



PowerNap



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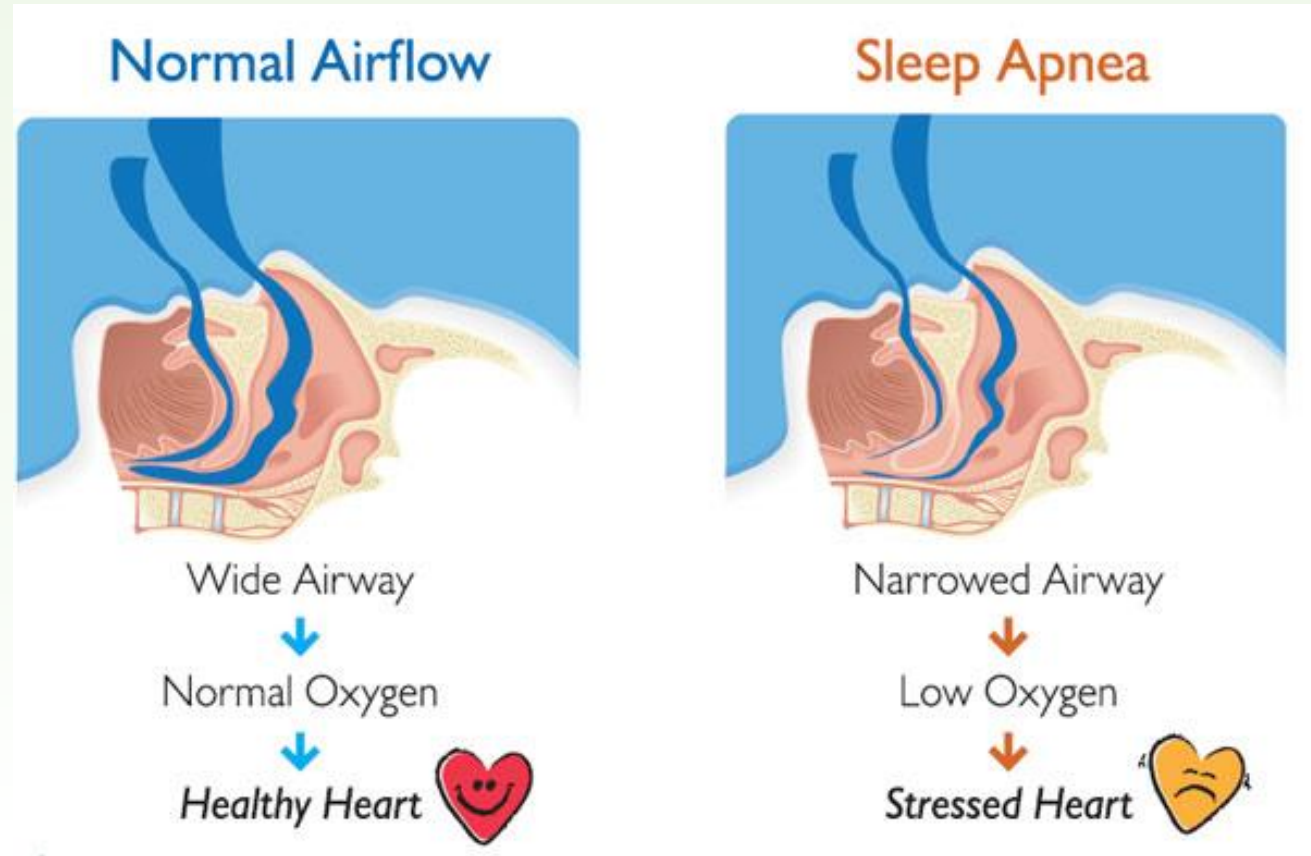


Meet Nana



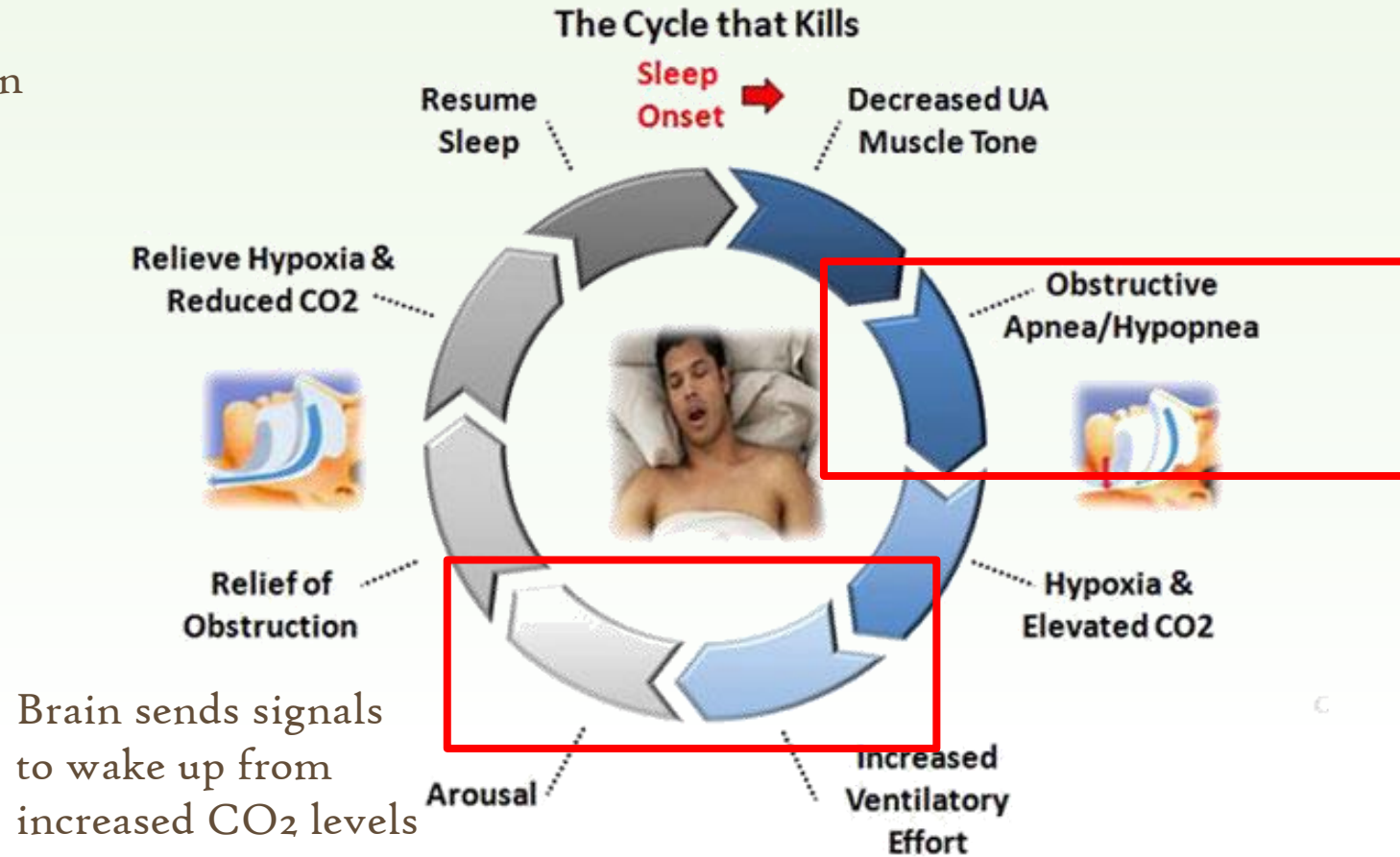
Sleep Apnea

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



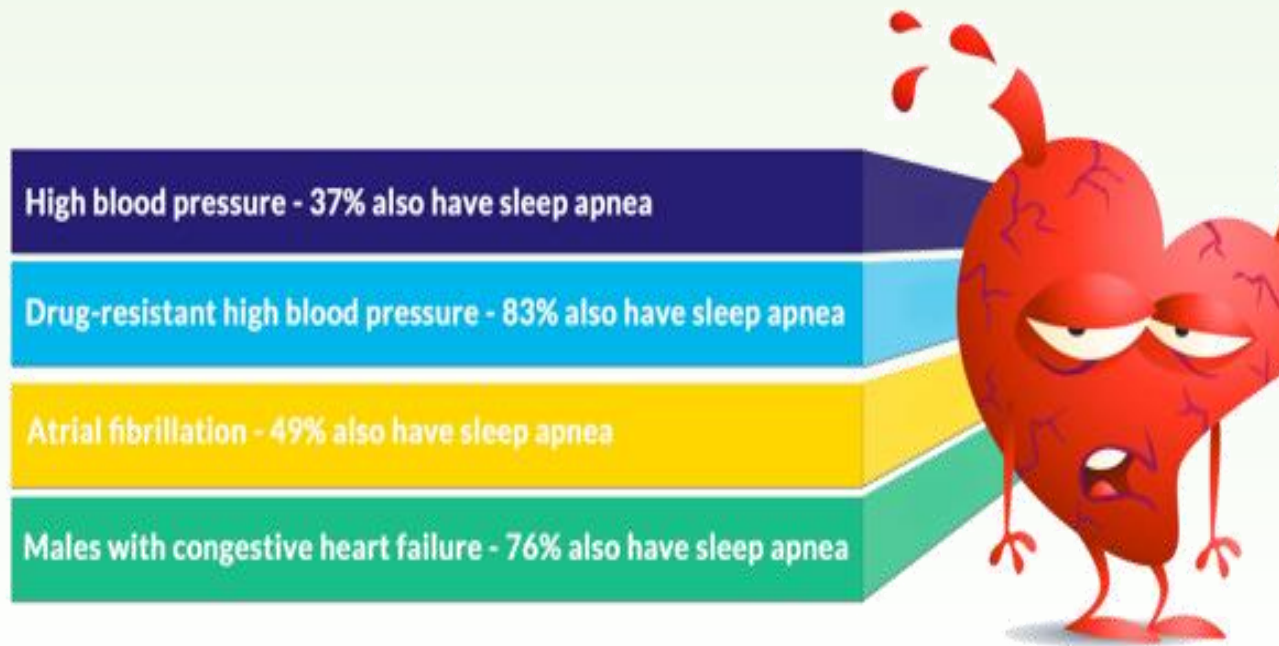
Obstructive Sleep Apnea

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



Throat muscles
intermittently relax
and block the airway
during apnea episode

Obstructive Sleep Apnea – Symptoms and Side Effects



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

Obstructive Sleep Apnea – Market Statistics

- USD 4.59 billion in 2016
- USD 6.70 Billion by 2021
- Forecasted CAGR of 7.8%



Target Population

- 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*

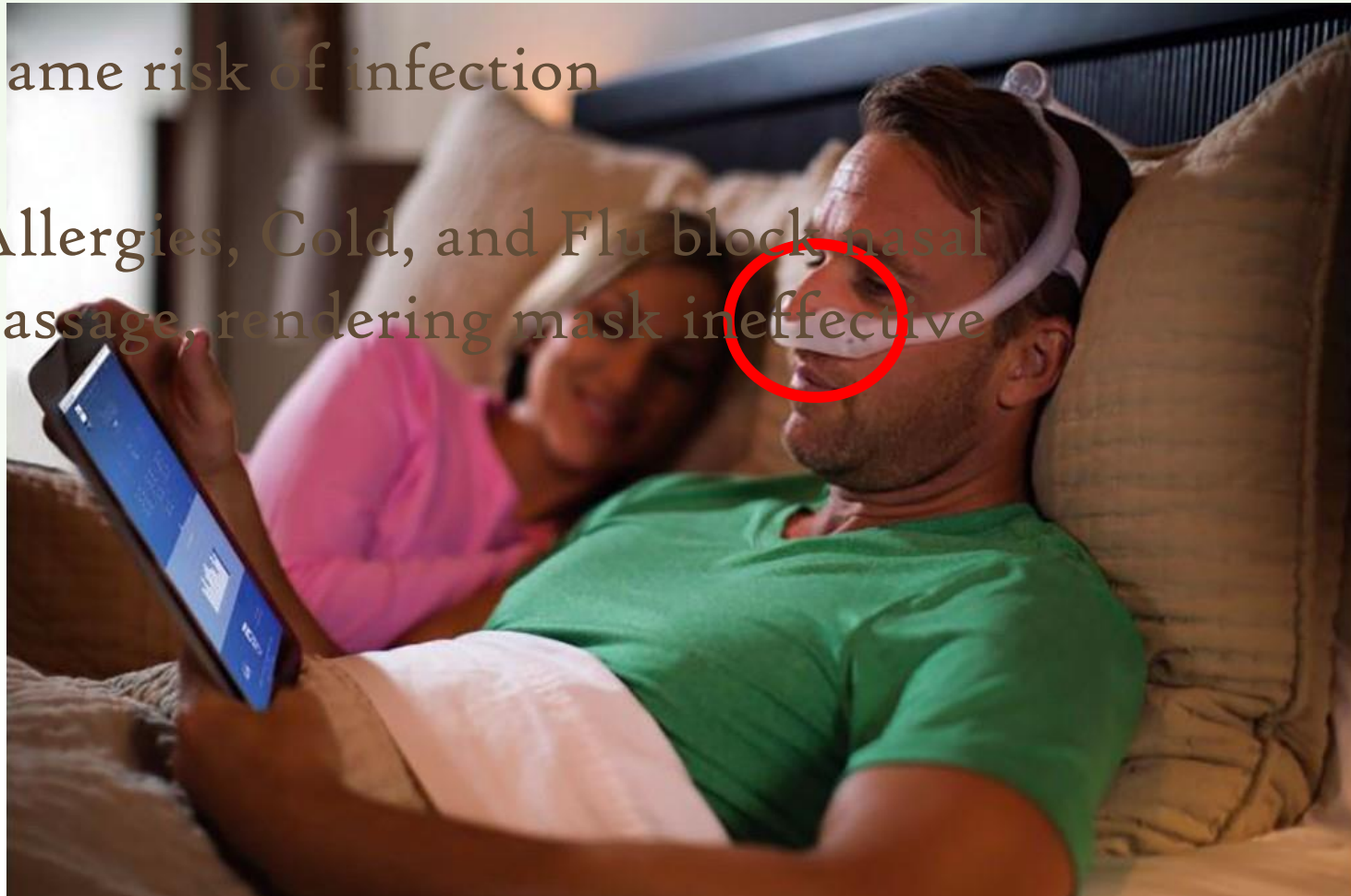
CPAP Machines



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

CPAP Machines – DreamWear Nasal Mask

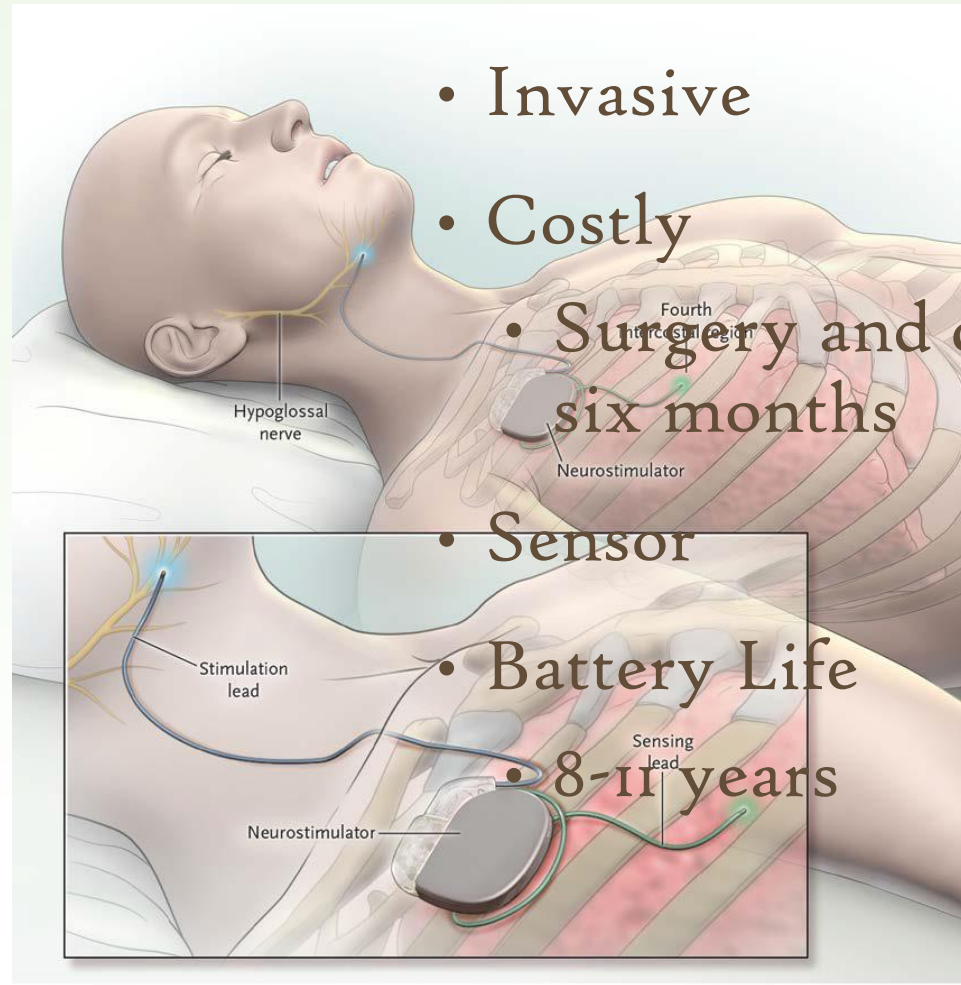
- Same risk of infection
- Allergies, Cold, and Flu block nasal passage, rendering mask ineffective



Surgical Procedures



Surgical Procedures – Inspire™ Implant



- Invasive

- Costly

- Surgery and check ups every six months

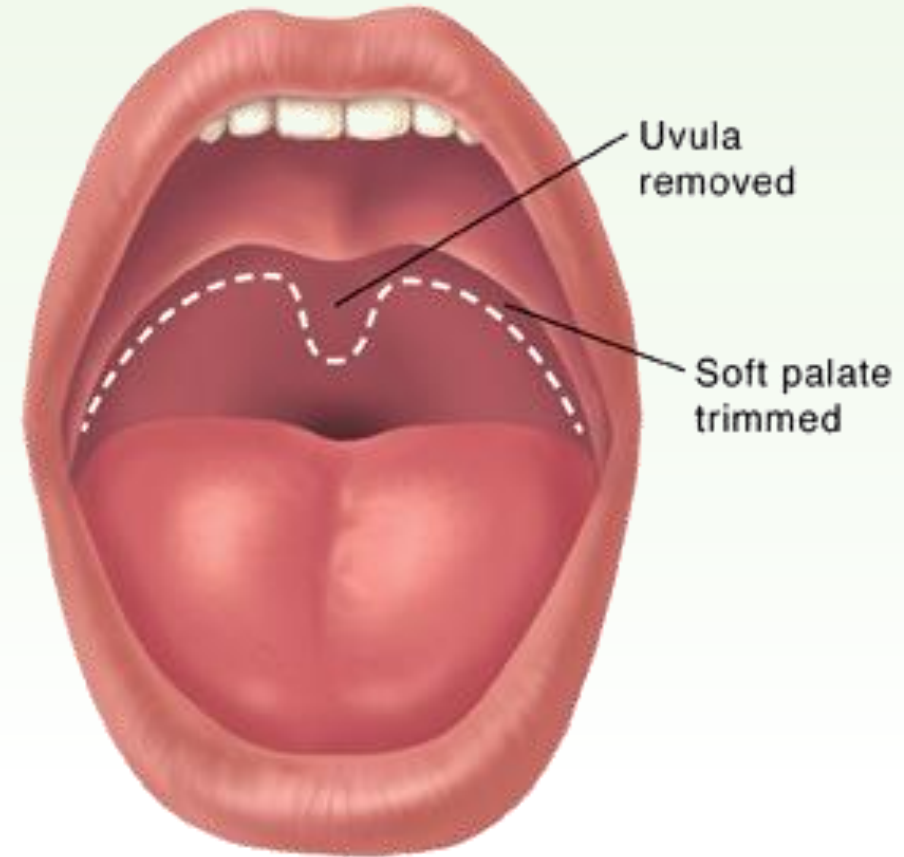
- Sensor

- Battery Life

- 8-11 years

Surgical Procedures - Resection

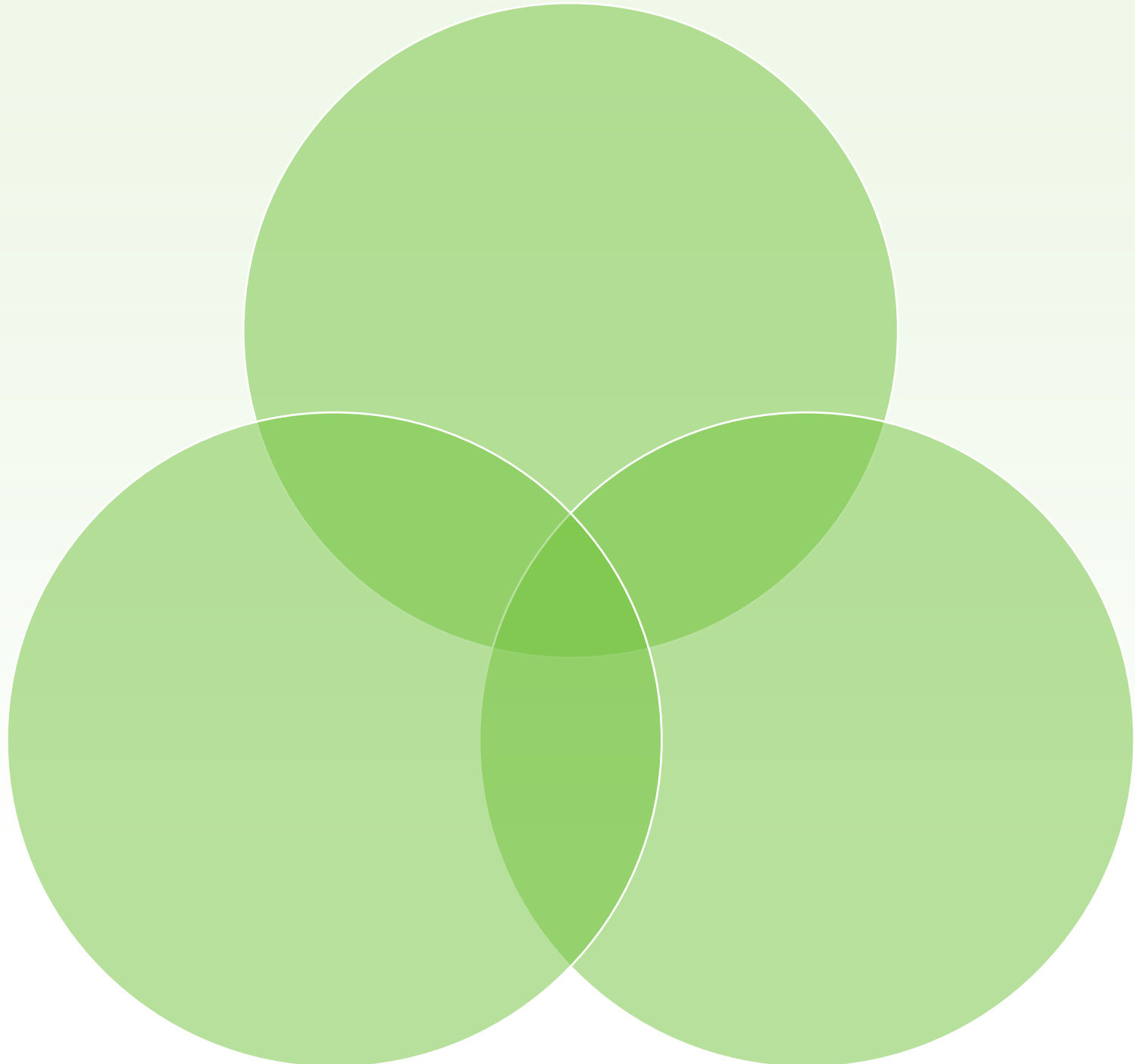
- Invasive
 - Requires incisions and anesthesia
- Expensive
- Not typically effective on its own

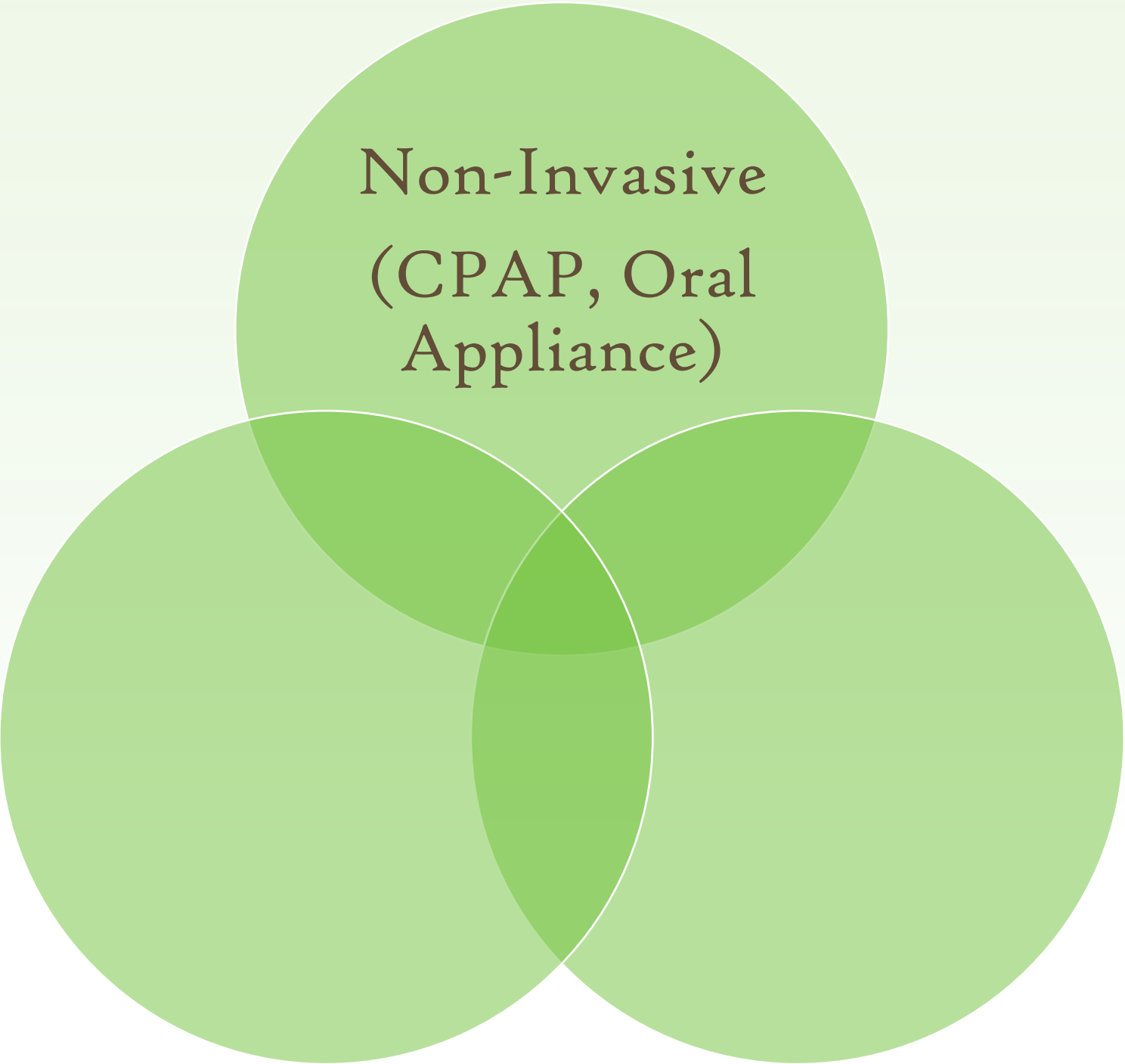


Oral Appliances

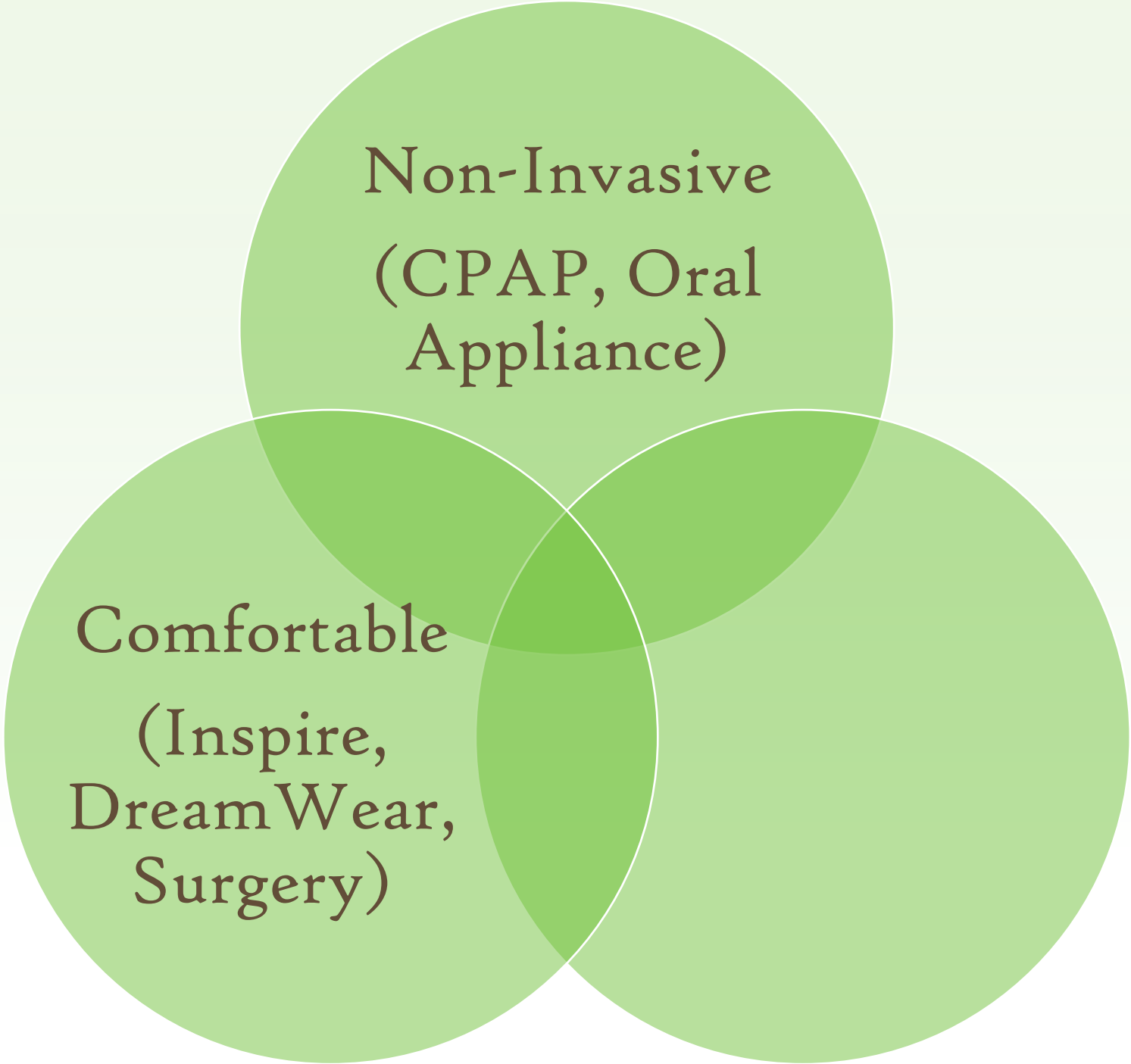
- Long term affect on dental structure
- Uncomfortable
 - Limited Motion
- No compliance data
- Impacts salivary function causing excess or deficit of saliva
- Lasts 3-5 Years





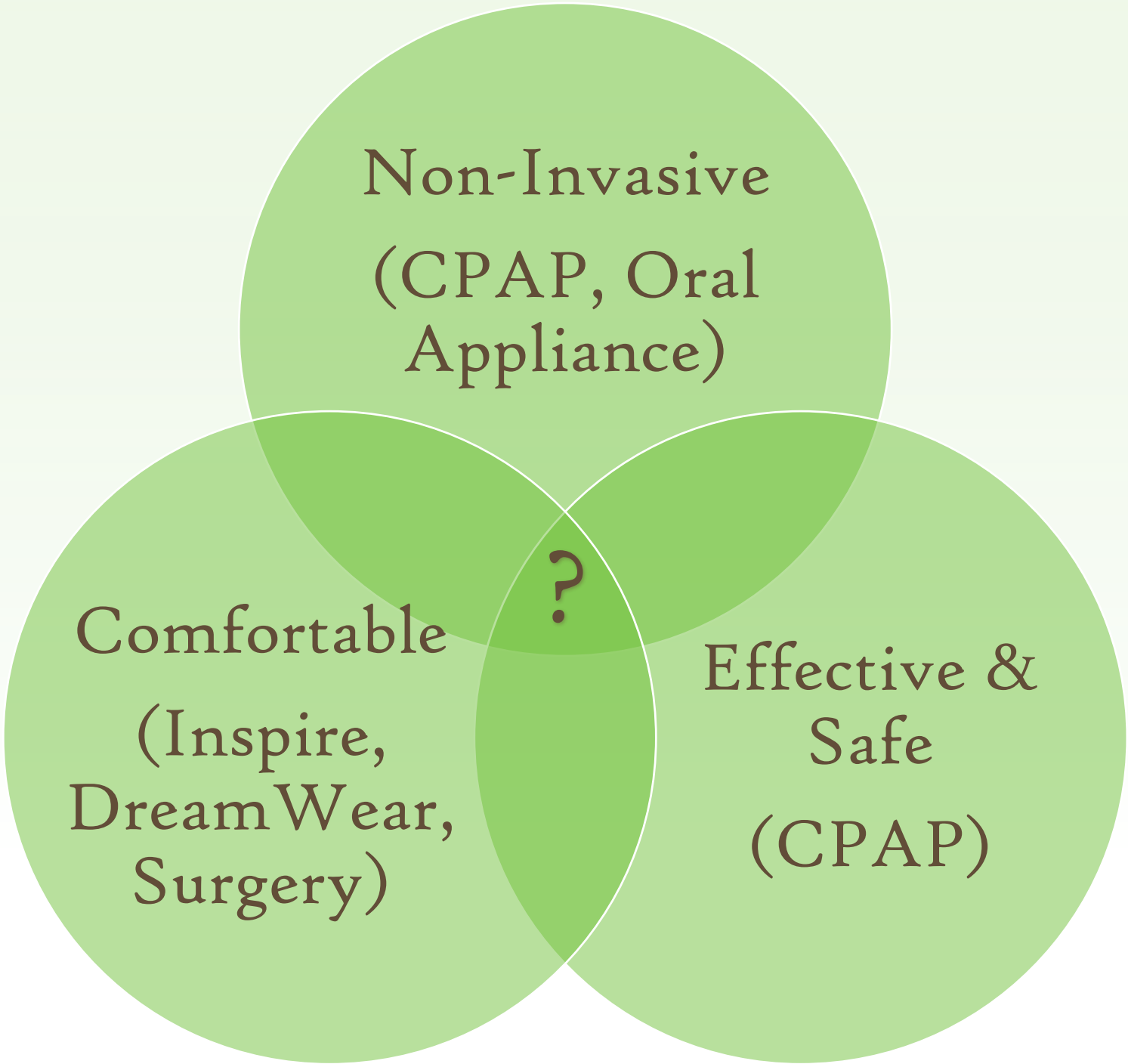


Non-Invasive
(CPAP, Oral
Appliance)



Non-Invasive
(CPAP, Oral
Appliance)

Comfortable
(Inspire,
DreamWear,
Surgery)



Non-Invasive
(CPAP, Oral
Appliance)

Comfortable
(Inspire,
DreamWear,
Surgery)

Effective &
Safe
(CPAP)

?

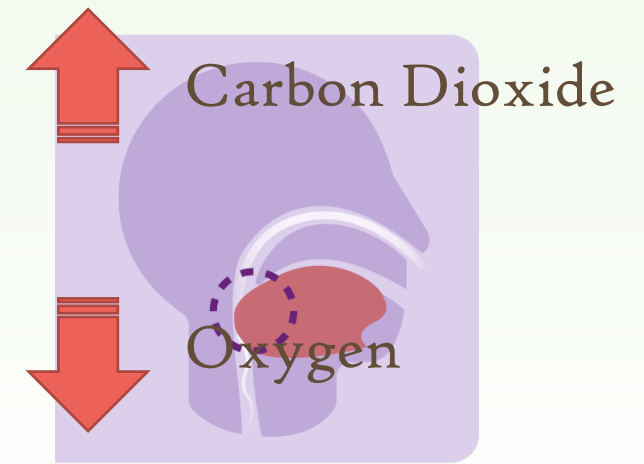
Our Design

- Electrically stimulating oral appliance

Device Overview



Non-obstructed airway

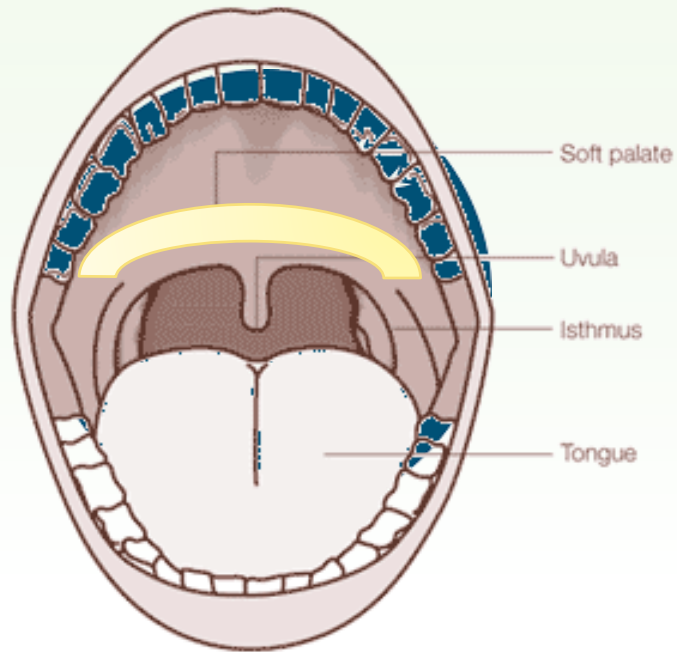


Obstructed airway

Our Design

- Electrically stimulating oral appliance

Device Overview

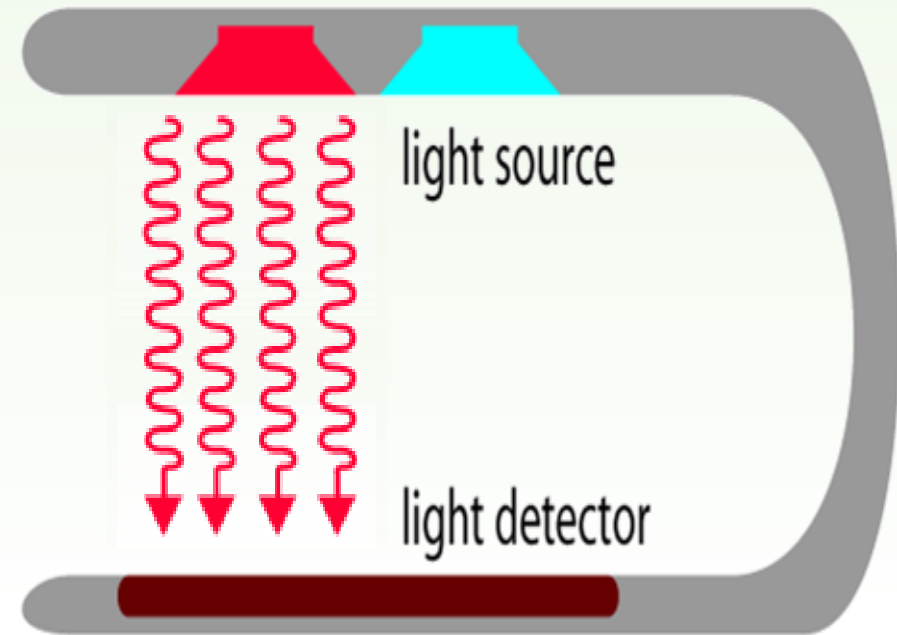


Warning
Low
oxygen levels

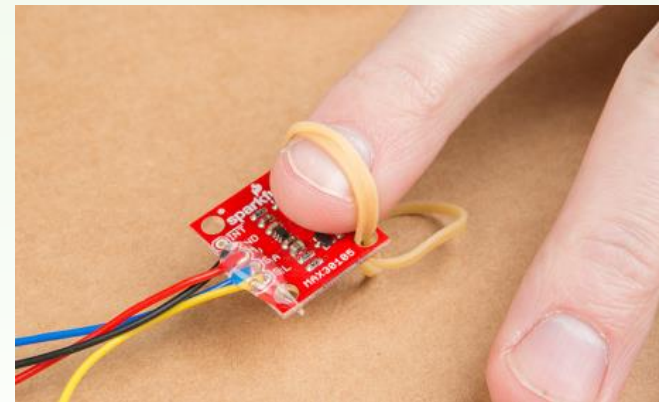


Pulse Oximetry Basics

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



Particle Sensor Specifications



MAX 30105 Pulse Ox and Particle Sensor
Arduino Set

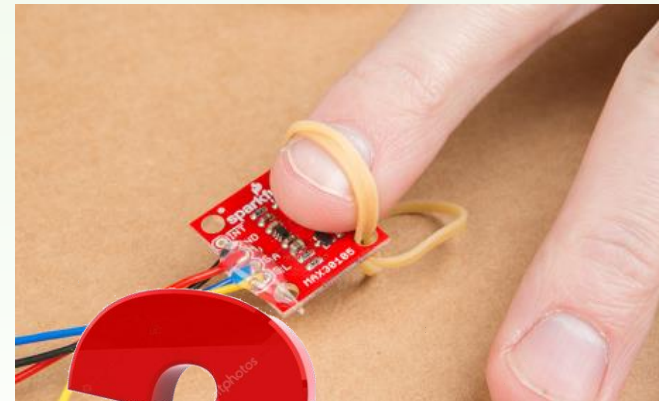
Particle Sensor Specifications

Finger

- Most commonly used
- Very sensitive

Buccal

- Lack of data
- Relatively New



Particle Sensor Specifications



- ✓ Order pulse oximeter set
- Construct pulse oximeter and test functionality

MAX 30105 Pulse Ox and Particle Sensor
Arduino Set

Particle Sensor Specifications



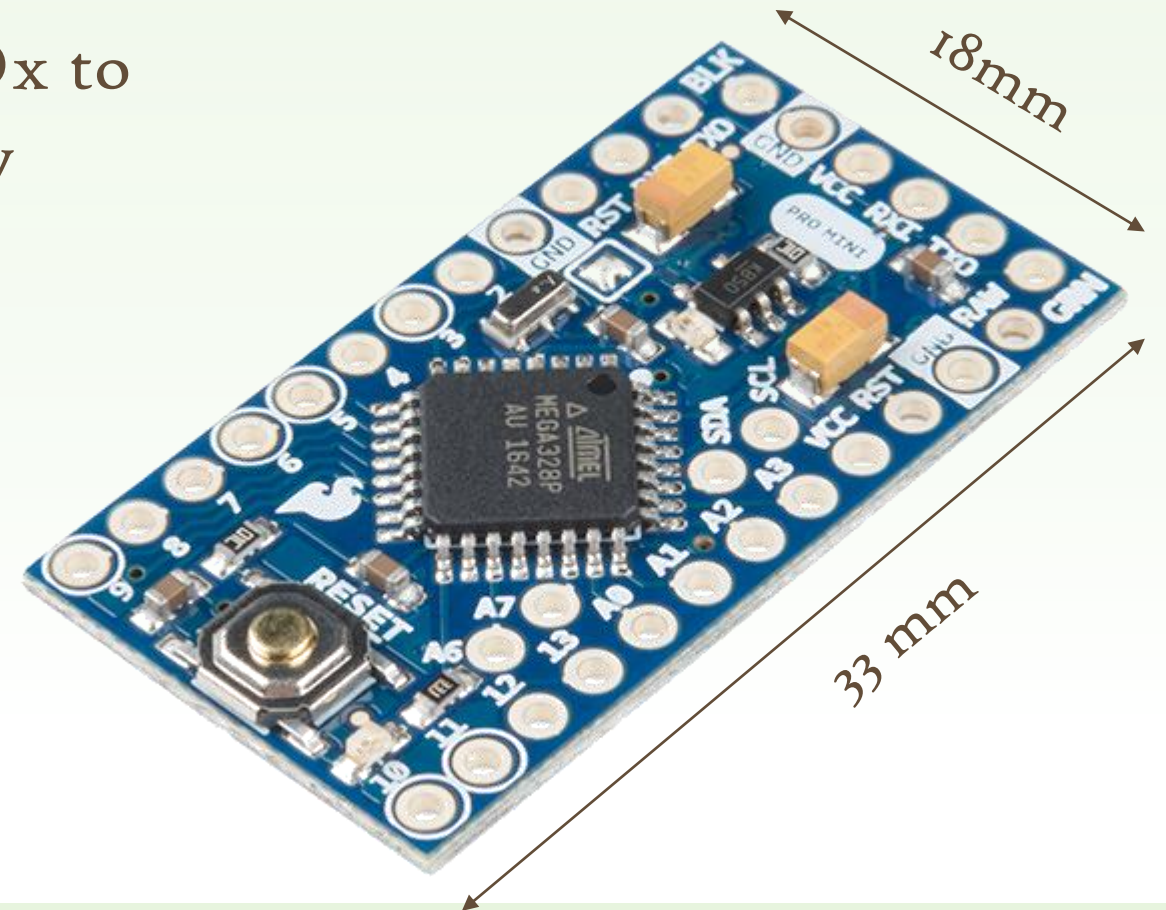
Still Needed:

- Value for Actuator response
Range: 91-94%

MAX 30105 Pulse Ox and Particle Sensor
Arduino Set

Micro- controller

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





Stimulatory
Region

Target Current:
3mA

Current Level
(mA)

Effect on Human Tissue

<1

Not perceived

1

Faint Tingle

5

Slight shock felt (not painful)

Above 10

Loss of muscular control

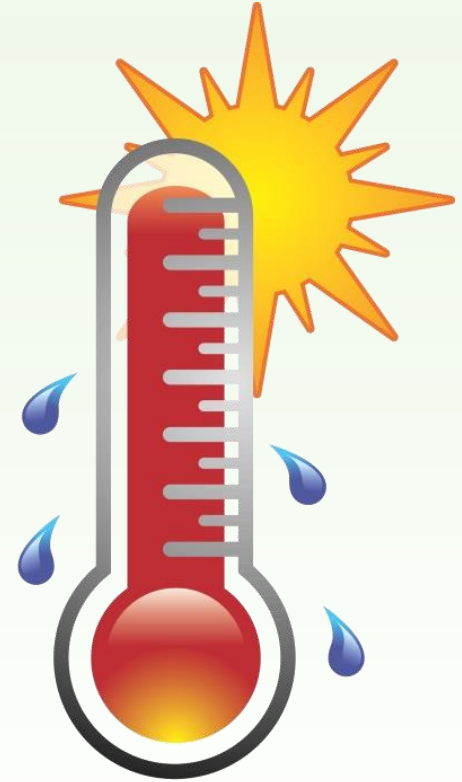
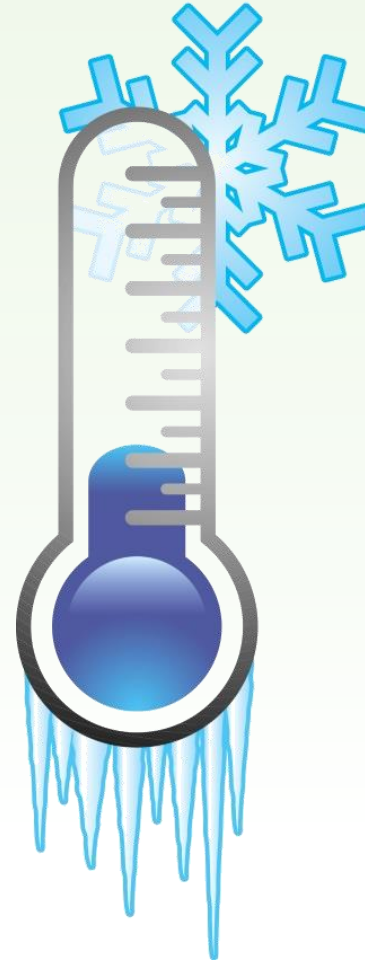
Requirements

Comfortable



Requirements

Comfortable



Requirements



Requirements

*Unrestricted
Motion*



Requirements

*Unrestricted
Motion*



ELEERA



Requirements

Non-Invasive



Requirements



Non-Invasive



Easy to...

- Maintain
- Calibrate
- Use every day

Technical Requirements – Casing and Supports

Material Requirements:

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



Acrylics



Polymers



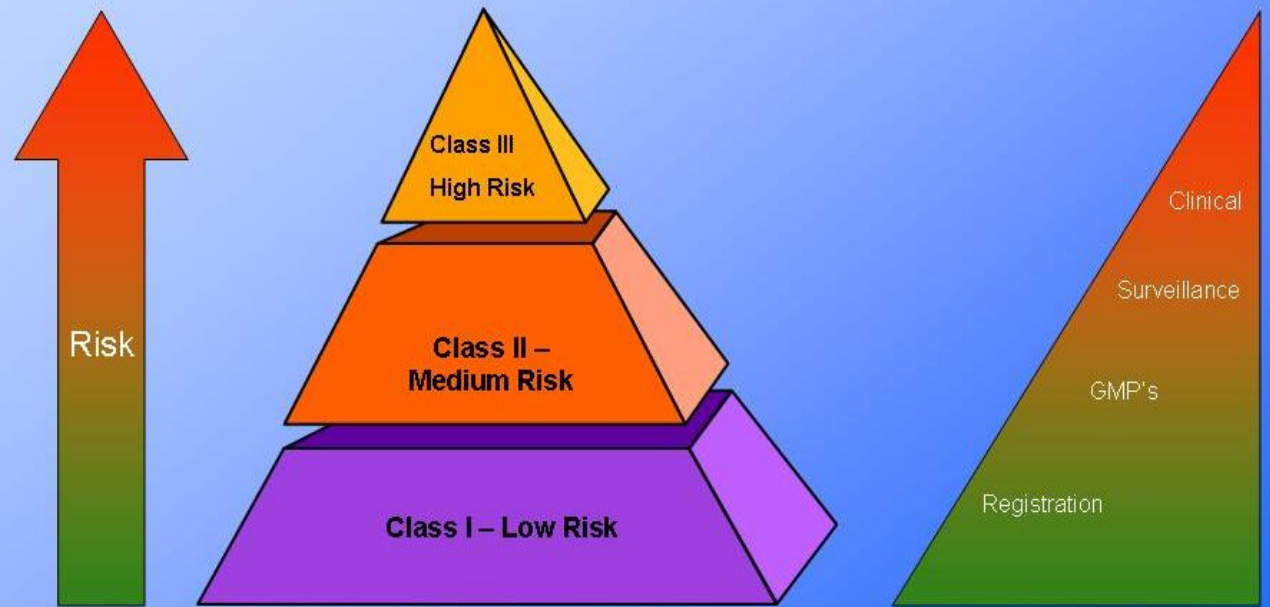
Laminates

FDA Classification

- Class I: General controls
- Class II: General controls with special controls
- Class III: General controls, Special Controls and premarket approval

Medical Device Classification – US FDA

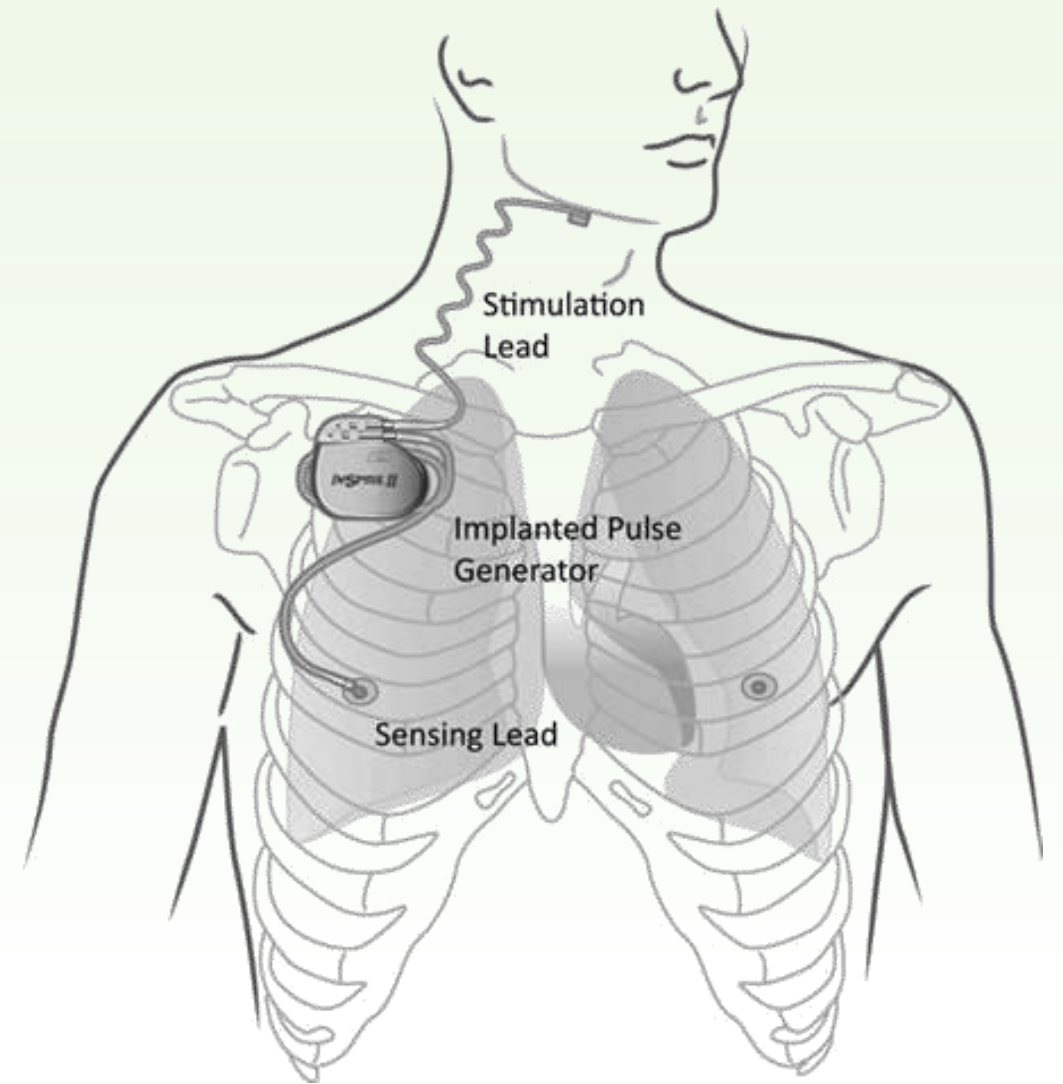
The higher the potential patient risk, then the greater level of investigation, testing, trials, controls to be established to permit device access to the US market.



[Home](#)

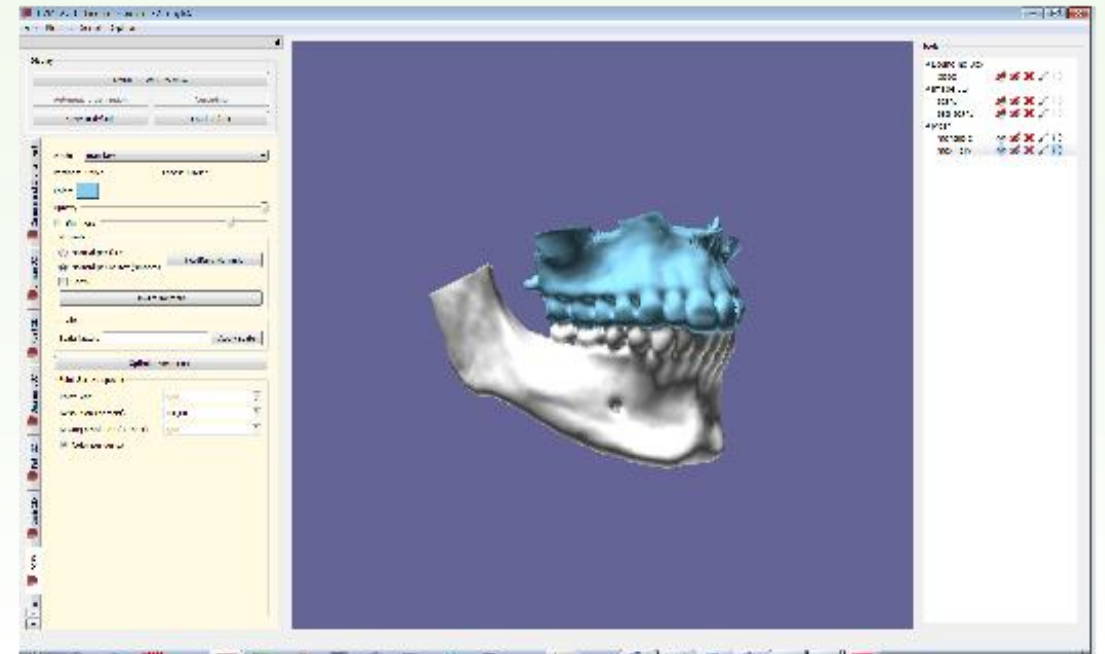
Predicate Device

- Inspire Implant
- Clinical trial: 126 patients
 - 68% experienced less apneas
 - 70% had a reduction in oxygen desaturation

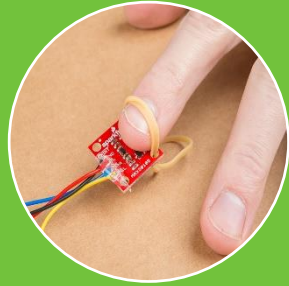


Simulation & Modeling

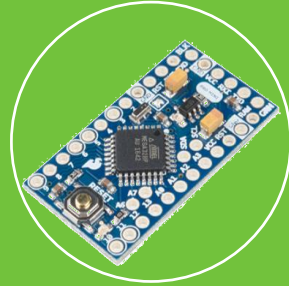
- Amira Software for 3D data visualization
- Intended use to interpret 3D scans of the mouth for use in printing our mouthpiece



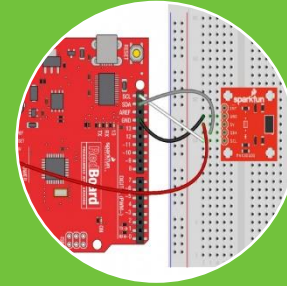
Experimental Test Plan



Pulse
Oximeter



Pulse Ox
+Arduino



Device



Budget and Bill of Materials

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



Timeline

December 11 – Final
Project Presentation

January 25 –
Modeling Complete

January 31 – Proof of
Concept Complete

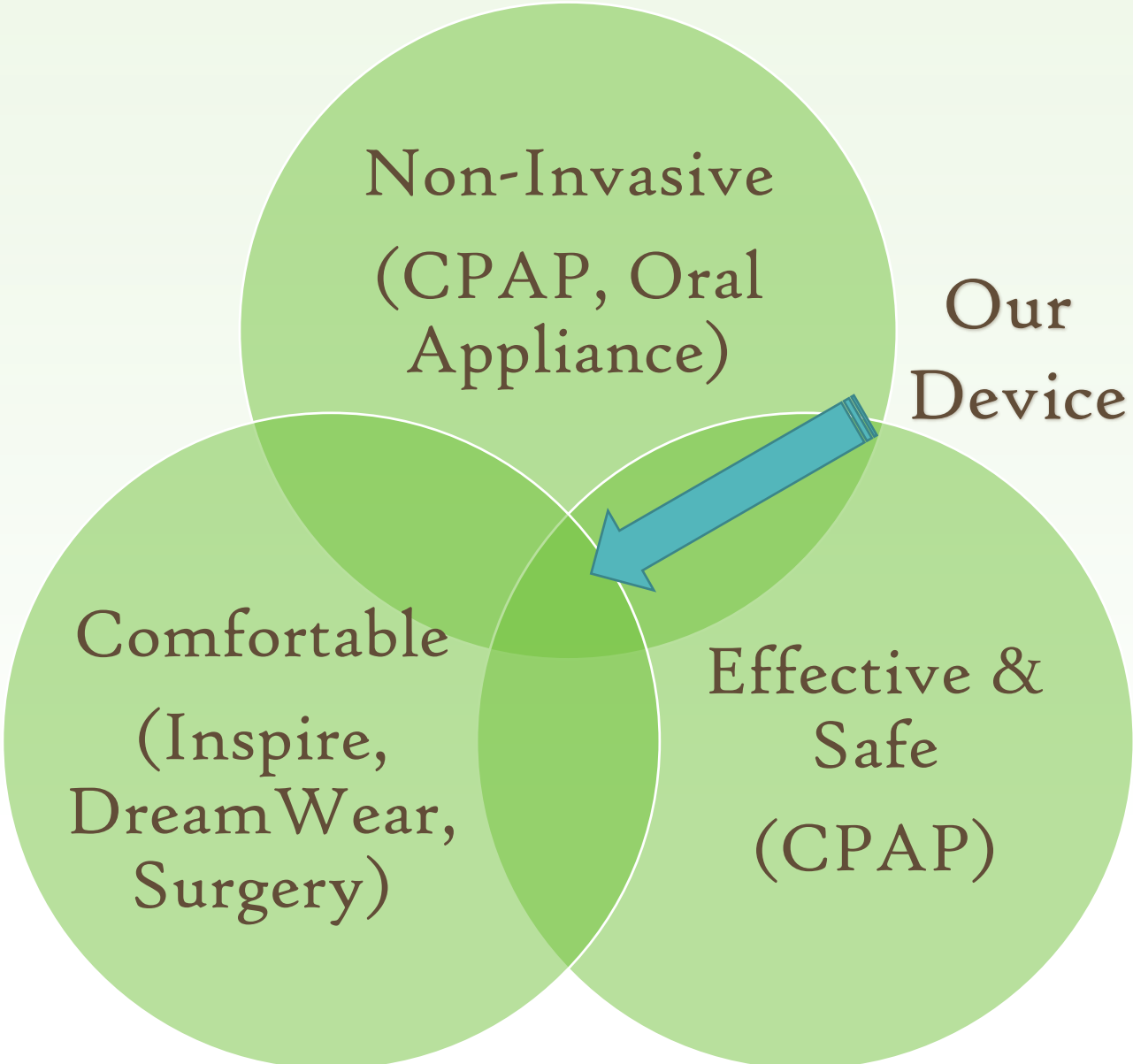
February 1 – April 1
Prototyping



Future Development and Plans – Current Issues

- Locating a biocompatible, conductive material for stimulatory section
- Potential addition of a microchip for compliance tracking
- Development of disinfection and maintenance protocol
- Future testing needed for calibration, tolerance, and efficacy data

Conclusion



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/.
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- “ProtoCentral AFE4490 Pulse Oximeter Breakout Board Kit.” *Protocentral*, www.protocentral.com/sensors/III2-protocentral-afe4490-pulse-oximeter-breakout-board-kit-642078949425.html.
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- “Inspire Medical Systems Ranks No. 2 on Cleveland Clinic's Top 10 Medical Innovations for 2018.” *Sleep Review*, 2 Nov. 2017, www.sleepreviewmag.com/2017/11/inspire-medical-systems-ranks-no-2-cleveland-clinics-top-10-medical-innovations-2018/.