Technologies for Ambulatory Mechanical Ventilation

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***Abstract*—Ambulatory mechanical ventilation is a critical aspect of the emergency healthcare system which has played a critical role in handling the pandemic situations like Covid-19. Globally, nations found the dire need for easy-to-operate and reusable electro-mechanical mechanisms for assisting Covid-19 patients, especially during transportation to critical care facilities. In this work, we have assimilated the information about emergency/ ambulatory mechanical ventilator design, manufacturing, and use. The information presented in this paper can assist in a better understanding of the basic requirements and develop valuable design features for futuristic products for mechanical ventilation**

Index Terms— Ambulatory Care, Mechanical Ventilation, Internet of Things (IoT).

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I. Introduction

Modern human society has faced several medical risks caused by phenomenon triggered by nature and accidents in the man-made facilities. As a result, the number of diseases affecting the populace has been steadily rising. There are no effective means that can predict the nature and severity of such random illnesses/ allergies. Moreover, in the absence of the specialized equipment required to treat such illness and sustain our way of life, we need to strengthen the proven basic healthcare systems to overcome the awful situations. The situation caused by Covid-19 has been dangerous, and it is an alarm for human society to raise our guards to tackle such menaces. There is an urgent need for innovative medical support s to system strengthen our medical infrastructure that should be economical, easy to operate, simple to maintain, and easy to dispose.

In one such attempt, the authors have pursued the idea of developing an ambulatory care automatic Ambu-bag-based ventilator system. During our work, we came across serval fundamental concepts about the domain of mechanical ventilation, which are systematically presented in this paper for the larger interest of the people working in this domain. This paper summarizes the research undertaken to evolve mobile and adaptable medical solutions for artificial ventilation systems, including the design, control, modeling, and simulation of the advanced technology applications in the medical industry.

A. COVID-19 and its Impacts

Since 2019, a positive-stranded enveloped RNA virus known as severe acute respiratory syndrome coronavirus-2 has had an adverse impact on the world, causing close to 50 lakh deaths due to ARDS (SARS-CoV-2). The respiratory system has become one of the most frequent sites of coronavirus infection due to the obvious existence of ACE-2 functional receptors, primarily located in pulmonary epithelial cells. The respiratory zone of the lungs contains pulmonary epithelial cells (type 1, type 2, and club cells), which are responsible for encouraging diffusion and secreting surfactant, which raises lung compliance and prevents alveolar collapse. The conducting zone is a different zone found in the lungs and is distinguished by elastic fibers, cartilage discontinuous plates, and pseudostratified ciliated columnar epithelium.

The culprit virus infects type 2 pneumocytes in 20% of infected patients with the aid of the host receptor ACE-2, which triggers the "cytokine storm"—a cascade of inflammatory mediators and chemoattractants—to arise. The resulting diffuse alveolar damage and acute respiratory distress syndrome result from the implicated T cells building up in the lung tissue during this process. In the current

global pandemic, mechanical ventilation is one of the cornerstones of controlling ARDS and is of the highest importance.

II. Literature Survey

A. Mechanical Respiration Systems

The need for technologically equipped ventilation systems has grown over the past few months as more COVID-19 patients are being treated. In truth, the current state of affairs for humanity is quite delicate. Even well-equipped hospitals had to make significant efforts to keep up with the rise in sick people, such as sharing one air supply with two patients, which meant they couldn't service every need at once in the overwhelming pandemic cycles. Scientists and engineers have developed low-cost, open-source mechanical ventilation solutions to address the global issue of ventilator scarcity. Hospitals or healthcare services were also quick to respond and adapt immediately to these developments. It is agreed that this strategy may be one of the most viable options for developing countries in demanding situations. It was noted previously and ever since March 2020 that approaches and equipment used particularly in medical care have become more adaptable due to the augmentation of automation technologies and technical improvement.

It was noted previously, and ever since then, approaches and equipment used have changed as a result of constant augmentation and improvement. Nearly 2,000 years ago, Claudius Galenus, a physician and surgeon in the Roman Empire, was one of the first researchers to emphasize the mechanical components of the ventilation process and its sensitive interaction with lung function. It is explicitly stated in Ayurveda (an ancient Indian medical science) that the functions of prana vayu are accountable for the human body's respiratory process.
Pranavaha Srotas are the tracts (Srotas) via which prana Vayu flows. Prana Vayu is compared to atmospheric oxygen, or amlajan, which refers to the base components of acids required to carry out life's essential processes. In ancient times during the Gupta period, ayurveda experts documented facts that clearly and categorically specified a trait in the process of respiration in human subjects [1][2].

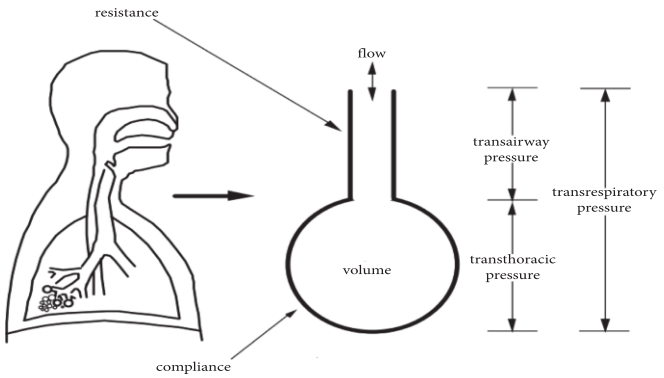

Figure 2: Simulation of a Ventilation System

Recently, during Covid-19 pandemic, Tran et. al [3] developed a platform for the mechanical design, the application of control rules, and several trials of both simulations and experiments. The bioinspired mechanism, finger-like actuator, and flow rate-based control are brand-new elements of the ventilator design that is being suggested. First, specific physiological characteristics are presented with an approximation of the lung model evaluation. This inquiry led to the creation of the control system, which can adjust to the biological body. To determine the proper performance of the closed-loop system, the model must also be integrated. The real-world model was built using the creative mechanical design concept that was proven using the open-source methodology due to these theoretical computations. Hardware modeling was done using mathematical formulas to predict the driving torque for the electrical actulators. The goal was the development of a mechanical ventilator with open-source hardware that is lightweight, highly mobile, and suitable for home-based treatment. The suggested ventilator's technical features include a finger-like actuator, a bioinspired mechanism, and flow rate-based control. According to this methodology, the lung's physiological model is thought to resemble some aspects of the human body closely.

Chiang Et al. [4] upgraded a single obligatory volume control mode of ventilation (VEMERS 1.0) to eight modes of ventilation for emergency use ventilators (VEMERS 2.0). The VEMERS-1.0 protocol was created in Chile during Covid-19. This development enabled the use of standard off-the-shelf pneumatic and electronic components for economic and easy manufacturing of ventilators on mass scale. The use of standard off-the-shelf commercial components ensures better availability and lower manufacturing costs without compromising the reliability. Moreover, no special parts need to be fabricated because of a wider variety of standard components

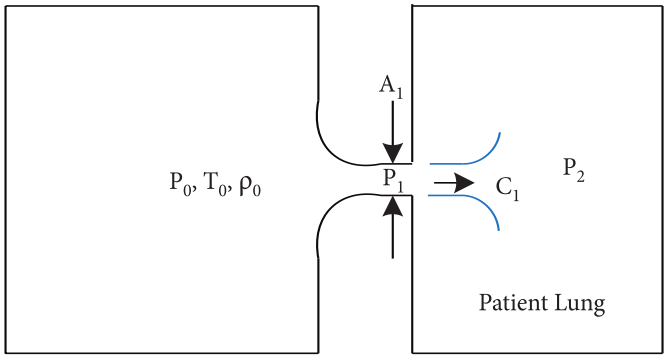

Figure 1: Choked Flow Principle in Inhalation Phase of Mechanical Ventilator

To create a constricted flow from the air mixture source to the ventilator inspiratory branch, VEMERS 1.0 and VEMERS 2.0 both rely on this technique. A choked flow makes it possible to manage the inhalation flow solely by adjusting the opening of a flow control valve, simplifying the ventilator's structure. The compressible gas flow equations that drive the inspiration control phase also govern the expiratory flow in this system.

Only on-off directional valves are required for the volume control mode of ventilation. The manual choke valve is used in conjunction with the inspiratory phase because it enables the fixed magnitude fixed inspiratory flow that is unique to this ventilation method. However, to implement the pressure control mode and its variations, a proportional valve must continuously change the airflow to attain and maintain the appropriate pressure level.

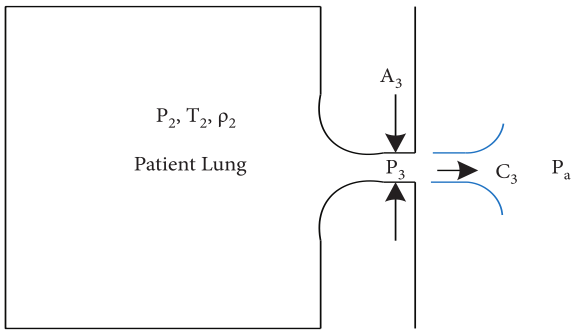

Figure 3: Pressure Control in Expiratory Flow

The eight ventilation modes focused on the upgrade versions of this system are:

Mode 1:	Volume Control Mode
Mode 2:	Assisted Volume Control
Mode 3:	Pressure Control Mode of Ventilation
Mode 4:	Assisted Pressure Control
Mode 5:	Pressure Support Mode of Ventilation
Mode 6:	CPAP (Continuous Positive Airway Pressure)
Mode 7:	BiPAP (BiLevel Positive Airway Pressure)
Mode 8:	High-Flow Nasal Cannula Oxygenation

B. Electronic Biomedical Systems

Marani et al. [5] reviewed three unique biomedical electronic projects in the Electronic Devices Laboratory at the Polytechnic University of Bari, Italy. The first project was a medical electronic-computerized platform for enabling a physician for real-time cardio-respiratory examination on a distant patient with complete control. The device can be deployed for rescue operations in an emergency without needing a medical facility for data monitoring, and it permits the moment of the patient. The authors reported that the developed electrocardiograph is the only wearable medical gadget available on the market and focuses on remote health monitoring; at the same time, there are no "intelligent" gadgets that can automate the rescue.

Secondly, Marani et al. [5] reviewed a low-cost, electronic medical system intended for the continuous, non-invasive real-time monitoring of breathing functions that used programmable integrated circuits with a high degree of miniaturization, automatization, and usability. The reported architecture supports a variety of signal processing techniques for biological applications.

Finally, Marani et al. [5] reported on a compact cardioholter system that allows the ECG signals to be sent through Bluetooth to six or twelve leads using a proprietary program. The proprietary software enables the downloading and processing of recorded tracings through digital filters and an easy-to-use interface. The unique feature of the product is its compact and miniature design.

In this work, Marani et al. [6] presents the design and prototyping of a novel pressure sensor-based electronic device for the analysis of lung sounds. The tool enables accurate processing, specific visualization (temporal and frequency graphs), and efficient auscultation of any lung sound. Additionally, it may be used to continuously monitor breathing processes in real-time, which is particularly helpful for diagnosing respiratory pathologies. It provides medical specialists with a non-invasive high-engineering device able to detect and analyze the most comprehensive number of data for monitoring the respiratory system by simply recording and evaluating lung sounds as a substantiated correlation between lung sounds and diseases.

III. Design Process of a Biotechnological Device for Medical Use

In this section, we discuss the basic underlying steps of the design process for developing an electronic/electro-mechanical device for medical/healthcare applications. These basic steps are universally accepted and are religiously followed by engineering design teams globally:

A. Problem Definition

The first step of the engineering design process is to gather as much information about the problem to be solved from all possible sources, including the end users/ customers, competitors' products, the information about the past history of the product development and the safety and regulatory compliances mandated by the local authorities. It is also necessary to understand as much as possible about the project regarding the scope/goals of the project and the necessary background information to achieve the objectives agreed by the engineering team, the strategic planner of the company, and the stakeholders.

Additionally, for designing a new medical device, we must have a thorough understanding of

- Medical issues to understand the constraints due to medical use.
- Biological and physiological issues to capture the basic knowledge of the medical specialty to which your device is targeted, including demographics.
- Technical issues to understand the engineering aspects of the product/project and the details of competing technology.

B. Preliminary Design

This phase is an ideation phase where the design team brainstorms and evolves several independent design concepts/ideas to solve the targeted problem for which an engineering solution is to be developed. In this stage, design evaluation is not necessary rather, capturing the design intent or a fundamental idea through brainstorming is required. These ideas must then be illustrated through flowcharts and diagrams to the extent possible.

C. Choose a Single Design to Pursue

Once an array of ideas that can lead to the possible design solutions are arrived at, the design team must then compare such shortlisted possible design ideas against the objectives and specifications laid down in the problem definition phase. We can also combine the positive aspects of different designs to form a single, final design. The expertise of the engineering design team has a great influence on the selection of the final design idea to be pursued. Thus, any kind of biased towards any technology or fundamental concept must be weighed against the time required before product launch, manufacturability, serviceability, safety, warranty, useful life, the cost to the customer, and disposal after the useful life.

D. Design Detailing

Once a particular design idea has been selected, a detailed design plan, including 3D CAD Models, must be prepared, and a detailed engineering analysis of all critical components must be performed to make a calculated assessment/guess of the design. The standard engineering simulation packages can be used for the analytical study of the product design. Once the simulation study indicates satisfactory results, we can proceed with the development of the manufacturing drawings and process details to make the prototype. At this stage, we should have the complete Bill of Materials (BOM) of the product containing: production drawings with dimensions of various components with details of datum references, dimensional tolerances, geometric tolerances, material specifications, standard fasteners, and ready-to-use (off-the-shelve) components etc. along with the sequence of manufacturing operations to be followed.
It is also useful at this point to build simple models. This is useful for understanding spatial relationships of the design in order to study how different parts fit together, etc. The creation of a 3D CAD model of the design assembly is also important for this phase.

E. Evaluate Design

Once a single design has been chosen, there should be continual evaluation throughout the design cycle to test the mechanical strength, thermal stability, vibration modes, electronic stability, electrical stability and safety, humidity control, and test for checking the functional and safety compliances. At this stage, the design is examined in its entirety before building the first prototype.

F. Prototype

Finalize all the design drawings and build a fully operational prototype of the device. It is better to consider 3D printing for fabricating casing and other panels to shorten the manufacturing lead time.

G. Evaluation of Prototype

At this stage the prototype must undergo the field trials to examine it for functional, operational and safety features in a controlled environment so that an estimate can be made for the product design for its performance under conditions it will encounter in practice.

IV. Leveraging Electronic Technology to Improve Healthcare Devices

Due to the onset of Industry 4.0, the concept of the Internet of Things (IoT) has evolved exponentially. The Internet influences many facets of a potential user's daily life. Keeping these considerations in mind, various IoT-based applications are being created in which every physical item is connected to the Internet via sensor devices. The complete implementation of this paradigm in healthcare is a mutual aspiration since it helps healthcare service providers to perform more professionally and patients receive better care.

Healthcare increasingly relies on IoT to improve access to treatment, improve quality of care, and, ultimately, cut healthcare costs. Healthcare devices are one of the IoT market's fastest-growing segments. Indeed, the value of this industry, also known as the Internet of Medical Things (IoMT), is expected to reach $176 billion by 2026.

Monitoring the patients is one of the most common applications of IoT devices in healthcare. IoT devices may collect health indicators such as heart rate, blood pressure, temperature, and other parameters from patients who are not physically present at a healthcare facility, eliminating the need for patients to travel to physicians or collect it themselves. This novel data collecting paradigm enables continuous and ubiquitous medical device access from any Internet-connected device.

When an IoT device collects patient data, it sends it to a software application where healthcare professionals or patients may view it. Algorithms can be used to evaluate data and provide recommendations or produce alarms. Intelligent devices, which include couple of sensors and microcontrollers, enable the IoT based system to be used for healthcare by precisely measuring, monitoring, and analyzing a wide range of health status data. These can include fundamental vital indicators like blood pressure and heart rate as well as glucose and blood oxygen levels. An IoT sensor, for example, that detects an exceptionally low heart rate in a patient may create an alarm so that healthcare practitioners may intervene.

The technologies required to create a Healthcare IoT (HIoT) system are critical. This is because the employment of specific technology can improve the capability of an IoT system. As a result, several cutting-edge technologies have been employed to integrate diverse healthcare applications with an IoT system.

The adoption of the IoT protocols for medical devices is likely to safeguard medical professionals while working with Covid-19 patients, particularly when monitoring and configuring equipment. One such piece of critical equipment is a medical ventilator that is

used to help people who are experiencing respiratory difficulty. Today, there is an excellent need for ventilators all over the world. This is because the number of Covid-19 patients has grown dramatically while the quantity of ventilators is quite restricted.

Therefore, there is a need for a respiratory aid that helps in the breathing process of a patient. The absolute volume and variations in the volume of the gas gap in the lungs accomplished throughout a few breathing actions are the most typical markers of ventilation. It necessitates the use of pressure, volume, and flow sensors. The sensor data modifies the microcontroller's activities. The microcontroller regulates the motor system of the ventilator pumps based on sensor data. The alarm, which provides information on patient characteristics such as exhaled volume or airway pressure, is an essential component of the respiratory system. The respiratory aid must be able to detect the patient's breathing actions. Using sensors, the MCU monitors variations in aspiratory flow and pressure. The monitor alerts if no inspiration is detected within a particular time.

The most importantly, the pneumatic system in an ambulatory ventilator contains two air supplies, which can be either oxygen or air, and supplied via a pressurized tank or a compressor. A gas mixture of suitable characteristics needs to be deployed to ensure the mixing of the proper ratios of the two gages in the compressed air tank. Two input valves of the gas mixer control the mixture composition, which comes from an air tank where the mixture is held at set pressure limits. If the mixture composition is correct and the air pressure range is correct, the system delivers this air to the patient to control breathing.

V. Conclusion

The above context discusses the ideas and methods of developing an affordable respiratory support device. It also indicates the absolute need for developing such a device brought to light by the COVID-19 situation that arose suddenly and the world was not ready for. The advancement of the new technologies offers great advantages for designing and developing superior, economical, reliable, and sustainable medical devices that can lead to a stronger and connected healthcare infrastructure

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