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Masi: A mechanical ventilator based on a manual resuscitator with telemedicine capabilities for patients with ARDS during the COVID-19 crisis

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ABSTRACT

In this article, we introduce a portable and low-cost ventilator that could be rapidly manufactured, to meet the increasing demand of ventilators worldwide produced by COVID-19 pandemic. These ventilators should be rapidly deployable and with functional capabilities to manage COVID-19 patients with severe acute respiratory distress syndrome (ARDS). Our implementation offers robustness, safety and functionality absent in existing solutions to the ventilator shortage (i.e., telemonitoring, easy-to-disinfect, modularity) by maintaining simplicity. The design makes use of a manual resuscitator as the core respiration component activated by a compression mechanism which consist of two electronically controlled paddles. The quality measurements obtained after testing on a calibrated artificial lung demonstrate repeatability and accuracy exceeding human capabilities of manual ventilation. The complete design files are provided in the supplementary materials to facilitate ventilator production even in resource-limited settings. The implementation of this mechanical ventilator could eliminate device rationing or splitting to serve multiple patients on ICUs.

Specifications table:

Hardware name	*Masi (https://www.proyectomasi.pe/)*
Subject area	• Medical
Hardware type	• Medical ventilator
Open source license	*CERN OHL*
Cost of hardware	*Approximate cost of production: 1000 USD*
Source file repository	*https://doi.org/10.17632/kvx6syk42x.1*

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2468-0672/

1. Hardware in context

The current COVID-19 pandemic is causing a rapidly increasing number of SARS-CoV-2 pathologies around the world. Based on the number of patients expected to contract the disease and especially those likely to require assisted ventilation, we are currently facing a potential shortage of mechanical ventilators [1,2].

Most COVID-19 patients who develop Acute Respiratory Distress Syndrome (ARDS) often require prolonged mechanical ventilation. Due to this and the limited number of ventilators, health professionals around the world have been forced to make difficult triage decisions for patient treatment [3]. The problem is further aggravated because of the complexity and expense of commercially available Intensive Care Unit (ICU) ventilators whose distribution has also been affected by the breakdown of regular supply chains and factories closures as a consequence of the pandemic [4].

Therefore, there is a critical need for health care facilities with sufficient number of ventilators because access to such equipment directly affects the number of deaths associated with the disease in an ICU. In response to this crisis, five innovation centered institutions in Peru gathered and conceived the Masi project, a team to develop a ventilator with sufficient functionality to safely treat COVID-19 patients with ARDS, while reducing the production time, logistical complications and cost to make ventilators available to assist and sustain the already saturated Intensive Care Units (ICU) system or any emergency point of care.

The ventilator design focuses on safe operation and reliable production while addressing the specific needs of COVID-19 patients with ARDS: minimizing part count, reducing or eliminating reliance on scarce parts and resources, ensuring viable implementation in different healthcare systems (from incipient systems like ours in Peru and other across the world) and seeking simple assembly, testing and use procedures by health-care personnel with limited experience on this type of ventilator system [5].

Modern ICU ventilators provide complex control and intricate feedback loops of a wide variety of respiratory parameters and ventilation modalities for highly specialized staff [6,7]. Regulatory requirements and certification procedure are understandably high, paired with the failure of supply lines and the difficulty in rapidly ramping up production of commercial ventilators slow down the healthcare system response. In the meantime, lives are at risk. In addition, some of the emergency ventilators which are still commercially available do not meet the medical requirements of the complex ARDS-like pneumonia associated with COVID-19 which requires pulmonary protective ventilation with careful control of pressure and volume as compliance of the infected lung tissue can rapidly deteriorate, which may lead the patient to a barotrauma or further lung injury. We are then left with an unmet need for COVID-19 pneumonia-appropriate and rapidly deployable emergency-use ventilators.

In this context the project Masi (word in quechua for "companion") was conceived to provide a low-cost emergency ventilator that can meet the ongoing growing demand while complying to basic healthcare regulations. Several healthcare regulation agencies such as the Spanish Agency of Medicines and Medical Devices (AEMPS), United States Food and Drug Administration (US FDA) and the United Kingdom Medicines and Healthcare products Regulatory Agency (UK-MHRA) have issued guidelines for emergency ventilators design and development. In the absence of a global standard for open source ventilators, most of the initiatives have adopted the UK-MHRA guidelines for Rapidly Manufactured Ventilator System (RMVS) [8] as the baseline standard for design and development of such ventilators. Masi has also been designed to comply with these guidelines and the General Directorate of Medicines, Supplies and Drugs of Perú (DIGEMID) verified that the design met the specified standards.

In addition, safety and easy usability by healthcare professionals are the two main factors considered in Masi development. Based on published literature and reported clinical experience [9–12], we determined the following ventilation features to be essential for safe use in patients in this crisis: Pressure and volume controlled ventilation modes, respiratory rate (RR), inspiratory time and forward-compatibility with external modular components such as adjustable positive end-expiratory pressure (PEEP) valves. Particularly, the ventilator interface has been designed in such a way that it requires minimal training to operate the ventilator without sacrificing ventilation modes available in more complex commercial ventilators (VC–CMV, PC–CMV and PC–CSV).

The design of Masi is unique compared to other open-source designs currently available in its compression mechanism, the ability to control various respiration parameters, simultaneous implementation of the aforementioned operation modes and real time monitoring through different portable devices. The design makes use of a manual resuscitator as core driver to insufflate air into the patient airways via a mask, similarly to other designs found in open projects like E-Vent of MIT [13] or ApolloBVM from Rice University [14] and closed-sources derivatives like OxVent of University of Oxford and King's College London [15] and Spiro Wave from 10xBETA [16].

In addition, basic alarms indicating high or low pressure and volume are implemented to notify the healthcare provider when desired parameters are not being met or if there is a significant problem with the system. Our approach provides predictable delivery of ventilated breaths and streamlined device production. Masi is a ventilator that, although based on the automation of a manual resuscitator, includes functionalities that can be related to a critical use ventilator such as the Medtronic Puritan Bennett 980. This is supported by the inclusion of invasive and non-invasive ventilatory types both mandatory and spontaneous. In addition, control and monitoring of oxygen concentration is provided. Therefore, it is also superior to some of those developed in the context of the emergency, such as the Spiro Wave. The PI, VT, and PEEP ranges meet the requirements of the MHRA guideline and were verified with specialists in the care of COVID-19 patients. A feature-wise comparison of Masi with the two ventilators which are already being used in ICUs is presented in Table 1.

Several source ventilator designs have been proposed during the outbreak. Most of the open alternatives shared to the community have been extensively reviewed in [10], including some notable designs distributed through the web like [17–19]. A particular useful taxonomic study that focuses on highlighting three important characteristics (i.e., buildability, adoptability and scalability) to make a project quickly deployable was presented in [20]. This taxonomy helped us to qualitative compare our ventilator with other projects including the percepction of three important parties: Engineers, healthcare personnel and managers respectively for a classification matrix divided on 4 quadrants: early projects/proof of concept, educational projects, hospital grade replacements and traditional hospital grade MVs. We consider this iteration of Masi in the quadrant of hospital grade replacement equipments, sacrificing a bit of buildability over other alternatives like E-vent and Openbreath by including ventilation modes with graphical feedback and a medical grade sterilizable casing and mechanism for a cleaner and straightforward adoption into our local emerging medical service system.

In the next sections we will present further design choices which were based by targeting safeness, effective ventilation and quick production. For validation, the device was tested utilizing a precision test lung and a gas flow analyzer with time-stamped data capture.

2. Hardware description

2.1. Functional blocks

Masi hardware is distributed in three mayor blocks: The ventilation circuit, the electrical circuit and the mechanical system, all of them controlled simultaneously by the firmware. These three functional blocks are presented in Fig. 1. The ventilation circuit comprises the pressurized medical air and oxygen inlet, the reservoir of the manual resuscitator, connections, valves, filters and pipes that go directly to the patient. The electrical circuit comprises the power supply unit, sensors, the control unit and the step motor. Finally, the mechanical system comprises the mobile manual resuscitator actuator and the metal structure containing all aforementioned parts (equipment housing).

2.1.1. Ventilation circuit

All the components of the circuit ventilation systems are medical grade and comply with regulations and permits for use in hospitals. The oxygen inlet is set in a low flux manometer with the recommended values provided to the clinician by Masi throught the FiO2 sensor feedback and serves flux to the reusable resuscitator. Masi's mechanical design allows the adaptation of multiple commercial reusable resuscitators (i.e, Besmed® PS-2103, the Ambu® Oval,etc). The possibility to adapt any commercial resuscitator increases its deployment speed and success rate in case this material are not standardized. Also, being a reusable device, it allows easy disassembly and sterilization by immersion in glutaraldehyde disinfectant or steam. In addition, a PEEP valve is located on the inspiration/expiration conduct at the end of the expiratory circuit connected to an HMEF filter. It is necessary to mechanically regulate the level of the PEEP valve each time for a new ventilation configuration. Fig. 2 depicts the external ventilation connections. The flow/pressure probe is connected directly to the board through the Masi peripheral input (see Section 6.3), the presure is measured directly and the flow is derived from the pressure difference between these two inlets.

2.1.2. Electrical circuit

Masi is powered by a grounded AC electrical outlet whit a protection fuse of 3A. The power is handled by an AC/DC Mean Well DRC-100 uninterruptible power supply (UPS) with a nominal power of 96 W and a self voltage input of 90VAC to 264VAC. The DRC-100 source provides electrical leakage protection and compliance with IEC 62368-1 and TPTC004. The output is set for a nominal load of 27.6VDC; in case of power failure, the equipment has a battery bank that allows an uninterrupted autonomy of at least three hours of operation complying with ISO 80601–2-80:2018(E), clause 201.11.8.101.1(C) which exceeds the MHRA-RMVS requirements of a minimum battery life of 20 min with hot-swapping capabilities to extend it to two hours. The sensing systems comprises three sensors. Two used in the calculations of flow and pressure control and a

Table 1
Functionality comparison versus two frequently deployed ventilators.

	Masi	Spiro Wave MIT Emergency Ventilator	Medtronic Puritan Bennett 980
Ventilation Type	Invasive Non-invasive	Non-invasive	Invasive Non-invasive
Mandatory type	Volume control Pressure control	–	Volume control Volume control plus Pressure control
Spontaneous type	Pressure support ventilation	Continuous positive airway pressure Bilevel positive airway pressure	Pressure support Tube compensation Volume support Proportional assist ventilation
Inspiratory pressure (PI)	(0–45) cmH2O	(0–40) cmH2O	(5–90) cmH2O
Tidal volume (VT)	200 ml to 800 ml	200 ml to 800 ml	25 ml to 2500 ml
End expiratory pressure (PEEP)	(0–20) cmH2O	(0–25) cmH2O	(0–45) cmH2O
O2%	(21–100) %	–	(21–100) %

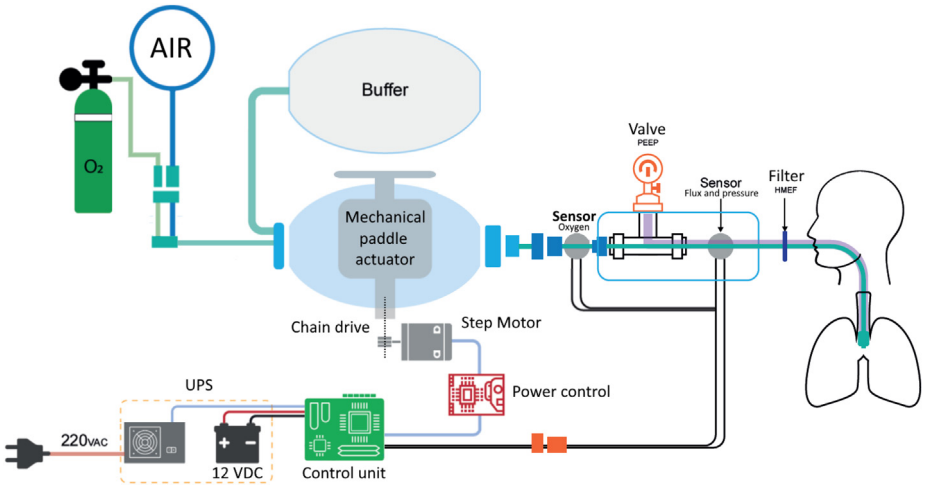

Fig. 1. Block diagram: Ventilation circuit, electrical and power control.

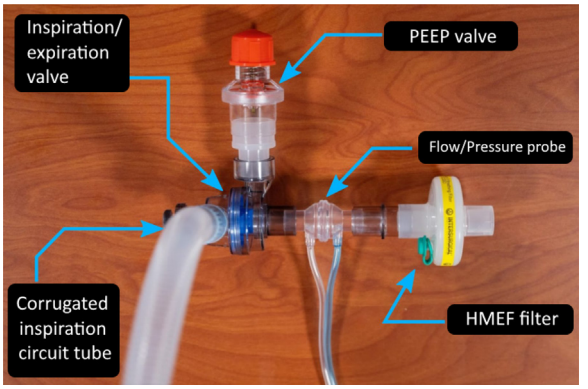

Fig. 2. External ventilatory circuit.

third one measuring the oxygen percentage. The first one is a differential pressure sensor SM9541-010C-D-C-3-S from SMi, which has a pressure range between −10 to 10 cmH2O and 1% full-scale accuracy. accuracy. The second one, an integrated pressure sensor MPVZ5010 from Freescale, with a range of 0 to 10 kPa and an accuracy of 5% at temperatures between 0 and 85 °C. The third sensor (CiTiceL AO2) which measures the oxygen percentage provides a full range measure with a resolution of 0.01%. At the initial configuration of the device, there is an internal test of the sensing system, setting a software failure flag, implemented in the control unit. In case the failure flag is set during operation, there would be screen, sound and portable devices alarms to alerts the clinicians. In these cases the clinicians can open the lid and begin to manually cycle the ventilator.

The sensing system comprises three sensors, two used in ventilation control and a third one to measure the oxygen percentage. The first one is a differential pressure sensor SM9541-010C-D-C-3-S from SMi, which has a differential pressure range between −10 to 10 cmH2O and 1 % FS accuracy. The second one is an integrated pressure sensor MPVZ5010 from Freescale, with a range of 0 to 10 kPa and an accuracy of 5% FSS at temperatures between 0 and 85 °C. The third sensor measures the oxygen percentage (CiTiceL AO2) provides a full range measure with a resolution of 0.01%. At the initial configuration of the device, there is an internal test of the sensing system. If during the test the failure flag is set, there would be an error showed on the screen. In case the failure flag is set during operation, there would be screen and sound alarms.

The engine module is driven by a DM556D controller. The DM556D offers low noise, vibration, and functioning temperature values. Its voltage is DC 24 V-50 V and it is suitable for all the 2-phase hybrid stepper motor whose current is less than 5.6A. The stepper motor is responsible for operating the compression mechanism of the manual resuscitator. It can operate continuously and has a high precision step control with a radial force of 75 N and axial force of 15 N. The motor is electrically isolated from the chassis, thus protecting the user and the system from any electric shock. The power console complies with

quality standards and electrical and mechanical protection according to the rules: EN60034-1, EN55014-1, EN55014-2, EN61000-3–2 and EN61000-3–3.

2.1.3. Mechanical system

The manual resuscitator drive mechanism is based on a system of paddles attached to an axis which serves as pivoting point (similar to a clamp), where the upper end of the pallets receives the force through a chain drive transmission. This system transforms the torque and rotational movement of the step motor to translation and force, which allows to compress the resuscitator with both pallets in a controlled manner.

The support structure, casing of the internal parts and the compression mechanism are made of austenitic stainless steel material AISI 304, selected for its high resistance to corrosion against cleaning products used for surface sterilization (Fig. 3). Also, it is not sensitive to magnetic fields, which allows to protect the sensors and electronics. Its pedestal has four antimicrobial wheels of 10 cm in diameter following the specification of the standard IEC60601–1 sub-clause 9.4.3 for mobile equipment.

2.1.4. Telemetric remote interface

The telemetry module allows mobile clients to connect to a web server hosted on the ventilator to display pressure, flow and volume graphs, the user can also select the programmable values remotely. The telemetric capabilities of the device are controlled from the Main Microcontroller (MM), that sends sample data, alarms, etc to the Telemetry Microcontroller (TM). The TM performs a connection setup upon the ventilator's power on sequence. This setup attempts to connect to a configured network. This configuration is done once at startup, and provides Masi with the required credentials to access the local network, from this point the operation can continue without any further manipulation and start the execution of its telemetry functions. The telemetry is performed via MQTT messages sent to a broker located in a cloud server. The use of a broker in this instance, allows for direct operation to the client applications without use of the server on this type of situations which reduces latency. Data is transferred from the mainboard to the telemetric module in buffered time windows of 3s containing 75 samples where is stored and broadcasted to each of the clients through a TLS cryptographic protocol provided by https://letsencrypt.org/ (ISRG, California, USA) ensuring the integrity of the transmitted data and security of the patients information. Fig. 4 depics the communication process.

2.1.5. Firmware

The controller and power board interacts with the ventilation circuit sensors driven by the firmware. Its is divided in four main blocks: Wi-FI communication, which allows Masi to be accessed remotely for patient monitoring; battery control which makes regulates and diagnostic the health of the power circuits, graphical interface driver and the central control which all other blocks are connected to. The files corresponding to each of these block are uploaded to the repository.

The firmware injection is performed through an atmel ICE for the ATMEGA files and through visual studio for the other two microcontrollers according to the following sequence:

- Build Masi-ControlFlash.7z files in atmel studio and load the compiled version in the ATMEGA 4809
- Load the ATMEGA 4809 EEPROM with the calibration file
- Build Masi-Bat.7z files in the ATMEGA 48 PB

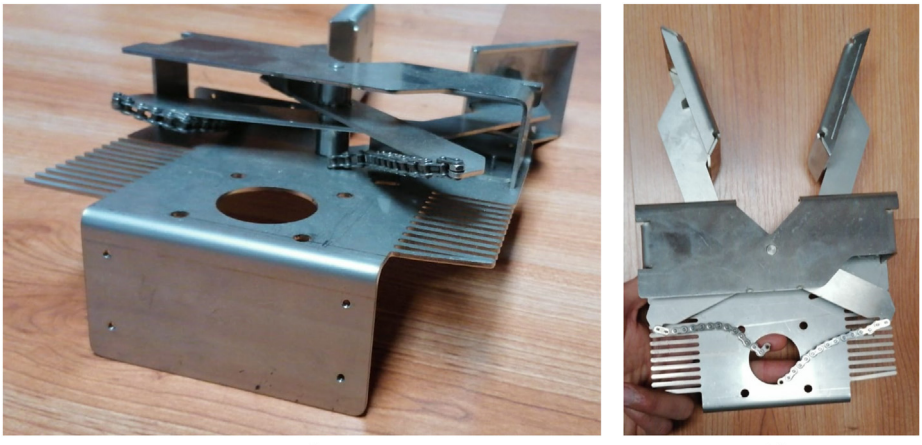

Fig. 3. (a) Front and (b) Back views of the compression mechanism (the manual resuscitator is highlighted in red).

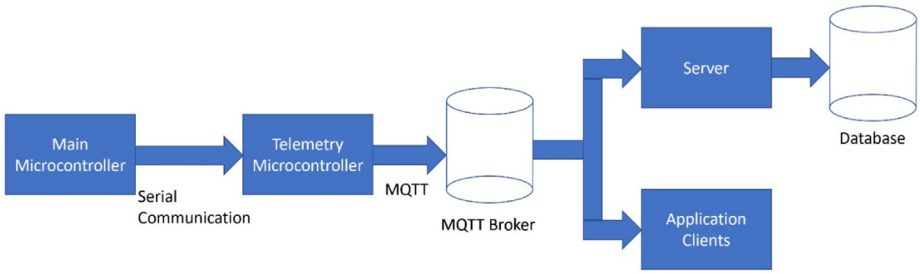

Fig. 4. Block diagram describing the telemetry data flow).

- Load the STM bootloader throught the board serial port
- Load the GUI interface design files in the touchscreen SD slot
- Build the Masi-GUI.7z files and load them in the STM32F103C8 through USB
- Build the Masi-TELE.7z files and load them to the ESP-WROOM through USB

Masi is capable of operating under three ventilation modes: VC–CMV, PC–CMV and PC–CSV to control volume and pressure (VC or PC respectively). The first two modes execute a continuous mandatory ventilation (CMV), where spontaneous breaths are not allowed between mandatory breaths and the third mode executes continuous spontaneous ventilation (CSV), where all breaths are spontaneous.

2.2. Device potential in the current crisis

- Masi has both mandatory and support ventilation modes. In addition, it offers tele-monitoring capabilities when paired with portable devices like laptops, cellphones and tablets.
- Masi has a novel chain drive transmission to transform the motor torque into compression through its double paddle system. This is superior to other other implementation seen in the literature which normally use only unilateral compression. It also has no backlash, and is far quieter.
- Unlike other emergency ventilators known to us, we offer a tactile screen design allowing visual feedback for monitoring and a fully alarmed ventilation operation suitable for life support.
- The system complies with UK-MHRA standards and its capable of being used clinically on ICU due to its robustness and easy-to-disinfect design.

Fig. 5 presents the assembled prototype and its interaction with different peripherals for patient monitoring.

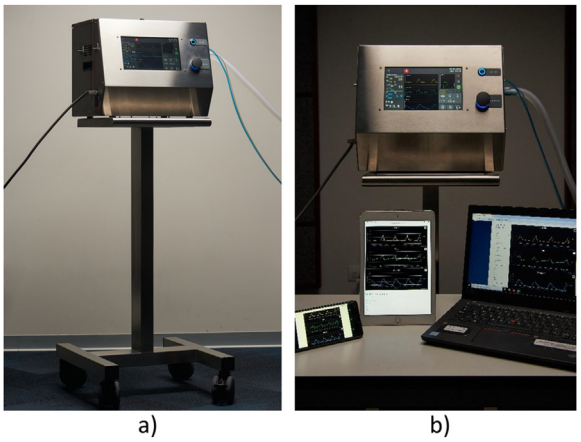

Fig. 5. (a) Front face of MASI (b) Patient monitoring on different periferals.

3. Design files

3.1. Electronic design

Design filename	File type	Open source license	Location of the file
control_avr_v15.sch	Schematic design file: It contains the electronic functional blocks and their connections	CERN OHL	https://doi.org/10.17632/kvx6syk42x.1
control_avr_v15.brd	PCB file: Component layout in the printed circuit board	CERN OHL	https://doi.org/10.17632/kvx6syk42x.1

3.2. Chassis and mechanism design

Design filename	File type	Open source license	Location of the file
Proyecto MASI - Blueprints	CAD design: blueprints for the chassis and support	CERN OHL	https://doi.org/10.17632/kvx6syk42x.1
Masi3DModel.stl	3D model file: Mechanism model (for reference)	CERN OHL	https://doi.org/10.17632/kvx6syk42x.1
Proyecto MASI - DXFs for laser cutting	DXFs model file: Pieces for construction	CERN OHL	https://doi.org/10.17632/kvx6syk42x.1

3.3. Firmware

Design filename	File type	Open source license	Location of the file
Masi-TELE.7z	Firmware: corresponding to the internet interface and telemetry capabilities and to be loaded in the ESP-WROOM	CERN OHL	https://doi.org/10.17632/kvx6syk42x.1
Masi-Bat.7z	Firmware: corresponding exclusively to the battery module control and to be loaded in the ATMEGA48PB	CERN OHL	https://doi.org/10.17632/kvx6syk42x.1
Masi-ControlFlash.7z	Firmware: corresponding to the main control block. To be loaded in the ATMEGA4809	CERN OHL	https://doi.org/10.17632/kvx6syk42x.1
Masi-ControlEEPROM_S1.eep	Firmware: corresponding to the sensor calibration. To be loaded in the ATMEGA4809	CERN OHL	https://doi.org/10.17632/kvx6syk42x.1
Masi-GUI.7z	Firmware: corresponding to the main user interface control. To be loaded in the ESP-WROOM	CERN OHL	https://doi.org/10.17632/kvx6syk42x.1
Masi-TELEboot.bin	Firmware: corresponding to the main control block. To be loaded in the STM32F103C8	CERN OHL	https://doi.org/10.17632/kvx6syk42x.1

4. Bill of materials

4.1. Ventilation circuit

Item	Model	Cost per unit (USD)	Source of materials
Manual resucitator	BESMED PS-2103	26.69	http://www.medicalonline.pk/index.php?route=product/product&manufacturer_id=46&product_id=620
Flow sensor	UPN Med - Hamilton	25.50	https://www.alibaba.com/product-detail/Hamilton-adult-neonate-flow-sensor_1600075112520.html?spm=a2700.details.maylikeexp.7.1ca09005woR2Di
Oxigen sensor	CiTiceL AO2	15.58	https://shawcity.co.uk/sensorrange/oxygen/ao2-citicel-with-molex-connector
Ventilation tubing	VentStar 180	11.31	https://afaith.en.alibaba.com/product/62562017488-817773859/Drager_Breathing_circuit_VentStar_disposable_1_8m_MP00356_disposable_coaxial_Breathing_hose_kit_Drager_Vent_Star_Coax_180.html

5. Build instructions

The build process is divided in three phases: The metal fabrication, the electronic fabrication and assembling. Details on each phase are presented as follow.

5.1. Metal fabrication

Metal mechanical manufacturing includes laser cutting, CNC bending, TIG welding, among others. The manufacturing of the main mechanical parts of Masi starts with the selection of a stainless steel plate, which will be the base for this piece. After a cleaning treatment of the steel plate, it is cut according to the plans with a laser cutting machine. One advantage of using laser cutting is to avoid regrinding for chip removal at the cutting edge, but it could also be cut with more traditional cutting techniques. Finally, it goes through a CNC folding process to shape the parts to be ready for the welding or coupling process. The design files for the ventilator housing, support and compression mechanism are published in the file repository.

5.2. Electrical circuit

ITEM	MODEL	Cost per unit (USD)	Source of materials
Power cable	-	6.50	https://www.digikey.fr/product-detail/fr/211018-06/Q123-ND/245572?utm_campaign=buynow&utm_medium=aggregator&curr=eur&utm_source=octopart
Power supply	Well DRC-100B	48.28	https://www.mouser.fr/ProductDetail/MEAN-WELL/DRC-100A?qs=7PCaVhlmG1qOJpT71768Vw==
A/C medical grade connector	06EK3M	19.14	https://www.digikey.fr/products/fr?keywords=06EK3M%E2%80%8E
Batteries x2	PC9-12SF2	28.87	https://www.digikey.fr/products/fr/battery-products/batteries-rechargeable-secondary/91?k=12V%209Ah
Differential preasurre sensors	SM9541-010C-D-C-3-S	22.97	https://www.mouser.fr/ProductDetail/Silicon-Microstructures-Inc/SM9541-010C-D-C-3-S?qs=emHYq6U3k7JJRVmJh1qRXQ%3D%3D
Integrated preasure sensors	MPVZ5010	16.97	https://www.digikey.fr/product-detail/fr/nxp-usa-Inc./MPVZ5010GW7U/MPVZ5010GW7U-ND/1168379
Microcontroller x2	ATMEGA48PB-AUR	1.00	https://www.digikey.com/en/products/detail/microchip-technology/ATMEGA48PB-AUR/5029499

(*continued*)

ITEM	MODEL	Cost per unit (USD)	Source of materials
PCB	-	8.34	https://aliexpi.com/YqOw
Screen	DMT10600T101	97.80	https://www.aliexpress.com/item/32882451208.html
Motor driver	DM556D	38.66	https://www.amazon.com/Motor-24-50VDC-Microstep-Performance-Engraving/dp/B073W88RZN/ref=sr_1_2?currency=EUR&dchild=1&keywords=DM556D&language=en_US&qid=1604169804&sr=8-2
Step motor	57HS112-3004	20.80	https://dewochina.en.alibaba.com/product/60676607521-220483332/good_quality_3_5A_nema_23_388oz_in_stepper_57HS112_3504_motor.html
STM	STM32F103C8	5.53	https://www.digikey.com/en/products/detail/stmicroelectronics/STM32F103C8T6/1646338
CTS-Frequency Controls	CB3-3I-18M432000	1.00	https://www.digikey.com/en/products/detail/cts-frequency-controls/cb3-3i-18m432000/663650
General Purpose Digital Isolator x3	SI8711AC-B-IS	1.00	https://www.digikey.com/en/products/detail/silicon-labs/SI8711AC-B-IS/3587157
Position Card Connector microSD	MEM2075-00-140-01-A	1.30	https://www.digikey.com/en/products/detail/gct/MEM2075-00-140-01-A/9859614?s=N4IgTCBcDaILIFE5gAwHYCsBaFKsEYAWPFfLAQRAF0BfIA
Isolated Module DC DC Converter	Shhd001A3B41Z	18.00	https://www.digikey.com/en/products/detail/abb-power-electronics-Inc./SHHD001A3B41Z/3878314?s=N4IgTCBcDaIMoAsEBMAMqCMBBAzAIQBYMAtEAXQF8g
Isolated Module DC DC Converter	PqME3-D24-S9-M-TR	12.00	https://www.digikey.com/en/products/detail/cui-Inc./PQME3-D24-S9-M-TR/7227629?s=N4IgTCBcDaIAoEcCyBRAzAWgCJgCwYGUBODJDAFQCUQBdAXyA
WiFi 802.11b/g/n Transceiver Module	ESP-WROOM-O2D	5.00	https://www.digikey.com/en/products/detail/espressif-systems/esp-wroom-02d-4mb/10259353

5.3. Electronic fabrication

The printed circuits were produced on double-sided fiberglass boards. Fig. 6 depicts a diagram describing the board functional blocks beginning by an initial division between the front panel and the electronic tray. The front panel contains elements that interact with the operator. These elements are: A touch screen controlled by serial commands, a mechanical encoder and button, that allows select and set operation values and an on/off button. The electronic tray contains an AC/DC power supply, UPS and the PCB.

The main PCB comprises the following elements:

- A self-latching circuit; when the on/off button is pressed the PCB is energized and activates a contact that allows to control it is own power supply.
- Three DC/DC isolated power supplies that transfer power without direct electrical connection.
- The control microcontroller processes a closed loop control of the system, acquiring data of the pressure sensors and controlling the motor.
- The screen microcontroller is in charge of the interaction between the operator and the equipment, shows the equipment ventilation graphs and generates the alarms of the system.
- The Wi-Fi microcontroller send the alarms and graphs of ventilation to a server in real time. So, a doctor can diagnose remotely.

The individual connections for each component and their corresponding routing at the final board are depicted in the.sch and.brd files respectively. This files are part of the source repository uploaded to the Mendeley database.

5.4. Assembling

The assembling procedure is divided in three phases: The front face assembling, the resuscitator compressor set up and chassis mount. The aforementioned sequence is depicted in Fig. 7. An overview of each step of the process is presented in the

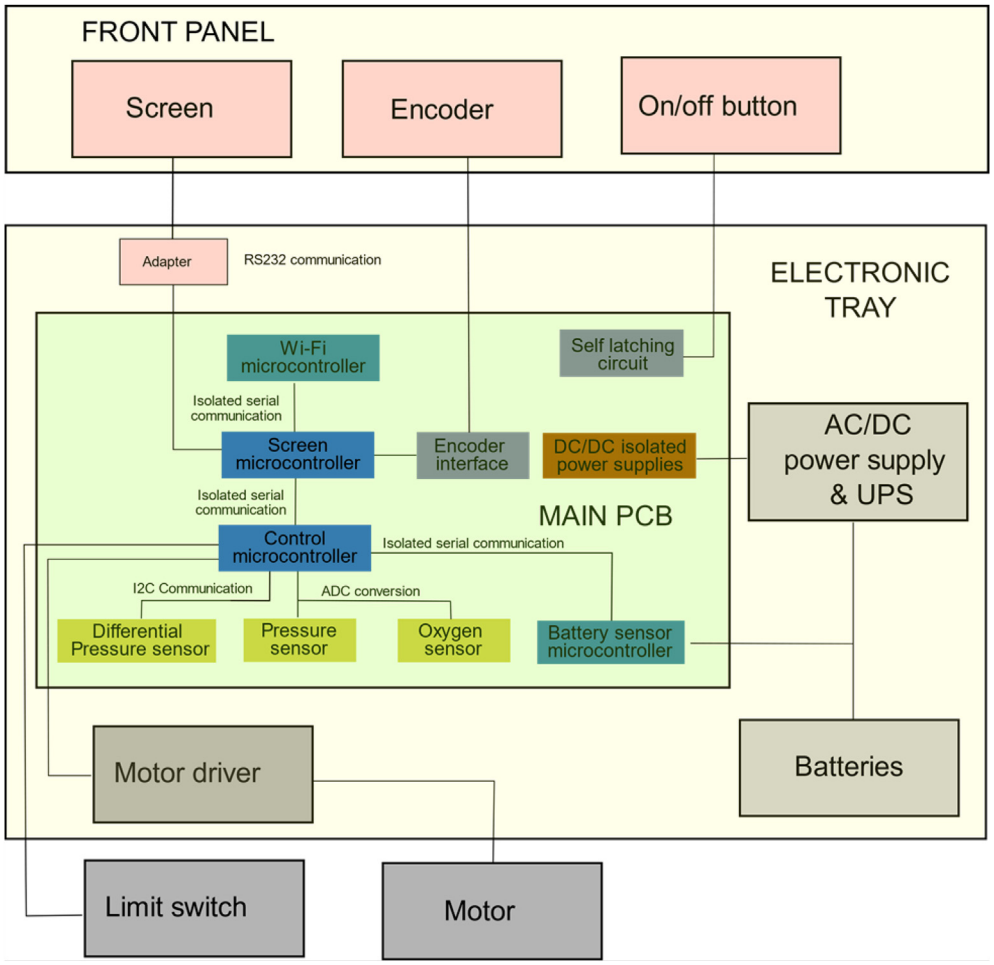

Fig. 6. Functional blocks present in Masi's board design.

next subsections and its complemented by a series of videos contained in the source repository uploaded to the Mendeley database.

5.4.1. Front face assembling

The front face is divided in two parts. The first contains the touch screen and physical interface buttons; the latter the control and power boards.

For the interface panel section, the three elements (screen and buttons) are placed in their corresponding holders as seen on Fig. 8a. On the other hand, the battery, UPS and the control and power board are distributed in the front face back plate shown in Fig. 8b. Both parts fit into each other vertically and are attached to each other by bolts as seen on Fig. 7a.

5.4.2. Resuscitator compression mechanism

The compression mechanism is the responsible for activating the manual resuscitator during operation. It can be divided in two main parts: the actuator and protection cover. The first comprising the step motor (and its supporting structure), the resuscitator holder, the driving mechanism and the compressing pads; the latter comprising the structure which separates the manual resuscitator from the actuator block (Fig. 9). For an intuitive overview of the assembling process, the corresponding explosive views including the list of parts are included in the repository files.

A complete view of the assembled compression mechanism is presented in Fig. 10, where the mechanism, motor and manual resuscitator are depicted in gray, black and blue respectively.

The process begins by mounting the step motor supporting structure, as shown in Fig. 11. Then step motor is attached to it at the same time than the stop sensors (for paddle feedback to the main board) and the pivots for the driving mechanism.

Next, the paddle system is mounted (Fig. 11 and the chain drive mechanism is set (Fig. 12b). When both paddles are fixed the cover plate is attached to the compression block (Fig. 12c). Finally, the chain drive is lubricated (Fig. 12c) and the structure is placed vertically to attach the manual resuscitator supporting plate (Figs. 13b and c)

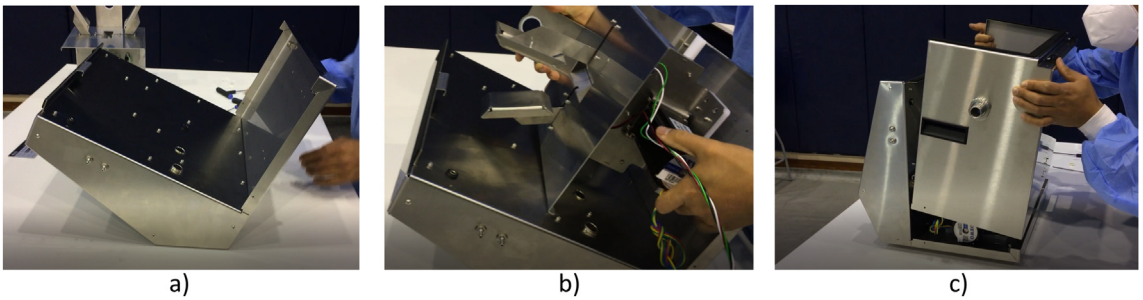

Fig. 7. (a) Assembled front face (b) Manual resuscitator compressor fixation (c) Chassis mount.

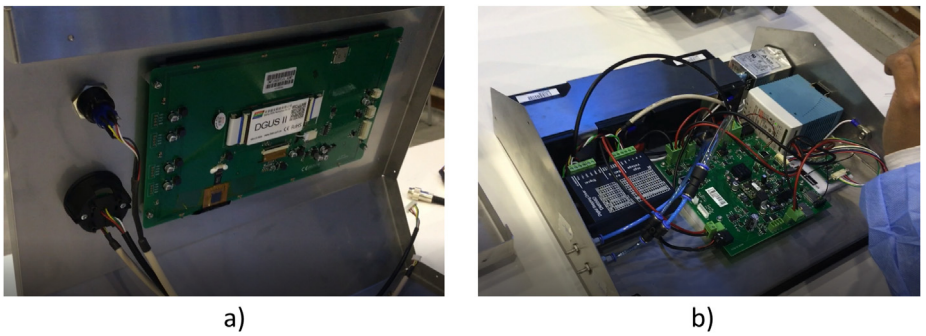

Fig. 8. (a) Touch screen and interface buttons (b) Control and power boards.

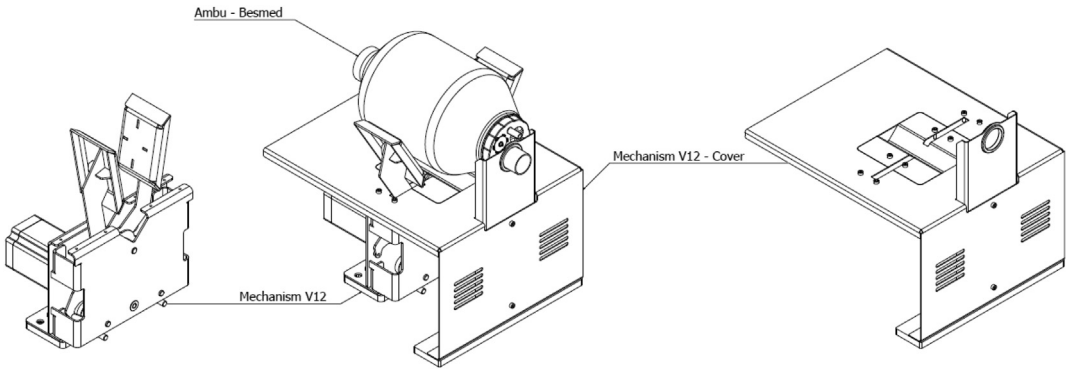

Fig. 9. (a) Actuator and Cover view of the compression mechanism.

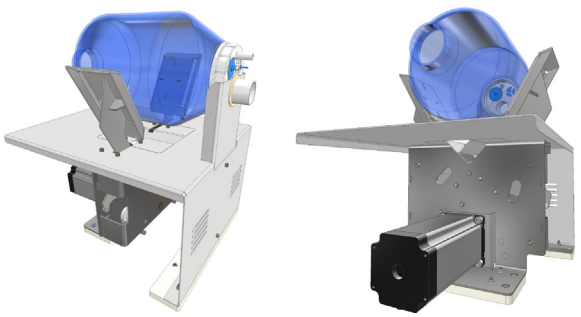

Fig. 10. (a) Back and front (b) view of the compression mechanism.

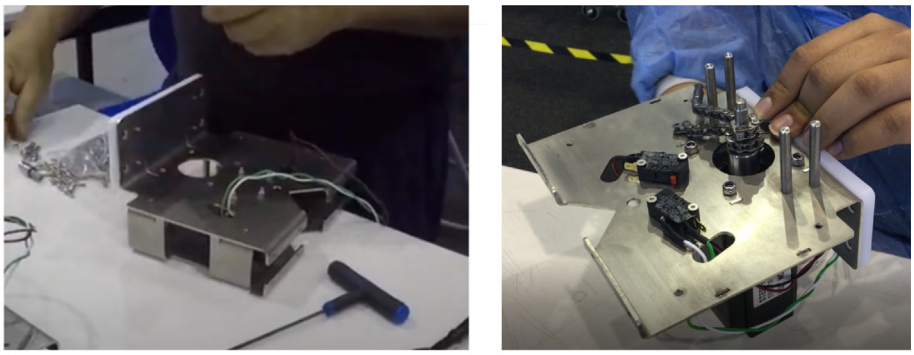

Fig. 11. (a) Motor supporting structure (b) Step motor mounting and driving mechanism assembly.

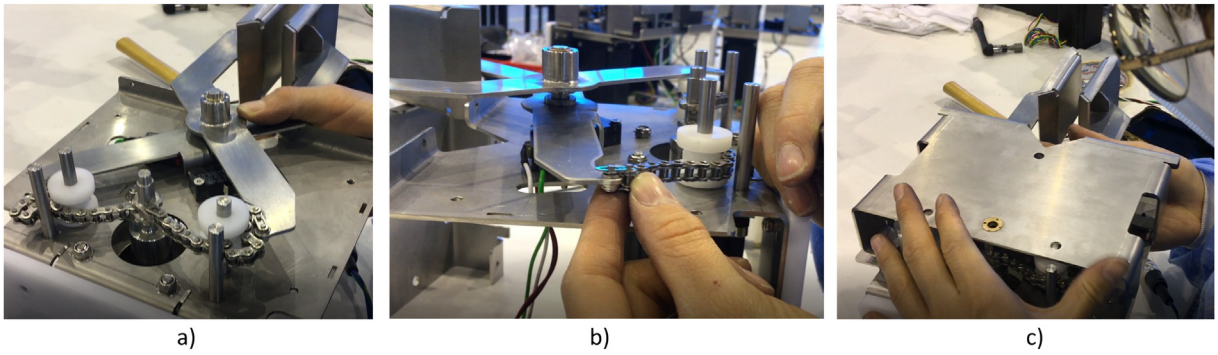

Fig. 12. (a) Paddle fixation (b) Chain arming (c) Cover plate.

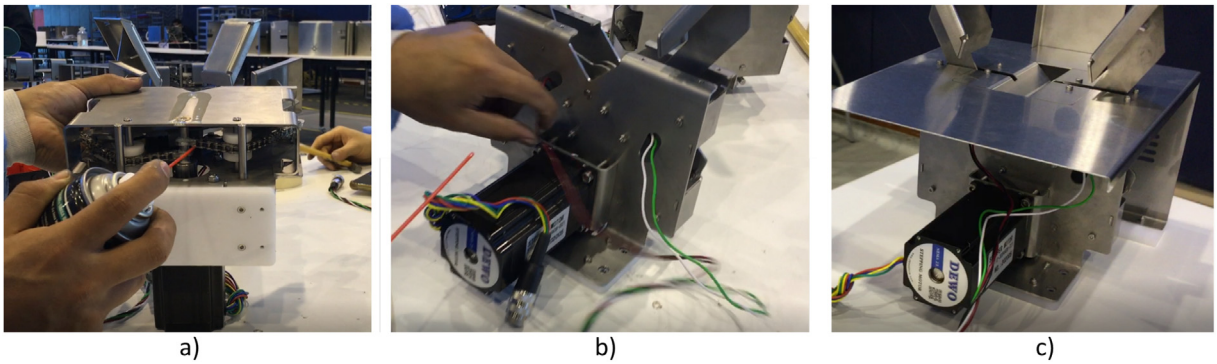

Fig. 13. (a) Mechanism lubrication (b) Final compression mechanism. (c) Manual resuscitator supporting plate.

5.4.3. Chassis mount

Once the compression mechanism has been assembled it is attached to the main chassis as depicted on Fig. 14a, the fan positioned in the back part of the upper cover plate is connected to the main board and the cover plate is latched to the main body completing the chassis structure (Fig. 14b). The ventilator circuit peripherals connections is presented at the end of the next section.

6. Operation instructions

The Masi ventilator is designed as a backup for patient ventilation in case of requiring invasive or non-invasive mechanical ventilation when no other commercial equipment is available at the hospital facility, mainly in the ICU. In that sense, the use of Masi should be evaluated according to the specific needs of each patient.

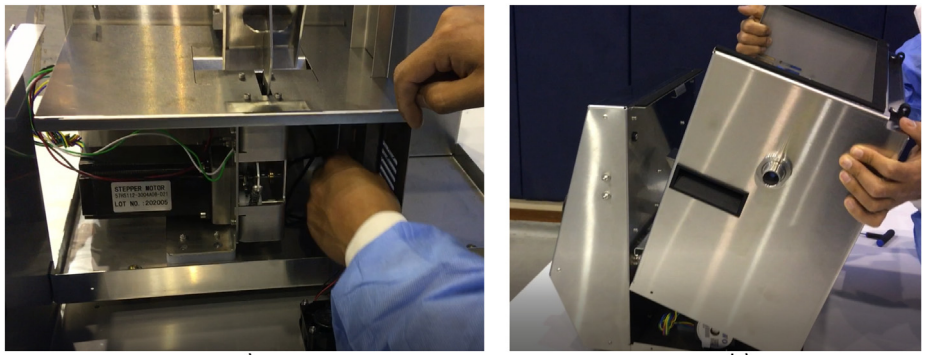

Fig. 14. (a) Ventilation connection to the main board (b) Upper cover back plate installation.

6.1. Required hardware

Masi is designed to make use of a wide range of instrumentation available at ICU. The minimum requirements for its proper deployment are:

- Endotracheal (ET) tubes and tracheotomy tubes
- HMEF filter (Connecting the patient's ET tube and Masi)
- Corrugated inspiration circuit tube.
- Compressed oxygen tank or compressed oxygen network.

Before ventilating a new patient, the corrugated inspiration circuit tubes, ET and HMEF filters must be replaced by clinical standard.

6.2. Internal connections

To verify the internal ventilation circuit connections proceed as follows: With the unit disconnected, use the knob at the top to open the fan cover (Fig. 15). Verify the connection of the manual resuscitator to the reservoir of oxygen and the inspiration circuit (Fig. 16a). Verify that the manual resuscitator and its oxygen reservoir have no leaks. To do this, cover the fan's inspiration output and press the resuscitator manual by hand, this must not deflate. Finally, verify the connection of the oxygen sensor (Fig. 16b).

6.3. External connections

First, connect the oxygen supply to MASI's left side input (Fig. 17a). Then, connect the corrugated tube from the patient's ventilation circuit at MASI's right output (Fig. 17b).

Then proceed to connect the ventilation peripherals. First, connect the patient's ventilatory circuit corrugated tube to the inspiration/expiration valve (Fig. 18a). Then, connect the flow sensor to the bottom connector of the inspiration/expiration valve with both the light blue and transparent hoses facing the ventilator (Fig. 18b). Subsequently connect the PEEP valve to the lateral inspiration/expiration valve connector (Fig. 18c).

Fig. 15. (a) Service knob, (b) Chassis top opening.

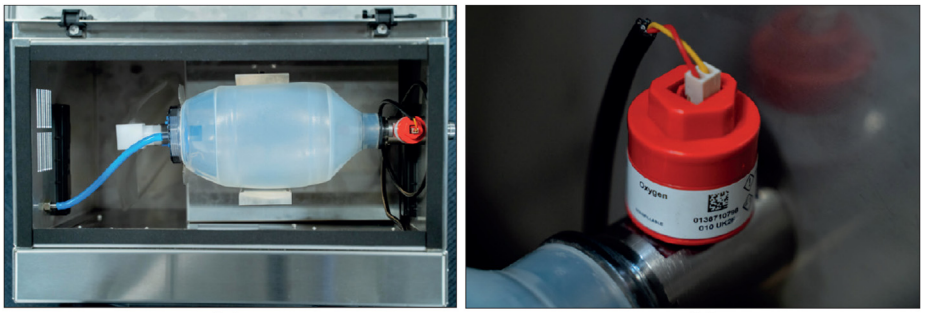

Fig. 16. (a) MASI internal view (top), (b) Oxygen sensor connection.

Fig. 17. (a) Oxygen input connection, (b) Oxygen output connection.

Fig. 18. (a) Inspiration/expiration valve, (b) Flow sensor and (c) PEEP valve connections at the external ventilation block.

Use the light blue and transparent hoses to close the flow sensor circuit at the right side of Masi by connecting them the upper intake and lower output respectively (Fig. 19a). Finally, connect the sensor output to the HMEF filter (Fig. 19b). After all the connections have been verified press the power button at the front face to turn on the device.

6.4. User interface (UI)

After Masi has been powered up the GUI appears in the frontal screen. The UI contains the metrics panel and three action buttons assigned to the alarm settings, troubleshoot and start ventilation.

The metrics panel is divided on three main sections which are highlighted by different colours in Fig. 20 in the following manner:

- The mode selection block is highlighted on white. It is automatically set on VC-CMV mode at boot (highlighted on yellow) and it can be switched to PC–CMV and PC–CSV on demand by the user. After selection, the colour of the tabs corresponding to other ventilation modes remain grey, indicating that they are not in use.

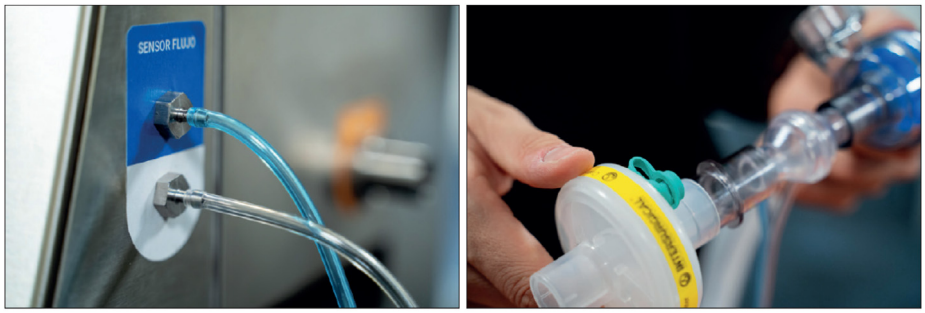

Fig. 19. (a) Paralel flux sensor circuit, (b) HMEF filter.

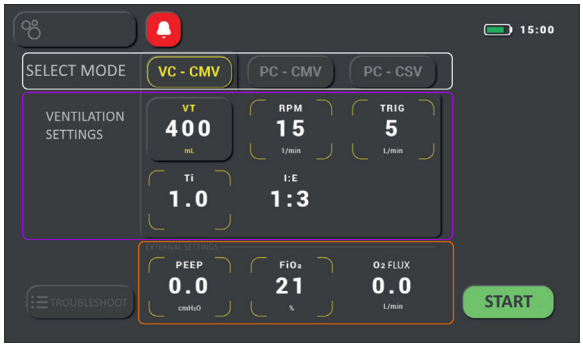

Fig. 20. Masi graphical interface.

- The ventilation settings block is highlighted on purple. If the user does not configure them before starting ventilation, the default value are set and shown on the screen. To change the values shown the user must select/touch the desired parameter box and turn the selector knob until the desired value is obtained. This process can be repeated for all the other variables. The configurable parameters in each ventilation mode and their default values are shown in Table 2.
- The external settings block is highlighted on orange. These are not automatically controlled by the device and are only referential. The values should match the settings of the two peripherals connected to Masi (i.e, PEEP valve and FiO2 controller). It is necessary to mechanically regulate the level of the PEEP and the oxygen valve each time a new ventilation begins.

The alarm settings button is represented by a white and red bell icon located in the UI's upper-left part and allows access to the alarm configuration screen (Fig. 21). Here, the user can review and modify the minimum and maximum values on the

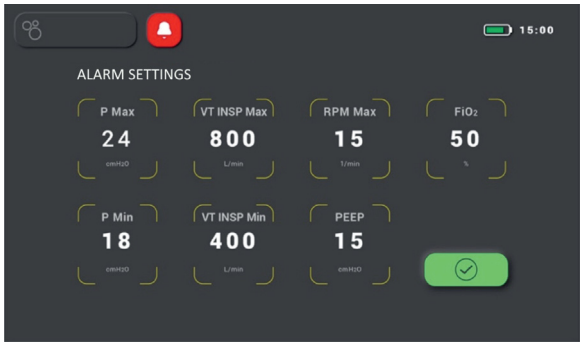

Fig. 21. Alarm configuration screen.

metered parameters that will trigger the alarm in case of threshold overflow. The setup of these values is similar to the ventilation setting procedure: select/touch the box containing the target parameter and turn the analog knob until the desired value is obtained. Table 3 summarizes the metered parameters and their default alarm values.

The troubleshooting button is located in the lower-left part of the GUI and it allows access to a screen where a technical report of the different units and sensors status is presented. This report serves as a quick self-diagnostic tool for the technical personnel.

Finally, the start button (represented on green) is located in the lower-right part of the GUI and triggers the ventilation to the patient when tapped.

6.5. Controlling the ventilation

Set up the parameters for the selected ventilation mode (Table 2), use the knob for setting the desired values (Fig. 22a), then press "START". Set the alarms for pressure, volume, breathing rate, difference from PEEP and FiO2 difference, then press the green button on the screen (Fig. 21). Once ventilation has begun, manually define the value of PEEP using the valve (Fig. 22b), the user must register the selected value on ventilation mode settings screen. After selecting the desired FiO2 value in the ventilation mode settings, Masi estimates the optimal oxygen flow intake. Use the recommended value to mechanically set the oxygen flow in the tank/wall supply accordingly. To modify any ventilation parameter select it on the UI screen and use the rocker knob in the lower right (Fig. 22a) a) to adjust it to the desired values. To confirm, press the "OK" button on green at the screen. Finally, to stop ventilation and turn off the equipment press the red stop button and tap "STOP VENTILATION" at the screen. Press the power button on the front during for 5 s and disconnect the device.

7. Validation and characterization

The device was designed to meet each of the requirements of the standards of the MHRA Technical Guide (2020). MHRA is a specification of the minimally clinically acceptable ventilator to be used in the initial care of patients requiring urgent ventilation in UK hospitals during the current COVID-19 pandemic caused by the SARSCoV-2 virus. A ventilator with lower specifications than this is likely to provide no clinical benefit and might lead to increased harm, which would be unacceptable for clinicians. The following tests will be divided in three sections: Electrical safety tests, Instrument control accuracy tests, Pressure limit tests:

Table 2
Programable parameters: Default, minimum and maximum values.

Ventilation mode	Parameter	Units	Default Value	Range	
				Min	Max
General	Trigger	L/Min	5	5	10
	FiO2	%	21	21	100
	PEEP	cmH2O	0	0	20
VC-CMV	VT	ml	400	200	800
	RPM	1/m	15	4	35
	Ti	sec	1	0.7	7.5
PC-CMV	PC	cmH2O	15	5	35
	RPM	1/min	15	4	35
	Ti	sec	1	0.7	7.5
PC-CSV	PS	cmH2O	10	5	30
	Cycle	%Vpeak	20	5	40
	Tapnea	sec	15	2	20

Table 3
Alarm settings: Default, minimum and maximum values.

Parameter	Units	Default value	Range	
			Min	Max
Pmin	cmH2O	10	0	60
Pmax	cmH2O	50	0	60
Vmin	L/min	100	50	800
Vmax	L/min	700	50	800
RPMmax	1/min	35	15	45
dPEEP	cmH2O	1	0	5
dFiO2	%	50	0	79

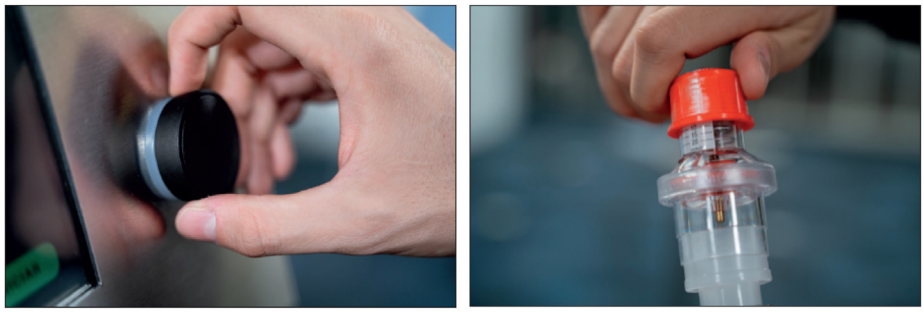

Fig. 22. (a) Selection knob, (b) PEEP valve setting.

Table 4
Current consumption measurement.

Operation state	Polarity	Measure (mA)					Mean (mA)
			2	3	4	5	
Stand-by	Direct	0.3	0.3	0.3	0.3	0.3	0.30
	Inverse	0.3	0.3	0.3	0.3	0.3	0.30
On-line	Direct	0.6	0.7	0.6	0.6	0.7	0.64
	Inverse	0.7	0.7	0.7	0.6	0.7	0.68

7.1. Electrical safety tests

First, the current consumption (Table 4) is calculated for the operating states of temperature (Heating) and temperature decrease (Cooling).

In addition, the values corresponding to the ground impedance (Table 5) measured at the 4 sides of the chassis and the leakage current to ground (Table 6) proved to be lower than the maximum admissible values according to the IEC60601–1 standard (Peru).

Table 5
Ground resistance test

Measurement point	Maximum admissible values (mΩ)	Measurement (mΩ)					
	IEC 60601-1 Standard (Peru)	1	2	3	4	5	Average (mΩ)
Lateral face 1	100	97	96	98	96	99	97.2
Lateral face 2	100	88	96	92	97	94	93.4
Lateral face 3	100	90	93	94	98	97	94.4
Lateral face 4	100	87	98	91	97	96	93.8

Table 6
Measured leakage current to ground.

Test parameters		Maximum admissible values (uA)	Measurement (uA)					Mean (uA)
Polarity	Neutro	IEC 60601-1 standard (Perú)	1	2	3	4	5	
Direct	Close	500	247	248	247	247	248	247.4
	Open	500	487	489	488	489	490	488.6
Inverse	Close	500	243	244	244	244	244	243.8
	Open	500	487	489	488	489	490	488.6

Table 7
Volume controlled ventilation values.

Sample	Compliance on the test lung [ml/cmH2O]	Resistance [ml/cmH2O]	Volume [ml]			Respiratory frequency [rpm]		I:E		PEEP		
			Set (Masi)	Measured (Masi)	Mean (Calib.)	Set (Masi)	Mean (Calib.)	Measured (Masi)	Mean (Calib.)	Set (Masi)	Measured (Masi)	Mean (Calib.)
1	50	5	200	255	**269.54**	20	**19.37**	2.4	**2.19**	8	8.3	**8.42**
2	50	5	200	196	**196.85**	12	**19.28**	1.7	**1.84**	12	12.4	**11.87**
3	20	20	200	220	**200.05**	20	**0.77**	1.2	**1.16**	8	8.4	**7.75**
4	20	20	200	213	**173.41**	12	**12.11**	1.3	**1.30**	8	8.1	**8.10**
5	20	20	200	212	**193.51**	20	**19.69**	1.3	**1.28**	12	12.2	**11.37**
6	20	20	200	207	**163.13**	12	**12.49**	1.3	**1.31**	12	12.3	**12.36**
7	10	50	200	162	**152.25**	20	**10.71**	1.4	**1.42**	8	8.1	**11.08**
8	10	50	200	204	**161.39**	12	**12.59**	2.2	**1.92**	8	7.9	**11.09**
9	10	50	200	209	**172.44**	12	**12.30**	2.4	**2.32**	12	12.5	**11.63**
10	50	5	400	403	**466.93**	12	**12.07**	2.0	**2.22**	8	8.4	**7.79**
11	20	20	400	444	**449.02**	12	**12.07**	2.7	**2.83**	8	8.0	**9.13**
12	20	20	400	378	**365.33**	20	**14.97**	2.3	**1.97**	12	12.2	**12.32**
13	20	20	400	414	**449.03**	12	**12.52**	3.5	**3.05**	12	11.9	**12.97**
14	50	5	600	651	**619.11**	20	**19.11**	1.9	**1.94**	8	8.0	**7.60**
15	50	5	600	609	**654.43**	12	**11.47**	2.0	**2.11**	8	7.9	**7.88**
16	50	5	600	650	**623.05**	20	**19.11**	1.9	**2.10**	12	11.9	**11.59**
17	50	5	600	605	**640.02**	12	**12.77**	2.0	**1.79**	12	12.0	**12.25**

7.2. Instrument control accuracy tests

For the following set of tests the ventilator was connected to the gas supply as specified for normal use configuration. The ventilator output was endorsed by the peripheral breathing system to a test lung for adults with varying compliance and resistance with an electronic ventilator analyzer. A ventilator calibrator simultaneously measuring the flux and pressure at the ventilator's output and the pressure in the lung. The derived average parameters from these measurements are reported in ATP conditions (ambient temperature and pressure) under a sensor data acquisition rate set at 100 samples per second during 30 respiratory cycles in the two following tables.

The first draft was performed on volume controlled mode and the results are presented in Table 7. The test was performed for different volume, respiratory frequency, inspiration to expiration ratio (I:E) to a set positive end-expiratory pressure (PEEP) with the artificial lung calibrated to different combinations of Compliance and Resistance. The accuracy analysis on these values are presented in Table 8 (in absolute percentages). The results revealed a maximum mean error of 11.8% for the set values and 9.4% for the measured values.

The second draft was performed on pressure controlled mode and the results are presented in Table 9.. The test was performed for different PIP, respiratory frequency, inspiration to expiration ratio (I:E) to a set positive end-expiratory pressure (PEEP) with the artificial lung calibrated to different combinations of Compliance and Resistance. The accuracy analysis on these values are presented in Table 10 (in absolute percentages). The results revealed a maximum mean error of 9.6% for the set values and 8.3% for the measured values.

7.3. Pressure limit tests

In this test the peak pressure was recorded while tidal volume setting the fan between the range of 400 to 700 ml on steps of 50 ml. and fixed values of 10 cmH2O, 20 rpm, 1:2 for PEEP, breathing rate and I:E ratio respectively. The values are shown for two cases of compliance 50 and 10 ml/cm$H_2$0 in Table 11.

Table 8
Accuracy on measurements under volume controlled ventilation.

	Accuracy on measurements (%)					
	Volumen	**Respiratory frequency**	**I:E**	**PEEP**		
Sample	**Set (Masi)**	**Measured (Masi)**	**Set (Masi)**	**Measured (Masi)**	**Set (Masi)**	**Measured (Masi)**
MIN	0.0%	0.4%	0.6%	0.1%	1.1%	0.0
MAX	34.8%	21.2%	60.7%	14.5%	38.6%	40.4%
MEAN	**11.8%**	**9.4%**	**10.5%**	**6.5%**	**8.1%**	**8.6%**

Table 9
Pressure controlled ventilation tests.

Sample	Compliance on the test lung [ml/cmH2O]	Resistance [ml/cmH2O]	PIP [cmH2O]			Respiratory frequency [rpm]		I:E			PEEP		
			Set (Masi)	Measured (Masi)	Mean (Calib.)	Set (Masi)	Mean (Calib.)	Set (Masi)	Measured (Masi)	Mean (Calib.)	Set (Masi)	Measured (Masi)	Mean (Calib.)
1	50	5	10	9	**9.98**	20	**21.34**	2.0	2.5	**2.23**	8	8.0	**7.52**
2	50	5	20	20	**19.55**	20	**20.94**	1.0	1.0	**1.06**	8	8.7	**8.42**
3	50	5	20	20	**21.01**	12	**11.92**	1.0	1.0	**1.01**	8	8.1	**8.02**
4	50	5	20	20	**19.62**	20	**21.30**	1.0	1.0	**1.11**	12	12.1	**11.63**
5	50	5	20	20	**21.47**	12	**12.39**	1.0	1.0	**1.12**	12	12.1	**11.59**
6	50	5	20	19	**19.61**	12	**12.18**	1.0	1.2	**1.32**	16	16.1	**15.54**
7	20	20	20	20	**9.94**	20	**12.04**	1.0	1.0	**0.42**	8	8.0	**7.38**
8	20	20	20	20	**20.41**	12	**11.84**	1.0	1.0	**0.97**	8	8.0	**7.53**
9	20	20	20	20	**20.33**	20	**19.79**	1.0	1.1	**1.15**	12	11.9	**11.23**
10	20	20	20	20	**20.37**	12	**11.88**	1.0	1.0	**1.00**	12	12.0	**11.47**
11	50	5	20	18	**18.50**	20	**20.77**	2.0	1.9	**2.02**	8	8.0	**7.93**
12	50	5	20	20	**20.47**	12	**11.89**	2.0	1.9	**1.93**	8	8.1	**7.94**
13	50	5	20	18	**19.98**	20	**21.02**	2.0	2.1	**2.33**	12	11.9	**11.36**
14	50	5	20	20	**22.67**	12	**13.53**	2.0	2.0	**1.13**	12	12.1	**12.07**
15	50	5	20	19	**19.53**	12	**11.88**	2.0	2.3	**2.54**	16	15.9	**15.31**
16	20	20	20	20	**20.05**	20	**19.79**	2.0	1.9	**1.93**	8	8.1	**7.77**
17	20	20	20	20	**20.36**	12	**11.86**	2.0	1.9	**2.00**	8	8.0	**7.51**
18	20	20	20	20	**20.19**	20	**19.68**	2.0	2.0	**2.13**	12	11.9	**11.41**
19	50	5	20	19	**19.42**	12	**11.87**	3.0	2.8	**2.78**	8	8.0	**7.79**
20	20	20	20	19	**19.06**	20	**19.73**	3.0	3.1	**3.20**	8	8.0	**7.58**
21	20	20	20	20	**20.40**	12	**11.89**	3.0	2.8	**2.74**	8	8.1	**7.69**
22	20	20	20	19	**19.09**	20	**21.04**	3.0	3.5	**3.42**	12	12.0	**11.51**
23	20	20	20	19	**19.37**	12	**12.13**	3.0	3.0	**3.11**	12	12.2	**11.75**
24	50	5	30	28	**27.93**	20	**20.91**	2.0	2.1	**1.97**	16	16.0	**15.58**
25	20	20	30	29	**29.74**	20	**19.70**	2.0	1.9	**2.01**	8	8.1	**7.21**
26	20	20	30	31	**31.17**	12	**11.95**	2.0	1.9	**2.03**	8	8.1	**7.16**
27	20	20	30	31	**31.14**	12	**12.08**	2.0	2.0	**2.06**	12	12.0	**11.46**
28	20	20	30	30	**29.76**	20	**21.05**	2.0	2.2	**1.93**	16	16.0	**15.43**
29	20	20	30	31	**31.16**	12	**11.90**	2.0	2.0	**2.26**	16	16.1	**15.48**
30	10	50	30	31	**30.55**	20	**20.04**	2.0	1.9	**1.99**	8	8.0	**7.47**
31	10	50	30	31	**31.18**	12	**11.72**	2.0	1.9	**2.01**	8	8.2	**8.03**
32	10	50	30	30	**30.53**	20	**20.28**	2.0	1.9	**1.95**	12	11.9	**11.51**
33	10	50	30	31	**31.18**	12	**12.11**	2.0	2.0	**1.98**	12	12.3	**11.78**
34	10	50	30	31	**30.57**	20	**19.79**	2.0	2.0	**2.16**	16	15.9	**15.30**

Table 10
Accuracy on measurements under pressure controlled ventilation

	Accuracy of measurements (%)						
	Volume		Respiratory frequency	I:E		PEEP	
Sample	Set (Masi)	Measured (Masi)	Set (Masi)	Set (Masi)	Measured (Masi)	Set (Masi)	Measured (Masi)
MIN	0.1%	0.2%	.2%	0.1%	0.1%	0.2%	0.3%
MAX	50.3%	50.3%	39.8%	57.9%	57.9%	10.5%	11.6%
MEAN	**4.5%**	**4.1%**	**3.6%**	**9.6%**	**8.3%**	**4.0%**	**4.4%**

Table 11
Peak pressure at different tidal volume setting

Test	Tidal volume [ml]	Flux [L/min]	50 ml/cmH2O Peak pressure [cmH2O]	10 ml/cmH2O Peak pressure [cmH2O]
1	**400**	22	17.2	44.26
2	**450**	25	17.89	44.68
3	**500**	28	18.55	44.25
4	**550**	30	19.47	43.74
5	**600**	33	20.31	43.95
6	**650**	36	21.58	44.12
7	**700**	38	21.56	44.67

8. Discussion and conclusion

The Masi ventilator makes use of a widely available resuscitator to drive flow with a simple mechanical system controlled by a widely available stepper motor, controller and system-on-a-chip computer. In addition standard control of PEEP is provided with a disposable off-the-shelf valve. Electrical, Ventilation and Peak pressure parameters were evaluated using a lung simulator. Moreover, Masi counts with a set of programmed alarms that surpass MHRA recommended setups.

Two important characteristics of Masi are its modularity (remaining as one of the most important added features to ventilators [21]) and telemetric capabilities. Mechanically each part of the mechanism can be replaced independently in case of malfunction without affecting its functionality. With regard to supplies; the sensors,valves,tubes and resuscitators could be replaced for similar models requiring minimal adaptations on hardware/firmware. Electronically it is divided in three blocks: user interface, power/control and telemetry, each of them as an independent logical system with its own controller and firmware. In addition its telemetric capabilities allows it to monitor the patient on real time, while ensuring the integrity and security of the data transmitted without incurring on any extra web service fee. Also, even when the device is designed to comply with high sterilization clinical standards other materials could be explored to implement the same hardware.

We believe Masi can significantly help to reduce the current ventilator shortage and be adopted by the community to continuously evolve to provide more functionalities and improved performance. The future course of action for Masi is aligned with the inclusion of new ventilation modes, particularly Synchronized Intermittent Mandatory Ventilation (SIMV) and the addition of an air compression module to achieve an even more accurate control of pressure and volume.

At the date of submission, 300 Masi units have been deployed to ICUs in our territory as the first locally designed and produced ventilators under the approval of DIGEMID (Peruvian regulatory authority), setting an important milestone on device manufacturing, leading to an initiative from PUCP and the Peruvian Institute of Technological Production to promote the fabrication of new medical devices and aiding our health professionals to save lives during the pandemic

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.ohx.2021.e00187.

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