

# TRAVELING WITH SLEEP APNEA

JERRITT SMITH



# TABLE OF CONTENTS

## MILESTONE 1



### Discovery

Technical Background .....	p. 1-5
Restrictions and Requirements .....	p. 6
Sleep Apnea Accidents .....	p. 7
Demographic Landmarking .....	p. 8
Contexts .....	p. 9
Market Landscape .....	p. 10-15
User Research .....	p. 16-19
User Interview #1 .....	p. 20-21
Sleep Apnea and Down Syndrome .....	p. 22
Stakeholder Mapping.....	p. 23

## MILESTONE 2



### Definition

Market Synthesis .....	p. 24 -25
DIY Solutions .....	p. 26-28
Quantitative Data .....	p. 29-30
Interview Questions .....	p. 31
Sleep Medicine Interview .....	p. 32-33
User Interviews .....	p. 34-38
Personas .....	p. 39
Experience Diagram .....	p. 40
Immersion .....	p. 41-43
Research Synthesis .....	p. 44-45

# TABLE OF CONTENTS

## MILESTONE 3



### Develop

Adherence Research .....	p. 46-49
Product Analysis .....	p. 50-51
Brainstorming .....	p. 52-61
Sketch Model 1 .....	p. 62
Sketch Model 2 .....	p. 63
Sketch Model 3 .....	p. 64
Sketch Model 4 .....	p. 65
Downselected Concepts .....	p. 66-72
Concept Screening .....	p. 73
Concept Proposals .....	p. 74

### Project Plan

Gantt Chart .....	p. 106
Works Cited .....	p. 107-108

## MILESTONE 4



### Deliver

Product Inspiration .....	p. 75
Evaluative Research.....	p. 76-80
Impact Vs. Effort Matrix .....	p. 81-82
Concept Refinement .....	p. 83-85
Peer Feedback .....	p. 86
Final Concept Sketch .....	p. 87
Concept Benchmarking .....	p. 88-89
Hero Shot Renders .....	p. 90-91
Physical Mockup .....	p. 92
Product Features .....	p. 93
Device Interface .....	p. 94-95
User Flow .....	p. 96-97
Sunrise Simulation Alarm Cock .....	p. 98
Daily User Survey .....	p. 99-100
Mobile App .....	p. 101
Hero Shot .....	p. 102
Moving Forward .....	p. 103-105

# MILESTONE 1

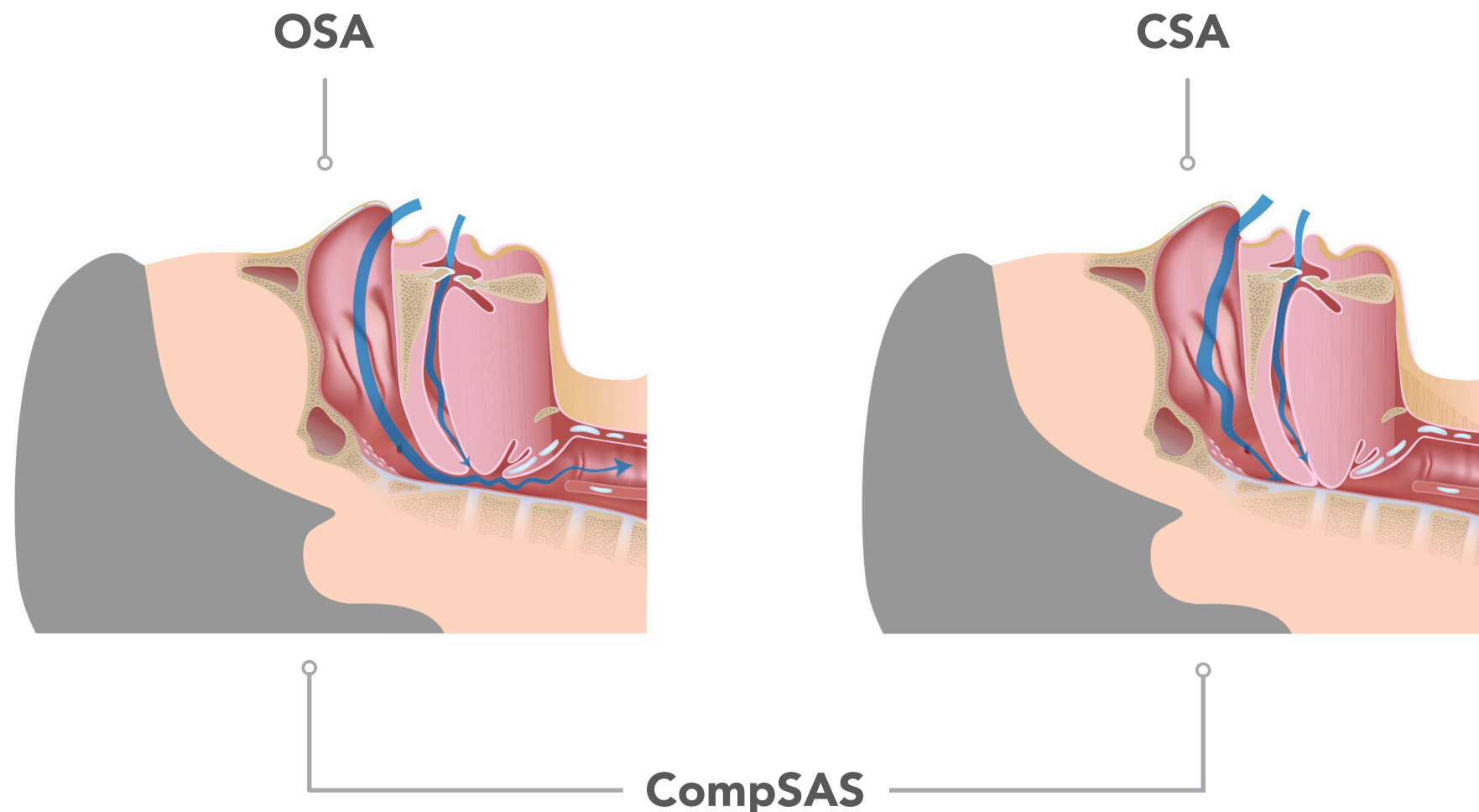


# TECHNICAL BACKGROUND

**Obstructive Sleep Apnea (OSA)** - The most common form of sleep apnea where the tongue and throat muscles relax and collapse, closing the oxygen pathway.

**Central Sleep Apnea (CSA)** - Brain doesn't send signals to muscles that control breathing. CSA is far less common than OSA. Cannot be treated with mandibular advancement devices

**Complex Sleep Apnea Syndrome (CompSAS)** - Both OSA and CSA.



Diagnosed by a **pneumologist** or **pulmonologist** via nocturnal polysomnography examination or home tests. Results are measured by the **Apnea Hypopnea Index (AHI)**, and **oxygen desaturation levels**.

**Severity by apnea events/hour**

Mild: 5-14

Moderate: 15-30

Severe: 30+

# TECHNICAL BACKGROUND

## Contributing factors:

- Excess weight
- Neck circumference
- Being male
- Hypertension
- Diabetes
- Hormones
- Parkinson's
- Age

## Symptoms:

- Loud snoring
- Breathing cessation
- Morning headaches
- Insomnia
- Irritability
- Fatigue
- Depression

## Risks:

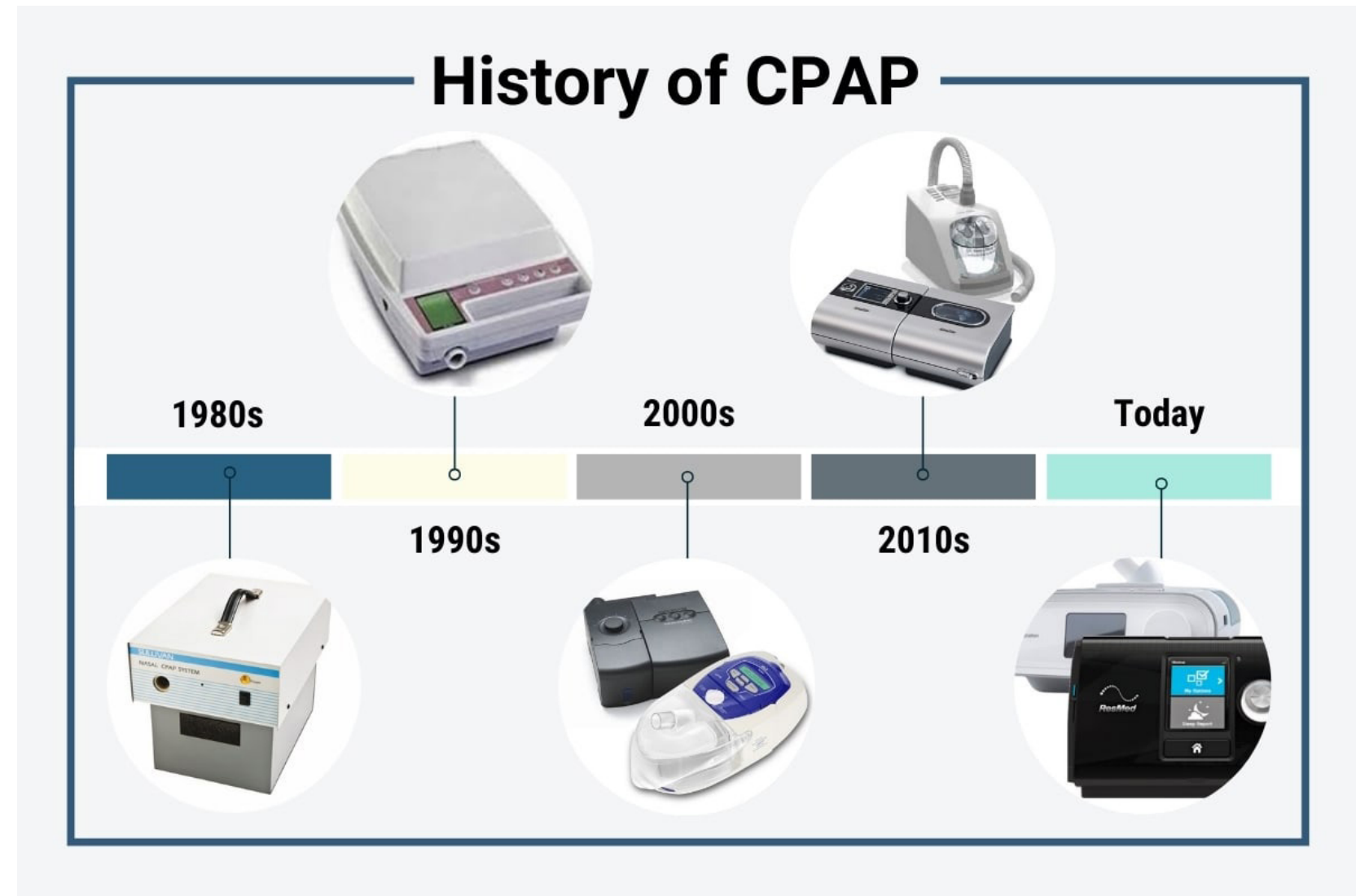
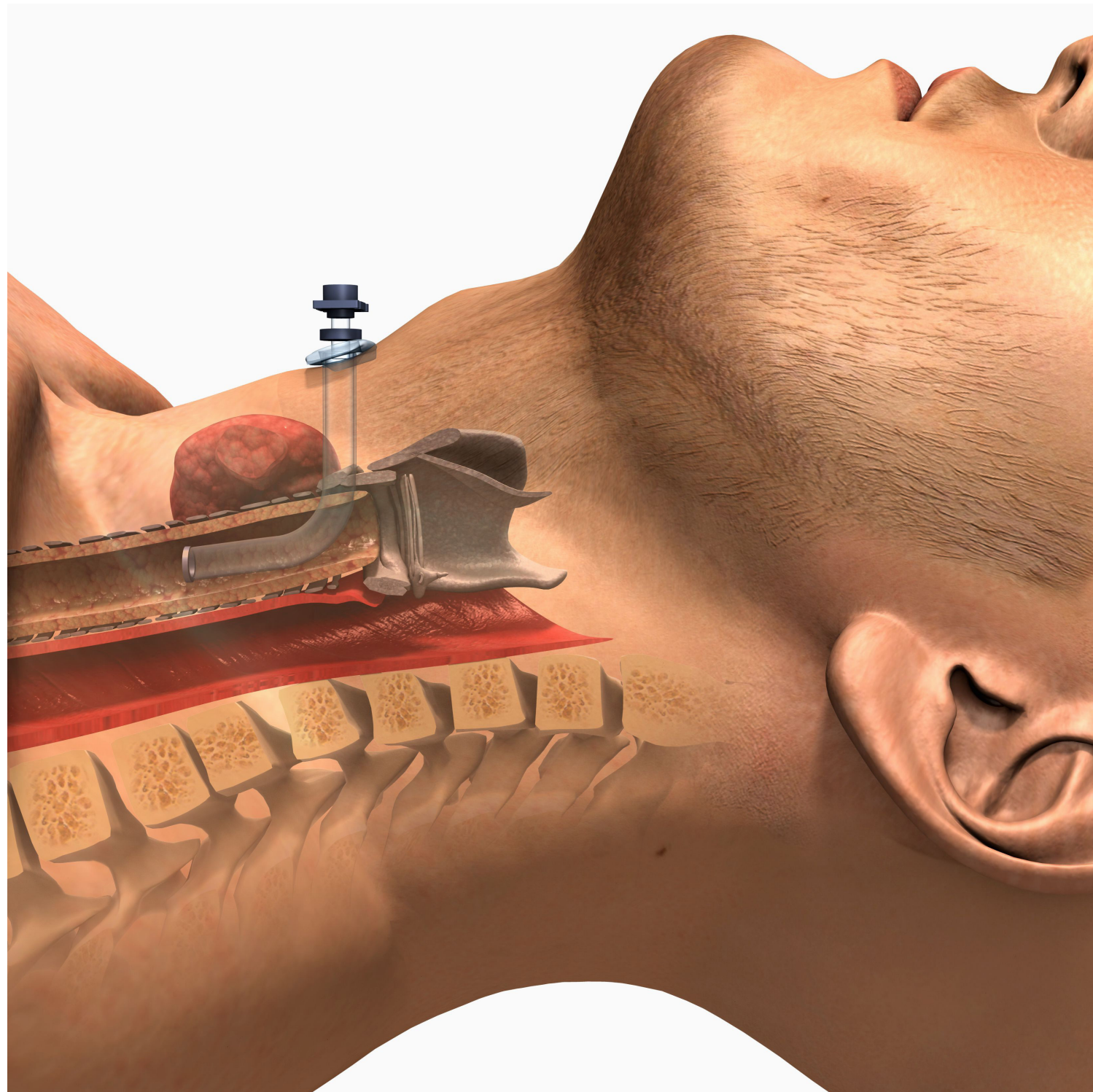
Sleep apnea increases your risk of **hypertension**. Obstructive sleep apnea can also increase your risk of recurrent **heart attack, stroke** and abnormal heartbeats, such as **atrial fibrillation**.

Typically, it is a combination of pre-existing health conditions which surface sleep apnea for the patient. Sleep apnea is difficult to detect and is often mistaken for depression due to a lack of sufficient sleep. In many cases, the sleep apnea patient's bed partner or family member complains about loud snoring or tells them they sometimes stop breathing while sleeping.



# TECHNICAL BACKGROUND

CPAP was invented in the 1980's  
Prior to that, people would get a tracheostomy



Over the years, CPAP machines have gotten smaller with functional variations, such as APAP and BPAP

Modern devices have a greater data capacity and a plethora of mask styles and options

# TECHNICAL BACKGROUND

## Treatment of sleep apnea:

### Continuous positive airway pressure - CPAP

Fixed pressure on inhale and exhale. Pressure is adjustable based on severity of diagnosis and experience of patient.

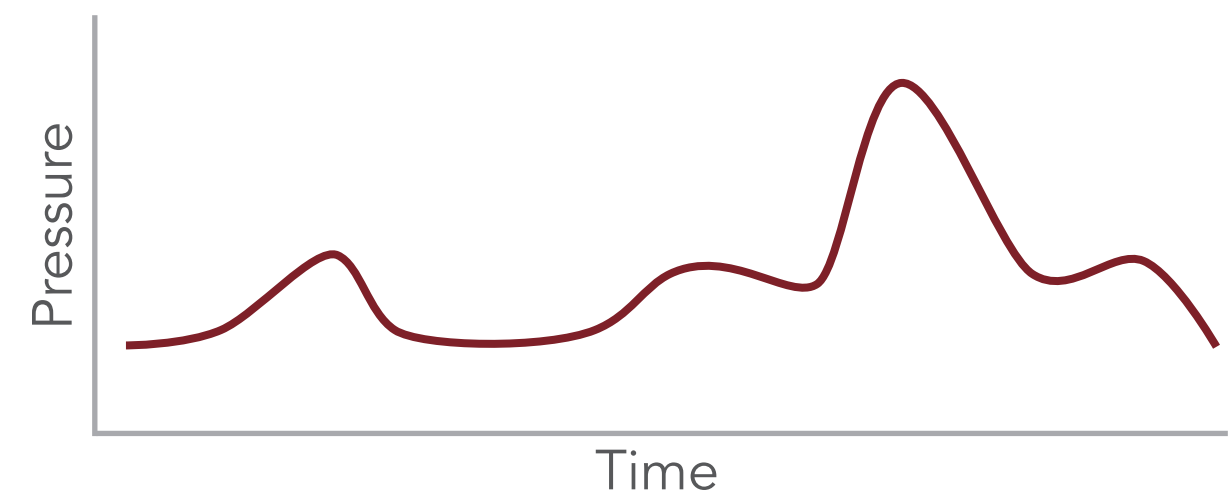
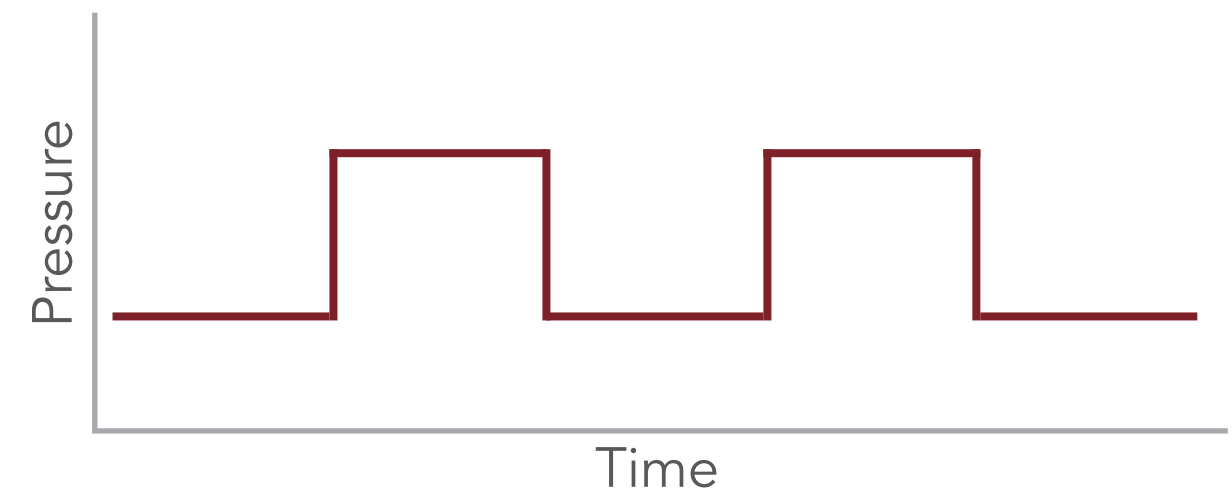
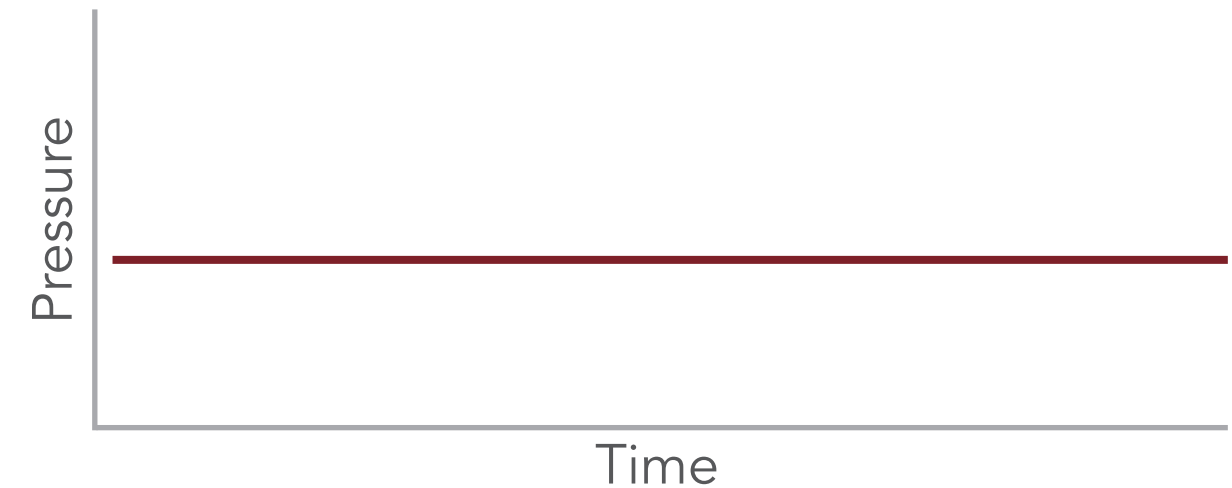
### Bi-level positive airway pressure - BPAP / VPAP

Two different pressures for inhale and exhale. The exhale pressure is weaker than inhale to prevent aerophagia, or accidentally swallowing air.

### Automatic positive airway pressure - APAP

Continually adjusts expiratory pressure to an optimal level for specific patient needs

**Typical pressure range:** 4-20 cmH<sub>2</sub>O  
cmH<sub>2</sub>O = centimeters of water column





# TECHNICAL BACKGROUND

## Treatment of sleep apnea:

### Mandibular advancement device (MAD)

Also known as oral appliances, shift the user's jaw forward, mitigating partial obstructions. These are most common treatments for snoring, but have proven effective in treating sleep apnea for some users.

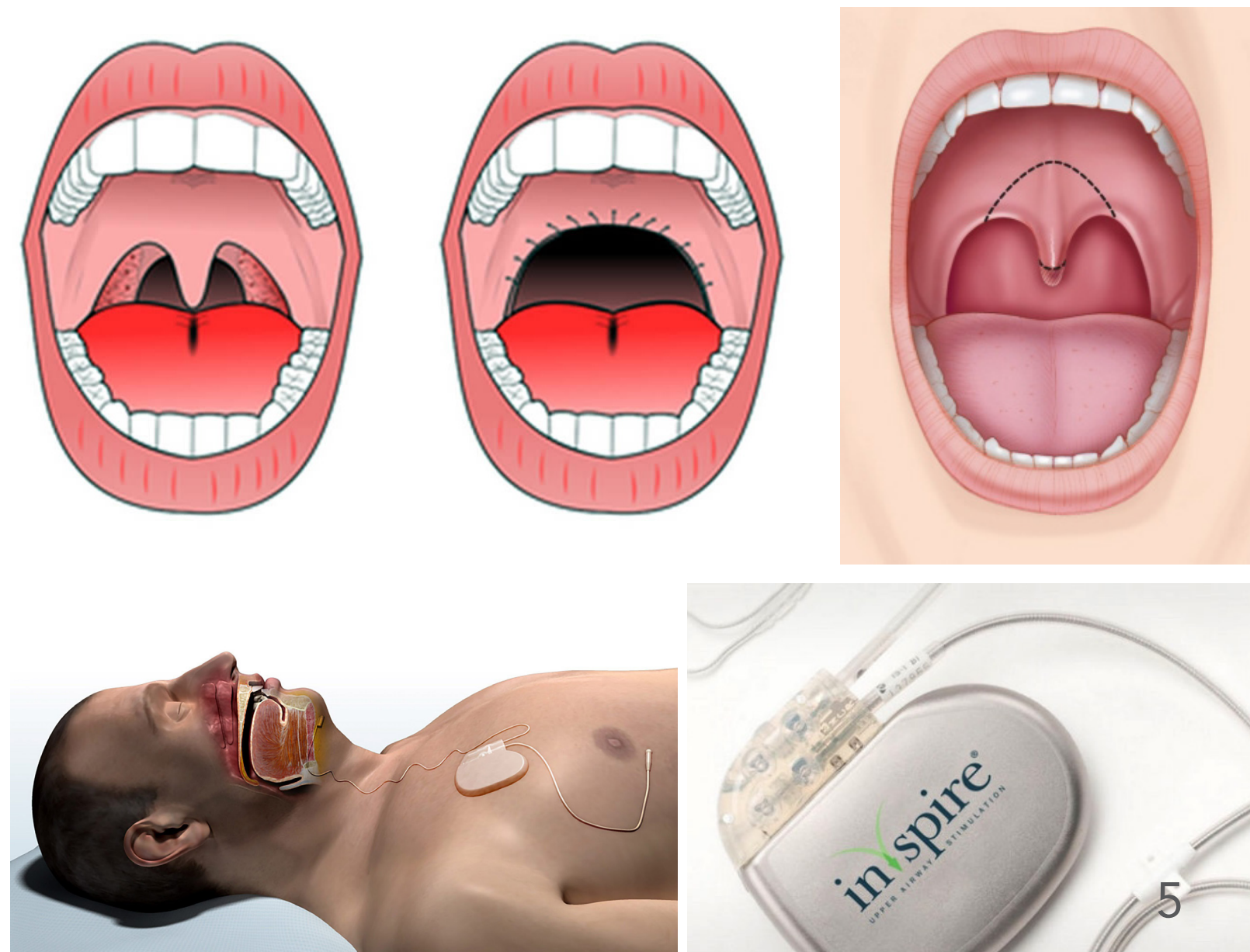
### Stimulation Therapy for Apnea Reduction (STAR)

Requires a procedure where a small impulse generator is implanted beneath the clavicle and a tunneled breathing sensing lead is placed between the external and intercostal muscles, and a tunneled stimulation lead attached to the branch of the hypoglossal nerve that produces tongue protrusion.

When the sensing lead detects inspiration, the impulse generator sends a signal via the stimulation lead to the hypoglossal nerve, resulting in forward displacement of the tongue. The impulse generator is similar in size and appearance to a cardiac pacemaker. Inspire is the only FDA approved STAR device today.

### Uvulopalatopharyngoplasty (UPPP)

This is a surgery which consists of tissue removal or rearrangement at the uvula, palate and throat walls, increasing the airway size and decreases tissue collapse.



# RESTRICTIONS AND REQUIREMENTS

## FAA Guidelines

**1 year of data** to show compliance for the FAA medical certificate and at **least 6 hours** clocked on the machine **85% of the time**.

As of 2015, there are **4,917** FAA certificated pilots being treated for sleep apnea flying with a special issuance medical certificate.

The National Transportation Safety Board investigated accidents in all modes of passenger transportation involving operators with sleep disorders and believes OSA to be a significant safety risk. The NTSB database lists **34 accidents – 32 of which were fatal** – where sleep apnea was mentioned in the pilot's medical history, although sleep apnea was not listed as "contributory" in those accidents.



## DOT Guidelines

To maintain compliance: Drivers must use a CPAP machine at **least 4 hours** per night, **70% of the time**. Drivers must have at least **90 days of data** to prove performance.

Stoohs, Guilleminault, Itoi and Dement (1994) conducted a study of 90 commercial long haul truck drivers and found that those with sleep disordered breathing had a **two-fold higher accident rate per mile** than drivers without sleep disordered breathing.

# SLEEP APNEA ACCIDENTS



Train conductor fell asleep on his passenger train and crashed, resulting in 4 dead and 63 injured

Truck driver with sleep apnea crashed a coach bus in Virginia. It was found he wasn't using his CPAP machine



Pilot overflow their destination because they fell asleep while flying

# DEMOGRAPHIC LANDMARKING

## New England Journal of Medicine

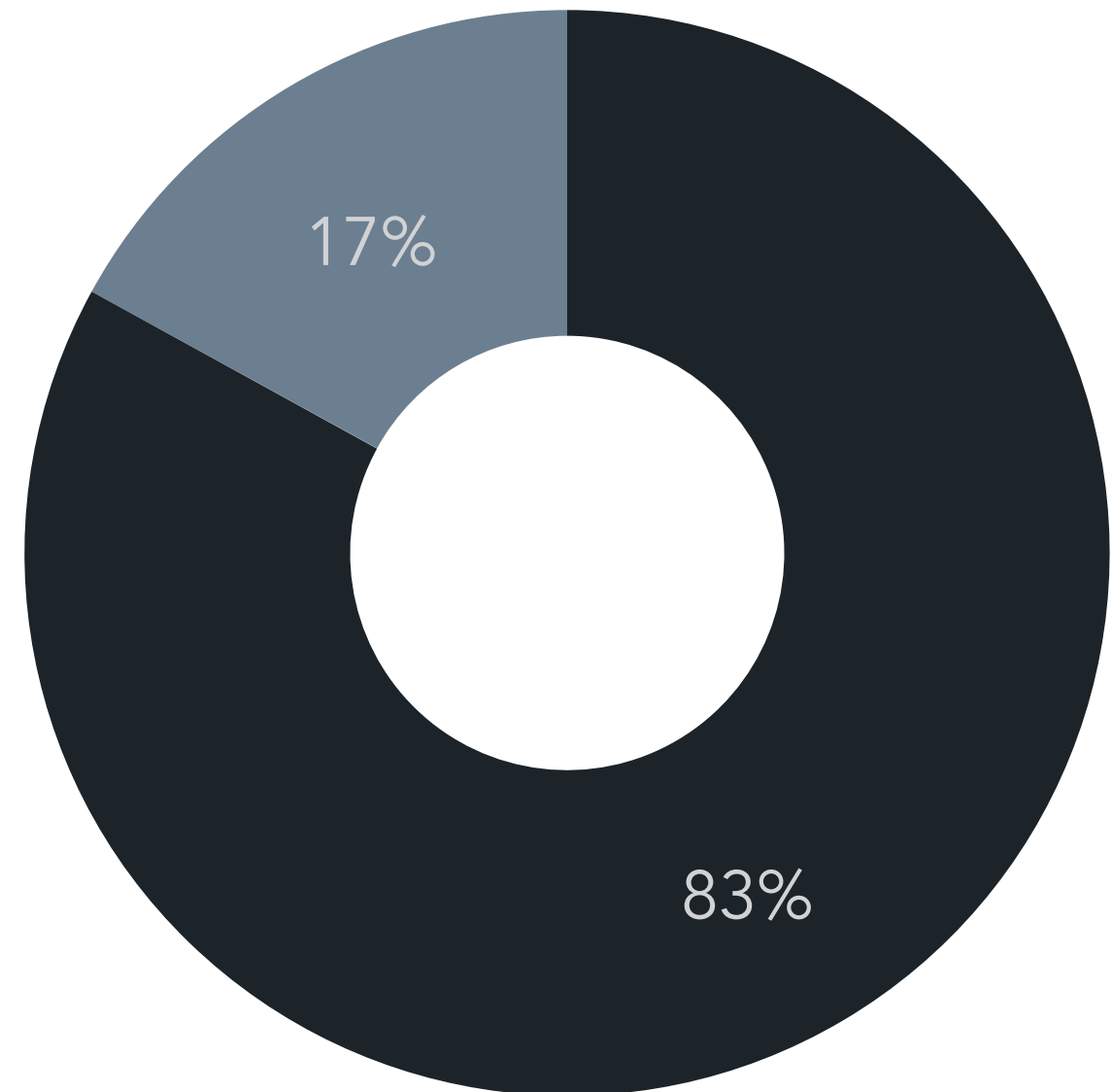
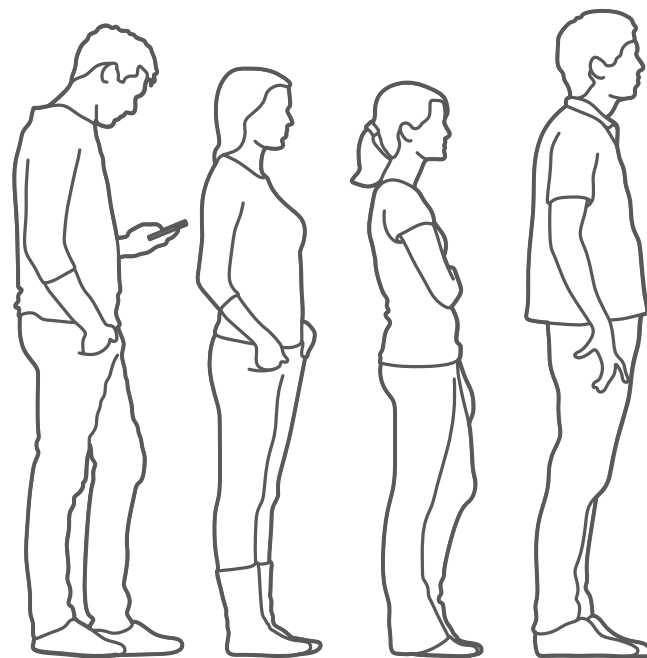
**24 Million** Americans don't know they have OSA

**4%** of the population **ages 30 and 60** years has sleep apnea

These percentages rise to **7% in adults over age 60**

## American Journal of Epidemiology

**17% of men and 9% of women ages 50-70** have OSA



In a study on sleep apnea and travel, of the 326 participants, roughly **83% were men, 17% were women**, and the mean age was **59 years old**

# CONTEXTS

Home



Airplane



Hotel



Airport



Transit



# MARKET LANDSCAPE

## Mandibular Advancement Devices (MAD)



**ZQuiet**

- Far more affordable than CPAP
- Can shift teeth from improper fit or prolonged use
- Not intended for use with CSA or moderate to severe cases of OSA



**SnoreRX**

- Adjustable for a variety of users
- Improves sleep apnea symptoms but doesn't eliminate them
- Doesn't hold sizing setting well



**MyTAP PAP**

- Enables use of CPAP without needing the headgear
- Limited mouth to nose adjustability
- Not effective for mouth breathers or chronic congestion

# MARKET LANDSCAPE

## Home CPAP Devices

### Philips Respironics Dreamstation 2



- Compact
- Better UX than previous model
- Design doesn't look like a CPAP machine
- Smooth startup



- Water reservoir is clunky and feels fragile
- Bluetooth connection issues
- Difficult to clean

### ResMed S10 AirSense Autoset



- Cool-down feature dries tubing
- Automatic start / stop
- Very quiet
- Automatic pressure adjustment

- Water reservoir is difficult to fill
- Tubing connects to the back of the machine
- Water reservoir leaks
- Bulky

# MARKET LANDSCAPE

## Travel CPAP Devices

### Z2 Auto Travel



- Small and portable
- Low power consumption
- Auto-start feature



- Loud and whistles
- No humidification or heat
- Settings are difficult to dial in
- Doesn't work as well when using external battery vs wall outlet

### ResMed AirMini Autoset



- Fits well in bag or backpack
- Disposable humidifier adapters
- Size is more discrete than regular CPAP machines

- Tube connection makes noise
- Not compatible with all masks
- Not enough room for accessories in provided travel bag

### Respironics DreamStation Go



- Usable with or without humidifier
- USB charging port
- Touch screen

- No auto-start
- Narrow tube is more noisy
- Attachable battery only lasts one night



# MARKET LANDSCAPE

## Product Spec Comparison

### Immersion Model



Size

6.48"x3.3"x2.02"

5.48"x3.3"x2.1"

5.9"x5.9"x2.3"

10"x4.6"x5.9"

10.11"x 6.24"x 3.34"

10.11"x 6.24"x 3.34"

Weight

0.65 lbs

0.66 lbs

1.86 lbs

2.75 lbs

2.94 lbs

0.9 lbs

Sound Level

26 dBA

30 dBA

27 dBA

26.6 dBA

27 dBA

31.4 dBA

Data Capacity

1 month

Cloud

>1 year

Cloud

<6 months

<6 months

Internal Battery

Yes

No

No

Yes

Yes

No

# MARKET LANDSCAPE

## Nasal Pillows



AirFit P30i

## Nasal Cradle



AirFit N30

## Full Face



AirFit F10

## Hybrid



AirFit F30i

## Oral



Fisher & Paykel

Multiple sleep positions / tossing

Forehead sensitivity

Nose sensitivity

Facial hair

Mouth breather / chronic congestion

Forehead / nose sensitivity

Nose and mouth breathing

- Small profile
- Least invasive
- Loud

- Small profile
- Easy to adjust
- Best compliance

- Good air seal
- Less mobility
- Hard on nose

- Easy fitting
- Good compliance
- Air leaks

- Good air seal
- Limited adjustability
- Hard on lips

# MARKET LANDSCAPE

## Alternative sleep apnea solutions



### Expiratory Positive Air Pressure (EPAP)

Creates back pressure on exhale to keep airway open enough for the next breath



### Myofunctional Therapy Water Bottle

Strengthens tongue muscles



### Chin Strap

For mouth breathers - keeps mouth shut while sleeping



### Inspire Tongue Stimulator

Stimulates tongue muscles. FDA Approved



### Anti-Back Sleeping Pillow

Prevents the user from sleeping on their back



### Wedge Pillow

Keeps upper body at an incline to prevent airways from closing



### Contour Pillow

Creates space for the CPAP mask on pillow

# USER RESEARCH

## Probing for insights on Reddit and Facebook

Learning what users **say** and **think**

### Asking broad, open ended questions:

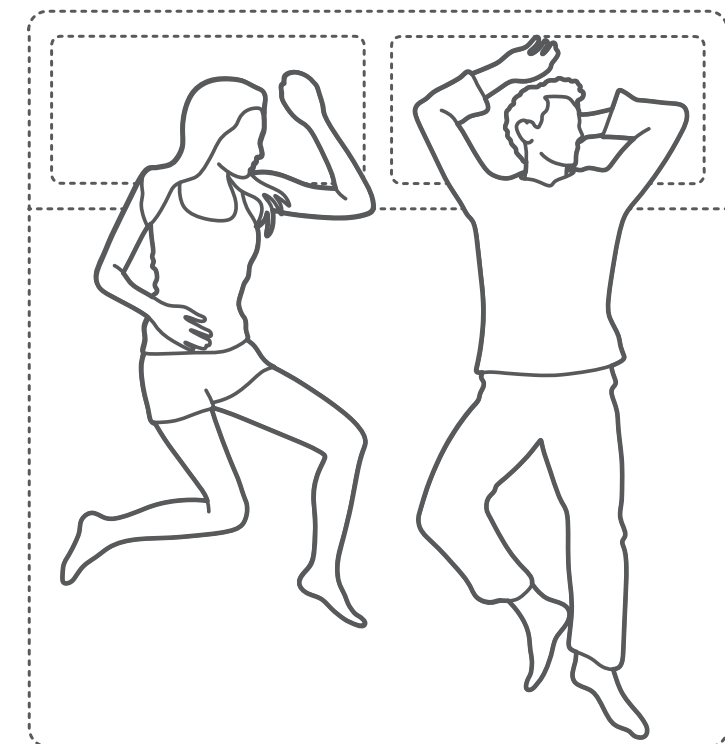
- What has been your experience traveling with sleep apnea?
- What sleep apnea therapies have you tried? What has worked best for you, and what didn't work as well?
- What CPAP machine do you use? Why?
- What does your routine look like preparing for travel with your CPAP machine?



r/CPAP  
r/sleepapnea



- Sleep Apnea Support
- Sleep Apnea Solutions
- Fun With Sleep Apnea



# USER RESEARCH

"I don't know how much of a 'beating' the travel devices can take. Can I put it in a roller bag and take it with me, or will the internal motor wear out prematurely?"

"I'd rather take something larger for better treatment so I can actually enjoy my time on the trip. If I don't get good sleep, I'll be miserable all day."

"Sleeping in hotels is usually a hunt for an outlet near my preferred side of the bed. I have been in some older places that don't have an outlet nearby and have had to get creative."

"One time while switching parts I left a huge gasket at home, the machine was useless. I ended up hand making a gasket and lots of duct tape and it ended up looking like an Apollo rescue and worked a bit."

"I clean my mask, headgear, and hose with warm water and liquid Ivory soap, and I change the disposable filters regularly."

"Definitely a HARD NO to checked baggage for the simple reason that I need it if my luggage gets lost. I was concerned about it being jostled around in the overhead bin, though."

"I nasal masks, but I always take a full face with me in case where I'm going I end up with blocked sinuses (for whatever reason). If I have space, I take my 12v car charger power supply too just in case I find myself away from a power socket but near to a vehicle."

"Let me tell you about the last time I traveled. It was to Hammond Louisiana. Two weeks after Ida hit. I got a travel CPAP just for that reason and power came from a generator and was on and off. So I run it off a goal zero battery. The battery lasts for about 12 hours but since the generator is on and off, it's more or less unlimited."

# USER RESEARCH

"Pre-covid I travelled a lot for work and used a DreamStation Go.

In order of annoyance:

Needing distilled water. I can't use the device without the humidifier.

Rain out in hotels. Gurgling sounds from the fluid in the tube. I use a heater tube at home and rarely have the problem there. In the morning I run the blower on the machine while im in the shower to dry out the tubing

Cleaning the mask (i wait until I'm home for the humidifier cleaning and just dump it in the morning and let it dry). I use CPAP wipes at home for the mask but sometimes can't pack them."

"I have to fill a tiny bottle of distilled water when I go overseas because once you go outside the US, it is not as abundant"

"I wish I could see the time on my CPAP machine while laying in the bed. It would also be nice if I could charge my phone and other devices from it. Kind of like a device hub on the hotel night stand."

"It is weird sitting on international flights trying to sleep wearing gear in public. It's hard enough to sleep in coach, adding a machine in a cramped space with nowhere to really set it out of the way is awkward."

Insights:

Most people take their CPAP as a carry-on when flying

People are embarrassed to use their CPAP machine in public on an airplane

There isn't enough room to comfortable sleep on an airplane with CPAP

# USER INTERVIEWS

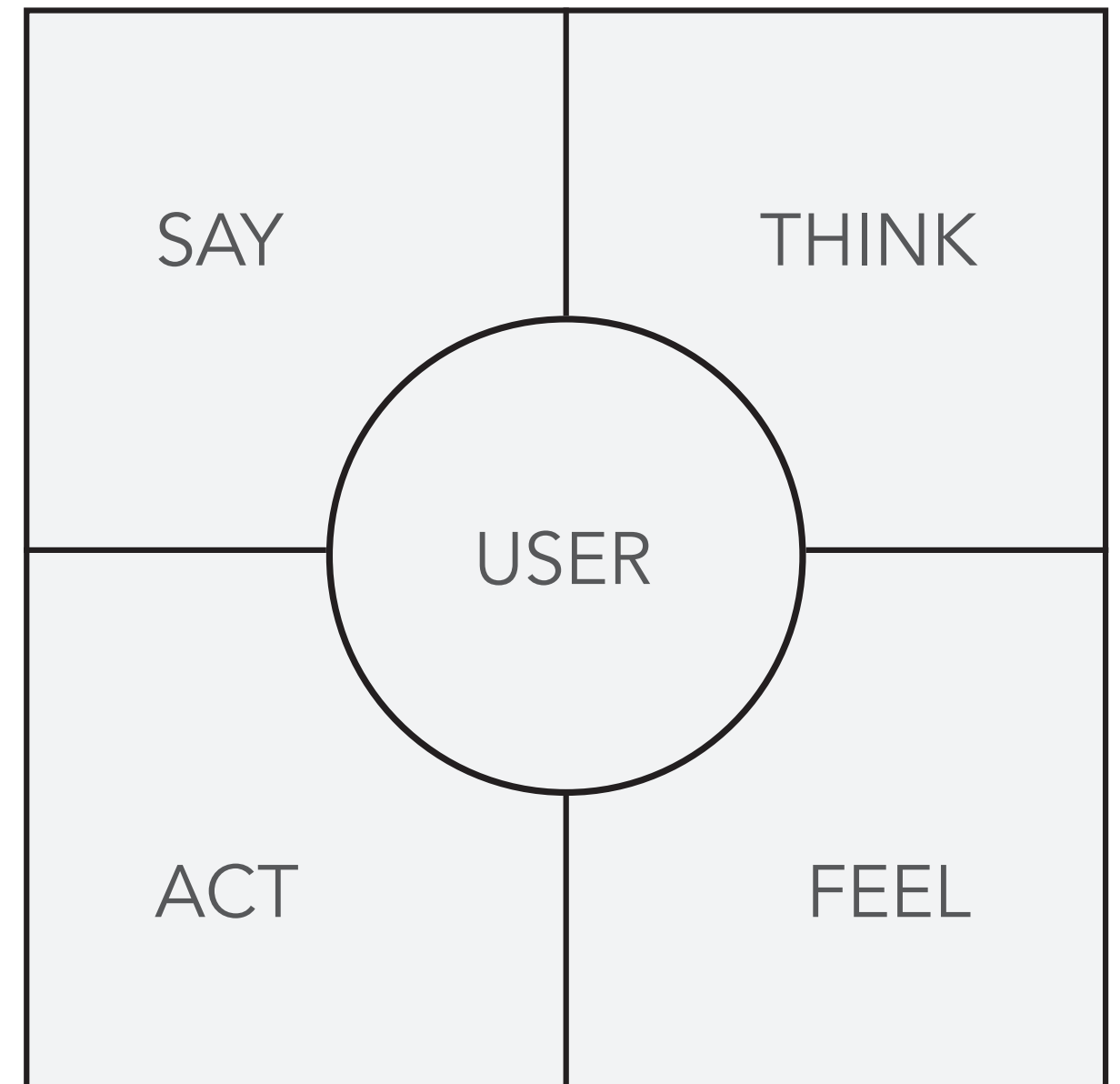
## INTERVIEW GOALS:

5 sleep apnea patients

1 sleep apnea patient partner or family member

1 pneumologist or sleep medicine equivalent

**Discover** what and how stakeholders...



# USER INTERVIEW #1 - GERRY

- Lives in Kansas
  - Pilot of 30 years
  - Has used a CPAP machine for 6 years - Diagnosed with moderate sleep apnea at 56
  - Open mouth sleeper
  - First tried nasal dialators and chinstrap - plugs would pop out
  - Took him ~30 days to get used to his mask
  - Uses 10cmH2O pressure
  - Carries 3 bags while traveling - flight bag, luggage, CPAP bag
  - People call him "bag lady" for carrying 3 bags
  - Keeps his CPAP bag in the cockpit on top of his flight bag
  - After each use, he wipes down his machine with sanitizing wipes.
  - Changes hoses, tank, and disposables every 3 months
  - Changes filter every 6 weeks
  - Face challenges reordering stuff when he'd like. Shipping is a struggle
  - Keeps a bin with his stuff in it and a bin for his son's stuff.
- "I've had two sinus surgeries. My doctor said I could get away with no longer using my CPAP machine. But I've gotten so used to it, it's become a habit and I get such good sleep with it"

"One time I was visiting my daughter and the hotel room didn't have any outlets between the bed. I had to call the front desk and have them send up and extension cord."



Large F20 mask



Resmed Airsense 10

On overnight trips, he puts the hose in a 1 gallon sealed bag, takes the water tank out and dries with kleenexes and has a big backpack that he puts the carrying case and puts it in the middle, carries a liter of distilled water in the backpack with it. He keeps the mask in the front compartment. Because he has pilot clearance, he never gets hassled for his machine at TSA security. If his machine doesn't use all the distilled water, he pours the remnants back into the liter jug.



# USER INTERVIEW #1 - GERRY

## Embracing new information with an open mind

Has a son named Noah with downsyntax who also uses a CPAP machine

His son was diagnosed with sleep apnea two years ago. His teachers noticed he was frequently falling asleep in class at school.

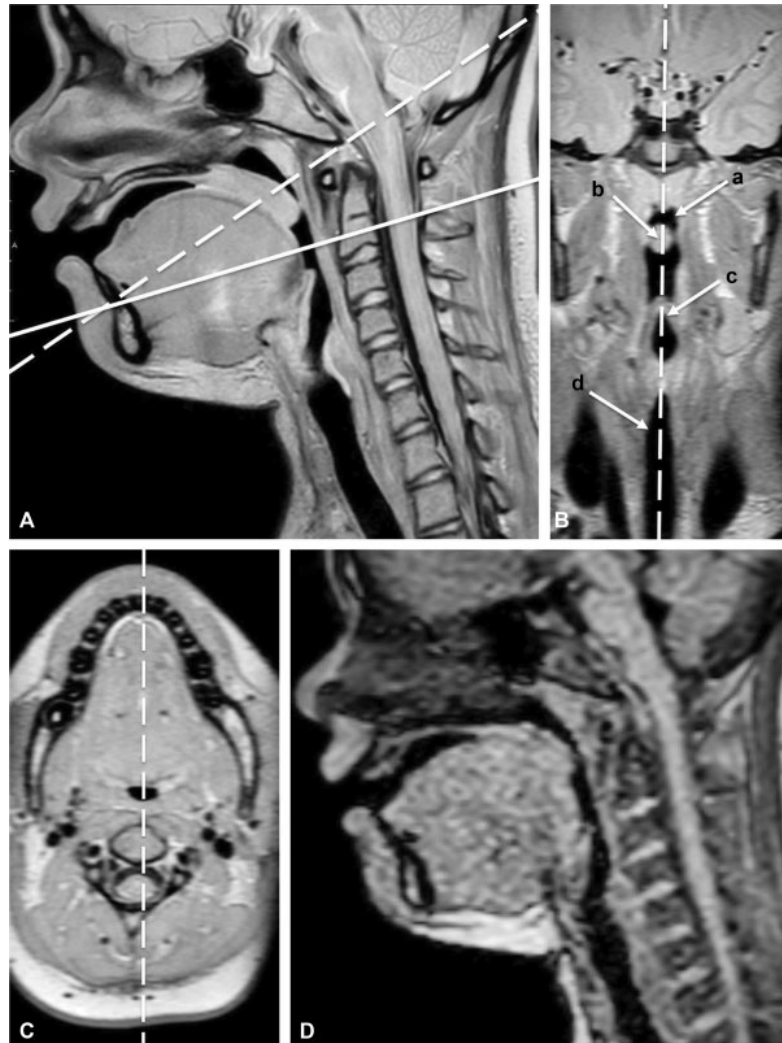
The doctors told Gerry they could either cut Noah's tongue or give him a CPAP machine to treat his sleep apnea. Gerry didn't want them to cut his son's tongue because Noah had so many years of speech therapy he was afraid that operation might ruin Noah's progress.

"When Noah sleeps on his back his tongue falls back, causing his sleep apnea. When kids with down-syndrome sleep, its better for them to lean forward in a seated position while sleeping because their tongue doesn't fall back. Since Noah's started using a CPAP machine he sleeps much better, even up to 10 hours. Many kids with down syndrome take off their masks after a few hours but I think because he sees me wearing it he knows it's ok."

# SLEEP APNEA AND DOWN SYNDROME

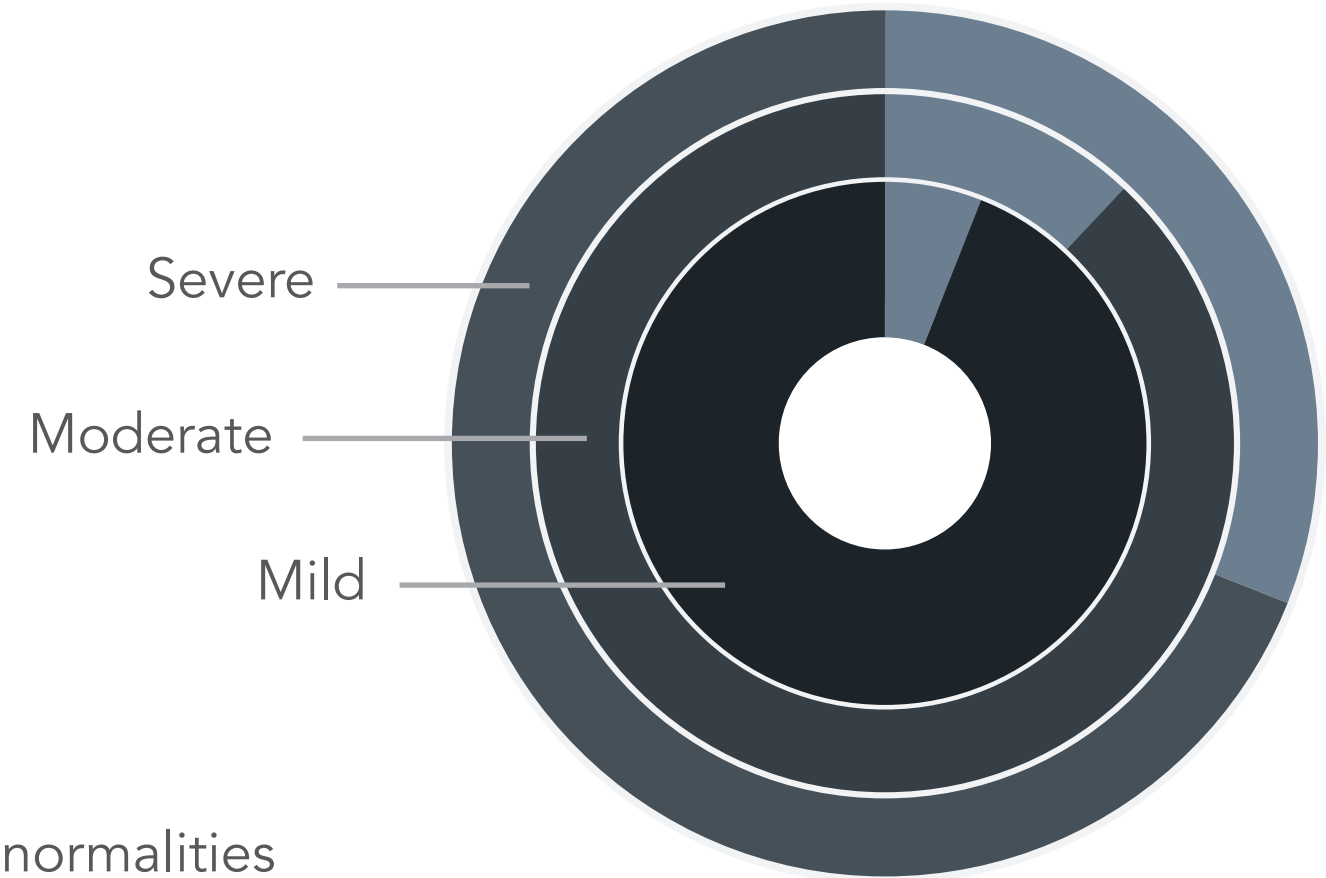
"In a study of 16 adults with down syndrome, 94% of people with Down syndrome had OSA; 88 percent had at least moderate OSA; 69 percent had severe OSA."

- Journal of Clinical Sleep Medicine



Down syndrome causes anatomical abnormalities that cause the airway to collapse easier

- Narrowed nasopharynx - Narrow upper throat
- Mandibular hypoplasia - shortened mandible
- Hypertrophic tonsils - enlarged tonsils
- Macroglossia - enlarged tongue
- Shortened palate



CPAP is underused in adults with DS due to the presumption that they will not tolerate it

# STAKEHOLDER MAPPING

## Sleep Apnea Patient

The sleep apnea patient has a high interest and influence. If the patient does not like their therapy device, it's likely they won't use it. It's important that they are able to find a device suitable for their needs. Pilots need to comply with FAA medical guidelines, so they need a device that's portable and can record their sleep.

## Health Insurance

The patient's insurance company has a medium interest and high influence on what kind of machine they will pay for. For example, CPAP machines that are labeled as personal travel devices are not covered and require exemption for pilots.

## Doctor

The patient's doctor has a high interest and high influence. They have greater influence in suggesting what type of sleep apnea therapy the patient receives. The doctor is responsible for helping the patient sleep better with suitable sleep apnea therapy and confirming or denying the patient their FAA medical certificate.

## Family Member / Bed Partner

The close family member or bed partner plays a role as a stakeholder because most commonly they are the one to point out the snoring or apnea events to the sleep apnea patient. A bed partner might complain if a sleep apnea therapy device such as a CPAP machine is too loud, or bothersome at night. The family member or bed partner might have a lot of interest and subjectively low influence on the type of sleep apnea therapy the patient receives.

High Influence	<b>Health Insurance</b>	<b>Doctor</b> <b>Sleep Apnea Patient</b>
Low Influence		<b>Partner</b>
	Low Interest	High Interest

# KEY TAKEAWAYS

Time is everything

Travel is hard on equipment

Data is required for FAA and DOT

Outlets aren't always accessible

It's embarrassing to use CPAP in public

Storage space is limited

Sleep apnea is vastly undetected in people with DS

# PROBLEM STATEMENT

How might we

improve the experience of traveling with  
sleep apnea?

# MILESTONE 2



# MARKET SYNTHESIS



- Highest rated, Most reliable
- Less portable



- Very portable, modular
- Poor user experience



- Highest adherence mask styles
- Performance depends on apnea needs



- FDA approved alternative
- Only treats mild OSA



- Less invasive than CPAP
- Ineffective for moderate to severe sleep apnea



- Favored CPAP Accessory
- Low portability



- Effective for some CPAP users
- Can cause back pain

# MARKET SYNTHESIS

## CPAP Machines

High Functionality  
Low Functionality



Market Opportunity



Low Portability

High Portability

## CPAP Accessories

High Portability  
Low Portability



Market Opportunity



Low Modularity

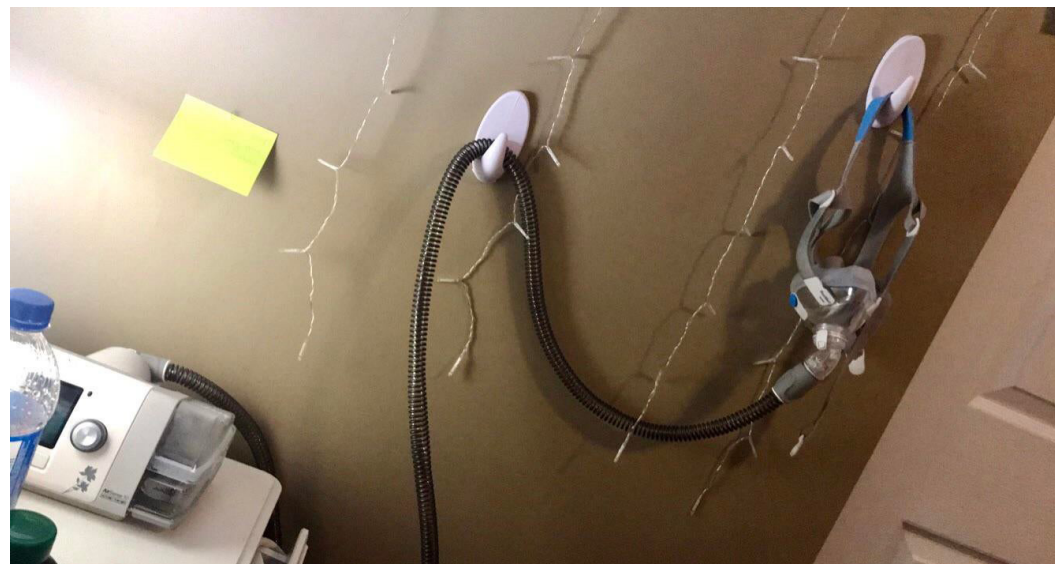


High Modularity



# DIY SOLUTIONS

"use command hooks to hang up your tubing and mask!"



Custom night stand for CPAP

"Better than nothing?- extra filtration hack, old thin t-shirt bit"



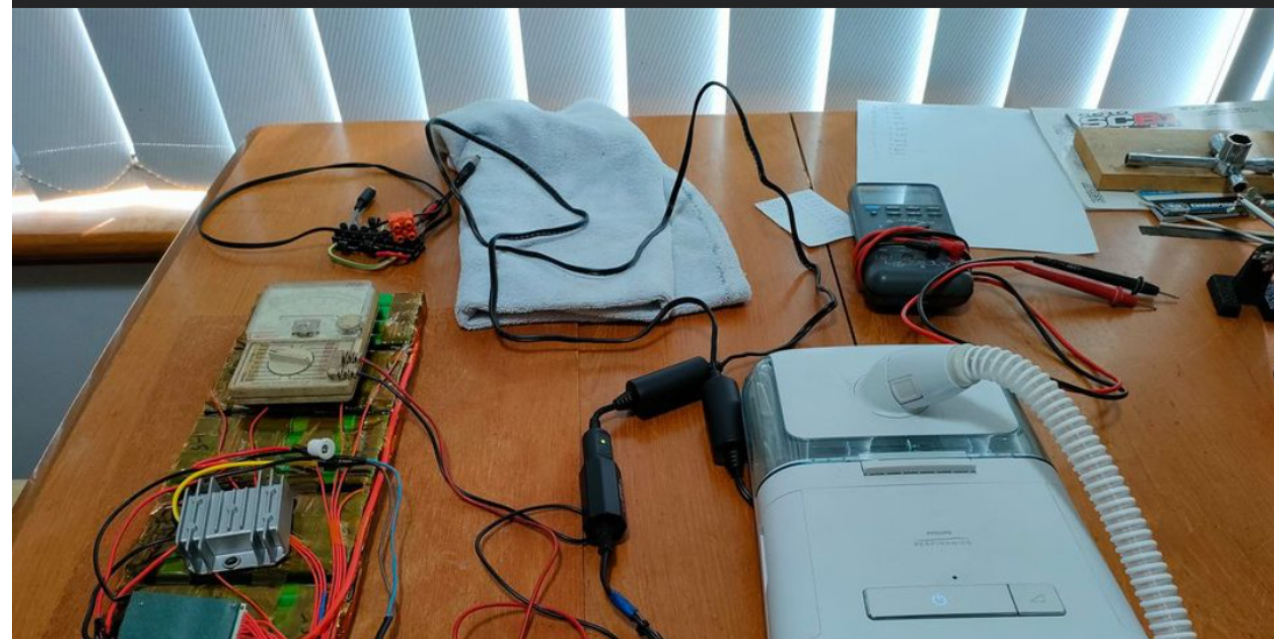
Bedside CPAP machine holder



Broom holder for tubing



Homemade battery for my machine. A repurposed electric skateboard battery.  
1st pic is a trial I posted some weeks ago. After testing.  
2nd pic, finished.



# DIY SOLUTIONS

## User Testimony

"I hate this thing, I hate this thing. It is the bane of my existence."

"I don't breathe bad, I breathe well - and I think I was unfairly diagnosed."

"I've been working on a way to fool this stinkin' thing..."

When the CPAP therapy doesn't help the user from the start, they feel frustrated and betrayed by their doctor.

Hyperlinked video, click to watch ^



Pascal T. 2 years ago

I didn't think I needed one neither, 'till I got a stroke!!! I was lucky enough to survive... Now I use this machine every single night, RELIGIOUSLY!!!

37 REPLY

# DIY SOLUTIONS

Users who need to comply with medical certifications fool their CPAP machine if they don't like using it. Common 'life hacks' include using a box, bottle, or bucket and a pump to provide back pressure for the CPAP machine to think they're using it.



# QUANTITATIVE DATA

## Survey of 50 users

- Sleep Apnea Support
- Sleep Apnea Solutions
- Fun With Sleep Apnea



## Describe your experience traveling with your CPAP machine with an emoji

30%



18%



12%



10%



10%



20%



## Explain why you chose that emoji

It is what it is, a necessary piece of equipment.

I get good sleep even when away from home

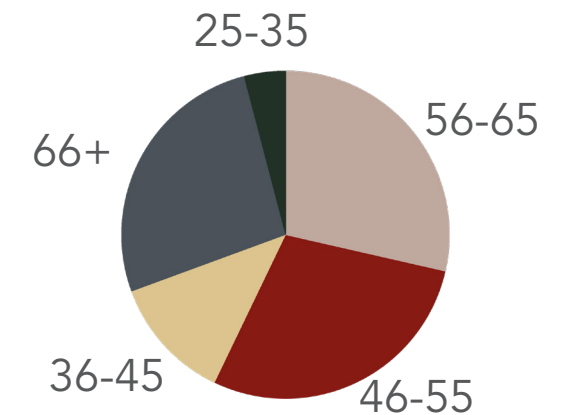
Neutral; it's just another device needed.

Another bag to mess with. Outlets never convenient. I wouldn't wear it on the plane though, that would be extremely embarrassing.

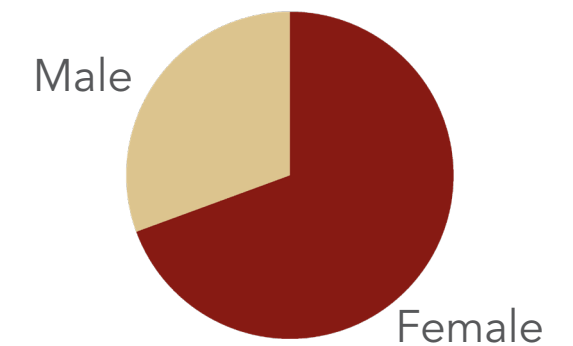
Pain to travel with, but something I have to do. Grin and bear it.

It's sometimes hard to get distilled water, and if you purchase from the hotel it's very expensive. I once paid \$8.00, because I didn't want to find a convenient store. If you cruise you need to make sure you preorder it and bring an extension cord with you.

## Age



## Gender



# QUANTITATIVE DATA

## Why was the survey ineffective?

Respondants were people with good adherence to CPAP. Most of them are generally happy with their CPAP machine

## So I asked myself...

What about those who stopped using CPAP? Or those who were hacking their CPAP?

How I sleep at night knowing my throat won't close shut and starve my brain of oxygen <sup>124</sup>times/hour



## So I asked a question for people who have sleep apnea, but don't use CPAP:

If you tried CPAP therapy but don't use it anymore, why didn't it work for you?

"I got worse sleep using CPAP"

"I couldn't get used to the pressure"

"None of the masks I tried fit right, I was always dealing with mask leaks. I would tighten them, but they would end up hurting my nose or face"

"It was stressful trying to keep my medical certificate, so I changed careers"

"I kept waking up feeling sick from my machine"

"I would always pull my mask off in my sleep. I couldn't keep the thing on so I switched to a mouth piece"

# INTERVIEW QUESTIONS

## **Sleep Medicine Interview Baseline Questions**

- Why does obstructive sleep apnea occur?
- How is sleep apnea typically detected or diagnosed?
- Who is most at risk for obstructive sleep apnea
- Which sleep apnea therapy have you found is most effective?
- What are some common problems people experience with different sleep apnea therapies?
- What are some of the risks with sleep apnea going untreated?

## **User Interview Baseline Questions**

- What has been your experience traveling with sleep apnea?
- What CPAP machine do you use? Why?
- What sleep apnea therapies have you tried? (CPAP/BPAP/APAP, MAD, Nasal Dilators)
- What does your routine look like preparing for travel with your CPAP machine?
- Walk me through the process you take while packing your sleep apnea machine?
- Describe your setup CPAP machine setup process at the hotel. What does your setup look like?
- Describe your process for cleaning your CPAP equipment

# SLEEP MEDICINE INTERVIEW

## Ken Kunisaki, MD, MS

Pulmonary physician, Dr. Kunisaki has had longstanding extramural funding from NIH, the Department of Defense, and VA for a wide range of clinical trials and observational studies in addition to over 140 published research papers.

### Insights

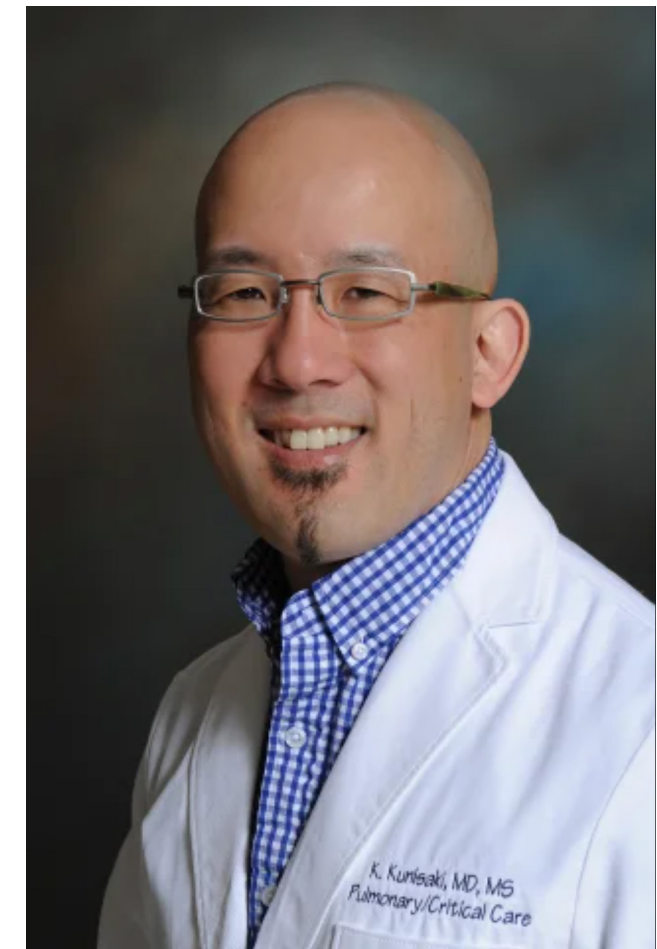
80% of people who have sleep apnea are undiagnosed

CPAP is by far the most effective therapy for sleep apnea, but adherence to CPAP is bad  
After 1 year, 60% of people keep using it

### Often the expectations between patient and doctor are misunderstood

Mask fit is the most important part  
Recommends wearing mask during the to get used to it  
Some patients require desensitization therapy (cognitive/behavioral therapy)

In response to people faking data to maintain their medical certificate:  
"It's very obvious when a patient sends in data and it looks absolutely perfect... but as doctors we have to give them the benefit of the doubt and remind them why they're using the machine - for their own health."



**Hypopnea** - going from sleep to awake, breaking the arousal threshold

**Apnea** - 10 second cessation of breathing

### Maintenance of Wakefulness (MWT)

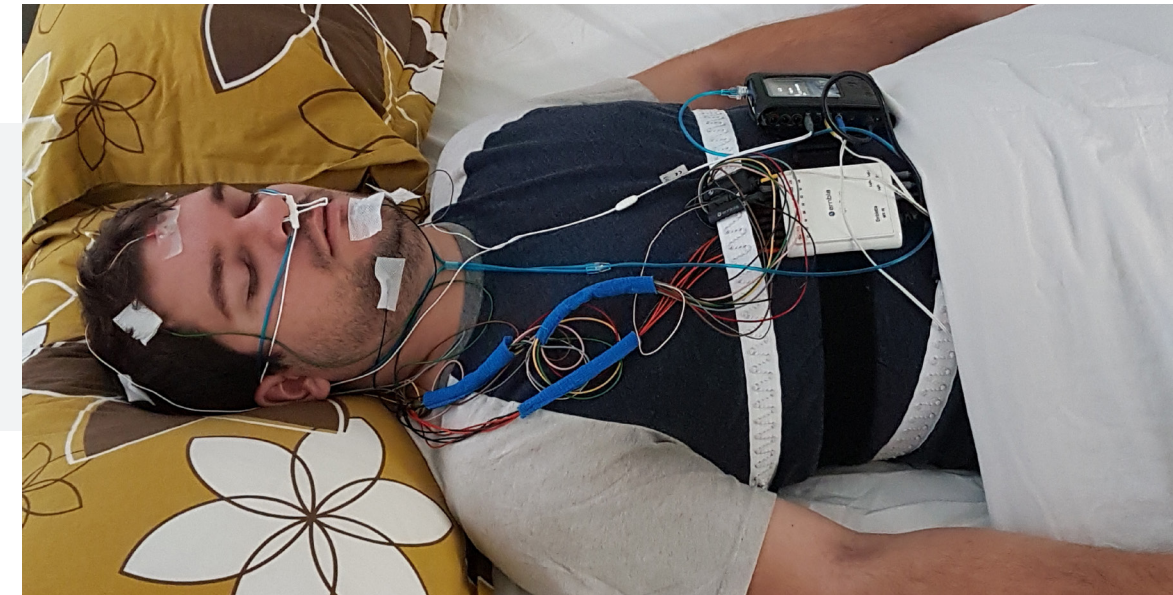
Test see if you can stay awake while left alone with nothing to do for multiple intervals

# SLEEP MEDICINE INTERVIEW

Dr. Kunisaki described the 4 types of sleep studies for diagnosis:

**Split-Night Polysomnography** - sleep is monitored half the night, and the next half a CPAP mask is put on the patient. Costs \$2000-3000

**Polysomnogram (PSG)** - unmonitored sleep in a lab



**Home Sleep Apnea Test (HSAT)** - take home test without EEG

**Peripheral Arterial Tone (WatchPAT)** - Overnight home test of oximetry, heart rate, actigraphy, body position, snoring, and chest motion. Least invasive of all sleep tests.





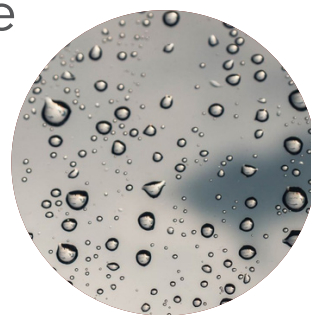
# USER INTERVIEWS

## Follow-up interview with Gerry

He once left his CPAP bag in the hotel van because the van driver forgot to hand it to him. He had to wait an hour to get it back

Always keeps extra small parts for his mask in his bag because he sometimes loses them. He loses the magnets for the mask most frequently. If he doesn't have spares, he can't use his machine.

He typically gets rainout in colder hotel rooms, and wakes up to gurgling in his tubing. In these instances, Gerry disconnects the hose and shakes the water on the carpet.



Carries distilled water with a 1 liter bottle. If the humidifier doesn't use all the water, he dumps it back into the bottle.



"I try to wake up an hour before I have to leave so I have plenty of time to clean and pack, but it typically takes 5 to 10 minutes to pack up my CPAP and tubing"

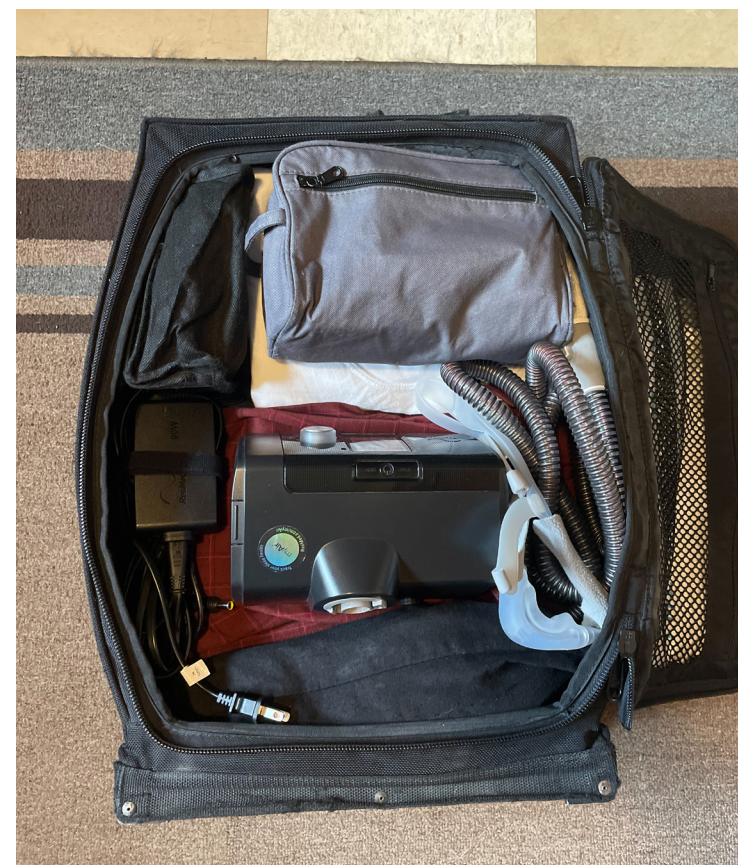
"Many other pilots won't get tested. They don't want a sleep apnea diagnosis jeopardizing their career, but I would bet about half the guys I talk to would be diagnosed with it if they got a sleep test. The kicker is, as of 2015, the FAA changed guidelines for flying with sleep apnea to be more accommodating"

# USER INTERVIEWS

## Martin

Packs CPAP machine in carry-on bag

- Doesn't like the hose attachment in back of his machine
- Doesn't use his humidifier while on trips
- Humidifier doesn't need to hold so much water
- Wants to be able to read the hours of use while using the machine. Screen also doesn't display the time of night
- Wants a longer hose for night time mobility
- Smaller machine with ability to hold one years worth of data. He was very concerned with his data
- Ability to plug in USB phone charger to the CPAP power adapter
- Wants an accessory bag holder for hose and power supply



# USER INTERVIEWS

## Kim - Truck Driver

When she first got her CPAP she was concerned she would lose her job. Her first several weeks on CPAP, she got worse sleep than usual. She has an issue with keeping it on in her sleep. While unconscious she would take it off, making it hard to get 4 hours of use.

“My travel experience is a little different. It’s difficult to clean and hard to get new hoses or masks. It might be interesting to study the fraud in trucking when it comes to forced testing, forced purchasing, shoddy testing and absolutely no medical follow-up after they get your money. It’s a black eye to all the medical professionals and patients that truly need this treatment. It seems a conflict of interest for a sleep lab to have their office on the same building/property as the trucking company that pays them for more customers.”

Kim’s perspective is that she’s getting scammed having to use her CPAP

Kim recently had issues with her mask leaving red marks on her face in the morning  
“It’s embarrassing starting my day with a red ring around my face”



I’m concerned about my privacy. If I get pulled over by a DOT officer and they can somehow check my sleep data, they could arrest me if I didn’t sleep well the previous night.

I carry couple gallons of distilled water with me, tonight as i was putting dirty clothes in laundry bag under the bed I realized one of the gallons had a pin hole it and leaked all over the floor. It can be a pain to have sleep apnea and live weeks at time in a truck.

I parked the truck and forgot the Cpap in it, so I’ve been sleeping without it since Friday night. I’d love to get one for home and one for the truck. I don’t think insurance will pay for another one yet, and I just want to get one as cheap as possible.

# USER INTERVIEWS

## Steve Cox

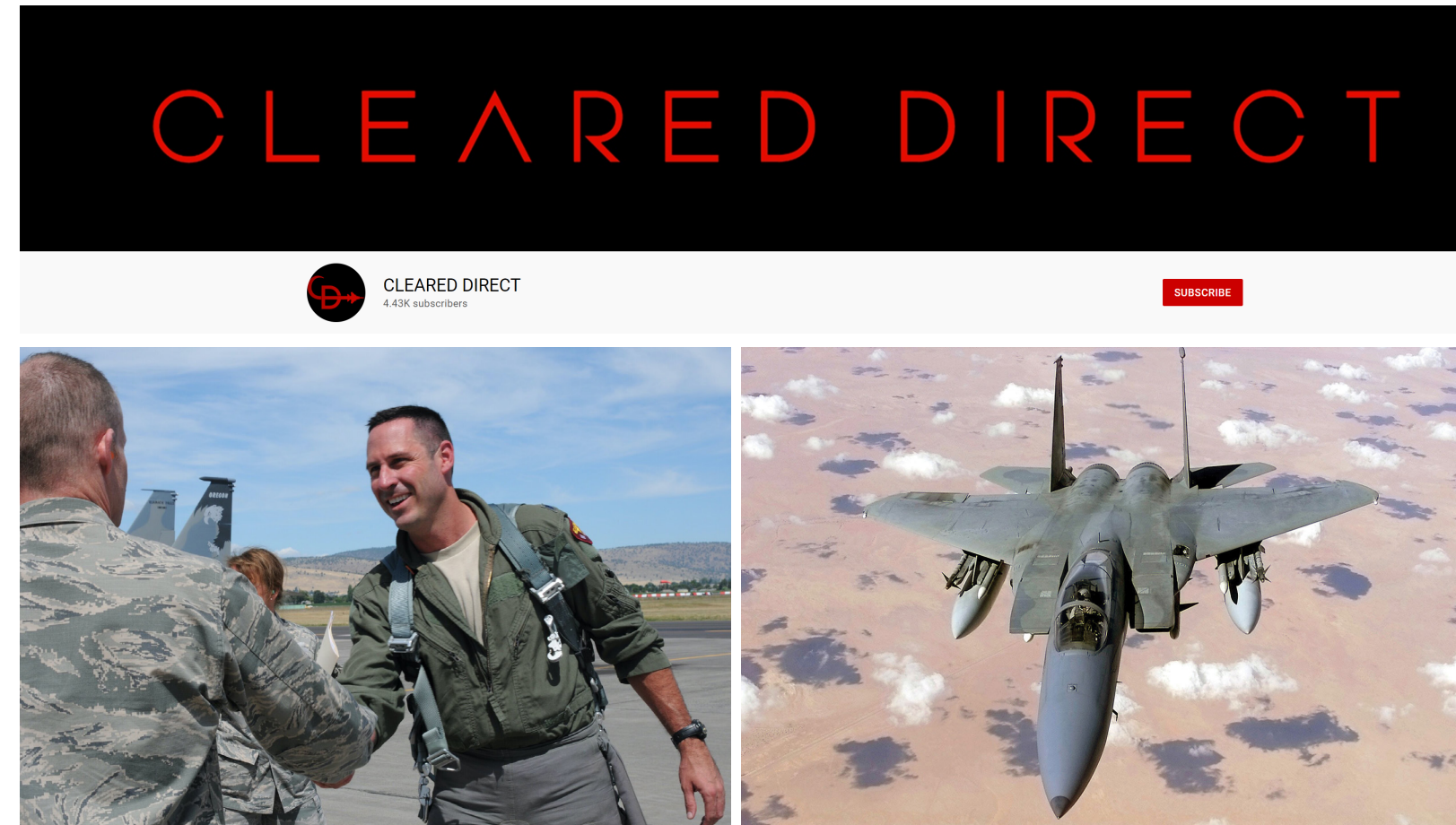
Steve is an accomplished pilot with over 20 years of experience flying commercially, for the United States Air Force, and the National Guard. He was diagnosed with sleep apnea at the age of 40 and has been using CPAP therapy since 2016. Steve also runs a Youtube channel covering all things pilot and aircraft related, and instructs pilot leadership and safety courses.

Department of Defense (DOD) and Federal Aviation Administration (FAA) medical certification

Initially tried to avoid CPAP. Wasn't overweight, but still had sleep apnea. Didn't have success with a mandibular advancement device. Had sinus surgery, but his sleep apnea still persisted.

Currently owns a Dreamstation 2 and Dreamstation Go, and gets about the same quality of treatment with all the CPAP machines he's used. The user interface on the dreamstation 2 is bad, touch screen feels crappy, and it's hard to access the humidifier.

Uses a nasal pillow (airfit resmeed P10), doctor says he should use a full face mask because he sometimes opens his mouth. Size 12 tubing



His Dreamstation Go has a two cases, one harrdshell for the device, and a bag for the tubing and mask. Steve likes that it has an internal power brick, so there's just a plug you pull out from the machine. He also likes that it has a USB port so he can plug his iphone into it.

You can only use the humidifier OR battery with the Dreamstation Go because the machine draws a lot of power when using the humidifier.

# USER INTERVIEWS

## Steve Cox

“It was hard for me to tell if I had sleep apnea. I thought I was just tired from the redevye flights and odd sleep schedule”

When he got his Dreamstation 2, his prescription pressure wasn't programmed into the machine. When he uses his CPAP machine at too low of a pressure, it doesn't work. He's been adjusting to sleeping on his stomach to get better sleep. He has to avoid sleeping on his back  
Doesn't usually bother with buying distilled water. Usually buys bottled water. Its also inconvenient because thee smallest container you can buy distilled water in is a gallon of water.

“As a fighter jet pilot, I'm used to positive pressure from the oxygen mask while flying, but it took me 3 months to get used to the positive pressure of my CPAP machine while sleeping.”

He built a custom nightstand specifically for his CPAP machine

Typically doesn't clean tubing on the road - but when he does, he uses dish soap at the sink.

Carries his CPAP and tubing in his carry on luggage

Takes him about 5 minutes for setup or pack up

Has a sore throat from not using his CPAP - tissue isnt used to obstruction during sleep

Has a mindset that he got tested for sleep apnea because he wanted to stay healthy

“As a young guy I probably wouldn't have cared as much. But now that I've got kids I want to be around for them as long as I can.”

### Top Values:

1. Quietness
2. Reliability
3. Good humidification
4. Easy cleaning
5. Good user interface

# PERSONAS



**Pete**

Commercial Airline Pilot

Moderate to severe sleep apnea

Federal Aviation Administration  
Medical Certificate

Spends 200 nights / year at a hotel

Time - task oriented



**Tony**

Truck Driver

Severe sleep apnea

Department of Transportation  
Medical Certificate

On the road most of the year

Headstrong



**Peyton**

US Air Force Pilot

Moderate sleep apnea

Department of Defense Medical  
Certificate

At base most of the year

Health-conscious

# EXPERIENCE DIAGRAM



**Pete**

Contexts



Home



Car



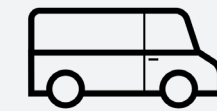
Airport



Airplane



Airport



Hotel Van



Hotel

Touchpoints

Packs CPAP and luggage

Drives to the airport

Walks to terminal and preps the aircraft

Flies airplane to destination

Gets off airplane, waits for hotel van

Rides hotel van to the hotel

Sleeps at hotel

Thoughts

"I get the best sleep at home"

"Packing is a pain. If I forget anything, I can't use the machine"

"I'm always nervous about my CPAP getting lost, damaged, or misplaced on at the airport, on the airplane, or in the hotel van"

"I never use my CPAP machine on flights, if I did it would be extremely embarrassing"

"Where is the nearest outlet?"

"Have I hit my time goal yet?"

"Did I clean my CPAP machine yet?"

Feelings



Objects



Insights / Opportunities

Improve organization

Improve durability  
Prevent lost baggage

Improve durability

# IMMERSION

## Transcend Mini Auto CPAP

Can be worn on the head, held in place by headgear and padded by a cushion at the bottom of the machine. A short tube connects the CPAP machine to the mask. This configuration is supposed to feel like you're wearing a hat, but requires the correct mask. The chamberless humidification (HME) uses a disposable hygienic heat moisture exchanger, and captures moisture from the patient's exhaled breath, providing warm humidification to prevent nose irritation and congestion.

Ideal for experienced CPAP users who are frequent campers, truckers, or business/frequent travelers who want a portable CPAP system to fit into luggage.

Not ideal for inexperienced users, or those who require high humidification. Is not FAA or DOT compliant because it does not track advanced efficacy data such as AHI.

7% louder than home CPAP machines





# IMMERSION

## Activities

The immersion phase of this research lasted one week in which the following activities took place:

- Test sleeping with two different masks styles
- Pack and unpack the CPAP machine and tubing each day for a week
- Carry the CPAP machine to and from classes each day for two weeks
- Clean the CPAP tubing



Philips Respironics DreamWear  
Nasal Mask



ResMed AirFit N10



# IMMERSION

## Observations & Insights

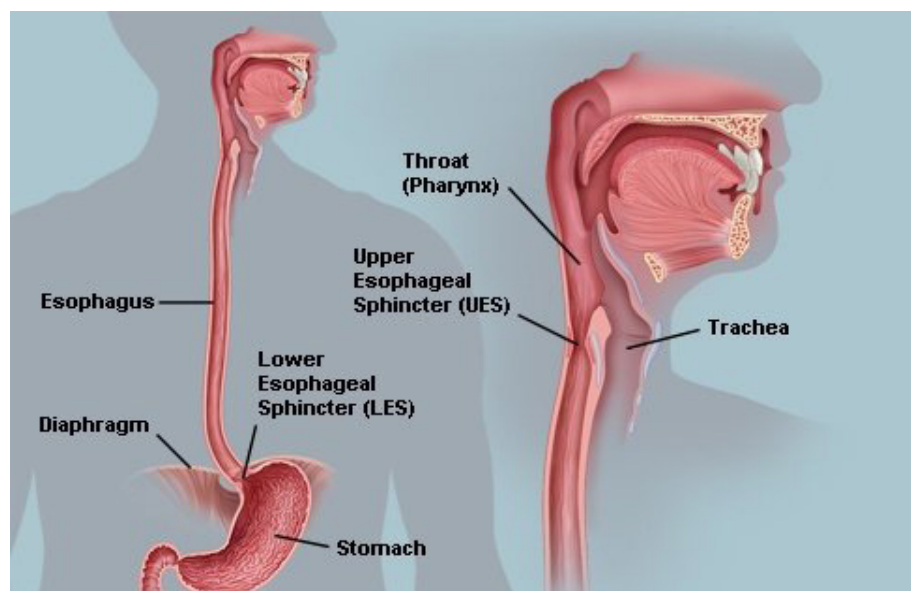
The tubing is difficult to manage. When I first opened the CPAP bag, the tubing jumped out like those snake-in-a-can gag gifts



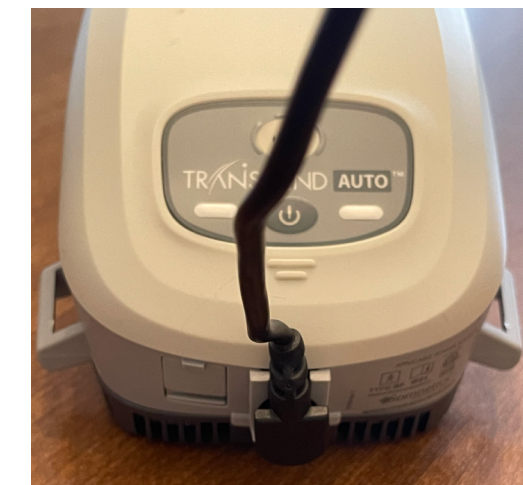
The CPAP bag size was tolerable, but the pockets didn't make sense where I should put each component



The bag also doesn't feel very protective if I were to drop it



Gave myself **aerophagia** from using the machine, where it forced air down my throat. I was only able to use it a couple hours total, but this might be the same experience for other new users



The charging port doesn't let you point the cable in other directions

# RESERACH SYNTHESIS

High priority

## Attitude

Health isn't a priority

Fear of losing employment

"Sleep apnea therapy is a scam"

Frustration with worse sleep results early on

CPAP is embarrassing to use

## Organization

Packing CPAP machine

Tracking time and data

Forgetting or losing CPAP parts

Preventing damage to the CPAP machine and components

Distilled water is hard to pack and acquire on the road

Finding an outlet near the bed

## Compliance

80% of people with sleep apnea are undiagnosed

The adherence rate in users after the first year of use is 60%, and has been recorded as low as 30%

The expectations between the patient and doctor are often misunderstood

## Fit / Comfort

Mask doesn't fit right

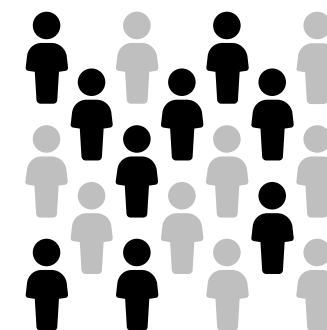
The CPAP pressure is too high or too low

Can't find the right mask style

Tubing is uncomfortable to sleep with

The mask leaves marks on the face in the morning

Low priority



# RESERACH SYNTHESIS

High priority

## Attitude

Health isn't a priority

Fear of losing employment

"Sleep apnea therapy is a scam"

Frustration with worse sleep results early on

CPAP is embarrassing to use

## Organization

Packing CPAP machine

Tracking time and data

Forgetting or losing CPAP parts

Preventing damage to the CPAP machine and components

Distilled water is hard to pack and acquire on the road

Finding an outlet near the bed

## Compliance

80% of people with sleep apnea are undiagnosed

The adherence rate in users after the first year of use is 60%, and has been recorded as low as 30%

The expectations between the patient and doctor are often misunderstood

## Fit / Comfort

Mask doesn't fit right

The CPAP pressure is too high or too low

Can't find the right mask style

Tubing is uncomfortable to sleep with

The mask leaves marks on the face in the morning

Low priority

**Attitude & comfort** are primary influences of **low compliance** in new users

# REVISED PROBLEM STATEMENT

How might we

influence user **attitudes** and improve **comfort** to increase CPAP therapy **adherence** for new users required to maintain a medical certification, such as pilots and truck drivers?



# MILESTONE 3

Ideation



# How might we

influence user **attitudes** and improve **comfort** to increase CPAP therapy **adherence** for **new users** to maintain a medical certification, such as pilots and truck drivers?



## Sleep shouldn't be so stressful...

Mask fit

CPAP machine noise

Maintaining compliance

Caring for your own health

Lifestyle adjustments

---

Pride

Privacy

Habit

Comfort

Convenience





# ADHERENCE RESEARCH

## **Educating the user**

Doctors uniformly underestimate the problem of nonadherence in their patients.

Hence, it becomes imperative to measure and evaluate patient adherence reliably.

In general, patients can be very accurate in reporting whether they are adhering to their treatment regimens if they are asked simply and directly.

Regular assessment of patient adherence by itself can lead to increased patient adherence.

## **Communication**

50% of patients leave their doctors' offices not knowing what they have been told. Studies have shown 50% of psychosocial and psychiatric problems are missed by physicians due to lack of proper communication

71% of patients stated poor relationships as a reason for their malpractice claims

communication with the patient's family and the patient's own perception of social support are significantly and positively related to adherence.

## **Modifying Beliefs & Behavior**

For interventions that are complex and require lifestyle modifications, it is worthwhile to address patients' beliefs, intentions, and self-efficacy.

Clinicians can optimize behavior change by ensuring that the patients:

1. perceive the risk due to lack of adoption of healthy behavior (percieved risk)
2. perceive their medical conditions to be serious (perceived severity)
3. believe in the positive effects of the suggested treatment (perceived benefits)
4. have channels to address their fears and concerns (perceived barriers)
5. perceive themselves as having the requisite skills to perform the healthy behavior (self-efficacy).

# ADHERENCE RESEARCH

## Improving compliance? Here's what research says

### **Simplifying regimen characteristics**

- Adjusting timing, frequency, amount, and dosage
- Matching to patients' activities of daily living
- Using adherence aids, such as medication boxes and alarms

### **Imparting knowledge**

- Discussion with physician, nurse, or pharmacist
- Distribution of written information or pamphlets
- Accessing health-education information on the Web

### **Modifying patient beliefs**

Assessing perceived susceptibility, severity, benefit, and barriers  
Rewarding, tailoring, and contingency contracting

### **Patient and family communication**

- Active listening and providing clear, direct messages
- Including patients in decisions
- Sending reminders via mail, email, or telephone
- Convenience of care, scheduled appointment
- Home visits, family support, counseling

### **Leaving the bias**

- Tailoring the education to patients' level of understanding

### **Evaluating adherence**

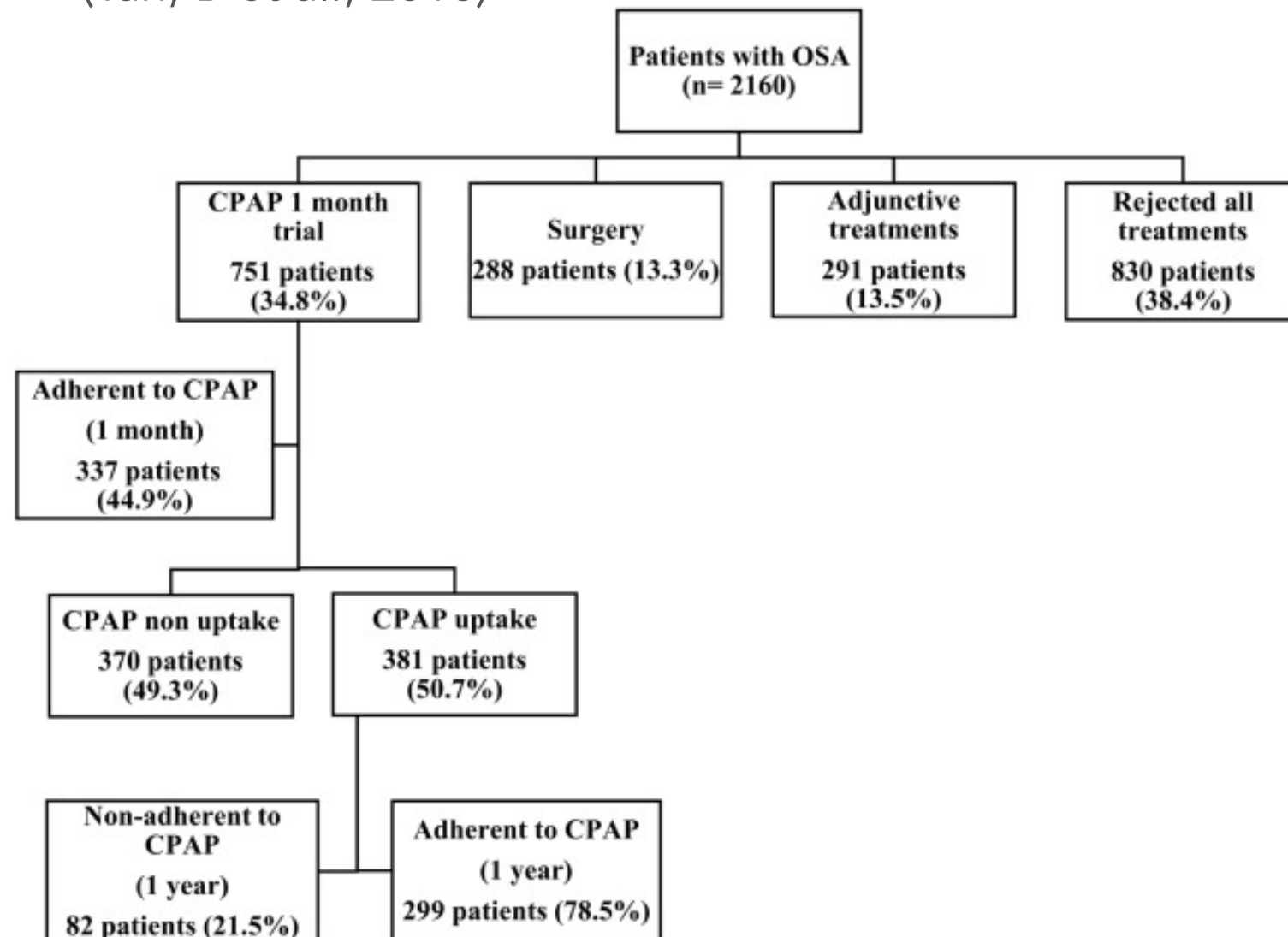
- Self-reports (most commonly used)

# ADHERENCE RESEARCH

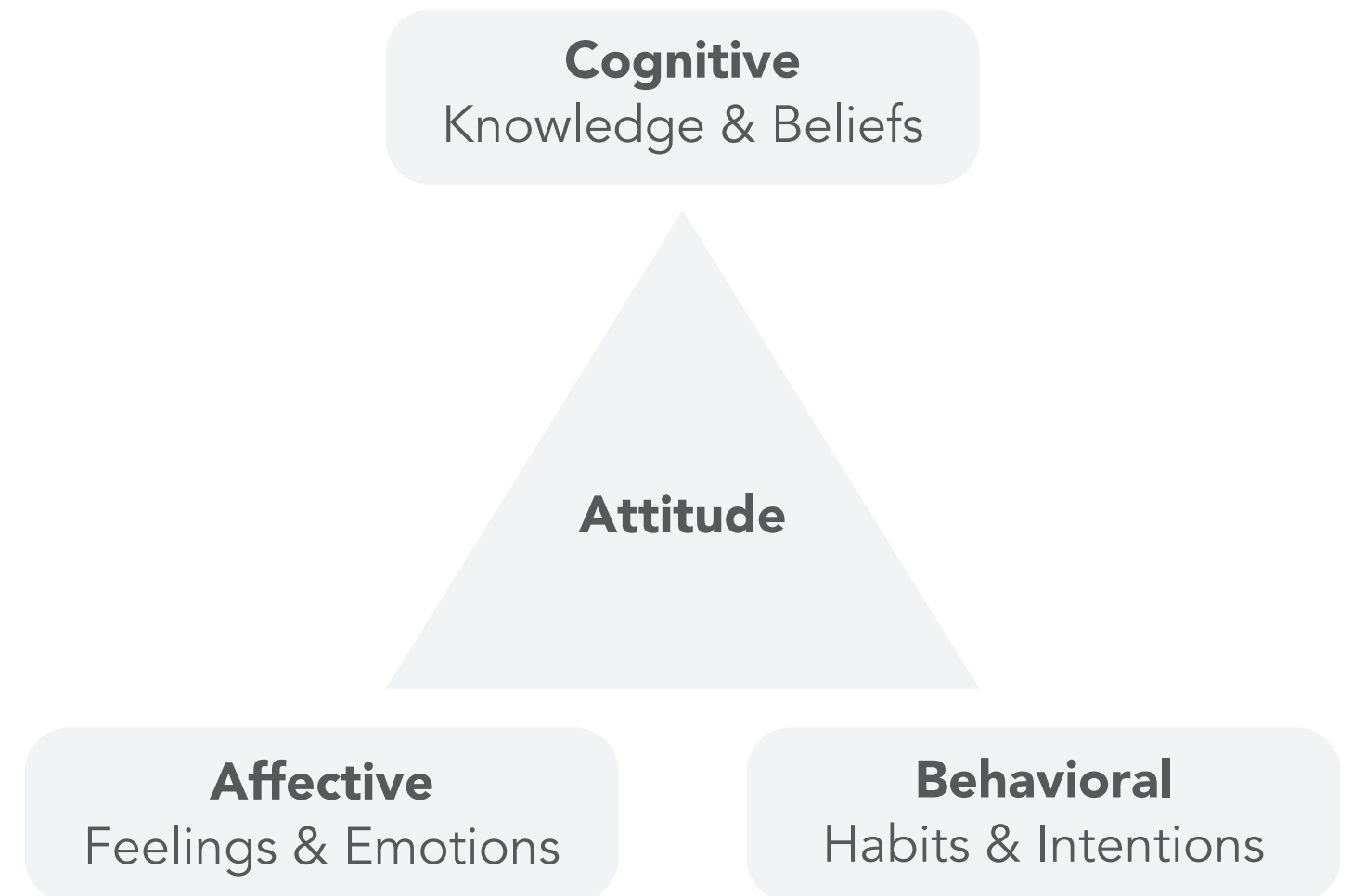
## Singapore research studying CPAP adherence:

Increasing adherence within the first month of CPAP therapy significantly increases the likelihood of long term adherence.

(Tan, B et al., 2018)

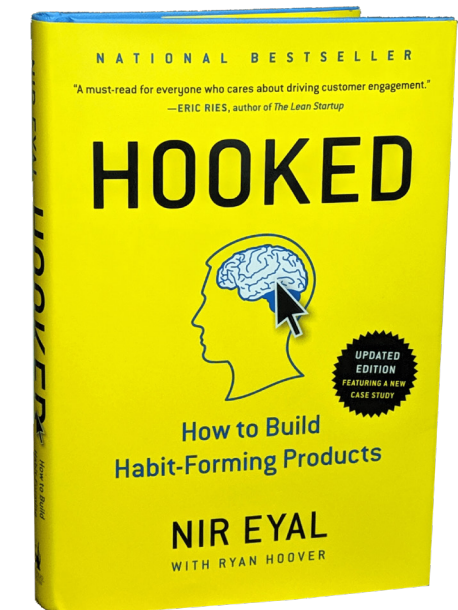
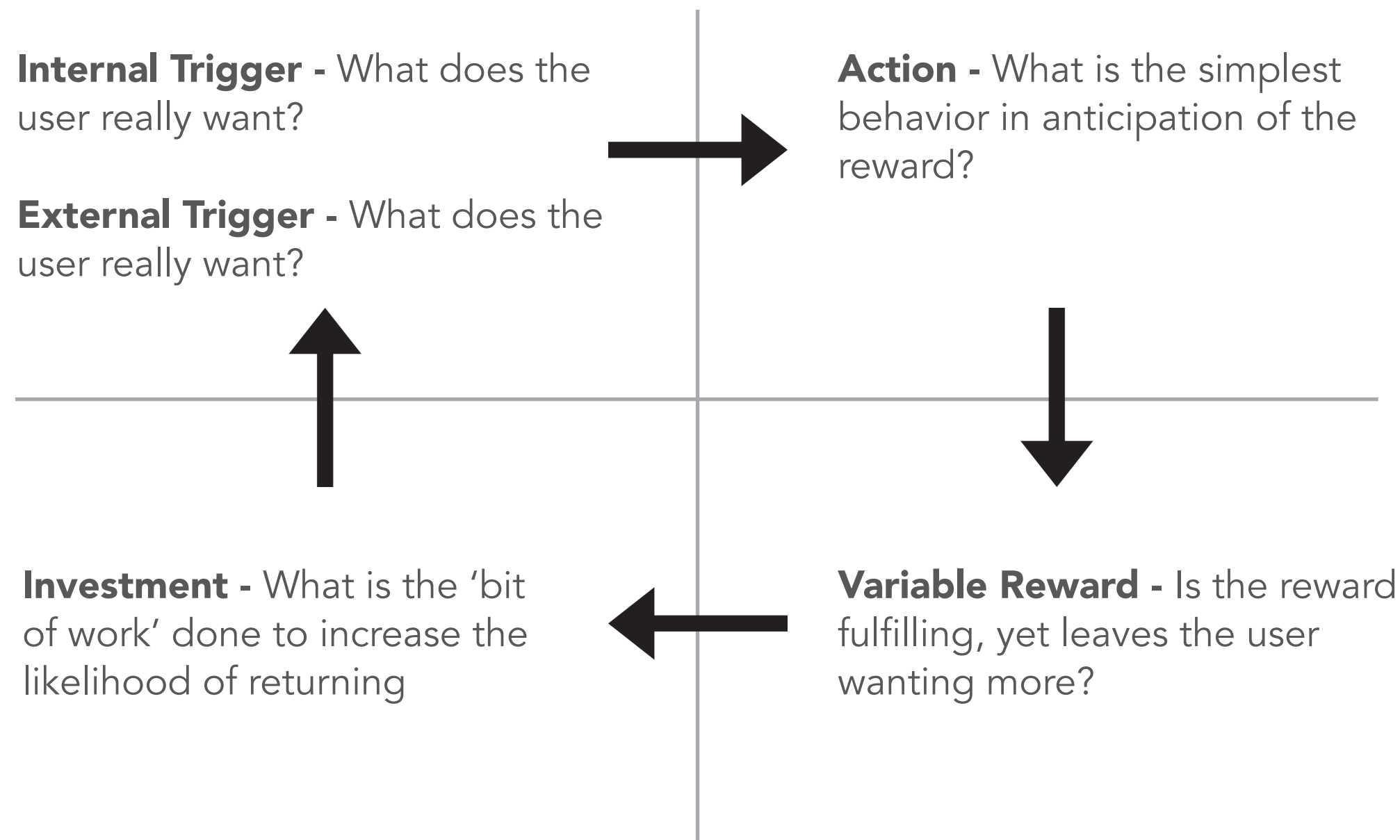


## Adjusting user attitudes



# ADHERANCE RESEARCH

## Reading and research on how to build habits in users



# PRODUCT ANALYSIS

## CPAP Teardown

Upon disassembling Transcend CPAP machine that I acquired, it is very evident that moisture control and prevention is important in the construction of CPAP machines. This CPAP machine has 5 gaskets, and multiple intermediary walls to prevent moisture from getting into different compartments of the machine, especially the circuit board. One thing this CPAP machine doesn't have that I will need to consider is a humidifier, which surely takes up additional room.

The air pump in the CPAP machine is relatively small, only about 1.5" tall by 2.25" in diameter. This tells me that the size of the CPAP machine could be scaled down. Further, I managed to track down the serial number in case I might need to purchase another for prototyping.



# PRODUCT ANALYSIS

## CPAP Mask

In the teardown of this nasal pillow CPAP mask, it appears to be relatively simple with very few parts. One notable thing about the materials of the mask is that most are soft. The tubing is a soft matte silicone, the strap has a squishy neoprene feel, and there are also two fabric cushions for where your cheeks touch the tubing. It was very easy to disassemble and reassemble.



# BRAINSTORMING

## Mind Mapping

CPAP Therapy

Portable

CPAP Tubing

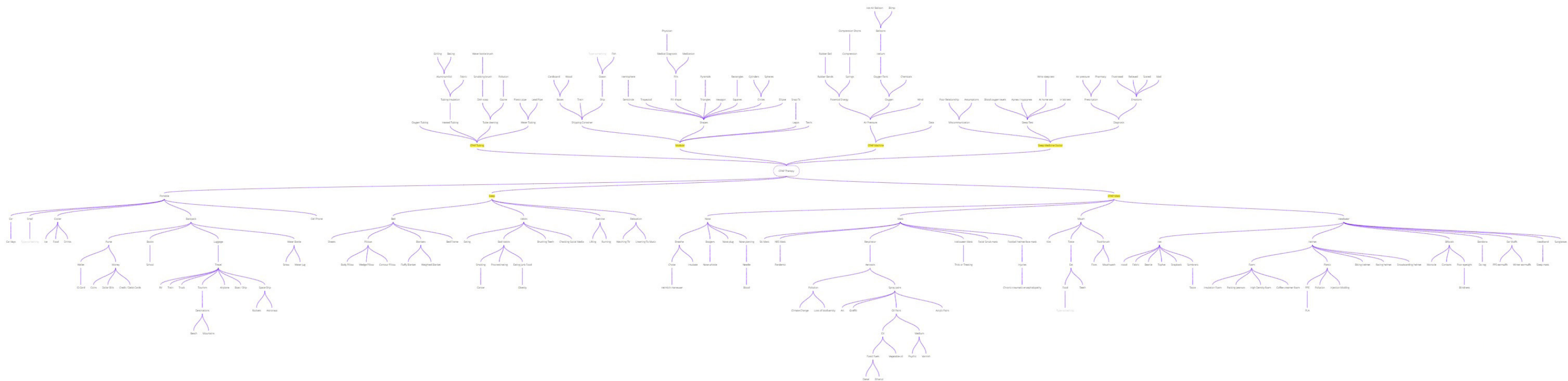
Modular

Sleep

CPAP Mask

CPAP Machine

Sleep Medicine Doctor



# BRAINSTORMING

22 Ideas

## End User Co-Creation Brainstorm

App Solutions

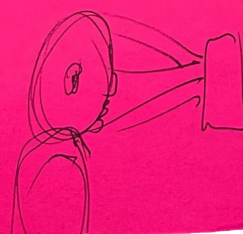
Prescriptive Software

App Feedback, feedback on how you're doing  
User set goals/minimums  
↳ notification if you're under your own compliance

Online software for facial sizing

A better system for finding the right mask

Prescriptive Scan to determine correct mask style & sizing

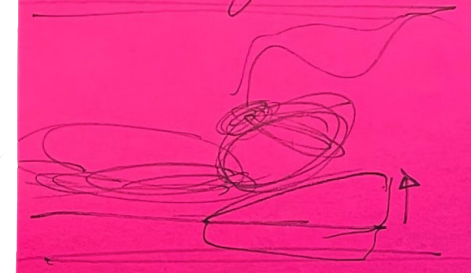


Sizing headset  
• Kit w/ measurement device  
• Nose dimension  
- Head size  
• measure from  
Nose - around head - back to Nose

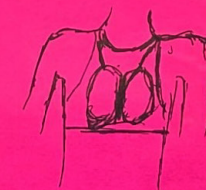


Inflatable Solutions

Pillow that inflates into a wedge

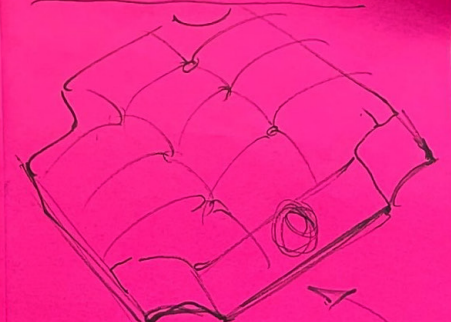


Nest with inflatable pillows



causes enough discomfort to make you sleep on your side

Inflatable Pillow



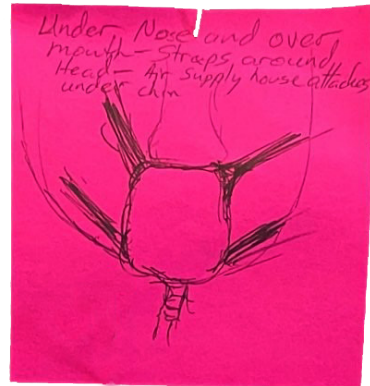
Contour Pillow



# BRAINSTORMING

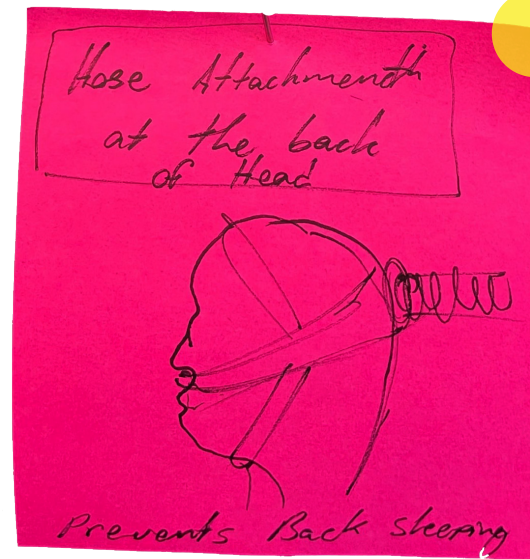
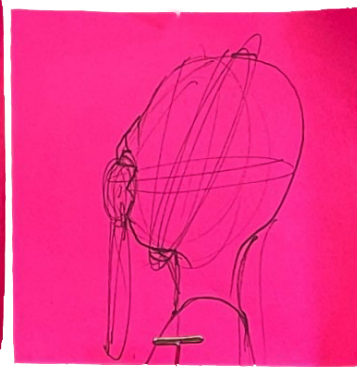
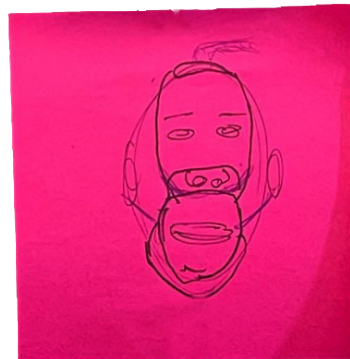
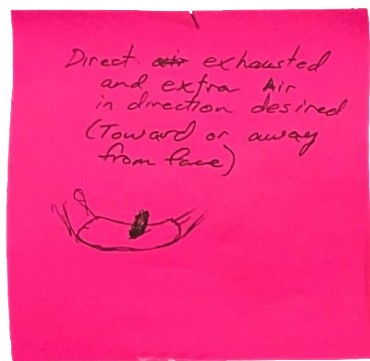
## End User Co-Creation Brainstorm

Mask Variations



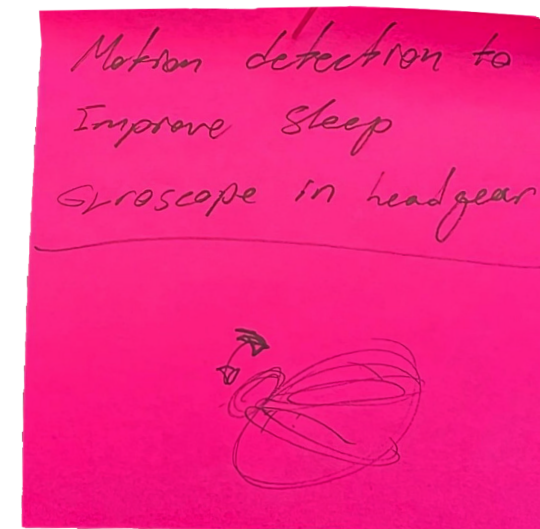
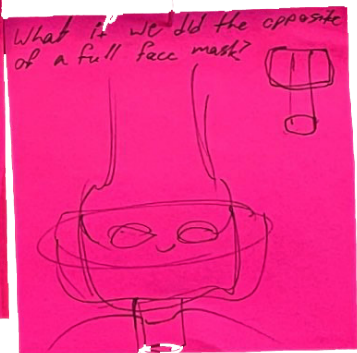
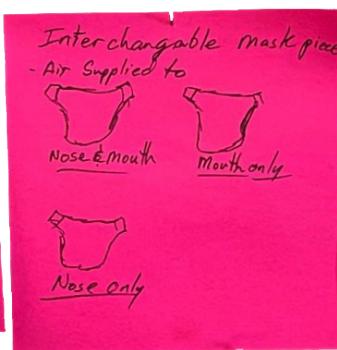
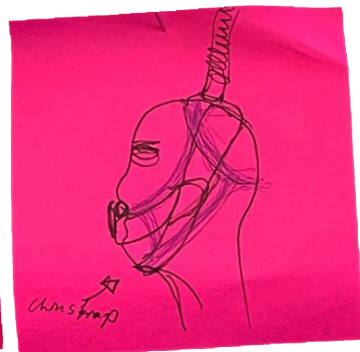
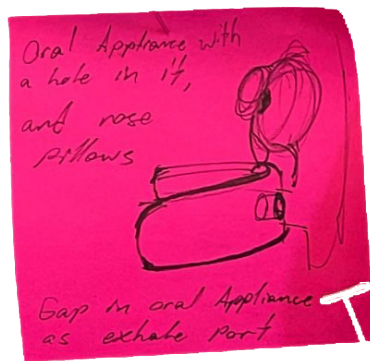
Hose Connection

Customized Mask Production



Sleep Motion Detection

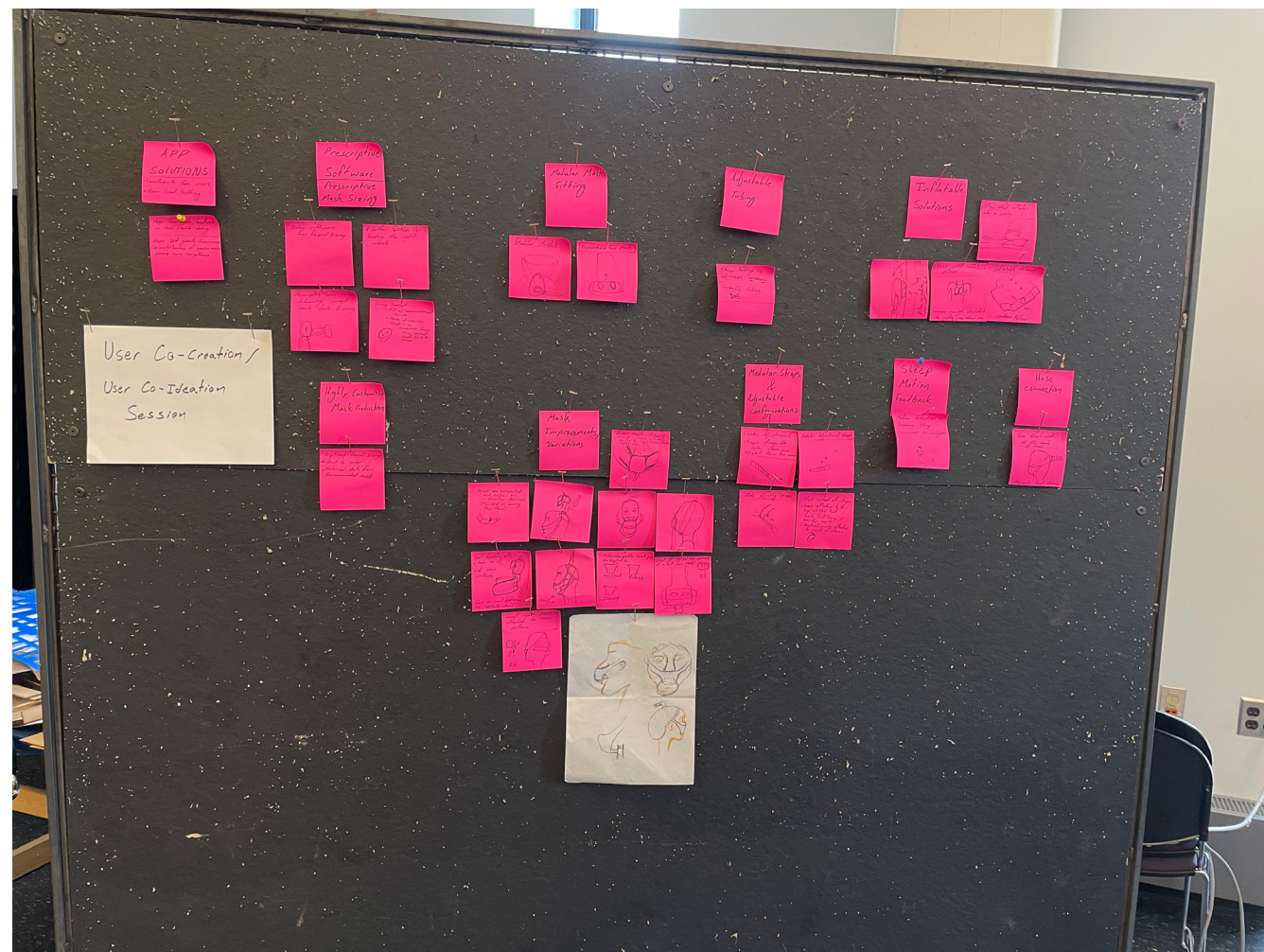
Digitized facial sizing  
3D Print to order  
- Historical data for Recommended mask



# BRAINSTORMING

## End User Co-Creation Insights

The co-creator focused primarily on mask fit and figuring out what mask size to start out with. He wasn't so interested in products that improve the travel experience as much as he was concerned about the quality of sleep the new user might get starting out.



High focus on:

Mask fit

Mask desensitivation

Individual goal setting

CPAP machine interface

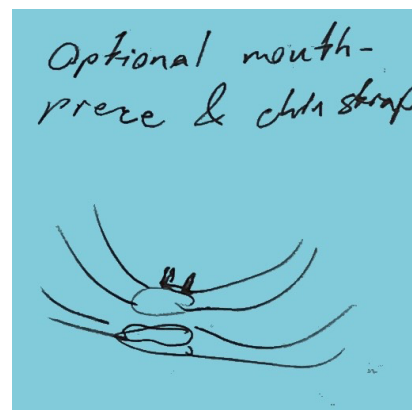
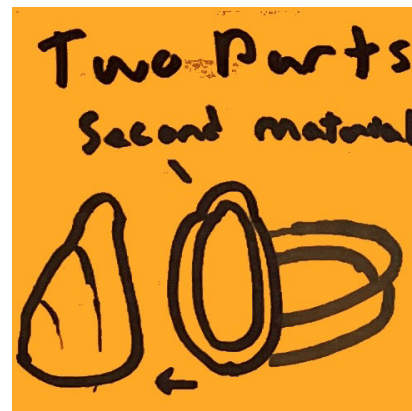
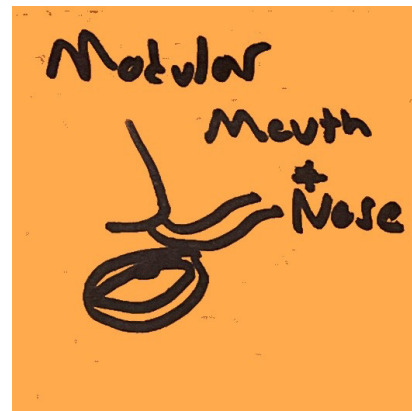
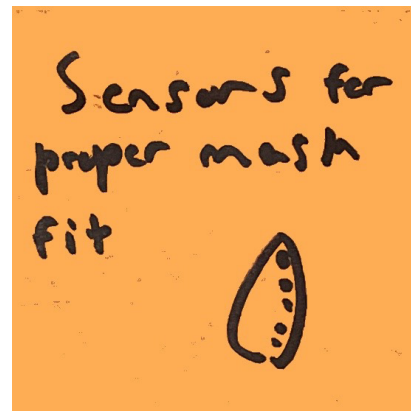
Finding the right mask

Mask production

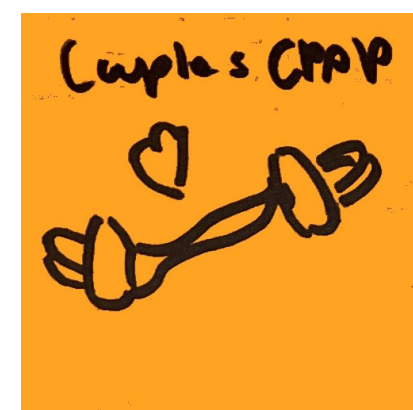
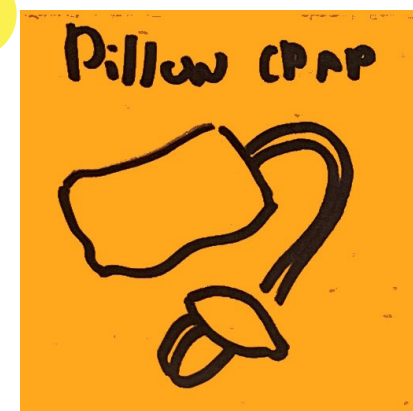
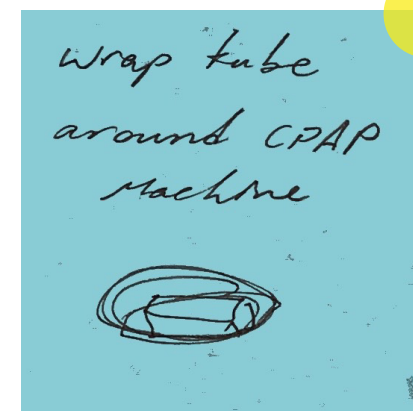
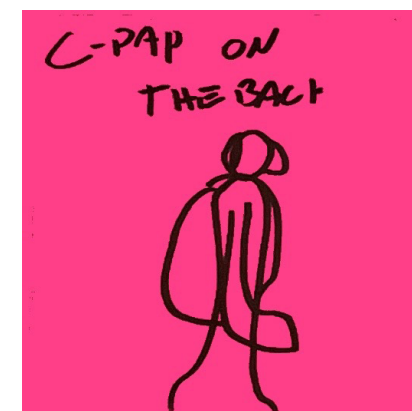
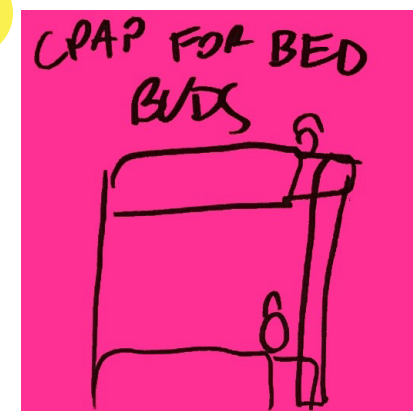
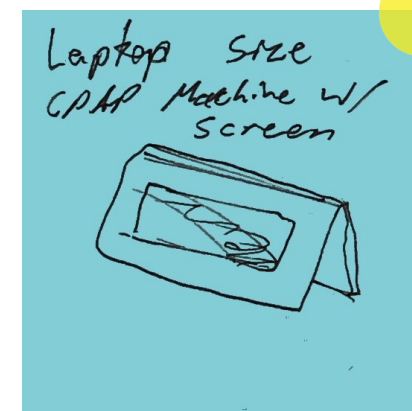
# BRAINSTORMING

## Small Group Brainstorm

### Mask Improvements



### Machine Configurations



# BRAINSTORMING

## Small Group Brainstorm

### App Solutions

Diet & exercise suggestions from app



Machine Rewards you for good sleep or good adherence



How WAS YOUR SLEEP?



Prescriptive process for pressure based on data & user input



more mask diagnostics  
↓  
Prevent people from cheating

PAIRS WITH SLEEP TRACKING

Sleep Points



BLOOD PRESSURE VITAL MONITORING

ALARM CLOCK CPAP



CPAP pillow w/ mask & machine in it



Alerts for removed hose

### Mask Technology

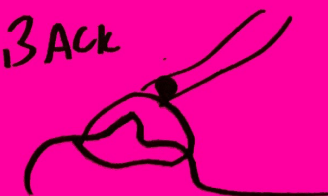
Buzzer for Alarm (ring)

CAPACITIVE MASK



MOTION TRACKING MASK

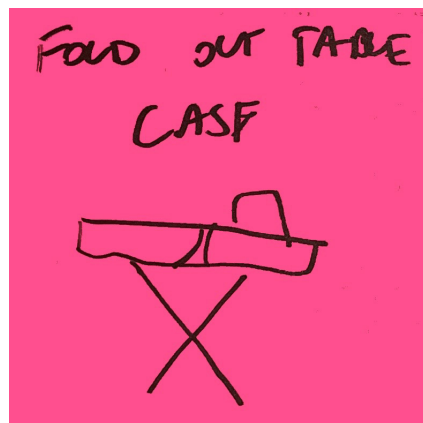
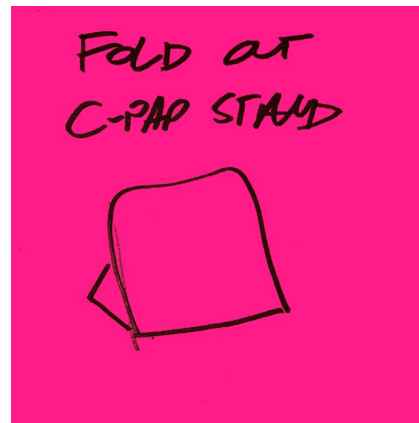
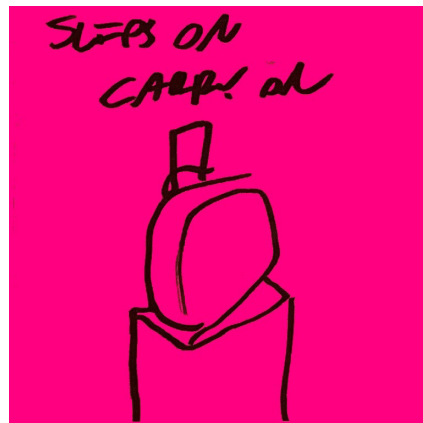
MASK CLOGS WHEN ON BACK



# BRAINSTORMING

## Small Group Brainstorm

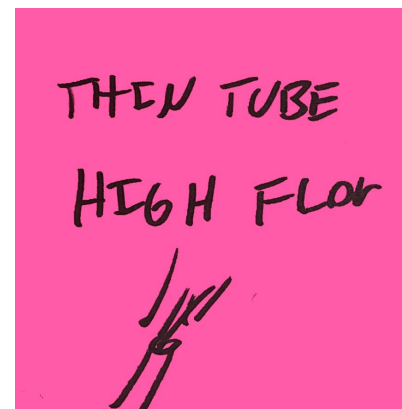
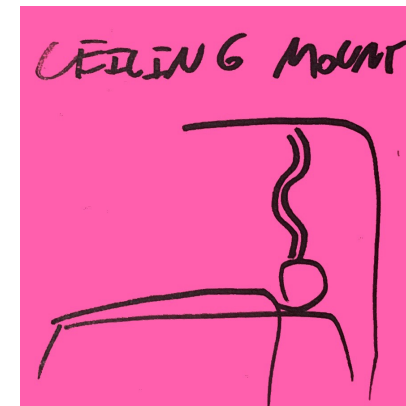
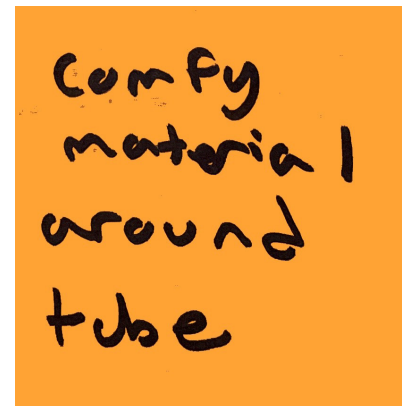
### Accessories



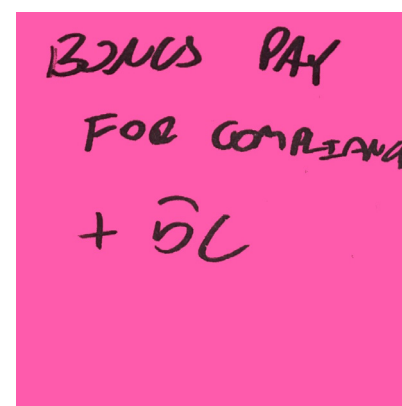
### Modular Straps



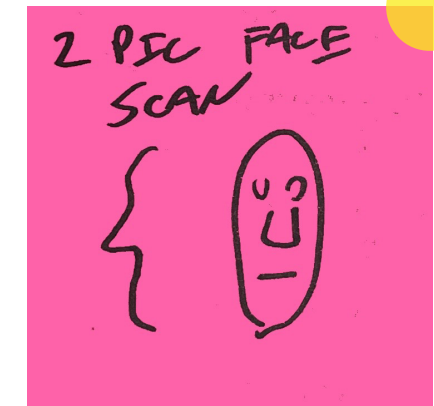
### Tubing Variations



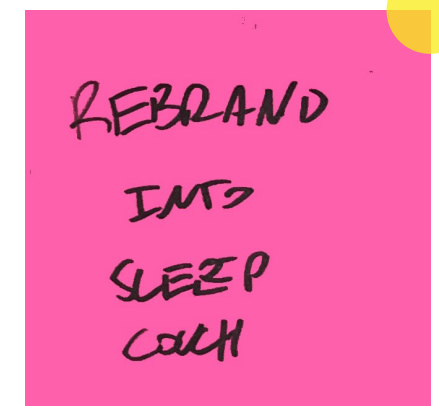
### Adherence Incentives



### Prescriptive Software



### Other



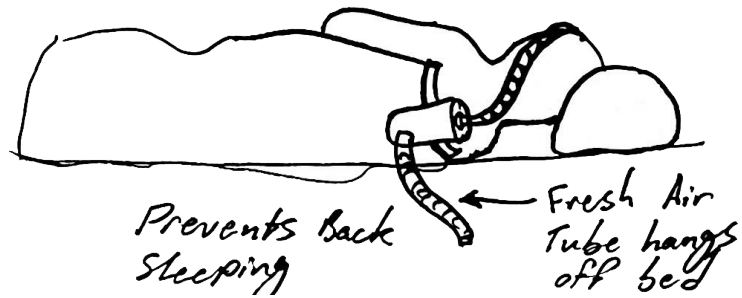
# BRAINSTORMING

37 Ideas

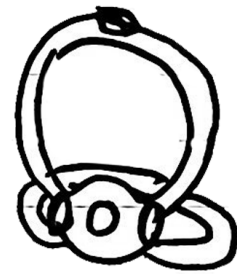
## Individual Brainstorming

### Mask Solutions

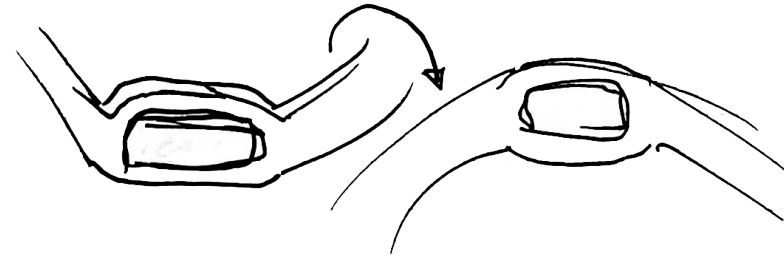
CPAP Machine Strapped To The Back



Modular Mask connection points



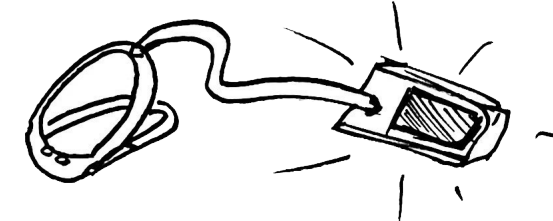
Mask geometry can be flipped upside down to make a new fit



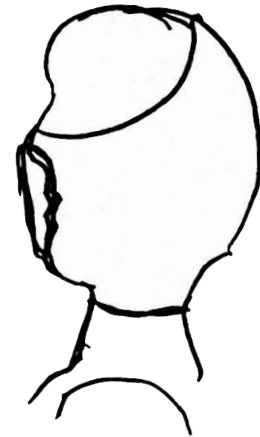
Desensitization mask attachment stimulates face for break-in period



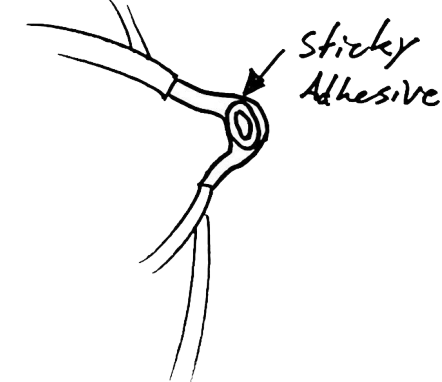
CPAP Light turns on when CPAP Mask is off



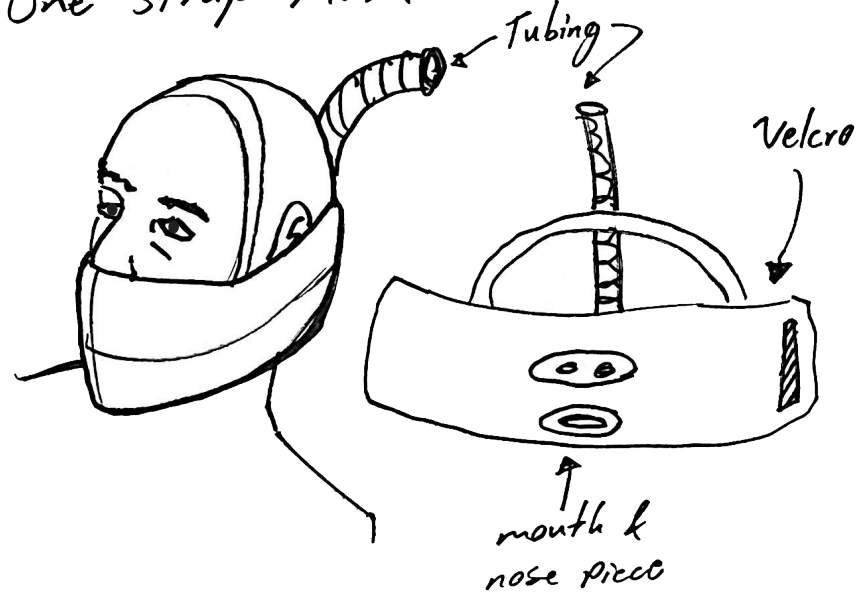
Compression fit Mask



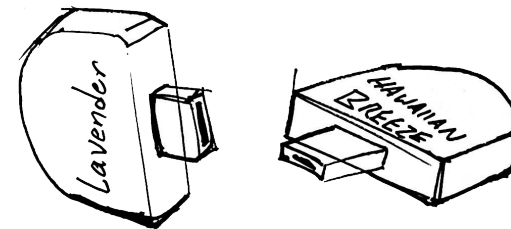
Stick-on Mask sticky adhesive



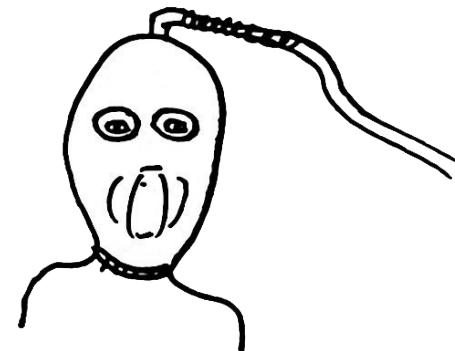
One Strap Mask



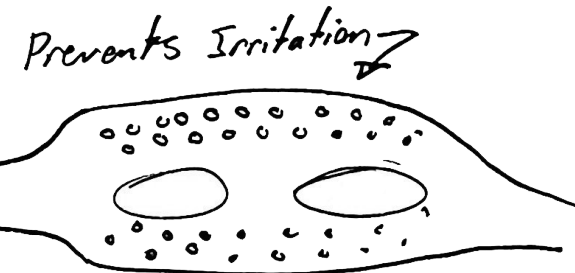
CPAP oxygen "Flavor" pods



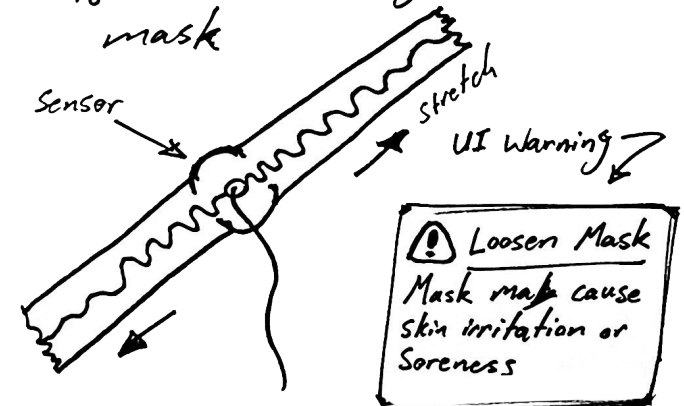
Ski Mask CPAP Mask



Mask That Releases Topical Numbing Cream



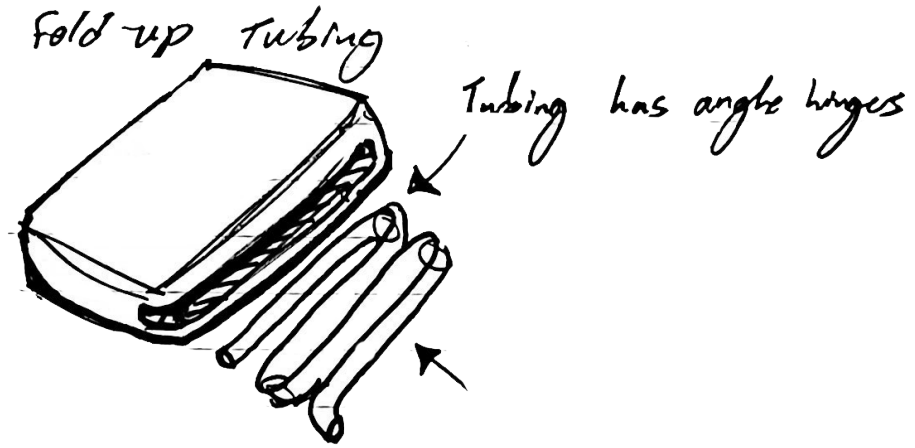
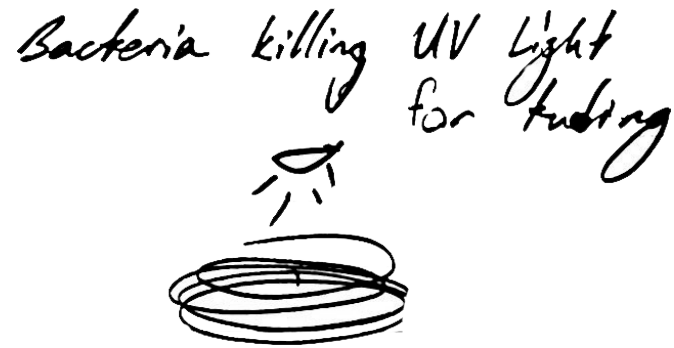
Sensors in mask strap to detect overtightened mask



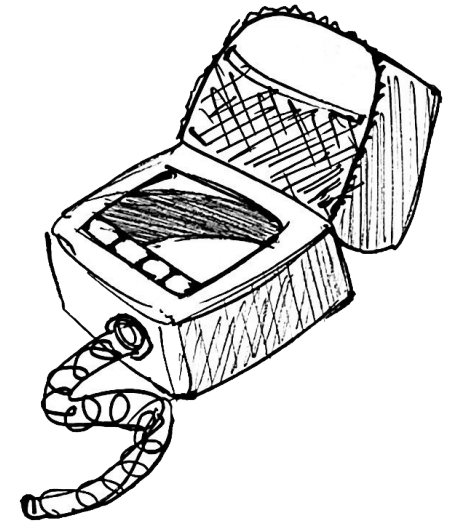
# BRAINSTORMING

## Individual Brainstorming

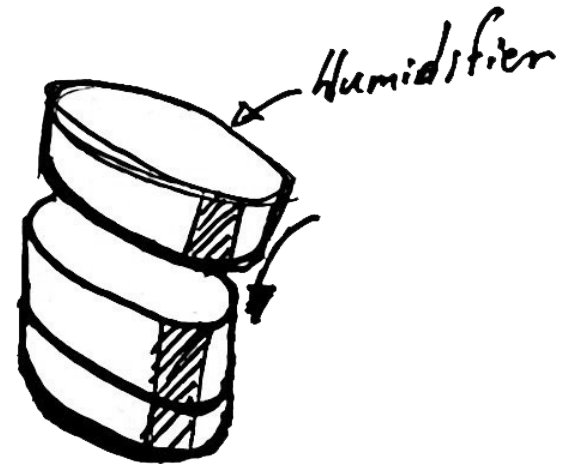
Storage Solutions



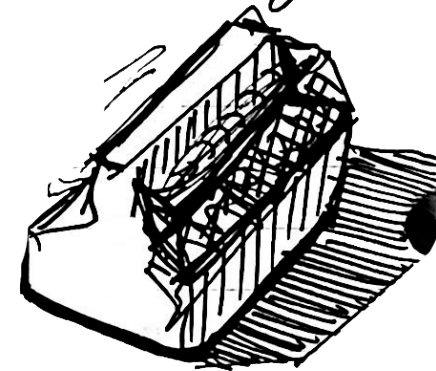
CPAP Machine is the Bag



Connectable feature Modules

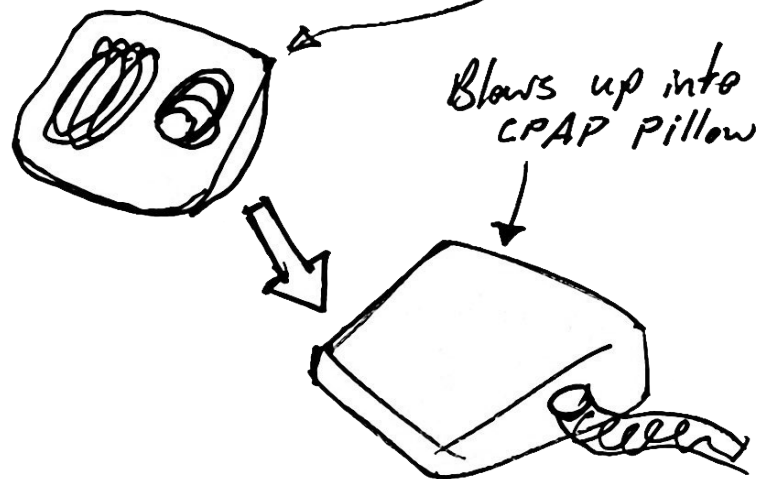


Machine has slots for tubing/Mask

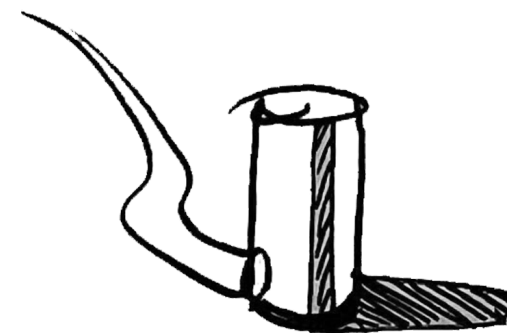


Blow-up pillow tubing & mask bag

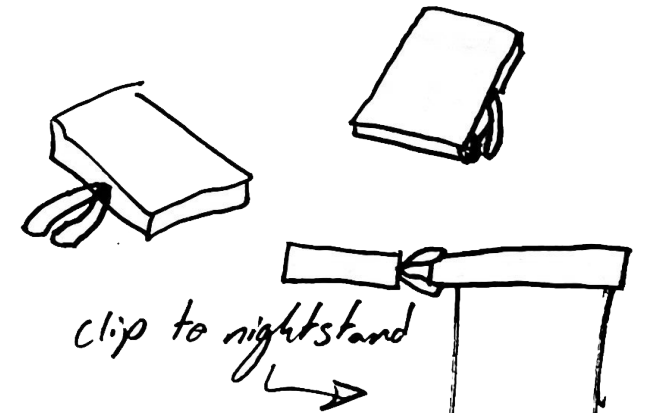
Holds mask & tubing



Water Bottle Size CPAP



Universal CPAP clip on CPAP Machine

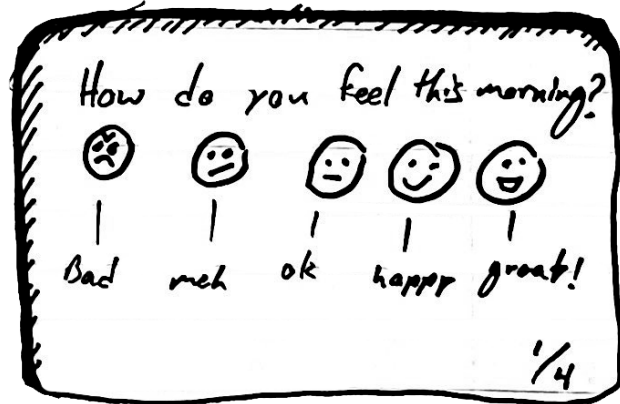


# BRAINSTORMING

## Individual Brainstorming

### Interface Solutions

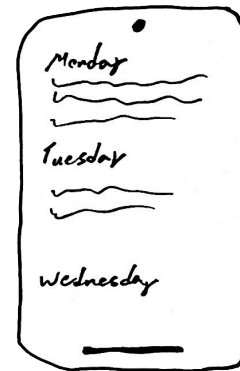
Routine Sleep Survey  
On the machine



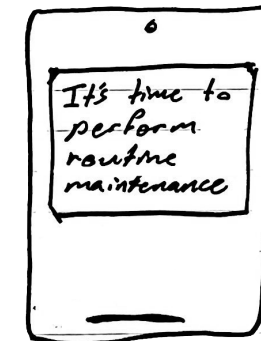
CPAP Screen Movie  
Streaming



CPAP Dream Journal



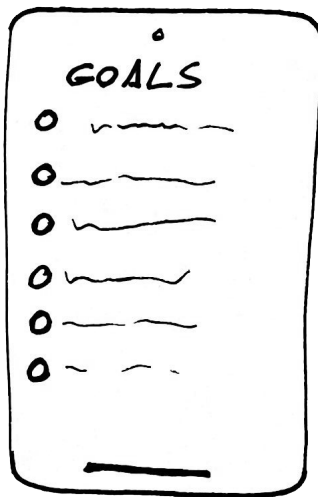
Clean the tubing reminders



Regular Doctor updates

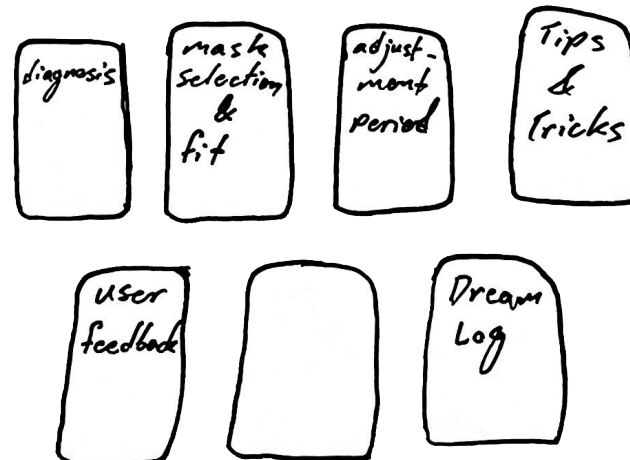


User sleep Goal setting & monitoring

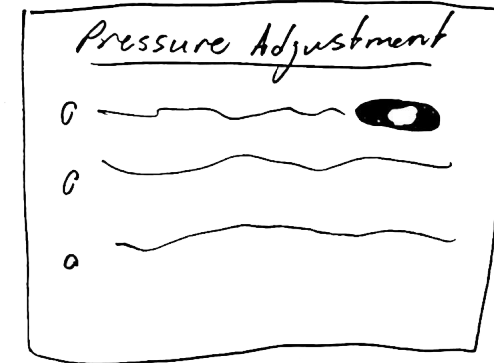


App that walks people through the  
sleep apnea adjustment process

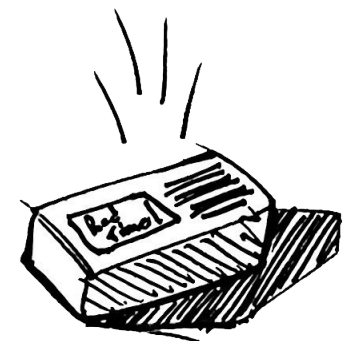
"CPAP Sleep Wellness"



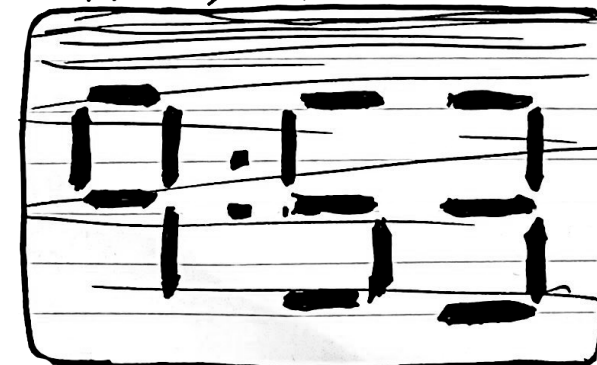
CPAP Machine UI  
Heuristics improvement



Machine Bedtime  
Alarm

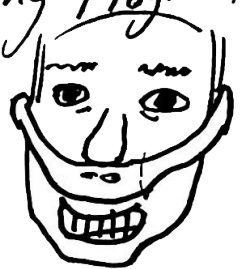


Alarm Clock Interface  
\*Make your hotel feel like home



CPAP Machine sleep  
Wellness Training Program

desensitization  
program





# SKETCH MODEL 1

## CPAP Stand Bag



This concept is a CPAP bag which converts into a stand for the CPAP machine and other accessories. It is a portable alternative for those whose cable doesn't reach the outlet from the nightstand.

The bag both keeps the users belongings safe and acts as a hybrid hard and softshell bag.

While this concept is interesting for the portability of the CPAP machine, mask, and tubing, it became evident after making this sketch model that it does not achieve the goal of increasing adherence. However, this sketch model is a good example of an accessory that could be used in conjunction with a stronger concept.

# SKETCH MODEL 2

## Side Sleeping Trainer



Made from a ziplock bag, masking tape, and a shoe string, this sketch model is a highly portable concept to prevent users from sleeping on their backs. Most apnea events happen when the user is sleeping on their back.

This exploration provided a quick mock up to discover how the concept might be further developed and incorporated into the CAPA machine system.

# SKETCH MODEL 3

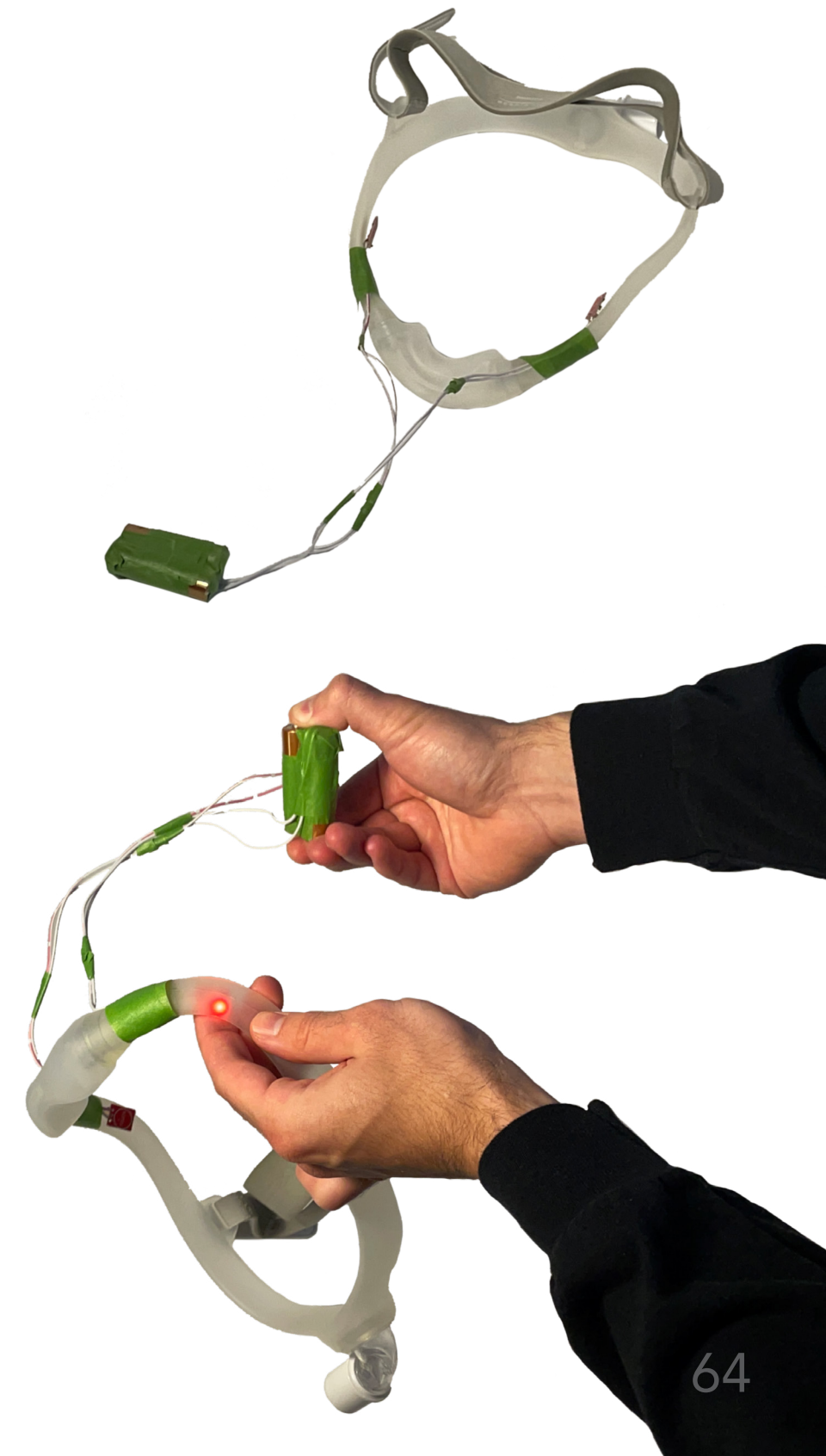
## Capacitive Sensor Mask



This concept uses capacitive sensors, LED lights, a battery pack, and a pre-existing CPAP mask as a structure.

The capacitive sensors are constructed such that the LED lights turn on, however in the actual concept the capacitive sensors might detect whether the user is wearing the mask or if the user accidentally removes the mask while sleeping.

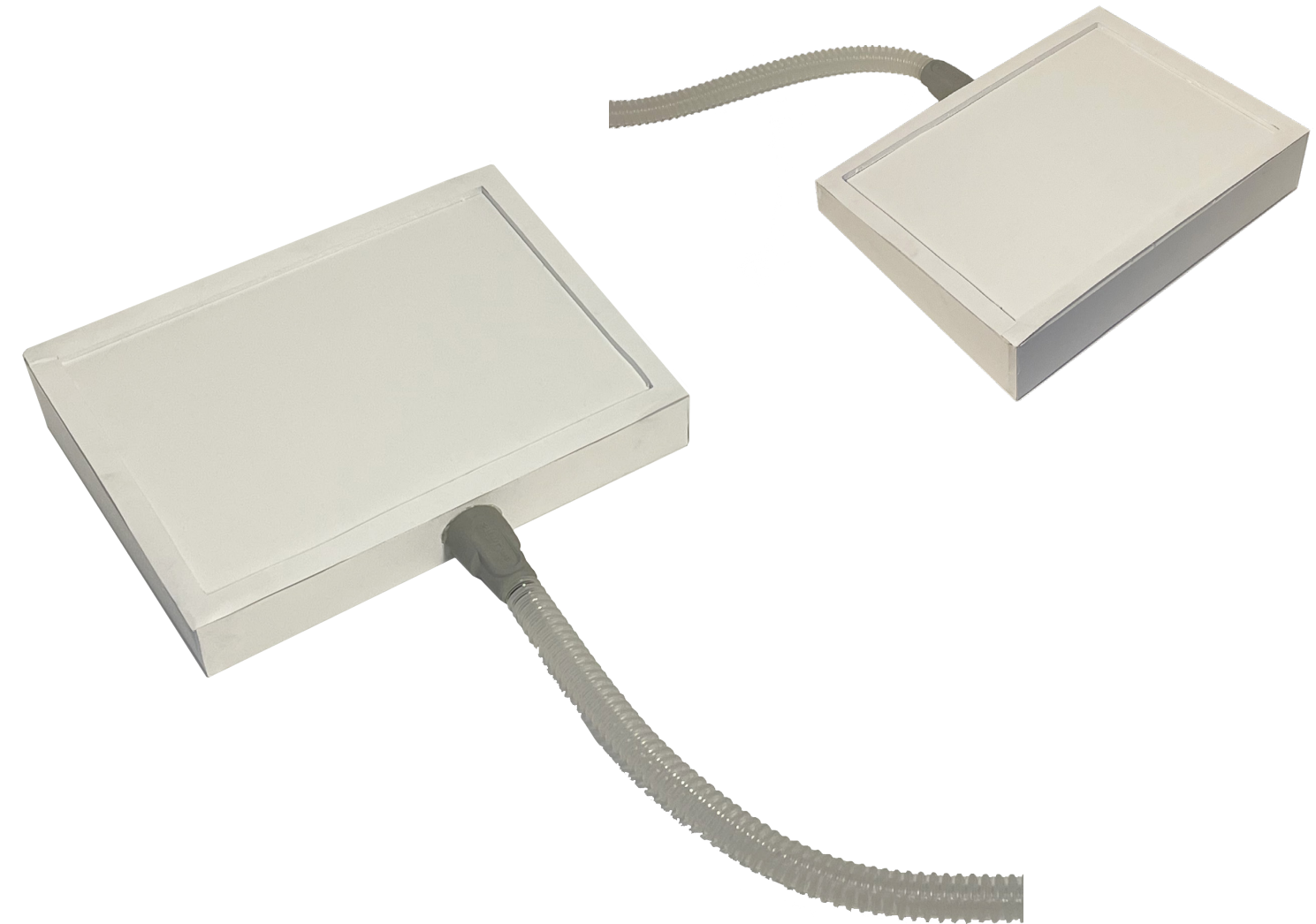
This sketch model reveals additional considerations to think about when incorporating sensors into the mask, such as where the wiring might go and which locations on the mask are good for skin contact.



# SKETCH MODEL 4

## Touch Screen CPAP Sketch Model

Exploring scale and ergonomics



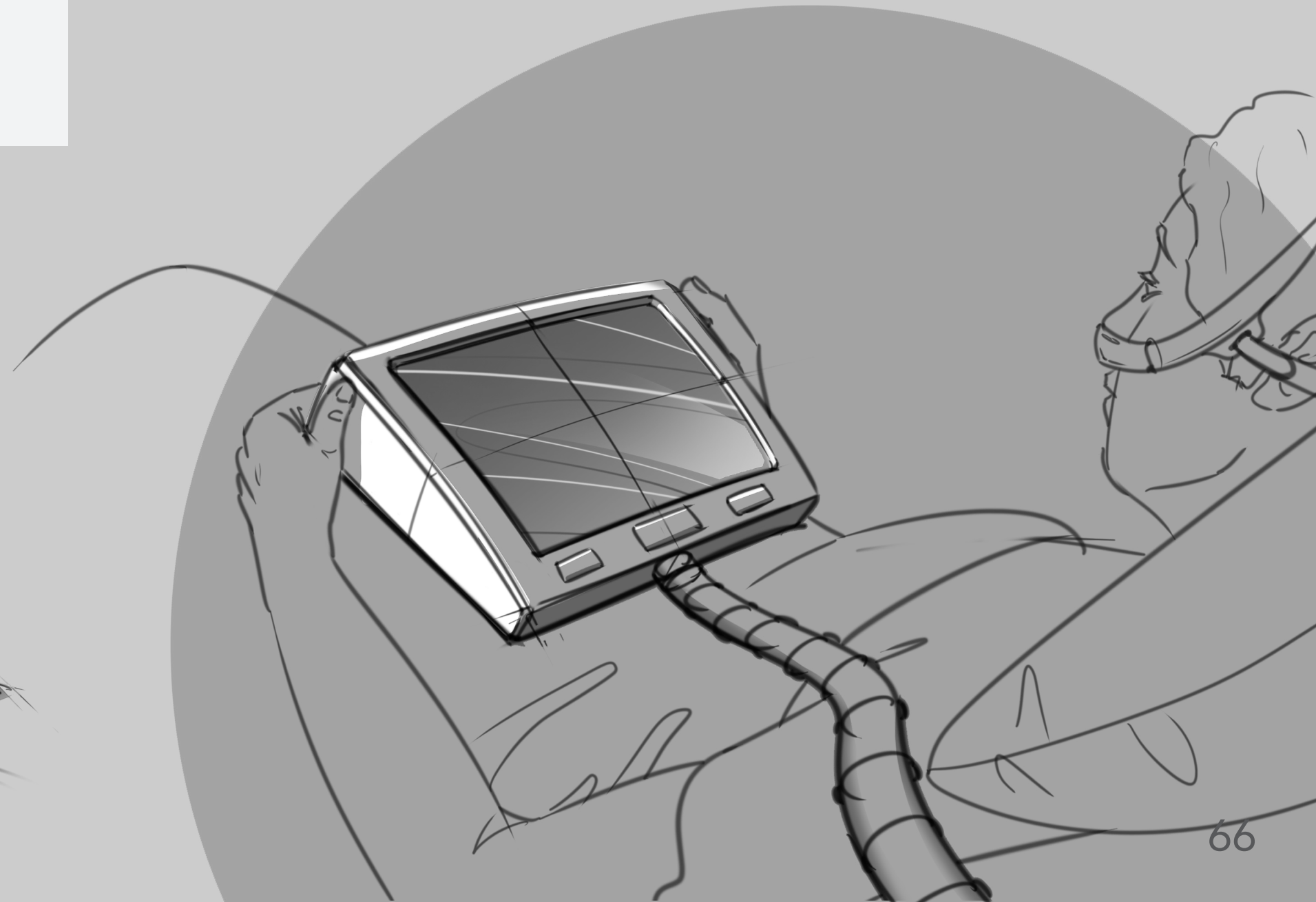
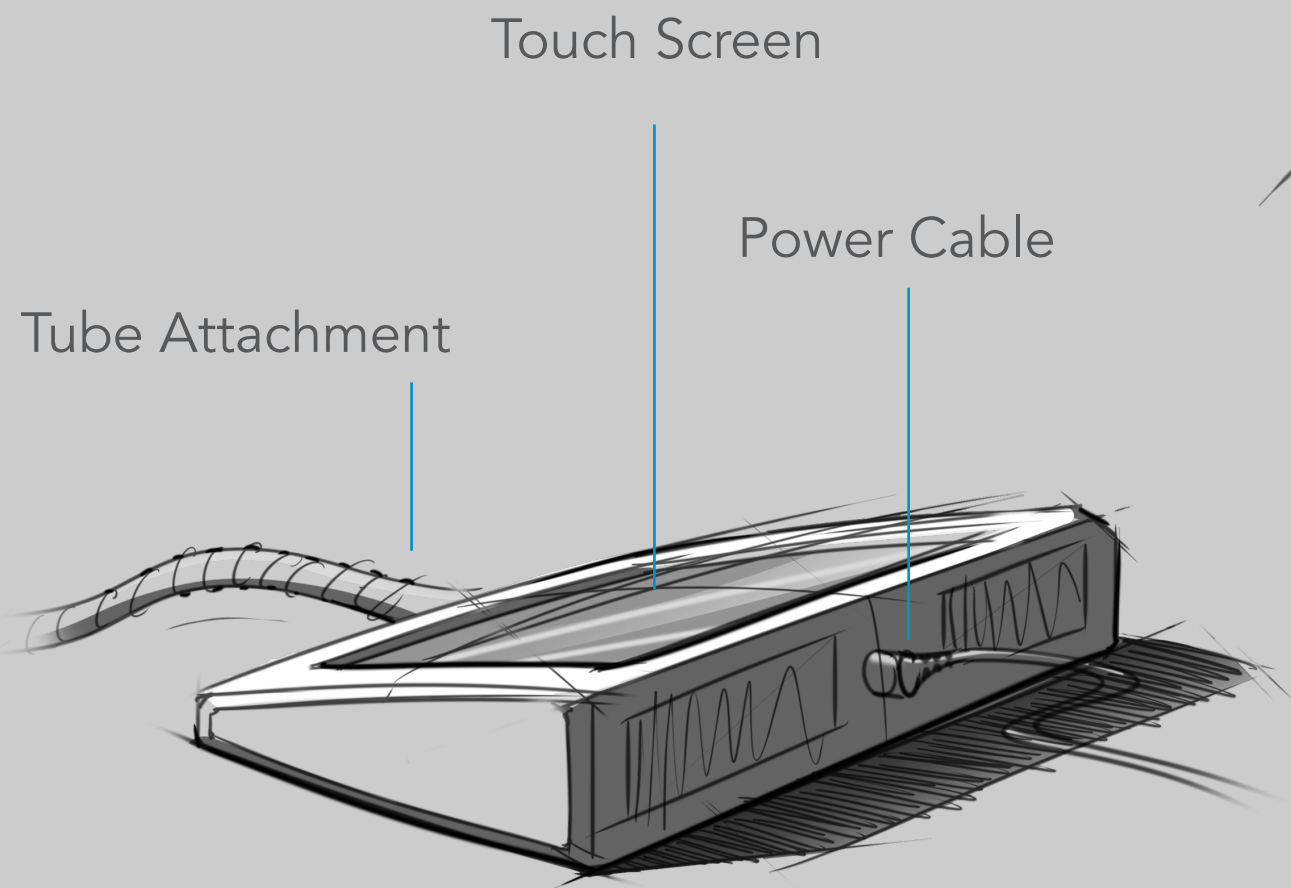
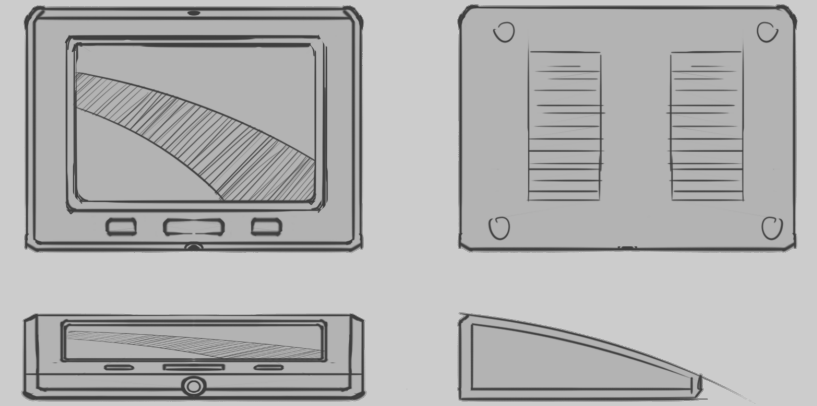
This sketch model helped me realize the importance of the CPAP tubing placement as it may not be comfortable with the tube pointing straight down while holding it. Further, this helped me test out the scale and how the machine might fit into a luggage for travel.

DOWNSELECTED CONCEPTS

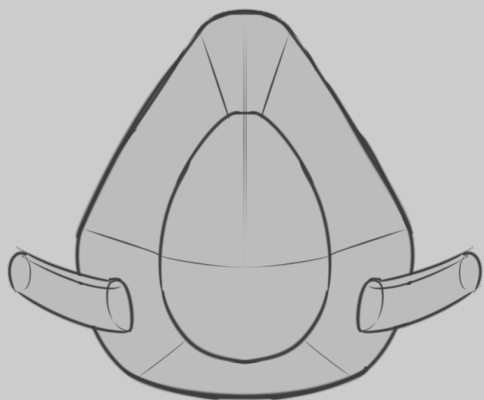
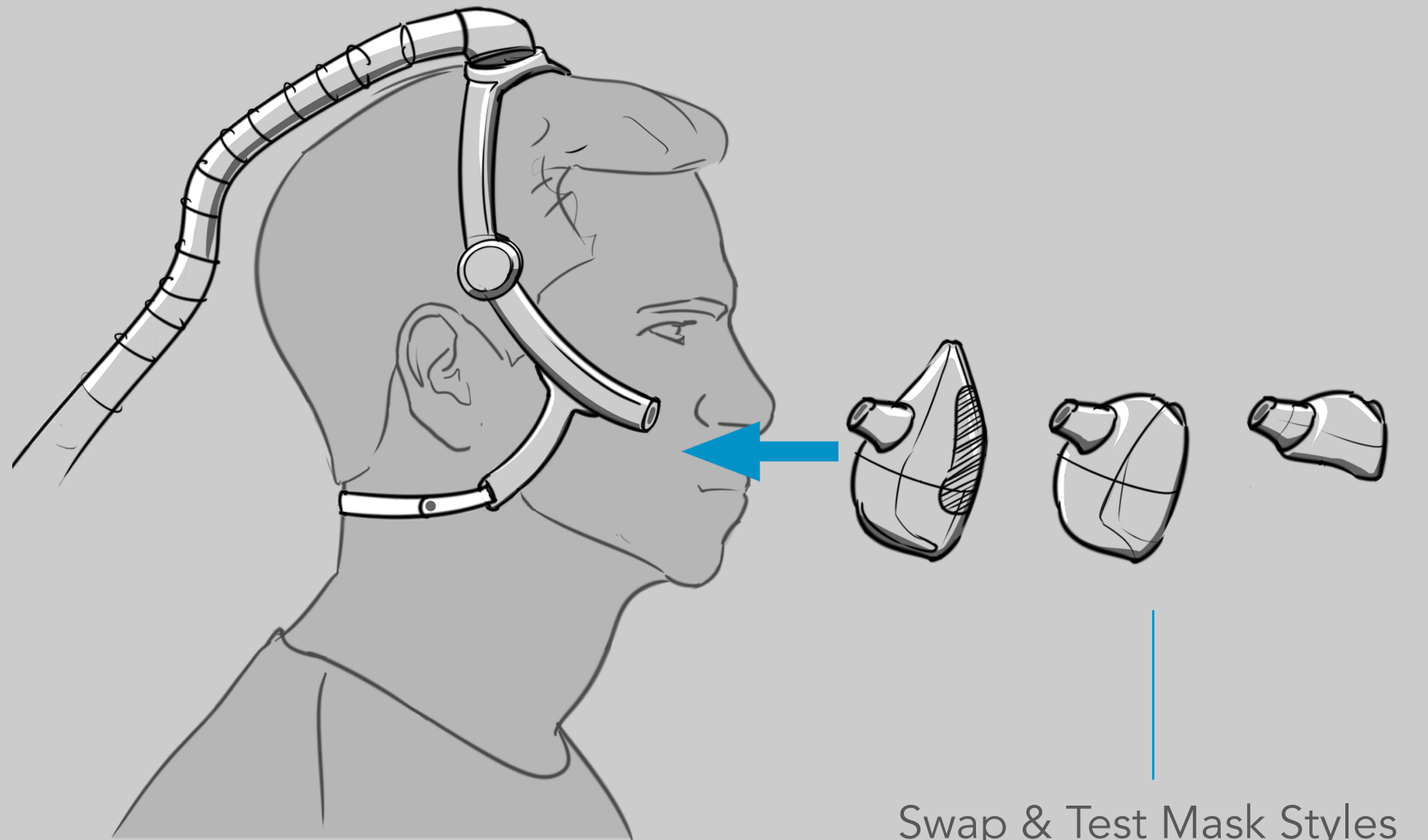
# A Touch Screen CPAP Machine

## Overturn the concept of CPAP therapy

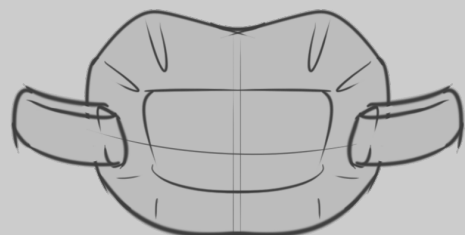
- Meditation
- Movies
- Music



# B Modular Mask & Adjustable Straps



Full Face

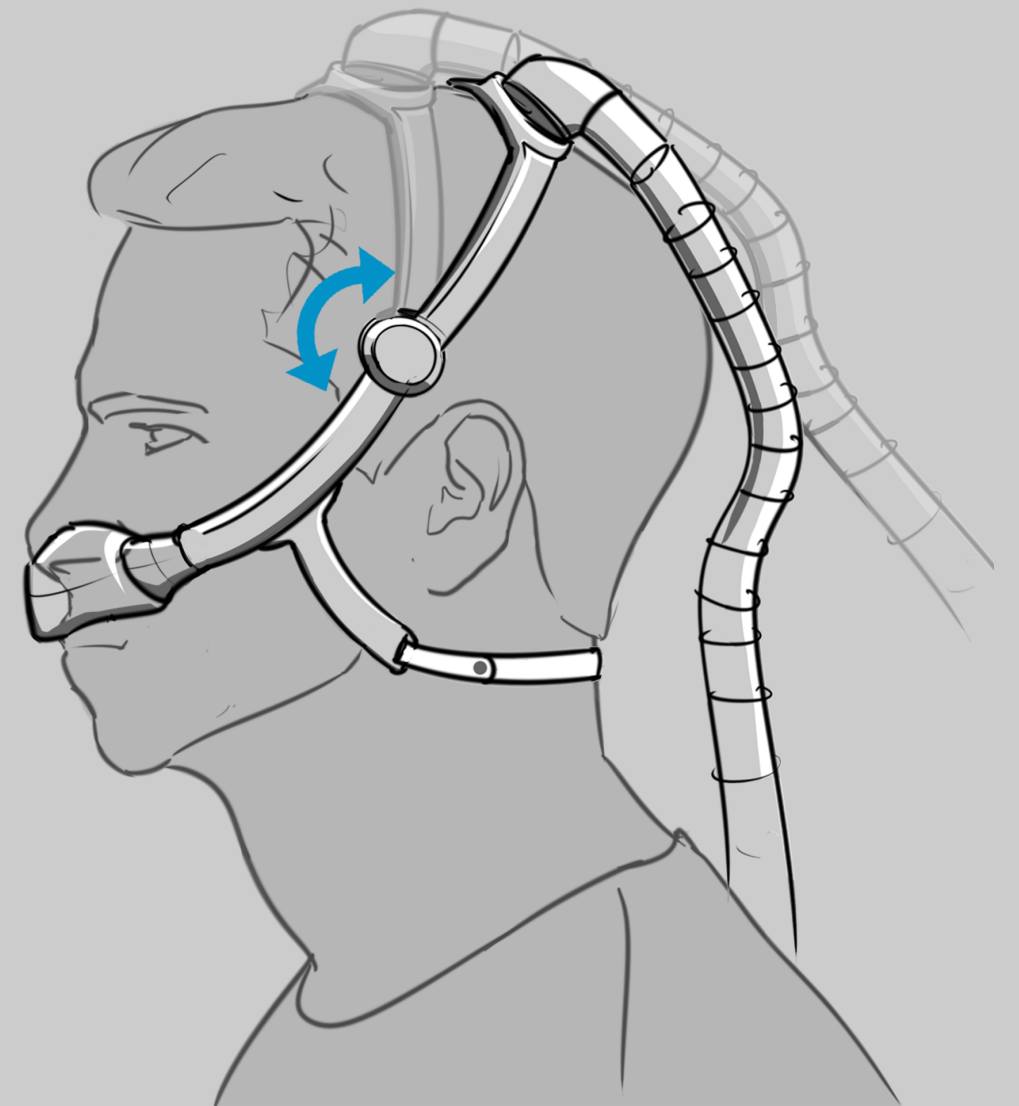


Hybrid



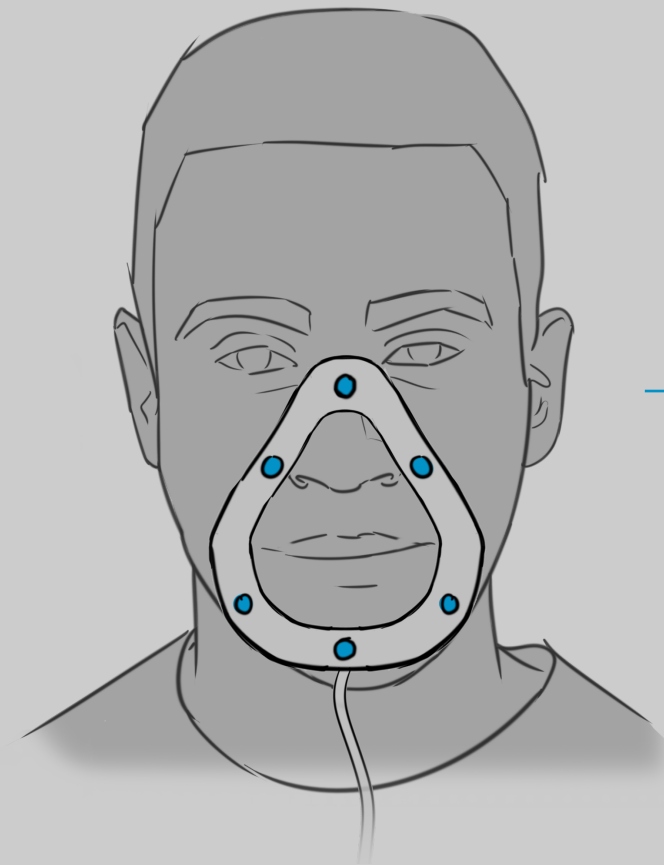
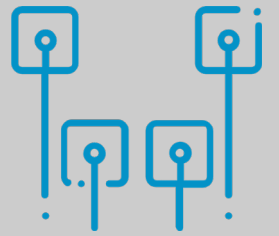
Nasal Pillows

Adjust Straps & Tubing Direction



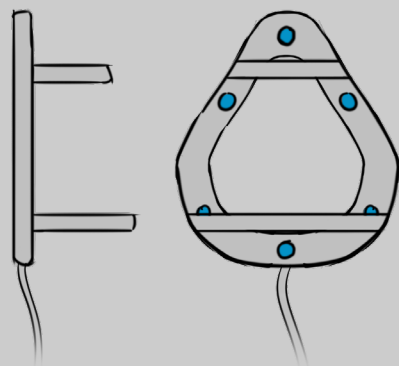
C

# Mask Desensitization Module

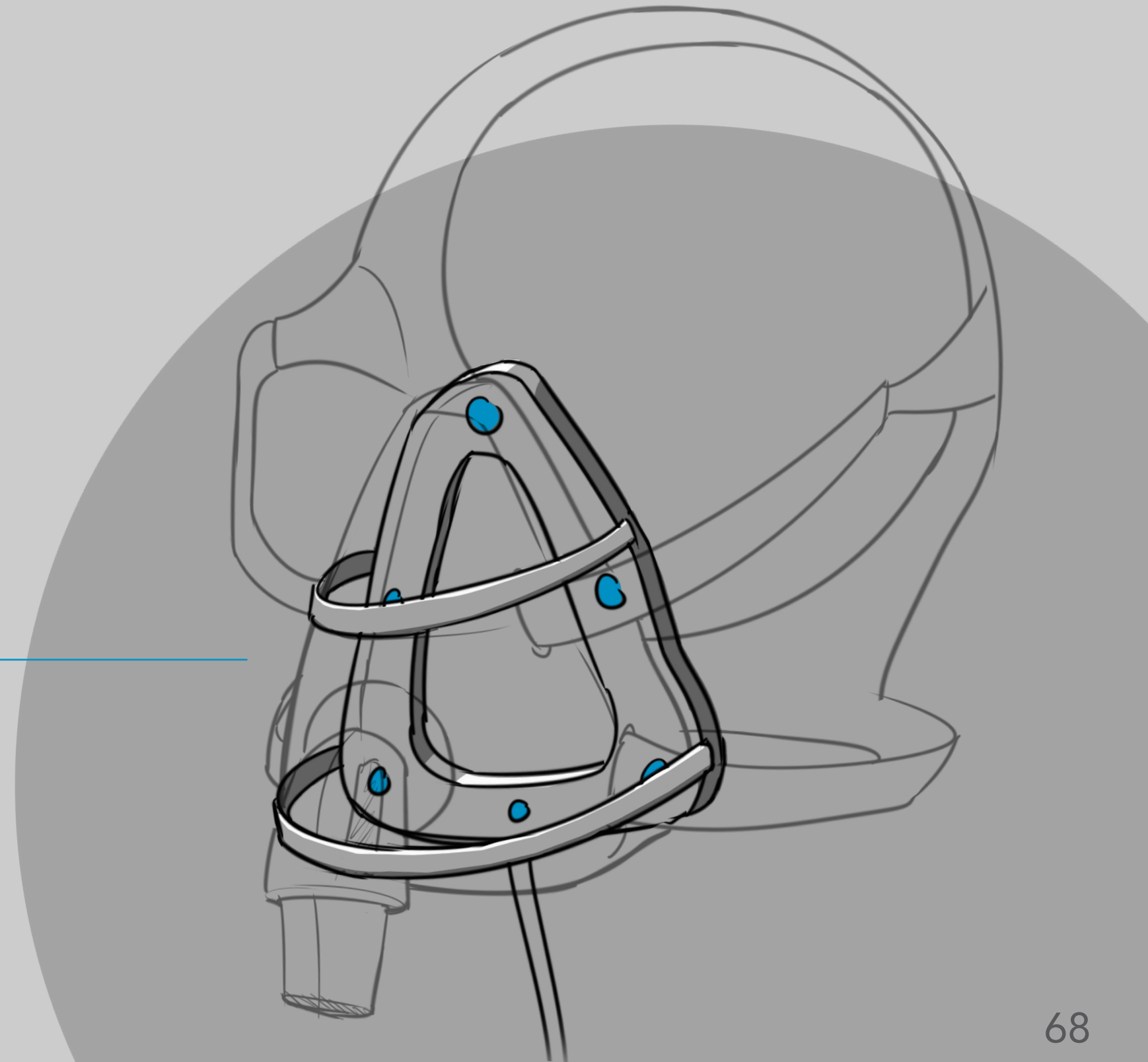


————— Muscle Stimulation

Straps Around Existing Mask



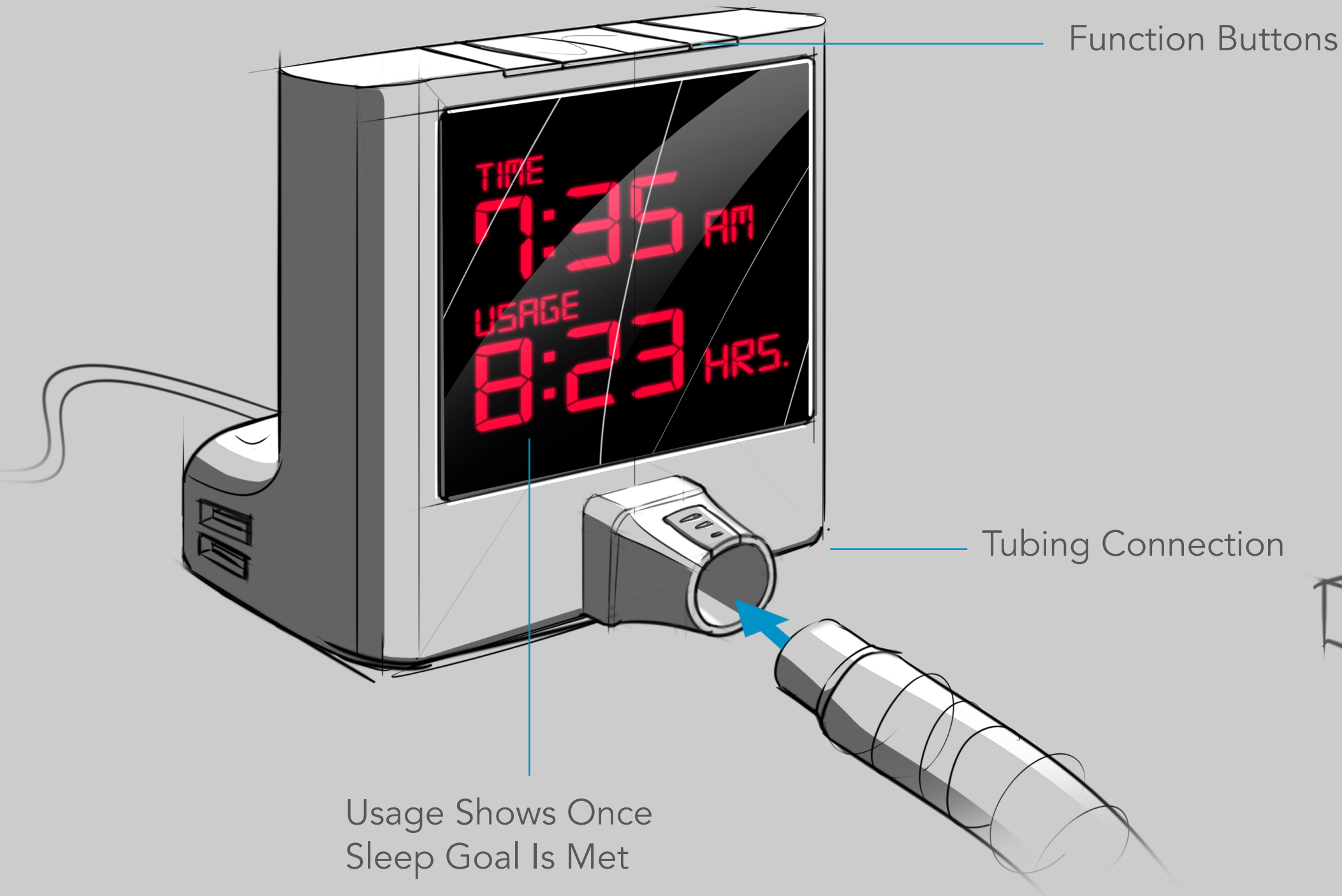
Shortens Desensitization Period





D

# Alarm Clock CPAP Interface

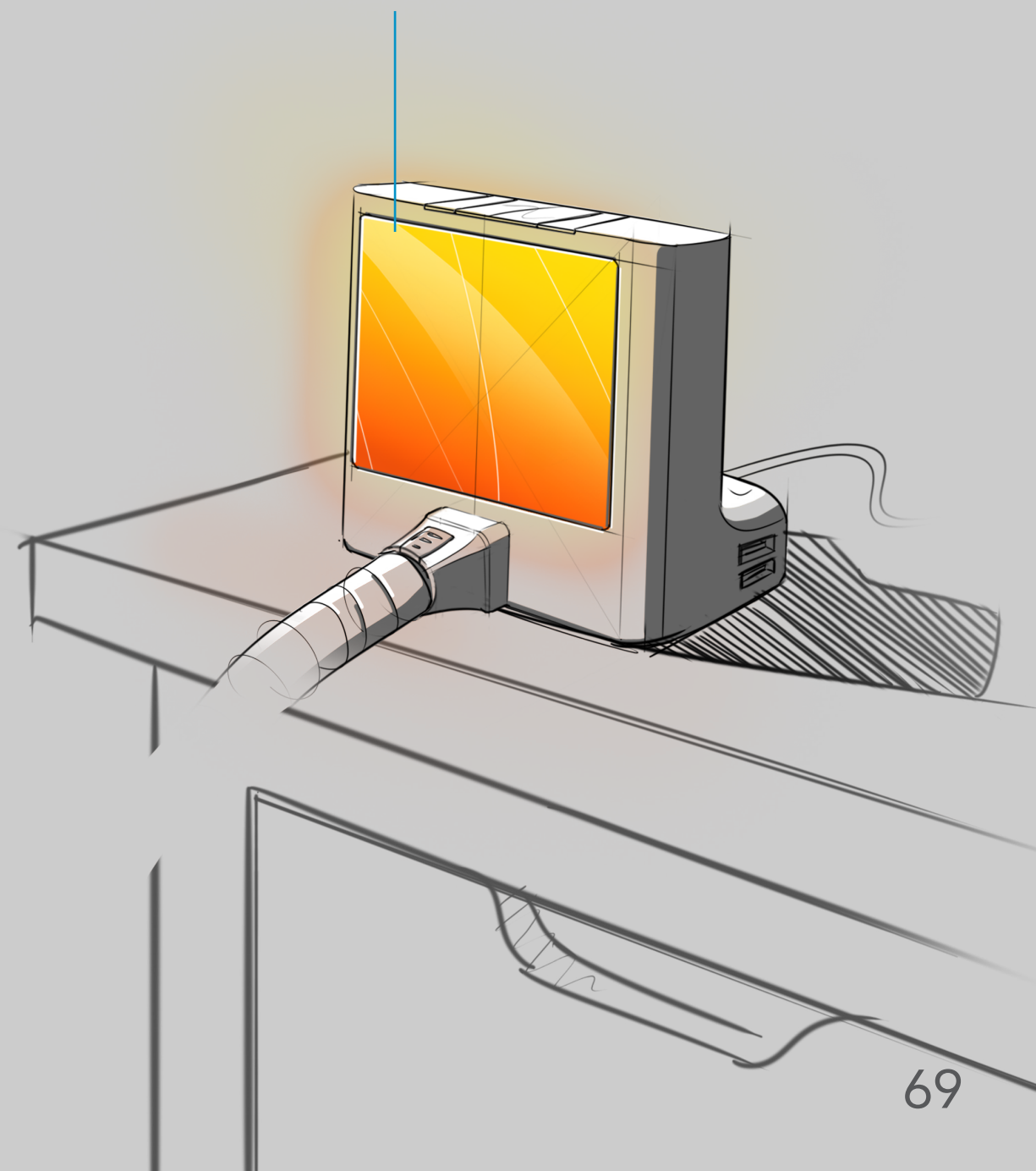


Function Buttons

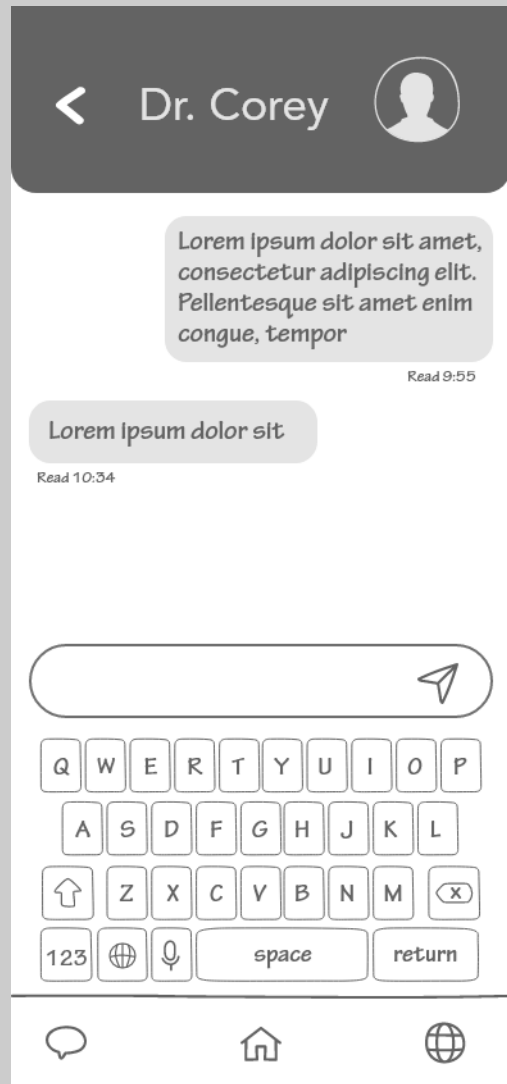
Tubing Connection

Usage Shows Once Sleep Goal Is Met

Sunrise Simulation



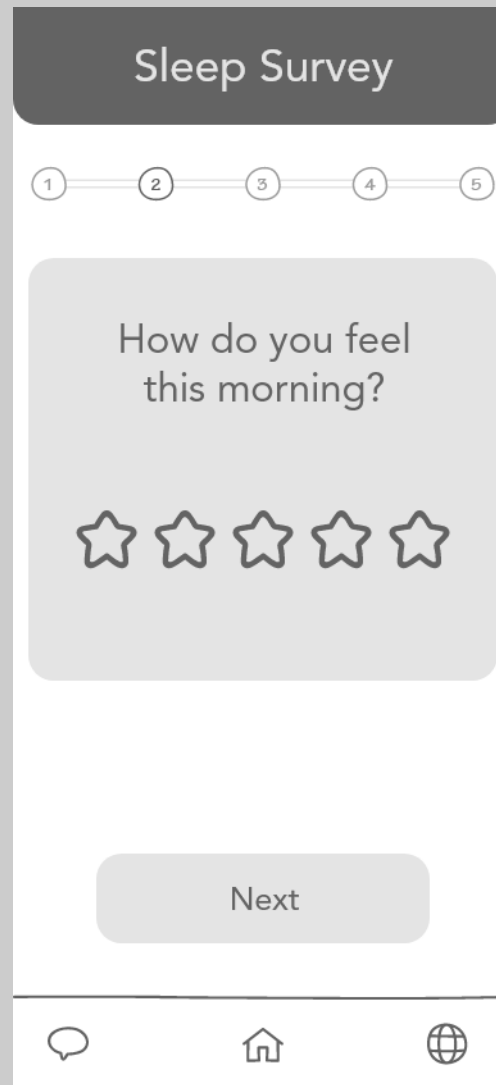
Increases Emotional Connection To The Product



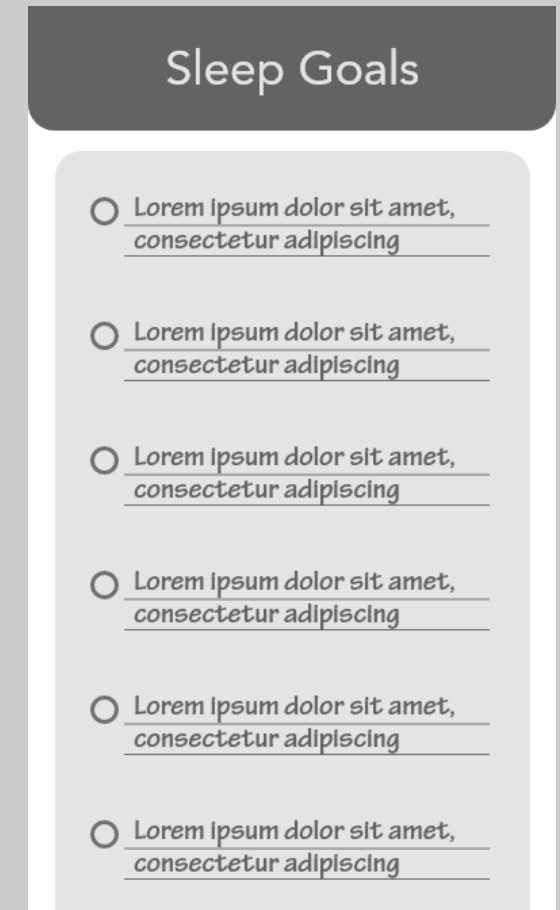
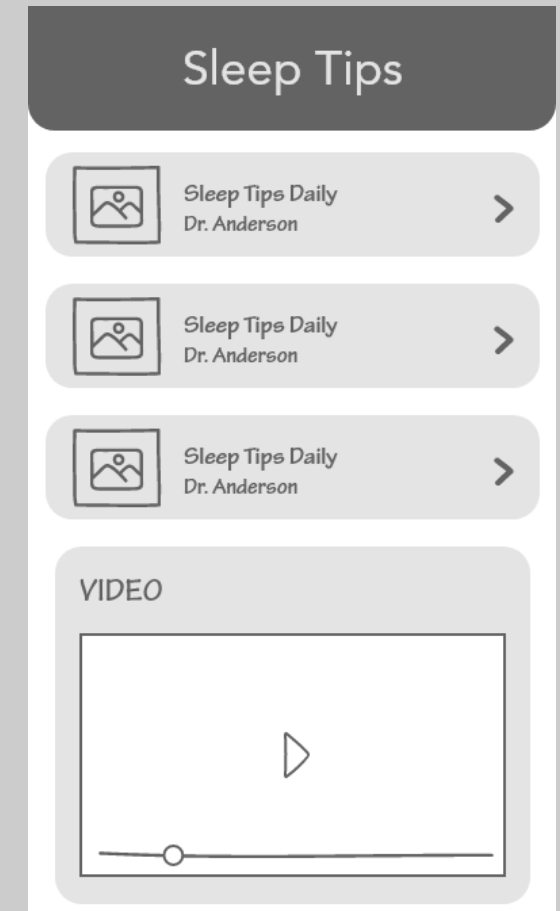
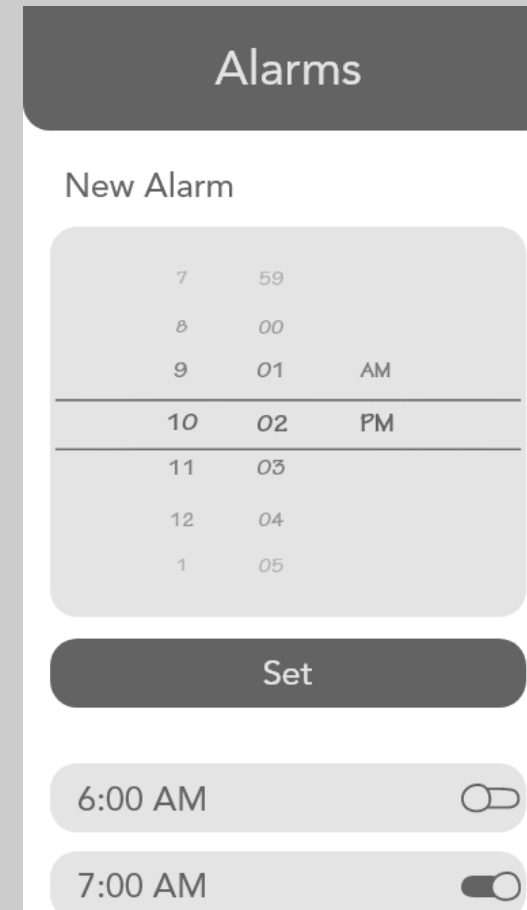
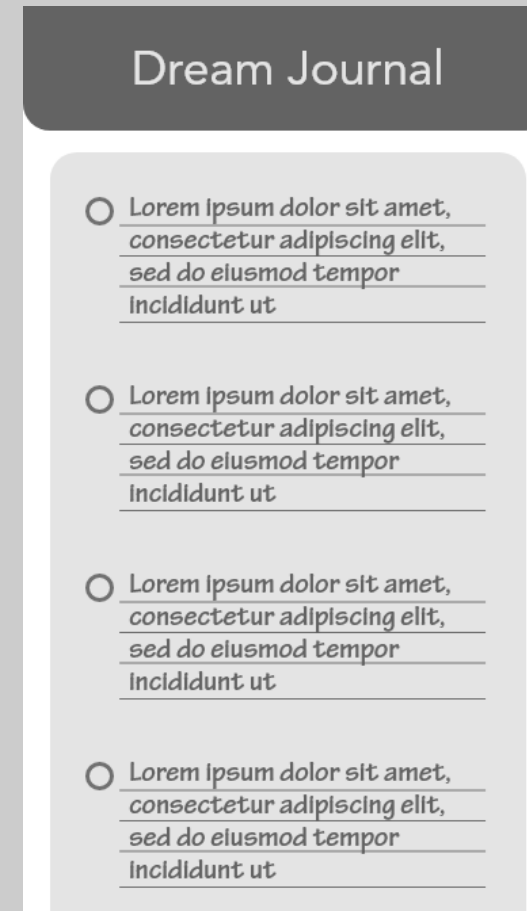
Patient-Doctor Communication



Track Progress



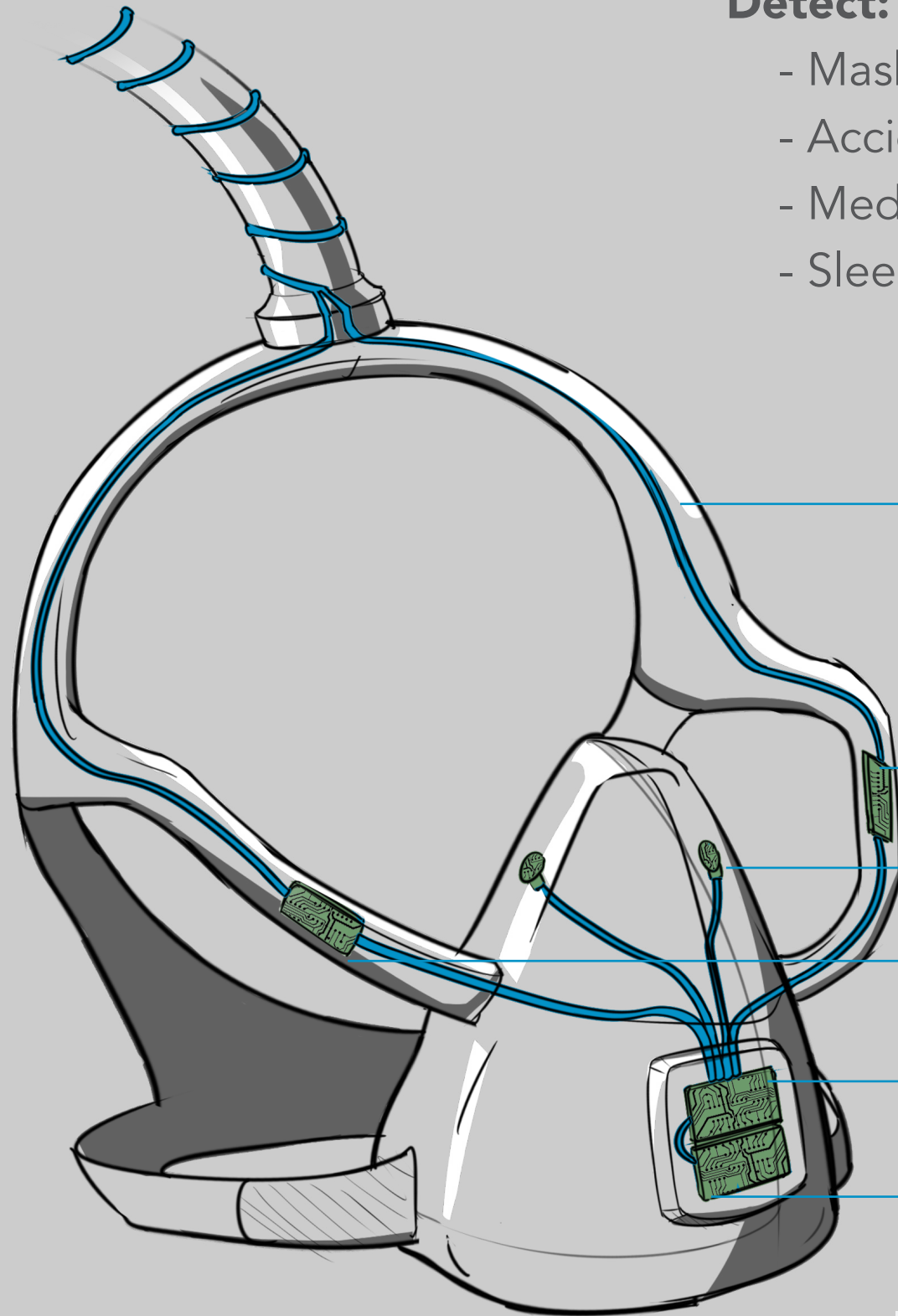
Habit Building Features



# F Non-invasive Home Sleep Diagnostics Mask

## Detect:

- Mask Leaks
- Accidental Mask Removal
- Medical Emergencies
- Sleep Actigraphy



Wires Route Through Tubing

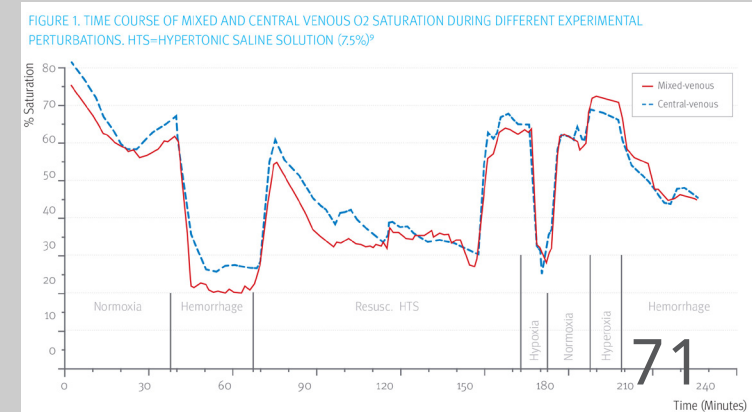
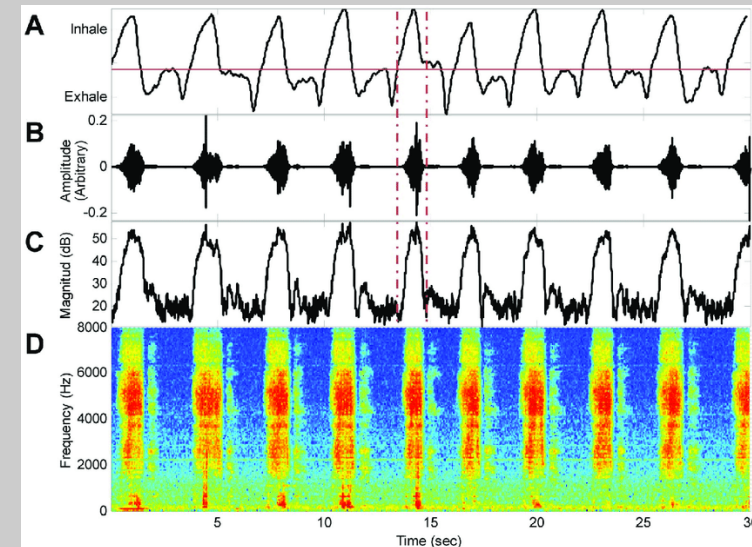
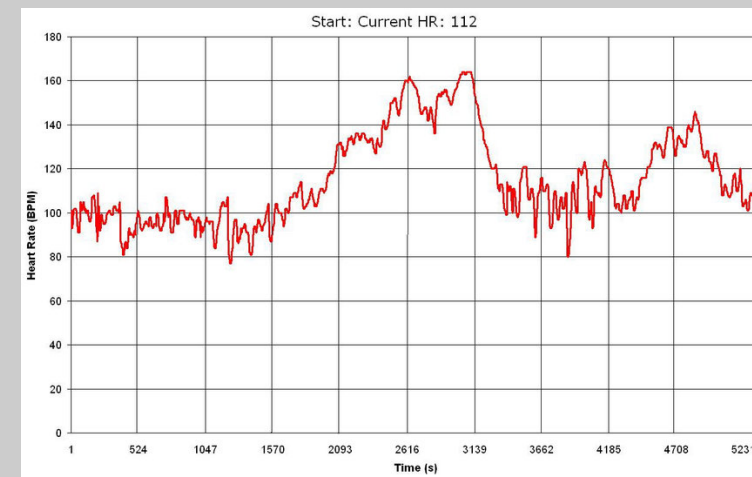
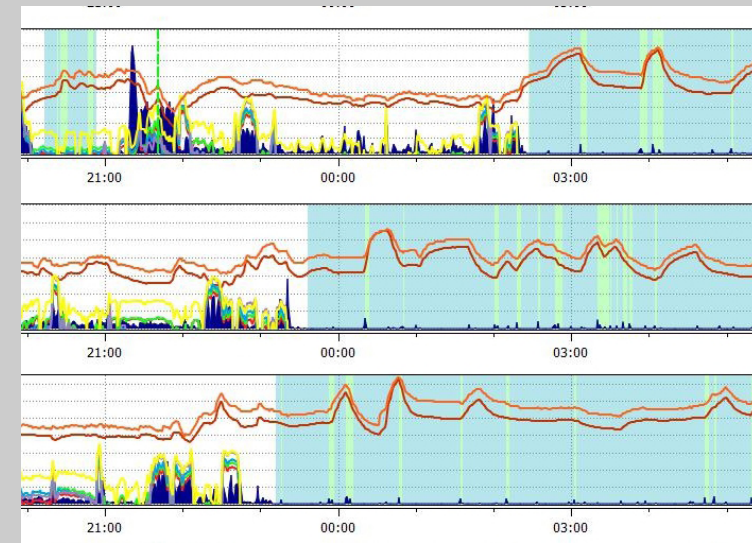
Heart Rate Sensor

Capacitive Sensors

Blood Oximetry Sensor

Snoring Audio Detector

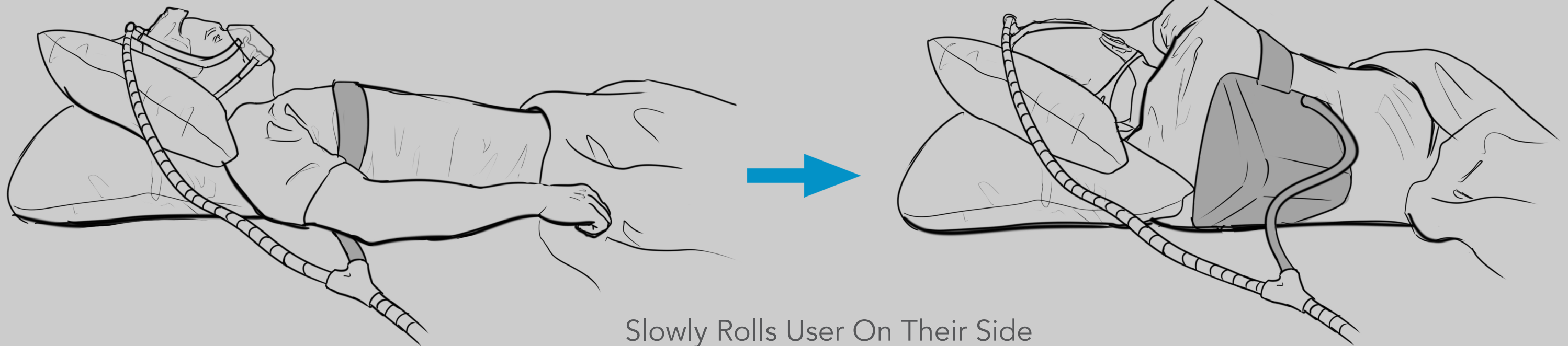
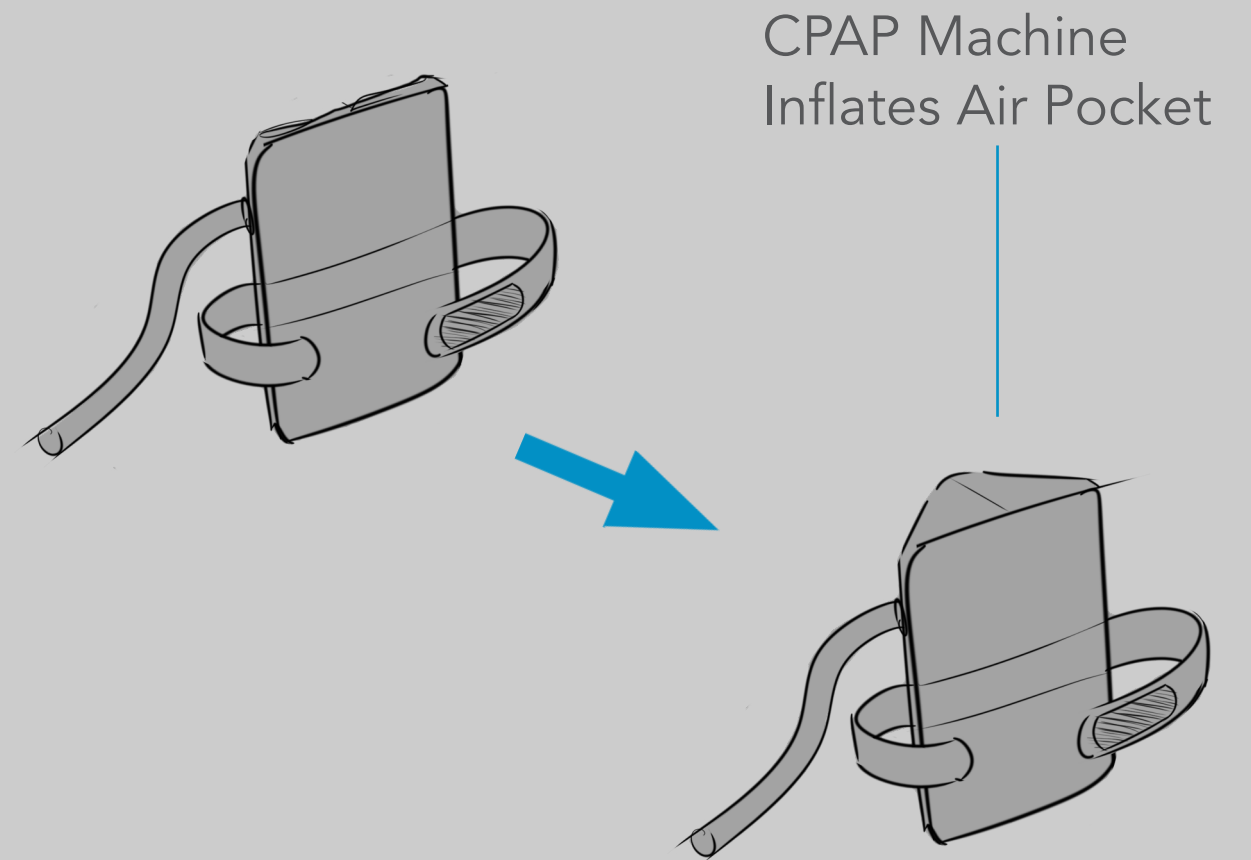
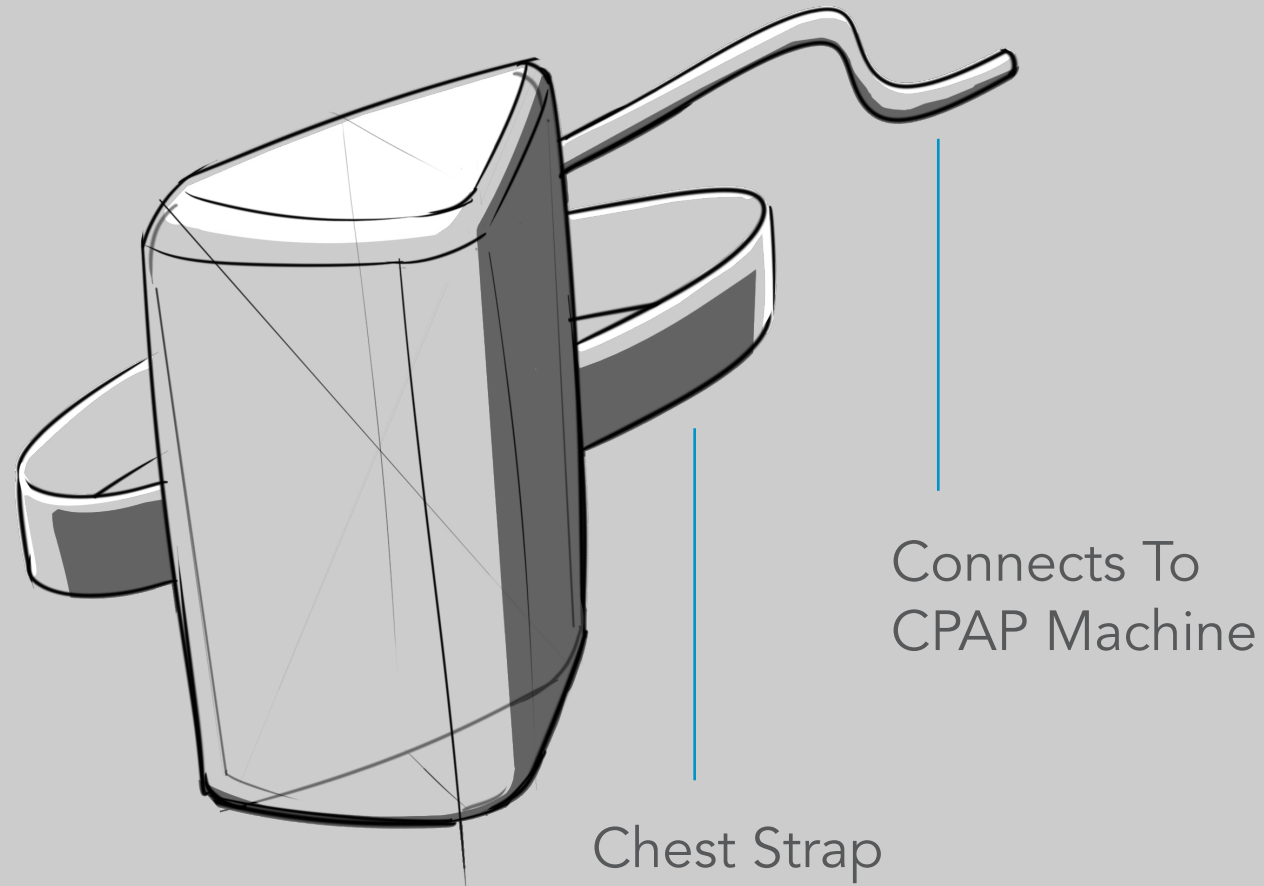
Gyroscopic Position Sensor



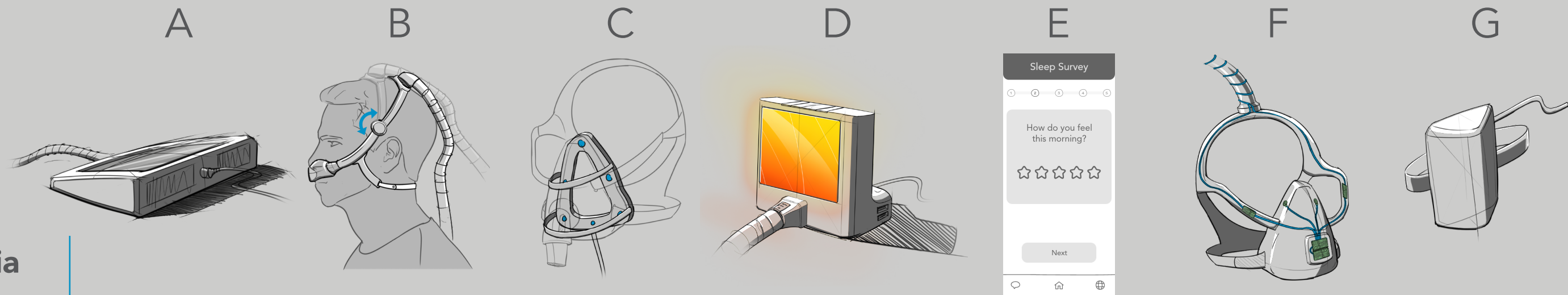
Find The Right Air Pressure Faster

G

# Inflatable Side Sleeping Trainer



# CONCEPT SCREENING

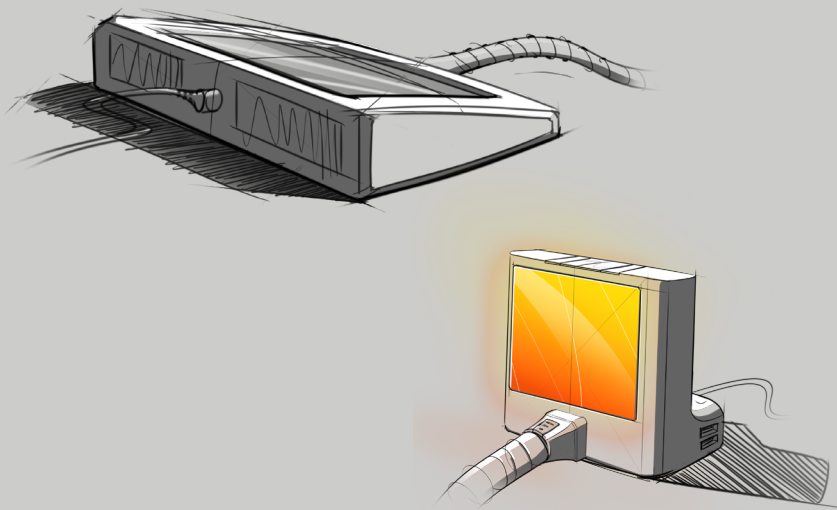


## Selection Criteria

	A	B	C	D	E	F	G
Enhances Comfort	+	+	0	0	0	0	+
Feasibility	+	+	+	+	+	0	+
Emotional Potential	+	0	0	+	+	0	0
Portability	+	+	+	+	+	+	+
Facilitates Habit	+	0	0	+	+	0	0
Total	5	3	2	4	4	1	3
Rank	1	3	4	2	2	4	3

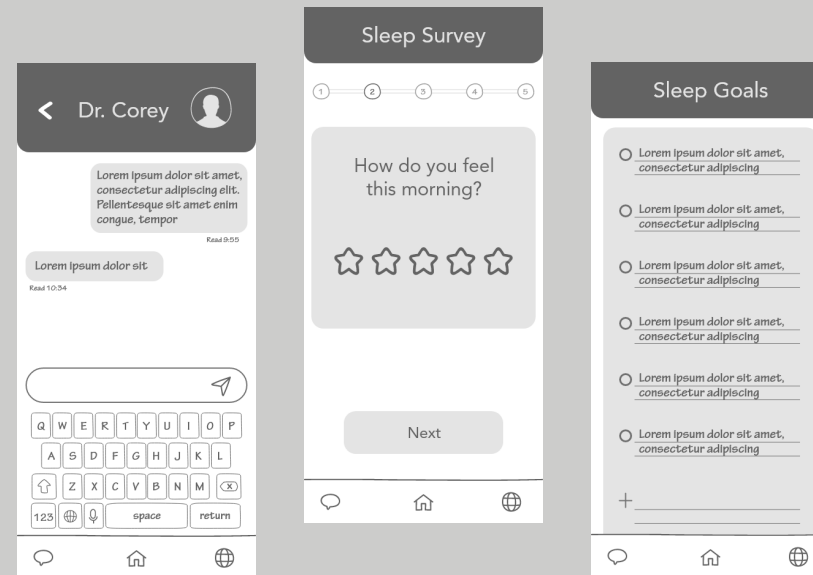
# CONCEPT PROPOSALS

## Touch Screen CPAP Machine



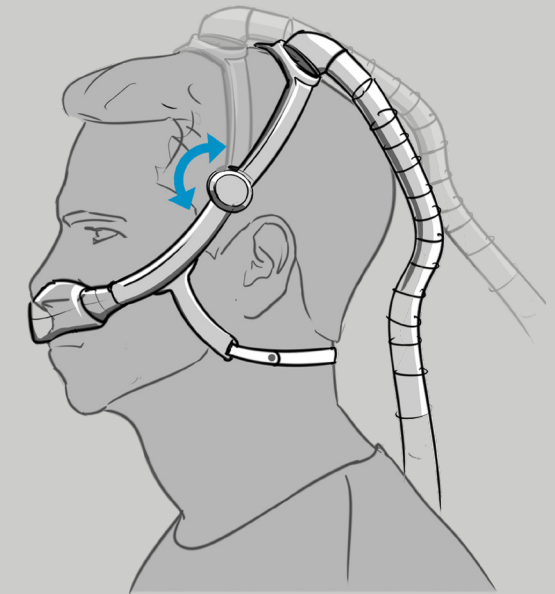
The touch screen CPAP machine was the highest scoring concept. It has the potential to enhance comfort, create habits, and tap into emotions in a similar way that our smartphones and tablets do. The user could watch movies, meditate, listen to music, and many more possibilities. This would enhance the concept of sleep therapy and provide a better experience for users.

## App



The sleep wellness app concept scored well for its potential to create habits for the user and the opportunity for better communication between the doctor and the user. These considerations each contribute to the goal in trying to improve adherence for new users.

## Modular Mask



Since mask fit is the number one consideration for new CPAP users, this modular mask concept would help users find which mask works for them faster without the lost time in communicating with their doctor. This puts more control and customization in the hands of the user. Additionally, this concept has the potential to fit a greater population of users.



Traveling with  
sleep apnea

MILESTONE 4

# How might we

increase CPAP therapy **adherence** for **new users** to maintain a medical certification, such as pilots and truck drivers?



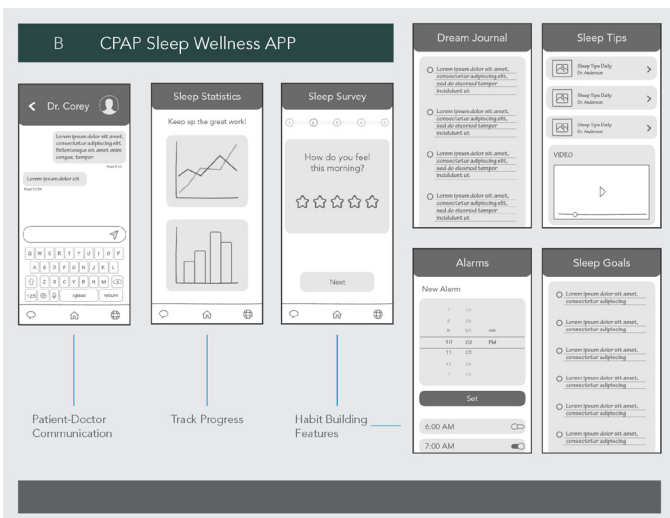
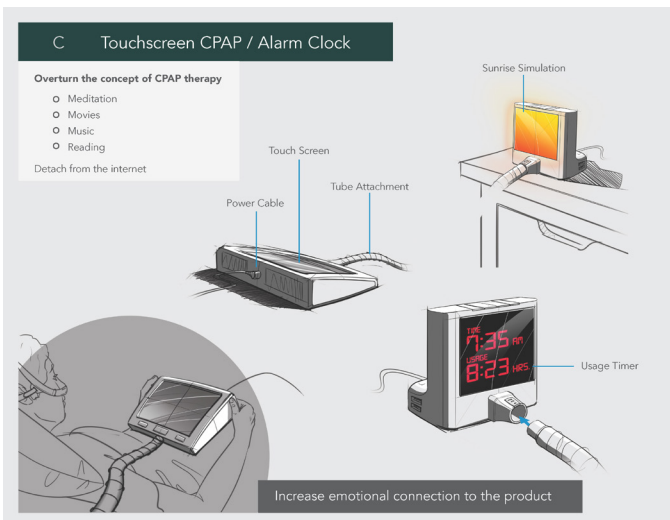
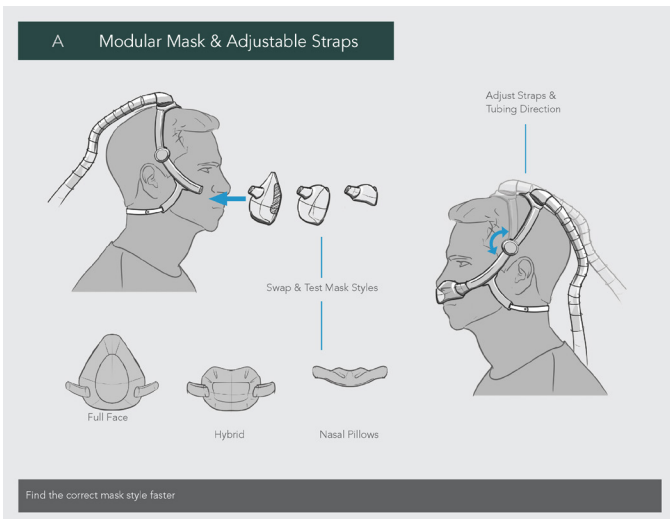
The problem statement was badly in need of refinement. This new problem statement addresses the core issue of CPAP therapy; adherence, and provides further context of new users maintaining a medical certificate for pilots and truck drivers. Within addressing adherence, the goal is to also address the behaviors, habits, and attitudes of users.



# PRODUCT INSPIRATION



# EVALUATIVE RESEARCH



In the evaluation of this concept, I talked to 5 different CPAP users for feedback. Three of the users were long-term users, and two were new users. For my standard operating procedure, I handed each of them a packet of paper and a pen. The packet contains introductions to each of the three concepts, a SWOT analysis chart for each concept, and lastly a concept scoring matrix. I talked them through each of the concepts, listened to their thoughts while filling out the SWOT analysis chart, and documented their justifications in scoring each of the concepts.

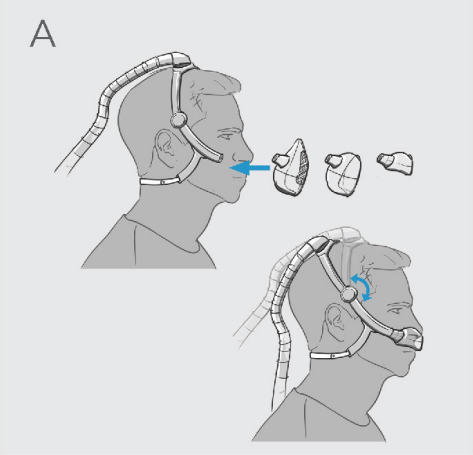
# EVALUATIVE RESEARCH

## Strengths / Opportunities

- + Highly adjustable for different tubing angles
- + Makes it easy to find the right mask
- + Prevents the doctor from prescribing the wrong mask
- + Could accommodate a variety of mask sizes

## Weaknesses / Threats

- It looks really bulky and heavy
- Hair could get caught in the hinge
- The hinge looks like it would hurt to sleep on
- Typically the doctor selects the mask for the patient
- The head band could slip off easily
- Different masks require a different machine pressure prescription

Concept Evaluation	
<p>A</p> 	
<p><b>Strengths</b> Good characteristics or uniqueness. What does the concept do well?</p>	<p><b>Weaknesses</b> Disadvantages or gaps in the concept</p>
<p><b>Opportunities</b> How could the concept be improved? What could be added or removed? Are there better alternatives?</p>	<p><b>Threats</b> What external factors act against this concept?</p>

# EVALUATIVE RESEARCH

## Strengths / Opportunities

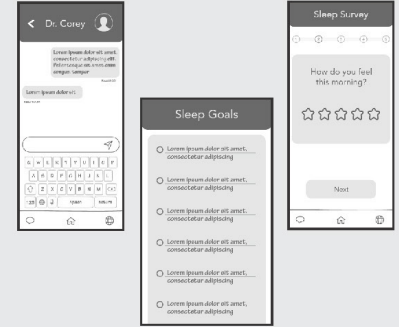
- + Communication & feedback
- + Goal setting
- + Likes the habit tracking feature
- + Could include a resupply feature in the app
- + Likes the idea of sending feedback to doctor

## Weaknesses / Threats

- Statistics can be discouraging
- The doctor likely wouldn't directly message the patient
- CPAP apps already exist, how is this different?
- Older people don't use their phones as much

Concept Evaluation

B



The image shows three mobile app screens. The first screen is a doctor's profile for 'Dr. Corey', featuring a 'Sleep Survey' button. The second screen is a 'Sleep Goals' tracker with a grid of checkboxes for each day of the week. The third screen is a 'Sleep Survey' asking 'How do you feel this morning?' with a five-star rating system and a 'Next' button.

Strengths	Weaknesses
Good characteristics or uniqueness. What does the concept do well?	Disadvantages or gaps in the concept
Opportunities	Threats
How could the concept be improved? What could be added or removed? Are there better alternatives?	What external factors act against this concept?

# EVALUATIVE RESEARCH

## Strengths / Opportunities

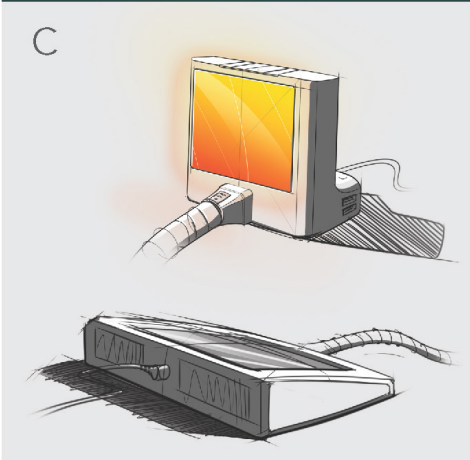
- + Sunrise alarm clock feature
- + Touch screen adds utility
- + Added portability is good
- + 4/5 could see themselves using it
- + Design could also address problems with mask removal in the middle of the night
- + CPAP interfaces need a big update

## Weaknesses / Threats

- Blue light could affect sleep
- The tubing is poorly placed. It would get in the way of using the device
- It still looks too much like a medical device
- Easily replaceable by an iPad

Concept Evaluation

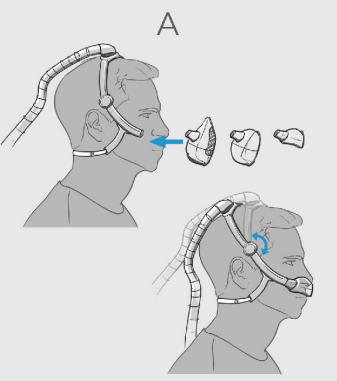

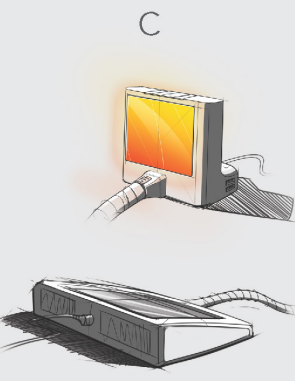
C



Strengths	Weaknesses
Good characteristics or uniqueness. What does the concept do well?	Disadvantages or gaps in the concept
Opportunities	Threats
How could the concept be improved? What could be added or removed? Are there better alternatives?	What external factors act against this concept?

# EVALUATIVE RESEARCH

Concept Ranking: Score each concept on a scale of 1-3, 3 being best

	A	B	C
<b>Selection Criteria</b>			
Enhances Comfort			
Feasibility			
Emotional Potential			
Portability			
Facilitates Habit			

After the users weighed the strengths, weaknesses, opportunities, and threats of each concept, I had them score the concepts based on five criteria:


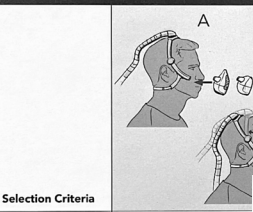
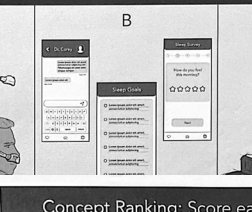
- Enhances comfort
- Feasibility
- Emotional potential
- Portability
- Facilitates habit

Concept A - Modular Mask: 8.8/15

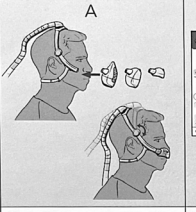
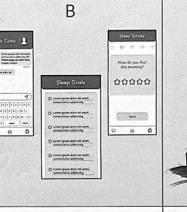
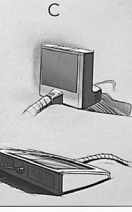
Concept B - CPAP App: 12.2/15

Concept C - Touch Screen CPAP Machine: 13/15

The users scored the CPAP app and touch screen CPAP machine the highest and recommended that a hybrid combination of the two has the most potential for success.

Concept Ranking: Score each concept on a scale of 1-3, 3 being best			
	A	B	C
<b>Selection Criteria</b>			
Enhances Comfort	2		
Feasibility	2		
Emotional Potential	2		
Portability	2		
Facilitates Habit	2		

Concept Ranking: Score each concept on a scale of 1-3, 3 being best			
	A	B	C
<b>Selection Criteria</b>			
Enhances Comfort	2	3	1
Feasibility	1	3	2
Emotional Potential	1	2	3
Portability	2	1	3
Facilitates Habit	2	1	3

# IMPACT VS. EFFORT MATRIX

## Hardware Features

- Touch screen
- On/Off button
- Power cable
- 12 volt power cable port
- Tubing insert
- Removable water reservoir
- Hot plate humidifier
- Tubing adapter

Many of the essential features fall under the high impact category, some of which are low effort, however are essential to the functionality of the device. There are, however, features such as the water reservoir and the humidifier, which aren't critical to functionality and require high effort to implement. This is something to consider in the prototyping phase.

High Impact	<b>On/Off button</b> <b>Tubing Adapter</b> <b>12V port</b> <b>Power cable</b>	<b>Touch screen</b> <b>Humidifier</b> <b>Water Reservoir</b>
Low Impact	<b>Tubing insert</b>	
	Low Effort	High Effort

# IMPACT VS. EFFORT MATRIX

## Software Features

- Interface
- Alarm clock
- Usage timer
- Sunrise simulation
- Goal setting
- Sleep survey
- Meditation
- Games

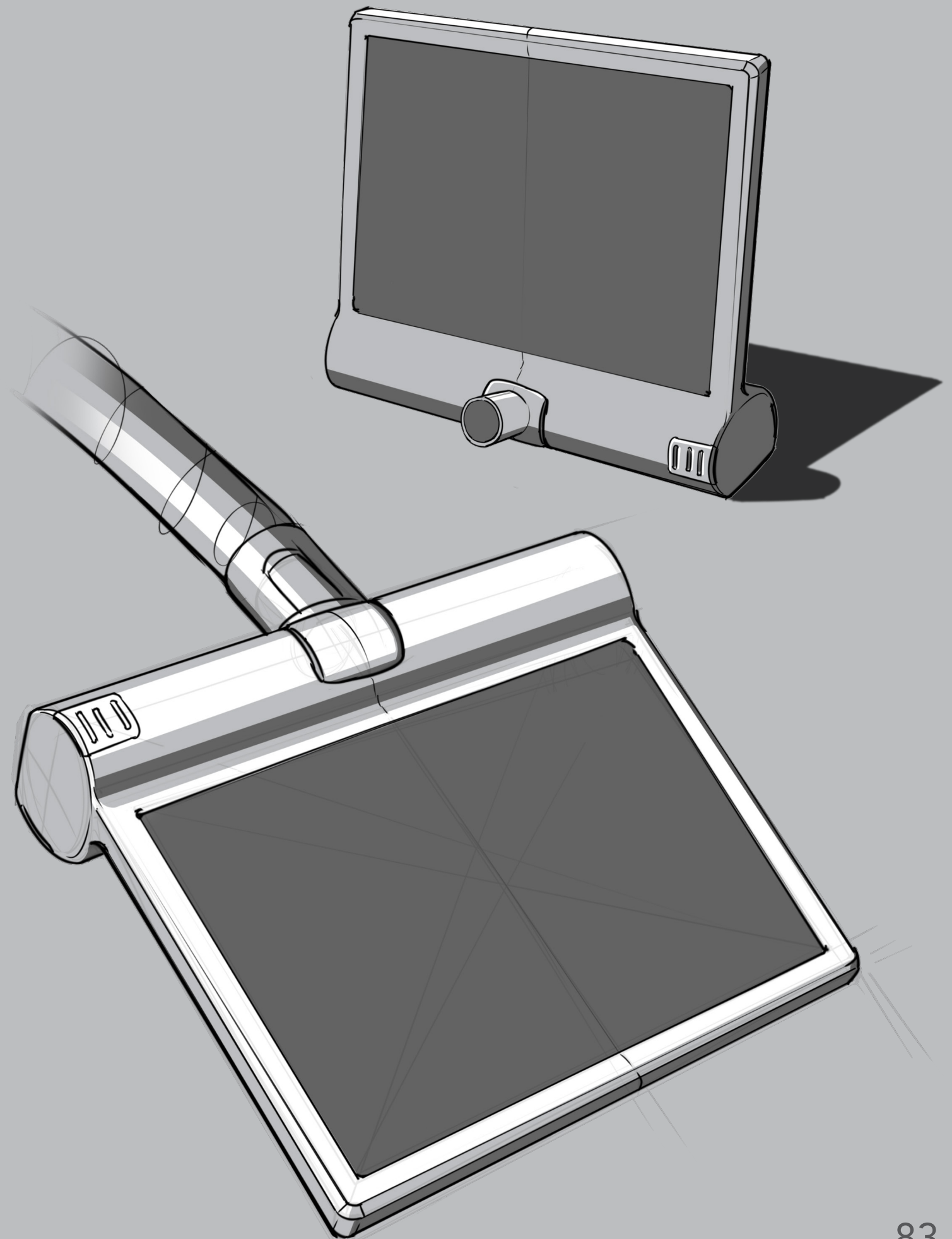
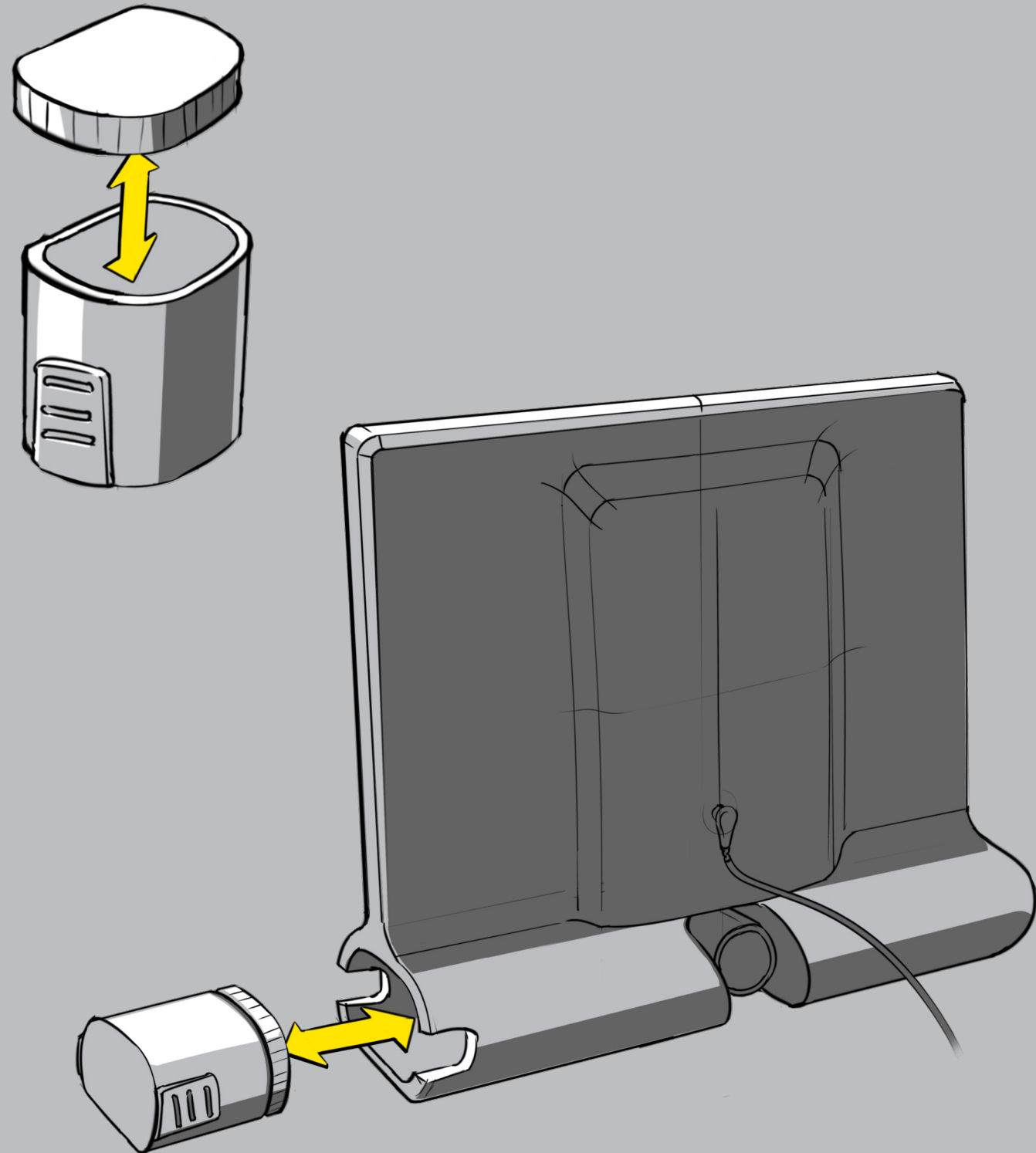
After the touch screen is implemented, it enables the use of additional software features for the user. Fortunately, several of these features are projected to be relatively low effort with a high impact. Further, the features that require high effort are essential to the user's experience, so they are considered high impact.

High Impact	<b>Alarm clock</b> <b>Meditation</b> <b>Games</b> <b>Usage timer</b> <b>Sunrise simulation</b>	<b>Interface</b>  <b>Sleep survey</b>  <b>Goal setting</b>
Low Impact		
	Low Effort	High Effort



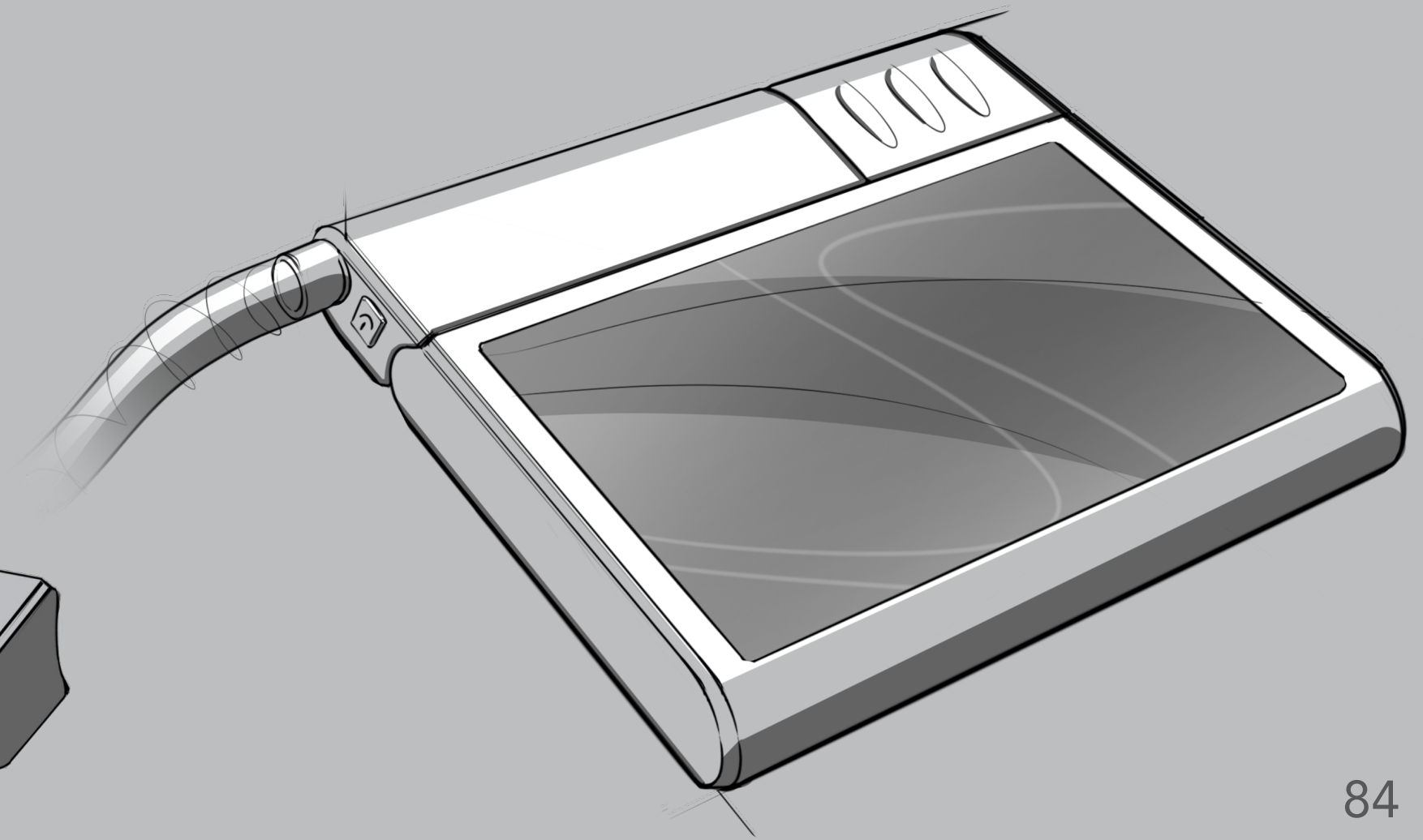
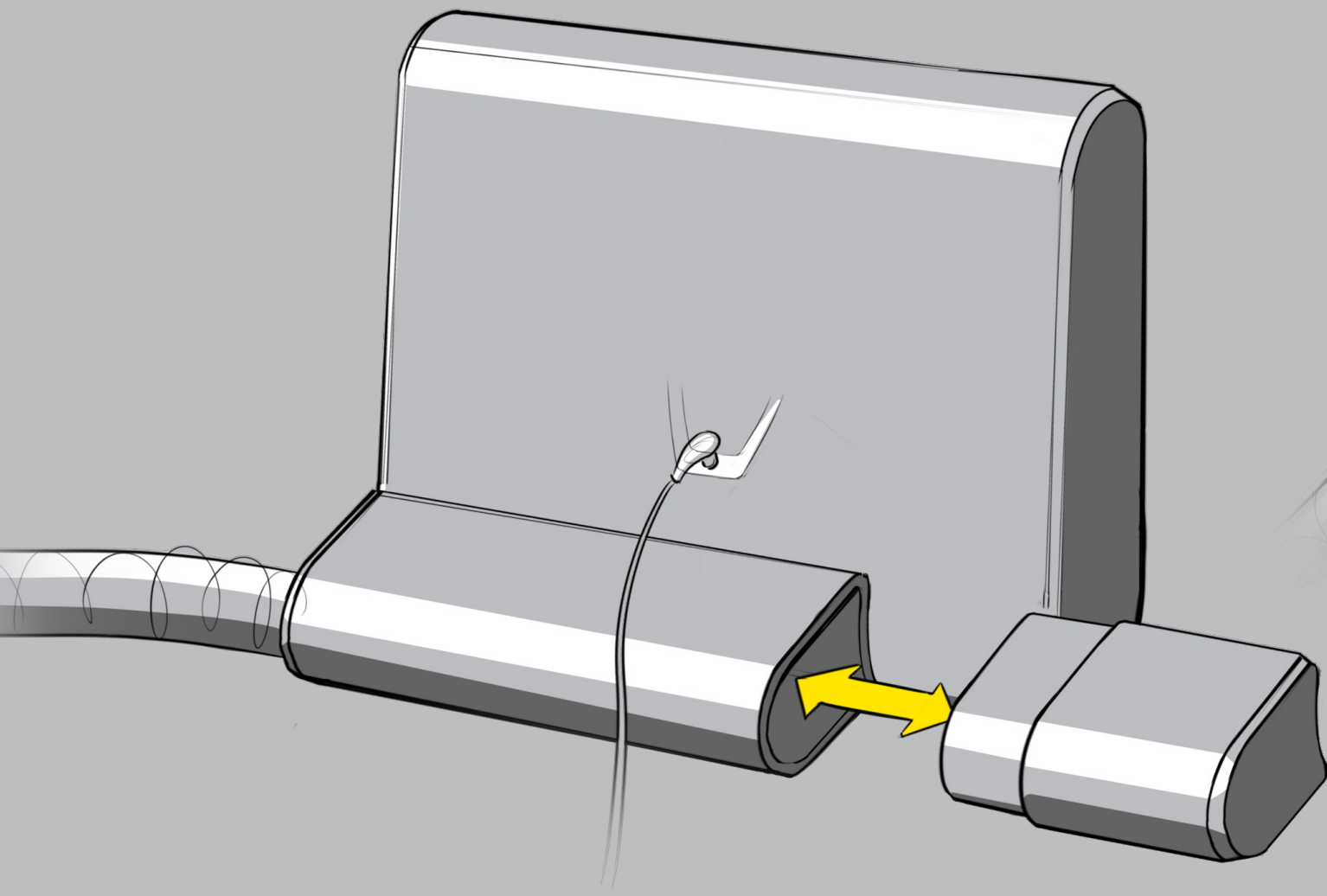
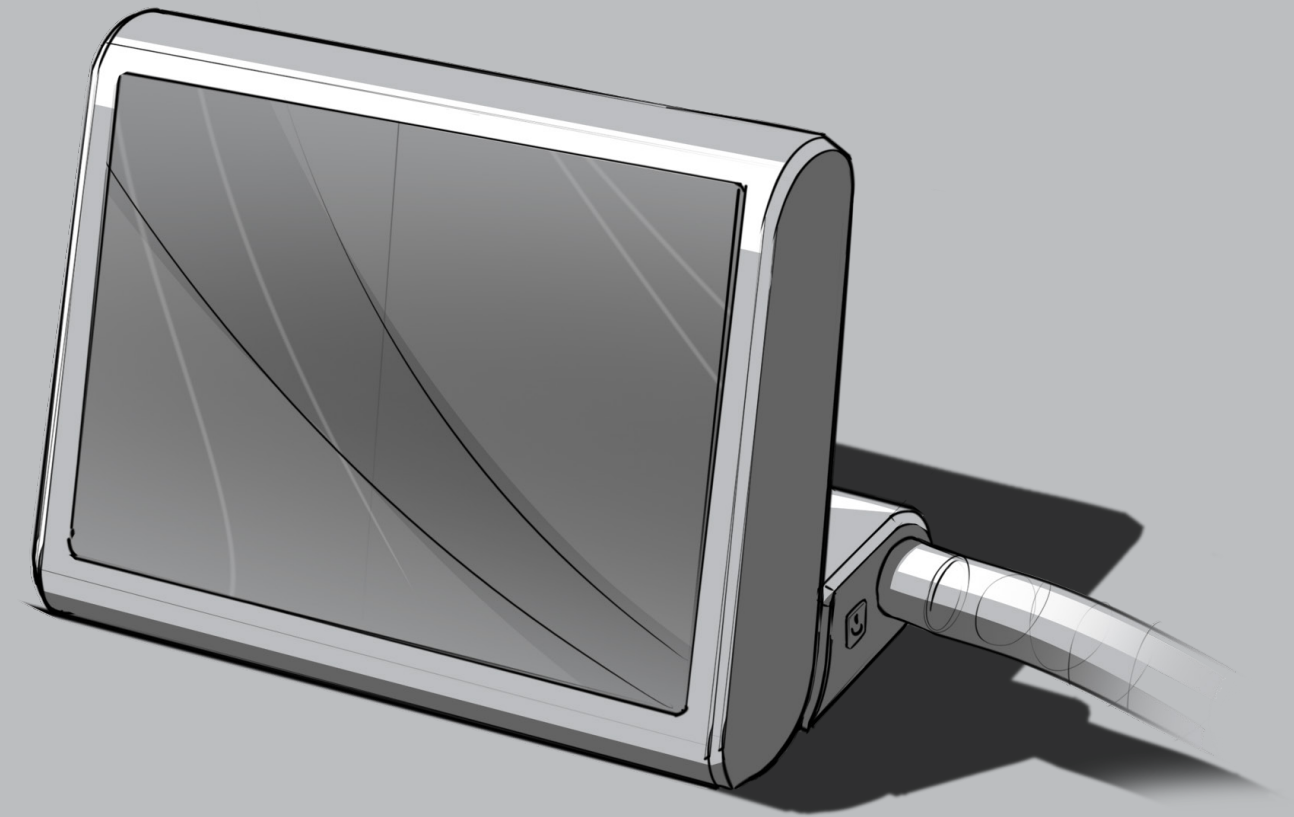
# CONCEPT REFINEMENT

Form #1



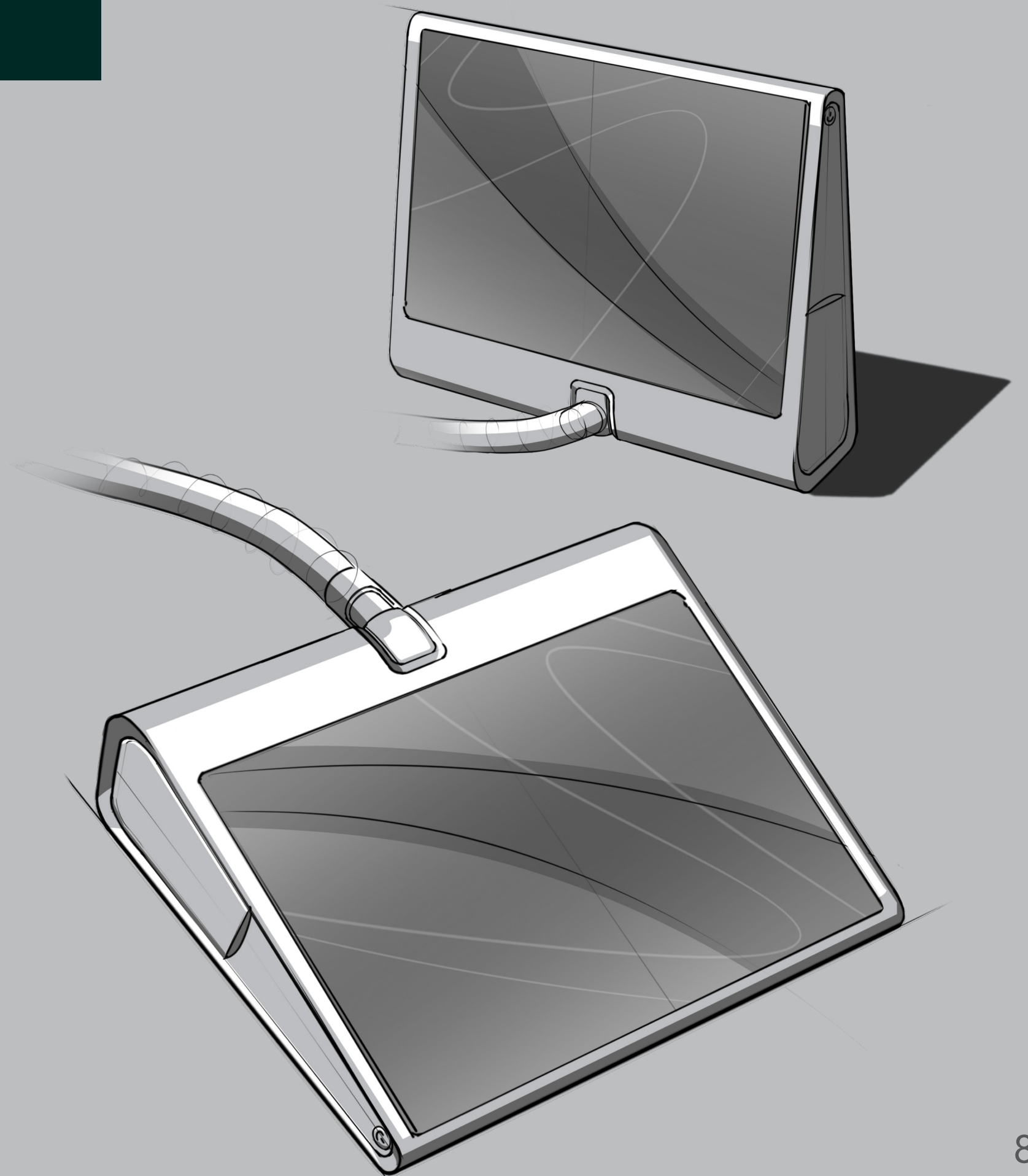
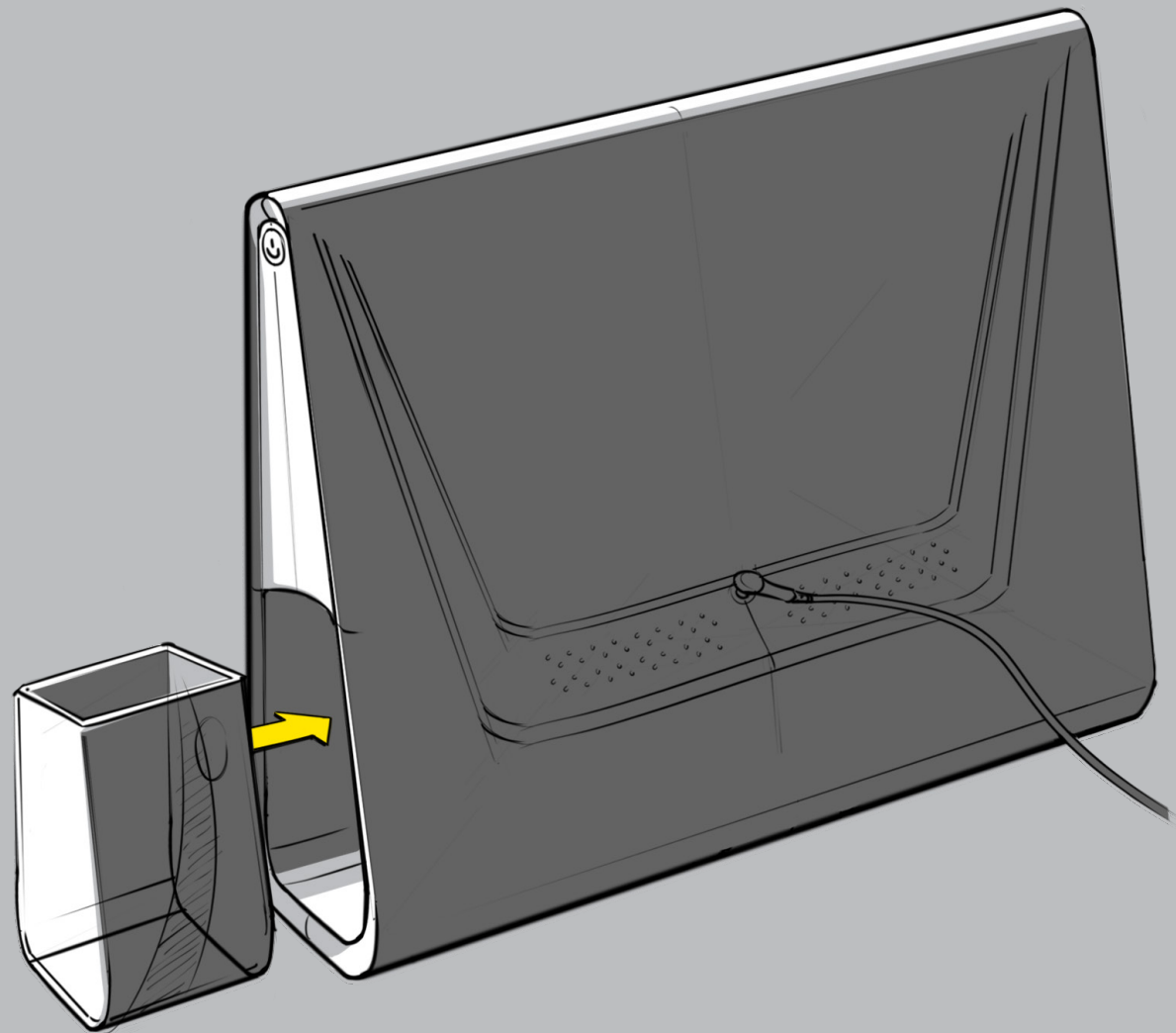
# CONCEPT REFINEMENT

Form #2

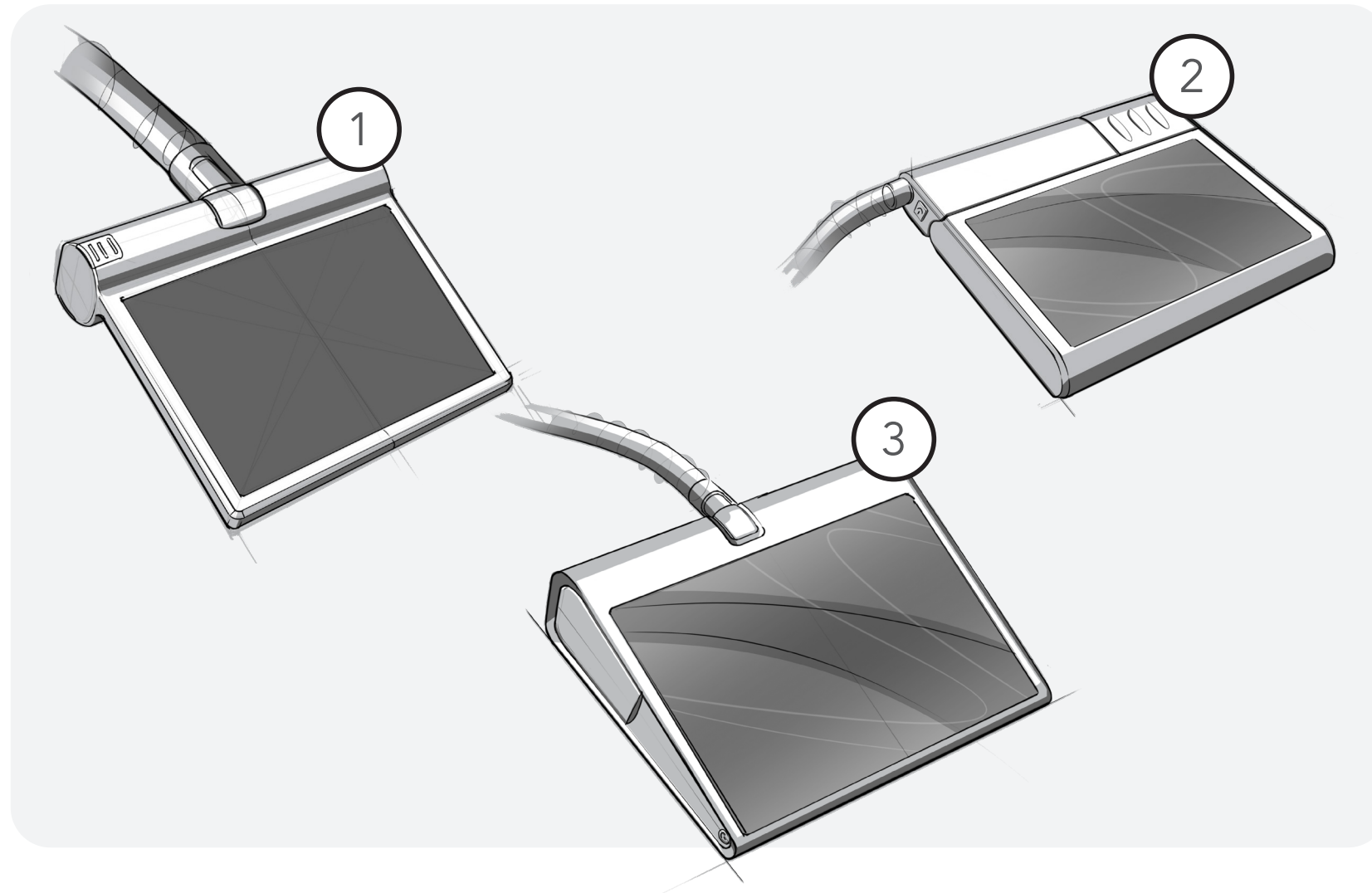


# CONCEPT REFINEMENT

Form #3



# PEER FEEDBACK



## Concept #1 Feedback

- Screen looks too thin
- Could break easier
- Too small for internal components
- Likes the rotating tube feature

## Concept #2 Feedback

- Folding part may not be possible
- Tubing connector may limit usability
- Likes that the screen spans full face

## Concept #3 Feedback

- Likes the rotating tubing connector
- Poorly placed power button
- May need rubber feet
- Overall favored concept

# FINAL CONCEPT SKETCH

Included iterations from peer feedback



# CONCEPT BENCHMARKING

Creature Comfort



The touch screen CPAP device with an integrated interface caters towards the creature comforts of users in its features and establishes an emotional connection with the user.

Low Portability



High Portability



Medical Appliance

This is unlike top competitors on the market which look like medical appliances, purely serving the purpose of the CPAP therapy.

# CONCEPT BENCHMARKING



To build upon the previous market opportunity page, the touch screen CPAP concept provides the highest utility interface than any other top CPAP device on the market. This enables the user to build a stronger connection to their device, which is important because they will be using it each night.







# PHYSICAL MOCKUP

To me, physically testing my designs is an essential part of my design process.

In creating my physical mockup, I 3D printed the model such that the tubing connector articulates and simulates some functionality of the CPAP device. I found this immensely helpful in critically evaluating the design and physically simulating the user flow in using the device.



# PRODUCT FEATURES



Adjustable Tubing Connector

Non Slip Rubber Feet

CPAP Tubing

Water Reservoir

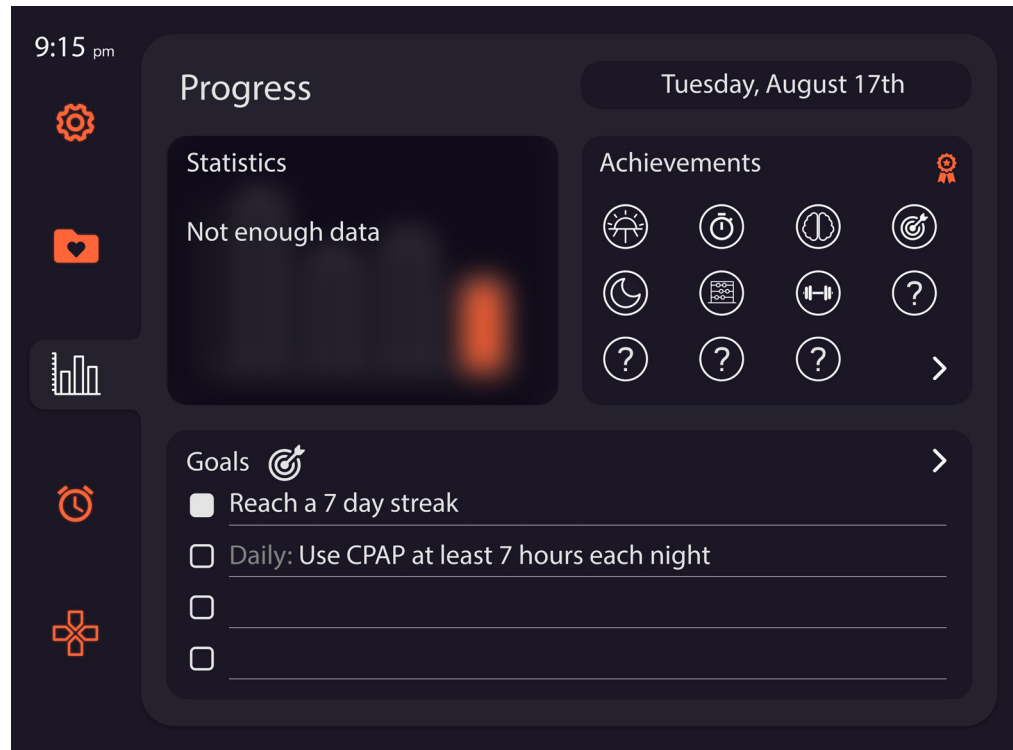
Blue Light Filtered Touch Screen

Pump Vents

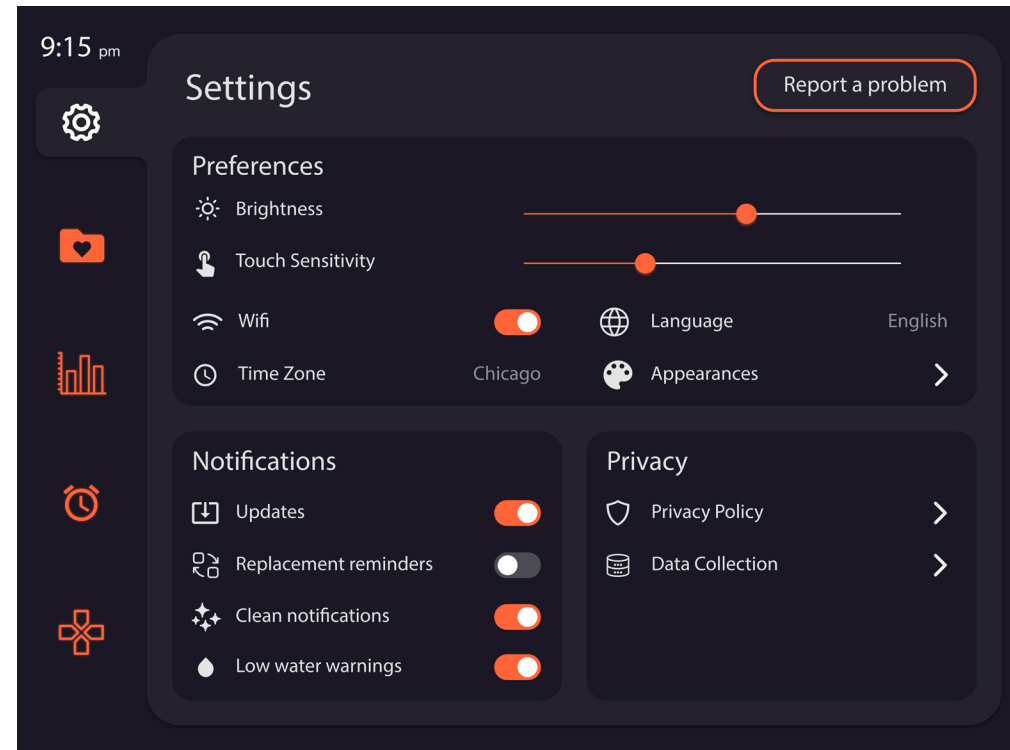
Power Button

12V Cable

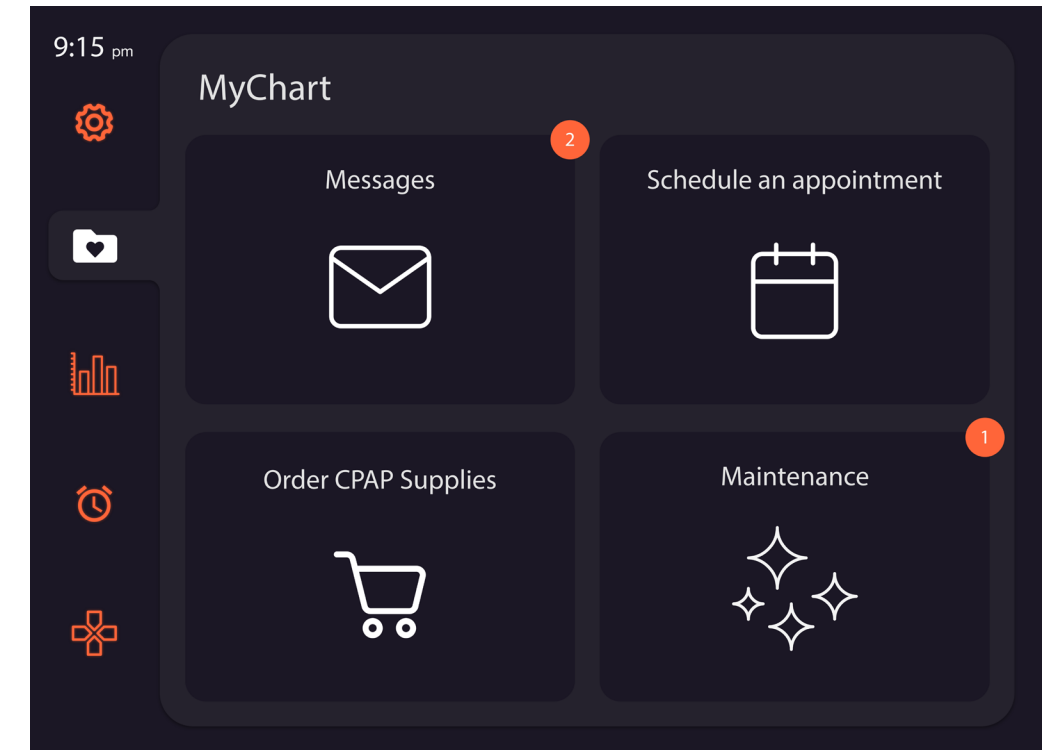
# DEVICE INTERFACE



The progress page enables the user to set their own goals, track their progress, and view their unlocked achievements. This is the landing page of the interface which shows when the user turns on the device. The statistics are hidden for the first few weeks until a trend of good adherence is shown because new users can be discouraged by poor statistics early on.

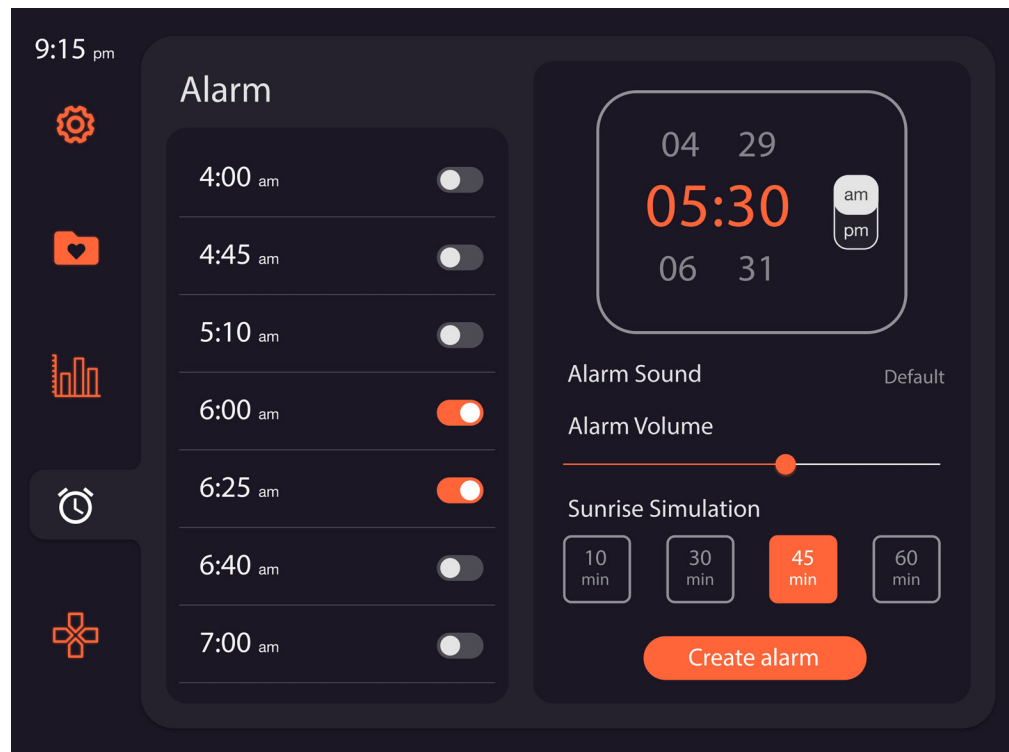


The settings page enables the user to configure their preferences, such as screen brightness, notifications, privacy, and appearances. This increases the user's sense of control over their device and their sleep apnea therapy.

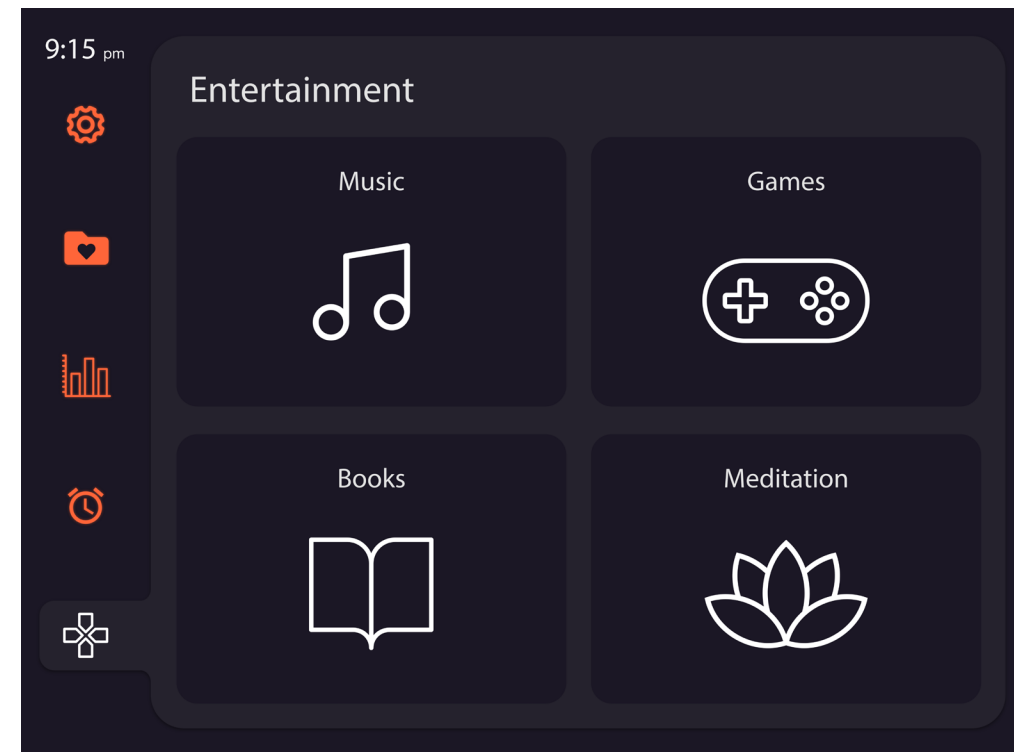


The device also has MyChart connectivity to enable effective communication between the patient and doctor. Here the patient may be notified of messages from their doctor, appointments, maintenance reminders, and CPAP resupply. It's been found that users are twice as likely to maintain adherence when enrolled in a CPAP resupply program.

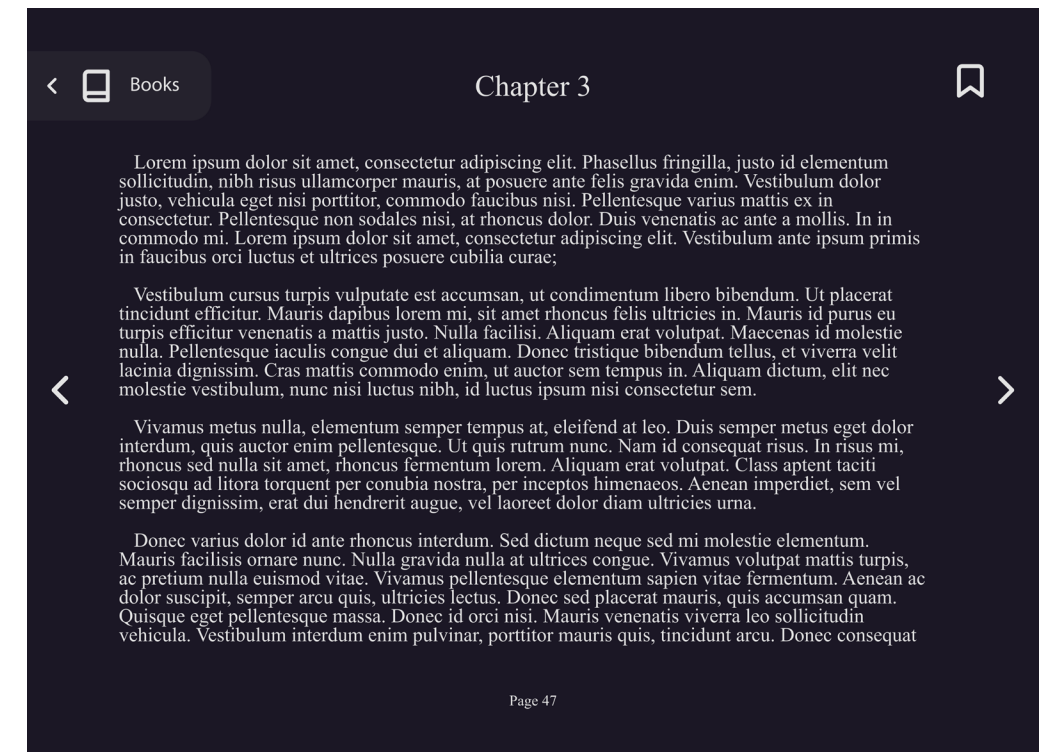
# DEVICE INTERFACE



The alarms page enables the user to customize their alarms, turn on or off alarms, and create new ones. Further, they can configure their alarm volume and sunrise simulation options.

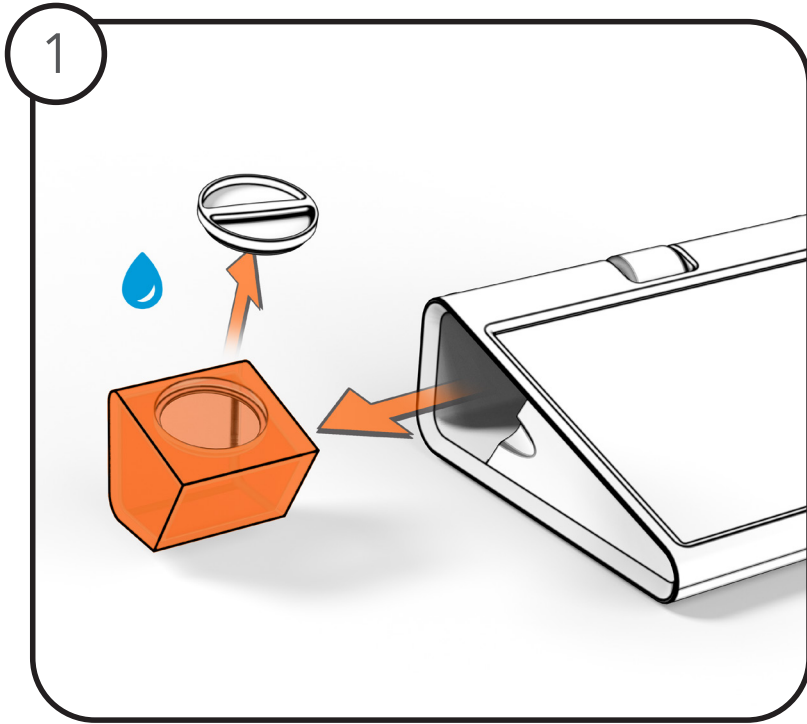


The entertainment page is a key function of this CPAP device. It turns this device ideology into the antithesis of the iPad or iPhone, without access to the internet which can keep us up at night. Instead, the entertainment features help the user escape the internet before bed while desensitizing to their mask and CPAP pressure. Desensitizing is essential to adherence.

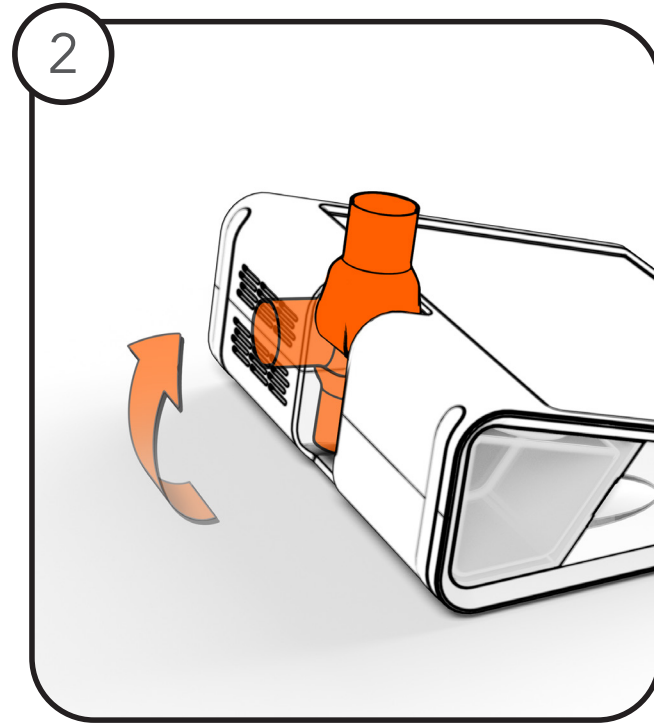


The books page is an example of one of the entertainments features the user might utilize before bed. It contains the same features many other reading applications might have, such as a bookmarks button, page numbers, and a library of books.

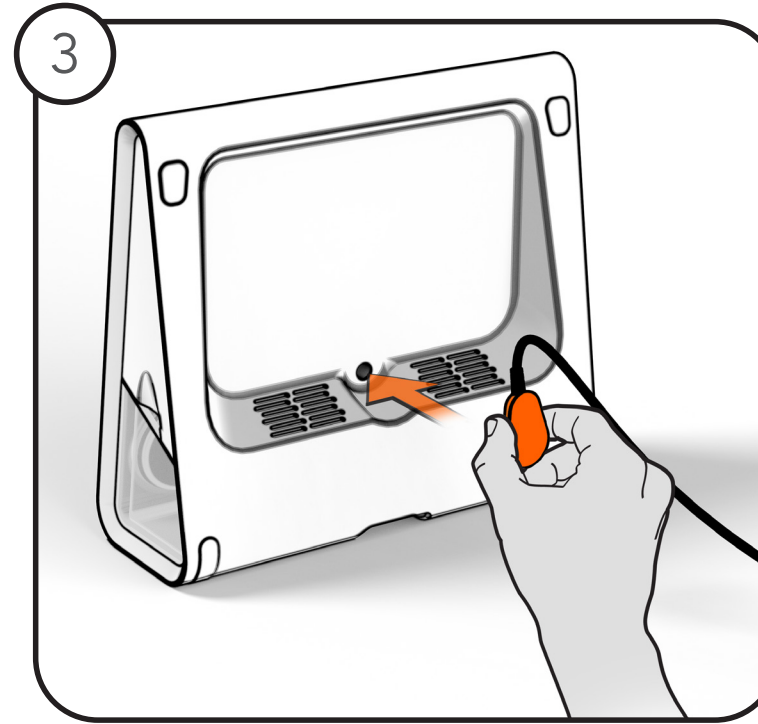
# USER FLOW



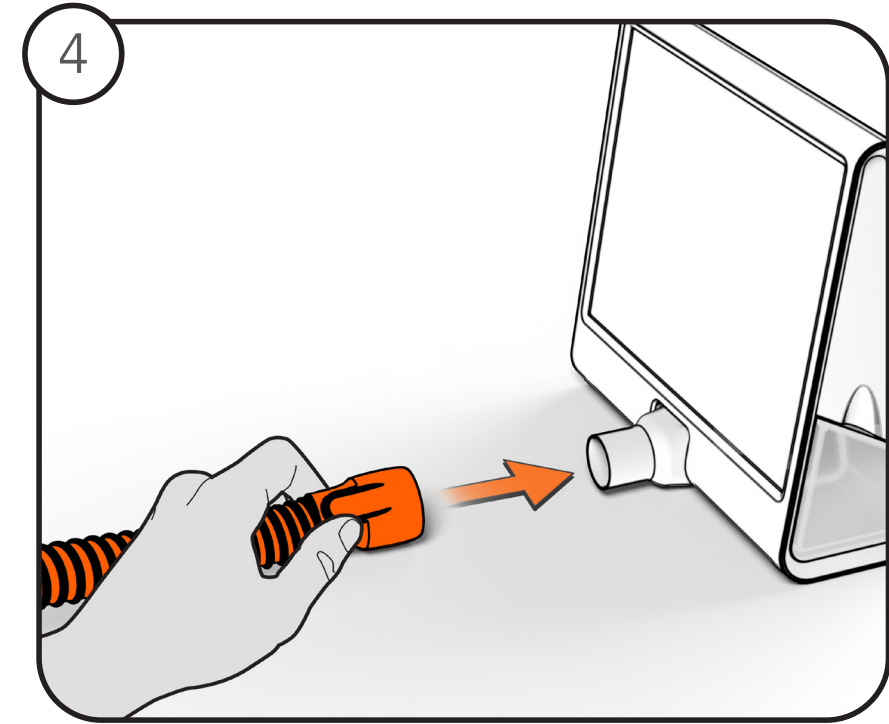
1 Remove the water reservoir, take off its' cap, and fill with water. The water reservoir is intended to hold one night's capacity of water, and be easily refillable and cleanable.



2 Rotate the tubing connector out. The tubing connector enables different angles of tubing for comfort and utility.

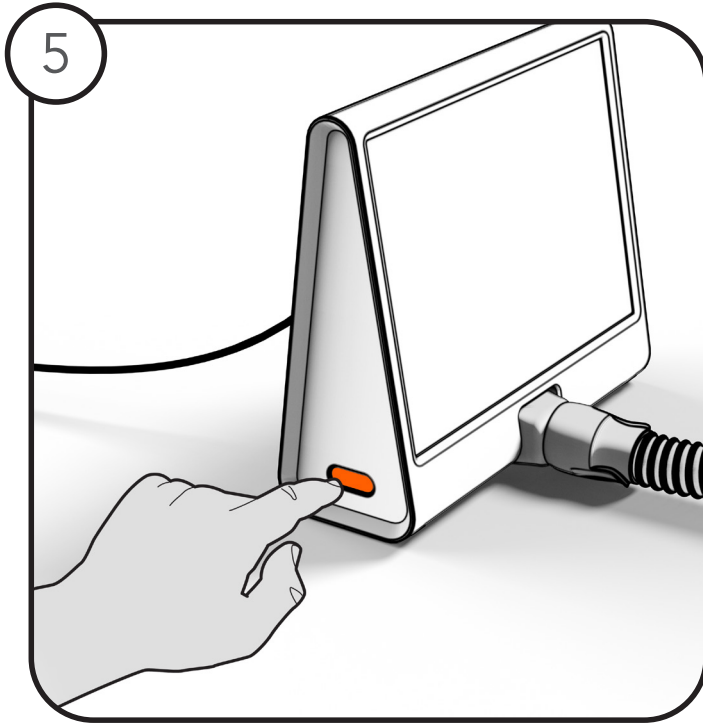


3 Connect the 12 Volt power adapter to the back of the CPAP machine.



4 Connect CPAP tubing to the tubing connector. The tubing connector articulates such that the device can be utilized in different configurations.

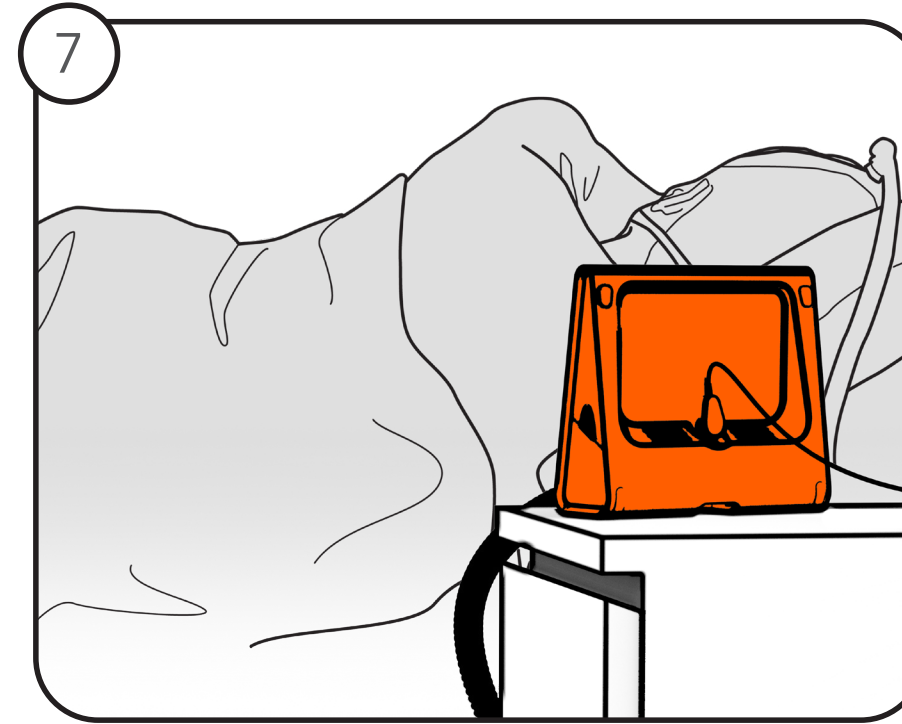
# USER FLOW



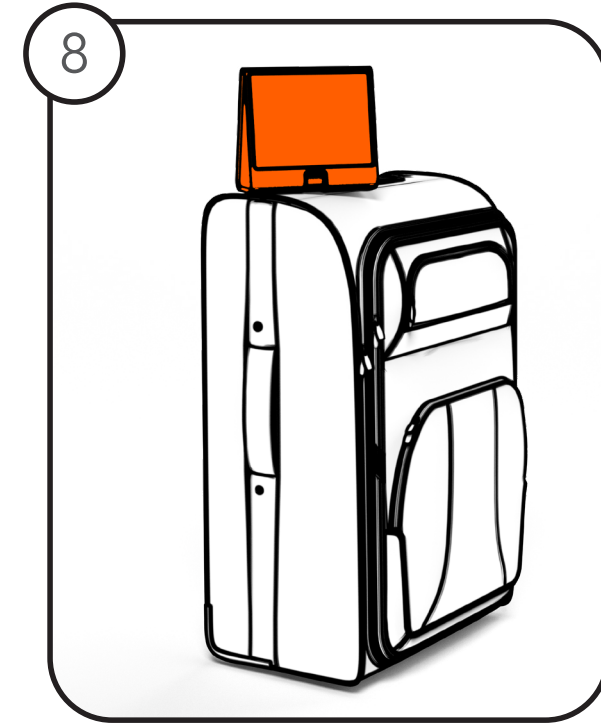
Press the power button on the side of the CPAP machine to turn it on.



Use any of the features on the machine, such as the music, games, books, or meditation features in the entertainment tab. This will help the user desensitize to their mask before bed.



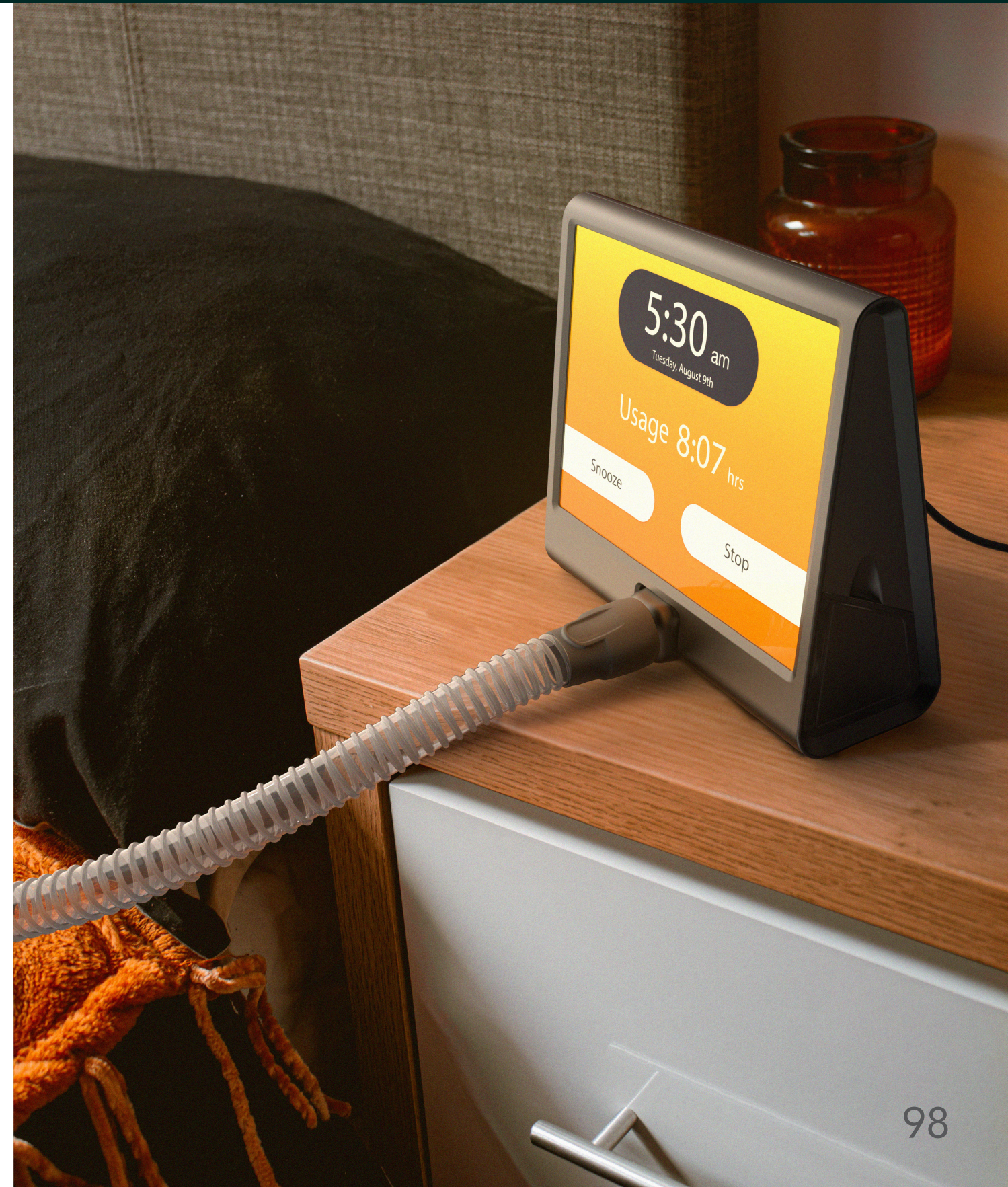
Set the CPAP device on the night stand on its end to use as an alarm clock.



Travel - This CPAP device is portable for frequent travel.

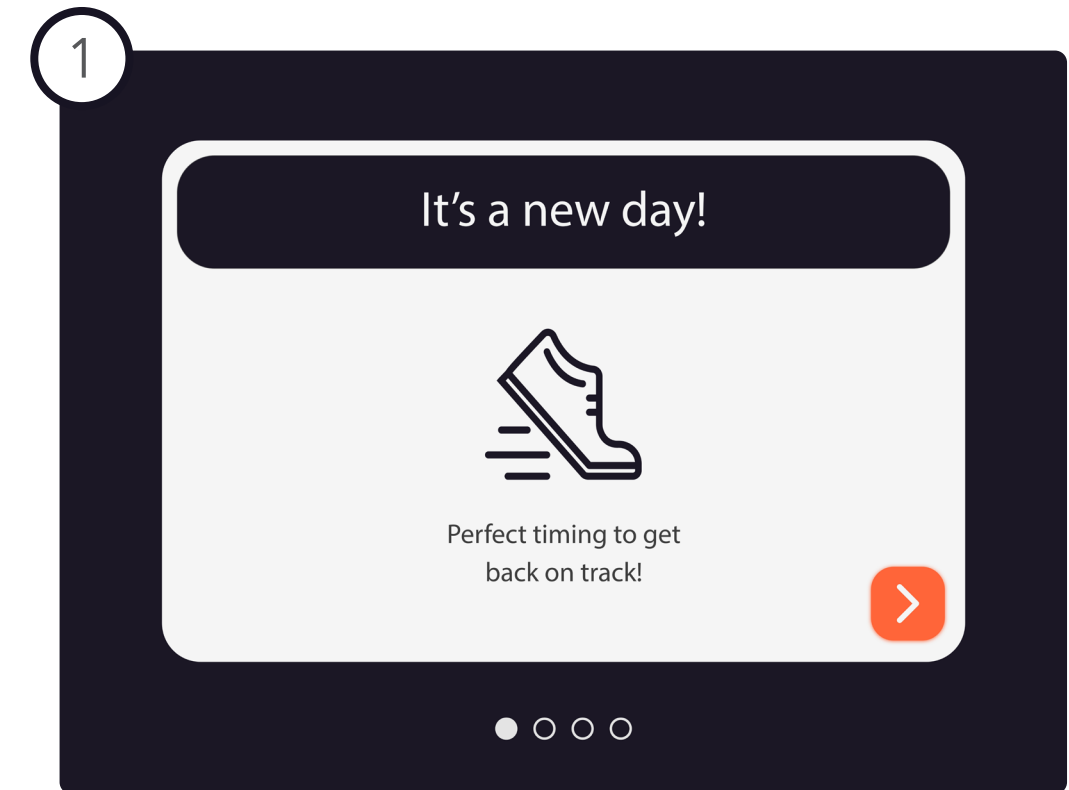
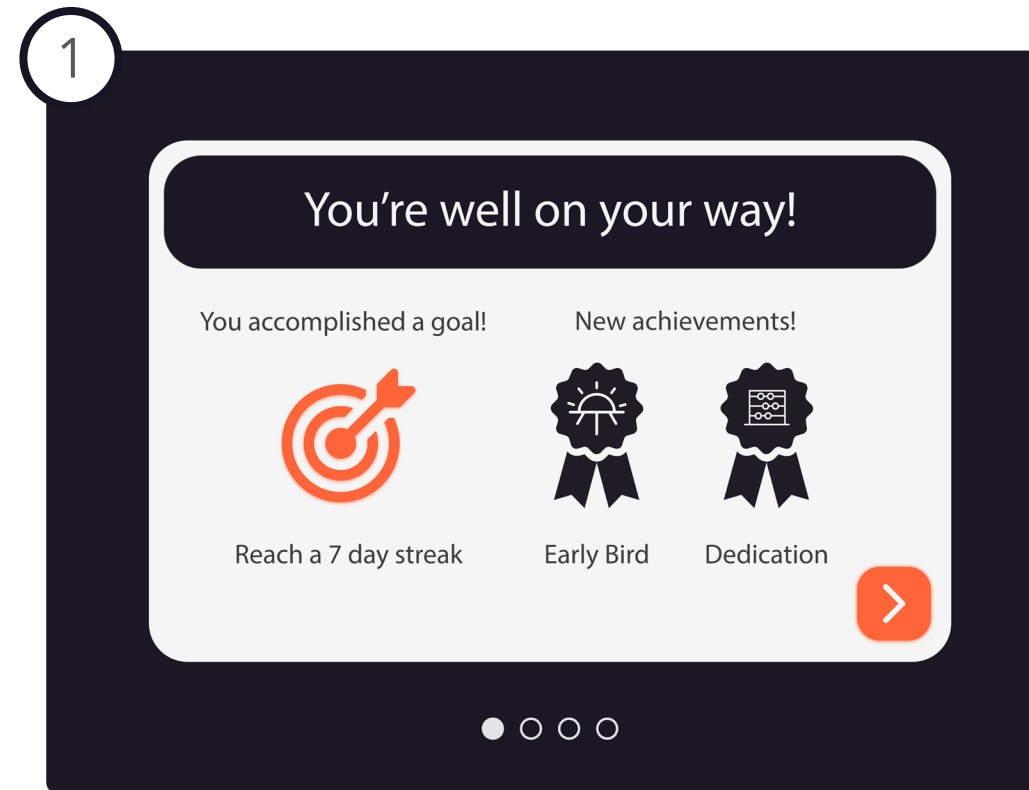
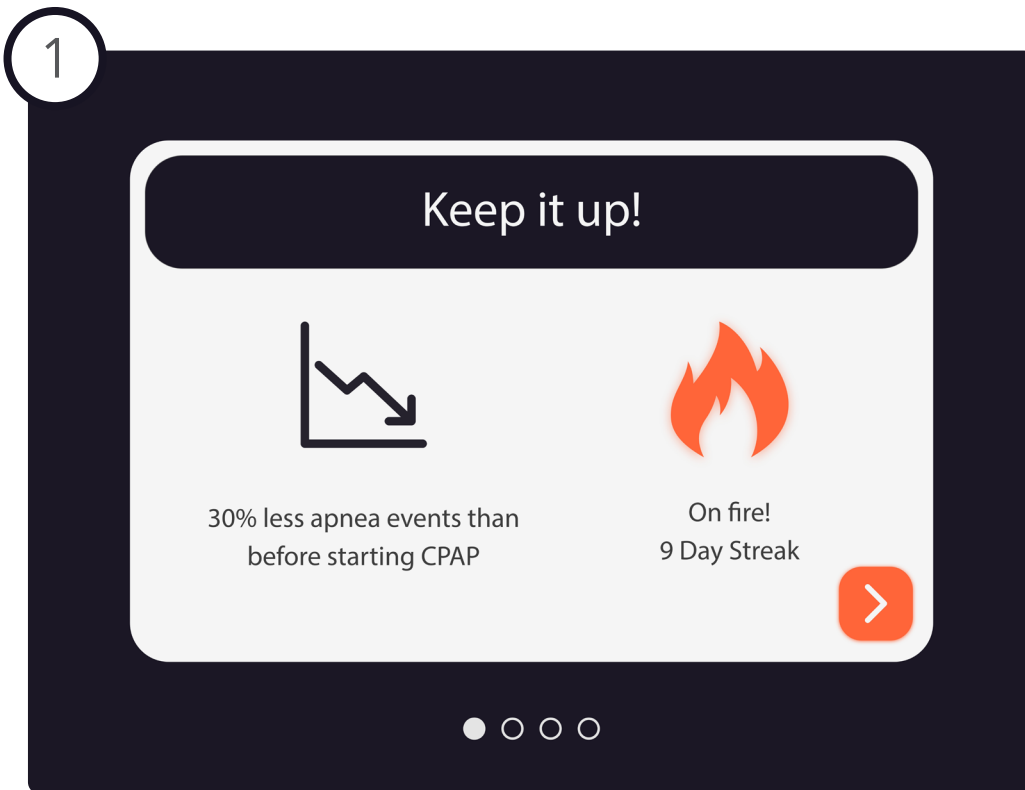
# SUNRISE SIMULATION ALARM CLOCK

One key feature of this touch screen CPAP therapy device is the sunrise simulation alarm clock. The sun controls the human body's circadian clock. For pilots and truck drivers with irregular hours, this clock may not be consistent with the natural sunrise. This simulation feature will help regulate the user's circadian clock and prevent jet lag, ultimately helping the user wake up feeling more refreshed.





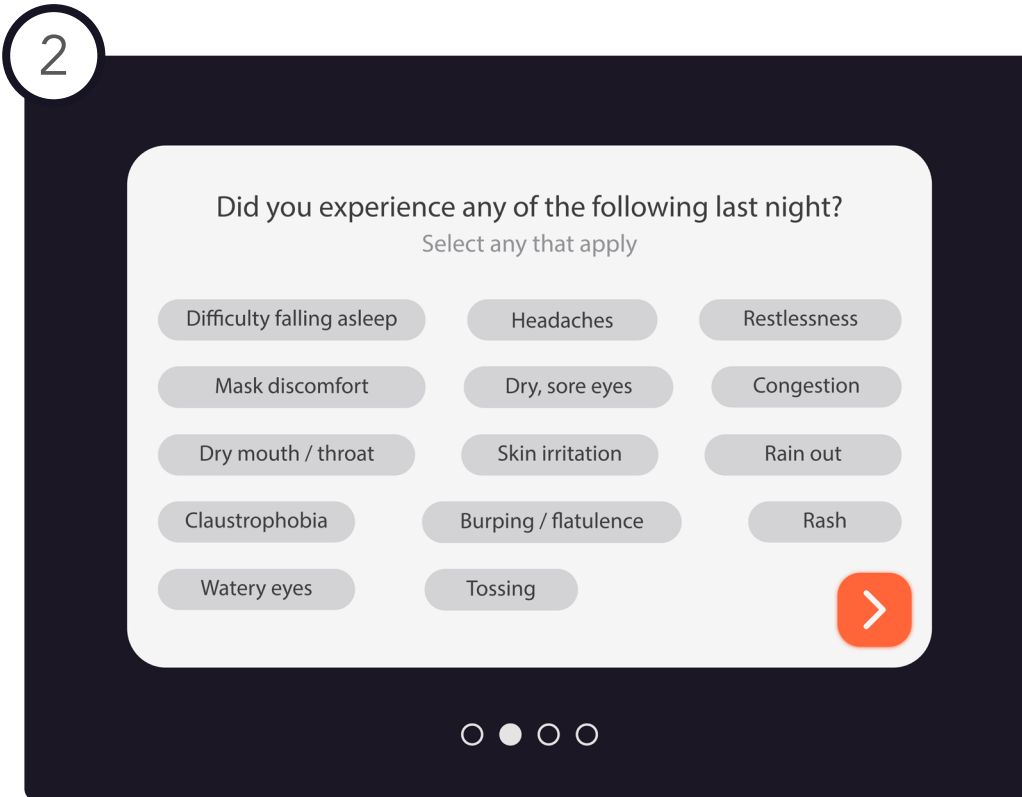
# DAILY USER SURVEY



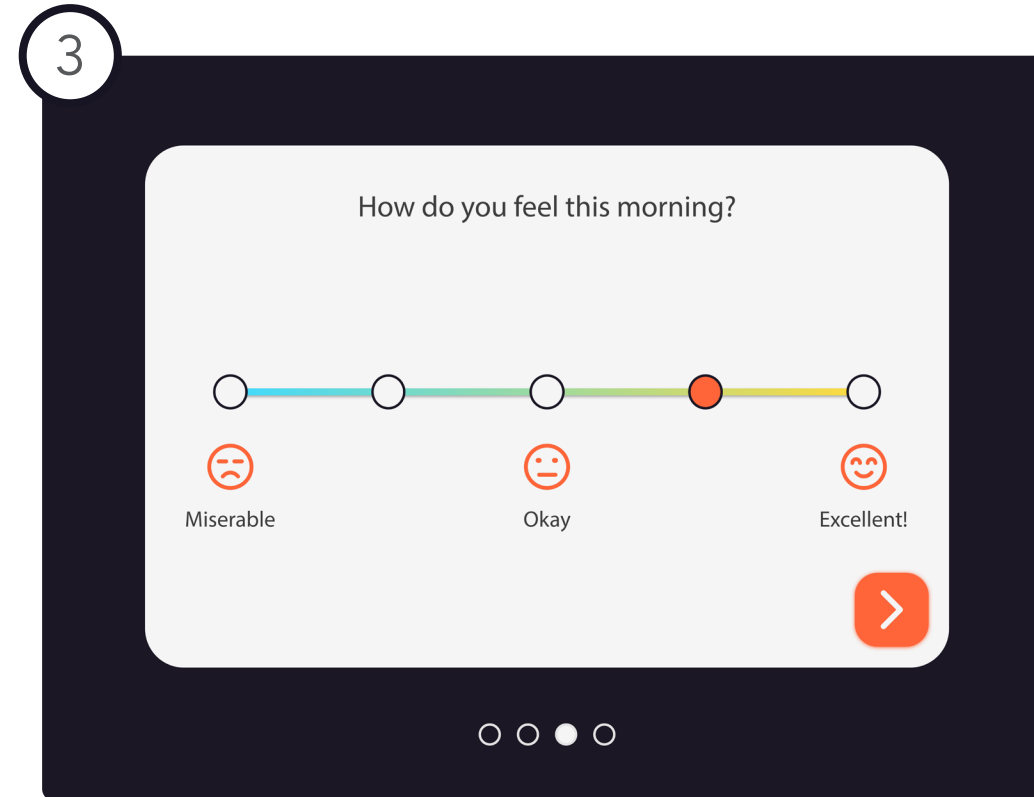
After pressing stop on their alarm, the user will be prompted with a short user survey. The first slide of this user survey gives the user a rewarding message, such as a new streak they reached, a goal they have accomplished, or an achievement they unlocked on the device. This is meant to give encouragement and a sense of accomplishment for the user. The first few months of therapy can be very frustrating and discouraging for the user. Commonly, the user has no source of encouragement in maintaining adherence other than the threat of losing their job.

In the event that the user discontinues nightly use, the CPAP machine might provide an encouraging message when the user starts using the device again.

# DAILY USER SURVEY

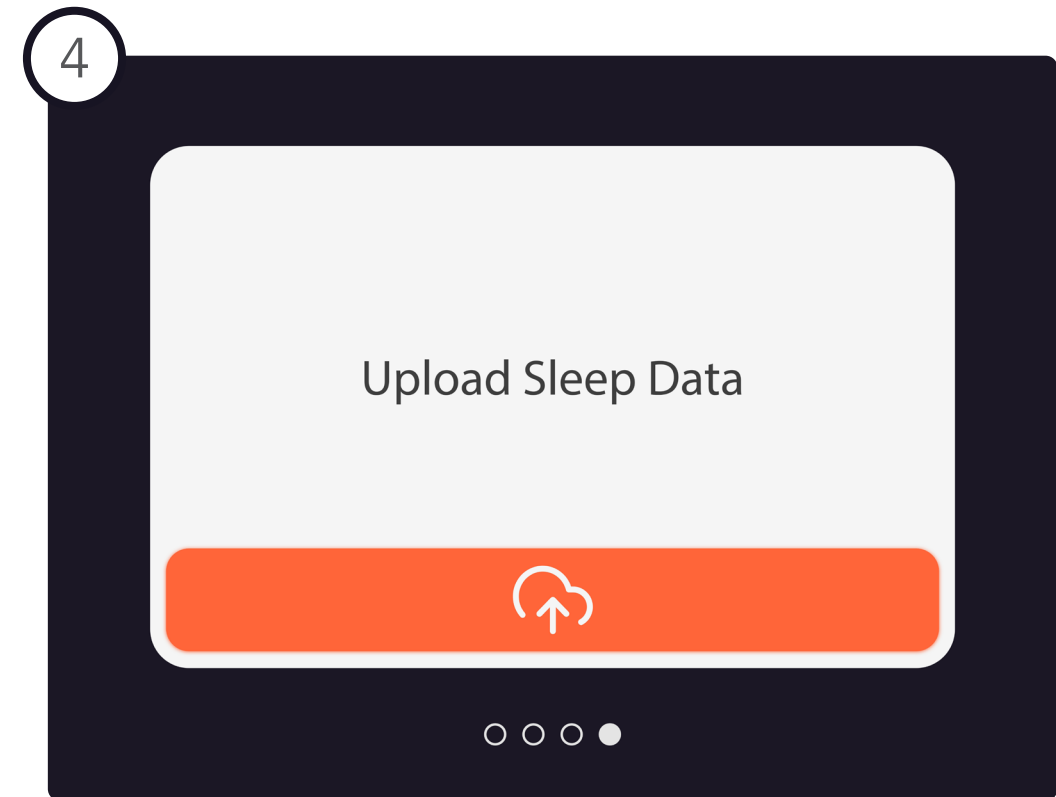


The second slide provides the user an opportunity to report problems they may be experiencing with their CPAP therapy, such as mask difficulties, pressure sensitivity, or issues with side effects as a result of the therapy. This way, the doctor can see what's wrong and address these problems earlier.



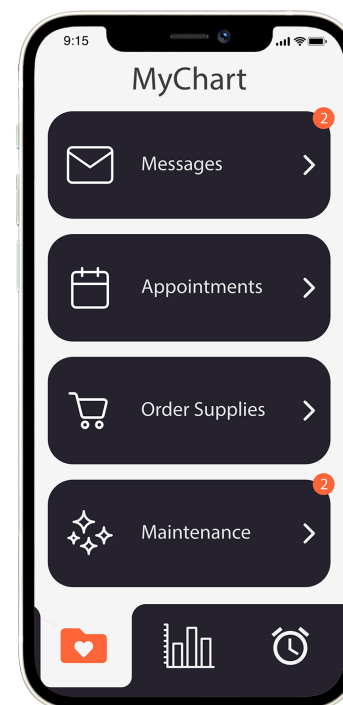
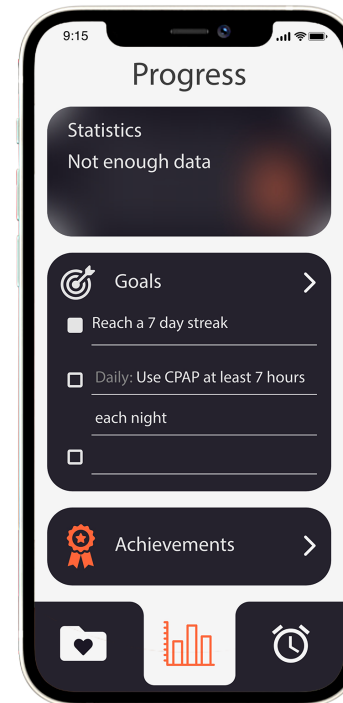
The third slide lets the user record their sleep quality if they would like. This is a qualitative assessment for the user to track their progress with CPAP therapy.

The daily user survey feature provides the user a sense of control over their CPAP therapy, and helps them express their frustrations along the way. Releasing and embracing negative emotions may be the key to improving adherence.



The last slide in the survey is to submit the feedback and sleep data to the cloud. This safely saves the data and sends it to their doctor for review.

# MOBILE APP



The accompanying app that goes along with the touch screen CPAP device facilitates further habit creation and convenience for the user. It includes a simplified version of the CPAP device interface, with the MyChart page, Progress page, and Alarms page. The user can view messages and notifications from their doctor about their CPAP device or necessary maintenance. They may also check in on their sleep progress and create goals on the go. In the instance the user might need to change their alarm clock on the go, they could create and set a new alarm and it would sync to their CPAP device ready for them when they go to sleep.



# MOVING FORWARD

## Concept Refinement

**Form** - I perceive the form of the current concept a first revision. I think there is opportunity to make adjustments with the proportions, and physical features that might enable a better user experience. This will come from early user testing with low fidelity mockup.

**Colors, materials, finish** - The current CMF feels a bit medical still, and a little bit too masculine. I want the device to feel more approachable for the user. I also think it might be cool to make the exterior customizable so the user can have a greater emotional connection to the product.

**Device case** - Since this is a portable device, it needs a carrying case, or some kind of solution to help protect it in transit. I could also incorporate ways to make it easier to pack in a luggage or backpack.

**UX/UI development** - The UX/UI will need a feature audit and some of the logistics worked out further. There could be features added and removed to streamline the app and improve the experience. Further, I think adding a light mode for daytime may be a suitable option for the user.

# MOVING FORWARD

## Research

**Usability study** - Spring semester I hope to conduct a few usability studies of my concept at various points of prototype fidelity to guide the refinement of the design. I'm also hoping to find more CPAP users and people to participate in the usability studies as well.

**Semantic differential scales** - Since this device plays into users emotions, I'd like to try to delve into how I can better understand the user psychology that influences their perception of the device. From my research this semester, I found a strategy which reliably uses scales that the user rates to reveal how they feel about the concept.

**CPAP regulations (FAA, DOT, FDA)** - As this is a medical device, it's critical that I'm at least aware of the regulations surrounding CPAP machines. I did some preliminary research on the FAA and DOT regulations, however, I would like to be well versed in what is and isn't compliant with regulations in case anyone were to ask.

# MOVING FORWARD

## Engineering

**Component sourcing** - Since I hope to take this project to full fidelity, I already know I'll need to find components to make it functional for user testing. This might include finding a compatible touch screen, robust reprogrammable single board computer such as a Raspberry Pi, a touch screen, battery pack, and air pump.

**Prototyping** - For prototyping I think I may want to do three different revisions throughout spring semester. The first being the low fidelity 3D print that I have to get form feedback. The second prototype may be semifunctional, where I discover the minimum space necessary for the internal components, and to get more user feedback. Then finally a full fidelity functional prototype which looks and functions. I want to take that to users for the usability tests as well.

**Programming** - Since this project requires an interface and electronic internals, I will have to dust off the ole coding skills. I might have to find a computer science student with skills to help me with this or provide guidance.

**Manufacturability** - Lastly, for the sake of practice and real world application, I hope to take manufacturability into all the parts of the project. This includes considering nominal wall thickness and draft of the device housing.

# GANTT CHART





# WORKS CITED

Mayo Foundation for Medical Education and Research. (2020, July 28). Sleep apnea. Mayo Clinic. Retrieved September 27, 2021, from <https://www.mayoclinic.org/diseases-conditions/sleep-apnea/symptoms-causes/syc-20377631>.

Lin, C. M., Davidson, T. M., & Ancoli-Israel, S. (2007). Gender differences in obstructive sleep apnea and treatment implications. *Sleep Medicine Reviews*, 12(6), 481–496. <https://doi.org/10.1016/j.smrv.2007.11.003>

r/SleepApnea - a layman's guide to PAP MASKS. reddit. (n.d.). Retrieved September 27, 2021, from [https://www.reddit.com/r/SleepApnea/comments/htm7m4/a\\_laymans\\_guide\\_to\\_pap\\_masks/](https://www.reddit.com/r/SleepApnea/comments/htm7m4/a_laymans_guide_to_pap_masks/).

Sleep apnea: Causes, symptoms, tests & treatments. Cleveland Clinic. (n.d.). Retrieved September 27, 2021, from <https://my.clevelandclinic.org/health/diseases/8718-sleep-apnea>.

Sequin, A. (n.d.). Everything you need to know about truck driver sleep apnea. Schneider Jobs. Retrieved September 27, 2021, from <https://schneiderjobs.com/blog/truck-driver-sleep-apnea>.

Bloch, K. E., Latshang, T. D., & Ulrich, S. (2015). Patients with Obstructive Sleep Apnea at Altitude. *High Altitude Medicine & Biology*, 16(2), 11–116. <https://doi.org/10.1089/ham.2015.0016>

Mayo Foundation for Medical Education and Research. (2018, May 17). CPAP machines: Tips for avoiding 10 common problems. Mayo Clinic. Retrieved September 27, 2021, from <https://www.mayoclinic.org/diseases-conditions/sleep-apnea/in-depth/cpap/art-20044164>.

Kuniar, Tomasz J., MD, & Morgenthaler, Timothy I., MD, FCCP. (2012). Treatment of Complex Sleep Apnea Syndrome. *Chest*, 142(4), 1049–1057. <https://doi.org/10.1378/chest.11-3223>

Sleep apnea in aviation. Sleep Apnea in Aviation | Federal Aviation Administration. (n.d.). Retrieved September 27, 2021, from <https://www.faa.gov/newsroom/sleep-apnea-aviation?newsId=18156>.

Treating sleep apnea reverses brain damage. Sleep Education. (2021, April 29). Retrieved September 27, 2021, from <https://sleepeducation.org/treating-sleep-apnea-reverses-brain-damage/>.

ASA Authors & Reviewers Sleep Physician at American Sleep Association Reviewers and Writers Board-certified sleep M.D. physicians. (n.d.). Common CPAP side effects & prevention. American Sleep Association. Retrieved September 27, 2021, from <https://www.sleepassociation.org/sleep-apnea/cpap-treatment/cpap-side-effects/>.

Obstructive sleep apnea is common in adults with down syndrome. Sleep Education. (2021, May 3). Retrieved September 27, 2021, from <https://sleepeducation.org/obstructive-sleep-apnea-common-adults-down-syndrome/>.

Landete, P., Soriano, J. B., Aldave, B., Zamora, E., Acosta, C., Erro, M., López Riobos, C., Ramos, M. I., Moldenhauer, F., & Ancochea, J. (2020). Obstructive sleep apnea in adults with Down syndrome. *American Journal of Medical Genetics. Part A*, 182(12), 2832–2840. <https://doi.org/10.1002/ajmg.a.61853>

Sleep apnea. AMAS. (2017, May 16). Retrieved September 27, 2021, from <https://www.aviationmedicine.com/article/sleep-apnea/>.

When you need to take snoring seriously. PatientsEngage. (n.d.). Retrieved September 27, 2021, from <https://www.patientsengage.com/conditions/when-you-need-to-take-snoring-seriously>.

# WORKS CITED

16, C. D. J. (2021, August 13). CPAP recap: Consumers launch class actions after Philips 'toxic' bipap and CPAP machines recall. Top Class Actions. Retrieved October 24, 2021, from <https://topclassactions.com/lawsuit-settlements/medical-devices/1026295-cpap-recap-philips-recalls-toxic-breathing-machines-consumers-turn-to-class-action-lawsuits/>.

Ferguson, C. (2014, June 27). Asleep at the Wheel: Could Mandating Sleep Apnea Tests for Transportation Operators Reduce Accidents? ABC News. Retrieved October 24, 2021, from <https://abcnews.go.com/US/asleep-wheel-mandating-sleep-apnea-tests-transportation-operators/story?id=24343717>.

Guardian News and Media. (2021, May 26). Pilot was asleep as plane flew over Brisbane and Gold Coast, report finds. The Guardian. Retrieved October 24, 2021, from <https://www.theguardian.com/australia-news/2021/may/26/pilot-was-asleep-as-plane-flew-over-brisbane-and-gold-coast-report-finds>.

Ill, A. H. (2017, August 8). Trump administration withdraws plan to test truck, bus and train operators for sleep disorder. The Washington Post. Retrieved October 24, 2021, from [https://www.washingtonpost.com/local/trafficandcommuting/trump-administration-withdraws-plan-to-test-truck-bus-and-train-operators-for-sleep-disorder/2017/08/08/c3c2ce3a-7b8e-11e7-9d08-b79f191668ed\\_story.html](https://www.washingtonpost.com/local/trafficandcommuting/trump-administration-withdraws-plan-to-test-truck-bus-and-train-operators-for-sleep-disorder/2017/08/08/c3c2ce3a-7b8e-11e7-9d08-b79f191668ed_story.html).

Rotenberg, B. W., Murariu, D., & Pang, K. P. (2016). Trends in CPAP adherence over twenty years of data collection: A flattened curve. *Journal of Otolaryngology-Head and Neck Surgery*, 45(1), 43–43. <https://doi.org/10.1186/s40463-016-0156-0>

Atreja, A., Bellam, N., & Levy, S. R. (2005). Strategies to enhance patient adherence: Making it simple. *Medscape General Medicine*, 7(1), 4–4.

Tan, B., Tan, A., Chan, Y. H., Mok, Y., Wong, H. S., & Hsu, P. P. (2018). Adherence to Continuous Positive Airway Pressure therapy in Singaporean patients with Obstructive Sleep Apnea. *American Journal of Otolaryngology*, 39(5), 501–506. <https://doi.org/10.1016/j.amjoto.2018.05.012>

THANK YOU

Jerritt Smith

