TOPIC: Technical Report_01 OpenBreath Device **|** 11:30 PM Friday, the 27th of March, 2020

This report aims to illustrate the features of the Open Breath lung ventilator, which is currently under advanced development by our in-house team of designers and engineers. Being in the development phase, the design may be subject to variations dictated by empirical requirements, which will be established and proven as soon as possible by the in-depth testing phase of the device, and by the public peer review phase.

The essential concept of the ventilator is the mechanical automation of a Bag Valve Mask (BVM), also commonly known as Ambu® bag, a medical device used in manual resuscitation in hospitals all over the world. We decided to use an Ambu bag as the pneumatic element of our ventilator for several reasons. First of all, because of its proven operational effectiveness and its extensive availability as a globally distributed, affordable component. It is also a certified medical device and can be easily combined with all other medical devices needed to ensure proper patient ventilation.

The lung ventilator is composed of two identical and opposing four-link lever-screw mechanisms, which synchronously compress an Ambu® self-expanding balloon (Fig. 1 label 6) equipped with a PEEP valve. Each system consists of four laser-cut bent stainless steel plates (in fig. 1 labels 1, 2, 3, 4), a trapezoid screw (in fig. 1 label 2.c) and its lead nut (in fig. 1 label 3). a), a Nema 17 stepper motor (in fig. 1 label 2.b) and two absolute or incremental rotary encoders, one axially positioned on the motor shaft (in fig. 1 label 2.a) and the other one on the hinge of the presser (in fig. 1 label 5).

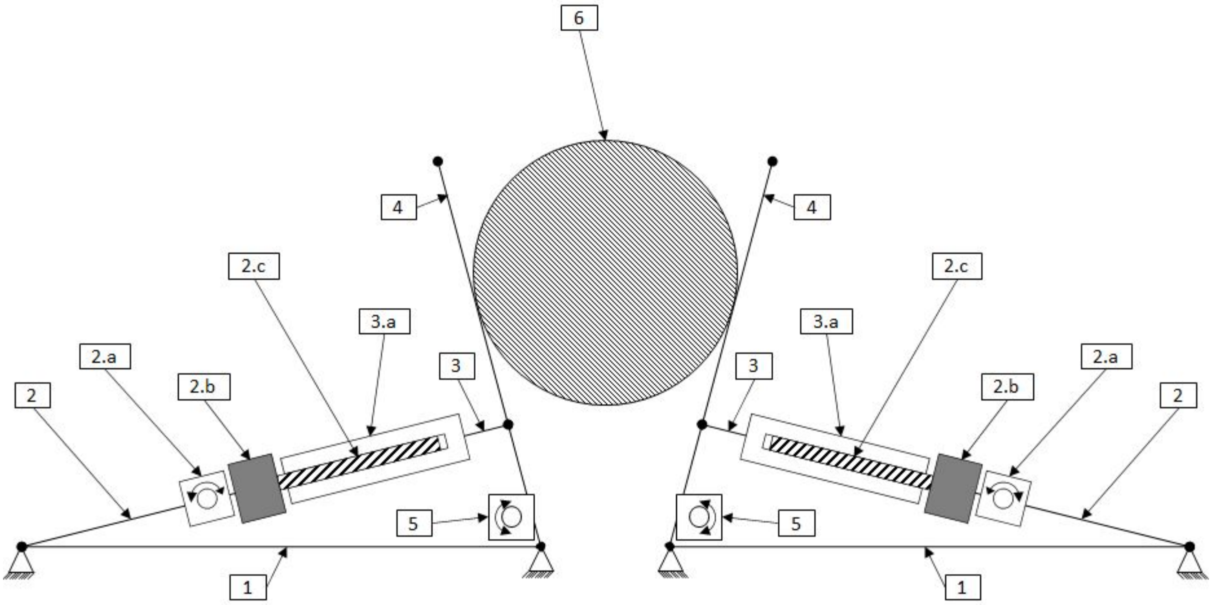

Figure 1.a - Scheme of the system in open position.

The encoders used can be both absolute and incremental according to the available supply. when incremental encoders are employed a homing operation will be carried out when the fan is switched on.

The stainless steel plates are hinged to each other by means of stainless steel pins and double flange IGUS technopolymer bushings, each axial sliding has a lifetime calculated by the manufacturer.

The trapezium screw and the lead nut are manufactured by IGUS, with calculated lifetime. The pressure application point of the lever-screw system is always tangent to the surface of the AMBU flask.

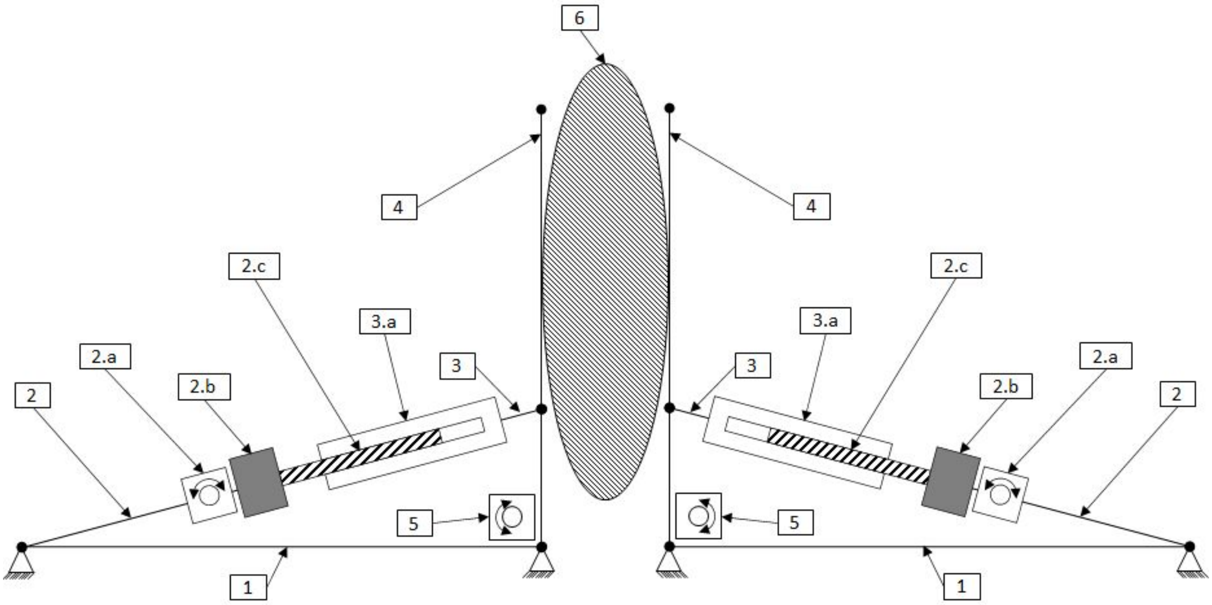

Figure 1.b -Scheme of the closed position systems.

The electronic system consists of a dual Motion Control (MC) system, a dual machine-operator interface system and a single embedded system used both for data display via web server and for alarm setting .

The single motion control system manages two stepper motors in open loop and supervises their movement by means of two absolute or incremental encoders, depending on the version in use. It also acquires pressure and air flow rate data via an I2C network.

The human-machine interface system takes care of acquiring the vital parameters from the operator and thereafter sends them to the motion control systems. Data is set by three incremental rotary encoders and a numeric keypad. The visualization is enabled by a LCD display, which includes an acoustic signal triggered by the set alarms.

The embedded system records all data, including the patient's vital parameters, and displays them on a web server application accessible from any device equipped with an internet browser (smartphones, tablets or PCs). In addition to this, it is possible to set alarms that will eventually be signalled both by the human-machine interface (HMI) and by the control panel hosted on the web server itself.

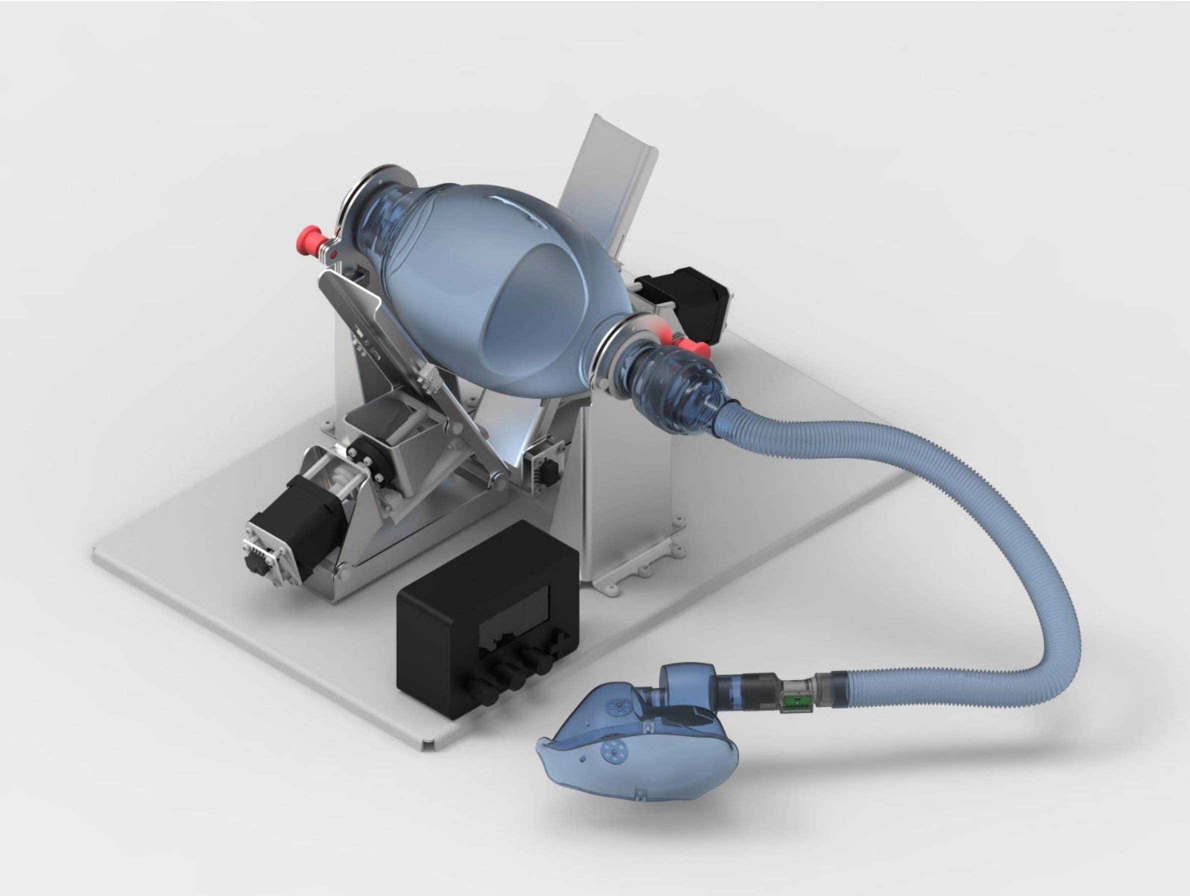

Fig. 2 - Overview, mechanics without external case.

M.C. systems, human-machine interface systems and sensors are completely redundant in all their components. This means that, in case of anomaly or failure of one of the boards, the remaining one takes absolute control over the system, guaranteeing its correct operation and immediately alerting the operator, who must promptly proceed to replace the ventilator.

In case one of the stepper motors fails, this will be deactivated, while the other one will increase the excursion and the speed of movement in order to keep the vital parameters output, set by the operator, unchanged. Contextually, the HMI system will warn the operator, who must replace the ventilator as soon as possible.

The motion control system acquires data from a pair of differential pressure sensors and a pair of flow meters, then compares the data of each pair and verifies that there are no discrepancies; otherwise, the HMI system will warn the operator.

The motion control system checks the effectiveness of the mechanical system by comparing the values of the encoder positioned on the motor shaft with those of the encoder positioned on the hinge shaft of the presser: if the deviations between the two values are too large, the HMI system warns the operator of a possible imminent mechanical fault.

The motion control system also regulates the air supplied to the patient according to two control modes:

1. CONSTANT PRESSURE:

The two pressors will compress the Ambu bag until the pressure threshold, set by the operator, is reached. A cut-off volume can also be selected at operator's discretion, when that level is reached, the ventilation cycle will be terminated.

2. CONSTANT VOLUME:

The two pressors will compress the Ambu until the volume threshold, set by the operator, is reached. A cut-off pressure can be selected at operator's discretion, when that level is reached, the ventilation cycle will be terminated.

These two control modes can be applied in two ventilation modes:

A. FULLY AUTOMATIC BREATHING:

In this mode, the frequency of ventilation is selected by the operator because the patient is unable to breathe independently.

B. ASSISTED RESPIRATION:

This mode of operation constantly monitors the flow of air-oxygen through flow meters. The patient's autonomic breathing is detected by increasing the monitored flow. When this occurs, the respirator pressors will compress the Ambu until the set pressure is reached and controlled by the pressure transducers.
When the motion control system detects a decrease in flow and a subsequent reversal of flow, the respirator goes into exhalation.

Positive end-expiratory pressure (PEEP) is regulated by a mechanical medical valve located near the Ambu outlet.

At this stage of development, the concentration of oxygen in the air supplied to the patient can be selected in three different sizes in this way:

- the concentration will be between 90% and 100% when using the Ambu with réservoir and oxygen tube connected to the oxygen distribution system of the hospital with flow between 12 and 15 lt/min;
- between 50% and 60% when using the Ambu connected to the oxygen tube without the réservoir;
- will be equal to the ambient concentration, or about 21% when used without réservoir or oxygen.

Note: The most accurate and efficient medical air-oxygen mixing system to be used with the Ambu system is still under study and will be subject to improvement before the final design is consolidated.

At present, the mechanical part is defined at 85%, so we expect to produce a prototype by March 29, 2020. After the latter we will start the development of the automatic controls and, if the system will meet the mechanical design requirements, we will freeze the mechanical design by starting the development of a plan for a production with medium runs. In parallel, we will accelerate software and electronic development.

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