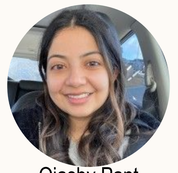
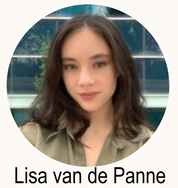
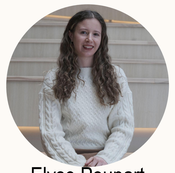
WEARABLE PERCUTANEOUS STIMULATOR FOR POLYCYSTIC OVARY SYNDROME (PCOS)


Ojasby Pant


Lisa van de Panne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ABSTRACT

Polycystic ovary syndrome (PCOS) is a common endocrine disorder that affects reproductive-aged women. It is characterized by hormonal imbalances that can lead to a variety of symptoms, including chronic pain, weight gain, irregular menstrual cycles, ovarian cysts, insulin resistance and decreased fertility [1]. Current pain management techniques, like pharmaceuticals, may have unwanted side effects and limited efficacy. This project focused on creating a discreet percutaneous electrical stimulator for pain management in PCOS patients. Research was conducted to determine the most effective signals for chronic and acute pain management. A 3D printed casing was designed to enclose the custom PCB containing the stimulator circuit and microcontroller. The device is attached to microneedle electrodes and is designed to be worn on the abdomen. An oscilloscope was used to confirm the signal output was as intended per design specifications.

INTRODUCTION

PCOS affects 1 in 10 women [2], and is the leading cause of infertility [3], yet the current available treatment options are extremely limited.

Studies have shown that there is a link between low frequency neuromodulation and the improvement of PCOS symptoms [4]. This is typically done transcutaneously or intramuscularly.

The capstone sponsor company, Neuraura Biotech Inc., has developed percutaneous microneedle patches that can be used to stimulate the peripheral nervous system.

The capstone team has developed the LoOop, a proof-of–concept prototype for a wearable stimulator unit to connect to Neuraura's PCOS microneedles.

CONSIDERATIONS

User Needs Criteria

User Interface/ Interactions

The device has a simple design with only the buttons necessary to control device functions. These include a power button, two buttons for intensity control, and one for toggling mode. LoOop is a flexible, wireless device that withstands day-to-day movement, tremaining discreet while worn by the user.

Design Solution

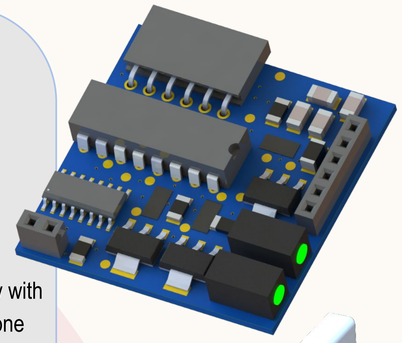
Printed Circuit Board

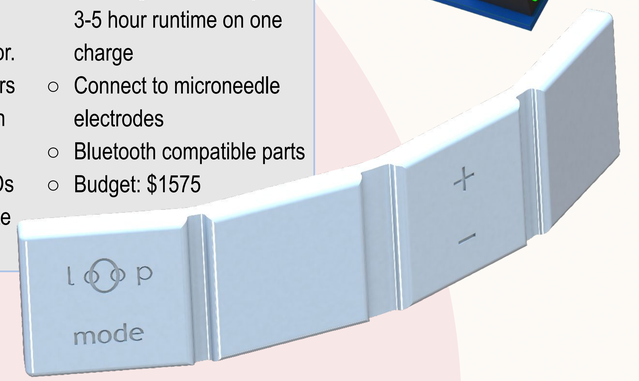
The custom PCB integrates the stimulator circuit components including a current sink and source, and a voltage regulator. The PCB also includes headers for interfacing signals between the charging module and microcontroller as well as LEDs and pushbuttons to incorporate the user interface.

Specifications

Neuraura Specifications

- Size: 16x4x0.8 cm
- Rechargeable battery with 3-5 hour runtime on one charge
- Connect to microneedle electrodes
- Bluetooth compatible parts
- Budget: $1575





DESIGN

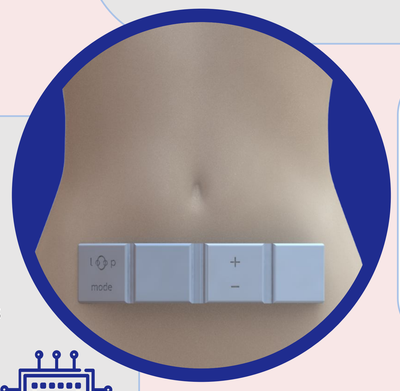
The prototype design consists of 4 main sections:

The **user interface** module includes the SAMD21E18, a 32-bit, low powered microcontroller, with a digital-to-analog converter. It also includes push buttons for user input, and LEDs to display the mode. The microcontroller is responsible for controlling the frequency and intensity of the waveforms.

The **stimulator circuit** contains an H-bridge that alternates current direction every pulse to prevent charge build-up, and a current mirror which uses both a current sink and current source, which are implemented using 2 LT3092 chips.

The **charge pump circuit** uses an LT8570 to step up the voltage from 3.3V to 40V, which is the voltage needed to power the stimulator circuit to produce the desired output current.

The **charging system** is made up of a 3.7V rechargeable coin cell battery, a TP4056 chip charging unit with a micro USB connector, and a voltage regulator.



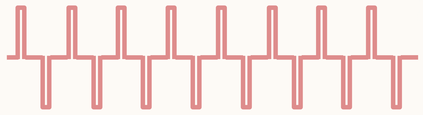
PCOS RELIEF SIGNAL

*not to scale

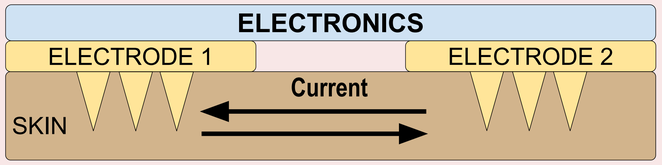
80 Hz Biphasic 2 Hz Bursts

PAIN RELIEF SIGNAL

*not to scale



100 Hz Biphasic



FUTURE WORK

- Outsourced PCB assembly will enable the use of smaller component packages, further reducing the device footprint and making it even more discreet
- Neuraura will use this device for bench-testing with their proprietary micro-electrodes
- Neuraura will be reprogramming the device to be controlled via Bluetooth from an app
- With human trials, Neuraura will hone the optimal waveforms of the device for PCOS symptom relief

RESULTS + DISCUSSION

- The system generates stimulation waveforms consistent with those found to provide PCOS relief in literature
- The prototype provides charge balancing for patient safety, consistent with waveform shapes in relevant regulatory filings
- The prototype includes implementation of complementary current sources to prevent leakage current for patient safety
- The device is sleek, flexible, comfortable to wear, and discreet

CONCLUSION

PCOS is a disease which to date has no cure. The LoOop will be a treatment option for women to decrease the impact of symptoms and improve their quality of life

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REFERENCES

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