

PowerNap: Electrically Stimulating Oral Appliance for Patients with Mild to Moderate Obstructive Sleep Apnea

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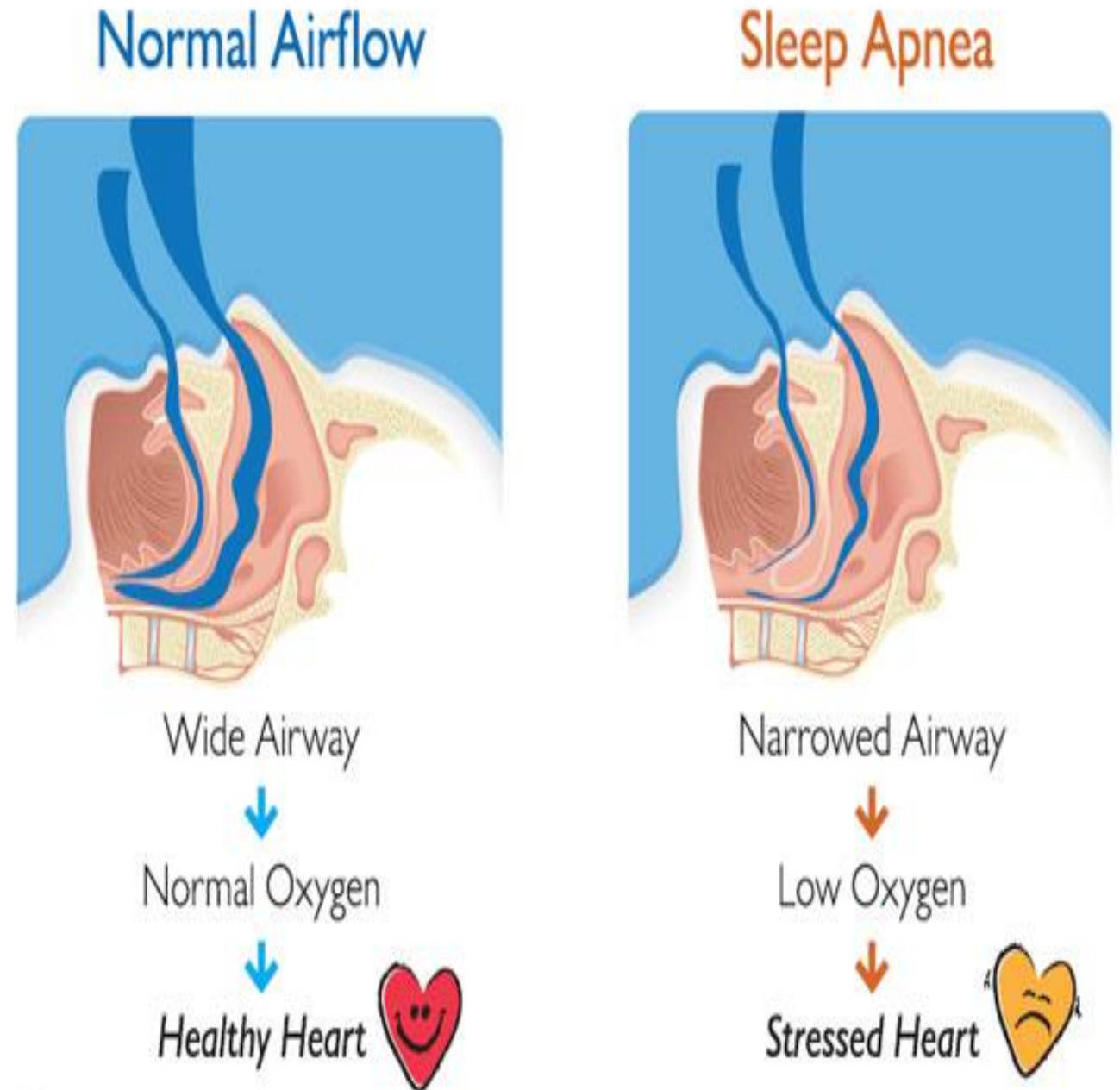
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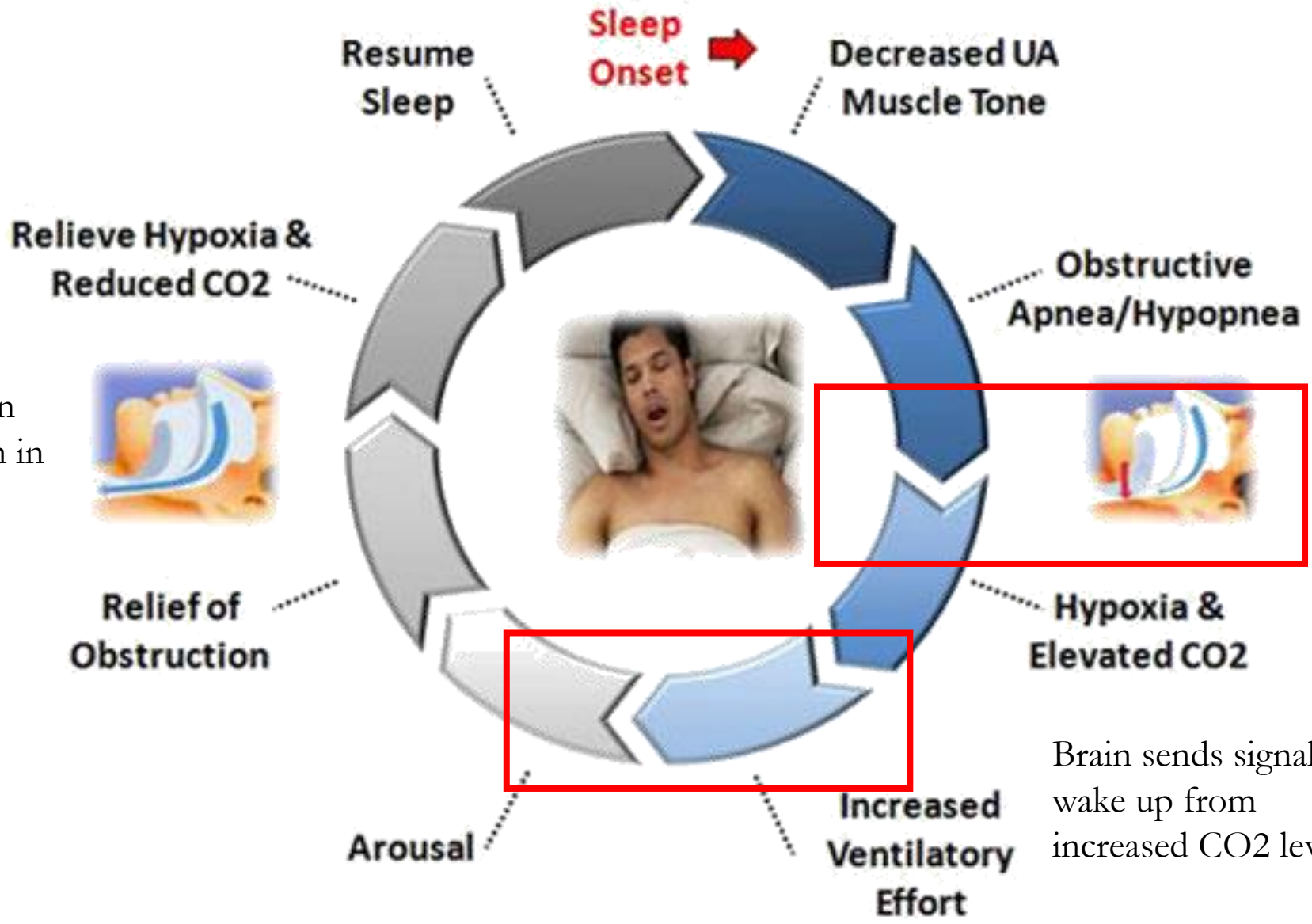
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Sleep Apnea

- Estimated 22 million Americans affected, 1 in every 15
- 80% are undiagnosed
- Three Types: Obstructive, Central and Mixed



The Cycle that Kills



Effects 4% of men and 2% of women in the US

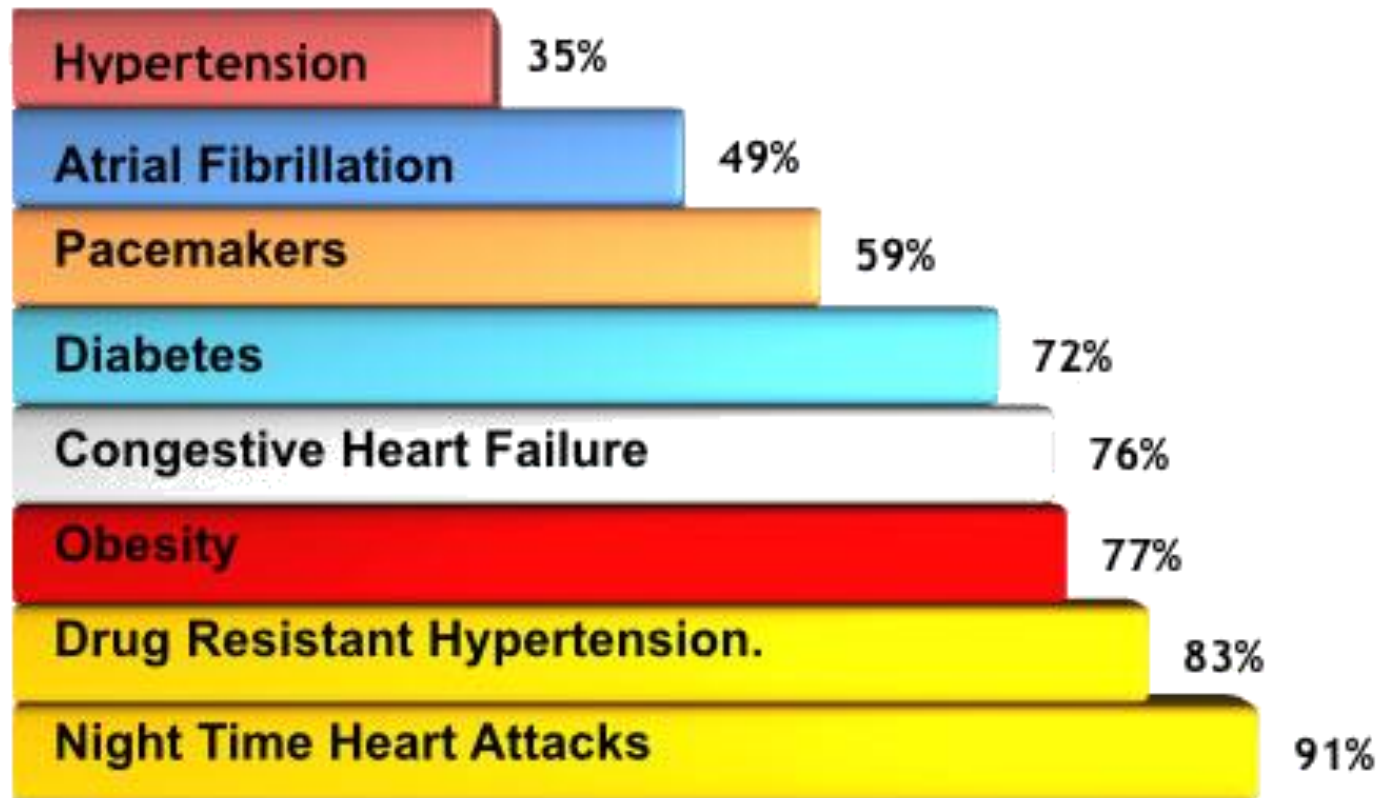


Throat muscles intermittently relax and block the airway during apnea episode

Brain sends signals to wake up from increased CO2 levels

Symptoms and Side Effects

Diseases Associated with OSA



- Snoring
- Abrupt Awakening
- High Blood Pressure
- Difficulty concentrating
- Hypertension
- Obesity

Clinical Input– What can we do about sleep apnea?

- Mild to Moderate OSA
 - Between 5 to 30 apneas per hour
 - 80%-93% blood oxygen levels
- Professional Input
 - Dr. David Huang – Board Certified Surgeon, Tallahassee Pulmonary Clinic
 - Dr. Ruby Williams – Oral Appliance Specialist, Tallahassee Pulmonary Clinic

Methods of Treatment



CPAP Machines

- Risk of Respiratory Infection
- Limited Motion during sleep
- Requires electricity and distilled water to operate

Oral Appliances

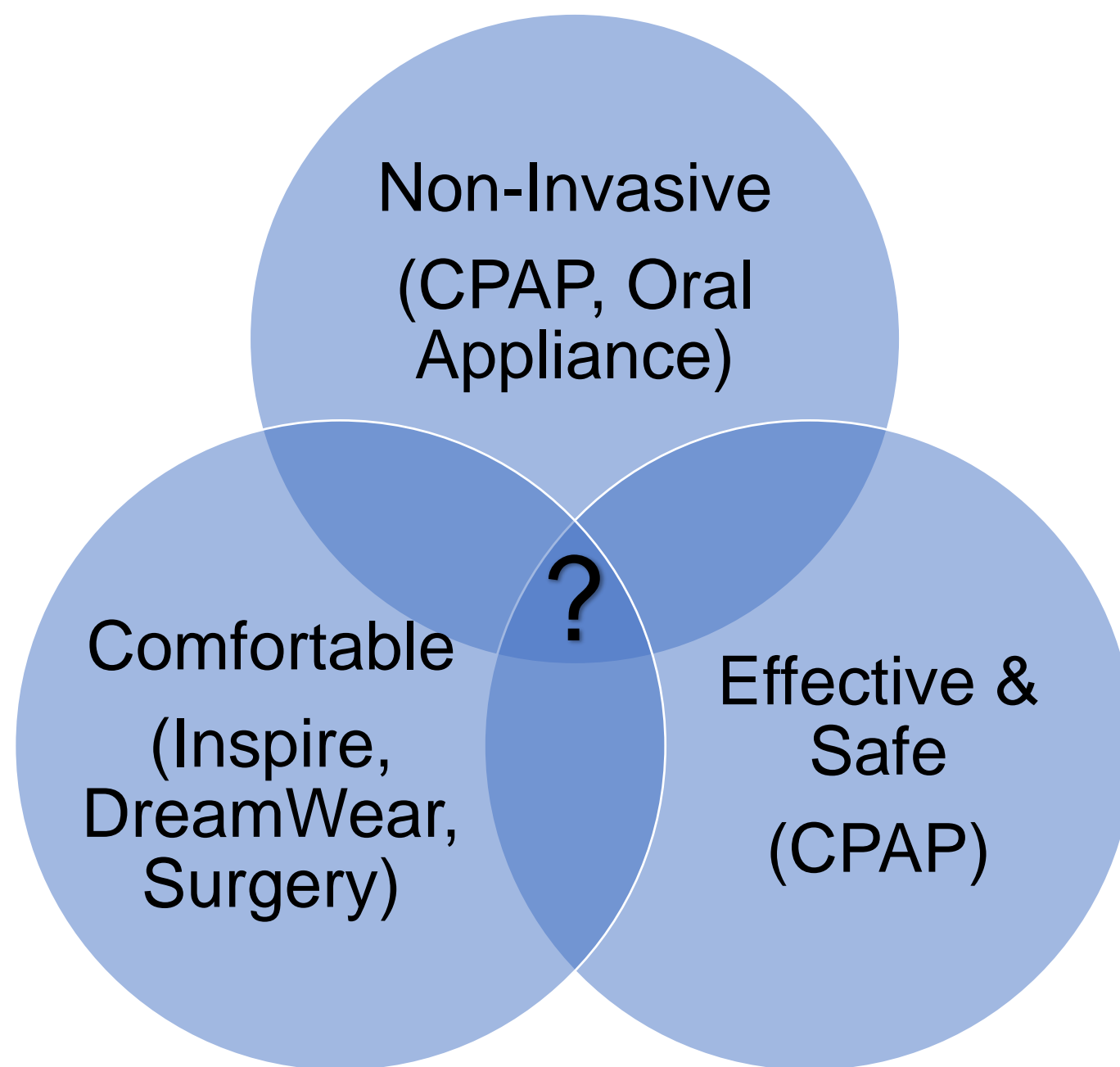
- Long term affect on dental structure
- Uncomfortable
- Impacts salivary function causing excess or deficit of saliva



Resective Surgery

- Invasive
- High risk of infection
- Costly





Soft Palate Anatomy

Musculus Uvulae

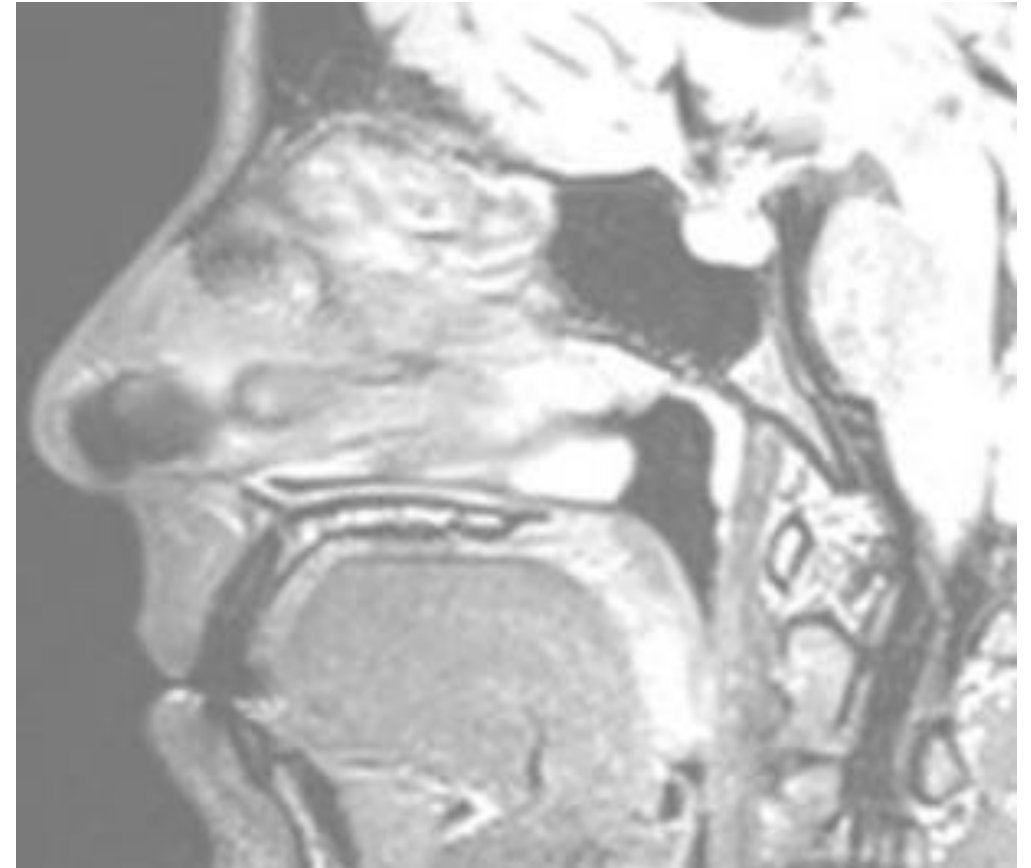
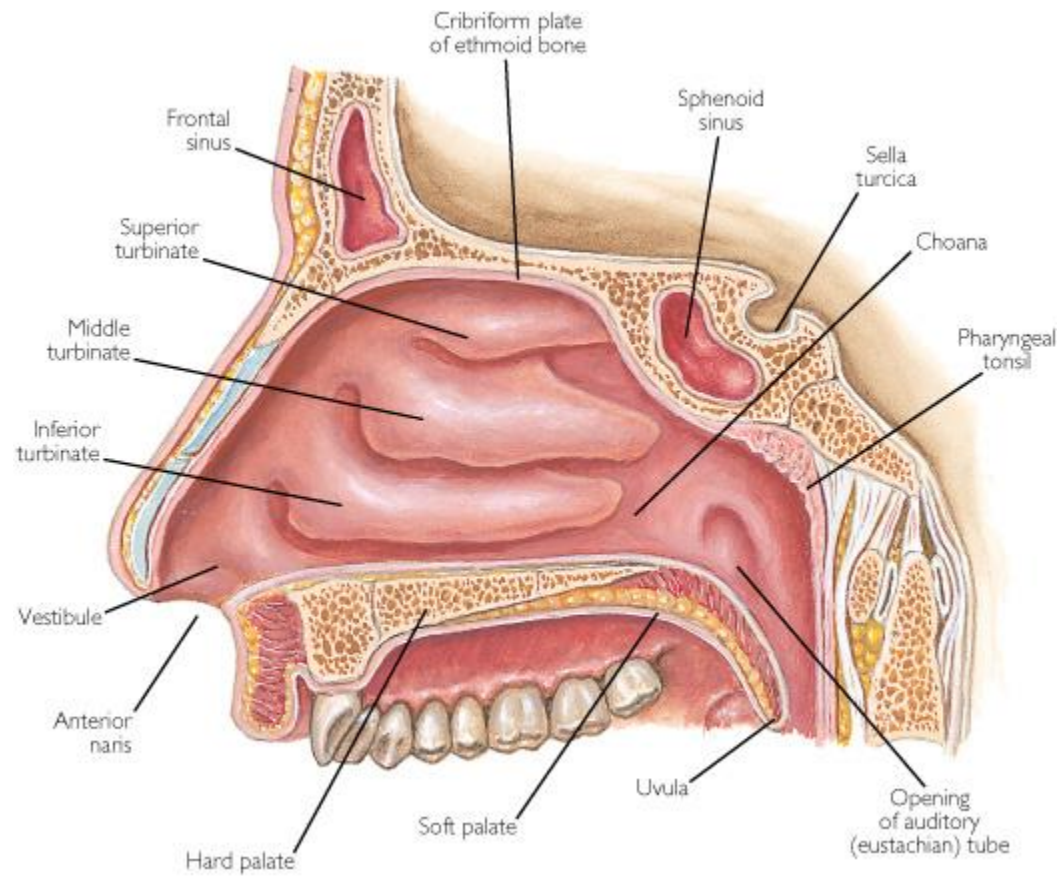
- Shortens and lifts soft palate upon contraction

Levator veli palatine

- Primary elevator of soft palate; lifts soft palate by pulling posteriorly



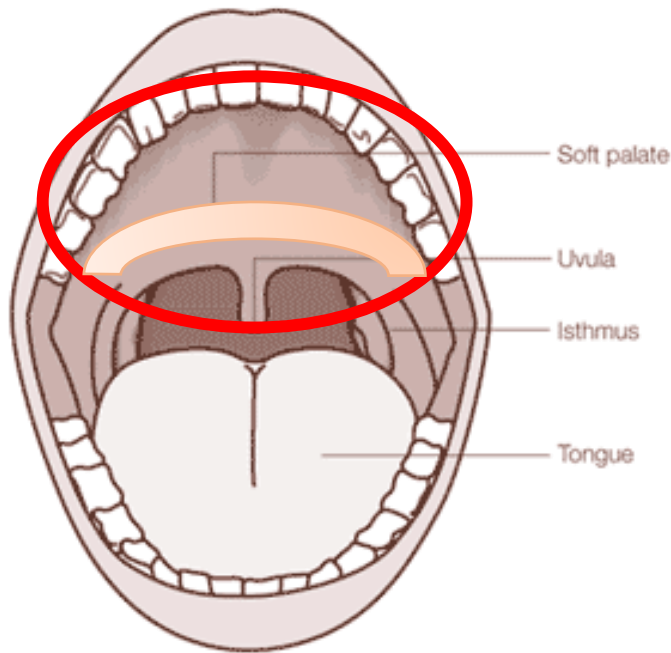
Soft Palate MRI



Conceptual Design

- Electrically stimulating oral appliance

Device Overview



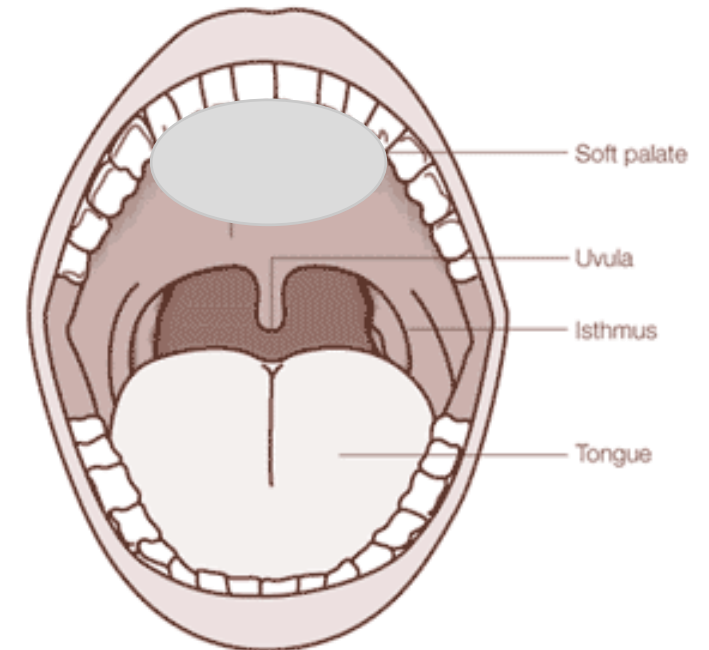
Pulse Oximeter

- Blood oxygen concentration during apnea episodes drop
- Target Stimulation: 3 mAmps Current
- Levels below 90% saturation are dangerous to human health
- Calibrated to each patient
- Mild Episodes: 95-90%
- Moderate Episodes: 89-80%
- Severe Episodes: below 80%
- Long Battery Life
- Potential Addition of data acquisition capability

Functional Requirements

Conductive

- Electrical stimulation delivered to soft palate
- Additional hardware embedded within
- Non-conductivity of key areas necessary



Functional Requirements



- Non-irritating materials (conducting and non conducting)
- Function well in oral mucosa
- Current oral appliance materials include acrylics, polymers, and chromium cobalt alloys

Functional Requirements



- Durable equipment that requires less frequent visits to the dentist office
- No surgical intervention for battery replacement or routine maintenance

Functional Requirements

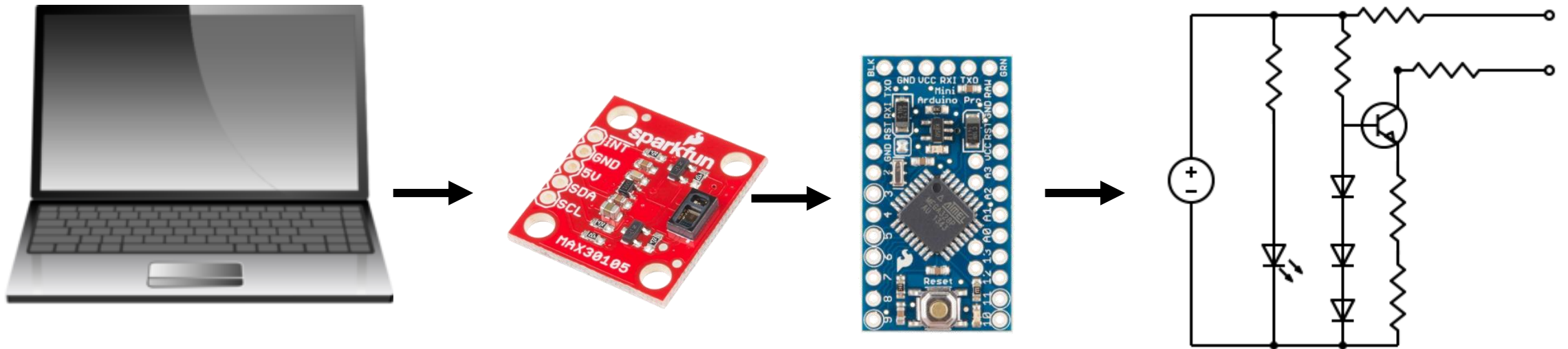
Easy to
Maintain

- More convenient product
- Reduces risk of secondary infections from improper cleaning

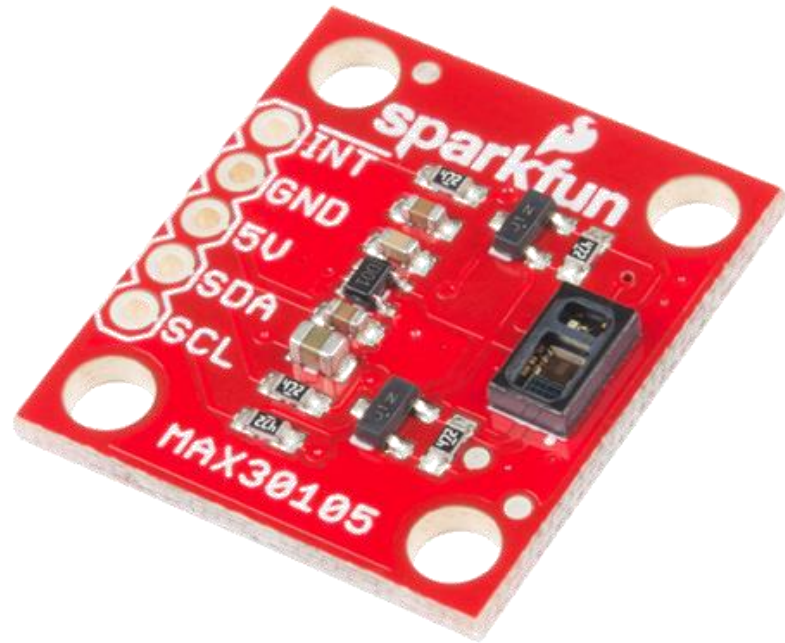


Technical Specifications

Delivery Mechanism



Technical Requirements - Pulse Oximeter



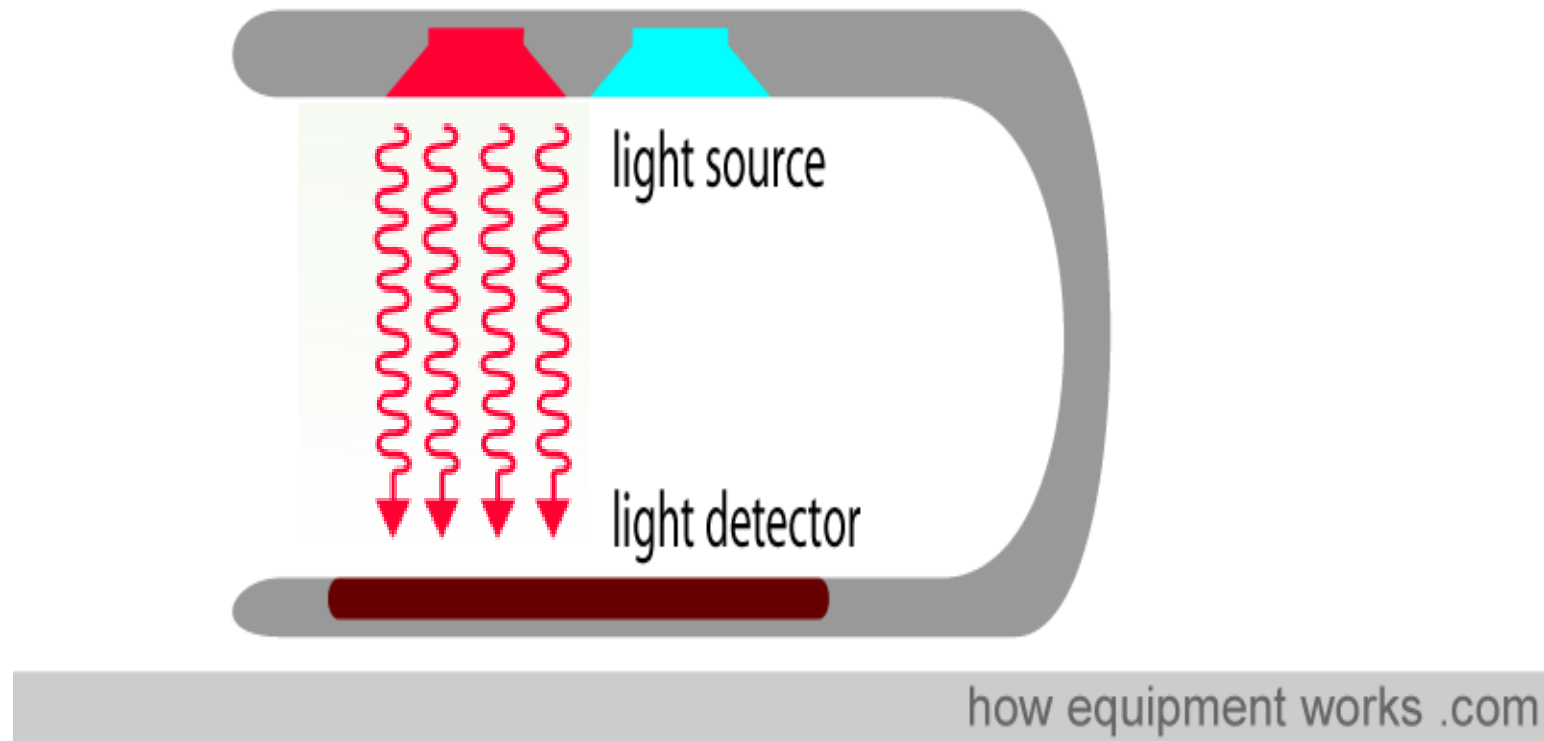
MAX 30105 Pulse Ox and Particle
Sensor Arduino Set

Pulse Oximeter

- Detects instantaneous changes in oxygen saturation
- Battery and all components protected from environment
- Must be accurate at levels approaching 90%

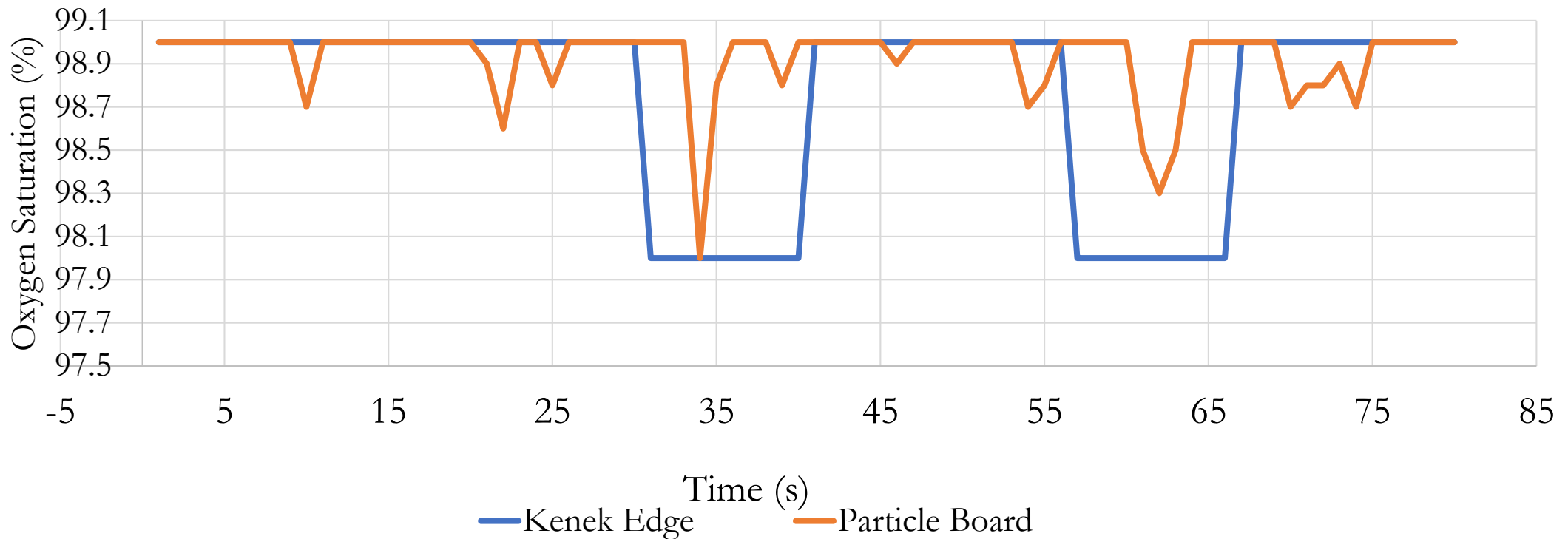
Pulse Oximetry Basics

- Blood oxygenation level measured by infrared and red light transmission through tissue
- Saturation level of blood oxygen = ratio of oxygenated to deoxygenated hemoglobin



Pulse Oximeter Data

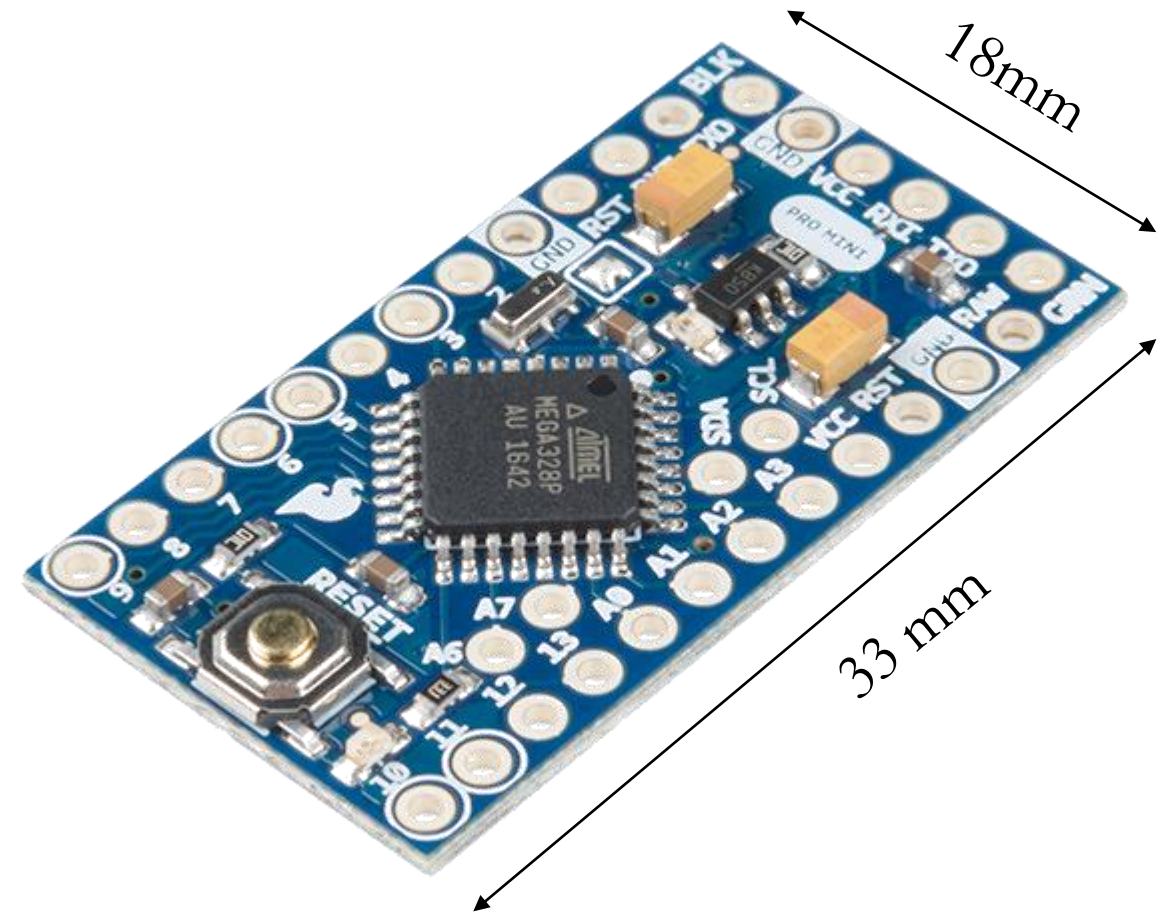
Kenek Edge & Particle Board Pulse Oximeter



Technical Requirements – Microcontroller Unit

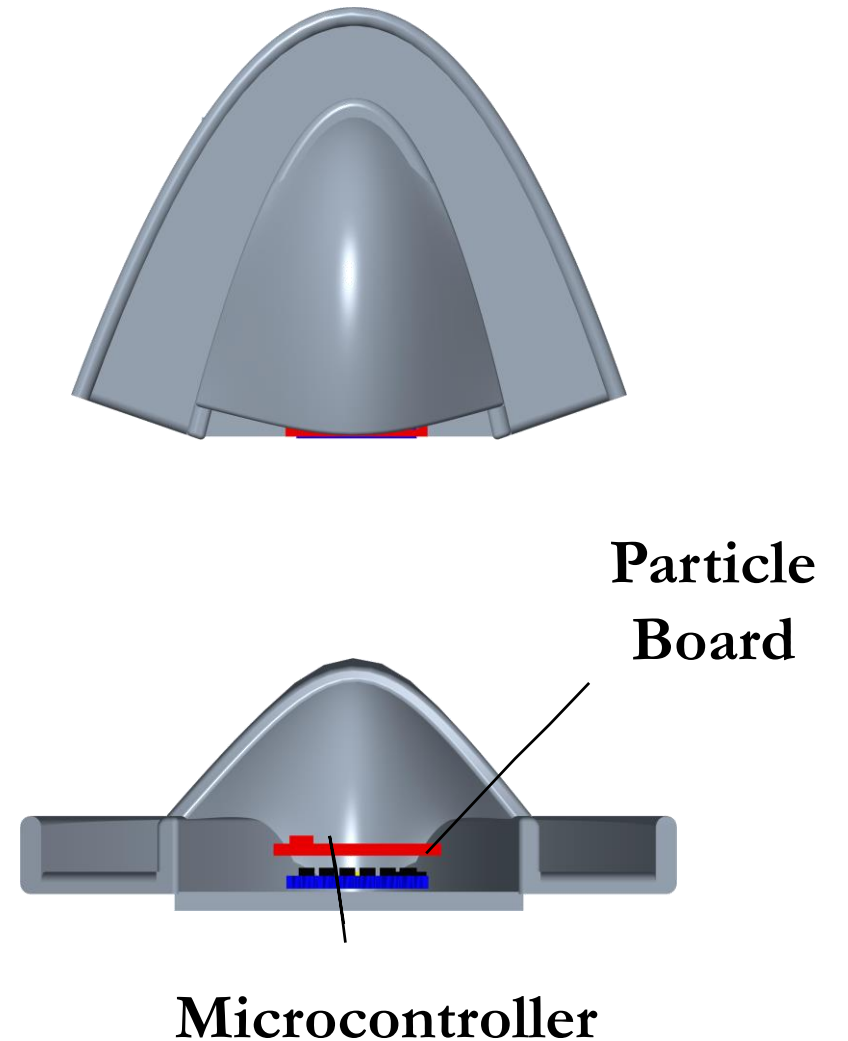
Microcontroller

- Interpret output from Pulse Ox to signal action from stimulatory region
- Model Ordered: Arduino Pro Mini 328 -5V/16MHz MCU

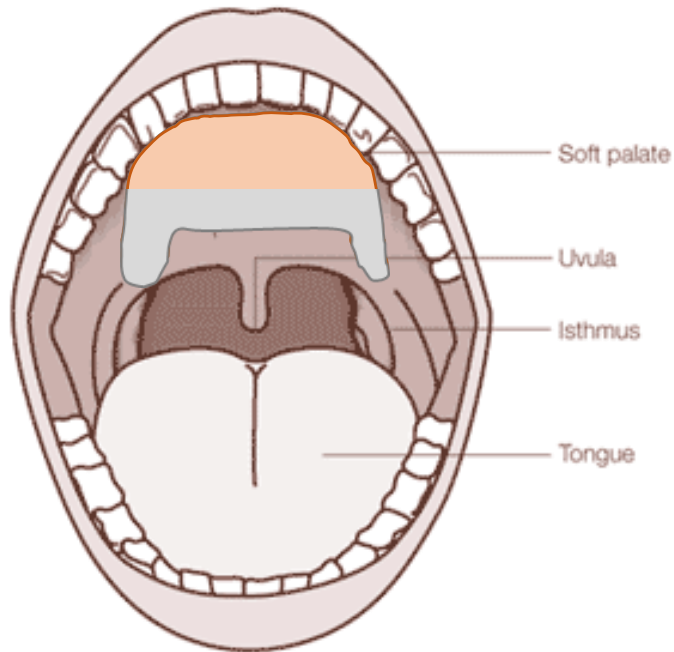


Conceptual Design

- Comfortable mouthpiece
- Thin, flexible lining on the roof of mouth
- Oxygen saturation monitoring
- Stimulation that will not wake the patient



Technical Requirements



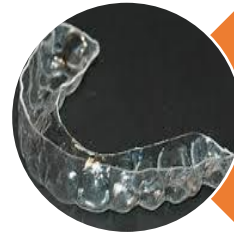
Non Conductive Casing and Supports

- Protect hard palate and tongue from electrical stimulation
- Mechanically secure mouth piece in place
- Houses sensor and circuit framework

Technical Requirements – Casing and Supports

Material Requirements:

- Nonconductive
- Supportive
- Biocompatible
- Durable
- Comfortable
- 3D Printer Compatible



Acrylics



Laminates

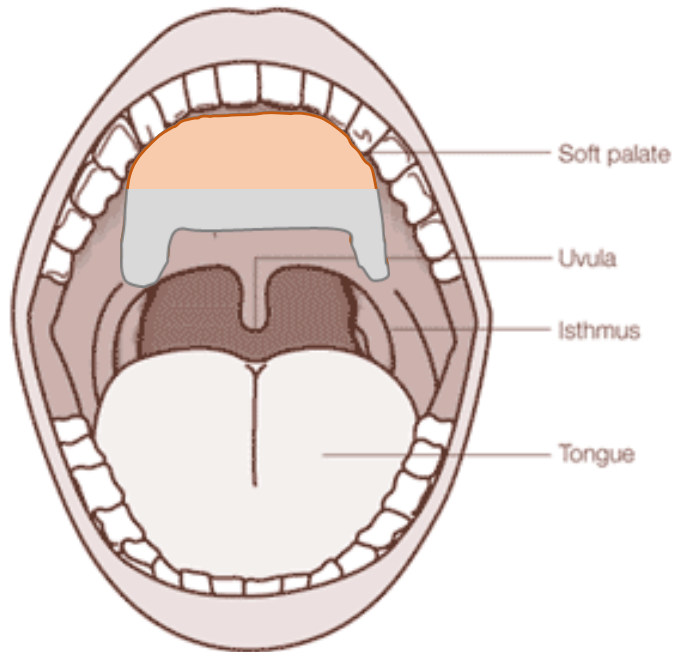


Polymers

Sentinel Hard Acrylics

- Easy to insert, adjust, and remove
- Can be modified slightly without the need for ordering a new/different appliance
- Can prevent teeth grinding and clenching or people suffering from TMJ

Technical Requirements



Flexible Contact Portion

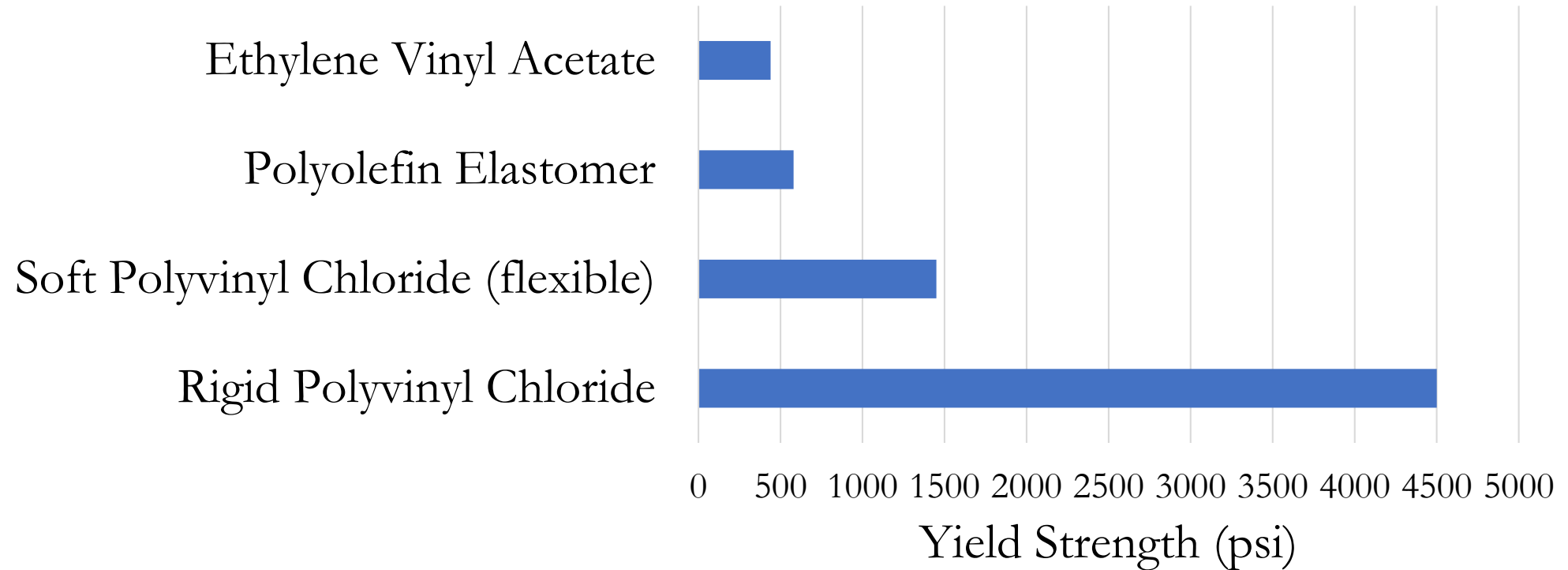
- Lightweight to prevent discomfort
- Flexible
- Supports electrical components

Flexible Portion

Species	Elastic modulus (MPa)	Yield strength (psi)	density (g/cm ³)
Rigid Polyvinyl Chloride	1500-3000	4500-8700	1.3-1.45
Soft Polyvinyl Chloride (flexible)	1.5-15	1450-3600	1.1-1.35
Polyolefin	8-113	580-2465	0.87-0.97
Ethylene Vinyl Acetate	15-80	440-5100	0.93-1.0

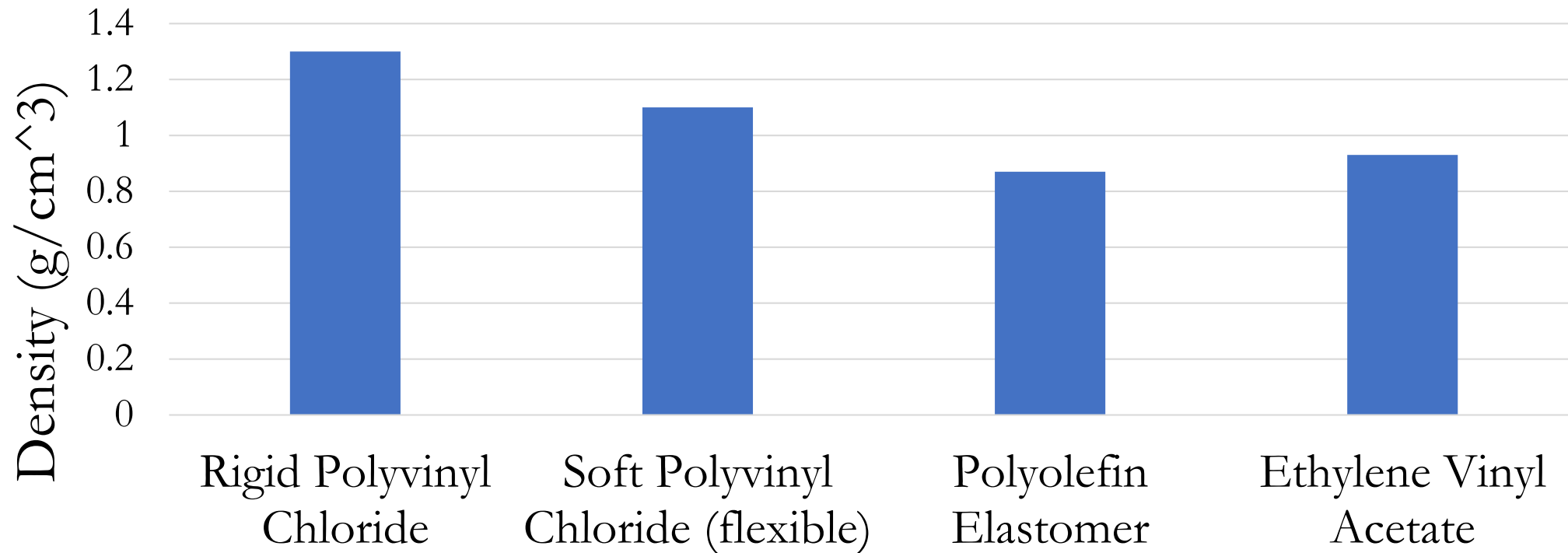
Flexible Portion

Yield strength for Flexible Materials



Flexible Portion

Density of Flexible Materials



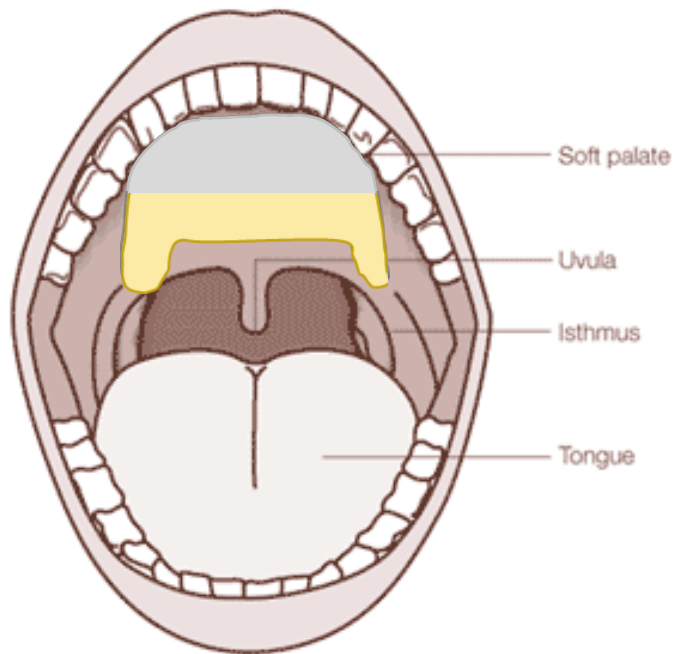
Polyolefin Elastomer

- Offers elasticity, softness, toughness, flexibility and durability
- Used in CustMbite MVP mouth guards
- Does not lose its shape while heating
- Biocompatible

Cleaning/sealing and corrosion

1. Rinse/scrub with toothbrush
2. Soak in clean water
3. Deep cleaning routinely

Technical Requirements



Stimulatory Region

- Targets only soft palate
- Deliver 3 mA current to obstructed airway
- Thermal considerations for material selection

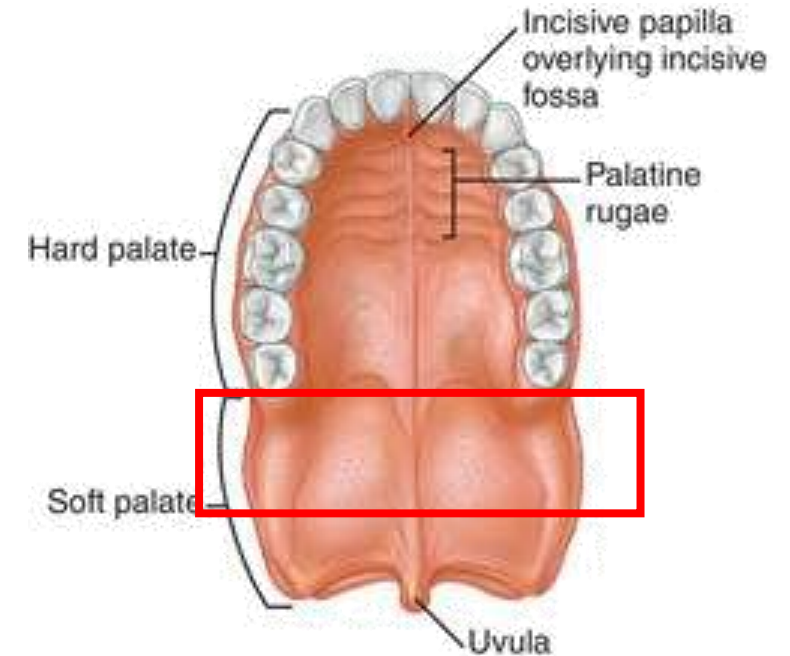
Duration of Stimulation

- In past studies, stimulation was used until muscle contraction
 - 500 milliseconds
 - But how much time is lost between signal transmission?
- Most long-term medical devices use pulse stimulation
 - Stimulation is applied if there is a lack of oxygen flow within a certain period of time

Technical Requirements – Stimulatory Region

Material Requirements

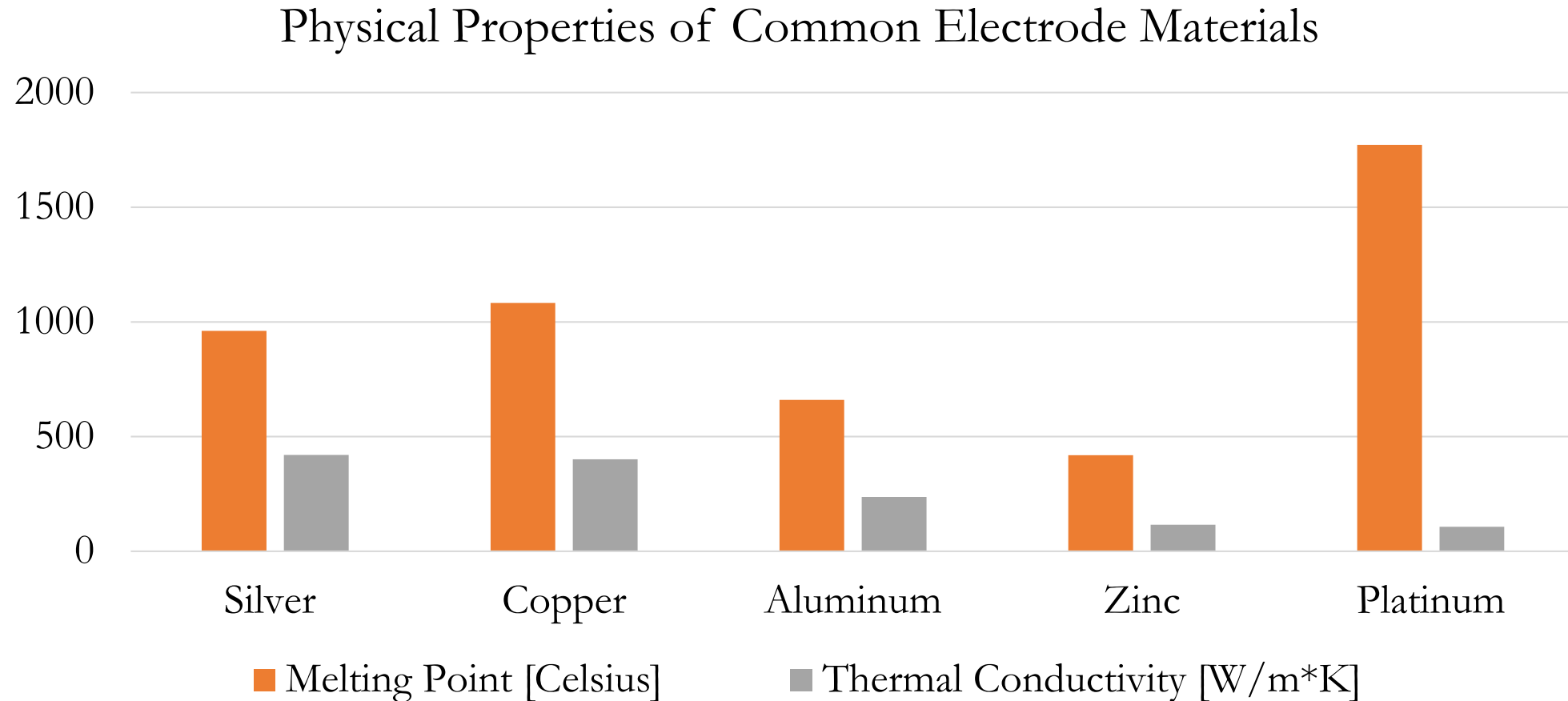
- Transmits a stimulation directly to soft palate
- Resistant to major temperature changes
- Limits area of stimulation
- 3D Printer Compatible
- BioCompatible
- Comfortable



Electrode Material: Platinum Alloy w/ Parylene

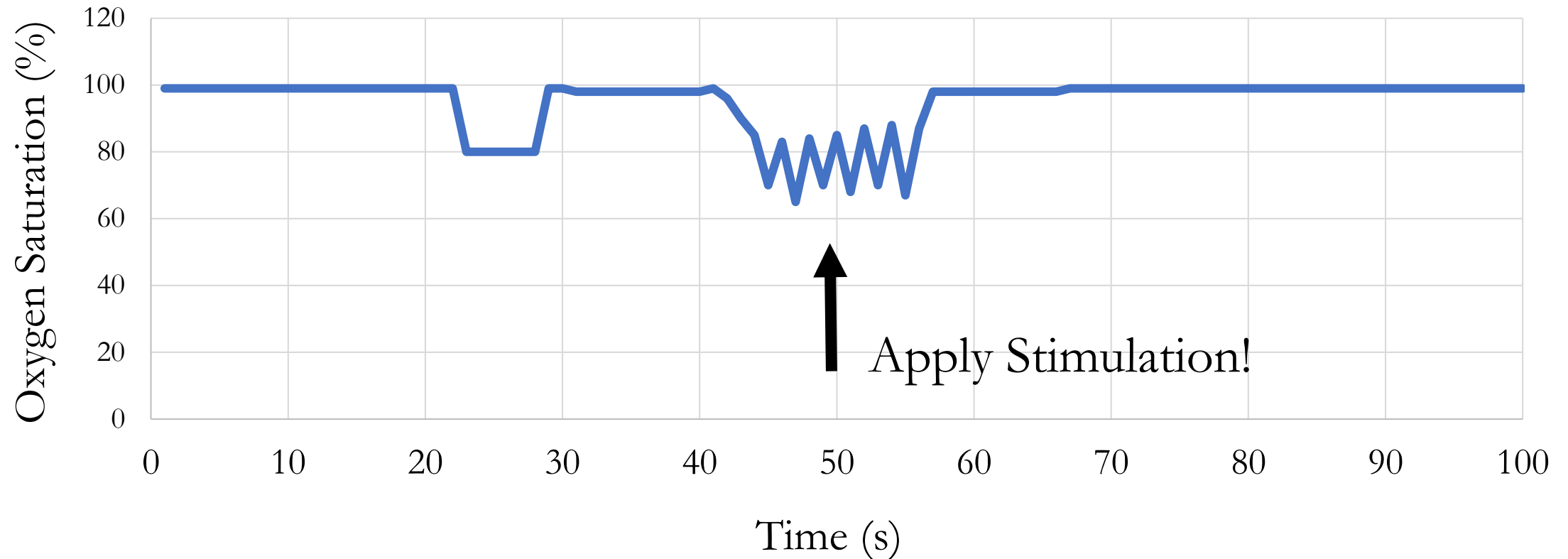
- Most Widely Used conducting alloys
 - Resistant to corrosion and high conductivity
 - Melting Point at 1772 degrees Celsius
 - Thermal Conductivity at 0.716 W/cm/K
- Parylene coating is biocompatible and resistant to moisture

Electrode Material: Platinum Alloy

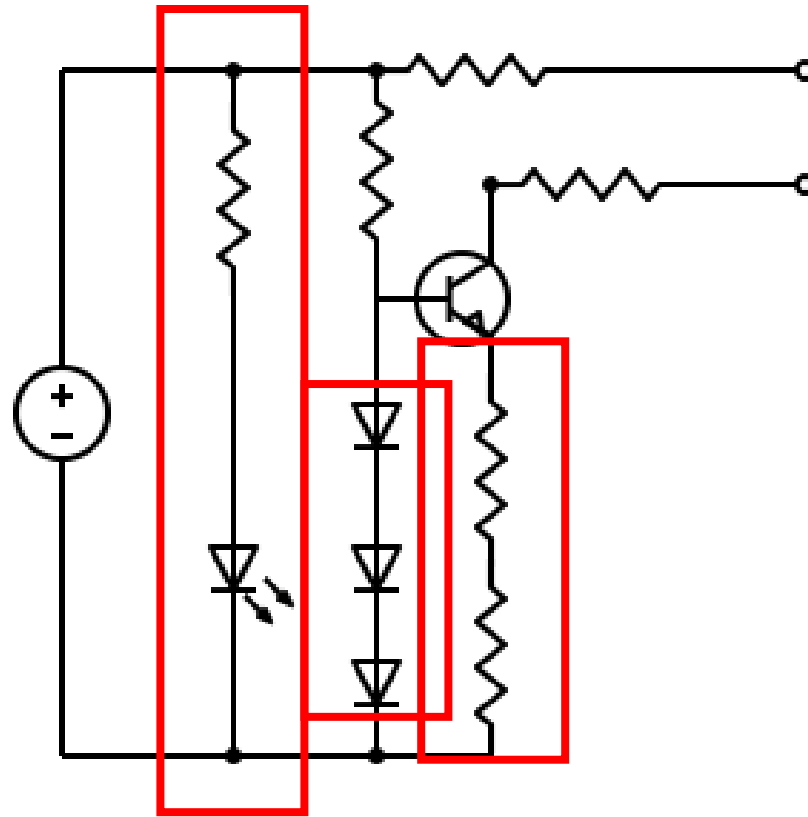


Stimulation

Artificial Oxygen Saturation



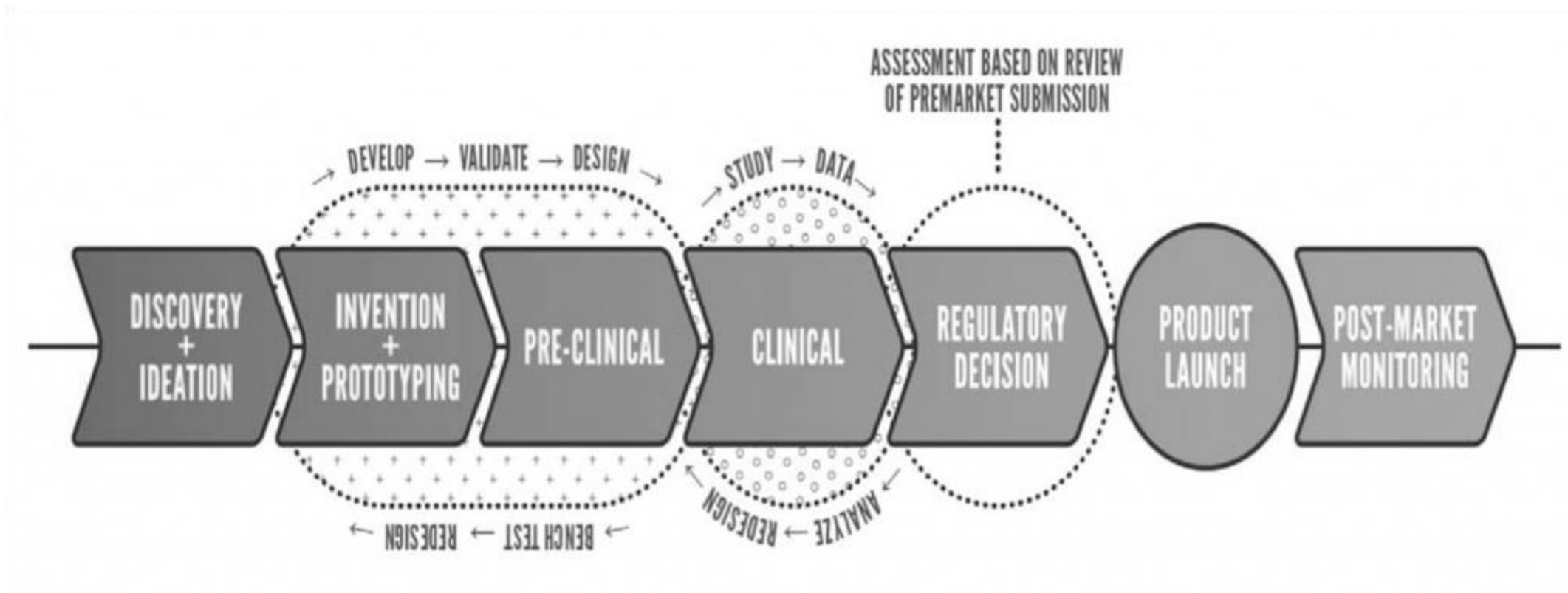
Safety Considerations



Prototype



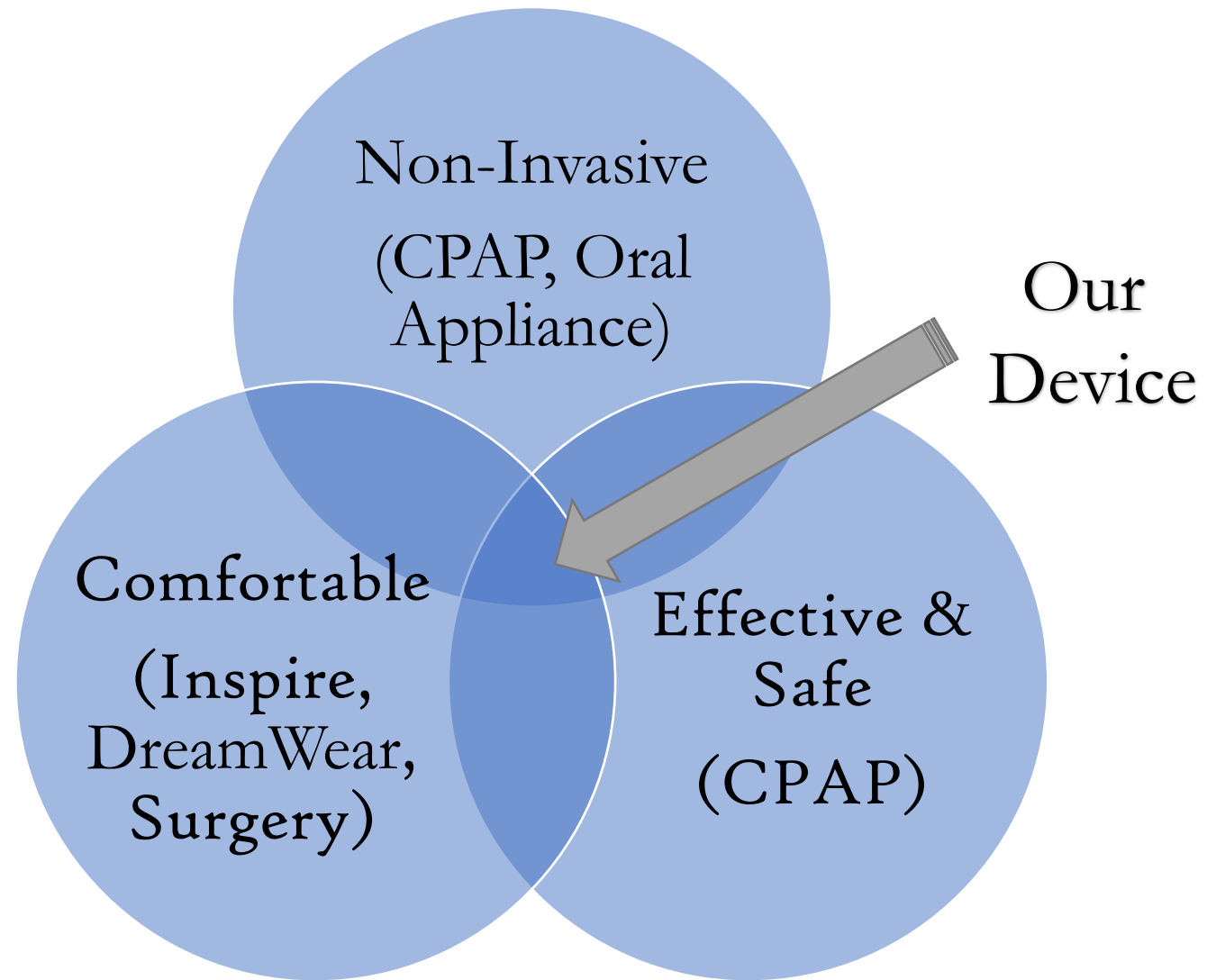
The Road Ahead



Future Development and Plans – Current Issues

- Potential addition of a microchip for compliance tracking
- Development of disinfection and maintenance protocol
- Future testing needed for muscle stimulation, safe levels, and prevention of leakage current

Conclusion



Thank you to:

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- Department of Mechanical Engineering
- Dr. Emily Pritchard, Course Instructor
- Dr. Cesar Rodriguez, Department of Biomedical Sciences
- Dr. Jerris Hooker, Department of Electrical Engineering
- Dr. David Huang, Tallahassee Pulmonary Clinic
- Dr. Ruby Williams, Tallahassee Pulmonary Clinic

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