VoltaFeet:
Verification and Validation

Senior Design Group 2
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Presented by Matt Heiken

Project Overview

Goal:

To build a **simple, long lasting,** treatment for **eliminating** toe/foot **microbes** as well as shoe and foot **odor** for a diverse population.

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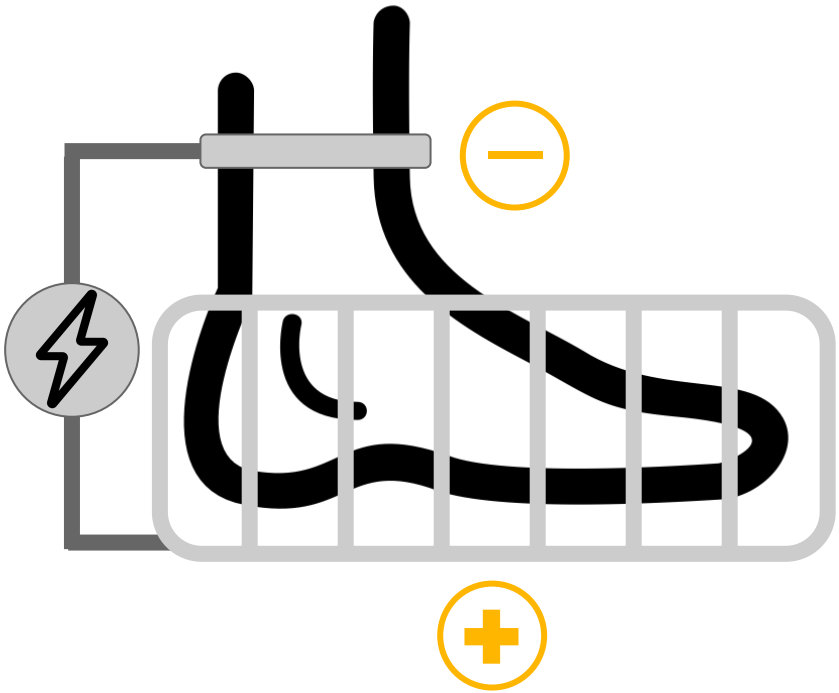
Users with:

- Bromodosis (stinky feet)
- Athlete's Foot
- Foot Wounds
- Diabetic Ulcers

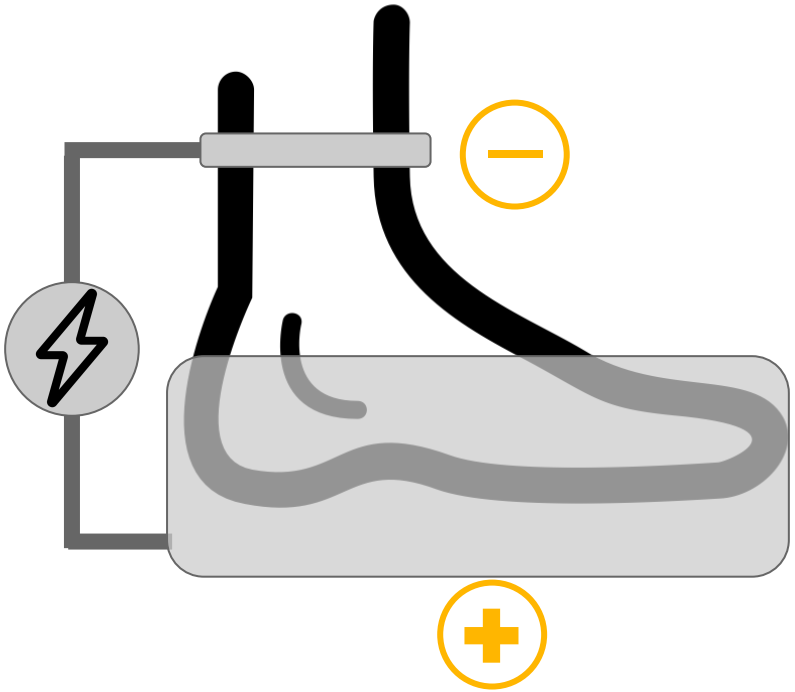
Project Overview



A sock that incorporates a mesh of silver wire and a lithium cell battery with a constant current source to conduct microamps of DC current for continuous and controlled release of antimicrobial silver ions onto the surface of the foot.

3V

Project Overview



A sock that incorporates a **conductive silver fabric** and a 3V lithium cell battery with a constant current source to conduct microamps of DC current for continuous and controlled release of antimicrobial silver ions onto the surface of the foot.

Updated Specifications

Category	Old Spec	New Spec
Diverse Sizing	Reliable for feet sized 4 through 12 men's and women's.	Manufactured in three different sizings (small, medium, and large) that encompasses feet sized 4 through 14 men's and women's
User Safety	Must not result in shocks or punctures after repeated loading during locomotion in any practical environment; If an electrical current is used, it must be less than 1 mA.	Must not result in shocks or punctures after repeated loading during locomotion in any practical environment; If an electrical current is used, it must be less than 5 mA.

New Specification

Category	Specification
Antimicrobial Penetration	Silver ion depth penetration comparable to other antimicrobial silver treatments.

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Antimicrobial Penetration	Silver ion depth penetration comparable to other antimicrobial silver treatments.

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

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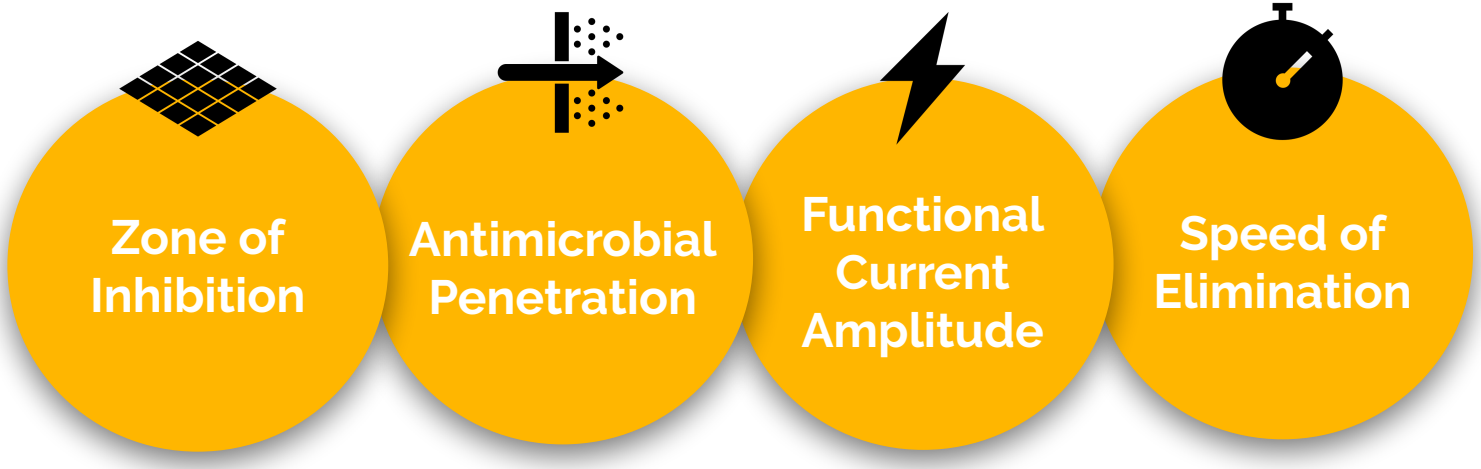
Verification Plan

Was the final product built correctly?

Important Considerations



Important Considerations

Zone of Inhibition

Antimicrobial Penetration

Functional Current Amplitude

Speed of Elimination

Grid size optimization: Finding the largest grid spacing that still provides antimicrobial effects to the entire area

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- Antimicrobial Penetration
- Functional Current Amplitude
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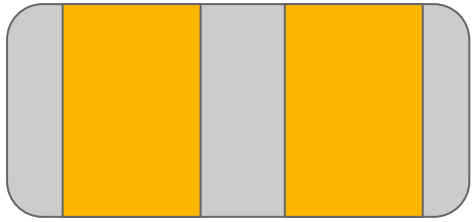

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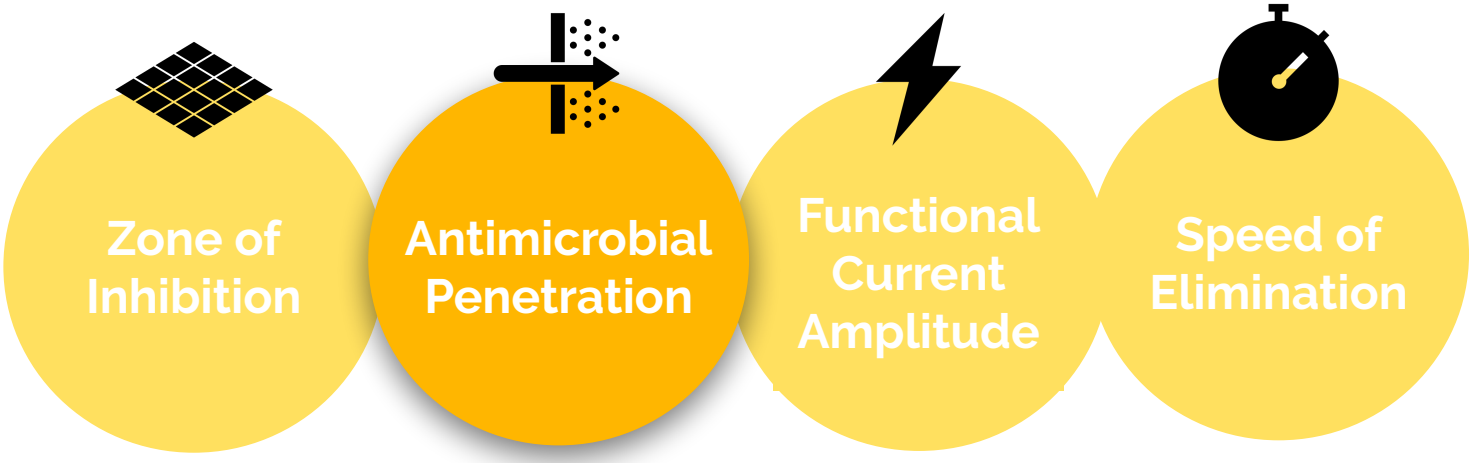
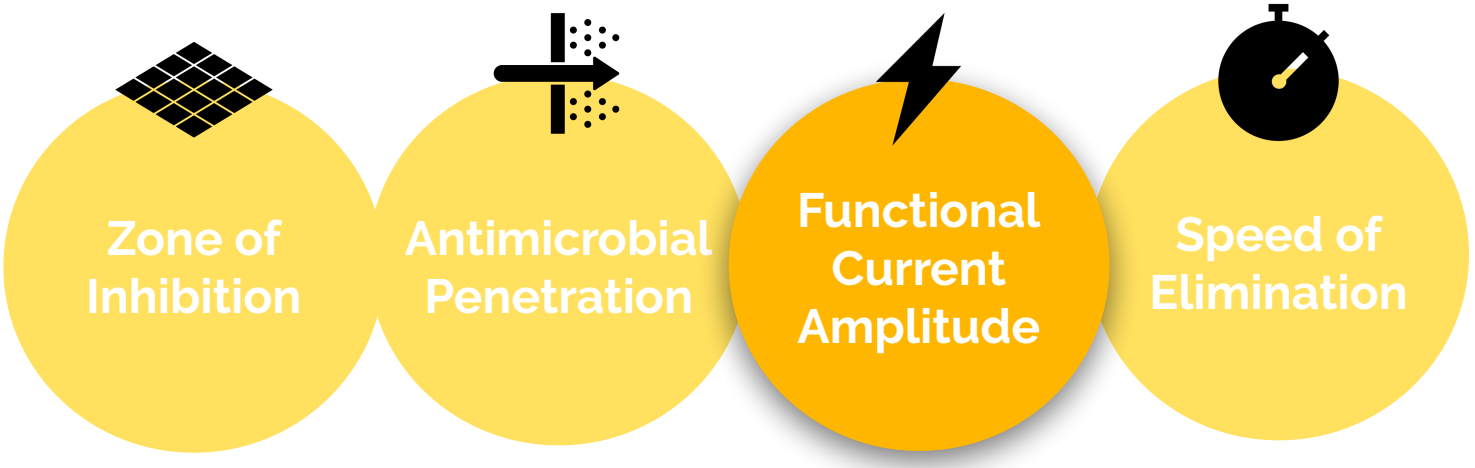


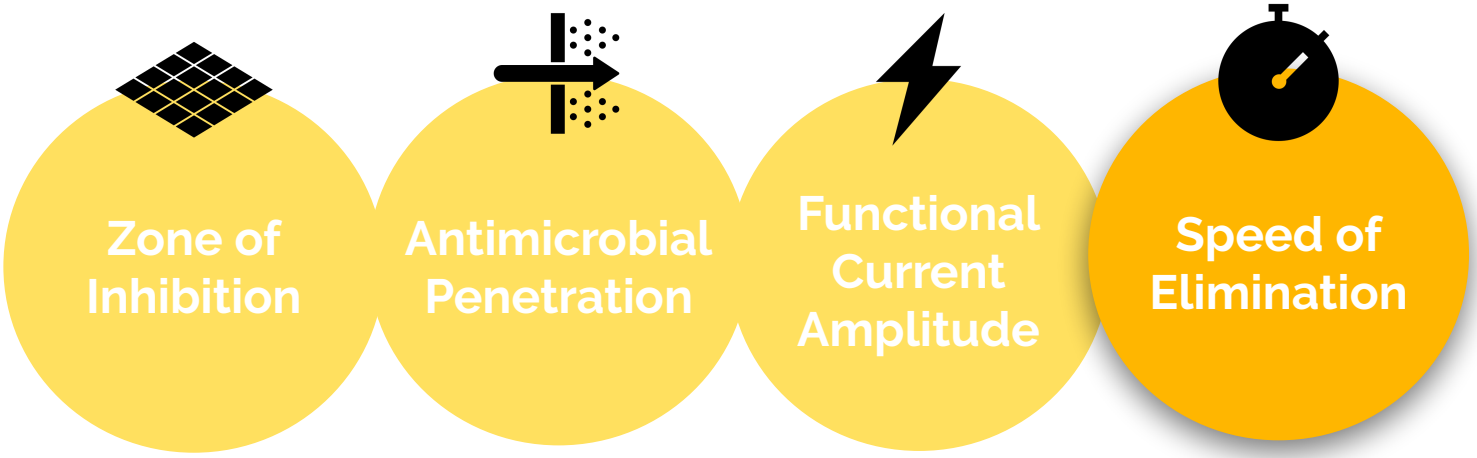
Silver penetration deeper than **0.1 mm**

Important Considerations



Current optimization: Balancing antimicrobial efficiency with battery life

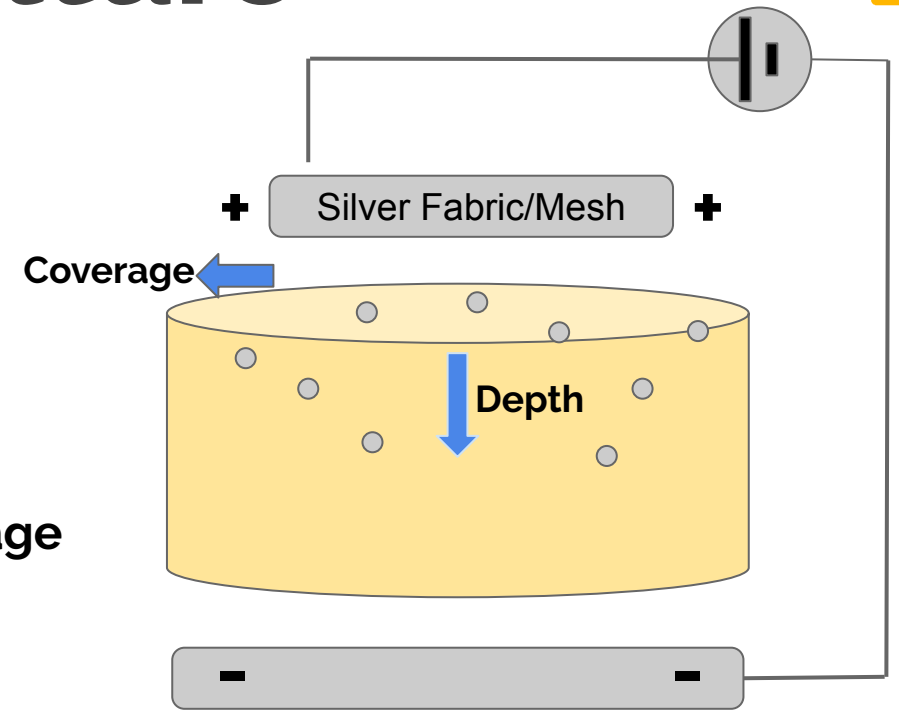
Important Considerations



Eliminates 99.9% of microbes/fungus in **12 hours**.

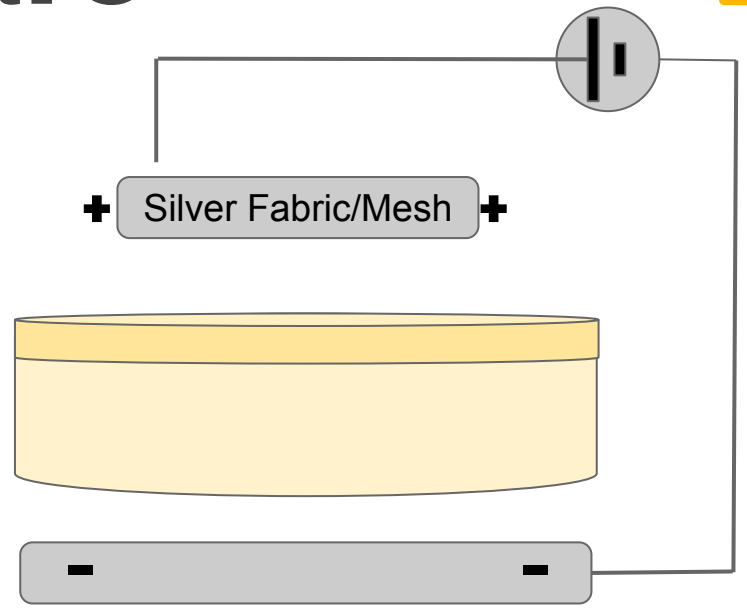
3D Cell Culture

- 3D soft agar E. coli culture
- Independent variables
  - Current amplitude
  - Surface Area
  - Type of Fabric/Mesh
- Measure **depth and coverage** over time



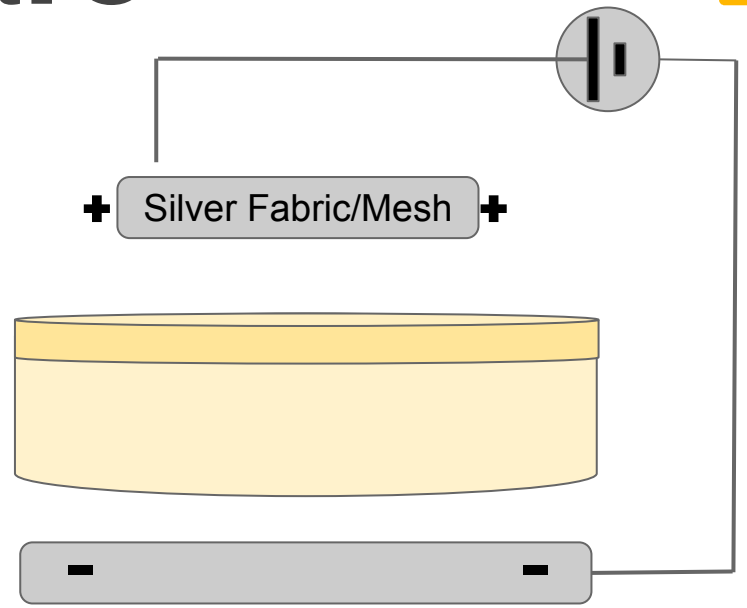
2D Cell Culture

- Testing the efficacy of silver on **multiple different microbial and fungal strains**



2D Cell Culture

- Testing the efficacy of silver on **multiple different microbial and fungal strains**
  - **However...** difficulties



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Validation Plan

Did we build the right product?

Important Considerations

Comfort

Functional
Duration

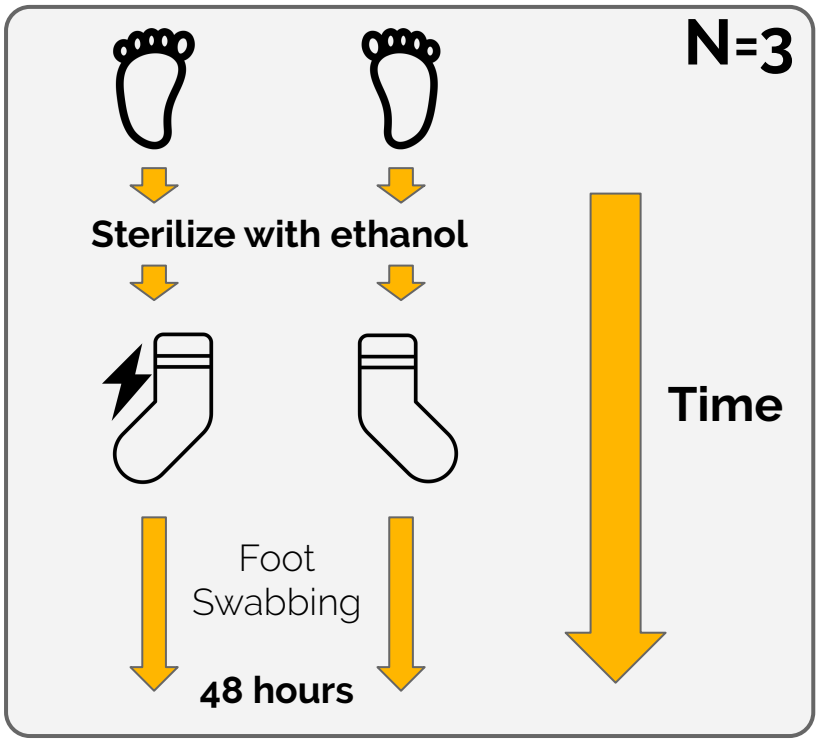
Weight

Testing Foot Sterility

Bilateral Control Experiment

Testing Foot Sterility

Bilateral Control Experiment



At different points in time:

- Foot swabs spread on nutrient rich agar plate and incubated from different parts of the foot

Independent Variable: Sock type
Dependent Variable: Colony count

Validating Quality

Face-to-Face Survey

Comparison of commercial prototype to normal sock

- Likert Scale (Ratings ranging from 1-5)
- Tested Specifications
  - Comfort
  - Appearance

Testing Longevity

> month

Limiting Factor: Battery vs. Silver Supply

Battery

Wearing the device on a regular basis and **frequently measuring voltage** with a voltmeter.

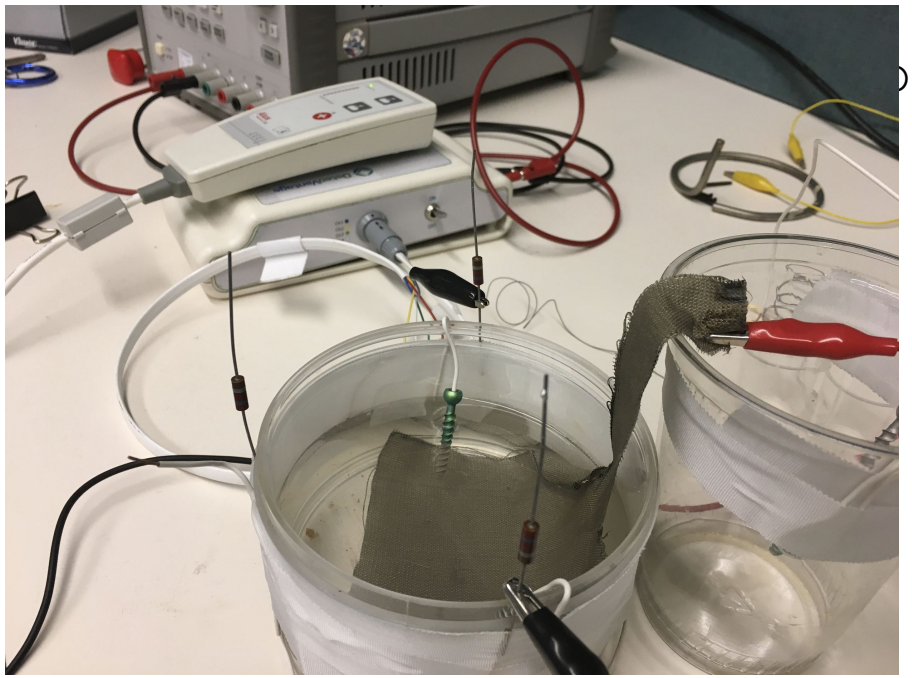
vs.

Silver Supply

Impedance curves: Measuring the impedance of the conductive fabric over time to determine the loss of silver

Testing Longevity

> month



ply

Silver Supply

Impedance curves: Measuring the impedance of the conductive fabric over time to determine the loss of silver

3

FDA Approval

How will we get our device approved?

VoltaFeet will rely on 510(k) premarket notification

> "A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is **at least as safe and effective**, that is, substantially equivalent, **to a legally marketed device** that is not subject to premarket approval."
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> -FDA.gov

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Legally Marketed Devices

- Acticoat Flex 7 Dressing (K083113) - **Class II**
  - Uses **silver coated nylon** and **silver ions** for **antimicrobial activity on the surface of the skin**
- Transcutaneous Electrical Nerve Stimulation (TENS) Device - **Class II**
  - utilizes **0-50 mA DC current on skin**

Current Status of Project

- Approval for cell culture

Current Status of Project

Approval for cell culture

Proof of Concept Testing

Current Status of Project

Approval for cell culture → Proof of Concept Testing

Prototyping

Current Status of Pro

Approval for cell culture

Prototyping

Current Status of Pr

Approval for cell culture

Prototyping

Current Status of Project

Approval for cell culture

Prototyping

➔ How do we do this better?

Thank you!

Questions?