NerveStim: Verification &Validation Report

GROUP 12: JACK ELLIOTT-HIGGINS, TAYLOR LAVENDER, & KATIE SIMONS

NerveStim Overview

Client: Dr. Matthew MacEwan

Need Statement: There is a need for a new pain management therapy for patients suffering from chronic pain after invasive surgery that does not foster dependence and does not require additional surgery or explantation

What it does: This device includes an external controller wirelessly connected to an internal bioresorbable implant. The implant will produce a high-frequency alternating current (HFAC) nerve block.

Changes from Progress Report

No changes to need statement, project scope, design schedule, or team responsibilities

Deleted specifications:

- Wireless communication frequency
- Wireless power range
- Charge length of implant
- Recharge duration of implant
- Transmission rate
- Wireless power safety

Changes from Progress Report: Controller Design Specifications

Size	13x18x5 cm
Weight	200 grams
Power source	Rechargeable
Communication	Wireless
Wireless Communication Range via Passive Powering	4 cm away
Wireless Communication Protocol	Passive Power
Biocompatibility	Does not need to be biocompatible
Transmission Voltage	150 – 250 mV
Transmission Duration	100 – 300 µS
Rechargeability Convenience	Device should not require the patient to spend excessive time recharging it

Recharge duration	Maximum 3 hours
Charge period	Minimum 1 week
Controller cost	Less than $200
Compatibility with Hardware	100% compatibility required
Security	100% secure
Energy Consumption	Less than 6 W
Sufficient Output	7 – 12 V
Time to Completion	6 Months
Compatibility with Battery	100% compatible
Accessibility	Accessible for all patients - is not prohibitively expensive and does not depend on smartphone ownership

Changes from Progress Report: Implant Design Specifications

Nerve cuff diameter	1.0 - 1.5 mm
Bioresorbable layers	9.9 ± 0.9 nm
Bioresorbable device viability	90 days
Weight	10 grams
Electrical stimulation frequency	14kHz-26kHz
Output Voltage	50 – 150 mV
Wireless Communication Range via Passive Powering	4 cm away
Wireless Communication Protocol	Passive Power
Biocompatibility	Must be biocompatible

Power source	Passive
Implant Safety	On/off mechanism
Implant Cost	Less than $200
Sufficient Power	0.5 - 200 mW
Time to Completion	6 Months
Safe Current Density	1 – 10 mA
HFAC block	Block necessary
Adjustable Size	Size should be adjustable

Verification Plan: Overview

Mechanical Measurements
- Weight
- Size
- Accessibility

Electrical Measurements
- Observational
- Mustimeter
- Oscilloscope

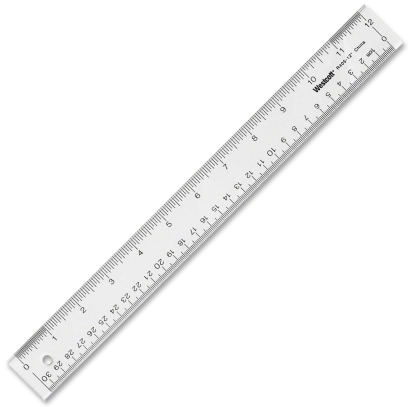
Non-Testable Specifications
- Biocompatibility
- Cost
- Time to Completion
- Security
- Nerve Block

Verification Plan: Mechanical Measurements

Weight
- Weight of implant
- Weight of controller

Size
- Nerve cuff diameter
- Controller dimensions

Accessibility
- Nerve cuff adjustability
- Controller accessibility

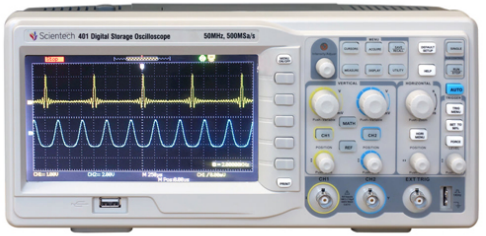


Verification Plan: Electrical Measurements

Observational
- Transmission duration
- Charge period and recharge duration
- Rechargeability convenience

Mustimeter
- Output voltage
- Wireless communication protocol and range via passive powering
- Implant power source
- Implant safety
- Implant sufficient power
- Safe current density
- Controller power source
- Transmission voltage
- Energy consumption
- Controller sufficient output

Oscilloscope
- Electrical stimulation frequency
- Compatibility with hardware
- Compatibility with battery



Verification Plan: Non-Measurable Specifications

Biocompatibility
- Biocompatible materials
- Viability in tissue

Cost
- $400 total cost

Time to completion
- Prototype completed by April 19th, 2019

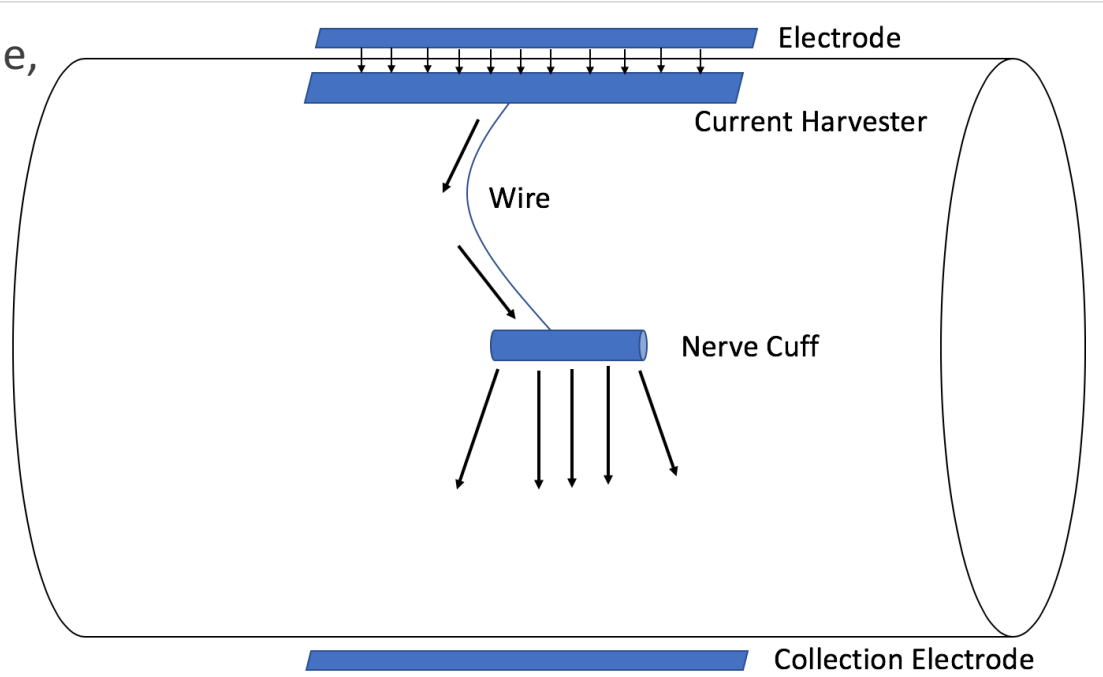
Security
- 100% device security and data safety

Nerve Block
- Verification outside project scope
- Experimental current range present at nerve cuff

Validation Plan

Primary aim to validate wireless component

- Wireless transmission will be tested in a medium with similar consistency to human flesh, such as tofu or saline bag
- Current will be measured at transmitting electrode, nerve cuff, and collection electrode
- Concern of shunting current



FDA Process

Class III Medical Device
- Often implantable
- High risk device
  - Electric stimulation of nerves

Premarket Approval
- Demonstrate device is safe and effective for intended use

Steps to Approval
- Bench top testing
- Inactive device implanted in rat to test biocompatibility
- Active device implanted in rat to test effectiveness
- Tested in larger animals or humans

Early Feasibility Study
- If approved, ~10 human clinical study can proceed

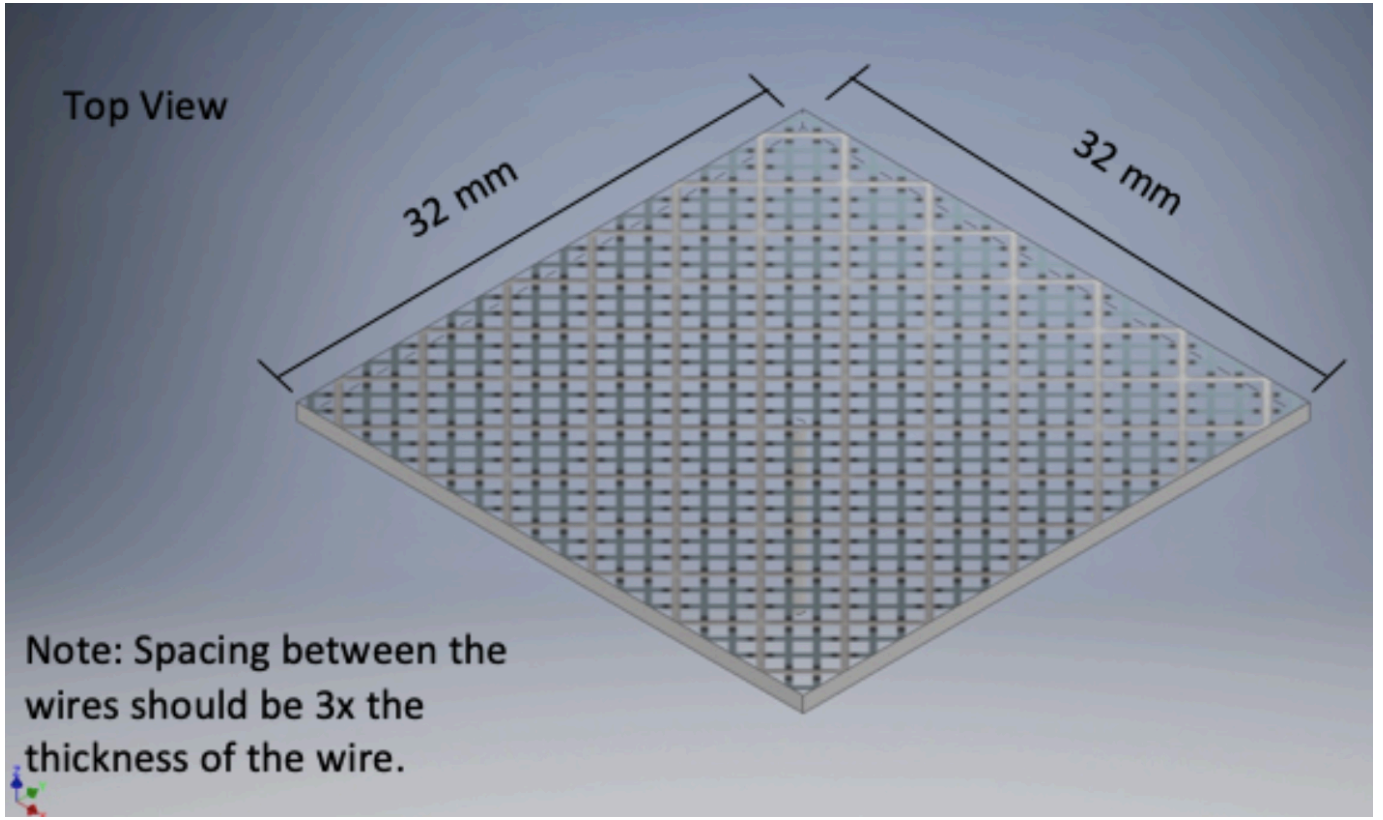
Approval and to market
- If effectiveness and safety are demonstrated, device can be marketed

Project Status

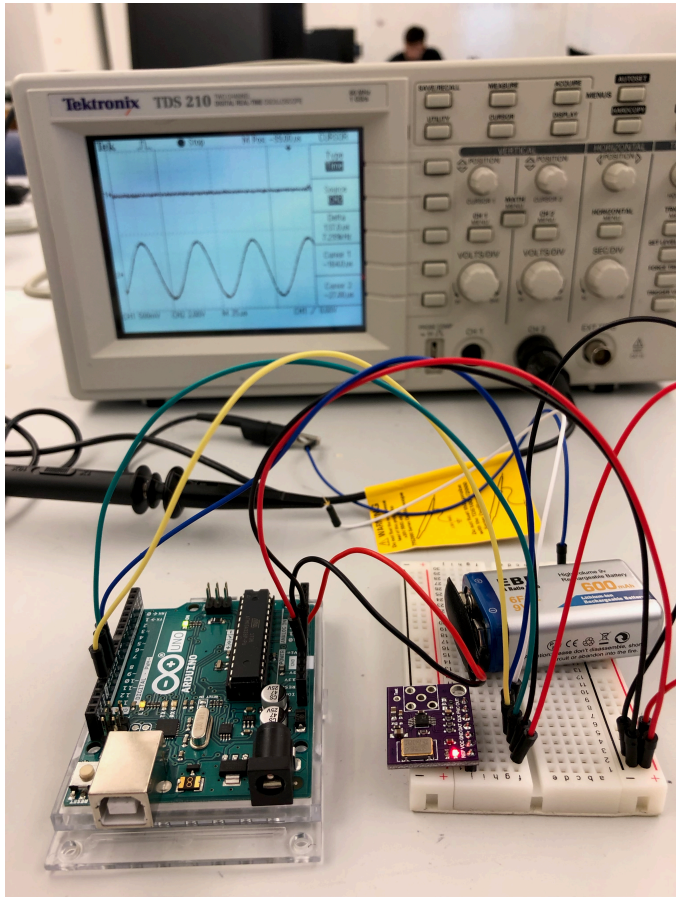
Completed
- Proof of concept testing

In progress
- Full controller prototype
- Implant current harvester

Next steps
- Robust code
- Benchtop testing
- Controller refinement
- Implant refinement



Proof of Concept Results



Function generator chip and Arduino microcontroller communicating

Frequencies between 14 kHz and 26 kHz generated successfully

Sine, triangle, and square modes generated successfully

Potentiometer read successfully

Powered device with battery

Sources

Rogers, John, et al. “Bioresorbable Pressure Sensors with Thermally Grown Silicon Dioxide Biofluid Barriers for Monitoring of Chronic Diseases and Healing Processes.”

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Questions?