

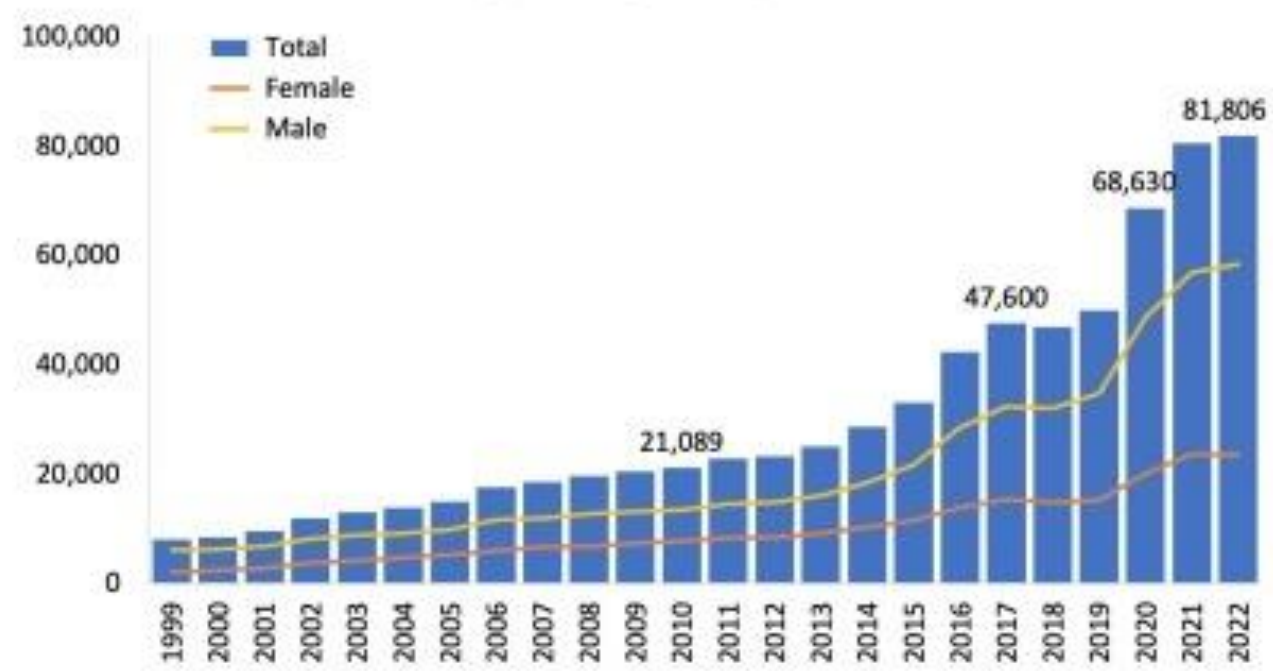
The Overdose-Sensing Injector

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Our Why

Over 80,000 lives were lost to opioid overdoses in the United States last year. This devastating statistic is not only alarming but is increasing at an exponential rate each year. While there are life-saving interventions available, such as naloxone (a drug that can rapidly reverse an overdose), there is a gap in its effectiveness. Often, no one is present to administer naloxone during an overdose, which turns a preventable tragedy into a heartbreaking and unnecessary loss of life. This underscores the urgency to innovate solutions in this area and increase accessibility to interventions to combat the growing crisis.

Figure 3. National Overdose Deaths Involving Any Opioid*, Number Among All Ages, by Sex, 1999-2022



*Among deaths with drug overdose as the underlying cause, the "any opioid" subcategory was determined by the following ICD-10 multiple cause-of-death codes: natural and acute synthetic opioids (T40.2), methadone (T40.3), other synthetic opioids (other than methadone) (T40.4), or heroin (T40.5). Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2022 on CDC WONDER Online Database, released 4/2024.

Our Research

Our research is centered on addressing the urgent and growing opioid overdose crisis by developing a groundbreaking naloxone auto-injection device. The project integrates biomedical engineering, physiology, and public health expertise to create a user-friendly, cost-effective device capable of autonomously detecting and responding to an overdose, filling a critical gap in emergency intervention. The components we chose (see "Our Sensor") allow for real-time overdose detection, focusing on minimizing false positives and ensuring rapid response. The device's placement on the upper arm was meticulously chosen based on physiological and sociological considerations. Subcutaneous or intramuscular injection in this area minimizes vascular risks and allows for discreet wear, addressing privacy concerns identified in a 2021 survey where 54% of respondents preferred a concealable design.

Additionally, the upper-arm placement reduces the likelihood of theft in vulnerable populations while maintaining the practicality of an easily wearable device. We've also established a tentative naloxone dosage of 2.0mg/0.4mL, balancing the need for effective overdose reversal with the potential for withdrawal symptoms in tolerant users. This dosage serves as a starting point, with plans for refinement through rigorous testing that adheres to FDA guidelines. Our testing framework explores ethical methodologies, including animal studies and comparisons to 'gold standard' tools like arterial blood gas devices or FDA-approved pulse oximeters to validate the accuracy of our detection system.

To deliver naloxone, we are researching mechanical injection mechanisms, including pneumatic, electric, and spring-powered systems, focusing on cost, ease of use, and integration into the device's armband design. Prototyping is underway, with circuit designs created using EasyEDA software and breadboard testing to validate functionality. Guided by research from the NIH, the *Harm Reduction Journal*, and other peer-reviewed studies, we are continuously refining our approach. We aim to meet conservative thresholds for overdose detection, minimizing false negatives while ensuring high efficacy. Through this comprehensive, multidisciplinary effort, we seek to bridge the gap in overdose response technology, providing a life-saving solution for individuals at the highest risk.

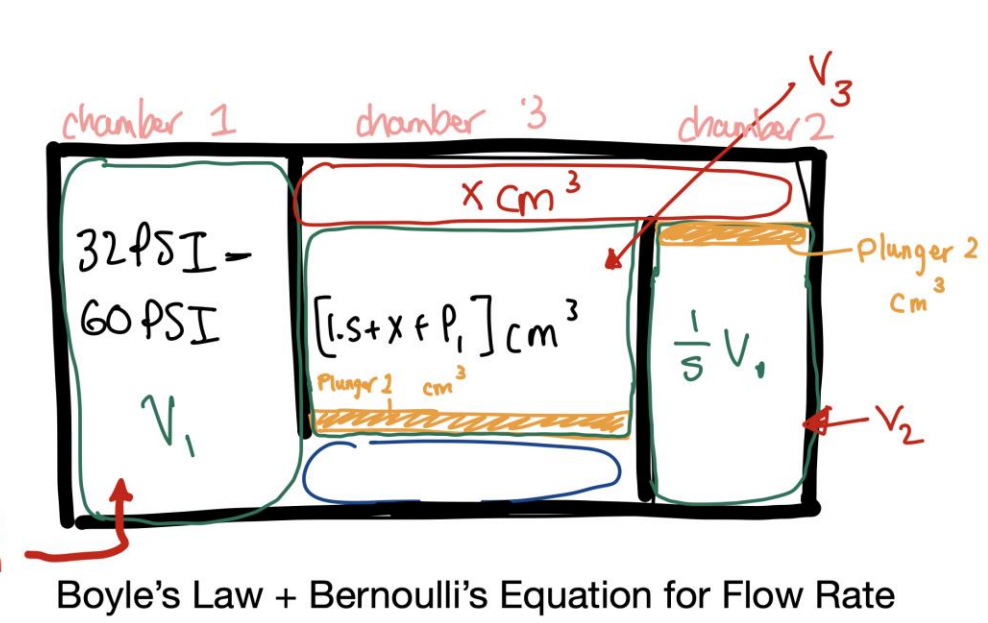
Our Timeline

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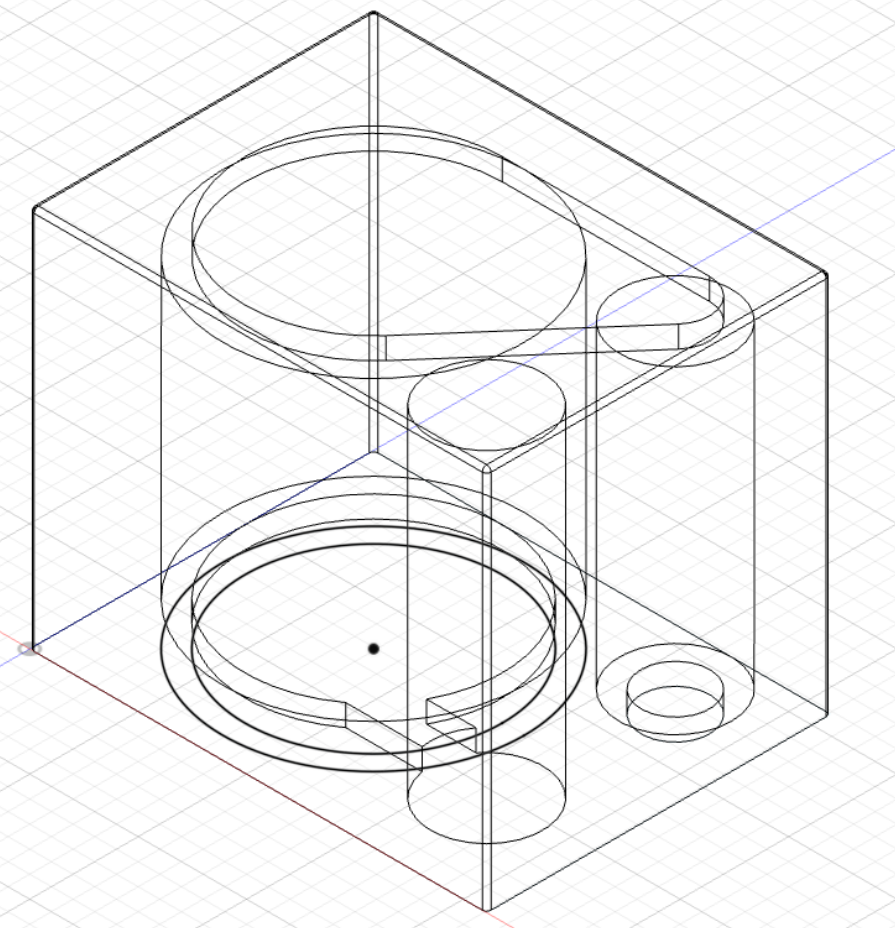
- Circuit Board Research & Design
WEEKS 1-5: EDA (Electronic Design Automation)
- Circuit Board Manufacturing
WEEKS 5-9: JLCPCB and Hive Makerspace
- Autoinjector Research & Design
WEEKS 10-15: Fusion CAD and BME Makerspace
- Software Development
WEEKS 10-15: TI Cloud Composer Studio IDE

Our Injector

Currently, our injector progress has been split. One team chose to focus on a mechanical design, which will hopefully be functional as early as next January but is larger than we are looking for in terms of final design and has drawbacks that the other team is looking to solve. The other team is in the process of designing a gas-powered injector, which would use inert gas to inject the naloxone. Although more technically complicated, the design of the gas-powered injector would minimize both cost and size and is, therefore, the preferred injecting mechanism. It is also the initial idea that was posed during the research stages of the design.



*Design 1: Used Boyle's Law and Bernoulli's Equation for flow rate to find optimized chamber sizing for maximum efficiency while minimizing size. Solved for parameters such as chamber volume, plunger area, and maximum pressure

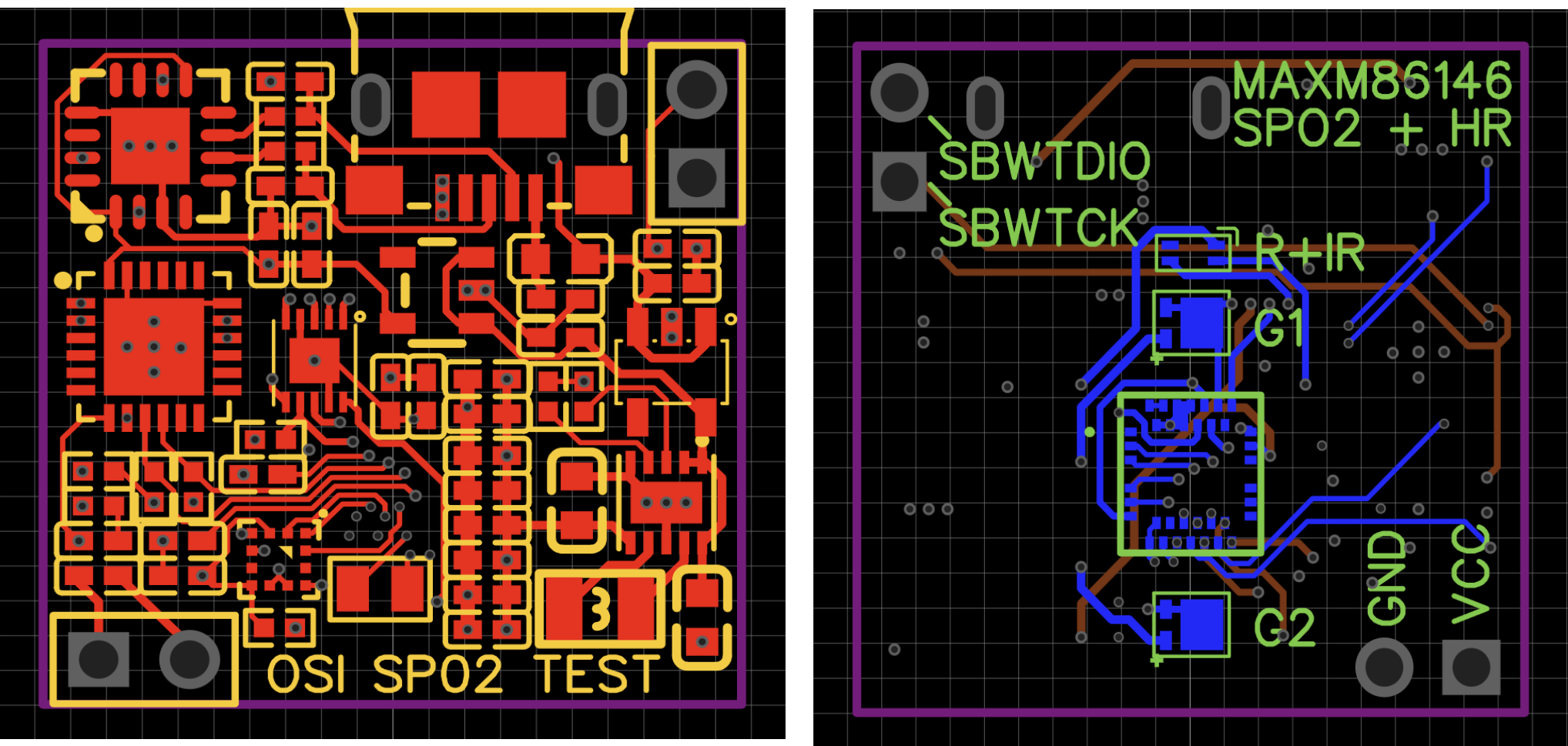


*Design 2 used fusion CAD to create both a 3D printable and machinable housing. In addition, we sourced U-type + O-type sealing gaskets to preserve pressure.

Our Sensor

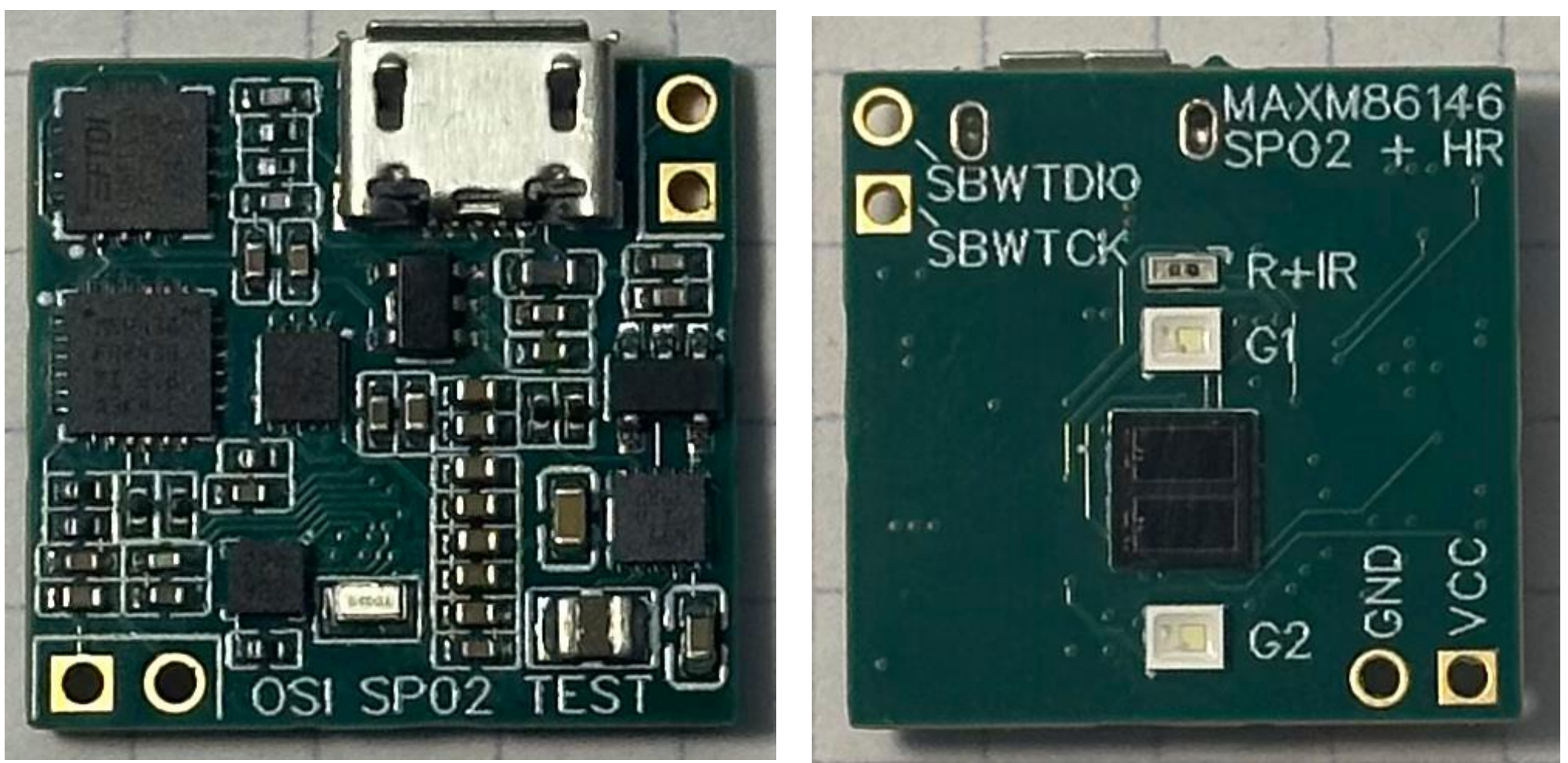
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This Fall, we moved from breadboard to printed circuit board. Our first prototype combines the heart rate + SP02 sensor, a microcontroller, and a USB interface. Our goal was to demonstrate a successful implementation of the sensing hardware and test/develop code for the host microcontroller. The board then displays the necessary debug information on a computer via USB. Here you can see the schematics of our PCB:

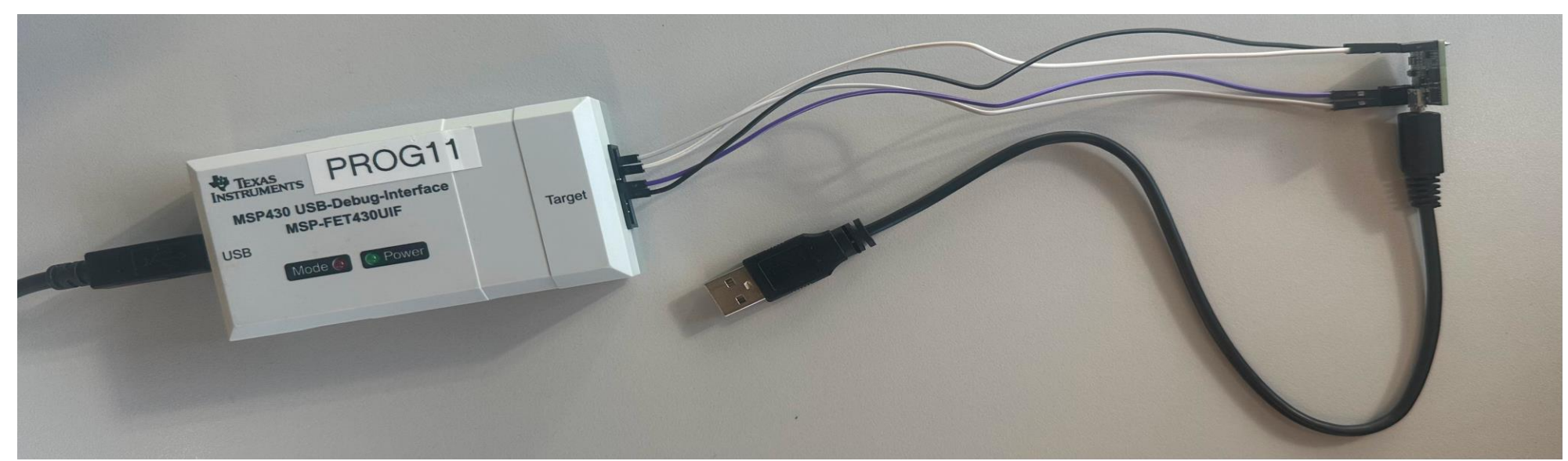


The biggest challenges we faced was balancing specification with many datasheets and ensuring signal integrity between the sensor/LEDs to ensure best accuracy.

After the boards had been manufactured, we had to overcome the challenges of SMD soldering. Here you can see images of the assembled boards



After the boards were assembled, our attention moved from hardware to software. To program and debug the device, we used the 2 wire JTAG protocol Spy-Bi-Wire. Below you can see the programming and debugging setup below.

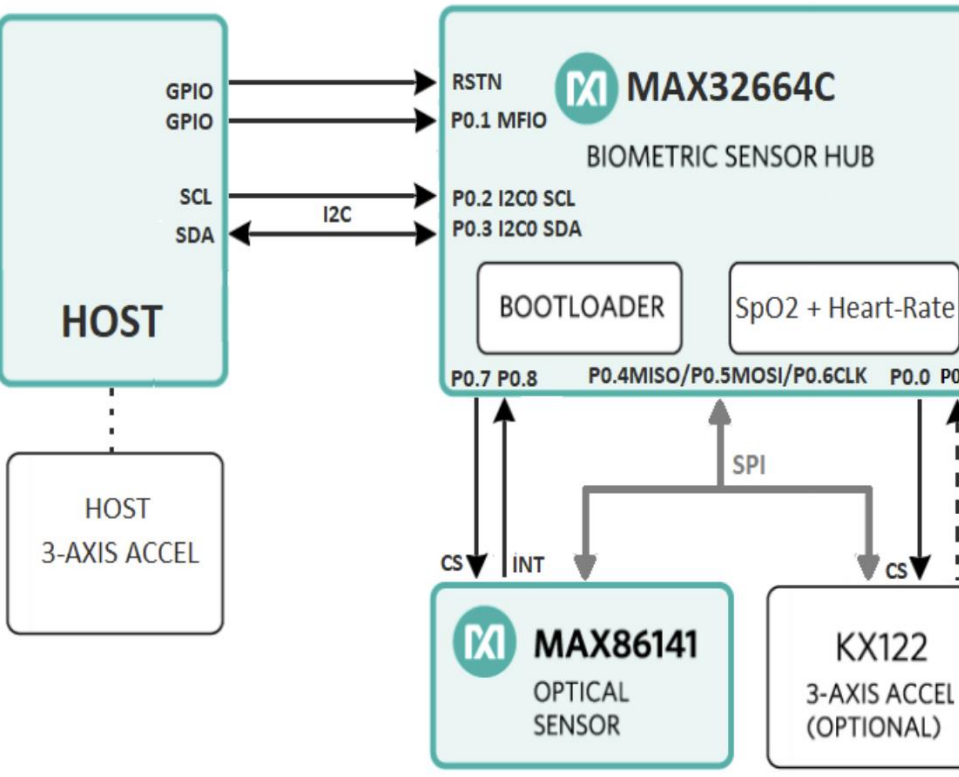


Our Software Development

Software development consists of using the MSPFET430 UIF debugger to interface to the board using Spy-By-Wire, a TI derivative of JTAG.

Software Features:

- 1) Backchannel serial UART connection through micro-USB to computer
- 2) Initialize sensor hub and peripherals using I2C communication with our MAXM86146 and read and write to the sensor.
- 3) Use commands through I2C to calibrate + program using a reference vice.
- 4) Use commands through I2C to fetch SP02 and heart rate data from sensor



Our Next Steps

This semester has been extremely productive for our team. Although we are not going to formally continue our project next semester, we still plan to devote time and attention to finishing and integrating the injector mechanism. In addition to applying for the InVenture Prize Competition next year, we have some continued goals we would like to finish, including:

1. Finish a proof-of-concept mechanical injector integrated with the overdose sensor by the end of next semester.
2. Work with Emory Midtown Hospital to test said sensor.
3. Integrate the sensor with a wearable band by the end of the following semester, minimizing the device to smaller dimensions by integrating the gas-powered injector into our design.
4. Apply for InVenture and continue from there! We feel great about the progress we've made, but still have much work left to do!

Our Acknowledgements

A special thanks to our Create-X mentor, Professor Tom Collins! Additionally, thank you to Nurse Christy for working with our team on using the Emory Midtown Hospital Arterial Blood Gas Machine! Thank you to Professor James Steinberg for assisting our team with the soldering process!