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Design Construction and Performance Test of a Low-Cost Pandemic Ventilator for Breathing Support

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Abstract: ***Mass casualty incidents such as those that are being experienced during the novel coronavirus disease (COVID-19) pandemic can overwhelm local healthcare systems, where the number of casualties exceeds local resources and capabilities in a short period of time. The introduction of patients with worsening lung function as a result of COVID-19 has strained traditional ventilator supplies. Mechanical ventilator is a medical device which is usually utilized to ventilate patients who cannot breathe adequately on their own. Among many types of ventilators Bag Valve Mask (BVM) is a manual ventilator in which a bag is pressed to deliver air into the lungs of the patient. In present work, a mechanical system along with speed controller has been developed to automate the operation of BVM. The constructed prototype contains crank, powered by servo motor, supported by wooden frame. To bridge the gap during ventilator shortages and to help clinicians triage patients, manual resuscitator devices can be used to deliver respirations to a patient requiring breathing support. With principal dimensions of 0.54*0.64 m^2, bvm weighs 0.9 kg and DC power convertor for supplying power for a continuous operation, the prototype can be moved easily. The dimensions of the frame are selected as such to be compatible with the physical dimension of Ambu bag. The performance of the device was tested using Airflow meter which illustrates that the Tidal Volume vs. Time graph of the automated system is similar to the graph produced by manual operation of the BVM, but with a mean deviation of 0.182 Litres with manual operation and 0.1 Litres with prototype. For patients who require ventilatory support, manual ventilation is a vital procedure. It has to be performed by experienced healthcare providers that are regularly trained for the use of bag-valve-mask (BVM) in emergency situations.***

Keywords: Mechanical Ventilator, Automated BVM, BPM, COVID-19, Ventilator design, Airflow meter

I. INTRODUCTION

Coronavirus disease 2019 (COVID-19) is increasing mortality rates by overwhelming medical infrastructure at the regional level [1-4]. Ventilation is an important treatment which is usually utilized to ventilate patients who cannot breathe adequately on their own. Patients with underlying lung disease may develop respiratory failure under a variety of challenges and can be supported by mechanical ventilators. These are machines which mechanically assist patients inspire and exhale, allowing the exchange of oxygen and carbon-dioxide to occur in the lungs, a process referred to as artificial respiration [2]. There are many techniques and methods of artificial ventilation, both manual and mechanical. Bag-valve mask (BVM) devices are ubiquitous in ambulances and healthcare environments, however require a medical professional to be present and constantly applying compression to provide the patient with respirations. While modern ventilators are computerized machines, patients can be ventilated with a simple, hand-operated bag valve mask (BVM) also [3]. Mechanical ventilators, which are essential for treating both influenza and COVID-19 patients in severe acute respiratory failure [5], are in critical short supply in some locations [6, 7]. During pandemics intensive care units (ICUs) do not have sufficient ventilators to treat all the patients requiring them, which forces triage and rationing [8]. This is despite national stockpiles of proprietary, mass-manufactured ventilators, which are simply not numerous enough due to prohibitive costs to service society during an extreme pandemic.

A. History of Artificial Ventilation

Ventilation with BVM is the commonly used technique to provide manual positive pressure ventilation to respiratory failing patients. From the mid-1500s until the early 1900s, artificial ventilation techniques reported in the literature recall only mouth-to-mouth and the use of bellows. Indeed, in 1472, Paulus Bagellardus published the first known book on childhood diseases and described mouth-to-mouth resuscitation by recommending to midwives to blow into the newborn's mouth if there is no respiration [9-11]. This shows that mouth-to-mouth ventilation was already considered at that time. In 1543, after further investigations on a porcine trachea with a reed for increasing animal's survival. This practice was taken over in 1559 by an Italian professor of anatomy Matteo Realdo Colombo who also described the tracheotomy's method. One century later, Robert Hooke, one of the greatest experimental scientists of the seventeenth century, repeated the Vesalius's experimentation using a strangled chicken model, which

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was ventilated by bellows. He demonstrated with this model that it was only the fresh air leak which caused death. In 1732, the first mouth-to-mouth ventilation case was reported on a coal miner. This latter revival was performed by the surgeon William Fossach [12]. He presented in 1744 at Edinburgh the case study of his mouth-to-mouth rescue [13]. In 1787, Baron Antoine Portal proposed, for respiratory insufficiency cases, to inflate the lungs of the new-born with air. The Scottish surgeon John Hunter, advocate of the experimental method in Medicine, who developed human bellows with pressure relief valve, recommended to the Royal Human Society in 1776 the need to apply artificial ventilation immediately for revival [11, 13]. Furthermore, in order to reduce stomach inflation, the major problem with bellows ventilation, he suggested pressing gently the larynx against the vertebrae [9, 14]. The bellows ventilation was condemned by the Royal Human Society and the French Academy of Medicine for lack of safety due to their first adverse effects. In 1745, John Fothergill listed singular advantages of mouth-to-mouth expired air ventilation compared to the bellows ventilation during recovery [9, 13]. He said that "the warmth and moisture of the breath would be more likely to promote the circulation than the chilling air forced out of a pair of bellows and that the lungs of one man may bear, without injury, as great a force as those of another can exert, which by the bellows cannot always be determined" [9]. Indeed, with mouth-to-mouth ventilation, it is impossible to increase pressure to be higher than that the human is able to generate. Nevertheless, an example of successful bellows ventilation has been reported by Fell in 1891 in a clinical trial. James Leroy d'Etiolles emphasized the need for early use of the bellows and recommended in 1828 a graduated bellows according to the patient size to reduce hyperventilation with high volumes which may induce barotrauma. In 1958, Peter Josef Safar, "the father of modern recovery," demonstrated the superiority of mouth-to-mouth ventilation over other methods of manual ventilation in a clinical study [15, 16].

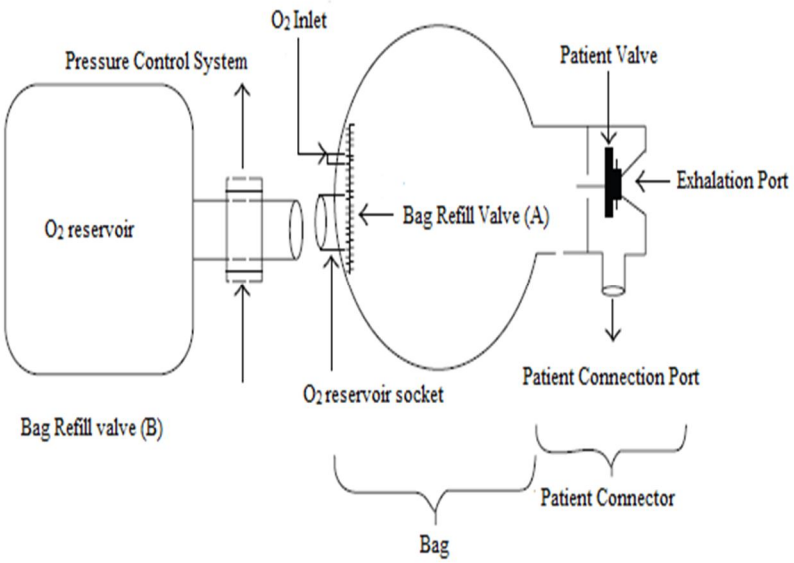


Fig. 1 Basic components of the BVM system (De Godoy et al. [11])

At the middle of the 20th century, several unidirectional valves were developed with different technical characteristics. The original bag-valve-mask concept was developed in 1953 by the German doctor Holger Hesse and his partner Danish anesthetist Henning Ruben, following their initial work on a suction pump. Their resuscitator, named "Ambu" (Artificial Manual Breathing Unit), was manufactured and marketed in 1956 by their company [17].

II. PREVIOUS WORKS ON THE DESIGN OF PORTABLE VENTILATORS

Stuart Fludger et al. [18] described various types of portable ventilators and their historical development. The concept of portable ventilators is rather new compared to ICU ventilators. Portable ventilators are evolved from the necessity of ventilating a patient during shifting or moving from one place to another. Ambu bag is often not reliable or it cannot be used for the unavailability of trained personnel. For these reasons, portable ventilators came into existence.

Portable ventilators vary by different parameters. In Table 1 comparison among three common portable ventilators is presented. [18] Harrison et al. [19] of Rochester Institute of Technology, New York, developed a traditional portable ventilator 'Mediresp II' further. A US patent by Reno L. Vicenzi et al. [20] describe a detailed construction of a portable emergency mechanical ventilator.

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Table 1:
Comparison Among Common Portable Ventilators [18]

Model	Power for cycling	Power for inspiratory flow	Internal battery supply	External electricity supply
VentiPA 200D	Pneumatic	Pneumatic	>1 year (alarm only)	N/A
LTV-1000	Electric	Electric	1 hr	Battery 12V DC
Oxylog 3000	Electric	Pneumatic	3 hr	10-32V DC, 240V AC

The present work is based on the automation of BVM to construct an emergency portable mechanical ventilator, similar to the work by Husseini et al. [21]. But in present work, mechanical arms and motors have been used to actuate the BVM, whereas, Husseini et al. used cam mechanism for the purpose. The technique used in present work proves to be more effective as it permits programming the required compression pattern, while in cam mechanism the compression pattern is fixed and unchangeable. So, more controllability can be achieved by implementing mechanical crank and servomotor to actuate the BVM.

III. DESIGN AND CONSTRUCTION

A. Design Assumptions

There are currently many open-source solutions that seek to disseminate manual resuscitator (bag-valve mask; BVM) ventilator designs with the hope of bridging the gap during the COVID-19 pandemic [22]. First, the design should ensure that the device does not degrade the BVM performance with regard to pressure V_T, and flow waveforms from repetitive device motion. Durability testing has to be performed not only on the mechanical system but also on the BVM device. For this work, automated BVM-based device could consistently deliver mechanical respirations with a variety of widely commercially-available BVMs. The automated BVM operation can be successfully implemented by completing following parameters 1) rapidly design and develop a volume-controlled automated manual resuscitator, 2) evaluate the parameters of V_T rate, and mean airway pressure over different resistance and compliance settings that would be representative of patients with varying lungs states, and 3) establish longevity and implementation of the device across multiple BVM models.

The design of the proposed automated BVM for adult patients can be considered on the basis of following assumptions as shown in Table 2. Air flow transducer will be used for testing purpose i.e., to measure tidal volume. Following data was collected and calculated with the help of a physician.

Table 2:
Expected Outcome from Prototype

Minute Volume	Respiratory Rate	Delivery Rate/Tidal Volume
5-10 l/min (Normal Rate)	20 breaths/min	0.25-0.5 l
30 l/min	30 breaths/min	1 l

The design assumptions are based on the work by Husseini et al. [21], as they determined the assumptions after necessary experiments taking the mechanical properties and dimensions of the Ambu bag into considerations. So, there assumptions can be taken without further experimentations. To automate the operation of Ambu bag, the mechanical system developed to compress the bag must be synchronized with the ideal motion that is maintained by a professional rescuer.

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B. Principle of Proposed Design

Where most emergency and portable ventilators are designed with all custom mechanical components, it was chosen to take an orthogonal approach by building on the inexpensive BVM, an existing technology which is the simplest embodiment of a volume-displacement ventilator. Due to the simplicity of their design and their production in large volumes, BVMs are very inexpensive and are frequently used in hospitals and ambulances. They are also readily available in developing countries. Equipped with an air reservoir and a complete valve system, they inherently provide the basic needs required for a ventilator. The developed system should have three control inputs for the variables: tidal volume (V_T), breathing rate per minute (BPM), and inspiratory-to-expiratory ratio (I/E). In Fig. 2, the schematic diagram of the proposed system is illustrated.

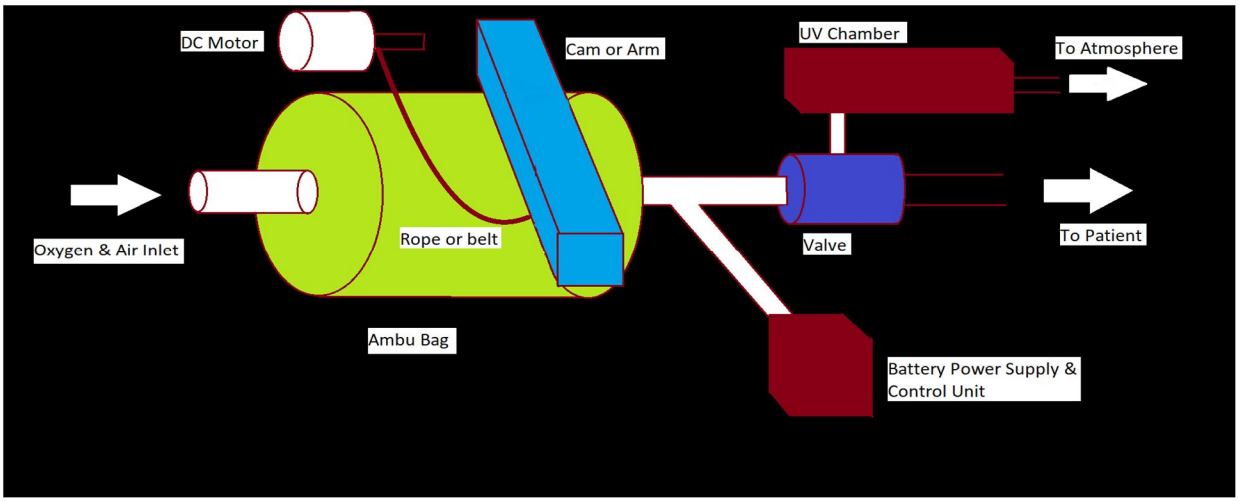


Fig. 2 Block Diagram/Working Setup

C. Components Used

The materials and equipment were selected on the basis of the design assumptions discussed previously. Materials and components needed to construct the prototype are presented in Table 3 with the total cost.

Table 3:
Materials and Components Used

Sr. No.	Component	Rating/Specifications	Price (in Rupees)
1.	Ambu Bag	Adult PVC Disposable Manual Resuscitator	1000
2.	Servo Motor	Verve 60 RPM 12V DC Motor	650
3.	LZQ-2 Flow Meter	Pressure: ≤0.6 MPa	1200
4.	DC Power Supply	12V 30A 360W DC	1200
5.	Motor Speed Controller	DC 6-60V, 0-30Amp	1300
6.	PVC pipes	As designed	160
7.	Project Board	54*64 cm^2	150
8.	Wires & Screw	As needed	70
		Total	5730

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D. The CAD Model

A CAD model of the frame designed is illustrated in Fig. 3. The model is developed using Siemens NX software 2019. The Ambu bag and other components to deliver power and control the motion is installed on the motor.

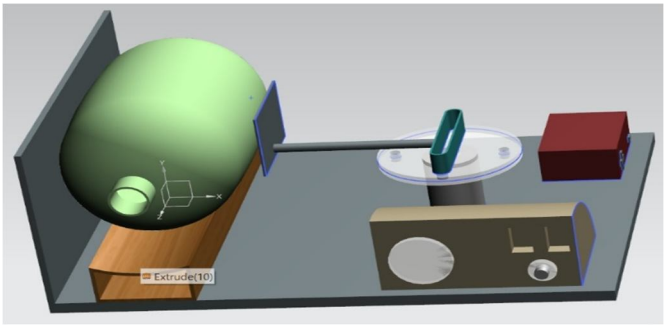


Fig. 3 Isometric View of CAD model

IV. RESULT AND DISCUSSION

A. The Constructed Model

The model automates the operation of BVM. The principal dimensions of BVM are 0.3m*0.1m*0.1m and weight is 0.9 kilograms with 1600ml capacity. Nonrebreathing valve with pressure limiting device wherein it will open if the inspiratory pressure is more than 60cms of water. Only AC to DC convertor or three 9V DC battery can be used to operate the device. Also, it can easily be carried to emergency spots. The control knob can be used to adjust the BPM required for different patients and for different ventilation settings. The constructed model is illustrated in Fig. 4.

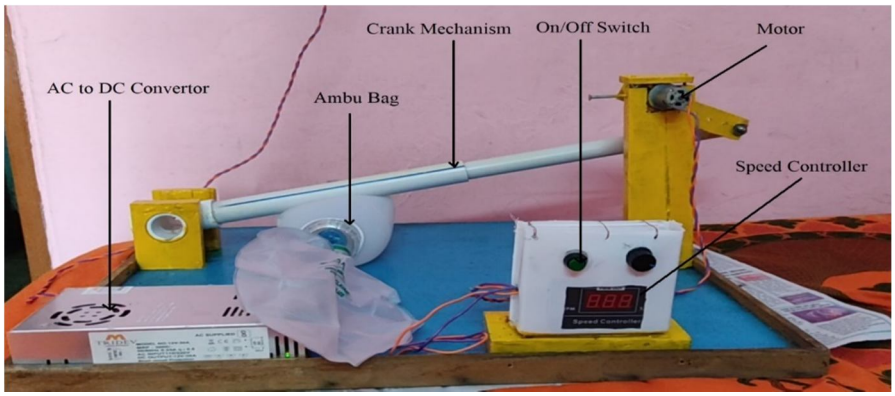


Fig. 4 Constructed Prototype

B. Performance Test

The developed prototype was tested using Airflow Meter. In Table 4 data of 20 BPM was obtained at particular pressure and RPM% was converted into BPM in order to obtain readings in one format.

Table 4:
Obtained for 20 BPM

RPM%	BPM
35	18
40	20
45	25
50	38
55	41
60	45
65	49
70	54
75	59

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The developed prototype was tested using air/oxygen flow meter. The experimental setup is illustrated in Fig. 4. The air flow meter records the airflow for every BPM. In Table 5 data of tidal volume for 20 BPM (for the pneumonia cases of COVID-19 patient lungs) is presented at a constant pressure. The lung tidal volume (Vt) vs BPM graph was obtained for the device and for manual operation. In Fig.5 the graph is presented.

Table 5:
Tidal Volume For Manual Operation Of The Bvm And For Constructed Prototype

BPM	Tidal Volume (Litres)	
	Manual	Prototype
1	1.9	1.5
2	1.6	1.3
3	1.9	1.5
4	2.1	1.5
5	1.5	1.5
6	1.7	1.3
7	2.0	1.5
8	1.4	1.3
9	1.7	1.3
10	2.0	1.5
11	1.5	1.3
12	1.7	1.3
13	2.0	1.5
14	1.4	1.3
15	1.4	1.3
16	1.7	1.5
17	1.8	1.5
18	1.5	1.3
19	1.8	1.5
20	1.8	1.5

The mean deviation of the tidal volume obtained from manual operation was 0.182 Litres or 182 mL and from prototype was 0.1 Litres or 100 mL.

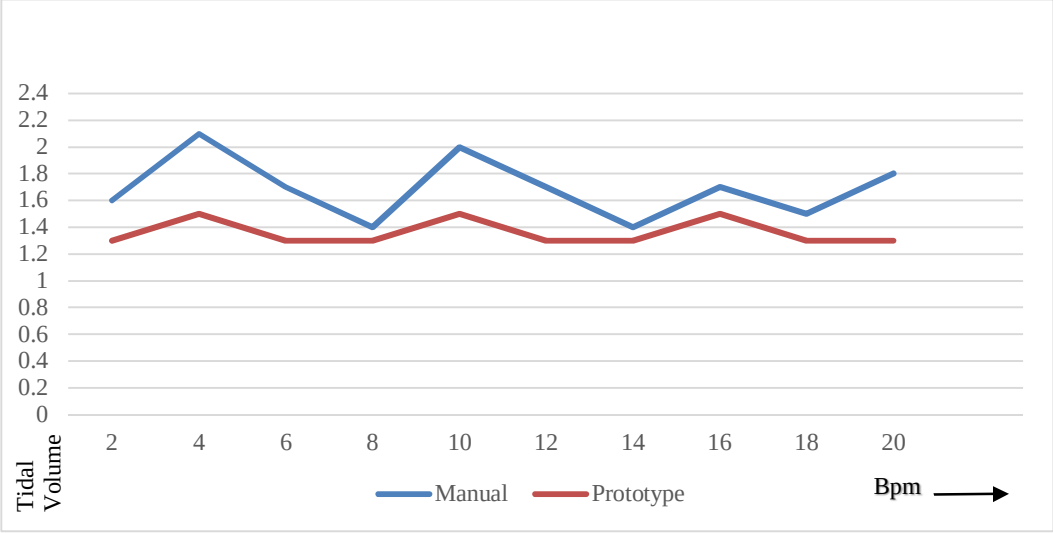


Fig. 5: BPM vs Tidal Volume comparison between manual and prototype.

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V. CONCLUSION

The use of an automatic, manually triggered ventilation devices for recovery may present valuable advantages over the standard manual BVM ventilation. Such devices may improve ventilation efficiency and decrease the risk of pulmonary overdistention. The project work proves the concept of automating the Ambu bag or BVM for developing a low-cost portable mechanical ventilator. Improvements of the model will lead to a successful and useable portable mechanical ventilator for actual emergency cases where existing sophisticated devices are not present. Although the device cannot perform like existing devices, its low cost justifies its use in emergency cases. As the COVID-19 crisis is overwhelming health care systems, leaving some institutions without an adequate supply of ventilators, the concept of automating the Ambu bag or BVM can be used for developing a low-cost portable mechanical ventilator for actual emergency cases where existing sophisticated devices are not present. The challenge is to develop devices and technologies that improve and secure the quality of manual ventilation.

VI. LIMITATIONS AND FUTURE SCOPE

A. Incorporating the possibility of self-inflating bag displacement, as well as the accuracy of the crank rod travel distance calibration, the tidal volume may differ from the set value within the standard error, which is approximately 10 mL.

B. During the tests, the servo motor was operated with the maximum current in the windings to cover the working range of the tidal volume and respiratory rate. These conditions lead to the excess heat buildup in the motor and the need for heat dissipation after several hours of continuous operation. Thus, to ensure ventilation it is necessary to use a motor cooling system in the form of a heat sink or active airflow.

C. UV filters can be used before releasing exhaled gases from the ventilator to atmosphere, it should be filtered out and make germ free. UVC at a specific wavelength, 254 nanometers, has been successfully used to inactivate H1N1 influenza and other coronaviruses, such as severe acute respiratory virus (SARS-CoV) and Middle Eastern Respiratory Syndrome (MERS-CoV).

D. During compression, the self-inflating bag may shift and rotate in the bag support, which will lead to a deviation of the set ventilation parameters. An elastic band is used as a fixing component.

E. Safety Features: -To ensure that the patient is not injured, the airway pressure can be monitored with a pressure sensor connected to a sensor output on the BVM. The same pressure sensor will be used for initiation of assist control triggering an alarm if the pressure rises too high, alerting the physician to attend to the patient.

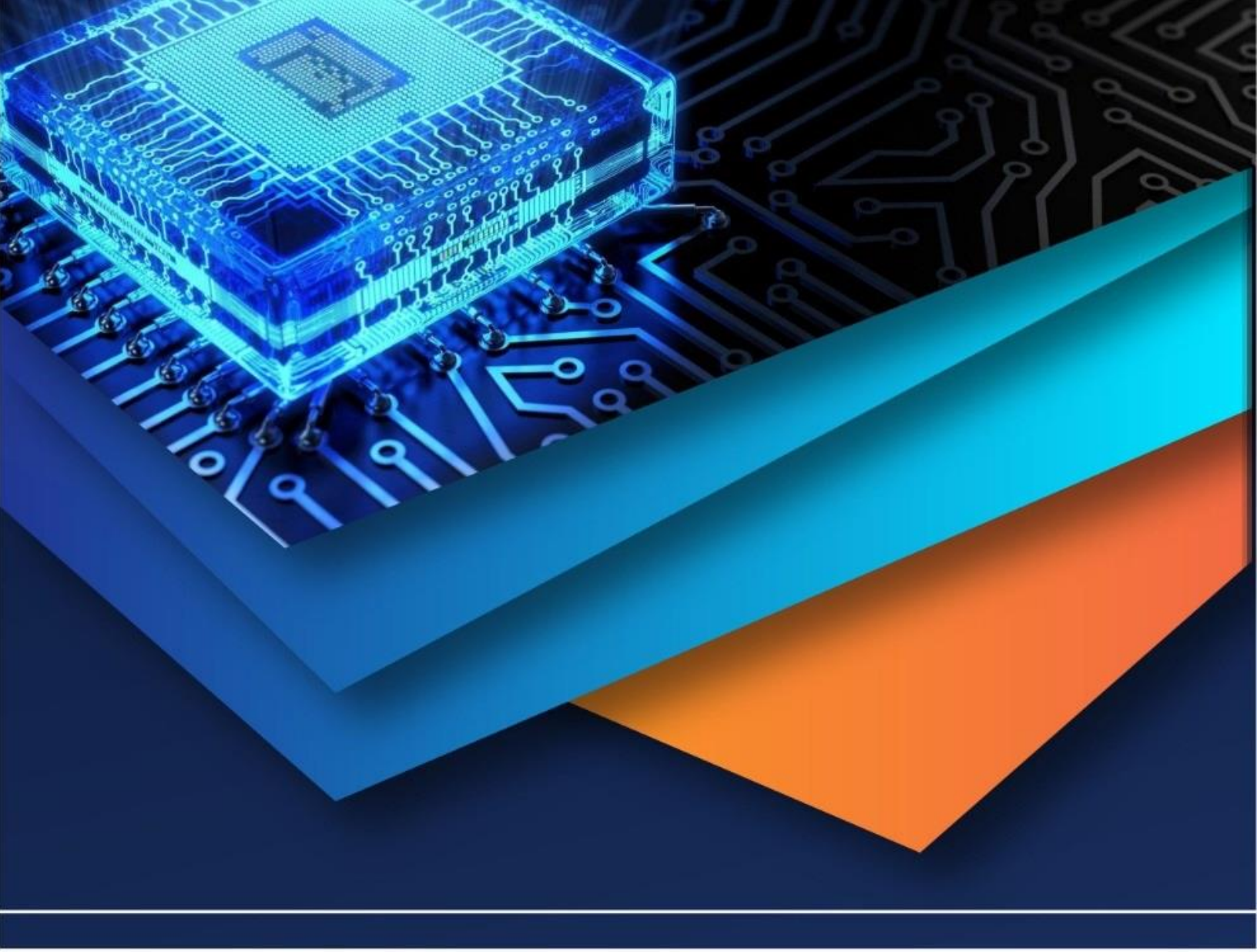
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