Design and Development of a Peripheral Nerve Stimulator to Aid in Testing for Diabetes

by
Anthony Megel, Honors Program Graduate
Angela Carrillo
Jessica Bolanos

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Abstract

Diabetes is a disease that can result in, among other things, a reduction of sensory nerve reception of the skin. This loss of sensation can be detected early and treated to reduce the risk of bodily injury and amputation. Using the industry standard Semmes-Weinstein Monofilament test, detection thresholds are determined by the force of light touch. This force targets the Meissner nerve receptors. Unfortunately, the force exerted by the filaments can weaken over time, thereby reducing the accuracy of the test. One solution proposed to detect the threshold levels by means of sensory vibration. This instrument, the Biothesiometer, has been found to correlate very poorly with industry standards. It is possible that the instrument stimulates a different sensory group, the Pacinian receptors.

A new design will attempt to correct problems found in the Biothesiometer and incorporate technology for reducing operator error. To stimulate the Meissner receptors, an appropriate frequency will be targeted. Also, an appropriate amplitude range must allow for detection of all levels of threshold. To eliminate or reduce the human error factor, the design must allow for repeatable test procedures. Of most interest is a common applied force. Hitting these targets will allow medical personnel to more accurately detect the onset and stages of diabetes.

Anthony Megel
Angela Carillo
Jessica Bolanos

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Problem Statement

Some diseases, especially diabetes mellitus, result in a loss or reduction of sensory nerve transmission from the skin. The loss of sensation is known as "peripheral neuropathy," and when detected early, it can often be treated to reduce complications. It is a major disability, and if left untreated the results can include bodily injury and amputation. Because sensory nerve evaluation is a non-invasive process, it can be widely used as a first-detect method without introducing painful blood-sugar tests. Detection of sensation loss is usually diagnosed with light touch or vibration, and its usefulness can extend past diabetes to include patients with thermal injuries or nerve damage.

To detect the loss of sensation, two methods exist. A set of monofilament instruments is the industry standard. This is called the Semmes-Weinstein Monofilament test, and it targets the Meissner Corpuscles, nerve receptors close to the skin surface. The test is conducted by pressing a filament at 90 degrees to the skin surface until the filament bows. If the subject can feel the force of the filament, that location is complete and the filament size is recorded. If the subject cannot feel the force, the next largest filament is selected and the procedure is repeated until the filament can be felt. Table 1 shows how the force of each filament relates to the different stages of peripheral neuropathy. The problem with the Semmes-Weinstein test, however, is poor repeatability. This can be caused by application at angles other than 90 degrees and by weakening of the filaments over time.

Table 1. Sensory evaluation chart for the Semmes-Weinstein monofilament test.

Target Force(grams)*	Hand & Dorsal Foot Thresholds	Plantar Thresholds
0.008	Normal	Normal
0.02		
0.04		
0.07		
0.16	Diminished Light Touch	
0.4		
0.6	Diminished Protective Sensation	Diminished Light Touch
1		
1.4		
2		
4	Loss of Protective Sensation	Diminished Protective Sensation
6		
8		
10		Loss of Protective Sensation
15		
26		
60		
100		
180		
300	Deep Pressure Sensation Only	Deep Pressure Sensation Only

One proposed solution to the Semmes-Weinstein monofilament test was an electric vibrating stimulator called a Biothesiometer. It is set at a constant frequency and has variable amplitude of vibration. The instrument is easier to use and can usually obtain results faster than the filament method. However, when compared to industry standards, the Biothesiometer produced correlation coefficients that ranged from 0.25 to 0.47. Therefore, results from the Biothesiometer cannot detect stages of peripheral neuropathy as effectively as the Semmes-Weinstein monofilament test.

Dr. Neal Latman in the Department of Life, Earth, and Environmental Sciences at West Texas A&M University has proposed a possible solution to the problem. The Biothesiometer

uses vibration to stimulate the receptors. If sensory transmission of the skin in degraded, the amplitude of vibration must be increased to be felt by the patient. The amplitude of vibration is adjusted by a rotary rheostat or potentiometer. (Both are names for an adjustable resistor; the difference is in the amount of resistance and therefore the power capacity of each. Rheostats are typically available up to 1000 ohms, while potentiometers may vary from 1k- to 25k-ohms.)

The Biothesiometer is set to vibrate at a constant frequency of 120 Hz at an AC input of 60 Hz. We have determined that the electric current to the stimulator is 60 Hz and that in fact each change of direction of vibration is considered one frequency cycle. For the vibration to be detected by the Meissner receptors, the frequency of vibration needs to be greater than 40 Hz and less than 100 Hz. Instead, the 120 Hz frequency of the Biothesiometer primarily stimulates the Pacinian receptors, a group of nerve cells below the Meissner receptors. Even if the frequency of vibration was correct, too much pressure applied to the skin could also cause the vibration to stimulate the Pacinian receptors. Therefore, a uniform, constant, and consistent pressure needs to be applied by the operator. A new design should incorporate a device to monitor or control the amount of force applied to the skin. This would not only increase the accuracy of the instrument, but it would also decrease human operator error, thereby allowing for better reproducibility.

Objectives

Our project will redesign a method of testing for peripheral neuropathy. Because the vibration method is faster and easier to use, it is the focus of this project. To create an effective design will require specific changes to overcome the problems the current vibration method is prone to. Therefore, our primary objectives are:

1. to redesign a sensory nerve tester,
2. to target Meissner nerve receptors, and
3. to create a high level of repeatability.

Completing these objectives should allow us to create a design that better correlates to industry standards. When these objectives are completed, we expect to deliver a prototype of the new design we have created. This prototype will have full capabilities, allowing it to be tested for accuracy and repeatability. Medical researchers will test to confirm that the design correlates to industry standards for detecting disease stages.

We must identify a target frequency range to stimulate the Meissner receptors. This is essential to accurately detecting sensory nerve diseases. We must provide an adequate range of vibration amplitude to distinguish between standard thresholds of *Normal Sensation, Diminished Light Touch, Diminished Protective Sensation,* and *Loss of Protective Sensation*. We must also incorporate into the design a system that allows for consistent pressure to be applied to each patient, thus allowing for a repeatable procedure.

Of the current test methods on the market, the Semmes-Weinstein Monofilament test is contained in a small tool pouch. The Biothesiometer is self-contained in a traveling case. Both devices are easily transportable to testing sites. Therefore, it is our secondary objective to keep

the product small and design it in a case that can be easily transported to the test subjects. This will allow for quicker, easier testing that can reach more people. Altogether, this design should provide better detection of sensory nerve reduction, preventing more people with diabetes mellitus from suffering bodily injury, amputation, and disease-related complications.

Design Constraints

Many of the design issues have been summarized above. There are five design constraints we must look at in order to create a feasible product:

1. required frequency,
2. amplitude range,
3. consistent pressure range,
4. size of the incorporated design, and
5. cost/funding to construct and test the design.

We have already determined that the required frequency needs to lie somewhere between 40 Hz and 100 Hz to target the Meissner receptors. To simplify the design and reduce the cost, a vibration of 60 Hz will be sufficient. The use of 60 Hz will allow for direct conversion of standard 60 Hz A/C outlet voltage without the need of expensive frequency drive equipment.

The amplitude is directly tied to the voltage supplied to the vibration device. Both need to be low enough so that the normal threshold can be detected and differentiated from levels of sensory loss. They also need to be high enough that subjects with sensation loss can easily be identified.

To allow for a consistent pressure range, the mounting of the stimulator must be carefully designed. The pressure could be prevented from increasing past a certain range or an electric shutoff could be integrated. Optionally, the stimulator could be mounted so that the fingertips could only apply a certain maximum force. Because the device will be designed as a test

instrument, it is important that the applied force be monitored at all times. A scale sensitive to one gram should be sufficient to provide a detectable range that can be sustained by the subject being tested.

Although the size of the design is not a high priority since this is a test instrument, a self-contained design is most desirable. Additionally, an easily transported device will allow the instrument to reach more people without them needing to schedule an office visit. The smaller it can effectively be constructed, the easier it will be to use and to test.

Although no budget constraints were initially imposed on the design team, costs were kept to a minimum. The simplest design that can get the job done properly is the best. This also implies a budget as low as effectively possible. Biothesiometers are mass-produced and still sell for several hundred dollars, so a prototype of our design constructed of individually purchased components could have a realistic cost of a few hundred dollars. Therefore, five hundred dollars was set as an unofficial spending limit. As we prepared a budget, we projected a cost of about half that as seen in Table 2 below.

Table 2. Initial cost projection for constructing a design prototype.

Voltmeter	$ 100
fuse and switch	$ 10
Variable resistance	$ 10
Vibration source	$ 25
Travel case	$ 30
Load cell	$ 35
Miscellaneous	$ 25
Total	**$ 235**

Phases

To efficiently design and develop a new system for detecting sensory nerve loss, certain phases were planned for the project. The following are the phases of the design:

1. Find usable components
2. Integrate system components and modify as necessary
3. Design product body/case
4. Produce/assemble working design
5. Preliminary testing – data acquisition device
6. Project report/conclusions and team presentation

The phases were set so the design objectives and criteria would fit into the project's timeframe. The schedule in Table 3 below allowed for appropriate planning and project monitoring.

Table 3. Schedule of planned phases and the approximate time needed for completion.

Phase	Time Needed	Expected Completion
1	2-3 weeks	February 23
2	3-4 weeks	March 16
3	1-2 weeks	March 23
4	1-2 weeks	April 6
5	1-2 weeks	April 20
6	2-3 weeks	May 7

At the conclusion of the project, a fully-functional prototype will allow researchers to determine that the correct nerve receptors, the Meissners, are being stimulated. This is expected to be a test instrument that may incorporate more features than a production design. The extra features will allow the researchers to calibrate the device to find the best solutions for an optimal production. They will also confirm if the vibration method is a suitable replacement for the Biothesiometer and an effective alternative to the standard Semmes-Weinstein Monofilament test.

Design Process

We had many design considerations, such as varying the frequency, pressure and voltage. We looked into A/C and D/C motors for the vibration. We found that for D/C motors, the voltage being applied determines the motor speed. Because we need voltage adjustments to vary the amplitude of vibration, we decided to operate the device on alternating current. Because most all A/C motors are constant speed, we researched how variable speed and variable frequency drives operated. Variable speed drives can be either electrical or mechanical and variable frequency drives (VFD) are only electrical. A VFD converts power to a new frequency in two stages – a rectifier stage and an inverter stage. These methods of frequency variation cost above $250, so the frequency will be fixed at 60 Hz. Because this is in the acceptable 40-100 Hz range, the device can be tested to confirm that this range is appropriate to stimulate the Meissner receptors.

We considered vibrating motors, such as the ones found in cell phones and pagers and quickly found that their ranges of vibrations were not high enough to provide adequate stimulation. Next, we decided to look into commercially available massagers. We looked into both single and multi-speed massagers, with a single probe. We decided to purchase the Con-Air® Touch N' Tone® with magnet attachment, model HM11M (see Fig. 2). We chose this model to investigate the vibration with minimal cost. This device contains an electromagnetic coil operating on alternating current. As stated previously, the theory behind an electromagnetic coil is that it exerts a magnetic force that varies in response to the amount of current flowing through it, so consequently the magnetic force varies with applied voltage.

Figure 1. The design coil was taken from this simple vibrating massager.

We started with a basic wiring of the coil and a 5 kΩ potentiometer rated at 0.5 watts to see if the minimum vibration was reached. Next, we introduced a 10-amp fuse to eliminate any component damage caused by electrical surges and a 125-volt self-illuminating switch. The new components were then mounted on a clipboard as shown in Fig. 3.

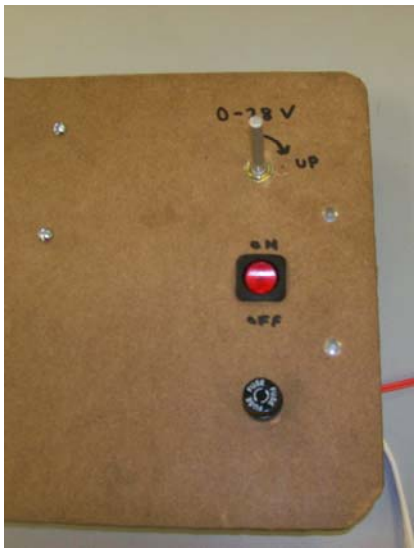

Figure 2. Top of the circuit board with initial components installed.

We found that the RadioShack® potentiometer that was purchased did not provide enough resistance to bring the voltage, and thus the vibration, to zero. We also soon discovered that it could not handle the sustained wattage of the coil. As a solution, we also introduced a 25.2-volt transformer to allow the 5 kΩ potentiometer to reach the minimum vibration possible. This new setup is shown in Fig. 4. The measured output from the transformer was actually 28 volts. However, this appeared to be insufficient in reaching a high enough threshold for subjects with severe levels of peripheral neuropathy, so we eliminated the transformer and replaced the 5 kΩ potentiometer with a 10 kΩ potentiometer with a higher power rating of 5 watts. The 10 kΩ potentiometer gave us both the minimum vibration we were seeking and a wide range of vibration so the device can accurately detect high, low and moderate levels of sensory nerve loss.

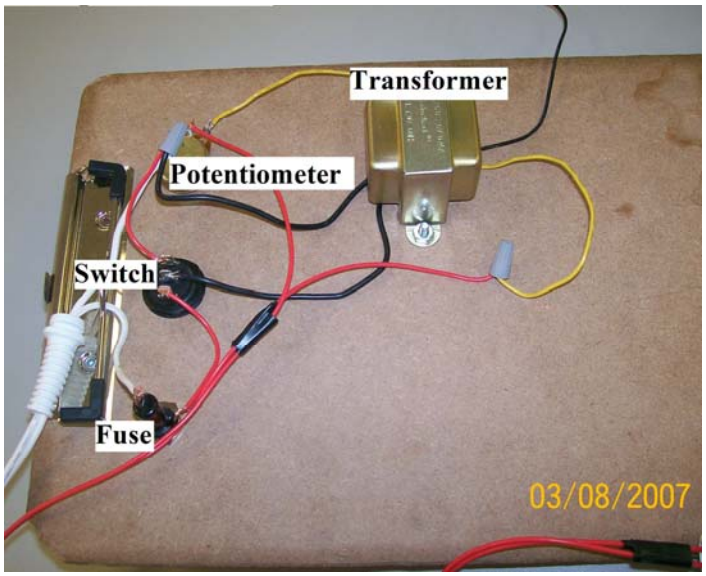

Figure 3. Bottom of the circuit board with initial components and transformer installed.

To achieve a true vibration rate of 60 Hz, we installed a rectifier which converts the full sine-wave electrical signal to a half-sine signal. This was mounted on a switch so researchers could test the effects of switching between 60-Hz and 120-Hz vibration. This gives the researchers a "control" to compare the frequency to instead of looking strictly at results from the Biothesiometer since we have other modifications in our design. Once we had our preliminary design and verified that all the specifications were met we started looking for voltmeters and scales. We ordered a Simpson analog panel A/C Voltmeter with a standard range from 0 to 150 volts from DigiKey, Corporation.

We discussed several different options for varying the pressure and decided on the Royal 3-lb. postal scale, model 17012Y (Fig. 5), which operates on a 9-volt battery. It has a wide range of loading and can be switched between units. The scale is also appropriate for handling the 256 gram-weight of the coil and human pressure exerted on it. Because different areas of the body have different pressure thresholds (see Table 1), we want to allow researchers to find different pressure ranges if needed. In order to effectively install the scale's load cell, we mounted the stimulator stationary instead of in a hand-held applicator.

Figure 4. The simple postal scale used to monitor the applied force of the stimulator.

We started mounting all of the components of our final design in a modified tackle box purchased at Wal-Mart®. All the components were mounted on the tackle box with a clipboard plate used as an added mounting face. The completed design in shown in Figs 5-9. Notice that the stimulator is mounted flush with the top panel (Fig. 8). This is a design feature added during the construction process to help with the stability of the applied force. With the side of the box cut out (Fig. 8) the subject can rest their hand on the panel and allow their finger to rest on the stimulator. At the same time, if any additional force is to be applied, the subject's finger will be pressing on the hole. This way, the subject cannot be tested with a deep pressure force that would stimulate inappropriate receptors.

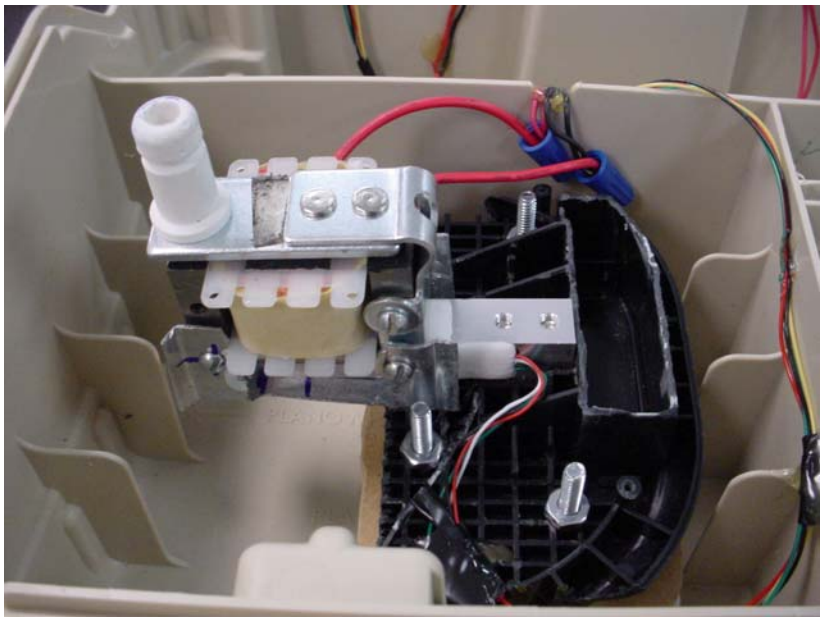

Figure 5. Mounting of the coil and stimulator on the load cell.

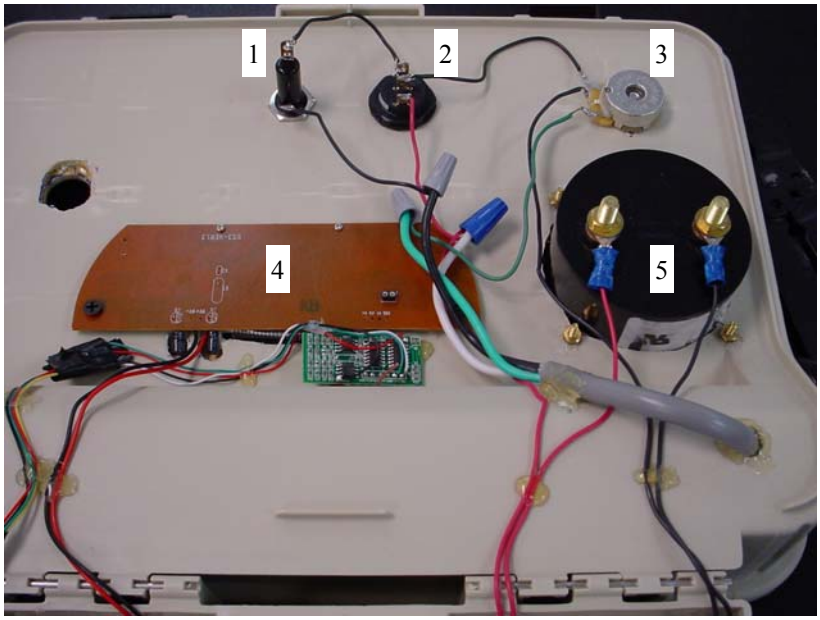

Figure 6. Underside of the mounting panel showing components installed:
(1) fuse; (2) switch; (3) potentiometer; (4) load cell circuit board; (5) A/C voltmeter

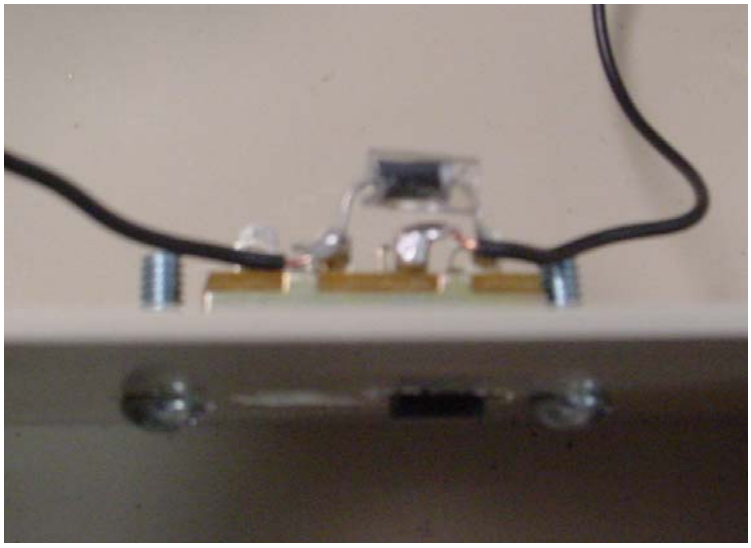
Figure 7. Installed rectifier switch allows 60- or 120-Hz vibration.

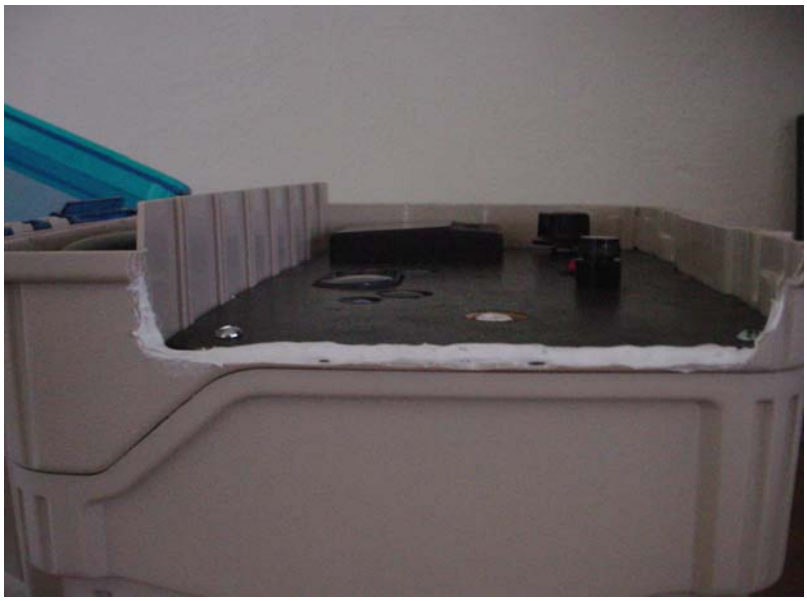

Figure 8. Side view showing level mounting of vibrating stimulator.

Figure 9. Top panel showing operating controls.

Once all the components were mounted, we worked on wiring the system. Once the all the components were wired together, the wires became complicated and messy. We secured the

wires with hot glue to the box. This way, when the operator opens the box to switch out the battery used for the load scale, the components will not become entangled. A wiring schematic is shown below in Fig. 10.

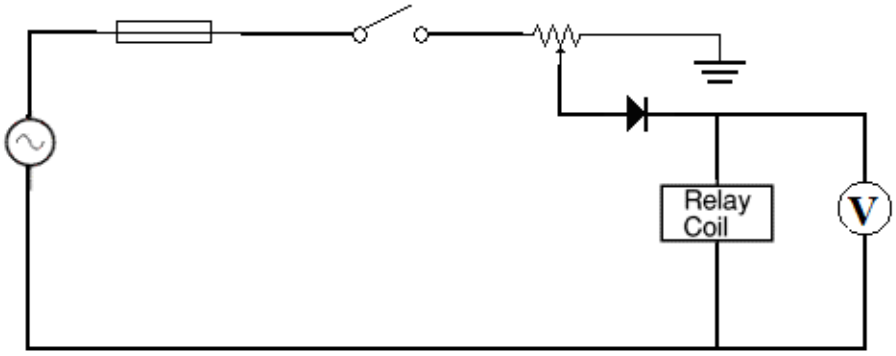

Figure 10. Wiring schematic for the assembled prototype

The expenses for this prototype fell well within the projected budget. Table 4 below shows the actual costs for the project.

Table 4. Final costs for constructing a design prototype to detect peripheral neuropathy.

Simpson Analog Panel Simpson Voltmeter	$ 85
10 A fuse and 120 V Switch	$ 5
10 kΩ potentiometer with 5 watt power rating	$ 5
Conair® Touch N' Tone® coil	$ 10
Plano Two-lid Tackle Box	$ 15
16 Gauge Grounded Outlet Cord	$ 10
Royal 3-lb. Postal Scale	$ 20
Miscellaneous	$ 10
Total	**$ 160**

The first design was fully built for seventy-five dollars less than our estimates. If, after testing, any improvements are needed, we still have money to take care of some issues immediately. Also, the electronic components used in this design can be purchased at much lower prices in higher quantities. Therefore, if this design becomes widely produced, the manufacturing costs will drop further. Considering that similar medical instrumentation sells for several hundred dollars, this design could provide a substantial profit margin if researchers find it to correlate well with the standard monofilament test.

Theory

Because the design uses an electromagnetic coil to supply vibration, it is important to understand how it works. The magnetic field of an electromagnet is produced by the flow of electric current. When the electric current is removed, the magnetic field disappears. Magnetic fields flow around the current-carrying wire. For this design, we have a coil. Wire is wrapped around an insulating material that surrounds a metal core. When the coil in energized, the metal core is in the path of the magnetic field and becomes magnetized. A magnetic field caused by a coil follows the right-hand rule. This is because, for a charged particle, the magnetic force is the cross product of the electron flow and the magnetic field as shown in Eqn. (1) below.

$$\vec{F}_B = q\vec{v} \times \vec{B} \quad \text{.....(1)}$$

where F indicates the magnetic force, q is the particle charge, v is the particle velocity, and B is the magnetic field.

In a coil, the current follows the circular path of the wire and the magnetic field flows around the wire. Therefore, the direction of the magnetic force is perpendicular to the electromagnetic face. We can use this principle to model a cantilever beam suspended above the electromagnetic coil as shown in Fig. 11.

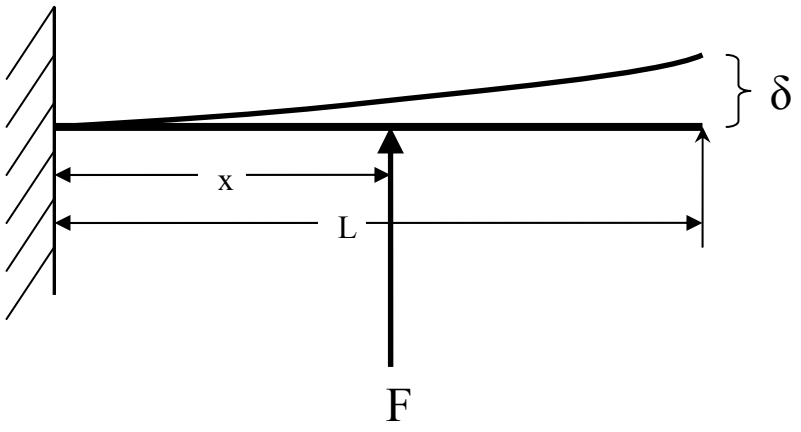

Figure 11. Cantilever beam model of stimulator base using magnetic force to produce vibrations.

Because we can assume the force is acting from the center of the coil, we know that *x* is simply *L/2*. The deflection, or in our case, the amplitude of vibration, is determined from Eqn. (2) below. Note that this is the maximum deflection, so we must be sure that the outer edge of the beam is where the stimulator is mounted.

$$\delta = \frac{Fx^2}{6EI}(3L - x) \quad \text{.....(2)}$$

But because we know the value of *x* in terms of *L*, Eqn. (2) can be rewritten as:

$$\delta = \frac{F\left(L/2\right)^2}{6EI}\left(3L - L/2\right) = \frac{FL^2}{24EI}\left(\frac{5}{2}L\right)$$

$$= \frac{5}{48}\frac{FL^3}{EI} \approx 0.104\frac{FL^3}{EI} \quad \text{.....(3)}$$

where *I* is the area-moment of inertia and *E* is Young's Modulus for the beam material. Because we are operating on A/C, we need to realize that the direction of current changes 60 times per second, as therefore so does the direction of the magnetic force. However, since we are using a

rectifier to reduce the electric signal to half-wave, we only need to be concerned with the force in one direction. Fig. 12 shows the rectified sine wave that the design will operate on.

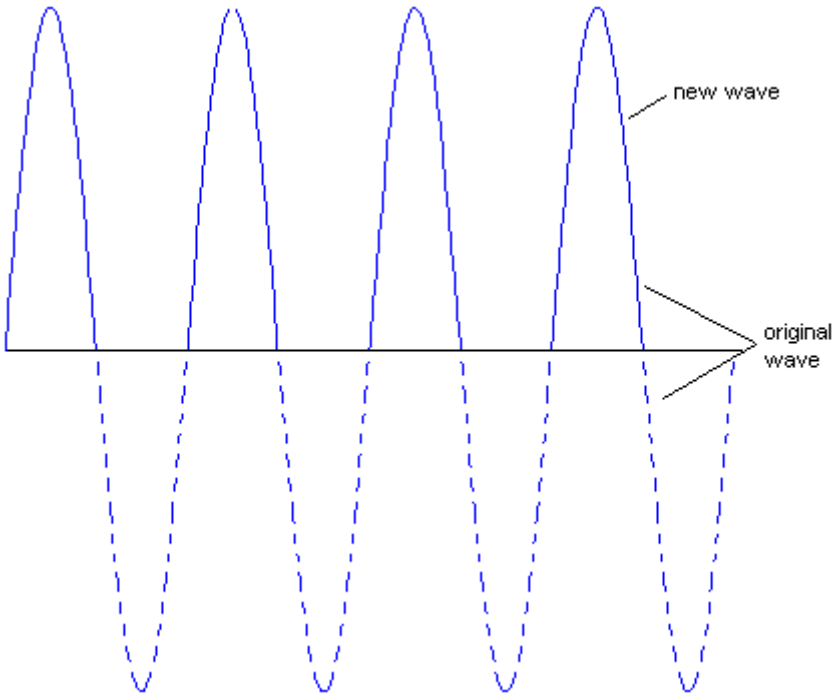

Figure 12. The rectifier removes the negative half of the voltage sine wave.

To determine the magnetic force requires the magnetic field to be known. This force is calculated as:

$$F = \frac{B^2 A}{2\mu} \quad \text{.....(4)}$$

The permeability of free space, μ, is known to be $4\pi \times 10^{-7}$ H/m (Henries per meter). The calculation in Eqn. (5) is used to determine the strength of the magnetic field in teslas.

$$B = \frac{\mu N I}{L} \quad \text{.....(5)}$$

The length of wire, L, is determined in this case as the circumference of the coil. The electric current, I, can be measured. However, the number of turns of wire, N, is nearly impossible to determine without destroying the coil. Therefore, testing should be conducted to determine the actual amplitude of vibration of various voltage inputs.

Summary

Peripheral neuropathy occurs when sensory nerve transmission is reduced or lost. Diabetes is a disease that can result in, among other things, a reduction of sensory nerve reception of the skin. This loss of sensation can be detected early and treated to reduce the risk of bodily injury and amputation. Current methods available for detecting peripheral neuropathy have downfalls, the most problematic of which is poor repeatability.

This new design attempts to correct problems found current methods incorporate technology for reducing operator error. The main focus points of the new design are:

1. To stimulate the Meissner receptors,
2. to detect all sensory threshold levels,
3. to eliminate or reduce the human error factor, and
4. to allow for repeatable test procedures.

Focusing on these points will allow medical personnel to more accurately detect the stages of sensory diseases such as diabetes.

The design was constructed for $160. If the instrument is effective in detecting sensory transmission loss, it could generate a high profit while reducing the cost to medical personnel. Researchers will test the device to determine its potential for replacing current methods and becoming a more effective way to detect peripheral neuropathy.

Continuing Research

As the design process reaches completion and the prototype is delivered, a student researcher under the instruction Dr. Neal Latman in the Department of Life, Earth, and Environmental Sciences at West Texas A&M University will attempt to confirm that the features implemented in this design allow for detection of sensory nerve disorders through vibrations. They hope to prove this device correlates to the Semmes-Weinstein monofilament test better than the Biothesiometer.

The design team will stay in touch with Dr. Latman as the testing progresses to offer addition modifications as necessary. He has already determined that a standard panel voltmeter is not sensitive enough to record voltage readings at low threshold levels. Therefore, a custom voltmeter will be built with a scale of 0 to 50 volts A/C. This expected delivery time for this meter is one week, and the team will have it installed before the device is finally handed over the Dr. Latman and his researcher for testing.

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Dr. Neal Latman – for bringing this project forth and for supporting the construction of a prototype and sharing the financial burden

Dr. Freddie Davis – for your support as Department Head and also for sharing the financial burden for constructing the device

Appendix A: Instructions

Please read all instructions carefully before attempting to operate the device.

The patient:

1. Make sure the subject is comfortably situated.
2. Explain the testing procedure to the subject before beginning. Allow them the opportunity to ask any questions before and during testing.
3. Look carefully and the tips of the subject's fingers and note any scarring, callusing, or unusual appearances on the "Comments" section of the "Subject Test Record" sheet.

The device:

1. Open the bottom latch and confirm that the load cell readout is connected to a standard 9-volt battery. Close and latch the case before proceeding further.
2. Make sure the control knob is turned fully in the counterclockwise direction.
3. Open the top of the case so that the control panel is accessible.
4. Connect the power cord to a 120-volt grounded U.S. outlet.
5. Press the blue "ON" button to turn on the load cell readout. Verify that the readout shows "0". If necessary, press the "UNITS" button until the desired measurement scale is displayed.
6. Flip the red power switch to turn the main power on. At this time, there should be no vibrations produced by the stimulator. If there is, verify that the control knob is turned fully counterclockwise before continuing.

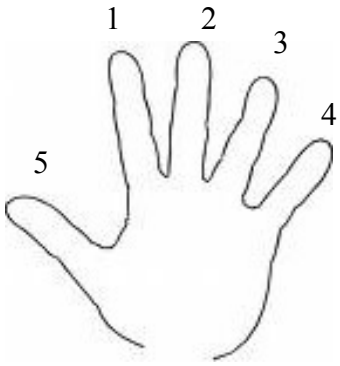
The test:

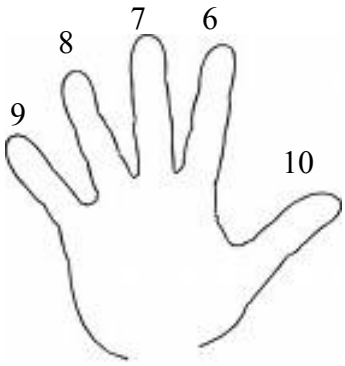
1. Ask the subject to rest their hand on the black panel at the side opening. Have them rest a finger on top of the stimulator. Verify that the load cell readout remains reasonably steady.
2. Slowly turn the control knob clockwise until the subject confirms that they can feel the vibration.
3. At this point, record the current voltage reading on the "Subject Test Record" sheet.
4. Repeat the procedure with the remaining fingers before switching to the other hand.
5. When testing is complete, turn the control knob fully counterclockwise, flip the red power switch off, and push the blue "ON" button to shut off the load scale. Unplug the instrument and fold the power cord into the back divider behind the control panel.

Appendix B: Subject Test Record

Name: _____ Examiner: _____

Date: _____





Left Hand: Right Hand:

1. _____ 6. _____
2. _____ 7. _____
3. _____ 8. _____
4. _____ 9. _____
5. _____ 10. _____

Comments: _____

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