# Prosthetic Control Board

*ECE 445 Project Proposal — Fall 2017*

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## Table of Contents:

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>2</td>
</tr>
<tr>
<td>Objective</td>
<td>2</td>
</tr>
<tr>
<td>Background</td>
<td>2</td>
</tr>
<tr>
<td>High-level Requirements</td>
<td>2</td>
</tr>
<tr>
<td>Design</td>
<td>3</td>
</tr>
<tr>
<td>Block Diagram</td>
<td>3</td>
</tr>
<tr>
<td>Physical Design</td>
<td>4</td>
</tr>
<tr>
<td>Functional Overview</td>
<td>6</td>
</tr>
<tr>
<td>External</td>
<td>6</td>
</tr>
<tr>
<td>Battery</td>
<td>6</td>
</tr>
<tr>
<td>EMG Sensor Board</td>
<td>6</td>
</tr>
<tr>
<td>External IO Board</td>
<td>7</td>
</tr>
<tr>
<td>Microcontroller</td>
<td>7</td>
</tr>
<tr>
<td>STM32F072RB</td>
<td>7</td>
</tr>
<tr>
<td>Motor Controllers</td>
<td>7</td>
</tr>
<tr>
<td>Pressure Sensors</td>
<td>8</td>
</tr>
<tr>
<td>Status LED</td>
<td>8</td>
</tr>
<tr>
<td>Temperature Sensor</td>
<td>8</td>
</tr>
<tr>
<td>Risk Analysis</td>
<td>9</td>
</tr>
<tr>
<td>Ethics and Safety</td>
<td>9</td>
</tr>
<tr>
<td>References</td>
<td>12</td>
</tr>
</tbody>
</table>
Introduction

Objective

As a company whose mission is to provide a feature rich prosthetic device, but at an affordable cost, PSYONIC has undoubtedly come to a crossroad as to which platform to continue development on. From arduino to teensyduino, PSYONIC has gone through several iterations of design and have decided upon a move to a more production-ready architecture with impressive toolchain support. This decision lead to discussion with the development team to move to an ARM based microcontroller.

Our solution to PSYONIC’s need for a robust, standards-adherent, and mass-producible control board is outlined in this project proposal. We intend to design a printed circuit board that fits into the palm of PSYONIC’s hand that will serve as a central controller to interface with motors, sensors, and other prosthetic hand subsystems. This board will include a revamped microcontroller architecture, multiple I²C interfaces, a temperature sensor, a status LED, and conformal coating. Together, this hardware platform will provide a drop-in replacement for PSYONIC to use in their current prosthetic prototypes.

Background

PSYONIC aims to provide inexpensive and feature-filled prosthetic devices to the masses, with the intention to have full costs covered by insurance. In pursuant of this goal, we propose an inexpensive, water-resistant controller board and associated codebase such that PSYONIC can easily interface with finger actuators, sensors, and patient input. This board will be designed for mass-manufacturing and provide built-in safety features. Additionally, our design will be geared towards helping PSYONIC adhere to regulations put forth by the US Food and Drug Administration (FDA) such that the entire prosthetic device can be more quickly approved for resale.

High-level Requirements

- A printed circuit board must be designed to support the power and signal requirements that facilitate microcontroller operation and sufficient I²C ports for communication with external devices.
- The microcontroller must write instructions to peripherals (led, motor driver) over I²C.
- The microcontroller must read data from temperature and pressure sensors over I²C.
**Design**

**Block Diagram**

Our project is broken down into three main sections. The first of which is an external section made up of the battery, EMG sensor board, and external IO board, all of which are subsystems inherent in PSYONIC’s design which sit outside of the scope of our project. The second section consists of the off-board peripherals (motor controllers and pressure sensors), which our high-level design requirements dictate our control board must interface with. The third major section consists of the on-board components (microcontroller, status LED, and temperature sensor) that act together to ingest sensor information, control state, and output status to the patient. These sections are shown below in Figure 1.

![Block Diagram](image-url)
Physical Design

The physical dimensions of our control board are restricted by the mechanical design of the prosthetic hand. As such, PSYONIC is working to finalize and send us the latest revision of dimension restrictions for the control board. Roughly speaking, our board will be a trapezoidal shape that roughly approximates the dimensions of the average female palm. Figures 2 through 6 show CAD renderings of how the Control Board (artist’s concept shown in Figure 5 and 6) will be mechanically placed inside the prosthetic device.

Figure 2: Upwards facing palm on which the Control Board will be placed

Figure 3: Mechanical mockup of Control Board on palm
Figure 4: Rendering of closed palm on top of Control Board

Figure 5: Render showing an artist’s concept of the Control Board
(not a technical design)
Figure 6: Artist’s concept of the Control Board shape

Functional Overview

External
There are three major blocks of this diagram that, although not a part of our project, are major subsystems of the PSYONIC prosthetic arm. These subsystems include a battery to provide portable power, an EMG Sensor Board that reads input from the patient’s arm, and an External IO Board that regulates USB-C charging and communicates with external devices via Bluetooth. All three of these subsystems have been encapsulated into a single block segment to represent other aspects of the PSYONIC product, which our project serves as a constituent part thereof.

Battery
A 7.4v 2200mah Lithium Polymer battery is currently used in the PSYONIC prosthetic arm to power the electronics and motors. Lithium Polymer batteries have a benefit for providing a large source of energy for a rather small and light form factor. They can also be re-charged if provided enough voltage though slow if the charging circuitry is lower than 1C (1*capacity of battery) of amperage. The downside to using lithium based batteries is the inherent danger that misuse can cause critical failure and potential external damage. Therefore protective circuitry is a must to limit the probability of such an event occurring.

EMG Sensor Board
The Electromyography (or EMG) Sensor Board is what actually allows a patient to control the PSYONIC prosthetic device. It works by sensing faint electrical signals from the skeletal muscles present in a patient’s amputated arm, enhancing them, and decoding those signals into actionable grasp patterns (closed fist, only hand, et cetera). This subsystem interfaces with the External IO board for communicating with external devices. Although not directly an aspect that is under the realm of our project, the board we are producing will communicate with the EMG
sensor board via I²C. The EMG subsystem will send the decoded grasp patterns to our control board. The EMG sensor board also takes input from the pressure sensors our board streams to it in order to provide haptic feedback to the user.

External IO Board
The External IO Board is a project a separate Senior Design group is completing. The subsystem works by utilizing the USB-C-PD standard to charge the battery and managing Bluetooth communications with external devices (such as a phone or computer). Communication between the External IO Board and our project is managed by the EMG Sensor Board and is generally out of scope of our project proposal.

Microcontroller

STM32F072RB
We will utilize a low cost microcontroller from ST electronics that uses an ARM®Cortex®-M0 architecture on a 32 bit RISC core. The microcontroller will run up to 48 MHz with various standard communication interfaces: I²C, SPI/I²S, HDMI CEC and USARTs. This will serve as the brain of the hand board taking in various command, analyzing data from several sensors, and sending control signals to the motor drivers.

Requirements: Communicate over I²C, send control signals to motor drivers, interpret sensor data.

Motor Controllers
Each finger of the prosthetic hand is actuated by a single motor with a gear and spring system. The motor is mounted to a printed circuit board that contains a motor controller and an encoder to measure relative motor position. These five motor controller and encoder combination PCBs communicate with our prosthetic control board via the I²C protocol. An external power connection will be provided by the battery, as higher voltage (7.4v) and current capacities are needed to drive the motors.

Our primary responsibility with the boards will be three-fold:
- We will replace the current data connections between the finger/motor board and our control board by redesigning both schematics to utilize a new, more sturdy physical connector.
- We will explore ways to increase the robustness of the physical board by use of conformal coating, which adds protection from minor water damage.
- Low-level drivers will need to be created for the new microcontroller architecture we are utilizing on our control board, such that we can effectively communicate with and send commands to motor controllers, as well as read encoder values.
Requirements: command the motor controller via I²C, read the encoder position via I²C, redesign board to make use of different physical connectors, apply a water protective coating

Pressure Sensors
In addition to vast freedom of movement the prosthetic hand possesses, each finger-tip is outfitted with a pressure sensor to act as a touch sensor. The data received from the pressure sensor can then be used to provide feedback to the user as a reference to what degree the fingers are imparting a force in its grasp. The feedback is fed as data to the EMG board which will perform haptic feedback based on the data fed from the microcontroller and in turn the sensors. These sensors are being implemented outside of our project, though we will be working towards interfacing with them.

Requirements: communicate over I²C to the microcontroller to provide pressure data, operate between 1.95 to 3.6V, rated to work at -10°C to 50°C, and accuracy of ±100pa.

Status LED
Every product needs some method of communicating information to the user, and in the case of the prosthetic hand it is two-fold as status/error messages can be provided to a customer and serve as a debug tool during product development.

Requirements: communicate over I²C, have multiple colors (red, green, and blue), and have a light viewable from at least a 90° viewing area.

Temperature Sensor
In consideration of the environment and use case envisioned for PSYONIC, extra safety systems and feedback greatly improves the reliability and safety of the product. This is where a temperature sensor comes in handy. The sensor will communicate via I²C with the microcontroller and send back the temperature of the control board. This will be helpful, as the waterproofing methods we plan to use for the control board have the potential to lock in heat. Additionally, this will act as a fail-safe in the event a patient accidentally picks up or spills a hot item or liquid on to the control board.

Requirements: stream temperature data over I²C and have the microcontroller safely shut down during overheating. A temperature sensor with a tolerance equal to or greater than ±1°C and an operating range from at least −20°C to 80°C must be selected.
Risk Analysis

The biggest risk posed to the success of this project is in respect to the low-level programming inherent in introducing a new Microcontroller architecture. Core libraries for interfacing with the motor controller, encoder, LED, temperature sensor, and EMG board must all be created on top of the I^2C protocol. Additionally, higher-level code will also need to be written to make use of the input from the EMG board, process it into actionable commands, and act as a fabric to work with the motor controller/encoder pair to actuate the motors.

Debugging is inherent when creating low-level drivers, and data sheets can be vague at times. These both dramatically increase the time spent developing and verifying correct operation. The ARM architecture and the toolchain we will be utilizing is new to us, so a learning curve will also be present in transferring skills we might otherwise be proficient in (for other microcontrollers) into those necessary for the success of this project.

An additional risk comes in the fact that the steps for applying conformal coating and/or potting to the circuit board designs must be completed after the designs have been created, manufactured, assembled, tested, and verified. Both methods of adding water resistance make it difficult to debug or replace parts in the circuit board after the coating has been applied. Although the application process is fairly easy, the waterproofing must be dealt with after the rest of the hardware aspects have been completed, which sidesteps the modularity and concurrency strived for in the rest of our project layout.

Ethics and Safety

The PSYONIC prosthetic arm is intended to be a medical device and, as such, carries a large selection of ethical and safety concerns. Our project is a contribution to a larger end product that is slated to go through FDA certification before being sold. As such, every aspect of our design choices must be influenced by the concern for patient safety and security. Subsections 1 and 5 of the IEEE Code of Ethics [1] make direct reference to the health and safety of people, as well as the directive of applying technology and understanding potential ramifications, respectively. These directives speak directly to the importance of the design choices we make.

The hardware design of our control board will essentially be in the palm of a patient's [albeit prosthetic] hand. As such, safety systems need to be in place to protect the patient from any
sort of electrical shock, unanticipated motor movements, overheating, or other unforeseen harms. With that said, the device still needs to strike a balance of affordability and flexibility while maintaining those rigorous standards.

The first aspect, dealing with preventing electrical shock, is handled in our design via several methods. The first of which is utilizing low-voltage signals throughout the entirety of our control board design. Additionally, implementing best practices such as properly sized ground planes on the circuit board can help absorb any unintentional over-current. The implementation of conformal coating is an additional step we are taking to protect both the patient and the medical equipment from accidental liquid spills and dust. Conformal coating works by adding a water-resistant [typically] silicone layer across the entirety of the circuit board components, which acts as a barrier between metal and any liquids.

Conformal coating or potting of circuit boards has the potential to lock in thermal energy close to the circuit board, which could result in overheating. Overheating is not just a concern based on waterproofing, however. Given patients will have no sense of temperature coming from their prosthetic hand, the possibility of unintentionally picking up a hot object is inherent. A temperature sensor is being positioned near the microcontroller on the control board towards the center of the design such that extreme temperatures can be quickly noticed. These high temperatures can act as safety stops, sending an interrupt to the microcontroller to fail safely (de-energize motors) and notify the patient via LED of a potential thermal-related error.

We are researching potential candidates for interlocking 4-pin connectors to use between our control boards and motor control boards. These connectors will provide more robust and secure ways to send signals to and from other subsystems without the possibility of a patient accidentally unplugging a device by hyperextending a finger or otherwise physically impacting the prosthetic device.

The software and firmware side of this project is not to be underestimated from a safety and ethics perspective. The first concern is that the PSYONIC device has little in the way of mechanical fail safes for the finger actuators. Due to the nature of their design, the primary method for mechanical safety is the limit on stall torque that the brushed motors can give. Previous examples of medical devices, notably the Therac-25, that lack hardware interlocks and rely solely on software requirements have taught us that appropriate software design directives must be taken in order to prevent harm to patients [2].

The EN/IEC 62304 standard defines software practices that are necessary to promote patient safety. To be specific, our project would be under the scrutiny attributed to Class B software, which is defined as having the potential for nonserious injury [3]. That classification carries with it the expectation that appropriate documentation will be present such that each software unit functionality is sufficiently stated and can be unit tested by continuous integration systems. This will be achieved by concretely defining functions such that their purpose is very specific, with any additional complexity to be completed at a more abstract level. Defining the expected input
and output in each function documentation will allow PSYONIC to pursue unit testing to meet FDA requirements more easily in the future.

Additionally, we will be auditing documentation and supplementing definitions for Software of Unknown Provenance, which represents supplementary libraries that are used. Just because libraries or other code bases have worked in the past does not inherently mean they are standards compliant or to be trusted, as the aforementioned Therac-25 showed.

The other primary concern with any medical device is the security of patient data. The Healthcare Insurance Portability and Accountability Act (HIPAA) dictates efforts that must be extended to protect patient confidentiality. To expand on this, the HIPAA Privacy Rule [4] specifies that PSYONIC would be a Covered Entity, which means they are a stakeholder in securing Protected Health Information (PHI). In order to approach these concerns with best practices in mind, our goal is to reduce attack vectors that could disclose PHI. As such, every aspect of code implemented for our control board will be done in such a way that no patient-specific identifiers or settings will have to be stored in memory. Instead, any settings pertaining to the patient will only be present on the EMG board and those will drive whatever input is given to the control board. The Health Information Technology for Economic and Clinical Health Act (HITECH Act) sets forth requirements about what constitutes a breach of confidential data, and the further specifies that these events must be responsibly disclosed [5]. By removing the potential for patient-specific information to be stored in our project’s scope, we limit the potential for that data integrity to be breached.

Finally, our concerns extend to the ensurance that PSYONIC will be able to effectively use the deliverables we give them, be it software, hardware, or both. This extends to the potential for our control board designs and codebase to be used in both the current hand implementation, as well as future designs. In order to achieve this, our design and code-base will be made as general as possible. For example, we will strive for our board layout (which is currently for a right hand) to be developed in such a way that the layout can be flipped to accommodate a left hand. Likewise, our codebase will strive to make all functions general, flexible, and modular in such a way that it can be easily utilized for left-hand operation, or be extended in the future. This is especially important if PSYONIC intends to add features or functionality. It also addresses best practices aforementioned pertaining to the pursuit of FDA approval.

References


In addition to the cited references above, we would like to formally recognize PSYONIC for providing the CAD renderings shown in Figures 2 through 6.