Author: BSc C.IJ. 'Stijn' Ponsioen
Student ID: 4441966

A Novel Smart Wearable for Parkinson's Disease

MSc Thesis:
Integrated Product Design
Industrial Design Engineering, TU Delft

DOPPLE

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Industrial Design Engineering TU Delft

Ir. Erik Thomassen	Graduation coach
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Dr. Ir. Jaap Haartsen	CTO & Chief Scientist
Ir. Johan Schreuder	Managing partner
Ir. Rachid Elouad	Human factors engineer
Ir. Tim de Jong	Human technology engineer

Zorginstellingen Pieter van Foreest

Mascha Slager	Manager
Nathalie Timmermans	Parkinson's physiotherapist
Parkinson clients	In rehabilitation or residing at ZPvF

Dutch Hospitals

Dr. Martijn Beudel	Neurologist, Amsterdam UMC
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Abbreveation Legend, glossary, and conventions

Abbreveation legend

PD	Parkinson's disease
IEM	In ear mo
SN	Substantia nigra
MS	Motor symptom
NMS	Non motor symptom
RBD	Rapid eye movement sleep behaviour disorder
PS	Prodromal symptom
FOG	Freeze of gait
IMU	IMU
CNN	Convolutnional neural network
NN	Neural network
DBS	Deep brain stimulation
CV	Computer vision
DSP	Digital signal processing
SOS	Save our souls
PvF	(de Zorginstellingen) Pieter Van Foreest
EoL	End of life (phase)
FAE	Finite element analysis
I2C	Inter-integrated circuit
SBC	Sub-band coding
BLE	Bluetooth low energy
6MWT	6-minute walk test
RAS	Rhythmic auditory stimulation
AR	Augmented reality
MVP	Minimum viable prototype
TRL	Technology readiness level
ADL	Activity of daily living
ML	Machine learning
STS	Sit-to-stand (test)

Glossary

The directly involved stakeholders (Dopple B.V., de Zorginstellingen Pieter van Foreest, my coach, and my chair know about the glossary and conventions used in this report. Both these sections are aimed to inform third party readers of this thesis, i.e. visitors of the TU Delft repository.

Terms	**Definitions**
PD client	a person with Parkinson's disease
True positive (TP)	the number of cases correctly identified as true
False positive (FP)	the number of cases incorrectly identified as false
True negative (TN)	the number of cases correctly identified as true
False negative (FN)	the number of cases incorrectly identified as false
sensitivity =	TP/(TP + FN)
specificity =	TN/(TN + FP)
accuracy =	(TP + TN)/(TP + TN + FP +FN)

Conventions

- Later on in the project when the name of the concept product "Dopple Earbuds" is introduced, I will refer to it as being a singular object. Even though the entire system consists of a smartphone, a cradle, and two IEMs (and a night stand).
- All (CAD) models, renders, infographics, visuals etc. in this thesis have been designed by the me (Stijn). For photographs, the photographer/owner is credited if the photograph was not shot by me or is not owned by me.
- All in-text referenced chapters, sections, and appendices are clickable and link to their corresponding destinations (one-way).

Summary

In the evolving landscape of medical technology, the pursuit of innovative solutions to enhance the quality of life for individuals with chronic conditions has never been more pertinent. This graduation report presents the culmination of a product design project aimed at addressing prevalent symptoms of individuals with PD.

Thesis client and goal
The goal of the design project is to deliver a concept product for Dopple B.V., a Dutch tech company specialised in head-worn audio smart wearables. Dopple wants to expand their competence into the medical market. This effectively limits the solution space to their product line.

Product and research scope
Thus, the core of this project revolves around the development of a smart wearable audio device equipped with modern technology. First and foremost, it obviates and delays the need for contemporary pharmaceutical remedies. Furthermore, it extends the care capabilities of medical experts such as neurologists and physiotherapists, besides simultaneously devoting less time to client feedback.

Through literature review, interviews with clients and said medical experts, current market assessment, and stakeholder analysis, the scope "freeze of gait & festination" was chosen.

Freeze of gait
Freeze of gait (FoG) is characterised as a sudden and temporary inability to move (forward) despite the intention to walk. Clients often describe it as feeling like their feet are glued to the floor. FoG episodes typically occur whilst walking and can be triggered by turning, starting to walk, neighbouring objects/people or crossing narrow spaces. These episodes significantly impact mobility and increase the risk of falls, affecting the quality of life for those with PD.

Festination
Festination is characterised by a rapid and short-stepped gait. It manifests as a need to walk faster with progressively shortened steps, often leading to a loss of balance. Clients describe it as feeling compelled to hurry forward with an inability to easily control or stop their movement. Festination typically occurs during walking and can be exacerbated by stress or an attempt to initiate or alter one's gait. Festination can lead to the same problems as FoG.

User testing
Several tests were conducted with PD clients of the partnering Dutch healthcare facility 'Zorginstellingen Pieter van Foreest', to evaluate the practical efficacy of the envisioned feedback mechanisms. Albeit with few clients the results turned out to be very promising. To showcase the merit of my tests, videos were taken, edited, and shown to the Thesis research group.

Product functionality
The "Dopple Earbuds" leverage the latest technology and resources, such as smartphone integration, neural networks, and efficient Bluetooth data transmission. Beyond mitigating FoG and festination, the Dopple Earbuds are adept at addressing a broader spectrum of PD-related symptoms and tasks. This includes object detection, heart rhythm monitoring, fall detection, remote monitoring, posture correction, maneuver assistance, hearing aid, SOS alerts, and stability support, encompassing a holistic approach to improving daily life for individuals with PD that experience one or more motor symptoms.

So, the concept product, a set of in-ear-monitors (IEMs) and a smartphone, is able to sense, actuate, and correct its wearer, and inform their care-taking stakeholders, for each of the mentioned functions.

Multi-faceted design
In terms of aesthetics, ergonomics, materials, and product architecture, these Dopple Earbuds are based on a previous set of IEMs designed by Dopple, however, adjusted to the needs of the generally elder targeted user.

Due to the involvement of neural networks, allowing for several functions to be carried out, careful memory allocation, battery consumption, data flow, and digital signal processing (DSP) strategies were envisioned. A client on the move implies some functions can be put in their activate state or on stand-by (and vice versa).

Through collaboration with healthcare professionals, engineers at Dopple, coaching from my chair Daan and coach Erik, and continuous design iterations based on user feedback, this project aims not only to contribute to a novel solution to the PD community but also to push the boundaries of what is achievable with medical assistance technology as opposed to current pharmaceutical approaches.

Table of Contents

Introduction

In this Master's thesis, the focus is on the development of the 'Dopple Earbuds', an innovative IEM tailored for aiding individuals with PD, particularly in mitigating the symptoms of FoG. This endeavor in Integrated Product Design has been guided by a dual objective: to innovate within the technical realm and to significantly enhance the quality of life for PD clients.

The project initiated with an in-depth analysis of the existing gap in medical and technological support for PD clients. This analysis underscored the necessity for an approach in the field of wearable technology, emphasising the integration of advanced sensors. Central to this endeavor was the understanding that an effective solution for FoG transcends mere technological innovation; it necessitates a profound comprehension of user ergonomics and interaction.

A substantial segment of this thesis was devoted to the exploration and refinement of various technological approaches to the conceptual realisation. Often these approaches sparked their own set of challenges, particularly in ensuring ergonomic suitability, as well as reasonable power draw for prolonged use. Both are critical factors in assistance devices.

The project was further enriched through collaborations with domain experts, stakeholders, and end-users. These interactions were instrumental in shaping the design and functionality of the Dopple Earbuds, steering the development towards a user-centered design approach that addresses the specific needs of PD clients.

Throughout the project, it became evident that the technical challenges encompassed not only precise engineering but also a deep sense of empathy towards the end-user. This understanding was pivotal in the iterative design process, ensuring that each decision prioritised the user's comfort and ease of use.

To summarise, this introduction sets the stage for a thesis that is more than a showcase of technical expertise; it is a narrative about bridging the gap between advanced technology and human-centric design, with PD as the main theme. The Dopple Earbuds exemplify this principle, representing a significant advancement in the realm of medical assistance devices.

A poem for PD clients (by me)

In the realm of a window, touched by rain's embrace,
PD stands as a pane, where droplets trace.
Each tiny droplet, a symptom in disguise,
Falling from the stormy, burdened skies.

The onset of PD, like raindrops' quiet cling,
Symptoms that from clouded heavens spring.
Adhering to the glass, a pattern they start,
A reflection of struggles, close to the heart.

As droplets merge, their journey begins,
Clinical onset, where deeper tales spin.
Sliding down slowly, a path set in stone,
An irreversible journey, often faced alone.

More symptoms join, in this downward slide,
A growing cascade, with nowhere to hide.
Each droplet's path, a mirror so keen,
Of PD's progression, silent and unseen.

Together they travel, a sorrowful sight,
Each droplet a battle, in life's ongoing fight.
On the window of existence, they tell a tale,
Of resilience and courage, against a storm that prevails.

For in each droplet, the story of a soul,
Navigating PD, seeking control.
Symptoms, like raindrops, may mark their path,
Yet in each, a strength, a distinct aftermath.

1 Preliminary design scope research

During the kick-off meeting on the 20th of September 2023 I showcased what the initial research I did as pertains to setting up a suitable design scope had brought us. The directions were valid PD related problems that could be designed for. However, I did not yet decide upon which scope would be the most applicable to the project. Thus, the delegates from Dopple, Daan, Erik, and I felt that choosing the right design scope should be a part of the project itself.

In this chapter the preliminary research is portrayed, ultimately resulting in five different scopes, from which I picked one, which in turn will dictate the course of the design project.

To get acquainted with the subject in the context of a graduation project I decided to conduct the following research activities:

- Stakeholder analysis
- SWOT analysis per stakeholder
- PD client interviews (Appendix A1, A2, and A3)
- Interview with PvF physiotherapist (Appendix G)
- Existing wearables study
- Motor symptoms of PD
- Non-motor symptoms of PD
- Prodromal symptoms of PD
- Current therapies and drugs
- What symptoms to address
- Potential problems and design opportunities
- Following the money in PD

1.1 Stakeholders interest vs influence c-box

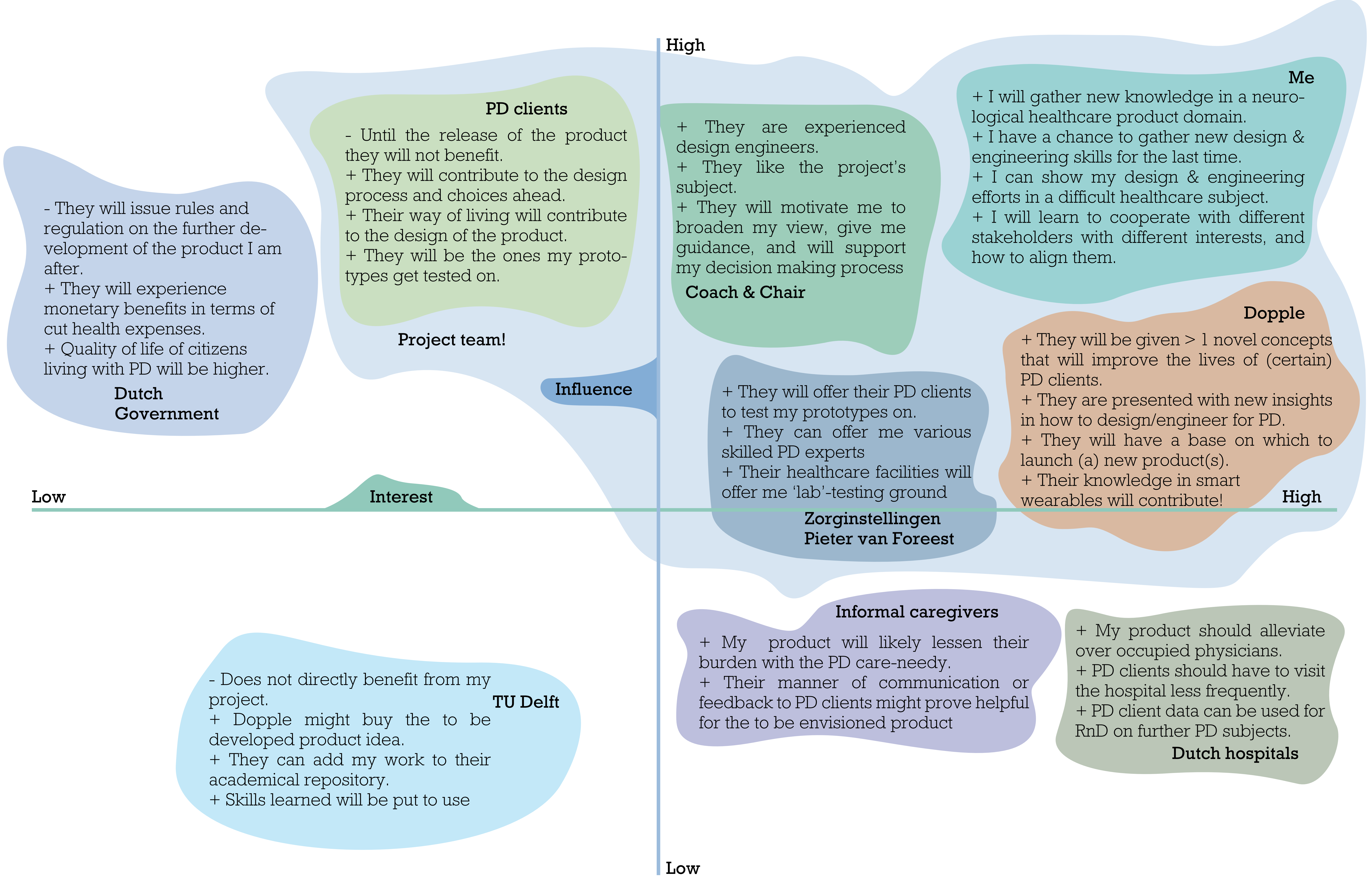


Figure 1.1.1: This c-box (a two dimensional graph) illustrates how all stakeholders are related to the project in terms of interest and influence (infographic by me).

1.2 SWOT analysis stakeholders

In this section I will elaborate on the stakeholder C-box, that mapped interest and influence, by fashioning a short excerpt that reflects their strenghts, weaknesses, opportunities, and threaths interrelated to the design project.

The time of their interaction with the concept product is not indicated, rather, how they contribute and benefit from the system as a whole.

Investigated stakeholders:
- PD clients
- Dutch Hospitals
- Dutch Doctors
- The Dutch government
- My Coach and Chair
- Zorginstellingen Pieter van Foreest
- Insurance Companies
- The TU Delft
- Regulatory Bodies (e.g. OMW)
- Dopple
- Informal Caregivers
- Technology Partners/Suppliers
- Me

PD clients

Strengths
- Enhanced mobility and independence due to early freeze episode detection.
- Increased confidence in moving around, reducing fear of falling or freezing.
- Resulting in improvement in overall quality of life.

Weaknesses
- Dependence on the device's accuracy and reliability.
- Potential discomfort or inconvenience of wearing in-ear devices regularly.
- Possible resistance to adopting new technology among some clients.

Opportunities
- Feedback from clients can drive improvements and innovations.
- Expansion to other mobility-related conditions
- Collecting gait and FOG data to train models.
- They will contribute to the design process and choices ahead.

Threats
- Technological malfunctions leading to mistrust.
- Inaccurate predictions causing either false alarms or missed episodes.

Dutch hospitals

Strengths
- Improved client care and monitoring capabilities.
- Potential reduction in hospital visits due to better at-home management.
- Their doctors have a new remedy for PD clients.

Weaknesses
- Implementation and training costs.
- Dependence on client compliance.

Opportunities
- Research collaborations, particularly in physiotherapy, neurology and geriatrics.
- Enhanced global reputation through the adoption of innovative client care technologies.

Threats
- Data privacy and security concerns.
- Technological obsolescence and the need for continual upgrades.

Insurance Companies

Strengths
- Potential cost savings from reduced hospital visits.

Weaknesses
- Liability and coverage complexities.

Opportunities
- Partnership in preventative healthcare.

Threats
- Cost of covering advanced technology for quite a large market.

Dutch Doctors

Strengths
- Improved client monitoring and data for treatment adjustments.
- Enhanced client-doctor communication through shared data insights (if the concept were to be coupled with an app that features data insight).

Weaknesses
- Need for training and understanding of the new technology applied in this concept product.
- Potential over-reliance on technology for client assessment.

Opportunities
- Research and publication opportunities.
- Better client outcomes leading to higher satisfaction and trust.
- Increasing their knowledge and means, thus client care.

Threats
- Liability issues in case of technology failure.
- Resistance from traditional practitioners.

Dutch Government

Strengths
- Opportunity to support innovation in healthcare technology, aligning with public health goals.
- Enhanced reputation in fostering cutting-edge research and medical advancements, if OMW opts to subsidise Dopple for the development of the concept product.
- Potential to reduce long-term healthcare costs by supporting preventive and advanced care solutions.

Weaknesses
- Challenges in adapting regulatory frameworks to new technology.
- Possible budgetary constraints in funding new healthcare initiatives.
- Need for interdepartmental coordination to support such innovative projects effectively.

Opportunities
- Collaboration with research institutions (like the TU Delft) and companies (like Dopple) to drive national research agendas.
- Setting a precedent for public-private partnerships in healthcare innovation.
- Export potential of Dutch-developed healthcare technology, enhancing the country's image in the global medical devices market.

Threats
- Risk of public funding being diverted to projects without guaranteed outcomes.
- Balancing privacy and ethical concerns, especially with data-sensitive technologies in healthcare.
- Potential resistance from traditional healthcare stakeholders fearing disruption.

Coach & Chair

Strengths
- Expertise and experience in guiding research, ensuring academic rigor and viability.
- Expertise in product design.
- Ability to provide critical feedback, ensuring a comprehensive and well-rounded approach to the thesis, to ensure I will perform on 'Ir.' level after the thesis.

Weaknesses
- Limited availability and time constraints might affect the frequency and depth of guidance.
- Potential differences in perspectives or academic interests/skills that might influence the direction of the research.
- Risk of over-reliance on their guidance, which might limit independent problem-solving and creativity.

Opportunities
- Collaboration can lead to innovative ideas, enhancing the quality and impact of my thesis.
- Their experience in the field can help in navigating complex research challenges.

Threats
- Misalignment in expectations or thesis goals between me and them.
- Their other commitments might limit their engagement with my project.
- Potential for feedback or guidance to inadvertently steer the project away from original objectives or innovation.

Zorginstellingen Pieter van Foreest

Strengths
- Enhanced care for Parkinson's clients.
- Opportunity to be at the forefront of adopting innovative health technologies.
- They have collaborative engagement power in terms of logistics, PD related (care) know-how, facilities, and PD clients.

Weaknesses
- Costs of implementation and ongoing maintenance.
- Training staff to effectively use and interpret the technology.

Opportunities
- Research partnerships and funding.
- Improved client outcomes and satisfaction.

Threats
- Technology may not integrate well with existing systems.
- Resistance to change from staff or clients.

Informal caregivers

Strengths
- Enhanced ability to monitor and support the client with PD, if an app/information conveyor were to be implemented.
- Gaining a level in understanding the severity (increase over time) of their care needy (same applies, if an app were to be introduced).
- Enhanced feelings of empowerment and involvement in the client's healthcare journey.

Weaknesses
- Potential reliance on the technology may lead to a false sense of security or overlook the nuances of personal care.
- Possible increase in caregiver burden if the technology introduces new complexities or responsibilities.

Opportunities
- Potential for feedback and insights from caregivers to improve the product.
- Their manner of communication or feedback to PD clients might prove helpful for the the to product
- The product will likely lessen their burden with the PD care-needy.

Threats
- Resistance to technology adoption due to lack of tech proficiency or preference for traditional care methods.
- Data privacy and security concerns, especially if caregivers have access to sensitive health data.
- Emotional and mental stress if the technology fails to predict or react to freeze episodes accurately.

Technology Partners/ Suppliers

Strengths
- Expansion into new markets.
- Access to advanced technology and expertise.
- Scalable production capabilities.
- Established quality assurance processes.

Weaknesses
- Dependence on the product's market success.
- Dependence on external sources for key components.
- Higher costs for quality parts.
  Need for efficient coordination and communication.

Opportunities
- Long-term partnerships and innovation.
- Expansion of business networks and market opportunities.
- Ability to create unique, customised product features that Dopple cannot do themselves

Threats
- Vulnerability to supply chain disruptions.
- Intellectual property and confidentiality concerns.
- Competition, as suppliers may also serve rival companies.

Regulatory Bodies (e.g. OMW)

Strengths
- Setting standards for emerging technologies.

Weaknesses
- Keeping pace with technological advancements.

Opportunities
- Ensuring client safety and data security.

Threats
- Over-regulation stifling innovation.

TU Delft

Strengths
- Opportunity for cutting-edge research and development.
- Attracting funding and partnerships.

Weaknesses
- Resource allocation challenges.
- Balancing academic and commercial interests.

Opportunities
- Faculty involvement in groundbreaking projects.
- Publications and intellectual property creation
- This concept product offers many MSc graduation and PhD candidate project opportunities to multiple disciplines.

Threats
- Potential conflicts between academic and commercial goals.
- Resource limitations impacting research scope.

Dopple

Strengths
- Diversification into medical technology.
- Potential new market and revenue stream.
- Their knowledge in smart wearables will contribute!
- They posses know-how in developing smart wearables

Weaknesses
- Challenges in meeting medical-grade product requirements.
- Potential lack of experience in the healthcare sector.
- Not every PD client might be able to operate their novel inventions.

Opportunities
- They will be given > 1 novel concepts that will improve the lives of (certain) PD clients.
- Collaboration experience with medical experts for product development.
- Expansion into other areas of medical wearables.
- They will be presented with new insights how to develop products for PD clients.

Threats
- Regulatory hurdles and certification requirements.
- Competition in the medical device sector, as FOG detection and mitigation is an emerging market (Cue2Walk, 2023) (Rollz, 2023).k

Me

Strengths
- Involvement in an innovative project with potential real-world impact.
- Opportunity to develop expertise in a specialised, growing field.

Weaknesses
- Potential for high stress due to project complexity.
- Balancing academic, research, side jobs, and personal life.

Opportunities
- Career advancement and networking.
- Gaining a diverse skill set in technology and healthcare.
- I will gather new knowledge in a neurological healthcare product domain.
- I have a chance to gather new design & engineering skills.
- I will learn to cooperate with different stakeholders with different interests, and how to align them.

Threats
- Intellectual property and data security concerns.
- Potential burnout due to project demands.

1.3 Explorative interview with PD clients

This section contains the insights from a focused group study involving PD clients. The objective of this research was to explore the receptiveness of these individuals towards smart wearables designed to improve their quality of life. It is imperative to conduct such studies because the unique challenges faced by PD clients require tailored solutions that not only provide functional assistance but also ensure ease of use and maintain the dignity of privacy.

I engaged five PD clients, all above the age of 70 and current users of hearing aids, to gather their candid perspectives on various technological tools and features. Through qualitative open-ended questioning, I allowed the patients to freely express their needs, concerns, and preferences. Through their open responses I have discerned not just a general willingness to accept technology, but specific conditions that must be met to ensure their adoption and sustained use.

The points below reflect the collective voice of the intended end user to inform future product development.

Acceptance of Technology
- Must be understandable.
- Must be controllable.

Smartphone App
- Acceptance conditional upon setup assistance.
- All participants had a smartphone.

Data Acquisition
- Willing if it leads to product improvement.
- Dopple logo viewed positively.

Physical Controls
- The less physical control required, the better.
- Tremors were observed in 80% of participants.
- Slow movements were observed in all participants.
- Rigidity observed in 80% of participants.
- Symptoms include stiff joints and muscle tension.
- Voice commands are essential for products targetted to this audience.

Product Features
- SOS function needed.
- Volume control is important.
- Noise canceling is potentially dangerous, especially whilst engaging in traffic
- Assistance in activity initiation is necessary.
- Feedback on algorithms is welcomed.
- Desire for less negative and more positive feedback from the product.

Camera Usage
- No issue with camera implementation in product as long as privacy is maintained; "As long as my private life remains private."

Wearable Preferences
- The lower the amount of total wearables carried, the higher the chance of intended use of these wearables.
- Positive feedback on replacing hearing aids, particularly ones without wires behind the ear and without causing irritation with glasses.
- Replacement of the SOS products (e.g. a necklace).
- Open to other audio wearable options like audio playback, phone calls, etc.

Photograph by Nathalie, with signed agreement *of PD Client PvF.*

The entire Q&A's of two PD clients are listed in Appendix A2. The other three PD clients did not want their answers to be directly included in this Thesis. Note: the rubric explained on this page are the extracted inderect anwers of all five PD clients.

1.4 Existing wearables

In recent years, the intersection of healthcare and technology has yielded remarkable advancements in the management of complex medical conditions. Among these conditions, PD stands out due to its multifaceted challenges. It presents a unique set of hurdles that often manifest in both motor and non-motor symptoms (MSs & NMSs).

For those living with PD, everyday tasks can become increasingly daunting as the disease progresses. In response, researchers, tech companies, and designers are creating novel wearable devices equipped with sensors, feedback systems, and AI. These devices offer the promise of enhancing client care by providing real-time monitoring, feedback, therapeutic support, and improved quality of life.

Recent studies have affirmed the effectiveness of wearable gadgets in appraising PD symptoms on par with conventional scale assessments (Del Din et al., 2016). These innovative devices surmount the limitations inherent in clinical evaluation scales concerning impartiality, precision, and acuity. It is worth noting that assessment scales' accuracy hinges on the subjective judgment and professional expertise of the evaluating physician, along with the emotional disposition, adherence, and recall bias of clients (K. Yang et al., 2016). Wearable technology elevates assessment precision by objectively quantifying sporting symptoms. Moreover, these wearables exhibit remarkable sensitivity, adept at discerning subtle motor irregularities (Mancini et al., 2019). This enables prompt or differential diagnoses, ongoing motion state surveillance, and extended remote motion monitoring (Delrobaei et al., 2018).

In clinical practice, quick evaluations often fall short in disclosing the genuine extent of symptoms or accurately mirroring clients' daily routines. Ergo, wearable devices furnish clinicians with a comprehensive dossier of clients' conditions in a single assessment, thereby optimising treatment strategies.

Furthermore, the beauty of wearable devices lies in their unrestricted temporal and geographical usage. Embracing these devices heralds a shift from centralised clinical care towards bespoke diagnosis and treatment.

In this section I will delve into the myriad capabilities of these devices, which range from motion sensing and symptom tracking to therapeutic interventions. My examination will not only focus on the various types of head-worn PD wearables available but also explore the unique features and targeted symptoms by non head-worn products.

Included products:
- KinesiaU (KinesiaU, 2022)
- SpeechVive (SpeechVive, 2023)
- Cala kIQ system (Cala Health, 2023)
- Parkinson's KinetiGraph System (PKG, 2019)
- SpeechEasy (SpeechEasy PD, 2018)
- Dr. Tass' glove (Stanford University, 2023)
- CUE1 (Charco Neurotech, 2023)
- Rollz Motion Rhythm (Rollz, 2023)
- Cue2Walk (Cue2Walk, 2023)
- Dopple's IEM products (Dopple, 2023)

KinesiaU is a comprehensive motor assessment system that has been developed for individuals to measure their PD symptoms. It utilises an app that can be operated on an iPhone or Android smartphone, in conjunction with a smartwatch.

The KinesiaU platform is the result of over fifteen years of development and validation by Great Lakes NeuroTechnologies, and it is considered a gold standard for objective sensor measurement in the study of movement disorders. It has been validated with an extensive amount of data across numerous scientific publications and presentations, showing outcomes for Parkinson's symptoms comparable to those assessed by expert clinicians.

Using KinesiaU involves performing simple tasks throughout the day while wearing a compatible smartwatch. The app generates reports that display symptoms across various time frames, providing insights into how symptoms respond to therapy and activities over days, weeks, months, and years.

KinesiaU
- Tremors
- Slowness of movement
- Dyskinesia

The SpeechVive is wearable audio device created to improve speech in people with PD and communication difficulties. It utilises the Lombard effect, an automatic vocal response to ambient noise, by playing a background sound in the user's ear. This sound triggers an involuntary increase in vocal volume and clarity, and a more normal speech rate.

Designed for daily use, SpeechVive is practical and unobtrusive, enabling users to wear it during various everyday activities. This constant usage helps individuals consistently maintain clearer and more effective speech in diverse social interactions and settings. The device's design focuses on real-world application, allowing for ongoing speech improvement outside clinical environments.

By promoting better speech patterns in natural environments, SpeechVive not only enhances communication abilities but also boosts the user's confidence in social interactions, making it a valuable tool for those with speech impairments.

SpeechVive
- Hypophonia (soft voice)
- Dysarthria (slow and unclear speech)

The Cala kIQ system counteracts tremors PD clients may have. The device focuses on the nerve impulses in the wrist, which are often the primary instigators of tremors.

The system operates by closely monitoring the nerve impulse behaviour that triggers tremors. Once these impulses are detected, the Cala kIQ system employs a method known as transcutaneous afferent patterned stimulation. This technique involves delivering carefully patterned electrical stimulation through the skin (transcutaneously) to the affected nerves. The objective of this stimulation is to disrupt and counteract the erratic nerve signals that cause tremors, thereby providing relief to the client

Cala kIQ system
- Essential tremor
- Parkensonian tremor

The Parkinson's KinetiGraph (PKG) System is a wrist-worn smart wearable that continuously logs and quantifies movement disorder symptoms, offering insights for the clinical management of PD related movement disorders. It persistently monitors the kinematics - the motion and movement patterns - of the client, thereby generating detailed and objective clinical reports.

These reports are pivotal in identifying and differentiating between various movement patterns associated with specific symptoms like bradykinesia, tremor, immobility, and dyskinesia. The precision and detail of the PKG System's data collection allow for a nuanced understanding of these symptoms, which can be challenging to discern and quantify through observation and potentially biased client feedback.

PKG System
- Essential tremor
- Parkensonian tremor
- Bradykinesia
- Immobility
- Dyskinesia

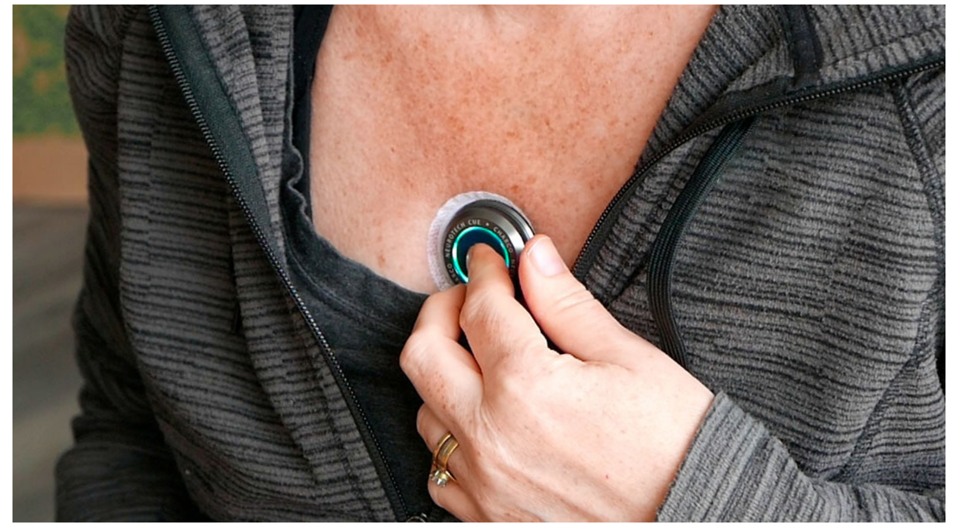
Image taken from YouTube video (nosilverbullet4pd, 2023)

Peter Tass, a neurosurgeon at Stanford School of Medicine, has developed a vibrating glove designed to alleviate symptoms of PD. This innovative treatment delivers patterned vibratory bursts of electricity to the fingertips, which can desynchronize neuron firing in the brain. PD symptoms, including tremors, muscle stiffness, and slow movement, are thought to be linked to abnormal simultaneous firing of groups of neurons. The glove operates at frequencies between 100 to 300 hertz, with early trials showing that wearing the glove for two hours, twice a day, can calm many of the symptoms.

This non-invasive treatment emerged from Tass's concept of "coordinated reset stimulation," which aims to reset abnormal neuronal firing patterns. His research indicated that not only does the vibratory stimulation help with motor symptoms, but it also appeared to improve NMSs like mood swings, depression, and loss of smell and taste. The glove represents a potential middle ground between existing treatments for Parkinson's, such as medication and deep brain stimulation (DBS), offering a non-invasive and possibly more accessible option for clients.

While early trials are promising, further research involving larger groups of clients is necessary to fully assess the effectiveness of the vibrating glove therapy. The glove is currently in the preparatory stages of clinical trials, with future studies aiming to test the impact of varying the frequency and duration of the vibrations across a broader participant base. The research is progressing rapidly, and updates on these trials are anticipated to provide more definitive conclusions on the therapy's potential benefits

Tass' research prototype glove
- Tremors
- Muscle stiffness and rigidity
- Slowness of movement
- Loss of balance
- Difficulty walking
- Mood swings and behaviour changes
- Depression
- Loss of smell and taste



The CUE1 device by Charco Neurotech is a non-invasive, wearable device that aims to improve movement symptoms in Parkinson's clients, such as stiffness and slowness. It uses focused vibrotactile stimulation and cueing to provide symptom relief, with user testing showing significant motor improvement. It's discreet, attached via an adhesive patch, and comes with a one-button operation. The device can be used alone or with an app to customize settings and track symptoms. Similar to Tass's glove, which also uses vibration therapy, the CUE1 leverages vibratory patterns to potentially reduce Parkinson's symptoms like tremors and rigidity

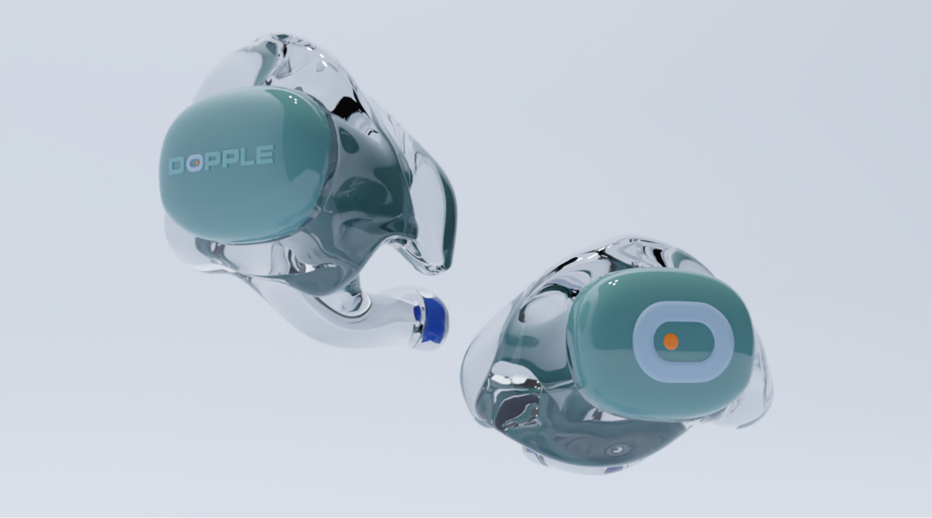
CUE1
- Stiffness
- Slowness of movement
- Freeze of Gait (Mackett, 2024)

Photograph by me, with signed agreement of PD Client PvF.

The Rollz Motion Rhythm is a specialised rollator designed for Parkinson's clients, particularly beneficial for those experiencing freezing episodes while walking. It features a unique rhythmic cueing system to help maintain a steady walking pace and can switch between rollator and wheelchair modes for versatile mobility support. The design focuses on ergonomic comfort and stability, with adjustable handles for a tailored fit. Additionally, its foldable design makes it convenient for transportation and storage.

Since the Dopple Earbuds share fundamental functions with the Cue2Walk, It deserves its own section.

Cue2Walk
- Freeze of Gait



Although Dopple has not yet designed any smart earables, they are listed here because their other products were researched thoroughly in terms of ergonomics, architecture, usability, and aesthetics. I deliberately included a render of the Dopple Earbuds as an image here.

Dopple IEM products
- No PD symptom yet.

1.5 Parkinson's disease

Disease definition
PD is a progressive neurodegenerative disease that primarily affects movement but can also lead to a variety of non-motor symptoms (NMSs). It is the second most common age-related disorder after Alzheimer's disease. It is characterised by the loss of dopamine-producing neurons, particularly in a region of the brain called the substantia nigra (SN). This loss leads to the primary motor symptoms.

Pathophysiological historical
In 1817, James Parkinson was the first to document the motor-related symptoms of what's now known as PD. In his seminal work, "An Essay on the Shaking Palsy," Parkinson gave a detailed account of these symptoms, originally naming the condition "shaking palsy" (Goetz, 2011). The disease was subsequently named in his honour and was more comprehensively described by Jean-Martin Charcot.

The identification of PD's cardinal motor symptoms (MSs) — tremor, stiffness, and slow movement — marked a pivotal moment in comprehending the disease. However, it wasn't until nearly a century later that the underlying anatomical causes of these symptoms were discovered. In 1912, Fritz Heinrich Lewy found protein deposits, now known as a defining characteristic of PD, in certain brain areas outside the SN. Following this, in 1919, Konstantin Nikolaevich Tretiakoff discovered similar deposits in the SN itself and named them Lewy bodies in honour of Lewy's earlier work. By the 1990s, it was established that α-synuclein was the primary component of these Lewy bodies, a crucial factor in PD, dementia with Lewy bodies, and multiple system atrophy (Goedert et al., 2013). Nowadays, the accumulation of α-synuclein protein as clumps (Lewy bodies) in neurons, contributing to dopaminergic neurotransmitter death, is the main marker for PD.

Risk factors and causes
While the exact cause of PD is unknown, the neurological field has done a lot of research on the potential causes of the disorder:

Exposure to environmental toxins
A study by Caballero et al. (2018) found a potential link between glyphosate exposure in farming and an increased risk of PD. The study showed that individuals exposed to glyphosate had a 33% higher chance of premature mortality from PD compared to those not exposed. Furthermore, Dardiotis et al. (2013) found that genetic factors related to pesticide processing in the body may increase PD risk when coupled with pesticide exposure.

Genetic Factors
While the majority of PD cases appear to be sporadic, approximately 10-15% of cases have a genetic origin. Mutations in specific genes such as PRKN, LRRK2, PARK7, PINK1, and SNCA have been connected to PD (Hernandez et al., 2016).

Age
PD is predominantly a disease of aging, with most people developing it after the age of 60. The risk of developing PD increases with age (Hindle, 2010). However, there is a cause at play that is decreasing the age limit where PD can occur, as the youngest client is now only twelve years old. The mean age at diagnosis is approximately 70, though this figure might be underestimated owing to the under-diagnosis in older populations. Numerous studies employ subjects whose ages are not representative of the broader population, and the impact of this selection bias warrants additional investigation (Macleod et al., 2018).

Gender
Males are more likely to develop PD than females, though the reasons for this gender difference are not entirely clear (Tysnes & Storstein, 2017).

Head Trauma
There is some evidence suggesting that repeated head injuries or severe head trauma may increase the risk of developing PD (Svensson et al., 2015).

Race and Ethnicity
PD appears to be more common in caucasian individuals compared to African Americans or Asians, but the reasons for these differences are not well understood.

Family History
Having a close relative with PD increases a person's risk of developing the disease, though the risk is still relatively low unless there is a known genetic mutation causing PD in the family.

Other Neurological Disorders
Certain neurological conditions, such as REM sleep behaviour disorder, are associated with an increased risk of developing PD later in life. More on this is the next section.

Diagnosis
PD is primarily diagnosed based on medical history, a review of signs and symptoms, and a neurological and physical examination. There are no standard diagnostic tests for PD, making it challenging to diagnose, especially in the early stages.

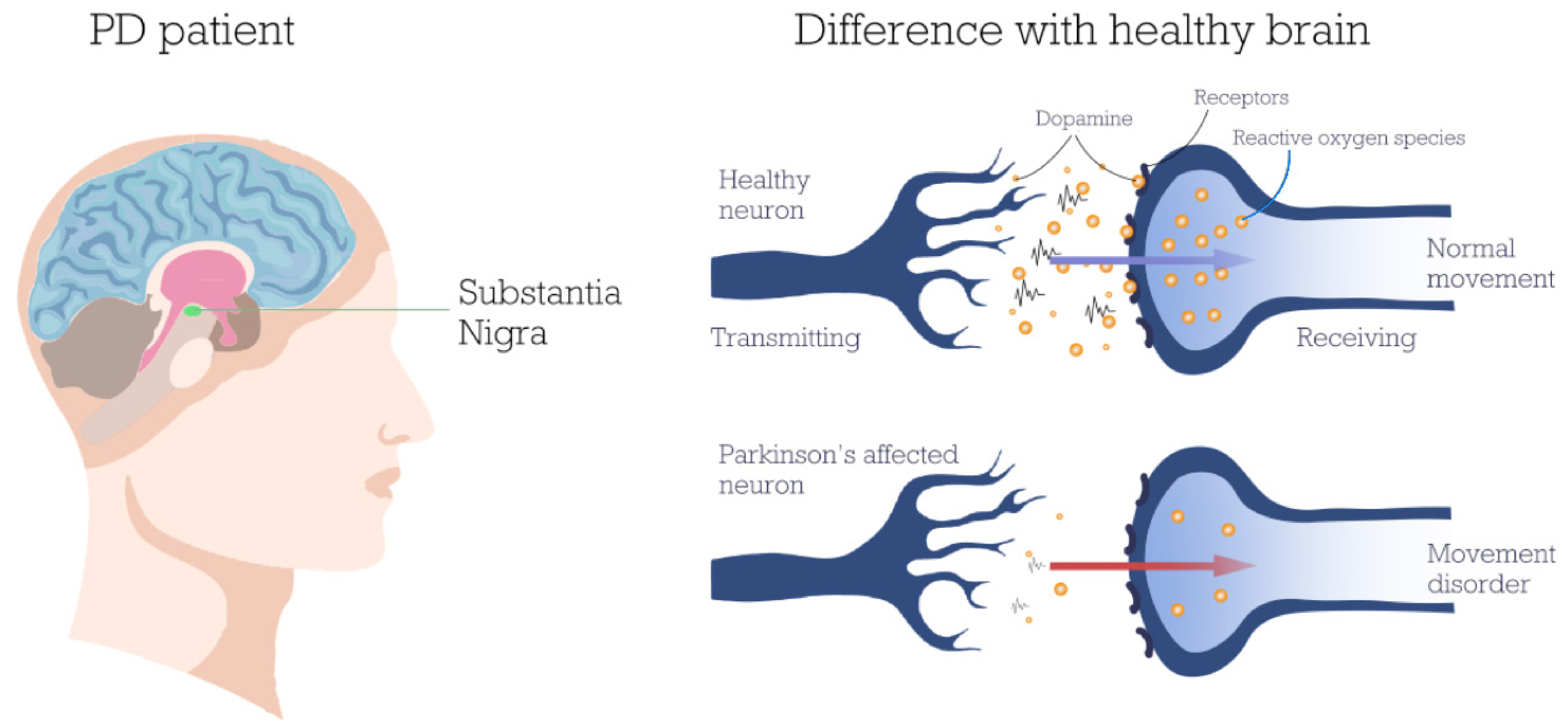


Figure 1.5.1: Visual representation of the main problem in PD.

1.6 PD symptoms

Motor Symptoms (MSs)
MSs in PD represent a group of physical challenges primarily associated with the impairment of motor functions. These symptoms arise due to the progressive degeneration of nerve cells in the brain that are responsible for the production of dopamine. Dopamine is a vital neurotransmitter which controles body movement, coordination, and the smooth execution of voluntary muscle activity.

In PD, the gradual loss of dopaminergic neurons in the mammalian central nervous system disrupts the delicate balance of neurotransmitters in the brain, leading to the characteristic MSs of the condition. The onset and progression of these symptoms can vary greatly among individuals but typically evolve over time, often starting subtly and becoming more pronounced. Worthy of note, most MS in PD are responsive to dopaminergic therapy.

In the following section, MS for PD are listed with the percentage of clients suffering from them. Interesting facts are also listed:

- Bradykinesia: 98% (Parkinson's Europe, 2023) slowness of movement and speed (or progressive hesitations/halts) as movements are continued.
- Muscle rigidity: 90-99% (Parkinson's Europe, 2023b)
- Rest tremor: 70-90% (Parkinson's Foundation, 2023a). Usually this is the first symptom showing the onset of PD.
- Loss of postural reflexes: 16% (Gu et al., 2014) Usually at a late stage of PD.
- Bulbar dysfunction (dysarthria): 80% (Patel et al., 2020)
- Neuro-ophthalmological abnormalities
- respiratory disturbances
- Stooped posture is observed in >30 % of individuals with PD (Kim et. al, 2021)

FoG
According to a meta analysis by Zhang et al. (2021) on 66 studies, the prevalence of FoG in PD subjects when adjusted for weight, was found to be 37.9% in the early stages (up to five years) and 64.6% in the advanced stages (nine years or more) .

Festination
In Nonnekes et al. (2018) their study involving 81 PD clients with an average disease duration of 8.5 years, 32% reported experiencing festination in the preceding month. Among these, over half found festination to significantly hinder their daily functioning. Furthermore, 35% of the clients experiencing festination also reported frequent falls attributed to this symptom.

Please note that prevalence rates can vary across different studies and populations.

MS targetability
The research to combat PD, and the devised wearables to curtail motor features PD offers is quite substantial. This obviously stems from the ample amount of presently available smart wearables conferred in the Existing wearables section.

Non Motor Symptoms (NMSs)
Although designing for pharmaceutics is outside the scope of this project, I want to know what PD does to the brain and to the body. Therefore, I will touch on it briefly, to get the gist of why LevoDopa is prescribed to PD clients. And why it is not a solution for NMSs.

NMS PD-like features were first identified in reserpine-treated rabbits, leading to the recognition of dopamine's central role in the disease. The use of LevoDopa, a dopamine precursor, was explored for PD treatment but had side effects like nausea and vomiting (Goldenberg, 2008). Combining LevoDopa with carbidopa resolved these issues, allowing LevoDopa to enter the brain effectively (Jankovic & Aguilar, 2008).

Long-term LevoDopa treatment leeds to motor fluctuations and involuntary movements (dyskinesias) due to intermittent dopamine presence. Monoamine oxidase (MAO) and catechol-O-methyl-transferase (COMT) inhibitors were introduced to improve LevoDopa's brain availability and reduce dyskinesias (Fox & Lang, 2008). This combination, along with carbidopa and LevoDopa, became a superior PD therapy (Schapira & Olanow, 2005).

As experts became more knowledgeable in PD-like MSs, NMSs of PD also gained recognition, challenging the traditional view of dopaminergic neuronal loss as the sole cause. It was discovered that Lewy body neurodegeneration affects various nervous systems. NMSs present challenges in disease identification and treatment due to their poor clinical diagnosis (Orimo et al., 2011).

Recognising the involvement of the olfactory bulb and lower brain stem in PD pathology, it became clear that NMSs might precede MS. This understanding has implications for disease models that solely target the SN, as it does not replicate the full spectrum of PD symptoms (Braak et al., 2003).

In the following section, NMS of PD are listed together with the percentage of clients suffering from them (if retrievable). Generally speaking, NMSs can be grouped in dysfunction categories because they are more distinct than MSs, Interesting facts and definitions are also listed (Váradi, 2020):

Psychotic Symptoms:
Impulse Control Disorders: prevalence varies widely, around 14% to 40% in PD clients on dopamine replacement therapy (Aarsland & Kramberger, 2015).

Hallucinations: prevalence approximately 22-38% in PD clients (O'Sullivan et al., 2008).

Sleep Disturbances:
- Restless Leg Syndrome: prevalence is round 15% in PD clients (Sarkar et al., 2016).
- Rapid Eye Movement Sleep Behaviour Disorder (RBD): prevalence is estimated to be about 33-46% in PD clients (Schapira et al., 2017).
- Sleep Apnea: prevalence is around 20-60% in different studies (Xu et al., 2019).
- Insomnia: prevalence as high as 37% in PD clients (Duncan et al., 2013).

Autonomic Dysfunction:
- Gastrointestinal Dysfunction: prevalence: Constipation affects about 50-80% of PD clients (Khedr et al., 2013).
- Orthostatic Hypotension: prevalence is around 30-58% in PD clients (Rodríguez-Violante et al., 2010).
- Sexual Dysfunction: prevalence varies but can affect more than 50% of PD clients.

Sensory Disorders:
- Pain: is experienced by 40-85% of PD clients (Tagliati et al., 2014).
- Paresthesia: Specific prevalence in PD not well established (Strecker & Schwarz, 2008).
- Anosmia: prevalenceis around 70-90% in early PD stages (Hillen & Sage, 1996).
- Ageusia: specific data for PD not widely available.

Mood Disturbances:
- Depression: prevalence is around 35-50% in PD clients (Martínez-Martín et al., 2012)
- Anxiety: prevalence of approximately 25-40% in PD clients (Aarsland & Kramberger, 2015).
- Apathy: can affect up to 40% of PD clients (O'Sullivan et al., 2008).

Cognitive Impairment:
- Impaired Judgment: Increasing with disease progression; specific numbers vary (Scarmeas et al., 2004).
- Identity Confusion: prevalence not well established (Sarkar et al., 2016).

Please note that prevalence rates can vary across different studies and populations.

NMS targetability
NMS are harder to treat than MS, less academical research has been done in this field, and they are ofttimes only medically manageable by means of invasive technologies (e.g. a DBS) and prescribing non-dopaminergic medications (Chaudhuri et al., 2016) & (Seppi et al., 2011).

Prodromal symptoms
The proposed timeline for PD symptoms indicates that primary MSs may only appear years after the disease has commenced (Hawkes et al., 2010). PD is viewed as a multi-system disorder affecting both the peripheral and central nervous systems, with MSs emerging relatively late compared to when neurodegeneration starts. The progression of PD can be divided into preclinical, prodromal, and clinical stages (Poewe et al., 2017).

In the preclinical stage, neurodegeneration begins in the SN, but there are no clinical signs. This is followed by a prodromal stage lasting over 10 years, during which continuous neuronal loss occurs, and some NMSs appear. After this stage, when 40% to 60% of dopaminergic cells are lost, the first MSs like bradykinesia, rigidity, and tremors become evident, marking the early stage of PD (Mahlknecht et al., 2015). The absence of early markers leads to ongoing neurodegeneration for a decade until MSs finally appear, making PD clinically apparent.

The early occurrence of certain NMSs in prodromal PD, such as RBD, constipation, loss of smell, and depression, has drawn attention in the diagnostic process. Recognising prodromal PD through the detection of these early NMSs might pave the way for design opportunities for products that mitigate the development of more severe MSs and NMSs.

Below several prodromal symptoms are listed (Roos et al., 2022):

- Constipation: prevalence of 60% (Yu et al., 2018). This symptom can reportedly prelude the clinical PD stage by 20 years (Adams-Carr et al., 2015). It is a good marker for PD due to its single question screening nature.

- Hyposmia: prevalence of >80% (Ross et al., 2008). It is likely the PD marker that precedes the first stage MS (Goldman & Postuma, 2014). Screening can be done with a simple kit but other neurodegenerative diseases have this symptom as well, so expert help is required.

- RBD: although this symptom has the highest specificity in predicting PD at an early moment, the necessity of using polysomnography hinders it in being used as an easy prognostic marker.

- Depression: prevalence between 40-50% (Reijnders et al., 2007). Persistent tiredness and lack of interest have also been recognised as early signs that may contribute to the development of depression. Depression in PD clients allegedly progresses in anxiety and panic attacks. Expert attention are a must for diagnosing depression.

- Cognitive impairment: prevalence around 20% at time of clinical diagnosis (Liepelt-Scarfone et al., 2022). This suggests that few clients are affected cognitively in the prodromal phase of PD. About 80% of clients develop PD related dementia over the course of the disease.

Please note that prevalence rates can vary across different studies and populations.

Prodromal symptom targetability
In terms of potential monetary gain for Dopple, addressing PD symptoms in their prodromal phase would take the cake. Especially granted the negated expenditures governments for PD. However, the initial expenses and operation intensity to develop wearables on such a large scale as to cover all potential PD clients are substantial. Based on the recommendation of physicians, who in their turn should require extra planological attention, and potentially the involvement of other stakeholders as well, are not to be underestimated.

Furthermore, with regard to people their well-being, it makes sense to design for prodromal symptoms. Tackling PD at its first commencement, i.e. observing a client before the onset of early cardinal symptoms can logically speaking ensure a higher quality of life throughout PD, more dedicated care, and ultimately delay clinical uptake.

Target symptom choice
Between the three mentioned categories of PD symptoms I render tackling a or multiple MS(s) to be the best choice.

1.7 Current PD therapies

Deep brain stimulation (DBS)
DBS is a surgical procedure used to treat certain MSs of PD, and other movement disorders. It involves the implantation of a device called a neurostimulator or neurostimulation electrode into specific areas of the brain. This device delivers electrical impulses to these targeted brain regions, modulating their activity and helping to alleviate the MSs, such as tremors, rigidity, and bradykinesia. The DBS procedure typically involves the following steps:

1. Preoperative Evaluation: Clients undergo a thorough evaluation, including neurological assessments and brain imaging, to determine if they are suitable candidates for DBS.
2. Implantation: During surgery, the neurostimulator is implanted into the brain, and the electrode is placed in a specific brain region. The exact location depends on the client's symptoms and individual needs.
3. Programming: After the surgery, the neurostimulator is programmed to deliver electrical impulses at the right frequency and intensity to control the client's symptoms effectively. The programming can be adjusted over time to optimize symptom management.
4. Follow-up: Clients require ongoing follow-up care with their healthcare team to monitor the effectiveness of the DBS system, make necessary adjustments, and ensure its long-term function.

DBS is not a cure for PD, but it can reduce the severity of MSs and improve the client's quality of life. It is often used when medications fail to provide adequate symptom control or when effects turn problematic. The neurostimulator can be adjusted, turned off, or removed. Overall, DBS is an important treatment option for individuals with PD who are seeking better symptom management and improved daily functioning. Information from the book: "Deep Brain Stimulation for Parkinson Disease" (Baltuch & Stern, 2007).

Traditional pharmacological intervention
Traditionally, PD is managed by subscription of pharmacological interventions, particularly dopaminergic therapies. However, the long-term use of dopaminergic drugs often leads to complications such as dyskinesia and motor fluctuations. This underlines the need for development of smart wearable solution offering alternatives, potentially delaying or even negating the need for early initiation of these medications.

Limitations current therapies
Levodopa is the most commonly used dopaminergic therapy. Its journey as a treatment for PD typically begins with a 'honeymoon phase.' This initial period, usually spanning several years from the start of the treatment, is noted for its effectiveness in providing consistent relief from PD symptoms without major side effects. During this phase, clients often notice a significant uplift in their quality of life, witnessing a considerable decrease in the symptoms associated with PD. Unfortunately, this beneficial phase is not permanent. As PD progresses, the impact of Levodopa diminishes. The end of the honeymoon phase is marked by the development of motor fluctuations and dyskinesias in clients, leading to a shift in the treatment approach, often incorporating additional medications or therapies to address the evolving symptoms and complications.

Dopaminergic therapies, including Levodopa, are not without long-term complications. Prolonged use of Levodopa, widely regarded as the most effective treatment for PD, can lead to Levodopa-induced dyskinesia (LID). LID is characterised by involuntary movements and can be severely debilitating (Jenner, 2008). Moreover, despite their usefulness in managing PD, dopaminergic agonists are typically used in conjunction with Levodopa. This indicates a reliance on Levodopa in the treatment regimen for PD (Goetz & Diederich, 1992).

Emerging non-pharmacological approaches
Advancements in non-dopaminergic treatments highlight the importance of alternative therapeutic strategies. Current research emphasizes the need to target multiple neurotransmitter systems, including serotonergic, noradrenergic, and glutamatergic systems, in addition to the dopaminergic system (Brichta et al., 2013). Besides, innovative approaches like gene therapy are being unravelled, focusing on targeting dopaminergic neurons in the SN directly (Senior, 2012).

The smart wearable I will design in this graduation effort should convey this philosophy.

1.8 Following the money in PD

To shed some light upon the amount of profit to be made for Dopple, I will briefly touch upon this subject.

Dutch PD healthcare expenses
The expenditures on care for PD in the Netherlands, and other forms of parkinsonism were estimated at €136,8 million in 2019. This corresponds to 0,14% of the total healthcare expenses in the Netherlands and 2,7% of the total healthcare expenses allocated for diseases of the nervous system and senses in that year. A significant portion (46%, €63,4 million) of the healthcare expenses for PD and parkinsonism in 2019 was allocated to pharmaceuticals and medical aids (including smart wearables for PD). Additionally, 23% was allocated to hospital care (€31,9 million), and 21% to primary care (€28,7 million) (RIVM, 2019).

I estimate that the potential volume of the market for smart PD wearables is (proportionally) larger than a fraction of the mentioned 46%, if the wearable is able to take away physician en expert workloads (Ponsioen, 2023).

The cost of PD in an ageing population
Most healthcare expenditures for PD and other forms of parkinsonism occur in advanced age groups because these conditions are primarily found among the elderly. Healthcare expenses for parkinsonism in individuals under the age of 55 are minimal. The highest healthcare expenditures are observed in the age group of 65 to 80 years. Healthcare costs are higher for males (56%) compared to females (44%). The estimated healthcare expenses for PD and other forms of parkinsonism amounted to €136.8 million in 2019 (RIVM, 2019).

In financial retrospect to the US
To put the numbers of the RIVM in perspective: the Dutch healthcare expenditures to a country with a large healthcare market, namely, the US (a market in which most smart PD wearables see first daylight), their government spends €24,1 billion on PD in 2017 (Yang et al., 2020). This corresponds to 0,73% of the US' healthcare expenditure in 2017 (€3,32 trillion) (CMS, 2017). This makes the US healthcare market suitable for penetration or terrain of expansion of my to be envisioned product.

Target audience size in the Netherlands
As 5% of people get PD, and 60-80% get FoG, with 17.530.000 people living in The Netherlands, about 600.000 people might benefit from this product. Of note here: other symptoms which the product will tackle are not taken up so the true amount is higher.

1.9 Scope selection

The Harris profiles shown on this page are the final result of the preliminary design scope research. All these scope requirements are weighted top-down from most to least important (obviously, all are relevant). The towers built from either black or white segments with the most weight at the top on the right of their red line will hit the ground first. This makes choosing a scope somewhat less subjective. However, aside for the fact that the Harris profile method opts scope 1 to be the most favourable.
I also felt during the preliminary scope research that devoting my thesis to a non pharmaceutical solution for freezing episodes and festination spoke to me the most, and that it was the scope where the most interesting and abundance of academic literature was present. The research question:

"Can we design a smart wearable audio device to mitigate FoG, and other MSs for PD?"

Which truely SPARKS (Tassoul, 2009) for me!

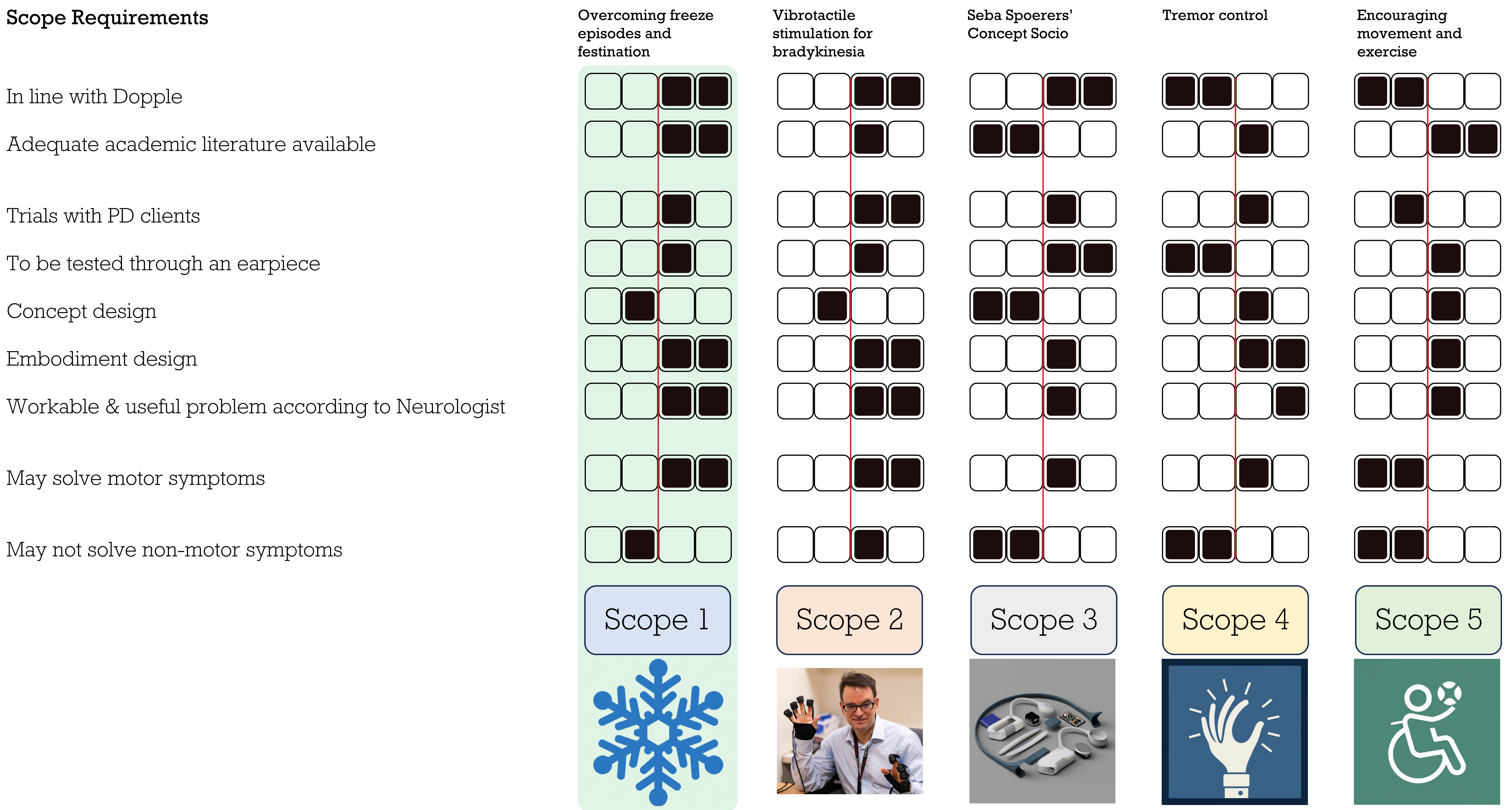


Figure 1.9.1: Harris Profiles motivating scope choice.

2 Thesis goals: A smart wearable for...

Development of a smart wearable device
The cornerstone of this thesis is the development of a state-of-the-art smart wearable device, specifically a set of IEMs, designed to mitigate the effects of festination and FoG. This device is not merely a conceptual exploration but a tangible solution, marrying advanced technology with practical usability. It leverages an inertial measurement unit (IMU) to detect festination and FoG native changes in the user's movement patterns, signalling the onset of a FoG episode. The IEM's design considers the unique ergonomic and auditory needs of PD clients, ensuring comfort and usability.

Integration with smartphone technology
Recognising the ubiquity and computing power of smartphones, as well as their convenient location (more on that later), this project harnesses their capabilities to enhance the functionality of IEMs. By offloading complex processing tasks, such as the analysis of IMU data through a convolutional neural network (CNN), to the user's smartphone, the IEM conserves power while maintaining efficiency. This integration facilitates additional features like remote monitoring, offering caregivers and medical professionals real-time insights into the client's condition.

Managing power consumption
To achieve the designed features of the IEMs, the power they consume must be planned thoroughly to accommodate for daily use. This is effectuated with calculations based on PD clients their gait characteristics, besides a careful investigation and estimation of sensor, CPU, and actuator consumption. As a guide, a user journey was taken up in the use-phase of the product journey.

Feedback mechanisms for FoG mitigation
A key focus of this thesis is the investigation of various feedback mechanisms to interrupt and mitigate FoG episodes effectively. The device utilises auditory cues, to provide sensory stimulation that can help 'unfreeze' the user's gait. The feedback is designed to be intuitive and non-intrusive. Furthermore, if the gait cadence of the user turns erratic, rhythmic auditory feedback (RAS) can be provided by the IEMs, re-aligning the user with their natural walking rhythm.

Empirical testing and analysis
To validate the efficacy of the user feedback and cueing, empirical tests involving real-life scenarios and obstacle courses are planned. These tests aim to quantify the device's impact on FoG episodes, and erratic gait cadence, measuring parameters like the duration and frequency of freezes, and the response time to feedback cues. This empirical approach ensures that the thesis findings are grounded in practical, real-world applicability.

Secondary motor symptoms (MSs) treatment
Having IMUs, and cellular connection present in the concept opens up a world of possibilities. It would be a waste if they were not utilised for the treatment of other symptoms, this will be elaborated upon in the Product functions chapter.

Additional product features
Since the mean age of PD clients is 70 (Macleod et al., 2018) and about two-thirds of people (living in the US) of that age require hearing aids (Lin et al., 2011), it is paramount that the IEMs must be equipped with that function. This is further underlined with the conclusion, from the PD client interview, that they benefit from having as little extra (smart) wearables as possible. Thus, the IEMs should also be able to be used for hearing-aid, listening to music, and hands-free phone calls.

Target audience
A detailed excerpt is proposed in the Target audience section.

2.1 FoG prediction models

From literature research I concluded that there are several positions on the body where IMU(s) can deliver adequate inertial data to train FoG prediction neural networks. The results of the literature research for IMU locations is made visible in Appendix D.

Improving existing models
Before I read Bächlin et al. (2010), Luigi Borzi, PhD and assistant professor of the Politecnico di Torino, presented me the work and FoG prediction model of O'Day et al. (2022). Since the engineers at Dopple believed the specificity and sensitivity scores of the IMU located at the head to be too low, I thought that training the previously existing model Luigi urged me to try or his model he later sent me, with more self-gathered inertial data from the ear would be a necessary step to fine-tune it for live usage with but 2 IMUs at ear location. Figure 2.1.1 shows a side-view of the worn proposed research prototype is shown.

After reading Bächlin et al. (2010) and adding two IMU's, I can assure that four IMU's (in a left and right IEM, in the smartphone carried in a hip pocket at one leg, and in the cradle carried in the) will achieve sufficient sensitivity and specificity data.

Furthermore, Dopple's engineers informed me about a previous study Dopple supervised. Two medical physics students from the Carl von Ossietzky University of Oldenburg in Germany showed that with very little data they were able to detect 12 different activities (walking, typing, talking, prone position, supine position, reading out, reading, resting position, jumping, jogging, cycling, and chewing), only provisioned with three channel in-IEM IMU data gathered, from two IEMs (Goehring, 2021). Dopple's engineers also send me a paper where researchers from the Vrije Universiteit Amsterdam showed that ear-worn IMUs can provide sufficiently accurate gait data, to test the efficacy of verbal instructions given to runners to alter their stance or time of flight, without changing their running cadence.

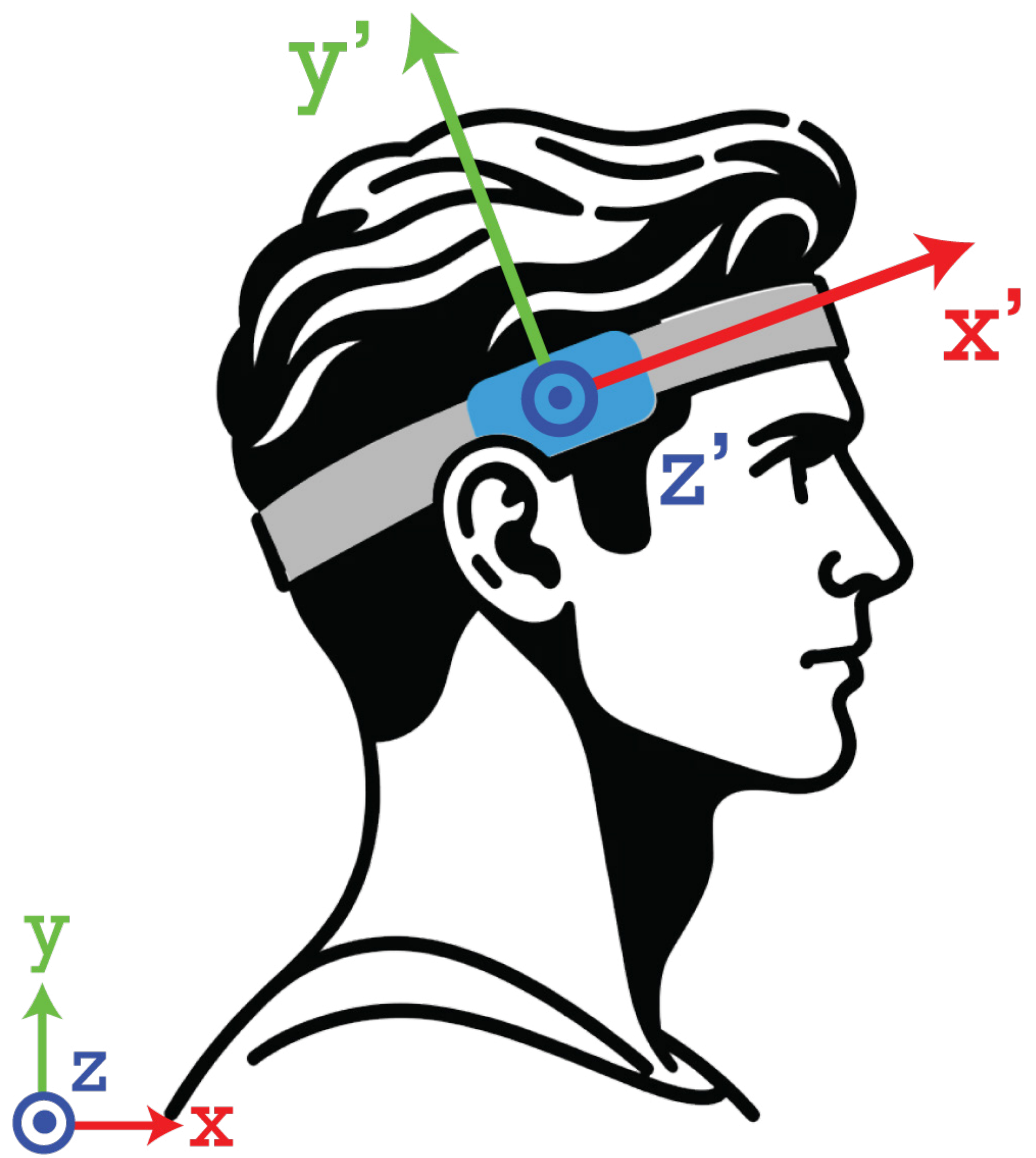


Figure 2.1.1: Harris Profiles motivating scope choice.

2.2 Obtaining inertial data

Devising a research prototype
Thus, I made the decision to spend time on the development of an inertial data collection prototype. Prior to reading the paper from Bächelin et al. (2010), I devoted considerable time to creating a protoype able to collect 9-axis inertial data with an IMU, to be precise:

- Linear acceleration vectors (in x, y, and z)
- Gyroscopic (rotational acceleration) vectors (around x, y, and z)
- Magnetic field vectors (in x, y, and z)

With additional leterature research, I deemed the collection of additional FoG episode data unnecessary. Thus, the rendered protype on this page was never built. Appendix E contains the scripted logic used for the software development to collect IMU data. Appendix I contains the links to the Github repositories containing code and data regarding FoG prediction models from Bächlin et al. (2010) and Borzì et al. (2023).

My plan was to make two times the same research prototype from:

1. Arduino NANO 33 IoT
2. Adafruit BNO055 IMU
3. DF Robot SD reader
4. SD card
5. Adafruit USB-C charger
6. Adafruit 1000mAh 3,7V LiPo battery
7. Grove Button(P) v1.2a
8. Grove Variable Colour LED v2.0
9. Grove Vibration motor v1.3
10. Conector cables
11. Flexible TPU casing
12. USB-C charging cable
13. Acrylic elastomer band

Figure 2.2.1: A render of the proposed inertialdata gathering research prototype.

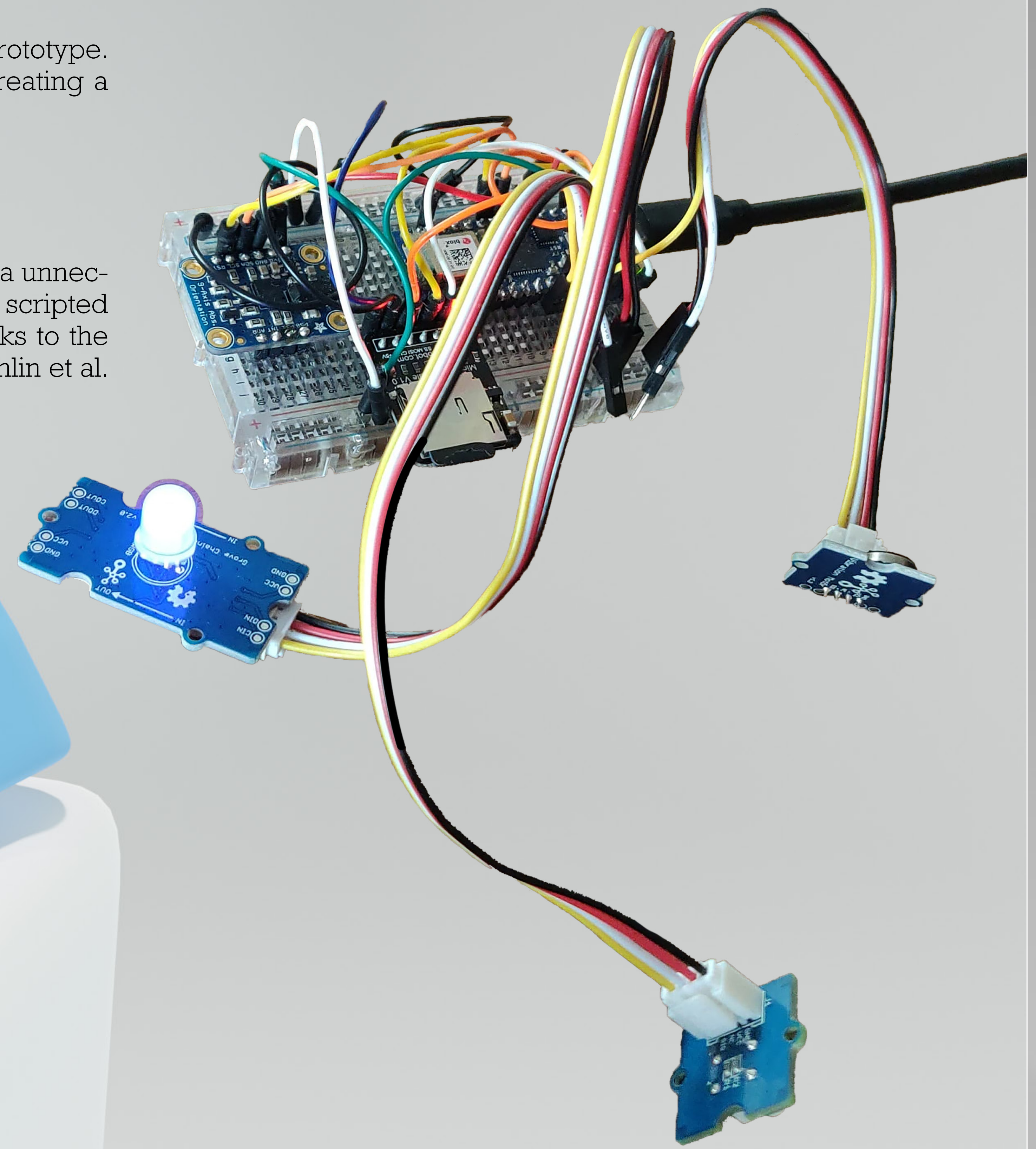


Figure 2.2.2: The prototype's electronics.

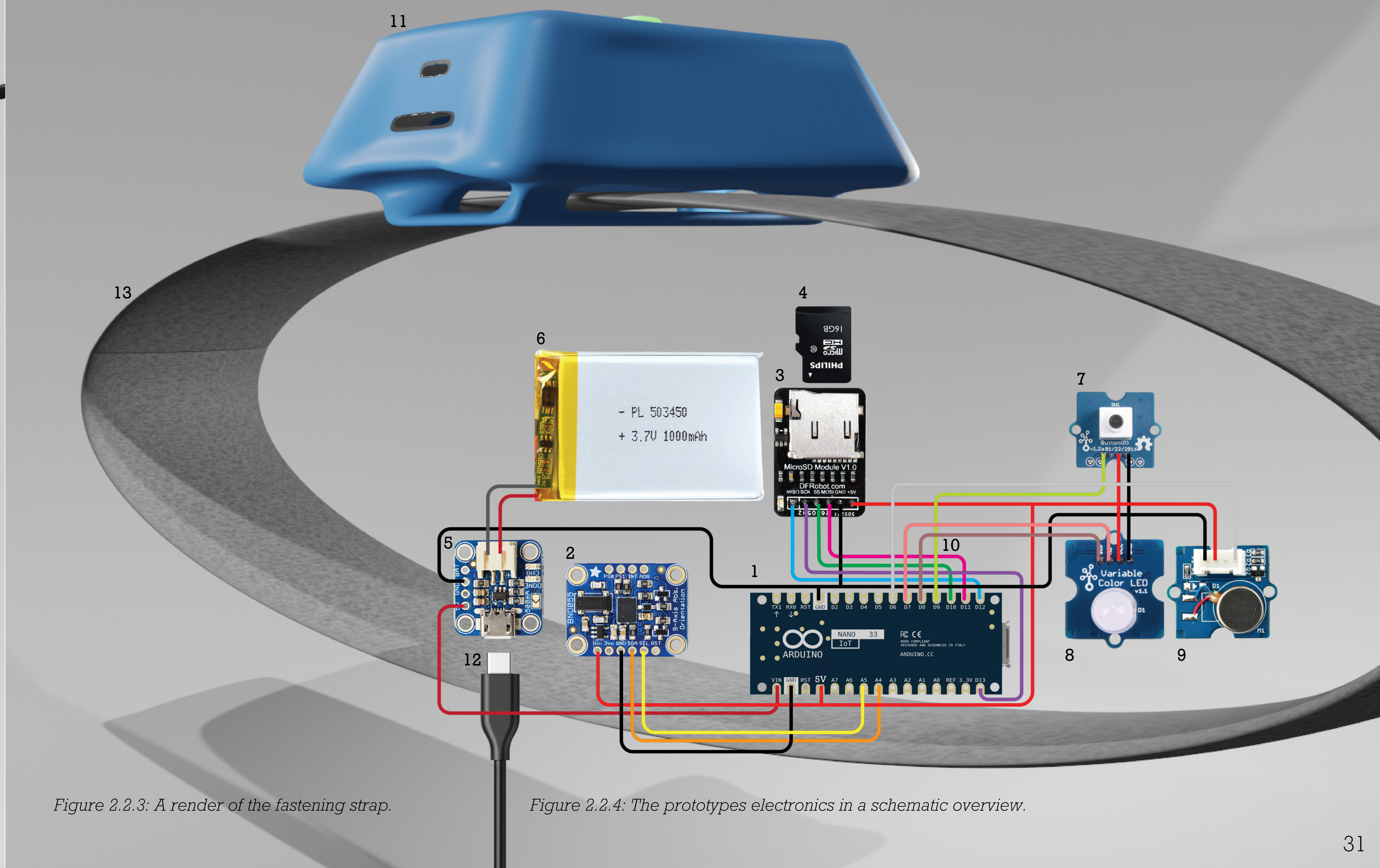


Figure 2.2.3: A render of the fastening strap.

Figure 2.2.4: The prototypes electronics in a schematic overview.

2.3 List of requirements: General

Technical Requirements

1. Accurate real-time detection of freeze of gait episodes.
2. A reliable algorithm for festination and FoG episode prediction.
3. Integration of high-quality IMUs. One in each earpiece, the native IMU in the user's smartphone, and one IMU in the cradle.
4. Long battery life, at least 16 hours, of which 14 hours stand-by or sleep time on a single charge. Reasoning for this choice in the Battery size calculation section and Device modes section.
5. Fast and convenient charging mechanism.
6. Water and dust resistance IP67.
7. Robust construction to withstand daily use.
8. Bluetooth for connection to a smartphone.
9. Compliance with medical device regulations.
10. Rigorous testing for reliability and effectiveness.
11. Adaptability for future technological enhancements.
12. On-device data processing capabilities.
13. Firmware updatable through a secure connection.
14. Low energy consumption design.
15. High-quality sound components for clear audio feedback.
16. The user must carry their smartphone in a pocket attached to the pants on the hip location.
17. The user must carry their Dopple Earbuds' cradle in their pants' pocket attached to the other leg (the opposite leg than where the smartphone is kept).
18. Automatic audio transmission quality check to assure longer product functionality.

Ergonomic Requirements

19. Comfortable for prolonged use, regardless of ear size and shape.
20. Wearable for at least 10 years (as human ears never cease to grow).
21. Non-irritating materials against the skin.
22. Lightweight design to reduce ear fatigue.
23. Easy to put on and remove, even with severe manifestation of tremor.
24. Suitable for users with varying levels of dexterity.
25. Non-intrusive, does not interfere with glasses.
26. The product must be able to completely replace hearing aids.
27. Easy cleaning and low maintenance.
28. PD clients without severe cognitive disability must be able to recalibrate the product.

Aesthetic Requirements

29. Discreet and unobtrusive design.
30. It must not look like a medical aid device.
31. Aesthetically pleasing, modern appearance.
32. Customisable appearance (colour, skins, etc.).
33. Compact size to minimise visibility, yet not be too small to use.
34. Attractive and informative product packaging.

User Experience Requirements

35. Immediate and intuitive feedback for FoG episode mitigation.
36. User-friendly interface, easy for elderly users.
37. Customisable audio feedback volume and type, with smartphone but also directly to product with the user's voice.
38. Emergency alert feature for caregivers.
39. Comprehensive yet not overcomplicated user manual, both physical and digital on the Dopple Earbuds PD client smartphone app.
40. Accessible customer support, including online FAQs and phone assistance.
41. Intuitive pairing and setup process.
42. Auditory battery life indication and connection status.
43. Multilingual support for global accessibility.
44. Tactile feedback for users with hearing impairments.
45. Voice control options for hands-free operation.
46. Seamless integration with smartphones and tablets.

Data Security and Privacy Requirements

47. Strong encryption for data transmission and storage.
48. Compliance with data protection laws (e.g., GDPR).
49. User consent options for data sharing.
50. Secure yet comprehensible multi-way user authentication methods.

Environmental and Sustainability Requirements

51. Device must use repairable and recyclable
52. Use of mechanical connections and fastening only (e.g. geometry, bolts, and nuts).
53. Use of sustainable materials in construction.
54. Energy-efficient operation to minimise carbon footprint.
55. Options for safe disposal or recycling.
56. Reduction of harmful substances in production.
57. Environmentally friendly packaging.
58. No child labour in any of the design, conceptualisation software, hardware, used materials, finishes, paints, parts, et cetera.
59. No exploitation or extortion of paid over age factory workers (globally).
60. A salary higher than the minimum wage yet enough to live a modest but fulfilling life as a factory worker.
61. Safe and non-toxic working/assembly conditions globally, by Dutch standards.
62. The manufacturing should comply with environmental regulations, minimising waste and harmful emissions.
63. The product assembly should be designed to minimise the need for manual labour, making use of automated assembly techniques where feasible.
64. Use of materials that are readily available and sustainably sourced to avoid a high impact of the supply chain.
65. The necessary components, materials, and other items for assembly, along with the shipping of the completed product, should utilise the transport mode with the lowest possible emissions.

Market and Compliance Requirements

66. Competitive pricing strategy.
67. Compliance with international standards (e.g., CE, FCC).
68. Market research to identify further customer needs and preferences.
69. Strategies for market penetration and growth.
70. Warranty and after-sales service provisions.
71. Production methods should ensure high durability and reliability of the finished product.
72. The design should take into account ease of disassembly for repair, recycling, or disposal at the product's EoL.

Production Requirements

73. Dopple must be able to produce the in-ear part themselves.
74. The design should facilitate ease of assembly to streamline the manufacturing process.
75. Components should be standardised where possible to reduce complexity and cost.
76. The product design must allow for efficient mass production without compromising quality.
77. The production process should be scalable, allowing for adjustments based on demand fluctuations.
78. Designs should enable easy integration of electronic components without risk of damage.
79. Quality control processes must be implemented to ensure that each unit meets the required standards before shipping.
80. Production planning should consider the potential need for future product variants or customisation options.
81. The production line should be flexible enough to incorporate updates or changes based on user feedback and technological advancements.

2.4 Implementing computer vision

Introduction
The integration of computer vision into the existing IEMs mark significant advancements, inter alia, in the management of FoG episodes. This addition aims to augment the robustness of the Dopple Drop's main function, which until now only relies on IMU data, by providing a more comprehensive analysis of the user's environment and movement patterns.

A logical addition
Computer vision technology offers a new dimension of environmental interaction, enabling the system to analyse visual cues that may precede a FoG episode. By processing real-time visual data, the system can detect potential obstacles or changes in terrain, factors that are often instrumental in triggering FoG. From my literature study I have concluded that practically all trials of gathering FoG episode data make use of a so-called obstacle course to trigger the FoG episodes. All of these are listed in the Festination and FoG: Preceding research section. This capability, combined with the existing IMU-based detection, paves the way for a smarter, more responsive solution.

The fusion of computer vision with traditional IMU based detection methods promises a more rigorous and robust system. By analysing visual environmental data, computer vision algorithms can identify imminent FoG episodes, offering real-time assistance and enhancing client safety. This integration aligns with the evolving landscape of smart healthcare devices, where precision and user-centric design are paramount.

Reasoning
The combination of visual and inertial data in FoG (Freeze of Gait) detection for PD clients promises synergy and a reduction in false positives and negatives due to several key reasons:

- Complementary data sources: Inertial data from the IMU provides detailed information about the wearer's movements, such as acceleration, orientation, and angular velocity. However, it lacks context about the environment. Computer vision fills this gap by providing visual context, identifying obstacles, terrain changes, and other environmental factors that could trigger a FoG episode.

- Enhanced accuracy: Each system has its strengths and limitations. IMUs are excellent for detecting motion patterns but can be prone to errors due to sensor drift or ambiguous movements that may resemble a FoG episode. Computer vision, on the other hand, can visually detect actual freeze episodes or environmental conditions leading to them, but may struggle with varying lighting conditions or occlusions. Together, they cover each other's weaknesses, leading to more accurate detection.

- Improved contextual awareness: Computer vision adds a layer of environmental awareness that inertial data alone cannot provide. For instance, it can detect a crowded room, uneven surfaces, or the edge of a sidewalk. Among others, these are all situations where FoG episodes are more likely to occur, as I was told by Nathalie . This contextual information, combined with the IMU data, results in a richer and more nuanced understanding of the user's situation.

- Reduction in false alarms: By cross-referencing IMU data with visual cues, the system can more effectively differentiate between actual FoG episodes and similar motion patterns (like slowing down or stopping intentionally). This reduces false positives, where the system incorrectly identifies a FoG episode, and false negatives, where it fails to detect an actual episode.

- Adaptive response mechanisms: The synergy between these two data types allows for the development of more sophisticated and adaptive response algorithms. The system can learn and adjust over time, understanding the specific patterns and environments unique to each user, leading to personalised and more effective intervention strategies.

- Real-time decision making:
The combination enables real-time processing and decision-making, essential in FoG management. Quick and accurate detection followed by immediate feedback (auditory or haptic) can significantly assist PD clients during critical moments.

Issues implementing CV
Operating a camera, its DSP, and transmitting yet another data stream to the smartphones CPU are power demanding activities. Future research must be done on how implementing cameras successfully in the Dopple Earbuds can be realised. Furthermore, Dopple stated that including CV into their products is maybe to big a step for them at the moment since this is not their main expertise. So for now the implementation of CV into the Dopple Earbuds can be seen as a recommendation.

Ground exclusion zone (= e)
From the side-view illustration in Figure 2.4.1, a ground exclusion zone can be identified. Its size can be calculated like d is. It is altered by how much the cameras look down. Further research is needed to find out what values for e are acceptable. Note that with the same FOV camera and a smaller e, objects in the environment above the conus become excluded from view. Such objects may also trigger festination and FoG.

Distance to near point (= d)
From Dined (2020) head mesurement data for Western European men and women above the age of 55. More specifically, a mean head depth (= 2*a) of 185[mm] ± st.d. 8[mm] and a mean head circumference of 560[mm] ± st.d. 19[mm]. Dined does not include an ear-to-ear measurement. However, we can calculate it. For this I assume that the circumference of the head at ear level is an ellipse. The circumference of an ellipse is (Raman, 2024):

$C \approx \pi(a + b)(1 + 3h/(10 + \sqrt{4 - 3h}))$
where $h = (a - b)^2/ (a + b)^2$

solving for b gives:

$b \approx -C/(\pi(1 + 3h/(10 + \sqrt{4 - 3h}))) + a \approx 40[mm]$

solving for d provides:

$d = b / \tan(15/2) \approx 303[mm]$

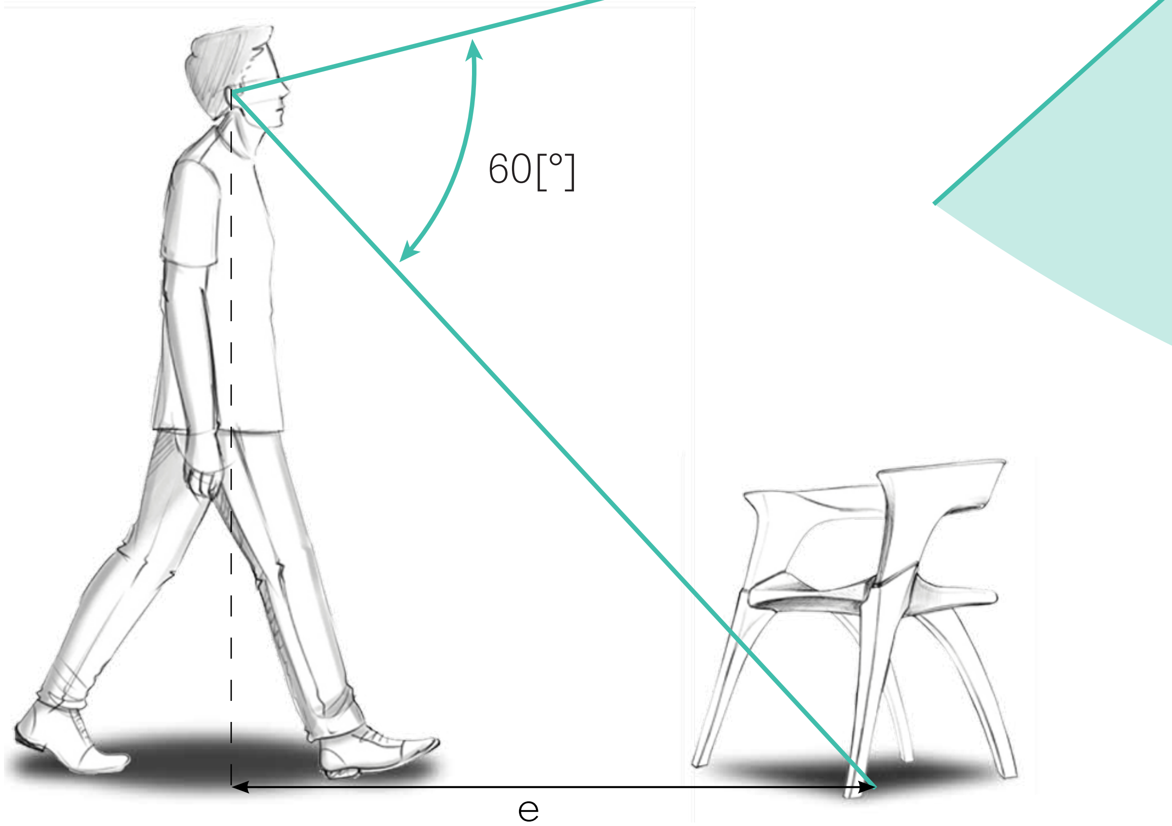


Figure 2.4.1: A side view of the stereo imaging FOV conus.

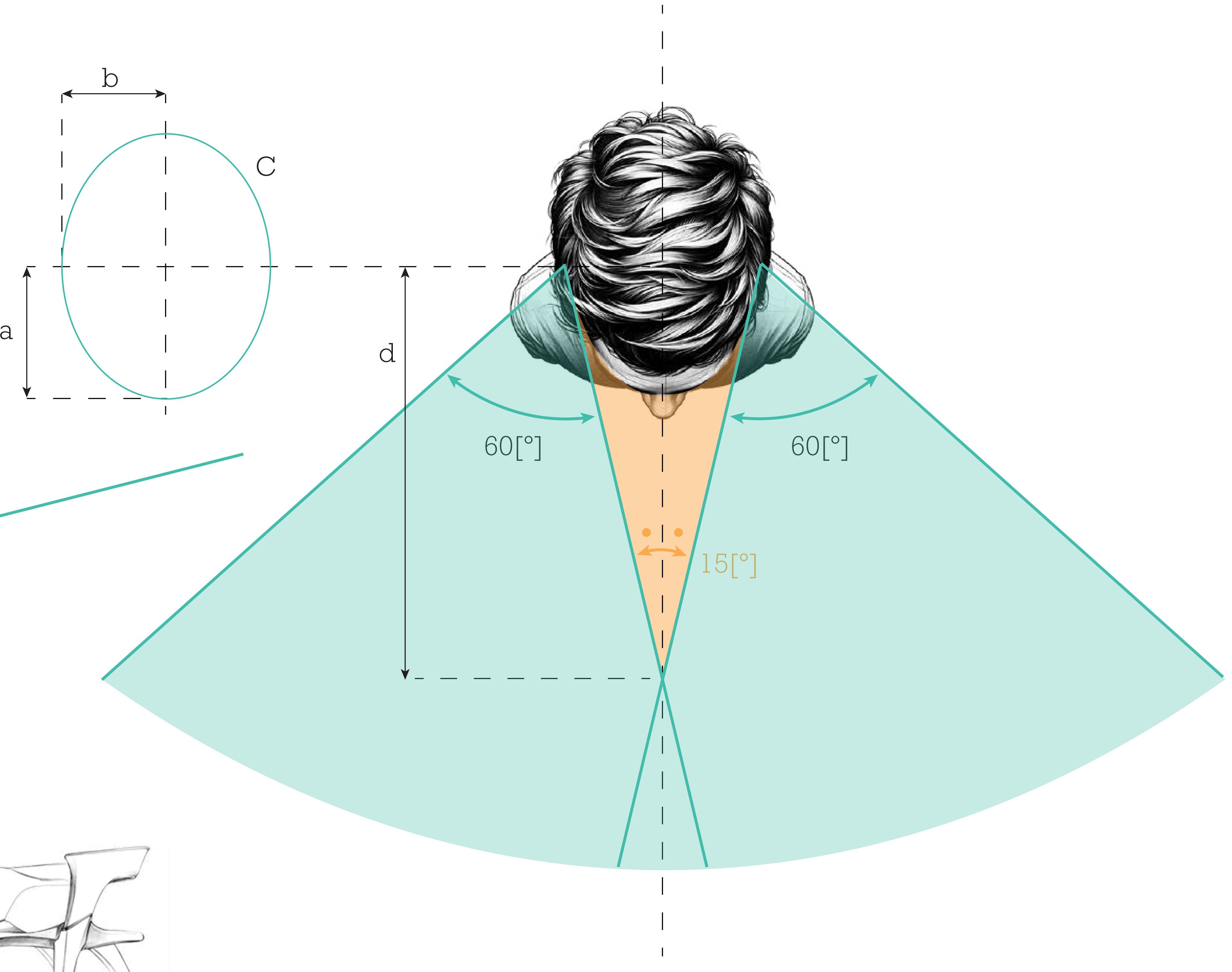


Figure 2.4.2: A top view of the stereo imaging FOV conus, highlighting the obstructed zone .

2.5 List of requirements: Computer vision

Technical Requirements

1. Integration of a miniaturised cameras capable of capturing high-resolution images in various lighting conditions.
2. These cameras should perform as a calibrated stereo system (i.e. the cameras should be aligned so that their front faces are co-planar. And their rotational axes (i.e. the normal vector through the middle of the lenses) should both be parallel to the saggital plane and orthogonal to the coronal plane.
3. Implementation of real-time computer vision algorithms for object detection and environmental analysis.
4. Sufficient processing power within the coupled smartphone to handle complex image processing tasks.
5. Sufficient battery power to send the necessary IMU data, as well as image data.
6. Robust data transmission systems to handle the bandwidth required for transmitting visual data.
7. Advanced software capable of analysing visual inputs in conjunction with IMU data for accurate FoG detection.
8. Ensuring low latency in data processing to provide real-time feedback to users.
9. Development of algorithms for distinguishing between different types of movements and environmental contexts.
10. Secure firmware update mechanism for updating computer vision algorithms.

Ergonomic Requirements

11. Design modifications to incorporate the camera without compromising the comfort of the earpiece.
12. Ensuring the added components do not significantly increase the weight of the device.
13. Maintaining the balance and fit of the earpiece even with the additional computer vision hardware.

Aesthetic Requirements

14. Integration of the camera in a way that maintains the discreet and sleek appearance of the device.
15. Designing the camera's placement to be unobtrusive and not detract from the overall aesthetic appeal.
16. Colour and material selection for the camera component to blend seamlessly with the rest of the device.

User Experience Requirements

17. User interface updates to accommodate settings and notifications related to computer vision features.
18. Ensuring the camera operation is intuitive and does not require technical expertise from the user.
19. Providing user control over the camera functionalities, considering privacy concerns.
20. Incorporating feedback mechanisms to inform users about the status of the camera and visual data processing.

Data Security and Privacy Requirements

21. Implementing stringent data protection for the visual data collected by the device.
22. Ensuring compliance with privacy laws and regulations regarding the use of cameras and visual data.
23. Providing clear user consent protocols for the collection and use of visual data.
24. Environmental and Sustainability Requirements
25. Assessing the environmental impact of the additional computer vision components and striving for minimal ecological footprint.
26. Selection of environmentally friendly materials for the camera and related components.
27. Planning for energy-efficient operation of the computer vision system to minimise battery usage.

Market and Compliance Requirements

28. Conducting market research to assess user acceptance and demand for the added computer vision functionality.
29. Adhering to additional regulatory standards related to the use of cameras in consumer health devices.
30. Preparing for potential challenges in market entry due to increased complexity and

Functionality of the product.

31. Privacy Requirements
32. Develop and implement a clear privacy policy specifically addressing the collection, use, storage, and sharing of visual data.
33. Ensure user consent is obtained in a transparent and understandable manner, especially for the use of camera data.
34. Implement user controls to enable easy opt-in and opt-out options for data collection and analysis features.
35. Regularly review and update privacy protocols to align with evolving data protection laws and standards.
36. Establish strict access controls and authentication measures to prevent unauthorised access to the visual data.
37. Ensure that data anonymisation and encryption techniques are used to protect user identity and privacy.
38. Design the system to collect only the minimum amount of data necessary for the functionality of the computer vision features.
39. Provide users with clear information on how their data is being used and for what purposes, promoting transparency.
40. Include options for users to access, review, and if necessary, delete their data from the system
41. Conduct periodic privacy impact assessments to identify and mitigate risks associated with data processing and storage.

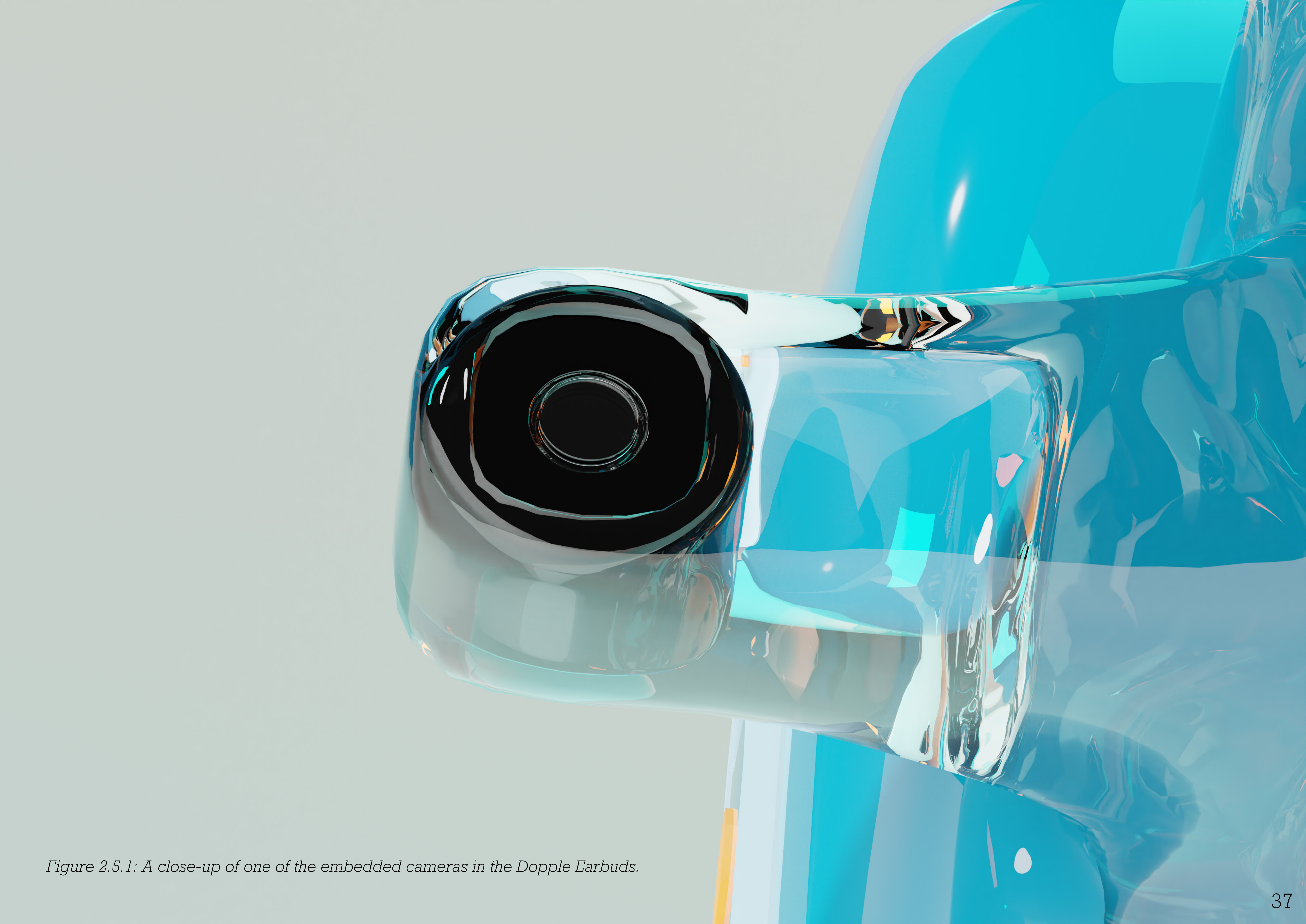


Figure 2.5.1: A close-up of one of the embedded cameras in the Dopple Earbuds.

2.6 Differentiation from Cue2Walk

The information on this page is publicly available on Cue2Walk their website (Cue2Walk, 2023). I deliberately choose to only highlight the difference between Cue2Walk, and the Dopple Earbuds because it is the only other non-pharmaceutical smart wearable product on the market that actively tries to predict FoG episodes, and cue walking and anti-freeze feedback to its user.

To understand how Cue2Walk differs from my concept product, it's important to compare their key features, target functionalities, and the technologies they employ. This section is based on what PvF physiotherapist Nathalie told me in person during my visits to the PvF, as well as what their website (Cue2Walk, 2023) tells us, supported with insights from recent academic references. Each bullet also entails my reasoning as to why the Dopple Earbuds is (not) a better product.

Location of wearable

- Feedback to the user is done via IEMs, so auditory cues are delivered directly to the ears. In this configuration the privacy of the wearer is ameliorated (e.g. FoG feedback is only heard by the user in public locations).
- Ear-worn devices such as the SpeechEasy or the SpeechVive devices, mentioned in the Existing wearables section, showed positive treatment effects without significant detrimental effect on hearing. This suggests that certain ear-worn devices can be effectively used by Parkinson's clients without major discomfort or adverse effects (Wang et al., 2017). Besides, my wearable Prototype (Sennheiser TVS 200 true wireless earpieces) proved to be a good substitution for a loudspeaker, and hearing aids. This was proven during the user feedback test.
- The Cue2Walk is a calve strap. PD is often accompanied by postural deformities, such as camptocormia (extreme truncal flexion) and Pisa syndrome (lateral trunk flexion), which can severely hinder a client's ability to bend over and perform tasks like fastening objects around their calves (Jankovic, 2010).

Type of cues provided

- My device solely delivers auditory feedback.
- Cue2Walk provides auditory, haptic, and visual feedback on the floor.
- The study by Donovan et al. (2011) observed a decrease in the number of falls among PD clients experiencing FoG when using visual cueing with laser lights projected onto the floor, as opposed to no aid. However, there is currently no conclusive academic evidence to suggest that transferring the laser light emitting device from a carried item (such as a walker (Rollz, 2023) or the laser walking stick) to an attachment on the human body is equally or more effective.
- First of all, it is common knowledge that PD clients react differently to cues. Thus, what cues are effective is something to be researched in the parameter calibration phase.

Integration with smartphone:

- The Dopple Earbuds are designed to work in tandem with a smartphone, offloading some processing tasks like neural network computations for FoG detection to the user's phone. This integration may also facilitate additional functionalities like remote monitoring or data analysis.
- Cue2Walk does have smartphone integration, but their fast Fourier transformations (FFTs) and other calculations making up the layers in the FoG episode detection algorithm take place in the device itself, rendering it more heavy, hence a larger battery is required. Furthermore, their smartphone integration is loaded with additional features beyond FoG assistance, making it more difficult to use for PD clients.

Sensors and data processing:

- The Dopple Earbuds product relies on IMU data from four IMUs and a neural network, resulting in accurate FoG prediction. Moreover, the IMUs situated IEMs provide more stable data than the Cue2Walk because their positioning cannot be altered, hence, the user-tailored custom in-ear shell always remains at the same rigid location.
- Cue2Walk use a similar IMU for detecting FoG episodes, but the processing is more localised within the device. They have patented their model two-fold under NL2031062A WO2023161359A1.

User interface and control:

- With the Dopple Earbuds, setting up the device and making adjustments to the setup is done only by voice, smartphone input is optional. I deliberately chose this because I uncovered during the client interviews that they cannot bide small physical input modalities like buttons or switches. These would be very small in either case.
- The user input on the Cue2Walk can be done on both a smartphone and other certain features on the Cue2Walk calve strap itself. This can become a nuisance for the user, hence the small input modalities.

Customisation and user experience:

- IEMs are small and can be easily concealed, offering a more discreet option for users. They are less likely to interfere with daily activities and are subject to fewer vibrations and random movement variations than devices attached to lower parts of the body due to inherent damping in the musculoskeletal system (Ferlini et al., 2021).
- Custom-moulded in-ear devices fit the specific anatomy of an individual's ear canal, providing improved comfort and stability (Navarro, 1980). This customisation ensures that the device fits securely and comfortably for continuous and long-term use.
- In-ear devices have been shown to capture high-quality brain activity and other physiological signals (Goverdovsky et al., 2016). The ear canal's proximity to the brain may offer advantages for certain types of biometric monitoring over devices placed on more peripheral parts of the body like the calves. During Advanced Concept Design, another Integrated Product Design Master's course, where Dopple was my client, they exclaimed their interest in expanding their IEMs into the medical field by leveraging sensing unique brain and body signals. IEMs for PD clients could in the future offer greater comfort and are far more convenient to wear compared to traditional scalp electroencephalogram (EEG) headsets or widely-used commercial blood lactate meters. Opening up the scope of the IEMs to be used for a range of NMSs in PD or even different neurodegenerative diseases.
- IEMs can serve multiple functions such as delivering audio, monitoring health, and providing communication capabilities, making them versatile tools for users (Kawsar et al., 2018).

Figure 2.6.1: Early iteration of Cue2Walk product, copyrights to this picture by (Cue2Walk, 2023).

2.7 Product development road map

Market analysis
Conduct an in-depth market analysis, understanding PD client needs, market trends, and competitor landscape.

Government and regulatory engagement
Engage with Dutch government entities and healthcare regulators for compliance guidance and potential support.

Partner collaboration
Establish collaborations with healthcare facilities, medical professionals, and insurance companies for trials and feedback.

Academic involvement
Recruit thesis and PhD candidates for innovative research and development contributions.

Prototype development
Develop minimum viable prototypes (MVP) reaching Technology Readiness Level (TRL) 5/6, focusing on core functionalities. E.g. device a miniaturised MVP for the stereo camera system, and deploy a live pipe-line version of the FoG episode detection algorithm to PD clients.

Expertise gap analysis
Conduct an analysis to identify necessary expertise for advancing the product to TRL 7.

Product testing
Implement comprehensive testing of the MVP, assessing technical performance, user experience, and safety.

Marketing strategy planning
Develop and execute a marketing strategy, including targeted advertising campaigns.

Outreach for client engagement
Initiate outreach to organisations and groups for reaching PD clients.

Production planning
Determine initial production quantity and staffing needs at Dopple for production scaling.

User experience mapping
Create detailed user scenarios to understand the end-to-end user experience.

Initial production and quality control
Finalize the initial production plan with a focus on manufacturing processes, supply chain, and quality assurance.

Real-world testing
Produce and distribute the TRL 8 product for real-world use and testing.

Data analysis and refinement
Collect and analyse data from TRL 8 testing, refining the product based on feedback.

Product finalisation
Prepare the product for full-scale launch as a TRL 9 product, incorporating final refinements.

Post-launch planning
Plan for post-launch activities including customer support, maintenance, and future enhancements.

Intellectual property management
Manage intellectual property issues, including patent filings and trademark registrations.

Manufacturing scale-up
Prepare for and execute a scale-up in manufacturing to meet anticipated market demand.

Distribution network establishment
Develop a distribution network, including logistics and channel partnerships.

Healthcare provider training
Develop training programs for healthcare providers on the use of the product.

Continuous improvement and feedback loop
Establish mechanisms for ongoing product improvement based on customer feedback.

Long-term sustainability plan
Develop a long-term sustainability plan addressing environmental impact and product life-cycle.

International market expansion
Plan for expansion into international markets, considering local regulations and market needs.

Community and client outreach
Engage in continuous community and client outreach for sustained awareness and product adoption.

Financial planning and funding
Develop a comprehensive financial plan including budgeting, funding, and revenue projections.

This roadmap outlines a detailed path from initial concept through to market launch and beyond, encompassing technical development, stakeholder engagement, market preparation, and long-term sustainability. Each step is designed to ensure thorough preparation and execution, ultimately leading to a successful product that meets the needs of PD clients and the market.

3 Product journey

In this chapter I will eloborate on the stages the Dopple Earbuds go through during its lifetime, starting from the pre-production choices, the user, the calibration phase, its assembly, product testing, getting acquainted to its destined user, the use-phase, repair and maintenance, and eventually its end-of-life (EoL) phase.

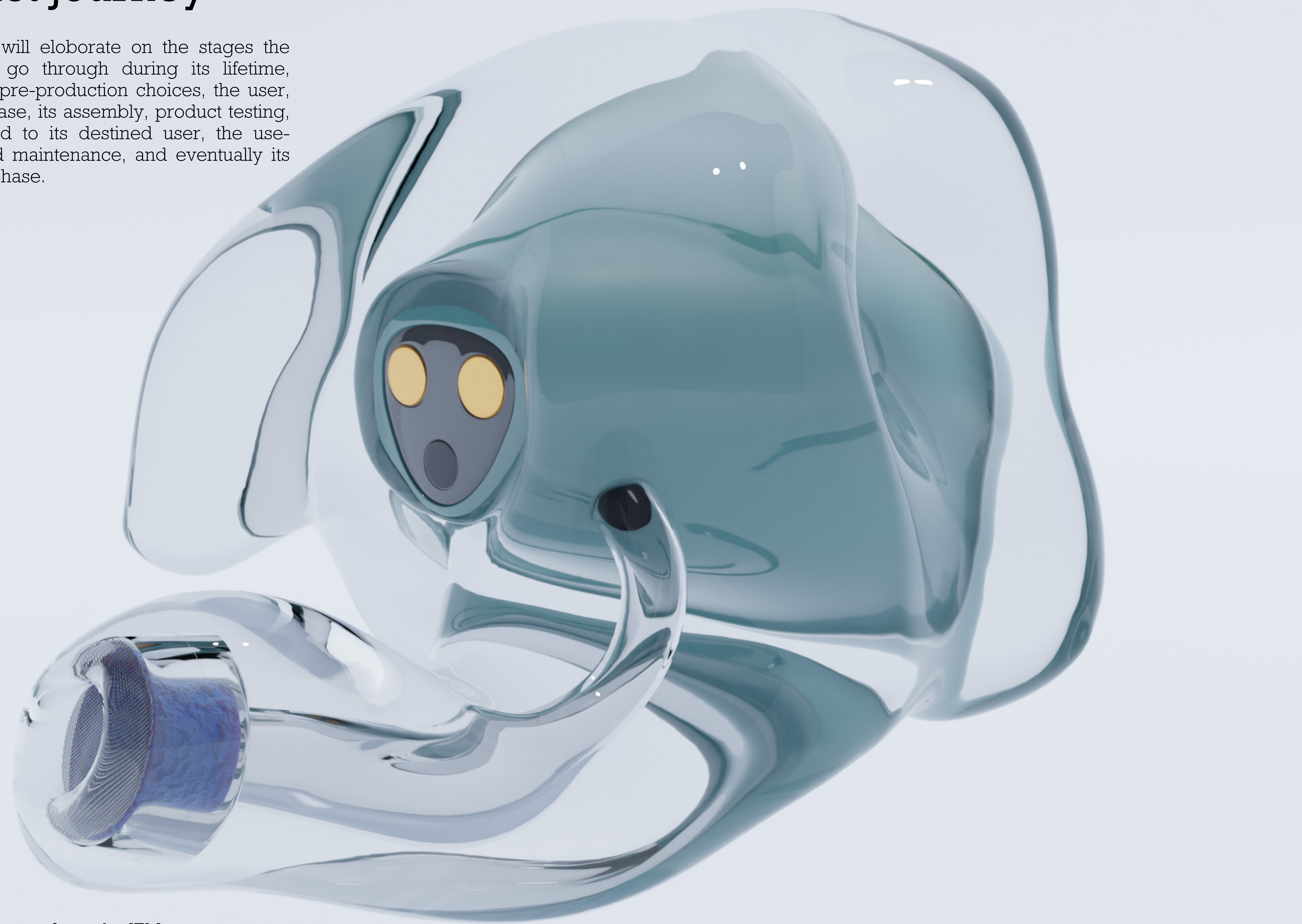


Figure 3.1: A close-up of one the IEMs.

3.1 Pre production choices

Bolt size
The size of the bolts do not require calibration but I find this a logical spot to include a calculation whether bolts are up to the task. The size subject for the bolts is an M1.4 8.8 grade steel bolt with minor diameter of 1,075[mm]. I chose these because they are the smallest bolts I can sufficiently assemble

Bolts use scenario calculation
I envisioned the use case where the Doppe Drops would be dropped from 2[m] high on a concrete floor:

1. Velocity at impact:
   E_potential = E_kinetic
   $m*g*h = 0.5*m*v^2$, where g = 9,81[m/s²] and h = 2[m]
   => v = sqrt(2*g*h) = 6,26[m/s].
2. System mass:
   Based on Figure 3.1.1, with an upper bound correction of +50% I deemed the system to weigh 0,015[kg].

Figure 3.1.1: I weighed my 1:1 prototype (my ear geometry, FDM printed from three walls thick PLA with an infill of 20% and a Sennheiser TVS200 IEM on a kitchen scale.

3. Momentum change:
   p = m * v = 15 * 6,26 = 0,0939[kg*m/s].
4. Impact time:
   I estimated the impact time to be t = 0,01[s].
5. Impact force:
   F = p/t = 9,40[N].
6. Force per bolt:
   In the worst case scenario (i.e. all the impact force goes through the bolts), each of the three bolts would be subjected to 9,40/3 = 3,13[N].
7. Maximum tensile load M1.4 bolt:
   Tensile strength 8.8 grade steel,
   T = 800[MPa]
   minor diameter = 0,001075[m]
   $A = pi * (d / 2)^2 = 9{,}08\times10^{-7}[m^2]$
   P = T * A = 726,4[N].

Conclusion
the loads are more than 2 orders of magnitude smaller than the scenario, so it is safe to say these bolts are up to the task in the scenario. Likely another part will fail first, such as the acrylic shell.

Discussion
It must be noted that this use scenario only handles impact forces distributed through the Dopple Earbuds co-linearly with the bolts centerlines, which in practice does not happen. Rather, they would likely already start to rotate mid-air. Besides, the Dopple Earbuds will have a very organic shape, which implies a non-linear and highly varying distribution of forces on impact. To satisfy the knowledge gap I give Dopple by replacing their mix of flexible and rigid glue to fasten the module and the shell, I will conduct a finite element analysis (FAE) study.

FAE study on shell
To simulate what it would do to the acrylic shell if the tip would hit the ground after a 2[m] high fall I did an FAE study. For this I made two simplified parts in SolidWorks resembling the module and a shell and two bolts to fasten them together within assembly. I did not use a third bolt because i could not get it to work in SolidWorks assembly.

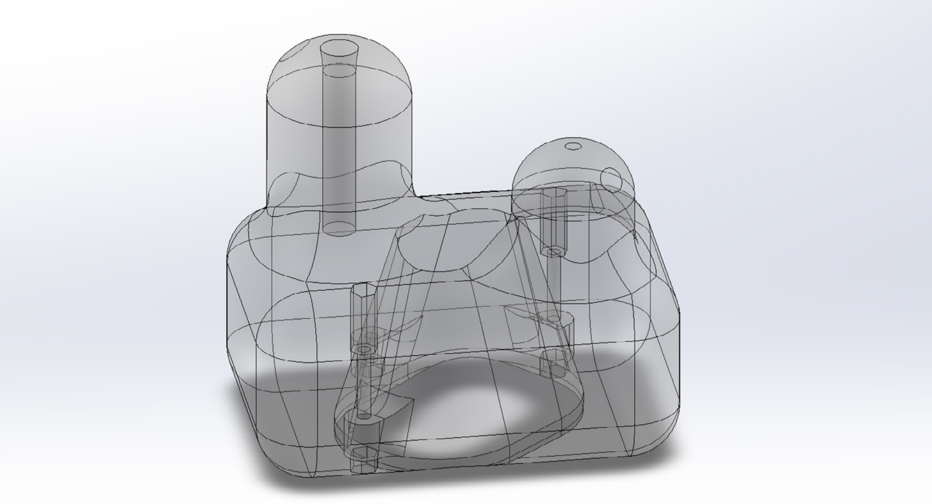


Figure 3.1.2: The 1:1 scale in-ear shell.

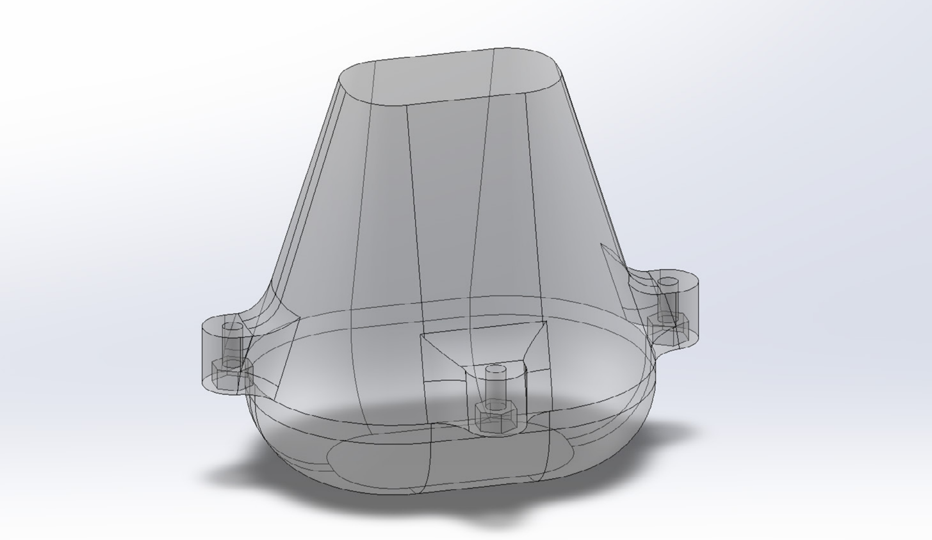


Figure 3.1.3: The 1:1 scale module.

I added roller supports to the top and bottom of the module, and to the four sides of the shell. In SolidWorks these types of supports are represented by green arrows. Furthermore, I added a force of 15[N] to an extruded planar cut on the in-ear canal part of the shell, represented by the pink arrows.

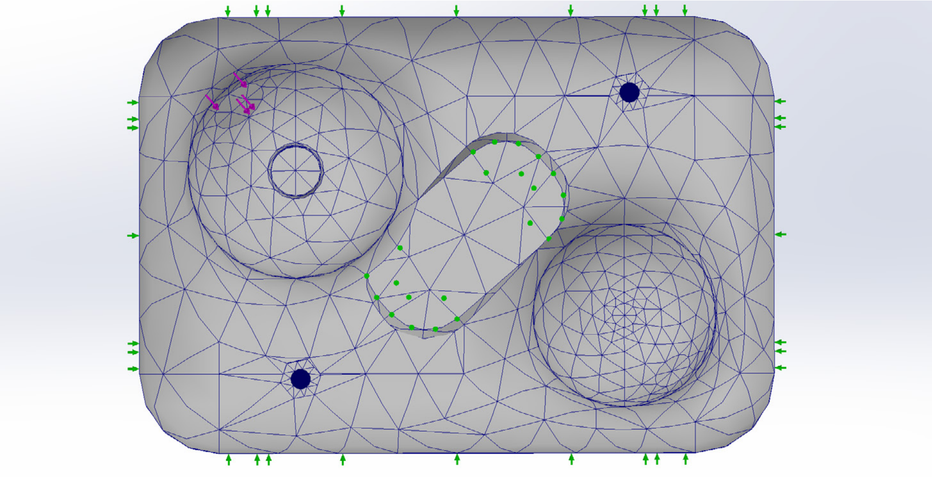


Figure 3.1.4: A top view of the assembly (in dark blue the bolts are shown).

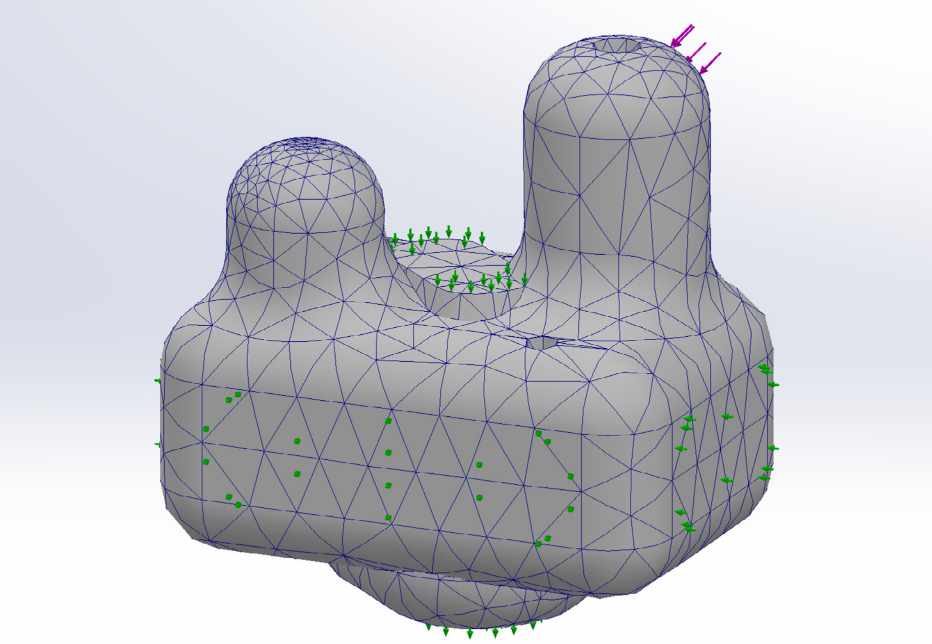


Figure 3.1.5: Isometric view.

The material used for the module and the shell are PC+ABS (50/50) and medium-high impact acrylic (PMMA) respectively.
As can be viewed in Figures 3.1.7, 3.1.8, and 3.1.9, in the proposed scenario, failure of the module can be neglected. All acting forces are considered three orders of magnitudes lower than those acting on the shell. For the shell. the von Mises stress does not exceed 1,534E+06[N/m²], the elongation strain does not exceed 4,486E-04[%], and the displacement does not exceed 8,657E-03[mm]. For comparison Table 3.1.1 contains the data from the FAE and Granta EduPack 2023 R2 (PMMA).

	Granta data	FAE data
Elastic limit/ von Mises*	48 [MPa]	1,5[MPa]
elongation at yield	4 [% strain]	0,00045 [% strain]

Table 3.1.1: Comparing calculated and material data (Granta EduPack R2, 2023).

*For this analysis it makes sense to compare the von Mises stress to the elastic limit of acrylic. The elastic limit indicates the maximum stress for elastic deformation, crucial for maintaining the shell's integrity and the in-ear geometry of its user. Meanwhile, the von Mises stress simplifies complex stress states into a single value, predicting the onset of plastic deformation. This comparison allows for reliability.

Conclusion
Comparing both the data from Granta and the calculated values from my own FAE study, I can conclude that this testing prototype would survive a fall from 2[m] on a concrete floor (i.e. very high fricrion coefficient and hardness).

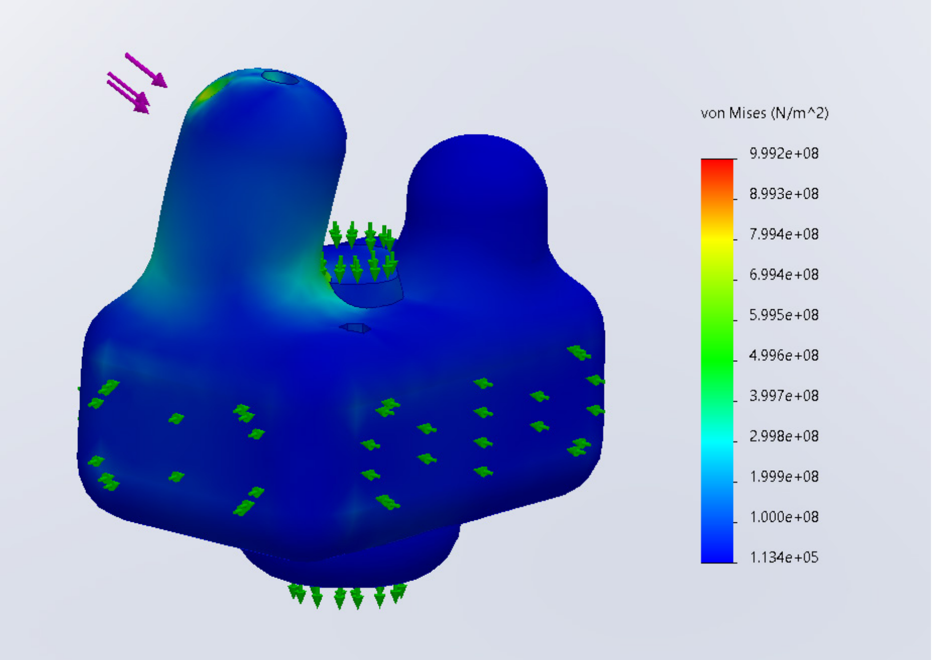


Figure 3.1.6: For comparison, this would be the result if the force would be equal to 5[kN]. This would grants a von Mises stress of about 700[MPa], plastically deforming the shell indefinitely

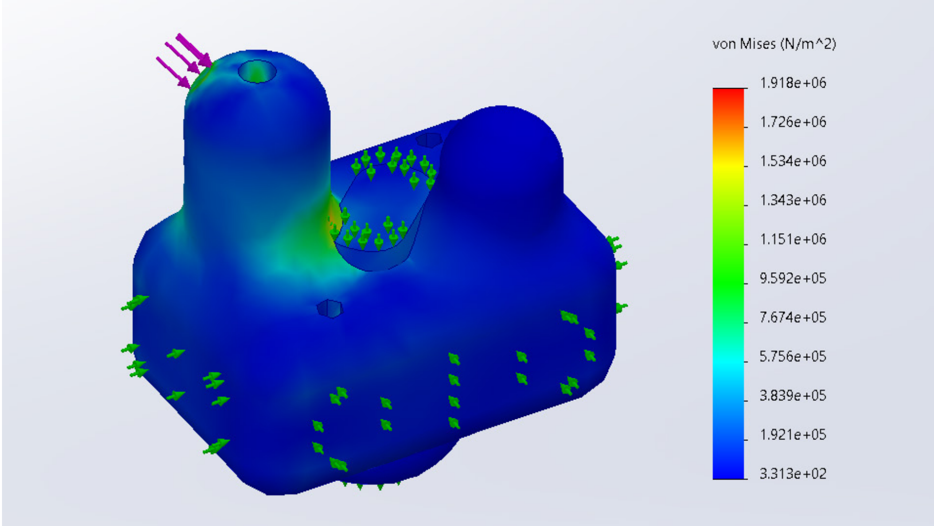


Figure 3.1.7: The von Mises stress in the test assembly.

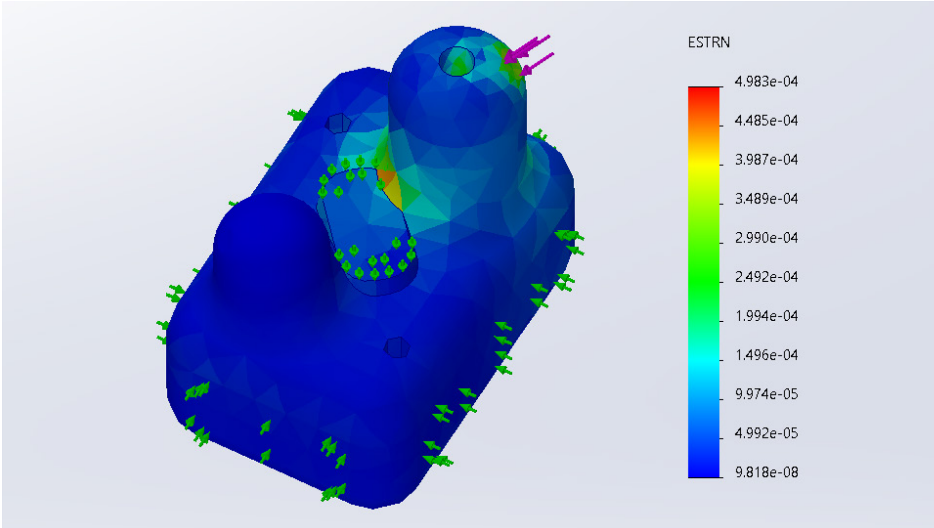


Figure 3.1.8: The elongation strain in the test assembly.

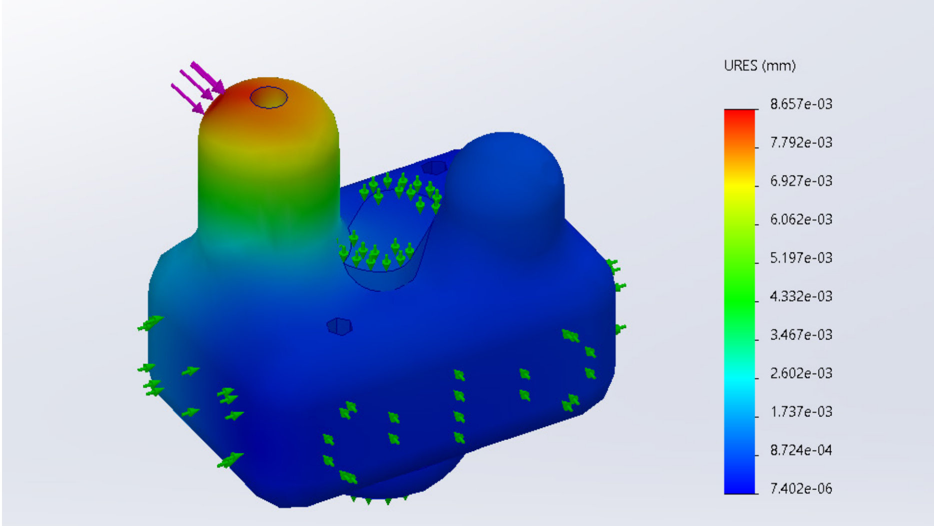


Figure 3.1.9: The displacement in the test assembly, as can be seen no displacements took place.

3.2 Calibration

This section contains explanations what calibration steps must be taken and why they are important for the device to function and be perceived by the user as intended. This phase requires the final geometrical form of the IEMs and the cradle, as well as some aesthetic features to be predetermined. This has parameterised implications for the positioning of some of the hardware.

Camera alignment
Like with fingerprints, there are no equal pair of ears. Since the cameras are tasked with depth perception, it is extremely favourable for them to be in the stereo calibrated setup as explained in the Implementing computer vision section. To achieve this, ensuring that the cameras' front faces are in the same plane (and prefereably tangential to the coronal plane) and their rotational axes are parallel to the sagittal plane is crucial for accurate stereo vision. The three planes of the human head are exhibited in Figure 3.2.1.

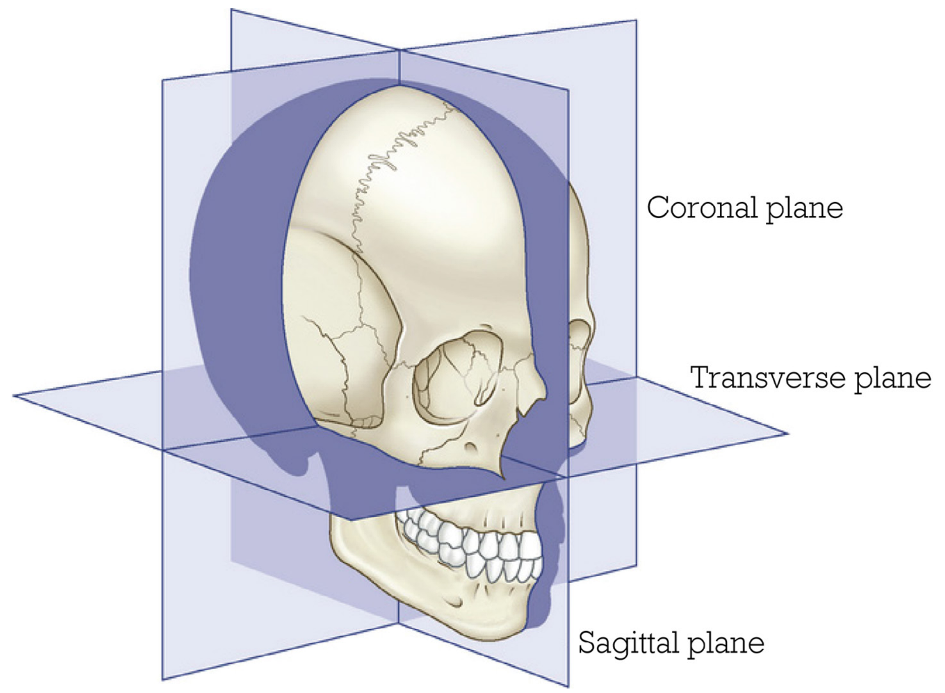


Figure 3.2.1: Reference planes through the human head.

Alignment strategies
Option 1: alignment with 'IMU-sticks'
The first strategy that came to mind thanks to Erik was to design straw-like products with two co-linearly aligned IMUs on each stick. If these IMU-sticks would be inserted in the hearing canals of the user, they could be used as a direction vector of each canal, by reading and comparing the gyroscopic data of the two IMUs. If positions from the point where the straw becomes visible outside the ear canal to a predetermined distance from the head and compared with a photograph from the front like in Figure 3.2.2, essentially, the rotational and translational displacement of these points could be utilised to parameterise a 3D model for aligning the cameras. However, ensuring safe testing is an issue. The inner ear organ is fragile and the sticks are required to be rigid. Furthermore, the inner ear is not rigid and does not resemble a homogeneous material. As no pair of ears are alike, several forms of the straws (thicknesses, geometries etc.), practically requiring a 3D scan of the inner ear to begin with. This brings me to option two.

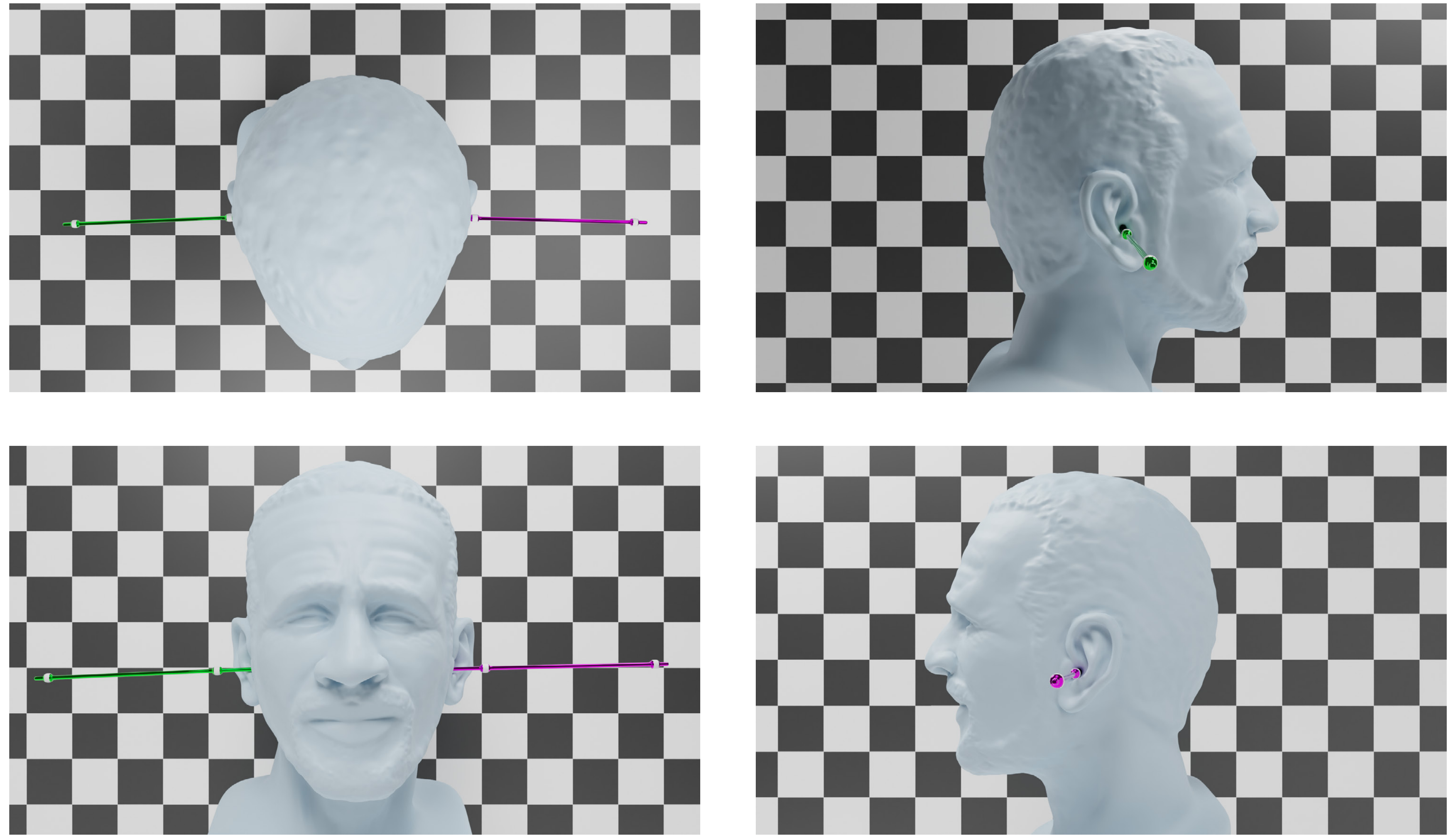


Figure 3.2.2: Top, right, front, and left view of Option 1 (render by me).

Option 2: 3D scanning and modeling
3D scanning acknowledes the diversity in ear shapes and sizes among individuals. To achieve a bespoke fit, this method entails creating precise ear molds, followed by their detailed scanning, and a scan of the head, with special focus on the precision of the ear region. a Dopple's engineers told me that this is more than possible with but one smartphone camera and a bit of time. This process must be exact to ensure the earpieces not only fit comfortably but also align correctly with the user's anatomy.

Transitioning from the 3D scans to a fully realised 3D model with accurately positioned cameras involves sophisticated software integration. The CAD add-on deployed for this purpose must compute the optimal locations for the cameras. This computation involves more than just the physical placement of the cameras; it also takes into account their field of view and any potential obstructions that might hinder their effectiveness. Therefor, the camera's on the product resemble the eyes of a snail.

The software's capability to integrate these computed locations into the earpiece design effectively is paramount. The integration must happen in a way that maintains the integrity of the design, the comfort of the wearer, and the functional efficacy of the cameras.

Preferred strategy
This second option is my choice as it offers a safe, and accurate way to make it work for anyone. 3D scanning equipment like they use for scanning limbs at Manometric (2024) to create custom braces has proven to be very precise. It is not irradical to imagine that with few tweeks, such a scanner they use at Manometric, or just a conventional handheld 3D scanner can be used to scan the 3D geometry of PD patiënts their heads. I should mention that Manometric their scanner is realy fast. A conventional scanner might require a brace
For the in-ear scan, the Lantos in ear 3D scanner is a favoured option for audiologists. It was developed by MIT in 2019 and has proven to be highly accurate (Gregoret, 2019). This technology has already been used to create in-ear monitors.

The scanner has a soft, flexible membrane at the end of a handheld wand. This membrane is initially collapsed. After the wand is inserted in the ear canal, the membrane is expanded to conform to the shape of the ear canal. The membrane is then filled with a fluid to shape it to the ear canal and outer ear. Once inflates, an optical system, scans the ear canal. As the camera captures images, it records the contours and dimensions of the ear canal in fine detail. The data captured is then processed to form a 3D model of the ear canal. The process is generally quick and more comfortable for the client compared to traditional ear impression methods.

Figure 3.2.3: Manometric limb 3D scanner (Manometric, 2024).

Figure 3.2.4: Lantos in Ear scanner (Lantos, 2019).

IEM IMU calibration
IMUs have to be calibrated to minimise errors considering external environmental factors such as magnetic fields and linear accelerations. By doing so, the calibration becomes more robust and relevant to real-world applications, where these factors can vary significantly (Filatov et al., 2015). This enables the Dopple Earbuds to be employed globally.

Smartphone IMU recalibration
A study of Middendorf et al. (2016) addresses the lack of standardised tests for verifying the correctness of sensor data retrieved from smartphone IMUs. The research implies that while IMUs in smartphones are functional, their accuracy can vary and may not always meet specific standards. This highlights the need for the calibration of the smartphone's IMU at in the calibration phase. Newer and more expensive smartphones often have better IMUs, this will improve the accuracy of their raw data.

(Re)calibrating an IMU
When (re)calibration is requested by the device, this happens via a auditory push message through the smartphone's speaker, and the IEMs. To calibrate the IMU of a Dopple Earbud, both IEMs should be placed in the cradle. From here the smartphone's speaker takes over the (re)calibration process via auditory instructions. Then, the cradle in turn must be stacked on top of the smartphone, and consequently, the stack on a flat surface, like a table top.

Firstly, the user is prompted to make sure that the environment is free from strong magnetic fields or vibrations for the best results.
The stack should lie there without movement for the magnetometers to calibrate, when the user hears the magnetometer calibration was a success, the are instructed to take the stake and rotate it around all three axes of the IMU to calibrate the gyroscope, sometimes pausing in a forty-five degree rotational offset from one of the planes orthogonal to its axes.

To calibrate the accelerometers, the user is asked to let the device travel in figure eight shaped paths, keeping the directonal vector of the device parallel to these paths.

Inter product system translations
The translation from the smartphone to the earpieces must me logged at a certain time interval to identify data drift. This can be done by analysing the quaternion data streams that are sent by the IMU. If the delta translational values of the IMUs (especially those between the two IEMs) have drifted more than say 30[mm] from the only location of the IMUs (as they are fitted in reference to the 'rigid' inner ear geometry), the IEMs have to be recalibrated. From experimenting with BNO055 IMUs (my choice for the Dopple Earbuds), I can tell that they do not uncalibrate quickly or often. It remains up to Dopple to investigate this further.

The delta translation between the IEMs and the smartphone is a less suitable indicator for measuring IMU decalibration since the user might forget to put their smartphone in their pants' pocket, e.g. leaving it on the table, or simply hold it in their hand to operate whilst being afoot.

Gait parameters
Accurately logging the user's gait parameters and patterns during the calibration phase is crucial for several reasons. Firstly, it allows for the creation of a personalised baseline of the user's unique gait characteristics, essential for the IEM to identify deviations that may indicate impending FoG episodes. By understanding the baseline gait patterns of the user, the device can more accurately detect anomalies or changes symptomatic of FoG, thereby enhancing the reliability and specificity of the intervention. This concept aligns with findings from Mileti et al. (2018), who emphasised the value of real-time gait recognition in improving medical assessment in PD.

Furthermore, this initial data gathering is vital for the FoG detection algorithms within the IEM. Since these require robust and individualised data to learn and adapt to the user's specific needs. The accuracy and representativeness of the initial gait data directly influence the effectiveness of the machine learning model in providing tailored assistance, as corroborated by the research of Schlachetzki et al. (2017), which demonstrated the feasibility of wearable sensor-based gait analysis in clinical applicability for PD.

Additionally, having a detailed log of gait patterns aids in the continuous improvement and fine-tuning of the device over time. As the user's condition or gait characteristics evolve (be it for the better or worse), the device can adjust its parameters to maintain efficacy. Before system deployment, the physiotherapist of the PD client should propose what type of 'bad' gait behaviour the PD client airs, and what their take on the efficacy of cueing types, i.e. specific auditive messages entails.

This adaptive approach ensures that the Dopple Earbuds remain valuable in treating FoG, even as the user's condition changes. A study of Moore et al. (2007) highlight the effectiveness of this long-term monitoring strategy of in the real natural environment, validating the importance of continuous data gathering for disease management.

Vocal calibration
First and foremost, the Dopple Earbuds' functions depend on the users' voice. Making sure that the device is not acting on a voice that is not originating from the user's mouth is vital.

A sound voice calibration allows for apt listening to the user's. This benefits the supervised learning aspect of the Dopple Earbuds' algorithms. As the device relies on user feedback to refine its detection of FoG episodes, incorporating voice input allows users to directly communicate with the device during real-time incidents. When a user verbally indicates either the occurrence of an unnoticed FoG episode or false alerts, this input becomes invaluable data. It helps the system to understand and differentiate between correctly and falsely detected FoG episodes more effectively, ultimately improving the sensitivity and specificity of the functions.

Moreover, given that PD can affect speech and voice patterns, calibrating the device to recognize the user's specific voice characteristics ensures that voice commands are accurately interpreted, enhancing the overall responsiveness of the system. This is particularly important in situations during a FoG episode, or before executing complex motor movement that require the cueing to be requested. Both these cases have put made me decide to rule out any manual interaction with the Dopple Earbuds.

Additionally, integrating voice calibration aligns with the user-centered design ethos of the Dopple Earbuds, emphasising the tailoring of the device to meet the unique needs and preferences of each user. This not only improves the user experience but also fosters a sense of trust and reliability in the device, essential for its adoption and effective use in managing the targeted symptoms.

3.3 Production

As this thesis mainly concerns concept design, the choice was made to keep the embodiment design part moderate. In this section three components will be handled: the module, the in-ear shell, and the connection of both, the bolts.

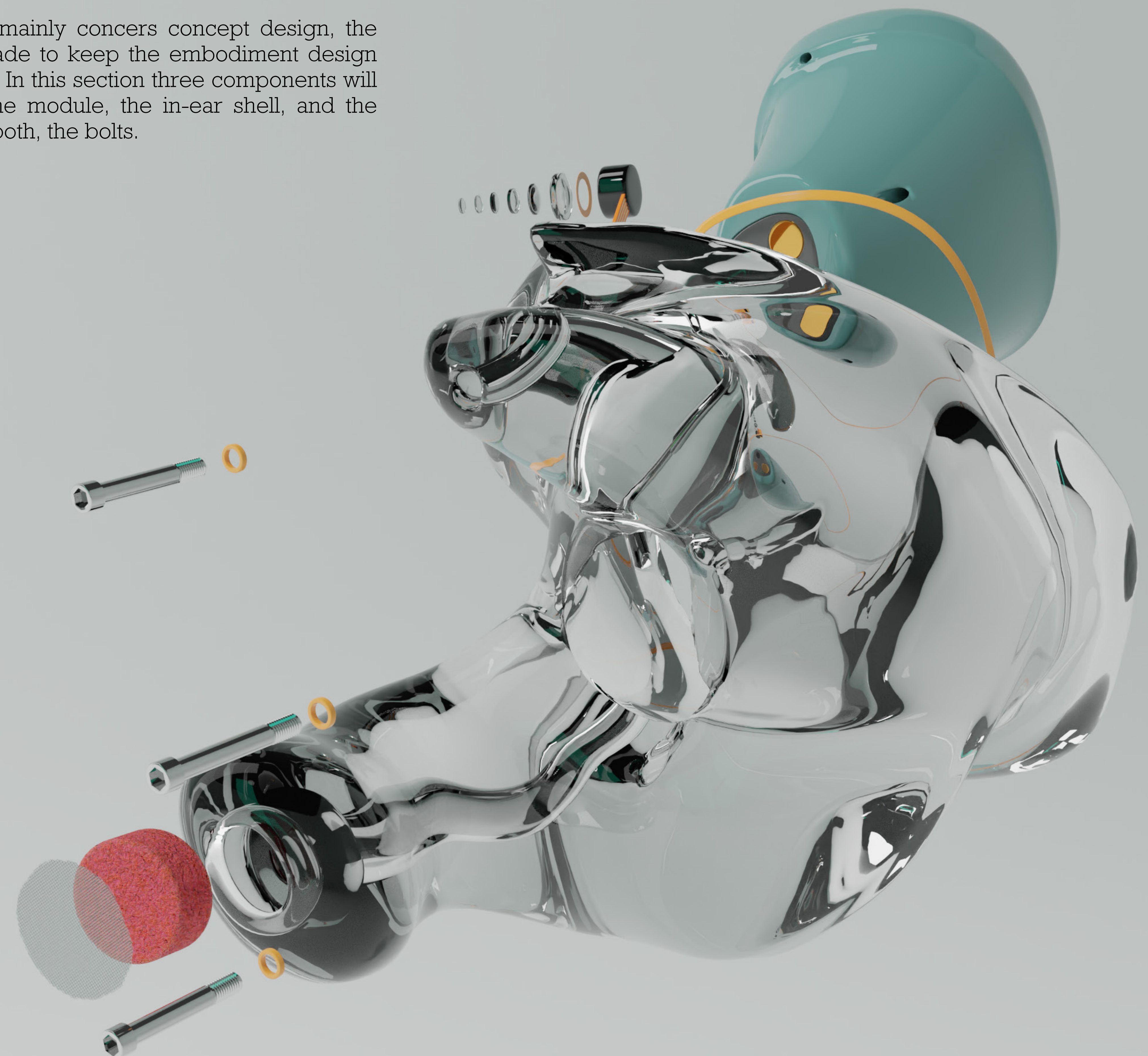


Figure 3.3.1: Exploded isometric view of a Dopple Earbud IEM.

In-ear shell
Besides being the only tailored part of the product, it is also volumetrically the largest. It houses the module, a camera, a dust resistant sponge, a water and earwax resistant film, and three bolts.

During one of my stays at Dopple I was told that their R&D team had uncovered a digital light processing (DLP) method that allows them to print crystal clear plastic (unclouded and without inclusions). I had never heard about this before. Ever since that method was discovered, I knew that this technique (of which I obviously do not posses the know-how) I should captivated on it for my product. DLP is a form of additive manufacturing where the minimal printing resolution is equal to the dimensions of the pixels in a liquid crystal display (LCD). DLP is also preferred because complex geometry becomes possible to print, with next to no support structures. A visual the DLP process is shown in Figure 3.3.2.

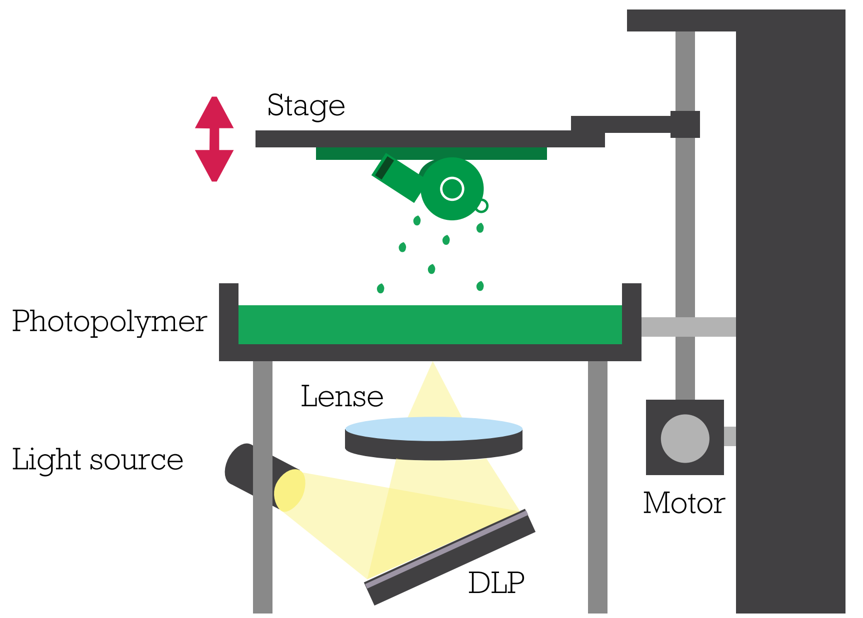


Figure 3.3.2: DLP uses a digital projector screen to flash a single image of each layer across the entire platform at once. This technology cures light-sensitive resin with UV light, building up layers one at a time to create a three-dimensional object.

The tailored approach to the in-ear shell primarily addresses the diverse anatomies of individual ears, ensuring precise alignment of the camera system and the module. Since each person's ear canal varies in shape and size, a standardised design would compromise comfort, retention, and equally important sensor accuracy.

Customising only the in-ear shell, as opposed to the entire module, strikes a balance between individualised ergonomics and manufacturing efficiency. This focused customisation minimises design and production costs while still accommodating the essential variations in-ear geometry.

In essence, the decision to customize solely the in-ear shell stems from the need to ensure optimal functionality and user comfort, while also considering the economic aspects of production and design, ensuring the IEMs' effectiveness and financial viability.

Bolts
The module and the shell are fastened together using three M1.4 Allen bolts, and embedded M1.4 locknuts in the module.

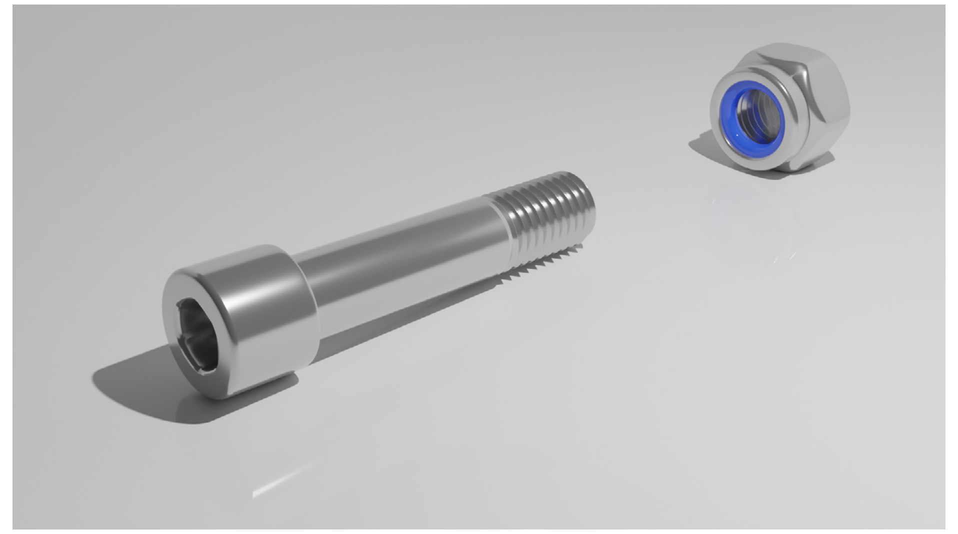


Figure 3.3.3: M1.4 bolt and locknut (embedded in module houseing)

Module
The module houses all the electronics, sensors, monitors (providin audio feedback), bolt fasteners (embedded nuts), camera connector part, and the battery. It houses a flex-PCB, a slightly larger than usual for IEMs battery, a bno-055 IMU, and a DSP unit. A visual of the modules' main components is shown in Figure 3.3.4. A visual of the modules' architecture is shown in Figure 3.3.5.

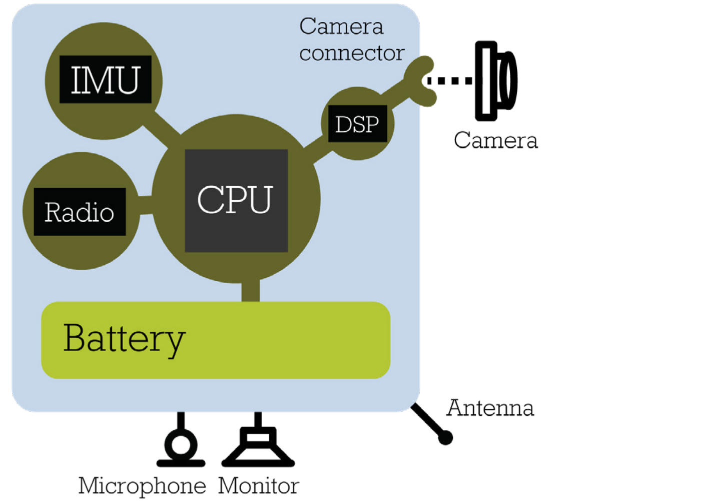


Figure 3.3.4: The main components of the module

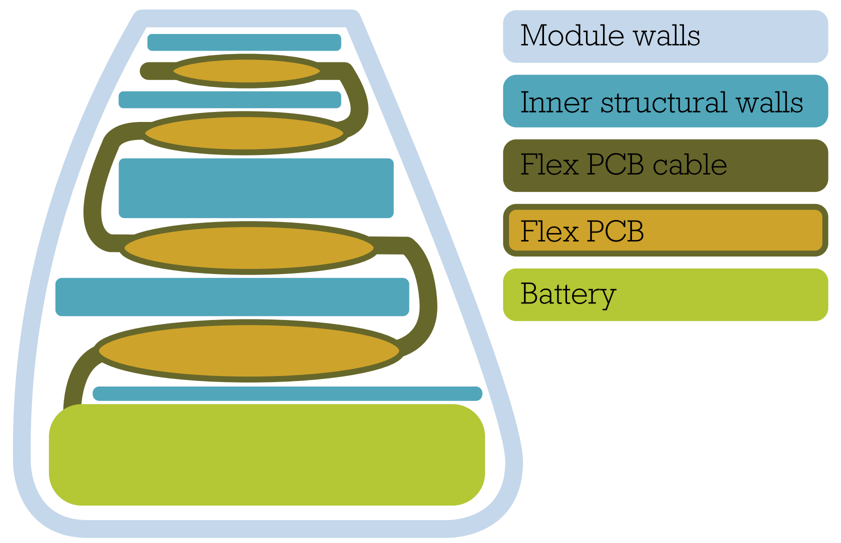


Figure 3.3.5: 2D inner module architecture

3.4 Assembly

Currently, Dopple's IEMs, are glued together with a flexible and a rigid glue type, as well as one self tapping screw. Glued connections are impossible to repair once seperated in such precision parts. Recycling is also made impossible in this setup.

In response to these challenges, a revised design has been proposed. This new design utilises three M1.4 Allen bolts compatible with M1.4 lock nuts, which are embedded in the module architecture. These are strategically fitted from the outside into the shell, along with a elastic retainer rings, crucial for maintaining the IP67 rating, indicative of its dust and water-resistant capabilities. An essential element in the assembly process is the integration of a sponge and metal mesh at the tip of the in-ear duct. These components serve to repel external elements like dust, water, and earwax, thereby protecting the internal mechanisms. Furthermore, the shell of the Dopple Earbuds incorporates a dedicated canal for the camera. Following the camera installation, the module containing the electronics is inserted into the in-ear shell.

To ensure the integrity and durability of the Dopple Earbuds, particularly regarding its water resistance, all components excluding the sponge and the metal mesh, are fitted with elastic waterproof retainers.

Figure 3.4.1 serves as a visual guide how to Dopple Earbuds are assembled (left out elastic reatainer assembly steps):

1. The camera attached to a flexible chord is inserted in the module + (left out) the mesh and sponge are pushed through the in-ear duct.
2. The camera is pushed into its canal and snaps into its form-fitted location.
3. The module is shoved into the in-ear shell.
4. The in-ear shell is bolted to the module with M1.4 locknuts.

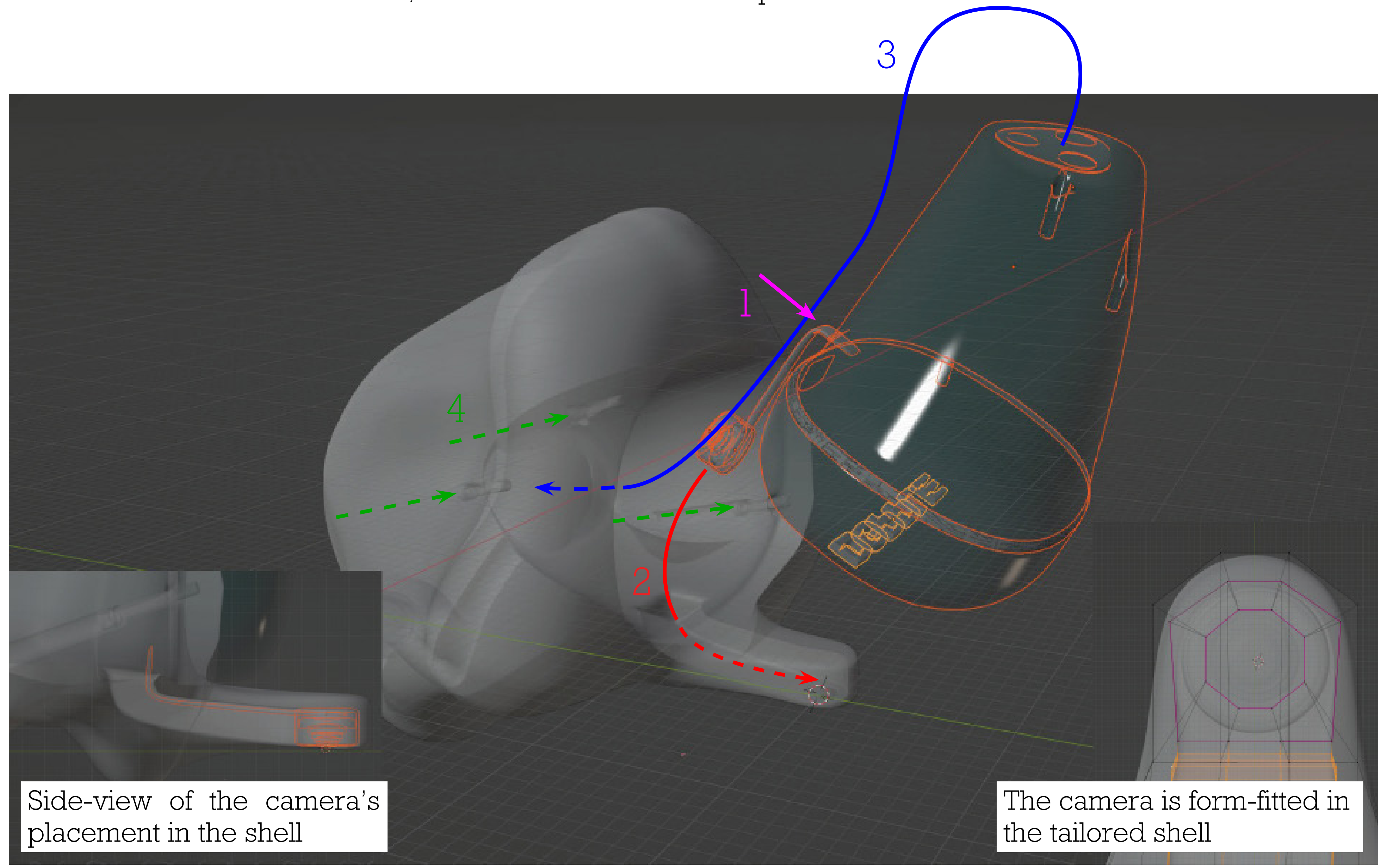


Figure 3.4.1: Assembly infographic Dopple Earbuds.

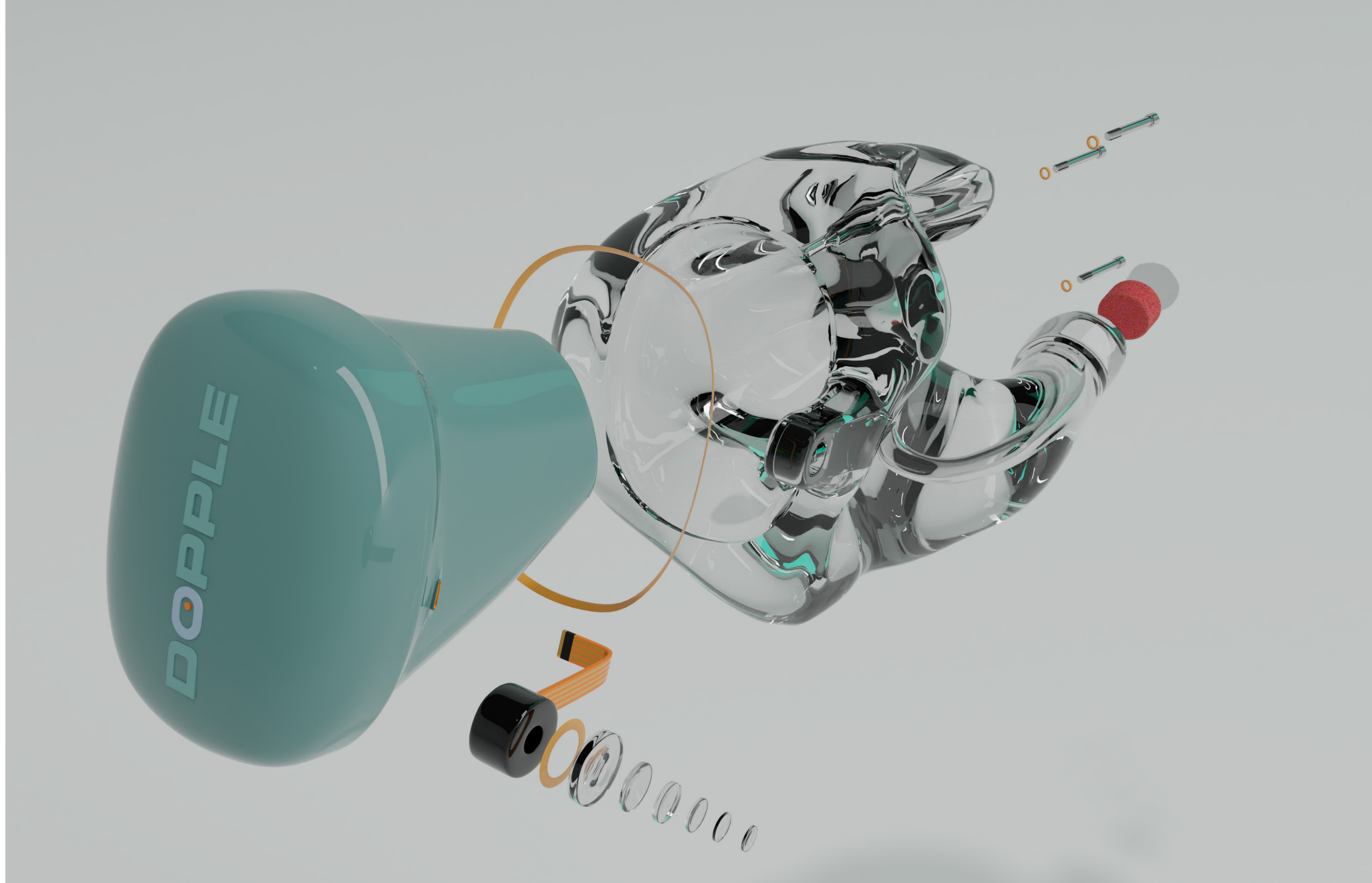


Figure 3.4.2: Exploded isometric view of a Dopple Earbud IEM.

3.5 Testing recommendation

Testing the Dopple Earbuds should focus on assessing how comfortable and intuitive in use the tailored IEMs combined with the smartphone are for daily use. It is crucial to gather subjective feedback on fit, weight, and ease of use, paying close attention to any discomfort or usability issues reported by its user. These user trials should be conducted in diverse environments (e.g., quiet home settings, noisy outdoor environments, and rain) to test the device's adaptability.

Algorithms
The algorithms, particularly those for FoG detection, require testing under controlled conditions that simulate real-life scenarios. This involves creating situations where FoG is likely to occur and measuring the accuracy of the device in detecting these events. It's important to record both the instances where the device correctly identifies a FoG episode and when it erroneously detects an episode (false positives) or fails to detect one (false negatives).

Vocal recognition and user interaction
Evaluate the system's ability to understand and respond to various user commands in different dialects, accents, and speech patterns. Testing should also consider ambient noise levels to ensure the device can reliably parse voice commands in realistic settings.

Smartphone app control
The app should be tested for user interface design, ease of navigation, and the responsiveness of the controls it provides. Connectivity tests are vital to ensure consistent and stable interaction between the smartphone app and the Dopple Earbuds.

System calibration status
The calibration process should be intuitive and straightforward for users, with clear instructions provided. The effectiveness of the calibration in setting up the device accurately for individual users must be assessed, including how well it adapts to different ear shapes and sizes.

Battery life and charging
Battery performance needs to be tested under various usage patterns to determine the actual battery life compared to the claimed specifications. Charging efficiency and the durability of the charging mechanism under repeated use are also critical.

Water and dust resistance
Rigorous testing should be conducted to verify the IP67 rating, ensuring the device can withstand exposure to dust and water without compromising functionality.

Durability and longevity
Simulated wear and tear tests can help determine the product's lifespan and identify any potential weaknesses in the materials or design.

Software and firmware updates
The update process should be smooth and user-friendly. Tests need to ensure that updates do not disrupt device functionality and that new features or fixes are effectively implemented.

Emergency and safety features
If the Dopple Earbuds include features like fall detection, their promptness and accuracy in emergency situations should be thoroughly evaluated.

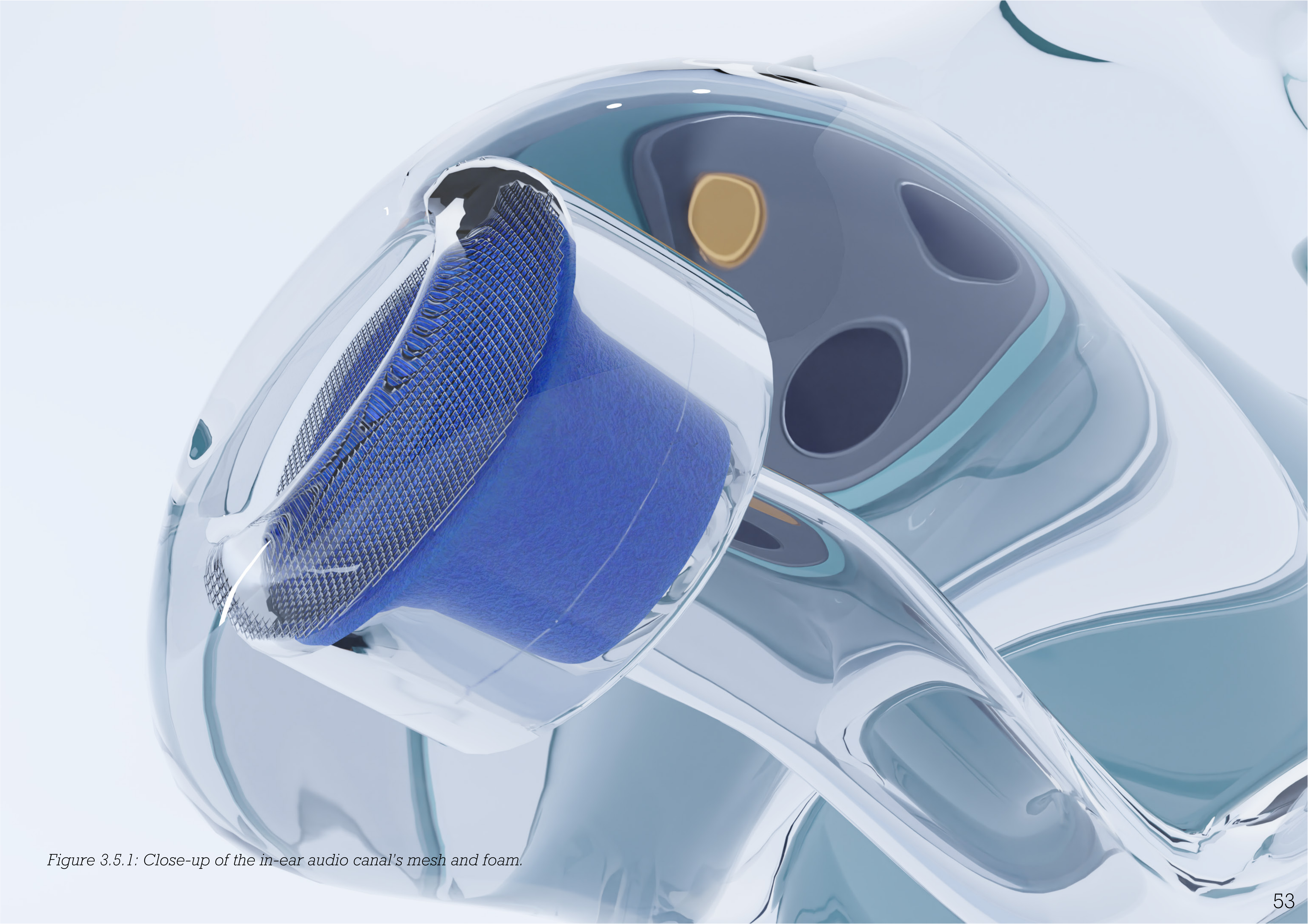


Figure 3.5.1: Close-up of the in-ear audio canal's mesh and foam.

3.6 (Pre-)use phase, repair, and EoL

In these stages, the Dopple Earbuds are introduced to their destined users, used, repaired, and finally disposed of. This involves customising settings and preferences to align with specific user needs, ensuring a seamless and personalised experience. To make it clear how to user should interact with the product to get the most out of it, I will devote this section to the exploration how they should approach its use.

Pre-use: User istructions
The introduction to Dopple Earbuds starts with an onboarding process where new users receive training materials and guides, essential for understanding the device's features and full potential. This stage is crucial for building user confidence. Then, users set up and (re)calibrate their Dopple Earbuds. This ensures optimal device functionality tailored to their needs, especially critical for PD clients.

Users are then guided through usage techniques, including voice input/control, smartphone app usage, re-calibration of the IMUs, engaging in video calls, device, and all other engements to be had, ensuring they benefit the most from the Dopple Earbuds. The Dopple Earbuds app should encompass all necessary information the users would want out of the app. The users are shown how they can give feedback on their experiences and suggested improvements.

Safety and health guidelines, particularly for PD clients, are provided, ensuring a confident and safe user experience. Educating users about the device's limitations sets realistic expectations and promotes appropriate use.

The journey with Dopple Earbuds extends beyond purchase, supported by ongoing updates and customer service. Users are kept informed about new features and improvements.

The active use-phase of Dopple Earbuds highlights the product's real-world performance. User experiences during this phase are integral to the continuous improvement of the device, ensuring it constantly adapts to evolving user needs, as PD is all about the edge-cases.

Use: Supervised learning
Incorporating supervised learning into the Dopple Earbuds' detection algorithms significantly enhances the device's performance over time. Inter alia, by the dismissal of existing less effective, or inclusion of novel auditive cues or cueing methods. It allows for continual refinement and adaptation to their sensitivity and specificity based on user feedback and interactions.

As the device is used, it collects data on how effectively it detects and responds to FoG episodes. The user can provide input, such as confirming when a FoG episode occurs or indicating a false alarm. Both should be conveyed vocally from user to the IEMs, as explained in the Calibration section.

The advantages of this approach are manifold. Firstly, it allows for a more personalised experience. Since every individual's symptoms and gait patterns i.e. what characterises their FoG episodes are unique, the device can tailor its responses to the specific needs of each user. Secondly, this adaptive learning helps in reducing both false positives and negatives, crucial for user trust and reliance on the device. Finally, supervised learning ensures that the device remains effective even as the user's condition or behaviours change over time. In essence, it transforms the IEMs from a static tool into a dynamic aid that evolves in tandem with its user, offering a more effective, responsive, and change-proof solution for managing FoG episodes.

Use: IMU recalibration
In a study by Middendorf et al. (2016), the authors addresses the lack of standardised tests for verifying the correctness of sensor data retrieved from smartphone IMUs. The research implies that while IMUs in smartphones are functional, their accuracy can vary and may not always meet specific standards. The users should be advised to use a relatively modern smartphone in combination with the Dopple Earbuds. A more modern smartphone means more modern sensors, which in turn implies more accurate data. The IMU of the smartphone and the Dopple Earbuds should be verified regularly, highlighting potential errors that have creeped into reading the data or sensor data drift. For example, from reading quaternion data it can be determined that the sensors have drifted, visualised in Figure 3.6.1.

Repair
This essential phase focuses on the upkeep of Dopple Earbuds. Regular maintenance, timely repairs, and updates ensure sustained performance and prolong the product's life. The part most susceptible to failure is the shell, but failure of the module is not ruled out completely. Therefore, the in-ear shell can be unbolted from the module, reprinted and bolted back together. Vice versa, a damaged module can be replaced if wear and tear it make it unfit for its intended use.

EoL
Finally, the Dopple Earbuds reach the End of Life phase. In this stage, the focus shifts to responsibly decommissioning the device. This involves re-using components, recycling parts wherever possible and ensuring safe disposal of non-recyclable components, all while minimising environmental impact. The EoL phase is as crucial as the others, embodying the commitment to sustainability and responsible consumption. Even though Dopple their products are small, they too have to make due with a sustainable approach to product design.

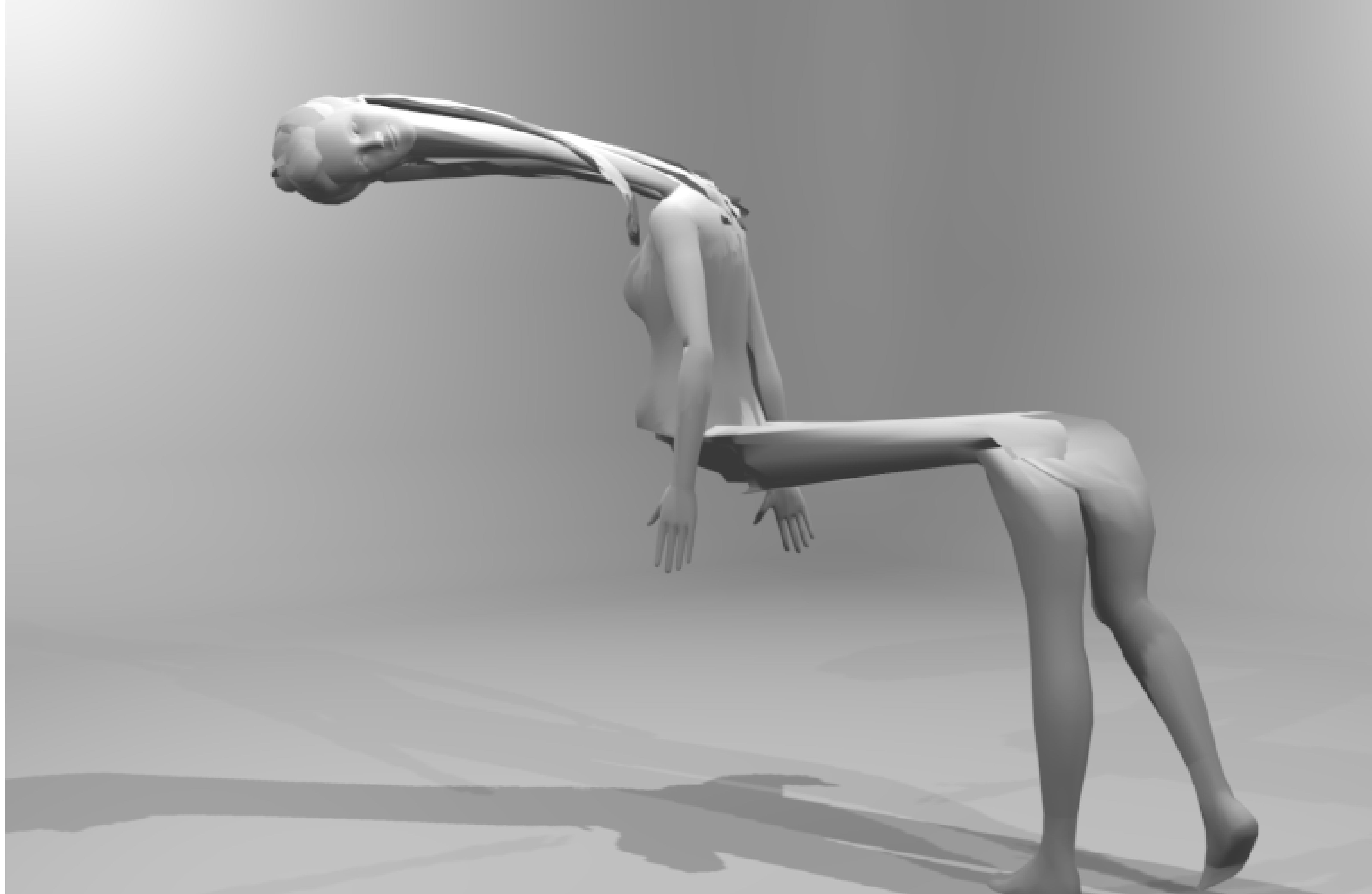


Figure 3.6.1: Visualising quaternion data drift. If the system measures this, recalibration is imminent.

4 Feedback cues

The realm of feedback cueing to combat PD MSs is multifaceted, encompassing a range of strategies tailored to individual needs. This chapter delves into the various types of feedback cues used in therapy, their adaptability, the crucial role of the physiotherapist, and how the Dopple Earbuds are to mimic the existing interaction between caregiver and PD client.

Adaptive feedback strategies
In the context of PD, feedback cueing is not a static process; it requires adaptability to remain effective. Techniques that initially prove beneficial may lose their efficacy over time as the individual's condition and responsiveness evolve. This necessitates a malleable approach to feedback cueing in rehabilitation therapy, where feedback strategies are regularly reviewed and adjusted if required. The Cue2Walk device illustrates this by offering varied feedback modalities (auditory 'beeps', or somatosensory vibrations) that can be adjusted based on the client's responsiveness and preferences (over time).

MSs and PD client specific cues
In a meeting with Dr. Beudel from the Amsterdam UMC, who is an international renowned PD-expert, I learned that each MS requires different cues to mitigate. Furthermore, an effective cue that mitigates a MS, or reduces its experienced severity, for one PD client does not imply that such a specific cue exhibits the same positive effect when presented to a different PD client suffering from the same MS. This again underscores the tailored approach.

Cueing might not just heighten attention but also improve movement timing and gait amplitude, stabilising walking patterns and reducing the likelihood of falls. Both visual and auditory cues can reduce FoG and enhance gait kinematics, underlined by some of the products from the Existing wearables section, with visual cues showing a more significant impact (Lee et al., 2012). This is notably not in favour of the Dopple Earbuds. But, it highlights that improper amplitude scaling is a key deficit in FoG. Auditory cues have limitations due to FoG's characteristic rapid movement cycles and disordered limb coordination, leading to greater response variability (Nieuwboer, 2008). Notably, inappropriate cueing can sometimes worsen FoG episodes (Moreau et al., 2008), emphasising the importance of careful cue selection once again.

Behavioural strategies for FoG episodes
A study by Ginis et al. (2018) shows that there are two different behavioural strategies to be discerned:

- Preserving optimal spatiotemporal control.
- Rescue strategies after FoG episode onset.

The positive impacts of both input types are linked to their ability to shift focus from more affected to less affected neural circuits.

Furthermore, they uncovered that effective methods for cueing strategies are subject to one fundamental mechanism: the PD client should be guided to step away from habitual coping mechanisms, towards a goal-directed motor control pattern. Here, Ginis et al. discern three encompassing roles to be fulfilled by any feedback cueing source:

1. The executive role:
   - Facilitating the response generation.
   - Prioritising the focus of attention.
2. The stabilising role:
   - Preventing a worsening gait pattern.
3. The preparatory role:
   - Re-integrating the coupling of postural control with gait initiation.

Positive effects of cueing
A study of Heremans et al. (2013) examined the impact of multi-session cued rehabilitation programs on PD clients with FoG. These interventions, ranging in duration from one week to six months, have generally shown beneficial outcomes in reducing the severity of FoG following the cued training. Furthermore, Kadivar et al. (2011) researched how training PD clients' gait with auditory cueing showed better retention of learning compared to those who received uncued training. Besides, the positive effects on FG were also maintained. The physiotherapist from the PvF also told me that cueing significantly influences daily life, but that the retrieval of cueing strategy is key before deploying it in a product that partially replaces the physiotherapist.

Limitations of cueing
While cueing generally shows short-term benefits, its long-term effectiveness varies based on the PD client and their rehabilitation wishes. Non-freezers exhibit lasting learning effects and transfer skills to related tasks, but freezers struggle to retain improvements and apply learned skills to uncued tasks. This increased cue-dependency among freezers aligns with the "guidance hypothesis" in motor learning, suggesting augmented sensory information during learning might foster dependency and hinder skill transfer (Ginis et al. 2018). Moreover, Ginis et al. (2018) implies that feedback cueing during a freezing episode could lead to cognitive overload, deteriorating the freezing episode. I experienced this myself during a feedback session at the PvF, but more on this in the next section. The timing of applying intelligent cues is critical, with the ideal approach being to anticipate and deliver cues before the onset of a potential FoG episode.

Dopple should conduct future research to explore customising cue-based rehabilitation for PD clients with FoG, aiming to maintain optimal spatiotemporal self-control and skill transfer by/to the PD clients.

Cue examples
During my feedback sessions at the PvF, the PvF physiotherapist told me about several auditory cues, aimed at negating festination and FoG episodes. to name a few (non-exhaustive), in the arresting gait state:

- Stop walking.
- Taking a deep breath.
- Ensure your feet are apart enough.
- Engage in gentle 'ice-skating' movements.
- Take wide steps sideways alternating with each leg.
- Lift but the knees high as if walking in one spot.

When the physiotherapist sees improvement, i.e. the decline in FoG episode potential, gait initiation feedback strategies can be provided. Alternatively, the following strategies can be used as feedback if festination is occuring but an FoG episode is still not imminent:

- Count out-loud to three, then take a big step.
- Swing with the arms in alternating fashion, then take a big step with the opposing leg, and continue.
- Take an 'ice-skating' step forward.
- The ankle is first to hit the ground (if the PD client is walking on their toes as a rescue strategy).
- Twist the leg outward during each step.

Over time, these may be modified or replaced with others like moving the hips outward or adopting different postures to address changes in the client's condition.

maneuver specific cues are proposed in the Fall detection section.

Incorporating RAS
Rhythmic auditory stimulation, involving walking to the beat of a metronome or music, can partially alleviate gait dysfunctions in PD. Its immediate effects include increased walking speed and stride length, and long-term benefits are observed with regular training programs. However, the effectiveness of rhythmic cueing varies among patients, largely dependent on their rhythmic abilities, which may deteriorate with the disease's progression. Patients with better rhythmic skills generally respond positively, while those with poorer skills may see no improvement or even a worsening in gait when using cues. For the PD clients that do benefit from RAS, the rhythm serves as a temporal template that helps them to re-establishing the regularity of disrupted gait patterns. RAS can be particularly effective in manoeuvring through challenging spaces, correcting posture, and mitigating freezing episodes (Bella et al., 2018). RAS is usually offered in the following forms:

- "one, two, one, two, ..."
- "beep, boop, beep, boop, ..."
- "beep, beep, beep, beep, ..."
- "left, right, left, right,..."
- Playing music

The role of the physiotherapist
The physiotherapist plays a pivotal role in the product-service system of PD management. They are not just facilitators of therapy but are integral in ensuring the functional optimisation of devices like the Dopple Earbuds IEMs. Their expertise is vital in selecting, adjusting, and monitoring feedback cues, ensuring that these strategies align with the client's evolving needs. Regular interaction between the client and the physiotherapist is crucial for the ongoing assessment and adaptation of the treatment plan.

Integrating multidisciplinary approaches
According to the physiotherapist of the PvF, a multidisciplinary approach has influence on the effectiveness of feedback cueing. Collaboration with logopedists or speech therapists can be particularly beneficial in refining auditory cues. Their expertise in vocal tones and frequencies can guide the development of more effective RAS cues, ensuring they are attuned to each client's auditory processing abilities.

Conclusion
In conclusion, feedback cueing in PD therapy is a dynamic and complex intervention, requiring continuous adaptation and a personalised approach. The integration of feedback cues, along with the professional guidance of physiotherapists and other specialists, forms a comprehensive strategy to manage PD symptoms effectively. Through such tailored interventions, PD clients can experience significant improvements in mobility, posture, and overall quality of life. The success of these interventions hinges on their ability to evolve with the client's condition, underscoring the importance of flexibility and professional oversight in PD management, parallel to smart wearables like the Dopple Earbuds.

4.1 User feedback tests

During two filming sessions at the PvF, insights were gathered on how and what feedback should be provided by the Dopple Earbuds to the PD clients. These sessions also served as a baseline for me to design the user-product interactions, and to find out how they should differentiate from one another per tackled symptom. The research method is elucidated in Appendix J. The camera footage of the feedback tests was used to edit videos. These were showcased during the green light meeting and the graduation final presentation.

On LevoDopa
A significant discovery was that PD clients, during the active phase of dopaminergic drugs, experienced markedly fewer instances of festination, bradykinesia, and FoG episodes compared to the inactive phase. Their movements, particularly in gait and initiation, improved significantly with medication, becoming smoother, quicker, and less jerky. Furthermore, turning radii were smaller. With one client, the improvements were so pronounced that it was challenging to discern the presence of PD.

Nonetheless, the two PD clients observed in the study still demonstrated a stooped posture even while on medication, underscoring the importance of the Dopple Earbuds in continuous symptom management. Additionally, as discussed in the Current PD therapies section, these clients may still be in the initial, honeymoon stage of their LevoDopa use, as indicated by the noticeable success of this aspect of their physiotherapy sessions.

On LevoDopa with walker
I noticed that gait in the on-state using a walker was generally slower than without a walker. Moreover, the stooped walking posture was more distinct, likely due to the fact that the PD clients could now rest their weight on the walker's handgrips. Additionally, turning radii increased with a walker, and the attention to the trailing leg was diminished. When the PvF physiotherapist instructed the PD clients to perform a 360[°] turn in place, they were unable to do so, resulting instead in them moving in a circular path.

Off LevoDopa
In the off-state, I had the opportunity to evaluate the effectiveness of providing gait-specific feedback to PD clients. Despite the limited number of participants, it was evident that my feedback played a significant role in reducing festination and aiding the mitigation of FoG episodes.

During the inactive phase of dopaminergic drugs, the PD clients behaved just the opposite of the on-state. Significant increases in festination, bradykinesia, and FoG episodes were noticeable. Gait and its initiation, deteriorated noticeably, as did the swinging of their arms during gait. PD usually renders one side of the body to become more physically impaired than the other. This was evident in one client particularly. When the physiotherapist asked if they could diagonally swing their arms (alternating to left and right leg swings), at some point, their worse arm froze behind their back. Contrary to FoG, unilateral upper limb freezing is common and occurs mainly on the disease dominant side (Vercruysse et al., 2011).

Likewise, the movement patterns in the off-state became more erratic, slower, and jerkier. Additionally, turning radii were larger. The PD clients suffered from shuffle gait, not able to lift up their knees without the feedback I gave them though the IEMs.

RAS
The effectiveness of rhythmic auditory stimulation (RAS) feedback was also evaluated during the off-state. A key discovery was the critical importance of selecting the appropriate type of cue. For instance, playing a PD client's favorite music to them, "Blue Suede Shoes" by Elvis Presley, at a tempo of 96[BPM], utilising on-ear headphones, manifested in significant deterioration of gait. Without the support of their walker, they would have certainly fallen. Conversely, when the same client in the off-state was provided with RAS in the form of counting "one, two, one, two, ..." at their native gait cadence, communicated via IEMs using my own voice, his gait regularity improved vastly.

With the other PD client I tested if providing the same cue, "one, two, one, two, ...", at their native gait cadence, resulted in faster gait. We walked across the hallway next to the physiotherapy gym between the same pillars (i.e. a set distance) for ten times. Of which, half were with RAS and the other half without. The resultes can be found in the table 4.1.1.

Run	Time (with RAS) [s]	Time (no RAS) [s]
1	18,12	19,39
2	17,85	25,32
3	16,11	19,19
4	18,44	21,40
5	20,72	22,97
Means	**18,248**	**21,654**

Table 4.1.1: Hallway traverse times with and without RAS cueing.

Cueing RAS increased the PD clients' gait speed by 15,73[%]. This difference was statistically significant ($p = 0.033$, paired smaple T-test). Furthermore, reflecting on my own observations, I can tell that with RAS the forward gait trajectory was much more linear (i.e. smaller directional vector in the coronal plane), than without employing RAS. Besides, the gait cadence seemed rhythmically more attuned, and the stride length felt longer. Unfortunately, the physiotherapy session demanded the PD client to partake in other exersices. Otherwise, I would have liked to measure gait cadence and stride length as well. Only one trial run was filmed, for the test runs I focussed on keeping the RAS as close as possible to the PD client's native gait cadence, as well as the stopwatch on my smartphone. Thus, stride length and gait cadence could not be analysed post hoc.

Movie fragment by me, Nathalie had to catch the falling PD client (with signed agreement of PD Client PvF).

4.2 Target audience

Ideal user profile
The Dopple Earbuds are particularly beneficial for PD patients who, despite their condition, are still ambulatory. A key symptom that makes users ideal candidates for the Dopple Earbuds is FoG. Similarly, those experiencing festination can also find considerable relief.

Central to the Dopple Earbuds' functionality is RAS cueing. PD clients who have shown responsiveness to RAS cueing and other forms of auditory feedback to counter symptoms are likely to benefit most. This auditory feedback forms the backbone of the device's intervention strategy.

In considering the potential users for the Dopple Earbuds IEMs, it's vital to explore the broad spectrum of functionalities they offer and how these capabilities align with the needs of different PD clients. While the primary focus of the Dopple Earbuds is on FoG and festination mitigation, the incorporation of additional features significantly broadens the user profile.

The device's object detection capability is a critical feature for users who require enhanced spatial awareness, particularly those who may struggle with vision impairments common in PD. This functionality makes the Dopple Earbuds suitable for individuals who would benefit from an additional layer of environmental awareness. Especially if it has not yet become clear or got unclear with time, to the medical staff or physiotherapists, what kind of environmental hurdles trigger FoG for the PD client at hand.

Besides, PD clients that have mild speech disorderds can benefit from the cameras in a video call with a caregiver and healthcare professional. Remote monitoring capability opens doors for them to track the patient's condition and respond accordingly. This feature is particularly beneficial for those who live alone or are under constant care.

Heart rhythm detection is another feature that can be pivotal, especially for PD patients with cardiac comorbidities. This function extends the device's appeal to those needing consistent monitoring of heart health.

Fall detection adds a layer of safety and assurance, making the Dopple Earbuds suitable for those at a higher risk of falls, which is a common concern among the elderly and those with advanced PD stages.

Lastly, posture correction and stability help are crucial for maintaining a good quality of life and preventing falls. The device can aid those with postural instability, a common issue in PD. similar to posture correction, maneuver aid is another feature that could benefit PD patients, especially those who face challenges in navigating tight spaces or making turns, which are often triggers for FoG episodes.

Exclusion criteria*
The Dopple Earbuds may not be the best fit for all PD patients. Those with severe speech disorders might find it too challenging to interact with the device effectively, given its reliance on vocal commands for some of its functions. Similarly, PD patients with advanced dementia may struggle with the cognitive aspects of operating and understanding the device.

The physical design of the Dopple Earbuds also necessitates certain physical capabilities from its users. For instance, the ability to self-equip the IEMs and operate a smartphone is a prerequisite. This requirement rules out PD clients with severe rigidity or mobility impairments who might not be able to manipulate the device independently.

Another unique aspect of the Dopple Earbuds is their reliance on object scanning for the optimal functioning of the camera system. This necessitates PD clients being willing to maintain a certain hairstyle that does not obstruct this process. Additionally, carrying a smartphone in one's pocket is crucial for the device's connectivity and functionality, thereby making it a prerequisite for prospective users.

*Even though 'exclusion criteria' might not be the nicest term to hear, I do not mean any negativity with it. It is just an academically correct way to denote exactly who is and who is not a suitable user.

Movie fragment by me, with signed agreement of PD Client PvF ('as unidentifiable').

5 Product Functions

In this chapter all main product functions will be addressed. To be covered are:

- The main and some secondary product functions.
- Some ancillary product features.
- The different modes in which the product system operates.
- A product function analysis.
- Additional research concerning PD gait characteristics.
- From the PD gait characteristics and sensor factsheets, an educated guess on the devices electricity demand is done.
- This chapter will be concluded with insights on the device's connectivity and how data is transmitted between the devices.

Figure 5: The Dopple Earbuds (from the thesis cover render).

Main product functions:
- Festination detection
- FoG detection

Secondary product functions:
- Object detection
- Festination & FoG detection
- Heart rhythm detection
- Fall detection
- Remote monitoring
- Posture correction
- Maneuver aid
- SOS function

Ancillary product features:
- Collect gait data
- Voice input
- Vibration feedback
- Control vibration feedback
- Audio feedback
- Control audio volume
- Control audio EQ
- Control visual feedback
- Local data logging
- Data upload to cloud
- Download & install soft- and firmware
- Overwriting previous soft- and firmware
- Call
- System calibration
- Assessment of wireless connection
- Wireless transmission
- In-ear detection
- Out-of-ear detection
- In-case detection
- Out-of-case detection
- Receive radio
- Charge
- Measuring charge
- Hearing-aid
- Language select
- Battery capacity check

5.1 Festination and FoG: Preceding research

Introduction
Festination and FoG are the main MSs that are tackled by the Dopple Earbuds. Festination, characterised by shuffle-gait and a rapid shortening of stride, and FoG, marked by sudden, involuntary cessation of movement are common yet complex phenomena experienced by PD clients that result in an increased risk of falls. Understanding these symptoms is crucial for enhancing the Dopple Earbuds' effectiveness. This section delves into the exploration of festination and FoG, outlining their characteristics, challenges, and interrelationship, and presenting key findings from recent research endeavors. The goal here is to gain a broader understanding of festination and FoG, ultimately leading to design improvements in the next section.

Research questions
The primary focus of this thesis revolves around several key questions aimed at enhancing the understanding and management of FoG and festination in PD by a smart wearable.

The first question addresses the integration of IMUs within IEMs, exploring the potential of this technology to detect and mitigate FoG episodes. This inquiry is particularly significant given the emerging role of wearable technology in healthcare.

Secondly, I delved into the effectiveness of feedback mechanisms within IEM devices for FoG mitigation. This aspect was inspired by insights from physiotherapist Nathalie from Zorginstellingen Pieter van Foreest, who emphasised the potential of timely and appropriate feedback in reducing FoG episodes. My investigation encompassed various feedback modalities, their incorporation into the Dopple Earbuds, and their potential in providing effective, real-time mitigation of FoG episodes. This aspect forms a fundamental part of the design project. Furthermore, since the inception of the concept, Dopple has placed considerable emphasis on this aspect, recognising its critical role. The success of the concept hinges on the ability to provide a sound answer.

The third main question focuses on the desirability and ergonomics of wearable technology in PD clients. Recognising the importance of user comfort and preference, this line of inquiry is aimed at ensuring that any developed technology is not only effective but also acceptable and desirable to the PD clients themselves.

Scientific contribution
The research contributes significantly to the field by proposing a standardised IEM tailored to PD clients. This innovation aims to improve the management of FoG episodes, enhancing client mobility and overall quality of life. By desk research, testing feedback mechanisms, and assessing PD client attitudes towards the technology, I seek to establish a baseline for effective, client/human-centric solutions in managing PD symptoms.

In essence, this research strives to bridge the gap between technological advancement and practical, user-friendly applications in healthcare, particularly for those suffering from PD. The primary objective is to develop a solution that not only represents the pinnacle of technological innovation but is also tailored to meet the needs and preferences of clients with PD.

Background on FoG and festination
After I started filming PD clients at the PvF, and did some follow-up research on the impressions gathered during filming, I came to know another prevalent symptom in PD: festination. FoG and festination are distinct yet related phenomena in PD, and both result in falls. Therefore, festination and FoG will both be taken as main target symptoms to be tackled by the Dopple Earbuds.

Studies suggest that between 50% and 80% of PD clients experience FoG at some stage of their disease, with festination also being a prevalent symptom (Zhang et al. 2021). While festination and FoG are distinct in their clinical manifestations, they are linked. Festination often leads to an altered gait pattern, which can trigger FoG episodes. This interplay is attributed to basal ganglia dysfunction in PD, leading to motor set deficits and altered motor cue production (Iansek et al. 2006). Consequently, the relationship between these two symptoms is complex, indicating a multifaceted motor control issue in PD. Understanding this relationship is critical, as it impacts both the assessment and management of PD. While FoG and festination are distinct motor control conditions, they are often interconnected. Festination involves a tendency to speed up with repetitive movements, and it may occur in isolation or in combination with FoG (i.e. walking in one spot). Environmental factors, attention, mental status, and medication use can influence both festination and FoG, suggesting a multifaceted relationship (Morris et al., 2008).

The gold standard for FoG episode assessment remains expert video analysis, yet this method falls short in capturing the true extent of the symptom in everyday client settings (Scully et al. 2021). This gap in assessment underscores the need for more precise and client-centric evaluation methods. Similarly, the episodic and variable nature of these phenomena poses challenges in detection and assessment, necessitating advanced and sophisticated tools for accurate monitoring (Coste et al. 2014).

The quantification of FoG typically depends on subjective instruments such as diaries (Erb et al., 2020) and the FoG questionnaire (Giladi et al., 2009), yet these methods fall short in accurately capturing the frequency and duration of FoG episodes. Technological progression, particularly in machine learning, now permits objective FOG detection in situ via IMUs (Buongiorno et al., 2019) and (Mancini et al., 2021). Current IMU-based approaches necessitate substantial domain expertise and lengthy development (Sigcha et al., 2020).

I must choose the questions I want to tackle in this thesis carefully, as this field of engineering and design has many sides, and as my coach en chair said, multiple interdisciplenary graduation or even PhD projects could (and later I found out: 'had already') emerge(d) within this subject. It is up to me to devote my time to the right topics, benefitting from and strengthening my design skills in healthcare product design.

In conclusion, the interconnected nature of festination and FoG in PD underlines the need for a nuanced understanding of these conditions. Addressing these challenges is paramount for enhancing client care and improving overall product design strategies in PD.

From data expansion to holistic analysis
Initially, I wanted to enlarge the amount of FoG data in existing databases, ultimately increasing the potential of existing models to be more precise in the detection of FoG episodes. This involved working on a prototype utilising IMUs to objectively capture and analyse movement data. However, further digging in academic literature made this redundant.

The CuPiD IMU dataset, a cornerstone of the research found, provided valuable insights. Here, data were collected from 18 PD clients, aged 49 to 89, who performed specific walking tasks designed to elicit FoG events (Bächlin et al. 2010). These tasks included walking with turns and navigating obstacles, mimicking real-life challenges faced by PD clients. The dataset, which recorded 184 FoG episodes, turned out to be pivotal in understanding the duration and characteristics of these episodes, providing a quantitative foundation for further analysis.

Supplementing this data, observations from real-world settings, such as physiotherapy sessions, offered qualitative insights into client experiences and symptom manifestation. By marrying quantitative IMU data with qualitative observations, a more holistic view of festination and FoG was achieved. This approach not only bolstered the understanding of these phenomena but also provided a robust foundation for developing the design parameters of the Dopple Earbuds.

FoG episode duration
The analysis of FoG duration, derived from the CuPiD IMU dataset and real-world observations, revealed critical insights into the nature of FoG episodes in PD. The dataset, which encompassed 184 FoG episodes across 11 out of 18 clients, indicated an average episode duration of 9,12[s] (Bächlin et al. 2010). Notably, a significant portion of these episodes are short, with 50.8[%] under 3 seconds and 64.7[%] under 5 seconds. From watching YouTube videos and filming freezers at the PvF durin physiotherapy, I observed similar freezing times. The duration of FoG events is crucial for detection methods (Bikias et al., 2021). Therefore, the client specific average freezing time should be included as a calibration parameter. , with more than half lasting under 3[s] . This finding underscores the transient yet disruptive nature of FoG, highlighting the need for swift and precise detection methods i.e. algorithms.

FoG detection algorithm input
Acceleration and gyroscopic signals:
Tripoliti et al. (2013) highlighted the use of signals from wearable sensors, including six accelerometers and two gyroscopes, placed on the clients' body to detect FoG events. This methodology involves stages like signal preprocessing, entropy calculation, and classification using algorithms such as Random Forests.

Multi-segmental acceleration data:
Moore et al. (2013) extended previous techniques to evaluate the optimal sensor placement and signal processing parameters for FoG detection, using seven sensors attached to various body parts. This study utilised intraclass correlation and sensitivity-specificity metrics for objective and clinical measures comparison.

Frequency-based freezing detectors:
Azevedo et al. (2014) adapted and extended frequency-based FoG detectors to include other associated gait pattern changes, like festination. The study emphasised the value of observing stride length and cadence to anticipate upcoming FoG events.

Power analysis of leg movement:
Moore et al. (2008) validated an ambulatory FoG monitor based on the vertical linear acceleration of the shank. The study utilised a freeze index defined by the power in specific frequency bands, demonstrating effective differentiation between FOG events and stand events.

Anomaly detection techniques:
Pham et al. (2017) developed an automated FoG detector using anomaly detection techniques, emphasising the importance of feature selection using correlation and clusterability metrics to detect FoG events.

Utilising a CNN for FoG episode detection:
A study from Borzì et al. (2023) introduces a real-time FoG detection algorithm using IMUs. The research involved data from 118 PD clients and twenty-one healthy subjects during daily activities. An IMU was attached to their waists, generating over seventeen hours of data and culminated 1110 freezing episodes. The algorithm, based on a CNN, demonstrated great performance, predicting FoG episodes over 50% of the time, with a delay of around 3.1 [s] on average in the primary dataset and 1.3 [s] in an independent test dataset. Specificity was high, exceeding 88% in the primary dataset and 93% in the independent test dataset, and reaching 100% for healthy subjects. The algorithm is robust, computationally efficient, and

suitable for real-time implementation in standalone devices for non-supervised environments, offering potential benefits in managing FOG in PD clients.

Other FoG detection model input gait parameters:
Brognara et al. (2019) list and show what gait characteristics are important for a FOG episode prediction model.

IMU sensor location
In the context of detection, the placement of an IMU is vital. Locations including the ankles, thighs, hips, back, and wrists have been applied by academic researchers. However, sensor placement closer to the lower legs and feet resulted in enhanced performance in detecting FoG episodes. I asked this to one of the papers' authors Luigi Borzi (Borzi et al., 2023), Assistant Professor at the Politecnico di Torino. He corroborated this observation, emphasising the proven efficacy of lower limb sensors in capturing relevant gait data.

This sensor placement insight is crucial for developing effective FoG detection technologies. Sensors optimally located can better capture the onset and cessation of these episodes, thereby facilitating timely interventions. Moreover, understanding the optimal sensor locations aids in the design of wearable technologies that are both functional and comfortable for PD clients, ensuring better compliance and effectiveness in real-world settings.

In conclusion, the analysis of FoG episode duration and the strategic placement of IMU sensors create effective FoG detection systems. These insights not only advance our understanding of FoG in PD but also pave the way for the Dopple Earbuds.

Feedback cueing methods
A critical aspect of managing FoG and festination in PD is the application of feedback cueing methods. These methods are designed to assist clients in overcoming motor blocks and improving gait parameters, thereby enhancing mobility and safety.

Peterson and Smulders (2015) explored the role of cues and attention in PD gait. They highlighted that external cues, like auditory and visual signals, can improve gait consistency and rhythm in PD clients. The study also emphasised the importance of cognitive function and attention in the effectiveness of these cues. While cues help in gait improvement, their impact varies depending on the type of cue and individual patient.

One of the primary feedback methods explored is RAS. It involves using auditory cues, such as metronome beats, beeps, or even the PD client's favorite song at their gait cadence, to pace steps and improve walking patterns. This method has proven to be safe, inexpensive, and effective for many PD clients, with studies showing notable improvements in gait parameters (Ashoori, Eagleman, & Jankovic, 2015).
Auditory cues with rhythm improve gait speed more than visual or proprioceptive cues, likely due to the higher level of integration of auditory rhythmical cues in taking steps (Rochester et al., 2009).

Visual cues represent another promising avenue. Tools like laser canes and projected lines on the floor have been shown to aid in reducing FoG and enhancing gait initiation and continuation. The effectiveness of these cues varies with individual preferences and the type of visual stimuli used (Nieuwboer et al. 2007).
Moreover, home-based cueing training that integrates both visual and auditory cues has shown efficacy in enhancing gait fluidity and balance. These personalised programs foster greater self-management of symptoms among clients, thereby not only empowering them in their daily lives but also providing relief and support to medical and physiotherapy professionals (Nieuwboer et al. 2007).

With advancements in wearable technology, wearable cueing devices offer new possibilities for personalised and adaptive cueing strategies. These devices can deliver auditory, visual, or somatosensory cues, facilitating more effective and convenient management of PD symptoms in home settings (Sweeney et al. 2019).

Lastly, intelligent cueing systems that provide feedback based on real-time gait analysis can offer more tailored support to stabilise gait patterns. These advanced systems are increasingly integrating wearable technology to adapt cues to specific gait abnormalities (Ginis et al. 2017). This is what the Dopple Earbuds are all about!

Conclusions
This section has provided an overview of FoG and festination in PD, highlighting their impact, interrelation, the challenges they pose, and what insight I got from researching their workings. The research conducted emphasizes the transient nature of FoG and the importance of optimal sensor placement for effective detection. The exploration of feedback cueing methods, including RAS, visual cues, and intelligent cueing systems, underlines the potential of technology in managing these symptoms.

Crucially, this research contributes to the field by proposing the integration of IMUs in a novel IEM product system for Dopple, tailored for PD clients. The goal is to develop a solution that is not only technologically advanced but also comfortable, desirable, and effective for clients. By addressing the multifaceted nature of FoG and festination, this section paves the way for the next section, in which the functions of the Dopple Earbuds will be handled.

Figure 5.1.1: The Dopple Earbuds with a light blue coloured module.

5.2 Festination and FoG: Design implications

In this section the design implications for the FoG and festination prediction and feedback functions, as well as the algorithm are drawn from the insights collected in the previous section. Here I also go in depth how the system should behave and what the data handling looks like.

Festination and FoG prediction algorithm
As mentioned, more often than not, festination precedes FoG. Therefore, recognising the occurrence of festination must be a main goal of the prediction algorithm, to increase the chance to mitigate FoG episodes and thus the risk of falling. As uncovered in a meeting with the CTO of the main competitor Cue2Walk, besides a multitude of academic sources stating the same, the prediction algorithm to be written and deployed should use techniques such as angular rate reversal algorithms. This is underscored by Dijkstra et al.'s (2010) research, where they attained 100[%] true-positive and 0[%] false-positive scores in testing their shuffle-gait event detection algorithm (also validated by Huzda et al. (2014)).

Furthermore, the festination and FoG detection algorithm must be multi-layered to yield the highest specificity and sensitivity scores possible. In the previous section, relevant background for algorithm design can be found in (Moore et al., 2008), (Bächlin et al. 2010), (Tripoliti et al., 2013), (Moore et al., 2013), (Azevedo et al., 2014), (Pham et al., 2017), (Buongiorno et al., 2019), (Mancini et al., 2021), (Bikias et al., 2021), and (Borzì et al., 2023).Leveraging gyroscopic and accelerometer data, the Dopple Earbuds can anticipate and provide auditory cues before FoG episodes occur.

It is up to Dopple's software engineers to develop their own live pipeline version of the FoG prediction algorithm. To aid in this development task, I contacted Luigi Borzì. He was willing post his full code-base to a Github repository, furnished with comments! This will greatly assist to the conversion of different IMU placements, e.g. the ears and smartphone location (the PD client their hip, i.e. pants pocket). Luigi also pointed me to the Github repository of Bächelin et al. of Stanford University, which contains their entire code-base. Both source URLs can be found in Appendix I.

Training the prediction algorithm
As mentioned in the Calibration section, during the calibration phase, the Dopple Earbuds' festination and FoG prediction algorithm learn what their users' regular gait but also FoG pattern pertains. After equipping the users with their IEMs and co-operating smartphone, they should walk across an obstacle course until the system attains sufficient sensitivity and specificity scores for the algorithm to pick up festination and FoG episodes in real world environments. Furthermore, like stated in the Use phase section; after the user sets foot into the real world, the device proceeds to improve sensitivity and specificity scores due to built-in supervised learning functionalities, guided by the user's voice.

Cueing types
Like stated by Peterson and Smulders (2015), what type of feedback works depends on the patient and their cognitive ability. I had the chance to find this out for myself with PvF PD clients, as mentioned in the User feedback test section. Essentially, the festination or shuffle gait can be surmounted by providing the right auditive cues to a patient. For stable gait, the Dopple Earbuds use RAS functionality. The concept of RAS stands central in the mitigation of FoG and festination symptoms in PD clients. The cueing method involves providing rhythmic auditory cues to facilitate more regular and consistent walking patterns (Ashoori, 2015).

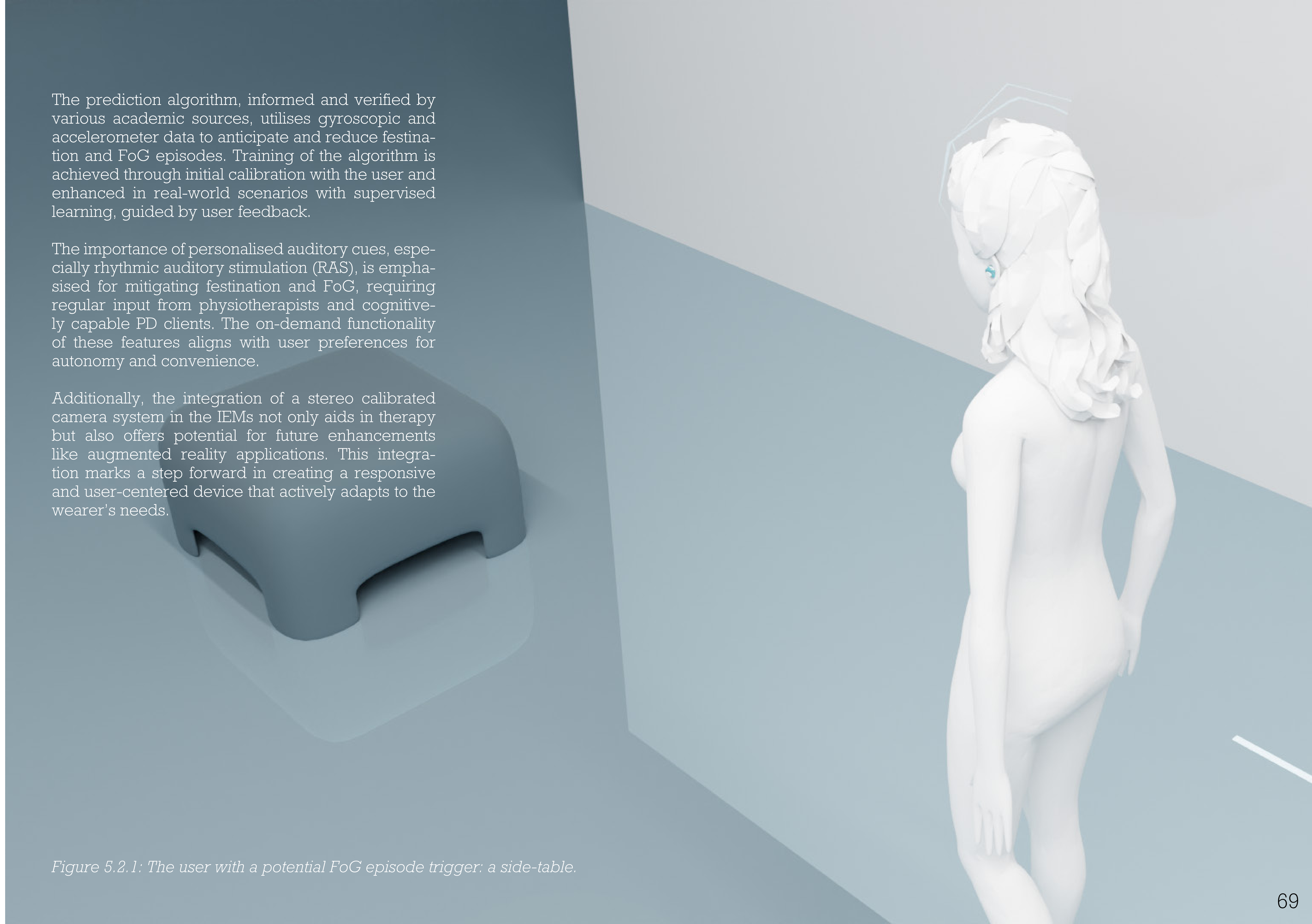
Declining festination and FoG feedback efficacy, measured by the reduction in percentage of mitigated freezing episodes and upsurge in festination intensity and duration, may be a precursor of auditive cues that initially did work, but now miss their mark, e.g. because of PD progression, a weakening cognitive state, or evidently something unknown.

On-demand functionality
As with the secondary product functions, festination and FoG mitigation by auditive feedback cueing must be an on demand feature. The Cue2Walk product has shown its virtue through the employment of this feature, enabling PD clients to initiate gait.

Cameras' interplay with FoG mitigation
In therapeutic contexts, the camera system proves beneficial for physiotherapists, offering insights into PD clients' real-world interactions and potential FoG triggers. This information guides personalised therapy, focusing on practical strategies to address day-to-day mobility challenges.
The integration of such a camera system potentially opens doors to future design alterations uses like augmented reality (AR) overlays for additional environmental information and gesture recognition for intuitive user-device interaction. It also enhances social interactions for users, potentially recognising faces and interpreting social cues, thus aiding communication. However, there is unfortunately no more time to further investigate the inclusion of AR into the concept.

In essence, the addition of a stereo calibrated camera system in the Dopple Earbuds IEMs significantly enriches user experience. It's not just about improved navigation and safety; it's about creating a more connected, responsive, and user-centered device that actively adapts to and interacts with its wearer's environment and needs.

Conclusion
In this section, algorithmic considerations and the design implications for the Dopple Earbuds' festination and FoG prediction functions have been tackled.



The prediction algorithm, informed and verified by various academic sources, utilises gyroscopic and accelerometer data to anticipate and reduce festination and FoG episodes. Training of the algorithm is achieved through initial calibration with the user and enhanced in real-world scenarios with supervised learning, guided by user feedback.

The importance of personalised auditory cues, especially rhythmic auditory stimulation (RAS), is emphasised for mitigating festination and FoG, requiring regular input from physiotherapists and cognitively capable PD clients. The on-demand functionality of these features aligns with user preferences for autonomy and convenience.

Additionally, the integration of a stereo calibrated camera system in the IEMs not only aids in therapy but also offers potential for future enhancements like augmented reality applications. This integration marks a step forward in creating a responsive and user-centered device that actively adapts to the wearer's needs.

Figure 5.2.1: The user with a potential FoG episode trigger: a side-table.

5.3 Fall detection

This section explores the intricacies of designing an effective falls detection system within the earbuds, considering both the technological requirements and the user experience.

Falls prediction algorithm choice
Focusing on falls detection, two seminal studies stand out, providing valuable insights and advancements in this area.

Machine learning algorithm
The first study, by Usmani et al. (2021), offers a comprehensive review of the application of machine learning (ML) in fall detection systems. The study emphasizes the need for advanced systems to improve the quality of life for the elderly, who are at a high risk of falls. It extends beyond traditional wearables, exploring a range of methodologies that incorporate ML algorithms, aiming to provide a more holistic understanding of the current state of fall detection technologies.

The methodology analysis in Usmani et al.'s paper is extensive, examining datasets, age groups, types of ML algorithms used, sensors, and system locations. The paper underscores the significance of ML in enhancing the accuracy and efficiency of fall detection, discussing the integration of these algorithms into existing systems. Emerging trends like smartphone integration and advanced ML methods in detection algorithms are identified, shaping the future of fall detection technologies. The study also tackles challenges like real-world performance, usability, user acceptance, and issues related to power consumption, sensing limitations, and privacy, offering insights into potential future research directions.

Expert rule algorithm (non-ML algorithm)
The second study, by Grisales-Franco et al. (2015), focuses on an algorithm for fall detection using inertial sensors in elderly adults. Their algorithm is designed to differentiate between actual falls and activities of daily living (ADLs), thus reducing false positives and improving detection accuracy. Employing a novel approach of threshold-based detection and analysis of residual events post-fall, the algorithm aims to capture the unique motion characteristics of a fall. The study uses three filtering methodologies to process acceleration data, isolating key fall-indicative features such as jolt (the rate of change in acceleration). Tested with a dataset including simulated falls and daily activities, the algorithm demonstrates improved performance compared to existing models, effectively identifying fall events with high accuracy.

The findings from Grisales-Franco et al.'s study are crucial for developing reliable fall detection algorithms, contributing to elder-care technology by providing robust and efficient solutions for a prevalent health risk. Their research aligns with the growing field of smart healthcare, where technology plays a critical role in emergency situations.

Together, these studies offer a view of the current landscape and future potential of fall detection technologies. Worthy of note is that I took some time looking for adequate academic sources following a ML and non-ML approaches. So, further desk research is required on this topic. Usmani et al.'s focus on ML algorithms complements Grisales-Franco et al.'s expert rule algorithmic approach. It is up to Dopple's engineers to base decide which of these two paths to take.

Near falls detection in earables
A study from Feld et al. (2023) investigates whether sensors placed at the ear are effective for detecting near-falls, a method contrasting with the conventional locations on the sternum or lumbar area. As hearing aids and earables increasingly incorporate IMUs, as will the Dopple Earables, utilising them for early fall risk detection becomes a possibility. The study, which involved inducing perturbations on a treadmill, found a high correlation between sensor signals at the ear and those at traditional body positions. This suggests that the ear could be a viable sensor location for monitoring gait instability, though the research was limited to a small dataset under laboratory conditions. Further investigation is needed in real-life settings, but preliminary results are promising for the use of ear-positioned sensors in near-fall detection.

IMU location sensitivity and specificity
I discovered that academic literature detailing the sensitivity and specificity scores of fall detection algorithms using head-worn IMUs is scarce. Nevertheless, I came across a study by Lin et al. (2020) that explores the use of an IMU in eyeglasses for real-time fall detection and risk reduction.
Upon detecting a fall, the system promptly transmits alarm messages to a data server through a wireless network. To enhance accuracy, a complementary filter is employed to counteract the instability and drift typically associated with angular measurements from accelerometers and gyroscopes. The functionality and efficacy of this system were demonstrated through experiments involving 120 falling and 450 non-falling actions across five participants. These trials yielded a fall detection algorithm accuracy of 95.44[%].

User scenarios
When a fall occurs, and it is picked up by the Dopple Earbuds:

1. Immediately, the cameras are switched from stand-by mode to active mode to capture any information regarding what could have caused the fall.
2. If the PD client lies on the floor after the fall, the camera with the worst view is switched off (it might be that the PD client is lying on the ground and the camera is obstructed)
3. Then, the user is asked by the Dopple Earbuds if they feel pain and if they can get back up.
4. Then, the user is asked if an SOS call must be made. If they confirm (via voice), they are asked who to call, this can be a caregiver, or an emergency number.
5. After this call, or if they decline the call, the user is asked to describe what happened.
6. When the user is done speaking for a 'bit', the after-fall-message is sent to the Dopple caregiver app and medical expert platform.
7. If the user called for help and it arrives, the user is asked to hand their smartphone to the caregiver/ones in aid to play back the video and the after-fall-message. This is favourable as the fall may have resulted in psychological or head trauma, rendering the PD client unable to entail what happened.
8. The IMU and camera data is stored on the Dopple app, and on Dopple falls database for future training of their falls detection algorithm.

When a fall did not occur, but it was picked up by the Dopple Earbuds regardless, at item '3' in the enumeration of the previous scenario, the user tells that they did not fall. In that case, the cameras are shut down, and the shot footage is wiped. The IMU data of the incident is labelled as false positive and saved to Dopple's falls database.

Conclusion
The exploration into designing an effective falls detection system within earbuds highlights the intersection of cutting-edge technology and user-centric design. The research, drawing from key studies by Usmani et al. (2021) and Grisales-Franco et al. (2015), underscores the potential of both machine learning and expert rule algorithms in enhancing fall detection accuracy in wearable devices. Feld et al. (2023) further contribute to this field by validating the ear as a viable location for sensor placement, expanding the possibilities for wearable fall detection systems. Lin et al. (2020), emphasise this claim by attaining a high fall prediction model accuracy score. This section culminates in proposed scenarios illustrating how a fall detection system should behave in real life scenarios by the Dopple Earbuds.

Figure 5.3.1: A fallen user.

5.4 Maneuver aid

The introduction of maneuver aid in the Dopple Earbuds was requested by three PD clients during client interviews. This section focuses on the design and integration of this function within the IEMs and how I intend the user-product interaction to be.

Understanding maneuver challenges in PD
Maneuver difficulties in PD clients are characterised by a range of MSs, including bradykinesia, impaired balance, reduced stride length, stooped posture, and festination. These challenges not only affect their ability to walk and navigate but also increase the risk of falls. Addressing these difficulties requires a multifaceted approach, integrating sensory cues, and real-time feedback to assist PD clients in safely navigating their environment.

Integration of maneuver aid
The integration of maneuver aid in the Dopple Earbuds involves leveraging the device's sensor technology and auditory feedback system. Utilising gyroscopic and accelerometer data, the IEMs can detect changes in gait patterns and provide real-time auditory cues to assist in correcting posture and enhancing stability during movements. This proactive approach aims to improve mobility and prevent potential falls during certain measurable maneuvers, contributing to increased autonomy and confidence in PD clients.
Secondly, in most cases, the activation of the maneuver aid function relies on an on-demand structure. Hence, I foresee certain maneuvers to be very hard for an algorithm to correctly discern, resulting in PD clients being overthrown by unwanted or unnecessary auditory feedback (i.e. false positives).

maneuver specific cueing
From the filming sessions at the PvF, I obtained insights on how to include specific auditory cues to aid PD clients in taking maneuvers. I will list the most important maneuvers, available academic literary sources, and their related auditory cues.

Turning 180[°]
A study by Willems et al. (2007) revealed that, unlike controls, PD clients tend to use a wider turning-arc and take smaller, narrower steps than healthy controls. They also showed a higher coefficient of variation in step duration (6.92%) compared to controls (4.88%, $P < 0.05$). This wide-arc turning strategy was more pronounced in freezers than non-freezers. Interestingly, auditory cues were found to reduce the coefficient of variation of step duration in PD clients during turning (from 6.92 to 6.00%, $P < 0.05$). While cueing decreased gait-timing variability during turning, PD clients still maintained a wider arc for turning compared to controls.
During the filming session the PvF physiotherapist mostly gave the feedback that the PD clients their trailing leg (this is the leg that has to travel the most during a turn, i.e. the leg furthest from the centre of the turn) must not be left behind. This is where the combination of the IMU in the cradle on the one leg, and the IMU in the smartphone on the other leg shines again. By analysing their data an auditory cue can be given to the PD client insisting to make a turn:

- "Do not forget your trailing leg has to turn too."

Standing up
A 2023 study by Martin et al. demonstrated that auditory cues significantly reduce body jerk sway, indicative of smoother movements, during a sit-to-stand (STS) test, thus enhancing the stability of PD clients compared to when no auditory cues are provided. Citing Martin et al. (2023) effective cues that reduced jerk sway i.e. increased stability include:

- "When I stand up, stand with me.". Here the tester sat opposite to the PD clients. This is not a viable solution as holograms or summoning others to mirror standing up cannot be a part of the Dopple Earbuds. Nonetheless, the fact that the visual cue of imitating someone's movements in a mirror-like fashion somehow works for the human brain is fascinating (Rizzolatti, 2004).
- "Reach to my hand.". This changed to "reach for an imaginary hand.", but further research must be done to assess the efficacy of this cue.
- "Stand to the ceiling.". This is something that can be directly used by the Dopple Earbuds.
- "Bend forward at your hips and stand until your back is straight". This cue can be used by the Dopple Earbuds after the smartphone and cradle their imu measure a certain z-displacement.

Conclusion
The incorporation of maneuver aid functionality in the Dopple Earbuds signifies a major advancement in wearable technology for PD clients. By integrating sensory data analysis with personalised auditory feedback, the maneuver aid system provides a solution to the complex mobility challenges in PD. This feature epitomises the intersection of technology and empathy, empowering PD clients to navigate their world with greater confidence and independence. The design implications of this feature underscore the commitment to creating a product that is both technologically advanced and attuned to the nuanced needs of its users.

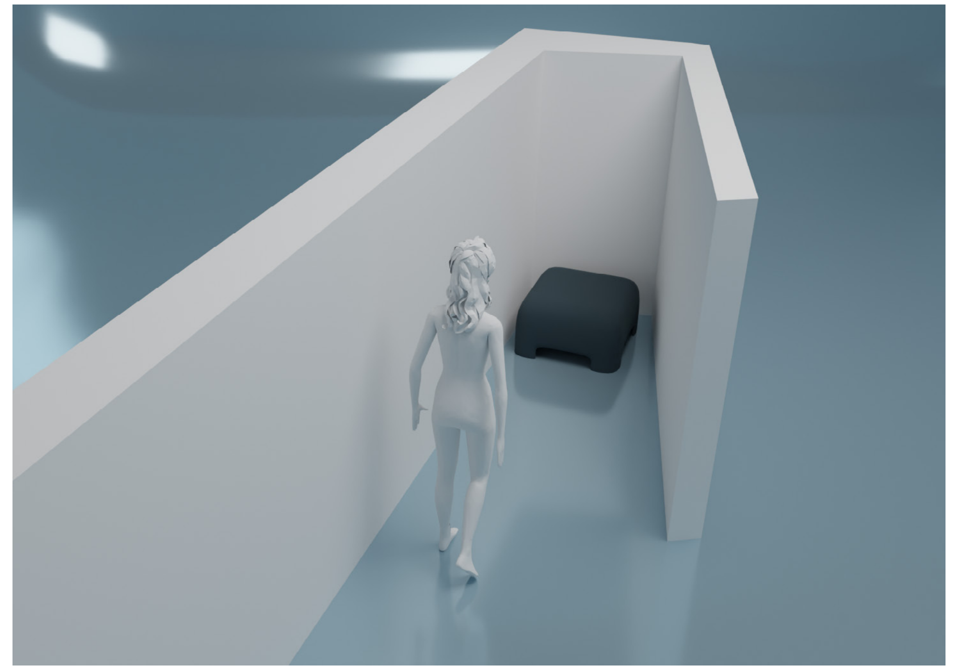


Figure 5.4.1: A user in a narrow space, in need of maneuver aid.


Figure 5.4.2: A user during a meneuver.

5.5 Posture correction

In the context of PD, posture control is a critical area that significantly impacts patients' quality of life. This section delves into the design implications of incorporating posture control functionality into the Dopple Earbuds, focusing on their potential to assist PD clients in managing the common symptom of stooped posture.

Understanding stooped posture in PD
A stooped posture refers to a bent or hunched forward position of the upper body and head. Having a stooped posture can affect balance and mobility. Studies by Rabin et al. (2016) and Kim et al. (2021) indicate the prevalence of a stooped posture experienced by PD clients and its associated health issues like back and neck pain, gait disturbance, dysphagia, and dyspnea. This postural deviation not only affects mobility but can also exacerbate other PD symptoms. Understanding its underlying mechanisms, Jacobs et al. (2005) demonstrated the potential of using IMUs to detect stooped posture, suggesting the efficacy of such sensors placed on the neck, in smartphones, or within IEMs for real-time posture assessment.

Smart wearable gap
There's a notable absence of a standardised treatment or method for evaluating interventions aimed at correcting stooped posture in PD, as noted by Srivanitchapoom & Hallett (2015). This highlights the need for innovative approaches, like the Dopple Earbuds, that can offer both real-time monitoring and contribute to developing effective treatment strategies in the form of auditory cueing and giving physiotherapists insight in the development and state of their clients' posture.

Design example that filled the gap
Filling in the gap mentioned by Srivanitchapoom & Hallett, the study by Van Wegen et al. (2018) offers promising insights into the efficacy of innovative interventions. Their research focuses on a posture correction and vibrotactile trunk angle feedback device, the UpRight (not taken up in the Existing wearables section), specifically designed for home use by PD clients with stooped posture. The hypothesis was that ambulatory use of UpRight would safely and feasibly result in a less stooped posture during daily activities.

In their methods, 15 patients wore UpRight for a week without feedback and then for another week with feedback. The results showed a significant decrease in trunk angle, measured with an IMU, averaging -5.4[°], from baseline to intervention, with no adverse events reported. Patients also found the device to be user-friendly and helpful for posture improvement. This demonstrates the feasibility of designing smart wearables that effectively reduce stooped posture, whilst underscores their potential acceptance among PD clients.

In conclusion, the study found that the feedback and correction device positively impacted ambulatory trunk angles and was safe and useful for self-managing stooped posture. This study presents a potential contrast to the absence of standardized treatment methods, suggesting that devices like UpRight and similar innovations such as the Dopple Earbuds, with capabilities for real-time monitoring and auditory cueing, ought to play a significant role in developing effective treatment strategies and providing valuable insights for physiotherapists on their clients' posture progression.

Incorporating posture control in IEMs
Utilising data from four IMUs allows for continuous monitoring of the user's posture, offering real-time feedback to facilitate posture correction. This proactive approach can potentially reduce the discomfort and complications associated with stooped posture. Furthermore, improvement of the PD clients' posture benefits other symptoms. Maintaining a sound posture will likely reduce the risk of falls, besides enhances client fitness, and deceleration of PD progression. All these factors contribute to the quality of life for PD clients (Schlenstedt et al., 2020).

Design Considerations
- The placement of IMUs is crucial to ensure accurate posture detection. The sensors must be sensitive enough to detect subtle changes in posture, providing reliable data for effective feedback.
- The Dopple Earbuds PD client app should offer an intuitive interface for users to understand posture-related feedback.
- The posture control feature can be tailored to complement physiotherapy routines, allowing therapists to monitor clients' posture remotely via their interface of the Dopple Earbuds app and adjust treatment plans accordingly.
- Ensuring the privacy and security of posture-related data is vital, particularly when integrating the IEMs with healthcare systems for remote monitoring.

Conclusion
The integration of posture control in the Dopple Earbuds will mark a significant advancement in PD management. By addressing the challenge of stooped posture, the product does not only improve the immediate comfort of PD clients but also will contribute to broader efforts in understanding and treating PD. This section underscores the importance of innovative design in healthcare technology, highlighting the potential of the Dopple Earbuds to be competitive on more than one part of the PD wearables market.

Figure 5.5.1: A user in need of posture correction.

5.6 Ancillary features

Hearing aid
Integrating hearing aid capabilities into the Dopple Earbuds is an intuitive decision, highly valued by interviewed PD clients at PvF. These earbuds not only enhance auditory experiences with high-quality sound amplification but also offer customisable settings to accommodate various hearing needs. Their dual functionality addresses the auditory challenges specific to PD individuals and seamlessly integrates with other key features such as auditory cueing for PD symptom mitigation, music playback, and call functions.

Feedback from PD clients highlighted common issues with their current hearing aids, including discomfort from the device's thread, running behind an on top the ear, interfering with their glasses' stems and the cumbersome task of weekly coin battery changes, a particularly challenging activity for those with prevalent tremor symptoms.

The Dopple Earbuds address these concerns effectively. Their design features an in-ear-only fitting geometry, eliminating any discomfort around the ear, and incorporates wireless charging capabilities, either in the cradle or on the night stand, simplifying the charging process and enhancing overall user convenience and comfort.

Call
The call functionality in the Dopple Earbuds is finely tuned for clarity and ease of use, facilitating effortless communication for PD clients. Prioritising voice clarity and incorporating effective noise cancellation, which can be safely enabled under certain circumstances, the Earbuds ensure clear and uninterrupted conversations. Mindful of the motor challenges typical in PD clients, the Earbuds' design features seamless integration with users' smartphones, offering a hands-free calling experience that is intuitive and easily accessible.

Similar to other on-demand features of the Dopple Earbuds, voice control activation is included for user convenience. This functionality becomes particularly crucial based on feedback from PD clients; the interviews highlighted the significance of reducing the number of manual interactions required to maximise the benefits from smart wearables. Therefore, enabling call functions through simple voice commands aligns with the need to minimise physical input, making the Earbuds more practical and beneficial for PD clients in their everyday life.

Music playback
Much like the call feature, the music playback capability of the Dopple Earbuds also supports the aim of minimising the number of smart wearables needed by PD clients.

The Dopple Earbuds music playback feature is tailored for both therapeutic and entertainment purposes, providing PD clients with a rich and balanced auditory experience. Recognising music's role in alleviating stress and anxiety, a common aspect of PD, the IEMs incorporate easy-to-use controls designed to suit the specific needs of PD clients. This functionality further aligns with the desire for fewer wearables, combining high-quality sound with therapeutic benefits in a single, user-friendly device.

Heart rhythm monitoring
Neurologist Dr. Beudel from Amsterdam UMC, as well as a professor gastro-enterologist at the Amsterdam UMC, advised incorporating a sensor in the Dopple Earbuds, highlighting the ear as an optimal location for measuring heart rhythm, blood oxygen saturation levels, and ECG readings. This addition introduces sensors for real-time monitoring of heart rhythm, essential for detecting any irregularities. Integrating this data with other health metrics within the IEMs provides a thorough health monitoring system, significantly enhancing PD management. The insights gathered are made accessible through the Dopple Earbud PD client app, caregiver app, and specialist app, ensuring comprehensive oversight for all involved parties.

Remote monitoring
Remote monitoring functionality in the Dopple Earbuds IEMs marks a significant step forward in PD care, offering a bridge between patients and healthcare professionals. This feature allows for the secure transmission of vital health data and facilitates telemedicine, enabling remote assessments and guidance based on visual and sensor data, thus enhancing the overall management of PD. Furthermore, it enables physiotherapists to monitor more clients in a given amount of time. Moreover, this function aims to represents the stated vision of the PvF.

Referring to the vision of PvF, a manager conveyed to the graduation project group during the green light meeting, as cited: "We strive for the PD clients to see their expert less and less, i.e. providing more proficient care. This is favourable because it decreases the workload on the medical specialists, and it allows them to devote their time to the PD clients needing physical treatment."

SOS
Numerous products, such as SOS necklaces, exist, yet PD clients demand as few additional wearables as possible. The Dopple Earbuds address this need with their integral SOS function, offering a fast and easy way for users to summon emergency assistance via voice control. Its design focuses on simplicity and efficiency, ensuring effortless activation even in difficult situations, thereby providing reassurance and improving the safety of PD clients. If both earpieces are lost utilising the smartphone for emergencies is the last resort.

5.7 Devices modes

To guarantee that the product is always functional for PD clients when required, having a range of device modes is advantageous. Three overcoupling modes are designed to conserve energy whenever feasible while providing a personalised experience to the user. Some modes are ancillary product features.

In-ear modes
Active mode
In active mode all algorithms and data collection functionality operate at full capacity to aid the user.

Stand (active) and sit (standby/sleep) detection
The Dopple Earbuds intelligently switch between walk and sit modes, using IMUs to detect and cameras to verify. Activating sit mode upon detecting that the user is seated activates standby mode

Standby mode
- Activated when the user is not actively using the IEMs but might need them again shortly. Upon activation the user gets an auditory message: "Entering standby mode.".
- The IEMs remain ready to quickly resume full functionality, maintaining a low-power state that allows for immediate reactivation of features like audio playback, call reception, or symptom mitigation functions.
- This mode is ideal for brief periods of inactivity.

Sleep mode
- A deeper state of power conservation activated after five minutes of standby mode. Upon activation the user gets an auditory message: "Entering sleep mode.".
- If an IEM's battery charge is low another message is provided: "Earbud battery at *number* percentage, please put it in the cradle.". If both IEMs have low power, the other IEM prompts the same message after the other has left the ear.
- More functions are powered down compared to standby mode. For instance, wireless connectivity is limited. Upon a trigger, provided by the smartphone, a mode-switch to standby is issued.
- This mode is suitable for situations where the IEMs are not used for several hours, like overnight or during extended periods when the user does not require main or secondary functions.
- Waking up from sleep mode will take slightly longer than from standby, as more functions need to be reactivated, and perhaps data to be transmitted within the system.
- Sleep mode switches to charge modes when the IEMs are charged.

One-ear mode
The Dopple Earbuds are designed to function even when only one IEM is equipped. This flexibility is essential for users who might prefer or require single-ear usage, or when the battery of one IEM runs out.

Adaptive noise cancelling
Noise-cancelling technology grants an immersive audio experience, especially beneficial in low-power mode, during calls, or while listening to music. Users can control this feature via the app or alternatively via voice, allowing them to choose when to block out ambient noise and when to remain aware of their surroundings, striking a balance between immersion and environmental awareness.

Customisable environment presets
With environment-specific presets, users can enjoy tailored audio settings for different surroundings. This personalisation enhances the listening experience in various environments, from quiet indoor settings to bustling outdoor scenes.

Selective Audio Enhancement
Selective audio enhancement amplifies crucial sounds like alarms or voices, assisting users with hearing challenges. This feature ensures that important audio cues are not missed, enhancing safety and communication.

In-app function selection
The accompanying Dopple Earbuds app provides users with the flexibility to select and customise various functions and settings of the IEMs. This feature empowers users to tailor their device according to their specific needs and preferences.

Out-of-ear modes
Charging in cradle or on night stand
The charging cradle and night stand can recharge the IEMs. Since the cradle is equipped with a BLE device, it is also able to download and install software and firmware updates, downloaded on and sent by the smartphone. The cradle and night stand act as central hubs. They ensure that the IEMs are charged, up-to-date, and ready for use.

Find my device mode
The 'Find My Devices' feature in the Dopple Earbuds PD clients app helps users to locate their lost IEMs or cradle by means of GPS tracking.

IMU (re)calibration mode
This mode is clarified in the Calibration section.

Synchronisation mode
Syncing collected (health) data and analysis with the Dopple Earbuds PD clients app maintains a comprehensive view of the user health status, among other insights that have to be conceived in future research and design cycles. This integration is invaluable for tracking health metrics, and embellishes a tailored user experience. This mode operates asynchronously from the other product features, meaning its operation is unaffected by any other mode.

5.8 Product function analysis

This section offers visual diagrams that describe the flows of electrical power, data, algorithms/functions, object input, and object output. With object I mean the 'loose' parts that make up the entire system:

- Wall power socket
- Left Dopple Earbud
- Right Dopple Earbud
- Cradle
- Nigh stand
- Smartphone

To keep the overviews of the system orderly and comprehensible, I will only address the two top levels of complexity.

First level
In the first level, only electrical power and data flows are depicted. A simplification I made is the bounding box around the earbuds. In practice, as discussed with Dopple's engineers, each individual IEM reciprocally transmits data to both the smartphone and the cradle. Moreover, this diagram exclusively represents Bluetooth data traffic and does not include the file transfer that occurs from the cradle to the IEMs when they are docked inside it.

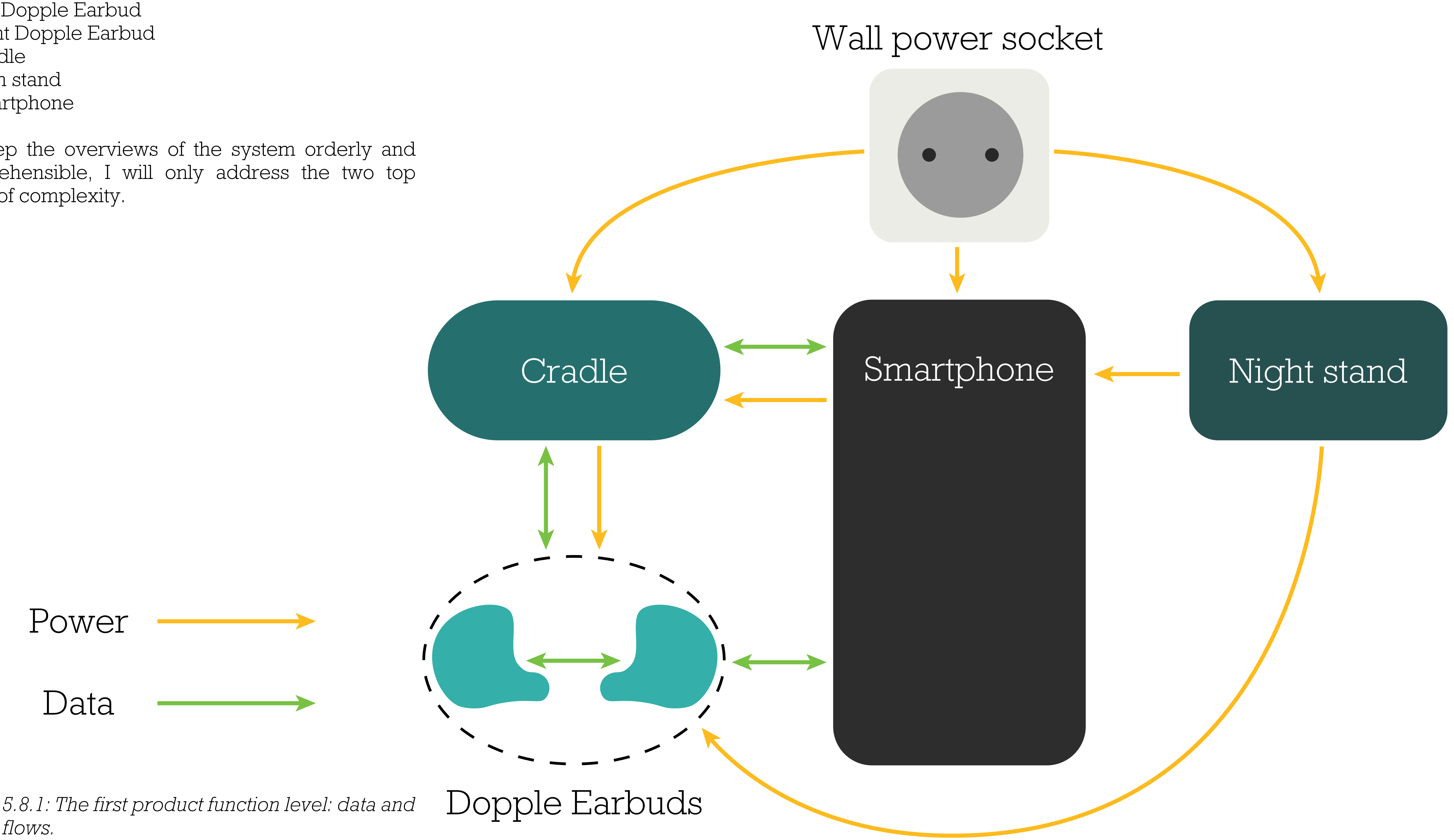


Figure 5.8.1: The first product function level: data and power flows.

Second level
In the second level, the objects become the functions and algorithms that make up the entire system. The information flows are defined as input and output. Information flows can be adjusted by the user, output by an algorithm or function. To safeguard the readability of this second level, the calibration phase prior to the product use phase is a process outside the scope of this thesis, as well as recalibration during the product use phase of the system is not taken up in the diagram.

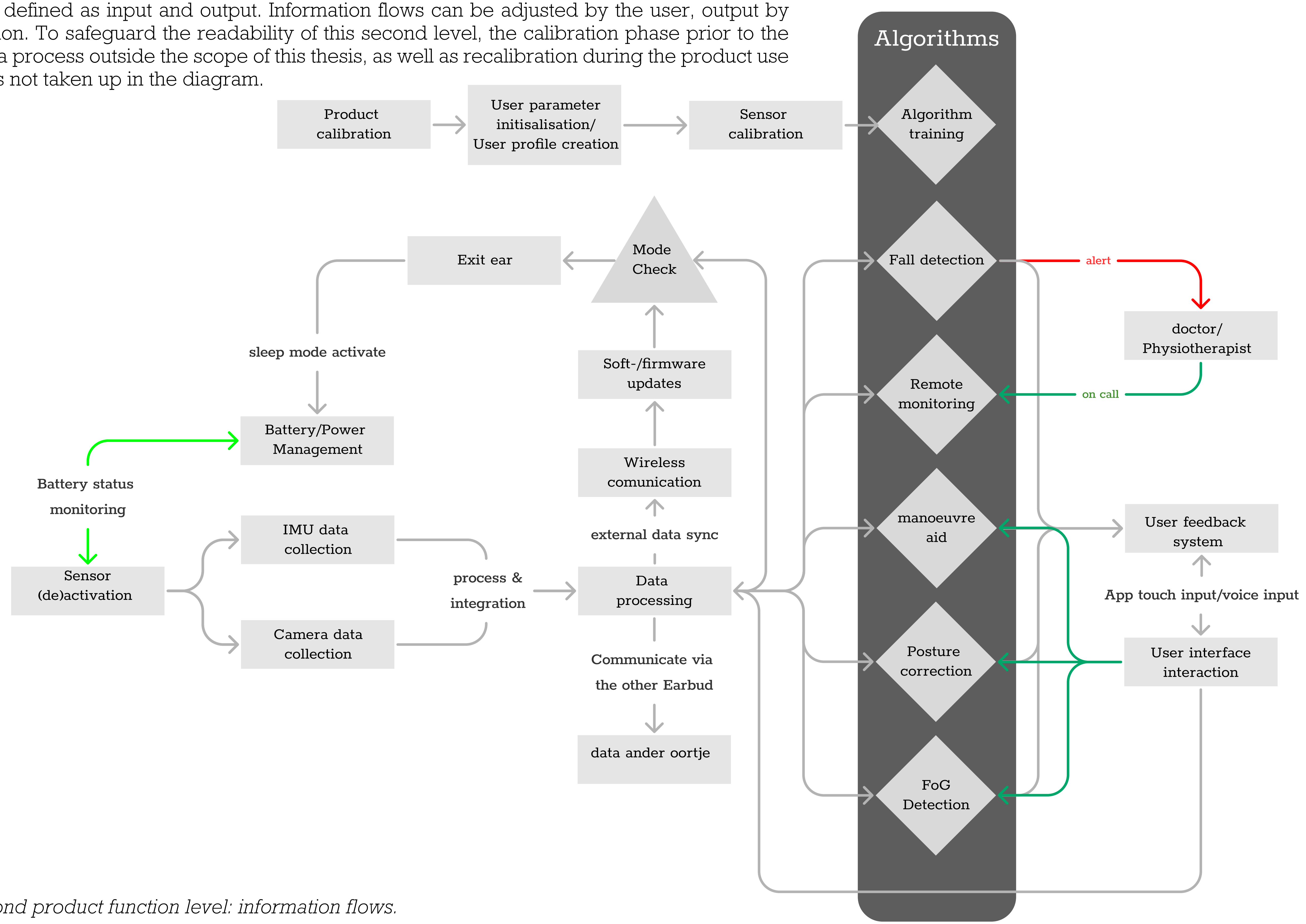


Figure 5.8.2: The second product function level: information flows.

5.9 PD gait characteristics

For the implementation of the product functions into the Dopple Earbuds, the power consumption calculation, and the algorithm design, it is necessary to get the gist of the gait characteristics of PD clients. In this section I want to make an educated guess on duration PD clients are on foot.

Healthy gait versus PD gait
A study by Zanardi and colleagues analysed thirty-five studies on the gait characteristics of healthy individuals, representing 14,015 participants (6808 women, 5135 men, and 2072 sex not specified). They determined the usual walking speed of healthy individuals to be 1,31[m/s].
In another meta-analysis they did on sixty-nine PD gait studies, they concluded that PD clients, partaking in self selected walking speed tests (SSWS), on average walk 0,17[m/s] slower than healthy individuals. The meta-analysis by Zanardi et al. also reveals the average stride length for PD clients to be 0.16[m] lower.

I confirmed the gait data established by Zanardi et al. by walking across the 100[m] athletic sprinting track close to my home 10 times, here I averaged a walking speed, cadence, and stride length of 1,34[m/s], 111[steps/min], and 0,72[m] respectively.

For general fitness, most adults should aim for 10,000[steps/day] even though PD clients might not achieve this (in the slightest), younger more vital individuals with PD might achieve this. As I intended to target them too, I adopt this step goal as a driving parameter.

Estimating active function time
The following calculations give an estimate on the expected time the device should be active, i.e. monitoring PD client gait:

1. v_pd = v_healthy - delta_v =1,31 - 0,17 = 1,14[m/s]
2. s_step_pd = 0,72 - 0,16 = 0,56[m]
3. t_step_pd = 0,56 / 1,14 = 0,5[s]
4. t_afoot_per_day_pd = 10.000 * 0,5 = 5.000 [s] = 83[min] = 1,5[hour] (roughly)

To compensate for the extra healthy individuals among PD clients that strive to 'go that extra' mile, and the fact that the some of the functions like the FoG detection algorithm have to be operational not only during movement, but also whilst standing, I add a factor of roughly a third to the active function time, rendering it to two hours or 120[min] in total. I will use this active time in the following section assessing the power consumption of the product.

Ancillary academic sources assessing PD gait characteristics
I think the method I took in estimating average gait duration, and thereby an estimated function time is adequate. However, for further development of the Dopple Earbuds, more research must be done to further narrow down PD clients' gait specifications. To elaborate on my work Dopple might fancy to look into academic sources that do not picture the same story:

- A study by Lamont et al. (2015) investigated factors influencing daily walking activity in people with mild to moderate PD. They found that individuals with PD spent around 77[min] walking per day, predominantly at moderate intensity, averaging about 6300[steps/day]. The study showed that disease severity was a predictor of time spent in moderate-intensity walking, while a combination of gait performance (measured by TUG Tests) and executive function predicted engagement in high-intensity walking activities. The research suggests that in addition to disease severity, gait, and cognitive factors, other personal and social factors might also significantly affect activity levels in people with PD.
- Lord et al. (2013) shows that fewer and fewer PD clients achieved the recommended 30 minutes of walking per day.
- Canning et al. (2006) found that individuals with mild to moderate PD walked shorter distances in the 6-minute walk test (6MWT) compared to healthy controls. Despite similar peak walking speeds, PD participants used a lower percentage of their maximum speed and their walking capacity was significantly limited by hypokinesia and muscle strength. This suggests benefits of high-velocity training for sustained walking ability in PD.
- In their 2023 investigation, Ginis et al. discovered that individuals with Parkinson's disease predominantly engaged in walking at lower intensities. On average, they spent 157,3[min] minutes walking at a pace of 1-19[steps/min] and 81.3[min] at 20-39[steps/min], with the duration decreasing at higher step rates. Notably, the longest continuous walking episodes were at the minimal intensity level, averaging 15.9[min]. It was also observed that prolonged walking sessions lasting 20[min] or more at any step rate were infrequent. These findings highlight the necessity of interventions designed to enhance walking intensity among Parkinson's patients. The full study provides a comprehensive analysis and is available.

5.10 Battery size calculation

In my one week long stay at Dopple, I also got the chance to talk to some of their systems engineers. Bert (electronic systems) and Frank (senior radio frequency systems) helped me to read data sheets of the sensors I proposed to use. This information is crucial in the process of finding out if the conceived earables concept is feasible.

In the intricate world of earbud technology, the significance of battery size cannot be overstated. It is a fundamental aspect that can dictate the success or failure of the product, particularly in designs where power efficiency and longevity are crucial. The complexity of this scenario is best understood by dissecting the numerous factors influencing power consumption, specifically in scenarios involving intricate data transmission and Bluetooth communication.

IMU data rate
To begin, let's explore the data generation within the Dopple Earbuds. The IMUs are pivotal, each axis delivering 16-bit data. With six axes involved, this equates to 96 bits per data set. Considering a refresh rate of 128 Hz, the data generation rate stands at 128 sets per second, translating to a data rate of 12,288[bit/s] for each earpiece. For a pair, this rate doubles to 24,576[bit/s].

Component power draw
The power consumption for Bluetooth, specifically for Bluetooth Low Energy (BLE), is approximately 15[mA] during active transmission. This becomes critical in calculating the overall power requirements. For continuous transmission 120[min], the power consumption can be approximated as 30[mAh].

However, this estimate is somewhat simplistic. In practice, additional power is consumed for operating the IMUs, processing data, and maintaining device operation, thus necessitating a larger battery capacity. Not accounted for in this initial estimate are the power demands of the IMUs themselves, the device's internal processing, the efficiency and consumption of the Bluetooth module, and the power consumption in idle or standby modes. The actual data packet size may also be larger due to additional information included in Bluetooth communication.

To delve deeper into the power consumption specifics, various components and their energy requirements must be considered. The static current, essential for keeping blocks active, is around 90[μA] in the power domain when the device is on. Each earpiece has a DSP block consuming 535[μA] and a micro-system domain of 250[μA]. The typical voltage (VDD) for these is 0.8[V]. Besides, BLE operates at 40[MHz]. The radio's static current during data bursts is approximately 250[μA].

The DSP's current ranges from a low of 15[μA/MHz] to a high of 100[μA/MHz] in worst-case scenarios. The SBC discrete cosine component for audio processing requires about 65[μA/MHz]. The Cortex M33 CPU, essential for BLE data transmission, processes sensor data via inter-integrated circuit (I2C) and typically operates at 40[MHz]. The crystal's active current is around 50[μA/Hz], but this only needs to be active 5 to 10[%] of the time, reverting to a static current of 90[μA].

In radio transmissions, for sending data at 25[kbit/s] as part of a 2[Mbit/s] stream, the current is about 0.13[mA] for VDDA at 1.8[V]. Additional currents in transmission modes include 0.65[V] at 1.1[mA] for the digital block and 3.8[mA] at 0.95[V], typical for a 3.7[V] system. When the radio is receiving, the currents are 1.8[V] at 0.13[mA], 0.65[V] at 1.1[mA], and 0.95V at 3.8[mA], all at 100% duty cycle.

The efficiency of these systems is typically around 85%, and the battery power can be calculated accordingly. The battery's power, divided by 3.7[V], gives the required current. In low power modes, such as transitioning from camera to active mode, energy savings can be achieved, but the transmission currents are significant. For instance, 1.8[V] with 0.04[mA] is needed just to keep the system under tension, and transmission at 0.8[V] can range from 6[mA] to 10.5[mA]. For a 24[kbit/s] data transmission, the current is approximately 2[mA], and for camera image transmission, it's around 8[mA].

Electronics fact-sheets and power calculations
The fact-sheets for all chosen sensors and chips from which I picked to make the educated guess of power consumption are sourced in Appendix C. The calculations for the mean power draw and required battery capacity are done using python. The script is listed in Appendix H.

For the following functions and estimated low power mode times (in PD Client rest) and active (differing per feature):

- Fall detection
- FoG detection
- Sit detection
- maneuver assistance
- Remote monitoring
- Camera operation

A total power consumption (Active + Low Power Mode) of 155.06[mWh], and required battery capacity of 20.54[mAh] were calculated. Note: these remain estimates.

5.11 System connectivity and communication

Results of poor BLE connection
Poor BLE connections can result in slower data transfer rates. This can be particularly problematic during live video feed of the IEMs during a fall or whilst remote monitoring. The IEMs might consume more power to maintain a connection in the presence of interference or weak signals. This can lead to faster battery drain. A worse connection can also imply a reduced effective range, rendering the IMU data from the IEMs useless since it is not used for predictions by the smartphone. Poor connections are more prone to disconnections and interruptions. In some cases, this might lead to data being lost or corrupted during transmission, which could also lead to critical failure of the functional algorithms.

Designing for effective system communication
A crucial design aspect is the decision to transmit IMU data from one IEM at a time. What IEM transmits is based on factors such as connection stability and battery efficiency. Utilising custom IEM's that do not self-dequip under normal circumstances, grants a rigid frame between both IEMs, i.e. the skull. This renders sending IMU data from both IEMs as a waste of energy because the data streams of both IEMs are equivalent, except for a translation from the one to the other ear.

Optimising battery efficiency and data accuracy
From previous experience in the form of image recognition, I predict that the power draw of the neural network (NN) responsible for the festination and FoG predictions will be quite substantial. Therefore, the decision was made to let the heavy matrix calculations required for the prediction model to function, run on the user's smartphone, located in their pants' pocket. In this arrangement the smartphone not only serves as a central data processing unit, it also leverages the smartphone IMU at a whereabouts closer to the feet of the PD clients. To underline this choice, I cite Luigi Borzì in one of his emails to me: "*Generally, the closer the sensors are to the lower legs and feet, the better the performance you can get.*"

Gait to cradle
Luigi also pointed me to Bächelin et al.'s (2021) discovery that leveraging more IMUs (at different locations) improves the festination and FoG prediction model's sensitivity and specificity scores (Appendix D). Therefore, I insist that the cradle, wherein the Dopple Earbuds are kept, charged, paired via bluetooth, and updated in terms of software, is also equipped with an IMU a BLE device to transmit its data stream to the smartphone. Like the smartphone, the cradle has to be carried in the hip-pocket of the PD client's pants. However, not in the same pocket as the smartphone. This has several reasons:

- Complementary data collection: The cradle's IMU would provide an additional perspective on the user's movement. Placing it in the opposite pocket to the smartphone helps capturing a more comprehensive range of bodily motions, such as detecting asymmetries in gait or body movements that might be missed if both devices are on the same side.
- Improved spatial awareness: This setup could enhance the system's understanding of the user's spatial orientation and movement dynamics. The differing locations of the cradle and smartphone allow for the gathering of data points from various axes and planes, contributing to a richer and more detailed movement profile.
- Redundancy and accuracy: Using three separate data sources (one IEM's IMU, the smartphone's IMU, and the cradle's IMU) provides redundancy, which can improve the overall accuracy of the system. If one device experiences a temporary issue or interference, the other can compensate, ensuring continuous and reliable monitoring.
- Minimised interference: Electronic devices can sometimes interfere with each other's signals. Keeping the smartphone and cradle's IMU in separate pockets can reduce potential electromagnetic interference.
- Enhanced algorithm calibration: Data from multiple sources is proven to be beneficial for calibrating algorithms, especially those related to movement and gait analysis. This can lead to improved detection of FoG episodes and more accurate feedback for the user.
- Potential for cross-device communication: This setup could allow for innovative cross-device communication strategies. For instance, if the cradle detects certain movements indicative of a specific condition or action, it could trigger the smartphone to perform a particular function, such as sending alerts or updating data logs.
- Ease of (re)calibration: When the IMUs of the system's parts (IEM, cradle, and or smartphone) need to be recalibrated, the IEMs can reside in the cradle. As they are fixed in the cradle, this improves the (re)calibration of the parts. Hence, they all have to take the same maneuvers, as explained in the Calibration section.

6 Ear-worn product ergonomics

During one of my stays at Dopple, I got the chance to talk to one of their human factors engineers. To prepare for the interview that took approximately one and a half hour, I wrote down some questions, these can be found in Appendix B. The knowledge gained during that interview is listed here in key points with explanation.

Pressure distribution and comfort
The design of an IEM should aim to avoid small pressure points and distribute pressure evenly, especially for long-term wear. Products that go deeper into the ear can become uncomfortable over time. A natural, open fit that is less deep in the ear enhances comfort.

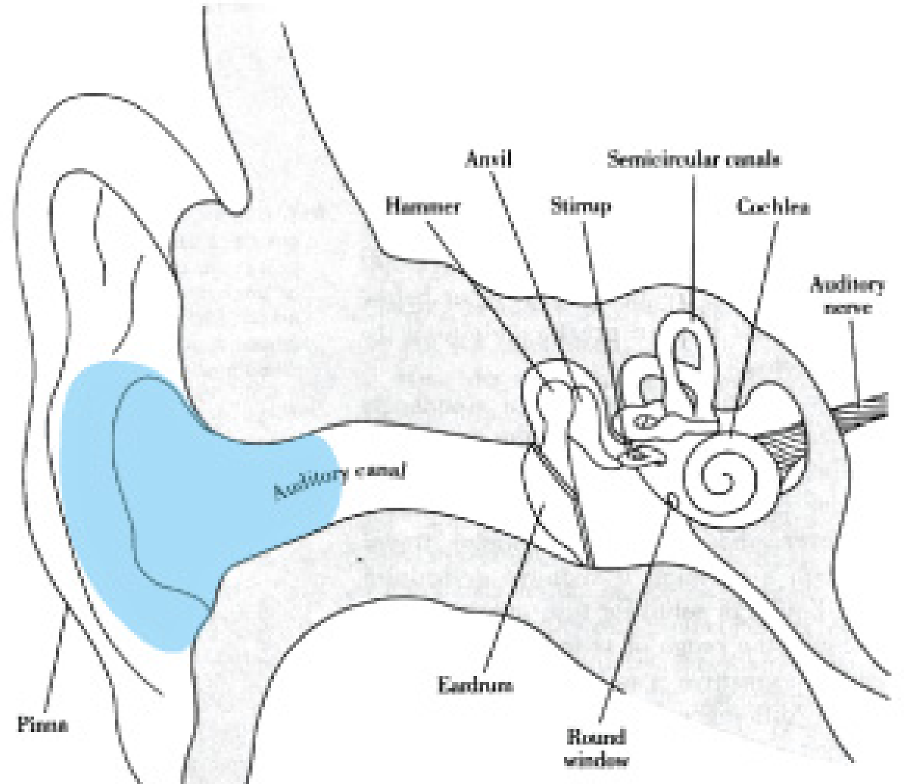


Figure 6.1: Space between earpiece and Eardrum.

Ventilation
Proper ventilation is crucial to avoid the occlusion effect (the sensation of the ear being sealed off), which can be more pronounced when eating. This ties into the design aspect of ensuring natural ventilation to allow the ear to 'breathe,' reducing issues like excessive wax production.

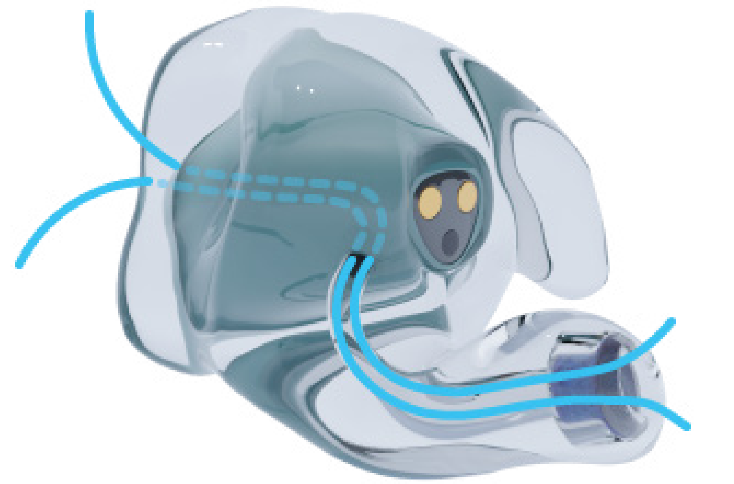


Figure 6.2: The open IEM principle.

Sound Quality
From PD clients interviews I found that practically all of them cannot be bothered with extra smart devices. Thus, I want them to only wear these IEMs, i.e. not require others to listen to music, radio or usage during phone calls (and carry the cradle and their smartphone). This poses the need for apt sound quality. The ear canal acts as a resonance chamber, naturally amplifying sounds between 1 and 3 kHz, which is critical for understanding speech, used as the main form of feedback for the user. There's a trade-off between the size of the speaker (driver) and sound quality.

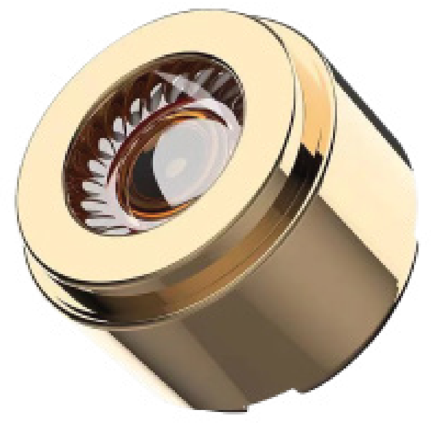


Figure 6.3: A high quality 6[mm] IEM driver.

A 6[mm] driver can provide good sound quality if it seals well with the ear. However, as discussed before, this is a trade-off with the ventilation of the inner ear canal. A whilst a driver diameter smaller than 6[mm] has a nice high frequency response, it requires a very tight seal to have any bass response. Furthermore, the majority of PD clients is older than sixty-five, that part of the population hears less high frequencies anyway.

A driver diameter larger than 6[mm] would require a tight seal. At the same time, it would only grant a better lower-frequency response, which is not a necessity in these earphones. Besides, Dopple's current IEMs with a 6[mm] driver have a good range to enjoy all types of music. This is something I tested extensively whilst writing this Thesis.

Retention
Secure retention of the product in the ear is vital. This can be achieved by designing it to connect at a minimum of three points in the ear, reducing movement and enhancing stability. I was told that Dopple's IEMs have shown retention success in any ear. Thus I will not design for edge-cases with regards to retention.

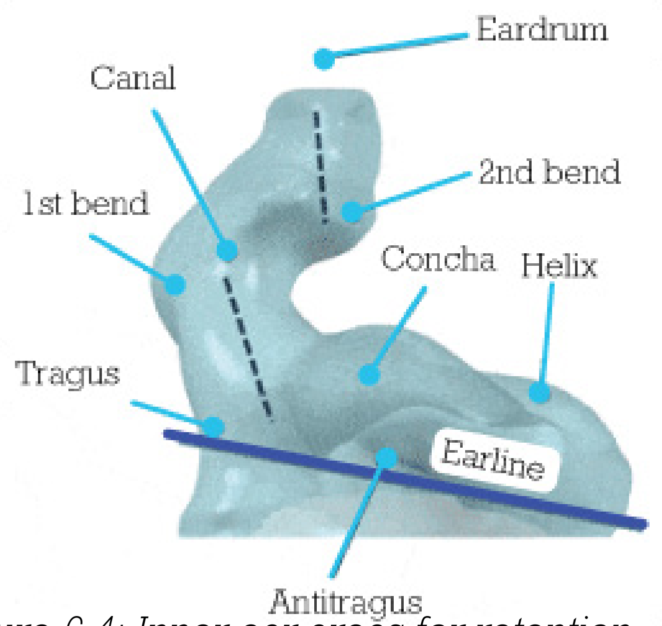


Figure 6.4: Inner ear areas for retention.

Figure 6.5: Retention visualised.

As can be seen in Figure 6.5, I was pushing with around 0,3[kg] of force. Only with the vector angled upwards and slightly out of my head I was able to unequip the model (visualised in Figure 6.6).

Figure 6.6: Only with a substantial force angled out of my head and upwards I was able do undo the model.

Variability in ear shapes

Ear shapes vary significantly among users. Some people have different shapes for each ear, requiring either modular designs or custom solutions. The design accounts for this variability to ensure comfort and effective sound delivery. How this was accounted for is talked about extensively in the Calibration section.

Figure 6.7: Every ear is different.

Material choices

Materials are chosen for biocompatibility, functionality, and aesthetic appeal. I have deleted the 'Chosen materials section' as it is not relevant for this stage in product design, and neither for Dopple.

Figure 6.8: The product is given a distinct feel due to its materials.

Durability and maintenance

Over time, ears can adapt to the shape of in-ear products, every 5 years the (Beter Horen, 2023) re-evaluation and possible remoulding to maintain a proper seal, especially in the hearing protection industry.

User experience over time

While there may be an initial 'wow' factor, because new technology seems amazing, ergonomically speaking, there should be as little nuisance as possible. Providing long-term comfort however, is a significant challenge. Generally speaking, many earbuds have been proven to be wearable for a long time, especially hearing custom-fitted aids. Furthermore, I was told by Dopple's engineers that they have a custom in-ear product that achieved comfortable wearing times of at least eight hours. Those benefits are reaped in the Dopple Earbuds as well, since the in-ear shell in this product is constructed and manufactured the same, considering product surfaces. The only difference being: the Dopple Earbuds will weigh a few grams more because of the battery and electronics, and the shell that is slightly larger for easier equipment, taken into account the tremors PD clients have. I wore the PLA 3D printed 1:1 scale in-ear models for 36 hours, so if a PD client ever forgets to unequip their Dopple Earbuds, this will not be a harmful situation. However, I could only sleep on my back. Sleeping on the side of the body with my head on the pillow was so uncomfortable that can safely say this would get noticed by the PD clients, and subsequently dequipped.

Figure 6.9: The 1:1 PLA model I wore for 36 hours.

Recharge and battery life

Battery life and recharge time are essential considerations, especially since rechargeable batteries have lower energy density. Most of Dopple's IEMs have a quick charge function where they can be charged to about 80% in 30 minutes. Having lunch or resting does not require to have the Dopple Earbuds in, making for the perfect time to charge them. During the night, the Dopple Earbuds can be put on the night stand, visible in Figure 6.10.

Figure 6.10: charging on the night stand.

Size and visibility

Users often prefer products that are less visible and protrude minimally from the ear. However, having asked this to the PvF PD clients, they generally do not care about it. One even said that he would wear large headphones if that would help him with his condition. Having shown the PD clients Figure 6.11, they all agreed that this form of the concept was acceptable.

Figure 6.11: How the worn product looks like (this instance without cameras protruding side-ways).

IEM size and weight implications

From the feedback user tests it became clear that PD clients can experience difficulty with equipping IEMs. This necessitates the need for the IEMs to be bulkier than Dopple's usual IEM stealthy design.

As mentioned before, human ears never cease growing. As the IEMs are closely fitted to the inner ear geometry, the medium high impact acrylic in-ear shell can become so large that the ergonomic quality decreases because of ear fatigue. To accommodate for this, parts of the shell can be printed hollow, visualised in Figure 6.12, to decrease the amount of printed material. However, this must be done with careful FEA to retain fracture toughness and rigidity.

Figure 6.12: Partially hollowed out shell (left), 100% infill DLP print (right).

7 Product aesthetics

Whilst product aesthetics is not a main focus of the project, it is important to note that the PD clients might have differing wishes with regards to the colour ways in which the Dopple Earbuds will be available. This chapter showcases some options.

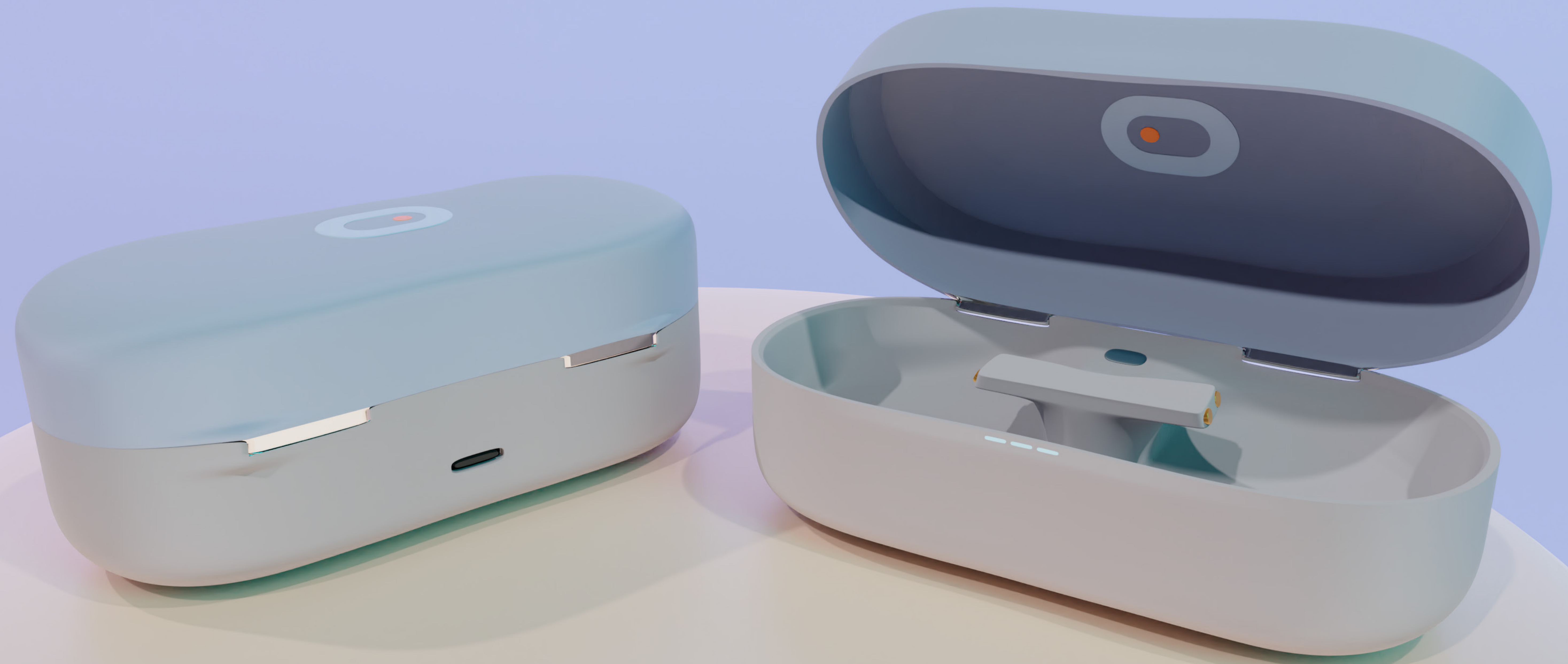


Figure 7.1: Sublimation allows for the application of any color to the polymer cradle. However, the stainless steel hinges cannot be colored through this method. To achieve colored hinges, anodising can be used as an alternative.

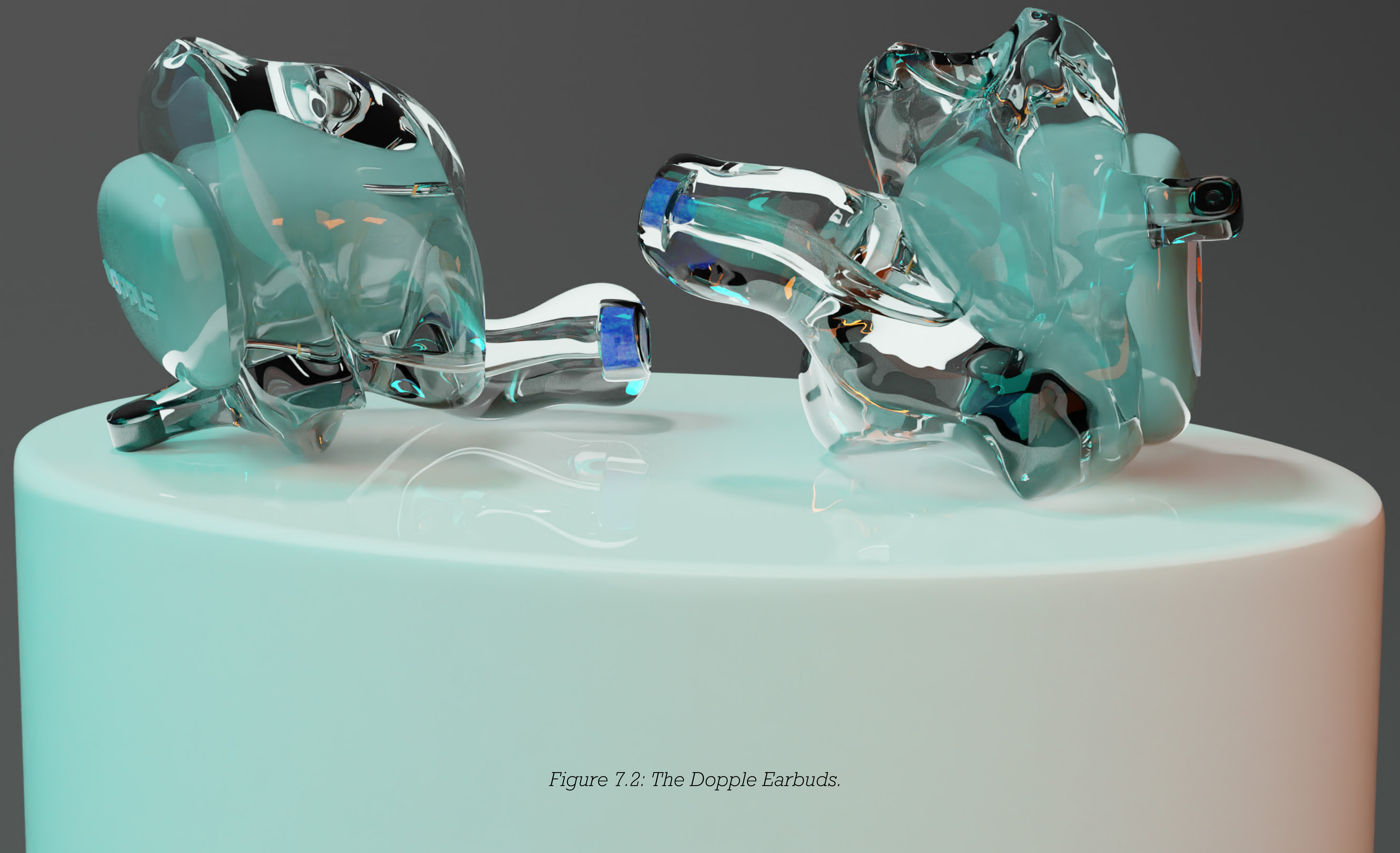


Figure 7.2: The Dopple Earbuds.

Figure 7.3: A caucasian skin coloured Dopple Earbud in a matte green bottom and high-gloss top cradle.

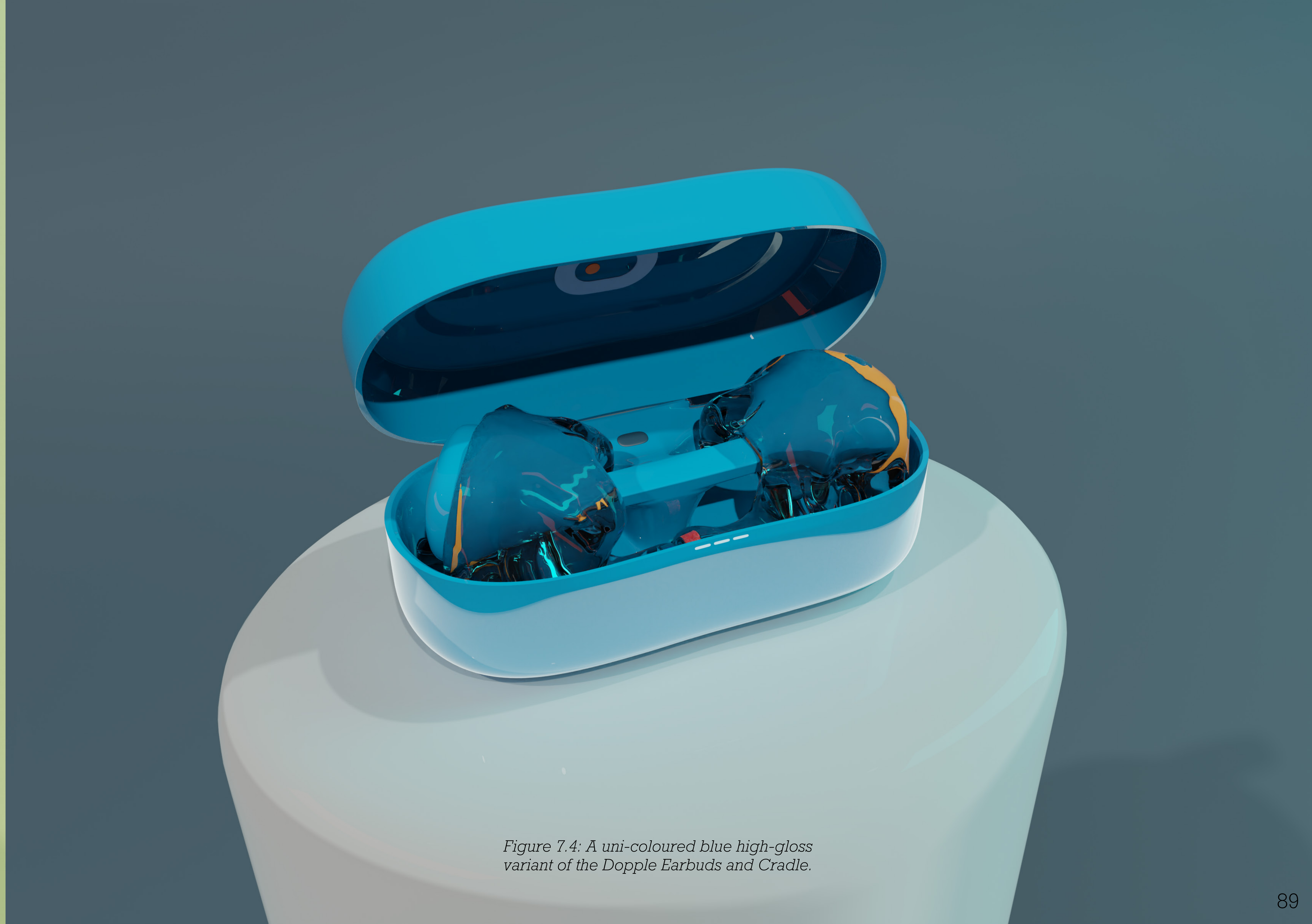


Figure 7.4: A uni-coloured blue high-gloss variant of the Dopple Earbuds and Cradle.

8 Dopple Earbuds 2-pager (EN)

Tackling symptoms with precision and care.

Primary Functions:

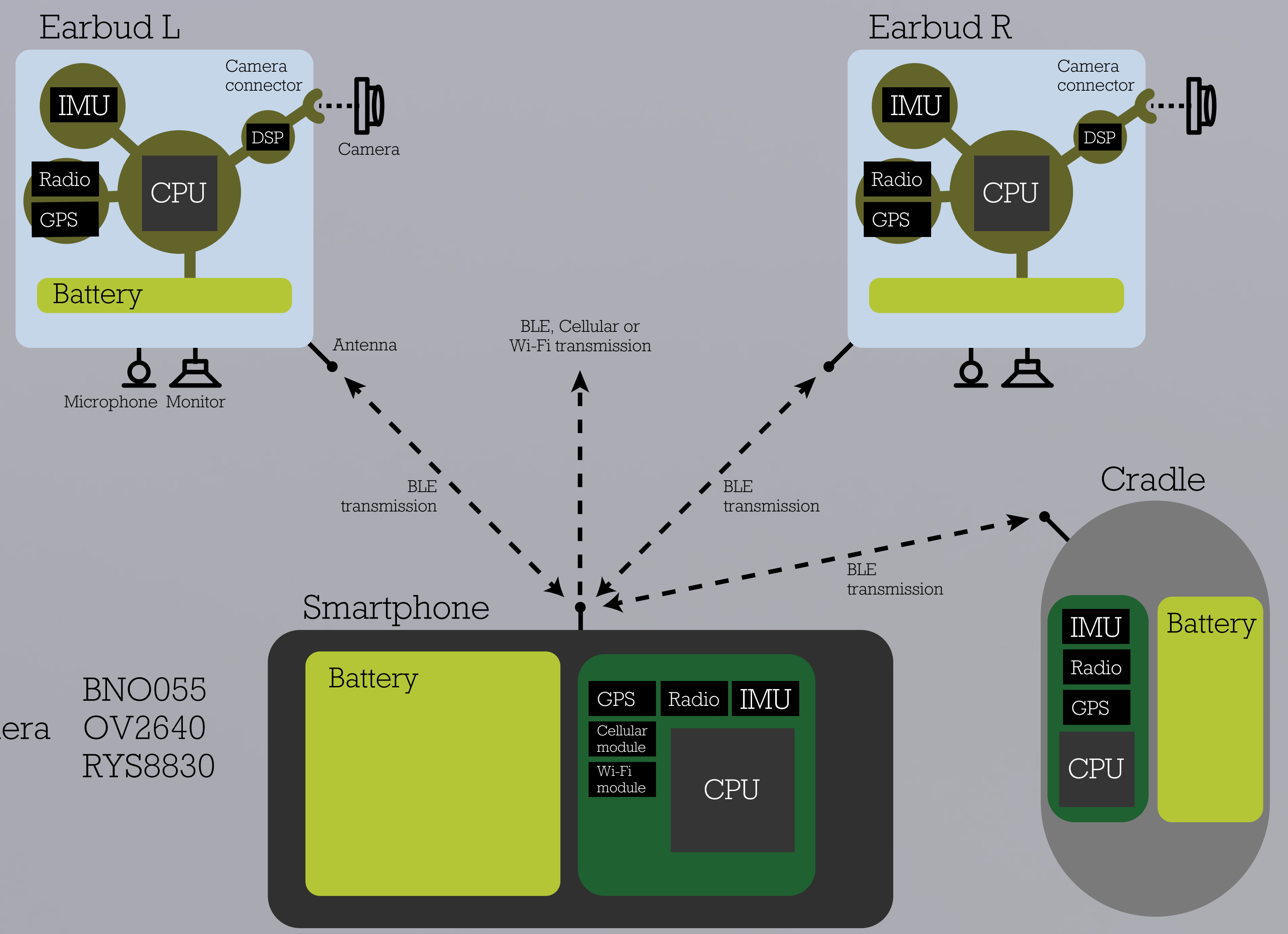
- Freeze of Gait (FoG) Mitigation: Harnessing advanced algorithms to predict and counteract FoG episodes, enhancing mobility and confidence.
- Festination Control: Intelligently detects and provides real-time auditory cues to stabilise walking patterns, reducing the risk of falls.

Secondary Functions:

- Remote Monitoring: Enables physiotherapists to track patients' progress and tailor rehabilitation programs remotely.
- Heart Rhythm Monitoring: Offers crucial health data, ensuring timely medical interventions.
- SOS Alerts: Instant emergency notifications, providing peace of mind for patients and caregivers.
- Music and Call Functionality: Combines therapeutic benefits with everyday convenience.

Seamless integration for enhanced care

- Dual Ear Monitors (IEMs): Work in synergy to deliver accurate health monitoring and effective symptom control.
- Smartphone App: Acts as the control hub, offering patients easy access to settings and therapists insights into patient progress.
- Charging Cradle: Ensures the IEMs are always ready for use, facilitating updates and syncs.



IMU	BNO055
Camera	OV2640
GPS	RYS8830

Relieving the burden on physiotherapists

Dopple Drops significantly reduce the frequency of in-person therapy sessions needed, allowing physiotherapists to focus on patients requiring more intensive care. By providing detailed data on patients' daily activities and symptom management, therapists can remotely adjust treatment plans, making care more efficient and responsive.

A solution that improves over time

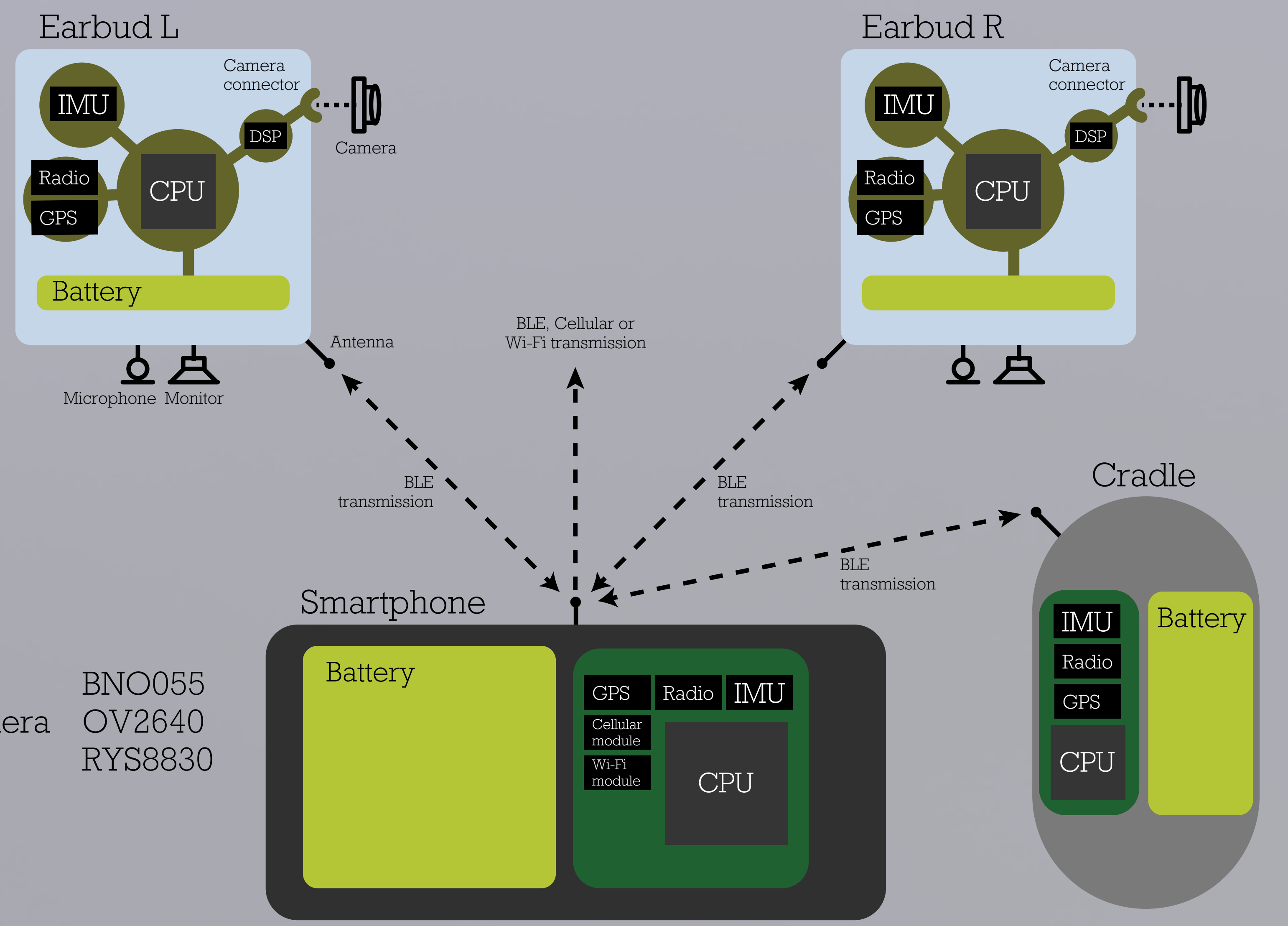
The Dopple Earbuds harness supervised learning, which ensures continuous refinement of its detection algorithms. Through voice iput from the user, the system progressively learns to respond better to individual symptoms and needs. Users can provide feedback through the app or voice commands, enabling the system to discern between true and false FoG episodes. This ongoing adjustment and fine-tuning mean that the RAS cueing and FoG mitigation, and fall detection become increasingly accurate and effective.

8 Dopple Earbuds 2-pager (NL)

Aanpakken van symptomen met precisie en zorg
Primaire functies:
- Bevriezing van de gang (FoG) vermindering: Geavanceerde algoritmes gebruiken om FoG-episodes te voorspellen en tegen te gaan, waardoor mobiliteit en zelfvertrouwen verbeteren.
- Festinatie beheersing: Detecteert op intelligente wijze en biedt real-time auditieve signalen om looppatronen te stabiliseren, waardoor het risico op vallen wordt verminderd.

Secundaire functies:
- Op afstand monitoren: Stelt fysiotherapeuten in staat om de voortgang van cliënten te volgen en revalidatieprogramma's op afstand aan te passen.
- Hartslag Monitoring: Biedt cruciale gezondheidsgegevens, zorgt voor tijdige medische interventies.
- SOS Alerts: Directe noodmeldingen, biedt gemoedsrust voor cliënten, naasten en verzorgers.
- Muzieken Oproepfunctionaliteit: Combineert therapeutische voordelen met dagelijks gemak.

Naadloze integratie voor verbeterde zorg
- Dubbele oormonitors: Werken samen om nauwkeurige gezondheidsmonitoring en effectieve symptoombeheersing te leveren.
- Smartphone App: Dient als het controlecentrum, biedt cliënten gemakkelijke toegang tot instellingen en therapeuten inzicht in clientenvoortgang.
- Oplaadstation: Zorgt ervoor dat de IEM's altijd klaar zijn voor gebruik, faciliteert updates en synchronisaties.



IMU	BNO055
Camera	OV2640
GPS	RYS8830

Verlichting van de last voor fysiotherapeuten
Dopple Earbuds verminderen aanzienlijk de frequentie van benodigde persoonlijke therapiesessies, waardoor fysiotherapeuten zich kunnen concentreren op cliënten die intensievere zorg nodig hebben. Door gedetailleerde gegevens te verstrekken over de dagelijkse activiteiten en symptoombeheersing van cliënten, kunnen therapeuten behandelplannen op afstand aanpassen, waardoor zorg efficiënter en responsiever wordt.

Een oplossing die verbetert met de tijd
De Dopple Earbuds gebruiken begeleid leren, wat zorgt voor continue verfijning van de detectiealgoritmes. Door steminvoer leert het systeem geleidelijk beter te reageren op individuele symptomen en behoeften. Cliënten kunnen feedback geven via de app of spraakopdrachten, waardoor het systeem leert om beter onderscheid te maken tussen bijvoorbeeld echte en valse FoG-episodes. Deze voortdurende aanpassing en verfijning betekenen dat de RAS-aansturing en FoG-vermindering, en valdetectie steeds nauwkeuriger en effectiever worden.

9 Future research opportunities

Here are several directions Dopple should consider attracting new student contracts for:

User experience (UX) design

- Deep Dive into User Journey: Map the complete journey of a Parkinson's client using the device. Identify pain points and moments of delight to enhance the overall user experience.
- Usability Testing: Conduct extensive usability tests with prototypes to gather qualitative data on the user's interaction with the device.
- Accessibility Features: Focus on making the device accessible to users with varying degrees of tech-savviness, dexterity, or other impairments.

Technology integration and innovation

- IMU count for improved predictions: Based on Luigi Borzi's recommendations, I made the decision to only use one IEM's IMU data, this is contradictory to Bächelin et al.'s discovery!
- AI and Machine Learning: Explore the integration of AI algorithms to personalize and adapt the device functionality based on user behaviour and feedback.
- Connectivity Enhancements: Enhance connectivity options, like Bluetooth LE for better smartphone integration or IoT capabilities for remote monitoring.
- Neural Net vs non-AI pipeline: Cue2Walk does not make use of a machine learning algorithm but rather a non-AI live FoG detection pipeline. It is of great value to compare performance characteristics between these two types.

Sustainability and life-cycle analysis

- Eco-friendly Materials: Investigate sustainable materials for the device, focusing on the environmental impact. Energy Efficiency:
- Work making the device more energy-efficient or incorporating renewable energy sources like solar charging. Recyclability and End-of-Life Plan: Develop a plan for the device's end-of-life, focusing on recycling and minimising electronic waste.

Design optimisation

- Ergonomic Improvements: Continuously refine the design for comfort, especially for prolonged use.
- Aesthetic Customisation: Offer options for personalisation in design and aesthetics to appeal to a broader user base.
- Modular Design: Consider a modular approach to the device, allowing for easier upgrades and repairs.
- Strength to weight improvement: To save DLP material in the shell, generative design methods can be applied to the in-ear shell's infill.
- Device power consumption: As the power calculations are based on guesses and fact-sheets of sensors and devices that might not be used in the end product, a more thourough investigation and calculation is imminent before the final development of the Dopple Earbuds.

Market research and strategy

- Competitive Analysis: Conduct a thorough analysis of competitors and similar products to find gaps and opportunities.
- Target Market Identification: Define and understand the broader target market beyond Parkinson's clients, like other neurological conditions.
- Pricing Strategy: Develop a comprehensive pricing strategy that considers production costs, market positioning, and customer value perception. Besides, reimbursement potential from insurer's perspective given the capability of the tool to prevent falls with sizable impending fracture and neurotrauma health care costs

Collaborations and partnerships

- Healthcare Partnerships: Collaborate with healthcare providers and institutions for clinical trials and endorsements.
- Academic Research: Partner with universities or research institutions for advanced R&D opportunities.
- Community Engagement: Engage with Parkinson's support groups and communities for feedback and advocacy.

Regulatory compliance and certification

- Device Certification: Navigate the process for getting medical device certification, ensuring compliance with health regulations.
- International Standards: Prepare the device for compliance with international health and safety standards for broader market reach.

Intellectual property and patenting

- Patent Research: Conduct thorough patent research to protect any novel features, concepts, or technologies developed.

Marketing and outreach

- Branding and Communication: Develop a strong branding and communication strategy to effectively reach your target audience.
- Digital Presence: Build a digital marketing strategy, including an informative website and active social media presence to engage potential users.

Post-launch activities

- Feedback Loop: Establish mechanisms for collecting user feedback post-launch for continual improvement.Customer Support: Develop robust customer support, including user guides, FAQs, and responsive help desks.
- Material suply chains for small product Re-envisioning suply chains: Rethinking the way Dopple should approach how they get their desired quantity of the materials they use in their products.

10 Reflection on graduation project

Here my tone of voice becomes as subjective as possible. I will reflect on the project from start to finish, whether the choices I made were good or bad, how I would do things differently in hindsight, and above all what I learned.

As I contemplate the journey of my Integrated Product Design MSc graduation project, I am engulfed by a myriad of emotions, thoughts, and lessons learned. This project, ambitious in its scope and complex in its execution, has been more than just an academic endeavour; it has been a transformative experience that has profoundly shaped my perspective as a product designer.

Prelude: scope selection

The journey of my graduation project began with the critical phase of scope selection, a foundational step that shaped the entire trajectory of my research and development efforts. Deciding the scope was not merely about choosing a topic; it was about identifying a need, a gap in the current technology and understanding where I could make a meaningful contribution.

The decision to focus on specifically on addressing the challenges of Freeze of Gait (FoG) and festination was driven by personal and academic motivations, as well as a personal favorite of mine; Harris profiles. The prevalence of PD and the profound impact of its symptoms on individuals' lives made it a compelling area for innovation. Furthermore, the technological landscape seemed ripe for advancements, particularly in the realm of wearable technology, where significant improvements could realistically be made.

In selecting this scope, I was drawn to the idea of merging technology with empathy: creating a product that was not only technologically advanced but also deeply attuned to the user's experience. The aim was to develop a solution that would significantly improve the quality of life for those living with PD, grounding the project in both technical rigor and human-centered design. Themes home to my coach Ir. Erik Thomassen's department (sustainable design engineering) chair Professor Daan van Eijk's department (human centered design).

This initial phase of scope selection was a period of extensive research, introspection, and consultation. It involved delving into the existing literature, understanding the current market offerings, and engaging with experts in the field and PD clients of the PvF6. This process highlighted the gaps in current solutions for FoG management, particularly in the context of real-world usability and effectiveness.

Selecting the right scope was a pivotal moment that set the tone for the entire project. It established the parameters within which I would work, defined the challenges I would tackle, and ultimately guided my journey towards creating a meaningful and impactful solution in the form of the Dopple Earbuds. This phase was not only about narrowing down a field of study but also about opening up a world of possibilities for innovation and contribution.

ideation and conceptualisation

After the scope was set, an idea quickly formed in my head; to develop a smart wearable device for PD clients, focusing on mitigating the challenges posed by FoG. The concept was to integrate advanced technology, such as an IMU and stereo calibrated camera systems, IEMs. Reflecting on the ideation phase, I must admit am proud of the boldness in choosing such a challenging and socially impactful topic. However, I realise that perhaps a deeper initial analysis of the technical feasibility and user needs might have better prepared me for the complexities ahead.

Design and development: balancing innovation and practicality

Throughout the design and development stages, I grappled with balancing innovative aspirations with the practicalities of ergonomics, materials, and electronics. The decision to incorporate features like pressure distribution, ventilation, and comfort in the earpieces was crucial. However, in hindsight, I see that I might have underestimated the challenges associated with integrating such advanced technology into a compact, wearable form. There were moments when the focus on technical innovation overshadowed ergonomic considerations, a balance I would strive to maintain better in future projects.

Technical challenges: a steep learning curve

Delving into the technical aspects, particularly the integration of the camera system and the calibration of IMUs, was both exhilarating and daunting. The learning curve was steep, and at times, the technical challenges felt overwhelming. Looking back, I would perhaps approach this with a more phased strategy, tackling one technical aspect at a time, to prevent feeling swamped by the complexities.

Collaboration and feedback: the value of diverse perspectives

One of the most enriching aspects of this project was the collaboration with experts, users, and peers. The feedback and insights gained were invaluable, though I occasionally found it challenging to integrate conflicting viewpoints. In retrospect, establishing a more structured framework for feedback collection and analysis could have streamlined this process.

Project management: lessons in time and resource allocation

In terms of project management, time and resource allocation were areas where I faced significant challenges. Balancing ambitious technical goals with the project timeline was a constant struggle. Reflecting on this, I have learned the importance of setting realistic milestones and being adaptable to changing circumstances. Prioritising tasks and perhaps even scaling down some aspects of the project for feasi bility would have been a more pragmatic approach.

Personal growth: skills acquired and confidence gained
On a personal level, this project has been a journey of immense growth. I have developed not just as a designer and engineer but also as a problem-solver and a communicator. The experience has bolstered my confidence in handling complex projects and has honed my skills in research, design, and technical analysis.

Concluding thoughts: a foundation for future endeavours
In conclusion, while there were moments of doubt and challenges that seemed insurmountable, this project has been a profoundly fulfilling chapter in my academic and professional life. The lessons learned are not just about product design but about perseverance, adaptability, and the pursuit of innovation. This project lays a robust foundation for my future endeavours, and I am eager to apply these learnings in my continuing journey as a product designer.

Currently, I just had a meeting with Dopple's engineers. He informed me that the think they that the first design cycle of the real product can start soon. For my work to be embodied in a real product would be a giant compliment to me a just effort in the direction of improved life for people living with PD.

My grandfather past away with this disease. He was suffering from FoG episodes and PD dementia. So, even though this product might not have been the best solution for him (besides being too late of course), I hope that it will be for other PD patients.

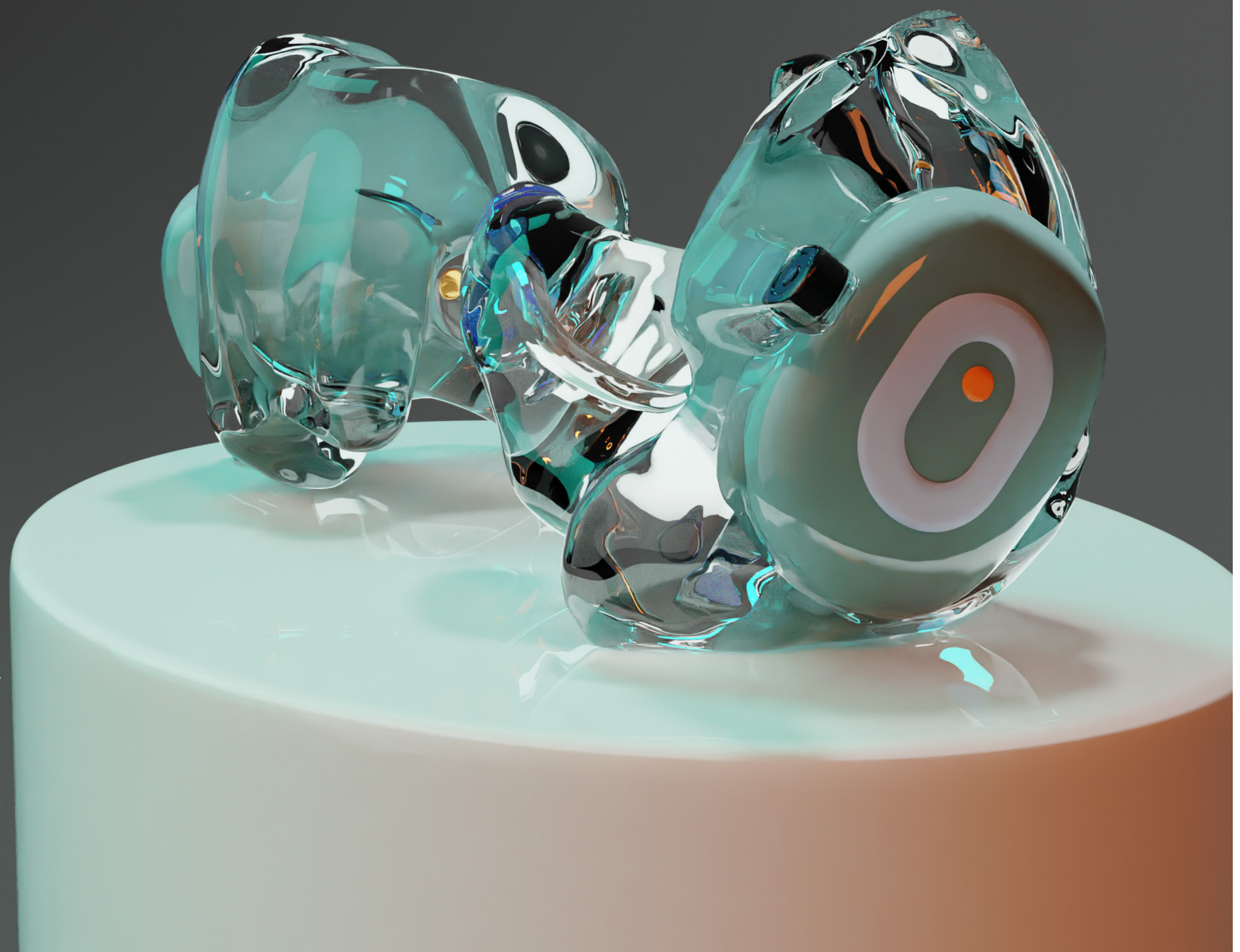


Figure 10.1: The final Dopple Earbuds render on a light-blue pedestal.

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12 Appendices

A1) PD client interview: Questions

This set of questions is designed to initiate an open-ended dialogue, providing you with qualitative insights into the needs, preferences, and concerns of Parkinson's clients regarding the proposed smart wearable device.

Before the interview, the potential participants are asked to read and sign the 'Informed Consent' forms, listed in Appendix A3. The signed versions of these forms are kept in my own possession until the graduation project is finished, after which they are deleted (if they are digitally signed) or burned (if they are signed by hand).

A) Introduction:
Could you please share a bit about your journey with PD?
How has Parkinson's affected your daily life, particularly in terms of mobility and independence?

B) Understanding Their Needs and Challenges:
Can you describe your experience with freeze of gait episodes? How often do they occur, and in what situations?
What strategies or tools do you currently use to manage or cope with these episodes?

C) Introducing the Concept:
We are developing a smart in-ear monitor that aims to predict and help mitigate freeze of gait episodes.
How do you feel about using technology to assist in managing your condition?
Have you used any wearable technology before? If yes, what was your experience like?

D) Device Specifics:
The device is designed to be worn in the ear, much like a hearing aid or wireless earbud. How comfortable do you feel with this idea?
Comfort:
- Can you describe what would make the device comfortable to wear? What are your preferences regarding size, shape, and material?
- What do you think about using an in ear monitor (explain what this is during the interview and show the model) that would fil the geometry of your ear? (for long-haried users)
- Would you wear your hair differently if that was a necessity?

Ease of Use:
- "What are your thoughts on the ideal way to interact with such a device? What specific functionalities would you want to access easily?"

Discretion:
- How do you feel about the visibility of the device when worn? What are your preferences regarding its appearance and discretion?

Battery Life:
- What are your expectations for the device's battery life and charging method? Could you describe a charging solution that would fit well into your daily routine?

Audio Feedback:
- What kind of auditory feedback would you find helpful or pleasing in the device? Are there specific sounds, voices, or cues that you would prefer?

Durability and Maintenance:
- What are your thoughts on the durability and maintenance needs of the device? Are there specific protective features or maintenance routines you would consider important?

Connectivity:
- How do you envision using the device in connection with a smartphone or computer? What kind of information or controls would you find useful to have through such connectivity?
- Customisation:
  In what ways would you like to customize the device, if at all? This could include sound levels, sensitivity settings, or aesthetic elements.

Emergency Features:
- What are your thoughts on including emergency features, such as alerts to caregivers in certain situations? How would you envision this functioning?

E) Feedback on Aesthetics and Design:
[Show examples] Here are some design concepts for the device. Which of these appeals to you the most, and why?
How important is the appearance of the device to you? Would you prefer something that stands out as a piece of technology or something more discrete?

F) Practicality and Usage:
In what situations do you think you would use this device the most?
Would you be comfortable with the idea of the device collecting data to predict freeze of gait episodes? Are there any concerns you have about data privacy and security?

G) Privacy Concerns:
How do you feel about the fact that the product has cameras?
Do you have privacy concerns about this product tracking your movemement and 3D surroudings data?
And what about sending those types of data to Dopple?

H) Closing and Additional Insights:
Is there anything you would like to add or emphasize that we haven't covered, especially regarding your needs and preferences?
Do you have any suggestions or advice for us as we develop this product?

I) Thank You:
Thank you for your time and insights. Your feedback is invaluable in helping us design a product that truly meets the needs of individuals with Parkinson's.

Notes for conducting the interviews:
Ensuring the interviewee is comfortable and understands the purpose of the interview.
Being empathetic and client, especially considering the challenges PD clients face.
Allowing flexibility in the conversation to explore topics they bring up that might not be directly covered by the questions.
Observing non-verbal cues and be ready to provide assistance or take breaks if needed due to the nature of their condition.
Maintaining confidentiality and assure them of the privacy of their responses, especially concerning personal health information.

A2) PD client interview: Answers

Some of the answers were the same from the two clients that agreed for their answers to be taken up in the thesis. For the cases this is true, a 'PD clients:' notation is used. For the contrary both clients are listed, i.e. 'PD client 1:', and 'PD client 2:' get their own excerpt.

A) Introduction:
PD clients: Issues with turning around while standing still and starting to walk without dragging their feet were mentioned as problems. Not having to think consciously about movement is also a challenge. A rollator with a laser feature is useful for resting moments.

PD client 1: They have had Parkinson's for 5 years, and symptoms have progressively worsened, particularly tremors. They were diagnosed after a suggestion from an acquaintance to see a doctor. Initially shocked, they've accepted the condition. Hand cramps and muscle stiffness make it hard to release a pen from their grasp. Levodopa medication is at its maximum dosage; tiredness in the evenings increases tremors and makes walking difficult. Movements are very slow in the morning.

PD client 2: Reported no significant changes in their condition after a hip surgery in 2013, but after a second hip surgery in 2017, the joint was deteriorating, and Parkinson's was diagnosed at age B) Understanding Their Needs and Challenges:

PD client 1: Does not often experience with freeze of gait episodes.
PD client 2: Described the main symptom as instability, partly due to spinal stenosis.

C) Introducing the Concept:
PD client 1: Open to using an in-ear device for stability.
PD client 2: Familiar with hearing aids and willing to adjust to devices with cameras.

D) Device Specifics:
PD client 1: Finds the idea of in-ear devices comfortable, especially if it helps adjust TV volume.
PD client 2: Uses a hearing aid but is not satisfied due to technical issues like noise and feedback.

Comfort:
PD client 1: Prefers a small in-ear device as glasses can cause discomfort by folding the skin.
PD client 2: Satisfied with the fit of custom-molded in-ear monitors.

Ease of Use:
PD clients: Not particularly concerned about the method of interaction with the device; it doesn't matter much.

Discretion:
PD client 1: Accepts the device's size, understanding there may be a period of adjustment.
PD client 2: Likes it to match the colour of their hair for discretion.

Battery Life:
PD clients: Prefer to charge the device at night and expect it to fit easily into the daily routine.

Audio Feedback:
PD client 1: Prefers practicing with music and singing for auditory feedback.

Durability and Maintenance:
PD clients: Maintenance routine should be simple, such as cleaning the in-ear part with a tissue every morning.

Connectivity:
PD client 1: Prefers minimal interactions and likes the idea of voice controls over manual operations.
PD client 2: Finds adjusting the device with a smartphone cumbersome; prefers immediate adjustments through speech.

Customisation and Emergency Features:
PD client 1: A call-for-help feature would be handy and prefers voice control over buttons.
PD client 2: Would use a physical button in emergencies and is open to talking to the device for other functions.

E) Feedback on Aesthetics and Design:
PD client 1: Favors a device that matches their hair colour.
PD client 2: Wants the device to stand out less.

F) Practicality and Usage:
PD clients: They are comfortable with the device collecting movement data and sending it to Dopple. They show no concerns regarding data privacy and security.

G) Privacy Concerns:
PD clients: They have no issues with the product having cameras or tracking their movement and 3D surroundings data.

H) Closing and Additional Insights:
PD client 1: Stresses the importance of independence and notes an increasing number of people are "coming out of the closet" with Parkinson's.
PD client 2: Dislikes having to use both a hearing aid and glasses; prefers a device that doesn't go in the ear to prevent skin damage.

I) Thank You:
PD clients express their gratitude for the opportunity to contribute to the development of the product.

A3) PD client interview: Consent form

Due to VGA legislation in the Netherlands, no names of participants are listed in this appendix, or in the rest of the thesis. I also have left out my own signature on purpose.

Delft University of Technology
HUMAN RESEARCH ETHICS
INFORMED CONSENT TEMPLATES
(Dutch Version: January 2022)

The following templates have been developed by the Human Research Ethics Committee (HREC) to assist you in the design of your Informed Consent materials for non-medical research involving human Research Subjects. **It is important to adapt this template to the outline and requirements of your particular study, using the notes and suggestions provided.**

For additional information or specific expertise on preparing your Informed Consent materials you can consult the following:

- The TU Delft Research Ethics webpages,
- Your faculty Data Steward, the TU Delft Privacy Team
- Our brief guide on Completing the HREC checklist
- Our Risk-Planning tool, Managing Risk in Human Research

If you have any questions about applying for HREC approval which are not dealt with on the Research Ethics webpages, please contact HREC@tudelft.nl

You can find guidance on Informed Consent together with **English versions** of the Informed Consent templates in the Informed Consent section of the Research Ethics webpages.

Key points to include	Suggested text
1. Level (eg: Masters, PhD, research) purpose, potential outcomes and implications of the study 2. The role of TU Delft and any third parties including funding body 3. Who participants are (eg: children, experts, students in a dependent role to the researcher) 4. What exactly what they are being asked to do 5. What if any Personal Data (Personally Identifiable Information and/or Personally Identifiable Research Data) will be collected, and how it will be used, published and managed. This should include clarity on: o how the data you collect will be used during the research o safeguarding personal information, maintaining confidentiality o de-identifying (pseudo/anonymising) data o controlling access to data, data archiving and reuse o (possible) data publication and dissemination, and o data archiving and the retention period for research data or criteria used to determine that 6. What physical, emotional or reputational risks might arise from participation either during or after the study, and what steps will be used to mitigate these risks 7. Participants' right to refuse to answer/withdraw from the study at any time 8. The right (or otherwise) of participants to request access to and rectify or erase personal data 9. Any remuneration for time/compensation for travel 10. Contact details of the Responsible Researcher and procedure for making complaints. **Note: the TUD Human Research Ethics Committee should not be included as a contact and does not deal with participant complaints.**	U wordt uitgenodigd om deel te nemen aan een onderzoek genaamd 'Test van feedback methodes in een slim oor dopje voor Parkinson Patiënten met *freezing* episodes'. Dit onderzoek wordt uitgevoerd door Cristiaan IJsbrand 'Stijn' Ponsioen van de TU Delft, onder leiding van Prof. Daan van Eijk en Ir. Erik Thomassen. De samenwerkingspartners zijn Dopple B.V. en de Zorginstellingen Pieter Van Foreest. Op deze dag zal Nathalie Timmermans er bij zijn en het onderzoek ondersteunen. Het doel van dit onderzoek is testen op welke methode auditieve feedback getoetst moet worden in de vorm van spraak communicatie middels bluetooth en oordopjes en zal ongeveer 60 minuten in beslag nemen. De data zal gebruikt worden voor De conceptuele ontwiKkeling van een smart wearable in-ear-monitor die op een niet farmaceutische wijze de symptomen van mensen met Parkinson tegen gaat (waaronder freeze of gait episodes). U wordt gevraagd om te lopen, mogelijk via een parcours om freezing bij het lopen op te laten spelen, waarop er gehandeld moet worden naar de auditieve feedback toegediend door Stijn. Zoals bij elke online activiteit is het risico van een databreuk aanwezig. Wij doen ons best om uw antwoorden vertrouwelijk te houden. We minimaliseren de risico's door: - Het blurren van camera footage (mocht u dit willen). - Het niet opslaan van persoonsgegevens (alleen de handgeschreven handtekening en naam onder dit formulier). - De data verzameld word niet gepubliceerd of anderszins online gezet. Uw deelname aan dit onderzoek is volledig vrijwillig, en u kunt zich elk moment terugtrekken zonder reden op te geven. U bent vrij om vragen niet te beantwoorden. Na 10 april worden de gemaakte filmpjes verwijderd. D.J.vaneijk@tudelft.nl C.I.J.Ponsioen@student.tudelft.nl [*doorklikken naar de survey betekent dat de deelnemers instemmen met de Opening Statement.*]

PLEASE TICK THE APPROPRIATE BOXES	Yes	No
A: GENERAL AGREEMENT – RESEARCH GOALS, PARTICPANT TASKS AND VOLUNTARY PARTICIPATION		
1. Ik heb de informatie over het onderzoek gedateerd 29/01/2024 gelezen en begrepen, of deze is aan mij voorgelezen. Ik heb de mogelijkheid gehad om vragen te stellen over het onderzoek en mijn vragen zijn naar tevredenheid beantwoord.	☐	☐
Separate 'yes/no' tick boxes allow you to make sure that your participant is actively affirming their consent. If the participant wants to tick the no box this allows you to clarify any points the participant is unsure about. ***If this is not applicable for your study, then remove the 'no' box.***		
2. Ik doe vrijwillig mee aan dit onderzoek, en ik begrijp dat ik kan weigeren vragen te beantwoorden en mij op elk moment kan terugtrekken uit de studie, zonder een reden op te hoeven geven.	☐	☐
This point should be modified accordingly where a legal guardian will be giving consent, and/or where a participant, outside the context of the research is in a dependent or subordinate position to the researcher.		
3. Ik begrijp dat mijn deelname aan het onderzoek de volgende punten betekent: • Dat ik word gefilmd (en ik er voor kan kiezen mijn gezicht te laten vervagen) en dat er bij deze film een audio opname zit, maar ik niet hoef te praten. o En deze opname slechts wordt vertoond bij Stijns presentaties van het concept product en wordt verwijderd na 10 april. o Binnen deze filmopname mag er geen herkenbare informatie van mij worden vastgelegd, en bij toeval dat dat toch gebeurt worden deze scenes er uit geknipt door Stijn. • Dat er gedurende de 60 minuten onderzoek vragen gesteld kunnen worden en mijn antwoorden opgeschreven worden. • Dat ik mijn mondelingen instemming geef per punt in dit consent formulier en Stijn de corresponderende boxen aankruist. • Dat ik geen gehoorapparaat kan dragen tijdens deze test.	☐	☐
Provide briefly what is relevant from the following: • *Describe in a few words how information is captured, using the same terms as you used in the Opening Statement, for example: an audio-recorded interview, a video-recorded focus group, a survey questionnaire completed by the enumerator…* • *For interviews, focus groups and observations, specify how the information is recorded (audio, video, written notes)* • *For questionnaires, specify whether participant or enumerator completes the form* • *For audio or video recordings, indicate whether these will be transcribed as text, and whether the recording will be destroyed. NB: Please consider whether audio or video recording is essential to your research.* ***As far as possible you should aim to minimise the Personal Data (PII and/or PIRD) you collect.***		
4. Ik begrijp dat mijn deelname aan het onderzoek NIET wordt gecompenseerd.	☐	☐
Include reasonable compensation for time or travel (if any) and how this will be disbursed		
5. Ik begrijp dat de studie 10 april eindigt (dit is Stijns afstudeerdatum).		
Please add the anticipated timing or how the date will be determined		
B: POTENTIAL RISKS OF PARTICIPATING (INCLUDING DATA PROTECTION)		

6. Ik begrijp dat mijn deelname de volgende risico's met zich meebrengt.: ☐ ☐

1. Onprettig gevoel van het oortje dat ik in mijn oor stop.
2. Het oortje niet hygiënisch is.
3. De mentale stress van meedoen aan het onderzoek me teveel kan worden.
4. Ik een verhoogde kans heb Covid op te lopen door Stijns aanwezigheid bij mijn fysiotherapie sessie.
5. De gebruikelijke risico's van het lopen onder begeleiding niet worden weggenomen door dit onderzoek.

Ik begrijp dat deze risico's worden geminimaliseerd door:

1. Stijn meet aan het begin de juiste afmetingen van het oortje aan en kan tijdens de test kan een nieuwe pasvorm aansluiten die geen irritatie opwekt. De oortjes zijn CE gecertificeerde producten van een A merk (Senheisser TVS 200), legaal voor verkoop in Nederland.
2. Stijn ontsmet alle onderdelen die mijn huid aan gaan raken grondig met alcohol.
3. Ik kan Stijn of Nathalie verzoeken dat ik stop met de test en rust neem.
4. Stijn doet de dag en ochtend voor het onderzoek een zelftest en draagt een mondkapje als ik dat wil. Bovendien ontsmet hij zijn handen grondig voor het overhandigen van de apparatuur.
5. Mijn fysiotherapeute Nathalie Timmermans zal mij fysiek ondersteunen tijdens de alle loop oefeningen tijdens het lopen bij de fysiotherapie.

- *Describe in a few words any risks associated with participating in the study, other than those relating to Personal Data and the potential for re-identification, for example: physical or mental discomfort; risks for participants in a surbordinate position to the researcher*
- *Describe also what steps you will take to mitigate these risks – such as device certification, or the ability to ask for the experiment to stop at any point*

7. Ik begrijp dat mijn deelname betekent dat er persoonlijke identificeerbare informatie en onderzoeksdata worden verzameld, met het risico dat ik hieruit geïdentificeerd kan worden: ☐ ☐

- Bij Stijns presentatie zullen medewerkers van de Zorginstellingen Pieter van Foreest aanwezig zijn die mij kunnen kennen.

Provide brief summaries of potential risks of re-identification (eg: public/professional reputation)

8. Ik begrijp dat binnen de Algemene verordering gegevensbescherming (AVG) een deel van deze persoonlijk identificeerbare onderzoeksdata als gevoelig wordt beschouwd, namelijk ☐ ☐

- Niet van toepassing

List the relevant issues: eg:
- *religion, political views*
- *Data concerning criminal activities will/may be collected and processed*
- *Research has a Data Processing Impact Assessment (DPIA) in place*

9. Ik begrijp dat de volgende stappen worden ondernomen om het risico van een databreuk te minimaliseren, en dat mijn identiteit op de volgende manieren wordt beschermd in het geval van een databreuk: ☐ ☐

- Stijns laptop is vergrendeld en is het enige medium waarop de filmpjes opgeslagen zijn en waarvan ze worden afgespeeld tijdens concept product presentaties binnen zijn afstudeerproject.
- Stijn vervaagd mijn gezicht mocht ik dat willen.

Provide brief summaries of the mitigating measures to be taken (eg: anonymous data collection, (pseudo-) anonymisation or aggregation, secure data storage/limited access, transcription, blurring, voice modification etc)

10. Ik begrijp dat de persoonlijke informatie die over mij verzameld wordt en mij kan identificeren, zoals 'Naam en Leeftijd' niet gedeeld worden buiten het studieteam. ☐ ☐

11. Ik begrijp dat de persoonlijke data die over mij verzameld wordt, vernietigd wordt op: 10 april. ☐ ☐

Please add the anticipated timing or how the date will be determined

C: RESEARCH PUBLICATION, DISSEMINATION AND APPLICATION

12. Ik begrijp dat na het onderzoek de geanonimiseerde informatie gebruikt zal worden voor: ☐ ☐

- afgespeeld tijdens concept product presentaties binnen zijn afstudeerproject.
- Een (cover)Afbeelding in Stijns report kan worden.
- Stijns afstudeerapport zal in de TU Delft repository komen zonder mijn persoonlijke informatie (1) en foto's (2).
  - (2) deze zijn slechts voor het rapport dat naar zijn begeleiders gaat en de eindpresentatie.

- *Please list any planned or possible outputs, e.g. reports, publications, website, video channel. This should also include any planned application (such as decision-making, policy- service- or product development. Consider any secondary use and whether knowledge sharing and benefits sharing needs to be considered, e.g. for indigenous knowledge.*
- *Please be explicit if the publication of recognisable images, quotes or other PIRD are anticipated and ensure specific agreement on this*

13. Ik geef toestemming om mijn antwoorden, ideeën of andere bijdrages anoniem te quoten in resulterende producten. ☐ ☐

14. geef toestemming om mijn naam te gebruiken voor quotes in resulterende producten: ☐ ☐

- Niet van toepassing

15. *If written information or other works are provided by the participants (e.g. in a reflection or other diary, or as images etc.) please check* https://www.tudelft.nl/library/copyright/c/what-is-copyright) *for information on copyright, and/or contact the Copyright Team for further information at* copyright-lib@tudelft.nl *and insert appropriate consent questions accordingly.* ☐ ☐

- Niet van toepassing

D: (LONGTERM) DATA STORAGE, ACCESS AND REUSE

16. Ik geef toestemming om de geanonimiseerde data [*leg uit welke data*] die over mij verzameld worden gearchiveerd worden in [*naam van data repository*] opdat deze gebruikt kunnen worden voor toekomstig onderzoek en onderwijs: ☐ ☐

- Niet van toepassing

17. *If relevant please add:* Ik begrijp dat de toegang tot deze repository [open, beperkt tot…,] is. ☐ ☐

- Niet van toepassing

If different from Explicit Consent points 8 and 9 above:
- *Specify in which form the data to be stored will be deposited, e.g. anonymised transcripts, audio recording, survey database, etc.; and if needed repeat the statement for each form of data you plan to deposit.*
- *Specify whether deposited data will be anonymised, and how. Make sure to describe this in detail in your Opening Statement*
- *Specify whether use or access restrictions will apply to the data in future, e.g. exclude commercial use, apply safeguarded access, etc.; and discuss these restrictions with the repository in advance.*
- *Include when the data will be deleted – or provide criteria for when and how that decision will be made*

Signatures

______________________ ______________________ __________________

Naam deelnemer Handtekening Datum

[Add legal representative, and/or amend text for assent where participants cannot give consent as applicable]

Ik, **de wettelijke vertegenwoordiger**, verklaar dat de informatie en het instemmingsformulier aan de potentiële deelnemer correct zijn voorgelezen, en dat hij/zij de kans heeft gekregen om vragen te stellen. Ik verklaar dat de potentiële deelnemer zijn/haar instemming vrijwillig heeft gegeven.

______________________ ______________________ __________

Naam wettelijke vertegenwoordiger Handtekening Datum

Ik, **de onderzoeker**, verklaar dat ik de informatie en het instemmingsformulier correct aan de potentiële deelnemer heb voorgelezen en, naar het beste van mijn vermogen, heb verzekerd dat de deelnemer begrijpt waar hij/zij vrijwillig mee instemt.

___Stijn Ponsioen______ ____________________ ____29/01/2024______

Naam onderzoeker Handtekening Datum

Contactgegevens van de onderzoeker voor verdere informatie: [Naam, telefoonnummer, emailadres]

B) Ergonomics expert interview

Comfort
1. What are the key factors in designing ergonomic in-ear monitors for prolonged use?
2. How can we balance the need for snug fit with user comfort regarding in-ear devices?
3. What are common discomfort issues with in-ear monitors and how can they be mitigated?
4. How do ear shapes vary among users and what design considerations are necessary for this?

Aesthetics
5. How important is the aesthetic aspect in the design of ergonomic devices?
6. Can you suggest ways to make functional ergonomic design aesthetically pleasing?
7. What current design trends are you seeing in wearable technology, particularly in-ear devices?

Materials
8. What materials do you recommend for in-ear monitors considering skin sensitivity and durability?
9. Are there any innovative materials that could revolutionize comfort in wearable tech?
10. How do material choices impact the overall weight and feel of in-ear devices?

Usability
11. What are the best practices for ensuring easy and intuitive interaction with small devices like in-ear monitors?
12. How can the design of in-ear monitors facilitate ease of use for people with varying levels of dexterity?

User Adaptation
13. How do you suggest we approach the design to cater to a diverse user base with varying ear sizes and shapes?
14. Are there any adjustable or customisable design elements that can be incorporated to enhance fit and comfort?

Health and Safety
15. What are the potential health risks associated with prolonged use of in-ear devices and how can design minimise these risks?
16. Are there any specific ergonomic guidelines that need to be followed in the design of wearable technology for health monitoring?

Environmental and Long-Term Use
17. How does the environmental impact (like humidity, temperature) affect the comfort and durability of in-ear devices?
18. What considerations should be made for the longevity and maintenance of these devices from an ergonomic perspective?

Technological Integration
19. How can ergonomic design principles be balanced with the technical requirements of smart features like sensors and Bluetooth connectivity?
20. Are there ergonomic challenges unique to integrating advanced technology like computer vision and IMUs into in-ear devices?

Feedback and Testing
21. What methods do you recommend for gathering user feedback on ergonomic aspects during the testing phase?
22. Can you share examples of ergonomic testing methodologies for in-ear devices?

C) Fact-sheets of proposed electronics

bno055 (IMU sensor)
- https://www.bosch-sensortec.com/products/smart-sensor-systems/bno055/

OV2460 (camera sensor)
- https://www.uctronics.com/download/cam_module/OV2640DS.pdf

RYS88630 (GPS module)
- http://reyax.com.cn/wp-content/uploads/2020/02/RYS8830.pdf

BLE module (Bluetooth Low Energy device)
No specific device was picked but here are some options. Dopple has enough experience with BLE modules so they will naturally choose a proficient type (somehow Indesign does not like this link, sorry for the inconvenience).

https://www.silabs.com/blog/small-bluetooth-chips-for-medical-devices-and-wearables?source=Media&detail=Google-PPC&cid=med-gos-blu-012924&s_kwcid=AL!16736!3!689238886545!b!!g!!small%20bluetooth%20chip&gad_source=1&gclid=CjwKCAjwkuqvBhAQEiwA65XxQI8RNCTQveXfEZo41AuwxiErhm6cMT9VRXiRVa82DGH10yoVXZFRjhoCXs8QAvD_BwE

D) Table IMU locations

Source	N sensors	Sensor placement	Realtime	Sensitivity [%]	Specificity [%]
Without sensor in upper limb					
Bachelin et al. (2009a)	3	Ankle, thigh, lower back	Yes	73.1	81.6
Jovanov et al. (2009)	2	Both on belt or knee or ankle or shoe	Yes	unknown	unknown
Niazmand et al. (2011)	5	Shank and belt	No	88.3	85.3
Mazilu et al. (2015a)	2	Ankles	Yes	97	unknown
Palmerini et al. (2017)	3	Shins, lower back	Yes	83	67
Camps et al. (2018)	1	Waist	Yes	92.6	88.7
With sensor in upper limb					
Cole et al. (2011)	3	Shank, thigh, and arm	No	83	97
Tripoliti et al. (2013)	6	Wrists, ankles, waist, and chest	No	81.9	98.7
Mazilu et al. (2015b)	2	Both wrists	Yes	90	83
Bachelin et al. (2021)	1	Wrist	Yes	83	88

Table D1) A comparative analysis between imu based FOG detection set-ups. This table is taken from Bächlin et al. (2021).

E) Scipted logic data gathering

1. calibrates the BNO055, with the Grove RGB led and vibration motor feedback in the following format:
a. RED light, when calibration state of accelerometer && gyroscope && Magnometer && system CALIBRATION levels are all equal to 0.
Vibration motor no vibration.
b. ORANGE light, when calibration state of accelerometer && gyroscope && Magnometer && system CALIBRATION levels are all equal to 1.
Vibration motor 1 time 3 sec vibration.
c. YELLOW light, when calibration state of accelerometer && gyroscope && Magnometer && system CALIBRATION levels are all equal to 2.
Vibration motor 2 times 3 sec vibration.
d. GREEN light, when calibration state of accelerometer && gyroscope && Magnometer && system CALIBRATION levels are all equal to 3
Vibration motor 3 time 3 sec vibration.
2. Tell the setup to wait until the button is pushed and held for 5 seconds. During this waiting time the led must stay GREEN.
3. Once it is pushed, the system should start acquiring "timestamp, raw Acc, raw Gyr, and raw Mag" IMU data on the SD card. Furthermore, the system should do this in a specific manner:
a. A dataFile on the SD card must be created with the name:
"1_" + "IMUDATA" + timestamp of start recording + ".txt"
i. Each time the setup saves a new dataFile on the SD cards, the Grove RGB led must emit a blue light for 3 seconds, after which it must switch back to WHITE until the next instance of dataFile creation.
b. The sampling rate of the data collection must be 40Hz, and the time between each line of data should thus be 25 ms, this must be consistent.
c. If the data collection is in progress the Grove RGB led must emit a WHITE light.
d. If the total duration of the data collection surpasses 60 seconds, the dataFile should be closed and stored on the SD card. Then immediately after, a new "IMUDATA" + new timestamp of start recording + ".txt" should be created on the SD card so that there is a uninterrupted data stream of 40Hz.
e. If the button is pressed again and held pressed for 5 seconds the setup should cease to collect data, and:
i. The grove RGB LED should emit a faded white light.
ii. If the last dataFile is shorter than 15 seconds, erase it on the SD module and keep the rest.
iii. If the last dataFile is longer than or equal to 15 seconds, keep it.
4. When the SD card is removed from the SD module, the calibration status of the BNO055 sensor should be erased, and the grove led should emit a RED light.
5. If the system is calibrated again and prompted to start data collection again, increase the first digit of the dataFile name by 1. For example, the following dataFile created on the SD card must be named:
"2_" + "IMUDATA" + timestamp of start recording + ".txt"
a. Repeat this process of including the data collection count every time a new data collection is prompted.
6. You are free to use every pin for the required hardware, as long as you document this well.
7. You are free to #include every Arduino library you want, as long as it is still available for Arduino IDE version 2.2.1, and compatible with the mentioned hardware.
8. Next to every important parameter or setting you devise in Arduino IDE, make sure to //comment what is happening there.

F) Product functions excell sheet

function	measuring?	processing?	receiving?	transmitting?	logging?	Earpiece L	Earpiece R	Smart phone	Charging case	Remarks	TODO
object detection	1	1	1	1	1					earpieces observe phone processes, image must be trqansmitted	
FoG detection	1	1	1	0	1						
heart rhythm detection	1	1	1	0	1						
fall detection	1	1	1	0	1						
remote monitoring	1	1	1	1	1					earpieces observe phone processes	
posture correction	1	1	1	0	1						
manoeuvre aid	0	1	1	0	0					earpieces observe and give feedback phone processes, phone shows areas/objects that were problematic and sends those data to doctor	
stability help*	1	1	1	0	1					IMUs on earpieces and phone collect, phone processes and logs	
collect gait data**	1	1	1	0	1					IMUs on earpieces and phone collect, phone processes and logs	
voice input	0	1	1	0	0					if the Erapieces are devoid of charge the phone's microphone is required during SOS calls & normal phone calls	
vibration feedback	0	1	0	1	0						
control vibration feedback	0	1	1	1	0						
audio feedback	0	1	0	1	0					if the Erapieces are devoid of charge the phone's microphone is required during SOS calls & normal phone calls	
control audio volume	0	1	0	1	0						
control audio EQ	0	1	0	1	0						
visual feedback	0	1	0	1	0					smartphone screen during app use, charging case should emit feedback lights for charge state and soft- firmware updates	
control visual feedback	0	1	0	1	0					smartphone app in-use, charging case should emitted light feedback lights should be controlable	
local data logging	?????????	1	0	1	1					if data is not required to be accessed on demand locally, it is transmitted and saved to disk phone.	Find out when what data has to be saved how and where?
data upload to cloud	0	1	0	1	1						
download soft- and firmware	0	1	1	0	0						
install soft- and firmware	0	1	0	0	1					this happens during charging, so the earpieces do not consume charge	
overwrite previous soft- and firmware	0	1	0	0	1					this happens during charging, so the earpieces do not consume charge	
call	0	1	1	1	0					microphone earpieces receive voice input and facilitate DSP, phone establishes connection and facilitates transmission of voice input	
system calibration	1	1	1	0	1				????????????		
connect wirelessly to each other	0	1	1	1	0					each other: between Earpiece L and R and the smartphone	
Assess wireless connection	1	1	1	1	0						
wireless transmission	0	1	0	1	0						
SOS function	0	1	0	1	0					microphone earpieces receive voice input and facilitate DSP, phone establishes connection and facilitates transmission of voice input. if the Erapieces are devoid of charge the phone's microphone is required during SOS calls & normal phone call	
in-ear detection	1	1	1	0	1					Can only happen I	
out-of-ear detection	1	1	1	0	1						
in-case detection	1	0	0	0	0						
out-of-case detection	1	0	0	0	0						
receive radio	0	1	1	0	0					Case requires bluetooth connection	
charge	0	???????????	0	0	0						
measuring charge	1	1	0	1	1					Logging because this is a valuable parameter to assess product longevity	
										* this function is only free during	
										** this function is free because it should be active during gait, then the FoG algorithm is running	
MAIN FUNCTIONS											
										bone conductie	
										microphone in oor (ondersteuning)	
										Stereo microphone 2x	

Note: the final included primary and secondary functions, as well as the ancillary features in the Dopple Earbuds are shown in the Functions chapter.

G) Q&A with PvF physiotherapist

In the fourth week of the project I arranged a meeting with physiotherapist Nathalie from De Zorginstellingen Pieter van foreest, the following text only concerns the insights I could draw from this meeting.

Diversity in parkinson's disease manifestations
Parkinson's disease presents a diverse array of challenges. Some patients may develop an addiction to physical exercise as a coping mechanism. Utilising an in-ear device in daily practice can help modify walking patterns, which tend to become smaller in those with PD.

The diagnostic complexity and development of parkinson's
Distinguishing between Parkinson's and parkinsonism is not always straightforward, and often it can't be definitively diagnosed in the early stages. Understanding how the disease develops over the first 3 to 5 years and identifying any comorbidities is crucial. A person who is just 60 may still be actively engaged in life, having different daily needs compared to older patients. Thus, it is suggested that the scope of age should be defined in the study.

Interactive and responsive technology in management
The use of rhythmic music can significantly aid mobility. The patient might wonder whether they can activate it themselves when they need support, such as when needing to visit the restroom. A person experiencing significant freezing might benefit from a familiar voice in the device cueing them to stand up with a count, providing conscious control and helping with movement.

The role of external stimuli in patient autonomy
External stimuli through an in-ear device can guide how to stand and walk. This tool could either support caregivers or offer self-initiated assistance during freeze episodes. It's crucial to establish whether the aim is to support the caregiver or empower the patient for self-assistance.

The impact of physical sensations and deep brain stimulation
Vibrations near the ear can be frightening; some patients coordinate well, while others find it distressing. Deep brain stimulation (DBS) can cause complications and is contraindicated for those sensitive to stress. Therefore, using musical cues, like marching to a specific beat, is preferred over vibrations near the head, which is strongly discouraged due to the risk of headaches and exacerbating anxiety.

Overcoming the autopilot challenge
Unlike individuals without PD who operate on autopilot, PD patients need to consciously train themselves not to panic when experiencing a freeze. Strategies like taking a deep breath, positioning the legs wide, opening the hips, and stepping forward can help. Breath control is also important, with some patients using the cue of taking large steps in the initial stages.

Physical response and medication efficacy
While an in-ear device might not influence a resting tremor, for some, levodopa is effective. A stiff brace can provide counterpressure, which in some cases, dampens the resting tremor as observed in public figures like Michael J. Fox. Patients might adopt strategies like sitting on their hands to manage tremors, which vary from being at rest to action-induced.

Addressing bradykinesia and preventing falls
With bradykinesia, feedback-driven training can improve incorrect movements. Festination, or shortening of steps leading to falling, is common among PD patients, which can be addressed through appropriate feedback and training.

Nighttime challenges and autonomic dysfunction
Nighttime disturbances in PD are challenging to address with an in-ear device. However, orthostatic hypotension, which involves a sudden drop in blood pressure upon standing, can be managed by checking for dizziness and advising hydration.

Pain management and movement encouragement
Pain can lead to reluctance in movement, yet it's essential for PD patients to remain active. Tackling prodromal symptoms is a vast challenge. Activities like PD-focused kickboxing can be beneficial as they engage the legs and offer a comprehensive challenge.

Recognising parkinson's disease beyond the stereotypes
PD is an expanding concern, growing independently from aging factors. It's the number one growing neurological disorder, and its link to pesticides suggests causes beyond just aging. It's crucial to dispel the stigma associated with the old man's disease and recognize that PD affects women and younger individuals too.

These insights highlight the need for personalised, adaptable interventions that cater to the unique challenges of each patient. They emphasize the potential of incorporating rhythmic cues, tailored feedback, and supportive technology to empower individuals with Parkinson's, enhancing their autonomy and quality of life.

H) Power calculations python script

```python
def calculate_power_consumption(component_current, time_hours, system_voltage):
    # Calculate power consumption in mWh
    return component_current * system_voltage * time_hours

def calculate_total_power_consumption(components_power):
    # Calculate the total power consumption by summing up all component powers
    return sum(components_power)

def calculate_required_battery_capacity(total_power, battery_efficiency):
    # Calculate the required battery capacity in mAh
    required_capacity = total_power / (battery_efficiency * 1000)  # Convert to mAh
    return required_capacity

# Constants for signal processing and BLE
static_current = 0.09  # in mA
dsp_current_per_earpiece = 0.535  # in mA
microsystem_domain_current = 0.250  # in mA
VDD = 0.8  # in V
BLE_frequency = 40  # in MHz
dsp_current_low = 0.015  # in mA/MHz
dsp_current_high = 0.100  # in mA/MHz
sbc_dct_current = 0.065  # in mA/MHz
cortex_M33_current = 0.050  # in mA/Hz
active_percentage = 0.1  # 10% of the time
radio_transmission_current = 0.250  # in mA
battery_efficiency = 0.85
system_voltage = 3.7  # in V

# Constants for other functionalities
active_mode_time = 2  # in hours
low_power_time = 14  # in hours
fall_detection_current = 8  # mAh
fog_detection_current = 2  # mAh
sit_detection_current = 0  # mAh (Negligible)
manoeuvre_assistance_current = 2  # mAh
remote_monitoring_current = 8  # mAh
camera_operation_current = 0.5  # mAh (5 seconds of operation)
current_draw_correction = 20.36

# Calculating power consumption for signal processing and BLE
signal_processing_power = calculate_power_consumption((dsp_current_per_earpiece + microsystem_domain_current + (BLE_frequency * (dsp_current_low
 + dsp_current_high) + cortex_M33_current) * active_percentage + radio_transmission_current), active_mode_time, VDD)

# Calculating power consumption for other functionalities
fall_detection_power = calculate_power_consumption(fall_detection_current, active_mode_time, system_voltage)
fog_detection_power = calculate_power_consumption(fog_detection_current, active_mode_time, system_voltage)
manoeuvre_assistance_power = calculate_power_consumption(manoeuvre_assistance_current, active_mode_time, system_voltage)
remote_monitoring_power = calculate_power_consumption(remote_monitoring_current, active_mode_time, system_voltage)
camera_operation_power = calculate_power_consumption(camera_operation_current, 5/3600, system_voltage)  # 5 seconds operation
low_power_mode_power = calculate_power_consumption(static_current, low_power_time, system_voltage)

# Function Calls
total_power_components = [signal_processing_power, fall_detection_power, fog_detection_power, manoeuvre_assistance_power, remote_monitoring_power
, camera_operation_power, low_power_mode_power]
total_power = calculate_total_power_consumption(total_power_components)
required_battery_capacity = current_draw_correction + calculate_required_battery_capacity(total_power, battery_efficiency)

print(f"Total Power Consumption (Active + Low Power Mode): {total_power:.2f} mWh")
print(f"Required Battery Capacity: {required_battery_capacity:.2f} mAh")
```


I) Codebases proposed algorithms

Luigi Borzì's Github respository
https://github.com/Lu1g1n0/Freezing-of-gait-detec-
tion-and-prediction

Bächelin et al.'s Github respository
https://github.com/stanfordnmbl/imu-fog-detection

J) User feedback test method

On this page, I have detailed my research methods to facilitate easy replication, including the script I developed for the user feedback test.

Preparation and Setup:
- Equip the client with a Bluetooth headset connected to a smartphone.
- Ensure the smartphone is equipped with the necessary software to trigger the 'feedback sequence' during FoG episodes.
- Prepare an obstacle course designed to safely trigger FoG episodes under controlled conditions.
- Have a physical therapist present throughout the test for safety and observation.

Initial Assessment:
- Conduct a pre-test assessment of the client's typical gait and any FoG occurrences without auditory feedback.
- Record baseline data on the frequency and duration of FoG episodes in a similar setup.

Safety Briefing:
- Brief the client and physical therapist on the test procedure, safety measures, and the role of the therapist in signalling FoG episodes.

Obstacle Course Walk through:
- Have the client walk across the obstacle course alongside the physical therapist.
- The therapist should closely monitor the client for any signs of a FoG episode.

Triggering Feedback Sequence:
- Upon the physical therapist's signal of a FoG episode, initiate the 'feedback sequence' as planned.
- The sequence includes verbal cues and rhythmic music to aid in overcoming the freeze.

Observation and Data Collection:
- Observe and record the client's response to each specific feedback cue.
- Note the time taken to overcome the freeze after each type of feedback.
- Document any changes in the client's gait or behaviour in response to the auditory cues.

Repeat Trials:
- Conduct multiple trials to gather a robust set of data.
- Vary the conditions of the obstacle course to test the feedback's effectiveness under different scenarios.

Safety and Comfort Checks:
- Regularly check on the client's comfort and well-being.
- Ensure the volume and type of auditory feedback are comfortable and not distressing for the client.

Post-Test Interview:
- After the trials, interview the client about their experience.
- Gather subjective feedback on the helpfulness, clarity, and preference for each type of auditory cue.

Data Analysis:
- Analyse the collected data to assess the effectiveness of the auditory feedback.
- Compare the FoG episodes' frequency and duration with and without auditory feedback.

Report Preparation:
- Prepare a detailed report with findings, including statistical analysis, client feedback, and observational notes.

Review and Follow-up:
- Discuss the findings with your coach, chair, and the participating physical therapist.
- Plan any follow-up studies or refinements to the feedback sequence based on the results.

K) Signed graduation project brief

DESIGN FOR our future — TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT
Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME
Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy".
Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name: Ponsioen 6925
initials: C.IJ. given name: Stijn
student number: 4441966
street & no.:
zipcode & city:
country:
phone:
email:

Your master programme (only select the options that apply to you):
IDE master(s): ★ IPD / DfI / SPD
2nd non-IDE master:
individual programme: - - (give date of approval)
honours programme: Honours Programme Master
specialisation / annotation: ★ Medisign / Tech. in Sustainable Design / Entrepeneurship

SUPERVISORY TEAM **
Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair: Prof. Daan van Eijk — dept. / section: HCD
** mentor: Ir. Erik Thomassen — dept. / section: SDE
2nd mentor: Dr. Ir. Jaap Haartsen
organisation: Dopple
city: Assen — country: The Netherlands

comments (optional): Zorginstellingen Pieter Van Foreest Delft is a collaborating partner from Dopple with whom I will collaborate as well.

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

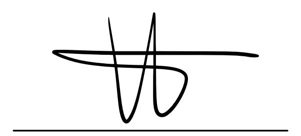
Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

IDE TU Delft - E&SA Department /// Graduation project brief & study overview /// 2018-01 v30 — Page 1 of 7

Procedural Checks - IDE Master Graduation — TU Delft

APPROVAL PROJECT BRIEF
To be filled in by the chair of the supervisory team.

chair: Prof. Daan van Eijk — date: 22 - 09 - 2023 — signature:



CHECK STUDY PROGRESS
To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair.
The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: ____ EC
Of which, taking the conditional requirements into account, can be part of the exam programme ____ EC
List of electives obtained before the third semester without approval of the BoE

★ YES — all 1st year master courses passed
NO — missing 1st year master courses are:

name: K.Veldman — date: 18 - 12 - 2023 — signature: Kristin Veldman (Digitally signed by Kristin Veldman Date: 2023.12.18 10:20:17 +01'00')

FORMAL APPROVAL GRADUATION PROJECT
To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **.
Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: APPROVED / NOT APPROVED
Procedure: ★ APPROVED / NOT APPROVED

comments

name: Monique von Morgen — date: 19 - 12 - 2023 — signature: Monique von Morgen (Digitally signed by Monique von Morgen Date: 2023.12.19 10:31:16 +01'00')

IDE TU Delft - E&SA Department /// Graduation project brief & study overview /// 2018-01 v30 — Page 2 of 7
Initials & Name: C.IJ. Ponsioen — Student number: 4441966
Title of Project: Designing a Smart Wearable for Parkinson's Disease Patients

Designing a Smart Wearable for Parkinson's Disease Patients — project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 20 - 09 - 2023 — 10 - 04 - 2024 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

The objective of this Master's Thesis project is to design a novel smart wearable device that addresses one or multiple challenges faced by individuals, living with Parkinson's disease (PD). The project will be conducted in collaboration with Dopple, a Dutch company that aims to specialise and compete in the healthcare smart wearables industry. Dopple stated that their interest concerning the wearing style of smart wearable mainly goes out earpieces, as that is their forte. Dopple aims to create innovative solutions that improve the quality of life for people with PD and they want to profit doing so. Also involved are the Zorginstellingen Pieter van Foreest in Delft. They are willing to let their PD patients be part of my research and prototype tests. Their paramedics may be consulted to fill knowledge-gaps when necessary. However, other paramedical expertise from hospitals lie within the research scope. My process will be overseen by a chair and mentor from the IDE faculty, as well as a mentor from Dopple. The design methods applied to effectuate the project are skills developed during the IDE BSc and IPD Msc programme, besides some new ones yet to unpack.

Main opportunities*:
Improving Quality of Life: A smart wearable tailored to Parkinson's patients can potentially improve their quality of life by providing assistance with daily tasks, monitoring symptoms, and enhancing mobility.

Remote Monitoring: The wearable can enable healthcare professionals to remotely monitor patients' condition and adjust treatment plans as needed, reducing the need for frequent in-person visits.

Early Detection: Continuous monitoring could aid in the early detection of symptom fluctuations, allowing for timely intervention and personalized treatment adjustments.

Data-Driven Insights: The wearable could collect a wealth of data on movement, tremors, sleep patterns, and more. Analyzing this data could provide valuable insights into the progression of the disease and its impact on patients' lives.
Personalized Therapy: Wearables could be used to deliver personalized therapy or rehabilitation exercises, helping patients manage their symptoms and improve their motor skills.

User Empowerment: Empowering patients with tools to monitor their own condition can increase their sense of control and engagement in their own care.

Main limitations as picture on next page.

*From my stakeholder research, literature review and expert interviews I will decide which opportunities and limitations I will include in the research scope.

space available for images / figures on next page

introduction (continued): space for images

image / figure 1: *From my literature, stakeholder and expert rev. I will decide what limitations i will include ir

image / figure 2:

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

• Ignoring symptoms
PD manifests in a wide range of symptoms, which can have detrimental effects on individuals' daily lives. Treating the condition and managing the symptoms are crucial to preventing their exacerbation. However, individuals often fail to recognise or address the symptoms in a timely manner. In this instance of the project,
the aim is to design a smart wearable device that can assist users in monitoring and managing their symptoms
effectively.
• Speech problems
PD can result in soft speech and difficulties in vocal coordination, leading to mumbling and communication challenges. The project will focus on developing a wearable device that can augment speech capabilities, enabling clearer and more confident communication for individuals with PD. Aphasia, dysarthria or dysphonia
are all relevant subjects to include in this instance of the scope.
• Breathing problems
A lot of PD patients live with poor oxygen intake. This can be the cause of speech problems, and other PD related symptoms. It also hinders rehabilitation.
• Balance and posture
Postural instability is a major movement symptom of PD, posing challenges to balance and increasing the risk of falls. Exercise and early physical therapy have been shown to improve gait, balance, and posture. This
project will explore the design of a smart wearable device that facilitates personalised exercises,

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

I am going to research the condition PD by means of literature review and expert interviews to establish a scope and determine the problem I want to design for. Furthermore, I will develop a design vision, design concepts that solve the chosen problem, validate and choose a concept, prototype the chosen concept and test it in TRL 4/5 environments. From the tests I will iterate the concept product's design and engineering.

This research should serve as a base to come up with auditive, physical, digital, aesthetic, and/or coded prototypes*, with which I can justify envisioned aspects of the concept product or fetch new insights a to be used in preceding concept product iterations. Ultimately I will strive for a TRL 4/5 concept product prototypes, tested in the Zorginstellingen Pieter Van Foreest on real PD patients.
Furthermore, I will present Dopple with*:
• Renders and 1:1 3D models of the final concept product
• Sensor + Actuator integration & Data analysis plan
• Audio feedback research for PD patients
• Material selection + manufacturing process
• Follow-up research directions, Cost & scalability analysis
• Product benchmarking to the existing market (if possible).

(All these to-be-presented values should aid me in my design process and will be conducted for the sake of my research and the embellishment of my to be envisioned concept product. But since I am doing the assignment at a firm, they may also colour to the project.)

* The course of my research will depict which ones are most adequate to research/deliver.

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 20 - 9 - 2023 — 10 - 4 - 2023 end date

year	2023														
Calendar week	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52
Days of study / week	2	4	4	4	3	4	4	4	4	4	2	4	4	4	0
Day counter (end of week)	2	6	10	14	17	21	25	29	33	37	39	43	47	51	51
Milestones	start												Mid term		
1st day of week	18-Sep	25-Sep	02-Oct	09-Oct	16-Oct	23-Oct	30-Oct	06-Nov	13-Nov	20-Nov	27-Nov	04-Dec	11-Dec	18-Dec	25-Dec
Milestone date	20-Sep												14-Dec		
Literature study & PD patient interview/observa	14														
Vision, project goal & design objectives					3										
Concept creation						22									
Concept validation												4			
Prototyping & User tests													8		

year	2024														
Calendar week	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Days of study / week	0	4	4	4	4	0	4	4	4	4	2	4	4	4	3
Day counter (end of week)	51	55	59	63	67	67	71	75	79	83	85	89	93	97	100
Milestones										Green Light meeting					Graduation
1st day of week	01-Jan	08-Jan	15-Jan	22-Jan	29-Jan	05-Feb	12-Feb	19-Feb	26-Feb	04-Mar	11-Mar	18-Mar	25-Mar	01-Apr	08-Apr
Milestone date										04-Mar					10-Apr
Prototyping & User tests	28														
Last design iterations										10					
Finishing writing & making final presentation													8		
Rehearsing final presentation															3

Every Friday I will work on a side job to earn a living (excluding the first and last week of my project, I will work 4 days a week regularly)

Holidays will be taken in:
2023; week 42 (1 day), week 48 (2 days) & week 52 (4 days)
2024; week 1 (4 days), week 6 (4 days) & week 11 (2 days)

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

I want to devote my career as a design engineer to research, develop, and design medical products. Designing for PD patients is tough (see main limitations section), therefore I deem it adequate to conclude my IPD Master's degree with it.

Competences to be used and sharpened:

- Product system mapping: I have done this before once during ACD, but I would like to do it more extensively this time around for my thesis project.

- Ergonomics design: I designed a falls prevention shoe for elderly in AED. I want to take the knowledge gathered there to the next level, with the increased target audience difficulty, being not only of age, but also suffering from PD.

- Rendering and visualising concepts and products: using Blender, which I enjoy doing in my spare time. It is also something I have done extensively for ACD and AED (amongst other courses).

- Embodiment design using rapid prototyping equipment and additive manufacturing machinery, again used extensively for ACD and AED. Besides, FDM and SLA usage are favorite hobbies of mine.

- Coding using Arduino IDE and Python. Again in my spare time I like to play with electronics and code programs that optimise my everyday life. I am into making image recognition DNNs (which I used for ACD as well, albeit quite lo-fi back then). I might find a suitable prototyping need within this project to sharpen my skills).

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

This project is in theme of concept design, as well as embodiment design. I like to not know where I am going to end up, yet I also really enjoy making and testing embodied prototypes/products. These facets are my favorites things in design engineering.