HEART JOULE

Progress Report 2

Product Design & Development

May 3, 2019

Team

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Executive Summary

According to the World Health Organization there are approximately 17.9M deaths globally from cardiovascular disease each year, of which 85% are due to heart attack or stroke.[1] Cardiac arrest, defined as "the abrupt loss of heart function in a person who may or may not have been diagnosed with heart disease," remains a primary contributor to mortality.[2] Within the United States alone, the American Heart Association ("AHA") estimates that more than 350,000 cases of out-of-hospital cardiac arrest occur per year, of which 90% of cases are fatal.[3]

Cardiopulmonary resuscitation ("CPR") is a critical component of cardiac arrest treatment. Unfortunately, a Purdue University study demonstrates the success rate of CPR at 5%-10%.
The researchers attribute the low success rate to improper application of force by both untrained laypeople and trained professionals. Guidelines indicate that proper CPR requires between 100 to 125 pounds of force. The Purdue study indicates that "60 percent of the CPR-trained rescue personnel pushed with more than 125 pounds, whereas more than 60 percent of those not trained in CPR failed to push with more than 125 pounds of force."[4]

The HeartJoules mission is to save the lives of more cardiac arrest patients by making CPR treatment easier and less physically taxing. To achieve our mission, we developed the Resuscitation Assistance Mechanism (RAM), the first device to mechanically assist with chest compression during CPR. In order to meet the unique needs of each possible use case, the RAM serves as platform technology. Leveraging bus modular architecture, the RAM attaches to multiple handle types tailored to the specific needs of each market segment. As a platform technology, the RAM can be licensed by medical device companies and customized to meet the needs of their customers. To date, our team developed two working prototypes (RAM v1 and RAM v2), informed by over 20 user interviews, over 25 concepts, and various sketch models.

Of note since our first Progress Report, we ceased pursuing the IoT-enabled Automated External Defibrillator ("AED") as a product. AEDs serve to shock the heart into its normal rhythm when the heart has gone into specific types of arrhythmia. According to the AHA, only 23% of out-of-hospital cardiac arrests are treatable by AED,[5] whereas 100% of cardiac arrest patients require CPR. While we view an IoT-enabled AED as a key improvement to enable faster location of patients, we focused our efforts on CPR, which impacts all cardiac arrest patients, as opposed to AEDs that impact only a subset of patients. We include the concept of an IoT-enabled AED in our patent application, but will not include this concept in our alpha prototype.

In this report, we first provide a detailed overview of the RAM and its specifications (Section 1). Next, we provide information on the process and milestones, as well as key decisions and the justification for those decisions (Section 2). We further summarize key due diligence that we conducted, including sustainability, financial, and patent reviews (Section 3). We conclude with an overview of our remaining steps, risks to be mitigated prior to our final design review, and recommended next steps for future commercialization (Section 4).

Section 1: The Device

The RAM is a first-in-class mechanical device that enables professional and lay users to perform manual CPR correctly and efficiently. The RAM accomplishes this by converting energy input by the user into an impulse delivered by the device to the patient. The design of the device offers users improved ergonomics when compared to traditional hand-on-hand CPR, reducing both fatigue and discomfort. Additionally, the device makes an audible "click" loudly indicating to the user when a chest compression was forceful enough and deep enough.

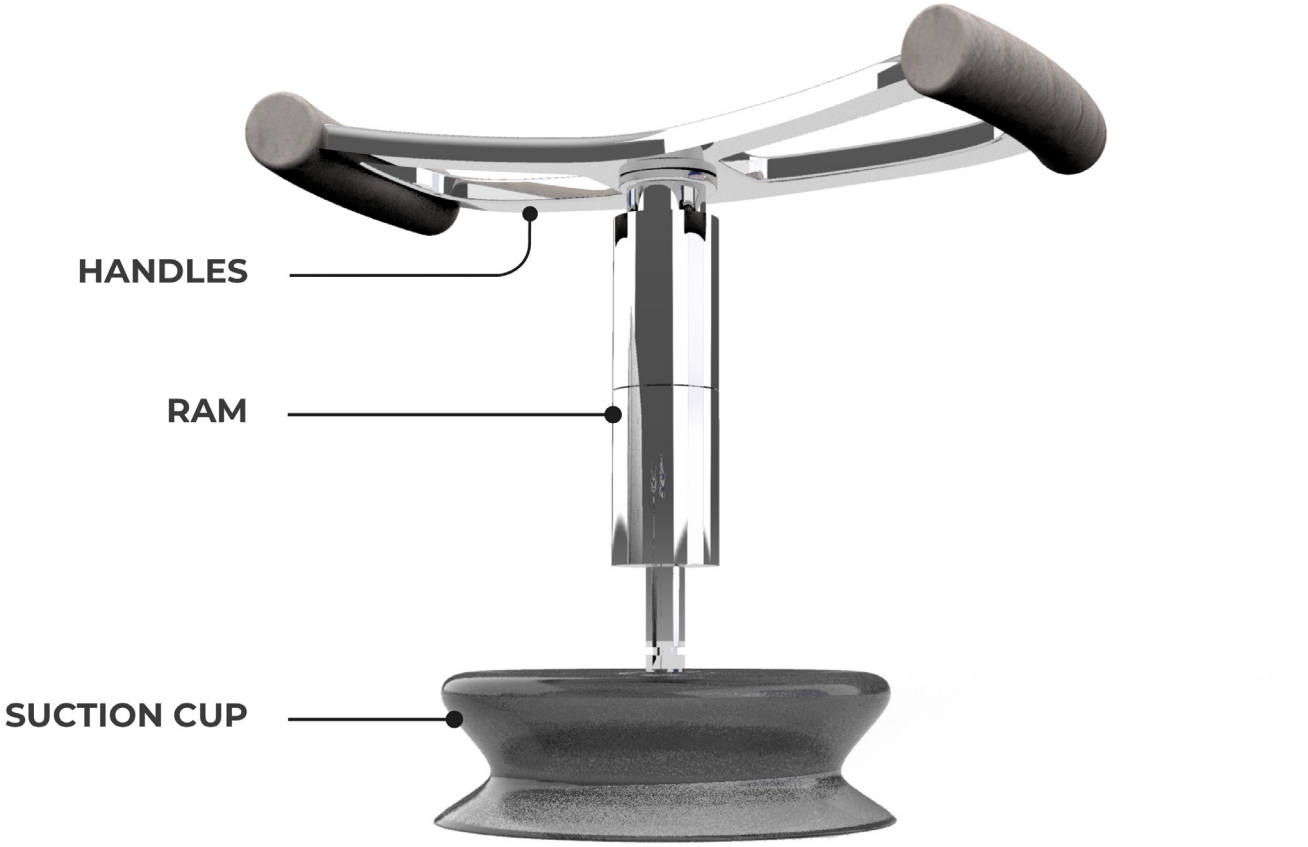


Figure 1: RAM assembly rendering

The core energy storage and impulse release functionality of RAM is inspired by the mechanics of an automatic center punch and intended to mimic the beating of a heart. The suction cup provides a distributed downward and a normal force to lift the patient's chest back up after compressions, preparing the patient for the subsequent compression. The handle provides improved ergonomics for the user and can be changed depending on user needs. In order to meet the unique needs of each possible use case, the RAM acts as platform technology by leveraging bus modular architecture. The core RAM module attaches to both the handle module (user facing) and the suction cup module (patient facing), as shown in Figure 1. As a result of the product architecture, the RAM easily reconfigures to attach to various handles and suction cups depending on the potential use case. The alpha prototype of the RAM (RAM V2) is made primarily of turned aluminum components including a plunger, a pusher, a hammer, a two-piece body, a cap, and is accompanied by two steel springs as shown in Figure 2.

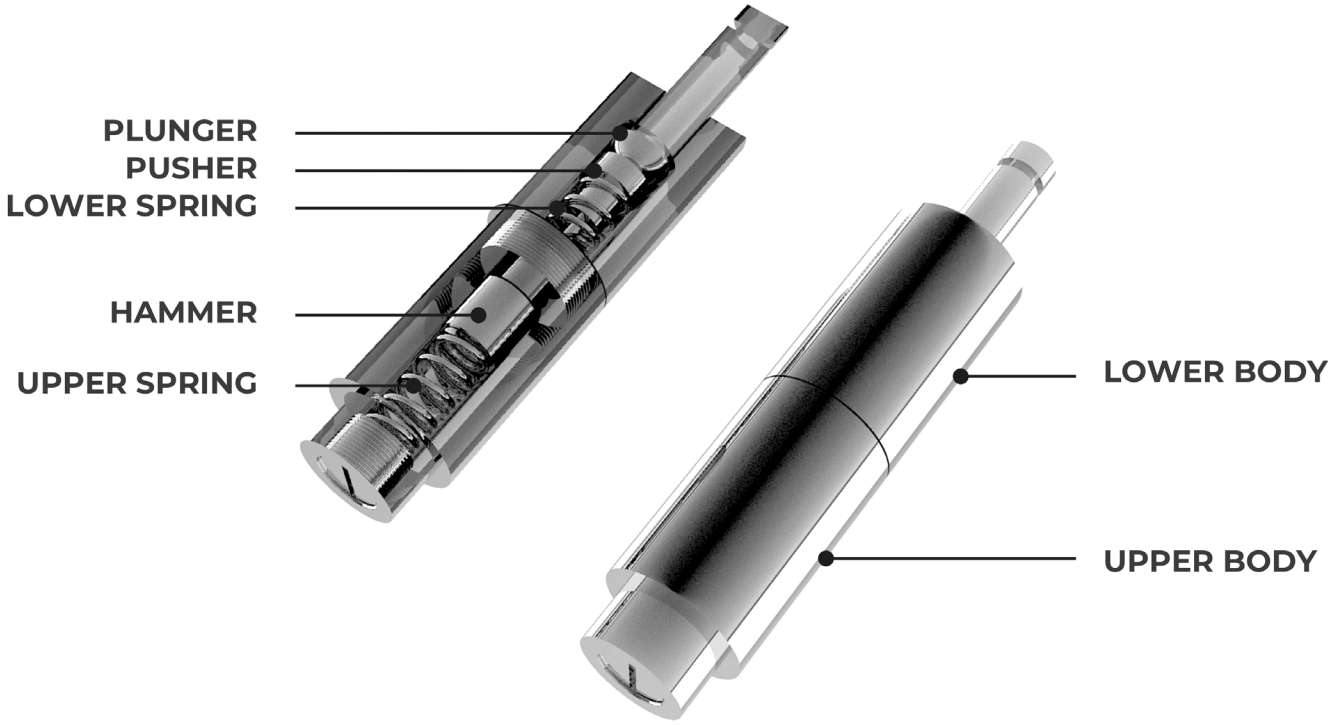


Figure 2: RAM Cross-Section and RAM

The RAM uses two springs in series to store energy input by the user. Once the RAM is compressed fully, the springs release the stored energy downwards into the patient to provide the appropriate compression. The user applies an approximately downward force on the handle, causing the plunger to move approximately linearly. The movement of the plunger in turn causes the intentionally mis-aligned pusher to move approximately linearly and causes the spring surrounding the plunger to compress. The movement of the pusher causes the hammer to move approximately linearly and causes the second spring surrounding the pusher to compress.

Once the device is fully compressed, the axial bore of the body contacts the tapered section of the mis-aligned pusher. As the pusher straightens axially, the end of the pusher contacting the hammer slips into the axial bore of the hammer. The slipping of the pusher into the hammer bore hole triggers the springs to release their energy downward from the hammer into the pusher. The energy is then released from the pusher into the plunger, into the suction cup and finally, into the patient. The diagram in Appendix A visually depicts the step-by-step energy storage and release process described above.

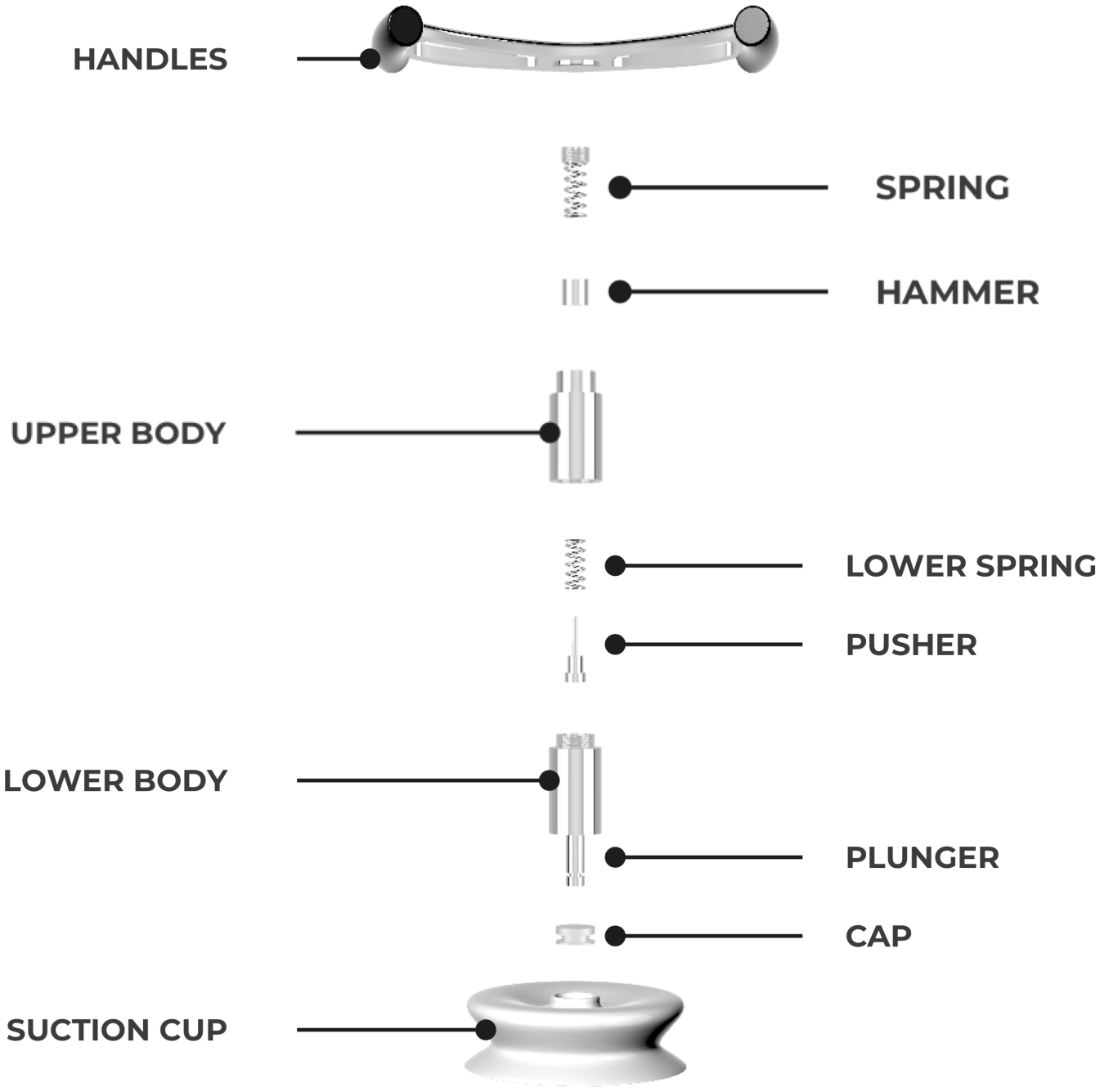


Figure 3: Exploded view of RAM

Critical to Function (CTF) Specifications

Table A below outlines the critical specifications required in order for the device to function, including the metric being observed, its target value, and its units. These specifications are derived from AHA guidelines regarding CPR. Importantly, these do not represent the only specifications for our device; additional specifications are found in the Bill of Materials below, as well as in Section 2 of this report. However, these specifications represent the minimum criteria for the device to be useful in administering CPR.

Metric	Value[6][7]	Units
Force applied to patient's chest when device properly compressed	100 - 120 (440 - 533)	lbf. (N)
Depth of chest compression when device properly compressed	1.6-2.2 (.041-.056)	Inches (m)
Time for spring and mechanism to unload	0.05 - 0.5	Seconds

Table A: Critical-to-Function Specifications

Bill of Materials

The purpose of this section is to list all of the components comprising the device, the material of each component, the weight of each component, and the cost to purchase each component. Table B below shows the bill of materials for the device considering manufacturing-level specifications. Of note, our prototype uses primarily aluminum parts (with the exception of steel springs and silicone suction cup) to increase the efficiency of prototyping. Further assumptions were made to estimate the at-scale (>10,000 units) production cost of each component.

Based on the below Bill of Materials (BOM), the device carries a total weight of 8.49 lb. The BOM indicates that the total parts cost for an assembled device is approximately $32.85. For our financial analysis, we assume that the total cost of materials and assembly will be approximately three times the cost of materials, or roughly $100.

Image	Component	Qty./Unit	Material	Weight (lb)	Materials Purchased ($)
Handle					
	Handle	1	Steel Silicone	4.14	11.00
Suction Cup					
	Suction cup	1	Silicone	0.5	5.00
RAM Components					
	Spring	2	Steel	0.25	2.00
	Pusher	1	Steel	0.25	2.50
	Plunger	1	Steel	0.6	2.00
	Upper body	1	Steel	1	2.50
	Lower body	1	Steel	1	2.50
	Hammer	1	Steel	0.25	3.00
	Cap	1	Steel	0.25	.35

Table B: Bill of Materials

Section 2: The Process

Mission Statement

The HeartJoules' team rallies to this mission, emphasizing to save the lives of more cardiac arrest patients. Every decision we make as a team ties back to our core mission to save lives. Our mission, shown to the right in italics, was changed since our prior report. Our team's original mission statement was "To save the lives of more cardiac arrest patients by making treatment devices more accessible and easier to use." Over the course of our primary market research, we discovered that physical exhaustion causes more user pain during CPR than the accessibility of devices.

To save the lives of more cardiac arrest patients by making CPR treatment easier and less physically taxing.

We further justify our change in mission based upon the size of the total addressable market. Specifically that 100% of cardiac arrest patients require CPR where as only 23% of cases are treatable by an AED. By slightly modifying our mission, we further improve the quality of CPR and increase the market potential for our product ~4-fold.

Team Organization

The HeartJoules entire team continues to meet at least twice a week to work on the project, review progress and discuss next steps. We begin team meetings with individual stand ups to report our status and any issues we were having. For ongoing task management and communication outside of meetings, we utilize text, phone calls, email and a Trello board.

Jonah led RAM CAD and physical prototyping efforts, which focused most heavily on metal prototyping. Elaine primarily led development of ancillary CAD models and renderings of our device, as well as other design content for our presentations and reports. Given his connections with police officers and first responders, AJ continues to lead user testing efforts, and also advises Jonah on mechanical engineering concepts for prototyping and works on overall project strategy, presentations, and reporting. Cristina led financial modelling efforts and ongoing project planning, life cycle assessment, and building our reports and presentations.

Project Timing and Risk Plan

Figure 4 below reflects the project plan that the HeartJoules team utilized throughout the semester. As of today, we have built our initial working prototype, and remaining activities include those shown in green: completing our final alpha prototype, conducting final testing and redesign, and preparing for our final design review. The remainder of this report provides further detail into the completed steps.

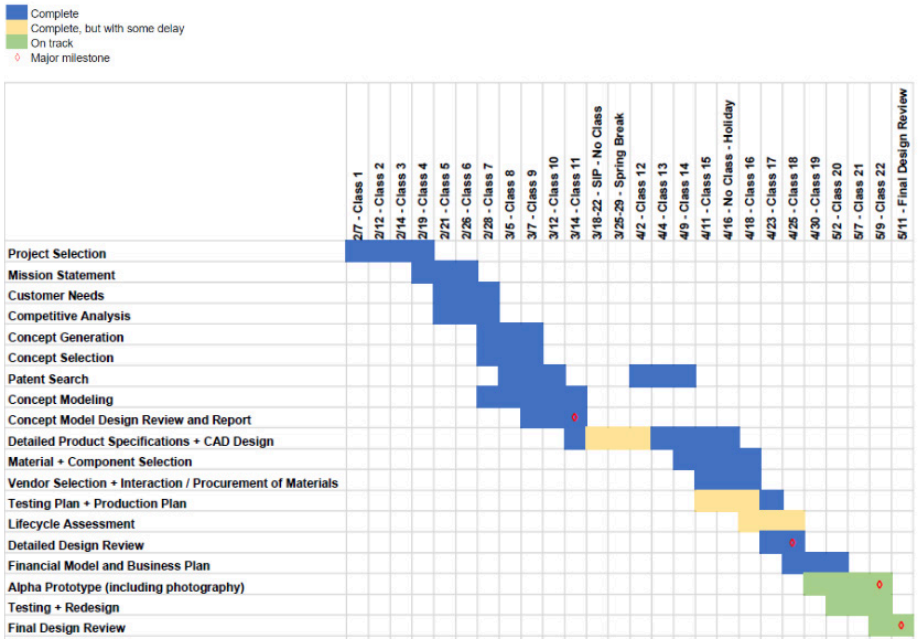


Figure 4: Project Plan

Market and Competitive Analysis

As discussed in our first report, we started our project by analyzing the full set of stakeholders involved in emergency treatment of out-of-hospital cardiac arrest. In order to determine potential user segments, the team developed a comprehensive system diagram and stakeholder map as depicted in Appendix B. Through this analysis, and as of the date of our last report, we had identified three key potential markets that we could target:

1. first responders and ambulance companies,
2. public spaces that keep AEDs and first aid equipment, and
3. individual consumers.

Since our last report, we focused our project on one concept: the manual compression assistance device. Hence were able to further focus on a market segment. The RAM is envisioned to be a device that is kept in public spaces next to AEDs, fire extinguishers, fire axes, or other first aid equipment. Data indicate that there are over 3.2 million AEDs in US public spaces. Other potential markets for the RAM include fire trucks and ambulances, though the market size is more limited. The data indicate that there are approximately 50,000 ambulances and 70,000 fire trucks in the USA. Conservatively assuming a maximum of 1 RAM per vehicle results in an incremental market size of approximately 120,000 (~4% of the public spaces market).

Since a mechanical device of this nature does not exist in the market today, there are no direct competitors to the product. Existing medical device companies, and specifically those that produce AEDs or automatic compression devices, could be competitors for this device, but are more likely to license this equipment from HeartJoules. Our most fierce competition is the status quo hand-on-hand manual CPR. To address this competition and ensure willingness to pay for this device, we will need to prove through clinical trials that this device increases the effectiveness of CPR. As shown in Figure 5, the HeartJoules device represents a departure from the traditional performance vs. cost tradeoff demonstrated by existing solutions.

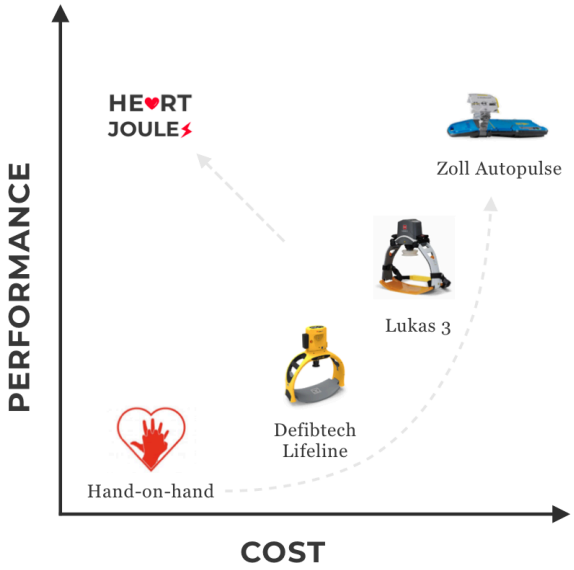


Figure 5: Competitive Landscape & Cost-Performance Curve

Our target market includes public spaces in the US like gyms, hotels, airports, and malls, which currently carry approximately 3.2M AEDs. Assuming a price of $500 per unit for our device, we estimate a total addressable market of $1.6B.

Customer Needs

Originally, the two key customer needs that emerged during our user interviews were:

- Ease of locating device and patient for first responders.
- Approachability of procedure for bystanders.

As previously discussed, we focused on making CPR easier and less physically taxing for bystanders. Many of our originally-identified customer needs remained relevant, but we removed those related to the administering of electric shocks through an AED. Table C is a weighted list of qualitative user needs, where asterisks are used to indicate the relative importance of different needs (**** is highest importance, and * is lowest importance).

1	*****The device treats cardiac arrest.**
2	*****The device applies sufficient force to the patient as per AHA guidance.
3	*****The device compresses the patient's chest to a depth sufficient per AHA guidance.
4	*****The device allows compressions at a sufficient speed per AHA guidance.
5	*****The device works when needed.**
6	*****The device does not jam.
7	*****The device is easy to use.**
8	*****The device is clearly labeled with instructions.
9	*****The device audibly indicates when it has been properly compressed.
10	***The device is lightweight.
11	*****The device is safe.**
12	****The device is approachable.**
13	****The device is ergonomic.**
14	****The device is versatile.**
15	**The device can accommodate multiple handles depending on use case.
16	***The device is affordable.**
17	***The device is sustainability manufactured.**
18	*The device is durable.
19	*The device requires infrequent replacement.
20	*The device uses recycled materials.

Table C: Customer Needs

Having identified the key customer needs for the device, we identified metrics that would allow us to test whether our device met those needs. Table D below outlines the metrics identified for each customer need, along with its level of importance (transcribed from above), its ideal value, and the units in which it will be measured.

Need	Metric	Importance	Ideal Value	Units
1, 2	Force applied when device is fully compressed and then released	5	100 - 120 (440 - 533)	lbf. (N)
1, 3	Depth of chest compression when device properly compressed	5	1.6-2.2 (.041-.056)	Inches (m)
1, 4	Time for spring and mechanism to unload	5	0.05 - 0.5	Seconds
5,6	Number of jams per 100 compressions	5	0	instances
7, 8, 9, 10	Frequency of improper use of device	5	<3	percent
11	Frequency of injury to patient	5	0	instances
12	Percentage of people that use device instead of hand-on-hand in user tests on dummy	3	75	percent
13	Percentage of people that report discomfort while using device	3	<3	percent
14, 15	Number of handles that can be easily attached to device	2	5	units
16	Percentage of potential customers that indicate willingness to pay of at least $500	1	80	percent
17, 18, 19	Average life of device	1	7	Years
17, 20	Percentage of recycled materials in device	1	>85	percent

Table D: Customer Needs Metrics

Concept Modeling and Selection

As of our last report, our team had developed concepts falling into three categories:

- A more affordable automated chest compression (ACC) device for first responders
- An AED with geolocation functionality for public spaces
- A manual compression assistance device

After deciding to focus on a manual compression assistance device, we developed additional concepts for handles and connection mechanisms before moving on to prototyping the device, as shown in Figure 6. Cardboard models of the device were made and shown to potential users, and feedback was collected. Appendix C shows various handle types that were created, along with illustrative quotes from user testing.

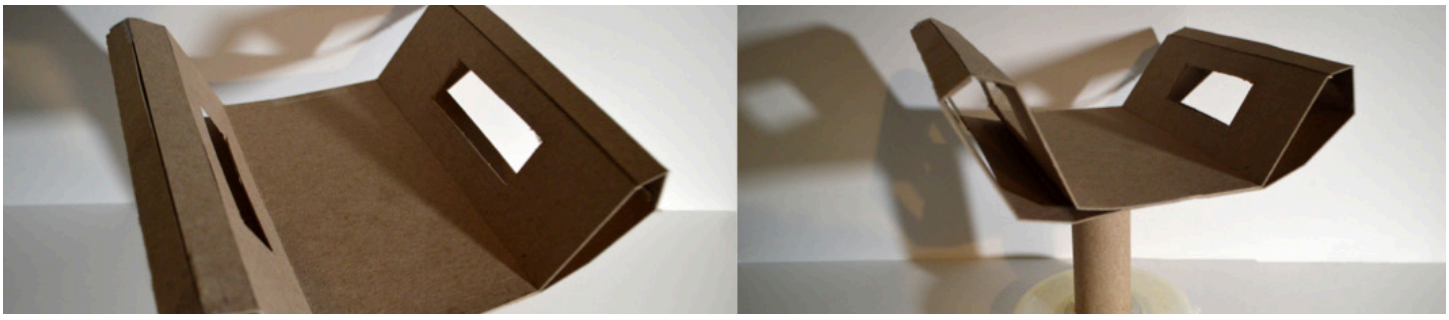


Figure 6: Sketch Model

Based on feedback from users, we identified and purchased seven handle types, as shown in Figures 7 - 13 below, and ultimately selected the handle in Figure 12 for our alpha prototype.

Figure 7

Figure 8

Figure 9

Figure 10

Figure 11

Figure 12

Figure 13

Final Specifications and Prototype V1

After testing various handle types, the HeartJoules team developed final specifications for the device, including finalizing the dimensions of the RAM components (Figures 14 - 17), and creating CAD renderings of the full device and handle options (Figure 18). Based on these specifications, version 1 of the prototype was built for our second design review (Figure 19).

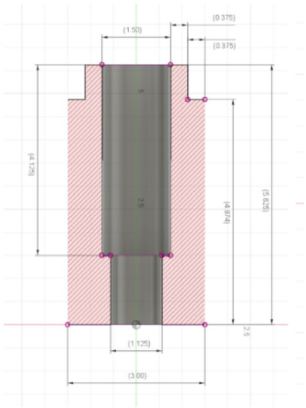


Figure 14: Lower Body Contains the pusher and lifter

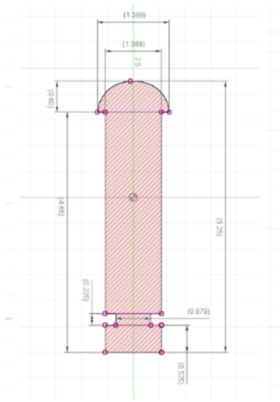


Figure 15: Plunger Connects to suction cup and acts as a linear bearing

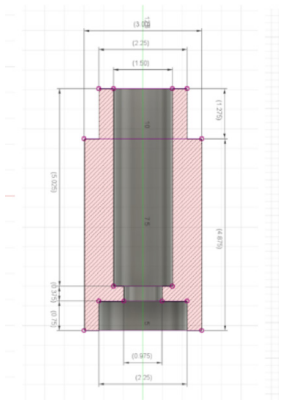


Figure 16: Upper Body Containsthe Hammer and holds lower body parts in

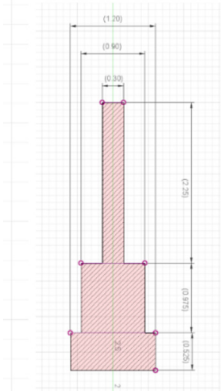


Figure 17: Lifter Lifts hammer and slips into the hole

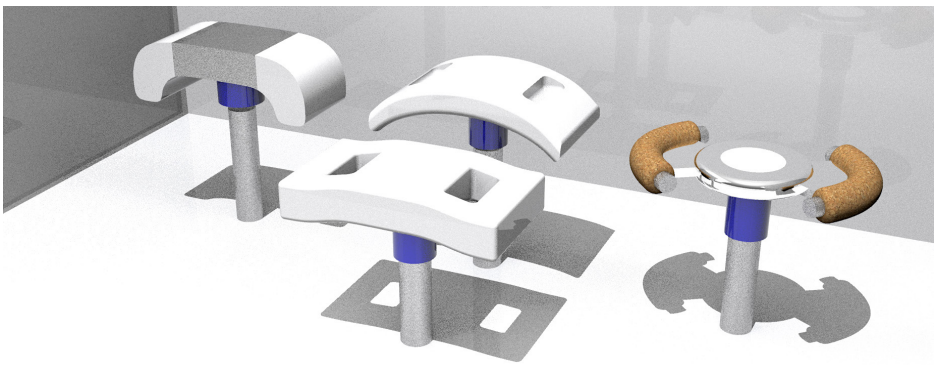


Figure 18: Handle CAD Renders

Figure 19: V1 of Prototype

Uncertainties

Having completed the final specifications for our prototype, we identified key remaining uncertainties to be addressed through testing and refinement of the prototype. Table E below summarizes these uncertainties and our mitigation plans.

Uncertainty	Mitigation
Jamming or aluminum on aluminum bearing surface friction	Refine prototype. Production device will be made of steel. Ensure correct tolerances are specified for manufacturing.
Product may be too cumbersome or unwieldy for user based on size and handle type.	Multi-configuration handle for user AB testing.

Table E: Uncertainties and Mitigations

Testing and Production Plans

To address uncertainties, the HeartJoules team is conducting both user and lab testing of the device. The overarching goal of this testing is twofold: (1) to ensure that the device is ergonomic for the user, and (2) to verify that the device meets the medical standards for chest compressions. Table F summarizes our testing plans for our alpha prototype.

Specification or Customer Need to be Tested	Testing Method
Force applied to patient's chest when device properly compressed	"Smart dummy" with force and depth feedback Scale with data logging
Depth of compression when compressed	Measurement markings on device
Time for spring and mechanism to unload	Slow motion video
Lack of jamming in device	User testing in aluminum and steel
Ease of use and approachability for user	User testing with multiple handle types
Ergonomics	User testing with multiple handle types
Versatility	User testing with multiple handle types
Affordability	User interviews
Sustainability	Life Cycle Assessment

Table F: Customer needs and testing methods

Section 3: Due Diligence

In order to justify future product development and commercialization efforts, the HeartJoules team conducted due diligence to understand the environmental impact of the product, its financial viability, and our ability to protect the intellectual property surrounding the device. Key takeaways from our analysis include:

- ***Sustainability***: The environmental impact of the production version of our device is approximately 23 CO_2 eq. kg per device for its full life, including manufacturing and transportation. This represents an opportunity for improvement.
- ***Financial:*** Based on the assumption that the device would be licensed and produced by an existing medical device company, we predict that a project to roll out this device would reach break even in approximately two years, with an NPV of $401,309,000
- ***Intellectual Property:*** Our initial analysis and conversations with patent attorneys have indicated that the device has utility, is novel, and non-obvious to one skilled in the art. As such, we are pursuing a provisional patent.

Life Cycle Assessment

We conducted a life cycle assessment ("LCA") of our device, using the Sustainable Minds software, in order to determine its environmental impacts.

- The assumptions made for our life cycle assessment are as follows:
  Each unit is expected to be kept for 7 years before replacement.
- The device will be made in China and shipped to the US by freighter (19,700 miles), then delivered by truck to a distribution center (1000 miles), and then shipped to customers by truck (300 miles).
- The device will be fully recycled at end of life.

We conducted the LCA first considering our alpha prototype, which is made primarily of aluminum, as a baseline, and then our production version of the device, made primarily of steel. Unfortunately, changing the device from aluminum to steel would present a 230% increase in environmental impact. However, this requires further evaluation. In this analysis, we have assumed the same useful life for both versions of the device. In reality, the steel version may have a longer useful life due to decreased risk of friction and jamming. Further analysis is needed regarding environmental impact of the device before production. It is worthwhile to note that the aluminum prototype reflects stainless steel under SBOM input due to stainless steel handle. RAM components are aluminum in this model.

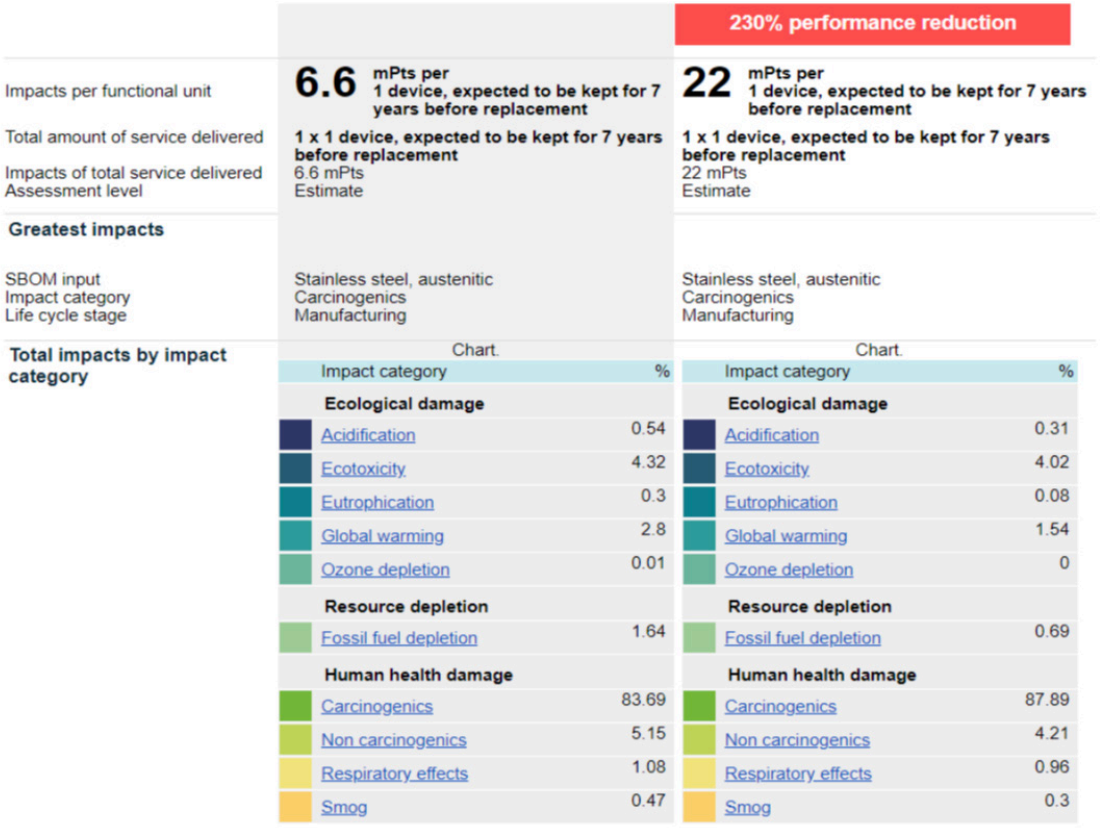


Figure 20: LCA of Aluminum Alpha Prototype (left) versus Steel Production Version (right)

Financial Model and Business Plan

Financial Model

Our financial model assumes a scenario in which an existing large manufacturer licenses the patent for the RAM and begins manufacturing it and selling it in-house. For our analysis, we made the following assumptions:

- Total cost of production for each device is $100, based on assembly cost of roughly three times the total cost of materials
- The setup and overhead costs associated with the new product will be $1,000,000 in the first two years, and $300,000 in years thereafter, including marketing
- The device will be sold at $500 per unit
- Sales volume will gradually increase over time, starting in year 2, to eventually reach all 3.4M potential customers (identified as public spaces with AEDs) by the end of year 4
  Cost of capital is 10%.

Under these assumptions, the model shown in Appendix D indicates that the project reaches break even during year 2, with an estimated NPV of the project of $401,309,000.

Sensitivity Analysis

Our team conducted sensitivity analysis considering our key financial uncertainties: sales volume, setup costs, and manufacturing costs, as shown in the table below. Sales volume faces uncertainty due to the risk that owners and administrators of public spaces may not view the device as necessary for purchase. Packaging this device along with regulatory-mandated AEDs could mitigate this risk. Setup costs may vary due to the unexpected nature of the FDA approval and clinical trial process.

Lastly, manufacturing costs are subject to variability in input prices, international tariffs, and other external factors. Based on this analysis, low sales volume appears to have the greatest effect on the NPV of the project. While we did not assess willingness to pay for the device as part of our sensitivity analysis, we expect that a reduced price will have a similar effect on NPV as did sales volume; further willingness to pay research is needed before production of the device.

Scenario	Break Even	Ending Cash Year 4, Q4
Base	Year 2, Q3	$1.388B
Low Sales (50% fewer sales in each period)	Year 3, Q1	$0.7B
High Setup/Overhead Costs (50% higher)	Year 2, Q4	$1.385B
High Manufacturing Costs (50% higher)	Year 2, Q3	$1.214B
Low Sales + High Setup/Overhead + High Manufacturing	Year 3, Q3	$0.6B

Table G: Sensitivity Analysis

Intellectual Property

To date, our team has conducted patent searches and held an initial meeting with patent attorney Bruce Sunstein. The patent searches that we conducted included both the concept presented in this report, the manual compression assistance device, as well as the concept that we chose to not pursue for this course, the IoT enabled AED.

In terms of the manual compression assistance device, the status quo for chest compression is entirely hand-on-hand or automated. No such device exists which aids the user to apply manual chest compressions with the correct depth and output force, and, accordingly, we concluded that our device provides utility, is novel and non-obvious given the competitive landscape.

Our patent search resulted in the identification of 5 patents that related to improving chest compressions, but that did not mirror the device that the HeartJoules team is creating. The patents that we identified relate to improvements to automated chest compression devices (WO 2014/057116 Al, US7775996B2, and US20040006290A1) or to the combination of automated chest compressions with defibrillation (US 8700147B2 and US7497837B2).

Refer to Appendix E for a more detailed overview of our patent search.

Conclusion and Future Work

Leading towards the final design review on May 11, 2019, the next steps for the HeartJoules team include:

- User and lab testing to confirm both form and function of the device
- Iterating on our alpha prototype based on feedback received
- Initiating steps with the MIT Technology Licensing Office to seek a provisional patent

After obtaining a patent, our goal is to license this technology from MIT in order to commercialize the underlying technology. In order to reach this goal, companies pursuing this opportunity need to:

- Conduct further user and lab tests to ensure user ergonomics and medical efficacy
- Demonstrate efficacy of the device in saving lives of cardiac arrest victims, seek FDA approval and conduct clinical trials
- Engage government regulators to seek inclusion of this device in AED-related regulation
  Conduct additional market research to validate willingness-to-pay assumptions
- Improve environmental performance of the device where possible
- Identify manufacturing partners and early customers

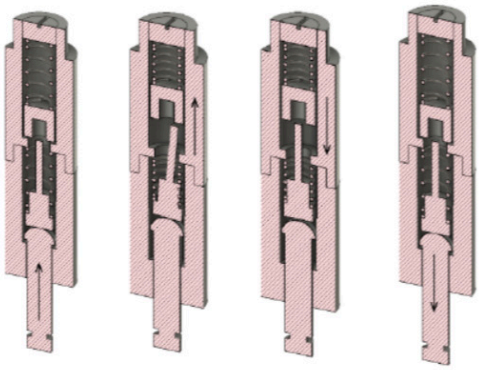
Appendix

Appendix A: RAM Mechanism

RAM Mechanism

When the plunger is compressed, the pusher and hammer are lifted up until a critical point at which the pusher straightens and slips into the hammer channel..

At which point the slip causes the entire compressed spring energy to be released onto the pusher and subsequently the plunger.



Appendix B: Market and Competitive Analysis

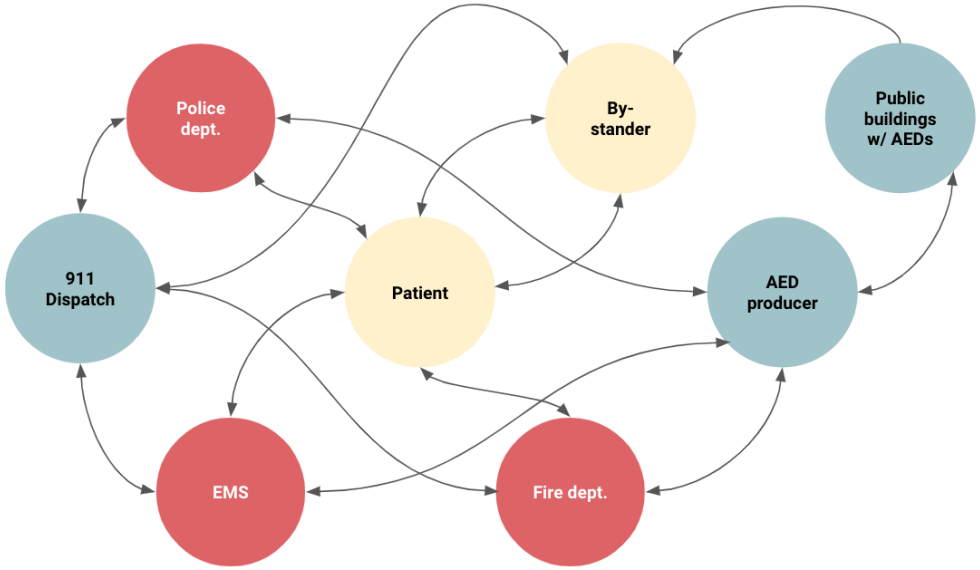


Figure 22: Stakeholder Value Chain of Out-of-Hospital Cardiac Arrest

	Market 1 **First Responders**	**Market 2** **Public Spaces + Businesses**	**Market 3** **Individuals**
End User	EMT, firefighter	Bystander to cardiac arrest (lay person)	Bystander to cardiac arrest (lay person)
Economic Buyer	Procurement personnel for ambulance company or fire department	Procurement personnel at university, gym, mall, etc.	Individual with risk factors for cardiac arrest
Use Case	Repeated, comprehensive on-site or in-ambulance patient care	Compliance with regulatory AED requirements	Quick, one-time treatment of cardiac arrest until EMS arrives
Size of Market	~50k ambulances in US ~70k fire trucks in US ~$1300 per unit =**$156M TAM**	~3.2M AEDs in public buildings in US ~$1300 per unit = **$4.16B TAM**	~735k people with heart attacks each year ~$100 maximum willingness to pay **$73.5M TAM**

Table H: Potential Markets

Product Name	Weight	Price
Defibtech Lifeline ARM	15.9 lbs	$12,995
Zoll AutoPulse Resuscitation System	23.5 lbs	$19,950
LUCAS 3 Chest Compression System	17.7 lbs	$15,950

Table I: Automated Chest Compression (ACC) Devices

Product Name	Weight	Max Power	Price
CELLAED Smartphone AED	0.66 lbs	200 J	$50
Altrix Medical Smartphone AED	Unknown – phone case only	Unknown	Unknown
Defibtech Lifeline AED Package	4.2-4.4 lbs	150J	$1,245
Defibtech Lifeline Fully AUTO AED	4.2-4.4 lbs	150J	$1,295
Defibtech Lifeline View AED Package	4.2-4.4 lbs	150J	$1,595
HeartSine Samaritan 350P AED Package	2.4 lbs	200J	$1,245
HeartSine Samaritan 360P AED Package	2.4 lbs	200J	$1,345
HeartSine Samaritan 450P AED Package	2.4 lbs	200J	$1,395
Philips HeartStart OnSite AED Package- M5066A	3.3 lbs	150J	$1,275
Philips HeartStart FRx AED Package	3.5 lbs	150J	$1,559
Philips HeartStart FR3 AED Package	3.5 lbs	150J	$2,520
Cardiac Science Powerheart AED G3 Plus	6.6 lbs	Unknown	$1,445
Cardiac Science Powerheart AED G3 Plus - Fully Automatic	6.6 lbs	Unknown	$1,445
Cardiac Science Powerheart G5 AED	5.7 lbs	Unknown	$1,695
Physio-Control LIFEPAK Express AED Package	4.5 lbs	360J	$1,295
Physio-Control LIFEPAK CR Plus AED Package	*4.5 lbs*	*360J*	*$1,695*
Physio-Control LIFEPAK 1000	*7.1 lbs*	*360J*	*$2,515*
ZOLL AED Plus Package	*6.7 lbs*	*200J*	*$1,699*
ZOLL AED Pro	*6.5 lbs*	*200J*	*$2,895*

Table J: Automated External Defibrillators (AEDs)

Appendix C: Additional Sketch Models

Figure 23: Butterfly spine: “Handles feel more substantial.”; “I’m holding this at an awkward angle pushing down, maybe add holes for thumbs or some kind of grip.”

Figure 24: Adjustable angle: “Push or pull?” (without suction cup attached); “Nice angle but maybe close the distance between handles and platform.”

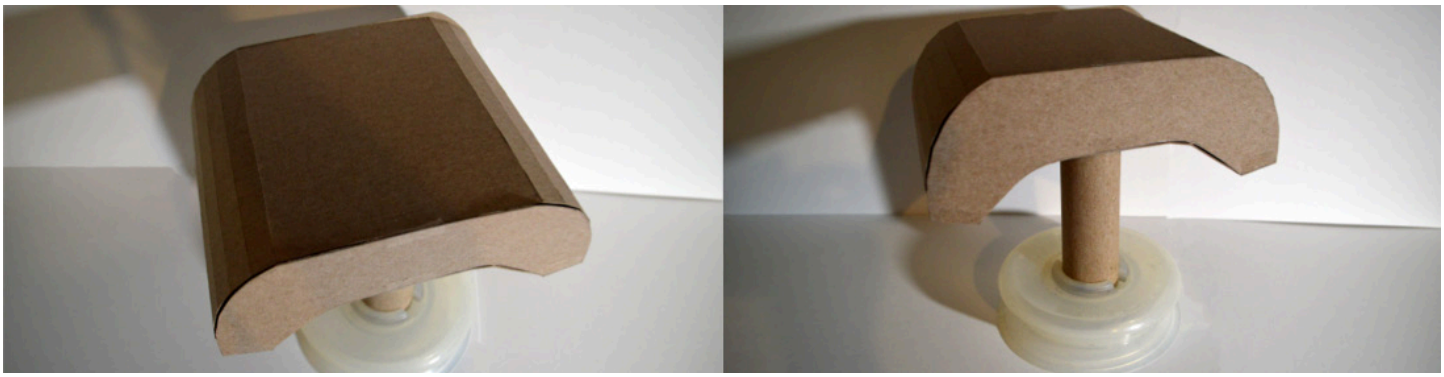


Figure 25: Grip: “Shape is intuitive for the action and easy to hold on to.”

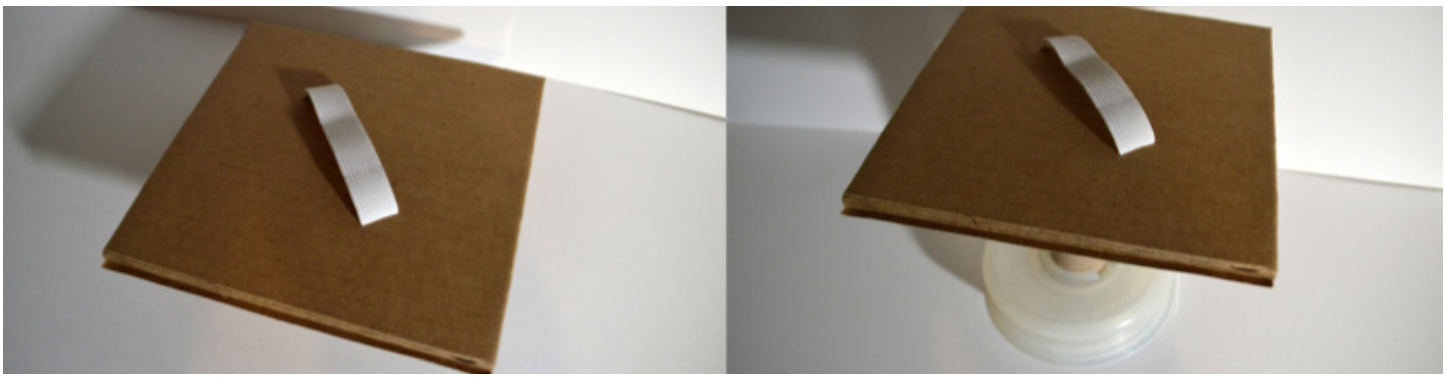


Figure 26: Strap and Push device: “Maybe combine with handles so there are 2 ways to secure the device.”

Appendix D: Financial Model

	Year 1				Year 2				Year 3				Year 4			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Beginning Total Cash	0	-1,000	-2,000	-2,300	-2,600	-2,500	-800	900	2,600	6,300	10,000	69,700	189,400	389,100	788,800	1,188,500
Setup Costs & Overhead	1,000	1,000	300	300	300	300	300	300	300	300	300	300	300	300	300	300
Development Cost	1,000	500														
Ramp-Up Cost		500	300	300												
Marketing Costs					300	300	300	300	300	300	300	300	300	300	300	300
Manufacturing Costs					100	500	500	500	1,000	1,000	15,000	30,000	50,000	100,000	100,000	50,000
Manufacturing Volume (units)					1,000	5,000	5,000	5,000	10,000	10,000	150,000	300,000	500,000	1,000,000	1,000,000	500,000
Manufacturing Price ($/unit)					100	100	100	100	100	100	100	100	100	100	100	100
Sales Revenue					500	2,500	2,500	2,500	5,000	5,000	75,000	150,000	250,000	500,000	500,000	250,000
Sales Volume (units)					1,000	5,000	5,000	5,000	10,000	10,000	150,000	300,000	500,000	1,000,000	1,000,000	500,000
Sale Price ($/unit)					500	500	500	500	500	500	500	500	500	500	500	500
Net Cash Change	-1,000	-1,000	-300	-300	100	1,700	1,700	1,700	3,700	3,700	59,700	119,700	199,700	399,700	399,700	199,700
Ending Cash	**-1,000**	**-2,000**	**-2,300**	**-2,600**	**-2,500**	**-800**	**900**	**2,600**	**6,300**	**10,000**	**69,700**	**189,400**	**389,100**	**788,800**	**1,188,500**	**1,388,200**
Net Profit	-1,000	-1,000	-300	-300	100	1,700	1,700	1,700	3,700	3,700	59,700	119,700	199,700	399,700	399,700	199,700
PV Year 1	-1,000	-909	-248	-225	68	1,056	960	872	1,726	1,569	23,017	41,954	63,631	115,779	105,254	47,807
Cost of Capital	10%															
NPV Profits	403,692															
NPV Investment Cost	-2,382															
NPV Project	401,309															

All figures in thousand $ unless otherwise noted

Appendix E: Patent Background

Resuscitation Assistance Module and AED Geolocation

Patent Review Background
April 26, 2019

Inventors
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Search words
Automated external defibrillator
Defibrillator location
Defibrillator monitor
Emergency defibrillator
Wearable defibrillator
Chest compression
Automated chest compression
Automated cardiopulmonary resuscitation

Background

- According to the World Health Organization, each year, there are approximately 17.9M deaths globally from cardiovascular disease. Of these deaths, 85% are due to heart attack or stroke. [8]
- Within the United States, the American Heart Association estimates that there are more than 350,000 cases of out-of-hospital cardiac arrest per year. About 90% of these cases are fatal. [9]
- A study conducted by Purdue University showed that the success rate of CPR is only 5%-10%, largely due to improper application of force by both laypeople and trained professionals. While CPR requires between 100 to 125 pounds of force, the study found that "60 percent of the CPR-trained rescue personnel pushed with more than 125 pounds, whereas more than 60 percent of those not trained in CPR failed to push with more than 125 pounds of force."[10]
- Expedient treatment is essential to the survival of cardiac arrest victims. For every minute that passes without CPR and defibrillation, the chances of survival decrease by 7–10%.[11]
- The majority of out-of-hospital cardiac arrests occur in public settings.[12] Due to state laws regarding placement of AEDs in public places, an estimated 3.2M AEDs have been placed in public settings.[13]
- In order to improve emergency response time and efficacy of CPR in cardiac arrest, the inventors have developed two inventions: (i) geolocation and network functionality for AEDs in public settings, to allow first responders to more quickly find cardiac arrest victims, and (ii) a mechanical device to be stored alongside AEDs in public places, which would assist individuals in more easily applying the appropriate force during CPR.

Description of Invention(s)

1. Spring-loaded manual device to store energy from user input in order to output a set mechanical energy impulse to the sternum / chest of the patient.
2. Additional logic, geolocation, communication, and "network" functionality for standard AED.

Novelty

1. HYPOTHESIS (needs prior art search) - status quo for chest compression is entirely manual or automated. No such device exists which aids the user to apply manual chest compressions with the correct depth and output force. A device which aids manual chest compressions by storing biomechanical energy input by the user in order to release a calibrated amount of energy a pre-determined depth into the patients chest in order to cause the heart to pump blood is both novel and potentially non-obvious given the competitive landscape.

2. HYPOTHESIS (needs prior art search) - status quo AED's do NOT have built in geolocation or 911/ emergency contact functionality built in. Furthermore, AEDs do not store or transmit patient heart data, EKG data, or blood pressure data. We envision a centralized data set being created based off of this data collected, which is anonymized so that it can be used by public health organizations/gov institutions to better understand cardiac arrest cases and response. A device which, when activated by the user, automatically notifies emergency response of the location and nature of the emergency is both novel and non-obvious given the competitive landscape.

Prior Art

Chest compression device
https://patents.google.com/patent/WO2014057116A1/en?oq=chest+compressions
Chest compression system
https://patents.google.com/patent/US7775996?oq=chest+compressions
Synchronization of defibrillation and chest compressions
https://patents.google.com/patent/US8700147?oq=chest+compressions
CPR chest compression device
https://patents.google.com/patent/US20040006290?oq=auto+chest+compressor
Chest compression device with electro-stimulation
https://patents.google.com/patent/US7497837?oq=chest+compressions
Automated external defibrillator (AED) with context-sensitive help
https://patents.google.com/patent/US20050070964?oq=AED
Confidence analyzer for an automated external defibrillator (aed) with dual ecg analysis algorithms
https://patents.google.com/patent/WO2016092480A1/en?oq=AED
Automated external defibrillator (aed) with dual ecg analysis algorithms
https://patents.google.com/patent/EP3229896A1/en?oq=AED
Automated external defibrillator (AED) with context-sensitive help
https://patents.google.com/patent/US8335562?oq=AED
Automatic external defibrillator (AED) with wireless communications
https://patents.google.com/patent/US20070032830?oq=AED

Confidence analyzer for an automated external defibrillator (aed) with dual ecg analysis algorithms
https://patents.google.com/patent/WO2016092480A1/en?oq=AED+compressions
Defibrillator that monitors CPR treatment and adjusts protocol
https://patents.google.com/patent/US9636510?oq=AED+compressions

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[11]https://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_301646.pdf
[12]https://cpr.heart.org/AHAECC/CPRAndECC/AboutCPRECC/CPRFactsAndStats/UCM_475748_CPR-Facts-and-Stats.jsp)
[13] https://readisys.com/the-aed-shortage/