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6 7

8 Enhancing Clinical Learning Through an Innovative
 9 Instructor Application for ECMO Patient Simulators

10

11 Abstract

12 Background. Simulation-based learning (SBL) employs the synergy between technology 13 and people to immerse learners in highly-realistic situations in order to achieve quality 14 clinical education. Due to the ever-increasing popularity of extracorporeal membrane 15 oxygenation (ECMO) SBL, there is a pressing need for a proper technological infrastructure that enables high-fidelity simulation to better train ECMO specialists to 16 17 deal with related emergencies. In this article, we tackle the control aspect of the 18 infrastructure by presenting and evaluating an innovative cloud-based instructor, 19 simulator controller, and simulation operations specialist application that enables real-20 time remote control of full-scale immersive ECMO simulation experiences for ECMO 21 specialists as well as creating custom simulation scenarios for standardized training of 22 individual healthcare professionals or clinical teams.

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Aim. This article evaluates the intuitiveness, responsiveness, and convenience of the ECMO instructor application as a viable ECMO simulator control interface.

26

Method. A questionnaire-based usability study was conducted following institutional ethical approval. Nineteen ECMO practitioners were given a live demonstration of the instructor application in the context of an ECMO simulator demonstration during which they also had the opportunity to interact with it. Participants then filled in a questionnaire to evaluate the ECMO instructor application as per intuitiveness, responsiveness, and convenience.

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Results. The collected feedback data confirmed that the presented application has an intuitive, responsive, and convenient ECMO simulator control interface.

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37 *Conclusion*. The present study provided evidence signifying that the ECMO instructor 38 application is a viable ECMO simulator control interface. Next steps will comprise a pilot 39 study evaluating the educational efficacy of the instructor application in the clinical 40 context with further technical enhancements as per participants' feedback.

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45 Keywords

Medical simulation, simulation-based learning (SBL), extracorporeal membrane
 oxygenation (ECMO) simulation, high-fidelity simulation, simulator control interface,
 instructor application.

49

50 Introduction

51 Simulation is playing an imperative role in improving the outcomes of clinical training 52 worldwide (McGaghie, Issenberg, Petrusa, & Scalese, 2010). Simulation-based learning 53 (SBL), a learning technique that utilizes technology and people to immerse learners in a 54 simulated situation that resembles real-life to achieve the anticipated learning goals, has 55 grown and matured in the last decades with a trajectory of increasing educational utility 56 (Lopreiato et al., 2016; McGaghie et al., 2010; Torrente et al., 2014). By bridging the 57 gap between theory and practice, SBL excels in providing an ample substitution for 58 direct patient care in a safe learning environment (DeCelle, 2015). Through its use of 59 experiential learning and deliberate practice, SBL allows the learners to apply 60 theoretical concepts, develop teamworking skills, experiment and safely make mistakes, rehearse technical procedures, and then take part in a facilitated and reflective learning 61 62 process during the debriefing of an immersive scenario or to receive constructive feedback from instructors on a skills workstation (DeCelle, 2015; Huang et al., 2014; 63 McGaghie, Issenberg, Cohen, Barsuk, & Wayne, 2011). A study on junior-level 64 65 baccalaureate nursing students signified that the use of high-fidelity simulation leads to improved skills performance (DeCelle, 2015). Also, according to a recent review article, 66 SBL excels in terms of speed of learning and the amount of information retained by 67 68 learners (Bilotta, Werner, Bergese, & Rosa, 2013). Hence, SBL is an ever-growing 69 pinnacle in the realm of clinical education.

In a given immersive simulated clinical case, where the learners interact with the 70 71 patient simulator, environment, and each other to achieve the intended learning 72 objectives, one or more facilitators are involved in monitoring the learners' actions and running the scenario. Between the facilitator and the simulator is the controller interface. 73 74 It allows the instructor, simulator controller, or simulation operations specialist to 75 manipulate simulation parameters to fit the scenario's intended learning objectives. 76 According to Lateef (2010), the rise of technology-controlled simulators aids learners 77 and educators in mastering procedures and treatment protocols.

In this article, we present a simulator controller interface that facilitates disseminating feedback and complies with the educational curriculum in order to facilitate learning to achieve reproducible learning outcomes.

The controller interface is a tablet application that utilizes the power of cloud 81 82 computing to radically improve SBL in the field of extracorporeal membrane oxygenation (ECMO). ECMO is a life-saving technique that uses a cardiopulmonary 83 84 bypass circuit to provide short-term respiratory and circulatory support for critically-ill 85 patients (Frenckner, 2015; MacLaren, Combes, & Bartlett, 2012). During ECMO, deoxygenated blood is continuously drawn, oxygenated, and then returned back to the 86 87 patient's circulatory system. Due to its urgent and complex makeup, the patient is 88 heedfully monitored around-the-clock by a multidisciplinary team of ECMO practitioners. 89 They are expected to be vigilant to various changes in the patient and the ECMO circuit,

and then resolving any detected issues to avoid further complications (Frenckner,2015).

The premise of this article is to present and evaluate the intuitiveness, responsiveness, and convenience of using a cloud-based instructor application developed to control an ECMO simulator, through a questionnaire-based usability study. The aforementioned three criteria were chosen as usability metrics of the application. Thus, the research question we attempted to answer was: *how intuitive, responsive, and convenient is the instructor application as a viable ECMO simulator interface?* Our hypothesis was that the instructor application complies with those criteria.

99 To provide a comprehensive picture of the application, we shall succinctly 100 introduce the overall simulation framework and where the application fits. The 101 framework consists of three elements: the ECMO simulator, the cloud where the 102 simulation parameters are stored, and the instructor application. In the following 103 sections, we will go through each of those elements. We will then present the 104 application in details and explain its effect on enhancing the simulation experience in 105 the educational context. Next, we will present the study design for validating our hypothesis, portray the results and discussion, and finally we conclude the article. 106

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Modular ECMO Simulator Overview

The system depicted in Figure 1 is the modular ECMO simulator developed in 110 111 collaboration between Qatar University and the principal public healthcare provider in the State of Qatar, Hamad Medical Corporation (HMC) for ECMO patient management 112 training (Aldisi, Alsalemi, Homsi et al., 2017; Disi, Alsalemi, Alhomsi et al., 2017). It was 113 114 chiefly designed to solve the dilemma of simulating color change while keeping costs to 115 a minimum. This has been achieved through an innovative way where thermochromic 116 ink, a substance that changes color based on temperature adjustment, is used to 117 replace real blood (Alsalemi, Disi, Alhomsi et al., 2017, 2018). By manipulating temperature, thermochromic fluid's color can be transformed from dark red to red. 118 119 allowing repetitive simulation of oxygenation and deoxygenation while circulating the 120 simulated blood through the ECMO circuit and patient simulator.



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- Figure 1: Block Diagram of Modular ECMO Simulator (Aldisi, Alsalemi, Homsi et al., 2017)
- 125 126

Furthermore, the simulator includes a multitude of simulation modules, each specifically engineered to mimic a certain ECMO phenomenon visually, audibly, or haptically. Examples are line shattering, bleeding, pump head noise, and others.

Beyond the modules is the ECMO console, an emulated touch screen interface of a commercially available ECMO machine that displays all related parameters (e.g. pressures, temperatures, rotations per minute, and venous or arterial oxygen saturation). All of those parameters are controllable either by the instructor (e.g. pressures and flow rate) or the learners (e.g. pump rotations per minutes and alarm threshold settings) and stored in a cloud database, which is described next.

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137 **The Cloud**

138 The simulator features a centralized data storage scheme, where all the simulation 139 parameters are stored in one database located in a cloud server. Consequently, relevant parameters can be wirelessly accessed (via Wi-Fi) from the simulation modules, ECMO console, and the instructor application (discussed next) in real-time. They can also send data to the cloud, which is then distributed (as needed) to corresponding parts of the system. This will result in an infrastructure capable of simulating complex scenarios with optimum realism and performance.

Figure 2 illustrates the structure of the cloud. Google Firebase is selected as the cloud database solution because of its real-time performance and compatibility with various devices and platforms (Alsalemi, Homsi, Disi et al., 2017; "Firebase Realtime Database," 2017). Thanks to Firebase's key-value database scheme, all simulator parameters are collected in a minimal text file (also known as a JavaScript Object Notation (JSON) file). So, download and upload speeds are maximized due to the small file size.

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Figure 2: Block Diagram of the Cloud. Nurse graphic adapted with permission from Freepik from Flaticon is licensed by CC 3.0 BY

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The Instructor Tablet Application

The core motivation of this article, as discussed in the introduction, is to fulfill the recent 159 need for proper control interfaces for high-fidelity simulations. In the case of our modular 160 ECMO simulator, we present the ECMO instructor application, a full-featured interface 161 that enables the instructor or simulation operations specialist to take full control of the 162 learning experience using touch controls. Figure 3 depicts the ECMO instructor 163 application. Utilizing the aforementioned cloud infrastructure, the application provides 164 165 direct and quick access to all ECMO console parameters and simulation modules. In addition, the instructor is able to design and save complete clinical ECMO scenarios 166 directly from the application, and then execute them on the simulator, which is a step 167 towards a standardized ECMO learning curriculum. To dive into the capabilities of the 168 169 instructor application, the two main sections are discussed: the live control panel and 170 the scenario designer.

Carrier V 12:22 AM Live Parameter Control de Control De rpm 2811 V (lpm) 4,14 Red Alert Red Alert sv₀₂ (mmHg) 52.8 Yellow Alert Pulue (mmHa) -89 Red Alert PArt (mmHg) 279 AP = -23 Pint (mmHg) 265 TArt (°C) 35.6 Tuen (°C) 36.1 Line Shattering Bleeding Hb (g/dl) 9.0 Het (%) 24.3 Deoxygenation Pump -

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178 Live Control Panel

179 The live control panel offers ECMO instructors full wireless control of the various modules of the simulator as well as ECMO parameters. The instructor can recreate 180 181 specific ECMO phenomena on-the-fly by simulating bleeding, line shattering, power disconnection, oxygenator pump noise, and deoxygenation (oxygenation failure). 182 Multiple modules can be executed in parallel, satisfying the needs of the ECMO 183 184 instructor. The emulated ECMO parameters that can be wirelessly controlled are: pump 185 speed (rpm) (as an override of learner setting to create a pump failure situation), venous and arterial pressures (mmHq), venous and arterial oxygen saturation (%), arterial and 186 187 venous-side temperature (°C), hemoglobin concentration (g/dl), hematocrit levels (%), 188 and flow rate (L/min). All aforementioned parameters are synchronized in real-time with 189 the cloud, which reflects almost instantaneously on the emulated ECMO console. Figure 190 4 showcases an example.

Figure 3: Screenshot of the Instructor Application

191



197 Scenario Designer

198 While the live control panel aids in carrying on-the-spot simulations, the scenario

199 designer enables the instructors to design and execute standardized ECMO emergency

200 scenarios. A scenario consists of a timeline where simulation modules are placed 201 chronologically with set parameters (Alinier, 2011). The potential for such standardized 202 simulation design approach is that it creates a framework for facilitating effective SBL 203 experiences for learners (Lioce et al., 2015; Young & Kozmenko, 2015). Depending on 204 instructor preferences, scenarios may run in a nearly automated manner according to a set flow chart or on-the-fly (Alinier, 2011; Young & Kozmenko, 2015). In this ECMO 205 206 instructor application, there are two types of modules: generic and emergency. Generic modules provide structural functionality to an ECMO scenario, whereas emergency 207 modules simulate actual ECMO circuit complications. Table 1 lists all applicable 208 209 modules.

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- 211

Table 1: ECMO Instructor Application Modules

Generic Modules		Emergency Modules	
1.	Stop simulation : stops the current simulation session.	1.	Bleeding : simulates patient bleeding using thermochromic ink for a specified period at
2.	Change parameters: manual adjustment of		one of the cannulation sites.
	ECMO parameters.	2.	Line shattering: simulates line shattering for
3.	Display message: shows a message on the		a specified period.
	ECMO machine GUI with an alarm.	3.	Power disconnection: simulates power
4.	Wait for action: used to conditionally execute modules based on the learner's actions.		disconnection to the ECMO machine for a specified period and runs the machine on
5.	Delay: pauses simulation for a specified		battery power.
	period.	4.	Deoxygenation : simulates blood oxygenation failure for a specified period.
		5.	Air in oxygenator pump: simulates air in oxygenator by introducing noise for a specified period.

In a given scenario, the instructor can add modules to the timeline, configure the settings, remove, and rearrange them. A module can be accompanied by a parallel module (e.g. bleeding alongside change parameters) to increase the realism of the simulation. Figure 5 depicts a sample scenario.

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When running a scenario, the sequence is transferred to the cloud. The simulator receives the sequence and commences execution. While running a scenario, emulated ECMO parameters can be adjusted on-the-spot, giving convenience to the instructor and realism to the simulation. Hence, the sequence designer is considered a step towards standardized ECMO training through a digital curriculum that addresses both the cognitive and behavioral skills demanded of an ECMO practitioner.

In the upcoming sections, an evaluation of the instructor application in practice is presented from the perspective of its intuitiveness, responsiveness, and convenience as a new tool emerging in the SBL field.

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232 Methods

233 Sample Size

Nineteen ECMO practitioners from HMC's ECMO team were recruited as volunteers in December 2017 to evaluate the modular ECMO simulator. Volunteers were invited without any incentive for enrollment to individually attend one of several ECMO simulator demonstration slots.

238 Table 2 summarizes the participants' demographics. Among the population, 74% 239 were male, with age varying from 25 to 64 years. The most common age group was 35-240 44 years old, which represented 47% of the population at the time the demonstrations were organized. The professions of the participants encompassed physicians, 241 perfusionists, nurses, and respiratory therapists. Nurses represented the largest 242 243 segment (42%). In terms of ECMO experience, the average was 4.7 years with an average of 75 patients cared. All participants had prior exposure to SBL including water 244 245 drills¹ and immersive scenario-based simulation as it is a requirement of being an 246 ECMO practitioner at HMC. 247

248 IRB Approval

The study was approved by HMC's Medical Research Center (#17231/17) and classified as "exempt" from full ethical review.

¹ A water drill is a short, hands-on session using an ECMO circuit (Thompson et al., 2014).

Participants	n (%)
Gender	
• Male	14 (73.6%)
Female	5 (26.4%)
Age (years)	
• 25 - 34	4 (21%)
• 35 - 44	9 (47%)
• 45 - 54	4 (21%)
• 55 - 64	2 (11%)
Profession	
Physician	5 (26.4%)
Perfusionist	5 (26.4%)
Nurse	8 (42.1%)
Respiratory therapist	1 (5.1%)
	Mean (±std)
ECMO experience (years)	4.7 (±3.2)
Number of patients cared for	75 (±52)

Table 2: Sample Size Demographics

253

254 Study Design, Assessment, and Statistical Analysis

Figure 6 shows the study design. The study proceeded as follows. First, participants 255 (one or two at a time) read the study brief and consent statement and then were given a 256 bedside explanation of the simulator functionalities. Next, the instructor application was 257 258 presented to the participants, where its features (i.e. live control panel and scenario 259 designer) were explained and demonstrated. The participants were given a chance to try the application firsthand in a vacant room within the Medical Intensive Care Unit. It is 260 261 noteworthy to mention that the participants came to the study according to their 262 availability (as intensive care unit staff) while on duty or between shifts.

263 264

[insert Figure 6] Figure 6: Study Design

265 266

267 Following the demonstration, the participants filled in an evaluation guestionnaire concerned with various elements of the simulator including the intuitiveness, 268 269 responsiveness, and convenience of the instructor application as a viable tool in ECMO SBL. The questionnaire-as a whole-was prepared for a usability study for the whole 270 271 simulator; however, seven questions were concerned with the instructor application's overall intuitiveness, responsiveness, and convenience. Table 3 lists all study 272 questions. The evaluation duration was 16.6 (SD 5.9) minutes on average per 273 274 participant (two outliers were excluded from the calculation to improve the accuracy of 275 the analysis (Motulsky & Brown, 2006)).

To analyze the questionnaire data, we have deployed descriptive statistics. Advanced analysis techniques such as correlation and analysis of variance were not used due to the simple nature of the study.

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Table 3:	Study	Questionnaire	Items
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Number	Question
1	How intuitive is the live control screen in the instructor App? (1: Not intuitive at all – 5: Very intuitive)
2	How intuitive is the sequence manager in the instructor App? (1: Not intuitive at all – 5: Very intuitive)
3	Overall, how responsive is the instructor App? (1: Not responsive at all - 5: Very responsive)
4	How convenient is the instructor App in creating ECMO training scenarios? (1: Not convenient at all – 5: Very convenient)
5	How convenient is using the instructor App on an iPad? (1: Not convenient at all – 5: Very convenient)
6	Are there features in the instructor App you believe are missing? Please state if any.
7	What are your comments about the Instructor App?

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282

283 **Results**

284 This section reports the study results as per the aforementioned methodology. Table 4 285 tabulates each measured criterion and its corresponding descriptive statistics. We 286 began with the intuitiveness of the instructor application as an ECMO simulator control 287 interface. On average, participants scored 4.8 and 4.7 out of 5 on the live control panel 288 and scenario designer respectively. The next measure was responsiveness of the application to the instructor commands. The average rating was 4.7 (out of 5). Lastly, 289 290 participants rated the convenience of the application in terms of creating custom training 291 scenarios and it being installed on an iPad tablet as 4.6 and 4.8 respectively. Figure 7 292 illustrates the results in a spider diagram, which shows the average rating of the three 293 measured criteria on a 2D plane.

Open-ended feedback on the ECMO instructor application can be summarized in two points: First, users of the application should be given a brief introduction on the functionality prior to using it for SBL. Second, laboratory reports and simulated blood parameters should be included in the scenario designer.

Table 4: Study Results Descriptive Statistics

Sample size n = 19				
Intuitiveness				
Live Control Panel	Mean = $4.79 (\pm 0.408)$ (out of 5) Min = 4.00 Max = 5.00			
	Mode = 5.00 Median = 5.00			
 Scenario Designer 	Mean = $4.74 (\pm 0.440)$ Min = 4.00 Max = 5.00			
	Mode = 5.00 Median = 5.00			
Responsiveness	Mean = 4.68 (±0.567) Min = 3.00 Max = 5.00			
	Mode = 5.00 Median = 5.00			
Convenience				
 Creating Scenarios 	Mean = 4.63 (±0.581) Min = 3.00 Max = 5.00			
 Running on an iPad 	Mode = 5.00 Median = 5.00 Mean = $4.78 (\pm 0.416)$ Min = 4.00 Max = 5.00			
	Mode = 5.00 Median = 5.00			



Figure 7: Spider Diagram of the Averaged Measured Criteria: Intuitiveness,
 Responsiveness, and Convenience of the ECMO Instructor Application

305

306 **Discussion**

307 SBL has matured over the years to become an indispensable clinical training approach 308 especially in ECMO, where teamwork, decision making, and critical thinking skills are 309 pivotal to successful patient outcome. On that account, there is an increasing need for a proper technical infrastructure to support the growth of SBL and build simulators that 310 311 are technologically fit for the learning purposes of specialized therapies and procedures, 312 whilst facilitating valid and relatively standardized learning opportunities (Scerbo et al., 2011; Young & Kozmenko, 2015). One important aspect is the control interface of 313 314 simulators. Hence, the aim of this study was to evaluate the intuitiveness, 315 responsiveness, and convenience of the modular ECMO simulator instructor application 316 as a viable tool in SBL. The application acted as the interface between the ECMO 317 instructor and the simulator, enabling full control of the simulation experience to aid 318 learners suspend disbelief, avoid negative learning, and achieve intended educational 319 outcomes (Bland, Topping, & Tobbell, 2014). We hypothesized that the application 320 complies with the aforementioned usability criteria of intuitiveness, responsiveness, and 321 convenience. In this section, we present a discussion based on the participants' 322 responses.

Analyzing the participants' response data, we observed that the average of the rating of intuitiveness, responsiveness, and convenience was 4.8, 4.7, and 4.7 (out of 5), respectively. Therefore, we conclude our hypothesis was confirmed and we can say that the instructor application is a usable simulator interface for high-fidelity ECMO SBL. 327 It is notable to mention that the results of this study do not imply the educational
 328 efficacy of the application in improving the learning outcomes of ECMO SBL. We
 329 therefore leave this topic for a later publication.

330 This study has several limitations, including the simplistic approach applied in 331 both data acquisition and analysis, the lack of reliability and validity data for the 332 proposed tool, and the fact that it involved a limited number of clinicians from a single 333 facility and no simulation operations specialists. Hence, the study can benefit from a 334 more thorough design with two groups of participants, longer assessment durations, 335 and a larger sample size involving ECMO practitioners from other institutions as well as 336 individuals who are more specialized in controlling patient simulators. The instructor 337 application has several limitations comprising the lack of some complementary features 338 such as vital sign monitor simulation and blood parameters in addition to rare delays in 339 data transmission. Those limitations will be tackled in future development of the 340 application.

341 Based on our SBL literature search, the use of our instructor application is novel. 342 According to Johnston and Oldenburg (2016), software did not play a part in ECMO SBL until recently. In the last decade, SBL has witnessed technological enhancements 343 344 with the notable examples of the Orpheus Perfusion Simulator, EigenFlow, and the Parallel Simulator ("Chalice Medical: Parallel Simulator," n.d., "EigenFlow ECMO 345 346 Simulator," n.d.; Morris & Pybus, 2007). The Orpheus Perfusion Simulator includes a 347 hydraulic model connected to an ECMO circuit and a screen that displays circuit 348 parameters. It is controlled through a laptop via a USB cable. On the other hand, 349 EigenFlow and Parallel Simulator incorporate remote control through an iPhone app and a Windows tablet respectively. They also provide an additional monitoring screen 350 351 that displays simulation parameters. Instructors can control various parameters such as hemoglobin and flow rate through the mobile application. However, some changes are 352 353 actually implemented in the ECMO circuit (e.g. running embolism from the application 354 will actually create obstructions in the circuit). Both applications wirelessly communicate 355 with the simulator peer-to-peer (compared to our cloud-based approach) and lack the 356 scenario designer functionality.

357

358 **Conclusions**

359 This article evaluated a novel ECMO simulator instructor tablet application from the 360 point of view of intuitiveness, responsiveness, and convenience. The application allows 361 real-time control of the ECMO simulation experience as well as creating standardized 362 simulation curricula. To evaluate the simulator, a usability study with 19 participants was 363 carried out. Participants were given a live demonstration of the instructor application in the context of the modular ECMO simulator and filled in an evaluation questionnaire. 364 365 The data have confirmed our hypothesis and verified the usability of the ECMO instructor tablet application in terms of intuitiveness, responsiveness, and convenience. 366 367 Future work includes an evaluation of the educational efficacy of the application in addition to the development of further features. 368

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481 **Declaration of Conflicting Interests**

482 The Authors declare that there is no conflict of interest.