Design and Development of an Automated Compression Mechanism for a Bag-Valve-Mask -Based Emergency Ventilator

*Edwin Calilung, Jason Española, Elmer Dadios, Alvin Culaba, Edwin Sybingco, Argel Bandala, Ryan Rhay Vicerra, Alma Bella Madrazo, Laurence Gan Lim, Robert Kerwin Billones, Siegfred Lopez, Dino Dominic Ligutan, Julius Palingcod, and Carl John Patrick Castillo

NEURONMEK Corporation

DML Bldg, Molino III, Bacoor, Cavite, Philippines *Corresponding author: edwin.calilung@neuronmek.com

Abstract – In response to COVID-19 pandemic, universities and related institutions around the world came up with various mechanical ventilator designs to help cope with the expected shortages of ventilators as the pandemic rages. Many of these designs are based on automating the manual operation of the Bag Valve Mask (BVM), a ubiquitous resuscitator device used for emergency ventilation or resuscitation of patients with breathing problems. In this paper, the mechanical design and development process for a BVM-based emergency ventilator is discussed. In particular, the evolution of the design from a simple, low-cost device to a more sophisticated system acceptable to pulmonologists and related medical practitioners is documented.

Keywords – emergency ventilator, COVID-19 ventilator, BVMbased ventilator, BVM automation

I. INTRODUCTION

The pandemic caused by the Coronavirus Disease 2019 (COVID-19) outbreak has spurred researchers around the world turn to an open-source emergency-type ventilator in response to and to help mitigate the demand for this life-saving device. These devices are envisioned to be used as an alternative by hospitals and medical facilities during a shortage of ICU-grade ventilators. [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] [11] [12]

In the case of the Philippines where currently there are already close to half a million cases of COVID-19, there is a growing number of severe COVID-19 patients waiting to have access to ventilators, particularly in the rural and provincial areas. To help the government in responding to this situation; NEURONMEK Corporation, an AI and Robotics automation start-up company embarked on developing an emergency ventilator design with the basic concept of making the design simple and cost-effective but safe to bridge the demand gap (at least when covid19 patients are waiting for access to ICU-grade ventilator systems) in the provinces and rural areas in the Philippines.

Our emergency ventilator system is inspired from an open-source disaster-situation ventilator model that utilizes the automation of the compressing procedure of a bag valve mask (BVM) as the working concept. This notion has been considered as a medically established and popularly known manually operated respirator or ventilator method for patients that need respiratory assistance and as such it was expected that it will facilitate and shorten the R&D process as well as testing and accreditation processes. [13] [14] [15]

Automation of the BVM operation that is usually manual will help eliminate virus exposure-risk for medical staff especially during the pandemic. Moreover, by automating the BVM compression process, it was expected that ventilation results will be consistent and reproducible as compared with manual operation that can be very tiring and skill dependent.

In summary, following are the expected benefits of using the automated BVM ventilator over manual BVM operation:

- 1. Controlled by a Programmable Logic Controller (PLC), for adjustable, reproducible and consistent delivery of required mechanical ventilation parameters as prescribed by medical practitioner,
- 2. Use of industrial grade components for reliable and consistent performance even in harsh environments,

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- 3. Reprogrammable control software for customization and future improvements,
- 4. Integrates medical grade sensors for safety and visualization of ventilation parameters in real-time,
- 5. Utilizes mechatronics design approach that integrates mechanical-electrical/electroniccomputing elements from the start of design process.

II. DESIGN OBJECTIVES

The main goal of this research and development work is to design, fabricate and integrate a BVM-based emergency ventilator device ready for clinical testing and FDA registration in the Philippines.

Specifically, the following objectives were set for:

- Mechanical design, fabrication, integration and testing of the BVM actuation/compression mechanism,
- Specification and integration of motor and drive system for the compression mechanism,
- Specification, integration and programming of controls, instrumentation, user interface and safety system,
- Preparation of the BVM-based emergency ventilator for safety testing and functionality testing in the mandated testing facilities of the Philippines' Department of Science and Technology (DOST),
- Undergo and pass the DOST testing protocols,

III. REVIEW OF LITERATURE

A. Bag Valve Mask (BVM)

Popularly known by its brand name as the Ambu bag or by its generic name as the manual resuscitator or the "self-inflating bag", the bag valve mask (BVM) is a handheld device conventionally used to deliver positive pressure ventilation to the patient's respiratory system especially for those who are unable to breathe or inadequately breathing. It was developed by the German engineer named Holger Hesse along with his co-developed, Danish anesthetists Henning Ruben in 1953, after initially developing a medically innovated suction pump. [16]

The device is normally used in hospitals as consideration of standard equipment situated in every emergency room or any other critical care facility. The American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care professionally suggest that "all healthcare providers should be familiar with the use of the bag-mask device." [14] The utilization of manual resuscitators to provide ventilation to a patient is frequently termed as "bagging" the patient and is routinely essential for medical emergencies whenever the breathing of the patient is considered insufficient or has halted completely. [17]

They are used within the premises of the hospital for temporary ventilation of patients that are dependent on mechanical ventilators whenever the mechanical ventilator is required to be evaluated for possible malfunction or whenever ventilator-dependent patients are mobilized within the hospital. It supplements air or oxygen directly into the lungs to expand them under controlled pressure, thus resulting to a method to deliver positive-pressure ventilation manually.



Figure 1. Construction and components of BVM [14]

B. BVM Automation Concept

One of the key issues of the COVID-19 pandemic is the sudden shortage of ventilators around the world especially for people who are diagnosed as severe with the disease. These are vital for keeping the COVID-19 patients alive, but there are insufficient to satisfy the enormous increase in the global demand. Around the world, there are many efforts to design and build an emergency ventilator by automating the actuation of the BVM.

Below are several efforts in this area:

- A group of engineers from Infineon developed a 3D printed lung ventilator to serve to address the deficiency of ventilator units due to the COVID-19 pandemic. The OpenVent team utilized the concept of a BVM to create a ventilator composed of stepper motors, 3D-printed parts, motor drivers, industrial sensors, and the Arduino compatible software. [18] [19]
- OpenVent-Bristol is developing a simple 'lowtech' open-source ventilator design for COVID-19 treatment. The design is also based on a Ambu bag ventilation concept. [20] [21]

OpenVent-Bristol V1.0: A simple BVM actuation ventilator

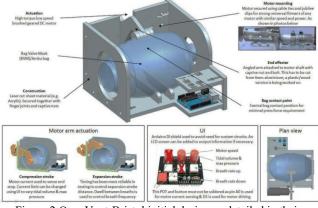


Figure 2 OpenVent-Bristol initial design as detailed in their website. [21]

C. Automation using Programmable Logic Controller

The programmable logic controller, popularly known as the PLC, is an industrial grade digital control computer that has been utilized for the control of different manufacturing processes. It is a small computer in the industrial setting specialized and optimized to handle incoming events at the time of occurrence. PLCs are now used in virtually every industry. PLC is a programmable, flexible, reliable, robust, and cost effective solution to automation. [22] [23] [24] [25] [26] [27] [28] [29] [30] [31]

The control task is applied into a graphical program known as the ladder logic diagram, which is one of the conventional methods of implementing logic in control circuits. They are termed as "ladder" due to the manner presented as vertical power rails and the horizontal steps that are individually parallel circuits between the common power rail. [25] [28] [32] [33] [34]

The operation of a PLC performs a cyclic scanning method that includes the following instructions:

- 1. The operating system of the PLC initiates the cycling and monitoring time.
- 2. The CPU begins reading the data sent from the input module and examines the status of all inputs.
- 3. The CPU starts to carry out the instructions set by the user or application program established in ladder diagrams in any compatible PLC programming language.
- 4. The CPU executes all the internal diagnostics, processing, and communication tasks.
- 5. According to the processed outcomes, it writes the data into the output module such that all outputs are up to date.
- 6. Then, the cycle is repeated provided that the PLC is in run mode.

The PLC architecture is like a computer's architecture as illustrated in Figure 3. It monitors, in a continuous manner, the input values from different input sensing devices like flow sensors, pressure sensors, accelerometer, weight scale, among others, and produces corresponding output relying on the nature of production and industry. The block diagram of PLC is composed of five parts namely: chassis, power supply, CPU, input and output module, and communication interface. [22] [23] [24]

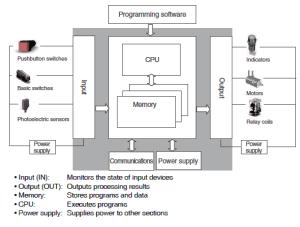


Figure 3 The Architecture of Programmable Logic Controllers

IV. MECHATRONIC DESIGN APPROACH AND BVM ACTUATOR DESIGN

The design of the BVM-based emergency ventilator system used the "Mechatronic" design approach which integrates mechanical, electrical/electronic and computing components at the outset of the process. Figure 4 shows the main components of the design which consists of the BVM Compression mechanism, PLC Based Control system, Control, Human Interface and Safety Software and the BVM device.

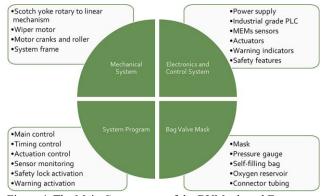


Figure 4. The Main Components of the BVM – based Emergency Ventilator

This paper focuses on the Mechanical BVM compression mechanism, although the design process integrates these 4 major components simultaneously according to the mechatronic approach.

A. BVM-based Ventilator Mechanical Design Components

The main mechanical components of the BVM-based ventilator design consist of the following:

- Compression mechanism
- Mechanism drive
- Compression pad or plate
- BVM cradle or holder
- Frame

The compression mechanism converts rotary motion from the motor through the mechanism drive to linear oscillating motion required for cyclical compression of the BVM. The compression drive transmits power from the motor to the mechanism. The compression pad or plate is linked to the compression mechanism and is responsible for the actual pressing of the BVM. The cradle serves to hold in place the BVM and provides reactive force to the compression force – for a 1-side compression mode of operation. Lastly, the frame holds the mechanical components together.

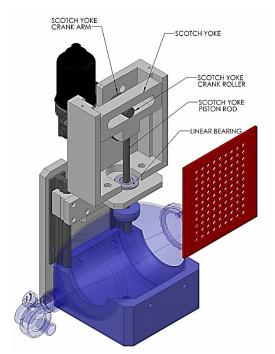


Figure 5. Scotch-yoke type BVM based Ventilator Design

B. Scotch-yoke Mechanism type of BVM ventilator

The first prototype of the BVM-based ventilator used a Scotch-yoke mechanism as compression mechanism and is driven by a commonly available automotive windshield wiper motor. The design is shown in Figure 5.

The Scotch-yoke compression mechanism type ventilator design was found to have the following advantages and disadvantages:

- The Scotch yoke mechanism is an example of mechanism that produces pure harmonic motion as such the linear oscillating motion is smooth with compression velocity naturally ramping up and ramping at the ends of the stroke,
- The mechanism itself is compact and with the one-sided mode of BVM compression, the resulting dimensions of the device was small and compact ideal for the requirements for an emergency use device,
- The car wiper motor drive with minor modifications already integrated a worm gear reduction mechanism and crank that fitted the requirements for the BVM compression parameters,
- The car wiper motor speed was easily controlled via PWM controller and the 12 volts dc power source requirement can be provided via dc battery for portable operation,
- The integration of the main components of the ventilator as shown in figure 5 had a very small footprint thereby requiring less space.
- The open BVM cradle design made bag removable and replacement quick and easy,

The main drawbacks of the design, however, were:

- The maximum torque delivered by the motor at each compression stroke was not in sync with the bag compression cycle as in the Scotch yoke mechanism the maximum torque occurs midstroke while the maximum load occurs at the end of the compression stroke when bag pressure is highest. Because of this it was observed that the wiper motor stalls towards the end of the compression stroke when load pressure is high. Moreover, the speed of the compression stroke changes with the load, and in particular the stroke speed decreases when load is high. This affects 2 important ventilation parameters of breath rate and I/E ratio.
- The use of a DC wiper motor as main drive of the Scotch yoke compression mechanism made it difficult to control the speed and position of the compression pad as it compresses the BVM in

each cycle. Position feedback was only provided by 2 digital proximity sensors positioned at the top and bottom of the compression stroke. The speed of the motor was also affected by the load. Because of these factors, the timing and rate of delivery of the required tidal volume of breath could not be controlled with precision. Moreover, tidal volume setting had to be manually set by changing the vertical position of the compression mechanism with respect to the BVM thereby changing the depth of BVM compression and tidal volume delivered.

C. Ball-screw Mechanism type of BVM ventilator

Due to the disadvantages of the Scotch yoke type design, a second major iteration of the design was made which changed the compression mechanism to a ball screw mechanism and the motor to a hybrid stepper motor. This new design is shown in figure 6 and had the following major advantages over the previous design:

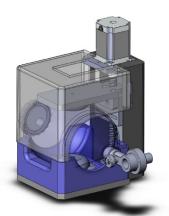


Figure 6 Ball-screw type BVM based Ventilator Design

- This design iteration was made to improve upon the main drawbacks of the previous design while preserving the good features. Thus, this design incorporated a linear ball screw mechanism to convert the rotary motion of the motor to linear motion required for BVM compression cycle and a hybrid stepper motor to drive the mechanism directly through shaft couplings. The ball screw mechanism transfers torque directly and uniformly as needed by the load with a constant mechanical advantage and constant speed reduction ratio based on the screw pitch. In practice this means that the maximum torque of the motor can be applied anytime during the stroke cycle.
- The use of a hybrid stepper motor drive provides full position feedback via integrated rotary encoder in the

motor and both position and speed control thru pulse and pulse rate-based control thru the hybrid stepper motor driver circuitry. In practice these makes possible the precision control of the breath rate and tidal volume delivery to the patient.

The use of the ball screw mechanism combined with hybrid stepper motor drive system allowed full control of the following important mechanical ventilation parameters which is required even for emergency type ventilators:

- Breath delivery rate in breaths per minute
- Tidal volume
- Inspiration Expiration ratio or I/E Ratio
- Volume-based ventilation mode
- Possibility for Pressure-based ventilation control with the proper instrumentation

V. CONCLUSION

The paper discussed the development of a BVM-based emergency ventilator and focused on two main mechanical design prototypes. It was shown that a simple compact and possibly low-cost ventilator design was possible using a modified scotch yoke mechanism driven by a car wiper motor. This design although simple and compact, did not allow full control of important ventilation parameters.

A second prototype that improves upon the weaknesses of the first prototype was developed that incorporates a ball screw mechanism and hybrid stepper motor drive system. This change made possible precise and full control of compression position and speed and allowed control of important ventilation parameters of breath rate, tidal volume, I/E ratio and volume-based ventilation mode.

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