

KINEXION DEVICES

Get moving again with drug-free pain management

Andrew Wandering
Ben Goodwin
Clara Brechtel
Evan Zhang
Gonzalo Arana
Ryan Forsberg

awanding@calpoly.edu
bsgoodwi@calpoly.edu
cbrechte@calpoly.edu
evzhang@calpoly.edu
garana@calpoly.edu
rforsber@calpoly.edu

Table of Contents

- Table of Contents*..... 1
- Executive Summary*..... 4
- Background*..... 6
 - Existing Research.....6
 - Current Treatment Methods.....7
 - Initial Customers.....8
 - Competitors and Related Businesses.....9
 - Market Analysis.....18
 - Insurance Coverage.....18
 - Applicable Codes.....18
 - Standards and Regulations.....19
 - Experimentation for Engineering Specifications.....19
- Business Development*..... 20
 - Interview List Generation.....20
 - Interview Question Generation.....20
 - Key Interview Insights.....22
 - Patients.....22
 - Physical Therapists.....25
 - Subject Matter Experts.....26
 - Key Insights Summarized.....27
 - Minimum Viable Product.....29
 - Landing Page.....29
 - Facebook Advertising.....31
 - Newsletter.....35
 - Business Model Canvas Development.....35
 - Remaining Assumptions.....37
 - Customer Profile and Value Map.....38
 - Customer Persona.....39
 - Revenue Strategy.....40
 - Financial Analysis.....41
 - Channel Strategy.....43
- Formal Product Definition*..... 44
 - Customer Requirements.....44

Use Cases	45
Engineering Requirements	45
Electrical Engineering Requirements.....	46
Mechanical Engineering Requirements.....	50
Design Development	55
Introduction	55
Prototype II: The X1- A Portable IFC Therapy Device	55
Why IFC?	55
Concept Designs	55
Electrical Design Development	58
Design Overview.....	58
LTSpice Simulations.....	61
PCB Design.....	64
Future Plans.....	65
Mechanical Enclosure Design Development	65
Introduction.....	65
Initial Design.....	66
Material Selection.....	68
Final Design.....	69
Finite Element Analysis.....	72
Manufacturing Plan.....	74
Fabric Design Development	75
DVP&R (Testing Protocols)	76
FMEA - Failure Mode and Effects Analysis	77
Team Development	78
References	81
Appendices	83
Appendix 1: Business Model Canvas Diagram Development	83
Appendix 2: Customer Interview Lists	85
Patient Interview List.....	85
Physical Therapist Interview List.....	88
Subject Matter Expert Interview List.....	89
Appendix 3: Interview Booth Set Up	90
Appendix 4: Interview Questions	90
Appendix 5: Use Case Requirements	92
Appendix 6: FMEA Table	93
Appendix 7: Team Contract	94
Appendix 8: Design Verification Plan and Report	100
Appendix 9: Archived Design Developments	101

Design Development	101
Hardware Development	101
Prototype 1: Knee Exercise Analytics.....	101
Appendix 10: Bill of Materials.....	Error! Bookmark not defined.
Appendix 11: Investor Pitch Deck	106
Appendix 12: IFC Circuit Schematic.....	112
Appendix 13: Engineering Drawings	114

Executive Summary

Our startup company's mission is to empower people with chronic knee pain to manage pain on their own, without the use of drugs. We accomplish this by providing accessible, convenient, and comfortable pain relief. Today, physical therapists and doctors alike prescribe opioids like hydrocodone, oxycodone, and morphine to relieve intense chronic pain that patients endure. Not only can this drop patients into an abyss of addiction, it also only masks symptoms and does not address any root causes of pain. Kinexion Devices' first product, the X1, provides portable 30-minute therapy sessions that reduce pain and inflammation and empowers people to take back control of their lives. The X1 provides drug-free Interferential Current (IFC) therapy in a light weight, wearable package. Therapy sessions come in 1-of-3 easy-to-use modes that produce 30-minute intervals of therapy. This therapy can be applied once or twice a day, depending on the severity of pain.

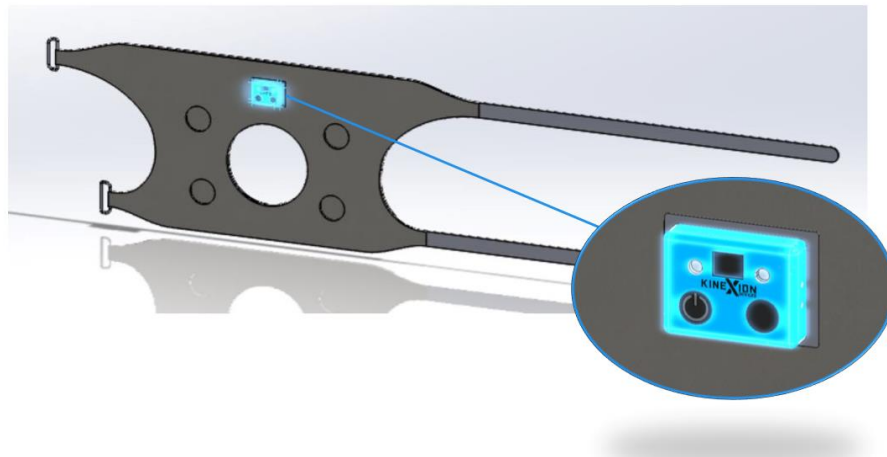


Figure 1. The X1 IFC Device

Previously, only individuals who could afford to go to a specialized healthcare clinic could receive this kind of pain relief management. In many cases, people who were unable to afford this care limited their lives in an effort to avoid or limit chronic pain and often resort to medications in the long term. Although most people have access to at-home treatment devices to relieve pain today, this field is still emerging. These devices are bulky, rely on wall outlet power, and many do not offer an intuitive method for setting up the electrodes for effective treatment. The X1 aims to address all

of these pain points. Currently our company has completed simulations for the circuitry that generates the IFC signal used in therapy. A circuit diagram and printed circuit board model of the device have also been completed.

Our next steps are to use the simulations to predict power consumption of the device and find a suitable battery to meet our 12-hour battery life requirement. At the moment it seems very likely that it will be difficult to find a battery that provides enough voltage in a small enough package to fit in our enclosure. Another concern is that one of the components on the PCB is just slightly too large to fit. Many of these challenges will need to be addressed through further research of components and potentially some development of newer technology. Finally, a prototype must be made in order to verify the simulations conducted and also to study properties of the device that cannot be simulated, such as the power consumption of a microcontroller and the heat dissipation of the device. Once these challenges are resolved, the X1 will be able to competitively provide convenient, at-home therapy that does not require the guidance of a trained professional. This is how we will get people moving again with drug-free pain management.

Background

Existing Research

Knee pain is a very common problem experienced by about 19% of the population. About 100 million Americans experience chronic knee pain, making it the second most common cause of chronic pain [1]. Pain due to knee problems is commonly felt in the front of the knee joint. There are various conditions that cause knee pain, some of the most common are ligament strains, osteoarthritis, patella-femoral syndrome, tendinitis, bursitis, Osgood-Schlatter disorder, and femoral fracture [2]. Of these conditions, we are particularly interested in chronic anterior knee pain caused by overuse. This includes pain associated with inflammation, nerve damage, scar tissue, tendinitis, and arthritis.

Anterior knee pain is one of the most common injuries experienced in activities that require repetitive knee extension and flexion, such as running, dancing, jumping, and biking. The most common cause of chronic anterior knee pain in athletes is patella-femoral pain syndrome (PFP), which is commonly referred to as “runners’ knee” [3, 4]. This injury is usually due to overuse and is common in endurance athletes such as runners and triathletes. For PFP, there is no surgical treatment option and patients are typically prescribed to 6-8 weeks of physical therapy. Rehabilitation methods used in physical therapy for this condition include muscle stretches and correction of biomechanical abnormalities [3].

Another common cause of chronic anterior knee pain is patellofemoral osteoarthritis. These patients have gradual development of anterior knee pain and stiffness with decreased range of motion. Many people start to see the first signs of osteoarthritis at the age of 45 and the condition continues to progress as people age [18]. Some risk factors include genetic factors, ageing, previous joint injury, and overuse [18]. Putting endurance athletes at high-risk of developing osteoarthritis. Most of these patients can tolerate walking on a level surface but experience discomfort when walking upstairs or during physical activity. To reduce pain, patients avoid flexion-extension activity and correct biomechanical abnormalities.

If patients are unable to reduce their pain after trying previous treatment methods such as physical therapy, many resort to total-knee joint replacement surgery. Osteoarthritis leads to a majority of the 700,000 total knee joint replacement surgeries each year [19]. While this is an effective treatment, total knee replacement often limits patient’s physical activity abilities and may not be an ideal treatment for active individuals [5].

Both injuries explained above are related injuries that may occur simultaneously. The pain associated with these injuries may be nociceptive or neuropathic pain. Nociceptive pain is caused by the activation of pain receptors, typically due to inflammation and tissue damage. While neuropathic pain is due to damage to the sensory nerve fibers. Joint pain is often a sign of neuropathic pain and is perceived by altered sensory nerves that project to the affected joint.

*Edit paragraph above

Current Treatment Methods

Various non-surgical methods exist to relieve knee pain in people suffering from the conditions described earlier. The most common methods to reduce knee joint pain are physical therapy and weight loss. These methods are the foundation of nonsurgical pain management to improve function of the knee. Physical therapy is an effective method to correct biomechanical movement that correct the root cause of pain [18]. Although physical therapy and weight loss may be the most effective treatment for people who live a sedentary lifestyle, active individuals may not receive as much benefit and commonly seek more aggressive treatment methods. The next step in treatment is for patients to start taking nonsteroidal anti-inflammatory drugs and consider regenerative injections, orthotic braces, or corticosteroid injections for short-term relief. If patients still do not experience pain relief, they may seek further opinions from orthopedic surgeons. If they are not a surgical candidate, these patients may consider opioid use for long-term relief [9].

Current drug-free treatment methods include injections, patella taping, acupuncture, orthotics, manual therapy, and electrotherapy [10]. Commonly used injections for osteoarthritis are intra-articular corticosteroid and hyaluronic acid injections. Corticosteroid injections are an effective therapy, but pain relief only lasts one to two weeks and they should not be given more than once every three months [20]. Hyaluronic acid injections are believed to support regenerative activity of cartilage but are still an investigative treatment that has shown contradictory results in clinical studies [19].

Electrical stimulation therapy or electrotherapy is another noninvasive treatment that has shown to have short-term and long-term effects on people experiencing chronic knee pain. Some types of electrotherapy are neuromuscular electrical stimulation (NMES), transcutaneous electrical nerve stimulation (TENS), and interferential current therapy (IFC) [22]. NMES uses low-frequency, low-amplitude electrical current to activate motoneurons and cause involuntary muscle contractions. TENS units use a biphasic current and low to high frequencies to stimulate sensory nerves to

block pain signals [22]. IFC is type of stimulation that uses two electrical currents that cross and work together to effectively stimulate large impulse fibers. The frequency of IFC meets the low impedance of the skin and provides deep tissue penetration that stimulates parasympathetic nerve fibers for increased blood flow. IFC differs from NMES and TENS because it allows deeper penetration of the tissue and increased blood circulation with more comfort [18].

Initial Customers

Our initial customer are people between the ages of 45-65 who participate in endurance sports. These individuals are at high-risk of developing chronic knee pain due to their age and activity level. They are extremely passionate about their sport and their pain does not stop them from competing in marathons or triathlons. They are also avoiding a total-knee joint replacement since that would likely be the end of their running career. Our initial customer data came from interacting with people in Facebook groups that pertain to “injured athletes.” The people in groups such as this are active individuals who engage in things such as running, weightlifting, or team sports, all at a recreational level.

To further engage with endurance athletes, we joined more Facebook groups that are specifically geared towards sports that they participate in. These Facebook groups include “Triathlon Nation”, “Runners Over 50”, and “Marathon Runners.” We identified many common themes between the people that we interviewed in these groups. Many people have been lifelong athletes who eventually started getting involved with long-distance running competitions. These people are highly motivated and are determined to compete in running events, even if they are experiencing knee pain. The most common ailment afflicting these athletes is “runner’s knee.” As mentioned before, this is a pain that is developed from overuse overtime, and has no no surgical intervention option. They have also seen a physical therapist and/or orthopedic surgeon before and did not receive much benefit. We also identified that pain killers, injections, ice, and heat-pads are the most common methods used to treat pain. We found that it is becoming a trend within our customer interviews that patients are seeking alternatives to treat their pain other than masking it with pain killers. In the chronic case, patients are not able to rely on pain killers alone as they would be consistently ingesting them which is unsustainable. We are confident that these people would choose a drug-free alternative over pain killers.

One of the most important things to note about our initial customers is their drive, intensity, and passion when it comes to continuing their endurance sports. These are individuals that have been running, and usually

competing, for a very long time. Giving up their running habits is simply not an option for them. Because of this, these ailing endurance athletes go to great lengths to subdue to the pain and continue to run. Within our interviews, there have been many accounts of athletes using nerve blocking injections or doping up with massive amounts of pain killers on the day of a race, just to be able to compete. The radical nature of the solutions these athletes are willing to use just to continue running shows the desperate nature of their search for a solution.

Unfortunately, there are individuals who would benefit from the use of our device but are contraindicated from using our type of device. Currently, an individual that uses an electrical cardiac pacemaker, a deep-brain stimulation device, or for use directly on a post-surgical site are contraindicated for use of interferential-current therapy by the FDA. IFC devices are approved by the FDA through the 510(k), pre-market submission pathway in which a device must just prove substantial equivalence to an approved predicate device. However, we predict that clinical studies would be beneficial to support the advantages of using our device over the competition. There may also be innovative aspects of our device that would need to be tested and proven through clinical studies.

A key stakeholder in interacting with our customers will be physical therapists. Even though we are no longer finding our customers while they are directly interacting with physical therapists, their view of our product is very important to the perception of our device because physical therapists will be a very early on source of information for many of our customers. We need to make sure that we can provide clinically relevant data through the initial uses of our device to prove the efficacy of our technology to physical therapists. This will allow us to have physical therapists as a key partner to prove to our customers that the medical community is behind our technology as well.

Competitors and Related Businesses

In the past few years, there has been a major push for the development of at-home pain management treatments, particularly those that can provide a drug-free solution. Recently, more physicians have been attempting to find new solutions to avoid the prescription of opioids due to their high potential of addiction. Pain is one problem that is never going to disappear, so consumers will always desire some solution for pain relief, preferably one that they can use in the comfort of their own home or on the go at their own convenience. Because of this, many companies have been working on ways to provide pain management options for their customers. We will highlight a few of these companies that we see as potential direct

competitors in the space, focusing primarily on pain relief treatments just for the knee.

AcuKnee



Figure 2. AcuKnee System bundle with Pain Warrior unit
“Help patients and athletes relieve their pain and get back on their feet, medication-free.”

Founded: 2012

Location: Farmington, Utah

Estimated Revenue: \$3.4 million

Target Market: Patients looking for a solution to chronic knee pain specifically

Description: The AcuKnee device is the strongest over the counter precision electrotherapy device and the only of its kind to be cleared by the FDA available without a prescription. The system combines state of the art electrotherapy with the latest developments in acute and chronic pain therapy to provide pain relief after a single 30-minute treatment once a day. The AcuKnee wrap provides patients with a portable alternative for pain management, allowing them to get quick relief either at home, work, or wherever they may be without the need for medication or a visit to the doctor.

Technology: The AcuKnee system comes with the patent-pending compression wrap that ensures maximum therapeutic effect and precise

treatment locations. Included is also the PTI Pain Warrior and Lead Wire Set. The Pain Warrior is a dual-channel, high output, preprogrammed TENS (transcutaneous electrical nerve stimulation) and NMES (neuromuscular electrical stimulation) electrotherapy unit. The Pain Warrior features 13 TENS and NMES modes with proprietary COM and HAN programs. The system also comes with 4 electrode conductors to allow the AcuKnee system to send electrical impulses to the knee at appropriate points to reduce levels. Using the concept of electro-acupuncture, the electrical stimuli and frequency sequencing help suppress interleukin-1 (IL-1), the cytokine responsible for regulating immune and inflammatory responses to ultimately reduce ongoing inflammation that can lead to chronic pain. 1 9V battery is also included. The wrap is also adjustable, allowing it fit up to a 30" thigh.

Pricing:

- \$269.49 for the complete AcuKnee System set
 - Set includes AcuKnee wrap, 4 pack of electrodes, 100mL Spectra 360 electrode gel, 1 PTI Pain Warrior with lead wire set
- \$249.99 for just the AcuKnee Wrap with New Lead Wires & Electrodes
- \$219.49 for the PTI Pain Warrior and Lead Write Set

Review: AcuKnee has received very positive feedback through customer reviews; many of their customers have reported having chronic knee pain for years until they started using the AcuKnee system. Users have even claimed that thanks to AcuKnee they have been able to return to their favorite recreational activities and have felt significant increase in mobility. However, since AcuKnee is a privately owned company they have no available sales reports to confirm their success. Additionally, a majority of the reviews published on their website and other online sources do not go past 2015, indicating that the company's sales may have significantly decreased despite the product still be available for purchase on their website. The wearable functionality of the AcuKnee device is something our team hopes to incorporate into our product as well. Although, with the requirement of the Pain Warrior attachment, their device is still not something one could wear during most activities that require a great deal of movement. This is one feature we're hoping to improve on with our device from Kinexion Devices. One interesting thing to note is that even though Acuknee was proven to have an increase in function and a substantial reduction in pain after a federally funded study from the National Center for Complementary and Alternative Medicine (NCCAM), the product is not as widespread as one would expect. Nonetheless, considering that the technology and design/functionality of their device is fairly similar to that of our own conceptual design, we felt it was worth looking into the

company as a competitor to see how we could avoid the same problems they are facing.

Oska Pulse by Oska Wellness



Figure 3. Oska Pulse unit with Large Compression Wrap and cable
“Committed to developing health and wellness technology-driven products that assist individuals in living a more active, pain-free lifestyle.”

Founded: 2015

Location: Carlsbad, California

Funding: \$5.5 million

Target Market: Anyone suffering from chronic pain

Description: Oska Pulse is designed to relieve acute or persistent pain right at the source, rather than just temporarily relieving the symptoms like most TENS devices do. The device is intended to be portable, lightweight, and can be worn on any part of the body where there is pain. Plus, Oska Pulse does not need to make direct contact with your skin or even be on your body. The signaling field has a diameter of 22", so Oska Pulse can be positioned near the area of pain and still be effective; within 8-10" of the pain is optimal. Oska Pulse is also one of the few devices of its kind that can be bought over the counter. Device specifications: 5.2" x 3.5" x 1.25"; 8 ounces.

Technology: The Oska Pulse unit uses Pulsed Electromagnetic Field (PEMF) therapy to relieve pain at the source by pulsing electromagnetic waves at precise frequencies. PEMF restores the positive and negative charges in the cell, enabling it to perform its natural function while speeding tissue

recovery. All frequencies are within the range of 1 -150Hz. The intensity of the PEMF is approximately 0.9milliTesla.

Pricing:

- \$399 for the 90-Minute Oska Pulse
- \$60 for a Large Replacement Compression Wrap
- \$40 for a Small Replacement Compression Wrap

Review: We chose Oska Wellness as one of our primary competitors because despite still being an Early Stage Series A venture, they've already been regarded as one of CNN's top recommendations for at-home pain relief treatments. On top of this, the OSKA Pulse received the 2017 Tech Co Startup of the Year and has been successfully trialed among US Special Forces. Oska is very popular in the media and has recently expanded its operations into India to help further production. The Oska Pulse id proven to be effective too. In a randomized, double-blind placebo clinical study, the majority of patients achieved significant pain reduction with Oska Pulse. Oska has also partnered with the Scripps Pain Institute and has received a great deal of support from many regarded physicians. Regarding our company, the Oska Pulse exhibits many of the same features we are hoping to employ in our own product; it's portable, lightweight, able to be worn during physical activity, and uses pulsed electromagnetic field technology. Despite total sales not being disclosed, Oska Wellness has still been fairly active in the past months and has garnered a great deal of support from investors, leading us to believe that they could be a considerable competitor.

LumiWave by BioCare Systems Inc.



Figure 4. LumiWave Single 200 LEDs and remote
“Shining a light on pain relief with near infrared light therapy”

Founded: 1999

Location: Parker, Colorado

Estimated Revenue: \$3.7 million

Target Market: Anyone suffering from chronic pain, no matter the age, would benefit from the LumiWave, but it’s primarily marketed towards athletes or physically active individuals recovering from an injury.

Description: The LumiWave device is a semi-portable pain-management solution for anyone experiencing chronic pain. The device was originally developed for sports medicine but is now used for a variety of pain management treatments. It’s not area-specific either, meaning that the LumiWave is able to help reduce pain when placed on any part of the body. It uses the same medical light therapy technology typically found at the doctor’s office for just 1/10th of the cost. The device was cleared by the FDA and offers fast pain relief without the harmful side effects of drugs.

Technology: LumiWave uses infrared light technology that consists of different wavelengths within the electromagnetic spectrum. The infrared light is able to penetrate much more deeply into the body’s tissues than visible or ultraviolet light. This allows it to stimulate the natural, biological processes needed for pain relief and tissue repair. The device uses medical-grade LEDs manufactured at the world’s only plant that guarantees 100% consistent energy delivery. The LumiWave is able to stimulate the body’s own biochemical processes by inhibiting pain signals by helping produce endorphins, releasing nitric oxide, reducing inflammation, and increasing

circulation and blood flow. Each LED pod has 49 LEDs and the temperature ranges from approximately 105.8 to 107.6 degrees Fahrenheit depending on the setting.

Pricing:

- \$349.99 for the LumiWave Single 200 LEDs
- \$499 for the LumiWave Double 400 LEDs

Review: We consider BioCare Systems a competitor due to that fact that, like Oska Wellness, their LumiWave device employs a very similar electrotherapy signaling technology that we are planning to incorporate into our own design. The LumiWave device is also the first product to receive FDA clearance in its product category and has 11 patents issued. Additionally, after multiple clinical trials, 97% of patients have stated that they experienced pain relief, 92% of consumers said they would recommend LumiWave to a friend, and 89% of doctors said they would recommend LumiWave for treating chronic pain. LumiWave has clearly gained a lot of support and great reviews, and has even been featured on CBS, the Oprah Winery Network, FOX Business, Business Insider, TechRepublic, and Sports Illustrated, proving that they definitely have a strong presence in the media. The versatility of the LumiWave device is very appealing to customers as it means that they only have to make a one-time purchase for a device with many different pain-relieving capabilities. This is something we would like to eventually incorporate into our device as well, however this would be much further down the road for our company. However, one downside to the LumiWave is that the device must be plugged in in order to work, so you could not use the product on the go. Since we're hoping to provide a more portable solution, this would be one aspect we're looking to change when designing our own device. Looking through user testimonials, many customers ranging from injured athletes to orthopedic surgeons have said that they felt the LumiWave has been very effective in pain relief. Most of the attention on LumiWave seems to have tapered off since 2017 when it was awarded "One of Runner's World's 15 Cool New Products" as BioCare Systems has moved on to newer efforts, but the device is still being sold online. BioCare Systems is a private company, so the sales reports are not accessible, but we still feel as though BioCare Systems is a noteworthy competitor and a company to look to for inspiration based on their success in the past.

Home H-Wave by Electronic Waveform Lab, Inc.



Figure 5. H-Wave Electrical Stimulation Machine
“Providing hope and tools to live a better life.”

Founded: 1981

Location: Huntington Beach, California

Estimated Revenue: \$5.5 million

Target Market: H-Wave is used primarily by patients with chronic pain, typically 40 years of age or older. H-Wave also targets physicians, therapists, and coaches as their customers since they can prescribe various treatments using their device.

Description: H-Wave is a multi-functional electrical stimulation device intended to speed recovery, restore, function, and manage chronic, acute or post-operative pain. It is a non-invasive drug-free alternative treatment. H-Wave is unlike most electrotherapy devices, such as TENS, because it focuses on relieving pain from the source rather than simply masking the symptoms. The treatments typically last 30-60 minutes and can be done in the comfort of one’s own home or a clinical setting. The Home H-Wave device is designed to relieve pain by increasing blood circulation and lymphatic drainage in the injured area in order to improve the range of motion and prevent disuse atrophy.

Technology: The H-Wave device generates a mild current to stimulate a mild non-fatiguing muscle contraction. The recurrence of these contractions helps to promote the creation of new blood vessels in the injured area to help introduce more nutrients and dispose of the waste materials that might build up with inflammation. The H-Wave unit has two modes: low frequency and high frequency. Low frequency mode operates at 1-2Hz and is used to normalize tissue to promote the ideal post-surgery recovery by promoting blood flow and angiogenesis, introducing more nitric oxide, and activate the lymphatic system for waste removal. The high frequency mode is used to

break up the chronic pain cycle by affecting the function of the sodium pump within the nerve to create an analgesic effect.

Pricing:

- \$3,300 for the H-Wave HomeCare Program (or 10 payments of \$330)
 - H-Wave HomeCare is a one-of-a-kind pain relief and rehabilitation program that includes the FDA-cleared H-Wave H4 prescription device and an extensive, multi-step process to ensure positive patient results.
 - Includes: H-Wave H4 device, 3 packages of electrodes, 2 sets of lead wires, 1 recharger, and carrying case
- \$6,300 for the H-Wave TotalCare Program
 - H-Wave TotalCare is a unique program that covers a lifetime of pain treatment for a single, global payment. This program empowers you to be involved in your own healthcare by providing an FDA-cleared, drug-free pain treatment device at your fingertips 24/7; and includes all associated supplies and device maintenance for the rest of your life.
- \$4,200 for the H-Wave 1 Year Program
 - H-Wave's 1 Year Program includes the FDA-cleared H-Wave H4 prescription device, ongoing supplies, accessories, device maintenance and personalized treatment plan development for a full year, all for one fixed cost.
- \$1,875 for the H-Wave Post-Op Program
 - H-Wave's Post-Op Program is an effective, drug-free approach to post-op recovery. It provides 24/7 access to the FDA-cleared H-Wave H4 prescription device, as well as on-going support and supplies for a flexible 90-Day period

Review: The H-Wave device has been reported by 78% of its users that it does result in significant pain reduction. 65% of patients also agreed that the device either reduced or eliminated the need for pain medicine. The H-Wave unit is also already pretty widespread, given that the company has been established for quite a bit longer than most other companies operating within this market; 70+ professional teams have signed on to use the H-Wave system. Electronic Waveform Lab, Inc. generates the most revenue out of our competitors, but one advantage we have is that their H-Wave unit is solely limited to stationary usage, whereas ours would be a wearable portable device. The H-Wave uses electrostimulation rather than the signaling technology we will be using, but given that they are in a similar enough realm, we deemed the company a competitor so that we can watch and learn from their clinical trials and customer reviews. As of now, the company is still active and manufacturing their products.

Market Analysis

Pain is one problem that consumers have had to deal with since the beginning of time; it has impacted just about every person on this planet and will never go away entirely. Because of this, there will always be a market for pain management as people continue to look for a solution. The total available pain management market was valued at approximately \$36.1 billion as of 2017. Narrowing down our scope for our company, the serviceable available market within the drug-free pain management medical device industry was still estimated to be worth approximately \$5.2 billion as of 2018. Dialing in our search even more so to focus on patients seeking pain management devices specifically for chronic knee pains, our predicted target market is still considered to be a \$4.4 million industry. We calculated this estimated value by looking at a 1% grab of the serviceable available market, then cross-referencing this value with our main competitors to see how it would compare. Plus, with a compound annual growth rate of 7.6%, the pain management market is expected to grow to a value of \$52 billion by 2022. This makes us very confident that this would be a good field to try and operate within.

Insurance Coverage

Insurance is a huge factor influencing the development of our product. Interferential current therapy is a treatment method recognized by insurance, therefore, there is an established code for reimbursement. However, interferential current therapy is a newer method of treatment and considered as an “investigative” therapy by some insurance companies. This means the therapy may not be considered as medically necessary and is not reimbursable by all insurance plans [11]. To improve insurance coverage of this device, we need to establish a standardized protocol for treatment and complete a clinical trial that proves efficacy of interferential current therapy when compared to a placebo group.

Applicable Codes

Insurance Reimbursement

HCPCS Code S8130: Interferential current stimulator, 2 channels

HCPCS Code S8131: Interferential current stimulator, 4 channels

Safety: Maximum Leakage Current Codes

IEC601-1,UL2601 Type BF NC: Normal operating condition, 0.5mA

IEC601-1,UL2601 Type BF SFC: Single fault operating condition, 1mA

Medical Device Standards

ISO 14971: Medical Devices – Application of risk

ISO 13485: Medical Devices - Quality management systems
ISO 10993: Biological Evaluation of Medical Devices
IEC 60601: Medical Electrical Equipment

Standards and Regulations

Since medical devices have direct impacts on public health, their design and implementation must meet strict quality and safety standards. The FDA's Center for Devices and Radiological Health regulates the sale of medical devices throughout the United States [2]. Each medical device is classified based on the device's intended use and subsequent health risks if issues arise. A class III device is issued higher regulatory control than a class I device. The FDA classifies Interferential Current Therapy devices as class II devices under the neurology panel.

As a class II device, this product will be submitted through the 510(k)-pre-market submission pathway. In addition, documentation of good manufacturing processes (GMP) must be provided. The 510(k)-clearance process typically takes 90 days. In order to submit through a 510(k), we must establish a predicate device that is already cleared by the FDA and uses the same technology for the same indication for use. If we do not have a predicate device, we will need to submit through the pre-market approval (PMA) or De Novo pathway. However, there are several interferential current therapy devices already cleared by the FDA.

Experimentation for Engineering Specifications

As with many medical devices and electronics in general, a physical prototype is critical in determining how well all specifications are being met. Due to the COVID-19 crisis, our team has not had the resources to develop a physical prototype this year. Although we do not have a physical prototype, we have laid out procedures for testing these requirements. *Appendix 8* shows *Design Verification Plan and Report* that lays out our procedure for testing that would occur once a physical prototype is developed.

Business Development

Interview List Generation

To develop our understanding of the knee pain management space, we have heavily turned towards social media. Facebook was our most abundant source of interview material by posting in injured athlete Facebook groups that we wanted to talk to people experiencing any type of knee joint pain. This returned people with a variety of different knee ailments that still cause them pain on a regular basis. Knee ailments that caused pain included osteo- and rheumatoid arthritis, patellar tendonitis (runner's knee), and general soreness. In most cases these were chronic conditions that had developed over time or as a result of a surgical procedure. This gave us a start as to which ailments really cause an individual to seek pain management techniques other than just pain killers.

We also continued to employ a grassroots approach by reaching out to people in our personal networks to find people experiencing knee pain. This continued to yield people for us to interview as we were interviewing anybody experiencing knee pain and not yet a specific condition. One new technique that we employed this quarter was to set up a booth with the caption of "Seeking a solution to knee pain? Come talk to us!" (Appendix 3). This proved to be a viable method as we were able to attract a few people to come talk to us over the span of only one day. This a technique we will utilize more in the future to get more diversity in how we find our customer interviews.

In our final round of customer interviews, we stuck to interviewing people within our initial customer type. These were endurance runners over the age of 45 who were experiencing the condition "runner's knee." People in this demographic were found through Facebook groups and mutual connections from previous interviews. Due to the COVID-19 pandemic, we were not able to set up any in-person events to attract potential customers to talk to.

Interview Question Generation

With our focus on pain management, we really need to understand an individual's knee pain as a whole. This includes how their knee pain comes about, what feelings are associated, how long they experience pain, solutions they have found, and how they find those solutions. A full list of our customer interview questions can be found in Appendix 4. The following explanation is describing the process of a scheduled in person interview. Beginning with how their pain comes about, we were really focused on the timeline of their knee pain. We start by asking if they have

had their knee pain diagnosed and how it first occurred. From there we strive to learn how often the pain occurs and how much this pain affects their daily lives. In this stage of the interview, it is very important for us to understand what feelings and emotions the individual is going through as they experience their pain. Overall, the goal is to understand what their use case would be for a pain management device. This will alter the methodology in which we deliver our solution. We have laid out our initial findings of the patient use case in Appendix 5.

Once we understand how their pain comes about and the frequency in which it occurs, we move to learn what solutions people are utilizing to treat their pain. These questions are directed to uncover if there are any other pain management device solutions that people are using to treat their knee pain. If they have found solutions previously, we then dig into how they went about finding these solutions. By learning how they find their pain management solutions, we are able to predict where to best position our marketing to reach our target customers. One of the alternative solutions that we are very interested in learning more about is pain killers. Thus far, customers have demonstrated a large desire to find alternatives to both over the counter and prescription pain killers when it comes to chronic pain management. If interviewees mention pain killers as a solution, we dive deeper into this topic to understand why they use pain killers and why they are seeking an alternative to them, if they are.

For our set up a table approach, we altered the questions we would ask interviewees to mesh better with a spontaneous interview. These questions can be found at the bottom of our customer interview questions document found in Appendix 4. For these interviews, they were structured towards determining if the individual we were talking to would fit our criteria to qualify for a scheduled interview. These questions sought to discover what type of knee pain a person was experiencing and what existing solutions they were utilizing. If we determined they had enough knee pain based on the duration and frequency of pain felt, we would ask them if they would be willing to have a longer interview with us. We were particularly interested in anybody that mentioned an alternative knee pain management technique, as we were not able to find many people who had tried alternative solutions.

When interviewing a physical therapist, we seek to understand what current pain management techniques they prescribe their patients, and if there are any major issues they wish to fix with these techniques. We also are focused on understanding how knee pain during a recovery affects the treatment plan a physical therapist has employed for their patient, and how proper pain management can improve that. Understanding the overall direction of the pain management industry will help us determine if our

device is something that will be adopted in the pain management community.

Key Interview Insights

The following section summarizes our insights from customer development interviews. This section includes interview highlights from fall, winter, and spring quarters. Although we have changed our focus since the Fall, these interviews contributed to our pivot to focusing on pain management. We also gained an understanding of the physical therapy industry and the relationship between the patient and physical therapist. Interviews completed this quarter focused on chronic knee pain management. Our goal this quarter was to speak with patients from a wider demographic who experience a greater range of knee pain and identify a group of people that are most in need of our device. Not all interviewees are discussed below though the comprehensive customer interviewee list is attached as Appendix 2.

Patients

Winter Quarter

Julia: High velocity hyperextension injury from practicing in the circus. Grade 6 injury that required 3 plates and 16 screws hold together her knee. A lot of nerve damage that causes most of the pain. Received genicular nerve ablation to reduce nerve pain. Ablation worked for 4 weeks but then the pain would come back. She has bad gait problems that she couldn't fix, so she later decided to get a total knee replacement. She does a lot of physical therapy and visits pain management specialist. Uses a lidocaine patch, ibuprofen, and TENS unit. She has no problem participating in the circus, but she still has a lot of pain when walking.

Robin: Has had 2 year of chronic pain from mountain biking. Pain is worst after a lot of time spent on her knee and after exercising. Not sure what is wrong with her knee but thinks it is runners' knee. Experiences pain at the top of the kneecap and has inflammation and scar tissue. Has done a lot to try to cure her pain but has concluded that the pain will never go away, and she needs to learn how to live with it. Has reduced her physical activity but it is very difficult to work since she has a job that requires hiking. She has tried proliferation therapy, dry needling, and acupuncture but all of these provide only temporary relief, not sure if they did much. She has tried 4 physical therapists who have not helped her progress and 5 orthopedic surgeons who said there was no surgical treatment. She is searching for a

long-term solution but feels hopeless. She is against using pharmaceuticals as a treatment.

Jenny: She is a long-distance runner and was training for marathon when her knee got sore. She continued to run on it, but it hurt so bad that she knew it was injured. Not sure what her injury is but thinks it is patellar tendinitis. Has tried physical therapy once a week but is a self-motivated person and thinks physical therapy is not helpful. She has paid out of pocket for ultrasound therapy and says that it helps instantaneously. Her knee aches throughout the day but aches worse during weeks that she does not have ultrasound therapy. She is a drug recovery counselor and does not take pharmaceuticals.

Vicki: Has chronic pain after a torn ACL and meniscus. She did not receive an ACL replacement and has learned to live without an ACL. Her pain has never fully gone away and has limited range of motion. The worst pain is when her knee gets stiff and she can't bend it. She has a hard time falling asleep and takes Aleve as a last resort to help her fall asleep. The most frustrating part is not being able to walk around at work when her knee hurts. She applies a heat pad in the morning before work to get her blood flowing and reduce inflammation.

Ronni: She is an endurance athlete and 3-time iron man finisher. After the 2nd iron man, she tore her meniscus from overuse. When surgeon went in, they found she genetically has less meniscus and she tore a meniscus in her right and left knees. She has tried Orthovisc injections and platelet-rich plasma injections. She is not sure if the injections were helpful, but she is hopeful that they were. She does not use pharmaceuticals but uses ice and electrical stimulation to reduce pain. She has stopped running but is now a spin instructor.

Jemma Jio: Jemma experiences knee pain whenever she exercises after tearing her ACL in both knees 5 years ago while playing soccer. She shared that it can be frustrating to try and go back to playing soccer or work out in general because she has to wear two fairly bulky braces on either leg that tend to limit her mobility somewhat. Typically, she'll use a heat pad in the evening as she's going to bed, but she hasn't tried much else than that.

John Fischer: John stated that he experiences knee pain whenever he exercises, which can then carry on throughout the next 10-12 hours. Since he tries to work out at least three times a week, this means that he spends the majority of his time dealing with pain in his knee. Currently, John will typically just ice his knee when it starts to hurt since he feels that the pain is bearable, and he doesn't want to pay for treatment. This leads us to

believe that we should start interviewing members from an older demographic to see if they would be more willing to pay for a treatment.

Vincent Mejia: Vinny deals with chronic knee pain, but it's even worse after exercising. He's experienced this for about 5 years. Often, it tends to go away to more of a dull throb, but it worsens again with activity. Currently, for treatment he just takes Advil for the pain, but most of the time it's dull enough that he can just ignore it. He's tried going to a few orthopedic doctors and they've said he has patellar tendonitis and misalignment in both of his knees. He's been referred to some physical therapists but has never gone because he'd need to go 3 to 4 times a week and he doesn't have time for that. Currently he is resting more and running less than he'd typically like, but it does feel as though it's making a difference. He says that for now, Advil will be sufficient.

Mayah Walker: Mayah tends to experience a sharp pain in her knee when exercising or if she presses down in a specific spot/angle, but only as long as pressure is exerted. Currently Mayah hasn't gone out of her way to seek pain relief techniques for her knee pain because she assumes it will disappear with time, and it's not very severe. She hasn't been referred to any pain management treatments but does want to try using an elastic band to stretch out her knee when it starts to hurt.

Spring Quarter

Melanie Aubrey: Melanie has played soccer for 35 years and tore her ACL, MCL, and meniscus in college. Since then, she has had many issues with her knees but has continued playing sports. Her left knee is now completely torn up on the inside but there is nothing else she can do besides total-knee joint surgery. She is worried that if she takes time off for a surgery, she will never get back to endurance sports. She is holding off on the total-knee joint surgery for as long as she can before she can no longer participate in long-distance running and triathlons. She currently uses Advil and ice to relieve her pain.

Joy Fischer: Joy is a tennis player who tore her ACL and meniscus three years ago during a match. She had surgery to repair the ACL but her knee has never gotten back to full recovery. She has not returned to tennis but has started competing in triathlons since it is easier on her knee. She received TENS therapy at the PT clinic but felt like it was a waste of time to go into the clinic for TENS therapy. Thought it would be more effective to do it at home, on her own.

Sharon: Sharon started running 2 years ago and started experiencing knee pain after 6 months of running. She went to see an orthopedist and they

diagnosed her with osteoarthritis. She has tried a series of three hyaluronic acid shots but that only relieved pain temporarily. She also went to physical therapy for three months but thought it was a waste of time.

Eyal Golan: Eyal ran his first half-marathon a year ago and started running with a running group. Shortly after, his knee started hurting during an 18-mile race. The pain would come back each time he ran and got to the point where it hurt too badly to run. However, he is very passionate about running and continued to run by managing the pain with advil and opioids. He recently got surgery for a torn meniscus but started running a month later and it is still in a lot of pain.

Sheryl Walsh: Sheryl tore her meniscus 8 years ago and her knee has never been the same. She competes in mountain bike races and has had a few falls that have further injured her knee. To manage the pain, she has tried cortisol shots, Orthovisc injections, and Motrin. Her pain is bad every day and one month she took so much Motrin that her stomach started bleeding and she was hospitalized. She still competes in triathlons, but she can't exercise two days in a row because the pain is so bad.

Amy Rosenthal: Amy's pain started 31 years ago when she was hit by a car while running and broke her tibia and fibula. It took 4 surgeries to get her leg reconstructed and she suspects that her knee joint cartilage was damaged during that process. Her knee pain started getting really bad 2 years ago from osteoarthritis and it is almost debilitating. She is considering getting a total-knee joint replacement, but she is not able to currently due to the pandemic. She can run once or twice a week with manageable pain but after getting surgery, she will not be able to run for 6-7 months. She currently uses a heat-pad and compression brace to relieve pain and provide extra stability.

Physical Therapists

Jason Sanders - PT, DPT, OCS, GCS: Huge problem is that 90% of people who need PT don't have access to PT, how do we give those people access? A lot of money is spent on patient engagement, his company is developing website called Everflex that has videos to guide people through exercises at home. Sees potential for internal ligament brace for ACL in the next 5 years, which would significantly decrease recovery time.

Michael Williams - PT, MSPT, OCS, ATC, FAAOMPT: Beneficial if technology for ACL patient could be used for total knee joint patients too. Sees more total knee patients and usually they are worse at doing exercises

due to the population demographic. Offered to run clinical studies on new technology with his patients.

Jonathon Grisanti - PT, DPT, OSC, CSCS: Utilizes various technologies to help improve patient outcomes including at-home exercise apps, slow motion camera apps, at-home electrode stimulator, and blood occlusion device. Technology used in clinic needs to be easy and fast to set up to take up minimal clinic time. Athletes travel far to visit him due to his advanced technology. Patients are not charged anything more for use of in-clinic technology. He advises patients to buy a mobile electrode stimulator for \$400, it is covered by some insurance.

Richard Goldbach - PT, MPT, OCS, CAE: Stated he is an “early adopter” of any new technology that helps his patients get better faster. Technology used in clinic needs to be backed with clinical research and data. Patients currently don’t understand when they are improving because they can’t physically see progress.

Brandon Weipert - PT, DPT, OSC: Recovery depends on the strength and performance of the entire body including hip, ankle, glute, quadricep, and hamstrings. Hard to quantify performance on a uniform scale, every patient is different, everybody moves differently. Length of recovery depends on their fitness level before injury. Insurance is getting worse and patient visits are limited so he works with patients to give them at-home therapy routines, no patient attends therapy for as long as they would like.

Subject Matter Experts

Dr. Dustin Grooms, Associate Professor at Ohio University - MED Kinesiology, PhD Biomechanics and Neuroscience: Neuromuscular retraining is critical for injured athletes. He is working with a start-up company to develop an augmented reality and virtual reality program that helps athletes improve neuromuscular motor skills. He was also given a grant for \$750,000 from the US Department of Defense to research how augmented reality experiences can physically change the brain function of soldiers recovering from ACL reconstruction. VR and wearable device technology are currently not affordable for at home use and affordable sensor devices do not provide real-time data feedback that is accurate enough.

Dr. Lynn Snyder-Mackler, Alumni Distinguished Professor at University of Delaware - PT, ATC, Sc.D, SCS, FAPTA: One of the most accomplished ACL researchers in the world with over 150 published research studies regarding ACL reconstruction recovery methods. Consults many companies

developing wearable devices to sensor knee movements including Stryker. What is our niche and how do we compete with these companies? There is a large market need for a device that accurately measures quadricep strength and is affordable for community clinics. PT's currently use hand-held dynamometers, but these are inaccurate, other technology that works better is \$50-100K.

Dr. Dimitri Delagrammaticas, MD - Orthopedic Surgeon: There is no gold standard protocol for ACL recovery, lots of contradictory research and nobody knows the best method. He works with PT to develop protocol for each patient, works with any PT that is convenient for the patient. There are many sensor devices out there, but he does not know anyone who is adopting them. He would not know what to do with the data. Any device with biofeedback would need to analyze data and recommend next steps.

Dr. Christopher Powers, Professor and Director of the Musculoskeletal Biomechanics Research Laboratory at University of Southern California - PhD, PT, FAPTA: He works with elite athletes and uses motion capture cameras to analyze their biomechanical movements. The ideal recovery program would be 3 PT visits per week for 9 months, this is over 100 visits and most people only receive 10-30 visits from their insurance. Every person will get a different experience, depending on their insurance coverage. The most critical part of the recovery is the time after the PT is done with them and when they are returning to sports. There is a huge grey area between the end of PT and returning to sports.

Dr. Trevor Cardinal, Professor of Physiology at California Polytechnic State University, San Luis Obispo - PhD: Trevor works in the biomedical engineering department, so we met with him to learn more about the physiological processes behind wound healing. In order to determine what technology would be best to use for our product, we first must understand what's happening when your body is repairing itself. Trevor talked to us about how the buildup of collagen (scar tissue) following an injury can sometimes go unregulated, which when partnered with chronic inflammation, can lead to wear and tear on the joint cartilage and could ultimately lead to osteoarthritis. This is what led us to deciding we would need a way to help flush out the buildup of interstitial fluid at the site of the injury.

Key Insights Summarized

During fall quarter, we verified that patients who are self-motivated throughout their recovery and complete their at-home exercises have a more successful recovery. Some factors keeping patients from completing their exercises are pain, fear of re-injury, uncertainty they are doing it right,

and low motivation. We found that patients who were hoping to return to high level sports were the most motivated and engaged in their recovery.

During winter quarter, we dove deeper in understanding the experience of chronic pain patients. We expanded our demographic from ACL patients to all athletes or any age who have experienced pro-longed knee pain. Most of the people we interviewed were athletes over the age of 45 who are experiencing pain due to overuse. This demographic is actively seeking solutions to relieve their pain. Many of the treatments they are using are investigative therapies that are paid for out of pocket. The goal of these therapies is to reduce pain or speed up the recovery process.

This quarter we continued to interview athletes over 45 who have chronic knee pain and identified a group that commonly experiences chronic knee pain. These people are athletes who participate in endurance sports such as marathon runners and triathletes. These are high-impact sports that require overuse of the knee joint. Additionally, as people age, they become more susceptible to developing osteoarthritis, especially if they have prior knee injuries. Most chronic knee pain can not be managed by interventional surgeries besides total-knee joint replacement, so these people often seek methods to prolong the lifetime of their native knee joint. Through interviews, we verified that these patients commonly seek several pain management techniques and there is no “one-size fits all” solution for chronic knee pain. These people often seek multiple opinions from health care professionals and resort to pain killers as a last resort pain management treatment.

In addition, we found that the main goal of physical therapists is to achieve patient recovery as efficiently as possible. They will readily adopt new technology if it is backed by research and data supporting that patients get better faster with the device. Most technology used in the clinic is an investment by the clinic and patients do not pay more to use this technology. The investment return for physical therapists is that their patients are showing better outcomes, therefore, orthopedic surgeons will send them more of their patients. We found one example of an electrode stimulation device that the physical therapists recommend the patient to purchase for about \$400. This device is covered by some insurance and is used as an at-home therapy device. After talking to the physical therapists, we are convinced that they are looking for interventional therapy technology that can speed up or enhance their patient’s recovery.

We are confident in our decision to sell this product direct-to-consumer since people are seeking methods to manage their pain on their own. The most effective pain management therapies are only available in health care settings and people with chronic knee pain are left on their own to research

pain management treatments that may help their recovery. We have found that after a couple years of knee pain, people feel hopeless that they will ever recover and hope to continue participating in their sport for as long as they can manage the pain.

Minimum Viable Product

For our minimum viable product, our goal was to develop a deeper understanding of the customer segment and corresponding demographics of people who are currently seeking a prescription-free solution to knee pain. In addition, we hoped to collect contact information of potential customers to be used for further customer development.

Landing Page

We began by implementing a landing page highlighting the value of our hypothetical product to potential customers. The key value proposition that we are offering to page visitors is “Drug-Free Pain Relief,” as shown on our home page in Figure 5. The assumption we are testing through this landing page is that people with knee pain are seeking an alternative to pain medication.



Figure 6. Home Page of Kinexion Devices Landing Page

We designed the subtitle to clarify our target audience to those with knee pain specifically and provide confidence to viewers that their injury recovery could be accelerated and improved with our product. To further increase the viewer’s trust in our product, the second section of our landing page describes to the reader the advantages of the pain management intervention method, interferential current electrical stimulation. This “How It Works” page is shown in Figure 6. We stress the fact that not only will their pain be relieved, but their body will naturally improve in function

after using our device. We also included images to emotionally sympathize with our target audience and demonstrate that our users can transition from discomfort and pain back to their sport or activity through the use of our device. The image of our hypothetical product displays a generic knee wrap that viewers would be familiar with using.

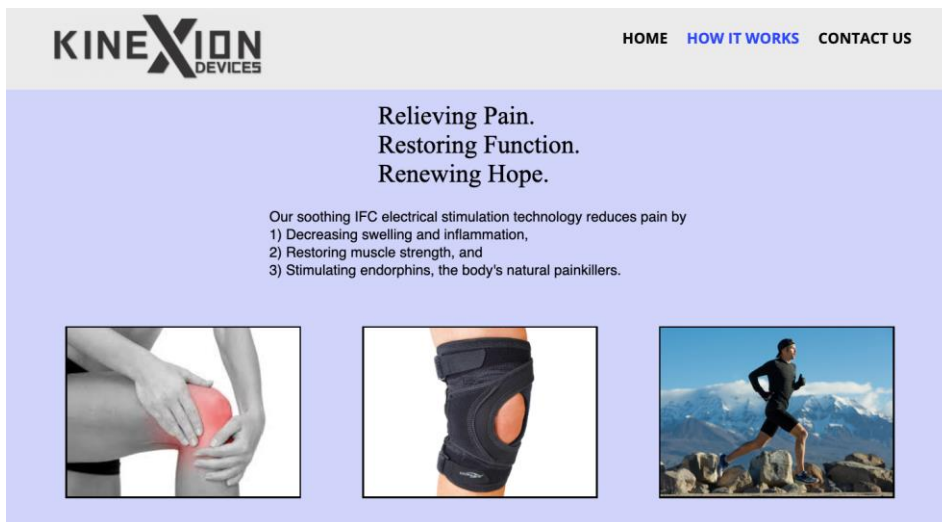


Figure 7. 'How It Works' Page of Kinexion Devices Landing Page

The concluding section of our landing page, shown in Figure 7, contains our call to action for the website viewer. We reiterate our value proposition of achieving pain management without medication and encourage the website visitor to sign up for our company newsletter to learn more about achieving pain relief. Additionally, the button on our home page with the call to action "Become Pain Free" redirects visitors to this page immediately. Finally, we include our social media links to Facebook, Instagram and LinkedIn so that website visitors have trust in the validity of our company and can contact us directly if they desire.

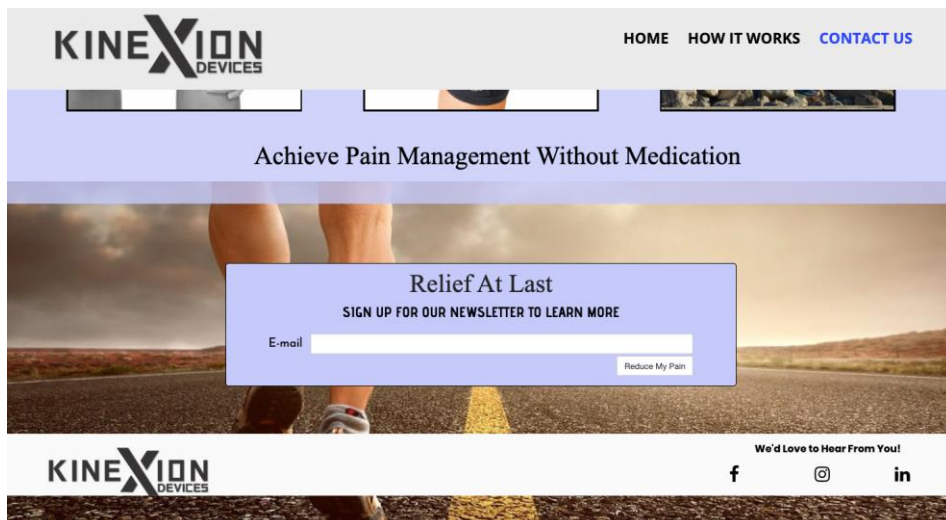


Figure 8. 'Contact Us' Page of Kinexion Devices Landing Page

In order to understand how our website is performing and gain insight into website visitor interest, we set up a Google Analytics account to monitor the landing page traffic. Google Analytics tracks the quantity and geographic location of page visitors, the average session duration, and many more metrics. Most importantly, we hoped to collect the contact information of interested potential customers and understand the form submission rate among page visitors.

As will be further explained in our next section on advertising, we decided not to direct customers who interacted with our advertisement to our landing page. Therefore, all reach was organic and resulted in 26 page visits and zero form submissions over the course of 3 days. The organic traffic was primarily derived from social media, with 18 users visiting from Facebook referrals and 1 user from Instagram. It is likely that these visitors were directed to our landing page after visiting our social media pages and clicking our website link on those pages.

Facebook Advertising

During winter quarter, we aimed to advertise our business online to generate leads and further understand our customer segments. In the beginning of the quarter, we implemented Google Ads to market our physical therapy device and encourage internet users to visit our website. However, we found ourselves on pace to spend over \$100 per week on the basic advertising plan and began researching other marketing strategies.

Our research led us to social media advertising through Facebook Business Manager. We opted to shift from Google Ads to Facebook advertising because the minimum advertisement budget for Facebook was only \$1 per day, as well as the fact that Facebook offers more advanced demographic analytics for audience targeting and success metrics. Because nobody on the team had experience with social media advertising strategies or the Facebook Business Manager service, we developed a business to business relationship with Tiamat Marketing Management, a digital marketing company founded and owned by a connection of our team. Through this relationship, our team gained a valuable business asset that offered guidance for success in digital marketing.

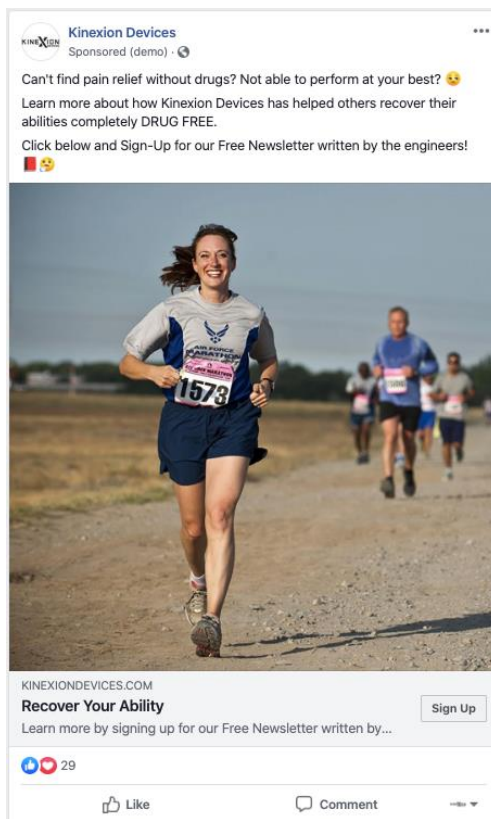


Figure 9. Kinexion Devices Facebook Advertisement

In order to generate leads and further understand our potential customer segments, we implemented a Facebook advertising campaign that demonstrated our value proposition to Facebook users and included our call to action of signing up for our company newsletter. An example of our company Facebook advertisement is shown above in Figure 8. Similar to our landing page, our advertisement emphasizes the opportunity for drug free pain management. Due to Facebook's advertising policy, we can not include any keywords in our advertisement that references the health of our target audience. Therefore, we can not specify "Knee Pain", "Arthritis" or "ACL" in our description or heading.

One advantage of Facebook advertising is their advanced audience targeting algorithms. When initiating the advertisements, we set up ten unique audience sets so that we could individually track our success metrics for each one to determine which demographics are most interested in our hypothetical product. The target audience can be filtered by geographic location, age, gender, language, and personal interests. The personal interests are interpreted by Facebook based on each user's involvement in Facebook groups and engagement with content. Multiple interests could be "Stacked," where anybody that has any of the interests qualifies, or the interests could be "Flexed," where only people who meet all of the required interests qualify. The audiences we initially set up were all worldwide, English speakers above 18. The uniqueness of the 10 target audiences was rooted in the interests of the users:

- 1) Running
- 2) Basketball
- 3) Sports
- 4) Biking (all types)
- 5) Weight Watchers OR Diet OR Plus Size Clothing
- 6) Diabetes AND Weight Loss
- 7) Arthritis AND Knee
- 8) Athlete AND Health and Wellness
- 9) Athlete AND Fitness and Wellness
- 10) Knee OR Joint OR Occupational Therapy OR Injury OR Physical Therapy

Facebook's advertising algorithm is constantly optimizing advertisement reach based on real-time results and data analytics. Therefore, when one target audience group is providing a high lead result rate, the advertisement is typically shown to people in that target audience more often. However, these results are also dependent on budget. We elected to spend the minimum on our advertising, \$1 per day for each set for a total of \$10 per day.

If an interested user clicks on our advertisement, they are prompted to submit a form with their name and contact information. This prompt is

shown in Figure 9. Facebook automatically collects the form submissions, as well as further details about submission times and the specific advertisement each submission came from for us to view. We decided to utilize Facebook’s form lead tool in order to increase the volume of impressions and results generated from our advertisements. If our advertisement redirected to our landing page, our theoretical sales funnel of the customer journey from seeing our advertisement to providing their contact information would be substantially longer. With the additional steps and lower efficiency, our results would undoubtedly decrease dramatically.

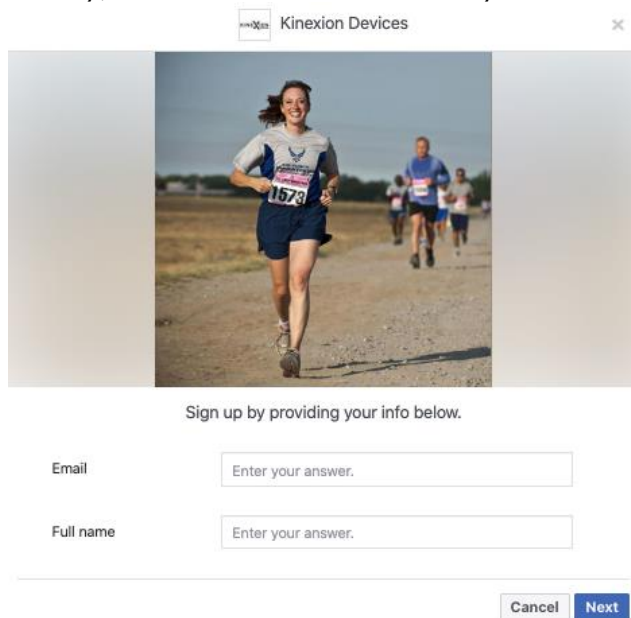


Figure 10. Kinexion Devices Facebook Advertisement Call to Action Form

The results of our Facebook advertising campaign, active from February 28th to March 9th (11 days), are shown in Table 1. We organized our results by target audience in order to determine which audiences were most interested in our offering. As seen in the table, the highest performing advertisement sets were people interested in “Arthritis AND Knee,” “Athlete AND Health, Fitness and Wellness” and “Running.” The lowest performing advertisement sets were “Sports,” “Weight Watchers OR Diet OR Plus Size Clothing” and “Diabetes AND Weight Loss.”

Table 1. Facebook Advertising Campaign Results

Success Metric	Unique Impressions per day	Click Through Rate	Form Submission Rate	Cost per Lead
Satisfactory	500	3%	0.1%	\$0.50
Excellent	1000	5%	0.5%	\$0.25
Running	1049	6.38%	0.42%	\$0.18
Basketball	1345	4.03%	0.25%	\$0.23
Sports	1293	3.88%	0.20%	\$0.31
Biking (all types)	1153	5.55%	0.36%	\$0.19
Weight Watchers OR Diet OR Plus Size Clothing	863	5.64%	0.34%	\$0.25
Diabetes AND Weight Loss	868	6.39%	0.39%	\$0.21
Arthritis AND Knee	811	7.25%	0.65%	\$0.14
Athlete AND Health and Wellness	861	8.15%	0.53%	\$0.15
Athlete AND Fitness and Wellness	1171	5.65%	0.47%	\$0.15
Knee OR Joint OR O.T. OR Injury OR P.T.	1096	5.99%	0.44%	\$0.16
Average	1051	5.89%	0.41%	\$0.20

Newsletter

From our Facebook advertising campaign, we received over 600 form submissions with contact information. To aid in our customer development, we hoped to collect data on the current pain management techniques of those who demonstrated interest in our product. To do this, we drafted an email newsletter and sent it to all of the emails that were collected during our advertising campaign. In this newsletter, we further explained the vision of our company and explained interferential current therapy and its efficacy. Finally, we invited readers to participate in a survey to better understand their current pains and the solutions they have utilized to manage their knee pain. Unfortunately, we received fewer than 10 survey responses. Based on this low response rate, we deemed the newsletter as an ineffective method of customer outreach and discontinued its progression.

Business Model Canvas Development

Included in Appendix 1 is the development of our business model canvas and the three major iterations we went through this quarter. The first iteration of our BMC reflects our pivot to a pain management device. In the initial stages of this quarter, we believed that we would continue to focus on ACL patients and their low adherence to at home exercises. We determined this was due to the pain experienced after surgery, and sought

to create a pain management device that would allow ACL patients to perform their at-home exercises. After performing further customer development in this space, we determined that ACL patients would not be the ideal customer base as they already have access to a wide array of pain management devices and represent a very small portion of the pain management market. We discovered there was a much wider range of people seeking knee joint pain management devices.

The second iteration of our BMC illustrates our pivot away from ACL patients specifically and really clarifies a lot of areas of our business plan for a pain management device. Beginning with our customer segment, we began to define the window in which people would consider our device and settled on a consumer facing device. We arbitrarily chose a pain duration of 2 weeks as the amount of time that pain would need to persist before an individual would consider trying our device. This was determined by finding the average amount of time people we interviewed would deal with pain before seeking a solution.

The value proposition defined in our second iteration has been cemented as our main value proposition. This states that our device helps people who experience knee joint pain relieve their pain with a drug-free alternative while outside of a clinical setting. We are currently testing if drug-free alternative is truly something our customers are seeking and something we can capitalize on. Relieving pain outside of a clinical setting is a very key component of our value proposition as this is what allows us to be a consumer facing device that will be used both at home and on the go for our customers.

Since we are now dealing with pain management, our key partners have changed to reflect this. Our key partners continue to include physical therapists, orthopedic surgeons, recovery subject matter experts, and insurance providers, but has also expanded to include chronic pain support groups, pain management physicians and clinics, and injured athlete support groups. Gaining traction with these key partners will provide us information towards our potential customers and truly understand how our customers make their pain management decisions.

One mistake we made in the second iteration of our BMC was by reversing the definitions of channels and customer relationships. This was caused by a confusion that channels are how we get our product to market and customer relationships are how we go about acquiring new customers and maintaining existing relationships. Our channels are an online website with associated technical support. Our customer relationships are direct through social media marketing, email newsletter, and in-person marketing

and indirect through physical therapist and physician referrals and pain management advocacy groups.

In the third iteration of our BMC, we narrowed our definition of our customer segment. We have moved away from the arbitrary pain duration of two weeks because of evidence found through our customer interviews. We defined our customer segment as two targets: those seeking acute post-surgical knee joint pain management and those seeking a chronic knee joint pain management solution. In both segments, we continued to investigate if we are directly competing as an alternative to pain killers, both prescription and over the counter.

Our current iteration of our BMC has seen us continue to narrow in on a more specific initial customer segment. Our customer segment is defined as active individuals over the age of 45 who experience chronic knee pain and the only surgical treatment available to them is a total knee replacement. This has come from the extensive customer interviews we have performed, which has led us to truly understanding who is most willing to try our product and be our early adopters. By properly defining our customer segment, we have also been able to succinctly state our value proposition. Our value proposition is, "We empower people with chronic knee pain to manage pain on their own, without the use of drugs." Customer interview evidence has shown that we will indeed be a competitor to pain killer drugs for our initial customers. We have also finalized the channels we will utilize to sell our product, being our own online website and selling on Amazon.

Remaining Assumptions

We do have some remaining assumptions about our customer. We are unsure why people have not tried this technology before. Interferential current therapy has existed for a couple of decades and has been shown to be more effective than TENS units, but many people we talked to have not heard of it. Some assumptions are that the technology is mainly used in the clinic and only few at-home devices exist. We are also unsure about the population of people that are looking for an alternative to pharmaceuticals for pain management. We assume that most people would favor a non-pharmaceutical solution over a drug solution. However, many chronic pain patients do use pharmaceuticals to manage their pain and we have not completed enough interviews to understand which patients believe drugs are their best option.

Another assumption is that we assume people are looking for a portable pain management solution instead of a stationary device. We have talked to a few people who have mentioned that they experience pain at

work or while exercising, but it is unsure if the majority of people would rather have a portable device over a device they can only use at their house. We have assumed that this device would follow the trend of consumer items being more portable, able to connect to their phone, sleek, and easy to use. However, these are all assumptions based on new consumer electronics and not based on a significant number of customer interviews.

Customer Profile and Value Map

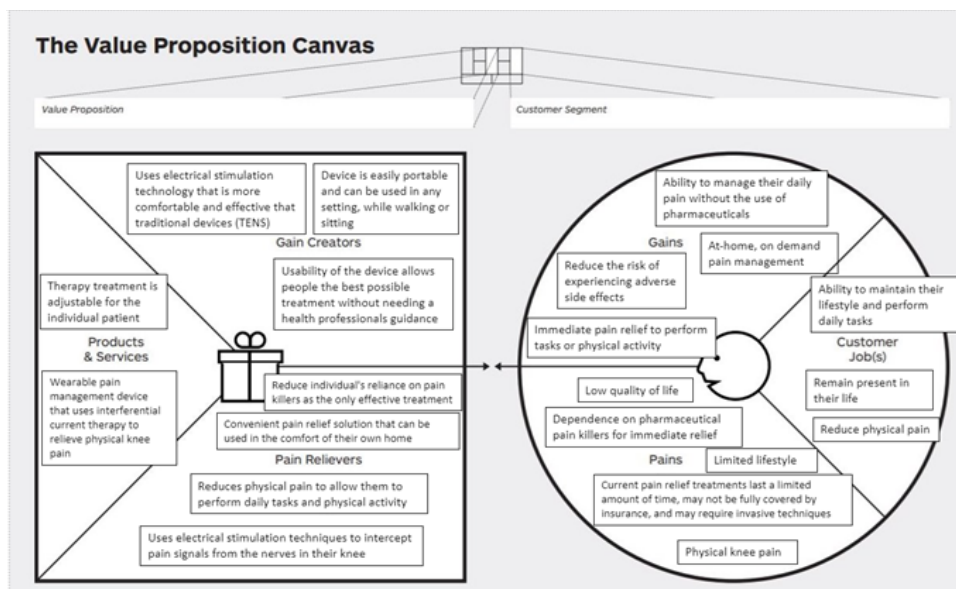


Figure 12. Value Proposition Canvas

Customer Persona

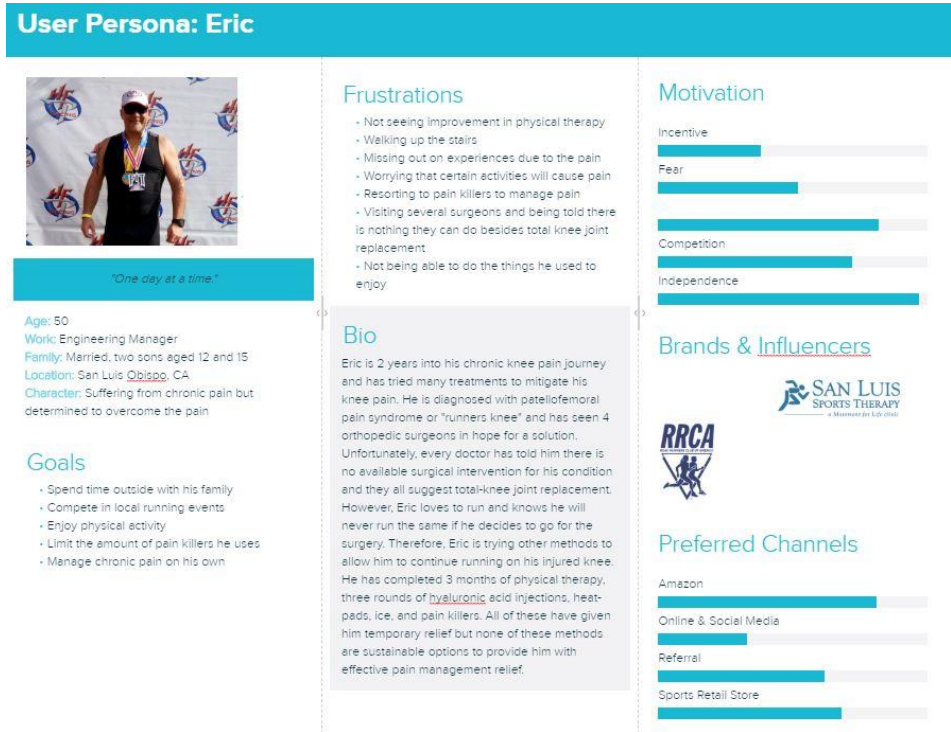


Figure 13. Customer Persona

Revenue Strategy

Based on our cost of goods and market research we determined the unit price for our product. We considered having a business model based on recurring subscription sales of electrodes, but we realized that customers could buy non-brand electrodes. We decided to put the bulk of the price in the device itself and have an option for recurring revenue.



Figure 14. Revenue Strategy

Financial Analysis

Kinexion

Unit Economics

Revenue	Dollar Cost	Percentage
One unit	\$130.00	100.00%

Cost of Goods Sold (COGS)		
Electronics Housing	\$5.16	3.97%
Fabric	\$8.35	6.42%
PCB	\$38.61	29.70%
Total	\$52.12	40.09%

Expenses		
Merchant Fees	\$4.07	3.13%

Contribution Margin	\$77.88	59.91%
----------------------------	----------------	---------------

We started our financial analysis with our Bill of Materials as a starting point. We determined our unit economics by estimating cost of materials and cost of shipping and manufacturing. We set a unit price based on market comparisons of similar products. Although TENS units are cheaper, based on our research, IFC does a better job of relieving pain and the sophistication of the technology allows us to charge more but still in the same relative area as other pain relief knee wear.

Table 2. Unit Economics

After looking at the unit economics, we looked at other costs and expenses that we will incur over the course of developing our product and getting it to market. Major upfront costs included FDA registration and approval which costs about \$8000 for a class II device. We also needed to account for clinical trials and device testing to make sure the device was proven to help patients with their pain. The bulk of the cost of goods was manufacturing. We tried to estimate the cost of how much injection molding would cost. We talk more about that in the mechanical section. We made these estimates by looking up quotes online. Besides those costs, we also looked at rent, salary, and other administrative expenses and put them all in a spreadsheet.

Table 3. Balance Statement

Selling, general and administrative	2020	2021	2022	2023
Advertising	200	52500	52500	52500 7 - 8 %
Bad debt				
Manufacturing	0	234540	234540	703620 45% of product unit cost
Depreciation				
Employee benefits				
Furniture and equipment	500	1000	2000	2000
Insurance - Workers' Compensation	0	0	816	816 \$68/month
Insurance - Business Owners' Policy (BOP)	0	0	744	744 \$62/month
Insurance - General Liability	0	0	552	552 \$46/month
Insurance - Professional Liability	0	0	504	504 \$42/month
Building Maintenance and Repairs	0	0	1630	1630 \$1.63/Sq.Ft. Annually at 1000sqft
Building and Facility Utilities Cost	0	0	2150	2150 \$2.15/Sq.Ft. Annually at 1000sqft
Janitorial Building Facility Costs	0	0	1370	1370 \$1.37/Sq.Ft. Annually at 1000sqft
Office supplies	0	828	828	828 \$92 per employee
Payroll taxes				
Rent	1,350	1,350	1,350	1,350 1.35 per sqft at 1000sqft
Salaries and wages	0	0	424,800	424,800 47200 per person at 9 people
Software	200	200	200	200 5.2% of expenses
Travel	0	100	500	1000
Utilities	120	120	1200	1200 2.10 per square foot.
Web hosting and domains	100	100	1200	1200
Totals	2470	290738	726884	1196464
Research and development expenses				
Research and development		500000	375000	375000
FDA Device Registration		\$5,236		
Injection molds and etc		4000	60000	60000
Patents		\$10,000		
Totals		519236	435000	435000

Table 4. Profit Loss Statement

Kinexion				
Twelve Months Ended December 31,	2020	2021	2022	2023
Sales and revenues				
Number of Units	0.00	100.00	10,000.00	30,000.00
Sales	0.00	13,000.00	1,300,000.00	3,900,000.00
Revenues of Financial Products	1,000.00	3,000,000.00	0.00	0.00
Total sales and revenues	1,000.00	3,013,000.00	1,300,000.00	3,900,000.00
Operating costs				
Cost of goods sold	0.00	5,212.00	521,200.00	1,563,600.00
Selling, general and administrative expenses	2,470.00	290,738.00	726,884.00	1,196,464.00
Research and development expenses	64.23	519,236.00	435,000.00	435,000.00
Total operating costs	2,534.23	815,186.00	1,683,084.00	3,195,064.00
Operating profit	-1,534.23	2,197,814.00	-383,084.00	704,936.00
profit margin	-153.42%	72.94%	-29.47%	18.08%
Total cash flow	-1,534	2,196,280	1,813,196	2,518,132

These numbers are estimates and many of the numbers were determined by searches online. However, we believe we could make a profitable business and launch our product within 3 years based on this analysis.

Channel Strategy

Due to a trend toward online sales, we decided to use our website and Amazon as our main channels. For advertising we would use Facebook and Instagram as our main platforms for outreach and we would use paid and free methods of advertising. For actual money transactions we would use either Shopify or Stripe to process the online orders.

Formal Product Definition

Customer Requirements

After our last round of customer interviews what we understand is that just about every person experiencing chronic pain is constantly seeking a permanent solution. Research has also showed us that physicians and patients are attempting to move away from the prescription of opioids and are seeking a device that can help reduce their pain without medication. For them to trust our product, our product must be effective in real trials and case studies. These are the metrics we have determined that will validate the effectiveness of our product.

Included below is our table of customer requirements, which are the results of all our customer interviews. This table contains the most important value propositions that we must meet for our customers to feel the need to buy our product. Many of our requirements are written in the sense of how the value proposition would help the patient’s chronic pain management.

Table 5. Customer Requirements

Value Proposition	Customer Requirement	Confidence	Risk to Achieve
User perceives less pain while using the product	Device effectively utilizes “distraction mechanism”	10	High
Alternative pain management option to pharmaceuticals	Device does not incorporate pharmaceuticals	9	High
User observes improvement in their daily pain levels, joint function, or injury recovery after using the device daily for a duration of time	Device uses therapeutic method that is proven to have long term benefits	7	Medium

User can change stimulation level applied	Controls on the device allows user to increase or decrease stimulation	5	Medium
User is able to easily determine the function/purpose of any controls on the device	Device is not overcomplicated and has intuitive controls	7	Low
User has a convenient pain management solution to use outside of clinician offices	Product is affordable, safe, and easy to use without the guidance of a clinician.	9	High
User can complete daily tasks while using the device	Device remains in place on the user's body while they are walking	7	Medium
User can easily transport the device wherever they need	The device is lightweight, wireless, and rechargeable	9	High
User is able to comfortably position the device around their knee	Device can adjust to various sizes depending on the customer	8	Low

Use Cases

There are three use cases we envision for our customers and our device.

1. Before heading out on a run, to increase blood flow and warm-up their knee.
2. After coming back from a run or other activity, to reduce pain and swelling.
3. Throughout the day when experiencing pain or soreness.

Engineering Requirements

These requirements were developed to satisfy the previously customer requirements that were extracted from the main value

propositions our product provides to people with chronic pain. All engineering requirements were categorized based on those same key customer requirements outlined previously. Specifically, we focused on defining the effective pain treatment, durability, user experience, portability, and safety requirements we intended to meet to ensure our product delivered our key values to our customers.

Electrical Engineering Requirements

Requirements that involve the electrical signal used during therapy have been modeled primarily off of electrical device safety regulations from multiple sources^{13, 14}, standard IFC treatment routines, and other devices that were cleared by the FDA¹⁵ and under FDA regulations. Table 6.1 contains these requirements which define how to provide effective pain treatment. From the research completed, it became apparent that the FDA requires no more than 100mA of current to be delivered to a 500 ohm load. This 500 ohm load represents a skin with very low resistance which is ultimately an unsafe condition. This would be likely to happen if point of electrode application is wet or if there are cuts present on the treatment area. Research also revealed that the optimal frequencies of the treatment signal (known as the interferential beat frequency) is between 1 and 150Hz with the most effective treatment happening at around 20-30Hz.

Table 6.1 Electrical Engineering Requirements - Effective Pain Treatment

Parameter Description	Engineering Requirement	Tolerance	Risk	Compliance
Output Current	100mA, 500 ohm load	Max	High	A, T
Output Voltage	50V Peak to Peak, 500 ohm load	Max	Medium	A, T
Carrier Frequency	4000 Hz, fixed	Absolute	High	A,T
Adjustable Frequency	4001 - 4150 Hz	Absolute	High	A,T
Interferential Beat Frequency	1 - 150Hz	Absolute	High	A,T

Waveform	Sinusoid with 0 DC Offset	Min	Medium	A,T
----------	---------------------------	-----	--------	-----

We aim to be there consistently for our customers through their entire recovery process. Table 6.2 defines the requirements that allow us to provide a durable, drug-free experience. Our electrical components will need to be selected and tested to ensure our device is functional for at least 3 years. Additionally, the X1 will come with an integrated rechargeable battery pack so that it is able to provide multiple treatment sessions without requiring any electrical maintenance. This design ensures that the device remains sealed so that the electronics, and therefore the safety and integrity of the device are maintained.

Table 6.2 Electrical Engineering Requirements - Durability

Parameter Description	Engineering Requirement	Tolerance	Risk	Compliance
Electrical Lifetime	3 years	Min	Low	T
Power Source	Rechargeable batteries	Min	Medium	A, T

The X1 represents a convenient, easy-to-use treatment platform. In order to meet this expectation, the device will offer 3 modes that adjust the frequency of one of the signals that are mixed to produce the electrical treatment. Consequently, this adjustment will result in three different interferential beat frequencies, each offering a different treatment intensity. This alongside with a battery life indicator will provide the ease-of-use that our customers value. Both of these requirements can be seen in Table 6.3 below.

Table 6.3 Electrical Engineering Requirements - User Experience

Parameter Description	Engineering Requirement	Tolerance	Risk	Compliance
-----------------------	-------------------------	-----------	------	------------

Low Battery Life Indicator	Green: >75%, Yellow: 25-75%, Red: <25%	±5%	Medium	T
Adjustable Frequency	4001 - 4150 Hz	Absolute	High	A,T
Waveform Adjustment Indicator	3 discrete modes	Min	Medium	I

Many of the devices currently on the market are large and must be plugged into a wall outlet. The following requirements ensure that we can provide our clients the freedom and convenience of portability. A battery life of 12 hours establishes a standard that each of the other requirements are built upon. In order to meet this 12-hour minimum, the circuitry for the device is simulated and so that the power consumption of the circuit can be minimized.

Table 6.4 Electrical Engineering Requirements - Portability

Parameter Description	Engineering Requirement	Tolerance	Risk	Compliance
Power	5W	Max	Medium	T
Battery Life	12 hours	Min	Medium	A, T
Battery Energy Capacity	1200mAH	Min	Medium	A, T
Charging Time	2 hours	Max	Low	A, T

Lastly, safety is of utmost importance for any medical device, especially when applying electricity to the body. In order to prevent any bodily harm, our device follows various safety standards by organizations such as the European Union, International Electrotechnical Commission, and

Institute of Electrical and Electronics. Our requirements outline groups of these standards that apply to our device. An auto-shut off feature and energy density are also specified to prevent accidental shock or electrocution in the event of a malfunction and to prevent any electrical burns when applying treatment, respectively.

Table 6.5 Electrical Engineering Requirements - Safety

Parameter Description	Engineering Requirement	Tolerance	Risk	Compliance
Patient Energy Transfer Safety	EN 60601-1	Absolute	High	A, T
Nerve and Muscle Stimulator Safety	EN 60601-2-10	Absolute	High	A, T
Enclosure Leakage Current Normal Condition	IEC601-1,UL2601 Type BF NC	Max	High	A, T
Enclosure Leakage Current Single Fault Condition	IEC601-1,UL2601 Type BF SFC	Max	High	A, T

Auto-Shut off feature	During charge, one waveform disfunctional and after 45 minutes of use	Absolute	High	T, I
Energy Density	0.5 W/cm ²	Max	High	A, T

Mechanical Engineering Requirements

Table 7.1 displays our mechanical engineering requirements that trace to our durability category. The key durability aspect of our mechanical design is the water resistance. We based our water resistance requirement on the Ingress Protection (IP) Code, IEC standard 60529, which classifies the degrees of protection that enclosures and casings provide against solid and liquid intrusion. Figure 15 shows an IP ratings chart with the defined classifications. Although we initially defined our water resistance requirement as IP68, the highest achievable rating, we eventually reduced our requirement to IP64. We further discuss this decision in the Mechanical Enclosure Design Development section below. Melting point and compressive yield strength are the other two durability requirements for our product. Based on our use case, our product should not be used in any artificially hot environments, so we set our minimum melting temperature at 140 °F which is larger than the highest recorded temperature on Earth.

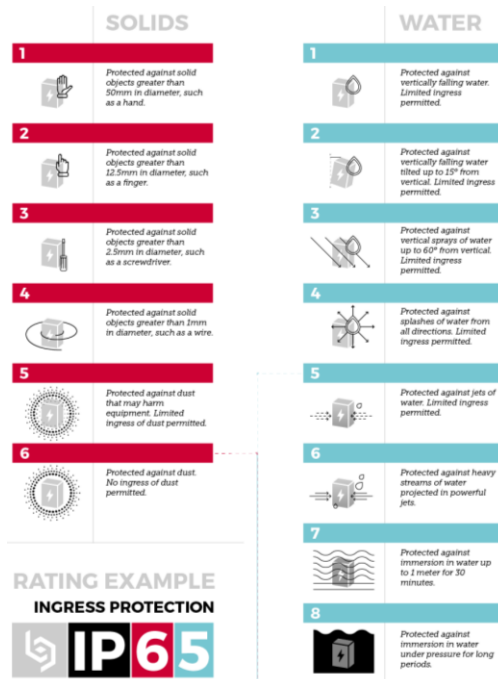


Figure 15. Ingress Protection Code Ratings Chart

Table 7.1. Mechanical Engineering Requirements - Durability

Parameter Description	Engineering Requirement	Tolerance	Risk	Compliance
Water Resistance	IP64	Min	High	T
Melting Point	60 ° C/140 ° F	Min	Low	S
Compressive Yield Strength	1000 psi/6.89 MPa	Min	Medium	A, S, T

Table 7.2 shows our mechanical engineering requirements that trace to our user experience category. Many of these requirements aim to define the ease of use of our device for the customer. As such, we defined the maximum set up time as 10 seconds because we believe the user should not spend much time simply putting on and turning on the device. We also

defined the diameter of any buttons we may have to ensure buttons are easy to find and press. Additionally, we included several indicator requirements: a battery level indicator, a charging indicator, and a waveform adjustment indicator. We believe these indicators serve a vital role in providing visual feedback that represents the current state of the device and its settings. Finally, we defined a compatible leg circumference to ensure our product will fit nearly every interested customer.¹⁷

Table 7.2. Mechanical Engineering Requirements - User Experience

Parameter Description	Engineering Requirement	Tolerance	Risk	Compliance
Set up Time	10 seconds	Max	Medium	T
Button Diameter	0.5 inches	± 0.25 inches	Medium	T
Battery Level Indicator	3 levels	Min	Medium	I
Charging Indicator	1 mode	Min	Low	I
Waveform Adjustment Indicator	3 discrete modes	Min	Medium	I
Compatible Leg Circumference	12-30"	± 0.5 inches	High	T

Table 7.3 displays our mechanical engineering requirements that trace to our portability category. Namely, we defined requirements for the maximum size and weight of our electronics enclosure and overall product respectively. These specifications ensure the product is not bulky and uncomfortable during use. For reference, the weight of an Apple™ iPhone X is 6.14 ounces.

Table 7.3. Mechanical Engineering Requirements - Portability

Parameter Description	Engineering Requirement	Tolerance	Risk	Compliance
Total Weight	6 oz	Max	Medium	A, T
Enclosure Height	0.5 inches	Max	Medium	T
Enclosure Length	1.5 inches	Max	Medium	T
Enclosure Width	2 inches	Max	Medium	T

Finally, Table 7.4 shows our mechanical engineering requirements that trace to our portability category. Because our device is primarily electrical, the most important safety requirement for our mechanical design is electrical volume resistivity, which is a fundamental property of a material that quantifies its ability to prevent electrical current flow. Conductive materials have a resistivity below 10^5 ohm-cm, whereas insulative materials have a resistivity above 10^9 ohm-cm. We require our mechanical design to oppose unintended current flow from our electrical components to the user, so we declared that our materials must be insulators. We defined the surface roughness of our product at 63 micro inches to reduce the chance of abrasions. Finally, we require that our device does not contain any common allergens, as listed, to prevent the possibility of an allergic reaction.

Table 7.4. Mechanical Engineering Requirements - Safety

Parameter Description	Engineering Requirement	Tolerance	Risk	Compliance
Electrical Volume Resistivity	10^9 Ohm-cm	Min	Medium	S
Surface Roughness	63 micro inches	Max	Medium	T

Hypoallergenic	No latex, formaldehyde, dyes, toxins or allergenic chemical additives	Max	Low	S, I
----------------	---	-----	-----	------

Design Development

Introduction

Early on in our company's development we decided that the focus of our work would be improving the status quo of knee brace technology used to help people suffering with knee-related issues. Our original product and the first prototype of this product were designed to take accurate and precise measurements of movement of the knee in order to improve the recovery process after ACL surgery. Although this specific device was not fulfilled, many of the ideas discussed during this phase became a priceless foundation for the X1 prototype we eventually moved towards. Details on *Prototype I* can be found in Appendix 9, but will be omitted from this section.

Prototype II: The X1- A Portable IFC Therapy Device

Why IFC?

Our pivot into pain relief allowed us to consider the benefits and lessons of the first prototype while also giving us an opportunity to revisit and reimagine the technologies that might be useful to our clients. With the knee still being the main anatomical focus of our product, we began researching different drug-free pain relief technologies. Our research showed four common technologies that are on the market today for pain relief: Interferential Current (IFC), Pulsed Electromagnetic Field (PEMF), Ultrasound, and Infrared therapies. We decided to work with an Interferential Current (IFC) device that is capable of deep tissue penetration. This treatment relieves inflammation, reduces swelling, and intercepts pain signals in the nervous system. This interception property of IFC directly tackles the value proposition we are aiming to provide as company: comfortable, convenient pain relief.

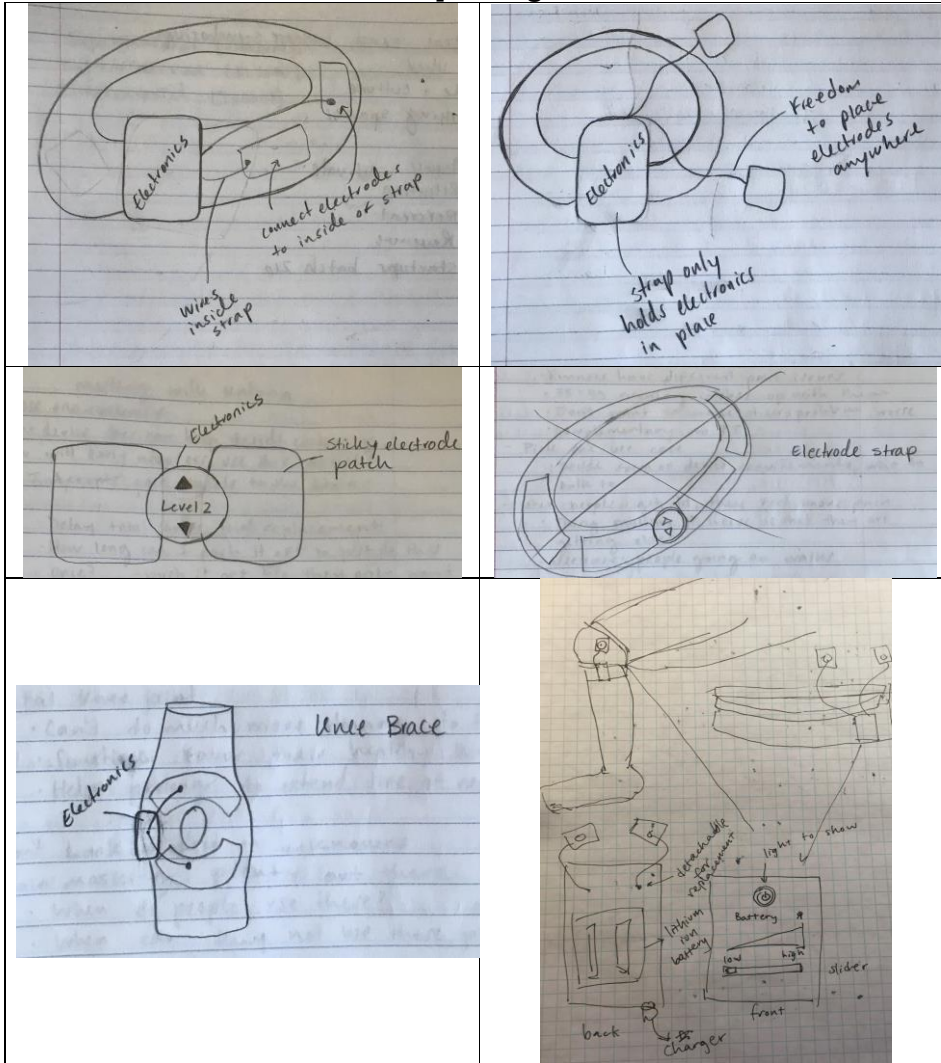
Concept Designs

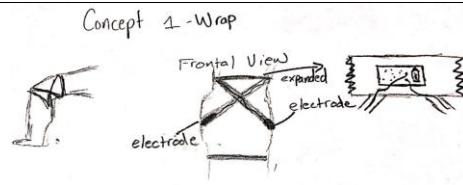
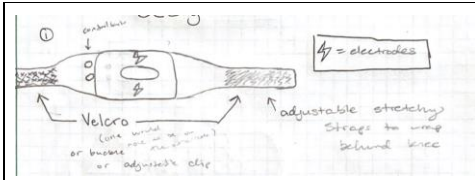
As mentioned in the introduction, there were many insights from our first prototype that influenced the design of the X1. The design of the X1 was one of these insights. From this baseline, we began re-imagining potential designs that included key aspects of an IFC device such as: electrodes and their placement, electrical housings, and mechanical interfaces as well as wearable materials. The following is a table of our designs.

Commented [RF1]: I don't think this is necessary. Plus it is currently a subheading of the introduction section

Commented [AJW2R1]: I agree for the why ifc section

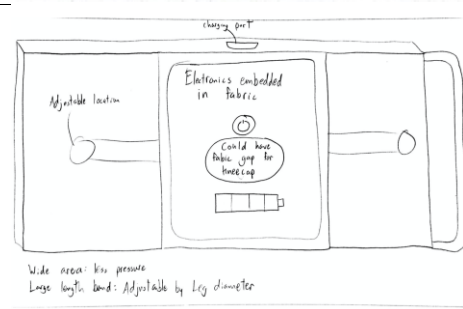
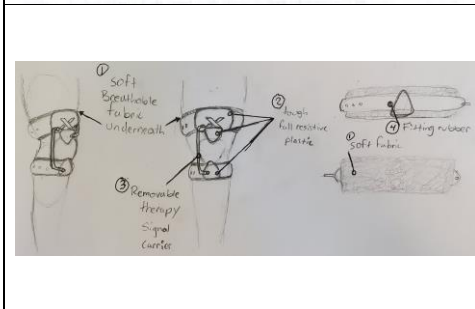
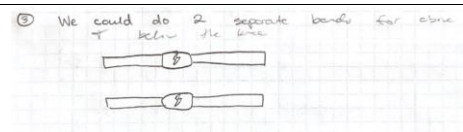
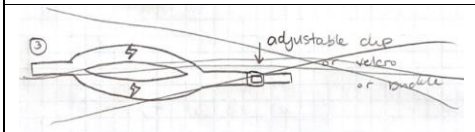
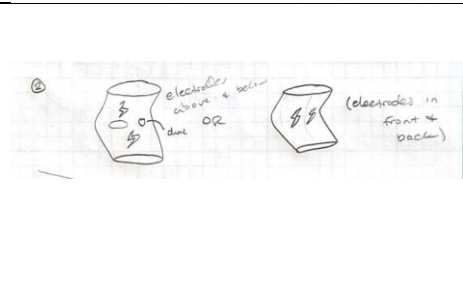
Table 8. Concept Designs for the X1

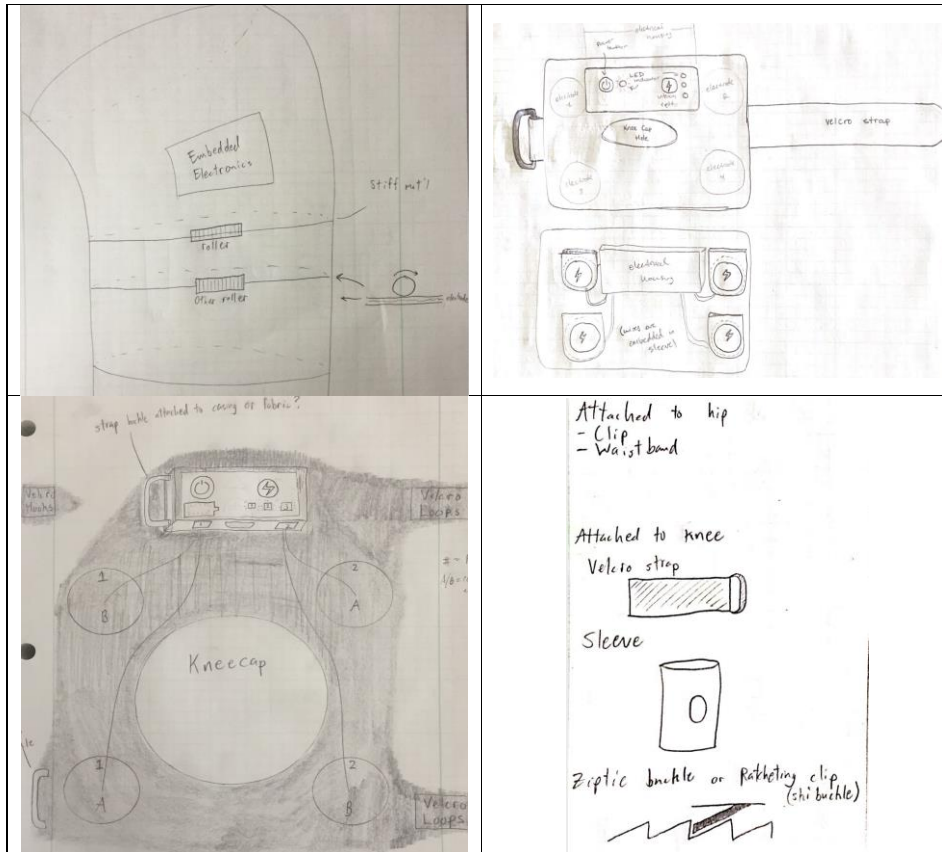




Concept 2 - Floating electrodes

- Same upper band
- No crossing x-bands
- Don't want too strong adhesive





This design sprint resulted the following decision: the X1 would be soft-fabric knee brace with integrated cables that led from a compact, enclosed electronic housing above the knee to four, discrete holes where electrodes are exposed to the skin.

Electrical Design Development

Design Overview

Like other electrical transcutaneous therapy methods, IFC devices use electricity to treat the body. The waves generated by these methods interact with the body differently based on each wave's properties. Due to the resistance properties of skin, low frequency electrical signals meet high resistance and cause the recipient pain, whereas high frequency signals

travel through tissues through the body easily and without causing pain.¹² These devices function by creating two high frequency sinusoidal waves in the 4KHz range. One of these waves is generated at a slightly higher frequency (0 - 150Hz higher) and at a 45-degree offset. *Figure 16* shows an example of two of these waves and the resulting wave when they interfere with one another. The resulting wave is of much lower frequency. This wave can safely and comfortably travel through the skin to provide the necessary therapy.

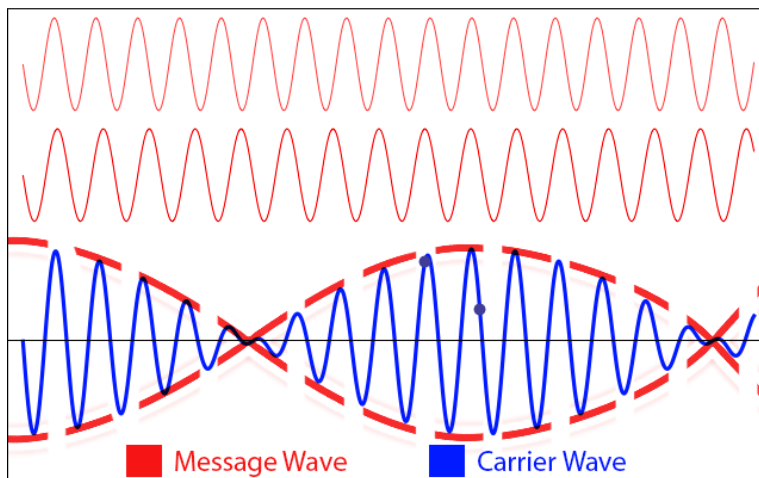


Figure 16. Interferential Current Waves Interacting

Figure 17 below shows a system diagram of our first IFC prototype and its underlying technology. This is a microcontroller-based device using a pre-modulated, two-electrode design. Pre-modulation refers to the amplitude modulation occurring in the IFC device prior to going through the electrodes. Traditional IFC devices use a four-electrode design with modulation occurring after going through the electrodes to inside the human body.

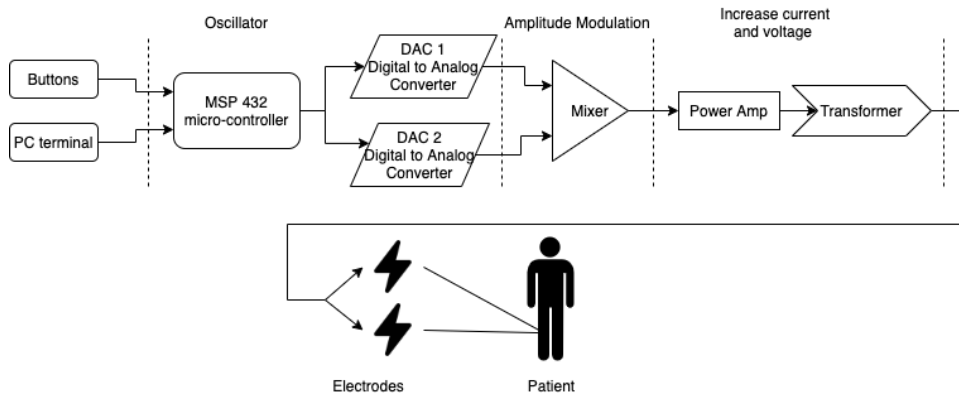


Figure 17. System diagram of IFC therapy device

The system diagram above is separated into subsystems by dotted lines. The first subsystem is a very basic interface to control the MCU with buttons and PC terminal. The next subsystem is the oscillator, digitally controlled by an MSP432 microcontroller. Below, another block diagram in figure 17 shows a visual representation of how the signal is created and modified. The MCU outputs digital signals to two DACs (digital-to analogue converters) that then generate individual voltage step increases that represent analog sine waves. DAC 1 is set at a constant 4kHz frequency and DAC 2 has adjustable frequency from 4.0 - 4.150kHz range. Both of the generated sine waves are summed together in the next subsystem, amplitude modulation. After modulation, the signal goes into power amplification and then a transformer to step up current and voltage before going to the pair of electrodes.

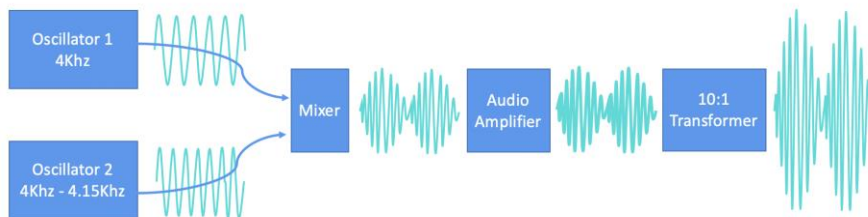


Figure 17. IFC signals being created and modified

Once we had an idea of what the general design would look like, we began researching specific components that would fit our circuit diagram for the device. The circuit diagram in Appendix 12 shows a schematic for one of the two electrode pairs used in treatment. Hardware parts were selected to produce the IFC treatment, with the power, space, and safety considerations in mind. We ensured that each part was rated for 5W of electrical power, which is what the device should be providing and also did our best to pick parts for the heat ratings that could be expected. Due to COVID-19 our team had little to no access to the resources we needed to physically build a prototype so that we could get an idea for actual operating power usage and temperatures.

LTSpice Simulations

In order to solidify our understanding of IFC and verify the circuit designs, we began creating simulations in the circuit simulator LTSpice. Our goals were to build a complete model that gave us accurate representations of waveform frequency, treatment voltage and current, as well as our device's power consumption with different load impedances applied. These impedances would simulate bodily conditions such as moisture, wounds, and scars. Simulations were the only means we had to test a potential prototype design.

One of the limitations we immediately encountered was the inability to find an existing simulation model for our microcontroller and our specifically chosen audio amplifier. In our final design, the microcontroller is responsible for taking input from the user input buttons and generate the two oscillating waves that combine to form the IFC treatment frequency. The microcontroller was replaced with two simpler electrical components that were able to together perform the necessary basic function of the microcontroller, to generate offset oscillating waves. Two 555 timer ICs were used to generate the desired signals for our oscillators. A 555 timer IC is a type of monostable multivibrator that you are able to have oscillate at specific frequencies.

Figure 18 shown below displays the full circuit schematic that was used to run simulations in LTSPice. The two circuits at the top portion of the image include the 555 timer ICs and generate the oscillating waveforms. The bottom portion of the image contains the circuit for the mixer portion of the IFC circuit. The schematic is complete through the mixer portion of the block diagram.

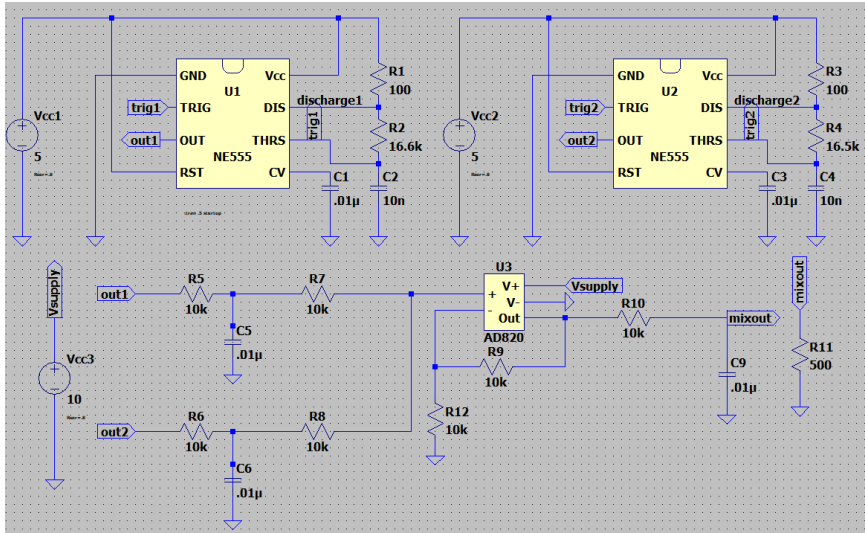


Figure 18. Full circuit schematic for simulations performed in LTSPICE.

The first step in the simulations was to generate the offset oscillating waveforms from the 555 timer ICs. The frequency of the oscillations of the multivibrator are controlled by the two resistors attached to each 555 timer IC and the duty cycle is controlled by the ratio of the two resistances. The equations used to calculate the values for the resistors are shown below in Figure 19.

$$f = \frac{1.38}{(R_1 + 2R_2)C_2} \quad D = \frac{\tau}{T} = \frac{R_1 + R_2}{R_1 + 2R_2}$$

Figure 19. Equations used to calculate resistances to be used with 555 timer ICs to generate correct frequency waveform. The left equation is to calculate frequency and the right equation is to calculate duty cycle.

The program MatLab was utilized to perform iterative analysis on different resistor values to achieve desired frequency and duty cycle. The resistance values given in the schematic achieve oscillation frequencies of 4 kHz and 4.02 kHz each with a 50% duty cycle. The output of each of the 555 timer ICs is shown below in Figures 20, 21. It was found there was about a 4% error between the theoretical values and the values necessary in simulation to achieve desired results.

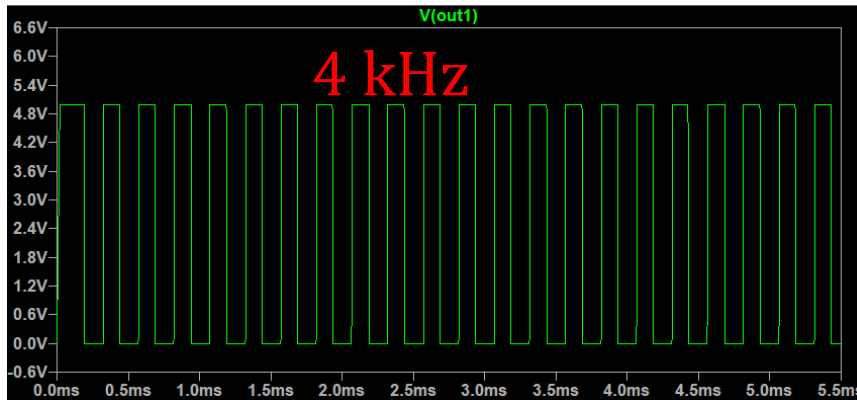


Figure 20. LTSpice simulation output of left 555 timer IC producing the low-end frequency of the IFC waveform.

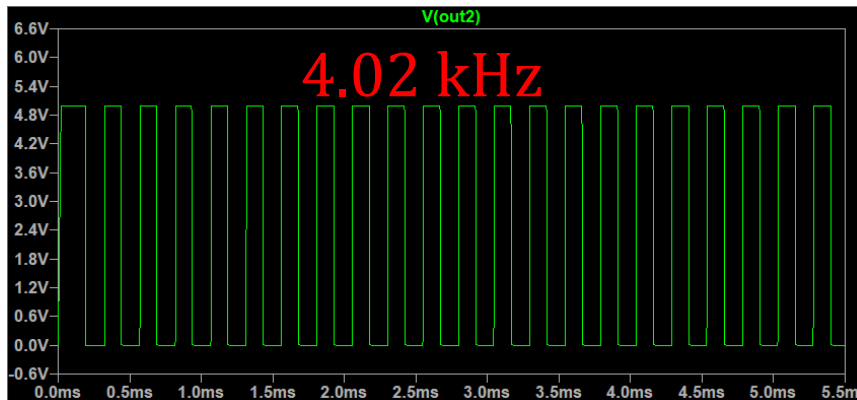


Figure 21. LTSpice simulation output of right 555 timer IC producing the low-end frequency of the IFC waveform. Output of left 555 timer IC producing the high-end frequency of the IFC waveform.

The outputs of the 555 timer ICs are then each sent to the circuit in the bottom portion of the schematic image, which is the mixer portion of the circuit. This is where the two offset oscillating waveforms are combined to form the IFC treatment frequency. The signals first each pass through a high-pass RC filter before entering an AD820 operational-amplifier to be mixed. Figure 22 below displays the output of the AD820 op-amp. The op-amp uses a gain of 1 so that the frequency of the signals is preserved perfectly. The output of the AD820 op-amp shows the simulation was able

to achieve the desired 20 Hz IFC treatment frequency, which is within our specified range of 1-150 Hz.

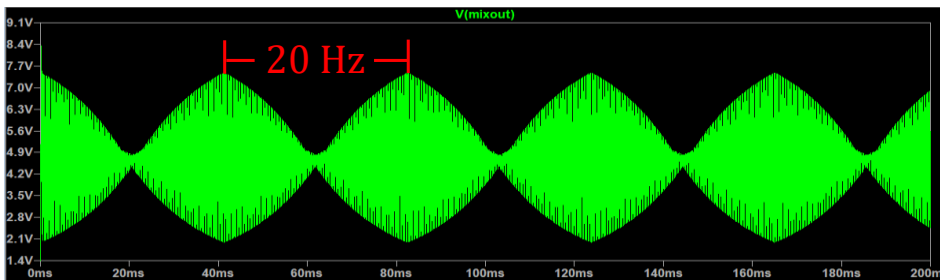


Figure 22. LTSpice simulation output of mixer AD820 op-amp showing an IFC treatment frequency of 20 Hz.

The goal for the simulations at the onset of testing was to be able to perform simulations on the circuit in its entirety. The purpose of this was to verify the final output into the electrodes and perform power analysis as well. Unfortunately, this proved to be too ambitious for the time we had for this class. The major obstacle that we are currently working to overcome is implementation of the power amplifier into LTSpice. LTSpice is created and owned by Analog Devices, so the preloaded models are only of Analog Devices products. The power amplifier we had chosen is made by Texas Instruments, and was not part of the preloaded models. In order to create a new component in LTSpice, you must create a subcircuit with specific properties as defined by the manufacturer. Even though the Texas Instruments power amplifier came with an associated LTSpice library file, it contained over 80 subcircuits that would have to each be individually implemented to build up the full amplifier. Implementing this one component would have taken more time than implementing the whole rest of the circuit. The focus then turned to searching for an Analog Devices equivalent power amplifier, but an equivalent model was not found. This means for future plans we would first physically test the Texas Instruments power amplifier before implementing the simulation model to make sure it is something that we would need to simulate.

PCB Design

With the components picked and simulations run, the next step was to build a printed circuit board to visualize the physical dimensions of our design. Our mechanical engineering requirements specify a maximum enclosure size of 0.5in x 1.5in x 2in in height, length, and width, respectively. This size constraint required that we minimize all space taken up by components on the board and that placement of components be made to ensure that the PCB fit in the enclosure. Figure 23 is the completed

preliminary PCB design. The placement of components was made to keep the device balanced while providing the necessary space for heat dissipation and placement of the user interface components. As mentioned, we have not been able to build a physical prototype to verify the treatment, heat, and power efficiency of this design.

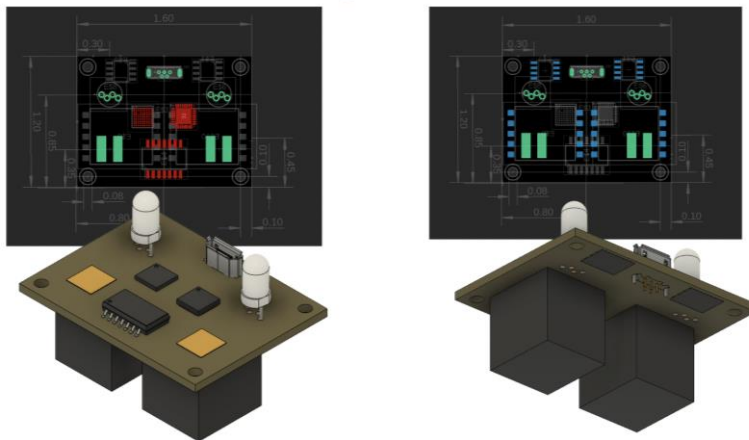


Figure 23. X1 Printed Circuit Board

Future Plans

Although much of the design has been verified with simulations, there are still some key barriers we expect to encounter as development continues. The first is that we still have to verify that the user experience decisions that have been made are actually a value for our customers. Just as important is the idea that a battery has not been added to the device yet. It is critical for us to find out the power consumption of the device as well as if there exists a battery that provides enough voltage and energy while still fitting in the required enclosure space. Once these limitations become more evident, we will be able to more accurately estimate any research and development time necessary before our product is able to enter the market.

Mechanical Enclosure Design Development

Introduction

Our product requires a housing, an exterior case or enclosure, in order to improve aesthetic appeal, simplify the user interface, protect the internal electrical components from debris and applied stresses, and ensure safety by preventing the user from coming into contact with the electrical

components. The most important requirements for our enclosure are the water resistance and the accessible user controls. If water or dust enters the enclosure and contacts the electrical system, damage and dysfunctionality is likely. This result would compromise the product and is therefore unacceptable. The accessible user controls and indicators are crucial for the operation of the product and safety of the user. The customer must be able to reliably turn the device on and off when desired as well as change the waveform signal to the preferred treatment. The stimulation mode control will allow the user to adjust the degree of stimulation they are receiving during use.

There are many electrical enclosures available for purchase from various suppliers. However, many are basic boxes that are meant to permanently close and do not have any user controls or ports. We decided to design our own enclosure using SolidWorks for many reasons. First, the design process revealed many design decisions that wouldn't have been considered if we chose a premade enclosure from an outsourced manufacturer. Additionally, we wanted to control our own documentation and have the ability to choose a manufacturing plan based on our eventual design. The manufacturing plan of the enclosure will be discussed in a following section.

Initial Design

We began by researching current design methods of electronics enclosures with a specific focus on waterproof designs. Our initial water resistance engineering requirement was IP68, which prevents intrusion of all dust and water when submerged for extended periods of time. For reference, Apple's iPhone models 7, 8, X, and XR all tout an IP67 rating out of the box, but Apple does not provide any warranty for water damage. The primary method of waterproof design for electronic enclosures is using rubber O-rings, which prevent liquids and gases from penetrating into the enclosure as shown in Figure 24. When an O-ring is placed into a groove and is compressed, it seals the passageway.

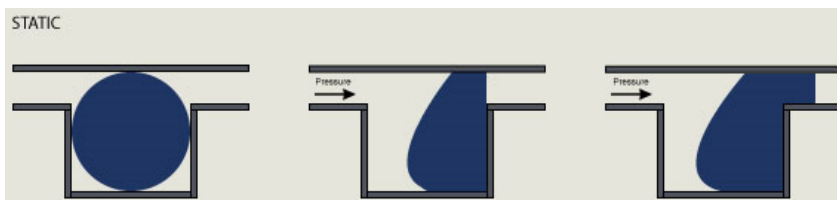


Figure 24. Functionality of O-rings, which prevent moisture from entering an electronic enclosure

We initially chose to use an O-ring to waterproof our enclosure because O-rings are functional, cost-effective and supplied in a variety of sizes. Figure 25 shows an isometric view of our initial design, which includes a groove for the O-ring and threaded holes in each corner for screws to fasten the enclosure lid to the body and compress the O-ring.

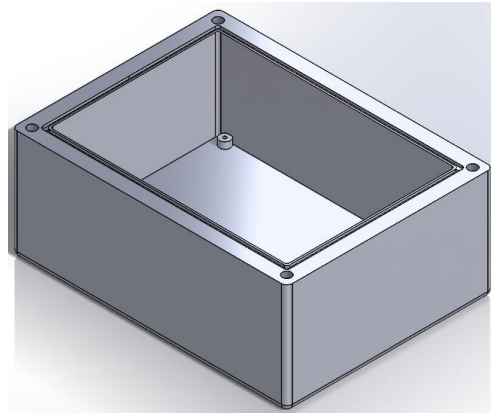


Figure 25. Isometric view of our initial enclosure design

We decided to mount the printed circuit board (PCB) to small pegs in the enclosure using screws, the most common method of securing a PCB in an electronics enclosure. Figure 26 shows a top view of our initial enclosure design, with the O-ring groove adjacent to the inner perimeter of the enclosure base. We chose to place the enclosure fasteners in the corners outside of the O-ring because moisture could enter through the holes.



Figure 26. Top view of our initial enclosure design

The main disadvantage of this design was size. The ideal enclosure wall would be strong enough to handle external stresses and as thin as possible to reduce overall size and maximize space for the electrical components. With both the O-ring groove and the holes for the enclosure screws, the enclosure wall thickness was larger than desired. Because size was an important engineering requirement, we decided to consider alternative designs to reduce the wall thickness.

After extensive research on enclosure design and ample consideration of our product's use case, we decided to reduce our water resistance engineering requirement from IP68 to IP64. IP64 states that our enclosure protects the electronics from all dust and from splashes of water from all directions. We believe this requirement more accurately represents our use case because user perspiration will be the primary moisture in contact with the product. Additionally, this less restrictive water resistance requirement allows us to expand our design options beyond O-rings to better optimize our design for a reduced size.

Material Selection

Throughout this preliminary design phase, we also focused much of our attention on material selection. Based on our engineering requirements, we wanted a material that was both strong and lightweight. Additionally, we specifically prioritized cheap materials that were also electrical insulators. Using these constraints, we selected the common thermoplastic polymer Acrylonitrile butadiene styrene (ABS). ABS is cost-effective and commonly

used in household and consumer products, such as Lego's, appliances, medical devices, and sporting goods because it is aesthetically appealing and light.

We chose ABS primarily for its mechanical and electrical properties. It is a strong electrical insulator, with an electrical volume resistivity ranging between $14-16 \times 10^{15}$ ohm-cm which is considerably higher than our engineering requirement. Additionally, ABS is a popular polymer because of its high yield strength, impact resistance and toughness. Finally, we chose ABS because of its manufacturing versatility and ease. ABS can be extruded, injection molded or machined.

Final Design

After reducing our water resistance engineering requirement, we shifted our design away from O-rings and towards adhesives. Not only can adhesives provide a waterproof seal for our enclosure, they also bond the two-piece enclosure together without the need for fasteners. This alternative achieves our design goal of reducing the size of the enclosure while maximizing space for the electrical components.

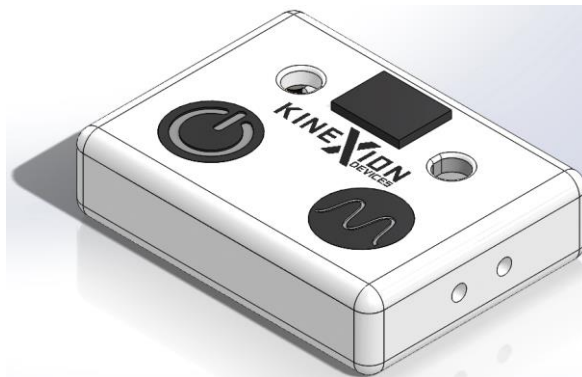


Figure 27. Isometric view of our final enclosure design

Figure 27 shows an isometric view of our final enclosure design. The enclosure meets our size requirement, with a width of two inches, length of one and a half inches, and height of one-half inch. The wires that carry the signal from the PCB to the electrodes interface with the enclosure on the side, while all other ports and user controls are located at the top of the enclosure, as shown in Figure 28.

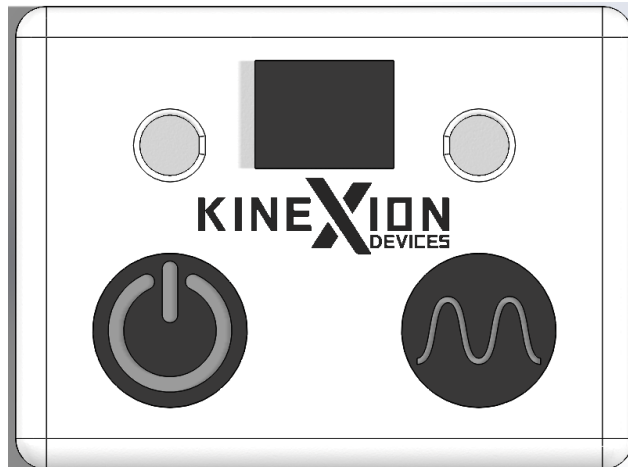


Figure 28. Top view of final enclosure design

We designed the enclosure lid to be symmetrical for an increased aesthetic appeal. There is a power button and a mode button, which changes the treatment signal based on the user's preference. These buttons will be standard silicone rubber buttons. Additionally, there are two holes which will house the two tri-color light-emitting diodes (LEDs) used as indicator lights. The light above the power button will display the battery status while the light above the mode button will indicate the current treatment mode based on its active color. Finally, the lid includes a Micro-B USB charging port which is covered by a removable silicone rubber piece to ensure water resistance.

Figure 29 shows the exploded view of our final enclosure design. As discussed earlier, we reduced the overall number of components and the wall thickness by electing to use adhesive to bond the base and the lid instead of fasteners. As the figure demonstrates, the base of the enclosure has a groove around the perimeter while the lid has an extrusion to ensure a strong adhesive seal that prevent water and dust from entering. We plan to use ABS cement as the adhesive, which is primarily used for bonding two pieces of ABS piping together and is suitable for our design. ABS bonds quickly and is also waterproof, a key characteristic.

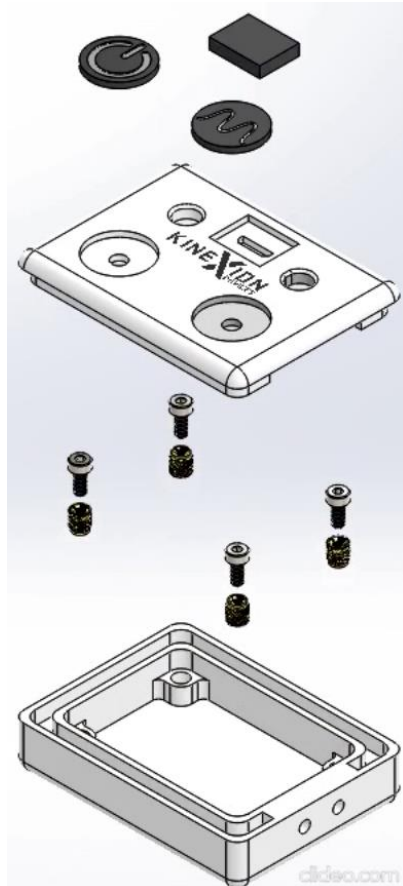


Figure 29. Exploded view of electronics enclosure

Figure 30 is a section view of the final enclosure design which exhibits the PCB mounting method we plan to implement. There will be four mounting platforms in the internal corners of the enclosure and each platform will have a number 30 drilled hole. Heat-set brass threaded inserts will be placed into each hole. When heated, the plastic in the hole melts slightly and then solidifies around the notches in the threaded insert, causing a strong, snug fit. The PCB will then be placed on the mounting platforms and fastened in place using M2 screws.

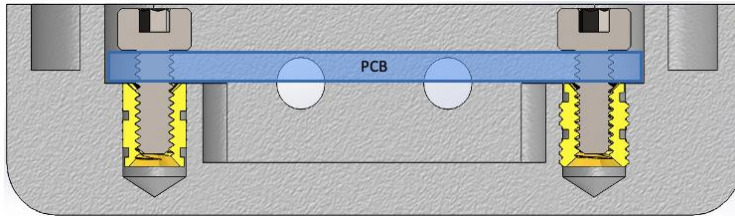


Figure 30. Section view of enclosure displaying printed circuit board mounting assembly

Overall, our current design meets most of our engineering requirements. Due to an unexpected inaccessibility to the Cal Poly campus because of Covid-19, we have not built a prototype of our electronics enclosure. Therefore, we have not tested our design to ensure it has met our water resistance requirement. All engineering drawings for this enclosure design can be found in Appendix 13.

Finite Element Analysis

We performed finite element analysis (FEA) through SolidWorks on our enclosure design to verify our material selection and design decisions. Specifically, we aimed to simulate our product's use and misuse cases to ensure that our current design would withstand the induced stresses.

Figure 31 demonstrates the simulation results for our first misuse case. For this analysis, we simulated the impact on the enclosure if it was dropped from a height of six feet. We determined the impact speed based on free fall kinematics and then calculated the impact force using the impulse-momentum theorem. As seen in the figure, the simulation predicted a maximum stress of 91 psi, which is significantly lower than ABS's yield strength of 4000-9000 psi. Therefore, this simulation demonstrated that our enclosure could be safely dropped from a height of six feet without any damage.

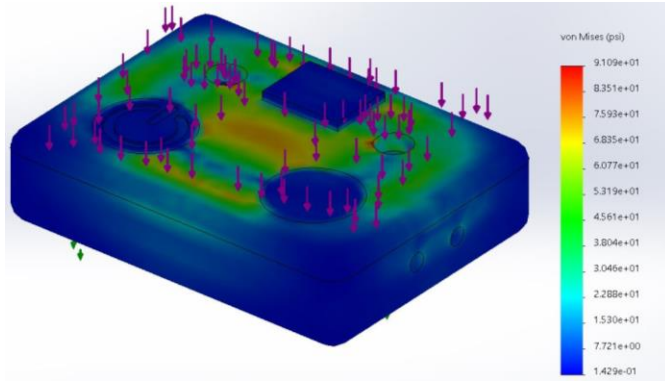


Figure 31. FEA simulation results for the misuse case of a six-foot drop

We conducted a second FEA simulation of a more severe misuse case. We intended to understand whether our enclosure would remain functional even if a 250-pound user tripped and fell on the enclosure during use. We utilized the same analytical principles to estimate the impact force on the enclosure as explained above, but used 250 pounds as the mass in the impulse-momentum theorem instead of six ounces. Additionally, we assumed the enclosure was just above the knee of the user and estimated this height as three feet. The results for this FEA simulation are shown in Figure 32 and demonstrate that the maximum stress on the enclosure would be about 17,000 psi.

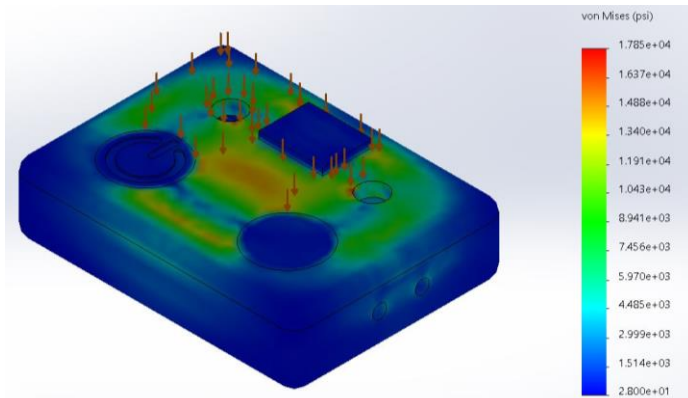


Figure 32. FEA simulation results for the misuse case of a 250-pound user falling on device

These results indicate that our enclosure would undoubtedly yield under the calculated stress. Although these results indicate an alternate design should be considered, we also analyzed the drawbacks of our analysis technique. Namely, our analysis assumes that a 250 pound user is falling from a height of three feet directly onto the enclosure and the enclosure absorbs the entire impact. This means that the user's body does not touch the ground at all during this fall, as the enclosure hits the ground first and all kinetic energy is absorbed by the enclosure. Furthermore, we do not deem this misuse case as one that our enclosure must be able to survive, as it is incredibly rare and based on user error. Upon considering these results, we deemed this simulation to be extraneous due to its unrealistic analysis. In the future, we plan to improve the accuracy of the simulation by refining our analysis techniques and simulation parameters.

Manufacturing Plan

As explained previously, ABS is versatile with many manufacturing processes available. Because our design is small and includes many features such as grooves and drilled holes, machining the part would be time consuming and expensive. Instead, we plan to use additive manufacturing methods such as 3D printing to prototype our enclosure on a small scale for testing and design improvements.

After prototyping, testing and improving the design, we will manufacture our enclosure through injection molding. Although injection molding has expensive upfront tooling costs, it offers an effective solution for a high-volume production at a low cost. Figure 33 depicts the parting line for our injection mold of the electronics enclosure. In order to adjust our enclosure design for injection molding, we intend to add drafts to all surfaces that are parallel to the pull direction (vertical). These drafts must be between one and four degrees to allow for easier mold separation. Additionally, we must account for the shrinkage of ABS during the manufacturing process. We determined the shrinkage rate of ABS to be 0.5%, indicating that we would oversize our enclosure to offset the size reduction.

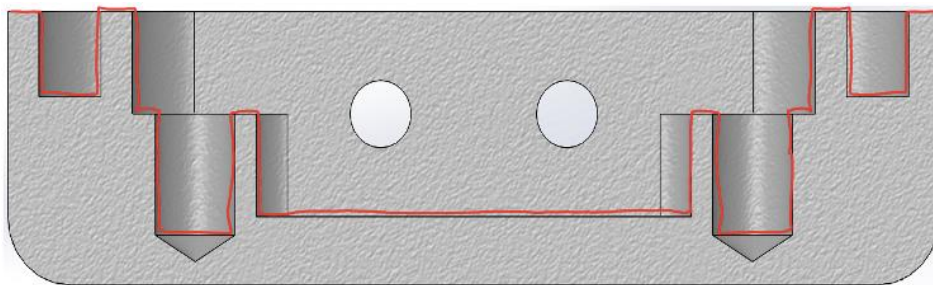


Figure 33. Section view of enclosure with injection mold parting line

We also plan to purchase the silicone rubber parts, heat-set threaded inserts, and fasteners of the enclosure assembly from a wholesale supplier. The bill of materials for our product can be found in Appendix 10.

Neoprene Base Design Development

In order to allow for our customers to be able to wear our device while performing their activities, we designed a main fabric base that would enclose the electrical components necessary for functionality. In regards to our decision on which material to use, we chose to move forward with neoprene as the main material of our base. The majority of knee braces prescribed today are manufactured using non-latex neoprene due to its elasticity and breathability. The flexibility of this material allows for the user to comfortably put on the device and expand to various leg diameters as necessary. Neoprene’s modulus of elasticity is ideal for this project since we would be able to stretch the fabric while putting on this device, while still allowing its natural contractility to help adhere the device to the customer’s knee.



Figure 34. Prototype of Fabric Base for Electrical Enclosure

When regarding the design of the base we wanted to be sure that we would not be restricting the mobility of the wearer while still providing enough room for the electrical housing. In order to ensure this, we created the center circle opening to allow for the protrusion of the user's knee cap and made the width of the primary base short enough such that when the customer is using the device, the popliteal fossa is left uncovered. For the customer to fasten the device, two Velcro hook straps will be sewn onto the side of the base panel which will then wrap around the user's leg to adhere to the two loop strips attached to the exterior of the device, allowing them to tighten the device to their preferred level of constriction.

The electrodes, as well as the wiring connecting each electrode to the device's battery within the electrical housing, are embedded within the fabric base of the device in order to keep our product sleek and portable. There are four pockets on the interior side of the neoprene panel that are intended to house each electrode. These pockets are created via an additional fabric layer that will be sewn on to the primary neoprene base during the manufacturing stages, as indicated by Appendix 13. This fabric layer will also be used to create an enclosure for the electrical housing such that it is secured, yet still allows the user to easily identify and access each of the controls. Four openings within the base allow for direct skin-contact from the electrodes as this is necessary to ensure the best possible conductivity and subsequent ideal treatment. Each opening is slightly smaller than the 1.75in electrodes in order to ensure proper placement.

When sending to the manufacturer, we plan to provide transparency slides in order to specify the margin of error for the neoprene base outline so that we do not require any additional machinery for the manufacturing process.

DVP&R (Testing Protocols)

The Design Verification Plan and Report document in *Appendix 8* provides a detailed overview of both the Customer and Engineering requirement testing methods. These methods will be used to verify both the need and functionality our device before it enters the market space. The version included is a preliminary outline of tests for our product. These tests are crucial in ensuring the safety and well-being of any person who uses our device. As noted earlier in the engineering requirements, there are very strict regulations in place when applying electrical signal directly to a person's body. Many international organizations have laid out standards for

these types of medical devices. Table 9 contains all of the standards which we have found to be applicable to our device.

Table 9. Applicable Standards

Standard ORG	Number	Title
IEC	60601	Medical Electrical equipment- Part 1:
IEC	60601-1-2	Medical Electrical equipment- Part 1-2:
IEC	60601-1-4	Medical Electrical equipment- Part 1-4:
IEC	60601-2-10	Medical Electrical equipment- Part 2-10
ISO	14971	Medical devices
ISO	13485	Medical devices quality management systems
IC council	93/42/EEC	EC Directive 93/42/EEC/Annex V, Article 3
IEC/EN	62304	IEC 62304 Ed. 1.0, Medical device software
IEC/EN	60601-1-6	Medical electrical equipment Part 1-6
ISO	9001	Quality management systems
UL	60601-1	Medical electrical equipment part 1

FMEA – Failure Mode and Effects Analysis

A table of Failure Mode and Effects Analysis in *Appendix 6* shows potential failure modes in the IFC system. This is a table that is constantly a work in progress as the technology continues to be developed. Each failure mode is analyzed for its severity, causes of failure, occurrence, how the system handles the failure, detection effectiveness, and its associated risk priority number (RPN). The RPN is a score that quantifies likelihood for the failure not to be detected, likelihood that failure will happen, and level of potential harm or damage. The most critical failure modes involve the electronics of the IFC device. Safety is the number one priority for Kinexion and the highest risks involve the device outputting incorrect current values to the human body.

Team Development

Before Kinexion Devices began, we were part of a larger unnamed team looking to launch a company that would promote environmental sustainability. The offshoot that would later become Kinexion Devices first emerged when Team Visionary Clara Brechtel presented the idea for a wearable device that could improve a patient's recovery experience post-knee surgery. Clara first had this idea after a conversation with orthopedic surgeon and longtime family friend, Dr. David Keblish, during which he mentioned that many patients face difficulties regaining full extension after undergoing a total knee replacement. Thus, transitioning the team into the realm of wearable medical devices. This alternative domain proved to be a great option as it not only homed in on a niche market that our team could capitalize on, but it also encapsulated each founder's original desire to help better the lives of others. The team that broke off was comprised of three biomedical engineers (Clara, Ben and Andrew), one computer scientist (Evan), and one mechanical engineer (Ryan) each with some previous experience or pre-existing interest in the medical field that would come into play when developing this device.

Our team started off by looking at devices designed specifically to help patients recovering from Anterior Cruciate Ligament (ACL) Reconstructive Surgery so that we would be able to focus on a particular subset of this large field. We did this with the intention of broadening out our device to other regions of the body once we perfect our initial design.

As our team dove deeper into the customer development phase of our project interviews, we quickly concluded that our consumer would be the physical therapists prescribing their patients with our product, rather than the recovering patients themselves who would have had to go out and buy our device on their own. Initial research indicates that most practicing physical therapists who work with a younger client base, primarily high school or college athletes, would be our early adopters. Many physical therapists are constantly seeking new and innovative technologies to incorporate into their practices to stay relevant and competitive with other clinics, thereby validating our problem domain.

To develop our Team Contract, we each shared our long-term intentions for the company so that we're all on the same page in regard to our level of commitment to the project. We then had each member reflect upon his or her past group project experiences and determine which habits were the most beneficial and which were the most detrimental to the team's success. Each positive aspect was then added to our contract as a guideline for what we expected of one another and from each negative aspect we created a

solution to serve as a preemptive approach for any potential conflicts later down the road. Team roles were distributed based on our individual strengths and weaknesses, but ultimately what helps keep our team on track is our plan to always double check each other's work. This way there's at least two people confirming that each part of the project is being done well and in a timely matter.

The primary indicative factor of our team's success will be our ability to communicate. Communication is crucial as we all need to be aware of which direction our company is headed in the event of any design pivots. Seeing as we're only required to meet in person twice a week, it's also important that we're all communicating when we're able to gather outside of class and what progress we've made individually. Sharing the knowledge gained from each interview is also extremely helpful for formulating new ideas since not every team member is going to be able to attend each time. As we dive further into the project, communication will only continue to grow in importance. Once subsections of our team begin to formulate in order to break up into separate software, hardware, and business-oriented groups, communication will be imperative to be sure we're all on the same page and operating at the same speed, otherwise critical details may fall through the cracks.

The second and third most influential parts of our team's dynamic go hand-in-hand. Preparation and follow-through are essential to our team's success. We made preparation a main part of our contract to help increase productivity in our meetings. By showing up to each meeting with any missed interview notes read, shared journal publications read, and the Trello reviewed in advance, it helps maximize the time our team can meet up to work. However, none of this preparation is being used if nobody is following through on the ideas being proposed. Thus, both aspects are necessary for our company's ultimate success. Additionally, our consequence of 1 push-up per minute late to team meetings ensures team member accountability for showing up on time and promotes team comradery.

Since Spring Quarter was online, our team adapted and evolved to communicate and work remotely on all aspects of the project. At the beginning we had issues with internet connections and miscommunication but overall we were able to be productive this quarter despite all the challenges we faced because we had already established a working structure for distributing tasks and ensuring that we got things done. Most of the details and decisions were made by each group that specialized in their specific area which reduced conflict and improved workflow. Our meetings have also gotten shorter due to our improvements in team dynamic and we were able to complete all our assigned tasks.

Our team is proud of everything we have accomplished this year. We have grown not only as individuals but as a team working toward a common goal. All of us have learned important lessons in communication and collaboration and we have practiced many aspects of entrepreneurship in our customer development and product design. Using our collective skills and experience we created a business concept and structure which theoretically would be a profitable company. We would like to give special thanks to Tom, Lynn and John for their continued support throughout the entire year and their advice on our project. Shout out to Jenny who helped us get setup with our electrical engineering Winter Quarter.

References

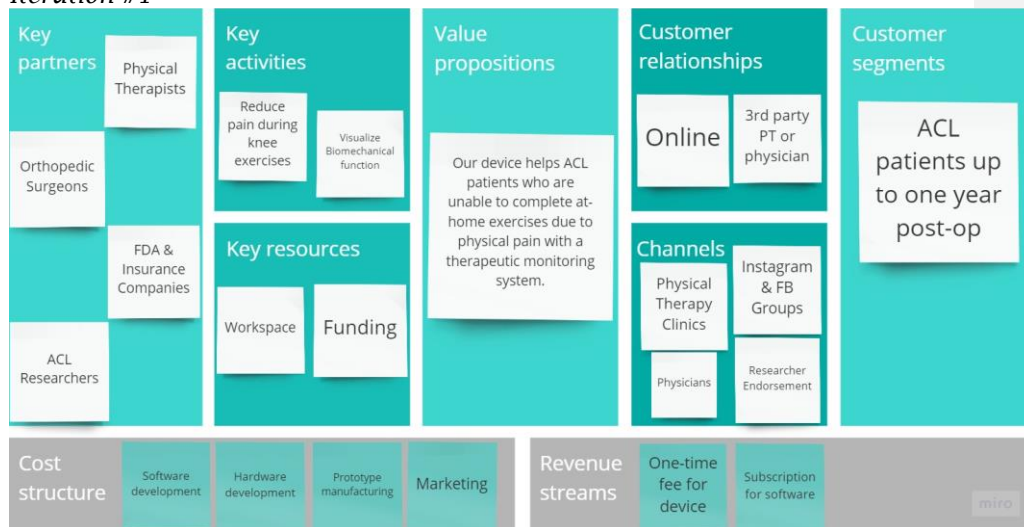
1. Peat, G., R. McCarney, and P. Croft. "Knee pain and osteoarthritis in older adults: a review of community burden and current use of primary health care." *Annals of the rheumatic diseases* 60.2 (2001): 91-97.
2. Houghton, Kristin M. "Review for the generalist: evaluation of anterior knee pain." *Pediatric Rheumatology* 5.1 (2007): 8.
3. Schwellnus, M. P., and E. W. Derman. "Chronic anterior knee pain in athletes: Common causes." *South African Family Practice* 47.8 (2005): 20-22.
4. Salati, Umer, et al. "Evaluation of knee pain in athletes: a radiologist's perspective." *Canadian Association of Radiologists' Journal* 68.1 (2017): 27-40.
5. White, Daniel K., et al. "Physical Function after Total Knee Replacement: An observational study describing outcomes in a small group of women from China and the United States." *Archives of physical medicine and rehabilitation* 99.1 (2018): 194-197.
6. Bass, Evelyn. "Tendinopathy: why the difference between tendinitis and tendinosis matters." *International journal of therapeutic massage & bodywork* 5.1 (2012): 14.
7. Thakur, Matthew, Anthony H. Dickenson, and Ralf Baron. "Osteoarthritis pain: nociceptive or neuropathic?." *Nature Reviews Rheumatology* 10.6 (2014): 374-380.
8. Agaliotis, M., et al. "Risk factors associated with reduced work productivity among people with chronic knee pain." *Osteoarthritis and cartilage* 21.9 (2013): 1160-1169.
9. Jones, Brandon Q., Carlton J. Covey, and Marvin Sineath Jr. "Nonsurgical management of knee pain in adults." *American family physician* 92.10 (2015): 875-883.
10. Collins, Natalie J., et al. "Efficacy of nonsurgical interventions for anterior knee pain." *Sports medicine* 42.1 (2012): 31-49.
11. Date, Equipment Effective, et al. *Medical Coverage Policy Interferential Current Stimulation*. 2013.
12. Goats, G. C. "Interferential Current Therapy." *Physiotherapy Treatment Modalities*, 1 June 1990, bjism.bmj.com/content/bjsports/24/2/87.full.pdf.
13. Raymond, Fish M., and Leslie A. Geddes. "Conduction of Electrical Current to and Through the Human Body: A Review." *Open Access Journal of Plastic Surgery*, 10 Oct. 2009, www.ncbi.nlm.nih.gov/pmc/articles/PMC2763825/pdf/eplasty09e44.pdf

14. SL Power Electronics Corp. "Leakage Current AN-113." SLPower, 2018, slpower.com/App-slpower/images/whitepapers/An113%20Leakage%20Current.pdf.
15. Zynex Medical Inc. "NexWave User's Manual." Zynex Medical, 8 Dec. 2017, www.zynex.com/files/nexwaveusermanual.pdf.
16. Treede RD, Rief W, Barke A, et al. A classification of chronic pain for ICD-11. *Pain*. 2015;156(6):1003-1007. doi:10.1097/j.pain.
17. Thurm, Blaise. "Choosing the Correct Knee Brace Size." *BraceAbility*, 31 Jan. 2019, www.braceability.com/blogs/info/correct-knee-brace-size.
18. National, C. G. C. U. (2014). Osteoarthritis: care and management in adults.
19. Maradit Kremers, Hilal et al. "Prevalence of Total Hip and Knee Replacement in the United States." *The Journal of bone and joint surgery*. American volume vol. 97,17 (2015): 1386-97. doi:10.2106/JBJS.N.01141
20. Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G. Intraarticular corticosteroid for treatment of osteoarthritis of the knee. *Cochrane Database Syst Rev*. 2006;(2):CD005328.
21. Gaines, Jean M., E. Jeffrey Metter, and Laura A. Talbot. "The effect of neuromuscular electrical stimulation on arthritis knee pain in older adults with osteoarthritis of the knee." *Applied Nursing Research* 17.3 (2004): 201-206.

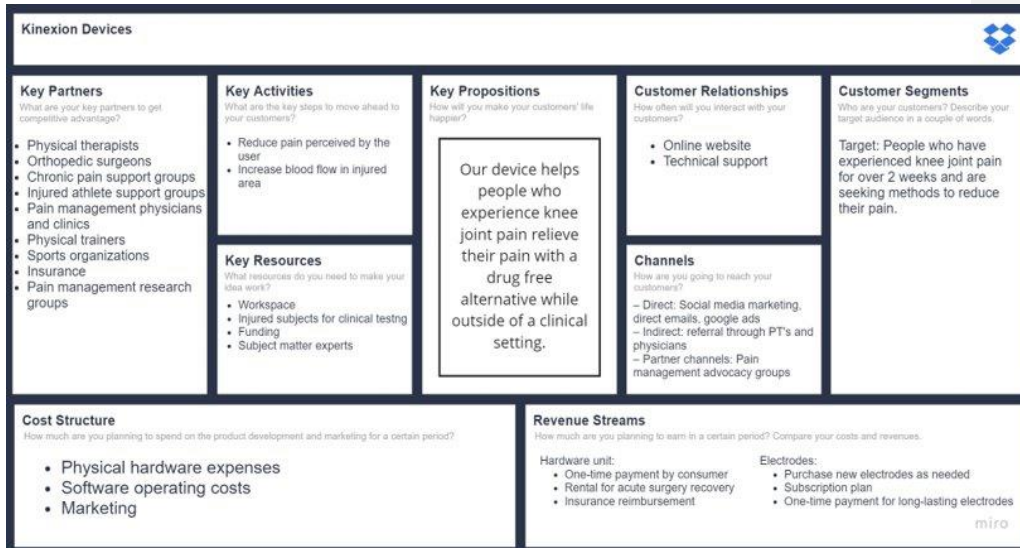
Appendices

Appendix 1: Business Model Canvas Diagram Development

Iteration #1



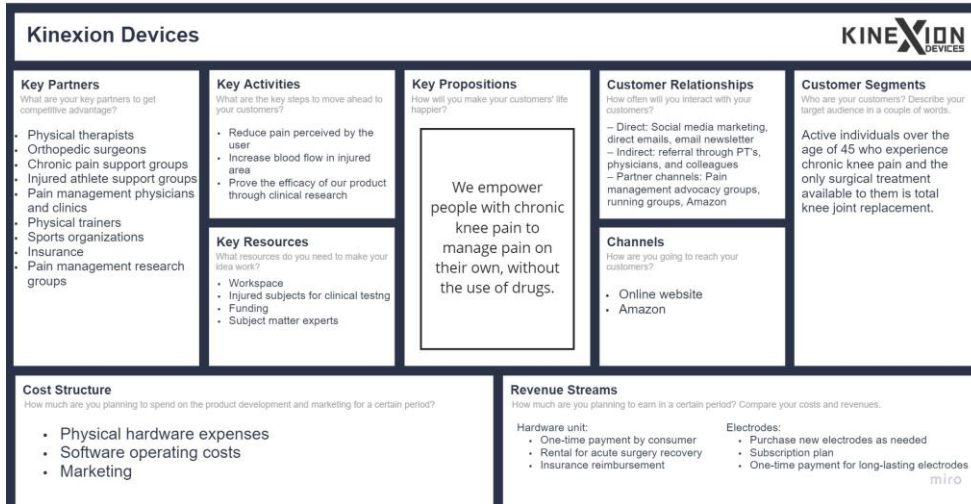
Iteration #2



Iteration #3



Current Iteration



Appendix 2: Customer Interview Lists

Patient Interview List

Name	Relevant Experience	Interviewer(s)	Interview Date
Stephanie Stringfellow	Former ACL reconstruction surgical patients who participated in physical therapy	Andrew, Clara, Ryan	10/24/19
Olivia Welch		Andrew, Ben, Clara, Ryan	10/24/19
Alexis Peltier		Andrew, Ben, Clara	10/26/19
Caroline Lamoureux		Andrew, Ben, Clara	10/26/19
Kiah Wieneke		Andrew, Ben, Clara	10/29/19
Sami Katwan		Andrew, Ben, Clara, Evan, Ryan	11/4/19
Henry Albert		Andrew, Ben, Clara, Evan, Ryan	11/5/19
Catherine Cranston		Clara	3/2/20

Ronni Robinson	Athletes who experience chronic knee pain	Clara	2/21/20
Vicki Ragucci		Clara	2/27/20
Jenny Fenn		Clara	2/27/20
Julia Campbell		Clara	2/28/20
Robin Welling		Clara	3/2/20
John Fischer		Ben	2/25/20
Vinny Mejia		Ben	2/25/20
Mayah Walker		Ben	2/25/20
Anny Rosenthal		Clara	4/14/20
Mrs. Thidandam		Ryan	4/14/20
Marco		Gonzalo	4/14/20
Sheryl Walsh		Clara	4/16/20
Cheri Barrett		Ryan	4/16/20
Fiona Cutner		Andrew	4/16/20
Jose Calsadas		Gonzalo	4/16/20
Ellie Brewer		Clara	4/17/20

Physical Therapist Interview List

Name	Relevant Experience	Interviewer(s)	Interview Date
Mark Allen	Orange County Orthopaedics & Sports Medical Group	Andrew, Ben, Clara, Evan, Ryan	10/23/19
Jason Sanders	Clinic Director: San Luis Sports Therapy - Templeton	Andrew, Clara, Evan, Ryan	11/6/19
Michael Williams	Clinic Director: San Luis Sports Therapy - Morro Bay	Clara, Ben	11/7/19
Jonathan Grisanti	San Luis Sports Therapy - San Luis Obispo	Andrew, Clara, Ryan	11/14/19
Jason Roda	Clinic Director: San Luis Sports Therapy - Paso Robles	Clara, Ben	11/18/19
Richard Goldbach	Clinic Director: San Luis Sports Therapy - Atascadero	Clara	11/19/19
Paul Teixeira	Clinic Director: Body and Balance Center	Clara	11/19/19
Brandon Weipert	Clinic Director: San Luis Sports Therapy - San Luis Obispo	Andrew, Clara	11/25/19
Bryan Woo	Clinic Director: San Luis Sports Therapy - Santa Maria	Clara	12/2/19
Brodie Sharpe	Physiotherapist - Australia	Clara	2/25/20

Subject Matter Expert Interview List

Name	Relevant Experience	Interviewer(s)	Interview Date
Dr. Dustin Grooms	Associate Professor at Ohio University - PhD in Biomechanics and Neuroscience	Clara, Ben	11/20/19
Dr. Lynn Snyder-Mackler	Alumni Distinguished Professor at University of Delaware	Andrew, Clara	11/25/19
Dr. Dimitri Delagrammaticas	Orthopedic Surgeon	Clara	11/26/19
Dr. Christopher Powers	Professor and Director of the Musculoskeletal Biomechanics Research Laboratory at USC	Clara	12/5/19
Jeff Troesch	Cal Poly Athletics Performance Specialist	Ben, Clara	1/21/20
Dr. Stefanee Maurice	Kinesiology Professor at Cal Poly	Andrew, Clara	1/28/20
Dr. Jafra Thomas	Kinesiology Professor at Cal Poly	Andrew, Clara	1/30/20
Dr. Trevor Cardinal	Anatomy/Physiology Professor at Cal Poly	Ben	2/15/20

Appendix 3: Interview Booth Set Up



Appendix 4: Interview Questions

Interview Questions for Pain

Patients

- What is the root cause of your knee pain?
 - How has your knee pain progressed since you first started feeling discomfort?

- Can you describe the pain that you experience?
- How long did you have pain before seeking treatment methods?
- What were the steps you followed to try and relieve your pain?
- Does your knee pain impact your daily lifestyle?
 - When does your pain most commonly occur?
 - How often do you feel this pain?
- What methods did you use to counteract this pain?
 - How effective were these methods?
 - What methods did you try that didn't work for you?
 - What methods do you wish you tried and were not able to? Why were you not able to?
 - How did you go about finding your pain management techniques?
- How do you feel about the use of pharmaceuticals in pain management?
- Do you have anything else to share?

Physical Therapists

- What techniques do you incorporate to help your patients with their pain during the recovery process?
 - Are you actively searching for new pain management techniques specifically? Or just ways to improve the recovery overall no matter the pain?
- Is there a way to differentiate between “necessary/beneficial pain” and “harmful pain?”
- When your patient is complaining of pain during their rehab, how does that affect your treatment plan?
 - How does it affect that individual session?

Booth Interview Questions

- Name
- Age
- Type of knee pain experienced
- How often and for how long?
- Do you see pain relief techniques for your knee pain?
- What pain relief techniques have you tried?
- How did you find those pain relief techniques?
- Can we have a follow up interview with you? (If applicable)

Appendix 5: Use Case Requirements

Mobile Active User

- Portability
- Mobility
- 30-45 minute ideal treatment (still need to verify why this treatment time)
- Ease of use (especially for expecting an older demographic)
- Uniqueness of technology (it makes them want to use it)
- Customizable treatment
- Self-guided care plan
- Multi-modal treatment for best effectiveness
- Chronic pain
 - Includes:
 - Runner's knee
 - Arthritis (osteo & rheumatoid)
 - Inflammation
- Time of day:
 - Falling asleep
- Fixed electrode placement

Post-Surgery User

- 30-45 minute ideal treatment (multiple times per day?)
- More complicated healing factors occurring
- High precision, less tolerance. More things can go wrong

- Care plan guided by PT/Ortho
- Younger/more active demographic
- Acute pain that can develop into chronic pain

Appendix 6: FMEA Table

FMEA								
Process Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity: How severe is the failure mode? (1-10)	Potential Cause(s)/ Mechanism(s) of Failure	Occurrence: How often does the cause of failure occur? (1-10)	Current Process Controls: How does the product handle the cause of the failure?	Detection: How effective is our current process control at detecting the potential cause? (1-10)	RPN
Initial StartUp	Device does not turn on	User cannot use product	8	Out of Battery	7	Display battery life indicator	3	168
		Frustrated user		Open/Short Circuit	4	Error indicator	9	288
		Unsuccessful pain relief		Faulty components	2	Error indicator	8	128
				Damaged Components	3	Not detectable	10	240
Current Transmission	Incorrect Level of Stimulus Applied	Unsuccessful pain relief	9	Worn out electrodes	5	Warning message	3	135
		Potential injury to user		Bad Power Amplification	2	Error indicator	8	144
		Use of the device is compromised		Incorrect input waveform	2	Error indicator	8	144
				Safety circuit failure	3	Error indicator / Redundant Components	5	135
				User inputs setting too high for comfort level	7	Upper limiter	3	189

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity: How severe is the failure mode? (1-10)	Potential Cause(s)/ Mechanism(s) of Failure	Occurrence: How often does the cause of failure occur? (1-10)	Current Process Controls: How does the product handle the cause of the failure?	Detection: How effective is our current process control at detecting the potential cause? (1-10)	RPN
Communication	No wireless connection to device	Unsuccessful pain relief	8	Damaged Components	3	Not detectable	10	240
		Use of the device is compromised		Bluetooth antenna malfunction	5	Error indicator	4	160
	Information incorrect	Unsuccessful pain relief	5	Corrupted Data	2	Restart communication subsystem	5	50
		Use of the device is compromised		Faulty protocol	5			125
	Frustrated user		Packet Loss	3			75	
Software Usage	Software malfunction	Unsuccessful pain relief	6	Bug in code	8	Software update check	8	384
		Frustrated user		Bad communication to microcontroller	5	Microcontroller restart	5	150

Appendix 7: Team Contract

Interdisciplinary Senior Project

TEAM GUIDE AND AGREEMENT

TEAM PURPOSE:

Cal Poly's "learn by doing" education is designed to shape students' future, in helping you grow and mature, and in preparing you for what lies ahead in the business/work world. The ability to work well on a team is a fundamental component of career success in almost every circumstance. This guide and agreement is designed for the **benefit of each team and to its team members**: to ensure appropriate and necessary alignment in teams, which will lead to individual accountability and responsibility, and ultimately, to team success.

TEAM ROLES/RESPONSIBILITIES/COLORS:

In reviewing the team roles and responsibilities below, be mindful of your individual strengths, your needs, and your expectations about the project/class. Collaborate and discuss as a team – what your vision is, what your individual strengths and expectations are. COMMUNICATE and work to continue to develop your strengths. Do not hide.

Teams will be more successful for each project or task if they assign, at a minimum, the following roles; these roles can be modified change among members as long as you are explicit about who is responsible for what. Some team members play multiple roles and some roles are played by multiple team members.

Roles:

- **Visionary** – original idea generator, sets and maintains cultures
- **Hustler** – market and customer facing evangelist
- **Magician** – marketer, story crafter, awareness creator
- **Designer** – creator of app, product, service and combinations thereof
- **Hacker** – builds and evolves the solution
- **Enabler** – organizer, financial, legal

Teams will also be more successful if they assign, at a minimum, the following responsibilities; these responsibilities can be modified change among members as long as you are explicit about who is responsible for what.

Responsibilities:

- **Organizer** – Set meeting dates, times, locations, follow up on others
- **Scribe** – capture results, maintains BMC
- **Research** – gathers and disseminates data
- **Contributor/Editor** – adds and refines content to BMC and presentation
- **Presenter** – leads presentation

List each team member and associated Role and Responsibility below:

Name	Role/Responsibility/Color(s)
Evan Zhang	Magician / Editor / Blue – Green
Ryan Forsberg	Hacker / Organizer / Gold
Andrew Wandinger	Designer / Research / Gold – Orange
Clara Brechtel	Visionary / Presenter / Orange
Ben Goodwin	Hustler / Scribe / Orange - Green

TEAM AGREEMENT

As a student team in this class, we understand and agree to the following expectations – keeping our individual learning/achievement goals AND our team's success in mind:

PERFORMANCE:

As team members, we all agree to be **active** participants, which includes, but is not limited to:

- A) **Communication:** *(fill in here how the team will communicate with each other and what your expectations are for each other regarding responsiveness)*

We are using a group text for online communication and meeting in person. We expect every member to read and acknowledge group online communication within 6 hours on weekdays and 12 hours during the weekend unless the team member has given 24-hour notice to the group about being non-responsive. It is expected that each member updates the entire team whenever something significant happens that will affect project progress or any other team member.

- B) **Preparation:** *(fill in here how the team expects each other to prepare for meetings and what your expectations are for each other regarding preparation)*

Complete tasks that have been assigned previously. Come prepared with new data and information or work that has been done. Offer suggestions for team progression. Don't arrive intoxicated. Members should check Trello once a day to stay updated with project tasks and deadlines.

- C) **Follow-through:** *(fill in here what your expectations are for each other regarding follow-up)*

We will create objectives at the beginning of every meeting and delegate tasks for every member to complete on their own. When we meet, we'll discuss and analyze the data that has been gathered and work on the solution together. We're using Trello to keep track of tasks and on-going assignments. Meetings should be planned 3 days in advance. We'll have team bonding for keeping our interactions fun and then we will have workdays for focused work.

- D) **Participation:** *(fill in here what your expectations are for each other regarding attending meetings and conference calls, etc. How many absences, if any, will be allowed? How must notification be handled?)*

We expect all group members to be available to meet during dedicated class time although we don't necessarily have to meet in the classroom. A 24-hour notice of inability to make a meeting is required unless there are extenuating circumstances. This class has same priority as midterm and finals. If we have online meetings, then no multi-tasking.

EXPECTATIONS FOR THIS CLASS

Each student chooses to enroll in this class for one of many reasons. Many do so with the intent to take a real shot at launching a startup company. Some for the entrepreneurial experience but, upon graduation, intend to go to work for an established company. There is no right nor wrong answer but understanding each of your team members expectations of the class helps to make for a better experience.

List each team member and expectation for this class below:

- If a task hasn't been finished after 4 meetings, the task is given to another member
 - o Repeated occurrences will lead to intervention with the team
- If majority of the group believes a member has not been contributing or is toxic, we will have a meeting discussing removal of the member

MEETINGS AND AVAILABILITY

We also understand that teamwork is a critical aspect to this class and therefore have determined and agreed upon standing weekly meetings to maintain team productivity and to meet all deadlines on all team assignments. If there is a need to change any meeting, we will notify each team member at least 24 hours in advance.

Our standing weekly meetings will be held as follows:

During class times on Monday and Wednesdays, and as needed on Friday, Weekends, and other mutually agreed upon times.

I agree that as a team member:

- A) I will attend every meeting; in the case of an emergency that requires my absence, I will notify the Organizer immediately. I will ensure that I take appropriate steps to make-up the learning and tasks I missed at the meeting and continue to contribute.
- B) If a particular member misses more than 3 meetings in a single academic quarter, I will work with the rest of the team to talk with this member. If this problem continues, we may choose to bring this to the attention of the instructor.

Name	Expectation
Evan Zhang	Gain experience and possibly go into the accelerator
Ryan Forsberg	Maybe making this as masters project
Clara Brechtel	A viable business in the accelerator
Ben Goodwin	Gaining hands-on experience in product development and potentially going into the accelerator
Andrew Wandinger	A viable business in the accelerator

SIGNATURE PAGE

We have read and understand this Team Contract. If at any time it becomes apparent that the Team Contract needs to be modified, we will consult with each other and come to agreement on the modifications.

Team: Kinexion Date: 10/20/2019

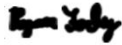
Name

Signature

Evan Zhang



Ryan Forsberg



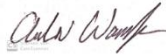
Clara Brechtel



Ben Goodwin



Andrew Wandinger



Note: Each member should keep a copy of this Team Agreement. A signed copy will be given to the professor.

Professor's Signature _____

Appendix 8: Design Verification Plan and Report

DESIGN VERIFICATION PLAN AND REPORT (Customer Requirements)									
Report Date		Company			Kinexion Devices				
TEST PLAN					TEST REPORT				
Item No	Customer Requirement	Test Description	Acceptance Criteria	Test Responsibility	TIMING		TEST RESULTS		NOTES or Actions Resulting From Test
					Start date	Finish date	Test Result	Responsible Student (Initials)	
1	Person comfortably wears the device for 20 minutes	User places the device on their knee and is instructed to wear the device until they are no longer comfortable	Pass: Customer leaves the device on for at least 20 minutes Fail: User removes the device in under 20 minutes	Ben	5/1/20	5/20/20			
2	Person perceives less pain while wearing the device	User completes a pain survey before and while using the device	Pass: User reports lower pain while using the device	Ben	5/1/20	5/30/20			
3	Person can easily use the device	Person takes 2 minutes to learn how to control the device with no outside guidance	Pass: User is able to turn on, turn off, and change stimulation levels of device	Clara	5/1/20	5/30/20			
4	Person has improved function after using the device	Person completes wellbeing survey, uses the device for 30 minute treatment, and completes survey again	Pass: Person scores higher on wellbeing survey after using device	Clara	5/1/20	5/1/20			
5	Person can walk around while wearing device for 30 minutes	User puts on device and goes on a 30 minute walk	Pass: Device stays within 1 inch of placement location after the walk	Clara	5/1/20	5/1/20			

DESIGN VERIFICATION PLAN AND REPORT (Engineering Requirements)												
Report Date		Company			Kinexion Devices							
TEST PLAN												
Item No	Specification	Test Description	Test Equipment	Personnel	Budget	Acceptance Criteria	Test Responsibility	Test Stage	SAMPLES		TIMING	
									Quantity	Type	Start date	Finish date
1	Weight	Weigh product using scale	Scale with satisfactory precision and range	One person	\$0.00	0.5 lb	Jenny	PV	2	C	5/1/20	5/1/20
2	Interferential Beat Frequency	Connect system to oscilloscope	Oscilloscope	One experienced engineer and a helper	\$0.00	150Hz +- 1Hz	Gonzalo	PV	3	C	5/1/20	5/1/20
3	Adjustable Carrier Frequency	Connect system to oscilloscope	Oscilloscope	One experienced engineer and a helper	\$0.00	4000Hz - 4150Hz	Ryan	PV	3	C	5/9/20	5/9/20
4	Waveform Type	Verify that wave is a Sinusoid	Oscilloscope	One experienced engineer and a helper	\$0.00	Sinusoid	Ryan	PV	1	C	5/5/20	5/5/20
5	Output Voltage	Connect to Multimeter	Multimeter	One experienced engineer and a helper	\$0.00	80Vpp +- 0.5Vpp; 500Ohm Load	Gonzalo	PV	10	C	5/5/20	5/5/20
6	Output Current	Connect to Multimeter	Multimeter	One experienced engineer and a helper	\$0.00	100mA	Gonzalo	PV	10	C	5/5/20	5/5/20
7	Waterproof - IP68	Submerge in water beyond 1m for 20 minutes	1 meter deep body of water	Any one or two team members	\$0.00	Device powers on and meets all other testing criteria	Gonzalo	PV	10	C	5/9/20	5/9/20
8	Dustproof - IP68	Leave device in dusty/windy area for an hour	Dust and fan	Any one or two team members	\$0.00	Device powers on and meets all other testing criteria	Gonzalo	PV	3	C	5/13/20	5/13/20
9												

Appendix 9: Archived Design Developments

Design Development

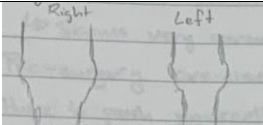
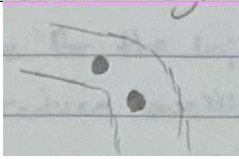
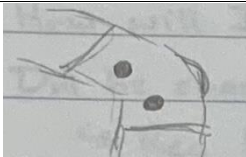
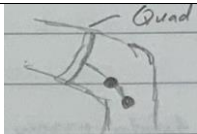
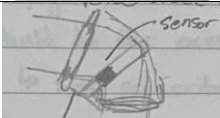
Hardware Development


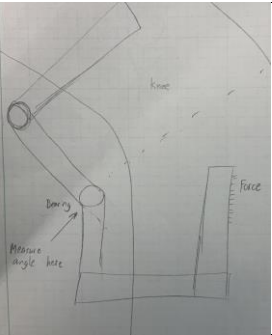
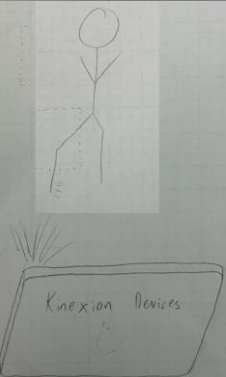
Prototype 1: Knee Exercise Analytics

Our team began the design process by researching existing or proposed solutions from competitors, academia, and other groups of individuals. Once enough customer research was done, our team began sketching ideas for measuring ACL recovery more effectively and quantitatively. Additionally, a trade study was done on the individual benefits and setbacks of a variety of sensors.

Before arriving at the top design, our team drew sketches of a wide variety of ways to record metrics indicative of the recovery process. Below are some of the sketches of ideas that were proposed.

Table 10. Hardware Design Prototypes

Symmetric Sets		-Sensors on both knees to compare progress of injured. -May be difficult to position and calibrate sensors properly.
Floating Sensor		-Two Pods -Wireless communication -Able to determine position relative to one another -Requires accurate and consistent placement
Molded Sleeve		- Holds sensors in precise location -Sensors attached inside sleeve -Secure for sports -Could cause discomfort or stiffness
Wireframe "Brace"		-Measures force of muscle, a unique recovery indicatory -Does not account for angle measurements
Flat Knee Brace Attachment		-Sensors attached to knee brace -Might discourage patients from taking off their knee brace when they should

Bottom-of-Foot Sensor		<ul style="list-style-type: none"> -Heel and pad of foot sensor -Measures landing of leg -Can tell if gait is affected -Can be used to test symmetry -May cause standing discomfort
Mechanical Angle and Force Measure		<ul style="list-style-type: none"> -Measures angle based on two plates positioned with a pivot -Measures stepping force mechanically -May be difficult to secure properly and cause discomfort
Mobile Optical Knee Analysis		<ul style="list-style-type: none"> -Phone application -Analyzes patient movement using vision algorithms -May require more sophisticated software algorithms and compute

From these original sketches, we began narrowing down our designs by comparing advantages and disadvantages of each. We concluded that our top design should be compact and convenient while still being able to offer as many metrics as possible. Along the way we incorporated various features from our many sketches. The result was a comfortable sleeve with two conductive strips to measure angle and force, two inertial measurement units to re-affirm our angle measurement, and a low power microcontroller to receive and store all of our calculations until they are ready to be transmitted.

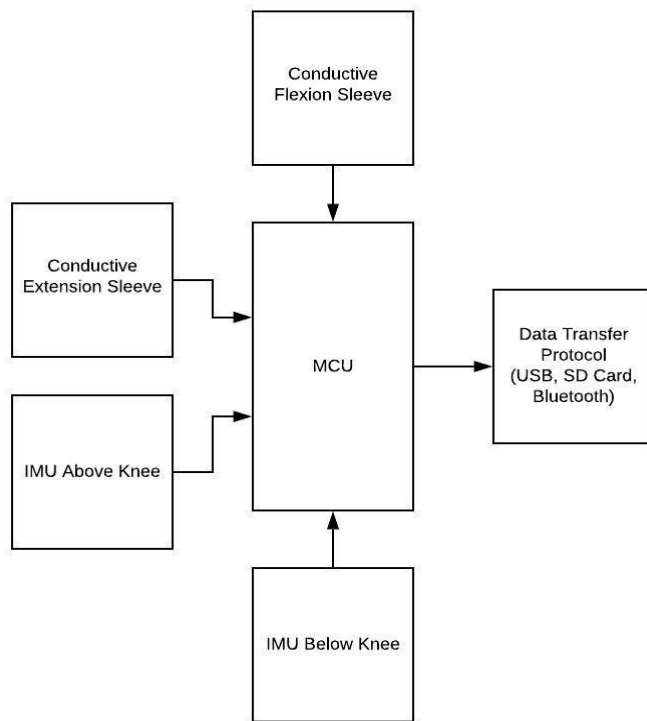


Figure 35. Block Diagram of Top Designs

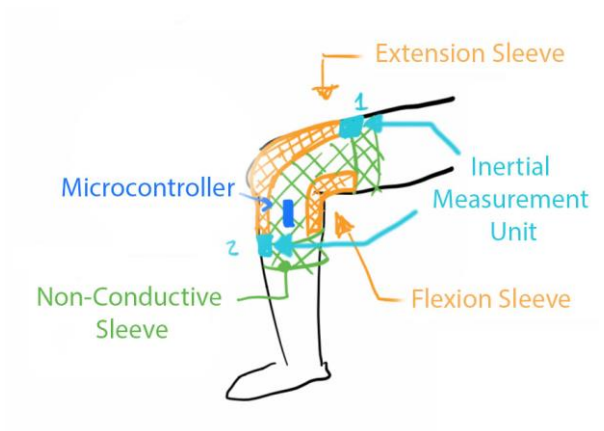


Figure 36. Concept Sketch for Top Design

With the data recorded the physical therapist can accurately assess the patient's performance in advanced. The feedback that this device provides will encourage patients to confidently complete the exercises that the physical therapists assign and reassure physical therapists that the exercises will not hurt their patients. As a result, this device will be able to save both the physical therapist and the patient valuable time by removing the need to relearn and perform exercises during follow up visits. Ultimately, the aim is to improve the recovery process and allow the patient to return to their sport and the physical therapist to help the next patient.

As our device is a wearable, it is bound to have many limitations. We are likely to run into risks involving limitations on memory, battery life, response-time, and computing power. We can mitigate each of these by ensuring that proper research is done on the capabilities of each sensor on the market so that we maximize the features of our device. Additionally, we can design our product iteratively to ensure that any tradeoffs in features and energy are only made to meet customer's needs. *Figure 36* shows how data about the patient is taken by the device and transmitted to an online records system where it can be securely stored and accessed by the physical therapist from any personal computer.

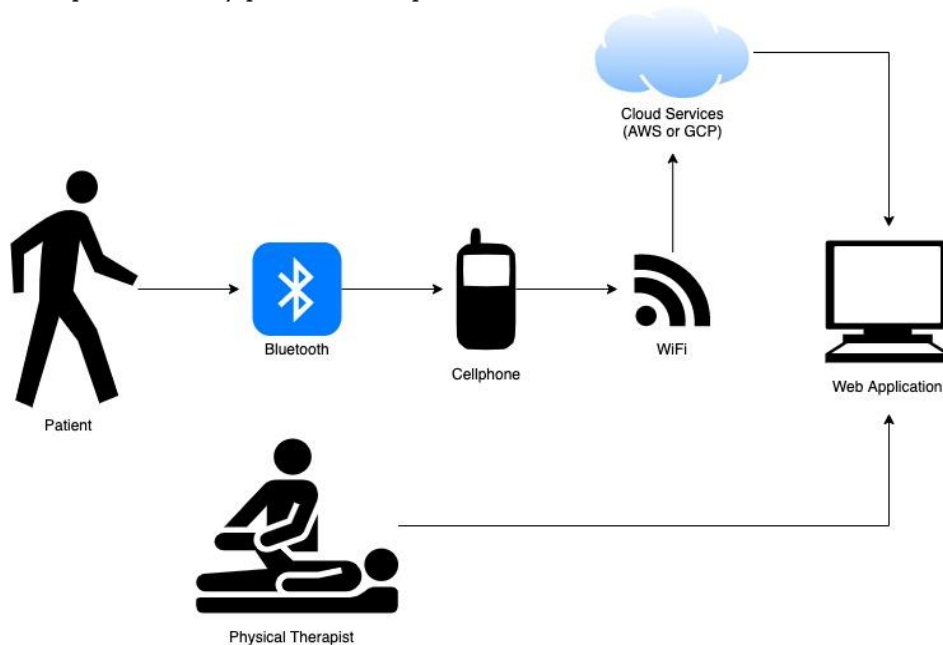


Figure 37. Prototype I: Software System Design

From a business perspective, there are a variety challenges that we may face. For instance: research and development may keep us from entering the market quickly enough to catch up with our competitors. Along the same lines, we may invest time, resources, and finances into a product or feature that our customer does not want. In order to prevent this our team will be continuously conducting market and customer research as the iterative process advances so that we can stay informed about and responsive to unexpected changes.

Accurate and responsive biotelemetry readings can be used to provide timely biofeedback to allow patients to confidently complete their exercise routines. This in turn results in higher quality recovery results in a shorter time and ultimately reduces the number of ACL reinjuries. This process provides data to the Physical Therapist that can be used to verify functionality of both knees throughout the rehabilitation process.

Appendix 10: Bill of Materials

Level 1	Level 2	Level 3	Level 4	Level 5	Manufacturer	Supplier	Unit Price	Quantity	Total Price
Product	Electronics Housing							1	\$147.50
		Enclosure Base						1	\$1.19
		Enclosure Lid						1	\$0.00
		Power Button						1	\$0.00
		Mode Button						1	\$0.00
		Charging Port Plug						1	\$0.00
		PCB Mounting Threaded Inserts				McMaster Carr	0.181	4	\$0.72
		PCB Mounting Screws				McMaster Carr	0.1182	4	\$0.47
		Acetone or ABS cement							\$0.00
	Fabric							1	\$107.70
		Base Fabric						1	\$0.00
		Velcro Strap 8"; 1" thickness				McMaster Carr	\$2.76	1	\$2.76
		Velcro Strap 10"; 1" thickness				McMaster Carr	\$3.19	1	\$3.19
		Electrode Wiring				McMaster Carr	\$9.95	1	\$9.95
		D-Ring				McMaster Carr	\$1.59	2	\$3.18
		Neoprene				Shaoning Gaoli	\$1.34/in ²	38.88	\$52.10
		Electrode				Vitality Medical	\$9.13	4	\$36.52
	PCB							1	\$38.61
		Control Unit						1	\$11.85
			Microprocessor - MSP432P401RIZXHT				\$7.17	1	\$7.17
			SMD Capacitor - 100nF				\$0.14	5	\$0.70
			Polar SMD Capacitor - 10V 10u				\$0.31	1	\$0.31
			Jumper - Zero Ohm				\$0.13	1	\$0.13
			SMD Capacitor - 4.7uF				\$0.47	1	\$0.47
			Fixed Inductor - 4.7uH				\$0.37	1	\$0.37
			LED Indicator Circuit					2	\$2.70
				Thick Film Resistors - 56ohms			\$0.16	1	\$0.16
				Thick Film Resistors - 86.6ohms			\$0.10	1	\$0.10
				Thick Film Resistors - 88.7 ohms			\$0.10	1	\$0.10
				Bulb Tri Color LED - HV-SRGB60			\$0.99	1	\$0.99
		Oscillator						2	\$3.94
			DAC - MCP4921T				\$1.97	1	\$1.97
		Mixer						2	\$1.78
			SMD Resistor - 10 kΩ				\$0.01	6	\$0.06
			Capacitor - 0.01uF				\$0.10	3	\$0.30
			Op Amp - LM324KNSR				\$0.53	1	\$0.53
		Amplification Circuits						1	\$18.34
			Class-D Audio Amp - 40W Stereo				\$0.97	1	\$0.97
			Transformer - 10.929:1				\$9.17	2	\$18.34

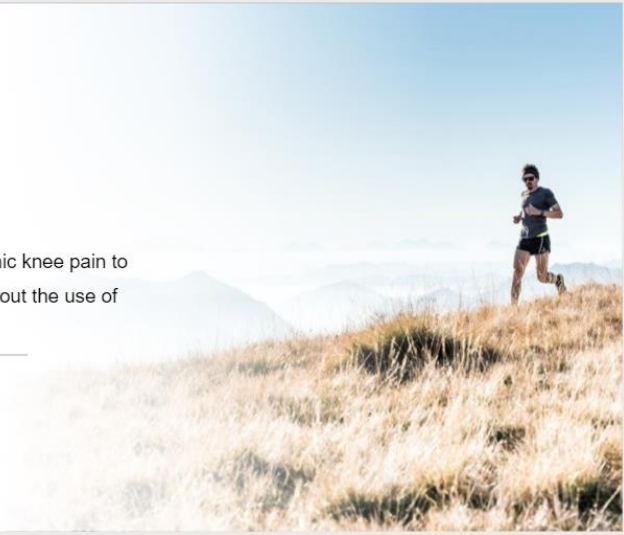
Appendix 11: Investor Pitch Deck



Get moving again with drug-free pain management.

Vision

We empower people with chronic knee pain to manage pain on their own, without the use of drugs.



Meet Eric



Eric

Age: Early 50's

Occupation: Manager at engineering firm

Marital Status: Married

Kids: Two sons, aged 12 and 15

Hobbies: Enjoys outdoor activities with his family such as hiking, camping, and biking. He participates in 4-6 running events a year and has finished 2 full marathons.

Unmet Medical Need

Frequent knee pain affects about 25% of adults



700,000 TOTAL KNEE JOINT
SURGERY'S EACH YEAR
(\$24 BILLION)



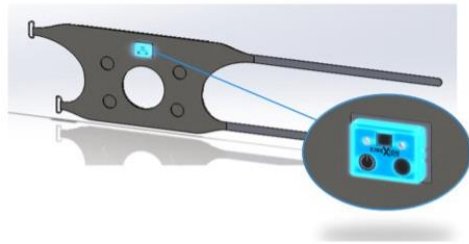
30% OF TOTAL OPIOID
PRESCRIPTIONS



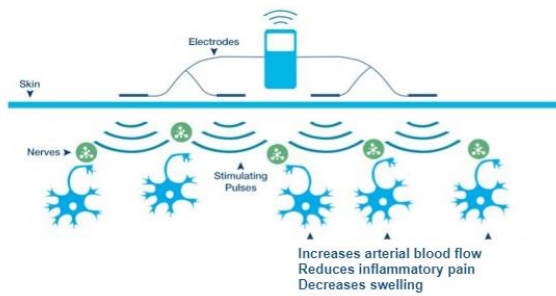
SYMPTOMS OF DEPRESSION IN
39% OF PATIENTS

Solution

A portable wearable device that utilizes interferential current electrical nerve stimulation to provide deep tissue pain relief and enhance recovery.

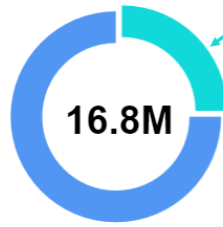


IFC Technology



Target Market

\$3,279
Average amount spent per person aged 45-65 on **non-surgical treatments**



Amount of people aged 45-65 who experience persistent knee pain

Target Market

- Pain persists over 4 weeks
- No available surgical intervention
- Live an active lifestyle
- Avoiding total knee joint replacement

\$13.8B
Total Available Market

Business Model

\$130
Per Device
Direct-to-Consumer

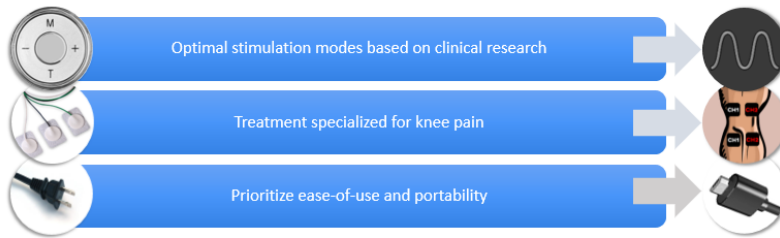
Channels:

- Direct-sales through our website
- Amazon

\$20  Recurring purchase every month

Key Differentiator

Our patentable technology provides users with effective pain relief outside of health care settings.



Competitive Analysis

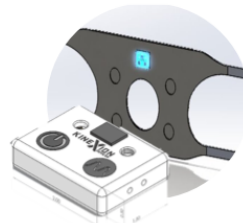
	KINEXION DEVICES	+AcuKnee®	COMPEX+	H-WAVE
Portable during treatment	✓	✓	✓	
Configures electrode placement for optimal treatment	✓			
Provides deep tissue pain relief	✓	✓		✓
Components contained in one unit	✓		✓	

Current Status



- Simulation verified treatment frequency
- Fully designed PCB

KINEXION
DEVICES



- Completed 3D model for user friendly, water resistant enclosure

Next Steps

June 2020

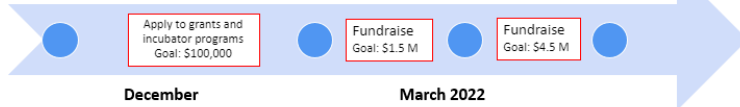
- Continue developing proof-of-concept

June 2021

- Start clinical testing
- Design freeze
- Develop regulatory strategy

September 2022

- Receive FDA clearance
- Launch Product



December 2020

- Verification and validation testing
- Complete physical prototype

March 2022

- Submit 510(k) for FDA class II clearance and registration (\$7622)
- Develop go-to-market strategy

The Team



Ryan Forsberg
Project Manager
Mechanical Engineer



Ben Goodwin
Mechanical Design
Biomedical Engineer



Clara Brechtel
Business Development Lead
Biomedical Engineer



Andrew Wandinger
Electrical Design
Biomedical Engineer

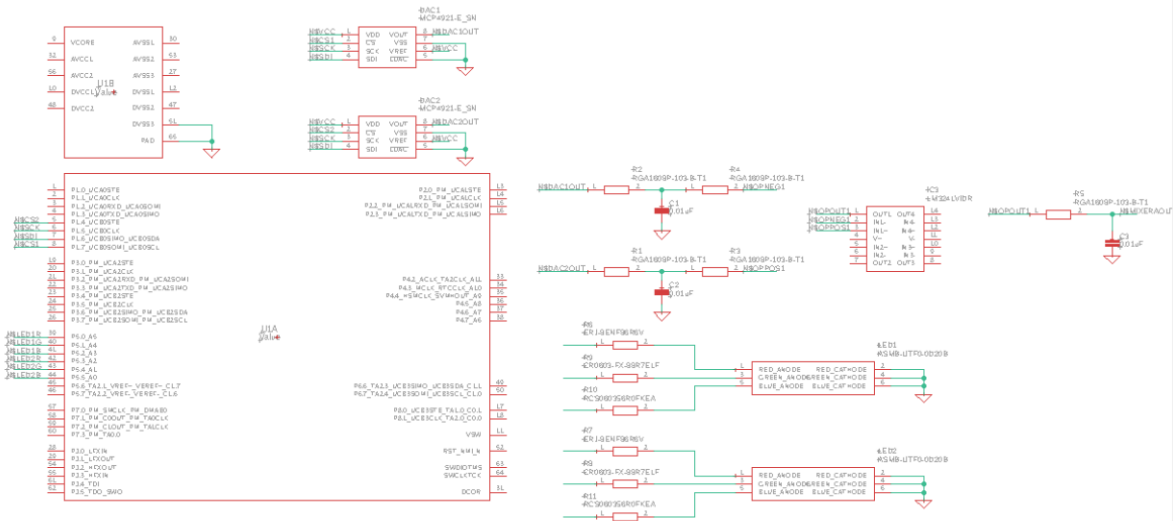


Evan Zhang
Product Design
Computer Scientist



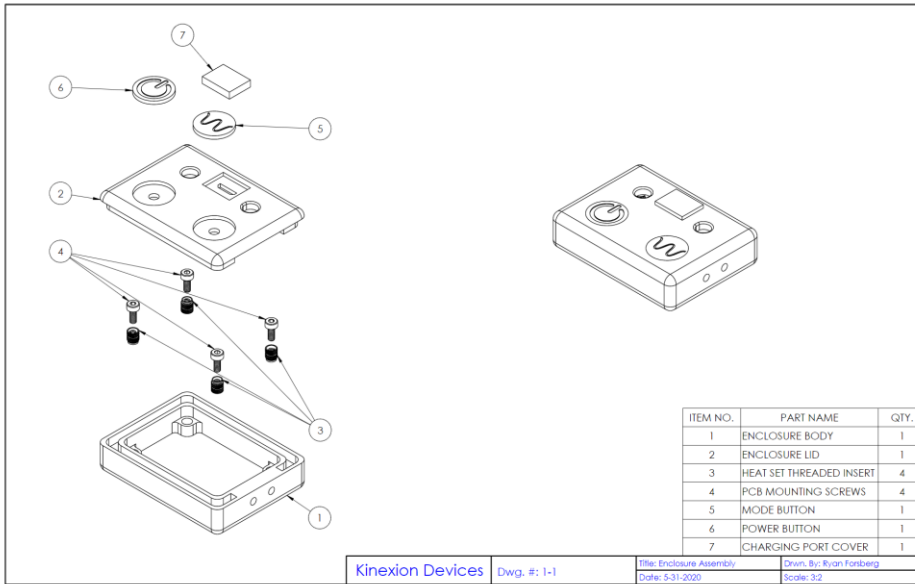
Gonzalo Arana
Engineering Lead
Computer Engineer

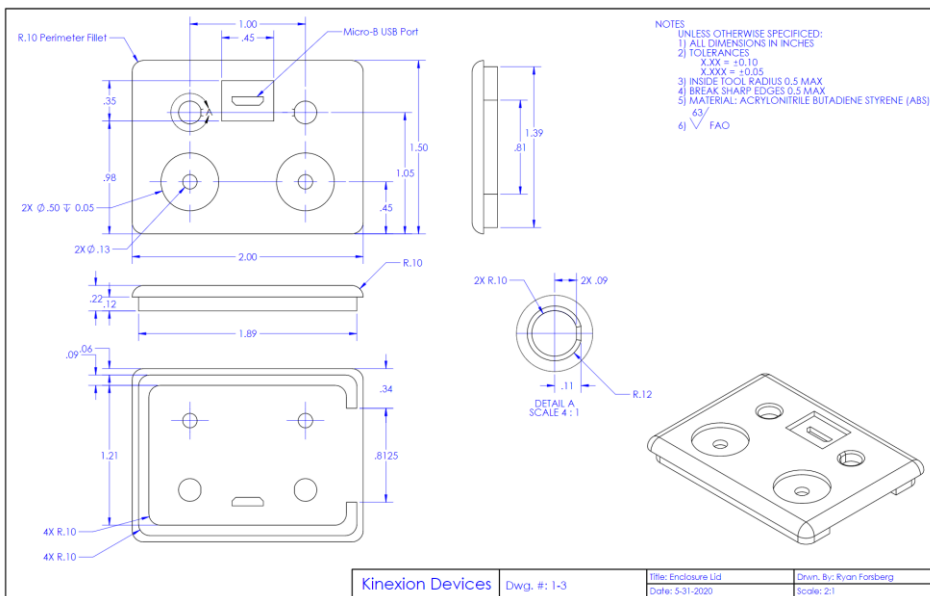
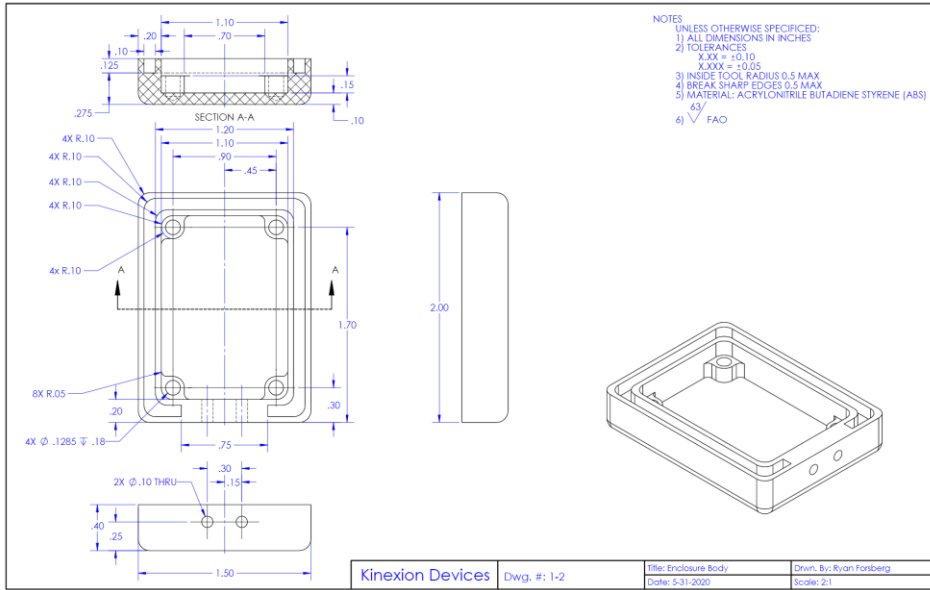
Appendix 12: IFC Circuit Schematic

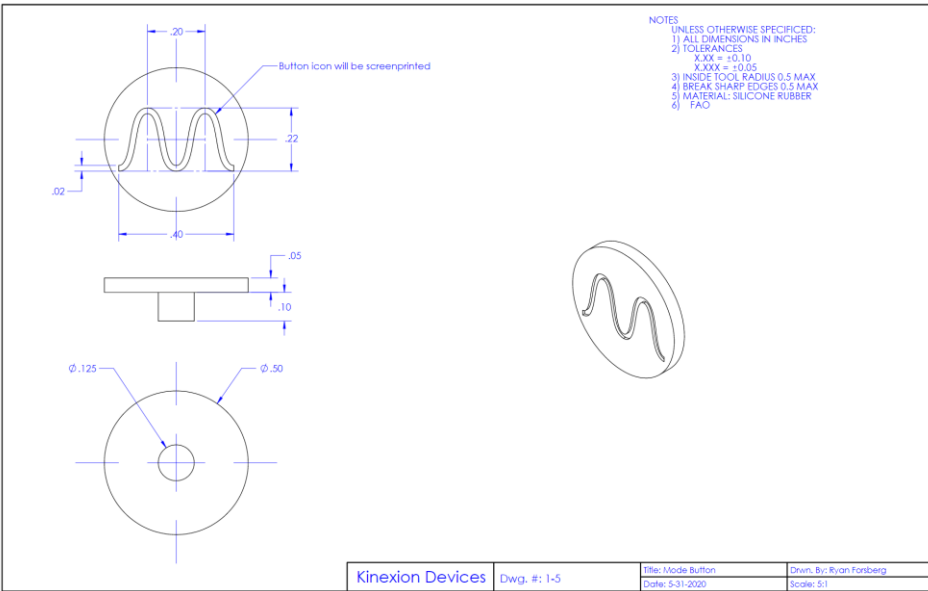
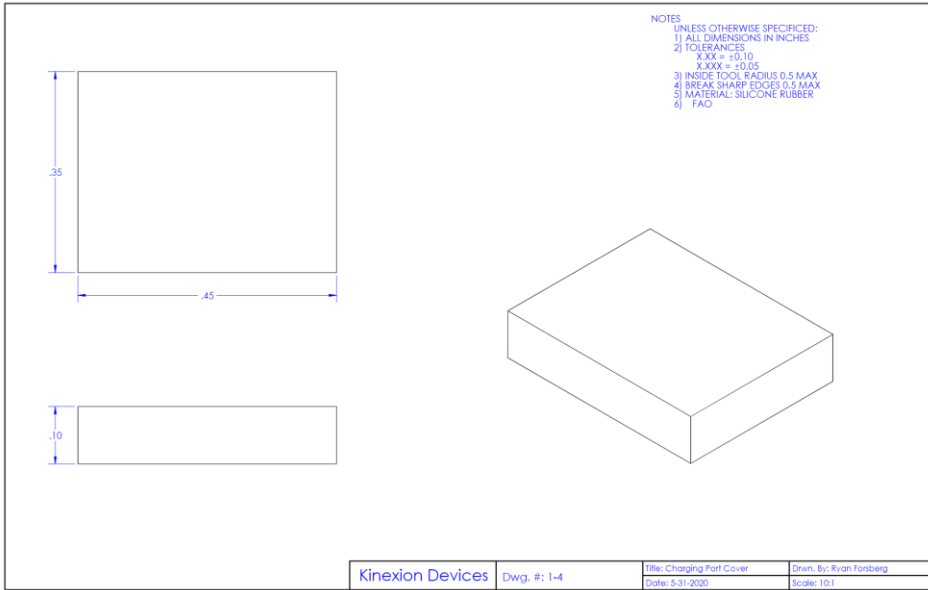


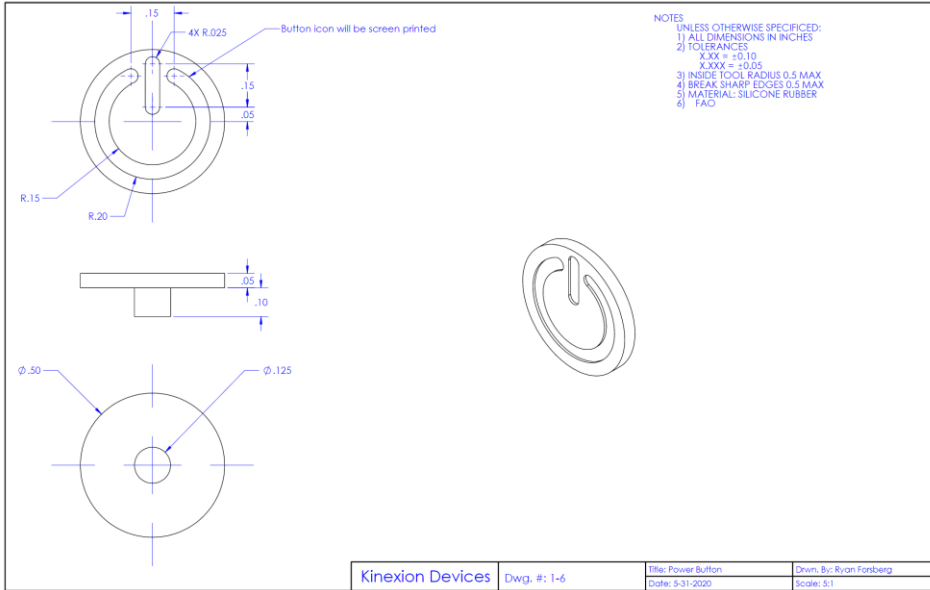
Appendix 13: Engineering Drawings

Electrical Housing









Neoprene Base

