

BE 4960 Senior Design Final Report - StepAhead
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May 5th, 2023

Abstract

Diabetic Peripheral Neuropathy (DPN) results from damage to the peripheral nervous system due to reduced circulation in diabetic patients. This causes immense pain in the extremities and increases risk of gangrene from benign injury, which leads to amputation. In 2022, 130,000 amputations¹ were performed as a result of DPN in the US. Early intervention significantly improves outcomes for DPN patients, reducing risk of amputation up to 75%². Currently, there is no at-home device that integrates novel nerve regeneration and pain reduction therapies while offering monitoring of infection and considers elderly, low-resource populations experiencing DPN symptoms. StepAhead addresses this need as an easily accessible, portable therapeutic and monitoring device that combines leading DPN therapies, infrared light (IR) and transcutaneous electrical nerve stimulation (TENS), with two infection monitoring methods, temperature and blood oxygen. By meeting standards set in literature, StepAhead allows patients to access at-home pain treatment while increasing their ability to receive effective footcare before serious infection develops. The physical device consists of an ergonomic, 3D-printed casing and a comfortable, sterile rubber insole to incorporate all electronics in one place. It is controlled via a connected remote with an LCD screen. An abnormal temperature or oxygen saturation level will prompt the user to contact a healthcare provider.

¹ Verrone Quilici, M.T., de Sa Del Fiol, F., Franzin Vieira, A.E., Toledo, M.A., Risk Factors for Foot Amputation in Patients Hospitalized for Diabetic Foot Infection. *J Diabetes Research*; 2016,

² Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050. *Archives of Physical Medicine and Rehabilitation* 2008;89(3):422-9.

Background / Introduction

Diabetic peripheral neuropathy (DPN) is a condition resulting from damage to the peripheral nervous system due to high concentrations of glucose in the blood of the extremities. This condition causes severe pain to afflicted individuals, and puts them at risk for ulcer development. 85% of amputations due to diabetes are directly correlated to DPN³, and these amputations have very poor outcomes- currently there is a 50% mortality rate for DPN patients within 5 years of amputation⁴. Early intervention and timely treatment, however, have the potential to reduce incidence of amputation by up to 75%⁵, highlighting the importance of treatment and diagnostics for DPN patients.

Women, South Asian populations, T2D (Type 2 Diabetic) patients, and the elderly are at higher risk of developing DPN symptoms⁶. Globally, 425 million people are estimated to be suffering from DPN, and this number is expected to rise to 628 million by 2045⁷. Consequently, there exists a significant population of patients experiencing DPN who receive their care in low-resource, rural settings that might be difficult to access. This suggests a need for a device that is implementable in these settings. It must be relatively low-tech, affordable, durable, and intuitive, with a long battery life, in order to adequately and appropriately serve the affected population. As in many social contexts, there exists stigma surrounding diabetes, or

³ Edmonds M, Manu C, Vas P. The current burden of diabetic foot disease. *J Clin Orthop Trauma*. 2021 Feb 8;17:88-93. doi: 10.1016/j.jcot.2021.01.017. PMID: 33680841; PMCID: PMC7919962.

⁴ Barnes, J. Aaron, et al. "Epidemiology and Risk of Amputation in Patients with Diabetes Mellitus and Peripheral Artery Disease." *Arteriosclerosis, Thrombosis, and Vascular Biology*, vol. 40, no. 8, 2020, pp. 1808–1817., <https://doi.org/10.1161/atvbaha.120.314595>.

⁵ Verrone Quilici, M.T., de Sa Del Fiol, F., Franzin Vieira, A.E., Toledo, M.A., Risk Factors for Foot Amputation in Patients Hospitalized for Diabetic Foot Infection. *J Diabetes Research*; 2016,

⁶ Alam, U., Sloan, G. & Tesfaye, S. Treating Pain in Diabetic Neuropathy: Current and Developmental Drugs. *Drugs* 80, 363–384 (2020). <https://doi.org/10.1007/s40265-020-01259-2>

⁷ Yovera-Aldana M, Velásquez-Rimachi V, Huerta-Rosario A, More-Yupanqui MD, Osoro-Flores M, et al. (2021) Prevalence and incidence of diabetic peripheral neuropathy in Latin America and the Caribbean: A systematic review and meta-analysis. *PLOS ONE* 16(5): e0251642.

acknowledging illness more broadly, remaining discrete and creating something with a familiar, unintimidating form, is imperative.

Current DPN pain management methods are limited and can be bucketed into four groups: spinal cord stimulation, medication, physical therapy, and lifestyle changes. Spinal cord stimulation is currently the most effective pain mitigating method, however it is highly invasive and has adverse complications such as infection and loss of therapy efficacy over time. The second method involves medication, typically in oral form. With diabetes limiting blood flow, the ability for drugs to reach the feet is often hindered. This creates delivery issues and a lack of efficacy. The third method is physical therapy. For a variety of reasons, such as distance, time and money, these options are inaccessible to most people. Further, these therapies don't directly target nerve pain. Similarly, lifestyle changes are also unlikely to be immediately effective. In terms of ulcer monitoring, the most common method is simply routine checks of your foot to see if there are any cuts or visible signs of infection.

The unfortunate truth is that there is no complete cure for DPN, which means all these individuals are living their daily lives in immense pain. We wanted our device to help increase the quality of life for these patients by incorporating novel pain mitigating therapies as well as provide a proactive method of monitoring for ulcer development to prevent infection and subsequent amputation. It was essential we incorporated these features into an accessible, affordable, durable, and intuitive product unlike any on the current market.

After much consideration and planning, the following needs specifications for our device were identified and recorded in the table below:

Table 1. Needs Specifications.

Category	Specification	Values	Justification of Need
Accessibility	Cost	< \$100	The product needs to be relatively affordable and the price aligns with or is lower than competitor products.
Performance	Battery life	~1 week	As a wearable, the slipper needs to work independently after charging for user flexibility.
	Pain Management	Decrease in patient pain scale	Combining novel therapy methods will allow patient access to additional treatment and ultimately more relief.
	Proactive Ulcer Monitoring	Early on-set detection of infection	Early detection of Ulcer infection greatly decreases the chances of amputation.
Physical	Shape	A slipper-shape fit to commercial standards	The slipper needs to be easy-to-use for diabetic patients who are experiencing difficulty or pain when putting on footwear.
	Dimensions	Small(~230mm) and Large(~250mm)	Since our device is a footwear, it needs to accommodate the needs for different sized feet of the patients.
	Material	Antibacterial, comfortable, and strong	The slipper needs to prevent infections (e.g. ulcers) and last long with electrical components working inside.

The group conducted extensive research and determined that transcutaneous electrical nerve stimulation (TENS) and infrared (IR) therapy as well as blood oxygen and temperature sensing were the best methods to meet the above goals.

TENS therapy sends square electrical waves through electrodes surrounding the affected area. This modulates transmission of pain impulses to the brain and inhibits nociceptive stimuli. It has been proven to aid in pain mitigation, improve circulation, and even induce some level of

reinnervation. IR therapy, in which diodes emit penetrating wavelengths that have been shown to promote local circulation, healing, and reduce chronic pain.

Additionally, it has been found that the oxygen saturation in an ulcerous foot is approximately 10% lower than in that of a healthy foot, and that temperature monitoring predicted 91% of impending foot ulcers 41 days before clinical presentation⁸. These findings suggest that temperature and blood oxygen monitoring will accurately detect the early stages of ulcer development, but only if the implemented monitor is accurate.

Not only did we feel these therapy and sensing methods would meet our performance needs specifications, they also will aid in meeting our physical and accessible needs as well.

Shown in Table 3 of the project overview section, existing products on the market targeted at DPN patients fail to offer therapeutic and monitoring components in tandem. While individual TENS units and IR therapy devices are marketed towards DPN patients, they focus on pain management, while ignoring the incredible impact that monitoring and early intervention can have on ulcer formation. With the exception of simple compression socks and other simple products aimed at increasing circulation in diabetic feet, the offered devices are sold at a high price-point, are bulky, and cannot be used discreetly.

⁸ Brooks E, Burns M, Ma R, Scholten HJ, Becker S. Remote Diabetic Foot Temperature Monitoring for Early Detection of Diabetic Foot Ulcers: A Cost-Effectiveness Analysis. *Clinicoecon Outcomes Res.* 2021;13:873-881

Project Overview

StepAhead's main objectives are to offer acute and chronic pain relief, assistance in regeneration of damaged nerves, simple monitoring for early stages of ulcer development, simple actuation, portability, and long battery life. There is currently no product in the market offering this functionality to patients. As many DPN patients are elderly, or based out of low-resource environments, StepAhead aims at targeting these users, providing them with an accessible, low-tech device that allows them autonomy and control over their own care. It is expected that StepAhead will work in tandem with existing healthcare infrastructure, encouraging users to seek out care before ulcer development, ultimately hoping to prevent amputation.

We expect that StepAhead users will have increased connection with physical therapists, primary care physicians, and other healthcare professionals seeking to treat DPN. For patients facing significant obstacles to participate in traditional healthcare systems (low resource, rural), we hope that the use of StepAhead will not only alleviate the everyday pain they feel, which can be preventative to participation in work, social activities, daily life, but will also draw awareness to the condition of the feet long before ulcers are developed. As the wealth gap in many countries continues to widen, we hope that StepAhead will offer low-cost treatment that increases positive outcomes. The short duration and discrete nature of the device should encourage use, even in communities with considerable stigma surrounding diabetes or DPN diagnosis.

In summary, StepAhead device is specifically designed to help patients manage diabetic peripheral neuropathy in the feet, which will have both immediate and broad impacts on patient care and quality of life. Immediate impacts consist of relief from pain and discomfort, increased mobility, and reduced use of medications. The broader impacts that would ensue from the StepAhead device consist of an overall increase in a patient's quality of life, the existence of a

more accessible and cost effective device, and an overall decreased burden on the healthcare system.

Technical Specifications

In tandem with meeting the physical specifications mentioned previously, we also created technical specifications that are vital to the device functioning and providing a patient with a meaningful benefit. All of our therapy methods are backed by extensive research that has proven to show substantial pain relief as well as signs of healing to patients. We proposed that if our device would meet the same standards set by research, then it would successfully meet all of the objectives mentioned above. Table 2 shows the specific technical specifications from research.

Table 2. Technical Specifications.

Specification	Values	Justification
Infrared Light	800-1200 nm > 50 W/cm ² ⁹	Infrared light has been shown to improve blood circulation and autonomic nervous system regulation. ¹⁰
Electrical Stimulation (TENS)	2 - 110 Hz with 80 μs pulse width 60 V 0 - 300 mA 5 - 30 minutes ¹¹	Electrical stimulation has been proven to improve blood flow and stimulate nerves. ¹²
Temperature Monitoring	Alert if: Change in temperature of	Acute temperature increases are proven to be a biomarker and causative factor of foot ulcers. ¹⁴

⁹ Zein, R., Selting, W., & Hamblin, M. R. (2018). Review of light parameters and photobiomodulation efficacy: dive into complexity. *Journal of biomedical optics*, 23(12), 1–17. <https://doi.org/10.1117/1.JBO.23.12.120901>

¹⁰ Salvi, M., Rimini, D., Molinari, F., Bestente, G., & Bruno, A. (2017). Effect of low-level light therapy on diabetic foot ulcers: a near-infrared spectroscopy study. *Journal of biomedical optics*, 22(3), 38001. <https://doi.org/10.1117/1.JBO.22.3.038001>

¹¹ Perez Machado, A. F., & Ferreira Santana, E. (2012). The effects of transcutaneous electrical nerve stimulation on tissue repair: A literature review. *Plastic Surgery*, 20(04). <https://doi.org/10.4172/plastic-surgery.1000786>

¹² Jin, H. K., Hwang, T. Y., & Cho, S. H. (2017). Effect of Electrical Stimulation on Blood Flow Velocity and Vessel Size. *Open medicine (Warsaw, Poland)*, 12, 5–11. <https://doi.org/10.1515/med-2017-0002>

¹⁴ Yavuz, M., Ersen, A., Hartos, J., Lavery, L. A., Wukich, D. K., Hirschman, G. B., Armstrong, D. G., Quiben, M. U., & Adams, L. S. (2019). Temperature as a Causative Factor in Diabetic Foot Ulcers: A Call to Revisit Ulceration Pathomechanics. *Journal of the American Podiatric Medical Association*, 109(5), 345–350. <https://doi.org/10.7547/17-131>

	$\Delta 4^{\circ}\text{F}/2.2^{\circ}\text{C}^{13}$	
Blood Oxygen Monitoring	Alert if: < 95% ¹⁵	Blood oxygen level has been used as a biomarker to identify diabetic foot ulcers. ¹⁶

Competition

Taking a further look into competitor analysis, Table 3 shows a comparison of StepAhead with other DPN products in the market with respect to functionalities and design. Given StepAhead is able to offer a unique combination of features that no current product is able to achieve, we did a comparison with products that share some similar functionality to that of our device.

Table 3. Comparison of StepAhead Device to Current Diabetic Peripheral Neuropathy Products

Options → Properties ↓	Smart Foot Ankle Relief Massager Brace	Doctor's Choice Diabetic & Neuropathy Crew Socks	QUINEAR Shiatsu Foot Massager	CAMECO Red & Infrared Light Therapy Shoe	StepAhead
Electrical Stimulation	✗	✗	✗	✗	✓
Intensity Adjustment	✓	✗	✓	✓	✓
IR Light Therapy	✗	✗	✗	✓	✓
Blood oxygen and temperature sensing	✗	✗	✗	✗	✓
Physical control box	✗	✗	✓	✓	✓
Portability	✓	✓	✗	✓	✓

¹³ Lavery, L. A., Higgins, K. R., Lanctot, D. R., Constantinides, G. P., Zamorano, R. G., Armstrong, D. G., Athanasiou, K. A., & Agrawal, C. M. (2004). Home monitoring of foot skin temperatures to prevent ulceration. *Diabetes care*, 27(11), 2642–2647. <https://doi.org/10.2337/diacare.27.11.2642>

¹⁵ Torp KD, Modi P, Simon LV. Pulse Oximetry. [Updated 2022 Aug 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK470348/>

¹⁶ Oropallo, A. R., Serena, T. E., Armstrong, D. G., & Niederauer, M. Q. (2021). Molecular Biomarkers of Oxygen Therapy in Patients with Diabetic Foot Ulcers. *Biomolecules*, 11(7), 925. <https://doi.org/10.3390/biom11070925>

Market Positioning

Current products available on the market for treating DPN mostly orient towards simple therapies, such as infrared, compression, or electrical stimulation, separately. Most of them do not have a monitoring component to their device, which is critical for the prevention of ulcer developments. Our device offers high-quality services with its ability to deliver both TENS and IR therapies, in combination with temperature and blood oxygen saturation level monitoring to DPN patients for improving blood circulation as well as ulcer prevention. Another goal of StepAhead is to make the device accessible to as many populations as possible, including the elderly and DPN patients in developing nations. From talking to doctors and physical therapists, it is apparent that a dire need exists in the DPN market for an effective yet affordable device. By using widely available and affordable therapies and sensor chips, StepAhead is able to minimize cost and offer the device at a low price without imposing financial burdens on DPN patients, which also secures StepAhead's unique competitive position in the market.

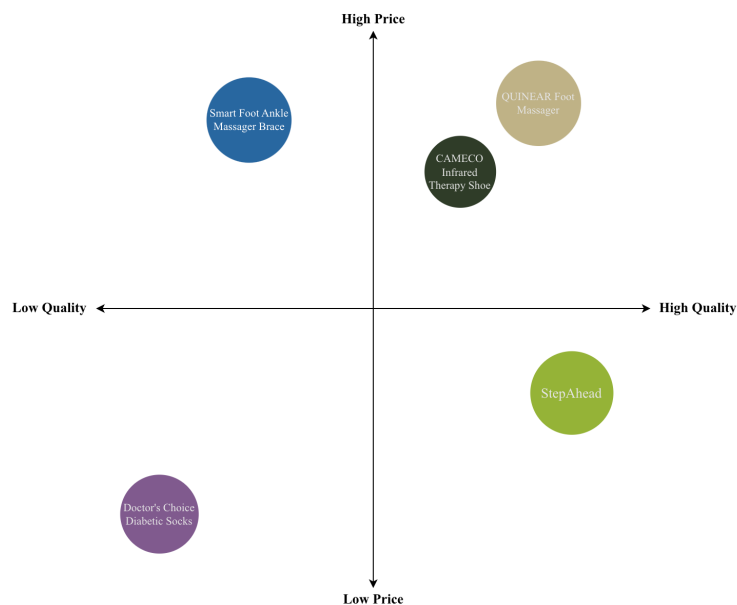


Figure 1. Market Positioning of StepAhead. StepAhead device holds a competitive advantage over other market competitors given its ability to deliver high-quality therapies as well as monitoring at a lower price compared to other products for treating DPN.

Cost

The estimated cost of manufacturing per device and the breakdown are shown in Table 4. It is a relatively low cost device considering it has integrated multiple functionalities.

Table 4. Estimated Cost Per Device

Category	Item	Price	Quantity	Total
Actuators	E-stim electrodes	~\$0.5/electrode	5	\$2.5
	Infrared Light Strip (850nm)	\$3.96/ft	3	\$11.88
Sensors	MAX30102 Oximeter	\$1	1	\$1
Other Misc Circuit Components	Wires, buttons and other misc circuit components from Stephenson Lab	\$0	N/A	\$0
	LCD Screen	\$6.27	1	\$6.27
	Arduino Uno from Stephenson Lab	\$27.6	1	\$27.6
	Rechargeable 9V batteries	\$8.5	2	\$17
Slipper Development	3D-Printed Slipper from Edu Commons	\$0	1	\$0
	PDMS supplies from Stephenson Lab	\$0	N/A	\$0
Total Cost				\$66.25

Revenue Model

One revenue model for the StepAhead device would be a direct-to-consumer sales approach. The device could be sold online or through retail channels at a price with a 3x markup from cost price. Although the current cost is at \$66.25, the cost is predicted to drop by 55% to \$30 if mass produced by replacing the Arduino Uno with customized low-cost printed circuit board (PCB). StepAhead plans to bring the device to market in fall 2025 after receiving FDA 510(k) clearance. Given DPN affects 425 million people globally and 3% of the total DPN population actively seeks for specific device treatment, StepAhead aims to gain 0.5% of market share in the first year, which gives a target population of 63,750. Assuming overhead and fixed costs to be 40% of the total revenue, StepAhead is predicted to generate 1.53 million in profit in the first year from selling the device.

StepAhead also plans to offer replaceable insoles, which functions as a subscription model. The top layer of the sole that includes the TENS electrodes would need to be switched out for sanitary purposes. Each replaceable insole is estimated to cost \$5 and will be priced with a 3x markup at \$15, which could be sold separately or bundled with the StepAhead device to create additional revenue streams.

Another alternative revenue model could be to partner with healthcare providers and insurance companies to offer the device as a covered benefit. This would require working with these organizations to demonstrate the cost savings associated with early intervention and reduced amputations, as well as the efficacy of the device.

Additionally, StepAhead could explore licensing or partnering with pharmaceutical companies that produce DPN therapies to offer a comprehensive solution to patients, allowing StepAhead to expand its reach and leverage the resources of established players in the industry.

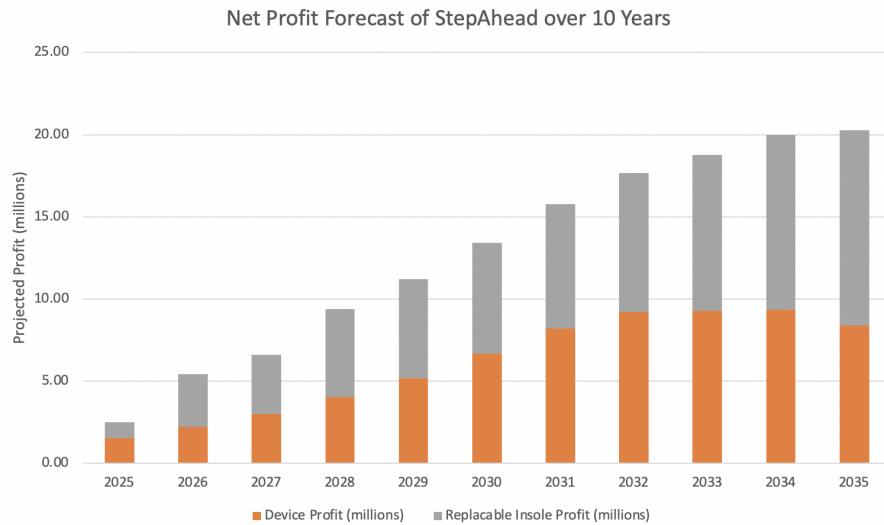


Figure 2. Projected Profit of StepAhead Device 2025-2035. With a product-to-market launch date of fall 2025 and a compounded annual growth rate (CAGR) of 12%¹⁷ in the DPN market, StepAhead is projected to generate a profit of \$2.49M in the first year and reach \$20.27M in 2035.

¹⁷ Bloomberg. (2020, June 2). Diabetic peripheral neuropathy market is expected to increase with a CAGR of 12% for the study period of 2017-2030: Bloomberg.com. Retrieved May 5, 2023, from <https://www.bloomberg.com/press-releases/2020-06-02/diabetic-peripheral-neuropathy-market-is-expected-to-increase-with-a-cagr-of-12-for-the-study-period-of-2017-2030>

Potential Limitations or Trade-offs with the Design

One trade-off with this multi-functional design is that StepAhead's IR coverage is smaller than most IR-only slipper products. For example, the Cameco product in Table 3 offers full IR coverage from all sides of the foot, but StepAhead cannot achieve this since TENS and sensors need to be in the insole. This will reduce the total power of IR in the product, but as will be mentioned in the Testing and Validation section, the total power of IR in StepAhead meets standards in clinical trials and research.

A secondary limitation is our target of keeping the device low cost. Naturally some level of limitations will be set on the robustness of materials and components used for the device simply because of cost.

Standards and Regulations

Our project will be under the regulations and standards curated by the following bodies: FDA, ISO and IEC.

FDA is a federal agency of the Department of Health and Human Services in the United States that is responsible for the supervision and control of the safety and efficacy of food, human and veterinary drugs, biological products, cosmetics and medical devices. Our project will need FDA approval. Our device will be a class II medical device based on FDA categorization of electrical stimulation devices¹⁸, belonging to the product code NHI. There has been FDA approval/clearance for similar technologies that produce electrical stimulation for pain relief. One example is a "Transcutaneous electrical nerve stimulator for pain relief", First

¹⁸ CFR - Code of Federal Regulations Title 21. [accessdata.fda.gov](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=882.5890). (n.d.). Retrieved May 5, 2023, from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=882.5890>

Relief[®]¹⁹. It went through a premarket notification 510(k) process and was cleared by the FDA in 2021²⁰. Our device is classified by the FDA in the class ‘Stimulator, Nerve, Electrical, Transcutaneous, With Limited Output, For Pain Relief.’ Relevant classification regulation codes are CFR 882.5890 and CFR 890.5850.

Internationally, our device will be regulated by ISO(International Organization for Standardization), which is an independent, non-governmental organization that develops standards to ensure the quality, safety and efficiency of products, services, and systems. These are the specific codes that are applicable to our project: ISO 14971 (Application of risk management to medical devices), ISO 13485 (Medical devices – Quality management systems - Requirements for regulatory purposes), and ISO 10993 (Biological evaluation of medical devices).

Since our project involves electrical stimulation as a therapeutic method, it is also subjected to standards and regulations of the IEC(International Electrotechnical Commission). IEC is an international standards organization that prepares and publishes international standards for all electrical, electronic and related technologies²¹. Our device will fall under the regulation codes for medical devices using electricity, which includes IEC 62366-1 and IEC 60601-1 (Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment)²².

¹⁹ First relief[®]. DyAnsys. (2023, February 7). Retrieved May 5, 2023, from <https://www.dyansys.com/products-applications/products/first-relief>

²⁰510(k) premarket notification. accessdata.fda.gov. (n.d.). Retrieved May 5, 2023, from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

²¹2023-05-04, 2023-05-03, 2023-05-02, & 2023-04-27. (2023, May 4). IEC everywhere for a safer and more efficient world. IEC. Retrieved May 5, 2023, from <https://iec.ch/homepage>

²²Lysechko, T. (2021, July 12). Which standards apply to your medical device? StarFish Medical. Retrieved May 5, 2023, from <https://starfishmedical.com/blog/which-standards-apply-to-your-medical-device/#:~:text=IEC%2060601%20is%20a,ctually%20a,multiple%20collateral%20and%20particular%20standards>

We will test the device to ensure similar voltages are produced compared to existing TENS devices and demonstrate the safety of our device. We will also compare the intended use and technical characteristics of our device with existing TENS devices. These will satisfy the requirements for 510(k) application²³.

²³Center for Devices and Radiological Health. (n.d.). Premarket notification 510(K). U.S. Food and Drug Administration. Retrieved May 5, 2023, from <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k#se>

Design and Development

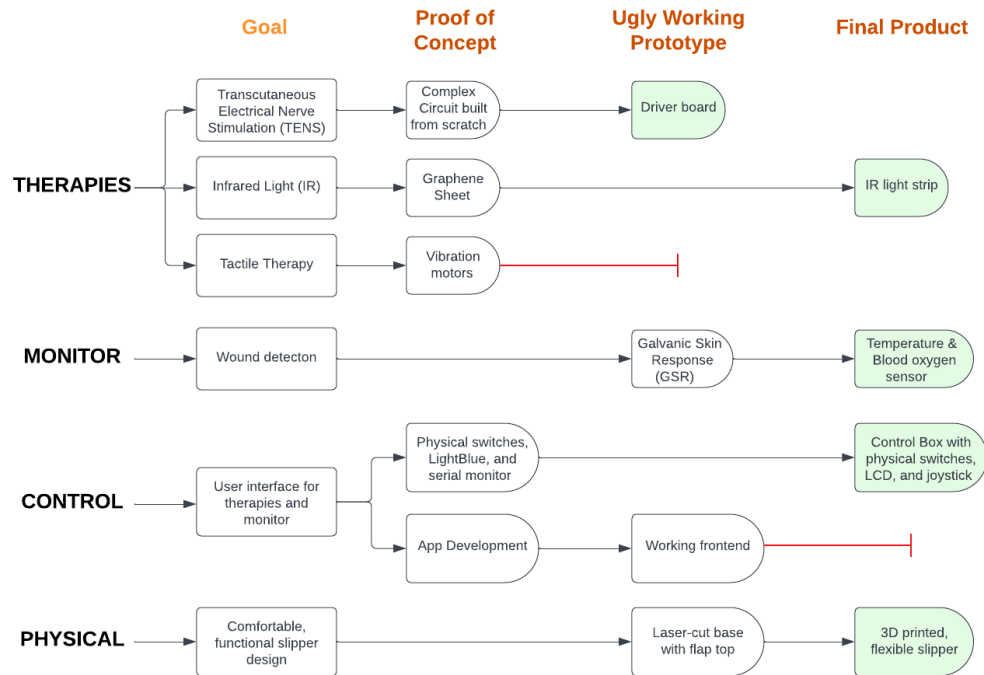


Figure 3. Evolution of the engineering design of StepAhead. Green boxes indicate design choices in the final product, and red lines indicate terminated designs or functionalities and the point of termination.

The overall evolution of the engineering design of StepAhead is shown in Figure 3. By the second month of designing StepAhead, a proof of concept (POC) to demonstrate the feasibility of the technology was developed. The core technologies then envisioned included three therapies: IR/heat, TENS, and tactile therapy. IR/heat was achieved by connecting a graphene sheet to a power source and could be turned on and off by a physical rocker switch. Peltier modules were also experimented with but were not successful. Initially, TENS waves were generated using modular circuits that utilized timer chips. However, the square waves generated were not very stable, had insufficient amplitude, and implementing multiple units was too bulky for the established needs specifications. Lastly, tactile therapy was achieved through two vibration motors. They were able to be controlled separately through a mosfet and bluetooth (LightBlue). The proof of concept demonstration showed the feasibility of the three therapies,

but for more stable remote control and output of therapies, we started to explore alternative methods to generate the same output afterwards.

Between POC and the ugly working prototype (UWP) at the end of the first semester, we continued to improve the therapy methods while exploring new possibilities, and began our design of the physical device. Relatively big changes were made with respect to the therapies. Based on conversations with Dr. Bruce Kothmann, we switched to a driver board to generate and amplify square waves for TENS for sufficient intensity, customizability, and ease of control. EMG electrodes available in the Stephenson Lab were used after cutting off the surrounding sticker part, leaving only the green part for sending TENS signals. After talking to some healthcare professionals in diabetes and conducting more literature research, tactile therapy was removed from the device due to conflicting evidence about its benefits and harm to DPN. Instead, we incorporated a Galvanic Skin Response (GSR) sensor as we learned from a diabetes doctor that cuts or ulcers on the foot can lead to a decreased resistance, which the GSR sensor measures. The resistance threshold for alert was determined based on the resistance of foot without injuries of some members in the team and literature research. Regarding IR, we began to switch from a physical switch control to digital control by bluetooth, arduino, and mosfet. However, after many experiments and research, digital control was not successful as the graphene sheet was drawing too much power and a heat sink for the mosfet could not prevent overheating. Thus for UWP, a physical switch on the side of the slipper base was used.

On the other hand, regarding physical design, we built a slipper with laser-cut base and a cloth flap on top. The laser-cut base enclosed all the electronics and followed a typical foot/insole shape. The side of the base was flexible, achieved by cutting thin, dense, parallel lines

on the material. The top of the slipper consisted of two cloth flaps that enclosed graphene sheets and could be connected via velcro. This is shown in Figure 4.

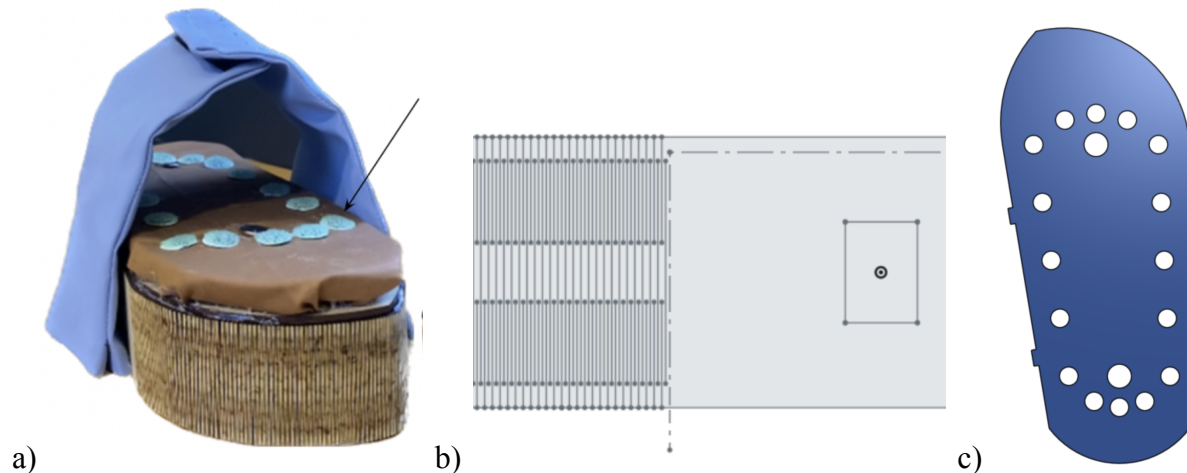


Figure 4. Picture and relevant engineering CAD drawings of UWP. a) Picture of assembled ugly working prototype (UWP). b) CAD sketch of the side of the base of UWP, where the left of the figure with dense, parallel lines allowed for flexibility of laser-cut material and correspond to the curved portions of the base. The box on the right was the hole for the rocker switch of the graphene sheet. c) CAD sketch for the top of the slipper base. The smaller circular holes on the sides were for the EMG electrodes for TENS, while the two big holes in the middle were for the GSR sensors.

In the spring semester, our primary goals were: 1) Improve on the sensor and therapy technologies, 2) Replace the laser-cutting based physical design with a 3D printed design, and 3) Integrate all the technologies with a control application on mobile devices.

Regarding the sensing technologies, we conducted more testing on GSR reading of the feet of healthy people without injuries and discovered that the reading varied significantly between individuals, likely because of the presence of callus or other physiological differences. This undermined our goal to alert users about the presence of any injuries based on resistance reading. Therefore, we conducted more literature research and interviews, eventually diverting to injury detection based on temperature and blood oxygen using the arduino MAX 30102 CHIP. The decision was based on the finding that there are much more standardized and shared patterns of temperature and blood oxygen changes due to the presence of a wound among individuals.

Regarding the two therapies, TENS was overall finalized as the driver board enabled sufficient voltage, individual control of electrodes for localization, and easy variation on pulse widths and frequencies for various modes. Details on the mode specifications are shown in Table 5. A switch from the EMG electrodes to professional TENS gel pads was made to make the interface replaceable and gel-free. However, the issue of remote control was still present for IR/heat. After cost-benefit analysis and more literature review, we decided to replace the graphene sheet with IR diode strips. The main cost of the switch is that the IR therapy StepAhead provided could only be mid-infrared light instead of the far-infrared light graphene could produce, and there was less, although still sufficient, literature research and clinical testing on the therapeutic effects of mid-infrared light. The benefits however, was the ability for us to achieve remote control of the therapy via mosfet, arduino, and bluetooth.

Table 5. Technical specifications and feelings mimicked of four TENS modes.

Mode	Feeling	Frequency (Hz)	Pulse width (μs)
1	Kneading massage	2	80
2	Knocking massage	90	80
3	Acupuncture	10	80
4	Cupping	47	80

For the physical design, we built two designs and iterated multiple times based on circuitry integration and wearing comfort. The two designs differed mainly on the top of the slipper, where one design left room for a cloth/flap based top similar to the UWP, while the other had a top integrated with the bottom similar to a common slipper. In the design with the top, we improved the design of the top by making it a detachable part that can fully cover the front half of the foot to maximize the effect of IR. For both designs, we designed the bottom based on

commercial insole products and the expected size of the circuitry, and picked a flexible TPU95 material for 3D printing for maximum comfort. The CAD models are shown in Figure 5.

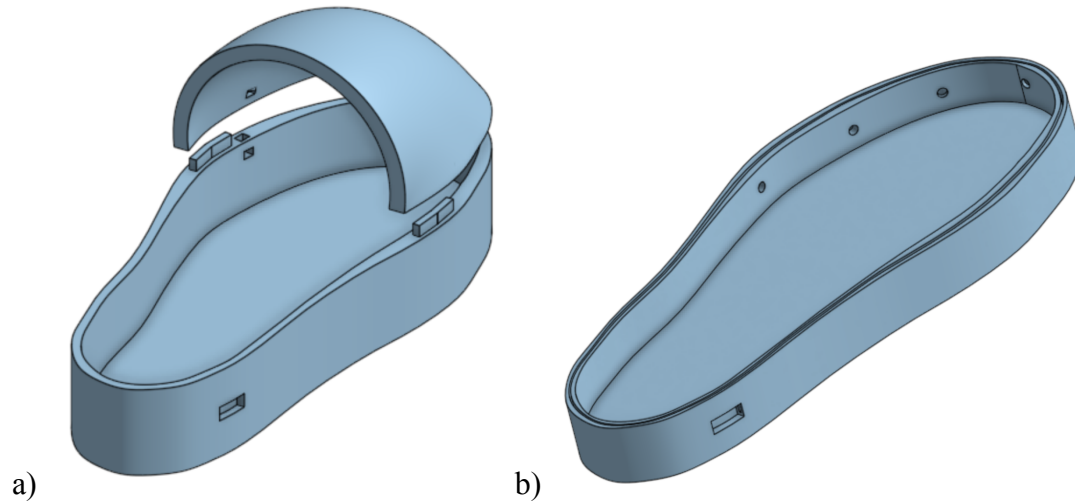


Figure 5. CAD models of two slipper designs for the final product. a) Design 1: slipper with integrated top. The IR light strip is secured to the inner side of the top, with wire entering the base through the connected hole-tunnel on the left side. The rectangular hole towards the back was designed for USB charging. b) Design 2: slipper with a slit for cloth flap. The series of small circular holes on the front of the base was designed for string/threads to secure the cloth. The rectangular hole on the side towards the back was designed for USB charging.

To secure all the circuitry in the base, we used PDMS, which allowed us to test all circuitry prior and then fix all electronics in place, thus preventing any damage or loosening of wires from external impacts. Small scale experiments with PDMS were performed first before using it to immerse all electronics.

Lastly, regarding the control interface, we experienced a lot of challenges and made many changes throughout the semester. None of the team members had previous experience in app programming/designing, and we were not able to follow the goals and deadlines set for the software component of the project. Due to insufficient communication between the hardware and software sides, unfortunately the app idea for digital control of the device was not successful, and we had to redesign the product with a tight deadline. Specifically, the portion of the arduino

scripts used to control the device would interfere with the bluetooth signal received by our mobile application, ultimately terminating connection and control of the device. For this reason, we chose to build a physical control box with rocker switches for the power of the device and each individual therapy and sensor, a joystick for the four modes of TENS therapies, and an LCD screen for sensor reading and alerts (Figure 6).

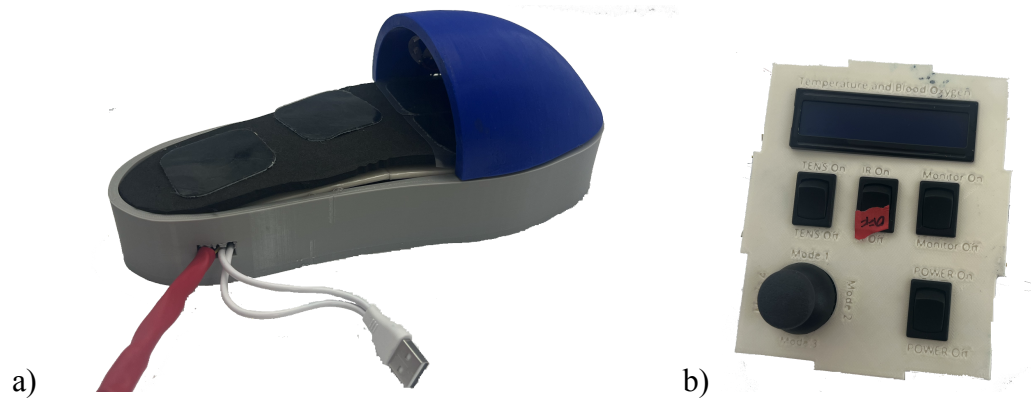


Figure 6. Final product. a) Picture of the assembled final product. The insole consisted of a removable foam with replaceable TENS pads. The gray base stored the majority of all electronics, with a USB charging wire (white) and a cable (red) connected to the control box coming out on the side. The blue top housed the IR light strip. b) Picture of the control interface, with an LCD that showed sensor reading, four rocker switches for device power, TENS, IR, and monitoring, and a joystick to select the TENS mode.

Testing and Evaluation

TENS

In order to validate the efficacy of the transcutaneous electrical nerve stimulation (TENS) therapy integrated into the StepAhead device, we first sought to recreate the values and specifications from existing literature that had shown a positive impact on healing and a reduction in acute and chronic pain. Using specifications from past research²⁴, four TENS modes were selected and recreated within the StepAhead device.

As shown in Figure 7, the TENS generation mechanism within the StepAhead device was capable of creating waveforms matching these specifications. The Analog Devices 2 Waveforms platform was used to confirm that the waves generated match the metrics used in prior research on patients with diabetic peripheral neuropathy. As will be discussed in further detail later on, due to an inability to test our generated TENS waves on DPN patients, recreating treatment found effective in literature was found to be sufficient for validation.

Research into current market offerings for TENS units found that most devices offered therapies with frequencies ranging from 2 - 120 Hz. This is consistent with existing literature and the programmed StepAhead TENS modes.

Finally, the use of a dual-gate transistor within the functional TENS circuit helps to regulate the level of current the patient receives and maintain a stable level of current throughout the therapy. This was monitored and validated over the Waveforms scope.

²⁴ Inamdar, M.U., Mehendale, N. A Review on Transcutaneous Electrical Nerve Stimulation and its Applications. *SN Compr. Clin. Med.* 3, 2548–2557 (2021).

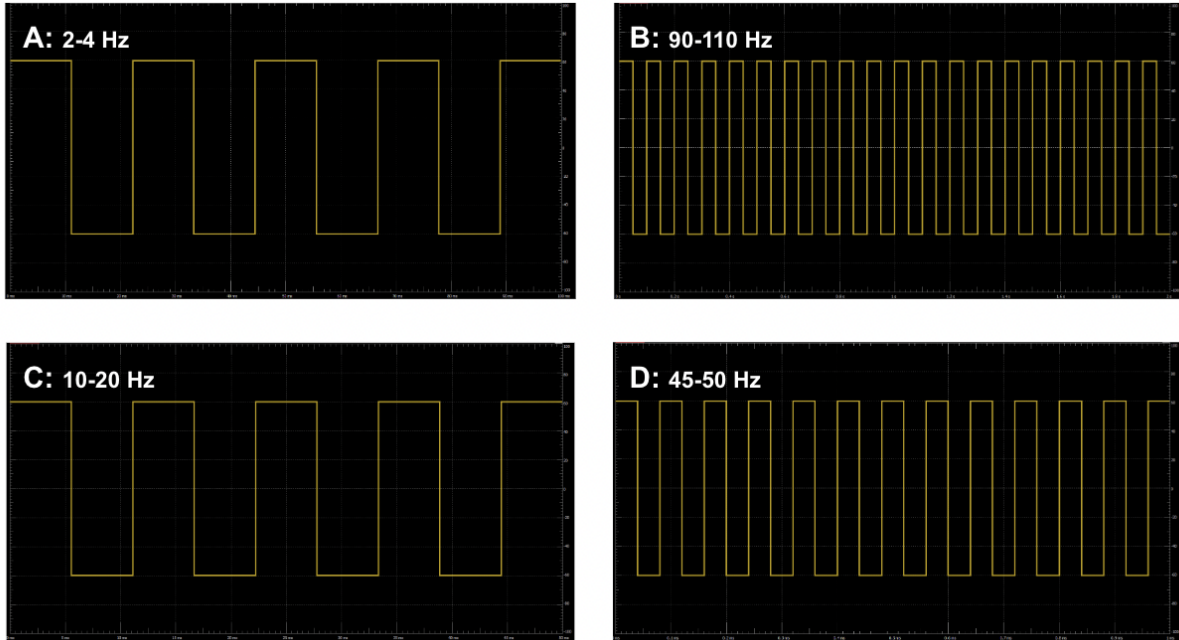


Figure 7: Waveforms of Generated TENS Signals. All amplitudes 60 V A) kneading massage, 2-4 Hz B) knocking massage, 90-110 Hz C) acupuncture, 10-20 Hz, D) cupping, 45-50 Hz

Infrared Light Therapy

Validation for the IR therapy was based on the technical specification of this functionality, as determined by past clinical trials and research. According to the literature on the effect of IR on pain management and blood circulation¹⁻⁴, the minimum amount of energy needed for IR therapy to be effective is about 50 W/m² and a wavelength of 800-1200 nm.

The source of our IR therapy is based on a variety of factors including the required wavelength, and the final IR light bulbs in the device emitted a wavelength of 850 nm, meeting the specification. We validated the power of therapy with an Infrared Power Meter (LS122 Infrared Power meter, Linshang) by putting the sensor of the meter within the “dome” of the device where the IR lights are secured to the top. This measurement was conducted three times on each of the two IR light bulb strips, and the power measured was consistently around 75 W/m² (Figure 8), with a mean of 75.1 W/m² and p-value 0.032, meeting and exceeding the

technical specifications of 50 W/m². The IR therapy component of StepAhead successfully satisfied and exceeded the technical specifications for scientifically proven effectiveness as determined by clinical trials and literature.



Figure 8. A representative reading of Infrared Therapy on LS122 IR Power Meter at 74.6 W/m². The reading was consistently around 75 W/m², meeting the technical specification of 50 W/m².

Additional testing on the safety of the therapy was performed. Temperature of the IR lights after 20 minutes of therapy, the recommended duration of the therapy based on past clinical research, should not exceed 42°C to prevent burning or other negative effects of high temperature ¹. Thermometer reading of the IR light was varied from 30 to 38°C, again meeting the safety requirement. Another safety requirement is the contact with the user's foot. During the design of the device the "dome" that stores the IR light was designed to be sufficiently higher than the typical height of a foot of people with a shoe size US 7.5 that there exists room between the IR light and the foot. This issue will be addressed as a potential improvement and the next step of the device is to cover the IR light with a thin layer of clear PDMS to prevent direct contact between IR and foot while ensuring sufficient IR light can pass through. Additionally, the instruction manual for this device will include a warning message that should the user's foot touch the IR light directly when trying on the device, they should refrain from using StepAhead.

Monitoring

The device employs a MAX30102 sensor chip to monitor blood oxygen saturation level and temperature. The sensor consists of a pair of high-intensity LEDs (red and infrared) and a photodetector. The MAX30102 functions by shining both lights onto the contact skin area and measuring the amount of reflected light using a photodetector. This sensor is shielded from ambient IR light by physical contact with the foot. To validate the temperature values obtained from the chip, we compared the readings from a temperature sensor to the readings collected from MAX30102, and they exhibited similar readouts with an accuracy of $\pm 1^\circ\text{C}$.

The blood oxygen saturation level reading is obtained and validated following an algorithm that calculates the percentage of SpO₂, or the amount of oxygen in capillary blood described as a percentage of the amount of oxy-hemoglobin to total hemoglobin. The formula is as follows:

$$\text{SpO}_2 = 100 \times \frac{C[\text{HbO}_2]}{C[\text{HbO}_2] + C[\text{RHb}]}$$

Equation 1: Blood Oxygen Calculation

where $C[\text{HbO}_2]$ and $C[\text{RHb}]$ are the concentrations of oxygenated hemoglobin(HbO_2) and deoxygenated hemoglobin(RHb), respectively.

In addition, the Beer-Lambert Law describes the attenuation of light with the properties of material through which the light is traveling:

$$A = \ln\left(\frac{I_0}{I}\right) = \varepsilon(\lambda)Cd$$

Equation 2: Beer Lambert Law

where A is the attenuation, I_0 is the incident light intensity, I is the received light intensity, $\epsilon(\lambda)$ is the molar extinction coefficient, C is the concentration of material and d is the optical path length. Considering the molecule compound of tissue, Beer-Lambert law is extended as follows:

$$A = d \left[\epsilon_{\text{HbO}_2}(\lambda)C[\text{HbO}_2] + \epsilon_{\text{RHb}}(\lambda)C[\text{RHb}] + \epsilon_{\text{other}}(\lambda)C[\text{other}] \right]$$

Equation 3: Beer Lambert Law Extended

Combining two formulas allows us to measure SpO_2 through molar extinction coefficients of HbO_2 and RHb .

Currently in our device, calibration of the SpO_2 readings is performed by taking 20 data points per second and averaging every 100 data points to obtain a relatively stable value and reduce fluctuations. The main limitation of testing and validation on sensing in the device is the lack of testing data for calibrating the SpO_2 specific for DPN patients. To release a device to market, the standards of SpO_2 measurement must meet the standards presented in the following FDA requirements:

- 1) ISO 80601-2-61:2017 – Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- 2) Pulse Oximeters – Premarket Notification Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff

According to the FDA, at least 200 data points evenly spaced between 70% to 100% saturation are required to assess performance, with subjects of varying ages, genders, and skin tones. The FDA stipulates that 30% of the volunteers should have dark skin pigmentation. The

overall error or root mean square error (RMSE) must be under 3.0% for transmissive pulse oximetry and under 3.5% for reflective pulse oximetry.

The current MAX3012 chip that we used in our device is largely fitted and calibrated for finger and wrist measurements. A foot-specific blood oxygen sensor is not widely available on the market, and this may lead to inaccuracy in data collection and calculations. In future iterations of the device, StepAhead's sensor hardware and algorithm must be recalibrated for measuring SpO₂ in feet specifically through subject trials to meet FDA-grade standards.

Looking Ahead

Future Directions

In the future, StepAhead device aims to incorporate user feedback. The purported effects of the offered therapies on pain management could be validated using the Visual Analog Scale (VAS) and McGill Pain Questionnaire (MPG) as a way to quantify and assess pain levels over time. The physical design of the StepAhead device would also benefit in patient feedback on fit, comfort, usability, and likelihood of retention. If StepAhead receives permission to launch in the market, different sizes of the device (Small: US 5-7, Medium: US 7.5-9, and Large: US 9.5-11) will be produced to accommodate the shoe sizes of most of the population. An app component will also be added in future iterations of the device to keep in track of the patients' performance over time and give customized feedback.

Another future step would be interviewing more healthcare professionals to further improve the device and getting in agreement with therapists to promote the device to patients. Ultimately, the goal is to both collaborate with providers in recommending or prescribing StepAhead to DPN patients and directly reach customers through pharmacies and online shopping platforms.

Forecasted Challenges

The main limitation currently for measuring the IR and TENS therapies is the lack of measurement for long term effectiveness of our specific StepAhead device real DPN patients. We expect future challenges to be mainly centered around:

- 1) The inability to recruit real DPN patients to test any immediate effect IR/TENS would have on pain management and increased blood flow in their feet.

2) The subjectiveness of pain, as an individual's experience with pain is highly variable and clinical trials could only use surveys evaluating pain from a scale of 1 to 10.

3) Insufficient time to track the long-term effect of therapy as the time needed for blood flow, protective sensation, and nerve regeneration to recover due to therapy exceeds the duration of the course.

Reflection

The StepAhead team struggled with validation for our device. Integrating user feedback and conducting a wider range of interviews with affected DPN patients would have increased our understanding of the needs of users and improved the function and form of our device. This was particularly relevant as the therapies used are relatively novel, mainly because there is no standardized, practical, daily treatment for DPN patients. By connecting with more professionals as well, we would have better understood the workflow between an at-home therapeutic and monitoring device and the work of physical therapists/healthcare professionals.

There were many evolutions of StepAhead, both in which therapies would be implemented, and in the overall purpose of our device. Interactions with the existing healthcare system were examined in depth, but an at-home therapeutic was ultimately decided upon. The focus on ulcer development came relatively late in the process, and many early directions had to be abandoned. When our purpose became clear, it was a much more direct path to our final product.

References

1. Verrone Quilici, M.T., de Sa Del Fiol, F., Franzin Vieira, A.E., Toledo, M.A., Risk Factors for Foot Amputation in Patients Hospitalized for Diabetic Foot Infection. *J Diabetes Research*; 2016,
2. Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050. *Archives of Physical Medicine and Rehabilitation* 2008;89(3):422-9.
3. Edmonds M, Manu C, Vas P. The current burden of diabetic foot disease. *J Clin Orthop Trauma*. 2021 Feb 8;17:88-93. doi: 10.1016/j.jcot.2021.01.017. PMID: 33680841; PMCID: PMC7919962.
4. Barnes, J. Aaron, et al. “Epidemiology and Risk of Amputation in Patients with Diabetes Mellitus and Peripheral Artery Disease.” *Arteriosclerosis, Thrombosis, and Vascular Biology*, vol. 40, no. 8, 2020, pp. 1808–1817., <https://doi.org/10.1161/atvbaha.120.314595>.
5. Verrone Quilici, M.T., de Sa Del Fiol, F., Franzin Vieira, A.E., Toledo, M.A., Risk Factors for Foot Amputation in Patients Hospitalized for Diabetic Foot Infection. *J Diabetes Research*; 2016,
6. Alam, U., Sloan, G. & Tesfaye, S. Treating Pain in Diabetic Neuropathy: Current and Developmental Drugs. *Drugs* 80, 363–384 (2020). <https://doi.org/10.1007/s40265-020-01259-2>
7. Yovera-Aldana M, Velásquez-Rimachi V, Huerta-Rosario A, More-Yupanqui MD, Osoreo-Flores M, et al. (2021) Prevalence and incidence of diabetic peripheral

neuropathy in Latin America and the Caribbean: A systematic review and meta-analysis. PLOS ONE 16(5): e0251642.

8. Brooks E, Burns M, Ma R, Scholten HJ, Becker S. Remote Diabetic Foot Temperature Monitoring for Early Detection of Diabetic Foot Ulcers: A Cost-Effectiveness Analysis. *Clinicoecon Outcomes Res.* 2021;13:873-881
9. Zein, R., Selting, W., & Hamblin, M. R. (2018). Review of light parameters and photobiomodulation efficacy: dive into complexity. *Journal of biomedical optics*, 23(12), 1–17. <https://doi.org/10.1117/1.JBO.23.12.120901>
10. Salvi, M., Rimini, D., Molinari, F., Bestente, G., & Bruno, A. (2017). Effect of low-level light therapy on diabetic foot ulcers: a near-infrared spectroscopy study. *Journal of biomedical optics*, 22(3), 38001. <https://doi.org/10.1117/1.JBO.22.3.038001>
11. Perez Machado, A. F., & Ferreira Santana, E. (2012). The effects of transcutaneous electrical nerve stimulation on tissue repair: A literature review. *Plastic Surgery*, 20(04). <https://doi.org/10.4172/plastic-surgery.1000786>
12. Jin, H. K., Hwang, T. Y., & Cho, S. H. (2017). Effect of Electrical Stimulation on Blood Flow Velocity and Vessel Size. *Open medicine (Warsaw, Poland)*, 12, 5–11. <https://doi.org/10.1515/med-2017-0002>
13. Lavery, L. A., Higgins, K. R., Lanctot, D. R., Constantinides, G. P., Zamorano, R. G., Armstrong, D. G., Athanasiou, K. A., & Agrawal, C. M. (2004). Home monitoring of foot skin temperatures to prevent ulceration. *Diabetes care*, 27(11), 2642–2647. <https://doi.org/10.2337/diacare.27.11.2642>
14. Yavuz, M., Ersen, A., Hartos, J., Lavery, L. A., Wukich, D. K., Hirschman, G. B., Armstrong, D. G., Quiben, M. U., & Adams, L. S. (2019). Temperature as a Causative

Factor in Diabetic Foot Ulcers: A Call to Revisit Ulceration Pathomechanics. *Journal of the American Podiatric Medical Association*, 109(5), 345–350.

<https://doi.org/10.7547/17-131>

15. Torp KD, Modi P, Simon LV. Pulse Oximetry. [Updated 2022 Aug 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK470348/>
16. Oropallo, A. R., Serena, T. E., Armstrong, D. G., & Niederauer, M. Q. (2021). Molecular Biomarkers of Oxygen Therapy in Patients with Diabetic Foot Ulcers. *Biomolecules*, 11(7), 925. <https://doi.org/10.3390/biom11070925>
17. Bloomberg. (2020, June 2). Diabetic peripheral neuropathy market is expected to increase with a CAGR of 12% for the study period of 2017-2030: Bloomberg.com. Retrieved May 5, 2023, from <https://www.bloomberg.com/press-releases/2020-06-02/diabetic-peripheral-neuropathy-market-is-expected-to-increase-with-a-cagr-of-12-for-the-study-period-of-2017-2030>
18. CFR - Code of Federal Regulations Title 21. [accessdata.fda.gov](https://www.accessdata.fda.gov). (n.d.). Retrieved May 5, 2023, from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=882.5890>
19. First relief®. DyAnsys. (2023, February 7). Retrieved May 5, 2023, from <https://www.dyansys.com/products-applications/products/first-relief>
20. 510(k) premarket notification. [accessdata.fda.gov](https://www.accessdata.fda.gov). (n.d.). Retrieved May 5, 2023, from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

21. 2023-05-04, 2023-05-03, 2023-05-02, & 2023-04-27. (2023, May 4). IEC everywhere for a safer and more efficient world. IEC. Retrieved May 5, 2023, from <https://iec.ch/homepage>
22. Lysechko, T. (2021, July 12). Which standards apply to your medical device? StarFish Medical. Retrieved May 5, 2023, from <https://starfishmedical.com/blog/which-standards-apply-to-your-medical-device/#:~:text=IEC%2060601%20is%20actually%20a,multiple%20collateral%20and%20particular%20standards>
23. Center for Devices and Radiological Health. (n.d.). Premarket notification 510(K). U.S. Food and Drug Administration. Retrieved May 5, 2023, from <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k#se>

Appendix A. Bill of materials and build procedure

List of Materials for Device

	Material	Quantity
Physical Materials	Dr. Scholl's WORK Massaging Gel Advanced Insoles	1
	Arduino Uno	1
	TENS electrodes	4
	PCA9685 16 CH 12Bit PWM Servo Motor Driver Board Controller	1
	Infrared (IR) light strip	2
	Protoboard	2
	MAX 30102 Blood oxygen & temperature sensor	1
	9V rechargeable battery with USB recharging cable	2
	PDMS silicone elastomer kit	1
	Access to 3D printer and both flexible TPU95 and strong, nonflexible 3D printing material	N/A
Software Materials	Arduino IDE	N/A

Build Procedure (Chronological Order)

A. Preparation of individual components

The first step in building StepAhead is to prepare the individual circuitry and 3D printed components. The steps A1 through A5 can be done in parallel.

A1. Build the CAD model of the slipper using any CAD software of choice, such as OnShape. All dimensions mentioned in this step can be adjusted as needed.

A1.1) Download the image of an insole with the desirable shape and size. Insert the image into Onshape and trace it on the top plane. Add an extrusion of the trace with about 5 cm in depth. Make a copy of the trace on the extrusion and slightly reduce the size of the trace. Remove the extrusion based on the copy of the trace of about 4.75 cm in depth.

A1.2) Extrude a 1 cm x 0.5 cm rectangular hole and a circular hole with 0.8 cm diameter on the outer side of the base towards the back through the side. The rectangular hole is for the battery charging cable and the circular hole is for the cable connected to the control box.

A1.3) Make two small removal extrusions of about 0.8cm in depth on the left and right of the top of the outer walls of the base (it should also be on the top plane) around the middle of the slipper. The specific shape of the extrusion is flexible as long as it is in between the two sketches of the insole done in A1.1.

A1.4) Make a small L-shaped tunnel from the top of the base walls to the inner side of the base wall. This is for the wire connected to the IR light strips to go through and should be towards the front. The L-shaped tunnel used in the final

product was based on a 0.3 cm x 0.3 cm square. Now the shell of the base of the slipper is complete. Refer to Figure 5 and C3 for a reference on the final look.

A1.5) Create a plane using plane offset based on the front plane. The offset distance should be adjusted to the specific shoe size, but should meet the slipper about in the middle. Create two concentric arcs that meet the outer and inner sides of the base wall, respectively. The distance between the top of the outer arc and the top of the slipper base should be around 9 cm.

A1.6) Using the loft function, create the top of the slipper based on the two arcs made in A1.5 and the top of the slipper made in A1.1. The start profile condition should be “normal to profile” with a start magnitude of 1.75-2.00 based on specific shoe size.

A1.7) Add two extrusions on the bottom of the top of the slipper with dimensions and positions corresponding to the two removal extrusions made in the base in A1.3. Make a symmetric L-shaped tunnel at a position corresponding to the one made in the base in A1.4. Now the top of the slipper is complete. Refer to Figure 5 and C3 for a reference on the final look.

A1.8) 3D print the two parts using TPU95 or other flexible materials.

A2. Build the CAD model of the control box using any CAD software of choice, such as OnShape. All dimensions mentioned in this step can be adjusted as needed.

A2.1) Create a press-fit box of the dimension 10 cm x 12 cm x 7.5 cm.

A2.2) On the top surface of the box, create a removal rectangular extrusion of dimension 7.1 cm x 2.4 cm for the LCD screen, four removal rectangular

extrusions of dimension 2 cm x 1.4 cm for the four switches, and a removal circular extrusion of diameter 2.5 cm for the joystick.

A2.3) Beside the extrusions in the appropriate positions, add text engravings for the specific functions the to-be-embedded electronic components correspond to. Above the LCD screen extrusion should say “Temperature and Blood Oxygen.” Above and below the four switch extrusions should say “TENS On” “TENS Off”, “IR On” “IR Off”, “Monitor On” “Monitor Off”, and “Power On” “Power Off.” On the four sides of the joystick extrusion should say “Mode 1”, “Mode 2”, “Mode 3”, “Mode 4.” Refer to Appendix B, Figure 2 for a final look.

A2.4) On the front surface of the box, add a circular removal extrusion with diameter 0.8 cm (the size used in A1.3). This is for the cable connected to the slipper device.

A2.5) 3D print the two parts using strong, non-flexible materials.

A3. Build the desired IR circuitry

A3.1) Cut the IR strip into smaller pieces along the scissor line printed on the strip into pieces that will fit to the top of the slipper made in A1.

A3.2) Solder the pieces together such that all IR diodes are in series. Solder two long wires to one end of the strip. The other end of the connected strips do not need wires.

A4. Build the TENS circuitry

A4.1) Solder the driver board SDA, SCL, VCC, and GND pins to the board.

A4.2) Connect the soldered wires to the appropriate pins on the Arduino UNO.

A4.3) Connect the driver board output pins to the appropriate electrodes on the sole of the physical device.

A4.4) Confirm that the driver board is acting appropriately using the Waveforms application, or a voltmeter if Analog Devices 2 is not accessible.

A5. Build the MAX 30102 circuitry

- A5.1) Solder the MAX30102 chip's VCC, GND, SCL, SDA pins with wires.
- A5.2) Connect the wires to corresponding pins in the Arduino UNO in the control box.
- A5.3) Calibrate with the first 100 sets of collected infrared and red light sensor data using MAX30102 algorithm.

B. Assembly of individual components

The second step is to assemble the individual components made in A1-5.

B1. Insert and secure the joystick, switches, and LCD screen onto the top surface of the control box. Place the rest of the circuitry in the base of the slipper. Solder the circuitry made in A3-A5 onto common, compact protoboards. A circuit diagram and wiring instructions are shown in Figure C1 and Figure C2. Leave wires connected to the LCD screen, switches, and joystick to be about 80 cm, and ensure that they go through the corresponding circular holes on the side of the slipper and the control box. Wrap heat shrink of suitable size around all wires that run between the slipper and the device between soldering.

B2. Close the control box. Shrink the heat shrink of the connection wires using a heat shrink gun.

B3. Mix PDMS Part A and Part B in a 9:1 ratio by weight and stir thoroughly. Safety precautions like gloves and goggles should be taken. Add dyes if desired. Pour the PDMS into the slipper base and ensure that all circuitry is immersed in the PDMS. Leave overnight or put in an oven at 50 degree Celsius for an hour for curing.

C. Quality Check Steps

C1. First, ensure that the sensing monitor is functioning properly. This monitor will first alert the user if a foot is detected via the LCD screen. If force is placed on the sole without reaction from the sensor, something has gone wrong. After calibration, a healthy foot will read values within the appropriate ranges for both temperature and blood oxygen levels.

C2. The TENS therapy is best validated using a Waveforms application, where the specific amplitude, pulse width, and frequency of the output waves can be observed. If this is not available, it can be validated using a voltmeter, or by simply placing your hand or foot onto the sole to feel the output electrical signals. The hardware is built so that voltage above a certain threshold cannot pass through the user.

C3. The IR therapy is best confirmed using an IR power meter, but can be detected using a phone camera. It is nearly impossible with the naked eye to validate whether or not it is on. This therapy, like the others, should be controlled by the switch from the control box. It should be an appropriate distance (about 2 fingers) from the user's foot.

Appendix B. User Manual



USER MANUAL

Thank you for purchasing StepAhead! StepAhead is a wearable, therapeutic and monitoring device designed to prevent the formation of ulcers due to diabetic peripheral neuropathy. The StepAhead slipper is meant to be used for daily monitoring and as-need pain relief therapy. Transcutaneous electrical nerve stimulation (TENS) therapy is offered in 4 pre-programmed modes with adjustable intensity and localization to mitigate acute pain. The electrodes that perform TENS therapy are located on the insole. Infrared light at a pre-set wavelength and intensity is offered to alleviate pain and promote long-term healing. The infrared LEDs are located above the feet, within the vamp. Monitoring is performed by blood oxygen and temperature sensors located on the insole. The monitored data can be easily seen on the LCD screen of the physical device control box.

Included in purchase:

- StepAhead Slipper and Remote Control
- USB Charging Cable
- User manual

Warnings/disclaimers:

1. Use of StepAhead supplements, but does not replace, routine foot care, including daily cleaning, regular self-examination by the patient, and periodic examination by healthcare professionals.
2. Inform your provider if you have an active foot ulcer and are using the StepAhead device.
3. StepAhead cannot diagnose any specific disease state and should be used in tandem with the recommendations of a healthcare professional.
4. The StepAhead slipper is intended to be used in inactive settings (sitting, standing), not while walking, running, or performing physical exercise.
5. Keep the device out of reach of children.
6. Do not use the device while charging.

Using the StepAhead slipper:

StepAhead arrives as a singular, one-size-fits all device. The user's foot can be oriented along the sole containing the electrode pads for ideal placement relative to pain points.

Charging:

Insert one end of the provided USB cable into the USB port located on the side of the device, as seen in figure 1. Connect to a power adapter, and plug directly into an electrical outlet. The StepAhead slipper must be fully charged before usage. Do not wear the slipper or attempt to run therapies while charging is taking place.

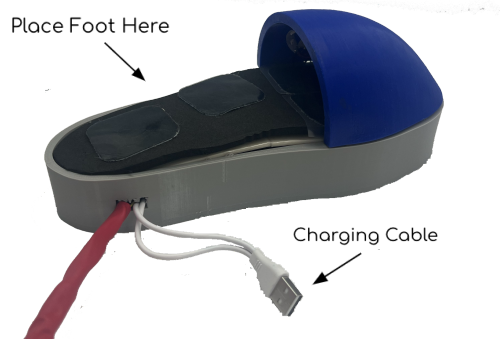


Figure 1. StepAhead Device Charging and Foot Placement Locations

Putting the Slipper On:

Once charged, confirm that the sole is inserted at the bottom of the slipper. Simply place the bottom of your foot in the slipper along the sole shown in figure 1 above. For best results the top of the slipper should be two fingers away from the top of the foot.

Using the Control Box:

To turn the device on simply switch the bottom right switch of the control box. The direction for power on and power off are easily labeled on the control box as seen in Figure 2.







Figure 2. StepAhead Control Box

Therapies can be selected from the physical control box:

- For IR therapy simply switch the middle switch of the control box labeled IR on (Figure 2) and use the device for your desired duration, typically 20 minutes or as prescribed by doctor.
- For TENS therapy simply switch the left switch in the middle of the control box labeled TENS(Figure 2). Once this has been completed, the desired mode can be specified using the joystick controller on the bottom left of the control box (Figure 2). Move the joystick in the direction of your desired therapy method. Table 1 below shows the differing offered therapy methods and their corresponding direction for selection. Therapies run for a specified duration, but can be overridden and turned off by flipping the switch on the control box.

Table 1. StepAhead TENS Therapy Modes

Mode	Feeling	Frequency (Hz)	Pulse Width (μ s)	Direction
1	Kneading massage	2	80	
2	Knocking massage	90	80	
3	Acupuncture	10	80	
4	Cupping	47	80	

To turn on the monitoring portion of the device, simply switch the right switch in the middle of the control box labeled monitoring.

Interpreting monitor readings:

The temperature and blood oxygen readings from the sensors are shown in the LCD screen on top of the control box. If StepAhead detects signs of infection or injuries, the word “Alert” will show on the screen, and the user is encouraged to inspect their foot for wounds and seek medical care promptly.

The thresholds for alert are based on literature research. Specifically, an elevation of temperature by 4°F or a drop of blood oxygen saturation to below 95% prompts the alert.

Cleaning and maintenance:

For best results, charge the StepAhead device daily or overnight.

The slipper should be cleaned using a disinfectant wipe or damp cloth weekly, but should not be run through a washing machine or submerged underwater. The sole at the bottom of the shoe is removable and washable or replaceable. It is recommended that the sole be replaced or thoroughly cleaned on a weekly basis, as it may come in contact with developing ulcers.

It is recommended to replace your StepAhead device after a year or so, depending on the frequency of use.

For disposal of the StepAhead slipper, follow national and local guidelines for disposal of devices containing batteries and electronics.

Storage:

For best results, store the StepAhead slipper in a dry, room-temperature location.

Do not cut, trim, or alter the sole or structure of the StepAhead slipper, as electronics and sensors may be affected.

Troubleshooting and Frequently Asked Questions:

Q: It seems that nothing is happening when I turn on the device and desired therapies. What should I do?

A: If it seems as if nothing is happening when the desired therapy or monitoring is turned on, turn the individual functionality switch off and try again. If the problem persists, turn on and off the whole device and confirm that the battery is fully charged. The StepAhead support line is also available should there be further issues.

Q: How often should I charge the device?

A: The batteries in the device can last for about three TENS sessions, three 20-minute IR sessions, and continuous monitoring during the sessions. It is recommended that you charge the device overnight if you plan to use the device the next day.

Q: How to interpret the results shown on the LCD screen?

A: The LCD screen displays the temperature and blood oxygen saturation levels of the foot. If only the two values are shown, it means that your temperature and blood oxygen levels are within the normal range and StepAhead has not detected any signs of infections or injuries in your foot. If the word “Alert” is shown, it means that the temperature and/or blood oxygen level measured is not within the normal threshold, and you are encouraged to seek medical care.

Q: What if the results shown on the LCD screen appear inconsistent or inaccurate?

A: If results shown on the LCD screen appear inconsistent or inaccurate, it is recommended to reach out to a medical care professional as soon as possible.

Q: I accidentally spilled liquid on the device or dropped it. What should I do?

A: You should wipe off any spillage as soon as possible and place the device in a dry environment. StepAhead is able to withstand some liquid spillage or external impact, so as long

as you did not immerse the device in liquid, drop it from an extremely high place, or let a very heavy object sit on top of it, the device should be able to continue to function normally. However, if some functionalities start to act abnormally, please refer to the previous questions for more information, or call the StepAhead support line.

Q: I have used StepAhead regularly for a while. How would I know if my DPN progresses or improves?

A: With regular use of IR and TENS, you should feel a decrease in pain in your foot and some recovery of protective sensation over time. If severe pain persists or new symptoms develop, please seek professional medical care promptly.

Appendix C: Engineering Drawings

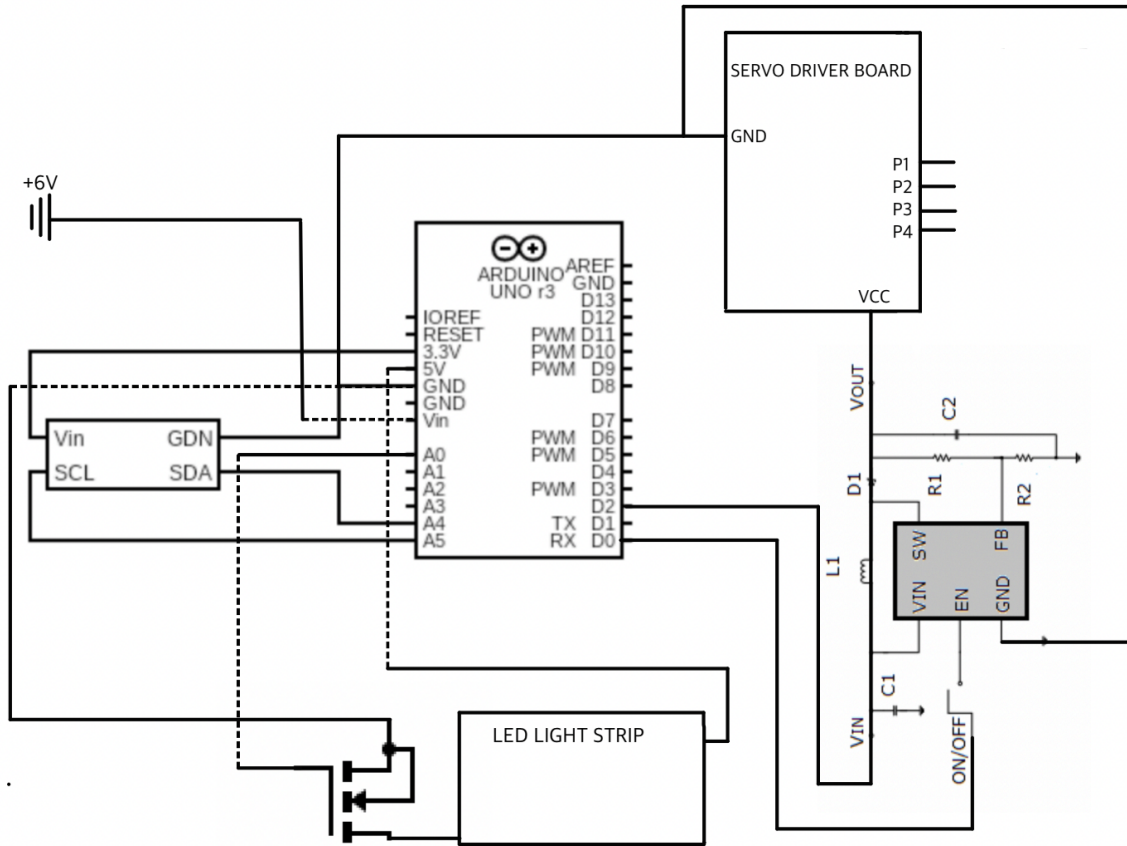


Figure C.1: Circuit Diagram. Electronic connections between component parts of the StepAhead device.

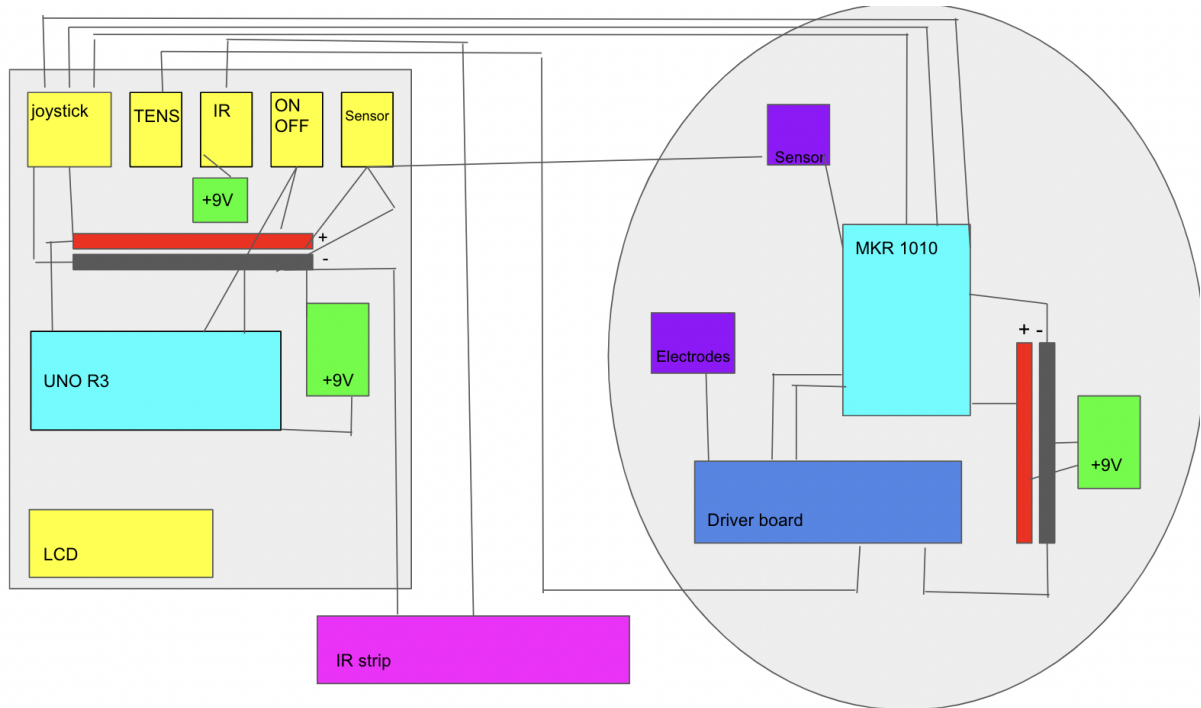


Figure C.2: Final wiring diagram. Individual circuitry components shown relative to their location in the final device.

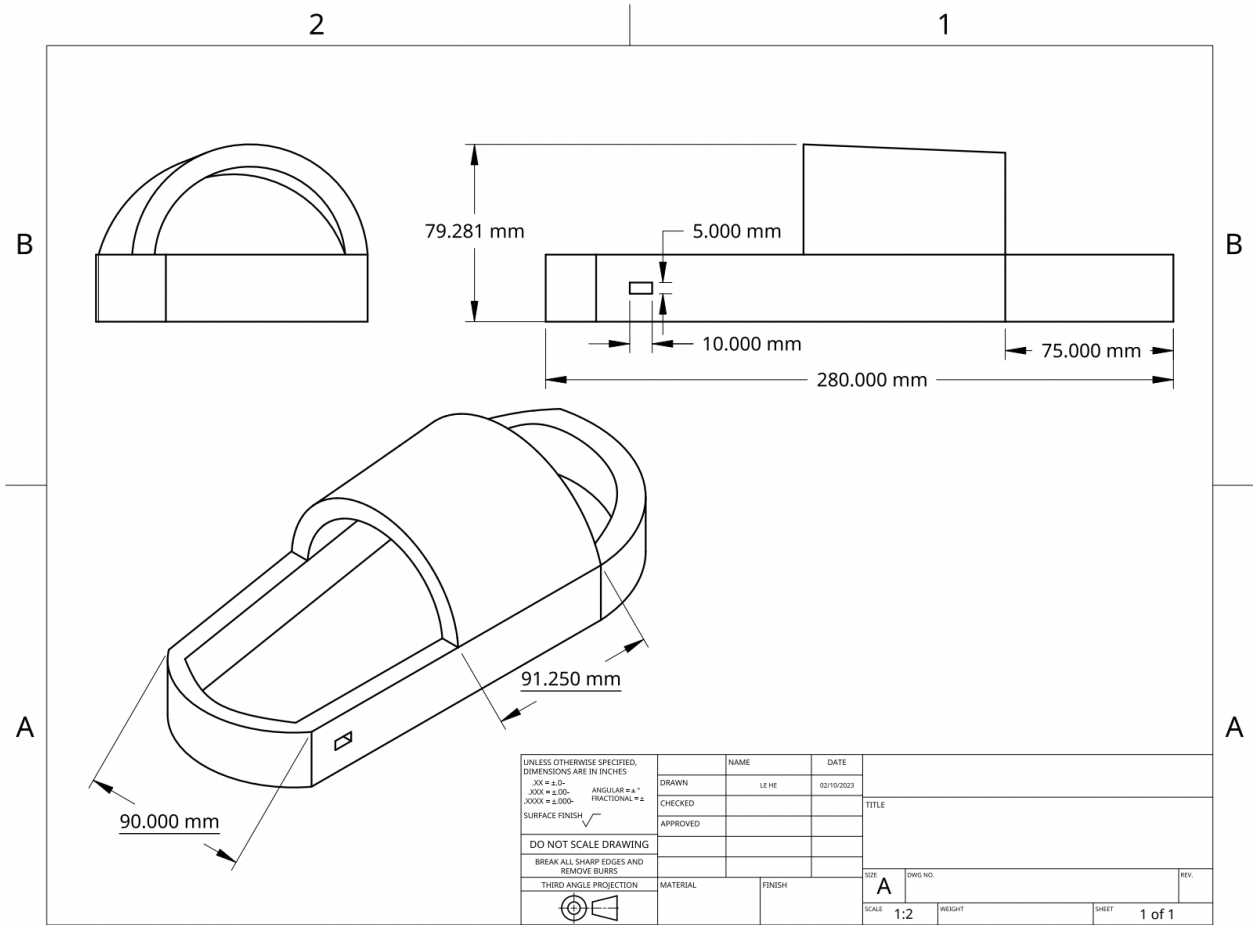


Figure C.3: Slipper CAD specifications. Dimensions and shape for the 3D printed slipper.