PURDUE UNIVERSITY®

WELDON SCHOOL OF BIOMEDICAL ENGINEERING

Engineering World Health Design Competition
Submission for:

AutoCPR: Low Cost, Accessible CPR

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May 30, 2017

Section 1: Problem Definition

This project is being completed in collaboration with medical students and professionals from the Universidad San Francisco de Quito (USFQ) in Ecuador. According to the Ecuadorians and the team's own research, there is a lack of access to effective cardiopulmonary resuscitation (CPR) especially in rural areas in countries such as Ecuador. Nearly 90% of people who suffer an out-of-hospital cardiac arrest (OHCA) die [1]. Additionally, cardiovascular diseases (CVDs) are the number one cause of death globally, contributing to 31% of all global deaths. Low and middle income countries account for at least 75% of these deaths [2]. CPR is a fundamental component of basic life support for cardiac resuscitation [3].

Physicians or paramedics working in rural areas may need to perform manual CPR for up to 45 minutes at a time [4]. This is an issue because performing CPR correctly requires both high physical and high mental demand, and there is evidence that as the maneuver continues over time, the probability of executing it effectively decreases. A manikin study showed the quality of chest compressions significantly declined within two minutes, suggesting that rescuer fatigue adversely affects the performance of CPR [5].

This problem became especially apparent after a magnitude 7.8 earthquake hit Ecuador in April 2016. The importance of developing an automatic and portable CPR medical device resides in the need to have a reliable method to properly perform CPR during emergency scenarios like the earthquake that struck Ecuador and left 663 victims dead [6]. Emergency response teams from USFQ who served in the affected regions during the earthquake estimated that dozens of victims died as a result of inadequate CPR maneuvers on their way to the medical centers.

There are only 1.72 physicians per 1,000 patients in Ecuador [7]. This means that there is usually only one understaffed and underequipped medical center serving thousands of people and that the majority of Ecuador's population is untrained in CPR. There are currently three main automated CPR devices on the market, the AutoPulse, Lucas 2, and ROSC-U [3]. However, these devices cost upwards of $12,000 and are inaccessible in countries like Ecuador.

There is a need to address the high patient mortality rate of individuals who suffer cardiac arrest outside the hospital. To combat rescuer fatigue, the solution should make it easier for the CPR administrator to provide effective CPR for an extended period until proper medical attention can be given. To address the limited access to medical professionals in rural areas, the device should be portable and easily stored in mobile units like ambulances and police cars. Additionally, the device should be easy enough to use such that a wide range of individuals can be qualified to perform CPR using the device. Finally, to make automatic CPR devices easily accessible and able to be deployed in large numbers in rural areas or after a natural disaster, the device must be cheap enough to be purchased in mass quantities by local governments and hospitals.

In summary, to address this need a portable, automated CPR device that costs less than $1000 to manufacture is proposed. The device must accommodate a variety of patient sizes, be operable with minimal training, and deliver at least 2.0 inches of chest displacement at 120 compressions per minute for 45 minutes with full chest recoil [8] [4].

Section 2: Statement of Impact

Currently, the most widespread chest compression solution is manual CPR. Manual CPR is performed by a rescuer until the patient is able to be defibrillated or put on advanced life support or if there is return of spontaneous circulation. The greatest benefit of manual CPR is that it requires no external instruments or special conditions in order to be utilized and save lives. However, the overall survival rate for a person undergoing an OHCA is about 10% [1]. Much of this low survival rate has been attributed to rescuer fatigue and lack of training. This is a problem that is abundant in Ecuador, where there are very few trained medical professionals and the time it takes to get a patient from a rural area to a medical center is especially high [4].

These problems with manual CPR have led to the development of automated CPR devices. The main devices currently on the market include Michigan Instruments' Thumper and Life-Stat, Physio-Control's Lucas' 2&3, Zoll Medical's AutoPulse, and Resuscitation International's ROSC-U. These devices can all effectively provide CPR using a variety of mechanical and electrical methods such as a piston with an electric driving force, a piston driven by O_2, a load distributing band, and an electromechanical actuator [9] [10] [11] [12]. The main pitfall for most of these devices is their prohibitive cost, making them unaffordable in rural and developing areas. The cheapest devices, made by Michigan Instruments, start at $4995 according to their website [13], though a quote from a sales representative put the cost of the cheapest Michigan Instruments device at $6,457. The Lucas 2, AutoPulse, and ROSC-U cost $14,495, $19,950, and $12,999, respectively [14] [15] [16]. With the cost of competitive devices being so much higher, the Michigan Instruments devices seem like a good option; however, these devices require O_2 or medical air to provide compression, which may not be available at all times in rural areas or during disasters. Another requirement for a device to be successful in a country like Ecuador is that the battery life must be long enough to transport a patient from a rural area to a medical center, the only existing devices that have a battery life longer than 30 minutes are the Lucas devices and the ROSC-U (although not recommended) [4] [9] [17] [11] [12].

Based on analysis of the existing solutions, there is an evident lack of affordable CPR solutions that can provide effective CPR for periods of 45 minutes without an external power source [4]. Additionally, the existing solutions require training for proper use, and thus are expected to be ineffective in emergency situations in rural areas or after a natural disaster where there will be a shortage of trained personnel. The proposed solution utilizes a low-cost crank mechanism to convert rotational motion provided by a DC electric drill motor into linear motion of a piston-like device and costs less than $1000 to manufacture. Uniquely, the device can be powered indefinitely by any car or boat motor, coming equipped with a backup battery. A simple on/off switch and a potentiometer for speed regulation are used to control the device. The device is easily secured on a patient, taking a first responder less than thirty seconds to do, and the device comes fully assembled; the steps to initiate CPR include strapping in the patient, turning the device on, and setting the speed of compression. The device is currently in the second prototype design iteration phase. Tests on electromechanical components of the first prototype validated that the device can deliver the necessary compression depth and rate on a CPR manikin. The overall device is lightweight at 10lbs, and the material cost is $540. The next prototype iteration will implement minor design changes based on feedback from firefighters, EMTs, and from Ecuadorian medical faculty and students at USFQ. With these improvements, this device has the potential to implement a simple, yet effective technology to improve access to quality CPR in developing countries.

Section 3: Required Specifications

The following table summarizes the design specifications taken into consideration for the development of the autoCPR device.

Table 3.1: Summary of design specifications

Condition	Design Specification
CPR Functionality	The device must be able to compress the chest – specifically the sternum – to a depth of 2-2.4 in. (4-6 cm.) [18].
	The device must be able to perform chest compressions at a rate of 100-120 compressions per minute [18].
	The device must be able to deliver at least 150lbf of compression to achieve the desired displacement design specification and overcome chest resistance [19] [20].
	The chest must be allowed to fully recoil between compressions; therefore, the chest should displace 0-2.4" [18] .
Compression Target	The contact surface area between the chest and piston should be no larger than 4.4in^2, the contact area of the LUCAS2 [20].
	The piston must be aligned over the lower half of the sternum [21].
Target Population	The device must be designed to administer CPR to adults [4].
	The device can accommodate patients with a chest circumference of 76 - 130 cm or 29.9 – 51.2 in [22].
	The device can accommodate patients with sternum height of 6.7-11.9 inches [23].
Portable	The device must be portable and fit in the back of emergency vehicles such as a police car or ambulance, which means the device should take up less than 16 cubic ft. of space [4] [24].
	Device must weigh less than 50 lbs. per OSHA lifting guidelines [25].
Easy to use	The device must take less than 2 minutes to assemble on the patient, matching the time a study showed the Zoll AutoPulse setup to be [26].
Environmental Conditions	The device must be able to work in a temperature range of 0-42 degrees Celsius at up to 100% humidity [4].
Automatic	The device must automatically administer CPR to a patient [4].
Long use time	The device must be able to administer CPR to a patient continuously for at least 45 minutes [4].
Low Cost	The total cost of the device to the buyer must be under $5,000 [13] [4].
Durable	The device must withstand 540,000 cycles, the equivalent of 100, 45 minute uses at 120 rpm.
Effective	The device must have as high of or higher survival rate than traditional manual CPR.
Safe	Device must not cause undue harm to the patient.
	Device must be able to be turned on or off quickly to prevent undue injury to patient.

Section 4: Implementation of Prototype

The autoCPR device innovates in areas where existing devices do not address needs of first responders in rural and developing areas. The autoCPR device has a primary focus on delivering effective CPR in the most compact, minimalist, and ultra-portable manner possible. The key components of the design are shown in the Appendix Figure A.4.1.

The innovations in the crank design, Appendix Figure A.4.1 (A), allow for delivering the required chest compressions in an extremely low-cost manner. Existing devices use expensive electric actuators, while a crank and inexpensive DC motor can provide the same force and displacement required at a fraction of the cost. To achieve the required 2-2.4" of compression, the crank required a radial linkage of length 1.2" connected to a motor capable of providing at least 180 in-lbs of torque.

Innovations in the strap design, Appendix Figure A.4.1 (B), will allow first responders to deploy the device on a wide variety of patients in less than 30 seconds. The strap design also allows for a secure attachment of the device to the patient during transport to medical facilities. The adjustable strap stabilizes the patient under the compression component. The frame interfaces with the compression subcomponent and is strong enough to withstand the reaction forces from the compression load. The frame is adjustable to fit varying patient sizes, portable, and easy to assemble. The frame also aligns the piston of the compression mechanism over the sternum. Due to the need of the device to accommodate varying patient sizes, the buckle was mounted on the side of the plate so that it would be located on the top of the chest for every patient.

The electronics component of the device, Appendix Figure A.4.1 (C), allows for full versatility and portability. The device can be powered by any 12V power source that can deliver sufficient power. The electronics innovation is focused on powering the device from a car, boat, or auxiliary battery during transport to advanced medical care facilities.

The power source is directly attached to a high-current motor driver capable of regulating up to 30A. The motor controller connects to a 12V motor capable of delivering at least 180 ft-lb of torque. The intended operation of the device is centered on intuitive design and ease of use for an untrained individual. The motor controller is connected to a simple ON/OFF switch and potentiometer. For safety purposes, both controls can turn the device off, but the ON/OFF switch is required to be on before the device can be operated. The potentiometer regulates current to the motor, and allow the user to easily control the rate and power of compressions. The electronic controls are easily operable with the accompaniment of clear instructions and labels on the device.

The prototype successfully delivered the recommended compression depth and rate on a CPR manikin. The device is lightweight at 10lbs, portable at 1 ft^3, and the material cost is $540. Figure 4.1 shows images of the final design.

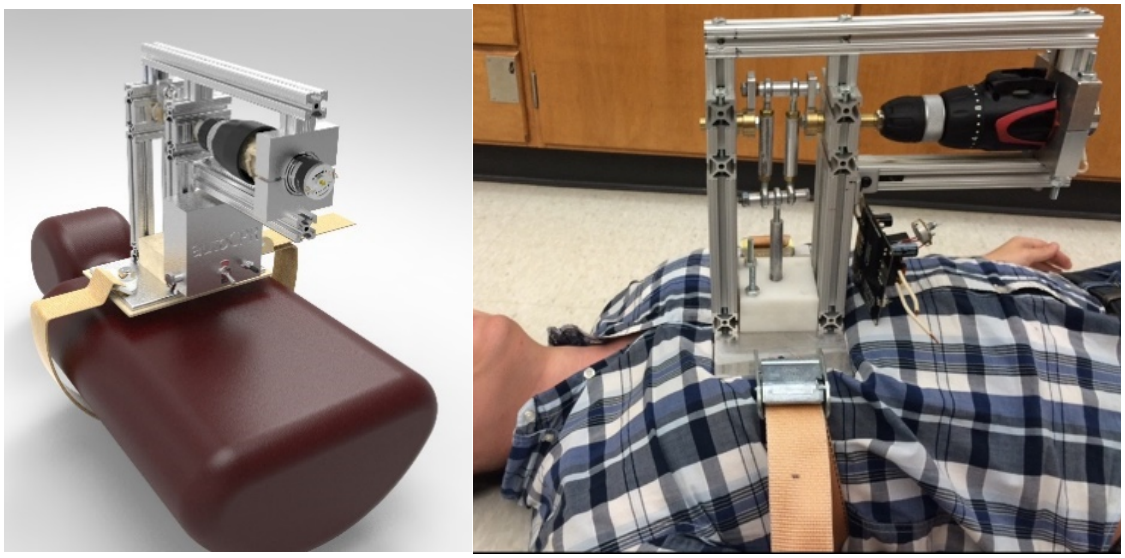

Figure 4.1: (A) CAD model of the final design **(B)** The final prototype strapped onto a patient

The final prototype of the autoCPR device is enclosed within a durable aluminum housing that is intended to prevent the device from suffering fall damage. Additionally, the enclosure provides a reaction to the torque caused by the motor, allowing the device to remain stable while delivering high torque. The final prototype of the device also uses modified car jumper cables to attach the device to any car or boat battery for portable operation.

The final prototype utilizes a crank mechanism to deliver high efficacy CPR to patients in remote settings without the need for batteries. The device can also easily utilize any 12V power source provided the source can supply the required current, shown in Appendix Figure A.4.2. In field applications, first responders can also carry cheap rechargeable battery packs with them to the patient, and hook the patient to the car or boat battery to provide uninterrupted CPR for as long as it is needed.

The final crank design utilized a “double crank” to provide symmetry and reduce wear on the joints of the device. This increases the device’s durability and reliability of the device long term.

The electronic controls of the device give first responders the ability to control the rate of compression, and give responders the control to stop the device to administer rescue breaths. The electronics of the device also have been designed to isolate the patient from dangerous, potentially high current loads required to provide compression. All wiring used in the device has been rated with 2x tolerances, and a high current bearing motor driver is being used to regulate all current flow between the power source and motor.

A demonstration of the device’s design and application is available on YouTube (https://www.youtube.com/watch?v=gqfQbqbTKNA).

Section 5: Proof of Performance

Completed Testing:
It has been verified that the design meets both the compression depth and rate requirements and can successfully achieve compression at a chest resistance of 75 lbs. Figure 5.1 below shows the device on the CPR manikin that was used for testing. The design of the crank system automatically achieves a compression depth of 2.4 inches, incorporating the compression of the piston head under load the device achieves 2.2 inches of compression. The device can compress at a rate anywhere from 100-120 compressions per minute, this can be dialed in by the user using the potentiometer. An audible click from the manikin was used to verify that the device successfully achieved compression. The device has been run for a duration of two minutes thirty times on the manikin without issue.

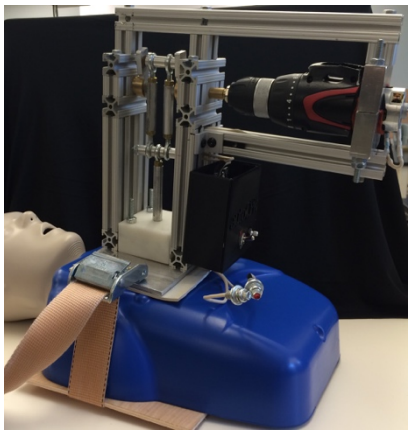

Figure 5.1: Setup for testing the device on the CPR manikin

It was verified that the device could successfully accommodate patients of varied sternum height ranging from 6.7-11.9 inches and chest circumference ranging from 29.9- 51.2 inches. The time it takes to secure the device on the patient was testing using both untrained people and medical professionals. Both groups were able to secure the device on the patient under two minutes with minimal instruction. The medical professional was a firefighter who was able to strap the patient in on his first try in twenty-two seconds, Figure 5.2 shows a picture of this test. Two people untrained in CPR and medical aid were much more successful in securing the patient quickly than one person. A user in one of the tests was a small female and she was successfully able to secure the device in 45 seconds on a large male on her own. The time data acquired is shown below in Table 5.1.

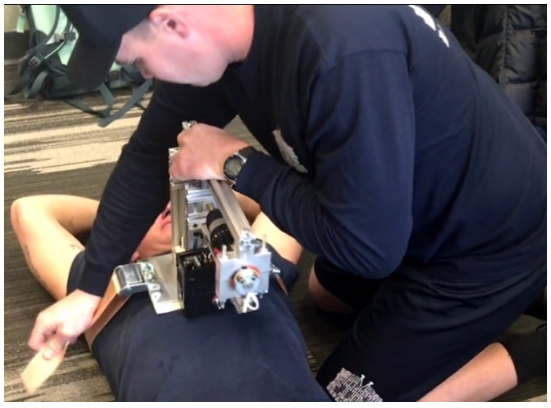

Figure 5.2: A firefighter securing the device on a fellow firefighter

Table 5.1: Summary of setup time data

Test #	Civilian- 1 person (sec)	Civilian- 2 person (sec)	Medical Professionals- 1 person (sec)
1	90	38	22
2	84	56	-
3	74	24	-
4	45	31	-
Average	73	37	-
St. Dev	20	14	-

The electronics were all verified to function as intended, visual inspection showed all wiring is isolated, and no exposed wiring will come in contact with patient or user, the device does not function when the safety switch is off, the safety switch successfully stops the device function immediately when turned off, and the motor is controlled reliably using potentiometer and switch, with no unexpected results. Other specifications met include the weight of the device, at 10 lbs., and the size of the device at 1 ft^3.

Further Testing:
The team would like to complete further testing; however, this is difficult due to the high cost of building prototypes and the need to keep the current prototype functional. The device still needs to be tested up to a maximum compression load of 150lbs and the durability of the device still needs to be tested by performing cyclic testing of the device for 45-minute time periods; this testing would be performed until the device failed. The team would also like to get additional time trial data, especially from more trained professionals.

Section 6: Business Plan

Potential Market Impact

A study by American Heart Association states that 70% Americans feel helpless in case of cardiac emergency for the reason that they are not aware of how to administer CPR [27]. The global automated CPR market was valued at $50.7 million USD in 2014, and is estimated to be worth $159 million USD by 2025 with a Compound Annual Growth Rate (CAGR) of 11% [27]. The major cost factors restricting the growth of automated CPR devices stem from low portability, high training requirements, and inconclusive results of efficacy [27]. In addition, existing solutions are priced between $6000-$12,000 USD, making them too expensive for wide distribution or use in rural areas with limited medical access [27]. Figure 6.1 provides an illustration of the global automated CPR device market by region in 2014.

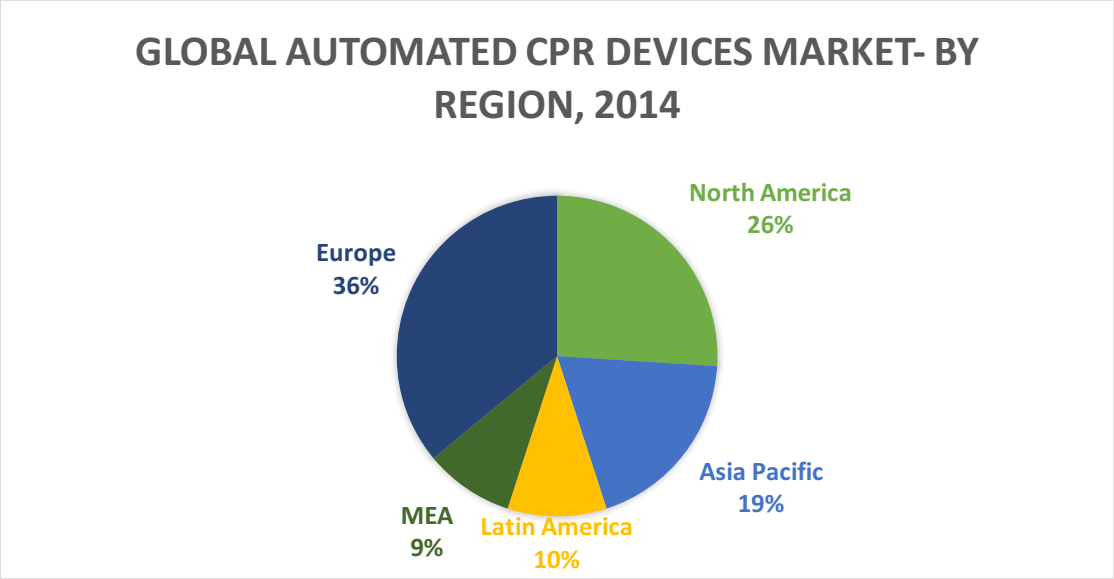

Figure 6.1: Global Automated CPR Market 2014, where MEA stands for Middle East and Africa [27]

Geographically, the global automated CPR devices market is segmented into four major regions: North America, Europe, Asia-Pacific, and Rest of the World (ROW). The European and North American markets together constituted about 62% of the global automated CPR market in 2014. The European market is expected to grow at the highest rates due to high adoption rates of CPR technologies and a high consumer understanding of the need for automated CPR devices. The North American market is expected to grow at a slightly slower rate due to the reluctance of health professionals and high initial costs of purchasing automatic CPR devices in large U.S. EMS systems [27]. The Asia-Pacific and ROW markets are predicted to also grow with the development of more cost-effective solutions for CPR. Technological advancements and increased awareness of cardiac arrest management in Asia and Latin America are projected to contribute to a rising demand for automated CPR devices. These markets present opportunities for a new product with a cost-effective solution, which is where autoCPR fits in.

Patent and Regulatory Pathways

Appendix Table A.6.1 shows that the risk of infringing on other patents is minimal. While certain features of various devices are patentable (i.e. the automatic belt tensioning system in the ZOLL Autopulse, the type of compression system used, etc.), the overall concept of an external cardiac compressor machine is not patentable in and of itself. AutoCPR uses a linear crank system not patented in other applications; however, the crank system is very unlikely to be patentable as the crank

mechanism is universal. An electric motor & controller, a power source, and a rubber piston head – the description of this device does not match any previous or emerging claims.

The patent strategy for this team is to obtain a utility patent, after first obtaining a provisional patent, and then move forward by creating, testing, and showcasing the prototype to the Ecuadorian Ministry of Public Health via our medical school contacts in Ecuador.

For Ecuador specifically, the design solution will be regulated by the Agencia Nacional de Regulacion, Control y Vigilancia Sanitaria (ARCSA Ecuador). Medical devices in Ecuador are registered through the ARCSA. There are two pathways to medical device registration in Ecuador. Some medical devices must go through the official registration process, while other devices may obtain a *Certificado de Requierimiento o No de Registro Sanitario* (Certification of Registration Requirement or No Requirement [CRRNR]). Though the ARCSA's risk assessment system closely resembles that of the European Union, no CE mark is needed is required for registration of a device within Ecuador. In contrast to the official ARCSA process which takes three to six months, a CRRNR may also be obtained within 15-30 days, and does not expire under current regulations **[28]**.

As biomedical equipment, the automatic CPR device is eligible to be entered for a CRRNR license **[29]**. Because the CRRNR is a quick registration process, has the least requirements, and does not expire, autoCPR will seek to obtain the certificate with assistance from our partners in Ecuador. Currently, the team is fine-tuning device specifications to meet all user requirements consistently.

Method for Manufacturing and Distribution

The device will be manufactured here in the US and then shipped out to Ecuador and other locations. Materials for manufacturing the device will be selected based on their ability to meet the design requirements at the lowest cost. Since the device requires a lot of power, nonconductive plastic material is preferred for safety.

The target distribution pathway for this device is the Ecuadorian Ministry of Health as well as any individual or group, such as emergency medical personnel, in need of a CPR machine where an AED is not available in Ecuador. The goal is to start in Ecuador using the connections that have been developed with the medical students and then expand from there in Ecuador and other countries.

Cost to Manufacture and Distribute

Manufacturing costs can be split into fixed investment costs and variable product costs. The fixed costs are upfront investments while the variable product costs may change with quantity of devices manufactured.

Fixed costs include machining investment, regulatory testing, regulatory consulting, and business related costs. Machining investment is approximately 20k to include buying a 3 axis mill, lathe, and required tooling. Regulatory testing covers the manufacture and testing of 10 devices to aid in both quality control and regulatory submissions. The regulatory consultant cost is the approximate cost of hiring a firm to receive device approval in Ecuador. Business related costs cover a space to lease to perform manufacturing and testing of the devices. Together the fixed investment costs are approximately $92,900.

Variable product costs include the raw materials to build the devices and well as machining and assembly costs. Materials for the device are approximately $540 in the current iteration. A second

design iteration is in progress which will reduce cost of materials for the device. Machining costs are estimated at 10 hours with a fair market rate of $75 and hour for approximately $750 to manufacture and assemble each device. Together this brings the variable cost of each device to $1290. A summary of costs is shown in Table 6.1. Distribution costs are estimated in the following Table 6.2.

Table 6.1: Estimated manufacturing costs

Fixed Investments	**Cost**	**Variable Product Investments**	**Cost**
Machining Investment	$20,000	Materials	$540
Regulatory Testing	$20,000	Machining*	$750
Regulatory Consultant	$30,000		
Business related Costs	$25,000		
Subtotal	$92,900	**Subtotal per device**	$1,290

*Estimated 10 hours at $75 per hour

Table 6.2: Estimated distribution costs

Investment	**Cost / 12 Devices**
Packaging Materials	$70
Shipping	$3,000
Subtotal per 12 Devices	$3,070

Plan for Funding

This device will not be reimbursed by Medicare or Medicaid because this device is not bought by a patient, but rather an entity such as a fire department, medical center, or first responder team, individuals would be billed for the emergency responder service similar to an ambulance ride. Medicare and Medicaid may cover the ambulance service, but not the autoCPR device directly. Additionally, the device is primarily designed to be used in Ecuador which is out of jurisdiction for both Medicare and Medicaid.

The competitive advantage of this solution is a key relationship with medical students in Ecuador who have access to directors and chief surgeons within the main medical centers as well as the rural medical centers, as well as the overall cost of this solution. This support from the medical students and their connections will give the team direct access to potential investors. The other competitive advantage of the device is its low, less than $2,000 cost, compared to its competitor devices priced at $12,000.

The team is seeking an angel investor for seed funding of $250,000 in exchange for equity in the company. Seed funding would be necessary in order to complete bench testing and develop a regulatory strategy. The amount requested will be used to manufacture a sufficient number of devices for bench testing and to achieve regulatory clearance. The devices cost approximately $1300 each and assuming 30 devices for benchtop and 30 for regulatory testing, the cost for devices alone is $80,000. When adding in regulatory, machining equipment, salaries, distribution, and overhead costs we are asking for initial funding of $250,000.

Appendix

Section 4

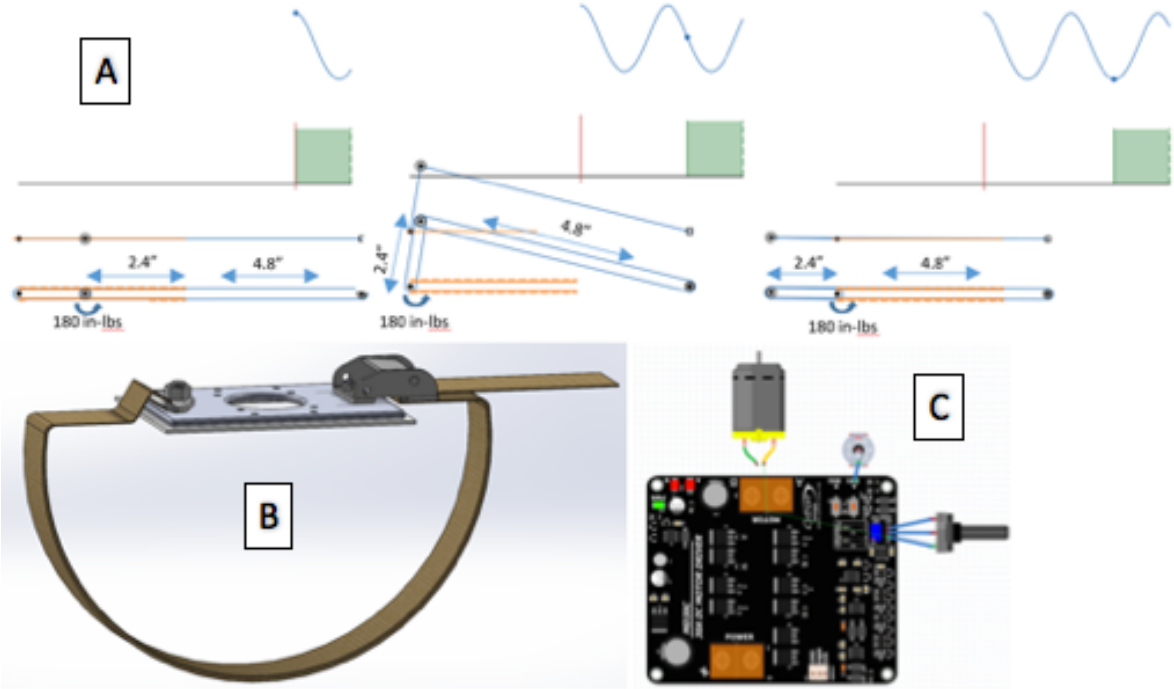

Figure A.4.1: **(A)** Crank mechanism to drive linear compression. **(B)** Model of strap design to stabilize patient and device. **(C)** Layout of final design of electronics subcomponent

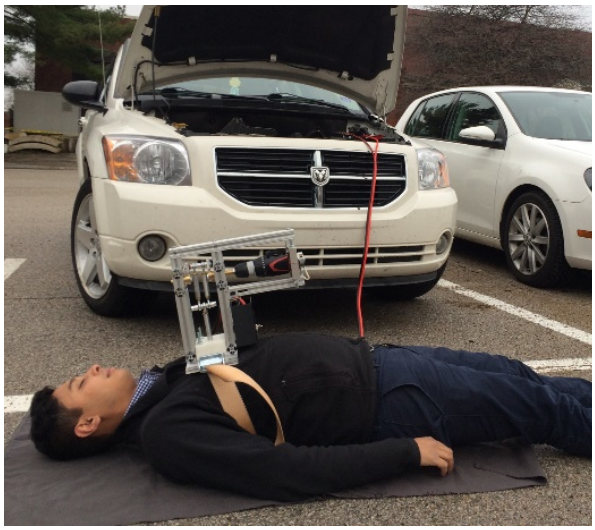

Figure A.4.2: Shows how the device can utilize a car battery for power

Section 6

Table A.6.1: Patent Search Results

Patent ID	Description
US7226427B2	Chest compression device that provides breathing gas under positive pressure to airways, that can electrically stimulate heart, and has a control unit to control both mechanical *and* electrical stimulation [30].
US6171267B1	Method of "high impulse" CPR comprising a chamber with expandable volume, a patient ventilator, a pressure regulator, a timing circuit, and other components [31].
US5743864A (expired)	Method of CPR that restrains thoracic cavity circumference with a non-extensible annular collar and applies a compression force from outside the collar to inside the collar onto the patient [32].
WO2015061677A1	CPR Apparatus with a rigid frame assembly including an arch and back plate for a human torso, as well as an attached compression module and drivetrain, a computerized controller with user interface and a power source connected to motor controller [33].
US7060041B1	CPR apparatus with an energized compressor assembly with actuator and a source of pressurized fluid, a torso wrap connected to the actuator that wraps around the patient, and a cylinder with an inside surface including a piston with telescoping piston parts [34].
US6066106A US7374548B2	Device for CPR that includes a belt that fastens around patient and has tensioning, brake, clutch, and motor components [35] [36].
US6939314B2 US7666153B2	Device for CPR with chest compression means utilizing a belt adapted to chest of patient as well as a means to tighten the belt repetitively at a resuscitative rate, a "bladder" between the compression "means" and the patient chest, and a defibrillator [37] [38].
US7118542B2 US7122014B2	Method for measuring the depth of chest compressions based on signals from an accelerometer attached to a compression device and/or defibrillator, a specific calculation process [39] [40].
US20150272822A1 (pending)	Support structure with chest compressor mounted on it and lateral supports attached to the support structure. Involves lateral compression synchronized with chest compression [41].
US8002720B2	Chest compression system that includes a back plate, a front part having space for a compression mechanism, and a connecting part on the side that can slide to be adjusted to fit the patient [42].

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