Assistive Technology for Opioid Addiction Recovery

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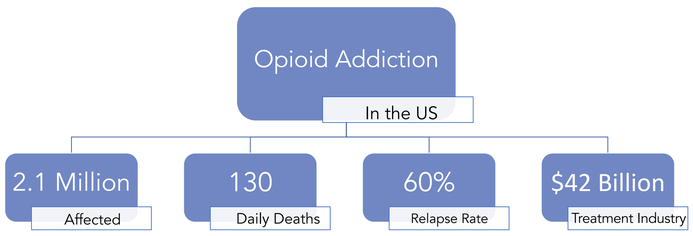
Introduction



Current Treatment Methods

Therapy
- Cognitive Behavioral Therapy
  - Individualized tools to target bad habits

Medication
- Methadone, buprenorphine, naloxone, and naltrexone
- Alleviate symptoms of withdrawal

Technology
- Percutaneous electrical nerve stimulation (PENS)
- Pain relief from acute withdrawal symptoms

Proposed Solution

Individualized addiction recovery utilizing physiological patterns to increase patient self-awareness and avoid relapse

Design of Solution

Electrodermal Sensor
Heart Rate Sensor
Trigger Button

Battery life indicator
Wi-Fi enabled

Adjustable straps
Silicone Encasing

Computer Interface will show EDA, HR and Event Trackers on an easy to understand platform

Testing Methods

Primary Research Findings
- Takeaways from interviews, market sizing

Circuit Considerations
- Prototype uses Arduino software to implement instantaneous reading of heart rate, electrodermal activity, and event tracking using commercial sensors and a button

Stress Test Study

Baseline Meditation
3-minute mediation sessions conducted using Headspace App

Trier Social Stress Test
15-minute test of brainstorming, presenting, and mental arithmetic

Data Processing
On both MATLAB and Google Colab using Python Heart Rate Analysis Toolkit, heartpy

Proof of Feasibility

Electrodermal Activity

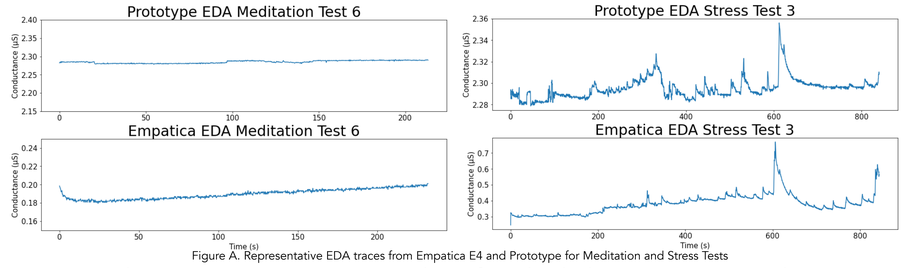


Figure A. Representative EDA traces from Empatica E4 and Prototype for Meditation and Stress Tests

- Figure A shows representative EDA readings from both the Empatica E4 and our prototype for a meditation (baseline) test and stress test separately.
- Corresponding peak features (i.e. time stamp, amplitude, recovery time.), validate our prototype's sensor as a viable alternative to Empatica E4.

Heart Rate

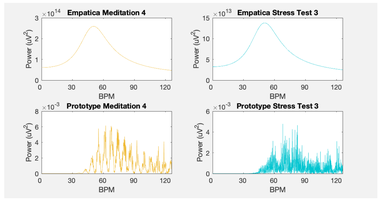


Figure B. Heart Rate data from the Empatica and Prototype

- Figure B shows that the frequency range is the same, but distribution shapes differ greatly, and prototype shows high levels of noise
- Moving forward, HR data collected from Empatica E4 will be used as a data source for proof-of-concept event extraction.

Significant Event Extraction

- Figure C shows significant events extracted from Stress Test #3 using overlaid EDA, HR, and event tracker data.
- Data from multiple devices can be integrated to the same display
- The highlighted areas indicate "significant" moments in the recording when the individual was showing signs of stress

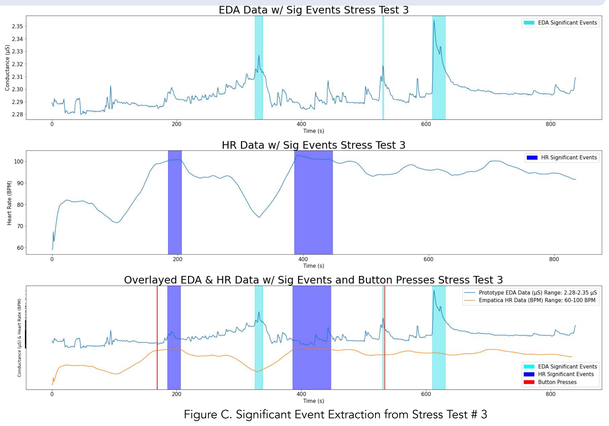
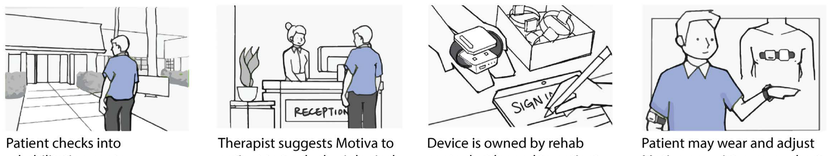


Figure C. Significant Event Extraction from Stress Test # 3

Fitting Into Existing Workflow



Patient checks into rehabilitation center

Therapist suggests Motiva to patient to track physiological reaction to stress

Device is owned by rehab center but loaned to patient, who is liable

Patient may wear and adjust Motiva on wrist, arm, or chest

Therapist reviews patient's diurnal biometric data to prepare for sessions

Patient can log events manually, while EDA and heart rate are automatically

LED display indicates battery life and device/ sensor status

Therapist discusses stressful events logged by biometric data with patient

Patient returns device once rehabilitation goals are achieved

Therapist approves patient's completion of goals

Patient leaves facility and device is given to next patient

Commercialization

Patentability

Wrist-Wearable body composition measuring device and body composition measuring method	Apparatus for Electrodermal Activity Measurement with Current Compensation	PPG Apparatus	System and Method for Identifying Ictal States in a Patient	Method and Apparatus for Generating Assessments Using Physical Activity and Biometric Parameters

Table A: Patented devices that have core features of Motiva in their first claim

Potential Remedies:
- Specific and narrow claim and In-licensing

Market and Reimbursement

Price
- Lower price compared to competitors
- Rehabilitation costs reduced due to decreased relapse rates

Coverage
- Medicare/Medicaid coverers medically necessary treatment
- Not covered due to use in tandem with other treatments

Manufacturing Costs
- The main parts of the prototype are two sensors, a button, other hardware and an injection-molded case for the parts.
- Estimating a bulk discount of 15% or using bulk costs

	Beetle	Battery	GSR	HR	Button	Strap	Casing	Total
Bulk Unit Price	$13.00	$5.06	$18.60	$5.75	$0.11	$1.50	$7.00	$51.02
Bulk Price (500 units)	$6,500.00	$2,530.00	$9,300.00	$2,875	$55.00	$750.00	$3,500.00	$25,510

Table B: Manufacturing Costs for 500 devices

Acknowledgments

We would like to thank Dr. Conrad Zapanta and Melanie Loppnow for their support and feedback throughout the project. We would also like to thank Jeremy Guttman and Biomotivate for partnering with us and making this project possible.

References

1. "Understanding the Epidemic." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 19 Dec. 2018, https://www.cdc.gov/drugoverdose/epidemic/index.html.
2. "510k: Evaluating Substantial Equivalence Premarket Notifications." FDA, 28 July 2014
3. https://www.fda.gov/media/82395/download
4. "General Wellness: Policy for Low Risk Devices" FDA, 27 Sept 2019
5. https://www.fda.gov/media/90652/download
6. Center for Devices and Radiological Health. (n.d.). Premarket Notification 510(k).
7. https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k
8. Lal,R. "Empatica Srl". U.S Food and Drug Administration
9. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181861.pdf
10. "510k Summary of Safety and Effectiveness FitBit." U.S Food and Drug Administration
11. https://www.accessdata.fda.gov/cdrh_docs/pdf13/K133872.pdf
12. Dr. Kremer. "Recommended Method for Determining Production Costs ." Ohio University, OU ME Sr. Design Project , www.ohio.edu/mechanical/design/Resources/CostsforSrD.pdf.
13. Kõpetz, Cătălina E et al. "Motivation and Self-Regulation in Addiction: A Call for Convergence." *Perspectives on psychological science : a journal of the Association for Psychological Science* vol. 8,1 (2013): 3-24. doi:10.1177/1745691612457575
14. "Substance Use Disorders." Medicaid.org, Nov. 2019, https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/substance-use-disorders/index.html
15. Wagener, D. . "Medicaid Paying for Rehab - List of Treatments Covered by Medicaid." https://americanaddictioncenters.org/insurance-coverage/using-medicaid-to-pay-for-rehab
16. "Time for a Change." Surgeon General.gov. https://addiction.surgeongeneral.gov/vision-future/time-for-a-change

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