July 24th, 2017

Dr. Andrew Rawicz
School of Engineering Science
Simon Fraser University
Burnaby, BC, V5A 1S6

Re: ENSC 405W/440 Design Specification for **Sockulation**

Dear Dr. Rawicz,

The following document contains the design specification for *Sockulation* by RippleRelief Medical. Our aim is to design a more effective method to prevent blood from pooling in the legs and feet. The Sockulation device will reduce the amount of swelling and discolouration in the feet and legs, as well as making it more comfortable to travel.

The design specification will provide a system overview, the overall system design, and specific design details of Sockulation. This document will be used as a guide for the design and development of Sockulation, particularly for the proof-of-concept and prototype phase of the design.

RippleRelief Medical is made up of a team of four skilled, hard-working engineering students from a wide range of disciplines consisting of Systems Engineering, Computer Engineering and Biomedical Engineering. Michael Jurewicz, Evelyn Kim, Kimberly Kunimoto and Daryl Seah are the creative driving force behind RippleRelief Medical.

Thank you for taking the time to review our design specification for *Sockulation*. If you have any questions or concerns regarding our document, please contact Daryl Seah, our Chief Communications and Operating Officer, by phone at (778) 708-8611 or by email at dseah@sfu.ca.

Sincerely,

Kimberly Kunimoto

Kimberly Kunimoto
Chief Executive Officer
RippleRelief Medical

Enclosure: *Design Specification for Sockulation by RippleRelief Medical*

Design Specification for *Sockulation*

Project Team: Michael Jurewicz
Evelyn Kim
Kimberly Kunimoto
Daryl Seah

Contact Person: Daryl Seah
dseah@sfu.ca
(778) 708 8611

Submitted to: Dr. Andrew Rawicz – ENSC 440
Steve Whitmore – ENSC 405W
School of Engineering Science
Simon Fraser University

Issue Date: July 24th, 2017

Abstract

In a nursing home for senior citizens, the majority of seniors are sitting down for long periods of time and have blood pooling in their lower legs and feet. The few solutions that exist include medication, surgery and compression socks. These solutions do not appeal or work for everyone. RippleRelief Medical aims to prevent blood from pooling in the user by creating Sockulation, a device that will massage the foot and lower leg in an upward pulse-like motion.

Sockulation will be developed in two phases. At the end of the first phase, Sockulation will be a prototype capable of compressing in an upward pulse-like motion. It will consist of three major layers, each with a certain functionality that adds to the efficiency of the device.

The three main layers in Sockulation are:

1. The inner sock layer, which will be made out of a material that is comfortable, breathable, and flexible, but firm enough to withstand the compression from the Nitinol.

2. The middle Nitinol layer, which contains the main functions of Sockulation. The Nitinol springs will wrap around the entire sock in segments to create the pulsing motion.

3. The outer mesh layer will protect the Nitinol wire and help cool it down. The hardware for Sockulation will be attached to the side of the upper calf for easy access and use.

The following document contains the design specifications and the user interface design for Sockulation. The deliverables due at the end of August 2017 and at the end of December 2017 can be found in this document.

Table of Contents

List of Tables

List of Figures

1.0 Introduction

Many people suffer from blood pooling or chronic venous insufficiency in the lower legs and feet when sitting for long periods of time. Pain, discolouration and swelling are just a few of the symptoms that can occur. Sockulation is a device that will comfortably fit around the lower leg and foot and will massage in an upward movement to prevent blood from pooling. The massaging motion will come from the muscle wire, Nitinol, which will have a current running through it using a Raspberry Pi 2 and a power source.

The idea for Sockulation came from the lack of viable solutions to blood pooling when travelling in tight spaces such as airplanes. The current solution to this problem is to wear compression socks and to elevate the foot, which is very difficult to do with limited leg room. Other solutions include surgery and medication which do not appeal to all people.

Sockulation is designed to be used in any location, whether it be in an airplane or at home. People over the age of 50 are the main demographic for Sockulation, due to the higher probability of being affected by blood pooling. Since the majority of users will be the elderly, Sockulation will be easy to put on and user friendly. The detailed design for Sockulation by RippleRelief Medical is described in the following design specification document.

1.1 Scope

This document describes the design of Sockulation and how it will meet the requirements from the document, *Functional Specification for Sockulation*. The designs described will be for the proof-of-concept device, as well as the final production design of the product. A test plan and the User Interface Design for Sockulation is also included and is found at the end of the document in the appendices.

1.2 Intended Audience

This document, which contains the design specification of Sockulation, is intended to be used by the members of RippleRelief Medical. During the development stages, this document will be used as a resource for engineers to view the overall design requirements of the device and to ensure the product functions correctly.

2.0 System Overview

Sockulation is a product designed to help users improve their blood circulation in their feet. Sockulation's primary target audience is long-haul truck drivers, long-haul flight passengers, office workers, and patients diagnosed with chronic venous insufficiency, all of whom would require the product to be portable enough to carry with the user. Aside from being portable, Sockulation will also be easy to interface as the primary target audience might be technologically inept. Sockulation will feature a simple switch to power the device on and off.

2.1 Project Design

Since portability is a crucial part for the success of Sockulation, a lot of attention was put into designing Sockulation to be portable and easy to carry around. Sockulation will be powered by a 10000mAh external battery pack that can be easily recharged. The battery pack will be detachable from the sock so that users can recharge the battery at their convenience. The design for Sockulation should also use as little components as possible to minimize its environmental footprint. Keeping these constraints in mind, Sockulation is optimized for easy to carry and use, even for the most technologically inept individual. Assuming a current draw of approximately 1A from the battery, the device should last up to 9-10 hours.

The key behind the design being portable is the use of Nitinol. Nitinol wires have interesting properties as the wires can form to a memory state when heated above a certain transition temperature. Sockulation uses Nitinol wires that revert to their memory state at a transition temperature of 45°C. The Nitinol wires will be pre-formed to a tighter state so that the wires will contract when heated past the transition temperature of 45°C. At temperatures lower than 45°C, the wires act like normal metal wires that can be easily formed physically.

Figure 1 shows the high-level design for Sockulation.

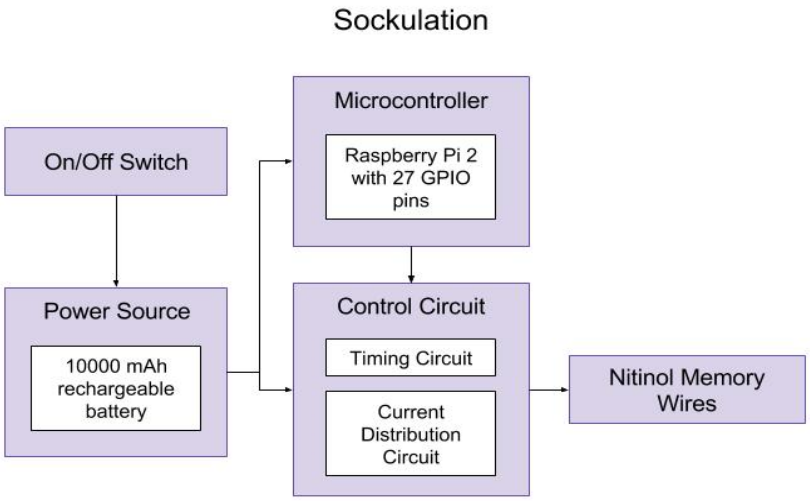

Figure 1: Sockulation System Layout

The 10000mAh rechargeable battery will be the power source for both the microcontroller and the control circuit. For the purpose of Sockulation, heat on the Nitinol can be produced by supplying current through the wire. The current through the Nitinol wire can vary to control the temperature of the wire. The GPIO pins on the microcontroller can be programmed to control different segments of wires easily.

2.2 Control Circuit

2.2.1 Timing Circuit

The input voltage is pulse-width modulated with equal timing of high and low signal to heat the Nitinol wires more evenly and effectively.

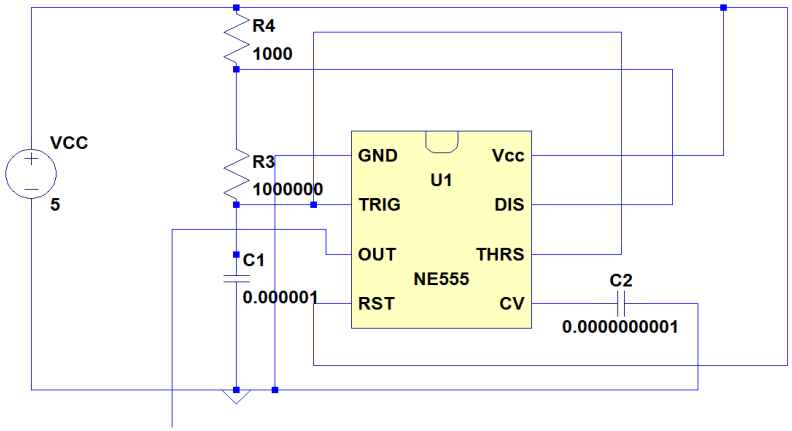

Figure 2: Timer Circuit Diagram

The circuit from Figure 2 is simulated in LT Spice and the output is shown in Figure 3.

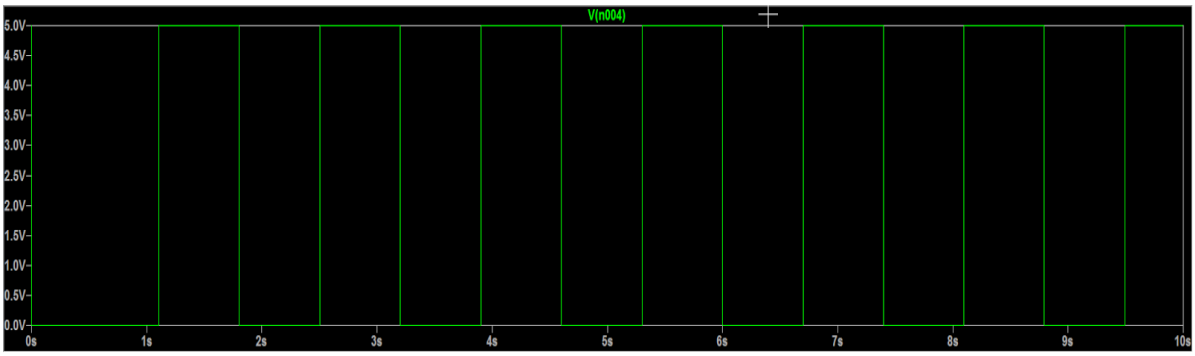

Figure 3: Timer Circuit Output in Voltage

As seen in Figure 3, the required pulse-width modulated voltage can be obtained by using a NE555 timer.

2.2.2 Current Distribution Circuit

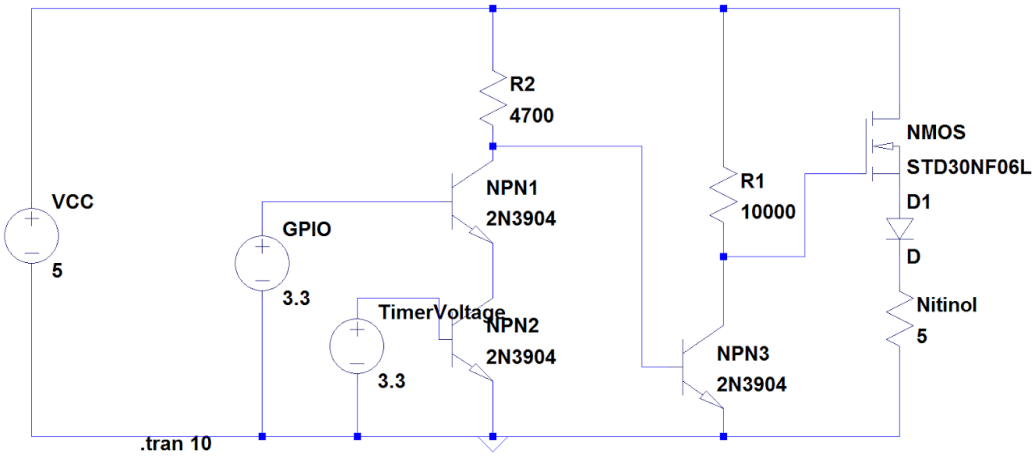

Figure 4: Complete Current Distribution Circuit

The current distribution circuit shown in Figure 4 demonstrates the logic for the heating of the Nitinol wire. Current only passes through the Nitinol wire when the GPIO and Timer Voltage is both at a high voltage. Since Timer Voltage is always oscillating between 0V and a high voltage, the heating of the Nitinol wire solely depends on the voltage of the GPIO pin. Hence, this circuit only heats the Nitinol wire when the GPIO pin connected to it is on.

3.0 Design Specifications

The design for the entire Sockulation prototype is displayed in the following subsections. Each section shall explain and demonstrate to the best of our ability the design choices we have made for the corresponding requirement. The reference to each requirement is located at the end of the document. Some production requirements may not be referenced in the design choices due to our current stage of development.

3.1 General Requirements

[R 3.1.1 - POCT] - According to general compression theory, pressure exerted evenly throughout a limb segment will lower its blood volume and graduated pressure will help blood flow circulation [1]. It is also recommended that any compression sock rated over 20mmHg should be consulted with a physician. By choosing a light compression sock as our inner layer of 8-15mmHg, we ensure a safe blood volume reduction, and the pulsation of the Nitinol is a graduated pressure that helps with venous blood return.

[R 3.1.2 - PROT] - The prototype of Sockulation is designed from the middle of the calf to the toes as this is the area where most blood pooling occurs [1]. We have chosen knee high compression socks to fulfill this requirement.

[R 3.1.3 - PROT] - Making the design able to withstand multiple weather environments is out of our knowledge and technical background. We have chosen to use this device in safe environments to focus our efforts in the therapeutic effect from the device, rather than allowing users to use the device anywhere.

[R 3.1.4 - PROT] - Other design limitations referenced in Section 3.2.2 of Nitinol wire and heat effects limits our design to work in relatively cool environments. We have chosen a threshold of 30°C to encompass as many environments that the device would be used in while not exceeding other important requirements such as [R 3.2.2.5 - PROT] to keep the leg from heating up.

[R 3.1.5 - PROT] - We have chosen to use a 5000mAh battery to allow the use of the device for over an hour. This is to allow the user to feel a therapeutic effect for the longest time possible while not interfering with the user's movement as stated in [R 3.1.11 - PROD].

[R 3.1.6 - PROT] - Just as socks have normalized sized for a range of feet, the chosen compression sock size will determine the sizes of feet that our product will work on. This means we would have multiple skews of Sockulation. For example the compression sock by Dr. Scholl's we have chosen for the prototype and testing, will work with shoe sizes 10.5-12 as seen in Figure 5 below.

Figure 5: Compression Sock Size Range

As well, the right amount of Nitinol spring forms to the specific sock size to ensure other requirements in Section 3.2.2.

[R 3.1.7 - PROT] - Sewn and attached to the top of the compression sock is the control box and battery. We chose the location for user interface reasons as stated in Appendix B and to move components away from the foot to improve mobility.

[R 3.1.8 - PROD] - A zipper is sewn into the top half of the compression sock to allow the user to put on the device with ease. A zipper was chosen over other alternatives such as buttons due to a better perception to the user of usability and more even pressure of the sock around the leg. A graphical representation of this design can be found in Appendix B in this document.

[R 3.1.11 - PROD] - The maximum weight on the product is 1 kg to reduce the effect of the user's movement with the device. We have chosen lighter components like the battery (198 grams), compression sock (37 grams), zipper (8 grams), Mesh (127 grams) and Raspberry Pi (45 grams) to a total of around 415 grams to meet this requirement. More specifics about component design choices can be found within Sections 3.2 and 3.3.

3.2 Physical and Operational Requirements

The physical design of Sockulation focuses on the three main layers, inner sock layer, Nitinol layer and the outer mesh layer.

3.2.1 Inner Sock Layer

The inner sock layer chosen is a graduated compression sock made by Dr. Scholl's and is rated at 8-15mmHg, meeting the maximum pressure of 20mmHg stated in requirement [R 3.2.1.3 - PROT]. By having a mild compression from the sock, it creates a stiff enough base to anchor the Nitinol along specific limb segments, and flexibility for movement to meet requirement [R 3.2.1.2 - POCT]. The material is made of 55% polyester, 41% nylon and 4% spandex and is strong enough to withstand materials being sewn to itself to fulfill [R 3.2.1.1 - POCT]. The material of the inner sock is less than 3mm and is not made of cotton which wicks away moisture and traps heat in accordance to [R 3.2.1.5 - PROT] and [R 3.2.1.4 - PROT]. The graduated pressure and fit of the sock reduces blood volume throughout the leg and reduces swelling along the limb segment it is on. By using this compression sock we can ensure that during our operation of the Nitinol wire, the leg maintains a constant even pressure and fulfills [R 3.2.1.6 - PROT]. Below are two figures of the chosen sock to show its size, shape and material.

Figure 6: Compression Sock

Figure 7: Compression Sock Material

3.2.2 Nitinol Spring

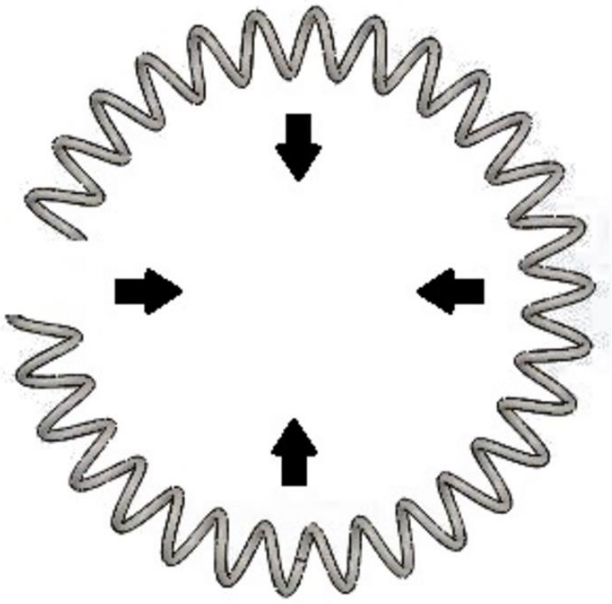

Figure 8: Nitinol Relaxed State

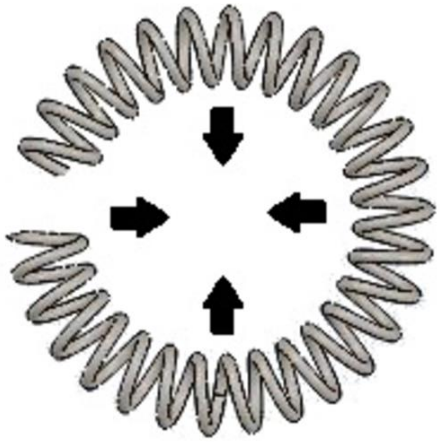

Figure 9: Nitinol Compressed State

A segment of the Nitinol spring is shown in Figure 8 and Figure 9. As it can be observed, the spring is initially at rest in a relaxed, stretched state. Once the device is powered on, the current runs through the wire and transitions to create even pressure around the intended limb segment as per [R 3.2.2.2 - POCT] and will not pinch the user due to increased surface area [R 3.2.2.6 - PROT]. The diameter of this compression depends on the intended limb segment but when in the relaxed position the springs should be exerting minimal pressure to the user's leg while the diameter in the compressed state would be on average 1in

smaller in diameter. The dimensions of the spring can be found from the compression sock chosen which has a maximum diameter of 5in as per [R 3.2.2.1 - POCT].

After testing multiple Nitinol wires in terms of the their diameter and transition temperature, we have chosen to use a transition temperature of 45°C and 0.4mm diameter Nitinol wire from Kellogg's Research Labs [2].

At the transition temperature of 45°C, we are able to keep the spring relaxed in room temperature and below, while reducing heat created by the wire to fulfill [R 3.2.2.5 - PROT]. The wire is also safe to touch while in the transition state temperature. The diameter was chosen due to the strength of the wire causing 2.7lbs of linear force and due to the current required to cause the wire to transition. In Table 1 below, we show the average current required to cause the wire to transition within a second as required by [R 3.2.2.9 - PROD].

Nitinol Wire Diameter	Current Through the Wire to Cause 1 Second Transition
0.25mm	0.4A
0.4mm	1.0A
0.5mm	2.0A

Table 1: Diameter vs. Current for Nitinol Transition within a Second

As we see from Table 1, a small increase in diameter of the wire causes an exponential increase in the amount of current needed to cause a transition within a second. Due to design limitations and battery life we are unable to effectively draw 2A for long periods of time. We would also require a higher voltage to reach 2A in the 0.5mm which becomes more hazardous to the user if a shock would occur.

We shape the Nitinol into a spring and then wrap the spring around a cylinder to create its cylindrical compression. With multiple Nitinol stages up the foot and leg, we are able to create a pulsating pulse of compression that creates a pressure gradient in the direction up the leg. Thus we fulfil creating blood perfusion through the leg and meet the requirements [R 3.2.2.4 - POCT] and [R 3.2.2.7 - PROT]. Figure 10 illustrates the direction of consecutive spring compression and intended blood flow.

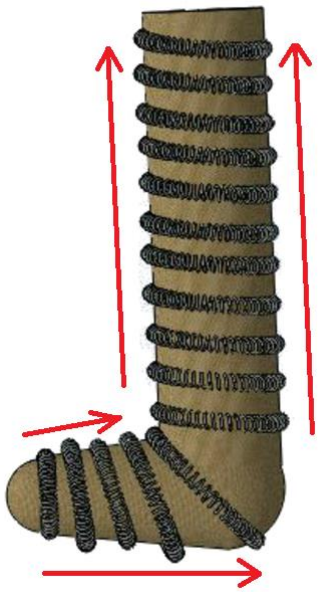

Figure 10: Domino Effect Spring Compression Causing Blood Flow

3.2.3 Outer Mesh Layer

The mesh chosen to protect the Nitinol wires and the user from harm is a nylon mesh used for multipurpose products that has great properties for our use in the outer layer of our prototype [3]. The mesh layer allows free airflow to the Nitinol springs with its 0.25in holes while being small enough to protect the user from the moving Nitinol which covers requirements [R 3.2.3.1 - POCT], [R 3.2.3.3 - PROT], and [R 3.2.3.7 - PROT]. Since the mesh will also be part of the zipper design to be easily removed and encompass the entire product we can fulfill [R 3.2.3.6 - PROT] and [R 3.2.3.5 - PROT].

The mesh fulfills the requirements [R 3.2.3.2 - POCT] and [R 3.2.3.4 - PROT] by being tightly knit nylon with a resin finish that gives it strength to protect the Nitinol springs from being tampered with and is light enough (127 grams per square meter) to not add any significant weight to the prototype.

We also have chosen nylon over polyester meshes due to the general higher flammability point and therefore melts before igniting [4].

For the final product, flame retardant fibers such as modacrylic should be a high priority to keep the users as safe as possible.

Figure 11 is a sample of the mesh used in the prototype design.

Figure 11: Outer Nylon Mesh Layer

3.3 Hardware Requirements

3.3.1 Timing Circuit

To increase the durability of the Nitinol wires, the voltage supplied to the Nitinol wires are pulse-width modulated with equal high and low voltage. Figure 12 shows the circuit for building an astable Pulse-Width Modulation circuit and Figure 13 shows the pin assignments on the NE555 integrated circuit chip.

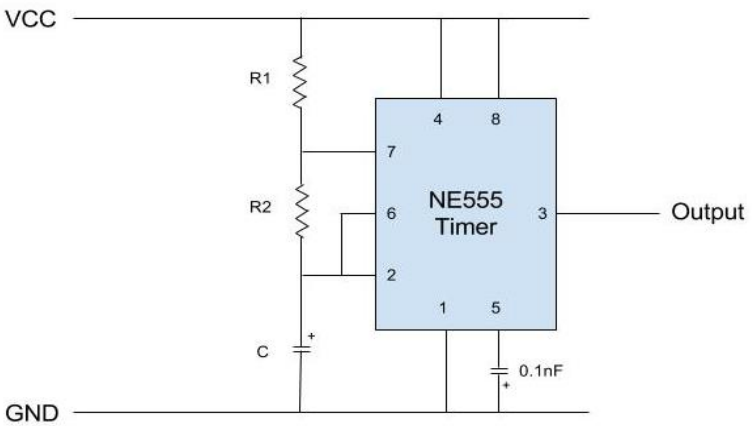

Figure 12: Pulse-Width Modulation Circuit

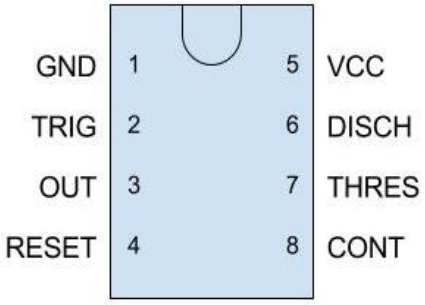

Figure 13: NE555 Timer Pin Assignments

The timing for the output of the timing circuit can be configured by adjusting the resistances and capacitance for R1, R2 and C1 as follows [5]:

$$(e1)\ Time\ High\ (T_h) = 0.693(R_1 + R_2)C_1$$
$$(e2)\ Time\ Low\ (T_l) = 0.693(R_2)C_1$$
$$(e3)\ Frequency = \frac{1.44}{(R_1 + 2R_2)C_1}$$
$$(e4)\ Duty\ Cycle\ Percentage = \frac{T_h}{T_h + T_l} \times 100$$

The chosen values for R1, R2 and C1 are shown in Table 2.

Component	Value
R_1	1000Ω
R_2	1,000,000Ω
C_1	1µF

Table 2: Pulse-Width Modulation Circuit Component Values

Applying equations e1 to e4, we get the following:

$$(e1)\ Time\ High\ (T_h) = 0.694sec$$
$$(e2)\ Time\ Low\ (T_l) = 0.693sec$$
$$(e3)\ Frequency = 0.721Hz$$
$$(e4)\ Duty\ Cycle\ Percentage = 50.025\%$$

The above configuration shall provide us with even and distributed heating of the Nitinol wire.

3.3.2 Current Distribution Circuit

The current distribution circuit is distributes current to the Nitinol wires if a signal is detected from the GPIO pins from the microcontroller. The current distribution circuit is shown in Figure 14.

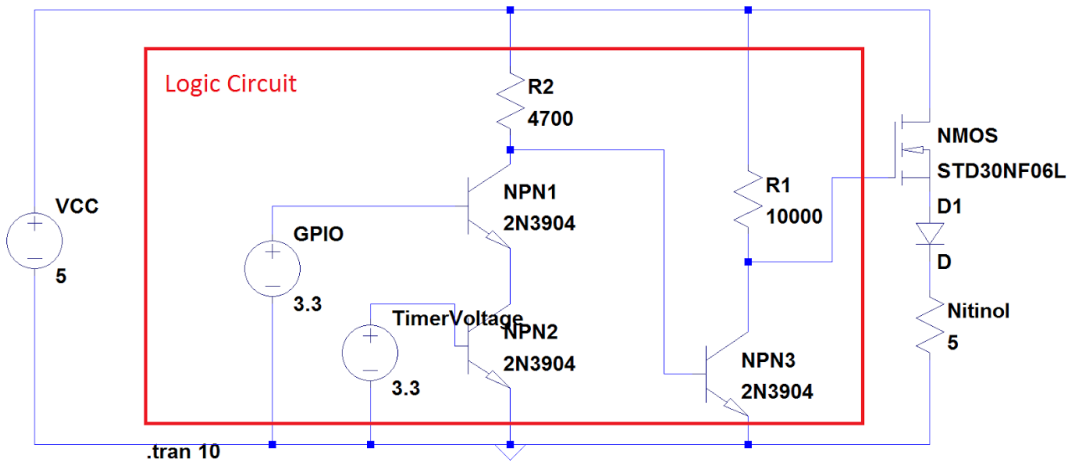

Figure 14: Logic Circuit Diagram

The circuit denoted in the red is used for circuit logic to control the NMOS component. The logic circuit acts as an AND gate between the GPIO and Timer Voltage. The NMOS component only activates when GPIO and Timer Voltage is high. Therefore, when GPIO voltage is low, the NMOS is deactivated. Current goes through the Nitinol wire when the NMOS component is activated, effectively heating the Nitinol wire up to its transition temperature.

Components R1 and R2 are chosen to be arbitrary resistors of high resistances to lower the current needed for the logic circuit to work. This will also help reduce heat generated by the circuit. An n-channel MOSFET transistor is chosen as opposed to a NPN BJT transistor because the MOSFET transistor allows for a higher current flow to the Nitinol wire when activated.

3.3.3 Overall Circuit

Figure 15 shows the combined circuit of the timing circuit and the current distribution circuit.

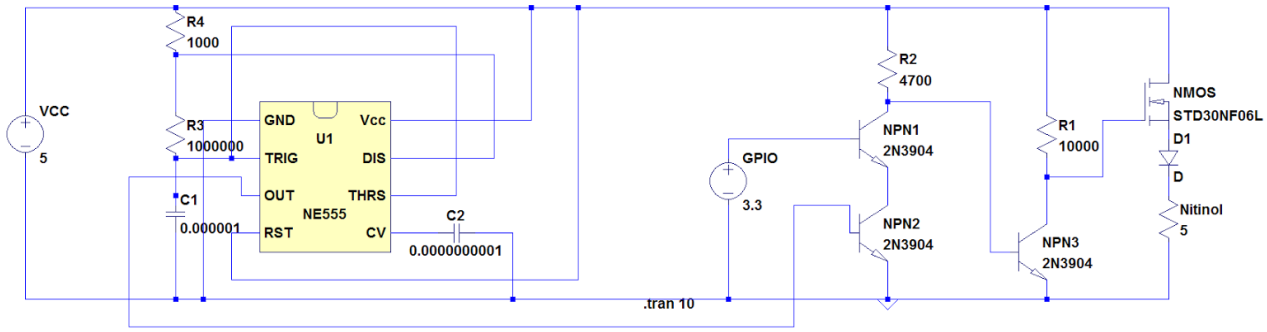

Figure 15: Complete Timing and Current Distribution Circuit

The current going through the Nitinol wire should be pulse-width modulated as designed. Figure 16 shows the results from the LT Spice simulation.

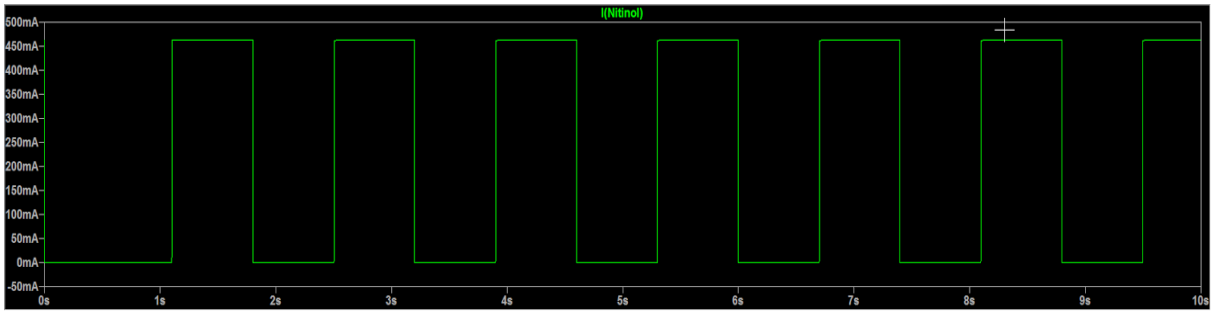

Figure 16: Current through Nitinol Wire

From Figure 16, we observe that the Nitinol wire is indeed being heated periodically. This method of heating the Nitinol wire prolongs the lifespan of the product.

3.3.4 I/O Requirements

The device should feature simple interfaces to toggle the device on and off. The switch selected as part of the design is the Model No. R13-66A from Jameco. The rocker switch of Sockulation can be found in Figure 17.

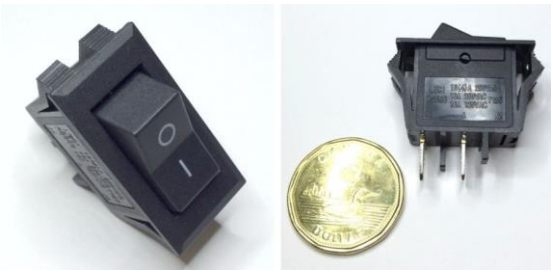

Figure 17: Rocker Switch R13-66A

The two pin rocker switch has the following specifications as shown in Table 3.

Switch Operation	On-Off
Maximum Operating Temperature	85°C
Minimum Operating Temperature	-20°C
Panel Cut Out Width	19.88mm
Brand	RS Pro
Contact Current Rating	16A @ 125V AC
Illuminated	No
Contact Configuration	Single-Pole, Single-Throw
Contact Resistance	50mΩ

Table 3: Rocker Switch R13-66A Specification [6]

As seen from the specification sheet from Table 3, the switch is able to handle up to 125Vx16A = 2000W of power. Since Sockulation would be powered at 5V and at a maximum current of 2A, the power source would only be able to produce 10W of power. Hence, the switch should handle the power requirement with ease.

3.3.5 Microcontroller Requirements

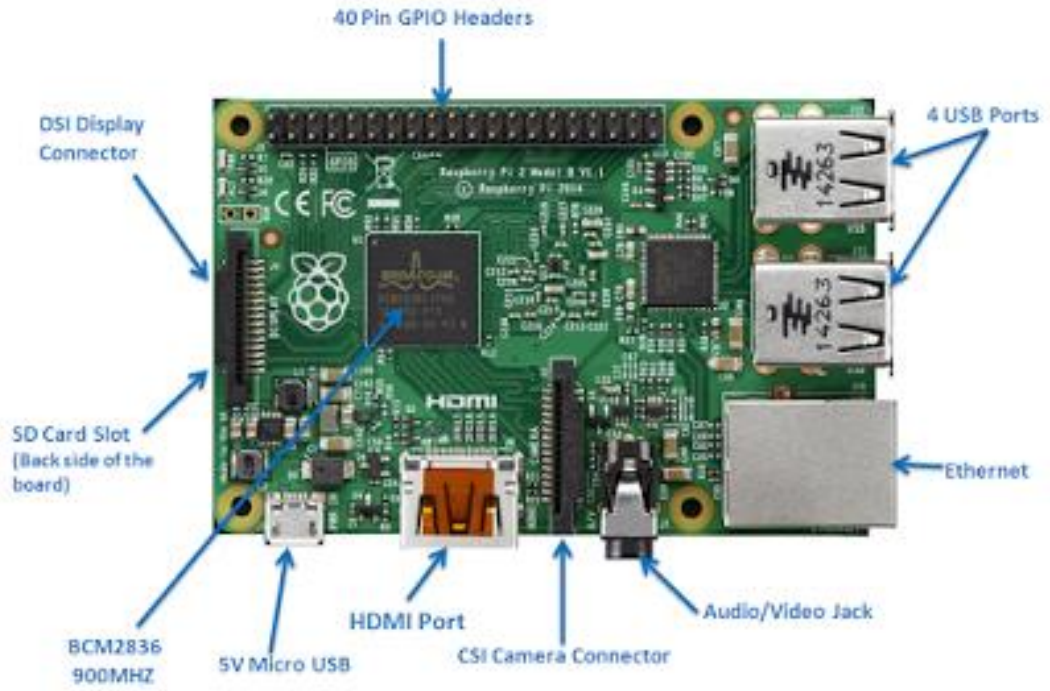

Figure 18: Raspberry Pi 2 Model B Components [7]

Figure 18 shows the overview of the microcontroller with its components defined. The microcontroller selected to control the heating of the Nitinol wires is the Raspberry Pi 2 Model B. The specification sheet for the Raspberry Pi 2 Model B can be seen in Table 4.

Raspberry Pi 2 Model B	
Chip	Broadcom BCM2836 SoC
Core Architecture	Quad-core ARM Cortex-A7
CPU	900MHz
GPU	Dual Core VideoCore IV Multimedia Co-Processor
Memory	1GB LPDDR2
Power	Micro USB socket 5V, 2A
USB	4 x USB 2.0 Connector
GPIO Connector	40 pin 2.54 mm (100 mil) expansion header: 2x20 strip Providing 27 GPIO pins as well as +3.3V, +5V and GND supply lines
Memory Card Slot	Micro SDIO

Table 4: Raspberry Pi Model B Specification [8]

As seen in Table 4, the Raspberry Pi 2 Model B allows Sockulation to include up to 27 sections of Nitinol wires to provide a more gradual pumping action.

3.3.6 Nitinol Heating

Figure 19 shows the part of the circuit with the Nitinol will be heated.

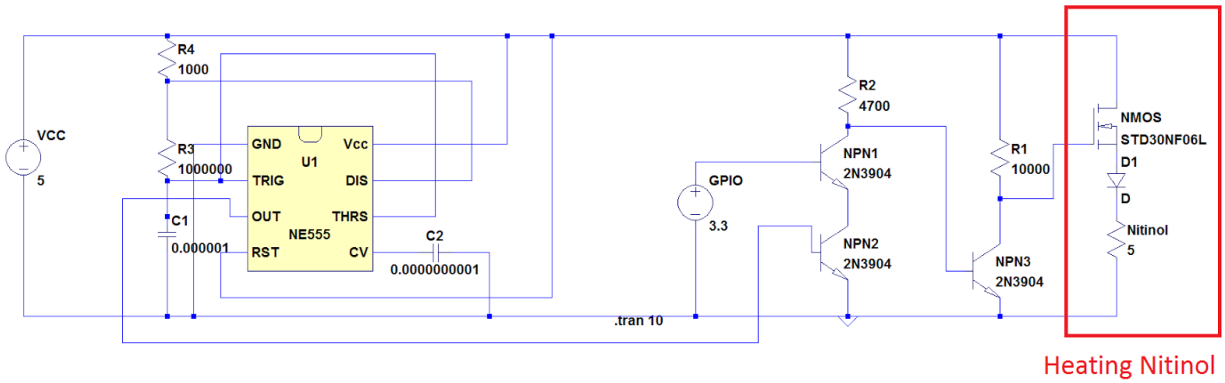

Figure 19: Complete Sockulation Circuit Diagram with Nitinol Heating

In order to heat the Nitinol to its transition temperature, enough current will have to be supplied to the wires. Upon multiple lab tests, it was determined that the Nitinol should be supplied a current of 0.8A-1.0A for effective heating. Therefore, the voltage drop across the

Nitinol wire should be 5V, since a Nitinol wire with length of 5ft has resistance of approximately 5Ω.

3.3.7 External Battery Pack

Sockulation will be powered by an external battery with a charge capacity of 10000mAh. Sockulation will be using an outsourced external battery pack from Anker, the PowerCore 10000. The battery pack will be removable and can be recharged at the user's convenience. Figure 20 shows the 10000mAh Anker battery pack.

Figure 20: Product Image of Anker PowerCore 10000 [9]

The specifications for PowerCore 10000 can be found in Table 5.

PowerCore 10000	
Weight	180g
Size	90x60x22 mm
Output	5V 2.4A
Input	5V 2A
Capacity	10000mAh

Table 5: Anker PowerCore 10000 Specification [9]

Following the specification found on Table 5, the external battery should suffice to supply enough current for the circuit. Each section of Nitinol wire would require a 0.8-1.0A current draw and the Anker PowerCore 10000 is able to supply up to 2.4A. Therefore, the external battery should be able to supply current to two different sections of Nitinol wire at any one time with ease.

3.4 Safety Design

In order to ensure that Sockulation is flawless and reliable in its function and safety of the user, several applications will be enforced. The temperature of the Nitinol wire will not exceed 45℃ to protect the user from experiencing uncomfortable heat. To prevent heat from being confined around the leg, a thin, breathable mesh cover will be encased around the Nitinol to allow heat to escape. In addition to heat safety, the mesh cover will help prevent the user from interacting with the components underneath. The device must not compress the leg to a point where the user experiences pain. To meet this concern, a threshold of 20mmHg will be met. All electrical connections will be contained to prevent unwanted handling, and all wiring will be grounded. The parts that make up Sockulation will be clear of toxic and hazardous material so that no harm will come to the user. Finally, all components of the device must not have sharp points or edges.

4.0 Conclusion

The intended purpose of Sockulation, a device that boosts ample blood flow in the leg and foot, is to provide a solution for people with inadequate blood flow that may lead to serious diseases if unattended to. Sockulation is meant to be used in environments where long durations of sitting occur, such as in airplanes and automobiles.

The system design of the device has three main requirements it must satisfy: physical, hardware, and safety. These proposed design features are based around the requirement specifications document and represent the elements that make up the prototype device. The physical design of Sockulation is centered on three layers: inner sock layer, middle Nitinol layer, and outer mesh layer. Their purpose is to contain all the necessary components and allow the user to wear the device. This function will be achieved with the implementation of a zipper to allow the foot to easily slip in and out. The hardware design will explain how the device is powered and controlled by meeting the requirements previously mentioned. As for the safety design, it is modelled around the physical and hardware designs but emphasizes on the specific safety concerns of the device.

To confirm the validity of the mentioned functions, a test plan in Appendix A has been prepared to show evidence of Sockulation's correct performance.

5.0 Appendix A: Test Plan

This appendix will outline a test plan for Sockulation to ensure the final product does not harm the user and functions correctly as outlined in the requirement specifications. It will focus on the hardware system and the main three layers of the physical system: the inner sock layer, the Nitinol layer and the outer mesh layer.

The tests are divided into several separate sections so that they can be executed in coordination with each other.

5.1 Physical System Testing

Test #	Item Tested	Expected Results	Outcome
	Overall System		
1.	Wearing Sockulation Steps: 1. Unzip the top of the product. 2. Put on Sockulation as simply as possible.	Sockulation can be put on without assistance. Sockulation fits comfortably around the foot and leg without being too tight or too loose. Not much adjusting is necessary to feel comfortable.	
	Comments:		
	Reviewed By:	Test Date:	
2.	Walking with Sockulation Steps: 1. Wear and activate the product in a sitting position. 2. Stand up and walk a short distance away, then come back to the sitting position.	The Sockulation device functions correctly at all times and does not stop the user from moving. The Nitinol springs should not be damaged in any way after the test.	
	Comments:		

	Reviewed By:		Test Date:
3.	<u>Therapeutic Functionality</u> Steps: 1. The user wears and activates Sockulation in a situation where blood would pool in their legs for 5 minutes. 2. After powering down the device take note of the effects without the device on.	When Sockulation is active it should assist the blood to flow up the legs. Any part of the leg or foot should not go numb or feel prickly due to insufficient blood flow. The foot should feel noticeably less swollen. When the device is off the leg should feel more swollen with less blood flow circulation.	
	Comments:		
	Reviewed By:		Test Date:
	Inner Sock Layer		
4.	<u>Compression of Nitinol Springs on the Inner Sock Layer</u> Steps: 1. Wear the device in a sitting position. 2. Turn the device on.	The inner sock layer withstands the compressing and the sewn attachments stay firmly fastened on. The user also does not feel any pinching from the wires, and only feels even pressure along the foot and lower leg.	
	Comments:		
	Reviewed By:		Test Date:
5.	<u>Heat Transfer to the Inner Sock Layer</u> Steps: 1. Without wearing the device, turn the device on. 2. Leave Sockulation running for 30 minutes. 3. Check the internal temperature of the	The internal temperature of the device should be lower than 30°C. There should no hot spots forming within any part of the inner sock layer that could transfer to the user.	

	device with a thermometer and check with a hand for any hot spots.		
	Comments:		
	Reviewed By:	Test Date:	
	Nitinol Layer		
6.	<u>Functionality of Nitinol Spring</u> Steps: 1. Wear the device in a sitting position. 2. Turn the device on.	When the Nitinol is compressing it should be firmly attached to the sock and stays in the same location throughout the function. It also compresses evenly around the limb, without causing pain to the user.	
	Comments:		
	Reviewed By:	Test Date:	
7.	<u>Stress Testing Nitinol Spring Functionality</u> Steps: 1. Without wearing the device, turn the device on. 2. Leave Sockulation running for 30 minutes.	The distance the Nitinol compresses and contracts is the same in every cycle. The pulsation of the Nitinol should look the same at the start and end of the test in terms of frequency.	
	Comments:		
	Reviewed By:	Test Date:	
	Outer Mesh Layer		
8.	<u>Heat Capacity of Mesh Layer</u> Steps: 1. Turn the device on for 10 minutes.	The mesh layer should not feel hot at any point. The layer should be wicking the heat away from the wires and allow adequate airflow to cool down.	

	2. Turn off the device and touch different spots of the mesh layer.		
	Comments:		
	Reviewed By:	Test Date:	
9.	<u>Integrity of the Protective Mesh Layer</u> Steps: 1. With the device powered off, check the integrity of the mesh layer. 2. With the device on, only look at the mesh layer and see that it maintain its integrity.	You should not be able to put a finger through the mesh layer at any point of Sockulation when it is powered off. When it is powered on, the mesh layer should not be pinched anywhere.	
	Comments:		
	Reviewed By:	Test Date:	

Table 6: Physical Test Cases

5.2 Hardware Testing

Test #	Item Tested	Expected Results	Outcome
1.	<u>Nitinol Current GPIO Switch</u> Steps: 1. Set up all circuit and microcontrollers as per design. 2. Using a Linux machine, connect to microcontroller via SSH. 3. Run Python Script to output from each GPIO.	Each GPIO Pins connected to a section of Nitinol should enable current through the Nitinol wire, effectively heating the wire.	
	Comments:		
	Reviewed By:	Test Date:	

2.	<u>Pulse-Width Modulated Voltage Testing</u> Steps: 1. Set up the circuit, microcontroller, device and power them on. 2. Using a multimeter, measure the output voltage from the timer circuit.	The timer circuit voltage should switch from high to low (on and off) periodically.	
	Comments:		
	Reviewed By:	Test Date:	
3.	<u>GPIO Output Voltage Testing</u> Steps: 1. Set up the circuit, microcontroller, device and power them on. 2. Using a multimeter, measure the output voltage from the microcontroller's GPIO pin	The microcontroller GPIO outputs the expected voltage of 3.3V.	
	Comments:		
	Reviewed By:	Test Date:	
4.	<u>Current Through Nitinol</u> Steps: 1. Set up the circuit, microcontroller, device and power them on. 2. Using a multimeter, measure the current running through the Nitinol wire.	The current through the Nitinol wire is within the threshold of 0.8-1.0A.	
	Comments:		
	Reviewed By:	Test Date:	
5.	<u>Power Switch Testing</u> Steps: 1. Initially have the switch off.	The device should power on when the switch is on, and power off when the	

	2. Turn the switch to the ON position.	switch is off. This will be indicated by an LED.	
	Comments:		
	Reviewed By:	Test Date:	

Table 7: Hardware Test Cases

5.3 Safety Testing

Test #	Item Tested	Expected Results	Outcome
1.	<u>Macro Shock Testing</u> Steps: 1. Connect a 500Ω resistor and an amp meter in series with a Nitinol spring. 2. Turn the device on and wait until the spring is compressed. 3. Measure the current flow when the spring is compressing. 4. Check each Nitinol spring.	The expected current should never go above 10mA, otherwise macro shock may occur to the user. If this happens the device has a failed grounding and must be sent to production for a fix.	
	Comments:		
	Reviewed By:	Test Date:	
2.	<u>Max Pressure Testing</u> Steps: 1. Place a pressure cuff inside Sockulation and inflate until it touches the wall of the inner layer. 2. Take note of the initial pressure. 3. Turn the device on. 4. Write down the maximum pressure exerted by Sockulation.	The pressure difference between the final and initial points should not exceed 20mmHg.	
	Comments:		
	Reviewed By:	Test Date:	

3.	<u>Stress Testing</u> Steps: 1. After completing tests 5.3.1 and 5.3.2 turn the device on for an hour. 2. Redo Tests 5.3.1 and 5.3.2 after the hour of stressing the device.	After the hour of stress testing, the expected results of the aforementioned tests should be confirmed.	
	Comments:		
	Reviewed By:	Test Date:	

Table 8: Safety Test Cases

6.0 Appendix B: User Interface Design

6.1 Introduction

Having a practical device that is capable of useful functions but is difficult to use is not a good way to gain the trust of potential users. That is why the user interface (UI) design is a critical feature of any engineering model. To meet the requirements of the average user of Sockulation, the device must be clear and simple in its appearance and objective while still meeting its functional requirements.

6.1.1 Purpose

This document will specify and determine the different aspects of UI design for the prototype version of Sockulation, and will analyze the user.

6.1.2 Scope

This section of the document will cover the seven fundamental principles of design as outlined by Don Norman in his book, *The Design of Everyday Things*: discoverability, feedback, conceptual model, affordances, signifiers, mappings, and constraints [10]. It will also contain engineering and safety standards that are universally accepted, as well as usability testing to demonstrate the validation and verification of Sockulation.

6.2 User Analysis

As a medical device that is capable of relieving swelling and pain in the leg and foot, Sockulation is mainly targeted towards elderly users. In order for correct interaction and utilization to occur, the device must be designed as simple as possible. To achieve this, Sockulation will be in the shape of a sock, an everyday product that everyone has seen and worn before. Since it may be difficult to put on a tight sock without scrunching it up, a zipper will be sewn to the sock in a vertical fashion that ends half way down the calf. This feature will ensure ease of wear-ability for the user. On the side, there will be a simple switch to power the device on and off. The function of the switch will clearly be indicated with the universal power symbols. When the device is powered on, an LED will blink to signal to the user that it is connected and ready to run.

6.3 Graphical Representation

Figure 21 and Figure 22 are hand drawn representations of the prototype for Sockulation. Figure 21 reveals the inside Nitinol layer with the hot and ground wires placed along both sides of the zipper and down to the toes and covered with a protective material.

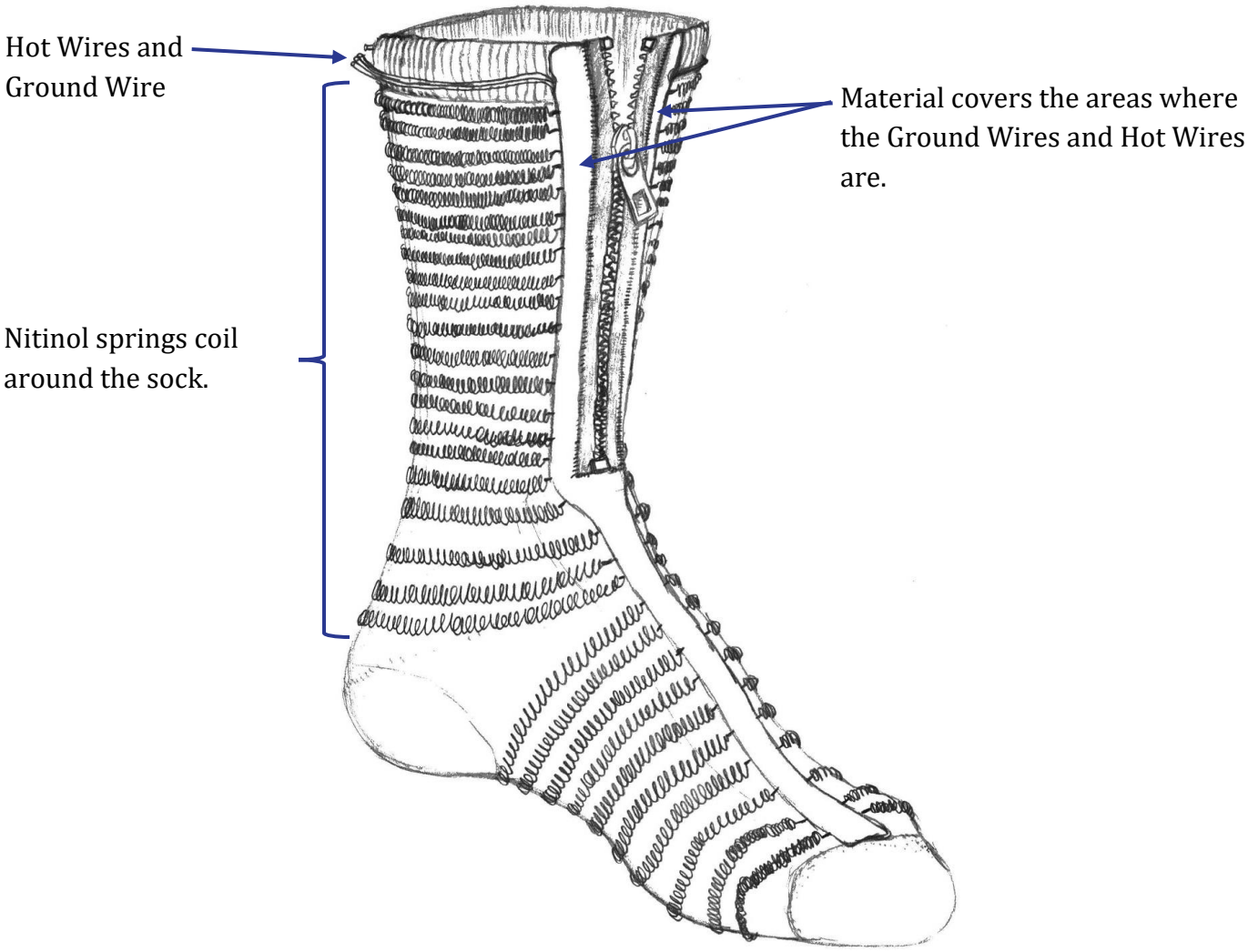

Figure 21: Inside View of Sockulation

In Figure 22, the box containing the device's hardware is attached to the upper side of the sock. The wires exiting the box continue in Figure 21 to be connected to the Nitinol wires. The outside of Sockulation is covered in a light mesh material to help cool the wires down when functioning.

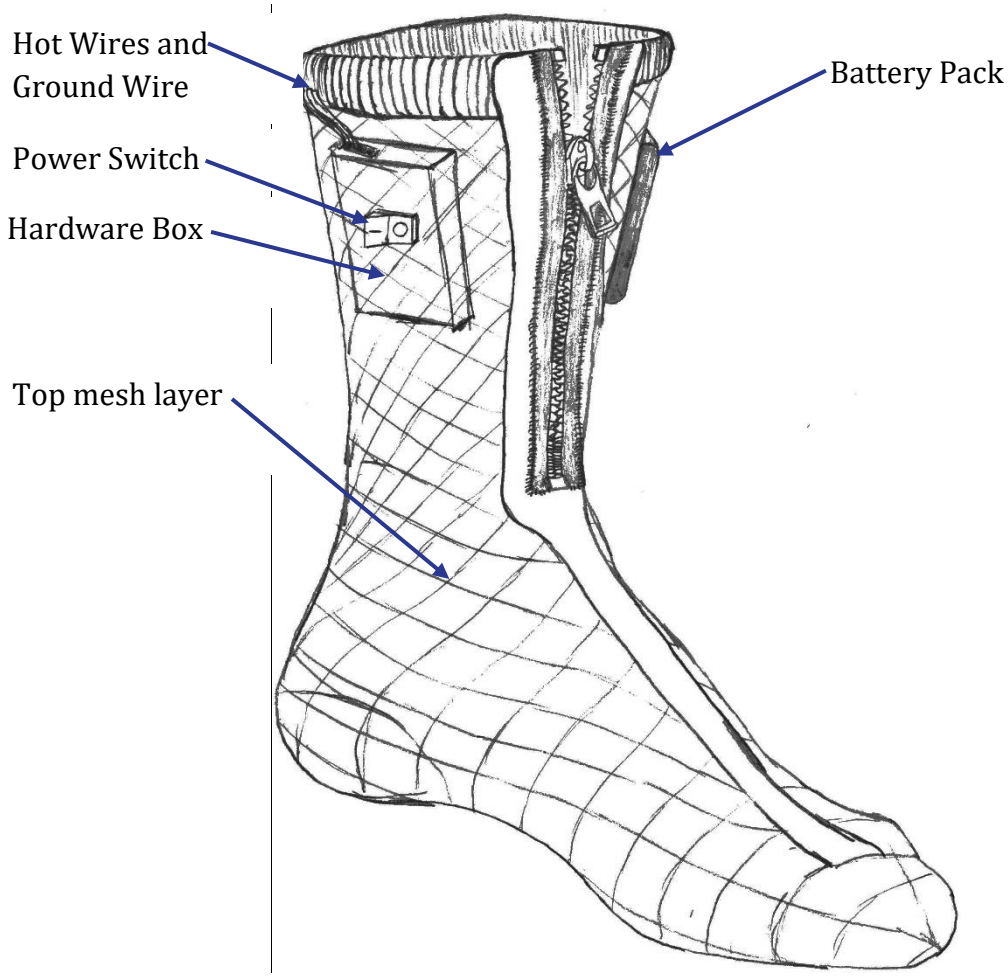

Figure 22: Outside View of Sockulation

6.4 Technical Analysis

The seven fundamental principles of design as defined by Don Norman [10] are needed to achieve a successful model and meet the goals of the users. Each of these principles were taken into account for our UI design and the next section will go into more detail on how each principle was enforced.

6.4.1 Discoverability

Discoverability is the ability of a piece of information to be found. In the case of our prototype and especially in our final product, it is the ability for the user to understand what the device does and how to use it. By making our product with discoverability in mind, we reduce the chance of accidental misuse and increase its accessibility. Using the

product as intended will maximize the effectiveness of our therapeutic medical device to the user. Understanding the discoverability of our design will help users find and focus on the tasks we want them perform.

The tasks that we want the user to perform in order are:

1. Unzip Sockulation for easier access.
2. Put on Sockulation until it fits comfortably.
3. Get into a sitting position.
4. Turn the device on.

The ways we help this information be conveyed is by:

1. Zipper is easily accessible and identifiable.
2. Sock shape and soft inner layer.
3. Nitinol springs show compressive and therapeutic function.
4. Control box with power switch.

6.4.2 Feedback

Feedback is a critical element of UI design as it can continuously provide information on the state of the device. Through this, it is possible to for the user to be notified of any changes to the device so they can carry out the next action. Factors that RippleRelief Medical have considered for Sockulation include the following:

- An LED will be turned on when Sockulation is turned on and the Nitinol wire starts compressing.
- When the power switch is powered on and the LED light turns on, the movement of the Nitinol wires will indicate to the user that the device is currently working.
- When the power switch is powered off, the LED will turn off and the movement of the Nitinol wires will cease to indicate the device is power off.

6.4.3 Conceptual Models

Similar to discoverability, a conceptual model makes it possible for the user to recognize what the device does. Additionally, it must be able to allow the user to understand and feel in control of the system. For example, the design of Sockulation was done to look similar to a sock in terms of usability and appearance. Since it is universally known to everyone what a sock is and how it works, a conceptual model can be easily built in the user's mind.

In our product we focused on three main components to create the conceptual models in our user's mind.

1. **Sock Shape** - By keeping the design of our product looking similar to a common piece of clothing we help the user understand that our device is meant to be worn. If we were to stray away from this design and into something that looks like a boot, then other unnecessary information would be conveyed to the user. For example that the device is heavy and hard to move in.
2. **Nitinol spring** - In our design the exposed Nitinol spring helps the user discover the functionality of the product. Coiled springs around the sock show the compression action to the user. As well, the mesh covering these springs helps the user understand that the compression springs should not be tampered with.
3. **Control box** - The controller box has all wire components coming to and from itself and shows the user where the brains of the product is. All control and power functions should be recognized by the user. In this case, the switch indicates how to operate the device and either a batter cover or a cord will show how the device will be powered.

6.4.4 Affordances

Affordances are aspects that make it possible for specific actions to be accomplished. It describes the relationship between the abilities of the user and the object that is being interacted with. For Sockulation, the zipper affords the user to put on the device easily. The batteries and battery pack afford the device to power on by directing the user to place them inside.

6.4.5 Signifiers

The signifiers in Sockulation are used to help the user understand how to operate the device. By using signifiers effectively, a stronger message of discoverability and feedback can be relayed to the user. The power switch will have the on and off symbols displayed to make it clear that the switch will turn the device on and off. An LED will light up when Sockulation is powered on to let the user know when the device is on, and will turn off accordingly when the device is off.

6.4.6 Mappings

Mappings allow the users to visually see the relationship between the controls they can use and the actions that follow. To realize this for Sockulation, the power switch will clearly be displayed by the side of the device near the top, minimizing the distance between the user and the control.

6.4.7 Constraints

Since potential misuse of the device may cause unwanted outcomes and safety hazards, constraints will be applied to Sockulation. These physical, logical, semantic, and cultural constraints will guide users on the correct path and help them easily understand the function of the device.

The biggest, clearest, physical constraint that Sockulation has is its obvious shape and structure. With its distinct sock appearance and small opening at the top, it should be clear that the device is meant to be worn on the foot. This will ensure that the device will not be wrongly worn on other parts of the body, such as the arm or head.

Other constraints includes the control box, which only allows the user to press the power switch (logical constraint) and the user is physically blocked from tampering with the electrical components of the device. The way to power the device would be constrained by the power cord plug or the specific battery used in the control box.

6.5 Engineering and Safety Standards

6.5.1 Engineering Standards

Engineering Standards	Description
ISO 9241-161: 2016 Ergonomics of human-system interaction -- Part 1: Guidance on visual user-interface elements [11]	This standard contains a list of generic visual user-interface elements and gives recommendations on the selection and usage of UI designs and their applications. It also allows for designs to change and evolve. Sockulation will follow the guidelines of this standard to implement human-centered designs and allow leniency for the development of particular features.

ISO/IEC 13251:2004 Collection of graphical symbols for office equipment [12]	This standard provides a set of graphical symbols that are universally used on office equipment. Sockulation will comply with this standard to appropriately display the power symbols on the power switch to indicate its function.
ISO/IEC TR 19765:2007 Information Technology -- Survey of icons and symbols that provide access to functions and facilities to improve the use of information technology products by the elderly and persons with disabilities [13]	As the majority of the targeted users, the elderly may have trouble understanding what certain icons and symbols mean. This standard plans to improve that problem by presenting a set of icons that are currently being used to allow the elderly and disabled to familiar themselves with information technology equipment. By contributing feedback of the interaction between the elderly and the symbols, this can help form the basis for an international standard.

Table 9: Engineering Standards

6.5.2 Safety Standards

Engineering Standards	Description
ISO 13849-1:2012 Safety of machinery -- Safety-related parts of control systems -- Part 1: General principles for design [14]	This standard determines the safety requirements for the design and integration of safety-related parts of the system, including software design. Sockulation will meet the guidelines for achieving the principles of safety functions in this standard.
ISO 13849-2:2012 Safety of machinery -- Safety-related parts of control systems -- Part 2:Validation [15]	This standard defines the procedures that the testing, analysis, and validation steps must go through in order to be approved. It includes the category achieved and the performance level achieved by the safety-related parts of a system. The section on testing in this document will cover the conditions of the testing Sockulation will go through.

Table 10: Safety Standards

6.6 Analytical Usability Testing

Analytical usability testing will be undertaken by the designers at RippleRelief Medical during the development of Sockulation and after the completion, to guarantee the validity of the usability of the device.

6.6.1 Cognitive Walkthrough

The cognitive walkthrough is when the designers evaluate the prototype from the perspective of a user. Below are the tasks the user will carry out to use Sockulation correctly.

1. Unzip the zipper and slide foot into the device.
2. Make sure foot is comfortable, and zip up the zipper.
3. Press the power switch to turn on the device.
4. Verify that the device is compressing and contracting and creating a nice pressure around the limb.
5. Use for any length of time necessary, or while battery is charged.
6. After use, turn off device by pressing the power switch again.
7. Unzip and remove device from foot.
8. Charge batteries if the battery pack indicates low battery.

6.6.2 Heuristic Evaluation

Heuristic evaluation is used to uncover usability problems in the user interface design of Sockulation. Designers evaluate by going through this process several times and conferring with each other at the end of the evaluation.

1. The device looks like a sock and is easy to slide onto the lower leg and foot.
2. The inside and outside of Sockulation is a comfortable and pliable material which is easy to handle.
3. The system turns on or off within a few seconds of pressing the power switch.

6.7 Empirical Usability Testing

During the development stages of Sockulation, empirical usability testing will occur to assist designers on improving the product for the users.

6.7.1 Personal Testing

RippleRelief Medical will be doing testing on a member of the team, Michael Jurewicz, during the development to gain feedback and to observe the results of Sockulation. This will be a key component in adjusting the design of each layer of Sockulation. The main focus during the testing of the prototype is the ability of the Nitinol to compress and

contract around the limb with enough pressure without hurting the user. While Michael wears the device, he will report if the temperature surrounding his limb is at a comfortable level when the device is both powered on and off. Since Michael will be the initial test subject, the prototype of Sockulation will be fitted to his lower leg and foot. This will result in poor feedback for size and fit of Sockulation for other users. Therefore it is necessary to test the device on various people, such as the SFU engineering student population, to get a wider range of feedback.

6.7.2 Expert Analysis and Laboratory Testing

One of the most valuable assets is an expert perspective on our products functionality and design. Extended experience and knowledge on the medical devices and technology can give our product more thorough feedback where we or other non-technical users could not imagine. More technical information like electrical safety and medical effectiveness would allow us to further redesign our product and increase its probability of success in moving forward into the market.

In our case we have contacted Andrew Blaber to be involved with our endeavour. He works at Simon Fraser University in the Aerospace Physiology Laboratory and works with modeling cerebral blood flow regulation under various environmental conditions. Our plan is to clearly communicate our goals with our product, Sockulation, and to demonstrate the proof of concept to Andrew Blaber. In turn we hope that a discussion can be made about the future of our final product design and help in discovering its weaknesses. With his support, more detailed empirical testing regarding blood flow could be planned after an initial design discussion. With laboratory testing we may obtain more evidence of medical therapeutic effectiveness in our product.

6.7.3 End User Testing

A more time consuming and important part of design feedback is conducting a hands on survey with users who have little to no technical background and are part of our market population. This helps immensely in accessing the success of our seven design aspects of user interface that we have involved into our product designed. For our medically therapeutic device, choosing survey applicants in our market demographic will help understand their needs and expectations in our product.

Users would be giving feedback through a questionnaire while being allowed to try on and use the product. Some of the important feedback we would want from our end users include:

- What were your first impressions of the device?
- Is the design aesthetically appealing to you?
- Do you understand what the product is used for?
- After getting to touch and try on the product, have you discovered anything new?
- How hard was the device to put on your leg and is it comfortable for you?
- After putting the device on and activating it, how would you describe the compression of the device on your foot?
- Does the device provide a massaging feeling to your leg?
- Do you feel your leg is less swollen and more blood is circulating?
- When would you most likely wear this device?

These surveys could be altered to focus on any weaknesses we find in our product and help for each stage of our product development from the prototype to the final product.

6.8 Conclusion

The User Interface is an important factor for the design of Sockulation. It assists RippleRelief Medical in making the simplest functioning design of Sockulation, and letting the user quickly and easily learn how to use the device. Each detail of the design considers the seven elements of user interface interaction as well as following the engineering and safety standards. Testing the device for users and designers are necessary for safety and functionality, as well as it being a practical way to assist in improving the design.

This user interface focuses mainly on functionality and ease of use for the prototype of Sockulation. The future design stages will improve on the functionality as well as making the design look attractive to the eye, resulting in a desirable solution to prevent blood from pooling in the legs and feet.

7.0 Glossary

Astable Pulse Width Modulation - Continuous oscillation of signals with no start or end point.
BJT (Bipolar Junction Transistor) - Semiconductor device with three doped Semiconductor Regions.
Chronic Venous Insufficiency - Condition where the valves in the legs are not working and blood cannot flow effectively.
Duty Cycle Percentage - Percentage of oscillating signal in its "high" state in a single cycle.
GPIO (General Purpose Input/Output) - Generic pin on the microcontroller whose behaviour can be controlled by the microcontroller at run time.
LT Spice - Freeware program used to simulate circuit.
Microcontroller - A small computer designed to execute simple code with GPIO pins.
MOSFET (Metal-Oxide-Semiconductor Field-Effect Transistor) - Four-channel semiconductor used for switching and amplifying devices.
NE555 Timer - An integrated circuit used as timers for circuit construction.
Nitinol - A metal alloy made from nickel and titanium with shape memory properties.
NMOS - N-channel MOSFET to implement logic gates.
NPN - A type of BJT that consists of a layer of P-type semiconductor between two N-doped layers.
Prototype - Preliminary model of a product, typically designed in iterations before deciding on the final design.
Pulse-Width Modulation - A technique in circuit construction to oscillate digital signals.
Raspberry Pi 2 - A small single board controller that will be used as the microcontroller.
SoC (System on Chip) - Integrated device that combines all components of a computer.
SSH (Secure Shell) - A network protocol used to remote control a device securely.
Transition Temperature - Temperature in which the Nitinol wire returns to its un-deformed state.

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3.1 General Requirements

[R 3.1.1 - POCT]	The product will reduce blood volume and create blood flow in the intended limb segment.
[R 3.1.2 - PROT]	The product will enclose the entire foot and up to the middle of the calf muscle.
[R 3.1.3 - PROT]	The product will be intended to be used indoors or any outdoor dry weather conditions.
[R 3.1.4 - PROT]	The product will remain operational in temperatures up to 30℃ without decrease in performance.
[R 3.1.5 - PROT]	The product will be able to operate for no less than 1 hour at a time.
[R 3.1.6 - PROT]	The product will be able to fit various sizes of feet.
[R 3.1.7 - PROT]	The circuit hardware will be strapped to the top length of the product near the middle of the user's calf muscle.
[R 3.1.8 - PROD]	The user will be able to put on the product and operate it with ease
[R 3.1.9 - PROD]	The operation of the device will be therapeutic to the user.
[R 3.1.10 - PROD]	The product will reduce the symptoms and signs of Chronic Venous Insufficiency.
[R 3.1.11 - PROD]	The user's movement will not be impeded drastically by the weight and size of the product.

3.2 Physical and Operational Requirements

3.2.1 Inner Sock Layer

[R 3.2.1.1 - POCT]	The sock material will allow other materials to be sewn upon it by being strong and impermeable.
[R 3.2.1.2 - POCT]	The material will be stiff enough to reduce the movement of the Nitinol and anchor the Nitinol along specific limb segments, but flexible enough to allow the user to move their foot.
[R 3.2.1.3 - PROT]	The sock will not exceed a maximum pressure at the ankle of 20mmHg.
[R 3.2.1.4 - PROT]	The sock will not exceed 3mm of thickness to reduce trapped heat.
[R 3.2.1.5 - PROT]	The material will be breathable to allow heat to dissipate from the operation of the Nitinol wire.
[R 3.2.1.6 - PROT]	The inner layer will provide even pressure around the limb throughout the length of the product.
[R 3.2.1.7 - PROD]	The sock material will be comfortable to wear for extended periods of time during the system’s operation.

3.2.2 Nitinol Spring

[R 3.2.2.1 - POCT] The Nitinol will be trained to compress into a spring that is coiled around a cylinder of a diameter no more than 5 inches.

[R 3.2.2.2 - POCT] When the Nitinol wire is contracting it will create even pressure around the limb segment.

[R 3.2.2.3 - POCT] Maximum compression of Nitinol wire will not cause harm to the user.

[R 3.2.2.4 - POCT] Compression of the Nitinol wire will cause blood perfusion through the veins of the limb segment.

[R 3.2.2.5 - PROT] The operation of the whole Nitinol system will keep the leg relatively cool.

[R 3.2.2.6 - PROT] The system will not pinch the user's skin during operation.

[R 3.2.2.7 - PROT] The Nitinol spring will create more pressure at the foot than the calf of the leg to respect the blood flow of the cardiovascular system.

[R 3.2.2.8 - PROT] The system's operation will continuously pulse pressure from the palm of the foot towards the calf muscle of the leg.

[R 3.2.2.9 - PROD] The Nitinol spring will be able to relax compression within 1 second of contraction.

[R 3.2.2.10 - PROD] The Nitinol wire will not exceed an operational compression pressure of 20mmHg.

3.2.3 Outer Mesh Layer

[R 3.2.3.1 - POCT] The mesh layer will allow free airflow to the Nitinol springs.

[R 3.2.3.2 - POCT] The mesh will be strong enough to protect the wires and electronics of the system.

[R 3.2.3.3 - PROT] The mesh will absorb minimal heat from the Nitinol.

[R 3.2.3.4 - PROT] The mesh material will be made of light material to limit the weight of the product and to reduce heat absorption.

[R 3.2.3.5 - PROT] The mesh layer will encompass the entire operational part of the Nitinol wires.

[R 3.2.3.6 - PROT] The mesh will be clipped on so that it is easily removable for repairs or changes.

[R 3.2.3.7 - PROT] The mesh will stop the user from touching the Nitinol operation or the wires.

[R 3.2.3.8 - PROD] The mesh will be flexible to allow free movement of the user's leg.