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Magneticure: Business Plan Proposal

A thesis submitted in partial fulfillment of the requirements for the degree of Bachelor of Science in Mechanical Engineering and the Honors Program

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Magneticure: Business Plan

be accepted in partial fulfillment of the requirements for the degree of

BACHELOR OF SCIENCE, MECHANICAL ENGINEERING

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May, 2010
Abstract

The purpose of the Magneticure Company is to provide medical devices which increase the comfort of patients during cancer treatment processes. Upon founding, the company will be centered on its inaugural product, the MagneLift. The MagneLift was designed as a hand-operated tool for the removal of permanent magnets from the skin during medical procedures. Its primary objective is to significantly reduce the pain experienced by patients as compared to the forceful removal of the magnet by hand.

Based on marketing surveys, it was determined that an estimated 1375 units could be sold in the first year at a cost of $90 per unit. Magneticure will require an initial investment of $300,000 to cover operating equipment and start-up costs. The projected timeframe for profitability is 22 months with the company breaking even after 43 months.
Acknowledgements

I would like to show my gratitude to those who made this thesis possible. This thesis was completed as a collaborative group effort and it is my pleasure to extend credit to Chris Nation, Chase Hancock, Dale Russell, Kyle Sadanaga, and Steve Schwade for their contributions to this thesis. All have played significant roles in the researching, writing, and editing all aspects of this business plan. Without their assistance, recommendations, and support this thesis would not have been possible.

I would like to thank Dr. Jonghwan Suhr for his advice and guidance throughout this semester’s Capstone course. I am very grateful for the opportunity to learn from his extensive expertise in engineering design and finite element analysis.

I would also like to thank Josh Varischetti for sharing his expertise on the business aspects of this thesis. His guidance was pivotal to the formulation of the marketing and financial aspects of the Magneticure business plan.

It is my pleasure to thank Dr. Candice Bauer for her instruction and recommendations on several aspects of this thesis. As a guest-lecturer, Dr. Bauer was an importance resource for advice on presentation skills, business plan requirements, and the steps of planning a business.

Finally I would like to extend my gratitude to the students of this year’s mechanical engineering Capstone course. Their constructive criticism and advice was invaluable in the editing and revision of this business plan.
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Executive Summary

Magneticure initially formed as a collaborative design team of six mechanical engineering seniors at the University of Nevada, Reno. The project, which focused on the design of a medical magnet removal device (MagneLift), provided the basis for the company. Magneticure, which is based out of Reno, Nevada, is structured as an LLC. The purpose of the company is to provide medical devices which increase the comfort of patients during cancer treatment processes.

The MagneLift product began as a collaborative research effort with a medical lab located in Reno, NV. The original purpose of the device was to safely and painlessly remove a permanent magnet from the skin of rats during a clinical trial. However, after a thorough literature search and market survey, it was determined that the MagneLift could be utilized in a wide variety of medical treatments that employ the use of an externally-applied permanent magnet.

The MagneLift magnet removal device is a hand-operated tool designed specifically for the removal of permanent magnets from skin. It can be used in conjunction with any medical treatment which involves the injection of ferrous particle-bonded drugs and an externally applied magnet which serves to attract the treatment drug. In current treatments, the magnet is forcefully removed by hand, which results in patient pain and discomfort. The MagneLift is designed to painlessly remove the magnet from the patient’s skin through the use of a ferrous rod and applied force from a spring in compression. This innovation will significantly alleviate any discomfort felt by the patient which will in turn increase patient confidence in the treatment process.
An initial marketing survey indicates that a market penetration of 0.1% is feasible. This leads to an estimate of 1375 units sold in the first year. The initial selling price was set at $90 based on survey results and comparisons with similar patient comfort products which exist currently on the market.

Magneticure will require an initial investment of $300,000. This amount will cover operating equipment and start-up costs. The projected timeframe for profitability is 22 months with the company breaking even after 43 months.

Magneticure intends to begin manufacturing and distribution within the next six months. Revisions to the design will be made as needed in order to increase ease of use and ensure a cost-effective manufacturing process.

**Business Description and Vision**

**Mantra**

Professional Patient Care is our Priority

**Mission Statement**

Magneticure exists to alleviate patient pain and discomfort during certain cancer and magnetic drug targeting treatments. The safety of the patients and the professionalism of the physicians are held paramount in all aspects of design, manufacturing, and marketing. Magneticure will continue to strive toward innovative solutions to patient care and comfort concerns.
Company Vision

Magneticure strives to establish a wide customer base of cancer treatment centers across the United States. These treatment centers, working closely in collaboration with other centers and hospitals, will provide advertisement for our product through conferences and professional connections. The company will endeavor to expand with other product lines which share the same goal of increasing patient comfort through innovative means.

Keys to Success

The keys to success for Magneticure are as follows:

1. Initial capital investments secured through investors, loans, or grants.
2. Provisional patent application filed.
3. Set-up and manage a sales interface via a website.
4. Begin to generate revenue from U.S. and foreign markets.
5. Successful acceptance of product by FDA.
6. Increased product development and continued market share gains.

Business Objectives

The principal objectives of Magneticure are as follows:

1. To achieve a 0.1% market penetration in the breast cancer and sensitive tissue treatment markets by year four.
2. Achieve sales profit $300,000 by year the end of year five.
3. Keep manufacturing and distribution costs below 60% or revenue.
4. Increase sales volume by 25% annually.
5. Self-sustaining by year four.
6. Greater than 25% return to investors by year six.
7. Develop new product lines.

**Brief History**

Magneticure was created by six seniors in the mechanical engineering department at the University of Nevada, Reno. It was created as a project for an entrepreneurship in engineering course (ME 452) and is centered on a magnet removal device for use in conjunction with an emerging field of cancer treatment methods that utilize permanent magnets. Current treatment involves the painful removal of the magnet by hand.

**Market Analysis Summary**

**Market Segmentation**

The market projections are based on the data trends from the survey and the following statistics provided by the Bureau of Labor and the Census Bureau:

| Table 1: Medical Professionals and Locations Available to Administer Treatment |
|---------------------------------|-----------------|
| Radiation Therapists            | 15,200*         |
| Registered Nurses               | 2,618,700*      |
| Oncologists                     | 12,261**        |
| Oncology Offices                | 9,123**         |
| Cancer Patients                 | 1,479,350**     |

* http://www.bls.gov

**http://www.census.gov

Although the average oncologist sees over 400 patients per month [Erikson, 2007], The MagneLift is primarily designed to be used in conjunction with treatments
targeting lumped and/or surface carcinoma or sarcoma type cancers which correspond to 13% of the all cancer diagnoses as shown in Figure 1.

![Market Segmentation](image)

**Figure 1: Market share showing percentage of applicable cancers**

On average there are 3 doctors for every 2 offices, combined with the projected market penetration of 0.1% leads to a projected demand of approximately 1375 units annually.

**Market Analysis**

Magneticure’s MagneLift magnet removal device is designed for use in conjunction with several medical treatments and thus the important demographics are those of the medical professionals performing the treatments or purchasing the equipment.

The results of the preliminary marketing survey indicate several important trends:

- Oncologists, Nurses and Administrators at an average office see more than 50 patients annually
  - On average about 15-20 meetings per patient are required for treatment
- Patient comfort and professionalism were valued over durability and price
• Respondents reported that a device designed for individual use only slightly increased the perception of professionalism.

This survey was conducted at a medium sized oncology office with a total of 30 samples and was suitable for planning purposes.

A previous formal survey also indicated a willingness of medical professionals to pay a higher price point than expected. This is most likely due to desensitization to prices with included liability costs which are ubiquitous in the realm of medical supplies.

**Industry Analysis**

The domestic health care industry is controlled by hospital buying and managed care groups (i.e. HMOs and PPOs). Both of these major players seek to reduce the total overall treatment cost per patient and thus shape the purchasing choices of doctors, nurses, and administrators. The challenge in the domestic medical device industry can be understood as offering a patient comfort and professionalism commensurate with price.

Although domestic markets allow sales through ease of logistics and proximity, foreign markets with socialized medicine represent a boon in three main areas [Shapiro, 2008]:

• Decreased liability (government assumed)

• Shorter review periods (government assumption of liability and limited patient rights)
• Instant market infiltration (government device/procedure approval is nationwide)

The socialized medicine markets, specifically those of Canada and Europe, require significantly less effort to overcome the initial cost inertia.

**Competition**

A product based on an emerging technology is by definition part of an emerging market. The initial competitive advantage provided by such a classification is short lived, however, due to a straightforward mechanical design. Competitors can understand and imitate the design, necessitating the use of other means of discouragement.

The plan to discourage must make careful use of price upon the certain emergence of competitors. Diligent market observation and aggressive methods to lower production costs will be employed along with regular defense of intellectual property. The following measures will be undertaken for successful protection:

• Non-Disclosure agreement

• Patent Application

• Inception of a legal fund (beginning in January 1, 2011)

Magneticure will be prepared for rigorous legal protection of concepts and ideas.

**Projected Buying Patterns**

In order to better understand the target demographic, a secondary marketing survey was conducted and analyzed. A sample of the survey is shown in Appendix A. This survey was given to registered nurses, doctors, and administrators in their respective places of business. The following useful trends were observed:
• Respondents believed the device will definitely or probably increase patient comfort
• Respondents were not sure that the device would increase professionalism
• Respondents reported that they or their employers would probably buy the device
• 72% of respondents believed that the $100 price point was appropriate (probably would buy)

This survey also included an option for design and design feature commentary. Many of the responses (i.e. excessive length, lack of grip, difficulty achieving necessary spring force) from actual prospective users were taken into account for the latest design and can be seen in the current model of the MagneLift.

**Description of Products and Services**

**Product Description**

The magnet removal device (MagneLift) was developed to assist with the medical processes using high strength permanent magnets. In current procedures, pain is inflicted on the patients when the magnets are being removed after the processes have been completed. The medical processes using these magnets are processes, such as magnetic drug targeting and cancer treatments, using ferrous particle injection. A permanent magnet is then placed on the skin for the duration of the treatment (~1 hour) and is then forcefully removed by hand resulting in patient pain and discomfort. A cancer treatment which uses this method and is currently being tested by a collaborative research group is fully explained in Appendix B.
The development of MagneLift eliminates the problem of patient comfort which is inherent to this type of treatment by reducing the patient’s pain significantly and increasing the patient’s emotional comfort through making the magnet removal process quick and easy. MagneLift is a device that uses a nonferrous housing with a ferrous rod and a spring force to remove the permanent magnet from the patient’s body. A medical professional places the device over the magnet and uses their thumb to push down the ferrous rod within the housing until it contacts the magnet. While the rod is being moved toward the magnet it compresses a spring which will use its force to pull the magnet from the patient into the housing. While being depressed a stop latch is released that will hold the ferrous rod slightly depressed so the magnet will remain inside the housing of the device. The device holds the magnet inside its housing until the stop latch is released. The medical professional can then remove the device from the patient’s body and then push the stop latch, releasing the rod pulling the magnet from the rod and releasing it from the device. The magnet is dropped out of the housing which can now be reused, completing the magnet removal process.

Scope

This innovative device applies to the above described cancer treatment as well as treatments involving magnetic drug targeting. These treatments are most feasible in situations where solid tumors exist close to the skin such as carcinoma or sarcoma. This allows for the most effective use of the permanent magnet as a means of collecting the ferrous particle-bonded drug. In the majority of these treatments a magnet of similar size and strength is used, which facilitates the use of the MagneLift for easy and painless removal of the magnet from the skin.
Clinical Advantages

The proposed clinical advantages of the product are an increase in patient comfort and the professionalism of doctors during the administration of certain cancer treatments.

Literature Search

A full literature search was completed in order to ensure all proposed intellectual property was fully protectable through a U.S. patent. Although several similar devices were found, it was determined that MagneLift did not infringe on any claims made.

Alternative medical treatments which use the principles of injectable ferrous particles were searched in order to determine the full scope of the market for MagneLift. Several patents and patent applications were found for medical treatments which use magnetic drug targeting as a way to contain drugs in a specified area of the body to speed up treatment results. Journal articles which chronicled the previous decade of academic research on magnetic drug targeting were also investigated. It was found that several research labs across America and in other parts of the world were in the process of completing both human and animal clinical trials. After the research was compiled, it was determined that these researched and patented medical treatments would be a viable addition to the potential market for Magneticure.

The full results of the literature search are in Appendix C.
Product Development

SWOT Analysis

Figure 2 shows a SWOT analysis of Magneticure’s MagneLift, which analyzes the strengths, weakness, opportunities, and threats to the company and product. A more detailed explanation of this diagram is in Appendix D.

![SWOT Analysis Table]

**Figure 2: SWOT Analysis of company and product**

Development Strategy

It was determined that the optimal design methodology for Magneticure would be the waterfall development model which is shown in Figure 3. This has allowed for a streamlined process which facilitates engineering analysis of the product and prototype. Since the product is relatively small with few components, it was comparatively simple to construct multiple prototypes, which has allowed for plenty of structural analysis of
different materials. Therefore, the design team has greatly benefitted from the ability to analyze different material stresses through Finite Element Analysis to find the best mode to move forward with the design.

![Waterfall development model](http://cnx.org)

**Figure 3: Waterfall development model utilized during product development procedure [http://cnx.org]**

While designing the MagneLift, several design objectives were considered. To maintain the sustainability of the company, it was necessary to design the product with a finite life. Thus, a higher volume of MagneLift devices would be sold as others wore out. It was decided that this failure would occur internally because an external failure would risk liability due to injury to the patient and/or physician.

Several design constraints dealt directly with the ergonomic features which included the ability to grip the device and the force required to depress the plunger. When creating the housing for the MagneLift, the diameter was considered in order to ensure a comfortable and adequate grip for a large majority of physicians. The length of the housing was also considered in order to balance the need for stability during positioning with the need for adequate spacing between the physician’s hand and the patient. In addition, the force required to depress the plunger was considered when designing the
plunger rod and spring assembly. It was necessary to design the device so that it was comfortable and easy to depress the plunger with a thumb.

Product Objectives

Design objectives

- 50% reduction in pain (using the Wong-Baker Pain Scale shown in Figure 4)
- 75% of patients experiencing an increase in emotional comfort based on questionnaire answered after treatment

![Image: Universal Pain Assessment Tool](http://www.pacificu.edu)

Figure 4: Face Pain Scale used to quantify pain reduction [http://www.pacificu.edu]

The main objective of Magnelift is a 50% reduction of pain that a patient experiences when the magnet is removed during specific cancer treatments. When the magnet is removed by hand, an external force is applied to the magnet to lift it from the patient’s body. When the magnet is being removed the patient’s skin undergoes elastic stretching which inflicts pain to the patient. MagneLift is designed to apply pressure to a magnet holder placed between the magnet and the patient. This ensures no stretching of the skin during removal of the magnet, significantly reducing the pain inflicted.
As a secondary objective to reduce the pain and discomfort experienced by the patient, MagneLift will impose a professional approach to remove the magnet, increasing the patient’s emotional comfort and enhancing the overall perception of the medical procedure. When the magnet is removed by hand there is a sense of underdevelopment and unprofessionalism. This is understandable, due to the significant amount of force which is applied by hand and consequently stretches the sensitive tissue. There is a level of professionalism expected during a medical procedure and with the use of MagneLift, this will be achieved.

The most effective way of quantifying the tangible benefits of using MagneLift is to conduct surveys of a patient’s physical and emotional comfort when the medical process is in clinical trials. For pain reduction and professionalism, the patients will first have to experience the removal of the magnets by hand then experience the removal of the magnet with MagneLift. The subjective nature of the data acquisition process necessitates a large sample size if an accurate trend is to be observed. This is not a foreseeable problem since the procedure will need to undergo clinical trials including a much larger sample size than what is required for an accurate reflection of the patient experience and the benefits of using MagneLift.

Product Design

The design and construction of a working prototype of MagneLift was completed in three steps.
1. Design analysis: Both Finite Element Analysis and analytical calculations were implemented. The design was analyzed for magnetic pull force, required spring force, spring fatigue, Von Mises stress, and displacement.

2. Material selection: The results from the design analysis were used to select the required materials and dimensions.

3. Testing: Several tests will be completed to verify the ease of use, continuity of the magnetic field strength, reliability of magnet removal, and number of cycles until failure.

A complete description of the product design process is explained in Appendix E.

**Product Development Timeline**

Adherence to a schedule was necessary for a successful completion of the prototype. A Gantt chart is shown in Figure 5 to provide a clear timeline of major deadlines for the creation of the MagneLift prototype.

![Gantt chart showing major milestones](image)

**Figure 5: Major deadlines for the creating of the final prototype.**

The major milestones in the design and construction of the prototype have been completed including the initial conceptualization, literature search, design analysis, and construction. The final prototype design idea has been completed through the use of...
SolidWorks modeling and FEA. The prototype has been constructed and is currently in the testing phase.

**Government Standards**

In order to ensure that the design and manufacturing of MagneLift is as safe as possible, the International Organization for Standardization standards for general medical equipment will be followed (11.040.01). This set includes standards for quality management (ISO 13485:2003), application of risk management (ISO 14971:2007), application of usability engineering (IEC 62366:2007), and primary packaging materials (ISO 15378:2006).

MagneLift is classified as a noncritical medical device since it is unlikely to come in contact with an open wound or blood and other bodily fluids. Therefore it is not necessary to fully sterilize the product between each use; instead a simple disinfecting regimen may be followed. The Center for Disease Control requires that the product be disinfected with an EPA-registered disinfectant [Guidelines…]. Proper cleaning instructions must be included with all products sold as per regulations. These instructions will be formulated to ensure that all government and industry standards are met.

**Liability**

Since Magneticure is a medical device company, liability is a main concern. There are three main areas of liability that must be addressed: defectively manufactured medical devices, medical devices with a defective design, and defectively marketed medical devices [Product Liability…].
A quality control division will be implemented in order to oversee all aspects of the design process. Extensive analysis and testing will be conducted on all parts and materials used in the final product. Safety features will need to be designed into the product to prevent improper use. It is essential to keep accurate and detailed records of all analysis and testing during this phase so that it could be used as evidence during a lawsuit to disprove any allegations of negligence. Quality control will also be heavily involved in the manufacturing process. Thorough testing will be completed on all materials and final products in order to ensure a high quality product. In order to avoid a defectively marketed device, thorough instructions will be written and supplied with every product. These instructions will include proper use, warnings against misuse, proper storage, proper cleaning and disinfection, and maintenance.

Unfortunately, even with these measures in place, there is no guarantee that a lawsuit will not result. Therefore, sufficient liability insurance is necessary. These policies are usually sold on a per item basis. Appendix F is a sample insurance application that will need to be submitted before manufacturing and distribution begin.

**After Market**

The idea of disposable covers for the MagneLift was considered as a possible add-on product and would keep the device sterile for use from patient to patient. However, it was found that such a product would be classified as non-critical and only a simple cleaning with an EPA-registered disinfectant is required. Therefore, it would be unnecessary to attempt to provide the customer with an add-on item that most likely would be purchased in bulk.
Although this product will not require routine maintenance, nor will it require much in the way of accessories, there are parts contained within the device that could potentially break due to wear. It will be more cost-efficient for both consumer and manufacturer to replace worn-out products.

A viable option for an after-market product would be the plastic magnet holder. This part would be replaced after each use for each use for medical sanitation reasons. A large quantity of these could be sold to be use with the reusable MagneLift model.

**Organization and Management**

**Organizational Structure**

Magneticure will be organized under the direction of the company president, Heather Culbertson. As the chief design engineer, Chris Nation will oversee all aspects of the design and will be responsible for ensuring that a working prototype is completed on time and under budget. Chris will also oversee all activities and responsibilities of the industrial engineer, materials specialist, and quality control manager. The marketing director, Chase Hancock, will handle all aspects of marketing and customer relations until Magneticure has the sufficient capital to add additional employees. The financial officer, Dale Russell, will balance the books, manage the budget, and oversee purchasing. The full company organizational structure is outlined in Figure 6.
Legal Structure

Magneticure will be structured as a Limited Liability Corporation (LLC). This will allow members’ assets to remain safe from the corporation’s debts and therefore makes which therefore makes it more attractive to potential partners and investors. Furthermore, it allows for the same tax efficiencies as a partnership.

Licenses Needed

- Business License
- Medical Devices, Equipment, and Gases (MDEG) License to Distribute obtained through state offices (NRS 639).
Principal Investigators / Key Personnel

Heather Culbertson—President

Heather Culbertson is currently a senior in mechanical engineering at the University of Nevada, Reno. She has gained extensive leadership and managerial skills through offices held in the school’s chapter of the American Society of Mechanical Engineers (ASME). She is currently vice-chair and has held the office of secretary in the past. She has gained project experience through research conducted and the University of Houston and the University of Nevada, Reno. She has experience working directly with customers through employment at a library and a retail store.

Chris Nation—Design Engineer

Chris is the most qualified person for this position because he has had more than 5 years in the machining and fabricating industry allowing him to foresee possible design problems. He is also proficient in SolidWorks allowing him to design and theoretically test the product before it is constructed saving on material and labor costs.

Chase Hancock—Marketing Director

Currently pursuing a B.S. in mechanical engineering, Chase is able to understand, promote and improve upon technical details and selling points for Magneticures’ Magnelift. This technical background in combination with successful projects in previous prototype development courses help give shape and place to an emerging product. Chase has also earned a B.A. in French and has lived abroad in both France and Spain, making him uniquely qualified to tap the expanding markets of socialized medicine. He also possesses important local connections to Oncological resources, providing much insight into both product development and marketing strategy.
Dale Russell—Financial Officer

Dale Russell is a senior Mechanical Engineering student at the University of Nevada, Reno. Through his coursework, Dale has excelled in structural and material analysis. In addition, he has served as a Civil Engineering Intern for the Nevada Department of Transportation for two summer terms. These internships helped create a solid foundation for engineering design and teamwork. Dale also worked as an Engineering Assistant for Vital Systems Corp. in which time he gained real-world work experience with Solidworks and ANSYS.

Steven Schwade—Industrial Designer

Mainly focusing on design revision ergonomics, it will be Steve’s responsibility to ensure that the product is in its most useable from. Having worked directly with customers for the past 10 years and supervising technicians for four years Steve has developed an understanding of the limitations of both the educated workforce and the general public. This experience will give an understanding of the common mistakes made when using the product and expedite the overall design/revision process.

Kyle Sadanaga—Quality Control Manager

Kyle Sadanaga is a mechanical engineering major at the University of Nevada Reno, planning to graduate in May of 2010. He has a strong background in customer service and public relations, which will incorporate well in a team atmosphere. He has also taken many engineering classes that heavily involve the design process, such as Engineering Communications and the first Design Capstone course. His years of experience in coaching and teaching will also be essential in communicating ideas to the
other members of the company, as well as bringing a sense of task management to the company.

Full resumes of all principle investigators are in Appendix G.

Facilities

The main facility in the physical construction of the prototype was the machine shop in the Palmer Engineering building. This included the machining of materials using specific devices such as the horizontal lathe, MIG welder, and horizontal chop saw. This machining was completed with consultation from machinist Tony Berendsen. He offered advice regarding dimensioning, use of machines, and tolerances to ensure the quality of construction of the MagneLift device.

For welding processes, the personal residence of Chris Nation was utilized. This also included the assembly of non-machined components, such as the spring.

The medical lab group facility was and still is the main testing facility for the rats and pain tolerances. Since they are the licensed professionals, they will be able to provide insight into industry standards, as well as testing of the prototype to provide a quantification of the reduction of pain. Furthermore, the medical test group will provide their thoughts on further improvements to be taken into account for future iterations of the device.

The Engineering Computing Center (ECC) is used for business meetings between company personnel, as well as between the company and potential investors. The computers and programs were used to critique the design of the prototype through the use of SolidWorks models and FEA to analyze forces and stresses within the device.
These facilities and resources were vitally important to the completion of the prototype, as it will not cost the company to make use of them.

For mass production, it was determined that outsourcing injection molding was the most financially feasible option. Magneticure will solicit bids from injection molding company in order to find the most inexpensive choice. The steel rod will be fabricated in the Magneticure warehouse since this is the most economical option. The MagneLift will also be assembled on site.

Acknowledgements

Several people outside of the group of six principle investigators were instrumental in the development of this product proposal and provisional business plan. Dr. Jonghwan Suhr and Josh Varischetti provided the team with their expert input concerning marketing, business plan formation, and product design. Candice Bauer offered her abilities as initial business plan analyzer. Tony Berendsen was supportive with advice concerning machining and tolerances. Without the help of these individuals, the Magneticure business plan would have stayed in the nascent stages of planning.

Strategy and Implementation Summary

Marketing and Sales Strategy

As a result of the second survey and extensive research the plan to market and sell the MagneLift has been expanded and further detailed. The process consists of three phases:

- Phase 1: Marketing and sales to animal trials and research groups. Immediate inception following receipt of necessary funding.
• Phase 2: Marketing and Sales to research groups conducting clinical trials on humans with the label “for investigative use only.” Immediate action may begin on European markets due to the European Union Clinical Trials Directive (EUCTD) progressive stance on hypothetical testing on humans [Bosanquet]. Health Canada and the Consumer Product Safety Bureau [www.hc-sc.gc.ca] take a similar stance.

• Phase 3: Marketing and sales based on FDA and European Medicines Agency approval.

Medical devices and processes, regardless of research locale, are almost universally accepted six months to a year earlier in the European Union than the United States [Fogorus]. This necessitates that Magneticure be present in the development stages of the Magneto-rheological fluid treatments with which it is associated at the appropriate time respective to their approval system. The promotional strategies have been adjusted accordingly.

**Promotion Strategy**

Two members of the Magneticure team will act as travelling sales representatives. They will have free samples for distribution and have been scheduled for the conferences and trade shows:

**PHASE 1**

• Society of Clinical Research Associates, Dallas, Sept. 24-26, 2010

• One east coast conference, TBD

• One west coast conference, TBD
**PHASE 2**

  - Specific heading that Magneticure falls under
- MEDICA, Dusseldorf, Germany Nov. 17-20\textsuperscript{th}, 2010
  - Clinical testing on humans underway in this city
- BIOMEDevice, Boston, May 2011
- Medical Design & Manufacturing East (MD&M East), New York, June 2011
- Other regional shows depending on team availability (Fall)

**PHASE 3**

See Sales Programs for permanent platforms instituted to aid with overall marketing and sales.

**Pricing Strategy**

With a budget revision, the MagneLift will be offered at a lower introductory price of $90. This a summation of the material costs, liability insurance, and total fixed costs and the projected worth of professionalism and comfort based on the survey results.

**Sales Forecast**

The sales projections have been broken down logically using the AIDA method [Harris, 2006]. Figure 7 breaks down the entire market to justify the 0.1% penetration figure.
Sales Programs

Currently the website is being constructed with the domain name www.magneticure.com. This is one of the main avenues for direct sales and dissemination of information about Magneticure’s products. Although most social networking sites are not acceptable means to market a medical device, there exist a multitude of opportunities via medical specific groups and forums that are easily linked back to the company website.

The use of existing large distribution networks is under consideration for marketing Phase 3, but not essential or relevant for the near future.

Secondary Survey and Target Market Data

Earlier surveys have established the target market as the doctors and registered nurses who would administer the cancer treatment for which Magnelift was designed to aid. In
order to better understand the goal demographic, a second more thorough survey was distributed in conjunction with a brief interview (when possible).

- Free sample products (150) to demonstrate, display and donate
- Two qualified company employees will act as sales representatives

**Sales Strategy**

The sales strategy will center on the 4 P’s suggested by the Small Business Administration: Price, Promotion, Products, and Placement.

**Financial Management**

**Start-up Cost**

The fundamental portion of new company’s budget is the start-up cost. Table 2 shows the considerations for start-up money needed for day one—this does not include operating costs as those will be discussed individually and in more detail.
Table 2: Start-up Expenditures

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost</th>
<th>Qty</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Machines</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Horizontal Lathe</td>
<td>$2,000</td>
<td>2</td>
<td>$4,000</td>
</tr>
<tr>
<td><strong>Patent</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$20,000</td>
<td>1</td>
<td>$20,000</td>
</tr>
<tr>
<td><strong>Business License</strong></td>
<td></td>
<td>1</td>
<td>$100</td>
</tr>
<tr>
<td><strong>Advertising</strong></td>
<td></td>
<td>4</td>
<td>$12,000</td>
</tr>
<tr>
<td><strong>Business Cards</strong></td>
<td></td>
<td>6</td>
<td>$450</td>
</tr>
<tr>
<td><strong>Office Supplies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Computers</td>
<td>$1,000</td>
<td>3</td>
<td>$3,000</td>
</tr>
<tr>
<td>Software</td>
<td>$5,500</td>
<td>1</td>
<td>$5,500</td>
</tr>
<tr>
<td><strong>Furniture</strong></td>
<td></td>
<td></td>
<td>$7,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$52,050</td>
</tr>
</tbody>
</table>

The machinery to be purchased is two gently used Baileigh PL-1440 Horizontal Lathes. The cost of each lathe is $2000 with a total expenditure of $4000. After a thorough patent search and assorted legal fees, the cost of the patent has reached $20,000. Other notable costs include the office supplies. The three computers purchased will consist of two desktop computers which will serve as a workstation for a design engineer and sales representative, and a laptop which will be utilized in the warehouse. Software for these computers includes Microsoft Office and one seat of SolidWorks. The total software cost is $5500—breaking down as $100 for Microsoft Office and $5400 for SolidWorks. In addition, three desks, several chairs, several light fixtures, rugs, an assortment of trash receptacles, fresh paint, and other necessary building renovations as
well as the labor costs to perform said renovations account for the furniture cost of $7000. The only other substantial start-up cost comes from advertising/marketing events that will start to introduce MagneLift. At $450 and $100, the business cards and business license, respectively, are trivial costs included in the start-up expenditures.

**Salaries and Fringe Taxes**

A substantial contribution to operational cost includes the salaries of Magneticure’s employees. There are six founding members who will serve as a major portion of the workforce to create the MagneLift, in addition to two part-time employees, which are needed to cover some assembly and manufacturing needs. Each founding employee has agreed to work for $35,000/year salary until the company is able to break even and offer added compensation. The part-time assembler and manufacturer wages will start at $8.00/hour and $18.50/hour, respectively. With each employee come his or her fringe benefits that are laid out in Table 3.

<table>
<thead>
<tr>
<th>Item</th>
<th>Rate</th>
<th>Employee Avg Salary</th>
<th>Estimated Part-Time Employee Wages (total)</th>
<th>Salaried Employees</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Security</td>
<td>6.20%</td>
<td>$35,000</td>
<td>$16,500</td>
<td>6</td>
<td>$14,043.00</td>
</tr>
<tr>
<td>Health Insurance</td>
<td>2.00%</td>
<td>$35,000</td>
<td>$16,500</td>
<td>6</td>
<td>$4,530.00</td>
</tr>
<tr>
<td>Medicare</td>
<td>1.45%</td>
<td>$35,000</td>
<td>$16,500</td>
<td>6</td>
<td>$3,552.50</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>$22,125.50</strong></td>
</tr>
</tbody>
</table>

Table 3: Fringe Benefits and Taxes. The total expense per year is roughly $22,000.
Prototype Cost

The cost of materials for prototype design and were fairly insignificant; however, the labor required was imposing. Costs for materials used are displayed in Table 4. The decision to utilize Nylon 101 over aluminum or stainless steel was based solely on two factors: the MagneLift is not under high stresses and the material cost is far less. Additional materials are laid out in Table 4. The R & D as well as construction time for the prototype accumulated more than 50 hours. The labor cost was assumed by Magneticure’s founding employees.

Table 4: Prototype Material Cost and Labor Breakdown

<table>
<thead>
<tr>
<th>Item</th>
<th>Vendor 1</th>
<th>Price 1</th>
<th>Quantity</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nylon 101</td>
<td>Protofab</td>
<td>$4.02</td>
<td>0.5 ft</td>
<td>$2.01</td>
</tr>
<tr>
<td>3/8” Cold Rolled</td>
<td></td>
<td>$1.05</td>
<td>0.54 ft</td>
<td>$0.57</td>
</tr>
<tr>
<td>Mild Steel Core</td>
<td><a href="http://www.onlinemetals.com">www.onlinemetals.com</a></td>
<td>$1.05</td>
<td>0.54 ft</td>
<td>$0.57</td>
</tr>
<tr>
<td>Bushing</td>
<td>Home Depot</td>
<td>$0.57</td>
<td>1 unit</td>
<td>$0.57</td>
</tr>
<tr>
<td>Spring</td>
<td>Home Depot</td>
<td>$0.55</td>
<td>1 unit</td>
<td>$0.55</td>
</tr>
</tbody>
</table>

TOTAL COST $3.70

Advertising

Advertising for Magneticure’s market is not typical. Because of the nature of the product, the best way to bring attention to MagneLift is to attend trade shows to offer demonstrations, free samples, and network. The average cost for a trade show is roughly $3000. This includes travel expenses, trade show fees, and product cost. The specific show dates and names will be covered in the marketing section.
Facilities

While prototype construction was handled within a team residence, more room is required in order to produce at the desired rate. Through Craigslist a warehouse of 1,800 sq ft in a commercial complex was chosen. The rent for this building is $1,100 per month.

Utilities

Utility costs considered include power, telecommunications, and waste management. NV Energy, Charter Communications, and Waste Management, Inc. have provided estimated utility costs totaling $15,000/year or $1350/month.

Cash flow Projections and Break even Analysis

As shown in Figure 8, at the end of month 22, production levels become significant enough to sustain the operating costs of Magneticure. All costs accrued up to that point minus revenues accrued to that point total $330,000. This amount includes the $52,050 in start-up expenditures. Because the founding members believe so adamantly in this product and its success, a total investment of $30,000 has been put together from the group—thus the total start-up capital needed to ensure proper funding is $300,000.
Upon an initial investment of $300,000, Magneticure is able to conduct day-to-day business. This can also be seen in more detail from the Cash-Flow statement (Appendix H). After 22 months of operation, the production levels are stable enough to reach profitability. In addition, the breakeven point falls under month 43. One year after breaking even, Magneticure anticipates a profit of $300,000. The breakeven analysis is displayed in Figure 9.

![Break Even](image)

*Figure 9: Break-even Analysis which shows 54 months as the break-even point*
Bibliography


“Guidelines for Environmental Infection Control in Health-Care Facilities”. Retrieved February 26, 2010 from <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm>


APPENDICES
Proposed Medical Magnet Removal Device

GENERAL INFORMATION: Emerging cancer treatment methods utilize the injection of ferrous particles into the skin near tumors and then use magnetic forces to manipulate them. The treatment is relatively pain free, but removing the magnet can be painful when the affected area is thin or sensitive tissue (breast cancer, etc.). This leads to the need for a removal device.

USAGE: The proposed device (pictured above) will have a straightforward method of operation. The magnet holding bay is placed over the magnet to be removed and the plunger is depressed by the user. The load spring is compressed, contacting the attached iron core with the magnet. The magnetic flux from the iron core has a larger attraction than that of the subdermal particles and the magnet is painlessly removed along with the device itself.

1. Will this device serve your professional needs?
   - Will this device serve your professional needs?  Definitely
2. Does this device have the potential to increase patient comfort?

- Does this device have the potential to increase patient comfort?  Definitely
- Probably
- Not Sure
- Definitely Not

3. How likely is your clinic\office\treatment center to buy Magnelift?

- How likely is your clinic\office\treatment center to buy Magnelift?  Definitely
- Probably
- Not Sure
- Definitely Not

4. Would you or your organization but this product at the $100 price point?

- Would you or your organization but this product at the $100 price point?  Definitely
- Probably
- Not Sure
- Definitely Not
5. Please list any comments related to the current design or design features:

Done

Please list any comments related to the current design or design features:
Appendix B: Collaborative Research Effort

Ferrous particles are injected into the cancer cells of a lab rat and then a high-strength permanent magnet is placed near the tumor. The magnet’s magnetic field reacts with the ferrous particle and begins to pull them towards it, damaging the cancer cells in the tumor as the particles move. As the particles move through the tumor and closer to the magnet, they reach an equilibrium point where they no longer move. The particles reach this point because the viscoelasticity of the tumor applies a counterforce against the particles, ultimately increasing to a force equal to the magnet’s force on the particles. This counterforce stops the movement of the particles in the patient’s body inside the tumor, where the particle will oscillate slightly and continue to damage the tumor. The ferrous particle injection process is used to damage or terminate cancer cells in order for the body’s immune system to recognize the cancer cells and remedy the problem itself. A schematic of this process is shown in Figure 10.

![Figure 10: Breast Cancer treatment currently being researched](image-url)
Appendix C: Literature Search

Related Product Patents

In order to ensure that MagneLift did not infringe on prior art, a thorough patent search was conducted. Although several products were found to have similar traits, it was determined that MagneLift did not infringe on any claims made by the inventors.

Patent number 3250962 – The “Permanent Magnet Lifting Device” (1966) is a device which uses a permanent magnet to lift metal objects and is shown in Figure 11. It includes a support frame, a permanent magnet, and an applied force that acts normally to a load. MagneLift is similar in that it includes a tube as a sort of frame and a spring which is capable of applying a force to the magnet. However infringement is avoided because this patent uses a permanent magnet to lift an object and MagneLift lifts the magnet itself.


diagram

Figure 11: Permanent Magnet Lifting Device [Palme, 1966]

Patent numbers 6015175 and 6086125 – The “Magnetic Holding Device” (2000) is a device which uses multiple magnets inside a pneumatically-controlled piston to hold
work pieces and is shown in Figure 12. There have been two separate iterations of this device, which is indicated by the two separate patent numbers. MagneLift is similar in that both products carry a magnet within a cylinder. However, infringement is avoided because this patent specifies an oval cylinder, a rodless piston, a fluid-driven piston, and the use of multiple magnets whereas MagneLift uses a rod inside a round cylinder to move a single permanent magnet.

![Figure 12: Magnetic Holding Device [Kovacs, 2000]](image)

Patent number 5428331 – The “Component substrate and method for holding a component made of ferromagnetic material” is a device designed to hold ferromagnetic materials during electroplating and is shown in Figure 13. MagneLift is similar in that both devices rely on the attractive forces of permanent magnets and ferromagnetic materials. However, infringement is avoided because this device uses a magnet to hold a ferromagnetic material whereas MagneLift uses a ferromagnetic material to lift a permanent magnet.
Furthermore, MagneLift is unique in that it is specified for medical purposes, whereas the above patents are designed for industrial applications only.

**Medical Procedure Patents**

Since MagneLift was designed for use with a specialized medical process, the initial market was too small for a feasible break-even point to be reached. Therefore it became necessary to research other medical processes which the device would be compatible with. Several patent applications were found for procedures that could benefit from the use of MagneLift.

Application number 11/317,163 – “Magnetic pole matrices useful for tissue engineering and treatment of disease”. This treatment is of the type known as magnetic drug targeting. Ferrous particles are bonded to drugs, such as chemotherapy, that need to be concentrated in a single area in the body close to the skin. A permanent magnet is applied directly to the skin in order to collect the drug in one area as shown in Figure 14. This process is similar to the one for which MagneLift was originally designed because it requires the removal of an externally applied permanent magnet. Practitioners of this
treatment could benefit from MagneLift because it would help to alleviate the discomfort resulting from the magnet removal.

Figure 14: Trapping of circulating magnetic bead/drug/DNA complexes by external magnet [Steinhoff, 2005]

Patent number 7189198 – “Magnetically guidable carriers and methods for the targeted magnetic delivery of substances in the body”. This treatment is similar to the above specified treatment in that it employs the basis of magnetic drug targeting. However, it is more specific in that it is designed specifically for the delivery of drugs to the vascular system. As shown in Figure 15, this treatment also employs the use of an externally applied permanent magnet, and therefore would be compatible with the MagneLift.

Figure 15: Externally applied magnet to collect drugs at a specified site in the vascular system of a patient [Harburn, 2007]
Application number 10/844,180 – “Magnetic particle-based therapy”. This treatment is also designated as magnetic drug targeting. However, it is different than the above two applications because it can be used to either diagnose or treat diseases and therefore covers a broader area of the medical industry. Similar to the above applications, this method also uses an externally applied magnet that requires removal at the end of the treatment and is therefore compatible with MagneLift.

Application number 10/584,781 – “Method and articles for remote magnetically induced treatment of cancer and other diseases and method for operating such article”. Although this treatment uses the principles of magnetic drug targeting, it differs because the collection of the ferrous particles is accomplished through an externally applied AC magnetic field. Since it does not use a permanent magnet, it cannot be included in the potential market as of now.

**Related Medical Research**

A further literature search was conducted into articles from peer-reviewed journals. These articles describe current research into differing types of magnetic drug targeting that is either currently being conducted or has recently been conducted in research labs across the country and in other parts of the world.

A theoretical model of magnetic drug targeting was simulated and tested at the University of South Carolina [Ritter, 2004]. Their results suggested that the use of magnetic drug targeting at local sites, such as a tumor, was very promising and feasible.

At the University of California in Los Angeles, researchers studied the effects of magnetic drug targeting in the use of chemotherapy to treat solid tumors in swine [Goodwin, 1999]. First they position a permanent magnet external to the skin and then
injected the magnetically-bonded chemotherapy drug. Their results conclude that an externally applied magnet is an effective method of retaining an injected drug in a single area of the body. Researchers in Germany confirmed the effectiveness of magnetic drug targeting with preliminary trials in mice and a clinical trial in humans [Lübbe, 2001]. Researchers in Colorado are in the process of conducting a clinical trial on humans with liver tumors [Rudge, 2001]. For these three research labs, their preliminary results are promising. However, more trials must be completed before this treatment can be brought to market.

All of the above explained research utilizes an externally-applied permanent magnet to collect cancer-treating drugs at a specific site in the body. The current removal method is by hand, but MagneLift could be employed in these treatments in order to increase patient comfort and the professionalism of the treatment.
Appendix D: SWOT Analysis

After extensive analysis, it was determined that the MagneLift’s main strength is the current existence of minimal direct competition once entry into the medical industry has been established. The results of a thorough search of existing patents and products indicated that no product currently exist on the market which serves the same purpose as MagneLift. However, MagneLift will be susceptible to extensive indirect competition in the form of competing cancer treatments. This provides an opportunity for growth of the company since Magneticure could expand to create further patient comfort products for use with multiple cancer treatments.

A key weakness is based within the company itself. Since initial market surveys indicate a minimal knowledge in the public domain concerning the intricacies of cancer research, it will be important that the company pools as many resources as possible to gather information for the product and the processes that it encompasses. In addition, liability insurance will increase the cost of the product to consumers, but since it is such a low cost to manufacture, the liability insurance should not have a large impact on costs. The magnetic procedure that MagneLift is designed for is currently pending final approval, and will still need to establish widespread use. However, during this process, the product may still be sold to those who are conducting experiments and tests with this treatment process.

There already exist patents and studies for the treatment of cancer that include the use of magnets. It is foreseeable that there will be a need for similar types of magnetic removal devices to supplement these processes. This can increase market potential, but
could lead to a threat in the market for this magnetic removal device; therefore, it will be vitally important to obtain a patent for this device as soon as possible. This will lead research into future iterations of the product and, more importantly, the possibility of adapting it to be universal with more than one magnetic treatment. Consequently, the potential market will expand which would lead to an increase in the prospective volume of units sold.
Appendix E: Product Design

Design Challenges

The development of MagneLift had some engineering design challenges because of the needed reliability and ease of use. The research and development of MagneLift provided the beneficial information in achieving the necessary goals for a successful business. The first and most important goal, and possibly the most difficult to achieve, was to determine the needed spring force of the pulling spring to remove the magnet from the skin and the main rod without being too difficult to operate for the user. This goal was so important because if an average medical professional cannot depress the rod then the device cannot be used and is rendered useless. The goal was the designing challenge of this product because the magnets being used with the medical processes have very high pull strengths, so the force that is exerted by the spring has to be strong enough to be able to remove the magnet from the patient but more importantly from the device’s main rod.

The second goal was to determine the specific materials needed for each different model, such as an inexpensive disposable model or a high quality, long-lasting model. The materials determined for the first product required high durability for a long lifespan, and also be easy to clean and reuse.

The third goal for MagneLift was to determine the most efficient process to mass produce it for the different models.

Prototype Analysis

A design analysis was done on every part of the Magnelift product to ensure that the design was sufficient to endure the forces being applied to it during extreme use. The
analyses were also administered to ensure that the product would fail internally when failure occurs. The spring was designed to fail at a certain number of cycles, so analyses and research were conducted to ensure that it failed at the designated cycle.

**Housing Analysis**

*Housing Top*

Three different analyses were done on the nylon housing, including a von Mises stress analysis as shown in Figure 16. A displacement analysis was also conducted as shown in Figure 17. Finally, a factor of safety analysis was completed as shown in Figure 18. In order to accurately administer these analyses, certain points on the housing needed to be constrained and then certain forces needed to be applied to other certain points on the housing to simulate the actual stress applied to the part. For the top housing part it was constrained at the cylindrical outside edge of the housing because while it is in use this outside edge does not move. A force of 13 lbs was applied to the inside edge of the top bushing of the part because when the main rod is being pushed up by the pulling spring and applies a load to the damping spring, the damping spring applies a force on the top bushing of the housing top. From the analyses a minimum FOS of 41.46 was achieved, ensuring the design.

![Figure 16: Von Mises stress analysis of the housing top](image-url)
The same three analyses were administered to the housing bottom to achieve the same sufficiency as shown in Figures 19--21. The bottom housing was constrained at the bottom edge of the part because this edge is what will contact the magnet holder and while it is in use it will hold the part in place and have to support the forces applied. A force was applied to the entire flat inside edge of the bushing where the pulling spring contacts the housing bottom because when the main rod in being depressed the force will be applied to the pulling spring and then transferred to the flat surface of the bushing in the housing bottom. A minimum FOS of 73.40 was achieved from the analyses proving the design of the housing bottom is sufficient.
Figure 19: Von Mises stress analysis of the lower housing

Figure 20: Displacement analysis of the lower housing

Figure 21: Factor of safety analysis of the lower housing

**Inner Parts**

**Main Rod**

Von Mises stress, displacement, and factor of safety analyses were also conducted on the main rod as shown in Figures 22–24. The same three analyses that were administered on the housing were also done on the main rod of the Magnelift product and from these three analyses the part design was proved to be sufficient. The critical points for the housing apply to the main rod as well, so the main was constrained along the
length of the cylindrical face of the rod because this surface is the point at where the forces are constraining against. A force of 13 lbs was applied to the entire face of the center washer of the main rod because when the rod is depressed against the force of the spring, the spring applies the 13 lb force against the washer which then pulls on the cylindrical face of the rod. The following figures show the stresses and displacements of the washer on the rod and also show a FOS of 39.63 ensuring a sufficient design.

Figure 22: Von Mises stress analysis of the main rod

Figure 23: Displacement analysis of the main rod

Figure 24: Factor of safety analysis of the main rod
Pulling and Damping Springs

The pulling and damping springs were analyzed using the following equation and graphs to determine the optimal springs so that the desired number of cycles could be endured. Designing the product to use a certain spring ensured the desired life and desired failing part of the product. However the pulling spring that needed to be used required a pull force high enough to be able to remove the magnet from the patient’s skin. The required force the pulling spring needed to exert was calculated using the Equation 1 which calculates the pull force of a magnet with one side contacting a magnetic surface. The pull force depends on the space between the magnet and the magnetic surface, along with the magnetic field strength of the magnet.

\[ F = \frac{B^2A}{8\times10^{-7}\pi} \]  

(1)

where \( F \) is the magnet pull force, \( B \) is the magnetic flux density, and \( A \) is the contact area between magnet and magnetic surface.

After the required force was calculated, the spring design was chosen so that the spring could only endure a certain number of cycles. Equations 2, 3 and 4 and Figure 25 were used in conjunction with each other to determine the desired spring design. Since the desired number of cycles is considered light service for a spring and according to the graph in Figure 25 along with the results of equations 2, 3, and 4, the specific spring design was determined.

\[ F = kx \]  

(2)

where \( F \) is the force required to compress spring a distance “\( x \)”, \( k \) is the spring constant, and \( x \) is the compressed distance of the spring.
where \( k \) is the spring constant, \( d = \) spring wire diameter, \( G \) is the spring’s shear modulus of elasticity, \( D \) is the spring mean diameter, and \( N \) is the number of active coils.

\[
\tau_{\text{max}} = K_w \frac{8P_{\text{max}}C}{\pi d^2} = 167\text{ksi}
\]

where \( P_{\text{MAX}} \) is the max force applied, \( K_w \) is the Wahl correction factor, \( C \) is the spring index(D/d), \( d \) is the spring wire diameter.

![Diagram showing torsional stress vs. wire diameter for different service conditions.](image)

**Figure 25: Spring fatigue life as a function of wire diameter and torsional stress**

**Prototype Material Selection**

MagneLiift will be constructed of the following five different parts.

1. **Housing:** A round two piece tubing of a nonferrous material with a 1” outer diameter and 5.00” length. It has molded bushings in the top and bottom piece to support and align the main rod. It also has a molded finger grip at the top of the tube with an open slot for the rod stop latch. A model of the housing is shown in Figure 26.
2. **Main Rod:** A solid round rod of a ferrous material with multiple diameters ranging from 0.25”-0.375” along its 4.75” length with 0.25”x20 male threads at the top for the *push button*. It also has a washer welded midway for spring placement. The main rod is shown in Figure 27.

3. **Pulling Spring:** A compression spring with a 0.5” inner diameter, 2.254” length and a $k=5 \text{ lb/in}$ spring force. The pulling spring is shown in Figure 28.
4. **Damping Spring**: A compression spring with a 0.5” outer diameter, .754” length and \( k=1 \text{ lb/in} \) spring force. The damping spring is shown in Figure 29.

![Figure 29: Damping Spring](image)

5. **Magnet Holder**: A flat round plastic plate with a molded cylinder to fit the magnet’s diameter. The magnet holder is shown in Figure 30.

![Figure 30: Magnet Holder](image)

**Prototype Assembly Process**

MagneLift was then assembled according to the following instructions.

1. Place the *damping spring* into the housing from the bottom of the housing.
2. Place the *main rod* into the housing sliding through the upper bushing.
3. Place the *pulling spring* into the housing, sliding onto the bottom half of the main rod.
4. Adhere the *lower housing part* onto the *upper housing part*. 
5. Screw the *push button* onto the top of the main rod until it is secure.

6. Assembly Complete

A fully-assembled model is shown in Figure 31.

![Figure 31: Assembled prototype model](image)

**Testing**

After a successful prototype is made, a series of tests will be conducted on it to ensure its reliability, durability and ease of use. It will be tested for ease of use on a variety of different people with different hand strengths, allowing them to use the device in a simulated process, while observing its ease of use and then asking them if it was too difficult or not. Since the MagneLift device needs to be used with a magnet holder to reduce pain, a magnetic field test will need to be conducted to ensure the magnet is still working properly with the medical process. The second test will determine its reliability and durability by using the device in a simulated process removing the magnet from the patient and the main rod of the device.

After all the preliminary tests are conducted, the product will be given to a laboratory where a breast cancer treatment process is being tested on lab rats. The
laboratory professionals will use the MagneLift device in conjunction with the treatment process on the rats and report back with results of the device’s performance.

**Concept**

The MagneLift device had multiple concepts of how it should be designed, there were three very distinct designs that were different from each other. One design was to depress the cylinder using a lever action that a user would squeeze against the housing. Another design was to be a syringe type process, having the user depress the rod with their palm by holding the housing with two fingers grabbing two finger loops molded into the housing’s top. The last design, which is the chosen design, consists of a rod which is depressed by the user’s thumb while the device is held in the palm of their hand.

**Critical Failure**

Since MagneLift is a medical device which is used in close proximity to sensitive tissues, it is imperative that critical failure occur internally to avoid injuring or adding further discomfort to the treatment experience. Therefore, the product was designed to failure at the weld of the spring depression washer. Although use of the product to critical failure is not expected, this designed failure point will afford the safest and most consistent method of failure.

The spring was designed to fail due to fatigue after 1000 cycles in order to introduce a lifecycle into the product. This will ensure the continued existence of a market for the MagneLift as physicians must periodically replace worn devices.
Appendix F: Liability Insurance Application

Medical Equipment Industry
Insurance Program Application
Claims-Made General Liability Coverage
For Medical Equipment Dealers, Manufacturers, Installers & Service Organizations

Firm's Name: ____________________________ Year Founded: ____________________________

☐ Proprietorship ☐ Corporation ☐ Partnership ☐ Joint Venture ☐ Subsidiary

Address: ____________________________________________
__________________________________________________________________________

Contact Person: ____________________________ Phone: ____________________________

Title: ____________________________ Fax: ____________________________

E-Mail Address: ____________________________ Company Website: ____________________________

Desired Effective Date: ____________ Desired Retroactive Date: ____________

Provide a brief overview of your operations:
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

* Please attach copies of any marketing brochures or literature that you have available.

SALES INFORMATION

<table>
<thead>
<tr>
<th>Source of Revenue</th>
<th>Sales Vol. ($) Nov 12 Mos.</th>
<th>Sales Vol. ($) Year to Date</th>
<th>Sales Vol. ($) 1st Prior Year</th>
<th>Sales Vol. ($) 2nd Prior Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Equipment Sales - US Mfg.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Equipment Sales - Foreign Mfg.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consumables/Supplies - Retail</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SERVICE/MAINTENANCE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Installations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* or foreign manufacturers with wholly owned US subsidiaries

Attach copy of most recent financial statement.
A. SALES OF PRODUCTS YOU DO NOT MANUFACTURE YOURSELF  □ Not applicable (skip to B.)

Check all products your firm sells manufactured by others:

☐ Diagnostic Radiographic Imaging Systems
☐ Magnetic Resonance Imaging Systems
☐ Ultrasonic Imaging System
☐ Therapeutic Radiation Systems and/or Therapeutic Radionuclides
☐ EKG/EEG
☐ Other: (See supplemental checklist)

Are any of the devices sold by your firm FDA Class III devices?

☐ Yes (specify) ________________________________
☐ No

Do you sell any products manufactured by a foreign supplier not domiciled in the United States?

☐ Yes (specify) ________________________________
☐ No

Are any products manufactured by others, but sold under your name?

☐ Yes (specify) ________________________________
☐ No

If YES, do you require:

Vendor Coverage?  □ Yes  □ No
Certificates of Insurance?  □ Yes  □ No  Limits: ________________________________
Favorable Hold Harmless?  □ Yes  □ No

Do you lease any equipment on a short-term basis?

☐ Yes (specify) ________________________________
☐ No

B. SALES OF ITEMS YOU MANUFACTURE  □ Not applicable (skip to C. below)

What products do you manufacture?  (Please specify)

________________________________________________________________________
________________________________________________________________________

Do you mix, modify of blend any injectable or ingestible products?

☐ Yes (specify) ________________________________
☐ No

Is your firm an FDA registered manufacturer of any products?

☐ Yes (specify) ________________________________
☐ No

Note: If YES, indicate on a separate page the product(s) manufactured and the annual sales volume in units and receipts. (Attach brochures on all manufactured products.)

Has there ever been a products recall on any products you manufacture or represent?

☐ Yes (specify) ________________________________
☐ No
Are any products you manufacture considered by the FDA as an implantable device?

- Yes (specify) ____________________________
- No

C. IF YOU ARE A MANUFACTURERS' REPRESENTATIVE ☐ Not applicable (skip to D. below)

List all manufacturers for whom you currently act as a Manufacturers' Representative. Indicate if Vendors Coverage is provided by the manufacturer.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Last Year Represented</th>
<th>Products</th>
<th>Vendors Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Use additional sheets if necessary)

Have you in the past ten years acted as a Manufacturers' Representative for the following type of equipment:

- Therapeutic equipment?
  - Yes (specify) ____________________________
  - No

- Invasive or implantable devices?
  - Yes (specify) ____________________________
  - No

- FDA Class III devices?
  - Yes (specify) ____________________________
  - No

D.USED EQUIPMENT REFURBISHMENT / SALES ☐ Not applicable (skip to E. below)

What used equipment does your firm sell? (Please specify)

Check all that apply:
- Diagnostic Radiographic Imaging Systems
- Magnetic Resonance Imaging Systems
- Ultrasound Imaging System
- Therapeutic Radiation systems and/or Therapeutic Radionuclides
- EKG/EEG
- Other: (see supplemental checklist)

<table>
<thead>
<tr>
<th>Year</th>
<th>Units</th>
<th>Volume $ Receipts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Year (estimate)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st Prior Year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd Prior Year</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Are any of the above devices FDA Class III devices?

☐ Yes (specify)
☐ No

Are any devices sold as “As Is” or without complete refurbishment to the manufacturer’s current level of safety?

☐ Yes (comment) ____________________________
☐ No

Attach copies of any warranties issued on used/refurbished equipment.

Do you or have you sold used equipment manufactured by companies other than those you normally represent?

☐ Yes (comment) ____________________________
☐ No

If YES, has your firm received factory training from the original equipment manufacturer (OEM) and do you have complete access to manuals, technical bulletins and factory parts?

☐ Yes
☐ No (comment) ____________________________

E. SALES/SERVICE OF DISCONTINUED PRODUCTS?  ☐ Not applicable (skip to F below)

List major types of equipment, supplies or services you have discontinued:

<table>
<thead>
<tr>
<th>Equipment / Supply / Service</th>
<th>Years Discontinued</th>
<th>Reason for Discontinuing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

(Use additional sheets if necessary)

F. INSTALLING EQUIPMENT  ☐ Not applicable (skip to G below)

Specifications for new installations for products (shielding, electrical, plumbing, structural, etc.) are done:

% by your customer % by manufacturer % by you

Are complete job records maintained indefinitely including job specifications, change orders and correspondence?

☐ Yes
☐ No (comment) ____________________________

Do you require written customer acceptance and sign off after installation and training?

☐ Yes
☐ No (comment) ____________________________

Do you use subcontractors?  ☐ Yes  ☐ No

If YES, indicate:

☐ Electrical  ☐ Mechanical  ☐ Plumbing  ☐ Health Physics
☐ Rigging  ☐ Transport  ☐ Maintenance
☐ Other: ____________________________
Do you require the following from subcontractor(s):
- [ ] Certificates of Insurance  Yes/No
- [ ] Additional Insured status  Yes/No

Do you directly supervise subcontractors?  Yes/No

If YES, do you require:
- [ ] Favorable Hold Harmless  Yes/No
- [ ] Waiver of Subrogation  Yes/No

C. SERVICING EQUIPMENT  Not applicable (skip to H. below)

Do you maintain complete service records at your location, including identification and source of all parts?
- [ ] Yes
- [ ] No

What are your basic educational training requirements for your technicians?

Comment:

How many of your technicians are certified Biomedical Equipment Technicians (BMET's)?

Do you service or have you serviced new or used equipment manufactured by companies other than those you normally represent?
- [ ] Yes

If YES, has your firm received factory training from the original equipment manufacturer (OEM) and do you have complete access to manuals, technical bulletins and factory parts?
- [ ] Yes
- [ ] No

H. CONTRACTS

Do you require written contracts on all equipment sales, services and installations?
- [ ] Yes
- [ ] No

Are there any circumstances under which your firm will contractually agree to accept liabilities or hold other parties harmless?
- [ ] Yes
- [ ] No

INSURANCE AND CARRIER INFORMATION

<table>
<thead>
<tr>
<th>Year</th>
<th>Carrier</th>
<th>Limits</th>
<th>Premium</th>
<th>Claims Made or Occurrence</th>
<th>Retros Date</th>
<th>Deductible</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>
LOSS HISTORY

Have any liability claims (general or product) been filed against you since your operations began?

☐ Yes
☐ No

If YES, please list below:

<table>
<thead>
<tr>
<th>Year</th>
<th># Claims Open</th>
<th># Claims Closed</th>
<th>Total Loss $</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Describe on separate page all individual losses.

Are there any other incidents, conditions, circumstances, defects or suspected defects which may result in claims against your firm?

☐ Yes (comment) ________________________________
☐ No

Hartford offers “prior acts” coverage under a claims-made policy. This coverage is applicable only to claims arising out of incidents that occurred on or after the retroactive date and which were reported to Hartford during the term of your policy.

No coverage will apply to the following:

☐ Incident, occurrence or injury occurring prior to the retroactive date.
☐ Claims or suits made against you prior to the effective date of the policy.
☐ Incidents that might reasonably be expected to result in a claim being made for which you or any of the named insureds are aware of, or reasonably should have been aware of prior to the effective date.

The differences between occurrence and claims-made coverage have been explained to me and I understand that I am applying for a claims-made policy based on this application.

I understand that completion of this application does not constitute acceptance of this application or obligate the company to issue the insurance applied for; However, facts and answers set forth in this application will be relied upon by the company as the basis of the contract should a policy be issued.

I warrant that the statements (answers) given above are true and correct, and that the applicant has not willfully concealed or misrepresented any material fact or circumstance concerning this application.

Applicants signature: ________________________________

Title: ________________________________ Date: ________________
### SUPPLEMENTAL CHECKLIST

<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>New Sales</th>
<th>Used Sales</th>
<th>Specify</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DIAGNOSTIC EQUIPMENT:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anesthesiology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other: Please Specify</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OTHER EQUIPMENT:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latex Gloves Or Other Latex Items</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disposable/Expendable Products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Film &amp; Developing Equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supplies/Equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Hospital Equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prosthetics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation Protection Shields</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutic Radiation Systems</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Defibrillators</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dialysis Equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endoscopic Electrosurgical Instruments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gas Analyzers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical Lasers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lithotriptors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterilizers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventilators</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OTHERS: Please specify</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Appendix G: Resumes

HEATHER M. CULBERTSON
158 Magna Carta Lane * Sparks, NV 89431
775-232-3188 * hmculbertson@gmail.com

EDUCATION:
University of Nevada, Reno
Bachelor of Science Mechanical Engineering
Minor in Mathematics
- Expected graduation May 2019
- 4.00 GPA

RELATED WORK HISTORY:
NSF Engineering Intern
University of Houston
- Characterized helium ion source of proximity lithography nanoprinting tool.
- Analyzed the beam current density’s dependency on source voltage and current.

Teaching Assistant/Grader
University of Nevada, Reno
January 2009—Present
- Graded papers for statics, fluid mechanics, and control systems classes.
- Prepared lesson plan and held laboratory session for numerical methods.

Mechanical Engineering Intern
Sierra Pacific Power Company—Reno, Nevada
Summer 2008
- Analyzed lighting density for new construction and retrofitting projects in the Reno area.
- Developed spreadsheet with macros to automatically and continuously compute and calculate data.
- Analyzed renewable energy incentive programs within the United States.

Student Worker
UNR Learning Resource Center—Reno, Nevada
2006—2009
- Worked in digital media library for the College of Education at the University of Nevada, Reno with spreadsheets, design lab, library software, cataloging books, and customer service.

PROFESSIONAL DEVELOPMENT:
Vice Chair, ASME,
UNR Student Chapter
May 2009—Present

Secretary, ASME,
UNR Student Chapter
May 2008—2009
Christopher Nation  
*Mechanical Engineer*

**Objective**
To become a part of a team where I can utilize my excellent engineering and efficiency skills along with my variety of experience in construction, automotive, computers and general maintenance.

**Experience**

<table>
<thead>
<tr>
<th>Company</th>
<th>Location</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aztec Designs</td>
<td>Las Vegas, NV</td>
<td>September 2000 – December 2005</td>
</tr>
<tr>
<td><strong>Welding-Fabrication</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apollo Enterprises</td>
<td>Las Vegas, NV</td>
<td>June 1995 – September 2000</td>
</tr>
<tr>
<td><strong>General Construction: Carpentry-Masonry-Electricity-Landscaping</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Education**

2006-2010 University of Nevada Reno

B.S. in *Mechanical Engineering* in 2010 from *University of Nevada Reno*

**Computer Skills**

- 3D and FEA Programs: SolidWorks, AutoCad, Ansys
- Microsoft Office Word, Excel, Power Point and Outlook
- MathCad, MatLab

**Interests**

My interests include a wide arrange of hobbies including outdoor activities, building custom furniture, fine dining, traveling.

**Tips**

I am a hard working, dependable employee. I work efficiently to accomplish any given task. I am self-disciplined and eager to learn new skills. I can prove myself able to learn any new line of work with enthusiasm.

References available upon request.
Chase Hancock
741 West Pueblo – Reno, NV 89509 – 775 247 8232 – chase@unr.nevada.edu

Objective: Further development and implementation of system and mechanical design skills through hands-on analysis practical experience.

Education:
University of Nevada, Reno
Projected Graduation Date: May 2010

University of Nevada, Reno
Graduation Date: December 2003

French Language & Literature, B.A.

Relevant Coursework:
ME 242 Dynamics, ME 444 Intermediate Dynamics and associated lab, ME 410 Control System Design, ME 422 Mechatronics (taking currently)

Experience:
Undergraduate Assistant in the EASY lab (electro-active systems and control), September 2009 through December 2009, University of Nevada, Reno
• Under the direction of Dr. Leang and Graduate students, research and construction of a wire proximity sensor to understand general behavior
• Integration of the sensor to a Labview VI for testing and analysis

Limousine Chauffeur and Bellman at the Peppermill Hotel and Casino, October 2004 to July 2006 and December 2007 until current Reno, Nevada
• Provided a variety of services in a busy, dynamic, and often crowded environment
• Created, maintained, and continued relationships with regular guests and players
• Efficiently multitasked and self-directed under minimal supervision

Skills:
• Solid Modeling with Solidworks and ANSYS
• Programming in C
• Circuit diagramming and analysis with PSPICE
• Simulation, Analysis, and Calibration with Autolev, Matlab, Labview, and Simulink

Interests:
• Photography
• Animal Physiology
• Foreign Language, Culture, and Film
• Triathlon
DALE RUSSELL
5650 El Paseo Drive #106 Phone: (775) 443-5475
Sparks, Nevada 89436 Email: dalerussell8604@gmail.com

EDUCATION:

• University of Nevada, Reno
  2007-2010
  Major: Mechanical Engineering
  Status: Senior with 3.6 GPA

• Western Nevada College, Carson City, NV
  2004-2007
  Major: Engineering Science
  Status: Transferred to UNR with 3.78 GPA

• Carson High School, Carson City, NV
  2000-2004
  Status: Graduated with HS Diploma

HONORS AND AWARDS:

• Dean’s Honor List University of Nevada, Reno
  - Fall 2007, and Fall 2008

• Dean’s Honor List Western Nevada College

• Outstanding Achievement in the Social Studies Curriculum
  - Carson High School 2004

SKILLS AND PROFICIENCIES:

• Proficient in the following programs:
  - Solidworks, Mathcad, Matlab, Word, Excel, PowerPoint

HOBBIES:

• Self-taught musician—Drums, guitar and piano
• Snowboarding
EMPLOYMENT HISTORY:

June 2008 – December 9th, 2008
Vital Systems Corporation
Engineering Assistant
Reno, Nevada
  • Surface Mount Technology (SMT) Programming
  • In-house box and penalization designs using Solidworks
  • Assist in quoting orders

December 2007 – March 2008
Clearwire
Sales Representative
Reno/Sparks, Nevada
  • Direct sales for internet and phone packages
  • Customer service

May 2007 – August 2007
Nevada Department of Transportation
Engineering Intern, Traffic Engineering Department,
District 2—Sparks/Reno, Nevada
  • Worked directly with the engineering staff on any projects available
  • Implemented several changes in signage, striping and other special pavement markings
  • Improved logic of current signage
  • Helped to devise a system to keep track of the Adopt-a-Highway program

August 2006 – December 2006
Western Nevada College
Lab assistant for Physics 181/182 (Engineering Physics I & II)
Carson City, Nevada
  • Set up experimental equipment for students
  • Answer questions about concepts or approach
  • Assisted in creating abstract experiments with the professor
  • Graded lab reports

May 2006 – August 2006
Nevada Department of Transportation
Engineering Intern, Office of Roadway Design
District 1—Carson City, Nevada
  • Updated state contract history information into a database
  • Worked closely with engineers to designate a budget for 2007
  • Collaborated with geotechnical and design engineers to design more cost-efficient roadways
  • I was one of three individuals overseeing a drilling project just outside Las Vegas, NV for an overpass abutment
STEVEN J. SCHWADE
1460 O Farrell St  Reno, NV 89503
775-233-3730  Schwades@unr.nevada.edu

EDUCATION:
University of Nevada, Reno
Bachelor of Science Mechanical Engineering
- Expected graduation December 2010

RELATED WORK HISTORY:

Mechanical Operations Supervisor  May 2005 - Present
Wild Island Inc.
- Supervised technicians responsible for maintaining all water park operations.
- Developed a training curriculum for new employees

Facility Manager  December 1999—Present
City of Reno
- Directly oversee a staff of 30 employees
- Customer service expert

Computer Programs:  MathCAD, MatLab, SolidWorks, ANSYS, LabVIEW, C++, EES, pSpice
Kyle H. Sadanaga  
142 Emerson Way  
Sparks, NV 89431  
Cellular (775) 741 - 6072  
Email: sadanaga@unr.nevada.edu

Education:

University of Nevada, Reno  Mechanical Engineering Major  2004-Present  
*UNR College of Engineering Dean’s List, Fall 2004, Spring 2005, Fall 2005

Work Experience:

Truckee Meadows Community College  Aug 19, 2009  Present  
-Tutoring and Learning Center Tutor  
*Work with students one on one during appointments  
*Help multiple students at a time in a group setting  
*Schedule follow-up appointments

Damonte Ranch Youth League  Sept 2008 – Present  
-Executive Board Liaison  
*Create and maintain youth officials schedules  
*Plan and organize practice times and games for 30 teams  
*Help manage finances as necessary

Big 5 Sporting Goods  Apr 28, 2005 – Present  
-Sales Associate  
*Public relations  
*Stock/rotate merchandise  
*Maintain cleanliness of store

Washoe County School District  Aug 2003 – Present  
-Boys Basketball Coach  
*Create and follow practice plans  
*Instruct and guide players on and off the court  
*Maintain calendar schedule for gym use by various teams

Washoe County School District  Oct 20, 2007 – June 1, 2009  
-Math Tutor  
*Assist students with math-related subjects, while improving study habits  
*Record attendance daily and keep semester attendance logs  
*Prepare students for tests and quizzes
## Appendix H: Financial Statements

### Table 5: Balance Sheet (FY11, 2nd QTR)

<table>
<thead>
<tr>
<th>Item</th>
<th>LIABILITIES</th>
<th>ASSETS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment</td>
<td></td>
<td>$4,000.00</td>
</tr>
<tr>
<td>Furniture</td>
<td></td>
<td>$7,000.00</td>
</tr>
<tr>
<td>Salaries and Wages</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Materials</td>
<td></td>
<td>$310.95</td>
</tr>
<tr>
<td>Advertising</td>
<td></td>
<td>$3,000.00</td>
</tr>
<tr>
<td>Rent</td>
<td></td>
<td>$3,300.00</td>
</tr>
<tr>
<td>Fringe Taxes</td>
<td></td>
<td>$5,066.25</td>
</tr>
<tr>
<td>Telecom/Utilities</td>
<td></td>
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<tr>
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Table 6: Balance Sheet (FY11, 3rd QTR)

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<tr>
<th>Item</th>
<th>Liabilities</th>
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</tr>
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<tbody>
<tr>
<td>Equipment</td>
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<tr>
<td>Furniture</td>
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<td>Salaries and Wages</td>
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<td>Materials</td>
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<td>Fringe Taxes</td>
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<td>Accounts</td>
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Table 7: Balance Sheet (FY 11, 4th QTR)

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<tr>
<td>Fringe Taxes</td>
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<td>Assets</td>
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<td>Furniture</td>
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<td>Fringe Taxes</td>
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<tr>
<td>Telecom/Utilities</td>
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<tr>
<td>Liability Insurance</td>
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Table 9: Year 1 Cash-flow Statement

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<th>February</th>
<th>March</th>
<th>April</th>
<th>May</th>
<th>June</th>
<th>July</th>
<th>August</th>
<th>September</th>
<th>October</th>
<th>November</th>
<th>December</th>
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<tbody>
<tr>
<td><strong>TOTAL CASH REVENUES</strong></td>
<td>$0.00</td>
<td>$4,500.00</td>
<td>$6,810.00</td>
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<td>$9,000.00</td>
<td>$11,250.00</td>
<td>$12,400.00</td>
<td>$13,350.00</td>
<td>$13,200.00</td>
<td>$13,000.00</td>
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<td>$13,750.00</td>
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<td>$100.00</td>
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<td>$1,250.00</td>
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<td>$22,000.00</td>
<td>$22,000.00</td>
<td>$22,000.00</td>
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<td><strong>TOTAL CASH DISBURSEMENTS (LESS)</strong></td>
<td>$75,188.75</td>
<td>$24,916.08</td>
<td>$25,126.28</td>
<td>$22,182.48</td>
<td>$18,615.65</td>
<td>$18,848.88</td>
<td>$26,082.08</td>
<td>$26,215.28</td>
<td>$26,748.48</td>
<td>$25,781.68</td>
<td>$31,014.88</td>
<td>$28,748.08</td>
<td>$376,891.67</td>
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<tr>
<td><strong>Cumulative Cash Disbursements</strong></td>
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**RECONCILIATION OF CASH FLOW**

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<th></th>
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<th>($69,604.83)</th>
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<th>($107,296.60)</th>
<th>($127,125.28)</th>
<th>($148,101.17)</th>
<th>($160,933.25)</th>
<th>($174,418.33)</th>
<th>($187,247.02)</th>
<th>($201,728.70)</th>
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<th>$123,750.00</th>
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<tbody>
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<td>$0.00</td>
<td>$4,500.00</td>
<td>$6,810.00</td>
<td>$7,200.00</td>
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<td>$9,000.00</td>
<td>$11,250.00</td>
<td>$12,400.00</td>
<td>$13,350.00</td>
<td>$13,200.00</td>
<td>$13,000.00</td>
<td>$13,000.00</td>
<td>$13,750.00</td>
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<tr>
<td>DEDUCT: TOTAL CASH DISBURSEMENTS</td>
<td>$79,188.75</td>
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<td>($25,126.28)</td>
<td>($22,182.48)</td>
<td>($18,615.65)</td>
<td>($18,848.88)</td>
<td>($26,082.08)</td>
<td>($26,215.28)</td>
<td>($26,748.48)</td>
<td>($25,781.68)</td>
<td>($31,014.88)</td>
<td>($28,748.08)</td>
<td>($376,891.67)</td>
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<td><strong>Table 10: Year 2 Cash-flow Statement</strong></td>
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</table>

<table>
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<tr>
<th>TOTAL CASH REVENUES</th>
<th>January</th>
<th>February</th>
<th>March</th>
<th>April</th>
<th>May</th>
<th>June</th>
<th>July</th>
<th>August</th>
<th>September</th>
<th>October</th>
<th>November</th>
<th>December</th>
<th>YEAR END</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<table>
<thead>
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<th>CASH DISBURSEMENTS (LESS)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Business Management Wages</td>
<td>$17,500.00</td>
</tr>
<tr>
<td>Machining Wages/Assembly Wages</td>
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<td>Materials</td>
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<tr>
<td>Rent/Mortgage Payments</td>
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</tr>
<tr>
<td>Fringe Benefits Paid</td>
<td>$1,688.75</td>
</tr>
<tr>
<td>Telecommunications Payments</td>
<td>$100.00</td>
</tr>
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<td>Utilities Payments</td>
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<tr>
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<td>Cumulative Cash Disbursements</td>
<td>$407,972.95</td>
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<table>
<thead>
<tr>
<th>RECONCILIATION OF CASH FLOW</th>
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</thead>
<tbody>
<tr>
<td>OPENING CASH BALANCE</td>
<td>($221,814.67)</td>
</tr>
<tr>
<td>ADD: TOTAL CASH REVENUES</td>
<td>$19,310.00</td>
</tr>
<tr>
<td>DEDUCT: TOTAL CASH DISBURSEMENTS</td>
<td>($19,310.00)</td>
</tr>
<tr>
<td>CLOSING CASH BALANCE</td>
<td>($222,814.67)</td>
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</tbody>
</table>

| |
|-----------------|-----------------|
| | $558,666.60 |

<p>| |
| |
|-----------------|-----------------|
| | $558,666.60 |</p>
<table>
<thead>
<tr>
<th></th>
<th>YEAR 3</th>
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<th>YEAR 5</th>
<th>YEAR 6</th>
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<tr>
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<tr>
<td>Materials</td>
<td>$8,595.00</td>
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<td>$14,490.00</td>
<td>$15,777.00</td>
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<tr>
<td>Injection Molded Housing</td>
<td>$12,204.90</td>
<td>$16,805.70</td>
<td>$20,575.80</td>
<td>$22,403.34</td>
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<tr>
<td>Advertising</td>
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<tr>
<td>Rent/Mortgage Payments</td>
<td>$13,200.00</td>
<td>$13,200.00</td>
<td>$13,200.00</td>
<td>$13,200.00</td>
</tr>
<tr>
<td>Fringe Taxes Paid</td>
<td>$20,265.00</td>
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<td>$20,265.00</td>
<td>$20,265.00</td>
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<tr>
<td>Telecommunications Payments</td>
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<tr>
<td>Utilities Payments</td>
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<td>$15,000.00</td>
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<tr>
<td>Start-Up Expenditures</td>
<td>$0.00</td>
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<tr>
<td>Liability Insurance</td>
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<td>$30,000.00</td>
</tr>
<tr>
<td>TOTAL CASH DISBURSEMENTS</td>
<td>$392,247.40</td>
<td>$425,828.20</td>
<td>$453,345.80</td>
<td>$466,684.84</td>
</tr>
</tbody>
</table>

RECONCILIATION OF CASH FLOW

<table>
<thead>
<tr>
<th></th>
<th>YEAR 3</th>
<th>YEAR 4</th>
<th>YEAR 5</th>
<th>YEAR 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPENING BALANCE</td>
<td>($262,861.78)</td>
<td>($152,810.78)</td>
<td>$118,059.42</td>
<td>$525,179.22</td>
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<tr>
<td>ADD: TOTAL CASH REVENUES</td>
<td>$515,700.00</td>
<td>$710,100.00</td>
<td>$869,400.00</td>
<td>$946,620.00</td>
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<td>DEDUCT: TOTAL CASH DISBURSEMENTS</td>
<td>($392,247.40)</td>
<td>($425,828.20)</td>
<td>($453,345.80)</td>
<td>($466,684.84)</td>
</tr>
<tr>
<td>CLOSING CASH BALANCE</td>
<td>($139,409.18)</td>
<td>$131,461.02</td>
<td>$534,113.62</td>
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