

Nourish | Dysphagia Therapy Device for Parkinson's patients

Submitted in partial fulfilments of the requirements
of the degree of

Master of Design

by

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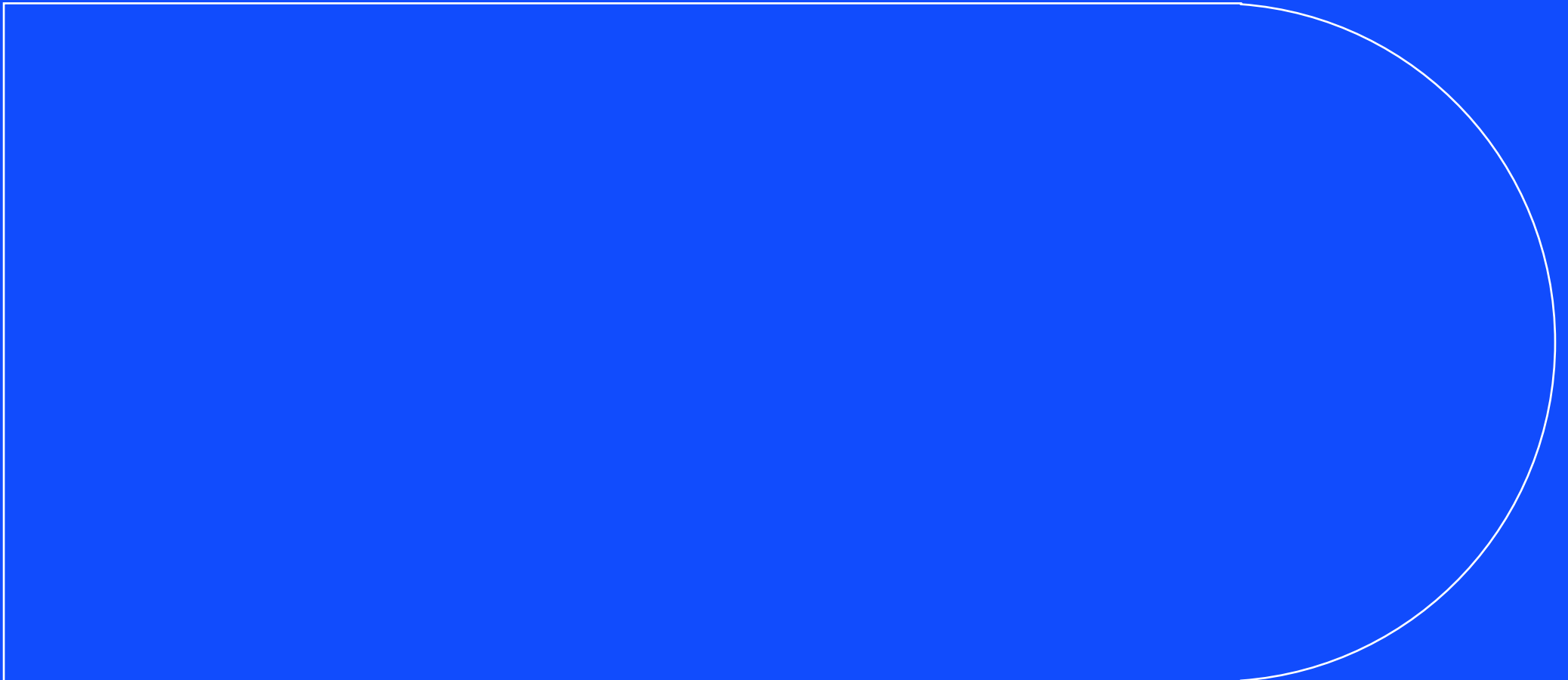
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Nourish

Dysphagia therapy device for
Parkinson's patients.

Project 3 Report by
Snehdeep Singh Pabla | Guided by: Prof. Purba Joshi



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Project Approval

This is to certify that the Industrial Design Project entitled **"Nourish | Dysphagia Therapy Device"** by Snehdeep Singh Pabla is approved for partial fulfillment for the Master of Design degree in Industrial Design.

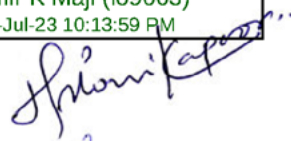


Prof. Purba Joshi
(Project guide)

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Samir K Maji (i09003)
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Signature of the Internal Examiner:



Signature of the External Examiner:



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Abstract

This project aims to design and develop a portable therapy device for Parkinson's patients suffering from the swallowing disorder known as dysphagia. The device based on the VitalStim NMES protocol integrates sensors and electrodes to induce electrical current to specific (which are patient specific) throat muscles which helps in muscle re-education. By thorough research of the medical and human condition, feedback and guidance from medical professionals the design aims to patient friendly device which provides tailored therapy which tracks the progress of the user's muscle response over time. The result will be a device which aims to allows the patient easy access to effective therapy without having to journey to the hospital and enjoy their gastronomic life without pains.



Introduction

Parkinson's is a debilitating neurodegenerative disorder which takes away one's joy of living. It saps one's energy, one's independence, one's freedom of movement, one's ability to communicate. The disease being an incurable disorder it becomes increasingly difficult and a more prominent part of a person's life as the disease progresses. And the idea to live a life of decency and dignity becomes difficult by each passing day. One of the conditions which can be induced by the disease is a swallowing disorder known as dysphagia.

Dysphagia, depending on its severity can take one away one of the most uniquely human pleasures, the joy of eating. Dysphagia makes eating a draining endeavor one has to endure multiple times a day. To treat this challenging condition there are current technologies and methods available to clinics and hospitals. However, the treatments are available only to medical professionals and at home devices are non-existent. Current solutions are often bulky, complicated to use and deploy, and look like something out of a horror movie.

The challenge was to create a product which can be used by the patient or their caregiver to provide care at home by not sacrificing in professional input. The project explores and proposes design interventions by thorough research of Parkinson's, Dysphagia, the medical viability of various technologies and modes of therapies which are used to treat the condition.





**"...not as a 'person with Parkinson's' but just as
a person.**

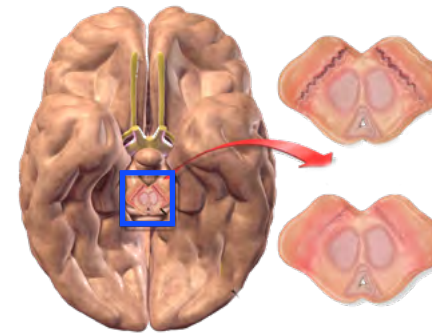
**In an ideal world Parkinson's should not be the
first thing that people find out about me, but
rather the last."**

– Matt R.

What is Parkinson's?

Parkinson's disease is a chronic and progressive neurodegenerative disorder that affects the central nervous system. Named after the British physician James Parkinson, who first described the condition in 1817, it is characterized by the gradual loss of dopamine-producing cells in the brain. As a result, individuals with Parkinson's experience a wide range of physical and mental effects that significantly impact their daily lives.

Physically, Parkinson's disease manifests through various motor symptoms that worsen over time. One of the hallmark signs is bradykinesia, which refers to the slowness of movement. Simple tasks like walking or getting up from a chair become increasingly challenging as the disease progresses. Patients may also experience rigidity, where their muscles become stiff and inflexible, making it difficult to initiate and control movements. Tremors are another common physical manifestation, often starting in the hands and later spreading to other parts of the body. These involuntary tremors can disrupt activities such as eating, writing, or even speaking.



The Substantia Nigra

Key Points:

- Loss of Nerve endings which produce Norepinephrine.
- Dopaminergic neurons in the substantia nigra gradually die, leading

to malfunction of this pathway thus creating motor problems.

- Diagnosis Becomes Challenging as there isn't a specific test to diagnose. It is based on the patient's medical history, a review of their signs and symptoms.



"Parkinson's doesn't take away
your life, but it takes **away your
pleasure of living**"

– Roberto S.



Symptoms

Parkinson's effects more than just the muscles and cause physical limitations, it also puts tremendous emotional and social strain on the lives of the people who suffer from it. And these aspects are often neglected and overlooked.

These symptoms include bradykinesia, where movements become slower and more difficult to initiate; tremors, which are involuntary shaking or trembling movements; rigidity, causing muscle stiffness and resistance to movement; and postural instability, leading to balance and gait difficulties.

Other symptoms encompass freezing of gait, micrographia (small and cramped handwriting), speech and swallowing difficulties, mood disorders such as depression and anxiety, cognitive changes, and sleep disturbances. Understanding these symptoms and their effects is crucial for diagnosing and

cognitive

- Executive Dysfunction
- Slowed Cognitive Processing
- Impaired Recall
- Impaired Time Perception
- Visuospatial Difficulties

motor

- Tremors of 4–6hz
- Pill-rolling tremors
- Rigidity
- Postural Instability
- Gait & Posture Disturbances
- Slurred Speech
- Mask-Like Facial Expression
- Hand-writing issues

neuropsychiatric

- Depression
- Anxiety
- Apathy and Anhedonia
- Pathological Gambling
- Compulsive Sexual Behavior
- Punding
- Daytime Drowsiness
- Insomnia
- Orthostatic Hypotension

gastrointestinal

- Constipation
- Impaired Stomach Emptying
- Excessive Production of Saliva
- Swallowing Impairment



Parkinson's in India

Parkinson's disease poses a significant health concern in India, affecting a substantial number of individuals. Estimates suggest that the prevalence of Parkinson's in the country ranges from **70 to 200 cases per 1,00,000 people**. While the disease can affect individuals of all ages, it is more commonly diagnosed in individuals **over the age of 60**.

According to a 2018 study

Risk of Parkinson's



- Early Onset Parkinson's **before the age of 40 is rare**.
- It is **even more rare** in younger i.e. less **than 30 yo people**.
- Its prevalence increased **notably in older age groups**.
- Mostly affects the **older age groups**.

India saw an est. **771,000 cases of Parkinson's**.
An est. **45,300 deaths** were due to Parkinson's



Parkinson's in India

Prominent Issues

Lack of Awareness

Awareness about Parkinson's disease is gradually increasing in India, although challenges remain due to limited access to healthcare facilities and the scarcity of specialized movement disorder clinics in certain regions. This can hinder early diagnosis and appropriate management of the condition. However, efforts are being made to improve awareness and knowledge about the disease across the country.

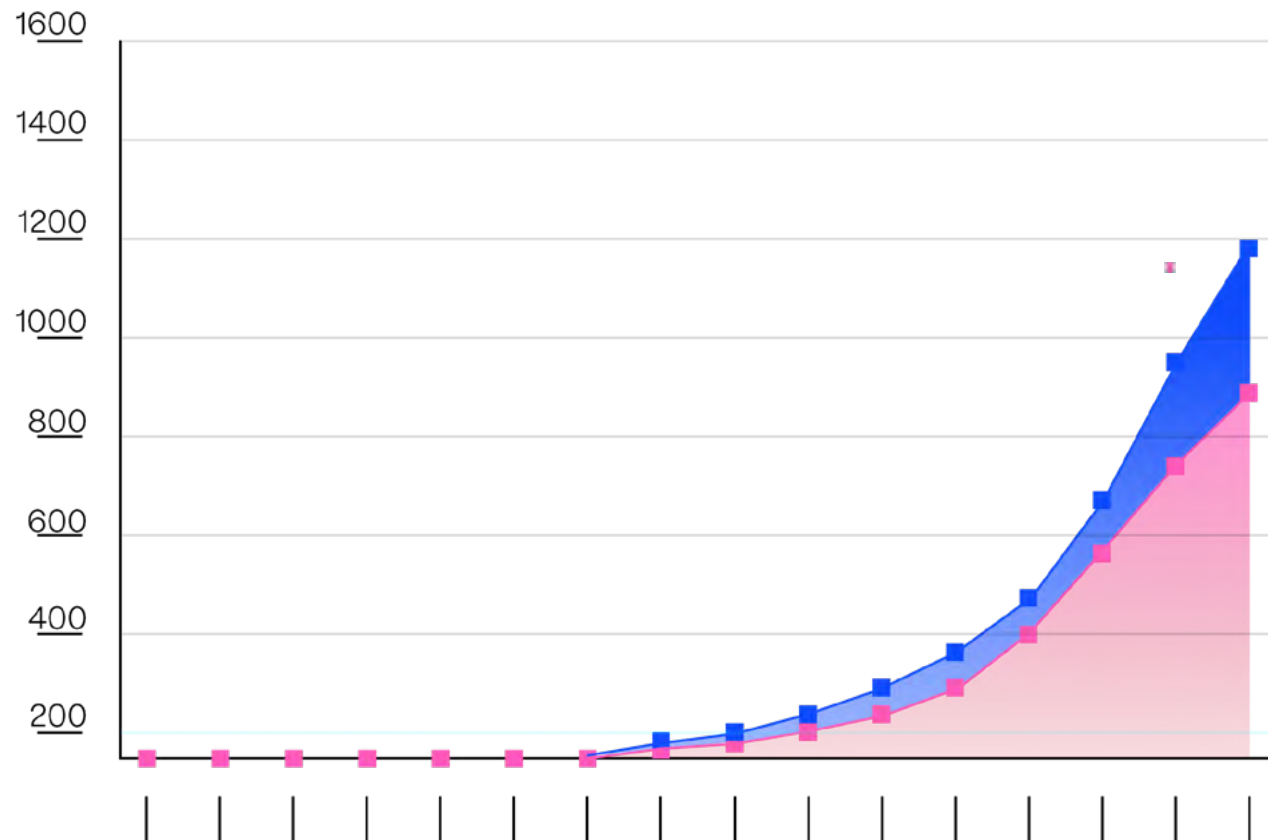
The management of Parkinson's disease in India follows a multidisciplinary approach, involving healthcare professionals such as neurologists, physiotherapists, occupational therapists, speech therapists, and social workers. Medications, including levodopa, dopamine agonists, and other symptomatic treatments,

are commonly employed to alleviate symptoms and enhance the quality of life for patients.

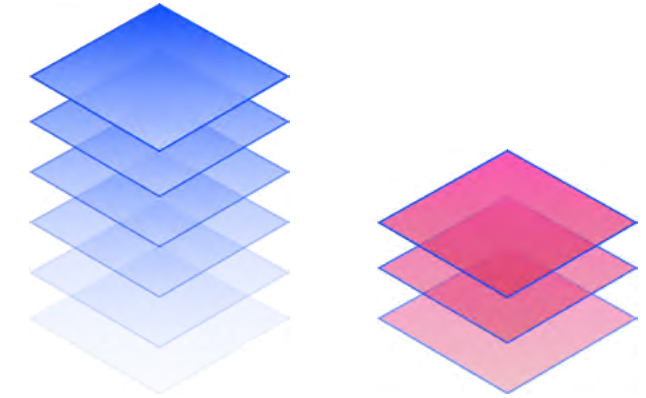
Community Support

In India, several support groups and organizations are dedicated to raising awareness, providing support, and advocating for individuals with Parkinson's and their families. These organizations play a vital role in improving access to resources, disseminating information, and fostering a sense of community among those affected by the disease. Through their efforts, they contribute to enhancing the overall well-being and support available to individuals living with Parkinson's disease in India.





Age-specific incidence rate of neurological disorders



Male

Female

The highest male to female ratio was observed for age intervals **40– 49 years and 50–59 years**. It decreases for the age intervals **60–69 years (2.03)** and **70–72 years**.

2X more likely to effect **men**



What causes Parkinson's?

The exact cause of Parkinson's disease is not yet fully understood. However, research suggests that it is likely to be caused by a combination of genetic and environmental factors. Here are some key factors believed to play a role in the development of Parkinson's

Genetics: Certain genetic mutations and variations have been associated with an increased risk of developing Parkinson's disease. These genetic factors can contribute to the dysfunction and degeneration of dopamine-producing neurons in the brain, which are central to the development of the disease.

Environmental Factors: Exposure to certain environmental factors has been implicated in the development of Parkinson's disease. Prolonged exposure to certain toxins, such as pesticides and herbicides, industrial chemicals, and heavy metals like lead, has been associated with an increased risk.

Oxidative Stress and Mitochondrial Dysfunction: Oxidative stress, which occurs when there is an imbalance between the production of free radicals and the body's ability to neutralize them, is believed to play

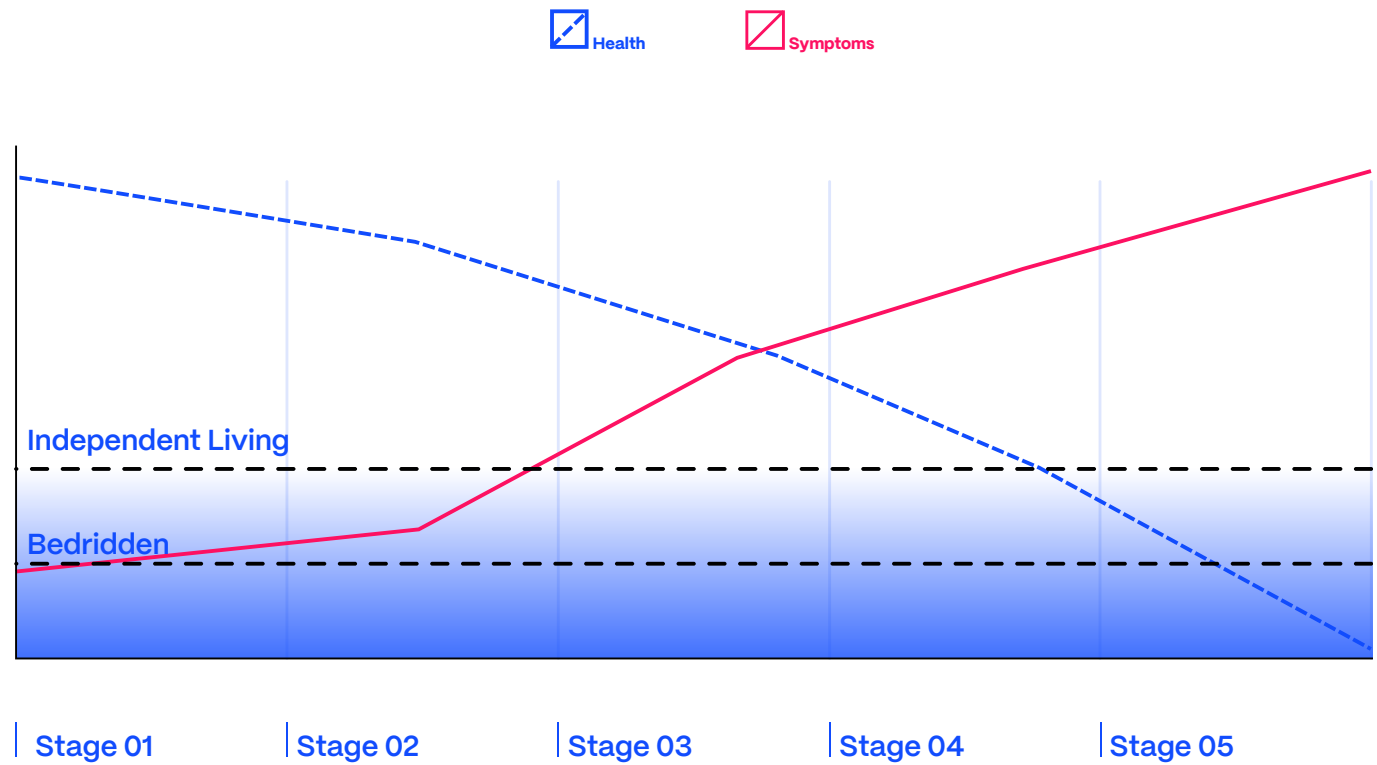
a role in the development of Parkinson's.

Alpha-Synuclein Accumulation: Parkinson's disease is characterized by the accumulation of abnormal protein aggregates, known as Lewy bodies, within neurons. These aggregates primarily consist of a protein called alpha-synuclein. The presence of Lewy bodies disrupts normal cellular function and can lead to neuronal damage and cell death.



Stages of Parkinson's

Parkinson's has 5 stages with each stage being a progressive worsening of cognitive and physical functions.



Stage 1 – Mild Symptoms

Mild Symptoms which generally don't interfere with daily activities. Symptoms at this stage can often be missed. Medications are prescribed to reduce symptoms at this stage.

mild tremors

mild tremors, exclusive to one side of the body.

postural change

it starts off as slight hunch or change in posture. Which may be barely noticeable, at first.

changes in walking

turning requires quick adjustments to balance and moving your head, upper body and lower body in sequence. If you have rigidity, this is especially difficult to do.

changes in facial expressions

the patient start becoming less expressive than before.



Stage 2 – Worsening Symptoms

In stage 2, the symptoms continue to worsen. The worsening symptoms makes daily tasks more difficult and take longer. But even then, the patient can continue to live on their own.

worsening tremors

tremors start to show more frequency and become harder to control.

movement rigidity

Muscle stiffness may occur in any part of the body. The stiff muscles can be painful and limit range of motion.

gait complications

Patients start noticing that their walking pattern has altered. Hesitation when they start walking starts to become a problem.

further changes in facial expressions

It can be hard to smile, raise your eyebrows or otherwise express your feelings using their face,



Stage 3 – Mid stage

In stage 3, known as the mid-stage it becomes increasingly difficult to live on your own. The patient becomes increasingly reliant on friends and family.

loss of balance

Balancing can be an issue, especially on uneven terrain. Needs minor assistance from objects or the surroundings to reorient. It's also difficult to turn.

regular falls

Falls become more common as balance worsens.

fine motor complications

Patients began to lose their fine motor skills which help them write, and perform many day to day activities.

slower reflexes

The reaction time becomes slow making it difficult to react to sudden changes in the environment.



Stage 4 – Fully developed

Symptoms become fully developed and severely disabling. The person is still able to walk and stand without assistance. The person needs significant help with activities of daily living and is unable to live alone.

stiffness in legs

Legs become very difficult to move and control. Knees are difficult, borderline impossible to bend.

assisted movement

Assistance of people or tools becomes necessary to move around. Independent movement is rare..

drooling

Excessive drooling, or sialorrhea, becomes common as the throat muscles weaken. Causes awkwardness in social situations and destroying elf confidence.

dystonia

It is a sustained or repetitive muscle twisting, spasm or cramp that can occur at different times of day



Stage 5 – Advanced PD

Most advanced and debilitating stage. Stiffness in the legs may make it impossible to stand or walk. Person is bedridden or confined to a wheelchair unless aided. Requires around-the-clock care.

Side effects from medications at these later stages can often outweigh the benefits.

total loss of independent movement.

Patients are unable to move at all. They have to use tools, aids and most importantly, a caretaker to help them take care of their basic needs.

bedridden

Due to loss of independent movement, the patient is mostly bedridden and loses the ability to any major movements.

24/7 nursing

As the patient cannot move, to take care of their basic needs a constant caretaker is required.

hallucinations and delusions.

Hallucinations and delusions become common. tactile, gustatory or olfactory hallucinations, which tend to co-occur with visual hallucinations.

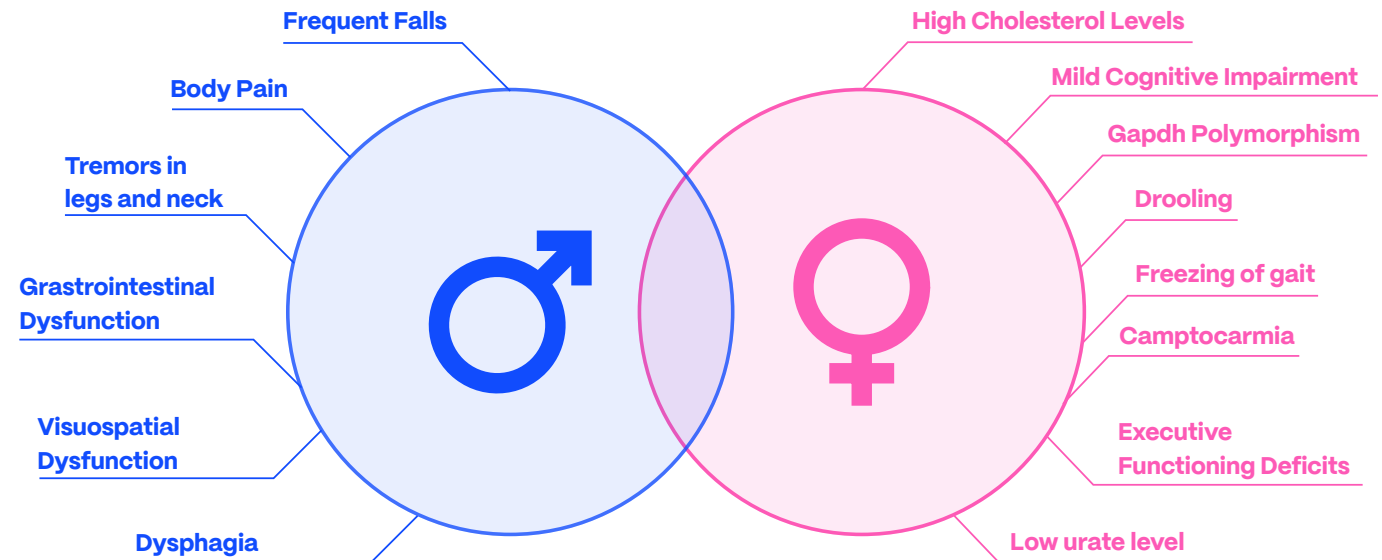
Unusual thoughts, beliefs or worries that aren't based on reality are a constant.



Prominent Symptoms

Women show distinctive symptoms as well as differences in the response to pharmacological therapies and deep brain stimulation procedure, and in the personal evaluation of the quality of life compared with men

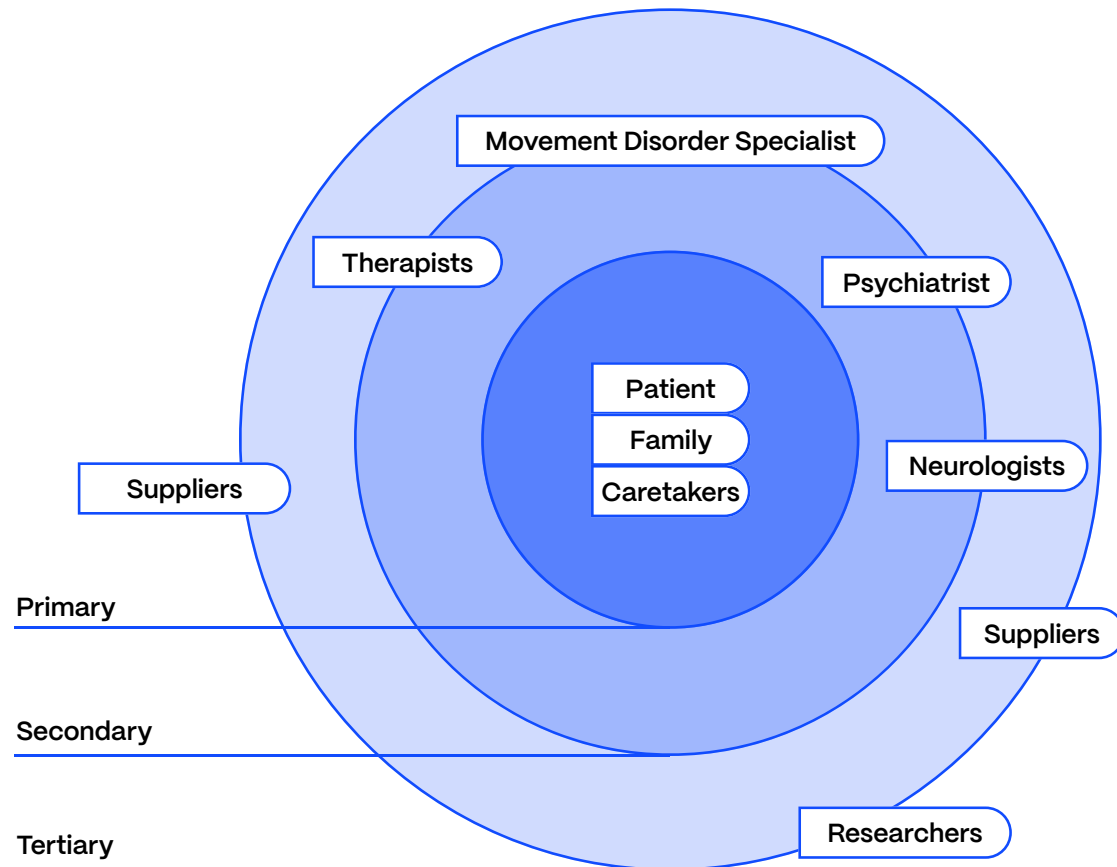
A recent study in the United States disclosed that women are also less likely than men to have informal caregiver support. As a result, more women use paid caregiver services than men. linked to the longer average lifespan of women and their inclination toward being caregivers rather than receivers of care.



Stakeholders

Parkinson's effects not only the patient, but their friends, family, profession, hobbies. Their entire close social circle becomes effected. As a person sooner or later, will require assistance from their loved ones or a professional caregiver.

There are a lot of stakeholders who are impacted.



Insights from Research Papers

Gait Performance

- ◆ Attention strategies and visual clues help in attaining equal stride length.
- ◆ Rhythmic motion of treadmill helps PD patients to regularize gait. Also improves step variability and stride length which become major risks for elderly people.

Diagnosis Confirmation

- ◆ Diagnosis of Parkinson's disease requires obtaining history regarding prodromal symptoms, family history, and current concerns.
- ◆ Examination must show the core features of bradykinesia and rigidity and/or tremor.
- ◆ Once history and physical examination features of parkinsonism are confirmed, the patient response to levodopa (or potentially other dopaminergic medications) is analyzed

to confirm Parkinson disease.

Work Life and Diagnosis

- ◆ More than half of the cases that were misclassified as PD suffered from some other form of parkinsonism.
- ◆ PD participants had a significantly lower muscle strength in the upper extremity but not in the leg.
- ◆ Majority of the PD participants reported that the disease interfered with their working capacity, and many indicated that they struggled to cope with their work demands. Still, the percentages of PD participants employed a decade after diagnosis (24%) was high

"Parkinson's doesn't take away your life, but it takes **away your pleasure of living**"
– Roberto S.



Products in the market

Products available in the market, were researched to have a gauge on the kind of work that's been done to help people with Parkinson's live their lives with dignity.

There are numerous innovative and purpose-built products available in the market to assist individuals living with Parkinson's disease in easing their daily lives. These products are designed with the specific challenges and symptoms of Parkinson's in mind, aiming to enhance mobility, independence, and overall quality of life. Ranging from assistive devices to smart technology solutions, these products address a wide range of needs, including tremor management, mobility support,

medication management, communication assistance, and fall prevention. By integrating ergonomic designs, intuitive interfaces, and advanced technologies, these products strive to empower Parkinson's patients, enabling them to navigate their daily routines with greater ease, confidence, and autonomy.



Toileting aids



Eagle Health Toilet to Tub
Sliding Transfer Bench



Hinged Elevated Toilet Seat



Toilet Roll Holder with
Invisia Handrail



Writing aids



Weighted Hand Writing Glove



Adult Weighted Deluxe
Universal Pen/cil Holder



Reading Focus Cards Combo Pack



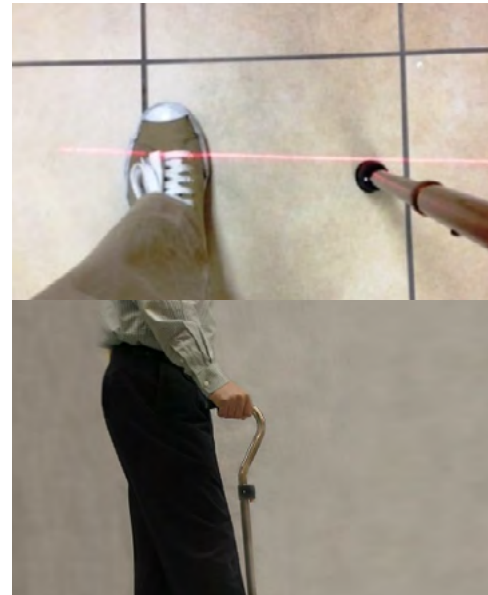
Walking Aids



U-Step 2 Tall Walker



In Step LaserCane!



Standers Auto Handy Bar Transfer Aid



Dressing aids



Dress EZ Dressing Aid



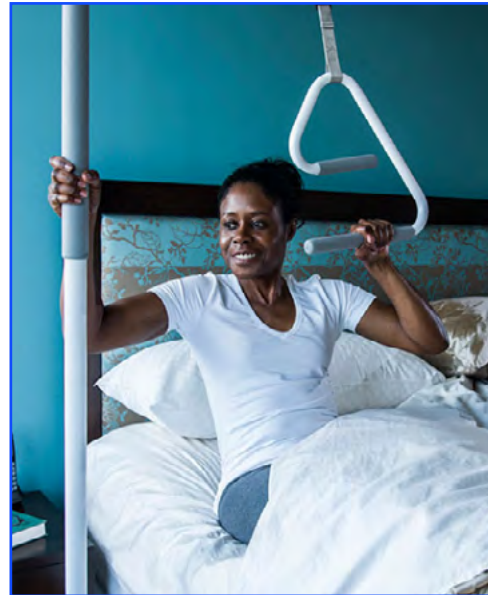
Standers Auto Handy Bar
Transfer Aid



Bedroom aids



Dress EZ Dressing Aid



Standers EZ Adjust Bed Rail



Standers Bed Caddy Pull Strap



Grooming aids



Long Handle Grip Sponges



Long Handle Body Washer



Bath Safe Adjustable Transfer
Bench w Arms and back



Weighted Cuff for
Disposable Razer



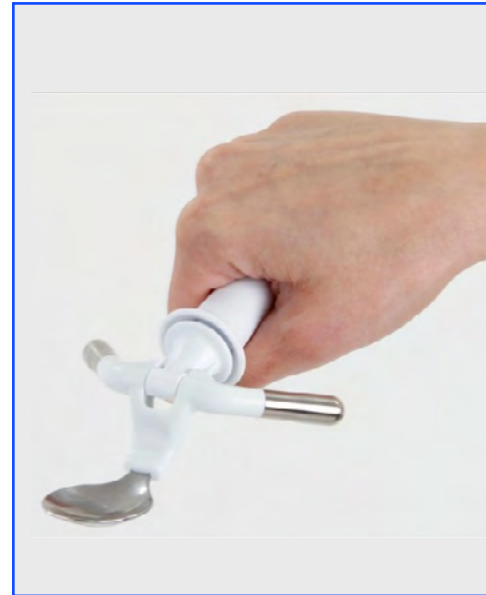
Dining aids



Weight Insulated Cups



Non-slip Scoopy
Scoop Plates



EliSpoon Balance Spoon



Handsteady Drinking Aid
with Rotating Handle



Talking to Doctors

To gain more knowledge, and more importantly knowledge about the Indian situation we sought out and contacted Doctors in Mumbai. We were able to contact 5 doctors from various specializations. Their invaluable insights from various points of view from an actual medical practitioner's perspective were a great contributor in the shaping the project.

Dr. Syed M. Zafer		Movement Disorder Specialist
Dr. Shruti Agrawal		Neurologist, Vaasi
Dr. Nilesh Chaudhary		Neurologst, Powai
Dr. Komal Ranuke		Speech Therapist, Powai
Dr. Vidya Rao Karane		Physioterapist, Powai



**"...(Parkinson's) makes you
appreciate every single moment
you're in, and times it by 100."**

–Shafaq



☀ **Dr. Nilesh Chaudhary –**
Neurologist, Hiranandani Hosp.

Balance and Gait

- ◆ Gait Apraxia and freezing, always need clues for walking visual or physical.
- ◆ Clues help. Auditory devices are available in the market that gives cue for walking.
- ◆ Risk of fall due to balancing issues.

Swallowing Problems

- ◆ Each patient has a different consistency of food they can swallow.

Tremors, Urinary Symptoms

- ◆ Mostly dealt with medicines.
- ◆ Muscles become stiff and unable to push or pull.

Other Tidbits

- ◆ Every patient will suffer from freezing of gait and swallowing issues but the duration varies.
- ◆ When diagnosed in ages of 60–70, the gait problem and swallowing appears after 5 to 7 years.
- ◆ Exercise and Physiotherapy helps a lot.

☀ **Dr. Shruti Agrawal –**
Neurologist, Clinic, Vasai

- ◆ Depression is a major symptom Parkinson's patients suffer from.
- ◆ Most patients are also sent to seek help with psychiatrists and therapists.
- ◆ Patients use different types of walking aids and wheelchairs.
- ◆ They make use of low cost laser sticks.

"... the important thing we have to do is make their lives a little easier."

– Dr. Nilesh Chaudhary



- ◆ To improve neural activity patients are encouraged to play mind games and puzzles.
- ◆ Young Onset Parkinson's is mostly affected by genetic factors.

Dr. Syed M. Zafer Movement Disorder Specialist

- ◆ More commonly seen in men, particularly who are more than 60yo.
- ◆ Levedopa is the main prescribed medicine.
- ◆ Taking high dosage of levodopa leads to abnormal involuntary movement in the patient.
- ◆ Also causes side effects like motor issues.
- ◆ Tremor dominant Parkinson is commonly seen in Men.
- ◆ Every Patient is unique, with unique symptoms



Finding Design Opportunities

After learning about Parkinson's, its effects on people and how to mitigate them, the products which are available and the Indian medical scenario, it was time to analyze and focus to find design opportunities.

As it is a sensitive medical topic, a lot of the symptoms are dealt with medically with treatments and medication. As the symptoms range from the cognitive to physical and even the neuropsychiatric. It becomes increasingly important to analyze and choose a problem which can be solved by the application of effective Industrial Design.



cognitive

Executive Dysfunction
 Slowed Cognitive Processing
 Impaired Recall
 Impaired Time Perception
 Visuospatial Difficulties

motor

Tremors of 4–6hz
 Pill-rolling tremors
 Rigidity
 Postural Instability
 Gait & Posture Disturbances
 Slurred Speech
 Mask-Like Facial Expression
 Hand-writing issues

neuropsychiatric

Depression
 Anxiety
 Apathy and Anhedonia
 Pathological Gambling
 Compulsive Sexual Behavior
 Punding
 Daytime Drowsiness
 Insomnia
 Orthostatic Hypotension

gastrointestinal

Constipation
 Impaired Stomach Emptying
 Excessive Production of Saliva
 Swallowing Impairment

A lot of the symptoms which are cognitive in nature are dealt with medical treatments or with mental therapy. This makes an **Industrial design interventions irrelevant**. If there is any possibility for one, it is increasingly difficult to design one. A major hurdle is to get the patients to talk in the first place. Due to the sensitive nature and societal

taboo associated with mental health in India, many patients refuse to talk about it. It was also discouraged by the Doctors we spoke to due to concerns with clearances and ethical reasons.

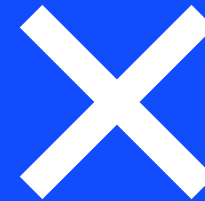
For mental therapy and support, a Communication Design or System Design support network is more

helpful than physical products. Mental health especially is a tricky one to solve with products as the struggles vary from person to person and are quite intimate. **Healthy interpersonal communication is key.**



cognitive**motor**

Tremors of 4–6hz
 Pill-rolling tremors
 Rigidity
 Postural Instability
 Gait & Posture Disturbances
 Slurred Speech
 Mask-Like Facial Expression
 Hand-writing issues

neuropsychiatric**gastrointestinal**

Constipation
 Impaired Stomach Emptying
 Excessive Production of Saliva
 Swallowing Impairment

After discussions and research it became clearer that Motor and some Gastrointestinal problems like Swallowing impairments, will be areas suitable for an Industrial Design project.

At this point, the brief was kept open to find opportunities within these areas. In order to gain better

understanding we sought help from the Doctors we spoke to earlier.

Dr. Nilesh Chaudhary from Hiranandani Hospital, Powai sought keen interest in the project and gave the group keen insights and areas which are in need of design interventions either due to lack of quality of available

solutions or because of entire lack of product availability.

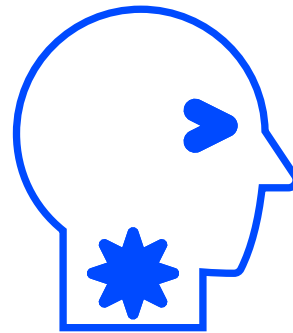


The problems which we were suggested to work on were:



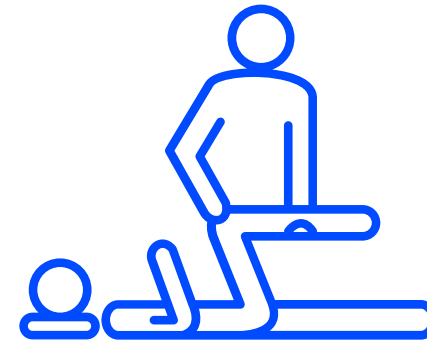
Freezing of Gait

Freezing of gait is a common and disruptive symptom experienced by many individuals with Parkinson's disease. It refers to a sudden and temporary inability to initiate or continue walking, resulting in a feeling of being "stuck" or "frozen" in place. This phenomenon often occurs during gait transitions, such as starting to walk, turning, or approaching obstacles. Freezing episodes can be unpredictable, making it difficult and frustrating for individuals to carry out daily activities and navigate their surroundings.



Swallowing Difficulties or "Dysphagia"

Dysphagia, or difficulty swallowing, is a common symptom that can be induced by Parkinson's disease. It occurs due to the impairment of the muscles involved in the swallowing process. Parkinson's-induced dysphagia can lead to problems such as choking, coughing, or the sensation of food getting stuck in the throat. This can significantly impact a person's ability to eat and drink safely, resulting in reduced food intake, weight loss, and increased risk of aspiration pneumonia.



Occupational Therapy Solutions

Occupational therapy plays a crucial role in helping individuals with Parkinson's disease maintain their independence and improve their quality of life. Occupational therapists work closely with patients to address the challenges they face in daily activities such as self-care, work, and leisure. Occupational therapy interventions may include exercises to improve fine motor skills, coordination, and balance, as well as strategies to manage fatigue, enhance energy conservation, and optimize work and home environments for safety and accessibility.



After a lot of deliberation and some research,
I chose to work on creating a product which
somehow solves the Dysphagia problem.

**"...I like to say, I have
Parkinson's, but
Parkinson's doesn't have
me."**

– John



The Design Objective

To somehow help dysphagia, by the means of a product design solution.

What?

An orthotic device that aids in reducing the symptoms that a patient with dysphagia experiences. The product will allow them to reduce the difficulties related to swallowing.

Must haves:

- ◆ Help with the swallowing motion.
- ◆ Support different variables which aid in swallowing.
- ◆ Should be usable without extensive prep.
- ◆ Must be usable by people despite accompanying symptoms.



Considering the user

The IDDSI framework is used to standardize and provide a consistent approach for the identification, description, and selection of texture-modified foods and thickened liquids in the management of dysphagia. It is designed to improve communication and understanding among healthcare professionals, caregivers, and individuals with dysphagia across different healthcare settings and countries.

The framework provides specific testing methods and criteria for each level to ensure accurate identification and consistency. It helps healthcare professionals, caregivers, and individuals with dysphagia select appropriate food and liquid consistencies based on their swallowing abilities and safety needs.



Kamla

A 78 year old grandmother who lives with her loving family. Was diagnosed with Parkinson's at the age of 67, and her symptoms have become more severe over the years.



Pains

Over the years, she has become unable to move around, and work on her own in any capacity. She is unable to move around the house without walking aids. Getting up from sitting and sleeping positions is also challenging.

She also has difficulty eating food. She has to drink water slowly as it can cause coughing. This makes her feel sad as she cannot enjoy her morning tea, which allowed her to lift her spirits in the morning after having her medicine. She feels like a very important piece of hers is missing because she cannot eat food.

Hopes

She wants to be able to live on her own terms once more. She is disheartened everyday when she has to ask someone for

help for the most menial of things. Because of this she feels isolated and lonely, which adds on to her fatigue and weakness.

She is unable to eat her favorite foods and feels frustrated by the limited options available to her. She misses them and feels that her quality of life has been significantly impacted.

Tech Literacy

Kamla is comfortable using a smartphone and a laptop, but she has limited experience with healthcare technology. Her family helps her manage her medical appointments and medications. She would be willing to try new technology if it could help her manage her dysphagia more effectively.



thinks and feels

Feels like a burden.

Tired and hopeless. Torn apart because they can't even perform a basic everyday function anymore.

Feels embarrassed because someone else has to feed them every time.

Depressed, suicidal tendencies.

Religious fears. Fears that they might have angered the gods or "Karma".

Thinks about what they could've done right or differently so they didn't have to see this day.

says and does

First tries to eat food normally.
Then over time reduces frequency of intake.
Then avoids eating food altogether.

Makes dietary changes to only eat food which don't have a thick or crunchy consistency.

Has to rely on her carer to feed her.

Expresses her pain and fatigue

hears

Pity from people around her, family and especially strangers.

Stigma and incorrect beliefs about her condition

Lots of unsolicited encouragement, reminding of her current situation.

The impact of her condition on her immediate family and people she lives with.

Kamla is surrounded by a loving and caring family with loads of encouragement. But encouragement only goes so far. After a while encouragement, especially unsolicited encouragement acts as reminder of your current and incurable predicament. Understanding what she feels, does and hears going around her becomes important.



Solutions?

Thinking from a larger overview into what elements in this problem can be changed and made better from a designer's POV.

Rethinking Food

Why does it need to be regular food? Changing the expectations for what "food" is by using meal prep with fortified ingredients, modified texture foods and other alternatives.

Rethinking food in terms of texture modification, consistency gradation may be used to gradually progress from pureed or thickened liquids to soft solids, and eventually to a regular diet

Rethinking Feeding

Reconsidering the aspects of how the patient is being fed, by giving them the required time, space and support.

On the carer's side by providing them the necessary tools and preparation they require. By helping the patient to alter their posture, controlling the food intake by helping them control the quantity of their morsels and other solutions.

Rethinking Eating

Why does the food need to be eaten? Why does it need to be chewed in the first place?

Rethinking Therapy

Rethinking therapy which is VitalStim, TENS or NMES in addition to the physical therapy the patient has to undergo. Currently all solutions require professional

supervision and/or the patient needs to travel to the hospital to get treated. Which, for a Parkinson's patient is a nightmare.



Concrete Design Brief

Rethinking Therapy

Designing an at home therapy device which uses a clinically proven therapy protocol like is VitalStim, TENS or NMES in addition to the physical therapy the patient has to undergo.

- ◆ A device which helps in therapy by using electrical stimulation. The device worn around the neck either while being awake or while resting.
- ◆ The device must be user operated. Minimal visits to the hospital.
- ◆ The must be comfortable, considering the climate and the physical condition of the user.
- ◆ Must be easy to clean.
- ◆ Must be soft to the touch.



Dysphagia

Rethinking Therapy

Designing an at home therapy device which uses a clinically proven therapy protocol like is VitalStim, TENS or NMES in addition to the physical therapy the patient has to undergo.

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- ◆ Must be soft to the touch.



Impacts of Dysphagia

Dysphagia in Parkinson's disease not only affects the ability to swallow but also impacts the various muscles involved in the chewing and swallowing process. Here are some additional effects of dysphagia on specific muscle groups and areas:

Slower Chewing and Prolonged Wait Times:

Parkinson's-induced dysphagia can lead to slower chewing, as the coordination and movement of the muscles responsible for chewing become impaired. This can result in longer wait times during meals, making the overall eating process more time-consuming.

Food Avoidance and Unintended Weight Loss:

Difficulties in chewing and swallowing certain textures of food can lead individuals to avoid those foods altogether. This can result in a limited diet and unintended weight loss due to the avoidance of foods that require more chewing or pose a higher risk of choking or discomfort.

Saliva Accumulation:

Parkinson's can also affect the control of saliva, leading to an accumulation of saliva in the mouth. This can cause drooling or difficulty managing saliva during eating, further impacting the overall eating experience and potentially affecting social interactions.

Effects on Lips, Palate, and Tongue Muscles:

The muscles involved in lip closure, movement of the palate, and coordination of the tongue can be affected by Parkinson's disease. These changes can contribute to difficulties in forming and manipulating food in the mouth, impacting chewing, bolus formation (the formation of a food lump), and subsequent swallowing.

Impact on the Larynx, Pharynx, and Esophagus:

Dysphagia can affect the function and coordination of the larynx, pharynx, and esophagus, which play crucial roles in the swallowing process. Impairments in these areas can lead to difficulties

in propelling the food bolus through the throat and into the esophagus, increasing the risk of choking or aspiration.



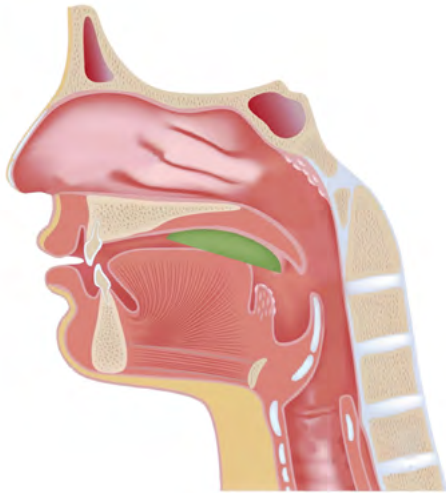
Classifications of Dysphagia:

Oropharyngeal Dysphagia: Oropharyngeal dysphagia refers to swallowing difficulties that occur in the mouth, throat, and upper esophagus. It typically arises from problems with the coordination and function of the muscles involved in swallowing. Causes of oropharyngeal dysphagia can include neurological conditions such as Parkinson's disease or stroke.

Esophageal Dysphagia: Esophageal dysphagia refers to difficulties in swallowing that arise in the lower esophagus, typically due to problems with the movement of food through the esophagus or the relaxation of the lower esophageal sphincter (LES). Causes of esophageal dysphagia can include conditions such as gastroesophageal reflux disease (GERD), esophageal strictures or narrowing, esophageal spasms, tumors, or motility disorders like achalasia.



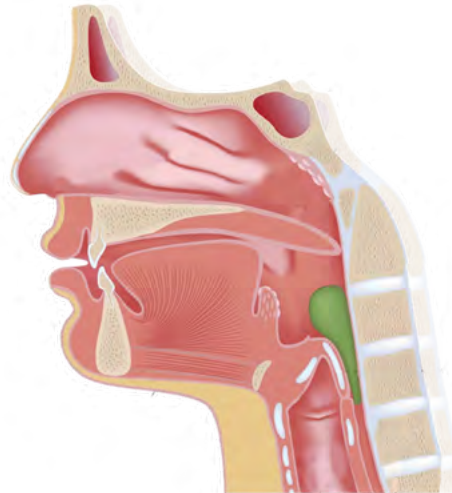
Swallowing Mechanism:



1.

1. Oral Phase:

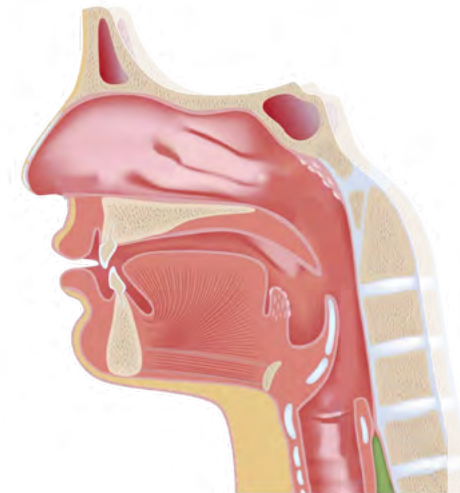
Initial stage where food is prepared and formed into a bolus. The tongue moves the food to the back of the mouth while the muscles in the cheeks and lips help contain it. Saliva is mixed with the food to aid in lubrication, and the bolus is propelled towards the throat by the tongue's upward and backward movement.



2.

2. Pharyngeal Phase:

The pharyngeal phase begins when the bolus reaches the back of the throat. It involves the rapid and coordinated movement of structures in the throat. The soft palate lifts to close off the nasal passage, and the larynx elevates to prevent food from entering the airway. The epiglottis, covers the entrance to the larynx, ensuring that the food enters the esophagus instead of the windpipe.



3.

3. Esophageal Phase:

The esophageal phase starts when the bolus enters the esophagus, a muscular tube connecting the throat to the stomach. Peristaltic waves, rhythmic contractions of the esophageal muscles, push the bolus downward towards the stomach. The lower esophageal sphincter (LES) relaxes to allow the bolus to enter the stomach while preventing stomach acid from flowing back into the esophagus.



The IDDSI Framework

The IDDSI framework is used to standardize and provide a consistent approach for the identification, description, and selection of texture-modified foods and thickened liquids in the management of dysphagia. It is designed to improve communication and understanding among healthcare professionals, caregivers, and individuals with dysphagia across different healthcare settings and countries.

The framework provides specific testing methods and criteria for each level to ensure accurate identification and consistency. It helps healthcare professionals, caregivers, and individuals with dysphagia select appropriate food and liquid consistencies based on their swallowing abilities and safety needs.



Purpose

By using a standardized framework, healthcare professionals can ensure that individuals with dysphagia receive appropriate and safe texture-modified foods and thickened liquids that match their swallowing abilities. It helps minimize the risk of choking, aspiration, or other complications related to swallowing difficulties.

The IDDSI framework also provides a common language and terminology that can be easily understood by healthcare professionals, caregivers, and individuals with dysphagia. This improves communication and reduces confusion when discussing and selecting appropriate food and liquid consistencies.

The framework promotes international standardization in the management of dysphagia. It allows for consistent practices and terminology across different countries and healthcare settings, making it easier for healthcare professionals to collaborate and share information.

The framework offers clear and practical guidelines for the preparation, testing, and

identification of texture-modified foods and thickened liquids. It simplifies the process of implementing dysphagia diets and facilitates training and education for healthcare professionals, caregivers, and food service personnel.



Levels

The framework consists of a continuum of eight levels, including four levels for texture-modified foods and four levels for thickened liquids:

Level 0 – Thin Liquids: Unthickened liquids, such as water or juice.

Level 1 – Slightly Thick: Liquids that are mildly thickened to have a slightly thicker consistency than water, but still flow freely.

Level 2 – Mildly Thick: Liquids with a thicker consistency, similar to nectar, where they can flow slowly in a continuous stream.

Level 3 – Moderately Thick: Liquids that are moderately thick, resembling honey. They pour off a spoon in a controlled manner and maintain their shape.

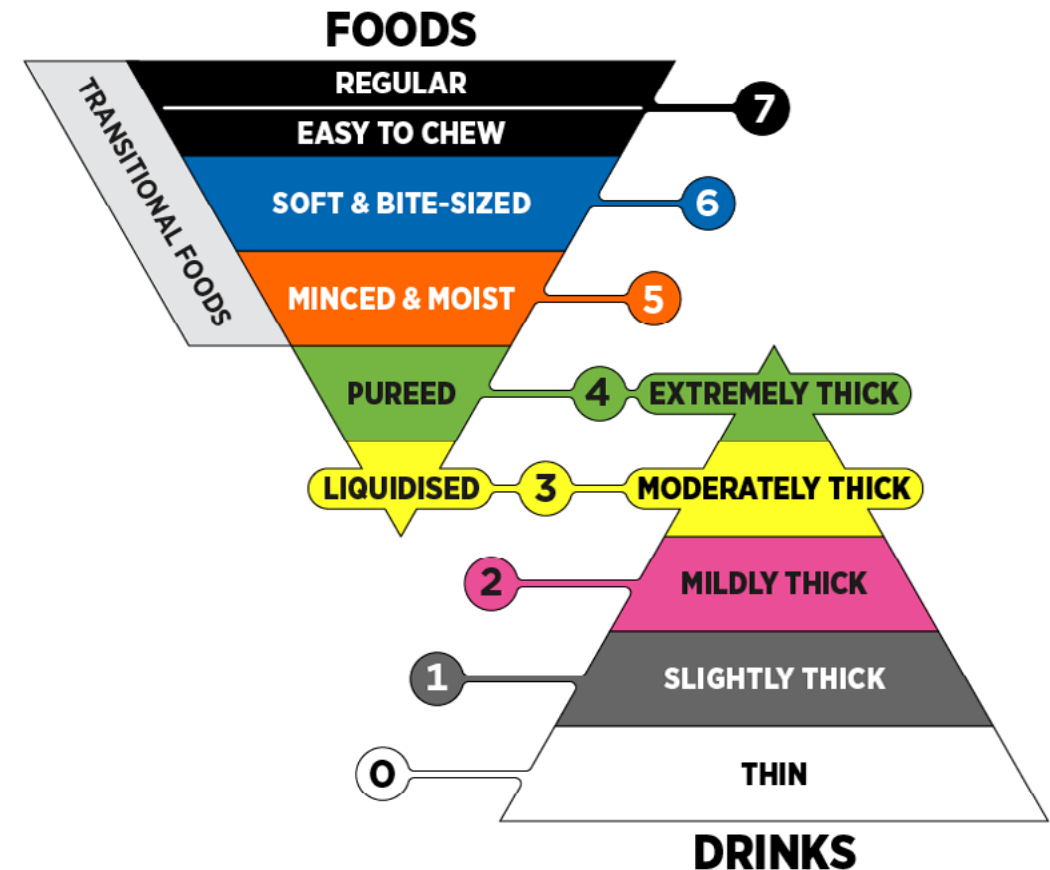
Level 4 – Pureed: Foods that are smooth, cohesive, and require

minimal chewing. They have a pudding-like consistency.

Level 5 – Minced and Moist: Foods that are soft, moist, and minced into small, easily manageable pieces. They require some chewing ability.

Level 6 – Soft and Bite-Sized: Foods that are soft, moist, and presented in bite-sized pieces. They require more chewing ability.

Level 7 – Regular: Foods that are regular in texture, without modification, suitable for individuals with no swallowing difficulties.



Learning about Electrical Stimulation

After learning about dysphagia, i started to look into electrical therapy as one of the potential solutions for the therapy.

I cam across NMES, TENS and VitalStim as potential applications. I poured over numerous research papers which have been detailed in this section.



NMES

Neuromuscular and Muscular Electrical Stimulation (NMES) is a therapeutic technique that involves the application of electrical impulses to nerves, which in turn causes the muscles to contract. This stimulation mimics the action potential generated by the central nervous system, promoting muscle activation and strengthening. NMES can be applied during functional movements or even without functional movement, depending on the specific treatment goals.

Over the years, NMES has been widely utilized to enhance muscle strength, prevent muscle atrophy, and facilitate rehabilitation, particularly in individuals who are immobilized or have limited mobility. By delivering targeted electrical stimulation, NMES can activate dormant or weakened muscles, leading to increased muscle mass, improved muscle tone, and enhanced overall physical performance.

One of the notable advantages of NMES is its versatility in application. It can be used in various settings, including clinical rehabilitation, sports training, and even

home-based therapy. Additionally, NMES can target specific muscle groups or specific muscle fibers within a muscle, allowing for focused and tailored interventions.

In addition to its muscle strengthening benefits, NMES has shown potential in promoting neuroplasticity and facilitating motor relearning. The repetitive muscle contractions induced by NMES can help improve motor control, coordination, and functional movement patterns, making it a valuable tool in neurological rehabilitation for conditions such as stroke, spinal cord injury, or neuromuscular disorders.

Application of NMES:

1. First, the patient should be seated comfortably in a way that allows muscle relaxation which is necessary for easier muscle stimulation.
2. Then, the skin should be inspected to make sure there are no skin abrasions and injuries.
3. Following that the skin should be properly cleaned with a piece of cloth and water or alcohol-based wipes and

it's very important to make sure the skin has been properly dried before the application of the electrodes on the skin.

Indications:

1. To improve muscle strength and prevent muscle atrophy.
2. To improve and maintain the range of motion around a joint.
3. To reduce muscle spasticity and spasms.
4. To increase cardiovascular function through the activity of large muscle groups.

Contra-Indications:

1. When placed over the carotid sinus.
2. When the patient has a pacemaker.
3. When we have areas of active tissue infection and devitalized skin.
4. When the patient is unable to comprehend instructions and provide feedback.



5. When the patient is pregnant.
6. When the patient has a peripheral vascular disease.

Effects of NMES on Swallowing Functions

kk According to "paper name",

In a comprehensive analysis, eleven randomized controlled trials (RCTs) involving a total of 784 individual participants were examined to assess the impact of Neuromuscular and Muscular Electrical Stimulation (NMES) on swallowing function in individuals with post-stroke dysphagia. The results of these studies provided valuable insights into the post-treatment effects of NMES in this patient population.

Among the eleven studies reviewed, ten of them (involving a total of 748 participants) reported significant improvements in swallowing function following NMES intervention when compared to control groups. These improvements were consistently observed across various outcome measures,

suggesting that NMES had a positive influence on the swallowing abilities of individuals with post-stroke dysphagia.

However, it is worth noting that one study (encompassing 36 participants) did not find any significant differences between the experimental and control groups in relation to the effects of NMES on swallowing function. Although this particular study yielded different results, it is essential to consider that it involved a smaller sample size compared to the other trials included in the analysis.

Overall, the majority of the analyzed RCTs indicated that NMES was associated with increased swallowing function in individuals with post-stroke dysphagia. These findings provide valuable evidence supporting the use of NMES as a potential therapeutic intervention to improve swallowing function in this specific patient population. Nonetheless, further research is necessary to explore the optimal parameters, treatment duration, and long-term effects of NMES in post-stroke dysphagia management.

Classifications of Dysphagia:

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esophagus, typically due to problems with the movement of food through the esophagus or the relaxation of the lower esophageal sphincter (LES). Causes of esophageal dysphagia can include conditions such as gastroesophageal reflux disease (GERD), esophageal strictures or narrowing, esophageal spasms, tumors, or motility disorders like achalasia.



TENS

Transcutaneous electrical nerve stimulation (TENS) is a therapeutic technique aimed at alleviating pain by utilizing low voltage electrical currents. This non-invasive therapy involves the use of a TENS unit, which is a battery-powered device designed to deliver controlled electrical impulses.

These impulses are transmitted through electrodes that are strategically placed on the surface of the skin. The placement of the electrodes can vary depending on the location of the pain or specific trigger points.

The TENS unit operates by stimulating the nerves in the targeted area, effectively blocking or diminishing the transmission of pain signals to the brain. The electrical impulses generated by the device can also trigger the release of endorphins, which are the body's natural pain-relieving chemicals. This dual mechanism of action contributes to the potential pain relief experienced by individuals undergoing TENS therapy.

One of the advantages of TENS is its non-invasive nature, as it does not require the use of medication or invasive procedures. The TENS unit is portable and can be easily

used at home or under the guidance of healthcare professionals. The intensity and frequency of the electrical impulses can be adjusted to suit the individual's comfort level and specific pain management needs.

TENS therapy has been used to manage various types of acute and chronic pain conditions, including musculoskeletal pain, neuropathic pain, and post-operative pain. It can be employed as a stand-alone treatment or as an adjunctive therapy in combination with other pain management approaches.

How does it work?

Transcutaneous electrical nerve stimulation (TENS) operates based on two main theories that explain its mechanism of action in providing pain relief. The first theory suggests that the electrical current produced by TENS stimulates nerve cells, thereby interfering with the transmission of pain signals. By activating these nerves, TENS may modify the perception of pain, effectively blocking or reducing its transmission to the brain.

The second theory proposes that TENS promotes the release of endorphins, which are natural pain-relieving

chemicals produced by the body. The electrical stimulation provided by TENS may trigger the release of endorphins, which then bind to opioid receptors in the brain and spinal cord. This binding process can inhibit the transmission of pain signals, resulting in pain relief.

Both theories highlight the potential mechanisms by which TENS exerts its pain-relieving effects. By either directly stimulating nerve cells or enhancing the release of endorphins, TENS aims to modulate the perception of pain and provide relief to individuals experiencing discomfort.

What is it used to treat?

TENS therapy has been used or is being studied to relieve both chronic (long lasting) and acute (short-term) pain. Some of the most common conditions for which TENS has been used include:

- Osteoarthritis (disease of the joints).
- Fibromyalgia (aching and pain in muscles, tendons, and joints all over the body, especially along the spine).
- Tendinitis (an inflammation or irritation of a tendon).



- Bursitis (inflammation of the fluid-filled sacs that cushion joints).
- Labor pain.
- Low back pain.
- Chronic pelvic pain.
- Diabetes-related neuropathy (damage to the nerves that connect the brain and spinal cord to the rest of the body).
- Peripheral artery disease ("hardening of the arteries" that circulate blood to the body).

When not to use it?

- An implantable device (cardioverter/defibrillator, neurostimulators, bone growth stimulator, indwelling blood pressure monitors). Do not use TENS therapy over or close to the areas where an electronic device is implanted. TENS could cause these devices to malfunction.
- Are pregnant. Do not apply TENS therapy to the abdomen; pelvic area; lower back; or to acupuncture points at the knee, hand or ankle. (However,

TENS can be used for labor pain.)

- Cancer. Do not apply electrodes to areas of the body where there is known or suspected cancer. Do not use TENS if you have undiagnosed pain and a history of cancer in the last 5 years.
- Epilepsy. Do not apply electrodes to your head, neck or shoulders. The impulses could cause seizures.
- Deep vein thrombosis or thrombophlebitis. Do not use TENS therapy as it may increase blood circulation, which may increase the risk of dislodging a blood clot.
- A bleeding (hemorrhagic) disorder or recent or actively bleeding tissue. TENS therapy could increase bleeding at the tissue site or increase the risk of bleeding in persons with bleeding disorders.
- Heart disease. Do not apply TENS therapy to the chest if you have heart disease, heart failure or arrhythmias.

In addition, TENS should not be applied:

- To infected tissues, wounds due to osteomyelitis or if you have tuberculosis. TENS therapy may result in the spread of infections.

- To areas of tissue that have been recently treated with radiation.
- To damaged skin (Except for open wounds where the intent is to use electrical stimulation to heal tissue. In these cases, therapy should be guided by a skilled therapist.)
- Near or over eyes or mouth, front or side of neck, or on the head.
- Near reproductive organs or genitals.
- To areas of the body that lack or have reduced sensation. In persons who have trouble communicating or who have mental impairment and cannot provide feedback to ensure the safe use of TENS.

NMES vs TENS

Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) are two types of electrotherapy techniques that utilize gentle electrical currents to target our nerves. While they share the commonality of electrical stimulation, each technique serves a distinct purpose in the realm of therapeutic interventions.



TENS primarily focuses on alleviating pain by delivering low voltage electrical currents to specific areas of the body. The electrical impulses generated by a TENS device are intended to stimulate nerve cells, potentially interrupting the transmission of pain signals and modifying the perception of pain. TENS is commonly used as a non-invasive method for pain management and can be beneficial for various acute and chronic pain conditions.

On the other hand, NMES is primarily employed to address muscular weakness and promote muscle activation. By sending electrical impulses to nerves that innervate specific muscles, NMES mimics the action potential originating from the central nervous system. This stimulation induces muscle contractions, aiming to strengthen muscles, prevent muscle atrophy, and facilitate rehabilitation, particularly in individuals with limited mobility or immobilization.

While TENS primarily targets pain relief, NMES focuses on muscle stimulation and enhancement. They have distinct applications within the realm of electrotherapy. TENS is commonly used

by individuals seeking pain management and can be self-administered with portable TENS devices. In contrast, NMES is often utilized in clinical settings under the guidance of healthcare professionals, including physical therapists or rehabilitation specialists, to address muscle weakness and promote functional recovery.



Current Products

Several current technologies are aiding in the management and treatment of dysphagia, enhancing swallowing function and improving quality of life for individuals with swallowing difficulties. It is crucial to go into the details of how and why they work for the individual.



AMPCare

This protocol is designed to improve the strength and coordination of the swallowing muscles, helping individuals with dysphagia regain their ability to swallow safely and efficiently.

The Ampcare Effective Swallowing Protocol involves the use of their proprietary Ampcare ESP™ (Effective Swallowing Protocol) system. This system includes a handheld NMES device and specialized electrodes that are placed on the skin over the targeted muscles involved in swallowing. The device delivers electrical stimulation to the muscles, aiding in muscle activation, strengthening, and retraining.

Pros

- ◆ Muscle Activation and Strengthening vis NMES.
- ◆ The combination of swallowing exercises alongside NMES.
- ◆ Treatment can be tailored to the individual.

Cons

- ◆ Professional supervision required.
- ◆ Cost and availability is highly dependant on the region and the medical professionals.
- ◆ Bulky.



Specifications:

Output Model	Ectrodes
Output Intensity	0-100mA
Channel Mode	Single and Co-Contraction Phase
Duration	50-250 sec
Mode Selection	Constant Charge
Set Intensity	Individual Channel Intensity Setting
Cycle Time	5/15, 5/20 and 5/25
Frequency	5-50 Hz
Ramp	1 sec
Treatment Time	5-30 minutes



VitalStim

VitalStim is a therapy system designed to treat dysphagia, a swallowing disorder. It utilizes Neuromuscular Electrical Stimulation (NMES) to target the muscles involved in swallowing and improve their strength and coordination. The therapy involves placing electrodes on the patient's neck to deliver mild electrical impulses that stimulate the swallowing muscles.

This stimulation helps to activate and strengthen the muscles, leading to improved swallowing function. VitalStim therapy is typically administered by trained healthcare professionals, such as speech-language pathologists, who tailor the treatment to the individual's specific needs. The therapy sessions are accompanied by targeted swallowing exercises to reinforce proper swallowing patterns. VitalStim has been used successfully in various clinical settings and has shown promising results in improving swallowing function for individuals with dysphagia.

Pros

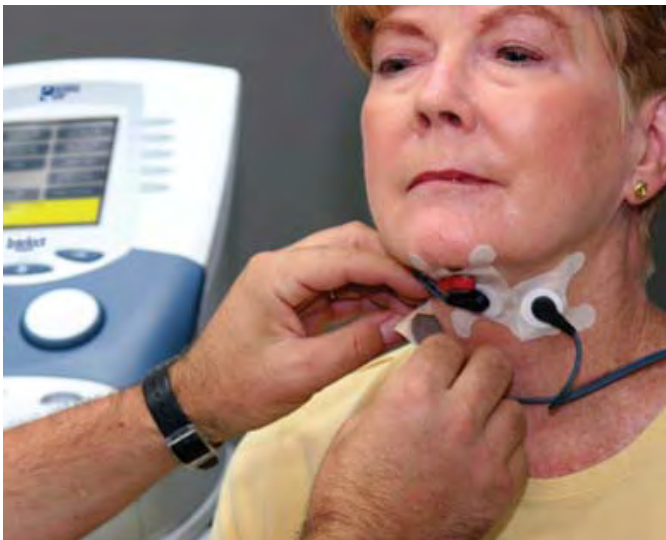
- ◆ Clinically proven effectiveness.
- ◆ Treatment can be tailored to the patient in this as well.

Cons

- ◆ Looks scary and uncomfortable (visually).
- ◆ The patient has to travel to the clinic or the hospital to get treatment.
- ◆ Requires medical supervision.
- ◆ The response to the treatment varies from patient to patient and is not guaranteed to have the same potent effect as it does in some patients.

Although, there is a smaller portable version of the device which is easier to carry, the treatment is still administered by a medical professional and is not recommended to be used at home.





VMS	
Output Mode	Electrodes
Output Intensity	0–25 mA (Constant Current)
Channel Mode	Continuous, Reciprocal, Co-Contract
Phase Duration	60–300 sec (10 % accuracy)
Set Intensity	Individual Channel Intensity Setting
Cycle Time	User Defined (ON time/OFF time 1–99s)
Frequency	1–80 pps (5 % accuracy)
Ramp Up/Ramp Down	0–3 sec
Treatment Time	1–240 min
Available on Channels	1, 2, 3, or 4

VitalStim Specifications	
Output Mode	Electrodes
Output Intensity	0–25mA (Constant Current)
Channel Mode	Co-Contract
Phase Duration	300 usec (10 % accuracy)
Set Intensity	Individual Channel Intensity Setting
Cycle Time	ON time 57s , OFF time 1s
Frequency	80 pps (5 % accuracy)
Ramp Up/Ramp Down	2 sec
Treatment Time	60 min
Available on Channels	1, 2, 3, or 4



Spectramed Aspire 2

The Guardian Aspire2 SwallowStim neuromuscular electrical stimulation (NMES) and biofeedback (sEMG) device offers many advantages with pre-set and customizable options. The sEMG biofeedback function provides an opportunity for capturing, measuring and visualizing electrical signals of the targeted musculature.

Dysphagia Therapy neuromuscular electrical stimulation protocols are designed to assist in the recruitment and re-education of the muscles used in the process of swallowing. Therapies are performed under the guidance of a clinician in an interactive process that combines stimulation with an effortful swallow.

This objective data gathering tool provides a foundation for baseline assessments, ongoing treatment progress and a positive feedback loop for patient interaction.

Pros

- ◆ Compact package.
- ◆ Communicates with iPad allowing to share data digitally.
- ◆ Multimedia training to use the product.

Cons

- ◆ Clinically Unproven.
- ◆ Requires medical assistance.



Specifications:

Power:	rechargeable lithium battery 7.4V
Safety class:	internal power BF type
Protection type:	Class II device
Shutdown current:	< 0.1mA
Operating current:	0 ~60mA
Frequency:	5 – 100Hz
Pulse width:	50 ~ 450uS (±10%)

sEMG

Measuring range:	10uV ~999uV
Highest resolution:	< 2uV
Input noise:	<10uV
Transmission bands:	120Hz ~ 1000Hz (-3dB)
Differential mode :	>5MΩ
input impedance	
Common mode:	>100dB
rejection ratio	

NMES

Frequency,	5-100Hz, biphasic balanced wave ±10%
Output intensity:	load 1000Ω, min 1mA, max 60mA



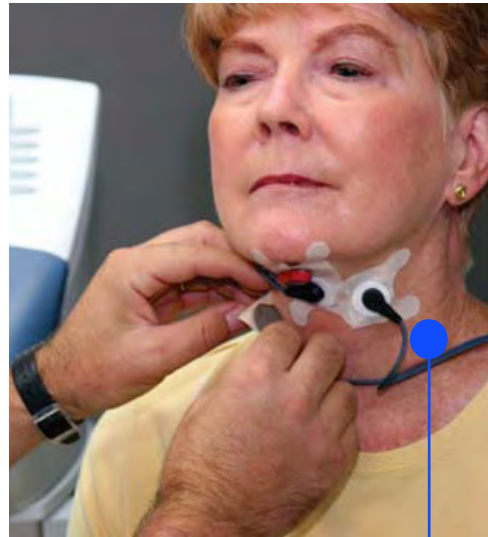
Design Analysis



1.

1. Non "User-Friendly"

The design is not user friendly. Special training required and more importantly, medical expertise. Visually, it's very oppressive. The patients get intimidated and stressed at the beginning. The products are designed to be used in a hospital setting so everything



2.

is designed to be single used and colour-coded for effective training.

2. Designed for a Secondary User

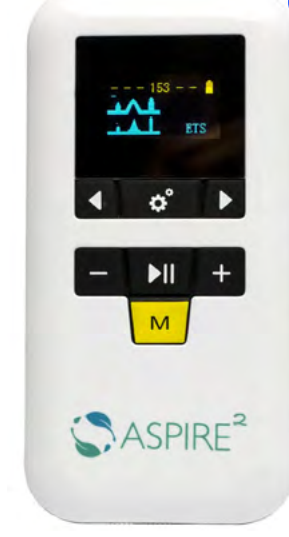
Designed for application via second individual. The patient cannot use the product on their own.



3.

3. Designed for Hospitals

Large, bulky. Designed for hospitals means everything is designed to be operated by a standing individual and with big large buttons and tons of raw data information.



4.

4. Raw Data.

The data and controls are obtuse and require frequent referral to the manual for proper usage. The data output is designed to be read by doctors and not the patient and a layperson.



Dysphagia Therapies

I started out by researching about the current therapies used to treat dysphagia.

This section lists and explains both the lifestyle and behavioral changes one has to partake in in order to deal with dysphagia.



NMES

Neuromuscular and Muscular Electrical Stimulation (NMES) is a therapeutic technique that involves the application of electrical impulses to nerves, which in turn causes the muscles to contract. This stimulation mimics the action potential generated by the central nervous system, promoting muscle activation and strengthening. NMES can be applied during functional movements or even without functional movement, depending on the specific treatment goals.

Over the years, NMES has been widely utilized to enhance muscle strength, prevent muscle atrophy, and facilitate rehabilitation, particularly in individuals who are immobilized or have limited mobility. By delivering targeted electrical stimulation, NMES can activate dormant or weakened muscles, leading to increased muscle mass, improved muscle tone, and enhanced overall physical performance.

One of the notable advantages of NMES is its versatility in application. It can be used in various settings, including clinical rehabilitation, sports training, and even

home-based therapy. Additionally, NMES can target specific muscle groups or specific muscle fibers within a muscle, allowing for focused and tailored interventions.

In addition to its muscle strengthening benefits, NMES has shown potential in promoting neuroplasticity and facilitating motor relearning. The repetitive muscle contractions induced by NMES can help improve motor control, coordination, and functional movement patterns, making it a valuable tool in neurological rehabilitation for conditions such as stroke, spinal cord injury, or neuromuscular disorders.

Application of NMES:

1. First, the patient should be seated comfortably in a way that allows muscle relaxation which is necessary for easier muscle stimulation.
2. Then, the skin should be inspected to make sure there are no skin abrasions and injuries.
3. Following that the skin should be properly cleaned with a piece of cloth and water or alcohol-based wipes and

it's very important to make sure the skin has been properly dried before the application of the electrodes on the skin.

Indications:

1. To improve muscle strength and prevent muscle atrophy.
2. To improve and maintain the range of motion around a joint.
3. To reduce muscle plasticity and spasms.
4. To increase cardiovascular function through the activity of large muscle groups.

Contra-Indications:

1. When placed over the carotid sinus.
2. When the patient has a pacemaker.
3. When we have areas of active tissue infection and devitalized skin.
4. When the patient is unable to comprehend instructions and provide feedback.

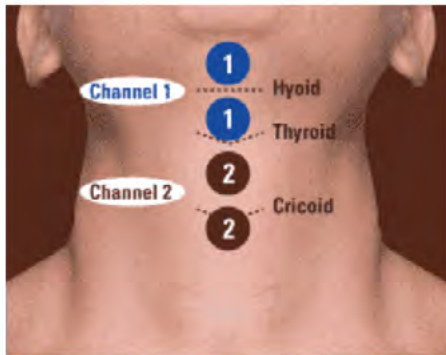


Understanding Muscle Points

To utilize NMES and TENS technologies in the product, it was crucial to understand which muscles groups and combinations thereof are targeted for effective therapy. VitalStim and other therapies target the muscle groups and combinations detailed in this section.



Placement 1

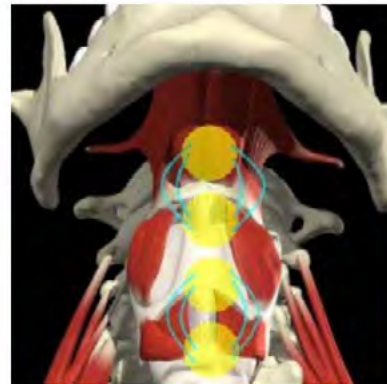


- All electrodes aligned vertically along midline
- First electrode is placed well above hyoid bone
- Second electrode is placed just below first one, above the thyroid notch
- 3rd and 4th electrode placed at equal distances below first two electrodes
- Bottom electrode should not end up below cricoid cartilage

Muscles reached

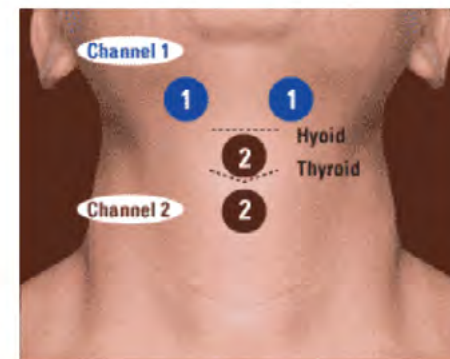


Superficial: mylohyoid, possibly sternohyoid



Deeper: geniohyoid, cricothyroid

Placement 2a

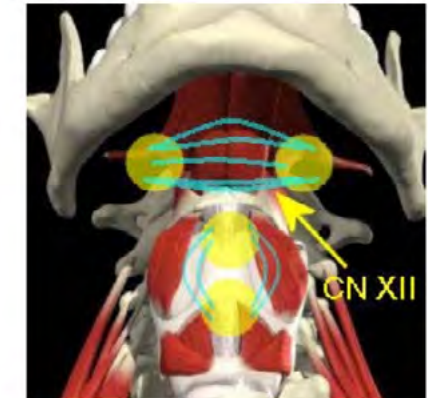


- Channel 1: electrodes aligned horizontally at or above hyoid bone
- Channel 2: electrodes aligned vertically along midline, top electrode at level of thyroid notch, bottom electrode below it

Muscles reached



Superficial: mylohyoid, anterior belly digastric

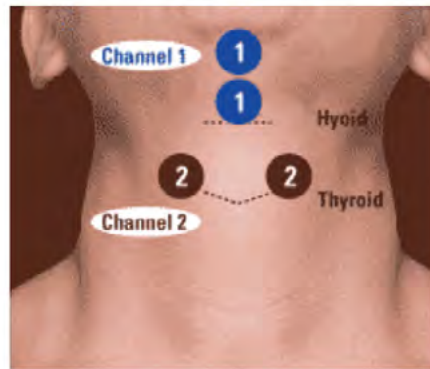


Deeper: geniohyoid, thyrohyoid, cricothyroid, possibly sternohyoid, possibly hypoglossal nerve

Screenshots from the VitalStim medical guide.

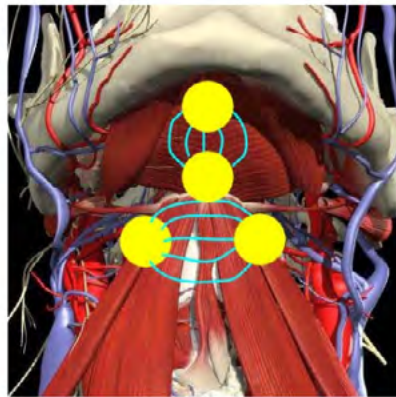


Placement 2b

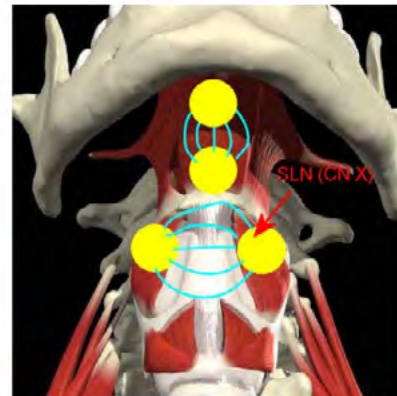


- Channel 1: electrodes aligned along midline, over geniohyoid belly
- Channel 2: electrodes placed at either side of thyroid notch, over thyrohyoid muscle belly

Muscles reached

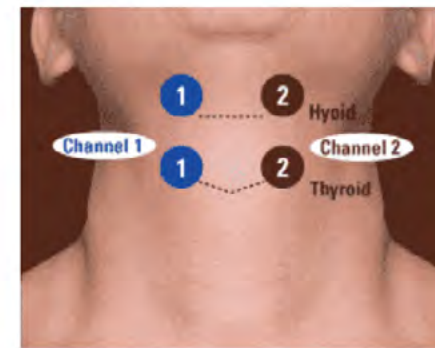


Superficial: mylohyoid, possibly sterno- and omohyoid



Deeper: geniohyoid, thyrohyoid, possibly superior laryngeal nerve (CN X)

Placement 3a

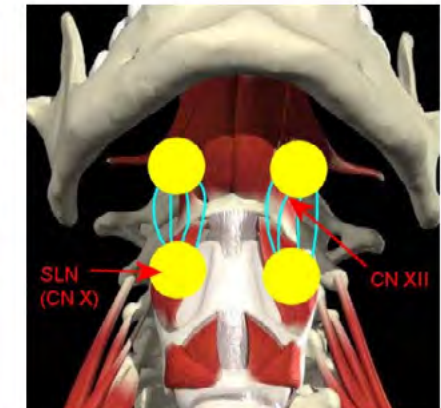


- Channels aligned vertically on either side of midline
- Top electrodes are placed just above hyoid bone
- Bottom electrodes are over the thyrohyoid muscle – at the level of the thyroid notch
- Note: DO NOT place electrodes too far laterally so as not to send current through carotid sinus

Muscles reached

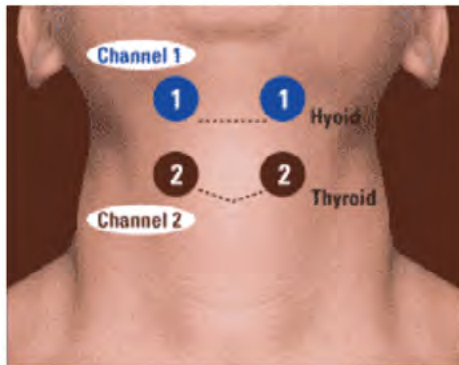


Superficial: anterior belly digastric, possibly sterno- and omohyoid

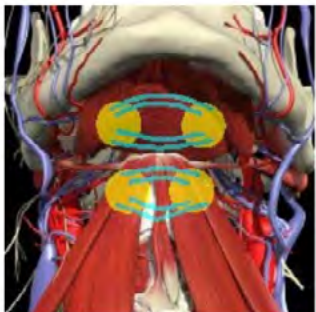


Deeper: thyrohyoid, possibly geniohyoid, possibly hypoglossal nerve, possibly superior laryngeal nerve (CN X)

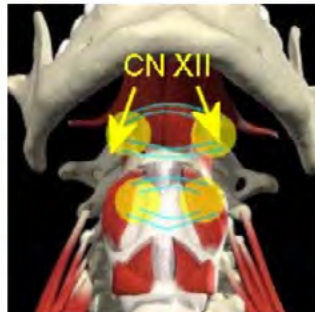
Screenshots from the VitalStim medical guide.

Placement 3b

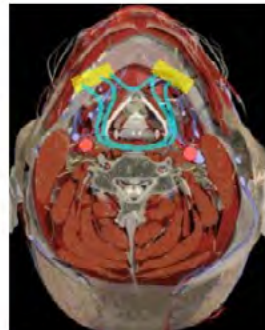
- Electrodes channel 1 aligned horizontally at or above hyoid bone
- Top electrodes are placed just above hyoid bone
- Bottom electrodes are over the thyrohyoid muscle – at the level of the thyroid notch
- Note: DO NOT place electrodes too far laterally so as not to send current through carotid sinus

Muscles reached

Superficial: mylohyoid, anterior belly digastric, possibly sterno- and omohyoid



Deeper: geniohyoid, thyrohyoid; middle pharyngeal constrictors (not depicted) *may* be stimulated as well with sufficient intensity; if top electrodes are placed far enough apart the hypoglossal nerve may be reached as well

**Placement 4a**

- Electrodes are placed over buccal branch of facial nerve
- Channel may be placed bilaterally
- Second channel may be placed superior to hyoid (as in top channel of placement 3b) to facilitate recruitment of CN XII
- Alternatively, 2nd channel may be placed on opposite side to increase facilitation of oropharyngeal sling

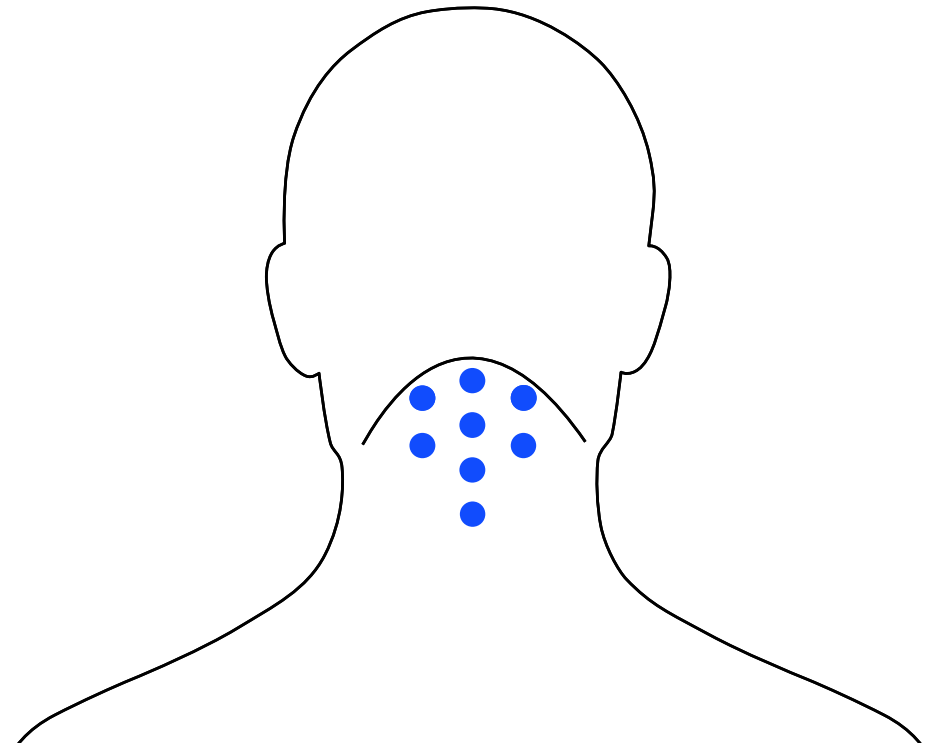
Placement 4b

- Electrodes are placed over main trunk of facial nerve
- Second channel may be placed superior to hyoid (as in top channel of placement 3b) to facilitate recruitment of CN XII
- Alternatively, 2nd channel may be placed on opposite side to increase facilitation of oropharyngeal sling

Screenshots from the VitalStim medical guide.

Mapping the points

Mapping the points allows us to understand the number of electrodes needed to make the product work with all the various patterns. While in discussions with Dr. Komal Ranuke, the frequency of use for Placement 4a was questioned as she had never come across this electrode position. The distance between the points remain largely dependent on the size of the neck and will vary greatly person to person. Which might become a problem when creating an at home solution.

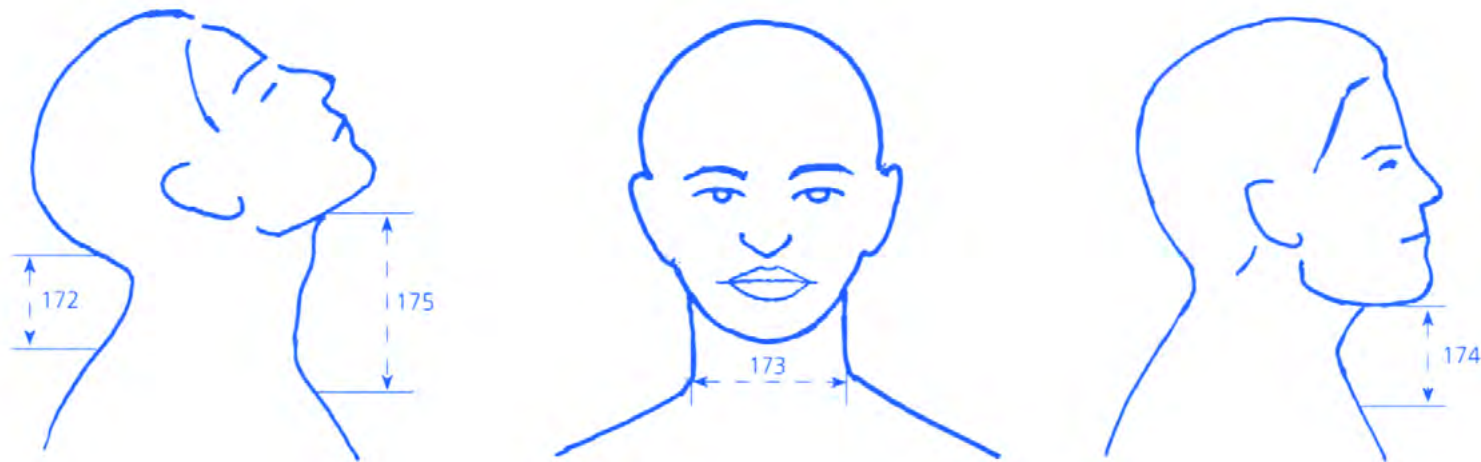


Ergonomics

R.No.	Parameters		Min	Percentiles					Max	Mean	±SD	Ratio
				5th	25th	50th	75th	95th				
172	Neck length, minimum (nm= not measured)	Male	0	13	27	42	55	80	92	43	19	0.03
		Female	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
		Combined	–	–	–	–	–	–	–	–	–	–
173	Neck breadth	Male	100	101	106	112	116	128	135	114	8	0.07
		Female	85	85	91	94	101	105	116	96	7	0.06
		Combined	85	89	101	109	115	125	135	109	11	0.07
174	Throat length normal	Male	47	58	73	82	93	109	130	84	15	0.05
		Female	42	55	72	82	99	119	135	86	21	0.06
		Combined	42	58	73	82	94	111	135	84	16	0.05
175	Throat length maximum (nm= not measured)	Male	94	104	118	129	139	162	175	130	16	0.08
		Female	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
		Combined	–	–	–	–	–	–	–	–	–	–
176	Throat length minimum (nm= not measured)	Male	0	0	0	23	36	47	56	22	17	0.01
		Female	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
		Combined	–	–	–	–	–	–	–	–	–	–



Ergonomics



The delta between the smallest neck and the biggest one is quite significant which might mean creating multiple sizes products because the precision required.



User Scenario

Parkinson's disease is a chronic and progressive neurodegenerative disorder that affects the central nervous system. Named after the British physician James Parkinson, who first described the condition in 1817, it is characterized by the gradual loss of dopamine-producing cells in the brain. As a result, individuals with Parkinson's experience a wide range of physical and mental effects that significantly impact their daily lives.

Physically, Parkinson's disease manifests through various motor symptoms that worsen over time. One of the hallmark signs is bradykinesia, which refers to the slowness of movement. Simple tasks like walking or getting up from a chair become increasingly challenging as the disease progresses. Patients may also experience rigidity, where their muscles become stiff and inflexible, making it difficult to initiate and control movements. Tremors are another common physical manifestation, often starting in the hands and later spreading to other parts of the body. These involuntary tremors can disrupt activities such as eating, writing, or even speaking.



Therapy, at home.

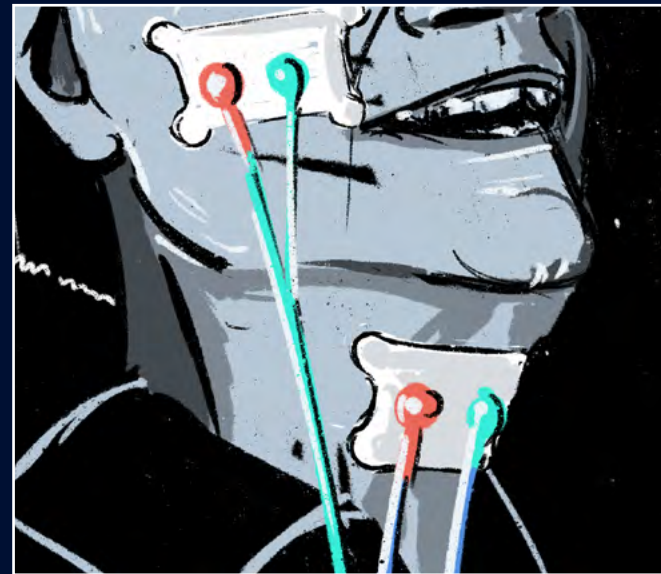
Reducing Travel

Going to the hospital for an individual is a stressful task, even if you're not going for yourself. It's even more stressful when you have Parkinson's. Depending on how severe the symptoms of your condition are, traveling to the hospital is a challenge in itself and often, a painful one.

Reducing the burden of traveling to and from the hospital is a small step to ensure proper care is being provided comfortably.

Patient Friendly

The solutions are designed, as mentioned earlier, for the medical professional in mind. The device will need to be radically redesigned in order to ensure easy usage by patients and/or their caregivers.



Therapy, while... (but not limited to)



Reading

The solution aims to be as comfortable and out of the way that the patient can focus on other active tasks, like reading.



Sleeping

It has to be comfortable enough to allow the user to be able to sleep if they so desire, during therapy.

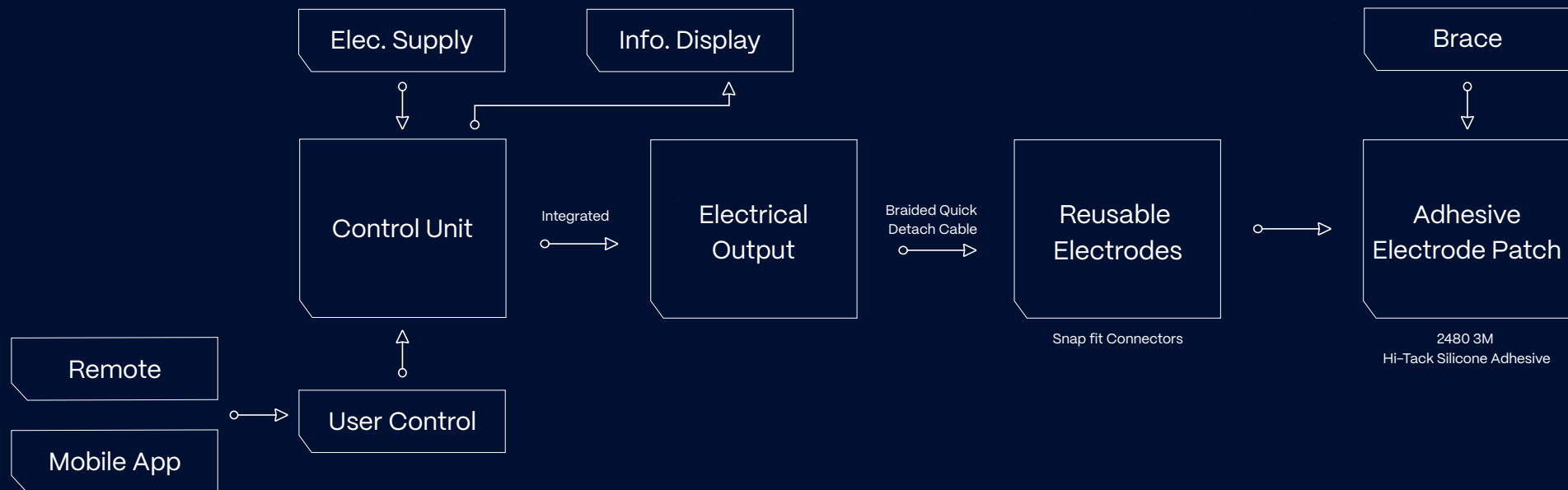


Watching TV

It has to be comfortable enough to allow the user to be able to sleep if they so desire, during therapy.



Diagramming the Design



The product system was diagrammed and detailed to find the optimum components and interoperability and find redundant components. This was done to ensure a streamlined experience to avoid confusion and mental

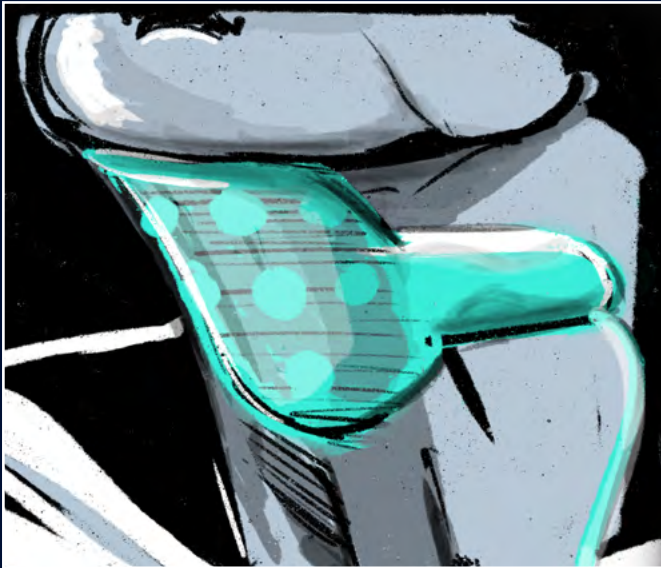
load while operating the product. Another use was to find possible problems which can occur, helping in reducing possible damage and harm to both the product and the patient.

The entire product system was divided into 3 parts.

1. The Brace or neck attachment
2. The control and power supply unit
3. And the mobile app.

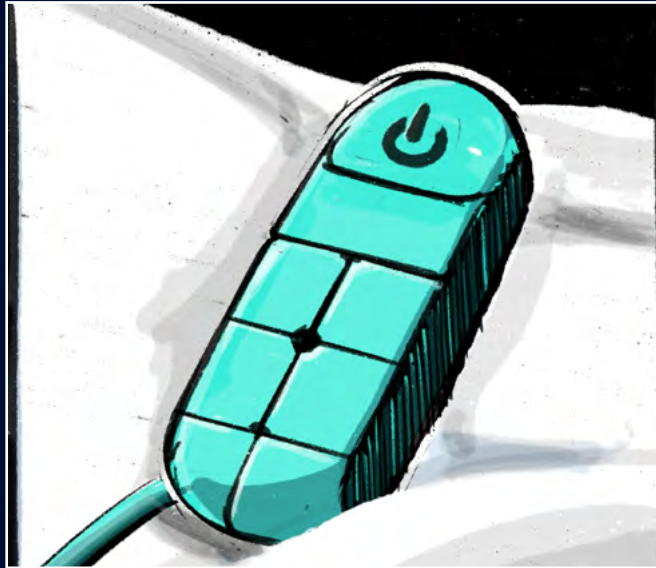


Main Components



The Neck Attachment

Some sort of device which is attached to the neck, comfortably. This will allow for electrical stimulation.



Controller/Power Supply

A controller which allows the user to control the intensity of the stimulation. This will also act as the power supply of the device.



Phone Application

The phone app will allow for data collection and sharing and also for controls.



Branding

One of the problems with the products is that none of them have a very effective brand language and identities. Partly, this is because it's not a product which is marketed towards consumers and also, because it targets a very specific and narrow target audience.

But as this is a user oriented a product, having a brand language becomes much more crucial.



Introducing...



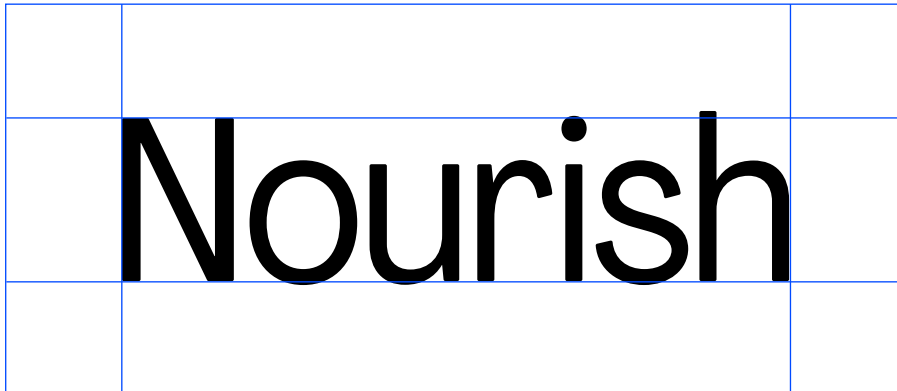
Nourish



Brand Moodboard – Neue Sanitary



Logo Mark

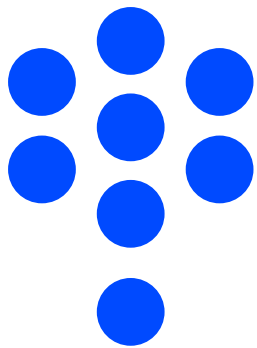


The logo mark consists of a slightly modified **Pangram Type Foundry's Agrandir typeface**, in its **Narrow Regular style**.

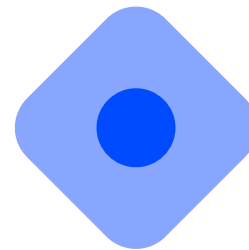
Chosen for its tall, narrow and clear characteristics. These characteristics embody the clean and honest outlook of the brand



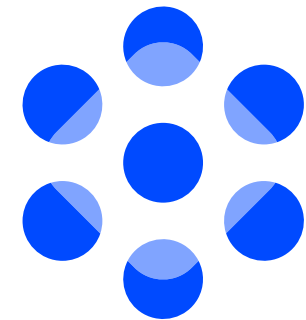
Logo Face



+



=



Nourish your **Body**

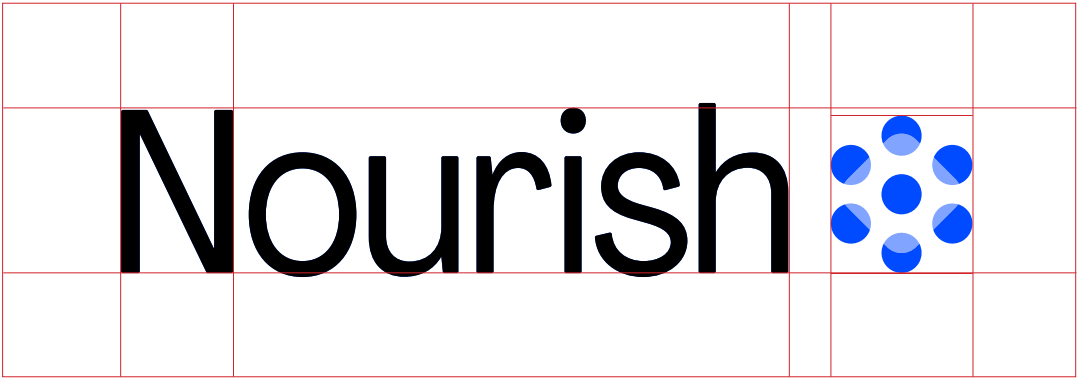
Nourish your **Soul**

Nourish

The logo face symbolizes total nourishment, nourishment of the body and the soul. **The VitalStim muscle target points** pose as **The Body** and an **Abstraction of an Eye** stands in as **The Soul**.



Logo



PANGRAM AGRANDIR

01 Narrow Regular / 02 Regular / 03 Bold

01 aAbBcCdDeEfFgGhHiIjJkK
02 lLmMnNoOpPqQrRsStTuU
03 vVwWxXyYzZ

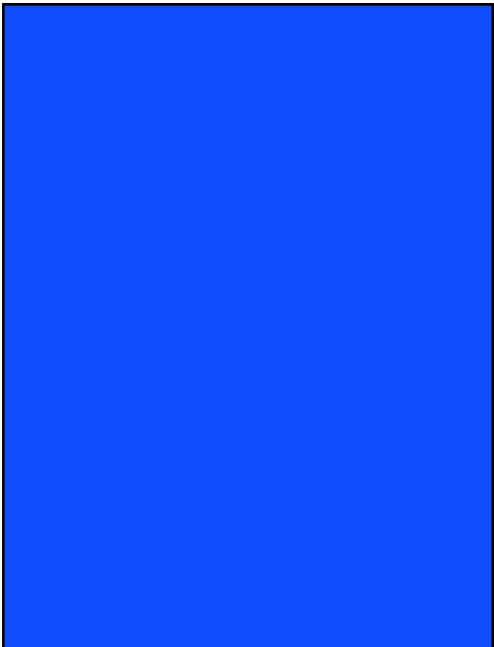
PANGRAM MORI

01 Book / 02 SemiBold / 03 ExtraBold

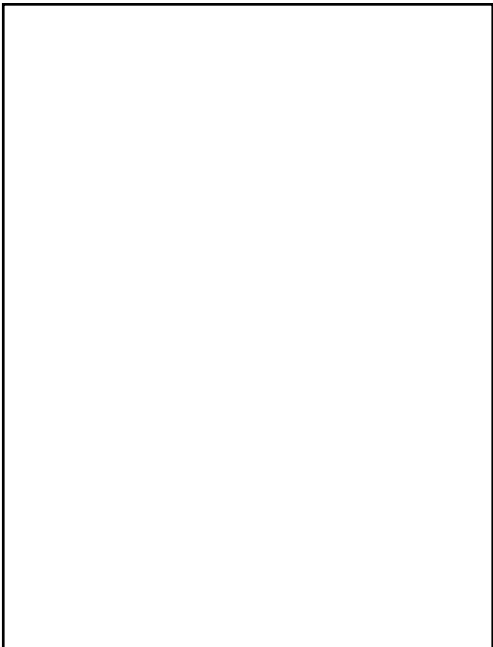
01 aAbBcCdDeEfFgGhHiIjJkK
02 lLmMnNoOpPqQrRsStTuU
03 vVwWxXyYzZ



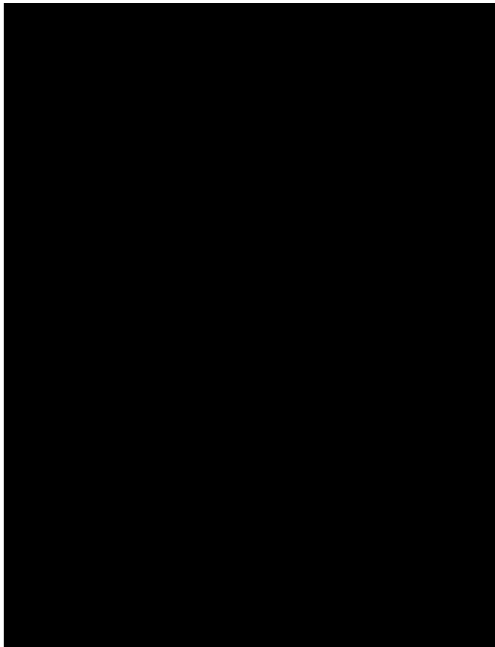
Brand Colours



00 24 255
#114cfd
Nourish Blue



255 255 255
#FFFFFF
White

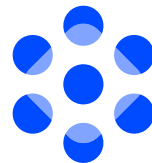


00 00 00
#000000
Black



Nourish

Nourish



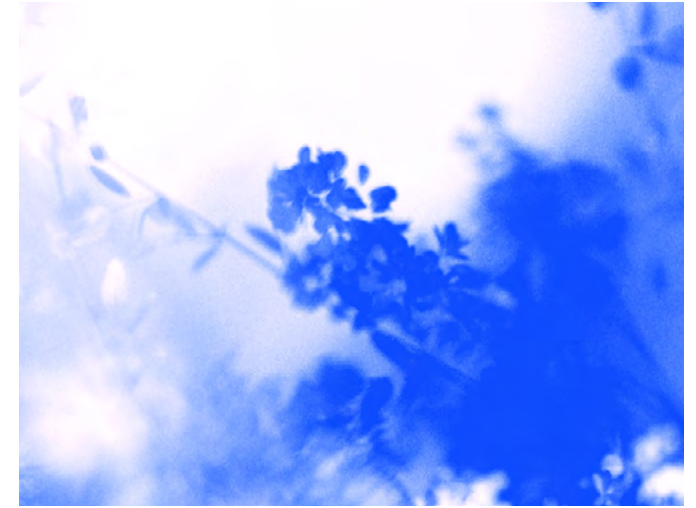


Concepts and Ideas

After the research was done I began with conceptualizing product design. This was done parallel to the branding and the user interface to ensure cohesion. While various application procedures, and methods of attachment, materials and component structures were considered, the underlying technology and bones remained largely the same as is dictated by the VitalStim and other e-stim processes.



Product Moodboard – Precision



Idea 1

In order to reduce the number of steps required to begin with therapy I thought of combining all the muscle points used in the VitalStim therapy into a single patch.

The patch is then strapped around the neck to ensure proper contact.

Pros:

Reduced number of steps.

Reduced complexity of placing the electrodes.

Less scary with only a single wire connecting to the product.

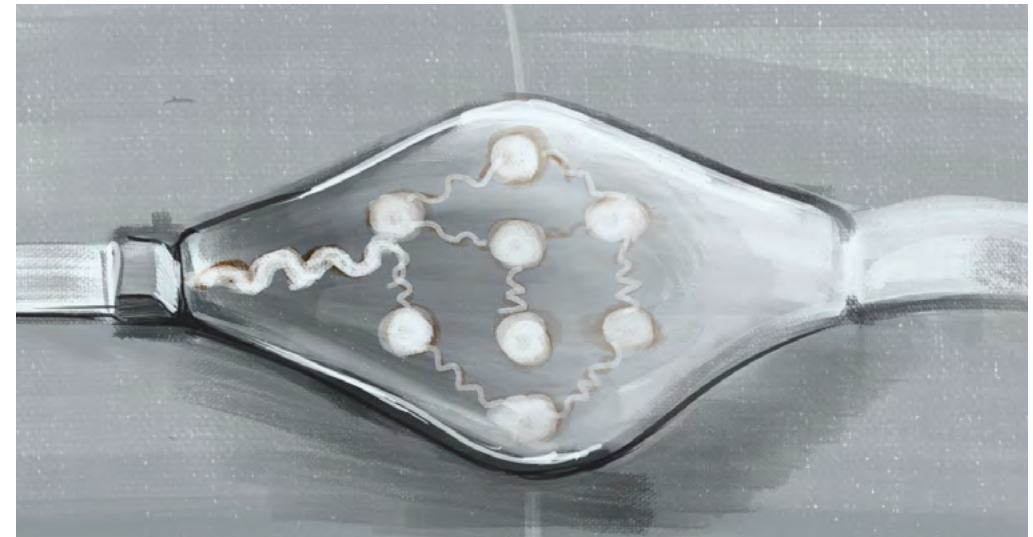
Soft Fabric strap.

Cons:

Stim points maybe not align properly on different neck sizes.

Breathability concerns. May

cause discomfort.



Idea 2

Taking the same points and similar to current electrode patches. But combining them into a singular, flexible patch.

This design would be without any strap going around the neck.

Pros:

Less possible discomfort around the neck.

Some degree of flexibility to fine tune the electrode placement.

Cons:

Limited flexibility.

Without any strap, its possible the patch comes loose.

Looks alien.



Idea 3

Making medical devices look less scary is a difficult task because of their complex nature. To try to hide the fact or make it look like a part of your outfit.

Reduces product life-span considerably.

Inspired by fancy summer collar shirts this variant would wrap itself around the user's neck with the help of a bandanna like fabric. Making it a fashionable and functional addition to the product.

Pros:

Fancy.

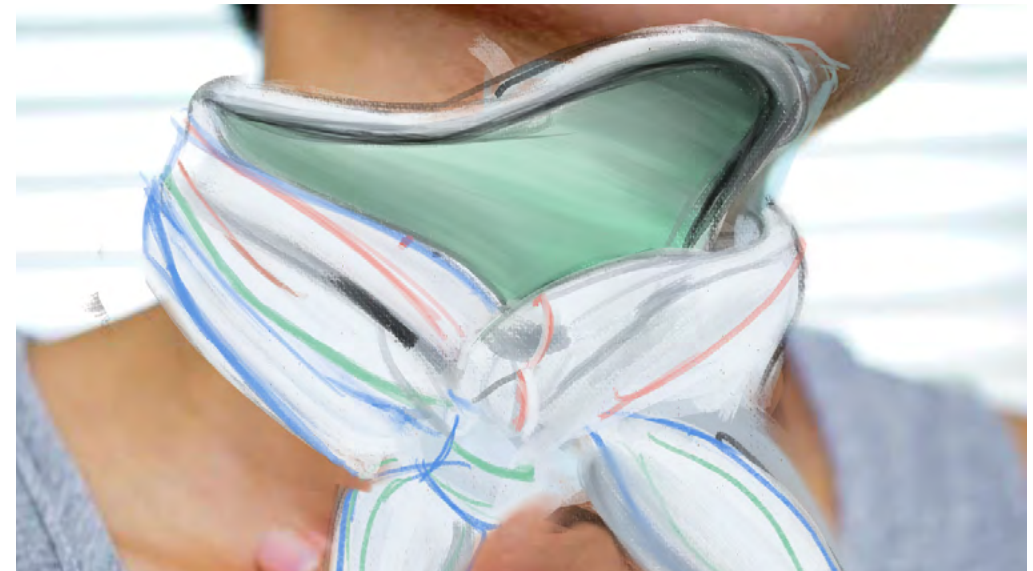
User adjusted comfort.

The soft fabric allows the neck to breathe

Cons:

The fabric will have to be washed regularly.

Hygiene concerns.



Idea 4

Trying a different approach to achieve the same goals, I tried to make the product look like a piece of jewellery, while also trying another "clamping" style for the neck. This time akin to a choker or a neck brace.

The first iteration goes the parametric jewelry approach and the second one does the same but with a soft fabric instead.

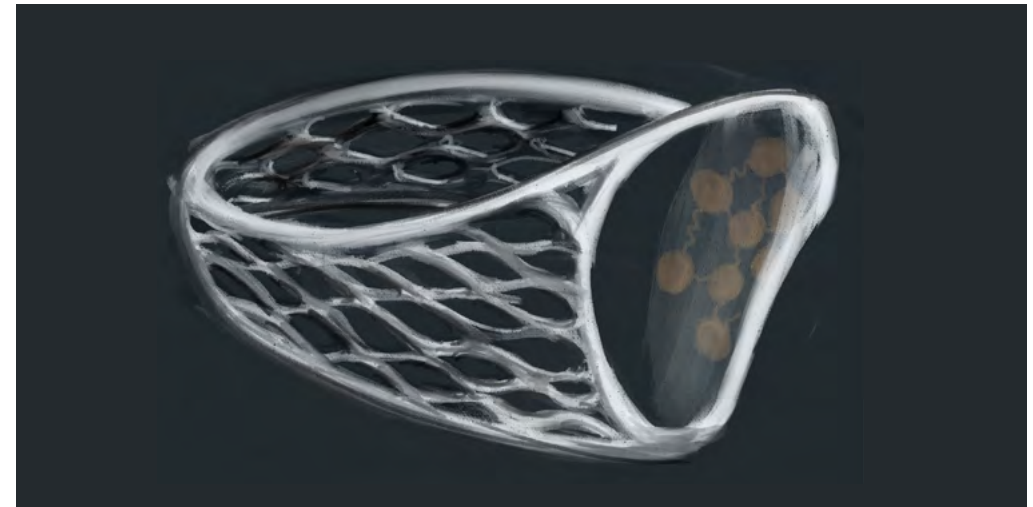
Pros:

- Easy to put on.

- Lots of breath ability, albeit only around the neck.

Cons:

- The clamping pressure will be difficult to get right for a lot of people because varying neck sizes and comfort zones.



Idea 5

As all the designs retained the same approach to the electrode placement. I began to rethink my initial electrode pattern plan.

The electrode points was changed to a more elaborate grid pattern, which will allow finer control over where the therapy is being applied. Which takes care fo the problem of placing the electrodes manually and perfectly on a specified region.

This grid was then attached to a flexible silicone like choker which allows the user to put it on without much of a hassle

Pros:

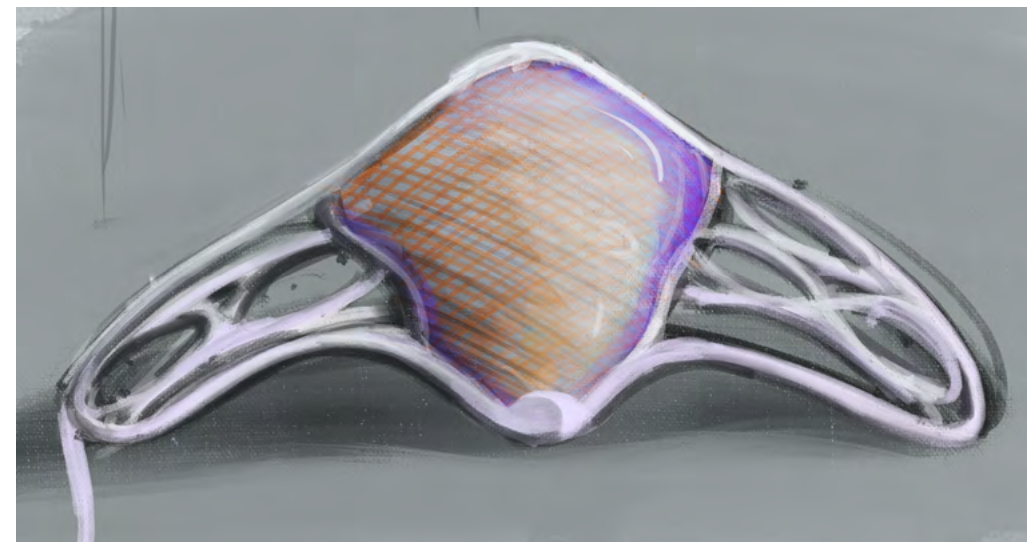
Finer electrode control.
Allowing for more users to be able to use the product without creating different sizes.

Easy to put on, similar to the previous idea

Cons:

Similar to the previous idea, the clamping pressure will be difficult to ascertain for a large group of people.

Adjusting and setting up the electrode grids to work might prove to be a hassle.



The Patch

1. Top Layer – Silicone

A top silicone layer which keeps the circuitry in place.

2. Middle Layer – Circuits

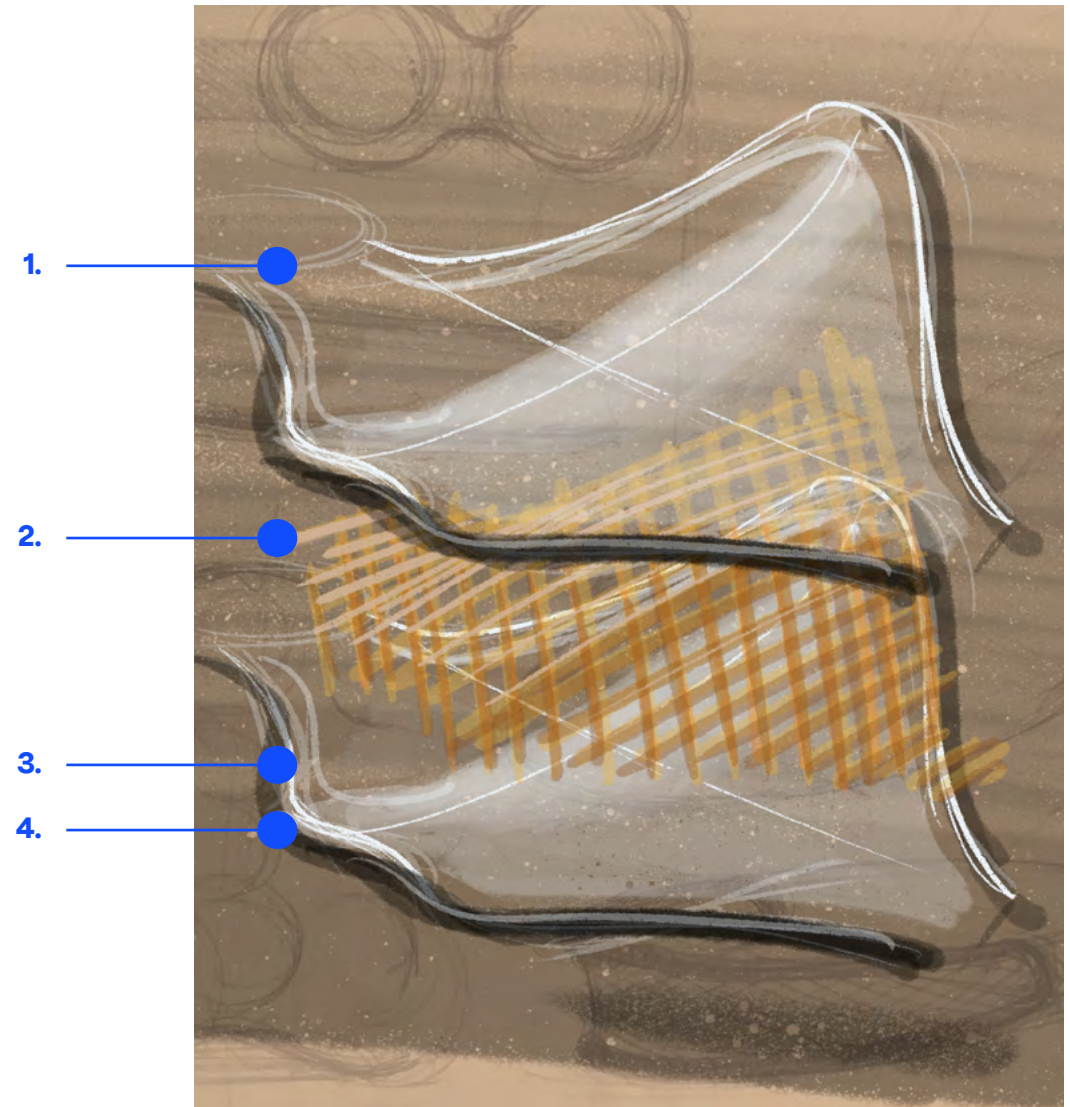
The circuit grid which are in contact with the conductive adhesive allow the currents to pass through to skin and the muscles below

3. Contact Patch – Silicone

The contact patch allows the electrode patches to poke through to allow conduction, while also separating the current pathways without interference.

4. Medical Adhesive

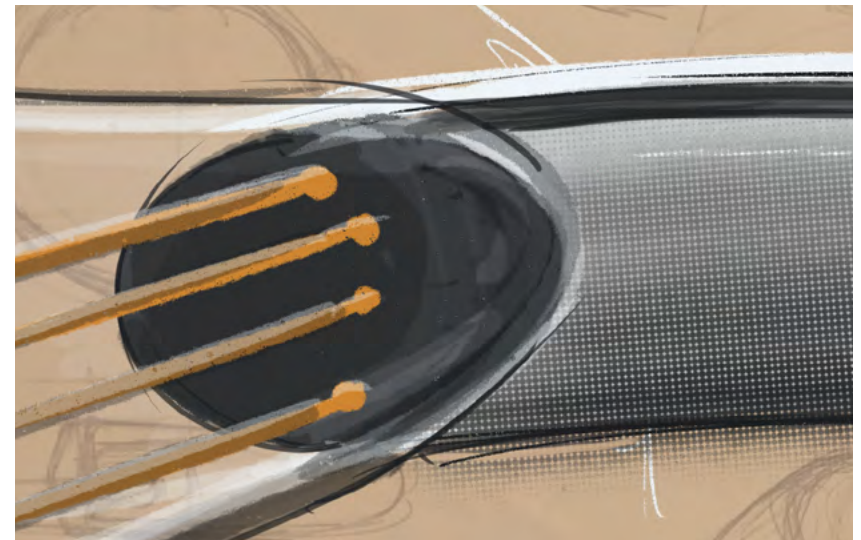
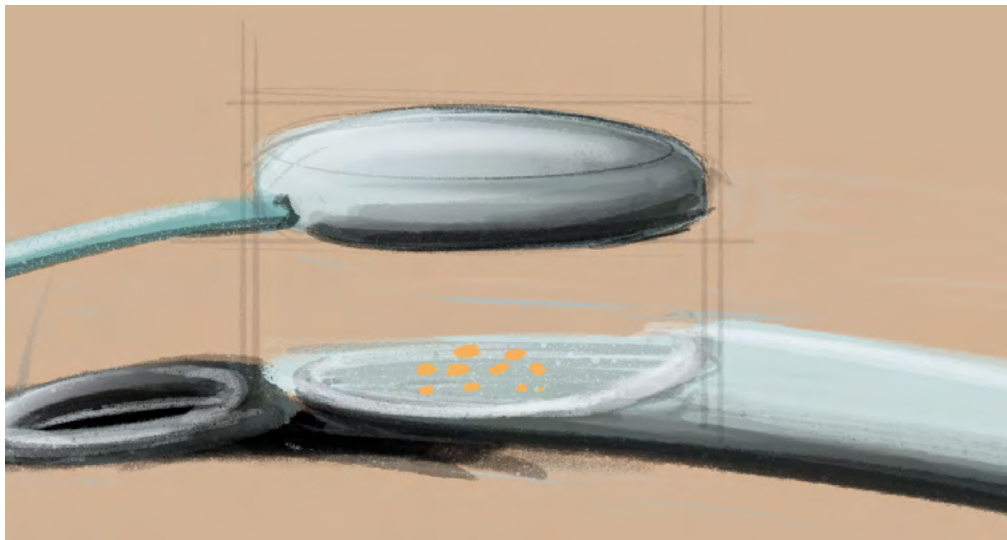
3M medical adhesive which allows the patch to remain in contact with the skin for prolonged periods of time without residue.



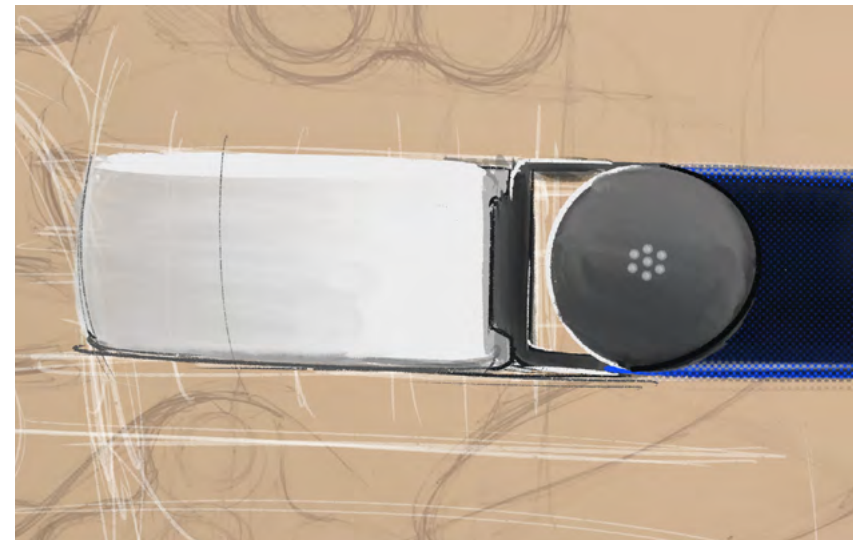
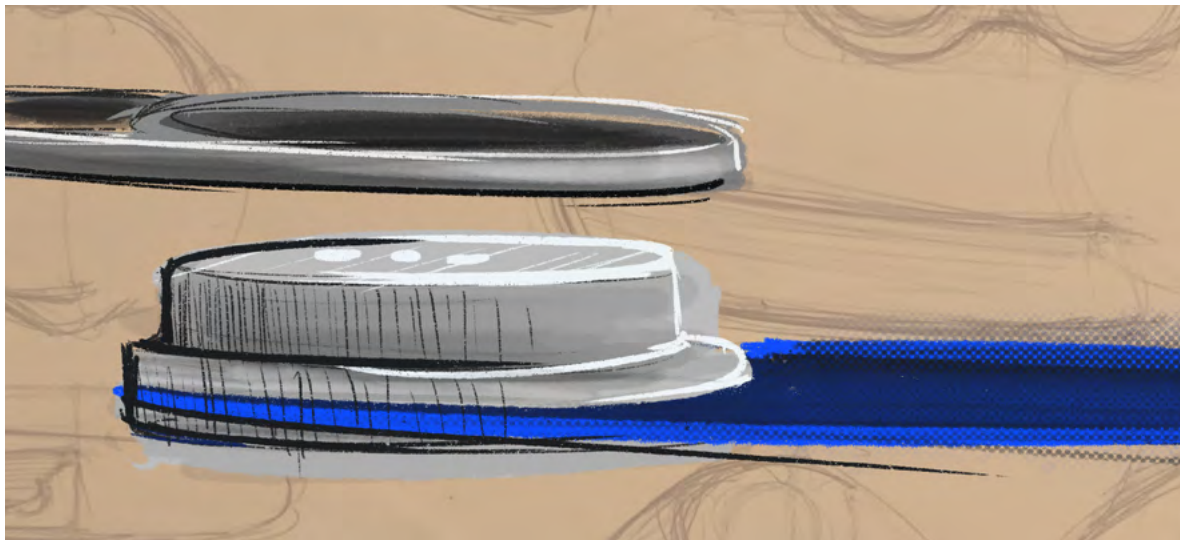
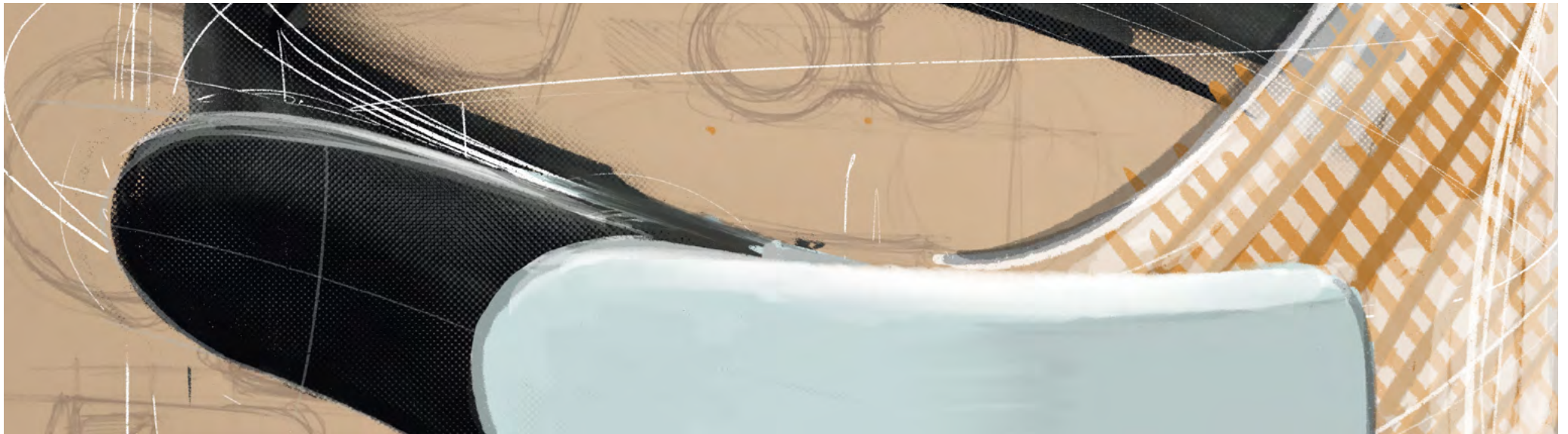
Patch Controller Housing

The patch comes in contact with the controller housing on the inside. Whether it's removable or not still needs to be decided. The housing connect magnetically to the controller and is powered using pogo pins. A status LED will light up to show that it's connected properly.

The magnetic attachment ensures no harm comes to the use in case the cable gets tangled and is pulled on accidentally.







Starting out with CAD

The large variation on the dimensions of necks found in the populus as well as the missing dimensions of female necks pose a significant hurdle in terms of getting the dimensions just right.

Dimensions are the first hurdle, then comes the challenge of making the patch wrap around the throat in just the right way.

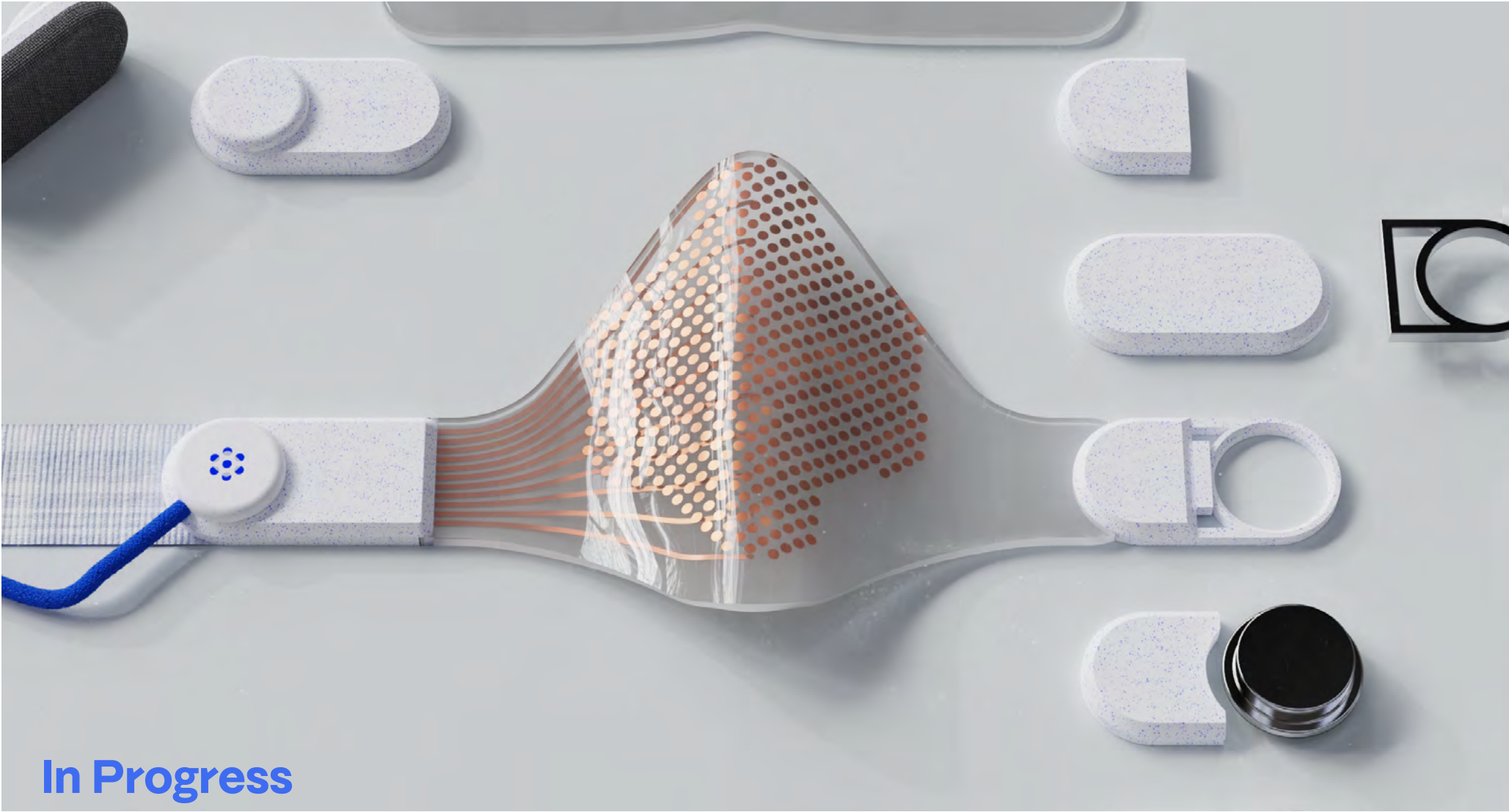
This section details the challenges and evolution of the patch.





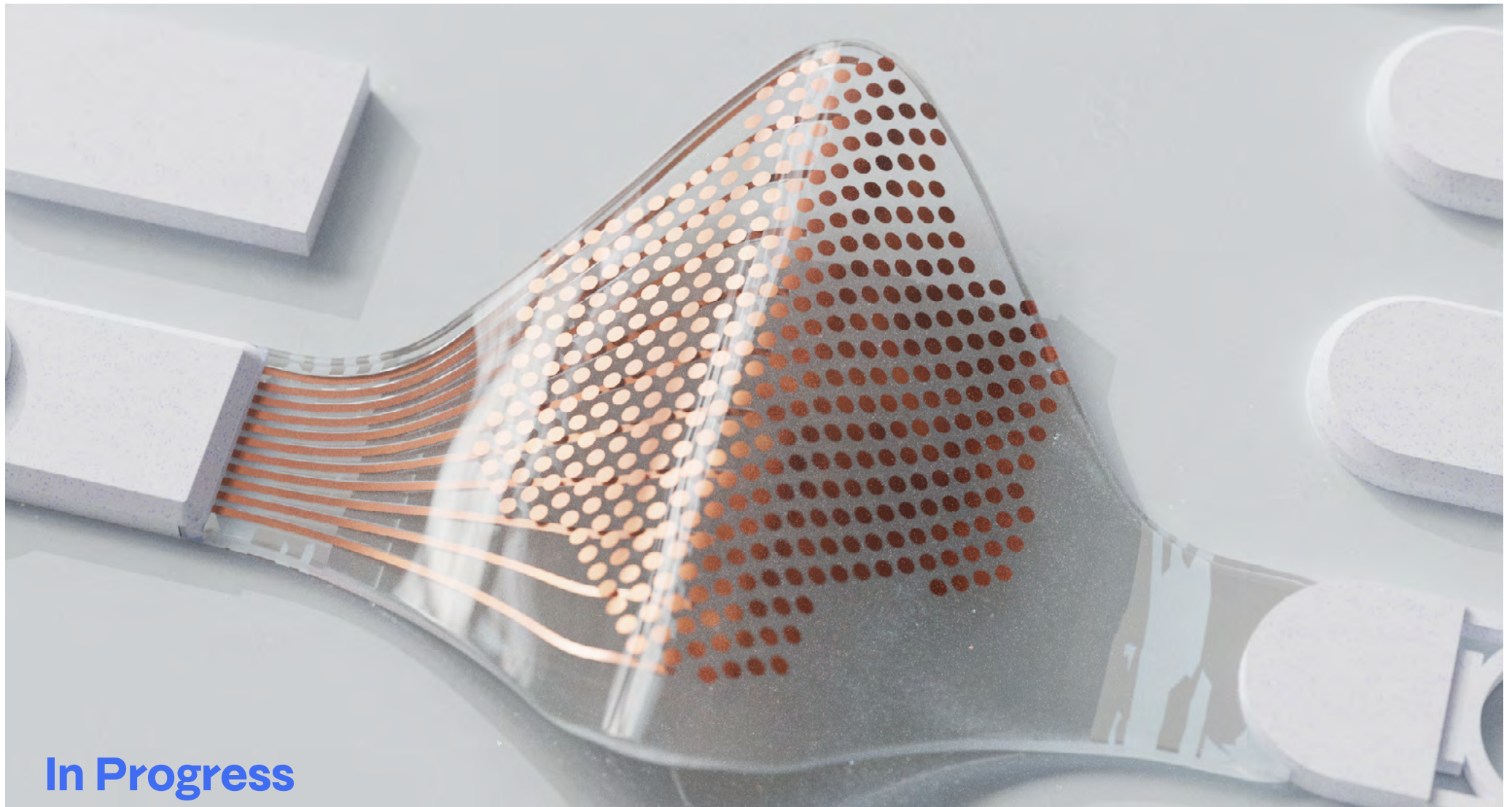
In Progress





In Progress





In Progress



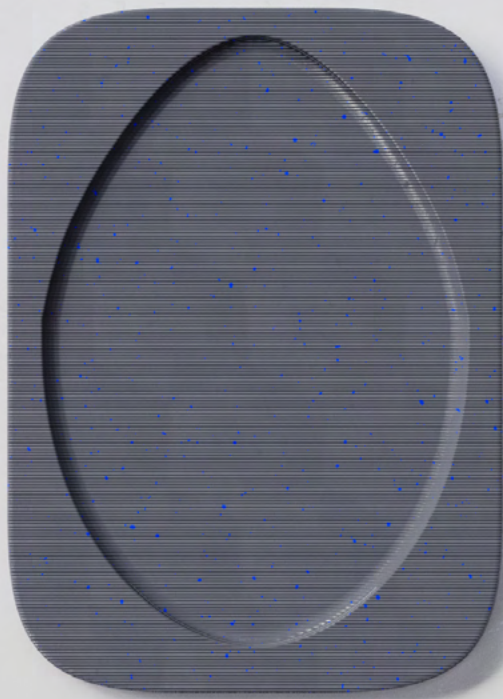


The patch went through a lot of physical iterations. The moulds were 3D printed and then the patches were created using silicone being poured in. As the patch were quite thin, a 2 part mould was not necessary.





Patch v1

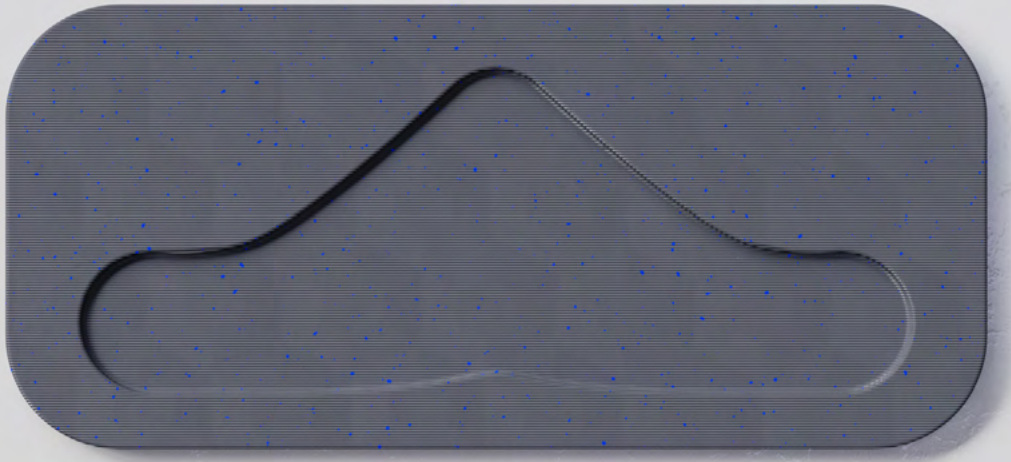


The first iteration of the patch was a tester patch to ensure it covers all the points on the neck of the chosen dimensions. No consideration was made on how the patch would attach or would wrap around then neck.

The test also was helpful to ensure the thickness was correct.



Patch v2

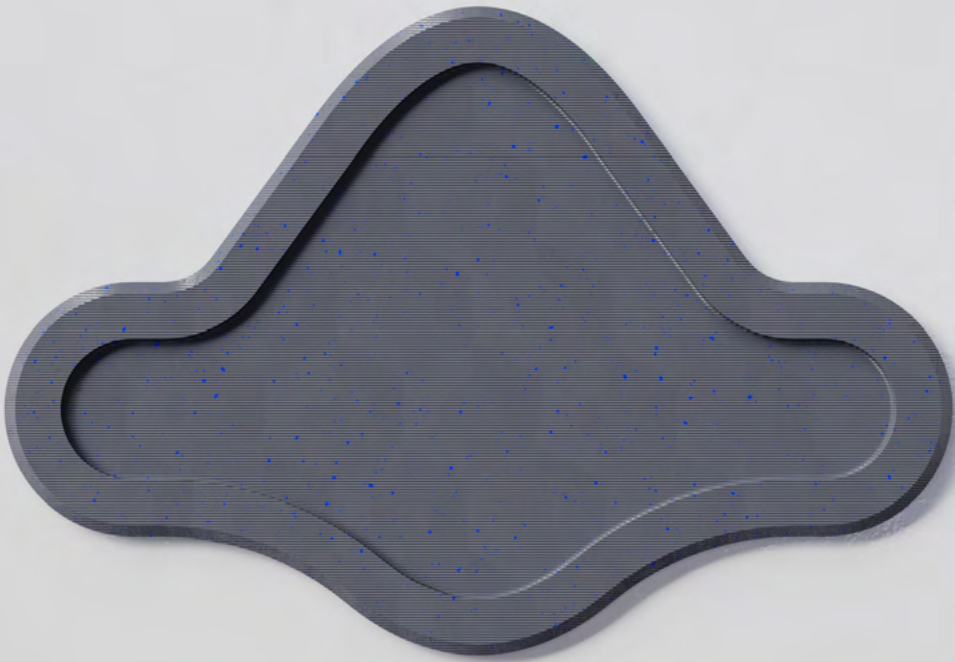


In the second iteration, I made the leaflets which would then attach to the control unit of the device using the first iteration as the base to ensure the patch wraps around properly.

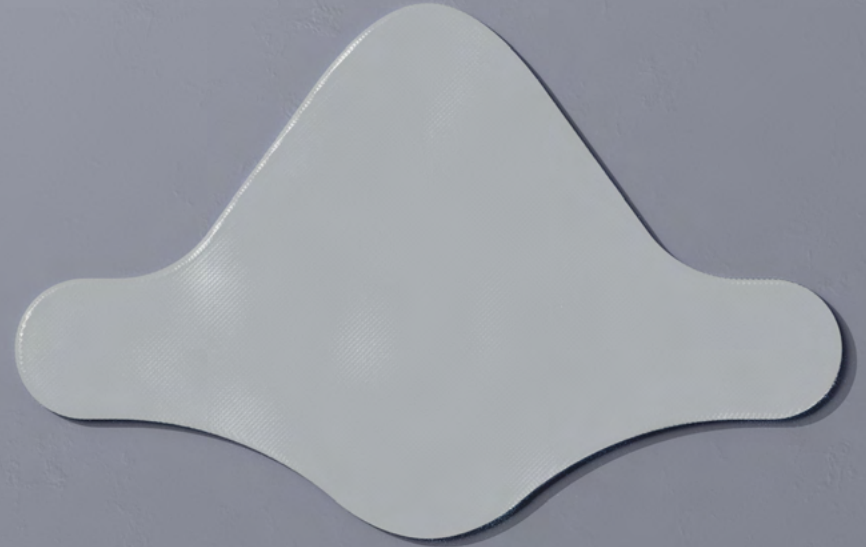
But the dimensions proved to bow around the neck improperly and the control unit would sit around too low around the neck.



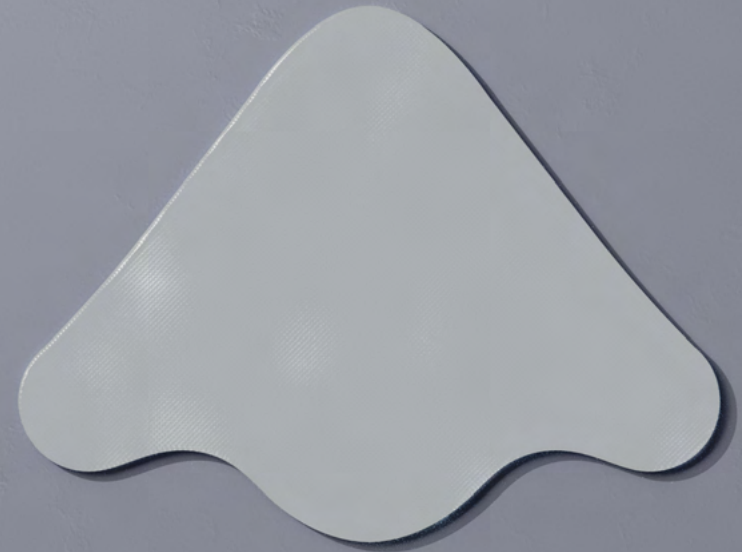
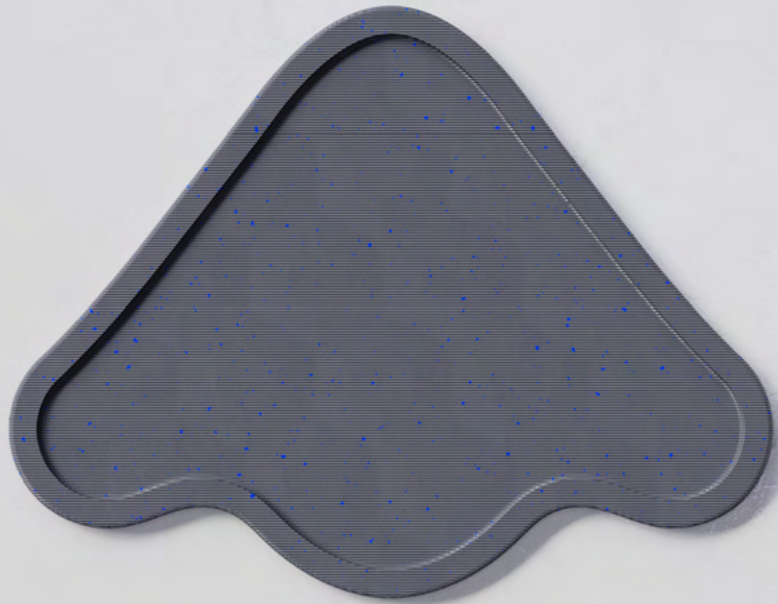
Patch v3



Then I made the decision to move the connection points upwards so that the patch sits in the correct position while also allowing the band to sit somewhere comfortable. But the issue was that the patch would wrap around angled upwards towards the jaw.



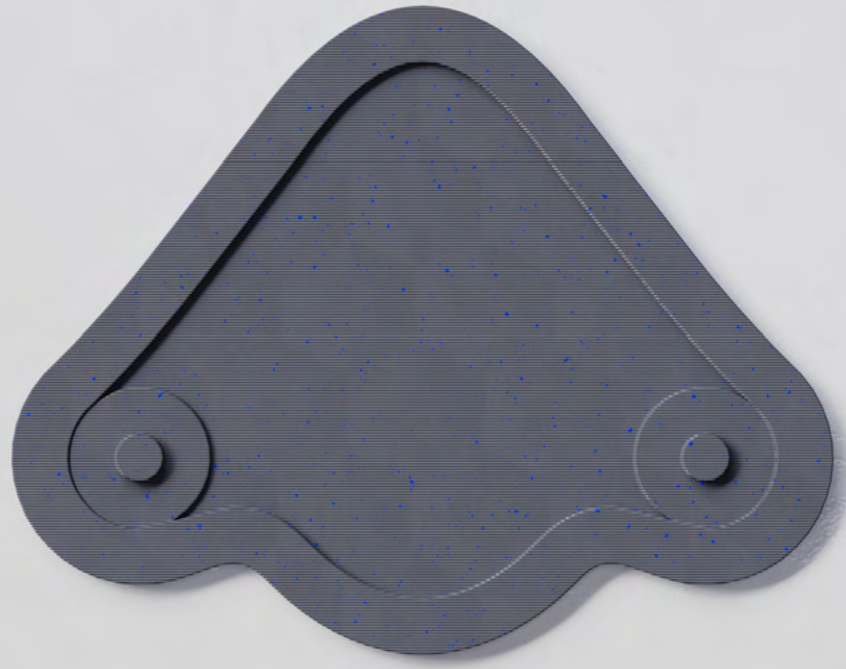
Patch v4



To fix the the angle of the wrap around, the connection point was then angled downward which allowed it to wrap in the desired position and angle.



Patch v5



Then it was time to add the rest of the details like getting the thickness right and adding manufacturing details to allow the snap joints and the connection points to connect properly.





Finally, I added a "piping around the edge to make the patch bit more soft without any sharp esges and to add some cushioning.

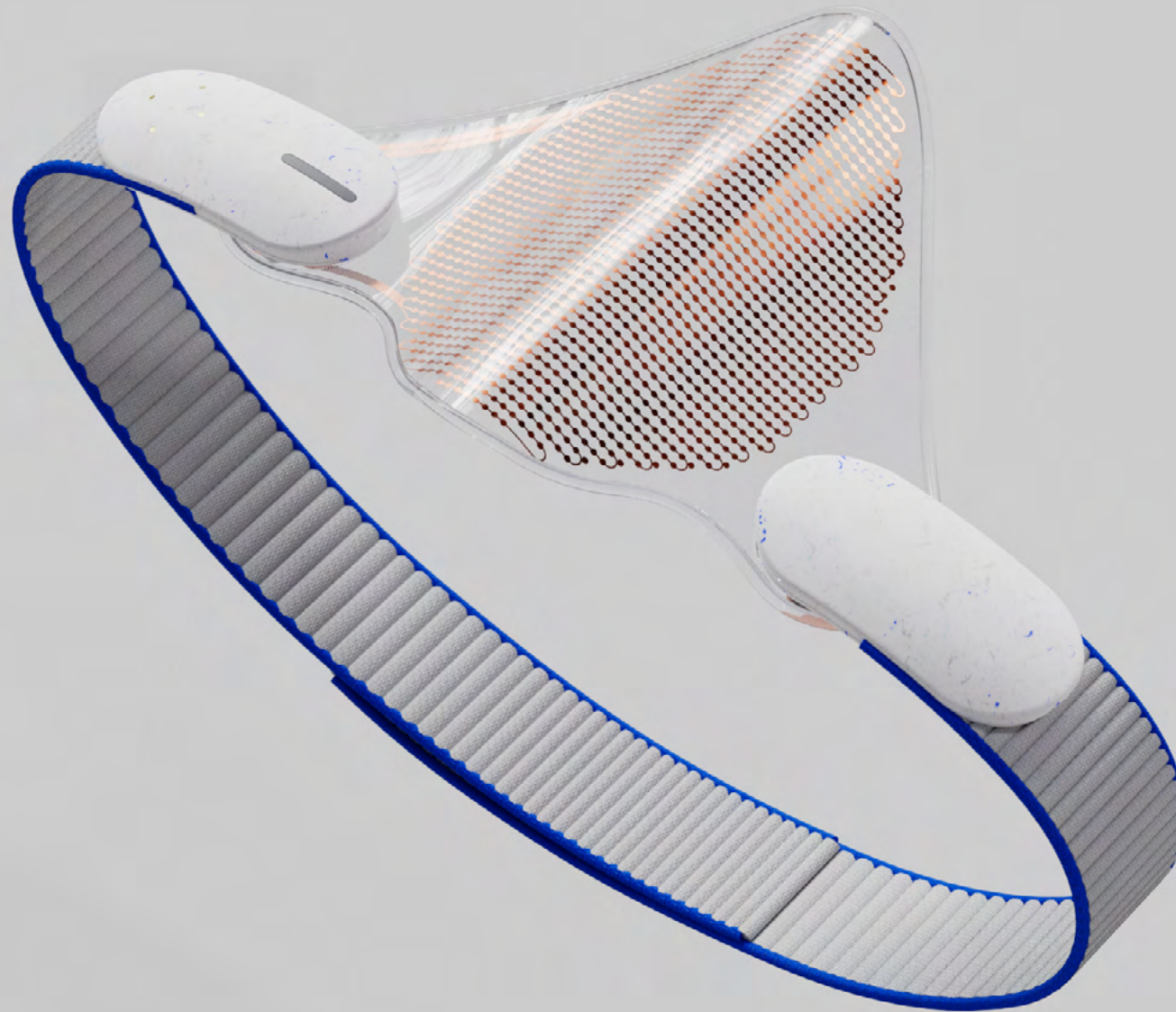


Final Design

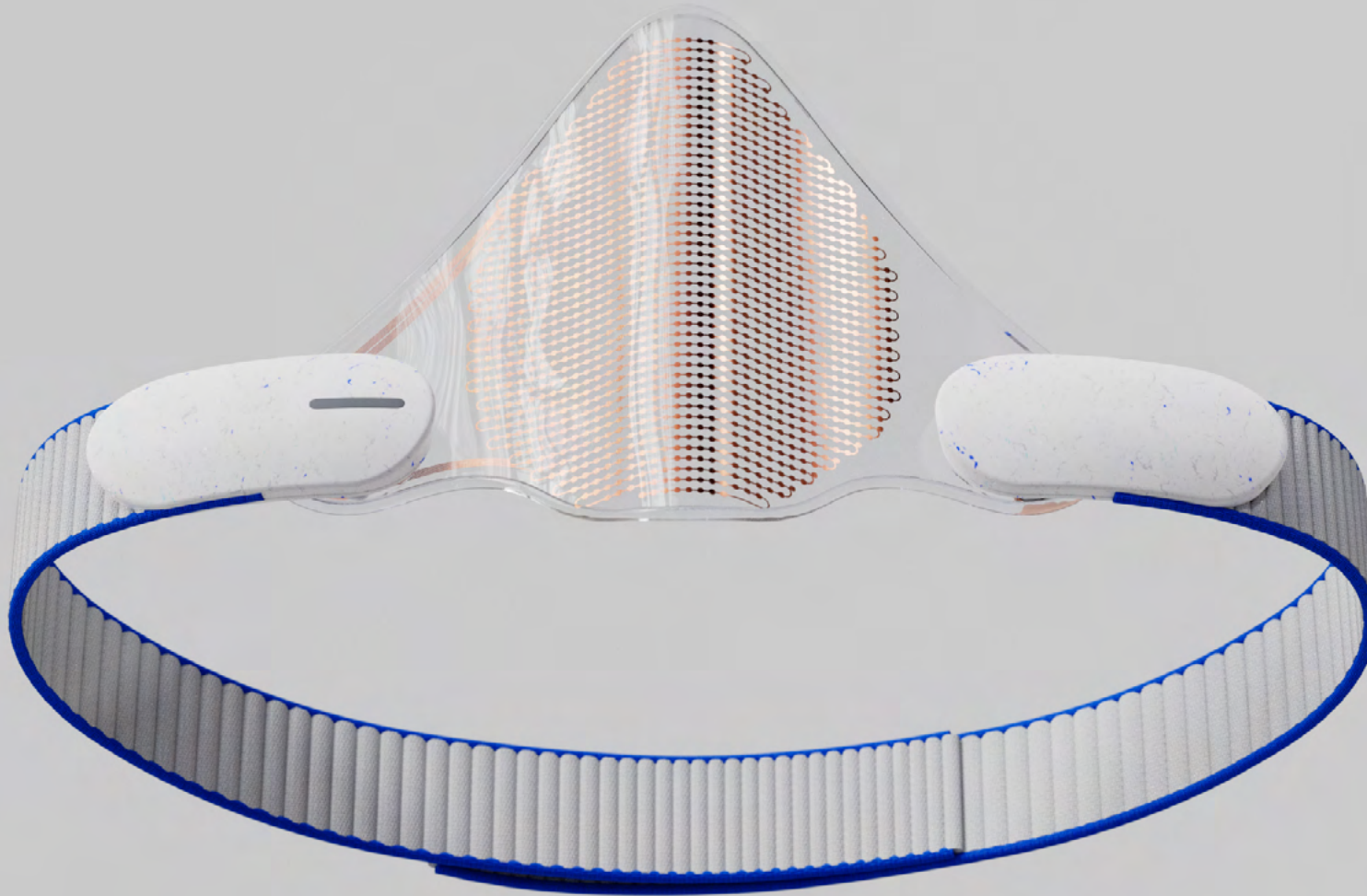
Work began on the interface of the app and product in tandem while conceptualizing the product to ensure the interaction was as simple as possible.

The section details the discovery of the physical and digital interactions of the product.





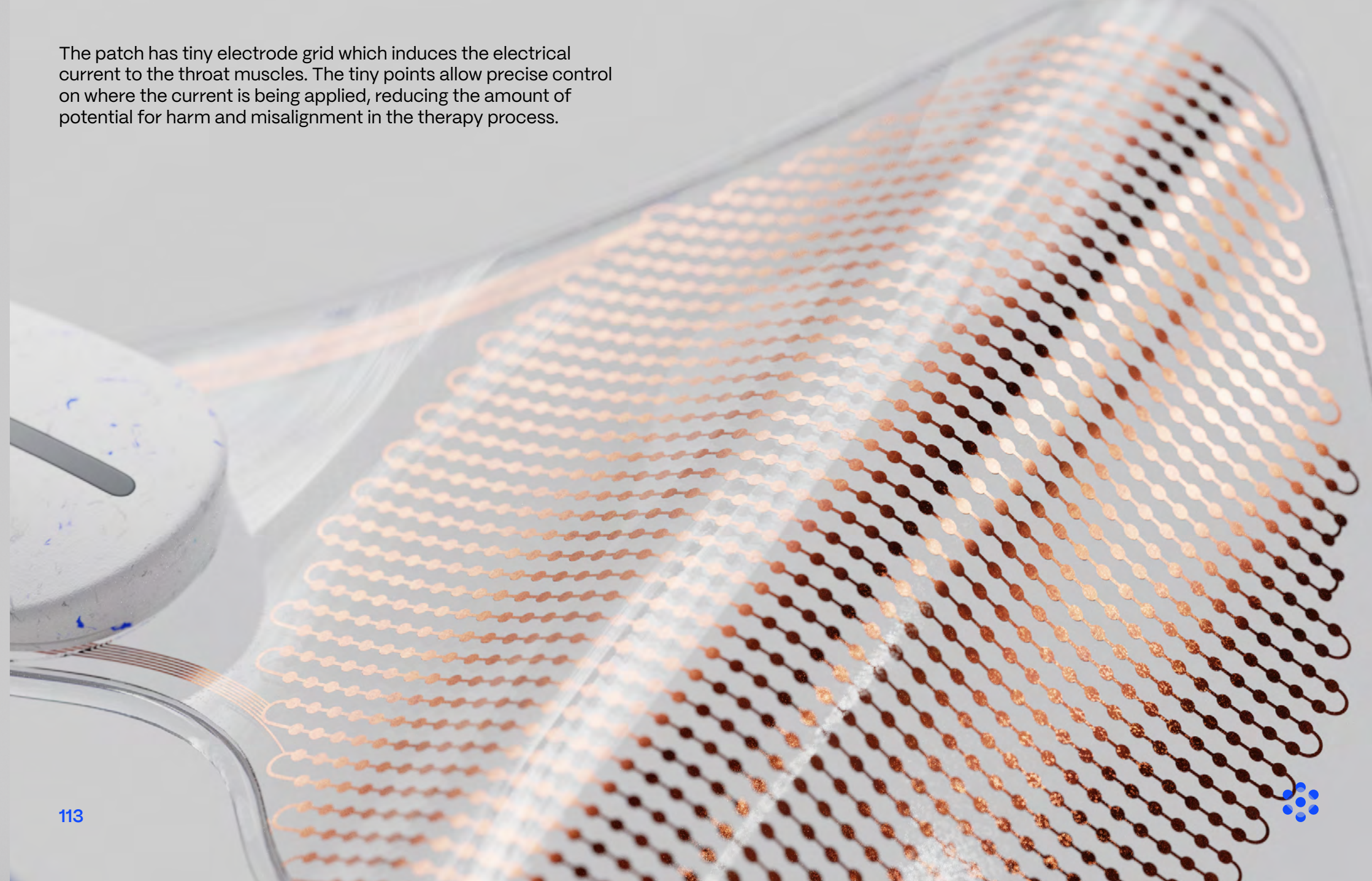
Patch v5



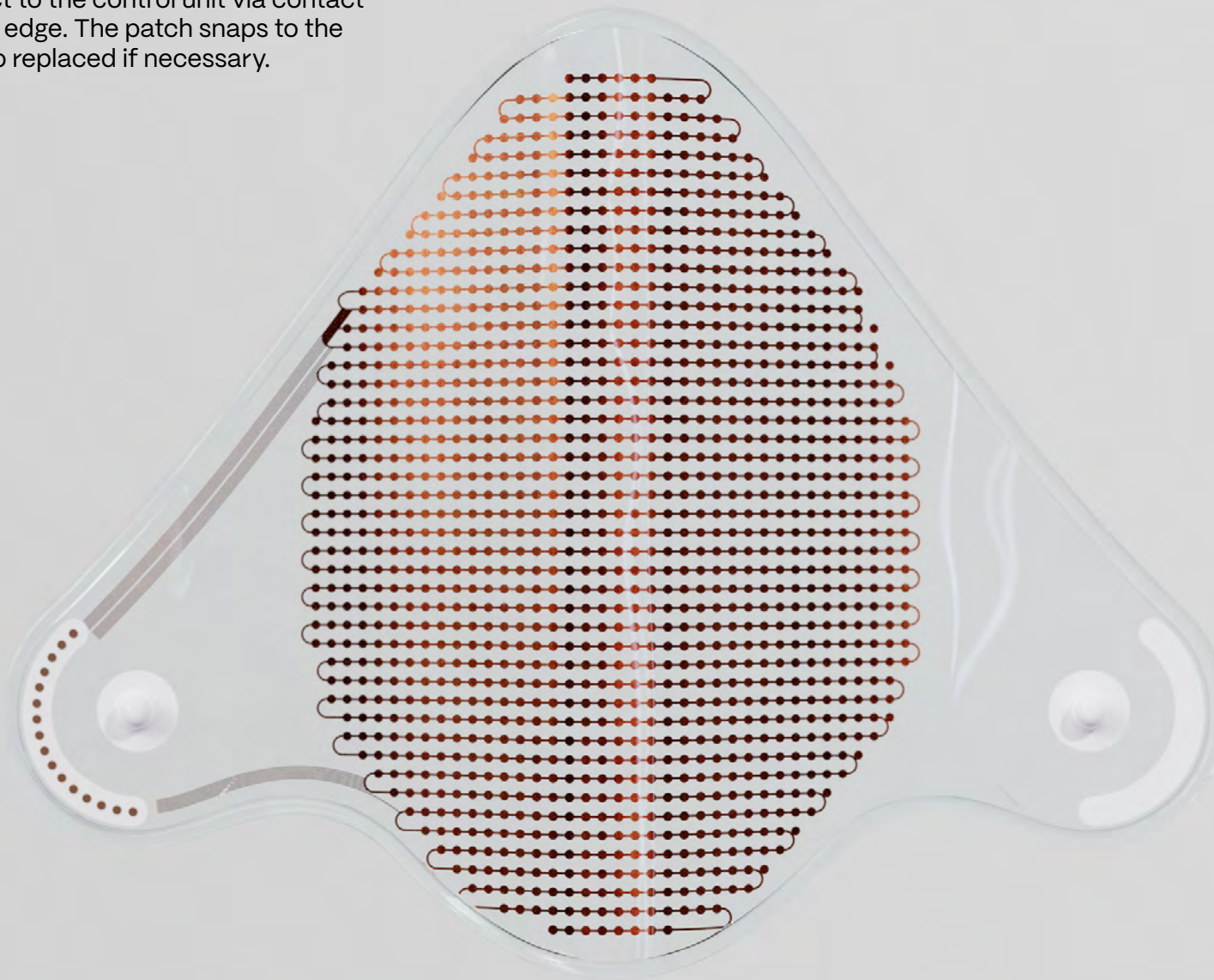
Nourish goes around the neck of the user and gently hugs the neck a plush, breathable neck band.



The patch has tiny electrode grid which induces the electrical current to the throat muscles. The tiny points allow precise control on where the current is being applied, reducing the amount of potential for harm and misalignment in the therapy process.

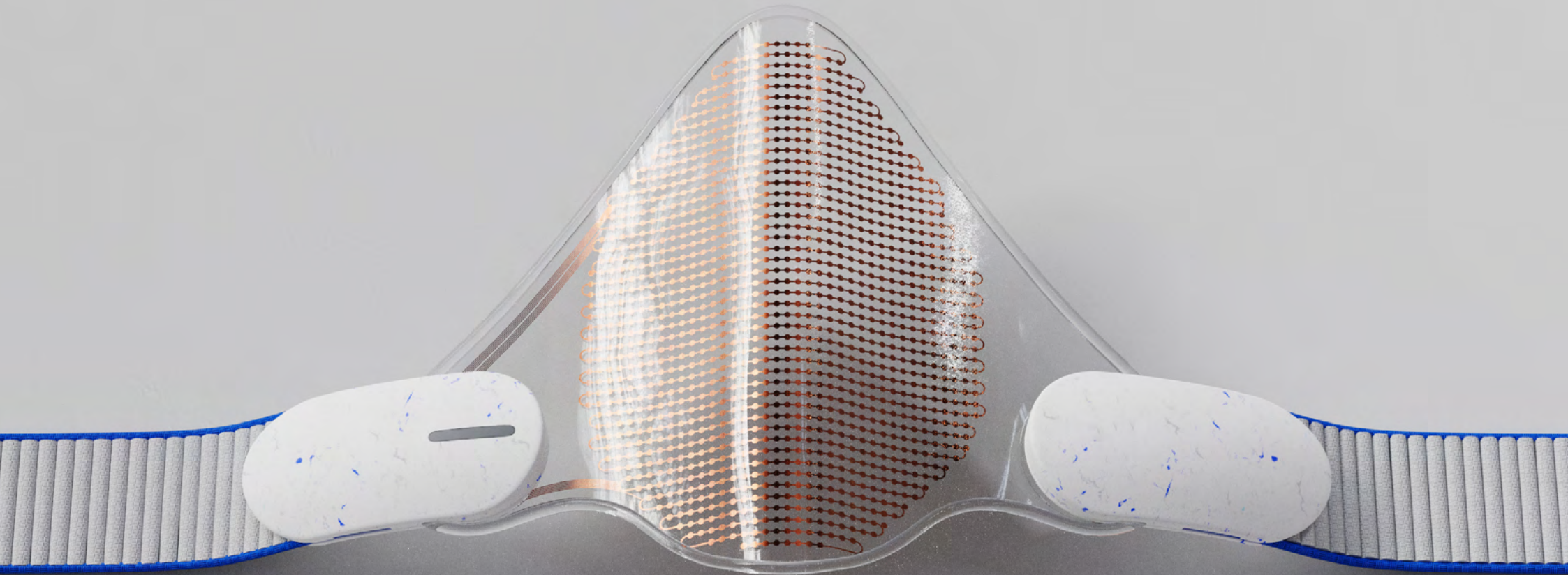


The electrodes connect to the control unit via contact pins located on the left edge. The patch snaps to the neck band allowing it to be replaced if necessary.



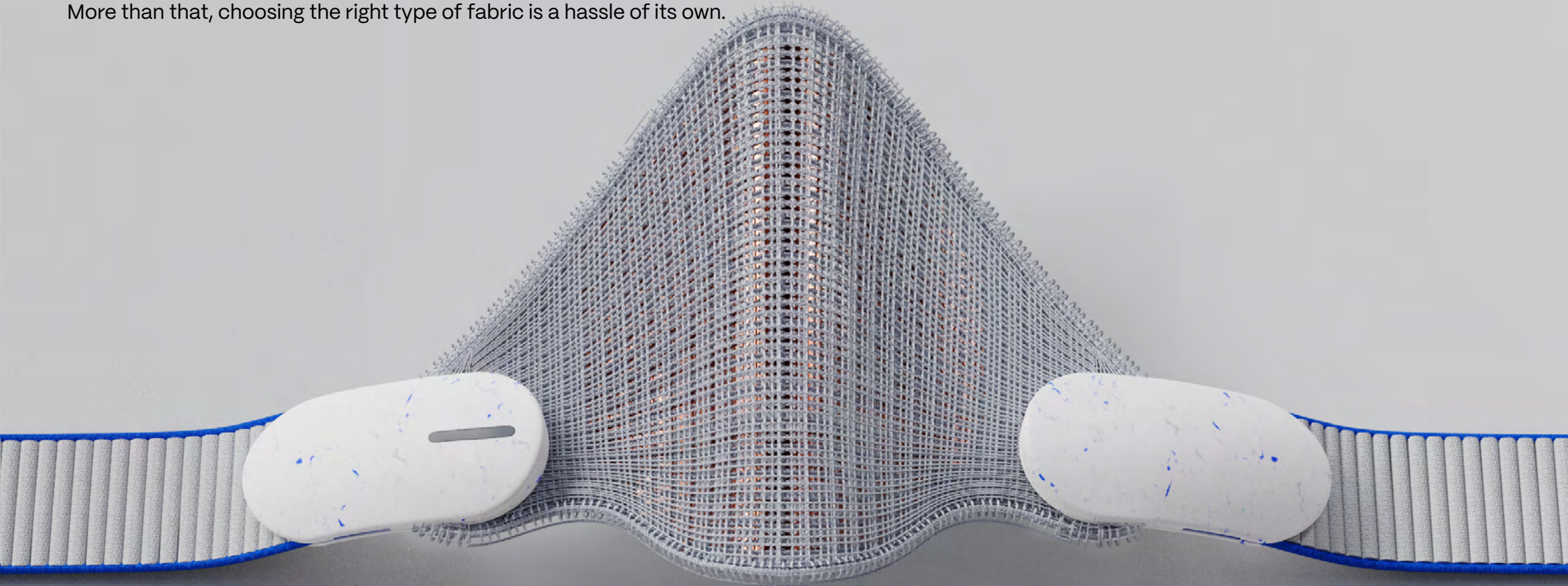


The patch is made of medical grade silicone with conductive 3M adhesive which adheres the patch to the neck to provide optimum electrical conductivity.



A patch made of cloth was also considered. But wear, cleanliness due to sweat and bacterial concerns, plus the fact that the patch will need to be washed, which is not possible due to the electrical components inside.

More than that, choosing the right type of fabric is a hassle of its own.



Control Unit



The control unit powers and shares data with the phone app. The unit also has a stop therapy button, in case the user feels discomfort during therapy, so that they don't have to fiddle around in the app and waste time.

The unit connects via a 4ft long soft braided cable to the magnetic puck. The magnetic puck is responsible for powering the device and the data to transfer.

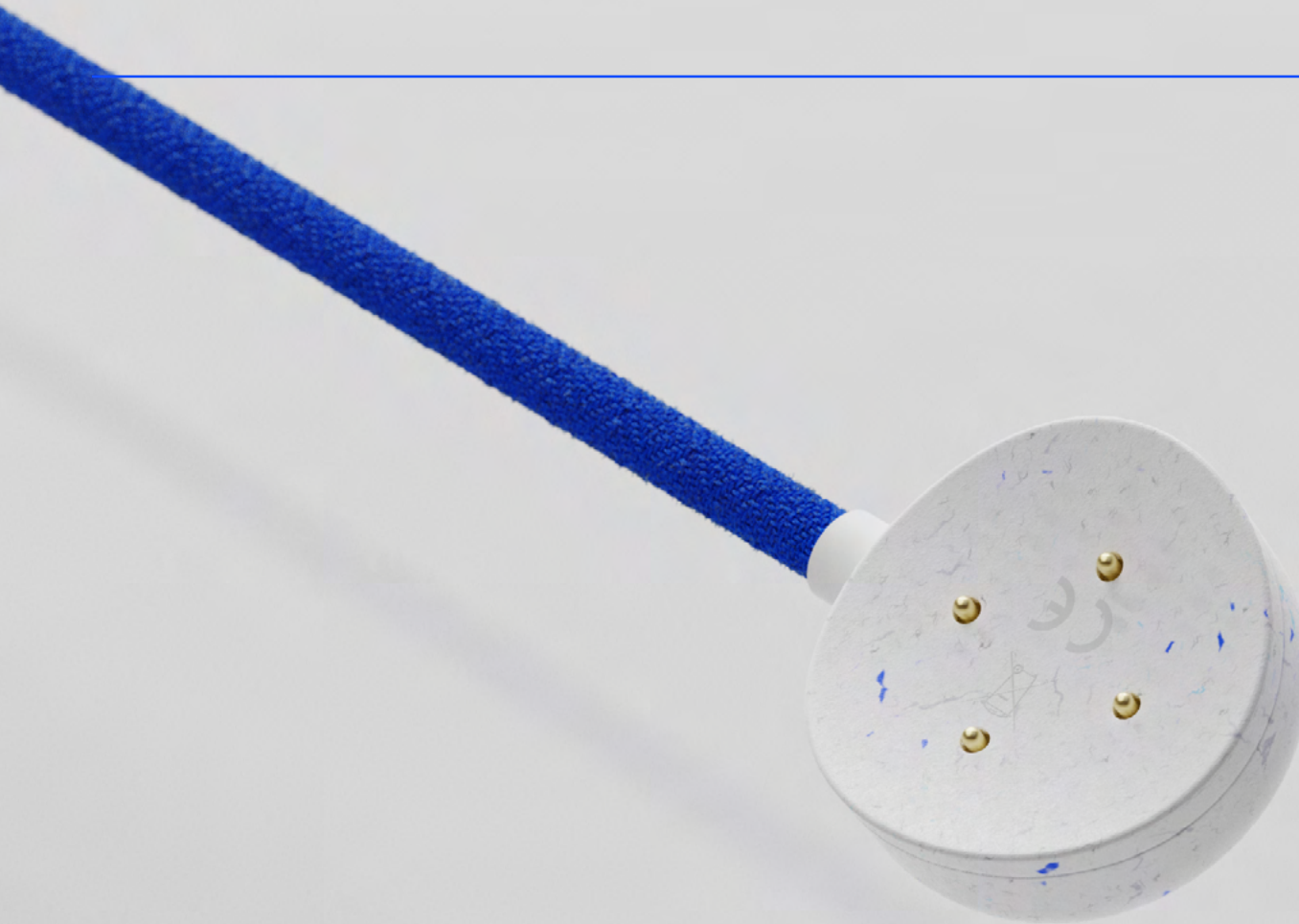






The puck went through many design iterations to get the perfect form factor so ensure proper grip without being too bulky.





The puck uses pogo pins and magnets to connect to the band. The internal curve of the puck ensures proper orientation, which is also aided by the curve of the neck band itself.

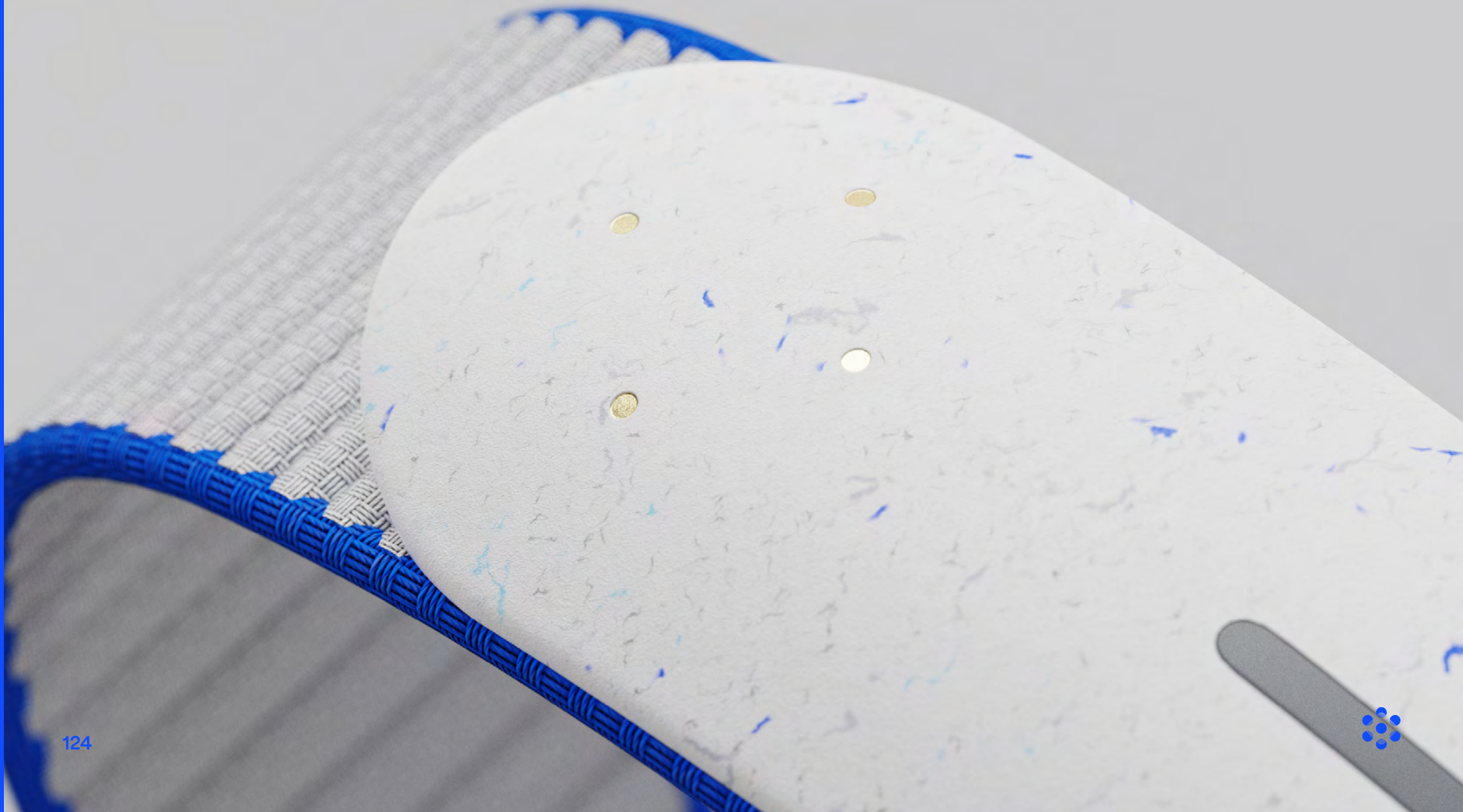




One positive, one negative and 2 data pins transmit the power and data to and from the the device.



The contact pins on the neckband.



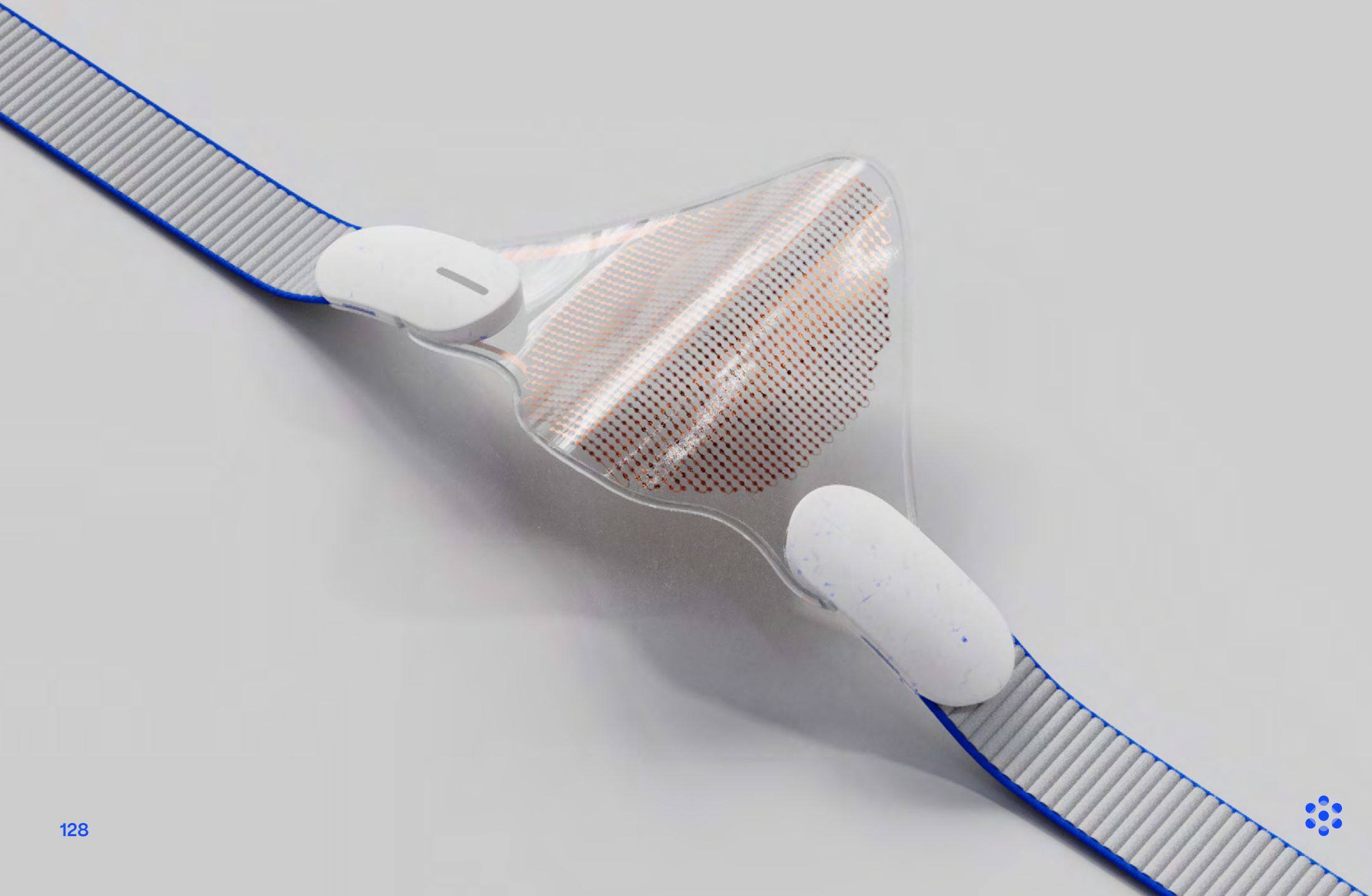




The light indicator turns blue when the neck band is being powered and working.



The light turns amber when it's in configuration mode.



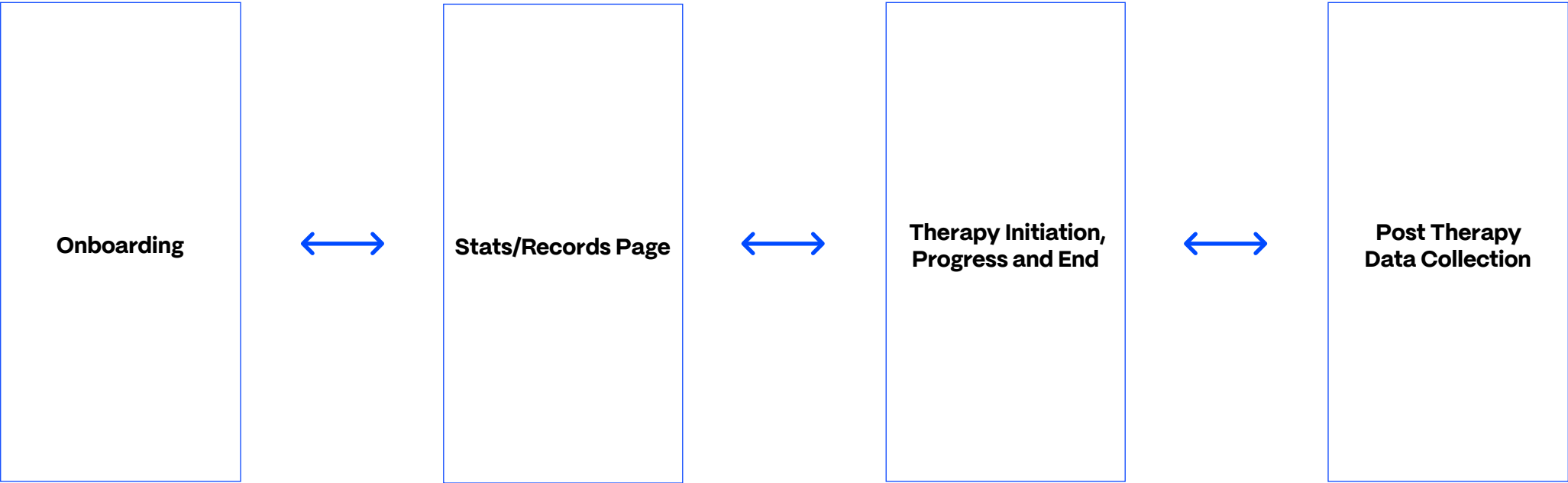
The Interface

Work began on the interface of the app and product in tandem while conceptualizing the product to ensure the interaction was as simple as possible.

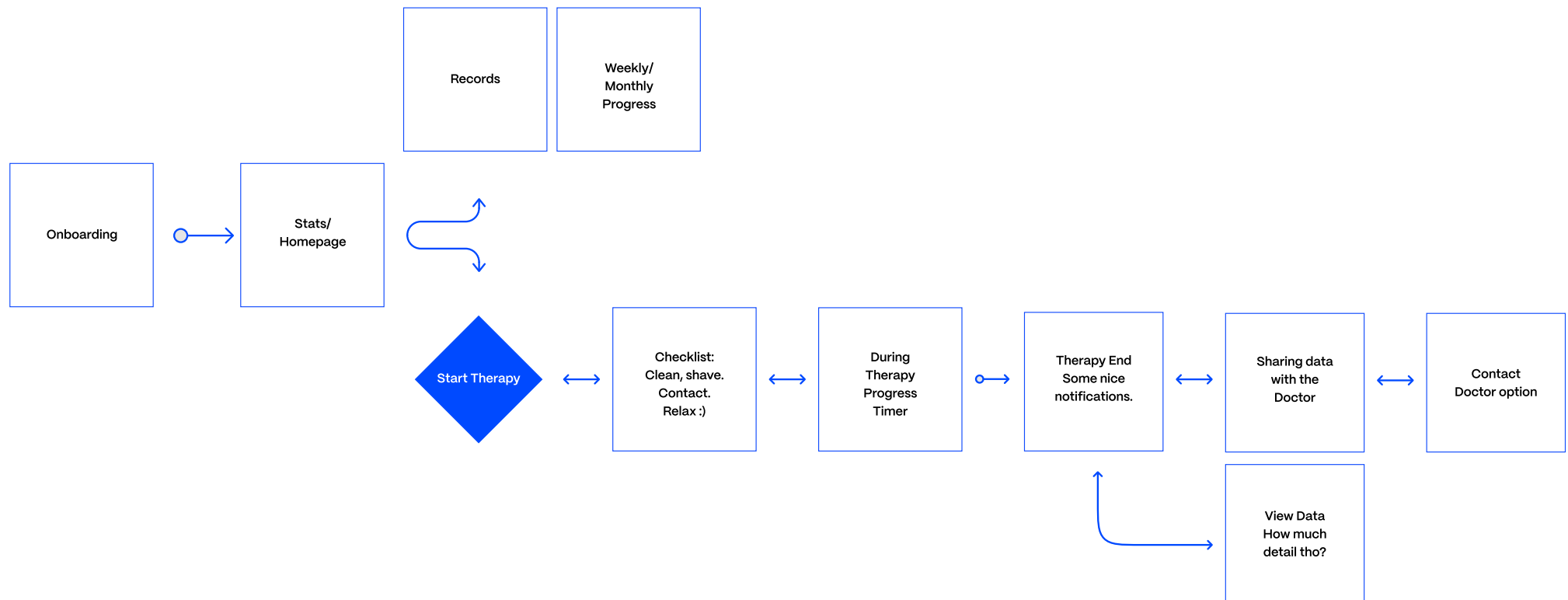
The section details the discovery of the physical and digital interactions of the product.



Sections



User Journey



Splash and Home screen

The home screen shows the therapy time goal for the day and also shows options to view past trends.

The Data will include:

Muscle Response
Therapy Time

The user can then proceed to start the therapy from this screen.



Therapy Initiation Checklist

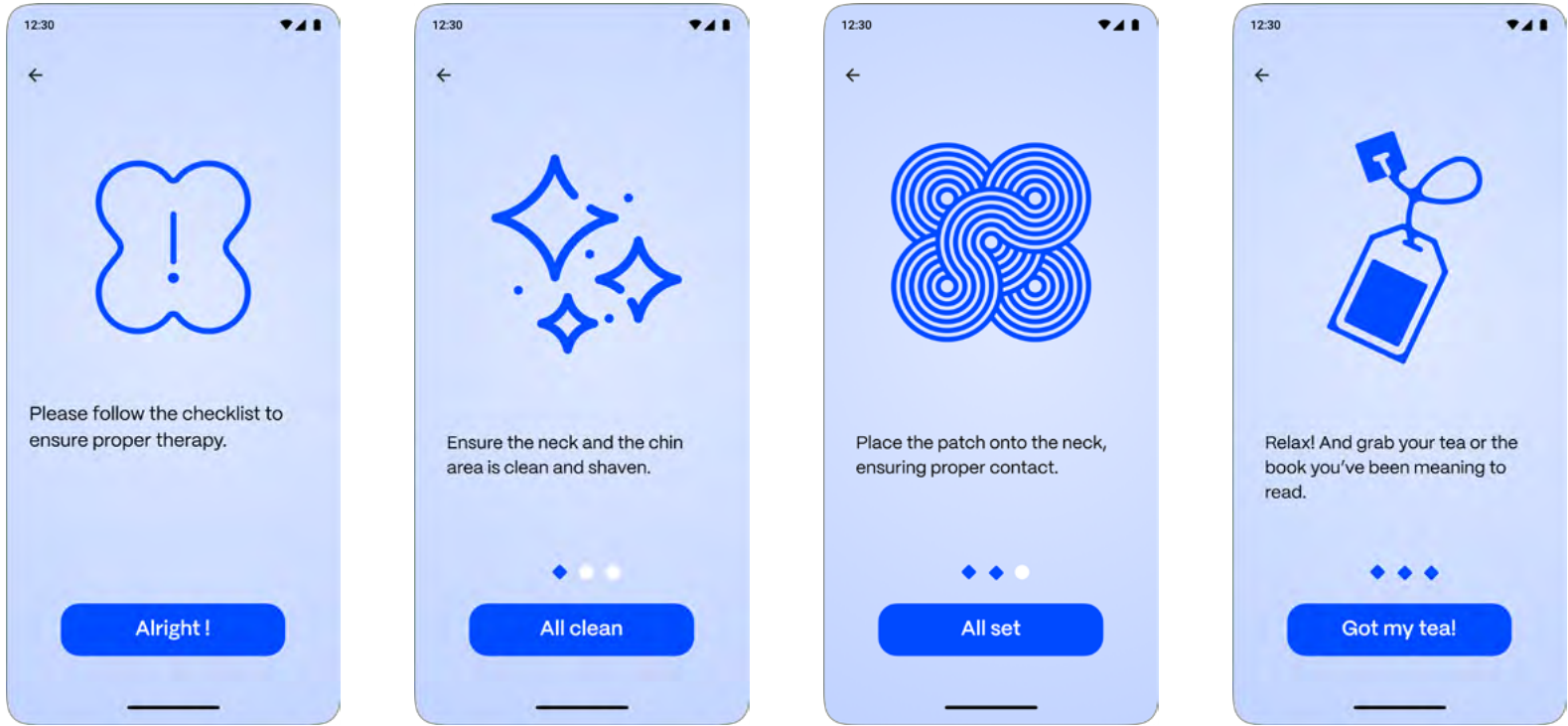
Before beginning therapy, a brief checklist appears. Making sure the user ensures the device is properly setup and ready to use.

The language to be used is still in progress, but the general tone will aim to be like talking to a friend without being cheesy..

Steps:

1. Make sure the throat area is clean.
2. Ensure proper contact between the throat and the device.
3. Get your tea and relax!



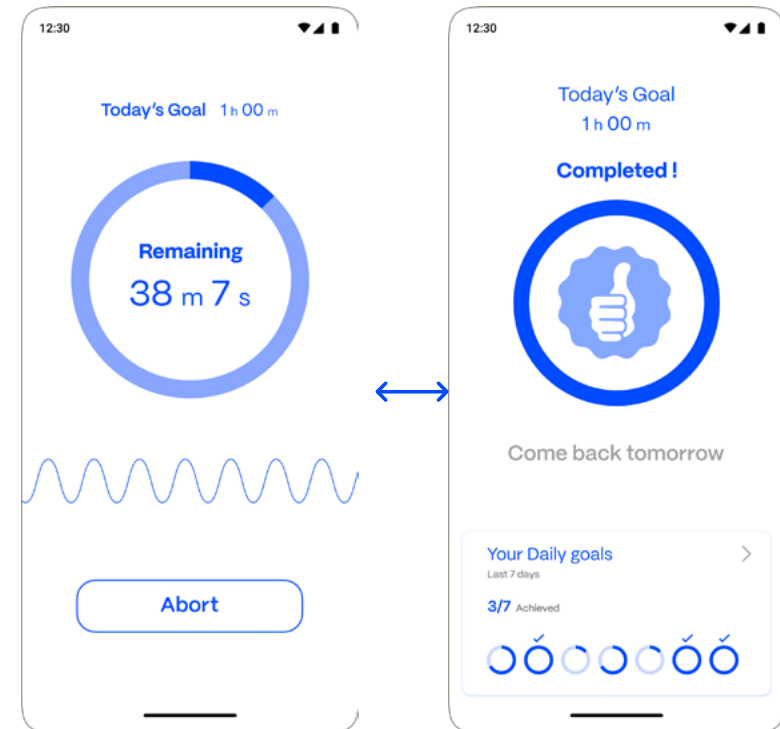


Therapy Screen and End

During therapy, the screen will show a timer showing the remaining time. The screen also shows a patient friendly graphic of the electrical-stim being applied in the form of a simple waveform.

When the therapy duration comes to an end, the data is then shared to the Doctor who can analyze and make changes to the intensity and frequencies if needed.

The patient can also view the data if they so desire to ensure transparent user data access.



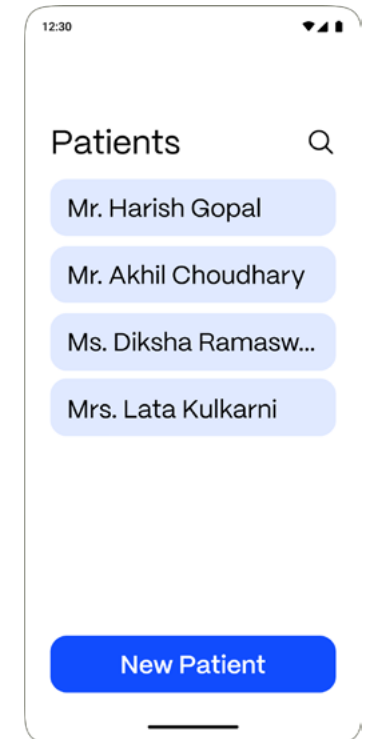
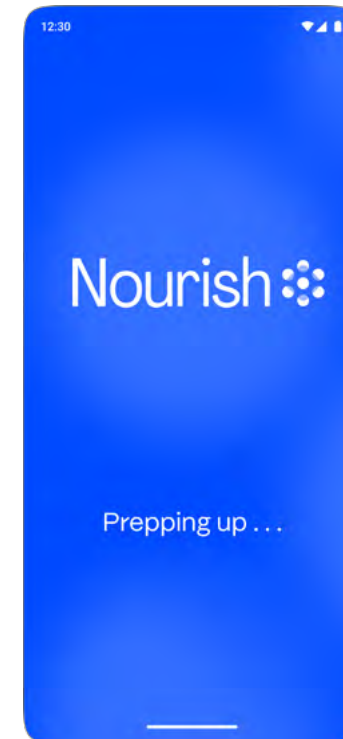
Doctor's Side

The Doctor's flow of the app allows the medical professional to setup the device before giving it to the user.

The app will allow for multiple patients to be tracked at the same time along with their current therapy history and past medical history to provide effective care.

The data trends collected from the device is available to view and verify.

The Doctor can make changes to device settings in accordance to the changes in muscle response over time.



The image displays four sequential mobile app screens for a patient registration process. Each screen has a status bar at the top showing the time as 12:30 and signal/battery icons.

- Screen 1: New Patient Information**
Fields: Name, Age, Sex, Address.
Button: Next
- Screen 2: New Patient Medical History**
Fields: General health, Symptoms, Difficulties index, Pain level, IDDSI index.
Button: Next
- Screen 3: New Patient Confirm details**
Fields: Latika Desai, 64, Female, Hiranandani Powai, Mumbai.
Text: (whatever rest of the fields should look like)
Button: Add Patient
- Screen 4: Analyzing Data**
A circular progress indicator with a blue segment, indicating the analysis phase.

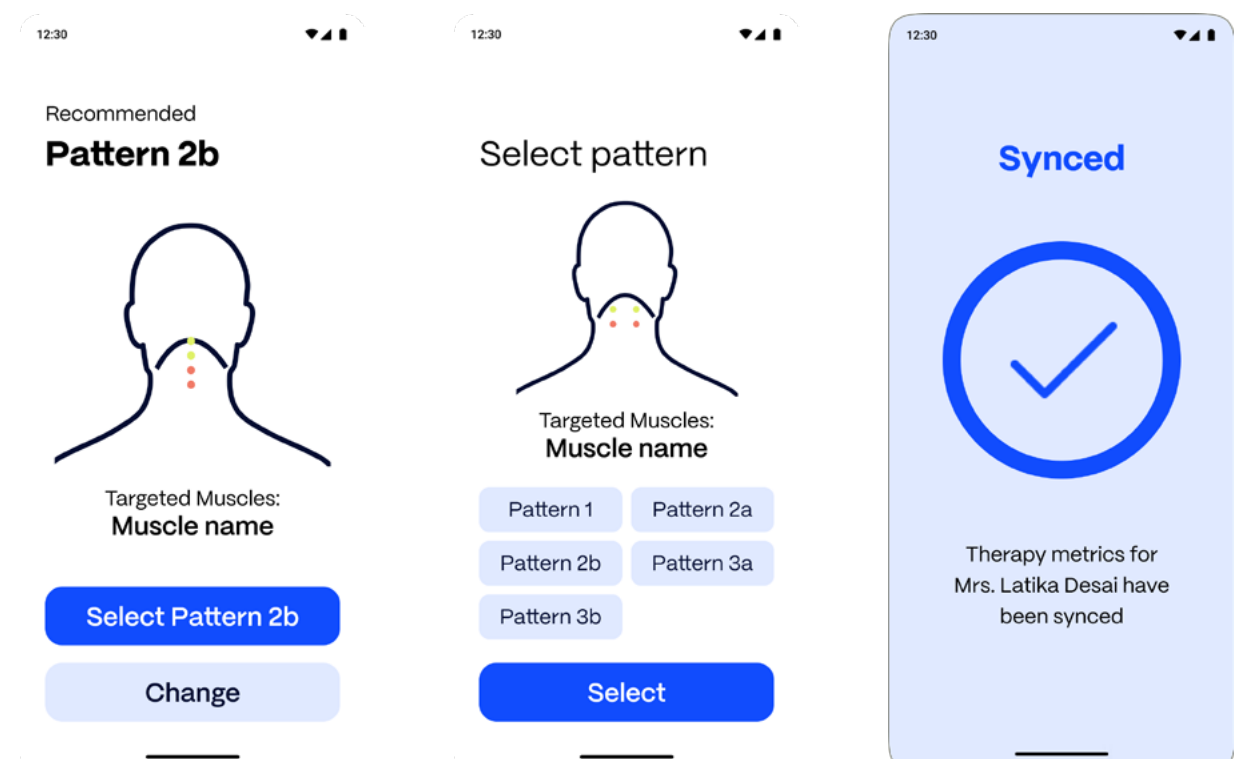
After selecting the "New Patient" option, the user (in this case the medical professional) will be shown the option to add the patient information, mainly their demographics and their medical history. The data is then analyzed by the app and it presents a recommended pattern which, if the doctor thinks is proper.



Pattern Selection

The doctor can choose to go with the recommended pattern or they can veto that pattern and choose their own if they think another pattern will better suit the patient's needs.

After successful selection the device is synced. and is ready to be used by the patient.



Conclusion and Feedback

The final jury feedback was quite positive, with hope for the product to be taken forward and developed further. The panel members commended the empathy for the user group and user focused design approach. The novelty and the simplicity of the device was also appreciated. The amount of research into the topic and the systemic approach to the product systems and data sharing aspects as well as

But it was not without critique and scope for improvement. One missing factor was the lack of costing for the product. Costing was challenging because of the lack on information on the parts due to the rarity, specialized nature and the complexity of the device. The panel felt that it must be ensured that the materials used for the product do not cause abrasions and are bio-compatible.

Another focus area for improvement which was mentioned was to look into parallel medical frameworks to ensure all the medical factors are taken care of. The device shouldn't inhibit or cause harm to other faculties like the nervous system or any other tangential muscle groups because of the device. A thorough medical overview will be required to ensure proper safety.



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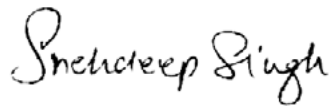
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- Physipedia – Neuromuscular and Muscular Electrical Stimulation (NMES)
- IDDSI – The IDDSI Framework



Declaration

I declare that this written report represents my ideas in my own words, and where others' ideas or words have been included, I have adequately cited and referenced the original sources. I also declare that I have adhered to all principles of academic honesty and integrity and have not falsified, misinterpreted, or fabricated any idea, data, facts or source in my submission. I understand that any violation of the above will be caused for disciplinary action by the Institute and can also invoke penal action from the source, from which proper permission has not been taken or improperly been cited.



Signature

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Date:

15 June, 2023



