The Sweat Sucker 9000

Sweat Management Vacuum Attachment for Transfemoral Prosthetics

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Executive Summary

A common problem for many transfemoral amputees is excessive heat and moisture inside their prosthetic socket. Our group aims to tackle this problem by designing and developing a vacuum pump attachment focused on sweat management that is compatible with the many transfemoral prosthetic sockets that are already out there on the market today. The vacuum attachment aims to provide the amputee a comfortable fitting socket, while still being able to withstand daily and athletic use. The main needs of the consumer were generated through online research and interviews with a practicing prosthetist and a transfemoral amputee. Through our research and the interviews, our team has designed a vacuum pump attachment with an included sweat evacuation chamber that sits at the base of a transfemoral prosthetic socket.

The design of the vacuum pump focuses on creating a tight and secure fit of the prosthetic socket through vacuum suspension. Due to a low volume of air in the prosthetic socket, the vacuum pump requires minimal energy, with the majority of power consumption used when creating the initial seal of the socket to the residual limb. Once the target vacuum level is reached, the pump only needs to account for any vacuum losses. Our product is able to use a lightweight vacuum pump in order to achieve these requirements, as well as provide a comfortable and secure fit.

The product features a removable sweat evacuation container, allowing the user to periodically empty the container without having to remove their prosthetic. The sweat container will be housed in a cylindrical carbon-fiber design. The sweat chamber will be kept at a low pressure in order to pull sweat away from the prosthetic socket. Through the use of hydrophobic mesh, the sweat will be guided away from any electrical components and into the sweat container.

The net present value of our product is estimated at $12.8 million. This value is based on an average of 10,000 units sold per year with a retail price of $1,600 at a production cost of $400.

In order to remove sweat buildup, amputees need to remove their entire prosthesis to dump out any pooling sweat contained in the socket. This is both indiscreet and unsanitary. Our product focuses on better sweat management in prostheses, allowing users to dispose of sweat in a more discreet and less cumbersome way. We introduce the Sweat Sucker 9000.

Mission Statement

Despite fast growing improvements and new technology continuously emerging in the medical field, amputation is still a very common phenomenon. In 2004, over 1.2 million people in the United States suffered from limb loss, with nearly one fifth of them being transfemoral amputations (across the femur).[1] Studies have shown that of those who are able to afford a prosthesis, 72% of people have problems with heat and sweating in the socket, and 57% are dissatisfied with the comfort of their prosthesis.[2]

The top main issues with today's prosthetic sockets include improper size and fit, skin irritation due to sharp edges and rubbing, and sweat accumulation within the socket. While many products on the market attempt to tackle a better fitting and more comfortable prosthesis, there have been very few products aimed towards solving the sweat accumulation problem within the socket, a problem that remains a daily concern and hindrance for many users.

Our group has designed and developed a vacuum pump attachment for transfemoral prosthetic sockets that focuses on providing a comfortable fit to the user and manages sweat collection in the prosthetic socket. Table 1 provides a more detailed description behind the mission statement.

Table 1: Mission Statement for Vacuum Pump Attachment for Transfemoral Prosthetic Sockets

Mission Statement: The Sweat Sucker 9000	
Benefit Proposition	- Easily accessible and removable sweat collection chamber - Ability to monitor liquid level in sweat chamber, sweat analysis, pressure, temperature, and battery levels - Durable against daily and athletic use
Key Business Goals	- Launch in Spring 2024 - Competitive pricing allows for target sales volume and margin - Profitable in 2nd quarter of year 2 - 10% growth
Primary Market	- Transfemoral amputees

Secondary Market	- Prosthetic Device Companies - Hospitals
Assumptions and Constraints	- Compatible with different transfemoral prosthetic sockets - Replaceable lithium ion battery
Stakeholders	- User - Retailers - Employees - Production department - Sales force - Service center - Legal department

Project Management Plan

The Project Management Plan was developed in order to help outline the necessary steps needed to create and prototype the design of the vacuum pump attachment. The team contacted a number of Oregon State University (OSU) faculty members as mentors and advisors for this project. Joe Baio, assistant professor in the college of Chemical, Biological, and Environmental Engineering, and John Selker, a distinguished professor in the college of Biological and Ecological Engineering, helped the team with the development and conceptual design of the final product. The team would like to extend special thanks to Emma Gibbs, an OSU alum and practicing professional prosthetist, and Rebecca Johnston, a Whitman College graduate and transfemoral amputee, for their willingness to be interviewed and provide research data and assistance in the development of the final product design.

Below is a Gantt chart (Figure 1) that provides a detailed timeline of the designing and prototyping process of the vacuum pump attachment within the given 10 week deadline. In addition, a design structure matrix was created in determining the order in which tasks can be completed and which tasks can be performed simultaneously (Figure 2).

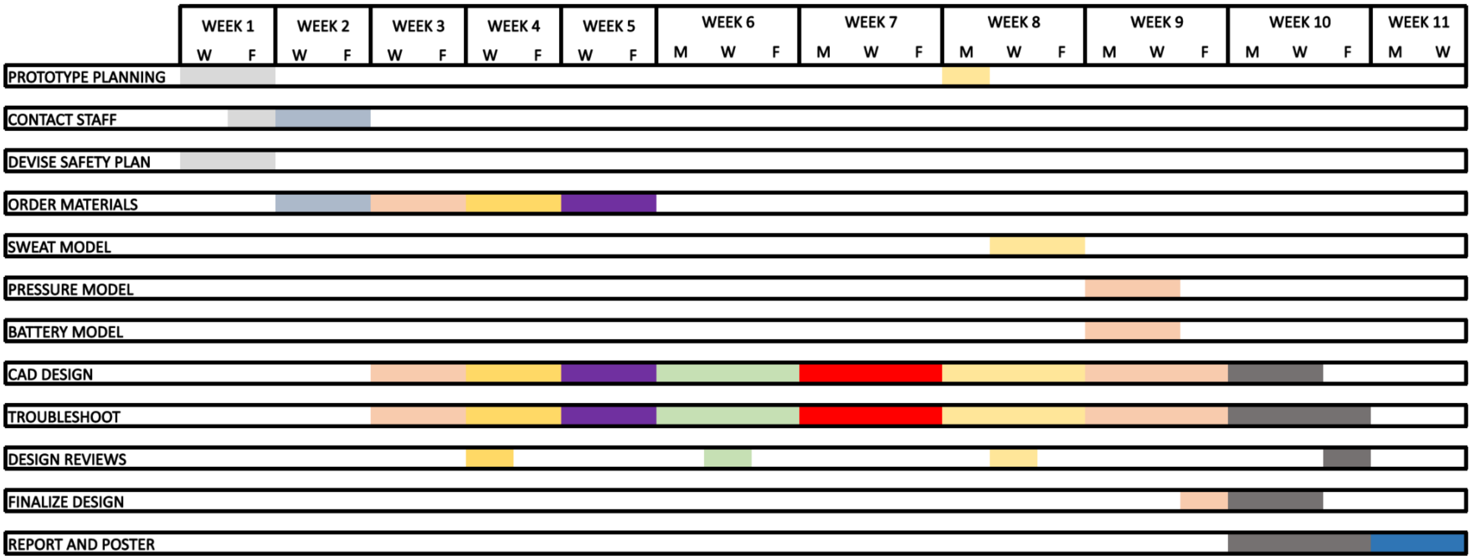


Figure 1 displays a Gant chart of the overall timeline in designing and prototyping the vacuum pump attachment.

Tasks		A	B	C	D	E	F	G	H
Asses safety risks	A	A						X	
Select materials	B	X	B	X		X	X	X	
Order Materials	C		X	C				X	
Contact Faculty	D				D		X	X	
Cost determination	E		X			E		X	
(3D print needed material)	F		X				F	X	
Assemble Vacuum prototype	G		X	X				G	
Assemble CAD model	H			X					H

Figure 2 provides a simple design structure matrix for the vacuum pump attachment product.

There were three main models that the team prototyped for the vacuum pump attachment. The first prototype was the sweat collection rate model (Table 2). This model determined how much sweat the vacuum pump could collect over a certain period of time. The second model prototyped the amount of power needed for the vacuum pump to last 12 hours (Table 3). The third model calculated the pressure loss within the vacuum chamber (Table 4). In addition, the computer-aided design software, SolidWorks, was used to model the stress of human activity and the weight of certain materials to determine which material would be best for the housing of the vacuum pump.

Table 2: Sweat Collection Model Prototyping Plan

Name of Model	**How much sweat can the vacuum collect over time?**
Purpose	Determine how much sweat a vacuum maintained at X pressure will draw away from a surface
Level of Approximation	Amount of liquid volume collected in a fixed amount of time
Experimental Plan	- Connect vacuum to a sealed container that contains a sponge saturated with water - Utilize a hydrophobic mesh to diverge sweat mixture into the collection container that will allow air to pass through - Set vacuum to desired power level required (1 amp, 12 volts) for desired pressure for a fixed amount of time - Monitor how much sweat is collected over time
Schedule	- 20 January: Select/order Materials and work on liquid separation filter design - 27 January: Finalize and Print liquid separation filter - 3 February: Assemble apparatus without sponge and test vacuum with sweat collection unit attached - 10 February: Saturate sponge with artificial sweat solution, place in cylinder (vacuum chamber), turn on the vacuum, and monitor for 2 hours. Check volume of sweat in collection unit - 17 February: Scale model in excel - 24 February: Final testing completed - 3 March: Analysis and Report of testing completed

Table 3: Vacuum Power Model Prototyping Plan

Name of Model	**How much power does the vacuum require for 12 hours of use?**
Purpose	Determine the power draw or the vacuum for the duration of use to find the necessary battery capacity
Level of Approximation	Voltage, aH of battery, Size, Weight
Experimental Plan	- Vacuum attached to a sealed cylinder with appropriate volume to represent free air space in the actual socket - Monitor wattage used by vacuum and pressure inside of the cylinder - Turn on the vacuum and track power levels using the same apparatus as the sweat collection model with the vacuum plugged into 120 V plug in - Leave the vacuum on for a fixed time and track aH used
Schedule	- 20 January: Select/order Materials and work on liquid separation filter design - 27 January: Finalize and Print liquid separation filter - 3 February: Assemble apparatus without sponge and test vacuum with sweat collection unit attached - 10 February: Saturate sponge with artificial sweat solution, place in cylinder (vacuum chamber), turn on the vacuum, and monitor for 2 hours. Check volume of sweat in collection unit - 17 February: Scale model in excel - 24 February: Final testing completed - 3 March: Analysis and Report of testing completed

Table 4: Pressure Loss Model Prototyping Plan

Name of Model	**Pressure loss from removing sweat chamber**
Purpose	Determine the extra energy required to pump for emptying the chamber a number of average times per duration of use
Level of Approximation	kPa, aH
Experimental Plan	- Add flap valve to cylinder representing the socket that snaps shut when sweat container is removed - Attach barometer to vacuum chamber and power sensor to wire - Turn on vacuum to get the chamber to the desired pressure - Remove the sweat collection unit breaking the vacuum, pressure difference drives flap closed - Track pressure loss and power consumption required to reapply vacuum
Schedule	- 20 January: Select and order materials needed - 27 January: Finalize the design of the vacuum and sweat chambers - 10 February: Assemble the model and test - 17 February: Scale model in excel - 24 February: Final testing completed - 3 March: Analysis and Report of testing completed

A safety plan (Table 5) was also created to identify any potential risks when working with necessary machinery, like a 3D printer, and other objects and materials during the prototyping process.

Table 5: Safety Plan for the Vacuum Pump Attachment

Risks	**Mitigation**
Electrocution	Keep water away from electrical components, do not remove the grounding prong from the plug. Keep tools away from hot wires.
Water/Liquid Spills	Immediately clean up the spill. Notify staff and everyone in the vicinity. Put up necessary signage.
Burns	Allow the machine to cool before touching the product and wear gloves when handling finished pieces. Know location of emergency first aid kit.
Liquid and Solid Waste Disposal	All members know proper disposal procedures for all equipment and materials.
UFP’s/Dust	Wear an appropriate face mask and eye protection. Leave the vicinity when the 3D printer is working. Periodically check on machine progress.
Explosions	Wear safety glasses. Pay attention to safety alerts from the machine.
Fire	Locate the fire extinguisher, check if it’s been serviced, learn how to use it. In the event of a large fire: Yell “fire” and run, preferably away from the flames. If on fire: Stop, drop, and roll.
Exposure to UV light	Avoid eye contact with the light. Wear appropriate protective gear.

Competitive Benchmarking

The prosthetic market is huge, with an estimated global market size of $9.64 billion. By 2030, it is projected to rise to $14.3 billion.[3] Limb loss covers a big chunk within the prosthetic market, with a global estimate of limb prosthetics projected to grow from $1.61 billion in 2022 to $2.33 billion by 2029 and a compound annual growth rate (CAGR) of 5.4% in the forecasted period. [4,5]

Though difficult with such a big market size, our team's main priority was to find a niche field in the world of prosthetics. The majority of our members were already very passionate about working with transfemoral prosthetic limbs. Thus, the specification of where on the body and what problem our team wanted to solve was already apparent. Yet, with the many different parts, needs, and issues concerning current prosthetic limbs, our team had to find a problem that really stuck out to all of us.

Our team originally focused on solving current problems user's have with the comfort, fit, sizing, and functionality of transfemoral prosthetic limbs. Our team found that the current transfemoral prosthetic sockets on today's market did not address many of these concerns, with the main focus on the functionality aspect of the socket. Thus, entry level prosthetics are often uncomfortable. Some are even unwearable at times due to unnatural angles, uncomfortable material, improper sizing, etc.

Through interviews with prosthetist experts and limb amputees about the overall landscape of transfemoral prosthetics, our team learned that an estimated 72% of people have issues with sweating and heat within their socket.[2] This is a main concern of users, as the heat and sweat allow for lubrication within the socket, resulting in unwanted movement of the limb within the socket. This friction between the limb and socket leads to painful blisters and sores.

Thus, managing and eliminating the sweat within the socket became our team's main priority. There are not a lot of resources available for removing sweat from the socket on the current market. Users have to fully take off their prosthesis, manually dump out the sweat, and clean the socket before attaching it back to the residual limb. [6]

Companies, such as Össur, have found a way to increase the comfort, stability, and responsiveness of their prosthetic sockets. The Direct Socket TF, a socket that does not require a liner, is an excellent product due to its robustness, secure but flexible, responsive design, providing the user very little, if any, discomfort, during use.[7] Other companies, such as Ottobock, have already created devices that can vacuum seal the prosthetic socket to the residual limb. This enhances the user's control and provides a better fit of the prosthetic limb during all types of activity and conditions.[8] However, both companies have still not focused on nor have found a way to combat sweat accumulation inside the prosthetic socket.

Using a similar concept to Ottobock's vacuum control and prioritizing sweat management inside the prosthetic socket, our team has developed a device that is able to suck out the sweat within the socket without the user having to completely remove their socket. Our design ensures comfort and stability, whilst reducing the risk of sores and limb movement within the socket through the removal of moisture.

Metrics and Final Specifications

To design the vacuum pump attachment, the team generated a hierarchical list of needs and specifications of prosthetic sockets determined from information gathered through research data and the personal interviews with Gibbs and Johnston.

List of Needs Statements:

* The prosthetic socket is affordable
*** The prosthetic socket accommodates for changes in body type
** The prosthetic socket is adjustable (automatically or manually)
** The prosthetic socket is easy to use without extensive training
* The prosthetic socket can withstand athletic activity
** The prosthetic socket is usable for sustained periods of time
** The prosthetic socket withstands years of daily use
! The prosthetic socket is swappable/replaceable
*** The prosthetic socket is usable in a wide range of temperatures
* The prosthetic socket can be used with various attachments (running leg, daily leg,etc.)
* The prosthetic socket has a universal joint for other attachments on the market
** The prosthetic socket is easily clean
*** The integrity of the prosthetic socket is not compromised by water/perspiration
! The prosthetic gives an indication of fit quality
* The prosthetic has an indicator for replacement required
*** The prosthetic socket material is non-irritating

Hierarchical list of primary and secondary customer needs for the thermostat. Importance ratings for the secondary needs are indicated by the number of ''s', with '***' denoting critically important needs. Latent needs are denoted by '!'.*

In addition to the needs statements that were generated above, a list of metrics was created in order to consider precise, measurable characteristics of the product (Figure 3). This process is to help determine how the product can help satisfy certain need statements.

Metric #	Need #'s	Metric	IMP	Units	Tech Specs
1	2, 3, 14	Good Fit	5	Scale	7-10
2	6, 7, 16	Duration Socket can be worn (daily activity)	5	hrs	20hrs
3	5, 6, 7	Duration Socket can be worn (athletic activity)	5	hrs	5 hrs
4	5, 7	Force before loss of structural integrity	3	N	2000
5	3, 4, 8, 10	Time to set up	1	mins	5 mins
6	10, 11	Compatibility with other existing products	3	List	
7	5, 6, 9	Breathability	3	R.E.T.	
8	6	Charge duration	4	hrs	20 hrs
9	10, 11	Compare to singe use alternatives (athletic vs. daily)	2	Score	
10	1, 10	Cost	4	$	500 - 10k
11	12, 13	Machine washable	1	Y/N	
12	5, 6, 7, 15	Longevity	3	years	3-5
13	2, 3, 16	Comfort	5	Scale	7-10

Figure 3 provides a chart of corresponding specifications (metrics, units, limitations) to each of the need statements.

Design Solution Concepts

After narrowing our focus on the problem of sweat management in prosthetic sockets and with continued research through interviews, scientific journals, etc., our team created a list of possible design solutions.

Possible Concepts

1. User operated hand lever/dial to drive hydraulic fluid in order to force viscous gel into gel matrix within carbon fiber socket to achieve desired pressure and fit
    a. No energy storage needed
    b. User sets pressure manually
    c. Doesn't automatically adjust during activity
    d. No chance for computer error
    e. Matrix would allow moisture to move away from the body
2. Heat activated gel inside matrix in a socket hardens in response to body heat to create a secure fit
    a. No energy storage needed (no charge time)
    b. Fit can change in response to body changes (resets at night when taken off)
    c. Doesn't allow for as much adjustment
3. Battery powered rotary pump attached to the socket that pumps gel into a matrix inside of the socket which surrounds the limb
    a. Computer system could monitor the pressure and fit
    b. Battery powered means we would need to optimize charging and run time
    c. Would need a reservoir to store extra gel
    d. Gel would be cushioning but allow for a snug fit
    e. Matrix would allow for sweat to sit away from the skin
4. Battery powered vacuum pump that pumps air out of the socket creating a seal on users appendage with sweat release
    a. Could incorporate a vent/exit for perspiration
    b. Vacuum would create a strong seal
    c. Carbon fiber shell
5. Suction fit prosthetic with an easily removable wicking sleeve/liner

   a. No energy required
   b. Wicking sleeve is removed as leg is inserted to create tight fit with little friction from leg-against-plastic
6. Airbag like sock for limb that goes inside prosthetic socket
   a. Ample cushion
   b. No energy needed on the prosthetic, pump could be external one time fill up
   c. Major con: Sweat and perspiration, probably control as well
7. Self casting gel socket
   a. Most prosthetic sockets have to be cast at a doctors office
   b. If socket could be “made” at home it could help patients in areas or situations where they can’t receive treatment
   c. Could be battery powered or manual
8. Multi-material socket
   a. Keep hard shell for structure but use flexible material in sensitive areas
   b. Flexible materials is able to change with changing limb
   c. Cons: probably sweat/heat
9. 3D-printed adjustable socket
   a. Customizable
   b. Modular to be able to be more adjustable
   c. More accessible if you have access to a 3D printer or company

In addition, our team created a table of possible materials that could be used in designing the final product (Table 6).

Table 6: Possible Material Choices for Final Product

Energy Storage	**Power Source**	**Material (for fit)**	**Material for cast**	**UI Method**
Battery (rechargeable)	Hydraulic lever	Non-newtonian fluid	Carbon Fiber	Hand dial on prosthetic
	Rotary pump	Viscous gel	Neoprene liner	Computer

				system
	Kinetic Movement	Compressed gas (inflatable)	Kevlar	Better grip/handle for pulling on
Body heat	Heat	Heat activated gel	Composite Materials	Pull cord (tying shoes)
		Vacuum socket		
		Hydrogel		

After generating this list of concept solutions, our team voted on the top three ideas that we all had interest in. Our team's top three concept solutions were:

1. User operated hand lever/dial to drive hydraulic fluid in order to force viscous gel into gel matrix within carbon fiber socket to achieve desired pressure and fit.

2. Battery powered vacuum pump that pumps air out of the socket creating a seal on users appendage with sweat release.

3. 3D-printed adjustable socket.

Concept Selection

In order to determine our product, our team created a concept-scoring matrix that used weighted categories based on a collective belief of importance (Figure 4). These categories included the cost, comfort, duration of which the product can be worn, flexibility in conforming to the residual limb, adjustability, ease of use, management of perspiration, breathability, the quality of fit, and the responsiveness of the product. Our team prioritized the comfort of the product, as we believed it would be the most representative category of customer satisfaction, followed by the management of sweat/perspiration.The lack of a solution to sweat management in prosthetic devices appears to be the largest impact to patient comfort based on our research.

			Concepts:				
		Adjustable Gel Filled Liner		Vacuum Pump w/ Sweat Release		3-D Printed Adjustable Socket (w/ Liner)	
Selection Criteria	**Weight %**	**Rating**	**Weighted Score**	**Rating**	**Weighted Score**	**Rating**	**Weighted Score**
Comfort	25.00%	4	1	3	0.75	4	1
Cost	5.00%	1	0.05	2	0.1	4	0.2
Duration can be worn (Battery/Comfort)	12.50%	5	0.625	3	0.375	4	0.5
Flexible/Changes w/body	5.00%	4	0.2	2	0.1	3	0.15
Adjustability	7.50%	4	0.3	1	0.075	3	0.225
Ease of use	7.50%	2	0.15	4	0.3	4	0.3
Water/Perspiration	20.00%	3	0.6	5	1	2	0.4
Breathablity	2.50%	3	0.075	2	0.05	2	0.05
Goodness of Fit	7.50%	4	0.3	4	0.3	3	0.225
Responsiveness	7.50%	1	0.075	4	0.3	4	0.3
	100.00%						
Total Score (1-5)			**3.375**		**3.35**		**3.35**
Rank			1		2		2
Prefered Rank			**2**		**1**		**3**

Figure 4 provides a concept-scoring matrix. This method used a weighted sum of the ratings to determine the concept ranks.

All of the design concept scores were close, with the adjustable gel filled liner in the top spot and the vacuum pump with sweat release and 3D-printed adjustable socket tied for second place. However, our team believed that the vacuum pump with sweat release concept would provide a better solution to the sweat management problem than the other two concepts. Thus, our final preferred top concept was the vacuum pump with sweat release.

Final Project Concept

Our final project concept was a vacuum pump attachment to mount between a customer provided socket and knee for transfemoral amputees. While we initially planned to encompass a socket into the design, it became clear that the unique geometry of patient limbs would make this task extremely challenging. We opted instead to cut the socket from the design, and focus on the sweat evacuation system. Considering the biomechanical importance of the location of the knee, we aimed to make our attachment as small as possible. Outside of its scale, the design features a cylindrical design with a vertical diaphragm separating 2 halves. One side houses a vacuum pump, battery, and sensor package at atmospheric pressure. The other side contains a removable sweat catch, kept at low pressure to pull sweat from the socket which is guided into said catch with a hydrophobic mesh. The product is vertically split in half in order to place components and to clean the product. We modeled an assembly process fitting our design language, utilizing clips to secure the halves in order to give the user definitive proof of properly located pieces. A CAD model of the final design is presented below (Figure 5).

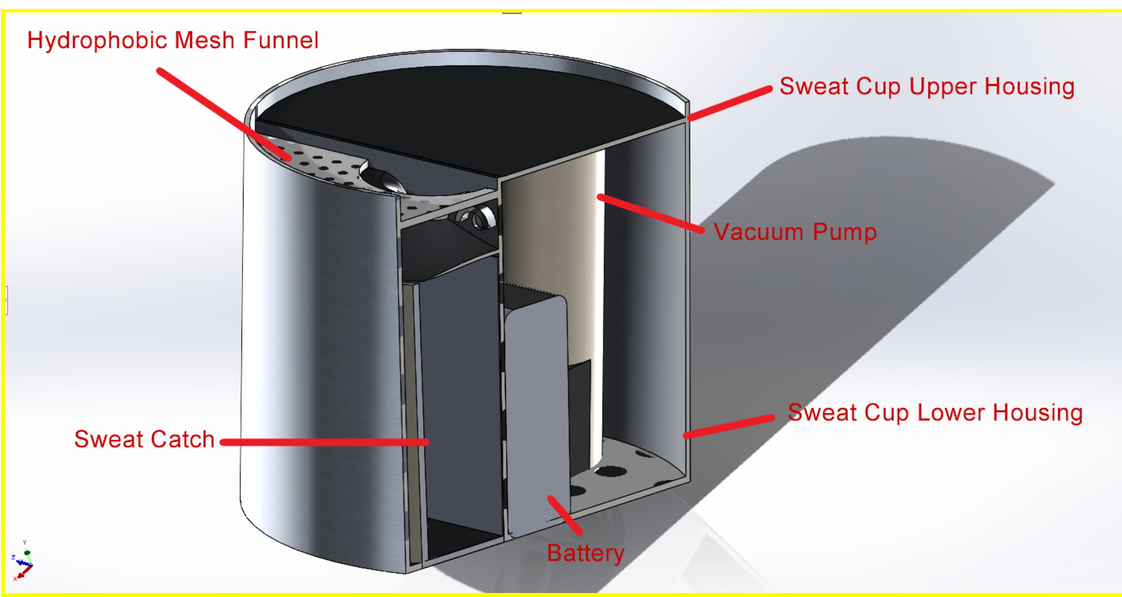


Figure 5 provides a simplistic breakdown of the major design features of the product.

Engineering Analysis of Design

Theoretical analysis and considerations

There were several considerations made when determining how to approach the design. For the safety of the consumer, we needed to ensure that the product could withstand the forces it was expected to endure. Additionally, we wanted a product that could run for a 12 hour period in order to fulfill a normal day's-worth of activity, so the power usage of the device needed to be determined, as well as the rate of pressure loss. If the product was to remove sweat, we needed to determine the rate of sweating for the average person to find a reasonable volume of sweat-catch to match our target needs.

Mathematical Calculations

The modeling of sweat tries to address the issue of fluid build up, the friction and movement that it causes within the socket, generating a lot of pain for the patient. For this, parameters such as the length and circumference of the leg were needed, the sweat rate per area, duration of the prosthetic use and the sweat storage capacity. All of these variables were then used to determine the sweat expulsion over the usage time. Figure 6 shows an example of the model using average leg dimensions for a male transfemoral socket. The sweat rate per area ranges from 8 to 15 grams per minute per square meter. This range is for active movement, but was selected to provide an overestimation of the sweat produced over time in order to make sure that all sweat is emptied and accounted for.

Variables:		
Leg Circumference	0.40	m
Length of Appendage	0.20	m
Diameter of Leg	0.10	m
Surface Area of Appendage	0.0879	m^2
Sweat Rate Per Area	9.00	g/min*m^2
Sweat Rate	0.791	g/min
Duration of Use (Daily)	10	hours
Total Sweat	474	mL
Sweat Rate	47.4	mL/hour
Storage Capacity	80.0	mL
Empty Sweat Every:	1.69	hours

Figure 6 provides a mathematical model for sweat production of the residual limb.

The second mathematical model we created was to figure out how much power was required to provide a vacuum to the appendage inside the socket. Input parameters include: volume of free air space in socket, desired vacuum pressure, assumed losses with daily use, duration of use, and desired socket application time. The main outputs of this model include the power requirements to create the initial vacuum and to maintain vacuum throughout daily use.

Figure 7 shows an example using dimensions of an average adult male leg. We assumed that the free air space in the socket would be about 15 percent of the volume of the appendage. Our selected vacuum pressure was 30 kilopascals as this is within the average range for existing vacuum sockets. We also assumed a 15 percent vacuum loss per hour for daily use.

Model for Wattage required to maintain vacuum at desired pressure with normal vacuum losses

	Leg Circumference	0.4	m	
	Length of Appendage	0.2	m	
	Diameter of Leg	0.1	m	
	Surface Area of Appendage	0.0879	m^2	
	Volume of Appendage	0.00157	m^3	
	Volume of Free Air Space in Socket	0.000236	m^3	
	Atomspheric Pressure	101.325	kPa	
	Desired Vacuum Pressure Level	30	kPa	
	Air volume Pumped out Initially	0.000236	m^3	
	Initial Pump Time	0.5	mins	
	Flow rate Required for initial vacuum	0.000574	m^3/min	
	Flow rate Requited for initial vacuum	0.574	L/min	
	Pressure in socket with 15% vacuum loss/hour	36	kPa	
	Flow rate required for losses	8.59E-05	m^3/min	
	Flow rate required for losses	0.0859	L/min	

Figure 7 provides an example of the mathematical model for the power requirements of the vacuum pump using dimensions of an average adult male leg.

With an operating time of 10 hours, the vacuum requires 114 milliwatts per day based on power equations for rotary pump vacuums and typical power losses. While this is a small amount of power, it is likely due to the small volume of free air space in the socket, as well as limited vacuum loss assumed by our model. These calculations can be seen in Figure 8.

Model for Wattage required to maintain vacuum at desired pressure with normal vacuum losses				
	Leg Circumference	0.4	m	
	Length of Appendage	0.2	m	
	Diameter of Leg	0.1	m	
	Surface Area of Appendage	0.0879	m^2	
	Volume of Appendage	0.00157	m^3	
	Volume of Free Air Space in Socket	0.000236	m^3	
	Atomspheric Pressure	101.325	kPa	
	Desired Vacuum Pressure Level	30	kPa	
	Air volume Pumped out Initially	0.000236	m^3	0.2356
	Initial Pump Time	0.5	mins	
	Flow rate Required for initial vacuum	0.000574	m^3/min	
	Flow rate Requited for initial vacuum	0.574	L/min	
	Pressure in socket with 15% vacuum loss/hour	36	kPa	
	Flow rate required for losses	8.59E-05	m^3/min	
	Flow rate required for losses	0.0859	L/min	
	Power initial	0.000682	kW	
	dP	71.3	kPa	
	Q	0.574	L/min	
	Power after energy losses	1.14E-03	kW	
	Power after energy losses	1.1366	W	
	Power for Vacuum Loss per hour	8.59E-06	kW/hour	
	dp	6	kPa	
	Q	0.0859	L/min	
	Time of daily use	12	hours	
	Power for Daily Vacuum Loss	0.000103	kW	
		0.103	W	
	Power for Daily Vacuum Loss w/ energy losses	0.172	W	
	Total Daily Power Requirement	1.240	W	
		1240	mW	

Figure 8 shows the daily power requirement of the vacuum pump.

Prototype descriptions and testing efforts

In order to accomplish these goals, we planned several prototype models. First, we built the product in Solidworks to apply simulations. The first simulation we used was for environmental sustainability in which we compared material choice between aluminum and carbon fiber. The materials showed comparable strength, but we wanted a material that would be economical and environmentally friendly to produce. Ultimately, we recognized that although aluminum is typically more eco-friendly to produce, it would require the design to be milled from an aluminum block which would be very expensive. We then used a Von Mises stress analysis to find the deformation of the product under a 300 pound force, which we used to increase the thickness of our product walls.

After modeling our design in Solidworks, we switched to working on physical prototypes to gather real use data. We planned a physical design prototype that could be utilized for several tests. The prototype was built with a water bottle to be used as a pressure vessel, with a hole drilled through the top to fit the pump inlet tube and pressure sensor wires. Inside, a water-soaked sponge fits within a funnel above a glass. We then applied several tests with the prototype.

Our first test involved checking the rate at which water could be pulled from the sponge under vacuum. The goal of this test was to prove that the sweat produced by the patient would be drawn into the cup through a pressure differential additional to the gravitational force. In the real product model, this would optimally draw moisture away from geometry that sweat might pool in. We found that the pressure difference increased the rate moisture was pulled into the catch, collecting the liquid at a rate twice as fast as without the vacuum.

Our second test focused on determining the pressure the pump was able to draw, the time to reach the target pressure, and the pressure loss over time. We utilized the same physical prototype but plotted our pressure over time. Unfortunately, our example pump was unable to reach the target 600 hPa, dropping to only 820 hPa inside our pressure chamber. We determined that by decreasing pressure leaks between the lid and inlet tube we could drop the pressure lower, so the inability to reach the target pressure was likely due to the rate of the pressure escaping rather than mechanical inability. In our final product, the utilization of rubber gaskets and one-way valves should compensate for the pressure leaks, improving the seal under vacuum. It took approximately 40 seconds for the container.

In tandem with our pressure readings, we noted the amperage drain by the product at 12 volts was approximately 0.7 Amps. By multiplying our voltage, amperage, and the amount of time the pump would need to be run in a day based on the pressure drop speed, we found we needed a battery capacity of 9500 mAh. Please note that these results were obtained using our prototype pump. By improving the seals of the actual final product, as well as using a higher quality vacuum pump, the energy capacity needs will greatly decrease.

Our third model measured the amount of pressure loss in the vacuum in order to determine how often the vacuum pump would need to activate to keep the seal on the residual limb. The same prototype setup was used for this experiment as well. The tubing from the vacuum chamber to the vacuum pump was clamped to ensure no air could flow back through the pump itself. The pressure change as the air made its way into the vacuum chamber was then graphed (Figure 9).

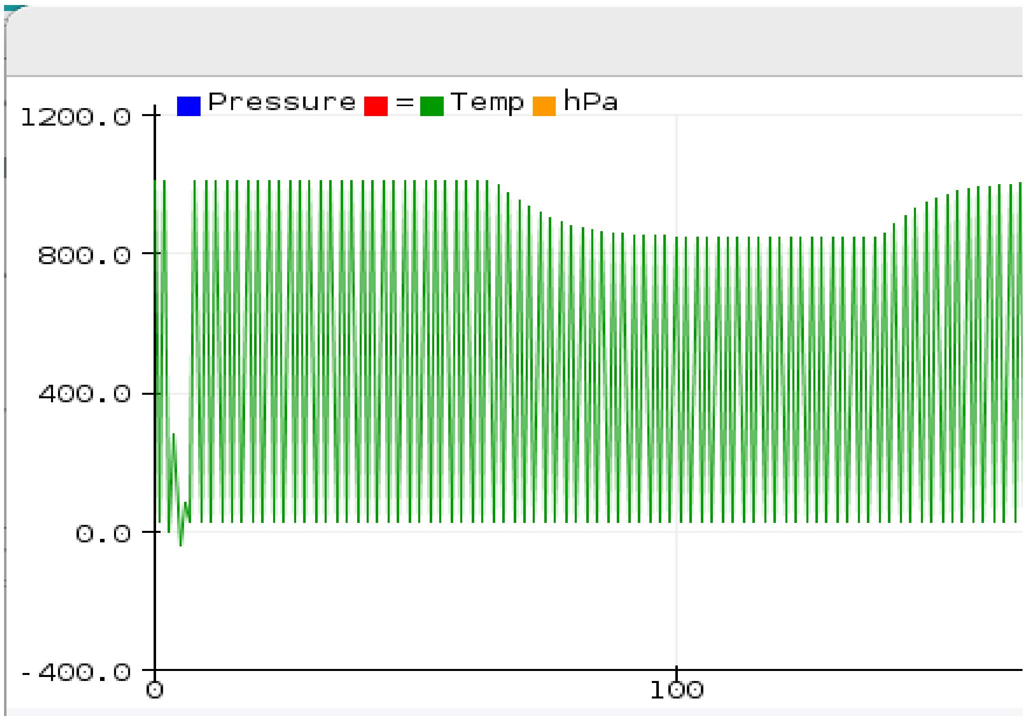


Figure 9 provides data of the pressure loss in our prototype setup.

It was found that the lowest achievable pressure was around 80 kPa. Our target range was between 50 to 80 kPa. It took about 50 seconds to reach the minimum pressure. The pressure losses of our prototype setup were rapid due to design constraints. In the final product and design, necessary gaskets and valves will be used to fully seal the chamber. This will help drastically reduce the amount of pressure loss, which, in turn, will increase the time between vacuum pump activation. In addition, with less vacuum engagement, the energy consumption of the product will decrease.

Human Factors Considerations

There are a few factors that must be considered for the use of our product. First and foremost, our product must be safe for the user. Second, the product must be easy to use and/or troubleshoot. Lastly, the user should enjoy using our product.

The primary safety concern in our product is the stability of our battery and electronic components. Batteries have the potential to overheat and even explode. To ensure that our product is safe, we will include a shut down mechanism in our code for pump operation. This code will shut off power delivery from the battery for a variety of scenarios. These can include, but aren't limited to, the temperature getting too high, the power levels getting too low, or the pressure getting too low for the user's limb. Also, as water and humidity can affect batteries, our product will completely isolate the battery from the environment and sweat cup. This will be done using a one way valve and gaskets between the chamber walls. This failsafe and water barrier will ensure that the battery does not pose any safety risk for the user. Similar to the battery failsafe, a similar system will be implemented monitoring the vacuum pump.

Our product is designed to be easily used by our users. First, we will provide a detailed manual for how to use, clean, and maintain our product. This will include how to adjust vacuum power levels, which, in turn, will control the pressure inside of the socket. There will also be instructions for removing the sweat cup while maintaining vacuum pressure in the socket. The product can easily be taken apart utilizing a system of clamps. This will make it easy for the user to remove and charge the battery, as well as clean the other components after use. With our simple yet robust design, users should have no problem learning how to use our system with the provided manual.

The third consideration for our customers is their experience while using the product. First, our product will provide the user with a secure and comfortable fit while drawing away sweat to a confined space in their prosthetic. This will allow for a more discrete method of sweat disposal, as well as a more comfortable fit than other prosthetics on the market. Another consideration is the noise made by our vacuum pump. To mitigate this we will not only be using one of the highest quality vacuum pumps on the market, but we also plan on adding acoustic foam to our housing. This will decrease the noise made by the pump as much as possible to make sure that the user has an enjoyable and discrete experience when using our product both in public and private spaces.

These considerations place user safety as the absolute key priority. However, we also consider other aspects of the user experience in order to provide the best product available. Our users will enjoy using our product because of its reliability and usability.

Design for Manufacturing

In designing, our team paid careful attention to how we were going to manufacture our product. Some of these considerations include our product assembly, sourcing of materials, housing construction, and standardization of assembly methods.

Both the vacuum pump and battery will be contracted and purchased from another manufacturer. This will save money by not having to design our own batteries or vacuum pumps. We also will not have to spend time and money manufacturing these components. The printed circuit board (PCB) and the pressure and temperature sensor will also be sourced from another company. The rest of the components will be assembled in house with the exception of the valves which are cheaper to purchase.

Product assembly will be as streamlined as possible using vertical assembly. The housing will be molded in two separate pieces including a top and bottom. Both the top and bottom elements of the housing will have snap-in locations for the battery, the PCB board, and the vacuum pump. This will eliminate the need for the use of screws or fasteners. The top and bottom pieces of the shell will have rubber gaskets, one way valves, and clamps placed on them by either a trained factory worker or a robot. The vacuum tubing will be cut to a specific length with the hydrophobic mesh attached via a rubber gasket. This tubing will be connected to the shell prior to the vacuum pump being inserted. After insertion, the tubing can easily be slid over the inlet of the vacuum pump. The pressure sensor will be connected to the PCB board by a trained worker, however, the battery will not be connected as the user will be able to do this themselves after shipping. This will allow for the product to be vertically assembled with its components all together after placing the vacuum pump and battery in place.

After the shell and inner components have been assembled, a worker will select the appropriate socket and leg fittings for the user's specific prosthetic. To secure the fitting, the factory worker will use a resin epoxy designed for joining the aluminum fitting with the carbon fiber housing.

Once the internal components are attached and the fittings are in place, the product must be packaged. For economical and sustainable packing, we have opted to use small cardboard boxes with butcher paper for cushioning. While in transit, the battery will be disconnected from the pump to ensure safety.

Design Economics and Cost Analysis

Our group has been able to create a marketable product with a net present value (NPV) of 12.8 million US dollars (Figure 10). While using our cost analysis for all of our components we determined that with large quantity orders, the cost for a single product is around $200 dollars. With production costs, shipping, and assembly, we estimate that our product will cost around $400 dollars to produce. We also expect this number to decrease over time as our team and process becomes more efficient.

The global market for prosthetics is large. Transfemoral prosthetics can cost up to $50,000 with cheaper models coming in around $5,000. Due to this, our team is charging a retail price of $1,600, a fair price due to the innovation and adaptability our product provides. Another benefit of our design is that it can be incorporated into prosthetics that users already own. Since our device attaches below the socket and above the knee joint, with some slight alterations, users can attach our product to their existing prosthetics to improve their experience. We are also able to sell our product directly to other prosthetic manufacturers so they can integrate it into their possible outdated designs.

As stated earlier, we have two potential markets for our product. These include selling directly to the consumer as well as selling to other manufacturers. Our device can be implemented into both prosthetics that are currently in use as well as new prosthetic devices produced by other companies. This increases our marketable areas which is why we estimate selling up to 10,000 units per year.

Values in $M *(except where noted)*	Year 1				Year 2				Year 3				Year 4			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales, product					2.88	3.60	3.60	4.32	2.85	3.56	3.56	4.28	2.82	3.53	3.53	4.23
Sales Volume (units/qtr)					*2,000*	*2,500*	*2,500*	*3,000*	*2,200*	*2,750*	*2,750*	*3,300*	*2,420*	*3,025*	*3,025*	*3,630*
Unit Wholesale Revenue, machines ($/unit)					*1440*	*1440*	*1440*	*1440*	*1296*	*1296*	*1296*	*1296*	*1166*	*1166*	*1166*	*1166*
Total Revenue					**2.88**	**3.60**	**3.60**	**4.32**	**2.85**	**3.56**	**3.56**	**4.28**	**2.82**	**3.53**	**3.53**	**4.23**
Product Development	0.50	0.50	0.50	0.50												
Equipment and Tooling			0.75	0.75												
Production Ramp-up				1.00	1.00											
Marketing and Support				1.63	1.63	0.13	0.13	0.13	0.13	0.13	0.13	0.13	0.13	0.13	0.13	0.13
Production, machines					1.05	1.25	1.25	1.45	1.13	1.35	1.35	1.57	1.22	1.46	1.46	1.70
Total Costs	**0.50**	**0.50**	**1.25**	**3.88**	**3.68**	**1.38**	**1.38**	**1.58**	**1.26**	**1.48**	**1.48**	**1.70**	**1.34**	**1.59**	**1.59**	**1.83**
Period Cash Flow	**-0.50**	**-0.50**	**-1.25**	**-3.88**	**-0.80**	**2.23**	**2.23**	**2.75**	**1.60**	**2.09**	**2.09**	**2.58**	**1.48**	**1.94**	**1.94**	**2.41**
Period Present Value	-0.49	-0.48	-1.19	-3.62	-0.73	2.01	1.97	2.39	1.37	1.76	1.73	2.10	1.18	1.52	1.50	1.82
Net Present Value	**$12.8 million**															

Figure 10 provides a table depicting the net present value for the vacuum pump attachment. Our product will become profitable during the second quarter of year two. To obtain these values, production cost is set at $400 with a retail cost of $1,600. The initial sales volume is 10,000 units per year with 10% growth.

IP Review and Considerations

In order to determine patent and trademark possibilities, our team researched and found similar patents related to our device (Figure 11). However, none of the patents found teach or suggest all elements of our product. Novel properties of our device include, but are not limited to, our sweat collection cup, use of hydrophobic mesh, and attachment capabilities.

PATENTS

Patent #	Date of Patent	Patent Name	List of inventors	Summary of pertinence for your design	URL
US7947085B2	5/24/11	Prosthetic device utilizing electric vaccum pump	Wilbur A. HainesJames M. ColvinMichael L. HaynesChristopher T. KelleyMark W. FordMark W. GrovesJeffrey A. Denune	Uses an electrical vacuum pump that can be attached to the prosthetic leg, which is similar to our design	Link to Patent
US10624767B2	4/21/20	Prosthetic system for sweat management	Grimur Jonsson, Andrew BACHE	Sweat management for prosthetic sockets	Link to Patent
JP7190209B2	12/15/22	Antimicrobial peptide derivative and use thereof	Yang, Li, Men, Can, Zhang, Xue, Yan, Hegu Wei Yuquan	The present invention relates to the field of biomedicine, mainly to antimicrobial peptide derivatives and uses thereof, especially hydrophobically modified antimicrobial peptide DP7 derivatives and uses thereof.	Link to Patent

TRADEMARK

Trademark #	Date of Trademark	Patent Name	List of inventors	Summary of pertinence for your design
97050568	9/29/21	AK Prosthetics	Adero Knott	This has been abandoneded, but it was for prosthetic limbs, namely, arms, legs, sockets, hands, feet, adaptive devices
90851426	7/27/21	Fountain Orthotics & Prosthetics		This has been abandoneded, but it was for prosthetic limbs, namely, arms, feet, and legs
90033703	12/8/20	Prosthetics in Motion	John G. Tutunjian	Custom manufacturing of prosthetics, Prosthetic limbs, namely, legs, arms, feet and hands.

Figure 11 shows different patents related to the use of vacuum in prosthetic devices.

In addition to research on patents and trademarks, our team devised several claims related to our vacuum pump attachment product.

Claims

1. A prosthetic device, comprising:
    a. A vacuum pump system adapted to attach to both the prosthetic socket and leg joint;
    b. A sweat disposal device that comprises an electronically powered vacuum pump attached to a battery which is located within a chamber of the housing separate from a sweat collection cup, a vacuum inlet line has a moisture block to prevent sweat from entering the vacuum, the sweat collection cup can be removed without interrupting vacuum within the socket.

2. The prosthetic device of claim 1, further comprising the use of hydrophobic mesh as the moisture block at the inlet of the vacuum pump.

3. The prosthetic device of claim 1, further comprising the sweat collection cup and prosthetic socket are under vacuum while the vacuum pump and battery are isolated and not under vacuum pressure.

4. The prosthetic device of claim 1, further comprising the housing separation which divides the vacuum pump and battery from both the prosthetic socket and the sweat collection cup.

5. The prosthetic device of claim 1, further comprising the housing that has universal attachments to join with the socket as well as the leg and knee joint.

6. The housing of claim 5, further comprising a functional opening for the user to remove the sweat collection cup without breaking vacuum in the prosthetic shell.

7. The sweat collection cup of claim 3, further comprising an indicator for when the cup is full of sweat.

8. The housing of claim 5, further comprising an airlock valve between the prosthetic socket and sweat collection cup.

Design for Environmental Considerations

Life Cycle Assessment

An environmental sustainability report was created for the final design of the prosthetic socket attachment using the computer program SolidWorks. The main region of manufacturing and use of the attachment is focused in North America, more specifically the United States of America and Canada (Figure 12). The assessment report focused on a number of variables including the assembly process, the energy type and consumption, the transportation factor, and the life cycle of the socket (Figure 13). Using these variables, Figure 14 breaks down how our final design will impact the environment through our carbon footprint, air, water, and energy consumption.

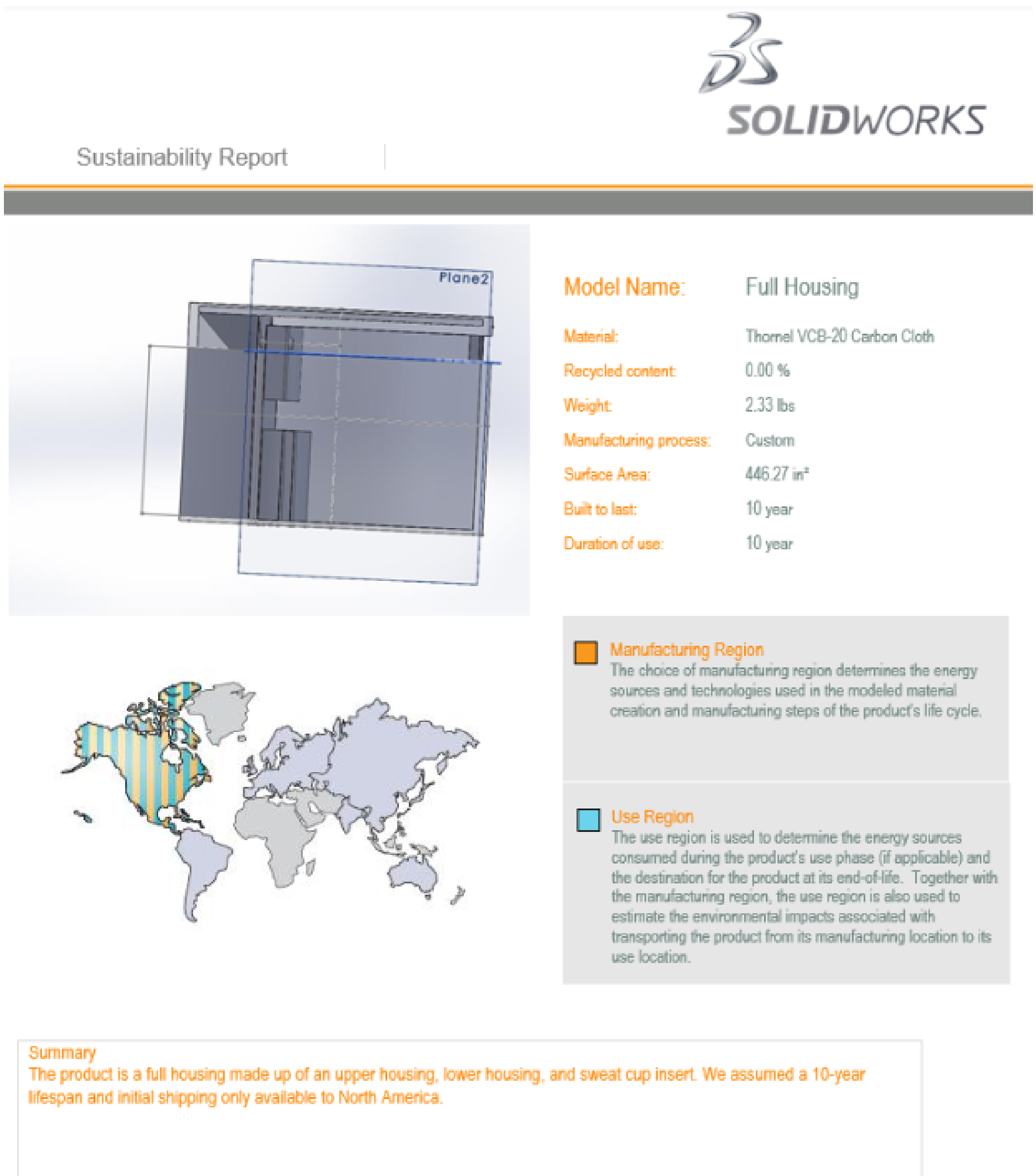


Figure 12 The sustainability report for the vacuum prosthetic socket design in the region will be manufactured and used.

Sustainability Report

Model Name:	Full Housing	Material:	Thornel VCB-20 Carbon Cloth	Weight:	2.33 lbs	Manufacturing process:
				Surface Area:	446.27 in²	Custom
		Recycled content:	0.00 %	Built to last:	10 year	
				Duration of use:	10 year	

Material	Thornel VCB-20 Carbon Cloth	0.00 %
Material Unit Cost	Not Defined	

Manufacturing

Region:	North America
Process:	Custom
Electricity consumption:	0.150 kWh/lbs
Natural gas consumption:	180 BTU/lbs
Scrap rate:	15 %
Built to last:	10 year
Part is painted:	Yes (Water-based Paint)

Use

Region:	North America
Duration of use:	10 year

Transportation

Truck distance:	2900 km
Train distance:	0.00 km
Ship distance:	0.00 km
Airplane Distance:	0.00 km

End of Life

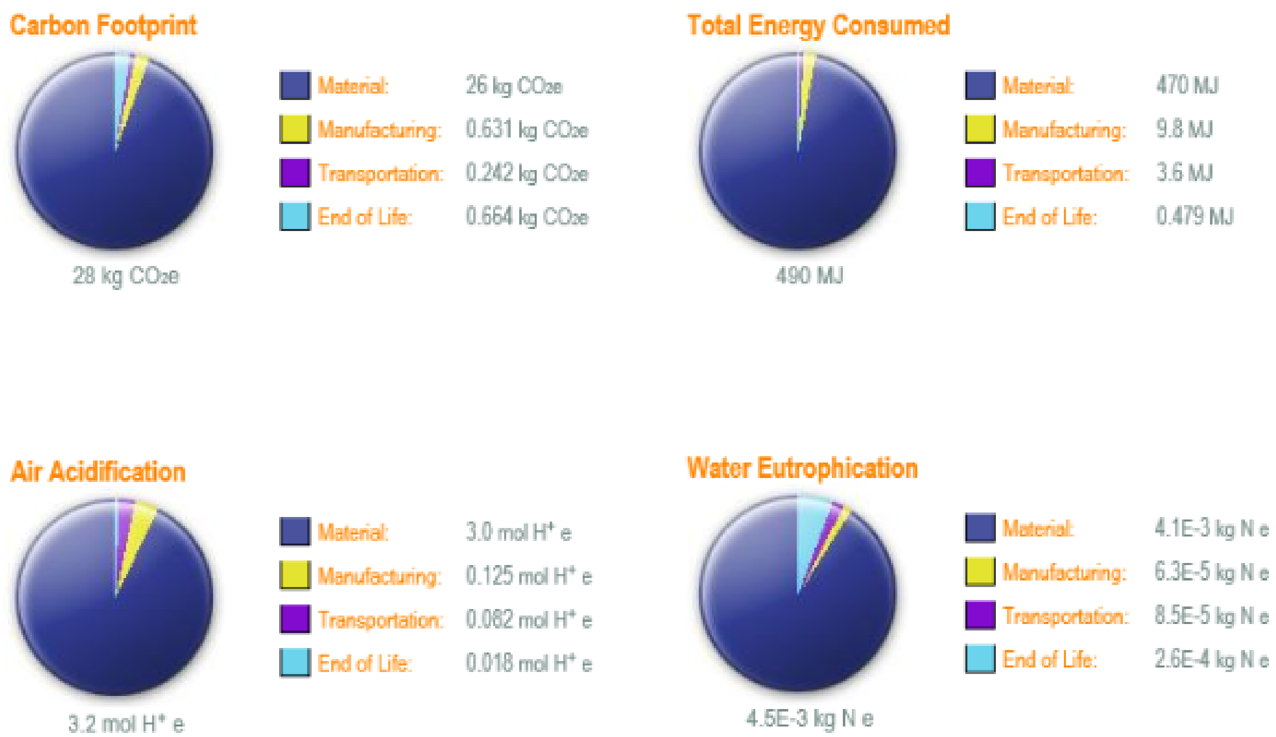
Recycled:	15 %
Incinerated:	5.0 %
Landfill:	80 %

Figure 13 The variables used for the life cycle assessment are pictured above.

Sustainability Report

Model Name:	Full Housing	Material:	Thornel VCB-20 Carbon Cloth	Weight:	2.33 lbs	Manufacturing process:
				Surface Area:	446.27 in²	Custom
		Recycled content:	0.00 %	Built to last:	10 year	
				Duration of use:	10 year	

Environmental Impact (calculated using TRACI impact assessment methodology)



Comments

The largest environmental cost is the material. We chose carbon fiber as it was the lightest material and it met our strength needs. One of the issues with carbon fiber is there is currently no great way to recycle carbon fiber so it is a one time use. To offset the recycling we designed our product to last 10 years. The TRACI impact assessment was used as this is currently the most accurate method for modeling LCA in North America.

Figure 14. The charts above display the breakdown of the lifecycle of the product by impact on the environment. Material impact has by-far the greatest damage.

Summary and Conclusion

Summary

The overall objective of this project was to create a prototype for a design that could decrease sweat in a transfemoral prosthetic socket and maximize comfort for the user. We did this by designing a vacuum pump powered attachment that would be used to evacuate sweat from the socket. The sweat is meant to be captured in a container that could be emptied without needing to remove any additional portions of the prosthesis. This attachment is meant to be placed just above the knee joint. In order to prevent liquid from entering the vacuum pump we included a hydrophobic mesh onto the end of the inlet of the vacuum pump. We also installed a pressure and temperature sensor to monitor the internal environment of the vacuum chamber. After performing our modeling assessments we found that the design is feasible with further investment. We 3D printed a prototype for the enclosure that would be used to house the sweat cup and vacuum pump as proof of concept.

Conclusion

In conclusion, our team took an idea and developed an initial product prototype for the transfemoral prosthetic socket vacuum pump attachment. This came with many obstacles along the way and required us to redesign and then design again. This project required us to learn new skills, network with professionals, and communicate across a multifaceted team. In just 10 weeks, we were able to find innovative solutions to the design challenges we encountered and tackle our objective of sweat evacuation and maximized comfort for transfemoral amputees. We did this with the help of many faculty members at Oregon State University and would like to give special thanks to the faculty who have been with us from the beginning providing valuable input, encouragement, and resources to help us accomplish our tasks. Thank you Dr. Baio, Jade, and Rachel. We sincerely appreciate your time and effort throughout this project.

Future directions and considerations

Our next steps for future design and prototyping include:

1. Adding a capacitive liquid level sensor, calibrated using the dialectrance of saline, within

the sweat chamber. This addition would allow us to determine the liquid level inside the sweat chamber in a moving environment. With this we would include a wifi addition on the sensor that would allow the user to use bluetooth to check the liquid levels.

2. Determining how to coat the model with antimicrobial material for protection against bacteria buildup due to the sweat.
3. Including an electrochemical sensor for sweat analysis, which can provide data for certain biochemical markers. These markers can be used to inform users about their overall health.
4. Incorporating hygroscopic material to draw away any remaining beads of water.

Reflection Statements

Noah Bach

Our group took on a technical challenge in designing our product. We ended up going slightly outside of our bioengineering background, but I feel that our group handled the challenges well. We brought in both mechanical and electrical engineering aspects and I feel that we adapted well. I can confidently say that each group member put their best effort into this project. We originally thought that we took on a feasible task for prototyping, but the further we got into the process, the more we realized that a full prototype was not possible with the budget provided. However, I feel that we have provided a solid proof of concept with an adequate prototype. Our group did a great job communicating and we were able to have productive meetings and brainstorms while balancing other courses. Throughout both terms each member was reliable and each member pulled their weight. Our group had a good dynamic for delegating tasks and coming up with solutions in a timely manner. Overall, I am very pleased with our group and I feel that we have come up with a marketable product while working around the limitations of our budget and time constraints.

Carter Doyle

I believe that our team did a very good job in designing and prototyping certain aspects of our product in the very short amount of time we were given to do so. Our product was not an easy task. We ventured more outside of the chemical aspect of bioengineering and into subjects that we were not as familiar with, like mechanical and electrical engineering. As always, there are lessons to be learned and improvements to be made. I think our team could have done better in communicating with one another, as well as scheduling meetings. Creating a purpose for our meetings, like a task/topic list to go over, would have been helpful for when we got together. In addition, we had a lot of delays in our prototype scheduling. Again, I think it was due to the lack of communication. I actually think we could have gotten further in our prototyping had we planned and been more put together. However, we also had a lot of prototyping restrictions due to budget constraints and ordering materials. Overall, I think we did well as a team and were able to provide a concrete design for the vacuum pump attachment with future design ideas for improvement.

Michael McAllister

This process ended up being an exciting challenge, though crazy in its off-and-on workloads. On weeks waiting for materials to arrive, it felt like there was little to accomplish, but once it was time to put material to the test, there was hardly enough time in a week to fit all of the project work. I am pleased with our design ideas, though I wish we had more time to continue building on the product. There are many potential expansions I think would be fun to continue work on. Overall the design process was a fun experience, and much more went into designing a product than I had considered before. Ultimately, a good team and a strong vision contributed to an excellent project, and the experience will doubtlessly prove fruitful in future work.

Ndubuisi Obasi

During the process of this project communication within the group has been great. Whilst certain people with natural leadership qualities lead the team from time to time, others who had a little more of a laissez faire approach were also able to shine. We also had issues with illness halfway through the term, causing more than half of the group to be gone at certain times, but this helped the other group members flourish, whilst also showing the depth of the team.

Skills we had used in prior terms were needed for volume measurement, flow rates and pressure control calculations. Being able to utilize these was a relief because it validated everything we had learned in the previous terms. The design aspect was very new to all of us however, because

I do not believe that any of us had worked on it before, it allowed us to have freedom and a certain level of positive naivety to explore different concepts. Whilst I do not know if this project will actually be doable in the future, I do think that it addresses some major issues within the field of prosthetics.

Jordan Porter

Our team picked a complex product to design. It was especially complex for us as we had to learn new skills outside the scope of our major. I also found this to be one of the most fulfilling aspects of the project. We took an ambitious idea and learned the skills necessary to make it into a thought out prototype. This project was not only an exercise in learning how to take an idea and turn it into a product but also an exercise in learning how to communicate effectively across a multifaceted team. This was probably the most challenging aspect of the project. We could have done a better job of planning in order to improve the productivity of our work sessions. In the end though we found the time to make it work and turn our prototype into a reality.

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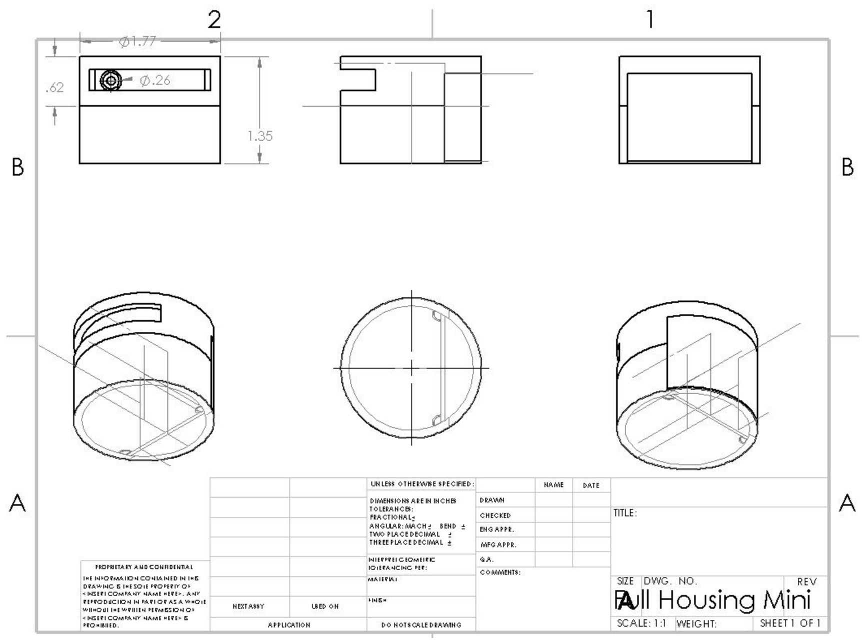
Appendix

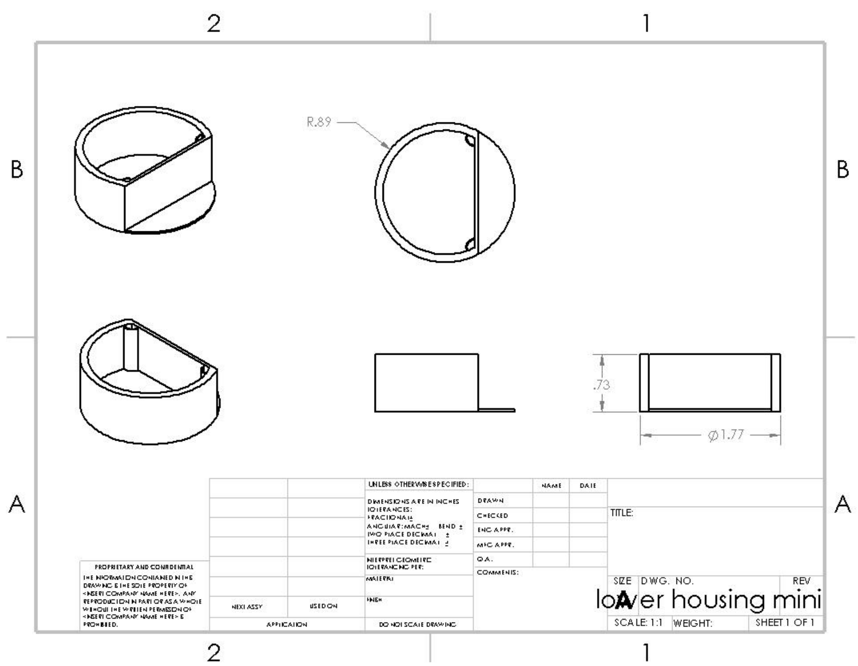
OSU Poster Draft

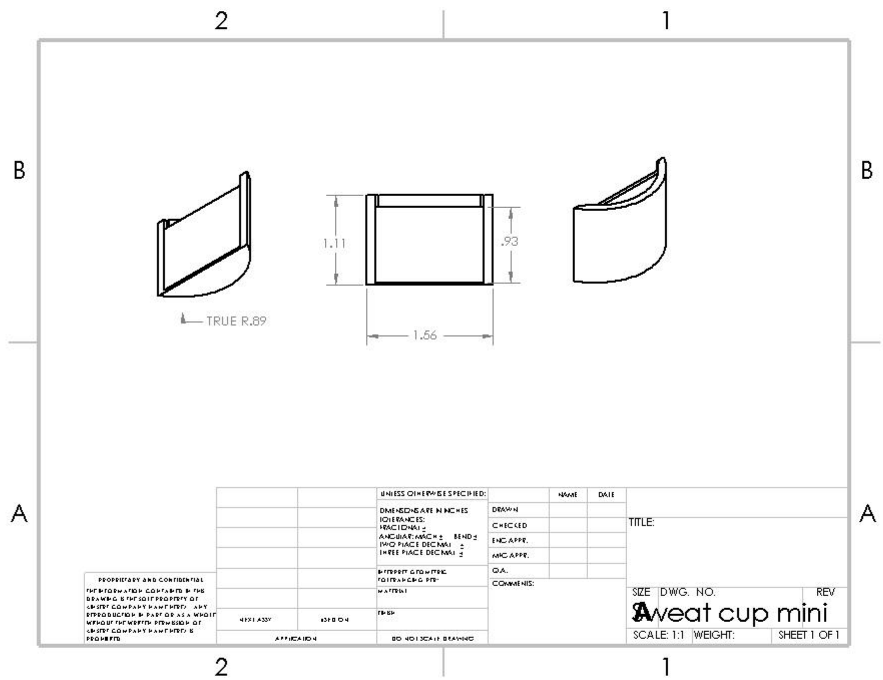
A draft of the team's poster for the 2023 Oregon State University Engineering Undergraduate Expo fair next term is presented below.

Solidworks Drawings

Schematics for product dimensions for different components, modeled at a minimum functional scale.



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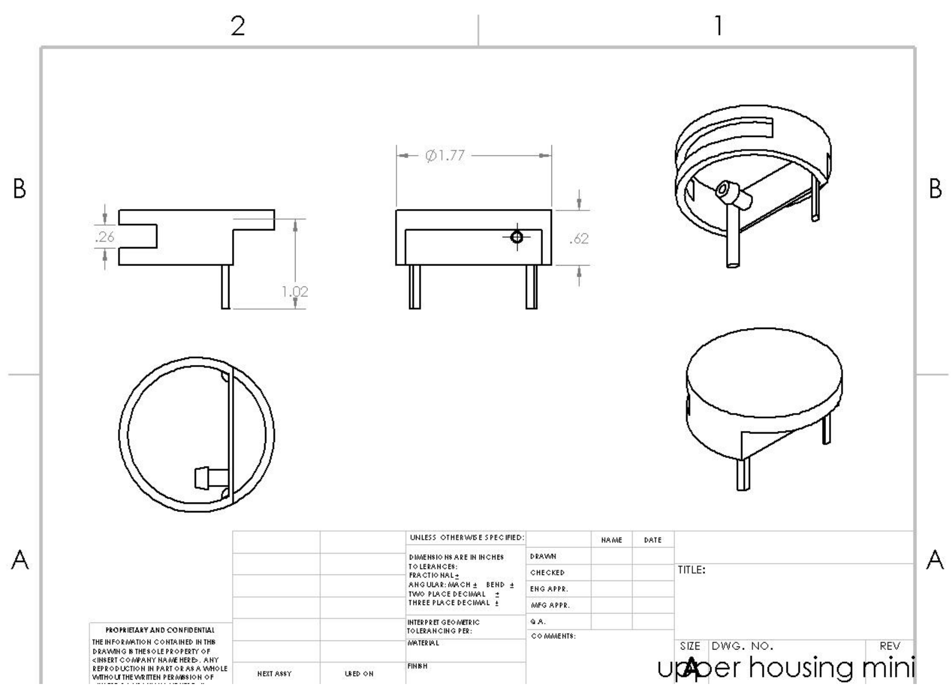
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COMMENTS:
NAME
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TITLE:
SIZE DWG. NO.
REV
upper housing mini
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