DEVICES TO IMPROVE INTEROPERABILITY BETWEEN SIMULATORS AND CLINICAL DEVICES FOR SIMULATION-BASED RESUSCITATION TRAINING AND RESEARCH

by

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Abstract

Medical simulation is frequently used to train medical professionals and emergency responders resuscitation skills. Existing simulators do not provide the necessary features to allow for realistic interoperability with clinical devices, namely smart defibrillators and physiological monitors. The use of unrealistic models in medical training has been observed to cause healthcare provider confusion and to reduce the effectiveness of training. Three devices were produced in this research to eliminate gaps in interoperability between simulators and clinical defibrillators:

1. The Anterior-Posterior (AP) Defibrillation Belt provides defibrillation capabilities to existing high- or low-technology simulators in multiple defibrillator pad placement configurations, namely AP and anterior-lateral (AL) pad placement.
2. The End Tidal Carbon Dioxide ($ETCO_2$) Sensor Signal Generator allows users to display and control an $ETCO_2$ waveform and numeric values on compatible clinical defibrillators and monitors.
3. The Zoll R Series Defibrillator Emulator interfaces pre-existing CPR performance measurement devices with customizable performance assessment and visualization applications.

All three devices have been demonstrated to be safe and reliable and have undergone preliminary efficacy testing in simulation-based training sessions. The devices created through this research provide a platform of "add-on" technologies that improve the interoperability between simulators and clinical defibrillators. The AP Belt, the ETCO2 Sensor Signal Generator, and the Emulator can be used to extend the functionalities of low- and high-technology simulators and simulator substitutes. By addressing common

connectivity issues in simulation-based resuscitation training, these devices are capable of increasing the effectiveness of resuscitation training for cardiac arrest to ultimately improve the quality of in- and out-of-hospital resuscitation.

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Preface and Acknowledgements

This dissertation is the compilation of my research at the Johns Hopkins Medicine Simulation Center. All work is original and unpublished, though work described in Sections 2 and 3 has been presented at two international conferences. Additionally, Betsy Hunt, Jordan Duval-Arnould, and I have four patents pending surrounding the technologies developed in this research effort. The educational need for many of these devices and their functional requirements, specifically for the Anterior-Posterior Defibrillation Belt and the $ETCO_2$ Sensor Signal Generator, described in Sections 2 and 3, respectively, were identified and brought to my attention by Betsy and Jordan. Jordan also developed part of the software in the final version of the First Generation $ETCO_2$ Sensor Signal Generator—this is denoted in further detail in Section 3.

Throughout the past two years, I have been provided with all of the resources that I could possibly need to stumble through, and sometimes solve, engineering challenges. Despite this rare opportunity to innovate without repercussions, the most meaningful part of this experience has been interacting daily with individuals with different experiences, skill sets, and stories. Specifically, I would like to thank Dr. Allen, Dr. Fackler, and all of the Johns Hopkins Medicine Simulation Center staff, all of whom have devoted both time and effort to teach me the basics of resuscitation and medical simulation. I am especially appreciative for my mentors at the Simulation Center, Betsy and Jordan. Betsy included me in any and all relevant learning opportunities in the clinical setting, providing me with invaluable exposure that not only significantly affected the work I have completed as a

part of this research but also changed priorities and goals for my future career. Jordan taught me everything I know about software development, which, in my opinion, is a miracle in itself! He has also been my confidant for all things technical throughout the past two years and for that, I thank him.

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1 Introduction

1.1 Overview

Nearly 570,000 Americans were affected by cardiac arrest in 2013 [1]. Approximately 16,000 children in the United States experience cardiac arrest annually [2], and in the pediatric intensive-care setting there is one cardiac arrest per 100 admissions. In-hospital pediatric survival has improved in recent years; specifically, the latest large registry-based study reported that risk-adjusted rates of survival to discharge increased nearly threefold between 2000 and 2009, from 14% to 43% [3]. Similarly, both the incidence and the survival rate of adult cardiac arrest have increased in recent years [4]. Unfortunately, there is large variability in reported survival rates and in the methods of documenting cardiac arrest in healthcare institutions; for example, reported survival rates for adults range from 11% to 45% [5]. These differences make it difficult to distinguish between variability in healthcare and/or documentation practices.

The quality of resuscitative efforts has been observed to considerably affect all patients, healthcare providers, and families involved. Simulation-based resuscitation training has been shown to be an effective means of training healthcare providers. Specifically, it has been demonstrated to improve the quality of chest compressions, reduce time to defibrillation and time to initiation of compression, and it has been repeatedly linked to improved clinical outcomes [6, 7, 8].

1.2 Context

1.2.1 Resuscitation Quality

The American Heart Association (AHA) and international cardiopulmonary resuscitation (CPR) and basic life support (BLS) guidelines establish that healthcare providers are expected to treat a cardiac arrest patient with immediate chest compressions (i.e. < 10 s to recognize and initiate AHA 2010) and, if indicated, defibrillation as rapidly as possible (ie. ≤ 180 seconds from pulselessness to shock). Defibrillation is the application of a therapeutic dose of electrical energy through a cardiac arrest patient's heart to depolarize the muscle and return heart to normal sinus rhythm. Every minute that CPR is delayed, the likelihood of survival is reduced by 10% [9]. The AHA recommends that chest compressions be at least 2 inches deep and should be delivered at a rate 100 to 120 compressions per minute with minimal pauses [10]. It has been repeatedly demonstrated that these quality performance measures are not met by providers in both clinical and simulated scenarios [11, 12, 13, 14, 15]. Delivery of CPR within AHA recommendations has been shown to significantly improve outcomes in clinical and animal studies [16, 17, 18, 19, 20]; additionally, maximizing the chest compression fraction, which is the proportion of time that a person has no pulse or inadequate circulation and is receiving compressions, has been associated with increased survival [21, 22]. Although most healthcare providers complete CPR training programs, knowledge and skill retention has been shown to decay rapidly over time in the absence of refresher courses. Retention of CPR skills varies by technical level as well as method of instruction [23, 24, 25, 26, 27, 28].

1.2.2 Feedback Tools: Debriefing and Smart Defibrillators

Structured post-arrest debriefings of CPR quality performance data have been shown to improve later performance of healthcare providers [6, 29]. Objective metrics, including chest compression rate and depth, time to defibrillation, and ventilation rate, and subjective assessments, relating to team work and communication, are discussed in such debriefings. It was demonstrated in an intervention study of 123 in-hospital resuscitations that the incorporation of weekly debriefing sessions significantly improved the ventilation rate and the compression depth, among other improvements in performance metrics, in comparison to baseline performance, which did not include formal debriefing [6]. CPR quality improvements were associated with an improved rate of return of spontaneous circulation (ROSC) [6]. These debriefing sessions incorporated metric data from a smart defibrillator.

Defibrillators with the capabilities to capture patient and resuscitation performance data have been termed "smart defibrillators." These technologies not only capture data from cardiac arrest events for potential use during post-cardiac arrest debriefing, but they also provide real-time feedback during resuscitation. Common metrics for real-time feedback are quality CPR metrics, such as chest compression rate, depth, and recoil, cardiac rhythm recognition, ventilation rate, end-tidal carbon dioxide ($ETCO_2$) levels, and timing cues related to chest compressions and defibrillation. The ZOLL R Series Plus defibrillator (ZOLL, Chelmsford, MA), a smart defibrillator, was introduced to the Johns Hopkins Hospital Children's Center in Baltimore, Maryland in 2011 as the standardized

model. It is now being rolled out in phases across the rest of the Johns Hopkins Hospital campus for the adult population. Most recently, in Spring 2014, it was fully deployed to the entire New Clinical Building, a two tower 560 bed state-of-the science adult and pediatric hospital. The completed transition will result in the full transition of the hospital, which has 1,059 beds and over 250 defibrillators, from the former standard (ZOLL M Series) to the new standard (ZOLL R Series). Several of the training devices included in this report were developed for use with the ZOLL R Series defibrillator; in particular, both the $ETCO_2$ sensor and the accelerometer-based quality CPR Puck, which are associated with the ZOLL R Series Plus, were researched and adapted for enhanced and expanded use in training and in practice.

1.2.3 Patient Simulators

The use of simulation across a number of healthcare disciplines is growing rapidly due to the associated increases in patient safety and healthcare provider quality assurance efforts [30, 31, 32]. Over 80% of polled Association of American Medical Colleges (AAMC) medical schools or their affiliated universities use simulation for education [33]. Healthcare simulation provides means for teaching, assessment, research, and medical institution improvement initiatives, all without sacrificing patient safety. Additionally, because simulation allows for standardization of event variables, simulation-based training can be repeated as needed to perfect providers' cognitive and psychomotor skills and to identify and eliminate human factors and logistical issues affecting performance.

Simulation can be categorized into five categories: verbal, standardized patients, task trainers, virtual patients, and human patient simulators. Resuscitation training generally involves half-body task trainers, which provide users an opportunity to practice BLS skills, or human patient simulators, which are full-body simulators with human characteristics. Due to the differences in fidelity provided by task trainers and human patient simulators, these simulators are termed low-technology and high-technology simulators, respectively. In general, high-technology simulators (HTS) can be defibrillated, while low-technology simulators (LTS) cannot. HTS offer a number of additional characteristics that add realism to basic procedural practice or complete scenarios, such as palpable pulses, visual chest rise and fall, and they can be intubated and delivered intravenous therapy (Fig. 1.1). Simulators that offer the ability to be defibrillated are especially important to this research because early and optimized defibrillation of cardiac arrest patients is one of the few therapeutics that can significantly affect clinical outcomes [34, 35, 36]. LTS offer a platform for CPR training, as users can practice chest compressions and ventilation with a bag-valve mask using these simulators. Evidence increasingly suggests that training using high-technology simulators results in significant performance advantages for learners in comparison with low-technology simulators [37, 38, 39].

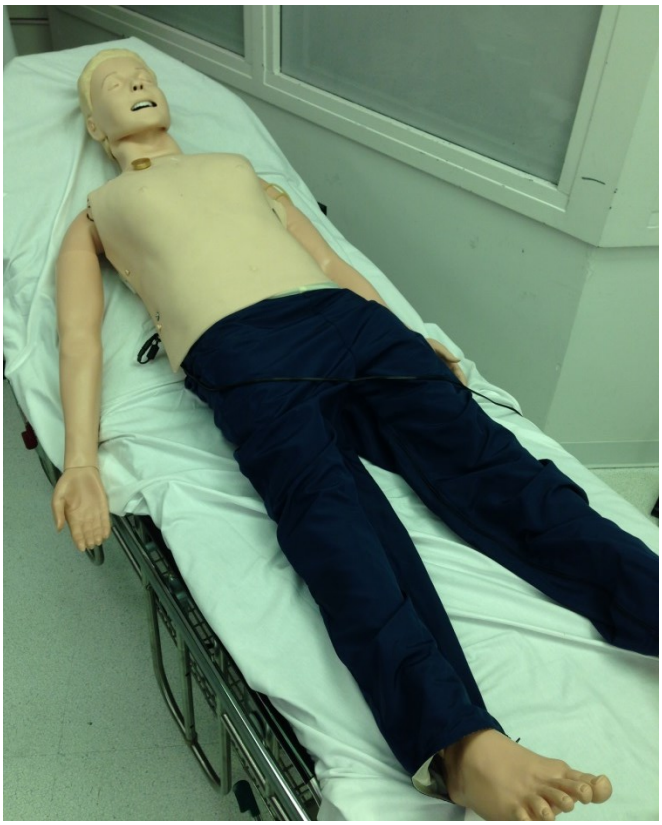

Figure 1.1. High technology simulator (HTS)

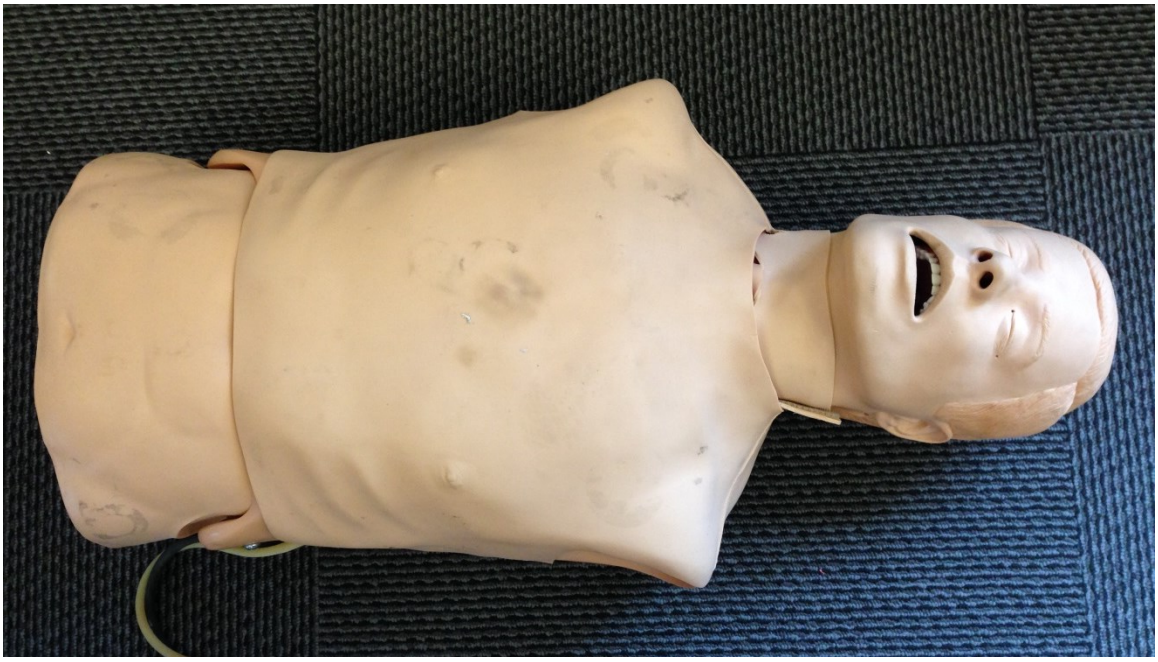

Figure 1.2. Low technology simulator (LTS)

All AHA CPR, BLS, and adult and pediatric advanced cardiovascular life support (ACLS and PALS) training courses use multiple forms of simulation for teaching and realistic skills practice. Most BLS courses use only LTS, which do not: (1) react dynamically to the user, (2) offer feedback in the form of changes in vital signs or visual/audio cues, or (3) look like real patients. HTS are generally not used for BLS because of their high prices. An increasing number of ACLS and PALS courses include training with HTS during simulated code scenarios. These simulators can provide a number of simultaneous event-related symptomatic cues in addition to reacting to trainee actions during the simulation. All HTS also provide a platform for recording performance metrics of trainees, allowing for additional learning through debriefing of simulated scenarios.

Despite the increasing realism of current HTS, there are still a number of technological barriers that must be addressed to improve the current state of the art. A limited number of physiological signals, such as heart rhythm, can be simulated by HTS and identified by healthcare providers using clinical diagnostic tools. However, most simulated signs/symptoms cannot be detected with clinical diagnostic tools, and therefore cannot be displayed on clinical monitors. HTS parameter changes can be viewed on a simulator-specific monitor, but these generally do not match clinical monitors. This gap in connectivity presents significant limitations when using simulation to train and assess user proficiency with medical devices, such as smart defibrillators.

The ZOLL R Series Plus defibrillator used in this institution has associated sensors, including $ETCO_2$ sensor, pulse oximetry sensor, and electrode pads, all of which function with human patients. Generally, these sensors do not work realistically with simulators, so during training the defibrillator screen is not populated with the patient data that would be used in a clinical resuscitation. These types of connectivity limitations result in reduced ability to complete effective resuscitation research and training, meaning providers cannot train to clinical standards of practice. We have observed confusion during in-service training at this hospital, most of which is caused by the inability to observe and practice realistic device functionalities with existing simulation technology. Additionally poor interoperability of HTS or LTS with clinical devices reduces research capabilities due to limitations of simulation-based resuscitation models.

1.3 Solutions

The initial motivation for this research was to improve the realism of resuscitation training at all levels for both in- and out-of-hospital cardiac arrest. The lack of clinical realism is a frequently referenced limitation of simulation training [40, 41], as it can affect the effectiveness of training. There currently exist a number of lapses in the interface between simulated physiological patient characteristics and clinical devices. By improving simulated patient interface with clinical devices, healthcare providers are able to train using their own devices, avoiding confusion in the translation of training to clinical practice.

High quality chest compressions and early defibrillation are the only therapeutics that have been demonstrated to significantly affect cardiac arrest patient outcome [34, 42, 22, 21]; so, we chose to focus on developing modular solutions that allow for more realistic visual and psychomotor skill interaction of the users with the simulator and clinical defibrillator. These solutions can be used to increase simulation training capabilities of HTS, LTS, and simulator substitutes. These hardware and software solutions have been shown to improve resuscitation training, research, and clinical performance; additionally, the described devices increase the fidelity of healthcare simulation for resuscitation training and provide improved performance feedback in training and in clinical practice.

1.3.1 Defibrillation Belt

Most HTS only allow for defibrillation with pads or paddles in the anterior-lateral (AL) position; and, the majority of simulators used for BLS training are LTS, which offer no defibrillation capability. This device upgrades all healthcare simulators to have defibrillation capabilities in both the anterior posterior (AP) and AL positions. The device allows for HTS, which typically have self-generated heart rhythms and are able to be defibrillated in the AL position, to also have AP functionality; and it allows for LTS, which typically have no heart-rhythm generation or defibrillation capabilities, to have AP and AL heart rhythm generation and defibrillation functionality when combined with commercially available heart rhythm simulators. When used with defibrillators that provide quality of CPR feedback and/or filter out compression artifact in the ECG rhythm, this device allows for more realistic population of the defibrillator screen, providing a more effective resuscitation training model.

1.3.2 $ETCO_2$ Signal Generator

A training environment with clinically relevant population of clinical device screens offers a more realistic simulation-based model with which to train and complete research. There is currently no known device that allows for generated signals to replace signals from $ETCO_2$ sensors as inputs to clinical monitors/devices. This device provides multiple means of signal generation and data encoding and transmission functionalities to realistically simulate diagnostic sensor inputs to clinical monitors/devices. The current prototype generates and encodes an $ETCO_2$ signal using an executable C# program on a PC, laptop, or tablet, and the digital signal is transmitted from the computer through a USB port to a defibrillator with monitoring capabilities.

1.3.3 Clinical Defibrillator Emulator

In-service trainings designed to teach the functionalities of clinical devices often do not allow learners to see or use the device in a clinically relevant scenario. For example, in-service training at this hospital does not provide users the opportunity to see the CPR quality feedback on the defibrillator display because of simulator-defibrillator connectivity limitations. The Clinical Defibrillator Emulator is a software program that emulates the defibrillator display and functional characteristics. It replaces the defibrillator to eliminate connectivity issues during basic CPR or defibrillation training, providing a less expensive, more effective in-service training tool. The user interface of the device software is run on a computer and matches the defibrillator user interface in appearance. Clinical defibrillator pads plug into associated hardware, and the computer

can calculate and provide real-time feedback regarding time to initiation of chest compressions, time to defibrillation, and chest compression quality via realistic cues on the emulated defibrillator screen.

2 Defibrillation Belt

2.1 Background and Motivation

American Heart Association (AHA) recommendations for cardiopulmonary resuscitation (CPR) concentrate on the immediate initiation of chest compressions and the defibrillation of patients with shockable rhythms within 180 seconds. Rapid defibrillation and high quality chest compressions have both been demonstrated to improve cardiac arrest outcomes; survival rates associated with witnessed, shockable sudden cardiac arrest decrease 3-4% per minute if bystander CPR is provided without defibrillation and decrease 7-10% per minute if neither CPR nor defibrillation is provided [35, 43, 44, 9].

AHA recommendations have recently been adapted to encourage defibrillator pad placement in either the anterior-lateral (AL) or anterior-posterior (AP) positions (Fig. 2.1). In-hospital providers caring for both adult and pediatric patients frequently place pads in the anterior-posterior (AP) position due to defibrillator manufacturer recommendations, which ultimately drive hospital protocol. For example, ZOLL® Corp. recommends AP positioning for pads used with the R Series defibrillator, which is the defibrillator used throughout the Johns Hopkins Hospital Children's Center. Some evidence suggests advantages for AP placement [45]; additionally, it has been observed at this institution and others that pediatric nurses often place pads on simulators, as they do on patients, in the AP position. In adult patients, AP pad placement is also becoming

common practice due to equivalent outcomes with defibrillation and demonstrated improved outcomes in cardiac pacing [45, 46].

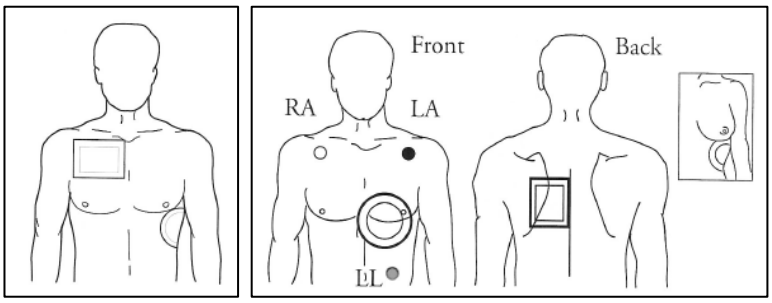

Figure 2.1. Anterior-lateral (left) and Anterior-posterior (right) defibrillator pad placement positions. Adapted from White [87] .

Simulation-based training can be an effective method of improving quality of CPR through hands-on training and practice. Evidence increasingly suggests that training using high-technology simulators (HTS) results in significant performance advantages across various healthcare practices for learners in comparison with low-technology simulators (LTS) [37, 38, 39, 47]. One of the key distinctions between HTS and LTS is the defibrillation capabilities of HTS. The majority of HTS currently used to teach BLS and PALS only allow for defibrillation with pads or paddles in the anterior-lateral (AL) position; and, the majority of simulators used for BLS training are LTS, which offer no defibrillation capability.

Currently, there are few HTS that allow for realistic training of AP defibrillation. As a result, AP pad placement on the majority of HTS negates the capability of the HTS to be defibrillated, cardioverted, or paced, as the pads, then, have no contact with the studs. American Heart Association requirements for BLS training courses involve online lessons to be completed individually, and then interactive classes with an instructor for skills practice and testing, both of which involve the use of simulation-based training. The current methods of teaching BLS are inadequate because the majority of simulators

used for standard BLS training to out-of-hospital providers offer no defibrillation capability, which limits the amount of realistic, hands-on learning that can take place in adult and pediatric BLS courses. Although there are some courses that do include HTS in training, these do not allow for defibrillation with AP pad placement. This gap in interoperability between clinical defibrillators and interfacing simulators limits the effectiveness of simulators for use in education, investigational and translational research, and clinical device deployment. In order to improve resuscitation practices, simulation-based models should (1) allow healthcare providers to use clinical devices as they would in practice for training and education, (2) allow investigators to observe realistic provider interactions with devices for research, and (3) allow for efficient assurance of devices prior to deployment within healthcare institutions for the assessment of device safety and efficacy.

A number of work-around solutions have been developed to increase interoperability between simulators and clinical defibrillators [48, 49, 50]; however, the majority of these solutions are temporary and require an operator to change simulator connectivity with a clinical device during simulation training, research, or testing. For example, resuscitation training studies at this institution required the trainer to attach a rhythm generator to the defibrillator at the same time trainees position pads on a LTS in order to allow for trainees to have a realistic interaction with the defibrillator. We introduce an engineering solution that has been developed to allow for realistic and reliable interaction between simulators and defibrillators, providing a platform for an improved model of interoperability in education, research, and clinical device deployment. This engineering

solution provides defibrillation capabilities to existing high- or low-technology simulators in multiple defibrillator pad placement configurations, namely AP and AL pad placement (Fig. 2.2).

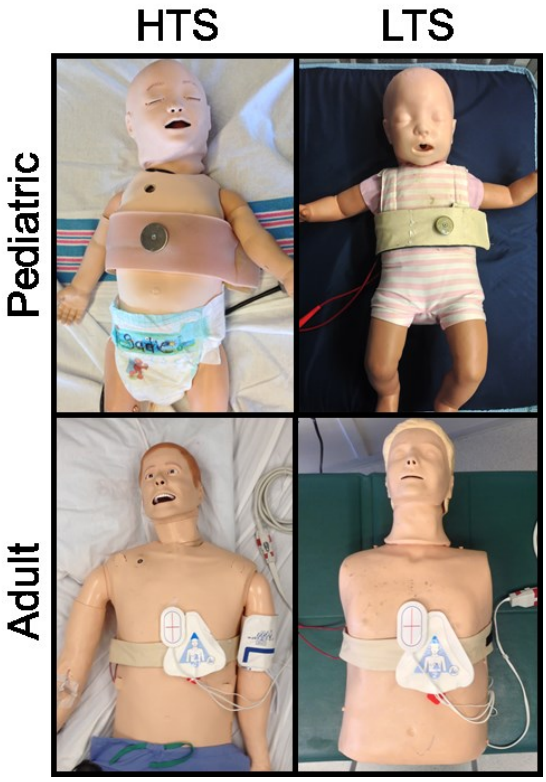

Figure 2.2. AP Belt Prototypes

2.2 Device Design

This device fulfills the unmet needs of providing AL and AP defibrillation capabilities to low-technology simulators and of providing AP defibrillation capabilities to high-technology simulators. It is a non-conductive 2” x 36” x 0.125” belt, made of silicon rubber or polyvinyl chloride plastic. The belt encircles the chest, and stainless steel disks act as conductive contacts. Contacts are secured to the belt with stainless steel hardware.

Test lead wire with silicone insulation is fastened to the conductive contact and embedded within the belt. Analog signal flow of the simulated heart rhythm is redirected from the point of generation to conductive contacts in the AP or AL position. Defibrillator electrode pads can be placed over these contacts to continue signal flow into the defibrillator, allowing for providers to defibrillate the simulator and for display of the rhythm on the defibrillator. This device is designed to safely conduct an average defibrillation voltage (10 kV) and current (25 A).

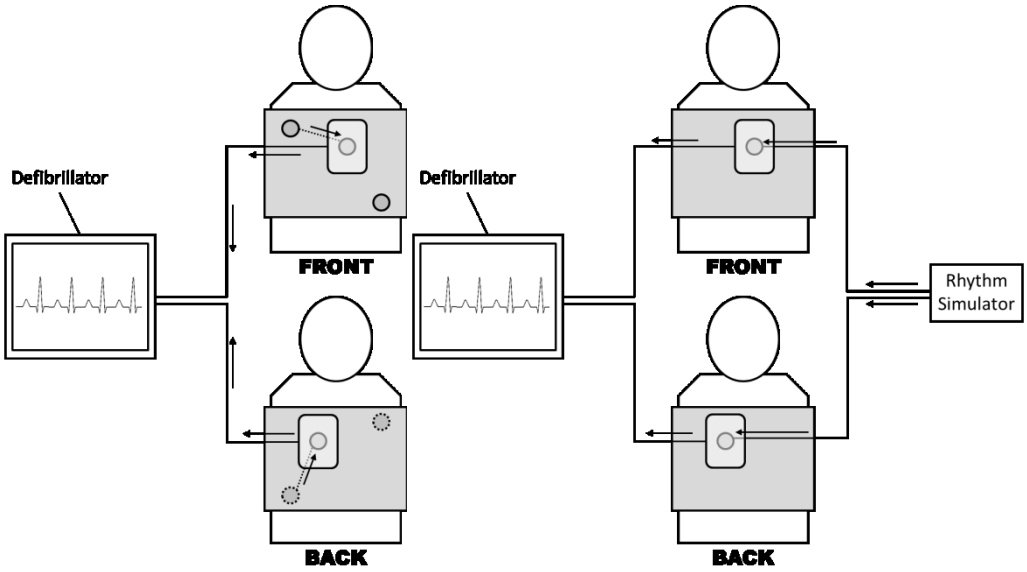

Figure 2.3. Diagram of device used with HTS (left) and LTS (right). Dotted lines show wiring/studs on a lower plane.

When used with high-technology simulators, which have AL defibrillation functionality, the device redirects simulated cardiac rhythm signals and defibrillator electricity from the simulator's internal heart rhythm generator to the defibrillation electrode pads via conductive contacts in the AP position, allowing for defibrillation in the AP position (Fig. 2.3, left and Fig. 2.4). This device can also be used with low-technology simulators or

simulator substitutes, such as a pillow, both of which do not have the functionality to be defibrillated in any position. When used with these non-defibrillatable simulators, the device directs the signal flow between an external rhythm simulator and the defibrillator (Fig. 2.3, right and Fig. 2.5). Analogue signal flow travels through the conductive studs in the AP or AL position via attachment of the electrode pads to the contacts and attachment of the device to the rhythm simulator, allowing for interchangeable AP and AL defibrillation functionality. Analog signal connectivity from point of generation to defibrillator is diagrammed with arrows. The LTS-specific device (Fig. 3, right) is diagrammed to allow for AP defibrillation functionality, but this same concept can be used to provide AL defibrillation functionality through changing the position of the conductive contacts to the anterior and lateral positions.

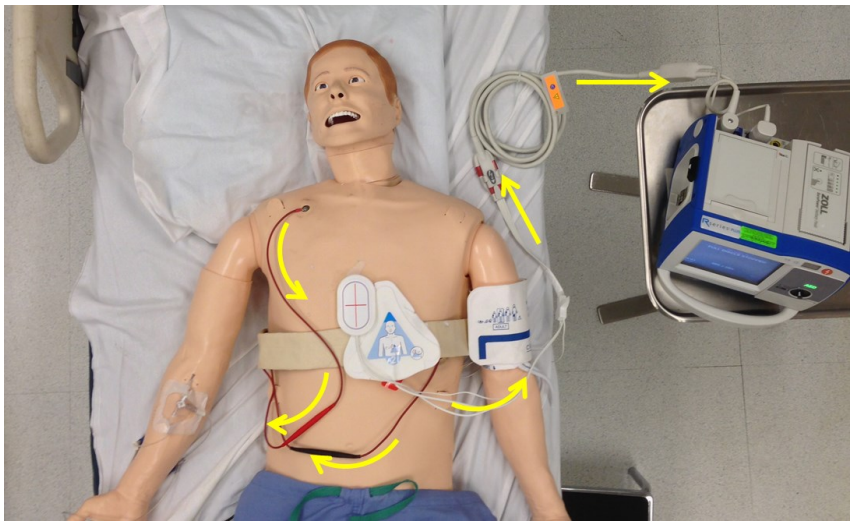

Figure 2.4. Signal flow through HTS-specific device.

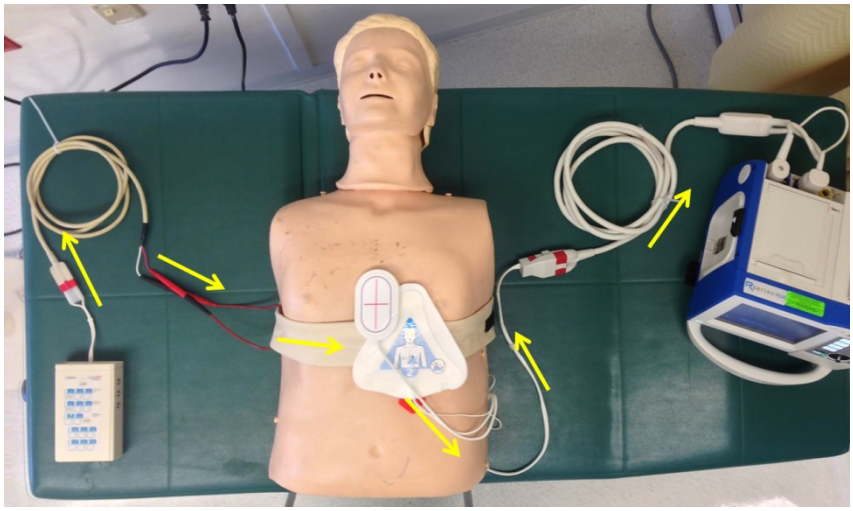

Figure 2.5. Signal flow through LTS-specific device.

2.3 Device Evaluation Methods

2.3.1 Safety Testing

Each device was defibrillated 20 times over 10 minutes at 30 second increments with a ZOLL R-Series Plus defibrillator. In the majority of simulation-based trainings, shocks are delivered at less frequent intervals; however, in training scenarios focused around repeated performance of the same tasks, as is frequently practiced in this institution, this timing replicates realistic defibrillation patterns. All adult devices were defibrillated using ZOLL OneStep CPR electrodes at 200J, and all pediatric devices were defibrillated using ZOLL OneStep Pediatric CPR electrodes at 100J. These defibrillation energies are the default shock amplitudes for adult and pediatric patients, respectively, for the ZOLL R Series Plus defibrillators at this institution. Impedance sensed by the defibrillator and energy and current delivered were recorded for each shock. Recorded data specific to the LTS with defibrillation belt and the rhythm generator were compared using one way

analysis of variance (ANOVA) with repeated measures. The recorded data for HTS and HTS with defibrillation belt were also compared using a one way ANOVA with repeated measures.

2.3.2 Efficacy Testing

This device has been used at the Johns Hopkins Medical Institute for both educational training and device testing. It was used in the following types of simulation-based trainings:

- Medical student BLS courses: The device was included in approximately half of the 12 4-hour training sessions that took place in Fall/Winter 2013. Each course has approximately 30 students. Students are grouped into 2-3 person groups for out-of-hospital contextual BLS training and are then grouped into 6 person groups for in-hospital contextual BLS training. The device has been included in both parts of the course, with the AP belt attached to a LTS for the out-of-hospital context and to a HTS for in-hospital context.
- Mock/in situ codes for Pediatric Rapid Response Team (RRT) Members: A Pediatric RRT training session and an *in situ* mock code are completed each month in the Simulation Center and in the Children's Center of the hospital, respectively. These simulation-based trainings incorporate a pediatric HTS and have a more realistic, in-hospital context. The HTS AP belt is included in the majority of these trainings. Pediatric RRT training sessions and *in situ* mock codes generally end up including ten or more participants and are meant to

practice the skills, teamwork, and logistics of both the first responders and the pediatric rapid response team.

- In-service training for defibrillators: The Johns Hopkins Hospital is in the process of replacing all defibrillators in the hospital, starting with the Children's Center. Current in-service training is lecture-style with pictures, videos, and demonstrations acting as the primary modes of training. In order to improve the efficacy of in-service trainings, a LTS with an AP Belt have been included in the training to allow users to realistically practice chest compressions, defibrillation, and pacing with the device.

Incorporation of the AP Belt in the above modes of simulation training is currently only meant to assess robustness and ease of use of the belt. Identified issues are iteratively addressed and deployed for subsequent trainings. Additional tests to assess the benefit of the device to user performance will be completed in the future.

After getting reports about issues with configuration of the defibrillators in our Children's Center that could not be identified through looking at the settings, a mobile simulation testing unit was set up to realistically test each device. This unit included a LTS with an AP Belt on a rolling cart. Using this equipment, it was possible to realistically test each defibrillator without a large, heavy full-body simulator. The AP Belt was also employed to assess configuration standardization of the ZOLL R-Series defibrillators at this institution. This mobile simulation unit was included as part of a comprehensive

assessment to identify configuration inconsistencies related to the CPR Dashboard™ display on the defibrillators, which provides feedback regarding CPR quality.

2.4 Results

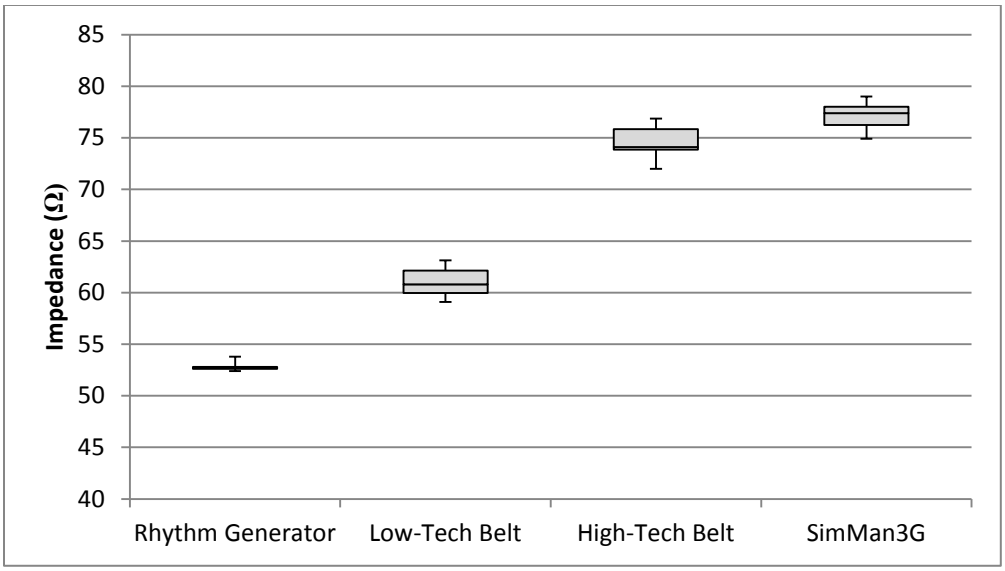

Figure 2.6. Impedance of commercial rhythm generator, rhythm generator with belt (low-tech belt), HTS with belt (high-tech belt), and HTS (SimMan3G), as measured by the ZOLL R Series defibrillator

Analysis comparing the impedance values generated during testing between the defibrillator used with the low-tech belt and the defibrillator with the commercial rhythm generator alone (Low-tech v. standard) and the defibrillator used with the high-tech belt and the defibrillator with the simulator (High-tech vs. standard) were performed using one way ANOVA with repeated measures (Tables 2.1 and 2.2, respectively). The model only considered two independent variables: (1) the configuration being tested and (2) the test performed; therefore, the assumption of sphericity was met and no correction regarding degrees of freedom was necessary. The results of the low tech test indicated significant differences between the impedance values generated between the standard

configuration and that using the Low-tech AP Belt, the results of the high tech test indicated no differences between the impedance values of the standard and the High-tech AP Belt.

Table 2.1. Average Impedance (±SD) of Rhythm Generator and Low-Tech Belt with ANOVA Results

Standard	Low-Tech Belt
52.7 ± 0.11 Ω	61.4 ± 1.84 Ω
p < 0.001	

Table 2.2. Average Impedance (±SD) of HTS and High-Tech Belt with ANOVA Results

Standard	High-Tech Belt
77.0 ± 1.45 Ω	75.5 ± 2.75 Ω
p = 0.50	

Based on the resistivity of stainless steel ($6.9\times10{-}7$ Ωm), of which much of the device hardware is composed, the resistance through defibrillation belt would be expected to increase approximately 2-4Ω ohms due to added material. The significant difference in the impedance values generated between the standard configuration and the Low-tech AP Belt may be explained differences in experimental setup. The commercial rhythm generator connects directly to the defibrillator in place of defibrillator pads, while the Low-tech AP Belt requires defibrillator pads to be connected to the defibrillator and to be placed over the AP Belt contacts. The resistance of the pad-contact interface likely adds this additional impedance. Both experimental configurations in the High-tech AP Belt tests required defibrillator pads to connect the defibrillator to the simulator.

Additionally, all sample sets had small, similar standard deviations. This indicates that, despite the defibrillations being delivered in rapid succession, the electrical properties of the device did not change. All measured impedances of both this device and commercially available devices fell within the ZOLL R-Series defibrillator Patient Impedance Range of 15 to 300 ohms, meaning all devices can safely be shocked by this defibrillator.

2.5 Discussion

The device reliability during repeated defibrillation has been demonstrated, as observed in safety testing, and it has already been employed for both educational and clinical engineering uses at the Johns Hopkins Medical Institute. The defibrillation belt's benefits extend to all 3 identified functionalities of healthcare simulators: education, research, and clinical engineering applications.

2.5.1 Use of Defibrillation Belt in Education

Evidence increasingly suggests that resuscitation training using HTS results in significant performance advantages for learners in comparison with LTS due to the ECG and defibrillation functionalities associated with HTS [37, 38]; however, there are few HTS that allow for realistic training of AP defibrillation. As a result, AP pad placement on the majority of HTS negates the capability of the HTS to be defibrillated, cardioverted, or paced, as the pads, then, have no contact with the electrical contacts of the simulator. The current methods of teaching AHA BLS are inadequate because the majority of simulators used for standard BLS training to out-of-hospital providers offer no

defibrillation capability, which limits the amount of realistic, hands-on learning that can take place in adult and pediatric BLS courses.

Realistic, hands-on training with clinical defibrillators has been shown to improve provider performance in simulation and clinical practice. It has been demonstrated that pediatric providers with hands-on experience with a defibrillator are 87% more likely to successfully defibrillate in a given period of time, providing a shock significantly faster than providers who had never defibrillated a patient/simulator [51].

In addition to providing therapeutic defibrillation capabilities, clinical defibrillators have advanced to include measurement of CPR quality, such as quantitative measures of chest compression depth, rate, and recoil. This information is only accessible if defibrillation pads are on a patient or connected to conductive contacts on the simulator, both of which provide a resistance greater than 15Ω between the defibrillator electrodes. In order to incorporate this CPR quality feedback in current resuscitation training, the defibrillator pads must be attached to a HTS. Using this device, pads only need to be attached to this device, regardless of what it is wrapped around (e.g. HTS, LTS, pillow), to use the CPR quality feedback provided by advanced defibrillators as a training tool.

Training programs in lower resourced areas often do not have access to HTS, so these providers often do not have the opportunity to train realistically with a defibrillator. Inaccessibility to adequate resuscitation training tools likely prevents providers in these areas from providing compressions and defibrillation effectively. Not only can this device be used with HTS and LTS, but also it can be used with the makeshift mannequins, such as pillows or recycled boxes, that have been observed in resuscitation

training in low resource settings. As opposed to most HTS, which weigh over 100lb. and typically cost more than $15,000, this device is approximately 2 lb. and material and labor costs total to less than $100. The ease of use, portability, and low cost associated with this device make it ideal for resuscitation training in low-resource areas.

2.5.2 Use of Defibrillation Belt in Research

This device provides a more realistic model for interfacing clinical defibrillators with simulators, affording a more accurate environment to observe user interactions with clinical defibrillators. A common "work-around" to allow providers to practice shocking during simulation is to connect a rhythm generator directly to the defibrillator in place of electrode pads. This results in incomplete population of the defibrillator screen because the defibrillator pads are not connected to the defibrillator. Use of the defibrillator belt with LTS and HTS, similar to the use of HTS alone, will provide a platform in which clinical defibrillator screens can be fully populated (Fig. 2.7). Connection of the defibrillator pads from the defibrillator to a patient provides a display of CPR quality metrics, specific setting defaults based on the type of pads attached, and a filtered ECG waveform on the ZOLL R-Series defibrillators used at this institution. Effective research regarding user interaction with clinical defibrillators is not possible if the monitor screen is not populated with realistic patient data. As every hospital sets up their defibrillator user screen differently and little data exists to prove which set up is the most effective, use of this device with clinical defibrillators allows for a more cost-effective research model to assess user interaction with clinical defibrillators in the future.

Figure 2.7. ZOLL R-Series defibrillator screen when attached to a rhythm generator (left) and when connected via pads to this device.

2.5.3 Use of Defibrillation Belt in Clinical Engineering Applications

Clinical Engineering is responsible for patient and provider safety in use of medical devices, including the configuration and testing of devices. During the deployment of the ZOLL R-Series defibrillators in this institution, CPR Dashboard™ settings were configured incorrectly, rendering the CPR quality metrics unavailable for use during codes on the defibrillator screen and after codes in the post-event defibrillator reports. Though configured and tested, clinical engineers were unable to detect this misconfiguration. Because of these incorrect configurations, the defibrillator display only included ECG (Fig. 2.7, left). Clinical engineers used rhythm generators to test the safety and functionality of defibrillators, specifically safety associated with the delivery of shocks, so tests were considered successful because the CPR Dashboard™, filtered ECG, and pad connectivity are not able to be assessed using the current modes of testing. Had the clinical engineers at this institution had this device to use for testing, providers would have had the real-time CPR feedback from the defibrillator during the first 6 months of device use. Most HTS could also be used for this function, but, again, this

device provides a less expensive and more mobile option for realistically testing clinical defibrillators.

2.6 Conclusion

There currently exists an interoperability gap in the interface between clinical defibrillators and healthcare simulators. When used with clinical defibrillators, neither LTS nor HTS provide accurate models for the effective use of simulation in education, investigational and translational research, and clinical device deployment. When used with HTS, LTS, or simulator substitutes, the defibrillation belt device introduced here provides a more realistic model for interfacing simulators with clinical defibrillators. The current prototype of this device has been demonstrated to be safe and effective for cross-departmental use in healthcare simulation.

3 $ETCO_2$ Sensor Signal Generator

3.1 Background & Motivation

3.1.1 End Tidal Carbon Dioxide

End tidal carbon dioxide ($ETCO_2$) is the measure of the concentration or partial pressure of inhaled and exhaled carbon dioxide. This diagnostic tool is generally used for ensuring appropriate placement of an endotracheal or breathing tube, but it has also been identified as a non-invasive measure that is highly correlated to circulation and cardiac output [52]. This correlation can be simplified to the concept that circulation allows cells to exchange carbon dioxide (CO_2) for oxygen at a higher rate; this blood flow, then, removes CO_2 from the body via the lungs, a process measured by $ETCO_2$.

The first reference to use of $ETCO_2$ as a CPR aid occurred in the late 1930's [53]; Rudolf Eisenmenger demonstrated the association between cardiac output, exhaled carbon dioxide, and outcomes during testing of his chest compression device, the "Biomotor," on dogs in cardiac arrest [53, 54]. Today, $ETCO_2$ is used to monitor the majority of in- and out-of hospital cardiac arrest patients due to researcher recommendations [11]. $ETCO_2$ has been demonstrated to be a very effective predictor of overall cardiac arrest outcomes, as Eckstein *et al*. recorded that individuals with $ETCO_2$ higher than 10 mmHg were four times more likely to survive; this correlation rate is higher than all other cardiac arrest outcome predictive factors, including age, gender, time to defibrillation, time to CPR, and presenting rhythm [11]. The American Heart Association recommends calibrating the

quality of CPR to the goal of maintaining an $ETCO_2$ > 20 mmHg without hyperventilating the patient [10]. Furthermore, a recent animal study demonstrated that performing chest compressions with the goal of maintaining $ETCO_2$ above 20 mmHg resulted in improved short-term survival outcomes in comparison to chest compression depth-directed CPR [55], indicating that $ETCO_2$ may be a better indicator of cardiac output than the standard metrics used to quantify chest compression quality. The ZOLL R Series Plus defibrillators used in this institution are equipped to monitor and display $ETCO_2$.

3.1.2 Connectivity Issues with Simulation-based Applications

Clinical monitors and smart defibrillators include a number of different sensors, such as electrocardiogram, $ETCO_2$, and pulse oximetry; sensors interact with patients to make necessary clinically relevant physiologic findings and measurements available to providers, thereby acting as indicators of provider performance. The majority of high-technology patient simulators are unable to provide the comprehensive set of connectivity elements for realistic interface between clinical monitors and simulators. Critical patient characteristics are, instead, displayed on simulator-specific monitors during training. Simulator-specific monitors do not reflect the user interface of clinical monitors and smart defibrillators. A small group of simulators have technology to allow for exhaling CO_2 via controlled release of CO_2 from canisters within the simulator, which would allow for semi-effective interconnectivity between simulators and clinical $ETCO_2$ monitoring devices. This option is controlled by a numeric scale that does not reliably correspond to desired $ETCO_2$ values. When used with colormetric $ETCO_2$ sensors, this solution is

acceptable, but the majority of in- and out-of-hospital providers use quantitative capnometry with numeric and waveform outputs of the partial pressure of expired CO_2. Additionally, the CO_2 exhalation function in capable simulators cannot be used for long periods, as the CO_2 canister depletes quickly.

It has been observed at this institution that unrealistic presentation of patient data during simulation-based training causes provider confusion and reduces training authenticity, demonstrating the need for a device that interfaces simulation technology with real clinical devices. The variation in user interfaces of clinical devices and simulator-specific monitors is demonstrated in Figure 3.1. As $ETCO_2$ is a newer accepted metric of resuscitation quality, effective training regarding the implementation of $ETCO_2$ monitoring during cardiac arrest is especially important.

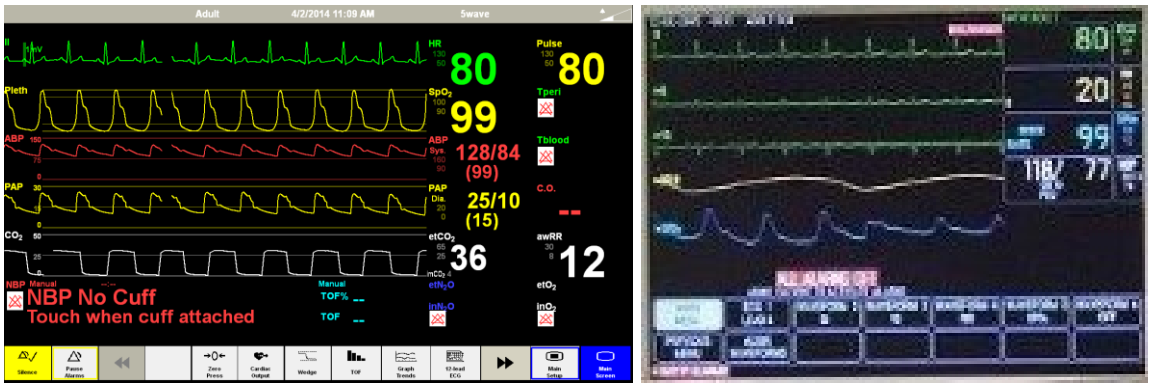

Figure 3.1. SimMan monitor (left) and GE Patient monitor (right)

The technology described here translates a number of $ETCO_2$ inputs, which replace the Respironics Capnostat5 $ETCO_2$ sensor output, to be displayed as $ETCO_2$ waveforms and numeric outputs on the ZOLL R-series defibrillator. Tested $ETCO_2$ inputs include, but are not limited to, the Laerdal SimMan 3G human patient simulator (Laerdal, Stavanger, Norway), a custom-designed waveform generator software, and printed rhythm strips.

3.2 Device Design

Figure 3.2. Capnostat5 End Tidal CO_2 Sensor

3.2.1 Capnostat5 End Tidal CO_2 Sensor Protocol and Specifications

The $ETCO_2$ sensor used in this research is the Philips Respironics Capnostat5 (Philips, Andover, MA) (Fig. 3.2). Respironics Capnostat5 capnograph senses the presence of CO_2 in the cuvette (Fig. 3.3) using non-dispersive infrared (NDIR) single beam optics. The sensor head holds all hardware required for measurement and analysis of the signal, so the connected monitor is not required to process the NDIR output. The Capnostat5 outputs an RS-232 digital signal with encoded $ETCO_2$ amplitude (0-99 mmHg) and respiratory rate (0-150 breaths/min). This digital signal is received by a connected monitor, such as the ZOLL R Series Plus defibrillator, to display $ETCO_2$ waveform, respiratory rate, and maximum amplitude value. The ZOLL R Series Plus display is shown in Fig. 3.4.

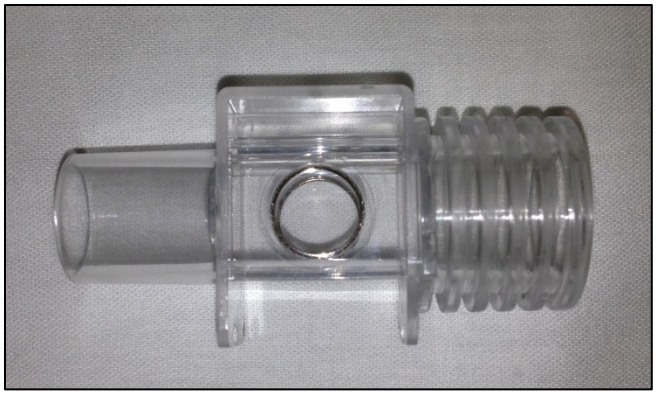

Figure 3.3. Capnostat5 End Tidal CO_2 sensor cuvette

Figure 3.4. ZOLL R Series Plus defibrillator display of Capnostat5 $ETCO_2$ sensor (boxed in yellow). Maximum amplitude and respiratory rate shown numerically on left sidebar, and $ETCO_2$ waveform displayed bottom center. (Adapted from ZOLL.com)

The Capnostat5 has an 8-pin Lemo-Redel connecter (Fig. 3.5). RS-232 digital communication occurs in two of these pins (Pin 5, 6) at a baud rate of 19200 with standard serial port configuration settings. The analog and digital sources (Pins 1, 4) and grounds (Pins 7, 3) are provided by and tied together in the monitor, but are kept separate in the sensor. Waveform synchronization (Pin 8) is a clock signal that oscillates from a

low state to a high state every ten milliseconds. This synchronization signal is also provided by the defibrillator. The pulses provided by this clock correspond to the timing of the serial communication between the monitor and the Capnostat5 sensor.

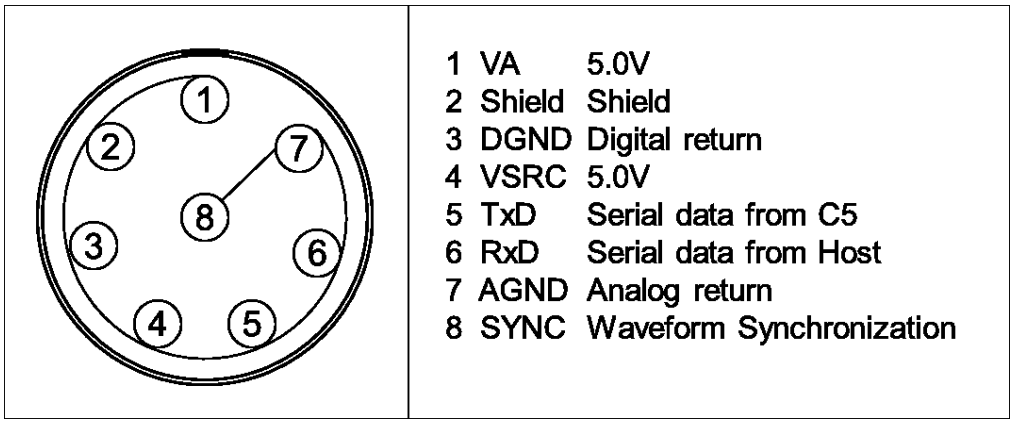

Figure 3.5. Capnosat5 (C5) pin-out.

The Capnostat5 $ETCO_2$ sensor and host monitor must complete a warm-up handshake before the Capnostat5 can begin to continuously send $ETCO_2$ data. This warm-up handshake takes approximately 480 msec. Once completed, the host monitor does not send any more serial data to the Capnostat5. If an error occurs within the system setup (i.e. sensor unplugged, Capnostat5 cuvette removed or obscured by patient secretions), the warm-up handshake between the two components must take place again. The specific data encoding protocols were provided to us under a nondisclosure agreement by Respironics. These protocols will be referenced, but not disclosed throughout this document.

3.2.2 Device Summary

Due to the unrealistic nature of simulator-specific monitors, a tool that interfaces simulators and clinical monitors is needed. Incorporating CO_2 exhalation functionalities into simulators does not afford users a confident level of control over the $ETCO_2$ values and waveform presented on the monitor. This device bypasses interconnectivity issues by replacing the Capnostat5 $ETCO_2$ sensor with a computer-generated Capnostat5 output. This allows for complete control over both the numeric and waveform displays on the ZOLL R Series defibrillator.

This technology is composed of software components, which manage $ETCO_2$ signal data, and a hardware component, which interfaces the software components to the clinical monitor or defibrillator. In its current format, this tool is configured to replace Respironics Capnostat5 Mainstream $ETCO_2$ sensor as an input to clinical monitors and defibrillators. The first generation prototype of this technology uses software components to manage numeric waveform generation, encoding, and data transmission, and the hardware components simply link the computer software to the $ETCO_2$ socket on the defibrillator or monitor. Signal flow is diagrammed in Figure 3.6. A second generation prototype was developed to improve the reliability of wireless signal transmission. In this prototype, a microcontroller controls all waveform generation, encoding, and transmission, and it communicates with a software component over a wireless network. The software component only acts as a remote controller user interface, allowing users to input desired respiratory rate and maximum $ETCO_2$ to manipulate the numeric waveform

created by the microcontroller. Signal flow of this prototype is diagrammed in Figure 3.7. Both generations of the prototype are described below.

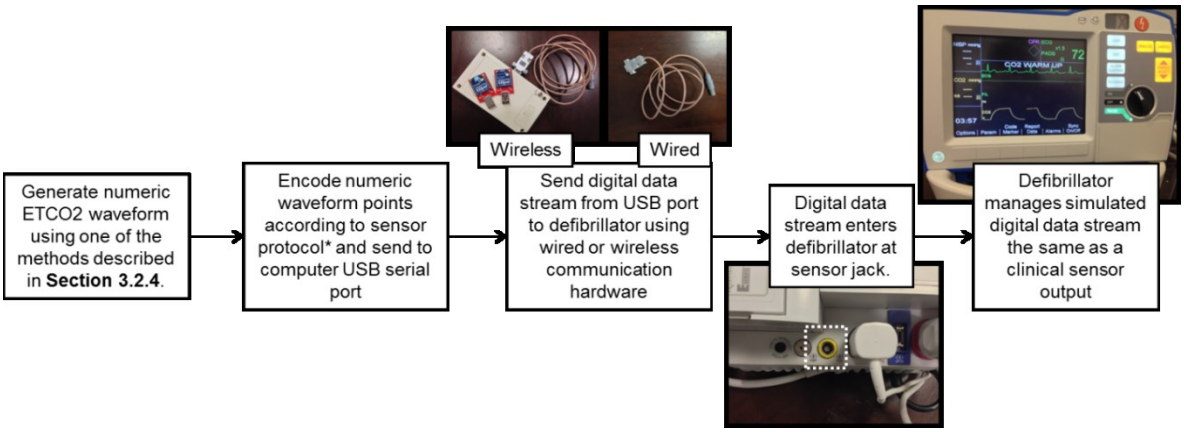

Figure 3.6. Diagram of First Generation Prototype signal flow.

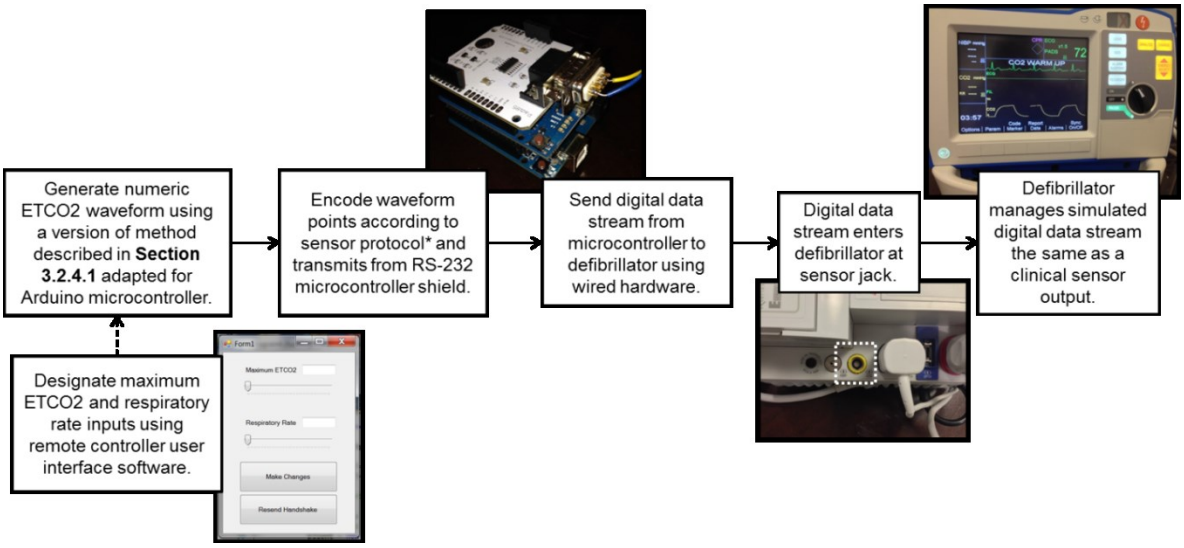

Figure 3.7. Diagram of Second Generation Prototype signal flow. Dotted line indicates optional communication between Remote Controller Software and microcontroller.

3.2.3 First Generation Prototype: Summary of Dynamic-Link Libraries

The software components are written in Microsoft Visual C# and individually manage $ETCO_2$ signal data encoding, decoding, sending, receiving, storage and retrieval. These modular components are organized into separate dynamic-link libraries (DLLs), so software can easily be re-used for multiple purposes. This flexible organization of DLLs forms a network of options for generating, storing, and displaying $ETCO_2$ signal data. The DLLs are organized as 14 classes within 5 namespaces and can easily be linked to various user interface forms (Table 3.1). The BreathingEngine namespace encompasses all signal generation functions described in Sections 2.3.1 and 2.3.2, and the PPTools provide the picture processing tools described further in Section 2.3.4. The C5ProtocolUtilities provide only decoding and encoding capabilities, so sending and receiving functionalities are provided by C5TransmitUtility and C5ReceiveUtilities, respectively, both of which reference the C5ProtocolUtilities for all Capnostat5-specific encoding protocols. Documentation of the methods, properties, and events in the referenced DLLs is provided in Appendix A.

Table 3.1. Summary of C# DLL organization

Breathing Engine	**C5Protocol Utilities**	**C5Transmit Utility**	**C5Receive Utilities**	**PPTools**
CO2ValueGenerator TelnetReceiver PressureSensorPoint CO2EventArgs	Decoder Encoder	SignalTransmitter	SerialReceiver PointListSerializer MaxETCO2EventArgs ValueEventArgs RespRateEventArgs	PPMethods PixValEventArgs

3.2.4 First Generation Prototype: Signal Generation Software

All generated numeric waveforms are encoded in a manufacturer-specified format that matches the sensor's digital signal encoding format. If the input signal is not recorded

directly from the sensor, it is encoded using a C# software encoding module. All inputs can be encoded and sent to a clinical monitor/defibrillator that utilizes the Capnostat5 encoding protocol or can be saved in simple XML format for later use. The $ETCO_2$ signal generators are described in greater detail below:

3.2.4.1 Equation-based Waveform Generator

A controllable, simulated $ETCO_2$ waveform has been generated via C# software. This software module (Fig. 3.8) is capable of creating a continuous waveform of interchanging exponential rise and decay based on user-defined parameters (Fig. 3.9). The simulated waveform is sampled to retrieve a stream of $ETCO_2$ waveform data points, which are encoded and sent to the R Series defibrillator.

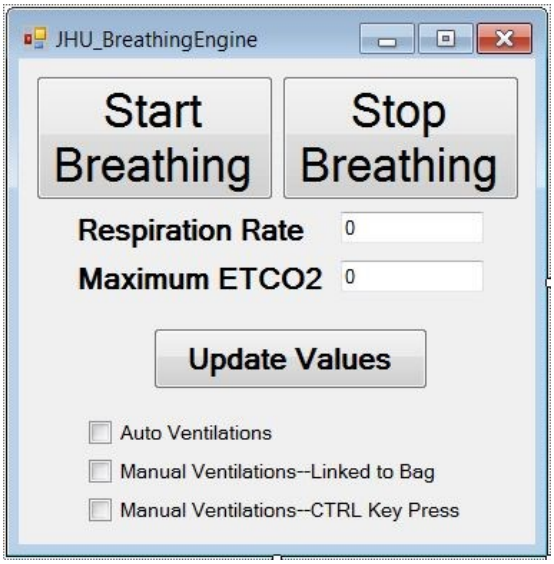

Figure 3.8. User interface for Equation-based Waveform Generator

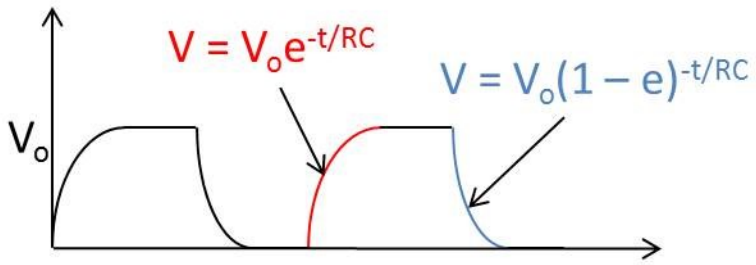

Figure 3.9. Exponential rise and fall equations utilized to generate controllable and realistic $ETCO_2$ curves.

3.2.4.2 Ventilation Sensor-Dependent Waveform

A simulated $ETCO_2$ waveform that directly reflects the actions of a provider's performance of manual patient ventilation (i.e. inspiration and expiration timing is controlled directly by a provider ventilating a simulator) can be generated via the Equation-based Waveform Generator software described in Section 3.2.4.1; the characteristics and equation parameters of this generated waveform, including visual and numeric respiratory rate and $ETCO_2$ amplitude, are dependent upon the output of a ventilation detection sensor.

The ventilation detection sensor is a pressure sensor (Freescale MPX5010 Pressure Sensor) that is connected to the bag valve mask (BVM), transducing the direct pressure within the cavity of the BVM to an analog signal. When a provider squeezes the BVM to manually ventilate the simulator, the pressure within the cavity increases, and the analog output of the pressure sensor changes accordingly. In the device's current configuration, the analog output connects to an Arduino Uno with Wifi Shield, which completes analog to digital conversion at 10 ms intervals and sends pressure information to a wireless network as a TCP Host.

A C# module accesses the sampled pressure readings as a TCP Client; when the pressure exceeds a threshold, the Equation-based Waveform Generator displays ventilations in the ZOLL R Series $ETCO_2$ waveform. The ventilation is displayed as a set exponential fall followed by an exponential rise, with an inspiratory flat line at zero amplitude for the duration of the pressure increase.

3.2.4.3 Replay a Recorded Capnostat5 Sensor Signal

A Capnostat5 sensor signal is intercepted during the monitoring of a real patient or a high-technology simulator. The intercepted signal is directly recorded to a computer to be saved as a digital byte stream, using C# software modules for receiving and decoding Capnostat5 data streams. The byte stream can be saved in a simple XML format using the storage software module and/or exported to a clinical monitor/device directly.

3.2.4.4 Digitized Waveform

Custom C# software has been developed to convert JPG and BMP images that contain a clinical waveform ($ETCO_2$, pulse oximeter, ECG), such as a print-out rhythm strip, to a digital stream of data points. Input images are, first, translated to grayscale; each pixel is binned by its grayscale level, allowing for separation of the waveform line from the image background. Waveform points are collected as all pixels binned within the adjustable waveform detection bin, and the pixels are scaled to time- and value-adjusted points using the background scale. The picture processing

software module outputs a point list, which can be directly sent to the encoding software module and, then, to a clinical monitor/defibrillator, or the data points can be saved in a simple XML format using the storage software module. The picture processing software module is demonstrated in Fig. 3.10.

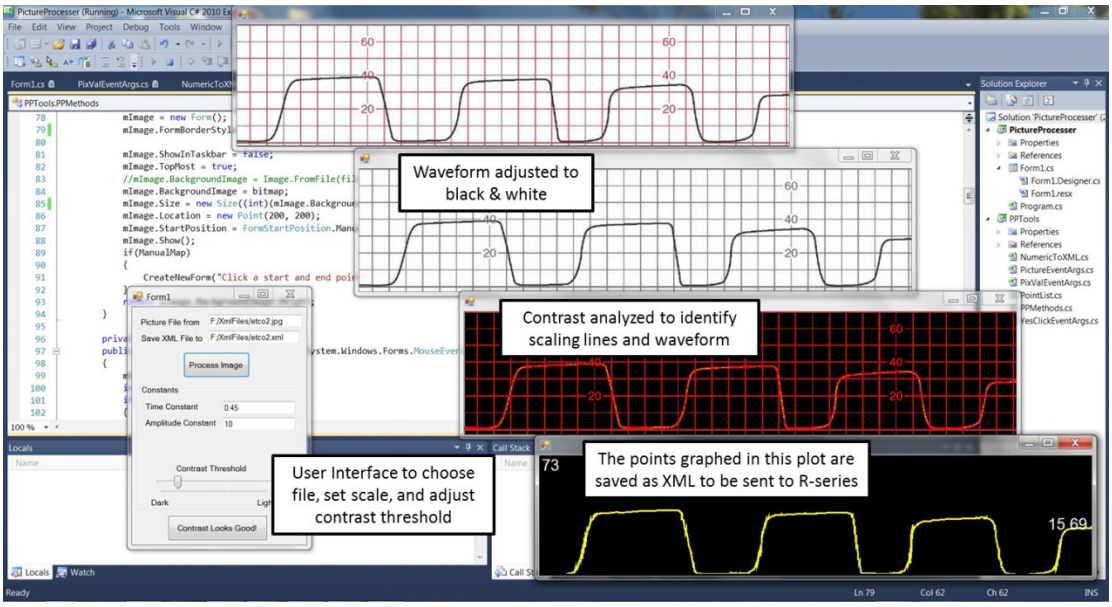

Figure 3.10. Picture processing software module uses a picture file of a printed monitor strip to generate a point-value XML list.

3.2.4.5 User Input through Simulator Controller

All HTS have a simulator-specific monitor with associated software-based user interface. This simulator-specific user interface can be used to control realistic and clinically measurable mannequin characteristics, such as heart rhythm, and to control non-measurable vital parameters that are projected on a simulator-specific monitor. The user-controlled waveform and numeric $ETCO_2$ values on the simulator software are used as an input into the encoding software (Fig. 3.11).

This transfer of simulated $ETCO_2$ data from the simulation software to our encoding software is made possible via the use of the simulator-specific software development kits (SDKs). A custom C# program was developed to link to the underlying simulator-specific software as the simulator is running. Once linked, the program retrieves each simulator software-generated $ETCO_2$ value as it is plotted on the simulator-specific user interface. These values are, then, sent in real time to encoding and sending DLLs to be displayed on the R Series defibrillator. The majority of code required for this signal generator input was completed by Jordan Duval-Arnould.

Figure 3.11. $ETCO_2$ waveform values collected from SimMan3G waveform generation software and formatted for transfer to ZOLL R Series defibrillator.

3.2.5 First Generation Prototype: Hardware

The sending software component routes the data to the hardware interface and finally into the defibrillator. The hardware component provides a vehicle for RS232 serial communication between the computer-run software programs and the clinical monitor or defibrillator. The signal can be sent to multiple monitors/defibrillators at once. Hardware interface prototypes allow for both wired and wireless communication between software modules and clinical monitors and defibrillators. The wired configuration uses extension cords to transmit, receive, and ground the digital RS232 signal from the C# software to the Capnostat5 jack on the monitor/defibrillator. The use of extension cords allows for universal connection and extension between the computer USB port and the monitor and/or defibrillator. The wireless configuration uses XBEE radiofrequency technology to wirelessly communicate with the monitor and/or defibrillator.

Because XBEE RF transmitters transmit and receive serially, any bi-directional communication interferes with existing wireless sending receiving taking place, thereby interrupting digital signal flow. Two pairs of Digi 2.4GHz XBee radio modules were used to allow for continuous bi-directional communication. Each pair communicates on separate channels to prevent crosstalk.

3.2.6 Second Generation Prototype: Microcontroller Functions

Due to unreliable signal transmission using the wireless configuration of the 1st Generation Sensor Signal Generator, a new wireless configuration with limited options was developed. In this 2nd generation prototype, an Arduino Uno R3 microcontroller with

a WiFi shield and an RS-232 shield (Fig. 3.12) was programmed to generate, encode and transmit the $ETCO_2$ waveform, similar to the Equation-Based Waveform Generator described in Section 3.2.4.1. Without communication with the Remote Controller Software, the microcontroller generates a default continuous waveform of interchanging exponential rise and decay with a maximum $ETCO_2$ of 30 mmHg, a respiratory rate of 15 breaths per minute, and exponential decay and rise constants of 0.2. The Arduino Uno microcontroller sends data from the RS-232 shield to the defibrillator using Capnostat5-specific encoding and timing protocols; additionally, the microcontroller is programmed to identify if the respiratory rate and maximum $ETCO_2$ value have been updated on the Remote Controller Software. If input values have been updated, the waveform and numeric constants on the defibrillator will be updated at the following inspiration phase of the waveform. The Remote Controller Software and the microcontroller communicate over TCP network protocols, so a wireless router is required.

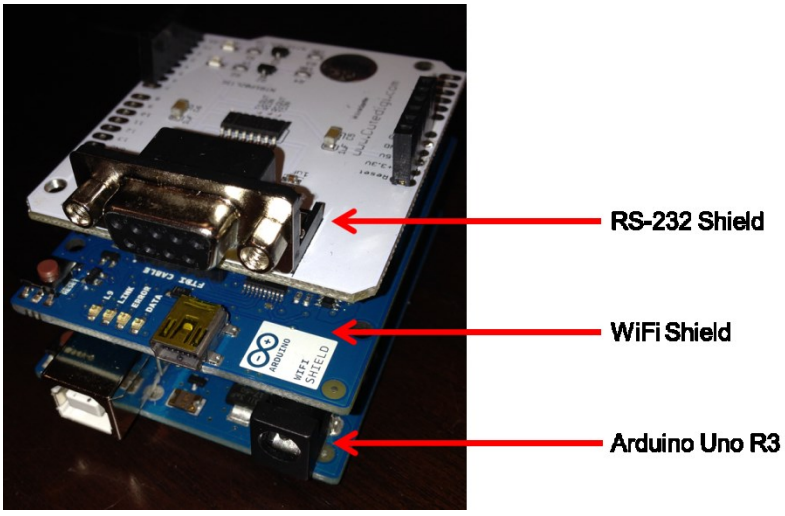

Figure 3.12. Microcontroller for Second Generation Prototype

3.2.7 Second Generation Prototype: Remote Controller Software

A C# software program with an integrated user interface was developed to allow the user to communicate remotely with the Arduino Uno microcontroller. This software uses similar TCP protocols to those in Section 3.2.4.2. The computer opens communications with the microcontroller each time it sends data and closes the connection after transmission is complete. It sends two numbers, a respiratory rate and a maximum $ETCO_2$ value, with each number encoded for easier identification by the microcontroller. The user interface also allows the user to manually transmit the digital handshake between the software and the defibrillator in case the signal is interrupted for any reason.

3.3 Device Evaluation Method

3.3.1 Efficacy Testing

This device has been used at the Johns Hopkins Medical Institute for both educational training and device testing. Use of this device for educational training took place in the forms of in situ mock codes, rapid-cycle deliberate practice provider training in the Johns Hopkins Hospital Simulation Center, and large group instruction for introduction of providers to ZOLL R Series defibrillator functions. These tests have lasted between 5-60 minutes.

3.3.2 Functional Testing

Both the wired and the wireless versions of the device were assessed for communication consistency by timing the duration of successful data transmission without

miscommunication between the computer and ZOLL R Series defibrillator. Miscommunications occur occasionally when this device is used for training, which requires the user to re-initiate the digital handshake between the software and the defibrillator. Ten trials were completed for each device, and if no miscommunications occurred, the trial was stopped after ten minutes. The distance between the computer and defibrillator was held constant at five meters for both the wired and wireless configurations. A ten-minute trial duration was chosen because the majority of resuscitation simulation scenarios are approximately ten minutes or less.

3.4 Results

Both prototypes have been incorporated into simulation-based training sessions at the Johns Hopkins Hospital. Efficacy testing of the first generation prototype demonstrated the need for a wireless $ETCO_2$ Sensor Signal Generator because hospital emergency codes, both in simulation and in the clinical environment, require the defibrillator to act as a mobile resuscitation device. Additionally, physically connecting the defibrillator to the computer became cumbersome if the defibrillator did not remain in the room prior to and throughout a training session. A second, recurring need is the lack of interoperability between device software and simulator-specific software. In simulation scenarios with high-technology simulators, two software programs, one for the simulator controller and one for the $ETCO_2$ Sensor Signal Generator, must be operated simultaneously by the simulation operator. This is not a problem when resources are not limited, and different technicians can operate each software program; however, in resource-limited occurrences

when the simulator operator is also responsible for providing educational feedback, having several software operational requirements may not be feasible. Options for the first generation prototype have been developed to address this issue, and work is ongoing to adapt the second generation prototype to offer interoperability with simulator-specific software.

Functionality tests for device reliability have been conducted. This device has been shown to successfully generate and encode $ETCO_2$ signals to replace the Capnostat5 sensor output, and hardware components effectively interface software-managed $ETCO_2$ data streams with the ZOLL R-series defibrillator. Table 3.2 shows the results of reliability testing, which assessed the duration of the communication between the $ETCO_2$ Sensor Signal Generator and the defibrillator was maintained without requiring re-initiation of the handshake between the two. If the communication remained uninterrupted, each test was stopped after ten minutes. All first generation wired prototypes were successful. The first generation wireless prototype trials were less successful with only 20% (2/10) successfully completing the ten minute trial. After a series of manipulations, 100% of the 10 trials of the second generation wireless prototype met the ten minute target. Unsuccessful trials are shaded in Table 3.2.

Table 3.2. Results of Functional Testing

Trial #	1st Gen. (Wired)	1st Gen. (Wireless)	2nd Gen. (Wireless)
1	10:00	10:00	10:00
2	10:00	7:26	10:00
3	10:00	1:12	10:00
4	10:00	0:16	10:00
5	10:00	10:00	10:00
6	10:00	0:14	10:00
7	10:00	0:14	10:00
8	10:00	0:48	10:00
9	10:00	0:52	10:00
10	10:00	1:55	10:00

3.5 Discussion

The 2010 AHA guidelines for CPR and Advanced Life Support (ALS) recommend capnography to measure the quality of chest compressions and guide the quality of resuscitation [56]. Additionally, $ETCO_2$ has been demonstrated to be the most sensitive and specific indicator of endotracheal tube placement in emergency settings, a practice for which errors can rapidly cause death or brain damage [57]. Existing add-on technologies, similar to the $ETCO_2$ Sensor Signal Generator, such as the ZOLL ECG Simulator and the extensive line of Fluke Biomedical Patient Simulators, are used to bypass simulator-monitor connectivity issues by connecting directly to clinical monitors.

No add-on technology currently exists to provide the user control over clinical $ETCO_2$ sensor signal display on clinical monitors and defibrillators in simulation-based training. Few high-technology simulators allow for the realistic integration of $ETCO_2$ into simulation-based training. Effective and realistic interfacing of $ETCO_2$ with clinical devices is necessary for device-based training and research, simulation-based training, and physiology recognition training and research.

3.5.1 Use of $ETCO_2$ Sensor Signal Generator for Device-based Training & Research

The time-dependency of resuscitation and the associated potential morbidity and mortality makes cardiac arrest a high-energy and, in many occurrences, stressful experience for providers; therefore, it is important that defibrillators and other resuscitation devices have user interfaces that limit adverse events [58]. Capnography is unique from ECG in that few options exist to allow for the display of $ETCO_2$ on a defibrillator screen for simulation-based training or device assessment, and all of these involve pushing real air through the sensor. Despite the importance of and need for human factors assessment of $ETCO_2$ visualization on monitors and defibrillators, few researchers have been able to assess the importance of $ETCO_2$ visualization on provider performance and, ultimately, on patient outcomes.

It is expected that all providers who use a particular medical device are trained on that device; however, training can vary from handouts to hands-on training. Limited training and training with gaps in realism have been seen to cause provider confusion and limit translation to clinical practice. Prior to the use of this device in simulation-based training

at this institution, confederates, who facilitate simulation-based education by acting as absent team members or as the simulators "parent", provided $ETCO_2$ information verbally to trainees during simulation-based training, and trainees are told during debriefing that $ETCO_2$ information would actually be on the defibrillator in clinical practice. Alternatively, simulator-specific monitors could be used instead of clinical devices for training. These gaps in realism left many providers unsure of how to proceed in clinical practice when $ETCO_2$ information was not displayed on the defibrillator screen, due to device or provider error. It has been demonstrated that even after training, many providers can not recognize their own proficiency with clinical devices [59]. This device limits those gaps in training to allow for more complete training with the ZOLL R Series defibrillator and other $ETCO_2$-compatible devices.

3.5.2 Use of $ETCO_2$ Sensor Signal Generator for Simulation-based Training

Human error in medical, nuclear and aeronautics fields can be attributed partially to limitations of simulation-based education and the associated negative learning that takes place [60]. In the context of simulation-based education, negative learning is the knowledge acquisition or practice of incorrect information due to an imperfect simulation and is generally caused by time acceleration, technological limitations, and learner errors [61]. The technological limitation of withholding $ETCO_2$ data from clinical monitors and defibrillators during simulation-based training has been observed to cause confusion during simulations at this institution. $ETCO_2$ data is instead displayed on unrealistic simulator-specific monitors or verbally provided by confederates. Despite debriefing

regarding the actual location of the $ETCO_2$ data on the ZOLL R Series defibrillator, many providers still are uncomfortable with the use of the defibrillator as an $ETCO_2$ monitor.

Educators at this institution are currently attempting to encourage the shift to using $ETCO_2$ on the defibrillator as opposed to the previous standard of using handheld $ETCO_2$ monitors. The negative learning taking place during frequent simulation-based training has made this switch more difficult than other recently enacted resuscitation protocols. This device reduces the negative learning that takes place during provider interaction with the ZOLL R Series defibrillator or Capnostat5-equipped clinical monitors.

3.5.3 Use of $ETCO_2$ Sensor Signal Generator for Physiology Recognition Training & Research

Few electronic visualization options exist for the collection, storage, and display of $ETCO_2$ waveforms. Although the shape of the waveform typically is not a priority in decision making during resuscitation, respiratory therapists and emergency medical professionals frequently use capnography to diagnose respiratory disorders. Using the signal generation options to either replay recorded $ETCO_2$ waveforms or to generate waveforms from printed rhythm strips, described in Sections 3.2.4.3 and 3.2.4.4, respectively, allows users to practice identification of respiratory disorders. The use of this device affords providers the opportunity to train for disorder recognition and identification realistically, eliminating potential for negative learning. Realistic capnography training, in which educators can control waveform characteristics in real-

time or load disorder-specific waveforms from a pre-existing set, is currently not an option for providers.

These signal collection options also provide researchers with greater options in the collection and organization of $ETCO_2$ waveform libraries. Many providers who diagnose patients based on $ETCO_2$ waveforms print and keep rhythm strips for future reference; however, these unique waveforms are generally not widely available. The functionalities provided by this device allow for electronic storage of all recorded and scanned waveforms. This opens opportunities for new modes of education and research for respiratory physiology.

3.6 Conclusion

Use of clinical monitors in simulation-based training of healthcare providers increases the authenticity of training scenarios and likely increases training effectiveness; however, existing simulators do not interface with clinical monitors realistically. Incorporation of this simulator-independent technology will allow for the transition of simulation-based CPR and ALS training to include clinical monitors and defibrillators without the need to alter existing simulators. This device effectively interfaces simulators to Capnostat5-compatable clinical devices for both research and training.

4 ZOLL R Series Defibrillator Emulator

4.1 Background and Motivation

CPR is a therapeutic intervention that can improve the likelihood of survival for victims of cardiac arrest. CPR is associated with myocardial oxygen delivery, tissue and organ perfusion and cardiac output. The degree to which CPR is effective in these regards is determined in part by the quality of CPR performed. Myocardial blood flow, perfusion, and cardiac output generally cannot be easily measured during a cardiac arrest, and often surrogate metrics that have been shown to be associated with patient outcomes are used to assess the quality of the resuscitative effort. CPR quality metrics, which include chest compression depth, rate, recoil, number and duration of compression interruptions, and compression fraction, can be measured in practice by capable clinical monitors to provide real-time and post-event performance feedback. Each metric can be evaluated against established guidelines--commonly AHA recommendations--and quantitative feedback can be given to providers. This data-driven method of debriefing provides opportunities for reflection on current performance and direction for future training and clinical implementation.

AHA recommendations and expert consensus state that chest compressions should: (1) be at least 50 mm deep for adults (~50 mm for children, ~40 mm for infants); (2) be performed at a rate of at least 100 to 120 compressions per minute; (3) allow for the chest wall to completely recoil; (4) be interrupted minimally (not to exceed 10 seconds per interruption), achieving a chest compression fraction greater than 80% [10, 62]. A number of existing CPR quality feedback devices are currently used in simulation-based

and psychomotor CPR training. Although there is little evidence demonstrating the effects of CPR quality feedback devices on patient survival, evidence suggests that CPR quality feedback devices can improve basic CPR skill acquisition and retention [63, 64], which are ultimately linked to patient outcomes.

4.1.1 CPR Quality Metrics

4.1.1.1 Depth

Chest compression depth is defined as the maximum posterior deflection of the sternum prior to chest recoil [65]. Increased chest compression depths, specifically depths greater than or equal to 50 mm, are associated with increased cardiac output, increased defibrillation success, and increased occurrence of return of spontaneous circulation (ROSC) [36, 6, 66, 67]. Chest compressions with a mean depth less than 38 mm have been associated with significantly reduced occurrence of ROSC and reduced survival rate [68]. Despite clear goals for chest compression depth, it has been observed that both in- and out-of-hospital providers frequently deliver chest compressions that are too shallow [11, 12, 68].

4.1.1.2 Rate

Chest compression rate is the frequency of compressions in a compression series and is generally reported in units of compressions per minute (cpm) [65]. At a rate of less than 100 cpm, patients were observed to have a reduced occurrence of ROSC, whereas a compression rate greater than 120 cpm is associated with reduced coronary perfusion pressure and reduced diastolic perfusion time [69]. Consistent with AHA guidelines, it

has been demonstrated that chest compressions maintained at a rate of 100 to 120 cpm are associated with increased survival rates [13, 62, 70]. Reporting of compression rate is similar to compression depth.

4.1.1.3 Recoil

Chest recoil is used to describe the chest compressor's complete removal of force on chest at the end of each chest compression, which allows for complete chest wall release. Leaning on the chest in the inter-compression time period is associated with reduced venous return and reduced cardiac output. Leaning is not uncommon [71, 72], and leaning generally increases with fatigue. There is little clinical data quantifying the amount of lean that corresponds to observed cardiac effects; however, animal studies show that leaning increases right atrial pressure and decreases cerebral and coronary perfusion pressure and left ventricular myocardial flow [73, 74]. Recoil is a newer CPR quality metric, and reporting varies from binary scoring of lean/no lean to quantitative measures of the amount of force on the patient's chest in the inter-compression time period.

4.1.1.4 Compression Fraction

Interruptions in chest compressions result in the cessation of cardiac output and coronary blood flow generated by quality chest compressions. Proportionally increased total interruption time has been associated with reduced ROSC and reduced survival to discharge in out-of-hospital cardiac arrests [21, 22]. Though some interruptions may be necessary during resuscitation, such as those associated with rhythm checks, in the

absence of advanced monitoring, and defibrillation, most interruptions in chest compressions in observed out-of-hospital cardiac arrests were due to avoidable human factors [12, 67]. Chest compression fraction is the proportion of CPR time that chest compressions are performed. CPR time generally is considered to start with the onset of pulselessness, or a state of poor perfusion insufficient to sustain life, and ends with the first occurrence of retained ROSC. Chest compression fraction should be greater than 80% [10]; the Johns Hopkins Children's Center has set a goal of at least 90%.

4.1.2 CPR Quality Feedback Devices

4.1.2.1 Smart defibrillators

Many defibrillators, both public access AEDs and manual defibrillators, incorporate CPR quality feedback in addition to defibrillation capabilities. ZOLL See-Thru CPR® defibrillators and Philips' Q-CPR®-functional devices incorporate an accelerometer that is placed directly under the compressor's hands to measure chest compression depth, rate, and recoil. The incorporation of Philips/Laerdal Q-CPR® technology in the pre-hospital environment increased mean compression depth statistically significantly, from 34 mm to 38 mm, and significantly reduced mean compression rate from 121 cpm to 109 cpm [67].

4.1.2.2 Simulators

A number of simulators have position sensors to assess CPR quality metrics; however the majority, with the exception of Laerdal's Resusci Anne® QCPR® trainer, do not provide feedback directly to the user or easily to simulator operators in real-time. The feedback format of Resusci Anne® QCPR® trainer does not match clinical feedback displays. It is

unknown whether this reduces translation to practice. Chest compression metrics for most simulators are displayed on the trainer's control screen and are available in the report for later review. Many CPR quality reporting tools associated with simulators lack the detail that some trainers and researchers require for effective CPR quality assessment.

4.1.2.3 Standalone Devices

Standalone CPR quality feedback devices have also been reported to improve chest compression performance [75, 76, 77]. A number of devices, including the Laerdal CPRmeter™, the Philips Q-CPR™ meter, the Xbox Kinect®, and metronomes, can be used to provide audio and/or visual feedback to providers. These devices are beneficial for the reinforcement of psychomotor skills, but are used primarily for training and are not employed in the clinical environment. Because psychomotor skills associated with chest compressions have been shown to degrade quickly, after approximately 6 to 12 months [78, 79], chest compressions performed in the clinical setting may not be performed proficiently without real-time feedback.

4.1.3 Limitations of Existing CPR Quality Feedback Devices

Although the previously mentioned CPR quality feedback devices have been demonstrated to improve skill retention, smart defibrillators and metronomes are generally the only devices used in clinical practice, and although their use is becoming more prevalent, it is far from ubiquitous in most medical settings. Use of an actual clinical device during training may be ideal in terms of realism, which has been shown to affect rate of skill decay and translation to practice [80] and has been observed to reduce

negative learning; however, the inclusion of clinical devices in training is generally prohibitive in terms of device costs, learner to device ratio, and performance data collection for tracking, review, and research. This system addresses limitations of using actual clinical devices during simulation-based training by emulating the clinical device interface, while using clinical CPR quality sensors to provide data on chest compression quality.

4.2 Device Design

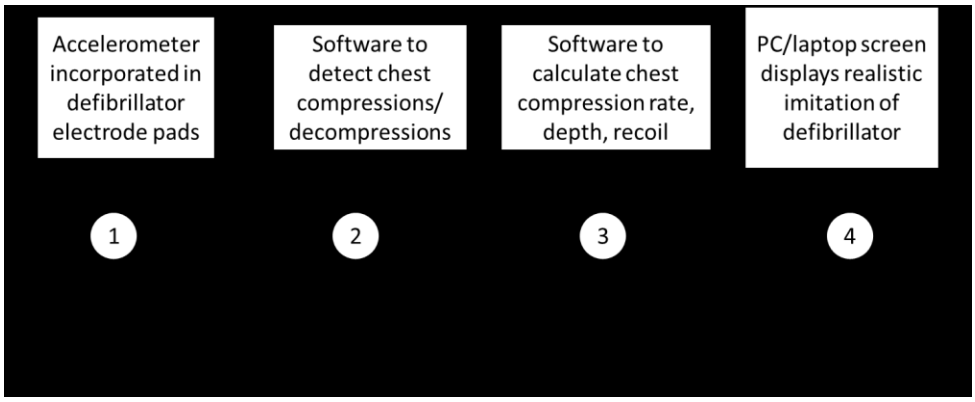

Figure 4.1. Workflow summary of hardware/software components.

This system interfaces pre-existing CPR performance measurement devices with customizable performance assessment and visualization applications (Fig. 4.1). The device's hardware includes clinical defibrillator pads with integrated accelerometer (ZOLL OneStep™ Complete Pads) and an analog-to-digital converter. Raw data are continuously sampled from the accelerometer output of the CPR quality sensor, minimally smoothed, and transmitted via serial communication to software components. Digital accelerometer data is filtered and is translated to position via linear estimation; compression depth, rate, and recoil are evaluated from calculated position data.

Performance data is then presented to the trainee and/or trainer in real-time. The user interface emulates the ZOLL R Series® defibrillator CPR quality visual and audio cues, providing a low-cost, customizable model for realistic BLS training. An interactive CPR quality score sheet is displayed at the end of training with compression metrics graphed in relation to common standards and AHA guidelines.

4.2.1 Hardware

Figure 4.2. ZOLL OneStep™ Complete Pads with "CPR Puck"

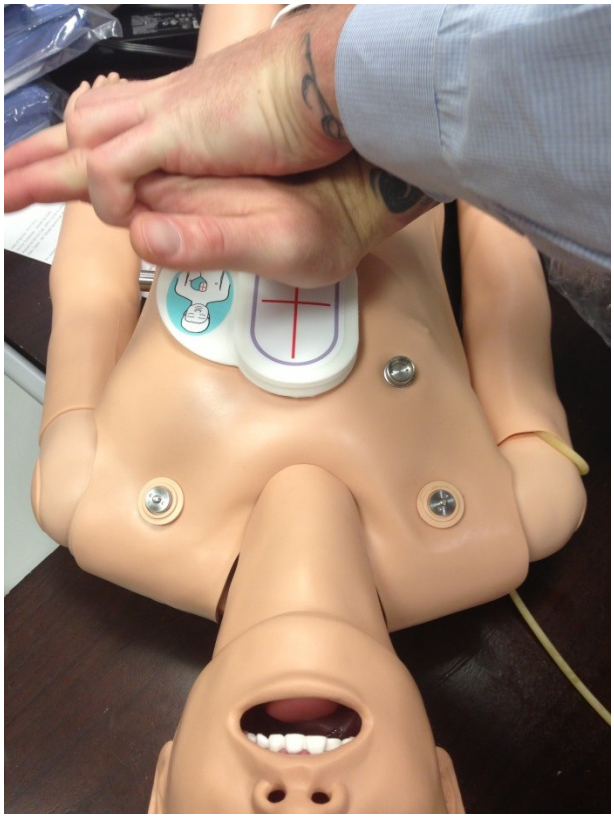

Figure 4.3 Placement of "CPR Puck"

The ZOLL R Series Plus defibrillator, which is used at this institution, uses the ZOLL OneStep™ Complete Pads (Fig. 4.2); these pads incorporate a thick foam oval, informally referred to as a "CPR Puck", which is placed under the compressors hands and directly on the patient skin (Fig. 4.3). The CPR Puck encases an analog ADXL 322/ADXL 327 accelerometer. The outputs corresponding to the axis of acceleration in the anterior-posterior plane, ground and source pins were identified from the electrode pads plug (Fig. 4.4). An Arduino Uno samples accelerometer output data at 10 ms intervals, completes analog to digital conversion, and minimally smooths data via continuous calculation of a running average over the previous ten data points. Digital

accelerometer data are transmitted from the microcontroller to a computer USB port via serial communication.

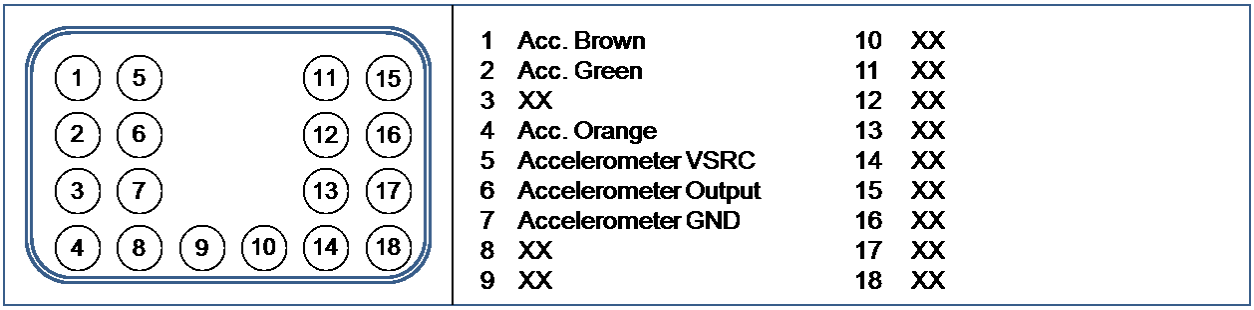

Figure 4.4. Pinout of relevant ZOLL OneStep electrode pad inputs/outputs for ZOLL R Series Plus defibrillator.

4.2.2 Software: Calculation of CPR Quality Metrics

Software written in Microsoft Visual C# manages the reception of raw accelerometer data, real-time conversion of acceleration to position, and calculation of CPR quality metrics. Real-time approximations of high-pass and low-pass filters with cut-off frequencies of 0.0001 and 0.005, respectively, were applied to raw accelerometer data to minimize signal noise, mostly caused by vibration of the sensor. In order to calculate real-time position of the CPR Puck from the acceleration data stream, acceleration data must be double integrated. A previously described method was used to approximate position from discrete acceleration points [81]. This method first estimates discrete velocity using the trapezoidal rule on the continuous time integral of accelerometer data in

$$v(t) = \int_{t_0}^{t} a(\tau)d\tau + v(t_0) \quad (1)$$

With t = nT, where T is the sampling interval and n is the sample count, to produce

$$v[n] = \frac{T}{2}(a[n] + a[n-1] + v[n-1] \quad (2)$$

Using the Z transform, the integration transfer function H(z) is calculated

$$H(z) = \frac{V(z)}{A(z)} = \frac{T}{2}\frac{1 + z^{-1}}{1 - z^{-1}} \quad (3)$$

Repeating the above transfer function to find x(n) from a(n),

$$X(z) = \big(H(z)\big)^2 A(z) \quad (4)$$

From which the equivalent discrete time function is obtained

$$x(n) = 2x(n-1) - x(n-2) + \left(\frac{T}{2}\right)^2 (a(n) + 2a(n-1) + a(n-2)) \quad (5)$$

Using this function, derived by [81], real-time position is calculated from the continuous acceleration data stream. Signal drift occurs occasionally using this method, as the

original signal function is more oscillatory than polynomial. Additional processing steps were added to eliminate potential drift; specifically, continuous linear estimation of position data is restarted at the beginning of each compression, identified by a negative change in real-time position. The end of a compression is identified as a local maximum in real-time position data, and the identified compression is double checked against thresholds to eliminate compressions with a depth less than 10 mm. This threshold catches and removes compression-like waveform characteristics caused by signal noise.

Once a compression is identified, individual compression rate and recoil are calculated: rate as the inverse of the time duration since the last compression, and recoil as the ratio of ending position to starting position. Calculation of CPR quality metrics initiates an event to automatically transfer numeric metrics from the thread on which calculations are taking place to the user interface thread. A library of the methods, properties, and events in the C# libraries designed to collect and calculate CPR quality metrics data is included in Appendix B.

4.2.3 Software: User Interface

The ZOLL R Series CPR Dashboard™ displays numeric compression depth and rate values (Fig. 4.5). Recoil is shown as a vertical bar that fills completely when the compressor allows for full recoil of the chest, measured in the ZOLL defibrillator by the release velocity. The perfusion performance indicator (PPI) visually indicates the overall performance of the compressor as the integration of compression depth, rate, and interruption times. The exact algorithm used to relate chest compression performance to

diamond fill is proprietary and unknown. The ZOLL R Series defibrillator also incorporates audiovisual feedback prompts, including “Good Compressions”, “Push Harder”, and metronome beeping at 100 beats per minute.

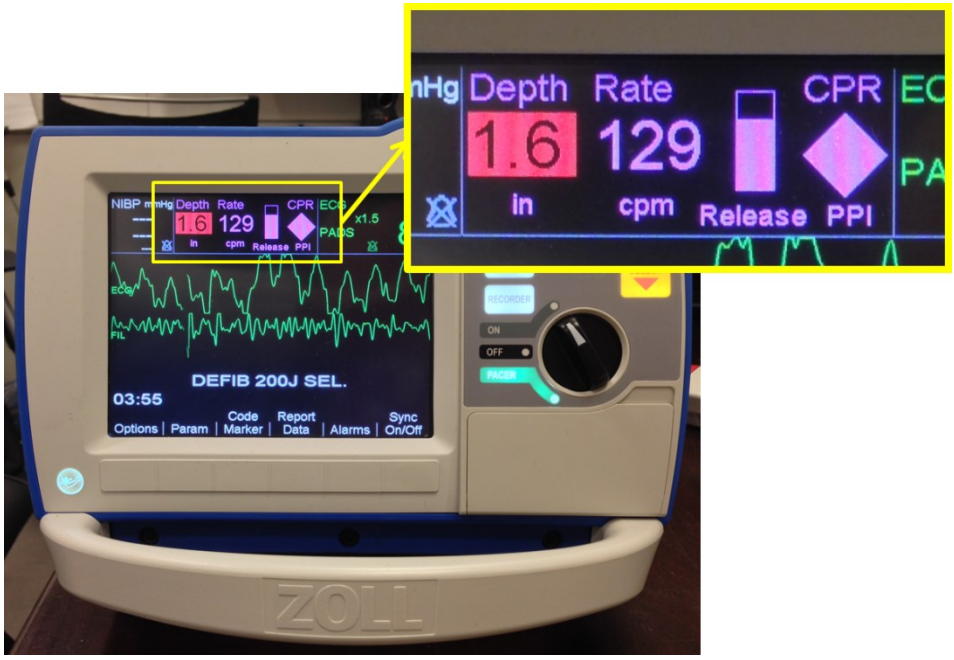

Figure 4.5. CPR Dashboard™ on the ZOLL R Series defibrillator

The user interface of this tool, created in C#, accepts new data sets of CPR quality metrics and uses this data to update the CPR Dashboard™ on the emulated defibrillator screen. The CPR Dashboard™ is updated with each compression. The depth and rate measured and recorded in this device are calculated in the same way as the ZOLL R Series defibrillator; however the recoil is calculated as the ratio of position change during decompression to position change during compression. The PPI diamond fill combines ratios of all CPR quality metrics to their respective AHA recommendations, with 1.00 being the maximum value for each ratio. The average of these ratios is proportional to the

size of the diamond on the emulator's CPR Dashboard™. This method of averaging provides a PPI diamond similar to that produced by ZOLL's proprietary method of PPI diamond fill. The device also emulates the various modes of the ZOLL R Series defibrillator (Fig. 4.6), providing training options for different groups of providers.

Figure 4.6. Emulator can switch between AED/Manual and Adult/Pediatric Mode displays

Once training is complete, users click the "Done" icon to view a complete performance report. The current format of this performance report includes 2 plots, one indicating compression depth by bar height and the second showing the compression rate charted on the Y axis as circles with the depth indicated by the extent of circle fullness. The performance report also displays calculated CPR quality metrics, including compression

fraction, number of interruptions, length of interruptions, and average rate, depth, and recoil. The report can be exported to html to allow for printing from a web browser. The score reporting form and html copy are shown in Figures 4.7 and 4.8, respectively.

Score reporting functionalities have also been extended to clinical chest compression data, so providers can receive standardized feedback from training and clinical practice. This is possible through the use of the ZOLL CodeNet report that is generated from each R Series defibrillator use. The CodeNet report can be exported to an XML file format. A C# software module parses the XML file and plots the collected compression data using existing performance reporting software modules. User interface methods and properties are not included because pre-existing class libraries were used to design the user interface.

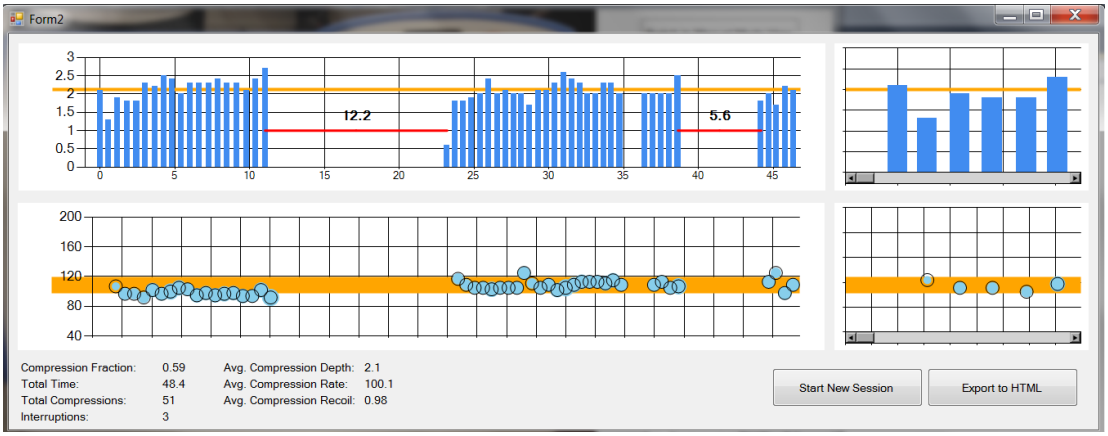

Figure 4.7. Screenshot of emulator score reporting form

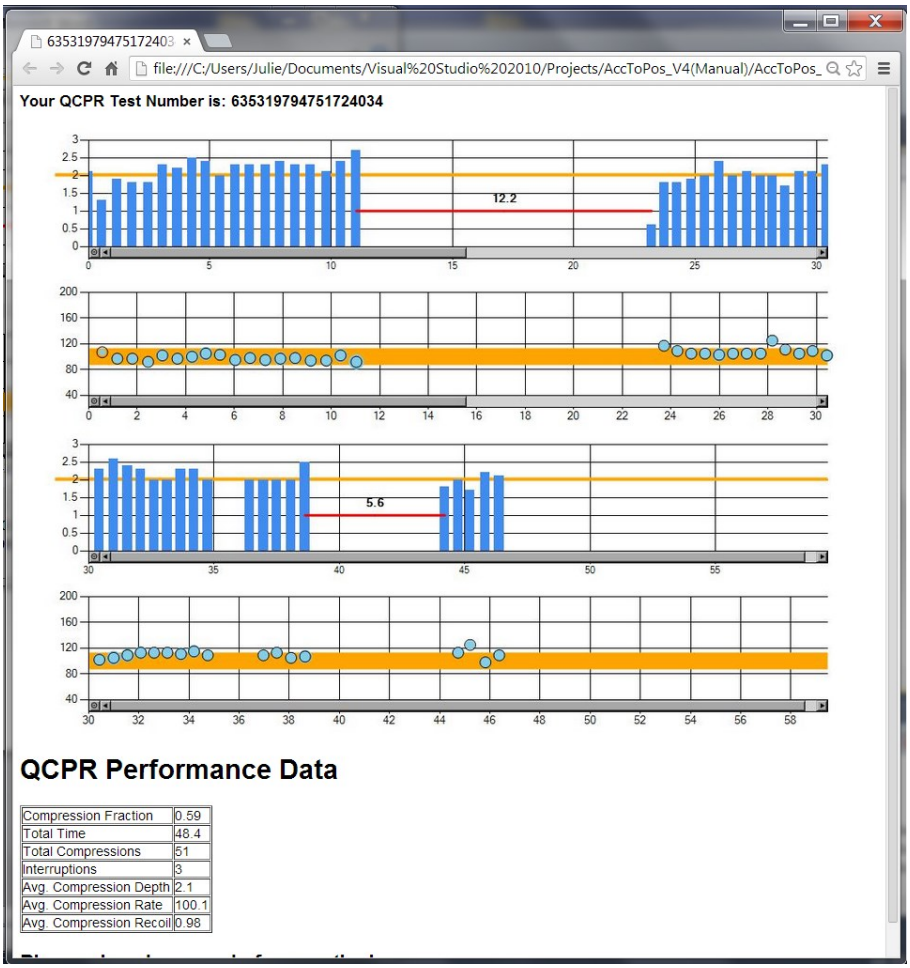

Figure 4.8. Screenshot of emulator html score reporting form.

4.3 Device Evaluation Methods

4.3.1 Assessment of Calculated CPR Quality Metrics

The CPR quality metrics calculated by this device from the streaming accelerometer data were compared to the metrics collected by the ZOLL R Series defibrillator. Two CPR Pucks were stacked and connected together, one of which was connected to the defibrillator, and the other was connected to a computer running the Emulator software. Three sets of 100 chest compressions were completed on top of the connected CPR Pucks. Test chest compression depth ranged from 0.5 to 4.0 inches, and rate ranged from

0 to 150 cpm. Calculated metrics were collected from both the defibrillator and the Emulator and were compared for compression count, depth, rate, and recoil. Regression analysis was used to compare the depth and rate values generated by the Emulator to the depth and rate values measured and recorded by the defibrillator.

4.3.2 Efficacy Testing

Research to test the effectiveness of this tool will begin in Summer 2014. The initial study, which is currently in the approval process by the Johns Hopkins Institutional Review Board, will assess the measured and user-perceived feedback quality of using this tool as compared to the ZOLL R Series defibrillator for training. Further tests will be required to identify differences in translation to practice between clinicians who trained with the R Series defibrillator, the Emulator, and a standalone CPR quality feedback device.

4.4 Results

Calculated CPR metrics were compared to output CPR metrics from the ZOLL R Series® defibrillator. The variance in calculated compression depth and compression rate between the CPR quality algorithm outputs is modeled by an $R^2 = 0.81$ and $R^2 = .99$, respectively.

4.5 Discussion

4.5.1 Training with clinical devices

High-technology simulators have continued to gain popularity in medical training due to increasingly accurate and realistic responses to user interaction, allowing users to achieve better clinical performance without involving real patients. Simulators provide functional

models for both basic procedural practice and detailed clinical scenarios. HTS now function realistically with a number of clinical devices, including defibrillators, diagnostic sensors, medical imaging tools, etc. Use of an actual clinical device in medical training may be ideal in terms of realism, which has been shown to affect rate of skill decay and translation to practice [80]; however, the incorporation of clinical devices in training can be prohibitive in terms of training device costs, learner to device ratio, and performance data collection for tracking, review, and research. Educators in the simulation field have traditionally suggested improved training opportunities with the development of more advanced technology, but it is possible that the resources required for this realism are not available for training.

Resuscitation training is required for the majority of providers in this hospital, resulting in tradeoffs for quality to meet the demand for the quantity of providers who require training. For example, this hospital is in the process of upgrading to a new defibrillator; most providers learn the device interface functionalities through separate in-service trainings despite frequent simulation-based BLS refreshers and trainings because of the limited number of devices allotted for simulation-based training. Because of the costs associated with designating expensive clinical devices for training alone, tools that emulate clinical device interfaces and functionalities, as this device does, could be very valuable to improving the existing state of simulation training. This device has been used to improve the realism of nurse education at this hospital and to provide CPR quality feedback during training, which was not possible previously due to a limited number of training defibrillators, training materials, and specialized knowledge and skills required to obtain data from actual defibrillators.

Structured, data-driven debriefing following resuscitation has been demonstrated to improve subsequent clinical performance. Efficiently collecting data from a number of different clinical devices following a simulation can be challenging, especially because most clinical devices used for resuscitation training do not integrate well with each other or with simulators. The device introduced here could potentially act as a model for other clinical device emulators. The current device emulates the ZOLL R Series CPR quality feedback and collects, analyzes, and stores provider performance data. A suite of like tools that realistically and inexpensively emulate clinical devices would allow for improved quality of widespread resuscitation training and would offer more effective post-training debriefing through the incorporation of quantitative performance data.

4.5.2 Chest compression feedback

Despite the existence of many technologically advanced devices to provide CPR quality feedback, it has been repeatedly demonstrated that CPR quality during training and clinical practice does not meet AHA guidelines [63]. BLS courses include repeated rounds of chest compression practice to achieve psychomotor skill proficiency; however, trainers often give CPR quality feedback based on observation alone and as a result feedback is limited. CPR quality feedback technology is not always incorporated into BLS courses due to the expense and when feedback is provided, it is usually has limited detail.

Research has demonstrated that the addition of CPR quality feedback improves performance during training [75, 82]; however, few CPR quality feedback devices can be used in both clinical practice and for training. And those that can be used clinically are generally not allocated to training because of resource limitations. As a result, there exists

limited research that gauges the importance of using clinically-realistic CPR quality feedback for training. This device bridges the gap between clinical realism and learner to device ratio limitations.

It has been suggested that providing CPR quality feedback in a broader resuscitation framework, as opposed to limiting feedback to chest compression-specific feedback, may improve the effectiveness of simulation training. For example, chest compressions directed by $ETCO_2$, and coronary perfusion pressure (CPP), and arterial diastolic pressure have been demonstrated to result in improved outcomes in animal studies [10, 55]. It may be beneficial to trainees to realistically train with information that would be available in clinical circumstances. The ZOLL R Series defibrillator has $ETCO_2$ sensing and display capabilities. Though the current emulator does not include $ETCO_2$-directed CPR quality feedback, this functionality will be incorporated into future prototypes to encourage providers to use all relevant clinical data to continue to improve resuscitation performance.

4.5.3 User interface research

Adverse events in medicine can often be attributed to poor interface design as opposed to human error [83]. The evaluation of user interfaces is well defined for other complex and high-risk industries, but the medical device industry often overlooks its importance [83, 84]. Advances in biomedical engineering have made the combination of medical technologies for patient treatment increasingly complex. Once medical devices are released, there is little comparative research that can be published regarding provider preference for and performance with medical devices. This device, which currently has

the same user interface as the ZOLL R Series defibrillator, can easily be altered for user interface research, providing a model for unbiased human factors research.

Potential user interface research in which this group is particularly interested is the clinical effects of displaying real-time CPR quality feedback in different displays. To our knowledge, this is an unexplored field. Our research to this point has included projecting existing clinical device user interfaces to a larger screen to identify possible influences on teamwork. In addition to changing the size of the screen, which is a much simpler task to complete with the emulator, we would also like to assess the translation of CPR quality metrics to new visual/audio cues and the grouping of traditional CPR quality metrics (i.e. rate, depth, recoil) with physiological CPR quality metrics (i.e. $ETCO_2$, CPP). The emulator provides an easily modifiable template for assessing the effects of user interface design in provider performance.

4.6 Conclusion

Differences between training-specific device interfaces and those used clinically can lead to trainee confusion and incomplete translation to practice. This technology interfaces pre-existing CPR performance measurement devices with customizable CPR performance assessment and visualization applications to provide effective CPR training that is both low-cost and clinically realistic. The quantitative feedback provided by the Emulator has been demonstrated to be comparable to the ZOLL R Series Plus CPR quality feedback. Additionally, the emulator provides a novel model for medical device human factors research.

5 Conclusion

5.1 Summary of Devices

Limitations in the interoperability of clinical devices and simulators create challenges in healthcare provider training and research. These challenges manifest in terms of cost-benefit, portability, ease and realism of provider-device interaction. The three devices designed and developed as part of this research provide solutions to these challenges. Of particular importance is the increased realism these devices facilitate during provider interaction with both simulated patients and smart defibrillators. Evidence suggests that increased realism improves the effectiveness of simulation-based training, and in the context of research, increased realism of device-simulator-provider interactions, allows for an increased model of resuscitation to study. These devices provide connectivity options (individually and in combination) to easily increase realism of a number of simulation-based resuscitation scenarios. These benefits are summarized in Table 5.1, and several example scenarios for use of the devices are listed below.

Table 5.1. Summary of Device Interconnectivity Options

	Realistic CPR Quality Feedback	Realistic $ETCO_2$ Feedback	Realistic Defib. Screen Population	AP Pad Placement	User Performance Data Collection	LTS-compatible	HTS-compatible	Interfaces with ZOLL R Series
AP Belt	X		X	X	X	X	X	X
$ETCO_2$ Sensor Signal Generator	X	X	X		X	X	X	X
Emulator	X	X		X	X	X	X	

5.1.1 AP Belt and $ETCO_2$ Sensor Signal Generator with HTS and Defibrillator

The HTS AP Belt can be used with the Sensor Signal Generator with signal input through the simulator's control interface (Section 3.2.4.5). This combination is used at the Johns Hopkins Simulation Center for most in-hospital contextual BLS trainings. It provides users with both sources of CPR quality feedback that would be available in the clinical environment—the CPR Dashboard (with depth, rate and recoil) and the maximum $ETCO_2$ value on the ZOLL R Series Defibrillator. Additionally, users must know basic defibrillator functionality to get this information, making user knowledge of the clinical device necessary to provide exquisite BLS during training. Because the $ETCO_2$ can be controlled by the HTS, the preprogrammed scenario can be used to drive $ETCO_2$ values and waveforms on the defibrillator, ideally unloading the trainer from having to control any of the equipment during training. Additionally, if the HTS is responsive to bag valve mask ventilation, the manual ventilation of the HTS will determine the $ETCO_2$ waveform characteristics on the defibrillator.

5.1.2 AP Belt and $ETCO_2$ Sensor Signal Generator with LTS and Defibrillator

LTS offer no defibrillation capabilities and are generally used for BLS courses to practice chest compressions and bag valve mask ventilation, meaning that users have very limited interaction with clinical defibrillators and generally do not receive data-driven feedback regarding CPR quality. A LTS and AP Belt can be used with a commercially available rhythm generator to allow for defibrillation of LTS and provide the required connective elements to populate the CPR quality feedback in the defibrillator's CPR dashboard. The

$ETCO_2$ Sensor Signal Generator can be used with the Ventilation Sensor to populate $ETCO_2$ waveform and values on the defibrillator and to provide responsive ventilation feedback to the provider managing the airway. Incorporating these two simple devices increases the fidelity of LTS resuscitation training considerably and provides a simulation platform in which the defibrillator can be incorporated.

5.1.3 Emulator for Multi-learner BLS and In-Service Trainings

Multi-learner (n > 10) BLS training is most often completed with each participant providing BLS to a LTS. It is not feasible for most training centers to provide a defibrillator, AP Belt, and $ETCO_2$ Sensor Signal Generator, as described in Section 1.2, to each participant. The Emulator provides a platform in which all users are provided with CPR quality feedback in a clinically-realistic format with only a laptop or tablet and a set of defibrillator pads. Additionally, in-service trainings are currently completed in a lecture-style format, meaning that few providers actually get hands-on practice with the device. If all users had access to an Emulator during training, they would be able to participate at the psychomotor level as functional elements are described. An increased interactive and hands-on training approach using the Emulator may influence provider knowledge and skill decay; more research in this area is needed.

5.2 Designing Devices for Modularity

The variations of available technologies in LTS and HTS make it necessary for training centers to choose simulators that meet the majority, but typically not all, of a trainer's

needs. Few customizable features are available, and those that are offered are generally extremely expensive; for example, a set of SimMan 3G Bleeding Modules, which are attachable trauma limbs for the SimMan 3G simulator, is priced over $3500. Because of the high costs of simulators and their accessories, training centers are frequently faced with tradeoffs in making a decision between simulators. The modularity granted by the technologies in this research provides trainers more flexibility in creating realistic scenarios. All of these technologies are "add-on" tools that link a range of simulators to clinical devices more effectively, resulting in an overall more realistic experience. Modularity was a recurring design theme throughout this research because a number of different simulators are used for different training purposes. Instead of requiring a new simulator for ideal resuscitation training, we opted to create tools to supplement all of the simulators at the Johns Hopkins Simulation Center and at other simulation centers. These tools can be built and deployed more efficiently because of their portability, ease of use, and low cost; and, they can be used seamlessly with a number of existing HTS, LTS, and simulator substitutes.

5.3 Continuation of this Research

5.3.1 Additional Research

The safety and reliability of these devices has been assessed and documented, and evaluation of the training effectiveness of these devices will continue as part of future research initiatives. All three devices will continue to be used in simulation-based training at the Johns Hopkins Hospital. Additionally, IRB applications are in the approval

stages for collecting data from participants who use the Emulator and the AP Belt. Summaries of the proposed studies are included in Appendix C.

5.3.2 Technology Transfer

All devices have been disclosed to the Johns Hopkins Technology Transfer Office. Materials Transfer Agreements will be completed for AP Belt in order for that device to be shared with partnered research centers in the United States, Tanzania, Malaysia, and Ecuador. Intellectual property strategies will be defined for all three devices with the ultimate goal of getting the AP Belt, the $ETCO_2$ Sensor Signal Generator, and the Emulator to training centers that will benefit from the incorporation of these devices into resuscitation training.

5.4 Conclusion

The devices created through this research provide a platform of "add-on" technologies that improve the interoperability between simulators and clinical defibrillators. The AP Belt, the $ETCO_2$ Sensor Signal Generator, and the Emulator all can be used to extend the functionalities of LTS, HTS, and simulator substitutes and are capable of addressing common connectivity issues in simulation-based resuscitation training. The use of tools such as these, which increase the realism of training, prevents trainees from learning sub-standard practices. Training with devices will likely reduce the risk of errors in clinical practice and increase the likelihood of improving provider performance. The safety and

reliability of these devices has been assessed, and the effectiveness and translation to clinical practice will be evaluated in future research.

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7 Curriculum Vita

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Summary:
Biomedical Engineering Master's student graduating in May 2014 with experience in technology development and engineering innovation. Academic research focus on the development of devices to improve healthcare simulation for resuscitation. Skilled in hardware and software creation and implementation, experiment design, and development of data-driven clinical performance assessments. Three poster presentations and one oral presentation at national and international conferences, three patents pending.

Education:
M.S. Biomedical Engineering, Johns Hopkins University, Baltimore, MD, May 2014
GPA: 3.81/4.00

B.S. Biomedical Engineering, Rensselaer Polytechnic Institute, Troy, NY, May 2012
GPA: 3.98/4.00

Industry Experience:
Marketing Analyst Intern, *Johns Hopkins Technology Transfer, Baltimore, MD*
Summer 2013-Present
Prepare marketing materials for inventions disclosed to JHTT
Review and evaluate technology assessment reports
Determine commercial potential for JHU technologies and identify commercial marketing leads

Soft Tissue Implant Research & Development Intern, *Covidien*
Summer 2012
Fabricated and mechanically-tested hernia mesh prototypes
Completed literature searches to identify and compare protocols for future preclinical studies
Completed Six Sigma and LEAD introductory courses

Soft Tissue Implant Pipeline Development Intern, *Covidien*
Summer 2010
Completed literature searches comparing hernia mesh materials and porosity
Analyzed and tracked FDA approvals of competitor products
Worked with Pipeline Development Team in planning timeline of production and release of products
Met with doctors who use Covidien products to get feedback for future product development

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Research Experience:

Graduate Thesis Research, *Johns Hopkins Simulation Center, Baltimore, MD*
Fall 2012-Present

Develop and prototype hardware- and software-based devices to realistically link simulation technologies to clinical monitors and diagnostic sensors, and implement devices in clinical training
Develop set of inexpensive, versatile tools to extend capabilities of low-technology simulators
Assess usability, safety, and effectiveness of devices through testing in simulation-based training and research
Participate in clinical training sessions and regular hospital M&M and resuscitation meetings
Three US Patent pending

Undergraduate Research*, Rensselaer Polytechnic Institute, Troy, NY*
Spring 2011-Spring 2012

Developed biomechanics experiments to study distribution of stresses on trabecular core and cortical shell in vertebral body under compressive loading
Mentored undergraduate student (Spring 2012), Mentored high school student (Summer 2011)
Researched effects of PTH, Bisphosphonate, and Fluoride treatments on osteoporotic rat cortical bone toughness and protein modifications

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Teaching Experience:

Graduate Teaching Assistant, *Johns Hopkins University, Baltimore, MD*
Fall 2012-Present

Teaching Assistant for *Freshman Modeling & Design* (Fall 2012), *Systems & Controls* (Spring 2013), and *Introduction to Business* (Summer-Fall 2013), *Systems Bioengineering Lab* (Fall 2013-Spring 2014)

Undergraduate Teaching Assistant, *Rensselaer Polytechnic Institute, Troy, NY*
Spring 2010

Responsible for teaching basic laboratory techniques to students in *Introduction to Cell Biology*
Wrote weekly quizzes to gauge the progression of student understanding in the class

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Awards and Honors:

Who's Who Among American University & College Students: Recognizing outstanding merit and accomplishment.
Tau Beta Pi: Engineering Honors Society. Inducted November 2010.
Tau Beta Pi Soderberg Scholarship: Awarded for outstanding scholarship and exemplary character as a senior student in engineering. April 2011.
Charles D. Dyce Prize: Awarded to School of Engineering student who has demonstrated high scholastic ability and involvement in extra-curricular activities and indicates potential for constructive leadership.
Liberty League All-Academic Squad: Recognized for GPA while playing Division III Varsity Sports for RPI.
RPI Leadership Award: Merit-based scholarship Award for academic standing and extracurricular activities.

Publications/Presentations:
Campbell J, Allen R, Fackler J, Hunt E, Duval-Arnould J. "Spoofing ETCO2 sensor data streams: A hardware and software package to interface simulators and real clinical devices," presented at 14th International Meeting on Simulation in Healthcare, USA, Jan 24, 2014.

Campbell J, Perretta J, Sullivan N, Hunt E, Duval-Arnould J. "A device to allow anterior-posterior (AP) defibrillation in simulators lacking AP electrode contact points," presented at 5th International Pediatric Simulation Symposia and Workshops, USA, April 25, 2013 and at 14th International Meeting on Simulation in Healthcare, USA, Jan 24, 2014.
**Abstract awarded 2nd Place Student at IMSH 2014. Presented as Oral Presentation.

Campbell J, Karim L, Tommasini S, Judex S, Vashishth D. "Effects of parathyroid hormone treatment in ovariectomized rats," presented at Orthopaedic Research Society Annual Meeting, USA, Feb 5, 2012.

Technical Experience/Skills:
Laboratory: Cell culture, Cell strain (Flexcell® Tissue TrainTM System), Contact Angle Analysis, Electronic circuit design and construction, Mechanical testing (Instron 5900 Systems), Micro-computed tomography, Micro-mechanical testing (EnduraTEC ELF3200), Protein Glycation

Software: ABAQUS, C#, LabView, MatLab, MS-Office, R (GNU S), SigmaStat, Simulink, Solidworks

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Leadership and Activities:

Club Field Hockey Team, JHU	Fall 2012-Present
RPI Varsity Athlete (8x): Field Hockey, Indoor Track, Outdoor Track & Field	Fall 2008-Spring 2012
Tau Beta Pi, Secretary, RPI	Spring 2011-Spring 2012
Biomedical Engineering Society, RPI	Fall 2011-Spring 2012