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CPR Smart Mannequin Proposal Report

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Submitted by:

Group 14

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Background Research

CPR Overview: Cardiopulmonary resuscitation (CPR) is an emergency procedure administered during cardiac arrest wherein chest compressions are performed to replace the pumping of the heart and allow blood to keep flowing through the body. It is reported that about 9 in 10 people who experience cardiac arrest outside a hospital die [1]. If CPR is administered within the first few minutes of cardiac arrest, the chance of survival can double or triple [1]. There are various CPR certification courses available, but you do not require a certification or formal training to administer CPR [1]. There are two commonly known versions of CPR, conventional CPR, which uses chest compressions and mouth-to-mouth breathing, and compression-only CPR, which is simply conventional CPR without mouth-to-mouth breaths [2]. This background research focuses on adult CPR only. The Canadian Red Cross training services have outlined steps for administering conventional CPR to adults, shown in Figure 1A in Appendix A. The official CPR guidelines from the Heart and Stroke foundation outline that compressions must be at least 5 cm in depth with complete chest recoil, be performed at a rate of 100-120 compressions/min, have minimal interruptions, and that the compressor should use a 30:2 compression-ventilation ratio, and switch out with another compressor every 2 minutes [3]. The hands should be centered on the chest, with shoulders directly over the hands and elbows locked [4].

Smart CPR Mannequins: Smart CPR aids provide users with meaningful real-time feedback that improves CPR performance. The devices provide information to instructors so they can be effective teachers and precise evaluators. Smart training aids are available with a wide range of features. A number of smart mannequins were investigated and a summary table can be found in Table 1 of Appendix B. The features focus on relaying critical information, such as depth and rate of compressions, back to the user through audio and visual cues. The smart devices can relay the information to a central display to give instructors statistics and infographics on the class. The devices' accurate, live feedback helps improve CPR training outcomes and retention [3]. An example of using smart mannequins was shown in a study where elderly participants learned how to perform CPR by watching a 30-min self-instructed video program while using an inflatable smart mannequin [5]. The CPR quality equaled a 4-hour professional class. After the training sessions, a smart mannequin was used to quantify the participants' CPR proficiency [5]. In trained professionals, live feedback from smart mannequins during CPR training improved performance and received high ratings for usefulness and ease of use [6].

Regulations for CPR Mannequins: As the smart CPR mannequin is used for training, and not for treatment or health monitoring, it is not classified as a medical device and needs no regulatory approval process. Instead, the regulations are defined by various first-aid training bodies and foundations, most popular being the American Heart Association (AHA) and their 2020 Guidelines [7]. The guidelines contain several recommendations and standards for the design that should be met in a successful training device, including the types of feedback given and the evaluation methods. While it is up to individual foundations to decide whether they want to use a particular mannequin for training, most base their decision on meeting the AHA Guidelines [8].

Patents
Patents of current designs were studied to better understand our market environment. The solutions found can be broken down into three main areas: regular mannequins, smart mannequins, and CPR feedback devices.

Regular Mannequins: These patents provide descriptions of the mechanical design and feedback system, such as spring design, simulating chest compressions and airways, and the mannequin anatomical structure [9], [10], [11]. They provide information on durability, portability, and manufacturing solutions [9], [10], [11]. One of the patents uses a fluid to provide a damping effect, stepping away from the linear spring method used in other cases, which research has shown to be more accurate of a real chest during compression [9].

Smart Mannequins: In addition to the mechanical design trying to mimic a realistic torso, this patent contains a sensor housing fitted with a force sensor and an acceleration sensor [12]. The patent goes in-depth about the types and layout of the sensors, explaining the idea behind having separate sensors working together as a fail-proof mechanism [12].

CPR Feedback Devices: These patents are for monitoring devices that use sensors to provide feedback on the quality of the CPR given during an emergency [13], [14]. One relies on pressure pads on the chest and back of the patient and uses the difference in the amplitudes and frequency collected to calculate compression and rate [14]. The second device uses an ultrasonic wave transmitter on the chest and a receiver on the back of the victim. The time of flight between the transmitter and receiver is used to calculate compression depth and the frequency [13]. As these are to be used on humans, it is less applicable to our training use case, however we could take inspiration from the solutions for the sensor setup and type of data collected.

Problem Statement and Needs Identification

Problem Statement: Lack of effective CPR education of laypersons in developing countries is currently hindering the administration of lifesaving treatment for out-of-hospital cardiac arrests (OHCA), which occurs with an annual incidence of 350,000 in the United States alone and has a mortality rate of approximately 90% [15]. A method to effectively and easily teach CPR to laypersons of various backgrounds and education is needed, ensuring that trainees can perform quality CPR in an emergency and retain the information and skill set for sufficient time.

Client Needs: The client requires a means of delivering effective CPR training to laypersons in developing countries. The client has allowed for an open-ended method of accomplishing this goal, giving examples such as a smart CPR mannequin, or a CPR training program. Although the client seemed more focused on a smart CPR mannequin, we intend to quell this bias as much as possible in our brainstorming process, as the problem statement outlines only that a CPR training solution be implemented. CPR training relies on providing the learner with the necessary information and skillset, and ensuring retention of the skill to later perform in an emergency setting. This requires professional instruction and repetition of good technique on a realistic subject. No matter the physical manifestation of the solution, it must be able to measure and give real time feedback to both the student and the instructor pertaining to the quality of chest compressions. Quality of chest compressions is broken down into quality of compression rate, depth, recoil, chest compression fraction, and hand position. The client has specified that ventilation is not a requirement for the CPR training they wish to give. Further research to justify this choice shows that compression-only CPR is easier for a layperson to perform, and that it results in similar survival rates for adult cardiac arrests of cardiac etiology compared to CPR with rescue breaths [16]. The client also requires that the quality-of-compression data be available to provide remote certification of CPR competence. The structure of CPR lessons is assumed to remain consistent with instruction followed by practicing the skill and receiving feedback. The client specified that electronic components need to have a shelf life greater than 2 years, so that the battery and components must last through regular use and possible charging. The aid must also be convenient to transport overseas, and must use universal conventions to be easily used in different countries.

Uncertainties and Challenges: The lack of robust and routine data collection surrounding OHCA in developing countries makes it difficult to put the problem statement and client needs into quantitative terms. The motivation behind this project was derived from lived experience and probabilistic evidence sourced by the client related to CPR training in developing countries. While there are studies that focus on OHCA in developing countries, those studies are, again, founded on limited statistical evidence. Furthermore, the client has listed many countries in which they have connections for a CPR training program to be started, but they have not decided which specific country they would like to target. This might present some issues when assessing feasibility of solutions in different countries, and designing for specific languages and cultures of learning. This could mean that we create our own scope and choose a specific country to target ourselves.

Design Criteria

The following design criteria are guided by minimum features of adult CPR mannequins established by the American Red Cross First Aid CPR certification courses and professional guidelines for performing CPR from the Heart and Stroke foundation [3].

Affordability: In discussions with stakeholders involved in CPR training programs, it was identified that having a low cost product is of significant importance. The product should be more affordable compared to current existing models and ideally, be easily purchased in developing countries. This will be quantifiable, with a goal to achieve a cost less than $172, which is the price for a basic feedback-capable mannequin available for sale [17].

Portability: The product should be easily portable. Devices that are too large become difficult to transport (especially overseas) and may discourage users from purchasing the product. This will be quantifiable, with a goal to have a design less than 7lbs, which is the weight for a standard CPR mannequin [18]. The device should be usable without electrical connection during use, be easily charged and/or require batteries that are universally accessible.

Safety: The device must have minimal safety risk. This means the integrity of all mechanical and electrical components is confirmed. At a minimum, the design will be as safe as current products on the market. The device should not include materials such as latex, which may cause allergic reactions in some users.

Accessibility: Operation should be easily understood regardless of prior knowledge, experience, or language(s) spoken. The product should incorporate as many non-linguistic cues as possible, such as lights, sounds, vibrations, etc., which can be adjusted to fit the needs of the user. If linguistic cues are needed, it should aim to be able to accommodate different languages.

Durability: The product should be made of materials that increase longevity and sustainability of the device, and be able to withstand a minimum of 125 uses [19]. The material should be minimally absorbent and easily disinfected, to mitigate the transfer of communicable diseases [19]. The instructions for decontamination must be simple and distributed with the product.

Feedback System: The feedback system should incorporate real-time simulated audio, visual or sensory cues which respond accurately to the depth, compression rate, and fraction. The feedback must accurately follow professional guidelines established by the Heart and Stroke foundation [3]. These guidelines identify a minimum depth of 5 cm, a compression rate of 100-120/ min, complete chest recoil, and minimal interruptions in compressions [3]. A successful feedback system will identify when the user is matching guidelines, nearing the guidelines, or failing to meet the guidelines. The feedback system may ideally notify the user when compression has exceeded 2 minutes, as it is recommended the CPR provider is changed every 2 minutes [3].

Ease of Manufacturing: A desirable design should be easily manufacturable. This will likely reduce the cost and make maintenance/repairs more accessible. Easily manufacturable designs will be identified by their use of standard parts, easily replaceable components, and the use of standard practices in manufacturing.

Sensor and Measurements: The sensor system of the design should collect reliable, robust and consistent data as it will be used downstream in providing the feedback to the trainee. As the measurements will be used as the foundation for the rest of the system, the data flow needs to be consistent under all conditions and pass a variety of stringent hazard analyses.

Design Criteria Challenges

The main challenges that will have to be addressed for this design will revolve around finding a good middle ground amongst the criteria defined above. When taken to the extremes, some of the design requirements are conflicting to one another, for example, extremely high quality sensors will not be the most affordable. Finding the optimal point to maximize each of them will be a significant obstacle, and will take planning and several iterations to get right.

Plan for Design Process

The project plan, deliverables, and detailed timeline is found in the Gantt Chart in Appendix C.

Semester 1: The team will participate in background research, design process planning, and problem identification and analysis. In October/November, members will generate initial design ideas and then select a final design after a design review. In early December, the team will order the required parts and/or begin fabrication of components.

Semester 2: The team will build, test, and refine the device. In January, the team will build the first prototype. In early February, testing will begin. In late February, a second prototype will be built with further testing. The rest of the term will be overflow in case challenges arise.

Potential Challenges: To build in semester 2, the preliminary design must be completed by mid-December to allow time for parts procurement and fabrication. If the majority of parts are to be fabricated, fabrication may be pushed to mid/late January. However, parts identification will start in mid November, so if it is identified that the majority of parts need to be fabricated, the Mechanical Sub-Team will adjust the schedule accordingly.

Fabrication Planning and Budget Considerations: All members will keep in mind the budget of $1000. All members will receive second-floor machine shop and hatch bay training for fabrication purposes.

Impact

Even in the U.S., the mortality rate from OHCA is still 90% on some 350,000 events each year. In developing countries, the belief that CPR can only be performed by medical professionals in hospitals is strongly held. It is evident that effective layperson CPR training would have a great benefit to unlearning this belief and saving lives around the world. In a scoping review performed by Thibodeau et al. pertaining to OHCA in Africa, several papers identified cardiovascular disease (CVD) as an underlying cause of OHCA, and discussed how the incidence of CVD is expected to double in Africa [20]. We can proactively prepare the public to deal with this impending increase in OHCA through the implementation of CPR training. The development of a feedback-based CPR training tool in this project will have a strong impact in this respect, as shown by studies that discuss the benefits of CPR training with feedback, compared to no feedback. One study found that people trained with just one minute of real-time visual feedback scored 10.8% higher than the people with no feedback in overall CPR score (which accounted for compression depth and rate, chest recoil, hand position) [21]. Another study had one group of participants watching an instructional video while practicing CPR on a mannequin, and another group receiving real-time computer-voice feedback on the quality of their CPR. The non-feedback group only improved from 5% to 8% of participants successfully meeting all the CPR criteria, whereas the feedback group improved from 4% to 19% [22]. Not only will this project have an impact on people requiring life support from witnesses to OHCA, but it will also impact CPR instructors. The American Heart Association discusses the difficulty of detecting inadequate CPR performance in traditional instruction practices, which makes it challenging to fine tune the feedback they give. They believe that implementing a more technologically advanced, feedback-based CPR training solution would help tackle this problem [23].

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Appendix A

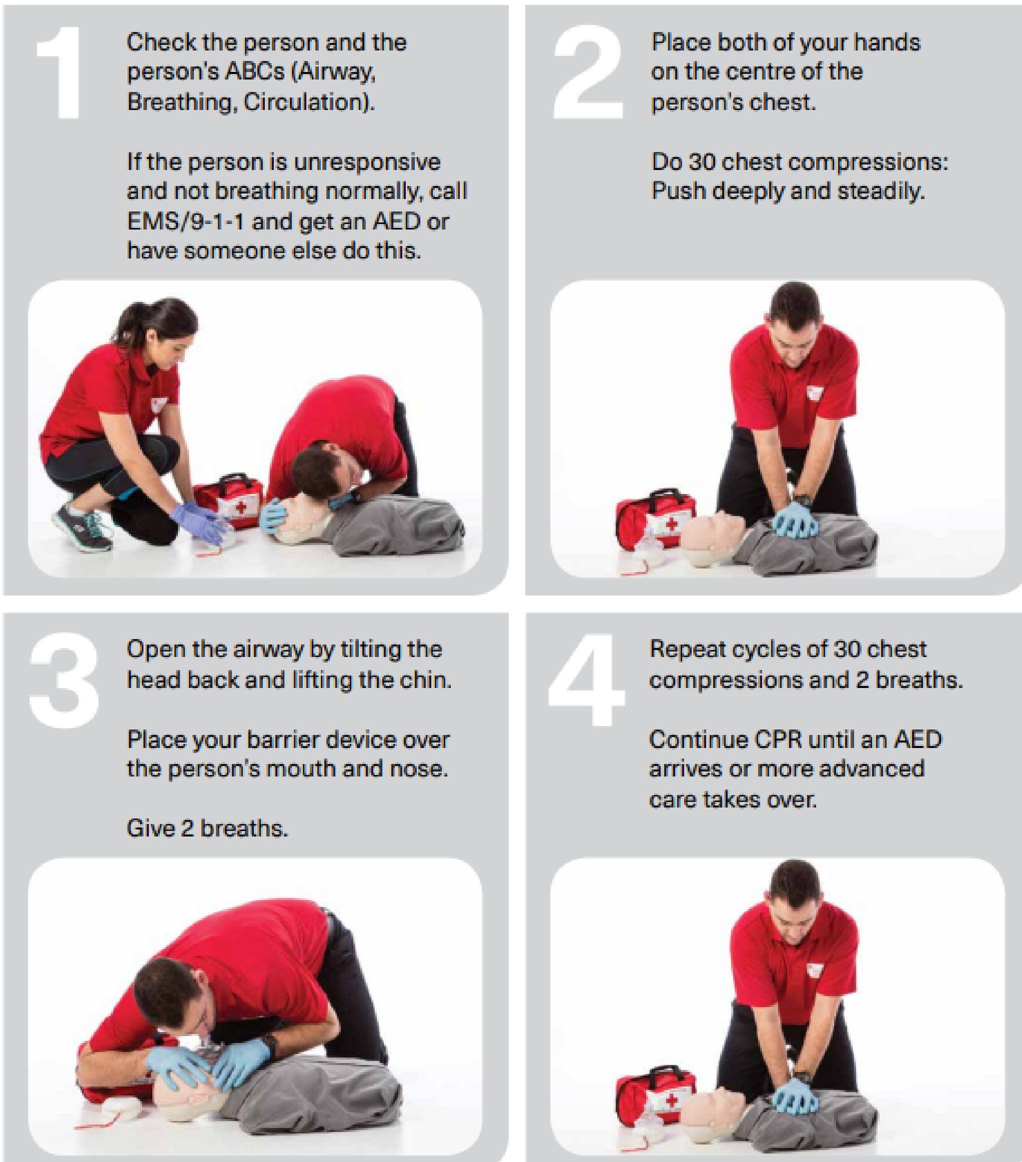

Figure 1A: Canadian Red Cross Conventional CPR Steps for an Adult [24]

Appendix B

Table 1: Current Smart Mannequins on the Market and Key Features

Product Name	Company	Description	Key Features	Cost (CAD)
Professional Adult Series 2000 Manikin [25]	Prestan	Realistic adult mannequin with advanced real-time feedback Fully compliant with industry guidelines Available in different skin tones	Compression rate Depth Recoil Ventilation Hands-off time Bluetooth connection Mobile app LED feedback	302.28
BLS CPR Pro – SM201 [26]	SmartMan	Adjustable-Real chest resistance Monitors performance and detects Mistakes	Real-time feedback Metronome External screen Compression modes	Not Available
Little Anne QCPR [27]	Laerdal	Quality CPR (QCPR) feedback technology Help instructors improve CPR training quality, classroom efficiency and learner engagement.	Real-time feedback Race competition Scoring Guidance	310
HAL® S315 Adult Airway and CPR Trainer with OMNI® 2 [28]	Gaumard	A CPR trainer designed for teaching resuscitation skills Realistic chest cavity resistance and recoil Performance report providing averages for CPR metrics	Real-time feedback Compression depth Rate Ventilation rate Excessive ventilation Metronome Resuscitation algorithm Checklists	2135

Appendix C

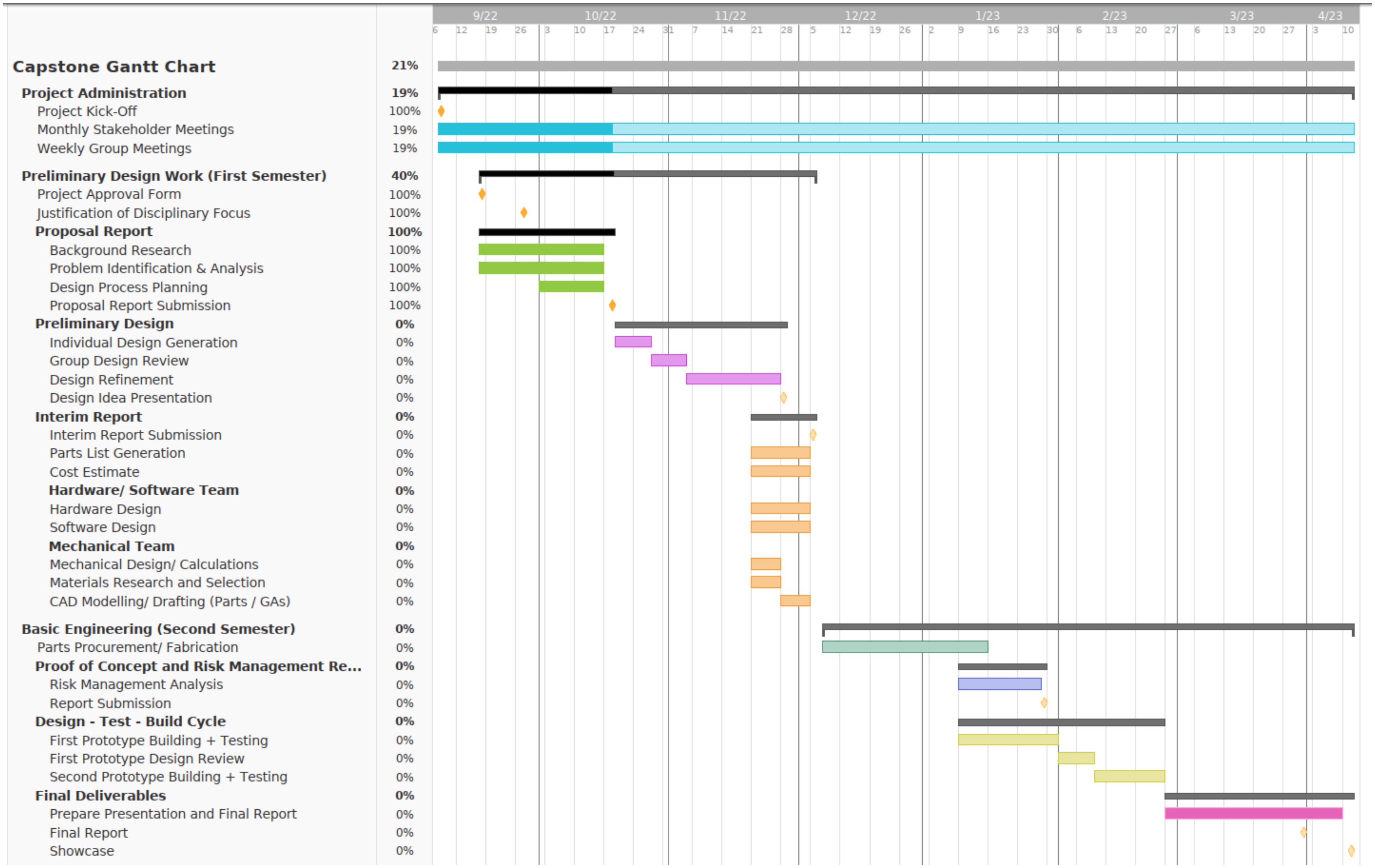

Figure 1C: Gantt Chart