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Automated ventilator prototype for COVID-19 patient treatment: the design and development of the electronic system

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ABSTRACT

The coronavirus disease 2019 (COVID-19) pandemic has created an urgent global demand for ventilators, respirators and various resuscitation devices. Various research and development organizations, private companies and individual engineers have collaborated and carried out the development of low-cost ventilation prototypes. In turn, doctors and nurses are collapsed due to the exponential increase in COVID-19 cases. This scenario worsens more when the tasks are manual in nature. The article`s objective to describe the electronic system designed, developed and implemented in a functional prototype of an automatic ventilator in order to be evaluated by a team of health professionals to be later used in cases of health emergencies. This system automates the manual ventilation task aided by a few medical resources in a scenario of scarce resources and is a temporary solution when a respirator is not available.

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1. INTRODUCTION

In mid-2020, the total number of coronavirus disease 2019 (COVID-19) cases exceeded several million and there were hundreds of thousands of deaths worldwide [1]. Acute respiratory distress syndrome (ARDS) has so far been the most common complication in COVID-19 patients requiring admission to the intensive care unit (ICU) [2]. Mechanical ventilation, originally developed in the early twentieth century within the context of the polio pandemic, has been revolutionary and evolutionary with respect to delivering optimized respiratory care for critically ill patients. An airway mask bag unit (AMBU), also known as a manual resuscitator or self-inflating bag, is a manual device to provide positive pressure ventilation for patients who are not breathing properly. The objectives of manual ventilation are: i) provide the patient with the necessary oxygenation to achieve adequate gas exchange, in emergency situations or transfers of intubated patients in the absence of a transport ventilator and ii) provide the necessary time for qualified healthcare personnel to safely perform an intubation [3].

The true incidence of hypoxic respiratory failure in patients with COVID-19 is unclear, it seems that around 14% will develop a serious disease that requires oxygen therapy and 5% the need for mechanical ventilation. The risk factors associated with respiratory failure that require mechanical ventilation are: advanced age (>60 years), male sex, and the presence of underlying comorbidities such as diabetes, neoplasms, and immunocompromised states [4]. However, taking into account various medical sources and health organizations, in Argentina and another country, there is a shortage of resources, both human and technological. This motivated this development, in order to facilitate the doctor and nurse, manual tasks to face the health

emergency with this automated system [5]. Ventilators based on the automation of a manual-resuscitator or self-inflating bag (AMBU) have the distinctive advantages of availability, minimal number of components, simple mechanism, low cost, and the ability for rapid deployment [6]. This article details the electronics of the system developed by the Institute of Scientific and Technical Research for Defense (CITEDEF) Digital Techniques Laboratory team [7] but does not fully detail the mechanical system developed by the Department of Applied Mechanics of CITEDEF, only briefly what it consists of. CITEDEF is a government agency belonging to the Ministry of Defense of Argentina [8] performing R&D for defense del país.

2. OPERATING PRINCIPLE

The bag valve mask (BVM) was chosen for the construction of the automated inflating resuscitator (AIR) as it is inexpensive, easy to use, widely available, and already has its own safety features. BVMs were created to temporarily replace mechanical ventilators during situations where mechanical ventilators are not available, and they function by manually providing positive pressure ventilation for patients who no longer have the ability to breathe. By incorporating the BVM, the AIR is intended to keep patients who need mechanical ventilation or ventilatory support, temporarily stabilizing their condition until a traditional mechanical ventilator becomes available.

A BVM has four parts: exhalation port, patient valve, self-inflated bag, and an oxygen inlet. Optional components include a positive end-expiratory pressure (PEEP) valve, an oxygen reservoir, and a pressure gauge. We call these connected parts the "patient circuit" [9]. The self-inflated bag is placed between two arms printed using a 3D printer. This arm connected physically by a mechanical system which includes several gears, and a reduction box handled by a steeper motor. The electronic system has two critical tasks. One of them is to acquire configuration parameters established by a medical staff and moving the prototype arms accordingly. The second one, the system has two air pressure sensors that can be connected to some points of the patient circuit, which inform the medical operator some parameters of interest in order to monitor the pressure insufflated [10].

The sequence: the system has a specific task that is responsible for executing the operation on the mechanical arms. To do this, the central processing unit (CPU) takes information from the user's configuration (performed by medical personnel) and translates it into an amount of movement to be performed. That is, to reach an angular value in a defined time and respond to the times and speeds of each phase of the operating cycle (opening and closing of arms). The user can view at any time, through the liquid-crystal display (LCD) display, the values of the potentiometers (% volume, beats per minute (BPM), TI, PMIN) and the status of the equipment. And, to ensure maneuvering and avoid unwanted changes in settings, a button was incorporated to confirm the settings [11].

Once the user confirms the desired configuration, the system performs an automatic homing operation, and begins the operation of opening and closing the arms at the indicated angles/times. To end the sequence operation or change the setting to another, the user can stop the maneuver with a button and restart the operation. If by any error the arms of the mechanical system reach any of the safety limit switches [12], the movement of the mechanical arms will stop immediately and the error status will be reported on the LCD screen and an audible alarm will be activated.

3. CONCEPT DESIGN

Initially, a work model was developed in which several changes were made on the initial requirements, where a large part of them resulted in the evolution of the knowledge of the solution sought by implementing agility criteria. This electronic module developed to respond to the instrumentation of a central microcontroller with advanced reduced instruction set (RISC) machines and originally acorn RISC machine (ARM [13]) architecture [14], which is fully capable of integrating the firmware solution under development and leaving free processing for future updates. The electronic system design is show in Figure 1.

4. CONTROLLABLE PARAMETERS AND OPERATIONAL CONSIDERATIONS

There are clinical situations in which professionals must setting the amount of air pressure in order to achieve adequate ventilation in the patient. The operational characteristics that were considered in the development of the electronic module were:

- Two individual pressure measurements: through the instrumentation and acquisition of two MPX type sensors [15] up to 70 mm H2O [16], [17].
- Four configurable parameters for the medical operator: by acquiring four potentiometers on the electronic board. These are: i) potentiometer 1-%volume: defines the amount of movement of the mechanical arms. Which defines the minimum pressurization of the patient circuit is detected and activates an alarm if this

occurs; ii) potentiometer 2-BPM: defines the opening and closing frequency of the mechanical arms; iii) potentiometer 3-TI: it defines the inspiration time, the active cycle in closing time of the mechanical arms according to the BPM; and iv) potentiometer 4-PMIN: which defines the minimum pressurization of the patient circuit is detected and activates an alarm if this occurs.

- An LCD display with 4 lines of text by 20 characters each, where the adjustment of the potentiometers, the pressure values recorded every 100 ms, and also the status of the alarms are displayed [18].

At the same time, this system contemplates various security situations by sensing abnormal operating situations. This translates into the implementation of sounding and displayed alarms to notify the medical operator that a fault situation has occurred, these are:

- Alarm 1: if the system detects a pressure lower than PMin setting.
- Alarm 2: if the system detects a pressure higher than 45 cm H2O [19].
- Alarm 3: if was a critical error on the mechanical system.

Note: Alarm 3 has a double function: the first one if one of the mechanic limit security switches was reached. The second is determined by a time where an optoelectronic mark was not found during the normal operation.

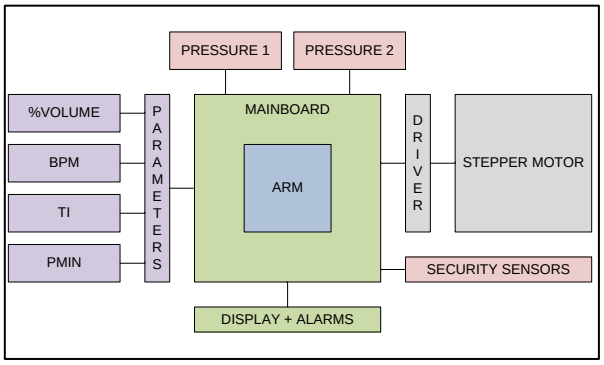


Figure 1. Concept design

5. ELECTRICAL HARDWARE

In the development of electronic instrumentation, the NUCLEO-F411RE [20], [21] development kit from STMicroelectronics was used, it is in charge of acquire and processing all the incoming signals to the system and execute a sequential algorithm to handle the driver and motor assembly. To do this, we have to develop a PCB motherboard with all the necessary components, sensors and connectors to integrate the NUCLEO-F411RE development kit, this is shown in Figure 2 and Figure 3. Among the notable characteristics of this module, in addition to the manufacturer's recommendation for its use in clinical and medical systems, we can mention the multiplicity of input and output ports for incorporating all the necessary signals and an internal 100 MHz clock that next to the memory space to be able to host all of the processing algorithms without losing performance. In turn, a monitoring port was left available for system debugging. This gives us the possibility of connecting a computer and monitoring in real time the values of the acquired pressures, the activation of the limit switches and the angle traveled by the mechanical arms. To view the information of the system, a WinStar WH2004A display of the alphanumeric type was implemented [22], the Figure 4 shows the user settings. To handle de stepper motor, the Stepperonline DM542 was used [23].

The mechanical system uses a NEMA 24 stepper motor [24], a Stepperonline model DM542 driver was equipped to operate it. This type of hybrid controller works with a programmable microstep resolution for greater precision (from 400 steps per turn to 40,000 steps per turn). The firmware developed for the ARM development kit has a sequential main loop that acquires each of the system's inputs and writes directly to the outputs. Each entry to the system and each exit from the system are independent, non-blocking firmware tasks, so the main loop is not affected or locked in each task. Each task runs on its own, freeing up the CPU upon completion. For this reason, the firmware can incorporate other tasks in the future, among which a processing space is contemplated to be able to execute the task of the open loop control system (opening and closing sequence of mechanical arms) [25]. The flow chart of the main loop and main interrupt services is shown in Figure 5.

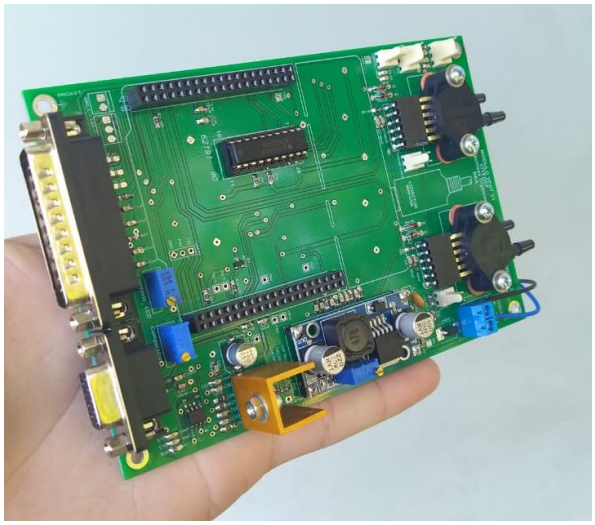


Figure 2. Mainboard for the NUCLEO-F411RE kit

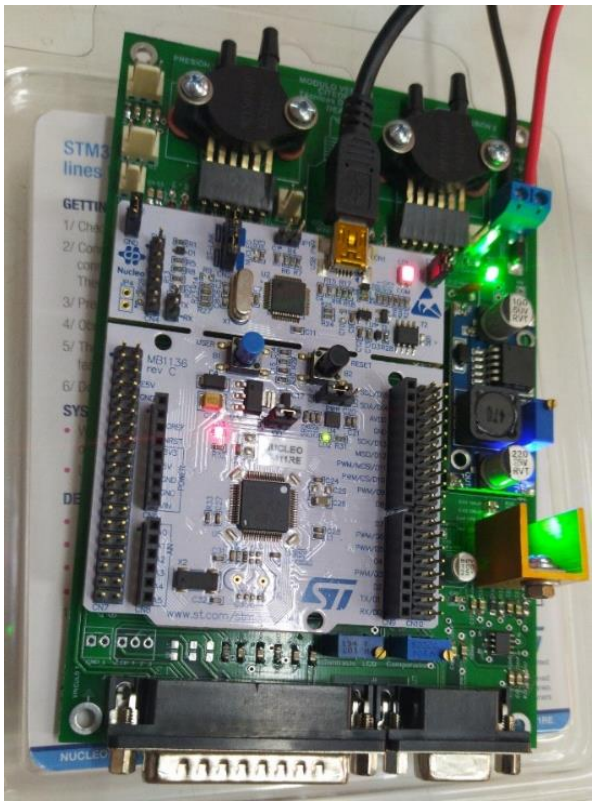


Figure 3. Final board with the NUCLEO-F411RE kit connected

Figure 4. Display with user settings (left) and display with pressures values (right)

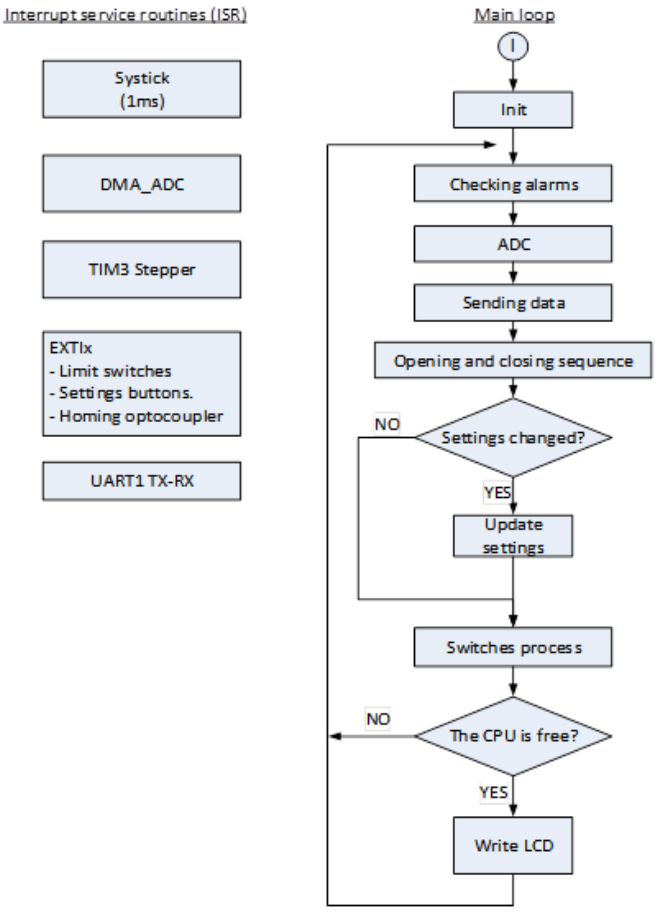


Figure 5. Firmware flowchart

6. RESULTS

Several system tests have been performed with different configurations (>40 times), and long-time system tests (>48 hours) in order to find bugs in the firmware, validate the electronic hardware and analyze the dynamics of the movement of the arms according to the established configuration and thus define the system error. The final system is shown in Figure 6. With an oscilloscope it was possible to measure the opening and closing cycles of the arms and we were able to calculate an estimated error of 3%. The Figure 7 shows and example of one test with the configuration settings in 24° and it´s results.

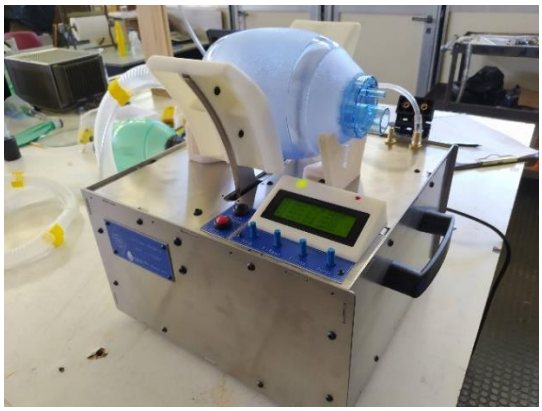
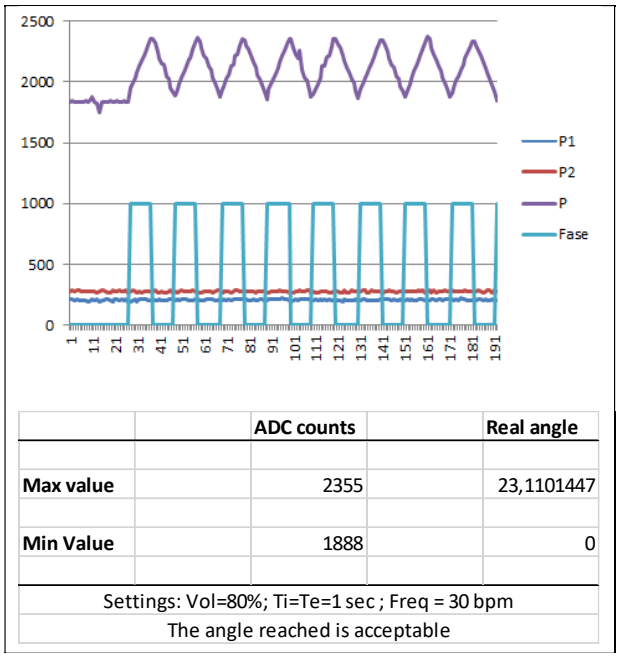


Figure 6. Final automated ventilator prototype with the electronic hardware and mechanical system



		ADC counts		Real angle
Max value		2355		23,1101447
Min Value		1888		0

Settings: Vol=80%; Ti=Te=1 sec ; Freq = 30 bpm

The angle reached is acceptable

Figure 7. Results with and opening and closing arms in 24° (P1 and P2 are the pressures in the system, P is the movement of the arms, fase is it is closing or opening)

7. CONCLUSION

This study describes the development of the electronic instrumentation necessary to integrate the monitoring and action solution according to a mechatronic system for the prototype of automatic mechanical ventilation. And according to the results obtained, this development could automate the operation of an AMBU bag, also understanding that the response of the system must be evaluated and approved to be used for this purpose. Despite being of public knowledge, due to the critical situation that the world is going through, special precautions were taken in the management of time, both technological and administrative, understanding the scarcity and saturation of the national and international market.

For this development, the way to buy most of the components locally was taken into account, although it is known that many electronic components are imported and the electronic stores that distribute them lacked stock. The hardware development was carried out in the home of each of the participants, and then integrated and finished in the laboratory. The working group took a dynamic to work in person with the minimum of personnel (and the rest of the group virtually) gradually and taking strict measures to preserve the health of each one of us.

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REFERENCES

[1] "Center for Systems Science and Engineering," Johns Hopkins University, Accessed: Jul. 1, 2020. [Online.] Available: https://coronavirus.jhu.edu/map.html.

[2] P. Gibson, L. Qin y S. H. Puah, "COVID-19 acute respiratory distress syndrome (ARDS): clinical features and differences from typical pre-COVID-19 ARDS," *The Medical journal of Australia*, vol. 213, no. 2, pp. 54-56.e1, 2020, doi: 10.5694/mja2.50674.

[3] Khoury, "From mouth-to-mouth to bag-valve-mask ventilation: evolution and characteristics of actual devices—a review of the literature," *BioMed research international*, 2014, doi: 10.1155/2014/762053.

[4] "Respiratory mechanical assistance in patients with COVID-19 (in Spanish)," Sociedad Argentina de Cardiología, Accessed: Jul. 1, 2020. [Online.] Available: https://www.sac.org.ar/consejos-cientificos/asistencia-mecanica-respiratoria-en-pacientes-con-covid-19/.

[5] A. Wallace, "Coronavirus: how ventilators work and why the desperate race to make more is key in the battle against covid-19 (in Spanish)," BBC News Mundo, 2020. Accessed: Jul. 1, 2020. [Online.] Available: https://www.bbc.com/mundo/noticias-52060716.

[6] "MIT emergency ventilator project," MIT - Massachusetts Institute of Technology, Accessed: Jul. 1, 2020. [Online.] Available: https://emergency-vent.mit.edu/.
[7] Instituto de Investigaciones Científicas y Técnicas para la Defensa, Accessed: Jul. 1, 2020. [Online.] Available: https://www.argentina.gob.ar/defensa/citedef.
[8] "Ministerio de Defensa," Accessed: Jul. 1, 2020. [Online.] Available: https://www.argentina.gob.ar/defensa.
[9] B. Gino, Z. Wang, P. d'Entremont, T. S. Renouf, and A. Dubrowski, "Automated inflating resuscitator (AIR): design and development of a 3D-printed ventilator prototype and corresponding simulation scenario based on the management of a critical COVID-19 patient," *Cureus*, vol. 12, no. 7, 2020, doi: 10.7759/cureus.9134.
[10] M. A. Holanda, "Basic modes of mechanical ventilation," Xlung, Accessed: Jul. 1, 2020. [Online.] Available: https://xlung.net/en/mv-manual/basic-modes-of-mechanical-ventilation.
[11] A. L. M. Carpio and J. I. Mora, "Ventilator management," StatPearls Publishing LLC, Accessed: Jul. 1, 2020. [Online.] Available: https://www.ncbi.nlm.nih.gov/books/NBK448186/.
[12] "Safety limit switches," Rockwell Automation, Inc., Accessed: Jul. 1, 2020. [Online.] Available: https://www.rockwellautomation.com/en-us/products/hardware/allen-bradley/safety-products/safety-sensors/safety-switches-limit.html.
[13] "ARM," Accessed: Jul. 1, 2020. [Online.] Available: https://www.arm.com/.
[14] "The Arm architecture," ARM, Accessed: Jul. 1, 2020. [Online.] Available: https://www.arm.com/architecture.
[15] "Pressure sensors-differential/gauge up to 10 kPa," NXP Semiconductors, Accessed: Jul. 1, 2020. [Online.] Available: https://www.nxp.com/products/sensors/pressure-sensors/differential-gauge-up-to-10-kpa:DG_10KPA#/.
[16] "Ventilators and ventilator accessories EUAs," FDA-U.S. Food and Drug Administration, Accessed: Jul. 1, 2020. [Online.] Available: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas.
[17] "Pressure Sensors," NXP Semiconductors, Accessed: Jul. 1, 2020. [Online.] Available: https://www.nxp.com/products/sensors/pressure-sensors:DRSNSPRSSR.
[18] F. Beloncle *et al*, "Accuracy of P0.1 measurements performed by ICU ventilators: a bench study," *Annals of Intensive Care*, vol. 9, no. 104, 2019, doi: 10.1186/s13613-019-0576-x.
[19] P. L. Silva and P. R. M. Rocco, "The basics of respiratory mechanics: ventilator-derived parameters," *Annals of translational medicine*, Vol. 6, No. 19, Oct. 15, 2018, doi: 10.21037/atm.2018.06.06.
[20] "STM32 Nucleo-64 development board with STM32F411RE MCU, supports Arduino and ST morpho connectivity," STMicroelectronics, Accessed: Jul. 1, 2020. [Online.] Available: https://www.st.com/en/evaluation-tools/nucleo-f411re.html.
[21] "NUCLEO-F411RE: STM32 Nucleo-64 development board with STM32F411RE MCU, supports Arduino and ST morpho connectivity," STMicroelectronics, Accessed: Jul. 1, 2020. [Online.] Available: https://www.st.com/en/evaluation-tools/nucleo-f411re.html.
[22] "Display Alfanumerico 20x4" WinStar, Accessed: Jul. 1, 2020. [Online.] Available: https://www.winstar.com.tw/es/products/character-lcd-display-module/wh2004a.html.
[23] "Digital stepper driver 1.0-4.2A 20-50VDC for Nema 17, 23, 24 stepper motor," OMC-Stepperonline, Accessed: Jul. 1, 2020. [Online.] Available: https://www.omc-stepperonline.com/digital-stepper-driver-10-42a-20-50vdc-for-nema-17-23-24-stepper-motor-dm542t.html.
[24] "NEMA 24 Stepper Motor 60x60mm (2.36x2.36in) holding torque up to 3.2Nm (453oz-in)," LAM Technologie, Accessed: Jul. 1, 2020. [Online.] Available: https://www.lamtechnologies.com/Product.aspx?lng=EN&idp=stpmtrn24.
[25] J. Svennebring, J. Logan, J. Engblom, and P. Strömblad, *Embedded multicore: an introduction*, Freescale semiconductor, 2009

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