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RESEARCH ARTICLE

Breaking the Cross Compatibility Barriers of Extracorporeal Membrane Oxygenation by Streamlining the Design

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ABSTRACT

Extracorporeal Membrane Oxygenation (ECMO) is a Class C medical device under CDSCO, which suggests that the medical device is classified as moderate to high risk. It acts as an extended life support device for patients with severe heart and lung issues for a prolonged period of time, compared to heart-lung machines. There is a cross-compatibility barrier in the medical device market, wherein each manufacturer will make modifications to the design in order to make them exclusively compatible with the solutions and repair kits provided by the Original Equipment Manufacturer (OEM). The proposed solution in this paper helps counter the cross-compatibility barrier of ECMO machines, especially when it comes to the centrifugal pump, which must be changed multiple times over the lifetime of the device. We are introducing a novel design for the ECMO machine, wherein the existing centrifugal pumps in the market are compatible without interrupting the functionality of the device in case of emergency situations and cases of logistical delays. Our solution makes it possible to use any of the popular centrifugal pumps available in the market, making it cross compatible and more practical compared to the OEM solutions provided by the popular manufacturing companies.

Keywords: Extracorporeal membrane oxygenation, Heart-lung machine, Original equipment manufacturer, Cross-compatibility, Centrifugal pump, ECMO machine.

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INTRODUCTION

ECMO, or extracorporeal membrane oxygenation, is a life-support technology used to provide prolonged cardiac and respiratory support to patients who are having a severe failure in their heart, lungs, or both, wherein the patient needs the life support for a prolonged period of time, normally starting from days to months.[1] The concept of artificial oxygenation and perfusion support was applied in 1953 by Gibbon for the first successful open-heart operation.[2] ECMO machine provides life-sustaining oxygenation and circulation, acting as a bridge for recovery, transplantation and other treatment methodologies. It is typically used in critical care settings for patients with severe, life-threatening conditions where patients whose heart and lungs are unable to function adequately on their own.

Assessment of ECMO Machine Functionality

The concept of ECMO is basically to bypass the functionality of the heart or the lungs, as per the requirement of the patient.[3] The basic functionality of an ECMO machine is to take over the function of the heart and lungs, allowing them to rest and heal. The process is initiated by drawing blood from the patient's body with the help of a cannula inserted into the patient's body via an artery or vein. The collected blood from the body is then passed through a pump, which helps in circulating the blood within the ECMO circuit.[4] Further, the blood within the ECMO circuit goes through an oxygenator which basically functions similarly to the lungs, wherein the deoxygenated blood will be oxygenated and carbon dioxide will be eliminated.[5] Since the blood is leaving the patient's body, the same will be cooled down to room temperature due to heat dissipation. In order to compensate for the heat dissipation and maintain the normal body temperature, the oxygenated blood is warmed before returning the same into the patient's body.

Types of ECMO

ECMO can be classified broadly into two types based on the configuration of the connection on the machine with the

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patient. The two types of ECMO are Veno-Arterial (VA) ECMO and Veno-Venous (VV) ECMO.[6]

Veno-Arterial (VA) ECMO

As the name suggests, blood is drained from a large vein like the femoral or internal jugular vein and is returned to a large artery like the femoral or carotid artery. This configuration of ECMO will be mostly used in cases of severe heart failure or cardiac arrest, in addition to respiratory failure. Some of the applications of the same include cardiogenic shock, severe heart failure, cardiac arrest, post-cardiotomy heart failure, Bridge to heart transplant or Ventricular Assist Device (VAD).

Veno-Venous (VV) ECMO

Similar to what VA ECMO does, the process in this configuration is highly similar, wherein blood is drained from a large vein and returned to a large vein. Either separate cannulas are placed in the femoral and internal jugular veins or a dual-lumen cannula in the internal jugular vein is used in this configuration. This configuration of ECMO Acute Respiratory Distress Syndrome (ARDS), severe pneumonia, pulmonary embolism, severe asthma or COPD exacerbations, trauma-related lung injury, and bridge to lung transplant. Some of the applications of the same include Acute Respiratory Distress Syndrome (ARDS), severe pneumonia, pulmonary embolism, severe asthma or COPD exacerbations, trauma-related lung injury, bridge to lung transplant.

ECMO Machine vs Heart Lung Machine

Both ECMO machines and Heart Lung machines seem to be very similar in terms of their functionality, but there are some key differences between these medical devices.[7] Even though both play a critical role in saving the lives of patients during medical interventions, the ECMO machine focuses on providing long-term support for patients with severe heart and lung failure with different permutations and combinations, while the heart-lung machine is essential for maintaining normal blood circulation in the patient body, during major surgeries where the heart and lungs are involved. The heart-lung machine, also known as cardiopulmonary bypass machine, as the name suggests, will temporarily replace the functionality of the heart and lungs, which will enable the patient to survive through surgeries such as heart transplantation, by compensating the functionalities of the said organs, which can last for hours. On the other hand, ECMO or extracorporeal membrane oxygenation, is a medical device that will act as a temporary replacement for the functionality of heart and relatively lungs and vice versa.[8] The same is used for a prolonged period of time, ranging from days to months for patients with severely low-functioning heart and lungs. The proportion of functionality may vary between the two said organs, for which the configuration of ECMO will also vary.

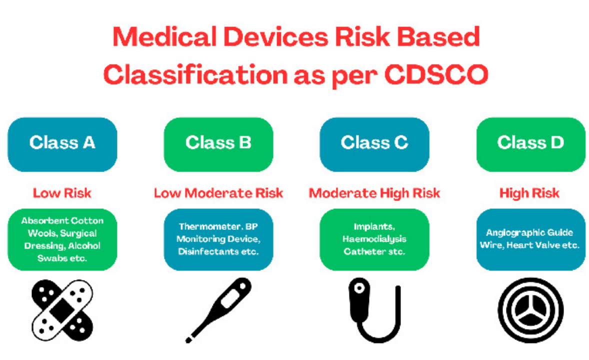

Fig. 1: Medical device risk based classification as per CDSCO

Classification of ECMO Machine under CDSCO

The Central Drugs Standard Control Organisation or CDSCO has classified medical devices into four categories:[9]

- **Class A:** Low Risk - Absorbent cotton wool
- **Class B:** Low Moderate Risk - Digital thermometer
- **Class C:** Moderate High Risk - Bone plate, bone screw
- **Class D:** High Risk - Heart valves

Refer to Fig.1 for more details regarding the classification of medical devices as per CDSCO. ECMO Machine is classified as a Class C medical device as moderate high risk under the cardiovascular category as an "Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure," which is supposed to support long-term respiratory/cardiopulmonary support for more than 6 hours, which assists in extracorporeal circulation and physiologic gas exchange for patients with acute respiratory failure or acute cardiopulmonary failure.

Brief market study of ECMO machines

As per a brief market study done informally from our side, it has been found that the Indian market is being dominated by two particular models of ECMO machines, namely the Rotaflow II System from Getinge,[10] which is a Sweden-based medical technology company and CentriMag System[11] from Abbott Cardiovascular, which is a US-based medical multinational company (MNC). As per sources, the Rotaflow II system demonstrated better hemodynamic performance compared to the CentriMag system. Also, the maximum flow rate of the Rotaflow II system (9.08 L/min) is higher than that of the CentriMag system (8.37 L/min).[12] The Rotaflow II also had a higher shut-off pressure, indicating less retrograde flow. Studies show that the Rotaflow II system has lower levels of red blood cell damage (hemolysis) compared to the CentriMag system.[13]

Functionality of centrifugal pump

The centrifugal pump plays a crucial role in the functionality of ECMO machines, as shown in Fig.2, by maintaining the circulation of blood through the ECMO circuit14. Some of the primary functions of the centrifugal pump in the ECMO machine include the following.

- *Blood circulation*

This is the primary function of the centrifugal pump, wherein it drives the blood from the patient body towards the ECMO circuit, ensuring continuous blood flow.[15]

- *Pressure regulation*

As the centrifugal pump controls the blood flow rate, the same

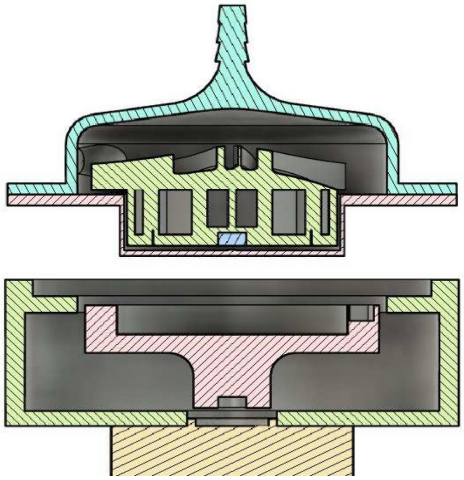

Fig. 2: Proposed Solution of Custom Centrifugal Blood Pump Holder

can be utilised for the regulation of the blood flow pressure. The same has to be maintained in order to avoid change in blood pressure within the ECMO circuit, causing problems while delivering the oxygenated blood back to the patient body.

- *Minimizing trauma to blood cells*

Blood cells can easily be damaged due to any external pressure or improper management, making them unviable for oxygenation.[16] The centrifugal pumps, especially the ones being used in the ECMO machines, are designed to be gentle, reducing the risk of destruction of red blood cells or hemolysis.

- *Ensuring consistent oxygen delivery*

Centrifugal pumps help in consistent oxygen delivery for the red blood cells within the ECMO circuit, by maintaining a stable and controlled blood flow. The consistent blood flow allows efficient gas exchange, ensuring that the blood returning to the patient is properly oxygenated and free from carbon dioxide.

Need and Frequency of Replacement of Centrifugal Pump

As mentioned in the functionality of centrifugal pumps, they play a major role in the proper and smooth functioning of the ECMO machine.[17] The centrifugal pump is essential for the proper circulation of blood throughout the ECMO circuit while maintaining blood pressure. The pressure regulation function of the ECMO machine helps minimize trauma to blood cells, especially the RBCs, preventing hemolysis. It also ensures the consistent oxygenation of the red blood cells, making it more efficient and effective.

As mentioned earlier in this paper, there are two different types of ECMO machines, which have been classified according to the configuration in which the cannula is being connected to the patient body. Each type of ECMO configuration demands a different replacement cycle for the centrifugal pump. The same depends on the type of application as well as the type of configuration used on the patient. The replacement cycle can vary between days to months according to the use case. The main reasons for the need for replacement of the centrifugal pumps in the ECMO machines is because they are prone to causing thrombus formation. Additionally, the heat generated by the bearings of the centrifugal pump as well as the durability, is limited due to the extreme conditions and pressure the pump is being exposed to.

As per some of the studies conducted and approvals given by medical device regulatory bodies, such as the Food and Drug Administration (FDA), European Medicines Agency (EMA) and Central Drugs Standard Control Organisation (CDSCO)[18] we have tried to identify the replacement cycle of the centrifugal pumps for different models which are available in the market. The approved replacement cycle for an ECMO machine as a right ventricular assist device (RVAD) is 30 days, but on the other hand ECMO machine as left ventricular assist device (LVAD), the replacement time is drastically reduced to 6 hours. On average, the replacement of the Centrifugal Blood Pump can be done around 10 to 14 days.[19]

Challenges in Cross-Compatibility

One of the major inconveniences faced by the hospitals is to get the replacement of Centrifugal Blood Pump for ECMO machines done. Especially in India, due to the hurdles in logistics and problems faced in the replacement, wherein the equipment manufacturer recommended service personnel have to do the replacement for the particular model making it a bad experience. The same is applicable to the service company, where the supply and replacement have to be streamlined, as the replacement is very frequent compared to other medical equipment services, even though the process of replacement is simple.

Another issue faced by hospitals in this area is the cross-compatibility issue, wherein a centrifugal pump, which a company manufactures will not be compatible with any other model of the ECMO machine, making the replacement process even worse. The same is done in order to provide a streamlined and effective design, but the trade-off factor becomes cross-compatibility. Even though a hospital is having a supply of more than a sufficient number of Centrifugal Blood Pump replacements, the same will only be compatible with the model of ECMO machine it has been designed for, making it even harder for the healthcare service providers.

Solving the Cross-Compatibility Barrier

The above-mentioned cross-compatibility issue has been found as a genuine problem faced by healthcare service providers, wherein, they have to depend on external authorized service companies for the replacement to be done, which is time-consuming and has many logistical challenges. The same can be approached for solutions in two ways, which include designing and making a universally compatible Centrifugal Blood Pump,[20] that is easy to replace by any healthcare service provider or to design an ECMO machine that can support any Centrifugal Blood Pumps that are readily available in the market.

We tried approaching both of the possible solutions to find the most feasible and practical one possible. Even though the former solution sounds better and easy to implement, by just designing a simple, universally accepted Centrifugal Blood Pump, there are many challenges that have to be surmounted for the same. Each ECMO machine will be designed differently, to accommodate the most effective solution a manufacturer can provide and the difference between two devices can be miles apart. It is important to consider the design changes that different manufacturing entities can bring which necessarily cannot be accommodated by the centrifugal pump.

Proposed Solution

As mentioned above in the paper, the two solutions are being analyzed and since the former solution is practically not possible to implement effectively for long-term support, we tried to approach the latter. This involved the design and development of a working ECMO machine that can accommodate the currently existing models of Centrifugal Blood Pumps wherein the replacement process has to be simplified and can be performed by any healthcare service provider within the hospital environment. This approach seemed more likely to work, as the primary design of the Centrifugal Blood Pump holder will be that of the proposed design mentioned in this paper, which can be supported by all the existing Centrifugal Blood Pumps available in the market, and if a newer design comes to the market, we have the luxury of making compatible adaptors for maintaining the cross-compatibility factor within the system or ecosystem of ECMO machines between the manufacturers and hospitals, solving the problem of logistics as well as need for a dedicated service personnel who belongs outside the hospital-manufacturer ecosystem.[21]

The design developed by us is shown in Fig. 2 demonstrating a custom-made holder for the ECMO machine, which has its own dedicated Centrifugal Blood Pump which can be utilised for the proper functioning of the ECMO machine.

In Fig. 3, the bottom section shows the Centrifugal Blood Pump holding part where the pump will be placed in position for the proper functioning. The design is tailored in such a way that the replacement of the Centrifugal Blood Pump can be done by any of the trained healthcare service professionals, who come under the hospital ecosystem, making it easier to access than the models of ECMO machines previously available in the market. The proposed design shown in Fig. 3 was fabricated and tested for real world testing. You can refer to Fig. 4 for the prototype of the proposed design.

Cross Compatibility of Proposed Solution

As we found in the market study done informally, focusing India as the primary market, we are taking Rotaflow II System and CentriMag System as the reference as these are some of the most populated ECMO machines within the hospital ecosystem. As we have designed and fabricated the prototype of the proposed design, the same was being used for testing the compatibility of the Centrifugal Blood Pumps from the mentioned models, which are readily available in the market and are being vastly used. The same has been divided into two cases as given below:

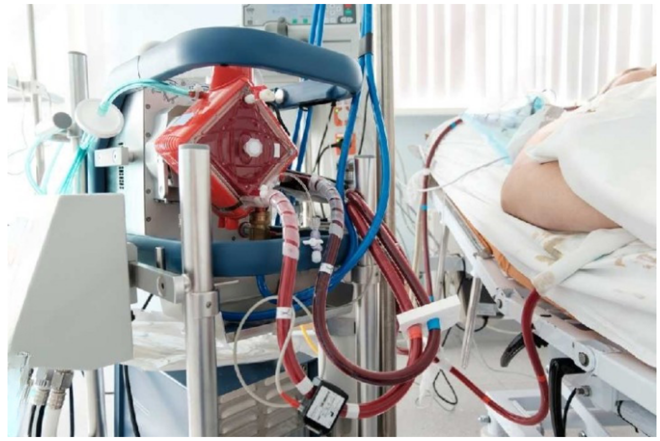

Fig. 3: Extracorporeal membrane oxygenation machine

Case 1

The prototype was checked for compatibility with the solution provided in the Rotaflow II System for the Centrifugal Blood Pump. The same was found to be directly compatible with the prototype proposed and designed as mentioned in this paper. For reference, Fig. 5 depicts the 3D model designed, wherein the bottom part of the same shows our solution of ECMO machine and the top portion denotes the Centrifugal Blood Pump provided in the Rotaflow II System. This shows the successful integration of the Rotaflow Centrifugal Blood Pump in the proposed design in this paper.

Case 2

The proposed prototype was checked for compatibility with the solution provided in the CentriMag System for the Centrifugal Blood Pump. It has been found to be not compatible with the design which has been depicted in Fig. 3. In order to solve this problem, we approached to design and develop an adapter, which can make the Centrifugal Blood Pump compatible with the proposed design. The same was designed, fabricated and tested for compatibility. The same has been found to be compatible with the proposed design of the ECMO machine, wherein, with the help of the adapter, we are able to make the Centrifugal Blood Pump compatible with our system. The

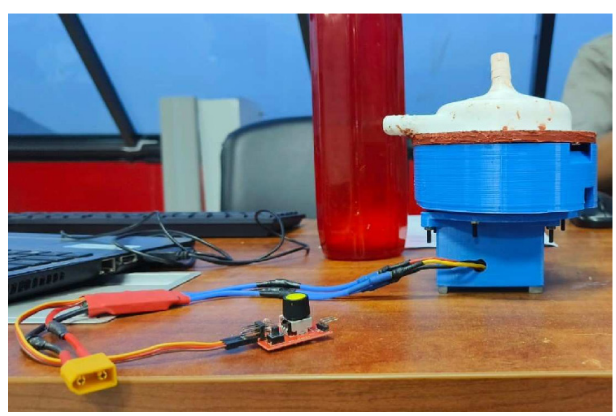

Fig. 4: Fabricated Prototype of Proposed Solution

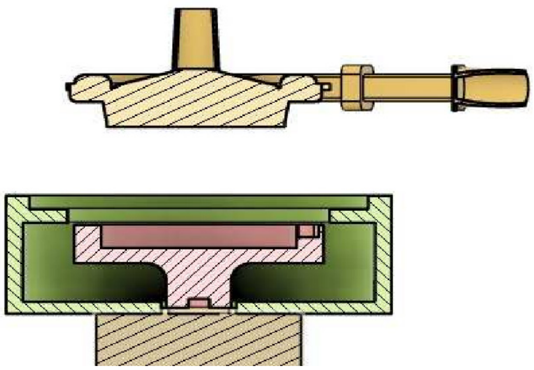

Fig. 5: Rotaflow Centrifugal Blood Pump with Proposed ECMO Machine

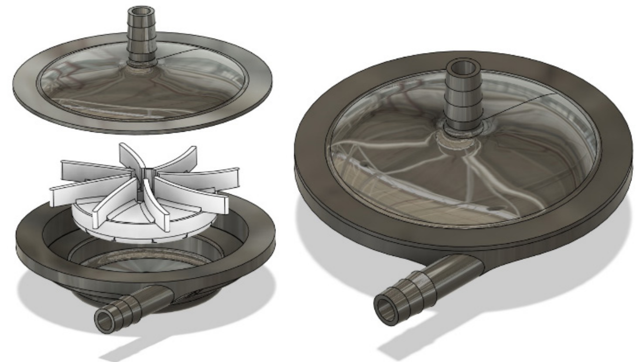

Fig. 7: Modified Design with Better Vacuum Creation

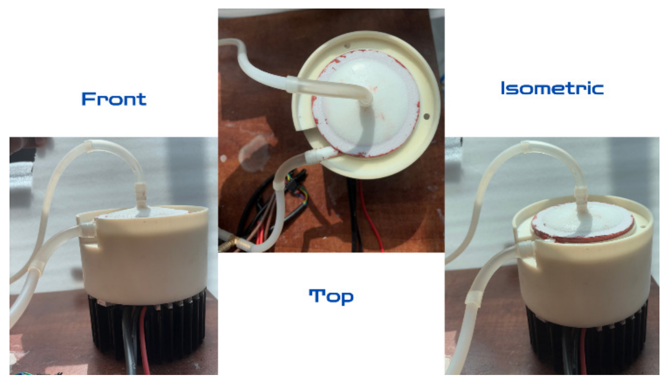

Fig. 8: Fabricated Prototype with Modified Design

design can be seen on Fig. 6, wherein, the bottom part shows the proposed design of the ECMO machine, the middle portion shows the adapter designed and developed exclusively for the CentriMag System Centrifugal Blood Pump.

Testing and Design Modifications

A proper setup to simulate and understand the functionality of the developed centrifugal blood pump was developed to understand the feasibility of the design and whether the proper functionality has been achieved or not. The results were unsatisfactory, as the blood pump was not generating enough vacuum to produce enough action for the flow of blood. So, a major redesign in the blood pump was designed, as shown in Fig. 6 and has been made as shown in the Figs 7 and 8..

The space within the cavity of the centrifugal pump has been modified in such a way that it will generate adequate vacuum for the proper functioning of the system. But one of the downsides of this design is the minimal compatibility of the centrifugal blood pump with CentriMag. The system is easily compatible with Rotaflow II system as well as the proprietary ECMO machine design, making it functionally as well as compatibility wise better.

Following is the output received from the setup which simulates the functionality of the centrifugal blood pump, which is showing positive results.

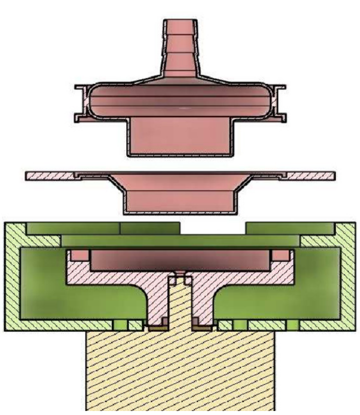

Fig. 6: CentriMag Centrifugal Blood Pump with Proposed ECMO Machine

RESULT AND OUTCOMES

The results presented in this article align with ongoing efforts in the medical device field to address the compatibility limitations of life-support equipment like ECMO, especially considering its classification as a moderate to high-risk device by CDSCO. Previous studies have highlighted the challenges posed by proprietary OEM restrictions, which limit component interchangeability and can complicate logistics, especially in critical situations where rapid component replacement is required. This paper's novel approach of designing an ECMO system compatible with widely available centrifugal pumps could significantly ease these logistical challenges and improve patient care by reducing dependency on specific manufacturers. However, a limitation to consider is the potential need for rigorous testing to ensure that cross-compatible components maintain safety and efficacy across various brands and emergency conditions. Further research could validate

Table 1: Speed vs Flow Rate

S. No.	*Speed*	*Flow Rate*
1	1500 rpm	2 l/min
2	2000 rpm	3 l/min
3	3000 rpm	4 l/min
4	4000 rpm	5.5 l/min
5	6000 rpm	7 l/min

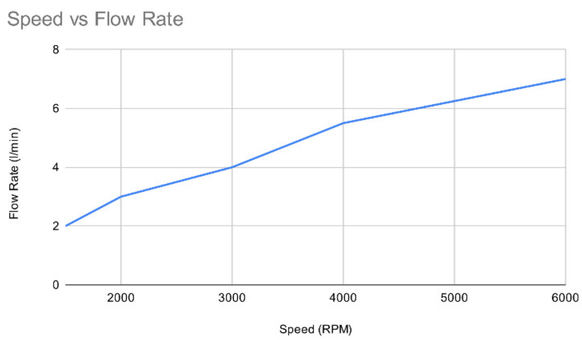

Fig. 9: Graph of Speed vs Flow Rate

these findings and explore broader applications, potentially encouraging more flexible designs in other high-risk medical devices.

In pursuit of addressing the cross-compatibility problem, this paper details the design and development of a working prototype for an ECMO system's centrifugal blood pump holder and motor. The two approaches considered were creating a universally compatible centrifugal blood pump and developing an in-house ECMO machine.22 While the former approach faced insurmountable challenges, the latter emerged as a more practical solution. The in-house design was successfully fabricated and tested for functionality and cross-compatibility, demonstrating its feasibility as an effective alternative. The output from the said setup is depicted via a graph shown in Fig. 9, wherein the values are justified in Table 1.

Compatibility tests conducted with two widely used centrifugal blood pumps yielded positive results. In Case 1, the Rotaflow II System demonstrated compatibility with the proposed design without requiring additional adapters. In Case 2, the CentriMag System required a custom adapter for integration, which was successfully developed, making it compatible. These outcomes underline the practicality and functionality of the proposed design in addressing cross-compatibility issues. Further validation and refinement of this system could significantly enhance accessibility and ease of use in ECMO applications while supporting seamless integration across diverse healthcare setups.

CONCLUSION AND FUTURE PROSPECTS

This paper addresses the critical issue of cross-compatibility in centrifugal blood pumps for ECMO machines, a significant logistical and operational challenge in the medical device industry. By proposing a streamlined ECMO machine design that accommodates pumps from various manufacturers, this research presents a practical solution that eliminates reliance on proprietary OEM components, thereby improving system flexibility and reducing logistical constraints. The approach also aligns with broader efforts in the medical field to design safer and more adaptable high-risk devices like ECMO systems.s Through the evaluation of two approaches—developing a universally compatible pump versus designing an ECMO system compatible with existing pumps—this study validates the practicality of the latter. A prototype was developed and successfully tested with pumps from the Rotaflow II and CentriMag systems, demonstrating seamless compatibility. These results suggest that the proposed design not only resolves compatibility barriers but also enhances the usability and maintainability of ECMO machines in critical care settings.

Future work will focus on refining the design to extend compatibility with other available pumps through adaptable interfaces.[23] Additional testing, including clinical trials, will be essential to validate the long-term safety, reliability, and performance of the system in diverse healthcare environments. This research paves the way for the development of more flexible, efficient, and patient-centered ECMO systems, contributing to improved outcomes in life-support scenarios.

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