QATAR UNIVERSITY

COLLEGE OF ENGINEERING

THE NEXT GENERATION ECMO CANNULATION TRAINING SYSTEM

BY

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ABSTRACT

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Title: The Next Generation Cannulation Simulator

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Extracorporeal membrane oxygenation cannulation (ECMO) is a life-saving procedure that temporarily replaces the cardiopulmonary system. To enable the procedure, one must apply cannulation to reroute the blood to the ECMO machine. Simulation based training (SBT) is proved to improve the performance of medics especially for critical procedures such as ECMO. The current pandemic proved the need for electronic cardiopulmonary resuscitation, as COVID-19 causes heart and lung failure. The proposed solution is a SBT that tackles designing and implementing a human circulatory emulation system for the context of ECMO. The thesis summarizes the technologies used in the state-of-the-art critical care human circulatory systems, focusing on cannulation, catheterization, and auxiliary devices. The solution is part of the overall ECMO SBT environment subsystem. The cannulation simulator comprises the closed-loop, cannulation access points, and embedded system. The closed-loop is the physical emulation of the blood vessels. A cannulation access point is the emulated entry area of the cannula in the femoral and jugular region. The embedded system is the system’s brain that controls the system transducers. The main parts of the system were completed successfully. This work offers organizations summery of existing emulators to get familiarized with the state-of-the-art technology and expand to implement the more extensive reach of state-of-the-art embedded system practices.

DEDICATION

I dedicate this thesis to my late father and my resilient working mother, that supported me my whole life and was my idol.

Also, dedicating the work to my community and people by helping provide affordable life-saving procedures training.

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CHAPTER 1: INTRODUCTION

Extracorporeal membrane oxygenation (ECMO) is a life-saving medical procedure with a relatively long-term respiratory and circulatory time compared to the typical ventilator. ECMO team is a multidisciplinary team that encompasses medical doctors, perfusionists, and nurses. ECMO is commonly used in cases where time needs to be bought for the body to recover from injuries sustained infections on the heart and lungs. To connect the machine to the body, one must perform cannulation to reroute the blood to the ECMO machine.

ECMO Cannulation is the act of passing a cannula through the human body to reroute the blood to the ECMO machine. The guidewire is inserted into the femoral region through the veins/arteries. Guided with an ultrasound device, the guidewire of the cannula is navigated through the patient's blood vessels to reach the heart in the case of the vein and reach the end of the femoral artery. After the guidewire reaches its desired location, A small cannula dilates the pass. Then, another bigger canula is finally used to direct the blood to the ECMO machine. Figure 1 shows the guidewire and the cannulas used for ECMO cannulation.

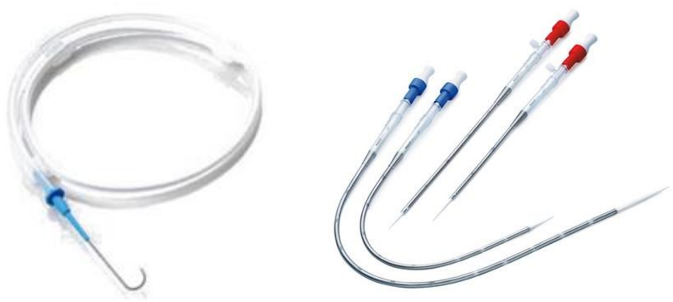


Figure 1. Cannulation tools guidewire (left), cannula (right).

The cannulation process is considered extremely dangerous as the guidewire could potentially cause fatal internal hemorrhage and the possibility of bleeding out from the insertion wound. In the case of a cardiac arrest, the body has 60 minutes before there is irreversible damage to the body, including the transportation of the patient; therefore, the fast reaction from the multidisciplinary ECMO team could mean the difference between life and death [1]. To prepare a medical team for using the ECMO machine and cannulation, there needs to be a risk-free and immersive environment to allow the team to harness the skill of ECMO cannulation safely.

Simulation-based training (SBT) provides a great solution and improves the cost efficiency of ECMO training as non-medical emulation of the ECMO-related devices is used [2], [3]. SBT excels in training multidisciplinary teams such as ECMO, which has a diverse team of perfusionists, doctors, and nurses [4]. In collaboration with Hamad medical corporation (HMC), Qatar university started developing a highly realistic, immersive, and cost-efficient ECMO SBT system. This thesis discusses the simulator’s features and delves into the design and implementation. While also, reviewing the existing human circulating simulation-based training.

1.1 Problem definition

In the rise of COVID-19’s pandemic, with the development of the disease into new variants, the need for patients to be put on ECMO while they recover increases. ECMO also represents a valuable resource for Qatar as the country has a high car accidents rate. In addition to ECMO providing a last resort to patients with a disease that requires the patient’s lungs and heart need to heal. To connect ECMO, one must perform cannulation to the patient, which entails inserting cannulas through the femoral region to reroute blood from the body to the machine. Because cannulation is clinically intensive, organizations teach their learners using simulation-based training to provide a highly immersive and consequence-free environment. Therefore, QU joined teams with Hamad medical corporation to develop high fidelity, cost-efficient

ECMO cannulation system. The small population of Qatar causes it to have a shortage in ECMO training as learning by shadowing is usually limited in addition to the inability to train on rare clinical such as the chance of the patient suffering from a seizure mid-cannulation. Qatar usually relies on expensive training abroad that. Therefore, a local SBT with advanced technology would help in providing cost efficient self-reliant training in addition to making Qatar a center of ECMO cannulation training in the gulf region.

1.2 Thesis methodology

The multidisciplinary project was divided into tasks that are based on its discipline. The disciplines included in the project are medicine, electrical and mechanical engineering. A literature review is a task that entails looking into the medical background of the human circulatory system to be emulated and the existing electrical and mechanical systems used to emulate it in the existing literature. Medical imaging of cannulation access points and stopping points of cannulas were studied to apply biomimicry in the design and implementation of the system. Twenty-two simulator systems were studied and rated to check existing work and inspire state-of-the-art technology. Reconstruction of the loop is a task that discusses creating a high physical fidelity loop to emulate the human circulatory system. Design and implementation of the embedded system are task-centered around choosing, testing, and designing the transducers and their circuits. Design and implementation of procedural emergencies are about studying existing medical emergencies and emulating them using electrical and mechanical systems, then applying biomimicry to emulate clinical emergencies. The overall ECMO system environment is to be integrated using an app. Finally, documentation represents documenting the project in the thesis and journal papers.

When designing the proposed cannulation system, the following aspects have to be considered:

1)Conceptual Fidelity; 2) Physical Fidelity; 3) Psychological fidelity; 4) cost; 5) Environment; 6) Maintainability; 7) Ingress protection; 8) Reliability; 9) Transient response;

The core standards came from the three aspects of fidelity, as they represent the main parts of a successful emulation. Lastly, the cost, maintainability, and environmental aspects come from the Ingress Protection (IP) table, reliability, and noise reduction, followed by the transient response. Conceptual fidelity measures how effective the SBT is at explaining concepts to the learners assessing the learners, and triggering educational scenarios to boost conceptual fidelity. Physical fidelity represents the ability of the simulator to imitate a natural human circulatory system. Ultrasoundable cannulation access points, mold designs based on medical imaging, and alternative routes for the cannula are all implemented to improve the physical fidelity. Psychological fidelity is the ability of the simulator to immerse the learner in the experience and put them in a state of high stakes: the procedural emergency and alert system help boost the psychological fidelity. The cost of the cannulation emulator is to be optimized to disrupt the high market cost and is set to 225$. Maintainability is a metric of how easy to fix damaged parts of the emulator; this is achieved by using off-the-shelf components. Environment limitation is the noise level recommended for hospitals and educational spaces set as 25db of SPL [37]. Ingress protection (IP) measures how shielded the system is from dust and water. The estimated IP of the system is X4 as in resistance to jets of water. Reliability is the probability of the system turning on every time used. Transient response measures the time the system needs to reach a functional state. Transient response was assigned a lower rate because the project was prototyping.

1.3 Thesis structure

The thesis comprises six chapters: introduction, literature review, proposed plan system, system implementation and results, discussion, conclusions, and future work. The introduction explains the basic idea of the thesis, problem definition, thesis methodology, proposed system standards, and thesis structure. The literature review includes the human circulatory system description and medical imaging showing the human body, discussing the state-of-the-art technology in human circulatory simulation, and rating them accordingly. The proposed plan system discusses the main aspects of the system and divides the system into three subsystems, the closed-loop, cannulation access points, and the embedded system. Similarly, System implementation discussed the results of the three main subsystems and how their designs were realistically implemented using additive manufacturing. The discussion delved into the problems encountered in the project and their importance. Lastly, conclusions discuss the work’s impact and surmise what was done throughout the thesis.

CHAPTER 2: LITERATURE REVIEW

To professionally design and implement a simulation-based training system for ECMO cannulation, one must review the anatomy of the human circulatory system and the existing simulation-based training systems.

2.1 Anatomical Review

When reviewing the human circulatory system from an SBT perspective, three main aspects are considered the focal points of the review (i) Heart; (ii) Blood vessels; (iii) Access points.

2.1.1. Heart

The heart is considered the central aspect of the human circulatory system as it pumps blood to the whole body. Since it is a cornerstone of the circulatory system, many critical care procedures cater to resolving issues in the heart. Therefore, having an accurate representation of the heart is quintessential to the success of the learning process. A computerized tomography (CT) scan of the heart could be seen in Figure 2, and to emulate it in a dual loop system, the heart can be divided into two regions. The key features are the big bulge which includes the right ventricle, left ventricle, and right atrium seen in region B. In addition, region A consists of the aorta, which is the artery that feeds the whole body with oxygenated blood [5].

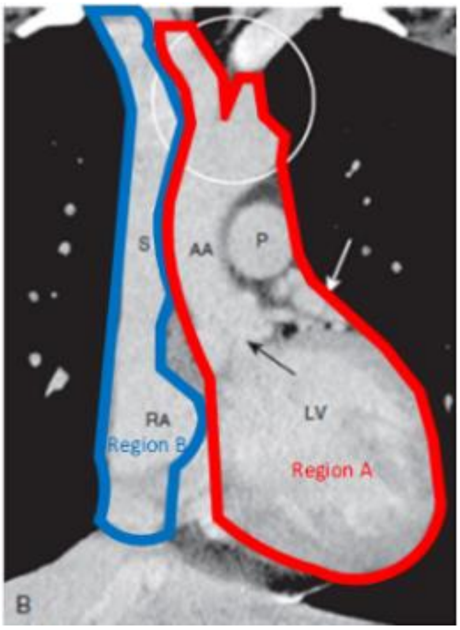


Figure 2. CT scan of the heart region. [5]

2.1.2 Blood vessels

Blood vessels are essential for SBT. Usually, when an operation is done on the heart, the clinicians cannot simply do it directly. That might risk damaging the heart, so one usually inserts one's tool into the blood vessels and passes it to the heart to decrease the procedures' invasiveness. The outer wall of the arteries is thicker, and its inner diameter is smaller than the veins [6].

2.1.3. Access points

The access points are essential to the training process because the entry point of the procedure tool is the first invasive step of surgeries and carries the risk of bleeding. In most invasive procedures, the access point is where the tool enters the circulatory system and is usually pricked by a needle to make an entry point. The tool is inserted after creating an entry point, such as a cannula in cannulation. Common access points are femoral and jugular blood vessels as they can provide enough space for the large bore cannula size required for ECMO and cardiac catheterization. Figure 3 shows the ultrasound of the femoral access point ultrasound is used as it is the expected standard for guiding procedures that involve the blood vessels as it can go through tissue and show the blood vessels. In Figure 3, the ultrasound of the femoral region is seen. The veins are about twice the size of both arteries combined. It is seen arteries are situated on top of the veins and remarkably close to them. The targeted artery is the common femoral artery to fit the desired cannula. Common femoral arteries split into two branches deep femoral artery (DFA) and the superficial femoral artery (SFA). The SFA is the artery that feeds the leg and should typically be avoided to keep blood flow in the leg [7].

Figure 3. Ultrasound of the femoral region.[7]

2.2 Existing Simulators

This section reviews two critical-care procedure simulators for the human circulatory system: extracorporeal membrane oxygenation (ECMO) cannulation and cardiac catheterization. ECMO is used as a relatively long-term ECPR and respiratory system [8]. Also, for the ECMO machine to be connected to the patient's body, one must undergo an intensely invasive procedure called cannulation. Cannulation is passing the cannula from the cannulation access point (i.e., Femoral or jugular region) through the blood vessels to the desired location. The desired location for the arteries is aortal bifurcation. The desired location for the veins is the inferior vena cava right below the heart near the hepatic vein [9]. Cardiac catheterization is passing a catheter from the femoral or radial region to the heart to unblock the Coronary artery or any blood vessel, injecting contrast dye to observe the heart clearly under X-ray or fix congenital disabilities in the heart [10]. The catheter and the cannula travel in the blood vessels risk contact with organs, potentially leading to fatality. Auxiliary medical equipment is an integral part of medical procedures. They monitor vitals and assist in the body's healing process by providing organ functionality while the organs heal. Therefore, incorporating auxiliary medical equipment in the emulation is quintessential. Figure 4 shows the taxonomy of the literature review where the simulators are categorized into simulators with a focus on ECMO, cardiac catheterization, and simulators work based on the auxiliary device simulation such as de-signing an ECMO machine or an ultrasound machine simulator.

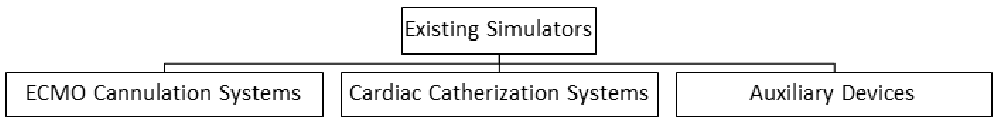


Figure 4. Review taxonomy.

2.2.1. Methods

In this subsection, the criterion of evaluating the existing work is discussed and analyzed. All the surveyed simulators are from academic literature, and the commercialized ones are available. The main evaluation points are fidelity and cost, usually tradeoffs. Multiple aspects of fidelity are observed when discussing fidelity, including conceptual fidelity, physical fidelity, and psychological fidelity. Conceptual fidelity is concerned with the sequence of events that the simulation-based training provides conceptual context to the learner. Experts could assess conceptual fidelity in the field and surveys before and after the training [11]. Physical fidelity measures how the simulator resembles a human circulatory system from the feeling to the guiding methods through the system, including fluoroscopy and ultrasound [12]. Psychological fidelity is concerned with how immersive the SBT experience is and the system's capability to duplicate the pressure in such engaging medical procedures. Cost as a criterion encompasses instantaneous cost and maintenance cost as they both equally contribute to the overall cost of some of the suggested solutions. The point of highlighting fidelity and cost is to showcase the aspect of cost effectiveness as most of the commercialized simulators have mediocre fidelity and a high price. This thesis is a guide to developing a sense to the cost of some features in order to guide the readers in designing the highest cost-effective simulators.

2.2.2. ECMO Cannulation Systems

Existing HCSC ECMO cannulation simulators in this subsection are analyzed and reviewed based on cost and fidelity. The considered simulators are from both academic research and commercialized simulators.

2.2.2.1 Cadaveric ECMO Cannulation Simulator

According to the authors, although medical cadavers have been previously employed for endovascular procedural training, the authors present the first transparent novel model capable of functional venous and arterial ECMO cancellation. A novel perfusion-capable mannequin simulation has been used to provide high-fidelity training in ECPR-related crisis resource management areas. Yet, the technical aspects of cannulation are challenging to recreate. This simulator has high physical fidelity as it uses real cadavers and average conceptual and psychological fidelity. Due to that, the cost of this simulation-based training is high. The cost is high because cadavers are not easy to acquire and are costly. Also, when training is done on such systems, disinfection of the whole system is required after the training to avoid infection to learners and uphold hygienic standards [13].

2.2.2.2 A High-Fidelity Surgical Model and Perfusion Simulator

An ECMO cannulation simulator for a neonatal model is presented in the manuscript [14]. The overall system seems cost-efficient, simplistic, and has mediocre overall fidelity. There is almost no heart emulation as it is a simple change of tubes. In addition, the blood vessels are not sufficiently realistic as there is no distinction between arteries and veins anatomy-wise which makes the physical fidelity lower. The simulated blood pressure is inaccurate as no pumps are used. No false simulated paths decrease the conceptual fidelity as the trainees would not differentiate between the arteries and veins. Lastly, the jugular cannulation access point is relatively realistic as it includes multiple layers that resemble flesh, blood, and skin. In addition, the tubes are of the 8 Frenches size as the cannula, which boosts the conceptual fidelity [14]. Figure 5 shows the proposed neonatal cannulation simulator.

Figure 5. Neonatal ECMO cannulation simulator [14].

2.2.2.3 ECMO Professional Simulator

Erler-Zimmer commercializes an adult cannulation simulator that is highly realistic and could simulate multiple scenarios but comes with a hefty price tag of around 19.4k USD, seen in

Figure 6. Although the heart is vital as a stopping point, it does not seem that the simulator includes an emulation of the heart, which lowers the physical and conceptual fidelity. The blood vessels are realistic flow-wise and customizable enough to simulate different scenarios. They have dual loops, including arteries and veins, as seen in

Figure 6, which significantly boosts physical and conceptual fidelity and allows for various scenarios. However, the blood vessel's emulation is not anatomically accurate from the sense of wrong tracks the guidewire can go through, which lowers the clinical fidelity. Lastly, the access points are ultrasound-able, boosting the conceptual fidelity and cost-efficient as the sizes are optimized. Still, the mold is not provided to fabricate the cannulation access point. Due to the simulator's unrivaled versatility, the overall fidelity is high [15].

Figure 6. Erler Zimmer adult cannulation simulator [15].

2.2.2.4 An extracorporeal membrane oxygenation cannulation curriculum

The research team is developing a neonatal cannulation simulator with high physical fidelity at the cannulation access points. This simulator has no heart emulation, focusing on the cannulation access point. The blood vessels have simplistic flow and only simulate the veins loop, decreasing the conceptual fidelity as fewer scenarios could be simulated. The cannulation access point is highly sophisticated as it has a lot of scenarios and includes blood oozing and other scenarios that make the simulator have high physical fidelity and increase the conceptual fidelity [16]. Figure 7 shows the simulator and oozing feature.

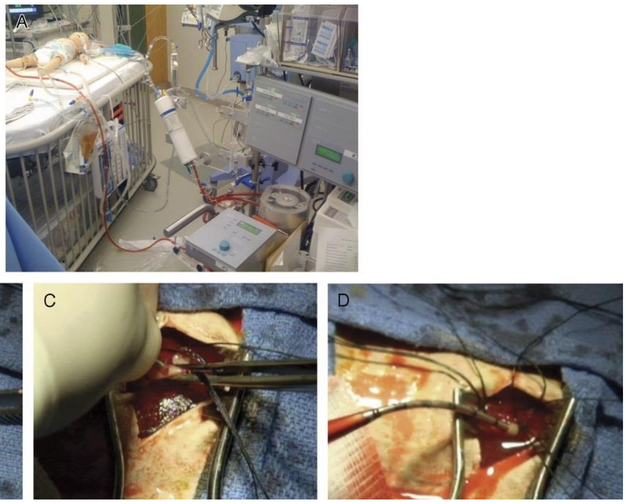


Figure 7. Neonatal ECMO cannulation simulator featuring oozing [16].

2.2.2.5 Neonatal cannulation simulator

The cost-efficient research team presents a neonatal cannulation simulator. There is no emulation of the heart in the simulator despite its necessity in identifying the stopping point of the guidewire and the cannula, which lowers the physical fidelity. The blood vessels are overly simplistic and contain only one loop with constant flow lowering the conceptual fidelity. The cannulation access point is not ultrasound-able, which decreases the conceptual fidelity of the simulator seen in Figure 8, which makes the overall fidelity of the simulator low [17].

Figure 8. Neonatal ECMO cannulation simulator [17].

2.2.2.6 Adult cannulation simulator

The research team developed a cost-efficient adult cannulation simulator that only costs around 100 USD per simulator. The simulator does not include a heart emulation which lowers the physical and conceptual fidelity. However, the blood vessels are of descent physical fidelity. Despite having one closed-loop, the tube circles back to make the other loop, which gives a dual loop with a single one. The cannulation access point is not good physical fidelity, which lowers the emotional fidelity that is especially important for the overall process. Still, it is very cost-efficient and emulates dilation [18]. The Endo circuit diagram can be seen in Figure 9.

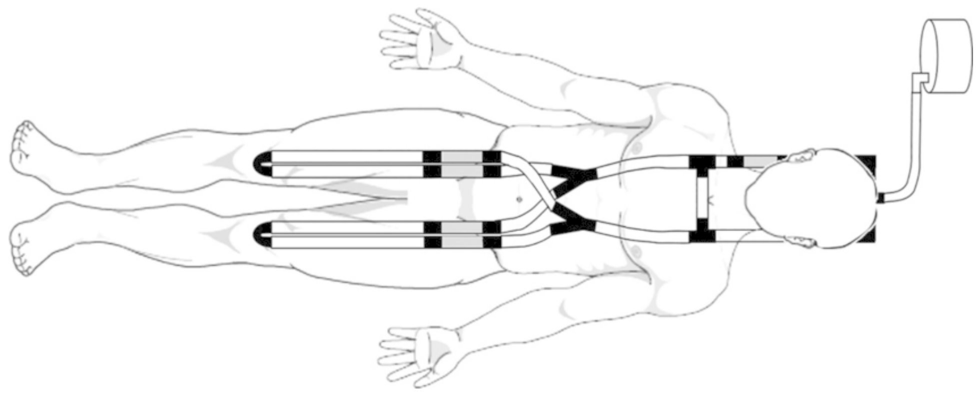


Figure 9. Endo circuit adult cannulation simulator [18].

2.2.2.7 ECPR simulation training mannequin

Pang showcases a simulator where 3D printing was used to create a robust ECPR training mannequin. A commonly available regular CPR mannequin with an airway feature was used as a base case for adjustment. A low-cost 3D printer was printed a modular plastic pelvis, improving its physical fidelity. A gravitational vascular system produced a medical silicone gel to simulate the femoral silicone vasculature. The outcome is a modified mannequin, part of the modular in-house ECMO cannulation and vascular structures combined with commercially available airway and CPR components, making the overall fidelity average. The total cost of developing the simulator was valued at 1,394 USD, seen in Figure 10 [19].

Figure 10. 3D Printed ECMO cannulation simulator [19].

2.2.2.8 ECMO surgical cannulation simulators

McMullan et al. proposed a novel surgical neonatal cannulation simulator. The simulator uses affordable, silicone-based ECMO cannulation systems and commercially available silicone pads combined to reproduce layers of skin, subcutaneous tissue, blood vessels, and bones, improving the physical fidelity. The authors are working on a percutaneous cannulation simulator designed to reproduce the cervical cannulation with dual-lumen VV ECMO cannulas. The focus increases the conceptual fidelity of the system. Its low cost makes it desirable and easy to produce. Still, its limited physical and conceptual fidelity sets it back as the pumping is primitive, and the system has limited scenarios to enact [20].

2.2.2.9 Training the component steps of an ECMO cannulation

The authors developed a cost-efficient ECMO cannulation simulator containing arterial and veins cannulation simulation at an access point in this research project. However, the system does not contain the heart or blood loop emulation, lowering conceptual fidelity. The team used cheap and easily replaceable components and 3D printing to construct an anatomically accurate cannulation access point simulator.

Still, the lack of having a dummy and other parts lowers the emotional fidelity seen in Figure 11 [21].

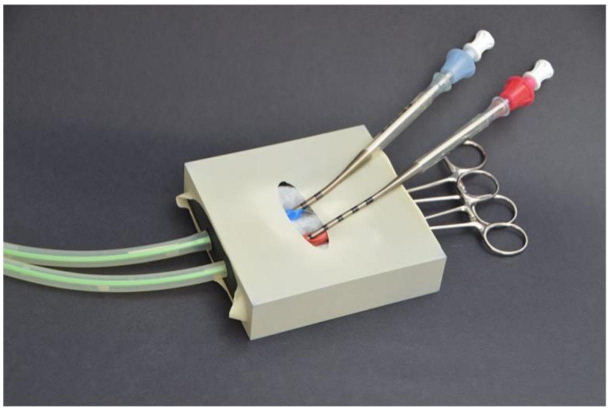


Figure 11. Cannulation access point simulator [21].

2.2.2.10 Next Generation Cannulation Simulator

The next generation cannulation simulator is a joint venture between Qatar University (QU) and Hamad medical corporation (HMC)-the governmental healthcare provider in Qatar- aiming to develop a high-fidelity low-cost ECMO cannulation simulator to train ECMO professionals locally. The research team has developed an ECMO cannulation simulator composed of three integrated parts: the heart, blood vessels, and access points. The heart emulation is a silicon rubber pad with a 3D printed mold. The pad has cavities that mimic the hepatic vein and the right atrium, essential for ECMO cannulation. The hepatic vein is the veinous cannula's stopping point, increasing conceptual fidelity. In addition to that, the heart pad does not include an arterial side because the arterial cannula stops at the femoral artery. Therefore, the double-walled blood vessels have natural blood flow, turbulent arteries, and laminar veins, increasing physical fidelity. The access point emulation is made similar to the heart pad. It features alternative tracks for the cannula to emulate the realistic difficulty of guiding the cannula and the guidewire through the human circulatory system, which boosts emotional fidelity. To complement the physical fidelity, the team also designed a procedural emergency system by measuring the force exerted on the renal vein to predict the chance of internal bleeding and incorporated a flow meter to measure the amount of bleeding. On the other hand, one drawback of the system is the drift in sensor reading and the need for recalibration [22]. The simulator has an overall high fidelity and can be seen in Figure 12.

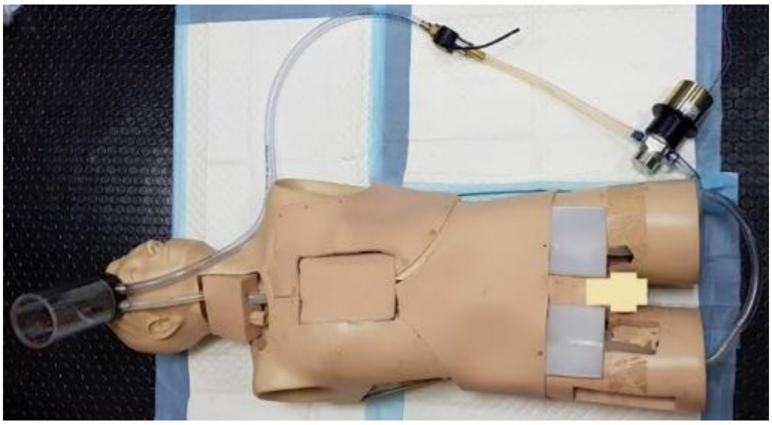


Figure 12. Next-generation cannulation simulator [22].

2.2.2.11 S2225 Pediatric HAL

Gaumard developed multiple patient simulators for SBT, including the cutting-edge pediatric HAL (**H**euristically programmed **Al**gorithmic computer). HAL was designed to create a life-like pediatric patient to train healthcare professionals to deal with multiple clinical emergencies and cases using high-end eye and facial expressions, realistic lung simulation, patient monitor support, airway, circulatory system emulation, and wireless connection. Combining these technologies makes this simulator very life-like and has high physical and conceptual fidelity. The simulator includes a wide range of interactive features, including the ability to make conversations and the device describing pain levels mimicking a human being and having an array of sensors to immerse the learner in the experience, comprehensively improving its emotional fidelity. The Hal simulator can be seen in Figure 13 [23].

Figure 13. Hal Pediatric nursing simulator [23].

2.2.3. Cardiac Catheterization Systems

This subsection focuses on cardiac catheterization and includes research projects and commercialized products.

2.2.3.1 Catheterization and Cardiovascular Interventions

The authors develop an adult trans-catheter cardiovascular simulator with high fidelity seen in Figure 14. The heart emulation in the simulator is anatomically accurate as it is made using a mold that was designed and implemented using additive manufacturing and liquid to emulate blood, improving physical fidelity. The blood vessels were of high fidelity as it includes the renal vein, and the mold is to be filled with silicone rubber that is ultrasound able. Although the blood vessels do not have a false path, the catheter could decrease the conceptual fidelity. The access point is made from ultrasound-able material and only includes the veins [24].

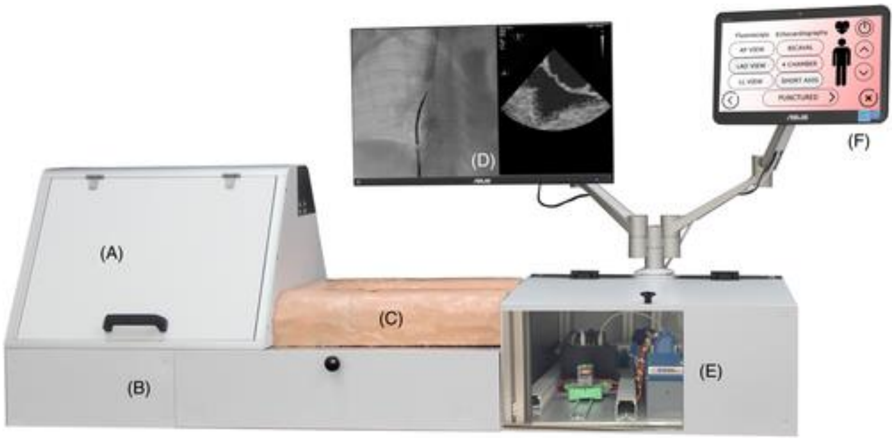


Figure 14. Multi-system cardiac catheterization simulator [24].

2.2.3.2 Beating heart porcine high-fidelity simulator

This research project showcases a trans-catheter cardiovascular simulator with high fidelity seen in Figure 15. The heart emulation of the simulator is of high fidelity as a real porcine heart is used for simulation. The blood vessels used are cannula connected to a pulsatile piston pump, increasing physical fidelity. On the other hand, there is no access point for the catheter lowering the conceptual fidelity [25].

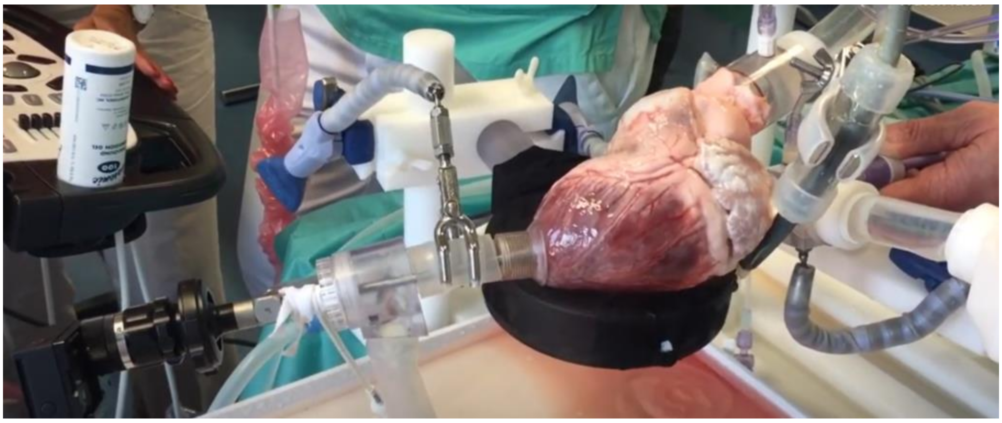


Figure 15. Porcine heart cardiac catheterization simulator [25].

2.2.3.3 Gen II femoral vascular access and regional Anastasia ultrasound training model

This product is a femoral vascular access point that could potentially be used for cannulation and catheterization. The simulator consists of only a femoral access point that is anatomically accurate and resembles the ultrasound of an adult femoral region in a very detailed way seen in Figure 16, which only provides limited physical fidelity [26].

Figure 16. Femoral region cardiac catheterization simulator [26].

2.2.4. Auxiliary Devices

This subsection is focused on simulators that are auxiliary device simulators. All the work discussed is research work.

2.2.4.1 Gen II femoral vascular access and regional Anastasia ultrasound training model

The authors constructed an innovative ECMO simulator system demo integrated into any currently usable full-body patient simulator and used it for medical research. The overall expense of the first simulator prototype is roughly USD 450 and USD 50 for disposable components. The simulator enables many possibilities concerning developing scenarios, particularly: deployment, perfusion, and transport of patients utilizing ECMO, providing conceptual fidelity [27]. The demo can be seen in Figure 17.

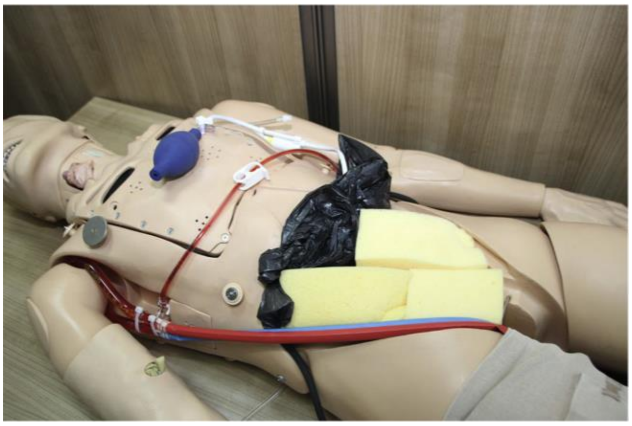


Figure 17. Adult ECMO simulator demo [27].

2.2.4.2 Design and development of a mechatronic training simulator for adult ECMO

Mehta has developed an ECMO mechatronic training simulator, which can help medical professionals gain the skills needed, gain familiarity, and reduce errors by practicing before the procedure in actual patients. The simulator is built as an ultrasound-compatible balanced simulator with functional components such as synthetic blood vessels, cannulation pads, and a color-varying blood simulator to mimic oxygenation and deoxygenation, increasing physical fidelity. The simulator is combined with a statistical model of human physiology to replicate real-time patient vital signs and monitor the operator's equipment improving conceptual fidelity. Results include successful cannulation under ultrasound scanning and a simple patient scenario of hypovolemia [28].

2.2.4.3 Hardware-in-the-loop test bench for artificial lungs

The authors propose constructing a hardware-in-the-loop test bench to address typical weaknesses such as sophistication, tediousness, and lack of repeatability. It was tested in a live laboratory while maintaining precise monitoring of the different control and simulation variables increasing conceptual fidelity seen in Figure 18. Current prototype results show that the proposed system allows high-fidelity testing of interactions with physiological ECMO conditions [29].

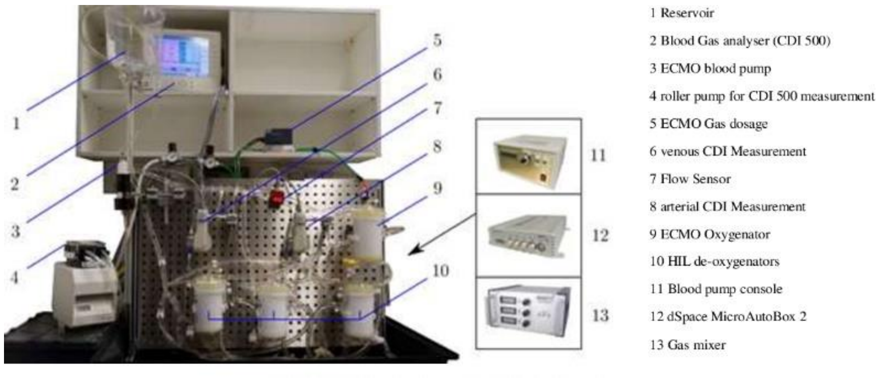


Figure 18. Artificial lungs simulator [29].

2.2.4.4 Hardware-in-the-loop test bench for artificial lungs

In this project, a hybrid cardio-pulmonary simulation platform was adapted for ECMO simulation with a specially designed ECMO hydraulic model. Standard ECMO configurations of VA and VV were the simulation modes. Preliminary tests indicate an improvement in left ventricular afterload for VA configuration and a rise in blood recirculation for VV one. Considering the location of cannulas, the geometrical architectures of the systemic vessels and actual oxygenation offer a more practical and forward-looking simulation strategy showcasing conceptual fidelity [30].

2.2.4.5 Simulation training for extracorporeal membrane oxygenation

This work describes a 1-day ECMO course that was given within the scope of ECMO simulation. An ICU simulated room was used, bundled with a high-fidelity mannequin. The simulator was utilized for training ECMO staff on various scenarios and instilling theoretical knowledge in lectures focusing on conceptual fidelity. Results report that all participants signify the awareness raised by the simulation alongside nurturing practical team-working skills [31].

2.2.4.6 Dynamic extracorporeal membrane oxygenation simulation

The authors showcase a patent on a system with a clamp for an ECMO circuit, an articulator connected to the clamp, and a simulator module connected to the articulator to send control signals. The system also includes a pump and a display module. The circuit comprises a conduit, and a flow regulating device is positioned to scenario a specific ECMO scenario [32].

2.2.4.7 Optical skill-assist device for ultrasound-guided vascular access

A central vein catheterization (CVC) was implemented in this research project. The preliminary simulator includes an access point and an ultrasound emulator that improves physical and conceptual fidelity. The system successfully helps learners visualize and train using the ultrasound machine and CVC. The medical imagining of the simulator is very accurate and human-like but lacks emotional fidelity, as seen in Figure 19 [33]. CVC is an essential type of catheterization applied as a secondary medical procedure. The highlight of the simulator is the auxiliary devices used in training.

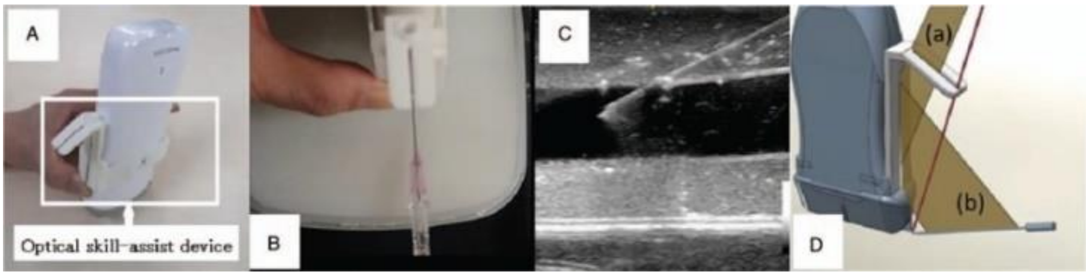


Figure 19. Central vein catheterization access point simulator [33].

2.2.4.8 ECMO simulation with affordable yet high-Fidelity technology

This research project was developed between QU and HMC to design an ECMO machine simulator and is the predecessor of Mahmoud et al. [22]. To eliminate multiple of the main flaws in the existing literature. The team has successfully patented using thermochromic ink to replace animal blood in training, effectively replacing animal blood commonly used for such training [34]. Replacing the blood with another material will provide a more straightforward method of simulating oxygenation -heating- and will end the need of disinfecting the whole loop after training, improving physical fidelity and cost-efficiency. The system is a modular training system with multiple modules to train the learners on different scenarios, including air in the ECMO machine loop and bleeding and more the ECMO machine simulator seen in Figure 20 [35]. The project resembles a modular, high-fidelity cost-efficient simulator with a primary drawback, which is hard to simulate the scenario of connecting a heater in line with the ECMO machine as that would interfere with the simulation, which highly improves the conceptual fidelity [36].

Figure 20. ECMO machine simulator.

2.2.5. Summary

Existing simulators share some key features, including an ultrasound-able access point to effectively train guided cannulation/catheterization but do not emulate the heart. However, it is quintessential to identify the stopping point of the guidewire. Real ECMO machine or medical equipment usage is widespread and makes the training process more expensive. Furthermore, actual blood or living components require a dis-infection process that makes the training not cost-efficient. The Erler Zimmer simulator seems to be one of the best simulators as it has a good balance, but it is expensive [13]. Competing with it on the title of the best simulator is Gaumard

Scientific's simulator, which simulates human sensory peripherals like eyes and reacting to pain and can make conversations with the learner, enabling a more immersive experience [14]. Allan's simulator had an exciting feature of oozing blood [15]. Zimmermann's simulator has a unique application of silicon rubber to make a close replica of the heart [16]. Table I and summarize the existing simulators and their main features. The complete review of each simulator is available in the review paper [17].

Table 1. Summary of existing cannulation simulators.

Simulator	Evaluation Metric			
	Overall fidelity	Cost	Features	Drawbacks
[22]	High	High	Training on cadavers	High price, disinfection required, actual equipment needed
[20]	Average	Average	Three layers access point	Inaccurate blood vessel simulation
[13]	High	High	Easy maintenance, ECG simulation, arteries, and veins simulated, include pulsatile flow	Expensive, Limited anatomical fidelity
[15]	High	High	Procedural emergencies, Realistic, Blood flow, tissue simulation	Expensive, veins only
[19]	Low	Low	Realistic shape	Veins only, Anatomically inaccurate
[18]	Average	Low	Low cost, Realistic appearance	Single closed-loop, No heart emulation
[23]	High	Average	Dual closed-loops, Realistic appearance	No heart emulation
[24]	Low	Low	Relatively cheap	Primitive simulator

Table 2. Summary of existing catheterization and auxiliary devices simulator.

Simulator	Evaluation Metric			
	Overall fidelity	Cost	Features	Drawbacks
[26]	Very high	Very high	multiple sensory peripherals, realistic biometric signals, and a fully immersive experience	Very expensive
[14]	Average	Average	Ultrasound emulation, Realistic ultrasound imaging	Only access point
[16]	High	Average	Fully ultrasound-able system, anatomically accurate system	It does not look like a patient
[27]	High	High	Anatomically accurate heart	Requires disinfection of equipment
[28]	High	High	Anatomically accurate access point	Only access point
[29]	Low	Low	Cheap auxiliary device emulation, Easy to maintain	Only demo for controlling the ECMO machine, no surgical training
[30]	NA	NA	Synthetic blood emulation, Vital signals generation	Insufficient details
[31]	High	High	Blood oxygenation, complete ECMO machine control	Requires disinfection, expensive oxygenation devices
[32]	Average	High	Blood oxygenation, complete ECMO machine control	Requires disinfection, expensive oxygenation devices
[33]	High	Very High	Blood oxygenation	Requires disinfection, expensive off the shelf systems
[34]	High	High	Blood oxygenation, complete ECMO machine control	Requires disinfection, expensive oxygenation devices
[35]	High	NA	Multiple scenarios, cannulation, and ECMO simulator	Only cannulation access point, no simulated blood
[21]	High	Low	No disinfection required, complete ECMO machine control, Modular design	Heater scenario interference

An important aspect to look at when reviewing the human circulatory system SBT is cost, as the learners need a lot of training before they are ready to operate on patients. Multiple simulators are cost-efficient, but one of the most cost-efficient simulators is the Endo simulator. It costs 100 dollars and simulates a dual loop simulation that even simulates dilation [18]. In addition, simulators such as Allan, Thompson, and Palmer simulators provide unique features with low costs, such as blood oozing, high fidelity, And layered cannulation access points, respectively [15], [19], [20]. It is worth mentioning that a central problem with the existing simulators is that most of them use real blood to emulate human blood, which causes the need for disinfection of the whole system, which is very costly. The only reviewed simulator that solved this problem with high fidelity is [21], as the research team found a simulation alternative to oxygenation in heating.

2.2.6. Gap in Knowledge

After reviewing the existing simulators, it could be noted that a knowledge gap exists in the need for a cost-efficient emulation of ECMO cannulation that also has a high conceptual, physical and psychological fidelity. Therefore, we proposed a new cannulation system to close the gap. The main contributions will include, but is not limited to, medical imaging-based cannulation access points molds that emulate inaccurate paths for cannulasand the inclusion of an embedded system that helps in immersing the trainee in high fidelity environment using pumps, sensors and linear actuators. The embedded system will allow for the inception of the procedural emergencies that allow for special clinical training, such as the seizure, heart and lung failure, and internal bleeding. This work is set to implement a cost effective high fidelity ECMO cannulation simulator with a projected cost of 750$ that has improved conceptual fidelity as it tackles the idea of understanding the basis of using an ECMO machine (controlling oxygenation and blood pumping. In addition to improving physical fidilty by showcasing a simulation based training system based on medical imagining in addition to including high fidelity access points using mechanisms that differentiate artires and viens. Psychological fidelity will be highly improved over the existing simulators using procedural emergencies that will immerse the learner in clinical occurrences such as encountering a seizure mid cannulation, lung and heart failure, bleeding and intertnal bleeding. Main expected disadvantage in the simulator is the drift in sensor readings and need for recalibration or replacement which is slightly remedied by having off the shelf components that are eazy to replace.

CHAPTER 3: PROPOSED SYSTEM PLAN

This chapter of the thesis discusses the proposed plan of the systems in the project. The project comprises three central systems the cannulation simulator, the ECMO machine simulator, and the instructor app. The cannulation simulator is a system fitted in a mannequin that emulates the human circulatory system. The ECMO machine simulator is a modular system that emulates the oxygenation machine and its emergencies. Lastly, the instructor app controls and monitors both of the other systems. This thesis will focus on the proposed plan and implementation of the cannulation simulator.

The system comprises three subsystems the cannulation simulator, the ECMO machine simulator, and the instructor app, as represented in Figure 21. The cannulation simulator is the part of the simulator that emulates the patient's body. The body is emulated using a dummy; the cannulation system comprises three parts: closed-loop, cannulation access points, and Embedded system. The ECMO machine simulator is an instrumental part of the simulator system as it replaces the expensive ECMO machine in training. The ECMO machine utilizes the concept of thermochromism to emulate blood oxygenation to avoid the sanitary problem of having to disinfect the system with high fidelity. The system utilizes a heater-cooler system that controls the amount of emulated oxygenation to simulate different clinical cases. Lastly, the instructor application is used to control the system remotely from the instructor's convenience. In this thesis, there will be a focus on the cannulation simulator and its implementation.

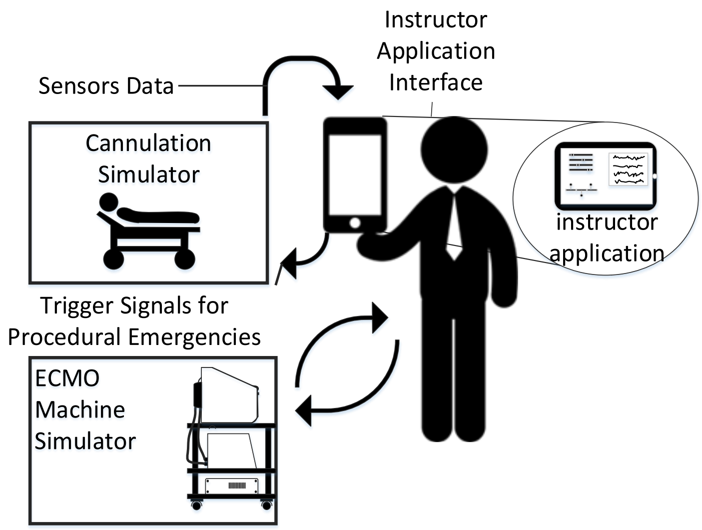


Figure 21. Block diagram of the ECMO simulator system.

3.1 Closed-loop

The closed-loop system of the cannulation simulator is composed of three essential parts the tubing system, as presented in Figure 22, the pumping system, and the sensors. The tubing system comprises two plastic and silicone tubes with different wall thicknesses to simulate veins and arteries, represented in blue and red. The pumping system comprises two pumps that emulate the heart pumping, simulating venous and arterial flow. The microcontroller controls the pumps to have pulsatile and laminar flow in the veins. The sensors in the system are force-sensing resistors (FSR) and flowmeters; the sensors are part of the procedural passive procedural emergencies. The force sensing meter is located in the alternative path of the cannula at the renal vein to measure the potential force exerted on it upon failure of navigating the guidewire through the circulatory system. The FSR is essential for the simulator as exerting so much force on the kidney in real life would cause fatal internal bleeding. The FSR is placed into the connector in Figure 23, right below the heart pad. The flowmeter sensor is used to calculate the deferential flow and calculate the leakage of simulated blood to measure the bleeding in the patient.

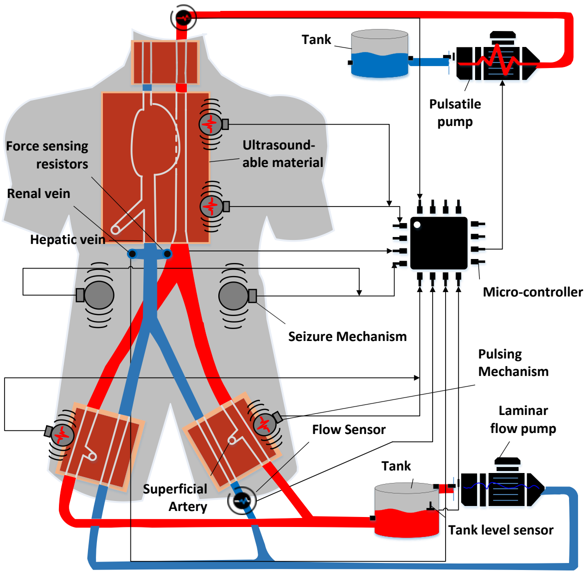


Figure 22. Block diagram of the cannulation simulator.

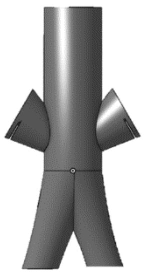


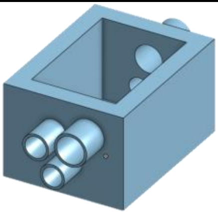
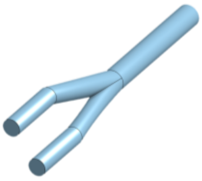
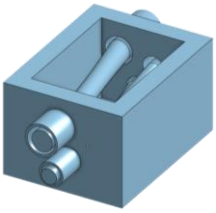
Figure 23. FSR connector.

3.2 Cannulation access point

The main parts of the cannulation access point are femoral pads, heart pads, and the pulsating mechanism. The femoral pads are located at the bottom of the mannequin and contain the blood vessels responsible for feeding the lower body. In this project, the pads are made from a custom-made mold made possible by additive manufacturing to ensure high anatomical realism. The custom-made design is based on an ultrasound image of the femoral region seen in Figure 3. The breakdown of the design is presented in Table 3.

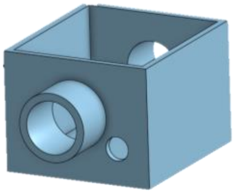
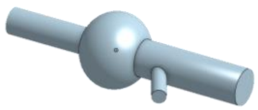
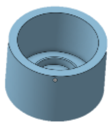
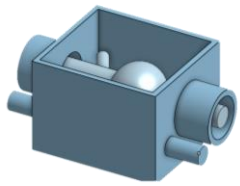
The heart pad is considered an essential part of the simulator as it represents the stopping point of the vein's cannula. The heart pad is created similarly to the femoral pad through a mold. In the case of the heart pad, a computerized tomography scan of the heart -seen in Figure 2- was used to design the mold to guarantee high anatomical realism. The heart pad mold design details can be seen in Table 4.

Table 3. Design of the femoral pad.

Part Name	3D model	Description
Body		• Exterior Body of the femoral pad • Based on an ultrasound of the femoral region
Arterial Rod		• Emulates splitting of femoral artery to the deep femoral artery and superficial artery
Veins Rod		• Emulates natural curvature in blood vessels
Overview		

Lastly, the pulsating mechanism is used to move the cannulation access points from the side of the arteries to emulate pulsating arteries under ultrasound, which is how the practitioners identify the arteries vessels from the veins. The mechanism type is cam-follower, which converts from rotary to linear. Table 5 showcases the design of the mechanism and its main features.

Table 4. Design of heart pad mold.

Part Name	3D model	Description
Body		• The exterior part of the body of the mold • Based on a CT scan of the heart
Venus Rod		• Features right atrium & Hepatic vein
Arterial Rod		
Plug		• Includes inner threading to center the veins rod
Overview		

3.3 Embedded system

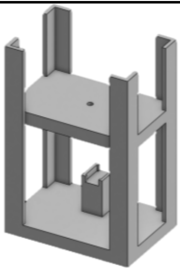
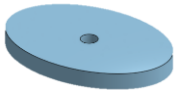
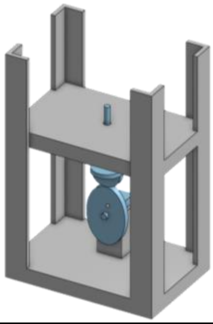
The embedded system is the brain of the cannulation simulator. The embedded system has three main functions: process the sensor data, control the pumps and the mechanism, and activate Procedural emergency. The system contains multiple sensors to monitor and assess the learner's skill. The differential flow is measured by measuring flow before and after the running system and using the differential flow, one can calculate the fluid loss from the system. The FSR in the system is used to measure the force made on the renal veins that lead into the kidney. Such measurement is taken to assess if the learner might cause internal bleeding. The embedded system controls two pumps. The arterial pump is a pulsatile pump that utilizes a pulse width modulation signal to control the DC-DC converter that powers the pulsatile pump.

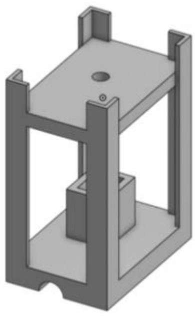
Similarly, the veins pump is a laminar flow. The laminar flow is controlled in the same technique, but the signal is constant. The activation of the procedural emergency happens through the embedded system as it controls the actuators. Lastly, the embedded system controls two linear actuator systems to emulate pulsation at the cannulation access point and to emulate a procedural seizure emergency.

3.3.1 Pulsing mechanism

The pulsing mechanism is a system that emulates the sensation of touching the cannulation access point as in clinical practice; learners distinguish between the arteries and veins side of the femoral region by feeling the femoral region as the heart pulse could be detected on the arteries under ultrasound. Simply put, the linear actuation of the mechanism causes pulse-like motion in the arterial side of the pad. Two options were designed, a cam follower mechanism and a linear actuator mechanism. The cam follower mechanism is designed with an oval shape, as seen in Table 5; the pulsing mechanism needed a redesign because of how unstable the cam-follower mechanism was. Therefore, the cam-follower was replaced by a linear actuator. Figure 24 (a) shows the mechanism design 3D model. The design was modified to have the actuator right under the arteries, and a trench was made for the wires. Figure 24 (b) shows the actuator inserted into the new mechanism design.

Table 5. Design of the pulsating mechanism using a cam follower.

Part Name	3D Model	Description
Body		• Top space reserved for the femoral pad • Lower space is for the rotation to the linear mechanism • The stand-in lower space is reserved for a DC servo motor
Cam		• Steep elliptical shape to have an instantaneous change in motion from the linear side
Follower		• Emulates natural curvature in blood vessels
Overview		• The DC motor rotates the cam, which results in translation in the follower. • Future improvement might include multiple mechanisms



(a)

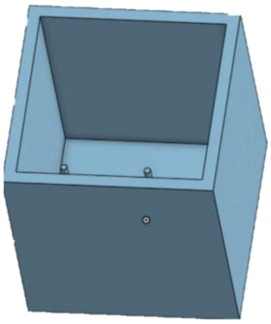
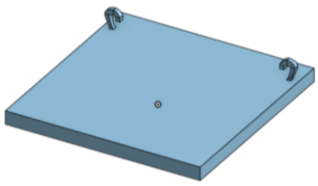
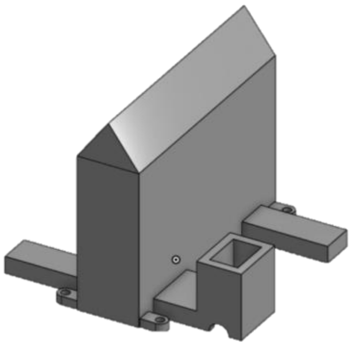
(b)

Figure 24. Pulsating mechanism (a) 3D model (b) actuator.

3.3.2 Seizure mechanism

The seizure mechanism was developed to emulate the procedural emergency of the patient having a seizure during cannulation. The system comprises two springs, a linear actuator, and the designed mechanism in Table 6. The point of the system is to have rhythmic motion at a constant speed. The same actuator used in Figure 24 (b) for the seizure system.

Table 6. Design of the seizure system.

Part Name	3D Model	Description
Body		• Tiny rods to fit into the base • Closed shape to prevent water leakage
Top		Rectangle shape fits in the body Hooks to connect to the spring in the base
Core		• Space for linear actuator • Holes for the rods • Trench for wires

CHAPTER 4: SYSTEM IMPLEMENTATION AND RESULTS

This chapter discusses the implementation of the designs of the NGCS divided into closed-loop, cannulation access points, and embedded systems. Closed-loop will be concerned with the physical loop of tubes and connectors; the cannulation access point will discuss the ultrasound-able flesh-like access point. The embedded system encompasses implementing all the embedded systems from actuation to sensing.

4.1 Closed-loop

The closed-loop comprises the system's physical loop, including valves, connectors, and tubes. The valves regulate the air bubbles in the system and get rid of them. The connectors are used to increase the physical fidelity of the system. The tubing physically connects the system and is the simulated blood vessel.

4.1.1 Valves

The valves in the system are used to help get rid of air bubbles in the system that get trapped in access points due to the elasticity that allows for air to accumulate in them. Various valves were tested, but a transparent one with a single exit was used to solve the problem seen in Figure 25.

Figure 25. Venus loop with valve.

4.1.2 Connectors

The connectors used in the loop were put to emulate alternative paths that the guidewire could potentially pass. The connectors are 3D modeled after the anatomy of the inferior vena cave, the femoral blood vessels, and the renal veins. The veins connector contains the FSR circuit, which is designed in cap form to divert the pressure around and avoid leakage due to the blockage of the simulated bloodstream. The connector is 3D printed using durable resin, and the caps are printed using TPU to be flexible to seal any leakage completely. The main connector is seen in Figure 25.

4.1.3 Tubing

The tubing is the vessel of the simulated blood. Multiple materials were tested for tubing, including PVC, silicon rubber, and others. The tubes need to withhold the temperature of the heated simulated blood while correctly emulating the proper sizing of blood vessels. PVC was chosen for the veins loop for its sturdiness and reliability. Silicon rubber was chosen for arteries to help in simulating dilation.

4.2 Cannulation access points

The cannulation access points are one of the quintessential parts of the SBT. It is the first step into the cannulation simulator; the access points should be ultrasound-able to allow guided cannulation. Access points should have high physical fidelity to simulate potential false tracks of the guidewire and provide a realistic feel for identifying the arteries and veins in the femoral region. To satisfy these criteria, the mold for the femoral pad and heart pad was 3D modeled based on the ultrasound and CT scan, respectively. The mold was then printed using a TPU flexible and durable resin mixture to create a tight silicon rubber mold with low to no leaks. The TPU and flexible resin were used for the mold's body, and the plugs were made from durable resin. The Femoral and Heart pad molds are seen in Figure 26.

To make the femoral and the heart pad, one must first use a lubricant to ensure the silicon rubber does not stick to the pad when it hardens. Then wrap the rods of the mold with cellophane to pull them quickly as the curvature in the rods makes them challenging to remove. The silicon rubber is first mixed thoroughly for 20 minutes using an electric mixer to ensure that the silicon rubber is bubble-free and consistent. Finally, the silicon rubber is poured into the mold smoothly and slowly to avoid the accumulation of air bubbles then the mold is tapped to release any air bubbles that were formed. Lastly, the pad is extracted by pulling out the rods using the cellophane and final peeling off the mold smoothly. The final femoral and heart silicon pads can be seen in Figure 27 and Figure 28, respectively.

Figure 26. Silicon rubber molds(a) Femoral and (b) heart pad mold.

Figure 27. Femoral silicon rubber pad (a) side view, (b) front view.

Figure 28. Heart silicon rubber pad (a) side view, (b) front view.

4.3 Embedded Systems

Embedded systems are the brain of the cannulation system; Their primary purpose is to monitor the sensors, control the actuators and trigger procedural emergencies. Monitoring the sensors includes acquiring their data and utilizing it to assess the learner. Controlling the actuators entails generating and transmitting control signals to the pumps and the linear actuators. Procedural emergencies are clinical complications that could arise central cannulation to prepare learners for it.

4.3.1 Sensors

The sensors used in the system are monitored using an Arduino Mega microcontroller and include an FSR sensor and the flowmeter circuit. The FSR circuit is a voltage divider circuit used to measure the resistance of the FSR and, therefore, the force at the connector. The FSR diagram can be seen in Figure 29. The flowmeter circuit is a direct connection on the microcontroller. A pin is connected to the ground, another to the voltage, and the last to an analog pin. The flowmeter circuit is seen in Figure 30.

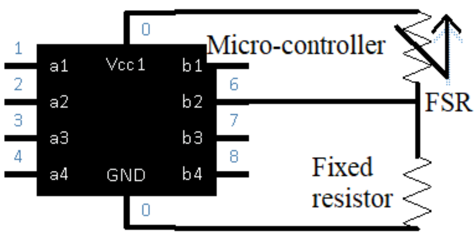


Figure 29. FSR circuit.

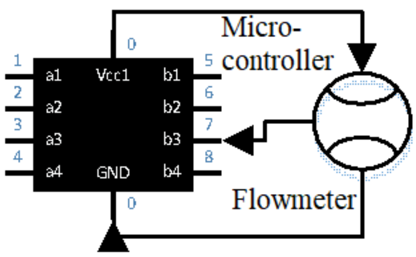


Figure 30. Flowmeter circuit.

4.3.2 Actuators

The actuators in the system are controlled through an Arduino mega and an Arduino UNO. The actuators circuits include a motor drive that provides isolation between high current circuit and low current circuit signal that controls the actuators from the microcontrollers. The pump circuit is the same for both pumps. The pump and the coding of the motor drive signal differ as they both require isolation due to the need for a high current to drive the loop. The circuit is seen in

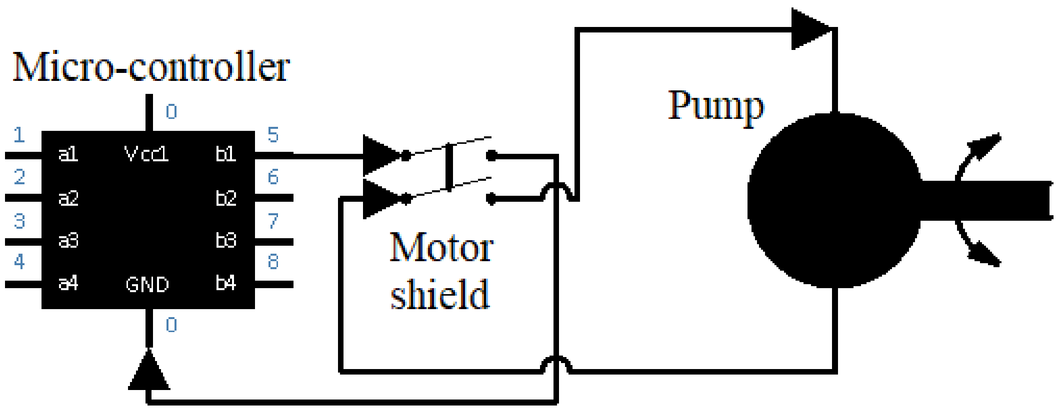


Figure 31.

Three pumps were tested to be implemented into the system. Two pumps were chosen to compare Koolance's connection to the loop and a variable expired dialysis pump. The Koolance pumps included a low flow pump and a high flow pump. Dialysis pump was chosen for its versatility, and good transient response in the end high flow pump from Koolance was chosen for the arterial loop, and the dialysis pump was chosen for the veins loop since it was the one that least produced air bubbles in the heart pad the three pumps are seen in Figure 32.

Similarly, the linear actuators systems are the same in the seizure simulator and pulsating mechanism. The linear actuator system implemented in the pulsating mechanism can be seen in Figure 34 with and without the femoral pad. The 3D model was printed in PLA with a high infill to support the femoral pad. The linear actuator circuit can be seen in

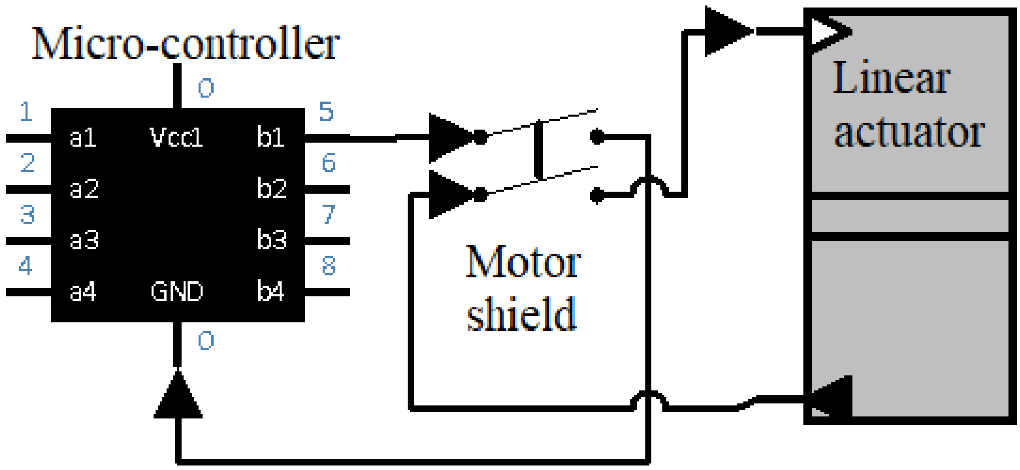


Figure 33, and it is composed of the motor drive, linear actuator, and microcontroller. The offset is chosen by controlling the wait time between alternating of the direction signal of the linear actuator. The frequency of oscillation is controlled by the input voltage of the linear actuator. The linear actuator system is designed in the mechanism to do an offset of 10mm and have a frequency of 60 oscillations per minute to mimic a heartbeat. The linear actuator system in the seizure simulator has an offset of 30 mm (maximum) and 70 oscillations per minute. The maximum offset and frequency were chosen for the seizure to have the maximum impact.

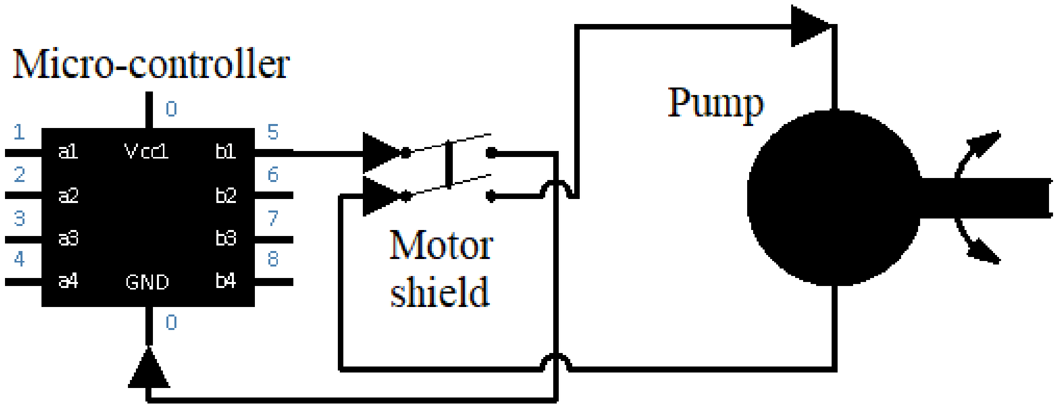


Figure 31. Pump circuit.

(a) (b) (c)

Figure 32. Different pumps (a) low Koolance, (b) high Koolance, and (c) dialysis pump.

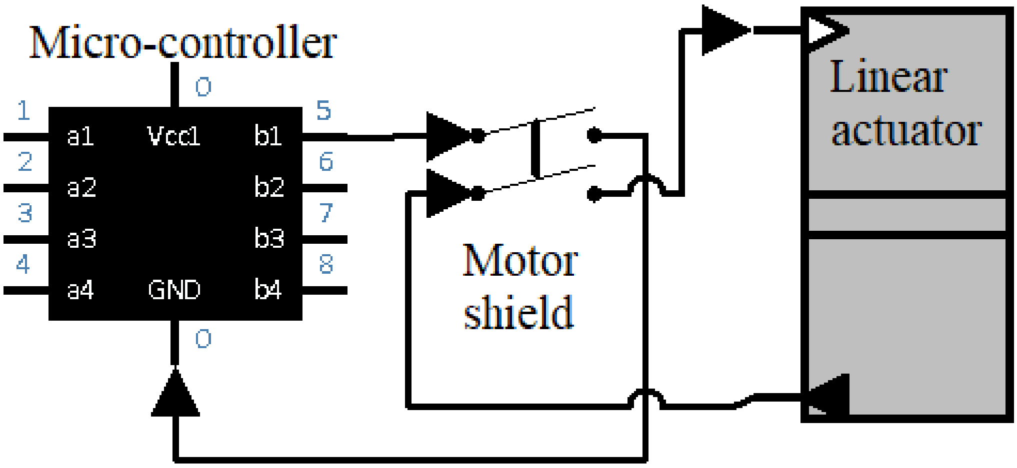


Figure 33. Linear actuator circuit.

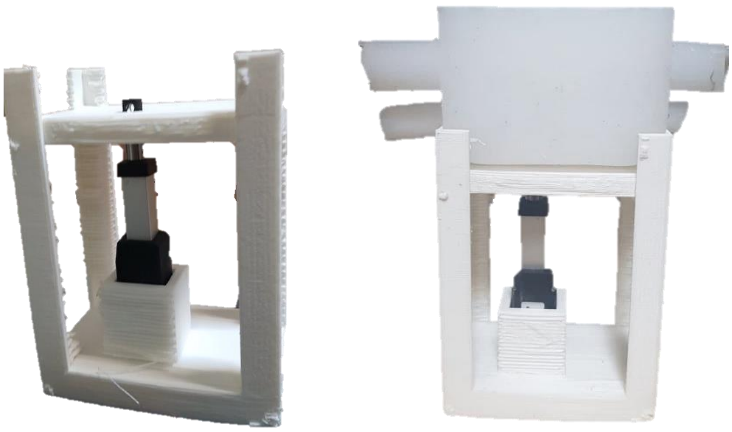


Figure 34. Pulsating mechanism implementation.

4.3.3 Procedural emergencies

Procedural emergencies are incorporated into the system to improve the overall conceptual fidelity of the system because it allows the learners to understand how to interact with clinical issues that might arise from performing cannulation, such as internal bleeding, bleeding, seizure, and heart failure. Internal bleeding is based on the idea of the guidewire going into the kidney in the process of cannulation, causing a rupture in the kidney and internal bleeding. Bleeding is a procedure that tests if the learner can control the amount of bleeding happening in the cannulation, which emulates the action in real life. The learner must do techniques like pressing on the wound to avoid bleeding. A seizure is an emergency where the patient suffers from a seizure while cannulation is happening or simply on the ECMO machine. Specific skills need to be done to avoid bleeding out or further damage. Heart failure is an emergency where the learner practices how to interact with a heart failure and how to treat the patient to extracorporeal cardiopulmonary resuscitation (ECPR) using the ECMO machine simulator.

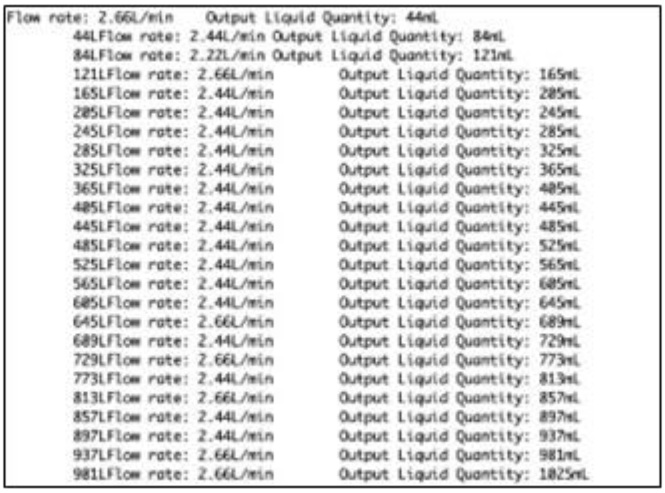
4.3.3.1 Internal bleeding

The procedural emergency of internal bleeding is implemented using the concept of force-sensing transducers. The idea is that the sensor located in the plus shape connector in the renal veins is used to estimate how much force the learner is exerting on the kidney as such injury could cause fatal internal bleeding. Two types of sensors were tested to be used in the system: load cells and force-sensing resistors. Load cells provided a sturdy and reliable sensor. Still, they had a problem with sensing levels, especially that off-the-shelf components were preferred to help keep the system modular and maintainable. Force sensing resistors made a great candidate because of their compactness, ease of connecting, and cheap cost compared to load cells.

On the other hand, the common FSR in the market is vulnerable to being submerged in water. FSR was chosen with a particular layer of waterproof coating. The FSR was calibrated by putting it into the system and forcing the guidewire into it while measuring the FSR resistance. To maximize detection, the voltage divider circuit resistor was selected to be equal to maximize the resistor's reading signal. There are no outputs of the signal but the microcontroller light-emitting diode was used to indicate the detection of force on the FSR.

4.3.3.2 Bleeding

The bleeding emergency tests the concept of the learners' ability to control the emulated bleeding in the simulator. Bleeding is considered an essential clinical case because some patients cannot afford to lose blood or can risk bleeding out. The amount of bleeding was conceptually going to be measured by calculating the differential pressure then multiplying it with the radius of the tube to calculate the estimated loss of simulated blood in the system. After implementing the solution, the readings were non-consistent and inaccurate due to tiny air bubbles in the system. A different sensor could be used to estimate the bleeding. A screenshot of the flowmeter output is shown in Figure 35.

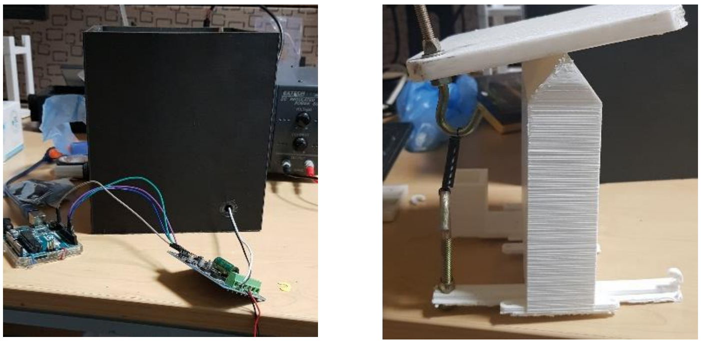


```
Flow rate: 2.66L/min    Output Liquid Quantity: 44mL
        44LFlow rate: 2.44L/min Output Liquid Quantity: 84mL
        84LFlow rate: 2.22L/min Output Liquid Quantity: 121mL
        121LFlow rate: 2.66L/min        Output Liquid Quantity: 165mL
        165LFlow rate: 2.44L/min        Output Liquid Quantity: 205mL
        205LFlow rate: 2.44L/min        Output Liquid Quantity: 245mL
        245LFlow rate: 2.44L/min        Output Liquid Quantity: 285mL
        285LFlow rate: 2.44L/min        Output Liquid Quantity: 325mL
        325LFlow rate: 2.44L/min        Output Liquid Quantity: 365mL
        365LFlow rate: 2.44L/min        Output Liquid Quantity: 405mL
        405LFlow rate: 2.44L/min        Output Liquid Quantity: 445mL
        445LFlow rate: 2.44L/min        Output Liquid Quantity: 485mL
        485LFlow rate: 2.44L/min        Output Liquid Quantity: 525mL
        525LFlow rate: 2.44L/min        Output Liquid Quantity: 565mL
        565LFlow rate: 2.44L/min        Output Liquid Quantity: 605mL
        605LFlow rate: 2.44L/min        Output Liquid Quantity: 645mL
        645LFlow rate: 2.66L/min        Output Liquid Quantity: 689mL
        689LFlow rate: 2.44L/min        Output Liquid Quantity: 729mL
        729LFlow rate: 2.66L/min        Output Liquid Quantity: 773mL
        773LFlow rate: 2.44L/min        Output Liquid Quantity: 813mL
        813LFlow rate: 2.66L/min        Output Liquid Quantity: 857mL
        857LFlow rate: 2.44L/min        Output Liquid Quantity: 897mL
        897LFlow rate: 2.44L/min        Output Liquid Quantity: 937mL
        937LFlow rate: 2.66L/min        Output Liquid Quantity: 981mL
        981LFlow rate: 2.66L/min        Output Liquid Quantity: 1025mL
```

Figure 35. Flow Sensor Output Readings

4.3.3.3 Seizure

The seizure emulator is used to emulate the occurrence of a seizure while in cannulation or after the patient is put on ECMO. The seizure emulator is designed using the linear actuator design 3D printed using high infill PLA to ensure that the seizure device can support the weight of the mannequin and conserve the force and make the system more sustainable. The system has springs on both sides to help maintain the rhythmic motion. The implementation of the seizure simulator can be seen in Figure 36.



(a) (b)

Figure 36. Implementation of seizure simulator (a) Body and circuit (b) core.

4.3.3.4 Heart Failure

A heart failure procedural emergency is designed to test the learner's response to a patient going through heart failure. The instructor from the instructor app controls the system's pump to emulate heart failure. The sequence was tested through a potentiometer and voltage divider circuit. Heart failure provides an excellent opportunity to test the learner's ability to perceive the function of the simulated heart to prepare the time-critical ECPR.

CHAPTER 5: DISCUSSION

The system has been correctly designed. The system has been implemented entirely except for the bleeding procedural emergency. Silicon rubber was used to recreate the cannulation access point, and additive manufacturing was used to design and make the molds of the silicon rubber. Additive manufacturing was also used to create the system's connectors that helped boost the physical fidelity. The tubing was composed of silicon and PVC tubes to allow suitable sizing for imitating the blood vessels. An embedded system was implemented to increase the conceptual and psychological fidelity of the system by incorporating the pumping of simulated blood in the system and pulsation at the femoral cannulation access point. Procedural emergencies were introduced to immerse the trainee in clinical cases that would require practice to navigate dealing with by the learners, such as internal bleeding, seizure, and heart failure. The loop and the mannequin where is the system will be inserted are seen in Figure 37.

The main issues encountered in the system were the air bubbles present in the pads, the FSR not being compatible with being submerged in water, leakage, and air accumulating inside the heart pad. Many tests were done to mitigate the air bubbles in the pads. Finally, a procedure was developed to create low air bubble pads using automated mixing of the silicon rubber and creating flexible molds. FSR was implemented in the system by coating it using a clear coat and making it resistant to high water pressure levels. Leakage was mitigated by redesigning the plus shape connecter and changing the FSR from a coin slot shape to a cap shape. The cap was also sealed by epoxy. The main idea of the redesign was to redirect the pressure from having at the tip of the connector to happening around a circular radius, reducing its damage to the system and stopping the leakage. The accumulation of air bubbles in the heart pad caused lots of damage in the system as it caused air pressure and damaged multiple pads, and it was combated by adding a valve that helped provide an exit for the air stuck in the loop and the heart pad.

Figure 37. The loop and mannequin.

5.1 Integration with the overall system

The cannulation was designed to complement the ECMO machine simulator and the instructor app by providing a high fidelity human circulatory emulator, and systems connect in two main ways the connection between the cannulation system and the ECMO machine and the instructor app. The ECMO system is a modular system that includes a heater-cooler unit, ECMO machine, instructor app, and patient unit. The heater-cooler unit is the core of the ECMO simulator and is where the emulated oxygenation happens on the thermochromic ink. ECMO machine module is the interface in which learners control the system and the pump noises. The instructor app controls and triggers emergencies on the ECMO system and is a firebase application to minimize delays. Lastly, the patient unit containing the cannulation simulator also includes line chattering and bleeding emergencies in association with the tubes of the simulated blood. The complete ECMO SBT diagram is seen in Figure 38.

The integration with the ECMO machine will start with replacing the end tubing of the ECMO machine connecting to the patient module to a cannula to connect the cannulation simulator with the ECMO machine. A new procedural emergency would be unlocked, the lung failure emergency. The lung failure emergency presents the clinical case of the lung not providing oxygenated blood to the body and will be available using the heater-cooler module in the ECMO machine emulator. The heater-cooler system will be assigned through the instructor by enabling them to choose a desired level of heating which will translate to the color of the thermochromic ink, allowing the learner to experience and understand how one can counter such emergency through increasing the simulated oxygenation from the ECMO machine using a heater-cooler controller knob. The integration of the cannulation simulator to the instructor app entails the sending of all the data of the sensors to the app to allow for the instructor to monitor the progress of the learners from a distance while also being able to trigger multiple procedural emergencies and observing the learner performance such as seizure and heart and lung failure emergencies. The control of the instructor app will allow for providing the ECMO SBT course online to adhere to the COVID-19 travel restrictions and guidelines.

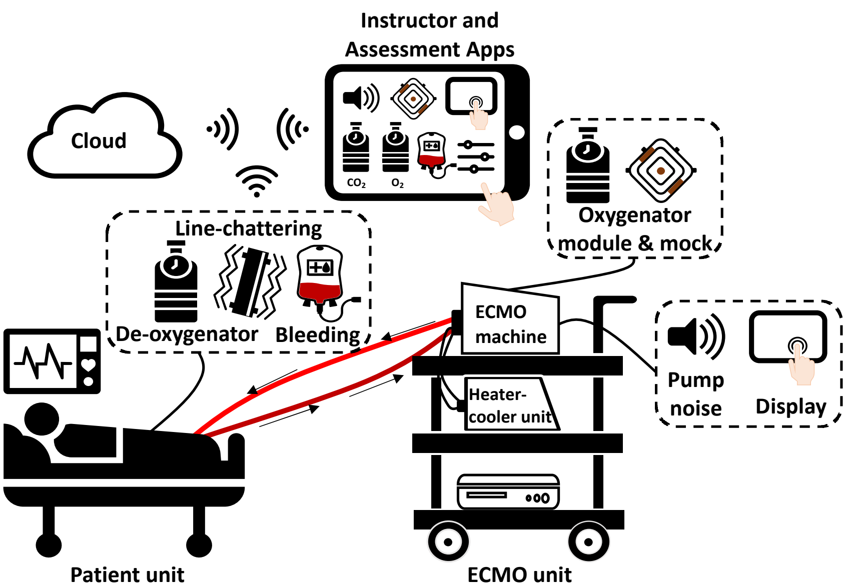


Figure 38. Overview of the proposed training system.

CHAPTER 6: CONCLUSIONS AND FUTURE WORK

The cannulation SBT system was successfully finalized by completing the closed-loop, cannulation access point, and embedded system. The novelty was achieved in the closed-loop by including false tracks that test the learners' anatomy. The novelty was achieved in cannulation access points. It was presented in inaccurate access points created using molds and clear ultrasound and CT scans representing false tracks and straightforward anatomically accurate design. Lastly, the novelty in the embedded system is the procedural emergencies such as the seizure simulator, heart and lung failure, and internal bleeding. The future work entails running a conclusive test into the system's efficiency in achieving the three types of fidelity (physical, psychological, and conceptual). The final tests would be done in HMC, the team did initial tests, but the periodical testing of the system stopped because of COVID-19 and the ICU being full throughout the pandemic. The tests included showcasing the initial prototype of the system to about 10 ECMO professionals, including medical doctors, perfusionists and nurses. The demo included an ultrasound guided ECMO cannulation as shown in Figure 39.

(a) (b)

Figure 39. Initial test at HMC (a) Ultrasound guided demo (b) cannula inserstion

Moreover, future work includes adding a heating-cooling unit to the cannulation simulator system to develop a more dynamic lung failure procedure. The instructor will control the unit in the cannulation simulator, and the learner will have control over the unit in the ECMO simulator boosting conceptual and psychological fidelity. Work is being done to expand the cannulation simulator's core idea to neonatal simulators that face their own alternate internal bleeding problem at the jugular cannulation access point. A review journal paper summarizing existing work and recommendations for an ideal simulator is published, three abstract journal papers that describe a general idea of the work and system were published, two conference IEEE papers successfully that describe the simulator embedded system and overall implementation were published, and two best papers awards were won.

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