Problem statement

One out of every two hundred Americans is an amputee, which totals up to over 1.7 million amputees in the United States today [1]. They live among us - some are obvious and others conceal their disability, leading relatively normal lives. Similar prevalence of amputation can be observed worldwide - there are 3 million upper limb amputees, 2.4 million of whom reside in developing countries. Depending on how the levels are classified, five percent of individuals in developing countries are amputated at the wrist, while 59 percent are amputated closer to, but distal to the elbow [2]. In America, fourteen percent of amputations affect the upper extremities. [1]. Of these, transradial amputations make up 60% of total wrist and hand amputations [3].

Through modern engineering, many lower-limb amputees are able to receive high-functioning prostheses, regaining the ability to perform most tasks and even becoming advanced athletes. Contrarily, only 80 percent of upper-limb amputees utilize a prosthesis on a daily basis [4] . Many upper-limb amputees are fitted with a prosthetic device that they don't use because it is bulky and has imprecise movements. Most prosthetic arms and hands in past decades either have the appearance of a real limb without high functionality, or are mechanical hooks which appear unsightly.

It is into the design challenge to replace the human hand that engineers and prosthetists enter. Invasive solutions, such as neural implants, may soon become a reality, but are not easily deployed in developing nations. Myoelectric devices have the ability to acquire electromyography signals from muscles in the upper arm from surface electrodes and then translate those signals into movements in a bio-inspired prosthetic hand. The movements in such hands are generally limited to a set of necessary grip patterns for common daily tasks. Industry-available hands are powerful enough to replace many functions of the missing hand. However, these devices are incredibly expensive. Even with rapid improvement in myoelectric prosthetic arms and hands, devices lack sensory feedback. Amputees with prosthetic arms are unable to know the joint angles of their prosthetics and the amount of force being applied by their prosthetics without looking directly at the prosthetic. In order to improve the functionality of prosthetic hands, devices that provide sensory feedback to users should be designed.

Mission statement

Prosthesis users encounter many fine motor challenges throughout their daily activities. Due to the lack of sensory feedback in current prostheses, we are designing an affordable sensory feedback system to be implemented into a 3D-printed myoelectric prosthetic hand. Due to the prevalence of upper-limb amputations in developing nations, we are motivated to develop a low-cost system. We plan to add barometric pressure sensors into the fingertips and proximal finger regions in order to measure forces applied to and by the prosthetic hand. Force information will be conveyed to the user through electrotactile stimulation via electrodes located on the upper arm. The magnitude of stimulation felt by the user will be proportional to the reading from the corresponding pressure sensor.

The goal of implementing electrotactile feedback into a prosthetic hand is to allow the user to use the prosthesis with high precision for both high-force and low-force tasks. For example, the hand needs to be able to hold an egg without breaking it or lift a heavy box without dropping it. Users will exhibit the increased ability to perform functional tasks through experiments conducted at the end of the design phase. The pressure sensors with myoelectric feedback to the user will be tested with amputee subjects for effectiveness, and we hope to ultimately implement the low-cost parts in developing nations.

Constraints & Input/Output Requirements

Constraints:

1. Product must be affordable
2. Parts must be standard and replaceable
3. Stimulation parameters must be tunable to individual users

Design Requirements:

1. The user is able to distinguish pressure magnitude
2. The user is able to distinguish pressure points
3. Feedback stimulation is comfortable
4. There is no danger of electric shock
5. Stimulation is consistent
6. The device is light weight
7. Device is easy to take on and off
8. Stimulation is silent
9. Device has aesthetic appeal
10. Device can be quickly turned off

Design Inputs/Outputs/Verifications

Many factors were considered when selecting design outputs and verifications for our client's design requirements. One of our first major design decisions involved the selection of a mode of stimulation. We compared electrotactile, vibrotactile, and a pressure analog as methods for stimulation using an evaluation table. By rating the importance of various features, we found electrotactile stimulation to be the best option for our device. These ratings are shown in Table 2. By selecting electrotactile stimulation, we verified that our stimulation would be silent, thus satisfying one of our ten design requirements. This design choice also helped ensure that our device would be light weight. Because wires and surface electrodes are so lightweight and compact, an electrotactile system would be not only lighter, but more aesthetic than a bulky mechanical system. Additionally, because electrode placement is forgiving and surface electrodes are so easy to remove and replace, our device will be easy to put on and take off.

Upon choosing electrotactile stimulation, we began to consider the placement of pressure sensors within the hand to optimize the user's ability to distinguish both the magnitude and location of the pressures exerted by the hand. We know that we must include multiple pressure sensors in the hand in order to sufficiently detect the most significant forces, but we were unsure as to the precise location of these key forces. To determine the optimal pressure sensor placement, we performed a finger painting experiment in which we painted various objects and examined the surfaces of the hand used to interact with them. We then selected the six most commonly used areas of the hand as locations for pressure sensors. This experiment can be seen in greater detail under the testing section of this report.

We also performed Six Sigma testing to determine the optimal material and sensor depth in order to optimize the sensitivity of the pressure sensors for daily tasks. The sensors needed to be sensitive enough to detect small forces, allowing the user to interact with delicate objects. The sensors also needed to have a saturation high enough to allow the user to know when he is exerting a large enough force to lift a heavy object. This experiment is also detailed under the testing section of the report.

In addition to these experiments and evaluations, we will also be adhering to various sets of engineering standards in order to ensure that our stimulation is consistent, comfortable, and safe. It is extremely important that the feedback signal be consistent in voltage, so the user is able to accurately interpret these voltages as their respective pressure magnitudes. To assure that stimulation is consistent, we must first quantify hysteresis and drifting and then implement a constant sensation controller. We will also follow the IEEE Guide on Shield Practice to eliminate noise. To assure that stimulation is comfortable, we will make sure the signal to noise ratio is very high, and will allow the user to set their own maximum and minimum stimulation voltages according to what is most effective, yet painless. In addition, we will assure that our system can output multiple waveforms

Table 1: Inputs and outputs mapped to verifications.

Inputs	**Outputs**	**Verification**
User can distinguish pressure points	- Multiple stimulation sites - Pressure sensors in multiple fingers - Stimulation sites are spaced out greater than two-point threshold	- Human trials
User can distinguish pressure magnitude	- Voltage is proportional to pressure sensed	- Six Sigma testing
Stimulation is consistent	- Quantify hysteresis & drifting - Implement constant sensation controller	- Follow IEEE Guide on Shield Practice
Device can be quickly turned off	- Button to immediately cease stimulation	
No danger of electric shock	- System is waterproofed - Electrical connections are reliable	- Follow OSHA wiring design & protection standards

Stimulation is comfortable	- High signal to noise ratio - User chooses max & min amplitudes - Code can handle multiple waveforms	- IEEE Guide on Shield Practice - Measure signal to noise ratio - Human trials
Stimulation is silent	- Implement electrotactile stimulation	- Human trials
Device is lightweight	- Use *Teensy* microcontroller - Use small, thin electrodes	
Device has aesthetic appeal	- Embedded pressure sensors in silicone Skin-toned electrodes - Electronics housed within prosthetic arm - Wires kept tidy	- Survey - Compare to hand without our additions
Device is easy to put on and take off	- Electrode position is forgiving - External hardware & wires are kept tidy	- Compare with existing devices

Table 2: Evaluation table used for the selection of stimulation type

Stimulation Methods		**Electrotactile - Multiple Electrodes**		**Mechanical - Pressure Analog**		**Vibrotactile**	
	Importance	Rating	Weighted Rating	Rating	Weighted Rating	Rating	Weighted Rating
Information Content of sensation	0.3	4	1.2	3	0.9	3	0.9
Size/Weight	0.2	4	0.8	1	0.2	2	0.4
Power Consumption	0.1	3	0.3	2	0.2	3	0.3
Comfort	0.3	4	1.2	3	0.9	3	0.9
Affordability	0.1	2	0.2	2	0.2	3	0.3
Total			**3.6**		**2.4**		**2.8**

List of Relevant Patents

1. Electrical stimulator for sensation feedback of human-emulated myoelectric artificial hand

Electrical stimulator for sensory feedback of prosthetic hand. Patent is very specific about electrical components (specific capacitors, etc) so we can get around it.

刘宏, 姜力, 李楠, 汤奇荣. Electrical Stimulator for Sensation Feedback of Human-emulated Myoelectric Artificial Hand. Patent CN 200810064586. 2 June 2010. Print.

2. Fitting system for a neural enabled limb prosthesis system

An instrumented prosthesis (IP), such as an instrumented prosthetic hand (IPH), can include sensors and can be connected to a neural stimulation system (NSS) or neural recording system (NRS), which includes an implanted system having electrodes. The NSS/NRS can also be connected to a software module, which can assist in calibrating the electrodes and mapping sensor values to stimulation parameters and/or mapping motor intent from recorded neural activity to control of prostheses.

Sathyakumar S. Kuntaegowdanahalli, Ranu Jung, James J. Abbas, Kenneth Horch. Fitting System for a Neural Enabled Limb Prosthesis System. The Florida International University Board Of Trustees, assignee. Patent US20140277583 A1. 18 Sept. 2014. Print.

3. Electro-tactile stimulator

A device for electrically stimulating the skin in response to an electrical signal includes a flexible substrate on one surface of which is formed an electrically conductive pattern having a number of electrodes. The present invention is related to devices for stimulating the skin in response to an external stimulus in order to aid a person who is sensorially impaired with respect to that external stimulus.

Christophe Jean-Paul Sevrain, Heather R. Schramm, Daniel G. Schmidt, Paul S. Hooper, Mary P. Thomas. Electro-tactile Stimulator. Sevrain-Tech, Inc., assignee. 22 May 1990. Print. 4. Myoelectric prosthetic hand force tactile feedback method and tactile feedback myoelectric prosthetic hand system

4. 3D force sensor mounted in wrist of prosthetic hand.

Vibration feedback with corresponding amplitudes and directions.

吴常铖, 宋爱国, 崔建伟, 李会军, 章华涛, 茅晨, 钱夔. Myoelectric Prosthetic Hand Force Tactile Feedback Method and Tactile Feedback Myoelectric Prosthetic Hand System. Patent CN 201110244446. 21 Mar. 2012. Print.

5. Vibrotactile Sensor for improved balance control

They have a pressure sensor array under one's foot. The array sends pressure recordings to a microprocessor which then converts that to balance information. The balance information is sent to a vibrotactile array around the leg in order to convey balance information to the person.

Oddsson, Lars, and Peter Meyer. Sensor Prosthetic for Improved Balance Control. RXFUNCTION, assignee. Patent US10511023. 14 Apr. 2003. Print.

6. Sensate Vibratory Prosthesis

A device to take force input from a prosthesis and convert it to a sonic output. The sonic output is connected to a bone stump so that the signal reaches the brain.

Vincent C. Giampapa. Sensate Vibratory Prosthesis. Patent US07072950. 13 Sept. 1988. Print.

7. System and method for force feedback

Force sensors in hand dictate amplitude of vibration feedback.

Harold H. Sears, Arthur D. Dyck, Edwin K. Iversen, Steven R. Kunz, James R. Linder, Shawn L. Archer, Reed H. Grant, Ronald E. Madsen, Jr. System and Method for Force Feedback. Motion Control, Inc., assignee. Patent US7438724 B2. 21 Oct. 2008. Print.

8. Peripheral sensory and supersensory replacement system

A sensor-based quantification, replacement, augmentation and analysis system is provided. The system includes an input device and an output display (including visual, vibrational, auditory and electrotactile displays as potential outputs). The input device includes an array of pressure or force (or other) sensors distributed over, and laminated within, an insole of a shoe (or other corporeal or non-corporeal device).

Breanne Everett, Marcel Groenland. Peripheral Sensory and Supersensory Replacement System. Orpyx Medical Technologies Inc., assignee. Patent EP2632323 A1. 4 Sept. 2013. Print.

9. Apparatus for transmission of information by electrocutaneous stimulus

In an apparatus for the transmission of information, comprising means for applying pulse signals representing a desired item of information to electrodes fastened to the skin of a human subject for thereby transmitting the information by electro-cutaneous stimuli

Susumu Tachi, Kazuo Tanie. Apparatus for Transmission of Information by Electrocutaneous Stimulus. Agency Of Industrial Science & Technology, assignee. Patent US4167189 A. 11 Sept. 1979. Print.

10. Keypad with Electrotactile Feedback

Pressure sensors in the keypad provide force feedback through electrodes to the user. Feedback electrodes are located at the top surfaces of the keys.

Hiroshi Horii Cynthia Kuo. Keypad with Electrotactile Feedback. Agency Of Industrial Science & Technology, assignee. Patent US13296391. N.d. Print.

11. Intelligent prosthetic hand system Prosthetic hand with vibrational or temperature feedback.

Piezoelectric electret collects tactile signal, controls whether hand continues grasping or not and sends feedback to stump.

方鹏, 匡星, 田岚, 李光林. Intelligent Prosthetic Hand System. Patent CN103519924 A. 22 Jan. 2014. Print.

12. Electrical stimulation system and methods for treating phantom limb pain and for providing sensory feedback to an amputee from a prosthetic limb

A system that relays sensory information and directly stimulates nerves (implanted electrodes).

Joaquin Andres Hoffer. Electrical Stimulation System and Methods for Treating Phantom Limb Pain and for Providing Sensory Feedback to an Amputee from a Prosthetic Limb. Neurostream Tech Inc., assignee. Patent US10030973. 27 Nov. 2007. Print.

13. Force touch sensation feedback and force intensity control method of mechanical artificial hand based on myoelectric control

Force touch sensation feedback and force intensity control method of prosthetic hand.

包加桐, 宋爱国, 崔建伟, 章华涛, 钱夔. Electrical Stimulation System and Methods for Treating Phantom Limb Pain and for Providing Sensory Feedback to an Amputee from a Prosthetic Limb. Patent CN101766510 A. 18 Dec. 2009. Print.

Six Sigma Experiments

In order to determine the best material to use to cover the fingertip sensor, as well as the optimal sensor depth within the fingertip, we performed a six sigma test. We desired to increase the saturation force of the fingertip in order to enhance the hand’s ability to exert the correct amount of force to pick up an object without dropping it. We tested two urethane rubber materials, vytaflex 20 and 40. Vytaflex 40 is a harder material, and therefore resulted in an increased saturation force. We also tested two sensor depths, 4mm and 5mm. The 5mm sensor depth allowed for the force on the fingertip to transfer throughout more material and therefore also resulted in an increased saturation force. For this reason, we chose to mold the fingertips out of Vytaflex 40 material and re-designed the fingers to allow for a sensor depth of 5mm.

To test the material and depth, we created molds of the same shape of the fingertip itself, and printed these molds inside of a cube shaped base in order to maximize stability during the tests. To measure force, the molded fingertip models were placed on a balance and a drill press was used to exert a point force on the center of the fingertip. Pressure readings from the sensor were simultaneously being read, and the saturation pressure was recorded.

Table 3: Six Sigma testing results

Material	Sensor Depth	Saturation Force (g)	Saturation Pressure (kPa)
Vytaflex 20	4 mm	46.2 ± 0.8	35.07
	5 mm	65.1 ± 4.4	50.82
Vytaflex 40	4 mm	49.7 ± 1.4	38.80
	5 mm	68.1 ± 1.7	53.16

Design

There were two main components of this project: the device to both send waveforms to the stimulation boxes and read from multiple pressure sensors as well as the modifications to the fingers.

The device uses an I/O expander (MCP23008, $5 per chip) to turn on and off reset pins on the sensors. The reset pin turns on and off I^2C communication for the chip while keeping the sensor active. By turning this pin off, the sensor is able to prepare a pressure reading, which takes 1.2ms, while the I/O expander is telling the next sensor to prepare a pressure reading. This system allows the readings from five sensors to be acquired in 7ms. In addition, the system is easily expanded to multiple sensors by adding I/O expanders to the board or purchasing an I/O expander with more pinouts. The device uses a demultiplexer (CD4051BE) to switch between stimulation boxes while sending stimulation waveforms to multiple electrode pairs. The waveform is also high-pass filtered to remove the DC offset and create a biphasic waveform. A Teensy microcontroller is used to convert pressure readings to stimulation magnitudes and to generate analog stimulation waveforms.

The existing CAD model of the fingertip had to be modified such that the inner cavity of the fingertip was at a depth of 5mm rather than 4mm, as determined by our six sigma testing. The channel through which the sensor wires run was also modified such that the wires could run through to the palm box of the hand instead of outside the fingers. Future iterations of the proximal finger segment will run together to allow safety and aesthetic appeal of the electronic components.

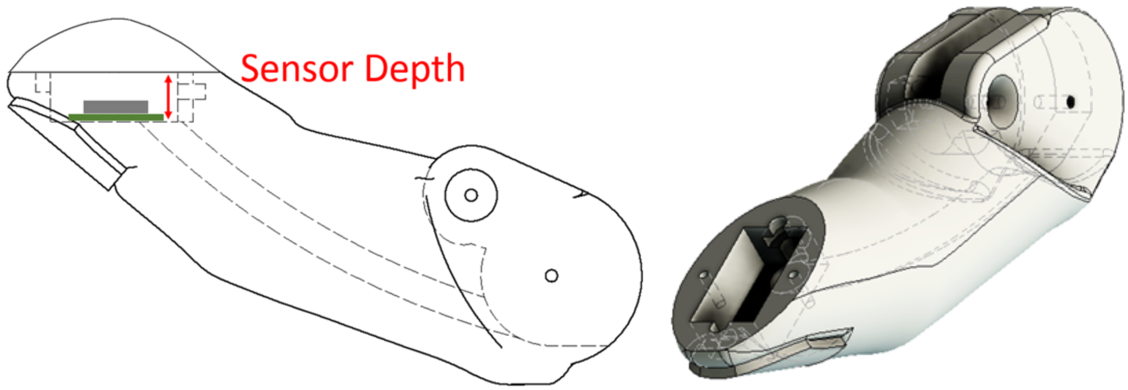


Figure 1: CAD drawings of the fingertip demonstrating sensor placement and cavity size

To embed the sensors within the hand, the pressure sensors were first connected to a small PCB and wired through the hollow finger. The PCB with the sensor were then glued to the base of the fingertip. Finally a cap mold was glued to the finger in order to shape the cavity for the injected vytaflex 40 material. The cap mold had two small holes, one for injection and one for air to escape. Once the vytaflex 40 was injected, the finger was allowed to cure for at least four hours. Upon removal of the cap mold, the final fingertip shape was formed. If air cavities were found, more vytaflex 40 was coated over the cavity to fill the hole.

Figure 2: Fingertip molding process

Once the fingers were completed, we removed the existing fingers of the prosthetic hand and replaced them with the fingertips containing pressure sensors. Because we were only able to use 3 stimulation boxes, we could only use three fingertips with sensors. These are located in the thumb, index, and pinky finger, but can easily be interchanged. All fingertips, however, were molded with vytaflex 40 in order to increase friction and enhance the user’s ability to pick up various objects.

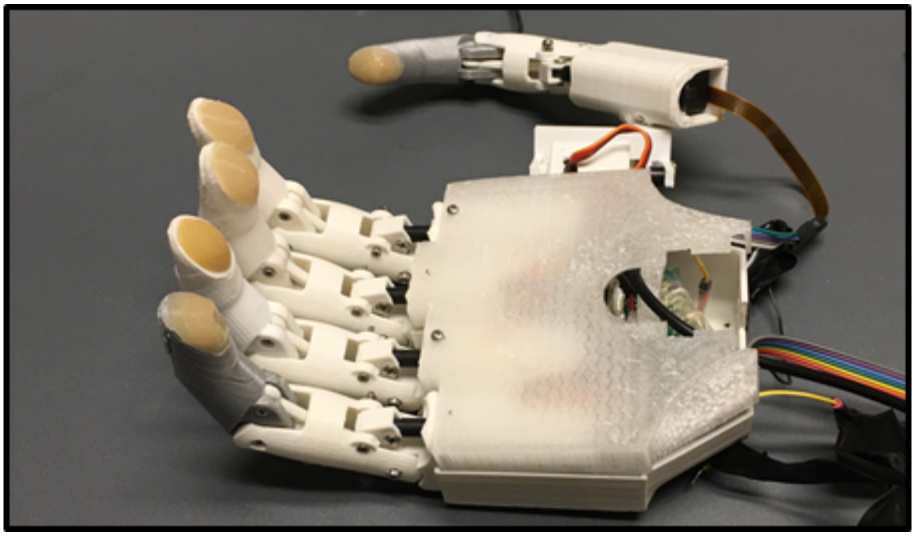


Figure 3: 3D printed myoelectric hand with fingertips replaced by our molded fingertips with pressure sensors.

Testing Performed

A finger-painting experiment has been performed to observe which part of the prosthetic hand is used to grasp various objects in order to determine where to put the pressure sensors. The results of the paint experiments are shown in Figure 4. Several different objects were grasped by the prosthetic hand, ranging from a full cup grip to a pinch of a ruler/book, to a handshake. Most actions were carried out using the fingertips, but the proximal segments of digits were used as well. The palm was only used in the handshake trial, so this is negligible. Based on the compiled results shown in Figure 1, we put together a priority table, shown in Table 4. This table ranks the importance levels of each digit segment, proximal and distal.

Figure 4: Painting experiments showed which parts of the prosthetic hand are most used. The six stars indicate the preliminary proposed sensor locations based on the five experiments. These decisions were made based upon priority levels shown in the table below.

Table 4: Based on the painting experiments in Figure 1, digits used in various grips are ranked below.

Priority Level	Digit Component
1.	2nd distal
2.	1st distal

3.	3^{rd} distal
4.	5^{th} distal
5.	2^{nd} proximal
6.	3^{rd} proximal
7.	4^{th} distal
8.	5^{th} proximal
9.	1^{st} proximal
10.	4^{th} proximal

While developing the system, the waveform produced was analyzed and compared to the waveform produced by the previous system. The waveforms were nearly identical. In addition, the sensation caused by our stimulation was described as “comfortable” by Aadeel. At all stages, safety tests were performed as well.

Once the system was developed, two tests were run. To begin with, the sensors in the thumb, index finger, and pinky finger were connected to the stimulation boxes through our system. A subject was then attached to the system with all three electrode pairs on their right arm. The subject was then blindfolded and was asked to identify which finger was being touched by the experimenter. The subject was able to identify the finger being touched with 100% accuracy when only one finger was being touched at a time.

In addition, hand was adjusted to move through a computer interface. The subject attached to the system and moving the hand was asked to pick up a can over multiple trials. Each trial was deemed a failed trial if the subject either dropped the can or the examiner heard a crack from the can, implying that the can was damaged. When the subject was allowed to look at the can, he scored a perfect 10/10 regardless of whether the stimulation system was attached to him or not. Though, when the subject was blindfolded and the stimulation system was not attached to him, the subject had 3/10 successes. When the subject was blindfolded and the stimulation system was attached, the subject had a perfect 10/10 successes. This shows that the system is able to help a user grasp an object without looking at it, a desired component of many prosthetic devices.

Figure 5: Setup used for the can-crushing experiment. An empty can was velcroed to the palm of the hand to prevent it from sliding as the fingers closed around it.

Table 5: Results from can crushing experiment, representing data from one test subject performing 10 trials for each set of conditions.

	Visual Feedback	Blind
Sensory Feedback	10/10	10/10
No Sensory Feedback	10/10	3/10

Budget

Table 6: Total cost of developing the sensory feedback system as well as cost per final product

Item	Total Cost	Cost per Hand
Vytaflex 40	$30	~$3
3D-Printing Materials	$30	No more than current hand
Pressure Sensors	$100	$30
PCBs	$40	$5
Chips	$50	$5
Assorted Electronics	$100	$20
Total	$350	~$63

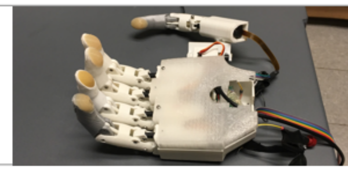
Cosmetic arm	$5,000	
Arm with split hook	$10,000	
Myoelectric arm with functional hand	$20,000 - $100,000	
Bretl Lab myoelectric hand with sensory feedback	$400	

Figure 6: Cost comparison to existing prosthetic hands on the market today. It is important to note that none of these existing hands are equipped with sensory feedback.

Recommendations and Future Work

The stimulation system developed by the ECE senior design team, shown in Figure 7, should hopefully gain IRB approval soon. Once this is done, the data acquisition system we developed can be integrated with the stimulation system and the entire feedback stimulation system can be embedded inside the prosthetic hand. Using the new stimulation system, we will eliminate the need for the large stimulation boxes, and will have a smaller and much more affordable system which is capable of outputting current waveforms through 5 channels.

We also believe that our electrotactile sensory feedback system as a whole, once integrated with the ECE team's stimulation system, will be integrated into other prosthetic hand models currently being developed by Bretl Research Group. These new prosthetic hands have more functional capabilities than the model we used, so our pressure feedback system will be even more valuable. With a different model of hand, it may be more feasible to include pressure sensors within the proximal finger segments, as was determined necessary by our finger paint experiment.

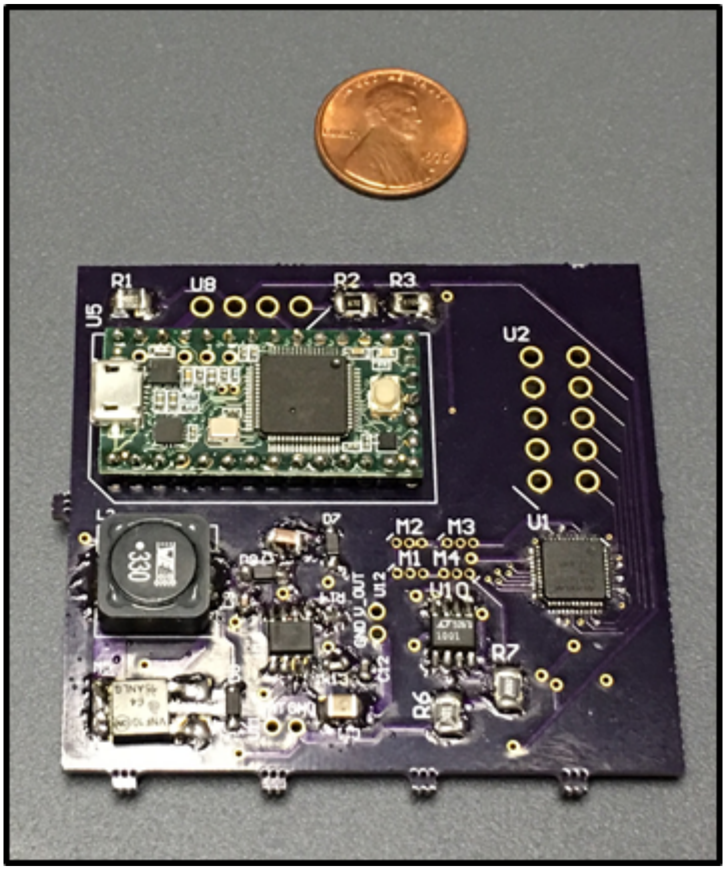


Figure 7: ECE team's stimulation system PCB

References

[1] "Amputation Statistics." Center for Orthotic & Prosthetic Care. Web. 20 Dec. 2015.
[2] LeBlanc, Maurice. "Give Hope - Give a Hand." Web. 20 Dec. 2015.
[3] "Statistics on Hand and Arm Loss." *Industrial Safety & Hygiene News*. Web. 20 Dec. 2015.
[4] Smith, Douglas. "Introduction to Upper-Limb Prosthetics: Part 1." InMotion. Web. 20 Dec. 2015.