The Retractable EKG Wiring Unit

Major Qualifying Project completed in fulfillment of the Bachelor of Science degree at Worcester Polytechnic Institute, Worcester, Ma

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Abstract

This project's goal was to determine whether our device idea could create a viable business. The electrocardiogram, a cardiovascular monitoring device, frequently becomes tangled, unorganized and less accessible to our end users. For a convenient set-up process, our device will solve these problems by allowing for the electrode leads to be wound up into the storage accessory, maintaining consistent organization, along with simultaneous sanitation. We accomplished this by researching proper information, validating our research with professionals, and conducting a feasibility analysis to determine commercialization potential. We concluded that our device would not create a viable business at its current state of functionality rather showing promise for a potential licensing deal. We created a year-long development plan for further commercialization.

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Table of Contents

Table of Figures

Authorship

This project was completed by two team members both contributing equally to the project. The table below represents the completed sections for our group including sections written by both of us. Additionally, both members of our group were involved in editing and formatting the paper in equal amounts.

Chapters/Sections	Primary Author
Abstract	Finn
Acknowledgments	Team
Executive Summary	Finn
Introduction	Kara
Background	Kara
Electrocardiogram Machine	Team
Proper Electrocardiogram Use	Kara
Organizational Structure of Hospital Operations and Decision Making	Kara
Intellectual Property	Finn
Patents	Finn
Licensing	Finn
Finance Options and Expenditures	Finn
Raising Start-up Capital	Kara
Production Costs	Finn
Methodology	Finn
Phase 1: Research	Kara
Background Research	Finn
Market Research and Industry Reports	Kara
Manufacturing	Kara
Intellectual Property	Finn
Major EKG Manufacturers	Kara
Phase 2: Customer Discovery and Validation	Kara
The Business Model Canvas and the Methodology of Steve Blank	Kara
Hypothesize and “Get Out of the Building”	Kara
Test, Validate, and Revise	Finn
Phase 3: Commercialization Decision	Team
Determining The Best Avenue of Commercialization	Finn
Results & Analysis	Team
Objective 1: Research Results	Kara
Market Research	Finn
Manufacturing	Kara
Intellectual Property	Finn
Objective 2a & 2b: Customer Discovery Results	Kara

Objective 3: Commercialization Plan	Team
References	Team
Appendix A: Development Plan	Team
Appendix B: Provisional Patent	Team
Appendix C: Business Model Canvas	Team
Appendix D: Surveys, Survey Results & Interview Questions	Team

Executive Summary

The electrocardiogram is a medical diagnostic device used to study the electrical and muscular functions of the heart. Whenever a patient shows any symptoms of having trouble breathing, chest pains, or a history of hereditary heart disease, an EKG test is usually called for. The end user of an electrocardiogram needs an organized configuration to get a successful reading as soon as possible. Our electrocardiogram accessory would help in maintaining a consistent organized set up, as well as both features of retractable electrode leads and simultaneous sanitation upon storage.

Goals and Methods

Our main project goal was to analyze the feasibility of starting a business from our medical device. To find out if our product was of commercial value, we had multiple objectives that needed to be accomplished. First, we had to research substantial background information. Afterwards we conducted interviews of medical professionals, collected surveys, and observed the medical setting to validate research, and further assess our commercialization potential. Participants in our customer discovery research ranged from registered nurses, doctors, nurse educators, nurse managers, biomedical engineers, hospital management, patent professionals and purchasing agents. This data collection allowed us to make a well-educated decision on the ability of starting a business. Our next step was to develop a commercialization plan for our device, which would revolve around the finalization of our design concept, intellectual property, the market condition, manufacturing costs, and potential medical device manufacturers. Upon conclusion of the method of commercialization, we entailed our recommendation for the Retractable EKG Wiring Unit's future development.

Results

After researching all of our deciding factors for creating a business, we were able to then analyze our results for future decision making. From our customer validation, we confirmed that there was a need for our device in the hospital setting as feedback from our end user was highly positive. With that being said, the medical device market was discouraging for potential market share, and was very competitive for direct sale distribution into hospitals. When interviewing the purchasing personnel of hospital management teams, we found that decision making for direct sales, as a vendor, to hospital was a very dynamic and time consuming process. We also discovered very quickly that new vendors are rarely negotiated with as larger established companies have a vast advantage in what they can offer.

Our next plan of action after ruling out a direct sales commercialization strategy was to evaluate potential intellectual property for our device, in order to consider a licensing deal. As our device was not made fully functional in our engineering phase, we were not able to pursue a utility patent. We did confirm that we had intellectual property, and applied for a provisional patent. This allowed us a period of 12 months to engineer a fully functional minimum viable product in a research and development phase and gave us a clear path of our strategy of commercialization.

Conclusion & Recommendation

We concluded our project goal of creating a business with our device was not feasible, however, it did have potential for a future licensing agreement. With our provisional patent, we plan to initiate a yearlong development plan in which a functional minimum viable product will be engineered. Once the MVP is solidified, a utility patent can be applied for, prior to soliciting medical manufacturers for a potential licensing contract agreement.

1.0 Introduction

The goal of this Major Qualifying Project was to answer the question, “can our product idea create a viable business?”. The product in question for our project was a retractable wiring unit for an electrocardiogram, that would offer a decrease in setup and storage time due to mechanically assisted wire coiling and automatic sanitation. In order to answer this question in its entirety, there were a few deeper, more systematic questions that needed to be answered. Starting a new business is not just one task, but a multitude of tasks, whose outputs come together to form what will, or will not be, a sustainable business. First, we discovered the feasibility of entering into the market with our device. Whether market penetration was feasible relied on a few factors. The main factor was whether or not the product trying to enter the market provided for a need, or fixed a particular problem. In other words, would somebody buy this device for its potential benefits and application? Aside from end user acceptance within the work environment, market penetration success depended on how difficult it would be to sell a product to a hospital. Discovering the answers to both of these concerns allowed us to transition to the next question. Depending on our market feasibility results, what is the best method of commercialization? Devising a plan on how to bring the device to market relied on whether a hospital or manufacturer would buy the product, and how difficult it was to sell to the end users and customers being targeted. Ultimately, deciding on a method of commercialization translated into how our new venture would sustain itself in sales, what our business model would be, and thus answered our question, “can our product idea create a viable business?”.

Our product idea was an organizational accessory to assist the consistent storage and sanitation protocol for the lead wires of an electrocardiogram machine. An electrocardiogram,

also called an ECG or EKG, is a device used to observe and analyze the electrical and muscular functions of the heart for further diagnosis. An electrocardiogram consists of ten different electrodes that are placed on various parts of the body to detect electrical impulses generated by the heart. The mechanical parts of the machine consist of; the electrocardiogram itself, a ten pin plug to connect to the ten different electrode wires, and the electrodes and corresponding wires.

Often times when an electrocardiogram is used, wires can get tangled and mixed up due to the lack of post use storage quality and care. It is not only an inconvenience to the doctor or nurse that is using the machine, but could also pose a hazard to patients in need of time pressing examination, when time needed to untangle and re-organize simply isn't available. Our device aimed at improving a few aspects of the device use. First, was to improve set up time and put away time by neatly storing the wires in their own spools, while also running the wires through a disinfectant soaked sponge while being cranked into storage. Second, was to improve the consistency of the quality at which the machine was stored every time after use. It would guarantee a perfect put away every time, along with a guarantee that the wires were disinfected every time as well.

The two precursor questions needed to meet our main goal were, was market penetration feasible, and what commercialization method was best? This project was broken up into three different phases of action to accomplish the objectives that assisted us in answering the two precursor questions. The phases were completed in a systematic way to logically determine whether we could create a viable business.

The first phase of action completed was our "Research" phase, with the objective of completing all literature research needed to accurately develop our product, and also accurately

hypothesize market penetration and eventually our commercialization method. These topics included how electrocardiograms function and their operational process, intellectual property rights, regulations, market research, hospital operational structure and decision making process, and ways in which to finance a new venture. These concepts did not only set a solid foundation of knowledge for our venture to develop on, but it also laid the groundwork toward answering our precursor questions. Market penetration feasibility was determined by how our device would work with already existing electrocardiograms, how strong our intellectual property was, and how a hospital made the decision to purchase an item. The sales method for commercialization was to be decided pending those answers

The second phase of action performed was our "Customer Discovery and Validation" phase. This phase had the objective to recapitulate and answer the former precursor questions and validate our literature research by using the "Customer Discovery" methodology created by famous entrepreneur, Steve Blank. His methodology encourages the founders of a new venture to hypothesize who the customers and end users of the product are, and hypothesize the various operations and sales strategies that the founders "think" will work to drive their venture. The chosen methodology uses Alexander Osterwalder's "Business Model Canvas" as the primary organizational tool to record and test the various hypotheses, which is what we used as our primary organizational tool as well. Using Blank's methodology, along with the canvas, we interviewed a number of people, consisting of medical professionals, biomedical engineers, and intellectual property professionals. The interviews validated our product with feedback from the hypothesized end user, and also tested our previous literature research, regarding the way in which hospitals make a decision to purchase an item. With the new information gathered, we were able to make a logical decision on the feasibility of penetrating the market with our

accessory, and subsequently allowed us to have a clearer vision of how to further commercialize our device.

The third and final phase of action for meeting our goal was the "commercialization plan" phase. The objective of this phase of action was to analyze our results from all the information that was gathered from both the literature research and interview data, and construct a plan for further commercialization. There were two ways for our product to enter the market, and that was a direct sales method to the hospitals, or obtaining a licensing agreement with an established electrocardiogram manufacturer. Making a decision on the two options depended on our final conclusion regarding the feasibility of market penetration with our device, which relied on end user acceptance, intellectual property strength, and how welcoming the hospital purchasing process is to new vendors. The final commercialization method chosen gave us the answer we were searching for pertaining to our original question, "can our product idea create a viable business?". If we were able to choose the direct sales method of entering the market, then yes, our product could have a run at creating a viable business. If we concluded that obtaining a licensing agreement with an established manufacturer was the best route for commercialization of our device, then our answer would be, no, due to the fact that licensing the device for the manufacturer to produce is technically not a business.

2.0 Background

The overall goal of our project was to find out whether our product idea could be formed into a viable business. To discover whether a business could be formed, we determined if entering the market would be feasible, and what strategy of commercialization would best suit our venture. To hypothesize feasibility and a commercialization method, topics that we needed to

research included electrocardiogram components and protocols, the structure of decision making operations within hospitals, intellectual property, and finance options. Alexander Osterwalder's business model canvas was used as a visual tool to begin organizing our hypotheses created while conducting our background research.

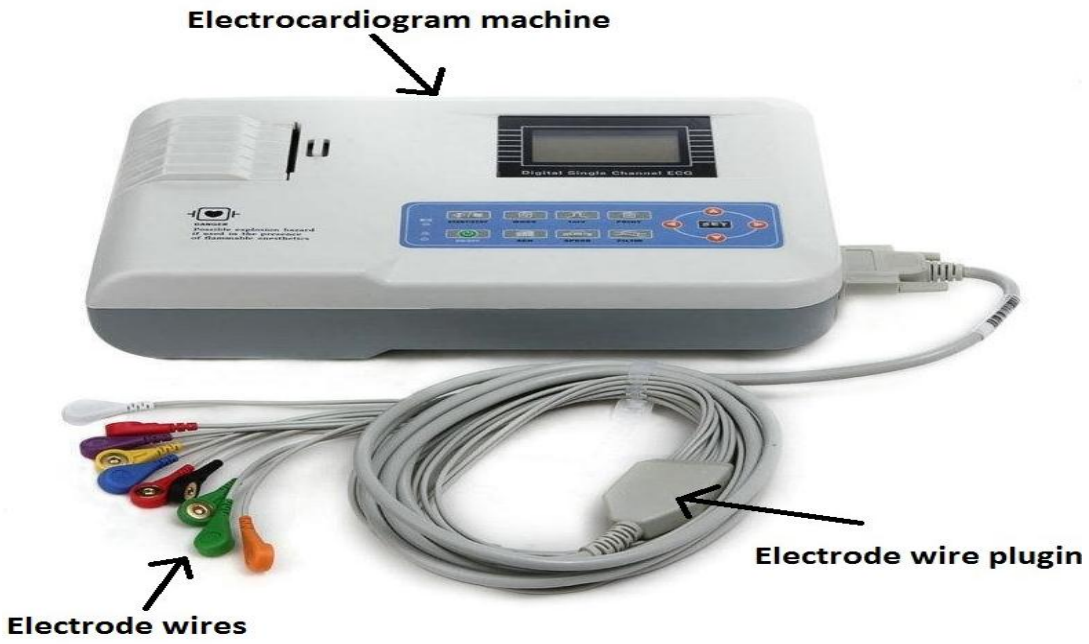
2.1 Electrocardiogram Machine

An electrocardiogram is a significant instrument found within all Emergency Rooms and doctor's offices. The electrocardiogram (ECG or EKG) is a diagnostic tool that is routinely used to assess the electrical and muscular functions of the heart (EMT Resource, 2014). An electrocardiogram is easy and simple to use, but the interpretation of the results requires a great extent of education and training. There are three main components to the machine; the instrument itself, including a monitor of some sort and the electronics of the machine, a specific number of wires to connect to separate electrodes, and the electrode pads. This device measures the rate and rhythm of a heartbeat, but can also give slight insight to heart blood flow.

The standard electrocardiogram has 10 wires, to produce 12 leads, or a signal of electrical activity. As you can see in **Figure 1** below, each wire is typically color coded to represent the various parts of the body to be connected to the corresponding electrode pad. There are 4 main extremity leads, which include a wire to the left and right arm, a neutral wire that gets stuck to the right leg, and a wire for the foot on the left leg (Garcia, 2015). The last remaining 6 wires get placed on various, specific parts of the chest. There are a variety of other types of machines, such as a 10 lead, a 5 lead, and a 3 lead electrocardiogram (Vanderbilt, 2015). Since the 12 lead machine was the version we found to be most commonly sold by major manufacturers, we focused our device to be an accessory of a 12 lead electrocardiogram. See Figure 1 below for a typical 12- lead EKG machine. There is a consistency among the different manufacturers for

electrocardiograms in the way the 12 lead wires connect to the main cable of the device. This similarity was important, because it gave us insight on the type of features our prototype needed to have, and the placement of those various features.

Figure 1 Electrocardiogram Machine



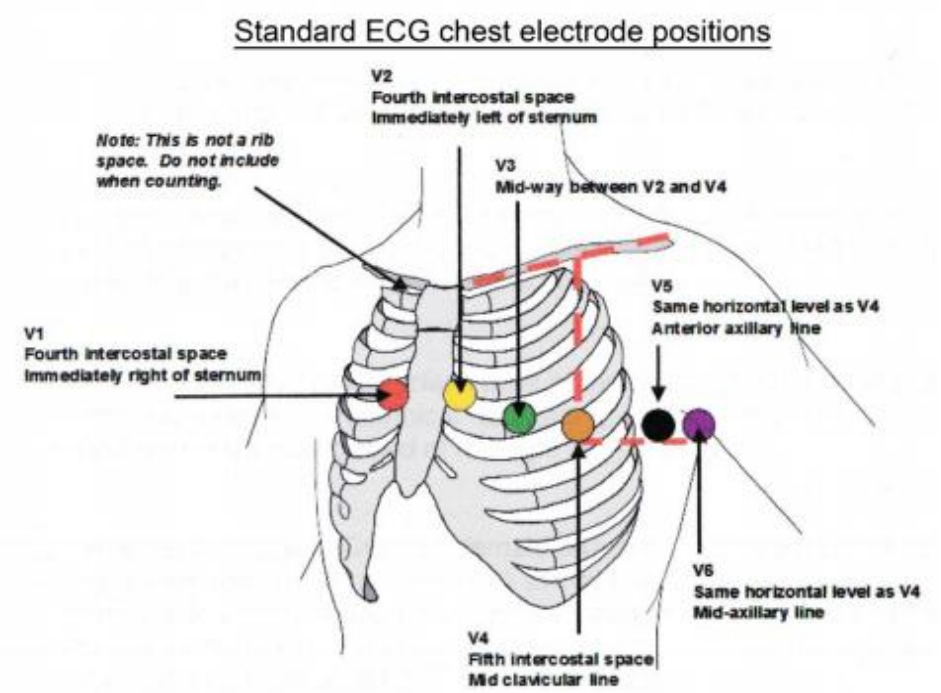
2.1.1 Proper Electrocardiogram Use

The electrocardiogram is fairly straightforward in its operating procedure. The machine gets turned on, and the patient personal information is recorded for the hospital's records. Once the patient's information has been logged, the nurse administering the electrocardiogram will untangle the wires if need be, stick the electrodes on the correct areas of the body, and place the color coded wire on the correct corresponding region of the body. See **Figure 2** below for the standard chest positioning (Eldridge, 2014). The nurse then starts the machine and allows the program to take the reading. The results of the reading are then printed out, and a doctor is called upon to validate the results, and suggest further treatment if need be.

Once the results have been validated by a doctor, the nurse unclips the wires from the electrodes, and throw away the electrodes. It is normal protocol to wipe down the individual wires with a disinfectant agent provided by the hospital. Once the wires have been disinfected, it is not specifically protocol, but common decency to wrap the wires in a neat fashion, instead of just bundle them in no specific fashion for the next person to use. The electrocardiogram machine is then plugged back into the wall to charge for the next person to use.

The design of our device prototype relied heavily on this information for a few reasons. First, because the protocol shows there is a systematic way of putting on the leads to the patients. This meant that the placement of the wires in our device needed to tailor to this, and make sure that the wires were not stored randomly. Second, we understood that our device needed a way of sanitizing the wires before storage as well. This added a new feature onto our prototype idea, which was a compartment on the front of the box to hold a disinfectant soaked sponge. The wires would pass through slits in the sponge, cleaning the wires as they get wrapped up. This added more value to our device, other than the capability of consistent storage quality.

Figure 2 Standard ECG Chest Electrode Positions



2.2 Organizational Structure of Hospital Operations and Decision Making

The operations within a hospital, which can also be classified as a large decision making process, are handled dynamically between the administration section of the hospital, and the clinical section of the hospital. The way these two sections interact is largely based on the type of hospital being referred to, whether the hospital is investor-owned or voluntary, or a freestanding hospital or a hospital that is a member of a multi-unit system of hospitals. Operational decision making within hospitals are constantly trying to determine, what benefit does the decision bring to the hospital as a whole, and who does it benefit, administration or clinical?

Administration consists of trustees, administrators, voluntary staff physicians, hospital-compensated physicians, and until recently, a growing number that involves nurses. These positions make up the major decision makers within the hospital, and are more likely to be

concerned with the decisions that pertain to the viability of the hospital itself. The clinical faction of the hospital consists of both the physicians and nurses of the establishment, and are primarily concerned with the decisions that will affect the care of patients. Administration is of course concerned about the quality of patient care, but focus mostly on management issues and allocation of resources, which in return are the driving factors for providing cost-effective care for patients. So although the goals of both sections seem to be different, one for monetary concern and one for care quality, both attempt to achieve an overall goal of affordable, quality healthcare for the patient, while also maintaining the viability of the hospital as a business.

"The most important point to understand about decision making in hospitals is that there is no single decision maker." (Shortell, 2016). The decision making process within a hospital is very dynamic, with the input of several officials of the hospitals swaying the end decision. The representatives that assist in the making of the final decision of a given problem consists of physicians, nurses, executive level administrators, and middle level administrators such as department heads. Depending on the matter at hand, one of these groups of people may have a larger input to the matter then the others. For example, doctors have most influence over things like practice protocol, staff privileges, and determining whether a patient can be released or not. Upper executives influence mostly hospital policy and scheduling in relation to external forces, while lower executive, such as department heads, influence decisions regarding staffing, budget, and providing supplies for the particular department (Institute of Medicine(US), 1983). To deal with the conflicting interests and influences, two models of authority have been created.

The first model is the "Dual Authority Model", developed by Pauly and Redisch and Harris (Shortell, 2016). This model divides the hospital into two main factions, the clinical side and the administrative side. The clinical faction of the hospital in this model has a large influence

on the daily operations of the hospital. The administrative faction of this authority model mostly exists to fulfill the needs the clinical factions' operations, and supply the facilities, supplies, and equipment for their use. In simpler terms, this model associates the clinical faction with a more demand driven operation, and the administration with a more supply driven operation, to provide for the needs of clinical. The second model is the "Shared Authority Model", which involves a more even decision making process between clinical and the administration, with more involvement of clinical and administrative data to better validate the decision (Shortell, 2016). This model is a bit more complex, and was derived through external societal and economical forces.

This research assisted the development of our project by helping us answer, how feasible is market penetration? The feasibility not only depended on end user acceptance, but also depended on the difficulty of convincing a hospital to purchase our device. By understanding the complexity in the process of decision making that is standard to hospitals, it put in perspective how difficult it would be to sell directly to these establishments. Along with assisting in the realization of how feasible entering the market was, it also gave insight to how we were going to potentially commercialize our device.

Commercialization for our venture consisted mainly of what form of "sales" was to be made, in order to generate a cash flow. For our venture, we hypothesized that sales would either be generated by directly selling to a hospital, or obtaining a licensing agreement with an already established electrocardiogram manufacturer. This evidence helped us to get an early idea as to what our commercialization method may consist of.

2.3 Intellectual Property

Proper protection of our intellectual property for our device was explored to determine whether we use a direct sales method for our device, or obtain a licensing agreement to obtain sales. When an inventor or any person representing an inventor's idea, wants to protect their intellectual property, they apply for a patent. If two or more people make an invention together, they would apply for a patent as joint inventors. A person who contributes only financially is not considered as a joint inventor, nor can he or she be joined in the application as an inventor. It is not difficult to omit or add a person as a joint inventor.

2.3.1 Patents

"A patent for an invention is the grant of a property right to the inventor, issued by the United States Patent and Trademark Office" (USPTO, 2014). Once a patent is granted, the patent owner has the legal authority to exclude others from making, using or selling the invention in that country without a license. A provisional patent can be issued and held for one year before a decision is made to further pursue a utility patent. A utility patent is a form of protection that "may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof" (USPTO, 2014). Patenting is an expensive process and depends on the type of invention you intend on patenting because attorney fees, as well as the patent search prices increase with more extensive inventions. Attorney prices range from $5,000.00 - $16,000.00 and patent search costs typically range from $1,000 - $3,000 dollars based on complexity.

The United States Patent and Trademark Office (USPTO) has offered inventors the option of filing a provisional patent application instead of the utility patent process. This was designed to provide a lower-cost initial patent filings. However, the attorney fees are still roughly

$2,000 to go along with a $130.00 filing fee. A provisional application provides the ability to begin on an early effective filing date in a patent application and permits the term "Patent Pending" to be applied in conjunction with the invention. Provisional applications may not be filed for design inventions. A provisional patent is the smartest way to acquire intellectual property protection before you are certain you will be carrying out your business venture.

2.3.2 Licensing

Licensing a patent was one of our two options to commercialize our invention. A patent license agreement is simply "nothing more than a promise by the licensor not to sue the licensee" (USPTO, 2014). Licensing our product to a manufacturer was a viable option once intellectual property was confirmed as the invention could have been sold to a manufacturer in multiple capacities of licensing agreements. The licensing contract agreement could be an upfront price or the inventors could receive royalties off of future sales of the influenced product. Some specific differences of agreements that we became aware of were whether it was an exclusive licensing agreement, non-exclusive agreement or if it was exclusive in certain territories. An exclusive licensing agreement entails that no person or company besides the named licensee could potentially exploit the intellectual property right, as well as the licensor who is not allowed to exploit the intellectual property even after an agreement is made. A non-exclusive licensing agreement allows the licensee the right to use the intellectual property, however the licensor remains free to sell the same intellectual property to any other licensees. When soliciting a licensing deal with companies it was apparent that an attorney or licensing agent should be present when going through the legalities of the contract in order to make sure a fair deal was put in writing without any loopholes or hidden connections.

2.4 Finance Options and Expenditures

2.4.1 Raising Start-up Capital

Any new business venture will need to decide how they are going to initially fund their business operation. There are many avenues in which capital can be secured and they are based upon the type of business being assembled, the amount of funding needed, the type of funding, and how to secure these finances. Understanding the options available will assist in making smart decisions to raise start-up funds in the early stages of our business.

There are two main types of financing for a potential new business venture, including debt financing and equity financing. Debt financing is when an investor provides you with a given amount of capital which must be repaid in a certain agreed upon manner. The loan is paid back in its entirety plus interest, which is a fixed value upon agreement. Investors benefit in the deal only by the interest accrued over time, and the business gets the necessary capital to start their venture. Debt financing can be cash flow based or asset based depending on the financial position of the new business founders. Cash flow debt financing involves strictly cash received by the venture in the course of their business successes. No assets of sufficient value are collateralized to pay off the loan. The financial institutions that offer cash flow based debt financing normally will require that the new venture has had consistent cash flow for some time and has promising future expectations, with evidence that the income will be continuous through the term of the loan. In order to lower risk the lender may add stipulations or covenants, which are requirements that must be followed or the investor may relinquish the deal or fine the business venture (Bussgang,1989). This is only to ensure that they will not be at a loss and will get their capital back if the business struggles. Asset based debt financing is used for businesses that do not have a history of a consistent cash flow, however have some valuable asset or

property to offer, if their debt cannot be repaid. This is called a lien, which gives the rights to the possession to the lender in the event that the agreement is not fulfilled.

Equity financing is very different from debt financing as the equity investor provides an amount of capital to the business venture in exchange for an agreed upon share of ownership. The equity investor shares in the ventures upside value creation and is also at risk for losses. There is no ceiling for the return on investment by the equity investor as they own a share of the business permanently. As this potential can be great investors are more willing to take part in riskier ventures with large upsides than a debt investor would normally be. This higher risk of investors also increases their demand of higher return on their capital investment (Bussgang, 1989). Equity investors are usually professionally managed firms whose business is investing in new ventures, asserting managerial control through positions on the company's board of directors, where they can make decisions as well as monitor the businesses performance.

The sources of funding that are available for new business ventures include self-funding, personal credit lines, crowd-funding, venture capital groups, angels and accelerators. Each of these sources have different characteristics that can be beneficial to a start-up, but it all depends on the particular business's position and needs, and the demand for investors to pursue a promising deal. The venture capital industry is an exclusive and small industry with about a thousand investors in the country. These are very well off companies that can provide capital to high risk ventures, even when they have uncertain outcomes and long pay-out periods. Venture capital groups will not usually fund small start-up costs for entrepreneurs, rather looking for potential breakthrough business ideas, typically technology based, that require a significant amount of money to get up and running (Schaufeld, 2015). Venture capital groups will look deeply into the infrastructure of the start-up to see if the right pieces of the puzzle are present to

create a profitable and efficient business. The start-up venture must have a clear vision and must demonstrate that they are a good buy for a venture group to invest.

Angel investors are individuals or groups of individuals who have cash to invest as well as expertise in certain markets of business, and are usually able to help entrepreneurs in business. Angel investors want to see a return on investment but are also interested in helping run businesses and launch successful start-ups. Angel investors are important sources of funding as they are more willing to deal with smaller investments that venture capital groups may pass on (Schaufeld, 2015).

Crowd-funding is another source of venture funding in which a large number of people can invest small amounts of capital in a business, which gives the business valuable capital that may have been too small for venture capitalist or angel investor. Crowd-funding allows the investors to obtain either equity in the business they invest in or receive a non-equity token, which can be anything of value that the business has, for example, a product sample, a special service or recognition (Bussgang, 1989).

Accelerators are an emerging source of funding where the organization gives a new venture cheap office space, coaching and mentoring to a business as well as some equity based financing, to "accelerate" a business into the market and towards their goals (Schaufeld, 2015). Accelerators can be very helpful for new business ventures with limited connections and experience by helping to connect them with advisers and experts that are otherwise difficult to get in contact with.

Lastly, a start-up could receive non-dilutive financing, which is ideal for the early development of technology and other intellectual property, especially in an academic environment. Non-dilutive financing is usually in the form of government grants and is

extremely helpful for the research stages of development that could be very expensive for a start-up company. This allows for pivots and trial and error in research without the expectations of an investor or the inability to afford continuing research.

All of these sources of funding are viable options for our new business venture. Finding the right deal and the right team to work with is essential in creating a successful start-up, and the source of your business's funding is inevitably one of your most important business partners. Our business will need to decide on the most reasonable and complete plan to raise capital and get our business off of the ground.

2.4.2 Production Costs

In order to understand production costs, our business must understand the laws of supply and demand. A firm would be willing to produce a certain amount of goods based upon the demand of consumers, and the price they are willing to pay in order to strategically supply a product with the economic goal to maximize profits (Bruns, 2004). Total revenue is the amount a firm receives for the sale of its output. Total cost is the market value of the inputs in which is used in production of goods. Hence, profit equals the total revenue minus the total cost. Costs of production can be divided into fixed costs and variable costs as fixed costs are those that do not vary with the production quantity, and variable costs do vary with the quantity of production. Total cost equals both total fixed costs plus the total variable costs, however, it is also quite important to be cognizant of the time frames that are being forecasted as in the short run fixed costs remain fixed, while variable costs keep their characteristics, but in the long term fixed costs become variable costs as production processes change over time (Bruns, 2004).

Another useful production cost a company should be aware of is its average costs. Average costs of each unit can be calculated by dividing the firm's costs by the quantity of output produced. The average cost of each good is the typical cost of each unit produced. It still takes into account fixed and variable costs just as the total costs are calculated. Average total cost equals the sum of both average fixed costs and average variable costs. When diving deeper into a firm's cost of production it is important to know that this includes all of the opportunity costs of creating its output of goods and services, more specifically involving explicit and implicit costs (Schaufeld, 2015). Explicit costs are the input costs that will require direct cash from the company, whereas implicit costs are input cost that do not require expenditures by the company. When total revenue exceeds both implicit and explicit cost, then profits will be earned.

This leads us to the production function which shows the relationship between quantity of inputs used to create the product, and the quantity of output of that product. The marginal product of any input in any production process is the increase in output that arises from an additional unit of that input. To decrease the means in which a company could produce another unit of output, either another worker is hired or an increase in input capital, allowing an additional unit to be created for a smaller cost. This can be seen in the marginal product equation which equates to the change in Y over the change in X. Where the change in X is the change in the firm's input use, and the change in Y is the change in quantity of output produced, resulting from the change in input. Following the law of diminishing marginal product, the marginal product will begin with an increase, however it will reach a point where the additional increase of input will either remain the same or it will decrease marginal production (Bruns, 2004). Marginal costs measure the increase in total cost that arises from an extra unit produced. This

helps the company to understand for each additional unit produced, how much that unit will cost and how pricing can or should change. Because marginal cost rises with the amount of output produced it reflects the property of diminishing marginal product.

Understanding the relationship between marginal costs and average total costs can help greatly when analyzing the trajectory of your average total cost. For example, whenever the marginal cost is less than the average total cost than the average total cost is falling, whereas whenever marginal cost is greater than average total cost, average total cost is rising. For a company, its cost reflect its production process as described in the various relationships above. When creating our proforma financial statements, a keen understanding of the noted financial tools will be vital to accurately project our start-ups finances. This analysis will also be essential to have for our day to day use in decision making as a business and future choices as a company. Planning for years in advance is necessary when starting your business and we will be looking extremely close at our financial data when it comes to our ability to have annual success as an organization.

3.0 Methodology

The main research goal of this project was to analyze the feasibility of creating a business with our device. In order to achieve this goal, we completed three phases of action that would allow us to accomplish certain objectives that would assist us in meeting our goals. Our first objective was to obtain extensive information in our “research” phase needed to accurately develop our product, and accurately hypothesize market penetration, following with our commercialization method.

Second, we conducted professional interviews and surveys as a part of a "customer discovery and validation" phase, with the objective to validate our primary literature research, along with validating our hypotheses regarding the answers to our goal questions and end user information. This adhered to the methodology of Steve Blank, by seeking the feedback of medical professionals, hospital management staff and intellectual property experts regarding our device.

Third, a "commercialization decision" phase, with the objective to evaluate all the results of the previous objectives, and make a logical decision on what our commercialization method should have been. In order to achieve these objectives, we used all resources available to us including online research, WPI databases available, and professional surveys and interviews. This section explains our methodology in detail for each objective we sought to fulfill, in order to reach our project's goal.

3.1 Phase 1: Research

Objective 1: Gather literature to accurately develop our product, and accurately hypothesize both market penetration feasibility and a commercialization method.

3.1.1 Background Research

Our literature research was our overall first step towards answering our research goal. It was important for us as a new venture to be extensively educated on the electrocardiogram, being the device that our product is an accessory for. We also needed to become very familiar with the business environment we were attempting to enter and to identify and understand the various options we would be faced with while constructing our business. We achieved this by searching the library databases and all literature we could obtain in order to make our initial assumptions

on what it took to start a business and commercialize our device. The databases used that were available through the Gordon Library of WPI consisted of sites such as PubMed, ScienceDirect, JSTOR, IBIS World, and Google Scholar

3.1.2 Market Research and Industry Reports

In order to enter the medical device industry, we thoroughly investigated the current market conditions and industry reports. The industry reports and market data were retrieved from IBIS World, being an industry report database available to us through the school. Other pieces of data, such as number of hospitals, employment number of various medical professions, and annual wages, were obtained through the U.S Bureau of Labor Statistics, and the American Hospital Association. We identified all aspects of the medical device industry including barriers to entry, regulation level and the rate of technological change amongst other facets of the industry. This research allowed us to construct the value analysis of our product for our customer and end user.

3.1.3 Manufacturing

For our project it was essential have an in-depth understanding of the type of materials needed, their price and costs of production. We roughly priced the cost of materials by the individual unit through an online materials vendor called OnlineMetals.com, as well as calculated the cost of manufacturing using the average salary of a machinist the United States. We then received an official quote from an IPG photonics material supplier which gave us a better understanding of potential pricing for the retractable EKG unit.

3.1.4 Intellectual Property

Intellectual property rights were very important for us regarding the protection of our idea when it comes to production. The procedure in which to file for a patent needed to be

understood, and the specific options available needed to be considered carefully. We researched these procedures through the United States Patent and Trademark Office website, along with the costs involved with filing for a patent. A patent protects our intellectual property from other manufacturers or businesses, and give us options when determining what kind of sales we are going to try and achieve. Whether we used a direct sales method or receive royalties through a licensing agreement with another company, having a patent for our device was the first step in any one of those processes for the utmost protection. We assessed the use of a provisional patent to protect our device as more commercialization feasibility analysis unfolded.

3.1.5 Major EKG Manufacturers

In the event that licensing was the best option for our business's success, we needed to research the manufacturing companies for EKG machines, and how we could potentially license with these companies. It will be pivotal to find which companies license the most regularly and by what agreements and terms. These manufacturers business tendencies will clearly define our path of licensing and will help clarify our new business venture's path. Manufacturers were contacted in attempt to gain information on licensing procedures of individual companies. This research will help us prepare for existing competitors in the market as well as what to expect in licensing our product.

3.2 Phase 2: Customer Discovery and Validation

Objective 2a: Validating our literature research by using Steve Blank's "Customer Discovery" methodology.

Objective 2b: Confirm market penetration feasibility through Steve Blank's methodology as well.

3.2.1 The Business Model Canvas and the Methodology of Steve Blank

The Business Model Canvas created by Alexander Osterwalder was our primary organizational tool to put together the various aspects of our new potential business. Along with the canvas, we utilized the Customer Development methodology founded by Steve Blank, a Silicon Valley serial-entrepreneur and entrepreneurship professor at a number of universities. Using the canvas, Steve Blank's methodology encourages the business founders to take guesses, or hypothesize, what their business entails, and what kind of customers will the business be generating revenue from. The main purpose of using the Customer Development methodology was to discover who exactly our customers and end users were, and validated our own ideas by understanding what these people do every day in their workplace, and get a first-hand look at the everyday challenges they face. We used this approach to help answer a few questions for our research goal by validating our literature and expanding upon the data by backing up our findings with hospital specific personnel.

3.2.2 Hypothesize and "Get Out of the Building"

Using the Business Model Canvas and Steve Blank's methodology, we started by hypothesizing what sort of content would be placed in each of the 9 boxes of the canvas (Refer to Appendix C). Our hypotheses consisted on who our end users would be, who our customer most likely was (in our case the end user and the customer were two different people), prove whether direct sales could work in a hospital setting, and determine whether there was a need for our device.

Once we made the hypotheses for our canvas, we then planned our strategy to "get out of the building". This entailed first, compiling a list of contacts that would allow us access to the sections of a hospital that we expected our end users and customers to be in. The created list was

compiled of anyone, family or friends, that would allow us to get our foot in the door, and be used as a stepping stool towards meeting new people. Our new candidates were derived through networking with the original professionals being interviewed, and sought contact information of the people they knew that would be beneficial for us to interview.

We then proceeded by setting up appointments to be able to interview these various professionals, whether it was in person or through a tele-communication program and web cam. Having an in person interview was our main goal when setting up the appointments, but scheduling and location can often be difficult factors to work around. (Refer to Appendix D for interview questions)

Aside from listening to the chosen professionals we interviewed, the goal of our face to face interviews was to be able to get into the workplace. This enabled us to observe for ourselves the environment being worked in, and link key points of our discussion with the interviewee to the actuality of the work environment.

Speaking with the appropriate people including medical professionals, biomedical engineers, and management staff gave us real life feedback from our device's end user, the decision makers in the hospital, as well as the rationale behind product approval and product implementation. This was beneficial to our project because it gave us the opportunity to validate our previously done literature research.

3.2.3 Test, Validate, and Revise

Through conducting our interviews, we had the opportunity to be able to test our previously hypothesized points for our Business Model Canvas. This "customer validation" showed us where we were right in our hypotheses, and where we were wrong. We were then able to take this information back for collaboration, and revise our canvas where it was needed.

This method of testing, validating through interviews, and revising our canvas was crucial to our education and insight on what our venture needed consist of, and also enabled us to gain knowledge that assisted us in decisions that required spending capital. This method first allowed us to identify our customer and our end user, and to determine whether they were the same person or not, considering that our end user and customer were going to be different people in the healthcare industry. We were then able to validate who we thought those people were, and were able to make changes and even add to that list of people on our canvas as needed. The interviews also gave us a chance to validate our value proposition with these customers and end users, and improve the value we bring based off first hand feedback from the people who matter the most to our business. This type of insight can save a new venture a good amount of capital, by not spending a bunch of money on a product that your customers may or may not like.

Validating our value proposition with our potential users and customers allowed us to tailor our product to have the attribute that the end user deems most valuable. This provides feedback for the feasibility of market penetration, considering that we received positive feedback from our end users about our device. If the end user didn't like our device, we most likely would not be able to sell it to anyone.

3.3 Phase 3: Commercialization Decision

Objective 3: Designing our commercialization strategy.

3.3.1 Determining The Best Avenue of Commercialization

Commercialization for our device consisted of two options, whether we could sell directly to a hospital, or if we had to obtain a licensing deal with an established manufacturer.

Once our research and customer discovery was complete we were able focus in on the pivotal sections of our potential business using the knowledge acquired from our previous phases. After evaluating the results from phase 1 and 2, we were able to make a logical decision that licensing was the best path of commercialization. To pursue a licensing agreement from an electrocardiogram manufacturer, a strategic plan was made to overcome the unforeseen problems in functionality that our device encountered towards the end of our literature research, and into the beginning of our customer discovery phase.

The development plan created was a yearlong project, using the time period a provisional patent would provide for further development of the device. We started this plan by applying for a provisional patent with the help of Todd Keiller, which guaranteed us a years' worth of time. We then proceeded with the construction of a Gantt Chart, to map out the various tasks that needed to be done during the provisional patent period. We then determined that we would attempt to sponsor an MQP team to extend this project concept, giving us access to not only the resources of WPI, but being able to acquire the appropriate engineering students to overcome the design problems encountered. Assuming the MQP application with the school is successful, we used the terms of the academic semester of the school, and the corresponding weeks, to create a term by term, weekly plan. The plan compiled the necessary tasks to engineer functionality, create a marketing plan, and use that marketing plan to achieve the desired licensing agreement.

We came to this conclusion by analyzing our findings from the two previous objectives. Before our first phase, we automatically assumed that we would be able to do direct sales with any hospital that was interested with our product. Once our research was done through our first phase, we started to understand how difficult market penetration directly through a hospital

would be by studying the operations of a hospital and how the typically purchasing process was conducted.

When executing our second phase, we were able to validate our research pertaining to directly selling to a hospital, along with being able to receive direct feedback from our end users on our device idea, and what they would benefit most from. We received very positive feedback from a variety of emergency room nurses, EKG technicians in the emergency room, and two biomedical engineers we met. The feedback consisted of how useful the device could potentially be pending ease of use, encouraging how the tangling of wires is a legitimate issue, and also gave us the idea that adding a sanitation feature would be beneficial to the value of our device. Our research was validated when we had the chance to talk to various nurse managers, purchasing agents, and the biomedical engineers as well. The interviews with the "administrative" positions of the hospital allowed us to get a scope of how much of a process making a purchase was, and also how hospitals actually try to stay away from vendors of any kind. We came to the conclusion that market penetration was possible, but not through direct sales. We identified through the positive feedback from our end users that there definitely was potential in the market for our device, but no way we would be able to directly sell to a hospital. In order to further commercialize our device, we would have to obtain a patent for intellectual property protection, and seek a licensing agreement with a manufacturer of electrocardiograms that already has an established selling relationship with hospitals. The manufacturer would then incorporate our device into their design, adding value to their device as a whole, and we would receive a royalty for every machine sold with our device on it.

4.0 Results & Analysis

The goal of this project was to answer the question, "can our product idea create a viable business?". By completing the systematic objectives described in our methodology, we were able to accurately determine our market penetration feasibility, and what our further commercialization method would be. We found that market penetration is feasible considering the extremely positive feedback received by our end users, but on the flip side, it would be a "marketing nightmare" to sell directly to hospitals. Based on that feasibility, we decided that obtaining a licensing agreement would be the best way to further commercialize our device.

4.1 Objective 1: Research Results

After completing our literature research, we were able to hypothesize a few points about the environment we were trying to enter with our product. These hypotheses were:

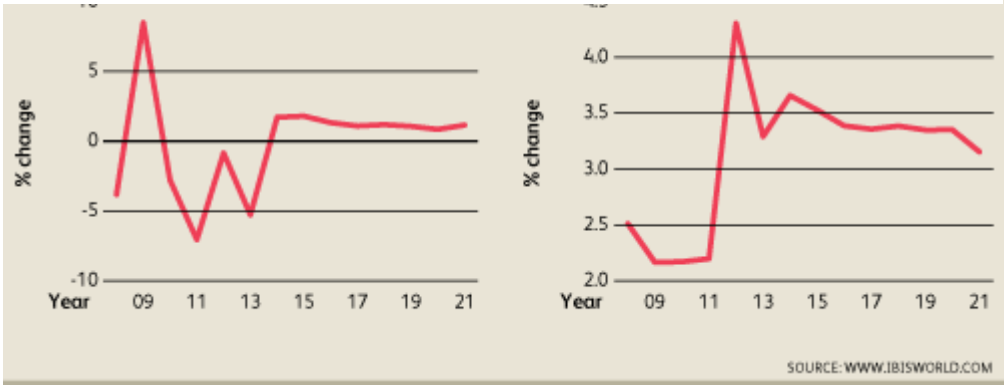
- Our end users of our device were going to be Registered Nurses, CRNs, and doctors.
- Our customers within a hospital would be nurse managers and purchasing agents.
- Considering the positive market conditions, and fairly low potential cost to produce one unit, we believed there would be a need for our device due to the money saved in time cut from the procedure.
- That direct sale was an option depending on the value proposition we had to offer, regardless of how the operational structure was.

4.1.1 Market Research

The total available market in the U.S was determined on how many registered hospitals in the U.S, which came to 5,686 registered hospitals The medical device manufacturing market in the U.S is an extremely competitive industry with typically high margins. The market is currently performing well and has been for the past 5 years, as in 2015, revenue is expected to

grow 1% to $44.2 billion and should continue to grow steadily to 2020 (Curran, 2016). With the economy's improvement and an aging population, as well as expanded healthcare coverage and technology, the market should enhance with increasing hospital visits. Patient visits and their diagnosed need for medical device use are the supply chain for medical devices, and with their increase, the demand for medical devices increases. Specifically, in cardiovascular healthcare, the increased population of 65 years old individuals or older, who statistically have higher chances of having health issues that require medical devices, will continue to annually grow and increase hospital visits, and therefore so will demand for medical devices. The growing number of adults over the age of 65 also decreases trend risk score for the medical device industry, as you can see in **Figure 3** (Curran, 2014).

Figure 3 Number of Physician Visits/ Number of Adults aged 65 and Older



Cardiovascular devices make up 27.6% of the 44.2-billion-dollar medical device market and are second to none.

The Patient Protection and Affordable Care Act which was effective as of January 1st, 2013, levies a 2.3% excise tax on the sale of all medical devices sold. (Curran, 2016) This obstacle could potentially inhibit innovation and the likeliness for investors to back medical device start-up companies as profits will take a hit for this tax. Along with this government

excise tax, another risk in the medical device industry is the shrinking revenue industry wide which will cause more competition for the remaining market.

This information further validates the market penetration feasibility we expect to take advantage of, but shows us how little of a market share there is within the industry. Also, the excise tax of medical device sales adds another, small, but valid reason as to why we would not do direct sales.

4.1.2 Manufacturing

The first step in figuring out how to obtain a working prototype of our device was to engineer and design a 3D model using software on the computer to give a general idea of both component and assembly size. The dimensions decided upon through our engineering and design work was the first factor of costing that we were able to figure out. Pending the material, the proper dimensions would allow us to purchase the proper sizes of materials for creating a prototype. With those dimensions in place, our next step was to decide on a material that the device and all of its components would be made of.

The material choice needed to be medical grade, which in our case pertained to the porosity of the material, sanitation capabilities, and overall strength of the material. The porosity of a material is very important in the medical field due to the aspect of infection control. Porous materials can harbor bacteria growth due to the entrapment of certain liquids, especially water. It was important that the material chosen was not porous, to avoid the growth of bacteria, and avoid infection of any kind to anyone. Sanitation capabilities of the material pertain to the potential degradation that can be caused by using liquid sanitation agents on the material. A material needed to be chosen that would not degrade and erode on contact with these cleaning agents, in order to keep its' form. The strength of the material also needed to be strong in order to assure

that there would be no breaks under any forms of stress. The stress exerted onto the components is minimal due to the function being performed, but we wanted to leave no possibility of the device breaking.

The two options of material "classes" we could use was either a medical grade metal, or medical grade plastic. We had two choices of medical grade metals that could have been used. These were austenitic 316 stainless steel and martensitic 440 or 420 stainless steel. Both materials would provide each separate attribute needed as stated above, but where very expensive.

Our second option was to pick from a wide variety of medical grade plastics. The Plastic that we chose is Ultra High Molecular Weight Polyethylene, or UHMWPE for short. The UHMWPE provided us with all of the necessary attributes such as water resistance, moisture resistance, micro-organism resistance, and resistance of most chemicals. The price of the material is much cheaper than the stainless steels also being looked at. An example of the difference in price between the two materials is, a piece of UHMWPE with the size of 12"x12"x3", a piece of material that can create a total of six component boxes, is roughly $120. A piece of austenitic 316 stainless steel with the size of 12"x4"x4", which can create 6 component boxes, but has roughly ½" of waste for each box made, has a cost of roughly $861.78. There is large difference in price between the two materials, so it is most practical for us to use the UHMW polyethylene plastic.

We received a quote from an IPG Photonics material supplier to see what the unit cost of the device would be when ordering parts in bulk. The estimated quote was for 100 sets of components that make 1 device per set, as shown in **Figure 4**. The material priced was the UHWMPE, with a unit cost being $22.84. This was a great example of how our unit price would

vary when buying in bulk. Refer to the table below from the estimate from IPG for component quantities and prices.

Figure 4 Manufacturer Quote

Part Name	Quantity	Price for UHMW Plastic (each)
Spindle	500	$0.58
Cover	100	$0.76
Crank Handle	100	$1.64
Component Box	100	$19.86
Totals		**$22.84**

4.1.3 Intellectual Property

Determining the strength of our intellectual property was one of the main driving components that would ultimately have a large impact on the future direction of our venture. Due to problems of functionality relating to engineering and design, Todd advised us that our idea was definitely feasible for commercialization, but needed to be fully functional. He assisted us in coming to the conclusion that our best move to have the opportunity to commercialize our product in any way was to take out a provisional patent.

4.1.3.1 Provisional Patent

Due to the lack of functionality of our device, that is in relation to the unforeseen problems that arose while engineering our idea, Todd Keiller, Director of Intellectual Property and Innovation at Worcester Polytechnic Institute, advised that we file for a provisional patent. A provisional patent is a non-patent filing that allows the inventor to have a year's worth of time to protect the idea of the device, and allow the owner to set a date for the filing of the formal patent claim, with only having to give a description, and no designs or artwork of the invention. This

years' worth of time can be used for research and development, along with finalizing all designs and art that pertain to the invention at hand. For our venture, the provisional patent claim would give us a year's time to further develop our product into a fully functional device, which would allow us to be applicable for filing a formal utility patent. A utility patent filed for a design that is not functional would be a useless action, considering that the device itself would never sell directly or be able to convince a company of a licensing deal anyway. The provisional patent would also be ideal for our particular situation, considering it costs only $130, as opposed to the issuing fee for a utility patent which is upwards to $480. We decided to follow through with obtaining a provisional patent in order to carry out our development plans for our device. (Refer to Appendix B). The provisional patent granted us a year to apply for a utility patent once the device is functional.

4.1.3.2 Future Utility Patent

After taking the year that the provisional patent would grant us, to engineer our device to be fully functional, we would then file for the utility patent that is guaranteed to us after the provisional patent has expired. The utility patent gained by the end of that year would allow us to take the next step in commercializing our product. Having the utility patent will grant us ultimate protection of our idea and device, allow us to start manufacturing, and give us the freedom to proceed with obtaining a licensing agreement

4.2 Objective 2a & 2b: Customer Discovery Results

The results of our customer discovery were able to validate who we thought our end users were, who our actual customers were, whether our device fulfilled a need, and validated whether a direct sales method as a vendor would be possible. We focused our research on purchasing decision making in the hospital, daily nursing protocols, proper electrocardiograph use, electrocardiograph use frequency, as well

as biomedical engineering analysis of products. With our customer and end user discovery results (see appendix E), we were able to make a majority of our future planning decisions necessary for creating a functional minimum viable product.

We were first able to identify who our actual end users would be. We were correct when hypothesizing that a registered nurse and a CRN were a part of that list, but completely wrong about doctors. We found out extremely soon that a doctor never actually uses an electrocardiogram machine, just assists in the reading and interpretation of the results. Instead, other positions such as a cardiologist, electrocardiogram technicians, and even an EMT would be considered our end users.

When assessing the value our product brought to our end users, we chose to travel to several hospitals in Massachusetts, as well as collecting separate interviews and surveys, in order to confer with as many medical professionals possible. There was an assuring amount of qualitative complaints regarding the traditional EKG machine set up being a nuisance to the medical professionals, as wires were frequently tangled, unorganized, and needed to be cleaned according to hospital code. Standard procedures for using electrocardiographs were discussed, explicitly how the typical set-up was, the current sanitation process, as well as protocol for transport of machines. We were also able to obtain quantitative data to complete our value analysis for our product including daily number of EKG's taken by each interviewee, how much time it took setting up the machine, average time of successful EKG reading, and time elapsed for sanitation and storage (See Appendix D for data). The job descriptions of these end users ranged from registered nurses, cardiologists, CNA's, EKG technicians, anesthesiologists and medical assistants. The feedback obtained from the medical professionals interviewed validated the need fulfilled and the pain eliminated that our product provides for the end user.

While visiting hospitals and continuing our customer discovery process we were able to speak with managerial positions pertaining to the purchasing decision chain, and the hierarchical structures of typical hospital management. We confirmed our literature review of the complex and time consuming relationship between the clinical and administrative sectors of a hospital. This knowledge was found by

speaking with nurse educators, nurse managers, biomedical engineers, and purchasing agents, from whom we received documents from their particular administrative manuals describing the different authorization levels of making a purchase. For example, in one medical center, non-capital items of services under $1,000 needed the approval of the department head, whereas items or services exceeding $1,000 needed to be approved by the department head as well as a VP board member. Additionally, we received a value analysis product request form which would be filled out by an employee, passed to their director, and then sent to purchasing for their review.

Even with consent of the purchasing department, the biomedical engineers must also evaluate and approve the appropriate brand and model from the wide variety of established manufacturers, to determine the best choice for the hospital. The dynamic relationship between administration and medical professionals proved to be a large inhibitor of a direct sales approach for our product. An even larger obstacle was the reluctance of hospitals to change vendors and take on the risk of a product from a startup company. This feedback allows us to conclude that applying a direct sales based strategy would not be realistic for the commercialization of our device, and licensing would be a better option.

Once we validated that licensing was the best option of commercialization for our venture, we were able to answer our hypothesis regarding who our customers were. Since we determined that direct sales would not be a good option, we would not be targeting hospital administrates to sell to. Alternatively, our "customer", would be the electrocardiogram manufacturer that we would seek a licensing agreement from.

4.3 Objective 3: Commercialization Plan

We determined that the best way to further commercialize our device was to obtain a licensing agreement with an electrocardiogram manufacturer. Evaluating our intellectual property showed us that filing for a provisional patent was the best option for us to have more time to develop a functional device. This gave birth to our development plan for the twelve

months the provisional patent will be on file for, before having to file for a utility patent to be able to license. We constructed our plan by first designing a Gantt chart, with our time span being 52 weeks of time. We then made the decision to attempt to sponsor an MQP to have access to resources and engineering majors.

The schedule of the project is planned as if the MQP team was to take place in A, B, and C-term. A-term would be used to improve the design to achieve functionality. After the design changes, the group would seek customer validation from the end users originally contacted, and re-design the device tailored to the feedback received.

By B-term, the device will be tailored to be the best it can. During B-term, determining potential manufacturers to license to, and establishing a marketing plan for those manufacturers will be developed.

C-term would then be utilized to initiate the marketing plan devised, and obtain a licensing agreement, along with applying for a utility patent for when the agreement is determined. The provisional patent would expire within the first couple weeks of D-term, so starting in C-term to obtain a licensing agreement should be ample time. Also applying for the utility patent within the first week of C-term would allow for ample time to have the utility patent filed by the time the provisional patent is expiring. The Gantt chart and description of the development plan is located in Appendix A of this document.

Conclusion and Recommendation

Conclusion

In conclusion to our project, we were able to answer our research goal question, “can our product create a viable business?”, and the answer is no, it cannot. We concluded with this answer for two reasons. The main reason for coming to this conclusion is due to the fact that

hospitals just don't like to do business with new vendors, or an entity they haven't established a business relationship with. It would be a marketing nightmare, having to tailor to every group of people within a hospital operation that makes decisions. The time it would take to accomplish all of these sales pitches, just to find out they are out of the question would be a huge waste of time. Since we wouldn't be directly selling to our customer, instead licensing to an established manufacturer, we technically would not have a viable, self-sustaining business. The second reason we concluded with not having a viable business is due to our intellectual property. Although we decided that licensing to a manufacturer was the best method to further commercialize our device, we would not be able to obtain this licensing agreement without having intellectual property rights for a functional device. A manufacturer would not license a not functional device, and we wouldn't give away a device idea without assuring it wouldn't get stolen.

This project challenged us to utilize information from our course work at WPI. Being both management engineering students, we found ourselves referring back to our required business classes such as financial statements for decision making, marketing, creating value through innovation, and data analysis for decision making. Aside from the business curriculum, we were able to utilize 3D modeling and design, along with the entrepreneurship class "Launching new ventures". This MQP fulfills the requirements for evaluating the competencies we have gained through our academic work.

Recommendation

Our recommendation for this project is to follow the development plan created in order to further commercialize our device. This will be pending whether sponsorship of a new MQP team will be obtained. Although the conclusion of the project was that we did not have a viable

business, the yearlong development plan is a totally valid way to take the next step toward commercializing the device.

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Appendix A: Development Plan

Retractable EKG Wiring Unit Development Plan

Submitted by: Patrick Finn & Attila Kara

Development Plan Table of Contents

1.0 Assessment

The corresponding development plan is devised with the goal of developing functionality into the design of the retractable electrocardiogram wiring unit, obtain a utility patent, and license the intellectual property to an electrocardiogram manufacturer. After validating a potential market, unexpected functional problems arose during the final engineering and design of the device in order to file for a utility patent. Without using electronic modification to the EKG electrode lead wires, it was undetermined how the device would achieve the capability of adapting to a pre-existing electrocardiogram machine.

2.0 Plan Overview

The development plan is set to run over the course of the next year, starting March 5, 2016, finalizing the project by the same date of the next year. The provisional patent allots this time, starting on March 5, with a year until expiration. During the summer until the next school year, a sponsorship of a Master Qualifying Project at Worcester Polytechnic Institute will be applied for. Pending that application, the development plan intends to follow the the term schedule of WPI, with the project being accomplished during A, B, and C-term. The project team will consist of a mechanical, electrical, and management engineering student.

2.1 A-term:

A-term will be utilized by the mechanical and electrical engineering student to design functionality into the device to produce a tangible prototype, while the management engineer establishes contact with the previously interviewed end users for this device. After a rapid prototype is produced, meetings with the end user will commence, encouraging criticism and suggestions about the device. Recorded feedback will be utilized to redesign, and the

evaluation/validation will be iterated with the previously contacted biomedical engineers, to receive their professional evaluation. A final redesign will commence for the final weeks after the meetings have finished.

2.2 B-term:

B-term will take the now fully functional device and have the intellectual property re-evaluated by Todd Keiller, director of intellectual property and innovation at WPI. The team will then commence with the proper paperwork and filings to start the 5-6 week process of obtaining a utility patent, which must be complete by the beginning of the next term. The remaining time of B-term will be used to determine potential electrocardiogram manufacturers to license to, and create a marketing strategy for each manufacturer. During the drafting process of the strategy, research, along with assistance from professors and advisors will help the team to set up the marketing strategy to be geared towards success. The group will have a final draft of the marketing strategy by the end of the term, and the utility patent will be fully completed and paid for the beginning of C-term.

2.3 C-term:

C-term will be the time to initiate the plan that is the marketing strategy. This is when the team will have to be most dynamic, keeping in mind that every company goes about handling business deals differently. Professional opinion from professors and advisors will be most useful during this time, which will better prepare the team for when the team talks to the companies over the phone. The first 30 second pitch with the right person over the phone could potentially lead to a more official business meeting, where potential real terms could be discussed. If an attempted company declines, changes to the marketing plan will be made, and the process will be started over with a new manufacturer. The goal by the end of the term, for March 5, 2017, is to obtain a non-exclusive licensing agreement with an established electrocardiogram manufacturer.

3.0 Development Resources

- All previously gathered literature research and market data.
- All established medical professional contact information, and previous interview results.

4.0 Targeted Tasks and Goals

This plan is in direct relation to the Gantt Chart displayed below:

- **March 5 - August 24**
  - **March 5, 2016:**
    - Provisional patent filing is complete. This date starts the 365-day period until expiration.
  - **March 15-August 24:**
    - Call Worcester Polytechnic Institute, receive information from registrar regarding filing to sponsor a Master Qualifying Project
    - Application for MQP sponsoring will be filed for, proper fees and expenses will be paid.
    - **Goals:**
      - Complete process for sponsoring an MQP with WPI, be ready for the start of the new school year.

- **A-term: August 25 - October 13**
  - **Week 1 & 2 (start 8/29):**
    - All team members engineer original design to incorporate functionality to the existing device.
    - Make edits to existing 3D models.
    - **Goal of Week 1 & 2:**
      - To obtain a functional device by the end of week 3.

  - **Week 3:**
    - Mechanical engineering and electrical engineering continue functional prototype design. Finish by end of week.
    - Use some form of rapid prototyping. Preferably a 3D printer on campus. Up to group discretion.
    - Management engineer begins arrangements (phone calls/email) to interview previously contacted end users.
    - **Goals of Week 3:**
      - Have a functional prototype completed for upcoming interviews.
      - Arrange a date and time with previous contacts, preferably during week 4.

- **Week 4:**
  - Attend arranged meetings with the end user to display functional prototype.
  - Allow the end users to evaluate the product, encourage ideas, and whatever input that comes to mind.
  - Record feedback, begin to determine what necessary changes need to be made while talking to contacts.
  - **Goals of Week 4:**
    - Complete all arranged meetings. Try to accomplish as many as possible. The more feedback obtained, the better.
    - Analyze feedback, begin redesigning prototype tending to feedback and suggestions

- **Week 5**:
  - Mechanical and electrical engineering students continue and finalize design modifications based on feedback.
  - Produce an updated prototype, by 3D printer, or whatever the chosen method was.
  - While redesign is taking place, management engineering student arranges meeting times with the previously contacted biomedical engineers, for second round of validation. Enough time must be given to produce an updated prototype
  - **Goals of Week 5:**
    - Redesign previous prototype.
    - Obtain an updated physical rapid prototype.
    - Arrange meeting times with biomedical engineers for the following week for professional prototype analysis and feedback.

- **Week 6:**
  - Finish the final meeting with biomedical engineers to obtain a professional evaluation of the prototype.
  - Analyze feedback, mechanical and electrical engineering students brainstorm to redesign based from the evaluation.
  - Management engineering will use the CAD files produced for the prototype to refigure a material and production cost.
  - **Goals of Week 6:**
    - Complete final meetings, obtain evaluation and feedback.
    - Apply evaluation to iteration of redesign.
    - Refigure rough material and production costs

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- **Week 7:**
  - Last week of term. If meeting with end users or biomedical engineers haven't been completed, this is the week to do so.

- Continue and finalize development of design and material costing.
- **Goal of Week 7:**
  - Finish all meeting if need be.
  - Finalize design and materials costing.

- **B-term: October 25-December 15**
  - **Week 1 & 2:**
    - Meet with Todd Keiller, have the prototype evaluated.
    - Complete any legal filings or further documentation needed to apply for a utility patent. This process will take 5-6 weeks to be completed.
    - **Goals of Week 1 & 2:**
      - Meet with Todd Keiller.
      - Accomplish all documentation needed to obtain a utility patent. The patent must be finished and obtained by the start of C-term

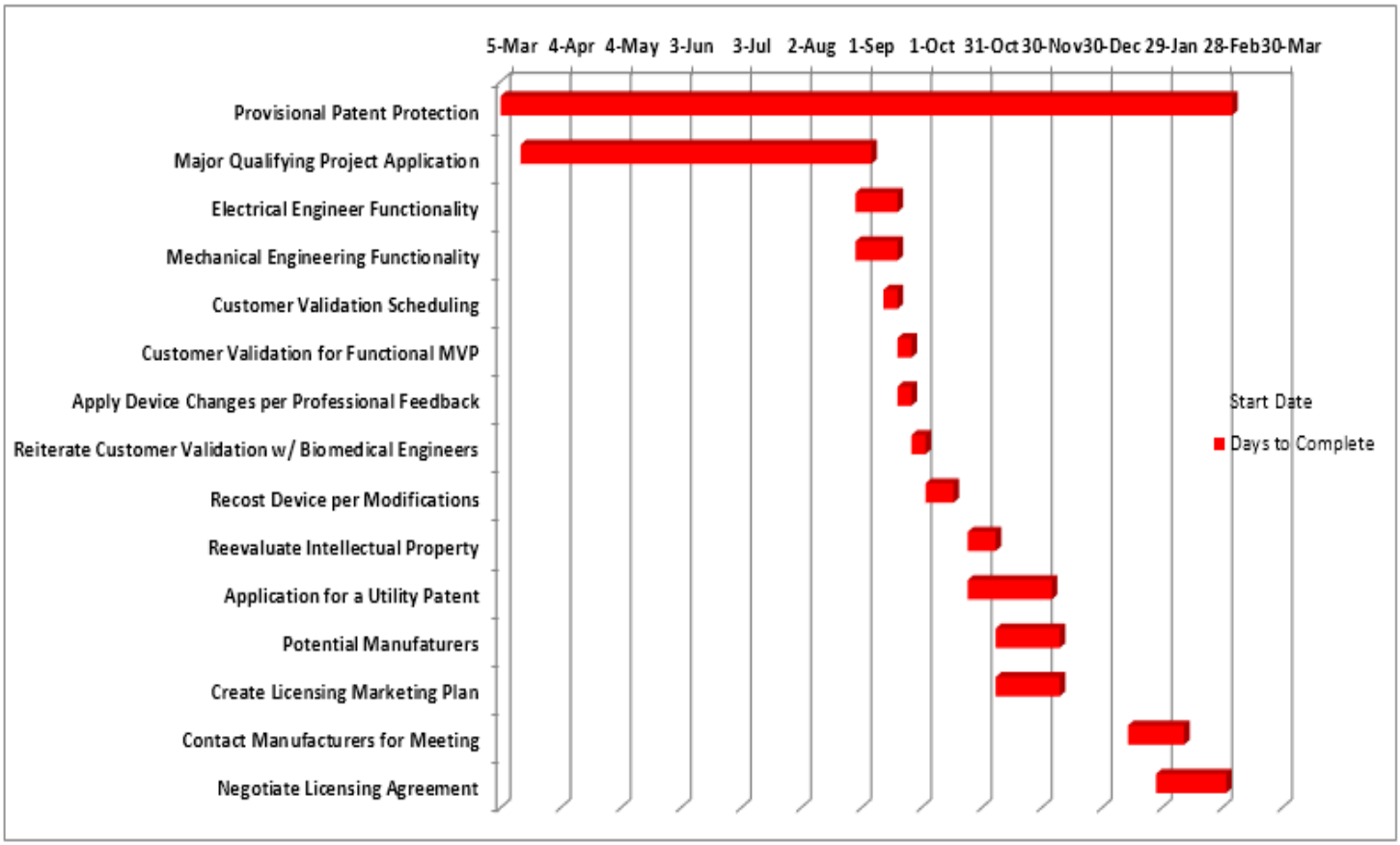
  - **Week 3,4, 5, 6, 7:**
    - Research electrocardiogram manufacturers who are potential licensing partners.
    - Determine the pieces of information needed to market the idea of licensing.
    - Draft a marketing plan to achieve a licensing agreement based on the benefits of our device, and what value it can bring to the manufacturer.
    - It is likely that each potential manufacturer will have its own marketing plan.
    - Seek advice from advisors, as well as Todd Keiller, and marketing/business professors. Seek what sort of information should be presented, and how the team should accomplish making contact with the right people.
    - Contact Todd Keiller to assure the utility patent will be owned by the start of C-term

    - **Goals:**
      - Have a finalized marketing plan(s) completed by the end of the term. This plan must be complete before any manufacturer is contact, being that sometimes a sales pitch needs to be given within the first 30 seconds to the right person on the phone in order to progress any further.
      - Have a completed and owned utility patent by the beginning of C-term.

- **C-term: January 12-February 3**
    - No week to week criteria on the fact that obtaining a business agreement such as licensing can be a complex and long process.
        - The marketing plan must be completely second nature to every group member. Calls cannot be made to manufacturers if this is not the case. Confidence is key.
        - Manufacturers must be contacted. The way in which a company will go about doing this sort of business varies greatly.
        - How the group handles all forms of communication, the second the first manufacturer is called, must be dynamic, which the group must be flexible to.
        - Through the process of obtaining the agreement, advice should be sought by professors to better adapt in order to be successful.
        - If a company declines, mistakes will be corrected, and the process will start all over with a new potential manufacturer.
        - **Goals:**
            - Successfully execute the devised marketing plans to ultimately obtain a non-exclusive licensing agreement with a manufacturer.
            - If a manufacturer is tried, but fails, a main goal is to take the experience and reasons of failure and translate them into a better plan.

5.0 Gantt Chart

Task	Start Date	Days to Complete
Provisional Patent Protection	5-Mar	365
Major Qualifying Project Application	15-Mar	175
Electrical Engineer Functionality	29-Aug	21
Mechanical Engineering Functionality	29-Aug	21
Customer Validation Scheduling	12-Sep	7
Customer Validation for Functional MVP	19-Sep	7
Apply Device Changes per Professional Feedback	19-Sep	7
Reiterate Customer Validation w/ Biomedical Engineers	26-Sep	7
Recost Device per Modifications	3-Oct	14
Reevaluate Intellectual Property	24-Oct	14
Application for a Utility Patent	24-Oct	42
Potential Manufaturers	7-Nov	32
Create Licensing Marketing Plan	7-Nov	32
Contact Manufacturers for Meeting	12-Jan	28
Negotiate Licensing Agreement	26-Jan	35
Provisional Patent Expiration	5-Mar	1



Appendix B: Provisional Patent

Retractable EKG Wiring Unit

BACKGROUND

1. Background

The use of an electrocardiogram machine is a time sensitive test reading that can be critically important in helping direct medical professionals into the next step of a patient's prognosis. The faster a patient with a cardiac or respiratory issue can complete an EKG test, the more likely the medical staff can ensure a person's health.

SUMMARY

[001] In the medical setting, organization and accessibility are crucial to maintaining efficient operations and a safe cleanly area. Machines and resources are shared within hospital settings and require convenient and accessible configurations for the end users. As most wired devices do, the electrocardiogram wires become tangled, unorganized and less accessible to our end users. This takes time away from the evaluation of patients and the next step in cardio-vascular care.

[002] Whenever a patient has any symptoms or has trouble breathing, chest pains or a history of hereditary heart disease, an EKG test is usually called for. This accounts for

many instances where an electrocardiogram test will be necessary increasing the need for an organized device

[003] A retractable wiring unit will solve these problems by allowing for the electrode leads to be wound up into the storage accessory, maintaining consistent organization, as well as simultaneous sanitation, for a convenient set-up process for future use

BRIEF DESCRIPTION OF THE DRAWINGS

[004] The present disclosure is further described in the detailed description which follows, in reference to the noted plurality of drawings by way of non-limiting examples of exemplary embodiments, in which like reference numerals represent similar parts throughout the several views of the drawings, and wherein:

[005] FIG. 1 illustrates an exploded design of the wiring unit;

[006] FIG. 2 illustrates the assembled design of the wiring unit;

While the above-identified drawings set forth presently disclosed embodiments, other embodiments are also contemplated, as noted in the discussion. This disclosure presents illustrative embodiments by way of representation and not limitation. Numerous other modifications and embodiments can be devised by those skilled in the art which fall within the scope and spirit of the principles of the presently disclosed embodiments.

DETAILED DESCRIPTION

[007] The following description provides exemplary embodiments only, and is not intended to limit the scope, applicability, or configuration of the disclosure. Rather, the following description of the exemplary embodiments will provide those skilled in the art with an enabling description for implementing one or more exemplary embodiments. It will be understood that various changes may be made in the function and arrangement of elements without departing from the spirit and scope of the disclosure as set forth in the appended claims.

[008] Referring to FIG 1, the exploded design shows the placement of each component, and how the components interact with each other. The device has 5 spools, that each hold two wires, to hold the 10 wires that consists of a 12 lead EKG. The spools are activated by pushing down a corresponding button on top of the spool to engage the spool with the crank screw used to provide radial motion to the spools. The front department of the device is a cavity that holds a sponge soaked with a sanitary agent. Each wire will be pulled through a slit in the sponge, wiping the wires as the get coiled into their corresponding spool.

[009] Referring to FIG 2, the assembled design shows the complete assembly of how the components come together to function. There are 5 spools, each holding 2 wires, a crank shaft to rotate the spools, and a hand crank to activate the crank shaft.

[010] Specific details are given in the description to provide a thorough understanding of the embodiments. However, it will be understood by one of ordinary skill in the art that the embodiments may be practiced without these specific details. For example, systems,

processes, and other elements in the instant disclosure may be shown as components in block diagram form in order not to obscure the embodiments in unnecessary detail. In other instances, well-known processes, structures, and techniques may be shown without unnecessary detail in order to avoid obscuring the embodiments. Further, like reference numbers and designations in the various drawings indicated like elements.

Changes may be made, within the purview of the appended claims, as presently stated and as amended, without departing from the scope and spirit of the present disclosure in its aspects. Although the present disclosure has been described herein with reference to particular means, materials and embodiments, the present disclosure is not intended to be limited to the particulars disclosed herein; rather, the present disclosure extends to all functionally equivalent structures, methods and uses, such as are within the scope of the appended claims.

[0012] What is claimed is:

1. A method to assist the consistent storage quality of the lead wires of an electrocardiogram machine, along with a simultaneous action of sanitation to sanitize the wires when being wrapped into storage.
2.

ABSTRACT

When operating an electrocardiogram, it is a common problem found by end users that the organization of the electrode lead wires can get tangled, and impede the set up and put away time of the operation. The device allows for consist, organized storage by retracting the wires

into an organization unit, along with sanitizing the wires while being stored. By creating this method, hospitals can become more efficient in time use while administering an electrocardiogram test, and ultimately save on costs. of operation through the end user.

Figure 1

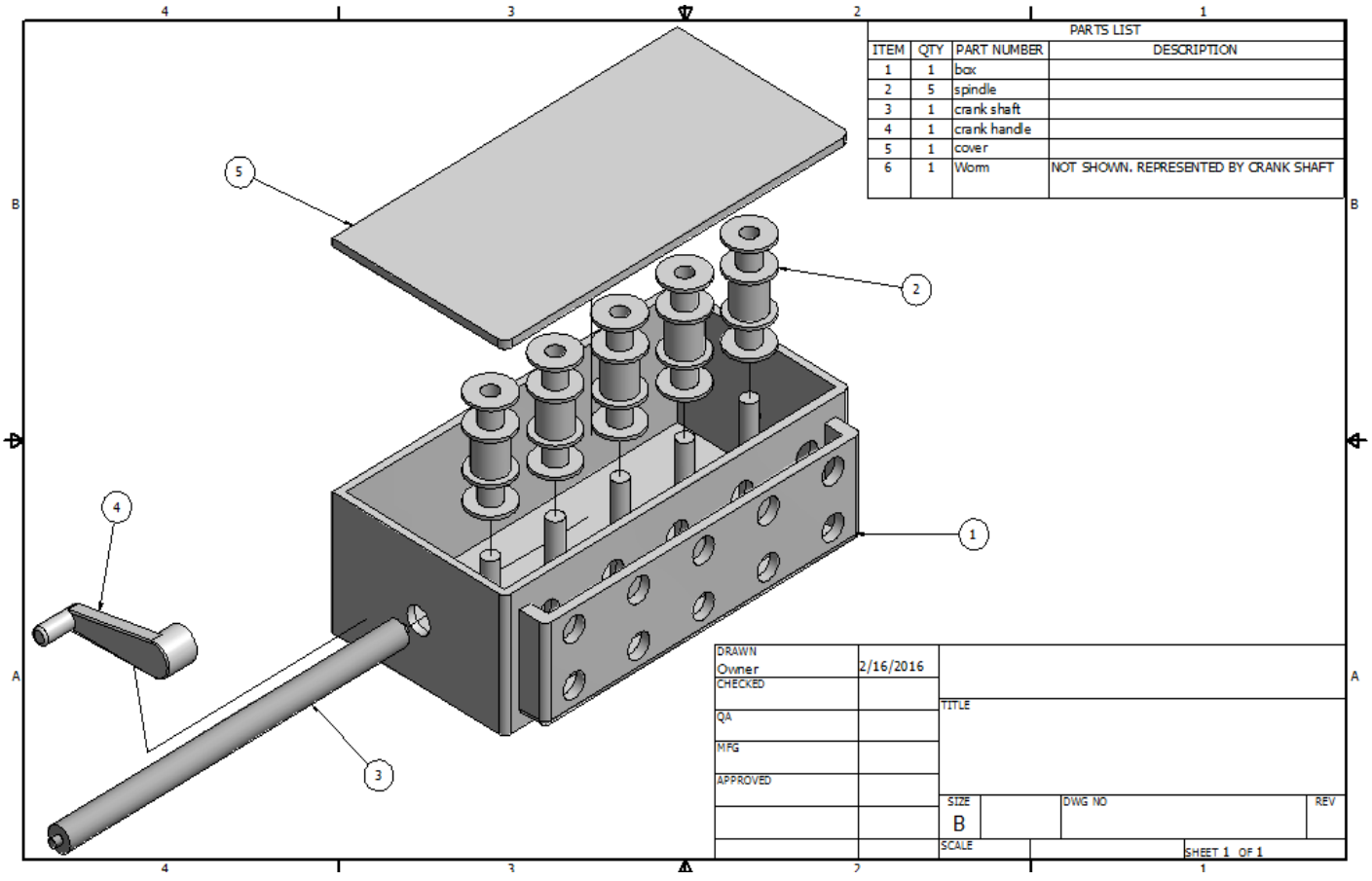
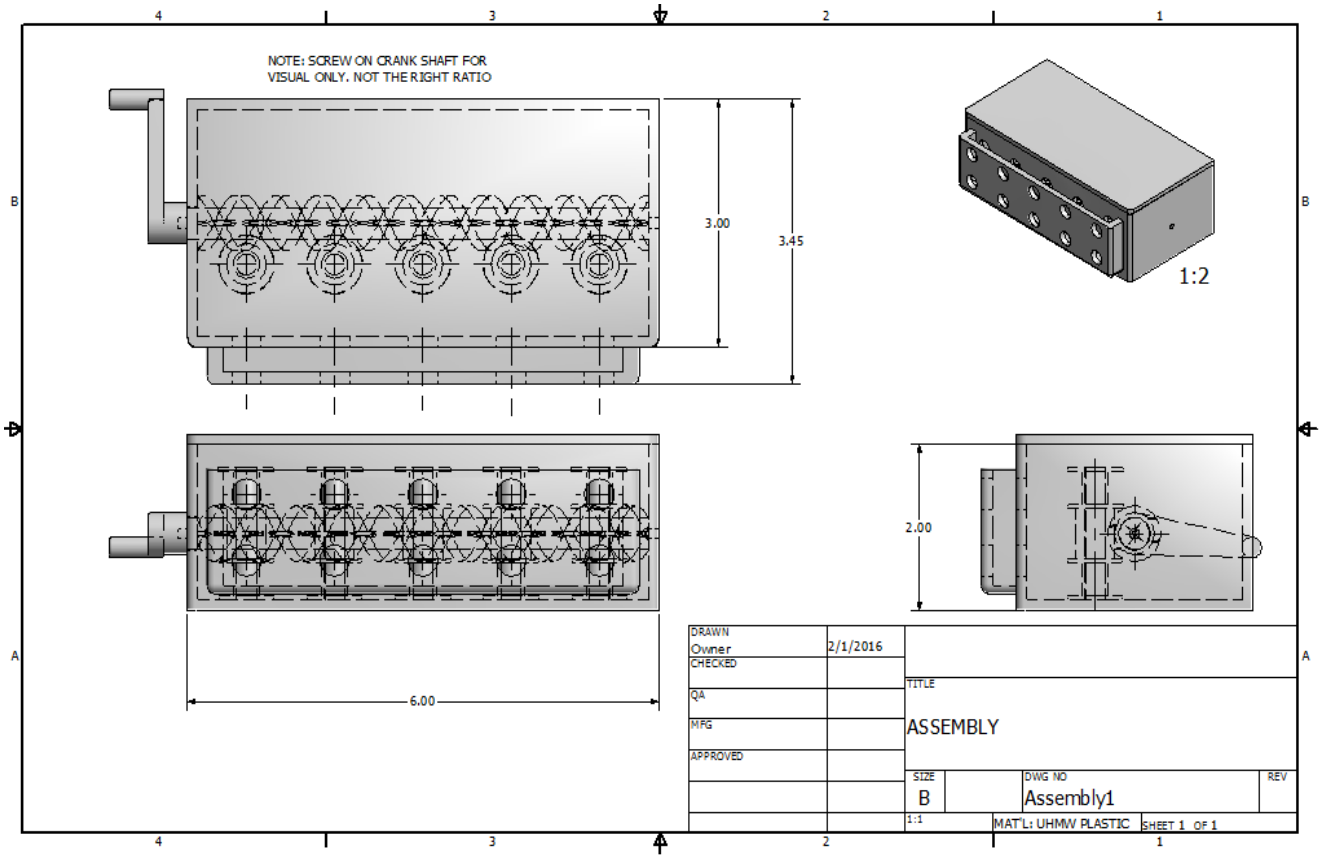


Figure 2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Appendix C: Business Model Canvas

The Business Model Canvas

Designed for: Retractable EKG Wiring Unit

Designed by: Patrick Finn, Attila Kara

On: 2/22/16

Key Partners

- Medical Device Manufacturers
- Material Suppliers
- Machining Companies
- End user feedback for Customer Validation

Key Activities

- How to sell a product to a hospital/clinic
- How to classify medical device
- Evaluating Intellectual Property
- Potential Pricing of Product
- Licensing Strategy

Key Resources

- Capital
- Provisional Patent
- Research & Development Time
- Potential Customers

Value Propositions

Impacted End Users
RN, CRN, Cardiovascular Technologist, EKG Tech, EMT, Anesthesiologist,

Pain Killers
- Neater storage
- Faster put away time
- Less tangled wires
- Less time wasted

Gain Creators
- Dollars saved to time savings
- Simultaneous sanitation
- Wire Retractability
- Saves effort
- Consistent Organization
- Time savings on sanitation

Customer Relationships

- Manufacturer contacts
- Supplier contact relationships

Channels

- Existing manufacturers distribution channels (licensing)

Customer Segments

- Electrocardiogram Manufacturers

Cost Structure

- Time
- Material
- Research & Development Costs
- Patent Expenses
- Attorney Fees

Revenue Streams

- Non- Exclusive Licensing Agreement
- Royalties

Appendix D: Surveys, Survey Results & Interview Questions

WPI 2015- 2016 MQP: Survey
Attila Kara
Pat Finn
Advisors: Karla Mendoza-Abarca, Frank Hoy

Salutations. We are senior students from Worcester Polytechnic Institute conducting interviews for our Senior Master Qualifying Project. We would like to ask for your participation in a brief survey. The goal of our Survey is to try to get a basic understanding of your daily routine in your profession and some daily inconveniences you might face. We as a group are essentially searching for potential business/entrepreneurial opportunities within your work environment, and to test out hypotheses of potential products that we have already come up with. We will not be searching for personal information other than your full name, what facility you work at, and what department. Individual responses will not be published, but an overall consensus of the answers we have collected will. This research will also help us to write our final deliverables needed for our project. This is entirely voluntary, and if the decision is made to participate, if at any time you feel uncomfortable and would like to skip a question, or discontinue the survey, this is absolutely acceptable. We appreciate you for taking the time out of your schedule to fill this out. Thank you.

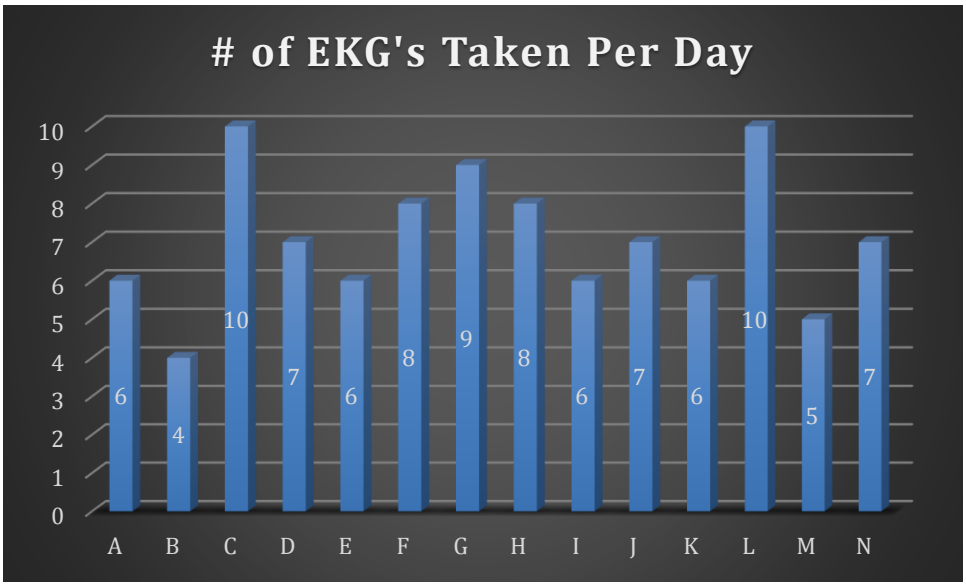
Date:
Name:
Job Position:
Years of experience:

- What kinds of tools do you use every day that require maintenance?
- How many EKGs do you take a day?
- How long does it take to apply the electrodes on a patient?
- How long does it take for a successful reading to take place?
- How long does it take to store the wires/electrodes after use?
- What is the sanitation process for an EKG machine?

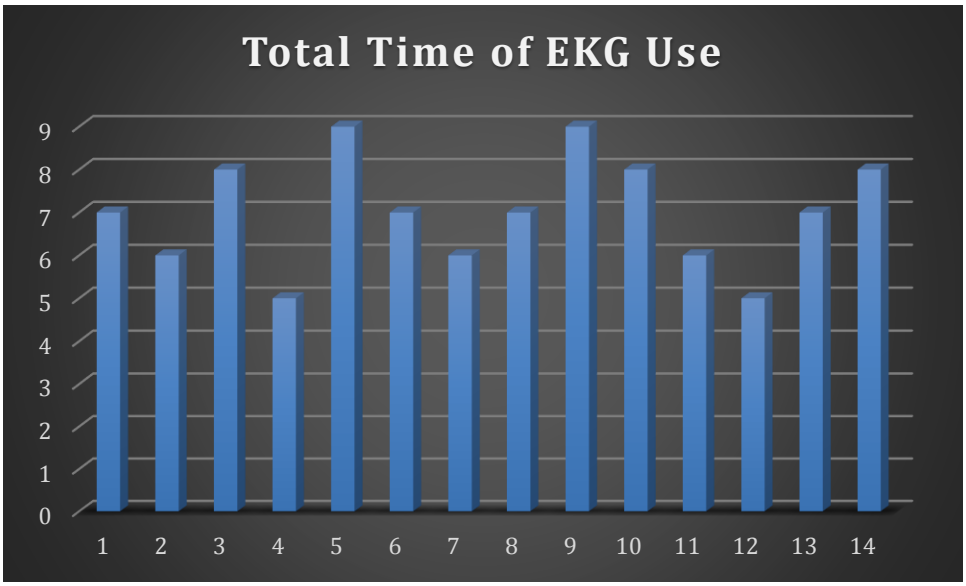
Survey Results:

These graphs are in direct correlation with the collected survey data.

Graph A: (Question 2) How many EKG's do you take a day?



Graph B: (Sum of Questions 3, 4 & 5) Total Elapsed Time of Use



Typical End User Interview Questions

Date:
Name:
Job Position:
Years of experience:
Contact email:
Contact Cell:

Getting to know the job position

- What is your job description?
- Who does your boss/ bosses consist of?
- How are you able to purchase new equipment?
    - How much do you have to spend on new equipment if you are allowed to choose?
    - Whose decision is it for what new items are purchased?

Getting to know the work day

- What kinds of jobs/task do you need to do daily?
    - Relating to patient, not relating to patient.
    - What are the difficulties/ hardships of the task? Frustrations?

What kinds of things are used daily?

- What kinds of tools do you use every day that don't require maintenance?
- What kinds of tools do you use every day that require maintenance?
    - What kind of maintenance must be done?
- What is the sanitation process for the tools used described above?
- Is there a specific storage process?
- How many EKGs do you take a day? Week? Patient #'s?
- How long does an EKG take? (how long is it supposed to, how long does it actually?)
    - What's the process?
    - What kind of data is written down and recorded?
    - how much does it cost to take an EKG?
- What is the sanitation process for an EKG machine?
- What is the storage process for an EKG machine?

Appendix E: Interview Results

9 Registered Nurses from 3 Separate Hospitals (cardiology, emergency-room, pediatrics)	
• Predominantly 12 lead EKGs • Just about every nurse reports to a nurse manager as their boss. • Any time something new is wanted, the proper paperwork needs to be filled and submitted with a nurse manager. Paperwork is relayed to the purchasing agent for evaluation. • First thing done during a shift is to tend to the assigned patients and follow procedure regarding paperwork, and patient care.	• EKGs were consistently estimated to be between 6-8 minutes, depending on how well the last person put away the machine. • Lead wires are always wiped down after administering the EKG test. • Storage is just wrapping the wires in an organized manner, and depends on how well the last person put away the machine. • Consistent complaints about having to untangle the lead wires

Biomedical Engineers	
• Work with technical side of products • Initiates conversation with competitors for better prices • Has a relationship with large companies, has leeway with prices based on other smaller items • Meet with purchasing committee's and hospital management for decision making purposes of technology • Confirmed entry into market through direct sales is a very hard process	• Some hospitals outsource their biomedical engineering teams to save money and regulate monthly budgets for supplies and available engineers • Insurance policies allow for constant monthly costs for the outsourced engineering teams • Biomedical Engineers trouble shoot malfunctioning devices and equipment regularly

3 Purchasing Agents from 2 Separate Hospitals	
• Hierarchical decision making process • Every hospital has a different protocol for purchasing and improving additional technology and supplies • Value analysis committee evaluates the request, usually consisting of Board Members, and purchasing committee members • There are value analysis forms for employees to request new equipment or supplies.	• Over 1,000$ considered capital equipment • Bio-Med would get involved with approving and advising orders • Compatibility to current equipment is a necessity • Companies have a stronghold on hospital sales • Vendors are put through a deliberate process before there company is considered for business

Nurse Educator & Nurse Manager	
• Processes requests for new technology or supplies • Vendors are not met with normally in the hospital setting • EKG machines and other equipment are shared throughout the floor	• Educate staff on proper use of machinery • Encouraged us to speak with biomedical engineers and purchasing department. • Important time protocols are taught and followed with each diagnostic technology.