Temperature Excursion Indicator

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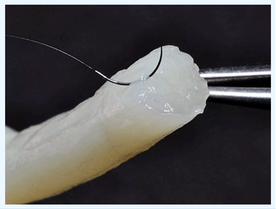
Background

Axogen's Avance® Nerve Graft, the #1 choice for hand surgeons performing nerve repair procedures, must remain frozen below -20°C to preserve the product's bioactive components. Current shipping and storage protocols lack built-in temperature indicators, leaving grafts vulnerable to undetected excursions caused by dry ice depletion, transit delays, or packaging failures. Surgeons currently rely on trust rather than verification when it comes to product integrity, potentially increasing the risk of compromised grafts.



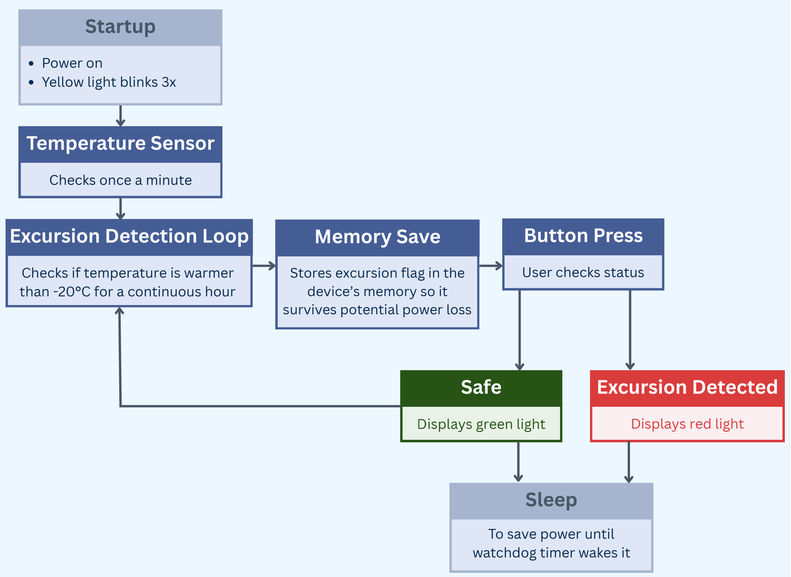
Problem Statement

A way to indicate shipment temperature excursions above -20°C that last for at least 1 hour for Axogen personnel, surgeon-customers, and the FDA to ensure that Avance Nerve Graft integrity has not been compromised by undesirable temperature deviations.

Functional Requirements

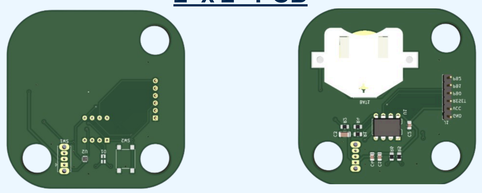
Requirement	Specification
Functionality	Display a notice that nerve graft was exposed to undesired temperature (> -20°C)
Compatability	Compatible with dry ice and freezing temperatures (-80°C)
Intepretability	Display clear and intuitive results
Disposability	Chemically and environmentally compatible for safe disposal.
Packaging	Compatible with packaging size and configuration
Lifespan	Appropriate functional lifespan of 5 days

Code



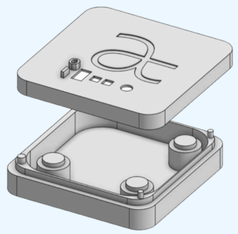
Iteration 1

2"x 2" PCB



Front Back

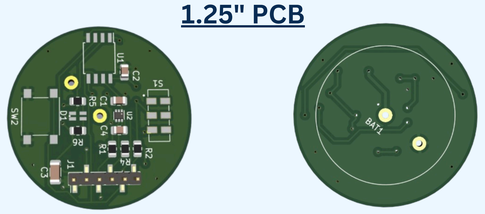
PCB Case



- ✓ Electrical components spaced out enough to prevent overheating and potential device malfunction.
- ✗ Larger than desired for packaging compatability and sleek design.

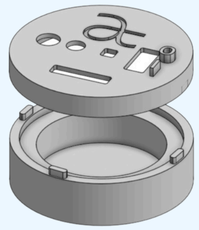
Iteration 2

1.25" PCB



Front Back

PCB Case



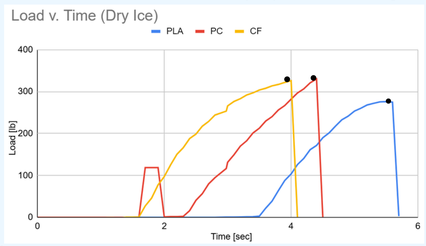
- ✓ Condensed components and battery pins directly soldered to board for a more cohesive design.
- ✓ Smaller, more compact design that fits better in Axogen's existing nerve graft packaging.

Testing

Tensile Testing

Procedure:

- Exposed dog bone strips of CF, PLA, and PC to dry ice and perfomed a tensile test
- Goal was to characterize mechanical properties after dry ice exposure



Conclusion:

- CF and PC did not fail

PCB Testing

Procedure:

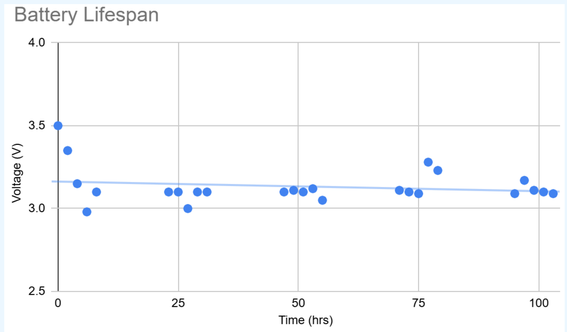
- 4 PCB Boards were placed in dry ice in the shipper
- Tested under varying circumstances over a 5-day period
- Excluding Board 1, Boards were checked 2x / day

Board #	Condition	Expected Result	P/F?	Follow Up
1	Left in Dry Ice	Green	P	N/A
2	Out of Dry Ice for < 1 Hr	Green	F	• LED turned red after less than an hour (Fail) • Reset & test failed again
3	Out of Dry Ice for > 1 Hr	Red	P	N/A
4	Taken out of Dry Ice	Red	P	• Fixed battery & reset • Restarted test & worked successfully

Battery Testing

Procedure:

- Battery placed in dry ice for 5 days
- Battery voltage and ability to turn on an LED was measured 5x / day



Conclusion:

- ~0.5V used by device in 5 days
- Battery expected to last an estimated 227 days

Shipping Testing

Procedure:

- Sent assembled device in 60lbs of dry ice to Axogen office in Tampa
- Sent a positive (expected green light) and negative (expected red light) device
- Goal was to ensure the device could function throughout shipping and withstand handling and transportation

Condition	Expected Result	P/F?
Positive (in dry ice)	Green	P
Negative (out of dry ice)	Red	P

Conclusions

All Requirements Met
✓ Functionality
LED light excursion indication at the end of shipment
✓ Compatability
Testing shows functionality in dry ice
✓ Intepretability
Green or red LED provides clear, intuitive results
✓ Disposability
Materials facilitate safe, easy disposal
✓ Packaging
Device is compatible with existing packaging
✓ Lifespan
Functional lifespan exceeds the 5 day specification

Future Work

- Reduce component timing drift by designing an insulating enclosure that protects the microchip from the cold temperatures
- Incorporate an external clock rated for -80°C
- Explore alternate manufacturing methods to optimize production, such as injection molding
- Incorporate an LCD screen to provide more intuitive status indication
- Further validate through real-world use with nerve graft shipment

Acknowledgements

We would like to thank our Axogen engineering mentors, Jacob Yarinsky and Ben Spearman, for their mentorship throughout this project. We would also like to thank our faculty advisors, Dr. Geiger and Ismael (Tito) Arroyo, for their continued support and feedback throughout the design process.

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