Mechanical upgrade to a proposed mechanical transition ventilation

Mejora en la parte mecánica a una propuesta de ventilador mecánico de transición

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Abstract

Due to the contingency situation that has been generated in various parts of the world and the declaration of a pandemic carried out by the World Health Organization against the Sars-CoV-2 virus, various people, educational institutions and companies are carrying out the development of mechanical ventilators that can meet the need for this equipment in their countries. This paper shows experiences obtained in the design and construction of a transitional mechanical ventilator that allows compliance with the minimum requirements that doctors and healthcare professionals consider when a person is piped. Also, it helps in the seek to comply the regulations that the federal government agency elaborates with the purpose of reviewing the existing proposals for open source mechanical ventilators. It also contains the technical requirements that are need to be covered by the designers. These regulations cover the feasibility for replicating the ventilators proposed, based on certain factors that will be described in this paper. Once the ventilators have been tested, its improvement is carried out from the mechanical part, considering the electrical element to be used, in order to obtain a transitional mechanical ventilator that could be easily replicated with national suppliers.

COVID-19, Ventilator, Transition

Resumen

Debido a la situación de Contingencia que se ha generado en diversas partes del mundo y a la declaración de Pandemia llevada a cabo por la Organización Mundial de la Salud ante el virus Sars-CoV-2, diversas personas, instituciones educativas y empresas están llevando a cabo el desarrollo de ventiladores mecánicos que pueden cubrir la necesidad de estos equipos en sus países. Este trabajo presenta una parte fundamental de la construcción de una propuesta de ventilador mecánico de transición que permita poder cumplir con los requerimientos mínimos que los médicos consideran cuando una persona es entubada buscando cumplir con la normatividad del organismo federal, para ello se hace uso de una revisión de las propuestas existentes de ventiladores mecánicos de código abierto, de los requerimientos técnicos a cubrir y de la factibilidad de réplica del mismo, con base a ciertos factores que se describirán en el artículo y una vez probado se lleva a cabo la mejora del mismo desde la parte mecánica considerando el elemento eléctrico a utilizar, con la finalidad de obtener un ventilador mecánico de transición que pudiera replicarse de manera simple con proveeduría nacional.

COVID-19, Ventilador, Transición

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Introduction

Due to the outbreak of a new coronavirus (SARS-CoV-2) identified as the etiological agent of pneumonia (COVID-19) in China, according to data from the publication of the Pan American Health Organization (2020, March 3) An identification was carried out among the patients who maintained similar symptoms and through a study published by the Center for Disease Control and Prevention of China in February of this year, it was identified that the spectrum of the disease was distributed in 81% of mild cases (cases of non-pneumonia and mild pneumonia), 14% of severe cases (dyspnea, respiratory rate greater than 30 / min, blood oxygen saturation less than 93%, PaO_2 / FiO_2 ratio less than 300, and / or pulmonary infiltrates greater than 50% within 24–48 hours), and 5% of patients in critical condition, with respiratory failure, septic shock and / or multi-organ dysfunction or failure.

According to the world health organization (WHO January 2020), it has been identified that the implementation of supportive therapies, including those that supply oxygen, has helped people with severe manifestations of COVID-19. Being the SARS-CoV-19 coronavirus identified as a virus with a very high contagion rate according to the WHO, it is estimated that it is from 1.4 to 2.5, although there are other estimates that manage it between 2 and 3, which means that each An infected person can infect 2 or 3 more people, but there may be people called "supercontagators" that can infect up to 16 people as indicated (Sarukhan, 2020) of the Barcelona Global Health Institute.

Based on the data that the WHO reports as of April 26, 3,200,000 people have been infected in the world and according to the information mentioned above, 14% of the people, that is, 448,000 could fall into the consideration of serious and require oxygen support.

According to the PAHO, some of the essential elements for oxygen supply that are approved by WHO are presented in Table 1:

Paper	Description
Mechanical ventilators	ISO10651-4: Lung ventilators that support a person in the breathing process.
Non-invasive ventilation (BiPAP)	It is a form of temporary respiratory support for patients who have shortness of breath that manage the Positive Airway pressure of two levels.
Portable ventilator	System with certain characteristics reduced to those of a mechanical ventilator.

Table 1 Oxygenation equipment considered for COVID-19 supportive treatment
Source: Own elaboration

Although mechanical ventilation is not really a therapeutic process, it is the most used technique for the management of critical patients who require support for the respiratory process.

The evolution of this process of keeping a person alive can be said to come from the glory days of the Egyptians, passing through Hippocrates according to his treatise on air (Ya, 2005), later in the year 175 After Christ Galen generated a first device based on bellows to supply air and so followed several scientists, such as Andreas Vesalius, Leonardo da Vinci, Robert Hooke, Robert Boyle, Torsten Thunberg and many more, who allowed to develop what today is known as a mechanical ventilator. For a further description of the evolution of a ventilator, see the work of Neri, *et al* (2013).

Mechanical ventilation is a life-support treatment that began to be widely used in 1950 due to a polio epidemic in Europe (Gutiérrez, 2011). This process is supported by supplying air and oxygen through a machine, facilitating gas exchange and respiratory work in patients with respiratory failure. The mechanical ventilator (MV), by generating a pressure gradient between two points (mouth / airway - alveolus) produces a flow for a certain time, which generates a pressure that has to overcome the resistance to flow and the properties elastic bands of the respiratory system obtaining a volume of gas that enters and then leaves the system.

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Generally, this type of device is found in the Intensive Care Units (ICU) of hospitals and is used to treat various conditions that require the support of the respiratory system, its use is restricted to specialist doctors such as intensivists, who know of certain models and brands, these equipments cover different ventilation situations and have a very high cost.

The COVID-19 pandemic has led to an increased use of mechanical ventilators, to support patients who require the use of them for between 7 to 21 continuous days. Faced with this situation and considering that almost half a million people may need to use a VM, the amount of equipment installed in hospitals is exceeded, so the need for support equipment that meets the needs of a serious COVID-19 patient, It has been an area of opportunity that various educational institutions, entrepreneurs and companies have tried to take advantage of to carry out the generation of low-cost VMs that could be considered as mechanical ventilators or transitional mechanical ventilators that can be more similar to ventilators non-invasive better known as BiPap.

These transition VMs have generally been developed as so-called open source products and what is sought with this process is that they could be replicated quickly anywhere in the world, having the opportunity to increase their production based on the need. existing. Generally, for their construction, they require the use of 3D printers for the development of parts, low-cost electronic elements such as generic microcontrollers and the use of numerical control machines (CNC) for parts where 3D printers are not the best option.

A work on the state of the art of mechanical ventilators (Pham et al, 2017) allows identifying their main characteristics, their advantages and disadvantages, as well as alternatives in their development.

Among the open source VMs there are different principles of operation, one of them is based on the flow of air through a turbine and its regulation through the management of pressure and flow sensors.

Likewise, there is another operating principle based on AMBU bags where the automation of the respiratory rate and air volume is sought as in the first commercial ventilators, the above is done by compressing the bag by electrical-mechanical means such as levers cranks, cams and connecting rods in conjunction with direct current electric motors, servo motors or stepper motors and with speed reduction mechanisms such as gears, endless screws, etc.

The project carried out in this work is related to the update of the mechanical part of an open source ventilator that handles the operating principle through AMBU bag, based on an existing proposal and that is fairly easy to achieve with the materials and equipment available at the faculty, and that its mechanical principle is related to the use of a cam and a lever, but when developing and testing it did not meet the technical volume requirements that a VM should have, so they were carried out changes in the dimensions of the cams and levers and not reaching the appropriate volume levels, it was necessary to evolve to another mechanical principle based on a crank rod, thus updating the mechanical principle of the reference ventilator, identifying that said proposal did not it met one of the signals to be measured essential for a MV and this signal can only be carried out by means of a mechanical action, likewise, the proposal was presented to a group of doctors who made observations for the mechanical structure, which would allow a device easy to handle by the medical team.

To explain this update in detail, the following sections are used, the first one puts into context the basic characteristics of a VM, the next one adds the characteristics of an AMBU bag-based ventilator, one more section describes the open source ventilator for reference, the following presents the implementation of the proposal and the evidence obtained, following the conclusions section and finally the references section.

Characteristics of a mechanical ventilator

A mechanical ventilator must have the ability to provide medical gas (air-oxygen mixtures) to the patient by controlling the variables of volume, pressure, flow, and respiratory rate.

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In addition to conditioning the gas through filters, a temperature and humidity variation system and through non-invasive or invasive mechanical ventilation devices.

MV must have the ability to monitor the patient's ventilation and respiratory mechanics, as well as offer alarms when conditions other than those expected are present. According to Gutiérrez, F (2011) the characteristics that an ideal mechanical ventilator should have are those described in Table 2.

No	Features
1	High capacity (volumes, pressures, flows)
2	Versatile (modes, clinical context, patient demand)
3	insurance
4	Easy to use
5	Accepted by patients
6	Cheap

Table 2 Ideal characteristics of a mechanical ventilator
Source: Gutiérrez, F., Mechanical Ventilation.

Mechanical ventilators such as those shown in Figure 1, are compact equipment that has a programming panel on the front, as well as a visualization system through a screen, where the ventilation modes are programmed, as well. It has data acquisition sockets, while in the back are generally the electronic system, pneumatic and gas mixing system, electrical connections and medical gases, as well as the equipment's cooling system. (Ramos, L. & Vales, S., 2012).

Latest generation ventilators

Figure 1 Types of ventilators
Source: Biomedical engineering course, Universidad de la República Montevideo Uruguay

The main variables that should be considered to observe in the VMs are:

Tidal or Tidal Volume, Respiratory Rate, Sensitivity, Inspiratory Flow, I: E Ratio, Inspiratory Time, and Peak Inspiratory Pressure.

The ranges that should be considered in each of them can be seen in the following Table.

Variable	Rank	Units
Tidal volume	200-600	ml
Breathing frequency	12-24	rpm
Sensitivity	-0.5 a 3 1-5	cmH_2O Pressure l/min flow
Inspiratory flow	7-12	l/min
I: E ratio	1:1, 1:2, 1:3	------
Inspiratory time	10-35	min^{-1}
Inspiratory pressure	10-30	cmH_2O

Table 3 List of important variables in Mechanical ventilators. Mechanical Ventilation art font

The above variables should also be considered in open source ventilators regardless of their purpose being transitional use.

Characteristics of an Open Source Mechanical Ventilator (AMBU bag)

An open source mechanical ventilator (OSMV) is one that provides the code to replicate it, as well as the licensing for others to freely reproduce it. The development of these ventilators is mainly managed in two ways, the first is that design communities make proposals, in the same community improvements are made that are shared and are free for anyone; the second path follows the process of the first, but the information that permeates is incomplete to be able to replicate it.

In the context of OSMV, the existing literature is very poor, there is some research on low-cost ventilators of portable systems but without enough information to be reproduced, however there are works that can be useful documents for open source designers (Kerechanin, C. , et al, 2004).

There are low-cost VM concepts that have been developed and prototyped, under the principle of a pump and air regulator that allows the use of hospitals' gas mixing systems and that have allowed the creation of sensors through 3D printers. (Fuchs, P., et al, 2017; Powelson, S., 2010).

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Another low-cost Ventilation proposal is to use an AMBU bag. Changes in the way of compression of the AMBU bag through an electrical-mechanical system of a pivoting arm pushed by an electric motor improves the traditional compression proposal (Husseini, A, et al, 2010).

Mkaram Shabid's studies have shown good characteristics compared to that of a conventional commercial VM (Shahid, M., 2019). By automating the AMBU bag, it is possible to regulate the respiratory rate and the volume of air, as in the first MV, as well as to regulate the relationship between inspiration and expiration, and the PEEP ratio. The Shahid system has two modes: 1) mandatory ventilation (old models) and 2) assisted ventilation (in most current systems). The device has knobs that control the tidal volume, respiratory rate, I: E ratio and inspiratory pressure, however it does not have all the elements: blueprints, code, etc., necessary to qualify as open source devices, however it is a good document for those OSMV developers based on AMBU exchange.

Likewise, as of February of this year, given the situation in Italy, different communities were created on the Internet for the development of open source projects, in particular in the development of mechanical ventilators, as is the case of Project Open Air. , AIR (innovative breathing aid forum), RepRap, Air Collective in Bulgaria, #EngineersAssemble among others.

Of all the proposals available at the start of the project, an analysis was made and the proposal of the A.I.R.E. community was considered. called Respirator23 promoted by the team called Resistance, to be replicated at the University, given the infrastructure and equipment available at the faculty.

Characteristics of the Mechanical Ventilator Respirator23 Open Source (ambu bag)

The low-cost, open source mechanical ventilator called Respirator23 is based on the Jackson-Rees system that consists of an anesthetic circuit that modifies the Mapleson D circuit with a reservoir bag that incorporates an escape mechanism for the exit of exhaled gases, such as shown in Figure 2.

Figure 2 Jackson-Rees system
Source: DCD products

This system consists of an AMBU-type bag as a reservoir element for the fluids, in addition to having connectivities by valves that allow air flow to the reservoir and later when compressing it, the fluid exits through another part of the circuit, sending the gas mixture to patient.

A team of Spaniards from different areas and with knowledge of medicine, biotechnology, 3D printing, mechanics, electronics, computing and industrial design created a working group called ReesistenciaT, which tried to carry out a mechanical ventilator design with minimal materials and automate the process of compression of an AMBU bag as Husseini did, but taking it to the open source level for rapid replication given the needs of ICUs in Europe and possibly throughout the world, the above was done within the Coronavirus group Makers, with the possibility that their proposal could be replicated anywhere in the world in the face of the COVID-19 pandemic.

Its mechanical design in its first proposals, of which the replica was carried out, consisted of the following 3D printed elements: A cam, a rocker made of 2 pieces that are joined with a bearing that comes into contact with the cam and It pivots on an M8 screw that anchors it to the structure of the box, and in its final part it is fixed to a blade with two M5 screws. In addition, it has a 3D printed bed that houses Jackson Rees' breathing balloon. All elements were made available in open source for reproduction on the web, as 3D files, like the example shown in Figure 3.

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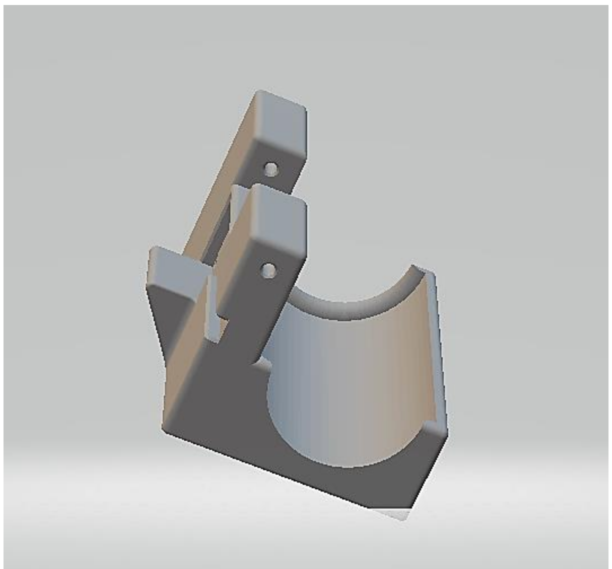

Figure 3 Respirator AMBU base 23
Source: Images respirator 23

Making some modifications over the weeks, your latest VMCA update is shown in Figure 4.

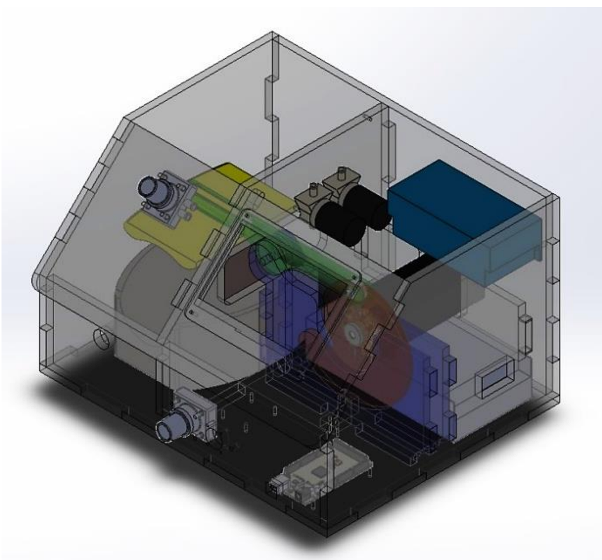

Figure 4 Respirator 23
Source: Images respirator 23

Implementation of the mechanical proposal

Based on the information from the Respirator23 and considering that all the mechanical part could be developed with the equipment that is in the school, the corresponding files were downloaded, and the following parts developed:

In 3D printer:

- Thrust part (shovel).
- Two arms that join the thrust with a bearing (rocker).
- PortaAmbu (bed).
- Two pieces in the form of a bearing.

In numerical control machine.

- Cam (in acrylic and wood).
- Two pieces that make up the rocker arm and motor support.

Likewise, the following elements were acquired: a 10 mm steel shaft, a bearing for skid, two 6/32 10 mm screws with nuts, an 8/32 10 mm screw with nut, the above in order to make the system is more robust and easier to acquire. All components can be seen in the assembled system in Figure 6.

Figure 5 Assembled Proposal of Respirator 23
Source: Own elaboration

The first test was done without printing the base of the AMBU bed called Base_23, because when viewing the Figure in the 3D printing software (see Figure 6), an overlap with the AMBU bed identified as balloon-support was identified in the shared documents for 3D printing.

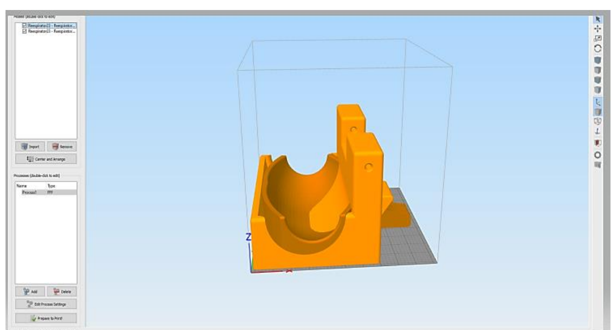

Figure 6 Overlap of Respirator 23 parts
Source: Own elaboration

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When carrying out the first tests of operation in terms of compression, as shown in Figure 7, it was identified that it made some compression of the AMBU bag, but it was until a lung simulator was put that it was possible to identify that it did not tidal volume requirements were met with Respirator 23 proposal.

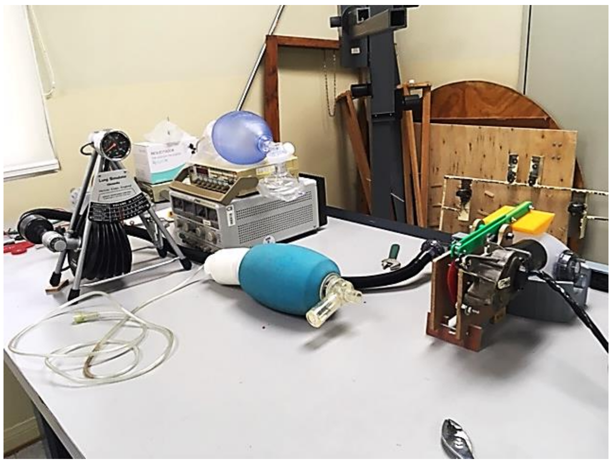

Figure 7 System with lung simulator
Source: Own elaboration

As identified alternatives, the first one used was the modification of the electrical system (motor), with the results shown in Table 4.

Type of motor	Speed (RPM)	Maximum torque Kgf-cm	Volume (ml)	Current (A)
DC 12V with gear	81	4.41	100	0.6 (no more)
DC 12V without gear	150	----	70	2.9
DC 12V Planeta-rio	84	93.6	250	4.9
Window Elevator	45	122.4	250	4.7
Wiper washer	64	183.5	300	4.2

Table 4 Respirator system test results23
Source: Own elaboration

From this test it was identified that the windscreen wiper and window lifter motors were the best option, they were tested on changing the cam, maintaining the profile of the original cam and making changes to it, but without significant changes. .

With this last change, it was identified that the motor required a greater current to reach the tip of the cam, for which a change was proposed in the mechanical design of the AMBU bag compression process, for which the force required to push 600 ml of the AMBU bag, starting from the pushing force:

$$F_E = P_e V_c \quad (1)$$

Where FE is the force of the thrust, Pe the specific weight that relates the density of the air and the AMBU and VC the volume that is displaced.

Being the density of the air and the AMBU defined as:

$$P_e = (\rho_{aire} + \rho_{AMBU}) * g \quad (2)$$

And if the density of the air is 1,225 kg / m3 and that of the AMBU, being silicone, 276 kg / m3 and the acceleration of gravity is 9.81m / s2, then the specific weight is:

$$P_e = (1.225 + 276) * 9.81 = 2{,}719.57\ kg/m^2s^2$$

Since you want to displace 600 ml, this is 0.0006 m^3, so the force of the thrust is:

$$F_E = 2{,}719.5 * 0.0006 = 1.631\ kgm/s^2$$

Equivalent to 15.86 N and 94.33 kgfcm

Then, calculating the force required (from the motor) to push a force of 15.86 N, considering the separation between the pushing force and the rocker (S1 = 9 cm) and between the force of the motor and the rocker (S2 = 12 cm) you have:

$$F_M = \frac{F_E * S_1}{S_2} = \frac{15.86*9}{12} = 11.89N \quad (3)$$

For the motors that have to compress the AMBU, an FM = 3.6 N is required, then the relationship between distances is:

$$\frac{S_1}{S_2} = \frac{F_M}{F_E} = \frac{3.6\ N}{15.86\ N} = 0.226 \quad (4)$$

So, if you keep the same distance between the rocker arm and the thrust, the distance between the engine and the rocker would be:

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$$S_2 = \frac{9}{0.226} = 39.82\ cm \tag{5}$$

Which would complicate the placement of the components.

For this reason, it was proposed to change the way of compressing the AMBU bag, considering a transmission through a crank-rod system like the one presented in Figure 8.

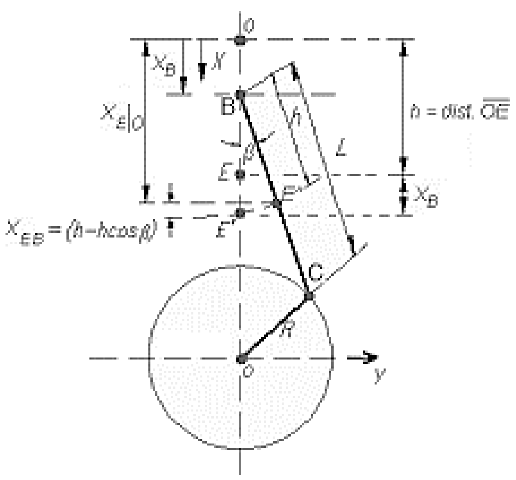

Figure 8 Crank-crank system
Source: Universidad Nacional de la Plata

Considering a crank of r = 4 cm and a crank of l = 20 cm, we have a relationship λ = 0.2 and the distance to travel through the thrust system defined by:

$$x = r * (1 - \cos\alpha) + l(1 - \sqrt{1 - \lambda^2 sin^2\alpha}) \tag{6}$$

It would be from 0 to 8 cm.

The torque required for the motor would be obtained by:

$$M = F * r[\sin\alpha + \frac{\lambda}{2}\sin 2\alpha] \tag{7}$$

Considering a required thrust force of F = 15.86 N, the torque required for the motor is:

$$M = 15.86 * 0.04m * [\sin 90 + \frac{0.2}{2}\sin 180] = 0.6344\ Nm$$

This is easily achieved with any of the wiper and window lifter motors, as presented in Table 6 in a test developed with a wiper motor.

Bag	Separation (cm)	Volume (ml)	Current (A)
Green	4	680	2.4
blue	4	640	1.8
Gray	3	600	1.9
Ambu	3	700	2.1

Table 5 Connecting rod-crank system test results
Source: Own elaboration

The final system being tested, like the one presented in Figure 9.

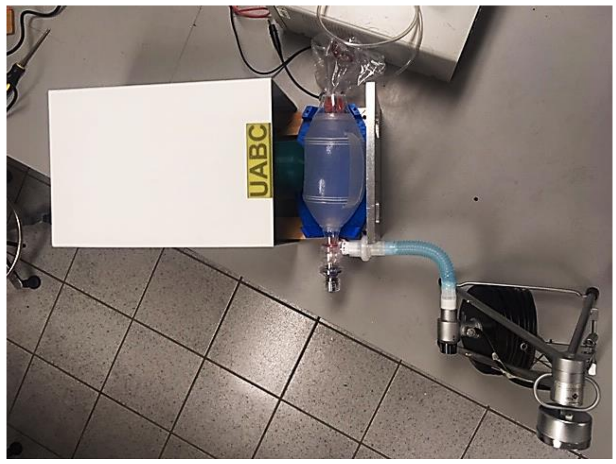

Figure 9 Crank-rod end system with lung simulator
Source: Own elaboration

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Conclusions

In this work, a proposal to modify the mechanical part of an Open Source Mechanical Ventilator has been presented, so that it complies with the ranges in the variables to be measured, it was identified that the basic proposal of a rocker lever did not cover the parameters to be measured. measure if not the energy capacity was greatly increased, for this, possible alternatives that are validated with their implementation are analyzed until the one that reduces the energy values and complies with the volume values is found, considering the same compression principle of an AMBU bag. The proposal can be improved if other compression alternatives are studied that were not touched on in this work.

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