

SmartStim: Final Report

TEAM 14: NATALIE NG & NATHAN SCHMETTER



SmartStim Overview

Client

Why is it needed?

What does it do?

Client: Dr. Matthew MacEwan, OsteoVantage

Need Statement: There is a need for the development of a subcutaneous device to safely decrease instances of **pseudarthrosis** in patients of bone fusion surgeries.

What it does:



SmartStim Overview



Prototype

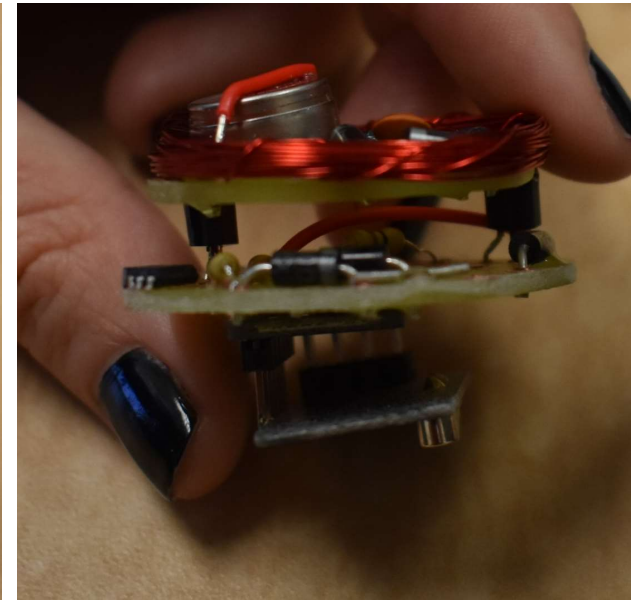
- Components
- Screw cap
- Surgeon's Wand
- Software
- Charging Backpack
- Electrical Connection

SmartStim Components:

1. Modified Pedicle Screw System
 - Circuitry
 - **Mechanical system**
2. Surgeon's Wand
3. Software
4. Charging Backpack

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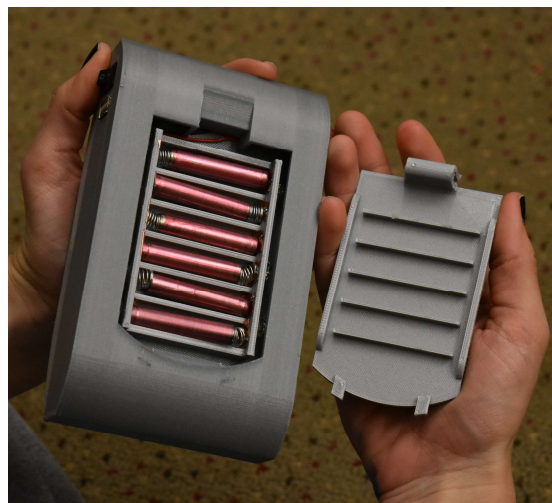
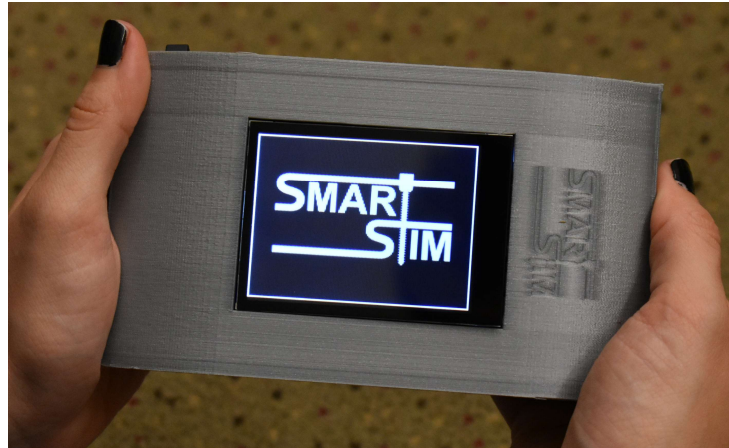
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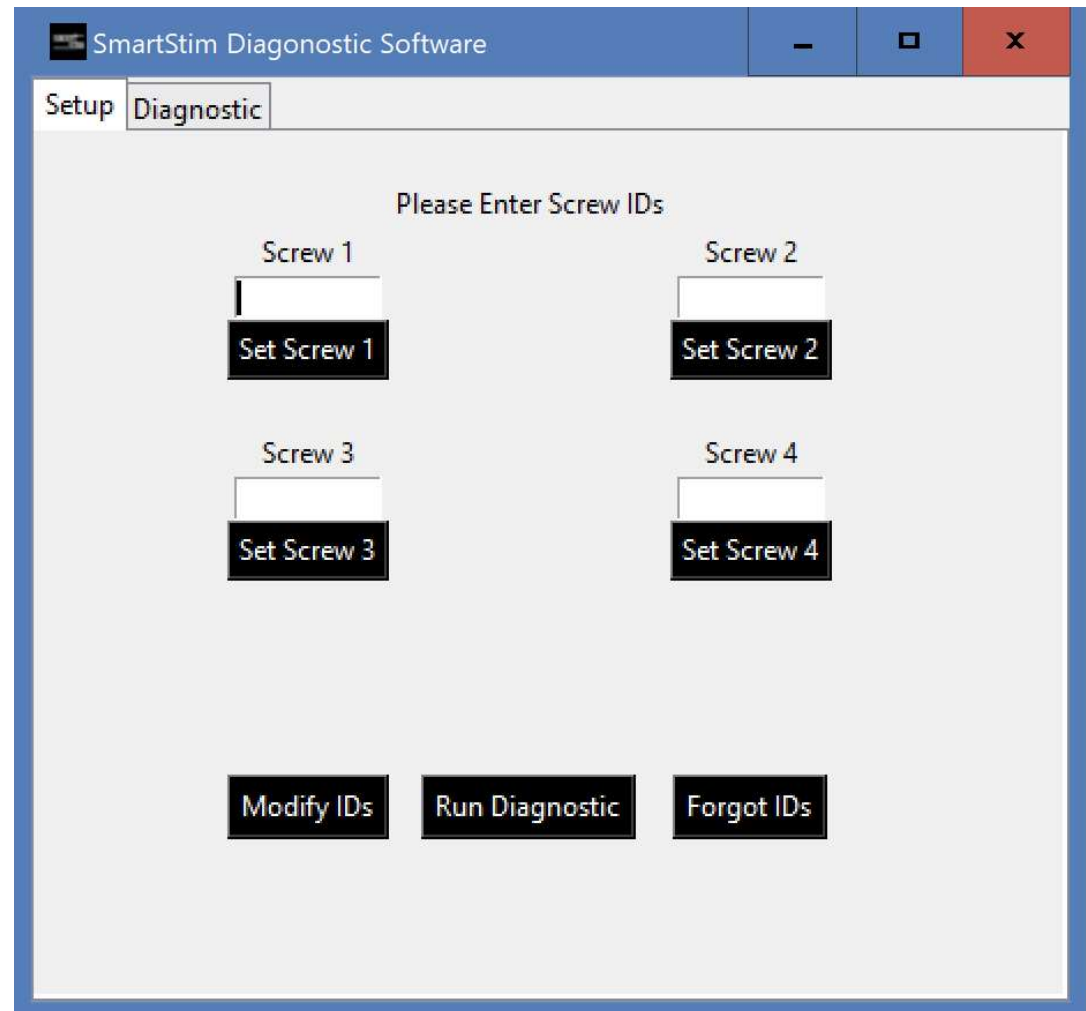
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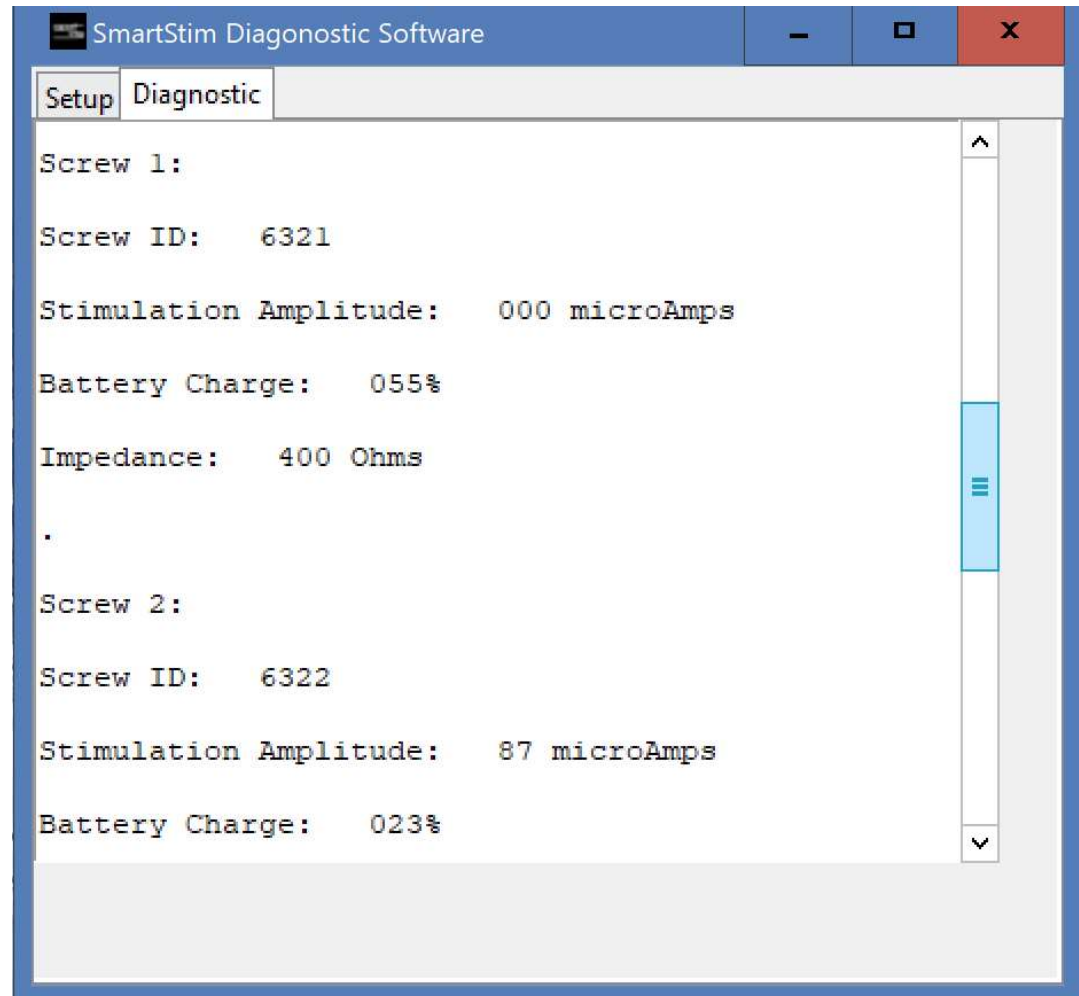
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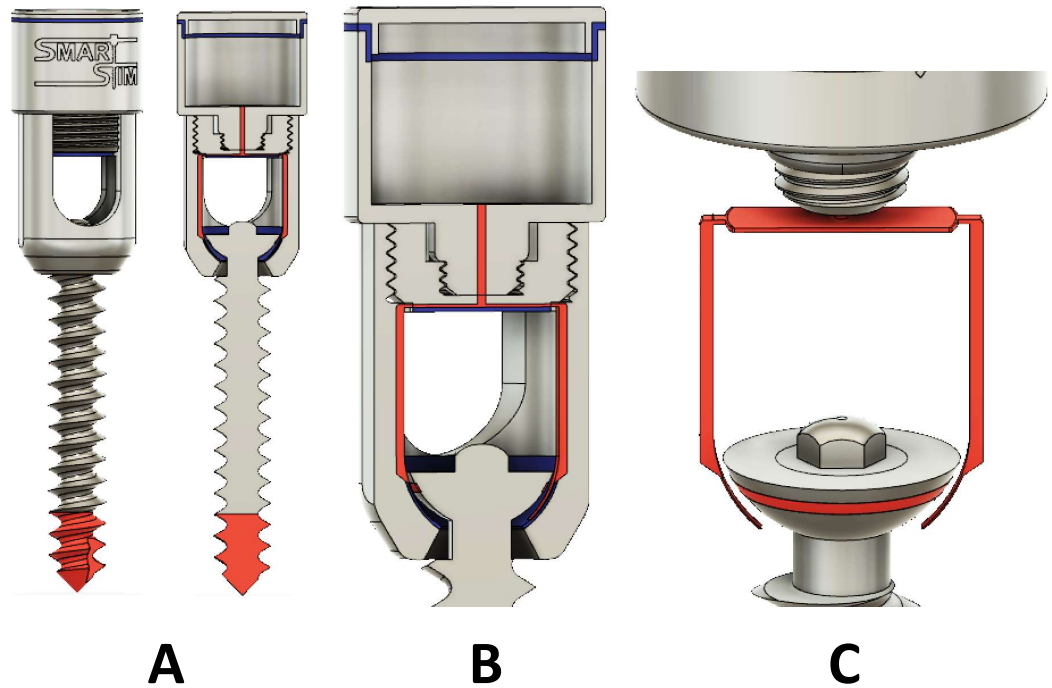
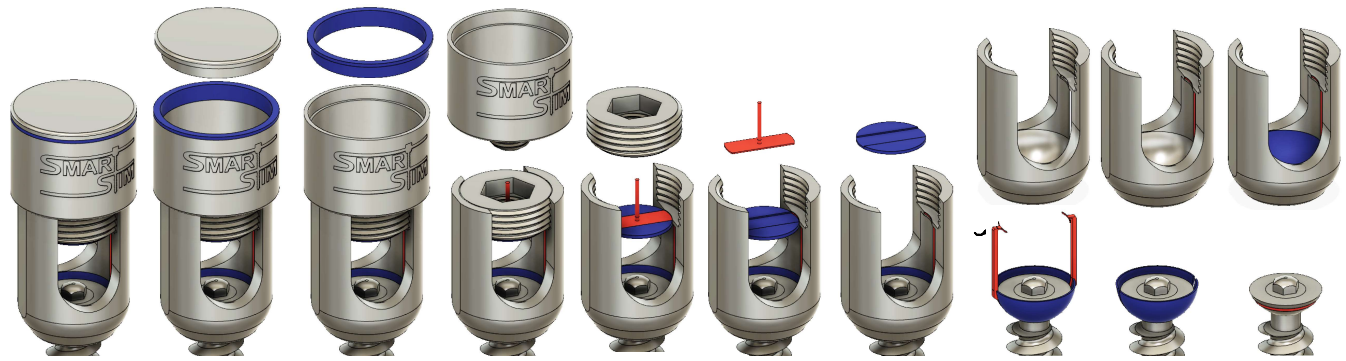
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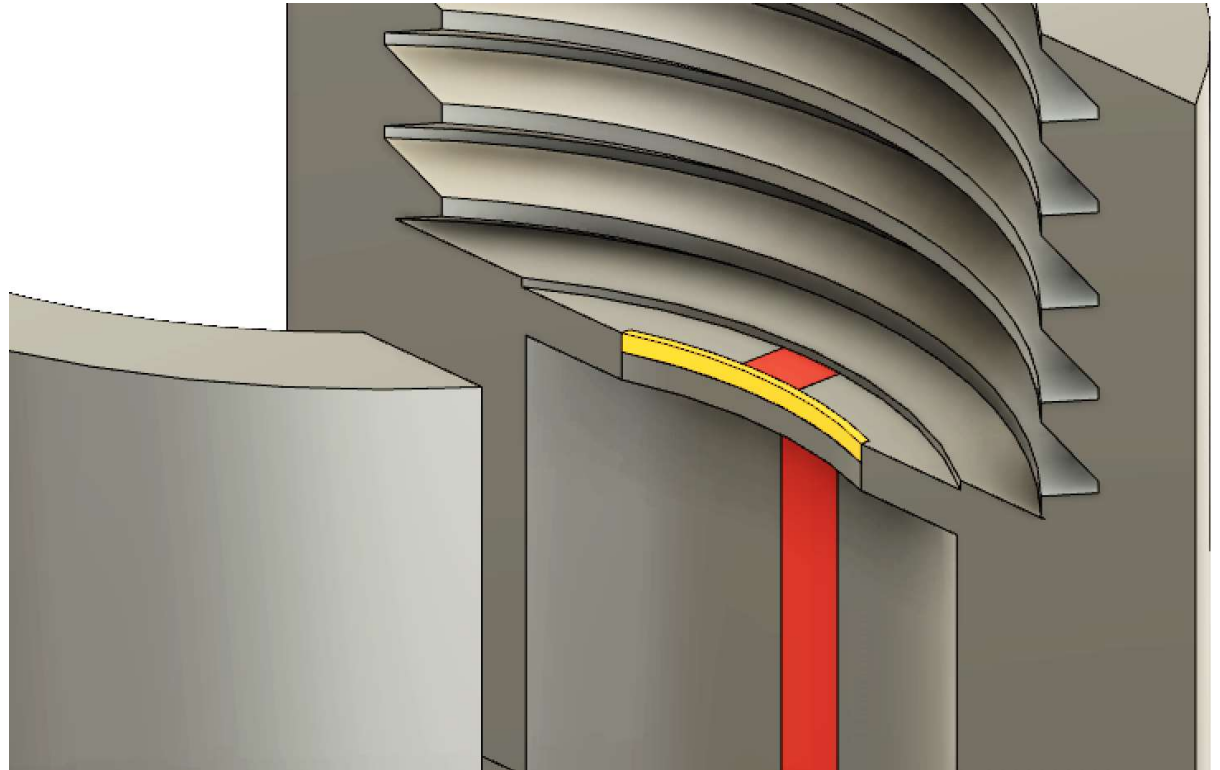
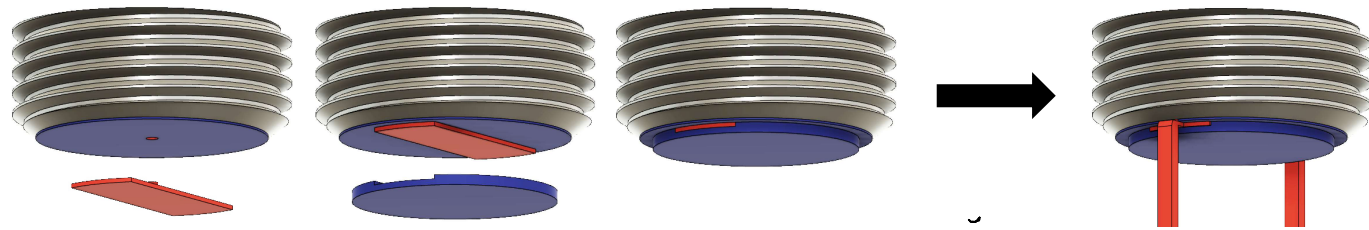
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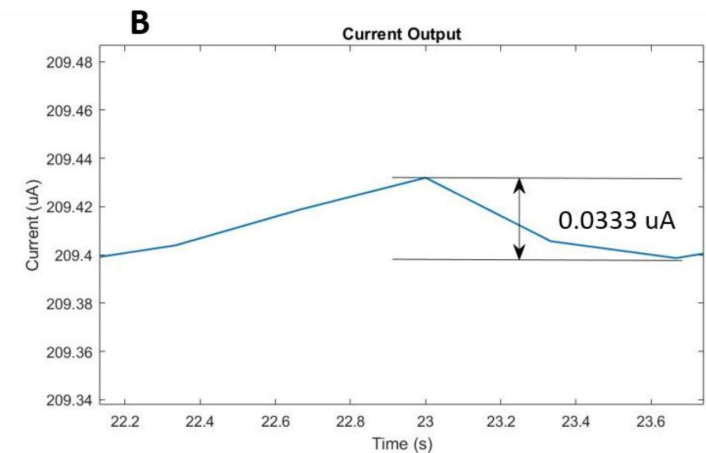
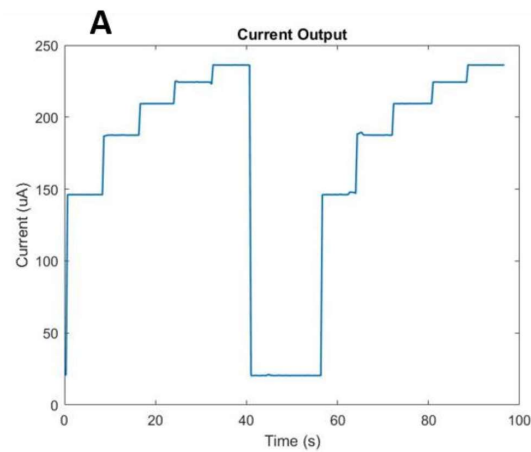
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Verification Data

- Current output
- Current modulation
- Software responsiveness
- Hardware safety mechanisms
- Inductive charging profile

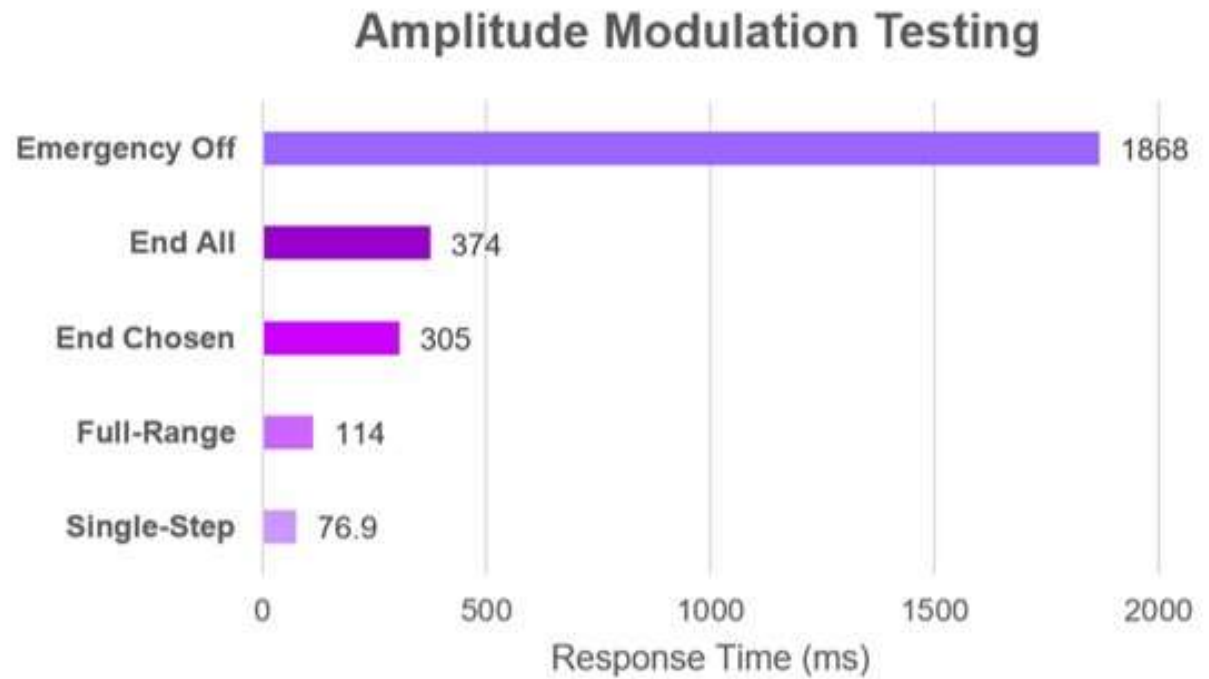
Design Specification: Addressable current output 10-200 μA
Design Specification: Steady-state fluctuation $\pm 3 \mu\text{A}$
Design Specification: $< 2.5\%$ overshoot



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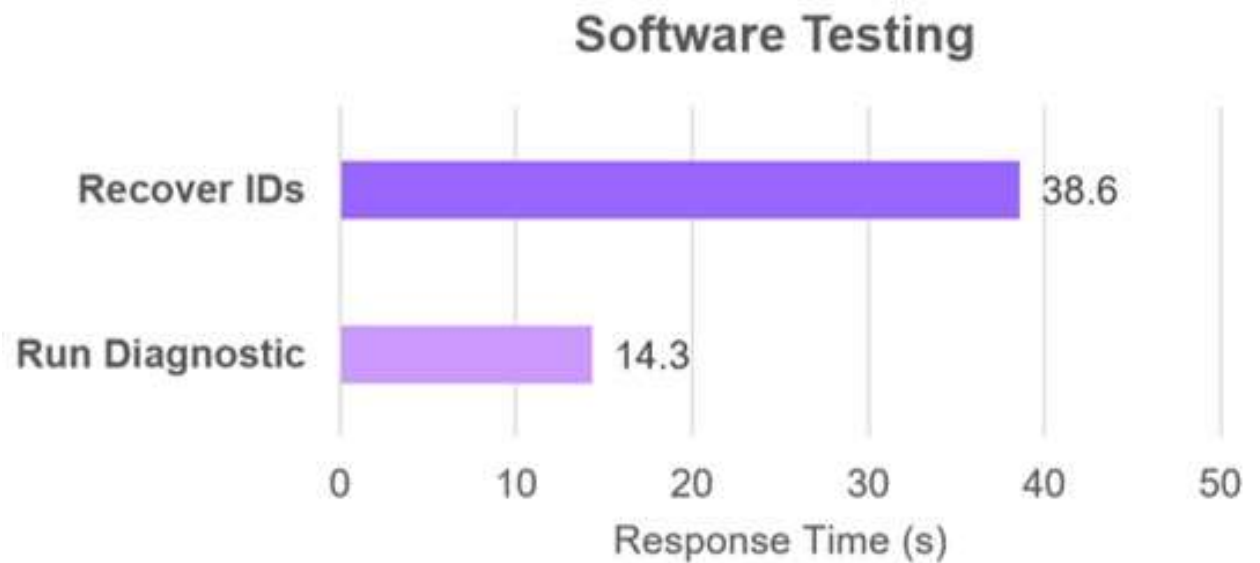
Design Specification: Remote modulation of amplitude < 15s
Design Specification: Emergency off < 15s



Verification Data

- Current output
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- Inductive charging profile

Design Specification: Respond to software in < 1 min



Verification Data

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Design Specification: Shutdown if temperature $> 39^{\circ}\text{C}$

Design Specification: Shutdown if current surge detected

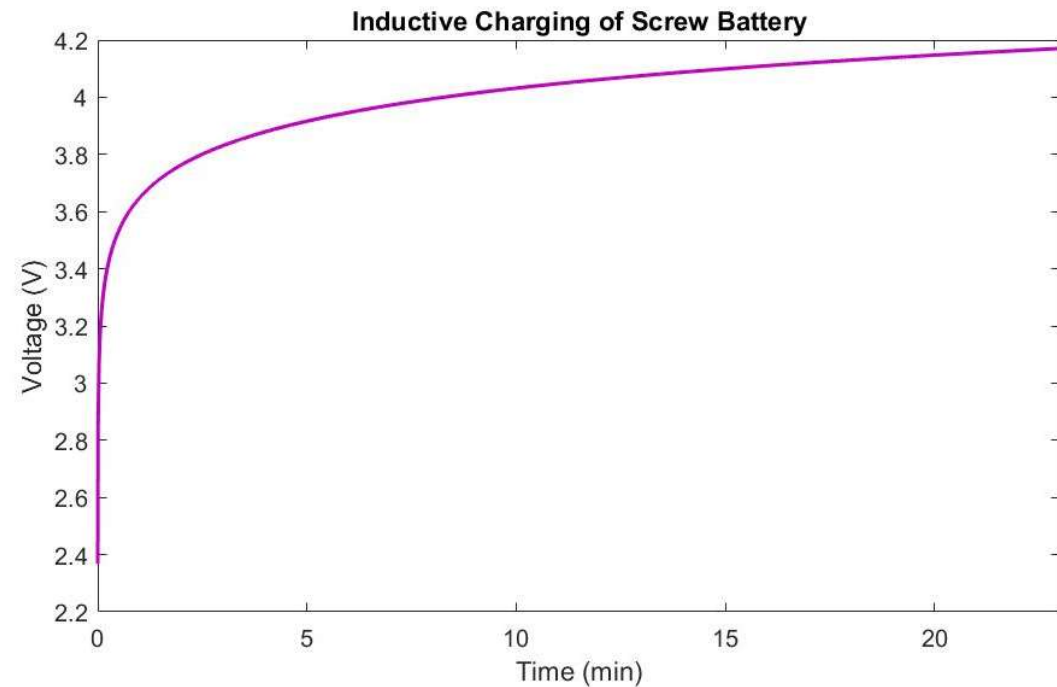
Hardware Safety Features	
Hazard	Response Time
High Temperature	10.5 s
Current Surge	258 ms

Verification Data

- Current output
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Design Specification: Inductive charging < 2 hrs

Design Specification: Backpack can charge screws $\geq 4x$



Validation

- Patient compliance
- Market viability
- Ethical concerns

“There is absolutely no doubt that I would be willing to comply with this procedure should have been applied to me.”

“She felt confident in her willingness to commit the time for charging of both the battery pack in the brace and the internal batteries.”

- Charlie Newcomen

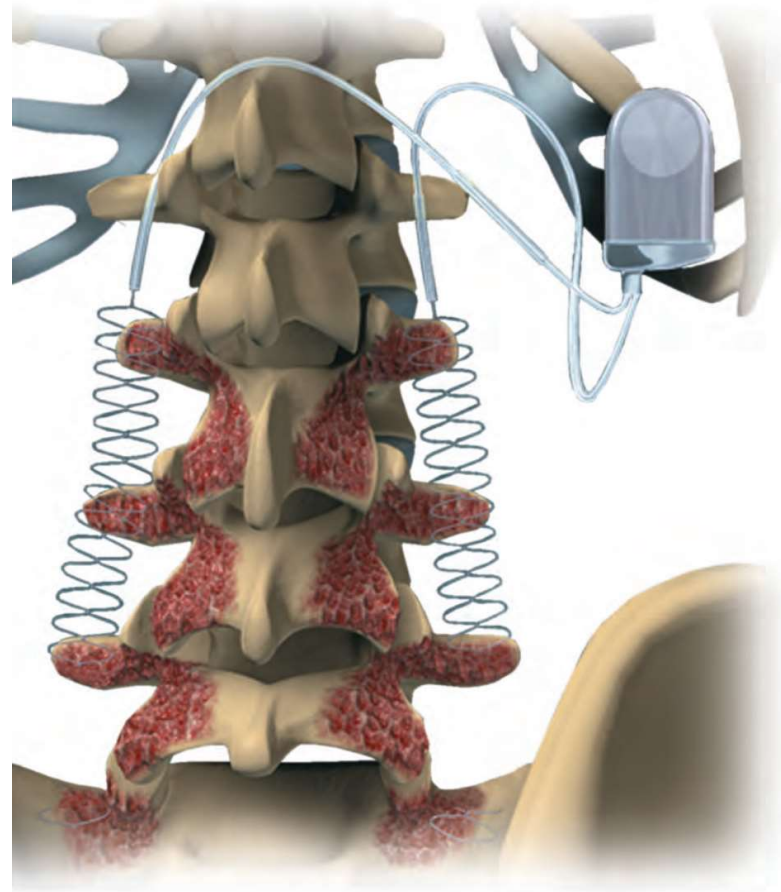
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Validation

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RF Hacking Concerns

- Need access to unique screw IDs or universal command
- No access to the primary microcontroller code
- Safe to eliminate stimulation
- Excess stimulation
 - Built-in current surge protection
 - No access to push higher than 200 μA (hard-coded limit)

Manufacturing

- Microchip programming
- Screw cap circuit
- Electrical connection
- Total cost



ATMega328PB+

Item	# Units	Price/unit
Silicon	1-25	\$1.36
Programming	0-500	\$0.26
Ink Dot		\$0.01
	Total	\$1.63

Manufacturing

- Microchip programming
- Screw cap circuit
- Electrical connection
- Total cost



- Can manufacture multilayer nano-wire circuits of the desired size
- Pots and places all surface mount components
- 2 week turn around time
- Rapid quote: \$200-300

Manufacturing

- Microchip programming
- Screw cap circuit
- Electrical connection
- Total cost



- Can manufacture intricate metal components with poured silicon or resin
- Charged for sit-down consultation to get a quote
- Estimate 3-5x normal pedicle screw cost: \$1,100-1,800

Manufacturing

- Microchip programming
- Screw cap circuit
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Cost to fabricate a single prototype:

Component	Cost
Programming	\$1.63
Circuitry	\$200-300
Mechanical screw system	\$1,100-1,800
Total	\$1,300-2,100

Future Directions

- Consult for **OsteoVantage**
- Pursue prototype manufacturing
- Sheep studies
- Incorporation of stimulation into existing brace structure
- Flexible screw number

References

1. Pakzaban, Peyman. "Spinal Instability and Spinal Fusion Surgery." *Background, History of the Procedure, Problem*, MedScape, Jan. 2016.
2. Lee, et al., "Lumbar Pseudarthrosis: Diagnosis and Treatment." *Seminars in Spine Surgery*, W.B. Saunders, Dec. 2011, www.sciencedirect.com/science/article/pii/S1040738311000542.
3. Walsh, Nancy. "Spinal Implant Prices Vary, Process Drives Up Costs." *MedPage*, March 2013. <https://www.medpagetoday.com/meetingcoverage/aaos/38021>