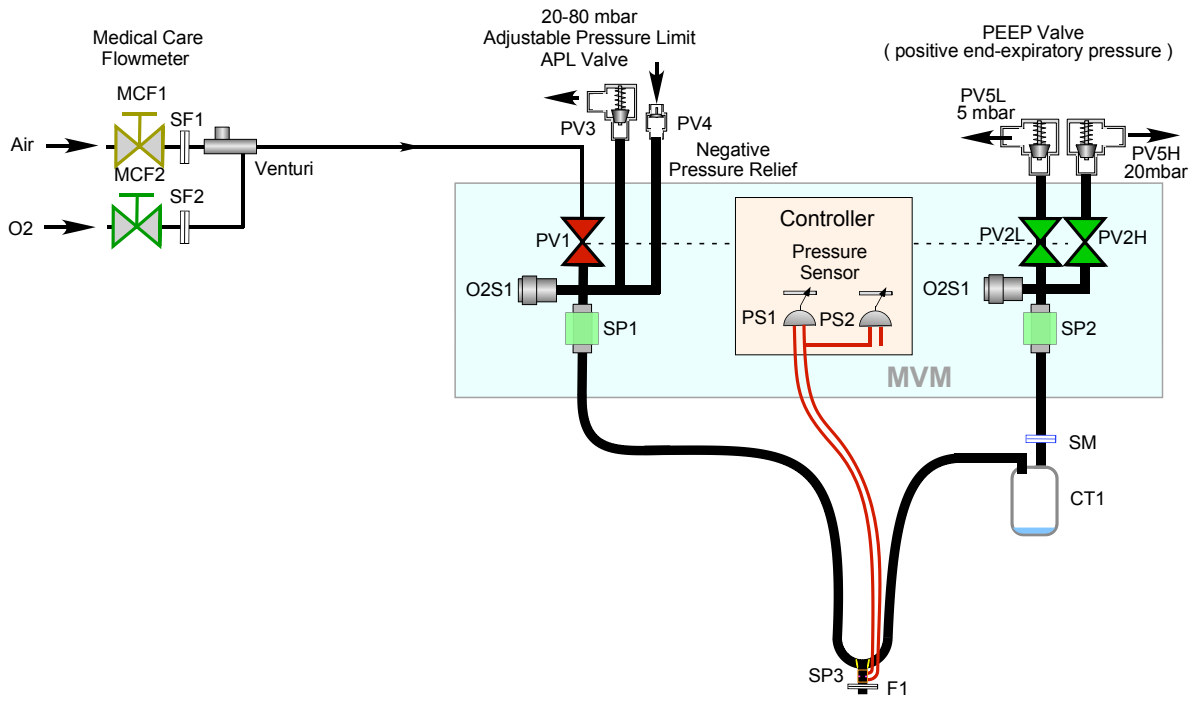

FIG. 1. Conceptual design and P&ID of MVM. Note: 1 mbar corresponds to the pressure of a H_2O columns of 1 cm height.

Sintered filters: the sintered filters SF1/SF2 remove particulate in the inline that can clog the pipes.

Venturi mixer: The oxygen and air flow are mixed in a medical venturi mixer device.

Air/Oxygen delivery proportional valve PV1: The incoming gas flow is controlled by the proportional PV1 with an industrial process control algorithm that ensures a proper respiratory *minute volume* is delivered to the patient;

Adjustable Pressure limit APL valve PV3: Mechanical valve that sets the value of the maximum inspiratory pressure in the range 20–30 mbar

Negative Pressure Relief valve PV4: a check valve to avoid any negative pressures when the patient is in active mode and demands more air. As long as there is a positive pressure in the respiratory lines this valve will remain closed. A bacterial/viral filter upstream may be required.

O_2 sensor S1: The optional O_2 sensor O2S1 is used to measure continuously the fraction of inspired oxygen FiO2.

Spirometer SP1: an optional digital spirometer is connected to the input line to monitor the peak and average inspiratory flow rates.

Breathing system: the breathing system, connected to the tracheal tube, supports the attachment of two plastic tubes of typical size 22 mm connecting respectively to pneumatic valves PV1 and PV2L(H), and to a smaller plastic tube leading to two differential pressure sensors PS1 and PS2 to monitor pressure and flow. The standard for connection of the breathing system is the 22 mm cone and socket combination defined in the standard [5].

Condensate trap CT1: the expiration tube passes through a condensate trap allowing for removal of condensed vapor from the patient's breath.

Silicone Membrane SM: the silicone membrane SM obstructs access to the machine of the wet flow.

Expiration valve PV2: high throughput PV2L(H) valves control the expiratory flow. An adequate orifice diameter guarantees the flow corresponding to the expiration of a proper respiratory minute volume at the given PEEP value.

Spirometer SP2/O2S1: an optional, second, digital spirometer and oxygen sensor are connected to the output circuit to measure the expiratory flow rates and oxygen intake.

PEEP Valve PV5: a set of mechanical valves that control the positive end-expiratory pressure in the range 5-20 mbar. A pair of Mechanical valves PV5L, PV5H control the PEEP in a higher (H) or lower range (L).

Bacterial/Viral-Retentive Filter F1: This disposable filter can be set on the line connected with the patient.

A CAD design of the MVM controller base assembly box of Fig.1 is shown in Fig. 2.

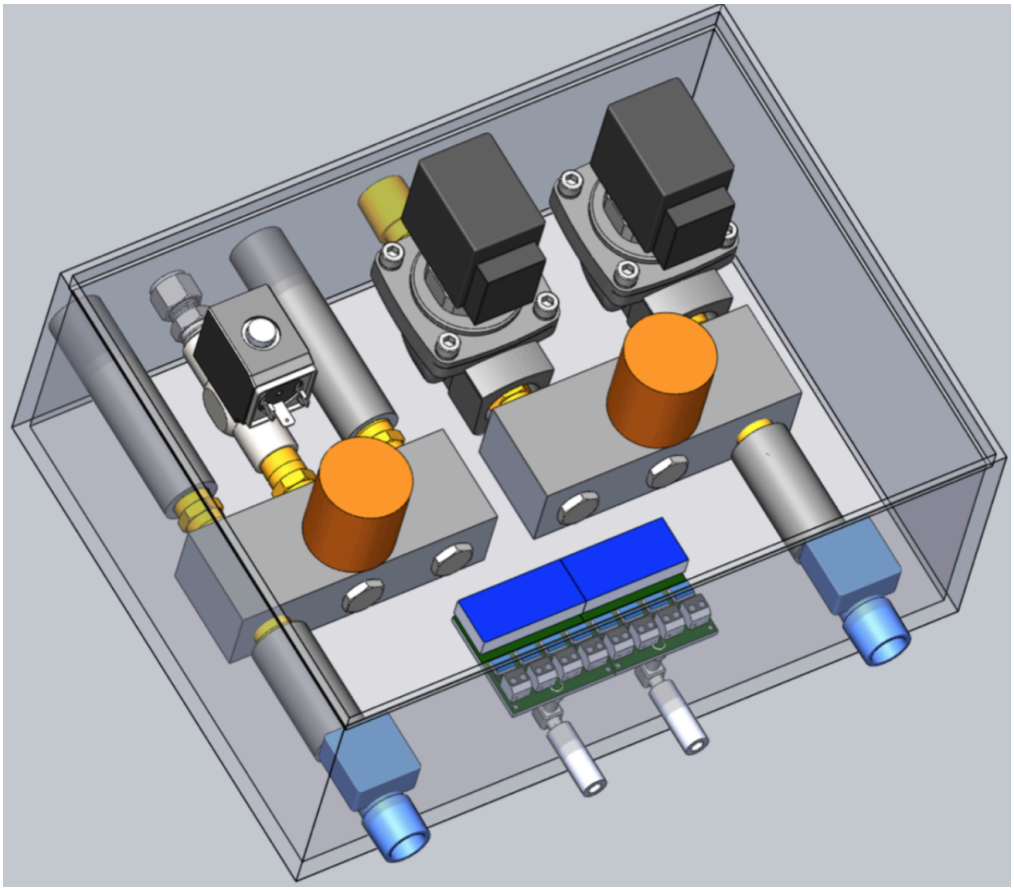

FIG. 2. The MVM controller base assembly with ports to connect.

3. CONTROL SYSTEM AND OPERATION

The control system performs supervision and actuation of the two valves (PV1 and PV2) based on the programmed respiratory cycle.

The pressure sensor, PS1, detects the pressure at the mask of the patient, which is then used by the control system to verify the pressure and then appropriately adjust the two valves to ensure that the pressure is always within the operating range: 20–30 mbar for the inspiratory phase and 5 mbar for the expiratory phase.

During the inspiratory phase, PV2 is closed and PV1 is open. When the pressure measured by PS1 reaches a constant value within the design range, at the end of the inspiratory cycle, PV1 is closed and PV2 is opened after a small pause. This allows the discharge of the lung pressure. The ending expiratory pressure is set by PEEP PV5.

The main controller runs on a (`Arduino`-compatible) micro-controller board based on a 32 bit micro-controller with WiFi/Bluetooth connectivity. All boards of this type have a small form factor and integrate all I/O functions required for this project.

A daughter board interfaces to the controller and provides four opto-coupled switches to operate the electrically-controlled pneumatic valves. The daughter board is provided with 24 V VDC supply and includes the low voltage regulator to supply the central unit.

The differential pressure gauges are based on a 60 mbar differential pressure sensor with a resolution better than 0.2 mbar.

The WiFi connectivity of the board offers the option for central monitoring and configuration. A buzzer and a high luminosity LED are available to signal alarms.

The MVM is equipped with an industrial power supply unit capable of at least 50 W and battery backup operated in fail-safe mode. Under normal circumstances, the power supply will feed the controller and keep the battery charged. In case of power failure, the battery will automatically provide the power for ongoing system operation for up to 30 min. The power supply is hosted in a separate enclosure to provide isolation between the oxygen lines and possible spark sources. The power supply unit will include two 12 V, 1.2 A h batteries.

3.1. Continuous Mandatory Ventilation mode

In the CMV configuration, the unit will operate the valves in regular cycles, defined by the operator through the inspiratory time, PEEP, and respiratory rate. The operator is also required to define the maximum inspiratory pressure threshold, which cannot be exceeded by the system for patient safety. Alarms are set on the basis of the inspiratory pressure, the minute ventilation, and the tidal volume, measured by the system itself. Preliminary ranges of values for control and alarm parameters are listed in table I.

TABLE I. Preliminary ranges of values for control and alarm parameters for MV mode operation of MVM.

Control parameter	**Range**	**Step**
Respiratory rate	4–50 rpm	1 rpm
Inspiratory time	0.4–1.5 s	0.1 s
PEEP	5–20 mbar	mechanical
Max inspiratory pressure	20–80 mbar	mechanical
FiO2	21–100 %	mechanical
Alarm parameter	**Range**	**Step**
Inspiratory pressure	10–80 mbar	1 mbar
Tidal volume	50–1500 mL	50 mL
Minute ventilation	2–20 slpm	1 slpm

3.2. Assisted Ventilation Mode

In AV mode, the patient triggers the ventilator. Inspiration pressure support is given at a preset constant pressure. The ventilator regulates the pressure during inspiration so that it corresponds to preset values within the operating ranges listed in table II.

TABLE II. Preliminary ranges of values for control and alarm parameters for AV mode operation of MVM.

Control parameter	**Range**	**Step**
PEEP	5–20 mbar	mechanical
Max inspiratory pressure	20–80 mbar	mechanical
FiO2	21–100 %	mechanical
Fraction of inspiratory flow	5–20 %	1 %
Alarm parameter	**Range**	**Step**
Inspiratory pressure	10–80 mbar	1 mbar
Tidal volume	50–1500 mL	50 mL
Minute ventilation	2–20 slpm	1 slpm

4. TESTS WITH A SILICON TEST BAG LUNG.

A series of tests with a silicon test bag lung has been performed in which the simulator lung was set to a number of different values of compliance and resistance. The pressure at the lung and the flow-rate as measured by PS1 and the SP1, respectively, were recorded.

An example of these data is shown in

Fig.3 shows the waveforms averaged over 10 cycles, for a simulated lung compliance (dV/dP) of 15 ml/mbar. The other parameters are displayed in the figures themselves.

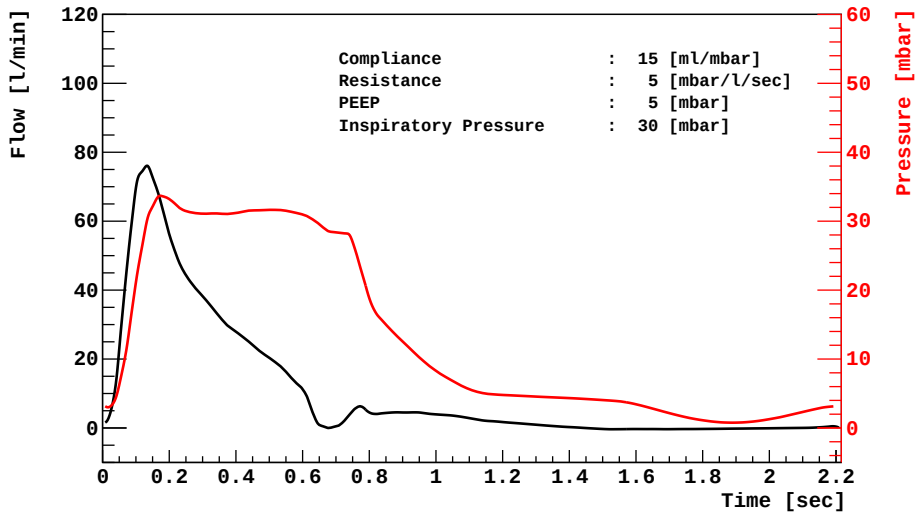

FIG. 3. Waveforms averaged over 10 cycles for a simulated lung compliance of 15 ml/mbar: the flow (black line), as measured by the spirometer SP1, and the pressure at the lung (red line) as measured by pressure sensor PS1.

Fig.4 shows the waveforms averaged over 10 cycles, for a simulated lung compliance (dV/dP) of 20 ml/mbar. The other parameters are displayed in the figures themselves.

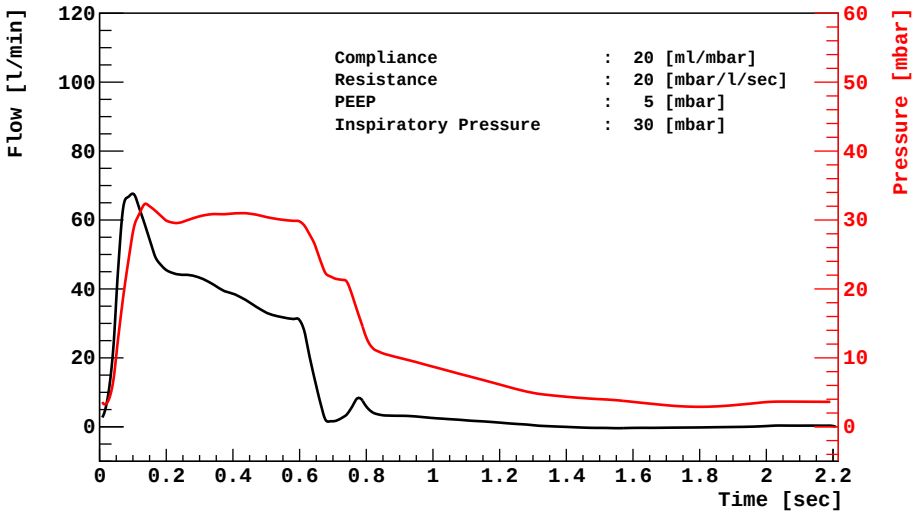

FIG. 4. Waveforms averaged over 10 cycles for a simulated lung compliance of 20 ml/mbar: the flow (black line), as measured by the spirometer SP1, and the pressure at the lung (red line) as measured by pressure sensor PS1.

Appendix A: MVM Control Unit

The MVM control system includes electronics that control the solenoid valves, and the sensors. Its configuration can be controlled locally with an LCD touch screen as well as remotely via wi-fi connection. A schematic description is given below:

1. Each MVM unit includes three electronic boards: a micro-controller; an interface board based on Raspberry Pi 4^{TM} with an LCD display; and the connection hub. The first two are readily available commercial components. The connection hub is a custom design by LNGS and is produced by Elemaster. The connection hub, shown in Fig. 5, includes the pressure sensor, the opto-controller for the solenoid of the valves, and the I2C ports for the gas flow meter.

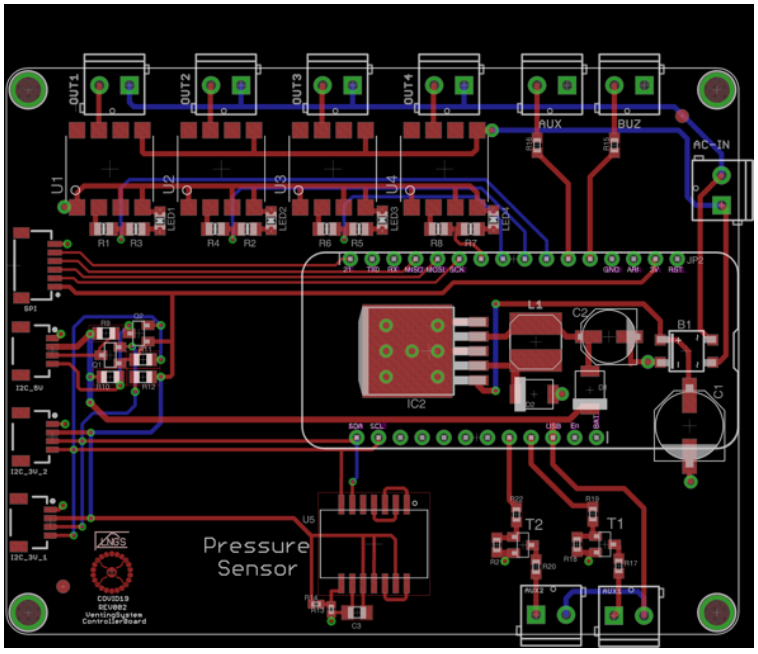

FIG. 5. The Gerber of the MVM connection hub for the MVM control system (preliminary version).

A prelimnary design of the GUI is shown in Fig.6.

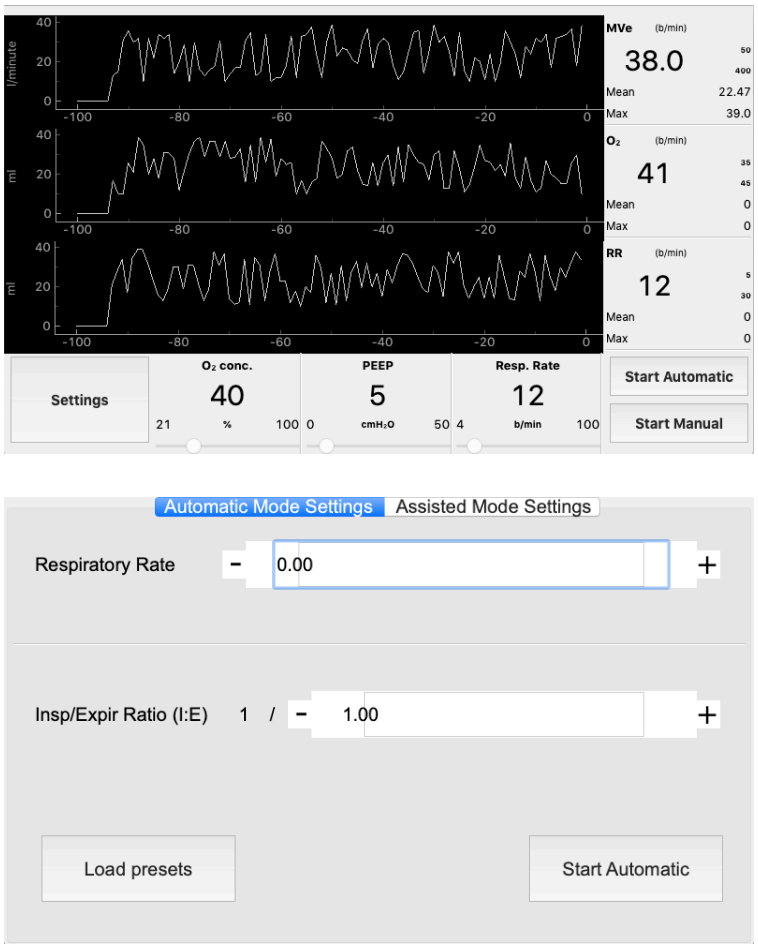

FIG. 6. GUI (top) and example setting of parameters (bottom) (preliminary version).

2. MVM units are designed to operate both in local and in remote modes, with the remote mode allowing for centralized control and monitoring. Moreover, it will be possible to update the firmware of the units and diagnose defective devices remotely over a network. To operate in remote mode:
   - A proper network infrastructure has to be deployed. The network should include several high reliability access points and routers with proper security measures for network integrity and data protection.
   - Network infrastructure must include one redundant installation of an MQTT server with database logging and workstations to allow operators to monitor the MVM units.
   - Remote configuration and monitoring of the MVM units is realized via the MQTT protocol with a proper user interface required for operators to centrally monitor the parameters and modify the configuration. The user interface runs in centralized mode on personal computer workstations. A second user interface can be implemented for mobile phones (using an already available MQTT applet configured properly). The applications have different levels of authorization and authentication. A scheme of the scalable proposed network of MVM devices is shown in Fig. 7. The network hardware connection is shown in Fig. **??**

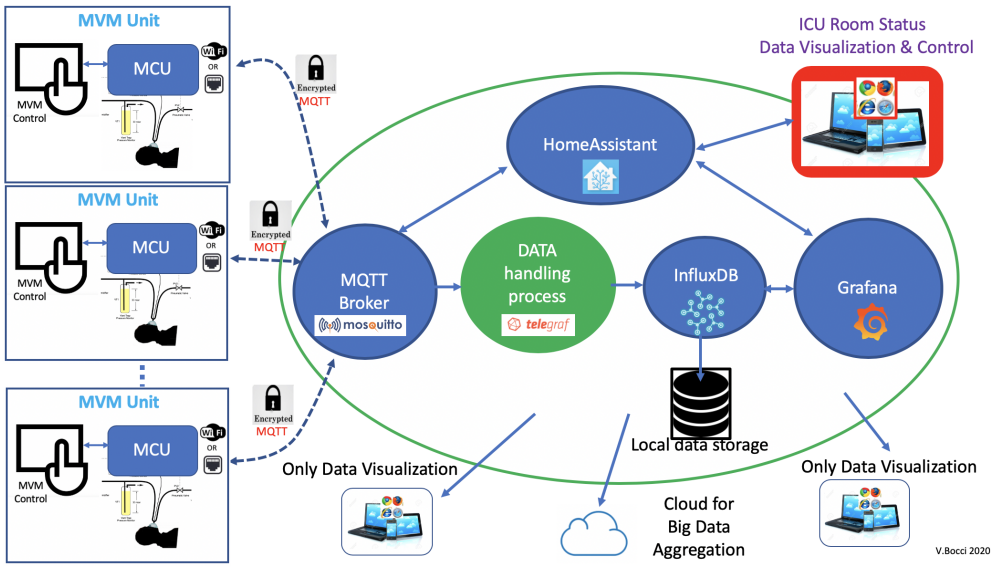

FIG. 7. The structure overview with the connection of the single components of the MVM network for remote control and monitoring of patients by the hospital staff.

- The critical operations of the valves and sensors are manged by the core firmware running on the micro controller.
- The local interface with the user is through a touchscreen LCD, which also displays operating parameters.
- The local Raspberry processor will also run the MQTT client to dispatch commands received from remote users.
- A validation procedure is foreseen to test the electrical and firmware functionality of the units once produced.

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