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A High-Realism and Cost-Effective Training Simulator for Extracorporeal Membrane Oxygenation

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ABSTRACT Medical simulators, employed in extracorporeal membrane oxygenation (ECMO), are burdened with costly equipment and low-fidelity methodologies. This dichotomy necessitated a new approach that eliminates high-costs and integrates with the critical care environment. This is especially applicable after the Coronavirus pandemic, where resources and supplies are evermore scarce. After examining the state-of-the-art and establishing a close collaboration with Hamad Medical Corporation (HMC), the main healthcare provider in Qatar, several criteria were identified to advance the cutting-edge. In this article, a high-realism, cost-effective ECMO simulator is presented. It runs on a novel blood simulation technology along with simulation modules. An instructor tablet application enables instructors to orchestrate the training experience wirelessly with real-time performance. It also includes a novel scenario designer for implementing consistent simulation curricula. A product-level simulator with high-fidelity casings is in the final integration phases. Current results include developing and testing the simulated blood circuit, simulation modules for hemorrhaging, line chattering, air bubbles noise, and a replicated console along with an integrated communications system. Nineteen specialists rated the fidelity of the system as highly realistic during a questionnaire-based study. It is expected to run a second study to evaluate the educational efficacy of the simulator as a first-of-its-kind in the region.

INDEX TERMS Simulation-based training (SBT), extracorporeal membrane oxygenation (ECMO), blood oxygenation, thermochromism, high-fidelity simulation.

I. INTRODUCTION

Patients with issues related to short-term respiratory or circulatory failure undergo a standard therapy referred to as Extracorporeal Membrane Oxygenation (ECMO) for newborns as well as adults to save their lives [1]. It was recorded that ECMO has saved more than 53,000 cases in life-threatening conditions with survival rates exceeding 70% [2].

The procedure includes pushing the blood via a pump to be circulated into an external circuit. The pump is also attached to a filter (or membrane) that provides a similar functioning to blood oxygenation [3].

Despite the fact that the ECMO therapy was reported to increase survival rates, patients are still subjected to side health complications. For example, internal bleeding, kidney failures, and strokes can occur due to anti-coagulation chemicals, which are used to prevent clotting [3]. Furthermore, patients' survival rates can be mitigated down to 40% due to common hardware complications to tube ruptures and oxygenator/pump failures [4].

One major key factor affecting wide adoption of ECMO is its overwhelming expenses. For instance, an ECMO unit costs around 130,000 USD and oxygenation units per patient cost approximately around 5,000-10,000 USD. Other disadvantages include high risk and complex and nuanced patient management, but most importantly, restricted numbers of ECMO-trained staff. Training based on ECMO are usually conducted both theoretically and practically providing critical qualities for ECMO patient management when performed, such as team communication and procedural intuition [5]. Recently, ECMO is deployed on some critical cases of the Coronavirus (COVID-19) epidemic, and has been successful

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in some hospitals worldwide [6]. However, conclusive studies on its effectiveness are yet to be published.

Educators employ simulation-based training (SBT) to complement or replace real patient encounters [7]–[9]. SBT constructs a secure atmosphere in which learners can easily grasp ECMO-patient interactions, instill professional skills, collaborate with participants from other healthcare fields, and improve the knowledge required of ECMO professionals in crisis response management (CRM) [9], [10].

Moreover, SBT offers the opportunity for ECMO centers to systematically evaluate clinician efficiency under stress and time constraints, benchmark their preparation for unusual emergencies and establish better problem-solving strategies [11]–[15]. It is also worth noting that an enhanced realistic simulator-training experience related to cannulation (and de-cannulation) is highly beneficial to better patient outcomes.

This article tackles the current limitations of ECMO training systems by building a comprehensive simulation and training system that encompasses both the patient and the ECMO machine used by Hamad Medical Corporation (HMC), the main healthcare provider in Qatar and a collaborator in our project. We build upon cost-effective methodologies while maintaining high-realism with modular components and the novel use of thermochromic ink.

The remainder of this article is organized as follows. A summary of related work is depicted in Section II. System design is presented in Section III. Current results are signified in Section IV, followed by conclusions in Section V.

II. RELATED WORK

ECMO is a bridge therapy increasingly used with critically ill patients who require cardiac and/or respiratory support. Although very specialized, high-risk, but potentially lifesaving, HMC in Qatar opted to introduce an ECMO program in its main government hospital in 2013. To ensure optimal patient outcomes, simulation was cornerstone of the program initiation and of all training activities. Accordingly, in the literature, there is a number of hardware ECMO simulators developed by medical training firms, universities, and hospitals for SBT purposes [16]–[19]. Six of the most recent state-of-the-art simulators were selected for review and comparison. When evaluating the six ECMO simulators, five metrics were used to asses each solution in order to identify merits as well as potential weaknesses. The criteria were realism, performance, feature-set, drawbacks, and ease of use. Realism is key to an ECMO simulator, as high level of fidelity is crucial due to the critical nature of ECMO operations and the significance of many observable and interrelated factors. Performance is defined by how well the simulator operates and its rate of error in emulating circuit issues coupled with the accuracy of readings. The features of the simulators determine what can be simulated, and what can be done to enhance the learning process, such as implementing predefined scenarios of circuit issues. Drawbacks identify the potential weaknesses in each existing solution. Table 1 compares the reviewed simulators in terms of the aforementioned metrics [20]. All existing ECMO simulators share the same weaknesses, which are mainly caused by the same reason. ECMO simulators use already existing ECMO systems, which reduces (a) cost-effectiveness, (b) portability, and (c) the number of ECMO machines that can be used for real patients. Thus, the simulator is required to generate factual and accurate values of temperature, pressure, flow, and numerous other variables to be detected and displayed by the ECMO machine. Such processes are difficult, complicated, and boosts the unit cost immensely. Additionally, it is required to setup the components of deoxygenators along with expending real blood in every training session. Both factors, ECMO machines and the mentioned components, increase the cost of the current simulator units significantly in addition to their maintenance cost. To overcome the aforementioned limitations, in this work, we describe the development of a high-realism, cost-effective ECMO training system for adult patient management. The system is built on top of a novel blood simulation technology along with extensible simulation modules controlled by an instructor tablet application for standardized training curricula. Usually, achieving high-realism while keeping costs in check is a difficult endeavor. In the proposed work, high-realism was achieved by inventing a new blood color simulation technology (i.e. thermochromic ink) and developing simulation modules that only focus on replicating the visual/audio/haptic outcomes of major ECMO emergencies. Moreover, the simulator has been benchmarked through the evaluation study, where participants rated most of the modules as ‘‘highly-realistic.

III. MATERIALS & METHODS

This section describes the research and development processes behind the proposed ECMO training system. The training system is focused on practically training practitioners for ECMO on adult patients. The system is expected to be used alongside a strong theoretical course to develop a solid foundation. Fig. 1 depicts the proposed system's block diagram comprising three physical subsystems: the patient unit, the ECMO unit, and the oxygenator all centered around the thermochromic loop. Each unit includes simulation modules as shown in the diagram. To control the operation of those modules, a communications system is developed, and connected to a tablet application for instructors to steer the training experience for a smooth learning experience.

A. THERMOCHROMIC LOOP

With high costs and contamination risks of using real blood in training, alternative schemes deem a necessity for minimizing expenses while maintaining high realism. Dye-colored fluids and water are common options used in simulations, notwithstanding, they do not reproduce scenarios with high fidelity. This is especially applicable when blood color change is a key indicator in many ECMO scenarios. In this work, we have devised a novel solution where color change can be simulated in training sessions while keeping costs and health risks to a minimum.

TABLE 1. Existing ECMO simulation systems.

Simulator	Metric				
	Realism	Performance	Features	Drawbacks	Ease of Use
NIJMEGEN ECMO Simulator [1]	High	Low	• Simulates typical parameters • Wireless control • Portable and configurable	• Requires ECMO machine • No predefined scenarios • Does not simulate color change and line shattering	• Only specialists can operate and control the machine • Instructor can control training session passively
CLR [2]	High only for few parameters	High	• Displays parameters via screen • Wireless control • Available with cannulation	• Requires ECMO machine • No predefined scenarios • Limited number of parameters to control	• Easy control • Simple user interface • Easy connection to ECMO machine
Orpheus Perfusion Simulator [3]	High	Good	• Simulates the typical and critical scenarios	• Requires ECMO machine • Does not use real blood	• Simple and relatively easy to setup and control
ECMO Patient Simulator (EPS) [9]	High	High	• Simulates numerous parameters • Programmable scenarios	• Uses real blood • Requires ECMO machine	• Complicated user interface
3Dmed ECMO Simulation Kit [4]	Relatively low	Low	• Uses artificial blood • Used for surgical cannulation of and connection to ECMO machine	• Requires ECMO machine • Very limited simulation • No software side	• Overly simple
Puślecki et al. ECMO Mannequin. [5], [6]	High only for few parameters	Good	• Controllable hydraulic system, allowing for pressure manipulation • The mannequin can be cannulated • Low cost	• Requires ECMO machine • Wired control	• Mannequin requires manual setup • Simple and relatively easy controls
Modular ECMO Simulator	High	High	• Uses thermochromic ink for blood simulation • Simulates many ECMO emergencies	• Requires a relatively expensive priming fluid, which has to be replaced every 12 hours	• Easy to use through tablet application

Thus, we introduce the thermochromic loop, which is considered the fundamental component of the training system. The loop was tested at HMC to validate its heat exchange configuration, circulation, and thermochromism. There was a clear, yet subtle contrast between oxygenated and deoxygenated blood color, and when the heater was turned off, the ink color became uniform, simulating hypoxemia.

The patented [21] technique employs thermochromism (i.e. a feature of a material that achieves reversible color changes with temperature) in water-based ink (i.e. mixed with non-staining dyes) to visibly replicate chronic hypoxemia (i.e. dark red 'blood' at both inlet and outlet tubes), oxygenation (i.e. regular color contrast between inlet and outlet tubes), and recirculation (i.e. all bright red tubes). The training ECMO circuit comprises of two physically separated modules responsible for heating/cooling thermochromic ink.

To achieve such effect, a two-component circuit is constructed. A plate heat exchanger (PHE) is used to control the temperature of the liquid. Chosen by being lightweight and holding adequate space, PHEs take two liquid streams (primary and secondary) and allow heat transfer from the hot stream to the colder stream by a thermal conductive layer. It is worth noting that the main stream of liquid in both systems is thermochromic fluid, and the secondary stream is either hot or cold water produced by an external heater-cooler system. Such thermal modulation results in a difference in temperature between the fluid in the drain pipe and the fluid in the return tube circuit and therefore a change of color. The Koolance HXP-193 was the chosen PHE to maintain the temperature of the liquid within 25-35°C. A tank holding the thermochromic ink at the 'patient' unit is pushed through a PHE that cools it below its activation point. Also, the Koolance PMP-300 brushless DC pump was selected to push the fluid controlled by the Teensy 3.2 microcontroller. It receives flow rate feedback via a Koolance INS-FM14 flow meter. The design of the circuit is shown in Fig. 2.

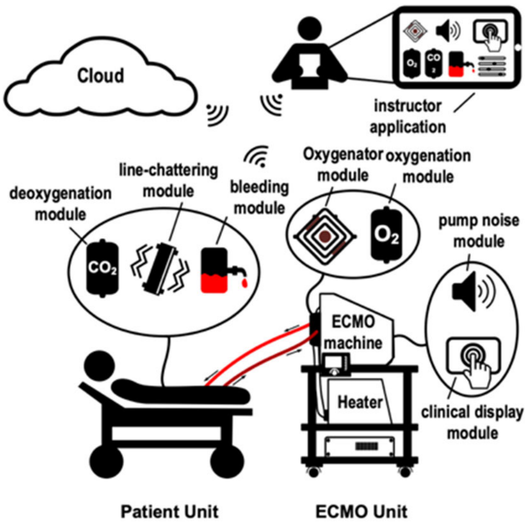

FIGURE 1. Overview of proposed training system.

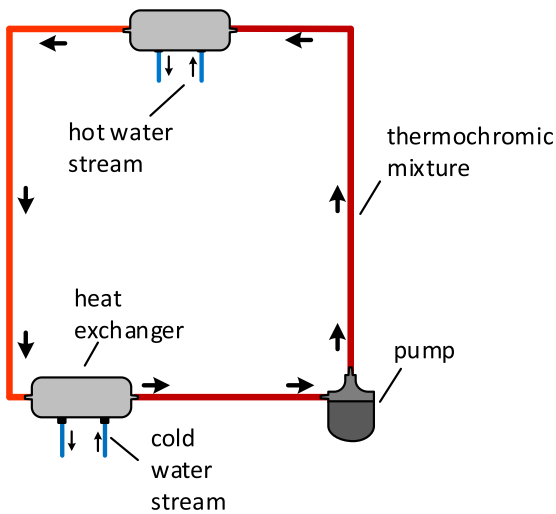

FIGURE 2. Circuit design of the thermochromic loop.

B. OXYGENATOR AND CASINGS

The oxygenator is one of the vital components in ECMO simulation. It serves as a decoy to bypass the main circuit into the heating and cooling circuits, in addition to containing two emergency modules (i.e. clotting and oxygenator noise). The component was firstly designed with 3D modeling software, then 3D printed as separate parts of varying materials (e.g. the front side is transparent while the tubes ports are printed with tough material). An assembly process is carried out to produce the oxygenator casing and its underlying electronics. Fig. 3 shows a 3D model of the replicated oxygenator.

To complement the oxygenator, the casings of the simulator are described as follows:

1) CARDIOHELP UNIT: a replica of the ECMO machine used at HMC. The design includes a full-body steel design and oxygenator connector space for high-fidelity simulations. The design also houses a screen of the Cardiohelp graphical user interface (GUI) to show current patient parameters and to adjust the settings of the machine. The GUI communicates with a CouchDB server and the instructor application (described next) to emulate real-time patient parameter changes.
2) HEATER UNIT: a replica of the HU-35 heater used by HMC. Instead of containing the complex heating device inside the original unit, the replicated case contains a PHE used to warm up thermochromic ink flowing in the circuit.

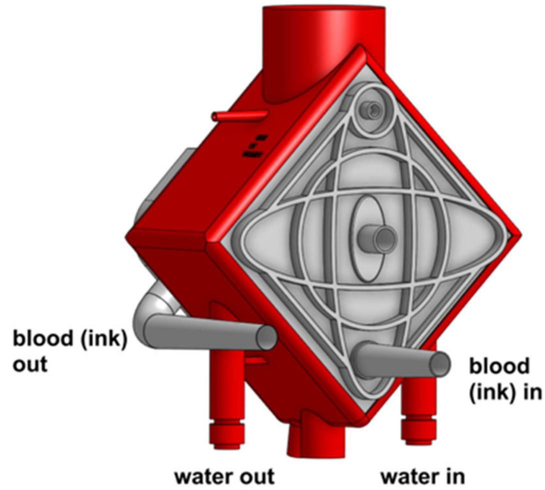

FIGURE 3. Replicated 3D model of the oxygenator.

C. INSTRUCTOR APPLICATION

The training system has been holistically thought out in the point of views of both the learner and the instructor. The teaching aspect has been supported by the development of two innovative software components: the instructor tablet application. The application is comprised of two parts: the scenario designer and the live control panel, both connected to a CouchDB cloud server for parameter and wireless scenario transmission. A full-working prototype has been implemented as depicted in Fig. 4.

The instructor application provides real-time performance of operating simulation modules and custom training scenarios. To achieve real-time performance, an improved communication infrastructure has been developed to accommodate the real-time needs of medical simulations. The new approach to developing an enhanced real-time communication system is focused on using the CouchDB cloud server. The central hub is a single-board Raspberry Pi 3 configured as a centralized server and as local wireless network to which multiple devices and modules can link, thereby forming a local private network. CouchDB configures the central repository as the system's server, where it builds a centralized archive accessible in real-time via various applications to 'post' or 'get' values. Within the ECMO training system, the simulation modules communicates with and the instructor application via the local network and CouchDB server to save, load, and modify parameter values, synchronizing parameters between the modules and the instructor application.

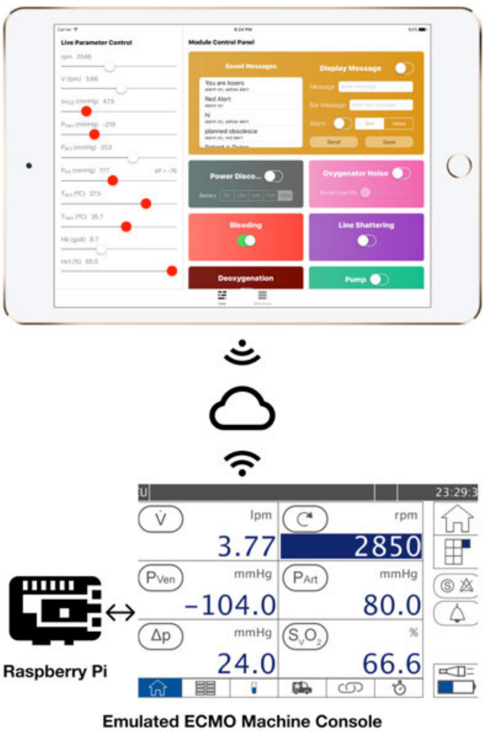

FIGURE 4. Overview of the instructor application.

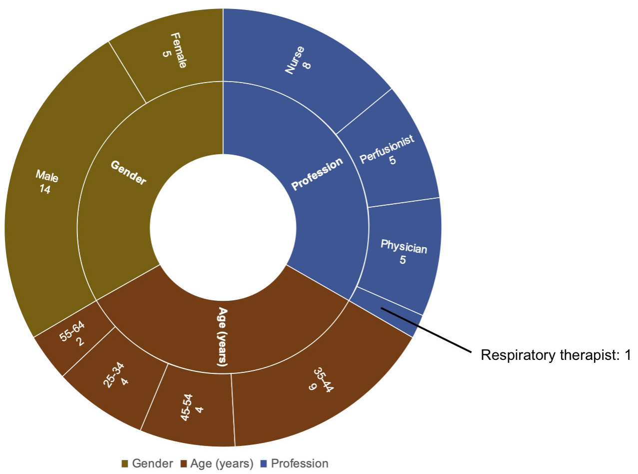

FIGURE 5. Study demographics.

D. STUDY DESIGN

In December 2017, nineteen ECMO professionals from HMC's ECMO team volunteered to score the program in-situ. Participants were invited to one of the simulator training sessions with no financial benefit.

Fig. 5 illustrates study demographics: 74% of the demographic is male, with age varying from 25 to 64. The most common age group was aged 35-44, comprising 47% of the study. Participant occupations included doctors, perfusionists, nurses, respiratory therapists. Nurses represented most common occupation (42%). In terms of practice, a mean value of 4.7 years with 75 patients cared was recorded. All subjects had previous SBT experience, including water drills (i.e. a short, hands-on session using an ECMO circuit) and scenario simulation.

All subjects enrolled in this research have given their informed consent, which has been approved by my institutional committee on human and/or animal research, and this protocol has been found acceptable by them. The study was approved by HMC's Medical Research Center (#17231/17) and classified as ''exempt'' from full ethical review.

Fig. 6 shows studies flowchart. Firstly, 19 participants were required to read the study description and consent form and received a hands-on session and demonstration of simulator functionality. The hands-on session involved running all the simulation modules, including bleeding, line chattering, pump noise, etc. as well as operating the instructor applications. For example, the instructor tablet application was presented and demonstrated to the participants, clarifying and explaining their roles (i.e. live control panel and scenario designer). Participants were offered the opportunity to experiment with the system in an empty space inside the Medical ICU. This can be recognized that the participants come to the analysis according to their availability either on duty or during shifts.

After the live demonstration, the participants completed an assessment form on the different elements of the simulator, including the intuition, responsiveness and usability of the instructor application as a feasible tool in ECMO SBT. Test duration was averaged at 16.6 (SD 5.9) minutes per participant (2 outliers were removed to improve analysis consistency).

The questionnaire–as a whole–was prepared for a usability study for the whole simulator; however, seven questions were concerned with the instructor application's overall intuitiveness, responsiveness, and convenience, which also included open-ended questions. Concise statistics were employed to evaluate the data from the questionnaire. Advanced modeling methods such as regression and variance analysis have not been utilized owing to the simplistic simplicity of the research.

IV. RESULTS

A. EVALUATION STUDY

The average scores (out of 5) for oxygenated and deoxygenated blood color consistency and the precision of the color contrast was 4.63, 4.79 and 4.53, respectively. The results are summarized in Fig. 7. Five samples of thermochromic liquid were obtained from the tank over a duration of 10 hours as their concentration level was quantified. Utilizing linear fit, the fluid was found to decay by 0.38 mg / mL per hour.

On the contrary, the expert participants scored 4.8 and 4.7 out of 5 on the live control panel screen and the scenario designer, respectively. The next metric is the responsiveness to the user's commands, which achieved an average of 4.7 (out of 5). Participants rated the application's capability in designing unique simulation scenarios as well as how good

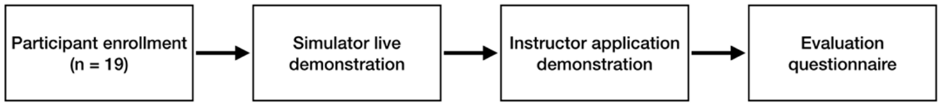

FIGURE 6. Flowchart of study.

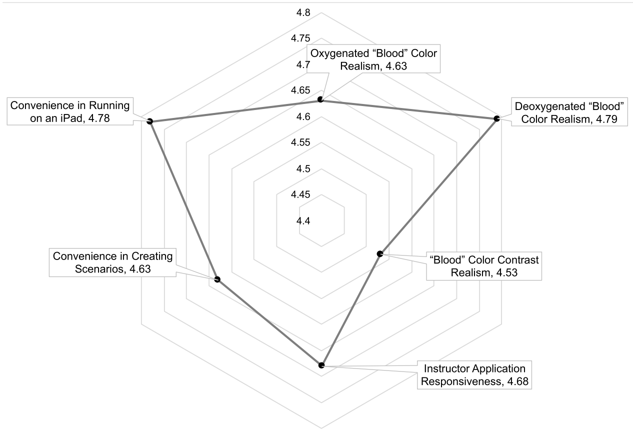

FIGURE 7. Study results summary.

was application running natively on an iPad tablet as 4.6 and 4.8, respectively.

B. SIMULATOR IMPLEMENTATION

During the past 3 years, the research team worked on surveying the literature, collecting data, and continuously developing a prototype of the system modules and the tablet application. Current implementation includes prototypes of the thermochromic system, emergency simulation modules, communications system, instructor application, emulated CARDIOHELP console, and HLS oxygenator replica. The instructor tablet application is the interface used to operate the training system and run emergency scenarios. Fig. 8 shows the current prototype of the modular ECMO training system.

For developing a formula for a practical and inexpensive blood-colored solution, thermochromic ink mixed with non-staining dyes. The implemented ECMO circuit reproduced realistic blood color change for both oxygenation and deoxygenation. The heat control circuit has an average cost of 300 USD to build, plus 40 USD/L of thermochromic mixed liquid. Nineteen ECMO experts graded the consistency of the simulated ‘blood’ at different states and the color difference between them as high-realism during the 10-hour live demonstration. During the evaluation, five thermochromic ink samples were collected from the container, where their concentration was gauged. Fig. 9 depicts the thermochromic ink in action at an ECMO simulation trial. The reader may need to zoom into the figure to notice the actual subtle difference between the two color states of blood color, which quite mimics the actual slight difference between the two states of blood color.

In order to re-create a realistic ECMO scenario, the intensive care unit (ICU) environment must be delicately simulated to induce a strong suspension of disbelief. This is crucial for high-fidelity simulations, where learners need to physically interact with the environment in order to the achieve the intended learning outcomes. For our modular ECMO training system, we have employed physical fidelity, the level to which the training system looks, sounds, and haptically feels, to achieve this goal [22]. We have started with the thermochromic loop (described earlier), developed realistic simulation modules and designed high quality casings that mimic the components used at the ICU. Fig. 10 shows the final printed circuit boards of the system.

Creating high quality casings that mimics the look and feel of actual machines is necessary for simulation immersion. The replicated Cardiohelp casing is constructed with a sophisticated container of various electronic components and a touch screen to emulate the machine’s software as well. We have employed a combination of steel metal cutting and 3D printing to fabricate the casing.

The ECMO machine connects with a magnetic coupling mechanism with the oxygenator (HLS Module Advanced 7.0). The oxygenator originally contains a membrane responsible for gas exchange outside the body. However, to save significant expenses (approx. 3,000 USD), we have fabricated the oxygenator from the outside excluding the expensive membrane thanks to the clever thermochromic loop that employs heat manipulations to change the ‘blood’ color. The oxygenator has been equipped with wirelessly-controllable pump noise and clotting modules to simulate related complications. The replicated oxygenator is currently in the final fabrication phases. Along with the ECMO machine and oxygenator, HMC uses a heater unit (HU 35) to regulate the patient’s temperature. We have designed and fabricated a replica of the heater unit that employs mild steel metal cutting.

The training system will be comprehensively assessed through a prospective cohort study at HMC. The study aims to evaluate the realism, ease-of-use, and educational efficacy of the modular ECMO training system as a tool for immersive ECMO simulation. The study includes evaluating participants through a comprehensive multiple choice question (MCQ) exam along with a questionnaire to collect feedback on the realism of various training system components.

High-fidelity training exercises help to achieve trainee suspension of disbelief and avoid negative learning, a cornerstone to effective SBT. High-realism devices and settings, though, are expensive, and need large monetary commitment. This is compounded by the ECMO SBT methods already being used. In addition to simulation facilities, ECMO centers providing SBT often focus on a working ECMO system alongside costly consumables.

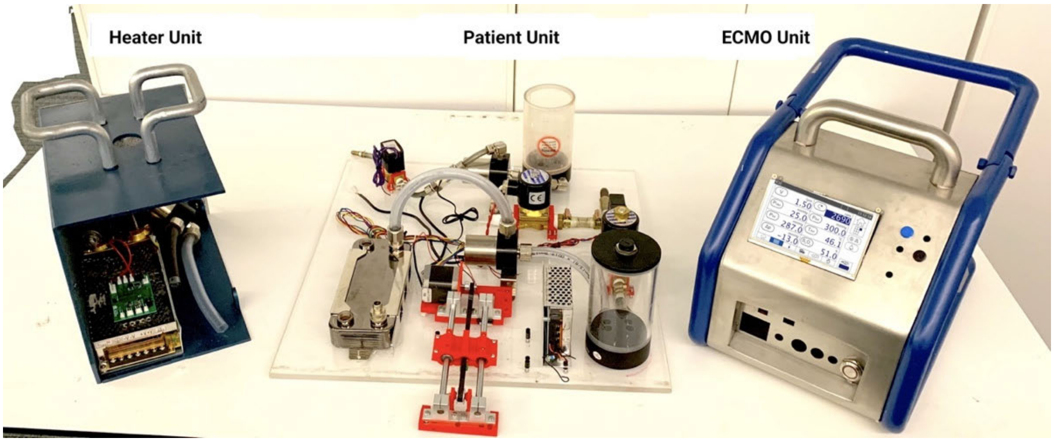

FIGURE 8. Current hardware setup of the simulation system.

FIGURE 9. Thermochromic loop simulating (a) oxygenation, (b) deoxygenation, and (c) recirculation.

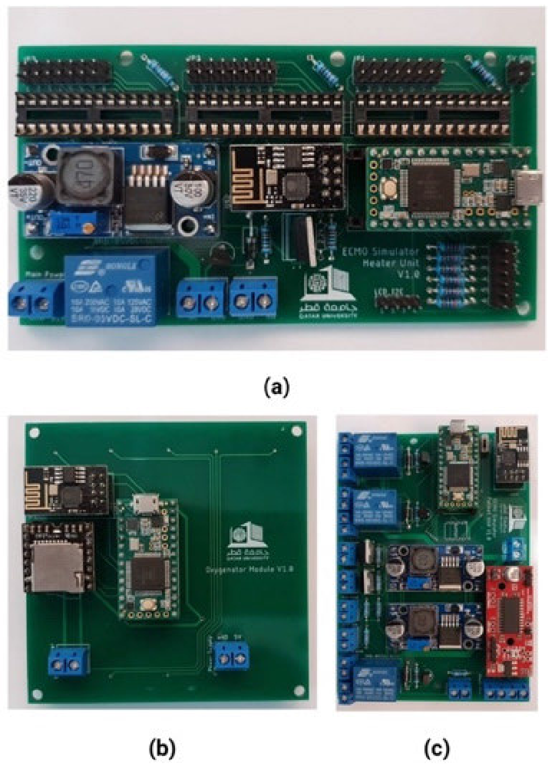

FIGURE 10. Simulator's printed circuit boards: (a) the heater, (b) the oxygenator, and (c) the patient unit.

As an initial validation of the current progress, the training has been evaluated at HMC through a questionnaire-based study. The realism of the thermochromic ink was tested by nineteen clinicians trained with differing rates of experience. The participant graded the outcome, on average, as high-fidelity. The most common piece feedback was that the oxygenated and deoxygenated 'blood' colors were too dark and should be lighter with a little darker shade of red, which can be resolved by increasing dyes' concentration. As previously stated, the systems were built to be extensible and adaptable to the unique requirements of the hospital in order to ensure optimum consistency for each ECMO center. For example, the line chattering module can operate in two modes: strong and moderate vibration to encompass the different line chattering configurations available in different hospitals world-wide.

The benefits of deploying our proposed ECMO training system include decreased cost of installation and repair, in addition to enhanced customizability and expandability. Overall, this breakthrough will greatly benefit the current ECMO SBT initiatives to further improve the learning of their participants. Current limitations of the training system include incomplete integration with the ICU, which can affect the anticipated suspense of disbelief. It of our future work plan to address those limitations.

Moreover, the team has participated in numerous local and international conferences including Extracorporeal Life Support Organization South and West Asia Chapter Conference (ELSO-SWAC 2017) that took part in Doha with two abstracts and two posters, which won best oral and poster presentation awards. Moreover, the team has been awarded first place in 11th QNRF UREP competition, and published several papers on the results in various aspects [22]–[25]. In addition, a pending non-provisional US patent application has been filed [21].

C. COVID-19 IMPACT ON SBT

Due to the significant and overreaching impact of the COVID-19 pandemic, ECMO centers have been receiving an outstanding number of patients. In some centers, the ICU reaches maximum capacity, which necessitated novel and rapid methods to deal with the overflow of patients [29]. From a first-hand perspective, in HMC's medical ICU, the overload on the staff and ECMO machines required obtaining additional ECMO machines and equipment to use on patients. The machines can be of a new brand, unfamiliar to the staff, which in some cases require prior theoretical and hands-on training. This has been carried in the form of theory mixed with quick simulation crash courses to familiarize the ECMO team with the slightly but important nuances of various ECMO machine types.

From a simulation standpoint, creating a simulation replica for an existing ECMO machine is quite beneficial in the terms saving an extra unit for a real need and creating a convenient platform for training on-the-go, when time is of utmost criticality. Also, the use of software is becoming increasingly crucial, especially when social distancing must be respected. As an example, the use of the instructor tablet application allows real-time orchestration and assessment of the learner, while aiding the instructor in maintaining a safe physical distance. Overall, SBT continues to play an instrumental role in preparing skilled staff to confront crises.

V. CONCLUSION

To complement the existing educational know-how of ECMO centers and meet the training needs of ECMO specialists, contemporary SBT needed a total revamp. A collaboration was established between QU and HMC to develop solutions that can be employed to train ECMO specialists under realistic conditions at a reasonable cost, minimizing reliance on real and expensive clinical equipment.

Presently, the training system in the big picture of regional medical simulation is a unique case study of how integrating medicine practice a with modular philosophy can reinvent training systems while keeping high-realism and cost-effectiveness in check. Once the instructional effectiveness of the training system has been checked our software will be used directly for potential ECMO training courses at HMC ICU. After successful local training runs, HMC plans to hold regional ECMO courses in Qatar using our training system as the central SBT device, paving the way for a regional training facility allowed by Qatar-made technology.

After installation of the proposed training system at HMC, the team would aim to commercialize the software to fulfill global demands for cost-effective simulation of ECMO. Further efforts to develop ECMO training systems for other widely deployed ECMO systems, such as the Xenios System and Maquet Rotaflow will be sought.

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