SmartStim:

Verification & Validation

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SmartStim: Overview

SmartStim: Update

- No changes to Need Statement
- Expansion of Project Scope
  - Functional Screw Cap Stimulator
  - Battery Backpack
  - Programming Wand
- Natalie Orr graduated

Verification Plan

- **Addressability**
- Mechanical Attachment
- Current Output
- Ease of Use for Surgeon
- Product Lifetime
- Patient Compliance
- Reproducibility
- Safety
- Size/Cost

- Can we remotely set and adjust the output current within 15 seconds?
- Can the entire system be shut down or rebooted within 15 seconds?
- Diagnostic Software
  - Can a full diagnostic be printed out in less than one minute?
    - Screw ID
    - Stimulation amplitude
    - Battery charge
    - Circuit impedance

Verification Plan

- Addressability
- **Mechanical Attachment**
- Current Output
- Ease of Use for Surgeon
- Product Lifetime
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- Safety
- Size/Cost

- Qualitative verification
- Will primarily experience compressive forces
- Torsional forces will be undirected
  - Impeded by smooth surface
  - Static friction

Verification Plan

- Addressability
- Mechanical Attachment
- **Current Output**
- Ease of Use for Surgeon
- Product Lifetime
- Patient Compliance
- Reproducibility
- Safety
- Size/Cost

- Available range: 10 - 200 µA
- Maximum allowable overshoot: 2.5%
  - 5 µA at maximum output
  - Variance of 5 µA or less has no discernable effect on efficacy or safety
- Fluctuation < |3 µA|
- Tested with DMM4050 recording

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Verification Plan

- Addressability
- Mechanical Attachment
- Current Output
- **Ease of Use for Surgeon**
- Product Lifetime
- Patient Compliance
- Reproducibility
- Safety
- Size/Cost

- Required steps
  - Mechanical installation
  - Electrical connection
  - Circuit initialization
- Installation of SmartStim < 5 minutes
  - < 75 seconds per device
- In-house testing of graphic user interface

Verification Plan

- Addressability
- Mechanical Attachment
- Current Output
- Ease of Use for Surgeon
- **Product Lifetime**
- Patient Compliance
- Reproducibility
- Safety
- Size/Cost

- Lifetime > 6 months
- Record cyclic decay of the Li-Ion battery using DMM4050
  - Postulate limit to number of battery cycles
- Battery Cycles > 24
  - Maximum charging frequency of once per week

Verification Plan

- Addressability
- Mechanical Attachment
- Current Output
- Ease of Use for Surgeon
- Product Lifetime
- **Patient Compliance**
- Reproducibility
- Safety
- Size/Cost

- Time to charge
  - Backpack < 3 hours
  - Implants < 2 hours
- 1 backpack charge = 4 implant charges
- On a single charge, implant can function for at least one week at maximum output
- Comfort

Verification Plan

- Addressability
- Mechanical Attachment
- Current Output
- Ease of Use for Surgeon
- Product Lifetime
- Patient Compliance
- **Reproducibility**
- Safety
- Size/Cost

- Minimal dependence on vertebrae size and/or spacing
- Test attachment in various orientations
- Are *Patient Compliance* specifications met for each vertebral geometry?
  - <2 hours to charge implants

Verification Plan

- Addressability
- Mechanical Attachment
- Current Output
- Ease of Use for Surgeon
- Product Lifetime
- Patient Compliance
- Reproducibility
- **Safety**
- Size/Cost

- Materials used are already approved for medical implantation
- Take current measurements to verify that leak current is less than 1 µA
  - Especially during charging
- Testing internal safety mechanisms
  - Shut down if temperature > 39.5 °C
    - Buffer before damage at 43.5°C
  - Shut down if output current > 200 µA

Verification Plan

- Addressability
- Mechanical Attachment
- Current Output
- Ease of Use for Surgeon
- Product Lifetime
- Patient Compliance
- Reproducibility
- Safety
- **Size/Cost**

- No larger than existing model used in rat studies
- Internal circuitry can be manufactured to fit within the mechanical design
- Total costs of manufacturing < $500

Validation Plan

- **Obstacles**
- Client Interactions
- Graphic User Interface Testing
- Competitor Comparison
- In Vivo Validation

Does the product reduce instances of Pseudarthrosis?

Can the product steadily output current at amplitudes found effective in literature?

Validation Plan

- Obstacles
- **Client Interactions**
- Graphic User Interface Testing
- Competitor Comparison
- In Vivo Validation

Concerted effort to maintain communications

Evolving Design

Continuous Validation Process

Validation Plan

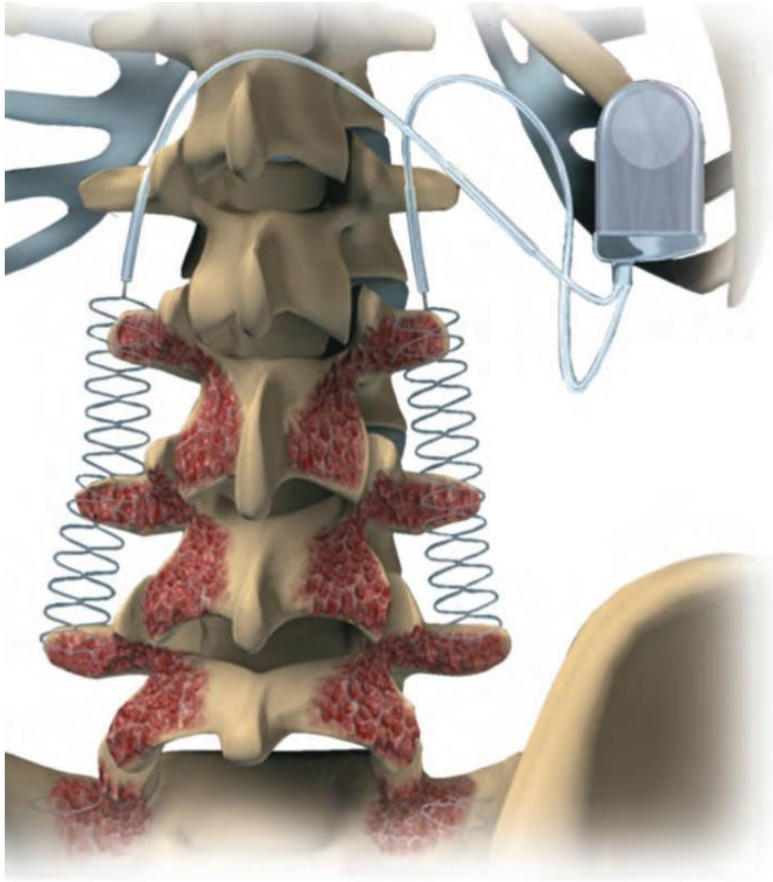
- Obstacles
- Client Interactions
- **Graphic User Interface Testing**
- Competitor Comparison
- In Vivo Validation

- *Ease of Use for Surgeon* is highly valued by our client
- Conduct usability testing
  - Dr. MacEwan
  - OsteoVantage members
- Feedback
  - How intuitive and robust is the GUI?
  - Are there unnecessary steps?
  - Are there missing functionalities?

Validation Plan

- Obstacles
- Client Interactions
- Graphic User Interface Testing
- **Competitor Comparison**
- In Vivo Validation

ZIMMER BIOMET



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Validation Plan

- Obstacles
- Client Interactions
- Graphic User Interface Testing
- **Competitor Comparison**
- In Vivo Validation

More flexibility

Does not require second surgery for removal

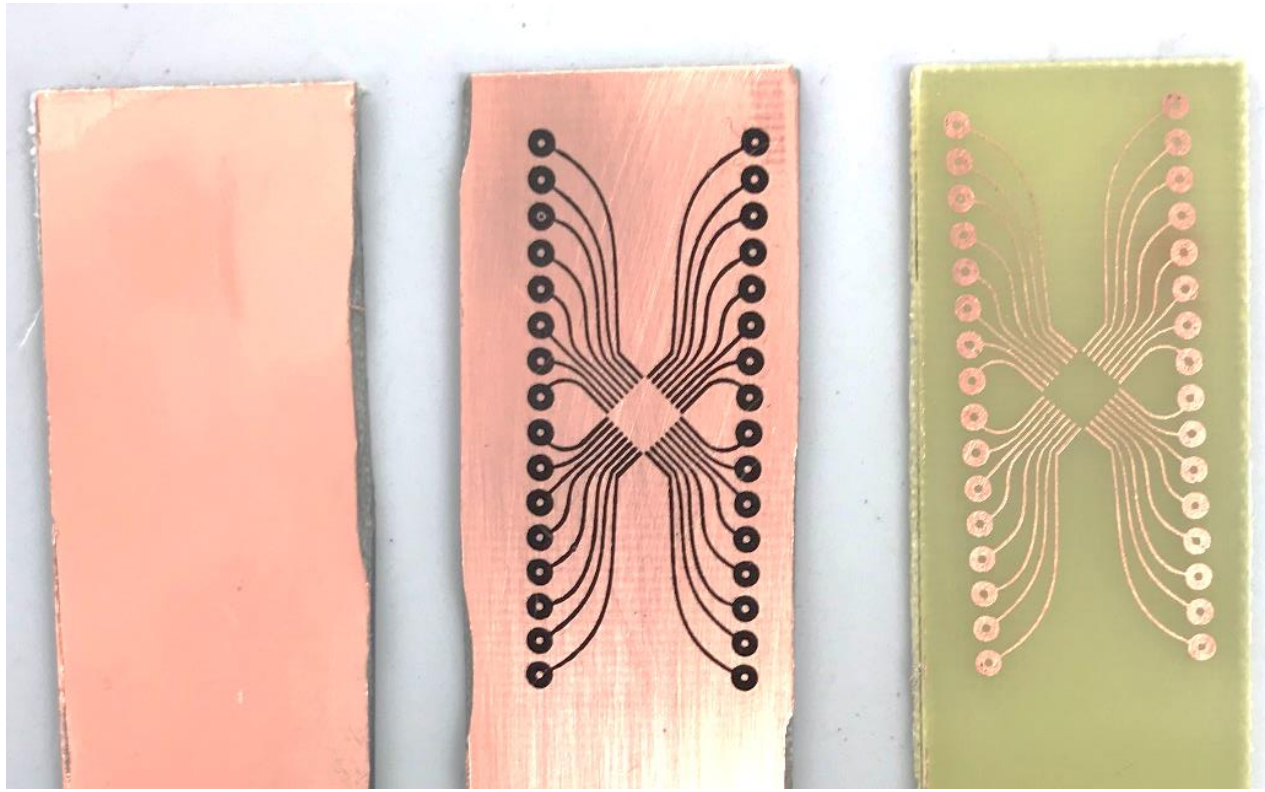
Validation Plan

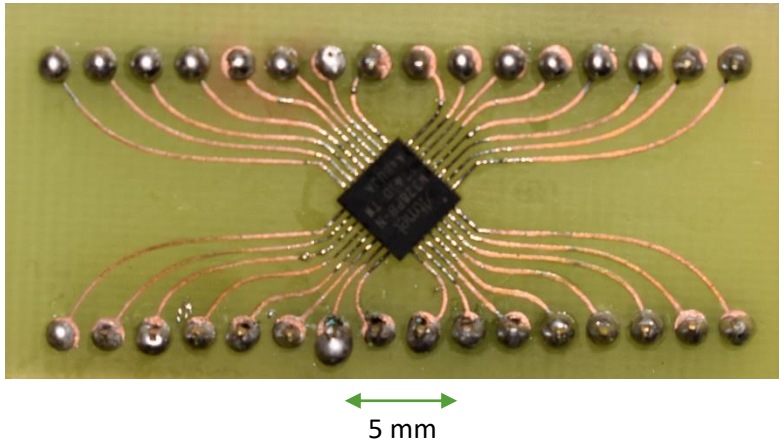
- Obstacles
- Client Interactions
- Graphic User Interface Testing
- Competitor Comparison
- **In Vivo Validation**

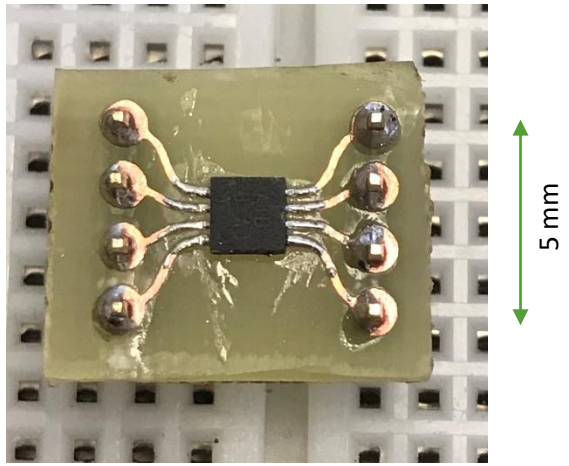
Working Scale Model

Proof of Concept

- **Full Scale Components**
- 500x Scale Model
- Adjustable Current Output Circuit
- Battery Backpack Charging Circuit
- Wireless Screw Charging Circuit
- Fully Functioning Graphic User Interface







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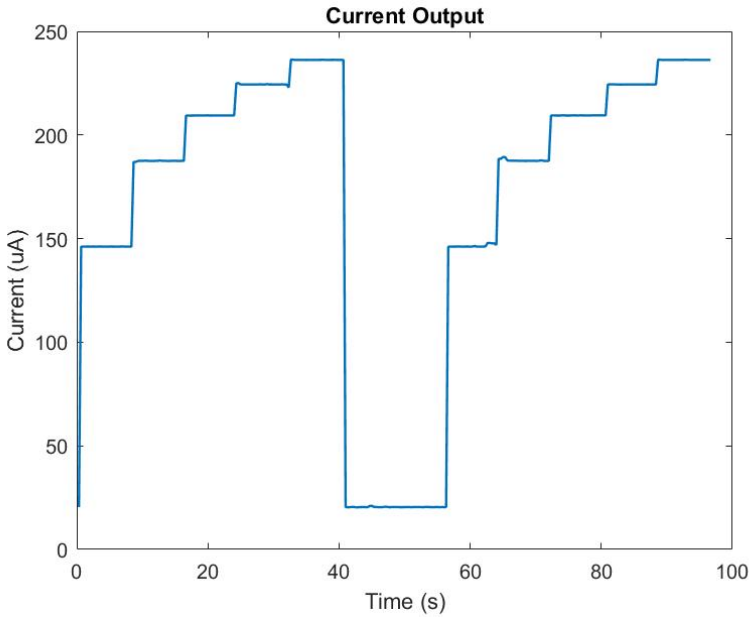

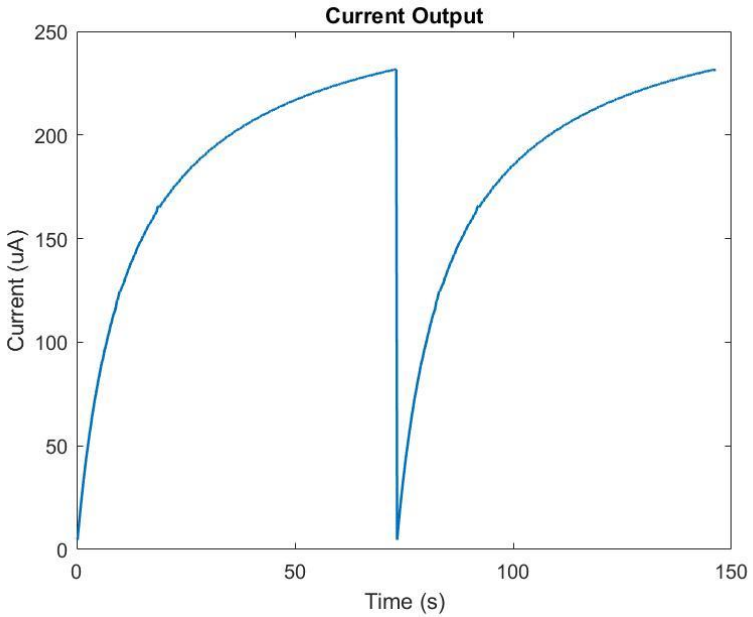

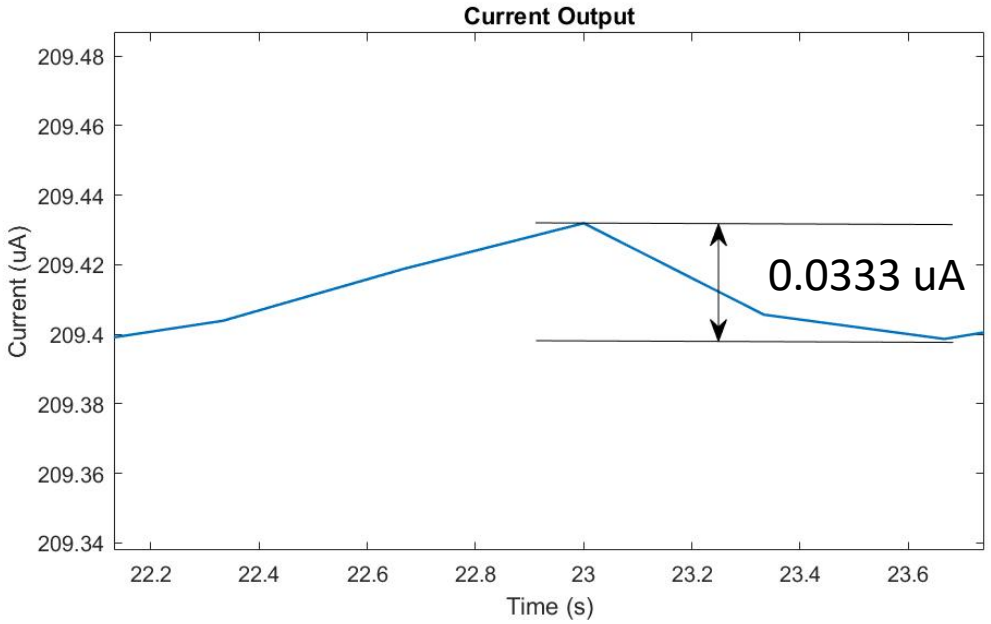

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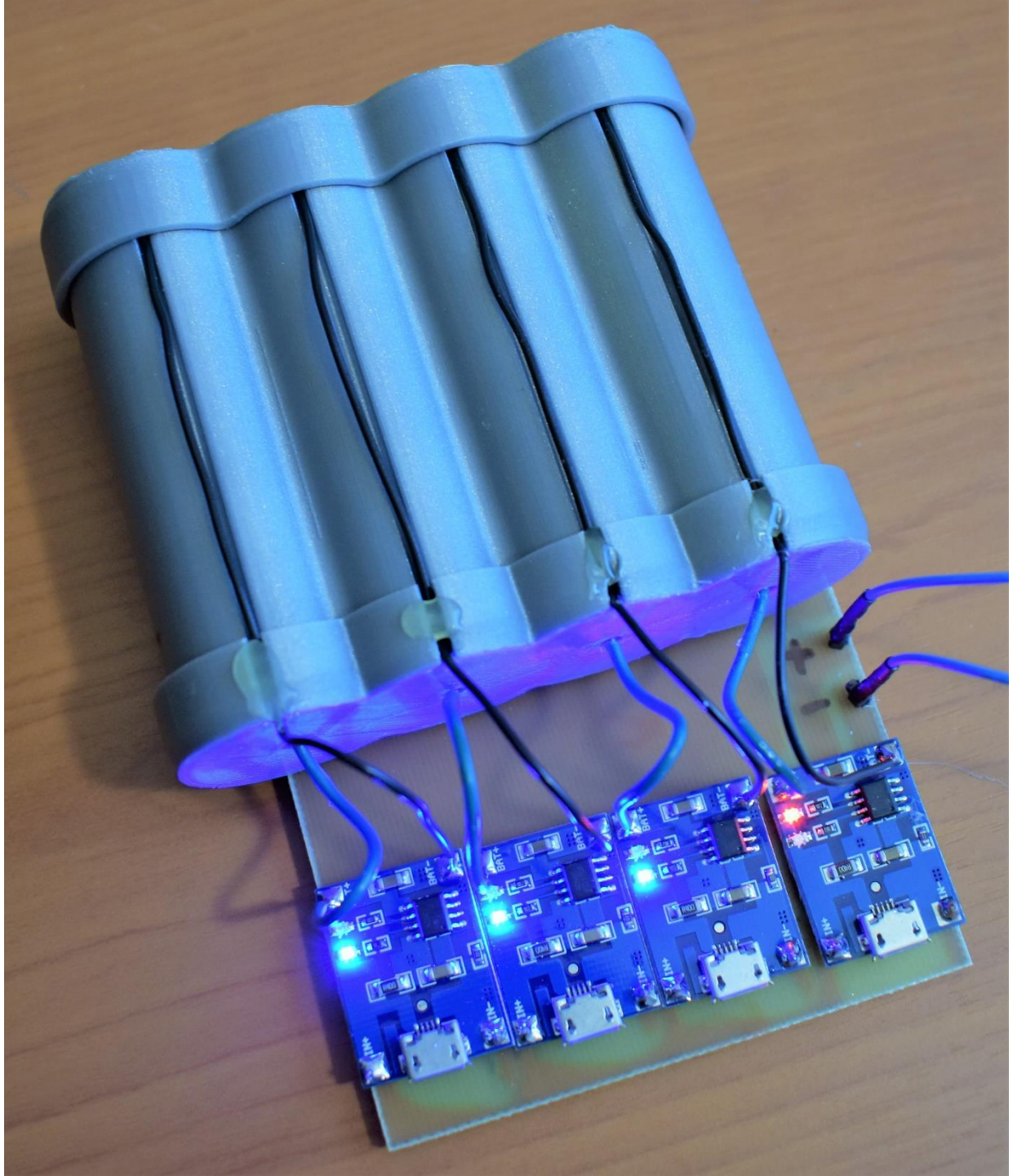

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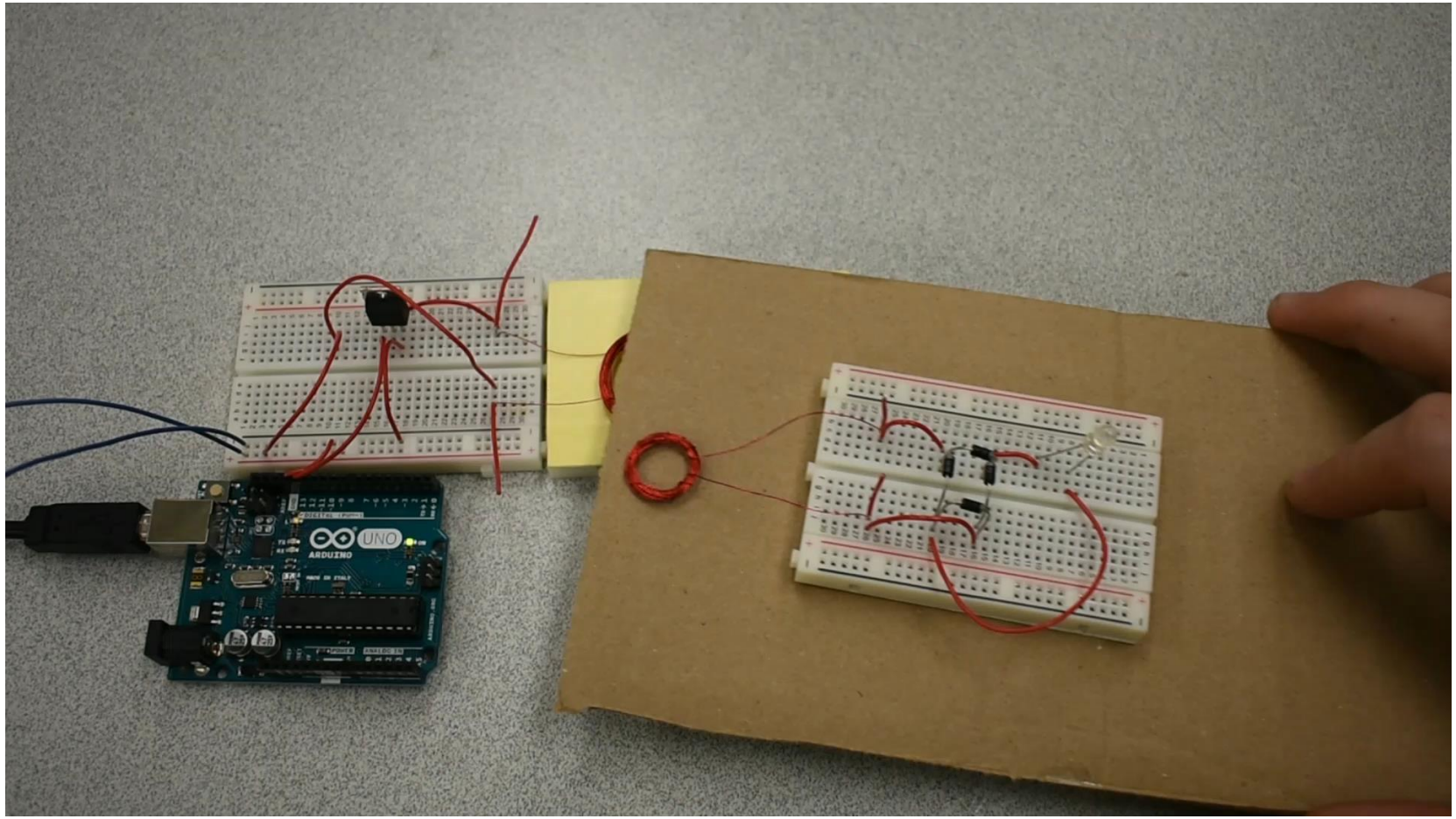

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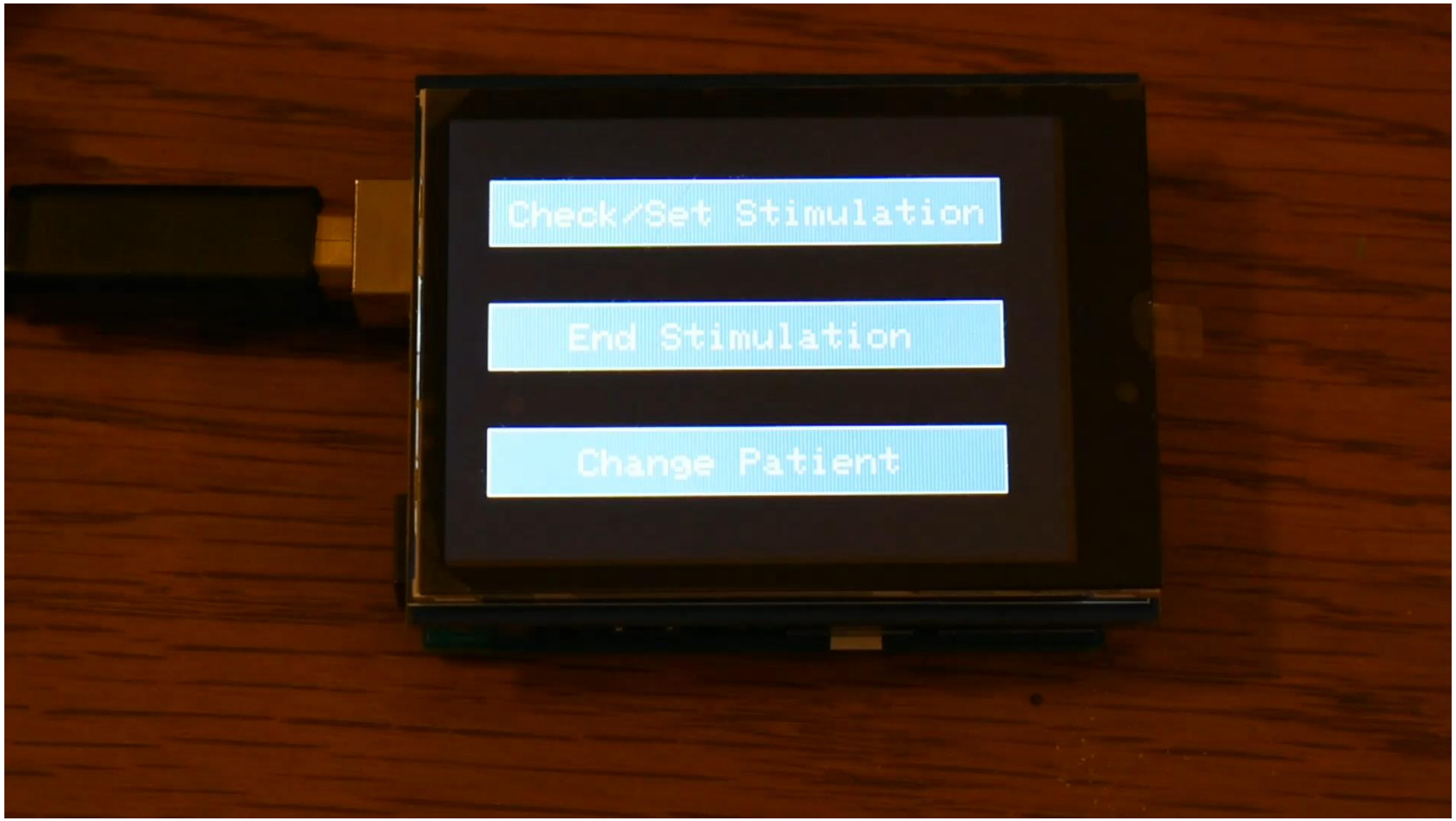

SmartStim: Status

- Completion by May 2018 deadline
- Next steps
  - Integrate RF transceivers into SmartStim system
    - Screw cap stimulation circuit
    - Battery backpack
    - Programming wand
  - Control output stimulation circuit from ATMega328PB
  - Fully assemble scale model with complete functionality

References

[1] MacEwan, Matthew R., et al. "Novel spinal instrumentation to enhance osteogenesis and fusion: a preliminary study." Journal of Neurosurgery: Spine 25.3 (2016): 318-327.

[2] Chen, Min, and Gabriel A. Rincon-Mora. "Accurate electrical battery model capable of predicting runtime and IV performance." IEEE transactions on energy conversion 21.2 (2006): 504-511.

[3] Dewhirst, Mark, et al. "Thermal dose requirement for tissue effect: experimental and clinical findings." Thermal Treatment of Tissue: Energy Delivery and Assessment II. Vol. 4954. International Society for Optics and Photonics, 2003.

[4] Khalifeh, Jawad M., et al. "Electrical Stimulation and Bone Healing: A Review of Current Technology and Clinical Applications." IEEE Reviews in Biomedical Engineering (2018).

[5] U.S. Food & Drug Administration. “Zimmer Biomet Recalls Implantable Spinal Fusion Stimulators Due to Potential of Harmful Chemicals Which May Be Toxic to Tissues and Organs.” Center for Devices and Radiological Health. Web. 1 March, 2018.