Periodic Leg Movement Exercise Device

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BME 401B: Verification and Validation Report

March 2, 2018

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Overview of Our Project

Periodic leg movements during sleep (PLMS) is a condition which disrupts sleep by causing uncontrollable jerking of the legs and arms. Approximately 3.9% of the total population experiences PLMS.[1] This number is significantly higher in those with underlying neural pathologies, such as multiple sclerosis, transverse myelitis, and spinal cord injuries. Counter stimulation is technique that introduces new sensations, such as leg movement or vibration, to counteract signals sent from the brain to the limbs that lead to the uncontrollable leg movements. This technique has helped relieve symptoms of restless leg syndrome, a similar and often co-occurring condition.[2] Our goal is to create a safe device for use during sleep that uses the principle of counter stimulation to alleviate the symptoms of PLMS.

Changes from Progress Report

We have had no major changes to our need, project scope, design specifications, design schedule, or team responsibilities since the progress report. Our need statement, project scope, and specifications can be found in Appendix A.

Verification Plan

Our verification plan is based on our design specifications, which are listed in full in Appendix A. A description of our intended verification plan for each specification is listed below. For those specifications essential to our device's function, we have also discussed changes that will be made if the device fails the verification plan.

Frequency of Movement: Our device should have an adjustable frequency range from 0.5 - 2.5 Hz. To verify this specification, we will run the device for 30 seconds at all possible frequencies and count the number of complete back-and-forth movements by the device during those 30 seconds. The frequency can be calculated using $frequency = \frac{\#\ of\ oscillations}{time}$.

This procedure will be repeated for periods of 15 seconds, 1 minute and 5 minutes. These time-averaged frequencies will then be compared to verify that they do not vary widely.

If our device fails to cover and stay within this specified frequency range or cannot stay consistently at a specified frequency, we will adjust the programming of the device or the motor.

Displacement: The device must not displace the users legs by more than 30 cm. The displacement will be measured using a meter stick or tape measure to determine the distance between the legs at the two most extreme oscillation points. Excess displacement could lead to discomfort or injury to the patient, so if we are not within our specified parameter, we will adjust the length of the mechanical track or the length of time for which the motor runs in one direction to keep the displacement within a reasonable range.

Force: The force that the platform exerts to move the user's legs should not exceed 150 N per leg, or 300 N total, to prevent harm to the user. To verify the force, we will measure the time taken for the device to complete a full oscillation, Δt, using a timer and the distance covered by a full oscillation, Δx, using a measuring tape. We will then calculate a time averaged acceleration using $a_{average} = \frac{\Delta x}{\Delta t^2}$. To find the maximum acceleration, we will model the platform movement as a sine wave. The time average value of a sine wave is 63.7% of its peak value, so the peak acceleration is given by $a_{peak} = \frac{a_{average}}{0.637}$. Once the peak acceleration is known, the peak force can be calculated as $F_{peak} = a_{peak} * mass$. The masses of human legs can be taken from physiological calculations to get a full range of possible masses.

Weight: The weight of the device should not exceed 10 kg to make it light and easy to use**.** We will weigh our device using a scale that can accurately read masses on the scale of 10 kg.

Cost: The cost of this device should not exceed $1,000. This will be confirmed by adding up the costs of the individual items used in making this device.

Dimension: The dimensions of the device should not exceed 70 cm by 200 cm, with the 70 cm width including the distance covered by the platform as it moves side-to-side. To verify this, we will use a tape measure to measure the distance between the furthest oscillated points, as shown in Figure 1. This distance should not exceed 70 cm. Because the device does not move along its other axis of motion, we will simply measure the width of the platform to verify that it does not exceed 200 cm.

Installation: Our product should not require daily assembly and disassembly, and should be possible to assemble while using a wheelchair. To verify this, we will have three users attempt to assemble and disassemble the device while using a wheelchair to determine if this is feasible.

Adjustable to Individual: Our device platform should accommodate legs with measurements of up to 70 cm in circumference, which corresponds to a diameter of approximately 23 cm, approximating the legs as cylinders. In order to provide a margin for error, we will assume the diameter is 30 cm, and use a tape measure to measure the space where the legs will rest.

Operating Time: This device should be consistently operable for up to 12 hours. To verify this, we will turn the machine on and videotape the device while it runs for 12 hours. We will then spot check random time points to see if the device is still running, and perform the frequency validation procedure described above to check the operation. Sufficient operating time is critical to the device functioning because the device must be able to operate overnight to alleviate PLMS, so if this specification is not met we will switch to a motor with a longer operating time.

Software Interface: The interface should be able to be used while the user is lying down, operate within a radius of 6 meters from the device, have minimal interference to the device's operation, and can change frequency or automatic/manual mode settings of the device. First, we will have a user positioned to use the device, and attempt to control it via remote control to determine if the remote is usable while the user is lying down. Second, we will test the functionality of the remote within a radius of 6 meters from the device. We will also test the device in a normal bedroom setting for 1 hour, and count the number of times the device is inoperable due to interference with the radiofrequency of the remote. Finally, we will set the frequency of the device using the software interface and perform the frequency verification test described above to determine if the software setting corresponds to an accurate frequency.

It is critical that the user have full control over the device in case they should experience harm or discomfort while operating the device. If the above specifications are not met for the remote control, we will allow the user to control the device using a 6-ft long cable to allow for both control and accessibility of the remote.

Safety: The device should cause no short or long-term harm to the user, contain no toxic materials or chemicals, contain no exposed wires or electrical components, have no harmful or disruptive loose cords, and use a low friction material to prevent bedsores. We will use Design Safe to assess the safety risks of the device. We will also conduct a separate verification test to determine whether the friction of the device is causing sores.The device will be used for a period of 7 hours, and the user will rate the discomfort they felt due to rubbing of the device padding according to the scale in Appendix B.

Comfort: The device should not be unpleasant to use and should allow the user to remain asleep or shift positions. It should also be no more than 20 cm above the height of the bed, and there should be less than 1 kg of weight attached to each leg. To verify these specifications, all three of our team members will sleep with the device and rate their comfort according to the questions in Appendix B. We will also weigh the mass of the material placed on top of each leg to confirm that it is less than 1 kg per leg, and measure the height of the legs relative to the torso using a tape measure or meter stick to confirm that it is less than 20 cm.

Sound: This device should have a noise level of less than 30 dB so as not to disturb the user's sleep. We plan to use a digital sound level meter to measure the sound levels at all different operating frequencies of the device.

Due Date: We will have a completed and fully working device as well as documentation of verification by May 1, 2018.

Validation Testing Plan

To aid in our validation plan, we identified our client's primary and secondary needs for this device. The primary needs were specified by our client and are absolutely necessary for client satisfaction. Our client and broader market primarily need a device that reduces the severity of PLMS, improves sleep quality, is comfortable enough for use while sleeping, and allows for control over the device movement if desired. These parameters are the most important for our client and are the main goal of our device.

In order to verify that these needs are met, we will continue to test the user's control of our device via the Software Interface verification testing plan. We will also test our working prototype ourselves as part of the comfort and safety verification testing plan to verify that it is comfortable enough for use while asleep. Once we have confirmed that the device is sufficiently comfortable and safe to use, we will give our client the prototype to test whether it can satisfactorily reduce the severity of PLMS and improve sleep quality. These phases of testing involving human users should be performed carefully - starting at small intervals of use - to minimize risk of injury to the users. To verify that our device does alleviate the symptoms of PLMS, we will direct our client to record her sleep with and without the device and self-report the number of leg movements and rate the severity of the leg movements using the survey in

Appendix B. Self-reporting is most appropriate in this case to protect the privacy of our client. We will also collect information on sleep quality with and without the device. If we fail to meet these primary needs, we may have to redesign our device to be more effective and comfortable to use, possibly through incorporation of more motors or padding. We may also add a vibrational component or look into other mechanisms of motion.

Secondary client needs include the option for use while awake, ease of use, simple installation, and an automatic function when the user is asleep. The device also should not disrupt anyone else sleeping in the bed. Several of these parameters will be achieved through verification of our specifications. For example, our sound and size specifications were designed to minimize disruptions to bed partners, and our verification testing will see that these specifications are met. For more holistic validation testing, we and our client will simulate the experience of setting up the device and controlling it while awake and allowing it to run automatically when asleep. We will first set up our device using a wheelchair, as many people in our target market, including our client, use wheelchairs. If this is difficult to do, we will reconfigure our device to improve ease of use. Our client will also set up our device in her bed and report on any difficulties encountered. She will test the device while awake and report on its effectiveness. The automatic function can be evaluated through video recording and self-reporting by the client on the success of the device. We will also survey her partner to ascertain the disruptiveness of the device to other people. If we fail to meet these secondary needs, we may incorporate minor changes to our device design, material, or programming.

Proof-of-Concept Testing

For the first half of the semester, we focused on controlling the speed and rotation of a DC motor via an Arduino microcontroller and a PWM motor driver controller. We set the motor to run in a fixed alternating pattern of clockwise and anticlockwise movement, which simulates the eventual motor behavior required to drive the platform. We also successfully allowed the user to control the motor speed via a hardwired connection to the computer, which will eventually be switched to a wireless connection to allow for better device accessibility.

Motor Network

We ordered a PWM Motor Driver that drives a single motor, so that an optimal amount of power is delivered to our motor. We connected the +5V pin of our driver to the +5V pin of our Arduino, the PWM pin on our driver to one of the Arduino’s PWM pins, the two input pins of our driver to two of the Arduino’s output pins, and the ground of the driver to the ground of the Arduino. We connected the power supply pins on the driver to our 12V AC to DC power supply adapter, and the mechanical output pins of our driver to our reversible, high torque motor. For proof of concept testing, we drew power from the computer via connection through a USB cable that was plugged into the Arduino. Once we finalize our code and circuitry we plan to draw all power from an AC power outlet. Appendix D shows a schematic similar to the circuit setup we used, with differences in the motor driver controller that was used and slight changes made in the powering of the driver. However, the circuit schematic shown in Appendix D is essentially the same as what we used to connect our components.

Initial Code

Our initial code, shown in Appendix E, tests whether the motor could run both clockwise and counterclockwise at given speeds. We used the serial monitor in Arduino to prompt entry of a speed within the motor’s range of speed. Once a speed is specified, the code runs the motor through a loop in which the motor alternately runs clockwise and counterclockwise for 3 seconds, braking for 1 second in between. The motor will continue running until the user specifies a new speed, at which point the motor will begin a new loop with the updated speed.

Overall Status of Project

During the first half of the semester, our main focus was connecting and driving the device's inner motor network. The results are described above in our proof of concept testing. We also finalized our platform design and the materials needed, and created finalized CAD drawings of our platform design. We plan to start building the outer structures and connecting this to the motor network and the software interface during the second half of the semester.

Platform Design

While we initially thought we would use heavy-weight durable plastic for our device, we realized that this is too expensive and difficult to work with. For the purposes of this project, we decided that we should use either a light-weight wood, such as Balsa wood, or sheet metal in the construction of the moving platform structure described in our progress report.

We will be building a bottom platform that will stay stationary on the bed and enclose the motor circuitry. This will be connected via a metal track to an upper platform, which the motor will move side to side. The top platform will consist of a rectangular indent, in which the feet and legs will be placed, with a padded flap that can be closed to cover the legs and hold them in place as the platform moves. The edges and corners of the rectangular indent will also be padded to increase comfort for the user. The CAD sketches for this platform are in Appendix C.

Next Steps

Our immediate next steps are to order the remaining parts needed for our platform and software interface. This includes the materials needed to build the platform as well as the radiofrequency transmitter and receiver. We plan to have the latter ordered before spring break. The next step will be to translate the DC motor's rotational movement into the translational movement of the platform, and to build the platform and integrate the motor to drive it. Finally, we will build the software interface and set it to control the device's movement.

References

1. Hornyak, Magdolna, et al. "Periodic Leg Movements in Sleep and Periodic Limb Movement Disorder: Prevalence, Clinical Significance and Treatment." *Sleep Medicine Reviews*, vol. 10, no. 3, 2006, pp. 169–177., doi:10.1016/j.smrv.2005.12.003.
2. Mitchell, Ulrike. "Medical devices for restless legs syndrome-Clinical utility of the Relaxis pad." Therapeutics and Clinical Risk Management, vol. 11, 3 Dec. 2015, pp. 1789–1794., doi:10.2147/tcrm.s87208.

Appendix A: Need Statement, Project Scope, and Design Specifications

Need and Project Scope

There is a need for a device to lessen the frequency and severity of nighttime periodic leg movements experienced by individuals with multiple sclerosis, transverse myelitis, spinal cord injuries or other neural pathologies in order to allow them to comfortably sleep through the night.

We propose to deliver to the client, BME faculty and students on the last day of class a prototype of an automated motion system which would include a safe device that can move the user's legs back and forth without waking the individual, an interface that allows the user to decide if and when the device is turned on and at what intervals, and documentation and programming code used in creating the device. The size and shape should allow the individual to use the equipment while sleeping in any sized bed, and the motion of the device should be easily controllable. Finally, the equipment should cost less than $1,000, so that it is a financially feasible purchase for those who need it. The prototype of the device and interface will be made available to the client by May 2018.

Design Specifications

Specification	**Metric**
Frequency of movement	0.25 to 2.5 Hz
Displacement	0 to 30 cm
Force	< 150 N per leg
Weight	< 10 kg
Cost	< $1000
Dimension	Length < 200 cm Width < 70 cm, half of the width of a full bed
Installation	Does not require daily disassembly/assembly 1 person sitting in a wheelchair can set up
Adjustable to Individual	Fits any leg circumference up to 70 cm Any leg length
Operating Time	At least 12 hours Adjustable
Software Interface	Allows user to control device program while lying down Operates in a range of 6 ft Wide range of control: automatic mode for sleep; manual control for wake Minimal interference
Safety	Causes no short or long-term damage to user Contains no toxic materials or chemicals and no exposed electrical components Cords not harmful or disruptive to user Low friction: avoids sores due to friction over long term use
Comfort	Lifts legs < 20 cm above rest of body < 1 kg weight attached to each leg Should not be unpleasant to use, allows user to remain asleep Allows user to shift positions throughout sleep (side, back, stomach, etc.)
Sound	< 30 dB_A
Due Date	May 1, 2018

<u>Appendix B: Verification and Validation Survey Questions</u>

Safety:
On a scale of 0 (meaning no rubbing or discomfort was experienced) to 10 (meaning painful friction sores were created while using the device), how much rubbing or discomfort did you encounter while using this device?

Comfort:
How many hours of sleep did you achieve?
Rate your quality of sleep from 0 (being worst) to 10 (being perfect and uninterrupted).
How many times do you wake up (on average) from PLMS each night without using the device?
How many times did you wake up while using the device?
On average, how severe from 0 (being least severe) to 10 (most severe) is your PLMS without using the device?
On average, how severe from 0 (being least severe) to 10 (most severe) is your PLMS while using the device?

For the Partner (if applicable):
How many times were you awoken from your partner's use of the device?
On a scale of 1 (being least disruptive) to 10 (most disruptive), how disruptive was the device's functioning to you?

<u>Appendix C: CAD Designs</u>

Dimensions of device in cm

Front view

Top View

Side View

Angle View

Appendix D: Motor Circuitry Schematics

Image source (modified to our circuit specifics):
https://howtomechatronics.com/tutorials/arduino/arduino-dc-motor-control-tutorial-l298n-pwm-h-bridge/

Appendix E: Arduino Code Controlling Motor

```
const int pwm = 3 ;  //initializing pin 3 as pwm
const int in_1 = 5 ;
const int in_2 = 6 ;
int speed = 0;
int serialValue = 0;

void setup()
{
 //sets up the pins
pinMode(pwm,OUTPUT) ;   //we have to set PWM pin as output
pinMode(in_1,OUTPUT) ;  //Logic pins are also set as output
pinMode(in_2,OUTPUT) ;

//opens the serial controller
 Serial.begin(9600);
```

```
//prompts the user to enter a speed within the correct range
 while (! Serial);
 Serial.println("Speed 0 to 255");
}

void loop()
{

//updates the speed based on serial input
if (Serial.available())
  {
    int tempSpeed = Serial.parseInt();
    if (speed >= 0 && speed <= 255)
    {
      serialValue = tempSpeed;
    }
  }

 if(serialValue != speed){
  speed = serialValue;
 }

//runs the motor through a set loop
if (speed != 0){
     //For Clock wise motion , in_1 = High , in_2 = Low
      digitalWrite(in_1,HIGH) ;
      digitalWrite(in_2,LOW) ;
      analogWrite(pwm,speed) ;

      //Clockwise for 3 secs
      delay(3000) ;

      //For brake
      digitalWrite(in_1,HIGH) ;
      digitalWrite(in_2,HIGH) ;
      delay(1000) ;

      //For Anti Clock-wise motion - IN_1 = LOW , IN_2 = HIGH
      digitalWrite(in_1,LOW) ;
      digitalWrite(in_2,HIGH) ;
      delay(3000) ;

      //For brake
      digitalWrite(in_1,HIGH) ;
      digitalWrite(in_2,HIGH) ;
      delay(1000) ;
}
}
```