Name:	**Obstructive Sleep Apnea (OSA)**
Purpose/Mission:	To design and build a device that is comfortable, safe, affordable, and effective at treating Obstructive Sleep Apnea.
Background:	The current treatment for OSA are uncomfortable or invasive, so many patients diagnosed with it are not compliant with treatment. We are trying to make a user-friendly device that is comfortable enough to allow the patient to sleep soundly while preventing the airway from being blocked. We would like to create an oral device that stimulates the relaxed muscles that inhibit breathing. Other options for treatment include surgery, a CPAP machine, or an oral device that holds the jaw or mouth in an open position at night.
Sponsors:	FAMU-FSU Department of Chemical & Biomedical Engineering and Mechanical Engineering, Dr. Pritchard, and Jim Moran School of Entrepreneurship.
Time Commitment from Sponsors:	Dr. Pritchard, Course Instructor: 5 Hours per week
Organizational Structure:	See Matrix
Resources:	We may need an advisor from the Electrical Engineering department. We would like to 3D the mouthpiece prototype or a mold of it, so we will likely need a contact at HPMI to facilitate that process.
Responsibilities & Duties:	See Matrix
Meeting Schedule:	We meet Tuesdays and Thursdays from 11:30A – 12:45P and Wednesday from 9:30-11:30 with each other and with advisors. Weekly progress review with sponsor. Final presentation on December 12 to class and sponsor.
Boundaries:	We'd like to build a device that incorporates the sensor and actuator to apply a stimulus when needed to prevent airway obstruction. The scope of our project may limit the ability to combine the sensor and actuator into one device. We also won't be able to prove the calibration conventionally as we are not able to test the device on human subjects.
How will we analyze:	We will create a functioning prototype of the project to assess performance and feasibility. The device must be able to sense low oxygen concentration to activate the applied voltage.
Presentation Format:	We will communicate our final result at the FAMU-FSU College of Engineering Senior Design Day 2018 through a poster and oral presentation. We aim to create a project binder to communicate our results for future teams.
Budget:	$500 through Dr. Pritchard Possible Additional Funds from Jim Moran School of Entrepreneurship.

Sign and Date:

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Obstructive Sleep Apnea

1. **Problem**
    a. **Problem Definition**

    To design and build a device that is comfortable, safe, and noninvasive for patients who suffer from Obstructive Sleep Apnea (OSA).

    b. **Key Customers / Use Case**

    There is an estimated 22 million Americans who suffer from sleep apnea. 80% of those with sleep apnea are undiagnosed. Our key customers are patients who suffer from mild to moderate Obstructive Sleep Apnea. This means they have 5-30 apneas per hour each night. More specifically, patients who cannot tolerate or who are uncomfortable with existing treatments.

2. **Problem Background**
    a. **Why is this a problem?**

    Obstructive Sleep Apnea (OSA) is when the soft tissues in the back of the throat, namely the soft palate, relaxes and blocks the airway. OSA causes restriction of oxygen flow during sleep. This can cause physiological symptoms as well as deprive the brain of oxygen. Patients with sleep apnea have a higher risk of stroke, heart attack and death if their sleep apnea goes untreated. Sleep apnea has also been found to correlate with night time heart attacks and hypertension.

    b. **Current Clinical Practice**

    Most patients with OSA use a Continuous Positive Airway Pressure (CPAP) machine to control their condition. A CPAP forces oxygen through the airway at high pressure to prevent obstruction, but is uncomfortable and bulky. It is typically a plastic mask that covers the nose and mouth that connects to a thick plastic tube that delivers the air and is attached to the actual CPAP machine. Phillips has come out with a Dreamwear nasal mask that claims to be a more comfortable alternative to typical CPAP machines. However, both masks are basically filters for germs and pathogens if the mask is not cared for properly. Patients are put at risk of contracting

respiratory infections from the potential buildup of bacteria and fungi in the tubes, reservoir, and masks. Those with allergies also cannot use the dreamwear device as they cannot breathe through their nose at all times.

Patients with severe sleep apnea may have surgery to remove part of the soft palate and the uvula, which is invasive and effective only 50% of the time. For those patients for which it is ineffective, they must also use another sleep apnea device to treat their apnea for the rest of their life. There is also a surgically implantable device option called Inspire. This device works by stimulating the hypoglossal nerve beneath the tongue in response to slowed or ceased pulse traced from the chest. The surgery is $30,000 and poses extra risk for infection and other surgical complications. In addition, the battery must be surgically replaced every 8-11 years and it cures about 78% of apneas. Since its approval in 2014, there have been over 1000 inspire implant surgeries. Long term effects of this therapy are promising. There have been significant improvements in OSA patient outcomes following the surgeries that have been performed. Inspire Medical Systems ranked No. 2 on Cleveland Clinic's Top 10 Medical innovations for 2018. Surgery, however, is not a viable first option for most patients with OSA, as they are primarily above the age of 50 and have an increasingly higher risk of complications from surgery.

Another option is an oral device which holds the mouth or jaw in an open position during sleep. This option is also uncomfortable and commonly causes excess salivation or mouth dryness. In addition, it can permanently affect the dental structure of the mouth through teeth shifting. It has to be replaced every 3-5 years, and costs an average of $850.

c. Current Market Assessment

The market for sleep apnea devices is valued at USD 4.59 Billion. It is projected to grow to USD 6.70 Billion by 2021 with a Compound Annual Growth Rate (CAGR) of 7.8%.

As far as we can tell, the market has not offered a product like this before. Any device that stimulates electrically such as this has only been surgically implanted which is more invasive than our approach. The market for an oral device that electrically stimulates the soft palate virtually doesn’t exist or has no competition. If this device is shown to work, it will be the only of its kind available.

3. **Interviews/Customer Input**

   We are in the process of gathering contact information for patients afflicted with sleep apnea and their loved ones affected by it. Each team member will contact patients and record their feedback. The aim of this is not to do human subject research but to ask OSA patients to respond to help us learn more about their experience.

   From some preliminary conversational sessions, some of the biggest complaints from patients and families of patients regarding CPAP machines have been the air temperature, noise, discomfort from the mask, tubing maintenance, and size of the machine. In addition, CPAP machines have no mechanism to function without electricity. In regions such as Florida where hurricanes are frequent, this means those patients have no safe way to sleep if they lose power. In addition, if tubing maintenance is not done properly, it puts patients at risk for respiratory infections. The mask may also be slightly dislodged during the course of the night, causing loud air whistles and groaning noises in the middle of the night, arousing the patient from sleep. The size of the machine makes traveling anywhere difficult since the machine is necessary for use every night. If a patient would like to travel with their CPAP machine, they currently need to pack away the whole machine and bring it with them.

4. **Functional Requirements**

   a. **Comfortable**

      The mouth guard needs to be comfortable for the patient to sleep in. First, the material that is used to construct the body of the mouth guard needs to fit well to the hard palate. There are additional thermal considerations to take for the material selection. The material that spans the length of the hard palate will have electrical components embedded within them. It needs to insulate the heat that may be given off by any electrical conduction so as not to cause discomfort or pain. The device also must be built in such a way that the electrical components are not uncomfortable if they are touching the hard palate. The material that is chosen for the soft palate stimulation section needs to be comfortable as well as conductive. The current design stimulates the soft palate through this material. Additionally, it need to be soft in order to mimic the existing tissue, but also possess insulating properties. The material cannot get too hot when passing a current through it, and the method of delivering

a stimulation directly to the soft palate may need to be slightly altered if thermal concerns persist.

The electrical stimulation also needs to be within a tolerable range of voltages, calibrated for each patient. We are currently looking at a range of voltages for stimulation within 9-10V. Since pain tolerances vary from patient to patient, each mouth guard would need to be calibrated to each patient. The voltage that is chosen needs to be strong enough to emit a response from the soft palate, but not too strong as to cause pain or wake a patient up.

Lastly, the mechanism that is built into the mouth guard needs to hold the mouth guard firmly in place without compromising the placement of the teeth. Current devices can pull on the teeth causing shifting. This can cause long term dental issues and is not ideal for comfort.

b. Affordable

To diagnose a patient with OSA, they must first undergo an overnight sleep study. These cost between $1,000 - $3,000. We propose selling a pulse oximeter that can be worn during the night and collect oxygen saturation data prior to subjecting patients to that study. If they are found to be at risk, they can then schedule a sleep study and use the pulse oximeter to wirelessly pair to our device should they deem it their best option.

The most common sleep apnea treatment is a CPAP machine, which ranges from $1,500-$3,000. This includes maintenance and equipment. The head masks used with the device need to be replaced every 6 months and cost $50-$200 each.

Oral appliances are also very expensive. According to the American Sleep Association, replacement, maintenance, and dental office visits for these appliances typically cost a patient $1800-$2000. They are replaced every 3-5 years.

Corrective surgery for sleep apnea costs $8,000-$10,000. Surgery for the Inspire device implantation costs $10,000 plus $20,000 for the device. It also requires surgery every eight years to replace the battery and specific check-ups every six months.

We want our device to be affordable for customers, so this financial barrier does not prevent them from proper sleep and breathing.

Therefore, we are trying to reduce maintenance costs and avoiding surgery to break down that barrier.

c. **Unrestricted Motion**

CPAP machines and many of the oral appliances currently on the market severely limit movement. CPAP machines connect to a mask via tubing and straps around the face. Some of the newer types of masks only cover the nasal passages, providing less restriction of the facial area. The mask, while smaller, still requires the extensive tubing and wires to allow the airflow necessary to open the airway. For some oral appliances, the lower jaw is often positioned so it is further out. This pulls the tongue away from the airway. The issues with some of these models is that it does not allow motion. Issues that arise from these types of appliances are that they can cause either severe dry mouth or excess salivation, making it very uncomfortable. In the long term, they can also cause the teeth to shift out of their regular position and permanently affect the patient's dental structure.

d. **Non-Invasive**

For patients who suffer from severe obstructive sleep apnea, surgery may be a viable option. Surgical procedures that are most common include shortening the soft palate, moving the jaw and tongue forward, and implantation of an electrically stimulating device. The efficacy of these procedures, for example for the uvulopalatopharyngoplasty (UPPP) is only 50% effective and is typically paired with other procedures. Our device should be something that provides a stimulus without the need for surgeries, and can be used in the comfort of a patient's own home.

The Inspire device also requires surgical implantation and is very costly. The device requires surgical battery replacement, but due to the age of most OSA patients this is not feasible and there is a higher risk involved for complications.

5. **Technical Requirements**

The device needs to be made of a comfortable, thermally insulated material. The material also must be relatively affordable so as to be competitive with other devices on the market. The device should not hold

the jaw or mouth in an uncomfortable way or a way that would lead it to be sore after use. It should not abrade the mouth or gums and should not cause excess salivation or dryness. The mouth guard must be well-fitted to the patient's mouth. The mouth guard will fit around the patient's teeth and extended to the soft palate along the roof of the mouth. This extension will encompass the points of electrical stimulus on the palate. The goal is to build a device that incorporates the sensor and actuator to be more mobile and compact. The sensor will send a signal to the actuator when the airway is blocked, causing an electrical stimulus in real time.

a. **Comfortable**

The device must foremost protect the mouth from the conductive components. By encapsulating the main electrical components in plastic or ceramic, we are able to significantly reduce the risk of "leakage current' harming the tissues of the mouth. With frequent use, electrical components can produce heat. We need to ensure the device does not get hot enough to cause discomfort or tissue damage. Our goal maximum temperature is 40 degrees celsius, which is about the temperature of a hot cup of coffee. However, we expect the range to be more of a few degrees of difference, as most medical devices hold to that standard.

b. **Affordable**

To compete with other oral appliances, the device must be affordable. It must be made of cost-effective and durable material to reduce the amount of times it must be replaced. It must be user-friendly enough that cleaning and recharging or changing the battery can be done at home and will not be another hospital expense.

c. **Unrestricted Motion**

The device must not have wires that can wrap around them or cause them sleep discomfort. It must fit them and hold their mouth in such a way that they do not suffer muscle soreness as a result of wearing the device, as this would decrease compliance.

b. **Materials**

We are currently researching viable materials with consideration to effectiveness, cost, and comfort. We are also taking into account thermal effects, as it will need to insulate the electrical stimulus from the rest of the mouth.

The three materials that are being taken into consideration are acrylics, polymers and laminates. The specifications that will be the deciding factor

will be thermal conductivity, support, biocompatible, durable, comfortable and 3D printing compatibility. Acrylic was found to have the lowest thermal conductivity followed by polymers and laminates. Acrylic and laminates are used in the 3D printing and polymers have limited use currently. We are still researching on conductive materials that can be 3D printed for the section of the device that will stimulate the soft palate.

6. **Timeline**

Complete Initial Interviews - November 7th, 2017

Initial Literature Review - November 7th, 2017

Debrief from Interview Findings- November 8th

Finalize Placement of Components - November 25th, 2017

Finalize Budget - November 27th, 2017

Complete computer modeling -January 25th

Complete first electric component tests -January 31st

Prototype Device - February 1st-April 1st, 2018

Final Presentations - December 11th, 2017

Begin work on final presentation materials- March 1st, 2018

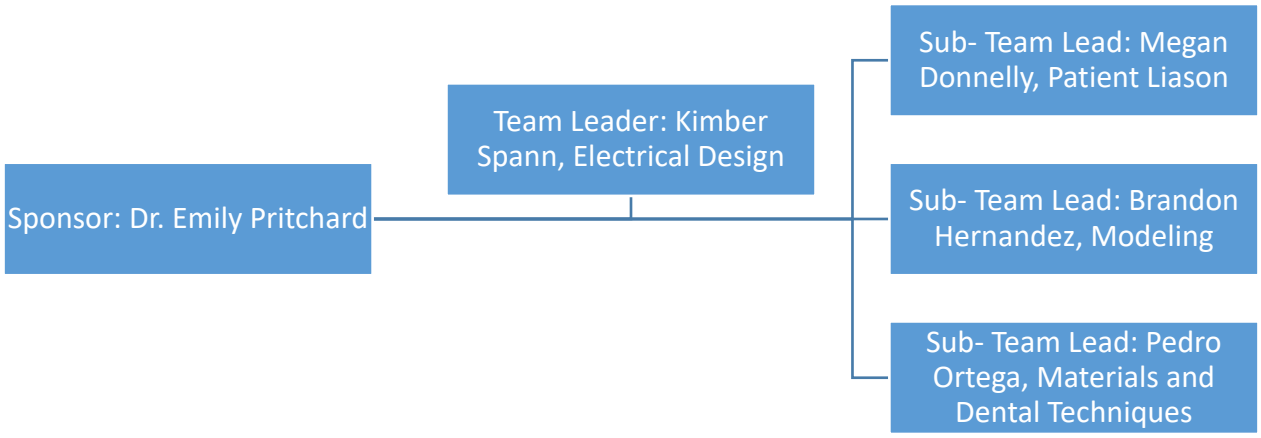
First draft of presentation materials - March 15th, 2018

FSU Senior Design Day - April 12th, 2018

7. **Budget**

Our current budget to work within is $500. If we plan to compete in the shark tank competition, we anticipate our budget expanding to accommodate that. We have budgeted estimates for our conductive and non-conductive materials, as we have seen comparables but haven't made a final decision yet. We have also specified a buffer should we need additional components for a new prototype.

Item Name	Cost
Pulse Ox Particle Board	$13.00
Arduino Mini	$27.00
Ancillary Components	$50.00
Non-Conductive Mouth guard Materials	$100.00
Conductive Material for Stimulatory Section (Approx.)	$100.00
Buffer for prototyping components	$75.00
Total:	$365.00



Roles & Responsibilities

1. Sponsor: Dr. Emily Pritchard

1) Ultimate authority and responsibility for the project
2) Provides funding for the project (initial funding, additional funds)
3) Approves changes to scope, as required
4) Removes obstacles that prevent the project from moving forward
5) Approves Project Charter and subsequent documentation
6) Provides updates to executive management
7) Resolves issues escalated by the project manager and/or core team

1. Project Leader: Kimber Spann

1) Develops the Project Charter and any other documentation in collaboration with the project team and resource managers for approval by the sponsor(s)
2) Ensures all given objectives and responsibilities of the team are properly documented and approved on the Roles Matrix
3) Provides subject matter expertise and functional ownership and accountability for project results
4) Leads core team meetings

2. Sub Team Leads: Megan Donnelly, Patient Liaison; Brandon Hernandez, Modeling; Pedro Ortega, Materials and Dental Techniques; Kimber Spann, Electrical Design.

1) Serves on the Core Team
2) Manages the sub team and pursues the team's given objectives (i.e. project tasks)

3) Provides regular status updates to the Project Manager/Leader, estimated time to completion, cause of variances, etc., as defined by the project
4) Attends and actively participates in project team meetings
5) Contributes to overall project objectives and specific team deliverables
6) Ensures tasks for team are completed on time
7) Schedules and conducts routine team meetings with project team and provides them status updates and project documentation, when necessary
8) Coordinates team activities related to project schedule
9) Performs assigned activities once the schedule is approved.

3. Team Member: Megan Donnelly, Brandon Hernandez, Pedro Ortega, Kimber Spann

1) Contributes to project schedule development in collaboration with Project Leader/Manager/Lead
2) Responsible for contributing to overall project objectives and specific team deliverables
3) Communicates project risks and escalates issues to team lead
4) Attends and actively participates in team meetings
5) Maintains appropriate records of work in progress which includes any necessary documentation
6) Notifies the team lead of any expected difficulties or issues arising
7) Performs assigned activities once the schedule is approved.

References

- **"Inspire Sleep Apnea Implant Treatment Offers Alternative to the CPAP Machine."** ***Apnea Today***, **20 June 2017, www.apnea.today/inspire-sleep-apnea-implant-treatment-offers-alternative-to-the-cpap-machine/.**

- **"How Much Does Sleep Apnea Treatment Cost? - CostHelper.Com."** ***CostHelper***, **health.costhelper.com/sleep-apnea.html.**

- **Michaud, Laci. "Alaska Sleep Education Center."** ***How much does a sleep apnea machine cost? Costs, Insurance, Rates***, **www.alaskasleep.com/blog/how-much-does-a-sleep-apnea-machine-cost-costs-insurance-rates.**
- **Huesmann, David. "Conductive Polymeric Biomaterials."** ***Advanced Science News***, **21 Nov. 2016, www.advancedsciencenews.com/conductive-polymeric-biomaterials/.**
- **"Sleep Study Details."** ***SleepApnea.org***, **www.sleepapnea.org/treat/getting-sleep-apnea-diagnosis/sleep-study-details/.**
- **"ProtoCentral AFE4490 Pulse Oximeter Breakout Board Kit."** ***Protocentral***, **www.protocentral.com/sensors/1112-protocentral-afe4490-pulse-oximeter-breakout-board-kit-642078949425.html.**
- **"Video: What happens during obstructive sleep apnea?"** ***Mayo Clinic***, **Mayo Foundation for Medical Education and Research, 8 July 2016, www.mayoclinic.org/diseases-conditions/sleep-apnea/multimedia/obstructive-sleep-apnea/vid-20084717.**

Project Logbook

***(All members present unless noted)**

09/26/17

Original Design Thinking Workshop

Obstructive Sleep Apnea- possible solutions to current treatments

-3-D printed CPAP mask

-Mouthguard

-Electricity Issue

-Botox? probably not data available

10/03/2017

Selection of Design Groups

Vote on which projects class wants to take on

OSA team- Pedro Ortega, Brandon Hernandez, Megan Donnelly, Kimber Spann

10/05/2017

Dr. McConomy Guest Lecture

Discussion of projects

Ask users in-depth questions, know your targets and extremes, find a way to quantitatively measure qualities.

10/19/2017

Speaker on Project Charter

GANT charts and project timeline

10/24/2017

Work on Project Charter

Deadline moved back until next week due to Megan and Kimber attending SWE conference

10/26/17

Megan and Kimber not present.

Further development and role definition on project charter.

10/31/17

Initial Draft of Project Charter submitted

produced independently using google documents

11/02/2017

Allocation of patients to call for initial interviews

Will call and email sleep clinics, leaders of support groups, etc.

11/07/2017

Lecture with Dr. Clark on Controls

Specific microcontroller requirements

Kimber-Discussion with Dr. Pritchard about project progress

Primary selection of pulse oximeter microcontroller

11/07/2017

Interview with Patient - Donna Muslin

Anonymous? No

Contact Back? Yes

11/09/2017

Group meeting, class time

Meet to discuss microcontroller options

Should we aim for the smallest one to make transfer into mouthpiece simplest, or choose one that is simplest to work with?

11/14/2017

Group Meeting at class time, discussion of electrical resources

Initial Interview with Dr. David Huang, 8PM

Conducted by Megan Donnelly

11/21/2017

Final discussion of electrical components needed and accessory items

Preliminary items chosen

11/22/2017

Compilation of Sparkfun Order e-mailed to Dr. Pritchard by Kimber

11/30/2017

Initial Contact Made - Dr. Ruby Williams

12/06/17

Practice Final Presentations

Feedback from Dr. Devine, Dr. Pritchard, Dr. Rodriguez and classmates

12/11/17

Final Oral Presentation of Project, 12:00PM

Feedback from Dr. Devine, Dr. McConomy, Dr. Pritchard, Dr. Rodriguez and classmates

12/14/17

Final Submission of Project Charter

Submitted by Kimber